Surgical Technique

A novel three-dimensional printed device to improve the safety of trocar insertion in hypotonous eyes

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The force required for trocar insertion in hypotonous eyes can cause significant deformation of the globe and result in an iatrogenic injury to the lens, posterior capsule, or retina from the sharp trocar tip. We developed a device designed to stabilize the globe and provide counterpressure without significant globe deformation during trocar insertion. Our novel device was modeled using computer-aided design software, three-dimensional (3D) printed, and validated in an ex vivo porcine model. The risk of trocar-retinal touch was evaluated by comparing the distance between the trocar tip and opposing retina with either a cotton swab or our 3D printed device. We found an increased distance between the retina and trocar tip at the time of trocar insertion using our novel device: 3.3 ± 1.3 mm (P = 0.035), suggesting an improved safety margin. This device has the potential to improve the safety of trocar insertion in eyes at risk of trocar-associated injury, including hypotonous, previously vitrectomized, and nanophthalmic eyes.

Key words: Instrument, surgical, trocar, vitreoretinal surgery

The advent of small-gauge vitreoretinal surgery has greatly improved efficiency and safety through the use of transscleral cannulas for instrument insertion. These cannulas are inserted over a trocar that creates the sclerotomy. However, insertion of the trocar cannula requires sufficient force to allow for penetration. In eyes with lower intraocular pressure, a cotton tip is pressed against the sclera opposite the trocar insertion point to stabilize the globe during insertion. Prior studies in both human and pig eyes have shown increased intraocular pressures as high as 63 mmHg during trocar insertion.[1,2] As a result, when inserting a trocar into a soft eye, there can be considerable deformation of the globe, which can lead to an iatrogenic eye injury.

A retrospective study reviewing difficulties in trocar insertion showed that it was not possible to safely insert at least one 23- or 25-gauge trocar cannula into a quarter of eyes with a preoperative intraocular pressure of less than 8 mmHg.[3] Instead, vitrector-assisted sclerotomy had to be performed. Other articles discuss complications such as inadvertent posterior capsule rupture due to the amount of deformation caused by trocar insertion into a hypotonous eye.[4] Several other complications are anecdotal and likely underreported, such as injury to the retina.

The current practice at our institution is to use a cotton swab to provide counterpressure and stability during trocar insertion. However, this focal point of opposing pressure significantly indents the eye opposite to the entry of a sharp trocar, raising concern for contralateral retinal injury. We propose a new instrument that helps the globe maintain its shape and promotes stability during trocar insertion.

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Our device was designed using computer-aided design software and 3D printed in a composite nylon–carbon resin, on a Mark Two 3D printer (Markforged, Boston, MA; Fig. 1). It is designed to fit the curvature of an adult globe and cup the quadrant opposite trocar insertion.[5] The dimensions of the device are a 60° subsection of a sphere with a radius of 12 mm. The height of the instrument is 10 mm, and the width at its widest point is 15 mm. The thickness of the instrument is 2 mm. We developed an experimental model that prospectively compared the deformity of the globe and the risk of trocar-retinal touch during trocar insertion. Two tools were compared using this model: a cotton swab and our novel device.

Freshly enucleated porcine eyes were stabilized on a mannequin head. A limited vitrectomy was performed with bottle height set at 13.6 cm (equivalent to an intraocular pressure of 10 mmHg). A cotton swab or the novel device was placed at the pars plana 180° opposite from the planned insertion of a 23-gauge trocar (Alcon, Fort Worth, USA) to serve as a counterpressure device. A line of known distance from the tip of the cotton swab was marked and acted as a fiducial marker, such that the tip could be estimated if it was

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not visible. A ruler was placed alongside the eye during image acquisition to ensure accurate measurements, and a pressure gauge was attached to the trocar to measure the insertion force. The trocar was inserted using rotary movements. All procedures were recorded using the NGENUITY 3D visualization system (Alcon, Fort Worth, USA). The videos were retrospectively reviewed frame by frame by two independent reviewers to determine the point of the minimum distance between the trocar tip and either the cotton swab tip or the middle of the novel device at the time of insertion [Fig. 2]. The minimum distance between the cotton tip or novel device and trocar tip was then measured using ImageJ (Version 1.49t, National Institutes of Health – available at http://imagej.nih.gov/ij). Univariate analysis was performed using the Wilcoxon signed-rank test. Statistical analysis was performed using JMP Pro Version 14.0 (SAS Institute, Cary, NC, USA).

**Results**

Measurements were obtained in seven porcine eyes. The average minimum distance between the sclera and the trocar tip when a cotton swab was used to stabilize was $11.1 \pm 2.5$ mm (range 6.9–13.8 mm) versus $14.4 \pm 2.3$ mm (range 10.8–17.9 mm) when our novel instrument was used to stabilize the globe. The difference of $3.3 \pm 1.3$ mm (range 0.5–6.1 mm) was statistically significant ($P = 0.035$). The measured insertion forces were 0.7 to 1.4 N – consistent with the published reports of average scleral penetration force.

**Discussion**

Sufficient intraocular pressure is required for trocar insertion; in hypotonous eyes, this can be generated by external compression. During traditional trocar insertion, both the trocar and the cotton swab tip indent the globe. Cotton tips compress the globe at a single point and as a result lead to the indentation at that location – frequently $180^\circ$ from the trocar, increasing the risk of contralateral retinal injury by the trocar tip. In our experimental setup with a porcine eye model and a low initial intraocular pressure, we measured an averaged increased safety margin of 3.3 mm as a result of our novel device’s unique design, which mirrors the contour of the globe [Fig. 2].

The globe of the eye can be simplified into a hydraulic system with the vitreous acting as an incompressible fluid. The counterpressure device works by displacing a volume of vitreous that stabilizes the globe opposite the device during trocar insertion. Because the fluid is incompressible, a counterpressure device with higher surface area contact requires less indentation distance in order to achieve an equal displacement volume. Thus, it lowers the risk for contralateral injury from the trocar tip by increasing the distance between the trocar tip and the opposing retina.

There are several other techniques in use by retina surgeons to overcome the problem of trocar insertion in hypotonous eyes. These include using an MVR blade to create a sclerotomy then suturing in the first trocar, injecting saline solution into the vitreous cavity to increase the intraocular pressure before attempting trocar insertion, using a cotton swab on its side to provide a larger surface area, using blunt forceps spread widely apart to stabilize the globe, and attempting to hold the globe stable with toothed forceps. We believe our device provides a zero-risk, noninvasive alternative to the use of an MVR blade or intravitreal injection of saline, as both of these alternatives can also lead to posterior capsular injury in a hypotonous eye. In comparison with a cotton swab on its side or spread forceps, our device provides a larger, more consistent surface area with the advantage of perfectly cupping the globe to provide superior stabilization.

The limitations of this study include the differences in dimensions between porcine and human eyes, and the inability to simulate the movement of a human eye in the orbit with an *ex vivo* model. A primary strength of this study was the ability to compare counterpressure devices using a consistent penetration force at a fixed intraocular pressure. Additionally, we show a practical use for 3D printed instruments in ophthalmic surgery. The 3D printing allows for inexpensive iteration of a new device and the ability to print the final design in a more expensive, biocompatible material – such as stainless steel – for implementation in human trials.
Conclusion
We believe that the instrument that we have described can improve the safety and ease of trocar insertion in eyes at risk of trocar-associated injury, including hypotonous, previously vitrectomized, and nanophthalmic eyes.

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Conflicts of interest
There are no conflicts of interest.

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