BOSTON KPro news
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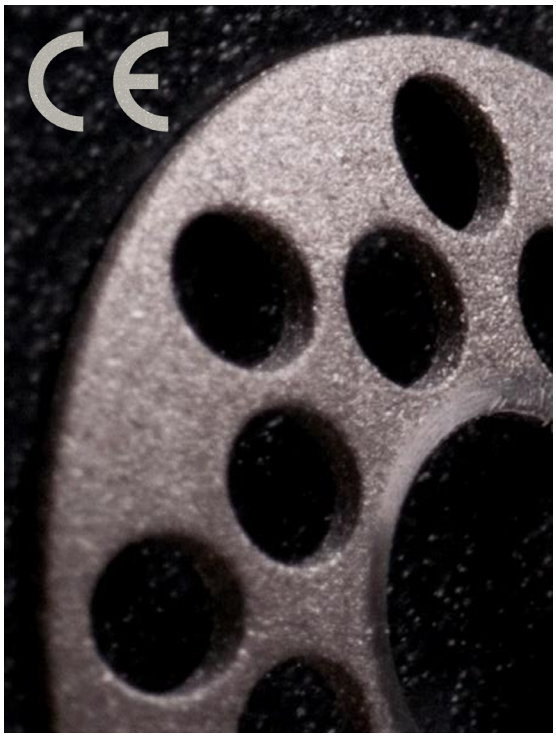
Exciting News for European KPro Users

Larisa Gelfand



After nearly three years of hard work, we have received the CE marking for our Boston Keratoprosthesis (Boston KPro) device.

This means that Boston KPro now complies with all applicable mandatory European Union product directives, such as safety, health, and environmental protection, and that the implantation of the device will now be reimbursable across the EU market, making it accessible to many more people with corneal blindness.

The CE marking has been granted specifically for the current "snap-on" design, which includes front plate, titanium back plate (8.5 mm diameter only), and titanium locking ring.

Per EU regulations, we can no longer provide European users with the Kontur contact lens because this product does not have the CE marking. However, any appropriate soft bandage contact lens available in the European market can be used.

In addition, in order to comply with EU regulations, we will be making changes to our distribution policy – ordering instructions will follow shortly.

We are currently in the process of building up new inventory with proper packaging and labeling per regulatory guidelines, which will take three to four months. In the interim, we will continue to ship the devices under the Compassionate Use Exemption.

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

HARVARD MEDICAL SCHOOL | DEPARTMENT OF Ophthalmology
Massachusetts Eye and Ear

Boston KPro *news*

In this issue:

The Boston KPro newsletter is published once annually.

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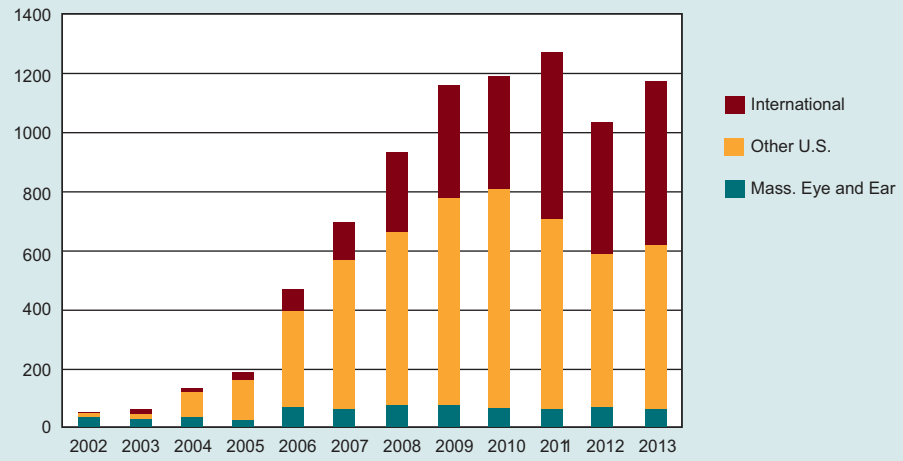
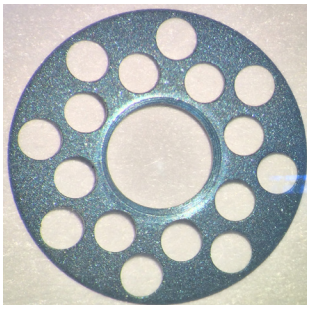
Boston KPro Usage

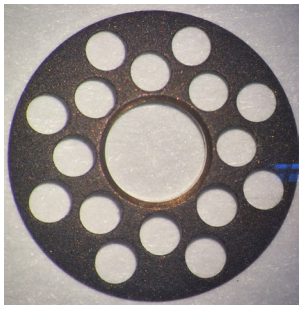


Coloring the Boston KPro Titanium Backplate

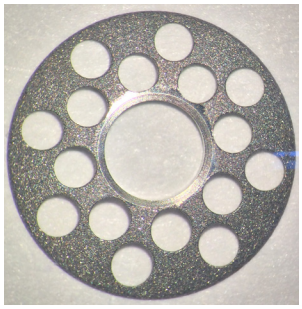
Eleftherios Paschalis, PhD



Blue Anodized



Brown Anodized



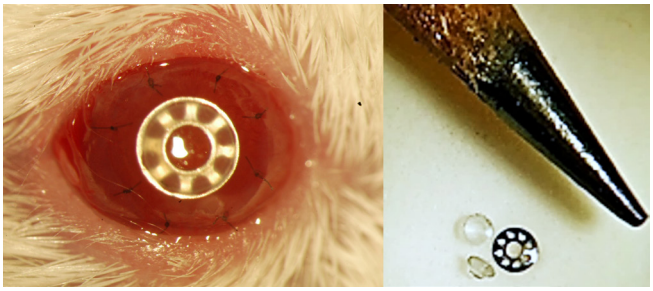
Non Anodized

The Boston KPro titanium back plate has many advantages over the previously used polymethylmethacrylate (PMMA) back plate, but its metallic shiny silver appearance makes it less cosmetically desirable and less socially acceptable by patients. Thus, recent improvements have focused on improving the cosmetic appearance of the device.

We colored the titanium back plate with an inert and biocompatible titanium oxide layer using a surface modification technique. Subsequently, we performed *in vitro* and *in vivo* tests to assure the safety and biocompatibility of the coloring process. A preliminary human study is currently underway. Among other improvements, which are currently under evaluation, the titanium coloring will help surgeons and patients overcome a significant aesthetic barrier.

Miniature Keratoprosthesis (m-KPro)

Alja Crnej, MD



The long-term complications associated with Boston KPro implantation, such as glaucoma, optic neuropathy, epiretinal membrane, macular edema, and retinal detachment, are still a threat to the long-term safety of the Boston KPro. The causes of these complications remain unclear but may be related to chronic post-operative inflammation, which is difficult to detect. Thus, we established a mouse model for Boston KPro in collaboration with Reza Dana, MD, MSc, MPH. The model will hopefully allow us to investigate the host's immune response to KPro implantation, specifically in the chronic stage, well after the acute wound healing period.

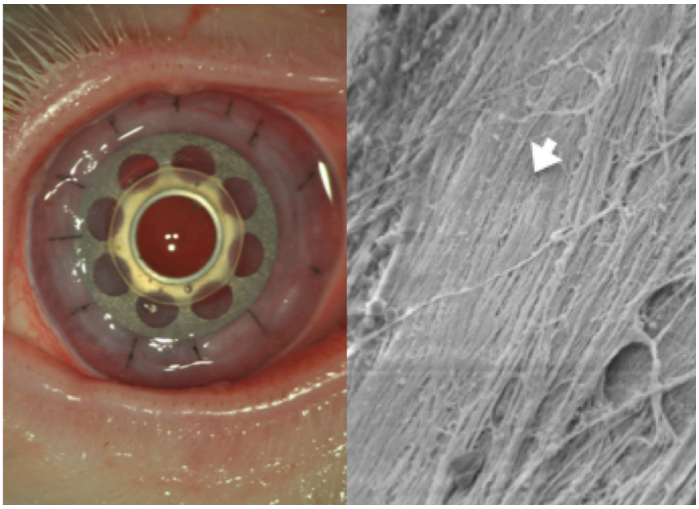
In the machine shop where human Boston KPros are manufactured a miniature keratoprosthesis (m-KPro) device was created consisting of a polymethylmethacrylate front plate and a titanium back plate, designed after the Boston KPro. The surgical procedure was identical to the implantation of Boston KPro in humans, and m-KPros were successfully implanted and retained in mice. There were no critical complications, such as endophthalmitis, corneal melting, device extrusions, leakage, or extensive inflammation. However, we observed mild to moderate donor and host corneal neovascularization. This allows us to quantify the release of inflammatory cytokines inside the eye. We anticipate that this m-KPro model will serve as a good experimental system for evaluating host responses after KPro surgery.

Coating the Boston KPro Stem with Titanium

Borja Salvador-Culla, MD

A close interaction between the tissues in the body and implanted medical devices directly influences safety and long-term clinical outcomes. In Boston KPro, the PMMA stem and the donor cornea never truly integrate, and the stromal remodeling next to the stem can result in tissue melting. This creates a space between their surfaces and facilitates the penetration of microorganisms into the eye. Consequently, despite the use of a topical daily antibiotic prophylaxis, which have reduced the risk of endophthalmitis, severe infections can occur, especially in non-compliant patients.

We explored the use of titanium-coated stem of the Boston KPro to see if titanium could enhance the adhesion of the corneal carrier and decrease the risk of endophthalmitis. Our preliminary in vivo results in animals showed good tolerance and benign tissue reaction of a titanium sleeve around the stem after several months (see figure). Our results also demonstrated that the titanium sleeve improved adherence of the rabbit cornea to the stem. Therefore, we believe that incorporating such an approach may improve the adhesion with the donor cornea and decrease the rate of infection and endophthalmitis in humans as well. Further experiments need to be completed before moving into a human clinical trial, but we anticipate quick progress based on our initial results [manuscript in submission].



Profiles of Distinguished Boston KPro Surgeons

Geetha Iyer, FRCS

Dr. Geetha Iyer is a senior consultant at the Dr. G. Sitalakshmi Memorial Clinic for Ocular Surface Disorders and the C.J. Shah Cornea Services at Sankara Nethralaya in Chennai, India. Her clinical interests include the management of Stevens Johnson Syndrome (SJS) and chemical injuries, keratoprosthesis, stem cell transplants, ocular surface tumors, and pediatric penetrating keratoplasty. To date, she has conducted more than 150 keratoprosthesis (KPro) surgeries, which include modified osteo odonto keratoprosthesis (MOOKP), Boston type 1 and 2 KPro, and Lucia type 1 and 2 KPro.

After completing her basic medical training at Seth GS Medical College and King Edward Memorial Hospital, Mumbai in 1999, she pursued post graduate training in ophthalmology and subspecialty training in cornea and external disease through a fellowship at Sankara Nethralaya in India. Under the mentorship of Dr. Giancarlo Falcinelli, she acquired training in the MOOKP procedure. Additionally, she completed an observership with Dr. Scheffer C. G. Tseng in ocular surface disorders and received training from Dr. Claes H. Dohlman in the Boston type 1 keratoprosthesis.

Dr. Iyer's research focuses on ocular surface disorders and improving clinical outcomes for patients with keratoprosthesis. She has a particular interest in preventing and treating laminar resorption in MOOKP by means of bone morphogenic protein. Along with clinicians in the Clinic for Ocular Surface Disorders, she is collaborating with Dr. James Chodosh at Mass. Eye and Ear/Harvard Medical School and the Boston KPro Foundation to contribute to the design and modification of the Lucia type 2 KPro. Working closely with vitreoretinal, glaucoma, oculoplasty, anesthesia, radiology and dental colleagues, this team offers a holistic approach to patients with severe ocular surface disorders. Notably, she and colleagues published clinical outcomes on 464 eyes (232 patients) with SJS in the March 2014 issue of *Graefes Arch Clin Exp Ophthalmol*. She shares her in-depth knowledge teaching courses and presenting at national and international meetings.

Kimberly C. Sippel, MD

Dr. Kimberly C. Sippel is the director of the Cornea Service, co-director of the Cornea Fellowship program, and an associate professor of ophthalmology at Weill Cornell Medical College in New York City. Her clinical interests include the treatment of severe ocular surface disease, corneal transplantation, and permanent keratoprosthesis surgery. As founder of the keratoprosthesis program at Weill Cornell/ New York Presbyterian, she has a particular interest in keratoprosthesis surgery in patients with severe ocular surface disease, a particularly challenging group, as well as in anterior segment imaging as it relates to keratoprosthesis surgery. Additionally, as a result of caring for patients in New York Presbyterian Hospital's large Burn Center, Dr. Sippel developed an interest in the optimal acute stage management of patients with Stevens Johnson Syndrome (SJS).

After graduating from Harvard College with honors in Biochemical Sciences, Dr. Sippel obtained her medical degree with the Alpha Omega Alpha distinction from Columbia University College of Physicians & Surgeons. After two years of General Surgery training at Massachusetts General Hospital, she completed her Ophthalmology residency training at Harvard Medical School followed by a Cornea fellowship at Massachusetts Eye and Ear. She has received numerous awards, including a Heed Foundation fellowship, the American Ophthalmological Society Knapp Foundation fellowship award, and the American Academy of Ophthalmology's Achievement Award.

Dr. Sippel completed several years of vision-related laboratory investigation as a Research Fellow at Massachusetts Eye and Ear in the area of ophthalmic molecular genetics and at Mass. Eye and Ear/Schepens Eye Research Institute in the area of corneal wound healing. She has authored numerous scientific publications and medical textbook chapters and has lectured on many clinical and research topics. In particular, her paper on the use of amniotic membrane in acute SJS was selected by the *American Journal of Ophthalmology* for presentation at the 'Editors' Choice Symposium' at the 2010 American Academy of Ophthalmology meeting.

Liqiang Wang, MD

Dr. Liqiang Wang is the vice director of the Department of Ophthalmology at the Chinese People Liberty Army (PLA) General Hospital. As a specialist in cornea and refractive surgery, she possesses expertise in laser vision correction surgery, femtosecond assisted keratoplasty surgery, complex cataract surgery, and artificial cornea surgery. In addition to being one of the highest volume corneal and refractive surgeons at Chinese PLA Hospital, she teaches residents and fellows about corneal, cataract, and refractive surgery as well as the clinical management and diagnosis of corneal and refractive conditions. She also is an experienced Boston KPro surgeon.

Dr. Wang completed her basic medical education at HeBei Medical University in China in 1994. Subsequently, she earned Master's degree and a PhD in ophthalmology from Chinese PLA postgraduate medical school before completing a two-year cornea fellowship at Massachusetts Eye and Ear. During part of her fellowship, she conducted research on biointegration of keratoprosthesis in Dr. Robert Langer's Laboratory at Massachusetts Institute of Technology .

After completing her fellowship, Dr. Wang returned to China and pioneered the use of the Boston KPro. Since returning, she has performed surgery on 85 patients, playing a vital role in restoring sight to blind patients, especially young patients with ocular burns.

As a clinician scientist at Chinese PLA general hospital, Dr. Wang continues to conduct basic science research on biointegration of KPro, tissue engineering the cornea using silk biomaterials, and stem cell transplantation. In collaboration with Dr. Claes H. Dohlman of Mass. Eye and Ear/Harvard Medical School, she is investigating the ability of messenchymal stem cells to increase the biointegration of Boston KPro. This work has been funded by a National Science Foundation of China grant.

Samir Melki, MD, PhD

Dr. Melki is the founder and director of the Boston Eye Group. He is also a member of the Cornea Service at Mass. Eye and Ear and an Assistant Clinical Professor of Ophthalmology, Harvard Medical School. As a specialist in corneal, cataract and refractive surgery, he has performed more than 11,000 refractive procedures and is at the forefront of utilizing novel intraocular lenses as well as femtosecond cataract surgery. .

After earning a combined MD/PhD from Vanderbilt University, Dr. Melki completed his ophthalmology residency at Georgetown University, which was followed by a fellowship in cornea and refractive surgery at Mass. Eye and Ear. In 2000, he founded the Boston Eye Group. From 2005 to 2013, he served as the medical director for ophthalmology at the UK specialist hospitals.

Active in the promotion of the use of keratoprosthesis around the globe, Dr. Melki published a retrospective analysis describing KPro clinical outcomes at Beirut Eye Specialist Hospital in Lebanon (*Cornea*, 2014). He also has long researched the use of a device that measures intraocular pressure (IOP) in patients with KPro. After working in collaboration with Dr. Claes H. Dohlman and demonstrating that the device is biocompatible in animals, Dr. Melki successfully implanted the IOP transducer in 2011 during a surgical mission in Lebanon; these data were first published in the June 2014 issue of *JAMA Ophthalmology*. Currently, Dr. Melki is working with Implandata GmbH from Germany to study the device in patients in the U.S.

A dedicated educator, Dr. Melki actively participates in the fellowship programs at both Mass. Eye and Ear and the Boston Eye Group. In collaboration with Boston University, he tutors students undergoing a Masters in Health Sciences. Additionally, Dr Melki is actively involved in instruction courses at the American Academy of Ophthalmology and the American Society and Refractive Surgery.

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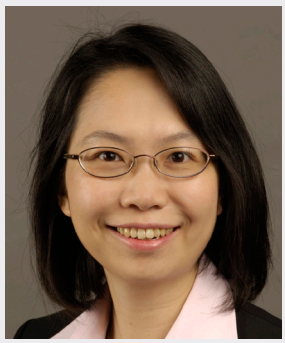

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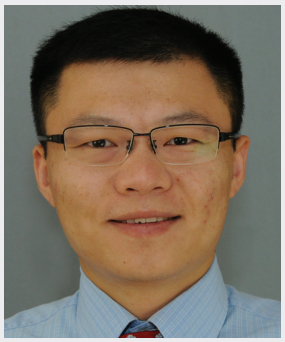

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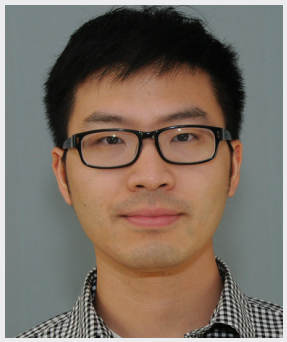

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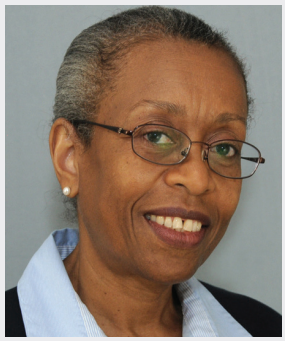

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Boston Keratoprosthesis Bibliography

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You're invited... Please join us!

American Academy of Ophthalmology Meeting

October 18-21, 2014
Chicago, IL, McCormick Place

SCHEDULE OF EVENTS

Monday, October 20

- **Boston Keratoprosthesis Users Breakfast**
  7:00am - 8:30am
  Place: Hyatt Conference Center McCormick Place.
  Clark Room (second floor)
  If you plan to attend please e-mail mlmoar@verizon.net

- **AAO Boston KPro Course**
  2:00pm - 4:15pm
  Course Number: 383 / Room S103D
  Course Title: The Boston Keratoprosthesis: Case-Based Presentations Highlighting the Essentials for Beginning and Experienced Surgeons.

  Senior Instructor:
  Kathryn A. Colby, MD, PhD

  Associate Instructors:
  Anthony J. Aldave, MD
  Esen K. Akpek, MD
  James V. Aquavella, MD
  Andrea Cruzat, MD
  James Chodosh, MD, MPH
  Claes H. Dohlman, MD, PhD
  Sadeer B. Hannush, MD

Tuesday, October 21

- **AAO Boston KPro Skills Transfer Course Lab**
  1:30pm - 3:30pm
  Course Number: LAB150A / Room N227B
  Course Title: Surgery for Severe Corneal and Ocular Surface Disease

  Course Directors:
  Ali R Djalilian MD
  Gunther Grabner MD

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