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CLINICAL INVESTIGATION

# Descemet stripping automated endothelial keratoplasty performed by trainees

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## Abstract

**Purpose** To assess the surgical outcomes of Descemet stripping automated endothelial keratoplasty (DSAEK) performed by trainees.

**Study design** Retrospective, case control comparative study.

**Methods** This study compared cases performed by trainees with those performed by an experienced surgeon. First 10 cases of DSAEK performed by trainees with more than 6 months follow-up periods were recruited. The surgical outcomes of DSAEK performed by the trainees (Trainee group) were compared with disease-matched pairs of cases performed by an experienced surgeon (Experienced group). Graft clarity, best spectacle-corrected visual acuity, corneal endothelial cell density, and incidence of intra- or post-operative complications were studied.

**Results** Forty-one pairs were recruited. The graft clarity rate was not different between the Trainee and Experienced groups, with 95.1% and 97.6%, respectively, maintaining clear grafts at 12 months postoperatively. Trainee best spectacle corrected visual acuity was significantly worse at 6 and 12 months postoperatively compared with the Experienced group, and percent decreases in corneal endothelial density was more in the Trainee group at 3 months following surgery (P = 0.0029). While intra- or late post-operative complication rates were similar in both groups, incidences of early post-operative complications such as double chamber formation or pupillary block were observed more frequently in the Trainee group than in the Experienced group (P = 0.049).

**Conclusion** DSAEK can be performed relatively safely by training physicians with careful preparation and supervision by attending physicians. However, careful case selection and education on management of air injected in the anterior chamber seemed to be a key to long-term success.

**Keywords** Descemet stripping automated endothelial keratoplasty · Surgical education · Postoperative complications · Corneal endothelial cell density

## Abbreviations

| | |
|---|---|
| PKP | Penetrating keratoplasty |
| DSAEK | Descemet stripping automated endothelial keratoplasty |
| BSCVA | Best spectacle-corrected visual acuity |
| ECD | Corneal endothelial cell density |
| PBK | Pseudophakic bullous keratopathy |
| ABK | Aphakic bullous keratopathy |

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## Introduction

Surgical education is an important task for physicians in academic based hospitals. The American Board of Ophthalmology in conjunction with the Accreditation Council for Graduate Medical Education (ACGME) has mandated the systematic assessment of surgical competence of ophthalmology residents in all residency programs. The number of cataract surgery procedures required for qualifications as surgeons proposed by the ACGME was increased to 86. (http://www.acgme.org/Portals/0/PFAssets/ProgramResources/240_Oph_Minimum_Numbers.pdf?ver=2015-11-06-120652-043). It is reported that many of the residents perform a higher number of cataract surgeries than required [1]. The educational program should form a balance between patients' welfare and trainees'

learning opportunities. While some studies indicate that the number of residency years was not a risk factor for intraoperative complications in cataract surgery [2, 3], others demonstrate that complications were more common in surgeons with early surgical experiences [4, 5].

In the field of corneal transplantation, however, very few education programs are reported. Although the ACGME proposes 5 cases of keratoplasty performing as surgeons or assistants, no educational programs have been published, at least to our knowledge. The reasons for this scarcity include relatively few numbers of surgical events as compared with cataract surgery; therefore, numbers of both trainees and supervisors are also relatively few. In addition, not all academic hospitals perform corneal transplantations on a regular basis. This is especially true in Japan, where the donor cornea supply is much lower than in the United States, and keratoplasty is more often performed on emergency basis because of the inadequate eye banking system.

The Tokyo Dental College, Ichikawa General Hospital is a leading referral hospital in corneal transplantation located in the Tokyo Metropolitan area, which has been performing approximately one-tenth of corneal transplants in Japan (around 200-250 cases annually). We accept trainees for corneal transplantation from other institutions, most of which start surgical training in our hospital. We recently reported the surgical outcomes of penetrating keratoplasty (PKP) performed by trainees under experienced physician's supervision, and demonstrated that the results were not different from those performed by an experienced surgeon [6].

However, the surgical methods in corneal transplantation have been rapidly changing, with the shift from PKP to endothelial keratoplasty, especially Descemet stripping and endothelial keratoplasty (DSAEK). Since surgical methods of DSAEK are considerably different from those of PKP, we need to adopt different approaches in surgical education as well. We consider it important to assess the surgical outcomes of DSAEK performed by trainees to evaluate the efficacy and safety of our surgical education program. Here, we report the results of our study on DSAEK outcomes performed by trainees, and a comparison of these results with those of similar surgery performed by an experienced surgeon.

## Methods

This is a case control, retrospective study on surgical outcomes of DSAEK performed by trainee physicians in our hospital. The study was conducted according to the Declaration of Helsinki, and approved by the Institutional Reviewing Board of our hospital (I 16-75). We reviewed all patients who had DSAEK from January 2011 to March 2015. We chose 6 trainees who performed DSAEK for the first time in our hospital. The participating trainees had between 5 and 10 years of ophthalmic experience and had completed their training in cataract surgery. Some of them had limited experience performing PKP. They had extended experience as surgical assistants in both PKP and DSAEK, and wet-lab training was performed regularly. The surgical outcomes performed by the trainees were compared with those performed by an experienced surgeon (JS) who had performed > 1500 corneal transplantation including > 300 cases of DSAEK.

The allocation of the patients was conducted in the following manner. In our hospital, donor corneas were obtained either from domestic eye banks (domestic corneas) or from an eye bank in the United States (Sight Life; overseas corneas). Those two eye banks share the same criteria in donor selection and procurement methods. Both eye banks preserve donor corneas with the intermediate preservation method using Optisol GS (Bausch & Lomb) as preservation media. We have reported that the postoperative outcomes of PKP were not different between the domestic and overseas corneas [7]. The patients selected one of the donor sources. Most of the patients referred to the experienced surgeon preferred to use overseas corneas as the surgery can be planned in a scheduled manner. As a result, trainees had opportunities for performing surgery on patients that selected domestic donor corneas.

The matching of the cases between eyes performed by trainees and the experienced surgeon was made under the following rules. 1) All DSAEK cases performed by the trainees were recruited (Trainee group). We collected data of first 10 cases of DSAEK. If he/she performed less than 10, all cases were included. 2) Disease-matched cases performed by the experienced surgeon (Experienced group) were collected. The cases were chosen with (1) same causative disease for DSAEK; if there were no corresponding cases, similar diseases were selected, (2) age ± 20 years, and (3) closest surgical date. Exclusion criteria included; a follow-up period of less than 6 months, surgery performed using non-standardized methods such as donor corneas prepared with femtosecond laser (iFS$^{R}$, Abbott Medical Optics), donor insertion with forceps, or a donor insertion devise (EndoSaver™, Ocular Systems Inc.,).

### Surgical methods and postoperative managements

DSAEK surgery was performed using the double-glide technique [8]. After retrobulbar anesthesia with 2% lidocaine, a 5.0-mm temporal corneoscleral incision was made. An anterior chamber maintenance cannula was inserted through the 2 or 10 o'clock paracenthesis, and Descemet's membrane stripping was performed with a reverse-bent Sinsky hook (Asico). The recipient's endothelium and Descemet's membrane were carefully removed using forceps. Pre-cut donor

grafts were trephinated typically at a diameter of 8.0 mm, and the endothelial surface of the donor lenticle was coated with a small amount of viscoelastic material. Donor tissue was gently inserted into the anterior chamber using a Busin glide (Asico) and Shimazaki DSAEK forceps (Inami) with the aid of guide glide to prevent mechanical contact with the iris or intraocular lens (IOL) [8]. Air was carefully injected into the anterior chamber, and the fluid between the recipient's stroma and the graft was drained from small incisions in the midperipheral recipient cornea. At 10 min after air injection, half of the air was replaced by balanced salt solution (BSS plus, Alcon). At the end of the surgery, 2 mg subconjunctival betamethasone was administered. In phakic patients, standard phacoemulsification and aspiration were performed using the phaco-chop technique with implantation of an acrylic IOL, followed by the DSAEK procedure.

Postoperatively the patients were prescribed topical 1.5% levofloxacin, (Crabit, Santen Pharmaceutical) and 0.1% betamethasone (Sanbetazon, Santen) five times a day, tapered over 6 months.

## Examinations

Preoperative central corneal thickness (CCT) was measured using anterior segment optical coherence tomography (SS-1000, CASIA, Tomey). Duration between the onset of corneal edema and surgery was calculated based on past history. Graft clarity, spectacle-corrected visual acuity (BSCVA), corneal endothelial cell density (ECD) were examined before surgery and 1, 3, 6, and 12 months following DSAEK. BSCVA was measured using a standard Snellen chart, and the results were converted into logarithm of the minimal angle of resolution (logMAR) for statistical analysis. ECD was measured using non-contact specular microscopy (Noncon Robo SP-8000, Konan). Since the preoperative donor ECD values were different between the 2 groups (described later), percent decreases in the ECD as compared with preoperative values were calculated. Intraoperative, early- and late-postoperative complications were recorded.

### Statistical analysis

Data were analyzed using Prism for Windows V.6.04 (GraphPad Software). To compare patients' age, donor age, BSCVA, preoperative ECD, % ECD decrease, preoperative CCT, duration of BK, follow-up period, and surgical time between the groups, two-tailed Mann–Whitney U tests were performed. Kaplan–Meier with log-rank test was used to analyze the graft survival rate. $\chi 2$ analysis with Fisher's test was used to analyze the incidence of postoperative complications among the groups. Data were expressed as mean ± SD. P value of $< 0.05$ was considered significant.

## Results

### Patient demographics

With the criteria described above, 41 cases were collected in each of the Trainee and Experienced groups. Thirty-eight pairs were completely matched with original diseases, and 3 had different but similar causative diseases. Demographic profile of the both groups is shown in Table 1. There were more women patients in the Experienced group than in the Trainee group (P = 0.041) for unknown reasons. Although duration between the onset of corneal edema and surgery was longer in the Trainee group than in the Experienced group (P = 0.002), there was no significant difference in the preoperative CCT between the groups (P = 0.48). Among original diseases, laser iridotomy-induced bullous keratopathy was the leading cause followed by bullous keratopathy following cataract surgery (pseudophakic bullous

**Table 1** Demographic profile of the patients

| | Trainee (n = 41) | Experienced surgeon (n = 41) | P value |
|---|---|---|---|
| Age (yrs) | 73.0 ± 12.9 | 72.0 ± 9.01 | 0.25 |
| Sex (M:F) | 21: 20 | 11: 30 | 0.041 |
| Surgical methods | | | 0.16 |
| DSAEK only | 33 | 27 | |
| Combined with cataract surgery | 5 | 12 | |
| Other surgery | 3 | 2 | |
| Preop CCT (μm) * | 727 ± 96 | 743 ± 95 | 0.48 |
| Duration of BK (months) ** | 10.8 ± 5.8 | 8.1 ± 7.9 | 0.002 |
| Follow-up (months) | 28.8 ± 2.67 | 24.1 ± 2.82 | 0.11 |
| Original diseases | | | 0.99 |
| PBK/ABK | 9 | 8 | |
| Laser iridotomy induced | 12 | 13 | |
| Fuchs' | 3 | 4 | |
| Post-glaucoma surgery | 2 | 2 | |
| Endotheliitis/iritis | 6 | 4 | |
| reDSAEK | 3 | 4 | |
| Post-PKP | 1 | 1 | |
| Birth injury/trauma | 2 | 2 | |
| Others/unknown | 3 | 3 | |

M = male; F = female; PBK = pseudophakic bullous keratopathy; CCT = central corneal thickness; ABK = aphakic bullous keratopathy; DSAEK = Descemet stripping automated endothelial keratoplasty; reDSAEK = repeated Descemet stripping automated endothelial keratoplasty; PKP = penetrating keratoplasty

*Three and 4 cases with reDSAEK in the Trainee and Experienced groups, respectively, were excluded

**Four and 5 cases were excluded in the Trainee and Experienced groups, respectively, due to lack of data

keratopathy; PBK, or aphakic bullous keratopathy; ABK) in both groups.

## Donor-related factors

There were no significant differences in donor age and death-to-operation time between the Trainee and Experienced groups (Table 2). Donor corneas in the Trainee group demonstrated higher ECD compared with those in the Experienced group, reflecting the different sources of donor corneas as described above. The Trainee group used grafts with smaller diameter than the Experienced group (P = 0.011).

## Graft survival

Figure 1 demonstrates the graft survival rate in Kaplan–Meier analysis. There was no statistically significant difference in the graft survival (P = 0.57). At 1 year 39 grafts were clear in the Trainee (95.1%) and and 40 (97.6%) in the Experienced group (P = 1.00). The final graft survival rates were slightly worse in the Trainee group (35/41 eyes, 85.4%) as compared with the Experienced group (38/41 eyes, 92.7%), however, the difference was not statistically significant (P = 0.48).

## Corrected visual acuity

BSCVA in the Trainee and Experienced groups are shown in Fig. 2. Both groups demonstrated statistically significant improvements in all observation periods as compared with preoperative values (P < 0.0001). The Experienced group showed significantly better BSCVA than the Trainee group at 6 and 12 months postoperatively.

**Table 2** Donor-related conditions of the Trainee and Experienced groups

| | Trainee | Experienced surgeon | P value |
|---|---|---|---|
| Donor age (years) | 68.5 ± 17.0 | 72.0 ± 9.01 | 0.45 |
| Death-to operation time (hours) | 122.3 ± 42.5 | 123.8 ± 26.2 | 0.73 |
| Preoperative ECD (cells/mm$^2$) | 2781 ± 363 | 2530 ± 347 | 0.0008 |
| Donor source | | | |
| Domestic eye banks | 41 | 6 | < 0.0001 |
| Overseas eye banks | 0 | 35 | |
| Graft diameter (mm) | | | |
| 7.00 | 1 | 1 | 0.011 |
| 7.50 | 7 | 1 | |
| 7.75 | 6 | 0 | |
| 8.0 | 22 | 30 | |
| 8.25 | 5 | 6 | |
| 8.50 | 0 | 3 | |

ECD = endothelial cell density

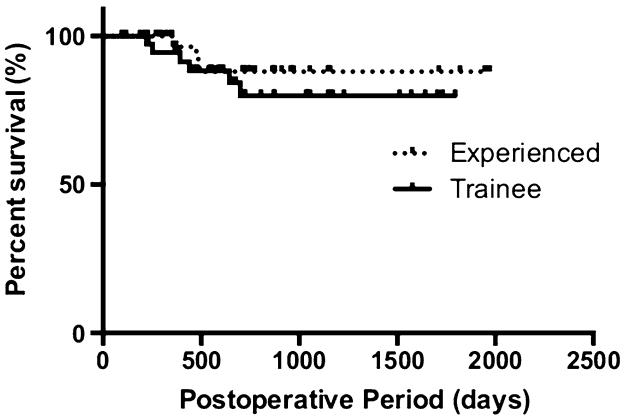


**Fig. 1** Kaplan-Meier analysis in the graft survival rate. There was no significant difference in graft survival between the Trainee and Experienced groups (Log-rank test, P = 0.57)

## Endothelial cell density

Figure 3 demonstrates the % decrease in the corneal endothelial density following DSAEK. The decrease was more significant in the Trainee group than the Experienced group at 3 months following surgery (P = 0.014). The % decreases tended to be smaller in the Experienced group in the other observation periods without any statistical significance.

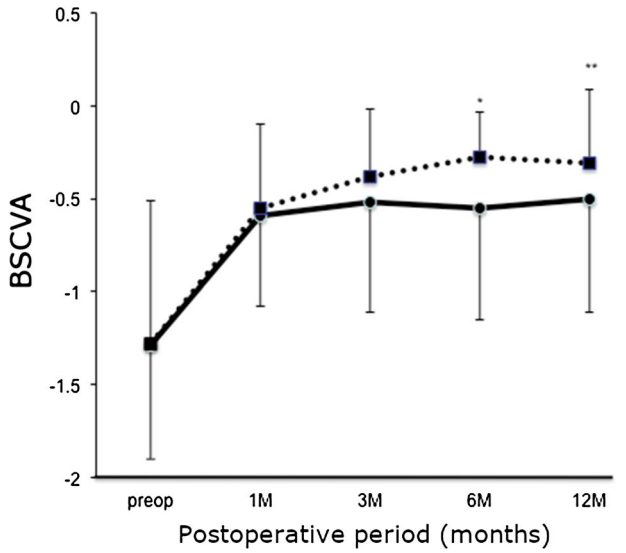


**Fig. 2** Changes in BSCVA following DSAEK. The Experienced group (dotted line) showed significantly better BSCVA compared with the Trainee group (solid line) at 6 and 12 months postoperatively (*P = 0.012, **P = 0.013)

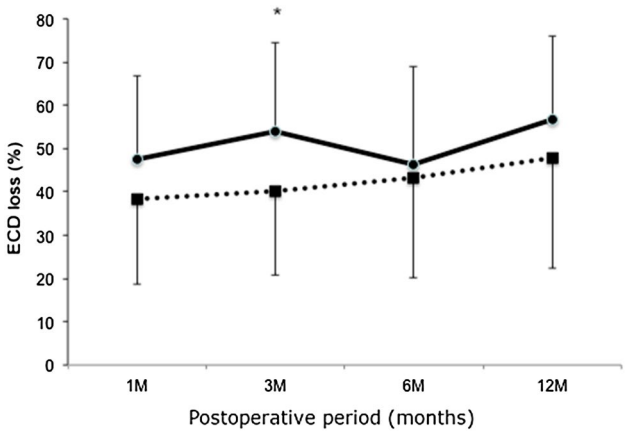


**Fig. 3** Percent decreases in the corneal endothelial cell density in the Experienced and Trainee groups. The Trainee group showed significantly more ECD decrease at 3 month (*P = 0.014)

## Surgical time

Mean surgical times in the Trainee group was 67.0 + 9.40 and in the Experienced group 49.4 + 27.7 min (Fig. 4, P = 0.0003). As the Experienced group included more cases with combined cataract surgery, comparison was made in cases with solitary DSAEK. The difference was more obvious with approximately 1.5 times more surgical time required in the Trainee group as compared with the Experienced group (65.3 vs. 43.0 min, P < 0.0001).

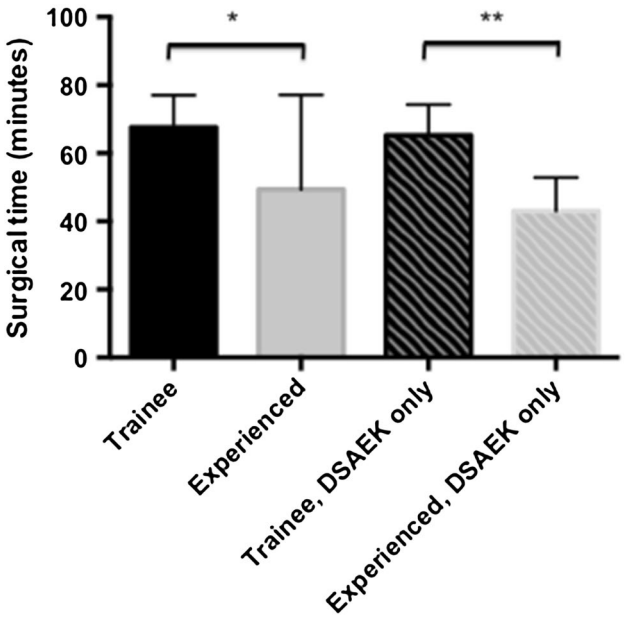


**Fig. 4** Comparison of the surgical time in the Trainee and Experienced groups. The former spent more surgical time than the former (left 2 bars, P = 0.0003). The difference was more obvious when eyes requiring combined cataract surgery were excluded (right 2 bars, P < 0.0001)

## Complications

Table 3 depicts the number of cases that had intra-/postoperative complications. While there was no significant difference in the rate of intraoperative complications in either group, the number of early postoperative complications was higher in the Trainee group as compared with the Experienced group (P = 0.049). The former group had 6 cases with double chamber formation and/or graft dislocation, and 4 cases of pupillary block requiring surgical manipulation. There were some postoperative complications in both groups, which in most cases could be controlled by medical treatments.

# Discussion

Recent advances in ophthalmic surgery require modifications in ophthalmic surgical education programs. Corneal transplantation is one type of surgical method that changed dramatically during the last decade. Lamellar component surgery such as endothelial keratoplasty and anterior lamellar keratoplasty replaced considerable number of PKP. In our previous report, we demonstrated that surgical outcomes following PKP including graft clarity, BSCVA, and corneal

**Table 3** Intraoperative and postoperative complications

| Complications | Trainee | Experienced surgeon |
|---|---|---|
| Intraoperative | | |
| Iris damage | 1 | 1 |
| Posterior capsule rupture | 0 | 1 |
| Early postop. | | |
| Double chamber/dislocation | 6 | 3 |
| Pupillary block | 4 | 0 |
| Others | | |
| PED | 2 | 0 |
| Retained cortex | 0 | 1 |
| Late Postoperative | | |
| CME | 1 | 2 |
| IOP rise | 3 | 4 |
| PCO | 0 | 3 |
| Others | Epithelial damage, CRAO, Endophthalmitis, ERM (1 each) | None |

PED = persistent epithelial defects; CME = cystoid macular edema; IOP = intraocular pressure; PCO = posterior capsule opacification; CRAO = central retinal vein occlusion; ERM = epiretinal membrane

endothelial density were not different between cases performed by trainees and an experienced surgeons [6]. The results indicate that, with proper education program, PKP can safely be performed by Trainees as well. The only difference was noted in the surgical time, especially in the running suturing, indicating that training for suturing is an important component in PKP tutoring. The shift in the keratoplasty method from PKP toward DSAEK created a need for modifications in the training program.

The results of the present study indicate that overall short-term surgical outcomes of DSAEK performed by trainee surgeons were comparable to those performed by an experienced surgeon, which is in accordance with a previous report [9]. In our study, over 95% of the grafts remained clear at 1 year postoperatively with significant visual improvements in both Trainee and Experienced groups. We consider the relatively abundant opportunity for wet-lab training and surgical assistants may help the trainee surgeons to perform DSAEK safely.

However, when we look at the results closely, there are some points that should be considered. Visual recovery and postoperative endothelial cell loss were somewhat poorer in the Trainee group as compared with the Experienced group. In addition, early postoperative complications including graft dislocation/double chamber formation and pupillary block induced by excessive air injection in the anterior chamber were more common in the Trainee group. It is reported that there is a learning curve in DSAEK, and modification of surgical technique is needed to reduce incidence of postoperative complications [10]. It should be noted, however, that there was no clear association between the occurrence of postoperative complications and poor prognosis (data not shown). Nonetheless, the present study indicates that careful case selections and surgical education including management of air in the anterior chamber are important.

Although patient-related conditions were carefully controlled, preoperative ECD of donor corneas was higher in the Trainee group than the Experienced group. The differences can be attributed to the different donor sources; more domestic corneas were used by the Trainee and more overseas corneas by the Experienced group. This was due to our surgical scheduling system as the attending surgeon has more referred patients requesting planned corneal transplant surgery. It is reported that ECD is higher in Japanese than in American patients [11]. The difference in donor ECD was likely to cause under- rather than overestimation, of the differences in surgical skills between the 2 groups. In addition, the Trainee group used a smaller diameter of grafts as compared with the Experienced group. The difference may be attributable to the trainees' and/or their supervisors' preference, presumably based on the concept that smaller grafts may be relatively easier to handle than larger grafts. This difference was unlikely to affect the postoperative outcomes including postoperative ECD as reported previously [12]. One may consider that the overall rates of ECD loss in both groups were higher than those of previous reports from western countries [9, 12]. This may be due to the differences in original diseases and/or severity of preoperative corneal edema. The causative diseases in our series included laser iridotomy-induced BK and PBK. On the other hands, Fuchs' dystrophy with relatively mild corneal edema is the leading cause in western countries.

The limitations of the present study include non-randomized allocation of the patients, and variability in surgical skills among different trainees. Although patient selection was mainly dominated by the selection of donor source by patients as described before, there may be some bias as there may be a tendency to encourage patients to have surgery by experienced surgeon, especially in difficult cases. We tried to reduce the bias by matching the original diseases between the 2 groups. It is true that there was some heterogeneity in surgical performance among trainees. We tried to reduce the bias by combining results from trainees as much as possible. Indeed, we did not find significant differences in surgical outcomes among different trainees (data not shown). We believe proper preparation such as having opportunities for surgical assistance or wet lab training combined with intensive intraoperative supervision by attending physicians resulted in above constant level of surgical performance even in relatively unskilled trainees.

In summary, this case controlled study indicates that DSAEK can be performed relatively safely by trainees as short-term outcomes were comparable to those performed by an experienced surgeon. In order to achieve long-term success, careful case selection and trainings on intraocular maneuvers is important.

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**Conflicts of interest** J. Shimazaki; None, D. Tomida; None, T. Yamaguchi; None, Y. Satake, None.

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