

Primary 23-gauge sutureless vitrectomy for rhegmatogenous retinal detachment

Mario R Romano, Ronald Das, Carl Groenwald, Theo Stappler, Joaquin Marticorena, Xavier Valldeperas, David Wong¹, Heinrich Heimann

Aims: To report a prospective non-comparative consecutive interventional study on the safety and efficacy of 23-Gauge transconjunctival sutureless pars plana vitrectomy for primary rhegmatogenous retinal detachment (RRD). **Materials and Methods:** Fifty eyes of 50 consecutive patients were recruited between June 2007 and January 2008. All surgeries were performed using the one-step 23-Gauge system with angled incisions. The surgical protocol consisted of a minimum of eight clinical visits: baseline, 1 day, 1 week, 1-, 3- and 6- months after the initial surgery. The endpoints were anatomical, functional results and complications arising from the surgery. **Results:** Anatomical success was achieved in 82% of cases (41 out of 50) with single surgery and rose to 98% (49 out of 50) with additional surgery. Mean visual acuity improved from logMAR 0.48(SD 0.36) to 0.26(SD 0.31), $P < 0.001$. Two cases with ocular hypotony, defined as an intraocular pressure ≤ 6 mmHg, that were associated with a choroidal detachment were seen. **Conclusions:** Acceptable anatomical and functional success rates can be achieved with primary 23-Gauge transconjunctival sutureless vitrectomy for RRD. We found that the approach technique is different from conventional vitrectomy and the complications arising from post surgical hypotony and leakage from sclerotomies are potentially higher compared to 20-Gauge vitrectomy.

Key words: 23-Gauge vitrectomy, rhegmatogenous retinal detachment, sutureless vitrectomy

In 2002, Hilton *et al.*, firstly reported the preliminary results of a retrospective series on 225 patients treated with 23-Gauge office-based vitrectomy with transconjunctival infusion needle device. The technique resulted as an effective approach for selected diseases of the posterior segment without significant complications.^[1]

Since then, pars plana vitrectomy using a 23-Gauge transconjunctival approach is rapidly growing in popularity and has become a significant component of the surgical routine program in many tertiary centers worldwide.^[2-4]

However, this trend is also met with some skepticism for the treatment of rhegmatogenous retinal detachments (RRD). Although recently published series report primary anatomical reattachment rates between 71 and 93%,^[2,3,5] the small-Gauge techniques remain still technically challenging and associated with significant complications.^[6] The aim of our study is to evaluate the effectiveness and safety of 23-Gauge transconjunctival pars plana vitrectomy in the treatment of primary RRD.

Materials and Methods

Study Design

We performed a prospective non-comparative interventional

St Paul's Eye Unit, Royal Liverpool University Hospital, Prescot Street, L7 8XP, UK, ¹Li Ka Shing Faculty of Medicine, University of Hong Kong, Hong Kong

Correspondence to: Dr. Mario R Romano, St. Paul's Eye Unit, Royal Liverpool University Hospital, Prescot Street, Liverpool L7 8XP, UK. E-mail: romanomario@email.it

Manuscript received: 05.10.10; **Revision accepted:** 04.06.11

study on 50 consecutive eyes with primary RRD treated by 23-Gauge transconjunctival sutureless pars plana vitrectomy. We included eyes with horseshoe tear, round hole and giant tear associated with RRD; eyes with dialysis, communicating schisis, high myopic macular hole, traumatic or post viral retinitis RDs were excluded from the study. We excluded patients younger than 18 years, with severe systemic disease, pregnancy as well as any uncontrolled ocular disease or previously failed retinal detachment surgery. All patients were recruited between June 2007 and January 2008.

Examinations

Pre-and postoperative examinations included a detailed history of previous ophthalmic surgery, best-corrected visual acuity using ETDRS charts, slit lamp biomicroscopy with particular attention to depth and inflammation of the anterior chamber, Tono-pen XL Applanation Tonometer (Reichert, Depew, NY, USA) for intraocular pressure (IOP), and indirect ophthalmoscopy. PVR was graded according to the updated Retina Society classification.^[7] Examinations were scheduled at baseline and then at 1 day, 1 week, 1-, 3-, and 6- months after surgery.

Surgical Technique

Surgery was performed under general anesthesia or local anesthesia with retrobulbar block. The surgical procedure was based on 23-Gauge transconjunctival sutureless vitrectomy using a one-step system (Alcon Laboratories, Inc., Fort Worth, TX, USA). The conjunctiva was displaced and 30° angled incisions were made through conjunctiva, sclera, and pars plana 3.5-4 mm from the corneoscleral limbus with a combined 23-Gauge blade-trocarr system in order to obtain tunnels parallel to the corneoscleral limbus. The ACCURUS® vitrectomy system with pneumatic vitreous cutter and halogen bulb light source

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10.4103/0301-4738.90487

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(Alcon Laboratories, Inc., Fort Worth, TX, USA) was used for all cases. The IOP was maintained between 30 and 40 mmHg using the vented gas forced infusion of the ACCURUS system. The 3D-vitreotomy mode with cutting rate of up to 2,500 per minute and suction of up to 500 mmHg was used. A core vitrectomy was performed and the posterior hyaloid was removed in all cases. Perfluorocarbon liquid (PFCL) was used in all cases to stabilize the retina in order to obtain a better trimming of the vitreous base. During vitrectomy, the vitreous base was thoroughly trimmed with transcleral indentation with the light pipe and drainage retinotomies were performed in 7 eyes. In 2 patients, a 180° peripheral inferior retinectomy was needed in order to mobilize the inferior retina and relieve tractions. The retinal periphery was inspected for retinal breaks, and any break found was treated. Fluid-air exchange was then performed with humidified air. At the end of the surgical procedure, air-gas mixture (C3F8 12%, in 42/50 eyes), Silicone oil (Oxane 5700 cSt, Bausch and Lomb, Toulouse, France, in 7/50 eyes) or Densiron-68 (Fluoron GmbH, Neu-Ulm, Germany, in 1/50 eyes) was injected. The choice of tamponade was made at the surgeon's discretion. All patients were postured face down for 3 h postoperatively; thereafter the patients were postured on the opposite side of the breaks or on the side of the break in the case of Densiron-68 tamponade. Posturing was maintained for 10-14 days. Silicone oil removal was planned within 4 months of the initial surgery (122±78 days) and was removed in all eyes. Before oil removal, all retinas appeared attached, the laser scars were pigmented and the retinotomies were scarred.

Outcome measures

The main endpoint of our study was the anatomical success with retinal reattachment. The anatomical reattachment of the retina was judged successful when the retina remained attached in the absence of any tamponade agent. We also analyzed the functional outcome and complications with particular attention to visual acuity, to changes of the intraocular pressure (IOP) and to the depth and inflammatory reaction of the anterior chamber.

Statistical analysis was performed using the SPSS software 12.0 (SPSS, Chicago, IL, USA). Power: 0.61, Beta Error: 0.39, Treatment effect size: 0.6. A statistical ANOVA test was performed for the analysis. A *P* value of ≤ 0.05 was considered to be significant.

Results

Patients and preoperative findings

Fifty eyes (28 phakic, 22 pseudophakic) of 50 patients (19 males, 31 females) with a mean age of 62 years (range 24-87 years) were treated with 23-Gauge transconjunctival sutureless vitrectomy for primary RRD [Table 1]. At the time of the preoperative examination, the macula was attached in 15 and detached in 35 eyes, with a mean extension of the detachment to 2.1 (SD 0.8) quadrants. The mean number of retinal breaks was 2.1±1.2, range 1 to 6. One patient presented with a break at the posterior pole. The retinal breaks were treated in 24 cases with cryotherapy alone, in 19 cases with endolaser photocoagulation and 7 cases with a combination of both. Eleven RRDs were complicated by PVR: eight eyes with PVR B and 3 eyes with PVR CP (1-4).

First post-operative day

The surgeons always aimed to achieve a complete tamponade

Table 1: Demographic characteristics of study patients

| | |
|-----------------------|--|
| Patient no. | 50 |
| Age | 62 ± 12 |
| Sex (male/female) | 19 / 31 |
| Phakic / pseudophakic | 28 / 22 |
| No. of breaks | 2.1 ± 1.2 |
| Break types | Horseshoe tear, round hole, giant tear |
| Macula status on/off | 15 / 35 |
| PVR | |
| B | 8 |
| C (1 - 4) | 3 |

filling. Only 9 out of 42 (21%) presented a complete gas filling on the first postoperative day. In all the other cases (33 out of 42, 79%), the filling was estimated to fill between 50 and 70% of the vitreous cavity. A complete silicone oil filling was obtained in most of the cases (7/8) and only in one case we found a slight underfill. The mean IOP was 11 mmHg (SD 2.3). Two patients developed ocular hypotony, defined as an IOP ≤ 6mm Hg, with choroidal detachment. Both cases were treated with a gas injections (air-C3F8 12%).

Two out of eight eyes presented a slight silicone oil leakage under the conjunctiva; in these two cases we did not find any further complications. Six out of 50 cases, five of which tamponaded with oil, received a single transconjunctival suture on the sclerotomy used for the infusion.

Anatomical Results

Retinal reattachment was achieved in 82% of cases (41/50) with one retinal operation and in 98% (49/50) with additional surgery. Nine re-detachments (9/50 eyes, 18%) occurred over the 6 months follow-up. In three eyes (3/50 cases, 6%) the redetachment could be seen in the inferior periphery under gas tamponade at one month postoperatively. In one eye, a re-detachment occurred following silicone oil removal. Between 3 and 6 months postoperatively, 5 eyes developed a retinal re-detachment from new retinal breaks. Four of these nine eyes developed an inferior retinal re-detachment that required a retinectomy. Patients with re-detachments were treated with revisional vitrectomy using silicone oil or Densiron-68.

Functional Results

At baseline examination, mean best-corrected visual acuity (BCVA) was logMAR 0.48 (SD 0.36), while at 6-month follow-up mean BCVA was 0.26 (SD 0.31) logMAR. Preoperative and postoperative (6-months follow-up) BCVA values were significantly different (ANOVA test, *P* = 0.001). BCVA improved in 44 out of 50 cases (88%), and decreased in 6 (12%), 2 of which presented with an attached macula at the time of surgery. At the last follow up 32/50 gained more than 2 lines, 6/50 lost more than 2 lines and 12/50 maintained V/A (± 2 lines). Table 2 summarizes the data.

Mean IOP was 14.6 (SD 3.2) mmHg at baseline; 10 (SD 2.8) mmHg at 1 day postoperatively; 11 (SD 2.3) mmHg at one week, 12.3 (SD 4.7) mmHg, 12 (SD 5.7) mmHg and 14.3 (SD 5.7) mmHg at 1-, 3-, 6- months follow-up respectively. In two cases, hypotony developed in the first day postoperatively

Table 2: Anatomical and functional outcomes at different follow-up intervals

| Variable | Baseline | 1 day | 1 week | 1 month | 3 month | 6 month | P baseline vs 6 month |
|----------------------|-----------|----------|-----------|----------|----------|-----------|-----------------------|
| Anatomical outcomes | | | | | | | |
| Initial success rate | 0 | 50(100) | 50(100) | 47(94) | 42(89) | 41 (82) | |
| Final success rate | | | | | | 49 (98) | |
| Functional outcomes | | | | | | | |
| Best VA logMar | 0.48±0.36 | 1.2±0.36 | 1.04±0.24 | 0.4±0.74 | 0.3±0.61 | 0.26±0.31 | P = 0.001 |
| Best VA ≤ 0.4 logMar | 40% (20) | 0% (0) | 2% (1) | 24% (12) | 46% (23) | 58% (29) | |
| IOP | 14.6±3.2 | 10±2.8 | 11±2.3 | 12.3±4.7 | 12±5.7 | 14.3±5.7 | P = 0.31 |

and persisted for three weeks. In one case, elevated IOP (31 mmHg) persisted through to the 3-month follow-up, but could be controlled with topical anti-glaucomatous medication. The difference in IOP was not significantly different between baseline and the last follow up at 6 months ($P = 0.31$ ANOVA test).

Complications

Anterior chamber shallowing occurred in 6 out of 50 eyes (12%), one of which was phakic. None of the patients had clinically significant intraocular inflammation. Posterior synechiae were detected in 2 out of 50 eyes (4%) at 1-month follow-up. Eleven out of 28 (39.2%) phakic patients developed cataract during the follow-up period, and 8 (16%) of them underwent cataract surgery. Two patients out of 50 (4%) presented with a choroidal detachment in the early postoperative period [Table 3].

Discussion

During the past years, 23-Gauge vitrectomy has evolved as a very popular operating technique in a relatively short period of time. The main reasons for its success are the easier transconjunctival pars plana access with less conjunctival scarring, shorter surgical time, decreased postoperative inflammation, and increased patient's comfort.

Table 3: Complications of 23-Gauge vitrectomy for rhegmatogenous retinal detachment over the 6 month follow-up

| Complication | Frequency | Percentage |
|------------------------------|-----------|------------|
| Newly diagnosed break | 6 | 12 |
| PVR | 1 | 2 |
| Old break reopened | 3 | 6 |
| Recurrent retinal detachment | 9 | 18 |
| Choroidal detachment | 2 | 4 |
| Shallow AC | 6 | 12 |
| Oil in AC | 0 | 4.8 |
| Hypotony | 2 | 4 |
| Raised intraocular pressure | 1 | 2 |
| Cataract | 11 | 39.2 |
| Posterior synechie | 2 | 4 |
| Elevated edge of retinectomy | 0 | 0 |
| Endophthalmitis | 0 | 0 |

Hypotony: IOP < 6mmHg; Raised intraocular pressure: IOP > 25 mmHg.

Nevertheless, several authors also pointed out the potential dangers of sutureless microincision vitrectomy techniques and the need for a careful selection of patients.^[3,6-8] Lewis even questioned the usefulness of such techniques, arguing that the postulated advantages of 23-Gauge vitrectomy are mostly anecdotic and not supported by scientific studies of acceptable standards, that they are of minimal relevance in the long term, and that the potential disadvantages of sutureless microincision vitrectomy surgery can be so severe that they might compromise the overall success of the surgical intervention.^[5] In this study, we report the anatomical and visual outcomes of primary rhegmatogenous retinal detachments treated with 23-Gauge transconjunctival sutureless vitrectomy. The limitation of our study is mainly related to the lack of a control group.

Advantages of 23-Gauge vitrectomy for RRD

An evident advantage of 23-Gauge vitrectomy and one of the reasons for its growing popularity for fresh RRD without PVR is the reduced inflammation of the anterior segment in the early post-surgical phase.^[3,6] In the long run, this leads to a reduced scarring of the conjunctiva with improved lubrication of the ocular surface.

However, when treating RRD, these advantages may be lost because of the need for equatorial or preequatorial deep indentation and cryotherapy.^[9]

Lesser inflammation of the anterior segment and lesser corneal astigmatism through the avoidance of scleral sutures usually lead to a faster visual recovery. However, when treating RRD, the importance of faster visual recovery is minimal, because intraocular gas tamponade is used in the majority of cases, which impairs vision for several weeks.^[10]

Disadvantages of the 23-Gauge Vitrectomy

With the new vitrectomy systems, the fluidics, the instrument flexibility, and light intensity are no longer the main issue.

However, according to some reports in the literature and the experience in our series, there seem to be some disadvantages that are associated with the 23-Gauge technique when compared to conventional 20-Gauge vitrectomy.

The 23-Gauge one-step trocar system in reality provides to 21-Gauge scleral opening. The post-surgical hypotony and leaking sclerotomy are as of now not yet solved problems in 23-Gauge vitrectomy.^[7] When occurring after RRD surgery, they cause clinically significant complications that can negatively influence the overall result.

The post-surgical intraocular pressure plays a physiological role in the formation of retinopexy and chorioretinal scar. A leaking sclerotomy also increases the risk of endophthalmitis and, most importantly, can lead to a significant decrease in the volume of the intraocular tamponade.^[8]

In our series, we observed relatively low postoperative IOPs, with a mean IOP of 10 (2.8 SD) mmHg on the first postoperative day and two cases of significant hypotony (IOP < 6 mmHg) that persisted during the follow-up period. The severity and the duration of the post-surgical hypotony are influenced by three main intraoperative factors: shape of tunnel incision, extent of the removal of the vitreous body base and choice of the intraocular tamponade.

The extent of removal of the vitreous body base can also significantly influence the post-surgical hypotony. Remaining peripheral vitreous body can enter the sclerotomies after the removal of the trocars and therefore prevent hypotony. If the removal of the vitreous body base is carried out very carefully (as it is usually recommended for the treatment of RRD), this may lead to a higher rate of post-surgical hypotony compared to 20-Gauge or 23-Gauge for macular surgery when a broad rim of peripheral vitreous is not removed.^[11]

Thirdly, the choice of the intraocular tamponade also plays a role. Having a greater surface tension, gaseous tamponades seal the sclerotomies better than silicone or liquids. Hence, hypotony is rarely observed in gas-filled eyes.^[7,11,12] Post surgical hypotony and the related problems represent a major complication^[7] that is not observed with conventional vitrectomy approach.

In our opinion, postoperative hypotony can interfere with the valve mechanism of the angled incision. The self-sealing tunneled incision works if the eye is maintaining it pressurized. In case of early postoperative hypotony, the sclerotomy valve will be opened with consequent increase in leakage. In our series, the hypotony and the underfilling of tamponade may contribute to the choroidal detachments (in both cases the IOP was ≤ 6 mmHg) and to the retinal re-detachments.

Another potential risk of 23-Gauge vitrectomy is bacterial endophthalmitis. In two large retrospective studies with several thousands patients, the incidence of endophthalmitis after 25-Gauge vitrectomy was significantly higher (0.84% or 0.23%) in comparison to 20-Gauge vitrectomy (0.03% or 0.18%).^[13] A recent retrospective comparative series performed on 4,021 consecutive 20-Gauge or 23-Gauge pars plana vitrectomies in a single institution, did not report any increased risk of endophthalmitis after 23-Gauge sutureless vitrectomy.^[14] Whether the rate of endophthalmitis is significantly higher after 23-Gauge vitrectomy than after 20-Gauge is a point of controversy. The reasons for this are the potentially "open" connection between the ocular surface and the intraocular space in the presence of a leaking sclerotomy and the post-surgical hypotony. In our series, we did not encounter any case of endophthalmitis.

The costs for 23-Gauge vitrectomy with the necessary access systems and instruments lie nowadays still clearly above those of 20-Gauge vitrectomy. Lewis calculated the cost of sutureless microincision vitrectomy surgery to be 3.4 times higher than that of sutured 20-Gauge vitrectomy surgery.^[5] Beside the higher costs for the intraocular instruments, it must be taken

into account that the higher rate of post-surgical complications caused by 23-Gauge vitrectomy may require additional surgery with higher subsequent costs.

The primary successful rate of previously published results of 23-Gauge vitrectomy series with more than 10 patients is between 71 and 93%.^[14] A recent prospective series on 24 eyes treated with 23-Gauge transconjunctival pars plana vitrectomy for RRD reported a success rate of 91.7% with one case of hypotony in the first postoperative day.^[15] Prospective series of the primary 20-Gauge Vitrectomy or buckle surgery show primary success rates between 71 and 95% or between 76 and 91%, respectively.^[16,17]

Even without published evidence, we believe that the intraoperative 360 degrees endolaser may improve the primary success rate and reduce the incidence of redetachment after sutureless pars plana vitrectomy.

The fact that now also complex RRDs can be treated with 23-Gauge technologies does not necessary mean that this is the best approach. The main advantages of this technique, described for macular surgery, are lost in RRD surgery because of the necessary longer operation times as well as the use of indentation and cryotherapy cause intraocular inflammation and reduce patient's comfort. At the same time, the surgeon must renounce to additional buckle surgery and accept a more demanding operating technique, higher costs, lower post-surgical pressure values and an apparently significant greater risk of endophthalmitis.

In conclusion, to keep the advantage of the use of transconjunctival sutureless vitrectomy, 23-Gauge system should be reserved for selected cases. We believe that the 23-Gauge wound construction and the new trocar-blade design could play a major role for the result, avoiding the hypotony and optimizing the tamponade effect.

There are some limitations to our study such as the lack of a control group, the limited follow up (6 months). Further prospective randomized trials are warranted to determine whether 23-Gauge approach may be superior to conventional treatments for RRDs.

We are currently performing a trial on 25-gauge vitrectomy for RRD and we believe that a 25-gauge high-speed vitrectomy with high flow-rate rather than 23-Gauge could play an important role in the treatment of retinal detachment, minimizing the risk of post-surgical hypotony and leakage from the sclerotomies.

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Cite this article as: Romano MR, Das R, Groenwald C, Stappler T, Marticorena J, Valdeperas X, *et al.* Primary 23-gauge sutureless vitrectomy for rhegmatogenous retinal detachment. *Indian J Ophthalmol* 2012;60:29-33.

Source of Support: Nil. **Conflict of Interest:** None declared.