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Cornea Society News

Advancing the treatment of corneal disease

A Cornea Society publication

Cornea pearls highlighted at Fall Educational Symposium

Attendees at the Cornea Society/Eye Bank Association of America Fall Educational Symposium in Chicago heard the latest pearls and results from studies related to Descemet's membrane endothelial keratoplasty (DMEK), Descemet's stripping automated endothelial keratoplasty (DSAEK), and deep anterior lamellar keratoplasty (DALK), among other topics.

P. James Sanchez, MD, Los Angeles, and co-investigators reported that DMEK performed using eye bank-prepared DMEK tissues can have excellent outcomes. The researchers led a retrospective observational study with the first 38 consecutive DMEK procedures performed by a single surgeon using pre-stripped DMEK tissues prepared by a single eye bank. There were no cases of total detachment, upside down graft, or infection.

Research with the "bubble in the roll" technique for DMEK focused on a safe and reliable approach for reproducible delivery of DM grafts in DMEK in a presentation given by **Friedrich Kruse, MD**, Germany. "The 'bubble in the roll' technique ensured correct position of the DM roll—overlap facing upward—at the end of injection in 248 of 250 consecutive DMEK surgeries and retention of the tiny air bubble in 242 of 250 surgeries," Dr. Kruse reported. The technique appears to overcome limitations of current graft injection techniques, Dr. Kruse and co-investigators concluded. They noted that current injection techniques implicate a random position of the graft after injection.

Although rejection rates after DMEK are much lower than those reported after DSAEK or penetrating keratoplasty, it can still occur. **Mark Terry, MD**, Portland, Ore., examined rejection rates following the use of a standardized postop steroid regimen. Researchers reviewed 223 consecutive DMEK eyes at 3 months or more postop. Patients used prednisolone acetate 1% on a standard regimen of 4 times a day for the first 3 months; their dosage was decreased every quarter unless it had to be modified for IOP issues. Steroids were stopped at 1 year. Four eyes experienced a rejection episode within the first 2 years after DMEK, leading to a 1.7% rejection rate. "All cases resolved the rejection episode after boosting topical steroid therapy, and all retained corneal clarity and excellent vision," Dr. Terry reported. Dr. Terry and fellow researchers concluded that rejection of DMEK donors can occur even with the use of potent steroid therapy and that stopping steroids at 1 year postop may be reasonable.

Marian S. Macsai, MD, and Douglas Lazzaro, MD, present the Troutman Prize to Fei-fei Huang, MM, at the Fall Educational Symposium.

Anthony Kuo, MD, Durham, N.C., reported on the use of intrasurgical swept-source microscope integrated optical coherence tomography (OCT) for real-time guidance during DALK. The microscope was used both ex vivo and in vivo. Researchers found that intrasurgical OCT can help monitor and guide the surgeon in real time during DALK. "Unlike regular surgical microscopes, ultra-high speed swept-source microscope OCT enables surgeons to directly assess lamellar dissection depth, needle depth, and big bubble creation," Dr. Kuo concluded.

Reporting results from the Cornea Donor Study, **Jonathan Lass, MD**, Cleveland, and co-researchers examined the long-term effect of donor diabetes history on graft failure and endothelial cell density (ECD) after penetrating keratoplasty. Researchers did not find a statistically significant association of donor diabetes history with 10-year graft failure, baseline ECD, 10-year ECD, or ECD values longitudinally over time in unadjusted analyses or after researchers adjusted for donor age and other covariates. There was a 23% 10-year graft failure rate in the 199 cases that received a cornea from a donor with diabetes, compared with 26% in the 891 cases that received a cornea from a donor who did not have diabetes. Researchers concluded that diabetes was defined only by historical data and that further study of graft success and cell loss is needed, along with more precise measures of donor and recipient diabetes.

Other highlights from the Fall Educational Symposium included the Claes H. Dohlman, MD, PhD Award presentation, the R. Townley Paton Award Lecture, and the Best Paper Award. CN

Cornea Society
Advancing the treatment of corneal disease

President's Message

Christopher J. Rapuano, MD

Dear Cornea Society members,

It was terrific seeing many of you at the American Academy of Ophthalmology meeting in Chicago in October. The Fall Educational Symposium held on Friday in conjunction with the EBAA was a huge success. We again 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 received the 2014 Claes Dohlman Award.

I want to thank and congratulate **W. Barry Lee, MD**, **Elmer Tu, MD**, and **Steve Kauffman, MD**, the program directors for Cornea Subspecialty Day, on a terrific program. Dr. Lee, in conjunction with the German Ophthalmological Society, organized a wonderful Cornea Society Symposium titled "Advanced Treatment of Ocular Surface Inflammatory Diseases." Congratulations also go to **Mark Mannis, MD**, the 2014 Castroviejo Medalist, who gave an inspiring Castroviejo Lecture. I am thrilled to announce that next year's Castroviejo Medalist will be **Elisabeth Cohen, MD**.

The Cornea Society Business meeting occurred during the Fall Educational Symposium. I again want to thank **Frederic Kruse, MD**, and **Enzo Sarnicola, MD**, who are rotating off the Board, for the tremendous job they both did over the past 4 years. I am very pleased to announce that **Esen Akpek, MD**, and **Bennie H. Jeng, MD**, were elected as new Board members. I want to thank **Tony Aldave, MD**, and **Terry Kim, MD**, for the great job at the Cornea Society DJ Party and Dr. Tu and **Shahzad Mian, MD**, for organizing and moderating the Cornea Fellowship Directors Breakfast.

The Cornea Fellows Educational Summit occurred in September in Tampa, Fla. I want to thank and congratulate the program chairs, Dr. Lee, Dr. Tu, and **Kathryn A. Colby, MD, PhD**, on a superb program. The feedback from the fellows was tremendous. It was such a success that we are going to do it again next year in Tampa, tentatively set for October 16–18, 2015.

By far the biggest project for the Society continues to be 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. Meeting registration and hotel reservations are available through the World Cornea Congress website (www.CorneaCongress.org).

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. The program committee met in Washington, D.C. in November to finalize the free papers and posters. It is shaping up to be the best World Cornea Congress ever. The big news is that, for the first time, we will have simultaneous translation into Spanish for the entire meeting!

Please feel free to contact me (cjrapuano@willseye.org) if you have any questions regarding the Cornea Society.

Sincerely,

Christopher J. Rapuano, MD
President

Cornea Day at AAO 2014

This year's Cornea Day embraced the theme "Restocking the Toolbox: Concepts and Techniques for the Toughest Jobs." Sessions highlighted topics including inflammatory disorders, cornea controversies, combination cornea, corneal surgery quandaries, and challenging cases.

Smoothing out the rough surfaces

Marian S. Macsai, MD, Glenview, Ill., discussed a specific case she treated of an 18-year-old ballerina who was diagnosed with limbal stem cell deficiency (LSCD) associated with contact lens wear. Dr. Macsai said this condition is a common problem, although not usually as severe as in this particular case. "But the reason we're not seeing it is we're just not looking for it," she said.

In this case, Dr. Macsai proceeded with aggressive treatment, starting with punctal plugs, which usually are not used initially. She proceeded with topical cyclosporine, prednisolone acetate, and polysporin/trimethoprim antibiotics until the defect resolved, and those were discontinued. In this particular patient, she recommended that the patient only use her contacts when performing. Dr. Macsai noted that she had to negotiate with the patient to not wear her contact lenses daily.

The take-home message, she said, is to look for late staining in contact lens patients, loss of limbal architecture, whorl-like epitheliopathy, and opaque epithelium arising from the limbus with late fluorescein staining.

Persistent epithelial defect

Bennie Jeng, MD, Baltimore, discussed persistent epithelial defect (PED), defined typically as an "epithelial defect that does not heal within the expected period of time." It is estimated that there are 40,000 PEDs annually in the United States. However, Dr. Jeng noted that with new information about better case selection, this number might have decreased.

Potential complications include infection, melting, scarring, perforation, and loss of vision. The standard medical treatments for this problem start with treatment of the underlying process, as well as the withdrawal of toxic medications. Standard surgical treatment for these cases could help, or there are advanced options, including autologous serum, amniotic membrane grafting, and scleral lenses.

"Managing a PED can be arduous for the ophthalmologist and definitely a burden on the patient," Dr. Jeng said. "When standard medical therapies fail, surgical options do exist." Other advanced treatment modalities have been proven to be useful, and experimental treatment options are under investigation and promising, he said.

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Johannes Menzel-Severing, MD, awarded Best Paper at Fall Educational Symposium

Monty Montoya, SightLife; Johannes Menzel-Severing, MD, University of Erlangen; Marian S. Macsai, MD, Cornea Society; and David Glasser, MD, Eye Bank Association of America

Johannes Menzel-Severing, MD, received the Best Paper Award at the Fall Educational Symposium on Friday, October 17 for his paper, "Toward Optimized DMEK: Which Graft to Order for Which Patient."

Since 2009, SightLife has generously supported the Best Paper Award, which highlights research by ophthalmology residents and corneal fellows.

"SightLife is proud to support the Best Paper Award that recognizes the research of residents and corneal fellows from around the world. At SightLife we are committed to finding ways to leverage innovation to transform lives and unlock life's possibilities for the 10 million corneal blind around the globe," said Monty Montoya, SightLife president and CEO.

The Fall Education Symposium is jointly hosted by the Cornea Society and the Eye Bank Association of America, and is held each year in conjunction with the American Academy of Ophthalmology annual meeting.

SightLife will again support the Best Paper Award at the 2015 Fall Education Symposium on Friday, November 13, 2015 in Las Vegas. The Call for Papers will open in June 2015. CN

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Top 5 tips

The afternoon session kicked off with surgeons offering tips and advice on a number of topics.

Reay H. Brown, MD, Atlanta, offered his top 5 pearls for combining glaucoma and cataract surgery. The first microinvasive glaucoma surgery (MIGS) device approved for use in the U.S. is the iStent (Glaukos, Laguna Hills, Calif.). "Cornea and cataract surgeons are just as important to the development of MIGS as glaucoma specialists," he said. MIGS is different from other glaucoma procedures because it is a chance to safely help your cataract patients who have glaucoma, and it is within your skill set.

Dr. Brown's first pearl was that MIGS is a new way of thinking about glaucoma surgery. The ab interno incision has minimal trauma and is not destructive by strict definition. It is safe with rapid recovery and is effective.

"Pick the right patient," he said as his second pearl. MIGS is not a replacement for trabs and tubes. Pearl 3 was to set proper expectations. The goal is to lower IOP, Dr. Brown said, and to perhaps reduce the number of drops a patient uses. But it is important to be realistic about pressure reduction.

"Learn the technique," he said, the fourth pearl. If you are going to be using new technology, expect challenges. But anyone who can do phaco can put in a MIGS device, Dr. Brown said. Pearl 5 was that this is only the beginning. There will be new MIGS devices both in the canal and in the suprachoroidal space, he predicted.

Juan Batlle, MD, Santo Domingo, Dominican Republic, shared 5 times that you need a femtosecond laser. He presented examples and looked at specific cases of when this technology is useful. Cases discussed included cataract with prior ICL surgery, small pupils, a shallow anterior chamber, white cataracts, and black cataracts. CN

Editors' note: Dr. Brown has financial interests with Ivantis (Irvine, Calif.), Transcend Medical (Menlo Park, Calif.), and Allergan (Irvine, Calif.). Dr. Batlle has financial interests with Abbott Medical Optics (Abbott Park, Ill.), Alcon (Fort Worth, Texas), Bausch + Lomb (Bridgewater, N.J.), STAAR Surgical (Monrovia, Calif.), InnFocus (Miami), OPKO (Miami), and Santen (Osaka, Japan). Dr. Jeng has financial interests with Santen. Dr. Macsai has no related financial interests.

WORLD CORNEA CONGRESS VII
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2nd annual Educational Summit wrap-up

In September 2014, the Cornea Society hosted the 2nd annual Cornea Fellows Educational Summit in Tampa, Fla. This was a 2-day, intensive educational program that included both classroom and skills transfer lab components. It was designed to complement and reinforce cornea fellowship training.

Developed to address educational challenges identified by cornea fellowship directors, the 2014 Educational Summit set out to provide additional training to improve diagnostic and treatment skills within the clinic setting, instruction on patient selection and surgical techniques for refractive surgery, and technique pearls for routine and complex cataract surgery and corneal transplantation.

Through an integrated training program in both refractive and corneal transplant surgery, the 2014 Educational Summit enhanced current fellowship training and prepared young ophthalmologists for their first years in practice. Led by course directors **Kathryn A. Colby, MD, PhD**, **W. Barry Lee, MD**, and **Elmer Tu, MD**, the small faculty to student ratio provided hands-on training and an informal lecture setting. **Michael W. Belin**, **MD**, **Bennie H. Jeng, MD**, **Marjan Farid, MD**, **Richard Davidson, MD, Shahzad Mian, MD**, and **Deepinder Dhaliwal, MD**, served on the Summit faculty. CN

World Cornea Congress preview

The World Cornea Congress, prior to the 2015 ASCRS•ASOA Symposium & Congress in San Diego, will feature a number of interesting sessions focusing on the cornea subspecialty. These will include the "Techniques and Technologies for Endothelial Keratoplasty" session, which **Terry Kim, MD**, Durham, N.C., will moderate. **Francis W. Price, MD, PhD**, Indianapolis, will give the keynote of that session on "The Evolution of Endothelial Keratoplasty: Where Are We Headed?"

Endothelial keratoplasty offerings

This topic is a big area in corneal transplantation right now, Dr. Kim said. The World Cornea Congress is designed differently from subspecialty Cornea Day, which occurs each year prior to the ASCRS•ASOA Symposium & Congress. The World Cornea Congress occurs only once every 5 years. Cornea Day is designed for cornea specialists and general ophthalmologists alike so they can return to their practices with pearls.

"World Cornea Congress is different because now we're getting more of a scientific and global perspective on issues like corneal transplantation," he said.

There are more talks on the academic and evidence-based level, Dr. Kim said.

"I think the audience will get some practical pearls, but in general the lecture topics are going to be broader in nature and more international in scope," he said.

"The World Cornea Congress is sponsored by the Cornea Society and has a very informative program that highlights the tremendous advances and progress that have been taking place in the cornea field from both clinical and research endeavors. This comprehensive 3-day meeting includes invited speaker, free paper, and poster sessions, and it continues to draw a huge domestic and international audience who are looking to hear and learn the latest and greatest in cornea," Dr. Kim said.

The endokeratoplasty session that Dr. Kim will moderate covers controversial, practical, and thought-provoking issues in both Descemet's stripping endothelial keratoplasty (DSEK) surgery and Descemet's membrane endothelial keratoplasty (DMEK) surgery. For the DSEK section, topics include the effect of graft thickness on visual outcomes in DSEK by **Sanjay V. Patel, MD**, DSEK surgery in complex eyes by **Kenneth M. Goins, MD**, and the optics of posterior lamellar grafts by **Jesper Hjortdal, MD**. The section on DMEK covers DMEK graft and recipient preparation techniques by **Frederick E. Kruse, MD**, surgical strategies to reduce complication rates by **Nicolas C. Pereira, MD**, the role and rationale for pre-Descemet's endothelial keratoplasty (PDEK) by **Amar Agarwal, FRCS**, and Descemet's membrane endothelial transfer surgery by **Gerrit Melles, MD**.

Dr. Kim said he is interested to hear the keynote from Dr. Price. He is curious about the issue of whether thin DSEK is worth considering as opposed to transitioning completely to DMEK, especially since many corneal surgeons are still actively performing DSEK because of the lower complication rate and shorter surgery time.

Dr. Price said there has been a huge revolution recently in corneal surgeries. "The last 10 years have been extremely exciting in cornea because corneal surgeries, as far as transplants go, haven't really changed for 30 or 40 years," he said.

The biggest change in the U.S. has been with endothelial keratoplasty, he said, where surgeons are transplanting just Descemet's and endothelium. Meanwhile, DSEK and Descemet's stripping automated endothelial keratoplasty (DSAEK) still use stroma, but the amount is getting continually smaller.

"The reason this has been so exciting is it's safer for the patient using smaller incisions," he said. "We get tremendously better vision that correlates with how thin the tissue is, and what was not suspected is that the rejection rates fall."

These changes have resulted in better outcomes for patients. Visual results with DMEK are similar to cataract surgery, both predictable and quick, Dr. Price said.

"In the next 10 years, I think we need to find better ways to do our corneal endothelial procedures in eyes with glaucoma," he said, because glaucoma will be a major cause for corneal transplants in the next 10 years.

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WORLD CORNEA CONGRESS VII

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Welcome to San Diego Reception
Wednesday, April 15
6:00–8:00 PM

Exhibit Hall Reception
Thursday, April 16
6:00–7:30 PM

Cornea Society DJ Party
Friday, April 17
9:00 PM–1:00 AM

FREE PAPER SESSIONS

- Ocular Surface Disease
- Ectasia and Cross Linking
- Selective Lamellar Keratoplasty
- Penetrating Keratoplasty and K-Pro
- Eye Banking and Corneal Dystrophies
- Infection Inflammation and Physiology
- Refractive Surgery and New Technologies

INVITED SESSIONS

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: Kathyrn 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 Kohnen, 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

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Cornea Society, AAO combined symposium highlights ocular surface inflammatory diseases

Edward J. Holland, MD, Mark J. Mannis, MD, 2014 Castroviejo Award recipient, and W. Barry Lee, MD

In "Advanced Treatment of Ocular Surface Inflammatory Diseases," a combined session with the Cornea Society at the 2014 American Academy of Ophthalmology (AAO) annual meeting, physicians discussed a variety of topics relevant to cornea specialists and other subspecialty physicians. The session also included the Castroviejo Lecture.

Ocular allergy requires patient history

Penny Asbell, MD, New York, discussed ocular allergy at the session, reviewing key issues in the topic.

"Almost a third of the world has significant allergies," she said, which is probably split between systemic allergy and ocular allergy. These may be seen as a nuisance and can interfere with daily activities. There can be a crossover between viral, bacterial, and allergic symptoms.

A patient history is the best way to begin to understand a patient's allergies. Dr. Asbell discussed different types of allergies, including seasonal, vernal keratoconjunctivitis (VKC), atopic keratoconjunctivitis (AKC), and contact lens intolerance.

She compared some of the major differences between AKC and VKC. "Age is a key differentiating factor," Dr. Asbell said. VKC is seen in younger patients, while AKC is seen in older patients. VKC is seen more often in males than females. They also differ in duration of the disease. VKC is limited and usually resolves at puberty, while AKC is chronic. Additionally, corneal scarring is common with both conditions, but it is not vision threatening with VKC, whereas it is vision threatening with AKC.

Dr. Asbell gave pearls for dealing with ocular allergies. For seasonal problems, it is key to rule out viral infection. For AKC, be sure to check for a skin condition. When dealing with contact lens intolerance, be sure to check under the lid.

Simple approaches to handle allergies should be considered, such as using air conditioning or air filtration, pet control, and avoiding outdoor activities during times of high pollen. Cold compresses and lubricating drops can also help, she said.

Castroviejo Lecture

The session concluded with the Castroviejo Lecture by **Mark J. Mannis, MD**, Davis, Calif., on "Points of Light in the History of Cornea." Dr. Mannis discussed important discoveries in the subspecialty of cornea and how they were conceived.

"Innovation begins with a new idea or insight," he said. It moves to enhancement or refinement by others to develop an idea, drug, or technique. There is then eventual improvement and/or replacement. Types of clinical discovery include novel surgical techniques/new instrumentations, new bio-anatomical insights, recognition of a new clinical phenomenon, pharmacologic discoveries, or new infrastructure development.

Dr. Mannis specifically highlighted points of light in the history of cornea, which include penetrating keratoplasty (PK), the discovery of endothelial function, contemporary corneal microsurgery, understanding of graft rejection, corticosteroids, the discovery of corneal stem cells, eye banking, and selective keratoplasty. He discussed the history and development of these techniques. PK can be traced back to 1906 to the first reported case by **Eduard Zirm, MD**. However, it would be his successors who would carry out clinical trials. **Anton Elschnig, MD**, **Vladimir Filatov, MD**, and **Ramon Castroviejo, MD**, also helped to advance PK.

Under the topic of new infrastructure development, Dr. Mannis highlighted the genesis of the eye bank. Not every clinical advance is surgical, bio-anatomical, or clinical, he said. The 1950s saw the proliferation of eye banks, with the Eye Bank Association of America established in 1961 and national medical standards established in 1980. In the last 2 decades, American eye banking has become increasingly efficient and comprehensive, Dr. Mannis said.

Based on current criteria, it is certainly not clear which endothelial procedure is truly superior to the others, he said. The ultimate goal is endothelial restoration or replacement without complex surgical procedures. He called for consistent data, not just marketing, when determining which procedure is better, Descemet's membrane endothelial keratoplasty (DMEK) or ultra-thin Descemet's stripping automated endothelial keratoplasty (DSAEK). CN

Editors' note: Drs. Asbell and Mannis have no related financial interests.

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Most glaucoma procedures can cause damage to the cornea. "There are multiple centers around the world that are doing research into regenerative treatments for the corneal endothelium or transplanting endothelial cells alone," Dr. Price said. He expects a lot of research looking into this in the next decade.

"I think that this World Cornea Congress is going to be huge because [this area] is changing so fast," he said.

Whether it is the way surgeons do transplants, reshaping the cornea for refractive surgery, or using SMILE (small incision lamellar extraction, Carl Zeiss Meditec, Jena, Germany), many exciting innovations are happening, Dr. Price said.

Keratoprosthesis and PK

In the session on "Keratoprosthesis and Penetrating Keratoplasty," **Kathryn A. Colby, MD, PhD**, Boston, will serve as moderator, with **Roberto Pineda, MD**, Boston, giving the keynote on "Corneal Transplantation in the Developing World: Lessons Learned."

Dr. Colby said that a number of talks in this session will address interesting issues with keratoplasty. Dr. Pineda has done a tremendous amount of international mission work, doing corneal surgery and setting up a keratoprosthesis program in several countries, including Ethiopia and Sudan, she said.

"I think his experiences over the decades of mission work will be both inspirational and enlightening for people attending the session."

Another talk will compare the long-term outcomes of repeat penetrating keratoplasty (PK) versus keratoprosthesis. For cornea specialists who deal with complicated cases, there is always the question of what to do after someone has had 3 or 4 failed keratoplasties, Dr. Colby said. This presentation will look at a patient population for outcomes and complications.

The talk by **Mona Dagher, MD**, will be important as well, Dr. Colby said. As outcomes with keratoprosthesis improve, more are being implanted; the main problem with long-term preservation of vision is progression of glaucoma. This talk looks at a large patient population and gives additional insights into why people lose vision to glaucoma long term with the Boston KPro (developed at Massachusetts Eye and Ear Infirmary, Boston), she said.

Dr. Colby is also interested in the presentation by **Juan Carlos Abad, MD**. He has been using oversized back plates for the KPro, which Dr. Colby also uses. It does appear that there is less retroprosthetic membrane formation using an oversized back plate.

"While glaucoma is the complication that is most devastating in terms of vision, retroprosthetic membrane formation is the most common complication after Boston KPro implantation," Dr. Colby said. "Any strategies that we can use to reduce its occurrence will be very helpful to KPro surgeons around the world." CN

Editors' note: Drs. Colby, Kim, and Price have no financial interests related to their comments.

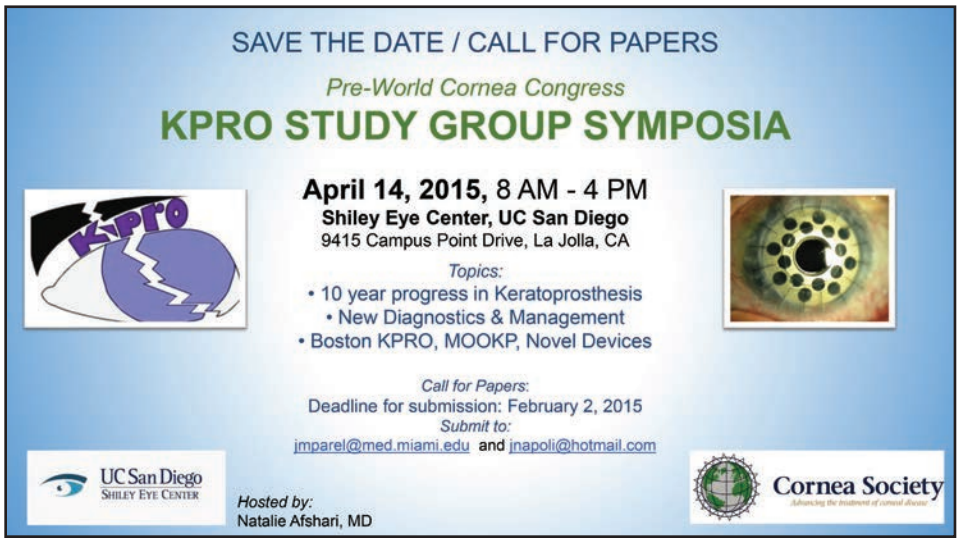
Cornea Society member Jessica Ciralsky graduates from AAO Leadership Development Program

On Monday, Oct. 20 at the Society Presidents' Recognition and Awards Session held in conjunction with the 2014 American Academy of Ophthalmology (AAO) annual meeting in Chicago, **Jessica B. Ciralsky, MD**, was recognized for her participation in the AAO's Leadership Development Program (LDP) XVI, class of 2014. Dr. Ciralsky was among a select group of 19 participants chosen for the LDP XVI, class of 2014, from among a large group that was nominated by state, subspecialty, and specialized interest societies. In January 2014, Dr. Ciralsky took part in a 2-and-a-half day interactive session in San Francisco covering a wide variety of leadership and association management topics. The meeting also included a visit to AAO headquarters to hear from the 2014 Academy President **Greg Skuta, MD**, and Academy vice presidents on key priorities for the Academy. Next was a trip in April 2014 to attend the AAO's Mid-Year Forum in Washington D.C., where Dr. Ciralsky visited members of Congress and their staff to discuss issues important to the medical profession as part of Congressional Advocacy Day. During a special session on Capitol Hill, she and her LDP colleagues also heard from 2014 U.S. Congressman Larry Bucshon (R-IN) about building effective relationships with legislators and how to best advocate on behalf of patients. The LDP class took part in honoring Congressman Bucshon as one of the Academy's 2014 Visionary Award recipients for his sponsorship of truth-in-advertising legislation, the Truth in Healthcare Marketing Act.

Dr. Ciralsky with Aaron Weingeist, MD, AAO LDP XVI director, and Daniel Briceland, MD, AAO 2014 Secretary for State Affairs/2015 Senior Secretary for Advocacy

During the final LDP XVI session in Chicago, Dr. Ciralsky heard from leadership of the AAO and the Pan-American Association of Ophthalmology regarding global collaborative efforts and key priority issues for organized ophthalmology and was encouraged to put her leadership skills to good use.

"Participation in the LDP program was an invaluable experience. I learned so many important skills that will help me throughout my career," she said. Look for good things from Dr. Ciralsky in the future! CN



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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.

DUREZOL®
(difluprednate ophthalmic emulsion) 0.05%

THE RESULTS YOU WANT. THE RELIEF THEY NEED.

Alcon®
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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 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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