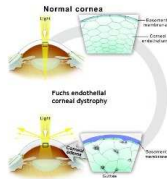
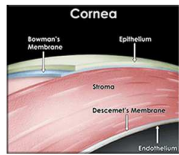


Descemet's stripping automated endothelial keratoplasty (DSAEK) is a novel technique for corneal endothelial dysfunction that has been requested for inclusion in the Galician Public Health Systems portfolio. In the Galician Government it is mandatory to evaluate new technologies for supporting reimbursement decision making. Thus, DSAEK's effectiveness and security was evaluated by a systematic review of the scientific literature.

The main causes of corneal endothelial failure are **Fuchs' endothelial dystrophy** and **aphakic or pseudophakic bullous keratopathy**. In the severest cases, the only treatment is corneal transplantation, with penetrating keratoplasty (PK) having been the gold standard over the last 50 years.



With the aim of reducing complications arising from this intervention, new techniques have been developed which come within the ambit of so-called endothelial keratoplasty, a procedure characterised by **replacing only the posterior layers of the cornea**. In this context, Descemet's stripping automated endothelial keratoplasty (DSAEK) is a novel technique with promising results.



Objective

The objective was to assess the efficacy/effectiveness, safety and cost of the DSAEK technique per se or in comparison with penetrating keratoplasty (PK), in patients with corneal endothelial failure.

Methods

A bibliographic search with no time limit was made in January 2013 of papers published in the principal systematic reviews data base: Health Technology Assessment, Centre for Reviews and Dissemination (CRD), Database of Abstracts of Reviews of Effects, National Health Service Economic Evaluation Database, Cochrane Library Plus and in general databases: Medline and Embase.

Results

Of a total of 583 papers retrieved, 20 case series and 2 economic evaluation studies fulfilled the inclusion criteria.

1. Effectiveness

- **Best-corrected visual acuity (BCVA)** improved after treatment with DSAEK, with statistically significant results vis-à-vis pre-intervention figures, attaining values of 0.6 to 0.8. DSAEK vs PK reported values of 0.45-0.56 and 0.125-0.38 respectively, although in some studies the difference was not significant.
- **Astigmatism** degree after DSAEK was not important with values of 0,5-0,15D.

2. Safety

- **DSAEK**
 - ✓ The **main complications** were primary failure (0%-12%), endothelial rejection (0.8%-8.5%) and graft dislocation-detachment (1.5%-23%).
 - ✓ The success of the intervention, defined as a clear corneal graft, was obtained **80.4%** at five years.
- **PK**
 - ✓ Endothelial rejection was the **most frequent complication**, with rates of 16%.

In terms of effectiveness and safety, outcomes were better in patients having no severe ocular comorbidities.

3. Cost

While one study reported that DSAEK was more cost-effective than PK, another one displayed that it was more effective, but also more expensive, than PK or femtosecond laser-assisted DSAEK and, depending on the maximum acceptable payment threshold, both DSAEK and PK could be cost-effective.

Conclusions

- In Fuchs' dystrophy and bullous keratopathy, data on the **effectiveness of DSAEK** indicate post-intervention improvement in uncorrected and best-corrected visual acuity in relation to baseline values registered prior to the procedure.
- Degree of **astigmatism** was similar after DSAEK and PK, with mild results in favour to the DSAEK.
- The most important **post-DSAEK complications** are linked to the viability of the graft, with the most frequent of these being dislocation-detachment and. In PK, rejection is the most frequent complication.
- The long-term graft survival rate is similar with both techniques.
- In DSAEK, the **learning curve** is a key factor and is directly linked to the success of the graft transplantation.
- **Economic evaluation studies** show that as compared to PK, DSAEK could be a cost-effective technique.
- The studies that assess DSAEK are case series, for the most part retrospective. The methodological quality of such studies tends to be low and limited, and so when it comes to recommending or discouraging the adoption of this technique, their results should be approached with caution.

Recommendations

- **Patients inclusion.** In the event of DSAEK being indicated, candidates likely to have better outcomes would be those presenting with **no severe ocular co-morbidities** (glaucoma, ocular hypertension). **Individualised assessment** would be necessary in the case of patients who, due to previous surgery (PK, glaucoma), performance of simultaneous intraoperative interventions and/or severe ocular co-morbidities, displayed a worse prognosis in terms of effectiveness and safety.
- The intervention would have to be performed at **reference centres** that were authorised/accredited to perform transplants, and by experienced surgeons because the success rate depends to a great extent on the learning curve.
- To reduce the cost of DSAEK, one alternative could be for **precut corneas** to be supplied by a reference eye-bank to the various centres that performed the technique.

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