Quality of Vision After Femtosecond Laser-Assisted Descemet Stripping Endothelial Keratoplasty and Penetrating Keratoplasty: A Randomized, Multicenter Clinical Trial

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- PURPOSE: To compare the quality of vision (straylight and contrast sensitivity) after femtosecond laser-assisted Descemet stripping endothelial keratoplasty (FS DSEK) and penetrating keratoplasty (PK).
- DESIGN: Prospective, randomized clinical trial.
- METHODS: SETTING: Multicenter (5 ophthalmic centers in The Netherlands). STUDY POPULATION: Eighty eyes of 80 patients with corneal endothelial dysfunction were included and were randomized to FS DSEK or PK. OBSERVATION PROCEDURES: FS DSEK and PK. MAIN OUTCOME MEASURES: Straylight, contrast sensitivity, astigmatism, uncorrected visual acuity, best spectacle-corrected visual acuity (BSCVA), and visual symptom score.
- RESULTS: Straylight at 12 months was 1.37 ± 0.2 logarithm of straylight for FS DSEK and 1.46 ± 0.2 logarithm of straylight for PK (P = .151). During 12 months of follow-up, there was a significant improvement of straylight and contrast sensitivity after FS DSEK (P < .001) and PK (P < .001). The change of straylight and contrast sensitivity correlated significantly with the change of BSCVA after FS DSEK (r = −0.645; r = 0.580) and PK (r = −0.370; r = 0.659). The visual symptom score was comparable between the 2 groups during the 12 months of follow-up.
- CONCLUSIONS: Improvement of straylight and contrast sensitivity was significantly correlated with an improvement of BSCVA. Straylight and contrast sensitivity were improved significantly after FS DSEK and were comparable with those after PK, although BSCVA was slightly better in the PK group.

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METHODS

THIS RANDOMIZED, MULTICENTER TRIAL WAS CONDUCTED at 5 ophthalmic centers in The Netherlands. Inclusion criteria were endothelial dysfunction caused by Fuchs endothelial dystrophy, aphakic or pseudophakic bullous keratopathy or posterior polymorphous dystrophy, a minimal age of 18 years, and a best spectacle-corrected visual acuity (BSCVA) lower than 20/50. Patients were excluded if they had undergone previous PK, had human leukocyte antigen typed keratoplasty, or were mentally retarded. The medical history was recorded, and all patients underwent a slit-lamp examination. Preoperative collected data included patient age, gender, refractive error, preoperative lens status, and ocular comorbidities.

- **SURGICAL PROCEDURES:** The surgical techniques of FS DSEK and PK have been described previously.11

- **OUTCOME MEASURES:** The primary outcome measures were straylight and contrast sensitivity. Secondary outcome measures included refractive astigmatism, topographic astigmatism, uncorrected visual acuity (UCVA), BSCVA, and visual symptom score. All outcome measures were measured before surgery and at 3, 6, and 12 months of follow-up.

  Straylight was measured using a straylight meter (C-Quant; Oculus GmbH, Wetzlar, Germany), which uses a compensation comparison method with a forced-choice technique.18 Clinical straylight measurement is a relatively new development to quantify quality of vision and was developed originally for visual acuities better than 0.7 logarithm of the minimal angle of resolution (logMAR). However, corneal transplantation patients often have visual acuities worse than that.

  The straylight value was expressed as a logarithmic intraocular straylight (log(s)) value. Higher values indicate more straylight and an increased sensitivity to glare.19 Two consecutive straylight measurements of the study eye and the nonstudy eye were obtained, after which an average amount of logarithmic intraocular straylight was calculated. The instrument derives a reliability value for each measurement, called the expected standard deviation, on the basis of known psychometric principles. A reliable value was defined as an expected standard deviation of less than 0.08 log units. The repeated measures design of the study

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**FIGURE 1.** Participant flow chart of femtosecond laser-assisted Descemet stripping endothelial keratoplasty versus penetrating keratoplasty. FS-DSEK = femtosecond laser-assisted Descemet stripping endothelial keratoplasty; PK = penetrating keratoplasty; PLD = posterior lamellar disc.
checked this reliability estimate against true reliability. Straylight values also were compared with a control group obtained from a previous database consisting of age-matched subjects with a clear cornea and no cataract.19 Eyes that were unable to perform the straylight test before surgery were substituted by the highest preoperative log(s) plus 0.1.

The contrast sensitivity was measured using the Pelli-Robson chart (Clement Clarke Ltd, Harlow, United Kingdom). This chart was chosen from among other available charts for its high reliability and validity compared with sinusoidal grating charts such as the Vistech and Functional Acuity Contrast Test.20–22 Patients were tested both monocularly and binocularly, using the best spectacle correction for distance vision on a testing distance of 1 m and a luminance of 85 candelas/m². The last triplet of letters, of which at least 2 letters were seen correctly, was recorded and expressed as a logarithmic contrast sensitivity value.23 Lower values indicate a better contrast sensitivity.

Topographic astigmatism was measured using the EyeMap corneal topographer (EH-290; Alcon, Fort Worth, Texas, USA). The UCVA and BSCVA were determined using the Early Treatment Diabetic Retinopathy Study letter charts and were converted to logarithm of the minimal angle of resolution measurements.24 Vision levels of counting fingers, hand movements, light perception, and no light perception were substituted by logarithm of the minimal angle of resolution values of 1.7, 2.0, 2.5, and 3.0, respectively.

Double-vision or distorted vision, glare, halo, blurry vision, and differently looking colors were reported by patients using a validated questionnaire.25 The grading of symptoms ranged from great deal, moderate amount, little, to none, and a score of 3, 2, 1, or 0 was assigned, respectively. Scores for each of the symptoms then were summed, and this resulted in a visual symptom score ranging from 0 (not at all bothered by any of the symptoms) to 15 (very bothered by all symptoms).25,26

**SAMPLE SIZE:** The sample size calculation of the main outcome of this randomized clinical trial has been described previously.11

**RANDOMIZATION:** All included eyes were assigned randomly to either the FS DSEK or the PK group. The randomization code was generated using a permuted block size of 2. The assigned treatment plans then were sent to the surgeon.

**STATISTICAL ANALYSIS:** Data were described as mean ± standard deviation for continuous variables and as individual counts and percentages for categorical variables. Differences between groups were analyzed using a Student t test for continuous data. The Pearson chi-square test was used to compare categorical data. Comparisons of preoperative data and postoperative data within a group were performed using a linear regression model. Correlations were assessed using the Pearson correlation coefficient in case of normal distributed data and using the Spearman test in case of abnormal distributed data. A P value of less than .05 was considered to be statistically significant. Statistical analysis was performed using SPSS software for

| TABLE 1. Preoperative Patient Characteristics of Femtosecond Laser-Assisted Descemet Stripping Endothelial Keratoplasty and Penetrating Keratoplasty |
|-----------------|----------------|----------------|
| FS DSEK         | PK             | P Value        |
| Eyes (n)        | 36             | 40             | NA             |
| Mean age ± SD (y) | 69.0 ± 8.8   | 71.4 ± 11.3    | .308           |
| No. women (%)   | 21 (58.3%)     | 27 (67.5%)     | .500           |
| Diagnosis       |                |                | .725           |
| Fuchs endothelial dystrophy | 21 (58.3%)   | 20 (50.0%)     |                |
| Pseudophakic bullous keratopathy | 15 (41.7%)* | 19 (47.5%)*    |                |
| Posterior polymorphous dystrophy | 0           | 1 (2.5%)       |                |
| Recipient lens status |                |                | .996           |
| Aphakic         | 1 (2.8%)*      | 1 (2.5%)*      |                |
| Phakic          | 21 (58.3%)     | 21 (52.5%)     |                |
| Pseudophakic    | 14 (38.9%)     | 18 (45.0%)     |                |
| Ocular comorbidity |              |                |                |
| Age-related macular degeneration/RPE changes | 12 (33.3%)   | 5 (12.5%)      | .030           |
| Cataract        | 8 (22.2%)      | 12 (30.0%)     | .442           |
| Glaucoma        | 1 (2.8%)       | 3 (7.5%)       | .357           |

FS DSEK = femtosecond laser-assisted Descemet stripping endothelial keratoplasty; NA = not applicable; PK = penetrating keratoplasty; RPE = retinal pigment epithelium; SD = standard deviation.

*One aphakic eye with iris-fixated anterior chamber intraocular lens.
RESULTS

• PARTICIPANT FLOW CHART: Eighty eyes of 80 patients were recruited, with 40 eyes in each arm (Figure 1). In the FS DSEK group, 4 patients did not receive the allocated treatment because of significant preoperative events (such as keratitis, corneal ulcers, or both) and eventually were excluded from the study analysis. All patients in the PK group received the allocated treatment. In the FS DSEK group, 29 eyes were available for analysis at the 12-month follow-up. After surgery, the cornea of 3 eyes remained edematous and did not clear up; this was defined as primary graft failure. Two eyes underwent PK before the 3-month follow-up, and 1 eye underwent repeat FS DSEK after 6 months of follow-up.

• PATIENT CHARACTERISTICS: Patients characteristics of the FS DSEK and PK group are listed in Table 1. The mean age of the FS DSEK group and PK group was 69.0 ± 8.8 years and 71.4 ± 11.3 years, respectively \((P = .308)\). In the FS DSEK group, 21 of 36 patients (58.3%) were diagnosed with Fuchs endothelial dystrophy, and 8 (38.1%) of these 21 patients also had visually significant cataract. These patients either underwent primary cataract extraction with IOL implantation \((n = 5, 62.5\%)\) followed by the FS DSEK procedure or a combined procedure of FS DSEK and cataract extraction with IOL implantation \((n = 3, 37.5\%). In the PK group, 20 of 40 patients \((50.0\%)\) were diagnosed with Fuchs endothelial dystrophy, and 12 \((60.0\%)\) of these 20 patients also had visually significant cataract. Ten \((83.3\%)\) of these 12 patients underwent a combined procedure of PK and cataract extraction with IOL implantation, and 2 of the 12 patients \((16.7\%)\) underwent a primary cataract extraction with IOL implantation before PK.

Before surgery, 34 patients \((85.0\%)\) in the PK group and 30 patients \((83.3\%)\) in the FS DSEK group required spectacle correction for distance vision; the remaining patients used no correction. Twelve months after FS DSEK, 23 patients \((79.3\%)\) used spectacles and 1 patient \((3.4\%)\) used soft contact lenses for distance vision. Five patients \((17.2\%)\) did not need a correction. Twelve months after PK, 26 patients \((66.6\%)\) used spectacles, 1 patient \((2.6\%)\) used a rigid contact lenses for distance vision, and 12 patients \((30.8\%)\) did not use a correction, with 7 of the 12 patients being unable to wear a correction because of anisometropia.

• INTRAOCULAR STRAYLIGHT: Before surgery, 43% of subjects had a visual acuity lower than the advised limit for straylight measurement \((0.7 \text{ logMAR})\). This limit seems a bit strict, because only 11 \((30.6\%)\) of 36 patients in the FS DSEK group and 13 \((32.5\%)\) of 40 patients in the PK group were unable to complete the straylight test. The mean logMAR BSCVA of these patients’ eyes was significantly higher in comparison with eyes of patients who did complete the test \((1.17 \pm 0.5 \text{ logMAR} \text{ vs } 0.67 \pm 0.2 \text{ logMAR}, \text{respectively} [P < .001], \text{in the FS DSEK group}; \text{and } 1.00 \pm 0.5 \text{ logMAR} \text{ vs } 0.59 \pm 0.3 \text{ logMAR, respectively} [P = .002], \text{in the PK group}). Figure 2 shows repeatability of the straylight measurement for all follow-up visits of the study eyes and for the nonstudy eyes \((P < .05 \text{ for all 4 comparisons}, F \text{ test})\). The repeated-measures standard deviation was 0.07 for the nonstudy eyes. For the study eyes, the repeated-measures standard deviations were slightly higher at 0.10, 0.09, 0.09, and 0.11.
for preoperative and postoperative values at 3, 6, and 12 months, respectively. So, the precision of the straylight measurements was not much less in the study eyes as compared with the nonstudy eyes, but the difference was statistically significant (P < .05 for all comparisons, F test). Repeatability was not dependent on straylight level, as is also evident in Figure 2.

Preoperative straylight values were not significantly different between the FS DSEK and PK group (1.97 ± 0.4 log(s) vs 1.97 ± 0.4 log(s), respectively; P = .926). During the follow-up, the straylight between the FS DSEK and PK group was comparable (3 months, 1.43 ± 0.2 log(s) vs 1.40 ± 0.2 log(s); 6 months, 1.42 ± 0.3 log(s) vs 1.41 ± 0.2 log(s); 12 months, 1.37 ± 0.2 vs 1.46 ± 0.2 log(s)). In both groups, there was a significant improvement of straylight during the 12 months of follow-up (FS DSEK, P < .001; PK, P < .001).

Straylight value as a function of age is shown in Figure 3. Eyes with too severe corneal edema that were not able to complete the straylight test were substituted by 2.46 log(s), which is notable in Figure 3. Before surgery, 13.9% (n = 5) of the patients in the FS DSEK group and 12.5% (n = 5) of the patients in the PK group had straylight values within the normal age-matched range, whereas the remaining patients had higher straylight values. Twelve months after FS DSEK and PK, 38.5% (n = 10) and 45.7% (n = 16) of the patients, respectively, had straylight values comparable with the normal age-matched range, and 11.5% (n = 3) and 2.9% (n = 1) of the patients, respectively, had higher straylight values, whereas 50.0% (n = 13) and 51.4% (n = 18) of the patients, respectively, had higher straylight values.

Before surgery, there was a significant correlation between the BSCVA and straylight value in the FS DSEK group (r = 0.461; P = .005) and PK group (r = 0.523; P = .001). At 3, 6, and 12 months after surgery, the correlation between BSCVA and straylight value was not significant in the FS DSEK group (r = 0.260, P = .209; r = 0.214,

**TABLE 2. Preoperative and Postoperative Contrast Sensitivity of Femtosecond Laser-Assisted Descemet Stripping Endothelial Keratoplasty and Penetrating Keratoplasty**

<table>
<thead>
<tr>
<th></th>
<th>FS DSEK, Mean ± SD</th>
<th>PK, Mean ± SD</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Study Eye</td>
<td>Fellow Eye</td>
<td>Binocular</td>
</tr>
<tr>
<td>Before surgery (log(c))</td>
<td>0.85 ± 0.4</td>
<td>1.26 ± 0.3</td>
<td>1.32 ± 0.3</td>
</tr>
<tr>
<td>3 mos (log(c))</td>
<td>1.28 ± 0.3a</td>
<td>1.27 ± 0.2</td>
<td>1.39 ± 0.2</td>
</tr>
<tr>
<td>6 mos (log(c))</td>
<td>1.22 ± 0.2a</td>
<td>1.27 ± 0.2</td>
<td>1.41 ± 0.2</td>
</tr>
<tr>
<td>12 mos (log(c))</td>
<td>1.28 ± 0.2a</td>
<td>1.25 ± 0.2</td>
<td>1.38 ± 0.2</td>
</tr>
<tr>
<td></td>
<td>P &lt; .001c</td>
<td>P = .992c</td>
<td>P = .365c</td>
</tr>
</tbody>
</table>

FS DSEK = femtosecond laser-assisted Descemet stripping endothelial keratoplasty; log(c) = logarithm of contrast sensitivity; PK = penetrating keratoplasty; SD = standard deviation.

*P value between FS-DSEK and PK.

aP < .05 versus preoperative in a linear regression model.

bP value of a linear regression model with 3 postoperative periods at the same time in the model.
P = .273; and r = 0.082, P = .696, respectively). In the PK group, the BSCVA was correlated significantly with straylight at 3, 6, and 12 months of follow-up (r = 0.363, P = .032; r = 0.492, P = .003; and r = 0.569, P < .001).

The change in intraocular straylight and BSCVA values from baseline to 12 months after surgery showed a correlation in the PK group (r = −0.370; P = .029), and in the FS DSEK group (r = −0.645; P < .001). An improvement of BSCVA was correlated significantly with a decrease of straylight in both groups.

### CONTRAST SENSITIVITY
Contrast sensitivities for both groups are shown in Table 2. Before surgery, 3 (8.3%) of 36 patients in the FS DSEK group and 3 (7.5%) of 40 patients in the PK group were unable to see the highest contrast at 1 m distance. Before surgery, contrast sensitivity of the study eye, fellow eye, and binocularly were not significantly different between the FS DSEK and PK groups.

At 3, 6, and 12 months after surgery, no significant difference in contrast sensitivity was found between the FS DSEK and PK groups. In both the FS DSEK and PK groups, contrast sensitivity of the study eye increased significantly after surgery. The binocular contrast sensitivity improved significantly after PK (P = .006), but not after FS DSEK (P = .365).

Before surgery, there was a correlation between BSCVA and contrast sensitivity in both the FS DSEK group (r = −0.640; P < .001) and PK group (r = −0.706; P < .001). After FS DSEK and PK, the change in contrast sensitivity from baseline to 12 months after surgery showed a correlation with the change in BSCVA during the same follow-up period (r = 0.508, P = .009, and r = 0.659, P < .001, respectively).

In the FS DSEK group, the correlation between straylight and contrast sensitivity was r = −0.504 (preoperative, P = .003), r = −0.541 (3-month postoperative, P = .005), r = −0.685 (6-month postoperative, P < .01), and r = −0.554 (12-month postoperative, P = .796). In the PK group, the correlation between straylight and contrast sensitivity was r = −0.434 (preoperative, P = .007), r = −0.492 (3-month postoperative, P = .003), r = −0.534 (6-month postoperative, P = .001), and r = −0.348 (12-month postoperative, P = .040).

### ASTIGMATISM
Refractive and topographic astigmatism outcomes are shown in Table 3. Before surgery, there was no significant difference in refractive and topographic astigmatism between the FS DSEK and PK group. At the 12-month follow-up, both refractive and topographic astigmatism were significantly higher in the PK group compared with the FS DSEK group (refractive, −2.98 diopters [D] vs −1.22 D, respectively; and topographic, 3.67 D vs 1.58 D, respectively). In the FS DSEK group, postoperative refractive and topographic astigmatism values were not significantly different from preoperative values. In the PK group, all postoperative refractive and topographic astigmatism values were significantly higher compared with those before surgery. During follow-up, these values showed a tendency to decrease. After 12 months of follow-up, all sutures had been removed in only 1 eye (2.5%) in the PK group.

Twelve months after surgery, the percentage of patients with a refractive astigmatism of ≤ 3.0 D was significantly

| TABLE 3. Preoperative and Postoperative Astigmatism of Femtosecond Laser-Assisted Descemet Stripping Endothelial Keratoplasty and Penetrating Keratoplasty |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|
| Refractive astigmatism (D)       | Range           | PK, Mean ± SD   | Range           | P Value*       |
| Preoperative                    | −0.98 ± 1.0     | −3.5 to 0       | −1.27 ± 1.2     | −5.50 to 0     | .275           |
| 3 mos                           | −1.38 ± 1.2     | −5.0 to 0       | −4.17 ± 3.4ab   | −14.0 to 0     | <.001          |
| 6 mos                           | −1.46 ± 1.3     | −5.0 to 0       | −3.21 ± 1.9ab   | −8.00 to 0     | <.001          |
| 12 mos                          | −1.22 ± 1.1     | −4.0 to 0       | −2.98 ± 2.0ab   | −8.75 to 0     | <.001          |
| P = .358ab                      |                 | P < .001ab      |                 |                |
| Topographic astigmatism (D)     |                 |                 |                 |                |
| Preoperative                    | 1.38 ± 0.6      | 0.47 to 2.90    | 2.16 ± 1.4      | 0.50 to 6.50   | .577           |
| 3 mos                           | 1.87 ± 1.1      | 0.25 to 4.30    | 4.59 ± 2.9b     | 1.00 to 15.70  | <.001          |
| 6 mos                           | 1.72 ± 1.0      | 0.27 to 4.14    | 3.74 ± 1.7b     | 0.50 to 6.83   | <.001          |
| 12 mos                          | 1.58 ± 1.2      | 0.27 to 6.40    | 3.67 ± 1.8b     | 1.40 to 7.70   | <.001          |
| P = .469bc                      |                 | P < .001bc      |                 |                |

D = diopters; FS DSEK = femtosecond laser-assisted Descemet stripping endothelial keratoplasty; PK = penetrating keratoplasty; SD = standard deviation.

*P value between FS DSEK and PK.

bP < .05 versus preoperative in a linear regression model.

cP value of a linear regression model with 3 postoperative periods at the same time in the model.
higher in the FS DSEK group compared with the PK group (86.2% vs 51.3%, respectively; \( P = .004 \)).

**UNCORRECTED VISUAL ACUITY AND BEST SPECTACLE-CORRECTED VISUAL ACUITY:** Before surgery and at 3, 6, and 12 months after surgery, there was no significant difference in UCVA between the FS DSEK and PK groups (Table 4). In the FS DSEK group, UCVA was significantly better at all postoperative visits compared with that before surgery. The UCVA in the PK group was significantly improved at 3 and 12 months after surgery compared with that before surgery (glare, 80.6% vs 72.5%, respectively; halo, 66.7% vs 82.1%, respectively). During 12 months of follow-up, the percentage of patients reporting halos decreased from 19.4% before surgery to 3.8% at 12 months after surgery. In the PK group, 43.2% reported no blurry vision at 12 months after surgery as compared with 0% before surgery. The number of patients reporting double-vision or distorted vision was not significantly different between the FS DSEK and PK groups during the 12 months of follow-up.

In both the FS DSEK and PK groups, a relatively high percentage of patients reported glare and halo symptoms before surgery (glare, 80.6% vs 72.5%, respectively; halo, 66.7% vs 82.1%, respectively). During 12 months of follow-up, the percentage of patients reporting glare symptoms (severity score 3) decreased from 25.0% to 15.4% in the FS DSEK group and from 20.0% to 8.1% in the PK group (Table 5). The percentage of patients reporting halos decreased from 19.4% before surgery to 3.8% at 12 months after surgery in the FS DSEK group and from 20.0% to 8.1% in the PK group (Table 5).

Before surgery, there was no significant difference in visual symptom score between the FS DSEK and PK groups (6.33 ± 3.0 and 5.70 ± 2.7; \( P = .343 \)). During follow-up, the difference in visual symptom score between the FS DSEK and PK groups was not significant (3 months, 4.70 ± 3.5 vs 4.74 ± 3.2 [\( P = .964 \)]; 6 months, 4.52 ± 3.7 vs 3.97 ± 2.7 [\( P = .484 \)]; 12 months, 3.78 ± 2.8 vs 3.49 ± 2.9 [\( P = .694 \)]). In both groups, there was a significant

### TABLE 4. Preoperative and Postoperative Visual Outcome of Femtosecond Laser-Assisted Descemet Stripping Endothelial Keratoplasty and Penetrating Keratoplasty

<table>
<thead>
<tr>
<th></th>
<th>FS DSEK, Mean ± SD</th>
<th>Range</th>
<th>PK, Mean ± SD</th>
<th>Range</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UCVA (logMAR)</strong></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>1.01 ± 0.4 (20/200)</td>
<td>0.22 to 2.0</td>
<td>0.88 ± 0.4 (20/150)</td>
<td>0.40 to 2.0</td>
<td>.133</td>
</tr>
<tr>
<td>3 mos</td>
<td>0.80 ± 0.2 (20/125)*</td>
<td>0.40 to 1.70</td>
<td>0.71 ± 0.3 (20/100)*</td>
<td>0.10 to 1.36</td>
<td>.144</td>
</tr>
<tr>
<td>6 mos</td>
<td>0.79 ± 0.3 (20/125)*</td>
<td>0.40 to 1.70</td>
<td>0.79 ± 0.3 (20/125)</td>
<td>0.14 to 1.36</td>
<td>.959</td>
</tr>
<tr>
<td>12 mos</td>
<td>0.73 ± 0.3 (20/102)*</td>
<td>0.34 to 1.70</td>
<td>0.68 ± 0.3 (20/96)*</td>
<td>0.10 to 1.46</td>
<td>.539</td>
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<tr>
<td>( P = .001^c )</td>
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<td>( P = .045^c )</td>
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<tr>
<td><strong>BSCVA (logMAR)</strong></td>
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<tr>
<td>Preoperative</td>
<td>0.82 ± 0.4 (20/132)</td>
<td>0.22 to 2.0</td>
<td>0.73 ± 0.4 (20/105)</td>
<td>0.18 to 2.0</td>
<td>.316</td>
</tr>
<tr>
<td>3 mos</td>
<td>0.65 ± 0.3 (20/90)*</td>
<td>0.22 to 1.70</td>
<td>0.40 ± 0.2 (20/50)*</td>
<td>−0.04 to 1.12</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>6 mos</td>
<td>0.64 ± 0.3 (20/87)*</td>
<td>0.26 to 1.70</td>
<td>0.35 ± 0.2 (20/44)*</td>
<td>0 to 0.86</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>12 mos</td>
<td>0.55 ± 0.2 (20/70)*</td>
<td>0.16 to 1.10</td>
<td>0.35 ± 0.2 (20/44)*</td>
<td>−0.04 to 0.98</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>( P = .004^c )</td>
<td></td>
<td></td>
<td>( P &lt; .001^e )</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BSCVA gain (logMAR)</strong></td>
<td></td>
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<tr>
<td>3 mos</td>
<td>0.15 ± 0.4</td>
<td>−1.06 to 1.34</td>
<td>0.33 ± 0.4</td>
<td>−0.48 to 1.48</td>
<td>.052</td>
</tr>
<tr>
<td>6 mos</td>
<td>0.14 ± 0.4</td>
<td>−1.06 to 1.30</td>
<td>0.38 ± 0.4</td>
<td>−0.40 to 1.46</td>
<td>.017</td>
</tr>
<tr>
<td>12 mos</td>
<td>0.24 ± 0.4</td>
<td>−0.34 to 1.50</td>
<td>0.38 ± 0.4</td>
<td>−0.24 to 1.30</td>
<td>.103</td>
</tr>
</tbody>
</table>

BSCVA = best spectacle-corrected visual acuity; FS DSEK = femtosecond laser-assisted Descemet stripping endothelial keratoplasty; logMAR = logarithm of the minimal angle of resolution; mos = months; PK = penetrating keratoplasty; SD = standard deviation; UCVA = uncorrected visual acuity.

*\( P \) value between FS DSEK and PK.

\( bP < .05 \) versus preoperative in a linear regression model.

\( cP \) value of a linear regression model with 3 postoperative periods at the same time in the model.
improvement of visual symptom score at all time points (FS DSEK, \( P = .017 \); PK, \( P = .006 \)).

**DISCUSSION**

THE PURPOSE OF THIS RANDOMIZED, MULTICENTER TRIAL was to evaluate the quality of vision (intraocular straylight and contrast sensitivity) and to correlate these quality-of-vision parameters to the refractive and visual outcomes after FS DSEK and PK. Previous studies reported limited visual outcomes after lamellar keratoplasty because of an interface haze, which may increase straylight.\(^{13,27}\) The main conclusion of our study is that both FS DSEK and PK are very effective at improving straylight, and no significant difference between the 2 groups was found. Although postoperative straylight is still increased, the increase is only 2-fold when compared with age-matched controls. In this group of patients with severely impaired vision, the reliability parameter (expected standard deviation) for straylight measurements proved to be very effective to ensure accurate measurements before and after surgery (Figure 2). This compared well with published values between 0.08 and 0.06 as well as with the limit values used for expected standard deviation of 0.08.\(^{19}\)

The straylight values in our study showed a significant improvement during the 12 months of follow-up in the FS DSEK and PK group. The largest improvement was seen from baseline to 3 months after surgery, and after that, straylight values remained stable up to 12 months of follow-up. A previous randomized clinical trial comparing deep lamellar endothelial keratoplasty (DLEK) with PK showed no significant change in straylight values after surgery.\(^{12}\) This difference in outcome may be explained by several factors. First, the preoperative straylight value reported in our study obviously was higher than in the study by Patel and associates, which may be the result of a higher degree of corneal edema resulting from long-term corneal decompensation.\(^{12}\) Furthermore, the preoperative BSCVA was better in the study by Patel and associates, which also may indicate a lower degree of corneal edema or a shorter duration of corneal decompensation.\(^{12}\)

After surgery, the percentage of patients with straylight values within the normal age-matched range in-
creased from 13.9% to 38.5% in the FS DSEK group and from 12.5% to 45.7% in the PK group. Despite the FS DSEK and PK procedure, 50.0% of the FS DSEK patients and 51.4% of the PK patients did not return to a normal straylight level. In contrast to the previously reported correlation between age and straylight after DSEK, we did not find a significant correlation between age and straylight after FS DSEK and PK. Postoperative straylight values were compared with those of normal age-matched controls, but the age of the donor cornea was not age-matched with the recipient cornea. This also may explain why the postoperative straylight values of the study eyes did not return to a normal straylight level. Also, 6 of 36 eyes in the FS DSEK group had residual central corneal haze after deturgescence of the recipient cornea. However, because the group of patients with a central corneal haze was small, we only can speculate whether this may influence the postoperative straylight value.

It has been suggested that BSCVA after endothelial keratoplasty is limited because of increased straylight values associated with the lamellar interface. In our study, the gain of BSCVA and straylight values was not statistically significant between the 2 groups. The correlation between the change in straylight and BSCVA from baseline to 12 months after surgery was significantly higher in the FS DSEK compared with the PK group, which was comparable with the results of a previous study. It also was reported that the greatest improvement of BSCVA after PK and DLEK occurred in the first 3 months after surgery, which was comparable with our speed of improvement of UCVA and BSCVA in the FS DSEK and PK group.

Contrast sensitivity can be affected by corneal edema, distortion, or cataract. In our study, we found a significant improvement of contrast sensitivity after FS DSEK and PK. There was no significant difference in contrast sensitivity between the FS DSEK and PK groups during the 12 months of follow-up. The contrast sensitivity test was performed with the best spectacle correction in place, which corrected the higher astigmatism in the PK group. The contrast sensitivity reported in our study is comparable with that of previous randomized studies comparing deep anterior lamellar keratoplasty or DLEK and PK and lower than the contrast sensitivity of healthy eyes.

Improvement of BSCVA correlated with an increase in contrast sensitivity after FS DSEK and PK. The lamellar interface prepared with the FS laser showed no significant decrease in contrast sensitivity when compared with the PK group. Furthermore, the largest improvement in contrast sensitivity was seen in the first 3 months after surgery, which was comparable with our other outcomes (straylight, UCVA, and BSCVA). When evaluating the binocular contrast sensitivity, there was a significant improvement in the PK group, but not in the FS DSEK group. This may be explained by the difference of the contrast sensitivity between the study eye and fellow eye within the 2 study groups. The difference between the study eye and the fellow eye in the PK group was larger as compared with that of the FS DSEK group. It can be speculated that a fellow eye in the PK group with a higher contrast sensitivity will provide a better binocular contrast sensitivity.

The BSCVA in our study was significantly better in the PK group compared with the FS DSEK group. This is in comparison with earlier studies and may be explained by a possible interface haze or irregularities of the interface. However, a randomized study showed a comparable BSCVA in DLEK and PK eyes during the 1-year follow-up. Recent DSAEK studies have reported a mean BSCVA of 20/34 to 20/44 at 6 to 12 months after surgery, respectively, which is higher than our results for the FS DSEK group. This may be explained by an increased opacification at the interface as a result of keratocyte activation by the FS laser or of a suboptimal smoothness of the stromal bed as compared with a microkeratome-prepared bed. Further, as previously mentioned, there were 6 patients in the FS DSEK group with residual central haze after deturgescence of the recipient cornea, and this may influence the final BSCVA.

Before surgery, blurry vision was the most frequently reported symptom in both the FS DSEK and PK groups, which is comparable with the results of the study by Boisjoly and associates. Twelve months after surgery, the percentage of patients with blurry vision decreased from 91.7% to 74.1% in the FS DSEK group and from 100% to 56.8% in the PK group. The preoperative visual symptom scores of our FS DSEK and PK groups were slightly higher when compared with those of a previous study. This may be explained by the difference of the different diagnosis of the graft candidates between the 2 studies.

Although astigmatism was significantly higher in the PK group, the percentage of patients with symptoms of double-vision or distorted vision was comparable between the FS DSEK and PK groups. Patients were instructed to answer the questions on visual symptoms when using their spectacle or contact lens correction, which could have influenced their response.

In the PK group, there were 7 patients who were unable to wear a correction because of anisometropia, in contrast to no patients in the FS DSEK group. The anisometropia can be explained by the higher amount of astigmatism in the PK group. This illustrates a clear advantage of FS DSEK in comparison with PK, which is a lower and stable astigmatism, as has been described previously.

In conclusion, this randomized study showed that FS DSEK resulted in an equally good improvement of straylight and contrast sensitivity when compared with PK. In addition, corneal astigmatism did not increase after FS DSEK. However, although the UCVA in both groups
was comparable and the visual symptom score decreased in both groups, BSCVA was slightly better in the PK group. Our results indicate that the quality of vision measured by contrast sensitivity, straylight, and changes in visual acuity after FS DSEK is comparable with that achieved after PK.

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Biosketch

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