First Results of a Photovoltaic Subretinal Prothesis for Restoration of Central Vision in Atrophic Dry Age-Related Macular Degeneration in the United States

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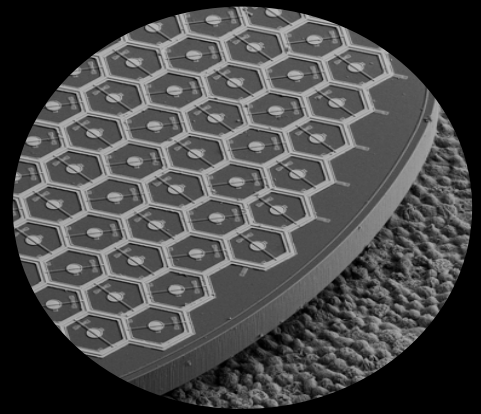


Financial Disclosure

- Y Le Mer, M Muqit, D Palanker are consultants for Pixium-Vision (Paris, France)
- D Palanker is the inventor of the PRIMA system. The patents are exclusively licensed by Stanford University to Pixium Vision.
- JA Sahel is a co-founder of Pixium Vision
- AW Eller and JN Martel: no financial interests

Photovoltaic Restoration of Central Vision in Advanced Atrophic AMD

PRIMA implant

- Array of subretinal photovoltaic electrodes within geographic atrophy
  - 2-mm wide, 30-µm thick wireless photovoltaic prosthesis (PRIMA, Pixium Vision, Paris, France), containing 378 pixels
- Electrical stimulation transmitted to RGCs which converts them to action potentials
- Wireless activation with near-infared light

Early Results

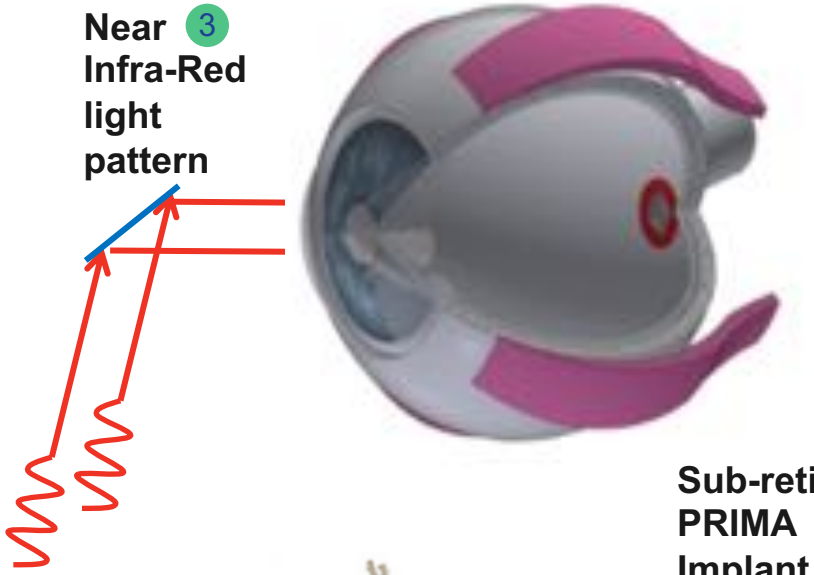
- 2 subjects have been implanted with the wireless photovoltaic subretinal prosthesis.
- Patients perceived visual sensitivity and bar orientation recognition in the former central scotoma without loss of residual natural acuity.
- No study-related serious adverse events have been observed at 3-month follow-up.

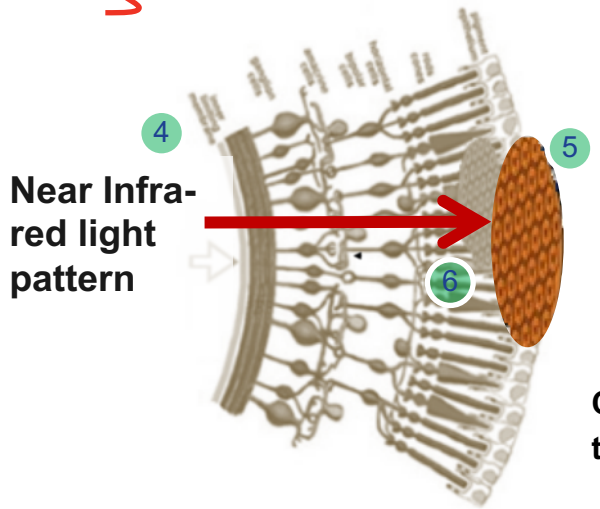
PRIMA system

1 Glasses with camera and mirror projector

2 Near Infra-Red light source (in Pocket Computer)

3 Near Infra-Red light pattern





4 Near Infra-red light pattern

5

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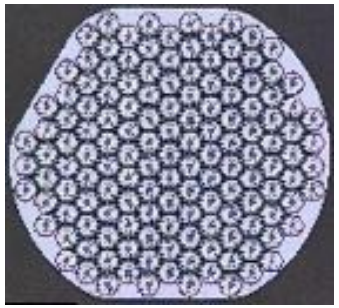
Sub-retinal PRIMA Implant



Chip is 2x2 mm and 30µm, the retina above the chip is ~0.1 mm thick, and has no photoreceptors

Early feasibility study design: safety and functionality

STUDY

Restoration of visual function in patients with advanced atrophic dry age related macular degeneration using the PRIMA system: open-label, non-randomized

CRITERIA

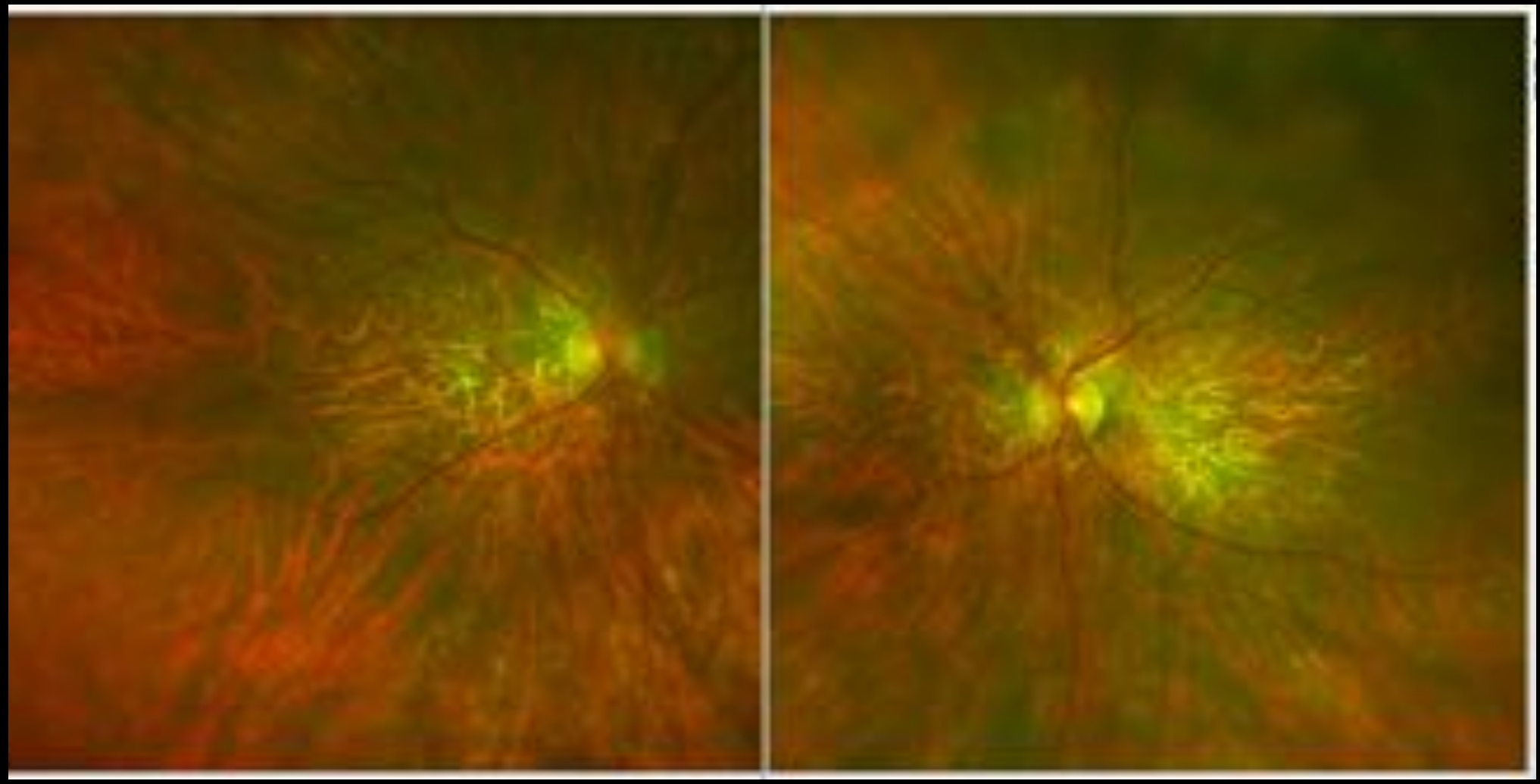
- 5 eyes of 5 patients
- VA < 20/400 (LogMar < 1.3)
- GA of at least 3 DD
- No CNV history
- No light perception in the atrophic area

Microperimetry:

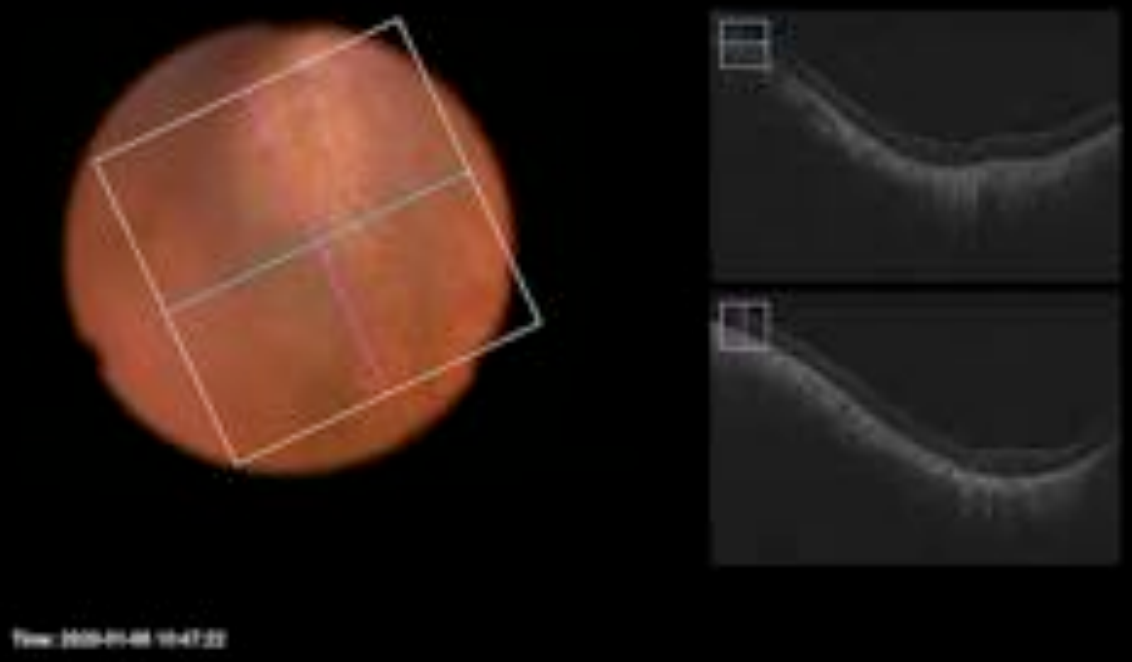
- Confirm the absolute scotoma in the atrophic area
- Identify the main PRL to ensure its preservation

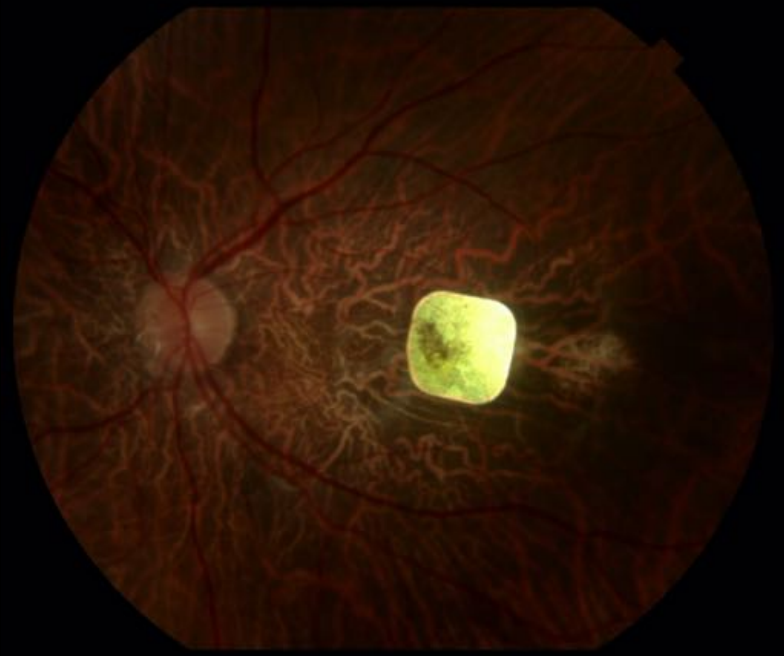
PRIMARY ENDPOINTS

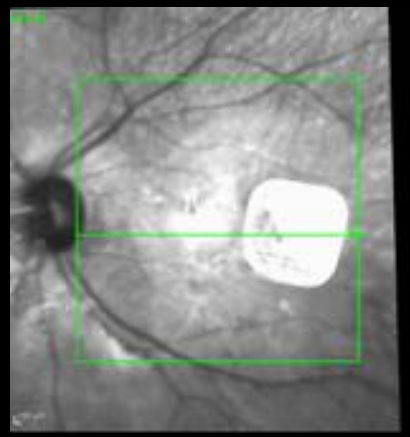
- Safety
- Elicitation of visual perception by electrical stimulation of the PRIMA implant
- Near visual acuity

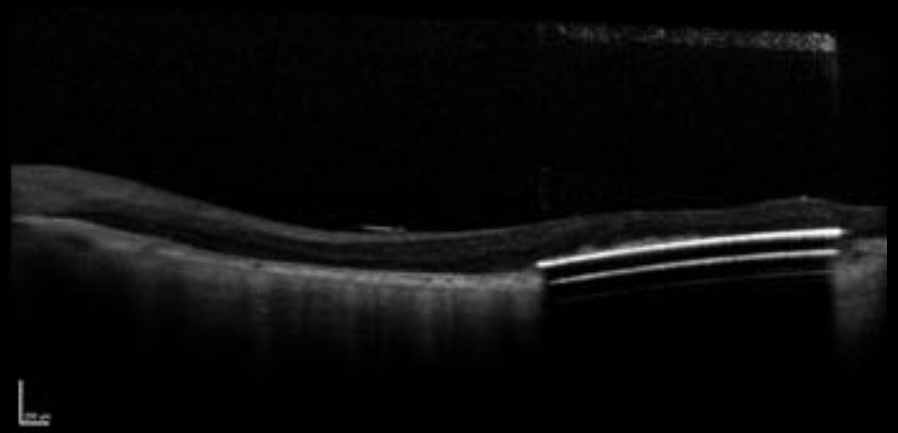


Surgery Video

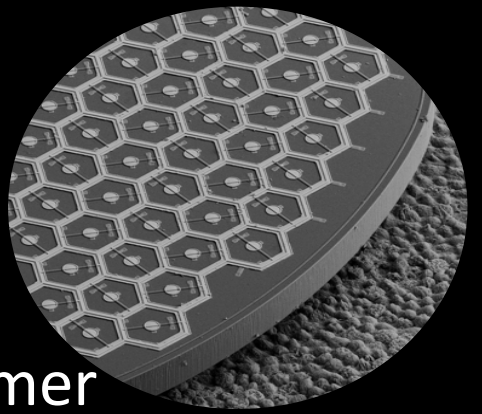






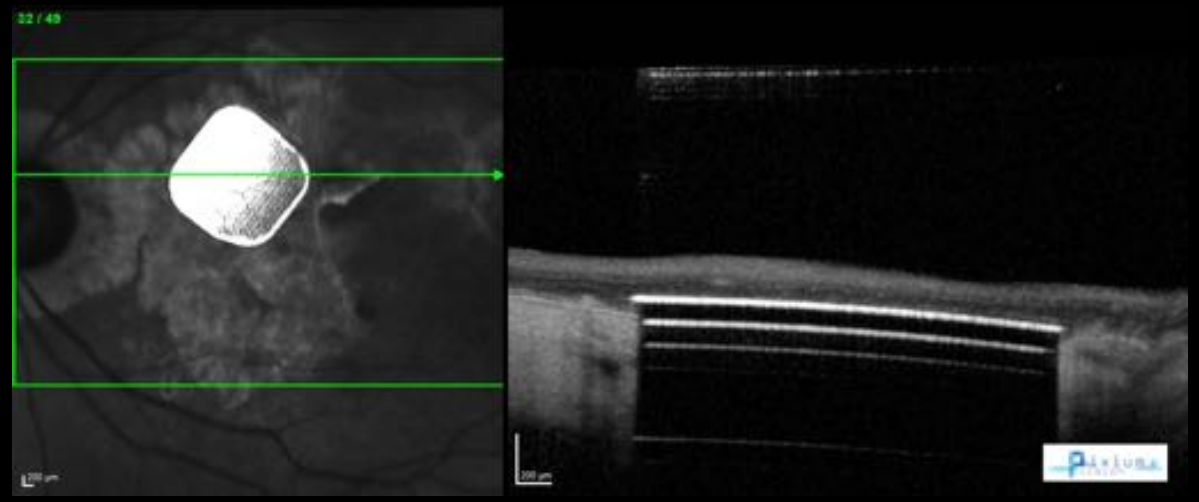


Preliminary Results



- 2 patients successfully implanted in 2020
- Recruitment is ongoing: University of Pittsburgh and Bascom Palmer
- Surgery duration ~ 2 hours
  - 1 patient GA, 1 patient local
- No decrease in residual natural vision compared to pre-operative visual acuity
- Vision training and low vision rehab sessions begun but then delayed due to COVID-19 pandemic
- Both patient perceived visual sensitivity and bar orientation recognition in the former central scotoma without loss of residual natural acuity
- Further testing of prosthetic vision is planned, including bar orientation, letter recognition, and acuity.

Future Directions



- Worldwide multicenter pivotal study is planned for early 2021
- Higher resolution implants with smaller pixels are being developed and tested in preclinical studies (Palanker's group at Stanford)
- Engineering advancements to visual interface and in-home use
- May have broad applicability to other retinal degenerations (RP, Stargardt)