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Comparative Cost-Effectiveness Analysis of Descemet Stripping Automated Endothelial Keratoplasty versus Penetrating Keratoplasty in the United States

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Abstract

Purpose—To perform a comparative cost-effectiveness analysis of Descemet stripping automated endothelial keratoplasty (DSAEK) and penetrating keratoplasty (PK) for corneal endothelial disease.

Design—Retrospective cost-effectiveness analysis

Methods—This cost-effectiveness analysis was performed from a third-party payer perspective with a 5-year time horizon. Probabilities of outcomes and complications of each of the procedures were calculated based on review of the published literature. A model was constructed to compare the costs and utilities associated with DSAEK and PK. Costs of donor tissue preparation, surgery, follow-up, post-operative complications and procedures were considered. Utility values were based on quality adjusted life years (QALYs) associated with visual acuity outcomes. Both costs and utilities were discounted at 3% per year. Sensitivity analyses were performed on key model inputs.

Results—Base case analysis found DSAEK to be less costly compared to PK (\$9,362 vs. \$10,239), with greater utility (3.15 QALY vs. 2.47 QALY). Sensitivity analyses revealed that even at graft failure rates for DSAEK approaching the rates for PK, DSAEK would still be cost saving. Varying the dislocation rate in our model shows that even at dislocation rates approaching 50%, DSAEK remains less costly. Further, with DSAEK rejection rates as high as 28%, DSAEK would remain a dominant procedure over PK.

Conclusions—Comparative cost-effectiveness analysis of DSAEK vs. PK indicates favorable cost and utility outcomes associated with DSAEK for treatment of corneal endothelial disease.

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Longer follow-up of DSAEK outcomes will provide more accurate information regarding long-term cost-effectiveness of the procedure.

Introduction

Penetrating keratoplasty (PK) has long been the definitive treatment for patients with corneal endothelial dysfunction, namely Fuchs' corneal dystrophy, pseudophakic bullous keratopathy, and aphakic bullous keratopathy associated with visually significant corneal edema. While PK offers patients the chance for markedly improved vision, it is associated with complications including prolonged visual recovery, induced regular and irregular astigmatism, suture-related problems, and late wound dehiscence.¹⁻⁴

Posterior lamellar keratoplasty techniques have gained increasing acceptance over the past decade. Initially described by Melles et al in 1998,⁵ there have been multiple technique modifications,^{6,7} culminating in Descemet stripping automated endothelial keratoplasty (DSAEK).⁸ DSAEK involves removal of the diseased endothelium and Descemet membrane, and subsequent replacement with a posterior corneal lamella prepared by automated microkeratome dissection. These technique refinements allowed endothelial keratoplasty to gain widespread acceptance for the treatment of endothelial diseases. In 2011, 21,555 endothelial procedures were performed, accounting for 47% of all corneal transplant surgeries in the United States (US).⁹ The selective transplantation of the endothelium through a small incision allows for speedier visual rehabilitation with lower rates of astigmatism and other suture related complications.¹⁰⁻¹² But there are also complications unique to DSAEK, including difficulties in preparation of the donor tissue, graft adherence, and higher rates of iatrogenic graft failure.¹³

Despite the rapid growth in DSAEK surgery, little is known about the cost-effectiveness of DSAEK compared with PK. Beauchemin et al¹⁴ evaluated the cost-effectiveness of posterior lamellar surgeries and PK in Canada, using a Canadian healthcare system perspective in a hypothetical cohort of 100 patients. The study found that posterior lamellar keratoplasty is less costly (−\$688/patient) and provides more utility (+0.13 quality adjusted life years/patient) than PK.

In this study, a cost-effectiveness analysis was performed, comparing DSAEK with PK for treatment of corneal endothelial disease in adults in the US.

Methods and materials

Visual acuity outcomes and complication rates source data

The peer-reviewed English literature was searched in PubMed in March 2011, without date restriction. Keywords in the search were *Descemet's stripping endothelial keratoplasty*, *Descemet stripping endothelial keratoplasty*, *Descemet's stripping automated endothelial keratoplasty*, *Descemet stripping automated endothelial keratoplasty*, and *penetrating keratoplasty*.

The abstracts of the 5554 resulting citations were reviewed and the 114 citations that involved studies of possible clinical relevance were reviewed in full text. Citations that pertain to endothelial keratoplasty procedures other than DSAEK or DSEK or to PK performed for reasons other than endothelial disease were excluded. Abstracts of meeting presentations were also excluded.

Studies with fewer than 30 eyes undergoing DSAEK were excluded to focus on studies with statistical analysis and not just case reports. Given the extensive literature on PK, studies with fewer than 200 eyes were excluded. For multiple studies that utilized the same database

of patients for analysis, the study with the largest number of patients was included in order to capture the most inclusive group, while preventing duplicate counting of outcomes in the same patient cohorts.

Publications included were large case series (>30 eyes for DSAEK, >200 eyes for PK), observational studies, and randomized controlled trials on DSAEK or PK for corneal endothelial disease with results on outcomes, adverse events, or complications. For the purposes of this analysis, outcomes data regarding Descemet stripping endothelial keratoplasty (DSEK) and DSAEK were combined. Studies which analyzed DSAEK or PK with concurrent cataract extraction and intraocular lens placement were also included, as similar outcomes have been shown for these procedures.^{15,16} A total of 32 studies were determined to be relevant to the assessment objective.

With the above-detailed inclusion and exclusion criteria, no studies were identified that presented data on rates of treatment for elevated intraocular pressure in patients undergoing PK for endothelial disease. Targeted search of the literature revealed two articles which offered information treatment of elevated intraocular pressure after PK for other corneal conditions.^{17,18} These studies were incorporated in this analysis to provide insight regarding treatment of post-PK elevated intraocular pressure.

Complications rates (Table 1) utilized in our model were based on the average, weighted by number of patients, of those found in the 32 studies included in this analysis.

Conversion of visual acuity to utilities

Utility values were based on visual acuity as has been described in previously published studies of patients with ophthalmic disease, and were derived from patient preferences in a time trade-off model.^{19–21} Average preoperative and postoperative best corrected visual acuities (BCVA) for DSAEK and PK were obtained through our systematic review of the literature and were converted to utility values using a previously published scale that relates Snellen visual acuity to utility values (Table 2).^{19,20}

Identification of Costs

Services billable to third party payers associated with surgery, patient follow-up, post-operative complications and medications were identified through a review of patient bills for each type of surgery. For the base case model, assumptions based on clinical practice were made regarding the number of follow-up visits. For DSAEK the model we used included 2 follow-up visits in the first year outside the 90-day postoperative global period; for PK, 5 follow-up visits were included. We assumed more follow-up visits for PK in the first year after surgery given the need for sequential suture removal in many patients. The complexity of these visits was assumed to be at a 99213 level. We also assumed that in the first year after PK topography would be obtained an average of 3 times outside the global period to aid in suture removal for astigmatism. Glaucoma specialist consultations were assumed to be at a 99203 level. The assumed cost of rigid gas permeable lens for high astigmatism included an office visit for fitting, the estimated cost of a lens and annual cost of cleaning solutions. In the base model, rebubble procedures were assumed to be performed in the operating room using CPT-4 code 66020. Costs were applied to each service using 2010 Medicare Fee Schedules for physician and ambulatory facility services, the 2010 Drug Topics Red Book²² for medications and personal communication with the Midwest Eye Banks (Ann Arbor, MI) for an estimate of eye bank fees (Table 3).

Model Design

This analysis was conducted from a third-party payer perspective, specifically Medicare in 2010. A decision tree with a five-year time horizon was constructed to assess the costs per quality-adjusted life-year (QALY) associated with DSAEK compared to PK. Portions of the first two years of the decision tree are presented in Figures 1 and 2. The probabilities, utilities and costs associated with each event (or branch) were incorporated into the decision tree to derive the QALYs and costs for each procedure. Microsoft Excel[®] was used to conduct the analysis. Both costs and QALYs were discounted at 3% per year.

Several assumptions were made in the model to address gaps in the published literature. All complications were assigned the utility value associated with the preoperative BCVA for that procedure. Patients were assumed to not have pre-existing glaucoma. Glaucoma that was medically treated was assumed to require only topical timolol maleate 0.5% twice daily and surgically treated glaucoma was assumed to require trabeculectomy alone with no additional medications. The graft failure rate was assumed to be equivalent in patients who developed glaucoma and those who did not.

The incremental cost-utility ratio (ICUR), is defined as $(\text{cost DSAEK} - \text{cost PK}) / (\text{QALY DSAEK} - \text{QALY PK})$. When the difference in cost and difference in QALY are both favorable to one treatment, the ICUR is undefined; that is, the treatment with lower costs and higher utility is said to dominate.

Sensitivity Analyses

The model was assessed using univariate sensitivity analyses. To test the robustness of the analysis a range of graft dislocation rates, graft failure rates, graft rejection rates, treatments for post-PK astigmatism, number of postoperative visits and visual acuity outcomes were evaluated. As a literature based review, this study was exempt from institutional review board assessment.

Results

The total discounted cost, measured in US dollars, associated with PK over a 5-year time horizon is \$10,239. The total discounted cost associated with DSAEK is \$9,362, for a difference in costs of \$877. Though our literature search found that DSAEK and PK have similar postoperative visual acuity outcomes (Table 2), DSAEK confers an addition 0.68 QALY over PK, because all postoperative complications were assigned the utility value associated with the preoperative BCVA for that procedure. The resulting ICUR is $-1,290$, indicating that DSAEK is a dominating service (less costly and higher QALY).

Sensitivity analyses resulted in a range of cost and utility differences. The graft dislocation base case rate of 16.1% was varied from 0% to 60% resulting in ICURs that range from $-\$1618/\text{QALY}$ to $\$579/\text{QALY}$, respectively. At a graft dislocation rate of 51.5% DSAEK is no longer a dominant procedure, and DSAEK is associated with slightly greater cost per QALY gained compared to PK (ICUR = $\$8/\text{QALY}$). In clinical practice, some surgeons perform rebubbling procedures for graft dislocation at the slit lamp or office treatment room. A model assuming the base case rate of 16.1% dislocations, but all rebubbling procedures performed in-office results in cost saving of \$1068 (rather than the base case savings of \$877) over the 5-year time horizon as compared to PK.

Early graft failure was defined as irreversible graft opacification in the first year after surgery and the rate after DSAEK was found to be 3.3% in our analysis. The rate of early failure would need to increase to 15.6% before DSAEK would no longer be cost-saving (ICUR = $\$20/\text{QALY}$). Late graft failure was failure that occurred after the first year. The

base rate of late graft failure after DSAEK was 1.4% per year. Varying the annual late graft failure rate of DSAEK revealed that a rate of 5.1% per year shifts DSAEK from being a dominant procedure compared to PK (costing less and providing greater utility) to having slightly greater cost per QALY gained compared to PK (ICUR = \$26/QALY).

Based on our review of the literature, allograft rejection rates after DSAEK are lower than after PK (5.9% per year vs. 10.6% per year); however, post-DSAEK rejection rates would have to reach a rate of 29% before DSAEK would no longer be dominant (ICUR = \$43/QALY).

PK was associated with a high astigmatism (>5 diopters) rate of 29.0%. Our base-case model assumed that after PK all patients with high astigmatism underwent rigid gas permeable contact lens fitting. Modeling for treatment of patients with post-PK high astigmatism to undergo refractive surgery for astigmatism correction (at a conservative hypothetical cost of \$1000 per eye) yielded additional savings of DSAEK over PK (−\$1003/QALY).

The base case assumed 2 postoperative visits outside of the global period for DSAEK and 5 for PK. Modeling for 5 postoperative visits for both procedures yielded an ICUR of −\$1260/QALY.

In our base case, BCVA after DSAEK was 20/40, providing an additional utility of 0.68 QALY over PK. Improving postoperative visual outcomes to 20/25 or 20/20 would provide additional utility of 0.90 and 1.07, respectively.

Discussion

In this study, we performed a cost-effectiveness analysis to quantify the relative costs of DSAEK and PK for treatment of endothelial disease based on a systematic review of the literature. DSAEK was found to be associated with a slightly lower cost of \$877 with 0.68 QALY gained over PK. In this model, DSAEK is not merely cost-effective, but cost-saving as compared to PK.

Graft dislocation is a relatively common complication of DSAEK, especially in a surgeon's early cases, with rates in the literature ranging from 0 to 82%.²³ In our base case analysis, a graft dislocation rate of 16.1% was assessed. Dislocation requires graft repositioning procedures performed either in the clinic or the operating room, with attendant costs. Further, dislocations are associated with greater incidence of graft failure^{24,25} and additional costs for treating those failures. Much of the literature available for our analysis reports surgeons' early experiences with DSAEK and may have inflated rates of dislocation due to the "learning curve" for performing this surgery. Dislocation rates have been shown to improve quickly with surgeon experience and with further refinement of surgical technique and mentoring there is evidence to suggest that even beginning DSAEK surgeons can attain dislocation rates in the range of 1%.²⁶ Sensitivity analyses, which vary the dislocation rate in our model show that even at dislocation rates approaching 51%, DSAEK remains less costly than PK. Of note, for surgeons who perform graft repositioning in the clinic rather than the operating room, there is no additional cost from the third-party payer perspective, resulting in even greater cost saving with DSAEK.

Limited data are available regarding graft survival after DSAEK. Although there is some concern for higher rates of early graft failure (within the first year after surgery) after DSAEK as compared to PK, our literature-based analysis did not find this to be the case.¹³ In fact, sensitivity analysis indicates that early graft failure would have to reach a rate of 15.6% before DSAEK is no longer the dominant procedure. At the time of our literature

search, only one published study provided data on 5-year graft failure rate in DSAEK (7%).²⁷ For the purpose of our model, this rate was divided over 5 years for an annual graft failure rate of 1.4%, much lower than the rate of 3.8% assessed for PK. Graft failure of any cause is associated with high cost given the need for subsequent repeat surgical procedures. Sensitivity analysis shows that if the annual graft failure rate for DSAEK were to approach a rate similar to that of PK, DSAEK would still be cost-saving; however, at graft failure rates above 5.1%, DSAEK would be more costly than PK. But even with an annual DSAEK graft failure rate as high as 5.5% the ICUR of DSAEK would only be \$208.14/QALY; this cost would still be considered minimal and an acceptable additional cost for the utility gained.²⁸

Our model assumes that the graft failure rate in patients who develop glaucoma is the same as for those who do not develop glaucoma. There is some evidence that failure rates are higher in patients who develop glaucoma, particularly in those who require additional surgery.²⁹ Based on our model, 15% of patients after DSAEK and 19% of patients after PK develop increased intraocular pressure, and may be at increased risk of graft failure. But given that the rates are similar after the two different surgical procedures, it is unlikely that a slight increase in graft failure rate due to new-onset glaucoma would significantly affect the cost-effectiveness analysis.

The current literature supports a lower allograft rejection rate for DSAEK than for PK (5.9% vs. 10.6%, respectively).^{10,25,30–36} Based on our model, even with DSAEK rejection rates as high as 28%, DSAEK would remain a dominant procedure over PK.

High astigmatism (>5 diopters) is a relatively common finding after PK. Our model assumed that these patients are treated with rigid gas permeable contact lenses; however, some patients may desire or require additional surgery for treatment of astigmatism. In our model, treating patients with high astigmatism with corneal refractive surgery at a cost of \$1000 per eye yielded an even greater cost advantage for DSAEK.

Our model analyzes many important complications associated with DSAEK and PK, but does not include all possible differences between the two techniques. Complications including suture-related complications, graft infection, and wound dehiscence were not modeled. Based on our inclusion criteria for DSAEK, one paper, by Shih, et al,³³ reported that 1 patient of their 126 (0.8%) developed suture abscess. There were no studies of PK that met our inclusion criteria that reported these complications. However, Hood et al³⁷ reported a suture-related infection rate of 1.0% and a non-suture-related graft infection rate of 3.5%. Christo et al³⁸ reported suture-related infiltrate in 12.7%, spontaneous loose sutures in 8.3% and wound dehiscence in 2.4%. Additional costs associated with the complications include antibiotics, additional follow-up visits, and in the case of wound dehiscence, operating room costs. Given that the loss of utility and additional costs, albeit low compared to overall cost, is weighted toward PK over DSAEK, modeling these complications would further strengthen the finding that DSAEK is cost-saving over PK.

Due to the retrospective nature of our evaluation, visual acuity was the only utility measure that was readily available for analysis. Based on the literature, the base case preoperative visual acuities were notably different for the two surgical techniques, with pre-DSAEK acuity of 20/90 and pre-PK acuity of 20/120. Final postoperative visual acuity both after uncomplicated DSAEK and PK was 20/40. Visual acuities were converted to utility values based on previously published time trade-off studies,^{19–21} and resulted in higher utility for DSAEK than PK due to lower failure rates. Sensitivity analysis showed that further improvements in visual acuity after DSAEK could further improve utility, with 20/20 vision resulting in a gain of 1.07 QALY. Further cost analysis should be performed on newer surgical techniques, such as Descemet membrane endothelial keratoplasty (DMEK), that

may provide improved acuity, albeit with some additional risks of graft dislocation, donor corneal tissue loss, and unknown long-term outcomes.³⁹

Though a great deal of data can be derived from the published literature, certain assumptions were made in our model. There is little published data regarding final visual outcomes of patients with complications. For our analysis, we used a surrogate quality value of assigning all complications the utility value of the preoperative visual acuity. Additionally, our model assessed utility based solely on final best corrected visual acuity. Although final visual outcome does capture some of the utility conferred by these procedures, there are other aspects to utility, including time to final visual outcome, quality of vision, and effect on quality of life by frequency of physician visits, for which quantified data are not available. Interestingly, our review found slightly better preoperative visual acuity in DSAEK compared to PK (20/90 and 20/120, respectively) suggesting that DSAEK is being performed at slightly earlier stages of disease, and possibly providing more years of life with improved quality, which is not assessed in our model with its limited 5-year time horizon. In this study, we included studies that analyzed DSAEK outcomes with samples of as few as 30 patients. As we gain more experience with this procedure with more patients and longer follow-up, average complication rates and visual acuity outcomes and other potential utility measures will need to be reassessed.

It is important to keep in mind that this analysis utilizes a third-party health insurance payer perspective. This includes costs that are important to insurers, but does not include direct or indirect costs incurred by individuals and their social support networks that could be captured by a cost-effectiveness analysis performed from a societal perspective. Additional costs associated with short-term or long-term disability and presenteeism (e.g. unemployment benefits, disability compensation, activity restrictions, etc.) were not included as consistent data for differences among services were unavailable. Given the improved speed of recovery and fewer postoperative visits associated with uncomplicated DSAEK surgery, the third-party payer perspective is likely providing a conservative estimate of the cost-savings associated with DSAEK as compared to PK.

Economic evaluations provide information about utility gains for expenditures associated with health care interventions. Evidence-based cost-effectiveness analyses in health care are essential to our decision making as we face the reality of our limited resources. As we gain more information about long-term outcomes of DSAEK and consider newer endothelial keratoplasty techniques, it will be important to continually reassess outcomes and complications of these procedures and their relative cost-effectiveness.

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Biography

Shreya S. Prabhu is a resident in ophthalmology at the University of Michigan Kellogg Eye Center. She received a Bachelors degree in Microbiology/Biochemistry from Boston

University, graduating with honors. She then received a Masters in Public Health and completed medication school at Boston University. She will be a fellow in Pediatric Ophthalmology at the Kellogg Eye Center in the upcoming year. Dr. Prabhu's research interests include economic evaluation in medicine.

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Figure 1. DSAEK decision tree

Decision analysis tree corresponding to the first two years following the Descemet stripping automated endothelial keratoplasty (DSAEK) procedure.

The circles represent chance nodes, whereby branches continue until year 5 (and associated costs and QALYs are calculated). The branches no longer continue when a triangle (or terminal node) is present. Patients are given the opportunity to repeat DSAEK once after graft failure, failed treatment and reposition.

Figure 2. PK decision tree

Decision analysis tree corresponding to the first two years following the Penetrating Keratoplasty (PK) procedure.

The circles represent chance nodes, whereby branches continue until year 5 (and associated costs and QALYs are calculated). The branches no longer continue when a triangle (or terminal node) is present. Patients are given the opportunity to repeat PK once after graft failure and failed treatment.

TABLE 1

Probabilities associated with postoperative complications of Descemet stripping automated endothelial keratoplasty and penetrating keratoplasty

Complication	DSAEK Probability	PK Probability	References
Graft failure in year 1 (not associated with dislocation or rejection)	3.3%	4.5%	10,24,25,30–33,40–50
Graft dislocation	16.1%	-	10,24,25,30–33,40–45,51,52
Successful repositioning	81.9%	-	10,24,25,31–33,40–45,52
Graft failure	18.1%	-	10,24,25,31–33,40–45,52
Annual graft rejection	5.9%	10.6%	10,25,30–36
Successful treatment	91.0%	61.3%	10,25,31,34–36
Graft failure after treatment	9.0%	38.7%	10,25,31,34–36
High IOP	15.0%	19.0%	30,31,33,52–56
Requiring medical treatment	99.3%	85.2%	17,18,30,31,33,52,53,55
Requiring surgical treatment	0.7%	14.8%	17,18,30,31,33,52,53,55
Astigmatism >5D	-	29.0%	47
Average annual late graft failure (years 2–5)	1.4%	3.8%	27,46,47,49,50

DSAEK=Descemet stripping automated endothelial keratoplasty; PK=Penetrating keratoplasty; IOP=intraocular pressure; D=diopter

TABLE 2

Visual acuity and utility values associated with Descemet stripping automated endothelial keratoplasty and penetrating keratoplasty

Surgical state	BCVA	Associated utility value	References
DSAEK			
Preoperative	20/90	0.7	10,30–32,40,43,55,57
Postoperative	20/40	0.8	10,27,30–32,40,43,45,55,57
PK			
Preoperative	20/120	0.67	47
Postoperative	20/40	0.8	47,50,58

DSAEK=Descemet stripping automated endothelial keratoplasty; PK=Penetrating keratoplasty; BCVA=Best corrected visual acuity

TABLE 3

Medical costs and Current Procedure Terminology codes associated with Descemet stripping automated endothelial keratoplasty and penetrating keratoplasty and their complications

Service	CPT code	Costs
Initial DSAEK		
Eye bank fee		\$3600
Surgeon's fee	65756	\$1168
Ambulatory surgical center fee	0244	\$2530
Anesthesia fees	144	\$237
Medications		
Prednisolone acetate 1%		\$203
Moxifloxacin 0.5%		\$82
Follow-up visits (x2)	99213	\$104
		Total: \$7924
Initial PK		
Eye bank fee		\$2900
Surgeon's fee	65730	\$1231
Ambulatory surgical center fee	0244	\$2533
Anesthesia fees	144	\$237
Medications		
Prednisolone acetate 1%		\$203
Moxifloxacin 0.5%		\$82
Follow-up visits (x5)	99213	\$260
Topography (x3)	92025	\$106
		Total: \$7550
Complications		
Repeat DSAEK		\$7924
Repeat PK		\$7396
Graft dislocation (Rebubbling)		\$1459
Surgeon's fee	66020	\$127
Ambulatory surgical center fee	0233	\$1095
Anesthesia fees	144	\$237
Graft Rejection Treatment		\$307
Prednisolone acetate 1%		\$203
Additional follow-up (x2)	99213	\$104
High IOP: Medical		\$266
Management		
Timolol (0.5%)		\$162
Additional follow-up visits (x2)	99213	\$104
High IOP: Surgical		\$4901
Management (Trabeculectomy)		
Glaucoma specialist initial visit	99203	\$78

Service	CPT code	Costs
Trabeculectomy	66172	\$1497
Surgeon's Fee		
Ambulatory surgical center fee	673	\$2823
Anesthesia fees	144	\$237
Medications		\$162
Follow-up visits (x2)	99213	\$104
Astigmatism >5D		\$344
Lens fitting	99203	\$78
Rigid gas permeable lens		\$150
Lens cleaning		\$116

DSAEK=Descemet stripping automated endothelial keratoplasty; PK=Penetrating keratoplasty; IOP=intraocular pressure; D=dipter;
CPT=Current procedural terminology