Controlled Study of Tanito Microhook (TMH) ab interno trabeculotomy combined with phacoemulsification for POAG/ PACG

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Abstract. To evaluate the efficacy of Tanito Microhook (TMH) ab interno trabeculotomy combinated with phacoemulsification in treating primary open-angle glaucoma (POAG) and primary angle-closure glaucoma (PACG). A retrospective comparative study was conducted to analyze 16 patients with primary open-angle glaucoma (POAG) who underwent phacoemulsification and TMH at the Second People's Hospital of Changshu from December 2021 to December 2022, along with 19 patients with primary angle-closure glaucoma (PACG) who underwent phacoemulsification, goniosynechialysis, and TMH. The follow-up period ranged from 12 to 24 months. The average preoperative IOP in the POAG group was (26.50±4.52) mmHg, and the average IOP was (18.00±1.67) mmHg at 12 months postoperatively, which was significantly lower than the preoperative value ($P<0.05$). The average preoperative IOP in the PACG group was (34.11±14.90) mmHg, and the average IOP was (18.67±0.87) mmHg at 12 months postoperatively, which was lower than the preoperative value ($P<0.05$). The average number of anti-glaucoma drugs used by the POAG group before surgery was (2.06±0.21) types, and the average number of types was (0.18±0.10) at 12 months postoperatively, which was significantly reduced compared with the preoperative value ($P<0.05$). The PACG group used an average of (1.89±0.15) kinds of anti-glaucoma drugs preoperatively, (0.68±0.17) kinds of drugs postoperatively, and the difference in the number of drugs used between preoperative and postoperative periods was not statistically significant ($P>0.05$). The complete success rate of the POAG group was 81.3% (13/16), and the conditional success rate was 18.7% (3/16). The complete success rate of the PACG group was 47.4% (9/19), and the conditional success rate was 52.6% (10/19). The intraoperative and postoperative complications in the POAG group mainly included one case of hyphema in the anterior chamber and one case of transient intraocular pressure elevation, while the intraoperative and postoperative complications in the PACG group included one case of shallow anterior chamber after surgery, four cases of hyphema in the anterior chamber, and three cases of transient intraocular pressure elevation. No serious complications occurred in either group. The combination of TMH with cataract phacoemulsification and intraocular lens implantation demonstrates a safe and effective approach for treating POAG. Additionally, when combined with goniosynechialysis (GSL), it may be a safe and effective treatment for PACG. However, the long-term efficacy still requires further investigation through large-scale prospective controlled studies.

Keywords: primary open-angle glaucoma, primary angle-closure glaucoma, microinvasive glaucoma surgery, Tanito Microhook ab interno trabeculotomy, intraocular pressure.

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1. Introduction

Glaucoma is a group of diseases characterized by characteristic optic nerve atrophy and visual field defects, with pathological intraocular pressure (IOP) elevation being its main risk factor. Glaucoma has a blindness rate of up to 8%, making it the most common irreversible cause of blindness worldwide. In 2020, there were more than 80 million glaucoma patients worldwide [1, 2], with 22 million in China, accounting for 1/4 of the global total. The risk factors for glaucoma include age, race, family history, and elevated IOP, of which IOP is the only modifiable risk factor for glaucoma at present, and all interventions work by lowering IOP. Current treatments for lowering IOP include: pharmaceutical therapy, traditional surgery, and minimally invasive glaucoma surgery (MIGS) [3].

In recent decades, glaucoma surgical treatment has predominantly relied on conventional filtering procedures such as trabeculectomy and glaucoma drainage devices (GDD) treatment [4]. Although the continuous refinement of surgical techniques and the utilization of antimetabolic drugs have somewhat enhanced the safety and long-term efficacy of trabeculectomy, this procedure still diverts aqueous humor through non-physiological pathways, resulting in early complications like shallow anterior chamber and cystoid macular edema due to excessive filtration. Furthermore, long-term complications encompass filtration bleb scarring and filtration bleb fistula.

Revised sentence: Hence, the primary objective for glaucoma specialists has always been to pursue a safe and effective surgical solution for glaucoma. In recent times, Minimally Invasive Glaucoma Surgery (MIGS) has gained global recognition due to its ability to overcome the aforementioned limitations [5]. With advancements in biomaterials science and minimally invasive technology, there have been significant enhancements in MIGS equipment. The approach of MIGS surgery involves four mechanisms aimed at reducing intraocular pressure: (1) improving aqueous humor outflow through the trabecular meshwork (TM), (2) increasing aqueous humor outflow via the choroidal fissure, (3) enhancing subconjunctival filtration, and (4) decreasing aqueous humor production. One of these techniques is Tanito Microhook (TMH) trabeculectomy [6] which entails cutting both the trabecular meshwork and inner wall of Schlemm's canal to alleviate resistance to fluid flow and subsequently lower intraocular pressure.

This study aims to assess the effectiveness of combining TMH with cataract phacoemulsification as a treatment modality for Primary Open-Angle Glaucoma (POAG) and Primary Angle-Closure Glaucoma(PACG), with an aim to offer a more cost-effective, efficient, and safe treatment option for POAG/PACG.

2. Materials and Methods

2.1. Methods

The retrospective study enrolled 16 patients with primary open-angle glaucoma (POAG) (16 eyes) and 19 patients with primary angle-closure glaucoma (PACG) (19 eyes). In the POAG group, there were 10 male participants and 6 female participants (mean age ± standard deviation [SD], 67.43±13.06 years). In the PACG group, there were 11 male participants and 8 female participants (mean age ± standard deviation [SD], 72.56±3.94 years). These individuals underwent phacoemulsification combined with trabecular meshwork hydromechanics treatment for cataract under the care of an ophthalmologist at Changshu Second People's Hospital from December 2021 to December 2022, and were followed up for a minimum duration of 12 months. In the PACG group and the POAG group, there were 2 cases and 1 case of patients who had previously undergone trabeculectomy, respectively. The remaining patients in both groups had not received any surgical intervention on the affected eye. Prior to surgery, all patients underwent pharmacological treatment for intraocular pressure control. This study adhered strictly to the principles outlined in the Helsinki Declaration; it was conducted in accordance with relevant ethical guidelines as stated by the Helsinki Declaration and formally approved by the Medical Ethics Committee of Changshu Second People's Hospital (IRB: 2021-KY-051). Furthermore, all enrolled patients were provided with comprehensive preoperative information, voluntarily signed informed consent forms along with related medical documents, ensuring study legitimacy and safeguarding patient rights.The patients' demographic data and surgical procedures are summarized in Table 1.

2.2. Surgical Procedure

All surgeries were performed by the same ophthalmologist, who performed phacoemulsification intraocular lens implantation combined with TMH for the POAG group and phacoemulsification intraocular lens implantation, trabeculectomy, and zonular dialysis for the PACG group. The surgical steps were as follows: First, 30 minutes before surgery, the patient was given a tropicamide-phenylephrine ophthalmic solution to dilate the pupil. During surgery, the patient was placed in a supine position, and the surgical site was sterilized and draped as per routine. The surgeon used 0.4% oxibacillin hydrochloride to anesthetize the eye surface, and a lid retractor was used to fully expose the eye. The conjunctival sac was then flushed with 0.5% povidone iodine, and the anterior chamber was flushed with irrigation solution to ensure cleanliness and sterility of the surgical area. Next, a clear corneal main incision and an auxiliary lateral incision were made at the 10 o'clock and 2 o'clock positions, respectively, with a size of 2.2mm. Then, a hyaluronic acid injection needle was used to inject viscoelastic solution into the anterior chamber, and the capsulorhexis needle was used to make a continuous ring capsulorhexis with a diameter of 5mm. Next, the irrigation needle was inserted between the cortex and the capsular bag, and water was gently injected. One could see the water flowing along the cortex and between the capsular bag and the posterior capsule, reaching the other side. Pressing gently helped separate the crystalline lens water and layer the water. Then, the phacoemulsification probe was used with the lowest energy to sculpt, divide, emulsify, and aspirate the nucleus of the crystalline lens. The residual cortex was aspirated using an I/A cannula, and if there were a few residual cortical fragments on the posterior capsule, a polishing device was used for polishing. Finally, the viscoelastic agent (medical grade sodium hyaluronate gel) is injected into the sack and anterior chamber, and the artificial lens is implanted into the sack using a pusher. Then, 0.01% carbachol intraocular injection solution is injected into the anterior chamber, and the pupil is contracted. The viscoelastic agent is then injected into the anterior chamber to expand the angle, maintain the anterior chamber; adjust the ophthalmic surgical microscope to tilt towards the surgeon by about 40°, place a anterior chamber angle mirror on the corneal surface, and use the anterior chamber angle mirror to observe the anterior chamber angle; uniformly and continuously inject a small amount of viscoelastic agent into the entire circumference of the anterior chamber angle to separate it, insert a TMH through the corneal main incision into the anterior chamber; especially for PACG group patients because they often have anterior chamber angle adhesion, a ciliary traction device is used to gently press the ciliary root to separate the adhered anterior chamber angle, until the lower 2/3 of the functional trabecular meshwork and the scleral ridge are observed. Then, the tip of the TMH is inserted into the Schlemm canal and gently slid, cutting open the inner wall and trabecular meshwork of the Schlemm canal and the trabecular meshwork on the left and right sides by about 150° to 180°; then, the I/A tube is used to suction out the residual viscoelastic agent, and water is injected to seal the corneal incision; after the operation, tobramycin and dexamethasone ophthalmic ointment is applied to the conjunctival sac to prevent postoperative infection, a gauze pad is placed over the eye and a shield is worn to ensure cleanliness and protection of the surgical site. Finally, the doctor instructed the patient to use Tobrex and Dymoxin eye drops locally and Prilocin eye drops and Olopatadine eye ointment.

2.3. Measurements

Collect measurements of intraocular pressure, visual changes, complications, and usage of anti-glaucoma medications post-surgery at the 12-month mark in both primary angle-closure glaucoma (PACG) and primary open-angle glaucoma (POAG) cohorts. Schedule follow-up appointments with patients at multiple time points including 1 day, 1 week, 2 weeks, 1 month, 3 months, 6 months, and 12 months after surgery to assess best corrected visual acuity (BCVA) and intraocular pressure levels for all participants. Document the types and quantities of administered anti-glaucoma medications. Conduct

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pre-operative perimetry and retinal nerve fiber layer (RNFL) assessments as well as post-operative evaluations after a duration of twelve months.

2.4. Statistical Analysis

The statistical analysis was performed using SPSS 26.0 software. Continuous variables conforming to a normal distribution were presented as mean ± standard deviation (SD). Single-factor repeated measures analysis of variance (ANOVA) was employed to compare intraocular pressure values at different time points, followed by pairwise comparisons using the LSD-t^ test. The Wilcoxon rank sum test was used to assess the difference in the number of anti-glaucoma drugs administered before and after surgery. A significance level of $p < 0.05$ was considered statistically significant.

Table 1. Preoperative baseline characteristics of the patient

Parameters	POAG Group	PACG Group
Average Age (years)	67.43±13.06	72.56±3.94
Gender (male/female)	10/6	11/8
Ophthalmic surgery (with/without)	1/16	2/19
Medication	2.06±0.21	1.89±0.15
IOP(mmHg)	26.50±4.52	34.11±14.9
BCVA	0.64±0.10	1.02±0.20

3. Results

3.1. IOP Reduction

The intraocular pressure of the operated eye in both the POAG and PACG groups significantly decreased at each follow-up time point after surgery compared to before surgery (all $P < 0.001$). Additionally, the preoperative intraocular pressure was higher in the PACG group than in the POAG group, with a statistically significant difference (all $P < 0.001$). However, there was no statistically significant difference in intraocular pressure between the two groups at any follow-up time point after surgery (all $P > 0.05$). These findings suggest that combined phacoemulsification cataract extraction, intraocular lens implantation, and trabeculectomy have effective intraocular pressure-lowering effects on both POAG and PACG patients. In particular, for the POAG group, there was a substantial decrease from an average of 26.50 ± 4.52 mmHg before surgery to 17.00 ± 1.55 mmHg at 12 months post-surgery, representing a reduction of approximately 35.84%. Similarly, for the PACG group, the mean preoperative intraocular pressure of 34.11 ±14.9 mmHg decreased to an average of 17.67 ±1 .41 mmHg at12 months post-surgery with a decrease rate of about18 .19%. (Table 2)Notably, no significant rebound in intraocular pressure occurred during the follow-up period.

Table 2. Intraocular pressure changes preoperative and postoperative surgery ($\bar{\chi}$±s,mmHg)

Group	Preoperative period	One day	One week	Two week
POAG Group	26.50±4.52	18.17±4.62	17.00±2.00	16.00±2.28
PACG Group	34.11±14.90	18.33±4.53	17.00±3.00	17.44±3.32
t value	-2.069	-0.069	0.000	-0.925
P value	0.059	0.946	1.000	0.372
Group	One month	Three month	Six month	Twelve month
POAG Group	16.67±1.63	17.17±2.04	17.33±1.51	17.00±1.55
PACG Group	16.78±2.22	17.22±1.56	17.78±1.72	17.67±1.41
t value	-0.105	-0.060	-0.515	-0.862
P value	0.918	0.953	0.615	0.404

Table 2. (continued).

Group	Twenty-four month	*F* value	*P* value
POAG Group	18.00±1.67	2.763	<0.001
PACG Group	18.67±0.87	13.056	<0.001
t value	-1.020		
P value	0.326		

3.2. Preoperative and Postoperative medications

In the POAG group, a mean of 2.06±0.21 types of anti-intraocular pressure medications were administered preoperatively, while postoperatively at 12 months, only 0.17±0.41 types were used, and this difference was found to be statistically significant (P<0.05). Conversely, in the PACG group, a mean of 1.89±0.15 types of anti-intraocular pressure drugs were utilized before surgery, which decreased to 0.68±0.17 types at the same time point after surgery; however, this disparity did not reach statistical significance (P>0.05). There was no statistically significant distinction in the number of anti-intraocular pressure drugs employed between the two groups prior to surgery (P>0.05), but postoperatively, the PACG group required a higher number compared to the POAG group with statistical significance (P<0.05). These findings indicate that combined phacoemulsification and TMH trabeculectomy is more efficacious in reducing intraocular pressure in patients with POAG than phacoemulsification and GSL combined with TMH trabeculectomy in those with PACG (Tables 3 and 4).

Table 3. Types of pre-operative and post-operative drugs reducing IOP

Group	Time	Drugs reducing IOP (species)			
		3	2	1	0
POAG Group	Pre-operation	6	5	5	0
	12M Post-operation	0	0	3	13
PACG Group	Pre-operation	3	11	5	0
	12M Post-operation	0	3	7	9

Table 4. The variation of pre-operative and post-operative drugs ($\bar{\chi}$±s, species)

Group	Pre-operative drugs	12M post-operative drugs	F value	P value
POAG Group	2.06±0.21	0.18±0.10	4.487	0.006
PACG Group	1.89±0.15	0.68±0.17	1.297	0.586
F value	1.685	3.455		
P value	0.290	0.019		

3.3. Success rate of the operation

In the primary open-angle glaucoma (POAG) group, 13 eyes (81.3%) achieved complete surgical success at 12 months postoperatively, while 3 eyes (18.7%) achieved conditional success. In the primary angle-closure glaucoma (PACG) group, 9 eyes (47.4%) achieved complete surgical success at 12 months postoperatively, while 10 eyes (52.6%) achieved conditional success. No cases of failure were observed in either group. The rate of complete surgical success was significantly higher in the POAG group compared to the PACG group (P < 0.05) (Table 5). These results demonstrate that combining cataract phacoemulsification with trabeculectomy using a trabecular micro-bypass stent is more effective for treating POAG than combining cataract phacoemulsification with goniosynechialysis and trabeculectomy for treating PACG.

Table 5. The success rate of 12 months post-operation

Group	Numbers of complete surgical success	Complete surgical success rate	Numbers of conditional surgical success	Conditional surgical success rate
POAG Group	13	81.3%	3	18.7%
PACG Group	9	47.4%	10	52.6%
T value		2.142		
P value		0.039		

3.4. Occurrence of surgical complications of surgical complications

The primary issues that may arise from TMH trabeculectomy surgery are temporary intraocular hypertension and bleeding in the anterior chamber (Table 6). In the POAG group, two eyes experienced complications after surgery: one eye had a brief episode of high pressure in the eye on the day following surgery, which was successfully managed and brought down to below 21mmHg; another eye had some bleeding in the front part of the eye, but it resolved naturally. Among those with PACG, one eye showed a shallow anterior chamber after surgery but improved without treatment when pilocarpine drops were stopped. Additionally, four eyes had some bleeding in this group; three cases cleared up within a week after surgery while one case required flushing on day seven post-surgery. It is important to note that all patients maintained stable vision and intraocular pressure throughout these events. Furthermore, three eyes from both groups experienced temporary high pressure on the day following surgery but responded well to treatment and returned to normal levels below 21mmHg. Importantly, there were no serious complications such as damage to corneal cells or tissues at risk for infection like endophthalmitis observed in either study group following TMH trabeculectomy procedures—suggesting its relative safety for treating glaucoma.

Table 6. The occurrence of surgical complications (eyes)

Complications	POAG Group	PACG Group
temporary intraocular hypertension	1/19	3/16
hyphema	1/19	4/16
Low intraocular pressure	0/19	0/16
shallow anterior chamber	0/19	1/16

4. Dicussion

The management of glaucoma heavily relies on surgical treatment, and the introduction of minimally invasive glaucoma surgery (MIGS) has brought about innovative approaches to surgical intervention for this condition [7]. MIGS aims to improve the outflow of aqueous humor by minimizing damage to ocular tissues or reducing its production. Trabeculectomy is a commonly performed surgical procedure within various MIGS techniques, which facilitates drainage of aqueous humor by releasing the inner wall of the Schlemm canal and trabecular meshwork. By restoring the natural pathway for aqueous humor drainage, it effectively reduces intraocular pressure. Trabeculectomy can be classified into endotrabecular and exotrabecular approaches, with an increasing preference among glaucoma specialists towards endotrabecular surgery due to its ability to spare conjunctiva and avoid filter bleb formation.

Aqueous humor, a vital fluid within the eye responsible for maintaining intraocular pressure and eye shape, flows through a complex network of channels including the trabecular meshwork, Schlemm's canal, collecting duct, and the suprachoroidal vein. These structures collectively form the outflow pathway for aqueous humor. In their study on ultrasound phacoemulsification combined with viscous trabeculectomy for chronic angle-closure glaucoma, Razeghinejad and Rahat discovered that resistance to aqueous outflow through both the trabecular meshwork and Schlemm's canal was comparable or even

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higher in some cases than that of the trabecular meshwork alone. Therefore, it is crucial to consider the role of the trabecular meshwork-Schlemm's canal outflow pathway in treating glaucoma, particularly primary angle-closure glaucoma (PACG). Minimally invasive glaucoma surgery (MIGS) offers various surgical techniques aimed at resolving obstruction within this pathway such as shaping or dilating Schlemm's canal, incising it or dissolving parts of the trabecular meshwork while also implanting microbypass stents. The ultimate objective of these techniques is to enhance aqueous humor flow into the collecting duct by either removing or bypassing obstructive elements within the trabecular meshwork or increasing its tension to effectively reduce intraocular pressure.

TMH is a novel microhook specifically designed by the Tanito [6,8,9] team for ab interno trabeculotomy, aiming to enhance surgical cutting ability and improve operability and efficiency. By refining the tip of the Sinakey hook, three distinct hook shapes - left, right, and straight - were created. This device offers several notable advantages: (1) It exhibits reusability without dependence on specialized or costly equipment, thereby significantly reducing surgery costs and enhancing practicality; (2) Its unique blade-like tip design enables easy insertion into the trabecular meshwork-Schlemm canal for internal wall incision without causing damage, resulting in convenient operation with reduced invasiveness and shorter duration; (3) The gradual and gentle sliding of the TMH within the Schlemm canal facilitates precise judgment of incision direction and depth based on resistance encountered during surgery; thus providing higher precision; (4) The inclusion of three different hook shapes expands the surgical field of view, enabling comprehensive cutting of the Schlemm canal which ultimately improves surgical success rates.

This study conducted a review and comparison of the efficacy and safety of TMH trabeculectomy in treating POAG and PACG. In the POAG group, postoperative intraocular pressure was significantly reduced, along with a significant decrease in the number of anti-glaucoma drugs used postoperatively, indicating that phacoemulsification combined with TMH trabeculectomy can effectively treat POAG while improving patient compliance with medication to prevent glaucomatous blindness. In contrast, although there was no significant difference in the number of anti-glaucoma drugs used before and after surgery in the PACG group, postoperative intraocular pressure at 12 months was significantly lower than pre-surgery levels when using phacoemulsification combined with GSL and TMH trabeculectomy to treat PACG. However, this approach had a lower success rate compared to treating POAG due to several reasons: (1) patients in the PACG group were all advanced or middle-stage patients whose aqueous humor drainage function after GSL reopening anterior chamber was poor; (2) some eyes in the PACG group could not fully open their anterior chambers according to UBM examination results; (3) TMH trabeculectomy sites were more likely to adhere and close off for patients with PACG than those with POAG; (4) prior closure of anterior chambers before surgery may have deprived small canals from adequate aqueous humor drainage function leading to increased resistance behind ciliary bodies.

5. Conclusion

In conclusion, the combined use of TMH adhesive tubulotomy and cataract phacoemulsification presents a safe and effective treatment option for primary open-angle glaucoma (POAG). Additionally, this approach has shown promising results in effectively managing primary angle-closure glaucoma (PACG) when used in conjunction with GSL. However, it is important to acknowledge that this study has certain limitations as it was conducted at a single center and had a relatively small sample size. These factors may restrict the comprehensive evaluation of treatment outcomes. Nonetheless, these findings underscore the potential of Tanito's hook-sticky tubulotomy combined with cataract phacoemulsification as an effective strategy for managing glaucoma. To further validate the long-term efficacy of this surgical technique, future studies should consider conducting multicenter prospective clinical trials to provide more robust evidence for its application in clinical practice.

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References

[1] FLAXMAN S R, BOURNE R R A, RESNIKOFF S, et al. Global causes of blindness and distance vision impairment 1990-2020: a systematic review and meta-analysis [J]. Lancet Glob Health, 2017, 5(12): e1221-e34.

[2] BARKANA Y, DORAIRAJ S. Re: Tham et al.: Global prevalence of glaucoma and projections of glaucoma burden through 2040: a systematic review and meta-analysis (Ophthalmology 2014;121:2081-90) [J]. Ophthalmology, 2015, 122(7): e40-1.

[3] JAYARAM H, KOLKO M, FRIEDMAN D S, et al. Glaucoma: now and beyond [J]. Lancet, 2023, 402(10414): 1788-801.

[4] GUPTA S, JERIA S. A Review on Glaucoma Drainage Devices and its Complications [J]. Cureus, 2022, 14(9): e29072.

[5] CHAN P P M, LARSON M D, DICKERSON J E, JR., et al. Minimally Invasive Glaucoma Surgery: Latest Developments and Future Challenges [J]. Asia Pac J Ophthalmol (Phila), 2023, 12(6): 537-64.

[6] TANITO M, SANO I, IKEDA Y, et al. Short-term results of microhook ab interno trabeculotomy, a novel minimally invasive glaucoma surgery in Japanese eyes: initial case series [J]. Acta Ophthalmol, 2017, 95(5): e354-e60.

[7] GURNANI B, TRIPATHY K. Minimally Invasive Glaucoma Surgery [M]. StatPearls. Treasure Island (FL). 2024.

[8] TANITO M, SUGIHARA K, TSUTSUI A, et al. Midterm Results of Microhook ab Interno Trabeculotomy in Initial 560 Eyes with Glaucoma [J]. J Clin Med, 2021, 10(4).

[9] TANITO M, SUGIHARA K, TSUTSUI A, et al. Effects of Preoperative Intraocular Pressure Level on Surgical Results of Microhook Ab Interno Trabeculotomy [J]. J Clin Med, 2021, 10(15).