Feasibility Study of a Neural Interface System for Quadriplegic Patients

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Objective: Develop an implantable neural interface system to provide quadriplegic patients with an output signal directly from the brain to a computer.

Design: Preclinical studies, prototype testing, and clinical trial.

Setting: Animal laboratory, outpatient clinic, patient home.

Participants: Macaque monkeys and five quadriplegic patients.

Intervention: Implantation of BrainGate™ microelectrode array sensor on the motor cortex surface. The array is connected to an amplifier, a decoder, and a patient-computer interface. The decoder correlates neural signals to desired actions using mathematical algorithms (linear regression).

Main Outcome Measures: Safety assessment and ability to move a cursor to targets on the computer screen.

Abstract

Preliminary Device Efficacy

Device testing began on July 12, 2004 and continues at present, with more than 20 sessions being completed.

Single-unit neuron recordings from motor cortex have been made over multiple sessions. The BrainGate™ System has been able to measure and record spike activity with a signal to noise >2.

Background

Needs for People with Impaired Motor Function

People with severe motor impairments have several common needs, regardless of the exact etiology of their paralysis. Activities of daily living that often are the most challenging to a person with quadriplegia include:

- feeding
- bathing
- grooming
- bladder and bowel
- transfers
- mobility

The device may someday increase independence in people with physical disabilities by linking thought directly to computers, environmental controls, wheelchairs, and nerve or muscle stimulators, etc., functional electrical stimulation (FES).

Research and Product Development Goals

- By providing an easy-to-use neural cursor, enable someone to use e-mail and internet phone control to communicate.
- Improve independence via environmental controls, such as bed positioning, television, lights, and thermostats through a desktop application.
- Improve mobility by interfacing with powered wheelchairs.
- Longer-term, cortical control could be interfaced with stimulators and other devices to provide closed-loop systems that improve respiratory, bladder and bowel control and move limbs via FES or robotics.

Surgical Implantation

In June 2004, after obtaining informed consent, a surgical procedure consisting of an incision and 3 cm diameter craniotomy located above the right primary motor cortex was conducted under general anesthesia. A 4x4 mm, 100 channel sensor was implanted on the surface of the cortex, specifically in the precentral gyrus immediately posterior to the superior frontal sulcus. The surgery lasted approximately 3 hours and was uneventful. The patient was discharged to his primary residence 3 days post-surgery where he recovered for 3 weeks prior to initiation of device testing.

Device Safety

There were no post-surgical complications. No adverse events or other study-related complications have been reported. Safety assessments include daily checks of connector, weekly nurse visits, and monthly physician exams including neurological and mental status exams.

Key Study Eligibility Criteria

- Age 18 to 60 years
- Able to speak understandably
- Quadriplegia due to spinal cord injury, muscular dystrophy or stroke where quadriplegia is:
  - Complete quadriplegia (bilateral C2-C4)
  - Incomplete quadriplegia with muscle grade at specific cord levels as follows
    - ≤ 3/5 at C5
    - ≤ 2/5 at C6
    - ≤ 2/5 at C7-T1 + lower extremities
    - ≥ 12 months post-injury

Future Directions

The study will be expanded to additional sites and patients. A wireless version of the device is in early stages of development.

CAUTION: Investigational device. Limited by Federal (USA) law to investigational use – only being studied in USA.

References