

Defining MIGS

Procedures should share certain characteristics to be considered truly microinvasive.

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The past few years have seen a rise of less invasive glaucoma surgical techniques, including the emergence of microinvasive glaucoma surgery (MIGS). With this rise, however, come questions over what truly qualifies as a MIGS procedure and what may not. Many in the field have begun using the term *MIGS* to describe any procedure short of complete filtering surgery.

DEFINING MICROINVASIVE

We are entering a renaissance in glaucoma treatment with the availability of MIGS and the possibility of new drug delivery options that will move the focus away from topical drops. Our treatment paradigm for glaucoma runs the spectrum from drops to lasers to more aggressive and higher-risk surgeries such as trabeculectomy and tube shunts. Yet we have known for many years that there is an opportunity to treat elevated IOP by methods that are interventional but not as extreme, perhaps, as a procedure such as trabeculectomy. The need for a procedure that matches the safety profile of cataract surgery and the efficacy of pharmaceuticals is the basis of MIGS.

When the acronym *MIGS* was first coined, it referred to a “minimally invasive” procedure, similar to what we hear in other facets of surgery and medicine. Unlike other minimally invasive procedures in general, however, when we work on the eye, we are truly working on a microscopic level. A genesis of the term was needed, and so “minimally invasive” became “microinvasive.” The difference is subtle, but it is an important distinction to make, as this differentiates MIGS procedures and what they involve from other surgical procedures.

It is important to note the definition of the word *invasive* in this context. The term *invasive* is often used to indicate incision size. This leads many to believe that a glaucoma procedure is MIGS if the incision is small enough. This is not the case in my opinion.

In this context, *invasive* does not simply mean incision size but specifically refers to how *much* we are invading.

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How much are we altering tissue, destroying or removing tissue, or changing the normal balance of the eye? Even through the smallest of incisions, a procedure may have a dramatic impact on the delicate tissues of the eye, and such a procedure would not qualify as “microinvasive” no matter how small the incision. The term *microinvasive* means minimally altering the essential anatomy or physiology of the eye, leaving it almost untouched. That is the true idea behind MIGS.

For example, tube shunts such as the Ahmed Glaucoma Valve (New World Medical) and the Baerveldt glaucoma implant (Abbott Medical Optics) enter the eye through a small 23-gauge needle track, yet they involve extensive external dissection and carry significant postoperative risks. Most surgeons agree that these procedures would not be considered microinvasive.

MIGS procedures share five distinct qualities: (1) an ab interno, microincisional, conjunctiva-sparing approach; (2) minimal trauma to and disruption of normal anatomy and physiology, with devices that exhibit a high level of biocompatibility; (3) moderate to high IOP-lowering efficacy; (4) an extremely positive safety profile; and (5) rapid recovery by the patient. Although other procedures may share some of these traits, they do not necessarily fit the true definition of MIGS.

Nonpenetrating glaucoma surgery is a classification that can include any ab externo drainage procedure that facilitates aqueous humor filtration through a natural trabeculo-Desemet window. It is a much broader classification than MIGS, and the two terms should be differentiated. Nonpenetrating glaucoma surgical proce-



dures involve significant alteration of the anatomy and natural physiology of the eye, involve conjunctival and scleral incisions with the removal of scleral tissue, and require highly technical and variable dissection. Risks include perforation of the trabeculo-Desemet window, potentially necessitating conversion to trabeculectomy. Examples of nonpenetrating surgery include viscocanalostomy, deep sclerectomy, and canaloplasty. These are truly elegant procedures and appear to provide an improved safety profile compared with trabeculectomy, but they do not embody the qualities of MIGS.

Endoscopic cyclophotocoagulation, performed with an ab interno approach, has been described as a treatment for both open-angle and angle-closure glaucomas, and it offers a relatively safer (and less powerful) option for IOP lowering compared with trabeculectomy. Due to the destructive nature of this procedure (ablation of normal ciliary epithelium), its level of invasiveness appears beyond that of MIGS.

MANY MIGS APPROACHES

Within MIGS, there are various approaches—including Schlemm canal, the suprachoroidal space, and the subconjunctival space. Schlemm canal approaches include microstenting and microcauterizing procedures.

Some of my colleagues have debated whether microcauterizing Schlemm canal procedures such as the Trabectome (NeoMedix) qualify as MIGS. Although cauterization of the trabecular meshwork may be considered destructive, this procedure removes diseased tissue and appears to have a reasonable safety profile and thus embodies most of the qualities of MIGS procedures.

Schlemm canal microstents, which enhance normal physiologic aqueous outflow through device placement, could be considered classic MIGS devices, with extremely favorable safety profiles. The iStent Trabecular Micro-Bypass Stent (Glaukos) was the first ab interno glaucoma device approved by the FDA and is the device most often discussed in regard to microstenting of Schlemm canal. The iStent inject (Glaukos; not available in the United States) is a second-generation version of the device. Another device, the Hydrus Microstent (Ivantis; not available in the United States) bypasses the trabecular meshwork and also acts to scaffold open Schlemm canal.

Moving away from the canal of Schlemm, microstenting into the suprachoroidal space has received attention as a potential MIGS option. The CyPass Micro-Stent (Transcend Medical; not available in the United States) and iStent Supra (Glaukos; not available in the United States) are two MIGS devices designed to enhance aqueous flow into this physiologically unconventional outflow pathway from the eye.

Subconjunctival outflow is also being explored with use of the Xen Gel Stent ab interno MIGS device (AqueSys; not available in the United States). This device, combined with use of the antimetabolites, can achieve IOP lowering similar to that of a trabeculectomy (unpublished data, 2014). The subconjunctival outflow mechanism appears to be more potent than with Schlemm canal and suprachoroidal space MIGS devices, and it also carries a slightly greater risk. Thus, I call this type of approach “MIGS-plus” to indicate the comparatively enhanced efficacy.

COMMON CHARACTERISTICS

A number of MIGS devices are currently in development, each with its own specific risk-reward-effort ratio. All feature the MIGS characteristics outlined previously: ab interno approach, minimal disruption of normal anatomy and physiology, extremely favorable safety profile, at least modest efficacy, and rapid recovery by the patient.

It has been a fascinating journey working with many companies in this space, and I hope it continues. NeoMedix was the first on the scene with an alternative ab interno method for MIGS. Glaukos led the way in development and commercialization of the first FDA-approved MIGS device. Ivantis, Transcend, and AqueSys are hot on their trail to continue this progress.

I continually remind my colleagues and myself about the need for evidence-based data to help support the utilization of these devices, and I hope for more clinical trials and research in these areas. Cost-effectiveness studies are needed to further support and identify appropriate usage for our glaucoma patients. We have seen only the first phase of MIGS devices, and I expect more innovation and development in this area to further enhance glaucoma care.

It is interesting to speculate how the introduction of new drug delivery options may provide synergy with MIGS devices. We now have a greater breadth of options for our glaucoma patients than ever before, with the possibility of treating glaucoma at an early stage with safer and more effective treatments. ■

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