

Comparison of Visual Outcome of Successful Descemet Membrane Endothelial Keratoplasty and Penetrating Keratoplasty

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ABSTRACT

Objective: To compare the visual outcome in patients undergoing penetrating keratoplasty (PKP) with descemet membrane endothelial keratoplasty (DMEK).

Study Design: A quasi-experimental study.

Place and Duration of the Study: Department of Eye, The Armed Forces Institute of Ophthalmology, Rawalpindi, Pakistan, from January 2022 to June 2023.

Methodology: A prospective analysis of fourteen patients who underwent PKP in comparison with another group of fourteen patients who got the DMEK surgery was done. The evaluation of visual and refractive outcomes was done postoperatively. Fisher's exact test was used to compare visual acuity grouped into categories between two surgical procedures.

Results: Fourteen eyes from each group that were PKP and DMEK were included in the analysis. The best corrected visual acuity after 6 months was better in the DMEK group compared with the PKP group ($p = 0.003$) and these results were consistent after twelve months ($p = 0.006$) keeping the DMEK group superior in visual outcome over the PKP group.

Conclusion: PKP and DMEK play distinct roles in the treatment of corneal disorders, each with its own set of indications. However, DMEK resulted in a better visual outcome when compared to the PKP. Although quality of life improved in both groups, it was found to be better in the DMEK group compared to the PKP group.

Key Words: Visual acuity, Descemet membrane endothelial keratoplasty, Penetrating keratoplasty, Corneal transplant.

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INTRODUCTION

As the most frequently performed organ transplant globally, corneal transplant techniques have evolved over the decades.¹ Full-thickness corneal transplantation, penetrating keratoplasty (PKP), remains the gold standard for the treatment of corneal blindness, despite the introduction of the novel surgical techniques of lamellar keratoplasties.^{2,3} These techniques include deep anterior lamellar keratoplasty (DALK), Descemet membrane endothelial keratoplasty (DMEK) where the selective transplantation of Descemet's membrane and endothelium is done, and Descemet's stripping automated endothelial keratoplasty (DSAEK), in which the Descemet membrane and endothelium are replaced with a thin layer of donor stroma, Descemet membrane and endothelium.²

Moreover, the technique of PKP has also undergone modifications to reduce risks associated with it, such as immune rejection, delay in wound healing, refractive surprise, suboptimal visual outcome, and high or irregular astigmatism.³

In spite of these modifications, the visual outcomes remain suboptimal. Lamellar keratoplasty (LK) techniques were invented in an effort to minimise these risks leading to poor visual outcomes. Immune rejection, astigmatism, and wound-related complications have gone down substantially. Above all, visual outcomes were also reported to be better in internationally published data. A retrospective study done between 2000 and 2020 in a French corneal transplantation unit proved that DMEK has replaced PKP for Fuchs' endothelial corneal dystrophy (FECD) and in cases where the anterior segment is normal with an intact posterior capsule.⁴ Some studies have shown that not only the clinical measures but also the vision-related quality of life assessed by questionnaires months after PKP and DMEK have reported an improvement, with not much difference in the vision of the two during long-term follow-up.⁵⁻⁸ However, limited studies have been conducted in Pakistan to evaluate the results of this LK in Pakistani population. Therefore, these results will be a contribution to the already available literature.

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This study was performed to evaluate and compare the visual outcome of patients undergoing PKP and DMEK in terms of visual acuity at 6 months and 12 months after the procedure.

METHODOLOGY

A quasi-experimental study was conducted at the Armed Forces Institute of Ophthalmology, Rawalpindi, Pakistan, from January 2022 to June 2023. The study sought ethical approval from the Institutional Review Board prior to starting participant enrolment. Ethics guidelines of good clinical practice and Helsinki's principles were followed. The minimum required sample size was calculated to be 28, using the 'OpenEpi online sample size calculator' considering the odds ratio of 22.2 for positive family history as risk factor for Keratoconus (being the most common indication for the corneal transplant),⁹ 5% risk of disease in patients unexposed to strong family history,⁹ 95% level of confidence, 5% alpha error, and 80% study power.

Twenty-eight consecutive patients, who planned to undergo either PKP or DMEK as per indications in accordance with guidelines, were included in this study. All the patients attended the corneal unit at the Ophthalmology department of the hospital from where they were recruited. The exclusion criteria covered all the factors that could be a source of low visual potential other than those related to the cornea, including uveitis, any manifest cataract, posterior capsular opacities, vitreous or retinal abnormalities, and all those eyes that had been vitrectomised. For DMEK, patients with a stromal subepithelial opacity were also excluded. Patients who were unable to understand or follow the instructions required for objective refraction were also excluded from this study. All patients received the information regarding the transplant, the complications associated with it and the frequent follow up required after the transplant. Written informed consent was obtained.

Patients underwent careful preoperative evaluation; field experts decided the most suitable procedure for the patients, either PKP or DMEK. All Corneas were imported from the USA and transplanted before their expiry date by the same expert surgeon. They were stored and transported in Optisol-GS (corneal storage medium) at the optimum temperature. Preoperative visual acuity (VA) and the best-corrected visual acuity (BCVA) were measured using Snellen's Chart and were converted to the logarithm of the minimum angle of resolution units (logMAR) chart for statistical analysis. The same was done at 6-month and 12-month follow-ups postoperatively. Refraction was done by the same experienced optometrist who was blinded to the type of surgery the patients had undergone to minimise the assessor's bias. All patients were followed up, at 6 month and 12 month following their surgery. Questionnaires were filled-out by the patients or their attendants accompanying them in the presence of an observer who was not aware of the type of surgery they had undergone. At these follow-ups, all patients were also asked about their satisfaction related to VA.

The data were managed and analysed by using the Statistical Package for Social Sciences (IBM SPSS version 23.0). The normality of data was assessed visually by histogram and statis-

tically by using the Shapiro-Wilk's test which indicated that the data were not normally distributed. The descriptive statistics were performed and reported as median and IQR for continuous variables, while frequency and percentages were reported for categorical variables. Median age was compared between the two groups using the Mann-Whitney U test. The VA values were grouped into categories and were compared between two surgical procedures using the Fisher's exact test. A p-value of less than 0.05 was considered statistically significant.

RESULTS

There were 28 patients included in the study, with 11 (39.3%) females and 17 (60.7%) males. The median age was reported to be 60 years with an interquartile range of 22 years. Majority of the participants, i.e. 12 (42.9%) belonged to the age group of 41-65 years. In the PKP group (n = 14) there were 9 (64.2%) males and 5 (35.7%) females, while in the DMEK group (n = 14) there were 8 (57.1%) males and 6 (42.8%) females. Table I shows the baseline characteristics of study participants belonging to both groups.

The overall distribution of various indications between the two study groups is given in Figure 1. The DMEK group included all fourteen patients presenting with pseudophakic bullous keratopathy, while in PKP group, 3 (21.4%) patients had pseudophakic bullous keratopathy, in addition to 6 (42.8%) with keratoconus with stromal scar, 2 (14.2%) with unknown cause of scarring, 2 (14.2%) with corneal dystrophy, and 1 (7.1%) with post-trauma scar.

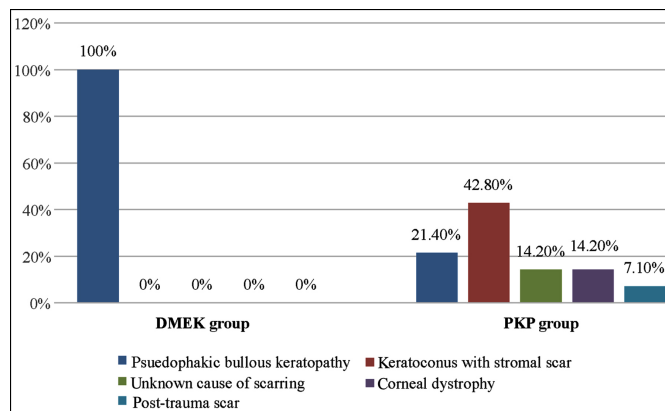


Figure 1: Distribution of indications between the two study groups.

Figure 2 shows a preoperative and 6-month postoperative comparison of an eye with pseudophakic bullous keratopathy that underwent DMEK surgery. Figure 3 shows the preoperative and 6-month postoperative comparison of an eye with corneal opacity that underwent PKP surgery.

The preoperative BCVA in the logarithm of the minimum angle of resolution units (logMAR) is given in Table I for DMEK and PKP groups. The postoperative BCVA after 6 months and 12 months is shown in Table II. At both 6 months and 12 months, a significant difference in the visual outcome was reported between the two study groups, where a higher number of participants in the DMEK group had VA of 0-0.3.

Table I: Baseline characteristics of study participants (n = 28).

Characteristics	Overall (n = 28)	DMEK Group (n = 14)	PKP Group (n = 14)	p-value
Median age, IQR	60, 22	64.5, 16.25	50.5, 46.25	0.164 ^a
Age groups				0.006 ^{*b}
<18 years	3 (10.7%)	0 (0%)	3 (21.4%)	
18-40 years	4 (14.3%)	0 (0%)	4 (28.6%)	
41-65 years	12 (42.9%)	10 (71.4%)	2 (14.3%)	
>85 years	9 (32.1%)	4 (28.6%)	5 (35.7%)	
Gender				1.000 ^b
Male	17 (60.7%)	8 (57.1%)	9 (64.3%)	
Female	11 (39.3%)	6 (42.9%)	5 (35.7%)	
Preoperative VA				0.463 ^b
0.8 - 1.0	1 (3.6%)	0 (0%)	1 (7.1%)	
1.1 - 1.3	4 (14.3%)	1 (7.1%)	3 (21.4%)	
1.4 - 1.9	8 (28.6%)	5 (35.7%)	3 (21.4%)	
2.0 - 2.3	15 (53.6%)	8 (57.1%)	7 (50.0%)	

*Significant p-value, ^aMann-Whitney U-test, ^bFisher's exact test.

Table II: Comparison of postoperative BCVA at 6-month and 12-month (n = 28).

	Postoperative best-corrected visual acuity at 6-month					p-value
	0 to 0.3	0.4 to 0.7	0.8 to 1.0	1.1 to 1.3	1.4 to 1.9	
DMEK	5 (35.7%)	6 (42.9%)	1 (7.1%)	2 (14.3%)	0 (0%)	0.003 ^{*a}
PKP	0 (0%)	1 (7.1%)	1 (7.1%)	9 (64.3%)	3 (21.4%)	
	Postoperative best-corrected visual acuity at 12 month					p-value
DMEK	5 (35.7%)	3 (21.4%)	3 (21.4%)	3 (21.4%)	0 (0%)	
PKP	0 (0%)	0 (0%)	2 (14.3%)	8 (57.1%)	4 (28.6%)	

DMEK: Descemet membrane endothelial keratoplasty, PKP: Penetrating keratoplasty. *significant p-value, ^aFisher's exact test.

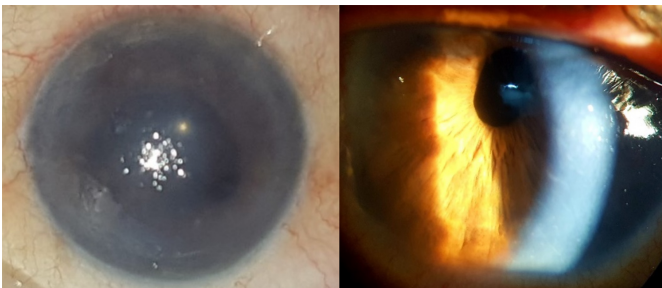


Figure 2: The preoperative and 6-month postoperative photograph of an eye with pseudophakic bullous keratopathy that underwent DMEK.

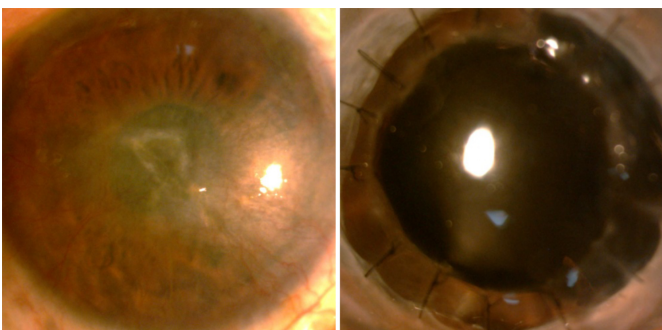


Figure 3: The preoperative and 6-month postoperative photograph of an eye with corneal opacity that underwent PKP.

DISCUSSION

PKP has been used as a treatment option for a multitude of corneal diseases over the years, however, in 2006, Melles *et al.*¹⁰ proposed that the diseased endothelium could be replaced by the healthy donor endothelium, and this was presented as DMEK. DMEK has the added advantage of

replacing only the diseased corneal endothelium, thus drastically reducing the risk of graft rejection.^{11,12} Published literature has proven that with endothelial keratoplasties, the risk of graft rejection is low and the visual outcome is better as compared to the PKP.¹³⁻¹⁵

Indications reported for corneal transplantation from January 2011 to December 2018 in Catalonia (Spain) included bullous keratopathy (BK; 1574; 20.5%), FECD and other endothelial dystrophies (1373; 17.9%), re-graft due to endothelial failure (1051; 13.7%), and keratoconus (865; 11.3%). Of these keratoplasties, 63.4% were PKP, which was mostly done in the BK patients, while DMEK was their procedure of choice for the FECD.¹⁶ These indications are different from the present study's as there is a low prevalence of FECD and other corneal dystrophies in Pakistan.

Research showed that the preoperative vision in 99 eyes that underwent DMEK was better in the Western population as compared to the Pakistani population. No patient in this study had a BCVA better than 1.1 LogMAR; however, in their study, 71 (72%) had a best-corrected acuity worse than 20/40 Snellen's (0.3 LogMAR), while 28 (28%) had a BCVA better than 20/40 Snellen's (0.3 LogMAR).¹⁷ Similarly, for PKP, the studies reported a better vision in the patients who underwent PKP as compared to the present data.¹⁸ This is because of the difference in the indications for the transplant between the two populations. Other factors include the late time of patient presentation in Pakistan and the delay after which the patient actually undergoes the transplant.

Vasiliauskaite *et al.* evaluated the ten-year survival probability and the visual outcome of the DMEK graft and concluded that, in addition to a satisfactory survival of the grafts, there was a remarkable BCVA over the years. Using Snellen's chart, it reported that 98% had BCVA >20/40 (0.3 LogMAR), 89% had BCVA >20/25 (>0.1 LogMAR), and 64% had BCVA >20/20 (0.00 LogMAR)¹⁷. Yuksel *et al.* revealed in their study that patients who underwent PKP showed an improvement in BCVA from 3.00-0.54 LogMAR preoperatively to 1.30-0.00 LogMAR after one year.¹⁸ Although, the results of the above two studies cannot be compared as they were conducted in different hospitals keeping a different sample size, both revealed that DMEK was a superior procedure to PKP as far as BCVA is concerned.

In the present study, the aim was to compare the subjective refraction done in patients who were intervened with the DMEK vs. the PKP group. Twenty-eight eyes of 28 patients underwent either of the surgical procedures and the VA observed at 6 months and 12 months showed improvement in both the groups. However, remarkable improvement was observed in the DMEK group as detailed in the results. Six months postoperative, all patients were asked about their satisfaction related to VA. A positive patient satisfaction was reported postoperatively, except for those who had a graft failure, and their vision remained poor. Patients who underwent DMEK reported quick visual recovery, enabling them to perform their daily tasks in the early postoperative period, in contrast to the PKP group, where this ability was achieved after a longer period.

Despite the challenges, the advancement of DMEK surgery by well-trained surgeons is playing a pivotal role in the restoration of the vision.¹⁹ An anonymous survey done by Alnahdi *et al.* showed the frequency of DMEK being done relied strongly on the expertise of local surgeons as well as the availability of corneal a bank, thereby elaborating that DMEK was not a common procedure in South Asia.²⁰

This study had a few limitations. There could be a selection bias as there was no randomisation. Although the frequency of DMEK surgery is gaining momentum, still total number of patients undergoing this complicated surgery is limited. This led to a relatively smaller sample size, which might have affected the statistical power. However, it is observed that similar limitations in comparable studies published internationally exist.^{21,22}

CONCLUSION

In spite of the study limitations, a statistically significant difference between the two groups proves that DMEK is a superior procedure as far as recovery time and quality of vision are concerned. Efforts must be made to train the surgeons and paramedical staff to enable them to conduct this surgical procedure in their hospitals across the country.

ETHICAL APPROVAL:

This study was carried out after obtaining approval from the Institutional Review Board and Ethical Committee of the hospital.

PATIENTS' CONSENT:

Informed consent was taken from all patients who participated in the study.

COMPETING INTEREST:

The authors declared no conflict of interest.

AUTHORS' CONTRIBUTION:

TAJ: Conception, design, drafting of the work, and critical review of the manuscript.

AH: Design, drafting of the work, data acquisition, analysis, and interpretation of data.

WM, SP, JA: Final approval of the manuscript.

MS: Design of the work.

All authors approved the final version of the manuscript to be published.

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