

# NOVEL SUPRACHOROIDAL DELIVERY SYSTEM ENABLES INJECTION OF HIGH VOLUMES AND RAPID DISTRIBUTION INTO THE POSTERIOR SEGMENT

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## PURPOSE

Determine efficacy and safety of a novel suprachoroidal (SC) delivery device in Non-Human Primates (NHP).

## METHODS

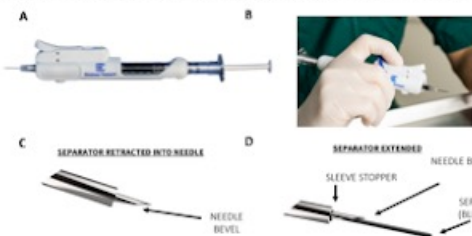
- Six live and six cadaver NHP eyes were injected with 150 or 200µL Indocyanine Green (ICG) dye.
- The delivery system's needle was inserted tangentially into the sclera, followed by extension and retraction of a blunt tissue separator to create a tunnel into the choroid allowing ICG administration (Fig 1,2).
- Animal eyes were examined by biomicroscopy, fundus imaging and OCT imaging at baseline, immediately after the injection, and at 1, 3 and 24 hours post injection.

FIG 1: NOVEL TECHNOLOGY AND METHOD FOR SUPRACHOROIDAL DELIVERY



The bevel of the device is partially and tangentially inserted into the sclera up to a controlled depth set by the device's sleeve stopper, followed by extension and retraction of the blunt tissue separator which opens a channel to the choroid via which therapy is injected.

FIG 2: THE SUPRACHOROIDAL DRUG DELIVERY SYSTEM



A. Suprachoroidal injector (Everads Therapy, Israel) compatible with standard luer lock syringe. B. Device in "separator retracted" position C-D. Bevel with separator retracted / extended.

## ICG DISTRIBUTED THROUGHOUT THE POSTERIOR SEGMENT IN BOTH CADAVER AND LIVE NHP EYES

FIG 3: Scleral flat mount. Cadaver eyes were injected with 150µL ICG in the inferior temporal quadrant. Following dissection, posterior segments were photographed under a dissecting microscope. (S- Superior, N-Nasal, T-Temporal, I-Inferior)

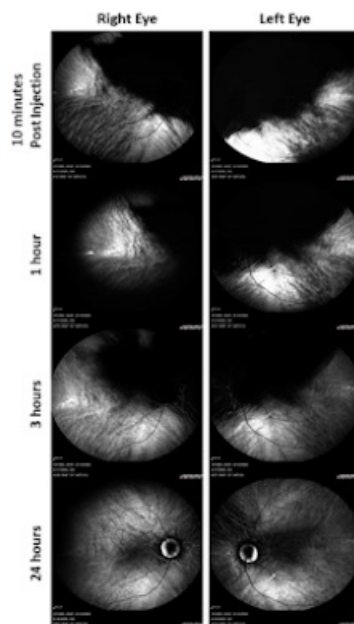


FIG 4: OCT images. Live NHP eyes were injected with 150 or 200µL ICG in the inferior temporal quadrant. Fluorescence fundus imaging demonstrated ICG distribution (white areas) throughout the posterior segment, reaching the macula within 24 hours post injection. Bilateral fluorescence fundus images (50° centered on the fovea) were captured at indicated time points post SC injection of ICG using a Topcon TRC-50EX retinal camera with ICG excitation/emission filters.

## RESULTS

### NO ADVERSE EVENTS WERE OBSERVED FOLLOWING SC INJECTION UP TO 24 HR POST INJECTION

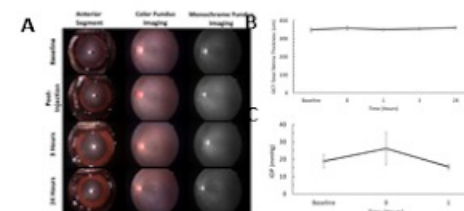


FIG 5: A. Anterior segment, color and monochrome fundus images revealed no suprachoroidal blebs, retinal detachments or hemorrhages associated with SC dosing. No ICG was detected in the vitreous or subretinally. No inflammatory reaction was observed post dosing as confirmed by slit lamp examinations. B. No significant changes were observed in retinal thickness by SD-OCT ( $p=0.267$ ). C- A mild, statistically non-significant elevation in IOP was observed immediately post injection (mean  $\pm$  SD:  $7.28 \pm 5.57$  mmHg,  $p=0.212$ ) and was spontaneously resolved within the first hour after dosing.

## CONCLUSIONS

- Suprachoroidal (SC) injection of 150- or 200 µL ICG dye was successfully performed in primate eyes.
- SC injection was well tolerated, with progressive distribution through posterior pole immediately following injection and continuing over 24 hours to achieve distribution to the macula and optic nerve
- Opening a tangential path with the blunt tissue separator enabled safe and extensive distribution of large volumes throughout the posterior segment.
- This device may provide safe and effective delivery of treatments to the macula region and posterior pole.

## FINANCIAL DISCLOSURES

Hagay Drori and Miriam Mangelus are employees of Everads Therapy Ltd.; Ygal Rotenstreich and Ifat Sher are consultants and shareholders of Everads Therapy. Avner Ingerman and Yoreh Barak are consultants and hold options in Everads Therapy.