A Review of Contact Lens Fitting for the Boston Keratoprosthesis

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Disclosure Statement:
• Nothing to disclose

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Background

- According to the WHO, there are 285 million visually impaired individuals worldwide, of whom 39 million are blind.
- It is estimated that 10 million is due to corneal blindness, 4th largest cause
- Only 100,000 corneal transplants are performed each year worldwide due to the lack of kidneys, corneas, and due to problems in the field of public health.
- There were 46,196 corneal transplants performed in the U.S. in 2011 (60%)

Corneal transplantation is one of the most commonly performed and successful organ replacements in the world.

- Survival rates
  - 90% at 1 year
  - 60% and 90% at 5–10 years
  - 97% at 5 years for KC
- Many receive a second or even third transplant.
- Survival of subsequent grafts lags behind that of primary transplants.

A large outcome study of repeat corneal allotransplantation showed that approximately 80% of second grafts failed within 5 years after surgery, and essentially all third and subsequent grafts failed within the same period.

Availability of donor tissue is an issue worldwide but not in the U.S.

This shortage, as well as complications of multiple surgeries, motivates the development of artificial corneas.
**Corneal Graft Failure - Causes**

- Stevens-Johnson Syndrome
- Corneal neovascularisation
- Uveitis
- Herpetic simplex keratitis
- Previous failed grafts
- Active inflammation
- Young age
- Additional surgical procedures at the time of PKP
- Large grafts

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**History of Artificial Corneas**

The concept of an artificial cornea is over 200 years old. The first keratoprosthesis was described in 1789 during the French Revolution by Guillaume Pellier de Quengsy. The first reported human KPro surgery with a quartz crystal implant was performed by Nussbaum in 1855. Guillaume Pellier de Quengsy’s brother, also an ophthalmologist, may have actually been the first to perform the surgery in a human.

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**Artificial Corneas - Review**

When host tissue is compromised to the extent that repetition of traditional transplant surgery becomes too challenging, or the primary diagnosis makes for a guarded prognosis, artificial corneas are an option.

**Examples Include:**
- AlphaCor
- Osteo-odonto-keratoprosthesis or OOKP
- Contains dental tissue wrapped with autologous oral mucosal cells.
- Boston KPro Type 1 and Type 2

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**Alpha Cor**
Artificial Corneas- Review

- Developed by Claes Dohlman
- Most common with over 3,500 implanted
- Uses a cross-linked human donor cornea interface
- Overall retention rate of the KPro Type I in the United States reported to be 85% at 6.5 months and 60% at 24 months
- Available in either a single standard pseudophakic plano power or customized aphakic powers (based on axial length)
- Adult (8.5 mm diameter) and pediatric (7.0 mm diameter) sized back plates
- Machined from PMMA by J.G. Machine Co., Woburn, Massachusetts

Boston K Pro Type 1

The type II format is reserved for severe end-stage ocular surface disease desiccation, and is similar to the type I device but requires a permanent tarsorrhaphy to be performed through which a small anterior nub of the type II model protrudes

The goal of the K Pro is to restore an area of clear tissue at the visual axis
Post operative care is prolonged and can be challenging:
- corneal melting
- infection
- glaucoma
- development of retroprosthetic membranes
- tissue necrosis
- leak
- retinal detachments
- epithelial downgrowth
- prosthesis extrusion

**Post Operative Complications**

**Retroprosthetic Membranes**

- Stromal downgrowth was the major element of the retro-prosthetic membranes.
- Metaplastic lens epithelium also contributed to opacification.
- Florid membranous inflammation was not a prominent finding.
- Further advances in prosthetic design and newer antifibroproliferative agents may reduce membrane formations.

**Design Improvements**

- Addition of holes (at present 16 holes) in the back plate allows diffusion of nutritive aqueous to support donor graft stroma and keratocytes.
- Second, in 2004, a titanium locking c-ring was added to prevent intraocular disassembly of the device.
- Third, in 2007, the design was changed from a threaded (screw-type) assembly to a threadless design which simplified assembly and produced less damage to the cornea.
- The most recent advance in design is the implementation of a titanium back plate which likely improves biocompatibility and reduces complications such as retroprosthetic membranes (RPM) and stromal corneal melts.
The Role of Bandage Lenses

Hydrophilic bandage contact lenses worn on an extended wear basis have been advocated as a method to prevent corneal desiccation and subsequent tissue melting.

Successful fitting of lenses in this population can be challenging

• multiple ocular surface issues
• abnormal topography of the eye
• concurrent use of medications

The Role of Bandage Lenses


Initial Examination

❖ Lids & Lashes (MGD, bleph, surgical or traumatic abnormalities)
❖ Conjunctiva (glaucoma drainage interventions (blebs and GDD), scars, symblepharon, scleral thinning, etc.
❖ Shape of the cornea

Select a lens based on the physical exam

❖ Soft are the mainstay of therapy
❖ Lenses are worn on an EW basis, sometimes for many months at a time
❖ In some cases, a soft sihi lens can be used
❖ In our experience, custom CTL yield a better fit
❖ Use of hybrids has been reported (Beyers et al)
❖ We have used RGP for potential acuity

Visante ??
Fitting Considerations - Glaucoma

Nearly half of our patient population had glaucoma prior to implantation of the K Pro.

- Use of a keratoprosthesis is a risk factor for development of glaucoma.
- The presence of GDD and blebs can complicate the fitting of a contact lens.
- If a lens is too tight and impinges on a bleb, or if a lens is too mobile and chafes an anterior or cystic bleb, blebitis can occur.
- If a GDD is implanted at the time of surgery, posterior placement away from the cornea helps to facilitate easier post operative lens fitting.

Fitting Considerations - Air Bubbles

- If the prosthesis graft junction is very steep or irregular, air bubbles can form in the post lens space.
- Air bubble intolerance over host tissue can be difficult to treat if you have a superficial bleb.
- Sometimes changing the diameter can help, larger will maximize surface area.
- Use of a syringe filled with saline can eliminate bubbles in an otherwise well fitting lens.

Fitting Considerations - Oxygen

- Large lenses cover more of the ocular surface, and in many cases, the available larger diameter lenses do not fit well.
- If oxygen transmission is not important for the prosthesis itself, large lenses do cover more of the remaining host tissue.
- Oxygen transmission is important for the host tissue as well as the corneal epithelium.
- It is not uncommon to see significant neovascularization in the host tissue, and it is theoretically possible that extended wear of a low dK lens may increase this risk.
- A larger study comparing rates of neovascularization formation among K Pro patients who are in low versus high dK lenses would help to answer this question.

Fitting Considerations - Lens Deposits

- Many of the patients who receive a Boston Keratoprosthesis have complex ocular histories.
- Most have suboptimal tear film quality, and control of blepharitis, dry eye, and meibomian gland disease is important.
- Poor tear film can predispose to contact lens deposits such as jelly bumps.
- The associated increase in cytokines and other inflammatory mediators could increase the risk of complications or result in an inability to tolerate contact lens wear.
Biofilms may impact drug bioavailability

Nau, Amy; Zambelli, Alison; Brothers, Kimberly; Dhaliwal, Deepinder; Romanowski, Eric; Shanks, Robert M. Diffusion of Antimicrobials Across Silicone Hydrogel Contact Lenses (submitted)

Kimberly M Brothers; Amy C Nau; Eric G Romanowski; Robert Shanks. Dexamethasone diffusion across contact lenses is inhibited by Staphylococcus epidermidis biofilms in vitro. (in press, Cornea)

1. The diffusion of moxifloxacin, PHMB, and amphotericin B through silicone hydrogel contact lenses was measured.
2. Absorbance readings for each drug were taken at 1, 5 10, 30, 60, 120, 240 minutes after the antimicrobial was added to the contact lens and allowed to diffuse.
3. PHMB and moxifloxacin diffusion was detectable at the 30 min time point.
4. Amphotericin B diffusion remained below the limit of detection within the 4 hour experimental period.

Conceptual design of dexamethasone diffusion experiments

- Non-biofilm and biofilm covered lenses were placed on 0.45 μM filters in 6 well dishes.
- Dexamethasone was added to the concave side of the lens.
- PBS below the filter was collected at 18 hours after the antimicrobial was added to the contact lens and allowed to diffuse.
- Dexamethasone diffusion was calculated.

Non-Biofilm

Biofilm (24 h)

In vitro contact lens diffusion model

Results Diffusion Assay

- Using the contact lens diffusion model, the diffusion of moxifloxacin, PHMB, and amphotericin B through silicone hydrogel contact lenses was measured.
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Fitting Considerations- Replacement Schedule

- Practices vary according to how often bandage lenses are changed.
- Certain practices related to poor optical arrangements and problems related to the risk of infection.
- Practices of the contact lens vary in length and in duration and in the setting of contact lenses, we felt it important to evaluate the impact of this on the development of drug delivery systems.
Retrospective review
Cultures

• IRB approval
• Retrospective consecutive case review
  • Oct 1, 2009 to July 1, 2013
  • All patients requiring BCL received
    • Culture of Cornea, Conjunctiva + Lid
    • Blood, Chocolate, Sabourauds, Thioglycolate Broth, Gram Stain
• Data: BCL indication, surgery date, CL insertion date, culture date, antibiotic prophylaxis, steroid use, culture results, effect results had on clinical management
• Analysis - Descriptive + Generalized Estimating Models

Results

• 141 Cultures of 26 patients
  • 38.5% female, 61.5% male
  • Mean cultures/eye = 5 (range 1 - 12)
• Mean Kontour Lens: 42.2% culture positive
• 44.6% at least 1 resistance
• Mean non-Kontour Lens: 88% culture positive
• 50.5% at least 1 resistance
• Chance of + Culture = no significant difference (p < 0.502)
• Chance of any resistances = no significant difference (p < 0.582)

Results - Resistant Organisms

• 23.5% of all cultures grew a resistant organism

Results - Sub-Therapeutic Antibiotics

• Therapeutic Dosing: 86.7% culture positive
• 41.7% at least 1 resistance
• Subtherapeutic Dosing: 82.5% culture positive
• 53.2% at least 1 resistance
• Chance of + subculture = no significant difference (p = 0.449)
• Chance of any resistances = no significant difference (p = 0.382)
• Number of resistances = no significant difference (p = 0.183)

No difference in bio burden or resistance patterns with sub-therapeutic dosing schedule.
Conclusions

- Antibiotic prophylaxis necessary as 84% are culture positive
- Of these, 23.5% grew a resistant organism
- Moxifloxacin more effective (73.7% had 1 or more positive culture) vs. Polytrim (100% had 1 or more positive culture)
- Most common organism: Coag neg Staph

Fitting Considerations - Clare

- Glare disability was a common complaint among several of the patients. None of our patients were fit with disposable color lenses for glare mitigation.
- Use of painted irises on custom lenses would be a good option for these patients. However, these lenses need to be replaced on a frequent basis.

Fitting Considerations - Billing

- Many insurance companies have historically been reluctant to pay for medical lenses.
- Diagnoses should be coded as bandage contact lenses with the appropriate medical codes.
- New bandage lens codes 92070 to 92082 are available.
- For lens supply use 9907.
- Follow up visits billed to medical insurance.

Retrospective Chart Review

Study Aims

Aims: To perform a retrospective chart review of those patients who have undergone artificial corneal implantation with the Boston Keratoprosthesis Type 1.

Study Design

Single-center retrospective chart review of patients who had undergone implantation of the Boston Keratoprosthesis in one or more eyes from January 2006 to 2011 at the UPMC Eye Center.

Inclusion Criteria:

Patients included male and female over the age of 18 who had been fit with bandage contact lenses as part of their postoperative management. We received IRB approval to waive written consent for this study.
Specific Aims

To determine the types of contact lenses that were used for bandage lenses
To determine the number of trial lenses to achieve a successful fit
To determine the failure rate for contact lenses
To ascertain lens related complications
To determine the replacement schedule
To determine post operative visual function

Our hypothesis was that providing an optimal fitting lens with the highest dK material available, coupled with frequent lens replacement and proper antibiotic management would lead to fewer post-operative complications as well as longer retention times of the Boston Keratoprosthesis.

Results- demographics

Twenty two eyes of twenty patients met the criteria for this review.
The age range was 30 to 90 years of age. There were 11 men and 10 females.
72% of eyes had a serious co morbid ocular condition, 31% had glaucoma.
Only three of the patients had a fellow eye with useful vision.
In eighteen patients, the contra-lateral eye had profound low vision ranging from 20/200 to light perception.
The average number of transplants in our population before placement of a Boston Keratoprosthesis was 3.4.

Results- Lens Data

• K's are not really possible.
• Physical examination (oblate/prolate)

Visante
Summary of Lens Types

<table>
<thead>
<tr>
<th>Lens Type</th>
<th>Notes</th>
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<tbody>
<tr>
<td>Kontur 16-22mm</td>
<td>#1</td>
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<tr>
<td>Hard lens/PRS/TPS</td>
<td>#2</td>
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<tr>
<td>Clarity</td>
<td>#3</td>
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<tr>
<td>Hard lens sphere</td>
<td>#4</td>
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<tr>
<td>Soft lenses</td>
<td>#5</td>
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Results - Vision

- Visual acuity prior to surgery in all operated eyes ranged from light perception to 20/200.
- By six months after the surgery, 12 eyes had 20/200 or better, with 7 eyes attaining better than 20/80 best corrected Snellen distance acuity.
- Most patients are still in a low vision situation.

Baseline Visual Acuity

<table>
<thead>
<tr>
<th>BCVA after K Pro (6m)</th>
<th>20/400</th>
<th>20/200</th>
<th>HM</th>
<th>20/200</th>
<th>HM peripherally</th>
<th>20/200</th>
<th>HM CF @2'</th>
<th>HM</th>
<th>CF @2'</th>
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Complications

Given the EW profile, we expected more complications:

1) Two cases of fungal keratitis
2) Lens deposits
3) Antibiotic noncompliance
4) Follow-up noncompliance
5) Refits if initial fit very early

Use of both an antibiotic and an steroid regimen is important.
## UPMC Protocol

<table>
<thead>
<tr>
<th>Time Point</th>
<th>Action</th>
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<tbody>
<tr>
<td>Contact Lens Fitting</td>
<td>1 week - 1 month post op</td>
</tr>
<tr>
<td>Contact Lens Fitting</td>
<td>Contact lens fit (custom trials ordered prn)</td>
</tr>
<tr>
<td>Contact Lens Fitting</td>
<td>Steroid Regimen Invariant 1 drop every day after initial taper</td>
</tr>
<tr>
<td>Contact Lens Fitting</td>
<td>Antibiotic dosing at sub-therapeutic levels with rotation of classes to avoid resistance</td>
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<td>Anterior to identifying and early intervention with corneal transplants is needed</td>
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## Discussion

Our results showed that it is not usually possible to use a standard silicone hydrogel bandage lens on patients with a Boston K Pro:

- There is a high degree of variability in post-operative corneal topography
- Antimicrobial dosing at sub-therapeutic levels with rotation of classes to avoid resistance
- Patients must be prepared to endure long-term and frequent follow-up care
- Counselling of patients regarding the need for postoperative care, including screening of contraindications for the use of contact lenses, is an important part of this preoperative discussion
- Anterior to identifying and early intervention with corneal transplants is needed

## References