Glaucoma Now is a continuing medical education publication. Distributed worldwide, our goal is to educate and update general ophthalmologists, glaucoma specialists and ophthalmology residents. International leaders in the field of glaucoma are invited to contribute to this journal, sharing their most recent insights.

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A newsletter is sent out to participants registered to the program.

Main topic:
“Minimally Invasive Glaucoma Surgery”
Minimally Invasive Glaucoma Surgery

Core Concepts
- MIGS procedures are highlighted by their enhanced safety, enabling their usage earlier in the treatment paradigm and conducive to combining with cataract surgery.
- Schlemm’s canal MIGS procedures have the highest safety profile of all glaucoma surgeries, but are limited by episcleral venous resistance and downstream resistance.
- Suprachoroidal MIGS devices are designed to provide a more controlled cleft procedure, with potentially significant lowering dependent on the size of the suprachoroidal lake.
- Subconjunctival MIGS devices produce external filtering blebs and approach IOP targets similar to trabeculectomy (trab) with a safer and typically more physiological manner. The development of these new procedures into those that are blebless (Table 1). We prefer to subdivide these procedures based on their outflow tendency to flatten out.

2) Definitions
MIGS has been defined as procedures that have an ab-interno approach, are minimally traumatic, with at least modest efficacy, extremely high safety, and rapid recovery. MIGS procedures can be classified based on their outflow mechanism — whether Schlemm’s canal, suprachoroidal, or subconjunctival. MIGS procedures into those that are blebless

1) Introduction
Minimally (or Micro) Invasive Glaucoma Surgery (MIGS) is a term that was introduced over 4 years ago. Questions remain as to what is MIGS? What is the role of MIGS in the current glaucoma treatment paradigm? And how is MIGS evolving?

MIGS is a novel genre of devices and techniques that aim to lower IOP in a safer and typically more physiological manner. The development of these new procedures is dependent on benefit-to-risk ratio, as well as intraoperative and postoperative intensity, cost-benefit, and reimbursement.

surgical options stemmed from the large gap that existed between topical medications on one hand, and traditional glaucoma surgery on the other side. The goal of MIGS procedures is often not just IOP reduction, but reduction and/or elimination of topical medications. This is important considering the poor adherence to medications seen with glaucoma patients. Many of these procedures are combined with cataract surgery, while others have been pegged as a possible standalone procedure.

3) Procedures and devices
Schlemm’s canal procedures are located in one of the safest places to enhance outflow and to do so physiologically. The concept is to bypass the trabecular meshwork, thereby removing the primary point of resistance to aqueous outflow and the site of disease in most glaucomas. However, episcleral venous resistance — while protective against hypotony — limits the amount with which IOP may be lowered. This approach is likely the most technical of all the MIGS techniques. With conventional outflow, location of collector channels and aqueous veins are likely important to reduce outflow resistance. Considering the canal as a 360 degree vessel, it appears that once we get past 4 clock hours, the resistance to outflow tends to flatten out. Furthermore, the ability to place the bypass or remove resistance in the vicinity of major collector channels and/or aqueous veins is likely to further enhance the amount of resistance reduction and IOP-lowering. These procedures can be considered as either micro-stenting, micro-cutting, or micro-ablative procedures.

One of the most commonly discussed and published MIGS device is the iStent (Figure 1). This titanium 1mm stent has a snooked in the anterior chamber and an open half-pipe that resides in Schlemm’s canal thereby allowing aqueous to bypass the trabecular meshwork. Early randomized prospective studies compared phacoemulsification cataract extraction with intra-ocular lens insertion combined with a single (Stent with phaco alone) or combined with phaco alone at 1-year. Subsequent studies comparing the use of two iStents with phaco versus phaco alone found IOP-lowering from 24.2 to 17.6 mmHg on no postoperative medications.

The Trabecome, an ab-interno trabeculotomy technique using micro-ablation is another approach to enhancing Schlemm’s canal outflow. This procedure has been found to lower IOP to the mid-teens (again, often with some medications) with a 30-40% IOP drop, either combined with cataract surgery or as a standalone procedure, as well as having an excellent safety profile. A comparative study of phaco+iStent vs phaco+trabecome
found similar IOP-lowering but with less medications and less postoperative hyphema in the iStent group.17

Schlemm’s canal micro-cutting techniques also include the Gonioscopic Assisted Transluminal Trabeculotomy (GATT) procedure. Similar results to other Schlemm’s canal procedures with mid-high IOP targets and significant IOP lowering with high safety. Recently, a plethora of similar techniques, including the ABC (ab-interno canaloplasty), the Trab360 and Visco360 procedures, and the Kahook Dual Blade have been introduced as Schlemm’s canal procedures that either remove a large strip of trabecular meshwork and/or create ab-interno viscodilation. Further data on these procedures are forthcoming.

Another internal MIGS approach is to enhance uveoscleral outflow by draining aqueous into the suprachoroidal space. These procedures follow the notion of a large retosopic area in this space with potential IOP-reduction. Previous cleft procedures were traumatic, less-controlled, and resulted in potentially wide swings in IOP. Recent MIGS procedures into this space include ab-interno placed micro-stents designed to provide a more, and thus controlled access to the suprachoroidal space, with maintenance of pressure using stent placement. Two such devices are the CyPass micro-stent and iStent Supra micro-stent (Figure 3). These devices have also been studied primarily in conjunction with cataract surgery. A recently published large randomized control study comparing phaco + CyPass versus phaco alone found 65% of phaco/CyPass patients reached a post-CyPass IOP <18 mmHg versus 4% of phaco-alone.15 This study also found safety was comparable with phaco-alone.

Both Schlemm’s canal approaches and suprachoroidal MIGS devices appear to be reasonably helpful when combined with cataract surgery in an effort to reduce medication burden in a safe and effective manner. Although these devices and MIGS procedures lack the potency of external filtration, the attraction of a safer procedure may allow them to be considered earlier in disease and comfortably combined with phaco. There are some instances where they may be performed as a standalone procedure: mostly for mild-to-moderate glaucoma where IOP targets are more modest (mid-to-high teens). Patients also must be prepared to use medications to reach these targets or lower.

To enable further IOP-lowering, albeit with external filtration, the Xen gel stent and its ab-interno micro-stent that creates a communication between the anterior chamber and the trabecular outflow pathway (Figure 4) has the ability to create a more posterior bleb that is desirable, what is known as the Xen goal of this procedure. The use of Mitomycin-C is often necessary to help modulate wound healing. Early published results show a very good safety profile of this device, while approach (approaching IOP reduction that are closer to trabeculotomy standards). This enables this device to be considered as a standalone procedure, or combined with phaco if needed. The ability to efficiently and effectively create an external filtering bleb through an ab-interno approach is an attractive alternative to trabeculotomy (trab) for many patients and may allow this device to be considered for patients with earlier disease (less damage) due to its enhanced comparative safety and control.

Although not strictly a MIGS procedure, the InnFocus micro-shunt is delivered through an ab-exitro approach, and can produce a more posteriorly placed well tolerated bleb (Figure 5). It also is often used with Mitomycin-C and has been found to also lower IOP to trab-like levels into the low-normal range and provide a very good safety profile.16 Both the Xen and the InnFocus devices have IOP more than iMIGS devices, although they do rely on creation of an extraocular bleb albeit with what appears to be a more controlled, safer, and better tolerated procedure with faster recovery than often with trabeculotomy. These devices are thus more likely to be used as a standalone procedure for patients requiring a potent IOP-lowering drop, and/or combined with phaco for lower IOP targets.

4) Conclusion

It is exciting to see a new era of glaucoma interventions with MIGS procedures. No doubt, much more data, longer-term results, and cost-effectiveness studies must be produced to better understand their role. The use of MIGS also requires a change in the mindset of the clinician to move towards addressing adherence in a more interventional and proactive way. The opportunity to combine many of these devices with phaco in a safer manner has helped reduce medication burden while providing modest IOP-lowering. External filtering and MIGS procedures may approach IOP targets similar to trabeculotomy but with a more controlled, less-invasive, and potentially safer approach. The potential synergy with advances in drug delivery and MIGS may further broaden the application of these procedures. As with any therapy, the balance of benefit and risk must be considered in an individualized, patient-centric manner. We look forward to more developments in this growing field of interventional glaucoma.

References


What’s New
Update on MIGS

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Core Concepts
• Newer techniques are evolving with the promise of less risk of vision-threatening complications.
• Most need more study before being placed in our range of anti-glaucoma surgical strategies.
• A summary of current knowledge is provided in Table 1.
• Possible utilization of various MIGS procedures based on glaucoma severity is proposed in Table 2 – based on current knowledge; subject to change as more information and experience become available.
• While no comparative studies are available yet, possibly some of these newer procedures will allow us to consider surgical treatment earlier in the glaucoma treatment algorithm.
• Safety and predictability of effectiveness will determine this.
• Enhanced interest in better surgical approaches to glaucoma portends exciting times ahead.

1) Why MIGS?
The goal of glaucoma surgery is to lower intraocular pressure (IOP) to a level that will retard or prevent further loss of ganglion cells and, thus, loss of vision. Standard glaucoma surgeries such as trabeculectomy and ExPRESS shunts, external tube-shunts like the Ahmed, Baerveldt and Molteno styles and transcleral cyclophotocoagulation are major surgeries.

While they are very often effective at lowering IOP and preventing progression of glaucoma, they have many potential complications that can interfere with vision temporarily or permanently, such as prolonged hypotony, hemorrhage, leaking blebs and bleb related infections.

Recently, several new glaucoma procedures have emerged, designed to minimize some of the visually threatening complications of conventional glaucoma surgery. These new surgeries are collectively called minimally invasive glaucoma surgery (MIGS) because they are performed through very small incisions; they reduce complications by miniaturizing the older procedures or finding new aqueous drainage pathways. While they reduce the incidence of some of the potentially devastating complications, they are less effective. The MIGS group of operations are divided into:
• miniaturized versions of trabeculectomy (e.g. Xen and Midri-Arrow implants)
• trabecular bypass operations (e.g. Trabectome, Trab360, iStent)
• suprachoroidal shunts (e.g. Cypass or Glaukos shunts) and
• gentler versions of laser photocoagulation (e.g. endocyclophotocoagulation and Micropulse cyclophotocoagulation).

2) Miniaturized Anterior Filtering Operations
External filtering operations have been the mainstay of glaucoma surgical care. The main vision-threatening complication is hypotony usually from excessive filtration. Hypotony can lead to other complications that reduce vision such as suprachoroidal hemorrhages, maculopathy, corneal decompensation, cataract and optical instability. Because of the adjective use antifibrosis agents like mitomycin C, potentially devastating late bleb leaks and bleb-related infections are more common.

The newer approaches to filtration using smaller incisions and diameters reduce the risk of overfiltration. One such device, the MIGS-Arrow Glaucoma Device is a tiny tube made of a biocompatible polystyrene compound that has shown promising results in a multinational study of 79 patients (average IOP 11.6 at two years) with a low rate of hypotony (<10%, all transient). IOP reduction seems to persist even into the third year in a high risk-failure population. The MIGS-Arrow is implanted ab externo under conjunctiva and into the anterior chamber. Because of its small size, the conjunctival incision is very small, facilitating watertight closure. Clinical trials are underway for U.S. Food and Drug Administration (FDA) approval.

A similar device made of collagen and implanted ab interno via a trans-corneal incision is the XEN Gel stent. While no results have been published, reports of early trials also have been promising. This device has a CE mark and is undergoing trials in the USA to obtain FDA approval.

3) Trabecular Meshwork Bypass
Based on studies by Chandler and Grant, aqueous outflow obstruction in open angle glaucoma is assumed to lie in the trabecular meshwork. Removal or bypassing of the trabecular meshwork should restore normal or near-normal outflow.

Ab externo trabeculotomy was tried but found to be ineffective in adult open angle glaucoma. However, trabeculotomy with the Trabecome, an electrosurgical device that is inserted ab interno into Schlemm’s canal to ablate a 1 mm swath of trabecular meshwork over 160 degrees or so, has shown to be effective in many patients to reduce both IOP and dependence on anti-glaucoma medications when performed once or when combined with cataract extraction.

Complications include transient hypotony (about 20%) and early post-operative pressure spikes. The procedure requires a relatively expensive console as well as a disposable hand piece.

Similar results seem to be obtained with a device that inserts a suture-like material into Schlemm’s canal under gonioscopic control and once the suture has been threaded 180 degrees, is pulled out of the eye taping 180 degrees of trabecular meshwork. The device (the Trab360) can then be turned around and the other 180 degrees of trabecular meshwork torn through the same incision. Although the handheld piece is not reusable, since no capital equipment is required, it may be more affordable than the Trabecome.

A similar result can also be accomplished with the iCath device (Ellex) which can be threaded 360 degrees through a small incision under gonioscopic control and then pulled noose-like to tear the entire trabecular meshwork (Gonioscopic Assisted Transluminal Trabeculotomy-GATT). All these procedures have the advantages of a small incision, relatively low serious complication rates and usability with or without cataract procedures. When they work, they generally reduce IOP to around 16 and appear more suitable for mild to moderate glaucoma, with higher target IOPs.

Yet another strategy with the same goal is to make precise holes through the trabecular meshwork into Schlemm’s canal with an excimer laser. No pricing is available yet for the equipment, but it is likely to be costly.

One company has adapted their trab630 instrument to inject viscoelastic into Schlemm’s canal, dilating it to reduce IOP. No published reports are available for this procedure to date.

Another approach to bypass the trabecular obstruction is to place ab interno a tiny snooked-like device to shunt aqueous from the anterior chamber directly to the Schlemm’s canal. The intent is to reduce or even eliminate the need for antiglaucoma medications. The Trab40 device inserts a device that is pulled into the anterior chamber via a small (~2mm) corneal incision. The inserting instrument crosses the anterior chamber to the area of the trabecular meshwork opposite the incision, the leading edge engages the meshwork and slides into Schlemm’s canal leaving a small snoked-like protrusion in the anterior chamber. A randomized controlled trial comparing the iStent combined with cataract surgery

PROCEDURE
TRABECTOME
ISTENT
HYDRUS
TRAB 360
EXCIMER LASER TRABECULOTOMY
CYPASS
MIDI-ARROW (INFOCUS)
XEN GEL
AP- APPROACH
Internal
Internal
Internal
Internal
Internal
Internal
External
External
ALONE OR WITH CATARACT SURGERY
Alone
With
With
Alone
With
With
Both
Both
NUMBER OF SUBJECTS
46
117
50
26
18.8
4
21
37
INITIAL IOP (MMHG)
25.7
18.4
14.8
19.8
23.9
12.4
12.4
15.4
LENGTH OF LAST FOLLOW UP (MOS)
24
24
24
20
12
11.1
11.1
12.4
IOP @ LAST F/U
16.6
16.0
16.9
19.8
15.4
14.9
11.1
15.4
# MEDS @ LAST F/U
40%
19%
N/A
32%
23%
N/A
54%
31%
% REDUCTION
1.2
0.2
N/A
0.2
0.9
0.8
0.3
0.9
Table 1. Some reported data for various MIGS procedures (N/A = not available)

Table 2. Possible Patient Selection for MIGS procedures based on current knowledge; likely to change as more information and experience become available. (MPTCP = micro pulse trans-scleral cyclophotocoagulation; ECP = endocyclophotocoagulation; GDD tube = glaucoma drainage device tube shunt)
surgery with cataract surgery alone showed no difference in IOP at two years but a reduction in medication needs. When successful, the procedure seems to maintain good IOP out to three years. For further IOP reduction two or more stents can be inserted in the same eye. The iStent is approved by the U.S. FDA and despite a rather high price, has become popular, especially when combined with cataract surgery. A similar product, the Hydrus with a longer arc of metal and a scaffold structure (3 clock hours of the canal is supported) is being trialled; it seems to achieve IOP in the mid teens at two years with reduced medication needs and low complication rates.

4) Suprachoroidal shunts
Cyclodialysis was a relatively common procedure for glaucoma especially in aphakic eyes in the middle of the last century. A simple tube shunting fluid from the anterior chamber to the suprachoroidal space could lower IOP reliably. Currently, one device, the Cypass has received CE mark approval in Europe with data submitted to the FDA. This is a tiny tube, made of nylon-like material, inserted ab interno across the anterior chamber under gonioscopic control into the suprachoroidal space. To date there have been few serious complications. IOPs have settled in the mid-teens whether performed with or without concomitant cataract surgery. A similar device under study is the iStent SUPERA.

5) Newer approaches to Cyclophotocoagulation
Cyclodestructive procedures whether performed trans-sclerally with freezing or with laser energy have been a last gasp effort to control IOP. Laser energy has or without concomitant cataract surgery.

Figure 1: Classification of glaucoma surgery. Modified from Shaarawy.

References
11. Sommer T, Fossos G, et al: The iStent Supra. A similar product, the Hydrus with a longer arc of metal and a scaffold structure (3 clock hours of the canal is supported) is being trialled; it seems to achieve IOP in the mid teens at two years with reduced medication needs and low complication rates.
13. For further IOP reduction is modest, these are useful for mild to moderate open angle glaucoma cases, particularly combined with cataract surgery.
14. The newer gel stent, Xen increases subconjunctival filtration and acts like a trabeculoplasty, its target population may be different from canal-MIGS.
15. Core Concepts
• The most commonly used MIGS are aimed to enhance Schlemm’s canal outflow including the Trabecome, iStent and Hydrus microstent. As intraocular pressure reduction is modest, these are useful for mild to moderate open angle glaucoma cases, particularly combined with cataract surgery.
• The newer gel stent, Xen increases subconjunctival filtration and acts like a trabeculoplasty, its target population may be different from canal-MIGS.
• iStent, Hydrus microstent and the subconjunctival-MIGS: the Xen gel implant.

Figure 1: Classification of glaucoma surgery. Modified from Shaarawy.

3) Suprachoroidal drainage
MIGS

The Cypass and iStent SUPRA can achieve suprachoroidal drainage. Further study will determine whether target populations for the suprachoroidal-MIGS are similar to those for canal-MIGS.

4) Subconjunctival filtration
MIGS

The Xen Gel stent is a permanent device that connects the anterior chamber to the subconjunctival space (figure 2). The XEN is the model that has been commercially launched in some parts of the world; currently it is available in EU, Turkey, Canada and Switzerland.

Being a subconjunctival-MIGS, the XEN is claimed to reduce IOP more significantly than other MIGS procedures; it might be useful for a different target population: it acts more like a trabeculotomy. Patients with higher IOPs may be suitable for the XEN as the final IOP is determined by Xen’s lumen and length (Hagen-Poiseille equation). Target eyes have open angle glaucoma with indications for a trabeculectomy and have at least 2 clock hours of healthy conjunctiva in the target area. Xen has been used in a case of previously failed trabeculectomy. Secondary glaucomas should be avoided; further studies are required to refine those patients most likely to benefit from the Xen.

References

1) Introduction
One key factor to achieve success with minimally invasive glaucoma surgery (MIGS) is implantation of the device of choice (eg: iStent Generation 1, iStent inject, Hydrus, Cypass, iStent SUPRA and Xen) in the correct location. The chance of doing so is maximized by appropriate patient selection and by attention to a number of factors during surgery.

2) Pre-operative Assessment

Pre-operative gonioscopy is mandatory. Suitable eyes are those with a wide open angle or those in whom the angle is likely to open widely following removal of cataract. Implantation in angles that are narrow may be technically difficult and lead to peripheral anterior synechiae (PAS) and stent obstruction or corneal decompensation if the implant touches the corneal endothelium. Eyes with evidence of elevated episcleral venous pressure may not be suitable for a trabecular meshwork bypass stent as there is likely to be insufficient pressure gradient to lower intra-ocular pressure (IOP).

3) Intra-operative:

Under filling the anterior chamber with visco-elastic makes intra-operative goniocopy difficult.

Avoid limbal blood vessels when positioning the corneal incision as bleeding will obscure the view.

1) Head & Microscope Position

When filling the anterior chamber with visco-elastic, under filling will result in a decreased goniocopy view. If this may aid identification of Schlemm’s canal from blood reflux, it makes intra-operative goniocopy technically difficult. Application of the gonioscope when IOP is low will easily cause corneal striae and result in poor contact between prism and cornea (figure 2). Adding more visco-elastic to the anterior chamber will increase the IOP, thus eliminating the striae and poor contact. With further filling of the anterior chamber, the IOP will rise further and eventually reach a point when Schlemm’s canal collapses. Theoretically it may be more difficult to implant some stents such as Hydrus and iStent Generation 1 under these conditions, whereas others such as iStent inject, Cypass and Xen may be little affected.

When considering the position of the corneal incision, this can make the difference between easily performing stent implantation or having great difficulty. The location determining the site of entry of the introducer and the section of angle to which the surgeon has access. It may also have an unintended effect on the view through the gonioscope. The coreo-scleral limbus is vascular so too peripheral corneal incisions can cause bleeding that will track across the corneal surface and become embedded in the visco-elastic used to coat the lens with the cornea (figure 3). As a result, blood obscures the view and the surgeon will be frustrated by the repeated need to clear the ocular surface. This is easily avoided by positioning the incision mid-peripherally, away from peripheral corneal blood vessels.

References
STATEMENT OF NEED AND PROGRAM DESCRIPTION

Recent months and years have seen significant advances in our understanding of glaucoma. Much has been learned, not only about damage mechanisms and pathogenesis, but also about diagnosis and management. Treatment options – both medical and surgical – continue to expand. This program will review this new knowledge with an emphasis on incorporating recent insights into day-to-day practice.

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Participants have an implied responsibility to use newly acquired information to enhance patient outcomes and professional development. The information presented in this activity is not meant to serve as a guideline for patient care. Any procedures, medications, or other courses of diagnosis or treatment discussed or suggested in this activity should not be used by clinicians without evaluation of their patient's conditions and possible contraindications or dangers in use, applicable manufacturer's product information, and comparison with recommendations of other authorities.

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