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24-Month Results of iTrack Global Data Registry to Support the Role of Canaloplasty for Treatment of Glaucoma

Shamil Patel MD[1], David Lubeck MD[2], Keith Barton MD[3], Nathan Kerr MD[4], Nir Shoham-Hazon MD[5], Mary Qiu MD[6]

[1]*Eye Physicians & Surgeons of Arizona, Scottsdale/Glendale, AZ, USA*
[2]*Arbor Centers for Eye Care, Homewood IL, USA*
[3]*Moorfields Eye Hospital, London, UK*
[4]*Centre for Eye Research Australia, East Melbourne, AUS*
[5]*Miramichi EyeNB Centre of Excellence, New Brunswick, Canada*
[6]*Cole Eye Institute, Cleveland, OH, USA*

Disclosure for Shamil Patel, David Lubeck, Keith Barton, Nathan Kerr, Nir Shoham-Hazon, Mary Qiu

In compliance with COI policy, ESCRS requires the following disclosures to the session audience:

Shareholder	No relevant conflicts of interest to declare.
Grant / Research Support	No relevant conflicts of interest to declare.
Consultant	Nova Eye Medical, Inc.
Employee	No relevant conflicts of interest to declare.
Paid Instructor	No relevant conflicts of interest to declare.
Speaker Bureau	No relevant conflicts of interest to declare.
Other	No relevant conflicts of interest to declare.

Presentation includes discussion of the following off-label use of a drug or medical device:
None.

Results*

Demographics

The iTrack™ Global Data Registry comprises approx. 20 sites in the USA, Canada, Europe, Asia and Australia.

Patients	n (%)
N	254
Gender	
Male	121 (47.6%)
Female	133 (52.4%)
Ethnicity	
African/Caribbean	37 (14.6%)
Asian	5 (2.0%)
Caucasian	160 (63.0%)
Hispanic	3 (1.2%)
Māori or Pacific Islander	1 (0.4%)
Middle Eastern	9 (3.5%)
Mixed	1 (0.4%)
Other	10 (3.9%)
Missing	28 (11.0%)
Age (years, mean±SD)	72.5±10.1
With prior glaucoma laser or surgery	
Yes	88 (25.6%)
No	256 (74.4%)
Further glaucoma procedure	
Yes	17 (4.9%)
No	327 (95.1%)

Preoperative measurements	Mean±SD
Cup-to-disc ratio	0.67±0.18 (n=322)
Visual field	-5.85±6.68 (n=310)

Eyes	n (%)
N	344
Laterality	
Left	170 (49.4%)
Right	174 (50.6%)
Glaucoma stage**	
Mild	200 (58.1%)
Moderate	66 (19.2%)
Severe	44 (12.8%)
Missing	34 (9.9%)
Diagnosis	
Primary open-angle glaucoma	291 (84.6%)
Primary angle-closure glaucoma	0 (0%)
Secondary open-angle glaucoma	21 (6.1%)
Normal tension glaucoma	5 (1. 5%)
Ocular hypertension	25 (7.3%)
Juvenile open-angle glaucoma	2 (0.6%)
Type of Secondary open-angle glaucoma	
Glaucoma caused by corticosteroid	1 (0.29%)
Pigmentary glaucoma	4 (1.16%)
Pseudoexfoliative glaucoma	13 (3.78%)
Uveitic glaucoma	0 (0%)
Undefined	3 (0.87%)
Concurrent cataract surgery	
Combined	318 (92.4%)
Standalone	26 (7.6%)
Type of iTrack	
iTrack	256 (74.4%)
iTrack Advance	88 (25.6%)

***MD better than –6dB (mild), –6db to –12dB (moderate), and worse than –12dB (severe)*

**Based on pooled data from eyes across both the combined with phaco and standalone canaloplasty groups.*

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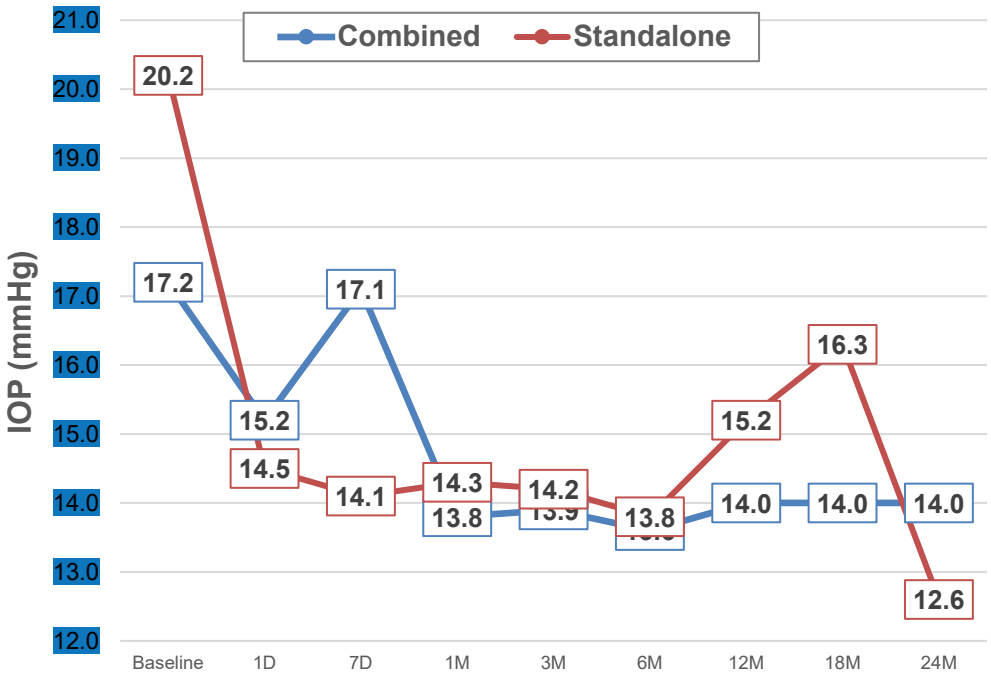
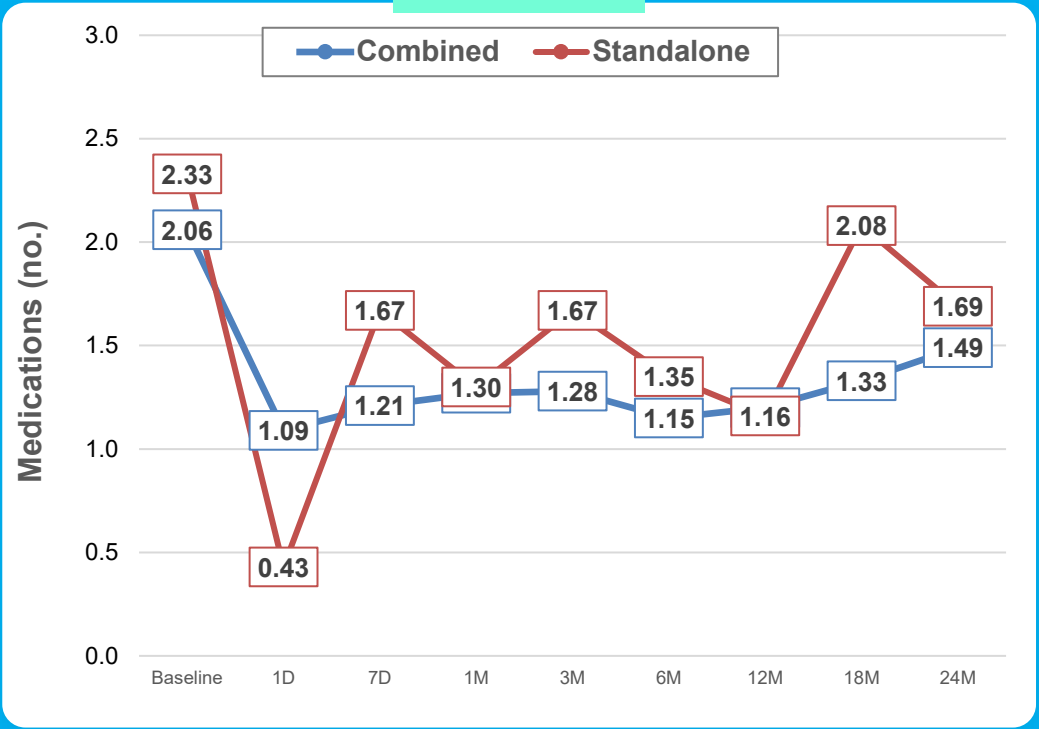
IOP Reduction, 24 Months (All Eyes)



Time point	Mean±SD	% reduction	n	p value vs baseline
Baseline	17.2.±5.3	-	313	-
Month 6	13.6±3.6	-20.8%	224	<0.001
Month 12	14.0±3.5	-18.3%	282	<0.001
Month 18	14.0±4.1	-18.6%	156	<0.001
Month 24	14.0±3.5	-18.6%	150	<0.001

Time point	Mean±SD	% reduction	n	p value vs baseline
Baseline	20.2±7.1	-	24	-
Month 6	13.8±3.4	-31.5%	17	0.002
Month 12	15.2±6.7	-24.9%	19	0.009
Month 18	16.3±7.0	-19.4%	12	0.143
Month 24	12.6±3.0	-37.5%	13	0.001

Meds Reduction, 24 Months (All Eyes)



Time point	Mean±SD	% reduction	n	p value vs baseline
Baseline	2.06±1.1	-	313	-
Month 6	1.15±1.3	-44.3%	224	<0.001
Month 12	1.20±1.3	-41.7%	282	<0.001
Month 18	1.33±1.4	-35.6%	156	<0.001
Month 24	1.49±1.5	-27.9%	150	<0.001

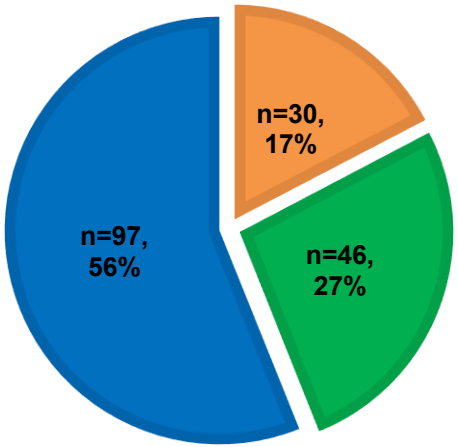
Time point	Mean±SD	% reduction	n	p value vs baseline
Baseline	2.33±0.9	-	24	-
Month 6	1.35±1.3	-42.0%	17	0.002
Month 12	1.16±1.4	-50.4%	19	<0.001
Month 18	2.08±1.4	-10.7%	12	0.043
Month 24	1.69±1.5	-27.5%	13	0.014

Visual Fields Outcomes

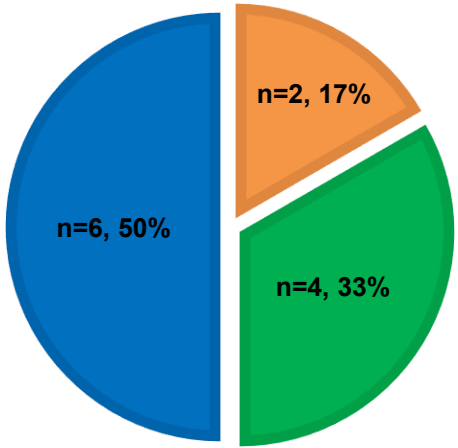
Group*	N	Mean follow-up (months)	Baseline (dB)	Last Follow-up (dB)	Change (p value)
Combined with phaco eyes	173	15.6±7.7	-5.58±6.10	-5.06±6.05	0.52±3.78 **(p=0.104)**
Standalone eyes	12	14.8±9.7	-8.58±10.0	-7.25±7.53	1.33±3.99 **(p=0.273)**

**Only eyes with both baseline and LFU data available are included.*

Combined eyes



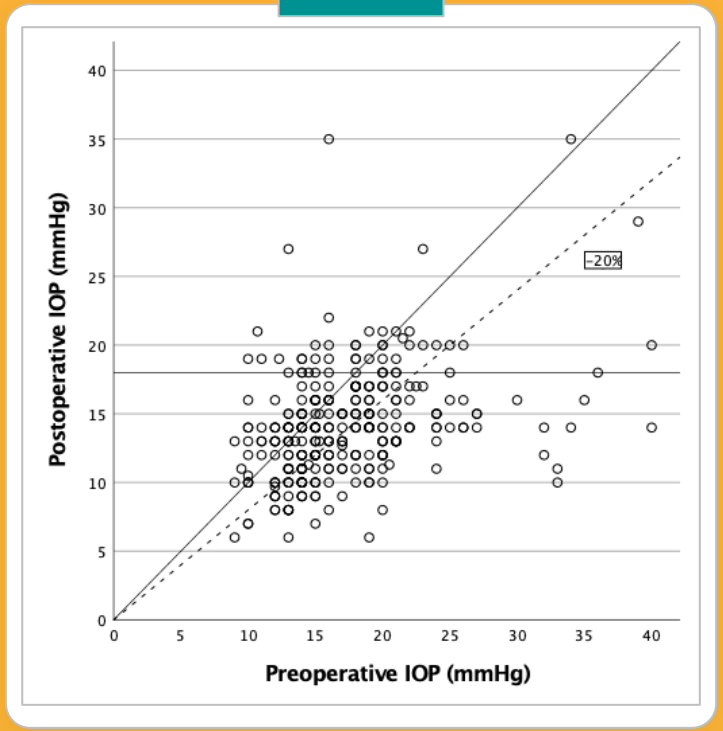
Standalone eyes

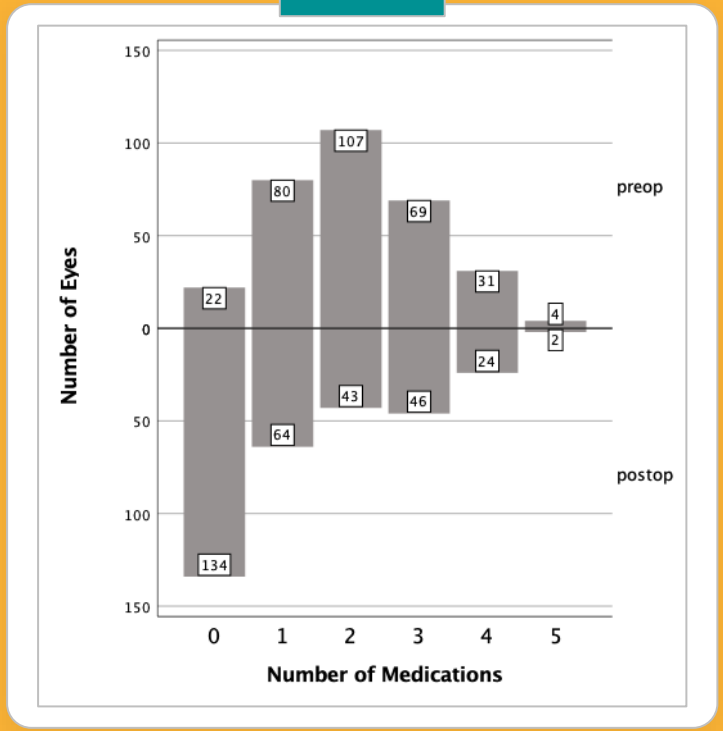


Change in VF MD (dB)	Description
Lost more than 2 (< -2 dB)	Worsened
Gained more than 2 (> +2 dB)	Improved
Between -2 and +2 (-2 dB ≤ x ≥ 2 dB)	No Change

Combined group: IOP and Meds outcomes

Eyes with at least 12m data (n=313), baseline vs postop (last follow-up: mean 20.4±7.9 months)





Note for scatterplot: Each point (eye) demonstrates preop and postop IOP outcomes. Points on or below the *dashed line* indicate eyes with ≥20% reduction in IOP from baseline. Horizontal line represents 18 mmHg. Graphs developed under the *Design & Reporting Glaucoma Trials - World Glaucoma Association*

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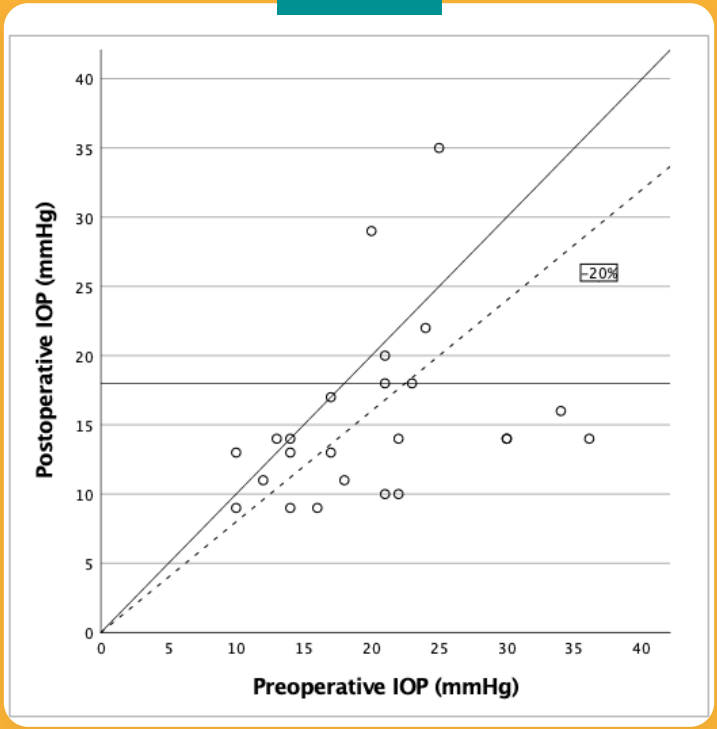
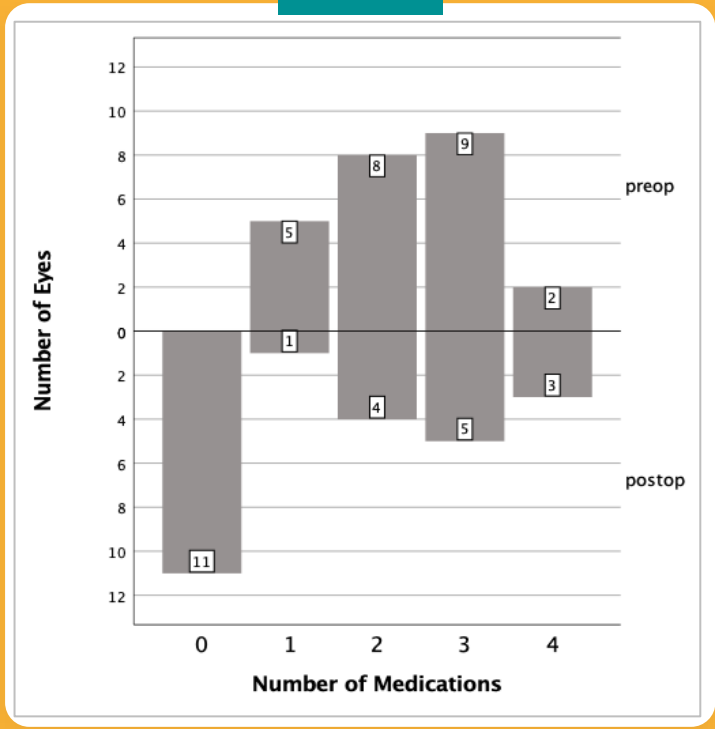
Standalone group: IOP and Meds outcomes

Eyes with at least 12m data (n=24), baseline vs postop (last follow-up: mean 21.3±7.7 months)





Note for scatterplot: Each point (eye) demonstrates preop and postop IOP outcomes. Points on or below the *dashed line* indicate eyes with ≥20% reduction in IOP from baseline. Horizontal line represents 18 mmHg. Graphs developed under the *Design & Reporting Glaucoma Trials - World Glaucoma Association*

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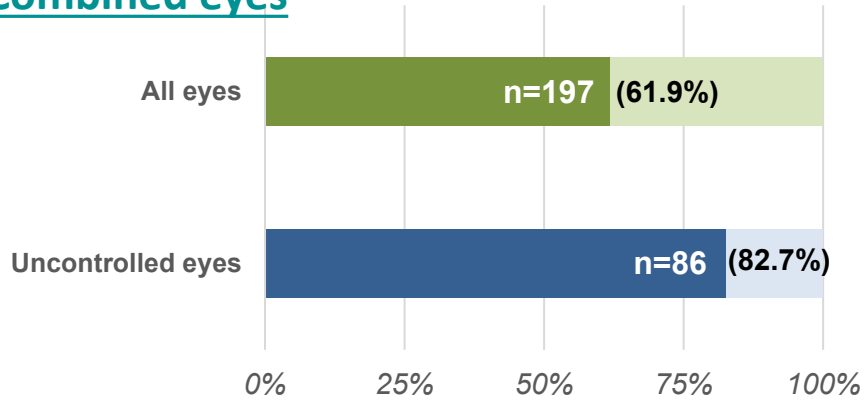
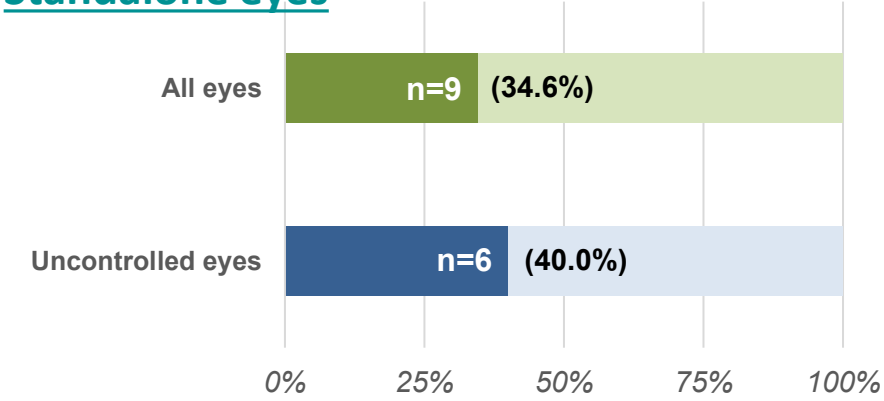
Success Rates

Success defined by achieving criteria set by the American Academy of Ophthalmology

Combined eyes



Standalone eyes



AAO Criteria

An eye was considered to have achieved ***Success*** if it met either of the following criteria:

Criterion 1) IOP no increase, and meds decrease by at least 1

Criterion 2) IOP ≤21 mmHg and reduced by at least 20%, no increase in meds

Note: Combined eyes are considered successful if they meet either Criterion 1 or 2, while Standalone eyes must meet only Criterion 2 to be considered successful.

Uncontrolled IOP eyes defined as preoperative IOP > 18mmHg

Complications and Interventions*

Intraoperative complications	n (%)
No	**343 (99.7%)**
Yes	**1 (0.3%)**
Descemet membrane detachment	*1 (0.29%)*

Postoperative complications	n (%)
No	**336 (97.7%)**
Yes	**8 (2.3%)**
Aqueous misdirection	*1 (0.29%)*
Cystoid macular oedema	*1 (0.29%)*
Hyphaema (>10% anterior chamber)	*4 (1.16%)*
Prolonged intraocular inflammation/uveitis	*1 (0.29%)*
Retinal detachment (unrelated to canaloplasty)	*1 (0.29%)*

Secondary glaucoma procedures	n (%)
All Eyes	**17 (4.9%)**
Ab-externo canaloplasty	*1 (0.29%)*
EX-PRESS Glaucoma Filtration Device	*1 (0.29%)*
Glaucoma Drainage Device	*3 (0.87%)*
Preserflo MicroShunt	*2 (0.58%)*
Trabeculectomy	*1 (0.29%)*
XEN GEL stent	*2 (0.58%)*
Selective Laser Trabeculoplasty	*4 (1.16%)*
MicroPulse Transcleral Cycophotocoagulation	*3 (0.87%)*

**Based on pooled data from eyes across both the combined with phaco and standalone canaloplasty groups.*

Conclusion

This prospective multi-center observational study demonstrated that **ab-interno canaloplasty performed with the *iTrack* and the *iTrack Advance* microcatheter resulted in a significant reduction of IOP and anti-glaucoma medications up to 18-24 months postoperatively**.

Ongoing data collection through a dedicated registry is planned to further strengthen the statistical power of the findings and refine their clinical applicability.