

# A Novel Dual Blade Device For Goniotomy: 9 Month Follow Up

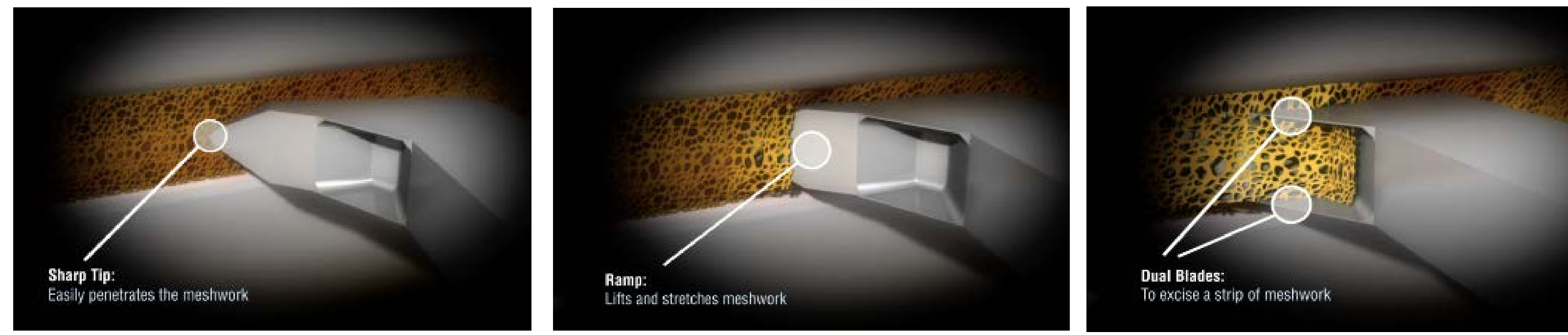
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## PURPOSE

The aim of this study is to assess the clinical experience with the Kahook Dual Blade (New World Medical, Inc., Rancho Cucamonga, CA) for performing goniotomy in adult glaucomatous eyes. The novel design of the device allows for excision of trabecular meshwork (TM) tissue.

Figure 1: Device Design Features



## METHODS

- Multicenter, prospective cohort study.
- Glaucoma patients >18 years of age undergoing goniotomy with the KDB under gonioscopic visualization. Patients with previous glaucoma surgery were not excluded.
- Surgeons were surveyed about their intraoperative experience.
- Data collected on glaucoma type and severity, concurrent surgeries, preoperative glaucoma medications and intraocular pressure (IOP) and intraoperative complications.
- In follow up visits (Day 1, Week 1, Month 1, Month 3, Month 6, Month 9), patient IOP, glaucoma medications and complications were recorded.

## RESULTS

### EASE OF USE

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.

Figure 2: The anterior wall of Schlemm's Canal is visible after TM excision with the KDB (Source: Dr. Seibold)

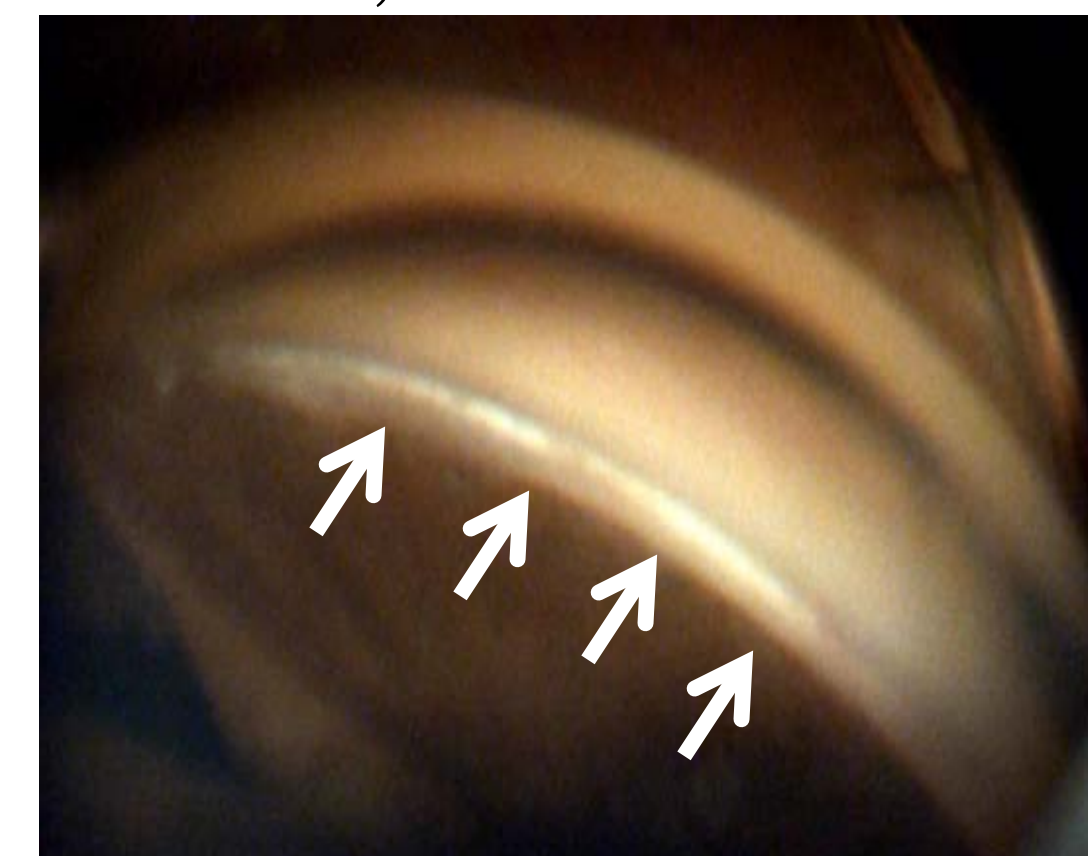


Figure 3: AS-OCT image after KDB treatment. Arrows indicate area of TM removal revealing minimal residual leaflets. (Source: Dr. Radcliffe)

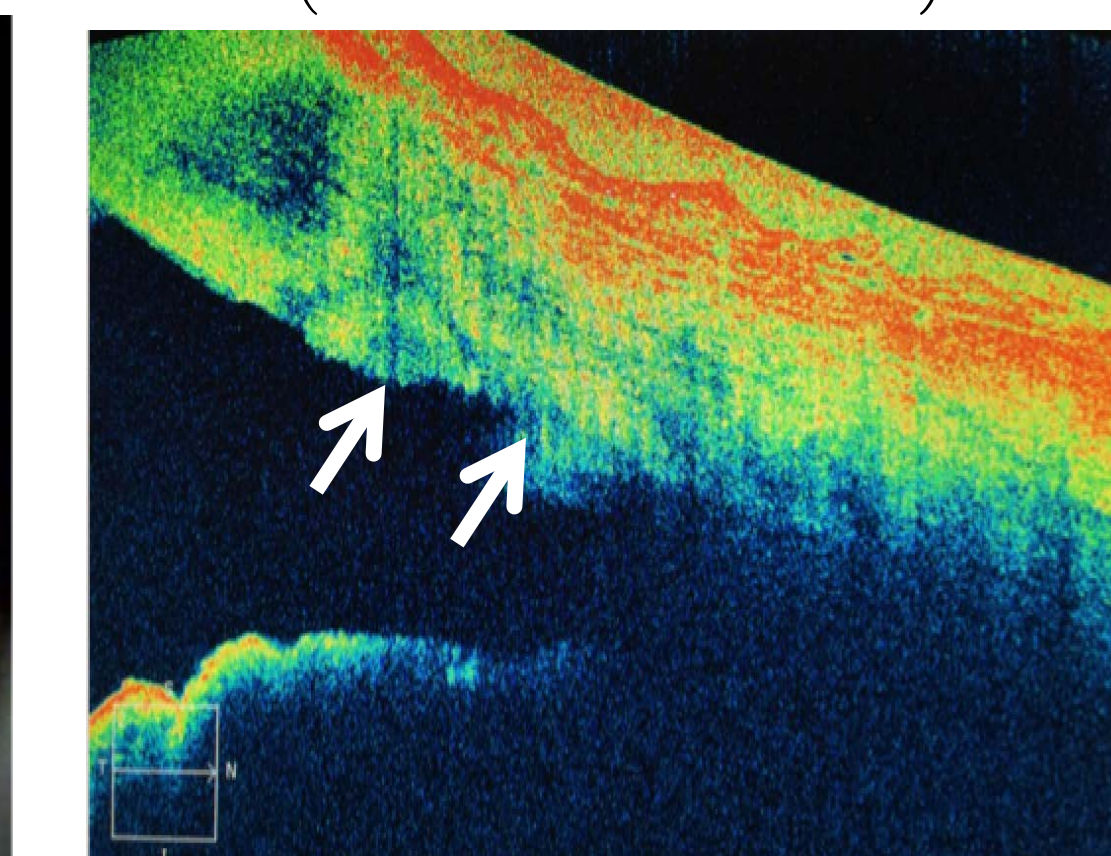
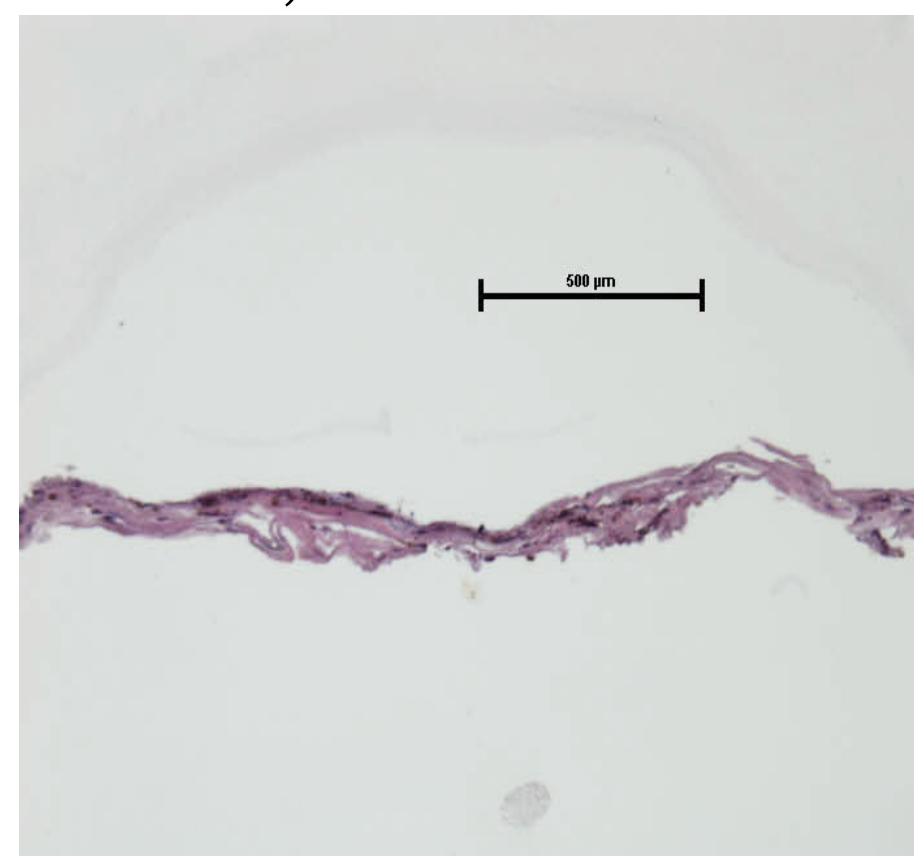


Figure 4: HE-stained TM strip harvested from a KDB procedure. (Source: Dr. Seibold)



• 122 eyes, 8 Surgeons

### SURGERY PERFORMED

- **Combined Phaco+KDB (59.8 %)**
- Combined KDB+PHACO+ECP (13.9 %)
- Combined KDB+ECP (15.6 %)
- Standalone KDB (6.6 %)
- Combined KDB+Other (4.1%)

- Average TM degrees excised: **114.5 ± 18.4**
- The excised TM strip was removed from the AC in **93%** of cases

### GLAUCOMA TYPE

- Pseudoexfoliation 8 (6.6%)
- **Primary Open Angle Glaucoma 85 (69.7%)**
- Angle Closure Glaucoma 16 (13.1%)
- Pigment Dispersion Glaucoma 8 (6.6%)
- Normal Tension 5 (4.1%)

### GLAUCOMA SEVERITY

- Mild – 37 (30.3%)
- Moderate – 34 (27.9%)
- **Severe – 50 (41.0%)**
- End-Stage – 1 (0.8%)

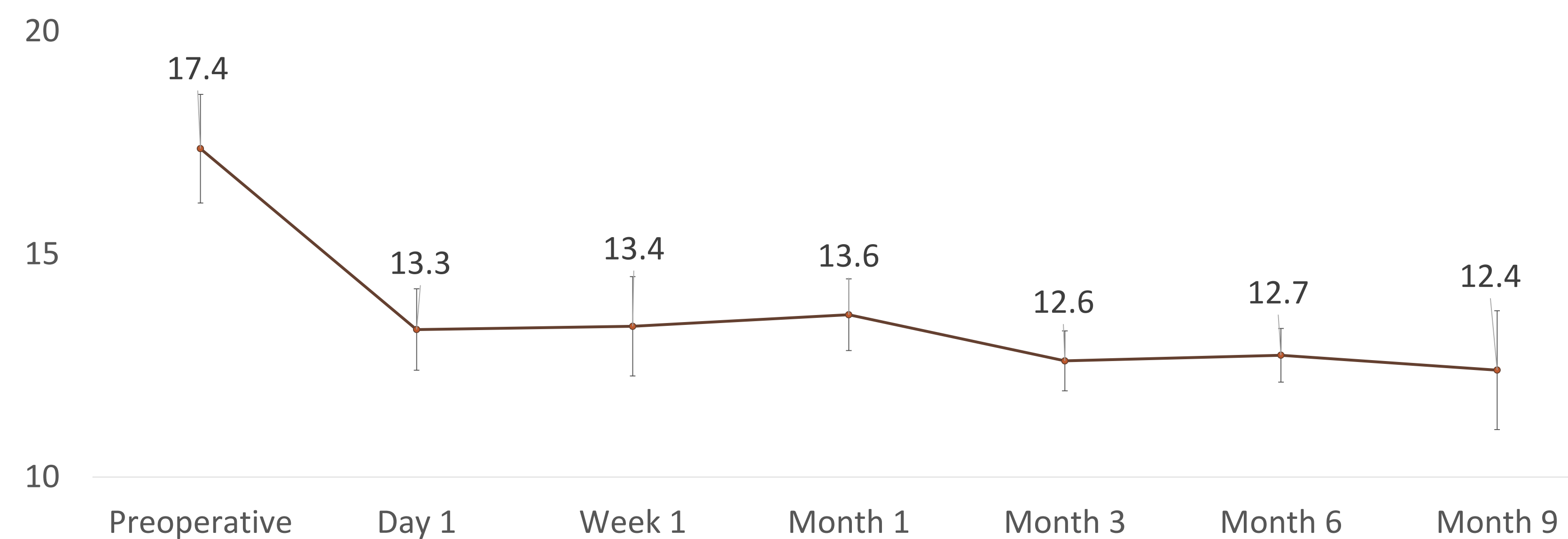
Table 1: Results for all eyes

	Pre-Op (n=120)	Day 1 (n=120)	Week 1 (n=120)	Mon. 1 (n=119)	Mon. 3 (n=115)	Mon. 6 (n=89)	Mon. 9 (n=38)
Mean IOP	18.7±6.7	13.0±4.5	14.5±6.6	14.2±4.3	13.5±3.9	12.9±2.5	12.9±4.2
Mean Difference	Reference	-5.7*	-4.2*	-4.5*	-5.2*	-5.8*	-5.8*
Mean Meds	1.8±1.3	0.7±1.1	0.9±1.2	0.9±1.1	1.0±1.1	1.0±1.1	0.7±0.8
Mean Difference	Reference	-1.1*	-0.9*	-0.9*	-0.8*	-0.8*	-1.1*

\* Significant at an alpha of 0.05

Mixed Models ( $\alpha$  of 0.05) was used for analysis with adjustment for multiple comparisons: Bonferroni, Significant at an alpha of 0.05. Two cases of reoperation for IOP control were excluded from tables and graphs without any significant impact on the results.

Graph 1: IOP with 95% CI for combined Phaco+KDB cohort



Graph 2: Meds with 95% CI for combined Phaco+KDB cohort

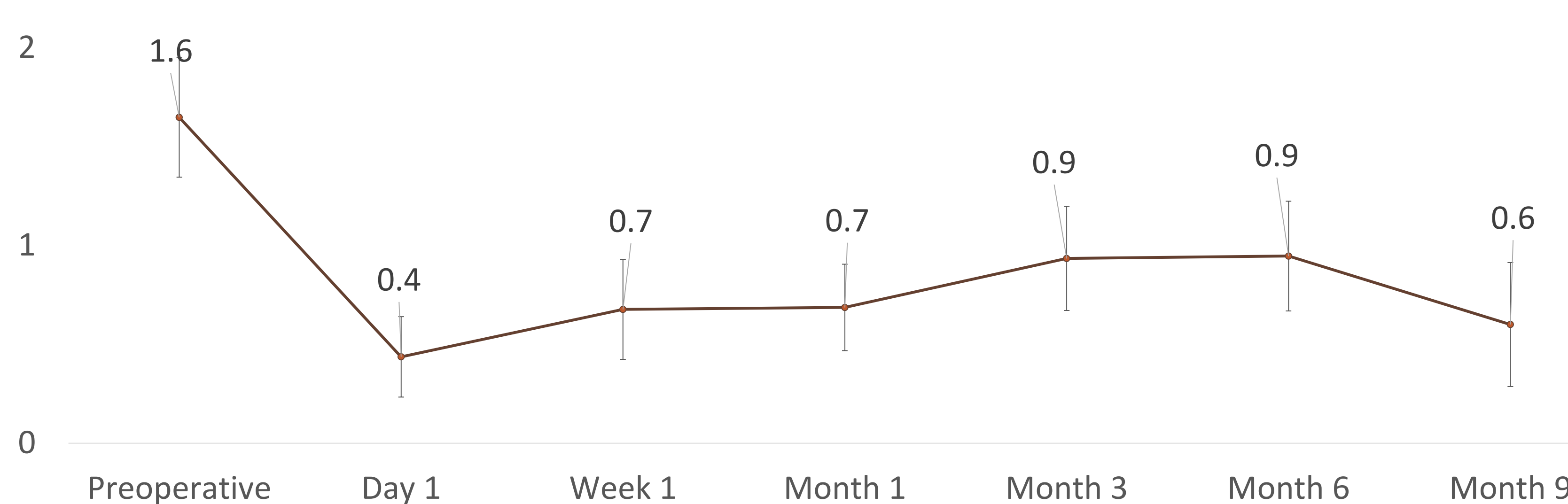


Table 2: Results from combined Phaco+KDB cohort

	Pre-Op (n=71)	Day 1 (n=71)	Week 1 (n=71)	Month 1 (n=71)	Month 3 (n=70)	Month 6 (n=57)	Month 9 (n=25)
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*
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*

\* Significant at an alpha of 0.05

Table 3: Percentage of eyes with a reduction of at least one IOP lowering medication compared to Pre-Op

	Day 1	Week 1	Month 1	Month 3	Month 6	Month 9
All Surgeries	56%	54%	56%	55%	59%	73%
Phaco+KDB Cohort	63%	62%	60%	61%	63%	80%
P-Value	<0.001*	<0.001*	<0.001*	<0.001*	<0.001*	<0.001*

\* Significant at an alpha of 0.05

### Adverse Events

Intraoperative blood reflux was observed in **39%** of cases, with **9%**, **3%** and **0.8%** of cases having retained blood at day 1, week 1, and at an additional visit between week 1 and month 1, respectively. **Eight patients** had IOP spikes with 6 at week 1, one at month 1 and one between the two time intervals. **Four** of the IOP spikes were associated with retained viscoelastic or retained blood. **Two** patients required additional glaucoma surgery for uncontrolled IOP. All other complications were rare and considered minor.

## CONCLUSIONS

- Overall, surgeons were satisfied with the usability and safety of the device.
- The KDB ophthalmic knife allows for minimally invasive excision and removal of TM as a standalone procedure or combined with cataract extraction.
- There was a statistically significant improvement in visual acuity over the study period compared to preoperative measures.
- In Combined Phaco + KDB cases, IOP lowering reached a mean difference of **-5.0 mm** at 9 months with **80%** of eyes experiencing a reduction in the use of at least one IOP lowering medication.

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### DISCLOSURES

New World Medical, Inc. manufactures the Kahook Dual Blade (KDB)  
 Employment New World Medical, Inc. – Khaled Bahjri, Suhail Abdullah  
 Consultant New World Medical, Inc. – Mark C. Jasek  
 Financial Support New World Medical, Inc. – Nathan M. Radcliffe, Jesús Jimenez Román, Leonard Seibold,  
 Gabriel S. Lazcano, Jason K. Darlington, Cyril K. Dorairaj, Ahmad Aref, John P. Berdahl