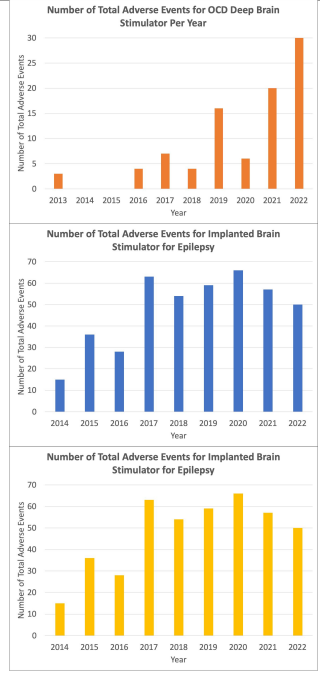
Purpose

Brain computer interfaces (BCI) allow direct communication between the brain and an external apparatus such as a computer or robotic limb. These devices hold potential to treat paralysis, amputations, neurological disorders, and degenerative disorders. This research compares the approaches of two BCIs, Neuralink's Link device and Synchron's Stentrode. Neuralink uses open brain surgery to implant a microchip that directly contacts cerebral tissue. In contrast, Synchron relies on an endovascular approach in which an electrode-containing stent sits in the superior sagittal sinus, a major brain vein. This research aims to recommend a prioritization in the development of brain computer interfaces.

Results

Whereas OCD Deep Brain Stimulators and Implanted Brain Stimulators for Epilepsy showed an increasing trend of adverse events, Intracranial Neurovascular Stent showed a steady trend ($p<0.01$; $p<0.007$; $p>0.3$). The sharp increase in adverse events for the invasive brain technology is concerning, as clinical experience should correlate with decreases in adverse events. Possible excuses for this rise in adverse events include an increase in procedures performed, as well as patients arriving in worse conditions than previous years. However, as deep brain stimulators were first developed in 1987, the former justification is unlikely to be true.



Methods

In this study, pre-clinical and clinical trial results are used to indicate potential adverse events of Neuralink's Link device and the Stentrode. Because Neuralink and Synchron's products have yet to pass clinical trials, this research also compares adverse events of OCD Deep Brain Stimulators and Implanted Brain Stimulator for Epilepsy, representative of the invasive Neuralink microchip, and Intracranial Neurovascular Stents, representative of the non-invasive Stentrode.

The Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database catalogs adverse events of medical devices. The MAUDE database divides adverse events into categories of deaths, injuries, and malfunctions. The database was searched using the product codes "OLM" and "NJE" from January 2013 through December 2022, and "PFN" from 2014 through December 2022.

Conclusion

The alarming increase in adverse events of the OCD Deep Brain Stimulator and Implanted Brain Stimulators for Epilepsy suggests discretion in the usage of invasive BCIs. Neuralink's method carries the advantage of a higher signal bandwidth and the ability to access deeper parts of the brain. However, the Link device induces inflammation and glial scar tissue buildup in the brain, which interferes with neuron regeneration and disturbs the recording of neural signals. Preclinical studies of Neuralink's microchip revealed infections and injuries following implantation. While the instrument may not record information from deep areas of the brain, the Stentrode does not induce scarring or damage brain tissue. The Stentrode has demonstrated safety in both preclinical and human clinical studies. Based on these findings, it is recommended that minimally invasive approaches such as Stentrode be prioritized in brain computer interface research.