

# UPDATE ON MICROINVASIVE GLAUCOMA SURGERY



Current and future options in this rapidly evolving space.

BY MICHAEL GREENWOOD, MD



The emergence of microinvasive glaucoma surgery (MIGS) has allowed cataract and refractive surgeons to treat glaucoma earlier and more safely compared with filtration surgery. Because MIGS procedures are mostly performed ab interno, they will not interfere with cataract surgery planning or induce astigmatism at a later date. MIGS also

gives patients an opportunity to reduce their dependence on topical medication, agents that negatively affect the ocular surface, so quality of vision can improve.

This article provides a brief update on current and future MIGS options that fit into cataract and refractive surgeons' toolboxes.

## CURRENT OPTIONS

### Trabecular Meshwork

#### *iStent Trabecular Micro-Bypass Stent*

The *iStent Trabecular Micro-Bypass Stent* (Glaukos) drains aqueous flow into Schlemm canal from the anterior chamber, effectively bypassing the damaged or blocked trabecular meshwork (see *Watch It Now* on p. 67). The device has proven to be effective. Ferguson and colleagues recently analyzed *iStent* placement with cataract surgery in 350 eyes with open-angle glaucoma. In the study, mean IOP decreased from  $19.13 \pm 6.34$  mm Hg preoperatively to  $15.17 \pm 3.53$  mm Hg ( $P < .0001$ ) 2 years postoperatively, and the mean number of medications decreased from  $1.19 \pm 1.00$  preoperatively to  $0.61 \pm 0.96$  ( $P < .0001$ ).<sup>1</sup>

These researchers reported similar findings in a study population with pseudoexfoliative glaucoma.<sup>2</sup> The investigators also found the *iStent* to be effective in pseudophakic patients, with the IOP decreasing from  $20.26 \pm 6.00$  mm Hg preoperatively to  $13.62 \pm 4.55$  mm Hg postoperatively ( $P < .01$ ) and the number of medications reduced from  $1.95 \pm 1.01$  preoperatively to  $1.69 \pm 1.28$  ( $P > 0.05$ ) 1 year postoperatively.<sup>3</sup>

Although the *iStent* is currently only FDA approved to be used in combination with cataract surgery, the implant can be used in a variety of situations.

#### *Ab Interno Canaloplasty*

Ab interno canaloplasty (ABiC) involves placing a microcatheter (*iTrack 250A*; *Ellex*) into Schlemm canal and

threading it for 360°, which permits complete access to the collector channels without leaving behind any devices. ABiC can be performed as a standalone procedure or in combination with cataract surgery (see *Watch It Now* on p. 67).

In a recent study of 130 patients who underwent ABiC in combination with cataract surgery, mean IOP decreased from  $17.1 \pm 5.0$  to  $13.1 \pm 2.1$  mm Hg at 12 months ( $n = 34$ ).<sup>4</sup> The mean number of medications was  $2.0 \pm 1.0$  at baseline and decreased to  $1.0 \pm 1.0$  at 12 months. Ninety-eight patients who underwent ABiC as a standalone procedure had a preoperative IOP of  $21.5 \pm 7.4$  mm Hg at baseline. Twelve months after surgery ( $n = 14$ ), mean IOP was reduced by 36.74% to  $13.6 \pm 1.20$  mm Hg. The mean number of medications dropped from  $3.0 \pm 1.0$  at baseline to  $1.0 \pm 1.0$  at 12 months.

#### *Trabectome*

Approved by the FDA in 2006, the *Trabectome* (NeoMedix) was the first MIGS procedure. The surgeon uses microelectrocautery to ablate the trabecular meshwork and inner wall of Schlemm canal. *Trabectome* surgery may be performed independently or in conjunction with other intraocular procedures such as cataract extraction and IOL placement (see *Watch It Now* on p. 67). Researchers recently reported the 10-year outcomes of 5,435 cases (2,250 eyes underwent ab interno trabecular ablation plus phacoemulsification).<sup>5</sup> Ninety months postoperatively, IOP had decreased from an average preoperative level of  $23.0 \pm 7.9$  to  $16.5 \pm 3.8$  mm Hg ( $P < .01$ ), and the number of glaucoma medications had dropped from  $2.6 \pm 1.3$  to  $1.6 \pm 1.3$  ( $P = 1.00$ ). These results represent an approximately 30% reduction in IOP from baseline, with a significant decrease in medication reliance.

#### *Kahook Dual Blade*

The *Kahook Dual Blade* (New World Medical) removes the trabecular meshwork tissue more completely than a simple incision; it surgically creates a cleft more resistant to closure and produces more sustained IOP control.<sup>6</sup> Major advantages of the procedure are that it can be performed alone or simultaneously with cataract surgery, it requires no additional materials or equipment, and it can be used in cases of mild to severe glaucoma (see *Watch It Now* on p. 67).

## WATCH IT NOW

**Michael Greenwood, MD, implants the iStent Trabecular Micro-Bypass Stent.**



**Mahmoud A. Khaimi, MD, demonstrates ab interno canaloplasty to restore the aqueous outflow pathway.**



**Sameh Mosaed, MD, combines Trabectome surgery with cataract extraction.**



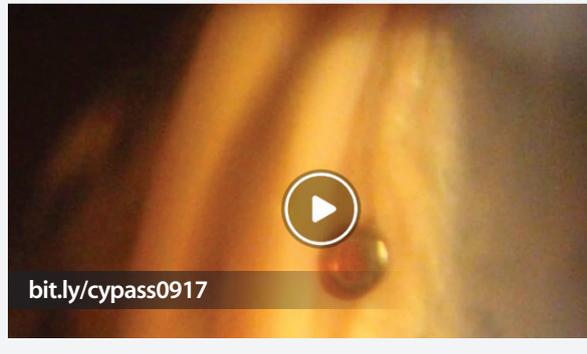
**John Berdahl, MD, presents his goniotomy technique using the Kahook Dual Blade.**



**In this episode of Glaucoma Today Journal Club, Steven Sarkisian Jr, MD, explains how to perform ab interno trabeculotomy with the Trab360.**

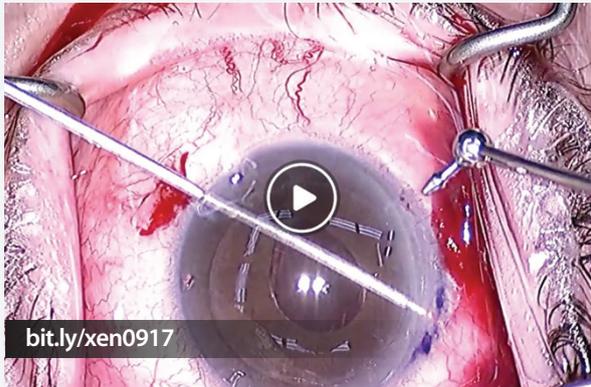


**Russell Swan, MD, implants the CyPass Micro-Stent.**



## WATCH IT NOW

Dr. Greenwood shares his first Xen case.



In this episode of CRST Journal Club, Cathleen McCabe, MD, joins James Katz, MD, to share data on the Hydrus Microstent and to describe the device and its implantation.



John Berdahl, MD, implants the iStent Supra in a patient with a history of Trabectome surgery.



In a recent study, 71 eyes underwent cataract surgery combined with the Kahook Dual Blade procedure. The baseline IOP in this group was  $17.4 \pm 5.2$  mm Hg, and the mean number of hypotensive medications was  $1.6 \pm 1.3$  preoperatively. Nine months postoperatively, the mean IOP was  $12.4 \pm 3.4$  mm Hg, a decrease of 5 mm Hg or 28.7% ( $P < .001$ ), and the number of medications decreased to  $0.6 \pm 0.8$  ( $P = .005$ ).<sup>7</sup>

### Trab360

The Trab360 (Sight Sciences) allows surgeons to unroof 360° of the trabecular meshwork. The ophthalmologist makes a small incision in the trabecular meshwork, advances the probe of the device into Schlemm canal for 180°, and then performs a push-pull motion to unroof the canal. The maneuver is then repeated in the other direction (see *Watch It Now* on p. 67).

In a small study of 26 patients with a mean follow-up period of  $131.5 \pm 101.6$  days, the IOP measured  $19.8 \pm 6.4$  mm Hg preoperatively, and the mean number of medications was  $1.1 \pm 1.2$ .<sup>8</sup> At final follow-up, the mean IOP was  $13.5 \pm 4.6$  mm Hg, and the mean number of medications was  $0.2 \pm 0.5$ , with 19 patients (73%) requiring no medication.

### Supraciliary Space

#### CyPass Micro-Stent

Instead of the traditional pathway of aqueous flow, the CyPass Micro-Stent (Alcon) targets the alternative uveoscleral pathway and allows aqueous to flow from the anterior chamber to the supraciliary space. The device is approved for use in conjunction with cataract surgery (see *Watch It Now* on p. 67).

In a multicenter, interventional, randomized clinical trial of patients who underwent cataract surgery plus placement of the CyPass versus cataract surgery alone, mean IOP decreased by 7.4 mm Hg in the microstent group compared to 5.4 mm Hg in the control group ( $P < .001$ ).<sup>9</sup> Sixty-one percent of the microstent group and 44% of the control group had an unmedicated IOP between 6 and 18 mm Hg. In addition, 85% of microstent subjects versus 59% of the control subjects were free of medication postoperatively.

### Subconjunctival Space

#### Xen Glaucoma Treatment System

The Xen Glaucoma Treatment System (Allergan) aims to lower IOP by creating a subconjunctival drainage pathway. Early this year, the FDA approved the device as a standalone procedure for refractory glaucoma. Prior to implanting the stent, the surgeon places an antimetabolite medication such as mitomycin C in the subconjunctival space. The device is inserted via a needle injector system that passes from the anterior chamber through the trabecular meshwork and sclera, after which it exits under the conjunctiva. The stent is

then deployed. It allows aqueous to flow from the anterior chamber to the subconjunctival space (see *Watch It Now* on p. 68).

Researchers recently reported the results of a study of 41 eyes of 33 patients with open-angle glaucoma who underwent implantation of the Xen in combination with cataract surgery.<sup>10</sup> The mean preoperative IOP was  $22.5 \pm 3.7$  mm Hg on  $2.5 \pm 0.9$  medications. After 12 months, the mean postoperative IOP measured  $13.1 \pm 2.4$  mm Hg (mean IOP reduction of 41.82%) with a mean of  $0.4 \pm 0.8$  medications.

## FUTURE OPTIONS

### Trabecular Meshwork

#### *iStent Inject*

The *iStent Inject* is the second-generation trabecular meshwork bypass stent from Glaukos. The device is currently in phase 3 FDA trials. During this MIGS procedure, two devices are placed in the trabecular meshwork.

In a small study, 20 patients underwent cataract surgery plus implantation of two *iStent Inject* devices and were observed for  $47.4 \pm 18.46$  months.<sup>11</sup> Mean baseline IOP measured  $19.95 \pm 3.71$  mm Hg with medication and  $26 \pm 3.11$  mm Hg after washout. Mean end follow-up IOP was  $16.25 \pm 1.99$  mm Hg, representing a reduction of 36.92% or  $9.74 \pm 3.14$  mm Hg ( $P < .001$ ) from baseline washout IOP. The mean number of medications decreased significantly from  $1.3 \pm 0.66$  to  $0.75 \pm 0.79$  ( $P = .017$ ). Forty-five percent of patients were free of medication by the end of follow-up.

#### *Hydrus Microstent*

Currently in phase 3 FDA trials, the *Hydrus Microstent* (Ivantis) is a crescent-shaped trabecular bypass device that is 8 mm long and straddles 3 clock hours of Schlemm canal (see *Watch It Now* on p. 68). The aim is to access a greater number of collector channels than could be accessed via a smaller device and to dilate the canal. The device acts as a scaffold and does not block the collector channel ostia. Researchers studied 100 patients who underwent cataract surgery alone or in combination with the *Hydrus* procedure and were observed for 24 months.<sup>12</sup> A significantly greater proportion of the combined patients reached the endpoint of a 20% reduction in diurnal IOP (80% vs 46%,  $P = .0008$ ). The IOP was also significantly lower in the combined group ( $16.9 \pm 3.3$

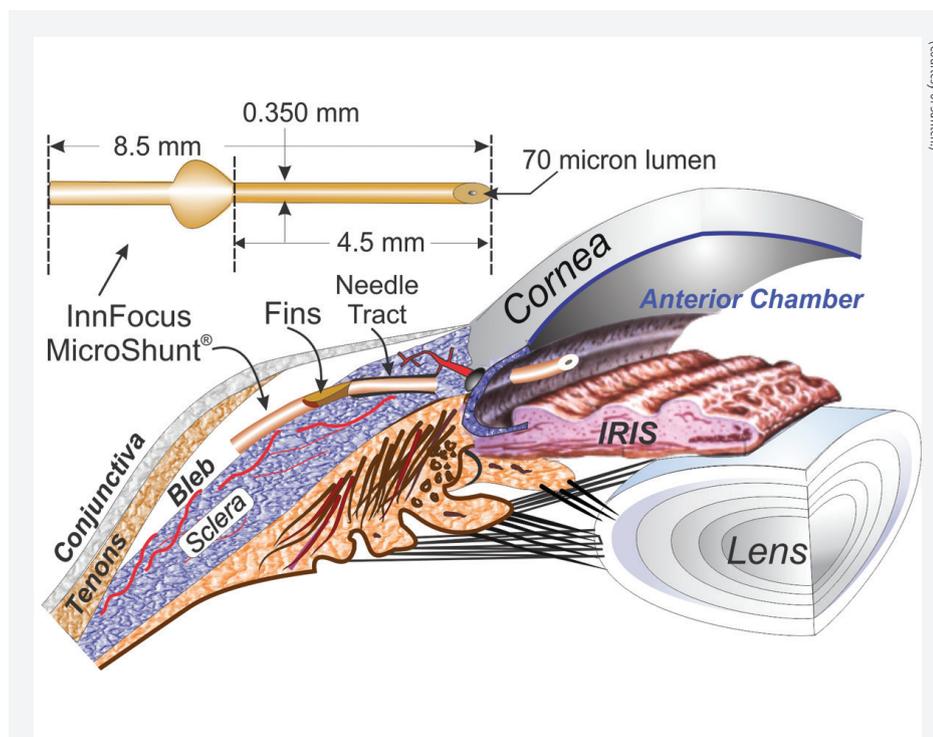


Figure. The InnFocus MicroShunt is an ab externo drainage device.

vs  $19.2 \pm 4.7$  mm Hg,  $P = .0093$ ). A much higher number of patients in the combined group achieved a decrease in ocular hypotensive medication (73% vs 38%,  $P = .0008$ ).

### Supraciliary Space

#### *iStent Supra*

Limited data are available on the *iStent Supra* (Glaukos), which is in phase 3 FDA trials. Like the *CyPass*, the *iStent Supra* targets the supraciliary space (see *Watch It Now* on p. 68). Forty-two patients underwent implantation of the device as a standalone procedure.<sup>13</sup> The mean preoperative IOP was  $20.4 \pm 2.4$  mm Hg, with all patients on two medications, and  $24.8 \pm 3.4$  mm Hg after washout. Postoperatively, all patients were placed on travoprost, and their mean IOP measured 13.2 mm Hg or lower at 1 year. Ninety-eight percent of the eyes were considered as success (decrease in IOP of  $\geq 20\%$  with a reduction of one medication). In the remaining eye, the IOP measured 18 mm Hg, with a reduction of one medication. Furthermore, 90% of patients achieved a postoperative IOP below 15 mm Hg with a reduction of one medication.

### Subconjunctival Space

#### *InnFocus MicroShunt Drainage Device*

The *InnFocus MicroShunt Drainage Device* (Santen; Figure) is an ab externo subconjunctival glaucoma device.

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Compared with other MIGS procedures, implantation of the MicroShunt involves more steps akin to trabeculectomy. Surgery requires a peritomy and dissection of a scleral pocket to allow insertion of an 8.5-mm-long tube with a 70- $\mu$ m inner lumen under the limbus into the anterior chamber. Intraoperative antifibrotics are used, as during trabeculectomy.

In a nonrandomized study of 23 patients who underwent placement of the MicroShunt with or without cataract surgery, overall qualified success (IOP  $\leq$ 14 mm Hg and IOP reduction  $\geq$  20%) was 95% at 3 years.<sup>14</sup> Mean IOP decreased from 23.8  $\pm$  5.3 mm Hg at baseline to 10.7  $\pm$  3.5 mm Hg at 3 years, and the mean number of medications per patient was reduced from 2.4  $\pm$  0.9 to 0.7  $\pm$  1.1.

## CONCLUSION

MIGS procedures continue to be developed to permit the simultaneous treatment of cataracts and glaucoma. More data become available each month. The future is bright for both patients and surgeons. ■

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