Development of FORGE, a new glaucoma drainage device

Posterboard#: B0102

Abstract Number: 3527 - B0102

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DisclosureBlock: Faruk H. Orge, Code C (Consultant/Contractor) Recordati, Code C (Consultant/Contractor) Volk, Code C (Consultant/Contractor) Regeneron, Zeina Salem, None; Carol B. Toris, None;

Purpose

The FORGE Schlemm's canal drainage device (a novel MIGS) was designed to improve drainage through the trabecular outflow pathway. It is a scaffold that is not inserted into the Schlemm's canal but rather tacked to the surface of the trabecular meshwork (TM) by a row of adjacent 2 tines creating 2 sets of openings. These tines create 2 holes in the TM and tent the TM over the holes to prevent closure of the holes. This design was evaluated for its ease of placement and effects on outflow facility (C).

Methods

The study examined pairs of human donated globes within 48 hours of death. Outflow facility (C) was measured by a multilevel constant pressure perfusion method. After calibration of the setup, baseline measurements of facility were made in paired eyes, followed by insertion of different prototypes of the device in one eye and sham procedure (incisions in the TM without device placement) in the paired eye. Both eyes were measured at the same time. Values are in ul/min/mmHg. After a series of experiments to test the curvature of the device, number of barbs and installation method, the final design was chosen for further analysis. Ten pairs of eyes were tested.

Results

When compared to baseline, the device increased outflow facility by 94% compared to the sham eyes of 9.7%. The C, change from baseline and percent change from baseline of the device eye was significantly greater than that of the sham eye.

Conclusions

| The FORGE MIGS shows potential as a novel treatment for ocular hypertensio | Γhe F | FORGE MIGS | shows potential | as a novel | treatment for | ocular hypertension |
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