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ISTENT INJECT W AND KAHOOK DUAL BLADE FOR TREATING MILD-TO-MODERATE GLAUCOMA

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Abstract.

**Background:** This is a review article to contrast the lowering effect of intraocular pressure of two minimally invasive glaucoma surgery (MIGS) devices namely iStent inject (the second edition) versus excisional goniotomy using Kahook dual blade (KDB) as a combo procedure with cataract surgery, as well as post-operative best corrected visual acuity BCVA loss for those with mild to moderate primary open-angle glaucoma.

**Design:** A review article comparing two MIGS devices.

**Method:** Randomization of patients into two categories, one-hundred procedures for iStent inject and the other one hundred for Kahook Dual Blade (KDB). Intraocular pressure (IOP), BCVA, and adverse events were recorded. The fundamental results were the IOP, the post-operative visual acuity, and refractive errors.

**Results:** One-hundred operations for each procedure were evaluated and the BCVA loss by two rows or more one year post-operatively. Each procedure seems to have the same safety profile and the same effect on visual acuity (P=0.11).

**Conclusion:** Each device reduces the IOP as well as lowers the rates of serious complications; therefore, it is considered the most appropriate for those with mild-to-moderate glaucoma. This report aims to describe two currently used MIGS procedures, their effects on IOP both as stand-alone surgeries and when incorporated with phacoemulsification, and postoperative visual results for mild to moderate glaucoma.

**Trabecular micro bypass.**

The evolution and development of "Micro-Invasive Glaucoma Surgery (MIGS)" has introduced fresh and impressive growth to the treatment of glaucoma platform. It is customarily utilized for patients with mild-to-moderate open-angle glaucoma who planned or scheduled for phacoemulsification surgery, MIGS, in comparison with more aggressive glaucoma surgeries with high complication rates and the possibility of extended postoperative convalescence, is characterized by being efficacious, of lower surgical trauma, reliable unharmed characterization, and with rapid recovery. It can re-institute the eye's natural outflow to lower "intraocular pressure (IOP)" [8,9].

A multitude of MIGS procedures have been published in the literature; this review would discuss two of these modalities: "(iStent, Glaukos, Inc.)," and excision of a strip of trabecular meshwork with the "Khaook Dual Blade (KDB) (New World Medical, Inc.)". Each one uses a dissimilar methodology bypassing trabecular meshwork.

Regarding the former, it is inserted through "trabecular meshwork" in a way that the proximal end sticks out into the anterior chamber, while the distal end stayed in the "canal of Schlemm" [10]. Removing a ribbon of trabecular meshwork over multiple clock hours can make a world of difference in treating Glaucoma. By doing this, we're essentially opening up a wider pathway for communication between the anterior chamber and the post trabecular meshwork distal outflow system. This procedure is known as KDB and it's suitable for all types of Glaucoma, regardless of severity. On the other hand, iStent is designed specifically for early-stage (mild to moderate) Glaucoma cases [11-16].

**iStent inject W (second generation) Placement with phacoemulsification cataract surgery:**

The iStent inject is one of the most miniature medical implants ever known, and it is measured 360 microns in depth and width.
The iStent device is shaped like an arrow and designed to be inserted through the wall of trabecular meshwork with the head residing in “Schlemm’s canal”. Its central lumen is 80 microns in diameter enabling the aqueous move from the anterior chamber to “Schlemm’s canal”, where it exists through four 50 micron side flow outlets so that it allows multidirectional aqueous outflow, bypassing the trabecular meshwork - the primary stumbling block to fluid drainage in open-angle glaucoma- (Figure 1) [17]. The iStent inject is composed of nonferromagnetic titanium and is “heparin-coated” to promote flow. Two stents are preloaded into a disposable injector, allowing insertion for two or three clock hours during the phacoemulsification procedure. The iStent injection was CE marked in 2010 and FDA-approved in 2018. The motif of the configuration of the stent is to restore physiological aqueous outflow directly to the Schlemm’s canal [18].

![Figure 1. iStent design and dimensions [17].](Image 313x316 to 567x358)

Whether combined with cataract surgery or implanted alone, studies show that the second-generation iStent devices significantly reduce intraocular pressure (IOP)18 and the sum of eye drops required to bring IOP under control. In many cases, the entire elimination of topical medication needs has been achieved by trabecular bypass iStent [19].

Trabecular micro-bypass stenting may also reduce diurnal IOP variation, which may minimize the risk of progression [20]. Meanwhile, physiological episcleral backpressure may mitigate the risk of hypotony seen in more invasive glaucoma procedures, including transscleral devices [20,21].

The iStent inject W is a straightforward surgical intervention, and it is implanted either as a stand-alone glaucoma surgery or incorporated with a phacoemulsification procedure. The postoperative visual results after combined cataract and trabecular micro-bypass procedures are similar to stand-alone cataract procedures [22].

The use of iStent inject W has been shown in many studies to consistently and reliably reduce mean IOP while reducing medication burden [18,19] it is considered a safe procedure that does not affect visual outcomes or recovery when combined with cataract surgery and as it spares the conjunctiva, which leaves doors open if the patient requires more invasive glaucoma procedures in the future.

Adding iStent injection does not affect visual outcomes. For example, a study comparing 76 combined surgeries with 50 cataract-only surgeries found no significant difference in the percentage of the eyes within 0.25, 0.5, or 1.0 diopter of the refractive target [23].

The expenses of iStent injection are balanced by lowering the medication price burden, lowering the frequency of requiring further surgeries, lower transportation, and disability costs. From a financial point of view, it is considered an attractive choice for French people with mild-to-moderate open-angle glaucoma the study concluded [24].

One European, prospective, and multicenter (Synergy) trial, which followed nearly a hundred patients known to have open-angle glaucoma who had taken at least two topical antiglaucoma eye drops underwent implantation of two devices of iStent as a stand-alone surgery and were followed for one year [25], four-fifth of patients had stable postoperative CDVA of 20/40 after one year.

The outcome, whether stand-alone or combined with phacoemulsification, the data from many studies support the safety of iStent injection. In addition, the obtainable records strengthen the capacity of iStent insertion in keeping superb visual acuity while reducing the IOP and the burden of using topical medication in those who have cataracts.

The average intraocular pressure and being less reliant on antiglaucoma topical medications with iStent-phaco in its pivotal trial were eight per cent (from baseline) with eighty-seven percent diminution in topical treatment use at one year. By the second year, the intraocular pressure lowering result stayed constant. The iStent in its second generation brings about an average intraocular pressure diminution of two to ten percent from the baseline and seventy-five to eighty percent in medication within six to twenty-four months of a postoperative visit when done with phacoemulsification as a combo procedure [26,27].

![Figure 2. Kahook Dual Blade and gonioscopy-assisted transluminal trabeculectomy](Image 313x316 to 567x358)

Khaook dual Blade and gonioscopy-assisted transluminal trabeculectomy:

The Khaook Dual blade (KDB) (new World Medical Inc.) (Figure 2) [28], excises the whole medial portion of "the trabecular meshwork" as well as the inner block of the "Schlemm's canal", Goniotomy is done with this kind of blade, and it is a minimally invasive surgical choice for those with mild to moderate glaucoma. The wall of the sclera dose not infringed by surgical operation, so it is unaccompanied with a bleb formation and the subsequent potential bleb-related complications. By excising the diseased trabecular tissue, the KDB gives an aqueous straightforward entrance to the collector channels, bypassing malfunctioned trabecular meshwork and the distal outflow system. In spite of the fact that goniotomy performed with the KDB, is similar to the procedure performed with the Trabectome (Neo Medix), the KDB does not necessitate a cash investment; the expenses are confined to that of the blade and a goniolens, resulting in a much lower price per patient with the KDB compared with the Trabectome [28].
Presumably, the KDB goniotomy procedure as a stand-alone or incorporated with a phacoemulsification procedure can attain favourable postoperative outcomes. In addition, KDB has a decently lower financial worry on those planned for MIGS than other implantable MIGS operative modalities; therefore, it is a favourable option for mild-to-moderate glaucoma [29].

The retrospective analysis of a hundred patients has revealed some fascinating results. Surprisingly, more than a quarter of glaucoma cases in the phaco-KDB group had refractive errors greater than 0.5 D, while one-third of cases in the phacoemulsification category developed refractive errors [29]. Although it's worth noting that the difference was not statistically significant (P=0.11), it's still an exciting discovery. In light of these findings, Dr Hirabayashi’s clinical case proposes a groundbreaking solution. According to his research, using phaco-KDB may significantly reduce refractive errors following glaucoma treatment [29]. This method promises better vision for patients compared to conventional filtration surgery and other MIGS surgical approaches. Imagine the possibilities of a world where patients no longer have to suffer from impaired vision due to refractive errors after glaucoma treatment [31].

In a groundbreaking study, Dorairaj et al. [32], compared the outcomes of two different surgical techniques for treating cataracts. The first group underwent Khaoak blade and phacoemulsification, while the second group received a combined iStent and phacoemulsification treatment. After just six months of post-surgical check-ups, both groups saw significant improvements in their mean CDVA. What's more, there was no notable difference in CDVA between the two groups of patients. In another study by Sieck et al. [29], visual results were compared between Khaoak blade and phacoemulsification, as well as phacoemulsification on its own. The findings were astounding - refractive errors of more than ±0.5 D occurred in a quarter of eyes in the phaco-KDB category, compared to two-thirds in the phacoemulsification category. This study sheds new light on the effectiveness of different surgical techniques and highlights the importance of choosing the right one for each patient.

In a recent study, Dorairaj et al. [32], compared two groups of patients who underwent different treatments for their eye condition. The first group received the traditional Khaoak blade and phacoemulsification while the second group underwent a newer procedure combining iStent and phacoemulsification. After just six months of follow-up, both groups showed significant improvement in their visual acuity, with no notable difference between the two groups. Meanwhile, Sieck et al. conducted a separate study comparing the outcomes of KDB with phacoemulsification and phacoemulsification alone [29]. Interestingly, they found that more than a quarter of eyes in the phaco-KDB group had refractive errors of more than ±0.5 D, compared to two-thirds of eyes in the phacoemulsification-only group. These results suggest that the combination of KDB and phacoemulsification may be a better option for some patients (p=0.11).

The KDB-phaco intervention lowers the intraocular pressure by nearly twenty-five percent and reliance on topical treatment by around forty-five to sixty-five percent one year after surgery [12,32,33]. In terms of complications of these MIGS procedures, a prospective randomized clinical trial in eyes with mild to moderate open-angle glaucoma was examining these sorts of unwanted effects: the intraocular pressure elevation was by far the most common undesirable result, occurred in 31.7 percent and 33 percent in KDB-phaco and iStent-phaco in the follow-up visit, respectively. Happily, such elevation typically resolves on its own. Posterior capsular opacification was found in 8.5 percent of KDB-phaco and 6 percent in iStent-phaco. Blood reflux into the anterior chamber during the procedure and on day one postoperatively is an anticipated incident in angle-based surgery and was not counted as a complication. However, the blood remaining in the anterior chamber for more than a week was considered a complication (hyphema) and it was reported in 3.7 percent in the former procedure and only 1.2 percent for the latter one. Only one eye in both categories shows a cycloidalysis cleft [34].

The significance of MIGS.

1. It is recognized that phacoemulsification procedure as a stand-alone surgery lowers the mean intraocular pressure in patients with primary open-angle glaucoma. Research suggests the outcome remains for five years or more [35]. However, the piled-up information indicated that the IOP-lowering effect of cataract surgery alone is doubtful and usually inadequate to reduce reliance on topical eye drops that control IOP. For example, a recent retrospective analysis by prof Baudouin and colleagues of 70 eyes of POAG patients undergoing phacoemulsification cataract surgery found an average intraocular pressure reduction of 6%. The intraocular pressure reduction ranged from 1 mmHg to 8 mmHg was unpredictable. In approximately 1 out of 5 cases, patients experienced an increase in intraocular pressure (IOP) after their surgery, with over 12% of cases seeing IOP levels surpassing 30 mm Hg. Fortunately, there is a less invasive option available - utilizing the iStent in conjunction with cataract surgery. This alternative has shown promising results and is worth considering as an effective and efficient option for patients [36].

2. Due to the popularity of the daily use of topical anti-glaucoma eye drops, ocular surface toxicity is a common comorbidity in a patient with glaucoma. Monotherapy may be satisfactory; however, many patients require two or even three topical medications to achieve target IOP. Studies have shown a significant prevalence of ocular surface disease among those suffering from glaucoma. The more the number of topical drops used, the more the symptoms of toxicity are deemed to occur. The addition of topical medication may adversely affect its efficacy, thus compelling patients and physicians to probe the cost-and-benefit ratio of adding more topical medications to patients’ disease management. Trabecular micro-bypass surgery escorts cataract patients' ocular surface with glaucoma and affords a better quality of life for patients.

3. One must signal that early intervention may help avoid the progression of glaucoma to cause severe visual impairment, including blindness. The consequences of the advanced glaucoma intervention study propose that lowering the pressure inside the eye is accompanied by a better field of vision [37].
When comparing surgical intervention to eye drops for the lowering of IOP, "the collaborative initial glaucoma treatment study" showed that in an eight-year follow-up, those treated surgically had lower IOP levels (15mmHg vs. 18mmHg) presented with similar visual field progression rates [38].

**Conclusion.**

As the MIGS room expands and more treatment options become available, it is increasingly crucial for surgeons to understand the specification of each device and the guidelines for how to implant them safely and successfully. With proper candidate selection with appropriate techniques, MIGS offers eye care professionals the capability to provide tangible benefits to their patients soon after treatment regarding IOP control and visual outcome. Therefore, it is prudent that we do not waste time observing disease progression; instead, be more prompt in treatment.

**Recommendation.**

This review highlights the crucial role of gonioscopy in modern glaucoma surgery. It's not just an add-on tool, it's the first step towards mastering minimally invasive glaucoma surgery (MIGS). The review highlights the essential steps of setting up the microscope, tilting the patient's head, and using a surgical gonio lens. Adequate training is key, and attending workshops or wet labs can help you master this procedure.

**REFERENCES**