Long term visual results of Prima chip in patients with geographic atrophy

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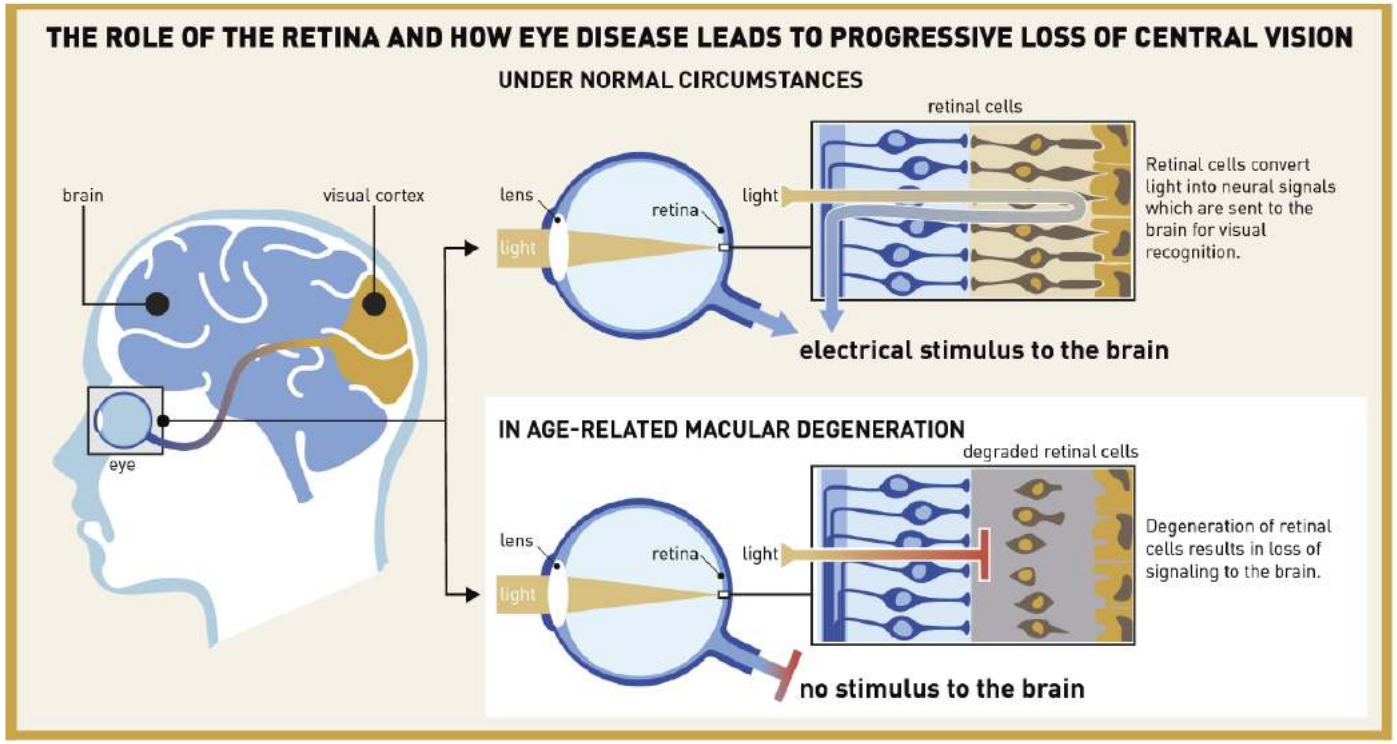
- Purpose: To evaluate the long term central prosthetic vision with the photovoltaic subretinal implant activated by augmented-reality glasses and simultaneous perception of the natural peripheral vision in patients with geographic atrophy.

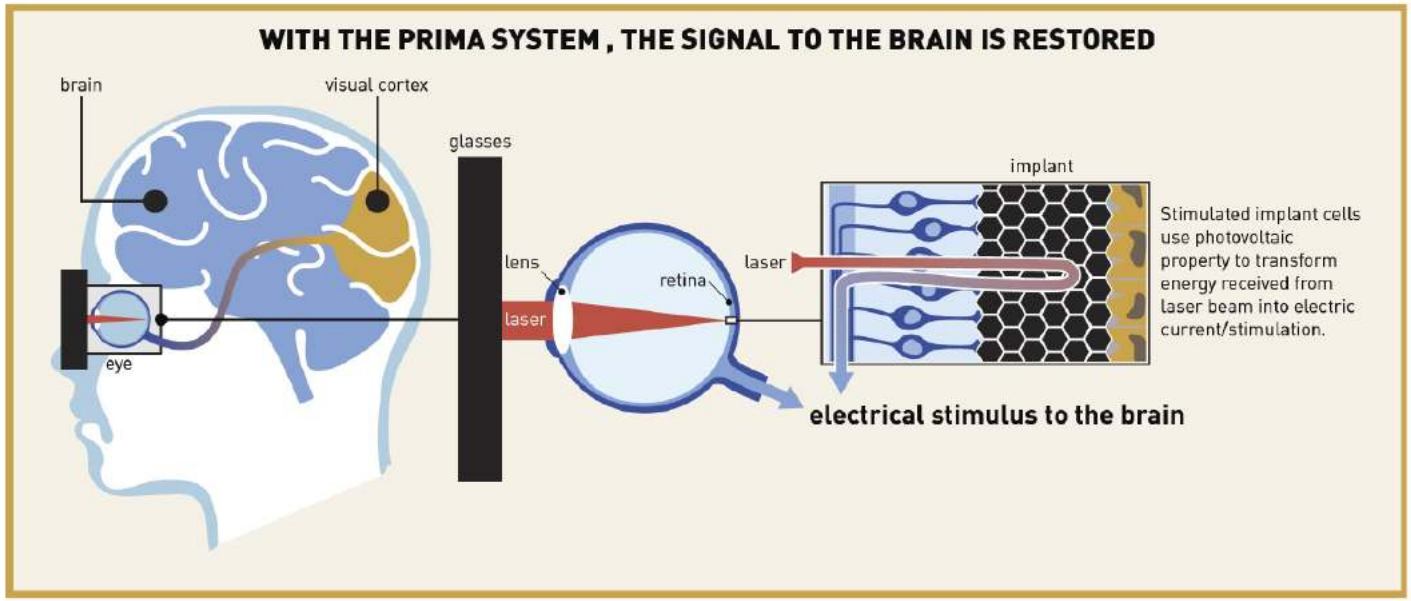
- Methods: Five patients with visual acuity ≤20/400 due to geographic atrophy of at least 3 optic discs diameters and no foveal vision have been implanted with a wireless photovoltaic chip (PRIMA, Pixium Vision) of 2x2mm in size, 30µm in thickness, containing 378 pixels of 100µm in width. Each pixel in the implant converts pulsed near-infrared light (880nm) projected from video glasses into electric current to stimulate the nearby neurons in the inner nuclear layer of the retina. Prosthetic acuity was assessed using electronic magnification. Simultaneous perception of central prosthetic and peripheral natural vision was evaluated under room lighting.

- Results: In all patients, the chip implanted under the macula remained stable and functional. One patient passed away after 18 months, and the 4 others have a follow-up extending now 3 years. No decrease in natural eccentric visual acuity was observed in any of the study eyes. All 5 patients could perceive white-yellow patterns with adjustable brightness, in retinotopically correct locations within previous scotoma during the follow-up period. With electronic magnification visual acuity of 20/63 was reached. Under room lighting, patients could simultaneously use prosthetic central vision and the remaining peripheral vision in the operated eye and in the fellow eye.

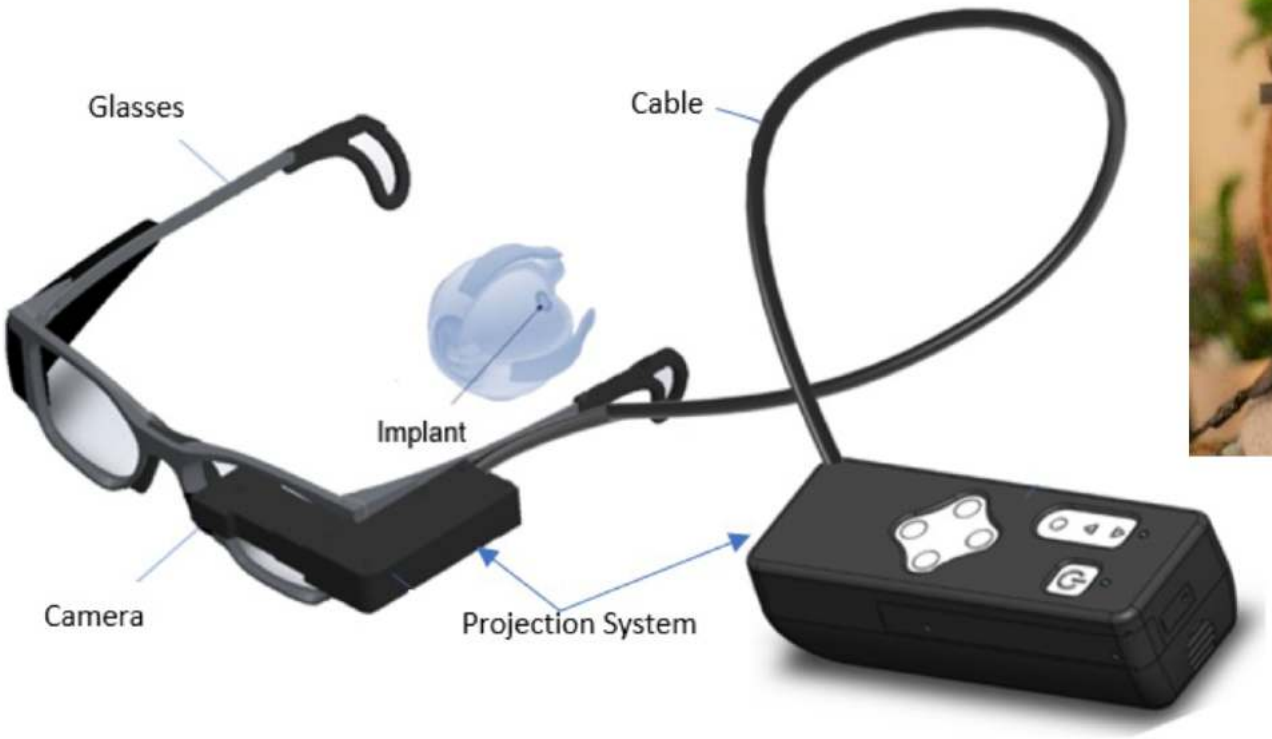
- Conclusions: Wireless chip PRIMA implanted under the atrophic macula in patients with geographic atrophy remains stable and functional during the 3 years of follow-up. The implant provides central visual perception with acuity close to the single pixel size of the photovoltaic array. Augmented reality glasses enable simultaneous perception of the central prosthetic and natural peripheral vision under room lighting, while electronic zoom provides significantly higher resolution.

PRIMA mechanism of action



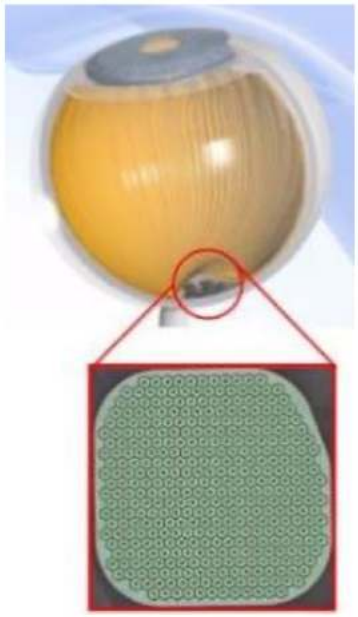


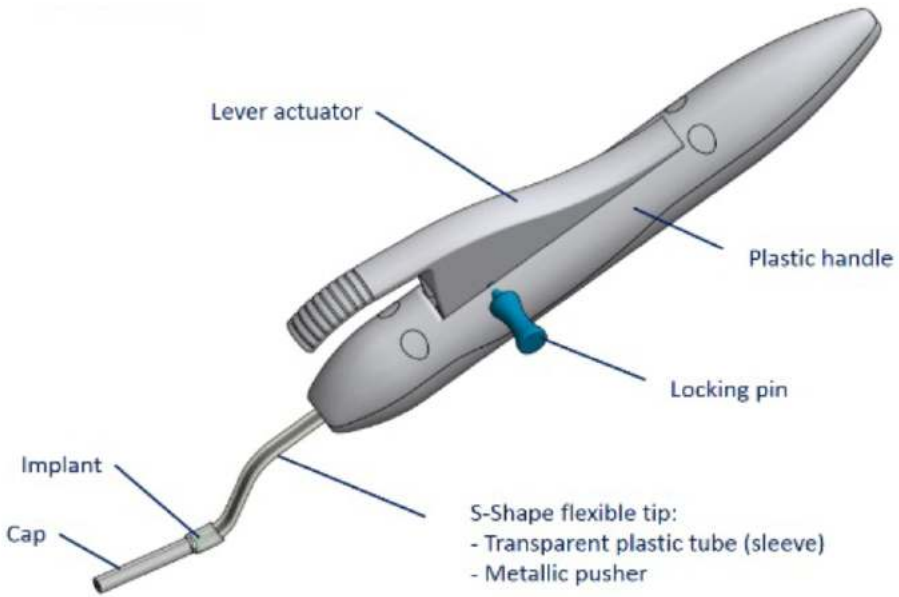
The PRIMA retinal implant system



Illustrations for information purposes – not indicative of actual size or clinical outcome

Implant and Delivery System Design





Implant features:

- Implant size:
  2 mm x 2 mm x 30 µm
- 378 pixels
- Pixel size: 100 µm

PRIMA, Human Feasibility Studies in patients suffering from Advanced dry-AMD

FEASIBILITY STUDIES

Feasibility Study of Compensation for Blindness With the PRIMA System in Patients With Dry Age Related Macular Degeneration

CRITERIA

- 60 years or older
- Visual Acuity of LogMAR 1.3 (20/400) or worse
- No foveal perception

ENDPOINTS

Visual perception with PRIMA implant, visual acuity and safety assessment after implantation.

PRIMA-FS
ClinicalTrials.gov

5 patients implanted in France
Recruitment closed
Positive interim data available

CLINICAL SITES

Fondation Ophtalmologique Adolphe de Rothschild

Dr. Y. Le Mer
Dr. J-F Girmens

PRIMA-FS-US
ClinicalTrials.gov

5 patients in USA – **Recruitment open**
Safety assessment at 12 month after implantation

Pr. J. Sahel
Dr. J. Martel

Pr. B. Lam,
Pr. N. Gregori
Pr J.-M Parel

UPMC LIFE CHANGING MEDICINE

Bascom Palmer Eye Institute
UNIVERSITY OF MIAMI HEALTH SYSTEM

Feasibility Study in France

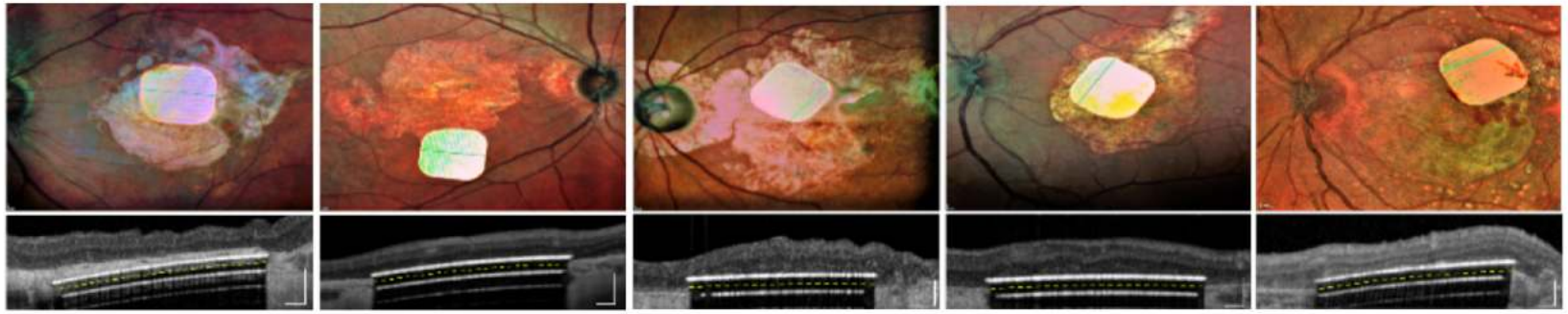
Feasibility Study of Compensation for Blindness With the PRIMA System in Patients With Dry Age Related Macular Degeneration

The primary objective of the feasibility trial is to demonstrate that the subjects have visual perception elicited by the PRIMA System.

The key-inclusion criteria imply that the patient:

- Is **60 years** or older at the date of inclusion;
- Has a confirmed diagnosis of **advanced dry age related macular degeneration** with an atrophy size of at least 3 optic disc diameters;
- Has best corrected visual acuity in the study eye of **logMAR 1.3 (20/400) or worse** measured by ETDRS;
- Has **no foveal perception** measured by micro-perimetry in the study eye;
- Has a **refraction of study eye between –3 and + 4** (limits included) for patients with IOL (there is no refraction criteria for patients with natural lens);
- Understands and accepts the obligation to present for all schedule follow-up visits.

PRIMA Feasibility Anatomical Results



**The implant appears in OCT twice thicker due to higher refractive index of Si compared to that of the retinal tissue.*

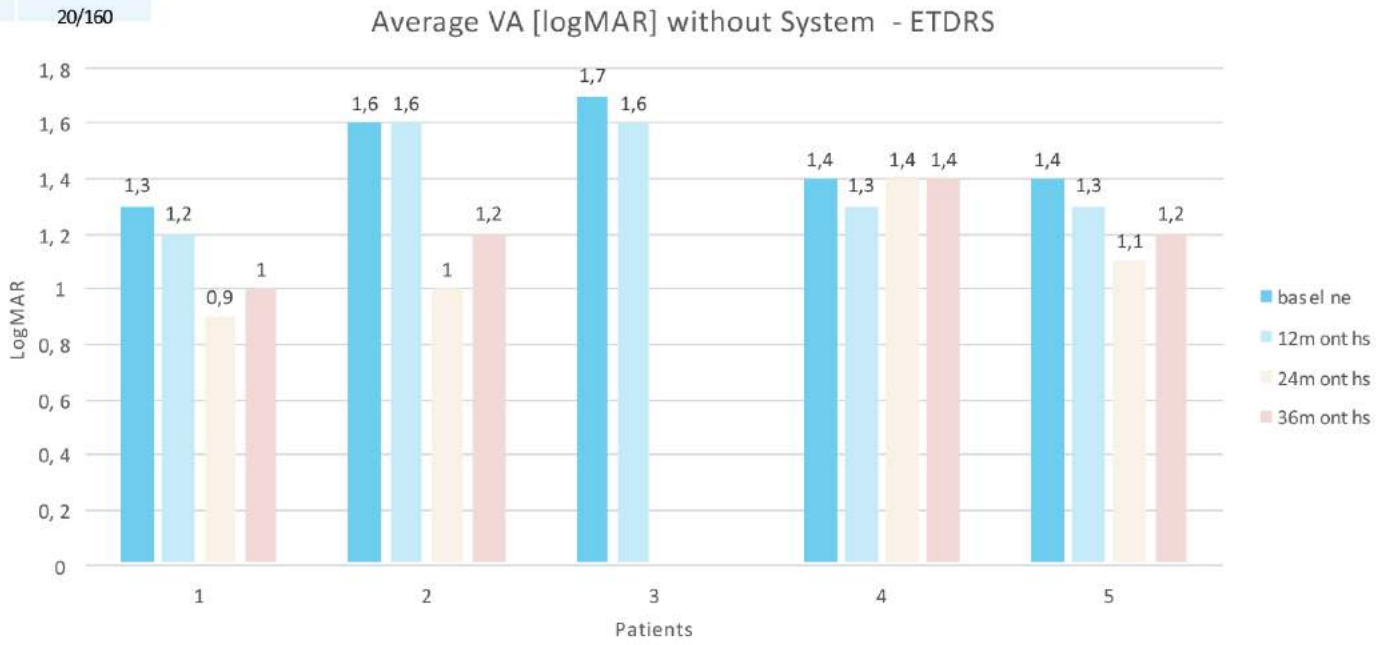
Dashed line indicates position of the back side of the implant resting on Bruch's membrane.

Implant location in the macula	Intra-choroidal	Central subretinal	Central subretinal	Off-center subretinal	Central subretinal
Average distance from implant to bottom of INL at 3, 6, 12 months (µm)	127 103 138	34 28 39	43 35 39	37 38 35	51 39 37

Palanker et al., Photovoltaic Restoration of Central Vision in Atrophic Age-Related Macular Degeneration, Ophthalmology 2020

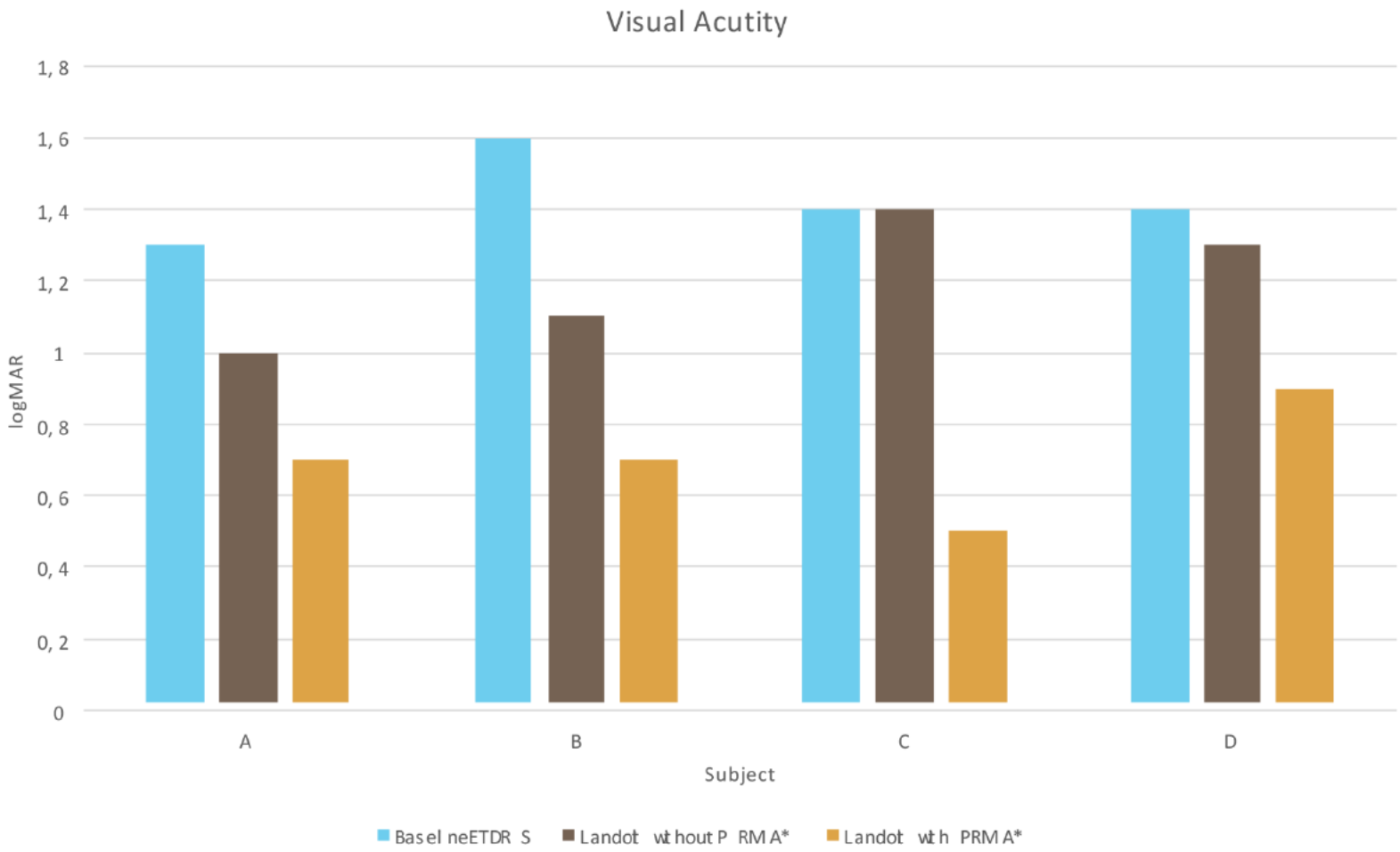
Natural visual acuity (ETDRS) of study eye in Feasibility study

LogMAR	Snellen
1,7	20/1000
1,6	20/800
1,4	20/500
1,3	20/400
1,2	20/320
1,1	20/250
1	20/200
0,9	20/160



PRIMA could be safely implanted under the atrophic macula while preserving the residual natural peripheral visual acuity, measured via ETDRS in the Feasibility study

PRIMA Feasibility visual acuity tests



*Data captured at 24 month after implantation, system includes a zoom function

PRIMA Feasibility daily living observations

Single case reports may not be representative for other patients using the PRIMA System

Feasibility studies : Conclusions

- Subretinal implantation of the wireless PRIMA microchip in atrophic dry AMD is feasible.
- No decrease in residual natural vision compared to pre-operative visual acuity.
- ALL 5 patients reached the functional primary end point of the feasibility study (visual light perception in the former scotoma).
- PRIMA provided the best prosthetic visual acuity to date
- Most subjects are able to read single letters and small words
- Some patients are able to read words and small sentences in different light conditions (Outdoors and ambient light)