Update on Keratoprosthesis

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Disclosures

- I have no financial interests in any of the techniques or products discussed.

Penetrating Keratoplasty

- First successful PK performed in a human by Zirm (1906)
- Advancements in techniques and instruments
- Standard of care for replacing diseased cornea
- Very good success rates overall

Keratoprotheses

- Realization that corneal transplantation never successful in some cases
- First suggested by Guillaume Pellier de Quengsy (1771)
- Rabbit trial by Nussbaum (1853)
- Glass implant in human by Heusser (1855)
- High extrusion rate and success of PK’s diverted interest in early 20th century
Keratoprostheses

- Boston (Dohlman)
- OOKP (Strampelli)
- Biosynthetic corneas
- AlphaCor (Chirila)
- Cardona
- Seoul
- BIOKOP
- SupraDescemetic
- Champagne cork
- Choyce
- Fyodorov
- Hydroxyapatite
- Legeais
- Parel-Lacombe
- Pintucci
- OKP (Temprano)

Boston Keratoprosthesis

- 1965: Developed by Claes Dohlman, MD at MEEI
- 1970: use of fresh corneal graft as carrier
- 1990: significant design changes
- 1992: FDA approval for sale
- 1998: identification of pre-op prognostic categories
- 2003: addition of locking ring
- 2007: threadless stem/back plate
- 2010: titanium back plate

Boston Kpro usage

- PMMA
- Type I: through cornea only
- Type II: through the eyelid
- 2 sizes:
  - aphakic/pseudophakic

Set up

Boston Kpro News, Fall 2011, number 8
Newer set up

New back plates

New back plates

Boston Keratoprosthesis

Courtesy of Claes Dohlman, MD

Boston Kpro News, Fall 2011, Number 8
Boston Keratoprosthesis

Indications for use

- Multiple failed grafts
  - HSV

- LSCD
  - Aniridia
  - Idiopathic
  - Chemical burns
  - Autoimmune

- Pediatric patients

Clinical Outcomes

- Avg f/u 8.5 mo (range 0.03 - 24 mo)
- Pre-op BCVA:
  - <20/200 in 96%
- Post-op BCVA:
  - >20/200 in 57%
- In eyes with > 1 year of follow up, BCVA:
  - >20/200 in 56%
  - >20/40 in 23%
- Graft retention was 95% at 8.5 mo


Clinical Outcomes

- 37 eyes of 37 patients (36 Type I)
  - Mean age 66.3 years
  - Mean follow-up 16 mo (range: 6-28 mo)
  - No intraoperative complications
  - Pre-op avg BCVA: CF
  - Post-op avg BCVA: 20/90 (range LP to 20/25)
    - 84% eyes improved 2 lines or better
    - 8% had worse vision
  - 36 (97%) Kpro’s were retained:
    - 1 Type II in OCP patient extruded and was replaced

Complications

- Post-operative complications:
  - Retroprosthetic membranes: 65%
  - Increased intraocular pressure: 38%
  - Glaucoma progression: 13.5%
  - Endophthalmitis: 11%
    - 3 of 4 d/c post-operative antibiotics


Retention rates

- Multi-center: (141 Kpro in 136 eyes of 133 pts)
  - 95% at 8.5 months
- Wills: (37 eyes of 37 pts)
  - 97% at 16 months
- Jules Stein: (57 Kpros in 50 eyes of 49 pts)
  - 84% at 17 months
- UC Davis: (40 eyes of 35 pts)
  - 80.0% at 33.6 months

Patient G.M.

- 51 yo M s/p chemical burn at age 26
  - s/p PK OU x4
  - Pre-op vision HM OU
- Boston Kpro implantation OS 2/09 at UCSF
  - POD #1: UCVA 20/40
  - POW #1: UCVA 20/30
  - No longer needs help walking.
  - Can read a magazine.
  - Can see his grandkids for the first time.

Patient Y.Z.

- 70 yo W s/p chemical burn to face 37 years ago in China
  - LP OD, NLP OS
  - Extensive symblepharon and obliteration of fornices
- Kpro evaluation
  - Good tears
  - Incomplete eyelid closure
    - Recommended eyelid surgery
  - Kpro in 2010 OD
    - BCVA now 20/50
Boston post-operative regimen: antibiotics

- Standard patient receiving Boston Kpro after multiple graft failures:
  - 4th generation fluoroquinolone 2-4 times daily and tapered over 1-2 months
  - Then once daily polymixin B/trimethoprim for life (broad spectrum with sufficient gram positive coverage, and it is inexpensive)

- Autoimmune patients, chemical burns, and only eyes:
  - Vancomycin (14 mg/ml with 0.005% BAK) once daily plus a fluoroquinolone 2-4 times daily and tapered to once or twice daily (for both) for life.
  - Fluoroquinolone can be replaced by polymixin B/trimethoprim for life

Boston post-operative regimen: steroids

- Prednisolone acetate 1% starting at four times daily, gradually tapered to once daily after 2-3 months, and then eventually stopped
- Caution in autoimmune diseases as long-term steroids can contribute to tissue melt
Boston post-operative regimen: antifungals

- Not routinely given in Boston
- In hot, humid areas, brief periodic bursts of antifungals may be necessary:
  - Amphotericin B 0.15% twice daily for 1 or 2 weeks every 3 months.

Rate of endophthalmitis using this regimen

- 2% over 5 years
- Mostly due to non-compliance
- Includes a high rate of autoimmune cases

Intraocular pressure

- Most surgeons place tube shunt at time of Kpro if patient using 1-2 glaucoma drops
- No good way to measure IOP postoperatively
  - Can follow serial optic nerve imaging
- Active area of research

Cost-utility of Boston Kpro

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Cost in $/QALY</th>
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<tbody>
<tr>
<td>Initial cataract surgery</td>
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<tr>
<td>Second eye cataract surgery</td>
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<td>Penetrating keratoplasty</td>
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<td>Boston Keratoprosthesis Type I</td>
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<td>Boston Keratoprosthesis Type II</td>
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<td>PDT for SF CNV 20/40 VA / 20/200 VA</td>
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<td>work for pts with prosthetic joints</td>
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Conclusions

- Improvements in the design of keratoprosthesis as well as post-operative regimens have improved outcomes
- Broad range of indications for keratoprostheses
- Continued research will yield further improvements for the treatment of eyes that are not good candidates for routine corneal transplantation