

Development and Application of a New T-shaped Internal Trabeculotomy Hook (T-hook)

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Purpose: We introduce a newly designed T-shaped internal trabeculotomy hook and compare its surgical outcomes with those of Kahook dual blade (KDB) surgery.

Patients and Methods: One eye each of seventeen and sixty-one patients underwent T-hook and KDB surgeries, respectively. Post-surgical intraocular pressure (IOP), medications, visual acuity, and prevalence of IOP spikes and hyphema were compared between the two cohorts.

Results: The utility of the T-hook was excellent and enabled the easy opening of the Schlemm's canal. The pre-surgical IOP of 25.6 ± 7.5 mmHg in the T-hook cohort decreased to 14.1 ± 4.3 (-41.2% reduction) and 15.0 ± 3.1 mmHg (-39.3% reduction) at 3 ($P<0.001$) and 6 months ($P=0.003$), respectively. Pre-surgical medications of 2.8 decreased to 2.3 and 2.0 medications, respectively, at 3 and 6 months. The best-corrected visual acuity (BCVA) improved from the pre-surgical logarithm of the minimum angle resolution (logMAR) of 0.148 to -0.012 at three months ($P=0.036$). While the pre-surgical IOP of 24.9 ± 4.3 mmHg in the KDB cohort decreased to 16.5 ± 5.7 mmHg (-35.5% , $P<0.001$) and 16.1 ± 3.4 mmHg (-33.5% , $P<0.001$) at 3 and 6 months, respectively. Reduction in medications at 3- and 12-month timepoints (from 2.8 to 1.7 and 1.7, respectively; $P<0.001$) and improvement in BCVA at three months (from 0.106 to -0.025 logMAR, $P<0.001$) were also significant. There was no difference between the T-hook and KDB cohorts in terms of the pre-surgical IOP ($P=0.15$) and post-surgical IOP at 1 ($P=0.27$), 3 ($P=0.17$), 6 ($P=0.47$), and 12 months ($P=0.11$, Mann-Whitney *U*-test). The prevalence of a post-surgical IOP spike in the T-hook and KDB cohorts was 41.2% and 47.5%, and that of post-surgical hyphema was 17.6% and 26.2%, respectively.

Conclusion: The novel T-hook was easy to use and was as useful as the KDB device in performing internal trabeculotomy.

Keywords: minimally invasive glaucoma surgery, MIGS, trabecular meshwork, nonpenetrating glaucoma surgery, Schlemm's canal, double mirror gonio lens, T-hook

Introduction

Minimally invasive glaucoma surgery (MIGS) is a safe and minimally traumatic surgical intervention for patients with mild-to-moderate glaucoma. Among the three types of MIGS (trabecular-based surgery, suprachoroid-based surgery, and subconjunctival drainage surgery), Trabecular-based surgery has gained popularity owing to its simplicity and high safety profile. Trabecular-based surgeries involve incision of the trabecular meshwork from the anterior chamber side and opening of the Schlemm's canal is effective in lowering intraocular pressure (IOP).¹⁻⁵

Recently, internal canal-ectomy, canal-otomy, and implantable devices such as iStents, Hydrus, and canal expanders have been put into practical use. Internal Schlemm canal openings using hooks, blades, and sutures are simple and inexpensive procedures. Several studies have reported that a greater extent of Schlemm's canal opening does not lead to a greater degree of IOP reduction;⁶ however, other studies have reported that IOP reduction by opening of the trabecular meshwork (TM) utilizing a Kahook dual blade (KDB) or hook overwhelms IOP reduction by iStent.⁷⁻⁹ Previous reports suggest that the KDB and Tanito micro hook are time-saving and useful for effective IOP reduction with good cost performance.^{1,4} The safety profile of internal trabecular-based surgery has been previously reported.¹⁰

Despite the popularity of KDB and Tanito microhooks, these devices have shortcomings that require revision. The blades of these devices are vertically oriented to the shaft and may pierce through the Schlemm's canal and injure its outer wall. Penetration of the outer wall of the Schlemm's canal may injure the band of extracanalicular limbal lamina (BELL),¹¹ a juxta-canal backyard tissue that includes the collector channel and hinge or outlet valve of the collector channel.¹² Another issue is the difficulty of incising the Schlemm's canal near the corneal entry of the blade or hook; the angle of insertion into the trabecular meshwork becomes too tight and increases the risk of impairing the outer wall of the Schlemm's canal. To address this problem, we developed a new device, the T-shaped Trabeculotomy Hook (T-hook; Figure 1A).

The design of the T-hook was improved from versions 1 to 5 to reduce the risk of destroying the outer wall of the Schlemm's canal. The prototypes of the T-hook are shown in Figure 1B.

Subjects and Methods

Patients and Treatment

A T-hook was used in 17 eyes of 17 patients, and the outcomes were compared with those of 61 patients who underwent KDB surgery. The surgeries were indicated for patients with high IOP despite the use of topical medications, those with progression of visual field defects and/or deterioration of visual acuity in eyes with concomitant glaucoma and cataract.

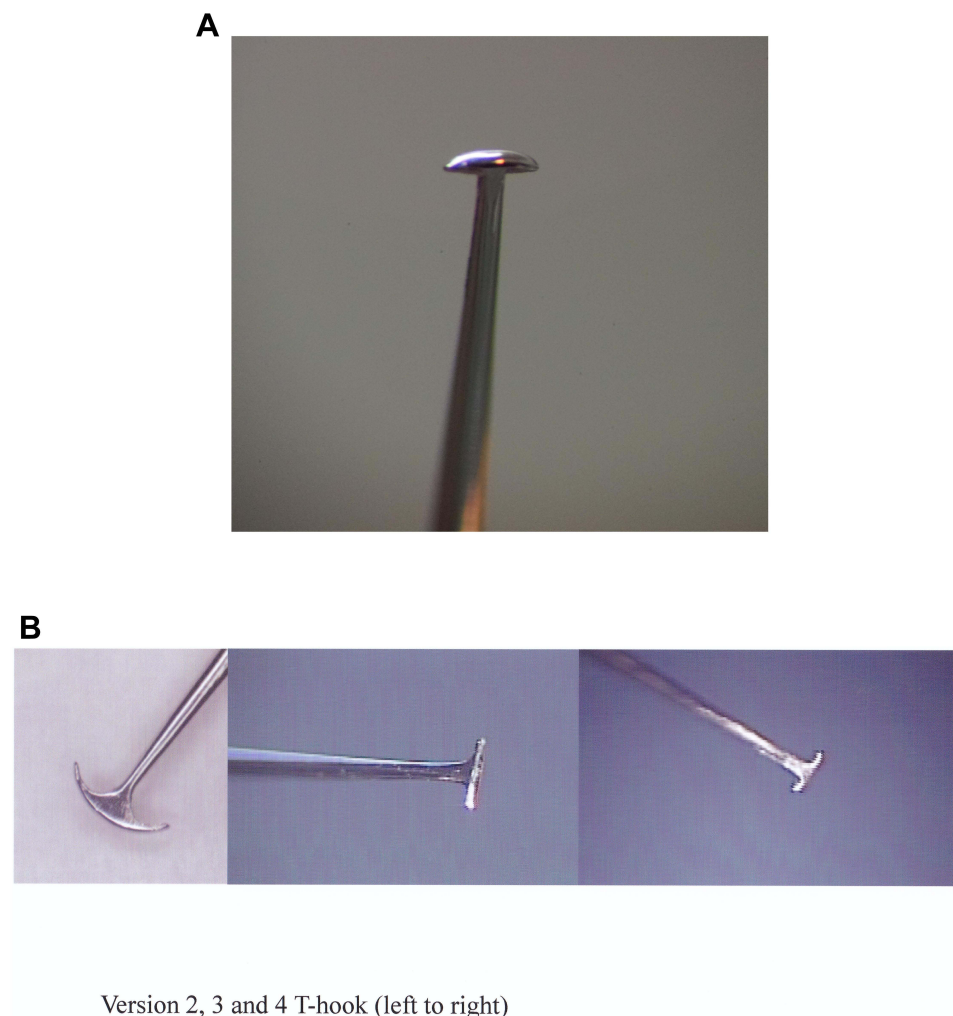


Figure 1 (A) Overview of the T-hook. The tip of the T-hook is curved to avoid damaging the outer wall of the Schlemm's canal, and the blades on both sides can easily open the trabecular meshwork. The T-hook can cut both the left and right trabecular meshwork using a single insertion procedure. If surgeons create three different corneal incisions with a 120-degree distance using a double mirror gonio lens (ex. Ahmed Gonio lens), a 360-degree internal trabeculotomy can be performed. (B) Photographs of the prototypes of the T-hook. The angle, thickness, and configuration of the tip were changed 5 times.

The use and risk of the new device and KDB was explained to the patients and informed consent for surgery and the use of data for reports were obtained from all patients before surgery. This retrospective study aimed to compare the outcomes between the KDB and T-hook cohorts. The study design was approved by the internal review board of Senshokai and the procedures were performed in conjunction with the tenets of the Declaration of Helsinki.

A photograph of the T-hook is shown in Figure 1A. The tip of the T-hook has a curved back to avoid injury to the outer wall and to avoid penetration of the outer wall by the device. The width is 200 μm and the thickest portion is 200 μm . The device is made of stainless steel, tolerates autoclave disinfection, and is thus re-usable. We designed the hook, and it was manufactured by Handaya Co., Tokyo, Japan.

Inclusion Criteria and Exclusion Criteria

The inclusion criteria were eyes with a history of high IOP exceeding 21 mmHg, mild open-angle glaucoma with concomitant cataract designated for combined glaucoma and cataract surgery, a post-surgical follow-up period exceeding 3 months, and visual field defects less than -20 dB using a Humphrey visual field analyzer.

The exclusion criteria were angle-closure glaucoma, secondary glaucoma, history of previous intraocular surgery, uveitis, vitreoretinal diseases, and corneal diseases that hampered visualization of the angle. After confirming the safety profile of the T-hook and obtaining approval from the IRB, the surgical procedure was converted from the KDB to the T-hook in August 2021 following the same inclusion and exclusion criteria.

Surgical Procedures

In this study, MIGS was combined with concomitant phacoemulsification aspiration and implantation of the intraocular lens. When both eyes were treated, the eye with the higher pre-surgical IOP was selected for analysis.

The first step in T-hook surgery is the creation of corneal paracentesis at the 10 o'clock meridian. After the injection of viscoelastic material, anterior capsulorhexis was performed, and additional viscoelastic material was injected into the anterior chamber to open the peripheral angle. A small amount of viscoelastic material was placed on the surface of the cornea, and an Ahmed surgical Gonio-lens (UADVX-H, Ocular, Bellevue, WA 98004, USA) was placed on the cornea. The T-hook was slowly inserted into the eye, entering the Schlemm's canal, and moved laterally to incise the trabecular meshwork (Figure 2). After a 60 to 80-degree incision in the trabecular meshwork, the T-hook returned to its original position, and the contralateral 60-to-80-degree trabecular meshwork was incised with the opposite blade of the same T-hook (Figure 3).

The procedure for the KDB surgery has been reported previously.¹³ After completion of the MIGS procedure, the corneal paracentesis wound was expanded to 2.6 mm and conventional phacoemulsification aspiration and implantation of the intraocular lens were performed. After cataract surgery, 0.25% acetylcholine solution was injected into the anterior chamber and the corneal wound was closed with one 10-0 nylon suture. After disinfection of the surgical area with povidone-iodine solution (Nitto Medic, Toyama, Japan) and antibiotic ointment (Ofloxacin, Santen Osaka), the eye was patched. Antiglaucoma medications were administered in cases where post-surgical IOP was high. Antibiotics (0.3% Gatifloxacin Senju-Co, Osaka) and steroid eye drops (0.1% betamethasone, Shionogi, Osaka) were used for one month

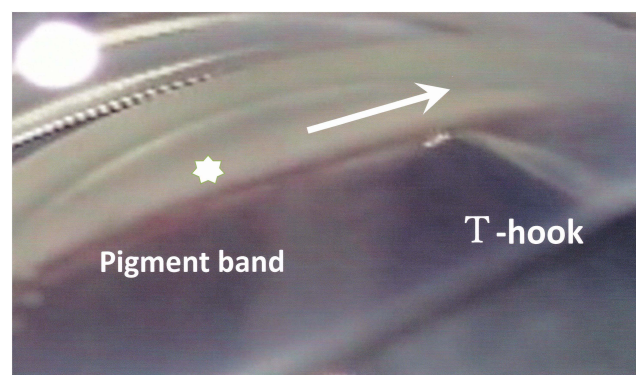


Figure 2 Images of the surgical procedures for dissection of the right trabecular meshwork. The asterisk indicates the first insertion site. Note the scarcity of bleeding events.

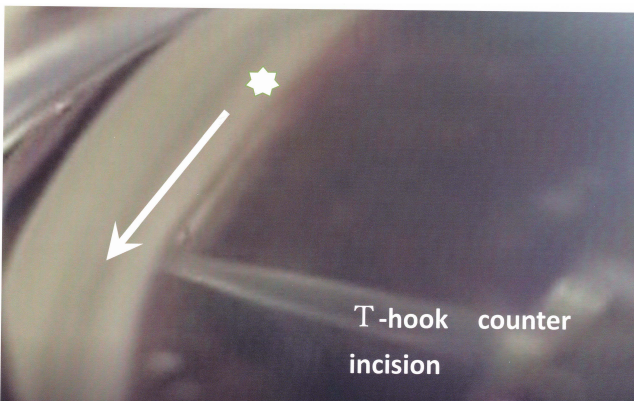


Figure 3 Images of surgical procedures for dissection of the contralateral trabecular meshwork.

after the surgery. After the surgery 2% pilocarpine was administered for 2 weeks to avoid formation of the peripheral anterior synechia.

For Kaplan–Meier life table analysis, the criteria for success were an IOP less than 17 and 21 mmHg under topical medications at two consecutive examinations.

The definition of the spike in this study was a recorded IOP ≥ 5 mmHg higher than the pre-surgical IOP within one week after surgery. Hyphema was defined as a ≥ 2 mm bloody “niveau” formation in the anterior chamber.

Statistical Analysis

The Mann–Whitney *U*-test, Student’s *t*-test, Wilcoxon signed rank test, and Kaplan–Meier life table analysis were used to compare the outcomes of T-hook and KDB surgery using Bell-Curve for Excel software (Social Survey Research Information Co., Ltd Tokyo).

Results

We did not experience any difficulty in inserting the T-hook into the Schlemm’s canal. The ease of inserting the hook and opening the Schlemm’s canal did not change with repeated use of the T-hook for at least 20 times.

Table 1 shows the baseline characteristics and prevalence of spikes and hyphema in the two cohorts. Twenty-eight eyes of the 28 patients and 113 eyes of 113 patients underwent T-hook and KDB surgeries, respectively. The pre-surgical IOP of 5 and 39 eyes in the T-hook and KDB cohorts, respectively were less than 21 mmHg, and the follow-up periods of 6 and 13 eyes in the T-hook and KDB cohorts, respectively were less than 3 months, and these eyes were excluded from this study. Finally, one eye each of 17 and 61 open-angle glaucoma patients who underwent T-hook surgery and KDB surgery, respectively, were included in the statistical analysis. There were no significant differences in age or refractive error between the KDB and T-hook cohorts (Table 1).

The pre- and post-surgical IOP, medications, and visual acuity are shown in Table 2.

Table 1 Baseline Demographics and a Prevalence of Spike and Hyphema in the Kahook Dual Blade and T-Hook Cohorts

		Age	SE	HFA MD	F/U Period	Spike ≥ 5 mmHg	Hyphema 2 mm
KDB	N	61	59	58	61	Yes/No	Yes/No
	Mean $\pm$ SD	69.6 $\pm$ 12.9	−3.31 $\pm$ 4.31	−8.88 $\pm$ 7.47	796.4 $\pm$ 519.0	29/32 (47.5%)	16/45 (26.2%)
P between KDB and T-hook cohort		0.965 [†]	0.52 [†]	0.030 [†]	0.0000 [†]	0.785 ^{††}	0.542 ^{††}
T-hook	N	17	17	15	17	Yes/No	Yes/No
	Mean $\pm$ SD	69.5 $\pm$ 11.4	−2.55 $\pm$ 4.26	−13.81 $\pm$ 8.46	186.7 $\pm$ 103.7	7/10 (41.2%)	3/14 (17.6%)

Notes: [†]P value utilizing Student’s *t*-test, ^{††}P value utilizing Fisher exact test.
Abbreviations: SE, spherical equivalent refractive error; HFA MD, Humphrey visual field analyzer mean deviation before surgery; F/U, follow up; SD, standard deviation.

Table 2 Pre- and Post-Surgical Intraocular Pressure, Medications, and Visual Acuity After Kahook Dual Blade and T-hook Surgery

		Pre-op IOP	Post-op IOP					% IOP reduction			Medications			LogMAR BCVA	
			1W	1M	3M	6M	12M	3M	6M	12M	Pre-op	3M	12M	Pre-op	3M Post-op
KDB	N	61	60	60	58	57	55	57	55	55	61	58	53	61	58
	Mean $\pm$ SD	24.9 $\pm$ 4.3	22.0 $\pm$ 8.8	17.1 $\pm$ 6.0	16.5 $\pm$ 5.7*	16.1 $\pm$ 3.4*	16.3 $\pm$ 3.0*	35.5 $\pm$ 20.0	33.5 $\pm$ 14.9	33.2 $\pm$ 14.7	2.8 $\pm$ 1.5	1.7 $\pm$ 1.3*	1.7 $\pm$ 1.3*	0.106 $\pm$ 0.226	-0.025 $\pm$ 0.417*
T-hook	N	17	17	17	15	11	5	15	11	5	17.0	15	5	17	16
	Mean $\pm$ SD	25.6 $\pm$ 7.5	21.2 $\pm$ 12.1	15.7 $\pm$ 3.1	14.1 $\pm$ 4.3*	15.0 $\pm$ 3.1*	13.8 $\pm$ 3.0*	41.2 $\pm$ 23.1	39.3 $\pm$ 21.0	43.3 $\pm$ 18.6	2.8 $\pm$ 1.3	2.3 $\pm$ 1.0	2.0 $\pm$ 1.2	0.148 $\pm$ 0.429	-0.012 $\pm$ 0.175*
M-W-U test P value		0.148	0.403	0.272	0.167	0.466	0.106	0.441	0.524	0.244	0.826	0.039	0.585	0.453	0.173

Notes: *P<0.05 utilizing Wilcoxon signed rank test (compared with pre-surgical value). M-W-U test: Mann-Whitney U-test P-value compared between the KDB and T-hook cohorts.

Abbreviations: IOP, intraocular pressure; w, week; M, month(s); Pre-op, pre-surgical; post-op, post-surgical; logMAR, Logarithm of the minimum angle resolution; BCVA, best corrected visual acuity; KDB, Kahook dual blade surgery.

In the T-hook cohort, the pre-surgical IOP of 25.6 ± 7.5 mmHg decreased to 14.1 ± 4.3 ($P < 0.001$), 15.0 ± 3.1 ($P = 0.003$) and 13.8 ± 3.0 mmHg ($P = 0.043$) at 3, 6 and 12 months, respectively (analysis utilizing Wilcoxon signed rank test (WSR-test)), and pre-surgical medications reduced from 2.8 ± 1.3 to 2.3 ± 1.0 ($P = 0.086$) and 2.0 ± 1.2 ($P = 0.180$, WSR test) at 3 and 12 months, respectively. The best corrected visual acuity (BCVA) significantly improved from 0.148 ± 0.429 logarithm of the minimum angle resolution (logMAR) to -0.012 ± 0.175 logMAR ($P = 0.036$, WSR-test).

In the T-hook cohort, the mean IOP reductions were $41.2 \pm 23.1\%$ and $39.3 \pm 21.0\%$ at 3 and 6 months, respectively. Spikes of IOP (≥ 5 mmHg) and hyphema exceeding 2 mm occurred in 7 of 17 eyes (41.2%) and 3 of 17 eyes (17.6%), respectively (Table 1).

In the KDB cohort, a pre-surgical IOP of 24.9 ± 4.3 mmHg was significantly reduced to 16.5 ± 5.7 ($P < 0.001$), 16.1 ± 3.4 ($P < 0.001$), and 16.3 ± 3.0 mmHg ($P < 0.001$) at 3, 6 months and 12 months post-surgery, respectively (analysis using WSR-test). The mean IOP reduction at 3 and 6 months was 35.5 ± 20.0 and $33.5 \pm 14.9\%$, respectively. Anti-glaucoma medications decreased from pre-surgical number of 2.8 ± 1.5 to 1.7 ± 1.3 and 1.7 ± 1.3 at 3 ($P < 0.001$) and 12 months ($P < 0.001$, WSR test: Table 2), respectively. The BCVA improved from 0.106 ± 0.220 logMAR to -0.025 ± 0.417 logMAR ($P < 0.001$; WSR test). Spikes in the IOP and hyphema exceeding 2 mm occurred in 29 of 61 eyes (47.5%) and 16 of 61 eyes (26.2%), respectively. The prevalence of spike and hyphema was slightly lower in the T-hook cohort; however, the differences in the prevalence of spike ($P = 0.785$) and hyphema ($P = 0.542$) between T-hook and KDB cohort were not significant according to the Fisher exact test.

The success probability to achieve 21 mmHg at 6 months for T-hook and KDB was 1.0 ± 0 and 0.948 ± 0.0293 , respectively, and the difference was not significant according to the Log rank test ($P = 0.351$). Similarly, the probability of success in achieving 17 mmHg at 6 months for T-hook was 0.725 ± 0.141 and that for KDB was 0.672 ± 0.0617 , $P = 0.957$ according to the Log rank test. There was no significant difference in the probability of success between the cohorts according to Kaplan–Meier life table analysis (Figures 4 and 5).

Discussion

The inner wall of the trabecular meshwork was fragile and easily opened by the T-hook. It took only 1–2 min to open the Schlemm's canal in the range of 120° to 150° . When performing KDB, one of the concerns for surgical interventions utilizing a “sharp” blade is the risk of damage to the juxta-canal tissues, such as the BELL.¹¹ In other techniques, the trabecular meshwork can be opened using other devices such as the Trabectome. In the case of the Trabectome, tissue damage by heat dissipation may be minimal;¹⁴ however, the 550kHz electrode power may be strong enough to coagulate

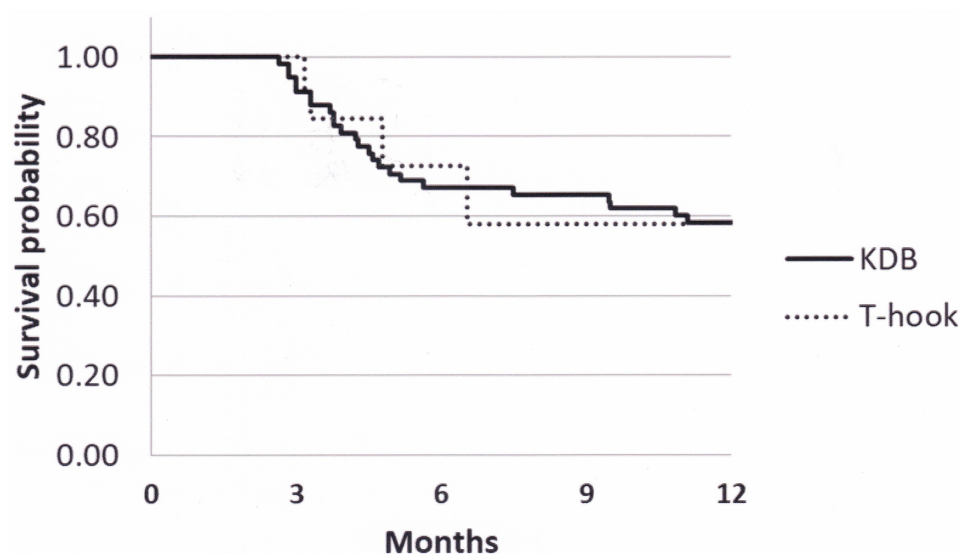


Figure 4 Probability to achieve an IOP of 17 mmHg assessed by Kaplan–Meier life table analysis. Log rank test revealed no difference between the T-hook and KDB cohorts ($P = 0.957$).

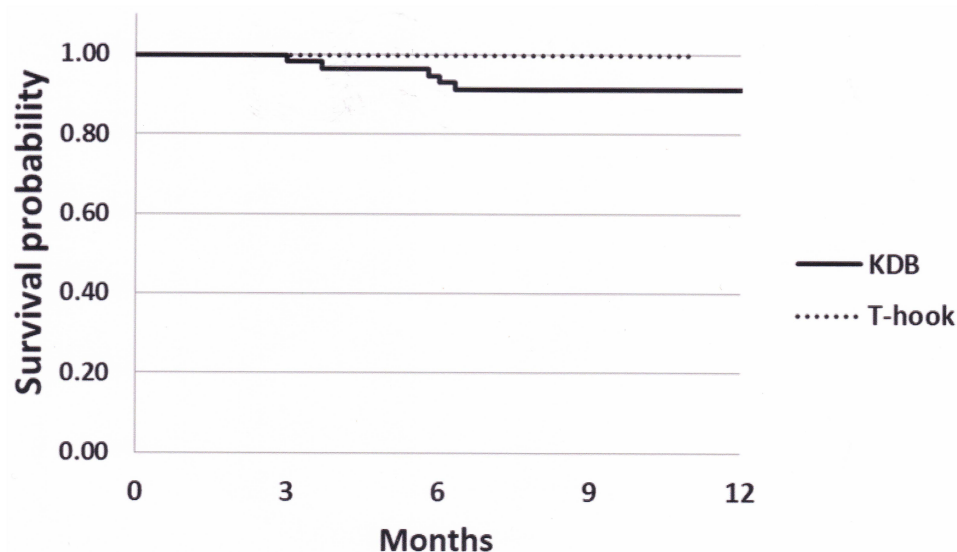


Figure 5 Probability to achieve an IOP of 21 mmHg assessed by Kaplan–Meier life table analysis. Log rank test revealed no difference between the T-hook and KDB cohorts ($P=0.351$).

the fine valve-like pump system of the trabecular meshwork.¹² Using the dull blade of the T-hook instead of an overly sharp blade or electrode may be more appropriate for opening the Schlemm's canal without injuring the neighboring tissues. In addition to the safety profile, a re-usable device would be useful in reducing the cost of internal trabeculotomy. For the post-surgical IOP, there was no difference between the KDB and T-hook cohorts for up to 6 months, and the probability of success in opening the Schlemm's canal was not affected by the use of a re-usable steel device. In this study we excluded eyes with pre-surgical IOP less than 21 mmHg from a statistical perspective. If we set the success criteria of 21 mmHg and 17 mmHg, it will be difficult to assess the probability of success in eyes with pre-surgical IOP <21 mmHg. Success probability using percentile IOP reduction will be the subject of future studies.

The surface of the top of the T-hook device is curved and has a low chance of stinging in the outer wall of the Schlemm's canal. Conversely, the sharp blade of other devices may occasionally enter the outer wall of the Schlemm's canal. If the device stings the outer wall, the backyard tissue of the BELL¹¹ may be damaged, and accidental bleeding may occur, hereby hampering the opening of the Schlemm's canal.

The advantage of a lower risk of injuring the outer wall of the Schlemm's canal with the T-hook may be reflected in the lower incidence of post-surgical hyphema in the T-hook cohort (17.6%) than in the KDB cohort (26.2%). Although the difference in the prevalence of hyphema between the T-hook and KDB cohorts was not significant in this study, it may become significant with an increase in sample size.

Trauma to the valve-system,¹² BELL¹¹ and collector channels by sharp devices may affect long-term IOP control; however, this possibility has not been proven well and is a subject for future studies.

Limitations of This Study

This pilot study assessed the short-term effects of the T-hook. The small sample size and short follow-up time may be concerning. Studies with long-term follow-up and large sample sizes are needed in the future. In this study both the T-hook and KDB were combined with cataract surgery. Cataract surgery alone can decrease post-surgical IOP,¹⁵ thus, the effects of the T-hook alone on post-surgical IOP is a subject for future studies. In this study we analyzed the outcomes in eyes with high pre-surgical IOP exceeding 21 mmHg. To study the effects in patients with low pre-surgical IOP, success criteria with percentile IOP reduction may be appropriate. A study on percentile IOP reduction will be analyzed in the future.

Conclusion

We developed a new T-shaped hook for the internal opening of the Schlemm's canal. The surgical procedure is simple and easy to perform. The surgical outcome of the T-hook was comparable to that of KDB.

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Disclosure

The authors are currently applying for a patent for the design of the T-hook. The authors report no other conflicts of interest in this work.

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