New Instruments

A 30 G 'POSTERIOR CHAMBER MAINTAINER' FOR PREVENTION OF TRANSIENT HYPOTONY DURING SCLEROTOMY CLOSURE AT THE CONCLUSION OF 3-PORT PARS PLANA VITRECTOMY

Andrew W. Trippiedi, BS*†
Justin Gutman, MD†

*From the *Hackensack Meridian School of Medicine, Nutley, New Jersey †Retina Center of New Jersey, Bloomfield, New Jersey*

At the conclusion of a standard 23- or 25-gauge 3-port pars plana vitrectomy, it is not uncommon for one or more of the sclerotomy sites to leak. Previous studies by Lakhanpal et al,[1] have reported an incidence of 7.1% of small-gauge vitrectomies requiring at least one suture at a single sclerotomy site. The type of wound construction can impact the frequency of incompetent wounds. In addition, trocar size, primary vitrectomy versus a reoperation, high myopia, and the age of the patient can affect the rate of wound leaks encountered. Lin et al[2] observed that leaking wounds are not common, especially in primary vitrectomies, but they are encountered on occasion by every surgeon.

Removal of the infusion trocar cannula from an eye with a wound that does not self-seal, can result in the rapid development of hypotony. Previous reports by Khanduja et al[3] describe hypotony occurring in as many as 25% of the cases of sutureless vitrectomy. This is especially common in patients with a history of previous vitrectomy as described by Mimouni et al.[4]

Surgeons attempt to anticipate and mitigate the extent and duration of hypotony, especially if the surgeon encounters wound leaks from the two instrument trocars that may have required suture closure. When it is believed that the sclerotomy from the infusion trocar will also leak, a suture is simultaneously passed while the infusion trocar is removed. This allows for a rapid closure of the wound and helps the surgeon to place the suture more accurately through the sclerotomy site, because the trocar itself provides a guide for the needle track. When the wound does leak despite the above rapid suturing, the

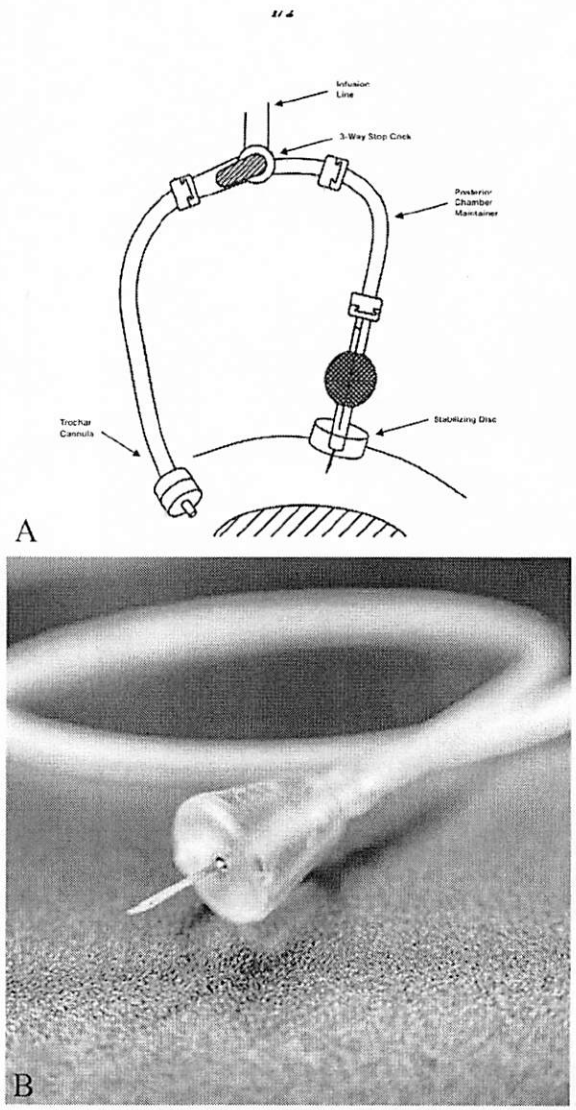

Fig. 1. A. The PC Maintainer is attached to a 3-way stopcock that diverts flow from the 25- gauge infusion trocar. **B.** A closeup of the device showing the stabilizing base from which a 30-gauge needle protrudes.

Justin Gutman, MD holds the patent for the posterior chamber maintainer. None of the other authors have any proprietary interests or conflicts of interest related to this submission.

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Reprint requests: Justin Gutman, MD, Retina Center of New Jersey, 1255 Broad Street, #104 Bloomfield, NJ 07003; e-mail: justingutman@gmail.com

conjunctiva balloons up, making it difficult to see the underlying sclera and difficult to pass the stitch accurately. Inaccurate needle passes prolong and exacerbate the degree of hypotony. Even in the best scenarios when the stitch is passed perfectly and tied quickly, an unsafe degree of hypotony can still be unavoidable.

When the surgeon determines that the globe is too soft, the remedy is to use a 30-g needle on a syringe filled with BSS or sterile air or gas, and to introduce the needle into the vitreous chamber through the pars plana to reinflate the eye to the appropriate pressure. A 30-g needle puncture is known to reliably self-seal. During those moments before the eye is repressurized, the eye is at risk for rebleeding from vessels that had been ligated during surgery, bleeding from the angle, decompression retinopathy, and choroidal hemorrhage. Mukkamala et al[5] reported that although cases of decompression retinopathy often have favorable outcomes, with visual acuity in as many as 85% of eyes returning to baseline, it may still lead to ocular morbidity.

The 'posterior chamber maintainer' (Vortex Surgical, Saint Charles, MO) seeks to solve these problems by maintaining the intraocular pressure after removal of the infusion trocar, even if that wound is found to be incompetent and leaking rapidly. Instead of reinflating the globe after the eye has lost pressure, this device is preplaced through the pars plana and can be left in place hands-free, providing infusion pressure to the eye as the leaking wound is addressed. This not only will prevent transient hypotony during the surgery, but also may allow for easier closure of the infusion trocar wound site, if necessary. The device has been named the 'posterior chamber maintainer,' but it should be noted that anatomically, the device is placed in the vitreous chamber.

Design of 'Posterior Chamber Maintainer' and Surgical Utility

The 'posterior chamber maintainer' consists of a 30-gauge needle measuring 4 mm in length. The needle is attached to a length of tubing. The tubing has an adapter to hook up to the infusion line via the 3-way stopcock. Most critical to the design is a "stabilizing disk," which helps to keep the needle perpendicular to the eye wall, preventing any tilt or torque of the needle that could threaten the phakic lens or retina. Figure 1.

Before the infusion trocar is removed, the PC maintainer needle is inserted into the vitreous chamber in the inferonasal quadrant of the sclera, 3.5 mm posterior to the limbus. Figure 2A. The tubing is then taped to the drape over the patient's nose. It is then left in place, hands-free as the stabilizing disk prevents movement. The flow of fluid or air is then diverted by turning the 3-way stop cock, forcing flow through the PC Maintainer needle. The infusion trocar is then removed and sutured if necessary. Figure 2B. Any fluid that leaks from the wound is compensated for by the flow through the PC maintainer and IOP is never compromised. Once the surgeon is satisfied with the wound closure, the 30-g PC maintainer needle is removed, leaving a self-sealing wound at the conclusion of the case. Figure 2C. See supplemental video for further information (http://links.lww.com/IAE/B965).

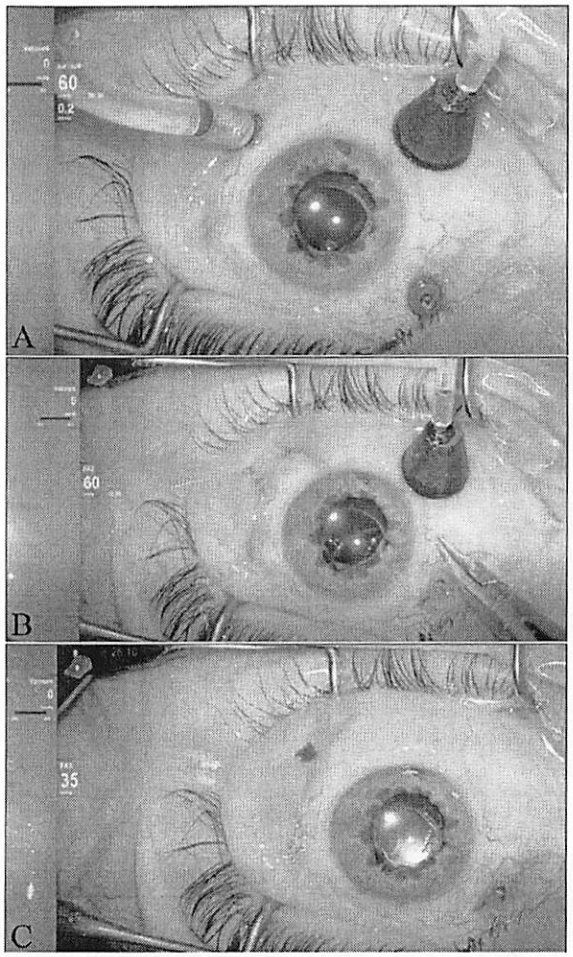

Fig. 2. A. Here is a picture of the device after being inserted, before removal of trocars. **B.** The PC Maintainer assures that there is no transient hypotony after removal of the infusion trocar. **C.** The PC Maintainer uses a 30-gauge needle, which self-seals after removal.

COLOR

Pilot Experiences

We conducted a retrospective review of 50 consecutive total cases. All 50 cases were repeat pars-plana

Table 1. Results From Cases With and Without PC Maintainer

	With Posterior Chamber Maintainer	Without Posterior Chamber Maintainer
Transient intraoperative hypotony	0/18	15/17
Cases of intraocular hemorrhage on post-op day 1, endophthalmitis, suprachoroidal hemorrhage or effusion, or postoperative rapid progression of cataract	0	0

vitrectomies. This study adhered to the guidelines of the Declaration of Helsinki. We contacted WCG IRB and received their approval for a retrospective chart analysis. We compared two separate arms in the study. One arm included 25 cases of repeat vitrectomy, without the 30-g PC maintainer available for use, because they were conducted at the hospital ASC where a consignment for this device has not yet been obtained. The second arm included 25 cases of repeat vitrectomy performed at a private ASC where the 30-g PC Maintainer device was available for use, and is routinely used on every case performed there, including the 25 cases highlighted in this study. Cases of primary vitrectomy, and vitrectomy for retinal detachment when a gas or oil tamponade would be necessary were excluded. All 50 cases used 25-gauge trocars. The intraocular pressure from the infusion source was kept at 35 mmHg when all trocars were removed in both arms. In the PC Maintainer arm, there were 16 cases of silicone oil removal, 6 cases of reoperation for nonclearing vitreous hemorrhage from PDR, 1 reoperation for nonclosure of macular hole, and 2 reoperations to place a secondary IOL for aphakia. The arm with no PC Maintainer included 13 cases of silicone oil removal, 7 reoperations for nonclearing vitreous hemorrhage from PDR, 2 reoperations for recurrent epiretinal membrane, and 3 reoperations to place a secondary IOL for aphakia. As the primary data point, we looked at the incidence of transient hypotony that required the eye to be reinflated after the removal of the infusion trocar. Hypotony was diagnosed by the surgeon intraoperatively by digital palpation. Transient hypotony was recorded if the surgeon determined it was necessary to reinflate the eye, and this reinflation was mentioned in the operative report. We also looked at safety data including the incidence of postoperative intraocular hemorrhage, suprachoroidal effusion or hemorrhage, rapid postoperative progression of cataract, or endophthalmitis. The results of the trial revealed that the rate of leak from the infusion trocar wound was 72% (18/25) in the arm that used the PC Maintainer and 68% (17/25) in the arm where no PC Maintainer was available. In the arm that used the PC Maintainer, 0% (0/18) of the eyes required reinflation, because hypotony was never encountered. In the arm where the PC Maintainer was not available, 88% (15/17) of the cases required the globe to be reinflated because of an unsafe degree of hypotony encountered Table 1. T1

Conclusion

The 'Posterior Chamber Maintainer' was found in this pilot experience to be safe and effective. It allows for maintenance of intraocular pressure at the conclusion of pars-plana vitrectomy, reliably preventing transient hypotony in these cases. With less hypotony encountered, the chance for ocular morbidity may be reduced, although in this trial, superiority of surgical outcome with our device compared with the standard of care was not demonstrated. Further experience will be needed to determine whether the PC maintainer improves patient safety.

Key words: pars plana vitrectomy, posterior chamber, 3-port pars plana vitrectomy.

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