EARLY IMPLANTATION RESULTS OF THE FLUIDVISION AIOL IN SIGHTED EYES
Financial Disclosure

Allergan
Bausch and Lomb
Eyeonics
Glaukos
Harvest Precision
iScience
3 - D Vision
LensAR
PowerVision
ReVitalvision
WaveTec
Background

- FluidVision AIOL previously implanted in blind eyes
- Results correlated with 5-8D accommodation
- Current study is first to demonstrate accommodation in sighted eyes – in two phases
FluidVision Lens Design Goals

- Implantation in conjunction with conventional cataract surgery
  - In capsular bag
  - Standard insertion procedure
- Produce power change by fluid movement between haptics and optic, resulting in a shape change of the anterior lens surface
- Provide 5-10D of accommodation
- Accommodate forwards - same way as natural physiologic system
- Deliver through 4mm incision
FluidVision Design
Phase 1 Clinical Trial Design

- Purpose of this phase was to demonstrate the lens:
  - Provides excellent visual acuity
  - Has correct base (distance) power
  - Changes shape in response to accommodative stimulus
- Lens used in Phase 1 capable of internal shape change but not anterior power change
- Internal shape change measured by Visante OCT after administration of pilocarpine
- Included 3 implants into healthy, intact capsules
Phase 2 Clinical Trial Design

- Purpose of this phase to demonstrate the lens:
  - Provides excellent visual acuity
  - Provides >5D accommodation
- Power change measured using push down test
- Up to 20 implants total; reporting today on 1st three implants to reach 30 day follow-up
Clinical Results – Mechanism of Action

- All 6 patients demonstrated significant lens movement when stimulated with pilocarpine.
- Lens movement averaged ~100 microns at up to 3-month follow-up.
- Movement corresponds to shape change of anterior optic - approximately 5-6 diopters of accommodation.

![Typical OCT Image](image-url)

- Distance vision
- Accommodated
Clinical Results - Visual Performance

- All 6 patients had acuity of 20/40 or better, despite other ocular disease and sutures still being in place
- All patients were within 1 diopter of emmetropia
- All patients demonstrated significant accommodative movement
- Accommodation averaged 5.6D
Clinical Results - Summary

<table>
<thead>
<tr>
<th>Patient</th>
<th>BCDVA</th>
<th>S.E.</th>
<th>Accommodation*</th>
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<tr>
<td><strong>Phase 1</strong></td>
<td></td>
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<tr>
<td>1</td>
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<td>-0.75D</td>
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<tr>
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<td>+1.0D</td>
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</tr>
</tbody>
</table>

* Note that for patients in Phase 1, accommodation is calculated based on OCT measurement of lens movement; for patients in Phase 2, it is based on standard push down test.
Future Plans

- Up to 20 patients expected to be enrolled in Phase 2
- Injectable device expected later this year
  - Very similar in design to this device
  - Expected to offer 50% greater accommodation
  - Will be injectable through ≤4mm incision
Study Conclusions

- Early results in sighted eyes confirm the FluidVision lens provides excellent visual acuity and offers >5D of accommodative power.
- FluidVision lens mimics natural accommodation with shape change and “forward” accommodation.
- No change in surgical technique will be required.
Thank you for your attention