KERATOPROSTHESIS

Eye Learn

All about the Eye

Dr. Krati Gupta

Dr. Saurabh Deshmukh

www.eyelearn.in

KERATOPROSTHESIS

Keratoprosthesis a) Types b) indication 8+2 J2018

Write a note on " Kerato-prosthesis"? (10) D2011

Definition

Keratoprosthesis is a surgical procedure where a severely damaged or diseased cornea is replaced with an artificial cornea to restore useful vision or to make the eye comfortable in painful keratopathy.

It is usually the last option for the surgeon and the patient who has visual potential in an eye with severely compromised cornea.

Concept

- The basic concept of using an artificial cornea to replace a damaged and opaque cornea is as obvious as placing a window on a house to be able to see out.
- Keratoprosthesis restores sight to an eye with damaged cornea by means of a special tube that acts as a "periscope" from the eye to the outside world.
- The keratoprosthesis extends both inside the eye and outside into the environment.
- The tube passes out of the eye either through the eyelids or between the fused lids.
- The tube is ordered to a specific optical power to help restore the patient's sight, but the patient may have to wear refractive correction for clear vision.
- It provides patients with just a type of tunnel vision.
- The extent of the visual field increases with increasing diameter and decreases with increasing length of the optical cylinder.

Year	Author	Procedure
1789	Pellier de Quengsy	Glass lens in silver ring for leukomatous cornea
1853	Nussbaum	Published the first human trial using quartz crystal implant
1860	Heusser	Inserted a glass plate in the cornea of a 19 year old patient
1898	Dimmer, Salzer	Celluloid plates and egg membranes were used to stabilize glass lenses in the cornea
1930	Verhoeff	Use of Quartz button
1935	Filatov	Implanted penetrating glass device into leucomatous cornea and covered it with a double conjunctival flap
1950	Stone & Herbert, Cardona	PMMA prosthesis designs in rabbits
1963	Strampelli B	Osteo - odonto – keratoprosthesis
1979	Pintucci	Pintucci keratoprosthesis
1998	Chirila	AlphaCor Prosthesis
	Cardona and coworkers	Cardona device
	Singh & worst	Worst 'champagne cork'
1960 FDA-1992	Claes H. Dohlman	Boston Keratoprosthesis Type 1

- All these all Keratoprosthesis failed within weeks or months.
- The interest in keratoprostheses declined following the development of successful penetrating keratoplasty (PKP) in the first decade of the 20th century
- The realization that transplanting a human cornea would not be successful in all cases of corneal blindness
- During the Second World War, the incidental discovery of corneal tissue tolerance to plexi-glass fragments from airplane canopies suggested a new direction for future research

As an alternative to PK in certain cases

- Corneal opacification is a leading cause of blindness worldwide effecting 10 million people. Disease or trauma can cause loss of corneal transparency and loss of vision.
- When this process becomes irreversible, it is treated surgically by Penetrating Keratoplasty (PK).
- Major Limitations of PK

i. Depends on availability of healthy human corneas
ii. Requires a technically sophisticated Eye Banking System
iii. Grafted corneal button may itself not remain transparent
iv. It is subject to immunologic rejection
v. Rarely but donor corneal tissue can transmit devastating disease (Hepatitis, Jacob- Creutzfeldt disease)

Indications

Candidates for keratoprosthesis implantation can be classified into three main prognostic groups. In increasing order of success, these groups are:

1. Autoimmune-related corneal opacity and ulceration,
2. Chemical injury, and
3. Corneal allograft failure (non-autoimmune).

General indications for use of individual keratoprosthesis devices

Device type	Corneal allograft failure	Chemical injury	Severe autoimmune disorder
OOKP	−	+	+
AlphaCor	+	−	−
Boston KPro	+	+	+

Indications

Kpro	Indications
OOKP	chemical injury Cicatricial conjunctivitis with corneal blindness in severe mucous membrane pemphigoid
AlphaCor	Corneal allograft rejection, **Contraindicated** in herpes simplex keratitis, autoimmune disorders, and can become opaque with specific combinations of topical medications.
Boston Kpro	Opacity when accompanied by extensive corneal neovascularization making allograft success unlikely. Opacity with limbal stem cell deficiency syndromes including but not limited to aniridia,

Kpro indications-

- A temporary device is used intra-operatively to aid in visualization and is removed following surgery. The examples include Eckardts keratoprosthesis, Landers Foulk and Landers wide field lenses
- Permanent keratoprosthesis are used to treat patients with severe corneal disease where corneal transplantation is inappropriate or has repeatedly failed

Temporary	Permanent
• Severe ocular trauma for anterior and posterior segment reconstruction, • Cataract extraction, • Modified triple procedure, • Vitreoretinal surgery in cases of corneal opacity or ocular trauma • Combined penetrating keratoplasty and vitreoretinal surgery.	• Multiple failed penetrating Keratoplasty/ Amniotic membrane 1. Graft failure in non-inflammatory conditions- corneal edema, dystrophies 2. Graft failure in eyes post-inflammation- Herpes simplex Keratitis, Zoster, Infectious ulcer, Uveitis 3. Chemical injury 4. Ocular cicatricial pemphigoid (stage 3 & 4) 5. Stevens – Johnson syndrome • Trachoma (stage C0 according to WHO) • Vascularized corneas with complete stem cell loss and dryness or stem cell grafting • Bullous keratopathy- cases with stromal scarring, lamellar or full-thickness procedures may be required, while Kpros may be considered after serial graft failures. • Paediatric corneal opacities PK is primary procedure

Prognostic categories with the Boston keratoprosthesis (2009)

Prognostic category	Examples	Long-term outlook
Autoimmune diseases	Stevens-Johnson syndrome Mucous membrane pemphigoid Uveitis, lupus, rheumatoid arthritis, others	Guarded
Chemical/thermal injury	Acid, alkali, other chemical Heat Corneal allograft rejection Aniridia	Fair
Other	Post-traumatic Post-infectious Corneal degenerations Corneal dystrophies	Good

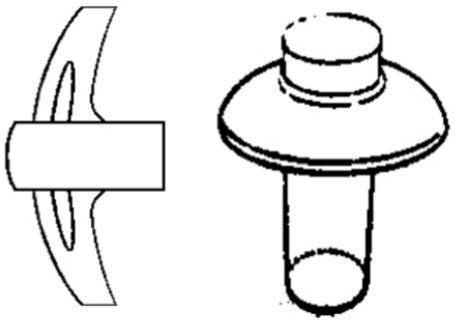
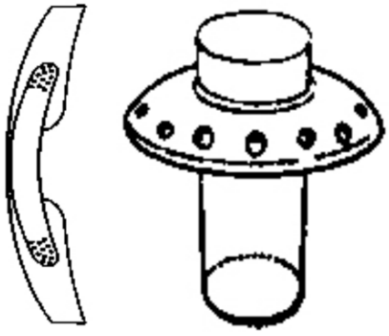
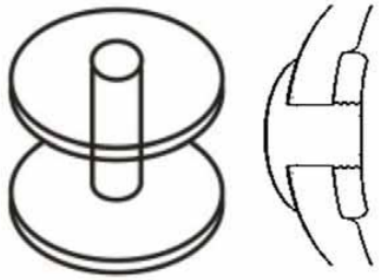
- In general, a KPro is offered to patients with bilaterally poor vision to the degree of hand moments or light perception.
- Only one eye should be offered a KPro, and the second eye should be kept as a spare and must be treated fully for glaucoma and other pathology as appropriate in order to preserve the visual potential.
- Patients having both eyes suitable for KPro must be carefully counselled to choose the eye for KPro implantation.

Types

Designs and Materials - Consists of Optical cylinder and supporting flange.

Non Biointegrated (Optical cylinder materials)	Non Biointegrated (Supporting flange)	Biointegrated Supporting Flange (Autologous tissue)
Polymethyl methacrylate (PMMA) – most commonly used material Glass Ceramic Quartz, Silicon	Methacrylate Teflon Dacron mesh Polycarbon	Tooth and bone (osteo-odonto-keratoprosthesis) Cartilage (chondro-keratoprosthesis) Nail (onycho-keratoprosthesis)

Keratoprosthesis designs have primarily been variations of 3 main types.

First Type	**Second Type**	**Third Type**
PMMA stem with skirt embedded within the cornea	Transparent membrane with porous edges inserted into the cornea	PMMA 'collar button' with cornea between the plates
• It is most commonly used. • The optical core is stabilized by a permanently attached supporting plate or skirt implanted in a pocket created in the collagen lamellae of the corneal stroma. • Consists of central optical cylinder, supporting flange, PMMA stem. • Skirt placed intralamellarly in the stroma (made of perforated grids of PMMA, nylon, Dacron, proplast/ covered by transplanted autologous tissue/ lid skin)	• Consists of transparent plate with a porous periphery, allowing tissue ingrowth into the pores. • Such designs have been made of polytetrafluoroethylene, polyurethane, or modified gels. • By using suitable pore size, these devices have been well colonized with tissue elements which might help to anchor the device and prevent future extrusion.	• Less common type has a collar button shaped device consisting of two plates joined by a stem, which constitutes the optical portion. • This is inserted into the patient's cornea or a donor cornea so that the plates sandwich the corneal tissue between them. • The optical stem is short, allowing a generous field and wide plates stabilize the stem so that it cannot easily deviate from the axis to the macula.
		

PMMA- Advantages and disadvantages

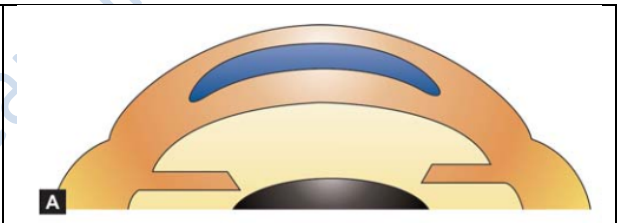
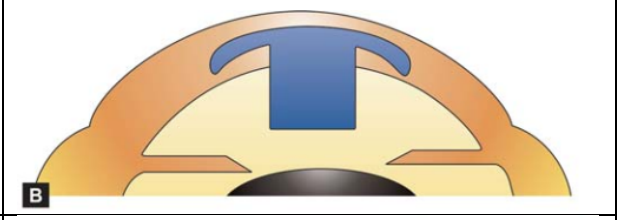
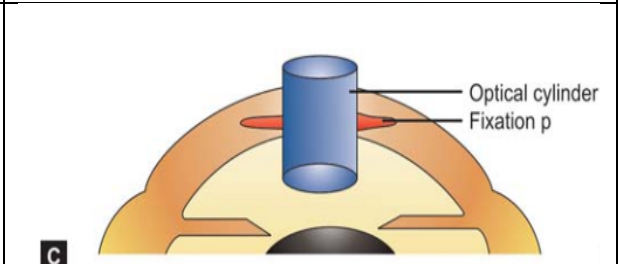
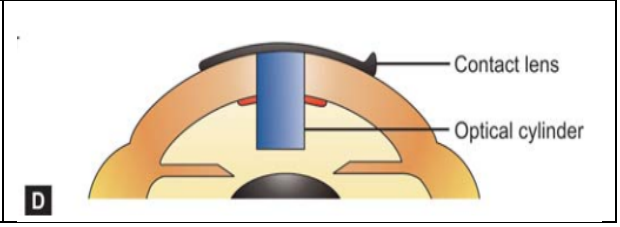
Advantages	**Disadvantages**
1. Excellent transmission of light 2. Completely Transparent 3. Biologically Inert	1. Rigid and Hydrophobic 2. At points of attachment to the stroma, lack of elasticity creates stress that contributes to stromal necrosis and melting

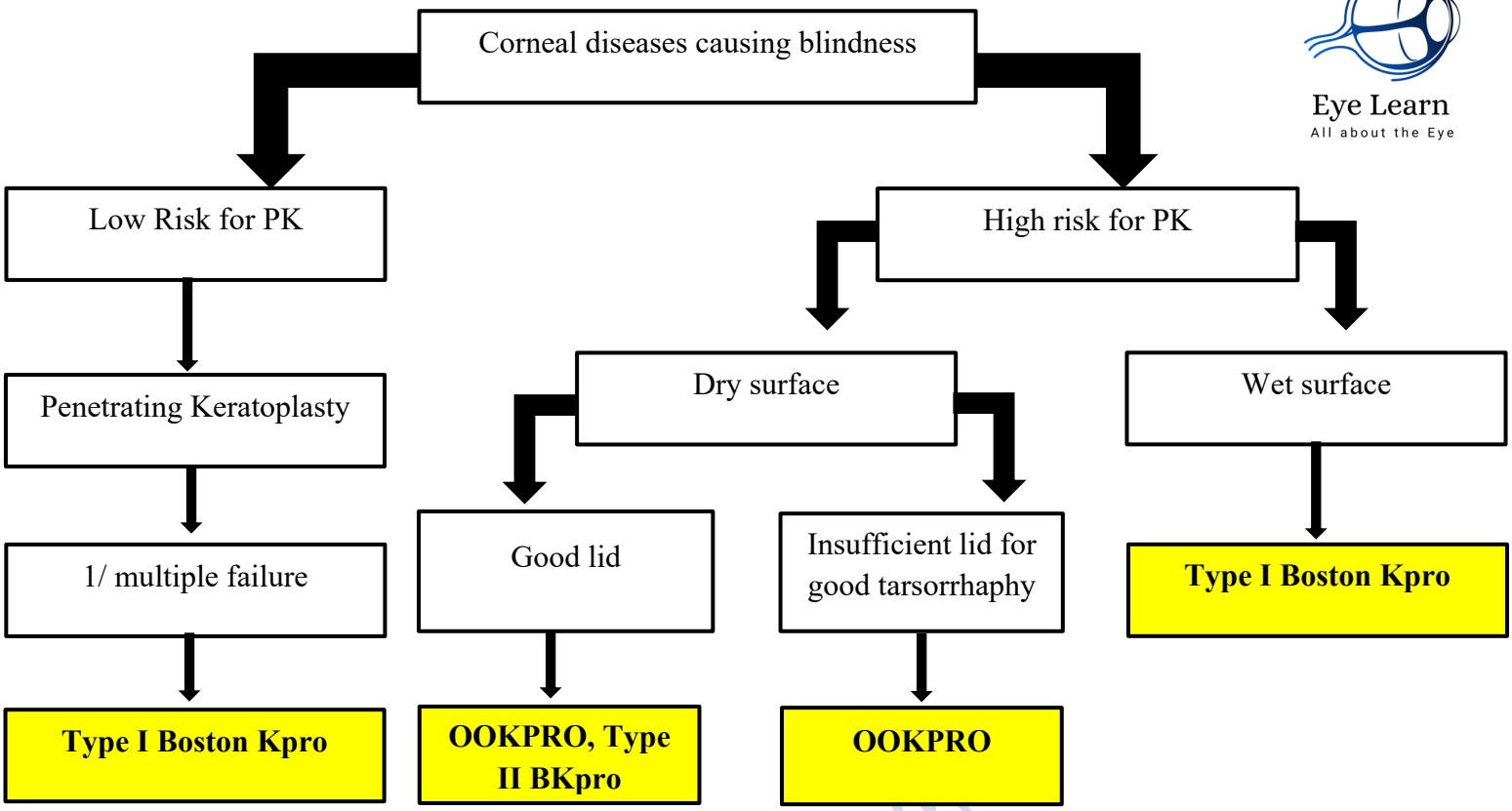
4. Can be shaped to produce High Quality images 5. Retains its shape and clarity with age	3. The elastic mismatch between the rigid plastic and the adjacent flexible tissue prevents formation of a tight interface, creating gaps that allow epithelial down growth and leakage of aqueous humour. 4. Nutrients are unable to diffuse through PMMA, so an optical center of this plastic may not be able to support epithelium on its anterior surface. 5. Cells and fibrous material do attach to the posterior surface, requiring surgical removal to restore vision.

Based on material

PMMA	Choyce, Boston keratoprosthesis
Polycarbonate	Champagne cork keratoprosthesis
Polyurethane	Seoul keratoprosthesis
Hydrogel(PHEMA)	AlphaCor keratoprosthesis
Hydroxy-apatite	Leon-Barraquer keratoprosthesis
Dacron	Pintucci keratoprosthesis

Classification of keratoprosthesis designs

Non-penetrating	Intralamellar	
Penetrating	Anterior Posterior	
Perforating	• Intralamellar • Anterior – Cardona through and through keratoprosthesis – Ceramic keratoprosthesis – Dohlman keratoprosthesis – Type-I: for wet eyes – Type-II: for dry eyes – Osteo-odonto-keratoprosthesis – Boston KPro (I and II) – Champagne-cork keratoprosthesis.	
Perforating	• Posterior – Nut and Bolt keratoprosthesis	



Pre-operative assessment

1. It is essential that the eye to be undergoing keratoprosthesis surgery, be free from initial insult of injury, physical or chemical, active inflammation or infection.
2. Intraocular pressure should be adequately controlled with no evidence of glaucomatous damage to the optic nerve head.
3. A good visual potential must be elicited with the aid of light projection, pupillary responses, ultrasonography of the posterior segment and electrodiagnostic tests.
4. Prior to surgery, a detailed history should be taken to assess the corneal condition and determine if the patient is a good candidate for the keratoprosthesis surgery.
5. Parameters to be noted include visual acuity, accuracy of light projection, intraocular pressure, evaluation of blink and tear mechanism, signs of chronic inflammation, whether the patient is phakic, pseudophakic or aphakic, optic nerve head cupping, ultrasound B-scan and A-scan.
6. Oral cavity assessment for OOKP surgery is essential.

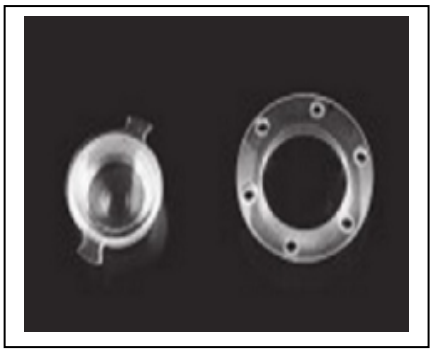
Optical properties

- The KPros are manufactured to match the refractive need of the individual patient according to their lens status. (phakic /aphakic/ pseudophakic).
- For the pseudophakic eye - a single standard power (45 D) is manufactured.
- For aphakic eyes of different axial lengths devices with varying degrees of power are made to match the patient's need as closely as possible.
- Thus, the axial length of the individual aphakic patient is always requested from the surgeon to allow the choice of a KPro that theoretically matches the dioptric requirement of the eye to be operate

A. Temporary Keratoprosthesis

1. Landers Temporary Keratoprosthesis

- Use of temporary keratoprosthesis during PPV was first described by Landers et al. in 1981.
- The first temporary keratoprosthesis was biconcave optical cylinder 5 mm in length made of polymethyl methacrylate (PMMA) and had 7.2 mm in diameter.



- Landers third-generation wide-field temporary keratoprosthesis:
  - Hard plastic PMMA device with a 1 mm cylinder protruding to
  - the anterior chamber.
  - Choice of diameters: 6.2 mm, 7.2 mm, or 8.2 mm.
  - A mushroom-shape corneal surface of a diameter 15.5 mm.
  - 6 suture holes in the periphery
  - Durable and reusable.
  - Can be sutured firmly to the globe
  - Has a convex anterior surface to facilitate viewing to the posterior pole and periphery of the retina

- Trunkless Landers wide-field temporary keratoprosthesis:
  - With no central trunk extending down into the opening in the cornea.

2. Eckardt Temporary Keratoprosthesis:

- Made of silicone.
- Having a diameter of 10 mm of the outer cylinder and a diameter of 7 mm of the inner cylinder.
- 2.8 mm in length.
- Becomes cloudy after reusing as there were no holes for sutures and the silicone became damaged after multiple suture trucks.
- The view into the peripheral retina was limited.

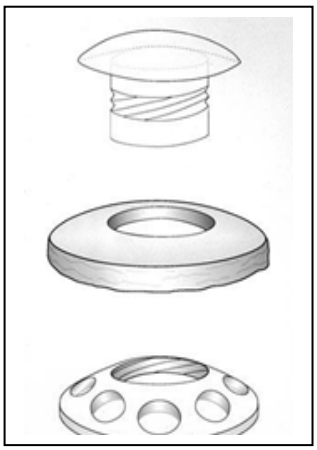
B. Permanent Keratoprosthesis

1. Boston Kpro

- Under development since 1960s, FDA approval 1992.
- Poly methyl methacrylate (PMMA) - a clear plastic with excellent tissue tolerance & optical properties.
- PMMA was introduced in ophthalmology after WWII and was found to be the perfect material for IOL.
- Dr.William Stone in 1947 performed the surgery using PMMA Kpro
- Boston Keratoprosthesis is the innovation and design of Professor Claes H. Dohlman in 1974.
- The Boston Type I Kpro is the most widely used device & is indicated in eyes with reasonable blink and tear production mechanism.
- The Boston Type II Kpro may be indicated in patients with severe ocular surface disease, poor ability to maintain a moist ocular surface, and forniceal foreshortening with inability to wear a contact lens & is reserved for patients with extreme dry eyes, symblepharon, SJS and OCP where there are no fornices to support the device.

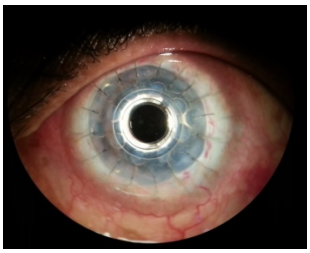
Indication	Advantages	Contraindications
1. Two failed grafts, with poor prognosis for further grafting 2. Vision less than 20/400 in the affected eye 3. Minimum vision of Light Perception 4. Lower than optimal vision in the opposite eye	1. Long-term (many years) stability and safety. 2. It is also known for having excellent optics. 3. Its optical system can provide excellent vision if the rest of the eye is undamaged	1. Unilateral vision loss 2. End-stage glaucoma or uncontrolled glaucoma 3. Posterior segment pathology 4. Presence of a functioning KPro in the fellow eye

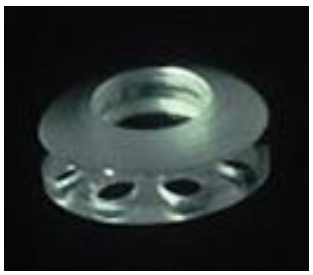
Design



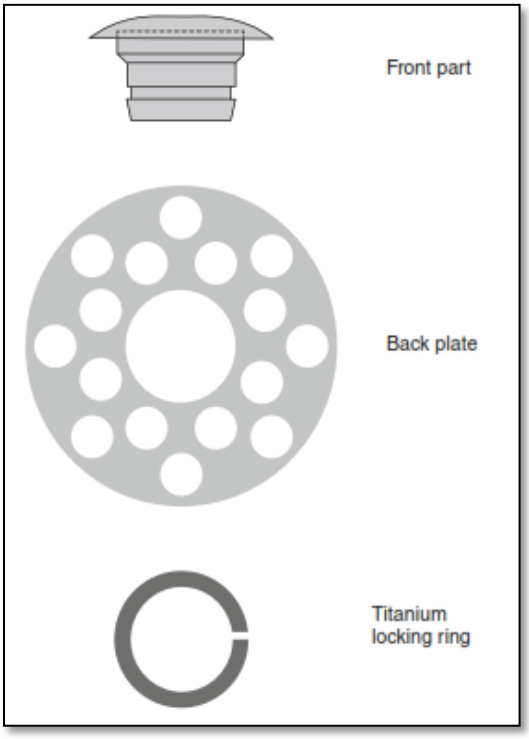
The Boston Keratoprosthesis consists of two plastic parts that clamp a corneal graft. The graft is then sutured into the patient's cornea like a standard graft.

- Collar button design
- There is a front plate and back plate sandwiching a fresh donor corneal graft
- Titanium locking ring is used to secure the front & back plates and corneal complex to prevent any inadvertent unscrewing of the complex.





Type I Kpro

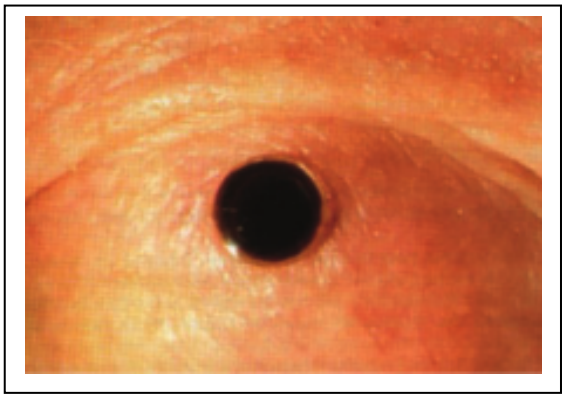


- Diameter(Front plate/optic), 5.0,6.0,7.0mm
- Stem 3 segments & groove (1st next to front plate)
- 1st segment: height 0.62mm, diameter 3.35mm
- 2nd segment: height 0.84mm, diameter 3.0mm
- Groove: Height 0.33mm, Diameter 2.74mm
- 3rd segment: variable height

- Back-plate Diameter-7.0-8.5mm
- Central hole diameter: 3.0mm
- Plate thickness next to hole is 0.8mm & 0.6mm at periphery
- 16 holes of 1.17mm diameter
- Smaller back-plate(children): diameter of 7.0mm with 8 holes of 1.3 mm diameter
- Outer diameter: 3.6mm
- Inner diameter: 2.8 mm
- Thickness:0.23mm

- Its refractive power can be selected based on axial eye length and phakic v/s aphakic status of the patient.
- The back plate has 16 holes to facilitate direct communication with the aqueous for nutrition and hydration of the cornea.
- The donor corneal tissue is placed between the front plate and the back-plate, with the plate being snapped or screwed onto the stem (newer designs are threadless and can be snapped together).
- The whole assembly is locked together with a titanium locking ring.
- The anterior-posterior length of the whole assembly is 3.7mm, allowing or a visual field of 60 degrees.
- The whole assembly can then be sutured to the recipient eye like a typical corneal transplant.
- The typical anterior surface power of this device is 43-44 dioptres.
- Aphakic eyes require a variety of powers depending on the axial length.

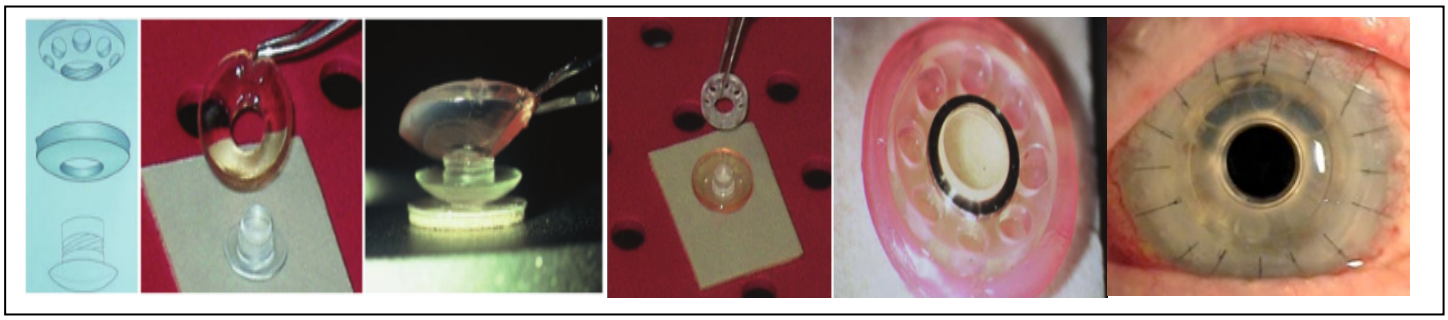
Type II Kpro



- The Boston Type II KPro is similar in design to the Type I.
- It has with an added anterior cylinder that protrudes through a permanently closed upper eyelid, and is used in end-stage dry eye ,Symblepharon, Sequelae of some autoimmune and inflammatory disorders, Stevens-Johnson Syndrome, OCP.
- for patients with severe ocular surface disease where there are no fornices to support the device.
- This design has a 2 mm long anterior nub off the front plate for through the rub penetration.
- Front plate diameter of 6mm
- Posterior plate diameter of 8.5mm with 8 holes
- 4.7mm in length
- 40 degree field of vision
- Back plates holes are important to allow the nutrients to reach the graft keratocytes from the aqueous.

Surgical procedure

- The most current Boston KPro comes packaged with the following components: anterior front part (optic), posterior back plate (small or large size by surgeon choice), titanium locking ring, 3.0-mm dermatologic punch, white plastic hollow pin, double-sided adhesive tape, and a contact lens.
- The Keratoprosthesis Unit (KPro plus donor graft carrier) is typically assembled prior to addressing the patient's cornea.
- It is easiest to assemble the KPro on a separate stable table with adequate lighting.
- While an operating microscope can be used, it is often quicker and easier to use loupes or standard reading glasses.
- The recipient cornea should be marked and donor-sized according to the surgeon's standard protocol.
- The ‘standard’ or large KPro back plate is 8.5 mm in diameter.
- A donor button smaller than 8.5 mm makes suturing the Kpro assembly to the recipient difficult.
- A 9.0-mm donor in an 8.75-mm recipient bed is preferred.
- The donor cornea is placed endothelial side up and a trephine punch is used to punch the donor button, measuring 8.5 mm.
- Next, using the supplied 3.0-mm punch, a central 3.0-mm hole is created in the center of the donor button.
- It is important to ensure that the 3.0-mm opening is well centered; otherwise the donor cornea may not be adequately exposed outside the front plate, making suturing problematic.
- The anterior plate, or optic, is placed face down on the table (the adhesive may be used to stabilize the front plate, but this is optional).
- Viscoelastic, such as Viscoat, should be applied to the front plate's stem, back surface of the optic, and the corneal button's endothelium to increase lubrication.
- The graft is then slid down over the stem. The white hollow pin is then used to gently push the graft into its proper position, apposed to the back surface of the front plate.
- The recipient cornea is then trephined as for conventional PKP (trephine diameter 0.5 mm less than donor trephine size). The donor cornea will be at least 8.5 mm and often larger, necessitating a large recipient bed. (In countries where donor corneas are not readily available, the patient's own cornea can be used as a carrier for the KPro if it is not highly vascularized and lacks any evidence of necrosis.)
- Many surgeons perform a limited pars plana dry vitrectomy prior to opening the eye, but after performing a partial-thickness trephination.
- Hemostasis may be obtained with either cautery or topical fibrinogen.
- In phakic eyes, a lens extraction is always performed and some surgeons choose to place a posterior chamber intraocular lens.
- For pseudophakic eyes, a well-centered posterior chamber lens is typically left in place. Anterior or iris supported lenses should be removed and a deep central core vitrectomy is performed.
- The KPro/donor carrier is then brought into place and secured, typically with 12 or more interrupted nylon sutures (either 10-0 or 9-0).
- At the conclusion of the case, a bandage contact lens is placed
- Surgery usually concludes with the intracameral injection of 0.4 mg dexamethasone.
- Post op steroid E/D ,antibiotic E/D used.
- Post op F/U at 1,2.4 weeks, then monthly.
- Each visit IOP and VA noted and soft contact lens changed.



Superficial keratectomy of 8.5 mm of donor cornea then a 3mm central punch done → The donor button is then placed over the stem of the front plate → Back plate is slid into place on top of this without screwing or turning → A titanium locking ring is then pushed onto the remaining exposed stem until an audible snap is heard

The multicenter Boston Type 1 Keratoprosthesis study (MBTKS)

- 141 type I Boston Kpro surgical procedures from 17 surgical sites from january 2003- september 2005 in 136 eyes of 133 patients
- Mean follow-up of 8.5 months
- retention rate of 95%
- BCVA > 20/40 in 23%
- BCVA > 20/200 in 57%
- Failure for visual acuity to improve from the Boston Keratoprosthesis was attributed to underlying ocular disease such as advanced glaucoma, macular degeneration, or retinal detachment
- The most common complications of keratoprosthesis implantation were retroprosthetic membrane (24.8%), high IOP (14.8%), vitritis (4.9%), and retinal detachment (3.5%).
- Less common complications included necrosis of tissue around the synthetic device and macular edema.
- In a second, single-center study of 40 eyes, the retention rate was 83% at 19 months.

Complications

1. Necrosis of tissue around the Keratoprosthesis (which if unchecked can lead to leak, infection, extrusion)
2. Melt in the wet eye (Type I device)-now a minor problem
3. Skin retraction in the dry eye (Type II device)- still a problem
4. Postoperative Uveitis –can lead to the following:
   - Retroprosthetic Membrane
   - Vitreous Opacities
   - Retinal Detachment
   - Macular Oedema,Epiretinal Membrane,etc
5. Glaucoma – especially in stevens Johnson Syndrome, pemphigoid,chemical burns.
6. Infection – Endophthalmitis –now rare

2. Osteo odonto Kpro (MOOKP)

- The OOKP was first described by Strampelli in 1963
- Later modified (MOOKP) by Falcinelli and coll.
- It uses the patient's own tooth root and surrounding alveolar bone to support a centrally cemented optical cylinder.
- Multi staged procedure, surgery in mouth and eye and requires cross speciality experience.
- There is long term retention of the implant.
- Can uniquely withstand in a dry eye where no other device will work nearly as well.

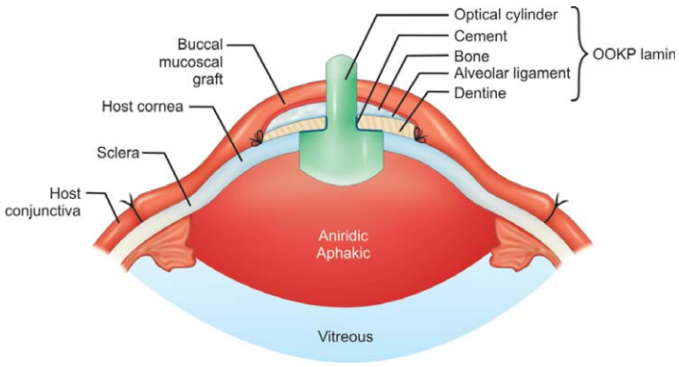
Principle:

- The basic principle of OOKP involves bypassing the ocular surface with a patch of buccal mucous membrane (BMM) and replacement of the anterior segment structures with an osteo-odonto-acrylic lamina.
- Use of wide single rooted tooth with surrounding alveolar bone to fashion a plate as carrier for PMMA optical cylinder covered by buccal mucosal membrane, the dentine being separated from the alveolar bone by dentoalveolar ligament.
- This stimulates the environment in the mouth wherein the gingivial mucosa stops proliferating following contact with dentoalveolar ligament decreasing the risk of RPM and extrusion.
- The mucous membrane can withstand dry conditions of the environment and quickly regenerate after restoration of the moisture, and also survive over inflammation to some extent.
- The alveo-dental lamina integrates well with the ocular tissues and can retain for a number of decades in successful cases.

Indications- B/L blindness in case of

Indications- B/L blindness in case of

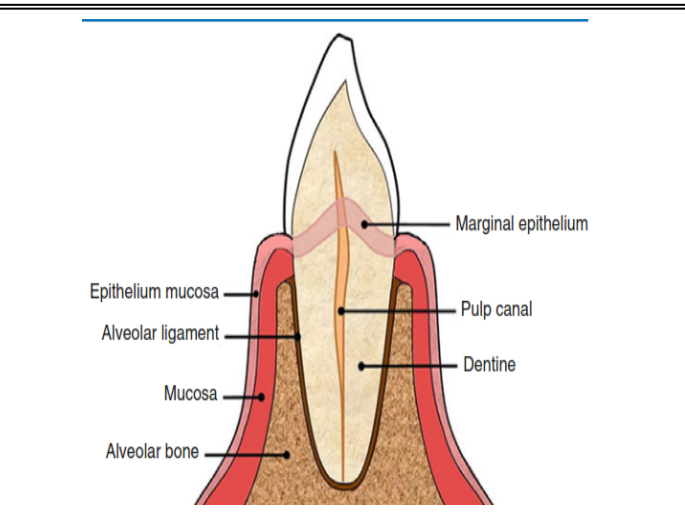
1. SJS
2. OCP stage 3 or 4
3. Lycell syndrome
4. Acquired epidermolysis bullosa
5. Trachoma (stage 0 as per WHO)
6. Chemical injury
7. Physical injury
8. Loss of lids(Crouzon disease)
9. Vascularized cornea with complete stem cell loss and dryness due to other causes
10. Aniridia with severe corneal changes
11. Multiple failed PK
12. Corneal failure after vitrectomy with silicone oil filling that cannot be removed safely



Contraindication-

1. Edentulous patient
2. NPL
3. <17 yr
4. Oral hygiene is poor
5. mucosal disease is present
6. In the presence of other dental problems
7. Posterior segment pathology-RD
8. Mentally unstable patient.
9. Unavailability for long follow-up
10. Unrealistic visual and cosmetic expectations

Absolute



- For edentulous patients and patients <17 years- dental allograft with immunosuppressive, high incidence of lamina resorption.

Design

- Central PMMA optic surrounded by a skirt that comprises an annular wafer taken from an autologous tooth.
- Prior to implantation in the eye, OOKP is pre-implanted into the cheek to allow pre-colonization of the osteodental skirt with autologous fibroblasts.
- It has lower extrusion rates as osteodental skirt provides a conducive initial environment for cell colonization & these cells facilitate G-H integration & therefore stable anchorage of prosthesis.
- Optical cylinder
- Dioptric power of PMMA cylinder is 50-60D in aphakic eye & varies with axial length
- A slight variation in curvature of posterior segment will change D power of cylinder.
- Hence, each cylinder is based on the axial length of the eye.
- Length of anterior part-5.75-6.00mm, posterior part-2.25-2.50mm.
- Total length is 8.25mm

Pre-operative assessment

- Detailed history- primary diagnosis / previous surgery
- Previous surgical interventions
- PL and normal USG b scan are a pre-requisite.
- An inaccurate projection of rays (PR) is not a contraindication- as severely diseased ocular surface may lead to inaccurate PR.
- Intraocular pressure is usually assessed by digital tonometry
- Electrodiagnostic tests can be done to aid in assessment of visual potential
- Oral assessment includes assessment of oral and dental hygiene and state of buccal mucosa.
- Ideal tooth in size and shape with best surrounding bone is canine(upper/lower)
- Other single rooted tooth can be used in absence of canine.
- Clinical and radiological assessment of the tooth.
- Orthopantomography (OPG), X-ray & Spiral CT scan of canines is carried out for selection of a suitable tooth with the assistance of an oromaxillofacial surgeon.

Surgical Technique

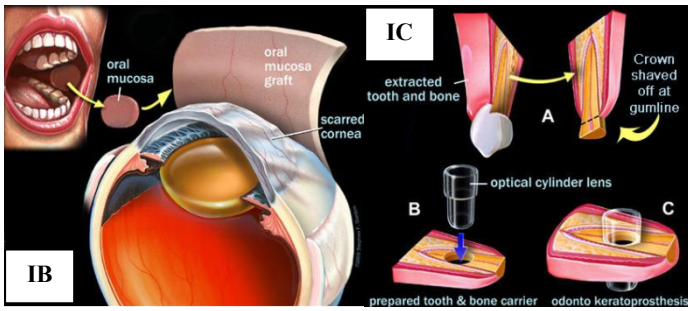
Fornix reconstruction may be needed before initiating keratoprosthesis surgery in some cases.

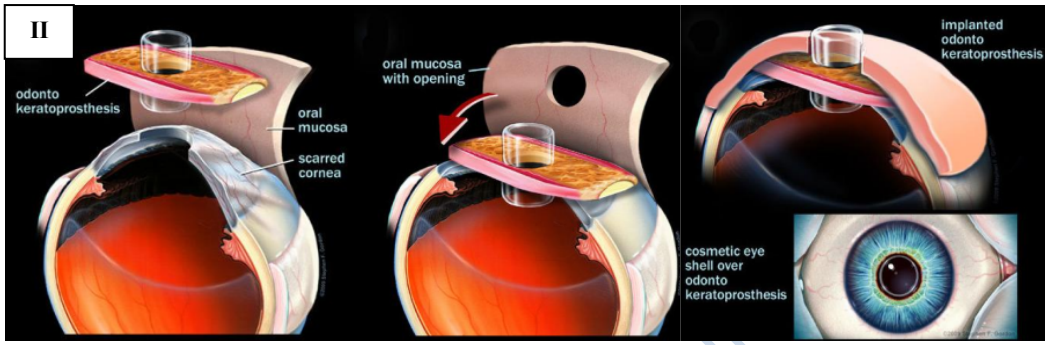
Stage I	A. ICCE+ Ant Vit+ total iridectomy+PK B. Mucous membrane grafting C. Preparation of Osteodentalacrylic lamina (ODAL)
Stage II	Implantation of ODAL over buccal mucosa

Stage 1A	Stage IB
• Superficial keratectomy • Fibrovascular pannus removal • Cryotherapy • Intracapsular cataract extraction • Anterior vitrectomy • Total iridectomy • Complete removal of these structures is done to reduce the possibility of postoperative glaucoma and formation of retroprosthetic membranes. • Tectonic PK if required • Helps in assessment of posterior segment • Deciding visual prognosis	• Done usually 6 weeks after stage IA • Often in combination with IC • Full thickness mucous membrane graft (MMG) harvested from the buccal mucosa. • The extent of MMG should be extend from upper to lower fornix and measures around 3-4 cm in diameter. • Corneal epithelium removed and Bowmenectomy done • The graft is trimmed of excess fat & soaked in cefuroxime solution before suturing. • MMG is sutured over damaged cornea at insertion of 4 recti muscles and sclera In four quadrants with 6.0 vicryl • Buccal mucosa supplies blood to bone • Protects anterior surface of the lamina • Acts as barrier against microbial infections
Stage IC- Involves preparation of ODAL	**Stage II**
• Upper canine is chosen for preparation of lamina. • The tooth with the surrounding alveolar bone is extracted. • Fashioned into lamina with bone on 1 side & dentine on other. • Care to preserve alveolar dental ligament. • Neck is cleared of the gingivial tissue. • Open dental pulp canal & remove all soft tissue. • Crown is cut off • Central hole is drilled,customized PMMA optical cylinder is cemented with acrylic resin.(1mm dentine on either side of cylinder) • ODAL is then placed in the subcutaneous pouch in the orbitozygomatic area for next 3 months to develop vascularization and to promote the growth of connective tissue.	• Spiral CT is performed prior to stage II to r/o resorption of lamina & document its measurements. • This is performed 3 months after stage IB+IC • ODAL is dissected off from the subcutaneous pouch and examined for its integrity prior to proceeding with ocular surgery • Ocular surgery is commenced by reflecting the mucous membrane. • Flieringa ring is sutured in place and the center of the cornea is marked • The central cornea is trephined according to the posterior diameter of the cylinder. • ODAL is placed with the cylinder centered over the corneal trephination and sutured. • Centration is confirmed by disc+ mac on IDO • Altered by placing tension sutures if required. • The MMG is reflected back on the lamina with a central trephination through which the anterior cylinder protrudes out

Tibial Kpro

- For patients without teeth.
- Use of heterologous transplant from tibia.
- Obtained from upper part of medial area of tibia, 10mm in diameter and 3 mm thick disk is taken.
- Optic cylinder is inserted in the centre like OOKP and fixed to the bone.





Failure of OOKP

A major cause for anatomical failure of the OOKP is laminar resorption resulting in

Decreased thickness Defects in the lamina Loosening of the optic cylinder	Aqueous leak Altered refraction Endophthalmitis leading to catastrophic visual loss.

- Clinical detection of laminar resorption can be difficult until late sequelae such as laminar tilt and loosened cylinder have developed.
- Endophthalmitis may be the first clinical manifestation of laminar resorption
- Serial imaging of the lamina and comparison of its dimensions with CT or electron beam tomography can detect resorption early.
- Risk factors for laminar resorption include

Allografts Young age (contraindicated in less than 17 years) Tibial lamina	Persistent inflammation Smoking Use of steroids.

- Patients with these risk factors should be watched more closely.

Complications

Ocular	**Mucous membrane /ODAL**	**Oral**
Glaucoma RPM Vitritis Endophthalmitis Retinal detachment	MMG thinning MMG necrosis Expulsion of cylinder Extrusion of prosthesis	Oro-antral fistula Damage to Parotid duct Damage to adjacent teeth Mandibular fracture

Systemic complications- if patient is on immunosuppressive

Stage I	**Stage II**
Intra-operative- Risk of globe perforation Post-operatively- Lamina and mucous membrane infection lamina resorption	Vitreous hemorrhage Choroidal & retinal detachment Post-operative vision may be limited by a pre-existing condition such as glaucoma/ macular disease. Resorption of lamina, fistula formation & extrusion of optical cylinder

- Trophic changes of the buccal mucosa after stage I/II leading to erosion- can be related to bony spur on optical lamina.
- Treatment- Flap is lifted off and any bone eroded removed with smoothening.
- RPM- rare d/t removal of iris, lens, ant vit.
- If develops & is visually significant- YAG/ PP membranectomy

Buccal mucosal Harvest site

- It is left to granulate, usually it granulates in 2-4 week
- Occasionally there is excess scarring resulting in limitation of mouth opening.
- Treatment- Mouth opening exercises, massage of the scar, incision of the scar bands

Alveolar graft harvest site

- Due to poor healing at the site resulting in exposure of the roots of the adjacent teeth.
- Maxillary sinus involvement.
- Prevention- Dental damage can be avoided by using fine blades & careful technique.
- Damage to maxillary sinus can be prevented by not making the apical cut too high but if the root is very close to the sinus, this complication is unavoidable.
- Treatment- If the dental damage has occurred the patient should be asked to keep a careful watch so as to initiate a prompt treatment.
- Maxillary sinus breach can be closed by advancement of the surrounding mucosa.
- Oroantral fistula- obturator will be needed to prevent nasal reflux until formal closure.

Oculoplastic complications in OOKP

- Forniceal & tarsal conjunctival cicatrization a/w ocular surface inflammation and primary disease.
- Patient may have shallow fornices ,UL/LL entropion,wide palpebral fissure
- Cicatricial entropion is corrected by lamellar division through grey line incision.
- Permanent lateral tarsorrhaphy, medial canthoplasty, lateral canthal sling and upper retractor recession using anterior and posterior approach to reduce palpebral fissure.
- In case of BMM thinning, ulceration +/necrosis – exclude/ treat underlying infection.
- Taking swabs from graft should be performed on routine basis.
- After successful treatment of infection, mucosoplasty should be performed by mobilization of thick buccal mucosal tissue from the periphery to the centre using bipedicled / transposition flaps followed by regrafting the peripheral donor site with fresh tissue.
- Failing that a new MMG can be used.

- If none works- anterior lamella of the upper lid can be undermined and pulled over the optical cylinder to de-epithelize the MMG, allowing posterior lamella to fall back.
- Opening can be made in the anterior lamella for the cylinder to protrude.
- A cosmetic shell with custom made hole to fit into the optical cylinder,

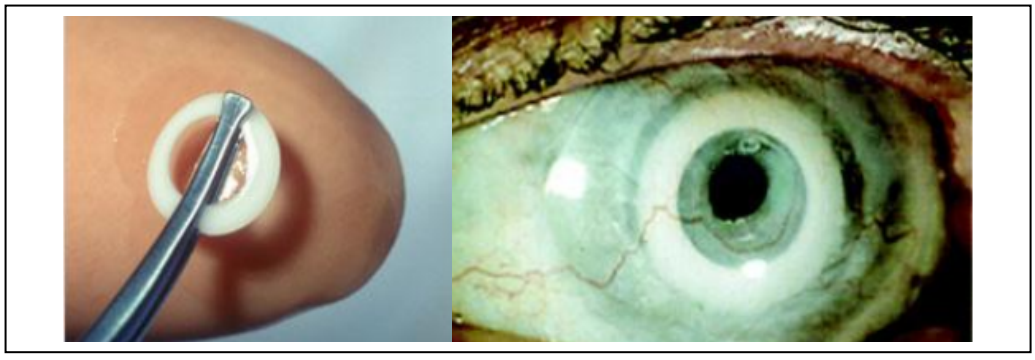
3. Chirila (AlphaCor) Prosthesis

- The AlphaCor was developed at the Lions Eye Institute in Western Australia, first being implanted in human eyes in 1998.
- It is the newest keratoprosthetic device.
- It was FDA-approved in August 2002 for patients at high risk for donor penetrating keratoplasty (PKP).

Design

- The implant is a 7-mm diameter, one-piece, non-rigid synthetic cornea.
- It is composed of an outer skirt that is an opaque, porous, made of single biocompatible high-water content PHEMA (poly-2-hydroxyethyl methacrylate) sponge that encourages bio-integration with host tissue & a transparent central clear optic core made from low water content PHEMA with refractive power in situ similar to human cornea.
- 2 zones, a clear central optical core and an opaque spongy skirt, made by polymerizing the pHEMA under conditions of differing water content.
- It has an interpenetrating polymer network which is a junction between the skirt & central optic and serves as a permanent bond.
- It is available separately for aphakic eyes (AlphaCor-ATM) and phakic/ pseudophakic eyes (AlphaCor-PTM)
- The posterior surface of the optic is in direct communication with the anterior chamber and the anterior surface of the optic is covered with the anterior corneal lamella and conjunctival flap, with the skirt being within the lamellar pocket.

Principle- The ability of the outer skirt to be colonized by invading keratocytes resulting in integration of the device with surrounding tissues.



Indications/ inclusion criteria

- Stevens-Johnson syndrome, severe inflammation and in severe dry eyes.
- Adequate tear production assessed by unstimulated Schirmer test with a value of at least 50% of normal
- VA from <6/60 to light perception
- Previous failed grafts with a poor chance with further PKP
- Functioning retina
- Absence of advanced glaucomatous optic neuropathy
- Well-controlled glaucoma on treatment.

Contraindicated - in herpes simplex keratitis

Advantage- It does not need a donor cornea as in Boston Kpro however it is less commonly used.

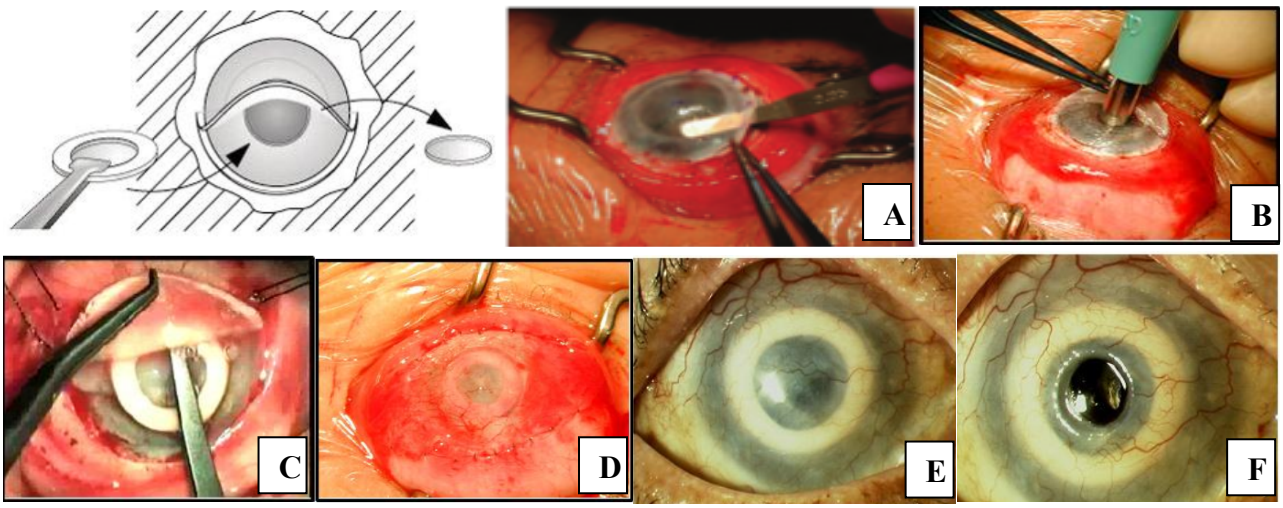
Surgical Procedure-

In Stage I

1. 360° conjunctival peritomy
2. Debridement of the corneal epithelium
3. A corneal incision is made and dissection instruments are used to continue the corneal dissection throughout the circumference of the corneal graft, thereby creating an intralamellar pocket
4. Superior half of the cornea is dissected into two layers, superficial and deep, each of about 50% thickness, through a superior paralimbal 180° incision extended to form a pocket in the inferior cornea
5. Superficial corneal flap is then reflected inferiorly to expose the deep cornea, to allow trephination of the central posterior lamella with a 3.5 mm disposable intrastromal trephine to enter the anterior chamber
6. An intrastromal trephine is used to remove the central posterior corneal lamellae for insertion of the device
7. An AlphaCor sizer, used to test the size and centration.
8. The AlphaCor is placed between the two layers within the intralamellar pocket, centred over the posterior lamellar opening
9. The superficial flap is then replaced and sutured at the limbus with interrupted 10/0 nylon.
10. After insertion of device & closure of the limbal incision, surface is covered with a Gundersen conjunctival flap
11. If the Gundersen flap is inadequate to cover the cornea an amniotic membrane graft may be required.
12. In cases with healthy ocular surface, Gunderson flap may not be required, High O_2 permeability CL (high Dk/t) may be used.
13. Subconjunctival injection of antibiotic and steroid are given in immediate posr operative period.

In Stage II

1. Performed approximately 2 months after Stage I
2. The overlying conjunctiva created by the Gundersen flap is removed.
3. Tissues superficial to the AlphaCor optic (anterior corneal lamella) are removed to expose the optical zone.Trephination of the central 4mm of the conjunctival flap and anterior corneal lamellae.



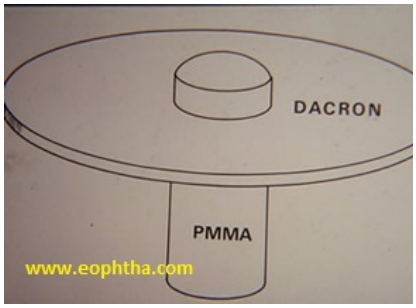
A. Corneal dissection with creation of intralamellar pocket.

B. Trephination of the central posterior lamella with a 3.5 mm disposable intrastromal trephine
C. The AlphaCor is placed between the two layers within the intralamellar pocket.
D. Closure of the limbal incision & covered with a Gundersen conjunctival flap
E. AlphaCor post op after stage I
F. AlphaCor post op after stage II

Complications

1. Corneal Melt
2. Retroprosthetic Membranes

3. Pintucci Keratoprosthesis



- It was introduced by Pintucci in 1979 with Dacron tissue as the supporting
- element with the aim of significantly reducing the complication rate.
- useful modality of treatment for bilaterally corneal blind Asian patients.

Indications

- The Pintucci KP can be implanted in thinned or perforated corneas,
- In corneas with stromal melting
- In eyes that have undergone several procedures including penetrating keratoplasty, other KP implantations, and glaucoma, cataract and vitreoretinal surgery

Design

- The supporting element of the Pintucci KP is made of a biointegrated Dacron fabric skirt that allows 3 dimensional colonization by newly formed vascularized connective tissue.
- The Dacron mesh is fixed to a medical grade PMMA optical cylinder (5.5 mm long and 3.5 mm wide).
- The spaces between the filaments allow biological colonization of surrounding tissue
- The main characteristics of Dacron tissue are
  - Softness and pliability, thus preventing aseptic corneal necrosis by mechanical stress;
  - It is chemically inert, and therefore not subject to reabsorption;
  - It can be autoclaved.
  - Is easily cut into the desired shape; and it can be sutured.
  - In this way the colonized dacron tissue plays a trophic and a mechanical role.
  - When healed, it becomes fully integrated with the surrounding tissues both biologically and mechanically, acts as a barrier to microbial contamination.

Surgery

1. Before surgery, examination of the conjunctiva and lids is very important because reconstructive plastic surgery is often necessary prior to the main surgery, as in cases of trichiasis, lagophthalmos.
2. The surgical technique to implant a Pintucci keratoprosthesis consists of two stages.
3. In the first stage, the central part of the cornea is marked with gentian violet.
4. General anesthesia with nasal intubation is preferred.
5. The keratoprosthesis is introduced upside down with the optical cylinder vertical in the inferior orbito-palpebral sulcus pocket.
6. The orbicular muscle is sutured with 8.0 Dexon and the skin with 6.0 black silk.

7. In severe dry eye, the lacrimal puncta are closed with diathermy.
8. A free labial mucosa graft is dissected and sutured on the cornea.
9. Antibiotic ointment is instilled and lids closed. The second stage is performed after about two months.
10. The colonized keratoprosthesis is removed from the lower lid and the cornea is partly exposed by dissecting the oral mucous graft.
11. The cornea is trephined with a Franceschetti trephine.
12. The optical cylinder is placed and the colonized Dacron tissue is sutured.
13. During follow-up, the dacron tissue must be examined carefully for erosion through the surrounding tissues, loosening, aqueous leaks and infection.

The most common **complication**, especially in extremely dry eyes, is the oral mucous necrosis.

4. Champagne Cork Keratoprosthesis (Singh-Worst Kpro)

- The main characteristic of this device is the fixation of the device to the healthy and stable sclera instead of the diseased cornea.

Indications- It is better suited for vascularized corneas like post SJS, OCP, chemical burns and severe dry eyes.

Design

- It has a polycarbonate structure with a dual fixation principle.
- The anti-conical shape of the KP creates a "valve" on the cornea, ensuring a watertight situation.
- The "equatorial" scleral fixation keeps the valve around the trephined hole.
- The steel suture fixation on the equatorial sclera takes care of preventing extrusion(A&B)
- The structural organization of the device ensures a wider visual field.
- It has been successfully used worldwide as well as in India.

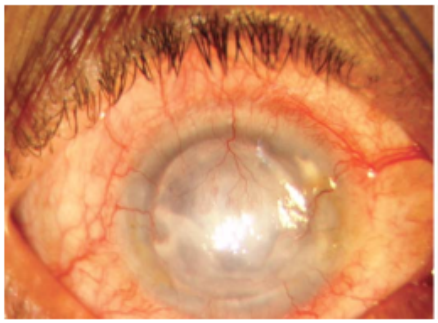
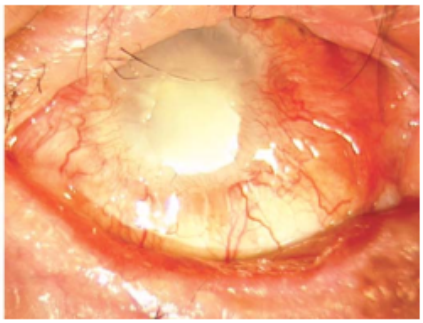


Fig. 6.10.5.15: Severely vascularized cornea



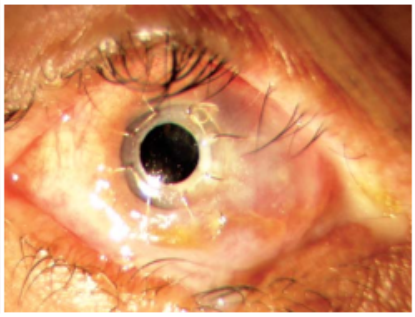
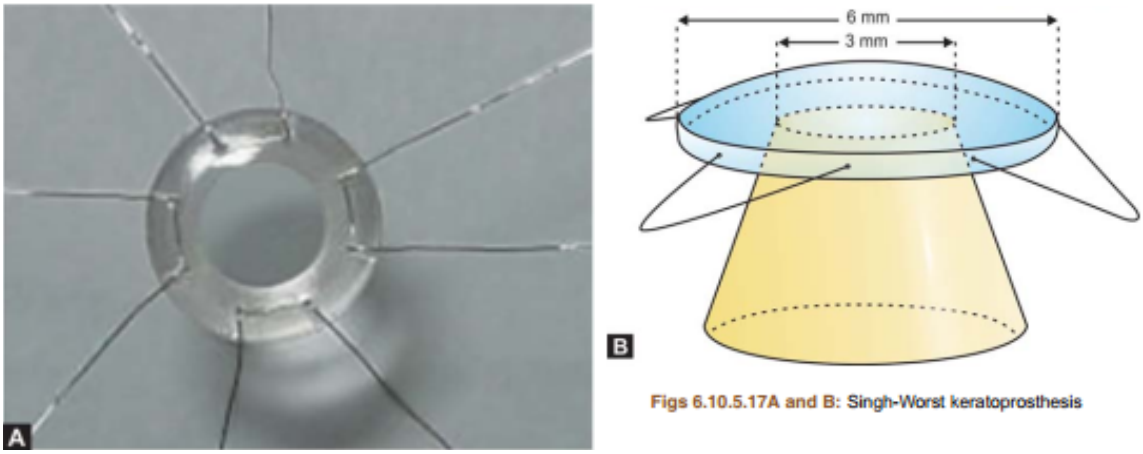


Fig. 6.10.5.16: A case with Singh-Worst keratoprosthesis in situ

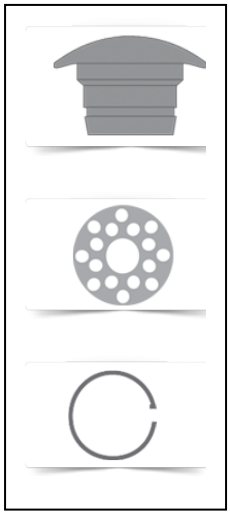


Figs 6.10.5.17A and B: Singh-Worst keratoprosthesis

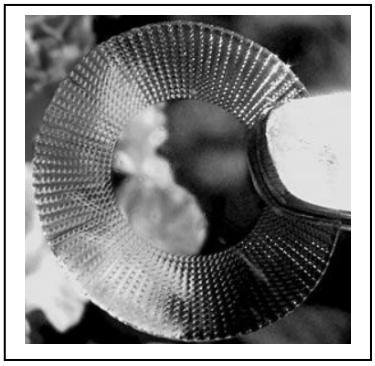
5. Seoul-type Keratoprosthesis (S-KPro)

- This keratoprosthesis consists of an optic portion made of polymethyl methacrylate (PMMA),
- A skirt of polypropylene or polyurethane, and haptics of monofilament-polypropylene (Prolene).
- The main difference between the conventional keratoprosthesis and S-KPro is the method of fixation to the eyeball.
- In the case of S-KPro, the skirt is anchored to the cornea, and the polypropylene haptics are anchored to the sclera to improve stability.

6. Auro Kpro



- Auro K pro design is similar to Boston Keratoprosthesis.
- The KPro is made of clinical grade PMMA.
- It consists of three parts,
  - ➢ The front part (front plate with stem).
  - ➢ The back plate.
  - ➢ The lock ring



7. Stanford Kpro

- Very recent Kpro
- Incorporates the grafting of the bioactive factors with a change in bulk material design was developed by Davis Mayung, Curtis Frank & Christopher Ta at Stanford

Design

- Core & skirt Kpro is based on a mechanically enhanced hydrogel material called Duoptrix.
- It consists of a double network of poly ethylene glycol & polyacrylic acid (PEG/PAA) in its central optic component that supports the growth of epithelial cells.

- Surrounding optic is a micro- perforated rim designed to promote peripheral tissue integration with host eye.
- The design strategy integrates a number of strategies that have been untapped in corneal tissue engineering.
- This class of materials is distinguished from single hydrogel by their high strength despite high levels of water (60-90%).
- The double network combination is particularly advantageous for an optical device due to high strength, transparency & permeability of blend, as well as intrinsic protein resistance & biocompatibility of its components PEG,PAA.
- The team has also used a versatile photochemical surface modification strategy to site-specifically tether cell adhesion-promoting biomolecules to these otherwise non-adhesive hydrogels.
- A further innovation is the application of photolithographic patterning to the fabrication of the device, which provides high level of control over the shape and structure of a hydrogel & potentially over growth & differentiation of cells.
- Longer trials are ongoing. Tolerated well in animal models upto 6 weeks.

8. Newer Kpros

- **Collagen based Kpro**
  - Collagen-based biosynthetic corneas, designed to mimic ECM of corneal stroma have been developed and extensively evaluated in animal models over last 7 years
  - Human recombinant type II(RHC III) was crosslinked with water soluble carbodiimides and fabricated into optically transparent corneal substitues for transplantation.
- **KPro at Filatov Institute, Ukraine**
- **MICOF Kpro**
- **Fyodorov–Zuev KPro**

Ideal Keratoprosthesis

- It should have specific aspheric optic variables
- It should block UV rays
- Allow full visual field
- Optic should be sufficiently rigid to avoid optical aberrations and astigmatism, but sufficiently elastic to allow measurement of IOP.
- Full wound healing (biointergration) should take place at the periphery, allowing defence against introcular infections, epithelial down growth, as well as eye rubbing and minor trauma.
- Artificial materials used should be non toxic and not degraded in lifetime of patient
- Penetration by topical medication should be good.
- Inexpensive
- Posterior surface should be highly polished & non sticky to avoid RPM.
- It should flush with rest of ocular surface to enhace comfort & to reduce mechanical shearing forces on it.
- It should be soft for suture needles to pass through it nut strong enough thet the suture material donot cheesewire.

Postoperative Treatment

All Boston Type I keratoprosthesis surgery patients require postoperative antibiotics, steroids, and, if possible, a bandage contact lens.

1. Antibiotics

- **Intraoperatively**, -1 g of cefazolin intravenously (if not allergic to penicillin/cephalosporins) & subconjunctival antibiotic.
- **Postoperatively**

i. **Oral Antibiotics-** Short course of oral antibiotics may be considered if the risk of infection is high (e.g. immune ocular surface disease or severe keratoconjunctivitis sicca).

- Cephalosporin - 500 mg two to three times daily or
- Fluoroquinolone - moxifloxacin 400 mg once daily for 5 to 7 days.

ii. **Topical Antibiotics**

- Patient is started on a newer-generation fluoroquinolone four times daily. This is maintained indefinitely. Compliance is emphasized on every visit. Eventually, the frequency may be reduced.
- Topical vancomycin in a concentration of 10–25 mg/mL (14 mg/mL +BAK) has been popularized by the Massachusetts Eye and Ear Infirmary.
- This may be prepared by a hospital or compounding pharmacy and maintained for as long as the surgeon deems the eye vulnerable to infection.
- In high-risk cases based on the presenting diagnosis, the nature of the surgery, concomitant disease, or clinical setting, maintaining vancomycin indefinitely is recommended.

iii. Fungal keratitis or fungal colonization BCL suspected

- Amphotericin B 1.5 mg/mL may be used four times daily
- An antifungal may also be used prophylactically in high-risk cases (e.g. severe ocular surface disease).

2. Corticosteroids

- Steroids are injected intravitreally at the end of surgery (400 µg of dexamethasone or 4 mg of triamcinolone).
- Steroid drops (Prednisolone acetate 1%) are used postoperatively four times daily, for the first 4 to 6 weeks, tapered to twice daily and maintained indefinitely.
- Increased inflammation is suspected, such as opacification of the fenestrations in the posterior plate or the development of a retroprosthetic membrane, a series of peribulbar triamcinolone injections (20–40 mg each) may be offered.
- Short course of oral steroids may be considered in cases of sterile vitritis.

3. Glaucoma management

- Postoperatively, IOP is assessed by finger palpation.
- Evaluation of the ONH and performing serial threshold perimetry to rule out any incipient glaucoma.
- If glaucoma suspected, topical antiglaucoma therapy may be started with good penetration.
- Oral carbonic anhydrase inhibitors
- In many instances glaucoma tube-shunt drainage device placement is necessary
- If the patient has poorly controlled glaucoma preoperatively/ is expected to have low-grade chronic inflammation, which usually leads to severe angle compromise- consider placing a tube-shunt in the anterior chamber or vitreous cavity, after performing a vitrectomy, either preoperatively or at the time of keratoprosthesis surgery.

4. Soft contact lens

- Patients undergoing Boston Type I keratoprosthesis surgery should be fitted with BCL over the anterior plate, to be worn around the clock and, ideally, indefinitely.
- The lens decreases the evaporative forces on the ocular surface, and creates a moist chamber around the neck of the keratoprosthesis, maintaining hydration and viability of the carrier donor tissue.
- Careful monitoring of persisting epithelial defects behind the contact lens is important.
- Management may include frequent lubrication and oral doxycycline.
- The author favors a Kontur lens, 16.0 mm in diameter and 9.8 mm base curve with no power.
- The lens may be replaced on an as-needed basis in the setting of protein build-up on the lens.
- Protein build-up may develop on the anterior plate of the keratoprosthesis itself.
- This may be wiped off at the slit lamp with a moist cellulose sponge.
- Spherical power refractive error may be built into the lens.
- If Lens fits loosely, leading to easy dislocation, consideration may be given to fitting the patient with a larger and tighter Kontur lens (available in 18 mm diameter and 8.3 base curve).
- Other bandage contact lenses with similar properties may be considered as well.
- In certain instances, there may be a role for a hybrid lens (e.g. Synergeyes).
- Finally, if the bandage contact lens cannot be maintained over the ocular surface under any circumstance, closer follow-up is in order, giving consideration to placement of a temporal and, on rare occasion, nasal tarsorrhaphies.

It should be noted that the postoperative management of the AlphaCor™ artificial cornea is very similar to that of the Boston Type I keratoprosthesis with two notable differences:

1. There is no role for a bandage contact lens over the AlphaCor™ device.
2. AlphaCor™ researchers have documented the usefulness of topical medroxyprogesterone 1% suspension postoperatively. Its anti-collagenase properties may decrease the incidence of melt/extrusion.

Osteo-odonto-keratoprosthesis

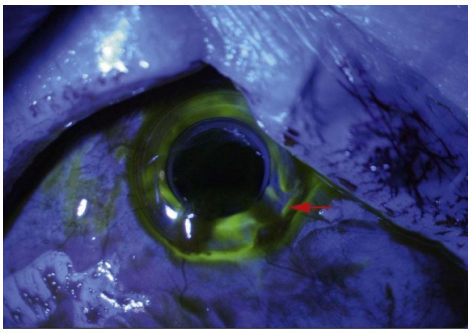
If and when it is successfully performed, there is very little postoperative care required other than a short course of systemic antibiotics, systemic steroids for the management of chronic or recurrent inflammation, and oral carbonic anhydrase inhibitors, as needed, for intraocular pressure control.

Postoperative Patient Evaluation

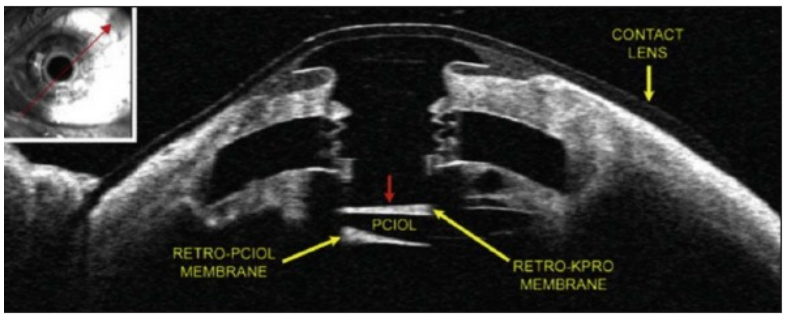
1. **Follow-up**: evaluated on the first postoperative day, a week later, 2 to 3 weeks after that, and then on a monthly basis for the first few months before dropping to quarterly follow-up indefinitely.
2. Each examination should include measurement of **visual acuity**.
3. **Assessing intraocular pressure** either with palpation of the globe through the lid, or visual inspection of scleral indentation of the globe at the limbus in response to application of digital pressure through the lid or a cotton-tipped applicator at the limbus. Pneumotonometry may have a role but applanation and electronic tonometry are not usually useful.
4. **Slit lamp biomicroscopy** is employed to evaluate the position of the bandage contact lens, any protein deposits on the contact lens or keratoprosthesis front plate, the anterior and posterior plates of the keratoprosthesis, and any details of the anterior segment that are visible, including the iris, the intraocular lens implant, and the posterior capsule, when present. Removal of the bandage contact lens

may be undertaken to evaluate the corneal surface surrounding the anterior plate. Any epithelial defects should be documented and followed.

5. In most cases, a cuff of epithelium will grow over the peripheral edge of the anterior plate and maintain a tight seal. The examiner may **look for leaks using fluorescein**.
6. Further along in the postoperative period, early opacification of the fenestrations in the posterior plate usually indicates low- to moderate-grade inflammation that should be approached aggressively with an increase in topical steroids or placement of peribulbar triamcinolone.
7. Document the early development of a **Retroprosthetic membrane** that is more amenable to the YAG laser before it becomes thicker and vascularized.
8. The posterior segment may be evaluated visually with a 90 or 78 diopter lens (ONH+ Macula)
9. 'Small pupil' diagnostic lenses may allow a wider view of the peripheral retina.
10. Monitor appearance of the **optic nerve head**, visually or with imaging (Heidelberg retina tomograph)
11. Periodic **threshold perimetry**, concentrating on the central field and looking for early evidence of glaucomatous field defects. With latest Boston Type I keratoprosthesis design, most patients are capable of a 60° angle of visual field.
12. **B-scan ultrasonography** may be performed whenever peripheral retinal pathology is suspected or there is any evidence of intraocular inflammation that suggests endophthalmitis or sterile vitritis.
13. **UBM & ASOCT** to look for subtle clues that may explain any difficulties encountered in the postoperative period, including the relationship between the iris and the posterior plate, the positions of the tube shunt and intraocular lens implant, the development of retroprosthetic membranes, and the status of the anterior vitreous.



. 152.5 Fluorescein dye showing aqueous leak around neck of keratoprosthesis (*arrow*).



ig. 152.6 Anterior segment optical coherence tomography (OCT) after keratoprosthesis surgery.

Avoidance of Complications

It is common knowledge to all surgeons that the best way to manage complications is not to get them in the first place.

- **Device modifications**

1. The Boston Type I design modifications of late 2002 include separate anterior and posterior plates that are assembled around the carrier corneal tissue -fenestrations in the posterior plate to facilitate aqueous nourishment of that tissue
2. A titanium locking ring - to decrease the chance of dislocation of the posterior plate into the anterior chamber
3. A titanium posterior plate that may be less prone to inciting anterior segment inflammation

- **Healthy donor tissue**

1. The recommendation of using healthy donor corneal tissue as a carrier compared to the historical acceptance of any donor tissue, including tissue that was previously frozen or stored in glycerin.
2. Healthy donor corneal tissue has been associated with better coupling of the donor carrier around the neck of the prosthesis and a decrease in the incidence of corneal melts.

- **Paradigm shifts in postoperative management that added immensely to its success:**

1. **Long-term topical antibiotic coverage-**

➢ Use of a wide-spectrum antibiotic, such as a newer-generation fluoroquinolone, has led to a marked decrease, if not elimination, of intraocular infections.
➢ This was earlier unacceptable to most specialists due to the concerns regarding development of resistance.

2. **Regimen Vanco +FQ-**

➢ Intraocular infections in the past were always with Gram-positive organisms.
➢ The new recommendations include the addition of vancomycin to the fluoroquinolone in case with high risk of infections such as those from previous inflammatory conditions and moderately severe dry eye.
➢ Some surgeons, the author included, prefer to use vancomycin in every case.

3. **Intra- and postoperative use of corticocosteroids**.

➢ The author generally recommends an intravitreal steroid injection at the end of the case.
➢ Followed by topical steroids postoperatively and,
➢ When the need arises, the appropriate placement of peribulbar triamcinolone.

4. **The maintenance of a bandage contact lens over the keratoprosthesis indefinitely**

➢ This creates a moist environment around the neck of the keratoprosthesis, and diffuses evaporative forces, leading to a decrease in corneal stromal melts and device extrusion.
➢ Bandage contact lens decreases mechanical forces between the lid and the anterior plate, which may lead to mobilization of the device.

5. **Aggressive management of glaucoma**

➢ Pre-, intra-, and postoperatively, if necessary with the use of a glaucoma tube-shunt drainage device.

Postoperative Complications and Management

Postoperative complications following Boston Type I keratoprosthesis surgery may be managed medically and/or surgically

1. Retroprosthetic membrane

- Retroprosthetic membrane has emerged as the most common complication after keratoprosthesis surgery
- Usually, the patient presents with a slight decrease in vision.
- On examination, there are suggestions of mild chronic inflammation such as opacification of the posterior plate fenestrations, together with a retroprosthetic membrane.

- Consideration should be given to increasing the topical steroids or placing a peribulbar injection of triamcinolone (20–40 mg).
- As per MBTKS, 25% -developed RPM, most of which did not require treatment. Majority could be treated with Nd :YAG laser and few required surgical membranectomy.
- 25-64% at 1 year follow-up
- Histopathology of RPM- avascular fibrous tissue membrane representing host stromal cell downgrowth over the stem of the device onto the backplate, that migrate through gaps in the posterior graft–host junction.
- RPM formation seems to be more prevalent in individual with chronic inflammation such as autoimmune diseases and uveitis.
- Development of titanic back plates have reduced incidence

Treatment

- Most keratoprosthesis surgeons, however, feel that early membranectomy with the YAG laser is indicated to avoid thickening of the membrane, thus requiring higher-power settings that may lead to pitting of the optical element of the keratoprosthesis.
- In the event that the YAG laser cannot create an acceptable opening in the retroprosthetic membrane/ If membrane thick,leathery and vascularized, surgical intervention using a two- or three-port vitrectomy set-up may be required to create an opening in or excise the retroprosthetic membrane.
- For boston kpro vit+membranectomy can be performed
- However removal of prosthesis and repacement with new one is preferred
- At the time of laser or surgical membranectomy, placing a peribulbar injection of steroid may reduce the chance of recurrent membrane formation.

2. Loss of the soft contact lens

- Loss of the soft contact lens is not uncommon.
- Every effort should be made to maintain the contact lens over the anterior plate of the keratoprosthesis. When this is not possible, consideration may be given to placement of a tarsorrhaphy
- Also, in the event of significant protein build-up on the contact lens, it may be replaced

3. Sterile vitritis

- This is a rare but recognized complication after keratoprosthesis surgery and suspected to result from an immune etiology.
- Patients usually present with decreased vision in an otherwise quiet-looking eye.

- The view to the posterior pole through the optical element is compromised, and B-scan ultrasonography reveals vitreous veils and condensation.
- Although most surgeons may choose to perform a vitreous tap for smear and culture and inject antibiotics, sterile vitritis usually resolves on its own.
- Peribulbar or oral steroids may have a role, as well.

4. Elevated intraocular pressure

- Single most serious complication with incidence upto 75% following sx leading to irreversible loss of vn
- Causes- chronic low grade inflammation, progressive angle closure, anterior displacement of iris have been implicated.
- IOP measurement is difficult- by DT, glaucoma evaluation and follow-up based on VF, SD-OCT for status of optic nerve, Time domain and spectral domain OCT may be useful in documenting the stability of the device around the stem.
- VEPs significantly reduced in OOKP patients with glaucoma vs controls(79%).
- **Treatment**
- Elevated intraocular pressure may be managed in the usual fashion with topical and/or systemic antiglaucoma therapy.
- Topical rx is effective in pts with boston type 1 Kpro
- Systemic rx can be used with boston type 2 and MOOKP
- If unsuccessful, consideration may be given to placement of a glaucoma tube shunt in the eye.
- If the eye is vitrectomized, the tube shunt may be placed in the vitreous cavity.
- Alternatively, consideration may be given to endocyclophotocoagulation.
- In rare instances, the glaucoma device may be shunted to the maxillary or ethmoid sinus, as well as to the lacrimal sac
- AGV+OOKP not to be done simultaneously as per reports to reduce risk of hypotony.
- Baerveldt implant has some advantages as the occlusion of tube with absorbabale suture is possible

5. Endophthalmitis

- Dreadful complication following kpro sx
- Often evidence of leak seen
- The presentation is similar to nonkeratoprosthesis endophthalmitis cases with a painful, inflamed eye, accompanied by decreased vision.
- B-scan ultrasonography reveals a dramatic increase in echo densities and veils in the vitreous cavity.
- This is a rare event after keratoprosthesis surgery, especially in the setting of dual antibiotic use (fluoroquinolone and vancomycin).
- **Treatment** includes leak repair, tap the vitreous cavity for smear and culture followed by injection of the antibiotic and topical antibiotics.
- Fungal infection suspected change contact lens and give topical amphotericin and systemic anti-fungals required.
- At the Wills Eye Institute, this is usually 1 mg of vancomycin and 2 mg of ceftazidime together with 400 µg of dexamethasone.

6. Retinal detachment- Bkpro, OOKPRO

- Most common posterior segment complication with an incidence of 16.9 %

- Symptoms- sudden onset floaters, flashes of light/ shadow across vision.
- Choroidal detachments can also develop in eyes with KPro, in as many as 17 % of patients
- **Surgical Treatment** with buckle or vitrectomy is performed
- Repair may be undertaken without removing the keratoprosthesis since the view to the posterior segment may be reasonable with the binocular indirect ophthalmic microscope (BIOM) attachment to the operating microscope.
- Some vitreoretinal surgeons prefer a wider view.
- In that instance, the cornea/keratoprosthesis complex is removed and replaced temporarily with an intraoperative keratoprosthesis (Eckdart of the vitreoretinal surgeon's choice to complete the posterior segment surgery before another Boston Type I keratoprosthesis in a corneal transplant carrier is sutured into position.
- Other posterior segment complications including vitreous hemorrhage as well as choroidal effusion or hemorrhage are usually managed conservatively.
- Again, it should be noted that the view through the Boston Type I keratoprosthesis optical element is frequently adequate to evaluate and manage posterior segment pathology.
- Achievement of anatomic success is limited by the presence of chronic retinal scarring or proliferative vitreo retinopathy (PVR) and visual outcomes tend to be worse in these cases.
- Endoscopic surgery has several advantages- not needing to view through optical cylinder, not needing to detach membrane or lamina in OOKRO. Disadvantage- learning curve, expensive instruments.

7. Corneal melts and keratoprosthesis extrusion

- Persistent corneal epithelial defects around the keratoprosthesis may be the earliest sign of keratolysis.
- The epithelial defects begin the melting process with failure to re-epithelize leading to infection/ trophic process and subsequent device failure.
- On molecular level- immune mediators and collagen attack corneal stroma.
- 2 most common causes of corneal melts are HSV and retained lenticular matter.
- They should be monitored closely and managed with aggressive lubrication, maintenance of a bandage contact lens, and oral doxycycline.
- Corneal melts were more common before the paradigm shift to using a long-term bandage contact lens over the front plate of the keratoprosthesis.
- The multicenter Boston Type I Keratoprosthesis Study Group found that the retention rate was 90% overall and 95% amongst non-autoimmune, nonchemical burn patients.
- SLE and anterior segment OCT are helpful in detection and f/u of corneal thinning around kpro.
- Any leak on siedels test,USG to be done to see choroidal effusion.
- Melts tends to occur at the base of Boston Kpro.
- **Treatment** – rule out HSV 1st
- If melts are seen then replace the whole thing with fresh graft and put new kpro.
- In MOOKP, resorption of buccal mucosa can occur, new graft can be placed.
- Resorption of osteo odonto lamina can occur,serial CT scan is to be done yearly.
- If much resorption of dentine has occurred entire thing should be replaced.
- Occasionally a lateral tarsorrhaphy may be necessary.
- Management includes a prompt return to the operating room for repeat reconstruction of the anterior segment, either with donor corneal tissue alone or another Boston Type I keratoprosthesis, assuming that the visual potential at that point justifies further surgery of this type.
- Progressive melts- lamellar graft / repeat attempt at PKP.

- In case of AlphaCor , medroxyprogesterone may not influent the incidence of melt related complications which likely to be associated with HSV, but it may have a protective effect with regards to melt onset and severity.

Conclusion

- Current research is aimed at improving, on the one hand, the anatomical results by using more biocompatible materials that provide better integration with the host tissue, and on the other hand, at providing optimal long-term and sustained visual acuity to our patients.
- Keratoprosthesis still carries a somewhat greater burden postoperatively than standard keratoplasty. Successful outcome requires patient compliance, more frequent follow-up and more demands on physician time.
- Post-operative complications remain the great enemy to beat (mainly glaucoma, infection, and extrusion).
- However, in cases where further Keratoplasty appears futile, keratoprosthesis can be most rewarding.
- Future designs will have to incorporate newer materials that provide excellent optical properties, while at the same time become biointegrated with the ocular tissue.
- In short, the perfect keratoprothesis has yet to be discovered, although every day the goal gets closer.