

Ushering in the era of MIGS in India



ABSTRACT

Incisional filtration surgery with bleb formation has been the mainstay of glaucoma surgery for decades and is particularly useful in progressing or advanced glaucoma. However, the flipside of these procedures is the sight-threatening complications that may occur. Minimally Invasive Glaucoma Surgery has made in-roads in the past two decades – these are known to be high on the safety aspect and therefore can be used much earlier on in the disease spectrum. Some of these relatively new devices and procedures are now available in India also.

Keywords: Cycloablation, endoscopic cyclophotocoagulation, gonioscopy-assisted transluminal trabeculotomy, iStent, micropulse diode, MIGS, minimally invasive glaucoma surgery, trabecular meshwork, trabeculotomy

INTRODUCTION

Glaucoma encompasses a heterogeneous group of diseases that are identified by a characteristic chronic optic neuropathy with correlating visual field defect/s. Although several risk factors are known, intraocular pressure (IOP) is the most important one as it is the only modifiable one. Therefore, all management modalities – medical, laser, or surgical, are directed toward IOP alone. Medical management is the mainstay of treatment for the majority, but a significant proportion of glaucoma patients require a surgical procedure for the control of the disease. Up until recently, surgical procedures that were available included only those that drained in the subconjunctival space [Figure 1A] (trabeculectomy and glaucoma drainage devices). Although efficacious, it is precisely this manner of drainage with the creation of a bleb that is responsible for either failure due to fibrosis or

long-term sight-threatening sequelae (hypotony, leakage, infection, etc.) or both. It is perhaps this morbidity associated with these procedures which is the prime determinant of its use mostly in medically resistant, refractory, and usually advanced glaucoma. However, over the past two decades, several innovative procedures and devices^[1,2] have spawned out of a concern for increased safety in glaucoma surgery such that it can be offered to the patient much earlier on in the disease spectrum, especially in combination with cataract surgery. These are called minimally or microinvasive glaucoma surgery (MIGS). Minimally invasive procedures are the way forward not only in ophthalmology (extracapsular


VANITA PATHAK-RAY

Centre for Sight, Hyderabad, Telangana, India

Address for correspondence: Dr. Vanita Pathak-Ray, Centre for Sight, Road No. 2 Banjara Hills, Hyderabad - 500 034, Telangana, India.
E-mail: vpathakray@gmail.com

Submitted: 03-Feb-2022
Accepted: 03-Mar-2022

Revised: 27-Feb-2022
Published: 21-Apr-2022

Access this article online	
Website: www.kjophthal.com	Quick Response Code 
DOI: 10.4103/kjo.kjo_13_22	

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

For reprints contact: WKHLRPMedknow_reprints@wolterskluwer.com

How to cite this article: Pathak-Ray V. Ushering in the era of MIGS in India. Kerala J Ophthalmol 2022;34:3-7.

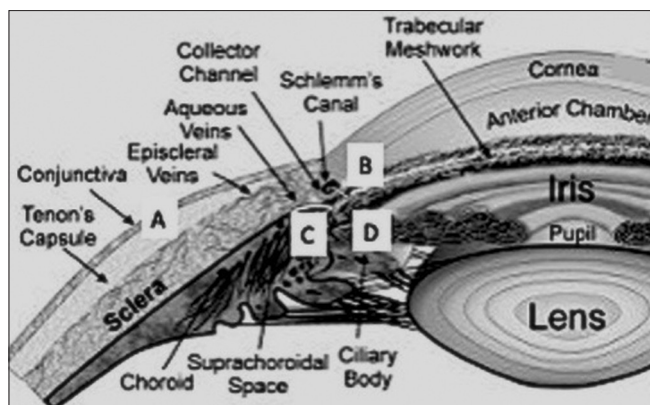


Figure 1: Section of the eye showing subconjunctival drainage (A) and through the trabecular meshwork (B) along with suprachoroidal space (C) as well as the ciliary body (D)

cataract surgery being replaced by microincisional cataract surgery, Descemet membrane endothelial keratoplasty vs. penetrating keratoplasty, etc.) but also in other surgical specialties too. For instance, in spinal surgery, conventional fusion techniques have now been replaced with prostheses with better outcomes, even though it comes at a much greater cost.

WHAT IS MIGS?

“MIGS” is a term applied to a wide range of implants, devices, and techniques that lower IOP with less surgical risk than the more established bleb-forming procedures (trabeculectomy, glaucoma drainage devices viz. Ahmed glaucoma valve, Aurolab aqueous drainage implant).

Such a surgery usually tends to have the following characteristics: less or minimally invasive or traumatic to the conjunctiva (there are exceptions – e.g., XEN, PreserFlo), usually “ab-interno,” usually bleb-independent, usually combined with cataract surgery with reduced surgical time, rapid visual recovery, and high safety profile. These latter characteristics along with the fact that they are cosmetically more acceptable too, make these procedures very patient-friendly.

The Food and Drug Administration or FDA (of the USA) described MIGS as “a type of IOP-lowering device used to lower IOP using an outflow mechanism with either an ab-interno or ab-externo approach, associated with little or no scleral dissection and minimal or no conjunctival manipulation.”^[3]

WHAT ARE THE TYPES OF MIGS?

MIGS devices and procedures utilize the hitherto surgically untapped pathways of drainage including the trabecular

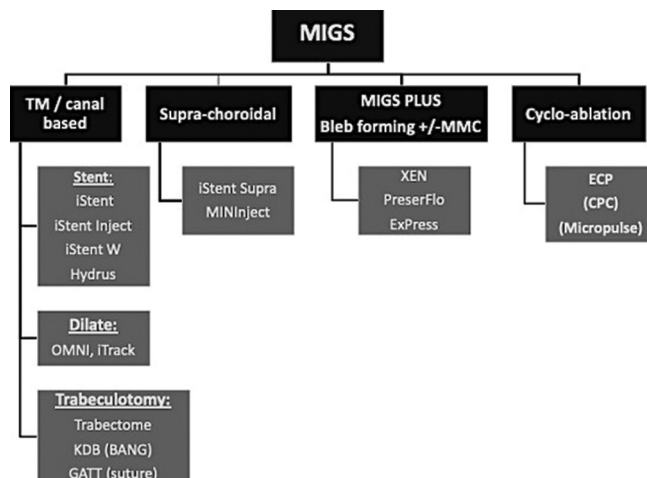


Figure 2: Classification of minimally invasive glaucoma surgery

meshwork (TM) [Figure 1B], suprachoroidal space [Figure 1C], and also targets the seat of aqueous production – the ciliary body (CB) itself [Figure 1D]. While the former two pathways need an open angle, the cycloablative procedures targeting the CB can be used independent of angle status. Therefore, the devices and procedures [Figure 2] may be categorized as those that increase trabecular outflow through the Schlemm's canal (SC) – which can be stented with iStent®, iStent® Inject, or iStent® Inject W (all Glaukos Corp, CA, USA) or with the Hydrus (Alcon, Tx, USA). Or it can be dilated with OMNI (Sight Sciences Inc. CA, USA) and iTrack (Nova Eye Medical, SA). Or a trabeculotomy can be done with several devices and procedures – Trabectome (NeoMedix Corporation, CA, USA), Kahook Dual Blade (New World Medical, CA, USA), or a 360° trabeculotomy can be performed by doing a gonioscopy-assisted transluminal trabeculotomy (GATT) with an OMNI device. Devices that can be placed in the suprachoroidal space are iStent® Supra (Glaukos Corp, CA, USA), MINject (iStar Medical, Belgium), etc. Cycloablation or cyclophotocoagulation can be done either by directly viewing and targeting the CB with the assistance of an endoscope (Beaver-Visitec International, MA, USA) or through the transscleral route with the micropulse diode (Iridex, CA, USA) causing less collateral thermal damage compared to the conventional continuous-wave one.

There is another group of devices categorized as MIGS-Plus as they do not strictly satisfy all criteria of MIGS because they drain into the subconjunctival space creating a bleb and therefore can demonstrate all complications related to this type of drainage. These include the XEN (Allergan, Dublin, Ireland) and PreserFlo (Santen, Osaka, Japan).

WHAT ARE THE INDICATIONS OF MIGS?

Mild-to-moderate open-angle glaucoma – be it primary open-angle glaucoma or pseudoexfoliation glaucoma or even

pigment dispersion syndrome. It is generally not indicated in primary angle-closure glaucoma unless the angle opens up post laser peripheral iridotomy. Intolerance to topical medications and other barriers for continued usage of antiglaucoma medications (AGMs), for example, allergy, poor compliance and adherence, concerns about lifelong cost of therapy, etc., are also indications for MIGS procedures.

WHAT IS THE EFFICACY OF MIGS?

Randomized control trials (RCTs)^[4,5] and systematic reviews and meta-analyses^[6-9] of several of these procedures, with or without cataract surgery, indicate that the IOP lowering efficacy lies in the range of 25%–40% at around 1-5 years follow-up and a reduction of medication of approximately 40%–50%. Generally, the subconjunctival bleb-forming devices have a greater reduction in IOP but also required more bleb-management in the postoperative period. Another systematic review^[10] concluded that although MIGS is efficient in the reduction of both IOP and AGM and demonstrate a good safety profile but the evidence is mainly derived from noncomparative studies and that further good quality RCTs are warranted.

A recent overview of Cochrane systematic reviews^[11] and network meta-analysis of MIGS in open-angle glaucoma reported that some MIGS may afford patients greater drop-free disease control than cataract surgery alone.

A position paper on MIGS^[12] published by the American Glaucoma Society favored patient access to these procedures and also those efforts that permit the clinician and patient to decide jointly which intervention(s) along the entire spectrum of care are best for them based on their unique circumstances.

WHAT ARE THE COMPLICATIONS OF MIGS?

Complications associated with MIGS are usually infrequent and mostly transient due to the less-invasive approach compared to trabeculectomy and tube shunt surgery.^[13] Hyphema due to reflux occurs commonly after TM procedures (up to 70%); acutely elevated IOP has been observed in 2%–21%, peripheral anterior synechiae and Descemet's membrane detachment have also been described. However, shallow or flat anterior chamber and hypotony are usually transient and choroidal effusion rarely occurs.

HOW IS MIGS DIFFERENT TO THE CURRENT GOLD STANDARD?

As stated before, there are several advantages of MIGS procedures and devices. As most of these devices and

procedures are bleb-independent, risk of hypotony is low; other bleb-related complications and side-effects are also avoided, with the exception of subconjunctival filtering MIGS-Plus devices (XEN, PreserFlo). Thus, early and late bleb leak, blebitis, bleb-associated endophthalmitis, and bleb dysesthesia are all avertible. However, quite such as trabeculectomy, failure of bleb due to episcleral fibrosis is a real concern in subconjunctival MIGS-Plus filtering devices.

Other advantages include – shorter operating time, can be easily combined with phaco surgery, rapid recovery, and early visual rehabilitation without need for increased frequency of postoperative visit/s. Furthermore, they can be offered earlier on in the disease, rather than the need to wait for the disease to progress or become uncontrollable and/or advanced. Reduction in the use of AGM has the added advantage of increased compliance and adherence with improved quality of life. Being atraumatic to the conjunctiva, trabeculectomy can still be performed, should it be required in future.

The main disadvantage of these MIGS procedures is its modest ability to reduce IOP. There appears to be a downstream resistance to flow below 16 mmHg in the SC drainage routes – this presents a potential limitation of trabecular restoration in patients with glaucoma in the presence of normal aqueous inflow.^[14] Further lowering requires additional aqueous suppression treatment, which can be a real disadvantage if low target IOP is indicated or medication use is to be avoided.

It is therefore generally not recommended in advanced disease, nor in situations where IOP is uncontrolled despite maximally tolerated medications. Furthermore, they require the additional skill of intraoperative gonioscopy. The cost of these devices can also be a barrier to its uptake.

TIPS FOR A SUCCESSFUL MIGS PROCEDURE

Successful implantation of a MIGS device (or procedure) demands a new set of skills, hitherto not taught or

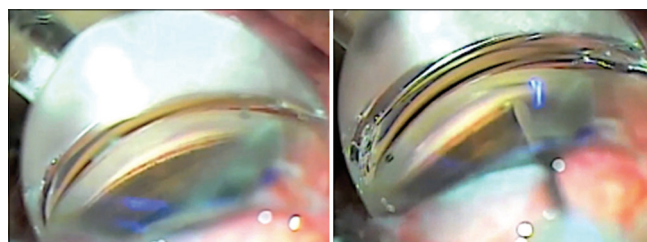


Figure 3: Intraoperative gonioscopy with wide open-angle and “en-face” visibility of the trabecular meshwork (left) and iStent® trabecular micro-bypass being implanted (right)

sparingly imparted in our training programs. The single most important aspect is the practice of intraoperative gonioscopy with a direct gonio lens and the familiarization of the angle structures under high magnification, and the ability to demonstrate forward-facing or “en-face” view of the TM [Figure 3, left]. For this purpose and for best visualization, the microscope needs to be rotated 35° toward the surgeon and the patient’s head (and eye) has to be turned 35° away from the surgeon. Furthermore, a temporal approach is best suited for MIGS procedures. Preprocedure, preplanned intraoperative gonioscopy in this manner in several routine temporal incision phaco alone procedures go a long way in the preparedness for the actual procedure.

HOW RELEVANT IS MIGS IN INDIA?

Poor and variable availability of specialized health care, late access and presentation, affordability, and greater occurrence of angle-closure disease when compared to developed nations are all factors that contribute to increased glaucoma-related morbidity in a country like ours. Even though MIGS procedures are desirable as they are bleb-independent with a better safety profile, on the face of it, for all the reasons stated, its use in our population may appear to be limited. However, a significant proportion of ocular hypertensives or early glaucoma patients, who are on multiple AGM and are due to undergo cataract surgery may be offered MIGS along with it. Another group of patients seem to be emerging – those that are intolerant to multiple AGM – they too will benefit from conjunctiva-sparing procedures, as blebs tend to fail in such eyes. In any case, a bleb-producing invasive procedure may seem excessive in both these scenarios. Furthermore, as conjunctiva is not disturbed, MIGS do not compromise future filtration, if required.

However, the expense may be a major consideration, especially in developing countries. Furthermore, with the exception of cyclophotocoagulation, these devices and procedures do not have relevance in synechiae angle closure. Nonetheless, when seen from the perspective of the patient, it not only improves their quality of life with none or fewer AGM but also lesser postoperative visits and faster visual rehabilitation postsurgery.

Currently, there is limited availability of MIGS devices and procedures in India when compared to the Western world. The MIGS that is available consist of mainly those that target the TM to unroof the SC or those that ablate the CB. Most of the MIGS that target the TM are the low-cost versions of their Western counterparts – use of prolene suture in GATT for 360° unroofing of SC versus OMNI and use of a bent needle

in BANG or Bent-needle Ab-interno Goniotomy instead of KDB (regulatory approvals not yet granted in India) to perform a trabeculotomy. The Trabectome is available in some centers, but the electrocautery probe is disposable in nature and incurs a recurrent cost, even after the capital expenditure (capex) is made for the acquisition of the machine.

The cycloablative diode procedures – endoscopic or transscleral micropulse diode – require capex too; the former utilizes a reusable probe obviating recurrent cost, but not the latter.

The newest entrant in the world of MIGS in India is the iStent® and iStent® Inject (Glaukos Corp, CA, USA) – the very first procedure was done in September 2021 [Figure 3, right]. These are the smallest devices known to humankind and are considered trabecular micro-bypass.

There is a paucity of data related to MIGS procedures in Indian eyes, few are available but mainly in cycloablative procedures. Endoscopic cycloablation can be considered the “original” MIGS, as it was described by Uram^[15] in the early 1990s. It has achieved moderate success in open-angle glaucomas^[16] (and refractory too) but its value seems to be in primary angle-closure disease, the real scourge of our country, where it may prove to be a game changer.^[17-22] Micropulse diode may also prove beneficial^[23,24] but there is a need to build up more evidence in primary glaucomas.

In summary, due to its enhanced safety profile, even though IOP control is modest, MIGS devices are designed to address the treatment gap that exists between medical therapy and the more aggressive traditional surgical options. They also help to decrease the AGM burden and therefore impact positively on compliance and adherence issues in glaucoma therapy. MIGS devices are expensive largely due to the research and development costs being recouped by the industry that developed them. On the other hand, ophthalmologists tend to be dismissive of it primarily citing the cost, without actually performing a single procedure of MIGS. For the purpose of bridging the gap between medical therapy and the leap to incisional surgery, ophthalmologists providing glaucoma care will need to overhaul current practices in the management of the disease and invest time and effort in the learning of intraoperative gonioscopy-based MIGS procedures. Therefore, the cost may not be the greatest limiting factor in the widespread adoption of MIGS in a country like ours.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

REFERENCES

1. Saheb H, Ahmed II. Micro-invasive glaucoma surgery: Current perspectives and future directions. *Curr Opin Ophthalmol* 2012;23:96-104.
2. Pathak-Ray V. Advances in glaucoma surgery: Paradigm shift in management. *Oman J Ophthalmol* 2016;9:1-2.
3. Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) devices: Guidance for Food and Drug Administration Staff. US Food and Drug Administration. Available from: <https://bit.ly/2L95zwp>. [Last accessed on 2015 Dec 15].
4. Ventura-Abreu N, García-Feijoo J, Pazos M, Biarnés M, Morales-Fernández L, Martínez-de-la-Casa JM. Twelve-month results of ab interno trabeculectomy with Kahook Dual Blade: An interventional, randomized, controlled clinical study. *Graefes Arch Clin Exp Ophthalmol* 2021;259:2771-81.
5. Samuelson TW, Chang DF, Marquis R, Flowers B, Lim KS, Ahmed II, *et al.* HORIZON investigators. A schlemm canal microstent for intraocular pressure reduction in primary open-angle glaucoma and cataract: The HORIZON study. *Ophthalmol* 2019;126:29-37.
6. Healey PR, Clement CI, Kerr NM, Tilden D, Aghajanian L. Standalone iStent trabecular micro-bypass glaucoma surgery: A systematic review and meta-analysis. *J Glaucoma* 2021;30:606-20.
7. Gillmann K, Mansouri K. Minimally invasive glaucoma surgery: Where is the evidence? *Asia Pac J Ophthalmol (Phila)* 2020;9:203-14.
8. Guo CY, Qi XH, Qi JM. Systematic review and meta-analysis of treating open angle glaucoma with gonioscopy-assisted transluminal trabeculotomy. *Int J Ophthalmol* 2020;13:317-24.
9. Kaplowitz K, Bussell II, Honkanen R, Schuman JS, Loewen NA. Review and meta-analysis of ab-interno trabeculectomy outcomes. *Br J Ophthalmol* 2016;100:594-600.
10. Lavia C, Dallorto L, Maule M, Ceccarelli M, Fea AM. Minimally-Invasive Glaucoma Surgeries (MIGS) for open angle glaucoma: A systematic review and meta-analysis. *PLoS One* 2017;12:e0183142.
11. Bicket AK, Le JT, Azuara-Blanco A, Gazzard G, Wormald R, Bunce C, *et al.* Minimally invasive glaucoma surgical techniques for open-angle glaucoma: An overview of cochrane systematic reviews and network meta-analysis. *JAMA Ophthalmol* 2021;139:983-9.
12. Fellman RL, Mattox C, Singh K, Flowers B, Francis BA, Robin AL, *et al.* American Glaucoma Society Position Paper: Microinvasive glaucoma surgery. *Ophthalmol Glaucoma* 2020;3:1-6.
13. Yook E, Vinod K, Panarelli JF. Complications of micro-invasive glaucoma surgery. *Curr Opin Ophthalmol* 2018;29:147-54.
14. Overby D. Basic science behind trabecular meshwork surgeries. *Acta Ophthalmol* 2013. [doi: 10.1111/j.1755-3768.2013.1734].
15. Uram M. Combined phacoemulsification, endoscopic ciliary process photocoagulation, and intraocular lens implantation in glaucoma management. *Ophthalmic Surg* 1995;26:346-52.
16. Francis BA, Berke SJ, Dustin L, Noecker R. Endoscopic cyclophotocoagulation combined with phacoemulsification versus phacoemulsification alone in medically controlled glaucoma. *J Cataract Refract Surg* 2014;40:1313-21.
17. Francis BA, Pouw A, Jenkins D, Babic K, Vakili G, Tan J, *et al.* Endoscopic Cycloplasty (ECPL) and lens extraction in the treatment of severe plateau iris syndrome. *J Glaucoma* 2016;25:e128-33.
18. Hollander DA, Pennesi ME, Alvarado JA. Management of plateau iris syndrome with cataract extraction and endoscopic cyclophotocoagulation. *Exp Eye Res* 2017;158:190-4.
19. Lin MM, Rague A, Turalba AV, Lee H, Falkenstein IA, Hoguet AS, *et al.* Differential efficacy of combined phacoemulsification and endocyclophotocoagulation in open-angle glaucoma versus angle-closure glaucoma. *J Glaucoma* 2019;28:473-80.
20. Pathak-Ray V. Intermediate results of phaco-endocycloplasty in an exclusive cohort of angle closure glaucoma: Potential for change. *Int Ophthalmol* 2019;39:2257-65.
21. Pathak-Ray V, Choudhari N. Phaco-endocycloplasty versus Phacotrabeculectomy in primary angle-closure glaucoma: A prospective randomized study. *Ophthalmol Glaucoma* 2020;3:434-42.
22. Pathak-Ray V. Protocol for titrated endocycloplasty when combined with phacoemulsification in an exclusive cohort of angle closure glaucoma. *J Glaucoma* 2019;28:e177-8.
23. Ariga M, Nivean, Nivean PD, Madanagopalan VG, Mohan S. Micropulse trans-scleral diode laser cyclophotocoagulation in refractory glaucoma: An initial experience in Indian eyes. *Int Ophthalmol* 2021;41:2639-45.
24. Pathak Ray V. Micropulse transscleral cyclophotocoagulation Cyclo G6 laser at low energy levels: Initial results in Indian eyes with advanced glaucoma treated in a single session. *Indian J Ophthalmol Case Rep* 2021;1:292-6.