

Insertion of Planar and 3D Matrix-style Electrode Arrays Using Ultrasonic Vibration **Decreases Electrode Shank Damage While Maintaining Electrode Recording Integrity**

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Introduction

- Intracortical electrode arrays (IEA) provide precise spatial recording of extracellular neural signals with high temporal precision, however, chronic recordings lose recording fidelity over time due to the host's foreign body response (FBR).
- Some approaches to minimize the FBR include using small diameter (<20 µm) electrode shanks and "floating" arrays which move with the brain decreasing stress at the electrodetissue interface.
- Small diameter carbon fiber electrode shanks have demonstrated a decreased FBR but have a lower absolute buckling force, requiring secondary support during insertion.
- Vibrated insertion has been shown to decrease insertion force and tissue damage in peripheral and brain tissues.
- The NeuralGlider[®] Inserter (NeuralGlider) is an ultrasonic transducer capable of coupling to various electrode types, allowing vibrated electrode insertions, decreasing tissue damage and improving insertion of small electrodes without secondary insertion support.



A. Langevin style Transducer COMSOL model driven at 1V was used to optimize head to tail mass ratio and horn morphology. Device resonance frequency was estimated at 26.8 kHz with a displacement magnitude of 0.09 µm/V. B. Transducer is potted in silicone and encased in an aluminum housing to maintain alignment during operation. C. Transducer axial displacement was measured at increasing power outputs to validate using Keyence LK-H052 optical encoder. D. Insertion forces with and without vibration quantified ex-vivo (Sprague-Dawley (rat), male 150-200 g). E. Vibration reduces maximum insertion force and tissue surface deformation. F. Vibrational reduction of insertion force in 0.85% agar and ex-vivo rat brain from E. analysis: Student's T-test: *p<0.05.

NeuralGlider[®] Neural Implant Inserter

- Ultrasonic Actuator produces axially-directed micro-vibration of electrode shanks during insertion; Actuator power dictates displacement magnitude.
- Micro-positioning linear stage (0.5 µm resolution) mounts to stereotaxis and controls insertion velocity
- RoHS compliant Control Box.
- Low profile USB microscope Camera, with Stereotaxis Mount included.
- LabVIEW-based GUI controls the Micro-positioner and Actuator and records position data.
- Couplers are available for a wide range of IEA styles, offering clamping and vacuum coupling options optimized for specific probe designs.







A-C. Couplers developed to integrate various recording electrodes with the NeuralGlider Luer Hub. Omnetics connectors are clamped using a screw-type "Array clamp" (A) while flexible and 3D arrays can be held and released using alternative hands-free methods (B-C). D. Average reduction of force observed for various electrodes inserted 1.5 mm depth into two-layer agarose model (0.5% base/1.5% top). NeuralGlider Inserter coupler type and Actuator power settings vary by array to maximize reduction of force for individual probe design (0.5-1.5W).

Vacuum coupled 3D arrays can be inserted into porcine cortex without damage to electrode or nearby neurons



A. NeuroNexus Matrix arrays (4x8-2mm-200-600-177), held using custom 3D printed Couplers with pump/vacuum pressure. **B.** Vibrated insertions into dual layer agarose model (1.5% 500 µm top/ 0.5% 3 cm bottom) demonstrate reduction of peak insertion force. Slow insertion speed (0.05 mm/s) results in incomplete insertion without vibration **C.** Unwired NeuroNexus Matrix Array- 2 mm target insertion depth- with and without vibration. Vibration (3W Power) allows for complete insertion of Matrix Array without damage to electrode shanks. (N=12; n=6 Control, n=6 Vibrated). **D.E.** Study completed with York Cross pigs (N=2, male, 6 wk of age). Average unit waveforms recorded ~30 min post-operatively for 1 hr. Single unit activity sorted using Spike Interface, SpyKING Circus spike sorting software. Four largest amplitude average waveforms demonstrate ability to record single unit activity from vibration inserted probes.

Improved Outcomes in vivo – Carbon fiber arrays can be implanted without PEG support and provide improved recording



A. High density carbon fiber (HDCF) electrode arrays inserted 1.5 mm into primary somatosensory cortex without vibration (Control) result in significant tissue dimpling. Vibrated (1 W Power) HDCF electrode array insertions reduces tissue deformation. B. Single-units identified 24 hr-1 wk. post implant demonstrate increased amplitude in Vibrated insertion subjection compared to Control. Subjects: N=8 Sprague Dawley rats (Male, n=4 Control, n=4 Vibrated). Single unit activity sorted using Spike Interface, SpyKING Circus spike sorting software. **C-D.** Vibrated HDCF electrode arrays have more active electrode channels with more identified single units 2-3 wk. post insertion compared to Control.

Do you have a specific insertion or surgical challenge?

Let us know! We're continually establishing research partnerships to increase NeuralGlider's compatibility with new electrode types.

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Days Post-implant

Days Post-implant

Summary

Ultrasonic vibration of electrode shanks decreases required insertion force.

Ultrasonic vibration results in increased electrode impedance reflecting decreased fluid volume around electrode shanks and improved shank-tissue interface

Ultrasonic vibration of electrode shanks increases number of identifiable units during the first two weeks post-implantation of carbon fiber electrodes.

Future investigations will focus on methodological steps to maintain long-term (> 2 wk) increases in action potential amplitude, and number of identifiable units.

References & Acknowledgements

Lin T, Lo Y, Lin H, Li S, Lin S, Wu H, Chu M, Lee C, Lin I, Chang C, Liu Y, Chen T, Lin Y, Shih YI, Chen Y. MR imaging central thalamic deep brain stimulation restored autistic-like social deficits in the rat. Brain Stimulation. 2019;12(6): 1410-1420. Kozai TDY, Jaquins-Gerstl AS, Vazquez AL, Michael AC, Cui XT. Dexamethasone retrodialysis attenuates microglial response to implanted probes in vivo. *Biomaterials*. 2016;87:157-169.

Garyfallidis E, Brett M, Amirbekian B, Rokem A, van der Walt S, Descoteaux M, Nimmo-Smith I and Dipy Contributors (2014). DIPY, a library for the analysis of diffusion MRI data. Frontiers in Neuroinformatics, vol.8, no.8.



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