Comparative Assessment of Surgical Outcomes for ERM Peeling Using Intraoperative OCT Guided Membrane Removal Versus Complete ILM/ERM Peeling

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OBJECTIVE To compare anatomic and surgical outcomes of intraoperative OCT guided membrane peeling to compete ILM peeling for the removal of ERM in the DISCOVER study.

PURPOSE Intraoperative OCT (iOCT) is an emerging imaging modality used in vitreoretinal surgery, yet there is limited data on the comparative outcomes of iOCT-guided membrane peeling to complete ILM peeling for the removal of ERM. In this study, we compare outcomes for ERM surgery between traditional ILM peeling technique and iOCT-guided ERM removal.

METHODS The DISCOVER study is an IRB-approved prospective study evaluating the use of iOCT in ophthalmic surgery. We compared eyes in the DISCOVER study undergoing ERM surgery and a cohort of eyes with ERM that underwent vitrectomy with mandated ILM removal. In the iOCT cohort, ICG staining was performed with removal of ERM+/-ILM. iOCT was performed after the initial peel and if complete ERM removal was confirmed then no additional peeling was performed. In the ILM/ERM cohort, restaining with ICG was performed after initial ERM removal and residual ILM was then removed. Outcomes for VA, ERM recurrence on OCT, and reoperation rates at 6 months following surgery were assessed.

RESULTS The iOCT group included 151 eyes and the ILM/ERM cohort included 111 eyes. Baseline mean VA in the iOCT group was 20/55 and 20/50 in the ILM/ERM group (p=0.41). At 6-month follow-up, mean VA was 20/32 in iOCT and 20/31 for ILM/ERM (p=0.480). The anatomic significant ERM recurrence rate was 2% in the iOCT group and 0% in the ILM/ERM group (p=.14). There were no visually significant recurrent ERM in either group and no patients required reoperation for ERM (0%).

CONCLUSION Intraoperative OCT-guided ERM peeling demonstrated similar visual acuity and anatomic improvements without the need for sequential ILM peeling. Furthermore, no patients had visually significant ERM that required reoperation. A future multi-center randomized comparative trial is being designed to further evaluate the differences and potential benefits of iOCT in vitreoretinal surgery.

HUMAN RESEARCH Yes: Approved by institutional review board

Patient Comfort and Antimicrobial Efficacy of Aqueous Chlorhexidine Versus Povidone Iodine as Disinfectant Prior to Bilateral Intravitreal Injections

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OBJECTIVE To assess patient comfort and antimicrobial efficacy using aqueous chlorehexidine versus povidone iodine prior to bilateral intravitreal injection

PURPOSE Topical povidone iodine (PI) is widely used as an ocular surface antiseptic for intravitreal injections (IVI). While PI is generally well-tolerated, it is also associated with ocular discomfort. Aqueous chlorhexidine (AC) has been described as a better-tolerated antiseptic. We compared pain scores, ocular surface characteristics, and bacterial microbiological properties between PI 5% and AC 0.1%.

METHODS A prospective single-center, randomized, masked study of patients receiving same-day bilateral IVI of anti-VEGF with PI and AC for ocular surface decontamination prior to IVI. Each patient had one eye randomized to PI or AC; the second eye received the other agent. Each eye underwent microbiological culture prior to and after instillation of topical disinfectant. Both eyes received topical proparacaine 0.5%. After IVI, a slit-lamp fluorescein exam was recorded for each eye noting elements of a standardized quantitative grading system (ocular staining score, OSS). Patients rated their pain (scale 0-10) for each eye one minute after instillation of either PI or AC and one day post-procedure.

RESULTS One hundred eyes of 50 patients were included. The average patient age was 68 years (range 39-92) and 60% were male. Eyes receiving PI had a significantly greater pain score compared to AC immediately after injection (1.44 vs 0.44, $p<0.001$). This difference was seen on post-procedure day one, but did not reach statistical significance (1.04 vs 0.48, $p=0.06$). There was a larger portion of eyes in the PI group that had a greater fluorescein staining score ($p<0.001$), and also patches of confluent staining [39 (78.0%)] compared to the AC group [25 (50.0%)], ($p=0.001$). Eyes that received PI had a significantly higher OSS, i.e. worse corneal epitheliopathy (4.22 vs 3.1, <0.001). There was no statistically significant difference between either upper or lower eyelid rates of culture positivity following administration of PI or AC. There was no difference in rates of adverse events between groups ($p=0.99$) and no cases of endophthalmitis occurred.

CONCLUSION Povidone iodine demonstrated a greater degree of ocular surface discomfort and corneal epitheliopathy compared to aqueous chlorhexidine during same-day bilateral IVI. The disinfecting agents showed similar efficacy with no difference in microbiological testing or adverse events. Aqueous chlorhexidine may be a better-tolerated alternative to povidone iodine for antimicrobial prophylaxis during IVI.

HUMAN RESEARCH Yes: Approved by institutional review board

What Are the Keys to Maximizing Visual Performance on a 3D Digital Assisted Vitrectomy System

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OBJECTIVE To define the ideal parameters for maximal visual performance on a 3D Digital Assisted Vitrectomy platform

PURPOSE To assess how TV viewing distance, Camera Aperture and Microscope Magnification affect key measures of visual performance (Depth of Field and Lateral resolution) on a 3D Digital assisted vitrectomy system and compare to a standard microscope.

METHODS Multiple test subjects were tested to determine their depth of field (DOF5-15 target Edmund Optics) and lateral resolution (1951 USAF Resolution target Thorlabs) using a 3D Digital assisted vitrectomy system (Alcon NGneuity) or standard microscope (Ziess Lumera 700). The TV viewng distance was varied from 1.2m to 2.0m, the camera aperture was altered from 30% to 50% to 75% and the microscope zoom was assessed at low (10x), medium (15x) and high (20x).

RESULTS Depth of Field (DOF) was maximized when using a camera aperture of 30% and the lowest magnification (10X). TV viewing distance did not affect the DOF results. DOF with 30% camera aperture always exceeded that achieved with the standard micrscope. Increasing microscope magnification uniformly reduces DOF results. Lateral resolution (LR) was maximized with a TV viewing distance of 1.2m and the highest microscope magnification (20X). Camera aperture had a more subtle effect on lateral resolution with better scores generally at the smaller aperture of 30% but these did not reach statisitcal signficance. Increasing micrscope magnfication resulted in statstically better LR across all apertures. Although better LR scores

were achieved with a TV viewing distance of 1.2m than 1.5m the difference was only was statisitically significant at 2.0m.

CONCLUSION A 30% camera aperture with a TV viewing distance of 1.2m results in the best Depth of Field and Lateral resolution scores with a 3D Digitally Assisted vitrectomy system. Low (10x) microscope magnification optimizes Depth of Field while high (20X) microscope magnification maximizes Lateral Resolution. With these parameters, DOF and LR on a 3D DAVS exceeds the scores with a standard microscope.

HUMAN RESEARCH No: Study does not involve

Thermal Sensor Camera Integrated With the Argus II Retinal Prosthesis System Improves Recognition of Heat Emitting Objects

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OBJECTIVE Could the integration of a Thermal Sensor Camera with the Argus II Retinal Prosthesis System improve heat-emitting object recognition to Argus II users?

PURPOSE To explore the benefits of a Thermal Sensor Camera (TSC) integrated with the Argus II retinal prosthesis for assisting users localize and recognize heat- emitting objects and to navigate eluding impact with persons

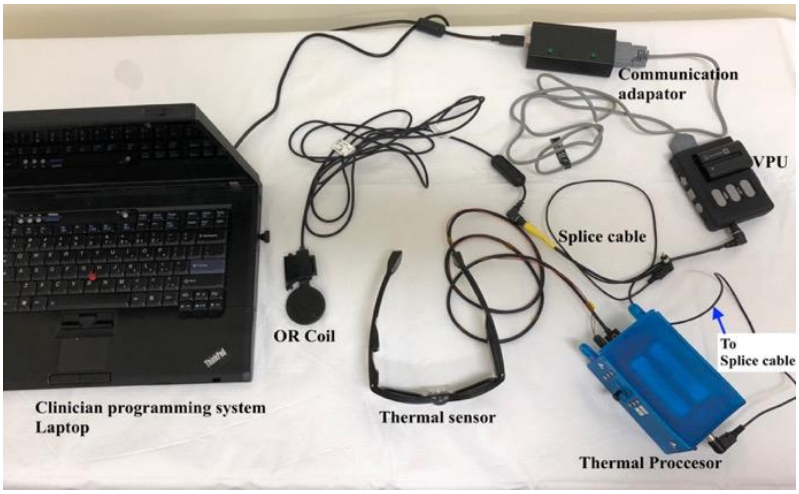
METHODS Five Argus II retinal prosthesis users participated in two tasks: (1) object recognition and (2) navigation. The first tasks involved: a) localizing the heat-emitting objects by indicating the number of objects present and their location and b) identifying a specific heated object out of 3 presented on a table. heat-emitting objects included a toaster, flat iron, electric kettle, heating pad, and mug of hot water.The navigation tasks, involved: a) localizing and walking towards people inside a small room in dark and light conditions, and b) localizing the people present in a hallway and walking down a hallway while avoiding impact with people.

RESULTS for the first tasks, subjects more accurately identified the number of heated domestic objects displayed ($p = 0.012$), the location of the objects on the table ($p = 0.043$), and the

specific type of object presented (p=0.013) with the TSC integrated to the Argus II vs Argus II camera. For the second tasks, subjects could more accurately localize people in the small room using the TSC in both the light condition ($p < 0.001$) and the dark condition ($p < 0.001$). In addition, walking down a hallway, subjects had less collisions with people standing (p=0.028) and correctly identified more people standing ($p<0.001$) with the TSC than with the Argus II.

CONCLUSION The thermal sensor camera integrated with the Argus II camera helps users to locate heat-emitting objects and people more precisely than the Argus II alone. The integration of the thermal sensor camera with the Argus II has the potential to improve patient safety.

Object recognition with the Thermal Sensor Camera integrated with the Argus II Retinal Prosthesis System.



Integration of the Thermal Sensor Camera with the Argus II Retinal Prosthesis System

HUMAN RESEARCH Yes: Approved by institutional review board

Clinical Experience With the SCS Microinjector™ for Suprachoroidal Injections by Ophthalmologists

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- Cherry Wan, MS

OBJECTIVE To describe the results of a pooled retrospective analysis on the clinical experience using the SCS Microinjector for suprachoroidal (SC) injection of CLS-TA (triamcinolone acetonide suspension).

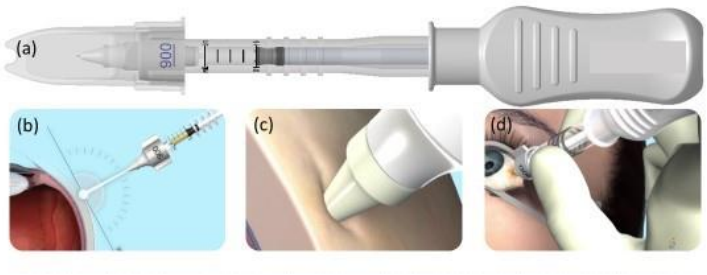
PURPOSE A novel microinjector has been developed to deliver a proprietary formulation, CLS-TA, into the suprachoroidal space (SCS) to treat ocular conditions. Successful SC injections must deliver drug through the sclera into the space between the sclera and choroid without violating the vitreous cavity. Physician experience regarding the SCS Microinjector and proper needle length selection is presented.

METHODS A retrospective analysis was performed with data from two uveitis clinical trials evaluating SC injections of CLS-TA administered at Baseline and week 12. All injecting physicians underwent standardized training for proper SC injection techniques: positioning the needle perpendicular to the globe; 4-4.5 mm posterior to the limbus; compressing the conjunctiva and sclera to first create a dimple, before injecting the drug over several seconds. Unique to performing a SC injection, the injecting physician must actively gauge for a loss in resistance during injection to determine if the SC space has been reached, starting with the 900 µm needle and graduating to the1100 µm needle if needed.

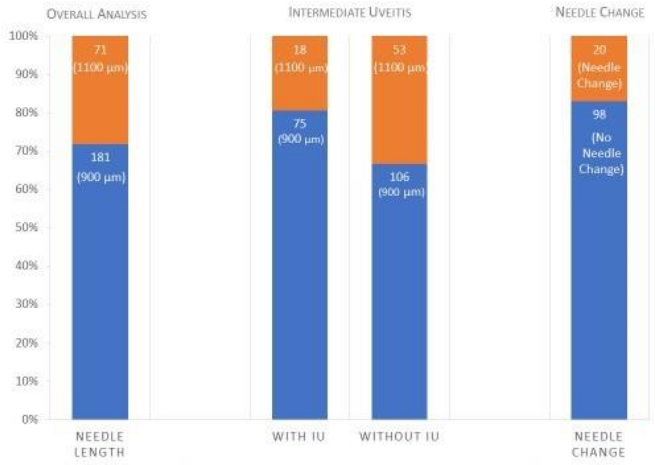
RESULTS A total of 252 injections (134 patients) were included in the retrospective analysis. 72% (181 of 252) of all injections were completed with the 900 µm needle with the others completed with the 1100 µm needle due to anatomic variations. 83% (98 of 118) of the subjects completed the treatment course (two injections) with the same length needle. SC injections with 900 µm needles were completed at a statistically higher percentage for subjects with intermediate uveitis (81%, 75 of 93), compared to subjects without intermediate uveitis (67%, 106 of 159, p=0.02). There was no statistical significance for various uveitis subtypes (anterior, posterior, pan), uveitis disease course (acute, chronic, or recurrent), uveitis disease duration (limited, < 3 months or persistent, > 3 months), or disease onset (insidious or sudden), relative to needle length.

CONCLUSION The preparation and subsequent SC injection of CLS-TA require training for the administering physician specialist and can be accomplished in an in-office setting. Despite the potential limitations of small sample size and the retrospective nature of the analysis, the

findings on needle length demonstrate that most suprachoroidal injections in these subjects can be completed with the 900 µm needle.



Caption for Figure 1: (a) SCS Microinjector – specially designed to deliver drugs suprachoroidally. (b-d) Three steps are critical for a successful suprachoroidal injection: the needle is to be oriented perpendicular to the globe, 4-4.5mm posterior to the limbus; the conjunctiva and sclera are compressed to create a dimple; the injection is administered slowly over several seconds.



Caption for Figure 2: 181 out of 252 SC injections were completed with the 900µm needle. SC injections using the 900um needle were administered at a statistically significant higher percentage for subjects with intermediate uveitis. 98 out of 118 subjected evaluated in the analysis required no needle change for the two injections at Baseline and week 12.

HUMAN RESEARCH Yes: Approved by institutional review board

Flow Dynamics of 10K Beveled-tip and 7.5K Flat-tip Vitreous Cutters

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- Akito Hirakata, MD

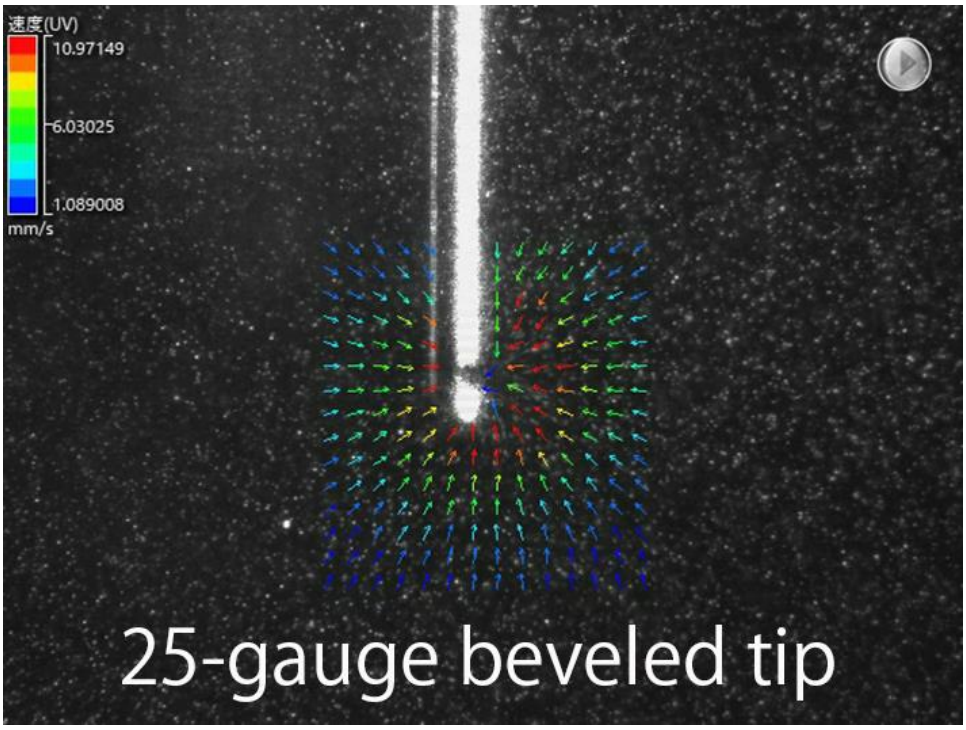
OBJECTIVE A beveled tip vitreous cutter may enhance efficiency of vitreous cutting and reflux of fluid by the shape of the tip.

PURPOSE To evaluate flow dynamics of beveled and flat tip vitreous cutters.

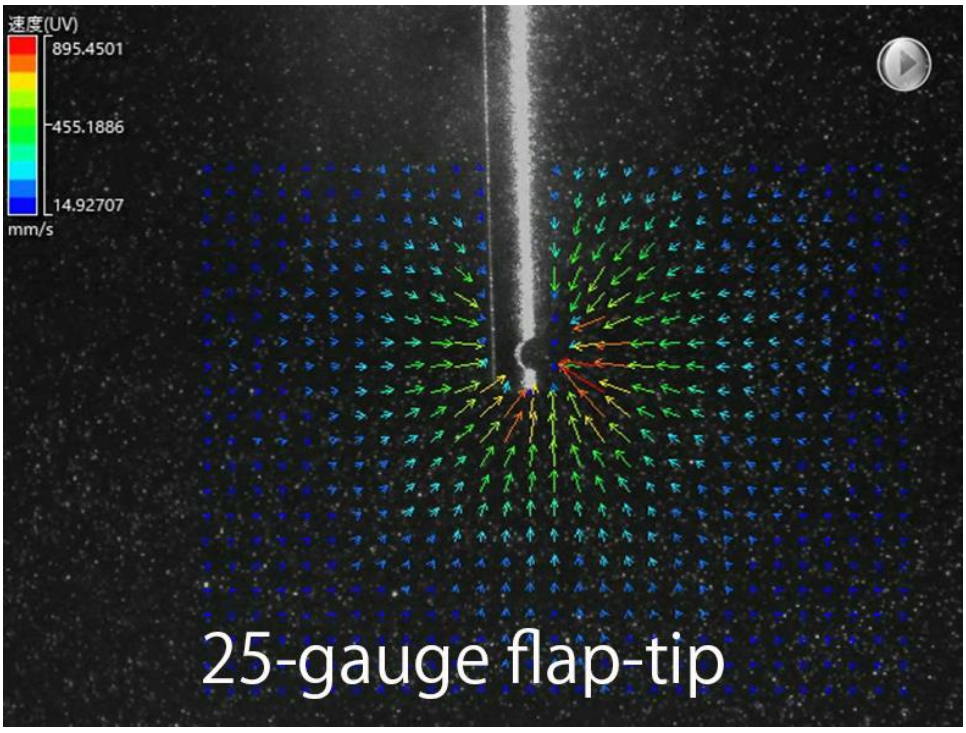
METHODS Flow dynamics of balanced salt solution and swine vitreous which was visualized with fluorescent polymer microspheres and linear beam of green laser with 25-gauge and 27-gauge 10K beveled-tip and 7.5K flat-tip vitreous cutters (Alcon laboratories, TX, USA) was observed with a high-speed camera (HAS-D71, DITECT, Tokyo). Efficiency of aspiration during cutting of fluid and vitreous and reflux of fluid were measured.

RESULTS The movement of fluid and vitreous was observed to aspirate from all directions towards the opening port with the high-speed camera. The main stream of fluid in reflux mode with the beveled tip cutter was angled at approximate 30 degrees against the cutter according to the angle of the beveled tip, which was tilted comparing to the flat-tip of 60 degrees. The volume of vitreous at 650mmHg aspiration was 2.77±0.56 ml/min (25-gauge) and 1.40±0.27 ml/min (27-gauge) with beveled-tip cutters at 10K cut/min and 2.01±0.27 ml/min (25-gauge) and 1.30±0.20 ml/min (27-gauge) with flat-tip cutters at 7.5K cut/min . The volume of aspirated vitreous increased according to the increase of cutting ratio. However, the volume of aspirated fluid decreased according to the increase of cutting ratio. In reflux mode, the volume of extracted fluid increased according to the reflux pressure.

CONCLUSION The 10K-beveled tip vitreous cutters enabled to increase vitreous cutting efficiency and to enhance usage of reflux mode by blowing fluid in more straight direction.



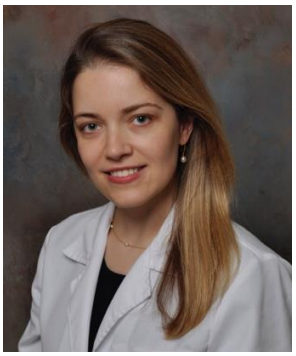
Flow dynamics chart of a 25-gauge beveled tip vitreous cutter at maximal aspiration.



Flow dynamics chart of a 25-gauge flat-tip vitreous cutter at maximal aspiration.

HUMAN RESEARCH No: Study does not involve

Computer Assisted Visual Rehabilitation in Retinal Prosthesis Recipients



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- Jay Alberts, PhD
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OBJECTIVE The impact of Computer Assisted Rehabilitation ENvironment (CAREN) virtual reality system on visual rehabilitation of Argus II retinal prosthesis recipients.

PURPOSE The field of retinal prostheses is expanding. However, the best post-operative visual rehabilitation is not established. The field is lacking outcomes-based visual rehabilitation and does not focus enough on dual tasking and functional goals. We performed a single-center interventional pilot case series to evaluate the feasibility and effectiveness of using the CAREN system in Argus II patients.

METHODS Four Argus II patients (3 male and 1 female, ages 72, 76, 81 and 61 years) participated. Participants underwent a baseline assessment, eight functional visual rehabilitation sessions utilizing the CAREN system (2x/week for 4 weeks), a post-interventional assessment, and an 8-week follow-up survey. Assessments consisted of a combination of visual function testing and functional mobility and balance tests.

RESULTS The use of CAREN in retinal prosthesis patients is feasible as all patients could interface with the system and no adverse effects were observed. All subjects were noted to have improvement on dual tasking (walking while using Argus II) with 38 and 14 percent improvement in distance walked on a flat and hilly surfaces, respectively, from baseline to the end of study. 14 percent improvement was noted in distance walked while localizing objects. 28

percent improvement was noted on functional mobility testing (standing up, following a line on the floor, going around an obstacle, and returning to a chair). Balance was assessed using postural sway measurements with 33 percent improvement on double leg postural sway.

CONCLUSION Novel methods of visual rehabilitation for retinal prostheses recipients such as Computer Assisted Rehabilitation ENvironment (CAREN) virtual reality are feasible and result in improved dual tasking, functional mobility, and balance in the current sample set. The development of clinic and home virtual reality platforms based on computer-assisted rehabilitation should be assessed in the future.

An Argus II subject utilizing the CAREN system that consists of 10-camera motion capture system (Vicon Inc., Oxford, UK), D-Flow control software (Motekforce Link) with a 180° curved projection screen and a six degree of freedom motion platform and treadmill. For safety, subjects donned a harness, have access to handrails on the treadmill, and are accompanied on the CAREN system by a physical therapist or physical therapist assistant.

HUMAN RESEARCH Yes: Approved by institutional review board

The Impact of Gauge Size, Surgical Volume, and Cutter Probe Design on Surgical Efficiency

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OBJECTIVE Data compiled from the Stellaris machines showed higher volume surgeons and smaller gauge probes had shorter vitrectomy time, while new dual port cutters displayed even shorter vitrectomy times.

PURPOSE To assess the impact on surgical volume, gauge size and vitrectomy port design on surgeon efficiency in pars plana vitrectomy surgeries performed on the Bausch and Lomb Stellaris platform.

METHODS Machine logistics of Bausch + Lomb's Stellaris devices were collected from over 1,550 machines across multiple institutions and included 114,737 posterior ophthalmic surgeries conducted by 2,278 surgeons from 2002 to 2017. Surgical volume was classified into three groups: high volume (≥ 20 surgeries per month), intermediate volume (6 to 19), and low volume (≤ 5). Surgical measures including surgery time, laser, aspiration and vitrectomy parameters, were compared based on surgical volume and based on gauge (G) size. An additional cohort of data was obtained on the more recent Stellaris Elite devices utilizing a dual port vitrectomy probe in 2018.

RESULTS Average surgery time among high volume (HV) surgeons (51.0 ± 34.0 min, n = 25,780) was significantly ($P < 0.01$) lower compared to intermediate volume (IV) (57.1 ± 35.7 min, n = 52, 607) and low volume (LV) (71.4 ± 48.0 min, n = 34,199) surgeons. IV surgeons had the

shortest vitrectomy cut time (373.7 seconds) vs HV (394.1 sec) and LV (450.2 sec) ($p<.01$). LV surgeons had higher avg aspirating duration (621.5 sec) than IV (504.4 sec) or HV (506.4 sec) surgeons ($p<.01$). LV surgeons had higher avg laser time and higher avg power settings than either IV or HV surgeons. 25G surgeries required the least amount of fluid (51.9 ml, n= 25,022) vs 23G (63.8 mL, n = 45,962) and 20G(70.8 mL, n = 22,455) ($p<.01$). 25G surgeries had lower average vitrectomy time (349.0 sec) vs 23G(409.9 sec) and 20G (440.5 sec) surgeries ($p<.01$). 25 G dual port cutters had an avg vitrectomy time of 263 sec as compared to 384 sec with the 27G dual port cutter ($p<.004$).

CONCLUSION In this large database of vitrectomy surgery, high volume ophthalmic surgeons had greater measures of surgical efficency. Additionally, 25 G surgeries were associated the lowest fluid usage and shortest vitrectomy times in comparison to other gauges. Finally 25 G dual port cutters had lower average vitrectomy times as compared to 27 G dual port cutters and 25 G standard port design.

HUMAN RESEARCH Yes: Exempt from approval