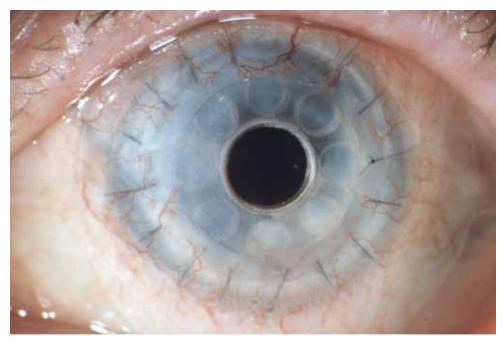
BOSTON KPro news

Antimicrobial prophylaxis for life: as important as ever

FALL 2011 | NUMBER 8



ata drawn from thousands of keratoprosthesis cases is showing that the judicious use of daily antibiotics can successfully lower postoperative infection rates. In the past, postoperative bacterial endophthalmitis frequently occurred after any type of keratoprosthesis, which contributed to the poor reputation of the procedure. Grampositive bacteria, by far, have been

the most common culprit. Infections rarely occur during the first few months postoperatively, but may surface later, and are often related to obvious tissue melt and leak. Autoimmune diseases (Stevens-Johnson syndrome, ocular pemphigoid, graft vs. host disease, atopy, etc.) have been the most vulnerable to infection. The events have, in the most cases, resulted in rapid destruction of the eye.

However, it has become increasingly clear that very small amounts of antibiotics applied topically every day to the operated eye can be very effective in preventing bacterial infections. While this seems counterintuitive, our experience gained from thousands of KPro cases indicates that daily application of a light prophylaxis can be effective for many years without complications; it is also clear that, without any prophylactic antibiotics, the risk of infection is still very high. On the other hand, an excess of antibiotics can make the eye susceptible to fungal infections. Therefore, choosing the right antibiotic in the right concentration is very important for the long-term success of keratoprostheses. While many surgeons recommend different regimens, the procedures we follow in Boston have been very effective and are summarized here (Infectious Disease specialists Marlene Durand, MD and Irmgard Behlau, MD have been consulted):

1. For the standard patient receiving a Boston Keratoprosthesis Type I after multiple graft failures, we usually give a fourth-generation fluoroquinolone

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A Boston Keratoprosthesis update from the Harvard Medical School/ Mass. Eye and Ear Department of Ophthalmology





BOSTON KPro *news*

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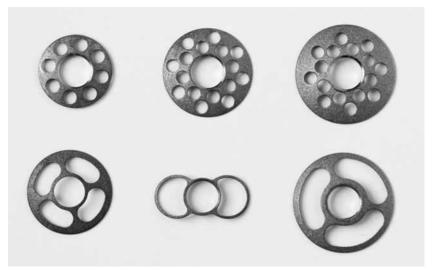
The Boston KPro newsletter is published once annually.

Co-Editors:

Rhonda Walcott-Harris James Chodosh, MD, MPH Claes Dohlman, MD, PhD

Titanium back plates await FDA approval

itanium is a material that has widespread application in medical bioengineering. For example, it is used in joint replacement, tooth implants, pacemakers, brain shunts, and artificial limbs; moreover, it has the reputation of being very inert and tissue friendly. Because of its versatility and strength, the Boston KPro team tested titanium as a potential material for making the back plate of the Boston KPro. As a first step, tissue culture experiments with epithelial cells showed titanium to be better tolerated than polymethyl methacrylate (PMMA).¹ Subsequent studies in rabbits and, since 2005, in patients have demonstrated that titanium is clearly superior in several respects: it can be machined to a very thin, yet strong and unbreakable plate; appears to cause less postoperative inflammation in the anterior chamber than PMMA; and demonstrates statistically lower rates of the frequency and severity of retroprosthetic membranes.²,³ Another advantage is that titanium is non-magnetic and, thus, compatible with MRI testing.



Titanium back plates of various dimensions and designs. Upper row: 7.0 mm, 8.5 mm and 9.5 mm diameter.

Since the titanium back plate is a new material, FDA approval is required before we can market and distribute this type of KPro in the United States. Several stringent FDA measures must be met before approval is granted. For example, the FDA has deemed the ethylene oxide sterilizers in local Boston area hospitals insufficient for "industrial" use; this requires that we send all packaged KPros to a South Carolina facility where long-term feasibility testing is underway. We anticipate that these measures, coupled with the FDA processing cycle, will result in a six to 12 month timeframe before we receive FDA marketing approval. Clearly, our KPro manufacturing has entered a new, more complex phase.

^{1.} Ament JD, Spurr-Michaud S, Dohlman CH, Gipson IK. The Boston Keratoprosthesis: comparing corneal cell compatibility with titanium and PMMA back plates. *Cornea* 2009; 28:808-811.

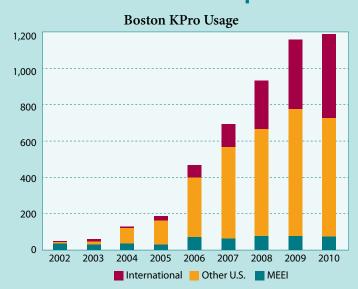
^{2.} Dohlman CH, Todani A, Ament JD, Chodosh J, Ciolino JB, Colby KA, Pineda R, Belin MW, Aquavella JV, Graney J. Titanium vs. PMMA back plates for Boston Keratoprosthesis: Incidence of retroprosthetic membrane. *Invest Ophthalmol Vis Sci*, 2009; ARVO poster # 1505.

^{3.} Todani A, Ciolino JB, Ament JD, Colby KA, Pineda R, Belin MW, Aquavella JV, Chodosh J, Dohlman CH. Titanium back plate for a PMMA keratoprosthesis: clinical outcomes. *Graefes Arch Clin Exp Ophthalmol* 2011; in press.

CE Mark will make KPro available in Europe

n order to distribute the Boston keratoprosthesis throughout Europe, which includes 27 countries with a population of approximately 500 million, we recently began the process to obtain CE Marking. CE Marking is a mandatory conformity mark for medical products marketed in the European Union (EU), along with Iceland, Liechtenstein, and Norway. The term, CE stands for "European Conformity" and is considered a quality mark similar to FDA device approval in the U.S. CE Marking indicates compliance with EU legislation regarding health, safety and environmental concerns related to the design and manufacturing of a medical device. CE Marking indicates to any government official that the product can be marketed, and ensures the free movement of the product within the EU.

Fully meeting the rigorous EU standards necessitates changing where and how we sterilize our devices, and upgrading many of our internal procedures. Once all of these changes are in place, we expect to receive approval within a year from now.



Since 2002, about 6,000 KPro devices have been implanted worldwide.

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starting at 2-4 times daily and tapered over 1-2 months, followed by once-daily polymyxin B/trimethoprim (generic form of Polytrim[™]) for life. The latter drug is broad spectrum with sufficient gram-positive coverage; it is also inexpensive.

2. In autoimmune patients, chemical burns, and only eyes, we initially give vancomycin (14 mg/ml with 0.005% benzalkonium) once daily plus a fluoroquinolone initially 2-4 times daily, tapered to once or twice daily (for both) for life. Inclusion of vancomycin is important even though it has to be specially made up. Eventually, fluoroginolone can be substituted by the much cheaper polymyxin B/trimethoprim as the second agent, for life.

Under any circumstances, compliance with daily medication for life is extremely important and must be emphasized repeatedly.

Corticosteroids are usually given topically as prednisolone acetate 1.0% with the same regimens as following penetrating keratoplasty. Treatment is often started with 4 times daily, gradually tapered to once daily over 2-3 months and, in many cases, eventually stopped. Caution is urged regarding long-term steroids in autoimmune diseases where they can contribute to tissue melt.

We do not routinely give antifungal prophylaxis in Boston. In hot, humid areas, brief periodic bursts of antifungals may be necessary (e.g. Amphotericin B 0.15% twice daily for 1 or 2 weeks every 3 months). If fungal colonization of the soft contact lens is identified, lens exchange plus a period of Amphotericin is advisable. In fungal keratitis (white sheen around the KPro stem) or outright endophthalmitis, the addition of systemic antifungals is necessary. Prognosis is usually good as long as the infection is identified early.

With the above listed prophylactic medication, the rate of infections can be kept very low. Our present rate of destructive endophthalmitis within five years postoperatively is 2% (mostly due to non-compliance). This includes a high percentage of autoimmune cases. However, lack of compliance with daily medication, which is especially challenging in developing countries for many reasons (e.g. cost of medical supplies or scarcity of medical personnel) is still very troubling. A significant research effort is currently underway to make the Boston KPro simpler, less expensive and — most of all — safer in the long run. We hope to have some good news in this respect in the near future.

Visit us! www.meei.harvard.edu/shared/ophtho/cornea2.php

Profiles of distinguished KPro



Virender Singh Sangwan, MD



Jimmy K. Lee, MD

Dr. Virender Singh Sangwan completed his basic medical education and ophthalmology training at Maharshi Dayanand University, Rohtak, Haryana, and a cornea fellowship at LV Prasad Eye Institute (LVPEI) in Hyderabad. He went on to complete an immunology and uveitis fellowship at Harvard Medical School in 1998. He is currently Associate Director and Head of the Cornea and Anterior Segment, Ocular Immunology & Uveitis Services at LVPEI.

Dr. Sangwan is noted for his spirit of innovation and ability to translate basic science discoveries into clinical applications. Among his accomplishments, Dr. Sangwan perfected the method of limbal stem cell culturing to produce transparent, stitchable epithelium, and successfully transplant them to patients. His work represents the largest successful human trial of stem cell technology in the world, and has enabled him to restore vision to over 600 patients blinded by burns and damage to the ocular outer surface; his work has been published in the journal Nature. Additionally, he devised a method to co-culture conjunctival and limbal stem cells and to use the resulting tissue to restore vision in extreme cases of ocular surface damage. For these contributions, Dr. Sangwan was awarded the Shanti Swarup Bhatnagar Prize in Medical Sciences in 2006, and the National Technology Prize by the Department of Biotechnology in 2007.

Dr. Sangwan has served as Field Medical Director of Orbis International, Inc., NY and has lectured extensively. He is the recipient of numerous awards and serves on several editorial boards. Dr. Sangwan is presently the Coordinator for Collaborative Research Projects between LVPEI and VisionCRC, a cooperative research center initiative of the Australian government. He is also an Adjunct Associate Professor at the University School of Medicine & Dentistry, University of Rochester, New York, USA. Dr. Sangwan also has been deeply involved in the eye banking movement in India.

Dr. Sangwan is married to Vandana, a dentist, and they have two children daughter, Twinkle and son, Sahil.

Dr. Jimmy K. Lee is the Director of Cornea and Refractive Surgery at the Yale Eye Center. He specializes in laser vision correction surgery, including LASIK, LASEK, PRK and PTK. His surgical expertise also includes complex cataract surgery and artificial cornea surgery. Dr. Lee is an experienced Boston KPro surgeon.

Dr. Lee's research interests include new technologies in refractive surgery and improving surgical techniques for DSEK (Descemet's

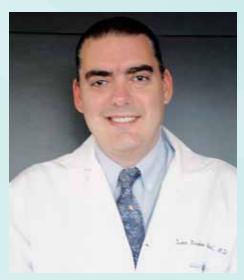
surgeons

Stripping Endothelial Keratoplasty). A member of the American Academy of Ophthalmology and American Society of Cataract and Refractive Surgery, he has published many peerreviewed articles and is a scientific reviewer for numerous ophthalmology journals. In addition, he frequently lectures on refractive surgery and corneal transplantation at national and international scientific meetings.

Dr. Lee graduated Phi Beta Kappa from Johns Hopkins University and obtained his medical degree from Cornell University Medical College. Following his residency at Albert Einstein Montefiore Hospital, he completed a fellowship in Cornea, External Diseases, and Refractive Surgery at the Wilmer Eye Institute of The Johns Hopkins Hospital. He is a Diplomate of the American Board of Ophthalmology.

Dr. Juan Carlos Abad received his medical degree from the Institute of Health Sciences CES in Medellin, Columbia and completed his ophthalmology residency at Georgetown University Medical Center, DC. As a cornea fellow at Mass. Eye and Ear ('95-'97), Dr. Abad worked on the KPro to develop an animal model that could be tested for different device retention strategies; he also studied the histology of explanted KPros to better understand the factors that contribute to corneal melts (epithelial invasion vs. stromal necrosis), and contributed to the article "Keratoprosthesis: preoperative prognostic categories," published in the journal Cornea in 2001, an article which remains current today. During the latter part of his fellowship, he assisted with implementing the KPro program in the Dominican Republic.

After completing his fellowship, Dr. Abad returned to his native Colombia in 1997, where he pioneered the introduction of the Boston KPro. Since then, he has performed surgery on 47 patients (43 with the new model since 2004), helping to restore sight to long-standing blind patients. In 2010, Dr. Abad presented at the World Cornea Conference V1 (Boston) on improving KPro retention through the use of medroxyprogestrone, doxycycline, and by avoiding MMP activating antibiotics and glaucoma agents. He frequently lectures and gives courses on the topic throughout Latin America. He is currently advocating an aphakic approach with a complete pars plana vitrectomy (in most cases) to decrease inflammation, interdevice membranes, facilitate glaucoma shunt insertion and long-term success (no vitreous blockage), and to facilitate KPro re-dos when needed. Dr. Abad runs a private practice in Medellin, Colombia.



Juan Carlos Abad, MD



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Rony Sayegh, MD Optics Mass. Eye and Ear



Eleftherios Paschalis, PhD Bioengineering Mass. Eye and Ear



Andrea Cruzat, MD Surgical Innovations Mass. Eye and Ear



Anita Nathan Shukla, MD **Surgical Innovations** Mass. Eye and Ear

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We apologize for inadvertent omissions.

Poster Presentations

American Academy of Ophthalmology (2010)

Deepak Sobti, Brendan M. McCleary, William G. Gensheimer, Garrick Chak, Matthew D. Gearinger, Mina Chung, James Aquavella. Pediatric keratoprosthesis: Outcomes and quality of life. Poster # 58.

Javaneh Abbasian. Ultrasound biomicroscopy used preoperatively for surgical planning in patients undergoing Boston KPro Type 1. Poster # 353.

Amar P. Patel, Joseph T. Nezgoda, Syril Dorairaj, Tiago S. Prata, John A. Seedor, David C. Ritterband. Surgical outcomes of the Boston Keratoprosthesis. Poster # 359.

The Association for Research in Vision and Ophthalmology (2011)

Joshua H. Hou, Jose De la Cruz, Ali R. Djalilian. Predictors of keratoplasty failure after keratolimbal allograft transplantation and long-term outcomes of Boston Keratoprosthesis implantation as subsequent salvage therapy in ocular surface disease. Poster # D847

Pejman Bakhtiari, Jeffry Welder, Clara Chan, Jose De la Cruz, Edward J. Holland, Ali R. Djalilian. Surgical and visual outcomes of the Type 1 Boston Keratoprosthesis for the management of aniridic fibrosis syndrome in congenital aniridia. Poster # D848

Danli L. Xing, Christine Chiou, Mark Mannis, John Keltner. Glaucoma detection in Boston Keratoprosthesis patients. Poster # D852

Ofelya Gevorgyan, Anna Hovakimyan, Anthony J. Aldave. Complications and outcomes of Boston Type 1 Keratoprosthesis surgery in Armenia. Poster # D853

Ashley Dahl, Kristen M. Hawthorne, Bradford Mitchell, Gerald McGwin, John S. Parker. Early sight restoration and high retention after Boston Keratoprosthesis in non-autoimmune patients. Poster # D854

Sahar Kohanim, Tulay Cakiner-Egilmez, Robert W. Dunphy, Mary K. Daly. RTVue CAM anterior segment OCT imaging of epithelial lip overriding front plate of Boston Type I Keratoprosthesis. Poster # D855

Travis C. Rumery, Shahzad I. Mian, Fernando Heitor de Paula. Outcomes of endocyclophotocoagulation in Boston Type 1 Keratoprosthesis. Poster # D856

Joann J. Kang, Maria S. Cortina, Jose De la Cruz. Visual outcomes of Boston Keratoprosthesis implantation as the primary penetrating corneal procedure. Poster # D857

Mark Krakauer, Shivani Gupta, Asim V. Farooq, Jose De la Cruz, Maria S. Cortina, Peter Setabutr. Oculoplastic considerations in keratoprosthesis surgery. Poster # D858

Joseph Panarelli, Anne Ko, Julian P. Garcia, Paul A. Sidoti, Michael R. Banitt. Angle closure by anterior segment optical coherence tomography after Boston Keratoprosthesis. Poster # D859

Lee Kiang, Mark I. Rosenblatt, Rachel Sartaj, Donald J. D'Amico, Kimberly C. Sippel. Surface Epithelialization of the Type I Boston Keratoprosthesis Front Plate. Poster # D860

Jose De la Cruz, Maria S. Cortina, Jin-Hong Chang, Dimitri T. Azar. Scanning electron microscopy analysis of explanted keratoprostheses. Poster # D861

Trucian A. Ostheimer, Jose de la Cruz, Maria S. Cortina. Corneal graft thinning in Boston Type 1 Keratoprosthesis patients. Poster # D862

Fernanda P. Magalhaes, Heloisa M. Nascimento, Ana L. Hofling-Lima, Lauro A. Oliveira. Postoperative regimen of Boston Type I Keratoprosthesis with topical 0.5% moxifloxacin and 5% povidone-iodine. Poster # D863

Alex W. Cohen, Michael D. Wagoner, Anna Kitzman, Kenneth M. Goins. Outcomes of corneal transplantation with the Boston Type I Keratoprosthesis. Poster # D864

Julia C. Talajic, Sebastien Gagne, Younes Agoumi, Mona Harissi-Dagher. Longterm results regarding the impact of glaucoma on vision following Boston Keratoprosthesis Type I surgery. Poster

Yvonne I. Chu, Christopher C. Shen, Michael D. Straiko, Crawford Downs, Neda Shamie, Stuart K. Gardiner, Steven L. Mansberger. Assessment of intraocular pressure in eyes with keratoprosthesis. Poster # A612

Jennifer S. Huang, Simon K. Law, Fei Yu, Joann A. Giaconi, Anne L. Coleman, Joseph Caprioli, Anthony Aldave. Glaucoma management in patients undergoing Boston Type I Keratoprosthesis implantation. Poster # A68

Basu S, Senthil S, Sangwan VS. Correlation of anterior chamber angle morphology with progression of glaucoma in eyes with Boston Type I Keratoprosthesis. Poster # 85

Mines MJ, Ryan DS, Sia RK, Weber E, Pasternak J, Stutzman RD, Wroblewski KJ, Bower KS. On the case: Deconstructing a keratoprosthesis. Poster # 67

You're invited. Please join us!

American Academy of Ophthalmology Meeting

October 22-25, 2011 | Orlando, Fl

Schedule of Events

Friday, October 21

■ 8:30 a.m. – 4:30 p.m.

Cornea Society/EBAA Fall Educational Conference

Rosen Centre Hotel

Sunday, October 23

■ 11:37 – 11:57 a.m.

Whitney G. Sampson Lecture: "Artificial Corneas and Contact Lenses" Claes H. Dohlman, MD, PhD

Orange County Convention Center, Room W311

■ 10:15 a.m. – 12:30 p.m.

Instruction Course: "Corneal Surgical Tips for 2011"

Senior Instructor: David G. Huang, MD

Orange County Convention Center, Room W203c

■ 3:15 – 5:30 p.m.

Instruction Course: "Surgery for Severe Corneal and Ocular Surface Disease"

Senior Instructor: Gunther Grabner, MD

Orange County Convention Center, Room W104a

Monday, October 24

 \blacksquare 7:00 – 8:30 a.m.

Boston KPro Users Breakfast: James Chodosh, MD, MPH, moderator

Hilton Orlando, Lake Lucerne Room

For further information contact mlmoar@verizon.net

■ 7:00 – 8:30 a.m.

Pediatric Keratoplasty Association, Breakfast at AAO

Kathryn Colby, MD, PhD: "Pediatric Keratoprosthesis: Promise and Perils," The Peabody Orlando, Room Bayhill 18

■ 9:00 – 11:15 a.m.

Boston KPro Course: "The Boston Keratoprosthesis: Essentials for the Beginning and Experienced Surgeon"

Senior Instructor: Anthony J. Aldave, MD

Orange County Convention Center, Room W309a

Tuesday, October 25

■ 7:30 – 8:30 a.m.

Breakfast with the Experts: Moderator: Peter Zloty, MD

Orange County Convention Center, Room Hall A1

■ 2:00 – 4:15 p.m.

Instruction Course: "Extreme Cornea: Diagnostic and Management Dilemmas in Your Practice"

Senior Instructor: Ula Jurkunas, MD

Orange County Convention Center, Room W204c

■ 10:15 a.m. – 12:30 p.m.

Instruction Course: "Interdisciplinary Approach to Keratoprosthesis Surgery and Management from the Subspecialist's Perspective"

Senior Instructor: Jose de la Cruz, MD

Orange County Convention Center, Room W207c

KPro Events 2011-12

2nd EuCornea Congress

September 16-17, 2011 Reed Messe Wien GmbH, Messeplatz 1, PF 277, A-1021 Vienna, Austria

27th Biennial Cornea Conference

September 30-October 1, 2011 Starr Center for Scientific Communications 185 Cambridge Street, Boston, MA

European Association for Vision and Eye Research 2011 Congress

October 5-8, 2011 Creta Maris Convention Center Crete, Greece

World Ophthalmology Congress 2012

February 16-20, 2012 Abu Dhabi National Exhibitions Abu Dhabi, United Arab Emirates

Cornea Day

Friday, April 20, 2012 McCormick Place West Chicago, Illinois

The American Society of Cataract and Refractive Surgery

April 20-24, 2012 Chicago, Illinois Applications for KPro course submitted, Senior Instructor: José de la Cruz





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