

A Comparative Study of 23-Gauge and 27-Gauge Vitrectomy for Puckers or Floaters, Including Evaluation of the Effect of Combined Phaco-Vitrectomy Surgery on Postoperative Outcome

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Keywords

Vitrectomy · 27-Gauge · 23-Gauge · Inflammation · Redness · Sclerotomy · Pain · Postoperative recovery · Combined phaco-vitrectomy

Abstract

Introduction: A single-center, prospective randomized comparison of postoperative recovery between 23-gauge and 27-gauge surgical approaches in vitrectomy was performed.

Methods: A single-center, prospective randomized comparison of postoperative recovery between 23-gauge and 27-gauge surgical approaches to evaluate efficiencies and postoperative outcomes of the two surgical gauges. Eighty patients who were scheduled to undergo pars plana vitrectomy (PPV) for floaters or macular surgery were treated with either 27-gauge or 23-gauge techniques and assessed for efficiency of the procedures as well as a variety of postop indicators of pain and inflammation. **Results:** 27-Gauge vitrectomy took 90 s more time compared to 23-gauge surgery. Wound closure was significantly easier in 27-gauge than 23-gauge. Less postoperative eye reddishness was seen in 27-gauge compared to 23-gauge. A trend towards less inflammation was seen in 27-gauge. **Conclusion:** Overall, the trial showed that 27-gauge has the better postoperative outcome compared to 23-gauge PPV. Combining vitrectomy with phaco-surgery did not influence the study outcome parameters.

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Introduction

While vitrectomy was first described in 1971 [1], it was only adopted as a commonly used technique in ophthalmology in the early 1980s. In its first phase of mainstream use, vitrectomy was performed transscleral, after peritomy of the conjunctiva and exposure of the sclera to make the vitrectomy incisions. These incisions required suturing at the end of the surgery. The size of the commercially available instruments used initially in vitrectomy was 0.91 mm, otherwise known as “20-gauge.”

Since then, there has been a great deal of progress in the techniques, tools, and procedures used in vitrectomy. The developments have reduced the time required for specific surgical procedures, improved the accuracy of these procedures, and enhanced postoperative outcomes for the patient. The gauge of instrumentation has been reduced over time, driven by the potential that finer gauges offer in clinical benefits. Simultaneously, other innovations have been introduced to circumvent technical issues associated with finer gauges.

In 2002, the first 25-gauge vitrectomy instruments became available [2]. This development enabled the introduction of a new surgical approach – transconjunctival surgery. In this technique, the conjunctival is left undetached, and vitrectomy surgery is performed through funnel-shaped instrument cannulas that are retracted

from the eye at the end of the surgery. In ideal conditions, these incisions require no suturing at the end of surgery. The transconjunctival approach, smaller incision size, and the omission of sutures at the end of the procedure aimed to accelerate recovery after vitrectomy surgery and reduced the postoperative morbidity for the patient.

However, there were several disadvantages with the first 25-gauge instruments. The inserters of the instrument cannulas lacked sharpness and required some force to be applied on the eye to insert. In addition, the smaller diameter of the instruments made them very flexible, which made the surgery much more difficult. And the smaller inner lumen of the vitrectome reduced the flow of vitreous aspiration, which significantly increased the duration of the surgery. Finally, the smaller diameter of the endo-illumination instrument reduced extensively the amount of intra-ocular light coming from a (halogen) light source. Due to these issues, many surgeons returned to use of 20-gauge instruments.

In 2005, the use of 23-gauge instruments was introduced [3]. These instruments allowed the surgeon to perform transconjunctival vitrectomy surgery, but the instruments were a little larger in size and were also technically enhanced with less flexibility and improved inner lumen that allowed better flow and light throughput. The improvement was so significant that many surgeons adopted this gauge of instruments entirely in favor of 20-gauge.

More recently, 27-gauge instruments became available [4]. Although these are even smaller than the 25-gauge instruments, the improved design of these instruments (that include features, such as twin duty cycle cutters), in combination with improved vitrectomy devices that provide good vacuum and flow rate, and markedly improved light sources (including xenon and LED), allow the surgeon to perform a significant percentage of pars plana vitrectomy (PPV) cases using this technique. Due to the extremely small size of the incision, suturing is rarely required, incisions tend to be closed immediately when the instruments are retracted from the eye. Postoperative recovery can also be spectacular – the day after surgery, and with such good results that it is even often difficult to see which eye was operated on.

Several studies have measured the differences between the same procedures performed with different gauge instruments. Mentens and Stalmans [5] published a comparative report between the 20-gauge and 23-gauge approach in 2009. It concluded that 23-gauge surgery clearly produced indications for better postoperative morbidity [5]. However, despite improved shape and sharpness of incision blades in 23-gauge instruments, su-

turing of the incisions still remains required in a significant percentage of patients.

This study aims to objectively measure a possible difference in postoperative outcome after vitrectomy surgery for either floater removal or macular surgery, with or without combined cataract (phaco-) surgery between 23-gauge or 27-gauge.

Materials and Methods

Patient Inclusion

The patient population involved a total of 80 patients who were scheduled to undergo PPV for floaters or macular surgery with or without combined cataract (phaco-) surgery. The procedure time in these surgeries shows little variation, hence influence of surgical duration on postoperative inflammation was avoided. By including patients requiring floater or vitreomacular traction/pucker surgery only, the study could be focused on vitrectomy procedures that did not involve a tamponade and so this could be eliminated as a study variable.

Alongside this, the criteria for inclusion were age over 18, no prior vitrectomy surgery in the study eye, and no prior inclusion in this trial. Patients were excluded on the basis of serious heart, lung, liver, or kidney dysfunction; proliferative diabetic retinopathy, endophthalmitis, uveitis, and other eye disease that impacts the outcome of vitrectomy surgery; HIV; a history of drug abuse, or alcoholism; participation in other drug or medical device clinical trials before screening for this trial; pregnancy, preparation for pregnancy during clinical trial, or breast-feeding; belief by the investigator that a patient's condition would hinder the clinical trial, such as a tendency to mental stress, loss of control of mood, or depression.

An 80-patient randomization list was generated using <http://randomizer.org> to determine which surgeries were performed using 23-gauge and which were performed with 27-gauge instruments.

This randomization list was masked for the surgeon: the study arm was only visible for the surgeon just prior to the next patient scheduled for surgery. The difference in size of instruments was, of course, necessary to know during surgery. Reference was made to the size comparison between vitrectomes and intra-ocular forceps. All surgeries were performed by the same surgeon (P.S.).

Surgical Procedure

Vitrectomy was performed using an EVA phaco-vitrectomy system (D.O.R.C. Dutch Ophthalmic Research Center [International] B.V.), which was used in combination with a trocar system, light fiber, vitrectome, and laser fiber, either in 23-gauge or 27-gauge. In case of combined lens surgery, phaco-emulsification was applied through a 2.0 mm incision using a 45° angled 1.8 mm beveled phaco needle (see online suppl. Digital Content 1 listing the details of the surgical disposables used; for all online suppl. material, see www.karger.com/doi/10.1159/000515118).

In case of combined surgery, the infusion canula was installed first, after which the phaco procedure was performed and a hydrophilic plate-shaped IOL type Zeiss CT Asphina, AT Torbi, AT Lara (toric), or AT Lisa (toric) was inserted (Carl Zeiss, Jena, Germany).

After connecting the infusion canula to the infusion line, a core vitrectomy was performed in vacuum mode and intermediate cut speed, followed by a vitreous base shaving in flow mode at highest cut speed. If a posterior vitreous detachment was not present prior to the surgery, it was (successfully) created in all included patients.

Full details of the instruments and products used in the procedures are listed in online supplementary Digital Content 1. All instruments used were CE-certified.

Before, during and after the surgery, the same medication and antiseptic treatments were applied, with patients following a standard clinical path. This included:

- Preoperative application of Mydriaserit to dilate the pupil.
- Preoperative antiseptic treatment with isobetadine.
- BSS plus infusion liquid during the surgery.
- Injection of parabolbar triamcinolone and clindamycin at the end of the surgery.
- Postoperative dexamethasone anti-inflammatory eye drops.
- Additional medication at the discretion of the investigator was not precluded and was administered as appropriate per patient case.

The patients were operated under local anesthesia, local anesthesia with sedation, or general anesthesia, depending upon the surgeon's and patient's preferences and general status of health. In the patients who were phakic and over 50 years old, the surgery was combined with a cataract surgery (phaco-emulsification). As in the standard of care, the patients stayed overnight in the hospital after the surgery.

Clinical Outcomes

With the primary outcome of the trial to determine whether ultra-small-gauge surgery (27-gauge) improves postoperative outcome and patient morbidity, the following parameters were assessed:

- Postoperative redness on day 1 postoperative (ascertained from photographs of the patients' eye and compared to a photographic scale 0–4, online suppl. Digital Content 2 showing the grading photos used).
- Postoperative inflammation (ascertained from measurement of flare [anterior chamber flare] [in photon/ms] and clinical assessment by slit lamp, graded according to "Tyndall" [0–3] and "Cells" [0–3]). Anterior chamber flare was measured in an operator-independent assessment. The measurements were taken on day 1 postop using a KOWA FM-700 laser cell flare meter, in both eyes of the patient.

Due to logistical reasons, a flare measurement could only be obtained in the first 50 patients included in this trial.

To obtain additional outcome parameters for both 23-gauge and 27-gauge techniques, the following postoperative parameters were also assessed:

- Visual acuity (using logMAR BCVA scaling).
- Intra-ocular pressure (mm Hg).
- Pain assessment, measured using a questionnaire with a visual analogue scale. A questionnaire was given to the patient upon discharge from the hospital with questions to assess the postoperative recovery. The patients were asked to mail completed questionnaires back after 1 week. See online supplementary Digital Content 3 showing the grading scale and questionnaire used.
- Surgery time. This was measured as the time lapse between start of vitreous cutting (core vitrectomy) and start of vitreous shaving. This time interval was chosen because it can be assumed

Table 1. The possible influential variables identified in the study

Parameter	23-Gauge	27-Gauge	<i>p</i> value
Anesthesia type			0.2219
Phaco power used			0.8899
ILM peeling			0.407
Vital dye used			0.626
Surgery indication			0.169
Medication use			0.9248
Number of laser coagulations			0.5664
Age			0.4425
Profession			0.1978

that the duration of this phase of the surgery is most influenced by the size (hence flow) of the vitrectome.

- Action to close sclerotomies. These were graded as:
 1. None – spontaneous closure after cannula removal.
 2. Massaging of sclerotomy with blunt instrument.
 3. Pinching of sclerotomy with forceps.
 4. Injection of air bubble.
 5. Suturing of sclerotomies required.

The clinical investigation was terminated 1 week postop.

Statistical Analysis

The results from this clinical investigation are presented through the use of descriptive statistics. No hypothesis testing was performed for this investigation.

For continuous variables (except age) and data that followed a normal distribution, the *t* test was applied with data reported as means and SDs per group. Otherwise, a signed-rank test of Wilcoxon was performed, and the data were reported as medians and interquartile ranges.

For count data, the Pearson's chi-square test was applied to compare the groups, and the data were reported by counts and proportions by group.

For all analyses, the level of significance was a 5% two-sided significant level.

Results

The study groups used were well balanced with respect to surgical indication and surgical technique (Table 1). 27-gauge vitrectomy took (only) 90 s more time than 23-gauge. Wound closure was significantly easier in 27-gauge compared to 23-gauge. Less subsequent redness was seen in 27-gauge (as determined by an independent grader). A trend towards less inflammation was seen in 27-gauge (Table 2).

It is often claimed that combining vitrectomy with phaco-surgery induces more postoperative inflammation and/or increases the occurrence of surgical complications. In this study, 51 out of 80 patients underwent com-

Table 2. Comparison between 23-gauge and 27-gauge vitrectomy

Parameter	23-Gauge	27-Gauge	<i>p</i> value	Interpretation
Surgery time (core vitrectomy)	4.01 (3.34–5.60)	5.42 (4.46–6.34)	<0.001	23-G > 27-G significant → 90 s difference
Action to close sclerotomies			<0.001	27-G > 23-G significant
None	2.4%	48.72%		
Massage	2.4%	10.26%		
Pinching	4.9%	0%		
Air bubble	61%	20.51%		
Suturing	24.4%	2.56%		
Pain and discomfort (questionnaire)			0.9677	No difference (day 1 – week 1)
Eye reddishness (0–4)	2 (1.5–3)	1 (0.5–2)	<0.001	27-G > 23-G significant
Visual acuity day 1 (decimal)	0.4 (0.017–0.7)	0.4 (0.25–0.7)	0.3294	No difference
AC flare (50 patients)	24.7 (14.98–31.68)	17.2 (13–25.4)	0.1932	27-G > 23-G trend
Adverse events intra- and postoperative			>0.2	No difference

Table 3. Comparison between vitrectomy and phaco-vitrectomy

Variable	Phaco + vitrectomy (<i>n</i> = 51)	Vitrectomy only (<i>n</i> = 26)	<i>p</i> value
Intra-ocular pressure	12 (8–17)	11 (8–13.75)	0.3127
Eye redness	2 (1–2)	2 (1–2.25)	0.4654
Sclerotomy closure			0.4078
Visual acuity (decimal)	0.5 (0.2–0.7)	0.35 (0.22–0.70)	0.65
Flare measurement	21.4±3.1 (14.25–27)	17.2±3.1 (11.8–25.85)	0.5149
Adverse events			>0.8

bined surgery. There was no difference in postoperative inflammation, eye pressure, visual acuity, or incidence of adverse events between patients that had combined lens surgery compared to patients that underwent only vitrectomy (Table 3).

Discussion/Conclusion

The debate between the advantages and disadvantages of 27-gauge vs. 23-gauge instrumentation for vitrectomy prior to this trial centers around the facts that on one hand, due to its finer diameter, 27-gauge instrumentation produces smaller incisions and, therefore, potentially leads to less inflammation and/or hemorrhaging and a reduced requirement to suture the sclerotomies. However, the fineness of instrumentation could also result in slower surgery with longer procedure times and in this respect possibly be responsible for more inflammation.

The larger bore of 23-gauge instruments create larger incisions that can potentially lead to more inflammation and more hemorrhaging. However, faster surgery can be achieved with larger diameter instruments enabling a shorter procedure and possibly less inflammation.

Our study demonstrates that 27-gauge offers the best postoperative outcome overall. In recent years, innovations in instrument design have brought improvements in 27-gauge instruments that have overcome some of the potential limitations, including greater stiffness, reinforced instrument base, and adapted design of, for example, intra-ocular forceps, optimized backflush instruments that enable passive backflush. Furthermore, surgical system and instrument design enhancements have also increased the illumination output for 27-gauge addressing one of the most frequently cited limitations of 27-gauge surgery.

Also, our study indicates that performing a micro-incision phaco-emulsification procedure in combination with vitrectomy does not increase the amount of postoperative inflammation nor the incidence of adverse events.

This study has several limitations: it was a single-center, single-surgeon study in a relatively limited number of patients. A multicenter study could be considered for better powered conclusions, including a comparison between 27-gauge and 25-gauge instruments rather than only 23-gauge instruments.

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Statement of Ethics

This research complies with the guidelines for human studies and was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. All study subjects have given their written informed consent. Prior to the start of the prospective study, approval was obtained from the UZLeuven Ethics Committee on human research (local reference number S61408).

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Conflict of Interest Statement

P.S.: Johnson&Johnson: speaker fee and travel reimbursement, Bausch + Lomb: advisory board and consultancy, DORC: advisory board and consultancy, Haag-Streit: travel reimbursement, Nano-Retina: consultancy, Ophtec: consultancy, ReNeuron: advisory board, Vitreq: consultancy, Zeiss: consultancy.

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Author Contributions

P.S. is the only author of this article and was responsible for the designing of the study protocol, performed all the surgeries, supervised the data collection, and wrote the manuscript.