VITREOUS INCARCERATION IN SCLEROTOMIES AFTER VALVED 23-, 25-, OR 27-GAUGE AND NONVALVED 23- OR 25-GAUGE MACULAR SURGERY

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Purpose: To study the patterns of vitreous incarceration at sclerotomy sites by ultrasound biomicroscopy in patients subjected to valved or nonvalved small-gauge pars plana vitrectomy.

Methods: A prospective comparative study of 88 eyes affected by epiretinal membrane and macular hole. Patients were divided into four groups: valved or nonvalved 23-gauge (16 eyes each) and valved or nonvalved 25-gauge (20 eyes each); their vitreal disposition was compared by ultrasound biomicroscopy. Vitreal disposition was also assessed in 16 eyes of 16 patients subjected to valved 27-gauge pars plana vitrectomy.

Results: Three vitreal patterns were identified: P0 (vitreous not visible or vitreous strand distant from the sclerotomy site), P1 (vitreous strand parallel to and in contact with the sclerotomy site), and P2 (vitreous strand entrapped in the sclerotomy site). The effect of valved trocar use on vitreous incarceration seemed to be somewhat beneficial, but no statistically significant effect could be shown (odds ratio: 0.85, 95% confidence interval: 0.42–1.74, $P = 0.657$). Similarly, no differences in vitreous incarceration were shown among vitrectomy gauges (23, 25, or 27) both in a model including valved trocars only ($P = 0.858$) and in a model with all available data ($P = 0.935$).

Conclusion: In 23- and 25-gauge macular surgeries, postoperative vitreous incarceration does not seem to be reduced using valved cannulas and was similar to that observed in 27-gauge surgery.

RETINA 37:1948–1955, 2017

The sclerotomy site remains an object of study even in the era of small-gauge pars plana vitrectomy (PPV). Postoperative wound closure, conjunctival bleb formation, and vitreous incarceration at the sclerotomy site have all been investigated.[1–20] Vitreous incarceration may plug the sclerotomy, impacting wound closure and conjunctival bleb formation, and consequently the risk of postoperative hypotony and endophthalmitis.[6,11,13] Moreover, postoperative contraction of incarcerated vitreous can lead to postoperative retinal break formation and recurrent vitreous hemorrhage.[11–23] Vitreous shaving around the sclerotomy site in humans and the cannula extraction technique and, recently, the vitrectomy degree in different areas of the vitreous cavity in animals have all been found to be related to the amount of vitreous incarceration.[11,13,16]

The PPV armamentarium has recently been enriched with valved cannulas, thus eliminating the need for plug placement during instrument exchange.[24] These cannulas have been proven to boost intraocular safety in animal models by preventing intraoperative fluctuations in both infusion pressure and intraocular pressure.[24]

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Recently, valved cannulas have been associated with higher final anatomic success after rhegmatogenous retinal detachment repair, although single surgery success, functional outcomes, and complications were similar to the nonvalved treated eyes.[25] However, the use of valved cannulas may render the insertion of soft tip instruments more difficult and might increase the rate of retained perfluoro-n-octane.[25]

We wanted to verify whether this increased intraoperative stabilization is associated with different postoperative patterns of vitreous incarceration at the sclerotomy site. This verification is believed to be useful, as recently reported by Oellers et al.[25] This was performed by studying vitreous appearance in patients subjected to valved or nonvalved 23- or 25-gauge PPV, using postoperative ultrasound biomicroscopy (UBM). Moreover, eyes treated with valved 27-gauge PPV (27-gauge nonvalved cannulas were not available) were compared with 23- and 25-gauge valved PPV treated eyes.

Materials and Methods

Subjects

This prospective study included 88 eyes of 88 patients. The inclusion criteria were being affected by idiopathic epiretinal membrane or macular hole (MH) and being subjected to primary 23-, 25-, and 27-gauge PPV without intraocular complications, between February 2015 and March 2016 at the Ophthalmology Section of the Department of Medicine, Surgery and Neuroscience, University of Siena, Siena, Italy. The exclusion criteria were as follows: coexisting ocular disorders, except cataract; patients requiring PPV for indications other than those mentioned above; patients previously subjected to intraocular surgery, except cataract surgery; and patients with no identifiable sclerotomy site at slit-lamp examination. The research adhered to the principles of the Declaration of Helsinki, and the institutional review board approved the study. Patients were treated after being informed of the nature of the treatment being offered, its potential risks, benefits, adverse effects, possible outcomes, and after having signed a consent form.

Each patient underwent a complete preoperative evaluation, including the measurement of best-corrected visual acuity, anterior segment examination, dilated fundus examination using indirect ophthalmoscopy with scleral depression, and slit-lamp biomicroscopic observation of the vitreous and the retina. The presence or absence of posterior vitreous detachment (PVD) was defined by biomicroscopic observation using a 90-diopter lens, optical coherence tomography examination, and B-scan ultrasound. All patients underwent optical coherence tomography evaluation of the macular disorder. We used an optical coherence tomography classification when describing MH characteristics.[26]

Patients were enrolled consecutively and were assigned on an alternate basis to one of the following groups: 23- or 25-gauge PPV with valved cannula; 23- or 25-gauge PPV with nonvalved cannula; and valved 27-gauge PPV. The patterns of vitreal appearance at the sclerotomy sites were compared between the 23- and 25-gauge valved and nonvalved groups. In addition, the vitreous appearance in valved 27-gauge treated eyes was analyzed (27-gauge nonvalved cannulas were not available) and compared with the 23- and 25-gauge valved treated eyes.

Surgical Technique

All patients underwent 23-, 25-, or 27-gauge PPV performed by the same surgeon (G.M.T.). The sclerotomy sites were located in the inferotemporal, superotemporal, and superonasal quadrants. The conjunctiva was anteriorly displaced away from the intended sclerotomy site with forceps in order to purposefully misalign the conjunctival and scleral incisions. A trocar was inserted 3.5 mm from the corneoscleral limbus at an angle of approximately 30° parallel to the limbus. Once past the trocar sleeve, the angle was changed to be perpendicular to the surface and the cannula was inserted into the eye. The cannula was held in place with forceps and the trocar was removed. The endoilluminator and the vitrector were placed through the superior sites. Pars plana vitrectomy was performed using the Constellation vitrectomy instrument (Alcon Laboratories Inc, Fort Worth, TX). A panoramic viewing system with wide-field contact lenses (Advanced Visual Instruments, Inc, New York, NY) and a flat lens were used for intraoperative visualization. In the absence of PVD, it was induced with the vitrectomy probe in the "cutter-off" mode placed over the optic disk. Epiretinal membrane and internal limiting membrane peeling were performed using either triamcinolone or indocyanine green. Fluid/air exchange was performed in every patient. Air was substituted with gas (C_3F_8, 8%) in the MH cases. Any leaking sclerotomies were sutured.

Postoperative Examination

Patients were subjected to a complete ophthalmologic evaluation the day after surgery and in the subsequent follow-up visits.

Ultrasound biomicroscopy (Model P40, Paradigm Medical Industries Inc, Salt Lake City, UT) was

performed at the sclerotomy sites between 30 and 40 days after surgery, once the tamponade had completely disappeared. To avoid bias, the ultrasonographer (A.M.) was masked to the patient grouping and diagnosis. To identify the precise sclerotomy location, the patients were examined by slit-lamp (small black dot on the sclera and/or presence of converging episcleral vessels) and the sclerotomy site was marked with a sterile surgical marking pen. The sutured sclerotomies were not evaluated. Ultrasound biomicroscopy examination was performed using a high-frequency transducer (50-MHz) with the probe oriented both radially and tangentially to the limbus in order to intersect and detect the entire sclerotomy tract. Examinations were performed with the patient in a supine position; drops of topical anesthesia were instilled before examination. A polymethyl methacrylate shell was inserted between the eyelids and filled with 2.5% methylcellulose as a coupling agent. The probe was always perpendicular to the ocular surface. The gain was set at between 60 dB and 80 dB to have a clear display of the structure and simultaneously minimize the ultrasound noise. We found 3 patterns of vitreous/sclerotomy relationship classified as P0 (vitreous not visible or vitreous strand parallel to but distant from the sclerotomy site); P1 (vitreous strand parallel to and in contact with the sclerotomy site); and P2 (vitreous strand entrapped in the sclerotomy site) (Figures 1–3).

Statistical Analysis

Linear and logistic regression models were used to investigate the differences among the study groups, including trocar type and vitrectomy gauge, regarding continuous and categorical or nominal variables, respectively.

Multilevel models were used to investigate the effect of covariates on vitreous incarceration pattern, with individuals as random effects to account for the correlated nature of measurements at multiple sclerotomy sites. Because of the ordinal nature of the response variable, ordinal logistic regression was used, and the odds ratio (OR) of a higher level of incarceration was obtained.

A sample size calculation was not performed because of the constraints imposed by the time-consuming UBM measurement; hence, a convenience sample was recruited. However, we performed a post hoc calculation of the minimum detectable OR using the actual number of sclerotomies in each group of valved/nonvalved trocars in relation to the three vitreous pattern groups. This analysis used absolute frequencies recorded in the 23- and 25-gauge vitrectomy groups because the 27-gauge vitrectomies were all valved. A power analysis for a Cochran–Mantel–Haenszel test was used for this purpose.

The statistical significance level for all univariate analyses was always set to 95% ($P < 0.05$).

All statistic computations were performed using Stata 14.1 statistical packages (StataCorp, College Station, TX).

Results

Table 1 shows well-balanced clinical characteristics across the subgroups at baseline. No differences were found for mean age ($P = 0.538$) or for the distribution of categorical variables such as sex (0.553), diagnosis (0.999), lens status (0.813), or tamponade (0.989).

In 23-gauge surgery, eight sclerotomies were sutured at the end of the procedure (four in the valved and four in the nonvalved group). In 25-gauge surgery, three sclerotomies were sutured at the end of the procedure (1 in the valved and 2 in the nonvalved group). In valved 27-gauge surgery, no sclerotomy was sutured at the end of the procedure. All the nonsutured sclerotomies were identified and analyzed postoperatively in all groups.

Fig. 1. Pattern 0. Radial scanning plane; 25-gauge surgery. **A.** The internal hole of the sclerotomy site (arrowhead) shows no vitreous. **B.** At the internal hole of the sclerotomy site (arrowhead), UBM shows a vitreous strand (white arrow) parallel to but distant from the sclera.
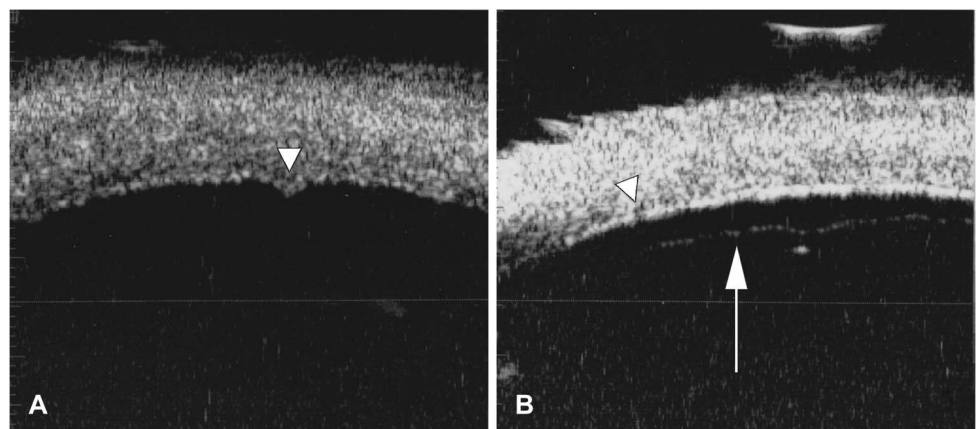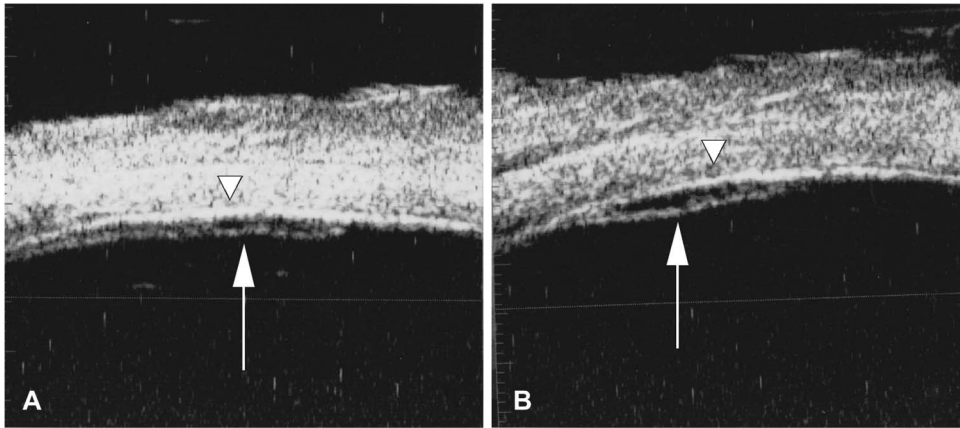
Fig. 2. Pattern 1. Radial scanning plane; 25-gauge surgery. **A** and **B.** Vitreous strand (white arrow) parallel to and in contact with the sclera without incarceration. Arrowheads indicate the internal hole of the sclerotomy site.

Figure 4 presents the distribution of vitreous incarceration patterns for each subgroup of trocar type and vitrectomy gauge, summing up all sclerotomy sites (total number: 253 sclerotomies). P0 pattern (no incarceration) seems slightly more prevalent in valved versus nonvalved 23- and 25-gauge vitrectomies, P1 slightly more prevalent in nonvalved versus valved 25-gauge vitrectomy, however, differences are negligible and figures overlap regarding P2 pattern (more severe incarceration) frequency.

The effect of valved trocar use on vitreous incarceration appeared to be somewhat beneficial, but no statistically significant effect could be shown both in a model including all data (OR: 0.85, 95% confidence interval: 0.42–1.74, $P = 0.657$) and in a model with 23- and 25-gauge vitrectomy data only (OR: 0.78, 95% confidence interval: 0.36–1.66, $P = 0.518$). Similarly, no differences in vitreous incarceration were shown among vitrectomy gauges (23, 25, or 27) both in a model including valved trocars only ($P = 0.858$) and in a model with all available data ($P = 0.935$). A post hoc power calculation in 205 sclerotomies with complete data in the 23- or 25-gauge vitrectomy groups yielded a minimum detectable OR of 2.17, meaning that we were able to detect large differences in incarceration patterns between valved and nonvalved trocars, but we were still unable to detect smaller differences, as also shown by the width of the 95% confidence interval in our estimates.

All other analyses were based on a model including all data as described hereafter.

Table 2 presents ORs of association with vitreous incarceration pattern for all variables in a model including the whole sample. The frequency of vitreous incarceration halved for every 10 years of age ($P = 0.014$), possibly related to the effect of PVD, which was a strong protective factor as it reduced incarceration by almost 10 times ($P < 0.001$). The superotemporal sclerotomy site was at higher risk of incarceration ($P = 0.001$). The use of gas tamponade led to an increased frequency of incarceration with respect to air ($P < 0.001$) as did, to a borderline extent ($P = 0.034$), phakic compared with pseudophakic status.

No patients experienced postoperative hypotony. No difference was found in the MH closure rate
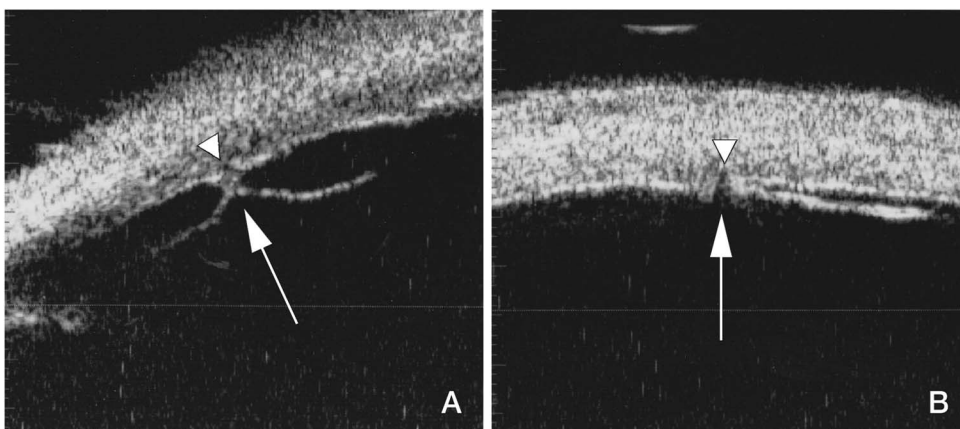

Fig. 3. Pattern 2. Radial scanning plane; 25-gauge surgery. Vitreous strand (white arrow) entrapped in the sclerotomy site. The internal hole of the sclerotomy site (arrowhead) shows two different modalities of scleral wound healing (**A**, increased amount of tissue on the internal surface of the sclerotomy site; **B**, loss of substance on the internal surface of the sclerotomy site).

Table 1. Baseline Characteristics Across Subgroups of Surgeries With/Without Valved Trocars and 23-, 25-, or 27-Gauge Vitrectomy

Gauge	23		25		27
Valve	Valved (n = 16)	Nonvalved (n = 16)	Valved (n = 20)	Nonvalved (n = 20)	Valved (n = 16)
Age (mean)	71.1	72.2	72.0	69.9	72.7
Diagnosis (% MH)	38	38	35	40	38
PVD (% yes)	75	69	80	80	69
Lens status (% pseudophakic)	19	31	20	15	25
Tamponade (% gas)	44	38	35	40	38

(all MHs closed) or in rhegmatogenous complications after at least 5 months of follow-up.

Discussion

The use of valved vs. nonvalved cannulas creates a difference in intraocular stabilization during the surgical procedure because we do not routinely insert plugs every time we remove instruments when using nonvalved cannulas.[24] Thus, we wanted to verify whether the increased intraoperative stabilization achieved with valved cannulas corresponds to different postoperative patterns of vitreous incarceration at the sclerotomy sites.

The patterns of vitreal disposition at sclerotomy sites described in the literature are not uniform. These differences are linked to the method of analysis: direct visualization, UBM, or optical coherence tomography.[1,11,16] However, even considering UBM studies alone, an official UBM classification of vitreal patterns at the sclerotomy site does not exist. Sabty et al[16] based their scoring grade on the echographic intensity of the vitreous and its disposition at the sclerotomy

site, whereas other authors[17,18] only studied the occurrence of vitreous incarceration ecographically described as "dense lines that radiated from the internal hole of the incision into the vitreous cavity." In the present series, the classification pattern adopted was related to the three morphologic dispositions that repeatedly came to light during UBM analysis. We classified them as P0 (vitreous not visible or vitreous strand parallel to but distant from the sclerotomy site); P1 (vitreous strand parallel to and in contact with the sclerotomy site); and P2 (vitreous strand entrapped in the sclerotomy site). We decided to differentiate between P0 and P1 because the highly reflective vitreous strand in contact with, although not entrapped in, the sclerotomy site (P1) was considered at greater risk for postoperative complications than the less reflective vitreous strand distant from the sclerotomy site (P0). Analogously, we decided to differentiate between P1 and P2 because vitreous entrapment (P2) was considered at greater risk of postoperative complications than simple contact (P1).

The homogeneity of the groups, which represents an important point in evaluating the reliability of our results, has been assessed and confirmed. The populations showed no differences in the following characteristics: male/female, phakia/pseudophakia, epiretinal membrane/MH, and air/gas ratios. Moreover, no difference between groups was present in relation to intraoperative maneuvers that have previously been shown to be associated with vitreal incarceration. In particular, Benitez-Herreros et al[11] found that cannula extraction with the light probe inserted (instead of removing the cannula with the plug introduced) reduced the amount of vitreous incarceration. In this respect, the characteristics of our populations, valved or nonvalved, at the end of the procedure are very similar, because both valved and nonvalved cannula extraction was performed without pulling the vitreous inside the eye, as the light probe does.[11] Moreover, Benitez-Herreros et al[13] found that the source of the incarcerated vitreous, core or pericannular, was related to different closure competencies at the 23-gauge
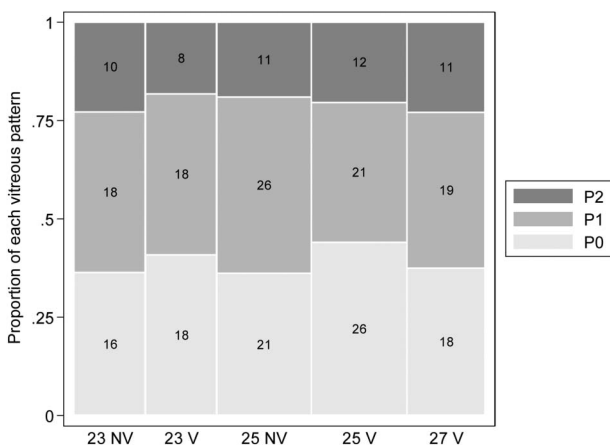

Fig. 4. Frequency of vitreous patterns for each subgroup of nonvalved (NV) (23- and 25-gauge) or valved (V) (23-, 25- and 27-gauge) trocars. Numbers within the figure are the absolute number of sclerotomies (total = 253) for each pattern and group, while the y-axis refers to the percentage for each group.

Table 2. Association of Each Variable With Severity of Vitreous Incarceration

Covariate	OR	P
Age (per 10 years)	0.46 (0.24–0.91)	0.014
PVD (vs. none)	0.11 (0.05–0.23)	<0.001
Valved (vs. nonvalved) trocar	0.85 (0.42–1.74)	0.657
Site: inferotemporal (ref)	1	0.025*
Site: superonasal	1.37 (0.74–2.57)	0.319
Site: superotemporal	2.82 (1.51–5.27)	0.001
Lens status (phakic/pseudophakic)	2.50 (1.08–5.88)	0.034
Gas (vs. air)	4.28 (2.23–8.59)	<0.001
Gauge (vs. 23, ref)	1	0.935*
Gauge 25	0.96 (0.44–2.11)	0.920
Gauge 27	1.15 (0.42–2.15)	0.726

*Test for the overall effect of the covariate.

sclerotomy site in their animal model. This implies that the vitrectomy degree may alter the amount of vitreal incarceration[13] and confirms the previous finding in 20-gauge surgery of Sabti et al,[16] who found that the vitreous shaving of sclerotomy sites with scleral indentation significantly reduced vitreous incarceration. By including only epiretinal membrane and MH eyes, we reduced the bias linked to the extent of vitreous removal. In fact, in our experience, the entity of vitreous removal may partially differ according to the clinical scenario (e.g., MH, vitreous hemorrhage, rhegmatogenous retinal detachment, and proliferative vitreoretinopathy). The homogeneity of the vitreal characteristics at entry is also important when performing a comparison between groups. There were no differences in the presence of PVD at entrance between our groups. Most of the human studies evaluating vitreous incarceration have enrolled patients with a variety of diagnoses, which were probably associated with different PVD status at entry and different vitreous base constitutions,[3,16–18] whereas in this study only vitreomacular interface disorders were included. Moreover, our evaluation was performed in all groups once the internal tamponade (air or gas) had disappeared. Only Gutfleisch et al[17] evaluated patients without the tamponade at the end of the procedure, whereas other authors[10,18] evaluated vitreous incarceration with the tamponade inside, which might have influenced both the amount of vitreous incarceration and its visualization.

In this homogenous clinical scenario, the patterns of vitreal appearance were not significantly different between the valved and nonvalved groups both for 23- and for 25-gauge PPV. In addition, no difference was present when each group was compared with the others, thus yielding equivalent results no matter the caliber or the presence/absence of the valved cannulas.

In terms of caliber, the similarities of postoperative vitreal appearance are confirmed by the results of 27-gauge surgery, which was associated with no different vitreal patterns as compared with valved 23 and 25 gauges.

The similarities in vitreal appearance among our groups were associated with an absence of differences in the MH closure rate or rhegmatogenous complications. No eye had postoperative hypotony nor postoperative retinal breaks in the course of follow-up.

In all groups, vitreous incarceration was correlated with younger age, the absence of PVD at entry, as well as with gas tamponade and the superotemporal sclerotomy site. Younger age and absence of PVD could be seen as interdependent factors, in fact, younger patients are less likely to have a PVD at presentation. In our series, the intraoperative induction of PVD never induced hyaloidal separation up to the extreme periphery (the separation being completed only in the postoperative period), as occurs in patients with an already present PVD. This might influence the postoperative vitreal pattern. As for gas tamponade, it could be linked to the absence of PVD because, in the present series, gas tamponade was used only in MH patients, which presented PVD in only 42.4% of cases. Alternatively, more so than a pushing effect exerted on the residual vitreous by an extended tamponade, which seems unlikely, the gas tamponade might change the structure of the residual vitreous, possibly augmenting vitreous reflectivity and consequently its visualization through UBM. This may be confirmed by the significant correlation between P2 and the superotemporal sclerotomy site. In fact, after the first week spent 12 hours/day face down, our MH patients spend most of their time in a seated position until gas disappearance, thus resulting in a prolonged effect on the superior residual vitreous. The different vitreal patterns in the different quadrants is in disagreement with Sabti et al[16] and in agreement with Bhende et al,[27] although in the latter study, the sclerotomy site most frequently associated with vitreal incarceration was the inferotemporal one. However, the present results can hardly be compared with those obtained by other series[3,6,10,16–18,27] because the indications for PPV in previous studies were highly variable and the surgical techniques often different.

The P2 pattern occurred in 20.5% of the 253 sclerotomies analyzed in this study. Because all the sclerotomies studied were self-sealing at the end of the surgical procedure and because vitreous incarceration has been demonstrated to be inversely correlated with incisional leakage in an animal model,[1] we would have expected a higher incidence of the P2 pattern, as reported by Avitabile et al,[18]

López-Guajardo et al,[6] Benitez-Herreros et al,[13] and Gutfleisch et al.[17] However, Texeira et al[3] found a 0% entrapment rate.

In the present series, the improved intraocular stabilization obtained using valved cannulas[24] does not seem to correspond to a reduced rate of postoperative vitreal incarceration in macular surgery because no significant differences in vitreal patterns were found between the valved and nonvalved cannula groups, and no difference was present when comparing each of the 4 groups (23-gauge valved and nonvalved, 25-gauge valved and nonvalved) against each other. In addition, the vitreal patterns were similar between 27-gauge (only valved) and 23- and 25-gauge valved groups, meaning equivalent results no matter the caliber. Different vitreal status at entry (i.e., the absence/presence of PVD) and different tamponades might influence residual vitreal patterns at the sclerotomy sites.

The conclusions of our study are limited by its inability to detect differences between valved and nonvalved trocars with an OR below approximately 2 because of the small sample size. However, it is difficult to obtain UBM measurements for a large sample of patients and our series represents a significant contribution to this issue suggesting that no substantial effects are achieved when valved trocars are used to try to reduce vitreous incarceration in the sclerotomy site.

Our results apply to macular surgery, and we cannot exclude the possibility of different results being achieved under different clinical and vitreal conditions.

Key words: 23-gauge pars plana vitrectomy, 25-gauge pars plana vitrectomy, 27-gauge pars plana vitrectomy, valved cannula, nonvalved cannula, vitreous incarceration at sclerotomy site, ultrasound biomicroscopy, iatrogenic retinal tear.

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