EXTENDED REPORT

25-gauge vs 20-gauge system for pars plana vitrectomy: a prospective randomised clinical trial

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Aim: To compare 25-gauge vs 20-gauge system for pars plana vitrectomy in a prospective, randomised, controlled clinical trial.

Methods: Three-port pars plana vitrectomy was performed in 60 patients belonging to 2 groups. Evaluations were performed preoperatively, intraoperatively, during the first three postoperative days, at 1 week, and at 1 and 3 months. The main outcome measure was time for surgery, divided into duration of wound opening, vitrectomy, retinal manipulation and wound closure.

Results: The total duration of surgery showed no significant difference between the groups ($p=0.67$). The 25-gauge group showed significantly shorter duration of wound opening ($p<0.001$) and wound closure ($p<0.001$). In contrast, the vitrectomy duration was significantly longer in the 25-gauge group ($p<0.001$). Conjunctival injection and subjective postoperative pain showed significantly lower irritation in the 25-gauge group ($p<0.001$ for both).

Conclusion: The 25-gauge vitrectomy system offered significantly improved patient comfort during the first postoperative week. The smaller surgical openings facilitated wound healing and minimised pain. Duration of surgery was comparable between the two systems—the shorter time needed for wound opening and closure in the 25-gauge group being equalised by the longer vitrectomy duration. Intraoperative as well as retinal manipulation and illumination caused more surgical difficulties using the 25-gauge system.

Three-port 20-gauge vitrectomy systems have been the gold standard for vitreous surgery since 1974.¹ During the past 30 years, its instrumentation has successfully been developed further. The standard system, demanding conjunctival incisions and sclerotomies of 0.89 mm diameter (20 gauge), was subsequently made smaller and less traumatic. For example, a 23-gauge system was developed in the 1980s by Peyman², and 23-gauge-sized instruments have been mainly used for paediatric ophthalmic surgery.

In 2002, a 25-gauge system was developed and made commercially available by Fujii *et al.*³ First reports have emphasised several advantages in the use of the new sutureless transconjunctival system.^{4–6} One advantage was a gain in time for surgery by avoiding extra efforts to open and close sclera and conjunctiva separately. This subsequently minimises surgically induced trauma and foreign body perception otherwise caused by manipulation and sutures, as well as the possible reactions related to the suture material itself. This was supposed to reduce the duration of the convalescence period and of the postoperative inflammatory response. The micro-cannulas of the system permit interchangeability of instruments between entry sites and might protect the vitreous base from mechanical traction.

On the other hand, suction and flow rates in the 25-gauge system are significantly lower than the comparable parameters in the established 20-gauge technique, as a result of the smaller diameter of the 25-gauge system.⁷ This could eventually cause difficulties in removing tight vitreous strands, epiretinal membranes, or denser haemorrhages or clots. Membranes too thick or too big in size to be cut inside the eye could lead to enlargement of the sclerotomy and change of instrument sets. The time advantage gained by the use of the sutureless technique could perhaps be lost by the need for a longer vitrectomy time or longer retinal manipulation time in order to remove the same amount of vitreous through the smaller calibre of the instrument, or because of difficulties in grasping

with finer forceps. Although single advantages and disadvantages have been reported in case series, precise evaluation in a prospective randomised clinical trial is missing.

The aim of this study is to compare the functional and clinical differences between a 20-gauge surgical system and the newly developed 25-gauge system for pars plana vitrectomy.

METHODS

A randomised prospective controlled clinical trial was designed, comparing the two vitrectomy systems in a group of diseases requiring uncomplicated vitreoretinal surgery. Patients with vitreoretinal pathology such as preretinal membrane, posterior uveitis, uncomplicated vitreous haemorrhage, synchysis scintillans, macular oedema or macular hole were included. Cases requiring silicone oil tamponade or pre-vitrectomised or retinally preoperated patients were excluded. Only one eye per patient was included in our study. Surgery was performed by two experienced randomly surgeons (S.B., U.S.). The number of subjects to be studied was determined by statistical pre-study evaluation (by the two-group *t*-test, with a 0.05 two-sided significance level). Sixty patients were divided into two randomised groups, 30 for the 25-gauge system (25 gr) and 30 for the 20-gauge system (20 gr). In all cases, a minimum of 80% of vitreous was removed. Institutional review board approval and complete informed patient consent were obtained for all patients, and all interventions followed standard of care practices for these vitreoretinal diseases.

The data collected included patient age, sex, the duration of surgery, divided into duration of wound opening, vitrectomy, retinal manipulation (in eyes with macular holes, pucker and oedema) and wound closure. Furthermore, the postoperative subjective pain, conjunctival injection, eye pressure, visual acuity, the retinal situation, as well as intraoperative or postoperative complications were evaluated. In addition, the

Abbreviation: IOP, intraocular pressure

Table 1 Summary of qualitative baseline values

	20 gauge	25 gauge	p Value of Fisher's exact test
Sex			0.18
Women	16 (53.3)	22 (73.3)	
Men	14 (46.7)	8 (26.7)	
Diagnosis			0.71
Macular hole	15 (50)	11 (36.7)	
Preretinal membrane	14 (46.7)	18 (60)	
Synchysis scintillans	1 (3.3)	1 (3.3)	
Combined cataract surgery			1
No	8 (26.7)	9 (30)	
Yes	22 (73.3)	21 (70)	
Eye			0.44
Left	13 (43.3)	17 (56.7)	
Right	17 (56.7)	13 (43.3)	

Values are given as n (%).

surgeons' judgements of surgical tools and technical difficulties were documented.

Examinations were performed the day before surgery, the first, second and third postoperative days, at 1 week, and at 1 and 3 months after surgery.

Intraoperative time measurement

A stopwatch was used from the beginning of the first cut into the conjunctiva. Measured criteria used for evaluation were the time needed for conjunctival and scleral preparation, for vitrectomy (consisting of the vitrectomy itself and the retinal manipulation) and for withdrawal of the cannulas, closing and suturing of sclerotomies and conjunctiva.

Assessment of conjunctiva

The conjunctival injection was measured on a scale ranging from 0 to 4: (no conjunctival injection), 1 (light), 2 (medium), 3 (high) and 4 (heavy).

Assessment of postoperative recovery

Pain and discomfort were measured using a grading scale from 1 to 4: (no pain), 2 (light), 3 (heavy) and 4 (severe).

Intraocular pressure

Intraocular pressure (IOP) was measured using Goldmann applanation tonometry.

Visual acuity

Visual distance acuity using the log minimum angle of resolution charts according to the guidelines of the Treatment of Age-Related Macular Degeneration with Photodynamic Therapy study (test distance 4 m, letter-by-letter scoring, chart luminance 100 cd/m²) and visual reading acuity using

standardised, German-language Radner reading charts were measured using the patient's optimal refractive correction.^{8,9}

Surgical technique

All patients underwent surgery in general anaesthesia. The two surgical systems used (Oertli Instrumente AG, Berneck, Switzerland and Alcon Laboratories Inc, Fort Worth, Texas, USA) were commercially available, with comparable cutting rates of 1200–1500/min (20–25 Hz). Only the suction rate had to be higher in the 25 gr (400–500 ml/min vs 150–200 ml/min).

In the 25 gr, the trocars were placed through the conjunctiva and the sclera by shifting the conjunctiva sideways. After vitrectomy, the trocars were removed and the sclerotomies covered by the conjunctiva.

In the 20 gr, the conjunctiva was opened in a nasal triangle and in a temporal quadrangle 1 mm from the limbus, and then the scleral incisions were performed. After vitrectomy, the sclerotomies and conjunctiva were closed with vicryl 7-0 sutures.

Statistical methods

The treatment groups were compared with respect to the duration of wound opening, vitrectomy, retinal manipulation, wound closure, as well as their sum (total duration of surgery). The sum represents the primary end point of the study. We further considered the improvement in visual acuity 3 months postoperatively, IOP at days 1 and 2 after surgery, and conjunctival injection and postoperative pain, as well as the area under the curve, documented at baseline, days 1, 2 and 3, at 1 week, and 1 and 3 months after surgery. For patients who were unable to read the largest test sentence, the Radner value was set to 1.5.

As most end points exhibit strongly skewed distributions with heavy ties, the treatment groups were compared using the exact Wilcoxon's rank sum test. The improvement in distance

Table 2 Summary of quantitative baseline values for each treatment group

	20 gauge					25 gauge					p Value of Wilcoxon's test		
	Min	1.Q*	Mean (SD)	Median	3.Q†	Max	Min	1.Q	Mean (SD)	Median		3.Q	Max
Visual acuity (ETDRS)	0.04	0.33	0.48 (0.23)	0.51	0.62	0.86	0.20	0.37	0.50 (0.18)	0.47	0.62	0.88	0.54
Reading acuity (Radner)	0.20	0.50	0.60 (0.20)	0.60	0.70	1.00	0.10	0.30	0.52 (0.24)	0.55	0.70	1.10	0.94
Eye pressure (mm Hg)	10.0	12.0	14.4 (2.50)	14.5	16.0	20.0	8.00	12.5	14.7 (3.30)	15.0	16.0	22.0	0.69

ETDRS, Early Treatment Diabetic Retinopathy Study; Max, maximum; Min, minimum.

*First quartile, mean.

†Third quartile, mean.

and reading visual acuity 3 months after surgery was investigated by exact one-sample Wilcoxon's tests.

RESULTS

The treatment groups were compared with respect to the baseline measurements (tables 1 and 2). No significant differences were found for the baseline values.

Regarding the duration of surgery, we observed that the 25 gr showed a significantly shorter duration of wound opening ($p < 0.001$) as well as wound closing ($p < 0.001$) compared with the 20 gr. By contrast, vitrectomy duration was significantly longer in the 25 gr compared with the 20 gr ($p < 0.001$). There was no significant difference between the two groups regarding the duration of retinal manipulation. Finally, the total duration of surgery did not show significant difference between the two groups ($p = 0.67$). These results are presented in table 3.

The visual distance and reading acuity changes from baseline until 3 months after surgery were also similar in both groups. A significant increase in distance visual acuity (20 gr: $p = 0.02$; 25 gr: $p < 0.001$) and a significant improvement in reading acuity (20 gr: $p = 0.01$; 25 gr: $p = 0.003$) were observed in both groups 3 months after surgery.

During the first two postoperative days, the 25 gr showed more eyes with low pressure (< 10 mm Hg), but no severe hypotonies (< 6 mm Hg) were observed. During days 1–2, the IOP dropped below 10 mm Hg in nine patients of the 25 gr and in two patients of the 20 gr (Fisher's exact test $p = 0.04$). The maximum difference in IOP from baseline at days 1 and 2 was significantly smaller in the 25 gr than in the 20 gr (day 1: $p = 0.011$; day 2: $p = 0.003$). During the first 2 days after surgery, IOP was > 20 mm Hg for two patients in both treatment groups. After 3 days, IOP levels no longer differed significantly.

Conjunctival injection as well as subjective postoperative pain showed significantly lower irritation in the 25 gr ($p < 0.001$ for both) compared with the 20 gr.

Both groups showed no significant difference regarding the amount of vitreous removed ($p = 0.24$), the amount of applied gas tamponade ($p = 0.24$), as well as the area under the gas % time curve measured at days 1, 2, 3 and at 1 week after surgery.

In 11 of 30 (37%) patients of the 25 gr, one or more technical difficulties occurred during surgery: in seven cases the vitreous cutter and the endoinstruments were insufficient to dissect tight vitreous or epiretinal membranes. In four cases the light source was inadequate to provide sufficient illumination. Two cases showed blockage of instruments in the trocar system, and the trocars had to be replaced. In three cases suction was too weak to remove blood effectively from inside the eye. Membrane peeling and rotation of the globe were hindered by the increased flexibility of the 25 g endoinstruments in three cases. Five cases, for the sake of patients' security, required an intraoperative switch to the 20-gauge system; in two cases the switch of instruments affected only the light source. No postoperative complications occurred in the 25 gr.

In the 20 gr, bad visualisation was described in 1 of 30 (3%) eyes, but did not affect proper surgical progression.

In two cases, vitreous haemorrhages occurred on the first postoperative day after 1 month, both cleared without surgical intervention. Retinal detachment developed in 2 (6.7%) cases, which could be cured only by a second vitrectomy. One of these cases showed multiple inferior breaks on the second postoperative day, whereas the other presented a macular hole retinal detachment without any peripheral break 4 months after surgery.

DISCUSSION

In 2002, Fujii *et al*³ introduced a 25-gauge system for transconjunctival sutureless vitrectomy. Their initial experiences were summarised in a retrospective review of 35 cases, postulating an overall safety of the new system and faster patient recuperation. However, no objective inflammation grading scale was used, and the patients were observed only for 1 day. In a following comparative interventional study, the same authors showed a significantly reduced operating duration using the new 25-gauge system.⁴ We did not test this particular system in our study. However, the results are in contrast with our findings. A possible explanation could be that in several cases (ie, sheathotomy, epiretinal membrane peeling) no vitrectomy was performed before or after retinal manipulation when using the 25-gauge system, and no detailed information was given about the amount of vitreous removed.

Since then, several authors have published their initial and further experiences with the new system: Ibarra *et al*⁵ retrospectively studied 45 consecutive patients and found no intraoperative complications, no postoperative hypotonies and no necessity to convert to the 20-gauge system, but postoperatively found 1 (2.2%) case of inferior retinal detachment, 1 (2.2%) case of macular hole and 79.3% (23 of 29 phakic eyes) of cases with worsening of cataracts. The small and more flexible instruments did not allow the surgeon to move the eye sufficiently, and lower posterior segment illumination caused difficulties. The authors found that less peripheral vitreous removed possibly caused anterior vitreoretinal traction and retinal tears or detachment.

In a non-randomised study, Rizzo *et al*⁶ compared 46 patients (26 (25 gauge group) vs 20 (20 gauge group)) reporting no surgery-related complications, with postoperative pain significantly lower in the 25-gauge group, but with pain level assessed only 1 week after surgery. No postoperative hypotony was observed, the mean duration of surgery was significantly shorter in the 25-gauge group. Only a core vitrectomy was performed, and the amount of vitreous removed was not documented. The postoperative inflammatory score at the follow-ups showed significantly lower inflammation in the 25-gauge group. This is consistent with our findings. In their study, preoperative visual acuity was significantly better in the 20 gr. At 1 month, the improvement in visual acuity was significantly higher in the 25 gr, but after 6 months no difference in visual acuity could be found. In our study, the

Table 3 Summary of surgery time values and p values of the Wilcoxon's rank sum tests for group comparison

Time (s)	20 gauge	25 gauge	p Value (Wilcoxon's test)
Opening time	306 (143)	173 (80)	0.001
Vitrectomy time	490 (239)	774 (328)	< 0.001
Retinal manipulation time	378 (283)	504 (366)	0.18
Closing time	357 (83)	112 (153)	< 0.001
Total surgery time	1530 (499)	1564 (626)	0.67

Values are mean (SD).

preoperative as well as the postoperative visual acuities were comparable in both groups.

Description of postoperative hypotony by several authors

Lakhanpal *et al*¹⁰ published 140 consecutive cases of 25-gauge vitreoretinal surgery, and found suturing of transconjunctival sclerotomies necessary in up to 7.1%, because of bleb formation. Neither intraoperative complications nor conversion to the 20-gauge system was reported; the IOP was stable and no retinal detachment occurred.

In a retrospective study of 41 eyes, Yoon *et al*¹¹ saw transient hypotony of 4 mm Hg in one eye. A further retrospective study of 71 eyes by Yanyali *et al*¹² showed hypotony between 6 and 10 mm Hg in 16.9% of the eyes on the first postoperative day, but normalisation within 1 week. Liu *et al*¹³ published a case report regarding a patient with a 360° choroidal detachment on the first postoperative day, suspected to be postoperative hypotony. So far only one case of endophthalmitis after 25-gauge vitrectomy has been reported.¹⁴

In a randomised prospective study of 30 patients, Chang *et al*¹⁵ measured time for combined surgery, comparing 20-gauge vs 25-gauge systems only for preparation and closure of sclerotomies, neglecting conjunctival opening and closing and measuring the time for phacoemulsification and that for pars plana vitrectomy together, leaving the time distribution unclear. No objective staging of ocular redness was performed and not all 25-gauge instruments were available. Oshima *et al*¹⁶ performed a retrospective review of 150 eyes having previously undergone 25-gauge vitrectomy, phacoemulsification and intraocular lens implantation, observing postoperative transient hypotony in 13% (18 eyes) of cases 1 week after surgery, 1 (0.67%) case of retinal detachment, but no case of endophthalmitis.

In our randomised prospective controlled clinical study, we found 25-gauge vitrectomy to be a safe and effective system for the management of a variety of uncomplicated vitreoretinal diseases, especially those cases requiring lesser intraocular manipulations. However, setting of the trocars requires a learning curve, and the higher flexibility of the instruments hinders management of tight membranes. The 25-gauge system offers significantly higher patient comfort during the first postoperative week, and the risk of postoperative severe complications such as retinal detachment and vitreous haemorrhage seems to be lower. This could be related to the fact that trocars were used in the 25-gauge cases, and also to the smaller incisions. In our study, 80% of the vitreous was removed in all cases and great care was taken to remove the posterior hyaloid in every case, whereas only core vitrectomy of unknown amount was done in the other studies. We believe that, for this reason, the total duration of surgery showed no difference between the two groups. The important factor that emerged was a clearly higher patient comfort with the 25-gauge system. This is in accordance with many other studies.^{3 5 6} Whether a higher percentage of postoperative hypotonies that we and others observed might lead to a higher rate of endophthalmitis needs to be investigated further.¹⁴ Although the learning curve for the 25-gauge sutureless vitrectomy must

be considered, higher flexibility and lesser mechanical stability can lead to a limitation of surgical indications and increased costs when an additional 20-gauge vitreous surgery system has to be provided. Further study as well as technical development will be needed to improve the principle of sutureless transconjunctival pars plana vitrectomy and to minimise intraoperative handicaps as well as potential postoperative risks.

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