

# Effectiveness of Temporary Keratoprosthesis in Vitreo-Retinal Surgeries



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## ABSTRACT

**Purpose:** To determine the effectiveness of temporary keratoprosthesis in facilitating successful combined penetrating Keratoplasty and vitreoretinal surgery.

**Study Design:** Retrospective interventional case series.

**Place and Duration of Surgery:** Department of Ophthalmology, Peshawar Medical College, from January 2020 and December 2023.

**Methods:** A retrospective study was conducted which included 15 patients who underwent combined penetrating Keratoplasty and temporary keratoprosthesis-assisted vitreoretinal surgery. Data for pre and postoperative visual acuity, IOP, retinal attachment and graft status were obtained from hospital records. Surgical success was determined by the presence of a clear corneal graft, stable retinal attachment, normal intraocular pressure, and maintained or improved visual acuity. Data was analyzed using SPSS version 24. An independent test was employed to compare continuous variables between patients with successful and unsuccessful surgical outcomes.

**Results:** A total of 15 cases with mean age of  $39.27 \pm 15.88$  years were included in this study. Visual acuity improved in 33.3% of cases, worsened in 13.3%, and remained stable in 53.3%. Postoperative corneal opacity occurred in 73.3% of patients, while 26.7% retained a clear graft. Functional vision was achieved in approximately 40% of the cases while only 13.3% were considered surgical success.

**Conclusion:** Complete surgical success was attained in only a minority of cases, and functional vision was achieved in less than half of the patients. Graft failure was the predominant postoperative complication, while corneal laceration with posterior segment pathology was the most frequent surgical indication.

**Keywords:** Keratoprosthesis, Retina, Penetrating keratoplasty, Retinal detachment, Visual acuity.

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## INTRODUCTION

Diffuse corneal edema, suture-induced corneal distortion, or corneal scarring can significantly obstruct posterior segment visualization.<sup>1</sup> Optimal retinal visualization is crucial for successful vitreoretinal surgery, requiring a closed globe and

transparent ocular media.<sup>2</sup> While pharmacological intervention or surgical manipulation can sometimes improve corneal clarity, severe corneal pathology often necessitates corneal tissue removal or transplant to achieve the necessary visual access for posterior surgical intervention.<sup>3</sup> Corneal opacities can significantly hinder the clear visualization of the ocular fundus.<sup>4</sup> They can stem from damage to any or all the corneal layers and are often a consequence of chronic inflammation, trauma, or infection.<sup>5</sup> These visual barriers offer a substantial challenge in the management and evaluation of pathologies of anterior and posterior segment.<sup>6</sup>

Once considered an insurmountable challenge, the

surgical treatment of posterior segment pathologies is now feasible through advanced techniques such as pars plana vitrectomy (PPV) with temporary keratoprosthesis (TKP) and endoscopic PPV.<sup>7</sup> The integration of TKP with vitreoretinal surgery provides a valuable approach for managing vitreoretinal disorders in cases with insufficient corneal clarity.<sup>8</sup> Temporary keratoprostheses are supplementary devices sutured to the corneal bed improving accessibility to the posterior segment. It is positioned at the surgical outset and provides clear visualization during vitreoretinal manipulation. The keratoprosthesis is removed upon the completion of the surgery and it is replaced with a corneal graft.<sup>8</sup>

The concept of keratoprosthesis dates back to 1789, when Pellier de Quengsy, a French ophthalmologist attempted to restore vision using a glass disc encased in a silver ring. This approach paved the way for future developments. The discovery of well-tolerated polymethylmethacrylate placed in the corneas of World War II soldiers stimulated advancements in biocompatible keratoprosthesis materials.<sup>9</sup> Consequent developments in the design of this device and post-surgery management have led to better outcomes, increased utilization of these implants and expanded applications. Since the development of initial PMMA models which were introduced in 1981 by Lander, temporary keratoprosthesis has undergone significant advancements.<sup>1</sup> However, these early designs had limitations in terms of distortion, visual clarity, and leakage. The silicone-based Eckardt keratoprosthesis provided a substitute but their durability proved inferior to other PMMA counterparts.<sup>10</sup> In 2000, the introduction of Aachen keratoprosthesis marked a turning point exhibiting flexibility and adaptability for complex corneal conditions.<sup>2</sup> Presently, the two commercially available options for temporary keratoprostheses are the Eckardt® and Landers Foulks models.<sup>8,11</sup>

The surgical planning of vitreoretinal procedure is significantly impacted by the location and degree of corneal opacity. Mild to moderate corneal opacities are mostly managed by surgical techniques or preoperative topical therapy to decrease corneal edema. When sufficient corneal clarity is not achieved by these approaches, alternative surgical options become essential.

The present study was conducted to assess the effectiveness of a temporary keratoprosthesis with vitreoretinal surgery in patients with posterior segment

pathology and insufficient corneal clarity in a tertiary care center of Peshawar, Pakistan.

## METHODS

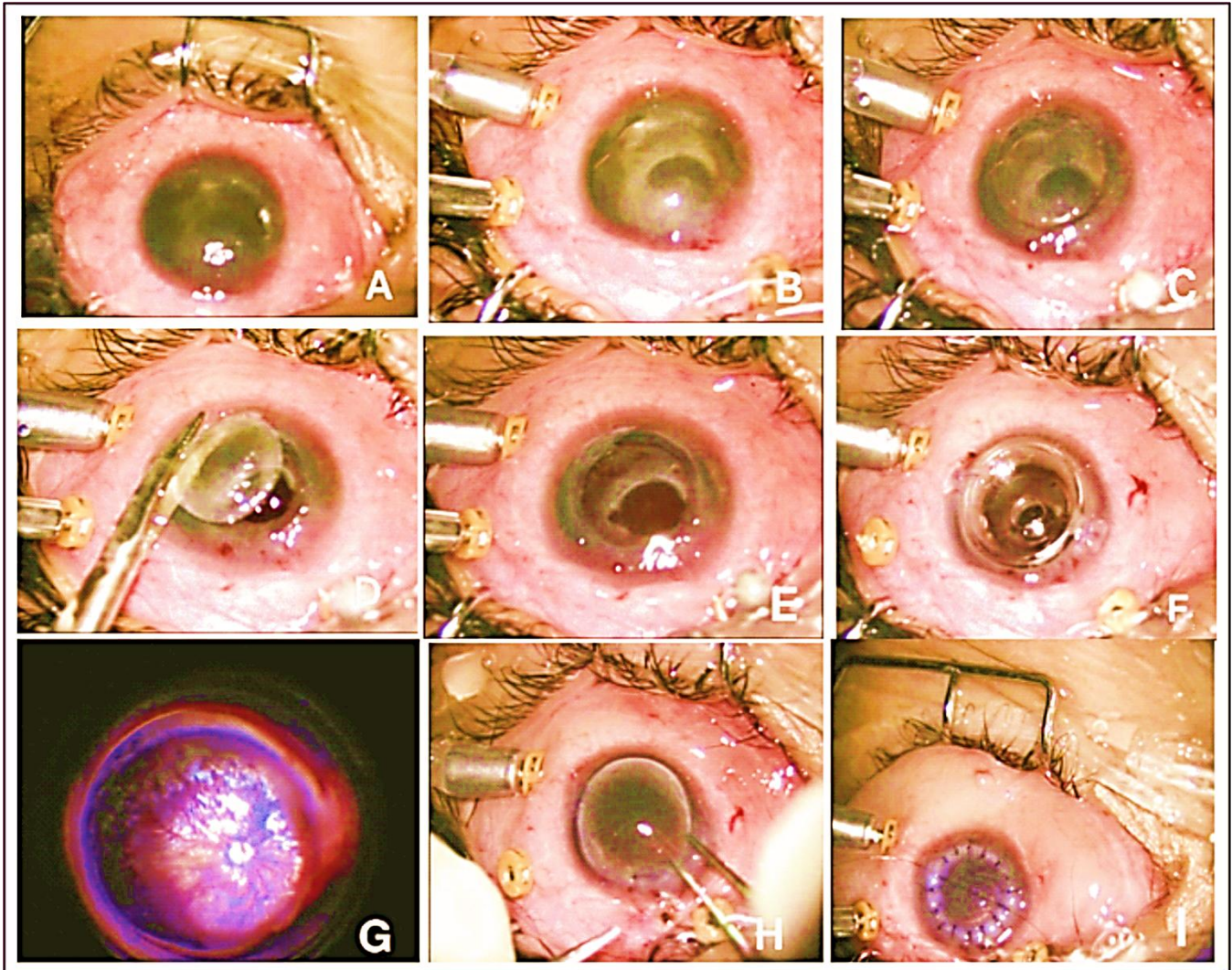
A retrospective review was conducted on 15 patients who underwent combined penetrating keratoplasty and temporary keratoprosthesis-assisted vitreoretinal surgery between January 2020 and December 2023. Data was obtained from patient records at the Department of Ophthalmology, Peshawar Medical College. The ethical approval was obtained from Institutional Review Board of Prime Foundation Pakistan (**Prime/IRB/2024-1076**).

This study was conducted in accordance with the ethical guidelines outlined in the Declaration of Helsinki. After obtaining Institutional Review Board approval, a review of medical records was conducted. Due to the retrospective nature of the study, patient data were rendered anonymous, thereby waiving the requirement for informed consent.

Patients were included in the study if they underwent a combined surgical procedure involving penetrating keratoplasty (PKP) and temporary keratoprosthesis (TKP)-assisted vitrectomy. The inclusion criteria were patients with corneal opacity that prevented clear visualization of the posterior segment for surgical management, retinal detachment or other vitreoretinal conditions requiring pars plana vitrectomy, and a combined surgical approach encompassing pars plana vitrectomy, TKP placement, and PKP and patients with a record of minimum followup period of 6 months. Patients with missing medical records, incomplete follow-up data, or a follow-up period less than 6 months were excluded. Patients with traumatic corneal injuries underwent primary repair surgery to treat the corneal wound. After a minimum of 3-week gap, a second surgical procedure was performed involving TKP placement, PKP and PPV.

Data included patient's age, gender, history of ocular trauma, visual acuity, intraocular pressure (IOP), ophthalmic examinations and investigations. Given the severe visual impairment of all patients, traditional Snellen chart measurements were not feasible. Instead, visual acuity was categorized as hand movement (HM), Counting fingers (CF), perception of light (PL), or no light perception (NLP). At follow-up, visual acuity, intraocular pressure, corneal graft transparency, and retinal attachment were

evaluated.



**Figure 1:** Surgical steps (A) Corneal opacity, (B) Insertion of 23 gauge sclerotomies, (C) Corneal Trephination (C)(D)(E) Removal of Recipient Corneal Button, (F) TKP secured to the corneal bed (G) Fundus viewing with TKP (H)(I) Donor corneal button suturing & Removal of the TKP.

IOP was determined using Goldmann applanation tonometry or with a tonopen. Normotension was defined as IOP between 8 and 21 mmHg. Corneal graft failure was determined by the development of irreversible corneal opacity.

The primary measures of success were corneal graft clarity, retinal attachment, maintenance of normotension, and visual acuity improvement or stabilization. Functional vision was considered achieved when the final visual acuity was at least hand motion. Surgical success was defined by the presence of a clear corneal graft, an attached retina, normotension, and either maintained or improved visual acuity compared to the preoperative state.

All surgical procedures were conducted under general anesthesia by a senior vitreo-retina surgeon adhering to strict sterile conditions after obtaining informed written consent from all the patients. A 23-gauge sclerotomy trocar was inserted in the inferotemporal quadrant for irrigation/ infusion canula. Two additional sclerotomies were created for 23-gauge Endo light probe and vitrectomy cutter to perform PPV (Constellation, Alcon, Fort Worth, TX, USA) as shown in Figure-1(B). The patient's cornea (recipient) was trephined with 7.25 mm corneal trephine (Hessburg Barron, USA) and micro corneal scissors as shown in Figure-1(C, D, E). Cataract removal was performed if needed, followed by the

implantation of an intraocular lens. A TKP (7.5mm, Landers, Bellevue, USA) was secured using two 6.0 Vicryl sutures (ETHICON, Johnson & Johnson, USA) to the corneal bed as shown in Figure-1(F).

The EIBOS wide-angle imaging system (Möller-Wedel, Germany) was used to view the posterior segment during surgery as shown in Figure-1(G). Basic steps of vitrectomy such as core vitrectomy, shaving of the vitreous base, peeling of membranes and removal of intraocular foreign body (if needed) were performed. Perfluorocarbon fluid (Deca, Ophthafutur, ExciMed, Malaysia) was used to flatten the retina. Endo laser photocoagulation and retinectomy were also performed where indicated. After air fluid exchange, silicone oil 1000 cst or 5000 cst (RS-OIL 1000 & RS-OIL 5000, ALCHIMIA, Austria) were used as a tamponade where indicated. Air was also used as an internal tamponade in one of the cases. Sclerotomies were closed with 7.0 vicryl sutures (ETHICON, Johnson & Johnson, USA). Donor corneal tissues were provided by CorneaGen, Seattle, USA. In the last phase of the surgery, the TKP was removed and 7.5mm donor corneal button was sutured with 16 interrupted 10/0 nylon sutures (ETHICON, Johnson & Johnson, USA) as shown in Figure-1(H, I).

Postoperative management included topical moxifloxacin (Vigamox, Alcon, Novartis Company, USA) and dexamethasone (Maxidex, Alcon, Novartis Company, USA) applied 6 times for two weeks and then tapered accordingly. Cyclopentolate (Cyclopen 1%, Ethical Pvt Ltd, Pakistan) was prescribed twice daily.

Data was entered, coded, and analyzed using SPSS Statistics version 24. Data normality was assessed using the Shapiro-Wilk test, which indicated a normal distribution ( $p > 0.05$ ). Descriptive statistics were performed for all variables. Categorical variables, including gender, cause of injury, visual acuity, graft outcome (successful or failed), and retinal status (attached or detached), were summarized using frequency distributions and percentages. Continuous variables, such as age, preoperative and postoperative intraocular pressure, time between injury and presentation, and follow-up duration, were described using means and standard deviations. Independent t-tests were used to compare continuous variables between cases with successful and unsuccessful outcomes. Chi-square tests were employed to examine differences in categorical variables, such as gender.

Statistical significance was set at a p-value of less than 0.05.

## RESULTS

Table 1. Summarizes the demographic and clinical characteristics of 15 patients undergoing open-globe surgery. Participants ranged in age from 14 to 63 years, with a mean age of  $39.27 \pm 15.88$  years. Male patients accounted for 66.7% (n=10) of the sample while females comprised of 33.3% (n=5). Corneal laceration along with retinal detachment was the most frequent reason for surgery, occurring in 8 (53.3%) cases. Other indications for ocular surgery included metallic intraocular foreign body along with corneal laceration and retinal detachment in 4(26.6%) cases, corneal opacity with retinal detachment in 2 (13.3%) cases and nucleus drop combined with bullous keratopathy in one (6.6%) case Table 1.

The preoperative visual acuity examination revealed that 10 (66.7%) cases had PL, 4(26.7%) had a VA of HM, and CF 30cm was observed in only 1 (6.7%) case. Postoperative visual acuity was PL in 8(53.3%) cases, HM in 3(20%) cases, and one case (6.7%) each of NLP, CF20mm, and CF 10mm. Visual acuity improved in 5(33.3%) cases, decreased in 2(13.3%) cases and remained unchanged in more than half of cases 8(53.3%).

The mean preoperative IOP was  $14.07 \pm 1.66$ , while the mean postoperative IOP was  $17.20 \pm 7.56$ . Most of the patients had post operative opaque corneas 11(73.3%) while 4(26.7%) maintained postoperative clear graft. More than half of the patients had detached retina, 8 (53.3%) and 7(46.7%) had attached retina postoperatively (Table1).

Graft failure along with other postoperative complications were observed in 11(73.3%) cases. Followed by RD in 8(53.3%) and raised IOP in 3(20%) cases. Phthisis was reported in 2(13.3%) cases, macular atrophy in one 1(6.6%) case while one case had no postoperative complications(Table1).

The tamponade used in majority (86.6%, n=13) of the cases was silicone oil 1000 cst, silicone oil 5000 cst was injected in one case while air was used as a tamponade in one case. The mean interval between injury and presentation was  $18.87 \pm 9.84$  weeks (minimum 4 maximum 40 weeks). The mean follow up period was  $9.13 \pm 2.80$  months (minimum 5 maximum 14 months).



Functional vision was achieved in 6(40%) cases. Surgical success was achieved in only 2 (13.3%) cases. No significant correlation was observed

**Table 1:** Demographic and clinical characteristics of the cases.

Case No.	Age (Years)	Gender	IOP		Visual acuity		Cause /Injury	Post-op graft status	Post-op retina status	Tamponade (cSt)	Complications	Surgery status
			Pre-op	Post-op	Pre-op	Post-op						
1	35	Male	15	27	HM	CF close 10mm	Corneal laceration, Metallic Intraocular foreign body, RD	Opaque cornea	Attached	1000	Raised IOP, Graft failure	Unsuccessful
2	40	Female	18	20	PL	PL	Corneoscleral laceration, RD	Clear graft	Attached	5000	Macular atrophy, scarring	Successful
3	28	Male	15	20	PL	PL	Corneoscleral laceration, RD	Opaque cornea	Detached	1000	Failed graft Recurrent RD	Unsuccessful
4	55	Male	15	20	CF 30 cm	CF 2 m	Nucleus drop, Bullous keratopathy	Clear graft	Attached	Air	None	Successful
5	44	Male	12	14	HM	CF 20mm	Intraocular foreign body, Corneal laceration, RD	Opaque Cornea	Attached	1000	Graft failure	Unsuccessful
6	53	Female	15	3	PL	PL	Corneal laceration, RD	Clear graft	Detached	1000	Phthisis, Recurrent RD	Unsuccessful
7	22	Male	15	29	PL	PL	Corneoscleral laceration, RD	Opaque cornea	Detached	1000	Failed graft, Recurrent RD, Raised IOP	Unsuccessful
8	26	Male	12	15	HM	HM	Corneal laceration, RD	Opaque cornea	Attached	1000	Failed graft	Unsuccessful
9.	63	Male	14	18	PL	PL	Corneoscleral laceration, RD	Opaque cornea	Detached	1000	Failed graft, Recurrent RD	Unsuccessful
10.	37	Female	14	18	PL	PL	Corneal laceration, RD	Clear graft	Detached	1000	Recurrent RD, PVR	Unsuccessful
11.	63	Male	12	14	PL	HM	Corneal opacity, RD	Opaque cornea	Attached	1000	Failed graft	Unsuccessful
12.	32	Female	12	4	PL	NLP	Intraocular foreign body, Corneal laceration, RD	Opaque cornea	Detached	1000	Graft failure, Recurrent RD, Phthisis	Unsuccessful
13.	14	Male	15	13	PL	HM	Corneal Laceration, RD	Opaque cornea	Attached	1000	Failed graft	Unsuccessful
14.	21	Male	14	15	HM	PL	Intraocular foreign body, Corneal laceration, RD	Opaque cornea	Detached	1000	Failed graft, Recurrent RD	Unsuccessful
15.	56	Female	13	28	PL	PL	Corneal opacity, RD	Opaque cornea	Detached	1000	Failed graft, Recurrent RD, Raised IOP	Unsuccessful

**Table 1** Details of 15 cases studied. (M= male; F= female; pre-op= pre-operative; post-op= post operative; HM= Hand movement; CF= counting finger; PL= perception of light; NLP= no light perception; CL = corneal laceration; IOFB= intra-ocular foreign body; RD= retinal detachment; ND= nucleus drop; BK= Bullous Keratopathy; cst = Centistokes).

between age, gender, postoperative IOP, and follow-up duration when comparing successful and failed cases ( $p > 0.05$ ). There was a statistically significant difference between successful and unsuccessful cases in terms of interval between injury and presentation ( $p < 0.05$ ) (Table 2).

**Table 2:** Comparison of Demographic and Ocular Features in successful and unsuccessful cases.

Patient demographic and ocular characteristics	Successful cases (n= 2)	Unsuccessful cases (n=13)	P value
Mean Age (years)	47.50 ± 10.6	38.0 ± 16.44	0.39
Gender (Male: Female)	1:1	9:4	0.9
Preoperative IOP (mm Hg)	16.50 ± 2.12	13.69 ± 1.31	0.29
Interval between injury and presentation (weeks)	8.0 ± 0.0	20.54 ± 9.50	<b>0.0047</b>
Follow up period (months)	7.0 ± 2.82	9.46 ± 2.75	0.41

## DISCUSSION

In our study, only 2 cases (13.3%) were classified as complete surgical successes, while 13 cases (86.6%) were deemed unsuccessful. A retrospective analysis conducted in 2019 reported a 50% success rate in cases where vitreoretinal surgery was performed in conjunction with temporary keratoprosthesis. This discrepancy in success rates may be attributed to differences in injury type and severity, the extent of tissue damage, the interval between injury and treatment, the degree of proliferative vitreoretinopathy, and the quality of the corneal graft.<sup>1</sup>

To evaluate the efficacy of the surgical intervention, success was determined by a combination of factors including a clear corneal graft, stable retinal attachment, normalized intraocular pressure, and stable or enhanced visual acuity. In case no 1, 11, 13 visual acuity was improved, and retina was attached but were considered surgical failure due to post operative opaque cornea. In case no 1, 5, 11 and 13, the visual acuity was improved, and retina was attached but due to graft failure these cases could not be considered complete success.

According to literature, temporary keratoprosthesis offers a promising solution by providing clear visualization, maintaining ocular integrity and timely intervention. It also improves the overall surgical outcomes by protecting the corneal graft from potential harm during the vitrectomy procedure.<sup>8,12</sup> Moreover, temporary keratoprostheses enable bimanual surgical techniques within a closed

environment, reducing the chances of complications such as neovascularization, corneal damage, and anterior segment adhesions.

Prior to the concept of temporary keratoprosthesis, patients with corneal and vitreoretinal pathologies were subjected to either a staged surgical procedure or an open-sky vitrectomy. While anterior and posterior segment conditions can be addressed via open-sky vitrectomy, its association with increased risk of perioperative hypotony and other serious complications often limit its use. Another alternative is endoscopic plana vitrectomy, but availability of specialized equipment is a constraint. Temporary Keratoprosthesis has emerged as a valuable treatment modality to maintain ocular health and prevent irreversible vision loss. Existing research demonstrates substantial heterogeneity in both functional and anatomical outcomes, with pronounced disparities evident in complication profiles, corneal graft survival and visual outcomes.<sup>12</sup>

A clear view of cornea is crucial for optimal vitreoretinal surgical outcomes. In cases of corneal opacities, TK provides an alternative by facilitating clear surgical visualization in patients with corneal opacities.<sup>13</sup> The temporary keratoprosthesis provides a surgical environment akin to standard vitreoretinal surgery, depth perception, coordinated instrument use, wide-angle views, and a controlled surgical field.<sup>14</sup>

In our retrospective analysis, the mean age of the participants was  $39.27 \pm 15.88$  years ranging from a minimum of 14 years to a maximum of 63 years. A male-to-female ratio of 2:1 was observed demonstrating male predominance in the study sample. The primary reasons for surgery in over half of the cases were corneal laceration with retinal detachment (53.3%). The most common cause of corneal laceration is high-impact injuries involving objects like sharp tools, metal fragments, or even everyday items such as fingernails. These are reported as causes of ocular injuries in the previous reports as well.<sup>15-17</sup> According to another study, intraocular foreign bodies were the cause of injury in 50% of cases.<sup>6</sup>

In our study, the visual acuity was either improved, decreased, or remained stable. In contrast, a 2024 study reported exclusively improved or stable visual acuity without instances of decline.<sup>12</sup> This may be attributed to the absence of complications such as raised IOP, proliferative vitreoretinopathy and phthisis which were found in our study. They did not report

any such complications in their study. In another study, the Eckardt-style temporary keratoprosthesis was utilized in six cases involving five eyes undergoing simultaneous penetrating keratoplasty and pars plana vitrectomy. This device ensured optimal visualization of posterior and peripheral intraocular structures while maintaining a closed system

throughout the procedure.<sup>18</sup>

Functional vision was achieved in cases where final visual acuity was HM or better. Visual acuity improved or remained stable in 86.6% of cases in the present study. These findings align with a retrospective case series from a New Jersey hospital, where visual acuity maintained or improved in 80% of patients.<sup>19</sup> Another study comparing improvement or stability of visual acuity found higher rates in the ocular trauma cases (86%) than in non-trauma cases (78%).<sup>20</sup>

Normal postoperative intraocular pressure was observed in 10(66.6%) patients, while the other 5 cases had a high IOP. These results align with a previous study demonstrating normotensive IOP in 62.5% of patients following combined vitreoretinal surgery and temporary keratoprosthesis surgery.<sup>1</sup> The retina was detached in more than half of the patients (53.3%) while the rest of the patients had attached retina (46.7%). This finding is contradictory to a study where 75% of the cases had retinal attachment.<sup>1</sup>

Postoperative complications are primarily determined by the severity of the initial condition and the intricacy of the surgical procedure. Reported complications in literature encompass corneal graft failure, recurrent retinal detachment, phthisis bulbi, persistent hypotony and proliferative vitreoretinopathy.<sup>7</sup> Our study identified graft failure, macular atrophy, macular scarring, recurrent RD, phthisis and PVR as postoperative complications. A primary challenge following this complex surgical intervention is the elevated risk of graft failure. Additional surgical procedures performed concurrently with penetrating keratoplasty can intensify and prolong inflammation, thereby increasing the risk of graft rejection. To potentially mitigate this risk, the donor cornea transplantation can be delayed by temporarily replacing the trephined corneal button.

Majority of the patients had post operative opaque cornea 11(73.3%) while 4(26.7%) had postoperative clear graft. Our results are consistent with the finding reported in a study in which graft failure was reported in 60% of the case.<sup>7</sup> However, another study utilizing retrospective analysis of cases reported that only 37.5% had graft failure and 62.5% had clear graft.<sup>1</sup> Variations in graft failure rates may be ascribed to differences in patient ophthalmological profiles, heterogeneous group characteristics, and the diversity of surgical interventions and the quality of the graft.

The optimal timing for surgical intervention following ocular trauma remains a subject of debate. While delaying surgery to minimize graft rejection risk has been proposed, this approach may compromise visual function due to delayed retinal management. Our findings indicate a significantly shorter mean time from trauma to surgery in case of unsuccessful cases. There was a significant association between successful and unsuccessful cases in terms of interval between injury and presentation. These findings are consistent with an earlier study with retrospective evaluation of cases, where there was a significant association between successful and failed cases in terms of time to surgery (p value = 0.043).<sup>1</sup>

The study was limited by its retrospective design and small sample size (n=15), which inherently constrained the ability to establish causal relationships and generalize findings to a broader population. Moreover, the absence of a control group precluded a rigorous assessment of the intervention's efficacy. These methodological constraints necessitate cautious interpretation of the results and emphasize the need for larger, prospective studies to elucidate the treatment's impact.

## CONCLUSION

The results of this study underscore the challenges associated with managing open-globe injuries and highlight the need for further research to improve patient outcomes. However, despite the challenges, temporary keratoprosthesis in facilitating penetrating keratoplasty and vitreoretinal surgery remains a viable option.

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**Patient's Consent:** Researchers followed the guidelines set forth in the Declaration of Helsinki.

**Conflict of Interest:** Authors declared no conflict of interest.

**Ethical Approval:** The study was approved by the Institutional review board/Ethical review board (IRB/2024-1076).

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