

# Indications for Temporary Keratoprosthesis, Anatomical and Visual Outcomes

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## Abstract

**Purpose:** Vitreoretinal surgery can be difficult or impossible in patients with corneal opacity. One solution for this problem is use of temporary keratoprosthesis (TKP). We report anatomical and visual outcomes of this combined surgery in our institution.

**Methods:** We retrospectively reviewed charts of patients in whom a TKP was used between 2006 and 2010 with follow-up of at least six months. Several variables such as indications for surgery, pre and postoperative visual acuity (VA), postoperative intraocular pressure (IOP), graft status, retinal status and postoperative complications were evaluated. Successful surgical outcome was defined as maintenance of clear graft, anatomic reattachment of retina, and controlled IOP.

**Results:** A TKP was used in 58 eyes, 43 (74.1%) of them were traumatic. Posterior segment comorbidity were retinal detachment in 39 (67.2%) eyes, vitreous hemorrhage in 19 eyes (32.8%) and endophthalmitis in 13 eyes (22.4%). All patients had corneal opacity due to scar, edema or blood staining. Postoperative VA was improved in 16 eyes (27.6%) of patients, and was unchanged in 31 eyes (53.5%) and was decreased in 11 eyes (18.9%) at the final visit. Postoperative VA was statistically better than preoperative VA ( $P < 0.001$ ) whether patients had retinal detachment or had not. Poor visual outcome (BSCVA  $\leq$  hand motion) was seen in 49 eyes (84.5%). Only 9 patients (15.5%) achieved ambulatory vision in involved eye (BSCVA  $\geq$  counting finger or  $^{20}/_{200}$ - $^{20}/_{800}$ ). Corneal grafts remained clear in 19 eyes (32.7%). 11(18.9%) eyes had successful surgical outcome. 4 eyes (12.1%) out of 33 eyes that had not become phthisic were at risk for phthisis bulbi.

**Conclusion:** Our results of simultaneous vitreoretinal surgery and penetrating keratoplasty (PKP) using TKP showed that in most patients, vision did not improved and in many patients eye cosmesis was not preserved, probably because our patients had more severe retinal and optic nerve dysfunction.

**Keywords:** Temporary Keratoprosthesis, Keratoplasty, Vitrectomy, Trauma

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## Introduction

Vitreoretinal surgery requires good visualization through a clear cornea. Corneal opacities can interfere with posterior segment visualization and surgery. One modality treatment for these patients is penetrating keratoplasty (PKP) as a primary surgery. But the delay due to postoperative corneal graft healing can be worsened the prognosis of the retinal disease. Also, any intraocular surgery, specially prolonged and complicated surgery, can threaten graft clarity due to endothelial cell loss and endothelial rejection. The use of a temporary keratoprosthesis (TKP) has not this disadvantage and allows earlier surgical intervention in eyes with coexisting vitreoretinal and corneal disease. Landers et al<sup>1</sup> presented first series of TKPs in 1981 that allowed a simultaneous surgery of corneal and retinal disease. In 1987, Eckardt<sup>2</sup> described a 7.0 mm disposable, widefield, silicone TKP that has the advantage of providing greater visualization of the peripheral fundus than Landers-Foulks keratoprosthesis. In 1993, Landers and Toth<sup>3</sup> designed a new, reusable wide field Landers TKP with 6 sutures holes. Also, the use of TKP has also been used for the combination of PKP and cataract procedures.<sup>4</sup> Landers wide field keratoprosthesis material is polymethylmethacrylate that replace opaque cornea in a trephined corneal bed and provides a clear medium during surgery.

Potential candidates for this combined procedure often have grave ophthalmic conditions, like devastating trauma and endophthalmitis. The decision to observe versus performing the procedure is complicated and interdisciplinary and involves ethical dilemmas of doing the best to restore versus be avoiding wastage of time, cost, and graft tissue and wrongly conveying hope. The purpose of this retrospective analysis is to provide tangible evidence on the outcome of TKP, pars plana deep vitrectomy, PKP in a tertiary care setting at Farabi Eye Hospital.

## Methods

We retrospectively reviewed all patients underwent combined pars plana deep vitrectomy and PKP using TKP between 2006 and 2010 with follow-up of at least six months. Patients with follow-up less than six months were excluded. All necessary data were

collected from the examination charts in the Vitreoretinal and the emergency services of Farabi Eye Hospital. We had analyzed several variables such as indications for surgery, preoperative and postoperative best corrected visual acuity (BCVA), intraocular pressure (IOP) after surgery, and complications after surgery.

Visual acuity (VA) was divided into 3 categories depending on whether acuity improved, remained stable, or worsened. A change in BCVA was defined as more than 2 Snellen lines (if Snellen visual acuity was possible). If VA was less than  $20/400$ , VA was documented as finger counting ability, hand motion, light perception, and no light perception. Any change among these categories was considered a significant change in vision. Vision was considered stable if it remained within the same category.

Successful surgical outcome was defined as maintenance of clear graft, anatomic reattachment of retina, and controlled IOP.<sup>5</sup>

Ambulatory vision was defined as  $20/200$ - $20/800$  or counting finger. Poor visual outcome defined as postoperative VA less than ambulatory vision (hand motion or less).

Eyes with combined ocular hypotonia and corneal edema defined eyes at risk for phthisis bulbi.

Ocular hypotonia were considered as IOP less than 7 mmHg.

The relative afferent pupillary defect (RAPD) was graded as the conventional rule from 1+ to 4+, supposing 4+ as no change in pupillary size.

During 2006-2010, 77 eyes of 76 patients underwent this combined surgery using TKP, of whom we could not to examine 19 patients due to compliance or address changes.

Fifty-eight eyes from 57 patients were treated with this surgical modality. Preoperative diagnosis of posterior segment involvement was based on B-scan echography. Surgeries were performed by several vitreoretinal specialists and corneal specialists using standardized protocol. All TKPs were Landers wide field TKP. Under general anesthesia, a conjunctival peritomy was made at inferotemporal and superior quadrants. Three sclerotomies were made with a micro vitreoretinal blade and an infusion cannula was placed in the inferotemporal

quadrant. Patient's cornea was trephined with 7 or 8 mm barron suction trephine. The patient's corneal button was cut with corneal scissors. The 7.20 or 8.20 mm Landers wide field keratoprosthesis was sutured to corneal and episcleral tissue with six interrupted 6-0 vicryl sutures. Vitreoretinal surgeon performed pars plana vitrectomy and procedures such as retinotomy, endolaser photocoagulation, and injection of silicon oil as required. After posterior segment operation was completed, the TKP was removed. Donor cornea was punched from endothelial side with 7.5 or 8.5 mm barron punch in an 0.5 mm oversized manner and was sutured to the host rim with 16 interrupted 10-0 nylon sutures. The donor corneas were all of good optical transplant quality (Iranian Eye Bank defines good as mean endothelial cell density of more than 2000/mm<sup>2</sup>). Sclerotomy sites were closed by 6-0 vicryl sutures and conjunctival peritomies were closed by 8-0 vicryl sutures. Subconjunctival steroid and antibiotics were injected. Postoperative care included topical antibiotics qid for 1 to 2 weeks, cycloplegics TDS for two to four weeks, and steroid medications (betamethasone 0.1%), tapered over time.

Statistical analysis was performed using SPSS 16. Some descriptive tests,  $\chi^2$  test, man witney u test, wilcoxon test and t-test were performed in order to detect differences between groups.

## Results

Fifty-eight eyes of 57 patients were operated on using a TKP. Mean age of patients was 39 years (range, 6-78 years). 46 (79.3%) patients were male. Mean age of patients that underwent this type of surgery and did not have any postoperative visit at 6 months or later was 38.4 years (range, 7-78 years). 11 (57.9%) of these excluded patients were male. Mean follow-up period was 22.01 months (range, 7-48 months). VA before surgery was counting finger in 2 eyes (3.5%), the perception of hand motions in 14 (24.1%), light perception in 37 (63.8%) and no light perception in 5 (8.6%). 45 out of 48 patients that had recorded RAPD in their medical charts, had RAPD (2+ or more) before combined surgery. All 43 trauma patients (74.1% of the total) had a history of primary repair of corneal and or scleral lacerations.

The median time between the trauma and surgery using TKP was 6 days (range, 1-48 days). The most common corneal indication for surgery (Table 1) was corneal edema or corneal blood staining (due to trauma) and distortion (due to repair of corneal laceration) which was present in 43 (74.1%) eyes. In 13 (22.4%) eyes (endophthalmitis cases), intervention was required due to corneal infiltration and edema. Endophthalmitis causes were cataract surgery in 9 eyes, bleb associated in 2 eyes, trauma in 1 eye, and corneal ulcer in 1 eye. Other causes of corneal involvement are shown in table 1.

Pars plana deep vitrectomy was applied for retinal detachment in 20 (34.5%) patients. In 15 (25.9%) eyes, there was vitreous hemorrhage and retinal detachment; in 13 (22.4%), there was vitreous involvement due to infectious process. Other causes of posterior segment involvement were shown in table 1.

The IOP after combined corneal and retinal surgery was below 7 mmHg in 22 (37.9%) eyes. In 28 (48.3%) eyes, IOP was between 7 and 21 mmHg and in 8 (13.8%) eyes; IOP was higher than 21 mmHg. VA recorded at the final visit of each patient improved in 16 (27.6%) eyes. It was unchanged in 31 (53.5%) eyes and worsened in 11 (18.9%) eyes. 14 (24.1%) eyes had no light perception. In trauma patients, mean time intervals from trauma to combined surgery were 7 days, 7.5 days and 6.2 days in the categories of VA improved, VA unchanged, VA deteriorated, respectively (P=0.2). Postoperative VA was statistically better than preoperative VA in trauma group (P<0.001) but in endophthalmitis group, postoperative VA was not statistically better than preoperative VA (P=0.11). Postoperative VA was statistically better than preoperative VA (P<0.001) whether patients had retinal detachment (P=0.002) or had not retinal detachment (P=0.007). But more patients without rhegmategenous retinal detachment (RRD) (42.1%) experience improvement in vision compared to only 20.5% of patients with RRD had improvement in vision (P<0.05) (Table 2). Only 9 patients (15.5%) achieved ambulatory vision or better in involved eye (VA $\geq$ finger count or <sup>20</sup>/<sub>200</sub>-<sup>20</sup>/<sub>800</sub>). Only in one eye postoperative best spectacle corrected visual acuity (BSCVA) was <sup>20</sup>/<sub>50</sub>. Poor visual outcome

(VA  $\leq$  hand motion) were seen in 49 eyes (84.5%). We had seen the following complications or observations in postoperative period at final visit of patients (Table 1). In 4 eyes (6.9%) retinal detachment was seen. Due to poor visual potential, these eyes were not operated again. In two eyes (3.5%), extensive macular scar was present that severely limited VA. Anterior segment complications at final visit of each patient included corneal edema in 39 (67.2%) eyes, vascularization of graft in 24 (41.4%) eyes, graft suture related complications (loose suture, vascularized suture, sterile infiltration) in 20 (34.5%). The corneal transplant was clear in 19 (32.7%) eyes. 16 eyes (37.2%) in trauma group and 3 eyes (23%) in endophthalmitis group had clear graft (P=0.279). Repeat graft (descemet stripping

automated endothelial keratoplasty) was performed in one eye that had a healthy retina and developed endothelial failure due to endothelial rejection (BSCVA was  $20/50$  prior to endothelial rejection). This second graft failed due to interface opacity and final BSCVA was  $20/200$ . Other failed grafts were not subjected to repeat PKPs because of a poor posterior segment visual potential. 25 (43.1%) eyes developed phthisis bulbi. Mean follow-up of patients with phthisis bulbi was 24.2 months (7-48 months). 4 eyes (12.1%) out of 33 eyes that had not become phthisis bulbi were at risk for phthisis bulbi. Mean follow-up of these patients was 10.2 months (7-16 months) which statistically less than patients with phthisis bulbi (24.2 months). 11 (18.9%) eyes had successful surgical outcome.

**Table 1.** Preoperative and postoperative corneal and posterior segment findings

Preoperative corneal involvement	Preoperative posterior segment involvement	postoperative complications
- Corneal edema or distortion and blood staining due to trauma 74.1% (43 eyes)	- Rhegmatogenous retinal detachment 34.5% (20 eyes)	- Retinal detachment 6.9% (4 eyes)
- Corneal edema and bacterial corneal ulcer in infectious postoperative endophthalmitis 22.4% (13 eyes)	- Rhegmatogenous retinal detachment and vitreous hemorrhage 25.9% (15 eyes)	- Extensive macular scar 3.5% (two eyes)
- Presumable herpetic corneal scar 1.7% (one eye)	- Vitreous hemorrhage without RRD 6.9% (4 eyes)	- Cyclitic membrane 1.7% (one eye)
- Decompensated cornea due to complicated cataract surgery 1.7% (one eye)	- Intraocular foreign body and RRD 6.9% (4 eyes)	- Corneal edema 67.2% (39 eyes)
	- Intraocular foreign body without RRD 1.7% (one eye)	- Graft vascularization 41.4% (24 eyes)
	- Nuclear fragment in vitreous 1.7% (one eye)	- Graft suture related complications including loose suture, vascularized suture, sterile infiltration 34.5% (20 eyes)
	- Endophthalmitis 22.4% (13 eyes)	- Phthisis bulbi 43.1% (25 eyes)
	- Advanced proliferative diabetic retinopathy 1.7% (one eye)	

**Table 2.** Effect of preoperative rhegmatogenous retinal detachment on visual acuity outcome

	RRD+	RRD-	P
VA unchanged	26 eyes (66.7%)	5 eyes (26.3%)	0.031
VA improved	8 eyes (20.5%)	8 eyes (42.1%)	
VA worsened	5 eyes (12.8%)	6 eyes (31.6%)	

RRD: Rhegmatogenous retinal detachment

## Discussion

TKP allowed earlier treatment of posterior segment disease in the presence of corneal opacification, without the limitations and risks of open-sky vitrectomy. When we compare visual and anatomical outcomes in our study with others reported in literature, we find a wide range of prognosis. This is due to heterogeneous composition of patients in term of disease severity and type of diseases in these studies. Therefore, visual outcome in our patients was less favorable than those of other reports in the literature<sup>5-8</sup> and was better than those in some other studies.<sup>9-12</sup> Range of VA improvement and deterioration in literature in this type of surgery was 16<sup>11</sup>-82%<sup>5</sup> and 18<sup>7</sup>-60%<sup>9</sup> respectively. When we decide to perform a surgical intervention in eyes with extensive damage, poor visual outcome and probability of inducing sympathetic ophthalmia in the fellow eye should be considered. However, repair of severely damaged eye may be appropriate in many patients with RRD, because Ivanisevic reported that in untreated rhegmatogenous retinal detachment, complete loss of vision and development of proliferative vitreoretinopathy was found in all cases, with a large percentage of eyes eventually deteriorating to no light perception and phthisis.<sup>13</sup>

Although the retrospective nature of this study limits comparisons among cases, we have found some correlations. VA change was more favorable in trauma group than endophthalmitis group ( $P=0.052$ ) (Table 3). Due to small sample size,  $P=0.052$  was considered statistically significant. This means that indication of surgery was prognostic factor for visual outcome. Visual outcome in our trauma group was better compared to endophthalmitis group. This may be due to extensive and severe retinal ischemia and necrosis in endophthalmitis cases. Our

traumatic cases had more limited visual outcomes than those reported by Gallemore and Bokosky.<sup>7</sup> They report that VA improved in 82% and decreased in 18% of trauma group. This difference may be due to the inclusion of eyes with more severe posterior segment damage. Factor associated with better visual prognosis in our study was preoperative retinal status (42.1% improved vision in RRD-versus 20.5% in RRD +,  $P<0.05$ ). In majority of patients with RRD (79.5%), surgery did not improve VA, but in many patients without RRD (42.1%), surgery improved VA. This means that patients without RRD may be better candidate for this type of surgery and patients with RRD had lower chance for improvement of vision. In trauma patients, time interval between trauma and combined surgery was not a prognostic factor for VA outcomes ( $P=0.2$ ).

All of our patients with no light perception before surgery had no improvement in VA postoperatively in contrast to Hua Yan<sup>14</sup> who reported 5 out of 7 patients with no light perception experienced improvement in visual acuity after surgery.

It should be noted that such cases are very much heterogeneous in terms of trauma severity and natural course; and designing a randomized study is not practical either, due to ethical issues and availability of cases. The other point is that the vision may not be a suitable outcome measure; normal IOP and globe integrity, and cosmetic outcome are better indicators. For instance, we showed that the mean follow-up of patients at risk for phthisis bulbi was statistically less than patients with phthisis bulbi (10.2 vs. 24.2 months,  $P<0.001$ ). This suggests that visual and anatomical outcomes may progressively deteriorate over the time.

**Table 3.** Relationship between indication of surgery and visual acuity change before/after surgery

	Trauma group	Endophthalmitis group	P
VA unchanged	22 eyes (51.2%)	8 eyes (61.5%)	0.052
VA improved	14 eyes (32.6%)	1 eyes (7.7%)	
VA worse	7 eyes (16.2%)	4 eyes (30.8%)	

VA: Visual acuity

## Conclusion

In conclusion, vitreoretinal surgery can be possible in patients with corneal opacity using TKP to spare any damage to the permanent graft replacing.

It is already known - and confirmed in our study - that such devastatedly injured eyes have poor visual prognosis but our

observation also showed that these patients have poor prognosis in terms of globe salvation as phthisis happens in the majority of the eyes. The decision over 'to perform or not to perform' the TKP with vitrectomy in such eyes remains unresolved.

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