An Analysis of Bilateral Near Visual Acuity at 24 month post-VisAbility Implant

BARRIE SOLOWAY, M.D.

MEDICAL DIRECTOR, REFOCUS GROUP

Disclosures

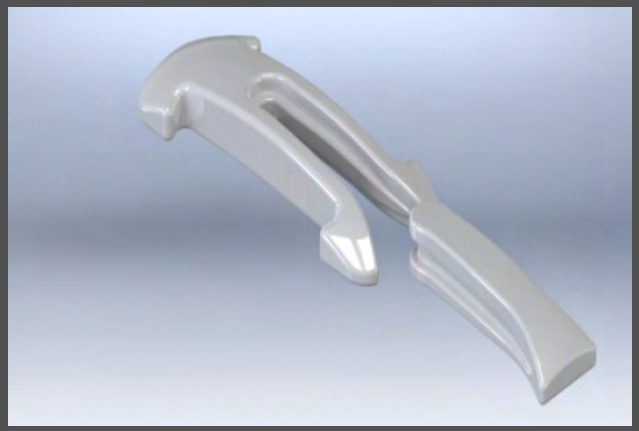
Financial Disclosure

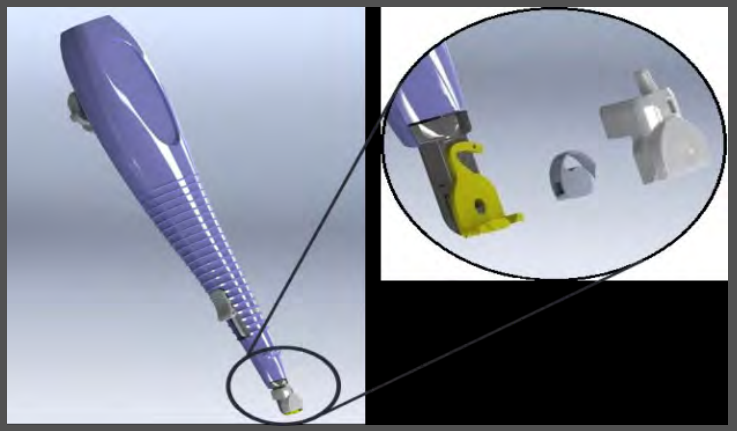
- Consulting and travel fees paid by Refocus Group, Inc.
- Medical Director, Refocus Group, Inc.

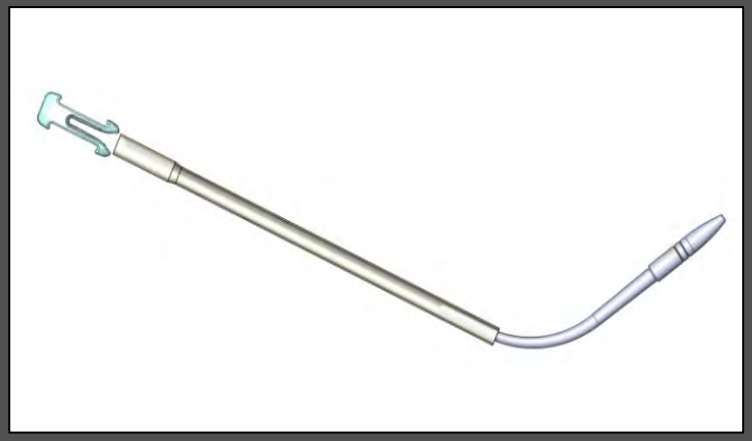
Investigational Disclosure

- The PresVIEW™ Scleral Implant is an investigational device and is limited by United States law to investigational use.
- This device is CE marked and available in Europe and elsewhere through Refocus Ocular **Europe,** B.V., Netherlands

PresVIEW™ Implant System

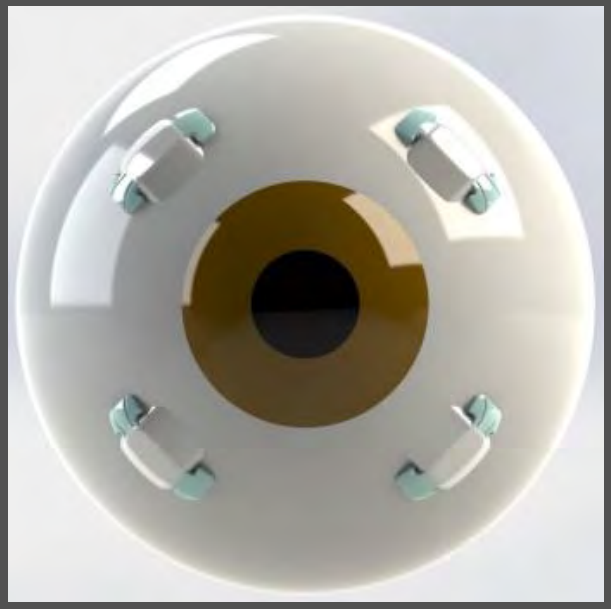






Refocus Procedure

1. Create Conjunctival opening
2. Create a lamellar scleral tunnel
3. Insert the Refocus Scleral Implant
4. Repeat in remaining three oblique quadrants
5. Repair conjunctival opening



FDA IDE G970152: P277-5 Clinical Trial

INCLUSION CRITERIA

Between 50 and 60 years of age

BCDVA and BCNVA of 20/20 or better – both eyes

Sloan DCNVA @ 40cm between 20/50 and 20/100

Manifest refraction spherical equivalent (MRSE) between –0.50D and +0.75D

No more than 1.00D of astigmatism

Phakic

EXCLUSION CRITERIA

Chronic ocular inflammation

Scleral thickness <530 microns

Previous invasive ocular surgery

Previous EOM surgery

Chronic ocular disease

Chronic systemic disease

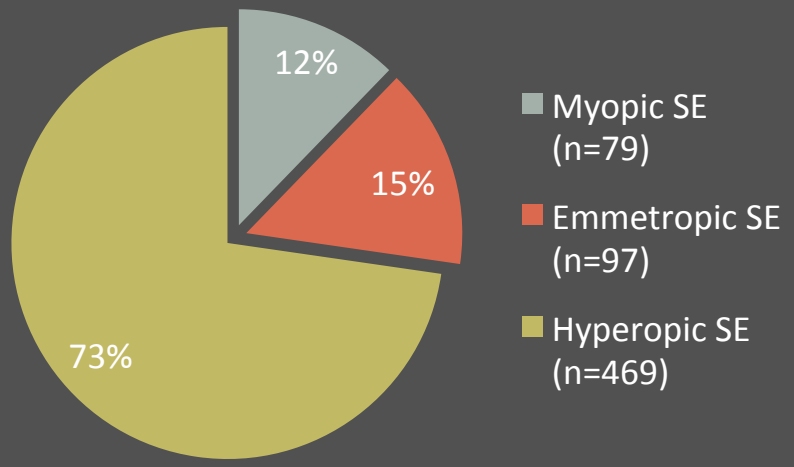
Allergies to medications

Clinical Study: Results

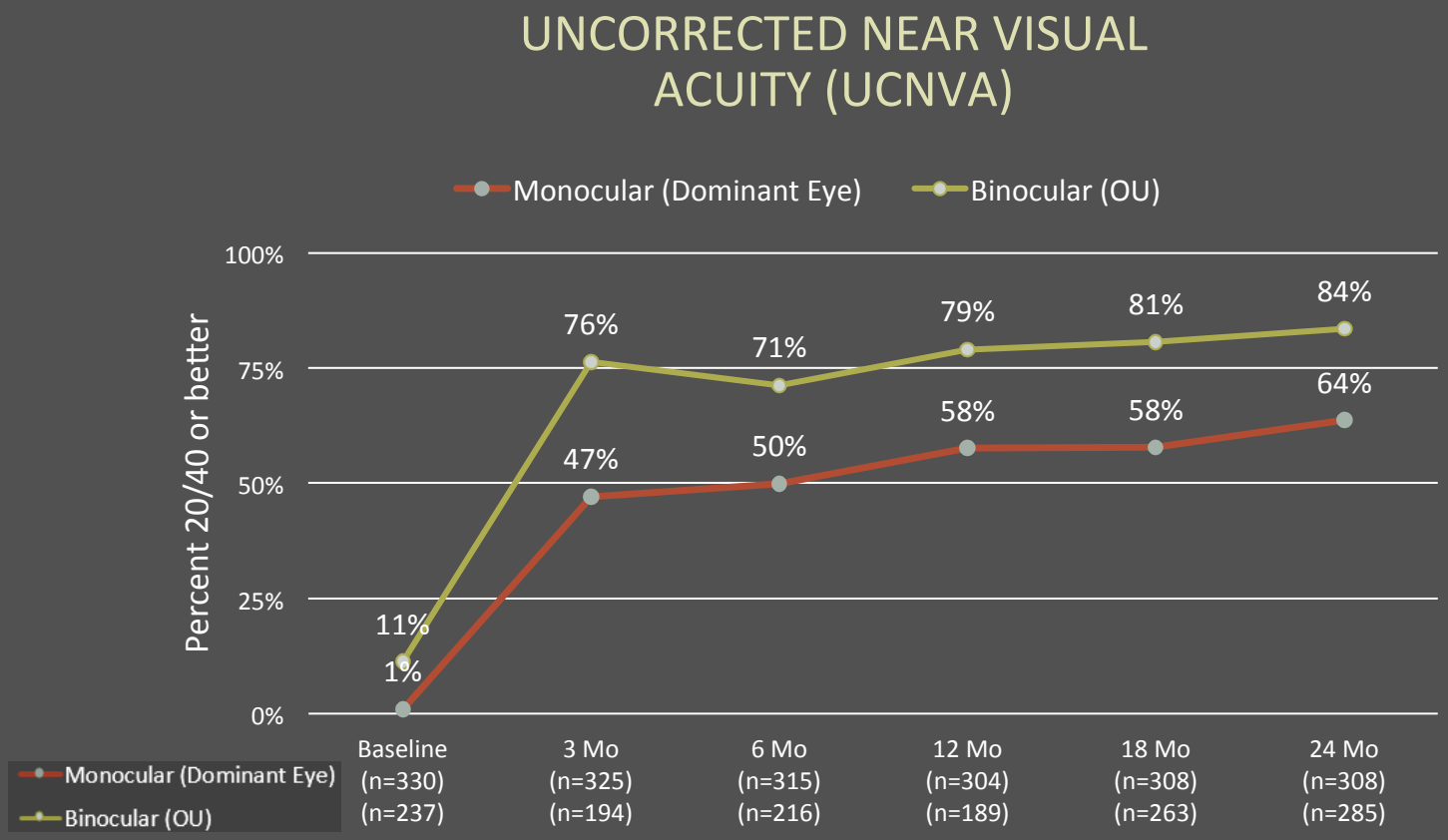
Demographics

- 645 eyes of 330 subjects have completed the surgery
  - 24 month follow-up complete
- Average Age 54.2
- Gender
  - Males = 54.3%
  - Females = 45.7%
- Manifest SE
  - Average = +0.29D
  - Range: -0.625D to +0.875D

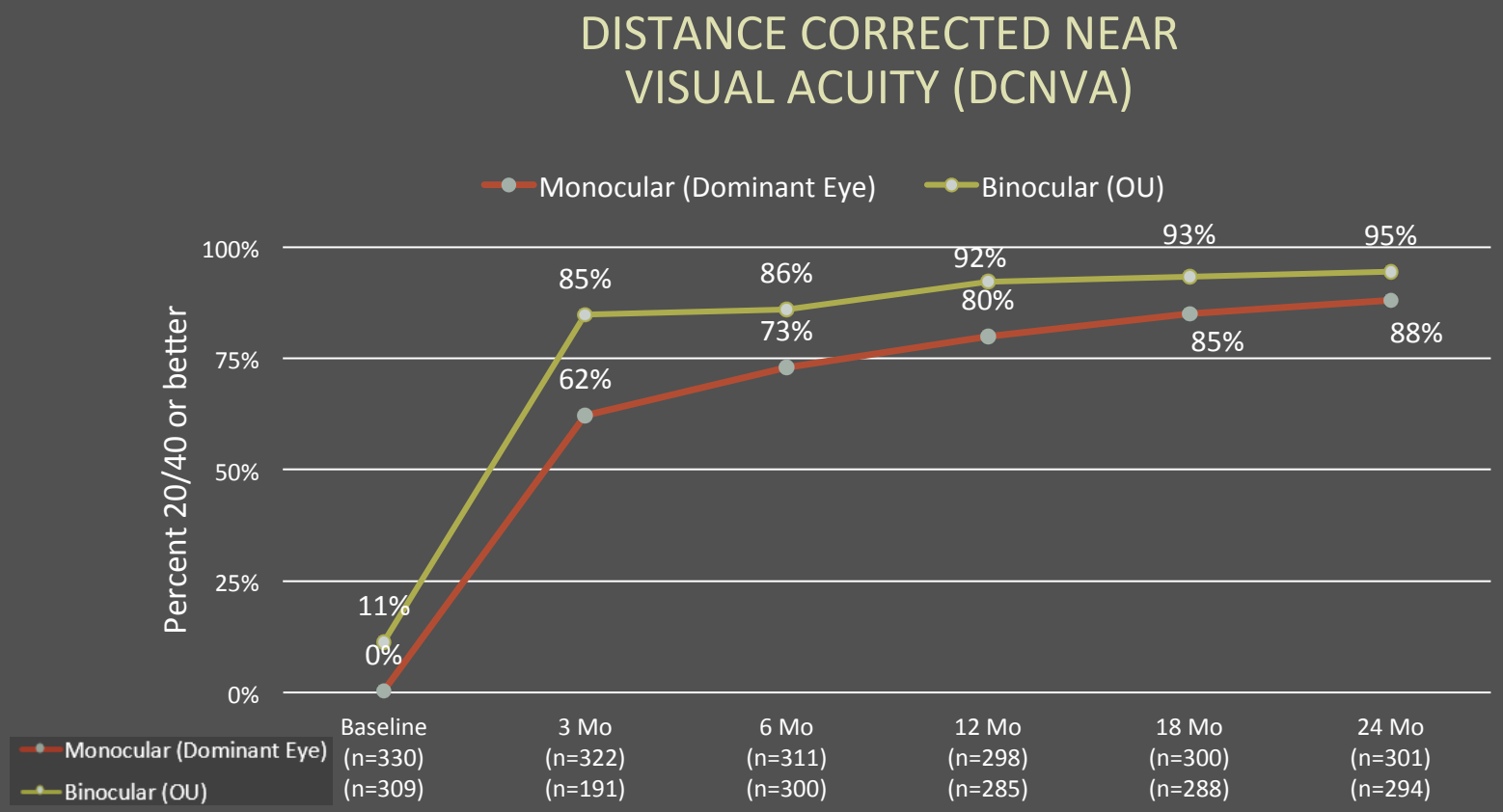
Distribution by Pre-op Manifest Refraction Spherical Equivalent (MRSE)



Uncorrected Near Vision Changes Over Time



Distance Corrected Near Vision Changes Over Time



Summary

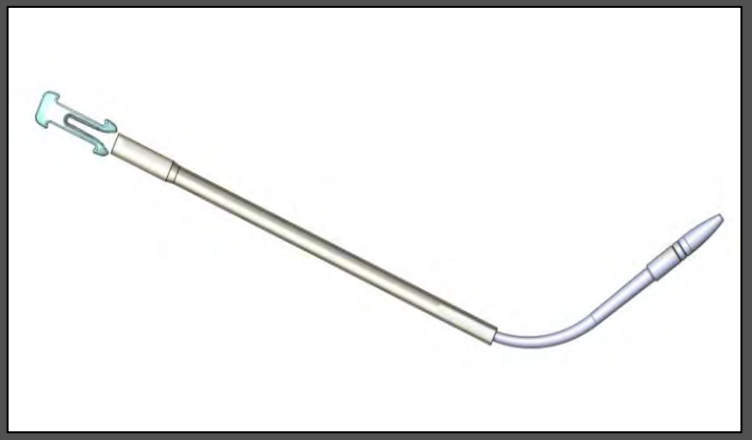
Conclusions

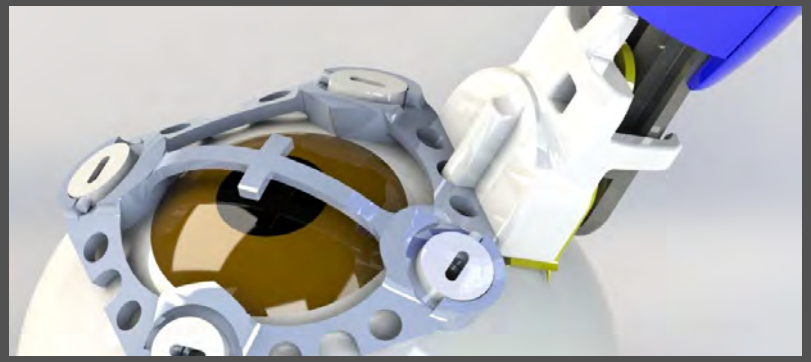
- Study results suggest PresView™ scleral implants may be effective in restoring near and intermediate vision in emmetropic presbyopes
- Near visual acuity continues to improve through 24 months
- 20% higher rate of binocular UCNVA at 24 months may be due to the inclusion of non-dominant eye, however, when DCNVA is examined, only a 7% higher rate of achieving 20/40 or Better persists.

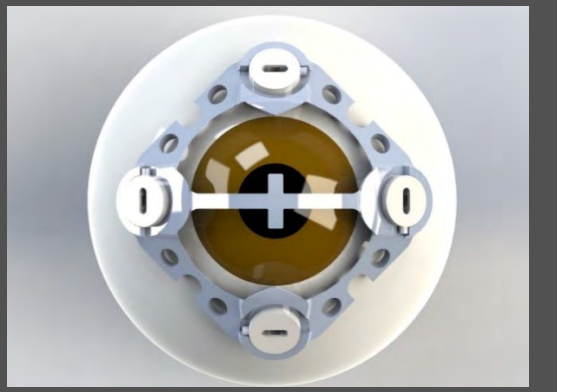
Current Study: US FDA IDE G140205
360 subject, 14 center with randomized control group

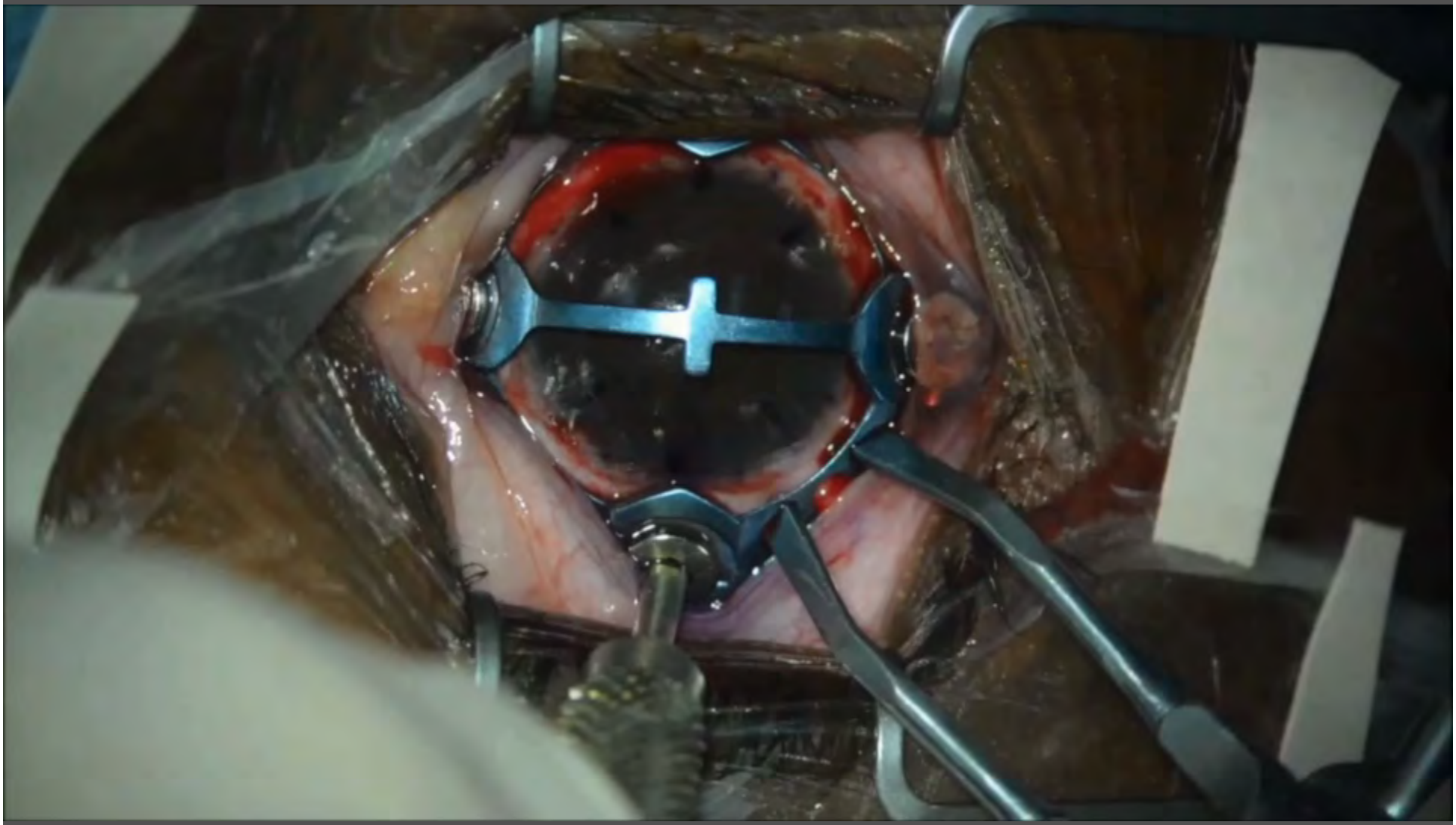
- Improved incision system and surgical procedure (VisAbility^{tm} Implant System)
- Study started in November 2014
- Anticipate complete enrollment and surgery of this cohort should be by end March 2016
- 12 Month follow-up will be completed in Q2 of 2017.

VisAbility™ Implant System
+ Docking Station for consistent results









Thank you for your attention