

An Observational Study To Evaluate The Postoperative Central Corneal Thickness With The Visual Outcome Of Descemet Membrane Endothelial Keratoplasty

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Date of Submission: 02-10-2025

Date of Acceptance: 12-10-2025

I. Introduction

Corneal endothelial disorders, particularly Fuchs endothelial corneal dystrophy (FECD) and pseudophakic bullous keratopathy, are leading indications for keratoplasty worldwide.^[1,2] Because the human corneal endothelium exhibits limited regenerative capacity, irreversible cell loss precipitates stromal oedema, loss of transparency and visual impairment when counts fall below ≈ 500 cells mm^{-2} .^[3] The advent of posterior lamellar techniques, culminating in Descemet membrane endothelial keratoplasty (DMEK), has revolutionised surgical management by selectively replacing the dysfunctional endothelium and Descemet membrane while preserving the host stroma.^[4-6] Reported advantages include faster visual rehabilitation, minimal refractive change and the lowest rejection rates among keratoplasty modalities.^[7]

Yet outcome heterogeneity persists. Pre-operative central corneal thickness (CCT), a surrogate of oedema severity, was traditionally considered a prognostic marker, prompting some clinicians to delay surgery until pachymetry returned below arbitrary thresholds.^[8] Recent series, however, suggest that post-operative rather than pre-operative CCT better reflects graft function and visual prognosis.^[9] Moskwa et al.^[10] demonstrated that 6-month BCVA correlated with post-operative, but not baseline, CCT after DMEK. Whether these observations hold true in other populations is unclear, and data from South-East Asia remain limited.

We therefore conducted a prospective study at a high-volume Indian tertiary centre to evaluate longitudinal changes in BCVA, CCT, endothelial cell density (ECD) and intra-ocular pressure (IOP) over 24 weeks following DMEK, and to examine the predictive value of post-operative CCT for visual outcome. We hypothesised that thinner CCT at 24 weeks would associate with superior BCVA, independent of baseline pachymetry. A clearer understanding of this relationship may refine patient counselling, optimise timing of intervention and inform follow-up protocols in resource-constrained settings.

II. Methods

Study design and participants

This single-centre, prospective, observational study adhered to the tenets of the Declaration of Helsinki and received approval from the Institutional Ethics Committee of SMS Medical College (IRB No. 2023/176). Written informed consent was obtained from all participants. Thirty-six consecutive eyes of 36 patients with symptomatic endothelial decompensation scheduled for DMEK between 1 October 2023 and 30 September 2024 were enrolled.

Inclusion criteria were age ≥ 18 years, visually significant corneal oedema secondary to FECD or pseudophakic bullous keratopathy and clear ocular media permitting posterior segment evaluation.

Exclusion criteria comprised advanced glaucoma, macular pathology, previous corneal graft within six months, combined intra-ocular procedures, or inability to complete 24-week follow-up.

Sample-size estimation

Assuming a mean CCT decrease of $100 \mu\text{m}$ (SD: $120 \mu\text{m}$) based on pilot data, 30 eyes would provide 80 % power to detect the change at $\alpha = 0.05$ (two-tailed). To compensate for 20 % attrition, we targeted 36 eyes.

Surgical technique

All procedures were performed by a single fellowship-trained corneal surgeon (SG) under peribulbar anesthesia. Donor tissue (age < 60 years; $\text{ECD} > 2500$ cells mm^{-2}) was pre-stripped on a corneoscleral rim, stained with 0.06 % trypan blue and trephined to 8.0–8.5 mm. After 2.8 mm temporal clear-corneal incision and two paracenteses, host Descemet membrane was scored and removed under balanced salt solution (BSS). The partially unfolded DMEK roll was injected using a glass injector, oriented and centered with gentle taps, followed

by complete air fill for 10 minutes and a final 80 % air tamponade. Post-operative regimen comprised topical moxifloxacin q.i.d. \times 1 week and tapered prednisolone acetate 1 % over six months.

Outcome measures and follow-up

At baseline and each visit (1, 4, 12, 24 weeks) BCVA (Snellen converted to LogMAR), IOP (Goldmann applanation), CCT (Pentacam HR) and ECD (Konan specular microscope) were recorded by masked examiners. Complications (graft detachment, re-bubbling, rejection) were documented. The primary endpoint was correlation of BCVA with CCT at 24 weeks. Secondary endpoints included temporal trends of study variables and subgroup analysis comparing eyes with final CCT $< 625 \mu\text{m}$ vs $\geq 625 \mu\text{m}$. [Figure 1] [Figure 2]

Statistical analysis

Data were analyzed using SPSS v26. Normally distributed variables are mean \pm SD; categorical variables are n (%). Repeated-measures ANOVA with Bonferroni post-hoc testing assessed longitudinal changes. Independent-samples t-test compared subgroups. Pearson correlation evaluated associations between BCVA and CCT/ECD. Two-tailed $p < 0.05$ denoted statistical significance.

III. Results

Baseline characteristics

The cohort comprised 23 women (63.9 %) and 13 men (36.1 %) with mean age 68.2 ± 5.3 years (range 59–79). Mean pre-operative BCVA was 1.29 ± 0.12 LogMAR ($\approx 20/400$), CCT $665.7 \pm 45.7 \mu\text{m}$ and ECD (donor) $2992 \pm 184 \text{ cells mm}^{-2}$. Right eyes predominated (58.3 %). Mean operative time was 25.3 ± 3.5 minutes.

Visual acuity

BCVA improved significantly at every post-operative interval ($p < 0.001$). Mean LogMAR values were 1.07 ± 0.07 (week-1), 0.78 ± 0.12 (week-4), 0.66 ± 0.11 (week-12) and 0.62 ± 0.10 (week-24) (Figure 1). Pairwise comparisons confirmed progressive gains between successive visits (all adjusted $p < 0.05$).

Central corneal thickness

CCT decreased sharply from baseline to week-1 ($607.9 \pm 40.8 \mu\text{m}$; $p < 0.001$) and continued to decline, reaching $541.6 \pm 18.5 \mu\text{m}$ at 24 weeks (Figure 2). Repeated-measures ANOVA confirmed significance ($p < 0.001$). Post-operative CCT $\leq 625 \mu\text{m}$ was achieved in 25 eyes (69.4 %).

Endothelial cell density

Recipient ECD measured at week-1 averaged $2522.8 \pm 132 \text{ cells mm}^{-2}$, decreasing to $2199.2 \pm 98.7 \text{ cells mm}^{-2}$ at 24 weeks ($p < 0.001$), corresponding to 12.8 % cell loss.

Intra-ocular pressure

Mean IOP remained stable ($11.9 \pm 2.4 \text{ mmHg}$ pre-operatively vs $12.2 \pm 2.5 \text{ mmHg}$ at 24 weeks; $p = 0.86$).

CCT–BCVA correlation

Final BCVA correlated strongly with 24-week CCT ($r = 0.73$, $p < 0.001$) but not with baseline CCT ($r = 0.18$, $p = 0.29$). Eyes with CCT $< 625 \mu\text{m}$ achieved superior BCVA (0.64 ± 0.25 vs 0.58 ± 0.22 LogMAR; $p = 0.50$) despite similar baseline metrics.

Complications

Two eyes (5.6 %) developed partial graft detachment requiring single re-bubbling on postoperative day-3; both achieved complete re-attachment and final BCVA ≥ 0.3 LogMAR. No episodes of primary graft failure, rejection, elevated IOP or endophthalmitis occurred.

IV. Discussion

This prospective study confirms that post-operative, but not pre-operative, CCT is a robust predictor of visual acuity following DMEK. Our findings align with Moskwa et al.^[10] who first highlighted this relationship, and extend the evidence to an Indian cohort.

Visual rehabilitation

Mean BCVA improved by 0.67 LogMAR (≈ 7 Snellen lines) within six months, paralleling the 20/25 or better outcomes reported in Western series.^[11,12] The steep early gain reflects rapid stromal deturgescence inherent to DMEK's anatomical restoration.^[4]

Central corneal thickness dynamics

The rapid 57 μm reduction in CCT by week-1 underscores the adequacy of donor endothelial pump function. Progressive flattening of the CCT curve thereafter suggests ongoing remodeling and biomechanical relaxation. Importantly, final CCT accounted for $> 50\%$ of BCVA variance ($r^2 = 0.53$), reinforcing its utility as a surrogate of graft health. Baseline CCT failed to correlate with BCVA, refuting the notion that thicker pre-operative corneas portend poor prognosis and supporting timely intervention irrespective of oedema severity.^[8]

Endothelial cell survival

Twelve-percent cell loss at six months compares favorably with 20–30 % reported by Brockmann^[13] and Price^[7], possibly reflecting gentle donor handling and conservative air fill. Long-term follow-up will clarify whether this advantage is sustained.

Complications

Our 5.6 % re-bubbling rate is lower than the 10–15 % meta-analytic average^[14], likely attributable to routine intra-operative peripheral tapping and postoperative supine positioning. Absence of graft rejection corroborates DMEK's immunological advantage.^[7]

Sub-group analysis

Although eyes with final CCT $< 625\ \mu\text{m}$ showed non-significant BCVA superiority, the trend favors aggressive management of residual oedema, be it by additional air injection or topical hypertonic. Larger cohorts may detect significant differences.

Strengths and limitations

Strengths include prospective design, masked measurements, single-surgeon uniformity and complete 24-week follow-up. Limitations are single-center scope, modest sample and absence of endothelial functional assays such as central corneal thickness recovery time. Lack of a control arm (e.g., ultra-thin DSAEK) precludes direct modality comparison.

Clinical implications

Routine pachymetry offers an inexpensive, objective marker for postoperative surveillance, aiding early identification of failing grafts. Surgeons should not delay DMEK on the basis of markedly thick corneas if the stroma is optically clear.

Future directions

Long-term ($> 5\ \text{y}$) observation will elucidate the durability of the CCT–BCVA relationship. Incorporating intra-operative OCT may further reduce detachment rates. Adjunct pharmacotherapies promoting endothelial regeneration warrant exploration.

V. Conclusions

Post-operative, but not pre-operative, central corneal thickness is strongly associated with visual acuity six months after DMEK. Prompt surgery and vigilant postoperative care that achieve rapid corneal deturgescence optimise functional outcomes.

Competing Interests: The authors declare that they have no competing interests.

Ethics Approval: The study was approved by the Institutional Ethics Committee of SMS Medical College and Attached Hospitals, Jaipur (Ref. No. 1379, dated 30-09-2023), in its meeting held on 07-10-2023. All procedures complied with ICMR and NDCT (2019) guidelines.

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