Original Research Article

Clinical Outcomes Of Descemet Membrane Endothelial Keratoplasty (DMEK) Cases At A Tertiary Care Hospital In North India

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Abstract

Purpose: To analyze the clinical outcomes of DMEK in 200 cases. **Methods**: Prospective interventional study of cases of endothelial dysfunction (different etiologies) operated by a single surgeon. Endothelial Cell Density of the Donor cornea was > 2500 cells /mm^2 and donor corneal scroll was prepared by surgeon at the time of surgery. Postoperative Best Corrected Visual Acuity (BCVA), Endothelial Cell Density and complications were analyzed till one year postoperatively. **Results**: The indications were Bullous Keratopathy in 128 eyes (64%), Previous Failed Graft in 36 (18%), Fuch's endothelial corneal dystrophy (FECD) in 34 (17%) and Congenital Hereditary Endothelial Dystrophy (CHED) in 2(1%) cases. In phakic eyes with cataract 18 (9%), DMEK was combined with cataract surgery. BCVA of 6/6 was achieved in 8 (4%) eyes, 6/9 – 6/12 in 110 (55%) eyes, 6/18 – 6/36 in 53 (26.5%) eyes, 6/60 – 4/60 in 20 (10%) eyes and <3/60 in 9 (4.5%) eyes at the end of one year. Mean Endothelial Cell Density (ECD) decreased from 2674±158 (Before Surgery) to 2125±271 & 1940±275 at 6 months and 1 year respectively. The commonest complication was Descemet Membrane(DM) detachment in 22 eyes (11%) eyes of which 9 eyes required rebubbling. 4 eyes had primary graft failure. **Conclusion**: DMEK is a effective procedure in endothelial diseases with encouraging clinical outcomes & less complications .

Keywords: Clinical,outcome,hospital

Introduction

Great progress has been achieved in corneal grafting for endothelial failure such as bullous keratopathy, Fuchs' endothelial corneal dystrophy (FECD), previous failed penetrating keratoplasty and others. The once gold standard penetrating keratoplasty has been replaced by more advanced and superior techniques such as DSAEK (Descemet's stripping automated endothelial keratoplasty), UT-DSAEK (ultra-thin DSAEK) and most recently, DMEK.[1,2] With time and more experiences, DMEK has been evolved as a standardized, "no-touch" technique, with better results in terms of visual outcomes and endothelial cell loss (ECL).[13-15]The purpose of the present study was to report the indications, clinical outcomes and complications following consecutive 200 DMEK procedures at a tertiary referral eye hospital in North India.

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Material & methods

This was a prospective interventional study of DMEK cases operated between January 2017 to July 2019 by a single surgeon. Informed written consent was taken from all patients prior to the surgical procedure. The

study was conducted according to the Declaration of Helsinki. 200 eyes of 180 patients with endothelial diseases/dysfunctions of different etiologies, such as Bullous Keratopathy, Fuch's Dystrophy, previous failed keratoplasty and the others were included in this study. Preoperatively, all patients underwent Best Corrected Visual Acuity (BCVA) testing using the Snellen chart, slit-lamp evaluation, lens status, intraocular pressure (IOP) measurement and dilated fundus examination if possible. Ultrasonography (USG) B-scan was done in those eyes where the fundus details were not clearly visible.

Inclusion Criteria

1. Bullous Keratopathy (Aphakic & Pseudophakic)
2. Fuch's Dystrophy
3. Posterior Polymorphous Corneal Dystrophy
4. Iridocorneal Endothelial Syndrome
5. Congenital Hereditary Endothelial Dystrophy
6. Failed Keratoplasty

Exclusion Criteria

1. Stromal scarring
2. Keratoconus
3. Anterior stromal opacities
4. Aniridia
5. Extensive peripheral anterior synechia
6. Uncontrolled end-stage glaucoma
7. Aphakia with grossly distorted pupil
8. Significant posterior segment pathology

Donor cornea

Cornea stored in Modified McCarey Kaufman Medium(MKM) or Cornisol with Endothelial cell count more than 2500 /mm^2 (Topcon SP 3000P) was used as donor cornea.

DMEK graft preparation

DMEK graft was prepared by operating surgeon in the operating room just prior to DMEK roll insertion. Size of the graft was taken as 8 mm.

Surgical Technique

All surgeries were performed under peribulbar anesthesia except in children where it was performed under general anesthesia. For DMEK-alone cases, the pupil was constricted by instillation of 2% pilocarpine eye drops three times, 10 min apart, prior to surgery. Pupillary dilation was required in all phakic eyes where DMEK was combined with cataract surgery with intraocular lens implantation (Triple-DMEK). Inferior peripheral iridectomy was performed in all the cases . After the surgery, the patient was shifted to the recovery room and was asked to maintain a supine position for 24 hours. The patients were discharged the next morning after slit-lamp examination.

Postoperative Medications & follow up

Moxifloxacin eye drop was given 4 times daily for 14 days. Prednisolone 1% eye drop was given 6 times daily for one month & then tapered over 6 months to once daily and continued on the same dose. Carboxymethyl cellulose 0.5 % was given 4 times daily continuously. Bandage contact lens placed at the time of surgery was removed after the healing of epithelium.

Patient was followed up on day 1, day 7 and then every 1 month till 12 months. During each visit, BCVA was measured using the Snellen chart. A detailed slit-lamp examination was performed to check the graft transparency and IOP was measured.

Statistical analysis

Data was fed in Microsoft Excel. Qualitative data was presented as percentage and proportion. Quantitative data was presented as mean and standard deviation. Chi square test and T- test was used for statistical analysis. A *P* value of < 0.05 was considered statistically significant.

Results

Patients' demographics

Two hundred eyes of 180 patients with endothelial dysfunctions were included in this study. The mean age of the recipient was 64.4 ± 10.5 years. 126 recipients (70%) was female. The most common indication for DMEK in this series was Bullous Keratopathy in 128 (64%) followed by previous failed Graft in 36 (18%), FECD in 34 (17%) and CHED in 2 (1%) cases . Preoperatively, the BCVA in the affected eye was <3/60 in 195 eyes (97.5%) and 6/60 to 4/60 in 5 eyes (2.5%). In 18 (9%) eyes, DMEK was combined with cataract surgery (Triple-DMEK).Patient's demographics and clinical presentation details are shown in [Table 1].

Donor demographics-Around 202 donor corneas were used in this series for 200 DMEK procedures. The mean donor age was 63.5 ± 5.6 years (range: 25–70 years) and mean central ECD was 2674+-158 (Before Surgery). The mean DM-scroll preparation time was 8.2 ± 1.4 min (range: 4–17 min) considering all age groups. The DMEK-graft size used was 8.0 mm. In 2 (0.9%) donor eyes, the DM-E complex was damaged during DM-graft preparation and the grafts were used for DALK.

Visual outcomes-The overall visual outcomes in this large DMEK series were highly satisfying irrespective of the indication. BCVA of 6/6 was achieved in 8 (4%)

eyes, 6/9 – 6/12 in 110 (55%) eyes, 6/18 – 6/36 in 53 (26.5%) eyes, 6/60 – 4/60 in 20 (10%) eyes and <3/60 in 9 (4.5%) eyes at the end of one year. [Table 2] revealed that there is improvement in post op BCVA which is statistically highly significant. Photographs show pictures on day 1 , day 3 and 1 month post DMEK.

Endothelial cell density-Mean Endothelial Cell Density (ECD) decreased from 2674 ± 158 cells/mm^2 before surgery to 2125 ± 271 & 1940 ± 275 at 6 months & 1 year respectively.

Complications-The commonest complications observed in this series was DM detachment in various form in 22 (11%) eyes of which 9 (4.5%) required rebubbling with air. Four (2%) eyes had primary graft failure. Other graft-related complications were endothelial allograft rejection in 3 (1.5%). Two of the rejection episodes could be reverted by medical management but one of them required re-grafting. Within this study period, a total of 5 eyes (2.5%) required re-transplantation of which re-DMEK was performed in 3 (1.5%) eyes and secondary DSEK was done in 2 (1%) eyes. [Table 3]

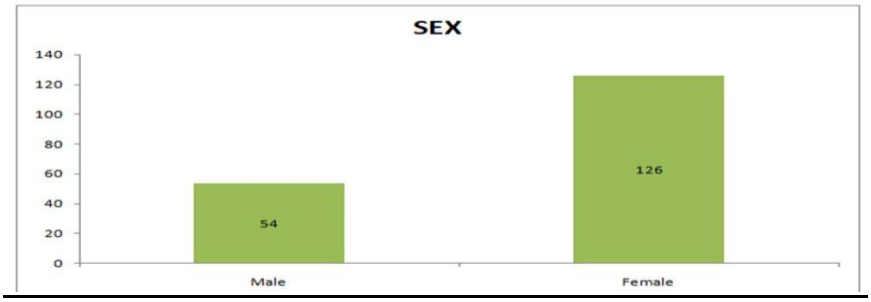

Fig 1: Sex distribution of cases

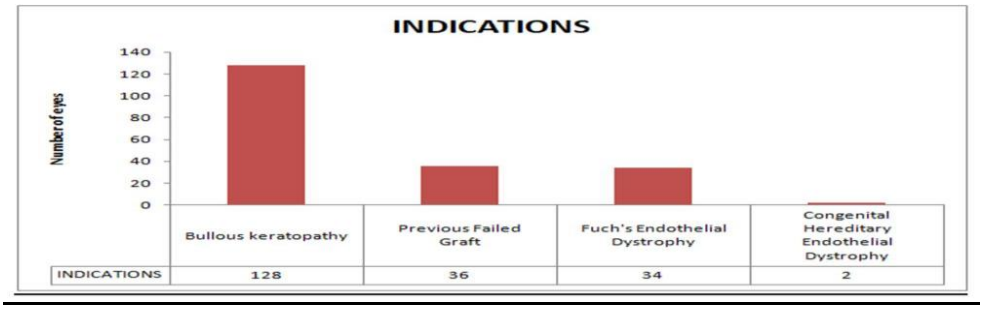

Fig 2:Indications of DMEK

Fig 3:Endothelial cell density preoperative and postoperative

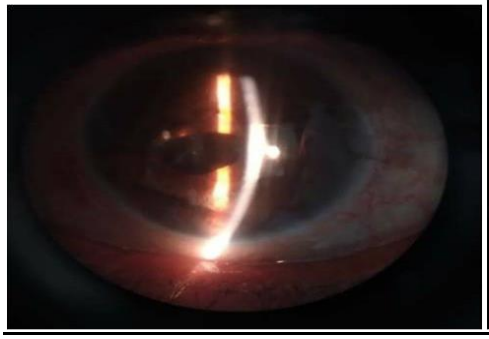

Fig 4:post operative one month with pupilloplasty

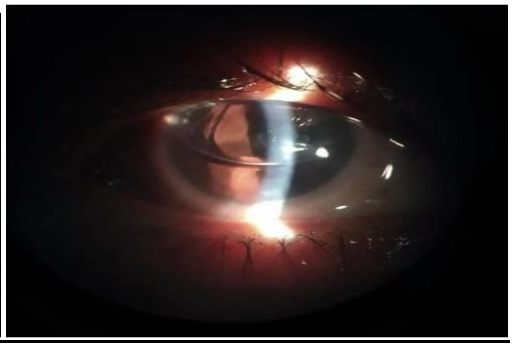

Fig 5:post operative 1 day

Fig 6 :Post op 1 month

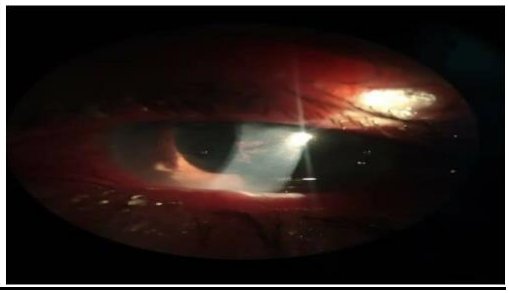

Fig 7:post op day 1 with F mark

Table 1:Pre op ocular status and demographics

S.no.	Criteria	Division	Eyes	Percentage
1	Sex	Male	54 cases	30
		Female	126 cases	70
2	Indication	Bullous keratopathy	128	64
		Previous graft failure	36	18
		FECD	34	17
		CHED	2	1
3	Preop BCVA	6/6	0	0
		6/9-6/12	0	0
		6/18-6/36	0	0
		6/60-4/60	5	2.5
		<3/60	195	97.5

BCVA:Best Corrected Visual Acuity;FECD:Fuch's Endothelisl Corneal Dystrophy;CHED:Congenital Hereditary Endothelial Dystrophy

Table 2:Comparison of pre op and post op BCVA

BCVA	Pre op	Percentage	Post op	Percentage
6/6	0	0	8	4
6/9-6/12	0	0	110	55
6/18-6/36	0	0	53	26.5
6/60-4/60	5	2.5	20	10
<3/60	195	97.5	9	4.5

X^2=245,P value=0.000(Highly Significant)
BCVA:Best Corrected Visual Acuity

Table 3:Complications of surgery

S.NO.	Criteria	Division	Eyes	Percentage
1	Intraoperative	Graft damage during preparation	2	0.9
2	Post operative	DM detachment	22	11
		Primary graft failure	4	2
		Endothelial graft rejection	3	1.5
3	Re-transplantation	Re-DMEK	3	1.5
		Secondary DSEK	2	1

DMEK -Descemet membrane endothelial keratoplasty;ECD - Endothelial cell count;ECL - Endothelial cell loss

Discussion

In this study, we evaluated the clinical outcomes of consecutive 200 eyes of standardize DMEK procedure performed by a single surgeon with a follow up upto 1 years postoperatively. The patients included were more of the heterogeneous cohort with different endothelial diseases. Our study showed that overall 59% of eyes achieved a BCVA of ≥6/12 after 12 months. There have been previous studies which revealed that up to 75% of DMEK eyes may achieve BCVA ≥20/25.[3-10] In our study patients had majorly PBK and advanced FECD with presenting BCVA of <3/60 in 97.5% which was different from most western reports.[3-9] Visual outcomes following DSEK/DSAEK and ultrathin DSAEK, showed continuous improvement in BCVA up to 3 years, while the vision stabilized in DMEK after 6 months in our series, suggesting that DMEK gives very good visual outcome in less time period.[1-13] Mean Endothelial Cell Density (ECD) decreased from 2674 ± 158 before surgery to 2125 ± 271 & 1940 ± 275 at 6 months & 1 year respectively. Postoperative mean ECD at 6 and 12 months in this series was higher compared to other series because the quality of donor was good with mean ECD of 2674 ± 158 cells/mm^2. The other reasons could be skill of surgeon in preparing the graft and no-touch technique while manipulating the donor. We can also say that due to same reasons, the mean ECL at 6 and 12 months were less postoperatively compared to other studies.[3-11,14-15] Bhandari *et al*. also showed ECL was only 24% after 6 months postoperatively which depended on skill of the surgeon during preparation and manipulation.[16] This series encountered fewer complications. There was 11% DM detachment in our study with rebubbling rate in 4.5% eyes which was quite less than the previously published reports.[5,11,17,18] Other studies showed that the learning curve is an important factor which lowered DM detachment with rebubbling rate (from 20% to 4.4%).[3,7,14,19] We had less iatrogenic primary graft failure (2%) as compared to other studies. [3,5,7,8,18,19] Reasons could be a skillful and experienced DMEK surgeon, who has more chances of avoiding and handling complications. Philips *et al*. recently published their comparable results with experienced DSAEK surgeon, transition to DMEK learning was less steep with minimum complications.[19] However, there was 1% to 5% allograft rejection rate within the first postoperative year after DMEK which was similar to previous studies.[3,5,9,20-22] Compared to other studies,[3,9,14,20] We had lower number of retransplantation cases as the rate of complications was low.Firstly, for harvesting the donor grafts, both MKM- and CSM- preserved corneas were used whose cost is much lower than that of the Optisol-GS medium (Bausch and Lomb, Rochester NY, USA). Bhandari *et al*. used only Cornisol-preserved donor corneas for DM graft preparation.[16],[23] The endothelial viability of 14 days was same for both the donor corneas stored in Cornisol and Optisol-GS media as published *in-vitro* study.[24] Secondly, in our study, there were more cases of of FECD patients (34%) than the other studies from India (5 to 10%).[23],[25] Even then, most of our patients presented late with presenting BCVA of <3/60 (97.5%) in advance diseases. Thirdly, iris was dark and anterior chamber was relatively shallow in most of the cases as compared to the western world.[26],[27] This made manipulation of the graft technically difficult. The hazy cornea with the dark iris made the visualization of the DM-scroll edges difficult. So the 'S' mark (or 'F' mark) on DM-side during graft preparation has high significance for right orientation of DM-graft after donor unfolding. The strengths of this study are a large sample size with heterogenous cohort, the use of uniform surgical technique and good follow-up data. However, the major limitation of this study that we have not segregated data as per the indications for

analysis. The other limitations are: it is a single-center, single-surgeon, prospective study.

Conclusion

Our results suggest that DMEK is a safe and effective procedure for endothelial diseases with encouraging surgical and visual outcomes. In addition, complications are less observed. ECD and ECL are acceptable with a low rejection rate to make DMEK an attractive alternative to DSEK/DSAEK. Further long-term studies are required to assess the survival of DMEK grafts in various endothelial diseases including the complicated cases.

Abbreviations

DMEK -Descemet membrane endothelial keratoplasty

ECD - Endothelial cell count

ECL - Endothelial cell loss

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