

Comparing Repeat Donor Corneal Transplantation to Boston Keratoprosthesis in Patients with Previous Graft Failure

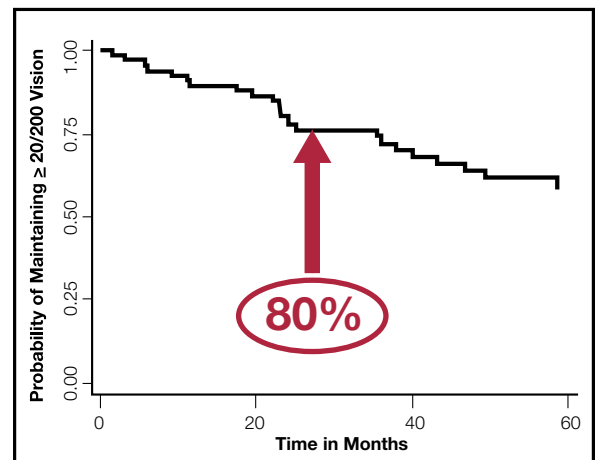
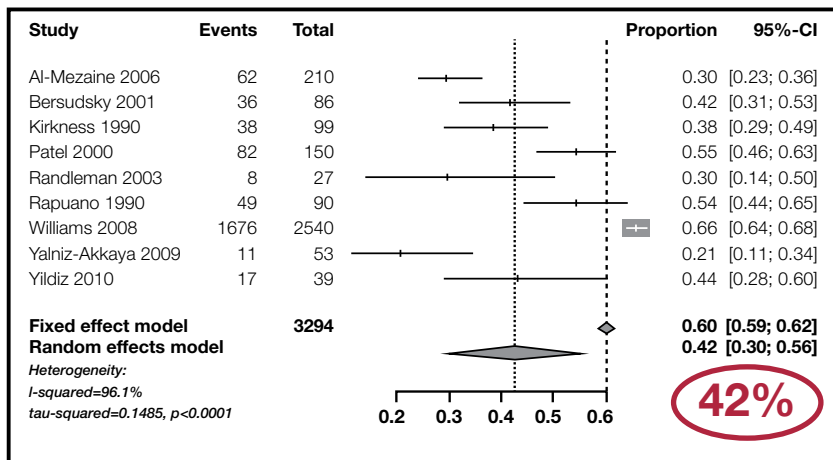
Sumayya Ahmad, MD, and Esen Akpek, MD

In 2013, when we became interested in the fate of repeat corneal transplantations, more than 46,000 corneal transplantations were performed in the United States. Repeat grafts accounted for the second most common indication for penetrating keratoplasty (PK), even though long-term outcomes are often poor. The Boston Type I keratoprosthesis (KPro) provides an alternative option to repeat PK. However, there are currently no guidelines to indicate which patients would be ideal candidates for a repeat PK versus a KPro. Despite the latest multi-center publications reporting favorable outcomes, there seems to be reluctance among

corneal surgeons to proceed with a KPro. Common practice is to perform multiple donor corneal transplantations in these patients until there is no reasonable expectation that the graft will remain clear. This likely translates into decreased likelihood of restored vision.

We performed a systematic review of published literature regarding repeat PK, as well as a review of a large multi-center cohort of patients who underwent KPro for previous graft failure to compare visual outcomes and complication rates.

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Penetrating Keratoplasty (PK)

Table and graph showing the random effects analysis evaluating the proportion of patients with repeat grafts who achieved 20/200 or better vision at 2 years. CI = confidence interval.

Type 1 Boston Keratoprosthesis (KPro)

Graph showing the probability of maintaining 20/200 or better vision with a Boston Type I KPro after graft failure at 2 years.

Ahmad S, Mathews PM, Lindsley K, Alkharashi M, Hwang FS, Ng SM, Aldave AJ, Akpek EK. Boston type 1 keratoprosthesis versus repeat donor keratoplasty for corneal graft failure: A systematic review and meta-analysis. *Ophthalmology*. 2016 Jan;123(1):165-77.

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



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Ophthalmology



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Integrated Micro-opto-mechanical Pressure Sensor in the Boston Keratoprosthesis

Eleftherios I. Paschalis, MSc, PhD; James Chodosh, MD, MPH; Claes H. Dohlman, MD, PhD

Although Boston KPro is the most successful keratoprosthesis to date, glaucoma remains a major complication, leading to vision loss in many patients. Unfortunately, standard tonometers cannot be used to measure intraocular pressure (IOP) in Boston KPro patients, and finger palpation is often inaccurate. Because delayed detection and treatment of elevated IOP can lead to irreversible optic nerve and retinal damage, there is a clear need for a reliable and accurate method to assess IOP in Boston KPro patients.

To address this problem, the KPro team developed a micro-opto-mechanical pressure system (MOMS) that is integrated in the optical stem of the Boston KPro device. The sensor provides contactless IOP measurements with very high accuracy. The MOMS is only 300 µm in diameter, and it is placed at the outer portion of the optical stem, thereby allowing unobstructed vision. Pressure measurements are performed using an external light detector that is connected to a fiber optic probe cable mounted on a slit lamp. We have tested the stability (drift) of the sensor in a dynamic environment for over one year, showing minimal pressure drift (<0.3 mmHg) across a range of pressures between -10 to +40 mmHg.

Boston Keratoprosthesis Fitted with MOMS Sensor



The first prototype devices for animal testing are now in development. This technology may be pivotal in the early detection and management of glaucoma, and we expect that it will help reduce vision loss in Boston KPro patients. Upon completion of a pre-clinical study in animals, the Boston KPro investigators at Mass. Eye and Ear will pursue a human pilot study.

The Boston KPro newsletter is published once annually.

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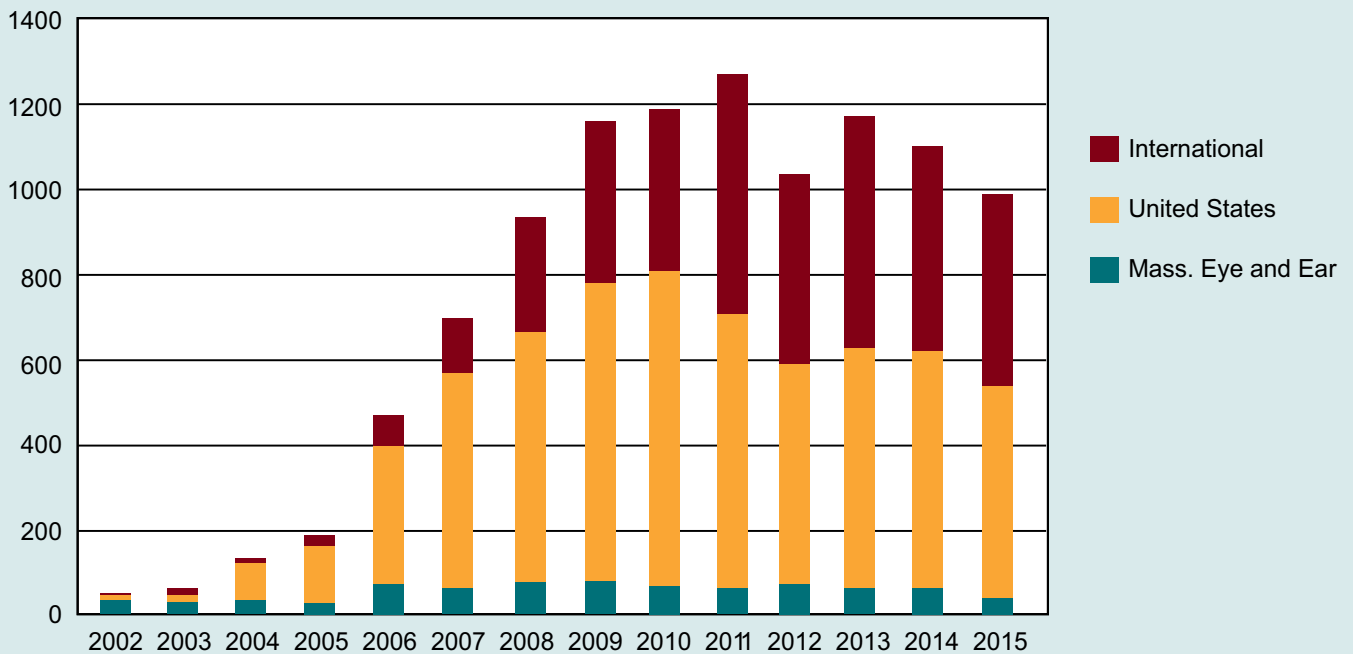
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We found that in the repeat PK group, there was a lower likelihood of maintaining a visual acuity of 20/200 or better at two years, compared with KPro implantation (42% vs. 80%). There was also a lower probability of maintaining a clear graft at five years after repeat PK (47%), compared to the probability of retaining the KPro (75%). Furthermore, the rate of progression of glaucoma was similar between repeat PK and KPro (25% vs. 30%, respectively). In general, in distinct contrast to common perceptions, the postoperative complication profiles were similar for both surgical procedures.

We found that underlying diagnoses, such as ocular surface disease, and the clinical setting, such as presence of glaucoma or a previous glaucoma surgery, had a profound impact on outcomes. Interestingly, the reports from developing countries had worse outcomes for the repeat PK analysis than the average we stated here, most likely secondary to poorer quality donor tissue and a sicker patient population. In contrast, tertiary care referral centers in developed countries reported somewhat encouraging results.

In 2013, only 624 KPros were implanted in the United States. In light of our results, we believe that the device may be under-utilized because of misconceptions stemming from historical reports about the KPro. Although KPro surgery was once considered a last-resort procedure, its new design and better post-operative management have led to better outcomes. For older, well-educated and compliant patients with multiple graft failures, the KPro seems to be superior to repeat PK. By increasing awareness of our findings among cornea specialists, more patients may benefit from use of the KPro device.

Boston KPro Usage (approximately 12,000 implanted to date)



Total Conjunctival Flap in KPro Surgery

Claes H. Dohlman, Jamal Al-Merjan, and Nadia Sadeq

A conjunctival flap, covering the whole cornea and secured at the end of Boston KPro Type I surgery, is a valuable and underutilized safety measure in many clinical situations. In the past, varying techniques were used sporadically by mid-20th Century surgeons (DeVoe, Girard, Choyce, Strampelli, Bertelsen, Temprano, and others) for their devices. The potential was more systematically addressed in a study of 38 cases of Boston KPro Type I with a total conjunctival flap.¹ At that time, tissue melt around the polymethyl methacrylate (PMMA) KPro stem was very frequent because the back plate was solid without perforation and therefore, blocked access of nutrients from the aqueous to the carrier cornea keratocytes. The later addition of large holes in the back plate ameliorated much of the problem. However, even though graft melt is now much less common, it can still occur, especially in patients with autoimmune diseases and in very inflamed eyes. In these cases, a total conjunctival flap (Gundersen style) can have pronounced prophylactic value.

Conjunctival Flap Procedure: Important Technical Points

- After the 360° limbal peritomy, the flap should be mobilized as one piece from the temporal side of the bulb.
- The flap should be moderately thick and wide enough to fit loosely over the whole cornea.
- All epithelial cells on the corneal surface must be removed beforehand (e.g., by 70% ethanol) so that there is a complete apposition of two fresh connective tissue surfaces.
- The edges of the flap should be sutured (without tension) to the corneal limbus with four to six 10.0 nylon sutures.
- A small, central opening is then made in the flap. Alternatively the opening can be postponed for up to a few weeks.
- The small opening will then spontaneously widen until the whole front plate of the KPro is exposed.
- Ideally, the flap should then bulge out around the front plate edge of the device.

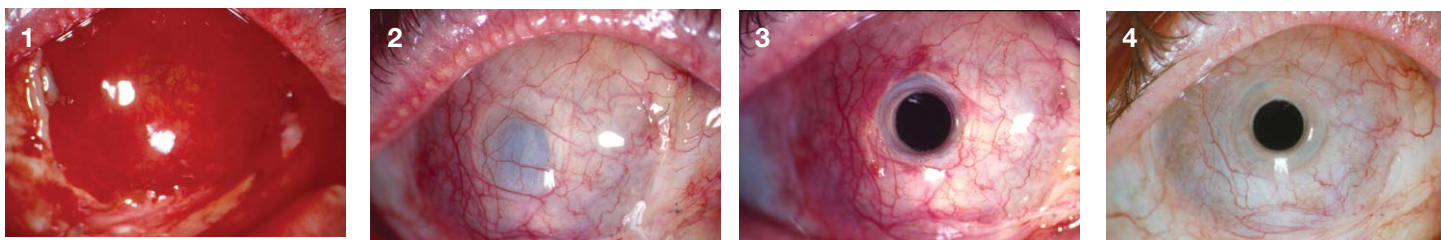
In such Boston KPro patients, the conjunctival flap will provide an intact epithelium that will prevent evaporative damage. It also protects the underlying stroma from inflammatory neutrophils in the tear film, which can release matrix metalloproteinases (collagenases, etc.) and cause tissue melt. Blood vessels will supply nutrients, and the α -2 macroglobulins in the blood may inhibit the destructive enzymes, thereby providing a second layer of defense against tissue melt. If the flap is thick, it builds up tissue around the KPro front plate and diminishes exposure damage.

Clinically, a conjunctival flap seems to have the same beneficial, protective effect as a soft contact lens when the latter is used around-the-clock (the flap serving as “poor man’s contact lens”). It has the advantage of permanency, whereas a contact lens is expensive and can get lost. The downside is the extra time a conjunctival flap mobilization will take at the end of the KPro surgery—perhaps 15 minutes. Also, in severe disease states, the patient’s conjunctiva may be so scarred or damaged that it cannot provide a flap.

Once a conjunctival flap is placed correctly and is well sutured without tension, the intact blood supply from above and below guarantees healing and permanence. (In contrast, a free flap of buccal mucosa, for instance, often fails over the KPro because there is a delay in establishing blood vessel connections.) Residual cosmetic problems are rare once the flap has healed, although veins in the flap area can occasionally remain somewhat dilated. (See pictures.)

Several conjunctival flap variations have later been suggested in repair of established melts.² Additionally, using thick conjunctiva with Tenon’s capsule has been proposed for difficult pediatric cases.³

In summary, adding a conjunctival flap to standard Boston KPro Type I surgery extends surgery time but can be very protective in situations where tissue melt otherwise would be likely and where soft contact wear is impractical.



Total conjunctival flap in Boston KPro Type I. (Opening delayed.) 1. First postoperative day 2. One month later 3. Two days post central opening 4. Seven months later

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Tissue Carriers for the Boston Keratoprosthesis

Andrea Cruzat, MD, and Miguel González, MD, PhD

Although corneal allograft tissue for the Boston keratoprosthesis is readily available and affordable in developed countries with established eye banks, the global need vastly exceeds supply.

Human corneal tissue can be scarce and expensive in developing countries, which is why a simple, safe, and inexpensive alternative to corneal allografts is desirable. One option is to explore methods that increase viability time.¹ In 2008, the Eye Bank Association of America estimated that the United States harvested more than 92,000 corneas, of which 30,000 were unsuitable for optical grafting. However, about 25% of the unsuitable corneas could have been preserved.²

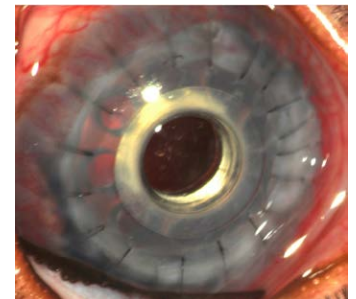
Several methods extend the time that a cornea can be stored—allowing the use of tissue that would otherwise be discarded. For instance, deep-frozen corneas have been shown to be as good as fresh tissue for the Boston KPro, but international shipping can be difficult.³ Gamma-irradiated human corneas, such as VisionGraft®, have been used successfully as carriers for the Boston KPro, but costs remain high.^{4,5} Glycerol-preserved corneas have been used for decades in lamellar surgery, and shipment is easy and practical.^{2,6}

In addition to preserving human tissue, various substitutes, such as autografts, xenografts, non-corneal autologous tissues, and laboratory-made constructs, may prove feasible as carrier tissue.¹

In countries with limited resources and no eye banks, the use of the patient's own cornea has obvious advantages, including low cost and easy logistics.⁷ While this approach is used in several countries, widespread adoption is limited by the health of the presurgical cornea. Sometimes the cornea is too damaged and thin, but many times a large conjunctival flap is extremely useful.⁸

In the future, laboratory-made tissue constructs may be an alternative carrier tissue.⁹ Researchers have successfully used carbodiimide crosslinked recombinant human collagen as lamellar grafts in humans.¹⁰ Synthetic tissue constructs would be low cost once mass produced and shipping would be easy. The challenge is making the constructs strong enough for full-thickness transplantations.

In addition to safety, KPro carrier tissue must also be low cost for the developing world. That is why corneal xenografts—particularly porcine corneas—are appealing. Porcine corneas are anatomically and physiologically similar to human corneas. They have comparable refractive power, size, and tensile strength, and they are readily available. As an example, porcine aortic valves and pericardia have successfully been used in humans for many decades.^{11,12} Recent genetic manipulation of pigs—in which the expression of specific antigens are reduced—is promising, but the costs remain high and availability is limited. We are currently studying inexpensive methods to sterilize and reduce xenograft antigenicity, hoping to make xenografts a real possibility as a KPro carrier for humans.^{13,14}



Decellularized porcine xenograft as a Boston KPro carrier in a Dutch-belted rabbit after 30 days of implantation.

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Profiles of Distinguished Boston KPro Surgeons

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

Brandon D. Ayres, MD



Dr. Brandon Ayres has been part of the Cornea Service at the Wills Eye Hospital since 2005 and part of Ophthalmic Partners since 2007. He serves as an Assistant Surgeon at Wills Eye Hospital and an Instructor in Ophthalmology at Thomas Jefferson University.

Dr. Ayres earned his medical degree and completed residency training at the University of Medicine and Dentistry of New

Jersey. He subsequently completed a fellowship at Wills Eye Hospital.

Dr. Ayres specializes in all forms of corneal transplantation, including KPro, full thickness corneal transplants, Descemet's stripping endothelial keratoplasty (DSEK), Descemet's membrane endothelial keratoplasty (DMEK), and deep anterior lamellar keratoplasty (DALK). In fact, he was the first person at Wills Eye Hospital to perform DMEK. He has broad experience with KPro—as both a high-volume surgeon and mentor to colleagues and fellows. Additionally, Dr. Ayres treats all forms of infectious eye diseases and ocular surface disease (dry eye), and he performs all types of refractive and cataract surgery, including LASIK, phakic lens surgery for myopia, and multifocal intraocular lenses. He is also interested in repairing traumatic eye injuries and the anterior segment.

An active researcher, Dr. Ayres has conducted several studies on the Boston KPro procedure. In a recent study, he compared the effectiveness of sequential vs. concomitant glaucoma drainage implantation and KPro surgery. He found that while concomitant surgery had a similar incidence of failure, it also had significantly more favorable visual outcomes compared to sequential surgeries.

In addition to his clinical and scholarly achievements, Dr. Ayres also trains ophthalmology residents and fellows. During his first year as an Attending on the Cornea Service, he became the youngest recipient of the Golden Apple Award for best resident teacher at Wills Eye Hospital. He also lectures nationally and internationally at numerous academic conferences and is a member of the American Society of Cataract and Refractive Surgery's Complex Cataract Committee.

Shahzad I. Mian, MD



Dr. Mian is the Terry J. Bergstrom Collegiate Professor for Resident Education in Ophthalmology and Visual Sciences at the University of Michigan/Kellogg Eye Center. He also serves the Department as Associate Chair for Education and is a Professor of Ophthalmology and Visual Sciences.

Dr. Mian earned his medical degree from the Emory University School of Medicine

and completed residency training at Wills Eye Hospital of Thomas Jefferson University in Philadelphia. Later, he completed a Cornea, Refractive Surgery, and External Disease Fellowship at Massachusetts Eye and Ear.

A prominent KPro surgeon, Dr. Mian specializes in cornea and refractive surgery. His clinical areas of expertise include corneal transplantation, cataract surgery, IntraLase, custom cornea LASIK, LASEK, photorefractive keratectomy, corneal rings, conductive keratoplasty, ocular surface diseases, corneal infections, dystrophies and tumors, and dry eye disease.

Dr. Mian's research is focused on corneal transplantation techniques, ocular graft versus host disease, KPro, and eye banking. In 2007, he received the Anthony Adamis Award for Outstanding Research from the University of Michigan Kellogg Eye Center.

A mentor to medical students and residents, Dr. Mian is committed to training future generations on the use of KPro. He has been Director of the residency training program at the Kellogg Eye Center since 2004 and previously served as Fellowship Director in the department. In 2003 and 2012, he received the Bergstrom Faculty Teaching Award, which is presented by ophthalmology residents. In 2013, his leadership potential and excellence in teaching were recognized when he was selected to participate in the Michigan Education Scholars Program.

Additionally, Dr. Mian serves as the Vice Chair of the Residency Review Committee for Ophthalmology, Co-chair of the Accreditation Board for the Eye Bank Association of America, and Senior Medical Director of Eversight Michigan Eye Bank. He also serves on the Board of Directors for the Cornea Society, the Eye Bank Association of America, and the Program Director's Council of the Association of University Professors in Ophthalmology.

Günther Grabner, MD



Dr. Grabner is Chairman emeritus and Professor of Ophthalmology at the Eye Clinic of the Paracelsus Medical University in Salzburg, and the Medical University in Vienna, Austria.

Shortly after earning his medical degree at the University of Vienna Medical School, Dr. Grabner founded Austria's first Eye Bank at the Vienna Medical University in 1977. He went on

to complete a Corneal and Uveitis Fellowship at the Francis I. Proctor Foundation for Research in Ophthalmology at the University of California, San Francisco.

Dr. Grabner subsequently returned to Austria and established the cornea and uveitis units for the second Vienna Eye Clinic in 1983, the former clinic of Professor Ernst Fuchs. Two years later, he started an ambulatory center for refractive corneal surgery at the clinic.

Dr. Grabner has been performing keratoprosthesis surgery since 1994. He has also served on the steering committee for the KPro Study Group for the past 15 years. This group—comprised of KPro surgeons and researchers from around the world—fosters clinical and basic research on KPro.

Dr. Grabner's research focuses on KPro surgery, as well as corneal and intraocular presbyopia and astigmatism surgery, and glaucoma epidemiology. Notably, he developed a system to precisely assess near visual acuity (the Salzburg Reading Desk) and participated in the glaucoma epidemiology study (Salzburg Moorfields Collaborative Glaucoma Study). To date, he has published more than 250 articles in peer-reviewed journals, authored several book chapters, and received several awards, including the 2012 Barraquer Medal and Lecture of the International Society of Refractive Surgery and the 2014 Ridley Medal and Lecture of the European Society of Cataract & Refractive Surgeons.

Dr. Grabner is a member of the ESCRS, EuCornea, the ISRS/AAO, the DOG and the Austrian Ophthalmological Society. He has also served on the editorial boards of several leading peer-reviewed ophthalmic journals, including the *Journal of Cataract and Refractive Surgery*, *Annals of Ophthalmology and Glaucoma*, *Klinische Monatsblätter für Augenheilkunde*, *Spektrum der Augenheilkunde*, and *Der Ophthalmologe*.

Bilal Faiz Khan, MD



Dr. Khan established the United Medical and Dental College in Pakistan, where he is currently an Associate Professor of Ophthalmology and Dean of Academic Affairs.

Dr. Khan underwent medical training at the Aga Khan University in Pakistan. Following his residency training in ophthalmology, he completed a research fellowship in Keratoprosthesis (KPro) and a

Cornea, Refractive Surgery, and External Disease Fellowship at Mass. Eye and Ear, Harvard Medical School.

As a research fellow, Dr. Khan was involved in the design and manufacturing process of the Boston KPro, under the supervision of Claes H. Dohlman, MD, PhD, Director of Boston KPro Research and Development at Mass. Eye and Ear. Dr. Khan also collaborated with Dr. Marshall Doane, PhD, former Senior Scientist at Schepens Eye Research Institute of Mass. Eye and Ear, and John Graney at the J.G. Machine Shop.

Dr. Khan later returned to Pakistan and became the first cornea specialist to use the Boston KPro in Pakistan. He established a busy cornea clinic, where he currently sees patients from all over the country, as well as from South Asia and the Middle East. He has treated many patients with corneal graft failures, chemical burns, infections, and trauma. As one of the few cornea specialists in the country, his patient base includes more than 200 patients with Stevens-Johnson syndrome, many of whom would benefit from ocular surface rehabilitation. His keen interest in research has pushed him to try new treatment methodologies for severe corneal abnormalities.

Dr. Khan also established the Creek General Hospital, a 500-bed, free charity hospital in Karachi—the largest city in Pakistan. This hospital is a tertiary care institution with both undergraduate and postgraduate teaching programs.

In the future, Dr. Khan hopes to establish an ophthalmology residency program at the United Medical and Dental College, and he plans to investigate the effects of Boston Type II KPro in patients with auto-immune disorders.

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



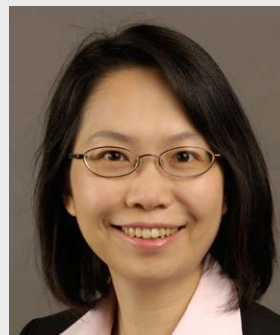
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Surgery, Clinical Research



Andrea Cruzat, MD
Clinical and Translational
Research



Eleftherios Paschalis, MSc, PhD
Bioengineering



Lucy Shen, MD
Glaucoma



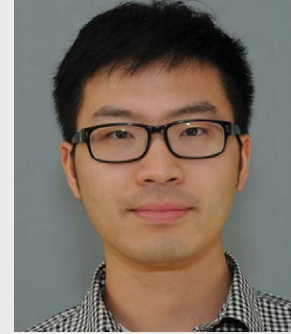
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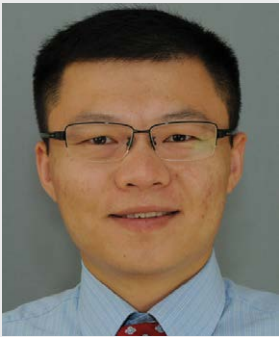
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Julie Stampfle
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Service Coordinator



Mary Lou Moar
Consulting KPro
Coordinator



Larisa Gelfand
Director,
Boston KPro Business
Operations

2014

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Join Us at These Upcoming KPro Events



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

September 10-14, 2016: Copenhagen, Denmark

- **Boston type 1 keratoprosthesis: From indications to innovations**
Prerequisite Course for Surgical Skills Training Course
Saturday, September 10, 5–6 p.m.
Leader: M. Soledad Cortina, MD
- **Boston KPro Surgical Skills Training Course**
Sunday, September 11, 8:30–10:30 a.m. and 11 a.m.–1 p.m.
Instructors: Alja Crnej, MD; Andrea Cruzat, MD



American Academy of Ophthalmology (AAO) Meeting

October 15-18, 2016: Chicago

- **Boston Keratoprosthesis Users Breakfast**
Monday, October 17, 7–8:30 a.m.
Hyatt Regency McCormick Place, Room CC10B/Jackson Park B
If you plan to attend, e-mail: kpro_service@meei.harvard.edu
- **AAO KPro Course**
The Boston Keratoprosthesis: Case-Based Presentations Highlighting the Essentials for Beginning and Experienced Surgeons.
Sunday, October 16, 2–4:15 p.m.
McCormick Place, Room N138
Senior Instructor: Kathryn Colby, MD, PhD
Instructors: Anthony J. Aldave, MD; Esen K. Akpek, MD; James V. Aquavella, MD; Mona Harissi-Dagher, MD; James Chodosh MD, MPH; Sadeer B Hannush, MD
- **AAO KPro Course**
Glaucoma Management in Patients with Boston Keratoprosthesis
Tuesday, October 18, 2–3 p.m.
McCormick Place, Room N140
Senior Instructor: Lucy Q. Shen, MD
Instructors: Simon K. Law, MD; Elise Vivian Taniguchi, MD; Angela V. Turalba, MD; Thasarat S. Vajaranant, MD
- **AAO Boston Type I Keratoprosthesis Breakfast with the Experts**
Monday, October 17, 7:30–8:30 a.m.
McCormick Place, Hall A
Senior Instructor: M Soledad Cortina, MD
- **AAO Surgery for Severe Corneal Ocular Surface Disease LAB114A**
Tuesday, October 18, 11 a.m.–1 p.m.
McCormick Place, Room N227B
Senior Instructor: Ali R. Djalilian, MD
Recommended Lecture: LEC114 Surgery for Severe Corneal and Ocular Surface Disease
Sunday, Oct 16, 10:15 a.m.–12:30 p.m.
Room E351



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