A Revolutionary Technology

Dr. Dohlman’s most notable achievement is the Boston Keratoprosthesis (KPro), a collar button design keratoprosthesis composed of a front plate with a stem, which houses the optical portion of the device, and a back plate with a slit. Available in Type I and Type II designs, the KPro Type II model is reserved for severe end stage dry eye conditions and is similar to the Type I except it has a 2 mm anterior nub designed to penetrate through a limbal incision.

A Promising Option for Many

The Boston KPro is now the treatment of choice for a growing list of corneal conditions, and the procedure of choice where corneal transplantation is expected to fail. When managed in experienced KPro centers, the prosthesis also is a life-changing intervention in patients who have suffered severe chemical injuries and blinding autoimmune disorders.

KPro Around the Globe

Despite millions of people requiring corneal transplants, there is a widespread lack of eyebanks and suitable donor tissues, especially in developing countries. KPro team members, especially Chodosh, MD, MPH and Roberto Pineda II, MD are working to make the KPro available to some of the world’s poorest areas. Pineda has helped to establish self-sustaining KPro clinics in developing countries, including India, Thailand, Sudan and Ethiopia, while Dr. Chodosh is working on developing a low-cost KPro to help bring its sight-saving benefits to these populations.

New Innovations

Current research efforts led by Eleftherios Paschalis, PhD, focus on improving KPro’s aesthetics by coloring the titanium back plate blue or brown. Collagen crosslinking, provided as part of a clinical trial at Mass. Eye and Ear led by Joseph Ciolino, MD, is also helping to strengthen the ocular tissue around the KPro and help maintain the prosthesis better. Furthermore, Dr. Colido and colleagues from Boston Children’s Hospital and Massachusetts Institute of Technology have developed a drug-eluting contact lens, which could improve surgical outcomes for patients with KPro by both protecting the ocular surface and promoting interaction developments of the cornea and anterior eye.

The Boston KPro has required a great collaborative effort among Harvard’s ophthalmic research community and close research partners at MIT. Turning the Boston KPro into a viable, clinical reality for patients has required multi-disciplinary expertise not only in surgery but in biomaterials, bioengineering, optics, inflammation, bacteriology, glaucoma, retinal detachment, plastics and contact lenses. – Claes Dohlman, MD, PhD

Inside:

• Post-operative Guidelines
• Managing Complications
• New Innovations

Boston Keratoprosthesis

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– Claes Dohlman, MD, PhD

American Academy of Ophthalmology Annual Meeting November 2015 Las Vegas, Nevada

• Boston KPro Users Breakfast
• Glaucoma Management in Patients with Boston Keratoprosthesis
• AAO KPro Course: The Boston KPro: The Essentials for Beginning and Experienced Surgeons

Dear Colleagues,

Nearly five million people in the world are blind from corneal disease or trauma, and millions more have corneal blindness in one eye. For some people, conventional corneal transplantation is a successful and life-changing intervention. Many others, however, suffer multiple transplant failures or have corneal conditions that make them poor candidates for traditional transplant.

Conceived at Mass. Eye and Ear in the 1980s by Class H. Dohlman, MD, PhD, the Boston Keratoprosthesis (KPro) has revolutionized the field of corneal transplantation over the last two decades. Since achieving FDA status in 1992, the Boston KPro has undergone continuous design innovations that have significantly improved the safety and long-term success of the implant. Today, the Boston KPro is the most commonly used corneal prosthesis in the world with more than 11,000 implantations to date in 66 countries by 598 surgeons. In 2014, KPro received European Conformity (CE) mark approval, making the device reimbursable across the European market and, thus, accessible to many more people.

This issue of Eye Insights™ offers treatment guidelines and recommendations from our KPro experts for maximizing the safety and effectiveness of the device, particularly for patients who suffer from glaucoma, autoimmune disorders, and post-operative infections. We hope you’ll find this information useful in your clinical practice. For more information on KPro and learn, please visit MassEyeAndEar.org. We also invite you to join us in Boston on October 16-17, 2015 for the Harvard Medical School Department of Ophthalmology’s 29th Biennial Cornea Conference. Hope to see you there!

Joan W. Miller, MD
Massachusetts Eye and Ear

UPCOMING EVENTS:

29th Biennial Cornea Conference October 16-17, 2015 | Boston, MA

Harvard Medical School Department of Ophthalmology Cornea Center of Excellence

American Academy of Ophthalmology Annual Meeting November 2015 Las Vegas, Nevada

• Boston KPro Users Breakfast
• Glaucoma Management in Patients with Boston Keratoprosthesis
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Related Reading

### Prophylactic Antibiotic Regimen

Daily antibiotics are recommended for life and regimens are subject to regional availability, cost and bacterial resistance. Option 1 is preferred at Mass. Eye and Ear.

#### Prophylactic Antibiotic Regimen

<table>
<thead>
<tr>
<th>Option</th>
<th>Antibiotic Regimen</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option 1</td>
<td>Polymyxin B / Trimethoprim (Polytrim™)</td>
<td>1-2 x/day</td>
</tr>
<tr>
<td>Option 2</td>
<td>Fluoroquinolone (4th generation)</td>
<td>1 x/day</td>
</tr>
<tr>
<td>Option 3</td>
<td>Fluoroquinolone (4th generation)</td>
<td>1 x/day</td>
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**Autoimmune or Monocular Patients**

Option 1: Polymyxin B / Trimethoprim (Polytrim™) 1 x/day

**Soft Contact Lenses**

After KPro implantation, a large, soft contact lens worn as extended wear is preferable. Contact lenses will be available in 30D and any diameter and curve that fits.

#### Troubleshooting Common Contact Lens Problems

- **Intention is a problem; increase diameter of soft contact lens to 15.75mm or soft lens.**
- **Soft contact lens is clear (no deposits), routine replacement is not necessary.** Mass. Eye and Ear recommends changing every 3–6 months in the clinic.
- **Refractive error-expanding deposits build up, requiring frequent replacement of the soft contact lens, switch to a hybrid lens (rigid gas permeable center with soft periphery).**
- **Corneal erosions develop over the tube of a glaucoma shunt and not the plate, increase the diameter of the soft contact lens and Add Vancycin drops on Polytrim alone.**
- **There is a significant mucous associated with the erosion, or if the erosion does not heal in 1-2 months after the soft contact lens change, consider surgical repair.**

### Fungal Prophylaxis

Signs of fungal presence include strawberry shaped deposits on soft contact lenses (colonization, figures A and B) and a white sheen around the stem (keratitis infection, figure C). If fungal infection is suspected, discontinue steroids before treating with anti-fungals. Additionally, the contact lens should be replaced if any signs of fungal colonization or infection occur.

### Autoimmunity

Although a small, but important, group of presumed autoimmune diseases (Stevens–Johnson syndrome, mucous membrane pemphigoid, graft-vs host disease, dermatitis, etc.) have the most favorable outcomes with KPro surgery, these patients also are the most likely to experience failure with standard laser in situ keratomileusis (LASIK) surgery. Hence, these patients have the most to gain from KPro implantation. The degree of prophylactic chronic inflammation can be predictive of postoperative complications.

### Glaucoma and Boston KPro

Ideally managed jointly with a glaucoma specialist, the prevention of glaucoma after Boston KPro surgery should be considered a priority at the time of KPro evaluation and during each postoperative visit.

- **Prior to KPro Surgery: Consider treating patients with glaucoma with eye drops prophylactically. If glaucoma is diagnosed during the operation, irrigating devices have also been used.**
- **After KPro Surgery:** Consider treating with timolol 0.5%. Consider treating with dorzolamide 2% + timolol 0.5% in cases where glaucoma is diagnosed intraoperatively. The tube is recommended to be placed in the pars plana if the patient had a full vitrectomy. The tube can also be placed in the pars plana if the patient had a full vitrectomy. The tube can also be placed in the pars plana if the patient had a full vitrectomy.

### Corticosteroids

To control inflammation after KPro implantation, prednisolone 1% drops 2-4 per day are recommended for the first month are recommended. After the first month, taper for adjustment of the prednisolone.

- **Intracameral Injection**:
  - **Dec 1**: 10 microliters
  - **Dec 2**: 5 microliters
  - **Dec 3**: 2.5 microliters
  - **Dec 4**: 1 microliter
- **Topical Diclofenac**:
  - **Dec 5**: 1 drop

**Autoimmunity**

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**Glucoma**

The diagnosis and follow-up of glaucoma in Boston KPro-implanted patients are complicated because of the difficulty of measuring intracocular pressure accurately with standard tonometers due to the rigidity of the KPro back plate. An alternative is finger palpation of the sclera, though this method can be subjective and only gives an estimate of the pressure.

**Infection**

Microbial keratitis is characterized by infection of the donor corneal graft, typically around the KPro area where uncontrolled infectious organisms can access the inside of the eye. Follow-up is essential to recognize infection before endophthalmitis can develop. Endophthalmitis, usually from Gram-positive bacteria, is almost always consecutive to microbial keratitis. Inflammation should be considered infectious until proven otherwise.

Microbial endophthalmitis can occur without signs of infection, and should be referred to a uveitis specialist if suspected. Treatment includes vitreous biopsy, intravitreal antibiotics, and an antifungal agent, depending on clinical suspicion.