TRANSLATION OF AN OFF-THE-SHELF, IMPLANTABLE CARDIAC MONITORING DEVICE FOR THE MEASUREMENT OF GASTRIC ELECTRICAL SLOW WAVE ACTIVITY, VALIDATED WITH HIGH-RESOLUTION ELECTRICAL MAPPING

Jarrah M. Dowrick[1], Peter Tremain[1], Lisa Jungbauer Nikolas[2], Sarah J. Offutt[2], Jonathan C. Erickson[3], Timothy R. Angeli-Gordon[1,4]

[1]Auckland Bioengineering Institute, University of Auckland, Auckland, New Zealand

[2]Neuromodulation, Medtronic, Minneapolis, MN, USA

[3]Department of Physics and Engineering, Washington and Lee University, Lexington, VA, USA

[4]Department of Surgery, University of Auckland, Auckland, New Zealand.

Motivation: Gastric electrical slow waves are one of the critical governing mechanisms of the mechanical activity of the stomach. Slow waves offer a biomarker of gastrointestinal function, where actionable biomarkers are critically needed. Gastric slow waves are often measured in acute studies using high-resolution flexible printed circuit (FPC) electrode arrays. For longer-term recovery studies, most slow wave recordings have been made using wired electrodes, with the wires passing transcutaneously through an incision or via the nasopharyngeal passage, resulting in discomfort and risks for infection during chronic implantation. Custom implantable slow wave recording devices are expensive to develop and challenging to translate to chronic studies or clinical applications. In this study, a clinically-approved wireless, implantable cardiac monitoring device, the Reveal LINQ™ (Medtronic plc, Dublin, Ireland), was translated to record *in vivo* gastric slow waves.

Methods: Ethical approval was granted by the University of Auckland animal ethics committee. Following anesthesia and laparotomy, a Reveal LINQ was placed directly on the serosa of 7 female weaner pigs (42 ± 2 kg) immediately adjacent to a validated FPC array (256 electrodes, 4 mm spacing; Fig. 1). Slow waves were recorded simultaneously from the Reveal LINQ and FPC electrodes for 7.5 min using customized settings. The signals captured by each device were aligned in time, and pairwise comparisons of the slow wave period, amplitude, signal-to-noise ratio (SNR), and downstroke width were performed. The time-averaged slow-wave signal for the Reveal LINQ and FPC array was calculated, and the signal morphology was compared (Fig. 2).

Results: The Reveal LINQ and FPC electrodes detected slow waves with comparable SNR (25 ± 5 dB vs. 26 ± 7 dB, respectively, $P = .59$) and period (22 ± 6 s vs. 22 ± 6 s, $P = .99$). The slow wave amplitude (0.6 ± 0.3 mV vs. 1.4 ± 0.5 mV, $P < .001$) and downstroke width (0.7 ± 0.3 s vs. 0.8 ± 0.3 s, $P = .008$) were significantly different between the Reveal LINQ and FPC electrodes. However, the slow wave amplitude captured by the Reveal LINQ was correlated with that of the FPC electrodes, suggesting that the amplitude difference is likely due to hardware amplifiers in the respective devices. Signal

morphology was similar between the devices, with the main discrepancy being a quicker recovery phase in the Reveal LINQ signals (Fig. 2).

Conclusions: These findings demonstrate the feasibility of recording gastric slow waves using a Reveal LINQ device. Small, programmable, leadless, two-electrode devices like the Reveal LINQ may offer an efficient solution for wireless, implanted, direct-contact monitoring of gastric electrical slow waves, enabling future research and clinical studies, for example, investigating post-surgical impacts on gastric slow waves.

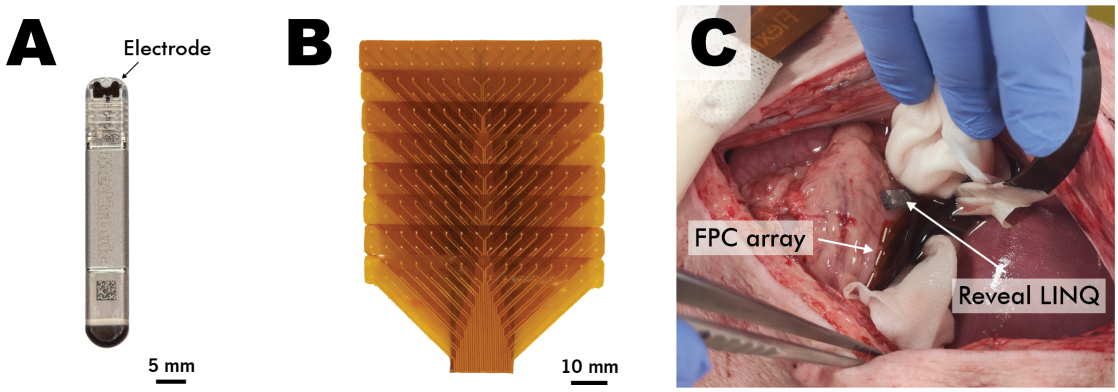

Fig. 1: An Reveal LINQ **(A)** and FPC array **(B)** placed on the serosal surface of the *in vivo* pig stomach **(C)**.

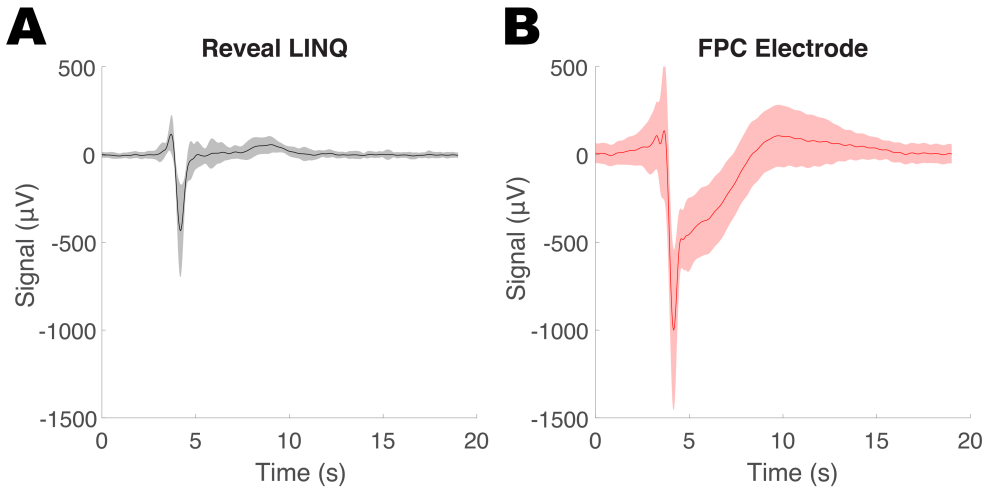

Fig. 2: Time-averaged slow-wave signals from **(A)** Reveal LINQ and **(B)** FPC electrodes. The solid line represents the mean signal, and the shaded regions indicate the standard deviation of the signals.