

## FDA Approval Obtained for the Boston Keratoprosthesis Type I Lucia Design

*James Chodosh*

Boston Keratoprosthesis (KPro) is a small, not-for-profit entity within Massachusetts Eye and Ear, a nonprofit specialty hospital and affiliate of Harvard Medical School. As the readers of this newsletter are well aware, Boston KPro markets devices intended for patients with otherwise irreversible corneal blindness in whom repeat corneal transplantation has failed, or because of ocular comorbidities would otherwise be expected to fail. Since the U.S. Food and Drug Administration (FDA) approved the device for marketing in 1992, more than 14,000 Boston KPro devices have been implanted. For patients with bilateral blindness with normal retinal function in at least one eye, but blind due to corneal opacity, implantation of a Boston KPro can lead to a miraculous improvement in vision, the restored capacity to work and study, and the ability to see loved ones' faces and to appreciate all the visual wonders the rest of us with normal vision take for granted.

Over the same time frame, hundreds of peer-reviewed articles on the device have been published by eye surgeons across the globe, many of these articles focused, very appropriately, on the potential complications of device implantation. Recognition of the potential complications detailed in these studies has helped lead to improvements to the device, better selection of surgical candidates for implantation, better informed surgical decision making, and more focused postoperative care, with rates of postoperative complications now lower than at any time since the initial FDA approval.

Indeed, the improvement of device outcomes has been and remains a major focus at Boston KPro. Over the last 25+ years, Claes H. Dohlman, MD, PhD, Professor Emeritus and former Chair of the Department of Ophthalmology at Harvard Medical School, and the inventor of the Boston KPro, instituted numerous modifications to his original type I device design. Dr. Dohlman introduced the placement of holes in the back plate and continuous contact lens wear after surgery, which together reduced rates of sterile keratolysis. Implementation of topical vancomycin once daily in KPro recipient eyes reduced the incidence of gram-positive bacterial endophthalmitis to almost zero. Development of the titanium back plate reduced the formation of retroprosthetic membranes, and a change to the titanium "Click-on" back-plate design improved the ease of device assembly by surgeons.

Dr. Dohlman also led KPro surgeons to more aggressively manage intraocular pressure before and after KPro implantation, in recognition of a central role for glaucomatous vision loss in those eyes that retain the device long-term. Finally, his recognition of inflammation as a key mediator of glaucomatous optic neuropathy after KPro implantation, particularly in those patients with corneal blindness from alkali corneal burn, has opened a new perspective on neuroprotection, with therapeutic implications that extend well beyond disorders of the cornea.

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



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# Boston KPro *news*

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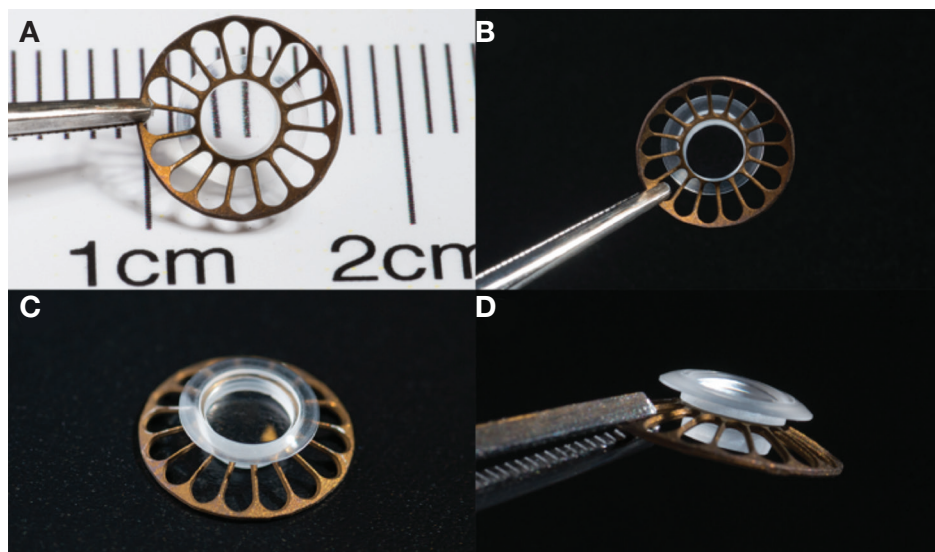
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**Figure.** Boston KPro, type I, Lucia design, anodized to a brown color. **(A)** Assembled device shown from posterior with surface over a line ruler showing a 7.75-mm diameter. **(B, C, D)** Three views of the Lucia design from different angles. Note the “petaloid” appearance with 16 symmetrically placed radial openings. The surface area of the openings exceeds that of the “Click-on” device. (Reproduced with permission from Bakshi et al. *Cornea* 2019;38:492-497.)

These and other advances are why the Boston KPro type I is today the most widely implanted keratoprosthesis worldwide. Nonetheless, the ever-growing regulatory costs associated with manufacturing and marketing a medical device in the United States led us, some eight years ago, to consider how to further improve the Boston KPro, while controlling the costs of manufacturing and regulation. After several years of hard work by the Boston KPro team, we are happy to announce FDA approval of the Lucia design, conceived and engineered to reduce manufacturing costs and simplify our inventory, while also providing an improved cosmetic appearance after implantation. The Lucia design (Figure) retains the two components and ease of assembly of the predicate “Click-on” type I device, but minor modifications in design have simplified its manufacturing. A single (titanium) back plate diameter (7.75 mm) was chosen halfway between the currently available 7 and 8.5 mm, in order to accommodate both adult and pediatric eyes with one device. The cosmetic appearance was improved by changing the shape of the back plate holes from round to radial, with a petaloid appearance. We are also able to impute an even more natural appearance by anodizing the back plate to better mimic a normal eye color.

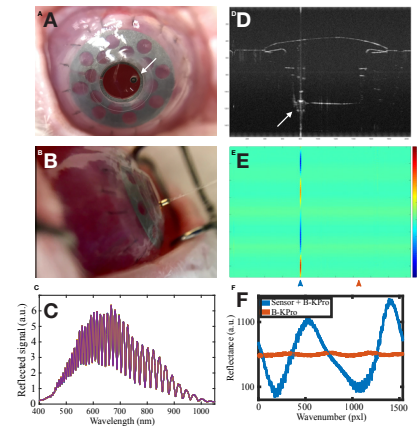
Successful outcomes after implantation of a Boston KPro requires daily topical antibiotics, careful management of intraocular pressure, and life-long postoperative follow-up. With the Lucia design, we hope to provide a device that can serve patients with corneal blindness into the next decade.

# Integrating a Pressure Sensor in the Boston KPro

Pui-Chuen Hui, James Chodosh, Claes H. Dohlman, Eleftherios I. Paschalis

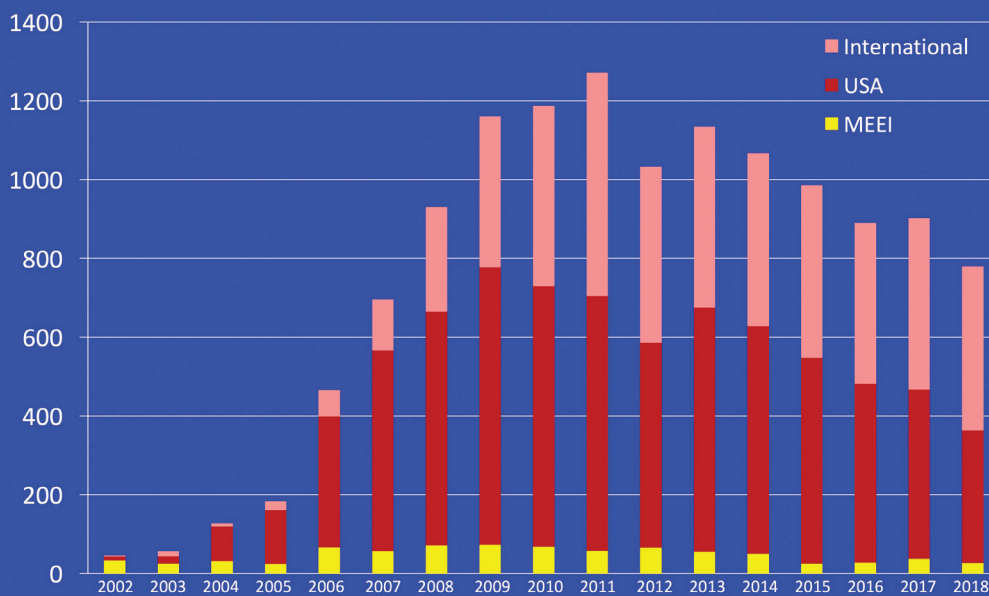
One of the most devastating complications of Boston KPro (B-KPro) surgery is glaucoma. Our inability to perform reliable and accurate tonometry over the rigid B-KPro plastic prevents early detection and treatment of elevated intraocular pressure (IOP) and leads to optic nerve and retinal damage. The Boston Keratoprosthesis Laboratory has integrated a micro-optomechanical pressure sensor in the B-KPro device (iB-KPro). Pressure readings are acquired using broadband light interferometry. The sensor is positioned at the periphery of the iB-KPro optical stem, fitted with a gold-plated micro-magnet sleeve that allows self-coupling with an external magnetic fiber-optic module (Figure A-C). An alternative approach for noncontact IOP interrogation was developed as well using hyperspectral analysis of the sensor's cavity length using existing bench-top optical coherence tomography (OCT; Figure D-F).

The sensor was stable for over two years *in vitro* with minimal drift in IOP measurements ( $\pm 0.8$ mmHg). Implantation of the iB-KPro in six rabbits was uncomplicated and reliable IOP measurements were obtained using the micro-magnet self-coupling technique. Pressure readings were accurate, but gradually began to deviate from the true IOP measured intracamerally due to dense retroprosthetic membrane (RPM) formation on the posterior surface of the optical stem. The severity of the RPM observed in rabbits is not often seen in human B-KPro patients; therefore, iB-KPro devices are expected to perform better longitudinally in humans. Our group is currently optimizing the systems to account for such biological perturbations in preparation for clinical studies.



**Figure.** (A) Rabbit eye implanted with pressure enabled iB-KPro. Integrated sensor at the periphery of the optical stem with a gold-plated micro-magnet sleeve around the sensor (white arrow). (B) IOP measurement in rabbit eye using external interrogation module and optical fiber fitted with a secondary micro-magnet (opposite in polarity) for rapid light coupling. (C) Optical interferometric spectra of the pressure sensor with overlapping spectra indicating stable coupling. (D) OCT B-scan of an iB-KPro (without the micromagnet). The sensing membrane is shown as the hyperreflective spot (white arrow). (E) Hyperspectral map of the iB-KPro optical path. Blue arrow: location of the pressure sensor; red arrow: a spot of the optical stem of iB-KPro. (F) Optical spectra of the pressure sensor and the optical stem (blue) and only the optical stem (red) extracted from the hyperspectral map. The x-axis is expressed as the inverse of the wavelength, i.e. the wavenumber, but is left uncalibrated.

## Boston KPro (over 14,000 implanted)

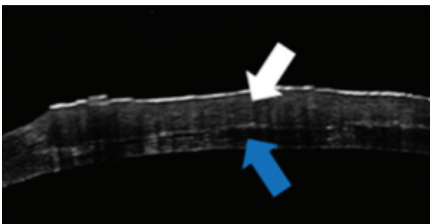


# Finding an Optimal Substitute for Human Donor Corneas

Mohammad Mirazul Islam, Roholah Sharifi, Miguel González-Andrades



**Figure 1.** Decellularized porcine cornea after applying gamma sterilization.



**Figure 2.** Rabbit cornea one week after anterior lamellar keratoplasty with a gamma-irradiated decellularized porcine cornea. Anterior segment optical coherence tomography shows the proper biointegration of the xenograft (white arrow: gamma-irradiated decellularized porcine cornea; blue arrow: rabbit corneal host).

It is estimated that 12.7 million people are waiting for corneal transplantations, which means that only 1 in 70 of those needing transplantations are served worldwide. To address the lack of donor tissue and the shortcomings associated with donor corneal transplantation, substantial efforts have been made to develop alternatives to human donor corneas. In this regard, corneal xenograft emerges as a possible substitute to the human cornea. However, the antigenicity and immunogenicity associated to xenogeneic tissues, which lead to rejection and failure of the graft, hinder their use in human patients.

In order to minimize the immune response and improve outcomes of the xenotransplant, it is critical to select an animal species with a similar composition and structure of corneal proteins compared to humans. Thus, we compared the amino-acid sequences and specific chemical properties of the most abundant proteins in the corneal stroma (collagen  $\alpha$ -1 (I),  $\alpha$ -1 (VI),  $\alpha$ -2 (I) and  $\alpha$ -3 (VI), as well as decorin, lumican, and keratocan) of 14 different animal species to those present in the human. Our results showed that pig cornea had the highest similarity score (91.8%) compared to the human.<sup>1</sup>

Despite the anatomical and chemical similarities of porcine corneas to human corneas, there are two main antigens present on the porcine cells that can initiate an immune response against the xenograft: alpha Gal ( $\alpha$ -gal) epitopes and N-glycolylneuraminic acid (NeuGc). Humans have natural antibodies that bind to those antigens, which can be detrimental for graft survival.<sup>2,3</sup> In our studies we have shown that by specific decellularization techniques, we can remove the cells from the corneal stroma and reduce the antigenic components of the porcine tissue (Figure 1).

In the context of bringing decellularized porcine corneas into clinical use, sterilization is an essential step for the success of the xenotransplantation, in order to avoid graft-associated complications in human recipients. However, little is known about the effect of sterilization on decellularized corneal xenografts. We evaluated the use of gamma irradiation on decellularized porcine corneas (Figure 1), demonstrating the optimal biocompatibility and optical and mechanical properties of the gamma-irradiated decellularized tissue.

The complement system also plays an important role in the immune and inflammatory responses associated with xenotransplantation. This was shown in a pig-to-rhesus corneal xenotransplantation experiment, where host complement components facilitated the rejection of the transplant.<sup>4</sup> However, it is unknown how the human complement system will react after contacting the xenogeneic tissue. Thus, we collaborated with Prof. Mollnes at the University of Oslo to develop an *in-vitro* human blood model to evaluate complement activation. Our preliminary results show that the decellularization and gamma sterilization of porcine corneas do not adversely influence complement activation against the xenograft.

Finally, we have recently started an *in-vivo* rabbit study to evaluate the real potential of gamma-irradiated decellularized porcine corneas as an alternative to human donor corneas. Our preliminary results show that this xenograft can be successfully transplanted in rabbits without causing acute graft rejection (Figure 2).

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# King Khaled Eye Specialist Hospital Keratoprosthesis Center of Excellence

José Manuel Vargas



The first Boston Keratoprosthesis Center in the Middle East opened on February 25, 2019 at King Khaled Eye Specialist Hospital (KKESH) in Riyadh, Saudi Arabia. Inaugurated in 1983, KKESH is a 250-bed hospital and is the largest ophthalmic tertiary referral center in the Kingdom. The goal of the institution is to improve eye care throughout the Kingdom and beyond using cutting-edge technology. Our professionals strive to offer the best eye care to their patients. A leader in education and research, KKESH excels in training professionals, conducting research, offering community health education, and developing outreach programs.



Under the guidance of CEO Dr. Abdulaziz AlRajhi, KKESH was granted re-accreditation by the Joint Commission for International Accreditation of Health Facilities, and recently received the Saudi Central Board for Accreditation of Healthcare Institutions Certification. At the end of 2018, Dr. AlRajhi, working with a team of coworkers, including Dr. José M. Vargas, Chairman of Anterior Segment Division; Dr. Deepak Edward, Director of the Research Department; and Dr. Hernan Osorio, Anterior Segment Division Consultant, created the first Boston KPro clinic in the Middle East.



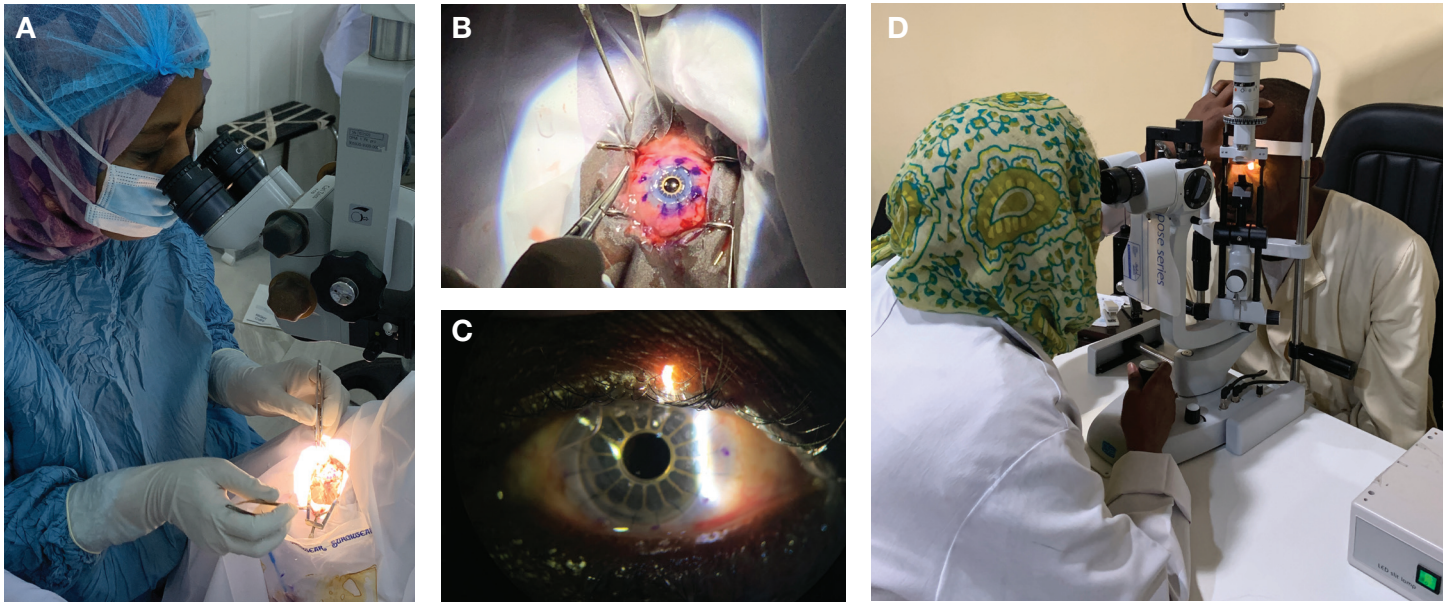
Developed by Claes H. Dohlman, MD, PhD, the Boston KPro is the most widely used artificial cornea in the world and is the only keratoprosthesis used in this institution. This new KPro Clinic represents a big step ahead in the treatment of patients with advanced corneal disease, providing prompt and effective treatment for them. The goal of the Center's cornea specialists is to decrease the incidence of complications and prolong the survival and retention rate of the device.

The creation of the Boston KPro clinic at KKESH will make ours the only center in the Middle East capable of bringing comprehensive medical treatment for patients with corneal blindness. This will be the only center in the Middle East for the treatment of severe ocular surface diseases in patients who are not candidates for standard corneal transplants. Following the opening ceremony, a video message with greetings from Dr. Dohlman played in our new Center.

**Figure. (A)** Outside view of the King Khaled Eye Specialist Hospital. **(B)** From left to right: Dr. Hernan Osorio, Anterior Segment Division Consultant; Dr. Abdulaziz AlRajhi, CEO of King Khaled Eye Specialist Hospital; Dr. José M. Vargas Chairman of Anterior Segment Division; and Dr. Deepak Edward, Director of the Research Department. **(C)** Following the opening ceremony, a video message with greetings from Dr. Claes H. Dohlman played in the new King Khaled Eye Specialist Hospital.

# Pilot Program in Sudan

Roberto Pineda II



**Figure. (A, B)** Dr. Amani operating inpatient using the Boston KPro Lucia design in February 2019. **(C)** Boston KPro type I Lucia design. **(D)** Dr. Honaida examining one of the Boston KPro Lucia patients.

This past February, I returned to the Makkah Eye Complex in Khartoum, Sudan, despite the protests that had begun in December 2018. Fortunately, these events did not disturb our mission, but the Sudanese Ophthalmic Congress was postponed that week.

This year marks 10 years since I first visited the institution. The emphasis has always been on treating corneal blindness and the use of the Boston KPro, which has helped many patients in Sudan. In the past, several of the cornea surgeons at the Makkah Eye Complex have made educational visits to Massachusetts Eye and Ear as either an International Council of Ophthalmology fellow (three-month scholarship) or observer for several weeks. Our most recent trip focused on the Boston KPro Lucia design with an anodized colored back plate using a corneal allograft. One Sudanese patient also received a Boston KPro type 1 “Click-on” model with a gamma irradiated VisionGraft KPro Ring.

Three patients—two men and a woman—received anodized titanium colored back plates for glare reduction and cosmetic improvement with the KPro, and did well with improved vision, even on the first postoperative day. Two of the patients who received the Boston KPro Lucia design had multiple corneal graft rejections, and the third patient had severe corneal scarring and neovascularization with cataract. There were no complications noted in the first week.

As usual, it was an exciting week with about 50 complex consultations in addition to the surgeries. We also had a chance to see some previous KPro patients, including one patient from eight years ago who was doing well. Of course, there are always challenges with KPro patients. One of our previous patients had a partial corneal stromal melt that required both medical and surgical intervention. However, overall, most of the Boston KPro patients continue to do well in Sudan, and we look forward to continuing our program next year.

# 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.

## Maria Fideliz de la Paz, MD, PhD



Dr. de la Paz is one of the few surgeons around the world who performs Boston KPro, osteo-odonto keratoprosthesis (OOKP), and Tibial bone keratoprosthesis, having learned from pioneers (late) Joaquin Barraquer and Jose Temprano. Aside from keratoprosthesis surgery, she specializes in ocular surface reconstructive and keratoplasty surgery. She also focuses on the medical treatment of ocular surface diseases such as dry eye, allergies, infectious keratitis, neurotrophic keratopathy, aniridic keratopathy, and others.

Dr. de la Paz earned her Bachelor of Science in Psychology (*cum laude*) at the University of the Philippines in 1991 and later earned her medical degree at the same university as a state scholar. She completed her ophthalmology residency at the Department of Health Eye Center in Manila, Philippines in 2000. She was a scholar of the Agencia Internacional de Cooperación Internacional and completed a clinical fellowship at the Barraquer Eye Center in Barcelona, Spain. In 2008, she joined the faculty of the Institut Universitari Barraquer and became a consultant of the Barraquer Eye Center, where keratoprosthesis surgery has been performed since the 1950s.

Dr. de la Paz earned her PhD at the Universitat Autònoma de Barcelona in 2016 upon presentation of her thesis, "Boston Keratoprosthesis Type 1: indications, long-term results and complications" (*cum laude*). She is the author of various book chapters on ocular tumors, aniridia, and keratoprosthesis. Committed to sharing her knowledge in the field of keratoprosthesis, she has published several manuscripts in peer-reviewed journals and also regularly lectures in Spain and abroad. She performed the first OOKP surgery in the Philippines in 2017 along with members of the Philippine Cornea Society, as part of her commitment to teach. She organized the 11th KPro Study Group Meeting in Barcelona in 2018, which was highly commended by international KPro experts.

## Federico Cremona, MD



Dr. Cremona is Associate Professor of Ophthalmology and Attending Physician in the Department of Ophthalmology at the Hospital de Clinicas "Jose de San Martin," University of Buenos Aires, Argentina.

He earned his medical degree from the University of Maimonides School of Medicine, Buenos Aires, Argentina (2003). He completed his residency at Hospital de Clinicas "Jose de San Martin," University of Buenos Aires (2003-2006), followed by a Cornea and Refractive

Surgery Research fellowship at Wills Eye Hospital, Philadelphia, PA, USA (2006-2007) and a Cornea fellowship at Hospital de Clinicas "Jose de San Martin," University of Buenos Aires (2007-2008). Dr. Cremona obtained the position of Cornea Service Director in 2014 at Hospital de Clinicas "Jose de San Martin," Buenos Aires, Argentina. Since then, he directs the training and practice of residents and fellows.

Dr. Cremona specializes in all forms of corneal transplantation and external eye diseases, with a special interest in keratoprosthesis surgery. He has performed over 60 KPro surgeries in public and private practice. His clinical expertise includes inflammatory, allergic, and immunologic diseases of the cornea and the conjunctiva. He performs a wide variety of anterior segments surgeries, including cataracts, corneal transplantation, and keratoprosthesis.

## Christopher P. Majka, MD



Dr. Majka is a fellowship-trained cornea specialist practicing in Corpus Christi, Texas. He is the Founder and Medical Director of Texas Eye Care

Network, a private practice integrated care network established to meet the growing eye care needs of South Texas. Dr. Majka and his team are responsible for restoring the sight of thousands of patients in need annually.

He completed his residency training at Kresge Eye Institute in Michigan, followed by cornea training at Duke University in North Carolina.

Dr. Majka is a nationally recognized pioneer in his field, bringing many new technologies and techniques to South Texas, including anterior segment restoration using the artificial corneal transplant, the Boston KPro. He appreciates the years of research and engineering that have resulted in the modern-day Boston KPro design that allows patients who would have otherwise remained "corneal blind" to enjoy quick visual recovery.

Aside from corneal transplantation and the KPro, Dr. Majka's clinical interests include cataract surgery, amniotic membrane therapy, laser vision correction, minimally invasive glaucoma surgery, and ocular surface restoration.

# THE BOSTON KPRO TEAM



**Claes H. Dohlman, MD, PhD**  
Translational Research



**James Chodosh, MD, MPH**  
Surgery, Translational  
Research



**Roberto Pineda II, MD**  
Surgery, Clinical Research



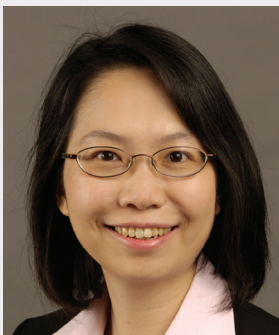
**Samir Melki, MD, PhD**  
Surgery, IOP Transducers



**Joseph Ciolino, MD**  
Surgery, Clinical Research



**Eleftherios I. Paschalis, MSc, PhD**  
Bioengineering



**Lucy Shen, MD**  
Glaucoma



**Reza Dana, MD, MSc, MPH**  
Translational Research

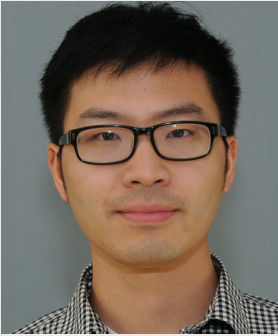


**Pablo Argüeso, PhD**  
Enzymology,  
Glycobiology

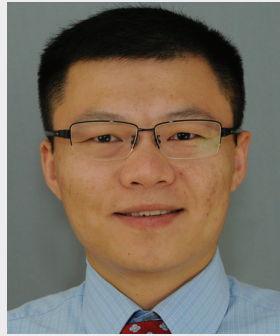


**Miguel Gonzalez-  
Andrades, MD, PhD**  
Clinical and  
Translational Research





**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



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**Sandra Vizcarra**  
KPro Laboratory  
Technician



**Rhonda Walcott-Harris**  
Administrative  
Assistant



**Alexandra Martinez**  
KPro Project  
Coordinator



**Mary Lou Moar**  
Consulting KPro  
Coordinator



**Larisa Gelfand**  
Director,  
Boston KPro Business  
Operations

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## Join us at these upcoming events. . .

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

September 14-18, 2019: Paris, France

#### **Boston Type 1 Keratoprosthesis: From Indications to Innovations**

Saturday, September 14, 5:00-7:00 pm  
Instructor: Maria Cortina, MD

#### **Boston KPro Wetlab (Alja Crnej, MD)**

Sunday, September 15; 8:30-10:30 am & 11:00 am-13:00 pm  
Pavilion 7, Paris Expo Porte de Versailles, Paris. Wetlab area, room 2.

### American Academy of Ophthalmology Annual Meeting



October 12-15, 2019: San Francisco, CA

#### **Boston Keratoprosthesis Users Breakfast**

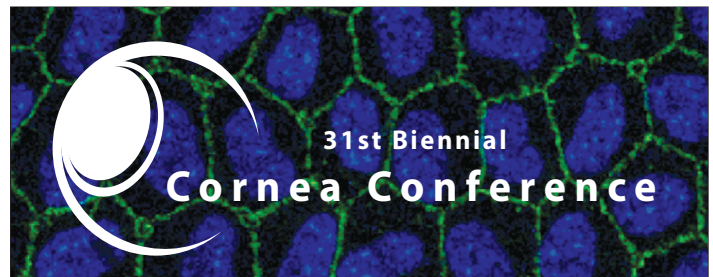
Sunday, October 13, 6:30-8:30 am  
Grand Hyatt San Francisco  
345 Stockton Street, San Francisco, CA  
Meeting Room: Skyline room located on the 36th floor

#### **Surgery For Severe Corneal Ocular Surface Disease (LAB126A)**

Monday, October 14, 2019, 10:30am-12:30pm  
Course Director: Ali Djalilian, MD  
Room: 4, South-Moscone Center, San Francisco, CA

#### **The Boston KPro: Case-Based Presentations Highlighting the Essentials for Beginning and Experienced Surgeons**

Tuesday, October 15, 2019, 9:00-10:00 am  
Senior Instructor: Sadeer B. Hannush, MD  
Instructors: Esen K. Akpek, MD; Anthony J. Aldave, MD; James V. Aquavella, MD; Kathryn A. Colby, MD, PhD; James Chodosh, MD, MPH; Mona Harissi-Dagher, MD  
Topic: Cornea, External Disease  
Education Level of the Course: Advanced  
Course Number: 607



### September 20-21, 2019 | 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

##### Friday, September 20



- Scientific and clinical presentations related to ocular surface, immunology and microbiology, and stroma
- Panel 1: Areas of Greatest Unmet Need in Cornea
- J. Wayne Streilein Lecture: Linda Hazlett, PhD
- Reception, poster session, and dinner at the Liberty Hotel

##### Saturday, September 21



- Scientific and clinical presentations related to endothelial biology and innovation
- Panel 2: Controversies in Corneal Pathobiology
- Claes H. Dohlman Lecture: Eduardo Alfonso, MD

[eye.hms.harvard.edu/cornea/conference](http://eye.hms.harvard.edu/cornea/conference)