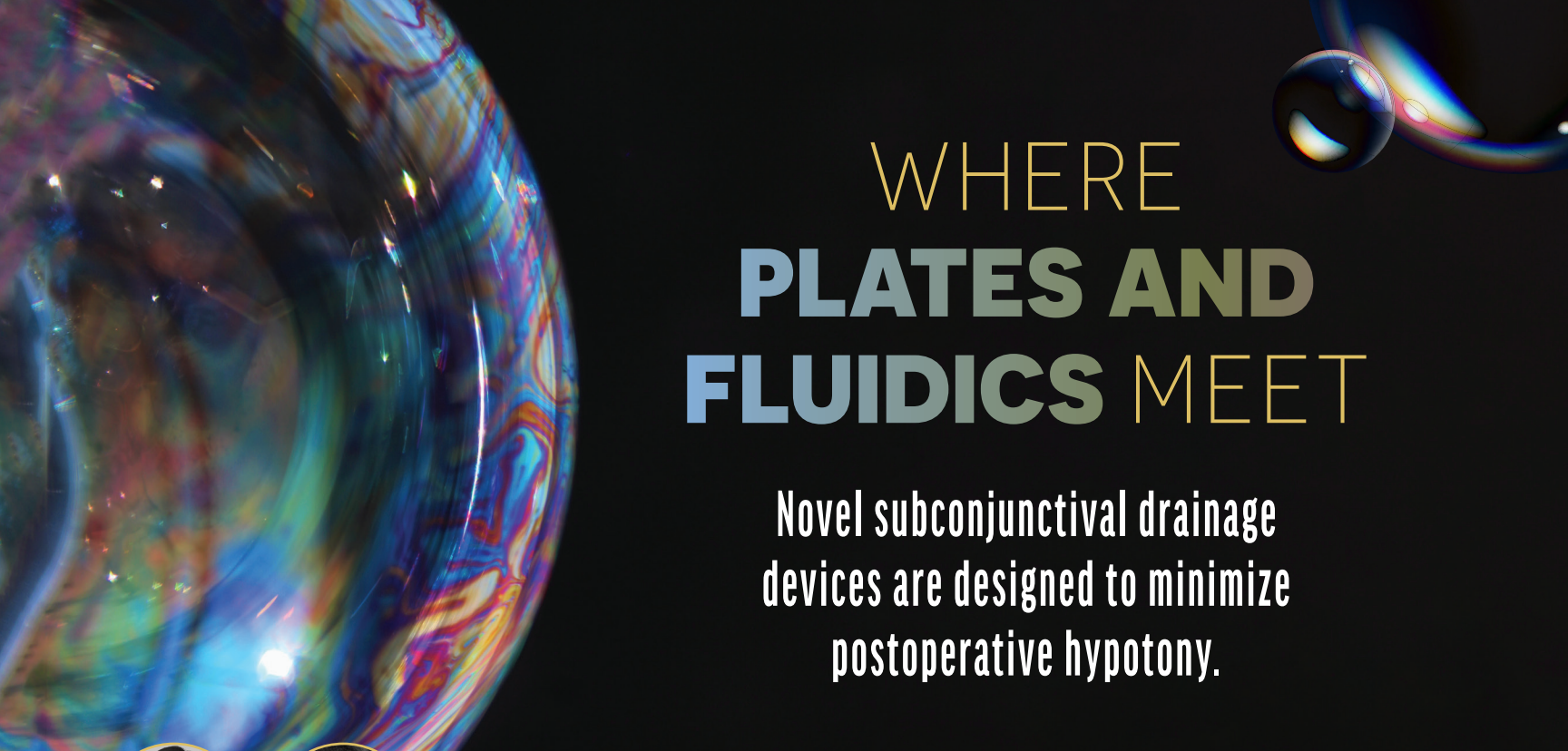

WHERE PLATES AND FLUIDICS MEET

Novel subconjunctival drainage devices are designed to minimize postoperative hypotony.

BY STEPHANIE WEY, MD, AND EYDIE MILLER-ELLIS, MD

The long-standing goal of incisional glaucoma surgery is to achieve a steady and sufficient reduction in IOP, especially in eyes with severe, progressive disease. Hypotony, numerically defined as an IOP of less than 5 to 6 mm Hg, remains a feared sequela of surgery. Clinically, hypotony raises the risks of choroidal effusion, a shallow anterior chamber, and maculopathy—complications that can require additional surgery and lead to further vision loss. Achieving the target IOP while minimizing the risk of hypotony can be a challenge.

Tube shunts have risen in popularity thanks to their lower risk of postoperative complications compared to trabeculectomy. This is especially true of the Ahmed Glaucoma Valve (AGV; New World Medical), which is the only valved drainage device available in the United States. In the Ahmed Baerveldt Comparison (ABC) Study, the risk of postoperative hypotony was much lower with the AGV than the Baerveldt Glaucoma Implant (BGI; Johnson & Johnson Vision), but the BGI was associated with a greater IOP reduction.[1] The reason that the BGI presents a higher risk of postoperative hypotony than the AGV is that the former lacks a valve and the plate must be encapsulated to a certain extent before the tube is opened to allow aqueous outflow. Various techniques involving the use of ligatures around the BGI's tube, a ripcord within the tube lumen, and fenestrations and wicks through the tube have been developed to facilitate an IOP reduction while preventing overfiltration and related complications postoperatively.

Innovating on the mechanical scaffolding provided by existing technology, several new devices have been developed that build on the plate or tube design of the aforementioned glaucoma drainage devices. The newer technologies incorporate features such as titratable valves, multiple outflow channels, and a decreased tube lumen caliber to minimize postoperative hypotony and maximize efficacy.

CALIBREYE

Postoperative aqueous flow modulation is the unique feature of the Calibreye Titratable Glaucoma Therapy Surgical System (Myra Vision). This capability is not afforded by tube shunt surgery and is provided to only a limited extent by trabeculectomy with laser suture lysis or releasable sutures.

The Calibreye shunt is 10 mm long, 1.6 mm wide, and 0.3 mm thick. Made of nitinol and silicone, the device is implanted via an ab externo approach with adjunctive mitomycin C (MMC). The shunt features two valved channels that can be independently modified with an office-based laser and one standard channel (the smallest in caliber) that allows constant aqueous flow. There are four resistance settings—baseline (standard channel open), moderate, high, and maximal—that can be adjusted at any time.

In a small feasibility study of 43 patients, none of the eyes treated with the Calibreye required bleb needling during the study period,

"WITH FEATURES SUCH AS SLIMMER LUMENS AND MICROCHANNELS, SEVERAL NOVEL GLAUCOMA DRAINAGE DEVICES HOLD PROMISE FOR DECREASING THE RISK OF POSTOPERATIVE HYPOTONY-RELATED COMPLICATIONS WHILE EFFECTIVELY LOWERING IOP."

and the vast majority of patients did not require topical medications.[2] The device's safety and efficacy will be assessed in the US-based Adapt trial.

VISIPLATE

The VisiPlate (Avisi Technologies) has an ultrathin, flexible plate that is made of an alumina core coated with parylene-C and is designed with a neck and body. The product has a maximum length of 9.5 mm, a maximum width of 6 mm, and an overall thickness of 25 µm.

The device is composed of a hexagonal matrix of microchannels, which serves as a platform for a diffuse, low bleb, similar to that created during a trabeculectomy. The presence of numerous outflow channels reduces the risk of occlusion, which can be a problem with single-lumen drainage devices. The neck of the plate is inserted into the anterior chamber and serves as the conduit for aqueous outflow. MMC is used to decrease fibrosis over the body of the device.

The VisiPlate was shown in a rabbit model to be safe and efficacious in lowering IOP.[3] The device is now being evaluated in a prospective, multicenter, open-label clinical trial in the United States.

PAUL IMPLANT

The Paul Implant (PGI; Advanced Ophthalmic Innovations; not available in the United States) is a winged, valveless drainage device made of silicone. Although similar to a BGI in plate surface area and shape, the PGI is distinguished by its tube diameter, with a small inner lumen of 127 µm (vs 300 µm for the BGI).

In a systematic review, the main implantation technique (76.9% of studies) involved threading a 6-0 polypropylene suture into the lumen as a ripcord.[4] Among the cases included in the review, the rate of hypotony was 9.7% (68 of 701 eyes). The rates of choroidal effusion and shallow chamber were 3.4% (27 of 805 eyes) and 5.9% (38 of 646 eyes), respectively. Of relevance is the variable use of MMC, which was left to surgeons' discretion. Small head-to-head studies have yielded similar rates of hypotony among the PGI, AGV, and BGI in both adult and pediatric patients with glaucoma.

AHMED CLEARPATH SMALL TUBE

The Ahmed Clearpath (New World Medical), a nonvalved tube shunt, became commercially available on the US market in 2019. The device has a flexible, curved silicone plate that comes in two sizes and anterior eyelets designed to facilitate suturing the plate to the globe. The latest iteration of the product, the Ahmed Clearpath Small Tube, became available in 2025.

Similar to the PGI, the Ahmed Clearpath Small Tube employs a narrower tube, decreased in diameter from the original Clearpath by approximately 60%. The original Clearpath was passed through the sclera in a track created with a 23-gauge needle, and the lumen of the device was occluded with a 4-0 polypropylene suture. The Ahmed Clearpath Small Tube, in contrast, can enter a sclerostomy created by a 25-gauge needle and be occluded with a 6-0 polypropylene suture.

In a single-center retrospective case series of 17 patients with the Ahmed Clearpath Small Tube, no cases of hypotony were reported.[5] Among all patients, the preplaced ripcord was left in place, and no ligature was used.

CONCLUSION

With features such as slimmer lumens and microchannels, several novel glaucoma drainage devices hold promise for decreasing the risk of postoperative hypotony-related complications while effectively lowering IOP. ■

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