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Early Outcomes of Combined Phacoemulsification and Ab Interno Tanito Microhook Trabeculotomy in Open-Angle Glaucoma

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Purpose: To study the early postoperative efficacy and safety of an Ab Interno microhook trabeculotomy (microLOT) combined with cataract surgery in patients with open-angle glaucoma.

Methods: This prospective, randomized, interventional study was conducted on consecutive patients with visually significant cataract and mild-moderate open-angle glaucoma. One hundred fourteen patients were included for analysis. The patients were randomized to undergo microhook trabeculotomy with phacoemulsification (group 1) or phacoemulsification alone (group 2). All patients were evaluated on postoperative day 1, 15, and 30, as well as 3, 6, and 12 months postoperatively. A P value < 0.05 was considered statistically significant. Baseline and follow-up visits were compared to determine significant differences in the number of antiglaucoma medications (AGMs), intraocular pressure (IOP), and best-corrected visual acuity.

Results: There were 57 patients in each group. The baseline characteristics were similar between the 2 groups, except the number of AGMs, which was greater in group 2. The mean preoperative IOP for group 1 (phaco-microLOT) was 26.5 mmHg $\pm$ 5.2 and group 2 (phaco-alone group) was 25.3 mmHg $\pm$ 3.1 which decreased to 12.5 mmHg $\pm$3.6 ($P < 0.001$) and 20.0 mmHg $\pm$ 2.7($P < 0.001$) at 12 months, respectively. Logarithm of the minimum angle of resolution visual acuity improved from 0.48 (interquartile range [IQR], 0.30−0.60) preoperatively to 0.00 (0.00−0.18) postoperatively ($P < 0001$) in group 1 and improved from 0.30 (IQR, 0.30−0.48) to 0.00 (0.00−0.00) in group 2 ($P < 0.001$). In group 1, the mean (standard deviation [SD]) AGM used preoperatively was 0.6 (0.9) which was significantly reduced to 0.2 (0.5) at 12 months postoperatively, whereas in group 2, at 12 months, the mean (SD) AGM used was reduced from 1.4 (0.6) to 1.1 (0.9). In group 1, 90.3% of eyes achieved complete success at the end of 1 year. The most common complication was hyphema, noted in 4 patients with 1 eye requiring an anterior chamber washout.

Conclusion: Ab interno microhook trabeculotomy (microLOT) combined with phacoemulsification in patients with open-angle glaucoma is an efficacious procedure with relatively minimal complications.

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Trabeculectomy is one of the most commonly performed surgical procedures in glaucoma management worldwide.[1] The creation of a fistula is associated with a variety of potential complications such as hypotony, bleb leak, choroidal detachment, suprachoroidal hemorrhage, and endophthalmitis.[2,3] Postoperative care is a long-term process with wound modulation and bleb management creating a potentially difficult postoperative course for both the patient and the surgeon, especially in developing countries.[4]

Minimally invasive glaucoma surgery (MIGS) is emerging as a popular choice in the surgical management of glaucoma, which confers a modest intraocular pressure (IOP) lowering as well as a reduction in antiglaucoma medication (AGM) burden with a more favorable safety profile compared with traditional glaucoma surgeries. The safety of MIGS procedures is the key appeal, especially when compared with the traditional filtering surgeries.[5] Most MIGS procedures act via the trabecular meshwork (TM), suprachoroidal space, or the ciliary body.[6,7] Although device-based MIGS are limited in India by their availability and cost, incisional TM-based procedures have gained momentum given their cost-effective nature.[8] Non−device-dependent, cost-effective MIGS procedures are essential treatment options for both the developing and developed world.

Trabeculotomy is performed to reduce IOP in glaucoma patients by cleaving the TM and the inner walls of Schlemm's canal (SC) thus reducing the resistance to aqueous outflow. The current version of trabeculotomy has evolved from an ab externo to an ab interno procedure.[9−12] Ab interno trabeculotomy can be performed using a variety of methods such as the Kahook dual blade goniotomy,

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microhook ab interno trabeculotomy, gonioscopy assisted transluminal trabeculotomy (GATT) and bent needle ab interno goniectomy (BANG) as well as other methods. The TM can be excised 180 or 360 degrees in GATT and up to a variable degree in the other procedures depending on surgeon preference[13,14] (*Invest Ophthalmol Vis Sci.* 62:3431, 2021). The basic premise of these MIGS procedures is to preserve the conjunctiva for future filtration surgeries and spare the patient from conjunctival or scleral incisions, filtering blebs, and potential subconjunctival wound modulation woes.[15] Moreover, if an ab interno bleless procedure can sufficiently lower the IOP and further prevent progression of a glaucomatous optic neuropathy, additional incisional surgeries may not be required.

The question that is currently being debated is whether to preserve or remove all of the TM. Though GATT is considered minimally invasive, it does open 360 degrees of the TM which does not leave any remaining untouched TM for potential further intervention. Additionally, GATT and other forms of ab interno trabeculotomy may destroy the active aqueous pump within the TM−SC complex. It is thought that in more advanced primary open-angle glaucoma (POAG), it is likely that the TM−SC pump mechanism is dysfunctional; however, it is impractical (if not impossible) to assess the pump mechanism and outflow capacity preoperatively.[16] Sparing some of the TM−SC complex may provide a chance for other further TM-based interventions through different drugs or surgeries in the future. As such, it is conceivable that a more limited trabeculotomy may offer a balance between IOP reduction and preservation of the TM tissue.[17] One additional consideration is the surgical skill involved in performing a limited ab interno trabeculotomy versus a full 360-degree trabeculotomy.

An ab interno Tanito microhook trabeculotomy (microLOT) requires a reusable, specially designed microhook (Inami & Co, Ltd) to cleave the TM and the inner walls of SC. This reusable instrument has a sharpened bent tip, which comes as straight, right-angled, and left-angled, and allows the surgeon to access all quadrants of TM, if desired. Although the prices of many devices are variable, an estimate of the cost of a reusable Tanito microhook is approximately $200 to $220 USD which is a significantly less than usual cost in the United States than other MIGS procedures like an iStent, KDB, OMNI, or iTrack catheter, which are significantly more expensive and single use. Moreover, there is a paucity of literature with prospective randomized controlled trials with goniotomy in general; speaking to the importance of studies like this one.[7,9,18] The aim of our study is to prospectively evaluate the surgical outcomes of combined phacoemulsification with microhook ab interno trabeculotomy in patients with POAG and visually significant cataract.

Methods

This is a prospective, randomized, interventional study conducted in the Glaucoma department of a tertiary eye hospital. It adhered to the tenets of the Declaration of Helsinki and complied with HIPAA requirements and local patient privacy protection policies. The study protocol was approved after a full review by the Institutional Research Ethics Committee before patient recruitment. The patients were recruited from November 2020 to April 2021 and were followed up for a period of 1 year.

Informed consent was taken and 1 eye of each patient satisfying the inclusion and exclusion criteria was considered for the study. Patients aged 40−70 years with mild-moderate (visual field mean deviation [MD] up to −12dB or better) open-angle glaucoma, mild-moderate pseudoexfoliation glaucoma (visual field MD up to −12dB), ocular hypertension, or visually significant cataract were included in the study. A visually significant cataract was defined as a lenticular opacity with a best-corrected visual acuity (BCVA) of 0.18 logarithm of the minimum angle of resolution (logMAR) or worse, and an operable cataract as revealed on slit lamp evaluation.

Monocular individuals, patients who had undergone previous ocular surgeries, those with angle closure or angle-closure glaucoma, uveitic and traumatic glaucoma, functionally moderate-to-severe field loss with a MD of worse than −12 dB, associated retinal pathologies, active inflammation and those who were unwilling/unable to provide consent were excluded. Patients who experienced inadvertent complications occurring during the course of cataract surgery were also excluded.

Procedure

On the day of the surgery, recruited patients underwent simple randomization to either group using a predetermined random list generated using the unweighted Bernoulli distribution protocol of the Analysis ToolPak add-in of Microsoft Excel (Microsoft Corporation, Redmond). Subjects, masked to the randomization, were assigned to a treatment group, based on the value at their rank (0 = microLOT with phacoemulsification, 1 = phacoemulsification alone). During follow-up, glaucoma specialists who were masked to the patient's group assignment, performed the postoperative examination and data collection. An unmasked glaucoma specialist performed postoperative gonioscopy. All of the surgeries were performed by a single experienced glaucoma surgeon (D.M.).

Patients were divided into 2 treatment arms; group 1 included patients who underwent combined phacoemulsification with ab interno Tanito microhook trabeculotomy (microLOT) and group 2 included patients who underwent phacoemulsification alone.

Surgical Technique

Adequate anesthesia was obtained via a peribulbar injection (3 mL of lignocaine + 50 IU/mL hyaluronidase and 1:200 000 adrenaline).

For group 1: a temporal clear corneal incision was made and routine phacoemulsification was done with the surgeon seated temporally. A foldable single-piece acrylic intraocular lens was implanted in the capsular bag.

Trabeculotomy was routinely performed after phacoemulsification. Viscoelastic material (1.4% sodium hyaluronate, Aurogel-Aurolab) was injected into the anterior chamber (AC) to widen the angle. After appropriate positioning of the patients' head (30−40 degrees away from surgeon) and microscope (30−40 degrees inclined toward surgeon), a Swan-Jacob gonioprism lens (Ocular Instruments) was used to visualize the nasal angle. Viscoelastic material was used as a coupling agent between the gonioprism and the cornea. A Tanito microhook (Inami & Co, Ltd) was introduced into the AC through the 2.2-mm clear corneal incision to approach the nasal angle (Fig 1A). The tip of the microhook was inserted into the SC and moved circumferentially over the desired clock hours to incise the inner wall of the SC and TM (Fig 1B). One can appreciate the white strip, which

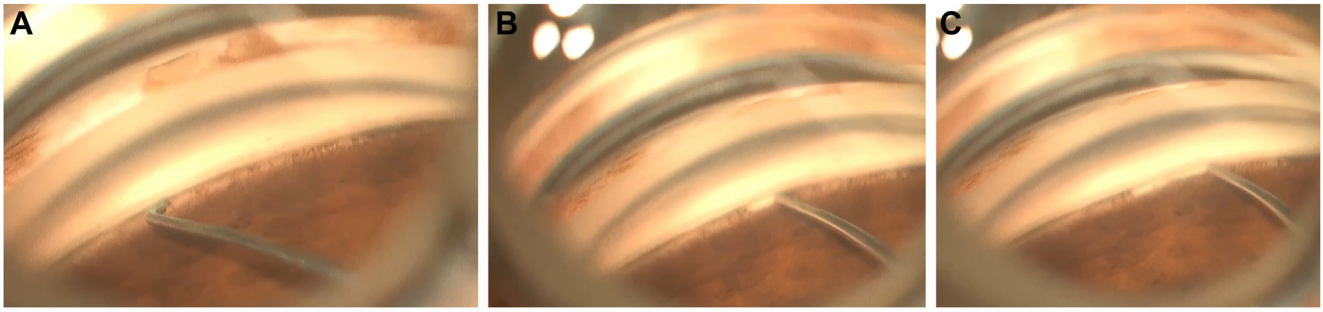

Figure 1. A, Intraoperative picture demonstrating the use of the right-angled Tanito microhook being placed into position in the nasal anterior chamber angle. **B,** Intraoperative picture demonstrating the Tanito microhook incising the trabecular meshwork and creating a goniotomy. **C,** Intraoperative picture demonstrating a 2-clock hour goniotomy created by the Tanito microhook.

represents the back wall of SC in Figure 1C, after several clock hours of a goniotomy has been performed. If the surgeon wished to treat more than just the nasal angle, the surgeon shifted positions and made an additional nasal side port incision. Through this additional nasal incision, the surgeon was able to treat the temporal angle. Around 10% to 15% of viscoelastic material was left, depending upon the blood reflux into the AC (the greater the blood refux, the greater the degree of viscoelastic fill in the AC). The corneal incision and port were closed by stromal hydration and intracameral moxifloxacin (0.1 cc, 0.5%) was injected.

In each case, the degree of trabeculotomy created and subsequent complications such as excessive bleeding, descemet membrane detachment, iris damage, etc., were documented.

Table 1. Demographics and Clinical Characteristics of the Study Participants

Clinical Characteristics	Group 1	Group 2	*P* value*
Number of subjects	57	57	
Age, yrs			
Mean (SD)	62.2 (8.4)	63.1 (8.2)	0.550
Range	41–76	44–78	
Gender, n (%)			
Male	35 (61.4)	36 (63.2)	0.847†
Female	22 (38.6)	21 (36.8)	
Eye, n (%)			
Right eye	29 (50.9)	30 (52.6)	-
Left eye	28 (49.1)	27 (47.4)	
CCT			
Mean (SD)	535.8 (1.9)	533.7 (1.9)	0.430
Range	496–568	498–568	
CDR			
Mean (SD)	0.7 (0.1)	0.6 (0.1)	0.215
Range	0.55–0.75	0.55–0.70	
Diagnosis, n (%)			
OHT	7 (12.3)	5 (8.8)	0.360†
POAG	35 (61.4)	30 (52.6)	
PXFG	15 (26.3)	22 (38.6)	

CCT = central corneal thickness; CDR = cup-disc ratio; OHT = ocular hypertension; POAG = primary open-angle glaucoma; PXFG = pseudoexfoliative glaucoma; SD = standard deviation.
*Independent samples *t* test.
†Chi-squared test.

For group 2: Temporal clear corneal phacoemulsification was done as previously described. The presence of any intraoperative complications was noted.

Postoperative Care

All patients were started on q2 hourly dexamethasone (0.1%) + chloramphenicol (0.5%) eye drops, as well as ofloxacin (0.3%) eye drops 4 times a day for 1week. The topical steroids were gradually tapered depending upon the condition of the eye over the following 1 to 2 months.

Follow-up evaluation was performed at day 1, day 15, and at 1, 3, 6, and 12 months postoperatively. Patients who missed > 2 consecutive visits or the final visit were considered "lost to follow-up." Visual acuity was evaluated by Snellen's distance visual acuity chart and then converted to logMAR values. At each visit, a careful slit lamp evaluation was performed and postoperative abnormalities, if any, were documented. Intraocular pressures were measured by Goldman applanation tonometry (AT900; Haag Streit International). Gonioscopy was performed at 1, 3, 6, and 12 months using an indirect nonindentation goniolens (Volk G-2) by an unmasked glaucoma specialist. The numbers of AGM and postoperative manipulations required were recorded.

Surgical success was defined as:

A) Complete success:
   a. Criterion 1: IOP between 6 and 18 mmHg, or a 20% reduction from baseline without AGM
   b. Criterion 2: IOP between 6 and 15 mmHg, or a 25% reduction from baseline without AGM

B) Qualified success; achieving the above-mentioned criteria with use of the same or fewer AGM.

C) Failure was defined as an inability to meet the criteria for success or requiring additional glaucoma surgery.

All statistical analyses were performed using the statistical software STATA (version 14.0). The sample size of 57 eyes in each group was determined with an assumption that 82.0% of eyes will achieve successful IOP control with 10% precision and 95% confidence interval.[18] Demographic and clinical characteristics are presented as the mean ± standard deviation (SD) for normally distributed continuous variables, or the median and interquartile range (IQR) for skewed variables. Categorical variables were presented in frequency (n) and percentages (%). The normality of the data was assessed using box and whisker plots and the Shapiro–Wilk test. To determine the association between the categorical variables, the chi-squared test and Fisher exact test were used. Postoperative comparisons of IOP and the average number of

Table 2. Comparison of Mean IOP between Group 1 and 2 at Each Visit

Patient visits	Group 1		Group 2		P value
	Mean (SD)	Range	Mean (SD)	Range	
Preoperative	26.5 (5.2)	21–50	25.3 (3.1)	22–34	0.161
Day 1	12.8 (4.3)	4–23	18.0 (2.9)	11–24	**< 0.001**
Day 15	11.8 (2.2)	8–16	17.5 (2.3)	13–25	**< 0.001**
Month 1	12.4 (3.6)	7–21	17.7 (2.5)	11–28	**< 0.001**
Month 3	11.3 (2.9)	6–21	17.6 (2.2)	1124	**< 0.001**
Month 6	11.0 (3.2)	6–25	18.2 (1.7)	1626	**< 0.001**
Month 12	12.5 (3.6)	6–24	20.0 (2.7)	1428	**< 0.001**

IOP = intraocular pressure; SD = standard deviation.
Independent *t* test; bolded *P* values (< 0.05) are statistically significant.

AGMs were performed using a paired *t* test and Wilcoxon sign rank test, respectively. Kaplan–Meier survival analysis was conducted to evaluate the cumulative IOP success throughout the follow-up period. Intraocular pressure spikes were defined as postoperative IOP ≥ 21 mmHg. A *P* value < 0.05 was considered statistically significant.

Results

A total of 114 participants were randomized, in equal numbers, into 2 groups. The baseline characteristics of the study groups were comparable with respect to age, sex, preoperative mean IOP and average logMAR visual acuity. However, the mean baseline number of AGMs was slightly greater in group 2 when compared with group 1. In both of the groups, the majority of patients were diagnosed with POAG (Table 1).

The mean preoperative IOP for group 1 was 26.5 mmHg ± 5.2 and for group 2 was 25.3 mmHg ± 3.1, which decreased to 12.5 mmHg ± 3.6 and 20.0 mmHg ± 2.7 at 12 months, respectively. At each postoperative visit, a significant decrease in mean IOP was seen in both groups. The degree of IOP reduction in group 1 was greater than the degree of IOP reduction in group 2 (Table 2). The percentage IOP reduction from baseline was 51.8% and 20.1 % on the final postoperative visit in group 1 and group 2, respectively (*P* < 0.001).

Out of 57 participants in group 1, 70.2% of eyes (n = 40) underwent 180 to 240 degree trabeculotomy and 29.8% of eyes (n = 17) underwent > 240 degree trabeculotomy. There was no significant difference in IOP reduction with respect to the degree of trabeculotomy at months 1, 3, 6, and 12 (Table 3).

Spikes in IOP (≥ 21 mmHg) were more common in group 2. The difference in IOP spikes were statistically significant at all postoperative visits except at month 1.

In group 1, the mean (SD) number of AGMs used preoperatively was 0.6 (0.9) which decreased significantly to 0.2 (0.5) at 12 months postoperatively; whereas in group 2, the mean AGM decreased from 1.4 (0.6) to 1.1(0.9). The reduction in AGM burden was greater in group 1 as compared with group 2, and the difference was statistically significant (Table 4).

In group 1, the median (IQR) preoperative and postoperative BCVAs were 0.48 (0.30–0.60) and 0.00 (0.00–0.18), whereas in group 2 the BCVAs were 0.30 (0.30–0.48) and 0.00 (0.00–0.00) respectively. A significant improvement in visual acuity was found in both groups.

Of the 10.5% intraoperative complications in group 1, 1.8% had an iridodialysis (1 clock hour), 1.8% had iris chaffing and 7.0% had a hyphema, whereas in group 2, 1.8% had iris chaffing. Of the 4 patients that had a postoperative hyphema in group 1, 1 patient underwent an uncomplicated AC wash (Table 5).

Among group 1 patients, complete success (using criterion 1), with an IOP ≥ 6 and ≤ 18 mmHg, or a 20% reduction from baseline without AGM, was observed in 90.3%, and qualified success was observed in 90.9%, at the end of 12 months. In group 2, complete success (using criterion 1) was observed in 0% and qualified success was observed in 49.1%, at the end of 12 months. When a more stringent success criterion (criterion 2: IOP ≥ 6 and ≤ 15 mmHg, or a 25% reduction from baseline) was applied, complete success and qualified success at the end of 12 months in group 1 was observed in 86.9% and 87.4% of patients, respectively; and in group 2 these values were 0% and 31.6%, respectively.

Figure 2 depicts Kaplan-Meier survival plot showing the cumulative probability of complete and qualified success as IOP ≤ 18 mmHg between the groups and Figure 3 depicts Kaplan-Meier survival plot showing the cumulative probability of complete and qualified success as IOP ≤ 15 mmHg between the groups; a log rank test was used to demonstrate a significant difference of success probability between the 2 groups (*P* < 0.001).

Discussion

Certain MIGS procedures offer low-risk, relatively standardized, and highly reproducible options for lowering IOP

Table 3. IOP Reduction Percentage with the Degrees of Trabeculotomy and Overall in Each Postoperative Visit

Patient visits	Degree of microLOT		Overall IOP Reduction, %	P value*
	180–240 n = 40; 70.2%	> 240 n = 17; 29.8%		
Day 1	47.1	59.2	50.7	0.022
Day 15	52.0	58.3	53.9	0.059
Month 1	49.8	56.4	51.8	0.123
Month 3	55.5	58.7	56.4	0.313
Month 6	56.7	58.6	57.2	0.844
Month 12	52.0	50.4	51.5	0.746

IOP = intraocular pressure; microLOT = ab interno microhook trabeculotomy.
*Wilcoxon rank sum test; *P* value < 0.05 (bold) considered statistically significant.

Table 4. Preoperative and Postoperative AGM Load in Each Group

Patient visits	Group 1	Group 2	*P* value
Preoperative	0.58	1.37	
1 month	0.21	0.92	< 0.001
3 months	0.16	0.89	< 0.001
6 months	0.14	0.86	< 0.001
12 months	0.16	1.08	< 0.001

AGM = antiglaucoma medication.
Wilcoxon sign rank test (postoperative AGM compared with preoperative.).

Table 5. Comparison of Intraoperative Complications between Group 1 and Group 2

	Group 1 (n = 57)		Group 2 (n = 57)		
Complications	*Frequency, n*	*Percentage, %*	*Frequency, n*	*Percentage, %*	*P* value
Iridodialysis	1	1.8	0	0	0.316
Hyphema	4	7.0	0	0	0.042
Iris chaffing	1	1.8	1	1.8	> 0.99
Total	6	10.5	1	1.8	0.051

Two-sample proportion test.

without the economic burden, hazards, and compliance problems of medications. Moreover, the safety of most MIGS procedures is greater than the safety of the more traditional incisional glaucoma surgeries. Many of these MIGS procedures can be safely combined with cataract surgery without significantly increasing the risk above standard phacoemulsification. However, the cost of most MIGS devices makes these procedures inaccessible to a large number of patients and surgeons around the world. In developing countries like India, an ab interno microhook trabeculotomy is a cost-effective alternative to many TM-based glaucoma procedures because the microhook is not disposable and can be reused countless times.[19]

In our study, the preoperative mean (SD) IOP in the phaco-microLOT group decreased from 26.5 mmHg ± 5.2 to 12.5 mmHg ± 3.6 ($P < 0.0001$) at 12 month post-operatively. Although the preoperative mean IOP was just slightly higher in phaco-alone group, the percentage reduction was significantly greater in the phaco-microLOT group at each postoperative visit. In a study by Tanito et al[18] where the patients underwent microLOT along with small incision cataract surgery, there was a similar reduction in mean (SD) IOP from 16.4 mmHg ± 2.9 to 11.9 mmHg ± 3.3 ($P < 0.0001$) at their final postoperative visit. In a head to head comparison between Phaco-Kahook Dual Blade (KDB) and Phaco-microLOT, Omoto et al[20] and Aoki et al[21] found that the percentage changes in the IOP and medication scores did not differ significantly. In combined phacoemulsification with BANG, the average IOP reduction at postoperative month 3 was 20.80% ($P < 0.0001$) according to Townsend et al (*Invest Ophthalmol Vis Sci.* 62:3431, 2021).

Although the IOP reduction was greater with the degree of TM excised in our study, the reduction was not statistically significant. Similar to our study, Sato et al[22] stated that the degree of SC excision did not impact the IOP reduction and AGM throughout the 12-month follow-up period. In contrast, the Mendicino et al[23] study stated that the degree of SC excision affects the IOP reduction after goniotomy. In a perfusion study of autopsy eyes, Rosenquist et al[24] indicated that increasing the extent of trabeculotomy can yield a greater degree of IOP reduction. It is possible that once 5 to 6 clock hours of the angle are opened, the marginal benefit of any additional trabeculotomy/goniotomy may be minimal, but this is yet to be definitively studied.

There was a significant reduction in medication burden in both groups, with the phaco-microLOT group performing significantly better than the phaco-alone group. However, in our study, the baseline mean AGM was slightly greater in the phaco-alone group. Similar results were recorded by Tanito et al,[18] Omoto et al,[20] Aoki et al,[21] and Grover et al[25] in their respective studies. A reduction in AGM burden after phacoemulsification alone has been previously reported by Kozera et al,[26] and similar results were seen in our study. There are various theories explaining the effect of lens extraction on IOP reduction.[27–30] In the 1970s, Bigger and Becker[31] reported a lower IOP after cataract extraction in glaucoma patients. Since then, various studies have reported the same result, yet the reduction in IOP after cataract extraction can be inconsistent and variable. Comparison studies of phaco with phaco-MIGS have shown promising outcomes, with the combination surgeries outperforming phaco alone.[32] In a study by Prata et al,[33] almost 40% of glaucoma patients lost IOP control during the first year after cataract surgery alone. Very similar results had previously been demonstrated by Shingleton et al.[34]

The most commonly encountered intraoperative complication reported in the phaco-microLOT group was intraoperative bleeding from the angle (4 out of 57 cases). This common and early postoperative complication was similar to the frequency of hyphema reported by Tanito et al.[18] Anterior chamber washout was performed in 1 patient as a secondary intervention. Similar results were reported by Aoki et al[21] in their study. Rare complications like an iridodialysis of 1 clock hour was noted in 1 case but this resolved spontaneously without any further sequelae.

Omoto et al[20] reported that a transient IOP spike was their most common late postoperative complication in phaco-microLOT group, which is relatively similar to our study. However, in our study we also observed that the IOP spikes were more common in the phaco alone group. In this same group, we also observed that glaucoma patients on topical medications experienced more IOP spikes (defined as IOP ≥ 21 mmHg) in the early postoperative period after cataract surgery.[35] Thus, as seen in other studies, combining cataract surgery with a MIGS procedure in patients with glaucoma results in a safer surgery with a lower chance of

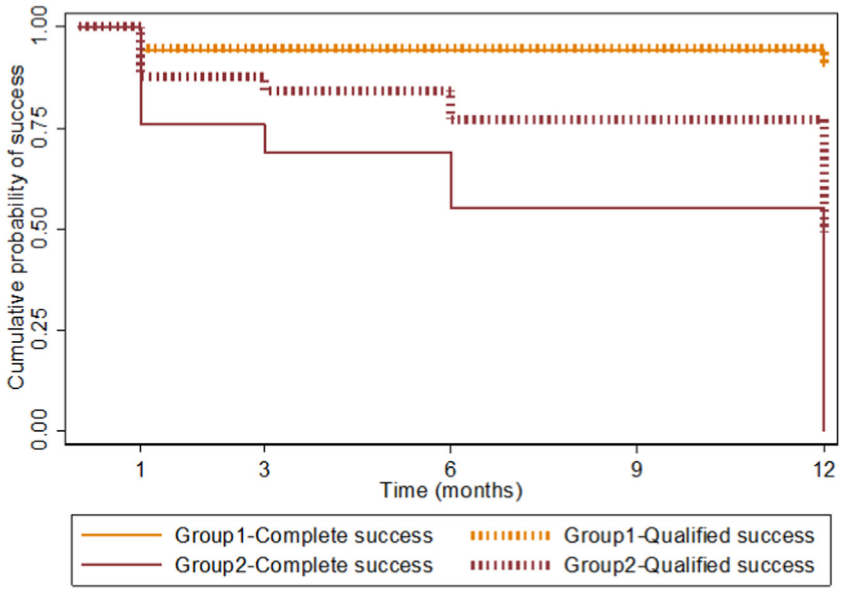

Figure 2. Kaplan-Meier survival plot showing the cumulative probability of complete and qualified success as IOP ≤ 18 mmHg between the groups.

postoperative IOP spikes, a decreased AGM burden, and an overall lower postoperative IOP.

In our study, complete surgical success at the end of 1 year in the phaco-microLOT was 86.9% (criterion 2: IOP control of ≤ 15 mmHg, or IOP reduction of ≥ 25%) group and 90.3% with a less stringent criteria (criterion 1: IOP ≥ 6 and ≤ 18 mmHg, or a 20% reduction from baseline without AGM). Tanito et al[18] reported successful IOP control in 79% of eyes (≤ 15 mmHg and IOP reduction of ≥ 15%) at the final visit in a phaco-microLOT group. Given the varied definitions of success by other authors, it is difficult to directly compare success rates; however, our study showed similar, if not greater, IOP and AGM reduction than other similar studies.

Ab Interno microhook trabeculotomy is an inexpensive procedure which allows preservation of the conjunctiva without a bleb and leaves the potential open for future additional filtration surgeries if required. Combining MIGS with phacoemulsification expands the scope of the procedure, improves safety of cataract surgery by protecting against an IOP spike, and offers a better quality of life to the patients.

There is limited literature on the efficacy of combined phacoemulsification and ab interno microhook trabeculotomy, especially in a comparative, prospective, randomized fashion. Most the of studies performed, until now, are retrospective in nature with a smaller sample size and noncomparative. To the best of our knowledge, this is the first randomized, prospective, interventional study

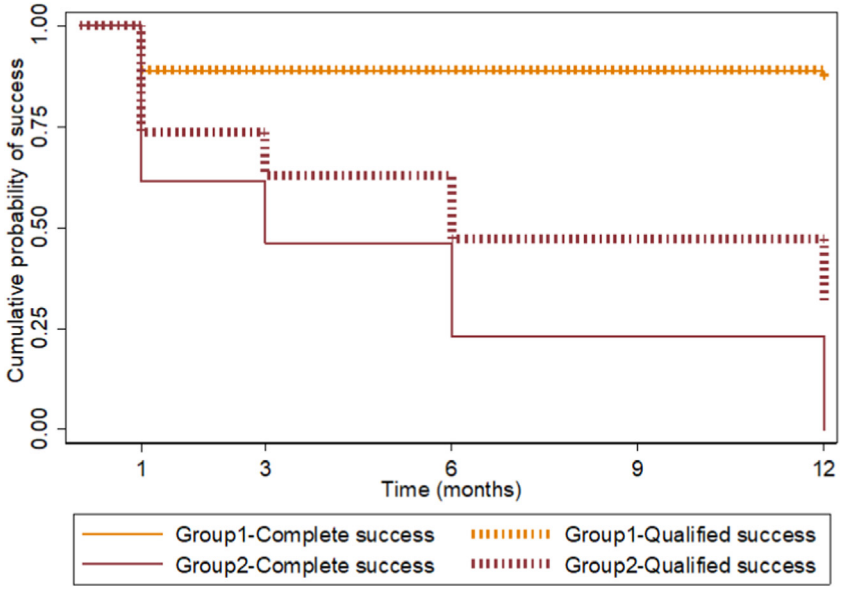

Figure 3. Kaplan-Meier survival plot showing the cumulative probability of complete and qualified success as IOP ≤ 15 mmHg between the groups.

performed to compare phaco alone with combined phacoemulsification and ab interno trabeculotomy.

Limitations of the Study

1. A relatively short follow-up period of 1 year is insufficient to assess the long-term safety and efficacy of the procedure.
2. The effect of ab interno Tanito microhook trabeculotomy on visual field was not assessed in our study.

Combined phacoemulsification with ab interno Tanito microhook trabeculotomy is efficacious in patients with mild-to-moderate open-angle glaucoma and visually bothersome cataract, with relatively minimal complications. It significantly reduces intraocular pressure and improves visual acuity with rare vision-threatening complications compared with cataract surgery alone. Performing an ab interno microhook trabeculotomy in combination with cataract surgery is a valuable addition to the glaucoma surgical armamentarium in developing countries. Equally important is the cost-effective nature of this surgery compared with most other MIGS procedures available.

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HUMAN SUBJECTS: Human subjects were included in this study. The study adhered to the tenets of the Declaration of Helsinki and complied with HIPAA requirements and local patient privacy protection policies. The study protocol was approved after a full review by the Institutional Research Ethics Committee before patient recruitment. The patients were recruited from November 2020 to April 2021 and were followed up for a period of one year. Informed consent was taken and one eye of each patient satisfying the inclusion and exclusion criteria was considered for the study.

No animal subjects were used in this study.

Author Contributions:

Conception and design: Maheshwari, Ramakrishnan, Pillai

Data collection: Maheshwari, Chautani

Analysis and interpretation: Maheshwari, Grover, Ramakrishnan, Pillai, Chautani

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Overall responsibility: Maheshwari, Grover, Ramakrishnan, Pillai, Chautani, Kader

Abbreviations and Acronyms:
AC = anterior chamber; **AGM** = antiglaucoma medication; **BANG** = bent needle ab interno goniectomy; **BCVA** = best-corrected visual acuity; **GATT** = gonioscopy assisted transluminal trabeculotomy; **IOP** = intraocular pressure; **IQR** = interquartile range; **logMAR** = logarithm of the minimum angle of the resolution; **MD** = mean deviation; **MIGS** = minimally invasive glaucoma surgery; **POAG** = primary open-angle glaucoma; **SC** = Schlemm's canal; **SD** = standard deviation; **TM** = trabecular meshwork.

Keywords:
Ab Interno Tanito microhook trabeculotomy (microLOT), Minimally invasive glaucoma surgery (MIGS), Phacoemulsification, Primary open-angle glaucoma (POAG).

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