Clinical Evaluation of a New Donor Graft Inserter for Descemet’s Stripping Automated Endothelial Keratoplasty

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BACKGROUND AND OBJECTIVE: To present clinical outcomes of Descemet’s stripping automated endothelial keratoplasty (DSAEK) using a newly developed donor graft inserter, the Tan EndoGlide (AngioTech, Reading, PA/Network Medical Products, North Yorkshire, UK).

PATIENTS AND METHODS: Six eyes of six patients with bullous keratopathy were treated with DSAEK using the Tan EndoGlide. Intraoperative and postoperative complications, postoperative donor endothelial cell densities (ECDs), and best-corrected visual acuity were recorded.

RESULTS: Five cases had no difficulties during donor graft loading into the Tan EndoGlide; however, the donor graft was folded inside-out into the Tan EndoGlide in one case, resulting in severe endothelial cell loss. All patients achieved a visual acuity of 20/63 or better at 12 months, with four patients reaching better than 20/32. Excluding the case with the graft folded inside-out, postoperative ECDs were 2,041 cells/mm² (mean loss: 22.9%) at 6 months and 1,973 cells/mm² (mean loss: 24.6%) at 12 months.

CONCLUSION: In this small preliminary series, the clinical outcome with the Tan EndoGlide was comparable to or better than that achieved with the conventional technique. Additional studies using a larger number of patients are required to fully evaluate the usefulness and potential advantages of this new donor graft inserter.

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INTRODUCTION

Recently, Descemet’s stripping automated endothelial keratoplasty (DSAEK) has been widely adopted for treatment of endothelial dysfunction.1-5 DSAEK completely eliminates surface corneal incisions or sutures, maintains much of the structural integrity of the cornea, and induces minimal refractive change, sug-

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gesting distinct advantages over standard penetrating keratoplasty. However, DSAEK entails more donor tissue manipulation than penetrating keratoplasty, raising concerns that DSAEK grafts may sustain more early endothelial cell loss. In particular, donor endothelial cell damage occurring during donor graft insertion into the anterior chamber is considered to be critical in all DSAEK procedures. Initially, donor graft insertion techniques focused on tissue folding and insertion with forceps. The forceps donor graft insertion technique is difficult for Asian eyes because they tend to have shallow anterior chambers with a small corneal diameter and it is impossible to avoid severe endothelial cell damage during insertion. Subsequent developments include the donor graft pull-through technique using an intraocular lens (IOL) sheet glide or double-glide technique (IOL sheet-glide–assisted Busin glide technique). Initial studies with these newer pull-through techniques suggest reduced endothelial cell loss compared with results from large series using conventional taco-folding forceps techniques. Recently, Professor Donald Tan from Singapore developed a new disposable DSAEK glide (Fig. 1A) (Tan EndoGlide; AngioTech, Reading, PA/Network Medical Products, North Yorkshire, UK) to optimize the pull-through technique. The purpose of this study was to investigate clinical outcomes in Japanese eyes using the Tan EndoGlide during DSAEK or non-DSAEK procedures.

PATIENTS AND METHODS

Patients

This prospective non-comparative study was approved by the Ethical Committee of Kanazawa University Graduate School of Medical Science and followed the tenets of the Declaration of Helsinki. Six eyes of six patients (one man, five women; mean age: 80.2 years) with bullous keratopathy were enrolled in this study (Table). Three patients had previous argon laser iridotomy for angle-closure glaucoma. Two patients had Fuchs endothelial dystrophy, and one had pseudophakic bullous keratopathy. Intraoperative and postoperative complications, including iatrogenic primary graft failure, graft dislocation, and pupillary block glaucoma were documented. Outcome measures included best-corrected visual acuity (BCVA) after 12 months and central endothelial cell density (ECD) before surgery and at 6 and 12 months after surgery. Central ECD was measured with noncontact specular microscopy (Nonconrobo; Konan Medical, Inc., Hyogo, Japan), using the center method as outlined by the manufacturer's software. Postoperative cell loss was calculated as the percentage of the preoperative donor ECD.

Statistical Analysis

The 95% confidence intervals (95% CIs) are reported along with mean 6- and 12-month percentage ECD loss. All data analysis was performed with SPSS Statistics 14.0 software (SPSS, Inc., Chicago, IL).

Surgical Technique

All surgeries were performed by a single surgeon (AK) from May to October 2009 at the Department of Ophthalmology, Kanazawa University Graduate School of Medical Science. All patients read and signed an informed consent document prior to enrollment. With the exception of the patients with Fuchs dystrophy (cases 4 and 5), Descemet’s membrane was not removed (non-DSAEK was performed) because those cases had no guttae and good visual acuity was expected without Descemet’s membrane removal.

All DSAEK and non-DSAEK procedures were performed as previously described, except for the donor graft insertion step. In brief, donor tissue was dissected with a microkeratome (ALTK Cbm; Moria Japan KK, Tokyo, Japan) equipped with a 300-µm head. After microkeratome dissection, donor tissue was transferred to a punching system and cut with a punch 8.0 mm in diameter (Barron donor cornea punch; Katena Products, Inc., Denville, NJ). For patients with cataract and endothelial failure (cases 1 and 5), a phacoemulsification procedure was performed from a 3-mm clear corneal temporal incision just prior to DSAEK or non-DSAEK; this had the benefit of creating more space in the anterior chamber to safely position the graft.

Four corneal fenestrations were performed to drain the interface fluid. Then, a small inferior iridectomy was created at the 6-o’clock position using a 25-gauge vitreous cutter under continuous irrigation from a 25-gauge anterior chamber maintainer (Kobayashi 25g DSAEK Chamber Maintainer; Catalog #AE-7802; ASICO, Westmont, IL) to prevent pupillary air block after surgery. Microkeratome-dissected donor tissue was transferred to a punching system and cut with an...
8.0-mm diameter punch (Barron donor cornea punch). Viscoelastic substance (Viscoat; Alcon Laboratories, Inc., Fort Worth, TX) was applied to the endothelial surface of the graft and the graft was pulled into the Tan EndoGlide (Fig. 1C) using long straight forceps (Tan Endoglide Loading Forceps; AngioTech/Network Medical Products), enabling automatic double-coil configuration of the graft (Fig. 1B). After double coiling, the glide introducer was secured onto the posterior end of the glide capsule to form a tight seal and the assembled Tan EndoGlide was ready for graft insertion into the recipient eye.

The recipient temporal tunnel was enlarged to a width of 5 mm. Descemetorhexis was performed only in cases with Fuchs dystrophy (cases 4 and 5). Then, the Tan EndoGlide was inserted through a temporal corneal incision. The anterior chamber was stable. The donor endothelial lamella was pulled into the anterior chamber by forceps introduced from the nasal limbus. The iris and intraocular lens were untouched due to the presence of the Tan EndoGlide’s anterior glide. (G) The surgical procedure for a complicated case (case 6). The donor endothelial lamella was folded inside-out (endothelium outside; see arrows) when loaded into the Tan EndoGlide. (H) Schema of the complication in case 6.
and the donor endothelial lamella was folded inside-out (endothelium outside) during placement into the Tan EndoGlide (Figs. 1G and 1H); the donor graft was gently pulled from the TEG and inserted into the anterior chamber using the IOL sheet–glide–assisted Busin glide technique (also known as Kobayashi double-glide technique). Unfortunately, this complication resulted in severe endothelial cell damage (69.5% ECD decrease after 12 months).

All six patients (100%) had a clear graft at 12 months with improved BCVA; all reached a BCVA of 20/63 or better within 6 months. Four patients (66.7%) achieved a visual acuity better than 20/32 and one patient (16.7%) achieved 20/20 within 6 months. In this series, no patient had limited visual potential attributable to retinal disorders. Postoperative ECD ranged from 1,273 to 2,597 cells/mm² (mean: 2,041 ± 532 cells/mm²) at 6 months. Mean postoperative cell loss rate was 22.9% (95% CI: 13.7% to 32.0%) at 6 months. For these five patients, the anterior chamber by forceps introduced from the nasal limbus was pulled into the anterior chamber by forceps introduced from the nasal limbus (Fig. 1F). After securing the wound with an interrupted 10-0 nylon suture, air was injected into the anterior chamber to press the donor tissue against the recipient cornea. Corneal massage was performed in all cases to eliminate residual fluid at the recipient–donor interface. The anterior chamber was left full of air, and the patient was instructed to lie on his or her back for at least 2 to 3 hours.

### RESULTS

The table summarizes clinical outcomes of the six patients. In all cases, the follow-up period after surgery was more than 12 months. Five cases (cases 1 to 5, 83.3%) had no difficulties during donor loading into the Tan EndoGlide and had no intraoperative or postoperative complications, such as donor graft dislocation or iatrogenic primary graft failure. In one patient (case 6), the donor endothelial lamella was folded inside-out during placement into the Tan EndoGlide (Figs. 1G and 1H); the donor graft was gently pulled from the TEG and inserted into the anterior chamber, and the donor endothelial lamella was folded inside-out. This complication resulted in severe endothelial cell damage (69.5% ECD decrease after 12 months).

### TABLE 1

<table>
<thead>
<tr>
<th>Case</th>
<th>Sex/Age (Y)</th>
<th>Eye</th>
<th>Surgery</th>
<th>Clinical Diagnosis</th>
<th>Complication</th>
<th>Initial BCVA and Manifest Refraction</th>
<th>BCVA and Manifest Refraction 12 Mo. Postoperatively</th>
<th>ECD (cells/mm²)a</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F/83</td>
<td>OS</td>
<td>nDSAEK + PEA + IOL</td>
<td>BK after ALI</td>
<td>No</td>
<td>20/200 (unmeasurableb)</td>
<td>20/25 (2.5 × 10)</td>
<td>2,190/1,273 (41.9% decrease)/ 997 (54.5% decrease)</td>
</tr>
<tr>
<td>2</td>
<td>F/76</td>
<td>OS</td>
<td>nDSAEK</td>
<td>BK after ALI</td>
<td>No</td>
<td>20/25 (0.5 – 0.75 × 35)</td>
<td>20/20 (0.5 – 0.5 × 60)</td>
<td>2,695/1,773 (34.2% decrease)/ 1,516 (43.7% decrease)</td>
</tr>
<tr>
<td>3</td>
<td>M/75</td>
<td>OD</td>
<td>nDSAEK</td>
<td>BK after ALI</td>
<td>No</td>
<td>20/500 (unmeasurableb)</td>
<td>20/32 (non-correctable)</td>
<td>2,714/2,997 (4.3% decrease)/ 2,557 (5.8% decrease)</td>
</tr>
<tr>
<td>4</td>
<td>F/87</td>
<td>OS</td>
<td>DSAEK</td>
<td>Fuchs</td>
<td>No</td>
<td>20/100 (+1.0)</td>
<td>20/63 (+2.5 – 5.0 × 60)</td>
<td>3,194/2,439 (23.6% decrease)/ 1,953 (38.9% decrease)</td>
</tr>
<tr>
<td>5</td>
<td>F/73</td>
<td>OD</td>
<td>nDSAEK + PEA + IOL</td>
<td>Fuchs</td>
<td>No</td>
<td>20/100 (-1.5 – 3.0 × 95)</td>
<td>20/25 (+2.5 – 3.0 × 80)</td>
<td>2,366/2,123 (10.3% decrease)/ 2,840 (20.0% increase)</td>
</tr>
<tr>
<td>6</td>
<td>F/87</td>
<td>OD</td>
<td>nDSAEK</td>
<td>Pseudophakic BK</td>
<td>Yesc</td>
<td>20/600 (unmeasurableb)</td>
<td>20/63 (+2.5 – 3.0 × 120)</td>
<td>2,770/823 (70.3% decrease)/ 844 (69.5% decrease)</td>
</tr>
</tbody>
</table>

BCVA = best-corrected visual acuity; ECD = endothelial cell density; OS = left eye; nDSAEK = non-Desmet’s stripping automated endothelial keratoplasty; PEA = phacoemulsification and aspiration; IOL = intraocular lens implantation; BK = bullous keratopathy; ALI = argon laser iridotomy; DSAEK = Desmet’s stripping automated endothelial keratoplasty.

aValues given as: preoperative/6 months postoperatively/12 months postoperatively.

bUnmeasurable due to severe bullous keratopathy.

cDonor endothelial lamellae folded inside-out; procedure converted to double-glide technique.
pared with mean preoperative donor ECDs (2,632 ± 385 cells/mm²).

DISCUSSION

When compared with penetrating keratoplasty, DSAEK has significant advantages for surgical treatment of endothelial dysfunction, such as faster visual rehabilitation and lower postoperative refractive error. However, with the current technique, major trauma to the donor endothelium is caused by tissue manipulation in folding the graft like a taco, even when the procedure is performed by experienced surgeons (34% cell loss after 6 months and 35% to 36% cell loss after 12 months). This is an especially serious problem in Asian eyes (62% cell loss after 6 months) because they tend to have shallower anterior chambers, making all DSAEK procedures inside the eye difficult. To circumvent such difficulties, several donor insertion techniques have been developed. Busin et al. reported reduced endothelial cell loss after DSAEK using the Busin glide pull-through technique (20.0% after 6 months and 23.5% after 12 months). The IOL sheet-glide–assisted pull-through technique has also been developed (25% cell loss after 6 months). We developed a double-glide technique (IOL sheet-glide–assisted Busin glide technique) because the use of only a Busin glide may cause iris and vitreous prolapse in small Asian eyes; this technique has been useful with relatively low endothelial cell damage rates (25.8% cell loss after 6 months).

Recently, a new disposable DSAEK glide was developed (the Tan EndoGlide) to optimize the pull-through technique. This device consists of three components: the glide capsule, the glide introducer, and the preparation base on which the glide capsule is preloaded. The glide capsule is a transparent oval plastic chamber with a flat “glide” portion anteriorly to prevent iris prolapse during insertion. An internal central ridge within the capsule enables automatic coiling of graft tissue into a double-coil configuration (Fig. 1B) when the graft is pulled into the chamber. In the current study, we conducted a small prospective case series of DSAEK or non-DSAEK procedures in Japanese patients using the Tan EndoGlide. As a result, all six patients (100%) showed an improved BCVA of 20/63 or better within 6 months. Four cases (66.7%) achieved a BCVA of 20/32 or better and one (16.7%) achieved 20/20 within 6 months. Three patients (cases 4 to 6) had postoperative astigmatism of 3 diopters or more after DSAEK/non-DSAEK; however, these patients already had astigmatism before surgery and induced astigmatism was minimal. Visual outcomes reported herein compare well with those from previous studies published on DSAEK. However, one would not expect technique of donor insertion to significantly influence visual outcome unless technique is extremely traumatic to endothelial cells, significantly reducing the quality of the implanted tissue.

During surgery, five of our patients (83.3%) had no difficulties during donor graft loading into the Tan EndoGlide and no intraoperative complications were noted. There was only a problem in one patient (case 6) in which the donor endothelial lamella was folded inside-out (endothelium outside) into the Tan EndoGlide, resulting in severe endothelial cell loss (69.5% ECD decrease after 12 months). In this case, donor graft insertion was converted to the sheet-glide–assisted Busin glide pull-through technique. With the exception of this single case, average endothelial cell loss using the Tan EndoGlide was 22.9% at 6 months and 24.6 at 12 months. It is still unclear why there was a 20.0% endothelial cell increase after 12 months for case 5; this may reflect some degree of cell count error. Five-year ECD has been correlated significantly with 6-month ECD, suggesting that Tan EndoGlide methods that reduce early cell loss may further improve long-term graft survival rates. Khor et al. recently reported amazingly favorable outcomes of DSAEK with the Tan EndoGlide for Asian eyes, with a 6-month cell loss rate of 13.1% (n = 20) and a 12-month cell loss rate of 15.6% (n = 11).

Despite potentially significant advantages of the Tan EndoGlide, meticulous care should be taken during donor graft loading because the donor graft can be inserted inside-out. The possible reason for donor graft inside-out folding may be due to a small entrance of the device; this complication may happen to any donor graft regardless of its size, shape, and edge contour. To avoid this complication, a stroking technique during donor graft insertion is strongly recommended (Fig. 2). By stroking the wings upward at the time of pulling in the donor graft, donor endothelial lamella can be successfully coiled. Stroking technique is easy; however, it is important when using the Tan EndoGlide. Alternatively, a smooth design from the preparation base to the glide capsule might help. The new version of the Tan Endo-
Glide (version 2.0) with a “mounting saddle” will help smooth donor graft loading.\textsuperscript{24}

For more scientific evaluation of donor endothelial damage during donor graft insertion, several investigators have performed laboratory examination using human tissue. Vital dye staining\textsuperscript{25} was used to assess the percentage of endothelial cells damaged.\textsuperscript{8,10,13} A laboratory study by Terry et al. suggested that incision width has a significant effect on endothelial cell loss regardless of donor graft insertion technique or device.\textsuperscript{10} With a 5-mm wide incision, 18.0\% endothelial cell damage by forceps insertion and 20.0\% damage by Busin glide was noted.\textsuperscript{10} In contrast, with a 3-mm wide incision, 30.0\% endothelial cell damage was noted by forceps insertion and 28.0\% damage by Busin glide.\textsuperscript{10} Mehta et al. compared taco-folded insertion and sheet-glide insertion in a laboratory study and concluded that endothelial cell damage was greater in taco-folded insertion (32.0\% damage) than sheet-glide insertion (9.0\% damage).\textsuperscript{13} Li et al. investigated endothelial cell damage using the Tan EndoGlide and found a 14.7\% damage rate,\textsuperscript{26} a result that is comparable with our preliminary laboratory data (10.3\% damage by Tan EndoGlide, unpublished data). Collectively, laboratory studies of the Tan EndoGlide are encouraging regarding a lesser degree of endothelial cell damage; however, it is still unclear whether the double coil configuration of the Tan EndoGlide’s internal lumen is optimal to protect endothelium.

As of a recent date relative to the writing of this article, at least six different injectors were undergoing clinical trials, mainly in the United States. The six devices are the Endoshield (Keramed, San Jose, CA), Harvey-Steinert injector (Rhein Medical, Tampa, FL), Al-Ghoul vacuum-assisted injector (Ension, Pitts-
burgh, PA), Neusidl corneal inserter (Fischer Surgical, Arnold, MO), Ide DSAEK injector (IDEEL, Kaneka, Osaka, Japan), and the EndoSaver Injector (Ocular Systems, Inc., Winston-Salem, NC). Most of these devices are similar in nature to IOL injectors using a “donor push-out” concept. Because most of these injectors have a bevel-down head instead of an anterior glide, we are afraid that iris prolapse might occur while injecting those devices into the shallow anterior chamber of the eyes of Asian patients.

We reported clinical evaluation of the Tan EndoGlide in Japanese eyes treated with DSAEK/non-DSAEK. Clinical outcomes were comparable with or better than those achieved with other devices; however, the number of enrolled patients in this study is limited. Additional studies using a large number of patients are required to fully evaluate the usefulness and potential advantages of this new donor inserter.

REFERENCES