Spring 2014 Vol 10, No. 2

Cornea Society News

Advancing the treatment of corneal disease

A Cornea Society publication

Dr. Rapuano and son climb world-famous peak

Christopher J. Rapuano, MD, and his son, Patrick, had a different Christmas than usual last year. They spent the day climbing Africa's highest peak, Mt. Kilimanjaro.

Dr. Rapuano said that the experience was a unique father/son adventure for him and Patrick, 22, who has graduated from college and is in the process of applying for medical school.

"This was the most physically strenuous thing I've done in a long time, if not ever. I've learned I'm up to that task," said Dr. Rapuano, director of the cornea service, Wills Eye Hospital, Philadelphia. "I also learned—I know it's kind of cliché—that life is short. If you don't take time to do special things like this, you'll never do them."

The climb took seven days with a support staff of 15. That team included a head guide, assistant guide, cook, and 12 porters. The slow climb was marked by the call of "polay, polay" in Swahili, which the guides tell climbers to prevent acute mountain sickness or altitude sickness. If climbers are struck by altitude issues from ascending too quickly, their hike can be cut short, even only an hour away from the top, known as the Uhuru summit.

The slow ascent provided Dr. Rapuano and his son with a once-in-a-lifetime experience. It was just the two of them and their support staff climbing the mountain by day and sleeping on the mountain in a tent by night.

"When would we ever spend two and a half weeks together, essentially 24 hours a day?" he said. "Just to be with him—neither of us are the most talkative people in the world—but to spend time together was just incredible."

Patrick and Dr. Rapuano standing atop Uhuru Peak, the highest point in Africa

Source: Christopher J. Rapuano, MD

Volunteering at Tenwek Hospital

The story begins with Dr. Rapuano's second oldest son's volunteer work at Tenwek hospital in Bomet, Kenya in the fall of 2013. Through a connection with Wills Eye Hospital, Patrick was able to work in the ophthalmology department at the hospital under the direction of hospital ophthalmologist **Ben Roberts, MD**. Patrick helped the hospital modify an electronic health records template and was trained as a surgical tech.

He used this training to assist at a cataract outreach program in South Sudan just before the recent civil conflict began in that country.

"They did about 250 cataracts in a week there. That was a pretty incredible experience for him," Dr. Rapuano said.

At the end of his two and a half months of volunteer time, Dr. Rapuano joined his son in Kenya and saw patients, gave some lectures, and performed corneal transplant surgery for a week at the hospital. The experience was new for him because of the conditions, he said. He called himself a "fairly conservative person" who is happy to be in his comfort zone.

"Seeing patients at Tenwek and doing surgery at Tenwek was certainly outside my comfort zone. Doing things without my regular equipment and sometimes with no equipment, the whole situation was very different. Then climbing a mountain was outside my comfort zone. It's not typical for me," he said.

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Cornea Society
Advancing the treatment of corneal disease

Spring 2014

President's Message

Dear Cornea Society members,

As secretary-treasurer and president elect over the past 4 years, I have been up on the podium during the annual business meeting at the Fall Educational Symposium the Friday before the annual American Academy of Ophthalmology (AAO) meeting announcing our healthy financial status. Afterward, Cornea Society members occasionally asked me, "What are we doing with our money?" I realized that I, and the Cornea Society in general, have been remiss in keeping our members informed as to our endeavors. In this letter, I will run through many of our activities and highlight a few important initiatives.

The Society continues to cosponsor Cornea Day at the ASCRS•ASOA Symposium & Congress with their Cornea Clinical Committee and run Cornea Subspecialty Day at the AAO annual meeting. We also organize symposia at the AAO and ASCRS annual meetings. We cosponsor the Fall Educational Symposium the Friday before the AAO annual meeting with the EBAA. Each year we hold a breakfast for the cornea fellowship directors to get together and discuss topics of shared interest in an informal setting. The Cornea Society also runs the *Cornea* journal. We are extremely happy that **Alan Sugar, MD**, the editor-in-chief, has made great strides over the past 2 years in both eliminating the backlog of publishing accepted papers and cutting the submission to print time in half. The Society also sponsors the VISTA dinner at the Association for Research in Vision and Ophthalmology and continues to support two task forces, the IC3D project spearheaded by **Jayne Weiss, MD**, and the limbal stem cell project spearheaded by **Friedrich Kruse, MD**.

In an effort to expose more young ophthalmologists to the field of cornea and the Cornea Society, we sponsor a young physicians dinner on the Friday evening right before both the ASCRS and the AAO annual meetings. Immediately following that dinner we sponsor the DJ party, which has become a hugely popular event. We are extremely grateful to **Tony Aldave, MD**, and **Terry Kim, MD**, for their superhuman efforts DJing the party. We also routinely sponsor a resident or fellow interested in cornea to attend the AAO Mid-Year Forum, with the goal of becoming a better advocate for the cornea subspecialty.

For the past few years we have cosponsored a program at the ASCRS•ASOA Symposium & Congress to help transition residents and fellows from being trainees to "real life." It includes free admission to Cornea Day or Glaucoma Day on Friday and a half-day program Saturday featuring topics such as coding, how to select a fellowship, choosing between academic medicine and private practice, and contract negotiation. While the residents and fellows have found this program excellent, they often express the need for more detailed discussion. Consequently, the Cornea Society is planning a pilot project tentatively called "Cornea University" to be tested in Boston in the fall and chaired by **Jessica Ciralsky, MD**. It would be for third-year residents and fellows and cover similar topics as listed above, but in a more comprehensive, in-depth fashion. If successful, we would take it nationwide with four to six regional meetings the following year.

In the fall of 2013, the Society ran the Cornea Fellows Educational Summit for the first time. More than half of the cornea fellows from around the country attended the two-day meeting that included didactics and wet labs. Given that we had a waiting list of fellows who weren't able to attend due to space limitations, we plan to run the Summit again this fall at a facility with a larger wet lab.

The big project for the Society over the next 15 months is organizing World Cornea Congress VII just prior to the ASCRS•ASOA Symposium & Congress in San Diego in April 2015. Given the significant amount of work planning such a meeting entails, we have formed a Planning Committee (**Donald Tan, FRCS**, **Marian Macsai, MD**, **Terry Kim, MD**, **Michael Belin, MD**, **Kathy Colby, MD**, **Barry Lee, MD**, **Vincenzo Sarnicola, MD,** and myself) and selected an Abstract Review Task Force with more than 15 members. The Planning Committee has reached out to several supranational Cornea Societies, including EuCornea, the Asia Cornea Society, and the Pan American Cornea Society, for suggestions regarding topics and speakers for the meeting. We are just beginning the process of developing the invited speaker program and will have calls for free papers later this year.

I want to thank Gail Reggio, the Society's executive director, for all her hard work helping us plan and organize the increasing number of activities in which we are involved. The Society has an excellent working affiliation with ASCRS; they help us with a variety of functions including marketing/communications, fundraising, grant writing and finances. In fact, Gail works out of the ASCRS office in Fairfax, Va. She arranged for me to visit the office for a day in early January to meet with the ASCRS staff including their leaders David Karcher and Don Bell, and I was very happy to be able to solidify our relationship. I will keep you updated on further developments in future newsletters.

Sincerely,
Christopher J. Rapuano, MD
President

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After they left the hospital and went on a safari, they set out for Tanzania and Mt. Kilimanjaro.

Climbing the mountain

Climbing Mt. Kilimanjaro was his son's idea, Dr. Rapuano said. Patrick learned that the mountain was close enough to the hospital to visit and climb, and suggested the idea to his father. It worked out perfectly, Dr. Rapuano said, with many factors falling into place to allow them to do the climb together, including his partners helping him with his on-call duties. **Sadeer Hannush, MD**, another member of the Wills Eye cornea service, who had previously volunteered at Tenwek and climbed Mt. Kilimanjaro, was helpful with advice and lending equipment.

As soon as Dr. Rapuano knew that they would be attempting to ascend the mountain, he began to train.

"I was very religious about using my elliptical machine and running. Whereas sometimes in the past I would say, 'I'm tired, I'm not going to exercise today,' it was basically every day that I could, I would exercise," he said.

He also had to prepare the equipment to make the climb—backpacks, clothes, etc., he said. Patrick carried a solar panel to charge their mobile phones, which was useful on the mountain, especially on Christmas to call their family back home.

The climb itself wound its way up the mountain with hiking during the day and sleeping in the evening. The cook would make meals for Dr. Rapuano and Patrick to eat, including pasta on Christmas. Each day, they made progress. Dr. Rapuano used hiking poles when he could. The mountain has difficult terrain in some areas, with the guides carefully showing the way, he said.

In the middle of the night on the summit day, the guide woke Dr. Rapuano and Patrick. They dressed in four layers of clothes against the cold. The next hours were intense, as they made their way up to the summit, walking in their guide's path through the dark.

Dr. Rapuano encouraged himself on so that he and Patrick could see the top of the mountain together. He said he was thinking: "Just put one foot ahead of the other and keep going, keep going, keep going. I can take another step, I can take another step," he said.

Finally, they reached the top, just as dawn broke and the sun streamed across the mountain.

Reaching that point was "exhilarating," Dr. Rapuano said.

"You've worked so hard—months to prepare and days to go up the mountain, and the last six hours, you've been climbing in the dark and you feel like you have succeeded in your goal. It's an emotional goal, it's a physical goal, it's an unpredictable goal because with acute mountain sickness, you could be an hour from the top and have to stop," he said.

"You're thrilled that you've made it through this unpredictable part and you're happy you emotionally made it, and you're happy you physically made it, and then you're at one of the most beautiful places you could think of with the sun coming up, and you're above the clouds. It's incredible."

"Then as you start to go down, the other people climbing up are asking, 'How is it up there? Is it worth it?'" he said. "And absolutely, it's worth it." **CN**

Contact information

Rapuano: cjrapuano@willseye.org

Cornea journal update

Alan Sugar, MD, Journal Editor

The journal has reached a state of balance between the rate of paper acceptance and the number of papers available for each issue. That means that once accepted, papers will appear in print in about four months. This relatively short delay is required for processing by the publisher and final proof corrections by the authors and the editor. Online publication prior to print occurs about two months earlier.

Cornea welcomes **Ken Kenyon, MD**, from Boston to the editorial board. Ken is a highly regarded corneal surgeon and investigator affiliated with Harvard and the Schepens Eye Research Institute. He has published many landmark corneal papers.

A paper in the March issue by Muftuoglu et al compares the use of air and SF6 for DSEK tamponade. The dislocation rate was less but the endothelial cell loss was greater in the SF6 group. A report from Rosenwasser et al documents the histopathology of interface opacity after DSEK. A laboratory study by Wollensak et al confirms the biomechanical effects of collagen crosslinking. **CN**

Cornea Day program to highlight hot topics

2014 CORNEA DAY
Sponsored by the Cornea Society and ASCRS

Cornea Day will cover cataract and refractive surgery, corneal infections, and keratoplasty procedures

This year's Cornea Day at the ASCRS•ASOA Symposium & Congress in Boston will take place on Friday, April 25. The program chairs for Cornea Day are **Terry Kim, MD**, professor of ophthalmology, Duke University Eye Center, Durham, N.C., and **Donald T.H. Tan, MD**, head and senior consultant, Singapore National Eye Centre, Singapore. Dr. Kim discussed the program and what to expect for the meeting.

"We always try to keep it dynamic and up to date," Dr. Kim said about the Cornea Day program. "This year will be no different."

As usual, the day will be split into four different sessions. This year's sessions will focus on advances in cataract surgery, including case and video presentations; refractive surgery, with a section featuring point/counterpoint discussions on a number of topics; current management of ocular infections, like bacterial, fungal, and parasitic keratitis; and video pearls in keratoplasty surgery.

The cataract session, which will be moderated by **Richard Davidson, MD**, Aurora, Colo., and **Sonia Yoo, MD**, Miami, will include topics such as femtosecond laser issues, astigmatism

correction options, dysphotopsias, and intraoperative aberrometry. "Femtosecond Laser Issues for the Cataract Surgeon" will have its own section within the cataract session and will explore such topics as using femtosecond cataract surgery in glaucoma patients, small pupils in these cases, and using manual versus femtosecond lasers for patients with white cataracts.

The refractive session will be moderated by **Natalie Afshari, MD**, San Diego, and **Christopher Starr, MD**, New York. Dr. Kim said that it will cover issues such as refractive surgery screening and the importance of identifying patients at risk for potential ectasia. "We will also have a unique point/counterpoint surgical section," he said. This setup will include participants taking opposite sides on controversial issues with a four-minute point and one-minute counterpoint per side. Topics to be discussed in the point/counterpoint section include corneal inlays versus monovision for presbyopia, PRK on flap versus flap lift for LASIK enhancement, and the use or avoidance of mitomycin-C in surface ablation cases.

A session on infections, moderated by **Francis Mah, MD**, San Diego, and **Elmer Tu, MD**, Chicago, will cover intriguing topics such as the pros and cons of testing and prophylaxis for MRSA, an update on the diagnosis and management of viral, fungal, and parasitic keratitis, and controversies in bacterial keratitis, including the use of corticosteroids and collagen crosslinking. Dr. Tan will give an update on the Asia Cornea Society Infectious Keratitis Study. The session will end with interesting and challenging case presentations and discussions from a panel of international experts in infectious disease.

The last session will be "Video Pearls in Keratoplasty Surgery: You NEED to SEE This," moderated by **John Hovanesian, MD**, Laguna Hills, Calif., and **Christopher Rapuano, MD**, Philadelphia.

"The audience will want to stay for this last session as it will consist of corneal transplant specialists who will share their pearls in various keratoplasty procedures using video as opposed to standard lecture slides," Dr. Kim said. "It's going to take place with a rapid-fire, interactive, and highly educational format."

Dr. Kim expects the final session to be a hit because it will encompass a variety of corneal surgery topics, including femtosecond PK, pediatric transplants, keratoprosthesis, DALK, and DSEK. **CN**

Contact information
Kim: terry.kim@duke.edu

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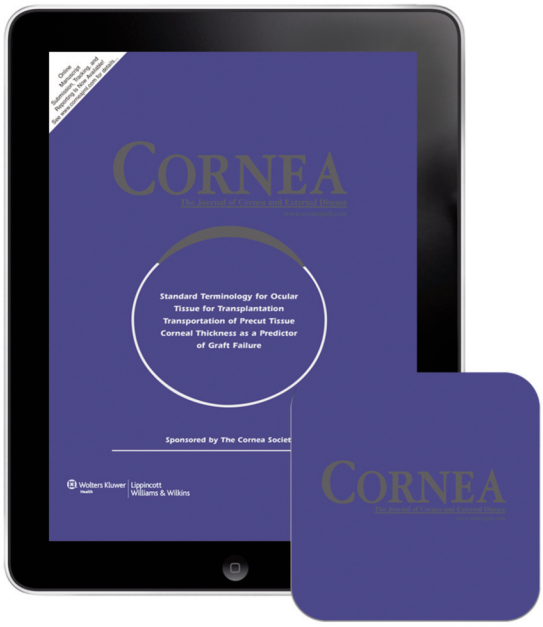

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WORLD CORNEA VII CONGRESS

SAN DIEGO

APRIL 15–17, 2015

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

Plan ahead to attend.

Submissions open August 2014.

www.CorneaSociety.org

Free registration for the 2014 ASCRS Residents and Fellows Program

U.S. and international residents and fellows qualify for complimentary registration to attend a half-day program and special events at the ASCRS•ASOA Symposium & Congress in Boston, April 25-29.

The American Society of Cataract and Refractive Surgery (ASCRS) and the American Society of Ophthalmic Administrators (ASOA) partnered with the Cornea Society to develop this all-inclusive educational experience for residents and fellows.

On Friday, April 25, attendees may register for Cornea Day or ASCRS Glaucoma Day. In the evening, networking opportunities include the Dinner for Young Physicians and the DJ event, "Battle in Boston." The half-day program designed especially for residents and fellows begins on Saturday, April 26. Sessions focus on critical aspects of business management and insights on how to begin a successful career. Attendees are also encouraged to network with faculty and committee members during the lunch roundtables and to attend the "Best Paper and Poster Awards."

U.S. residents and fellows may register for free to attend the entire conference and Cornea Day or ASCRS Glaucoma Day. International residents and fellows may register for a nominal fee. All programs and events require separate registrations. The Residents & Fellows Preview Program and online registration is available by visiting www.ascrs.org. **CN**

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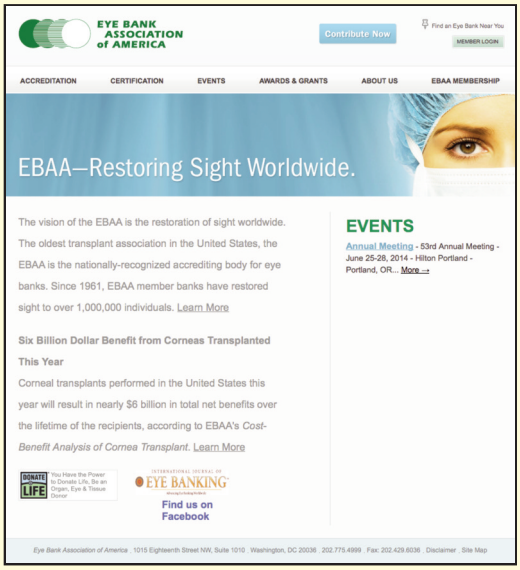
Earn CME credits at EBAA's "The Bridge to Sight" Annual Meeting, Portland, Ore., June 25–28

The Eye Bank Association of America's 53rd Annual Meeting "The Bridge to Sight" will include a number of new features, including the ability to earn CME credits for attending the Scientific and Medical Directors Symposia. The program will include thought leaders from within and outside the eye banking and transplantation profession, with meaningful education sessions and ample opportunities to exchange views and information with peers and colleagues. EBAA's Meetings Committee has focused on several ways to showcase the city through networking and social events. Hosted by Lions VisionGift and held in the Hilton Portland Hotel & Executive Tower, this is a conference you won't want to miss. Visit www.restoresight.org/ upcoming-events/annual-meeting for more information. **CN**



Cornea meeting of the
Italian Society of Stem Cells and Ocular Surface

XIII SICSSO Congress

Paestum (Salerno)

26-28 June 2014

KEY DATES

Deadline abstract submission: 30 November 2013

Early bird registration fee: 31 January 2014

www.sicsso.org

S.I.C.S.S.O.
Società Italiana Cellule Staminali e Superficie Oculare

Cornea Society/Vista Young Physician Dinner at ARVO

The Cornea Society is pleased to announce that this year's Young Physician Dinner & Case Presentations (Vista) Dinner will be held on Sunday, May 4, 6:30 p.m., at Maggiano's Orlando, 9101 International Dr., Suite 2400, Orlando, Fla. For many attendees, the Vista program is the highlight of the ARVO meeting. The program serves as a venue for young or aspiring corneal specialist to present interesting, unusual, or complex cases in a congenial environment and be able to openly discuss the cases with prominent corneal specialists. The program has been very popular in the past, and individuals will be admitted with advance registration only.

The program tends to fill to capacity. There is no charge for the program. Registrations can be made at ARVO@corneasociety.org. Young physicians, fellows, residents, and new Society members will be given preferential booking.

Call for papers

The deadline for abstract submissions is April 1. Abstracts should include name(s), degree, institution, presenter, and academic status (e.g., resident, fellow, attending) and year completed residency. The body of the abstract is limited to 150 words.

Abstracts should be sent to ARVOabstract@corneasociety.org. **CN**

DUREZOL®
(difluprednate ophthalmic emulsion) 0.05%

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

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Alcon®
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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.