

Supraciliary Drainage Without Entering the Anterior Chamber And Without Bleb: 24 Months Follow-Up Results

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INTRODUCTION

A new class of glaucoma drainage devices, called minimally invasive glaucoma surgery (MIGS) devices has recently emerged, and aims to provide a safer and less invasive method of reducing IOP compared to conventional incisional surgeries.¹

The ciliary scleral interposition device (CID, CILIATECH, France) is a novel MIGS implant designed to lower IOP of glaucomatous patients without entering the anterior chamber and without bleb. This 26-% hydrophilic acrylic implant has a size of 6 x 4 x 0.2 mm and can be inserted behind the limbus in the supraciliary space through two scleral incisions (Figure 1).

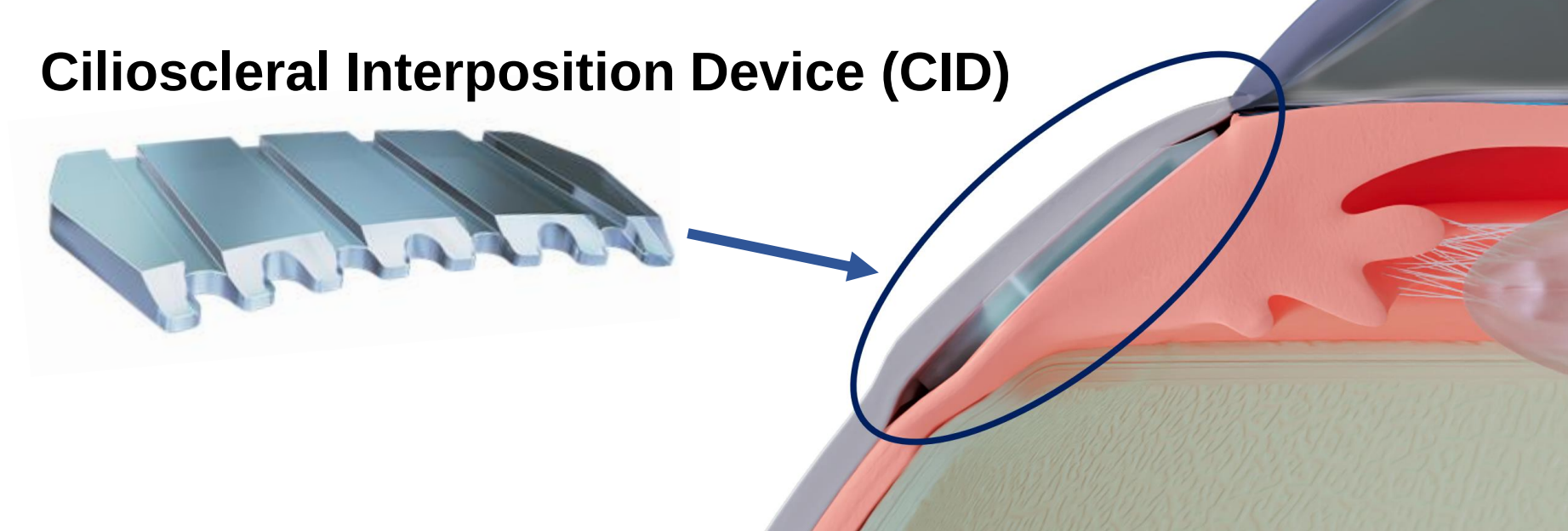


Figure 1. Schematic view of the CID and its ciliary scleral inter-positioning

AIM

The aim of this first-in-human study was to assess the safety and performance outcomes of this novel implant up to 24 months after implantation on patients with primary open-angle glaucoma (POAG).

METHOD

Study Design. Patients were enrolled in this first-in-human study from December 2020 to April 2021 in the Malayan Ophthalmological Center, Yerevan, Armenia. Patients with POAG Shaffer 3 & 4 with medically uncontrolled IOP > 21 mmHg, naive from prior glaucoma surgery and with an indication for glaucoma standalone surgery only were included. Eligible patients received either one CID (NCT03736655) or two overlapped CIDs (NCT04770324) in one eye.

Surgical procedure. Two 3.5-mm scleral incisions 2 mm posterior to the limbus and 5.5 mm distant from each other were performed. Then, viscoelastic was injected to separate the sclera from the ciliary body. One or two CIDs were then inserted through one of the incisions and forceps were used in the other incision to help positioning correctly the device. Finally, both incisions were sutured watertight. Postoperative regimen included antibiotics and anti-inflammatories for 2 weeks and prostaglandins for up to 1 month.

Performance and safety Outcomes. Follow-up visits were at 1 day, 1 week and 1, 3, 6, 12 and 24 months. At baseline and at each postoperative follow-up visits, concomitant medications were documented and IOP was measured using Goldmann applanation tonometer. Ultrasound biomicroscopy (UBM) and gonioscopy were also performed to observe device position and anterior chamber angle.

REFERENCES

1. Pereira ICF, van de Wijdeven R, Wyss HM, Beckers HJM, den Toonder MJM. Conventional glaucoma implants and the new MIGS devices: a comprehensive review of current options and future directions. Eye (Lond). 2021 Dec;35(12):3202-3221.

RESULTS

Patient demographics. A total of 41 patients (PP population) were analyzed in this study, with 20 patients receiving 1 CID and 21 patients receiving 2 CIDs. Mean age was 64.1 ± 9 years and 53.7 % of patients were female. At 24 months, 12 patients were lost to follow-up and one patient was dead.

Performance and safety outcomes. At baseline, IOP was 24.7 ± 3.8 mmHg and the preoperative number of medications was 1.8 ± 0.7 . After 1 or 2 CIDs implantation, IOP was 16.5 ± 5.4 at 3 months, 16.2 ± 5.0 mmHg at 6 months, 16.2 ± 3.7 at 12 months and 15.2 ± 3.7 at 24 months, corresponding to a IOP reduction of $\square 38\%$ compared to baseline (Figure 2-3). The postoperative number of medications also decreased to 0.1 at 3 and 6 months and to 0.2 at 12 and 24 months follow-up (Figure 4). Moreover, 85% of patients had no hypotensive medication at 24 months follow-up. No significant difference were found between patients who received 1 CID compared with patients who received 2 CIDs. No visual acuity decrease, nor visual field loss were observed up to 24 months following CID implantation. Moreover, no adjunctive treatment nor new surgery were necessary.

UBM examination and gonioscopy. CIDs were successfully inserted at the iridocorneal angle (Figure 5). No postoperative movement or subconjunctival filtration were observed at the different follow-up timepoints. Moreover, gonioscopy confirmed the absence of angle modification.

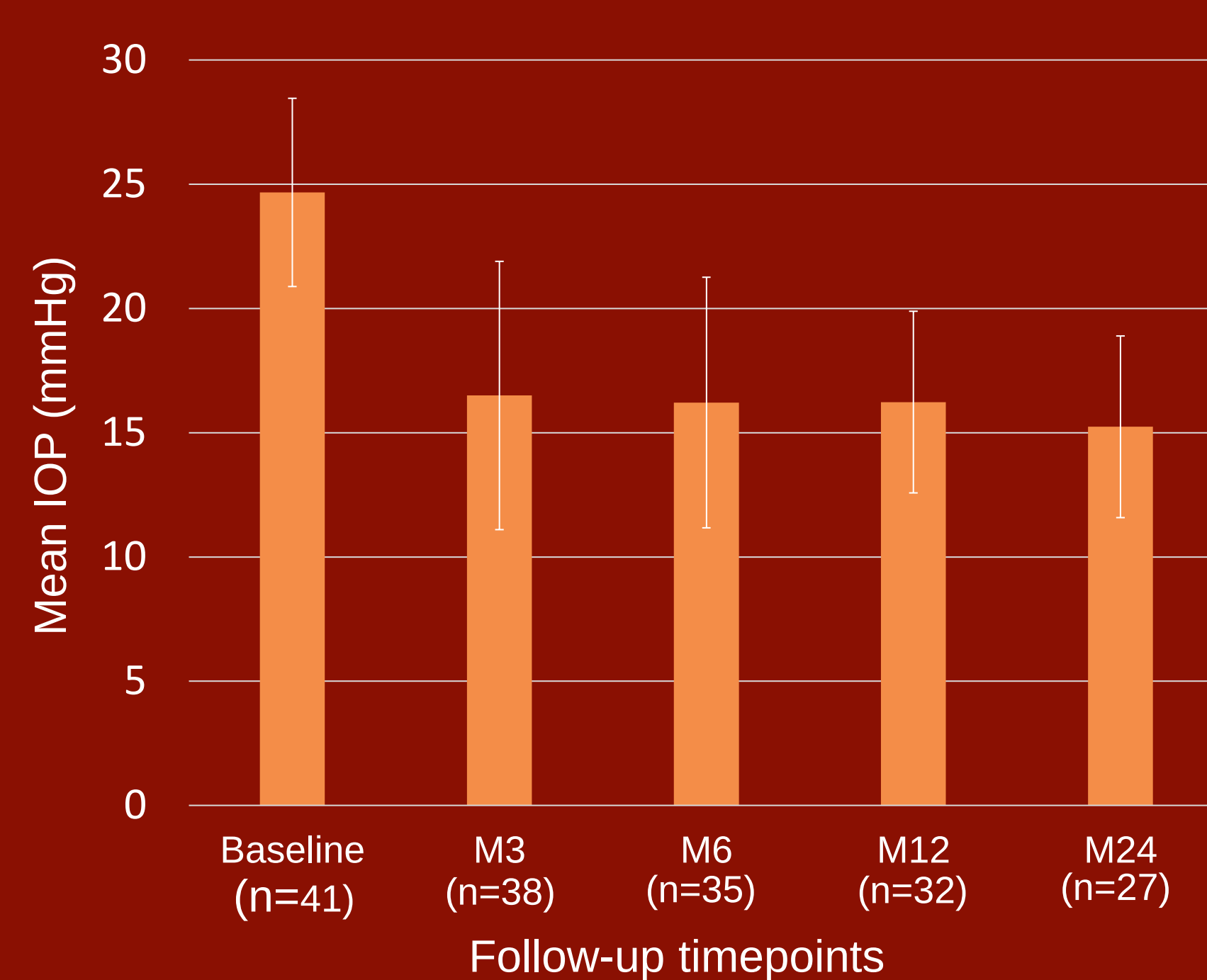


Figure 2. Mean ($\pm$ SD) IOP at baseline and at different follow-up timepoints after CID implantation

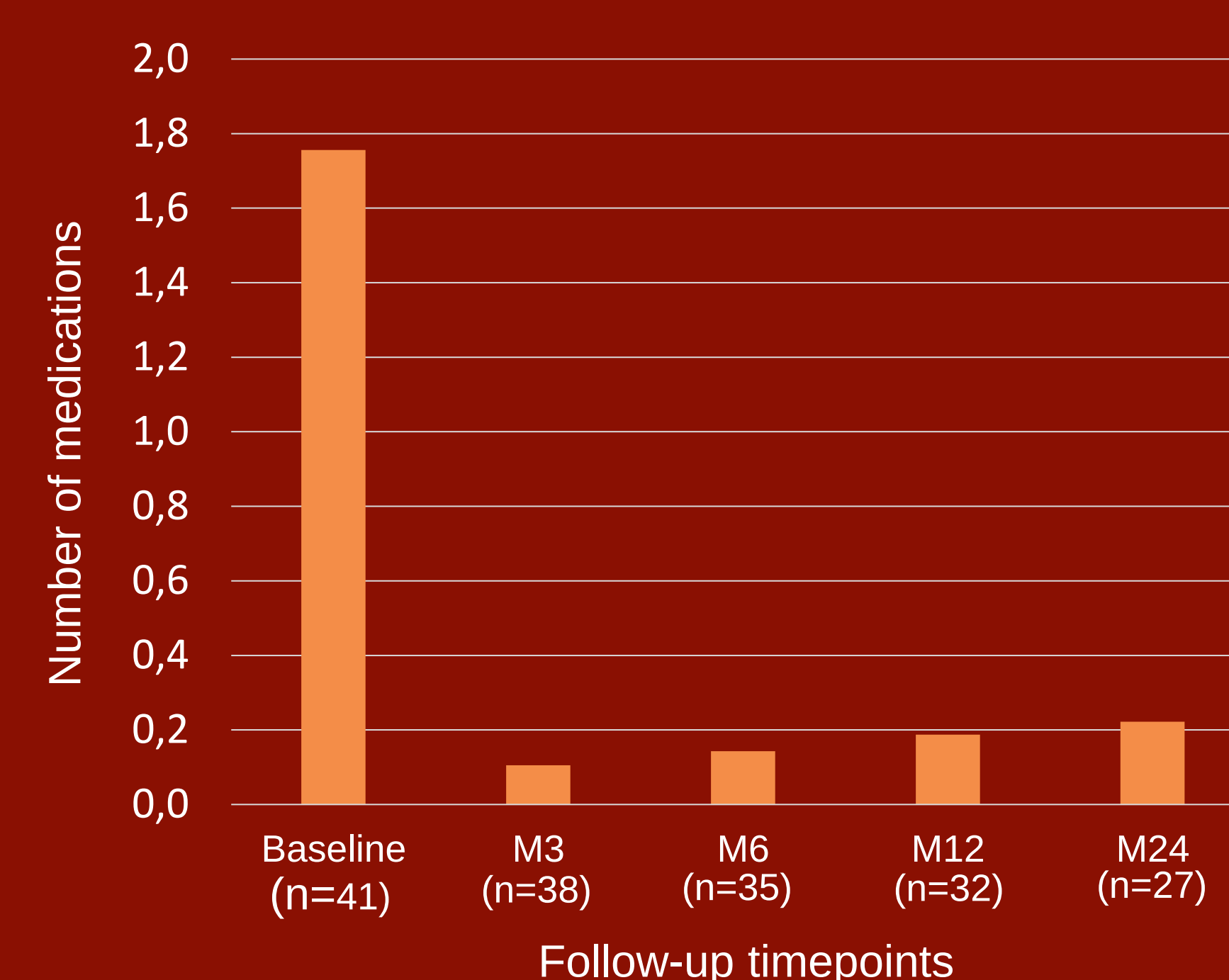


Figure 4. Mean number of medications at baseline and at different follow-up timepoints after CID implantation

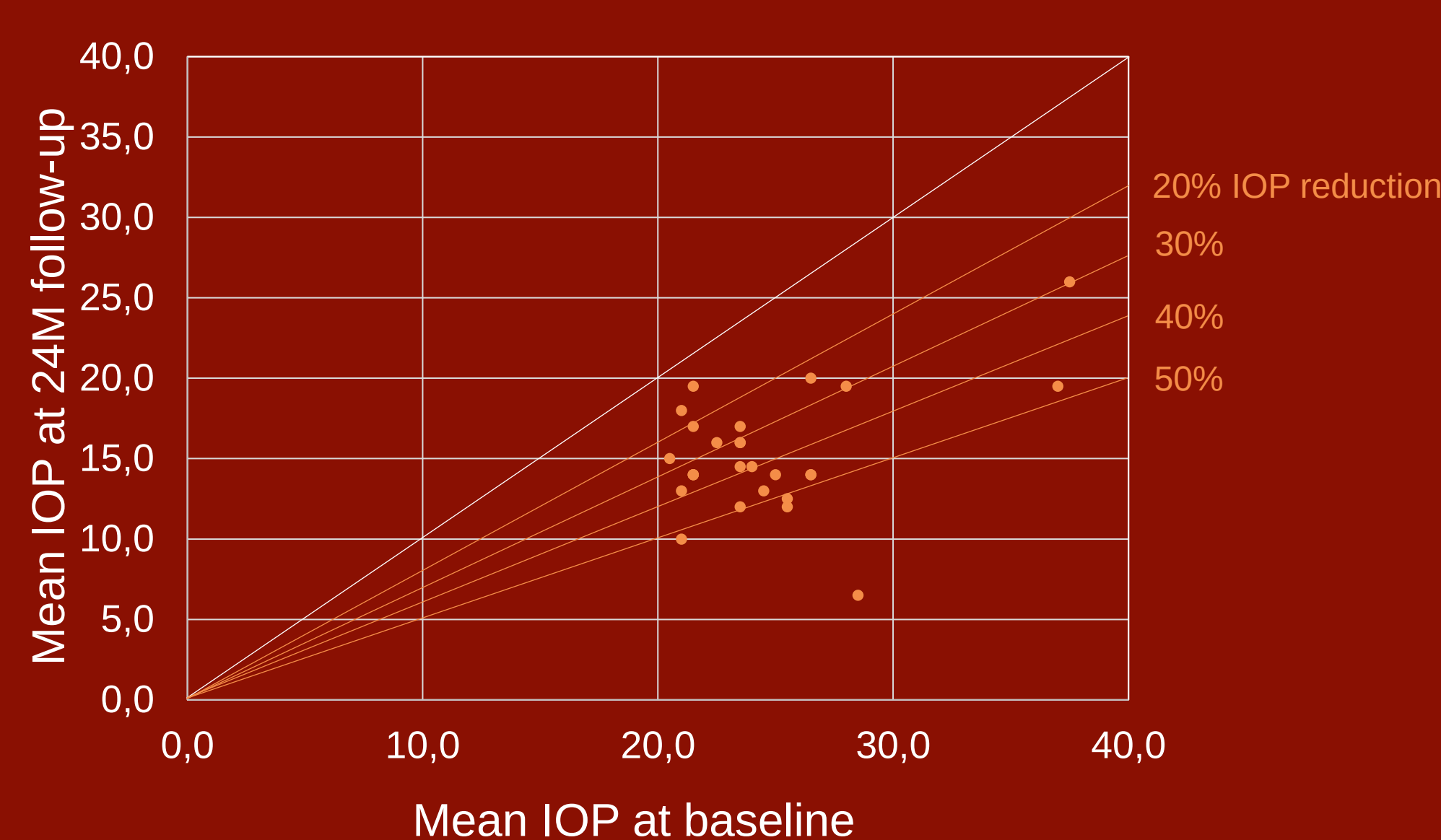


Figure 3. Scatter graph of baseline versus postoperative IOP at 24 months follow-up (n=27)

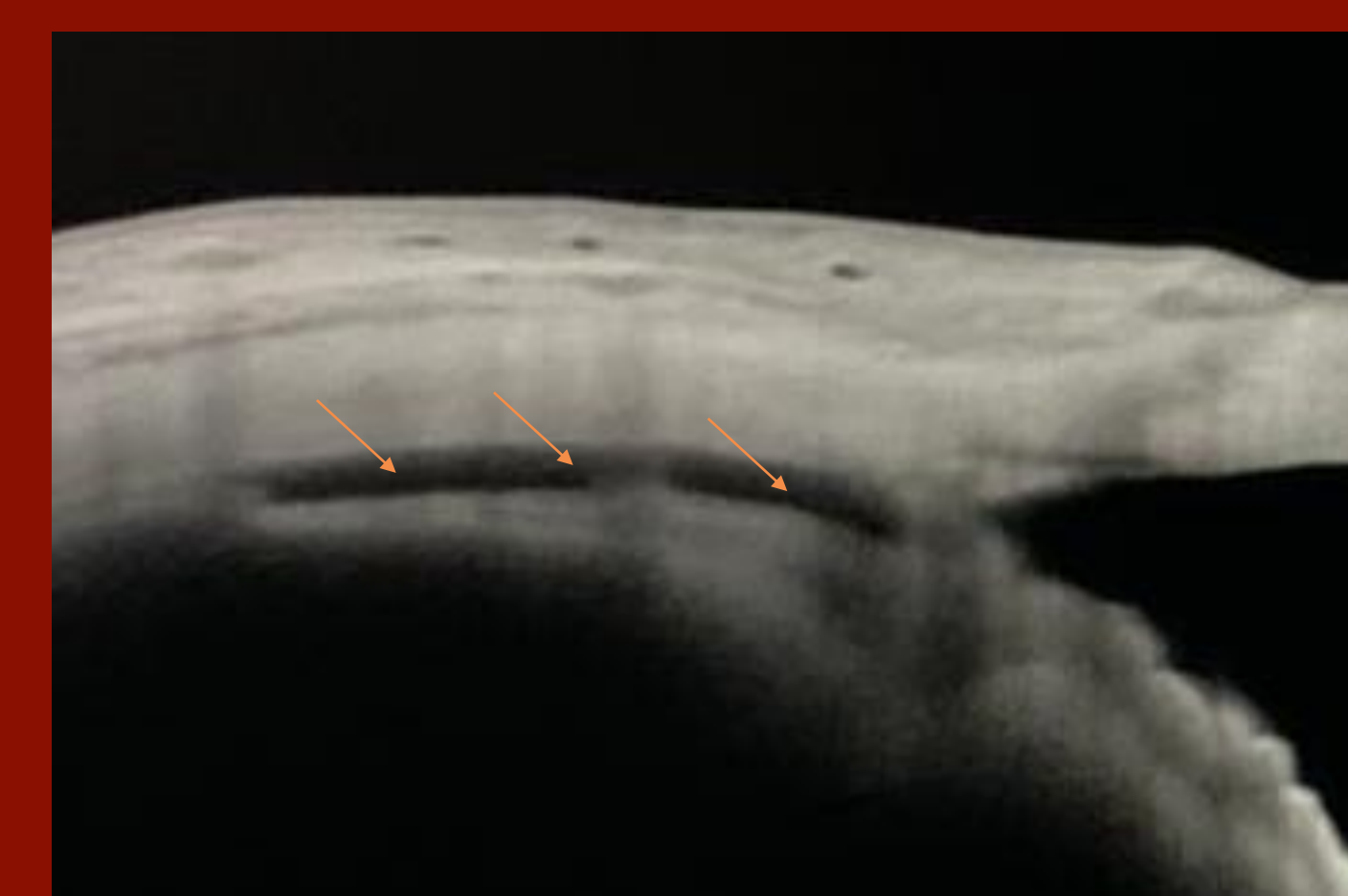


Figure 5. UBM image of the anterior segment of a patient implanted with a CID

CONCLUSIONS

- These results showed a statistically and clinically significant IOP reduction of $\square 39\%$ at 24 months after implantation of 1 or 2 CIDs on patients with POAG.
- At baseline, all patients had prescription for 1 to 4 hypotensive medications. At 24 months, 85 % of patients had no more prescription.
- No complications or adverse events (including angle modification and device movement) were reported during the study.
- No statistical difference was observed between patients who received 1 or 2 CIDs, suggesting that the implantation of a single device is sufficient to efficiently decrease IOP.
- Therefore, surgical enhancement of the uveoscleral outflow via physiological pathways, without opening the anterior chamber and without bleb seems to represent a very safe and efficient approach to decrease IOP and the burden of hypotensive medications of patients with POAG.

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