

Continuous Circumferential Trabeculorrhexis (CCT) Using Super-Elastic Memory-Shaped Nitinol

First-in-Human Experience of a Novel
Gonio-Interventional Technology

Disclosures

Iantrek, Inc.
New York Eye and Ear
Infirmary of Mount Sinai



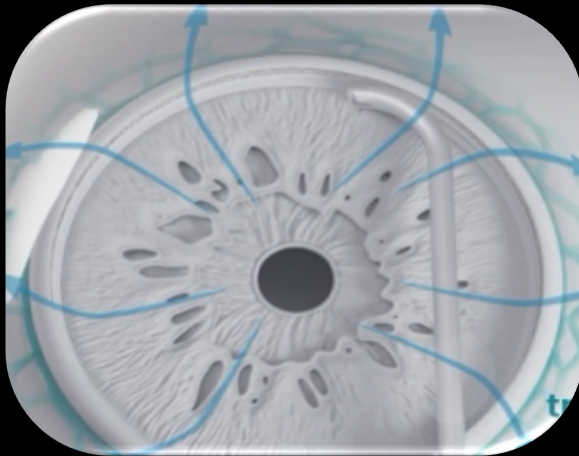
Gautam Kamthan, MD
Assistant Professor

New York Eye and Ear Infirmary of Mount Sinai

Tsontcho A. Ianchulev, MD, MPH; Iqbal Ike Ahmed, MD, FRCSC, ABO; Ernesto A. Calvo, MD, ABO;
Lautaro Vera, MD

Circumferential vs sectoral goniotomy

Limitations of existing gonio-instrumentation



- Current excisional canal interventions limited to sectoral goniotomy
 - Conventional gonio-instrumentation is rigid and inflexible (e.g. KDB)
 - Does not allow more than 90 degrees of excisional goniotomy
- Circumferential goniotomy offers higher efficacy over a single quadrant
 - Conventional circumferential options cut/rip TM, leaving residual tissue

Postoperative Time	Circumferential Trabeculotomy: % Successful ^a (95% CI)	Conventional Angle Surgery: % Successful ^a (95% CI)
1 year	90.7% (73.9–96.4)	57.1% (33.8–74.9)
3 years	79.9% (60.5–90.5)	52.4% (29.7–70.9)
5 years	75.2% (62.9–87.6)	42.3% (21.3–62)
10 years	75.2% (62.9–87.6)	42.3% (21.3–62)

Am J Ophthalmol 2017;183: 17–24
J AAPOS 2000;4:205–10

Continuous Circumferential Trabeculorhexis (CCT)

T-Rex (Iantrek, Inc.): Excisional /rhexis goniotomy using super-elastic nitinol filament



Inventor Dr. Ianchulev

- Fully titratable and controllable canal intervention
- Excisional circumferential trabeculorhexis
 - 100-300% more TM removal vs rigid, non-circumferential devices (KDB, Scion)
 - Complete removal of TM vs slicing options (GATT, OMNI)
- Designed for single and dual wall canalotomy
- Adaptive super-elastic memory shaped filament
- FDA-registered



Courtesy, Iantrek, Inc.



Excisional Circumferential Trabeculorhexis (CCT)

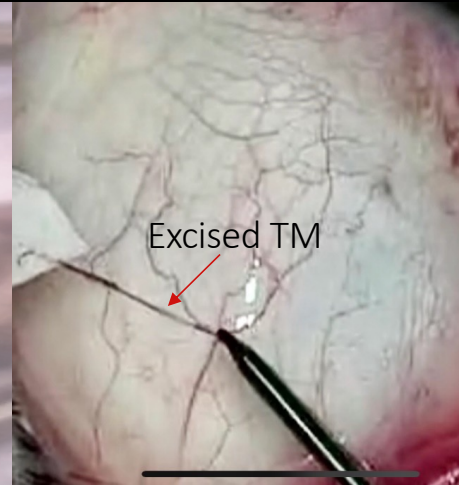
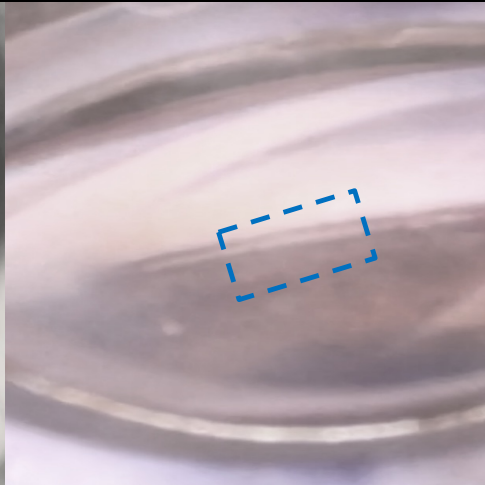
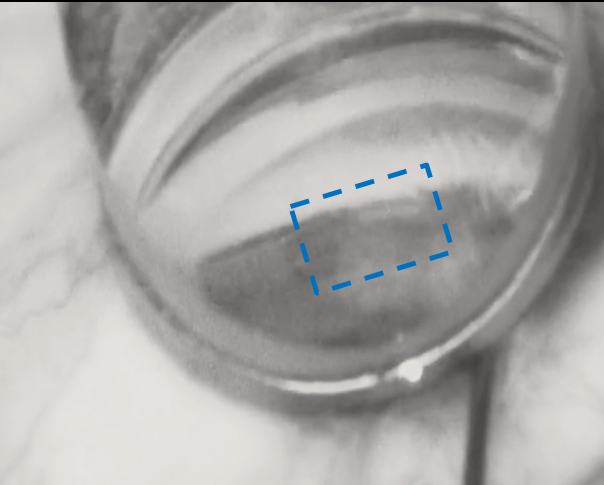
Ab-interno guided continuous goniotomy

With disinsertion / unroofing of the trabecular meshwork and inner canal wall

- The nitinol filament has a self-guiding tip for conforming trackability/followability in the canal
- The super-elastic filament has flexible column strength for guided forward disruption of the TM
- TM disruptor is designed for un-interrupted non-morcellating tissue rehexis

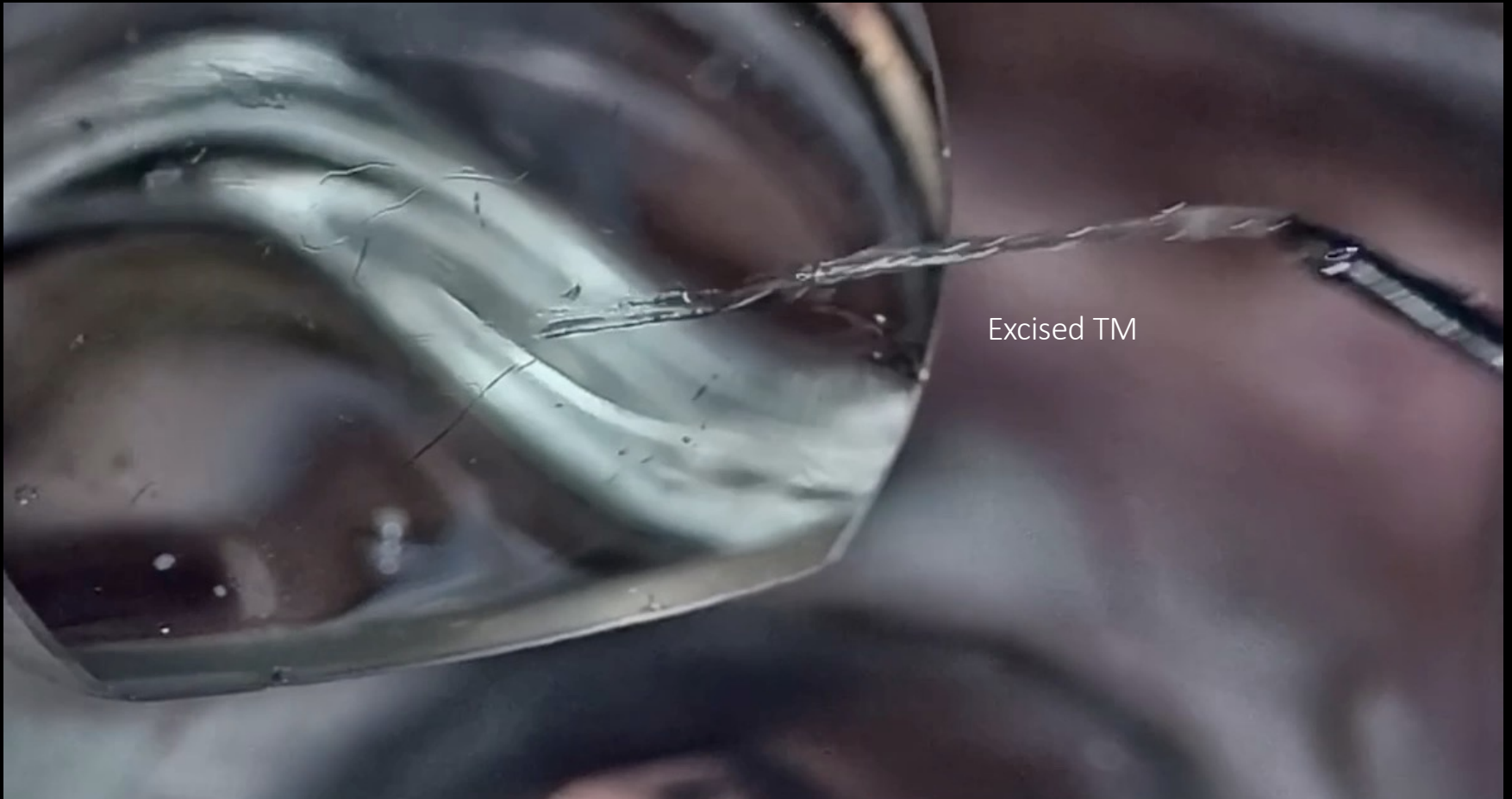
Pre-Op: Contiguous TM band

Post-Op: post-excisional goniotomy white band



Excisional Circumferential Trabeculorhexis (CCT)

Ab-interno guided continuous goniotomy



Initial clinical experience with the T-Rex technology

Ab-interno guided circumferential continuous trabeculorhexis (CCT)

N7 OAG patients were treated surgically with dual-outflow intervention

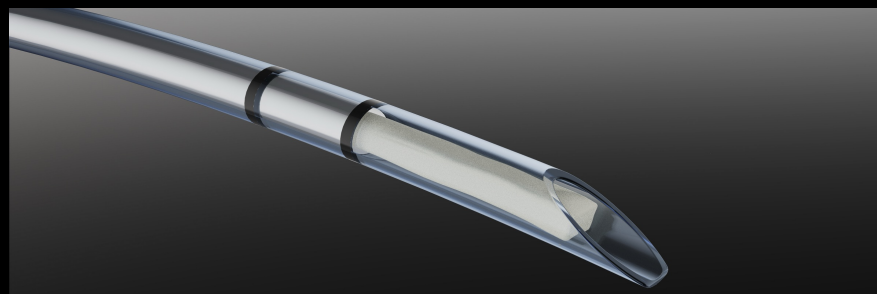
1. Trabecular intervention - T-Rex circumferential goniotomy (CCT)
2. Uveoscleral intervention - Bio-reinforced cyclodialysis with the AlloFlo™ bio-scaffolding implant
3. Standard phacoemulsification

1. T-Rex Canal Intervention



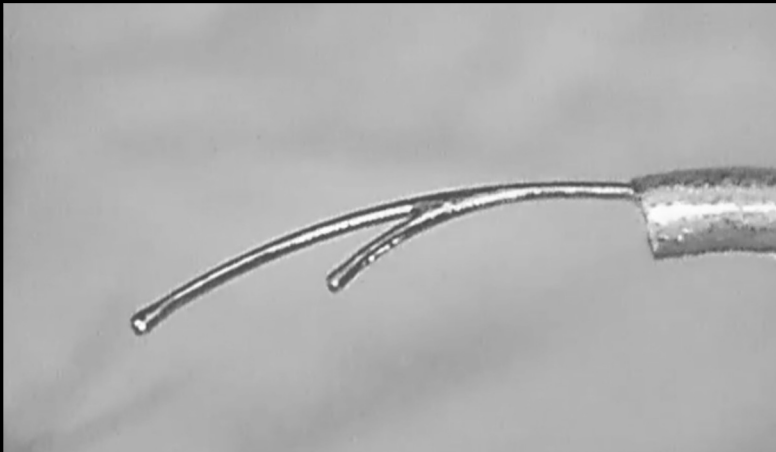
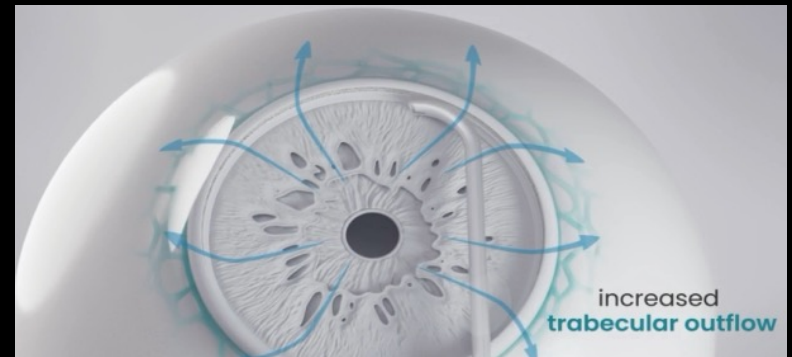
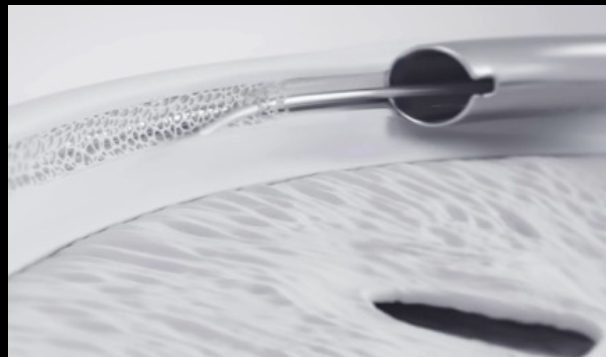
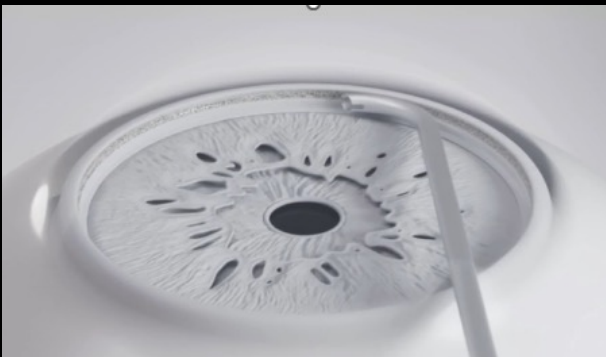
Courtesy, Iantrek, Inc.

2. Supraciliary Bio-Intervention



T-Rex Canal Intervention

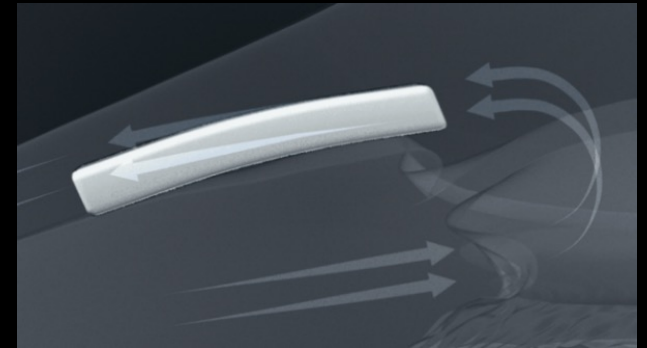
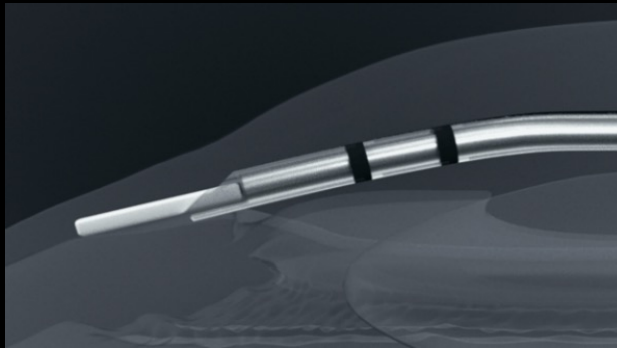
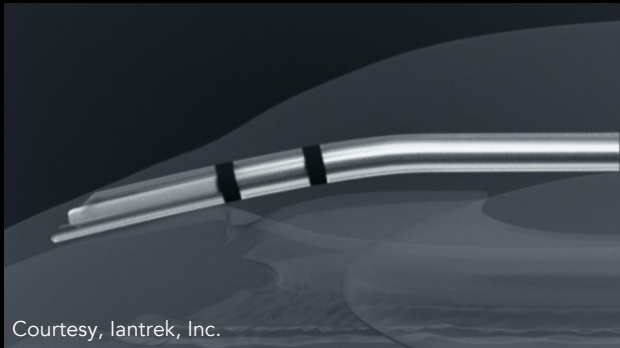
Ab-interno guided circumferential continuous trabeculorhexis



Courtesy, Iantrek, Inc.

Supraciliary Bio-Intervention

Bio-reinforced cyclodialysis



Results

Successful dual-outflow intervention in all subjects

- All 7 subjects had a successful supraciliary, canal and phaco intervention
- 1 subject had miLoop pre-treatment for advanced nucleus disassembly
- No intra-operative and post-operative AEs or SAEs

	Baseline	M1	M3	M6
IOP	19.1	11.4	11.9	12.2
Meds	1.0	0.71	0.86	0.80
ECC	2690.0			2429.3

Summary

- Successful dual outflow pathway implantable plus non-implantable ab-interno MIGS intervention was achieved in all subjects.
- There were no serious and clinically significant intraoperative complications.
- The initial MIGS intervention did not interfere with the successful completion of the subsequent MIGS procedure or follow-on phacoemulsification
- For optimal visualization, canal intervention should precede supraciliary intervention
- There was a sustained reduction in IOP from pre-operative baseline with a concurrent reduction in IOP lowering medications.
- There was no persistent and visually significant post-operative hyphema, hypotony or iritis