



Clinical Evaluation of blood-filling patterns in Schlemm's canal for Trabectome surgery

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BACKGROUND

Minimally invasive glaucoma surgeries (MIGS) have been developed as TM-targeted therapeutic options to enhance the outflow of aqueous humor (AH). However, the efficacy of these surgeries varies according to the post-TM AH outflow resistance.

Trabectome surgery (NeoMedix, Inc., Tustin, CA) is an ab-interno TM ablation via gonioscopic visualization, in which the blood reflux from the episcleral venous system through collector channels (CCs) into Schlemm's canal (SC) can be seen prior to the TM ablation. Previous reports^{1,2} showed that the blood reflux and blood filling patterns in SC may be predictive of surgical outcomes in some glaucoma surgeries, including canaloplasty and laser trabeculoplasty. However, the relationship between blood-filling patterns in SC and surgical outcome of Trabectome surgery have not been identified.

PURPOSE

To assess the relationship between blood-filling patterns in SC and surgical results at 1 year after Trabectome surgery combined with phacoemulsification.

MATERIAL AND METHODS

Study design: a retrospective cohort study

Participants: Primary open angle glaucoma (POAG) Japanese patients who had undergone Trabectome surgery combined with phacoemulsification at Okayama Saiseikai General Hospital between January 2016 and April 2018.

Subjects were classified into the 3 grades according to the blood-filling patterns in SC in order to compare the clinical data, including age, visual field mean deviation (MD), pre- and post-operative IOP, number of glaucoma medications, percentage IOP reduction, and surgical success rate at 1 year post-surgery. Surgical success was defined as an IOP \leq 15 mmHg and \geq 20% reduction in IOP.

Classification of the blood-filling patterns in SC:

Provocative gonioscopy was performed prior to TM ablation to classify the blood-filling patterns in SC into three grades pursuant to the previous study³ (Fig. 1).

Outcome measures

- Blood-filling patterns in SC before TM ablation
- IOP
- Glaucoma medications

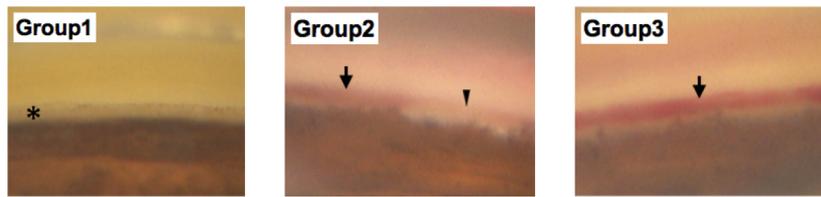


FIGURE 1. Blood-filling patterns in SC under gonioscopic view.

Group 1: No blood is filling in SC (black asterisk).

Group 2: Patchy or irregular blood filling pattern of SC. Arrow head points out the region of SC without blood filling. Arrows show the blood filling in SC.

Group 3: Complete filling pattern of SC.

RESULT

There were 105 eyes of 95 patients included in this study (Table 1).

TABLE 1. Baseline Demographic for All Patients Who Underwent Trabectome surgery combined with phacoemulsification.

Number of eyes	105
Gender (Male/Female)	55/50
Age (mean ± SD)	71.5 ± 7.0
Pre-operative MD (mean ± SD) (dB)	-11.23 ± 6.57
Pre-operative mean IOP (mean ± SD) (mm Hg)	17.1 ± 3.6
Pre-operative number of medications (mean ± SD) (n)	3.4 ± 1.0

Mean preoperative IOP of 17.1 ± 3.6 mm Hg significantly decreased to mean postoperative IOP of 13.3 ± 3.0 mm Hg at 1 year after Trabectome surgery combined with phacoemulsification.

A Kaplan-Meier survival analysis showed the success rate was 50.5 % at 1 year.

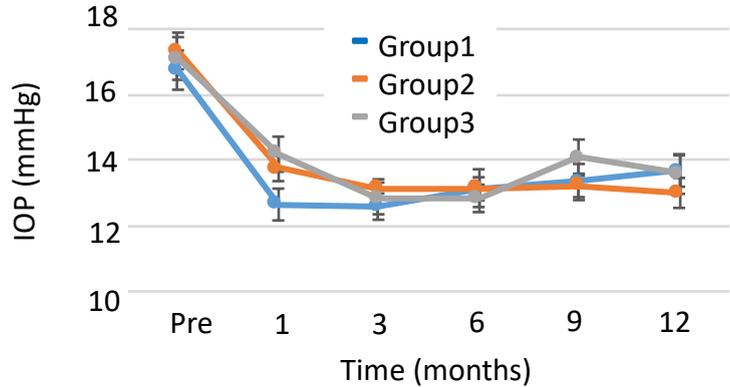


FIGURE 2. Average intraocular pressure in group 1, 2 and 3. Error bars represent standard error.

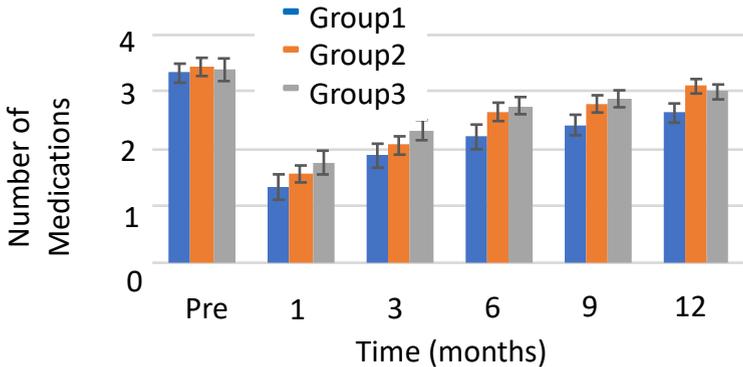
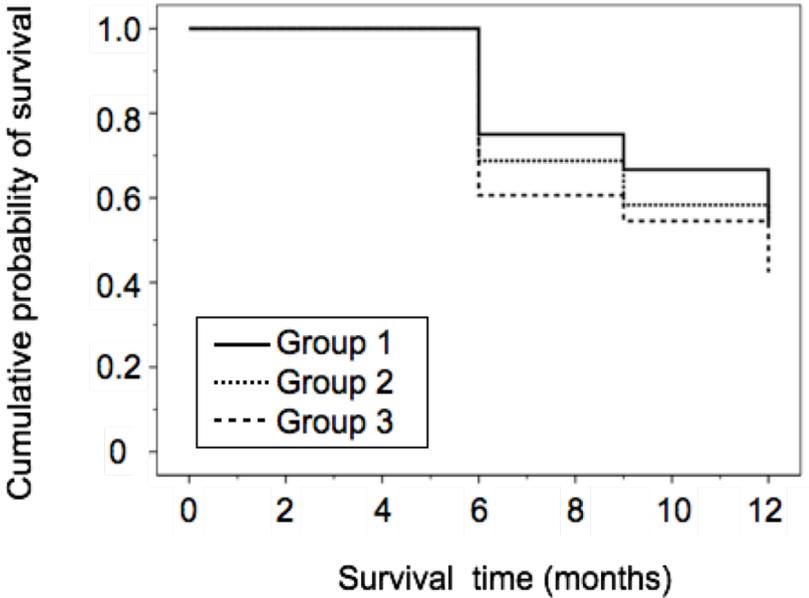


FIGURE 3. Average number of medications in group 1, 2 and 3. Error bars represent standard error.



	Number at risk						
Group1	24	24	24	18	18	16	13
Group2	48	48	48	33	33	28	26
Group3	33	33	33	20	20	18	14

FIGURE 4. Kaplan-Meier survival curve of cumulative probability of success (an IOP ≤ 15 mmHg and ΔIOP ≥ -20 % from baseline). Kaplan-Meier analysis showed 12 months success rate of 54.2% in group1, 54.2% in group2, and 42.4% in group3. Log-rank test, comparing between three groups did not show the significance. (p = 0.540)

TABLE 2. Between-group Analysis

	Group 1	Group 2	Group 3	p
Eyes (n)	24	48	33	
Gender (F/M)	15/9	24/24	16/17	0.523 ^a
Age (mean ± SD) (y)	73.1±6.8	71.4±6.3	70.3±8.1	0.213 ^b
Pre-operative MD (mean ± SD)(dB)	-11.6±6.3	-11.9±7.0	-10.0±6.0	0.505 ^b
Pre-operative mean IOP (mean ± SD) (mm Hg)	16.7±2.9	17.3±3.9	17.1±3.7	0.941 ^b
Pre-operative N of medications (mean ± SD) (n)	3.3±0.8	3.4±1.1	3.4±1.1	0.805 ^b
post-operative IOP at 12 months (mean ± SD) (mm Hg)	13.7±2.3	13.0±3.2	13.6±3.5	0.458 ^b
IOP reduction rate at 12 months (mean ± SD) (%)	16.9±16.2	22.9±20.2	19.9±16.7	0.256 ^b
Success rate at 12 months after surgery (%)	54.2	54.2	42.4	0.540 ^c
Post-operative at 12 months N of medications (mean ± SD) (n)	2.6±0.8	3.1±0.9	3.0±0.8	0.077 ^b

^aKruskal-Wallis test ^bFisher's Exact Probability test ^cLog-rank test

There were no significant differences between the blood-filling patterns in Schlemm's canal and age, pre-operative MD, pre- and post-operative IOP, pre- and post-operative number of glaucoma medications or surgical success rate.

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DISCUSSION

In this study, no significant association was found between the blood-filling patterns in SC and surgical outcome of Trabectome surgery.

According to the studies by electron microscopy⁴, 3D-microCT⁵ and OCT⁶, the configurations of CCs are variable and CC dimensions change pressure-dependently; the size and diameter of CCs are likely to decrease at higher IOP. Pathohistological study⁷ revealed CC entrance was obstructed by herniated endothelial cells of the inner wall of collapsed SC at elevated IOP. Therefore, lack of blood filling in SC may indicate malfunctioned CCs due to the CC entrance obstruction or higher IOP.

In our study, even the patients without blood filling in SC prior to ablation had almost the same surgical success rate as those with patchy/irregular or complete blood filling pattern in SC. This result may suggest malfunctioned CCs could be recanalized after the ablation of TM by Trabectome. This is in line with the previous study by Huang et al⁸. They demonstrated the aqueous angiographic patterns in living humans with indocyanine green (ICG), and showed that trabecular microbypass stent initially devoid of ICG signals led to increased aqueous angiographic signals.

Trabectome surgery may revive malfunctioned CCs and improve the AH distal outflow, leading to an IOP reduction.

CONCLUSION

Trabectome surgery is an effective procedure for low-teen IOP Japanese open-angle glaucoma patients, regardless of the blood-filling patterns in Schlemm's canal prior to ablation.