REVIEW

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Circumferential canal surgery: a brief history

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Purpose of review
Most microinvasive glaucoma surgery (MIGS) procedures bypass outflow resistance residing proximally in the trabecular meshwork and inner wall of Schlemm's canal. A novel procedure combining trabeculotomy with viscodilation adds to this by also addressing distal resistance of the canal and collector channel ostia. This review examines the development and evidence for both trabeculotomy and canaloplasty separately and the combination in a single procedure.

Recent findings
Recent aqueous angiography studies have confirmed the segmental nature of outflow through Schlemm's canal highlighting the need to address distal outflow pathway resistance. Combined trabeculotomy and viscodilation *ab interno* is a novel approach with a new purpose-designed device (OMNI Surgical System) becoming available to surgeons in early 2018. Recent results as both a standalone and combined with cataract procedure demonstrate significant intraocular pressure reductions with an average 41% reduction from baseline in the pseudophakic group.

Summary
Targeting both distal as well as proximal points of outflow resistance in the conventional pathway may prove to be a highly efficacious MIGS modality. Additional large prospective studies are currently ongoing to confirm these preliminary results.

Keywords
microinvasive glaucoma surgery, outflow resistance, trabeculotomy, viscodilation

INTRODUCTION

Elevated intraocular pressure (IOP) is the cardinal risk factor for development and progression of glaucoma [1▪▪]. Landmark studies such as OHTS and AGIS established the importance of IOP reduction [2,3]. Elevated IOP is a consequence of increased outflow resistance in the conventional (trabeculocanalicular) outflow pathway. Surgical interventions to reduce IOP aim to either circumvent the conventional pathway, as with filtration procedures, or remove or bypass resistance facilitating physiological outflow. Outflow resistance in the conventional pathway can be ascribed to three areas: the juxtacanalicular meshwork and inner wall of Schlemm's canal (50–75%); Schlemm's canal; collector channels (latter two up to 50%) [4–6]. Opening Schlemm's canal to the anterior chamber to bypass trabecular resistance was first attempted over 100 years ago by De Vincentiis [7]. Dilation of Schlemm's canal by various means to address downstream resistance is a more recent approach having its roots in ab externo nonpenetrating procedures like sinusotomy and viscocanalostomy [8,9]. Neither of these approaches address all three areas of outflow resistance while combining trabeculotomy/goniotomy with viscodilation of Schlemm's canal may.

For more than 100 years glaucoma surgeons have been trying to alter anterior chamber angle anatomy to enhance outflow and treat glaucoma. Angle surgery *ab interno* is currently undergoing a renaissance including trabecular and supraciliary implants, new surgical instruments for partial trabeculotomy ($\leq 120^{\circ}$), ab-interno procedures and systems allowing circumferential trabeculotomy, circumferential viscodilation, and most recently combined circumferential viscodilation with

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KEY POINTS

- Resistance to outflow is comprised of proximal (juxtacanalicular meshwork and inner wall of Schlemm's canal) and distal (Schlemm's canal and the collector channels) components.
- MIGS procedures including trabeculotomy and implants such as the iStent are primarily directed at the proximal components of resistance.
- A novel MIGS procedure (OMNI Surgical System) combining trabeculotomy with viscodilation addresses both proximal and distal points of outflow resistance in the conventional outflow pathway.

trabeculotomy (Fig. 1). This article reviews the clinical evidence for ab-interno trabeculotomy, ab-interno viscodilation, and the combination of both together.

A BRIEF HISTORY

Goniotomy, arguably the first micro-invasive glaucoma surgery (MIGS), became practical with the arrival the operating microscope and surgical goniolens. Barkan initially considered this operation ideal for 'chronic simple glaucoma' (i.e., open-angle glaucoma or OAG). While detailed outcomes are not available, where the incision was at least 90° pressure was 'normalized' through 24 months. Where the incision was less than 90°, normalized pressure was achieved only with adjunctive medication (miotics) although miotics alone (preoperation) were insufficient to achieve normal pressure [10]. Subsequently, goniotomy for adult OAG was largely abandoned due to inconsistent efficacy while becoming the treatment of choice for congenital glaucoma [11,12]. More recently, there has been a resurgence in ab interno goniotomy including the Trabectome, a device that electro-ablates the trabecular meshwork and inner wall of Schlemm's canal, and the Kahook Dual Blade, a single-use knife that makes parallel incisions in the trabecular meshwork creating a free strip of tissue. Like traditional goniotomy both are limited to treatment of the nasal arc from a temporal incision [13▪,14▪].

Belief that the trabecular meshwork was responsible for obstruction to outflow and disappointment with goniotomy as a surgical solution for OAG led to development of ab externo trabeculotomy. In addition the procedure could be difficult for many surgeons and there was a need for a procedure in children that could be done in the presence of corneal edema which prevented gonioscopy. This technique employed a nylon suture threaded and pulled through Schlemm's canal via three limbal

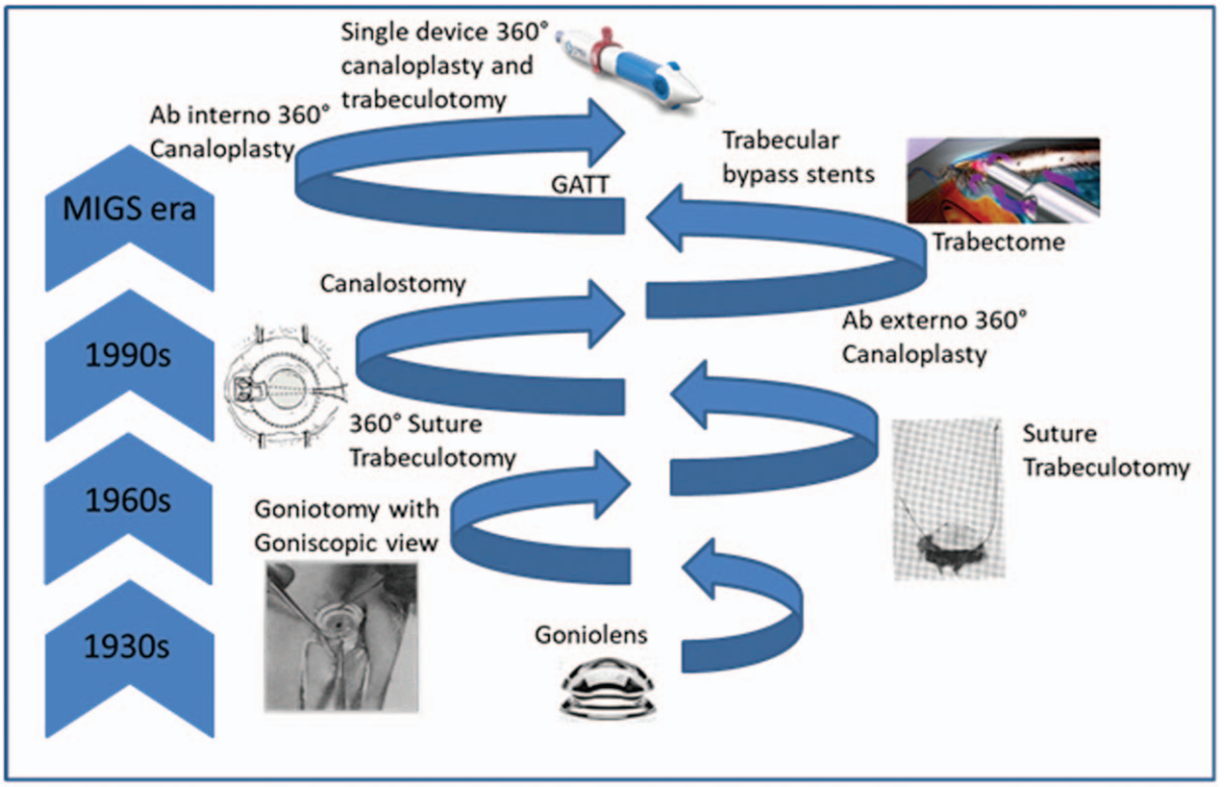

FIGURE 1. Innovation and evolution in canal-based glaucoma surgery.

incisions about 2 clock hours apart. When held at the third incision and pulled from the first, the suture 'appeared like a bowstring' in the anterior chamber having burst through the inner wall of Schlemm's canal and the trabecular meshwork [15]. This technique foreshadowed single incision approaches although provided only an approximately 120° trabeculotomy rather than a full 360°.

The 360° suture trabeculotomy was first developed as a pediatric procedure. A single cut-down is used for both entry and exit from Schlemm's canal. The suture's blue color allows visualization under transillumination with a goniolens ensuring accurate placement and the ability to follow progress as it is fed through the canal [16]. Better outcomes were obtained using the 360° technique in comparison with the partial 120° method in a head-to-head comparison [17,18]. A subsequent enhancement was the iTrack illuminated microcatheter (Ellex, Adelaide, South Australia, Australia) for improved visualization [19,20]. In adult eyes with either primary open-angle glaucoma OAG (POAG) ($n=25$) or secondary OAG ($n=18$) success (IOP reduced 30% and <18 mmHg on the same or fewer medications) was achieved by 84% (POAG) and 89% (secondary OAG) [21]. Circumferential ab-externo trabeculotomy came with several advantages over other trabeculotomy procedures. Fully opening Schlemm's canal to the anterior chamber results in a higher proportion of surgical successes [18]. Enhanced visualization allows more accurate placement in Schlemm's canal and consequently decreased likelihood of creating false passages into the anterior chamber or suprachoroidal space. Moreover, since the entirety of the angle is treated fewer repeated procedures with consequent increase in conjunctival scarring are required [16]. However, the required cutdown and manipulation of conjunctiva and the creation of a scleral flap, diminish the likelihood of a successful outcome for future filtration surgery, if required.

A minimally invasive ab interno approach, 'gonioscopy-assisted transluminal trabeculotomy' (GATT), was developed to avoid the tissue trauma of the ab externo procedure while maintaining the effectiveness [22]. In brief, a nasal paracentesis is created for suture entry. A second, temporal, paracentesis allows for entry of the blade used to create a small (1–2 mm) nasal goniotomy for suture insertion into Schlemm's canal. Micro forceps entering through the temporal paracentesis grasp the suture and feed it circumferentially around the canal. Grasping the tip of the suture and bringing it out through the temporal opening creates a 180° trabeculotomy; Applying tension to the proximal suture end completes the 360° trabeculotomy [22]. In a retrospective review of 72 POAG cases at 24 months including GATT with cataract surgery ($n=27$), GATT in pseudophakic patients ($n=19$), and GATT in phakic patients ($n=26$), IOP reductions were 8.4 mmHg (baseline of 22.5 mmHg), 8.9 mmHg (baseline of 24.7 mmHg), and 10.4 mmHg (baseline of 26.0 mmHg) [23▪▪]. Medication use was reduced from 2.9, 2.6, and 3.2 to 1.0, 1.6, and 1.8, respectively [23▪▪]. Success defined as IOP reduction of at least 20%, IOP of 21 mmHg or less and no reoperation for IOP was between approximately 60% (pseudophakic) and 80% (with cataract surgery) [23▪▪]. IOP reduction in a mixed cohort of secondary glaucomas was even greater (Table 1). As with most trabeculotomy procedures the most common adverse event was transient hyphema resolving within the first postoperative week.

Table 1. Intraocular pressure reductions (mmHg ± SD) in circumferential trabeculotomy studies

Reference	Procedure	Diagnosis	*N*	Baseline IOP	IOP at last follow-up (length of follow-up)	Percentage change
Chin *et al.* [21]	Ab externo 360°	POAG/SOAG	43	27.8 ± 12.2	12.9 ± 2.5 (18 months)	−53.6
Grover *et al.* [23▪▪]	Ab interno 360°	POAG				
		Phakic	46	26.0 ± 6.9	15.6 ± 5.7	−40.0
		w/Phaco	36	22.5 ± 5.4	14.1 ± 3.2	−37.3
		Pseudo	37	24.7 ± 6.2	15.8 ± 7.4	−36.0
		Other[a]				
		Phakic	30	30.9 ± 10.0	13.8 ± 4.5	−55.3
		w/Phaco	25	25.7 ± 6.3	14.5 ± 4.4	−43.6
		Pseudo	24	26.8 ± 7.9	13.4 ± 4.7 (24 month)	−50.0
Sarkisian *et al.* [25▪▪]	Ab interno 360°	POAG (83%)	81	23.7 ± 6.3[b]	15.7 ± 5.5[b] (12 month)	−33.8

IOP, intraocular pressure; POAG, primary open-angle glaucoma; SOAG, secondary open-angle glaucoma.
[a]Other included chronic angle closure, pseudoexfoliation, pigment dispersion, uveitic, mixed mechanism. Other OAG, trauma, steroid.
[b]SD estimated from error bars in published figure.

A similar operation can be accomplished with a purpose-designed device, the TRAB360 (Sight Sciences, Menlo Park, California, USA). The TRAB360 consists of a handpiece and cannula with a retractable microcatheter. Entering the eye through a single temporal clear corneal incision, the anterior chamber is crossed and a small goniotomy is made with the tip of the cannula. The microcatheter is advanced into Schlemm's canal through 180° with a control wheel on the handpiece. Withdrawing the cannula tears the meshwork and inner wall. Repeating the procedure in the opposite direction creates a full circumferential trabeculotomy [24▪]. A series of 81 eyes with refractory glaucoma was treated 360° with the TRAB360 as a standalone procedure (not with cataract surgery). Two-thirds of eyes were pseudophakic, most (91%) were OAG, all had a preoperative IOP at least 18 mmHg on medication, half had failed prior laser trabeculoplasty, and 19% had failed filtration surgery. Mean IOP was reduced from 23.7 to 15.7 mmHg at 12 months, a 34% reduction, while medications were reduced from 1.7 to 1.1. IOP reduction was even greater in the subset of eyes with baseline IOP at least 25 mmHg; from an average of 30.2 to 16.1 mmHg at 12 months. Mild hyphema occurred in about half of the eyes and, not surprisingly in this refractory group, 20 eyes required additional surgical intervention [25▪▪]. Outcomes for GATT and TRAB360 (Table 1) are similar. The main difference being the complexity of the procedure, number of incisions, and cost. The TRAB360 procedure is simpler and requires just one incision rather than two, however GATT can be performed with an inexpensive suture.

In contrast to trabeculotomy, canaloplasty addresses distal resistance in addition to its effects on the inner wall and trabecular meshwork. Canaloplasty originated with the realization that the IOP-lowering effect of canalostomy was due more to the viscodilation of Schlemm's canal and consequent disruption of lateral walls, inner wall endothelium, and bridging structures than it was to aqueous flow through a Descemet's 'window' and into the cut ends of Schlemm's canal [26]. As for circumferential trabeculotomy ab externo, access to Schlemm's canal is under a scleral flap. In contrast to trabeculotomy, in canaloplasty the microcatheter is not pulled through the inner wall of Schlemm's canal and the trabecular meshwork. Instead small amounts of viscoelastic are injected through the microcatheter around the full circumference of Schlemm's canal. In one variant a prolene suture is attached to the distal end of the microcatheter and looped through the canal as the microcatheter is withdrawn. The suture is tightened and tied off to stretch the inner wall and the trabecular meshwork [27].

Cameron *et al.* followed a series of 56 OAG patients that underwent ab externo 360° canaloplasty for 6 months [28]. The series included five eyes that had failed prior glaucoma surgery. The mean IOP at 6 months was decreased 34% from baseline (Table 2) and medications decreased from 2.1 to 0.2 [28]. In addition, ultrasound imaging showed that Schlemm's canal, often not visible prior to the surgery, could be visualized at 6 months [28]. Mean IOP reduction was not related to the extent of dilation (no dilation, 1 or 2, 3, or 4 dilation sites, 360° dilation) however the proportion of patients meeting IOP targets (<15, <18 or <21 mmHg) was directly related to degree of dilation [28]. Evaluation of canaloplasty in 90 African patients with POAG and using a tensioning suture resulted in substantial IOP reductions at 15 months (Table 2) [27]. In a large ($n = 127$ eyes), prospective study including adult OAG patients undergoing either canaloplasty alone ($n = 97$) or canaloplasty with cataract surgery ($n = 30$), IOP (all patients) was decreased 32% at 24 months and 36% at 36 months from preoperative baseline of 23.6 mmHg [29,30]. While only 5% of eyes were medication-free at baseline, 61 and 49% were medication-free at 24 and 36 months [29,30]. Interestingly, there was a significant relationship between distension of Schlemm's canal and IOP and medication reduction at 24 months although a comparison of the patients with and without a tensioning suture revealed no difference in terms of IOP or medication reduction at 36 months [29,30]. In a small series of 20 eyes with OAG (95%), Voykov *et al.* [31] reported sustained IOP reductions through 60 months of follow-up (Table 2) while decreasing medication use from 3.4 to 1.7 medications.

Vastardis *et al.* followed a cohort of over 500 POAG patients treated with ab externo canaloplasty for 1 year. Patients were stratified by standalone procedure or combined with phaco, and by glaucoma severity (early, moderate, advanced). Meaningful IOP reductions were achieved in all groups (Table 2) of between 3 mmHg (early, standalone) and 6 mmHg (advanced, standalone) while reducing medications from approximately 2.5 to less than 1 for all subgroups [32▪▪].

The ab interno approach (ABiC for AB Interno Canaloplasty) differs from the ab externo in that Schlemm's canal is accessed through a small goniotomy internally requiring only a small clear corneal incision rather than conjunctival dissection and a scleral flap. There is no tensioning suture. A small case series showed modest IOP reductions, however average baseline IOP was relatively low (18.5 mmHg). While patients were on one to three medications at baseline, 16 patients (80%) were medication free at last follow-up (maximum follow-up was 12 months;

Table 2. Intraocular pressure reductions (mmHg ± SD) in published canaloplasty studies

Reference	Procedure	Diagnosis	N	Baseline IOP	IOP at last follow-up (length of follow-up)	Percentage change
Cameron *et al.* [28]	Ab externo 360°	POAG	56	25.1 ± 8.7	16.7 ± 4.4 (6 month)	−33.5
Grieshaber *et al.* [27]	Ab externo 360° w/suture	POAG in Black patients	90	42.7 ± 12.5 (6–0 suture)	19.2 ± 6.4 (15 month)	−55.0
				45.0 ± 12.1 (10–0 suture)	16.4 ± 4.9 (15 month)	−63.6
Voykov *et al.* [31]	Ab externo 360° w/suture	OAG	18	25.7 ± 6.6	14.2 ± 3.4 (60 month)	−44.8
Lewis *et al.* [29]	Ab externo 360° w/suture	OAG	127	23.6 ± 4.8	16.0 ± 4.2 (24 month)	−32.2
Körber [33▪]	Ab interno 360°	POAG	20[a]	18.5 ± 3.4	15.5 ± 2.4 (9 month)	−16.2
Vastardis *et al.* [32▪▪]	Ab externo 360° w/suture	POAG	Standalone		(12 month)	
			Advanced 172	19.2 ± 6.4	13.3 ± 4.5	−27.9
			Moderate 51	20.7 ± 5.0	15.2 ± 4.0	[b]
			Early 39	21.3 ± 5.7	18.1 ± 3.8	[b]
			With phaco			
			Advanced 212	19.4 ± 7.5	14.5 ± 4.7	−16.5
			Moderate 51	19.5 ± 5.9	~14.5[b]	[b]
			Early 39	19.4 ± 7.3	~14.5[b]	[b]
Ondrejka and Körber [34▪▪]	Ab interno 360°	POAG	IOP ≥ 18 mmHg		(12 month)	
			72	24.6 ± 7.1	14.6 ± 2.8	−41%
			IOP < 18 mmHg			
			34	14.9 ± 1.8	13.6 ± 2.3	[b]
Brusini *et al.* [35▪]	Ab externo 360° w/suture	Steroid OHT	9	30.4 ± 6.8	13.7 ± 1.9 (12 month)	−54.9

IOP, intraocular pressure; OAG, open-angle glaucoma; POAG, open-angle glaucoma open-angle glaucoma.
[a] $n = 6$ at 9 months.
[b] Data not published, IOP estimated from published figure.

nine patients with ≥6 months follow-up) [33▪]. In a series of 106 eyes treated with the VISCO360 (Sight Sciences Inc.) stratified by baseline IOP, patients with baseline IOP at least 18 mmHg had an average 41% reduction in IOP (24.6 to 14.6 mmHg) at 12 months (Table 2). In patients with baseline IOP less than 18 mmHg, IOP was maintained while medications were reduced from 1.8 to 0.2 [34▪▪]. Promising results with canaloplasty have also been achieved in steroid-induced IOP elevation (Table 2) [35▪].

Both ab interno and ab externo 360° canaloplasty provide similar IOP-lowering efficacy (Table 2). This was confirmed in a paired-eye study where one eye was treated ab externo and the other ab interno. Results were essentially identical. At 12 months ab externo eyes had mean IOP of 13.5 mmHg on 0.9 medications (18.1 mmHg preoperative on 2.4 medications) while ab interno eyes had mean IOP of 13.8 mmHg on 0.8 medications (18.5 mmHg preoperative on 2.4 medications) [36▪▪].

TRABECULOTOMY COMBINED WITH VISCODILATION

In patients previously treated (1–54 months) with ab externo canaloplasty but whom were inadequately controlled, Voykov *et al.* [37] demonstrated additional IOP reduction by using the tensioning suture to perform an ab interno 360° trabeculotomy. In a larger, 88 patient cohort, Seuthe *et al.* [38] showed at 12 months a 41.2% reduction in IOP and reduction in medications from 2.7 to 1.6. These studies added trabeculotomy to canaloplasty, but only after many months, and only in patients not achieving sufficient IOP reduction. Combining the two different modalities and simultaneously addressing multiple points of outflow resistance could therefore prove more effective than either alone.

The OMNI Surgical System (Sight Sciences), provides the ability to perform a circumferential viscodilation and trabeculotomy using the same device. Given the short time this device has been marketed limited data are currently available. Brown *et al.*

reported promising preliminary results for a series of 54 eyes (41 where the OMNI was used with cataract surgery and 13 in pseudophakic patients). In combined cases and the majority of standalone (8/13) the treatment consisted of 180° viscodilation and trabeculotomy. Five eyes in the standalone group with more advanced disease were treated 360°. Mean IOP reductions were 5.8 mmHg in the combined cases and 10.0 mmHg for the standalone group [39▪▪,40▪]. In a European study of 24 eyes with early, moderate or advanced glaucoma and 18 months of follow-up, and including both combined with cataract surgery ($n = 10$) and standalone cases ($N = 14$), IOP was reduced from preoperative baseline of 18.7 to 11.4 mmHg for combined cases while medications were reduced 50% from an average of 2.8 to 1.4. In standalone cases IOP went from 23.4 to 14.0 (−40%) and medications from 3.0 to 2.0 over the same time period [41▪]. A large prospective study of this device used with cataract surgery is in progress (clinicaltrials.gov NCT03861169).

Elevated IOP is the leading risk factor for glaucoma and currently the only one treatable [42]. Outflow resistance is the result of contributions from distinct portions of the physiologic outflow pathway. In primates up to 75% of the resistance comes from the trabecular meshwork and in particular the juxtacanalicular tissue [4,43]. The inner wall accounts for 10% or less of resistance in normal eyes [44]. Morphometric and perfusion studies show that the cross-sectional area of Schlemm's canal averages 54% less and mean outflow facility 55% less in POAG eyes compared with normal, and that these measures are correlated, implicating canal atrophy as a source of resistance [45]. Moreover, the entire canal is not active, showing a 'segmental' pattern in tracer and OCT imaging studies [46,47▪▪]. A third point of resistance is the collector channels ostia (Fig. 2). In bovine eyes, light microscopy showed that increasing IOP resulted in herniation of the inner wall and juxtacanalicular tissue into the ostia of the collector channels [6]. Addressing all three of these points of resistance by combining viscodilation with trabeculotomy is appealing theoretically and practically. A single surgery with a minimally invasive approach provides maximum safety and minimum tissue disruption. No implant is left behind. The conjunctiva is not injured. The promise

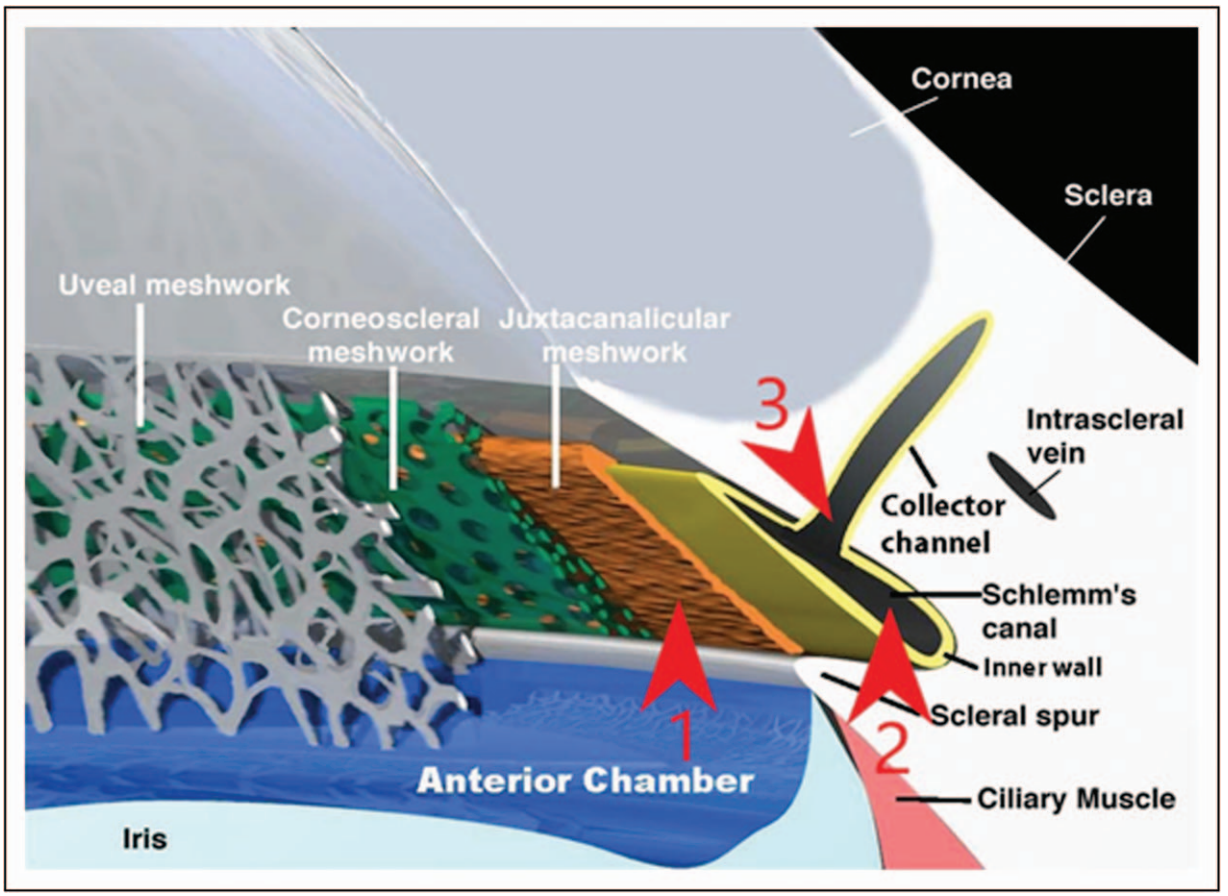

FIGURE 2. Conventional outflow pathway. Red arrowheads indicate three major components of outflow resistance. 1. Juxtacanalicular trabecular meshwork. 2. Schlemm's canal. 3. Ostia of collector channels.

of this multimodal, ab interno approach targeting all three sources of outflow resistance is supported today by historical data on the two individual procedures. Ongoing clinical studies and, importantly, clinical experience in the hands of surgeons will allow fair evaluation of safety, effectiveness, and the most appropriate patients. Laboratory studies including imaging/visualization in perfused cadaver eyes and aqueous dynamics studies can confirm the hypothesized mechanism of action.

CONCLUSION

The objective of glaucoma surgery has always been to facilitate egress of aqueous humor and restore IOP to levels consistent with optic nerve health, ideally restoring fluid dynamics to a normal equilibrium [48]. MIGS has revolutionized treatment and is changing the norms of clinical practice. The quest for glaucoma surgeries that provide efficacy while minimizing risk is over a century old and has culminated in the MIGS techniques of today providing the surgeon and the patient with an unprecedented diversity of options [7,49].

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Conflicts of interest

J.D. and R.B. are employees of Sight Sciences.

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