

Continuous Circumferential Trabeculorrhesis (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



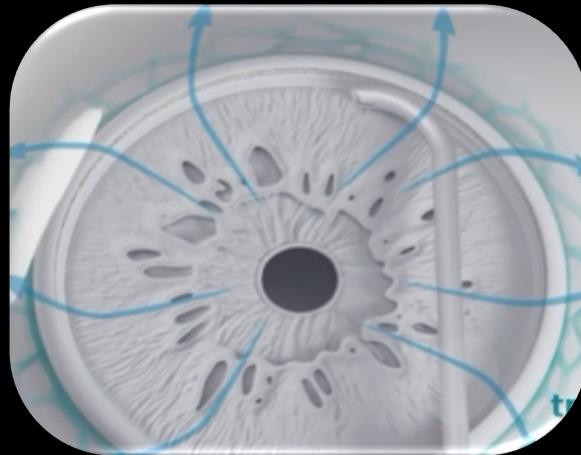
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Circumferential vs sectoral goniotomy

Limitations of existing gono-instrumentation



- Current excisional canal interventions limited to sectoral goniotomy
 - Conventional gono-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) |

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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.

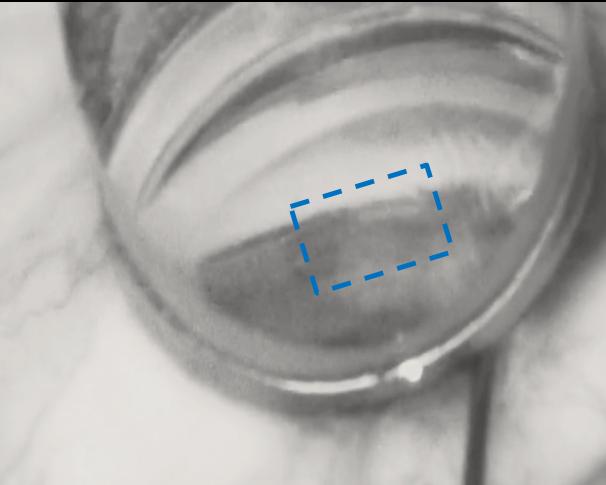
Excisional Circumferential Trabeculorhexis (CCT)

Ab-interno guided continuous goniotomy

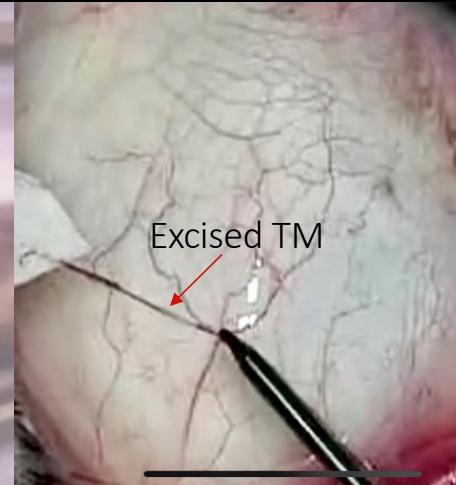
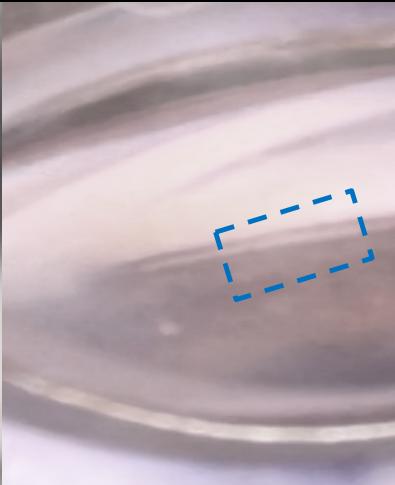
With disinsertion / unroofing of the trabecular meshwork and inner canal wall

- 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 rhesis

Pre-Op: Contiguous TM band

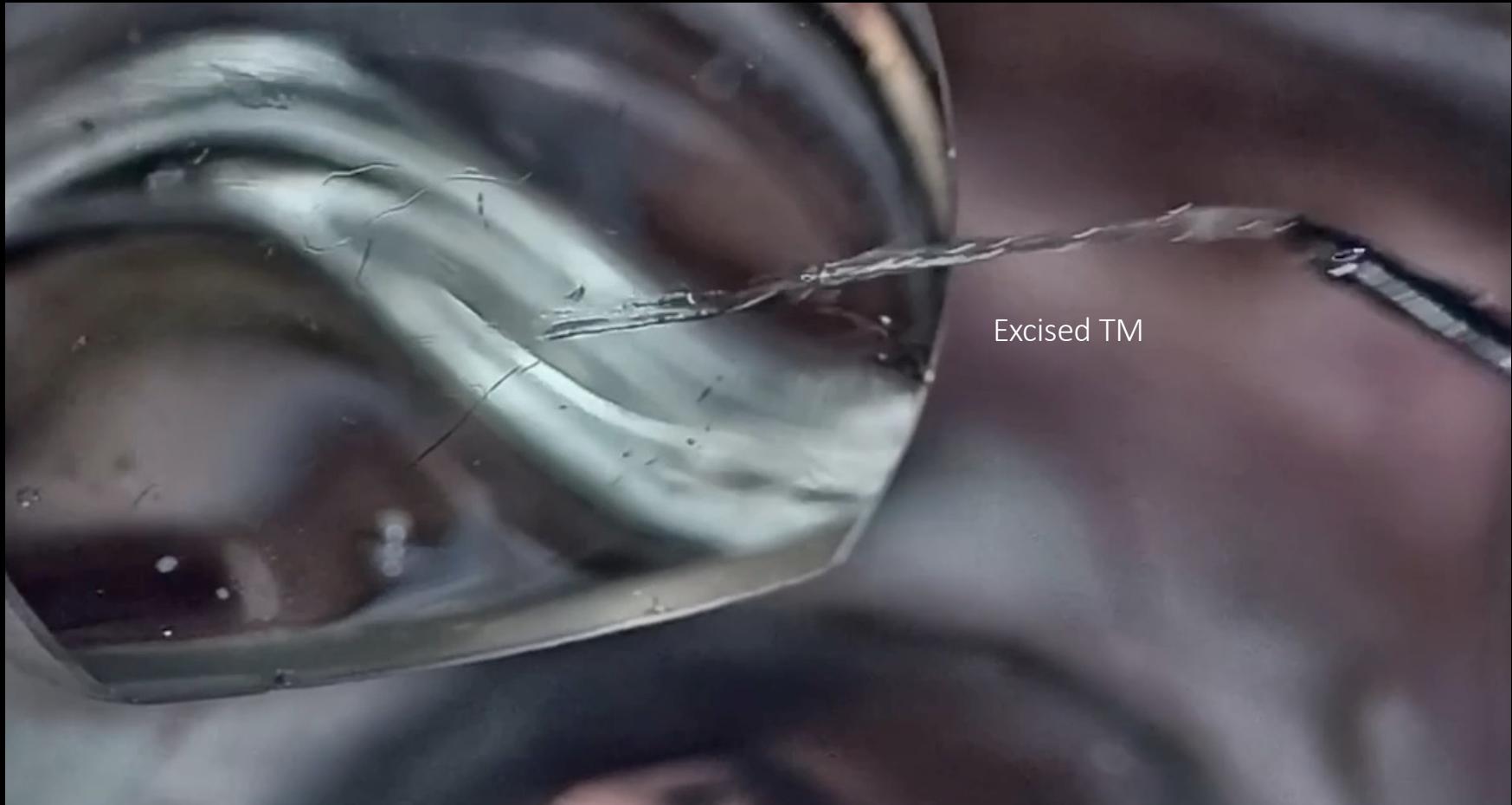


Post-Op: post-excisional goniotomy white band



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

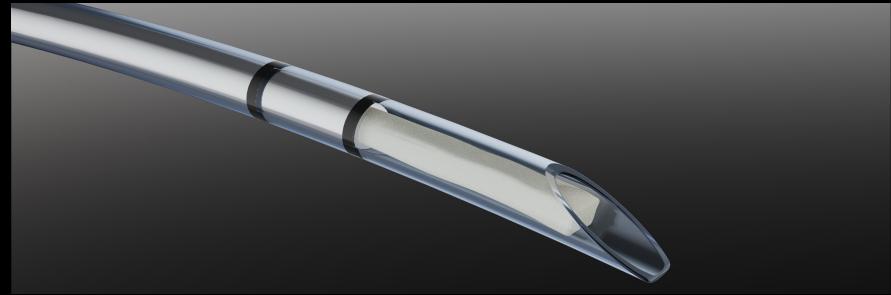
1. Trabecular intervention - T-Rex circumferential goniotomy (CCT)
2. Uveoscleral intervention - Bio-reinforced cyclodialysis with the AlloFlo™ bio-scaffolding implant
3. Standard phacoemulsification

1. T-Rex Canal Intervention



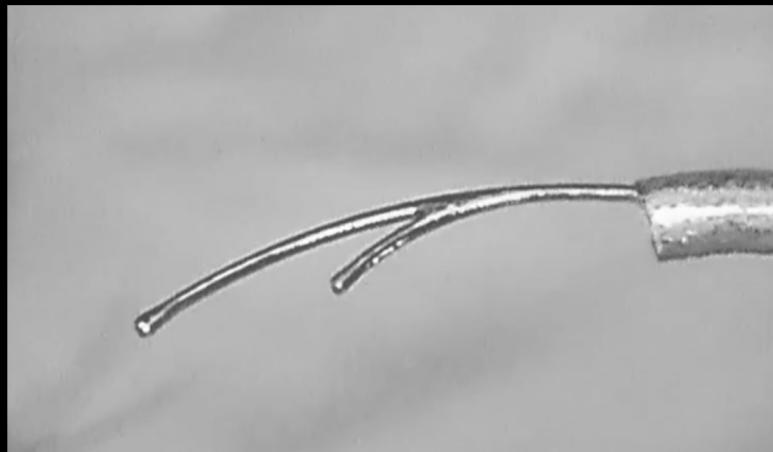
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2. Supraciliary Bio-Intervention



T-Rex Canal Intervention

Ab-interno guided circumferential continuous trabeculorhexis



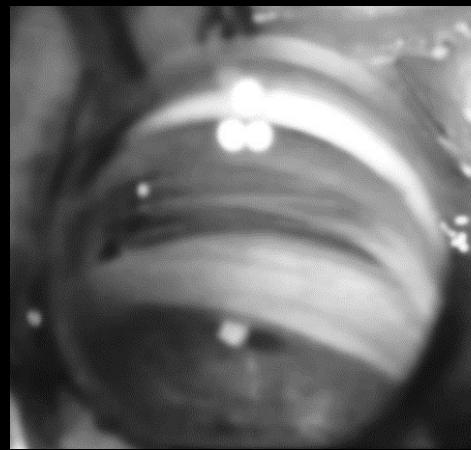
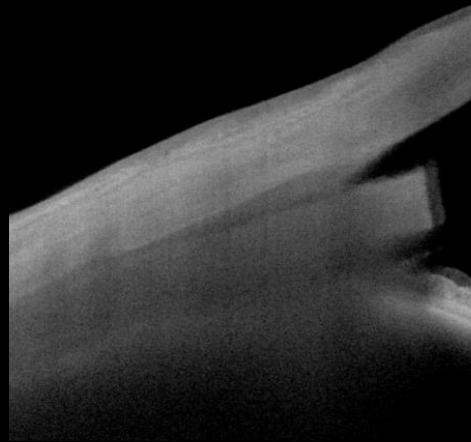
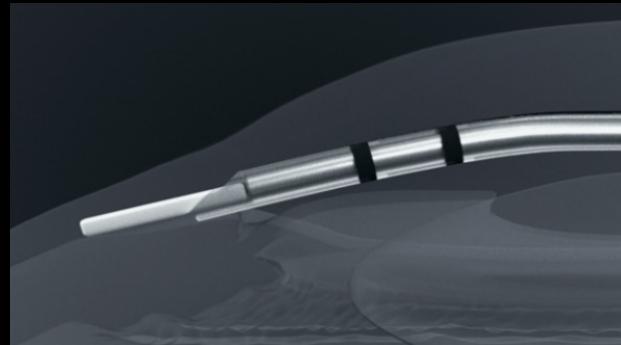
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Supraciliary Bio-Intervention

Bio-reinforced cyclodialysis



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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