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Early safety data for retrieval of a stent-based endovascular neural recording array

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Introduction: Safe retrieval of implanted devices is critical when surgical/device complications occur, or when designed for non-permanant use. We have previously reported the ability of our endovascular brain-computer-interface (BCI), the Stentrode™, to access the brain via blood vessels and acquire brain signals endovascularly from the primary motor cortex [1]. Here we investigated retrieval of the Stentrode from within a dural sinus of sheep after an implantation period of seven days to explore feasibility of device retrievability and its potential to be used as a temporarily implanted neurodiagnostic tool.

Material Methods and Results: Corriedale ewes (2 adults, 18&24 months, 45&60 kg, respectively) were used, since their dural sinuses are comparable in size to those of humans [1]. We implanted a Stentrode (40mm long self-expanding closed-cell nitinol stent shape-set to 10mm diameter) in the left transverse sinus. The proximal connector was secured transcutaneously for data acquisition. A ring electrode, placed into a subcutaneous pocket (~5cm wide) between the two scapulae, was used as the reference during unipolar brain signal acquisition. To assess the quality of the Stentrode-acquired brain signals, we recorded, steady-state visually evoked potentials (SSVEP) (g.Tec system, 0-100Hz bandpass, 50Hz notch) in response to a visual stimuli flickering at 3&6Hz. The Stentrode was retrived 7 days after deployment. The animal was monitored and allowed to recover for 30 days. Post euthanisation, the implanted and control dural sinuses were sectioned for histological processing and stained (H&E, Masson's trichrome, and Voerhoff-Giesen). Histological assessment was performed according to a predefined grading scheme (wall injury, inflammation, fibrin, haemorrhage, necrosis score, & endothelial cell loss etc.). For both animals, high quality SSVEP neural signals were acquired immediately after implantation and the retrieval procedure 7 days post-implantation was safe for the animal's general health and its dural sinuses.

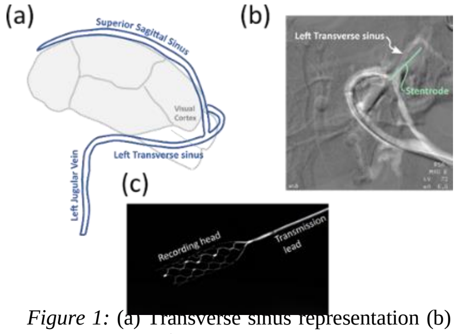

Figure 1: (a) Transverse sinus representation (b) X-ray image of the catheter assembly in the transverse sinus (c) Stentrode components.

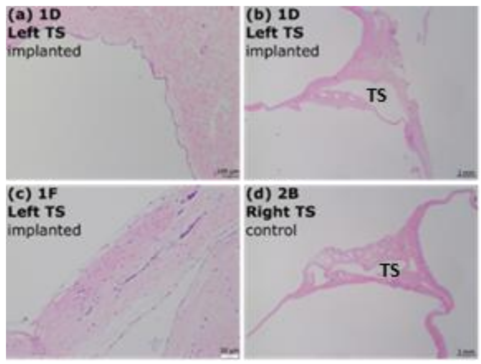

Figure 2: Histopathology of left TS (implanted) post-retrieval was similar to that of the control tissue (right TS). TS-transverse sinus, JV-jugular vein. (a) left TS with no histological lesions. (b) circumferential images of left TS with surrounding dura. (c) left TS, minor stromal inflammation, with scattered lymphocytes surrounding small vessels in the dural stroma. (d) circumferential images of the right (control) TS with surrounding dura.

Discussion: The device can record high quality signals shortly after implantation. The demonstrated feasibility of retreiving an endovascular BCI 7 days post-implantation supports further development of the Stentrode for application as a temporary recording device. A limitation of the study is that neointimal growth around implanted stent-like devices across weeks/months results in endothelialization. Complete endothelialization (>>7 days) may limit the retrievability of the Stentrode, a question that will be the focus of future work.

Significance: Retrieval of a stent-based endovascular neural recording array following 7 days of implantation can be performed with minimal to no observed effects on animals' general health and dural sinuses.

References:

[1] T. J. Oxley et al., "Minimally invasive endovascular stent-electrode array for high-fidelity, chronic recordings of cortical neural activity," Nat. Biotechnol., vol. 34, no. 3, 2016, doi: 10.1038/nbt.3428.