First-in-human clinical study to establish the safety and efficacy of automated non-contact translimbal Direct Selective Laser Trabeculoplasty: 6 months results

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Introduction: Direct SLT (DSLT)

Automated Direct Trans-Scleral Contactless SLT – The EAGLE System.

Fast & Accurate: No operator dependent variability

Automated:
- Trx target detection
- Eye tracking
- One click → 120 laser shots in 2 seconds

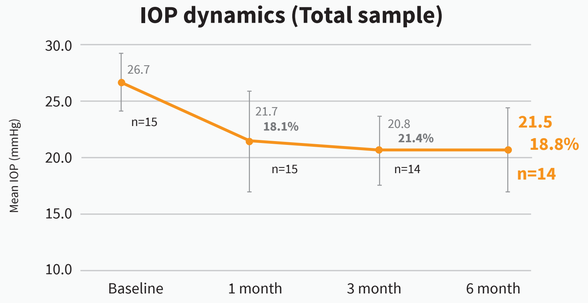
Contactless:
- Comfortable: No gonio-lens is needed
- COVID-19 "Friendly"
- DSLT ~⅓ of SLT laser energy reaching the TM

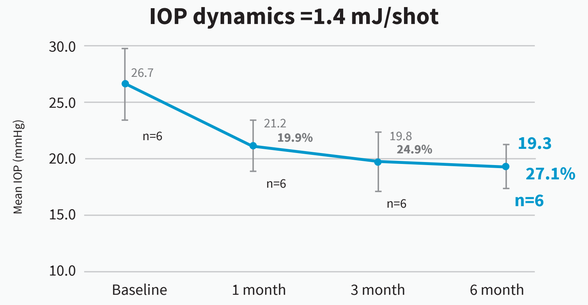


Demographics & Safety Results

Demographics
- Age: 66.2±8.4
- Sex: F=5, M=10
- Diagnosis: POAG 10, PXFG 1, OHT 4
- Medicated Pts 14/15
- 1.6±1.0 medications/pts
- VF MD dB (-2.0±1.6)
- VA, Snellen 6.6±0.2

Safety
- No SAE or sight-threatening adverse events
- AE: 4 mild sub-conjunctival hemorrhages
  - All resolved within 1d-1w without treatment nor sequalae

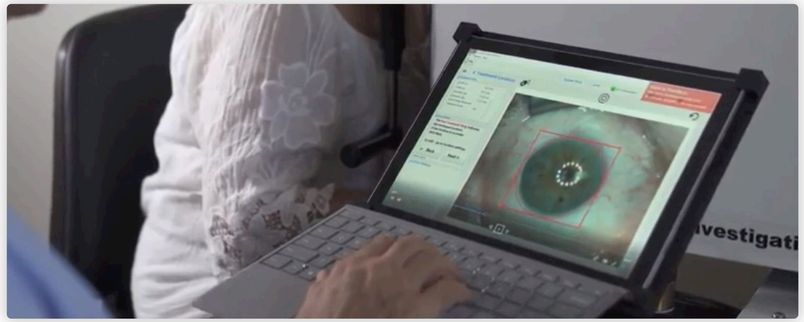




	Screening	6M
Medicated Patients	14	3
# Medications/Pt	1.6±1.0	0.4±0.9

Study Design

First-in-human, Single center, Single Arm, Masked clinical Study to assess safety and efficacy of the EAGLE System in POAG/OHT.
- N=15 Eyes
- IOP ≥22 mmHg, naïve or after washout
- 100 / 120 sequential non-contact 532 nm, Q-switched laser shots (0.8mJ–1.4mJ)
  - Automatically applied through the limbus
  - Guided by image acquisition and eye tracking algorithm
  - Duration ~2sec
- Results assessed at 1 hour, 3 hours, 1 day, 1 week, and 1, 3, and 6 months



Discussion & Conclusions

- The trial demonstrated **safety** and indicated **efficacy** of DSLT in POAG & OHT
- The laser treatment is automated and lasts **~2sec**
- The results calls for a confirmatory study
- A confirmatory RCT (GLAUrious) is currently being performed in Europe to **establish DSLT safety** and **efficacy** and to **compare it to conventional SLT**

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