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Manual DSEK in patients with Pseudophakic Bullous Keratopathy: Viable option in resource limited settings

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ABSTRACT

Purpose: Evaluation of success rate of manual DSEK in terms of central corneal thickness and BSCVA in patients of PBK.

Materials and Methods: Prospective, non-comparative, interventional study of 18 patients of PBK, who underwent manual DSEK between June 2021 to May 2022 with minimum six months to maximum 15 months post-operative follow up. DSEK lenticule was prepared by manual dissection. Push in technique with 26 G needle was used for graft insertion. Preoperative and post-operative CCT and BSCVA were measured and compared.

Results: Preoperative central pachymetry in patients (n=18) was (832±162) μm which significantly reduced in the post operative period. The mean thickness of lenticule on day 1 post op was 203±93.5μm which became 156±76 μm (p =.0436) at 6 months and remained almost same till last follow up. Pre operative BSCVA ranged from HM to 2/60 in these 18 patients which was improved in 16/18 eyes post DSEK. Eighty eight percent (15/17) patients had regained BSCVA of 6/60 to 6/12. In early post operative period, complications noted were, partial detachment of lenticule and pupillary block glaucoma which were managed accordingly.

Conclusion: Manual DSEK is feasible, low-cost widely accessible alternative to DSAEK/DMEK for patients of PBK with good visual outcome in resource limited settings.

Key message: Manual DSEK has short learning curve and it's training should be imparted to corneal surgeons for better outcome in PBK and other causes of endothelial decompensation.

1. Introduction

Pseudophakic bullous keratopathy (PBK), refers to the development of irreversible corneal edema after cataract surgery and intraocular lens implantation.[1] It is estimated that 1-2% of people undergoing cataract surgery will develop persistent post-operative edema.[2] In India PBK is the most common cause of endothelial decompensation.[3] The diagnosis of PBK is primarily clinical, based on detailed history of previous cataract surgery, careful evaluation of risk factors and slit lamp examination.[1] PBK is usually managed medically first.[4] However, if medical management fails, Corneal transplantation is the definitive treatment as it restores the normal structure and function of endothelial cells. It can be done in the form of Penetrating keratoplasty (PKP), Descemet membrane endothelial keratoplasty (DMEK) or Descemet's stripping automated endothelial keratoplasty (DSAEK)/ manual DSEK.[5–7] Among endothelial keratoplasties, DMEK has shown to have better graft survival and lower rejection

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rates.[8,9] Surgeons treating PBK with PKP would prefer to transition to endothelial keratoplasty.[10] Performing DMEK would be very challenging, given it's steep learning curve and therefore DSEK would be a suitable option to begin with. The availability of Automated Microkeratome is limited to few centers because of financial constraints so uptake of DSAEK as a modality of patient care has been limited amongst corneal surgeons in general. In such scenario, manual DSEK could prove to be a low-cost widely accessible alternative to DSAEK/DMEK.[3]

The chief author, undertook manual DSEK training for one month and attended additional manual DSEK skill transfer cum hands on workshop at R.P. Center AIIMS, New Delhi. With an aim to assess the success of manual Descemet's Stripping Endothelial Keratoplasty in patients of PBK in terms of improvement in central corneal thickness and BSCVA in a beginner's hand a prospective non comparative interventional study was conducted in the Department of Ophthalmology S.N. Medical College, Agra between June 2021 to May 2022.

2. Materials and Methods

18 patients of PBK were enrolled during the study period between June 2021 to May 2022 on the basis of inclusion and exclusion criteria. Manual DSEK was done in all cases by a single surgeon. The study was approved by the Ethical committee of the Institute (Registration no. ECR/1409/Inst/UP/2020) and an informed written consent was taken from all the patients. The trial was also registered in CTRI (Registration no.: 037477). All patients with the diagnosis of PBK, on the basis of presence of persistent corneal edema made by slit lamp biomicroscopy and ASOCT were included in the study. Patients with other causes of bullous keratopathy, lagophthalmos, uncontrolled intraocular pressure, active inflammation/infection in the eye, presence of extensive PAS, severe anterior segment abnormalities and severe dry eye were excluded from the study. A minimum 3 months time period post cataract surgery was kept to make eye quiet. ASOCT was used preoperatively to measure CCT then on day 1post op to measure lenticule thickness, overall central corneal thickness, to see attachment and correct orientation of lenticule and then on subsequent follow up visits to compare the findings (Figure 1).

Simple tabular analysis was used to present the results. Descriptive statistics is calculated in term of mean and standard deviation. Chi square test has been used for significant association for categorical variables. Analysis of variance test has been used for the test of significance. Post hoc test was also used to assess the significance difference between the groups. A p value of less than 0.05 was taken to be statistical significant.

2.1. Donor tissue specification

This study was conducted in a resource limited setting, where, in the absence of donor specular microscope, certain criteria were used for choosing the tissue for manual DSEK. The maximum age of donor 60 years, maximum retrieval time within 6 hours of death, phakic eyes, stored in cornisol, having 10 mm clear zone with 3 mm scleral rim were considered for manual DSEK.

2.2. Steps of surgical procedures

All the cases of manual DSEK were performed under peribulbar anaesthesia. Preoperatively no pressure lowering drugs were given to any patient except two patients with preexisting Glaucoma, who were asked to continue with their topical & systemic anti glaucoma medication.

2.2.1. Manual preparation of donor lenticule

First the donor cornea was mounted on artificial anterior chamber (AAC). After marking the centre, with guarded knife of 350 micron depth, 2 clock hour incision was given at the limbus and initial lamellar dissection was started with crescent knife followed by straight lamellar dissector up to mid cornea and then to the opposite limbus with curved lamellar dissector. Average time taken in lenticule preparation was seven minutes. After this, the tissue was taken from the AAC and positioned on the teflon block with endothelium side facing up.

2.2.2. Recipient bed preparation

After placing speculum, epithelial debridement was done whenever required. After marking the center, side port entry was made at 9 or 6 o′clock, depending on the site of scleral /corneal tunnel(superior/temporal). Trypan blue (0.06%) solution was injected into Anterior Chamber through this side port to stain the descemet's membrane. After 30 seconds, AC was washed with BSS and filled with dispersive viscoelastics. Then descemetorrhexis was performed and descemet membrane was completely scored with a reverse sinsky hook within the boundaries of circular template mark. Then 5mm scleral/corneal tunnel was made (superiorly/temporally). AC was then washed thoroughly to remove all viscoelastics and formed with BSS.

2.2.3. Transplantation of donor lenticule

The trephination of donor lenticule with a desired size disposable trephine was done. A drop of cohesive viscoelastic agent and a drop of BSS was placed at the tunnel to facilitate the insertion of lenticule into the AC. With the help of two lim's forceps, lenticule was transferred at the tunnel with endothelial side down and was gently inserted into the anterior chamber with bevel up 26 G Needle. A small pilot air bubble was then injected through side-port to see centration of lenticule. If it was not centered,

centration of the donor lenticule was done by massaging and stroking the cornea with a flat cannula or iris repositor. The scleral tunnel and side port were secured with 10-0 Nylon sutures. After that air was injected in the AC through a separate entry by 26 G needle mounted on 2 c.c. syringe to achieve complete air fill and high IOP of more than 40 mm Hg for 10 min to create tamponade for the adhesion of donor lenticule to recipient bed. Double ring sign was always checked for the correct orientation.(Figure 2) At the end of the surgery some air fluid exchange was done and air bubble of 5-6 mm was left in Anterior Chamber. The conjunctiva was then closed by 10-0 nylon sutures and subconjunctival injection of 0.5 ml gentamycin and dexamethasone was given along with a drop of atropine 1% and moxifloxacin 0.5%. After placing BCL the eye was patched. The patients were instructed to lie supine for a minimum period of 8 hrs.

2.2.4. Post operative management and follow up

In the post op period, E/D 1% prednisolone acetate, E/D Moxifloxacin 0.5%, E/D homatropine 2% and E/D sodium hyaluronate 0.2% were started with tapering doses over 6 weeks. BCL was removed after a week. Patients were reviewed at weekly intervals for a period of 1 month, then every fortnight for next 1 month then at monthly intervals thereafter. Uncorrected visual acuity (UCVA), Best Spectacle Corrected Visual Acuity(BSCVA), IOP (digital /GAT), detailed slit lamp examination, Fundus and ASOCT were done and documented on every visit in each case.

3. Results

The demographic characteristics of the study participants are mentioned in Table 1. The mean age at the time of presentation was 61.89 ±6.83 years and mean duration of presentation post cataract surgery was 42.61± 37.66 months. All surgeries were uneventful without any intraoperative complications. This could possibly be a result of constant wet lab practice. The mean preoperative central pachymetry of 18 patients was 832±162μm which significantly reduced in the post operative period. One patient who was on dialysis due to B/L renal failure was lost in follow up before completion of minimum 6 month follow up. The final evaluation was done in 17 patients. The post operative CCT came down to 688±207μm in 17/18 patients who completed minimum 6 month post operative follow up. The mean CCT in 8 patients out of 18,who completed 12 month follow up was 660±74μm (p=0.029). The mean post op CCT of 2 patients who completed 15 month follow up was 630±13.4 (Tables 2 and 3). Lenticular thickness is depicted in Tables 4 and 5. The mean thickness of lenticule on day 1 post op on ASOCT was 203±93.5μm which became 156±76μm (p =.0436) at 6 months in 17/18 patients and remained almost constant in 8/18 patients even after 12 months. Two patients out of eighteen who completed 15 month follow up had mean lenticular thickness of 133.5±33.2μm. Pre operative BSCVA ranged from HM to 2/60 in these 18 patients. At 6 month post op follow up,15/17 patients (88%) had BSCVA of 6/60 to 6/12. In 8 patients, who completed 12 month follow up and 2 patients who completed 15 month follow up, BCVA remained same as it was at 6 month post op F/U(Table 6). In 16/17 patients cornea remained clear post DSEK till last follow up (Figure 3). Post operative BSCVA was better in patients who presented to us within 5 years of cataract surgery. In immediate post operative period, one patient developed partial central detachment of lenticule, one patient had air induced pupillary block glaucoma, and these complications were managed with necessary interventions.

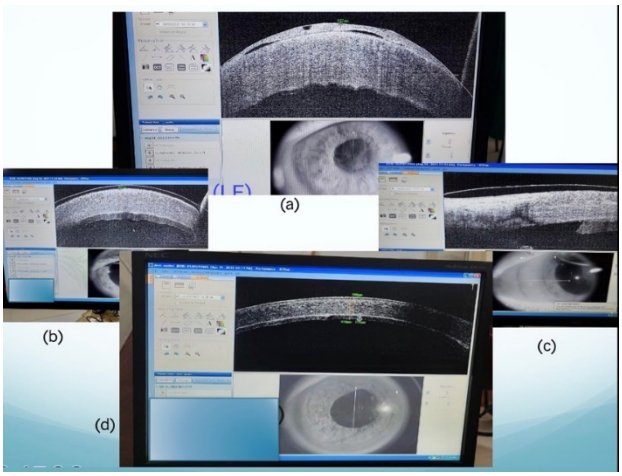

Fig. 1: (**a**): Pre op CCT; (**b,c**): Day 1 post op ASOCT line scan is used to measure lenticule thickness on day 1 post op, attachment and orientation of lenticule is also assessed; (**d**): ASOCT on subsequent follow up visits to measure overall CCT and thickness of lenticule

4. Discussion

Conducting DSEK without using specular microscope preoperatively makes this study unique, with no similar study reported in literature so far and we followed certain criteria to choose a donor tissue for DSEK. P.C. Mittal et al[11] evaluated the various factors affecting transparency of graft in penetrating keratoplasty and supported the fact that age of donor does not significantly affect the transparency of graft, whereas retrieval within 6 hours and early transplantation definitely gives better final visual outcome in patients post DSEK. Out of 18 patients, 12(66.67%) were females and in 15/18 (83.33%) patients SICS (camp cataract surgeries) were done. In fourteen out of eighteen patients, there was no visual recovery after cataract surgery. Kapoor et al[12] study support the fact that camp surgeries have more complication rates. Three patients who presented 60 months post cataract surgery, improved symptomatically after manual DSEK though their visual recovery was not

Table 1: Baseline characteristics

Particulars	No.	%
Age of patient (yrs.)		
≤60	8	44.44
>60	10	55.56
Sex		
Male	6	33.33
Female	12	66.67
Eye		
RE	12	66.67
LE	6	33.33
Post Cataract Surgery Duration(months)		
< 24	9	50.00
24-60	6	33.33
>60	3	16.67
Type of Cataract Surgery		
Phaco	3	16.67
SICS	15	83.33
Systemic Comorbidities		
NS	11	61.11
DM	2	11.11
HTN	3	16.67
HTN+DM	1	5.5
B/L Renal failure	1	5.5

NS(Non significant), DM(Diabetes mellitus), HTN(Hypertension)

Table 2: CCT (microns)

	CCT									
	Pre-op (N=18)		**Day-1 (N=18)**		**6-months (N=17)**		**12-months (N=8)**		**15-months (N=2)**	
	No.	%	No.	%	No.	%	No.	%	No.	%
400-500					2	11.76				
501-600			2	11.11	6	35.29	3	37.50		
601-700	3	16.67	3	16.67	2	11.76	3	37.50	2	100
701-800	6	33.33	5	27.78	4	23.53	2	25.00		
801-900	5	27.78	4	22.22	0	0.00				
901-1000	3	16.67	3	16.67	2	11.76				
>1000	1	5.56	1	5.56	1	5.88				

Table 3: Statistical analysis of CCT (μm)

	N	**Mean**	**SD**	**f-value**	**p-value**
Pre-op	18	831.83	161.58	3.234	0.029
Day-1	18	775.61	145.37		
6-months	17	688.12	207.62		
12-months	8	660.88	73.46		
15-months	2	630.00	13.4		

CD(critical difference) at 5%=21.15

Table 4: Lenticule thickness (microns)

	Lenticule Thickness							
	Day-1 (N=18)		**6-months (N=17)**		**12-months (N=8)**		**15-months (N=2)**	
	No.	%	No.	%	No.	%	No.	%
<100	3	16.67	4	23.53	1	12.50		
100-150	2	11.11	6	35.29	3	37.50	1	50
151-200	4	22.22	1	5.88	1	12.50	1	50
>200	9	50.00	6	35.29	3	37.50		

Table 5: Lenticule thickness

Lenticule Thickness	N	Mean(μ)	SD
Day-1	18	203.06	93.49
6-months	17	156.76	78.00
12-months	8	162.38	67.87
12-months	2	133.50	33.20

Table 6: Uncorrected Visual Acuity (UCVA) and BCVA on Snellen's chart

Snellen's VA	Pre-op (N=18)		6-months (N=17)		12-months (N=8)		15-months (N=2)	
	UCVA (%)	BCVA (%)	UCVA (%)	BCVA (%)	UCVA (%)	BCVA (%)	UCVA (%)	BCVA (%)
NIG		18(100)						
HM	1(5.56)							
FCCF	6(33.33)		1(5.88)	1(5.88)		1(12.50)		
FC 1 FT	5(27.78)							
FC 2 FT	3(16.67)							
FC 3 FT								
PL+PRacc								
1/60	2(11.11)		1(5.88)		1(12.50)			
2/60	1(5.56)							
3/60			1(5.88)		1(12.50)			
4/60			2(11.76)	1(5.88)	2(25.00)	1(12.50)		
5/60			3(17.65)					
6/60			3(17.65)	4(23.5)	1(12.50)			
6/36			5(29.41)	2(11.8)	2(25.00)	1(12.50)	1(50)	
6/24			1(5.88)	3(17.6)	1(12.50)	1(12.50)	1(50)	
6/18				4(23.5)		4(50.00)		1(50)
6/12				2(11.8)				1(50)

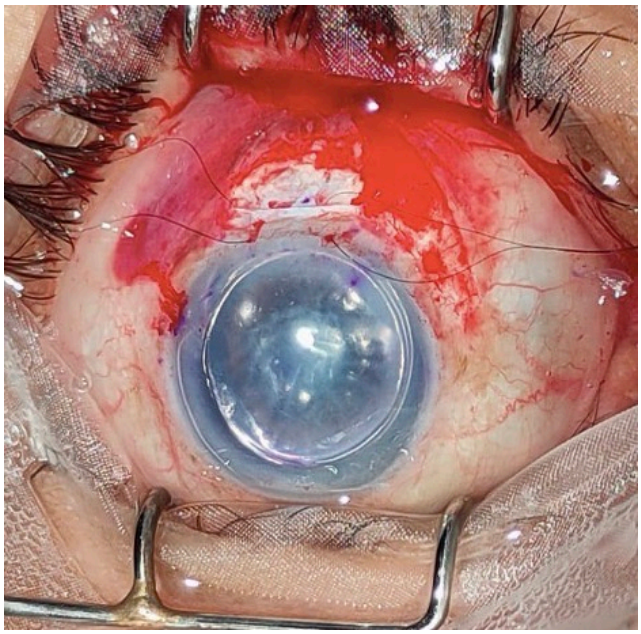

Fig. 2: Intraoperative pic showing double ring sign indicative of correct orientation

good. The reason for poor visual recovery was the presence of subepithelial/ stromal scarring in these patients (Table 1).

During preparation of lenticule, the aim was to make an optimally thin lenticule with uniform thickness manually, which was achieved in all donor corneas except one. In that tissue, full thickness perforation occurred in the beginning during incision, so dissection was started from other site and completed. Though uniform thickness could not be achieved in this case as found on day one ASOCT line scan but this lenticule also adhered well to host bed without any interface gap. Samar Basak et al[3] also reported complications in 13 (3.0%) out of 430 eyes during donor dissection. The lenticule thickness in initial cases was more than 200 microns which decreased significantly to around 150 microns in later cases. This was due to regular wet lab practice by author which reflected in the improvement in surgical skill and confidence with increasing number of cases. It was observed that lenticular thickness is directly related to time taken in visual recovery after manual DSEK. Patients who had lenticule thickness < 100 μm gained uncorrected visual acuity 6/36 within 1 month in comparison to those where lenticule thickness was >100 microns, who took near about 3 months in gaining same UCVA. Acar, Banu Torun et al[13] also suggested that thin grafts showed better postoperative BCVA as compared to medium-thick and thick grafts. A study done by Jeroen van

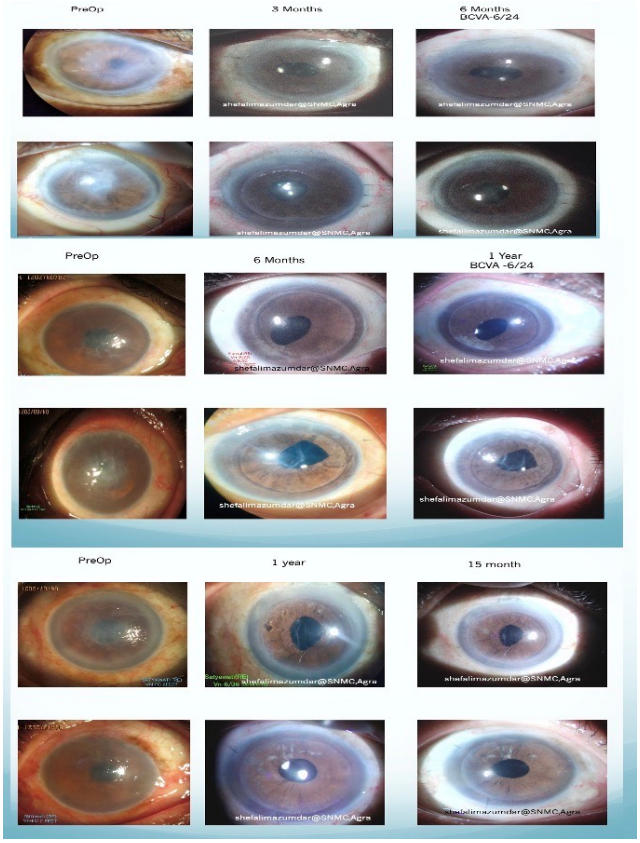

Fig. 3: Slit lamp pics ofthe patients completing follow up from 6 months to 15 months

Rooij et al. which had a longer follow up than our study found no correlation between graft thickness and final visual outcome after 3 years post DSEK.[14]

Post operative complications were seen in two out of eighteen cases in the early post-op period. In one case there was partial detachment of lenticule on day one post-op which was managed by rebubbling. Terry et al[15] reported a 50% detachment rate in the first 4 eyes, which was reduced to 4% in the next 100 eyes after altering their DSEK technique to include so-called roughening the recipient peripheral bed for better graft attachment. In our study following this technique of roughening the recipient's peripheral bed, we had a lower detachment rate in the initial 18 cases. One of 18 cases had pupillary block glaucoma, managed by air fluid exchange in the operation room on the same day. Samar Basak[3] in his large series of 430 cases mentioned that detachment/dislocation and pupillary block glaucoma are two most common complications in early post-operative period in 4.9% and 2.8% patients respectively. In the literature, different studies have shown various complications and their managements post DSEK.[16–18]

In this study, it was observed that preoperative central corneal thickness is directly related to time taken in visual recovery after manual DSEK. Patients who had pre-op CCT between 600-700μm gained uncorrected visual acuity 6/36 within 1 month whereas those who had pre op CCT between 800-900μm, took near about 3 months in gaining same UCVA. The final visual outcome in our study however was not significantly affected by preoperative CCT. This is supported by a study conducted by Neiter E et al.[19] The BCVA at 6 month F/U in 17 patients ranged from 4/60 to 6/12 and remained same till last F/U visit at 12 month in all 8 patients and in 2 patients at 15 month post op. A review article by Lee WB et al[16] has also shown that the average best-corrected Snellen visual acuity (mean, 9 months; range, 3-21 months) post DSEK ranged from 20/34 to 20/66 (6/9P to 6/24P) similar to our study and supports that manual DSEK is no inferior to DSAEK in terms of final visual recovery of patients.

5. Conclusion

Manual Descemet stripping endothelial keratoplasty is a safe, feasible, low-cost surgical procedure with good visual outcome for patients of PBK. This study being unique that without using donor specular microscope, one can use donor tissue for manual DSEK. Though some of our cases have completed more than a year's follow up but as the sample size is small, longer follow up results of manual DSEK in the setting of multi-center trials are needed to ascertain it's success. It can be an attractive alternative to penetrating keratoplasty in resource limited settings for poor patients with endothelial diseases.

6. Source of Funding

None.

7. Conflict of Interest

None.

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