RETINA AUSTRALIA 2022 RESEARCH GRANT: FINAL REPORT

CENTRE FOR Eye Research Australia

Project title

Improving real-world mobility and assessing long-term safety outcomes with a retinal prosthesis ("Bionic Eye")

Investigators

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Project synopsis

Four participants with end-stage retinitis pigmentosa (inherited retinal disease) were implanted with a second-generation Australian bionic eye (retinal prosthesis) in 2018 as part of a clinical trial (clinicaltrials.gov #NCT03406416). The 2-year clinical trial demonstrated excellent device stability and improved orientation and mobility (laboratory-based), functional vision and activities of daily living outcomes, with an intensity-based visual processing method (Lanczos2). However, objects with a poor contrast relative to the background (i.e. white against white) were not well-detected and shadows in real-world settings were accidently detected as objects with Lanczos2 method. Hence, we developed a novel depth-based vision processing method (Local Background Enclosure; LBE), aimed at improving these specific shortcomings identified within the initial clinical trial.

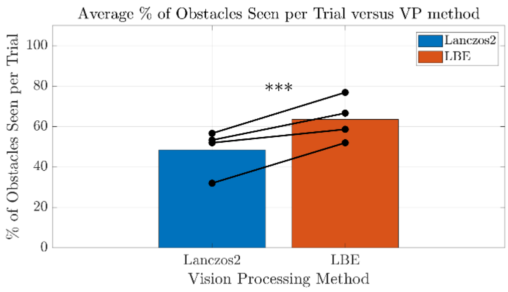

Figure 1 – Overall percentage of obstacle seen per trial for Lanczos2 and LBE

In the recent extension study, we measured visual outcomes with the LBE method in the four participants already implanted with a bionic eye in both a controlled laboratory environment (obstacle avoidance task, white background) as well as in a real-world environment (novel outdoor streetscape protocol) designed to specifically test conditions that frequently include shadows. We also monitored the long-term safety and functionality of the device out to 4 years after implantation as a secondary outcome that is of vital importance to prospective bionic eye recipients.

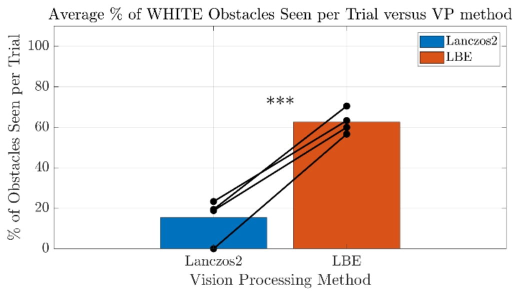

Figure 2 – Percentage of white obstacles seen per trial with Lanczos2 and LBE processing methods.

Results

1. Obstacle avoidance task: Overall, LBE performed significantly better than Lanczos2, for the detection of obstacles (Figure 1). For low contrast (white) obstacles, LBE performed markedly better than Lanczos2 (Figure 2), whereas for high contrast (black) obstacles, Lanczos2 performed better (Figure 3). Critically, LBE performance was equivalent in detecting both high and low contrast obstacles, whereas Lanczos2 is only able to reliably detect high contrast obstacles. Therefore, LBE is a better all-round vision processing algorithm for everyday use indoors, less biased by the contrast of the object in the environment. LBE also outperformed Lanczos2 for the detection of mannequins, overhanging boxes and large bins, whereas Lanczos2 outperformed LBE for detection of ground-based boxes.

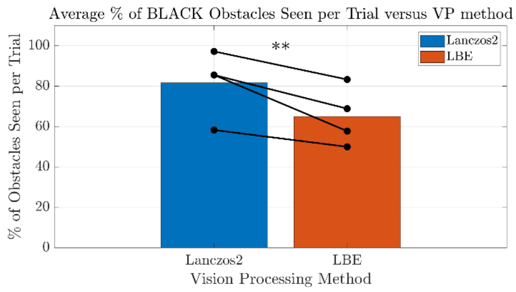

Figure 3 – Percentage of black obstacles seen per trail with Lanczos2 and LBE processing methods.

2. **Novel outdoor streetscape protocol:** Our protocol is the first real-world streetscape-based work conducted with a retinal prosthesis. Regulatory authorities have emphasised the importance of presenting data showing relevance of bionic eyes to the real-world setting. Participants encountered typical obstacles in an urban streetscape, including parked vehicles, rubbish bins, street signs, poles, trees, overhanging branches, path shorelines and pedestrians. They also encountered typical challenges on an urban streetscape including shadows and window reflections.

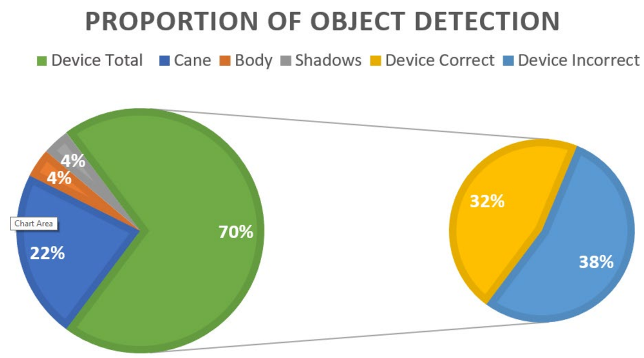

Figure 4 –Object detection as a proportion of all objects detected.

As a proportion of all objects detected, the highest proportion were made using the device (70.3%; Figure 4). This is markedly higher than detections with the cane (22.3%) or body (3.8%). This demonstrates the usefulness of the device to detect objects in real-world settings to give advance warning to the user of an object in their path. Detected objects were correctly identified by the device 34.4% of the time using LBE and 30.6% of the time using Lanczos2, so vision processing method did not alter the object identification ability of the retinal prosthesis. Shadows were incorrectly identified as objects exclusively by Lanczos2 and accounted for 3.5% of all detections. This demonstrates that LBE successfully addresses one of the shortcomings of Lanczos2, with no instances of participants mistaking shadows for objects. The time to complete the tasks was not significantly different across LBE and Lanczos2.

After completion of the tasks, participants were asked to self-report their orientation and mobility performance and preference of visual processing method. Participants commented that overall the device added a degree of confidence in their ability to navigate their environment with comments such as “prevents [me] walking into trees,” enabled the “pick up [of] obstacles in advance,” “would be helpful for doorway detection” and that the device “gives an awareness of what is around” and the ability to “track moving objects.” Preference across the Lanczos2 and LBE processing methods was varied with each mode preferred depending on the scenario.

3. **Safety profile and long-term device functionality:** Psychophysics testing demonstrated that the function of the device and the level of stimulation required to elicit a visual response has remained stable across all participants. This is an important finding, as it indicates excellent reliability and functionality of the device over a 4 year time period. In addition to functional assessments, analysis of the safety of the implant has also been closely monitored at 6 monthly intervals with clinical examination, colour fundus photography and optical coherence tomography (OCT). These assessments have demonstrated the safety and stability of the device with no adverse events occurring across all participants. Together, the psychophysical and clinical assessments demonstrate the device is likely to be viable for long-term use.

Academic outcomes – Accepted international conference abstract

Lauren Moussallem; Lisa Lombardi; Matthew A. Petoe; Rui Jin; Maria Kolic; Elizabeth K. Baglin; Carla J. Abbott; Janine G. Walker; Nick Barnes; Penelope J. Allen, *Navigational outcomes with a depth-based vision processing method in a second generation suprachoroidal retinal prosthesis*, ARVO, April 23-27 2023, New Orleans, USA.

Conclusion

The outcomes of this study are critical to optimising the visual processing strategy and to establish the real-world efficacy of the unique Australian bionic eye. The depth-based vision processing method performed better overall than the intensity-based method navigating an obstacle course seeded with both high and low contrast obstacles. Hence, there is potential for the depth-based method to be incorporated into the bionic eye vision processing system to aid navigation. The device also demonstrated application in real-world environments for the detection of everyday objects. Additionally, the functionality of the bionic eye system and safety and stability of the suprachoroidal prosthesis over a 4-year period was established.