TITLE: Descemet Stripping Automated Endothelial Keratoplasty: A Review of the Clinical and Cost-Effectiveness

DATE: 26 November 2009

CONTEXT AND POLICY ISSUES:

Penetrating keratoplasty (PK), which requires the removal of all layers of the cornea, has been the standard treatment for corneal endothelial disorders, although there are many disadvantages to this procedure.1-3 With the hope to improve patients’ outcomes, Descemet stripping automated endothelial keratoplasty (DSAEK) and Descemet stripping endothelial keratoplasty (DSEK) are new procedures used to treat advanced disease of the corneal endothelium.4,6 In these procedures, the patient’s endothelium and Descemet membrane are removed and replaced with the donor’s endothelium, Descemet membrane, and posterior stroma. Unlike DSEK that uses manual dissection,6,7 DSAEK uses a mechanical microkeratome to dissect the donor’s tissue. Both DSAEK and DSEK are modifications of an earlier endothelial transplantation technique called posterior or deep lamellar endothelial keratoplasty (DLEK) that requires lamellar dissections of both the patient and the donor corneas.8-10 Evidence on the clinical and cost-effectiveness of DSAEK as compared to DSEK, DLEK, and PK is needed.

RESEARCH QUESTIONS:

1. What is the clinical effectiveness and safety of Descemet stripping with automated endothelial keratoplasty for patients with corneal endothelial disorders?

2. What is the cost-effectiveness of Descemet stripping with automated endothelial keratoplasty for patients with corneal endothelial disorders?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including OVID Medline, The Cochrane Library (Issue 4, 2009), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international health technology...
agencies, and a focused Internet search. The search was limited to English language articles published between 2004 and November 2009. Filters were applied to limit the retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, controlled clinical trials, and economic studies.

SUMMARY OF FINDINGS:

What is the clinical effectiveness and safety of Descemet stripping with automated endothelial keratoplasty for patients with corneal endothelial disorders?

The literature search identified one prospective, non-randomized study on DSAEK\(^{11}\) and one health technology assessment on DSEK and DSAEK.\(^{12}\) No randomized studies were found.

The prospective study compared the visual outcomes and complications of PK to DSAEK, DSEK, and DLEK.\(^{11}\) One hundred seventy-seven eyes of 161 patients with corneal edema resulting from Fuchs endothelial dystrophy, pseudophakic bullous keratopathy, aphakic bullous keratopathy, failed graft, or iridocorneal endothelial syndrome underwent either DSAEK (n = 45), DSEK (n = 16), DLEK (n = 68), or PK (n = 48). Outcomes of interest were uncorrected visual acuity (UCVA), best-corrected visual acuity, endothelial cell loss, refractive astigmatism, and post operative complications such as primary graft failure, graft rejection, and graft dislocation. The average follow-up time was 12 months. Findings are summarized in Table 1.

Table 1: Main Outcomes from Bahar et al.\(^{11}\)

<table>
<thead>
<tr>
<th></th>
<th>PK</th>
<th>DLEK</th>
<th>DSEK</th>
<th>DSAEK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Best-corrected visual acuity*</td>
<td>20/53</td>
<td>20/80</td>
<td>20/56</td>
<td>20/44</td>
</tr>
<tr>
<td>Uncorrected visual acuity*</td>
<td>20/112</td>
<td>20/96</td>
<td>20/89</td>
<td>20/71</td>
</tr>
<tr>
<td>Endothelial cell loss</td>
<td>39.6 ± 26.3%</td>
<td>43.4 ± 22.2%</td>
<td>38.2 ± 22.0%</td>
<td>36.4 ± 15.2%</td>
</tr>
<tr>
<td>Refractive astigmatism**</td>
<td>3.78 ± 1.91D</td>
<td>1.61 ± 1.26D</td>
<td>1.86 ± 1.1D</td>
<td>1.36 ± 0.92D</td>
</tr>
<tr>
<td>Graft failure</td>
<td>2.2%</td>
<td>2.9%</td>
<td>0%</td>
<td>2.1%</td>
</tr>
<tr>
<td>Graft rejection</td>
<td>2.2%</td>
<td>4.4%</td>
<td>0%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Graft dislocation</td>
<td>0</td>
<td>8.8%</td>
<td>12.5%</td>
<td>15.6%</td>
</tr>
</tbody>
</table>

DLEK = deep lamellar endothelial keratoplasty; DSAEK = Descemet stripping automated endothelial keratoplasty; DSEK = Descemet stripping endothelial keratoplasty; PK = penetrating keratoplasty

* The higher the ratio, the better the outcome

** The lower the diopters (D), the better the outcome

For best-corrected visual acuity, DSAEK had the best outcome, while DLEK had the worst. The differences between PK and both DLEK and DSEK were inconclusive, whereas the difference between PK and DSAEK was significant (p = 0.001). For uncorrected visual acuity, DSAEK had the best outcome and PK had the worst. The differences between techniques were inconclusive. Endothelial cell loss was similar for all techniques. For refractive astigmatism, DSAEK had the best outcome, and PK had the worst; the differences between PK and the other three techniques were significant (p < 0.0001). DSEK had the best outcome and DLEK had the
The worst outcome for graft failure and graft rejection and the differences between techniques were inconclusive. Graft dislocation outcomes were the best for PK, while DSAEK had the worst. The differences between PK and the other three techniques for graft dislocation were significant ($p = 0.0004$). The study concluded that DSAEK provided better best corrected visual acuity and uncorrected visual acuity and less severe refractive astigmatism as compared to DSEK, DLEK, or PK, but had a higher dislocation rate than the other groups. Limitations to this study may be that the follow-up period was 12 months which may be too short to assess long-term outcomes, and a possibility of selection bias because it is not a randomized trial.

The health technology assessment reviewed the published literature on the effectiveness and safety of DSEK and DSAEK for the treatment of corneal endothelial disorders. The search included studies published up to February 2009, and there were 34 studies identified. There was one randomized controlled trial included comparing precut versus surgeon-dissected graft, and all other studies were case series or observational studies. The analysis combined DSEK and DSAEK together, and there were no comparisons of findings between the two different techniques. The most common complications from DSEK and DSAEK were graft dislocations (mean 14%), followed by graft rejection (mean 10%) and primary graft failure (mean 5%). Average endothelial cell loss was 42% at 12 months. Average best-corrected visual acuity ranged from 20/34 to 20/66. The health technology assessment concluded that the evidence suggests DSEK and DSAEK are safe and effective treatments for corneal endothelial disorders.

What is the cost-effectiveness of Descemet stripping with automated endothelial keratoplasty for patients with corneal endothelial disorders?

The literature search did not identify any studies on cost-effectiveness of DSAEK for patients with corneal endothelial disorders.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

The comparative evidence from the one prospective study identified suggested that DSAEK provides significantly better best-corrected visual acuity and higher improvement in refractory astigmatism than PK. DSAEK also seems to result in better uncorrected visual acuity compared with PK, but the difference was inconclusive. However, the study also showed that DSAEK had a significantly higher rate of graft dislocation as compared with PK. The health technology assessment found that DSAEK and DSEK were effective in the treatment of corneal endothelial disorders, although there was a 14% rate of graft dislocation. No economic analyses about DSAEK were identified. The limited information identified on the clinical and cost-effectiveness of DSAEK may be a consideration for decision-making. Randomized studies comparing DSAEK to other techniques as well as cost-effectiveness studies are needed.

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