



Pre-World Cornea Congress
KPRO STUDY GROUP
SYMPOSIUM
Program

April 14, 2015, 7 AM – 5:30 PM



SHILEY EYE INSTITUTE
UC SAN DIEGO

9415 Campus Point Drive, La Jolla, CA

Hosted by:

Natalie Afshari MD
DrAfshari@ucsd.edu

Organized by:

Jose de la Cruz
josedlc@uic.edu

Jean-Marie Parel
jmparel@med.miami.edu

- VENUE **GOLDBERG AUDITORIUM** (at Moores Cancer Center behind the Shiley Eye Institute)
- 7:00am Registration & Continental Breakfast + uploading morning talks
- 8:20am **Welcome/Introduction** *Natalie Afshari, Jose De La Cruz, Jean-Marie Parel*
- 8:30am **I. Boston KPro International/growth**
Moderators: Anthony Aldave, James Chodosh
- 8:30am Globalization of KPRO – *James Chodosh*
- 8:40am International Growth – *Antony Aldave*
- 8:50am Russia KPRO - *Boris Malyugin*
- 9:00am PanKPRO Initiative – *Victor Perez, Jose De La Cruz, Andrea Cruzat, Guillermo Amescua*
- 9:10am *Discussion*
- 9:20am **II. What have we learned in the last 10 years about complication and management of?**
Moderators: Esen Akpek, Victor Perez
- 9:20am Glaucoma – current problems and future fixes – *Jeffrey Goldberg*
- 9:30am Pre-operative evaluation and tamponade consideration in patients undergoing keratoprosthesis – *William Freeman*
- 9:40am Extrusion/melts - *Esen Akpek*
- 9:50am Retroprosthetic membranes – *Jose De La Cruz*
- 10:00am Infections – *Guillermo Amescua*
- 10:10am *Discussion*
- 10:20am **Coffee Break**
- 10:50am **III. New Diagnostics/Not yet widely used methods in:**
Moderators: Mark Rosenblatt, Kathryn Colby
- 10:50am Introduction of imaging in KPRO – *Jose De La Cruz*
- 11:00am Glaucoma imaging in KPRO – *Andrea Cruzat*
- 11:10am New developments in tissue modifications for improved outcomes of the Boston KPro – *Joseph Ciolino*
- 11:20am Advantages/Disadvantages in new backplate size/materials – *Kathryn Colby*
- 11:30am Presence of silicone oil, no prior corneal surgery and postop contact lens use – *Natalie Afshari*
- 11:40am Novel approaches to KPro: an oculoplastics perspective – *Don Kikkawa*
- 11:50am *Discussion*
- 12:00pm **IV. Rapid Fire Free Papers** 6 min max
Moderators: Natalie Afshari, Juan Alvarez de Toledo, Jose De La Cruz
- 1:00pm *Discussion*
- 1:10pm **Lunch** + uploading afternoon talks
- 2:10pm **V. MOOKP/Boston Type II**
Moderators: Jim Chodosh, Mark Mannis
- 2:10pm Improvement MOOKP current procedure & update in complication management – *Victor Perez*
- 2:20 pm Tibial KPro - *Maria de la Paz*
- 2:30 pm Differences in Type I and Type II – *James Chodosh*
- 2:40 pm *Discussion*
- 2:50pm **Group Photograph in front of Shiley Bldg and move to Shiley Eye Institute**
- VI. Novel Devices and True integrating Artificial Corneas**
Moderators: Claes Dohlman, Robert Weinreb, Eduardo Alfonso
- 3:20pm In search of true integrating artificial corneas - *Mark Rosenblatt*
- 3:30pm KeraKlear - *Yichieh Shieuey*
- 3:40pm Implantation of an electronic pressure sensor with Boston KPro – *Thomas Neuhann*
- 3:50pm Contact lens drug delivery and how it could benefit the Boston KPro – *Joseph Ciolino*
- 4:00pm What do MOOKP and KPro patients see? – *Heather Durkee, Victor Hernandez, Jean-Marie Parel*
- 4:10pm *Discussion*
- 3:20pm **VII. Rapid Fire Free Papers** 6 min max
Moderators: Maria de la Paz, Joseph Ciolino, Yichieh Shieuey
- 5:20pm *Discussion*
- 5:30pm **Final Remarks /Conclusion** *Natalie Afshari, Jose De La Cruz, Jean-Marie Parel*

Rapid-Fire Free Papers

Morning Session – Moderators: *Natalie Afshari, Alvarez de Toledo*

- 1 **Incidence of Stevens-Johnson Syndrome and Chemical Burns to the Eye: Relevance to Keratoprosthesis Surgery** - *Michelle White*
- 2 **International Outcomes of the Boston Type I Keratoprosthesis in Stevens-Johnson Syndrome** - *Anthony Aldave*
- 3 **Boston Type 1 Kerato-Prosthesis In High Risk Cases** – *Juan Alvarez de Toledo*
- 4 **Long Term Outcomes with Boston Type 1 Keratoprosthesis in Ocular Burns** - *Lauro Oliveira*
- 5 **The advantageous use of Boston KPro in managing combined anterior and posterior segment pathology. A Case study** - *Hatem Kobtan*
- 6 **Adjunct CXL of Carrier Cornea in two types of Keratoprosthesis. Technique and Outcomes** - *Anastasios John Kanellopoulos*
- 7 **Boston type I Keratoprosthesis assisted with intra-prosthetic amniotic membrane (*AmniotiKPro* sandwich technique)** - *Alejandron Navas*
- 8 **Prognostic Value of Peri-Prosthetic Tissue Loss for Corneal Melting - Results of a Longitudinal Anterior Segment OCT Study in Patients with Boston type 1 Keratoprosthesis** - *Rodrigo Muller*
- 9 **Outcomes of primary Boston Type 1 keratoprosthesis placement** - *Kimberly Hsu*
- 10 **Impact of Pars Plana Vitrectomy on Complications in Aphakic Boston Keratoprosthesis Patients** - *Allister Gibbons*

Afternoon Session – Moderators: *Maria de la Paz, Joseph Ciolino*

- 11 **Effect of keratoprosthesis on the eye. An animal study** - *Alja Crnej*
- 12 **Scanning Electron Microscopic Analysis of Biofilm Formation in Explanted Human Boston Type I Keratoprostheses. Sterile vs Infectious Case Comparison** - *Kavitha Sivaraman*
- 13 **KPro: What is the relationship between surface quality and biofilm adherence?** - *Heather Durkee*
- 14 **Optimization of Titanium Surface Characteristic in Boston Keratoprosthesis Backplate** - *Eleftherios Paschalis*
- 15 **Management of end stage corneal disease and chronic uveitic hypotony by combining the Boston type 1 keratoprosthesis with pars plana vitrectomy and silicone oil fill** - *Tayyeba Ali*
- 16 **Five to Ten Year Follow-up of Boston Type 1 Keratoprostheses Demonstrates Stable Visual Acuity and Retention** - *Anthony Aldave*
- 17 **Experience with Dohlman-Doane type I keratoprosthesis** - *Sergio Kwitko*
- 18 **Novel Strategies to Improve Keratoprosthesis Outcomes** - *Juan-Carlos Abad*
- 19 **Crosslinking of Donor Corneal Tissue with Glutaraldehyde (GA) for Keratoprosthesis** - *K.S.Siddharthan*
- 20 **Setting up a Keratoprosthesis Service in a Tertiary Care Public Funded Hospital in India** - *Radhika Tandon*

Incidence of Stevens-Johnson Syndrome and Chemical Burns to the Eye: Relevance to Keratoprosthesis Surgery

Michelle White, James Chodosh, Jisun Jang, Claes H Dohlman

Massachusetts Eye and Ear Infirmary, Harvard Medical School, Boston, MA, USA

Purpose: This study was designed to estimate the incidence and distribution of SJS-spectrum (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis, Toxic Epidermal Necrolysis/Stevens- Johnson Syndrome overlap), and of chemical burns (alkali or acid burn of the cornea/conjunctiva) in the United States (US) and project the number of patients that may benefit from keratoprosthesis surgery worldwide.

Design: Population based observational study.

Subjects: All patients evaluated in 961 hospital-based US emergency departments between July 1, 2010 and June 30, 2012.

Methods: Patients identified retrospectively utilizing two years (2010 and 2011) of Nationwide Emergency Department Sample (NEDS) data in the US. SJS-spectrum and chemical burn cases were identified using *International Classification of Diseases, Ninth Revision, Clinical Modification* diagnostic codes.

Results: A mean of 3,849 new SJS-spectrum cases per year were identified in the US, resulting in an incidence rate of 12.40 new cases per million per year. Similarly, a mean of 15,798 new chemical burn cases per year were identified, resulting in an incidence rate of 50.89. The mean age of patients with SJS-spectrum was 48.6 and the mean age of patients with chemical burns was 34.5. While there was no gender difference for incidence of SJS-spectrum, men were twice as likely to suffer from chemical burn compared to women, in the US.

Conclusions: Nearly four thousand people in the US become afflicted with SJS-spectrum every year. How many eventually end up bilaterally blind and in need of intervention is not known. If the incidence of SJS-spectrum is approximately uniform the world-over, extrapolation from the US figure would amount to about 87,000 new cases per year in the world. Similarly, over 15,000 chemical eye burns are reported in the US per year. Extrapolation to the world is difficult since incidence and severity are anticipated to be higher in the developing world than in the US. Still, using a US incidence rate, a minimum of 350,000 burn accidents would be expected to occur worldwide every year. When SJS-spectrum and chemical burns result in severe corneal damage, keratoprosthesis surgery may be the only option to restore vision in the future.

Contact: Michelle.White@MEEI.HARVARD.EDU

International Outcomes of the Boston Type I Keratoprosthesis in Stevens-Johnson Syndrome

Anthony J Aldave, Jamie K Alexander, Samar K Basak, Dominga B Padilla, Fei Yu

The Jules Stein Eye Institute, UCLA, Los Angeles, CA, USA

Purpose: To determine the factors influencing outcomes of Boston type I keratoprostheses implantation in patients with Stevens-Johnson syndrome (SJS) and to compare the results with those implanted in patients without SJS.

Methods: Data was collected regarding Boston type I keratoprosthesis procedures performed by three surgeons at three centers: Stein Eye Institute in Los Angeles (UCLA) between May 1, 2004 and July 1, 2013; and Disha Eye Hospital in Kolkata, India and St. Luke's Hospital in Manila, Philippines between March 1, 2009, and January 1, 2014.

Data was collected for each procedure regarding the preoperative characteristics, the surgical procedure(s) performed, interval post-operative visual acuities, keratoprosthesis retention, and complications. Statistical analysis was performed to identify significant differences between the SJS and non-SJS populations in terms of visual acuity, retention and complications. Statistical analysis was performed to identify predictors of retention failure in the SJS population.

Results: During the study periods, 234 keratoprosthesis procedures were performed in 209 eyes of 201 patients by the three participating surgeons, with 40 of the procedures performed in 27 eyes of 26 patients with SJS. Compared to the non-SJS series, procedures in SJS patients were more frequently performed as repeat keratoprostheses (33% vs. 8%, $p<0.001$) but less frequently in eyes with glaucoma (26% vs. 71%, $p<0.001$) or multiple prior penetrating keratoplasties (15% vs. 59%, $p<0.001$). A significantly greater percentage of patients with SJS had a CDVA with the keratoprosthesis $> 20/200$ at last follow-up compared with patients without SJS (96% vs. 63%, $p=0.001$). Several post-operative complications were more common in SJS patients, including corneal stromal necrosis (59% vs. 8%, $p<0.001$), corneal infiltrate (30% vs. 10%, $p<0.001$), and persistent corneal epithelial defect (59% vs. 24% $p<0.001$). These complications led to a higher rate of retention failure and secondary surgical procedures in comparison to non-SJS eyes (0.306/eye-year vs. 0.068/eye-year, $p< 0.001$). However, following repeat implantations, eyes with SJS were no less likely to ultimately retain a keratoprosthesis (81% vs. 89%, $p=0.335$).

Conclusion: The Boston type I keratoprosthesis is an effective means to restore vision in patients with SJS. Although retention failure and several post-operative complications are more common in SJS patients, sight-threatening complications such as endophthalmitis and retinal detachment are not. Given this, and the lower incidence of glaucoma in SJS patients, nearly all SJS patients have a final CDVA with the keratoprosthesis $> 20/200$.

Contact: aldave@jsei.ucla.edu

Boston Type 1 Kerato-Prosthesis in High Risk Cases

Alvarez de Toledo J^{1,2}, de la Paz MF^{1,2}, Michael R², Mantaras J², Barraquer RI^{1,2}, Seyeddain O³, Grabner G³

¹ Centro de Oftalmología Barraquer, Barcelona, Spain; ² Institut Universitari Barraquer, Universitat Autònoma de Barcelona, Spain; ³ University Eye Clinic, Paracelsus Medical University, Salzburg, Austria

Purpose: To analyze the anatomical and functional results, complications, post-surgical additional procedures of the Boston K-Pro type 1 implantation in high-risk cases in two Ophthalmology Centers.

Methodology: Retrospective case-series on twenty high-risk cases of chemical burn or muco-cutaneous syndrome which underwent Boston K-Pro implantation. Standard Boston K-Pro type 1 surgical technique with no additional surgical measures was used in all cases. Visual results, anatomical retention, postoperative complications and additional procedures were the main outcome measures.

Results: Eleven patients were operated in Barraquer Eye Institute of Barcelona and 9 patients in University Eye Clinic in Salzburg. Eighty-five % were male and 15% were female. Mean age was 45.6 years. Primary diagnosis was alkali burn in 6 eyes, non-specified chemical burn in 3, Lyell's syndrome in 3, acid burns in 2 (10%) ocular cicatricial pemphigoid in 2 and non-specified muco-cutaneous syndrome in 1 case. Mean previous number of keratoplasty procedures was 1.95 (0-10). Mean follow-up was 36.17 months (3-78.5; only 3 cases had less than 6 months of follow-up). Mean pre-op visual acuity (BCVA; Log-Mar units) was 2.11 (2.6989-1), post-op BECVA (best-ever corrected VA) was 0.64 (2-0.07918125) and last visit BCVA was 1.34 (3-0.04139269). Retention of the prosthesis was achieved in 14 cases (70%). In the 6 cases of extrusion, the mean extrusion time was 26.5 months (4-52). Prosthesis was replaced in 4 cases, 3 being retained at the end of the study and one case had a second extrusion, which ended in a tectonic keratoplasty. The other 2 cases were also treated with a tectonic keratoplasty.

Complications were frequent and included retro-prosthetic membrane in 9 cases (45%), glaucoma in 7 (35%), extrusion in 6 (30%), melting in 4 (20%), choroidal detachment in 3 (15%) endophthalmitis in 3 (15%), vitreous hemorrhage in 1 (5%), and descemetocoele in 1 (5%). Additional surgical procedures were YAG-laser membranotomy in 9 cases (45%), new prosthesis replacement in 4 (20%), tectonic keratoplasty in 4 (20%), enucleation in 1 (5%) conjunctival autograft in 1 (5%) and pars plana vitrectomy in 1 case (5%).

Conclusions: Anatomical and functional results of the Boston K-Pro type 1 are satisfactory in high-risk cases. Presence of serious complications is common, additional procedures are frequently needed and the final long-term outcome can be compromised.

Contact: alvarezt@barraquer.com lizeldelapaz@yahoo.com

Long Term Outcomes with Boston Type 1 Keratoprosthesis in Ocular Burns

Lauro Augusto de Oliveira, Fernanda Pedreira Magalhães, Flavio E. Hirai, Luciene Barbosa de Sousa

Department of Ophthalmology, Federal University of São Paulo, São Paulo/SP, Brazil

PURPOSE: To report long term outcomes of Boston type I keratoprosthesis (BKPro) in the management of ocular burn injuries.

METHODS: This was a prospective study including all cases of BKPro implantation for ocular burns at the External Diseases and Cornea Service of the Federal University of São Paulo, between February 2008 and February 2015. Twelve patients (12 eyes) were enrolled. Procedures performed to manage ocular injury were identified, and data were collected regarding patients' ocular history, surgical procedure(s) performed, and postoperative outcomes, including visual acuity, retention, complications and required surgical procedures.

RESULTS: A total of 13 Type 1 BKPro were implanted in 12 eyes of 12 patients. The mean follow-up period was 61.2 (5 - 83 months). Preoperative best-corrected visual acuity (BCVA) ranged from count fingers to light perception. Postoperative BCVA was better than 20/200 in 83% of the patients and better than 20/60 in 58.3% of the patients. The overall BKPro retention rate was 83.3%. The most common complications were retroprosthetic membrane formation (41.6%) and persistent corneal epithelial defect evolving to corneal melting (33.3%). Patients who underwent ocular surface procedures such as limbal transplantation prior to BKPro implantation had a lower incidence of corneal melting/thinning ($p = 0.07$), although this was not statistically significant.

CONCLUSION: The anatomical and functional results identified in this study support the use of BKPro in managing bilateral limbal stem cell deficiency secondary to ocular burns.

Contact: laopadilha@gmail.com

The advantageous use of Boston KPro in managing combined anterior and posterior segment pathology. A Case study

Hatem Kobtan

Department of Ophthalmology, Cairo University, Cairo, Egypt

A 34 year old who was referred to our service with advanced corneal abscess due to a corneal infection of 1 month duration. Examination revealed advanced corneal melting with areas of iris prolapse seen and a vision of light perception. Culture revealed a coagulase negative staph infection which responded to amniotic membrane transplantation with topical antibiotic treatment which resulted in healing and extensive vascularization of the cornea. Ophthalmic ultrasound revealed a total retinal detachment with anterior PVR. At this point a parsplana vitrectomy through a Landers Wide Field Temporary Keratoprosthesis 8.2mm Lens with extensive dissection of proliferations at vitreous base and 360 retinotomy-retinectomy with silicone oil injection at the end of the procedure. The patients graft was re-sutured at the end of the procedure with postoperative follow up by ultrasound. A total retinal detachment open funnel configuration with epiretinal membranes was seen 3 weeks later. A second attempt at reattaching the retina using Landers temporary Keratoprosthesis but this time after flattening the retina with heavy liquid perflorocarbon the Boston KPros was secured after removing the Landers Keratoprosthesis and the procedure is finalized with the exchange of the PFC silicone oil exchange while clear visibility is maintained through the Boston Keratoprosthesis.

Results: The patient postoperative visual acuity improved from light perception to 6/36. The case demonstrates the value of Boston KPro in visual rehabilitation in cases with extensive vascularized recipient beds as well as the added advantage of working with KPro in complex cases with posterior segment pathology that requires concomitant intervention.

Contact: h_k1970@hotmail.com

Adjunct CXL of Carrier Cornea in two types of Keratoprosthesis: Technique and Outcomes

Anastasios John Kanellopoulos

The Laservision Institute, Athens, Greece

Purpose: The purpose of this study was to evaluate safety and efficacy of very high-fluence collagen crosslinking (CXL) as a means of increasing cornea rigidity and reducing enzymatic digestion in two keratoprosthesis techniques (a) in the vehicle cornea of Boston keratoprosthesis (Kpro) Type1 and (b) in foldable interlamellar partial thickness corneal pocket.

Methods: In Boston Keratoprosthesis, eleven consecutive cases (5 with repeat cornea graft failure, 4 ocular cicatricial pemphigoid, and 2 chemical burn) received donor-vehicle cornea pre-treatment with very high-fluence prophylactic collagen crosslinking in two sessions. The donor cornea was initially cross-linked with intrastromal riboflavin instillation through a femtosecond-laser-created pocket; followed by superficial CXL. All cases, at the completion of the CXL pre-treatment, had the cornea center trephined with femtosecond laser; the vehicle cornea was trephined with a 9-mm donor punch and the Kpro Type1 was fitted onto the cross-linked donor cornea. We evaluated visual acuity, corneal surface and donor vehicle cornea stability. Mean follow-up was 7.5(1 to 9) years. In foldable interlamellar partial thickness corneal pocket (KeraKlear XT Artificial Cornea, Keramed, CA, USA) we investigated a case with severe ocular surface disease due to limbal stem cell deficiency, resulting in cornea blindness. The inlay prosthesis was previously implanted as an inlay in a donor vehicle allograft cornea that underwent collagen cross-linking (CXL) prior to trephination and interlamellar inlay implantation. The inlay-vehicle cornea complex was transplanted in a fashion similar to penetrating keratoplasty with a 9.5mm diameter.

Results: In the Boston Kpro cases, mean uncorrected visual acuity improved from light-perception to 20/60. One case needed follow-up surgery, due to significant melt in the host cornea. None of the eyes developed melts and/or infection, especially on the vehicle cornea on which the keratoprosthesis was fitted.

In the Keraklear case, the patient was followed for a period of one year. Visual acuity improved from light perception to the 20/400 within 1 month of surgery and remained stable during the follow-up period. The view through the central cornea remained clear during the follow-up period and there was no melting of the surrounding cornea or extrusion of the implant.

Conclusions: Pre-treatment with intrastromal and superficial very high-fluence collagen crosslinking in conjunction with keratoprosthesis appears to be a safe and effective adjunctive treatment aiming to increase vehicle donor cornea rigidity and potentially increased resistance to enzymatic degradation. This application may serve to enhance the biomechanical stability and external disease susceptibility of the donor vehicle cornea in these advanced external disease cases. The novel CXL technique may reduce the incidence of vehicle cornea melt in similar keratoprosthesis operations.

Contact: ajkmd@mac.com

Boston type I Keratoprosthesis assisted with intra-prosthetic amniotic membrane (*AmniotiKPro* sandwich technique)

Alejandro Navas, Julio C. Hernandez-Camarena, Juan Carlos Serna-Ojeda, Arturo Ramirez-Miranda, Enrique O. Graue-Hernandez

Department of Cornea and Refractive Surgery, National Autonomous University of Mexico, UNAM, Mexico City, Mexico.

Purpose: To describe a technique of Boston type 1 keratoprosthesis (KPro) implantation assisted with intra-prosthetic amniotic membrane.

Methods: Patients with severe ocular surface inflammation and corneal blindness underwent KPro implantation assisted with intra-prosthetic amniotic membrane. This technique uses a cryopreserved amniotic membrane disc positioned directly beneath the front plate, with the donor cornea placed after creating a “sandwich” between the front plate, the amniotic membrane disc and the donor cornea.

Results: KPro remained in place and the amniotic membrane well attached, with improvement in the uncorrected visual acuity and with anterior segment optical coherence tomography showing the intra-prosthetic amniotic membrane attached and filling the virtual space between the donor cornea and the anterior plate of the KPro.

Conclusion: This technique could provide an epithelization scaffold and an anti-inflammatory and antimicrobial platform in patients known to have underlying severe inflammatory ocular surface disease and altered ocular immunity. A decreased incidence of tissue melting and KPro extrusion could be a potential benefit with this technique, at the same time the antimicrobial properties of the amniotic membrane and the mechanical closing of the gap between the optical stem and donor cornea are thought to decrease the rate of the keratitis and endophthalmitis associated with KPro.

Contact: alejandronavas@institutodeoftalmologia.org

Prognostic Value of Peri-Prosthetic Tissue Loss for Corneal Melting - Results of a Longitudinal Anterior Segment OCT Study in Patients with Boston type 1 Keratoprosthesis

, Elise Taniguchi, Andrea Cruzat, Bernardo M Cavalcanti, Claes H Dohlman, Pedram Hamrah

Massachusetts Eye and Ear Infirmary, Boston, MA, USA.

Purpose: To prospectively evaluate the presence and alterations of potential spaces and areas of tissue melting (gaps) in the donor cornea, under the Boston Type 1 Keratoprosthesis (K-Pro1) front plate, as well as corneal epithelial tissue lipping over the edge of the front plate (epi-lip), using anterior segment-optical coherence tomography (AS-OCT).

Methods: AS-OCT (RTVue OCT, Optovue Inc., Fremont, CA) was performed at the device-donor corneal interface in all 4 quadrants around the K-Pro1 at two time points (mean follow-up time of 1.3 ± 0.98 years). Presence, alterations, and size of gaps between the front plate and the donor cornea, as well as epi-lips, were evaluated at baseline and follow-up.

Results: Forty-two eyes of 36 patients were assessed (mean of 4.8 ± 2.9 years after surgery), and 25 eyes of 23 patients were analyzed at follow-up. From 154 OCT quadrants imaged at the first visit, 56 (36.3%) revealed a gap under the front plate. The gap area was on average $12.7 \pm 33.3 \mu\text{m}^2$. Among the quadrants with gaps, 19 (34%) revealed no epi-lip, while among the quadrants without gaps, only 3 (3.0%) had no epi-lip ($p < 0.0001$). In addition, the epi-lip area was significantly smaller among the quadrants with gaps compared to quadrants without gaps (22.1 ± 23.8 and $49.5 \pm 49.8 \mu\text{m}^2$, $p < 0.0001$). There was a significant correlation between the gap area and epi-lip area ($r = -0.33$, $p < 0.0001$). On follow-up examination, 60% of the quadrants remained without gaps (from 20 eyes), 17% remained stable or regressed (from 12 eyes) and 23% progressed (from 12 eyes), with one eye advancing to extrusion and two eyes having had a prior history of extrusion in the previous K-Pro. Among those quadrants with gaps that progressed, 30% had no epi-lip during the first visit while, among those quadrants that remained stable or regressed, 18% had no epi-lip. Finally, among those quadrants that remained without gaps, only 3% had no epi-lip ($p < 0.0001$). The relative risk for progression of gaps at the follow-up visits was 1.7 ($p = 0.07$); however, it was 3.2 in quadrants with no epi-lips during the first visit, compared to quadrants with epi-lip ($p = 0.0005$).

Conclusions: Patients with K-Pro Type 1 may demonstrate gaps under the front plate. The epi-lip may confer protection against development of gaps. While corneas in patients without gaps remain stable, presentation of gaps can progress and could demonstrate a risk factor for corneal melting, requiring closer follow-up.

Contact: rodrigo_muller@meei.harvard.edu

Outcomes of primary Boston Type 1 keratoprosthesis placement

Kimberly Hsu¹, Joann Kang¹, Jose de la Cruz¹, Maria S Cortina¹

Illinois Eye and Ear Infirmary, University of Illinois at Chicago Department of Ophthalmology and Visual Sciences, Chicago, IL USA

Purpose: To report longer term outcomes on patients who received a Boston Type 1 keratoprosthesis as the primary penetrating corneal procedure.

Methods: A retrospective study of patients who received a primary Boston Type 1 keratoprosthesis from 2008–2013 was conducted. Vision, complications, and additional procedures required were collected for patients who had greater than 1 year follow up.

Results: Twenty-four eyes of 22 patients received a primary Boston Type 1 keratoprosthesis during 2008 – 2013. Mean follow-up was 47.4 months (range 13.3 to 75.2 months). Preoperative vision ranged from 20/100 to LP. At last follow up, 70.8% of eyes achieved at least 20/200 vision and 37.5% of eyes achieved greater than or equal to 20/50 vision. Postoperative complications included RPM (37.5%), increased intraocular pressure (58.3%), and macular edema (25%). There were no cases of endophthalmitis. Retention rate was 79.2%.

Conclusions: In patients who are at high risk for graft failure with traditional penetrating keratoplasty, the Boston Type 1 keratoprosthesis may be a good alternative. Years after the procedure, many patients retain improved vision, although close follow up is warranted to monitor for complications.

Contact: kimberlyhsu@gmail.com jnapoli@hotmail.com mcortina@uic.edu

Impact of Pars Plana Vitrectomy on Complications in Aphakic Boston Keratoprosthesis Patients

Allister Gibbons, Audina Berrocal, Thomas Albin, Daniel Waren, William Feuer, Jean-Marie Parel, Guillermo Amescua, Victor L Perez

Bascom Palmer Eye Institute, Department of Ophthalmology University of Miami Miller School of Medicine, Miami, FL USA

Purpose: To study the impact of pars plana vitrectomy (PPV) at the time of surgery, versus a limited anterior vitrectomy on the outcomes and complication rates of the aphakic model of the Boston Keratoprosthesis (B-Kpro).

Methods: Records of patients with the snap-on aphakic B-KPro implantation during 2007 to 2013 which had over 1 year of follow-up were reviewed. All pre-operative, intra-operative and post-operative data was recorded and analyzed. Special attention was made to differentiate the group which had received a PPV at the time of surgery and the both the incidence and timing to appearance of complications over the follow-up period.

Results: Forty-three eyes of forty-one patients were included in the study. Eighteen of these eyes had undergone a complete PPV at the time of the B-Kpro implantation, the other twenty-five had not. There were no significant differences in the preoperative, demographic characteristics, clinical background, or indications of B-Kpro in both groups. The group that had a PPV at the time of surgery had a statistically significant decrease of total complication rate observed in the Kaplan Meier Survival analysis ($p=0.0367$). Also, there was a clear trend for there to be less Retroprosthetic Membrane formation, glaucoma progression, and endophthalmitis ($p < 0.1$) in the group that received a PPV at the time of surgery.

Conclusions: The results of this retrospective review suggest that a complete PPV, done at the time of surgery, has a positive impact on decreasing the complication rates of patients undergoing aphakic B-Kpro implantation.

Contact: allister_gibbons@yahoo.com VPerez4@med.miami.edu

Effect of keratoprosthesis on the eye. An animal study

Alja Crnej, Masahiro Omoto, Thomas H Dohlman, Claes H Dohlman, Reza Dana

Massachusetts Eye and Ear Infirmary and Schepens Eye Research Institute, Harvard Medical School, Boston, USA

Purpose: To compare corneal inflammation after syngeneic and allogeneic penetrating keratoplasty (PK) and miniature Keratoprosthesis (m-KPro) implantation and to assess the extent of damage in the retina and optic nerve.

Methods: BALB/c (syngeneic) or C57BL/6 (allogeneic) corneas were transplanted onto BALB/c host beds as part of PK or m-KPro implantation. Corneal inflammation was assessed by determining the frequencies of CD45⁺ leukocytes, CD4⁺ T cells, CD11b⁺ dendritic cells, and Gr-1⁺ granulocytes/monocytes by flow cytometry and was analyzed by expression of the pro-inflammatory cytokines TNF α and IL-1 β using Real-Time qPCR at 8 weeks post-transplantation. In addition, the loss of retinal ganglion cells and optic nerve fibers was assessed 8 weeks after the surgery.

Results : Cell frequencies in the syngeneic and allogeneic m-KPro groups were higher compared to the syngeneic and allogeneic PK groups, respectively. The expression of TNF α was higher in synKPro, alloPK, and alloKPro groups compared to the naïve and synPK groups at eight weeks. The expression of IL-1 β was significantly higher in both KPro groups as compared to PK groups. The reduction in number of retinal ganglion cells and optic nerve fibers were higher in both allogeneic compared with syngeneic groups.

Conclusion: Although m-KPro device augments the inflammatory response in cornea after its implantation, allogenicity is greater contributor to inflammation. We suggest using syngeneic or decellularized corneal tissue as a Boston-KPro carrier. Results also suggest that retina and optic nerve could be damaged by chronic inflammation after allogeneic transplantation.

Contact: alja_crnej@meei.harvard.edu

Scanning Electron Microscopic Analysis of Biofilm Formation in Explanted Human Boston Type I Keratoprotheses. Sterile vs Infectious Case Comparison

Kavitha R Sivaraman^{1,2}, Joshua H Hou^{1,3}, Jin Hong Chang¹, Irmgard Behlau^{4,5}, M Soledad Cortina¹, Jose de la Cruz¹

¹Illinois Eye and Ear Infirmary, University of Illinois at Chicago Department of Ophthalmology and Visual Sciences, Chicago, IL USA; ²Bascom Palmer Eye Institute, University of Miami Miller School of Medicine, Miami, FL USA; ³University of Minnesota Department of Ophthalmology, Minneapolis, MN USA; ⁴Microbiology & Molecular Biology and Ophthalmology, Tufts University School of Medicine, Boston, MA USA; ⁵Infectious Diseases, Mount Auburn Hospital, Cambridge, MA USA.

Purpose: To describe the morphological distribution of host tissue and microbial biofilms on the intraocular surfaces of Boston Type I Keratoprotheses (KPro) explanted due to corneal melt.

Methods: Retrospective scanning electron microscopy (SEM) study of four explanted Boston Type I KPros composed of polymethylmethacrylate (PMMA) and titanium. SEM images of KPro-associated ocular surfaces were reviewed for the presence of inflammatory cells, microbes, and/or biofilm formation. One sterile KPro Type I was also imaged to serve as a device only control.

Results: All four KPros were explanted due to culture-negative, clinically 'sterile' donor corneal melt with impending KPro extrusion. In all cases, the rough, irregular surfaces of the device harbored more adherent corneal epithelia and stromocytes, inflammatory cells and bacteria than the smooth, polished surface of the KPro optic. One KPro showed not only evidence of prior bacterial colonization, but marked biofilm formation.

Conclusions: SEM images of explanted KPros explanted for 'sterile' corneal melt demonstrated evidence of biofilm formation, despite negative donor cornea cultures and the absence of clinical suspicion for infection. These results suggest that 'sterile' corneal melt may be due to inflammatory host responses to low microbial burdens as seen in biofilms and/or released antigens after antibiotic-induced lysis. There was increased adherence of host tissue cells and microbial biofilms on the non-polished surfaces of the KPro. Polishing the intraocular PMMA and titanium KPro surfaces may decrease microbial adhesion and biofilm formation in KPro patients, but what the impact this will have on rates of post-op endophthalmitis is unknown.

Contact: KXS3181@med.miami.edu josedlc@uic.edu

KPro: What is the relationship between surface quality and biofilm adherence?

Heather Durkee¹, Darlene Miller², Shawn P Kelly¹, Patricia L Blackwelder⁴, Mariela C Aguilar¹, Victor L Perez³, Guillermo Amescua³, Jose de la Cruz⁵, Jean-Marie Parel¹

¹Ophthalmic Biophysics Center, ²Ocular Microbiology Laboratory, ³ABLEH, Bascom Palmer Eye Institute, University of Miami Miller School of Medicine, Miami, FL. ⁴University of Miami Center for Advanced Microscopy (UMCAM) and Marine Geosciences (RSMAS), University of Miami, Coral Gables, FL, ⁵Department of Ophthalmology, University of Illinois Eye & Ear Infirmary, Chicago, IL, USA.

Purpose: To investigate the relationship between surface quality and biofilm adherence in explanted Boston Type I, Type II, and modified-osteodonto keratoprotheses (KPros) using confocal and scanning electron microscopy.

Methods: Failed KPros were collected from patients undergoing KPro explantation at Bascom Palmer Eye Institute, Miami, FL, USA. In the operating room, the KPro samples were placed in a container with balanced salt solution immediately after removal. The fresh, un-fixed KPro samples were stained with a live/dead fluorescent stain and confocal microscopy was performed to visualize the microbial adherence and cellular growth. Images were taken across the entire anterior and posterior surfaces of the KPro samples to characterize the complete anterior and posterior faces of the KPro specimen (including the optic, backplate, locking ring). After confocal microscopy, the KPro sample was fixed in 10% formalin, immersed in PBS buffer, dehydrated in a graded series of ethanol, dried in HMDS, and sputter-coated with Palladium for scanning electron microscopy. Images of the anterior and posterior surfaces of the KPro were obtained using SEM at multiple magnifications (30x–5000x).

Results: Confocal microscopy and SEM images revealed rough surfaces in all regions of the KPros. The confocal microscopy revealed cellular growth in areas of more irregularities. The high magnification SEM images showed many bacteria and biofilm colonies attached to the KPros. In one case, the patient also had an intraocular lens (IOL) which was analyzed as was the KPro to relate surface features to microbial adherence. The IOL had super polished surfaces with almost no microbial adherence.

Conclusion: A dual-imaging approach provided better visualization of the surface quality and biofilm/microbial growth on the surfaces of the failed KPros. Understanding the relationship between biofilm adherence and rough surface quality may bring to light the mechanism of KPro failure.

Contact: hdurkee@med.miami.edu jmparel@med.miami.edu

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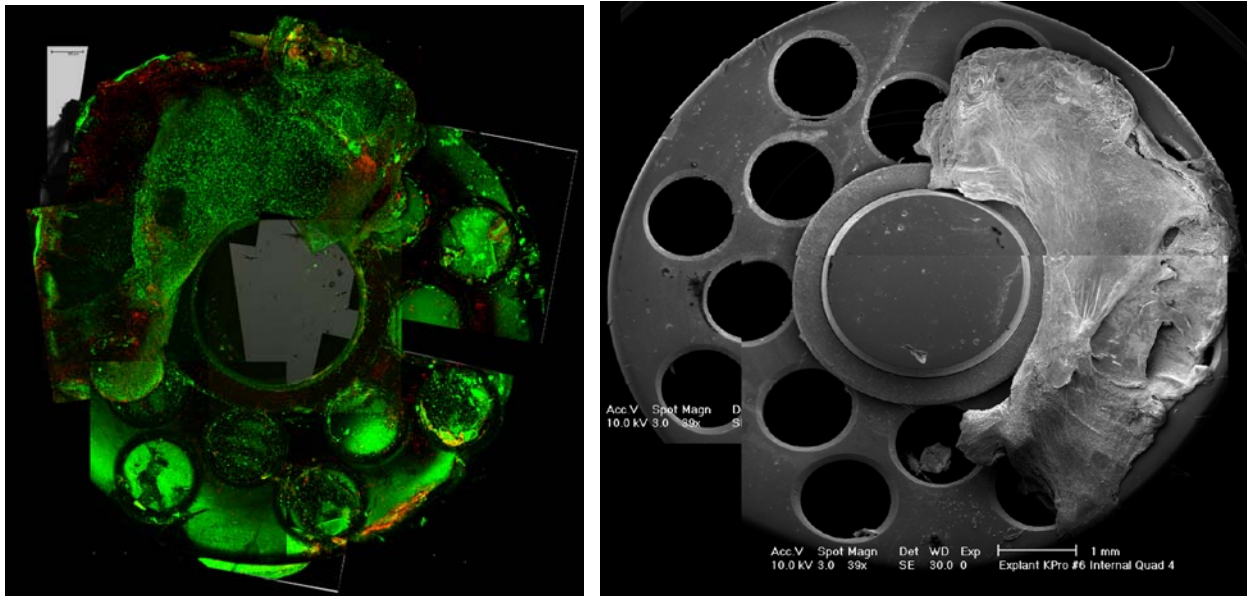


Figure 1: (Left) Confocal microscopy and (Right) Scanning electron microscopy images of internal KPro surface shows cellular activity and biofilm.

Optimization of Titanium Surface Characteristic in Boston Keratoprosthesis Backplate

Eleftherios I. Paschalis, Chengxin Zhou, James Chodosh, Claes H. Dohlman

Department of Ophthalmology, Boston Keratoprosthesis Laboratory, Massachusetts Eye and Ear Infirmary and Schepens Eye Research Institute, Harvard Medical School, Boston, MA, USA

Purpose: Even though titanium (Ti) has been extensively used in orthopedic surgery and dentistry, it was only recently approved by the FDA and Europe for use in the eye as Boston keratoprosthesis (B-KPro) backplates. A major limitation of Ti is the shiny metallic appearance which makes it cosmetically less favorable compared to previously used PMMA. To circumvent this limitation, B-KPro backplates have been systematically sandblasted to generate surface roughness and to reduce metallic reflection. The present work presents a method for changing the color of the Ti to somewhat match the natural color of the patient's eye and provides for the first time data of the impact of Ti surface roughness in human corneal cells.

Methods: Coloring of the Ti was achieved by electrochemically anodization that resulted in a Ti oxide film formation on the surface of the backplate. The thickness of the film was controlled by the applied voltage. The technique was evaluated in vitro (human corneal cells) and in vivo (rabbit intra-corneal implantation) for biocompatibility and safety. Rough Ti surfaces (RMS= 4.413, 2,426, 0.690) and polished (RMS= 0.175) were assessed in vitro using human corneal/limbal epithelial cells (HCLE), stromal fibroblasts (HCFs), endothelial cells and HeLa cells. Cell cytotoxicity and proliferation assays were performed. Cells were challenged with ascorbic acid, w/wt TGF β 1 to simulate the corneal micro-environment after injury and assessed for collagen deposition, cell morphology and α -smooth muscle actin (α SMA) expression.

Results: Coloration of Ti was achieved by anodization at 33 and 13.4 volts, respectively with a current supply of 3 Amps. In vitro and in vivo assessment showed no significant differences in tolerance compared to non-colored Ti. However rough Ti surface topography resulted to significant inhibition of HCLE and HCF cell proliferation, as compared to polished Ti. Polished Ti provided better cell adhesion, remarkable directionality in cell alignment and had parallel aligned, fibrillar collagen meshwork, while rough Ti had randomly aligned cells and collagen deposits. Challenge with TGF β 1 caused increased α SMA expression on the rough Ti surface, less collagen deposition and randomly oriented collagen fibrils as compared to those on polished Ti which had parallel aligned collagen fibrils.

Conclusion: Blue and brown Ti coloring was achieved by electrochemical anodization and was equally biocompatible and as safe as the standard non-coated Ti. Ti surface roughness significantly affected corneal cell expression, with epithelial and stromal cells being highly affected by the topography. Contrary to the established paradigm in orthopedics, polished Ti surface better facilitated corneal cell proliferation, matrix deposition, and reduced α SMA expression under TGF β 1 stimulation as compared to rough Ti surface. These results suggest that BK-Pro Ti coloring may improve the cosmesis and acceptance by patients and that controlled Ti surface roughness manipulation may provide better tissue biointegration (smooth surface) or reduced retroprosthetic membrane formation (rough surface) in the future.

Contact: Eleftherios_Paschalis@MEEI.HARVARD.EDU

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Management of end stage corneal disease and chronic uveitic hypotony by combining the Boston type 1 keratoprosthesis with pars plana vitrectomy and silicone oil fill

Tayyeba K Ali, Guillermo Amescua, Janet L Davis, Allister Gibbons, Victor L Perez

Bascom Palmer Eye Institute, Department of Ophthalmology, University of Miami Miller School of Medicine, Miami, FL, USA

Purpose: To review the outcomes of Boston type 1 keratoprosthesis (B-KPro) implantation in combination with pars plana vitrectomy and silicone oil for the treatment of end stage bullous keratopathy and uveitic hypotony.

Methods: This was a retrospective chart review. Six eyes of 5 patients underwent B-KPro implantation, pars plana vitrectomy, and silicone oil placement. All preoperative characteristics, including visual acuity and intraocular pressure, intraoperative events, and postoperative outcomes were analyzed.

Results: Mean patient age was 63.9 years (range 40.9-86.4 years). Mean pre-operative BCVA was logMAR 2.73 (range 2.60 to 3.00). Initially, a gain of visual acuity was seen in half the sample with mean BCVA logMAR 1.90 (Range 0.90 to 3.00). At final follow-up (mean 25.8 months and range 12 to 52 months), mean visual acuity was logMAR 2.23 (range 1.20 to 3.00) and no eye lost vision. Two eyes (33%) had previously undergone corneal transplantation, one of which was an endothelial keratoplasty (DSAEK). The other 4 eyes had a B-Kpro as their first corneal procedure. No intraoperative complications occurred, though one patient had a concomitant retinal detachment (RD) repair for pre-existing RD. B-KPro retention rate was one hundred percent. One patient developed a retroprosthetic membrane (RPM); no patients experienced complications such as melt, endophthalmitis, or extrusion. The one patient who had an RPM had a pseudophakic B-Kpro, which may have contributed to persistence of RPM. There were no uveitic flares and hypotony was controlled, though further intervention, including repeat SO fill in one patient, was required over the extended follow-up of these patients.

Conclusions: B-KPro implantation in combination with pars plana vitrectomy and intraocular silicone oil fill is a safe, though end-stage, procedure that maintains control of uveitis, can improve vision in some chronically hypotonous eyes, and may delay or prevent phthisis.

Contact: t.ali2@med.miami.edu

Five to Ten Year Follow-up of Boston Type 1 Keratoprotheses Demonstrates Stable Visual Acuity and Retention

Anthony J Aldave, Jaime Alexander, Fei Yu

The Jules Stein Eye Institute, UCLA, Los Angeles, CA, USA

Purpose: To evaluate the long-term outcomes of Boston type I keratoprosthesis implantation

Methods: A retrospective, interventional case series of eyes undergoing keratoprosthesis surgery by a single surgeon (AJA) prior to September 2009 with 60 months follow-up. Preoperative characteristics and postoperative outcomes including CDVA, complications and retention were determined.

Results: Sixty eight keratoprotheses were implanted in 54 eyes of 51 patients, with the initial procedure performed before September 2009 in all eyes. The mean follow-up was 66 months, with a range between 2 months and 10 years. The primary indication for keratoprosthesis implantation was corneal transplant failure (50% of eyes). Pre-operative CDVA was $\geq 20/200$ in 6% of eyes, while annual post-operative CDVA between 5 and 10 years after surgery was $\geq 20/200$ in 55%, 63%, 62%, 100%, 100% and 100% of eyes. Failure to obtain and maintain 20/200 CDVA following keratoprosthesis implantation was most commonly due to glaucoma. The most common post-operative complications were retroprosthetic membrane formation (48%), persistent epithelial defect formation (44%), and elevated intraocular pressure (24%). No eye developed endophthalmitis. Twenty six of the 68 keratoprosthesis (38%) implanted in 18/54 eyes (33%) were not retained (retention failure rate 0.088 eye-year), although only 2 retention failures occurred between 5 and 10 years after keratoprosthesis surgery.

Conclusions: The Boston type I keratoprotheses provide $> 20/200$ CDVA in the majority of patients 5-10 years following implantation. While glaucoma is the most common vision-threatening post-operative complication, endophthalmitis was not observed. The retention rate of the Boston type I keratoprosthesis remains stable more than 5 years after surgery, and is significantly higher than the repeat corneal transplant survival rate.

Contact: aldave@jsei.ucla.edu

Experience with Dohlman-Doane type I keratoprosthesis

Sérgio Kwitko^{1,2}, Tiago Lansini¹, Diane Marinho^{1,2}

¹Department of Ophthalmology, Hospital de Clinicas de Porto Alegre, Brazil

²OftalmoCentro, Porto Alegre, Brazil

Objective: To report the outcomes of Dohlman-Doane type 1 keratoprosthesis (Boston KPro) implantation in 36 eyes

Methods: A retrospective case series was performed on all patients undergoing Boston KPro implantation at Hospital de Clinicas de Porto Alegre, Brazil, performed between September 2005 and August 2014. A minimum follow-up of 6 months was required. Using a computerized patient database, 36 eyes of 30 patients were identified that met these criteria. Best-spectacle corrected visual acuity (BSCVA), complications and retention time of KPro were evaluated.

Results: underlying disease were failure of multiple previous corneal transplants in 19 eyes (keratoconus, bullous keratopathy, congenital glaucoma, angle-closure glaucoma, Fuchs dystrophy, and *Acanthamoeba* keratitis), alkaline burns in 11 eyes, Stevens-Johnson Syndrome in 3 eyes, graft versus host disease in 2 eyes, thermal burn in one eye, and aniridia in one eye. Preoperative visual acuity was 20/200 or worse in all eyes. Postoperative BSCVA ambulatory vision (20/200 or better) was achieved in 63% of the eyes after 3 years, 58.3% after 4 years, 47.6% after 5 years, and 57.1% after 7 years. Main causes for poor postoperative VA were glaucoma, retinal detachment and endophthalmitis. Postoperative complications included posterior capsule opacity in 27.8%, corneal melting in 25%, cystoid macular edema 22.2%, sterile vitritis in 19.4%, fungal keratitis in 13.9%, retroprosthetic membrane formation in 11.1%, anterior chamber fibrin membrane in 5.5%, retinal detachment in 5.5%, and fungal endophthalmitis in 5.5%. Sixteen eyes (50%) had preoperative glaucoma, and 6 other eyes (16.7%) developed postoperative glaucoma. Retention KPro rate was 100% in the first year, 91.7% in the second year, 88.9% in the third year, and 86.1% after 5 years of KPro implantation. Mean follow-up period was 64.7 ± 48.8 months (6 to 111 months).

Conclusion: Boston type I is a good option to restore vision in cases of corneal blindness in which penetrating corneal transplantation does not have a good prognosis. One main advantage is that it does not require systemic immunosuppression. Despite the potential complications, type I Boston KPro provided visual improvement in our series of patients with an otherwise poor prognosis. Immune diseases and ocular surface keratinization had the worst results. Retention rate decreases overtime due to late retroprosthetic membrane formation and corneal necrosis. Glaucoma is a frequent cause of poor visual rehabilitation in these patients.

Contact: sergio@oftalmocentro.com.br

Novel Strategies to Improve Keratoprosthesis Outcomes

Juan-Carlos Abad¹, Miguel Cuevas², James Jaramillo³, Maria Clara Jaramillo³, Oscar Villada⁴

¹Cornea and External Disease Service, clínica CLOFAN, ²Cornea, External Disease and Ocular Immunology Services, clinic CLOFAN and University of Antioquia, ³Ophthalmology Residents, University of Antioquia, ⁴Epidemiology Service, Hospital Universitario San Vicente Foundation, Medellin, Colombia.

Purpose: To report the clinical results of a group of 22 patients (22 eyes) which had a Boston type I keratoprosthesis (KPro) implanted in which novel surgical and postop modifications were introduced to try to improve the outcome.

Methods: Such strategies were 1) All patients were rendered aphakic; 2) Complete pars plana vitrectomy at the time of surgery; 3) Use of oversized titanium back plates; 4) Almost universal use of glaucoma draining devices (GDD); 5) Use of medroxyprogesterone and oral doxycycline and ascorbic acid; 6) Avoidance of medications that could activate collagenases such as topical fourth-generation quinolones, latanoprost and prednisolone acetate; 7) Cleaning of the bandage contact lens with iodine povidone at every patient's visit.

These patients were treated between January 2011 and November 2014 with an average follow-up of 18 months (range 3-39 months). There were 17 men and 5 women with an average age of 52±18 years (range 17-84 years). Fifty percent of the cases had a disease without active inflammation of the ocular surface, 23% had a history of chemical or thermal burns, 18% had diseases with active inflammation of the ocular surface and the remaining 9% had Stevens-Johnson syndrome. The Indications for implanting the Kpro were a failure of one or more corneal grafts in 59% of cases; 23% had had one or more Kpros with either PMMA or undersized titanium back plates that had extruded and 18% did had a hostile ocular surface for a primary penetrating keratoplasty. Eighty-six percent of the cases had a visual acuity (VA) ≤ 20/200 in the eye to intervene (6 cases had light perception). Visual acuity values better than 20/200 in 37%, 50% and 60% of the cases at the 3, 6 and 12 months visits. There were 2 Kpro extrusions (91% Kpro retention rate).

Results: The most frequent complication was poorly controlled intraocular pressure in 54%, requiring implant of a first or second GDD in 24% of the overall cases. Other complications were vitreous hemorrhage in 13%; retinal detachment in 4 patients (1 was successfully repaired); there were two cases of infections (endophthalmitis and keratitis) related to an inferotemporal GDD exposure and there was 1 case of retro-optic retroprosthetic membrane (RPM) related to an unoperated vitreous hemorrhage. There seemed to be less deposit in the backplate holes compared with prior PMMA backplate cases. Two patients had bare light perception at the end of follow-up.

Conclusion: Although Kpro extrusion and RPM formation (both behind the optic and in the backplate holes) seem to be reduced by the implementation of these techniques, glaucoma continues to be a problem in these very difficult patients.

Contact: jc@jcabad.com

Crosslinking of Donor Corneal Tissue with Glutaraldehyde (GA) for Keratoprosthesis – A preliminary report of cases

Kuttappalayam S Siddharthan, Jagadeesh K Reddy, Adithya Gowda, Rushita Kamdar

Cornea and Refractive Services, Sankara Eye Center, Coimbatore, Tamil Nadu, India

Purpose: The aim of this study was to investigate the possibility of induction of cross-links in donor corneal tissue in order to increase the stiffness as a basis for an ingenious technique of keratoprosthesis.

Methods: Collagenous biomaterials can be stabilized by chemical and physical agents and glutaraldehyde (GA) is the most commonly used crosslinking agent for collagen based biomaterials. It increases the crosslinks both intrahelical and interhelical and is thus known to increase the tensile strength of the tissue. Studies have shown that GA exerts the maximum biochemical effect on the cornea when compared to other cross-linking agents like genipin and UC- CLX.

At our clinic, we pre-treated the cornea with 0.5% GA for 4 minutes (adequate time for Schiff base formation) followed by thorough washing under running normal saline for 10 minutes to remove any residual glutaraldehyde which may have toxic effects after transplantation. It may be noted that higher GA concentration and longer reaction times may lead to formation of pendant GA related molecules rather than crosslinks. We then used this GA treated cornea as the donor tissue in the keratoprosthesis (Auro K pro manufactured by Aravind eye Hospitals, India) for five patients.

Results: During the surgical procedure of punching and then suturing the keratoprosthesis to the host bed, we noted increased stiffness of the graft biomaterial, attributed to the crosslinking effect of GA. On subsequent follow up, the pre-treated corneas re epithelialized well with no adverse effects on the eye. Two patients have 6 months follow up and three patients have 3 months follow up.

Conclusions: This increased tensile strength would in due course prevent donor tissue melt and leaks, this being the primary concern with widespread use of keratoprosthesis. Eventually it would lead to an increased life of the keratoprosthesis. In our presentation we will show the procedure of tissue treatment, surgical procedure and the post-operative results of these patients.

Contact: siddharthans@gmail.com

Setting up a Keratoprosthesis Service in a Tertiary Care Public Funded Hospital in India

Radhika Tandon, Onkila Bhutia, Ajoy Roychowdhary

¹Dr Rajendra Prasad Centre for Ophthalmic Sciences, ²Centre for Dental Education and Research, All India Institute of Medical Sciences, New Delhi-110029, India

Purpose: To review the long term outcome of keratoprosthesis surgical services delivery.

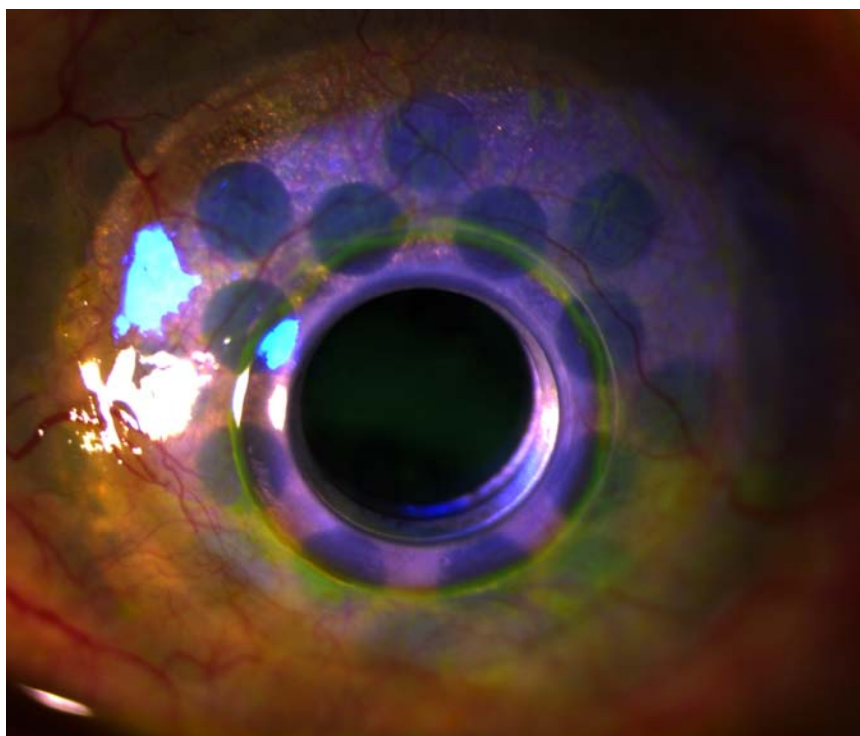
Methods: File notes, case records, administrative letters, grant applications, ethics submissions, clinical protocols notes and updates, clinic registers, operating room records, medical social workers records, applications to stores for purchase of medications and devices, follow up information and information provided by patient contact by telephone were gathered, catalogued and analyzed. Clinical and socioeconomic profile of patients, resources utilized, types of devices and surgical procedures, length and duration of surgery, surgical expenses, short term and long term results in terms of improvement in vision, change in quality of life, impact on family and life changing events, expenses incurred in visiting hospital and medications used, retention and complications were determined.

Results: An estimated total of 65 patients were operated at the centre of which 40 patients under care of the authors were included for detailed analysis. Age ranged from 20 to 72 years with a mean of 46yrs (SD 20) The underlying end stage corneal disease was attributed to Stevens Johnson Syndrome or Ocular Cicatricial Pemphigoid (38%), prior failed corneal grafts (40%), end stage limbal stem cell deficiency (5%) high risk keratoplasty with healed keratitis and neovascularization in 4 quadrants (5%), aphakia with silicon oil keratopathy (5%), combination of factors or others (7%). Devices used in sequential order of initiation of the introduction of surgical procedures to the service included: Singh Worst Champagne Cork KPro (13%), OOKP (28%), Boston Type 1 or its prototypes (48%), Boston Type 2 (3%) and temporary KPro assisted combined vitreoretinal and keratoplasty procedures (8%). The overall rate of improvement in vision was 95% and improvement in quality of life 80%. Long term clinical outcome in terms of retention rate including those who completed minimum 5 years of follow up and excluding those who had temporary KPro assisted keratoplasty was estimated to be 77%. Major ophthalmic complications noted included extrusion, endophthalmitis (10%), irreparable retinal detachment (3%), exchange due to instability (3%), surgical removal due to uncontrollable infection (3%) and progressive ciliary body failure leading to phthisis bulbi (5%).

Conclusion: Keratoprosthesis surgery offers a life changing option to patients with end stage blinding corneal disease. With passage of time and changing technology a better understanding of case selection, selection of devices and procedures, clinical protocols, anticipated outcome and estimated prognosis has emerged.

Contact: radhika_tan@yahoo.com

NOTES



Compliments of Juan Carlos Abad MD



For the KPro Study Group:

Jose De La Cruz
jnapoli@hotmail.com

Jean-Marie Parel
jmparel@med.miami.edu

This KPro Study Group Symposium is endorsed by the



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