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ORIGINAL RESEARCH ARTICLE

A study on Indications and Outcome of Penetrating Keratoplasty in a Tertiary Care Hospital

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ABSTRACT

Introduction: Penetrating keratoplasty (PK) is the standard surgical procedure for restoring vision in patients with severe corneal diseases. This study evaluates the indications and outcomes of PK in a tertiary care hospital setting.

Material and Methods: A prospective observational study was conducted at Shri Ram Murti Smarak Institute of Medical Sciences from August 2022 to January 2024, including patients aged 18 years and older who presented with corneal opacity. Data collection included demographic profiles, clinical histories, and post-operative outcomes, analyzed using statistical software.

Results: Among 79 patients, 62 (78.5%) were male, with corneal ulcers being the leading indication (46.8%). Notably, patients aged 61 to 65 years had the highest incidence of corneal ulcers (55.2%). Trauma was significantly associated with the need for PK (Chi-square: 45.5, $p < 0.001$), while diabetes showed no significant correlation. Visual acuity significantly improved post-operatively, with 64.6% achieving better outcomes at three months. Complications were noted in 17.7% of patients, with loose sutures being the most common (8.9%).

Conclusion: PK is effective in improving visual outcomes, especially in cases of corneal ulcers. However, careful monitoring of complications, particularly in patients using steroids, is crucial for enhancing surgical success.

Keywords: Penetrating keratoplasty, Corneal disease, Visual acuity, Complications, Trauma, Diabetes, Surgical outcomes.

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INTRODUCTION

Penetrating keratoplasty (PK), commonly referred to as full-thickness corneal transplantation, remains a vital procedure for restoring vision in patients with corneal diseases. It involves the replacement of a diseased or damaged cornea with a donor corneal graft and is employed when other surgical options, such as lamellar keratoplasty, are not viable.[1,2] Despite the advancements in corneal surgical techniques, penetrating keratoplasty continues to be the gold standard for treating a variety of corneal conditions, especially those involving full-thickness corneal pathology.

Indications for penetrating keratoplasty have evolved over the years, with corneal scarring due to trauma or infection, keratoconus, pseudophakic bullous keratopathy, and corneal dystrophies remaining the most common reasons for performing this surgery.[3,4] In developing countries like India, infectious keratitis, often secondary to trauma or poor contact lens hygiene, is a significant cause of corneal blindness, necessitating PK.[3,5] With the increase in aging populations and the rise in cataract surgeries, conditions like pseudophakic bullous keratopathy have also contributed significantly to the indications for PK.

The success of penetrating keratoplasty largely depends on factors such as the underlying corneal pathology, donor tissue quality, and post-operative management. While graft survival rates are high in non-inflammatory conditions like keratoconus, they tend to be lower in patients with infectious or inflammatory corneal diseases due to the heightened risk of graft rejection and recurrence of infection.[6]

This study aims to evaluate the indications and outcomes of penetrating keratoplasty at a tertiary care hospital. By analyzing the common causes leading to PK and the post-operative visual outcomes, complications, and graft survival rates, this research intends to provide a comprehensive understanding of the role and success of PK in treating corneal disorders. Insights from this study may aid in optimizing patient selection, improving surgical outcomes, and guiding post-operative care to enhance the long-term success of corneal transplantation.

MATERIAL AND METHODS

This study was conducted after obtaining approval and clearance from the Institutional Ethical Committee of Shri Ram Murti Smarak Institute of Medical Sciences, Bareilly, Uttar Pradesh. It was a prospective observational study aimed at evaluating the common indications and outcomes of penetrating keratoplasty (PK) in patients attending the Ophthalmology Outpatient Department (OPD). The study period was extended from August 1, 2022, to January 31, 2024.

The study population consisted of all patients aged 18 years or older who presented with corneal opacity during the study period and met the inclusion criteria. These patients were selected from the ophthalmology department, and those who consented to participate were included. The inclusion criteria comprised patients undergoing PK for optical, therapeutic, or tectonic indications. Exclusion criteria included patients unwilling to participate, those with secondary glaucoma, no perception of light, high myopia with degenerative changes, regrafting cases, excessive corneal vascularization, congenital conditions (such as rubella syndrome or Peter's anomaly), and those with complications such as vitreous hemorrhage, retinal detachment, or endophthalmitis as determined by clinical or imaging findings.

Data collection was performed using a structured proforma, which documented patients' demographic profiles, clinical history, pre-operative assessments, and post-operative outcomes. Detailed histories were obtained, including the onset and progression of visual loss, trauma or chemical injury, congenital or acquired conditions, and association with pain or prolonged medication use. Previous ocular surgeries, the site and extent of corneal opacity, and socioeconomic status were also recorded.

Clinical examinations included assessing visual acuity with Snellen's chart, evaluating pupil reactivity, and conducting slit lamp biomicroscopy to analyze corneal opacity, epithelial defects, vascularization, infiltrates, and edema. A fundus examination was performed to check the health of the retina and optic nerve, while B-scan ultrasonography was used to evaluate the posterior segment in cases with media opacity. This comprehensive assessment provided valuable insights into the patient's ocular health.

For statistical analysis, categorical variables were presented as numbers and percentages, while continuous variables were summarized as means ± standard deviations (SD). Quantitative data were analyzed using ANOVA, while qualitative data were evaluated using Chi-square tests, with Fisher's exact test applied when necessary. A *p-value* of less than 0.05 was considered statistically significant. The data were entered into Microsoft Excel and analyzed using SPSS software version 25.0.

A pilot study was conducted on 10 patients to assess the feasibility and reliability of the research tools and methodology. Reliability and validity were ensured by selecting clinical parameters based on established literature and expert opinions relevant to the study's objectives.

RESULTS

Among the total patients, 62 were male and 17 were female. Corneal ulcer was more common in both males (45.2%) and females (52.9%). Most patients with PBK were aged ≤55 years (42.9%), while corneal ulcers were prominent in older age groups (47.1% in 56–60 years and 55.2% in 61–65 years). In 29.1% of patients had diabetes, with the highest association seen in those with corneal ulcers (47.8%). Trauma was present in 46.8% of patients, most frequently linked to corneal ulcers (86.5%), with a statistically significant association ($p < 0.001$). Steroid use was documented in 49 patients, with the highest proportion observed in corneal ulcers (46.9%) and PBK (34.7%). Complications were reported in 14 cases, with the highest rate seen in spheroidal degeneration (21.4%) and corneal ulcers (42.9%) (Table 1).

Table 2 summarizes the visual acuity outcomes in patients undergoing keratoplasty. The visual acuity outcomes of patients undergoing surgery were assessed both pre-operatively and post-operatively. Prior to surgery, a significant proportion of patients demonstrated poor visual acuity, with 38 patients (48.1%) having a visual acuity of 3/60. Other notable pre-operative assessments included 16 patients (20.3%) with a visual acuity of 2/60, 7 patients (8.9%) with a visual acuity of 1/60, and 10 patients (12.7%) classified as having a visual acuity of 1/2/60. Only eight patients (10.1%) exhibited "PL present, PR accurate" vision, indicating a minimal level of visual perception.

In contrast, post-operative evaluations revealed a substantial improvement in visual acuity. The most notable change was seen in the "PL present, PR accurate" category, which increased significantly to 53 patients (67.1%). However, the group with a visual acuity of 2/60 saw a decrease, with only six patients (7.6%) reported post-operatively. Meanwhile, the visual acuity categories of 1/60 and 1/2/60 saw limited representation post-operatively, with 12 patients (15.2%) recorded at 1/2/60 and eight patients (10.1%) at 1/60. Importantly, data for the 3/60 category was not available following surgery. These results highlight a general trend towards improved visual outcomes following surgical intervention, indicating the

Table 1: Distribution of patient characteristics, risk factors, and complications across different corneal indications

Variable	*Corneal dystrophy*	*Corne al ulcer*	*Corne all opacity*	*Pseudo phakic bullous keratopathy*	*Spheroidal degeneration*	*Total*	*Statistics cs (Chi-square, p-value)*
Male	5 (8.1%)	28 (45.2%)	1 (1.6%)	20 (32.3%)	8 (12.9%)	62	0.47
Female	2 (11.8%)	9 (52.9%)	1 (5.9%)	5 (29.4%)	0 (0.0%)	17	
Age ≤55	3 (14.3%)	6 (28.6%)	1 (4.8%)	9 (42.9%)	2 (9.5%)	21	0.84
Age 56–60	1 (5.9%)	8 (47.1%)	0 (0.0%)	6 (35.3%)	2 (11.8%)	17	
Age 61–65	2 (6.9%)	16 (55.2%)	1(3.4%)	8 (27.6%)	2 (6.9%)	29	
Age ≥66	1 (8.3%)	7 (58.3%)	0 (0.0%)	2 (16.7%)	2 (16.7%)	12	
Diabetes (n = 23, 29.1%)	2 (8.7%)	11 (47.8%)	1 (4.3%)	6 (26.1%)	3 (13.0%)	23	0.90
Trauma (n = 37, 46.8%)	0 (0.0%)	32 (86.5%)	1 (2.7%)	3 (8.1%)	1 (2.7%)	37	<0.001 *
Steroid use	5 (10.2%)	23 (46.9 %)	2 (4.1%)	17(34.7%)	2 (4.1%)	49	-
Complications	2 (14.3%)	6 (42.9 %)	1 (7.1%)	2 (14.3%)	3 (21.4%)	14	-

Table 2: Pre-op *vs.* post-op visual acuity

Visual acuity	*Pre-op*	*Post-op*
PL presents PR accurate	8 (10.1)	53 (67.1)
1/2/60	10 (12.7)	12 (15.2)
1/60	7 (8.9)	8 (10.1)
2/60	16 (20.3)	6 (7.6)
3/60	38 (48.1)	NA

Table 3: Complications and their incidence

Complication	*n (%)*
Persistent epithelial defects	3 (3.8)
Loose or protruding sutures	7 (8.9)
Wound leak	2 (2.5)
Uveitis	3 (3.8)
Traumatic graft rupture	1 (1.3)
Microbial keratitis	4 (5.1)
Endophthalmitis	3 (3.8)
Graft failure	2 (2.5%)

potential effectiveness of the procedure in enhancing patients' visual acuity.

Table 3 presents the complications encountered in patients following keratoplasty, along with their respective incidence rates. The most frequently observed complication was loose or protruding sutures, affecting seven patients (8.9%). This was followed by microbial keratitis, which occurred in 4 patients (5.1%).

Other complications included persistent epithelial defects and uveitis, each affecting three patients (3.8%). Wound leaks were reported in 2 patients (2.5%), as well as graft failure, which also occurred in 2 patients (2.5%). Traumatic graft rupture was relatively rare, with only one patient (1.3%) experiencing this complication.

DISCUSSION

In our study, males were more prevalent in younger age groups, whereas females were predominant in the oldest group. Specifically, in the ≤55 age group, males comprised 26% compared to females at 29%. Males made up 23% in the 56 to 60 age group, 39% in the 61 to 65 age group, while females represented 24% in the ≥66 age group compared to 13% for males. In contrast, Singh *et al*. reported a higher mean recipient age of 46.56 years (± 16.02 years) with a similar male-to-female ratio of 1.57:1, while Tabin *et al*. noted a lower mean recipient age of 39.2 years (± 19.7 years) compared to our findings.[7] Thompson *et al*.'s study had a significantly higher mean recipient age of 67 years (range, 1–98 years) compared to our study.[8] Bajracharya *et al*. observed a slightly lower mean recipient age of 41.7 ± 19.9 years compared to our study, with a similar trend of more men undergoing keratoplasty than women.[9]

In this study, females had a slightly higher prevalence of corneal dystrophy (11.8%) and corneal ulcers (52.9%) than males (8.1 and 45.2%, respectively), while both genders were equally represented in post-penetrating keratoplasty cases. Males showed a higher incidence of pseudophakic bullous keratopathy (32.3%), and cases of spheroidal degeneration were exclusive to males (12.9%). Corneal ulcers were the leading indication for surgery across all age groups, especially in those aged 61 to 65 (55.2%) and ≥66 (58.3%), with a history of diabetes mellitus not significantly influencing the indications for penetrating keratoplasty. According to Kozioł *et al*., DM is a significant ocular condition that can impair vision quality and increase the risk of post-operative complications.[10] Blanco *et al*. suggest that utilizing donor tissues from individuals with a history of diabetes mellitus could reduce success rates, as both DM1 and DM2 in donors may affect the functional phenotype of corneal antigen-presenting cells, increasing the likelihood of graft failure.[11]

In this study, females had higher rates of corneal dystrophy (11.8%) and corneal ulcers (52.9%) compared to males (8.1 and 45.2%), while both genders were equally

represented in post-penetrating keratoplasty (PKP) cases. Males showed a greater prevalence of pseudophakic bullous keratopathy (32.3%), and spheroidal degeneration was exclusive to males (12.9%). Corneal ulcers were the leading indication for surgery, particularly in those aged 61-65 (55.2%) and ≥66 (58.3%).

Tabin *et al*. found that corneal opacity (37%) and adherent leukoma (35%) were the main indications for PKP.[7] Randleman *et al*. reported similar trends, with failed graft (29.1%) and bullous keratopathy (21.5%) as common reasons.[12] Patel *et al*. highlighted pseudophakic bullous keratopathy (27%) and failed graft (20%) as significant indications before regraft.[3] Chen *et al*. noted keratoconus (66.1%) as the primary indication for surgery.[13]

Bajracharya *et al*. identified active infectious keratitis (40.9%) as the most common indication,[9] while Ayalew *et al*. reported trachoma or leukoma (44%) as notable causes.[14] Thompson *et al*. emphasized pseudophakic bullous keratopathy (32%) and Fuchs' dystrophy (23%),[8] and Qing Pan *et al*. found herpes simplex keratitis (24.1%) to be a common reason for PK.[15]

In this study, most participants had poor uncorrected visual acuity (UCVA) pre-surgery, with 48.1% at level 3/60 for distant vision; however, by three months post-surgery, 64.6% showed significant improvement, and 75.9% achieved accurate light perception for near vision. Supporting this, Ayalew *et al*. noted a similar improvement in UCVA from a mean logarithm of 2.09 (SD 0.67) before surgery to 1.53 (SD 1.03) after two years.[14] Other studies reported varied outcomes, with Wagoner *et al*. finding vision improvement in 82.4% of eyes post-keratoplasty,[16] while Randleman *et al*. observed that 41% achieved best-corrected visual acuity between 20/20 and 20/40.[12]

In this study, the majority of patients (over 90%) did not experience complications after surgery, with the highest rates of issues being 8.9% for loose or protruding sutures and 5.1% for microbial keratitis. Common causes of graft failure noted by Tabin *et al*. included endothelial failure (43%) and increased intraocular pressure (15%)[7]

In Randleman *et al*., it was found that a significant portion, specifically 64.6%, of the grafts remained transparent, indicating successful outcomes post-surgery. This suggests that the majority of patients experienced positive results regarding graft clarity. [12]

Patel *et al*. found that 25% of regrafts failed over an observation period of 1 to 7.5 years, with 11% failing within the first six months and 55% within 18 months. However, among those who followed for two years, 74% had clear grafts, suggesting a favorable long-term success rate. [3] Similarly, Randleman *et al*. reported that nearly half of the cases achieved visual acuity of 20/40 or better post-surgery, with 45% reaching acuities between 20/50 and 20/150, while about 7.5% had acuities of 20/200 or worse, highlighting the variability in visual outcomes after the procedure. [12]

Thompson *et al*. documented a 10% incidence of graft failure, with endothelial failure and immunologic endothelial rejection identified as the most common causes. Furthermore, the study revealed the global mean graft survival rates at distinct time intervals, indicating the overall success rates of the procedure.[8]

In our study, we found no significant differences in complication rates post-penetrating keratoplasty across gender, age groups, or diabetes mellitus history, with overall complication-free rates at 82.3%. However, steroid use showed a significant association, with 24.5% of patients using steroids experiencing complications ($p = 0.04$). In contrast, Randleman *et al*. noted variations in graft clarity based on indications, with keratoconus showing the highest success rate for achieving 20/40 vision or better. [12]

Vanathi *et al*. identified infection as the leading cause of regraft failure, with 9 cases of recurrent herpetic infection and three instances of perforated graft ulcers, highlighting the need for careful monitoring post-surgery.[17] Chen *et al*. reported a one-year graft survival rate of 89.9% for keratoconus, with 85.3% of patients experiencing improved uncorrected visual acuity after surgery.[13] Ayalew *et al*. noted an overall graft survival rate of 80% at two years, varying by surgery indication,[14] while Bajracharya *et al*. found that 59.8% of eyes with infectious keratitis had perforated corneal ulcers, with bullous keratopathy being a key indication for older patients and keratoconus prevalent in younger children.[9]

In Rahman *et al*.'s study, around 21% of donor grafts experienced endothelial rejection, and 18% of patients developed glaucoma after penetrating keratoplasty, with an 8% incidence of microbial keratitis observed in 16 grafts.[6] Wagoner *et al*. highlighted a significant association between corneal edema and an increased risk of graft failure, particularly related to older donor age ($p = 0.004$) and the presence of complications ($p < 0.001$). [16]

CONCLUSION

In conclusion, this study highlights the demographics and clinical outcomes of keratoplasty patients, revealing that corneal ulcers are the most common indication, particularly among male and older patients. While trauma emerged as a significant predictor for keratoplasty, diabetes did not show a strong association with the type of procedure required. Importantly, patients demonstrated substantial improvements in visual acuity post-operatively, although complications, particularly

related to steroid use, warrant careful monitoring. These findings underscore the importance of targeted patient management to optimize surgical outcomes and minimize potential risks following keratoplasty.

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