

A New Pre-Descemet's Keratoprosthesis

Eleftherios I. Paschalis, Roberto Pineda II, Miguel Gonzalez-Andrades, Andrea Cruzat, Claes H. Dohlman

flex-KPro

Worldwide, there are millions of patients with corneal blindness who are not amenable to standard penetrating keratoplasty. For them, the only viable option is the implantation of an artificial cornea, such as the Boston KPro. However, corneal penetration to implant the device can lead to intraocular complications, such as endophthalmitis and glaucoma, as well as subsequent permanent vision loss. A less invasive keratoprosthesis that does not penetrate the eye, but has the advantages of the modern titanium Boston KPro, may be a safe alternative, as has been proposed previously.

The Boston Keratoprosthesis Laboratory has developed a novel keratoprosthesis, called flex-KPro, that is suitable for non-penetrating implantation. The device uses deep anterior lamellar keratoplasty

(DALK) and is designed for implantation over the Descemet's membrane. The flex-KPro is fabricated using a medical grade titanium alloy that allows the back plate to be superelastic and as thin as 40µm. A new optical stem and titanium sleeve support the new design and locking mechanism.

The device was evaluated in rabbits, and preliminary results are very promising. Ten months after flex-KPro implantation, the device remained well tolerated with minimal corneal inflammation and neovascularization (Figures A, B). The anterior chamber anatomy appeared undisturbed (Figure C), and the intraocular pressure remained normal. Further evaluation is currently underway in preparation for human clinical trials.

Flex-KPro in a Rabbit Eye

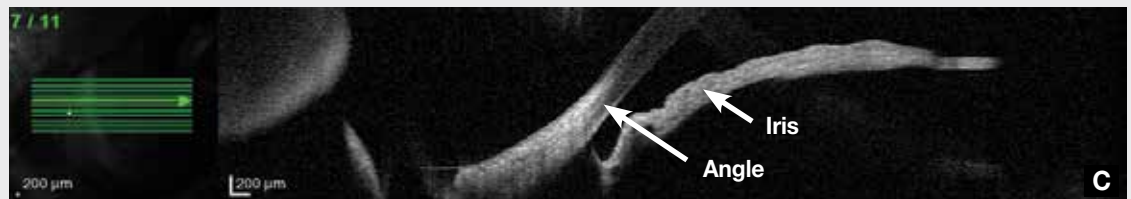


A: 1 week post-op



B: 10 months post-op

Flex-KPro was implanted in New Zealand white rabbits (n=3) using deep anterior lamellar keratoplasty (DALK). An allograft donor cornea was used as a tissue carrier. Post-operative photo at **a)** 1 week and **b)** 10 months. The flex-KPro was well tolerated and caused minimal corneal inflammation and neovascularization. **c)** At 10 months, the intraocular pressure was normal (<18mmHg) and similar to baseline, while the anterior chamber architecture was maintained. All eyes developed some degree of retro-prosthetic membrane, which was loosely attached to the posterior surface of the KPro stem. Successful removal was performed through the clear cornea using a 30G needle.



A Boston Keratoprosthesis update from
Harvard Ophthalmology / Massachusetts Eye and Ear



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Toward Practical, Inexpensive, and Safe Implantation of the Boston KPro

Miguel Gonzalez-Andrades, Claes H. Dohlman

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Here, the Boston KPro has been preassembled in a fresh corneal donor graft, placed in a vial with 5% Dextran, and gamma irradiated

Presently, the Boston KPro is assembled into a corneal graft by the surgeon in the operating room. The combination is then sutured into the patient's eye. This has led to occasional errors, and the logistics are cumbersome and expensive. To address these issues, the Boston Keratoprosthesis Laboratory is working to simplify this process

Preassembly of the device in a donor cornea, followed by gamma irradiation (an approved method for corneal grafts), would permit long-term storage and direct implantation without the need for assembly into a fresh corneal graft. However, for such a procedure to be approved, it has to be shown that gamma irradiation will not damage the Boston KPro.

Sterilization with Gamma Irradiation

We evaluated the effect of gamma irradiation in the same medical-grade PMMA that is used in the manufacturing of the Boston KPro. Fifteen-millimeter discs of PMMA were submitted to either ethylene oxide sterilization (currently used) or different doses of gamma radiation (10, 25, and 50 kGy). Biocompatibility, mechanical strength, and optical quality of the material were evaluated. Moreover, the feasibility of assembling the device in an allograft, followed by gamma irradiation for sterility, was also evaluated.

No differences in corneal epithelial cell biocompatibility were observed among the samples ($p > 0.05$). Mechanical evaluation by nanoindentation showed no alteration in the PMMA after irradiation. Optical evaluation showed similarly high levels of transparency for the ethylene oxide, 10 kGy, and 25 kGy groups. The absorbance of ultraviolet light was higher for the 25 kGy and 50 kGy groups. Technically, preassembly followed by irradiation was uncomplicated.

In summary, sterilization with gamma irradiation had no detectable influence on biocompatibility, mechanical, or optical properties of the device. Preassembly of the device in a donor cornea, followed by sterilization with gamma irradiation—which would allow for long-term storage and ease of implantation—may prove to be an efficient and safe way to provide KPro devices. FDA approval will be necessary before implantation, and is our next goal toward a practical, inexpensive, and safe KPro.

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Editor:

James Chodosh, MD, MPH
Director, Boston KPro Clinical Programs

Co-Editors:

Claes H. Dohlman, MD, PhD
Director, Boston KPro Research and Development

Larisa Gelfand
Director, Boston KPro Business Operations

Drug Delivery System for Biologics

Eleftherios I. Paschalis, Chengxin Zhou, Marie-Claude Robert, Demetrios Vavvas, James Chodosh, Claes H. Dohlman

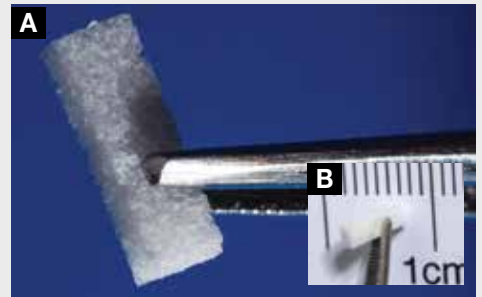
Biologic agents that target cytokines and growth factors are being applied to an expanding spectrum of human systemic and ocular disorders. However, one of the major limitations in the systemic administration of biologic therapies is the risk of systemic adverse events and rapid clearance from the body. Also, the topical application of biologics is hindered by the large molecular size and hydrophilicity of antibodies that limit penetration and bioavailability.

The Boston Keratoprosthesis Laboratory has developed a novel polymer-based drug delivery system (DDS) for sustained delivery of biologic agents to the eye (Figures A-C). The DDS provided sustained, zero-order delivery of anti-TNF- α antibodies *in vitro* and *in vivo* for one and three months, respectively. The antibodies were stable in the DDS for one year when sterilized with gamma irradiation and stored at room temperature.

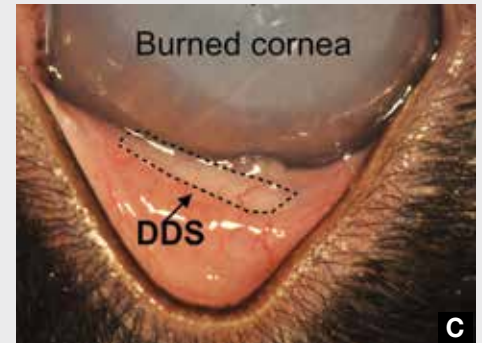
Studies in rabbits demonstrated the safety and efficacy for the treatment of ocular alkali burns using anti-TNF- α (Figure C). Most importantly, subconjunctival anti-TNF- α DDS in rabbit eyes achieved antibody penetration into the posterior segment and subsequent reduction of retinal inflammation, leading to marked neuroprotection following ocular burns. This is particularly important in light of the new findings that corneal alkali burns can cause irreversible retinal damage via inflammation, and that inhibition of TNF- α is protective.

Preliminary results using anti-VEGF DDS in rabbit corneal alkali burns showed marked improvement in corneal wound healing and re-epithelialization. The described drug delivery system opens new possibilities for the treatment of ocular diseases amenable to biologic therapy using FDA-approved drugs.

Drug Delivery System (DDS)



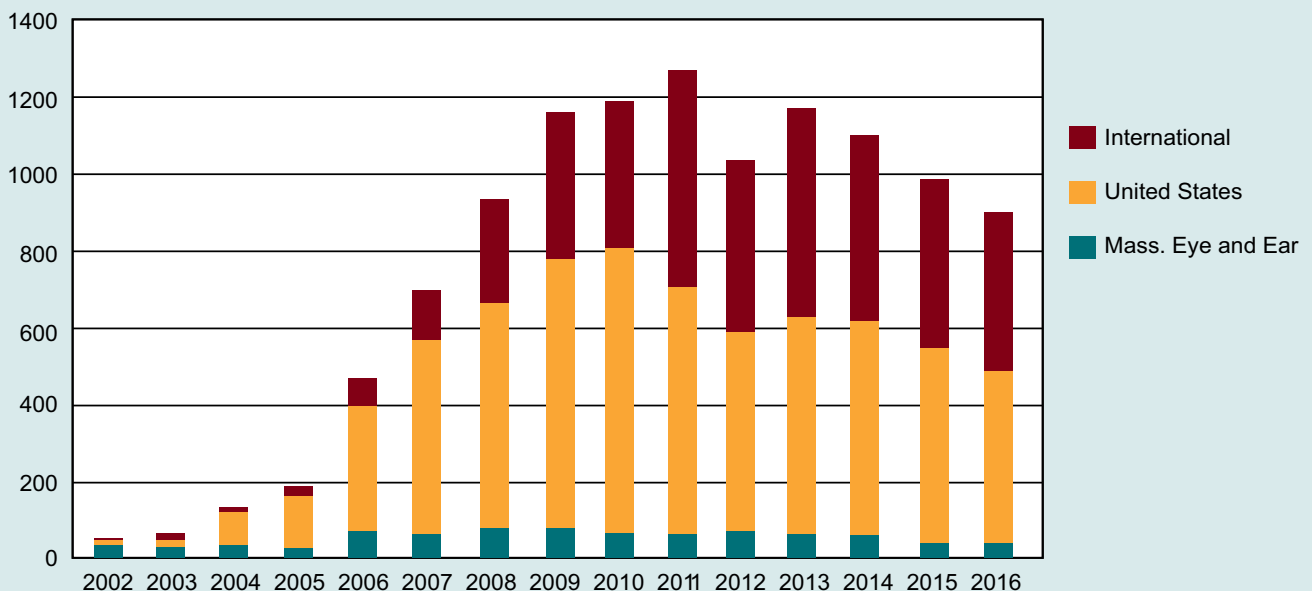
a) The antibody is loaded into the 3D porous network of the DDS using PVA carrier at desired concentrations. **b)** The drug delivery system can be trimmed and shaped as required.



c) DDS implanted sub-conjunctivally in a rabbit eye after corneal burn

Boston KPro Usage

(Approximately 13,000 implanted to date)



Decellularized Porcine Corneas as Human Corneal Substitutes for the Boston KPro

Mohammad Islam, Miguel González-Andrades



Decellularized porcine cornea after applying sterilization and crosslinking.

According to the World Health Organization, 285 million people throughout the world are visually impaired, and among them, 39 million are blind in at least one eye. One of the most common etiologies of blindness throughout the world is corneal disease. Ulceration and trauma cause 1.5–2 million new cases of cornea-related monocular blindness every year. The most widely accepted treatment for corneal blindness is the transplantation of a full-thickness, healthy donor cornea after removing the damaged tissue.

Unfortunately, the availability of donor tissue is substantially less than the demand for transplantation and has resulted in 10 million untreated patients worldwide, with an additional 1.5 million new cases every year. Moreover, other aspects, such as donor tissue quality and donor-derived infection, still challenge the success of transplantation in some areas. For instance, testing a donor tissue for transplantation can elevate the cost of corneal donor tissue to \$3,000 or more. For countries with limited resources, a suitable alternative to donor corneas is needed. Although natural and synthetic biomaterial-based artificial cornea development is progressing, the manufacturing of clinical-grade biomaterials is a high-cost process that requires GMP facilities and may be unaffordable for many developing nations.

Xenograft transplantation is considered an alternative to human donor corneas. For example, porcine corneas exhibit similarities to human corneas, including refractive power, size, and mechanical properties. Xenografts have been tested since the 1800s. In 1838, Richard Sharp Kissam transplanted a cornea from a six-month-old pig into the cornea of a young Irishman with a central corneal leucoma. During the same year, a sheep xenograft cornea was placed into a human patient. In most cases, the xenograft transplants failed due to a host immune reaction against the graft. In addition, cross-species diseases are a potentially major complication of xenograft transplantation. These complications might be avoided if the cellular component of the xenograft were removed, while preserving the extracellular matrix. Decellularization can be achieved by different methodologies, according to the species and the type of tissue or organ.

Decellularized corneas have been studied to evaluate their potential as corneal substitutes in the same or cross-species. Several research groups have described different protocols for decellularizing corneal xenografts, evaluating the obtained graft *in vitro* and in animal models. In 2015, decellularized porcine corneas were transplanted into patients for clinical evaluation in China. In this context, sterilization processes, such as gamma irradiation, might be applied to the decellularized xenograft to avoid graft-associated infections. Moreover, gamma irradiation also reduces the antigenicity of the tissue. Gamma-irradiated human corneas are already in use in place of fresh donor corneas for lamellar patch grafts and as carriers for the Boston KPro.

We are working to optimize the decellularization and gamma sterilization of porcine corneas to determine its potential as a carrier for the Boston KPro. Our results demonstrate the efficiency of the technique to optimally decellularize and sterilize the porcine cornea. (See photo.) Moreover, human corneal epithelial cells and keratocytes can grow and migrate into the decellularized xenografts. In the future, decellularized porcine corneas might provide a less expensive and more available substitute for human donor corneas in Boston KPro implantation.

KPro Egypt Mission

Roberto Pineda II



Corneal blindness remains a major health problem globally, as many countries lack eye banks and the necessary resources. Likewise, most patients with corneal blindness live in underdeveloped countries. One such country is Egypt. Although the nation is advancing rapidly, it still has a wide economic gap, and many patients travel far distances for medical care.

During a recent program in Cairo, Egypt, the Boston KPro Type I was employed to help restore vision in two patients with corneal blindness that was not amenable to traditional keratoplasty.



Dr. Roberto Pineda II (left) and Dr. M. Anis (right) with Mohamed after keratoprosthesis surgery

Click-on Aphakic Boston KPro Type I

The first patient was a 19-year-old man with aniridia who had a previous failed penetrating keratoplasty and Morcher large diameter aniridic intraocular lens (IOL) in the right eye. Vision prior to surgery was hand motion.

A click-on aphakic Boston KPro Type I was implanted after removal of the IOL and anterior vitrectomy.

On postoperative day one, his vision was 20/100, and the patient was very happy and giggling at his improved vision. He said it was better than his other eye.



Dr. Roberto Pineda II with Amina after her keratoprosthesis



Boston KPro Type I, Lucia Model

The second patient was a 75-year-old woman with a diagnosis of ocular cicatricial pemphigoid (OCP) who had a failed corneal graft in the right eye and scarring and vascularization in the left eye. Vision was hand motion in both eyes. There was mild fornix foreshortening and tarsal fibrosis in the left eye, but the surface was wet with a strong blink reflex. The patient's OCP was well controlled on immunosuppressants.

The patient underwent implantation of the Boston KPro Type I, Lucia model with removal of her IOL. (See photo on left.) No vitrectomy was necessary.

When the eyepatch was removed the next day, the patient began crying and exclaimed, "I can see!" Her vision was 20/60 with clear media and a healthy optic nerve. Her daughter posted the results on Facebook, and within hours, received more than 1,000 likes.

These cases highlight the impact and work of the KPro team at Massachusetts Eye and Ear. In several international studies, the device has been shown to be effective, providing similar results to those in the United States. Careful patient selection and attentive postoperative management are necessary to achieve successful long-term results.

Profiles of Distinguished Boston KPro Surgeons

These distinguished surgeons were selected based on their exceptional contributions to Boston KPro research, demonstrated excellence in clinical practice, and commitment to teaching the future leaders in the field.

Anthony J. Aldave, MD



Dr. Anthony J. Aldave holds the Walton Li Chair in Cornea and Uveitis and is Chief of the Cornea and Uveitis Division and Director of the Cornea and Refractive Surgery Fellowship Program at the University of California, Los Angeles, Jules Stein Institute.

Dr. Aldave has received numerous honors during his career, including the Alpha Omega Alpha Scholarship

Award for graduating first in his medical school class; the Heed Ophthalmic Foundation Fellowship; the American Ophthalmological Society-Knapp Testimonial Fund Fellowship; the first Claes Dohlman Society Award; and the Achievement, Secretariat, and Senior Achievement Awards from the American Academy of Ophthalmology.

Recognized as a leader in the field of KPro surgery, Dr. Aldave has performed more than 200 Boston KPro procedures in the United States. In addition, he has led Boston KPro surgery skills transfer courses in more than a dozen countries, and many of the surgeons that he trained have become the leading KPro surgeons in their countries.

Dr. Aldave is frequently invited to lecture at international ophthalmology meetings on the Boston KPro and has published 19 peer-reviewed articles on the subject. In addition, he is a member of the Boston Type 1 Keratoprosthesis Study Group and is a site principal investigator for the Vision Restoration with a Collagen Crosslinked Boston Keratoprosthesis Unit multicenter study.

M. Soledad Cortina, MD



Dr. Cortina is Associate Professor of Ophthalmology and attending physician in the Cornea Service at the Illinois Eye and Ear Infirmary, Department of Ophthalmology and Visual Sciences. She serves as Director of the Keratoprosthesis Artificial Cornea Program and Director of the Infirmary's Comprehensive Ophthalmology Faculty Practice and General Eye Clinic.

Dr. Cortina joined the Illinois Eye and Ear Infirmary at the University of Illinois at Chicago (UIC) as a board-certified cornea specialist in 2010. She earned her medical degree from the University of Buenos Aires School of Medicine, Argentina. She completed her residency at Louisiana State University (LSU) School of Medicine, followed by a research fellowship at LSU's Neuroscience Center and a clinical fellowship in cornea at UIC's Illinois Eye and Ear Infirmary.

Dr. Cortina specializes in all forms of corneal transplantation and external eye diseases, with a special interest in KPro. Dr. Cortina's research focuses on the regeneration of corneal nerves after corneal and refractive surgery. She also conducts multiple clinical investigations on KPro. Dr. Cortina is Co-editor of *Keratoprosthesis and Artificial Corneas: Fundamentals and Surgical Applications*—the first comprehensive textbook dedicated solely to KPro surgery and the artificial cornea.

Recognized internationally for her research in corneal surgery and the KPro, Dr. Cortina has presented at meetings and symposia around the world and has numerous publications in peer-reviewed journals. With a strong commitment to training the future generation of KPro surgeons, she serves as instructor in several KPro courses throughout the year and created an international Kpro fellowship at UIC.

David C. Ritterband MD, FACS



Dr. David C. Ritterband MD, FACS, is a Professor of Ophthalmology at the Icahn School of Medicine at Mount Sinai. He is currently the System Director of Refractive Surgery for the Mount Sinai Health System, as well as Assistant Director of the Cornea Service at the New York Eye and Ear Infirmary of Mount Sinai.

Dr. Ritterband earned his undergraduate degree from Duke University and his

Doctorate in Medicine from New York Medical College, where he was elected into the Alpha Omega Alpha Medical Honor Society. He served a transitional year internship at St. Vincent's Medical Center in New York and completed his ophthalmology residency at New York Medical College, where he was elected Chief Resident. He completed his Corneal and External Disease fellowship at The Eye and Ear Institute of the University of Pittsburgh School of Medicine.

A nationally recognized clinician scientist, Dr. Ritterband dedicates his time to clinical ophthalmic care, surgery, research, and teaching. He has published more than 65 peer-reviewed manuscripts, several book chapters, and more than 150 research abstracts. He is a frequent lecturer on cornea and refractive surgery topics—both locally and nationally.

His clinical interests span ocular infections, corneal transplantation (including artificial corneal transplantation with Kpro), cataract surgery, and laser refractive surgery.

A committed teacher and mentor, he has trained more than 32 clinical cornea fellows in the highly regarded AUPO-certified corneal fellowship program at the New York Eye and Ear Infirmary of Mount Sinai. As a mentor, Dr. Ritterband is committed to teaching future generations the Boston KPro technique.

Dr. Ritterband has received numerous awards, including an honor award from the American Academy of Ophthalmology, and has been named to *New York Magazine's* Best Doctors, Castle Connolly's Top Doctors, and the *New York Times Magazine's* Super Doctors. He has also received six resident teaching awards from the New York Eye and Ear Infirmary in the past 18 years.

Mark Wilkins, MD



Dr. Mark Wilkins has been a consultant at Moorfields Eye Hospital, where he has been head of the Corneal Service since 2005.

His interests include lamellar graft surgery and the Boston KPro. He has been using the Boston Kpro Type I since 2011, when he established a specialist service at Moorfields to treat patients with the device. Initially, the surgery was funded on a

patient-by-patient basis, but now the UK government has set aside funding for KPro surgery.

Today, Moorfields has a specialized KPro clinic that is run in conjunction with the Glaucoma Service (Dr. Nicholas Strouthidis) and Vitreoretinal Service (Dr. Louisa Wickham) to provide more streamlined care. Dr. Wilkins has performed more than 50 KPro procedures to date. The clinic sees patients from throughout the United Kingdom, frequently sharing care with local corneal specialists.

He has two publications in the KPro field:

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2. Ang, Man, Fenwick, Lamoureux, Wilkins. Impact of type I Boston keratoprosthesis implantation on vision-related quality of life. Accepted for publication in the *British Journal of Ophthalmology* 2017.

THE BOSTON KPRO TEAM



Claes Dohlman, MD, PhD
Translational Research



James Chodosh, MD, MPH
Surgery, Translational
Research



Roberto Pineda II, MD
Surgery, Clinical Research



Samir Melki, MD, PhD
Surgery, IOP Transducers



Joseph Ciolino, MD
Surgery, Clinical Research



Eleftherios Paschalis, MSc, PhD
Bioengineering



Lucy Shen, MD
Glaucoma



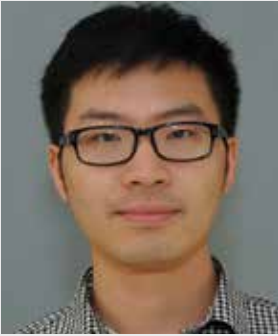
Reza Dana, MD, MSc, MPH
Translational Research



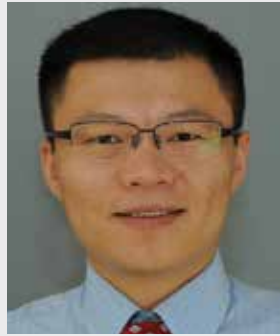
Pablo Argüeso, PhD
Enzymology,
Glycobiology



**Miguel Gonzalez-
Andrades, MD, PhD**
Clinical and
Translational Research



Chengxin Zhou, PhD
Translational Research



Dylan Lei, MD, PhD
Translational Research



Mohammad Mirazul Islam, PhD
Translational Research



Pui Chuen Hui, PhD
Translational Research



Sina Sharifi, PhD
Translational Research



Vassiliki Kapoulea, MS
KPro Research
Assistant



Sarah Kim, MS
KPro Research
Assistant



Sandra Vizcarra
KPro Laboratory
Technician



Rhonda Walcott-Harris
Administrative Assistant



Julie Stampfle
KPro Customer
Service Coordinator



Mary Lou Moar
Consulting KPro
Coordinator



Larisa Gelfand
Director,
Boston KPro Business
Operations

July 2015 and onward

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Join us at these upcoming events. . .

XXV Congress of the European Society of Cataract and Refractive Surgeons (ESCRS)

October 7–11, 2017: Lisbon, Portugal

Boston Type 1 Keratoprosthesis: From Indications to Innovations

Saturday, October 7, 5:00–6:00pm

Leader: M. Cortina, MD

Boston KPro Surgical Skills Training Course

Sunday, October 8, 9:30–10:30am and

11:00am–1:00pm

American Academy of Ophthalmology Meeting

November 11–14, 2017: New Orleans

Boston Keratoprosthesis Users Breakfast

Sunday, November 12, 7:00–8:30 am

Marriott at the Convention Center, Meeting Room:

Blaine Kern F

AAO KPro Course:

The Boston Keratoprosthesis: Case-Based Presentations Highlighting the Essentials for Beginning and Experienced Surgeons

Sunday, November 12, 4:30–5:30pm

Senior Instructor: Sadeer B. Hannush, MD

AAO KPro Course:

Surgery for Severe Corneal and Ocular Surface Disease

Director: Ali R. Djalilian, MD

Lab 124A – Sunday, November 12, 3:30–5:30pm

Room: 344-345, Morial Convention Center



October 12-14, 2017 | Boston, MA

The Biennial Cornea Conference is the premier global anterior segment eye research conference. The event brings together basic and clinical researchers in the field of cornea and ocular surface.

HIGHLIGHTS

Thursday evening, October 12

- Poster Session, hosted by Boston University School of Medicine in the Hiebert Lounge

Friday, October 13

- Scientific and clinical presentations related to ocular surface immunology and microbiology; endothelial cell biology; and innovation and new techniques
- J. Wayne Streilein Lecture:
Reza Dana, MD, MPH, MSc
- Cocktail reception and dinner at the Liberty Hotel

Saturday, October 14



A celebration of Claes H. Dohlman, MD, PhD, and his 60 years of contributions to corneal science and education

- Talks from past Dohlman Fellows
- Claes H. Dohlman Lecture:
Kazuo Tsubota, MD, PhD

eye.hms.harvard.edu/cornea/conference