The safety and efficacy of a second generation suprachoroidal retinal prosthesis

Penelope Jayne Allen, FRANZCO
East Melbourne, Victoria

Purpose:
The success of our prototype clinical trial (NCT01603576) of a suprachoroidal retinal prosthesis led to development of a second generation device, with the aim of providing visual information to profoundly visually impaired patients (NCT03406416). We believe that use of the device outside of the laboratory will confirm it’s real world benefit. We are assessing it’s safety and performance of orientation and mobility (OM) and activities of daily living (ADL) tasks pre-implant and post activation of the device in ON and OFF modes.

Methods:
The second generation device was implanted unilaterally in four participants with advanced retinitis pigmentosa. Post operative follow-up included clinical examination, fundus photography and optical coherence tomography (OCT). After a period of vision rehabilitation training, participants were assessed on three tasks; table-top search (TTS), doorway detection (DWD) and obstacle avoidance (OA) with device on and device off. Assessments were: prior to implantation (baseline, BL); and at 12-week intervals post device activation. No assessments occurred during the COVID-19 lockdown.

Results:
The surgery was uncomplicated. Post operative recovery was uneventful. Fundus imaging and OCT imaging confirmed the device position and the absence of retinal trauma. OCT imaging showed only minor movement of the device within the first three months.

All patients performed better for all tasks with device on compared to device off. For TTS, naming location of objects is good but identification is more difficult. DWD performance is excellent with Device On touch distance within 10 cm of target on average. Assessment of OA reveals that object detection is excellent but avoidance is moderate (Collisions = 17.3 to 36% Device On vs. 37.3 to 50% Device Off).

Conclusions:
A suprachoroidal retinal prosthesis can be safely implanted. Over eighteen months of follow-up clinical findings, fundus photography and OCT imaging confirmed safety and stability of the approach.

The initial results for the 44Ch suprachoroidal retinal prosthesis indicate that the device has the capability to improve functional vision for people with profound vision loss from RP. Further training, device refinement and familiarisation of visual input generated by the device could improve functional performance with the device and we continue to collect this data.