Original Article

A Prospective Randomized Study Comparing 27-Gauge Vitrectomy to 23-Gauge Vitrectomy for Epiretinal Membranes and Full-Thickness Macular Holes

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Abstract

Purpose: To compare the surgical and clinical outcomes of 27-gauge vitrectomy and 23-gauge vitrectomy.

Methods: We conducted a single-center, prospective, randomized study. Fifty-three patients affected by vitreoretinal interface disorders (epiretinal membranes and macular holes) were randomly scheduled to undergo 27-gauge (28 patients) or 23-gauge (25 patients) pars plana vitrectomy. The presence of any potential factor of increased baseline inflammation or eye anatomy influencing the surgery was criteria for exclusion. The time of surgery, postoperative intraocular pressure (IOP), state of sclerotomy wounds, rate of complications, postoperative pain, and indicators of inflammation were studied. We also introduced a new parameter to compare intraocular inflammation after surgery, given by the change in the number of intraretinal hyperreflective foci (HRF).

Results: The 27-gauge vitrectomy was 1.28 min longer than 23-gauge vitrectomy ($P < 0.05$). The day after surgery, the mean IOP value was significantly higher in the 27-gauge group (16.12 mmHg versus 13.04 mmHg in the 23-gauge group, $P < 0.05$), but this difference disappeared in successive follow-ups and the sclerotomy wounds closed after 2 weeks in the both groups. The rate of postoperative hypotony did not significantly differ in the two groups (10.71% in the 27-gauge group and 8% in the 23-gauge group the day after the surgery, $P = 0.94$). Less postoperative eye redness was seen in 27-gauge eyes (value 1 on the scale) compared to 23-gauge (value 2 on the scale) ($P < 0.05$), but there was no significant difference in intraocular inflammation (cells, Tyndall, and number of HRF, $P > 0.05$ for all).

Conclusions: The 27-gauge vitrectomy may have better outcomes in terms of IOP maintenance and cause less redness after the surgery but with a slightly prolonged surgery time and no other differences under other parameters (inflammation, rate of complications, postoperative pain, visual gain, and closure of the sclerotomy wounds).

Keywords: Epiretinal membranes, Full-thickness macular holes, Small-gauge vitrectomy, Vitreoretinal surgery

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Introduction

The introduction of 23-gauge (0.7 mm) pars plana vitrectomy (PPV) carried the idea of a transconjunctival microincision vitrectomy surgery, with self-sealing sutureless sclerotomy.[1] Wound leakage is a risk factor for postoperative hypotony, choroidal detachment, and endophthalmitis.[2,3]

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The 27G vitrectomy (0.4 mm) has been proposed as optimal to obtain self-sealing of scleral wounds,[4] less pain[5,6] and conjunctival damage, and early postoperative recovery.[7-13] However, the smaller diameter of the instrument could also cause prolonged vitrectomy time due to fluidics. 27G instruments are also known to have more flexibility, with

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less tilting and torquing capacity of the eye by the surgeon.[11] This study aims to compare the clinical and surgical outcomes of 23G and 27G surgical approaches.

We also examined and compared hyperreflective foci (HRF) between the two groups. HRFs are solitary, small (<30 μm), punctiform, medium-level hyperreflective lesions, visible on linear optical coherence tomography (OCT) scans.

According to the literature, HRF may be an *in vivo* biomarker of retinal inflammation, representing aggregates of activated microglial cells. They have been used as signs of intraocular inflammation in disorders such as diabetic retinopathy, age-related macular degeneration, and radiation retinopathy;[12] these pathologies were excluded in our study to avoid bias.

Methods

A single-center, prospective, randomized, comparative study was conducted, involving 53 eyes with epiretinal membrane (ERM), lamellar macular holes (LMH), or full-thickness macular holes (FTMHs) treated with 27G PPV (28 eyes) or 23G PPV (25 eyes) at the Department of Ophthalmology, Rovigo Hospital, in 2021. The eyes were assigned for 23G or 27G surgery using a 53-patient randomization list generated by http://randomizer.org. This study adhered to the principles of the Declaration of Helsinki and was approved by the local ethics committee (the Clinical Trial is registered on ClinicalTrials.gov, protocol number NCT05113212). Written informed consent was obtained from all the patients participating in the study. The ERMs were staged using an OCT-based anatomic classification according to Govetto *et al.*,[13] while the FTMHs were staged using the OCT-based anatomic classification according to the International Vitreomacular Traction Study Group.[14]

Factors that could potentially influence the results were criteria of exclusion. Patients with prior scleral buckling procedure or vitrectomy, high myopia >−8 diopters, high hypermetropia >+5 diopters, proliferative diabetic retinopathy, uveitis, endophthalmitis, patients with serious heart, pulmonary, hepatic, or renal dysfunctions, HIV patients, patients with a history of previous drug or alcohol abuse, patients who were participating in any drug or medical device clinical trials, pregnancy or breast-feeding, and patients under psychological stress were excluded.

All surgeries were performed by the same right-handed surgeon (LC) using an EVA™ phacovitrectomy system (D.O.R.C. Dutch Ophthalmic Research Center [International] B. V., the Netherlands), in combination with a trocar system, light fiber, vitrectome, and laser fiber, either in 23G or 27G. In the case of combined lens surgery, a 45° angled 1.8 mm beveled phaconeedle was used through a 2.0 mm incision, and a hydrophobic acrylic C-loop intraocular lens (Eyecee® One Crystal Preloaded, ©Baush + Lomb, Laval, Canada) was inserted. Stromal hydration was used to close the corneal incision.

Viscoat (Alcon Laboratories, United States) and Healon (AMO, Uppsala, Sweden), two types of viscoelastic materials, were alternatively used. The surgical parameters were as follows: for 23G PPV, cutting rate 8000 cpm DORC continuum range and linear aspiration 0–350 mmHg and for 27G PPV, cutting rate 8000 cpm DORC continuum range and linear aspiration 0–650 mmHg.

Intraocular pressure (IOP) was controlled by a system and equal to 20 mmHg. A surgical microscope, model Leica F40 (Leica Microsystems Life Science Division, Schweiz) with the NGENUITY® 3D Visualization System (Alcon Science, United States), was used for posterior visualization. The conjunctiva was moved from the planned sclerotomy site, and then the trocar was placed approximately 3.5 mm (pseudophakic eyes) or 4 mm (phakic eyes) posteriorly to the limbus. The trocar bevel was held up with the tip approximately 5° to the sclera. The trocar was then inserted to 50% of the scleral depth, until just past the end of the beveled tip. The handle of the trocar shaft was raised till it was at about 30° angle to the scleral surface and the insertion was completed in three quadrants: superotemporal, inferotemporal, and superonasal. Core vitrectomy was performed in vacuum mode and intermediate cut speed. A posterior vitreous detachment was created in all the patients if not already present. The ERM and internal limiting membrane (ILM) were removed in all cases. The ERM and ILM were double-stained using MembraneBlue-Dual (D.O.R.C. Dutch Ophthalmic Research Center [International] B.V., the Netherlands). Tamponades were not used, except for patients with LMHs, FTMHs, or in case of the presence of a retinal break (8 patients in the 27G group and 6 patients in the 23G group), where a fluid–air exchange was performed.

Following the surgical procedure, topical formulations comprising nonsteroidal anti-inflammatory drugs such as bromfenac (Yellox®, ©Baush + Lomb, Laval, Canada) were administered twice a day for 1 month, along with combinations of steroids and antibiotics as chloramphenicol plus betamethasone (Betabioptal®, Théa Farma S.p.A., Milan, Italy) 4 times a day for a week and then 2 times a day for another week. Mydriasis in patients was obtained with tropicamide 0.5% + phenylephrine 2.5% eye drops; preoperative antiseptic treatment with isobetadine was used; balanced salt solution plus infusion liquid was used during surgery; and postoperative dexamethasone anti-inflammatory eye drops were administered after surgery. The patients were operated on under local anesthesia.

The following outcomes were measured at 1, 7, 14, 30, 90, and 180 days after PPV:

- Postoperative pain (assessed through numeric pain rating scale,[15] ranging from 0/no pain to 10/worst pain imaginable) and postoperative recovery (patients were asked to fill out a questionnaire, available as a supplementary Figure 1, showing the questionnaire used).
- Eye redness (determined through eye photography of the

patient at a slit-lamp and compared to a photographic scale 0–4, available as supplementary Figure 2 showing the grading photos used).
- Inflammation of anterior segment of the eye, graded according to "Tyndall" and "cells" (evaluation through slit-lamp microscopy).[16] The same assessor graded the inflammation, to avoid operator-dependent variability. The assessor was unaware of the gauge of vitrectomy used.
- Variation in the number of HRF before and after the surgery.[12]

To count the HRF, we used a method mentioned by Midena *et al*.[12] We used software to have a semiautomatic and standardized detection of HRF in OCT horizontal 180° linear OCT scans of 8.8 mm centered on the fovea acquired in high-resolution modality with 100 Automated Real Times (ART) resolution before vitrectomy and 30 days after vitrectomy, using spectralis HRA + OCT (Heidelberg Engineering, Heidelberg Germany, Software 6.0.10.0). The inclusion criteria for the OCT scans were correct centering of the scan and an image quality >30 (value automatically provided by the instrument). The scan was cropped at 1500 µm from the fovea, highlighting the central 3 mm of the retina. The images were imported into an open-source available ImageJ software (ImageJ version 1.50; National Institutes of Health, Bethesda, MD; available at http://rsb.info.nih.gov/ij/index.html).[17] The cropped images were imported into the software and the 8-bit format was settled. The plugin "A_trous_filter.java filter" was then applied. The "denoised image" obtained was used as a mask for applying the *CLAHE* (enhance local contrast) tool setting (blocksize: 127; histogram bins: 256; maximum slope: 3.00). On the resulting image, the *Spot Counter* plugin was applied on the region of interest from the boundary between retinal nerve fiber layer and ganglion cell layer and external limiting membrane identified using the *Freehand selection function*. The following obtained values were then put into a database: (a) *n* (whole number of spots counted); (b) spot mean (average value of spot intensity); (c) image mean (average value of image intensity); and (d) list of each single spot intensity. The parameters were designed to prevent the software from counting any hard exudates or retinal vessels as HRF. Then, a further correction factor was used to avoid the influence of the average intensity of the OCT image on HRF count, and the average image intensity was multiplied by 2 and all HRFs with greater intensity were excluded.
- IOP (mmHg, assessed through Goldmann applanation tonometer). Hypotony was defined as an IOP <7 mmHg
- State of sclerotomy gaps (AS-OCT CASIA 2, Tomey, Japan). Wound closure was defined as the closure of all three sclerotomies in the operated eye
- Distance best-corrected visual acuity (DBCVA-logMAR)
- Central macular thickness (CMT) (SD-OCT, Heidelberg, Heidelberg Engineering, Heidelberg, Germany)
- Surgically induced astigmatism (SIA). The SIA was measured using the methodology described by Holladay *et al*. as the vector difference between the postoperative refractive astigmatism at the corneal plane and preoperative K readings. Keratometry data were obtained from AS-OCT Casia 2 (Tomey, Japan).[18] Additional endpoints were related to the moment of the surgery, like numbers of sclerotomies necessitating sutures or adjunctive maneuvers to be sealed (0, 1, 2, 3, or >3), intraoperative complications, time of vitrectomy, and time of peeling. The duration of the vitrectomy was defined as the time of the vitreous cutter operation; the surgery time for peeling was the duration of removal of the ERM and ILM using vitreous forceps.

Statistical analysis

T-test was applied when data followed a normal distribution, and results were reported as means and SDs per group. Otherwise, a rank-sum test of Wilcoxon was performed, and the data were reported as medians and interquartile ranges. For count data, Pearson's Chi-square test was applied to compare the groups and the data were reported by counts and proportions by the group. $P < 0.05$ was considered statistically significant.

Results

The two groups were homogeneous in terms of the number of eyes, age, axial length, CMT, DBCVA-logMAR, and IOP before the surgery. The mean age was 73 (SD = 7.82) years in the 27G group and 75 (SD = 6.69) years in the 23G group. Males and females were, respectively, 50% and 50% in the 27G group, while 52% and 48% in the 23G group. Demographic data and preoperative patient characteristics are listed in Table 1. The observed eyes are categorized into different stages, as outlined in Table 2.

Twenty-two of 28 eyes in the 27G group and 21 of 23 eyes in the 23G group underwent concomitant phacoemulsification surgery.

There was no need to suture the sclerotomy in any case. In some cases, a gentle massage of the sclerotomy site (10.70% and 4% in the 27G and 23G group, respectively) was necessary to favor the closure of the sclerotomies, with no significant differences in the two groups ($P = 0.56$).

We performed a fluid–air exchange only in a percentage of

Table 1: The demographics and preoperative data of the patients in 27G and 23G groups

Demographics and preoperative data	27G (*n*=28)	23G (*n*=25)	*P*
Age, mean (SD) (years)	73 (7.82)	75 (6.69)	0.11
Sex (%)			
Female	50	48	0.88
Male	50	52	
BCVA (logMAR), mean (SD)	0.34 (0.16)	0.32 (0.15)	0.5
CMT (µm), mean (SD)	433.88 (115.80)	433.76 (117.57)	0.4
IOP (mmHg), mean (SD)	15.2 (1.57)	15.5 (1.62)	0.39

BCVA: Best-corrected visual acuity, IOP: Intraocular pressure, CMT: Central macular thickness, SD: Standard deviation

patients (28.60% of cases in the 27G group and 24% of cases in the 23G group) when considered necessary (FTMH or in case of intraoperative finding of retinal breaks).

There were no significant differences in terms of adversities during surgery in either group (noniatrogenic retinal breaks found during surgery in 7.14% of cases in the 27G group and 4% of cases in the 23G group, managed with endolaser and using air as a tamponade) ($P = 0.62$), and the percentage of patients who took painkillers on the first night after the surgery was 7.14% in the 27G group and 4% in the 23G group, with no significant differences between the groups ($P = 0.62$).

After the surgery, we found no differences between the two groups in terms of anterior chamber inflammation (number of cells and Tyndall were almost identical in the two groups), but the eye redness value was inferior in the 27G group (mean value 1) the day after surgery when compared to the 23G group (mean value 2), with statistically significant difference ($P < 0.05$) [Figure 1]. This last difference disappeared during the follow-ups.

The mean number of HRF present before surgery decreased 1-month postoperation (89.9 preoperation versus 82.1 postoperation in the 27G group and 109 preoperation versus 82.7 postoperation in the 23G group) with no statistically significant differences between the two groups ($P = 0.7$) [Figure 2].

The day after the surgery, the IOP was significantly higher ($P < 0.05$) in the 27G group (mean value 16.12 mmHg) compared to the 23G group (mean value 13.04 mmHg), but no differences were found during the next follow-ups and the time of sclerotomy closure was identical in the two groups (2 weeks) [Figure 3]. However, the rate of hypotony was 10.71% in the 27G group and 8% in the 23G group the day after the surgery, with no statistically significant differences in the two groups ($P = 0.94$). There were no cases of ocular hypertension.

There were no significant differences ($P = 0.2$) in the SIA after surgery in the two groups.

DBCVA gain after surgery and CMT variation before and after the surgery was not statistically significant ($P = 0.8$ and $P = 0.07$, respectively) in the 27G and 23G groups.

We compared the surgery time in the two groups and the 27G group took 1.28 min more than the 23G group. The differences were statistically significant ($P < 0.05$). The time of peeling was medially 10 min in the 27G group and 8.92 min in the 23G group with no statistically significant differences ($P = 0.45$). The results are summarized in Table 3.

Discussion

This study suggests that in patients with ERM, LMH, and FTMH, 27G PPV gives some differences when compared to 23G.

Table 2: The classification of macular pathology in 27G and 23G groups

Macular pathology	Number of patients affected in 27G	Number of patients affected in 23G
FTMHs	1 (stage IV, medium diameter)	1 (stage IV, medium diameter)
LMHs	2	6
ERMs		
Stage I	2	1
Stage II	5	2
Stage III	8	9
Stage IV	5	3
MPHs	5	3

We used the optical coherence tomography (OCT)-based classification of Govetto *et al*. for the classification of the epiretinal membrane and the OCT-based classification of the International Vitreomacular Traction Study Group for the classification of the full-thickness macular holes. FTMHs: Full-thickness macular holes, LMHs: Lamellar macular holes, ERMs: Epiretinal membrane, MPHs: Macular pseudoholes

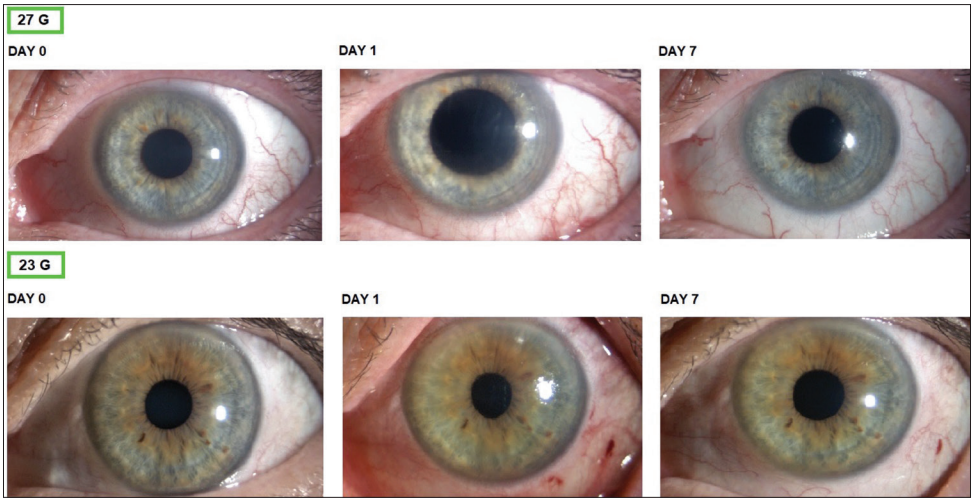

Figure 1: Comparison of the eye redness in 27G and 23G groups before and after surgery. A more marked redness is noticeable in the 23G group after the surgery

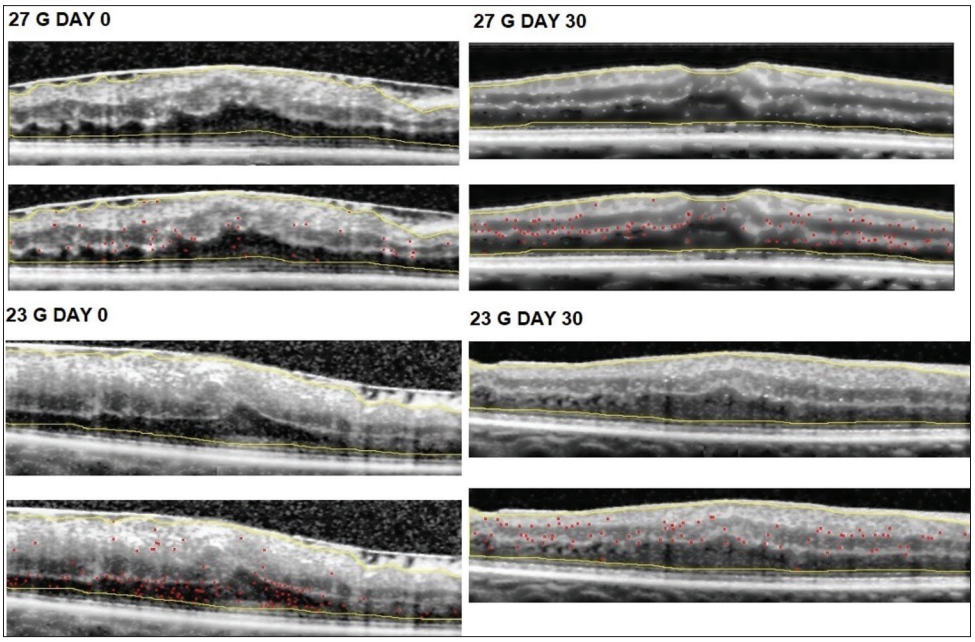

Figure 2: Comparison of hyperreflective foci (HRF) (marked as red spots in the figure) in 27G and 23G groups before and 1 month after surgery. The number of HRF decreased after surgery with no significant differences between the groups

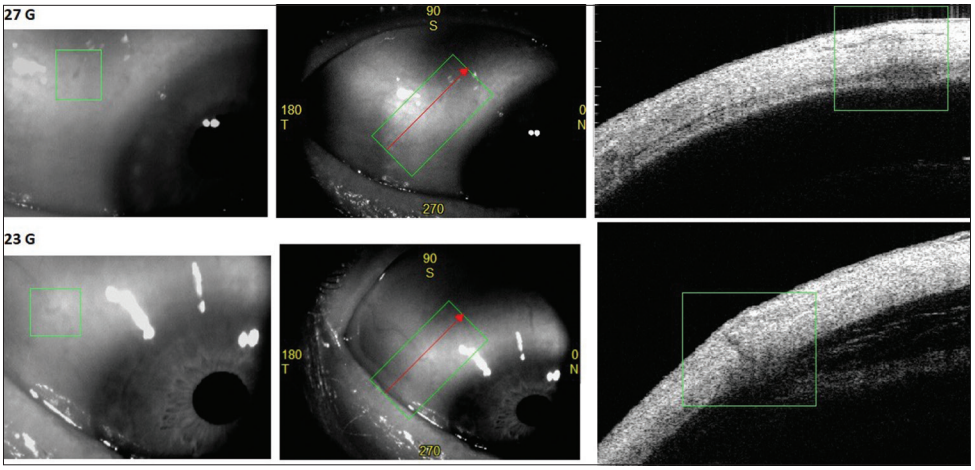

Figure 3: Comparison of sclerotomy wounds in the 27G and 23G groups 2 weeks after the surgery (anterior segment optical coherence tomography scans). It is noticeable that the wounds are closed in the both groups

In the 27G group, the average IOP reading on the day after the surgery was notably elevated compared to the 23-gauge group, with a difference of 3.08 mmHg. This difference could potentially indicate enhanced closure of sclerotomies, as theorized by Stalmans.[1] Charles *et al*., Jie Li *et al*., and Saleh *et al*. observed postoperative sclerotomy leaking after surgery and found better sclerotomy sealing after 27G vitrectomy.[19-21] Some studies also reported no cases of hypotony at all after 27G vitrectomy.[19,20,22,23] However, in our study, we found that the rate of hypotony and the meantime of sclerotomy closure were not different in the two groups.

It is notable that we used tamponades (air) only in a percentage of patients in the 27G group (8 cases) and in the 23G group (6 cases), while the authors in the abovementioned studies used a fluid–air and fluid–gas exchange or other kinds of tamponades in all cases, which is known to have a possible role in promoting sclerotomy closure.[1]

On the other hand, studies conducted on large samples with variable use of tamponades did not find different rates of hypotony in 27-gauge vitrectomy[22,24-27] compared to 23-gauge vitrectomy.[19,20,28-31]

We could explain these results by hypothesizing that the instrument diameter is not the only factor influencing the sclerotomy closure. Indeed, incision angulation is one of the factors that could induce variability. Theoretically, an angled incision, instead of a straight incision, can help prevent wound leakage by allowing the internal lip to press against the outer lip of the sclerotomy aided by the IOP and closing the wound.[32,33]

Table 3: The main results of the studied parameters

Studied parameters	27G	23G	*P*
BCVA gain (logMAR), median (IQR)	0.25 (0.15–0.39)	0.2 (0.11–0.39)	0.8
IOP on the postoperative day (mmHg), mean (SD)	16.12 (6.3)	13.04 (3.5)	<0.05
CMT (μm), median (IQR)	432.78 (359.62–505.94)	395.14 (339.99–460.30)	0.07
SIA, mean (SD)	0.2 (0.85)	−0.01 (0.5)	0.29
Core vitrectomy time (min), median (IQR)	6.5 (5.15–9.75)	5.22 (3.22–6.17)	<0.05
Cells, median (IQR)	1 (1–2)	1 (1–2)	0.9
Tyndall, median (IQR)	1 (0.5–2)	1 (1–2)	0.18
Reddishness, median (IQR)	1 (1–2)	1 (1–2.25)	<0.05
Actions favoring the closing of the sclerotomies (%)			
None	60.70	72	0.56
Massage	10.70	4	
Air	28.60	24	
Rate of complications during surgery (%)	7.14	4	0.6
Percentage of painkillers use (%)	7.14	4	0.6

The statistical significance of the difference found between the 27G and 23G groups is reported in the right column. Notably, the best-corrected visual acuity listed in the table is 6 months after the surgery, the central macular thickness is 1 month after the surgery, and the intraocular pressure was statistically significant only on the first postoperative day. Cells, Tyndall, and reddishness differences are intended for the day after the surgery. Statistical significance (*P*) was calculated by the Mann–Whitney test for data with nonnormal distribution, and by the *t*-test for data with normal distribution. Pearson's Chi-square test was applied to determine statistical significance for categorical data. BCVA: Best-corrected visual acuity, IOP: Intraocular pressure, CMT: Central macular thickness, SIA: Surgical induced astigmatism, SD: Standard deviation, IQR: Interquartile range

However, there are different results in the literature; indeed, Khan *et al*. found no differences in the hypotony rates when using straight or angled incisions,[32] while Awan found better sclerotomy sealing with angled incisions.[22]

In addition, significant manipulation of the sclerotomies due to the movement of the instruments during vitrectomy and membrane peeling can change the wound architecture from its original construction, making the wound relatively unstable and unpredictable, independently from the sclerotomy diameter.[27] Different surgeons with varying surgical techniques can cause variability in the results.

The disadvantage of 27G PPV is slightly prolonged surgery time. Indeed, in our study, the time of vitrectomy was significantly (1.28 min) longer than that for 23G PPV. The same results were shown by other authors,[1,17,18] while Saleh *et al*. found similar surgical time in both the groups, but there was some disparity in the sample size (22 patients in the 27G group and 44 patients in the 23G).[21]

Surgical trauma induces inflammation characterized by protein leakage and cellular buildup in the aqueous humor. Consequently, extended surgery duration stemming from the use of smaller instruments can potentially result in heightened inflammation.[34] However, it is worth noting that larger incisions may also contribute to increased inflammation and bleeding.[1]

In our study, the inflammation of the operated eyes, measured in terms of anterior chamber inflammation, was similar in the both groups in all the follow-ups, differently from the study of Stalmans, where it was a trend toward less inflammation in the 27G group.[1] However, Stalmans used a KOWA FM-700 laser cell flare meter to measure anterior chamber flare,[1] which is supposed to give more objective data, while in our study, the anterior chamber inflammation was assessed by an operator at the slit-lamp without aids, making it more difficult to determine subtle differences.

It is noteworthy that a recent systematic review and meta-analysis, which compared 27G and 25G surgeries for rhegmatogenous retinal detachment and ERMs, found similar results. Indeed, when compared with 25G, 27G vitrectomy was found to be an effective and safe surgical system with no differences in terms of best-corrected visual acuity, IOP, anatomical success rate, CMT, and intraoperative and postoperative complications, but with longer surgical time.[35]

We introduced a further and more objective parameter to compare retinal inflammation between the two surgeries, which was the variation of the number of HRF before and after the surgery, which resulted to be similar in the two groups. The mean number of HRF decreased after surgery in both the groups at 1 month, which theoretically means less inflammation, maybe due to interruption of the retinal traction given by the membrane removal. The results in the two groups were similar and the differences were not statistically significant.

In this investigation, the sole distinction observed regarding inflammation was the presence of reduced eye redness in the 27G group on the day following the surgery. This outcome could potentially be attributed to a lesser degree of tissue invasion associated with this group.[36]

No differences in SIA were detected between the two groups during the postoperative follow-ups.

DBCVA gain after the surgery and postoperative pain were similar in both the groups.

CMT was significantly reduced postoperation without variations between the 23G and the 27G groups. Combining vitrectomy with phacosurgery did not influence the study outcome parameters. These abovementioned results are comparable to other studies.[1,21]

This study has several limitations. It was a single-center and single-surgeon study with a limited number of patients. A multicenter study with a larger number of patients could give stronger evidence. Moreover, including 25G instruments in the comparison could give more complete results. Finally, the interpretation of data like redness and anterior chamber inflammation could be operator dependent.

In conclusion, this study showed that the 27G had mean IOP values higher than the 23G group on the first day after the surgery, less eye redness, and slightly prolonged surgery time. However, the rate of hypotony, intraocular inflammation, CMT, and visual acuity gain after surgery did not statistically differ between the groups. Further studies are warranted to confirm these results.

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Conflicts of interest
There are no conflicts of interest.

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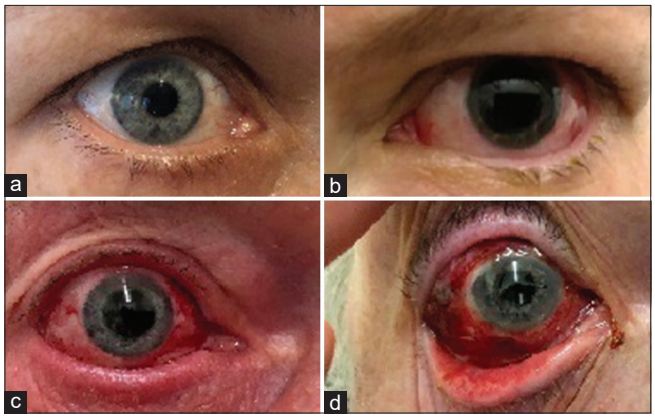
1. Are you self-employed / employed/ retired / disabled/other:
2. Did you sleep less well during the first night after surgery due to eye pain? Yes / No
3. Did you sleep less well during the first week after surgery due to eye pain? Yes / No
4. Did you wake up during the first night due to eye pain? Yes / No
5. Did you wake up during the first week due to eye pain? Yes / No
6. Did you take pain medication during the first night after surgery due to eye pain? Yes / No
7. Did you take pain medication during the first week after surgery due to eye pain? Yes / No
8. Did you use an eye cream after the surgery during pain or abrasive feeling? Yes / No

Supplementary Figure 1: The questionnaire was given to the patient upon discharge from the hospital with questions to assess the postoperative recovery. The patient was asked to give us these questions back after 1 week



Supplementary Figure 2: Grade 0: No reddishness. (a) Grade 1: Barely visible, (b) Grade 2: Partially bloodshed, (c) Grade 3: Diffuse bloodshed, globe only, (d) Grade 4: Diffuse bloodshed, including eyelids/orbit