

A Novel Dual Blade Device For Goniotomy: 12 Month Follow Up

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Purpose

The Kahook Dual Blade (KDB, New World Medical, Rancho Cucamonga, CA) is a single-use goniotomy knife designed to make parallel incisions in the trabecular meshwork (TM), allowing aqueous humor unimpeded access to collector channels.

The purpose of this study was to assess the intraocular pressure (IOP) lowering efficacy and safety of KDB goniotomy in adult glaucomatous eyes.

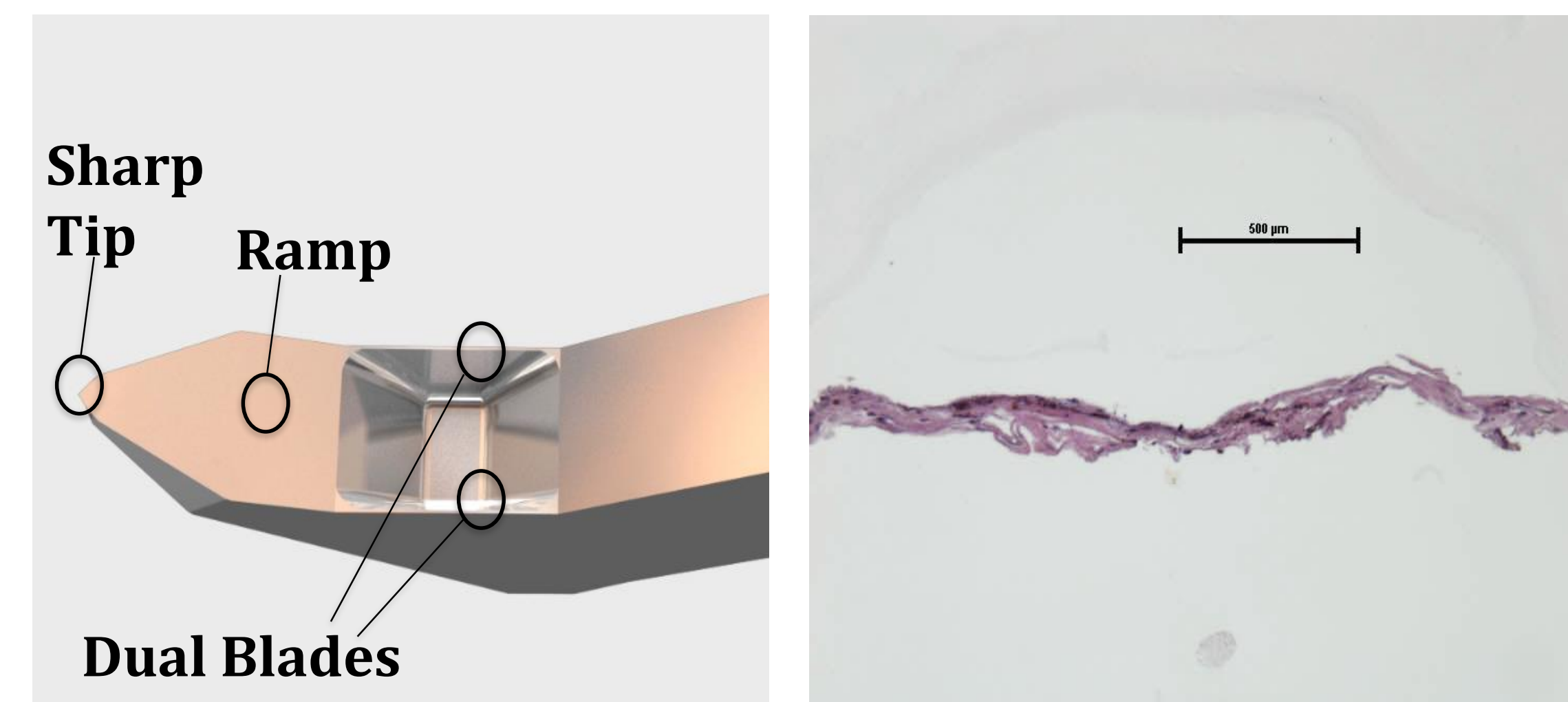


Figure 1: KDB Design Features

Figure 2: H&E-stained TM strip harvested after a KDB procedure. (Source: Dr. Seibold)

Methods

This was a multicenter, prospective, consecutive case series with eight participating surgeons. Six participating surgical centers were located in the US and one was in Mexico. The study included 122 glaucoma patients > 18 years of age undergoing goniotomy with KDB under gonioscopic visualization. Patients with previous glaucoma surgery were not excluded.

Surgeons were surveyed about their intraoperative experience. Data were collected on glaucoma type and severity, concurrent surgeries, preoperative glaucoma medications, IOP, and intraoperative adverse events. Patient IOP, glaucoma medications, and adverse events were recorded on follow up visits at Day 1, Week 1, Month 1, Month 3, Month 6, Month 12.

Results

Intraoperative data

- In **98%** of cases surgeons strongly agreed or agreed that:
 - The use of the KDB was straightforward.
 - Entry into the canal with the KDB was uncomplicated.
- In **99%** of cases surgeons strongly agreed or agreed that advancement of the KDB along the canal was smooth.
- Average TM Excised – **114.5^o±18.4^o**.

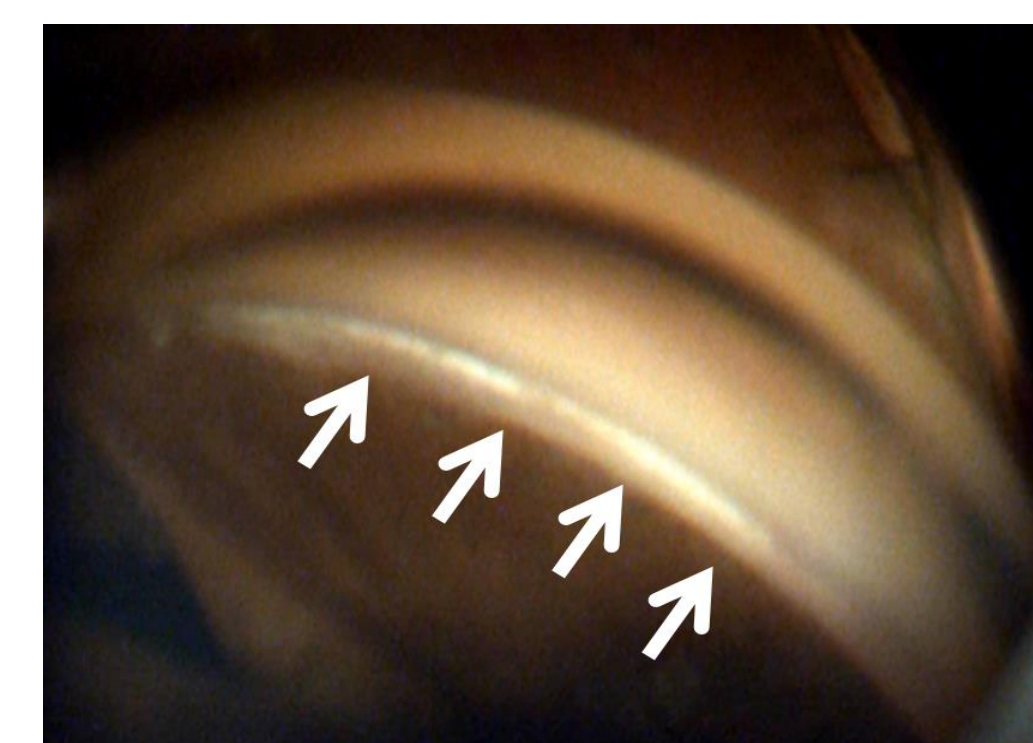
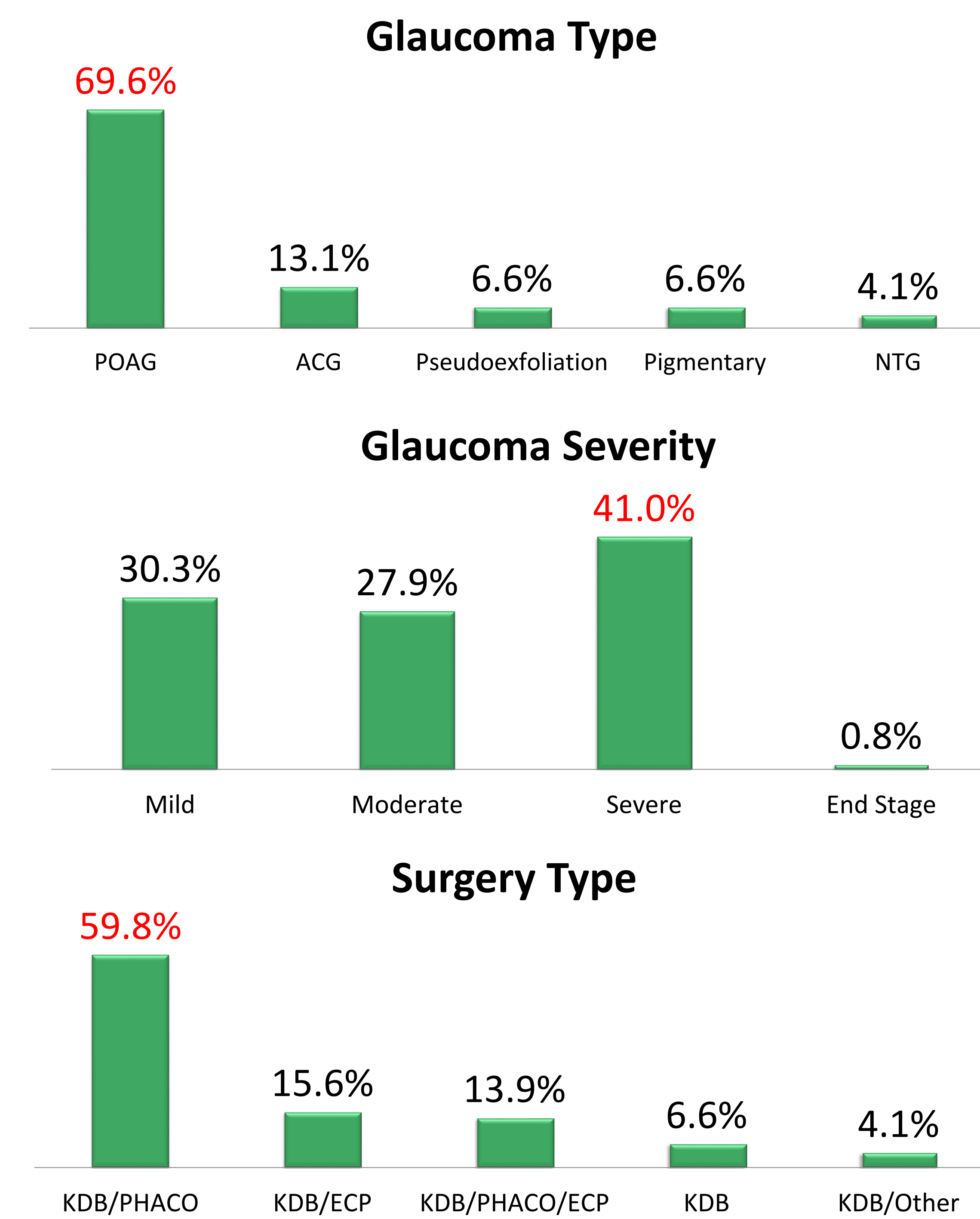


Figure 3: The anterior wall of Schlemm's Canal is visible after TM excision with the KDB (Source: Dr. Seibold)

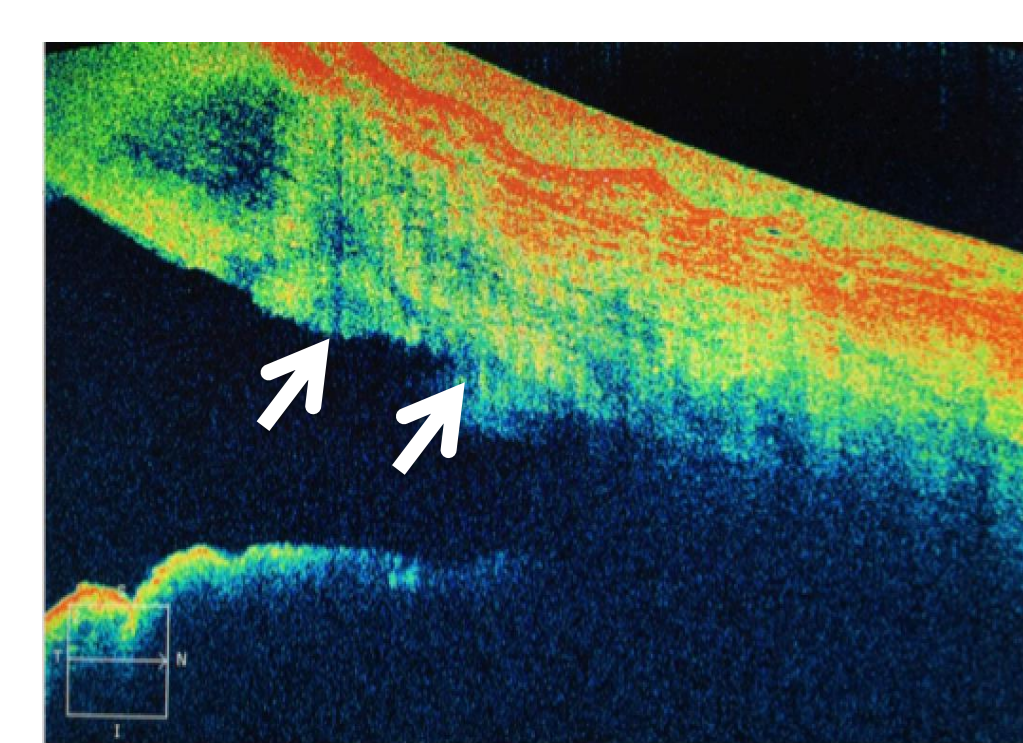


Figure 4: AS-OCT image after KDB treatment. Arrows indicate area of TM removal revealing minimal residual leaflets. (Source: Dr. Radcliffe)

Table 1: Treatment results for all eyes

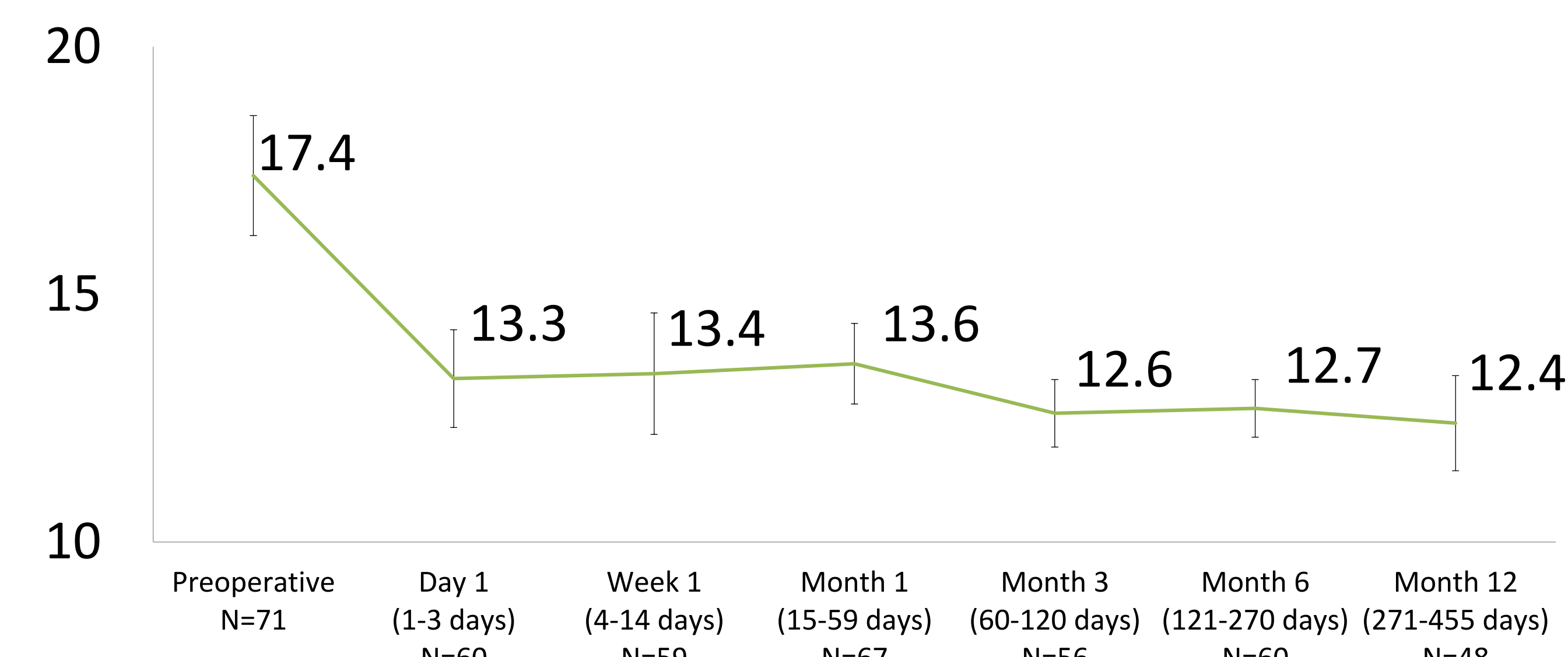
	Pre-Op N=120	Day 1 (1-3 days) N=106	Week 1 (4-14 days) N=103	Month 1 (15-59 days) N=114	Month 3 (60-120 days) N=89	Month 6 (121-270 days) N=90	Month 12 (271-455 days) N=66
Mean IOP	18.7± 6.7	12.8± 4.5	14.8± 6.8	14.3± 4.3	13.5± 3.7	13.0± 3.0	13.0± 2.6
Mean Difference	Reference	-5.9*	-3.9*	-4.4*	-5.2*	-5.7*	-5.7*
Percent Change of IOP	Reference	-32%	-21%	-24%	-28%	-30%	-30%
Mean Meds	1.8± 1.3	0.8± 1.2	0.9± 1.2	0.9± 1.1	1.0± 1.0	1.0± 1.1	1.0± 1.2
Mean Difference	Reference	-1.0*	-0.9*	-0.9*	-0.8*	-0.8*	-0.8*

Table 2: Treatment results for eyes post Phaco+KDB

	Pre-Op N=71	Day 1 (1-3 days) N=60	Week 1 (4-14 days) N=59	Month 1 (15-59 days) N=67	Month 3 (60-120 days) N=56	Month 6 (121-270 days) N=60	Month 12 (271-455 days) N=48
Mean IOP	17.4± 5.2	13.3± 3.9	13.4± 4.8	13.6± 3.4	12.6± 2.6	12.7± 2.3	12.4± 3.4
Mean Difference	Reference	-4.1*	-4.0*	-3.8*	-4.8*	-4.7*	-5.0*
IOP Percent Change	Reference	24%	23%	22%	28%	27%	29%
Mean Meds	1.6± 1.3	0.4± 0.9	0.7± 1.1	0.7± 0.9	0.9± 1.1	0.9± 1.1	0.6± 0.8
Mean Difference	Reference	-1.2*	-0.9*	-0.9*	-0.7*	-0.7*	-1.0*

* p<0.001 when compared to preoperative measurement. Mixed Models (α of 0.05) was used for analysis with adjustment for multiple comparisons: Bonferroni Significant at an alpha 0.05. Two cases of reoperation for IOP control were excluded from tables and graphs without any significant impact on the results.

Graph 1: Mean IOP for eyes post Phaco+KDB



Graph 2: Mean Medication use for eyes post Phaco+KDB

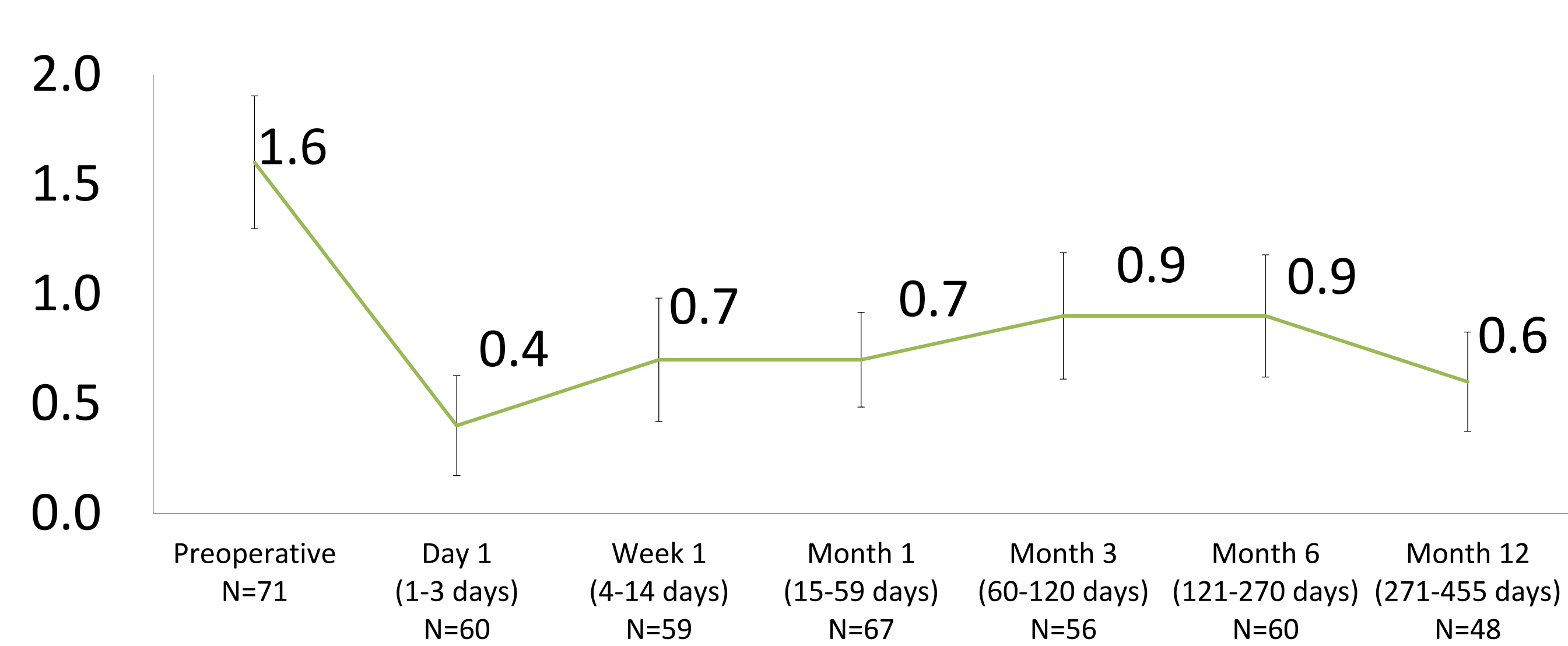


Table 3: Percentage of eyes with a reduction of at least one medication compared to baseline

	Pre-Op	Day 1 (1-3 days)	Week 1 (4-14 days)	Month 1 (15-59 days)	Month 3 (60-120 days)	Month 6 (121-270 days)	Month 12 (271-455 days)
All Surgeries	Reference	53%	53%	56%	58%	59%	70%
Phaco+KDB Cohort	Reference	59%	64%	60%	64%	60%	74%

Intra-Operative and Post-Operative Observations

Intraoperative blood reflux was observed in 39% of cases, with 10% and 4% of eyes having retained blood at day 1 and week 1, respectively. Four patients had IOP spikes at week 1 and one patient at month 1. The IOP spikes were associated with retained viscoelastic or retained blood. Two patients required additional glaucoma surgery for uncontrolled IOP (week 1, month 3). All adverse events were otherwise self limited and minor.

Conclusion

- Overall, surgeons were satisfied with the usability and safety of the KDB.
- KDB goniotomy allows for minimally invasive excision and removal of TM as a standalone procedure or combined with cataract extraction.
- IOP was reduced by 30% (-5.7mmHg) after 12 months of follow-up. Compared to baseline, 70% of eyes had a reduction of at least one medication at last follow-up.
- In combined Phaco + KDB cases, IOP lowering reached 29% (-5.0mmHg) at 12 months with 74% of eyes experiencing a reduction in the use of at least one IOP lowering medication.
- KDB goniotomy resulted in a significant and sustained lowering of IOP and medication use at 12 months of follow up.

Disclosure

New World Medical, Inc. manufactures the Kahook Dual Blade (KDB).
 Employment New World Medical, Inc. – Khaled Bahjri, Suhail Abdullah.
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