

A Systematic and Narrative Review of Safety and Complications in Minimally Invasive Glaucoma Surgery (MIGS) Between 2014–2024

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Introduction: Earlier intervention in glaucoma has been suggested to slow disease progression and preserve visual function and quality of life. Consequently, minimally invasive glaucoma surgery (MIGS) is increasingly used in mild-to-moderate glaucoma. Although numerous techniques and devices are available, their comparative efficacy remains debated: most procedures lower intraocular pressure to the mid-teens in primary open-angle glaucoma, but without clear evidence of superiority. As these surgeries are now offered to younger, otherwise healthy patients, safety has therefore become a central criterion in technique selection.

Methods: This PRISMA-based systematic review analyzed safety outcomes from peer-reviewed studies of the main MIGS procedures published between 2014 and 2024. Five databases were searched using current and historical device names. Non-clinical studies, case series, and nonstandard techniques were excluded from quantitative analysis but retained qualitatively to capture rare events. A total of 401 studies, representing 39,381 eyes and 68,917 eye-years of follow-up, were included. Highest reported and weighted mean complication rates were calculated by procedure type.

Results: Safety profiles varied. Trabecular bypass implants and ab interno canaloplasty were associated with low rates of serious adverse events and minimal anatomical disruption. Suprachoroidal devices carried higher risks of hypotony, inflammation, and malposition. Across all categories, chronic changes to angle anatomy and occasional re-interventions highlighted the potential for long-term sequelae, with endothelial cell loss emerging as a key concern for certain procedures. However, heterogeneity in definitions and reporting limited comparability. Common events such as hyphema and IOP spikes were inconsistently documented, while late complications like endothelial cell loss or peripheral anterior synechiae were often overlooked. This underreporting risks conflicting conclusions and undermines comparisons.

Conclusion: For patients with mild, stable disease or those undergoing opportunistic combined surgery, tissue-sparing procedures with the lowest observed complication rates may be preferable. Standardized definitions, long-term follow-up, and harmonized safety reporting are becoming essential.

Keywords: glaucoma, adverse events, canaloplasty, trabecular bypass, goniotomy, endothelial cell loss

Introduction

Glaucoma is a leading cause of irreversible blindness worldwide, affecting approximately 76 million individuals in 2020, a number projected to rise to 112 million by 2040.¹ This optic neuropathy is characterized by the progressive loss of retinal ganglion cells and nerve fibers, resulting in a functional loss of vision.² Traditionally, glaucoma management has relied on a stepwise approach starting with pharmacological therapies and moving to invasive surgical procedures once all topical options have been exhausted. This conventional approach comes with limitations, including the effect of long-term pharmacological treatments on quality of life and ocular surface health, that were shown to affect patient compliance and surgical success.³ It was also suggested that surgical treatments are often deferred for too long,⁴ and that early intervention may not only help preserve more functional vision but also prevent the disease from progressing into a more advanced stage which may be more difficult to control.^{5–7}

In response to these challenges, since the early 2000s, the field of glaucoma has seen a marked development of Minimally Invasive Glaucoma Surgery (MIGS) techniques, leading to a gradual shift in paradigm in glaucoma treatment.⁸ MIGS procedures are designed to enhance aqueous humor outflow through micro-invasive techniques, offering a safer and less invasive alternative to traditional surgeries. Over the past two decades, MIGS has evolved with the development of various devices and techniques targeting different anatomical pathways, including the trabecular meshwork, the suprachoroidal space and subconjunctival space. The superior safety profile of MIGS compared to traditional filtering procedures has enabled earlier surgical intervention for glaucoma, providing options both to improve quality of life and slow disease progression.^{5–7,9} As a result, there is a growing trend toward utilizing MIGS procedures earlier, in younger, healthier patients with mild-to-moderate glaucoma, or when post-operative follow-up may be difficult.^{10,11} In recent years, long-term safety has become a key concern in glaucoma surgery, particularly following the withdrawal of the CyPass Micro-Stent after 5-year data from the COMPASS-XT study revealed progressive endothelial cell loss.¹² Subsequent long-term studies have reinforced the need for systematic evaluation of surgical adverse events and endothelial safety across MIGS procedures.

Despite the multiplication of MIGS techniques and devices, there remains considerable debate regarding their comparative efficacy and safety profiles. Many studies and reviews over the last decade have compared these techniques, yet consensus on the most effective approach is lacking.¹³ Although some subconjunctival options were shown to have greater intraocular pressure-lowering potential, they were also more invasive, leading to more complications and subsequent surgical procedures. For this reason, most authors have now reclassified these procedures into a new category: micro-invasive bleb surgery (MIBS) or less-invasive glaucoma surgery (LIGS).¹⁴ Amongst MIGS, however, most procedures have been shown to effectively lower IOP to the mid-teens in mild-to-moderate primary open-angle glaucoma.¹⁵ In the absence of any clear superiority, the choice of MIGS in practice is often down to the personal experience and preference of the surgeon, and the availability in each country or healthcare system.¹³ However, as these procedures are increasingly offered early in the disease course to otherwise healthy patients, the key criterion behind the choice of procedure has started to shift towards the safety of these techniques.¹⁰ Yet, although several reviews have discussed individual procedures, there remains no broad, cross-technique synthesis of safety outcomes across all major MIGS categories, despite an increasing emphasis on the subject.

Therefore, the objective of this review is to systematically compare the safety profiles of all major MIGS procedures published over the past decade, providing pooled complication rates and highlighting long-term safety considerations, including endothelial health, across techniques. In doing so, this review aims to inform clinical decision-making and guide future research in this evolving field.

Methods

This systematic review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines to ensure transparency and reproducibility.¹⁶ The primary objective was to analyze safety outcomes of minimally invasive glaucoma surgery (MIGS) techniques published in peer-reviewed literature between 2014 and 2024.

Initial Search

A comprehensive search was conducted across five major electronic databases: PubMed, EMBASE, Web of Science, Cochrane Library, and Ovid, on the 21st of October 2024. The search strategy involved specific keywords encompassing both current and historical names of MIGS techniques and devices, as well as trade names, alternative designations, and procedural descriptions.

- **Trabeculotomy and Goniotomy Techniques:** Trabeculotomy, Trabectome, Goniotomy, Kahook Dual Blade (KDB), Microhook, TrabEx, Gonioscopy-Assisted Transluminal Trabeculotomy (GATT), TRAB360, High Frequency Deep Sclerotomy (HFDS), Excimer Laser Trabeculotomy (ELT / ELIOS), Femtosecond Laser Image-Guided High-precision Trabeculotomy (FLIGHT)
- **Trabecular Bypass Devices:** Hydrus Microstent (Hydrus), iStent Trabecular Micro-bypass (iStent, iStent inject, iStent inject W, iStent infinite)
- **Canaloplasty Techniques:** Ab Interno Canaloplasty (ABIC), Viscocanaloplasty, OMNI, iTrack, VISCO360 (VIA 360, Streamline)
- **Suprachoroidal Techniques:** CyPass Supraciliary Micro-Stent (CyPass), STAR-based Supraciliary Implants (STARflo, MINIject)

Articles published in English between January 2014 and October 2024 were identified and included for screening.

Article Screening and Selection

Subsequent selection was carried out to retain only clinical reports in humans, excluding animal experiments, and laboratory studies. Duplicates, successive publications on the same cohort of patients, and studies lacking numerical complication rates were excluded. In cases of multiple reports on the same cohort, only the publication with the longest follow-up was retained for analysis. In order to avoid statistical bias, case reports, case series and reports which inclusion criteria involved a specific complication were excluded from the main analysis but retained for discussion in the narrative review. The screening process was carried out independently by two co-authors, and any discrepancy was resolved through discussion.

Data Extraction and Analysis

Data were extracted using a standardized form, including for each study: its year of publication, design, reported conflicts of interest, number of eyes enrolled, mean follow-up duration, surgical technique used, intraocular pressure and medication changes across the study period, and the rates of all reported complications. Definitions of some complications such as IOP spikes, hyphema, and hypotony varied substantially between studies and were not always specified. Where available, the exact definition used in each report was recorded. For the purposes of pooled analyses, however, complications were extracted and categorized as reported by the original authors. As a result, a given term may encompass a spectrum of severities. When studies reported complete data sets from different procedures or subgroups, these were analyzed separately. When reports included a phacoemulsification control group, data were collected for this group as well to serve as comparator.

Results were grouped up by type of procedure to be analyzed. Weighted mean complication rates were calculated for complication rates across studies by using the number of enrolled eyes in each cohort as coefficients. Complications without numerical rates, that were described qualitatively without frequencies, were excluded from calculations but noted for qualitative discussion in the narrative review. For rare complications with zero events reported across all included primary cohorts, a zero-event adjustment (continuity correction) was applied when a high-quality meta-analysis of the same underlying trials reported non-zero events. This approach was used only to mitigate zero-event bias for specific outcomes and did not alter study inclusion or weighting. All statistical analyses were conducted using MedCalc (v.19.1.7, MedCalc Software, Ostend, Belgium).

Results

General Description

The initial search yielded a total of 4,952 articles from electronic databases. After removing duplicates and applying inclusion and exclusion criteria, 401 studies from 41 countries were retained for analysis, encompassing a total of 39'381 eyes with follow-up durations ranging up to 10 years (weighted mean: 21.0 months), totaling 68'917 eye-year of observation for review. The PRISMA Flowchart including the distribution of retained articles by surgical technique is 184 shown in Figure 1.

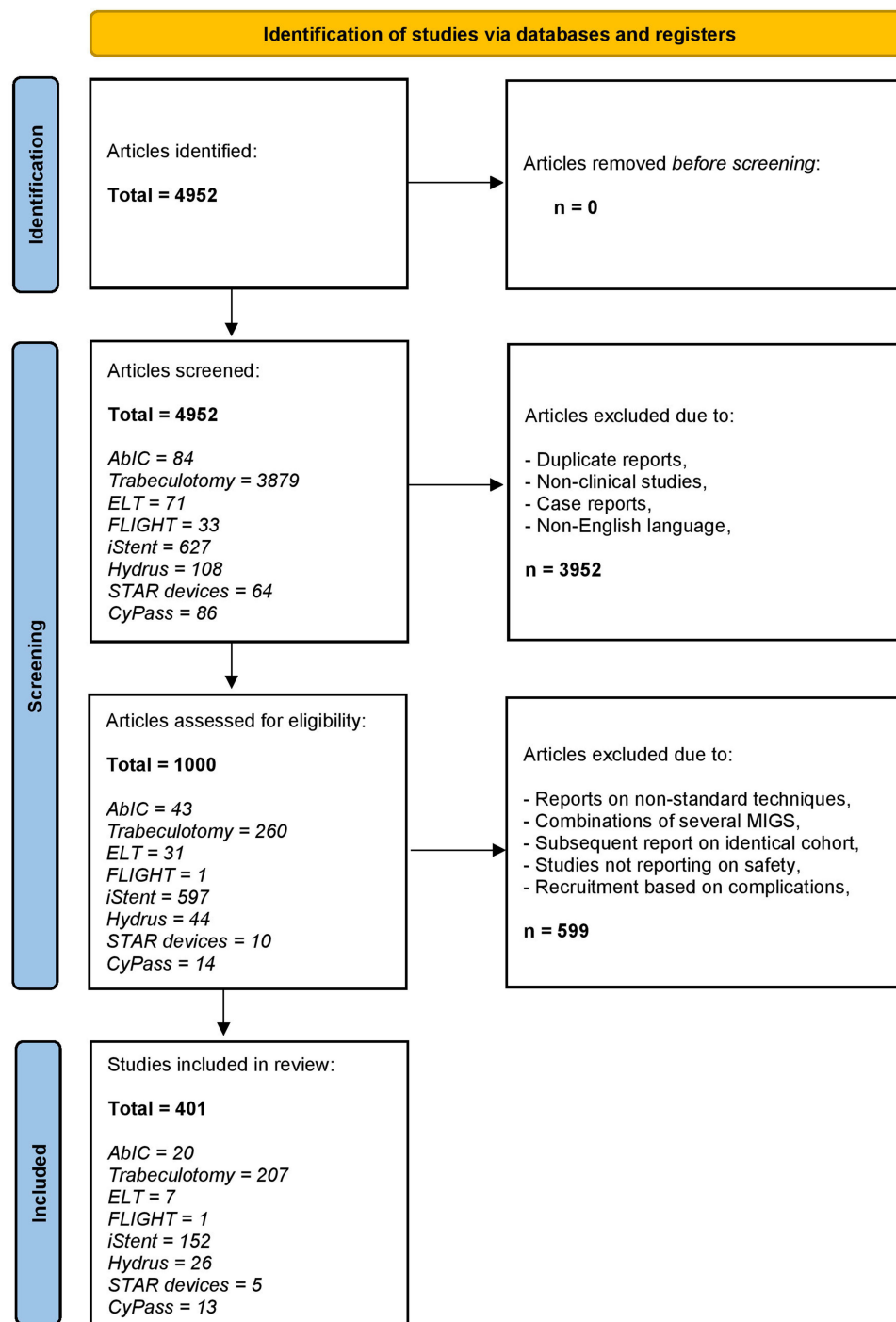


Figure 1 PRISMA flowchart illustrating the number of articles identified, screened, and included in the systematic review. The chart also presents the distribution of articles by surgical technique. Because some comparative studies investigated multiple techniques, the total number of articles at each stage is lower than the sum of articles attributed to each individual technique.

Efficacy Endpoints

Postoperative outcomes across all techniques were consistent in terms of IOP reduction. The weighted mean postoperative IOP across all MIGS procedures was in the mid-teens (14.6 mmHg), irrespective of the device or pathway targeted. Similarly, surgery resulted in on average a reduction of the mean number of antiglaucoma medications by 1.97.

Safety Endpoints

Canaloplasty

Ab Interno Canaloplasty (AbIC)

Ab Interno Canaloplasty (AbIC) is a MIGS technique that enhances aqueous humor outflow by viscodilating Schlemm's canal and its associated collector channels while preserving the trabecular meshwork. This technique employs a microcatheter to navigate Schlemm's canal circumferentially, injecting a controlled amount of viscoelastic material to dilate the canal and improve outflow dynamics.¹⁷

A total of 20 studies encompassing 1,322 eyes were analyzed, with 6.8% being prospective studies and 32.2% involving standalone procedures. A total of 16 different types of complications were recorded. Among these, transient hyphema was the most frequently observed, occurring in 4.6% of cases, though with considerable variability across studies (0–100.0%). Intraoperative hyphema was often attributed to successful catheterization of Schlemm's canal and was considered a marker of procedural success rather than a complication by some authors.¹⁸ The hyphema typically resolved spontaneously within a few days to a week, without intervention.

Intraocular pressure (IOP) spikes were another commonly reported issue, occurring in up to 44% of cases, with a weighted mean of 4.19%. Although definitions of IOP spikes varied among studies, they were commonly defined as an IOP exceeding 30 mmHg or increasing by at least 10 mmHg above baseline. These spikes were transient and generally managed with topical or oral antihypertensive agents. The suspected mechanisms involve postoperative inflammation, a buildup of aqueous cytokines, and residual viscoelastic material obstructing aqueous outflow.¹⁹ Reports suggest that older patients and those with advanced glaucoma may experience more pronounced IOP spikes due to compromised outflow pathways or disturbed aqueous pump function that are more sensitive to transient postoperative obstruction.^{20,21} Postoperative fibrinous reactions and macular oedema were not uncommon, reported in up to 5.6% and 11.1% of cases respectively, supporting the inflammatory theory.²²

Hypotony was rare, with a mean incidence of 0.30%, and was typically mild and self-limiting.²³ Nonetheless, and although this was only observed in ab externo canaloplasty, Brusini described rare events (0.9%) when a catheter would cheese-wire through the trabecular meshwork, resulting in an involuntary trabeculotomy, which was associated with higher risks of hypotony.²⁴ Although this was not specifically reported in most studies, Konopińska et al suggested such situations may arise from difficult or improper catheterization of Schlemm's canal, which they identified as the most common intraoperative complication in canaloplasty.²⁵ Describing such a combined technique with the OMNI surgical system, Klabe and Kaymak reported hypotony with choroidal effusion in 7.9% and lens-cornea touch in 2.6%.²⁶

Descemet's membrane detachment (DMD) is a significant complication associated with canaloplasty, reported in up to 3.7% of AbIC cases. Authors have previously reported incidences of DMD from 1.6% to 9.1% for all types of canaloplasty,^{27,28} and 0.04% to 0.52% for phacoemulsification.²⁹ Reports suggest a higher risk of DMD during combined phacocanaloplasty.²⁷ The mechanism of DMD in AbIC is believed to involve excessive pressure during viscoelastic injection, which may disrupt Schlemm's canal walls and cause bleeding and detachment. Although simple cases can be self-limiting and resolve spontaneously within weeks, haemorrhagic, persistent, or more extensive cases have led to chronic corneal oedema, staining and long-term visual axis compromise. Authors have emphasized the importance of controlled catheter withdrawal to mitigate the risk of DMD, although it has been reported even by most experienced surgeons.²⁸

Overall, we identified a weighted mean incidence of clinically significant loss of visual acuity of 0.3% following AbIC, although Gallardo reported the complication in 13.0% of its standalone AbIC subgroup.³⁰ However, the author attributed these changes to ocular surface disease. Other rare complications included cataract formation in 0.17%, and

induced astigmatism in 0.06%. No cases of endophthalmitis, retinal detachment, or severe inflammatory reactions were reported in any of the analyzed studies.

Overall, AbiC demonstrates a favorable safety profile, with a low incidence of severe complications and an approach that mostly preserves angle structure integrity. While transient hyphema and IOP fluctuations are relatively common, they are typically self-limiting and manageable with conservative measures. The main procedural challenge remains the risk of Descemet’s membrane detachment and post-operative inflammation, which may require specialist management (Figures 2 and 3).

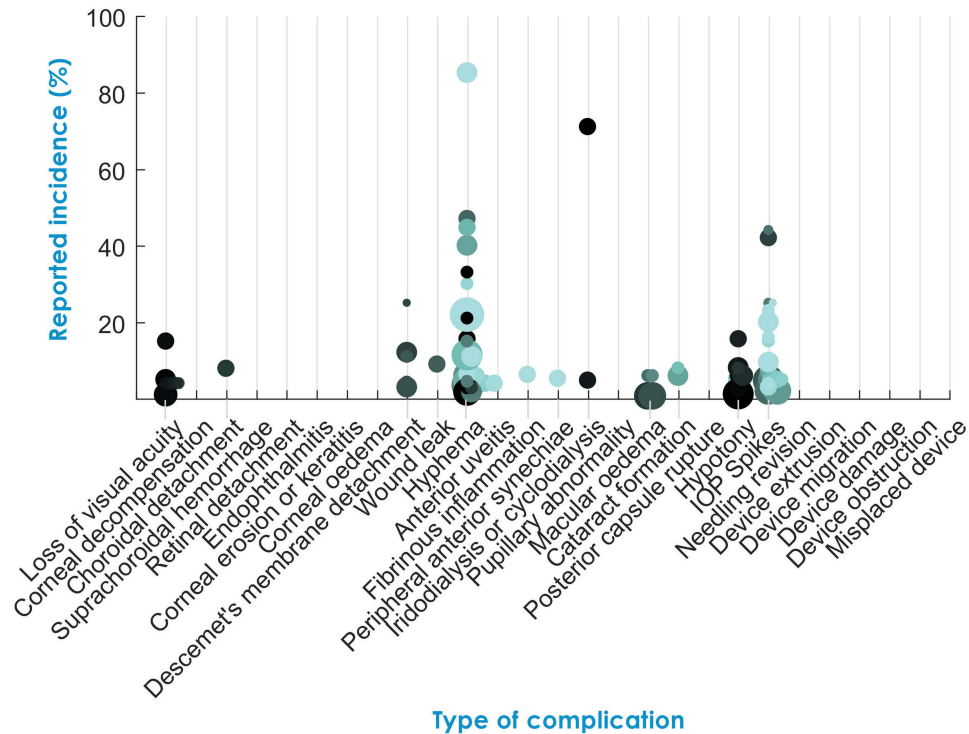


Figure 2 Incidence of reported complications following ab interno canaloplasty (AbiC). Each dot represents a study, plotted according to the incidence (%) of a specific complication (y-axis) and the type of complication reported (x-axis). The size of each dot is proportional to the number of eyes included in the respective study. When multiple reports documented complications with identical prevalence values, the dots were slightly offset to improve visual clarity. Color variation is used solely to distinguish overlapping or adjacent data points and does not carry analytical meaning.

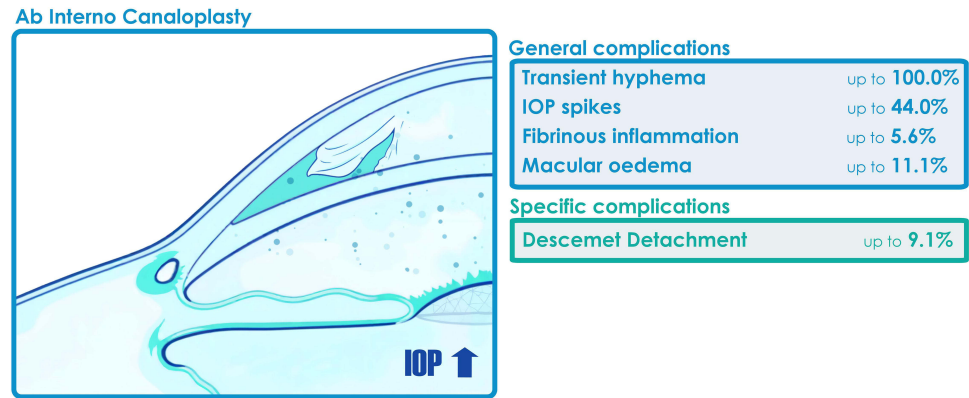


Figure 3 Graphic summary of the main complications reported following ab interno canaloplasty (AbiC), based on their incidence and clinical relevance, including transient hyphema, intraocular pressure spikes (upward arrow), fibrinous inflammation, macular oedema, and Descemet detachment.

Goniotomies And Trabeculotomies

Trabeculotomies

Trabeculotomies, including Gonioscopy-Assisted Transluminal Trabeculotomy (GATT), Kahook Dual Blade (KDB), and other forms of goniotomies or trabeculotomies using sutures, microhooks, bent needles, OMNI, or Trabectome devices, are ab-interno procedures targeting the trabecular meshwork. These techniques function on the principle that the trabecular meshwork is the primary site of aqueous humor outflow resistance in most cases of open-angle glaucoma.¹³ By excising, ablating, or incising the trabecular meshwork, trabeculotomy procedures enhance access to Schlemm's canal and collector channels to improve conventional outflow. GATT achieves this through a 360-degree circumferential trabeculotomy with a microcatheter or suture. Other techniques, such as KDB or Trabectome, involve manual excision or thermal ablation of the trabecular meshwork, while micro-hooks and bent needles provide a controlled incision of a segment of Schlemm's canal.

In total, 207 studies on trabeculotomies were analyzed, encompassing 16,857 eyes. The most frequently studied techniques were GATT (4,798 eyes) and KDB (4,809 eyes). One-quarter of these studies were prospective (25.0%), and 37.1% involved standalone surgeries. A total of 22 different complications were recorded.

Among them, transient hyphema was the most commonly reported, with an overall weighted mean incidence of 29.0%. This was higher in GATT (46.15%) than in other techniques (22.17%), with reported incidences ranging from 0 to 100% across studies. Hyphema is often considered a marker of procedural success, as it indicates exposure of the collector channels, but excessive or prolonged hyphema can, in rare cases, necessitate surgical intervention.³¹ A need for washout was documented in a weighted mean of 0.07% of all cases, and up to 1.04% in GATT. Persistent hyphema exceeding four weeks was reported in 6% of cases in some cohorts.³²

Postoperative intraocular pressure (IOP) spikes were frequently observed following trabeculotomy procedures, with rates varying up to 50% depending on perioperative management strategies. In the present review, we observed a weighted mean incidence of 7.97% for all techniques, with an increased risk following GATT at 10.85%. These spikes typically occurred within the first two postoperative weeks and were linked to transient blockage of outflow pathways due to inflammatory debris, blood accumulation, or viscoelastic remnants. However, spikes persisting after two weeks were often associated with PAS and fibrotic tissue over the trabecular meshwork and required medication reinstatement.³³ Some reports documented the need for systemic IOP-lowering therapy, including oral carbonic anhydrase inhibitors in 72.5% of cases and intravenous mannitol in 21.6%.³⁴ Anterior chamber paracentesis was required in 31.4%, and in 11.8% of cases, additional surgical interventions were necessary to control persistent elevations. Notably, younger patients and those with higher preoperative IOP were at greater risk of these spikes, and failure to manage them adequately was associated with poorer long-term outcomes. However, a randomized trial by Sato and Kawaji suggested that tissue sparing procedures, targeting the trabecular meshwork on 180° rather than 360°, resulted in significantly fewer IOP spikes (26–29% vs 47%) and macroscopic hyphema (6–9% vs 26%).³⁵

Supraciliary effusion is a known risk following trabeculotomy procedures. While the overall reported incidence was relatively low at 1.99% in GATT and 0.61% across all other trabeculotomy techniques, imaging studies systematically assessing postoperative eyes revealed much higher rates, ranging from 41 to 92%.^{36–39} The effusion typically manifests within the first day postoperatively and is often attributed to traction on the ciliary muscle fibers during the circumferential trabeculotomy incision. Supraciliary effusion tends to remain asymptomatic, resolves spontaneously in most cases within a month and is rarely associated with long-term complications. However, persistent or large effusions, particularly those associated with hypotony, may require intervention. Cyclodialysis clefts and ciliochoroidal detachments were documented in isolated reports following KDB and other goniotomy techniques.^{40–43} These were associated with excessive incision depth, particularly when the surgical instrument inadvertently penetrates structures posterior to the trabecular meshwork. Especially when the blade or microhook extends beyond the intended plane of the trabecular meshwork, disrupting the structural integrity of the ciliary body. Ciliochoroidal detachments were reported in an overall weighted mean 0.08% of cases, but in a systematic imaging study, Akagi et al reported incidences of 42% at day 3 and 15% at day 10, with an inverse correlation between detachment grades and IOP.³⁸ In one reported case, a cleft associated

with prolonged hypotony and macular choroidal folds was detected two months postoperatively by ultrasound biomicroscopy, and was successfully managed with multiple sessions of argon laser photocoagulation.⁴⁴

Peripheral anterior synechiae (PAS) are another notable postoperative complication, particularly following microhook trabeculotomy. Matsuo et al reported that 86% of eyes developed PAS within one year, raising concerns about potential long-term reductions in outflow capacity.⁴⁵ This may occur due to inflammatory changes at the incision site or fibrotic healing responses, which can counteract the procedure's intended benefits. The long-term impact of PAS on surgical outcomes remains an area of active investigation. While PAS formation was not reported following KDB and OMNI procedures, it was present in 0.46% of GATT cases, suggesting a greater tendency for synechiae formation when Schlemm's canal is extensively disrupted. Nevertheless, the absence of clinical symptoms and the necessity to perform a postoperative gonioscopy to assess PAS formation would unsurprisingly lead to the under-representation of this complication outside of systematic targeted studies. The healing response following GATT and microincisional trabeculotomy was also studied by Rao and Mukherjee, who observed variable patterns and levels of scarring on OCT following these procedures.⁴⁶ Trench pattern extending onto the cornea were more common following GATT, and were indicative of intense fibroblastic scarring of Schlemm's canal, themselves predictive of guarded surgical prognosis. Allan et al observed similar findings when trabecular meshwork remnants were incompletely removed, promoting angle structures fibrosis.⁴⁷

Hypotony was an infrequent complication of trabeculotomy techniques, with an overall weighted mean incidence of 0.2%. However, individual reports suggested incidences as high as 10% in some randomized control trials.⁴⁸ Other rare but significant complications included DMD, macular edema, corneal edema, and iridodialysis. DMD was reported in 0.5% of all trabeculotomies, with higher rates in standalone GATT (0.2–5.4%). Macular edema occurred in 0.34% of cases, while corneal edema was reported in 0.50%, with a higher incidence in GATT and KDB than in partial trabeculotomies performed using bent needles or micro-hooks.

Though their safety profiles differ based on the specific device and surgical approach, trabeculotomies are relatively safe techniques compared to more invasive filtering procedures. Evidence is accruing to confirm that more invasive and extensive treatments produce more intense inflammation and chronic scarring of the angle structure, the long-term effect of which still warrants further research. The relatively high rates of transient complications such as hyphema, IOP spikes, and supraciliary effusion underscore the importance of patient selection, as well as close postoperative monitoring and individualized perioperative management strategies (Figures 4 and 5).

ELT and FLIGHT

Excimer Laser Trabeculostomy (ELT) and Femtosecond Laser Image-Guided High-Precision Trabeculotomy (FLIGHT) are two laser-based variations of the trabeculotomy technique. ELT uses excimer laser to create microperforations in the trabecular meshwork to reduce outflow resistance into Schlemm's canal.⁴⁹ FLIGHT is a newer approach employing a femtosecond laser to achieve a similar goal with the objective, in theory, to optimize its precision and minimize collateral thermal damage.⁵⁰ While ELT is an ab interno procedure, requiring direct contact between the laser probe and the trabecular meshwork, FLIGHT is non incisional and performed ab externo in a non-sterile environment.

ELT

Although covering relatively long periods, publications on ELT remain scarce. Seven studies analyzing ELT included 1,352 eyes were analyzed, with a mean follow-up of 36.1 months, extending up to 96 months. None of the studies were prospective, and 14.61% of procedures were performed as standalone surgeries.

In combined procedures, up to 3.7% of cases were reported to exhibit intraoperative capsular rupture.⁵¹ One case of iris trauma was also reported. Intraoperative bleeding was observed in up to 58% of cases, though only 5.8% developed clinically significant hyphema requiring monitoring.⁵² Overall, the rate of reported hyphema was 5.94%. However, several reports, although they were included in the present review for the sake of completeness, did not make any mention of safety or report any adverse event, which may result in a dilution of incidences reported in other reports. Signs of inflammation were also observed post-operatively, with corneal oedema and Descemet folds in as many as 37.1% of cases.⁵¹ Although corneal oedema resolved over time, Riesen et al still reported Descemet folds in 12.2% at

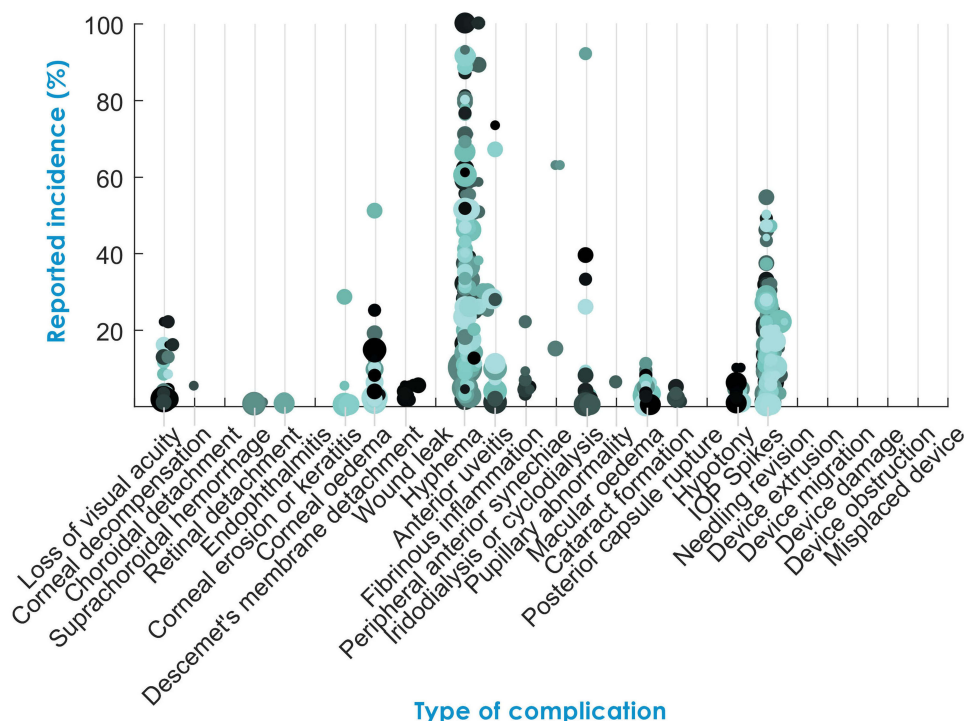


Figure 4 Incidence of reported complications following trabeculotomy. Each dot represents a study, plotted according to the incidence (%) of a specific complication (y-axis) and the type of complication reported (x-axis). The size of each dot is proportional to the number of eyes included in the respective study. When multiple reports documented complications with identical prevalence values, the dots were slightly offset to improve visual clarity. Color variation is used solely to distinguish overlapping or adjacent data points and does not carry analytical meaning.

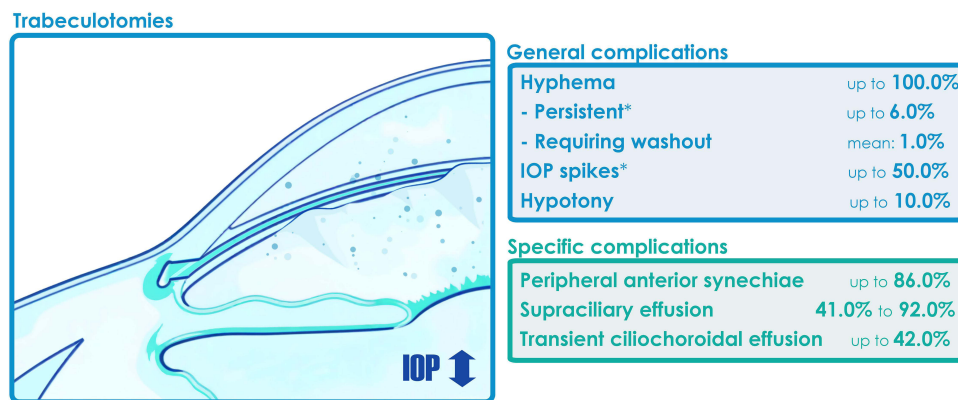


Figure 5 Graphic summary of the main complications reported following trabeculotomy, based on their incidence and clinical relevance, including hyphema, intraocular pressure spikes and hypotony (double-sided arrow), peripheral anterior synechiae, supraciliary effusion, and transient ciliochoroidal effusion. Risks of persistent hyphema and intraocular pressure spikes (indicated by asterisks) are reduced with tissue-sparing procedures.

one-week and 1.7% at one-month. Nevertheless, they did not report any incidence of corneal decompensation though 8-years. Cystoid macular oedema was also reported in 0.91% overall and up to 3.7% in some reports, with a greater incidence at 3 months than at 1 month.⁵¹

Transient IOP spikes were reported in up to 24.5% of eyes within the first postoperative days, but these spikes were self-limiting and successfully managed with medication.⁵¹ On average, the incidence of IOP spikes across all studies on ELT was 6.98%. Hypotony was recorded in 0.69% of cases (range 0–2%), resulting in choroidal detachment in up to 0.64% and suprachoroidal haemorrhages in up to 0.32%.

Despite slightly higher rates of corneal edema and choroidal detachment, ELT demonstrates a safety profile comparable to some traditional trabeculotomy procedures. Although the presence of clinical markers of intense post-operative inflammation may raise concerns about endothelial health, long-term reports, including an 8-year follow-up study, have not identified any instances of chronic inflammation or corneal decompensation. Prospective trials are needed to confirm these findings.

FLIGHT. Data on FLIGHT safety and efficacy remain limited, with only one published study available to date. This first-in-human prospective, single-center pilot study included 18 eyes from 12 patients with open-angle glaucoma, followed for up to 24 months.⁵⁰

No serious laser-related adverse events were reported at any follow-up period. The most common postoperative event was blood reflux into the anterior chamber, which occurred in 11 out of 18 eyes (61.1%) within the first two hours postoperatively, confirming Schlemm's canal patency. However, this blood reflux was only visible under gonioscopy and resolved by postoperative day one, with no impact on vision. Conjunctival hemorrhage was observed in 3 eyes (16.7%), attributed to the suction ring used to stabilize the patient interface rather than the laser treatment itself.

At 24 months, two eyes (11.7%) experienced a loss of two or more lines of best-corrected visual acuity. One case was attributed to glaucomatous progression, while the other was associated with cataract development. Additionally, one eye (5.6%) developed moderate cystoid macular edema at three months, which resolved with topical nepafenac by six months. No incidence of IOP spikes, corneal decompensation, hypotony, or peripheral anterior synechiae were observed throughout the study. However, data remain scarce and further research is warranted to confirm the favorable safety profile of FLIGHT.

Trabecular Devices

Hydrus Microstent

The Hydrus Microstent is an 8-millimeter-long crescent-shaped metallic device designed for implantation through the trabecular meshwork and into Schlemm's canal via an ab interno approach. The device spans three clock hours of the canal and its open design functions by scaffolding and dilating Schlemm's canal without obstructing collector channels openings. Through its proximal end, it also provides a bypass of the trabecular meshwork.⁵³

A total of 26 studies on the Hydrus Microstent were analyzed, encompassing 2269 eyes. Nearly half of these studies were prospective (46.6%), and 6.9% involved standalone surgeries. The mean duration was 33.0 months. A total of 12 different types of complications were recorded. Among the recorded complications following Hydrus Microstent implantation, transient hyphema remains the most commonly reported. Incidence rates vary, with some cohorts documenting it in up to 36.4% of cases (overall weighted mean: 19.74%).⁵⁴ In the vast majority of instances, hyphema resolves spontaneously within the first postoperative week without requiring any intervention. However, there has been several individual reports of persistent hyphema, occasionally in the context of chronic inflammation such as Uveitis-Glaucoma-Hyphema Syndrome, chronic granulomatous iritis, or macular oedema requiring surgical explantation of the device.^{55,56} While in most cases, subtle malposition of the Hydrus Microstent was identified as a cause of the adverse event, in some instances the device appeared to be well positioned. For this reason, and although the exact incidence of these events is unknown but certainly rare, some authors caution the use of the Hydrus Microstent in eyes with angle closure and all secondary glaucoma except pigmentary and pseudoexfoliative glaucoma, or patients on dual anti-thrombotic therapy.⁵⁵

Although post-operative IOP spikes have been observed following Hydrus Microstent implantation, they are less common than in other MIGS procedures, with incidences ranges from 0% to 15.6%. The present analysis identified a weighted mean incidence of 1.46% across the literature, below the incidence of 4% reported in the HYDRUS II trial.⁵⁷ Most of these IOP variations were transient and resolved within the first few days.

Two other adverse events reported following Hydrus Microstent implementation are the progressive formation of peripheral anterior synechiae (PAS) and the post-operative extrusion of the distal tip of the device. Although the clinical relevance of either of these observations is not yet known, and some authors have reported on the absence of association with surgical outcomes, studies have reported an incidence of PAS formation in up to 20.0%,⁵⁸ with occurrence rates increasing with time in longitudinal reports.^{53,57} Notably, PAS led to device obstruction in up to 7.3%, requiring laser

treatment in some cases.⁵⁹ It has been speculated that chronic mechanical tension from the device stretching Schlemm's canal may provoke low-grade inflammation, promoting the formation of PAS and ultimately obstructing aqueous flow in the affected area of adhesion. Because PAS are often asymptomatic and require specific gonioscopic assessment to be detected, many studies have not actively searched for them, most likely leading to underreporting and contributing to an artificially low overall weighted mean incidence rate (1.29%). This potential underestimation, along with concerns that PAS formation might be specifically linked to Hydrus Microstents' design, has led to its inclusion as a primary endpoint of an ongoing prospective multicenter trial (The INTEGRITY Study), to better define its incidence and clinical impact. Regarding device extrusion, Laroche et al reported a case series of 5 mispositioned Hydrus Microstents, in which the distal tip was found to extrude into the anterior chamber postoperatively.⁶⁰ The authors hypothesized that this may be related to the device's pre-set curvature or to the presence of adhesions or herniations in Schlemm's canal during device insertion. In this small case series, the mispositioning was not associated with any significant adverse effects, such as corneal decompensation or vision-threatening complications, over up to 19 months, and the authors concluded the clinical impact of the extrusion was minimal. There are, however, anecdotal descriptions of Hydrus devices asymptotically protruding into the anterior chamber for several years before causing corneal decompensation. Other authors have also reported intraoperative challenges with Hydrus Microstent implantation, such as difficulty advancing the device within Schlemm's canal or the tip diverting toward the iris root, which may contribute to malpositioning.⁶¹ Potential complications related to device explantation, impacts on future surgeries, and endothelial cell loss are discussed in the sections below.

Other rare complications included transient anterior uveitis in 1.96% (range 0–63%), transient hypotony in 0.26%, cystoid macular oedema in 0.09% (range: 0–2.4%), and corneal erosion in 0.04%.

The Hydrus Microstent demonstrates relatively low complication rates, though chronic PAS formation and other rare adverse events such as device extrusion and chronic inflammation should be monitored to ascertain their clinical significance. Although endothelial cell loss was not the primary focus of the reviewed studies, the long-term impact of the Hydrus Microstent on corneal health remains an area of interest and is further discussed in a dedicated section (Figures 6 and 7).

iStent Technologies

The iStent technology is one of the earliest and most widely utilized forms of MIGS. Although its design evolved over time its working principle remains unchanged. Implanted ab interno, a number of heparin-coated titanium stents bypass the trabecular meshwork, providing 80micrometer aqueous channels into Schlemm's canal. The first-generation iStent device involved a single L-shaped implanted through the trabeculum via a swiping motion. The second generation iStent inject involved two straight stents implanted directly via an injector in two different quadrants. The iStent inject W was a refinement of the iStent inject design, essentially with a wider flange to reduce the risk of over-implantation. Finally, the third generation iStent infinite is similar to the iStent inject W, but involves the consecutive implantation of 3 stents, placed 2-to-3 clock hours apart.⁶²

In all, 152 studies on the iStent technology were analyzed, encompassing 13,637 eyes. Over a third of these studies were prospective (41.3%), and 12.1% involved standalone surgeries. A total of 29 different types of complications were recorded over study durations spanning 10 years for the original iStent and 84 months for the iStent inject.

iStent – 1st Generation. Over the 6'281 eyes reviewed, the most commonly reported complications of the original iStent device were transient hyphema, stent malposition, and lumen obstruction. Hyphema was the most common complication, reported in 2.21% of cases on average (range 0–40%) and in most cases, resolving spontaneously within days to a week without intervention. Interestingly, Shalaby et al showed that the use of chronic antithrombotic therapy did not increase the risk of hemorrhagic complications following iStent implantation.⁵⁴ Although no case of persistent or recurrent hyphema was reported in clinical trials, several individual case reports described delayed onset hyphema several months postoperatively, occasionally associated with iritis, and attributed to malpositioned stents angled toward the ciliary body. In all cases, device removal was required to resolve the issue.^{63–65} Mantravadi et al also described a single case of inadvertent implantation of an iStent into the supraciliary space during cataract surgery.⁶⁶ Despite the displacement, the patient remained clinically stable, and no adverse events occurred. The report emphasizes that malpositioning of the

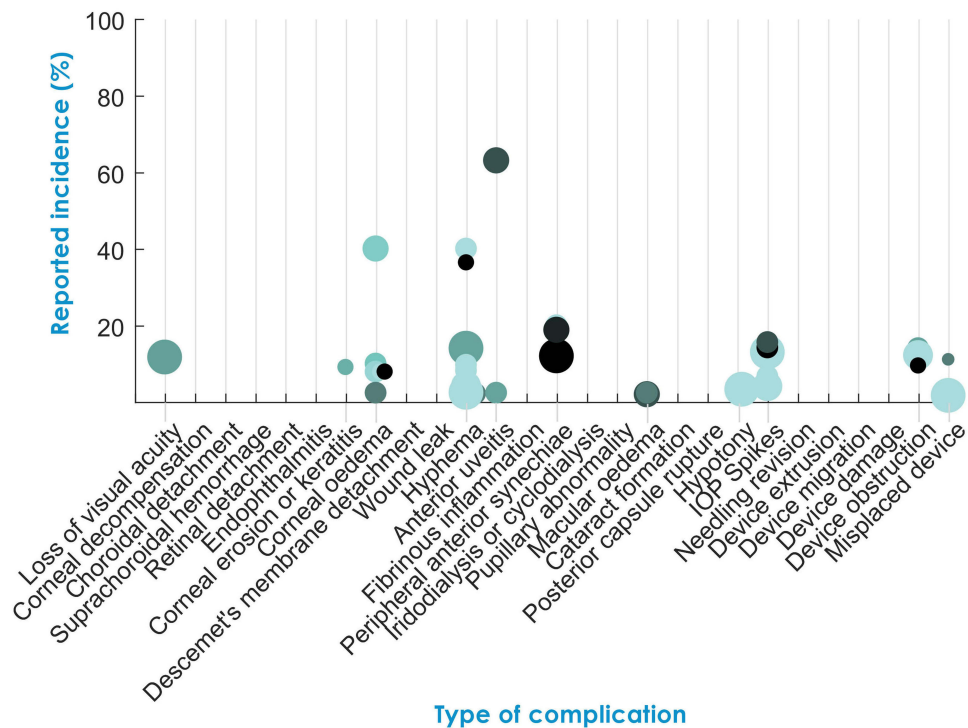


Figure 6 Incidence of reported complications following Hydrus Microstent implantation. Each dot represents a study, plotted according to the incidence (%) of a specific complication (y-axis) and the type of complication reported (x-axis). The size of each dot is proportional to the number of eyes included in the respective study. When multiple reports documented complications with identical prevalence values, the dots were slightly offset to improve visual clarity. Color variation is used solely to distinguish overlapping or adjacent data points and does not carry analytical meaning.

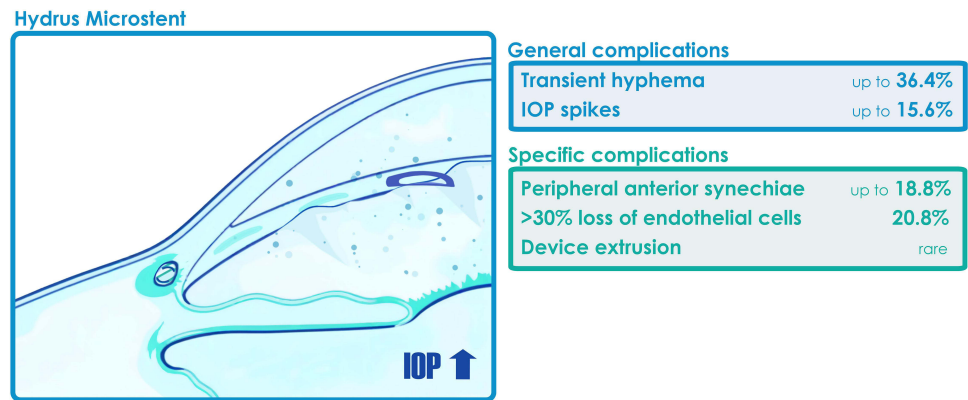


Figure 7 Graphic summary of the main complications reported following Hydrus Microstent implantation, based on their incidence and clinical relevance, including transient hyphema, intraocular pressure spikes (upward arrow), peripheral anterior synechiae, significant loss of endothelial cells, device extrusion.

iStent is rare and may not require intervention, as only iris- or ciliary- contacts were associated with reported complications. Overall, stent malposition or obstruction were reported in 0.93% of cases (range 0–27%). When the nature of stent obstruction was described, it was generally attributed to iris tissue blocking outflow rather than peripheral anterior synechiae.⁶⁷ The latter were reported in 0.44% of cases.

Intraocular pressure spikes were reported in up to 38.9% of cases (weighted mean: 5.7%). Other complications, such as hypotony (0.13%, range 0–20%) and corneal edema (0.4%, range 0–8.9%), were rare and were generally self-limiting.

While no case was reported in clinical trials, a few individual reports of endophthalmitis were described in the literature following cataract surgery combined with iStent implantation. Although intraocular infection is a risk of any

intraocular procedure, Chaves et al identified direct trauma from the tip of an eyedrop vial shortly after surgery as a contributing factor in at least one case.⁶⁸ In a large retrospective study of 979 cases of endophthalmitis managed at Wills Eye Hospital, Starr et al observed a prevalence of 0.13% following all MIGS procedures, including iStent, Hydrus, and CyPass.⁶⁹ This supports previous reports by Sabharwal et al who calculated a rate of endophthalmitis of 0.1% following combined MIGS procedures across the US Medicare population between 2016 and 2019.⁷⁰ This is similar to the rates reported in various studies for standalone cataract surgery.⁷¹ Interestingly, Starr et al reported that none of the iStent were removed, suggesting that implant removal in MIGS-associated endophthalmitis may not be necessary unless they were deemed a perpetuating factor for the infection.⁶⁹

In a 10-year study of iStent implantation with cataract surgery, Neuhann et al underlines the absence of long-term complications such as angle structure scarring or corneal decompensation.⁷² In the context of a favourable safety profile, the main risks to consider with the first generation iStent are the post-operative IOP variations and the rare occurrence of ciliary body trauma through improper positioning.

iStent inject. While relying on the same micro-bypass mechanism, the iStent inject represents a refinement over the first-generation iStent, with the introducing two straight, smaller-diameter stents implanted via an injector system. Unlike the original iStent, which required a swiping motion for implantation, the inject system allows for more controlled delivery.

In all, 6'778 eyes with the iStent inject were analyzed. The most commonly reported postoperative complication was transient hyphema, with an overall weighted mean incidence of 6.13% (range: 0%–100%). These wide variations may be attributed to the fact that, as in most trabecular surgeries, hyphema was typically caused by blood refluxing through the stent, indicating functional distal aqueous pathways. For this reason, some authors considered it a desirable event and chose not to report it. Importantly, no case of persistent or recurrent hyphema requiring device removal was identified in the literature on the iStent inject. This marks a key distinction from the original design and may be the key differentiating factor between physiological blood reflux and traumatic hyphema. This is mirrored by the findings of Shalaby et al who identified, in a direct comparative study, significantly lower rates of hyphema and IOP spikes following iStent inject implantation (8.5% and 5.6%, respectively) than with the first-generation iStent (9.9%, 13.6%) or the Hydrus (36.4%, 6.1%).⁷³ On the other hand, stent malposition and obstruction appeared to be substantially more frequent in the iStent inject than in the first-generation device, reported in up to 44.9% of cases in in vivo imaging studies.⁷⁴ Notably, this was primarily due to excessive depth of implantation rather than malalignment with Schlemm's canal. Prospective imaging studies suggested that stent positioning remained stable over time, with no evidence of migration, even when initially placed too deep.⁷⁵ These malpositioned stents were not reported to cause clinically significant inflammation, hyphema, or endothelial cell loss, and did not typically require removal of the device. This absence of associated complications probably resulted in the under-reporting of stent malposition and an overall weighted mean incidence of 0.59%. Except in a single case of endophthalmitis, there is no report of iStent inject requiring removal in the literature.⁷⁶

Postoperative intraocular pressure spikes were observed in 1.75% of cases (range: 0%–29.0%), with most resolving spontaneously within the first few days. Unlike trabecular bypass procedures involving excision or ablation, the iStent inject does not typically induce peripheral anterior synechiae formation, with a mean reported incidence of 0.24%. Other infrequent complications included transient anterior chamber inflammation (weighted mean 0.20%, range 0%–6%), corneal edema (0.47%, range 0%–10%), and hypotony (0.04%, range 0–0.4%).

Serious complications following iStent inject implantation were rare. As for the first generation of iStent, although large cohort studies did not report any case of endophthalmitis, individual reports were published. Notably, Lam et al reported a case of *Rothia mucilaginosa* endophthalmitis following combined cataract surgery and iStent inject implantation, that progressed towards retinal detachment despite stent explantation; however, vision in the affected eye was partially preserved.⁷⁶ In another case, *Staphylococcus epidermidis* endophthalmitis occurred after the same combined procedure, with symptoms manifesting five days postoperatively.⁷⁷ The infection was successfully managed with intravitreal antibiotics, and the iStent inject did not need to be removed. While the exact mechanism of infection cannot be ascertained, the authors speculated that concomitant neutropenia in an underlying immunocompromised state may have contributed to the patient's susceptibility for infections. Previously reported incidences of endophthalmitis in combined MIGS procedures (0.1%) included iStent inject devices, and these individual observations are in keeping with these numbers.

The iStent inject resolves some key limitations of the first-generation device by minimizing direct trauma to the trabeculum, resulting in decreased rates of IOP spikes or hyphema, and essentially removing the risk of iris or ciliary body trauma. Outside of the risks common to all intraocular surgeries, the main specific risk of the iStent inject remains that of misplacement, although the main consequences of this may be more in terms of effectiveness rather than safety (Figures 8 and 9).

iStent inject W. The iStent inject W was developed as further improvement over the iStent inject design, featuring a wider flange to enhance visualization and reduce the risk of over-implantation into Schlemm's canal. This modification aimed to address concerns about deep implantation observed with the iStent inject while maintaining the same mechanism of action.

Amongst 506 eyes studies, the most commonly reported complication was transient hyphema, observed in similar incidences as with the iStent inject (6.22% mean weighted incidence, range 1.8%–8.6%). Interestingly, no event of iStent inject W malposition was reported in the literature. Although no studies were specifically designed to assess the position of these devices, several authors suggested that the larger flange improved implantation control and reduced the risk of misplacement.^{78,79} Although this was a rare device-related event rather than a typical surgical misplacement, in a single case report Shimada et al described two connected stents being ejected simultaneously during iStent inject W implantation.⁸⁰ A review of the surgical video suggested that the injector was damaged when the trocar shaft was bent during injection. The devices were removed and reimplanted using a new injector.

Intraocular pressure spikes occurred in 4.74% of cases (range: 0%–6%). Like other trabecular bypass stents, these pressure elevations were transient and typically resolved within the first few postoperative days. Other postoperative complications included anterior chamber inflammation (weighted mean 0.34%, range 0%–2%) and corneal edema (0.97%, range 0%–7%). These rates were in line with those reported for the iStent inject and were typically transient. No device extrusions or significant postoperative infections were documented in the literature.

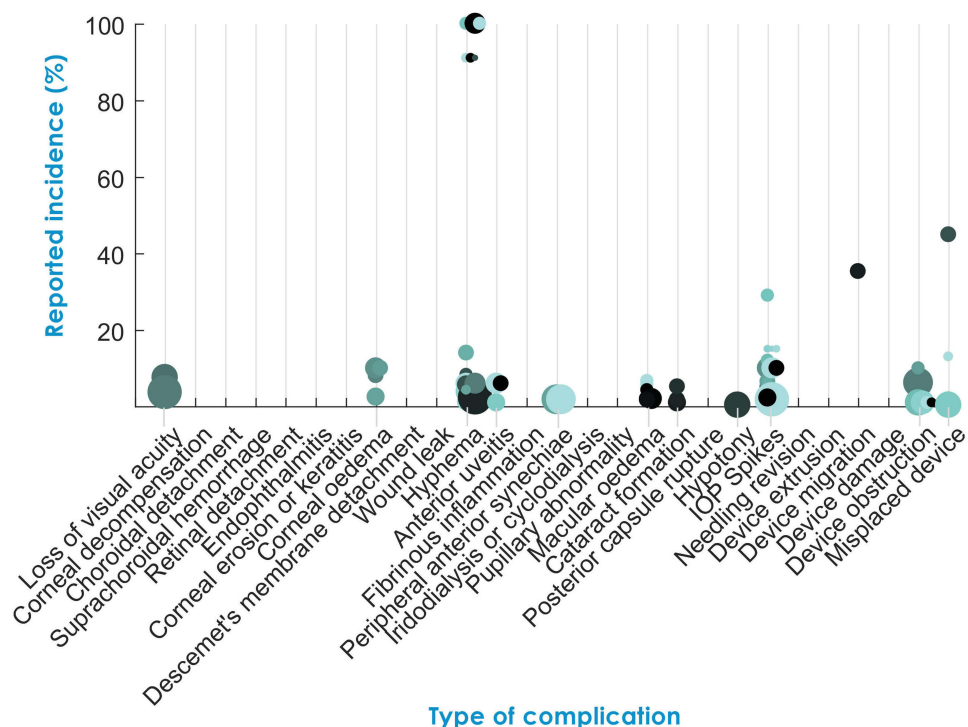


Figure 8 Incidence of reported complications following iStent inject implantation. Each dot represents a study, plotted according to the incidence (%) of a specific complication (y-axis) and the type of complication reported (x-axis). The size of each dot is proportional to the number of eyes included in the respective study. When multiple reports documented complications with identical prevalence values, the dots were slightly offset to improve visual clarity. Color variation is used solely to distinguish overlapping or adjacent data points and does not carry analytical meaning.

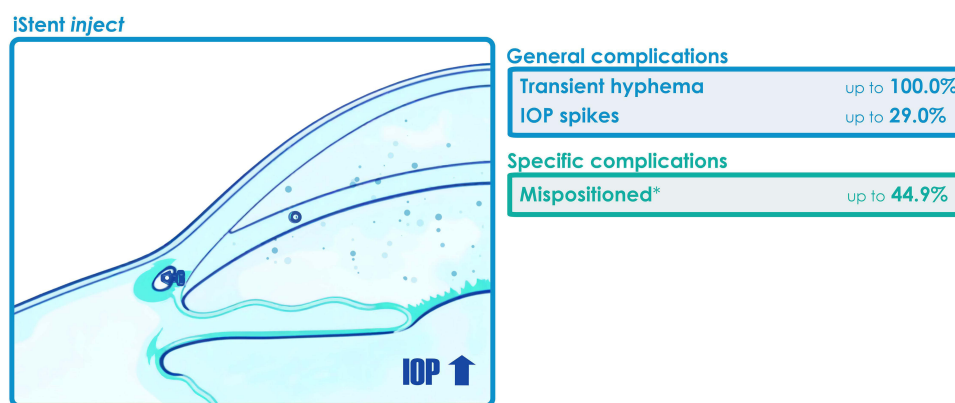


Figure 9 Graphic summary of the main complications reported following iStent inject implantation, based on their incidence and clinical relevance, including transient hyphema, intraocular pressure spikes (upward arrow), and mispositioned stents. Risks of overimplantation and mispositioning (indicated by an asterisk) are reduced with iStent inject W procedures.

Although data on the iStent inject W is still building up with only 7 published reports to date, it appears to share the same favorable safety profile as the iStent inject, with anecdotal reports of more controlled and reliable implantation. **iStent Infinite.** The iStent infinite is the most recent evolution of the trabecular micro-bypass system designed for standalone implantation in eyes with uncontrolled open-angle glaucoma despite prior surgical or medical therapy. It consists of three iStent inject W devices implanted two-to-three clock hours apart.

There is currently only one study available on the iStent infinite, in which 84.7% of the 72 eyes included underwent the procedure following previously failed glaucoma procedures.⁸¹ In this study, the most frequently observed post-operative complication was transient intraocular pressure (IOP) elevation, requiring oral medication in 2.8% of cases and a step up in the surgical management with tube shunt surgery in 4.2%. Significant hyphema was reported in 4.2% of eyes, but all cases resolved without sequelae, although it was associated with stent obstruction in one case (1.4%). Another case of stent obstruction was observed in preexisting focal goniosynechia and resolved with the use of pilocarpine. Device malposition was also noted in two cases (2.8%) within the same eye: these were described as a deep implantation and one stent implanted in an unintended quadrant. Both cases were attributed to impaired intraoperative visualization due to corneal arcus and striae, and neither required any subsequent intervention. Except for one case of hyphema, all of these adverse events were observed in the subgroup of eyes that had undergone prior surgery.

Mild perioperative inflammation was recorded in 6.9% of cases. Some serious postoperative events were observed, although they were all attributed to preexisting ocular disease or subsequent tube shunt surgery. These included loss of best corrected visual acuity (8.3%), visual field loss ≥ 2.5 dB (6.9%), macular edema (2.8%), and hypotony (1.4%). No serious device-related adverse events such as stent explantation, endophthalmitis, corneal decompensation, or hypotony maculopathy were recorded.

Although the complication rates reported in the single available publication on iStent infinite may initially appear higher than that of prior versions of the iStent, direct comparisons are limited by the distinctively high-risk population studied, many of whom had undergone prior filtering procedures, and the fact that reported complications notably included adverse events resulting from secondary tube shunt surgery. Nevertheless, their risk profile appears to share similarities with the iStent inject W. Additional long-term data will be essential to further characterize and confirm the safety of this device in broader clinical use.

Suprachoroidal Devices

STAR-Based Supraciliary Implants

The MINInject implant is a 5 mm-long, flexible, microporous silicone device designed for ab interno supraciliary implantation. It acts on uveoscleral outflow to lower intraocular pressure.⁸²

Across five reports encompassing 121 eyes, covering both the current MINIject device and earlier suprachoroidal designs such as STARflo, 85.12% were prospective studies, and all described standalone procedures. The mean follow-up duration across studies was 15.1 months, with a total of 17 different types of complications recorded.

The most frequently reported complications were IOP spikes, observed on average in 39.2% of eyes overall (MINIject + earlier STARflo designs; range 0–70.0%), and in 26.1% of MINIject cases (range 0–48.4%). While most were transient, some required temporary IOP-lowering medication or further surgical intervention. Anterior chamber inflammation occurred in 6.7% of all eyes (range 0–30.8%; 11.0% in MINIject), and hyphema in 10.5% overall (range 0–22.6%; 13.1% in MINIject). Vitreous hemorrhage occurred in 1.7% of cases.

Device-specific complications included implant mispositioning in up to 28.6% of STARflo cases and up to 27.8% of MINIject cases, requiring repositioning.⁸³ These were primarily due to excessively deep placement in the suprachoroidal space, resulting in reduced drainage efficacy and requiring surgical repositioning.⁸³ One MINIject device (1.37%) migrated into the anterior chamber and required explantation.⁸² Some of these complications were attributed to an earlier injector design deficiency that affected the dual-operator delivery tool, leading to implantation issue, and difficulty fully retracting the sheath.⁸⁴ In the STAR-II trial, these delivery-tool deficiencies prompted the ethics committee and competent authority in Germany to withdraw initial trial approval after enrollment (while permitting continued protocol follow-up to study completion).⁸⁴ The trial status was unchanged in France and Spain. These deficiencies resulted in implant malpositioning in some cases, and the manufacturer subsequently introduced a single-operator delivery tool to mitigate these issues. In addition, in 2024, a field safety notice was issued after 6 misplacements of the MINIject-S in the ciliary body were identified among 78 devices implanted in Switzerland (7.7%).⁸⁵

Hypotony was also relatively common, reported in 9.9% of eyes overall (range 0–28.6%), associated choroidal folds or detachment in 3.3% (range 0–14.3%). These events were less common with MINIject (3.9%). Most cases resolved spontaneously or with conservative treatment; however, one MINIject case (1.37%) required Healon GV injection to stabilise the anterior chamber.⁸⁴ Corneal complications were more prominent in early STARflo models, with corneal decompensation reported in up to 28.6% of eyes⁸⁶ and endothelial cell loss averaging 41.5% at 24 months.⁸⁷ In contrast, MINIject studies reported corneal edema in 6.6% of eyes and a mean endothelial cell loss of 5% at 24 months.⁸⁴ Cataract formation or postoperative lens opacities were reported in 6.8% of MINIject cases. In the most recent MINIject data, decreased visual acuity occurred in 22.5% of eyes (range 0–30.8%). Two-thirds of these events were transient or unrelated to the device, often reversible through standard management such as cataract surgery. Permanent visual loss was rare but documented, including cases of *phthisis bulbi* and intraoperative expulsive hemorrhage in STARflo recipients.⁸⁷

Other MINIject-related complications included pupil abnormalities or corectopia (6.5%), presumably due to ciliary body trauma, iris root entrapment or postoperative inflammation. Descemet's membrane detachment occurred in one case (1.37%).

From an anatomical point of view, the suprachoroidal approach may be more disruptive than most angle-based MIGS procedures. This may contribute to the comparatively higher complication rates reported with MINIject relative to more conservative techniques, within the limitations of heterogeneous study designs. It was already established that subconjunctival MIBS, now often labeled “less-invasive glaucoma surgery” (LIGS), has a different safety and efficacy profile than other MIGS.⁸⁸ Although more reports are warranted to clearly establish the long-term safety profile of the MINIject, it may be anticipated that, like MIBS, suprachoroidal approaches such as MINIject may become recognised as a separate safety class within the MIGS spectrum (Figures 10 and 11).

CyPass Microstent

The CyPass Micro-Stent is a 6.35 mm-long, fenestrated polyimide tube designed for ab interno implantation into the suprachoroidal space, aiming to improve uveoscleral aqueous outflow and lower intraocular pressure (IOP). The device was withdrawn from the market in August 2018 after the COMPASS-XT trial demonstrated significant corneal endothelial cell loss at five years, leading to long-term concerns about safety.¹² This issue will be discussed in greater detail in the dedicated section on endothelial cell loss in MIGS. Across 13 studies analyzing 1,920 eyes, 71.5% were prospective, and 40.1% involved standalone procedures, with a mean follow-up duration of 30.2 months, extending up to 60 months.

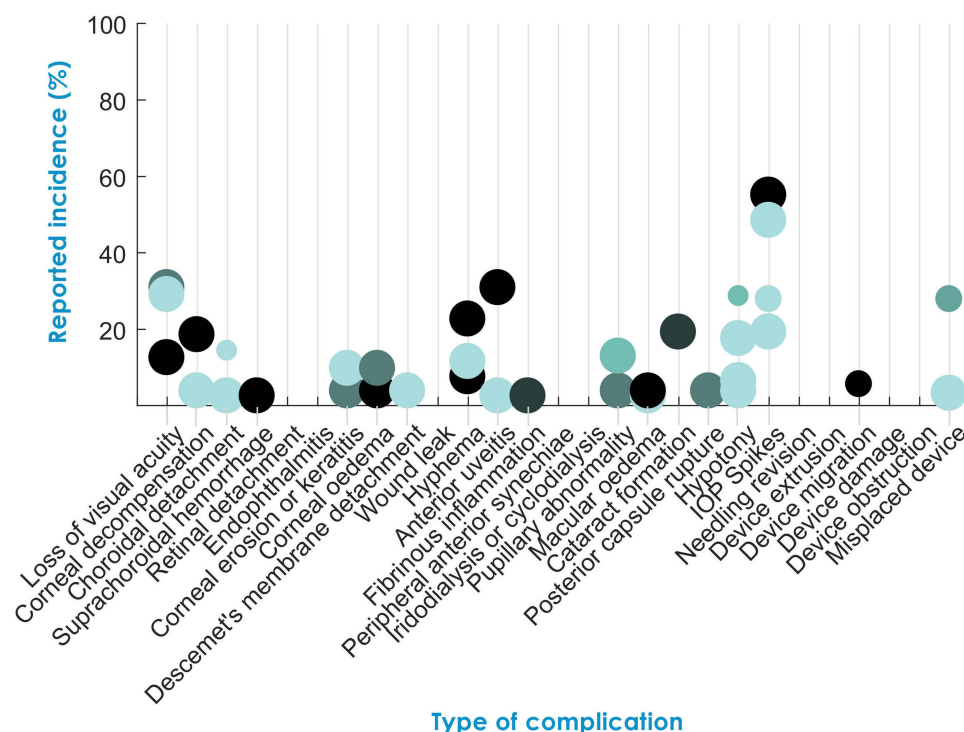


Figure 10 Incidence of reported complications following STAR-based supraciliary devices implantation. Each dot represents a study, plotted according to the incidence (%) of a specific complication (y-axis) and the type of complication reported (x-axis). The size of each dot is proportional to the number of eyes included in the respective study. When multiple reports documented complications with identical prevalence values, the dots were slightly offset to improve visual clarity. Color variation is used solely to distinguish overlapping or adjacent data points and does not carry analytical meaning.

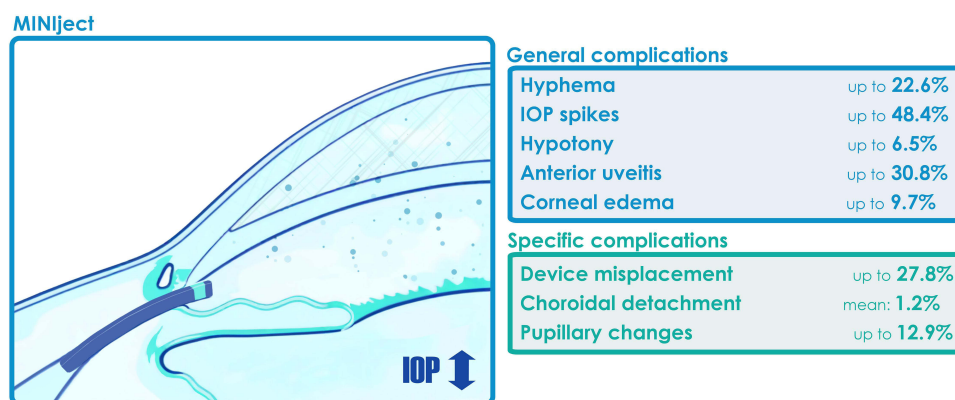


Figure 11 Graphic summary of the main complications reported following MINInject implantation, based on their incidence and clinical relevance, including hyphema, intraocular pressure spikes and hypotony (double-sided arrow), anterior uveitis, corneal oedema, device misplacement, choroidal detachment, and pupillary changes.

The most frequently reported postoperative complication was hypotony, reported in 3.53% of cases (range 0–6.2%), with 0.16% experiencing choroidal detachment (range 0–4.7%). While most cases resolved spontaneously, some required medical or surgical intervention, including intraluminal suture occlusion or argon laser treatment, particularly in cases with significant choroidal detachments.⁸⁹ Intraocular pressure spikes following CyPass implantation were not commonly reported overall, with a mean incidence of 2.05%. However, some authors, notably Gabbay et al, documented IOP spikes in 28.10% of eyes, raising concerns that these events may be linked to the closure of the suprachoroidal cleft over time.⁹⁰ According to the authors, as the cleft heals and fibroses, suprachoroidal outflow diminishes, potentially leading to sudden IOP elevations and surgical failure.

Device-specific complications also included improper positioning and device migration into the anterior chamber. A case series by Fili et al described 8 eyes in which CyPass Micro-Stent had to be removed following corneal decompensation 4 years after implantation.⁹¹ In all of these cases, they noted migration of the device into the anterior chamber, occasionally with endothelial contact.

Other complications included hyphema, occurring in 2.92% of cases (range 0–16.4%), and anterior uveitis (0.11%, range 0–0.9%), which was generally mild and self-limiting, although persistent inflammation contributed to poor outcomes in select cases. Descemet's membrane detachment (0.79%) and retinal detachments (0.05%) were reported but rare. Although loss of visual acuity was recorded in up to 11.2% in the COMPASS-XT trial (weighted mean: 1.62%), this was often attributed to cataract progression (3.97%) and corneal edema (1.15%). Macular edema occurred in 0.16% of cases, and was typically transient.

The case of the CyPass, with its market withdrawal despite promising results in the first three years of use, serves as a cautionary tale, emphasizing the critical importance of endothelial health and the need for long-term safety trials.

Phacoemulsification

Phacoemulsification, the standard surgical procedure for cataract surgery, is widely regarded as a safe and effective intervention, and is also known to lower IOP modestly in many patients, and in some clinical contexts more substantially.⁹² Since a large proportion of MIGS procedures are still combined with cataract surgery, standalone phacoemulsification may serve as a control for complication rate. A total of 28 studies on MIGS involved a phacoemulsification-only control group, encompassing 1,885 eyes, with 45% of these studies being prospective. The mean follow-up duration was 23.34 months, with some studies reporting data up to 60 months.

Complications following cataract surgery alone were infrequent and generally mild. Overall, loss of visual acuity occurred in 0.21% of cases (range 0–6%), and transient corneal edema was reported in 0.21% (range 0–5%) and typically resolved without intervention. Posterior capsule rupture was observed in 0.1%, and no occurrence of vitreous prolapse was reported. Posterior capsule opacification, a common long-term complication, was recorded in 0.21% of cases, while macular edema occurred in 0.05% (range 0–1.5%). Retinal detachment was a rare occurrence at 0.05%, and there were no reported cases of endophthalmitis across the analyzed studies. Likewise, subconjunctival hemorrhage, corneal erosion, anterior uveitis, pupillary abnormalities, and pain or glare were not reported in any of the reviewed articles.

Intraocular pressure (IOP) spikes were documented in 2.11% of cases (range 0–25.6%), with most spikes being transient. Refractive deviation from the expected outcome was reported in 0.13% of cases.

Although the reported incidence of these complications vary widely across studies, the observed incidence rates in the present study are notably lower than those typically reported in the broader scientific literature with, for instance, posterior capsule rupture reported in 0.5% to 5.2% of cases,⁹³ and macular edema in 1.17%.⁹⁴ This difference underscores how study design, patient selection, and reporting practices, especially in trials involving MIGS, can influence reported incidence rates. By providing this contextual baseline, the phacoemulsification data help illustrate how the review and statistical process itself may affect complication incidence reporting, and emphasize the need for caution when attributing complications specifically to MIGS in combined procedures.

General Considerations

Endothelial Considerations

Because corneal endothelial cells do not regenerate and their number naturally decreases with age, any procedure that compromises their density poses a lifelong risk to patients. The progressive nature of endothelial cell loss (ECL) implies that, over time, repeated surgical interventions may have a cumulative effect on corneal transparency, potentially leading to corneal decompensation, visual impairment, and diminished quality of life. As ECL cannot be routinely detected in standard clinical follow-up unless it becomes advanced and symptomatic, its study requires specific, long-term imaging protocols such as specular microscopy. In this context, a pivotal contribution to the field was made by Ahmed et al, which remains the most comprehensive comparative assessment of endothelial safety in MIGS to date.⁹⁵

This post hoc 5-year analysis pooled data from the pivotal trials of iStent inject, Hydrus Microstent, and the CyPass Micro-Stent, all performed in combination with phacoemulsification and compared to respective standalone

phacoemulsification control groups. The primary endpoint was the proportion of eyes with clinically significant endothelial cell loss at 60 months, defined as an ECL $\geq 30\%$ from baseline. In terms of absolute ECL, at the 5-year mark, iStent inject demonstrated a comparable rate of significant ECL to the control group (9.4% vs 6.3%, $p = 0.77$) and no meaningful difference in mean ECD (2099 vs 2103 cells/mm², $p = 0.95$). In contrast, the

Hydrus Microstent showed a significantly higher rate of $>30\%$ ECL at 60 months (20.8% vs 10.6%, $P = 0.01$), and lower mean ECD (1967 vs 2117 cells/mm², $p = 0.004$). The CyPass Micro-Stent exhibited the highest rate of significant cell loss (27.2% vs 10.0%, $p = 0.02$) and the most pronounced reduction in mean ECD (1931 vs 2189 cells/mm², $p = 0.003$).

Beyond these static comparisons, the study provided insight into the respective patterns of ECL progression over time. In all groups, including phacoemulsification controls, the slope of ECL was steepest during the first three months after surgery. For the iStent inject, the rate of ECL paralleled that of the control group at all timepoints, with mean ECD differences of 8.8 cells/mm² at baseline ($p = 0.87$), 6 cells/mm² at 3-month ($p = 0.93$), 4 cells/mm² at 24-month ($p = 0.95$), and 4 cells/mm² at 60-month ($p = 0.95$). This suggests that neither the implantation nor long-term presence of the device caused progressive endothelial damage. The Hydrus showed a nonstatistically significant ECL at 3-month compared to cataract surgery, with an ECD difference of 76 cells/mm² ($p = 0.09$). Over time, however, the difference in ECL widened between the Hydrus and the control group, with ECD differences of 123 cells/mm² at 24 months ($p = 0.005$), and 150 cells/mm² at 60 months ($p = 0.004$). The CyPass group showed a similar, albeit more marked, pattern, with rapidly accelerating rates of ECL. Its differences in ECD as compared with the control group were of 1 cells/mm² at baseline ($p = 0.97$), 28 cells/mm² at 3-month ($p = 0.66$), 76 cells/mm² at 24-month ($p = 0.19$), and 258 cells/mm² at 60 months ($p = 0.003$). The latter two trends exhibit divergence from the control group at the first postoperative visit and continuing to widen through year five, which demonstrate a delayed but progressive loss of endothelial cells.

Beyond this seminal comparative study, the following device-specific review summarizes key ECL findings from the broader literature.

CyPass Micro-Stent

The importance of preserving endothelial health became particularly evident following the voluntary withdrawal of the CyPass Micro-Stent by Alcon. This resulted in particularly heightened vigilance around the issues of corneal health in glaucoma surgeries as all initial reports on the CyPass were promising, the progressive ECL only became visible in later analyses. As highlighted in the above publication, the COMPASS-XT trial revealed that the rate of ECL accelerated through the follow-up and, by 5 years, the loss of ECD had become statistically and clinically significant.⁸⁸ Post-market surveillance revealed that the depth of implantation played a critical role in endothelial outcomes; devices positioned too anteriorly led to direct corneal contact, exacerbating endothelial damage.

MINIject

The STAR-I trial reported a mean ECL of 5% at 24 months following implantation of the iSTAR device, with only one case of corneal decompensation (4%), occurring in a patient with preexisting low endothelial cell density.⁹⁶ Earlier publications on the previous STARflo device reported substantially higher ECL (41.5% at 24 months) and corneal decompensation in 12.5% of cases.⁸⁶ Additionally, Cseke et al described a case of decompensation attributed to direct endothelial contact.⁸⁵ It remains unclear whether the improved outcomes observed with iSTAR reflect design refinements or differences in surgical technique. Long-term, multicenter studies will be critical to confirm the long-term safety of this suprachoroidal device.

iStent inject

In the aforementioned report, Ahmed et al described how iStent inject combined with phacoemulsification resulted in an ECL comparable to that of standalone cataract surgery at all timepoints over the first 5 years post-operatively.⁹⁵ This confirmed the suggestions from other authors that concluded on the stability of ECD following iStent implantation. Interestingly, Gillmann et al have reported that iStent inject positioning had no impact on the ECD in the shortterm, even in a subgroup of mispositioned devices.⁷⁴

Hydrus Microstent

The HORIZON trial data, also synthesized by Ahmed et al, revealed that the Hydrus caused a non-statistically significant ECL initially, followed by a progressive increase in ECL over time, reaching statistical significance at 24 months.⁹⁵ Other reports focused on the immediate effect of the implantation procedure, and confirmed the absence of significant difference in short-term ECL compared to phacoemulsification alone, but highlighted the need for long-term analyses.^{97,98}

Trabeculotomy & Canaloplasty

Although implant-free procedures are often regarded as safer for the endothelium, Olgun and Karapapak described that, although standalone GATT appeared to cause less ECL than what was typically reported following cataract surgery, it still caused a statistically significant ECL of 6.2% at 6 months.⁹⁹ This suggests that even non-implant and non-heat-generating procedures can cause measurable endothelial cell loss, possibly due to surgical trauma, flow alterations, and postoperative inflammation.

Similarly, KDB does not leave any permanent implant in the anterior chamber. Nevertheless, there have been conflicting reports on its effect on endothelial cells. While a multicenter study reported modest ECL (3.4%) with no correlation to follow-up duration up to 29 months following KDB combined with phacoemulsification,¹⁰⁰ Ventura-Abreu et al documented a mean ECL of 11.8% following the procedure, although this still compared favourably to their phacoemulsification only control (25.2%). The authors questioned whether the surgical technique or intraoperative use of viscoelastic material could be responsible for these variations.

Concerning other forms of trabeculotomies, several reports suggested that they have a notable but non-statistically relevant effect on ECD. In a 159-eye retrospective report, Kasahara et al have observed a 9.6% to 13.6% ECL following trabeculotomy using a Trabectome device at 12 months.¹⁰¹ Following standalone AbIC using the iTrack device, Lubeck and Noecker have shown a 3.7% ECL at 12 months, with 18% of patients exhibiting an ECL over 10%.¹⁰² However, no longterm prospective data are currently available to assess whether the initial ECL observed following these procedures progresses over time.

Device Malposition and Removal

Although explantation of MIGS devices remains rare, the increasing adoption of these technologies has brought growing attention to the challenge of malposition and its potential consequences. Studies of the iStent inject report high anatomical stability and a low rate of clinically significant malpositions: even when stents are initially placed too deep, these typically do not require removal due to their inert behavior and absence of inflammatory sequelae.⁷⁴ In contrast, the explantation of first-generation iStents and iStent injects has been reported, with

Mark Sigona et al describing four cases in which devices were successfully removed prior to GATT.¹⁰³ In their series, explantation was technically straightforward and uneventful, aided by fibrous encapsulation that provided countertraction during removal, with all cases achieving effective IOP control postoperatively.

In contrast, in a small case series of four Hydrus Microstent explantations due to uveitisglaucoma-hyphema syndromes, Sachdeva et al described relatively straightforward explantation of stents in the early post-operative period, but a more complicated procedure when removing Microstents that had been in place for more than 6 months.¹⁰⁴ In these cases, strong tissue adherence was observed, which reportedly made the procedure more difficult, and all patients required secondary glaucoma surgery to control IOP elevations. These findings are supported by anecdotal experience from explantations during secondary procedures, including reports by Professors Keith Barton and Brian Ang, who document Hydrus Microstent removals involving the careful dissection of adherent iris tissue around the stent using vitreoretinal gripping forceps and scissors.^{105,106} These additional intraocular manipulations may theoretically be associated with an increased risk of secondary ECL and endophthalmitis. In one of these cases, the device had been noted to be extruding into the anterior chamber for 9 years before the patient started developing ECL and corneal decompensation, which were attributed to the device.¹⁰⁶ In Sachdeva et al' case series, intraocular inflammation improved within 3 to 6 months after device explantation, however, despite the relative ease of removal in early cases, all patients experienced some degree of visual loss, persistent macular oedema, or elevated intraocular pressure requiring

additional surgery.¹⁰⁴ Although the exact rate remains unclear, the malposition of Hydrus devices is not uncommon. Zimmerman et al found significant postoperative positional variability in 23 eyes, with the distal tip protruding into the anterior chamber in some cases.¹⁰⁷ However, none of these malpositions necessitated explantation during their study period. Nevertheless, gradual protrusion, persistent malalignment or iritis, and chronic PAS formation may compromise efficacy and potentially increase the risk of complications over time.

In the case of suprachoroidal devices such as MINiject, removal may present a greater concern.

Anecdotal evidence, notably from Jonescheit et al' poster at the European Glaucoma Society (EGS) congress 2024, alongside a histopathological study of explanted MINijects, shows that significant fibrosis may develop as early as two months after implantation, creating firm adhesion to adjacent tissues and potentially complicating explantation efforts.¹⁰⁸ Furthermore, in another anecdotal report, Keith Barton described a malpositioned MINiject, which had migrated anteriorly 6 months following implantation, in a patient requiring secondary trabeculectomy.¹⁰⁹ Although in that case, the ECD had remained stable, device migration may potentially lead to ECL and necessitate surgical reinterventions.

As these devices are being considered for increasingly earlier stages of glaucoma, the ability to reverse or remove them safely becomes clinically significant. Indeed, in mild disease, where the risk-to-benefit ratio is more delicate, surgeons should be reassured that removal, should it become necessary, can be performed without extensive trauma. However, this may not apply uniformly across all MIGS classes, and further studies are needed to better characterize the indications, techniques, and outcomes of device explantation across the expanding MIGS spectrum. In any case, as with any novel surgical technique, there is an inherent learning curve, and optimising patient head position and adjusting microscope tilt can improve access and visualisation of the surgical site, thereby increasing the likelihood of correct implantation and reducing the risk of malposition or subsequent complications.

Reoperation Potential

One concern with MIGS is whether any early, less invasive but also less effective, intervention may impair the success of subsequent filtering procedures should they become necessary. For angle-based MIGS such as iStent, Hydrus, AbiC, GATT, and KDB, the concern is more about potential angle structure trauma and scarring. Although there is no data directly comparing the outcomes of trabeculectomy in eyes with prior angle surgery and in surgery-naïve eyes, there were no reports of surgical complications caused by prior surgery. A question that may however be asked is whether the formation of PAS following some MIGS procedures known to lead to synechial formation, such as Hydrus Microstent or trabeculotomies, may impact the success of further surgery. Data on this subject remain scarce, but Rao et al had attributed early surgical failure of trabeculotomies to the presence of PAS and angle structures fibrosis.³² Besides, the fact that argon-laser trabeculoplasty (ALT) was reported to significantly increase the failure rates of trabeculectomy raises the question of whether surgically-induced scarring of angle structures may influence the outcomes of all future surgeries.¹¹⁰ Nevertheless, not all angle-based MIGS techniques lead to the formation of PAS or extensive scarring, and although further research on the topic is warranted, these procedures are generally deemed safe and non-detrimental for future management options.

An important consideration is therefore whether the MIGS technique is tissue-sparing or tissue-destructive. From a structural and physiological standpoint, preserving the trabecular meshwork, Schlemm's canal, and associated outflow structures may have important implications for maintaining long-term outflow function. Notably, recent studies using volumetric OCT imaging and phase-sensitive analysis have shown that angle structures form part of a dynamic, pump-like system responding to transient IOP fluctuations from ocular pulse, blinking, and eye movements.^{111,112} The trabecular meshwork and associated inlet and outlet valve-like structures coordinate to modulate aqueous flow in response to physiological stimuli. Furthermore, trabecular meshwork motion in response to pulse waves is not uniform but varies by location, suggesting a distributed network of dynamic function across the angle. Extensive disruption of this architecture could reduce the system's capacity for IOP self-regulation and adaptive response, especially as glaucomatous eyes already exhibit increased TM stiffness and reduced motion. As such, preserving this responsive, elastic system may help buffer pressure fluctuations that contribute to glaucoma progression, and maintain lower baseline IOP.

It may also be speculated that the nature and pattern of scarring may further influence these dynamics. AS-OCT studies show these scarring patterns can extend beyond the TM, potentially impairing natural outflow or the success of

future interventions.⁴⁵ Additionally, the extent of mechanical trauma during such procedures may modulate the recruitment of myofibroblasts and the degree of fibrotic remodeling. As such, the healing pattern, whether it be linear and confined or broad and fibrotic, could be a critical determinant in maintaining the physiological responsiveness of the outflow tract. Techniques like GATT and KDB were shown to involve extensive disruption of the TM and induce localized fibrosis, TM reattachment, and formation of synechiae. In contrast, more localized and tissue-sparing procedures such as AbIC and iStent inject appear to preserve the majority of the angle anatomy.

Moreover, the physical dimensions and degree of intracameral extension of implants may be important determinants of their complication profile. Although no comparative studies specifically addressed this issue, it has been suggested that longer or more protrusive devices may be more susceptible to micromovements induced by inertial forces, or the transmission of mechanical energy during blinking and eye movements.¹¹³ These dynamic factors could potentially contribute to implant migration or malpositioning over time. Additionally, it is reasonable to infer that larger devices, particularly when malpositioned, may carry a higher risk of damaging adjacent intraocular structures, including the corneal endothelium. Notably, significant structural trauma or excessive disruption of the iridocorneal angle, such as iris contact, extensive TM disruption, or canal overdistension, has been associated with the development of complications including hyphema-glaucoma-uveitis syndrome, PAS formation, and ECL.^{55,56,105} The removal of such devices may also become necessary if secondary surgical interventions are considered, either to minimize the risk of adverse events or because the implant compromises access to the angle. In contrast, smaller implants appear to exhibit greater tolerance to minor misplacements and are less likely to compromise intraocular integrity even in the instance when they are mispositioned.⁷⁴

On the other hand, some researchers propose that early MIGS intervention may actually improve subsequent surgical success by reducing the need for long-term topical medication, which is known to cause ocular surface inflammation and fibrosis.¹¹⁴ Lee et al recently confirmed the adverse impact of prolonged topical glaucoma medications on the long-term surgical outcomes in a large retrospective study.¹¹⁵ This supports the confocal microscopy study by Baiocchi et al comparing the conjunctival status of patients undergoing XEN Gel Stent implantation, trabeculectomy, or chronic topical medical therapy, which found that topical therapy induced the most significant inflammatory changes, followed by trabeculectomy, with XEN patients exhibiting the least conjunctival inflammation.¹¹⁶ This suggests that reducing conjunctival exposure to topical medications through early MIGS could help preserve the conjunctival environment, potentially improving the success of future surgeries.

Conclusion

This systematic review provides a comprehensive analysis of the safety profiles of minimally invasive glaucoma surgeries (MIGS) by aggregating complication rates from studies published over the last decade (Table 1). It is important to emphasize that this study was exclusively focused on the safety outcomes of MIGS procedures, without evaluating their efficacy in terms of IOP or medication burden reduction. While the broad inclusion of studies offers a detailed overview of reported complications, limitations inherent to retrospective data analysis must be acknowledged.

A primary challenge encountered in this review was the lack of harmonization in complication reporting across studies. Large inter-study differences in complication rates were observed for certain procedures as different studies used varying definitions and thresholds for common complications such as hyphema, IOP spikes, and hypotony. This heterogeneity led to inconsistencies in reported incidence rates. Some studies chose not to report certain complications deemed normal or expected for the procedure, while others only recorded complications occurring within specific time frames or affecting a minimum number of eyes. Additionally, the detection and reporting of complications were influenced by follow-up durations, clinical protocols, and diagnostic modalities, resulting in some complications being overlooked, particularly those without immediate clinical symptoms, such as ECL and PAS. Transient, self-limiting complications may also have been underreported, as they are not consistently documented in long-term studies. Moreover, in cohorts with multiple successive follow-up reports, initial publications occasionally included higher rates of intraoperative and early complications that were no longer reflected in later data, potentially due to attrition or selective follow-up bias.

Table 1 Weighted Mean Incidence of Complications Following All Studied Surgical Techniques, Based on the Number of Eyes Analyzed in This Systematic Review. Complication Rates are Presented as Percentages, with Values >1% Shown in Bold. Complications are Arranged in Tiers According to Clinical Relevance: the Top Tier Includes Vision-Threatening, Structurally Destructive, or Chronic Events; the second Tier Comprises Typically Milder or Self-Limiting Events, Although They May Still Be Clinically Relevant and Indicate Surgical Invasiveness; the Third Tier Includes IOP-Related Events (IOP Spikes and Hypotony), Encompassing the Heterogeneous Definitions Used Across Studies; and the Bottom Tier Includes Device-Related Adverse Events. Color Coding Reflects Clinical Concern: Green for Low Incidence, Orange for Moderate Concern, and Red for Higher Clinical Concern. Thresholds Were Set at 1% and 5% for Serious Complications, and at 10% and 20% for More Benign Adverse Events. “Endothelial Safety Concern” Refers to Evidence of Endothelial Cell Loss

	ABIC	All Trabeculotomies	GATT	KDB	ELT	FLIGHT	Istent	Istent Inject	Istent inject W	istent Infinite	Hydrus	CyPass	MINIject	Phaco
Number of Eyes	1322	16,857	4798	4809	1352	18	6281	6778	506	72	2269	1920	73	1885
Loss of visual acuity	0.30%	1.18%	0.59%	3.23%	0.00%	11.70%	0.06%	0.99%	0.00%	8.30%	0.62%	1.62%	22.49%	0.21%
Corneal decompensation	0.00%	0.01%	0.00%	0.02%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	1.35%	0.00%
Choroidal detachment	0.00%	0.02%	0.06%	0.00%	0.15%	0.00%	0.00%	0.01%	0.00%	0.00%	0.00%	0.16%	1.22%	0.00%
Choroidal hemorrhage	0.00%	0.02%	0.06%	0.00%	0.07%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Retinal detachment	0.00%	0.01%	0.04%	0.00%	0.00%	0.00%	0.02%	0.00%	0.00%	0.00%	0.00%	0.05%	0.00%	0.05%
Endophthalmitis	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Descemet's membrane detachment	0.23%	0.09%	0.20%	0.10%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	1.35%	0.00%
Endothelial safety concern	More data needed	Considered safe	Considered safe	Considered safe	More data needed	More data needed	Considered safe	Safe at 5-year	Considered safe	More data needed	Progressive loss	Unsafe at 5-year	More data needed	Considered safe
Corneal erosion or keratitis	0.00%	0.13%	0.02%	0.00%	0.37%	0.00%	0.08%	0.00%	0.00%	0.00%	0.04%	0.05%	5.21%	0.00%
Corneal oedema	0.00%	0.87%	1.47%	1.57%	4.64%	0.00%	0.40%	0.47%	0.97%	0.00%	1.66%	1.15%	6.56%	0.21%
Wound leak	0.10%	0.00%	0.00%	0.00%	0.30%	0.00%	0.00%	0.01%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Hyphema	4.60%	26.05%	46.15%	13.05%	5.94%	61.10%	2.21%	5.13%	6.22%	4.20%	19.74%	2.92%	13.07%	0.00%
Anterior uveitis	0.00%	0.65%	0.71%	1.46%	0.00%	0.00%	0.05%	0.20%	0.34%	6.90%	1.96%	0.11%	10.97%	0.00%
Fibrous inflammation	0.15%	0.11%	0.21%	0.17%	0.00%	0.00%	0.00%	0.20%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Peripheral anterior synechiae	0.00%	0.18%	0.46%	0.00%	0.09%	0.00%	0.44%	0.24%	0.00%	0.00%	1.29%	0.00%	0.00%	0.00%
Iridodialysis or cyclodialysis	0.00%	0.61%	1.99%	0.18%	0.00%	0.00%	0.05%	0.00%	0.00%	0.00%	0.00%	0.37%	0.00%	0.00%
Pupillary abnormality	0.00%	0.00%	0.00%	0.00%	0.09%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	6.48%	0.00%

(Continued)

Table I (Continued).

	ABIC	All Trabeculotomies	GATT	KDB	ELT	FLIGHT	Istent	Istent Inject	Istent inject W	istent Infinite	Hydrus	CyPass	MINIject	Phaco
Macular oedema	0.30%	0.21%	0.16%	0.56%	0.91%	5.50%	0.18%	0.18%	0.37%	2.80%	0.09%	0.16%	1.37%	0.05%
Cataract progression	0.17%	0.04%	0.05%	0.00%	0.00%	0.00%	1.13%	0.08%	0.00%	0.00%	0.00%	0.00%	6.84%	0.00%
Posterior capsule rupture	0.00%	0.00%	0.00%	0.00%	0.46%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.10%
Hypotony	0.80%	0.19%	0.35%	0.24%	0.69%	0.00%	0.13%	0.04%	0.00%	0.00%	0.26%	3.53%	3.94%	0.00%
IOP Spikes	2.60%	7.97%	10.85%	7.92%	6.98%	0.00%	5.70%	1.75%	4.74%	2.80%	1.46%	2.05%	26.07%	2.11%
Device extrusion	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Device migration	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.05%	0.30%	0.20%	2.80%	0.00%	0.00%	1.37%	0.00%
Device damage	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Device obstruction	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.93%	0.56%	0.00%	2.80%	0.98%	1.20%	0.00%	0.00%
Misplaced device	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.05%	0.59%	0.00%	0.00%	0.13%	0.21%	8.12%	0.00%

Another important factor influencing results was the frequent combination of MIGS procedures with cataract surgery, introducing a degree of confounding in attributing complications. While this reflects current real-world practice, it complicates the distinction between MIGS-related and phacoemulsification-related adverse events. Interestingly, complication rates for phacoemulsification-specific issues such as posterior capsule rupture were often lower than those reported in the broader cataract surgery literature. This discrepancy may reflect underreporting, but could also be due to rigorous patient selection criteria leading to the exclusion of more complex cases and the high level of surgical expertise common in larger trials. Consequently, caution is required when generalizing complication rates and interpreting mean incidence rates. Nonetheless, recognizing the types and relative frequencies of potential complications across different procedures remains of practical value in clinical decision-making.

While some variation is expected due to differences in surgical technique, patient selection, and surgeon experience, we took several steps to mitigate bias from external non-clinical factors. To address concerns of reporting bias, (1) we examined whether study design, financial conflicts of interest, or industry sponsorship correlated with the number or rates of complications reported and found no significant correlation, (2) we reported weighted mean incidence rates but also included the full observed incidence range to provide a more transparent representation of variability across all analyzed studies, and (3) we accounted for the possibility of underreporting by including in our narrative review case series and laboratory studies, allowing for rare but clinically significant complications to be documented. Together, these measures aim to ensure a representative and balanced account of MIGS safety, despite variations in reporting methodologies. Nevertheless, these challenges underscore the need for standardized complication reporting in glaucoma surgery. The establishment of uniform definitions, consistent follow-up protocols, and minimum reporting thresholds is critical to improving data quality and enabling meaningful comparisons between procedures.

The scope of this review was also limited by the inability to account for patient ethnicity, glaucoma subtype, surgeon experience, or learning-curve effects in a systematic way. Most cohorts were heterogeneous, and only aggregate, study-level data were available, without access to individual patient characteristics, surgeon identifiers, or case-sequence information. As a result, complication rates could not be stratified according to ethnicity, diagnosis, surgeon experience, or centre volume. While MIGS is frequently viewed as a lower-risk alternative to conventional filtering surgeries, this review confirms that all procedures, even the least invasive, carry certain risks. Complication profiles vary considerably between techniques. Trabecular bypass implants, for instance, generally display lower complication rates and fewer long-term adverse events than other MIGS categories. Though malposition or occlusion may affect efficacy, their safety profiles remain largely favorable. Angle-based trabeculotomy procedures are relatively safe, but commonly lead to transient hyphema and postoperative IOP fluctuations, with reports indicating transient intraocular bleeding and cilio-choroidal detachments in nearly half of cases for some techniques. Among suprachoroidal devices, although ECL may not be a chief concern with the newest devices, they all carry a higher risk of IOP instability and inflammation than most other MIGS techniques. Naturally, these risks must be weighed alongside the expected efficacy of the intervention. As such, the choice of MIGS procedure must be personalized, taking into account the severity and progression of disease, ocular anatomy, prior surgical history, and the patient's tolerance for risk, along with cost and healthcare system constraints.

In this context, and based on the safety profiles outlined in this review, one could cautiously suggest that in patients with mild, stable disease, or in those undergoing opportunistic surgery in the context of cataract extraction, the use of MIGS procedures with the lowest observed complication rates may be most appropriate. Particularly in younger or otherwise healthy individuals, where the long-term preservation of ocular tissues is paramount, procedures that are both tissue-sparing and structurally conservative should be favored. Among the options evaluated, the iStent technologies and ab interno canaloplasty (AbIC) appear to offer some of the most favorable safety profiles. Both techniques are minimally disruptive to ocular anatomy, preserve angle structure integrity, and carry low rates of serious adverse events. Although the iStent inject has traditionally been associated with risks of malposition, recent evidence suggests that the iStent inject W design, along with adequate surgeon training, can significantly reduce the incidence of such events, which appear to have limited clinical significance. In the case of AbIC, while statistical analyses indicate a similarly favorable safety profile, conflicting reports persist regarding the incidence of clinically relevant chronic complications such as macular edema and Descemet membrane detachment. Further research is warranted to clarify the long-term risk associated with

these events. Importantly, neither procedure appears to compromise the potential for future surgical interventions. Ultimately, however, the selection of a MIGS procedure must remain guided by individual patient characteristics, clinical objectives, and risk tolerance, particularly in view of the fact that this review does not address comparative effectiveness or cost considerations.

In conclusion, while MIGS technologies continue to evolve and expand, their integration into clinical practice must be accompanied by greater consistency in safety reporting to enable meaningful comparisons and support evidence-based surgical decision-making. As new devices emerge and longer-term data accumulate, standardized definitions and outcome measures will be essential to improving the quality of evidence. Until such frameworks are widely adopted, the pooled complication data presented in this review can help clinicians balance risks and benefits more accurately, tailor interventions to individual patients, and guide the design of future trials toward clearer and clinically relevant safety reporting.

Authors' Information

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Data Sharing Statement

All data used in this study were obtained from previously published sources and are publicly available. No new datasets were generated. Additional information is available from the corresponding author upon reasonable request.

Ethics Approval

No ethics approval was required as this work is a narrative review based solely on previously published data with no involvement of human subjects.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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