CORNEA

Analysis of posterior donor corneal parameters 1 year after Descemet stripping automated endothelial keratoplasty (DSAEK) triple procedure

Marco Lombardo • Mark A. Terry • Giuseppe Lombardo • David D. Boozer • Sebastiano Serrao • Pietro Ducoli

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Abstract

Background Although Descemet stripping automated endothelial keratoplasty (DSAEK) was demonstrated to be effective for the treatment of endothelial corneal diseases, a variable hyperopic shift has been measured as a common occurrence postoperatively. The aim of this work was to investigate the variance in the corneal and refractive responses to DSAEK combined with phacoemulsification

M. Lombardo · G. Lombardo Vision Engineering, Rome, Italy

M. A. Terry Corneal Services, Devers Eye Institute, Portland, OR, USA

M. A. Terry · D. D. Boozer Lions Vision Research Laboratory of Oregon, Portland, OR, USA

G. Lombardo CNR-INFM LiCryL Laboratory, Department of Physics, University of Calabria, Rende (CS), Italy

S. Serrao SerraoLaser, Rome, Italy

M. Lombardo · P. Ducoli IRCCS Fondazione G.B. Bietti, Rome, Italy

M. Lombardo (🖂) Via Adda 7, 00198 Rome, Italy e-mail: mlombardo@visioeng.it

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and implantation of intra-ocular lens (IOL), namely the DSAEK triple procedure.

Methods The refractive, topographic, and anterior segment optical coherence tomography (AS-OCT) data of 23 eyes treated with DSAEK triple procedure were analyzed. A mean refractive IOL target of -1.04 ± 0.09 D was calculated based on empirical data of our early experience to achieve emmetropia in all the eyes included in the study. Donor corneal parameters, i.e., graft diameter, thickness, and profile, were investigated in order to verify their possible role in the variable refractive shift after DSAEK.

Results Although the 1-year mean refractive outcome was close to emmetropia (-0.01 ± 0.89 D), the average difference between the targeted postoperative refraction and the 1-year postoperative spherical equivalent refraction was $+0.98\pm$ 0.87 D. Correlations of refractive change with central graft thickness (r=0.36, *p*=0.05) and graft diameter (r=0.45; *p*= 0.03) were statistically significant. AS-OCT analysis revealed how the graft shape, with graft thicker in the periphery compared with the center, contributed to reduce the radius of curvature of the posterior cornea, thus favoring the hyperopic shift postoperatively.

Conclusions DSAEK triple procedure provides negligible changes in the surface topography, however with a variable amount of hyperopic shift postoperatively. Central graft thickness and graft profile together contributed to approximately two-thirds of the variance in refractive shift postoperatively. Lenticule diameter provided a minor influence on postoperative hyperopic shift than other graft parameters.

Keywords Descemet stripping automated endothelial keratoplasty · DSAEK · Endothelial keratoplasty · Corneal topography · Donor graft geometry · DSAEK triple procedure

Introduction

During the last years, endothelial keratoplasty (EK) procedures have renewed the method to treat patients suffering from corneal endothelial diseases [1]. Currently, Descemet stripping automated endothelial keratoplasty (DSAEK) [2] has become the preferred EK technique worldwide. The use of microkeratome for donor graft preparation has been shown to achieve a more accurate and repeatable donor tissue thickness with a smoother interface in comparison with manually prepared donor tissue [3], i.e., Descemet stripping endothelial keratoplasty (DSEK). Graft preparation can be performed by the surgeon in the operating room immediately before donor tissue insertion or by an expert eye bank technician prior to surgery. In both cases, results of DSAEK from many centers have shown how the technique yields rapid and significant improvement in vision with no increase in endothelial cell loss or postoperative complications in comparison with former EK procedures [4–7]. On the other hand, the postoperative refractive outcome is not yet as accurate as expected: there has been, in general, reported an average hyperopic shift of approximately 1.00 diopter (D) or even more [4, 5, 8-10]. Since DSAEK can be performed in patients with clinically significant cataract that need concurrent phacoemulsification, it becomes desirable to identify factors that may affect predictability of surgical outcomes. Donor graft parameters (e.g., thickness, diameter, and profile) are the main variables that have been hypothesized to influence the refractive target after DSAEK; anterior corneal topography has been claimed to contribute only in those eyes with advanced corneal decompensation associated with epithelial changes.

To date, a few preliminary works [11–15] aimed to quantify how the various donor corneal parameters may influence the ultimate refractive outcome following DSAEK with or without combined phacoemulsification and implantation of intraocular lens (IOL), namely the DSAEK triple procedure.

The purpose of the present work is to investigate the influence of donor graft parameters on refractive outcome after DSAEK triple procedure and discuss the theoretical basis for optimizing the IOL power calculation prior to surgery.

Materials and methods

A total of 23 eyes of 23 patients was included in this study. All eyes underwent EK for Fuchs' dystrophy. An institutional review board-approved protocol and surgical consent form for EK was signed from all the patients. The study further followed the tenets of the Declaration of Helsinki. The series reported here includes 23 consecutive patients with no history of ocular pathologies or previous ocular surgery of a prospective EK protocol study, which have been operated by an experienced EK surgeon (MAT) at Devers Eye Institute (Portland, OR).

Surgical technique

Phacoemulsification cataract extraction and subsequent IOL insertion (AcrySof SN60WF, Alcon, Fort Worth, TX) were performed before stripping the Descemet's membrane using a scleral tunnel incision of 2.80 mm. DSAEK was then performed through the same incision, enlarged to 5.00 mm. Descemet's membrane was stripped, with the anterior chamber filled with Healon (Advanced Medical Optics, Santa Ana, CA), to a previously determined size of 8.00 to 9.00 mm. After scraping the peripheral recipient bed with Terry scraper (Bausch & Lomb, St. Louis, MO) to promote donor adhesion [16], the Healon was completely removed with automated irrigation and aspiration.

If the donor graft was prepared by the surgeon in the operating room, a Moria microkeratome system (Moria, Doylestown, PA) with a 300- μ m CB head was used in all the cases. Alternatively, if a precut tissue was used, it was obtained from the Lions Eye Bank of Oregon (Portland, OR), where the donor graft was prepared utilizing a Moria microkeratome and artificial anterior chamber system (AAC, Moria Inc., Doylestown, PA). Precut tissue was then shipped in Optisol-GS solution (Chiron Ophthalmics, Irvine, CA) covered by the anterior lamellar corneal tissue. In all the cases, the goal was to achieve an ideal thickness of 150 μ m for the donor lenticule. No special requests in regard to donor characteristics were made, except for a preoperative endothelial cell density (ECD) greater than 2,000 cells/mm².

After preparation, the donor lenticule was folded and grasped utilizing a single distal point fixation Charlie forceps (Bausch & Lomb, St. Louis, MO) and then unfolded in the anterior chamber with a combination of balanced salt solution and air. Once the graft was open and centered, residual fluid was removed using the Cindy sweeper (Bausch & Lomb, St. Louis, MO) for corneal surface compression and stroking, while the anterior chamber was completely filled with air. At the end of procedure, residual air bubble filling half of the anterior chamber volume was placed to support the graft postoperatively, with the pupil pharmacologically dilated. More details on the surgical technique can be found in previous works [16, 17].

Follow-up measurements

Patients included in this study underwent a complete ocular examination preoperatively and 6 and 12 months postoperatively. The examination also included corneal topography (TMS, software version 3.58, Tomey Corporation, Nagoya, Japan), ultrasound pachymetry (Ultrapach, Eye Technology, St. Paul, MN) and specular microscopy measurements of endothelial cell density (ECD; SP4000 noncontact specular microscope, Konan Medical Corp., Fair Lawn, NJ). Preoperative endothelial cell count was performed at the eye bank, which used an EB-3000 XYZ Eyebank specular microscope (HAI Laboratories, Inc., Lexington, MA). The preoperative central donor tissue thickness was measured at the eye bank (DGH Pachette 2, DGH Technologies Inc., Exton, PA) or by the surgeon prior to insertion of graft. Postoperative donor graft thicknesses were achieved with the anterior segment optical coherence tomography (AS-OCT, software version 1.0, Carl Zeiss Meditec AG, Jena, Germany). Corneal lamellar thickness measurements along the horizontal meridian were obtained using the measurement caliper provided by the software.

A software program was developed, using Matlab (version 7.0, MathWorks Inc., Natick, MA), to quantify the changes of the anterior corneal topography after the DSAEK triple procedure. This was achieved by importing all the preoperative and postoperative corneal data (.DAT files) into custom software for processing [18]. A central region of \pm 2.00 mm from the corneal vertex was investigated, as it most reliably represents the optically significant region of the cornea from which keratometry measurements are derived.

Statistical analysis

The Wilcoxon signed rank test was used to compare preoperative and 1-year postoperative data. Multiple comparisons were made between the preoperative graft parameters and the change in spherical equivalent (SE) refraction using the Steel-Dwass test. Correlation analysis of donor tissue characteristics with the changes in SE refraction was performed using the Spearman/Kendall rank correlation. A *p*-value of less than .05 was considered statistically significant for each test performed. The software program KyPlot (KyensLab Inc., Tokyo, Japan) was used for all statistical testing.

Results

There were 14 women and nine men with an average age $(\pm SD)$ of 64.73 ± 10.01 years. There were 15 cases in which the donor disc had been precut by an eye bank technician and eight cases in which donor preparation was performed by the surgeon in the operating room.

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The intent of surgery was to render all eyes as close to emmetropia as possible postoperatively, therefore the calculation of IOL power was based on our early experience with DSAEK that demonstrated a hyperopic shift in refraction [10]: the mean refractive IOL target was -1.04 ± 0.09 D (range -0.81 D to -1.16 D).

No dislocation of the graft was experienced in this series of eyes and no patient was re-operated for donor graft failure.

Refraction and corneal data are summarized in Table 1. The average difference between the targeted postoperative refraction and the 1-year postoperative SE refraction was $+0.98\pm$ 0.87 D. The mean preoperative refractive astigmatism was 0.85 ± 0.77 D; at the end of follow-up, the mean refractive astigmatism measured 0.91 ± 0.62 D (p=0.47). No statistically significant changes in the anterior corneal topography between the preoperative and 1-year postoperative examinations (<0.10 D; p=0.56) were measured. In addition, no statistically significant changes between the preoperative and 1-year postoperative and 1-year postoperative central corneal thickness (CCT) measurements (<25 µm; p=0.20) were determined.

Donor graft parameters

The average central ECD was $2,873\pm157$ cells/mm² (range, 2,649–3,145) before surgery, 2,107±216 cells/mm² (range, 1,802–2545; 28% mean loss; p<0.001) 1-year after surgery.

The mean graft diameter was 8.33 ± 0.32 mm. There was a positive and statistically significant correlation between lenticule diameter and induced refractive shift (also considering the IOL refractive target): r=0.45, p=0.03. The preoperative central graft thickness (CGT) measured $160\pm$ 34μ m; the mean 1-year postoperative CGT was $151\pm28\mu$ m (p=0.47). A moderate, statistically significant, positive correlation between refractive change and preoperative central graft thickness was measured (r=0.36, p=0.05). Mean (\pm SD) CGT and graft diameter values are summarized in Table 2. Statistical significance between the change in SE refraction and both the preoperative CGT (p<0.001) and graft diameter (p<0.001) values was found.

A non-uniform thickness profile of the graft was in general observed in all the eyes (Fig. 1): the mean thickness in the mid-peripheral (\pm 2.50 mm from the corneal vertex) and peripheral (\pm 4.00 from the vertex) graft regions, along the horizontal meridian, was 186±26 µm and 247±27 µm, with a non-linear thickening gradient between the center

 Table 1
 Average preoperative

 and postoperative refractive and
 corneal data during follow-up

^a Wilcoxon, preoperatively to 1 year postoperatively: *p*>.05

| =23 eyes | SE refraction $(D, \pm SD)^a$ | Anterior tangential curvature $(D, \pm SD)^a$ | Central corneal thickness $(\mu m, \pm SD)^a$ |
|----------------------|-------------------------------|---|---|
| reoperative | $+0.65\pm1.41$ | 43.91±1.73 | 662±58 |
| months postoperative | $+0.08 \pm 0.95$ | 44.19 ± 1.77 | 694±64 |
| year postoperative | -0.01 ± 0.89 | 43.96±1.70 | 686 ± 58 |
| | | | |

Table 2 Correlation ofrefractive change, preoperativecentral graft thickness, andgraft diameter

| n=23 eyes | Central graft thickness range (μm ; M \pm SD) | Graft diameter (mm; M ± SD) | Refractive change (D; M ± SD) |
|-----------|---|--------------------------------|----------------------------------|
| 5 | 100-130 (111±11) | 8.30±0.27 | -0.49 ± 1.61 |
| 11 | 131-170 (156±13) | 8.32 ± 0.36 | 0.21 ± 1.36 |
| 7 | >171 (200±8) | 8.36±0.24 | 1.12 ± 1.35 |

and periphery of the graft (Fig. 2). The result of adding a non-planar graft to the recipient tissue was to increase the thickness in the periphery of the whole cornea more than in the center. One year after surgery, mean total central corneal thickness was 686 ± 58 µm, mid-peripheral and peripheral total corneal thicknesses were 752 ± 60 µm and 893 ± 63 µm, respectively, as measured by AS-OCT.

A positive linear correlation, though it did not reach statistical significance, between the mid-peripheral (r=0.21, p=0.53) and peripheral thicknesses (r=0.15, p=0.61) of the cornea and the ECD loss during follow-up was measured.

A multiple linear regression model of refractive shift containing the preoperative CGT and donor graft diameter explained 29% of the variance in refractive shift ($R^2=0.29$, p=0.03); on the other hand, when performing the regression analysis with CGT and graft profile values (characterized by the second-order polynomial values of the quadratic regression equation), approximately 63% of the variance in refractive shift (p=0.05) was calculated (Fig. 3).

Discussion

From their introduction in clinical practice [19], EK procedures have encountered worldwide developing con-

sent from corneal surgeons to treat endothelial corneal diseases [5, 20, 21].

Since the vast majority of reports on refractive outcome have measured a variable hyperopic shift of approximately +1.00 D or more, as a common occurrence after DSAEK [2, 5, 8, 22], surgeons actually used to perform combined DSAEK and phacoemulsification targeting the IOL refractive power more myopic than intended, based on empirical data of their own early experience. On the other hand, such an approach can yield to error due to the variability in amount of hyperopic shift between patients: donor lenticule parameters have been hypothesized to be the main factors of postoperative refractive inaccuracy [11–15].

In this work, we aimed to identify which donor lenticule factors could primarily influence the predictability of refractive outcomes following the DSAEK triple procedure. Although the mean SE refraction was quite accurate 1 year postoperatively thanks to the implantation of a more myopic IOL than intended to achieve emmetropia, a mean hyperopic shift of approximately 1.00 D (with a SD higher than 0.8 D) was determined in this series of eyes, as also experienced by previous authors using either precut or surgeon-dissected donor tissues [7].

From our study, the anterior cornea was demonstrated not to contribute significantly to the postoperative change

Fig. 1 Example of Descemet stripping endothelial keratoplasty graft observed at highresolution AS-OCT. Image was taken 1 year postoperatively. The "flap tool" of the software system allows one to measure the central and peripheral thicknesses of the graft and host cornea at desired distances: here, measurements were taken at the corneal vertex, ± 2.50 mm from the vertex and at the edges of grafts. One may clearly note how the center of the graft is thinner than the periphery





Fig. 2 Corneal thicknesses averaged vertically across $\pm 4.00 \text{ mm}$ of the horizontal meridian 1 year postoperatively. The quadratic regression equations fit $(y = ax^2 + bx + c)$ to the profile of the graft (*dotted curve*), recipient cornea (*dashed curve*) and total cornea (*solid curve*) are shown. The positive second-order polynomial coefficient (ax^2) reflects the parabolic shape; the first-order coefficient (bx) is the point where the parabola crosses the y access and the constant (c) is the declivity at that point. The larger the coefficient ax^2 , the more closed the graph of a quadratic function appears, and the smaller, the

in manifest refraction [8, 10]. DSAEK with sclero-corneal tunnel incision was confirmed to be a surface topographic power neutral procedure, further without any increase in corneal or refractive astigmatism postoperatively.

A statistically significant positive correlation between preoperative central graft thickness and refractive change was measured in this study. Grafts thicker than $170 \,\mu\text{m}$ were associated with the highest hyperopic refractive shift, whereas grafts of $150\pm20 \,\mu\text{m}$ correlated with the best refractive neutrality postoperatively. The thinnest grafts (<130 μ m) were associated with a mean myopic shift in refraction of approximately -0.50 D. These results were

more open. Accordingly, a higher value of the coefficient ax^2 indicates a steeper curve. As one may note, the parabolic shape of the total cornea is closer than those of graft and recipient cornea alone, as evidenced by the highest value of second-order coefficient: when a graft of non-uniform thickness that is thicker in the periphery compared to the center is added to the posterior host cornea, it contributes to reduce the radius of curvature of the posterior cornea, thus increasing the negative power of this surface. The net result is a decrease of the corneal optical power

consistent with a model calculation performed by Dupps et al. [11] in which the thickest central grafts favored hyperopic shift following simple DSAEK.

Graft diameter was quite homogeneous in this series of eyes (9% of eyes received 9.00 mm donor button, 50% 8.50 mm and 41% 8.00 mm); on the other hand, a statistically positive correlation between lenticule diameter and induced refractive shift was calculated in this series, similarly to that reported by a previous work [12], in which graft diameters ranged between 7.00 and 9.00 mm.

One year postoperatively, i.e., when the corneal graft deturgescence has been measured to be stable [13, 23],

Fig. 3 Correlation of 1-year induced refractive shift (taking into consideration the IOL refractive target) and refractive shift predicted by a 2-predictor model incorporating preoperative central graft thickness and the second-order coefficient representing graft curvature $(R^2=0.63; p=0.05)$



AS-OCT images allowed the measurement of central and peripheral thicknesses of the cornea, revealing how the graft shape, added to the posterior host corneal interface, may influence the focusing properties of the corneal tissue. The fitted equation representing the curvature of the whole cornea's posterior surface in this series of patients had a higher value of coefficient ax^2 , and hence a greater curvature, than the posterior corneal interface of the recipient. Theoretically, the donor lenticule, thicker in the periphery than in the center, when added to the posterior recipient cornea, reduces the radius of curvature of the original posterior corneal surface, thus decreasing the effective corneal power, Φ , according to the thick-lens focal length equation [24]:

$$\Phi = \frac{1}{f} = (n-1) \left[\frac{1}{R_1} - \frac{1}{R_2} + \frac{t(n-1)}{R_1 R_2 n} \right]$$

A consideration of the thick-lens equation reveals that for a given index of refraction n and central corneal thickness t, there is an infinite number of combinations of R_1 (radius of curvature of the anterior cornea) and R_2 (radius of curvature of the posterior cornea) which will produce a given focal length f. In general, after DSAEK, either t or R_2 can vary leading to a change in the focal length of the corneal optics: for example, assuming R_1 and tconstant, as measured in the present series of eyes (see Table 1), a reduction of R_2 will increase the negative power of the posterior surface, thus increasing the effective focal length of the corneal optics. The thicker the graft peripherally in comparison to the center, the more the induced the hyperopic shift will be.

Yoo et al. [14] measured a significant correlation between the induced hyperopic shift and the ratio of CGT to peripheral graft thickness following the DSAEK triple procedure in a group of 11 eyes: 65% of the variation in refractive shift was explained by graft shape, however with a different mathematical approach from that used in the present work. Dupps et al. [11] have calculated in a small group of eyes (seven eyes) how CGT and profile together may account for approximately 85% of the variation in refractive shift after simple DSAEK.

In our study, we measured how central graft thickness and nonuniform thickness profile together contribute to the majority of the variance in the refractive response to DSAEK triple procedure. A two-predictor model containing the graft central thickness and the curvature coefficient for the graft thickness profile explained approximately twothirds of the induced refractive shift. Graft diameter, possible postoperative changes in the graft profile due to its response to the intraocular environment, and uncertainties in the IOL power calculation may accordingly explain the remaining one-third of the variable refractive response to DSAEK triple procedure. Indeed, lenticule diameter and central graft thickness together explained 29% of the variance in the hyperopic shift.

Actually, it is an object of debate whether the peripheral stromal surface of the graft, devoid of endothelial cells, may lead to peripheral hydration and additional thickening in the postoperative period, thus contributing to the hyperopic shift [23, 25]. In our series, we found a positive linear correlation, although one that was not statistically significant, between the 1-year mid-peripheral and peripheral thicknesses of the cornea and the central ECD loss during follow-up. Long-term studies will bring valuable information on this issue.

Limitation of this study is the lack of preoperative analysis of corneal profile with AS-OCT. Future prospective study including biometry data with preoperative and postoperative corneal data is warranted. We might, however, expect that with current microkeratome devices, having central and peripheral donor graft thicknesses into consideration for calculation of the IOL refractive target. would minimize variability and further optimize the refractive outcome after DSAEK triple procedure in the individual. Innovative surgical strategies to obtain a more planar graft shape and accordingly minimize the amount of postoperative hyperopic shift could be considered: between these are the redesign of the artificial anterior chambers and mechanical microkeratome plates to homogenize the cutting depth throughout the donor tissue [11, 26] and the creation of the donor tissue using a femtosecond laser with a hyperopic contact lens or adjusted nomograms [27, 28].

Disclosure Dr. Terry has a financial interest in the specialized instruments used in this surgery. The remaining authors have no financial or commercial interests in the materials presented herein.

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