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Multicenter trial on Descemet membrane endothelial keratoplasty (DMEK) First case series of 18 surgeons

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Purpose



Starting with any new surgical technique may be an intimidating proposition, even for experienced surgeons.

This has been particularly true with regard to DMEK, whose widespread adoption has been somewhat curtailed by the perceived difficulty of the operation

As a result, many corneal specialists – especially in the United States – continue to perform DSEK, rather than DMEK, as their primary procedure for endothelial transplantation, even though DMEK (properly performed) seems to offer superior visual results.

Therefore, we performed this study: a retrospective, multicenter inquiry into the outcomes (and complications) of DMEK during the learning curve of 18 surgeons

Setup



- DMEK was performed by 18 different surgeons in 11 countries
- Patients:
 - A total of 431 eyes of 401 patients suffering from Fuchs Endothelial Dystrophy (68%) and Bullous Keratopathy (32%)
- Main outcomes measured:
 - Best corrected visual acuity (BCVA)
 - Endothelial cell density (ECD)
 - Intra- and postoperative complications

World map of 18 participating surgeons and their locations



Patient Demographics

	No. (%)		
	(n=431 eyes)		
Patients	401		
Mean age (SD), [range in years]	70 (11%) [21-97]		
Men	162 (40%)		
Women	239 (60%)		
Lens condition			
Pseudophakic	358 (83%)		
Phakic	69 (16%)		
Aphakic	3 (1%)		
Unknown	1 (0.2%)		
Indication			
Fuchs Endothelial Dystrophy	294 (68%)		
ВК	137 (32%)		
-Pseudophakic BK	122 (28%)		
-Secondary BK	15 (4%)		



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DMEK surgical techniques employed by all surgeons: either the standardized "no-touch" or, one of several published "alternates"



Standardized 'no-touch' technique Dapena et.al, Arch Ophthalm 2011 Alternative unfolding techniques Liarakos et. al, JAMA Ophthalm 2013

Non-standard variations in technique, peculiar to individual surgeons



Type of technique		No. of eyes (%)	
Donor preparation	by eye bank	42	(10%)
	by surgeon	282	(66%)
Graft diameter	9.5 mm	365	(85%)
	8.0 – 8.5 mm	66	(15%)
Graft injection	Glass	216	(51%)
	Plastic	146	(34%)
Duration of air fill	< 1 hour	69	(16%)
	1-2 hour	304	(71%)
	>2 hours	58	(13%)
Extent of air fill remaining in			
AC after surgery	100 %	232	(54%)
	80-90 %	36	(8%)
	60-70 %	87	(20%)
	50 %	55	(13%)
	0 %	16	(4%)

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Results: BCVA





BCVA improved in 258 eyes (94%) 217 eyes (79%) ≥20/40 (≥0.5) 117 eyes (43%) ≥20/25 (≥0.8) 61 eyes (22%) ≥20/20 (≥1.0)

Results: ECD



ECD decline = 47% (± 20%) - Published average for "experienced" surgeons ~ 34%

What factors might explain the enhanced amounts of cell loss?

To investigate that question, we performed a Linear Regression Analysis Independent parameters evaluated:

- Lens status (Phakic, Pseudophakic, pIOL, AC-IOL)
- Type of Inserter used (Glass or Plastic)
- Storage medium (Organ culture, Cold storage, Fresh bulbi)
- Air bubble time (<1h, 1-2h, >2h)
- Size of air bubble left (%)
- Donor preparation (Surgeon, Eye bank)

no significant impact (P=0.441)

Results: Complications

	Complications	No. of complications (% of total eves) $(n-421)$	
	Intraoperative complications		yes) (11=451)
	Failure to unfold / insert / position DMEK graft	5	(1%)
	Postoperative complications and associated pathology	, C	(170)
	Total grafts detached	149	(35%)
	Partial detachment ≤1/3	80	(19%)
	Partial detachment >1/3	31	(7%)
	Partial detachment unknown extent	13	(3%)
	Graft upside down	7	(2%)
	Complete detachment	18	(4%)
	Detachments resulting in secondary keratoplasty	43	(10%)
	Primary graft failure	10	(2%)
	Secondary graft failure	27	(6%)
	Rejection (acute/chronic)	16	(4%)
	Secondary interventions		
	Total rebubbling procedures (102)	88	
	1 x	88	(20%)
	2 x	11	(3%)
	3 x	3	(1%)
	Total reoperations (79)	76	(18%)
	Secondary DMEK	46	(11%)
	Secondary DSEK / DSAEK	15	(3%)
	Secondary PKP	15	(3%)
	Tertiary DMEK	2	(0.5%)
NIOS	Quintary DMEK	1	(0.2%)

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The most notable "unexpected" complication was extra detachments.



Which parameters might affect Detachment incidence?

Plastic inserters were followed by more significant detachments (P=0.005)

Cold storage grafts were associated with **more detachments** than organ culture and similar to fresh bulbi (35%, 26% and 38% respectively) (*P=0.005*) Cold storage grafts were associated with **more extensive detachments** (*P=0.01*)

Shorter air bubble time increases the possibility for a more significant detachment (*P=0.019*)

Size of airbubble left No (P=0.08)

Donor preparation No (*P*=0.115)

Conclusion



DMEK – conducted according to both the standard 'no-touch" technique, and also alternate techniques – was feasible in most hands

Encouragingly, surgeons starting with DMEK achieved visual outcomes comparable to more experienced practitioners, albeit with slightly more complications.

These extra complications may be avoidable, and the result of personal variations in some of the ancillary aspects of the operation (graft storage, instrumentation materials, air bubble duration, etc.)