



Boston Keratoprosthesis Update

Newsletter VII: 2010 Editors: Rhonda Walcott-Harris and Claes Dohlman http://www.meei.harvard.edu/shared/ophtho/cornea2.php

Cost-Utility of the KPro Jared Ament, MD, MPH



Cost-utility of various medical interventions, adjusted to 2009 US dollars

Intervention	Cost in \$/QALY
Initial cataract surgery	\$2 023
Second eye cataract surgery	\$2 727
Penetrating Keratoplasty	\$12 194
Boston keratoprosthesis	\$15 525
Photodynamic therapy for subfoveal choroidal	
neovascularization with ARMD	
20/40 initial vision	\$104 158
20/200 initial vision	\$208 966
Coronary bypass surgery for occluded LAD artery	\$44 113
Chemoprophylaxis after occupational exposure to HIV	\$49 036
Primary pediatric heart transplant	\$52 417
Magnetic resonance imaging for equivocal neurologic	\$134 742
symptoms	
One day of chemoprophylaxis prior to receiving dental work for patients with prosthetic joints	\$696 692

Ament JD, Stryjewski TP, Ciolino JB, Todani A, Chodosh J, Dohlman CH. Cost-effectiveness of the Boston Keratoprosthesis. Am J Ophthalmol 2010;149:221-228.

During the past decade, there has been an explosion of interest in measuring the outcomes of medical care. There is also a growing recognition that patient perspectives are essential, both in making medical decisions and in judging the results of treatment. This is especially true when evaluating expensive and/or novel medical devices, such as the Boston Keratoprosthesis.

Preference-based quality of life (QOL) instruments are used to elicit patient's valuations for their current health state. The instruments used in cost-utility analyses generate a single QOL value, known as "utility", expressed on a zero to one scale, where zero represents the value of death and one represents the value of perfect health (the latter is often substituted in ophthalmology for perfect vision). *Utility* is a concept developed by economists to indicate the strength of an individual's preference.

Despite the increasing prominence of preference-based QOL instruments, a standardized rubric for what is considered "cost-effective" has yet to be clearly defined. A commonly cited guideline in the US and the UK (based on the costs and value associated with dialysis for end-stage renal patients) considers interventions costing below 50 000 \$/QALY as cost-effective. Nevertheless, as the Boston KPro continues to evolve in an environment of increasingly complex medical decision making and reimbursement structures, continued efforts to assess both costs and utilities is of paramount importance.



Boston KPro Usage

About 4500 devices have been implanted worldwide, over the years.

Fungal infections revisited Irmgard Behlau, MD



Prevention of complications after Boston Keratoprosthesis surgery such as tissue melt and bacterial infection, have vastly improved over the past 10 years with technical advances and topical antibiotics usage. Yet, we must remain diligent in patient follow up and antibiotics compliance. Fungal infections which are usually slow growing are less of a threat but they can occasionally occur, especially in hot, humid countries with a large rural population. If recognized in time, they are readily treatable and disasters are rare. Still, in high-risk areas, bursts of antifungal prophylaxis may be

advisable, such as:

Amphotericin B 1.5mg/mL (0.15%) twice a day for one week every three months

- or Miconazole 1%
- or Econazole 2%
- or Natamycin 5% suspension (limited penetration to deep stroma)

We are also exploring the use of Povidone-iodine (PVP-I) in various concentrations.



Fungal colonization of soft contact lens



Early keratitis: white sheen in graft next to the KPro stem



More advanced keratitis

KPro back plate developments



The upper two back plates, 7.0 mm and 8.5 mm in diameter, are the standard PMMA plates.

The lower three back plates are made of titanium, 7.0, 8.5 and 9.5 mm diameter.

In a few months titanium plates are expected to be approved by FDA and will then be offered to users as a safer alternative to PMMA plates.

Reimbursement to surgeon and facility for BKPro surgery

Rebecca Doherty

Clinical Reimbursement

Currently, obtaining reimbursement for keratoprosthesis surgery is successful. Medicare, Medicaid, private carriers, and most recently Blue Cross pay for this surgical service. Blue Cross nationwide appears to only reimburse after two failed grafts. However, in Massachusetts, they amended their coverage policy to include primary KPros done for anesthetic corneas, vascularized corneas, or in the setting of limbal stem cell failure.

a. Physician Payments

The current Medicare payment for Keratoprosthesis in Massachusetts is \$1,552. The additional PK (pseudophakic or aphakic) performed at the time of Keratoprosthesis insertion has been paid at 50% of the Medicare allowable (Massachusetts numbers from 2010 local area 01).

- i. CPT 65750 (aphakic PK): \$1,280 @ approx. 50% = \$640
- ii. CPT 65755 (pseudophakic PK): \$1276 @ approx. 50% = \$638

International and self-pay patients are charged a \$4,000 physician fee for Keratoprosthesis at MEEI.

b. Facility Payments

In split billing arrangements, the reimbursement is dependent on the insurance carrier. In FY10, Medicare reimbursed Massachusetts Eye and Ear Infirmary (MEEI) \$7,745 which included CPT 65770 (KPro surgery) and HCPCS (Healthcare Common Procedure Coding System) code C1818 (KPro device). In addition, MEEI has been receiving \$3,236 for HCPCS code V2785 (corneal tissue).

The Keratoprosthesis device itself is bundled with the Ambulatory Payment Classification (APC) payment for Medicare but is paid separately by Blue Cross.

International and self-pay patients are charged a facility fee of approximately \$9,000 which includes anesthesia costs and the price of the device.

c. Ambulatory Surgery Center (ASC)

If keratoprosthesis surgery is done in an ASC, in addition to billing a professional fee, a facility fee should also be billed. The Medicare ASC facility rate for CY10 for 65770 is \$6,256 with the Boston area wage index. This amount includes the cost of the KPro device. The corneal tissue is reimbursed separately. If the patient's own cornea is used as carrier for the KPro, this is would not be an issue.

J. G. Machine Shop

John Graney



J.G. Machine got its start 45 years ago and continues today as a small, family run business in Woburn, MA. They have built a reputation of being able to handle challenging projects and delivering high quality, precision machine parts. Owner John Graney, along with his daughter, Susan Kinneen has adopted the mindset that with a little persistence and a lot of experience, a method could be devised to manufacture almost anything.

Dr. Claes Dohlman was first introduced to Mr. Graney in 1999 while looking for someone to make and continue development on the Boston Keratoprosthesis. Until then, each KPro had been painstakingly made individually, by hand, in a small machine shop located at the Massachusetts Eye and Ear Infirmary (MEEI). The machinist who had been making them was preparing to retire so another option needed to be found. Dr. Dohlman's passion for the project impressed John and the potential to change so many lives was inspiration to take on the project. The challenge was met with vigor.

Over the next few years, several fellows from Dr. Dohlman's office collaborated with the staff at J.G. Machine about how best to utilize the measuring devices provided by MEEI and the perfecting of the polishing process. Many of the lenses made during this time were distributed by Dr. Dohlman for evaluation. Combining his own findings with feedback from other surgeons, Dr. Dohlman and Mr. Graney began to make improvements to the design. A snap ring was added to avoid the back plate unscrewing from the stem while in the eye. Screw threads were abolished and advancement in the back plate design (holes for nutrition) created a device that is better tolerated by the patient's eye and easier to assemble for the surgeon. Lately, back plates made of titanium have been machined routinely. The introduction of a dedicated computer controlled machine (CNC) has greatly improved quality and capacity for the increased demand.



John Mulrennan

James Carey

James Carey

The staff of JG Machine Co.

Profiles of distinguished KPro surgeons ...

Mark J. Mannis, MD, FACS



Dr. Mark J. Mannis is Professor and Chair of the Department of Ophthalmology & Vision Science, UC Davis Eye Center at the University of California, Davis. He also serves as Medical Director of Sierra Regional Eye and Tissue Donor Services in Sacramento, California. He completed his ophthalmology residency training at Washington University in St. Louis and a fellowship in Cornea and External disease at the University of Iowa. His primary research includes studies in the development of new anti-infective agents, corneal transplantation, visual rehabilitation of patients with corneal disease, and the management of oculodermal disease and diseases of the ocular surface. Clinically, he specializes in corneal surgery and diseases of the external eye. Dr. Mannis is editor/ author of five recent books: Cornea -now in preparation for its third edition published by Elsevier-a two volume comprehensive text on the cornea and external eye co-edited with Jay Krachmer and Edward Holland,

and cited as one of the 100 most important texts in ophthalmology of the 20th century; Eye and Skin Disease - a text for both ophthalmologists and dermatologists on skin diseases with ocular manifestations, co-edited with Marian Macsai and Arthur Huntley; Corneal Transplantation: A History in Profiles - co-authored and co-edited with Avi Mannis; Ocular Surface Disease coauthored with Edward Holland; and most recently, Contact Lenses in Ophthalmic Practice, a manual on contact lenses, translated and edited by Dr. Mannis. Dr. Mannis was Editor-in-Chief of the journal Cornea and is currently Editor in Chief of Vision Pan-America. He has published widely in peer-reviewed journals with over 130 published papers and is a reviewer for the Archives of Ophthalmology, the American Journal of Ophthalmology, Ophthalmology, and Cornea and Contact Lenses. Dr. Mannis is a recipient of the R. Townley Paton Award in eve banking from the Eye Bank Association of America and was a recipient of the Lew Wasserman Award in research from Research to Prevent Blindness, Inc. for his work in the development of antimicrobial peptides in ophthalmology. He recently completed a term as one of the Directors of the American Board of Ophthalmology and is President Emeritus of the Cornea Society. Dr. Mannis will assume the presidency of the Pan-American Association of Ophthalmology in 2011. He conducts a busy referral practice in diseases of the cornea and external eye based at the University of California, Davis. He has a special interest in prosthokeratoplasty and has implanted and published on his cohort of Boston keratoprostheses.

Mona Dagher, MD, FRCSC, DABO



Dr. Mona Harissi-Dagher completed her medical doctorate and residency in ophthalmology at Université de Montréal. She then pursued post-doctoral fellowship training in cornea, external eye disease, and refractive surgery at the Massachusetts Eye and Ear Infirmary where she was first exposed to the concept and practice of artificial cornea.

Dr. Dagher is currently assistant professor at the Université de Montréal. She brought back her expertise on keratoprosthesis surgery

to Canada after conducting considerable research and clinical work at Mass Eye and Ear Infirmary, Harvard Medical School.

Dr. Dagher has multiple publications on the Boston Keratoprosthesis in the peer reviewed literature as well as chapters in ophthalmology textbooks.

After implanting the Boston keratoprosthesis and restoring sight to a number of Canadian patients, Dr. Dagher was chosen "personnalité de la semaine" by La Presse and Radio-Canada.

Jose de la Cruz, MD, MSc



Dr. de la Cruz is Attending Surgeon and Assistant Professor on the Cornea Service at the University of Illinois Eye and Ear Infirmary, in Chicago. He also heads the Artificial Cornea Program at this institution. Dr de la Cruz earned his Bachelors and Masters Degree in Physiology from Indiana University, and his medical degree from Ponce School of Medicine, Puerto Rico. He completed his ophthalmology residency at New York Eye and Ear Infirmary where he also served as Chief Resident. He then went on to complete two years of clinical fellowship training in Cornea, his first at Massachusetts Eye and Ear Infirmary/Harvard Medical School and his second at the University of Illinois Eye and Ear Infirmary.

Dr. de la Cruz's primary research interest is keratoprosthesis surgery, management and design evaluation with particular interest in the use of anterior segment imaging to evaluate the interactions of the implanted keratoprosthesis with surrounding structures. He lectures nationally and internationally and does peer reviews on these topics for several ophthalmology journals. Since his fellowship years he has been actively involved in establishing new keratoprosthesis services in New York City, Chicago, Latin America and the Caribbean

Anun Vongthongsri, MD



Dr. Vongthongsri is an Associate Professor of Ophthalmology at Ramathibodi Hospital, Mahidol University School of Medicine, Thailand. Dr. Vongthongsri specializes in corneal and anterior segment disorders and refractive surgery. His clinical research interests focuses on selective keratoplasty, refractive surgery, and keratoprosthesis.

Dr. Vongthongsri received his M.D. degree from Chulalongkorn

University School of Medicine. He completed ophthalmology residency at Ramathibodi Hospital and fellowship in cornea, external diseases, and refractive surgery at the Eye Center, Washington University School of Medicine. After his fellowship, Dr. Vongthongsri returned to Ramathibodi Hospital and has served as the Chief of Cornea and Refractive Surgery Service since 2000.

Price Increase - November 10, 2009

Dear Boston Keratoprosthesis user,

Regrettably we have come to the point when a raise in price of our keratoprosthesis has become necessary. As of January 1, 2010, the cost will be <u>\$5000</u>, instead of the present \$3000.

The reason for this price increase is two-fold:

- 1. Our research effort, although quite successful, has also become increasingly expensive.
- 2. We have come to a stage when we have to pay increasing attention to regulations in many countries (CE mark, etc.). This is no minor matter and it is steadily getting more expensive.

Thus, after many years of keeping the cost of the Boston KPro down to make it maximally available, we now have to set a realistic price. We hope that this change will not cause any reimbursement difficulties. In spite of increasing expenses, we will continue our policy of reducing the price for countries that call ill afford the full cost. As before, we will do our utmost to help you to help your patients with severe corneal disease.

Sincerely,

Claes Dohlman, MD, PhD

New Collaborators



Frederick Jakobiec, MD, DSc Ophthalmic Pathology



Mark Fava, MD Cornea Specialist



Lucy Young, MD, PhD, FACS Retina Specialist



Borja Salvador, MD Research Fellow



Lucy Shen, MD Glaucoma Specialist

Letter regarding change in optical power categories

Recently the following letter was sent to all Boston KPro users:

Dear Boston KPro User:

As you know, we have up to now provided you with KPros having optical power that tries to match the axial length of the aphakic eye to be operated. The recommended axial length, as shown on the label, has been expressed with great precision down to a tenth of a millimeter, e.g. "recommended for an axial length of 22.8 mm."

However, after analysis of the refractive outcome, it turns out that such precision in numbers is almost meaningless. Postoperative refraction depends on suturing, wound healing, intraocular pressure, etc., to a degree that drowns out any gain in optical precision from using decimals. Therefore we have decided that from now on we will supply you with KPros for axial lengths expressed only in half millimeter ranges, e.g. 22.0-22.5, 22.5-23.0 mm, etc. – when we have run out of the present inventory. (The KPros will be machined for axial lengths of 22.25, 22.75 mm, etc.).

This change will simplify manufacturing, ordering, inventory and your scheduling without influencing refractive outcome in any major way. Theoretically, any optical error by using half-millimeter steps (with machining for a number half-way in between) would require a final correction of only between zero and maximally 0.75 diopters, plus or minus – a minute error compared to other factors. Many of our patients presently require correction anyway, either with glasses or with the contact lens that is needed for protection. A certain pinhole effect of the KPro stem also reduces the need for correction. The proposed simplification is not expected to be a problem.

KPros for pseudophakia will still be provided with a single power as before.

As always, if questions, feel free to ask us.

With best wishes,

Claes Dohlman, MD, PhD James Chodosh, MD, MPH Larisa Gelfand, Manager Boston KPro Program

Recent Boston KPro Literature - 2009 to present

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Sa-ngiampornpanit T, Thiagalingam S, Dohlman CH. Boston Keratoprosthesis in epithelial downgrowth. DJO 2009;15:1.

Ciolino JB, Dohlman CH. Biological keratoprosthesis materials. Int Ophthalmol Clin 2009; 49:1-9.

Klufas MA, Starr CE. The Boston Keratoprosthesis. An update on recent advances. Cataract & Refractive Surgery Today. September 2009;1-3.

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Todani A, Gupta P, Colby K. Type I Boston keratoprosthesis with cataract extraction and intraocular lens placement for visual rehabilitation of herpes zoster ophthalmicus: The "KPro Triple". Br J Ophthalmol 2009 Jan;93(1):119 (on-line video).

Aldave AJ, Kamal KM, Vo RC, Yu F. The Boston Type I Keratoprosthesis: improving outcomes and expanding indications. Ophthalmology 2009; 116:640-651.

Rivier D, Paula JS, Kim E, Dohlman CH, Grosskreutz CL. Glaucoma and keratoprosthesis surgery: role of adjunctive cyclophotocoagulation. Glaucoma 2009; 18:321-324.

Bradley JC, Hernandez EG, Schwab IR, Mannis MJ. Boston Type I Keratoprosthesis: The University of California Davis Experience. Cornea 2009; 28:321-327.

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Chew HF, Ayres BD, Hammersmith KM, Rapuano CJ, Laibson PR, Myers JS, Jin YP, Cohen EJ: Boston Keratoprosthesis Outcomes and Complications. Cornea 2009; (28):989-996.

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Dohlman CH, Grosskreutz CL, Chen TC, Pasquale LR, Rubin PAD, Kim EC, Durand M. Shunt to divert aqueous humor to distant epithelialized cavities after Keratoprosthesis surgery. Risk of Infection. Glaucoma 2010; 19(2):111-115.

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Harissi-Dagher M, Khan BF, Dohlman CH. The Boston Keratoprosthesis. <u>In</u>: Corneal transplantation. Rasik B Vajpayee, editor, Namrata Sharma, Geoffrey C Tabin, and Hugh R Taylor, co-editors. Vajaypee Brothers Medical Publishers. New Delhi, 2010.

Dunlap K, Chak G, Aquavella JV, Myrowitz E, Akpek E. Short-Term Visual Outcomes of Boston Type 1 Keratoprosthesis Implantation. Ophthalmology 2010; 117(4):687-692.

Ament JD, Todani A, Pineda II R, Shen TT, Aldave AJ, Dohlman CH, Chodosh J. Global corneal blindness and the Boston Keratoprosthesis Type I (Editorial) Am J Ophthalmol 2010; 149(4):537-539.

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Garrick C, Aquavella JV. A Safe Nd: YAG Retroprosthetic Membrane Removal Technique for Keratoprosthesis. Cornea 2010;29(10):1169-1172.

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Dohlman CH, Cade F, Pfister R. Chemical Burns to the Eye: Paradigm shifts in treatment. Editorial. Cornea, in press.

Pineles SL, Ela-Dalman N, Rosenbaum AL, Aldave AJ, Velez FG. Binocular Visual Function in Patients With Boston Type I Keratoprosthesis. Cornea, in press.

Beyer J, Todani A, Dohlman CH. Visually debilitating deposits on soft contact lenses in Boston Keratoprosthesis patients. Submitted to Cornea.

Cade F, Grosskreutz CL, Tauber A, Dohlman CH. Outcomes of Boston Keratoprosthesis in chemical burns. Submitted to Cornea.

Posters (ARVO 2010)

Wong JJ, Vajaranant TS, Wilensky JT, de la Cruz J. Glaucoma Implants for the Control of Intraocular Pressure with Type I Boston Keratoprosthesis. Poster # 1138

Rashid S, Kullman G, Lam HY, Colby K. Concurrent Cataract Extraction and Intraocular Lens Placement with the Type I Boston Keratoprosthesis: The K-Pro Triple. Poster # 1139

Rheaume MA, Jardeleza MS, Dohlman CH, Young LH. Risk Factors and Incidence of Retinal Detachment Following Boston Keratoprosthesis: A New Insight into an Old Problem. Poster # 1140

Haddock LJ, Leung E, Berrocal A, Perez V. Posterior Segment Complications of Permanent Keratoprosthesis at the Bascom Palmer Eye Institute. Poster # 1141

Xing D, Chiou C, Mannis M, Keltner J. Visual Fields and Retinal Nerve Fiber Layer Thickness after Boston Keratoprosthesis. Poster #1142

Lobo AM, Chodosh J, Papaliodis GN. Immunosuppressive Therapy with Mycophenolate Mofetil in Patients Receiving the Boston Keratoprosthesis. Poster # 1146

De la Cruz J, Blair MP, Gupta S. Assessment of Cystoid Macular Edema in Aphakic and Pseudophakic Patients with Boston Type I Keratoprosthesis Using Optical Coherence Tomography. Poster # 1147

Behlau I, Mukherjee K, Todani A, Klibanov AM, Gilmore MS, Spurr-Michaud SJ, Tisdale AS, Cade F, Dohlman CH. Covalent Attachment of N,N-Dodecyl, Methyl-Polyethylenimine to Boston Keratoprosthesis Materials Inhibits S. aureus Biofilm Formation without Cytotoxicity or Corneal Cell Reactivity. Poster #1148

Talajic F, Costescu S, Gagne M, Harissi-Dagher M. The Prevalence and Impact of Glaucoma on Visual Rehabilitation Following Boston Keratoprosthesis Type I Surgery. Poster # 1149

Rosenbaum RE, Siddique S, Pujari S, Foster CS. Boston Keratoprosthesis: Diseases, Outcomes and Complications. Poster #1150

Sobti D, Gearinger M, Chung MM, Aquavella JV. Keratoprosthesis and Peters Anomaly: Long-Term Outcome. Poster #1619

Goldman DR, Chiang A, Hu AY, Aldave AJ, Schwartz SD, Hubschman JP. Postoperative Posterior Segment Complications of the Boston Type I Keratoprosthesis. Poster # 2563

Invitation to KPro events - 2010

***** EVER 2010 Congress will be held in Crete, Greece. October. 6-9 at Creta Mario Convention Center.

2010 AAO Meeting in Chicago:

- * Cornea Society: KPro presentations, Friday October 15
- Boston KPro Users Breakfast: 7:00 AM 8:30 AM on Tuesday, October 19, 2010, the Hyatt Regency - McCormick Place, Room CC11. Moderator: James Chodosh, MD, MPH For further information contact <u>mlmoar@verizon.net</u>
- Boston KPro Course entitled, "The Boston Keratoprosthesis: Optimizing Outcomes". 10:15 AM – 12:30 PM on Tuesday, October 19, 2010, McCormick Place, Room N427D. Moderator: Anthony Aldave, MD.
- Breakfast with the Experts: Moderator: Peter Zloty, MD 7:30 AM 8:30 AM on Tuesday, October 19, 2010, McCormick Place, Room: Hall A





From Hand Movement to 20/30 vision (2.5 years postop)

Boston Keratoprosthesis E-Newsletter

Please let us know if you would like to receive the e-mail version of the newsletter or if your mailing address has changed.

E-mail your contact information to: <u>larisa_gelfand@meei.harvard.edu</u> or send via fax: (617) 573-4369 or (617) 573-4324

Name:	 	
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Phone number:	 	
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