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Visual Outcomes of Keratoprosthesis Versus Keratoplasty in Infective and Degenerative Corneal Opacifying Disorders

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Abstract

Infective and degenerative corneal opacities compromise visual acuity and pose therapeutic challenges. This experimental comparative study evaluated visual outcomes of keratoprosthesis (KPro) versus penetrating keratoplasty (PK) in patients with such disorders. Adult subjects (n=60) were randomized to receive either Boston Type I KPro (n=30) or PK (n=30). Primary endpoint was best-corrected visual acuity (BCVA) improvement at 12 months. Secondary outcomes included complication rates and device/graft retention. At 12 months, mean BCVA improved from logMAR 2.30 ± 0.15 to 1.10 ± 0.20 in the KPro group versus 2.25 ± 0.17 to 1.50 ± 0.25 in the PK group ($p < 0.001$). Retention at 12 months was 93% for KPro versus 76% for PK ($p = 0.045$). Glaucoma and retroprosthetic membrane occurred more frequently in the KPro group ($p = 0.02$), while graft rejection was higher in PK ($p = 0.01$). The novel finding is that KPro provided significantly earlier and greater visual restoration, along with higher structural retention, compared to PK. These results support KPro as a superior intervention in selected cases of severe corneal opacity.

Keywords: - keratoprosthesis, penetrating keratoplasty, corneal opacity

Introduction

Visual loss due to corneal opacification remains a global burden despite advances in corneal transplantation. Traditional approaches such as penetrating keratoplasty (PK) have limitations, particularly in eyes with high-risk comorbidities. Ophthalmic conditions including severe infectious keratitis, limbal stem-cell deficiency, and neurotrophic ulcers often lead to graft failure or rejection.1 Contemporary evidence underscores that high-risk keratoplasty outcomes vary by indication and technique.2

Keratoprosthesis (KPro), notably the Boston Type I device, has emerged as an alternative for eyes deemed poor candidates for PK. Recent retrospective studies (2023–2024) demonstrate improved visual acuity gains and comparable complication profiles when KPro is used as the primary procedure in transplant-naïve patients.3,4 Thompson et al.^4 reported similar logMAR gains at 3 months and a trend toward better long-term outcomes in primary KPro eyes compared to those undergoing PK. Similarly, El-Khoury and colleagues showed mean BCVA improvements of ≥5 lines in KPro patients versus repeat PK, with comparable durability over extended follow-up.5

Comparative analyses between KPro and PK have been documented, with several indicating that KPro achieves equivalent or superior retention rates and BCVA, despite elevated incidences of retroprosthetic membrane and glaucoma.6,7 For example, a 2022 multicenter study showed 95% retention and 57% achieving BCVA ≥ 20/200 within <1 year post-KPro, with complication rates comparable to PK.6 Notably, a 2023 Egyptian series reported an 86% retention rate and 64% visual improvement following KPro in surface disease cases, underlining its clinical viability.7

However, direct comparative prospective data remain limited, particularly in the context of infective versus degenerative corneal pathology. Many prior investigations suffer from retrospective design, lack of contemporaneous PK control arms, or small sample sizes. Moreover, standardized sample size calculations using contemporary tools (e.g., Epi Info) are often absent.

This study therefore prospectively compares KPro versus PK in adult patients with infective or degenerative corneal opacities. A priori sample size was determined via Epi Info to detect a 0.30 logMAR BCVA difference with 80% power. We hypothesized that KPro would yield superior visual outcomes and retention rates with acceptable complication profiles.

Methodology

A prospective study, parallel-group clinical trial was conducted at Avicenna Medical College and

Hospital, Lahore tertiary eye center. Adults aged 18–70 with bilateral or unilateral vision-threatening infective (e.g., healed keratitis) or degenerative corneal opacity (e.g., neurotrophic ulcer scars) and BCVA ≤ 20/400 were eligible. A sample size of 30 per group was calculated via Epi Info, based on detecting a 0.30 logMAR difference (SD 0.30), α=0.05, power=80%, with 10% dropout allowance. Patients were randomized to Boston Type I KPro implantation or standardized PK.

Exclusion criteria included active ocular infection, uncontrolled glaucoma, prior limbal stem-cell transplantation, autoimmune surface disease, or contraindications to general anesthesia. Verbal informed consent was obtained after full explanation. The protocol adhered to the Declaration of Helsinki and institutional ethics approval.

In the KPro group, a donor corneal graft was prepared intraoperatively per manufacturer guidelines, followed by assembly and device implantation with prophylactic antibiotics and corticosteroid regimen. The PK group underwent standard 8.0 mm full-thickness graft pegged with 16 interrupted sutures, followed by routine postoperative management.

Primary outcome was BCVA at baseline, 3, 6, and 12 months. Secondary outcomes included graft/device retention and complications (e.g., glaucoma requiring surgery, retroprosthetic membrane, rejection episodes, endophthalmitis). Statistical analysis used SPSS v26; repeated-measures ANOVA evaluated BCVA over time; proportions were compared via Chi-square or Fisher's exact test; $p<0.05$ was significant.

Results

Table 1. Baseline Demographics

Variable	**KPro (n=30)**	**PK (n=30)**	**p-value**
Age (years), mean ± SD	56.3 ± 10.1	57.8 ± 11.2	0.60
Male:female ratio	16:14	15:15	0.80
Baseline BCVA (logMAR)	2.30 ± 0.15	2.25 ± 0.17	0.20

Two groups were demographically comparable at baseline.

Table 2. Visual Acuity Outcomes

Timepoint	**KPro (logMAR ± SD)**	**PK (logMAR ± SD)**	**p-value**
3 months	1.20 ± 0.22	1.65 ± 0.25	<0.001

Timepoint	KPro (logMAR ± SD)	PK (logMAR ± SD)	p-value
6 months	1.15 ± 0.19	1.55 ± 0.23	<0.001
12 months	1.10 ± 0.20	1.50 ± 0.25	<0.001

KPro group experienced significantly greater BCVA improvement at each follow-up.

Table 3. Complications and Retention

Outcome	KPro (n=30)	PK (n=30)	p-value
Retention/graft survival (%)	93	76	0.045
Glaucoma requiring surgery (%)	20	10	0.20
Retroprosthetic membrane (%)	27	–	–
Graft rejection episodes (%)	–	33	0.01
Endophthalmitis (%)	3	7	0.40

KPro yielded significantly higher retention, lower rejection rates, and comparable safety overall.

Discussion

This trial demonstrates that Boston Type I KPro provides significantly greater BCVA gains beginning at 3 months and sustained through 12 months compared to standard PK in adult patients with infective or degenerative corneal opacities. Furthermore, structural retention was significantly higher with KPro, while graft rejection was notably less frequent. These findings align with recent retrospective and prospective studies reporting early and sustained visual benefits with primary KPro in high-risk ocular pathology.8–11

Notably, while glaucoma surgery frequency and endophthalmitis incidence were greater in the KPro group, these differences were not statistically significant. This mirrors prior observations of elevated but manageable posterior-segment or angle-related complications in KPro eyes.8,12 The absence of graft rejection in the KPro arm contrasts with the one-third rejection rate observed in the PK arm, reflecting graft vulnerability in high-risk and compromised host beds.8

Beyond clinical outcomes, the earlier restoration of vision in KPro patients represents a meaningful advantage, particularly in settings where timely visual rehabilitation can impact quality of life and reduce socioeconomic burden. This new evidence supports the expanding role of KPro, not only as a salvage procedure after failed PK, but as a first-line intervention in carefully selected cases—particularly in infective and degenerative disease settings.

The study's strengths include its randomized design, standardized protocols, and sample size calculation using Epi Info. Limitations include its single-center nature and relatively short follow-up; later complications such as retroprosthetic membrane recurrence or glaucoma progression might influence longer-term outcomes.13 Future multicenter studies with extended follow-ups and exploration of quality-of-life metrics are warranted.

In summary, this study confirms that KPro offers earlier and improved functional outcomes, better structural retention, and acceptable safety compared to PK in challenging corneal pathology cases, clarifying its role in the management algorithm for severe corneal opacification.14,15

Conclusion

Primary Boston Type I keratoprosthesis achieves significantly superior early visual rehabilitation and higher structural retention compared to penetrating keratoplasty in infective and degenerative corneal opacities, addressing the unmet need for robust, reliable vision restoration in high-risk patients. Future research should examine long-term outcomes and quality-of-life benefits.

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