COMPARISON OF CLINICAL OUTCOMES AND WOUND DYNAMICS OF SCLEROTOMY PORTS OF 20, 25, AND 23 GAUGE VITRECTOMY

MANISH NAGPAL, MS, DO, FRCS, SHARANG WARTIKAR, MS, KAMAL NAGPAL, MS

Purpose: To compare the benefits, the risks and the dynamics of port closure in different gauge vitrectomy systems.

Methods: Prospective, randomized, comparative study of 90 eyes undergoing 20, 23 and 25 gauge (G) vitrectomy for uncomplicated vitreous hemorrhage due to proliferative diabetic retinopathy, vasculitis, trauma, venous occlusions and others. An endoscope was used in five cases of each group to visualize the inside of sclerotomy ports.

Results: Vision improved from 0.048 (3/60) to 0.206 (6/24) ($p = 0.0021$), from 0.069 (4/60) to 0.389 (6/18) ($p < 0.0001$) and from 0.055 (3/60) to 0.286 (6/24) ($p = 0.0010$) with 20, 23, and 25-G systems, respectively. Re-bleeds occurred in 4, 1 and 4 eyes of 20, 23 and 25-G systems respectively and post-operative retinal detachment was seen in 2 cases of 20-G system. There were no cases of post-operative hypotony or endophthalmitis seen. With 23 and 25 gauge systems, significant amount of vitreous was seen blocking the inner lip of the sclerotomy ports.

Conclusion: The small gauge systems are safe and equally effective than the 20-G system for non-complicated vitreous hemorrhage cases with faster recovery and more comfort for the patient. Increased vitreous clogging with small gauge systems does not extrapolate to an increased risk of complications.

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Recent developments in the transconjunctival sutureless vitrectomy (TSV) systems[1,2] have considerably transformed patient management outlook in the field of vitreous surgery. In fact, based on the several reported advantages, TSV is becoming increasingly popular. The vitrectomy incision construction using the trocar and cannula method in the TSV systems differs from the conventional 20-gauge (20-G) vitrectomy incisions in several important aspects; either pre- or intra- or postoperative. It facilitates easy entry, with minimal trauma to the conjunctiva, sclera and the pars plana. Through-out the surgery, all instrument shafts pass through the sleeve of the cannula. This minimizes tissue manipulation and microtrauma due to repeated insertion and removal of instruments.[1,3] Transconjunctival sutureless vitrectomy has been shown to significantly decrease the overall operating time compared with conventional 20-G vitrectomy.[4] Reduction in the convalescence period and the postoperative inflammatory response has been reported.[1,5] The concept of port based flow limitation[6] has been hypothesized to increase the safety margin of this procedure. It decreases vitreous manipulation during the procedure and lowers the risk of drag on the peripheral retina, as compared with a larger port of 20-G system.

From the Retina Foundation, Gujarat, India.

Reprint requests: Manish Nagpal, MS, DO, FRCS, Retina Foundation, Shahibag, Ahmedabad-4, Gujarat, India; e-mail: drmanishnagpal@yahoo.com

But there is a compromise, since a smaller port increases the overall resistance to vitreous removal. The 25 gauge (25-G) systems also face concerns like relative lack of instrument rigidity, slower vitreous cutting ability, and suboptimal fluidics, all inherent to the reduced caliber of the instrumentation.[7,8] Intraoperative problems such as difficulty in insertion and deformity and instability of the microcannulae, self-disconnection of the infusion tip resulting in lens damage and the need to convert to 20-G have been reported.[9] Lately, however, tremendous evolution in instrument development and their availability has negated several of these problems. The 23 gauge (23-G) systems are emerging as a very viable approach balancing the pros and cons of the 20 and 25-G systems thereby leading to expansion in the indications of TSV.

On the basis of these reports and to determine the benefits and risks of the different gauge incisions, we undertook this prospective, randomized, comparative study. We wanted to determine differences, if any, in intra and postoperative behavior in eyes with vitreous hemorrhage posted for vitrectomy and operated through the three different gauge incisions; 20, 23 or 25-G. Anatomical and functional outcomes and postoperative clinical evaluation of the port stability were the main outcome measures.

Furthermore, to corroborate the clinical findings with the incision dynamics, we decided to evaluate in real-time, the interplay of the vitreous base and the sclerotomy sites with the cannulae in place and during their removal. We randomly assigned five cases each of the three subgroups of incisions to undergo endoscopic evaluation of the port dynamics using a 20-G endoscopic cyclophotocoagulator probe (Endo Optiks, Little Silver, NJ), with visualization via a monitor.[10,11]

Methods

For this study, we included eyes with vitreous hemorrhage due to different etiologies (like proliferative diabetic retinopathy, vasculitis, venous occlusions, blunt trauma, posterior vitreous detachment, etc.) that had persisted for 30 days or more. We excluded eyes with evidence of retinal or choroidal detachment on preoperative ultrasound (B-scan). We also excluded eyes undergoing resurgeries, those eyes with presence of conjunctival or scleral scarring and other coexisting ocular disorders such as glaucoma or uveitis. Also, eyes with media problems like significant cataract or corneal opacities were excluded. An approval of our institutional ethics committee was obtained for the study. We randomly distributed 90 consecutive eyes which fulfilled the above criteria into 3 groups of 30 eyes each. Eyes in groups A, B, and C underwent 20-G, 23-G, and 25-G vitrectomies, respectively. Endoscopic evaluation was performed in randomly selected five eyes from each group. The surgeries were performed between September 2006 and June 2007 and the results are based on the data collected till December 2007.

Detailed preoperative evaluation was performed in each case. This included visual acuity assessment using Snellen chart, intraocular pressure measurement using the auto-noncontact tonometer (NT-3000, Nidek), anterior segment slit-lamp examination, indirect ophthalmoscopy and B-scan ultrasound.

Group A underwent conventional 20-G three port pars plana vitrectomy. Conjunctival peritomy was made along the limbus to expose the sites of scleral ports. Diathermy was used when necessary and sclerotomies were made with a direct entry using 20-G microvitreoretinal blade (0.9 mm). Group B underwent 23-G TSV where self-sealing sclerotomies (0.75 mm) were made using the 23-G trocar-cannula system (Alcon laboratories, Inc., FortWorth, TX). Conjunctiva was displaced while inserting the cannula to misalign purposefully the conjunctival and scleral incisions. A beveled trocar was used and a two-directional oblique entry was made. Initial partial thickness entry into sclera was made at 45 degrees and then the trocar was passed perpendicularly. The cannula was held in place with forceps and the trocar was removed. Group C underwent 25-G TSV consisting of a similar but a single directional transconjunctival insertion of a cannula with a trocar (0.5 mm) perpendicular to sclera. In all groups the sclerotomies were made through the pars plana in the superonasal, superotemporal and inferotemporal quadrants, as per standard vitrectomy protocol. The inferotemporal cannula was the site of infusion and both superior quadrant ports were used for intraocular instrumentation. All cases were performed with the Accurus vitrectomy system and Accurus cutters with speeds upto 2,500 cpm (Alcon laboratories, Inc., FortWorth, TX).

Vitreous hemorrhage was cleared with the cutter. Subhyaloid hemorrhage when encountered was cleared by passive suction with a flute cannula. Vascular proliferations were endo-diathermized and endolaser photocoagulation with Iridex diode laser 810 nm was performed, either sectoral or pan-retinal, as the need may be. The retinal periphery was screened with indentation and any peripheral breaks, if found, were subjected to endolaser or cryotherapy.

In group A, all three ports and the conjunctiva was sutured with 8-0 vicryl at the end of the surgery. In groups B and C, the cannulae were removed in a slow controlled manner with prior lowering of infusion pressure and transient pressure was applied over the site with an indenter.

Five cases from each group that were selected randomly underwent endoscopic visualization of the port dynamics. For groups B and C, one port each was enlarged to 20-G at the end of the surgery to allow passage of the endoscope. This port was sutured in the end with 8-0 vicryl. We noted the movement of vitreous around the ports and the behavior of the inner lips of the sclerotomies during port closure. We also observed the movement of vitreous while the cannulae and instruments were being removed.

Postoperative examination was carried out on Day 1, Day 2, Day 7, 1 month, and 3 months. On each follow-up, detailed evaluation included visual acuity assessment using Snellen chart, intraocular pressure measurement, anterior segment slit-lamp examination and indirect ophthalmoscopy. Conjunctival and scleral wound closure was studied carefully in each case. Ultrasound B-scan and optical coherence tomography examinations with Stratus OCT3 from Zeiss were carried out where indicated. Meticulous attention was paid towards wound healing, especially to rule out complications such as hypotony and endophthalmitis.

Results

The average patient age was 46.81, 49.36, and 47.75 years in groups A, B, and C, respectively (Table 1). In the three groups, the patients had been symptomatic for a mean of 79.7, 66.57, and 83.3 days respectively. All patients in all three groups had a minimum of 3 months follow up.

In each group, proliferative diabetic retinopathy was the main cause of vitreous hemorrhage (60%, 56.6%, and 53.3% in groups A, B, and C, respectively). The other causes are summarized in Table 2.

In Group A, the vision improved postoperatively by an average of 4.3 lines from 0.048 (3/60) to 0.206 (6/24) ($P = 0.0021$) (Table 3). Visual acuity in Group B improved by an average of 5.43 lines from 0.069 (4/60) to 0.389 (6/18) ($P < 0.0001$) and in Group C by an average of 3.93 lines from 0.055 (3/60) to 0.286 (6/24) ($P = 0.0010$). All groups showed statistically significant improvement (by paired samples t-test) in visual acuity ($P < 0.05$) and also in lines gained at final follow-up ($P < 0.05$). However, there was no statistically significant difference (by independent t-test) between any two groups ($P > 0.1$).

Table 2. Causes of Vitreous Hemorrhage

Indications	Group A (20G)	Group B (23G)	Group C (25G)
PDR	18 (60%)	17 (56.6%)	16 (53.3%)
Vasculitis	6 (20%)	5 (16.6%)	7 (23.3%)
Venous occlusion	2 (6.6%)	4 (13.2%)	3 (10%)
Trauma	1 (3.3%)	2 (6.6%)	2 (6.6%)
PVD	2 (6.6%)	0 (0%)	2 (6.6%)
Others	1 (3.3%)	2 (6.6%)	0 (0%)

We found that the TSV systems used in Groups B and C, needed an average of 86 and 77 seconds, respectively, to place all three cannulas and an average of 27 and 34 seconds, respectively, to remove them (Table 4). In comparison, the 20-G system used in Group A needed an average of 517 seconds to create the ports and secure the infusion cannula and an average of 538 seconds to close them, inclusive of the time needed for conjunctival peritomy and closure.

In Groups A, B, and C, the average intraoperative time needed for the surgery (i.e., from the first entry of cutter to its final removal at the end of surgery) was 16, 19, and 24 minutes, respectively, and the average overall operative time (i.e., from placement of speculum to its removal) was 33, 21, and 26 minutes, respectively. Thus, 23-G cases required the least overall time.

Rebleeds were seen in four cases of Group A, 1 case of Group B, and 4 cases of Group C at an average of 41.75, 68, and 60.75 days, respectively, after the surgery. None of the cases in any of the groups had complications of endophthalmitis or corneal decompensation during follow-up. Postoperative retinal detachment was seen in two cases of Group A and none of Group B and C. None of the cases had evidence of hyoptony at first postoperative day follow-up, or subsequently. No significant progression of cataract was noted in any group in the duration of follow-up.

In one of the cases of Group C the shaft of the light pipe broke while attempting to clear the peripheral vitreous.

Table 1. Distribution of Cases

	Group A (20G)	Group B (23G)	Group C (25G)
Age (years)	46.81 (19–67)	49.36 (22–71)	47.75 (20–69)
Gender (male:female)	28:2	26:4	25:5
Laterality (right:left)	9:21	23:7	26:4
Duration of symptoms (days)	79.70 (41–167)	66.57 (33–136)	83.30 (38–123)
Follow-up duration (days)	198.43 (98–487)	192.23 (92–416)	204.26 (104–455)

Table 3. Visual Acuity Assessment

	Group A (20G)	Group B (23G)	Group C (25G)
Initial VA	0.048 (3/60) (6/18 to PLPR)	0.069 (4/60) (6/24 to PLPR)	0.055 (3/60) (6/24 to HM only)
Final VA	0.206 (6/24) (6/6 to PLPR)	0.389 (6/18) (6/6 to 6/60)	0.286 (6/24) (6/6 to HM)
P	$P = 0.0021$	$P < 0.0001$	$P = 0.0010$
Lines improved	4.30	5.43	3.93

Postoperatively, all eyes of Group A showed significant congestion, chemosis and minimal subconjunctival hemorrhage and also experienced foreign body sensations with overall discomfort. In contrast, 93.3% of Group B and 96.6% of Group C were quiet with no chemosis by Day 1 follow-up. Sclerotomy sites of 16.6% in Group B and 6.6% sclerotomy sites in Group C showed subconjunctival hemorrhages that resolved after an average of 8.3 days (range, 7–11 days).

Endoscopic examination of the dynamics of the port during closure revealed visibly greater amount of vitreous strands blocking the sclerotomies at closure in eyes where TSV systems were used, as compared with eyes that underwent conventional sclerotomies. We found the cannulae of the TSV system protruding 2 to 3 mm into the vitreous cavity. It was impossible to clear all the vitreous that immediately surrounded the cannula and this cuff was clearly seen endoscopically (Figure 1). On removal of the cannulae, this vitreous got pulled by the fluid egress and clogged the ports from the inside (Figure 2). However, the endoscopic examination of 20-G sclerotomy site failed to show similar amounts of residual vitreous.

Discussion

Reduction in the incision size in various surgical procedures has led to tissue trauma minimization and reduction in postoperative convalescence period.[12] This is due to reduced inflammation, lesser pain and faster healing. The challenge often has been to evolve the instrumentation and to standardize techniques so as to achieve results that are superior or at least comparable to large incision procedures. Of interest here is the development of 25 and 23-G TSV systems, which allow access into the vitreous cavity by incisions that are 0.5 mm and 0.75 mm in size, respectively, which shorten the operating time, obviate the need of sutures (and hence suture related inflammation) and remarkably reduce damage to the tissue.

In this study, we aimed to determine differences, if any, in intra and postoperative behavior in eyes with vitreous hemorrhage posted for vitrectomy and operated through the three different gauge systems. Furthermore, we used endoscopic views to evaluate the port dynamics during closure.

For this study, we chose cases of nonclearing vitreous hemorrhage which appeared uncomplicated on preoperative assessment. We excluded those with preexisting retinal or choroidal detachment, since that would have required greater intraoperative manipulation.

In all the three groups, no major intraoperative difficulties were noted. Clearing of vitreous hemorrhage was achieved satisfactorily in all cases in all groups. In one case of Group C, there was an accidental breakage of the light-pipe shaft during the surgery. Endolaser and endodiathermy worked effectively in all groups.

We felt that insertion and removal of the TSV cannulae had a short learning curve. We found that the TSV systems needed significantly lesser time as compared with the 20-gauge system both, to create the ports and to close them. This gain in time was compromised to an extent by the increased duration of vitrectomy required with smaller gauge cutters, 25-gauge taking the longest time. As compared to the 20-gauge system, the 25-gauge system required additional average 8 minutes and 23-gauge an additional average 3 minutes for clearing the hemorrhage.

Port-based flow limiting is inherently produced by smaller lumens. The reduction of the fluid volume

Table 4. Duration for Surgery

	Group A (20G)	Group B (23G)	Group C (25G)
Time for making of ports (seconds)	517 (428–651)	86 (55–124)	77 (53–122)
Duration of surgery (minutes)	16 (12–23)	19 (11–26)	24 (14–31)
Time for closure of ports (seconds)	538 (448–703)	27 (18–44)	34 (23–54)
Total duration for surgery (minutes)	33	21	26

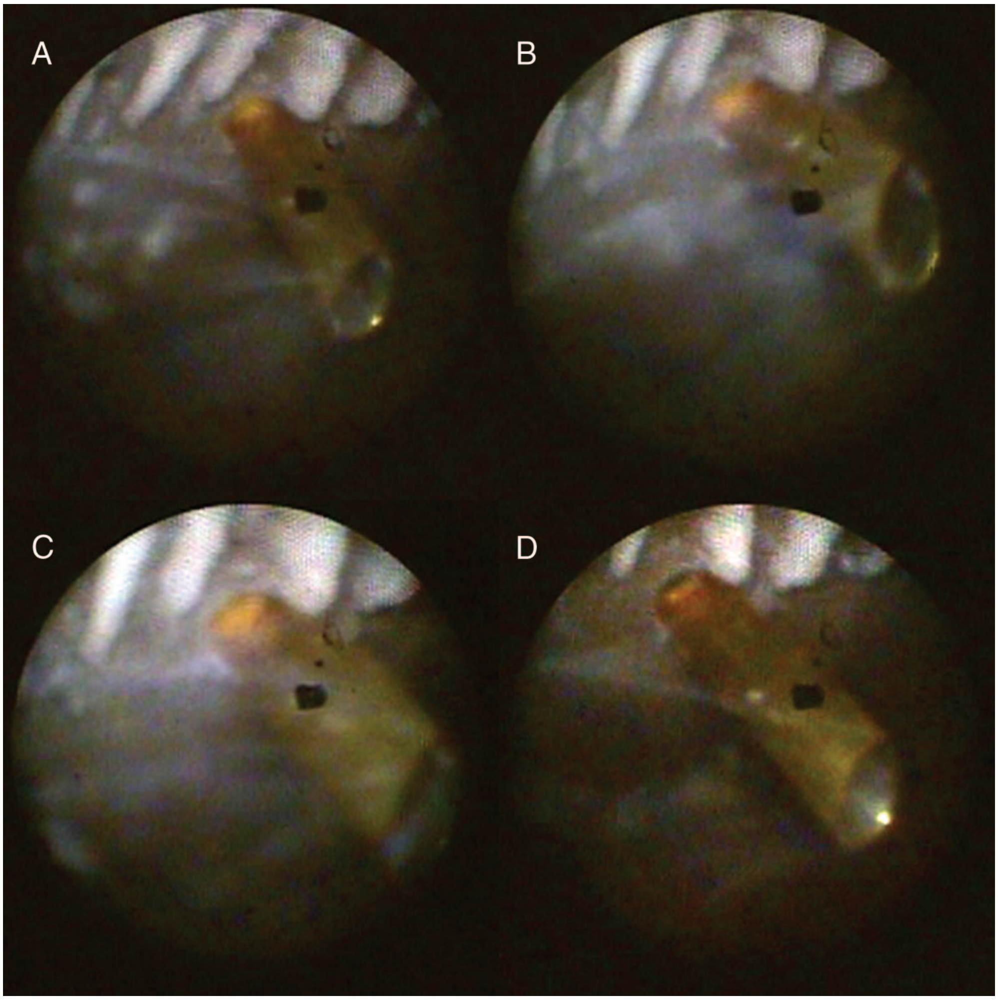

Fig. 1. Endoscopic views of a 25-G sclerotomy site with the 25-G cannula in place. Panels **A**–**D** show a cuff of vitreous surrounding the inner projection of cannula in the vitreous cavity.

traversing the port with each open-close cycle reduces cutter-induced motion of detached retina, thereby enabling safer removal of peripheral vitreoretinal traction. Hence a 25-gauge cutter, with its smaller port site provides increased stability and safety, while a 20-gauge cutter gives higher flow rates with relatively less accurate control.[6] However, lower flow rates, particularly with the 25-gauge systems are known to increase operating times. In 23-gauge system both the cutter and the infusion cannula have improved designs affording relatively higher flow rates and enabling the use of flow itself as a tool.[13]

In all groups there was a statistically significant improvement in postoperative vision. In Groups A, B, and C the vision improved by 4.3 lines, 5.43 lines, and 3.93 lines, respectively. This difference in visual acuity improvement between any of the two groups, however, was not statistically significant.

Patients in Group B and C showed lesser postoperative inflammation and faster recovery as compared with Group A patients. The minimally invasive nature of the TSV systems seemed to extrapolate to a higher level of comfort for the patient.

We examined endoscopically, the dynamics of the port during closure, in different gauge surgery. Although we could not quantify the amount, there were visibly greater amount of vitreous strands blocking the sclerotomies at closure in eyes where TSV systems were used, as compared with eyes that underwent conventional sclerotomies.

To explain this, we put forward a hypothesis.[14] The cannulae of the TSV system protrude 2 to 3 mm into the vitreous cavity; therefore, all the vitreous that immediately surrounds the cannulae cannot be cleared. As against this, the area around the 20-G sclerotomy is easily accessible with the cutter and it is possible to carefully remove all vitreous from there. Upon removal of a cannula from a TSV port, the egress of intraocular fluid pushes the residual vitreous, leading to its incarceration in the sclerotomy. In case of a 20-G sclerotomy, there may be lesser residual vitreous to clog the ports.

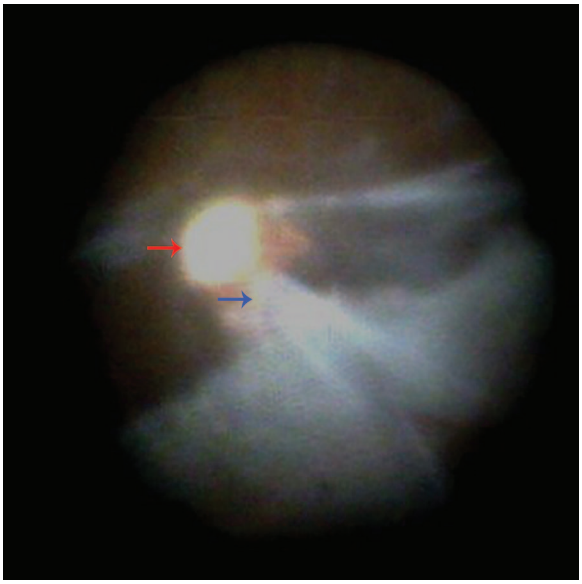

Fig. 2. Endoscopic view of a 23-G sclerotomy site (red arrow) after the cannula has been removed. Incarceration of vitreous is clearly seen (blue arrow) to be plugging the inner opening of the sclerotomy.

According to current beliefs, this vitreous clogging the ports could lead to increased rates of complications such as fibrovascular in-growth, recurrent vitreous hemorrhage and retinal breaks leading to detachment.[15–18] However, we saw that none of our cases in which TSV system was used, developed an iatrogenic break or retinal detachment at the last follow-up, whereas 2 eyes of 20-G vitrectomy developed retinal detachment postoperatively. Unsutured wounds, postoperative hypotony and lower infusion rates have been postulated to contribute to an increased risk of endophthalmitis after 25-G TSV.[19–21] We did not encounter any postoperative hypotony or endophthalmitis in any of the groups.

Thus, we did not experience increase in complication rate in spite of more vitreous clogging the sclerotomy ports and unsutured wounds. We think that while performing vitrectomy, the connection between the residual vitreous at the ports and the retina is severed, thereby rendering it harmless. We also believe that this vitreous may serve to seal the ports from inside and prevent further leakage. Kusaka[22] has observed that postoperative hypotony is commonly experienced if vitrectomy is performed at the vitreous base, also suggesting a role of the peripheral vitreous in plugging the sclerotomies.

Besides, in 20-G system all instrument shafts brush against the pars plana area during their entry and removal increasing the risk of damaging and dragging the vitreous base. The cannulae of the TSV system provide a protective sheath for the instruments to pass through without any such trauma. Also during the course of 20-G vitrectomy, when instruments are removed, at times vitreous beading is seen popping out from the ports. This again, is never encountered in the TSV systems.

We conclude that the TSV systems are certainly safe and equally effective than the 20-G system for noncomplicated vitreous hemorrhage cases. They provide a high level of comfort for the patient and the minimally invasive nature extrapolates to a faster postoperative recovery. On endoscopic views, we found that there is greater amount of vitreous clogging the inner lip of sclerotomies in TSV than in conventional vitrectomy. However, there was no corresponding increase in the rate of postoperative complications. We hypothesize that since the connection of the residual vitreous at the ports from the other tissues is severed, it does not pose any clinically significant problems. The 23-G TSV system combines the advantages of reduced surgical trauma and recovery time enjoyed with 25-G TSV system with the sturdier instrumentation and improved fluidics of the 20-G system making it a promising approach to efficiently and safely tackle the complete range of vitreoretinal surgical procedures with a single system.

Key words: sclerotomy ports, endoscopic view, vitreous incarceration, sutureless vitrectomy.

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