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**Refractive Accuracy and Visual Outcomes after combined Descemet
Membrane Endothelial Keratoplasty and Cataract Surgery: a French
multicentric study**

**Précision réfractive et résultats visuels dans les chirurgies combinées
cataracte et greffe endothéliale pure (DMEK) : étude française
multicentrique**

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Refractive Accuracy and Visual Outcomes after combined Descemet Membrane Endothelial Keratoplasty and Cataract Surgery: a French multicentric study

Précision réfractive et résultats visuels dans les chirurgies combinées cataracte et greffe endothéliale pure (DMEK) : étude française multicentrique

ABSTRACT

Purpose: Descemet membrane endothelial keratoplasty (DMEK) combined with cataract extraction and intraocular lens insertion (new triple procedure) limits postoperative refractive errors. The objective of this study was to assess refractive accuracy after DMEK combined with cataract extraction and intraocular lens implantation.

Setting: Four university hospitals (Rouen, Paris, Reims, Grenoble).

Design: This retrospective multicenter study included patients with symptomatic corneal endothelial decompensation and cataract.

Methods: The primary outcome was the difference between the target spherical equivalent and postoperative refraction at months 2 and 6. Secondary outcomes were visual acuity, keratometry, pachymetry and endothelial cell density.

Results: A total of 130 eyes of 111 patients (mean age 66.2 years) were included (94% with Fuchs' endothelial dystrophy). For a mean refractive target set at $-0.50 (\pm 0.57)$ D, the mean (95% CI) refractive error was hyperopia of $+0.49 (0.314; 0.664)$ D at 2 months and $+0.46 (0.299; 0.619)$ D at 6 months. Best corrected distance visual acuity was improved in all patients: from $0.49 (\pm 0.3)$ logMAR to $0.14 (\pm 0.14)$ logMAR at 2 months and $0.05 (\pm 0.1)$ logMAR at 6 months. Mean corneal thickness decreased from $621.6 (\pm 37.6)$ μm to $515.2 (\pm 42.6)$ μm at 2 months and $539.0 (\pm 39.0)$ μm at 6 months.

Conclusions: Good refractive accuracy was obtained after the new triple procedure with DMEK. Hyperopic shift is common after triple procedures, and its persistence should be evaluated in future studies in order to anticipate a change in its value to optimize intraocular lens power calculation.

Résumé

Objectif: Les nouvelles triples procédures associant chirurgie de cataracte et greffe endothéliale DMEK ont permis de limiter les erreurs réfractives. L'objectif de cette étude était d'évaluer la précision réfractive dans cette chirurgie combinée.

Méthodes: Cette étude rétrospective multicentrique réalisée dans 4 centres hospitalo universitaires (Rouen, Paris, Reims, Grenoble) a inclus des patients présentant une décompensation endothéliale symptomatique et une cataracte. Le critère de jugement principal était l'erreur réfractive qui correspondait à la différence entre la réfraction sphérique ciblée et la réfractive obtenue à 2 et 6 mois post-opératoire. Les critères secondaires étaient l'acuité visuelle, la kératométrie, la pachymétrie et la densité cellulaire endothéliale.

Résultats: Un total de 130 yeux de 111 patients (âge moyen de 66,2 ans) a été inclus (94% avec une dystrophie de Fuchs). La cible réfractive moyenne était de -0,50 ($\pm 0,57$) D, l'erreur réfractive moyenne (IC à 95 %) était une hypermétropisation de **+0,49** (0,314 ; 0,664) D à 2 mois et de +0,46 (0,299 ; 0,619) D à 6 mois. L'acuité visuelle corrigée de loin a été améliorée de 0,49 ($\pm 0,3$) logMAR à 0,14 ($\pm 0,14$) logMAR à 2 mois et 0,05 ($\pm 0,1$) logMAR à 6 mois. La pachymétrie a diminué de 621,6 ($\pm 37,6$) μm à 515,2 ($\pm 42,6$) μm à 2 mois et 539,0 ($\pm 39,0$) μm à 6 mois.

Conclusions: La **réfraction** obtenue dans ces triples procédures était satisfaisante. L'hypermétropisation semble être habituelle mais sa persistance devrait être évaluée dans les études futures afin de pouvoir l'anticiper pour le choix de la puissance de l'implant.

Key words: refractive accuracy, triple procedure, combined surgery, DMEK

Mots clés: **précision réfractive, triple procédure, chirurgie combinée, DMEK**

INTRODUCTION

In the past, penetrating keratoplasty, a full-thickness transplant procedure, was performed to restore corneal transparency in order to improve visual acuity. However, visual acuity after surgery could be impaired by severe residual spherical ametropia or astigmatism.(1) Penetrating keratoplasty remains nevertheless indicated for anterior corneal or stromal disorders.

Recently, new methods of endothelial keratoplasty have been developed and are used when damage is limited to the endothelium, for example in Fuchs' endothelial dystrophy. Descemet Membrane Endothelial Keratoplasty (DMEK), a partial-thickness cornea transplant, is the latest version of endothelial keratoplasty. During this procedure, the corneal endothelium and the Descemet membrane of the patient are replaced by the same histological structures from the donor.(2,3) DMEK has been shown to be associated with better visual outcomes and lower risk of graft rejection than previous versions of endothelial keratoplasty as Descemet-stripping endothelial keratoplasty (DSEK), and Descemet stripping automated endothelial keratoplasty (DSAEK) or penetrating keratoplasty.(4,5) DMEK also allows rapid sequential endothelial keratoplasty in fellow eyes due to faster return of visual function.

A cataract is frequently associated with endothelial disorders (for example in Fuchs' endothelial dystrophy). The feasibility of performing combined cataract surgery and endothelial keratoplasty in the course of the same operation has been demonstrated in previous studies.(5,6) **DMEK combined with cataract extraction and intraocular lens insertion (new triple procedure) limits postoperative refractive errors compared to the classical triple procedure which combines penetrating keratoplasty and cataract. This is due to a preservation of the majority of the corneal structure and in particular of the anterior face in case of DMEK.**

The objective of this study was to assess refractive accuracy and visual outcomes after DMEK combined with cataract extraction and intraocular lens implantation.

PATIENTS AND METHODS

Study design and selection of patients

This retrospective multicenter study enrolled consecutive patients with symptomatic corneal endothelial decompensation and cataract who had been operated in four centers (Rouen University Hospital, Paris University Hospital, Grenoble University Hospital, Reims University Hospital).

The study was conducted in accordance with the Declaration of Helsinki.

Surgical procedure

The surgical procedure was standardized in two steps. The first step was cataract extraction after classical phacoemulsification and then insertion of intraocular lens in the posterior chamber. The second step was descemetorhexis, and the placement of a pure endothelial graft (DMEK) into the anterior chamber and sealing of the wound with hydration only.

Endpoints

The following endpoints were assessed before surgery and at months 2 and 6: refractive target, spherical equivalent, refractive accuracy defined as the difference between refractive target and post-operative refraction, percentage of patients at ± 0.5 D, ± 1 D and ± 2 D from emmetropia and refractive target, best corrected distance visual acuity (BCVA), keratometry, global and corneal astigmatism, corneal pachymetry, endothelial cell density measured with specular microscope and postoperative complications.

Statistical analyses

The primary outcome was refractive accuracy at months 2 and 6. Secondary outcomes were BCVA, keratometry, pachymetry and endothelial cell density. No formal statistical hypothesis was tested and the statistical analysis was essentially descriptive. Comparisons of mean quantitative values were performed using Student's t-test for paired values. All tests were two-sided at the level 0.05.

RESULTS

Characteristics of patients at inclusion

A total of 130 eyes (46 from Rouen, 46 from Grenoble, 7 from Reims and 31 from Paris) of 111 patients (50 men and 61 women) with a mean (SD) age of 66.2 (9.6) years (range, 36–85 years) were included (**Table 1**). Surgery indication of the triple procedure were Fuchs' endothelial dystrophy for 122 eyes (94%), bullous keratopathy for 3 eyes (2.25%), decompensation associated with myopic phakic eye for 3 eyes (2.25%) and decompensation in acute angle-closure glaucoma for 2 eyes (1.5%).

All patients had the new triple procedure with cataract extraction and intraocular lens insertion combined with DMEK.

Calculation of intraocular lens parameters

The mean axial length was 23.7 (\pm 1.8) mm (range, 20.1–30.5 mm). It was measured using interferometry for 113 eyes (87%) and ultrasonography mode A for 17 eyes (13%).

Keratometry of the eye to be operated was performed with IOLMaster[®] (Zeiss-Meditec, Germany) for 113 eyes (87%). For 17 eyes (13%), keratometry was not possible and the

values of the contralateral eye were used for 15 eyes or a reference mean value for the 2 other eyes (43 D for the two axes).

Intraocular lens power was calculated using the SRK/T formula for 122 eyes (94%) with an axial length >22mm, Holladay's formula for 4 eyes (3%) and Hoffer Q for 4 eyes (3%) with an axial length < 22 mm.

Refractive accuracy

Spherical equivalent. The mean (SD) refractive target was -0.50 (± 0.57) D. The mean spherical equivalent was -0.01 (± 0.96) D at 2 months and -0.04 (± 0.94) D at 6 months (**Table 2**). The mean refractive error (difference between refractive target and post-operative refraction) was significant at 2 months: +0.49 D (95% CI, 0.314; 0.664). At 6 months, the mean refractive error remained significant compared to the value before surgery, but without significant difference compared to the 2-month value: +0.46 D (95% CI, 0.299; 0.619).

At 2 months, 34% of eyes were near emmetropia (± 0.5 D), 68% at ± 1 D and 95% at ± 2 D (**Figure 1A**). At 6 months, these values were 38%, 74% and 95%, respectively.

The percentages of patients at ± 0.5 , ± 1 and ± 2 D of the refractive target were 33%, 65% and 92% at 2 months and 36%, 65% and 94% at 6 months (**Figure 1B**).

Cylindrical refraction. Astigmatism values were reported in 113 eyes (87%) before surgery (**Table 2**). The mean values of (SD) corneal astigmatism were 1.18 (± 0.93) D before surgery, 1.15 (± 1.0) D at 2 months and 1.16 (± 0.85) D at 6 months. There was no significant difference in mean corneal astigmatism: -0.03 D (CI 95%, -0.334; 0.454) at 2 months and -

0.02 D (CI 95%, -0.503; 0.409) at 6 months. There was no significant difference in mean total astigmatism: 1.0 (\pm 0.97) D before surgery, 1.3 (\pm 0.84) D at 2 months and 0.92 (\pm 0.68) D at 6 months, corresponding to a mean difference of +0.30 D (CI 95%, -0.052; 0.623) at 2 months and -0.08 D (CI 95%, -0.324; 0.407) at 6 months. The mean total astigmatism of the contralateral eye was 0.97 (\pm 0.9) D.

Visual acuity

Mean (SD) BCVA before surgery was 0.53 (\pm 0.28) logMAR (i.e., approximately 3/10) for the included eye and 0.22 (\pm 0.23) logMAR (i.e., approximately 8/10) for the contralateral eye (**Table 2**). No eye had a loss of corrected visual acuity. Visual acuity was improved with a mean (SD) of 0.14 (\pm 0.14) logMAR (equivalent to 7/10) at 2 months (CI 95%, 0.255; 0.465) and 0.05 (\pm 0.1) logMAR (equivalent to 9/10) at 6 months (CI 95%, 0.327; 0.599).

There was a small but significant improvement in the mean visual acuity between month 2 and month 6 with a difference of 0.09 logMAR (CI 95%, 0.033; 0.138). At 2 months and 6 months, visual acuity was \geq 0.15 logMAR (i.e., \geq 7/10) for 62% and 85% of eyes, respectively.

Keratometry

Before surgery, keratometry was performed for 113 eyes (87%) with a mean (SD) value of 43.8 (\pm 1.6) D (**Table 2**). At 2 months and 6 months, mean keratometry values were 43.3 (\pm 1.6) D and 43.5 (\pm 1.57) D, respectively, corresponding to a decrease of 0.5 D at 2 months (CI 95%, 0.226; 0.886) and 0.3 D at 6 months (CI 95%, 0.234; 0.791).

Corneal thickness

Before surgery, the mean (SD) corneal thickness measured with pachymetry was 621.6 (± 37.6) μm ($n = 91$ eyes). It decreased significantly to 515.2 (± 42.6) μm at 2 months and 539.0 (± 39.0) μm at 6 months. The difference in the mean value at 2 months and 6 months was not significant. The mean value of (SD) corneal thickness was 587.2 (± 49.0) μm for the contralateral eye.

Endothelial cell density

Pre-operative endothelial cell density evidenced with specular microscopy in the peripheral area could be measured in only 36/130 eyes (27.6%). The mean (SD) density was 1102 (± 631) cells/ mm^2 before surgery. **Post-operative central endothelial cell density was 1482 (± 440) cells/ mm^2 at 2 months and 1416 (± 484) cells/ mm^2 at 6 months.** The mean endothelial cell density of the contralateral eye was 1296 (± 479) cells/ mm^2 .

Complications

During surgery, one graft was placed upside down and was then placed in the right position. Another graft had many dead cells as evidenced by Trypan blue, but it was used nonetheless.

Post-operative complications reported between day 1 and month 6 were: transient ocular hypertension at day 2 (resolution within 15 days of medical treatment); cystoid macular edema (equivalent to Irvine-Gass syndrome) which regressed after treatment with a topical nonsteroidal anti-inflammatory drug but was still unresolved at month 6; presence of cornea guttata on a graft that had been perfectly placed; herpetic keratouveitis at month 1 which resolved within one month of treatment with oral antiviral and corticosteroid eye drops; pupillary block just after surgery that required a small exsufflation of the air present in the anterior chamber (air was reinjected after 15 days due to graft detachment).

DISCUSSION

In the present study, good refractive accuracy was obtained after the new triple procedure with DMEK. The mean (SD) refractive target was $-0.50 (\pm 0.57)$ D and the mean spherical equivalent obtained after triple procedure was $-0.01 (\pm 0.96)$ D at 2 months and $-0.04 (\pm 0.94)$ D at 6 months. However, refractive error with hyperopisation was observed at both time points with a mean value of $+0.49$ D (95% CI, 0.314; 0.664) at 2 months and $+0.46$ D (95% CI, 0.299; 0.619). There was no significant difference between values at 2 months and 6 months.

Although few studies have assessed refractive outcomes in the setting of the new triple procedure, comparable hyperopisation has been reported. Thus, Laaser *et al* reported their results in 61 eyes that had DMEK and cataract surgery.(6) Their mean spherical equivalent was $-0.3 (\pm 2.8)$ D before surgery and $0.9 (\pm 1.5)$ D after surgery with emmetropia as the refractive target. Schoenberg *et al* assessed refractive outcomes in 108 eyes with Fuchs' endothelial dystrophy that had cataract surgery combined with DMEK.(7) Their mean refractive error was 0.43 D. More recently, Girbardt *et al* also reported this “hyperopic shift”.(8)

Hyperopisation does not seem to be related to cataract surgery, but rather to endothelial graft. Thus, Van Dijk *et al*, in a series of 300 eyes with Fuchs' endothelial dystrophy, observed a hyperopic shift of $0.33 (\pm 1.08)$ D at 3 and 6 months after DMEK without cataract surgery.(9) Parker *et al* analyzed the outcomes of 52 phakic eyes after DMEK and reported a hyperopic shift of 0.74 D.(4) In 56 eyes of 56 patients with Fuchs' endothelial dystrophy or bullous keratopathy operated for DMEK, Price *et al* observed a hyperopic shift of $0.49 (\pm 0.63)$ D.(5) Finally, in a more recent study, Yokogama *et al* studied astigmatism after DMEK and observed a hyperopic shift of $0.26 (\pm 0.74)$ D for the anterior surface of cornea and $0.56 (\pm 0.55)$ D for the posterior surface.(10)

Hyperopic shift has been observed not only with DMEK, but also with other types of endothelial grafts such as ultra-thin DSEK and DSAEK. In cases of isolated DSAEK, the mean hyperopic shift was 0.88 D for Langenbacher *et al*, 0.7 D for Clemmensen *et al*, 0.88 D for Jun *et al* and 1.19 D for Koenig.(11–14) Different authors have studied refractive accuracy in triple procedures combining cataract surgery and DSAEK and also evidenced hyperopic shift.(15,16)

The reasons for this hyperopic shift remain unclear and it seems important to anticipate value for each patient. For some authors, hyperopisation is associated with modifications in keratometry (decreased corneal edema) and posterior corneal geometry resulting from a graft that is thinner at the center than at the periphery as in the DSAEK.(11,12,17,18) **For Fritz et al, hyperopic surprises after triple DMEK particularly occur in corneas that are flatter centrally than the periphery because of edematous changes (oblate posterior profile).(19)**

For other authors, hyperopisation is the result of the disappearance of myopic shift due to decreased central stromal edema.(17) One could also hypothesize that refractive error is the result of keratometry measurement error in intraocular lens calculation. Indeed, anterior keratometry only considers the epithelial component of the cornea which is also impacted in cases of major endothelial decompensation with bullous keratopathy. This measurement error is estimated at -0.5 D after surgery as observed in our cohort.

In order to improve post-operative refractive accuracy, we used a mean target of -0.5 D. That trick seemed to work. However, there were some important errors that are difficult to explain at this time. **Fritz et al and Diener et al, have studied the different parameters that could be correlated with this phenomenon of hyperopisation.(19,20)**

Maybe intraocular lens calculation must be optimized.(21) However, intraocular lens calculation is more difficult in cases of combined surgery because of the increased number of

parameters to consider.(22) Different elements must be considered to improve refractive accuracy: keratometry method, measurement of axial length, calculation formula for intraocular lens and refractive target.

One solution could be the use of adjusted keratometry readings as suggested by De Sanctis and Chang proposed a nomogram and a mathematical model in order to achieve emmetropia.(23,24) Bonfadini suggested optimizing the refractive outcome of new triple procedures by adjusting the constant A of the formula for calculation of intraocular lens.(25) For the other endothelial grafts (Ultra-Thin DSEK et DSAEK), a similar adjustment appeared to be effective as reported by different authors.(11,17)

We observed a significant decrease in corneal thickness evidenced with pachymetry from 621.6 μm before surgery to 515.2 μm at 2 months and 539.0 μm at 6 months. This decrease is usual because the endothelial graft brings new endothelial cells which pump corneal water and therefore improve the corneal edema. This decrease in corneal thickness after surgery has been reported by other authors for DMEK alone,(5,18,26,27) new triple procedure with DMEK,(6,28) other endothelial grafts alone (ultra-thin DSEK or DSAEK)(18,29,30) or other endothelial grafts combined with cataract surgery.(15,23)

The absence of data after 6 months is the main limitation of this study. It would be interesting to prolong follow-up after surgery in order to assess the stability of long-term refractive outcomes. Another limitation is the retrospective design of the study.

In conclusion, the refractive accuracy obtained after the new triple procedure with DMEK was effective to treat endothelial disorders associated with cataract. The refractive accuracy obtained was better than after a classic triple procedure with penetrating keratoplasty, particularly for astigmatism. Anticipating a mean variation of 0.5 D could be a basis for

calculating intraocular lens power. In future studies, it would be interesting to assess the persistence of this hyperopic shift and to determine contributing factors to refractive error.

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Table 1. Patients' characteristics at inclusion

Characteristics	N=111
Female gender, n (%)	61 (55)
Mean (SD) age, years	66.2 (9.6)
Number of eyes	130
Surgery indication, n (%)	
Fuchs' endothelial dystrophy	122 (94)
Bullous keratopathy	3 (2.25)
Decompensation associated with myopic phakic eye	3 (2.25)
Decompensation in acute angle-closure glaucoma	2 (1.5).

Table 2. Main outcomes for refractive accuracy and other parameters

Parameter	N	Values
Spherical equivalent (D)		
Refractive target, mean (SD)	130	-0.50 (0.57)
Obtained spherical equivalent, mean (SD)		
Month 2	130	-0.01 (0.96)
Month 6	130	-0.04 (0.94)
Refractive error ^a , mean (95% CI)		
Month 2	130	+0.49 (0.314; 0.664)
Month 6	130	+0.46 (0.299; 0.619)
Cylindrical refraction (D), mean (SD)		
Corneal astigmatism		
Before surgery	113	+1.18 (0.93)
Month 2	113	+1.15 (1.0)
Month 6	113	+1.16 (0.85)
Total astigmatism		
Before surgery	113	+1.0 (0.97)
Month 2	113	+1.3 (0.84)
Month 6	113	+0.92 (0.68)
BCVA (logMAR)		
Before surgery, mean (SD)	130	0.53 (0.28)
Month 2, mean (SD)	130	0.14 (0.14)
Month 6, mean (SD)	130	0.05 (0.1)
≥ 0.15 ^b logMAR at 2 months, %	130	62%
≥ 0.15 logMAR at 6 months, %	130	85%
Keratometry (D), mean (SD)		
Before surgery	113	43.8 (1.6)

Month 2	113	43.3 (1.6)
Month 6	113	43.5 (1.57)
Corneal thickness (μm), mean (SD)		
Before surgery	91	621.6 (37.6)
Month 2	91	515.2 (42.6)
Month 6	91	539.0 (39.0)
Contralateral eye	91	587.2 (49.0)

BCVA, best corrected distance visual acuity; D, dioptries

^a Difference between refractive target and post-operative refraction

^b Corresponding to $\geq 7/10$.

Figure 1. Spherical equivalent obtained at Month 2 (M2) and Month 6 (M6) after surgery compared to emmetropia (A) or refractive target (B).

Figure 1

