Clinical Outcomes Of Beveled Tip, Ultra-High Speed, 25-Gauge Pars Plana Vitrectomy System

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Research Article

Keywords: Pars plana vitrectomy, microincisional vitrectomy surgery, ultra-high speed vitrectomy, beveled tip cutter probe

Posted Date: July 13th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-590252/v1

Abstract

OBJECTIVE

To report clinical outcomes of a 25-gauge, beveled-tip, 10000 cuts-per-minute (cpm) microincisional vitrectomy surgery (MIVS) system.

METHODS

Prospective case series of eyes undergoing primary pars plana vitrectomy (PPV) for common indications. Main outcome measures were: rate of achieving surgical objectives, operative time, number of surgical steps, use of ancillary instruments, corrected distance visual acuity (CDVA), and adverse events (AE).

RESULTS

Surgical objectives were achieved in all eyes. Mean total operative, core, shave and total vitrectomy times were 1891 ± 890, 204 ± 120, 330 ± 320, 534 ± 389 seconds, respectively. Mean number of surgical steps was 4.3 ± 1.5. Mean number of ancillary instruments used was 4.5 ± 1.9. Mean CDVA improved by 0.53 ± 0.56 logMAR units ($P < 0.001$) after 3 months. Postoperative AE included elevated IOP (8%), hypotony (6%), and re-detachment (2%). Majority (82%) had no postoperative discomfort.

CONCLUSION

Beveled-tip, 10000 cpm MIVS system effectively and safely performs common vitreoretinal procedures and may reduce operative time and ancillary instrumentation.

Introduction

In the 1970's, Robert Machemer performed the first closed-system, pars plana vitrectomy (PPV) using a single-port, 17-gauge (17G) system with a maximal cut rate of 400 cuts per minute (cpm).[1] Since then, the efficacy, efficiency and safety of PPV has improved with the introduction of microincisional vitrectomy surgery (MIVS), wide-angle viewing as well as new surgical techniques such as membrane dissection, internal subretinal fluid drainage, fluid-air exchange (FAX), and endophotocoagulation.[2–5]

Smaller gauge probes, faster cut rates and fluidics control have increased PPV precision, decreased operative times, hastened postoperative recovery and reduced postoperative pain and complications.[6,7] A recently introduced beveled-tip cutter probe (BTCP) with shortened port-tip distance potentially facilitates access to surgical tissue planes, permits an expanded range of surgical maneuvers and performs multiple functions (Fig. 1).[4,5] The purpose of this study was to describe the clinical outcomes and assess the utility of using a 25-gauge (25G), 10000 cpm btcp for the treatment of various vitreoretinal (VR) diseases.

Patients And Methods

This is a single-center, prospective case series of 50 eyes that underwent primary PPV performed at the Peregrine Eye and Laser Institute (PELI) from April 24 to October 24, 2019. The study was conducted according to the tenets of the Declaration of Helsinki. The study protocol and informed consent form was approved by the PELI-Institutional Review Board. Participants provided informed consent prior to enrollment. We included eyes with non-resolving vitreous opacification, epiretinal membranes (ERM), macular holes (MH), vitreo-macular traction (VMT), rhegmatogenous retinal detachment (RRD) or tractional retinal detachment (TRD), retained lens fragments (RLF), and dislocated intraocular lenses (DIS). We excluded eyes with history of glaucoma, scleral thinning, and recent (< 3 months) ocular infection.

The patients underwent comprehensive ophthalmologic assessment including corrected distance visual acuity (CDVA), intraocular pressure (IOP) measurement, slit-lamp and dilated fundus examination at all visits. IOP was measured using applanation tonometry during clinic visits and digital contact tonometry during surgery (Tonopen AVIA, Reichert Technologies, Depew, NY, USA). Elevated IOP was defined as > 22 mmHg while hypotony was defined as < 5 mmHg.

PPV was performed using 25G, 10000cpm BTCP (25G Advanced Ultravit, CONSTELLATION Vision System, Alcon Surgical, Irvine, CA, USA) by a trained retinal surgeon (HSU, PCU or JTF). A wide-angle viewing system (Resight 700, Zeiss Medical Technology, Jena, Germany) and high magnification contact lens (HR Direct High Mag Surgical Lens, Volk Optical, Inc., Mentor, OH, USA) provided surgical visualization. Trocars were inserted 3.5 mm from the limbus. Central vitreous was removed using the core vitrectomy setting (open-biased, IOP = 25 mmHg, maximum vacuum = 650 mmHg, cut-rate = 10000 cpm); peripheral vitreous was removed using shave vitrectomy setting (closed-biased, IOP = 25mmHg, maximum vacuum = 300 mmHg, cut rate = 10000 cpm).

For membrane peeling, visualization was enhanced using Brilliant Blue, Trypan Blue and soluble lutein (Doubledyne, Horus Pharma, St. Laurent du Var, France) which was refluxed onto the retinal surface using the BTCP. Initial ERM or internal limiting membrane (ILM) flap edges were created using ILM forceps or nitinol loops. Whenever safely possible, the BTCP was used to grasp the flap edge to perform membrane removal, otherwise forceps was used to complete the process.

For RRD, the 25G BTCP was used to aspirate subretinal fluid through extramacular pre-existing breaks or drainage retinotomies. Small residual amounts of fluid on the macular or optic nerve head surface were aspirated using a soft-tip, backflush handpiece (25-gauge, Grieshaber Advanced Backflush DSP, Alcon Surgical, Fort Worth, TX, USA). Endophotocoagulation was applied around the retinal breaks and in cerclage fashion along the equatorial region followed by placement of tamponade agents. The patients were typically followed up on postoperative Day 1, Week 1, Month 1 and Month 3.

The main outcome measures were rate of achievement of surgical objectives, total operative time (TOT) from first trocar insertion to last trocar removal, core vitrectomy time (CVT), shave vitrectomy time (SVT), total vitrectomy time (TVT = CVT + SVT) as recorded by the circulating nurse using a stopwatch, perioperative IOP, number of surgical steps, number of times ancillary instrumentation was placed into the eye, CDVA, and adverse events (AE). The number of surgical steps referred to the number of maneuvers that were executed: PPV, ERM or ILM peeling, FAX, endolaser treatment, gas or silicone tamponade, amniotic membrane application, lens material or IOL removal, and secondary IOL implantation. Pain at Postoperative Day 1 was reported by the patient using the following ordinal scale: 0 - no pain; 1 - mild pain not requiring medication; 2 - moderate pain less than half of waking day requiring medication; 3 - moderate pain more than half of waking day requiring medication; 4 - pain that is interrupting sleep and requiring medication.

Descriptive analysis was used for continuous and interval variables. Correlation analysis was also applied, where Pearson *r* coefficient was applied for interval level of data, while Spearman *r* rank coefficient for ordinal level of data such as pain scores. Level of significance is at 5%. Medcalc Statistical software version 19.2.1 was utilized for statistical calculations.

Results

Fifty consecutive eyes underwent PPV for various indications (Table 1). The mean patient age was 57.2 ± 13.5 (range, 16–84). Baseline CDVA ranged from 20/20 to light perception vision with a mean CDVA of 1.24 ± 0.88 logMAR units. The mean preoperative IOP was 13.2 ± 4.2 (range, 4–30) mmHg. The surgical indications were MH (22%), RRD (20%), vitreous hemorrhage (20%), ERM (12%), TRD (10%), DIS (6%), vitritis (6%) and RLF (4%). All RRD eyes were macula-off and all TRD eyes had foveal involvement as confirmed by optical coherence tomography. Thirteen (26%) had multiple surgical indications: MH + ERM (8%), VH + ERM (6%), TRD + VH (4%), TRD + Vitritis (2%), RRD + VH (2%), dislocated IOL + VH (2%) and VH + retinal tear (2%).

The surgical objectives were attained in all eyes. At the 3-month postoperative visit, the mean CDVA improved ($P < 0.05$) from 1.24 to 0.71 logMAR units. CDVA improved by 2 lines or more in 56%, remained unchanged in 40%, and decreased by 2 lines or more in 4% of eyes.

The mean TOT was 1891 ± 890 (range, 510–3930) seconds. The mean CVT, SVT, and TVT were 204 ± 120 (range, 60–594), 330 ± 320 (range, 90-1782) and 534 ± 389 (range, 155–2376) seconds, respectively. The mean number of surgical steps was 4.3 ± 1.5 (range, 1–9); the mean number of times ancillary instruments were placed in each eye was 4.5 ± 1.9 (range, 1–8) times.

Intraoperative AE included an iatrogenic retinal break in one eye (2%) and nicked retinal vessel in another eye (2%) which was easily controlled by increasing IOP. Postoperative AE included IOP elevation in 4 eyes (8%), hypotony in 3 eyes (6%) and recurrent RRD, in one eye with long axial length (2%). None of the eyes required sclerotomy suturing.

PPV using the 25G BTCP was well-tolerated. The mean postoperative Day 1 pain grading was 0.2 ± 0.5 (range, 0–2). Forty-one patients (82%) reported no pain, 2 (4%) reported mild pain, and 1 patient (2%) reported moderate pain.

The number of surgical steps demonstrated a positive correlation with TOT ($p < 0.05$), number of ancillary instruments used ($p < 0.05$), and postoperative Day 1 IOP ($p < 0.05$). The number of times ancillary instrumentation was used demonstrated a positive correlation with TOT ($p < 0.05$). Postoperative day 1 IOP was not correlated to TOT, number of ancillary instruments used, nor to CVT or SVT. Postoperative pain scores and CDVA change after 3 months were unrelated to other variables (Table 2).

Discussion

MIVS, or transconjunctival sutureless vitrectomy surgery as first described by Fujii and colleagues, has become the standard of care for VR surgery.[6,7] Incremental technological improvements such as higher cutting speeds, better fluidics, and cutter probe modifications such as the beveled-tip used in this study, continue to enhance the effectiveness and safety of PPV. This open-label, prospective case series demonstrated that a high speed, 25G, BTCP as utilized by multiple surgeons effectively and safely achieved the surgical objectives for common VR conditions. Improvements in postoperative visual outcomes were comparable to results of studies using similar gauge instrumentation.[8–13]

We observed no additional safety concerns using the BTCP. Common intraoperative complications such as retinal and vitreous hemorrhage, iatrogenic breaks, and postoperative pressure changes occurred at the expected frequency as in previous reports.[14–16] These were readily addressed using conventional measures such as laser photocoagulation, IOP elevation, gas tamponade and postoperative medications. The incidence of immediate postoperative hypotony and IOP elevation were similar to previous literature using conventional MIVS.[8–12, 17,18] The use of a smaller 27G probe may mitigate the risks for postoperative hypotony in complex cases.[19]

Recent meta-analyses have reported re-detachment rates of about 20.9% after primary PPV.[20] Smaller gauge instrumentation with improved vitreous cutting and fluidics may minimize iatrogenic tears and postoperative RD by reducing pulsatile traction, wound leaks, vitreous-wound incarceration, iatrogenic retinal trauma, and facilitating pre-retinal traction membrane removal. Re-detachment occurred in 1 eye treated for RRD which was at a higher risk because of very long axial length and was successfully treated with repeat PPV and silicone oil tamponade. No cases of endophthalmitis were observed in this series. The procedure was well tolerated by majority of patients who reported absence of pain within the first 24 hours after surgery.

We observed that mean and total operative times for individual phases of the PPV procedure were closer to the lower end of the ranges reported by similar studies using 25G probes (Table 3). Because case complexity and surgeon skill can independently influence operative time, a direct comparison of surgical efficiency across different practices and time periods is difficult and should be done with caution. The results of this study nevertheless suggest that employment of the 25G BTCP may decrease operative times. Total operative time was observed to be correlated with the number of surgical steps and ancillary instruments used. These 3 closely-related variables indicating surgical complexity were uniquely quantified in this study. As longer operative durations and frequent instrument entry and exit may increase the risk for complications, new advances that shorten operating and recovery times, enhance surgeon productivity, and lower procedural costs are always welcome.

Table 3
Comparison of surgical parameters across different 25G studies

Surgical Parameter	Indication	Instrumentation	Time (Minutes)
Total Operative Time	RRD	25G, beveled tip, 1000 cpm (Current Study)	39.0 ± 14.2
		25G, flat tip, 7500 cpm (Sborgia et al, 2019)[12]	64.4 ± 9.5
	ERM	25G, beveled tip, 1000 cpm (Current Study)	22.4 ± 4.1
		25G, flat tip, 5000 cpm (Naruse et al, 2017) [9]	32.7 ± 10.1
		25G, flat tip, 5000 cpm (Mitsui et al, 2016) [8]	16.1 ± 9.3
Total Vitrectomy Time	RRD	25G, beveled tip, 1000 cpm (Current Study)	14.4 ± 5
		25G, flat tip, 7500 cpm (Sborgia et al, 2019)[12]	20.8 ± 3.8
		25G, flat tip, 7500 cpm (Rizzo et al, 2017) [10]	19.6 ± 7.3
	ERM	25G, beveled tip, 1000 cpm (Current Study)	4.7 ± 1.7
		25G, flat tip, 5000 cpm (Mitsui et al, 2016) [8]	6.2 ± 2.7
	Various Indications	25G, beveled tip, 1000 cpm (Current Study)	8.9 ± 6.5
		25G, flat tip, 7500 cpm (Rizzo et al, 2011) [14]	18.4 ± 9.6
		25G, flat tip, 5000 cpm (Rizzo et al, 2011) [14]	26.4 ± 14.6

Abbreviations: **CPM**, cuts-per-minute; **ERM**, epiretinal membrane; **RRD**, rhegmatogenous retinal detachment; **SD**, standard deviation

We believe that the ultra-high speed BTCP can potentially improve surgical efficiency as we were able to utilize the BTCP to perform several maneuvers in place of forceps, scissors and soft-tip cannulas. The BTCP features a port opening that is significantly closer to the distal tip (0.009 inches), half the distance of conventional flat-tip probes (0.018 inches). This shortened port-tip distance improves access to surgical tissue planes and facilitates aspiration of preretinal and subretinal materials. We used the beveled-tip probe to remove subretinal fluid (SRF) from extramacular drainage sites, dissect pre-retinal membranes, aspirate pre-retinal heme, reflux vital dye stain onto the retinal surface, and complete PVD. New maneuvers such as the "lift-and-shave" and "shovel-and-cut" techniques enable surgeons to dissect diabetic membranes with greater facility and may lessen the use of ancillary instruments.[21,22] Fig. 2 shows how various surgical steps can be achieved by using the cutter probe alone (See Video 1 Supplemental Digital Content, Surgical Maneuvers). The multifunctional capabilities of this unique probe geometry have been supported by laboratory and clinical studies.[22,23] The smaller 27G BTCP may further improve tissue access but may also decrease vitreous flow.

It should be emphasized that a beveled-tip cutter is not optimal for performing all maneuvers. Ancillary instruments are preferable for many surgical steps, such as retinal scissors for dissecting adherent or broad-based diabetic membranes and membranes on detached, atrophic retina. We find that soft tip cannulas enable more complete FAX and cause less tissue trauma especially when aspirating over the macula and optic nerve head. Retinal forceps are still needed to initiate pinch-and-peel ERM and ILM peeling. The BTCP can be used in combination with a second instrument for manipulating and dissecting tissues. For example, with chandelier lighting, the BTCP can be used with a retinal pick to lift adherent posterior vitreous. The BTCP may also be used to grasp and gently lift dense membranes while the second hand operates retinal scissors for dissection. A learning curve exists for utilizing BTCP in a multifunctional role.

The results of this study lend evidence to the ability of ultra-high speed, 10000 cpm probes to shorten vitreous gel removal time. *In vitro* studies have reported a proportional relationship between vitreous flow and cutting speeds when using 50/50 or biased closed duty cycle across different cutter probe gauges.[24,25] The amount of aspirated vitreous collagen material is related to cutter characteristics as summarized in the equation:

Theoretical Vitreous Chunk Length = Flow Rate through Aspiration Line / (Cutter Port Surface x Cut Rate).[26]

By utilizing ultra-high cut rates, vitreous can be quickly segmented into smaller pieces facilitating smoother, less turbulent aspiration even when using smaller diameter lumen.[25] Higher cut rates can also enhance surgical precision and safety by minimizing pulsatile vitreous movement and avoiding iatrogenic retinal breaks.

Flow dynamic studies in porcine eyes have demonstrated faster aspiration and reflux velocities when using BTCP.[23] Beveled-tip geometry has been reported to prolong high aspirating pressures during the duty cycle and lower tip turbulence at the port opening.[23] The improved flow dynamics of the BTCP contribute to faster vitreous aspiration which may account for the shorter vitrectomy times observed in this study.

Our prospective study design included standardized measurement of efficacy and efficiency variables, such as operative times, number of surgical steps and ancillary instrument use. We also conducted correlation analysis to identify associations among variables. The inclusion of various VR conditions makes our results applicable to common indications.

The small patient population in our study prevents detection of rare events such as endophthalmitis, choroidal bleed, and subretinal migration of tamponade agents. A larger surgeon population may decrease potential data collection bias. The use of a single gauge MIVS system prevented comparison to other cutter probes. Masking procedures were not possible for this study potentially leading to subjective bias. Larger, randomized, controlled trials involving multiple surgeons are needed to fully compare the different probe designs.

In conclusion, an ultra-high speed, 25G, BTCP appears effective and safe for treating a variety of VR conditions and may reduce the use of ancillary instrumentation and operative time. Further studies are needed to fully elucidate the advantages and limitations of this novel probe design.

Declarations

Financial Disclosures: HSU has received speaker honoraria and research grants from Alcon Surgical. None of the other authors have any financial interests in the products mentioned in this article

Ethics Approval: The study was conducted according to the tenets of the Declaration of Helsinki. The study protocol and informed consent form was approved by the Peregrine Eye and Laser Institute (PELI) Institutional Review Board. Participants provided informed consent prior to enrollment.

Consent for Publication: Not Applicable

Availability of Data and Materials: All data generated or analysed during this study are included in this published article.

Competing Interests: HSU has previously received speaker honoraria from Alcon Surgical Inc. The rest of the authors have no possible competing interests to disclose.

Funding: None

Authors' Contributions: HSU was responsible for the conception and design of the study. HSU, VLOC, PSC and JTF contributed to the data collection. Data analysis and interpretation were done by HSU, VLOC and JCMA. HSU, VLOC and JTF contributed to the writing of the manuscript, while HSU, VLOC, JCMA and PSC did critical substantive revision of the final manuscript. Figures and tables were prepared by HSU, VLOC and JCMA. All authors approved the final version of the manuscript and have agreed to be responsible for the work.

Acknowledgments: Not applicable

Author's Information: Not applicable

Footnotes: Not applicable

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Tables

Due to technical limitations, table 1, 2 is only available as a download in the Supplemental Files section.

Figures

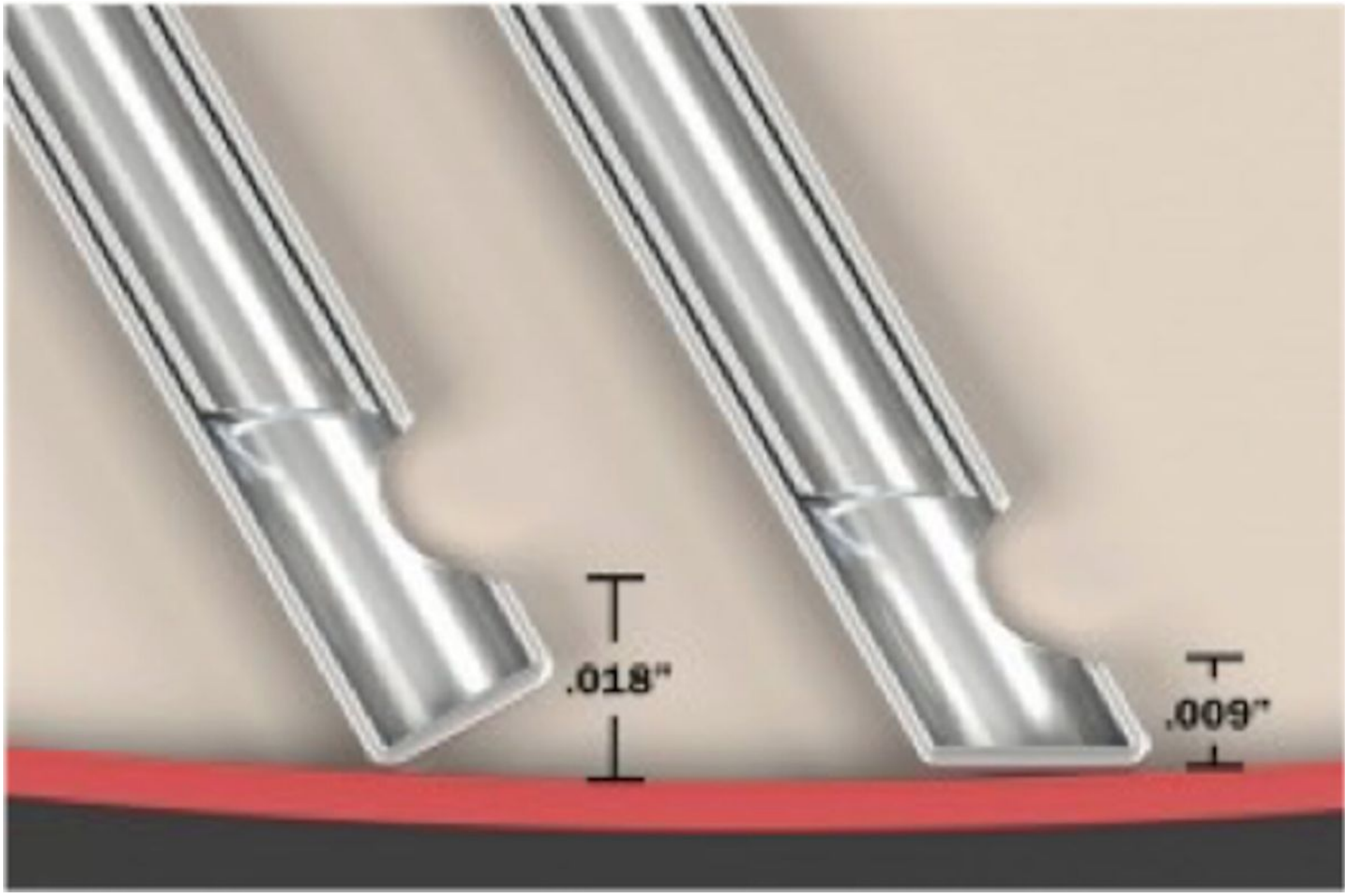

Figure 1

Schematic of the Beveled probe (right) compared with the conventional probe design (Alcon Laboratories, Fort Worth, TX, USA).

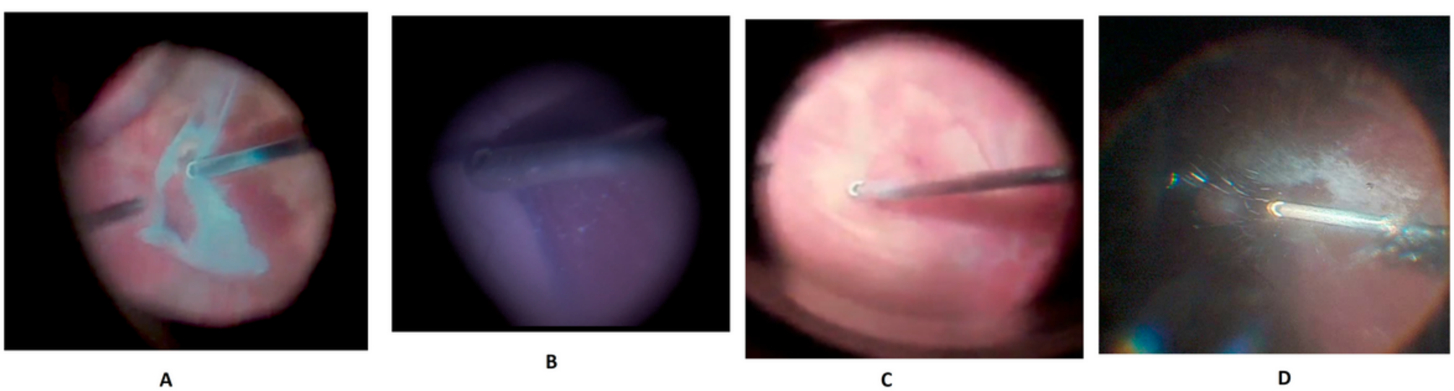

Figure 2

Surgical microscope view of 25-gauge, beveled-tip probe utilized to engage pre-retinal fibroproliferative tissues during membrane dissection (A), to peel the internal limiting membrane and overlying epiretinal membrane after staining with a combination of Brilliant Blue and trypan blue dye (B), and to remove a thin layer of heme near the retinal surface using aspiration mode only (C). An even, laminar flow of triamcinolone acetonide-stained vitreous into the port-opening can be achieved using open-biased duty cycle (D).

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Table2.CorrelationAnalysisofSurgicalVariables.xlsx
- Table1.Beveledtipultrahighspeed25gaugeparsplanavitrectomysystemstudydata.xlsx
- Video25Gfordiabeticretinopathysurgery.mp4