Circumferential Goniotomy with Superelastic Microfilament As Adjunct to Bio-Interventional Uveoscleral Surgery for Dual-Outflow Enhancement

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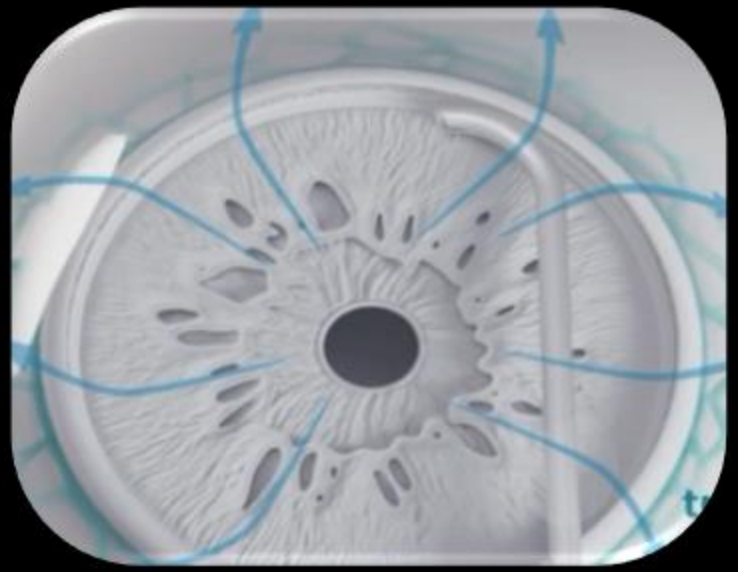
#108910

Purpose

- To introduce a novel circumferential trabeculorhexis device called C-Rex

- To review a case series of eyes who underwent dual-outflow, dual-modality surgery through combination of AlloFlo uveoscleral enhancement with C-Rex trabeculorhexis

Circumferential vs sectoral goniotomy
Limitations of existing gonio-instrumentation



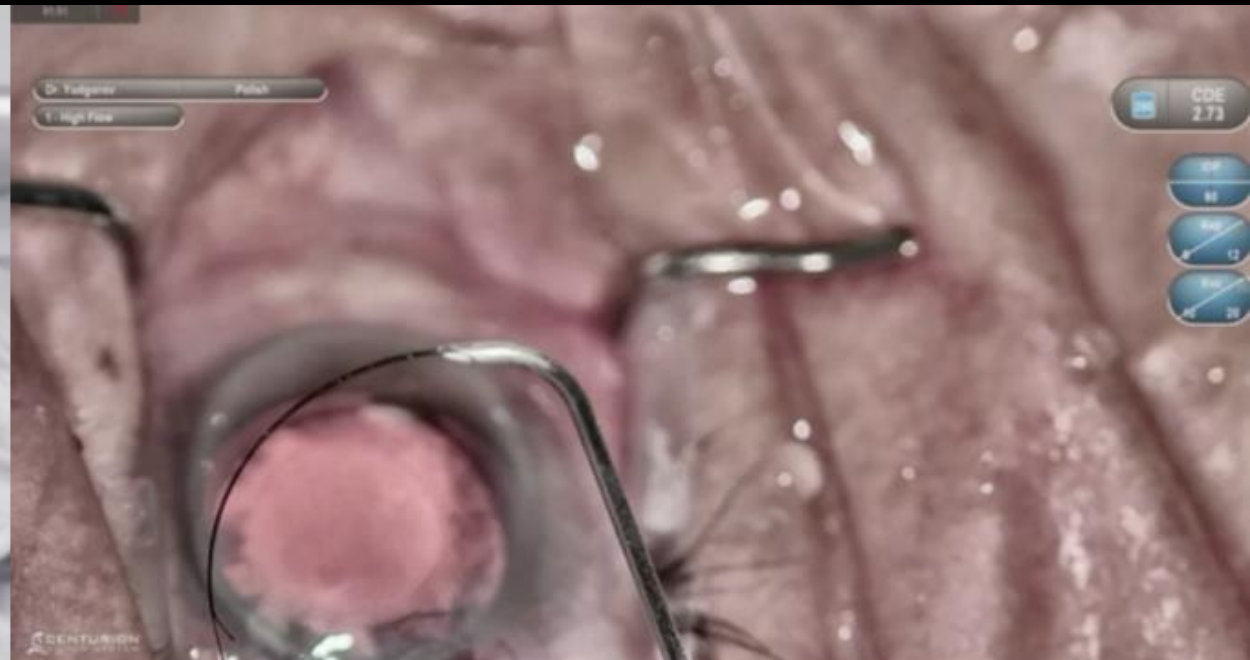
- **Lack of titratable comprehensive 0-360 excisional canal intervention**
- **Current excisional canal devices are limited to sectoral goniotomy/trabeculectomy**
  - **Existing ab-interno trabeculectomy instruments are rigid and inflexible (e.g. KDB)**
  - **Do not allow more than 90 degrees of excisional goniotomy**

Continuous Circumferential Trabeculorhexis

C-Rex: Excisional Canal Wall Rhexis Using Superelastic Nitinol filament

Inventor Dr. Ianchulev

- **Fully titratable and controllable canal intervention**
- **Excisional circumferential trabeculorhexis**
  - **100-300% more extensive TM removal vs rigid, non-circumferential devices (KDB, SION)**
  - **Potential for a more excisional removal of TM compared to slicing/incisional catheter based devices (GATT, OMNI)**
- **Adaptive super-elastic memory shaped filament**
- **FDA-registered**



Excisional Circumferential Trabeculorhexis

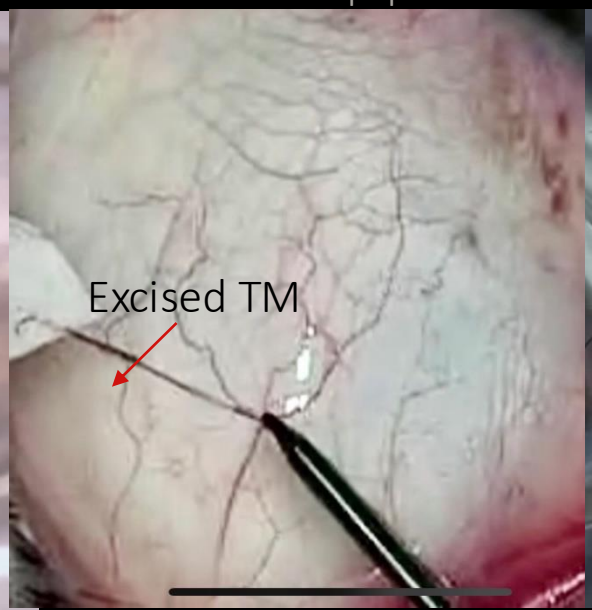
Self guided continuous goniotomy

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 rhexis**

Pre-Op: Contiguous TM band

Post-Op: post-excisional goniotomy white band



Combination MIGS

- Substantial IOP and medication reductions have previously been demonstrated by simultaneously increasing two both the conventional outflow and uveoscleral outflow systems

- This study investigated the safety and efficacy of the dual-outflow, dual-modality concept to facilitate both trabecular and uveoscleral outflow

Study

Dual Outflow Intervention with concurrent phacoemulsification

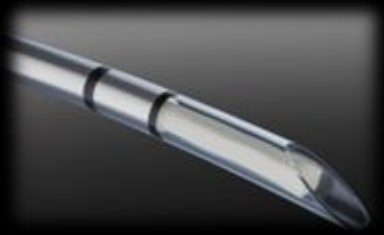
Retrospective Interventional Cohort: N = 19

Eyes with Open Angle Glaucoma and visually significant cataract

Interventions

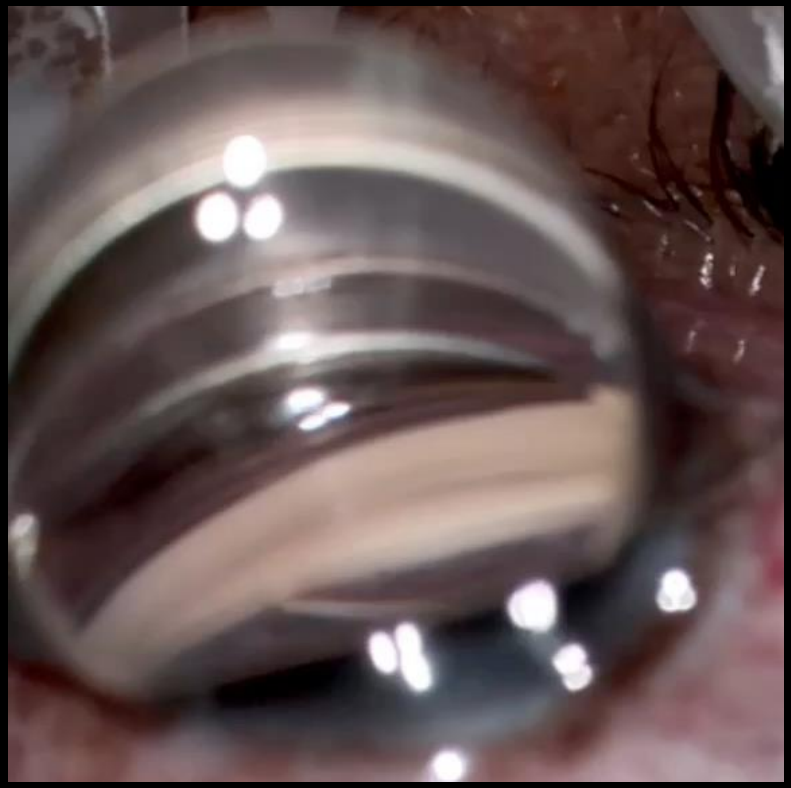
1. **Micro-interventional Trabecular Outflow Enhancement with the C-Rex circumferential 180 deg excisional goniotomy**
2. **Bio-Interventional Uveoscleral Outflow Enhancement with CycloPen and AlloFlo**
3. **Cataract Surgery**

C.REX



CYCLOPEN
ALLOFLO

Dual Outflow Intervention with concurrent phacoemulsification



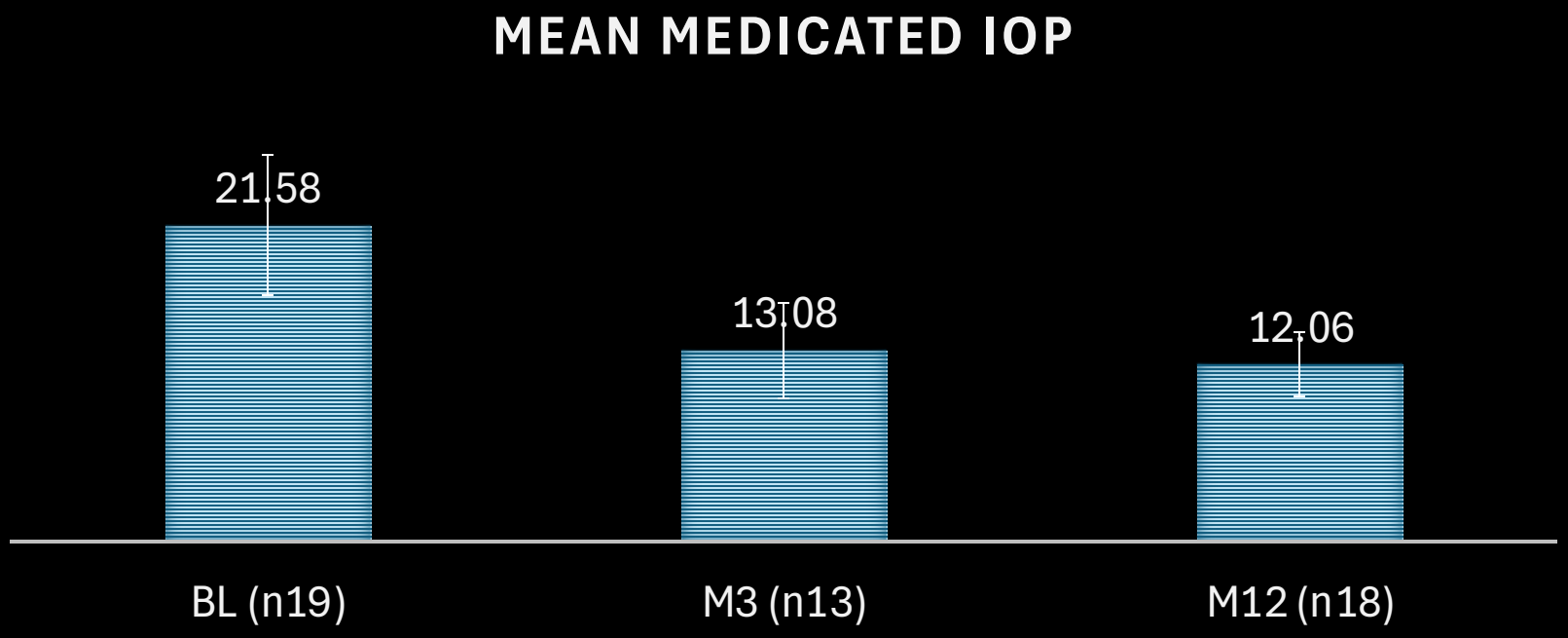
TRABECULAR OUTFLOW ENHANCEMENT
Step 1: C.REX CIRCUMFERENTIAL GONIOTOMY

UVEOSCLERAL OUTFLOW ENHANCEMENT
Step 2: CYCLODIALYSIS
ALLOFLO BIOTISSUE

Results

Successful dual outflow intervention was achieved in all subjects

There were no serious or emergent adverse events



44%

IOP reduction @ 12M

	Baseline	M3	M12
N	19	13	18
IOP (mean)	21.58	13.08	12.06
Meds (mean)	1.05	0.83	0.81

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IOP increase (10 mmHg or >30mmHg), n (%)	1(5.3%)
>2 lines drop in BCVA, n (%)	0
Persistent inflammation (>1M), n (%)	0
Severe inflammation (grade 4+), n (%)	0
Persistent hyphema (>1M), n (%)	0
Persistent corneal edema (>1M), n (%)	0
Bio-tissue migration, n (%)	0
Cystoid macular edema	0
Hypotony (IOP<6 mmHg)	0
Hypotony Maculopathy	0
Post-operative Laser Enhancement (SLT)	1
Secondary Glaucoma Intervention	0

Summary

- Dual outflow enhancement surgery was successfully performed in all subjects
- Circumferential excisional goniotomy can be performed using next generation Nitinol filament technology for trabeculorhexis
- The C-Rex trabecular micro-intervention did not interfere with the uveoscleral bio-intervention
- There was a sustained reduction in IOP from pre-operative baseline with a concurrent reduction in IOP lowering medications.
- There were no serious or clinically significant complications