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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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Purpose:
To test feasibility and safety of submacular implantation of a photovoltaic wireless prosthesis in 5 patients with central geographic atrophy, and to assess quality of prosthetic vision.

Methods:
A prospective study in patients with visual acuity ≤ 20/400 due to geographic atrophy of at least 3 optic disc diameters and with central absolute scotoma in the study eye. The 2-mm wide, 30-μm thick wireless photovoltaic prosthesis (Prima, Pixium Vision, Paris, France), containing 378 pixels (each 100-μm in diameter), was implanted subretinally within the area of geographic atrophy in the worse eye. The subretinal prosthesis functions in tandem with augmented-reality glasses containing a camera and near-infrared projector. Pixels in the implant convert light projected on the retina into electric current to stimulate the inner retinal neurons. Anatomic outcomes were assessed with fundus photography and OCT imaging.

Results:
To date, two subjects have been implanted with the wireless photovoltaic subretinal prosthesis. In both patients, the subretinal prosthesis remained within the geographic atrophy after implantation and 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. Three more implantations and further testing of prosthetic vision is planned, including bar orientation, letter recognition, and acuity.

Conclusions:
The photovoltaic wireless prosthesis (PRIMA) can be safely implanted under the atrophic macular neurosensory retina and can restore central visual perception in patients with advanced atrophic dry age-related macular degeneration. The full set of interim results for all 5 patients were expected by the end of 2020 but may be delayed due to the recent COVID-19 events.