

EndoGlide Versus EndoSerter for the Insertion of Donor Graft in Descemet Stripping Automated Endothelial Keratoplasty

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- **PURPOSE:** To compare 2 lenticule insertion methods currently in use for Descemet stripping automated endothelial keratoplasty (DSAEK).
- **DESIGN:** Prospective randomized single-masked study.
- **PATIENTS AND METHODS:** Twenty patients with Fuchs endothelial dystrophy and pseudophakic bullous keratopathy undergoing DSAEK surgery were included and randomized to the use of either EndoGlide or EndoSerter as a delivery method for the donor lenticule. Post surgery, patients were monitored for up to 1 year. Evaluation included corrected distance visual acuity (CDVA) and refraction. Specular microscopy images were obtained at the 6- and 12-month visits. Complications, including rebubbling rate, graft dislocation, and graft failure, were recorded.
- **RESULTS:** Twenty eyes were randomized to receive the Tan EndoGlide or the EndoSerter injector for lenticule insertion. Mean patient age was 65.9 ± 8.4 years and 70.3 ± 9.8 years in the Tan EndoGlide and EndoSerter groups, respectively ($P = .3$). Two eyes in each group needed rebubbling. The mean endothelial cell loss, including the rebubbled eyes, at the 12-month visit was 1093 ± 629 cells/mm² (range: 239–2109 cells/mm², mean percentage cell loss 41.2%) and 877 ± 566 cells/mm² (range: 116–1851 cells/mm², mean percentage cell loss 31.4%) in the Tan EndoGlide and EndoSerter groups, respectively ($P = .45$). Mean CDVA did not show a statistically significant difference between the 2 groups at the 6- or 12-month visit.
- **CONCLUSION:** The EndoSerter shows comparable results to the Tan EndoGlide. However, further investigation is warranted in order to validate these findings. (Am J Ophthalmol 2014;158:257–262. © 2014 by Elsevier Inc. All rights reserved.)

ENDOTHELIAL KERATOPLASTY HAS ADVANCED dramatically since its first introduction in the early 1990s as deep lamellar endothelial keratoplasty

(DLEK). Currently, Descemet membrane endothelial keratoplasty (DMEK) is gaining popularity. Despite its numerous advantages, which include a more rapid recovery, the avoidance of sophisticated and expensive machinery, and very low rejection rate,¹ at its current stage, DMEK requires advanced surgical skills and involves a very steep learning curve. Therefore, Descemet stripping automated endothelial keratoplasty (DSAEK) is still commonly used and efforts are being made to enhance this technique. One of the most challenging surgical steps of DSAEK surgery is the insertion of the donor lenticule into the recipient's anterior chamber with the least amount of endothelial damage possible. Although forceps delivery was shown to have equivalent safety and efficacy profile to facilitate delivery,^{2,3} it is considered to be a more challenging technique. For this reason different instruments have been developed to simplify lenticule insertion, and they have been shown to have variable endothelial-protective effects. The Tan EndoGlide (AngioTech, Reading, Pennsylvania, USA/Network Medical Products, North Yorkshire, UK), with a reported 12-month endothelial cell loss of 15.6%–24.6% in different studies,^{4–6} has addressed a few of the shortcomings of DSAEK surgery, such as endothelium-to-endothelium touch from lenticule folding and crush injury to the endothelium from mechanical compression, both of which lead to significant endothelial cell loss. Other instruments, such as the closed-chamber pulling-injection technique described by Macaluso⁷ and the Busin glide (Moria USA),⁸ offer similar properties. Recently, a new device called the EndoSerter (Ocular Systems Inc, Winston-Salem, North Carolina, USA) was introduced, and its safety and efficacy were demonstrated in a study comparing it to the previous forceps insertion technique, 6 months after DSAEK.⁹ Both of these devices, the Tan EndoGlide and the EndoSerter, enable rolling (instead of folding) of the lenticule, which reduces cell loss from endothelium-to-endothelium contact. However, the Tan EndoGlide uses specifically designed forceps to pull the tissue into the anterior chamber, usually from a nasal paracentesis, whereas the EndoSerter has a unique feature that enables self-deployment of the donor lenticule into the anterior chamber. The EndoSerter is directly connected to irrigation with balanced salt solution (BSS), which enables smooth insertion of the donor lenticule via retraction of the delivery

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scaffold once the inserter is fully inserted into the eye; the anterior chamber remains stable throughout the insertion process. This could hypothetically reduce endothelial cell loss even further.

In this study, we compare the safety and efficacy of the EndoSerter to that of the Tan EndoGlide in a series of 20 eyes, with a 12-month follow-up period.

PATIENTS AND METHODS

THIS PROSPECTIVE COMPARATIVE RANDOMIZED STUDY was approved by the institutional research ethics committee at the University Health Network, Toronto, Ontario, Canada. It is also registered as a clinical trial through the Clinical Trials Registry of the National Institutes of Health (NCT01791075), and information is publicly available (<http://www.clinicaltrials.gov>). The study included 20 eyes of 20 patients eligible for DSAEK surgery. All patients consented to participate in the study and to be randomized to receive either the Tan EndoGlide or the EndoSerter device for insertion of the donor lenticule during surgery. Patients were included in the study if they had Fuchs endothelial dystrophy and/or pseudophakic bullous keratopathy. In patients with a cataract, a combined phacoemulsification with intraocular lens implantation prior to DSAEK surgery was carried out. Patients were excluded from the study if they had a history of failed corneal transplant (penetrating or endothelial keratoplasty), peripheral anterior synechiae, vitreous loss in pseudophakic cases, or any potentially vision-limiting disease such as glaucoma, age-related macular degeneration, and diabetic retinopathy. Preoperatively, all patients underwent a complete eye examination including measurement of Snellen uncorrected distance visual acuity (UDVA), spectacle-corrected distance visual acuity (CDVA) where possible, slit-lamp examination, intraocular pressure measurement, and funduscopy. Preoperative endothelial cell count of the donor tissue was provided by the local eye bank using the Konan Keratoanalyzer EKA-98 (Konan Medical Corp, Hyogo, Japan).

• **SURGICAL TECHNIQUE:** Following detailed explanation of the surgery and the study objectives, all patients signed an informed consent. All surgeries were performed under neuroleptic anesthesia with sub-Tenon injection of a mixture of lidocaine hydrochloride 2% and bupivacaine hydrochloride 0.5%. In patients with a cataract, the cataract was first phacoemulsified using a 2.75-mm clear corneal temporal incision with subsequent intraocular lens implantation, followed by DSAEK surgery. The central 8.5 mm of the recipient's Descemet membrane was stripped through a limbal incision after epithelial marking of the recipient cornea for centration purposes and after anterior chamber maintainer insertion (when necessary,

with the use of the Tan EndoGlide). The donor tissue was prepared using the Moria automated lamellar therapeutic keratoplasty (ALTK; Moria SA, Antony, France) microkeratome equipped with a 300- μ m head and its associated artificial anterior chamber (Moria). Following the microkeratome pass, the anterior stromal "cap" was removed and the donor tissue was marked on its stromal surface for proper positioning. We used a direct marking technique in all cases, using a gentian violet water-based marking pen to make a small, peripheral, gentle mark on the stromal side of the donor. After the tissue was transferred to a punching system, it was cut with an 8.5-mm-diameter trephine, endothelial side up. The donor lenticule was then loaded onto the respective device. A temporal limbal incision of 4.5 mm (Tan EndoGlide) or 4 mm (EndoSerter) was fashioned. In patients who had cataract surgery first, the same main incision was used for lenticule insertion after incision enlargement to the appropriate size. Two preplaced 10-0 nylon sutures enabled quick closure of the wound once the donor tissue had been inserted. In the Tan EndoGlide group, the tip of the Tan EndoGlide device was apposed against the limbal incision and Tan forceps were inserted through a nasal paracentesis to assist in grasping and pulling the tissue into the anterior chamber. In the EndoSerter group, the device was inserted into the temporal incision after removal of the blocking guard, while the deployment rings were held firmly in order to prevent pre-ejection of the graft. Following optimal positioning of the device's tip into the wound lip, BSS irrigation was allowed through the device while it was moved forward so that the carrier edge could pass to the far end of the stripped stromal bed. The deployment wheels were moved forward while the carrier retracted in order to expose the graft until it was completely uncovered in the anterior chamber. The preplaced sutures were then closed and the tissue was apposed to the host stromal bed by injection of air into the anterior chamber. No venting incisions were applied. The eye was kept pressurized for 10 minutes. Some air was released along with BSS instillation to allow for an appropriately sized bubble in the anterior chamber. The patient was then left in the supine position for another hour in the recovery room and was instructed to stay supine for the following 24 hours after discharge.

• **POSTSURGICAL REGIMEN AND EVALUATION:** Postoperatively, patients were given a combination of antibiotic and corticosteroid drops (tobramycin 0.3% and dexamethasone 0.1%, Tobradex; Alcon Laboratories, Inc, Mississauga, Canada) 4 times daily for 1 month, and then switched to dexamethasone 0.1% (Maxidex; Alcon Laboratories, Inc) 4 times daily with a slow taper to once daily over 4 months. Subsequent to surgery, patients were evaluated on day 1, after 1 week, after 1 month, and then every 3 months. Evaluation included vision testing, manifest refraction, intraocular pressure measurement, and slit-lamp examination. Specular microscopy images were obtained using a noncontact

specular microscope (ROBO, Konan storage system KSS 300; Konan Medical, Hyogo, Japan) at the 6-month and at the 12-month visits. Image analysis was performed using the semi-automated center technique and endothelial cell density (ECD) was recorded. Careful attention was made to include at least 100 cells in the analysis of a high-quality image unless this was not possible owing to a low cell count (usually below 1000 cells/mm²). Complications, including rebubbling rate, graft dislocation, and graft failure, were recorded.

- **STATISTICAL ANALYSIS:** Sample sizes for each arm were calculated for a 5% level of significance with 80% power, from a standard deviation of 250 cells/mm² and a minimal difference of 220 cells/mm² between groups, assuming that a difference of less than 5% between the groups is likely to be related to intra-observer variability during image analysis. It was determined that 10 subjects would be required in each group of the study. Differences between continuous variables were tested using the Student *t* test for normally distributed data (ECD and endothelial cell loss). A *P* value of <.05 was considered significant.

RESULTS

TWENTY EYES OF 20 PATIENTS WERE INCLUDED IN THE study and were randomized to have the Tan EndoGlide or the EndoSerter for lenticule insertion. Mean patient age was 68 ± 9.1 years (range, 54.6–88.4 years). Table 1 summarizes the patients' demographic and postoperative refractive and visual acuity data for each of the tested groups. There was no statistically significant difference in mean CDVA between the 2 groups after 12 months of follow-up (*P* = .29). Preoperative mean ECD did not differ statistically significantly between the 2 groups (*P* = .19, Table 2). The mean endothelial cell loss (ECL) at the 12-month visit was 1093 ± 629 cells/mm² (range: 239–2109 cells/mm², mean percentage cell loss of 41.2%) and 877 ± 566 cells/mm² (range: 116–1851 cells/mm², mean percentage cell loss of 31.4%) in the Tan EndoGlide and EndoSerter groups, respectively (*P* = .45, Table 2).

- **SURGICAL COMPLICATIONS:** Two eyes (20%) in each group needed rebubbling. In the Tan EndoGlide group, the rebubbling was performed twice on the same eye on postoperative day 1 and postoperative day 2 and once on the other eye on postoperative day 7. Endothelial cell loss in these eyes was significantly higher than in the rest of the cohort. In the EndoSerter group, rebubbling was performed once in each eye and took place on postoperative day 1 and postoperative day 7. Endothelial cell loss in these eyes was higher than in the rest of the cohort, albeit not statistically significantly. Calculation of mean ECD and mean percentage cell loss in eyes that did not

need rebubbling still showed no statistical difference between the 2 groups after 6 and 12 months (Table 3). Analysis of ECL at the 12-month visit excluding the rebubbled eyes showed mean ECL of 842 ± 386 cells/mm² (range, 239–1360 cells/mm², mean percentage cell loss 32.2%) and 722 ± 490 cells/mm² (range, 116–1546 cells/mm², mean percentage cell loss 25.9%) in the Tan EndoGlide and EndoSerter groups, respectively (*P* = .6, Figure). None of the eyes had a rejection or a late failure during the 12 months of follow-up. Two eyes in each group had a slight paraxial dislocation that did not need any further surgical intervention. One patient in the EndoGlide group had a high intraocular pressure (36 mm Hg) on postoperative day 1 that was successfully treated by release of air from the anterior chamber.

DISCUSSION

SAFE INSERTION OF THE DONOR LENTICULE INTO THE ANTERIOR chamber is a significant challenge and a key step for successful outcome in DSAEK surgery. Different devices have been developed for this purpose, with variable success rates.^{2,3,5,7,8} In addition, various studies have been carried out in order to compare the safety and efficacy of these devices to each other.^{9–11} None of these studies has evaluated the long-term effectiveness of the more recently introduced EndoSerter. Our study shows for the first time that the EndoSerter achieves comparable outcomes to the Tan EndoGlide with regard to the success of DSAEK grafts after 12 months of follow-up in a cohort of 20 eyes.

Fuchs endothelial dystrophy and pseudophakic bullous keratopathy are among the most common indications for endothelial keratoplasty. Our stringent inclusion criteria enabled us to recruit a more homogenous group and to reduce bias probability resulting from variable degrees of surgical difficulty that can affect lenticule manipulation and, consequently, the success rate of the investigated procedure. As well, attention was paid to following the same surgical protocol in all cases and to adhering to manufacturer instructions for both devices.

In recent years, the Tan EndoGlide has been gaining popularity for assisting in DSAEK lenticule insertion. Two of the most thorough studies published by the inventor of the EndoGlide regarding the effectiveness of this instrument with respect to ECL have shown similar reassuring results. In the first study,⁵ reporting on the newly introduced Tan EndoGlide, 6 months and 12 months after DSAEK, Khor and associates showed an ECL of 13.1% (*n* = 20 eyes) and 15.6% (*n* = 10 eyes), respectively. None of the eyes needed rebubbling and none had a graft dislocation. In a more recent study⁴ the same author reported on a sample of 100 eyes with Fuchs endothelial dystrophy and pseudophakic bullous keratopathy undergoing DSAEK. The reported ECL was 13.7% at 3 months for

TABLE 1. Patient Demographics, Corrected Distance Visual Acuity, and Manifest Refraction Spherical Equivalent in the Tan EndoGlide and EndoSerter Groups, 6 Months and 12 Months Following Descemet Stripping Automated Endothelial Keratoplasty

	Tan EndoGlide Group	EndoSerter Group	P Value
Age (y), mean ± SD/range	65.9 ± 8.4/54.6–80.4	70.3 ± 9.8/60.5–88.4	.3
Eye (OD/OS)	7/3	9/1	
Sex (M/F)	3/7	5/5	
6 months post-op MRSE (D), mean ± SD/range	−0.03 ± 1.21/(−2.13)–(+1.38)	0.93 ± 1.7/(−1.63)–(+3.88)	.2
6 months post-op CDVA (logMAR), mean ± SD/range	0.44 ± 0.14/0.3–0.6	0.36 ± 0.25/0.18–0.7	.4
12 months post-op MRSE (D), mean ± SD/range	0.013 ± 1.17/(−2.13)–(+1.38)	0.69 ± 1.58/(−1.5)–(+3.63)	.29
12 months post-op CDVA (logMAR), mean ± SD/range	0.33 ± 0.12/0.18–0.54	0.23 ± 0.1/0.1–0.4	.29

CDVA = corrected distance visual acuity; D = diopter; MRSE = manifest refraction spherical equivalent; Post-op = postoperative.

TABLE 2. Endothelial Cell Density Before and After Descemet Stripping Automated Endothelial Keratoplasty With Postoperative Endothelial Cell Loss in the Tan EndoGlide (N = 10) and EndoSerter (N = 10) Groups

	Tan EndoGlide Group		Endoserter Group		P Value
	Mean ± SD	Range	Mean ± SD	Range	
Pre-op ECD (cells/mm ²)	2654 ± 210	2286–2884	2792 ± 208	2451–3025	.19
6 months post-op ECD (cells/mm ²)	1630 ± 652	554–2370	1952 ± 568	842–2950	.47
6 months post-op ECL (cells/mm ²)	1024 ± 702	486–2324	840 ± 599	48–1846	.77
6 months post-op ECL (%)	38.6 ± 26.5	18.3–87.6	30.1 ± 21.5	2–66.1	-
12 months post-op ECD (cells/mm ²)	1561 ± 597	629–2278	1915 ± 658	837–2882	.24
12 months post-op ECL (cells/mm ²)	1093 ± 629	239–2109	877 ± 566	116–1851	.45
12 months post-op ECL (%)	41.2 ± 23.7	9–79.5	31.4 ± 20.3	4.2–66.3	-

ECD = endothelial cell density; ECL = endothelial cell loss; Post-op = postoperative; Pre-op = preoperative.

TABLE 3. Endothelial Cell Density Before and After Descemet Stripping Automated Endothelial Keratoplasty With Postoperative Endothelial Cell Loss in the Non-rebubbled Eyes, Tan EndoGlide (N = 8) and EndoSerter (n = 8) Groups

	Tan EndoGlide Group		EndoSerter Group		P Value
	Mean ± SD	Range	Mean ± SD	Range	
Pre-op ECD (cells/mm ²)	2618 ± 218	2286–2884	2792 ± 233	2451–3025	.16
6 months post-op ECD (cells/mm ²)	1820 ± 334	1475–2370	2120 ± 597	1092–2950	.85
6 months post-op ECL (cells/mm ²)	798 ± 257	486–1208	672 ± 568	48–1822	.61
6 months post-op ECL (%)	30.5 ± 9.8	18.5–46.1	24.1 ± 20.3	2–65.2	-
12 months post-op ECD (cells/mm ²)	1776 ± 438	1107–2278	2070 ± 597	1368–2882	.29
12 months post-op ECL (cells/mm ²)	842 ± 386	239–1360	722 ± 490	116–1546	.6
12 months post-op ECL (%)	32.2 ± 14.7	9–51.9	25.9 ± 17.6	4.2–55.3	-

ECD = endothelial cell density; ECL = endothelial cell loss; Post-op = postoperative; Pre-op = preoperative.

57 eyes, 13.5% at 6 months for 61 eyes, and 14.9% at 12 months for 53 eyes. Primary graft failure occurred in 1 eye, and 2 eyes (2%) had complete donor dislocation needing rebubbling. Our higher rebubbling rate can partially account for this difference in ECL, as was demonstrated by Price and Price.¹² The latter study showed significantly higher ECL in the rebubbled group compared to the non-rebubbled group following DSAEK surgery. However,

even after exclusion of the rebubbled eyes from analysis, our ECL after 6 and 12 months was still higher than that reported by Khor and associates and cannot be explained by a learning curve (our surgeons were familiar with the EndoGlide device) or by the slightly larger lenticule with concordantly more endothelial cells transplanted by Khor and associates (mean lenticule diameter of 8.75 mm; range 8.25–9.5 mm vs 8.5 mm in our study). Our high ECL is in

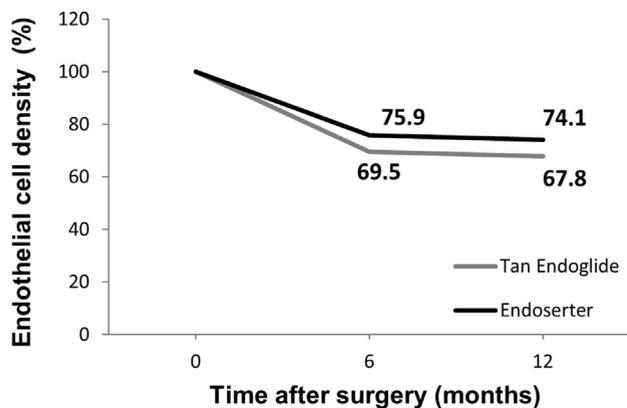


FIGURE. Mean percentage endothelial cell density in the Tan EndoGlide and EndoSerter groups (excluding the rebubbled eyes), 6 and 12 months following Descemet stripping automated endothelial keratoplasty.

agreement with 3 other smaller studies that have reported on DSAEK outcomes using the Tan EndoGlide device. Balidis and associates¹³ have shown an ECL of 25% (range, 23%–45%) in 9 eyes after 6 months of follow-up, with 2 eyes needing rebubbling. Similarly, Yokogawa and associates⁶ have shown a 24.6% ECL in 5 eyes post DSAEK after 12 months. A different prospective study by Gangwani and associates¹⁰ comparing the EndoGlide with Busin glide-assisted insertion of the posterior lamellar corneal graft in Descemet stripping endothelial keratoplasty (DSEK) showed significantly less ECL with the EndoGlide than with the Busin glide after 6 months of follow-up (25.76% vs 47.46%; $P < .0001$). This reported ECL with the use of the EndoGlide is still higher than the one reported by Khor and associates and cannot be attributed to the manual donor dissection, as ECL was shown to be comparable to the automated dissection.¹²

In addition, our ECL in the Tan EndoGlide group is in accordance with a previous study¹¹ demonstrating comparable ECL (25% after 6 months) using the Busin glide, which has similar lenticule-protective properties to the Tan EndoGlide.

There are limited data on the clinical efficacy and safety of the EndoSerter device. Foster and associates⁹ have shown an average ECL of 28.3% using the EndoSerter in a cohort of 70 eyes 6 months post DSAEK. Nevertheless, in their study endothelial cell counts were performed using the less accurate automatic cell count technique, and therefore further investigation is needed. Recently, a laboratory experiment assessing the ECL following EndoSerter lenticule insertion using a dual staining method found an ECL of $12.31\% \pm 4.74\%$.¹⁴ Our study shows 31.1% ECL

with the EndoSerter device, which comes down to 25.5% after excluding the rebubbled eyes. This clinical loss is still nearly double. However, a doubled clinical ECL is not surprising, as Khor himself reports on a double clinical loss with use of the Tan EndoGlide, compared to ECL in his own laboratory work. Unpublished data of 8% ECL (range 5%–13% in 8 eyes) was found in a laboratory-based experimental DSAEK model study evaluating ECL following lenticule insertion with the Tan EndoGlide using vital dye staining in eye bank eyes.¹⁰

Despite its different mode of action (self-deployment rather than forceps pulling), the EndoSerter did not show clinical superiority over the Tan EndoGlide. Both devices prevent ECD loss from endothelium-to-endothelium touch and damage to the endothelium from the internal lip of the incision. As well, rolling of the graft instead of folding it is another advantage of these devices. The main difference between the devices is the insertion mode. However, even if a crush injury happens to the small area grasped by the assisting forceps when using the Tan EndoGlide device, the resultant very peripheral endothelial damage is not significant enough to affect central ECD. This explains the comparable ECD loss between the 2 devices investigated in our study.

Spectacle CDVA including the rebubbled eyes was not found to be statistically significant between the 2 groups after 6 or 12 months ($P = .4$, $P = .29$, respectively). Indeed, one would not expect the visual acuity to be affected by variance in ECD as long as it is higher than the minimal ECD that supports a clinically clear cornea. Although the reasons for rebubbling can be multifactorial, including transient hypotony and thick donor lenticule, venting incisions were not used as part of the surgical technique, which may have also contributed to the high rebubbling rate found in our study. Price and Price¹⁵ have shown a reduction in donor detachment rate following DSEK from 13% to 3% after application of midperipheral clear corneal incisions. Similarly, in a recent experimental model, the importance of these incisions was demonstrated.¹⁶ However, reattachment was obtained in all rebubbled cases and, despite the lower endothelial cell count in these patients, their grafts remained clear at the end of the follow-up period and their final CDVA was not found to be affected by the rebubbling process.

In conclusion, the EndoSerter provides comparable results to the Tan EndoGlide. Mean ECD, ECL, CDVA, and rebubbling rate were similar in both groups after 12 months of follow-up, with slight trending toward better results with the EndoSerter. Nevertheless, larger groups with longer follow-up time will allow for more robust comparisons between these devices.

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Biosketch

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