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ORIGINAL PAPER

# Surgical outcomes of 27-gauge and 25-gauge vitrectomy day surgery for proliferative diabetic retinopathy

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**Abstract**
*Purpose* To compare postoperative outcomes of 27-gauge (G) and 25-G vitrectomy conducted as day surgery for proliferative diabetic retinopathy (PDR).
*Methods* One hundred eighty-five consecutive PDR patients (185 eyes) who underwent primary vitrectomy (27-G in 64 eyes, 25-G in 121 eyes) were analyzed.
*Results* The 27-G and 25-G groups did not differ significantly in preoperative Early Treatment Diabetic Retinopathy Study (ETDRS) score, age, or preoperative intraocular pressure. The proportions of simultaneous cataract surgery (27-G vs. 25-G: 59.4% vs. 62.4%) and air-filled eyes (76.6% vs. 85.1%) were not significantly different between two groups. Both groups showed significant improvement in ETDRS score at postoperative 1, 3, and 6 months (all, $P < 0.0001$). Mean gain in ETDRS score from baseline was apparently better in 27-G group than in 25-G group at 1, 3, and 6 months, but there were no significant differences (1 month: 20.3 vs. 13.1 letters, $P = 0.0703$; 3 months: 22.9 vs. 17.5 letters, $P = 0.1561$; 6 months: 24.3 vs. 19.3 letters, $P = 0.3313$). Operation time was apparently longer for 27-G vitrectomy, but there was no significant difference (54.0 vs. 51.1 min, $P = 0.3676$). The same was observed for postoperative intraocular pressure at postoperative day 1 (19.7 vs. 18.1 mmHg, $P = 0.1353$). Incidence of postoperative retinal detachment (1.6% vs. 0.8%) and reoperation due to vitreous hemorrhage (6.3% vs. 6.6%) was not different between two groups.
*Conclusions* The 27G system is as safe and as useful as the 25G system when used for PDR and can be expected to achieve earlier recovery of postoperative visual acuity.

**Keywords** Day surgery · Operative time · Proliferative diabetic retinopathy · 25-gauge vitrectomy · 27-gauge vitrectomy · Visual acuity

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## Background

Twenty-seven-gauge (G) vitrectomy was introduced as a less invasive surgery. This technique has evolved in recent years by the development of powerful light sources, ultra-high-speed cutter, improved intraocular pressure control, endoillumination technologies, wide-angle viewing systems, and heads-up three-dimensional system [1–6]. The 27-G vitrectomy was initially conducted mainly for epiretinal membrane, idiopathic macular holes, and vitreous hemorrhage. The indications for 27-G vitrectomy have since been expanded, including more complex diseases [7–18].

The surgical outcomes of 27-G and 25-G vitrectomy have been compared for epiretinal membrane [19–21], rhegmatogenous retinal detachment [22–24], and posterior segment disease [25]. Although 27-G vitrectomy requires operation time of 4 min longer than 25-G vitrectomy for epiretinal membrane surgery, using the 27-G system results in earlier recovery of visual acuity, improved central retinal thickness, and stabilized ocular pressure [19]. For this reason, 27-G vitrectomy may be a more effective technique for preserving the structure of conjunctiva than 20-, 23-, and 25-G vitrectomy [26]. Minor corneal surface changes and little induced astigmatic changes are expected to facilitate rapid visual rehabilitation after 27-G vitrectomy [27, 28].

However, there is no comparative study on the surgical outcomes of 27-G and 25-G vitrectomy for proliferative diabetic retinopathy (PDR) [29–31]. In the present study, we performed a retrospective study on 185 eyes that underwent vitrectomy for PDR to compare the postoperative outcomes of 27-G and 25-G surgery performed as day surgery.

## Methods

### Patients

In this retrospective study, 185 eyes of 185 patients (63 females, 122 males) that underwent primary vitrectomy day surgery for PDR between January 2010 and January 2018 were studied. This study was approved by the Ethical Committee of the Nihon University School of Medicine. Informed consent was obtained from each patient following an explanation of the vitrectomy procedures and potential adverse effects of the procedure. All surgeries were performed by two surgeons (H.S. and Z.N.). H.S. performed 56% of the 25-G and 51% of the 27-G vitrectomies. The proportions of surgeries performed by each surgeon did not differ between 25-G and 27-G vitrectomies ($P = 0.5707$). There were no significant differences in operation time, surgical indications, surgical methods, and surgical outcome between the series performed by the two surgeons. Patients requiring general anesthesia and systemic management, and patients who desired inpatient treatment were excluded from the study.

### Vitrectomy

Vitrectomy was conducted using the Constellation® Vision System (Alcon Laboratories, Fort Worth, TX). Preoperative antisepsis was started the day before surgery by instilling levofloxacin ophthalmic solution (Shionogi, Osaka, Japan) six times a day. One hundred and twenty-one consecutive eyes were operated by 25-G vitrectomy (Alcon Surgical) between January 2010 and January 2015 (25-G group). The remaining 64 eyes were operated by 27-G vitrectomy (Alcon Surgical) between February 2015 and January 2018 (27-G group).

Vitrectomy was performed under retrobulbar anesthesia in all patients. Flomoxef sodium (Shionogi, Osaka, Japan) was infused intravenously during surgery. After placing the lid speculum, the operative field was irrigated with 0.25% povidone-iodine freshly prepared before surgery by diluting 10% povidone-iodine (Mundipharma, Tokyo, Japan) with sterile physiological saline [32]. The conjunctiva was displaced slightly toward the cornea using forceps [33], and incisions were made to insert three valved cannula trocar systems obliquely at an angle of 30° and parallel to the limbus in a one-step procedure [34]. Twenty-five-gauge vitrectomy was performed using a cut rate of 5000 cuts per min (cpm) and linear aspiration of 0–650 mm Hg in all cases. Twenty-seven-gauge vitrectomy was performed using a cut rate of 7500 cpm and linear aspiration of 0–650 mm Hg in all cases. RESIGHT 700 (Carl Zeiss Meditec AG, Oberkochen, Germany) or contact lens (Hoya, Tokyo, Japan) was used for posterior visualization. During vitrectomy, the operative field was flushed repeatedly with infusion fluid or 0.25% povidone-iodine.

Proliferative membrane was removed using 25-G or 27-G internal limiting membrane forceps (Alcon Laboratories). No chandelier light source and no scleral buckling were used in all patients. Peripheral vitreous was excised until the cannula tip was exposed [35]. After removing each cannula, the sclerotomy roof was compressed on both sides with forceps to close the scleral wound. At completion of surgery, a triangular surgical spear was used to check for vitreous prolapse at all three ports. Transparent vitreous prolapsed through the scleral wound was excised with a cutter. In some eyes, gas tamponade was performed using 17% sulfur hexafluoride ($SF_6$; Alcon Laboratories) or 9% perfluoropropane ($C_3F_8$; Alcon Laboratories) in air, and 1000 centistokes silicon oil (Alcon Laboratories) was used as endotamponade. Finally, the operative field was irrigated with 0.25% povidone-iodine, and subconjunctival steroid (dexamethasone; Wako, Tokyo, Japan) and antibiotic (tobramycin; Shionogi, Osaka, Japan) were injected. Operation time was defined as the time taken to perform the whole surgical procedure. When simultaneous cataract surgery was performed, the total time taken to perform cataract surgery and vitrectomy was recorded.

Simultaneous cataract surgery was conducted in patients 50 years of age or older because cataract tends to progress after vitrectomy. Two types of viscoelastic materials; Viscoat (Alcon Laboratories) and Healon (AMO, Uppsala, Sweden) were used. Phacoemulsification (Constellation; Alcon Laboratories) was performed through an incision in the superior cornea. A foldable intraocular lens (SN60WF; Alcon Laboratories) was inserted inside the capsule bag. Scleral and corneal wound was closed with one nylon 10-0 suture and removed 1 week later.

Fluid–air exchange with 100% air was performed even in cases of diabetic vitreous hemorrhage. In cases of complicated diabetic tractional retinal detachment, fluid was substituted by gas or silicon oil. When replaced with 100% air or gas, the scleral wound was not sutured. When replaced with silicon oil, the scleral wound was closed with one stitch of absorbable suture through the conjunctiva at three sites.

### Pre and postoperative examinations

Patients were examined before 1 to 2 days, 1 week, 2 weeks, 1 month, 2 months, 3 months, and 6 months after surgery. Hypotony was defined as an IOP of 6 mm Hg or lower [7], and ocular hypertension as an IOP of 25 mmHg or higher [7]. Corneal epithelial damage, anterior chamber inflammation, vitreous inflammation, and the fundus were assessed periodically from day 1 to 6 months after surgery, using a slit lamp microscope and indirect ophthalmoscopy. Postoperative complications including hypotony, ocular hypertension, retinal detachment, endophthalmitis, and choroidal detachment were also detailed if present. Visual acuity was measured using the Landolt ring chart, and the result was converted to Early Treatment Diabetic Retinopathy Study (ETDRS) score for analysis. Gain of ETDRS score after surgery (postoperative ETDRS score − preoperative ETDRS score) was also analyzed.

### Outcome measures

The outcome measures were intraoperative complications, wound closure at the end of surgery, operation time for cataract and vitrectomy, IOP on postoperative day 1 and day 7, complications occurring up to six months after surgery, and visual acuity at 1 month, 3 months, and 6 months after surgery.

### Statistics

Statistical analyses were performed using SPSS software version 21 (SPSS, Inc., Chicago, IL). Values are expressed as mean ± standard deviation (SD) or percentage. Chi-squared test for independent variable or Mann–Whitney test was used to compare two groups. Paired *t*-test was used in intragroup comparisons. *P* values less than 0.05 were considered to be statistically significant.

## Results

### Baseline data

The 27-G group and 25-G group did not differ significantly in baseline and operative characteristics (Tables 1 and 2) including female/male ratio (27-G vs. 25-G: 19/45 vs. 44/77; $P = 0.4537$), age (56.0 ± 12.9 vs. 61.1 ± 12.5 years; $P = 0.0583$), and preoperative IOP (15.9 ± 2.9 vs. 15.8 ± 3.6 mmHg; $P = 0.5396$).

### Outcome measures

The 27-G and 25-G groups did not differ significantly in percent of simultaneous cataract surgery (59.4% vs. 62.0%; $P = 0.6643$) or percent of air-filled eye (76.6% vs. 85.1%; $P = 0.1493$) (Table 3). Operation time (54.0 ± 21.1 vs. 51.1 ± 21.9 min, $P = 0.3676$) was apparently longer in the 27-G group, but there was no significant difference.

As shown in Table 1, both groups showed a significant improvement in ETDRS score at

**Table 1** Comparisons of visual acuity between 27- and 25-gauge vitrectomy

| | 27-gauge vitrectomy ($n$ = 64) | 25-gauge vitrectomy ($n$ = 121) | $P$ value 27- vs. 25-gauge |
|---|---|---|---|
| Female/male ratio | 19/45 | 44/77 | 0.4537[a] |
| Mean age (range) | 56.0 ± 12.9 | 61.1 ± 12.5 | 0.0583[b] |
| Preop ETDRS score (letters) | 34.8 ± 25.3 | 42.0 ± 30.2 | 0.0877[b] |
| Postop | | | |
| (1 month) | | | |
| Postop ETDRS score (letters) | 55.5 ± 24.0 | 55.1 ± 23.6 | 0.8103[b] |
| Mean gain (letters) | 20.3 ± 27.7 | 13.1 ± 27.2 | 0.0703[b] |
| $P$ value[c] (preop vs. postop) | < 0.0001 | < 0.0001 | |
| Postop | | | |
| (3 months) | | | |
| Postop ETDRS score (letters) | 57.9 ± 24.9 | 59.51 ± 21.4 | 0.9539[b] |
| Mean gain (letters) | 22.9 ± 28.3 | 17.5 ± 28.1 | 0.1561[b] |
| $P$ value[c] (preop vs. postop) | < 0.0001 | < 0.0001 | |
| Postop | | | |
| (6 months) | | | |
| Postop ETDRS score (letters) | 59.9 ± 25.1 | 61.3 ± 21.0 | 0.8494[b] |
| Mean gain (letters) | 24.3 ± 29.6 | 19.3 ± 28.7 | 0.3313[b] |
| $P$ value[c] (preop vs. postop) | < 0.0001 | < 0.0001 | |

Except female/male ratio, all data are expressed as mean ± SD

*ETDRS* Early Treatment Diabetic Retinopathy Study; *Preop* preoperative; *Postop* postoperative

[a]Chi-squared test for independent variable; [b]Mann–Whitney test; [c]paired *t*-test

**Table 2** Comparison of ocular pressure Between 27- and 25-gauge vitrectomy

| Surgical system | Ocular pressure Mean ± SD (range) mmHg | | | Postoperative hypotony No. of eyes (%) | | Postoperative ocular hypertension No. of eyes (%) | |
|---|---|---|---|---|---|---|---|
| | Before | 1 day | 7 days | 1 day | 7 days | 1 day | 7 days |
| 27-gauge vitrectomy ($n$ = 64) | 15.9 ± 2.9 (7–26) | 19.7 ± 8.3 (7–47) | 18.1 ± 8.6 (5–61) | 0 eye (0%) | 0 eye (0%) | 8 eyes (12.5%) | 3 eyes (4.7%) |
| 25-gauge vitrectomy ($n$ = 121) | 15.8 ± 3.6 (8–28) | 18.1 ± 7.8 (6–46) | 15.9 ± 2.9 (7–40) | 2 eyes (1.7%) | 0 eye (0%) | 17 eyes (14.0%) | 3 eyes (2.5%) |
| $P$ value (27- vs. 25-gauge) | 0.5396[a] | 0.1353[a] | 0.5032[a] | 0.3011[b] | > 0.9999[b] | 0.7693[b] | 0.4200[b] |

[a]Mann–Whitney test. [b]Chi-squared test for independent variable

Hypotony was defined as an IOP of 6 mmHg or lower. Ocular hypertension was defined as an IOP of 25 mmHg or higher

postoperative 1 month (55.5 ± 24.0 vs. 55.1 ± 23.6 letters), 3 months (57.9 ± 24.9 vs. 59.51 ± 21.4 letters), and 6 months (59.9 ± 25.1 vs. 61.3 ± 21.0 letters) compared to preoperative ETDRS score (34.8 ± 25.3 vs. 42.0 ± 30.2 letters) (all, $P < 0.0001$). Mean gain in ETDRS score from baseline tended to be better in the 27-G group than in the 25-G group at 1 month after surgery (20.3 ± 27.7 vs. 13.1 ± 27.2 letters, $P$ = 0. 0703), and while the gains were apparently higher in the 27-G

**Table 3** Comparison of intraoperative and postoperative outcomes between 27- and 25-gauge vitrectomy

| Surgical system | Surgical procedure No. of eyes (%) | Exchange procedure No. of eyes (%) | Operation time Mean ± SD (range) min | Postoperative complication No. of eyes (%) |
|---|---|---|---|---|
| 27-gauge vitrectomy | PEA + IOL + VIT: 38 eyes (59.4%) | Air: 49 eyes (76.6%) | 54.0 ± 21.2 (15–127) | Retinal detachment: 1 eye (1.6%) |
| (*n* = 64) | VIT: 26 eyes (40.6%) | SO: 9 eyes (14.1%) | | Vitreous hemorrhage: 4 eyes (6.3%) |
| | | SF6: 5 eyes (7.7%) | | |
| | | $C_3F_8$: 1 eye (1.6%) | | |
| 25-gauge vitrectomy | PEA + IOL + VIT:75 eyes (62.0%) | Air: 103 eyes (85.1%) | 51.1 ± 21.9 (10–121) | Retinal detachment: 1 eye (0.8%) |
| (*n* = 121) | VIT: 46 eyes (38.0%) | SO: 17 eyes (14.0%) | | Vitreous hemorrhage: 8 eyes (6.6%) |
| | | SF6: 1 eye (0.9%) | | |
| *P* value 27- vs. 25-gauge | 0.6643[a] | 0.1493[a] | 0.3676[b] | 0.6674[a] |

*PEA* phacoemulsification, *IOL* intraocular lens, *VIT* vitrectomy, *SO* silicon oil

[a]Chi-squared test for independent variable, [b]Mann–Whitney test

group at 3 months (22.9 ± 28.3 vs. 17.5 ± 28 letters, *P* = 0.1561) and 6 months (24.3 ± 29.6 vs. 19.3 ± 28.7 letters, *P* = 0.3313), the differences were not significant.

On postoperative day 1, the IOP in the 27-G and 25-G groups was 19.7 ± 8.3 and 18.1 ± 7.8 mmHg, respectively (*P* = 0.1353), and hypotony rates were 0% and 1.7% (*P* = 0.3011), while ocular hypertension rates were 12.5% and 14.0% (*P* = 0.7693) (Table 2). On postoperative day 7, the IOP in the 27-G and 25-G groups was 18.1 ± 8.6 and 15.9 ± 2.9 mmHg, respectively (*P* = 0.5032), and hypotony rates were 0% and 0%, while ocular hypertension rates were 4.7% vs. 2.5% (*P* = 0.4200). IOP improved on day 7 compared to day 1 in both groups, although there were no significant differences between two groups.

There were no serious intraoperative complications in both groups. Postoperative complications consisted of retinal detachment (27-G vs. 25-G: 1.6% vs. 0.8%) and reoperation due to vitreous hemorrhage (6.3% vs. 6.6%), with no significant difference in incidence (*P* = 0.6674) between two groups. All cases recovered by repeat vitrectomy.

No postoperative endophthalmitis, sclerotomy-related retinal tears, and choroidal detachments were encountered in the 6-month follow-up period.

## Discussion

The present study showed that 27G vitrectomy is as safe and as useful as 25G vitrectomy for PDR and can be expected to improve visual acuity from the early postoperative day.

Various factors that potentially affect postoperative visual acuity following vitrectomy will be discussed, including the gauge of surgical instrument, operation time, postoperative IOP, surgically induced astigmatism, cut rate, postoperative inflammation, and postoperative complications. There was no difference in the ratio of air: gas: silicon oil exchange between the 27-G group and 25-G group, probably reflecting no difference in ratio of diabetic vitreous hemorrhage to complicated diabetic tractional retinal detachment between the two groups.

Regarding the relationship between gauge of instrument and postoperative visual acuity, our previous surgical results for epiretinal membrane showed that mean gain of ETDRS score at 1 month (27-G: 4.7 ± 8.1 vs. 25-G: 1.1 ± 13.6 letters, *P* = 0.0421) after vitrectomy was significantly better in the 27-G group, while the gains at 3 months (6.8 ± 9.4 vs. 4.6 ± 13.4 letters, *P* = 0.0835) and 6 months (7.8 ± 9.7 vs. 6.4 ± 12.7 letters, *P* = 0.0569) tended to be better in the 27-G group, although the differences did not reach statistical significance [19]. In the present study, mean gain in ETDRS score from baseline tended to be better in the 27-G group than in the 25-G group, although the difference was not significant (20.3 ± 27.7 vs. 13.1 ± 27.2 letters, $P = 0.0703$). At 3 months (22.9 ± 28.3 vs. 17.5 ± 28. letters, $P = 0.1561$) and 6 months (24.3 ± 29.6 vs. 19.3 ± 28.7 letters, $P = 0.3313$), the difference between two groups further decreased. The different finding in visual outcome between the two studies may be due to a smaller standard deviation in the previous series of epiretinal membrane than in the present PDR cases. Nevertheless, our results suggest that postoperative recovery of visual acuity in PDR is also more rapid when using the 27-G system compare to the 25-G system.

In our previous study, the operation time for epiretinal membrane was 36.7 ± 12.8 min with 27-G vitrectomy and 32.7 ± 10.1 min with 25-G vitrectomy, and 27-G vitrectomy took approximately 4 min longer ($P = 0.0323$) [19]. In the report of Mitsui et al. [21], the mean time of vitreous cutting for epiretinal membrane was 9.9 ± 3.5 min with 27-G and 6.2 ± 2.7 min with 25-G instrument and was also significantly longer when using the 27-G system ($P < 0.0001$). On the contrary, while the mean operation time for PDR in this study was approximately 3 min longer in the 27-G group (54.0 ± 21.1 min) compared to the 25-G group (51.1 ± 21.9 min), there was no significant difference ($P = 0.\ 3676$). Our PDR cases manifested diverse lesions ranging from diabetic vitreous hemorrhage to complicated diabetic tractional retinal detachment, resulting in large standard deviation of the operation time, which may be one reason for the lack of significant difference between 27-G and 25-G instruments. Taken together, 27-G vitrectomy takes a longer time than 25-G vitrectomy and may potentially affect postoperative vision.

The contribution of stabilized IOP after vitrectomy on rapid recovery of visual acuity has been studied in epiretinal membrane surgery. On postoperative day 1 after epiretinal membrane surgery, the hypotony rates were 2% in the 27-G group and 6% in the 25-G group, while the corresponding ocular hypertension rates were 4% and 11% [19]. Although there were no significant differences, more stabilized IOP was obtained using 27-G group compared to 25-G group. For PDR surgery in this study, IOP in the 27-G and 25-G groups on postoperative day 1 was 19.7 ± 8.3 and 18.1 ± 7.8 mmHg, respectively ($P = 0.1353$), while the corresponding hypotony rates were 0% and 1.7%, and ocular hypertension rates were 12.5% and 14.0%. Although there were no significant differences, more stabilized IOP was also obtained using the 27-G system compared to the 25-G system even in vitrectomy for PDR.

The method of constructing scleral wound is important to achieve stabilized ocular pressure postoperatively. Takashina et al. [20] reported that creating sclerotomy by angled incision in 27-G vitrectomy resulted in lower incidence of postoperative low intraocular pressure compared to straight incision in 27-G vitrectomy or angled incision in 25-G vitrectomy. For this reason, the authors created scleral wounds by angled incision for both 25-G and 27-G vitrectomy aiming to stabilize ocular pressure postoperatively [19, 34].

In the report of Mitsui et al. [21] for epiretinal membrane, the rate of surgically induced astigmatism was not significantly different between 27-G and 25-G groups. In the series reported by Hirashima et al. [28], 27-G vitrectomy did not induce substantial corneal topographic changes. Tekin et al. [27] also reported that minor corneal surface changes and induced astigmatism after 27-G vitrectomy may result in rapid visual rehabilitation after surgery. These findings indicate that the risk of surgically induced astigmatism by 27-G vitrectomy is equivalent to or less than that by 25-G vitrectomy. This is one factor that contributes to early restoration of visual acuity after 27-G vitrectomy.

In this study, 25-G vitrectomy was performed in all cases using a cut rate of 5000 cpm and 27-G vitrectomy a cut rate of 7500 cpm. We cannot deny the possibility that the difference in cut rate affected postoperative vision. However, there is no report on the relationship between cut rate and postoperative vision. Future research is necessary.

One of the potential factors affecting recovery of visual acuity is postoperative inflammation. Inoue et al. [36] conducted an animal study to compare postoperative intraocular inflammation following vitrectomy and reported that smaller gauge minimized inflammation associated with vitrectomy. Gozawa et al. [26] studied subconjunctival scarring after microincision vitrectomy surgery using 20-, 23-, 25-, and 27-G systems in rabbits and reported that 27-G vitrectomy may be a more effective technique for preserving the structure of conjunctiva. These findings indicating that postoperative inflammation is milder in 27-G vitrectomy than in 25-G vitrectomy is also related to early visual improvement.

Finally, the impact of surgery-related complications on recovery of visual acuity after vitrectomy is discussed. In our study, the incidence of postoperative complications was low in both groups. Vitreous hemorrhage occurred in 4 eyes (6.3%) and retinal detachment in 1 eye (1.6%) in the 27-G group, while retinal detachment occurred in 1 eye (0.8%) and vitreous hemorrhage in 8 eyes (6.6%) in the 25-G group, with no significant difference. There was also no difference in incidence of postoperative complications after epiretinal membrane surgery between 27-G group and 25-G group [19]. These results indicate that surgery-related complications are less likely to affect recovery of visual acuity.

This study had some limitations. This research was a retrospective study. Further, prospective study with larger number of cases is required to verify the present findings. The present study confirms that although 27-G vitrectomy takes approximately 3 min longer to perform compared to 25-G vitrectomy, low incidence of postoperative hypotony and ocular hypertension, few postoperative complications, and early postoperative recovery of visual acuity can be expected from this modality. Twenty-seven-G vitrectomy performed as day surgery is increasingly being used in the world.

#### Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethical statement** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Ethical approval** This study was approved by the Ethical Committee of the Nihon University School of Medicine.

**Informed consent** Before surgery, informed consent was obtained from each patient following an explanation of the vitrectomy procedures and potential adverse effects of the procedure. For the retrospective study, formal consent is not required.

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