• Clinical Research •

Implantation of trabecular micro-bypass stent using a novel "landing strip" technique

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Abstract

• AIM: To describe a novel technique of creating a landing strip within the trabecular meshwork to guide trabecular micro-bypass stent (iStent) implantation in patients who underwent phacoemulsification.

• METHODS: Thirty-four eyes from 30 patients who underwent iStent implantation after phacoemulsification from May 2014 to February 2015 were included in our retrospective study. All iStents were implanted *via* the "landing strip" technique. A 25-gauge microvitreoretinal blade was used to bisect the trabecular meshwork to less than 1 clock-hour, effectively creating a landing strip. The iStent applicator was pressed along the landing strip and then the stent was released into the trabecular meshwork.

• RESULTS: Of the 34 eyes with iStent implantation, 27 (79.4%) eyes had primary open-angle glaucoma, 6 (17.6%) eyes had pseudoexfoliation glaucoma, and 1 (2.9%) eye had ocular hypertension. At 6-month follow-up (*n*=17), the mean number of hypotensive medications decreased from 2.2±1.2 at baseline to 0.8±1.3 (*P*=0.05) and mean intraocular pressure decreased from 19.7±4.1 mm Hg at baseline to 16.7±2.1 mm Hg (*P*=0.58). Two eyes (5.9%) required subsequent trabeculectomy.

• CONCLUSION: The "landing strip" technique appears to be an effective way to assist with iStent implantation.

• KEYWORDS: iStent; trabecular micro-bypass stent; microinvasive glaucoma surgery; glaucoma; trabecular meshwork

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INTRODUCTION

Microinvasive glaucoma surgery has emerged in recent years as an alternative to traditional glaucoma surgeries. The trabecular micro-bypass stent, commonly known as the iStent (Glaukos Corporation, Laguna Hills, CA, USA), is a titanium stent inserted into the trabecular meshwork (TM) to create a direct channel between the anterior chamber and Schlemm's canal to increase aqueous outflow. It is typically implanted during phacoemulsification for patients with open-angle glaucoma and visually significant cataracts. The iStent has shown to be more effective in reducing intraocular pressure (IOP) and lowering the number of post-operative hypotensive medications than phacoemulsification alone[1-2].

The standard surgical technique for iStent insertion can be performed before or after phacoemulsification based on the preference of the surgeon. For optimal viewing, the head of the patient is rotated 35° away from the surgeon while the surgical microscope oculars are rotated 35° toward the surgeon. An ophthalmic viscoelastic device is inserted into the anterior chamber to widen the nasal angle. The iStent applicator is brought across the anterior chamber toward the nasal angle under direct gonioscopic view. The stent is released from the applicator, punctures the TM, and is inserted into Schlemm's canal[3].

With dimensions of 1 mm in length and 0.3 mm in height, it can be challenging to successfully place an iStent under direct gonioscopic view. Intraoperative challenges include poor angle visualization and stent malpositioning[1,4]. The purpose of the present study is to describe a novel technique of creating a landing strip within the TM to assist with iStent implantation.

SUBJECTS AND METHODS

Our retrospective study included all patients who received an iStent with phacoemulsification from May 2014 to February 2015. All surgeries were performed at Wills Eye Hospital by a single experienced surgeon (Moster MR). The Wills Eye Hospital Institutional Review Board approved the study following the principles of the Declaration of Helsinki.

Landing Strip Surgical Technique Although the iStent can be placed prior to phacoemulsification, the authors' preference is to place the stent after phacoemulsification. When the iStent is implanted after pseudoemulsification, the same temporal

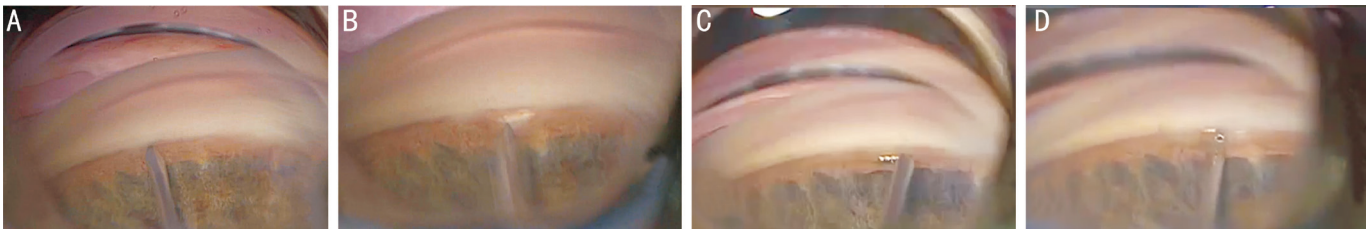

Figure 1 Landing strip technique for iStent implantation. A: A 25-gauge microvitreoretinal blade is used to bisect the nasal TM to create a landing strip; B: The landing strip improves visualization of the TM by providing a visual clue for the precise location of iStent implantation; C: The iStent applicator is pressed along the landing strip; D: The iStent is released from the applicator and directly implanted into the TM.

corneal incision used for phacoemulsification is accessed. An ophthalmic viscoelastic device is injected if needed based on the discretion of the surgeon to deepen the anterior chamber. The patient's head is rotated approximately 35° away from the surgeon while the microscope is tilted 35° toward the surgeon. A 25-gauge microvitreoretinal blade is used to bisect the nasal TM to less than 1 clock-hour, effectively creating a landing strip (Figure 1). Additional viscoelastic material is injected to widen the landing strip. The landing strip allows for improved visualization of the TM and serves as a visual landmark for precise implantation. The iStent applicator enters *via* the same temporal incision used for phacoemulsification and crosses the anterior chamber toward the nasal angle under direct gonioscopic view. The leading edge of the iStent applicator is pressed along the landing strip through the TM. The landing strip is visualized adjacent to the stent, confirming that it is positioned correctly, and the iStent is released from its applicator. The viscoelastic device is removed and the wound is hydrated with balanced salt solution.

Statistical Analysis Medical records were reviewed and data was analyzed using SAS Analytics Pro software, version 9.4 (SAS Institute Inc, Cary, NC, USA). The *t*-test was used to compare the data before and after operation. $P<0.05$ was considered statistical significance.

RESULTS

Stent implantation *via* this technique was performed in 34 eyes of 30 patients. A summary of patient demographics is shown in Table 1. Pre-operative and post-operative characteristics are shown in Table 2. Of the 34 eyes, 33 (97.1%) were taking at least 1 glaucoma medication prior to surgery. The mean follow-up time was 6.1±4.8mo (median, 5.5mo; range, 1d to 16mo). Three eyes (8.8%) from 3 patients were seen at 1-day follow-up, then lost to further follow-up. At 1-month follow-up (n=31) and 6-month follow-up (n=17), the number of ocular hypotensive medications significantly decreased ($P<0.001$ and $P=0.05$, respectively). At 1-month (n=31), 6-month (n=17), and 1-year (n=12) follow-up, 20 patients (64.5%), 7 patients (41.2%), and 4 patients (33.3%) were able to discontinue all glaucoma medications, respectively.

Table 1 Demographic and clinical characteristics of the study population *n* (%)

Characteristics	Study population
Age mean (range), a	74 (45-89)
Gender	*n*=30
F	21 (70.0)
M	9 (30.0)
Race	*n*=30
Caucasian	21 (70.0)
African American	8 (26.7)
Asian	1 (3.3)
Type of glaucoma	*n*=34
Primary open angle glaucoma	27 (79.4)
Pseudoexfoliation glaucoma	6 (17.6)
Ocular hypertension	1 (2.9)
Previous ocular surgery	*n*=34
Yes[1]	1 (2.9)
No	33 (97.1)
Previous laser therapy	*n*=34
Yes[2]	13 (38.2)
No	21 (61.8)
Follow-up	*n*=34
1d	34 (100.0)
1mo	31 (91.2)
6mo	17 (50.0)
1a	12 (35.3)

[1]One patient had trabeculectomy 18y prior to iStent placement; [2]All 13 patients had previous laser with selective laser trabeculectomy.

The mean IOP decreased compared to baseline at 1-month, 6-month, and 1-year follow-up ($P=0.99$, 0.58 and 0.76, respectively), but the difference was not statistically significant (Table 2). There were 3 eyes (8.8%) with increased IOP to 28, 42 and 48 mm Hg on post-operative day 1, which decreased to 12, 11 and 8 mm Hg, respectively, after removal of viscoelastic material through the corneal incision at the slit-lamp. Of these 3 patients, 2 ultimately required trabeculectomy due to elevated IOP despite maximal medical therapy. The first patient continued to have elevated IOP ranging from 38 to

Table 2 Mean pre-operative and post-operative number of glaucoma medications, IOP and visual acuity Mean (SD)

Parameters	Baseline	Follow-up					
		1mo	*P*	6mo	*P*	1a	*P*
Glaucoma medications	2.2 (1.2)	0.6 (1.1)	<0.001	0.8 (1.3)	0.05	1.6 (1.4)	0.56
Intraocular pressure	19.7 (4.1)	18.6 (3.0)	0.99	16.7 (2.1)	0.58	17.5 (4.7)	0.76
BCVA (logMAR)	0.33 (0.19)	0.15 (0.1)	<0.01	0.21 (0.2)	0.25	0.21 (0.3)	0.17

BCVA: Best corrected visual acuity; logMAR: Logarithm of minimum angle of resolution; SD: Standard deviation.

44 mm Hg at subsequent follow-up visits, so trabeculectomy was performed 3wk after iStent surgery. After trabeculectomy, the post-operative IOP was 12 mm Hg at 1-month follow-up. The second patient had trabeculectomy 5mo after iStent surgery when IOP increased to 52 mm Hg despite maximal medical therapy. The post-trabeculectomy IOP was 14 mm Hg at the most recent follow-up visit for the second patient.

The only intra-operative complication was hemorrhage in 1 eye (2.9%). The most common post-operative complications were transient hyphema (*n*=7; 20.6%), transient corneal edema (*n*=3; 8.8%), and subconjunctival hemorrhage (*n*=2; 5.9%), which all resolved by 1-month follow-up.

DISCUSSION

The purpose of the present study was to describe a novel technique of creating a landing strip to assist with iStent implantation. Our results showed that implantation using this technique significantly decreased the mean number of post-operative medications at 1-month and 6-month follow-up, consistent with findings from other studies[1,4-5]. At 1-year follow-up, there was a reduction in the number of hypotensive medications, although this result was no longer statistically significant, possibly due to the small sample size (*n*=12). Over 60% of patients were able to discontinue all medications post-operatively at 1-month follow up. Since patients often experience challenges adhering to hypotensive medications[6], reducing medications with stent implantation may help overcome these challenges. However, several studies have shown that the mean number of medications increases as follow-up time lengthens[4,7], which was seen in our study. Although the mean number of medications increased as follow-up time increased, 33% of patients had appropriate IOP without any medications at 1-year follow-up.

Our study showed that there was a decrease in IOP at 1-month follow-up and this IOP-lowering effect continued at 6-month follow-up. Other studies have also found that there is a delay in IOP reduction, as IOP continues to decrease at 6-month follow-up[4,8]. The mechanism of the iStent is to increase outflow of aqueous humor. The mean IOP at baseline in our study was 19.7±4.1 mm Hg, so reduction in IOP would theoretically be less in normotensive eyes compared to hypertensive eyes. In addition, it is possible to place more than 1 iStent during cataract surgery. Several studies have shown that implanting multiple iStents resulted in sustained IOP reduction with significantly fewer medications after 12mo of follow-up[9-10].

There were 3 patients with elevated IOP on post-operative day 1, and 2 patients ultimately required trabeculectomy. Stent failure in these patients may have occurred due to aqueous outflow obstruction past Schlemm's canal or post-operative TM dysfunction. Despite the possibility of failure, it is reasonable to consider iStent implantation to lower IOP since there are few adverse events or late-onset complications associated with the iStent[1-2].

In our study, the only intra-operative complication was hemorrhage seen in 1 eye, which supports the safety of iStent implantation seen in other studies[1-2]. The most common post-operative complication was a hyphema. Previous studies found that hyphema was common after iStent implantation[7-9], including a case series where hyphema was seen in 7 of 10 eyes[7].

Our study is limited by the small sample size and short follow-up period. Further follow-up is needed to determine the long-term outcomes of this technique. In addition, previous studies have shown that there is a reduction in IOP and number of glaucoma medications from phacoemulsification alone[11]. A major limitation of our study is the inability to discern the effect of phacoemulsification alone versus phacoemulsification with iStent implantation on reduction of IOP and number of glaucoma medications. Although several studies have shown that iStent may be more effective in reducing IOP and number of hypotensive medications than phacoemulsification alone[1-2], further research needs to be conducted. Another limitation is our study population mainly consisted of Caucasians and patients with primary open angle glaucoma. As a result, it is difficult to extrapolate our results to other races and types of glaucoma. Additional research is needed to determine the outcomes of this technique in other populations. Despite these limitations, the landing strip technique appears to be an effective way to assist iStent implantation.

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REFERENCES

1 Samuelson TW, Katz LJ, Wells JM, Duh YJ, Giampocaro JE; US iStent Study Group. Randomized evaluation of the trabecular micro-bypass stent with phacoemulsification in patients with glaucoma and cataract. *Ophthalmology* 2011;118(3):459-467.

2 Fea AM. Phacoemulsification versus phacoemulsification with micro-bypass stent implantation in primary open-angle glaucoma: randomized double-masked clinical trial. *J Cataract Refract Surg* 2010;36(3):407-412.

3 Le K, Saheb H. iStent trabecular micro-bypass stent for open-angle glaucoma. *Clin Ophthalmol* 2014;8:1937-1945.

4 Spiegel D, Garcia-Feijoo J, Garcia-Sanchez J, Lamielle H. Coexistent primary open-angle glaucoma and cataract: preliminary analysis of treatment by cataract surgery and the iStent trabecular micro-bypass stent. *Adv Ther* 2008;25(5):453-464.

5 Arriola-Villalobos P, Martínez-de-la-Casa JM, Díaz-Valle D, Fernández-Pérez C, García-Sánchez J, García-Feijoó J. Combined iStent trabecular micro-bypass stent implantation and phacoemulsification for coexistent open-angle glaucoma and cataract: a long-term study. *Br J Ophthalmol* 2012;96(5):645-649.

6 Gupta R, Patil B, Shah BM, Bali SJ, Mishra SK, Dada T. Evaluating eye drop instillation technique in glaucoma patients. *J Glaucoma* 2012;21(3):189-192.

7 Buchacra O, Duch S, Milla E, Stirbu O. One-year analysis of the iStent trabecular microbypass in secondary glaucoma. *Clin Ophthalmol* 2011;5:321-326.

8 Patel I, de Klerk TA, Au L. Manchester iStent study: early results from a prospective UK case series. *Clin Exp Ophthalmol* 2013;41(7):648-652.

9 Belovay GW, Naqi A, Chan BJ, Rateb M, Ahmed II. Using multiple trabecular micro-bypass stents in cataract patients to treat open-angle glaucoma. *J Cataract Refract Surg* 2012;38(11):1911-1917.

10 Ahmed II, Katz LJ, Chang DF, Donnenfeld ED, Solomon KD, Voskanyan L, Samuelson TW. Prospective evaluation of microinvasive glaucoma surgery with trabecular microbypass stents and prostaglandin in open-angle glaucoma. *J Cataract Refract Surg* 2014;40(8):1295-1300.

11 Friedman DS, Jampel HD, Lubomski LH, Kempen JH, Quigley H, Congdon N, Levkovitch-Verbin H, Robinson KA, Bass EB. Surgical strategies for coexisting glaucoma and cataract: an evidence-based update. *Ophthalmology* 2002;109(10):1902-1913.