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ORIGINAL RESEARCH

Comparison Of Surgical Outcomes Between Excisional Goniotomy Using The Kahook Dual Blade And iStent Trabecular Micro-Bypass Stent In Combination With Phacoemulsification

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Purpose: To compare 6-month surgical outcomes of patients who underwent phacoemulsification (Phaco) combined with iStent implantation (iStent) versus excisional goniotomy using Kahook Dual Blade (KDB).

Methods: Retrospective comparative case series of 58 iStent-Phaco eyes and 44 KDB-Phaco eyes operated upon by a single surgeon between 2016 and 2018. Preoperative, intraoperative, and postoperative intraocular pressure (IOP) and IOP-lowering medication data were collected. The primary outcome was the proportion of eyes using ≥1 fewer IOP-lowering medication at Month 6 while maintaining IOP ≤ 18 mmHg.

Results: Baseline IOP was 17.2 (standard error 0.7) in the KDB-Phaco group using a mean of 1.9 (0.2) medications; at Month 6, mean IOP was 14.8 mmHg P=0.002) on 1.0 (0.2) medications (P<0.002). Baseline IOP was 16.7 (0.4) in the iStent-Phaco group using a mean of 1.4 (0.1) medications; at Month 6, mean IOP was 14.2 mmHg (P<0.002) on 1.4 (0.1) medications P=0.374). Changes in IOP and medications were not significantly different between groups (P>0.05). Significantly more KDB-Phaco eyes than iStent-Phaco eyes (43.2% vs 17.2%, P=0.004) were using ≥1 fewer medications while maintaining IOP ≤18 mmHg at Month 6. Adverse events were uncommon and similar in nature and frequency between groups with the exception that more KDB-Phaco eyes than iStent-Phaco eyes (8 [18.2%] versus 1 [1.7%]) experienced an IOP elevation presumed to be related to steroid use.

Conclusion: KDB-Phaco and iStent-Phaco provided comparable IOP and medication reductions. The proportion of eyes able to discontinue 1 or more medications while maintaining IOP ≤ 18 mmHg was significantly greater in eyes undergoing KDB-Phaco.

Keywords: glaucoma, intraocular pressure, minimally invasive glaucoma surgery, iStent, Kahook Dual Blade

Introduction

For patients with co-existing glaucoma and cataract, the recent development of micro-invasive glaucoma surgeries (MIGS) has significantly expanded the range of options available for surgical co-management of these two common age-related conditions. Collectively the MIGS procedures offer improved safety over traditional filtering surgeries, albeit with reduced efficacy.[1,2] Individually, these procedures differ in many ways, from indications to safety to route of aqueous humor outflow. These differences inform

the process of selecting the appropriate procedure based on the characteristics and surgical goals of individual patients.

The iStent trabecular micro-bypass (Glaukos, San Clemente, CA) shunts aqueous humour across the trabecular meshwork (TM) into Schlemm's canal. The device's label specifies that the procedure is combined with cataract surgery in eyes with mild to moderate open-angle glaucoma (OAG).[3] In its pivotal trial, iStent-Phaco lowered IOP by approximately 8.1% from medicated baseline and reduced medication use by 87% at 12 months,[4] suggesting its optimal role is for medication reduction, although even the medication reductions were insignificantly different from those seen in eyes undergoing phaco alone at 24 months.[5]

The Kahook Dual Blade (New World Medical, Rancho Cucamonga, CA) is a surgical knife designed to excise a strip of TM in a procedure known as excisional goniotomy. The procedure can be performed at the time of cataract surgery or as a standalone procedure,[6] is effective in mild to advanced OAG,[6–9] and has been performed successfully in secondary glaucomas as well.[9–11] In clinical studies, KDB-Phaco lowered IOP by ~25% and medications by ~45–65%.[7,10,12,13] As a stand-alone procedure, KDB was showed to lower IOP by 40% and medications by 36%.[6]

In this analysis, we compare our outcomes with iStent and KDB in a sample of eyes representing the overlap in these procedures' indications—in mild to moderate open-angle glaucoma at the time of cataract surgery.

Methods

This was a retrospective analysis of data drawn from the health records of consecutive patients with coexisting open-angle glaucoma (OAG) and visually significant cataract who underwent phacoemulsification cataract extraction with placement of an intraocular lens combined with either implantation of an iStent (iStent-Phaco) or excisional goniotomy with the KDB (KDB-Phaco) by a single surgeon at the Mason Eye Institute, University of Missouri, Columbia, MO, between September 2016 and April 2018. The study protocol was reviewed and approved by the institutional review board, which granted a waiver of informed consent due to the study's retrospective design. A de-identified data set was analyzed to ensure subjects' confidentiality.

Subjects

Data were drawn from the charts of medically controlled glaucoma patients undergoing elective cataract surgery. In most cases, glaucoma surgery was added to cataract surgery with the goal of reducing the medication burden rather than reducing IOP. Consecutive eyes undergoing one of the two combined procedures described above between the specified dates and having a minimum of 6 months of postoperative follow-up were included in this analysis. Eyes with combined mechanism glaucoma with gonioscopically open angles permitting performance of the glaucoma procedures were included. Because the iStent is indicated for use only in eyes with mild or moderate OAG, any eyes with advanced OAG undergoing excisional goniotomy with the KDB were excluded from the analysis.

Data Collected

In addition to demographic and diagnostic information, data collected included best-corrected visual acuity (BCVA), applanation IOP, and IOP-lowering medications at baseline and 1 day, 1 week, and 1, 3 and 6 months postoperatively, as well as all intraoperative and postoperative adverse events.

Materials

iStent Trabecular Micro-Bypass Stent is manufactured by Glaukos (Sacramento, California). Kahook Dual Blade is manufactured by New World Medical (Rancho Cucamonga, California).

Surgical Techniques

In both the KDB-Phaco and iStent-Phaco groups, the glaucoma procedure was performed according to each's Instructions for Use under direct gonioscopy before the cataract procedure. Both procedures were performed in the nasal quadrant through a 2.4 mm temporal clear corneal incision. For excisional goniotomy, the KDB was introduced into the anterior chamber, its pointed tip engaged the TM until its heel rested within Schlemm canal, and then advanced approximately 4 clock hours to excise a strip of TM, which was then removed with forceps. For iStent implantation, the iStent on its inserter was introduced into the anterior chamber and advanced to the nasal angle, where the long arm of the device was inserted through the TM to rest within Schlemm canal, at which point it was released from its inserter, which was then used to gently push on the implant to seat its heel firmly in the canal. Cataract surgery was then performed in routine fashion. Postoperatively, 1 week of fourth-generation fluoroquinolone antimicrobial therapy and 1 month of tapering corticosteroid therapy with prednisolone acetate 1% were prescribed.

Statistical Analysis

The primary outcome of the study was the proportion of eyes deemed a surgical success, defined as reduction of IOP-lowering medications by ≥1 medication while maintaining IOP ≤18 mmHg at the 6-month time point. Mean IOP and mean number of IOP-lowering medications, along with their reductions from baseline, were determined at each time point by group, reported with their standard errors, and compared between groups using paired *t*-tests. The level of significance was taken to be 0.05. As the goal of this study was to describe the outcomes of one surgeon's experience with two procedures, no specific hypothesis was tested and no power/sample size calculations were performed. Statistical Analysis System (SAS) version 9.4 from SAS institution was used.

Results

Overall, 58 eyes of 40 subjects who underwent phaco-iStent and 44 eyes from 34 subjects who underwent Phaco-KDB and completed minimum 6 months of follow-up were included in this analysis. Demographic and glaucoma status data are given in Table 1; no significant differences between the two groups were identified. Overall, subjects were approximately 69 years of age, were Caucasian, and had mild POAG.

IOP Reduction

IOP and reductions from baseline at each time point for each group are given in Table 2. Both procedures lowered IOP significantly from baseline at Month 1 and beyond ($P<0.05$ for each procedure at each time point). In the KDB-Phaco group, mean IOP was reduced from 17.2 (0.7) mmHg at baseline to 14.8 (0.6) mmHg at Month 6 (2.5 mmHg reduction [14.5%], $P<0.002$). In the iStent-Phaco group, mean IOP was reduced from 16.7 (0.4) mmHg at baseline to 14.2 (0.4) mmHg at Month 6 (2.5 mmHg reduction [15.0%], $P<0.002$). At Month 6, there was no statistically significant difference in mean IOP reduction between groups ($P=0.38$).

Medication Reduction

The number of IOP-lowering medications and reductions from baseline at each time point for each group are given in Table 3. Medications were significantly reduced from Month 1 onwards in the KDB-Phaco group and insignificantly at all time points in the iStent-Phaco group. In the KDB-Phaco group, the mean number of medications was reduced from 1.9 (0.17) at baseline to 1.0 (0.17) at Month 6 (0.91 medication reduction [47.9%], $P<0.002$). In the iStent-Phaco group, the mean number of medications was remained from 1.4 (0.14) at baseline to 1.4 (0.14) at Month 6 (0.09 medication reduction [0.06%], $P=0.3738$). At Month 6, there was no

Table 1 Demographic And Baseline Glaucoma Status Data For Subjects By Study Group

		KDB-Phaco	iStent-Phaco	Significance (p)
Subject-level Parameters		**N=34**	**N=40**	**–**
Age (years), mean (SE)		69.1 (1.6)	69.5 (1.4)	0.879
Gender, n (%)	Male Female	20 (58.8) 14 (41.2)	22 (55.0) 18 (45.0)	0.816
Ethnicity, n (%)	Caucasian African-American Asian	20 (58.8) 25 (73.5) 4 (11.8)	22 (55.0) 31 (77.5) 5 (12.5)	0.381
Eye-level Parameters		**N=44**	**N=58**	
Glaucoma diagnosis, n (%)	Primary open-angle Combined mechanism Other	27 (61.4) 13 (29.5) 4 (9.1)	38 (65.5) 10 (17.2) 10 (17.2)	0.228
Severity, n (%)	Mild Moderate	34 77.3) 10 (22.7)	37 (63.8) 17 (29.3)	0.371
IOP-lowering medications at baseline, n (%)	0 1 2 3	5 (11.4) 11 (25.0) 15 (34.1) 10 (22.7)	12 (20.7) 20 (34.5) 15 (25.9) 10 (17.2)	0.378

Table 2 Intraocular Pressure Outcomes By Treatment Group

	Intraocular Pressure (IOP)								
	KDB-Phaco (n=44)				iStent-Phaco (n=58)				Significance (p)**
	n	Mean(SE)	Change From Baseline Mean(SE)	Significance (p)*	n	Mean(SE)	Change From Baseline Mean(SE)	Significance (p)*	
Baseline	44	17.2(0.74)	—	—	58	16.7(0.35)	—	—	0.4863
Day 1	44	14.5(0.98)	−2.71(1.15)	0.0234	58	18.3(0.84)	1.65(0.88)	0.0647	0.0040
Week 1	43	17.2(1.09)	−0.09(1.22)	0.9377	56	16.2(0.57)	−0.55(0.56)	0.3321	0.4061
Month 1	38	14.2(0.63)	−2.84(0.99)	0.0068	37	15.3(0.78)	−1.70(0.82)	0.0453	0.2824
Month 3	37	14.8(0.61)	−2.62(0.78)	0.0019	40	14.5(0.58)	−2.18(0.50)	<0.0001	0.6703
Month 6	44	14.8(0.56)	−2.45(0.73)	0.0017	58	14.2(0.41)	−2.48(0.45)	<0.0001	0.3789

Notes: *Within-group IOP change from baseline. **Between-group mean IOP.

Table 3 Medications Outcomes By Treatment Group

	Intraocular Pressure (IOP)								
	KDB-Phaco (n=44)				iStent-Phaco (n=58)				Significance (p)**
	n	Mean(SE)	Change From Baseline Mean(SE)	Significance (p)*	n	Mean(SE)	Change From Baseline Mean(SE)	Significance (p)*	
Baseline	44	1.9(0.17)	—	—	58	1.4(0.14)	—	—	0.0452
Day 1	44	1.7(0.18)	−0.23(0.14)	0.1148	57	1.3(0.14)	−0.16(0.09)	0.0715	0.1329
Week 1	44	1.3(0.19)	−0.59(0.19)	0.0026	58	1.4(0.14)	−0.07(0.09)	0.4375	0.7187
Month 1	43	1.4(0.19)	−0.49(0.18)	0.0098	51	1.5(0.15)	0(0.07)	1	0.5799
Month 3	43	0.9(0.16)	−0.93(0.18)	<0.0001	54	1.4(0.15)	−0.04(0.07)	0.5977	0.0572
Month 6	44	1.0(0.17)	−0.91(0.20)	<0.0001	58	1.4(0.14)	−0.09(0.10)	0.3738	0.0799

Notes: *Within-group IOP change from baseline. **Between-group mean IOP.

statistically significant difference in mean number of IOP medications between groups (P=0.080).

Surgical Success

At 6 months, 43.2% of KDB-Phaco eyes (19/44) versus only 17.2% of iStent-Phaco eyes (10/58) achieved a reduction of ≥1 medication while maintaining IOP ≤18 mmHg (P=0.004).

Safety

Adverse events are given by group in Table 4. IOP elevations presumably related to steroid use were the most common adverse events, occurring in 18.2% of KDB-Phaco eyes and 1.7% of iStent-Phaco eyes. Cystoid macular edema occurred in 3 eyes (2 KDB-Phaco and 1 iStent-Phaco). Hyphema persisting beyond 1 week occurred in KDB-Phaco eyes and no iStent-Phaco eyes. KDB-Phaco had a higher proportion of complications in the post-op period than iStent (P <0.002).

Discussion

This retrospective comparative study demonstrated that both KDB-Phaco and iStent-Phaco significantly and comparably

Table 4 Adverse Events By Treatment Group, N (%)

	KDB-Phaco (n=44) n (%)	iStent-Phaco (n=58) n (%)	*P* value
IOP elevation (steroid response)	8(18.2)	1(1.7)	
Cystoid macular edema	2(4.5)	1(1.7)	
Hyphema	2(4.5)	0(0)	
Total	12 (27.3)	2 (3.4)	<0.002

lowered IOP from preoperative baseline through 6 months of follow-up in eyes with mild to moderate OAG. However, medication reduction was significant only in the KDB-Phaco group. Furthermore, substantially more KDB-Phaco eyes (43%) than iStent-Phaco eyes (17%) were able to discontinue 1 or more medications while maintaining IOP ≤ 18 mmHg at 6 months (p=0.004).

These results are generally similar to those reported in other studies. In clinical studies, KDB-Phaco lowered IOP approximately 25% and medications by approximately 45–65% 6–12 months after surgery.[7,10,12,13] Baseline IOP was higher in these prior studies, likely accounting for differences in IOP reductions seen; the lower baseline IOP in our study suggests that most eyes underwent surgery for medication reduction than IOP reduction. In the iStent pivotal trial, mean IOP was reduced 8% from medicated baseline and medications reduced 87% from baseline 12 months after iStent-Phaco.[4] A recent study, similar to ours in design (retrospective, single surgeon, low baseline IOP [~17.5 mmHg]), reported mean IOP reductions of 12.6% and 14.3%, and mean medication reductions of 27% and 65%, in eyes undergoing KDB-Phaco and iStent-Phaco, respectively.[14]

In the current study and in the literature, the safety of these two procedures is also generally comparable. Interestingly, there were more postoperative IOP elevations in the KDB-Phaco group than the iStent-Phaco group. These were presumed to be related to steroid use, as they manifested typically after the first postoperative week and resolved with steroid cessation. The occurrence of steroid-related IOP elevations following trabecular bypass procedures is contrary to the long-held belief that steroid responses were related to the steroid-induced reduction of trabecular outflow, which should be irrelevant in eyes with patent trabecular bypasses. One theory is that, like TM cells, the cells lining the distal outflow system (Schlemm's canal, collector channels, episcleral veins, etc.) may have contractile properties, behave more like blood vessels, and may play a greater role in IOP regulation than previously thought.[15,16]

Given the generally comparable efficacy of these procedures in our study and in the literature, it is worthwhile to consider other attributes of these procedures that may inform the selection of the optimal procedure for individual patients. The iStent is labeled for use in eyes with mild to moderate OAG,[3] while KDB excisional goniotomy can successfully lower IOP across the spectrum of severity including advanced OAG.[6–10] The KDB is also effective in challenging secondary glaucoma such as angle-closure[9,10] and uveitic glaucoma,[11] and in contrast to the iStent's label, KDB excisional goniotomy can be performed as a standalone procedure.[6]

While the safety of the procedures has been demonstrated in clinical studies, there are potential safety differences between these procedures that may not manifest in relatively small clinical studies. The iStent is a titanium device that is permanently implanted into the eye. Over time, issues such as malposition, migration, and obstruction can occur.[4,17,18] The iStent's compatibility with magnetic resonance imaging (MRI) has been rated MR Conditional,[19] implying safety with lower-Tesla (3 T or less) systems but has not been evaluated with newer high-T (7 and above[20,21]) systems in development. Finally, some MIGS implants have been associated with endothelial cell loss (ECL).[22–24] In the case of the CyPass implant, ECL was not noted until after 2 years and was severe enough to warrant an FDA recall of the device.[22,23] In the case of the Hydrus, significant ECL was noted as soon as 2 years after implantation.[24] While there have been no reports of significant ECL associated with the iStent to date, there have been no studies of which we are aware that have evaluated ECL more than 2 years after iStent implantation. In contrast to these potential device-related issues, excisional goniotomy with the KDB does not require the permanent implantation of a device into the eye.

Our study is limited by its retrospective design. Procedures were selected based on individual patient characteristics and not by randomization. However, to minimize clinical differences that might arise due to the disparities in indications for these two procedures, we limited the KDB-Phaco cases included in this analysis to those subjects meeting the indications for iStent-Phaco (mild to moderate OAG without advanced OAG). Also, we limited cases to those undergoing combined phacoemulsification and glaucoma surgery in both treatment groups for standardization, as phacoemulsification alone is known to lower IOP for up to several years postoperatively.[25] Outcome measures—specifically IOP—were measured as per routine clinical practice and not under strict trial protocols. However, our results are meant to complement the existing robust body of literature by providing a description of these procedures' efficacy and safety when deployed in real-world use.

Conclusion

In summary, while KDB-Phaco and iStent-Phaco provided comparable IOP reductions, the proportion of eyes able to discontinue 1 or more medications while maintaining IOP ≤ 18 mmHg may be greater in eyes undergoing KDB-Phaco.

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