The Application of Implant Technology for Cybernetic Systems

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Objective: To assess the usefulness, compatibility, and long-term operability of a microelectrode array into the median nerve of the left arm of a healthy volunteer, including perception of feedback stimulation and operation of an instrumented prosthetic hand.

Setting: The study was carried out from March 14 through June 18, 2002, in England and the United States.

Results: The blindfolded subject received feedback information, obtained from force and slip sensors on the prosthetic hand, and subsequently used the implanted device to control the hand by applying an appropriate force to grip an unseen object. Operability was also demonstrated remotely via the Internet, with the subject in New York, NY, and the prosthetic hand in Reading, England. Finally, the subject was able to control an electric wheelchair, via decoded signals from the implant device, to select the direction of travel by opening and closing his hand. The implantation did not result in infection or any perceivable loss of hand sensation or motion control. The implant was finally extracted because of mechanical fatigue of the percutaneous connection. Further testing after extraction has not indicated any measurable long-term defects in the subject.

Conclusions: This implant may allow recipients to have abilities they would otherwise not possess. The response to stimulation improved considerably during the trial, suggesting that the subject learned to process the incoming information more effectively.

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INTRANEURAL INTERFACES allow for the selective recording and stimulation of nerve fibers.1,2 Microelectrode arrays contain multiple electrodes that become distributed within the fascicle of the mixed peripheral nerve. In this way, direct access can be gained to axons from various sense organs such as cutaneous receptors, muscle spindles, or motor neurons to specific motor units. The device therefore enables a multichannel nerve interface.3

In this report, we investigate the use of a microelectrode array to form a bidirectional link between the human nervous system and a computer. Ethical approval for the research to proceed with one of us (K.W.) as the subject was obtained from the Ethics and Research Committee at the University of Reading, Reading, England. Approval for the experimental neurosurgery was granted by the Oxfordshire National Health Trust Board, which oversees the Radcliffe Infirmary, Oxford, England.

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METHODS

NEURAL IMPLANT EXPERIMENT

On March 14, 2002, at the Radcliffe Infirmary, an array of 100 individual needle electrodes (Figure 1) was surgically implanted into the median nerve fibers of the left arm of a healthy, right-hand-dominant man aged 48 years. The array measured 4 x 4 mm, with each of the electrodes being of uniform length (1.5 mm). An incision was made at the wrist and extended for 4 cm centrally over the median nerve; a second 2-cm centrally located incision was made 16 cm proximal to the wrist. An electrode passer was inserted under the skin between the 2 incisions by means of a tunneling procedure; the array was then introduced to the more proximal incision and pushed distally along the passer (Figure 2), such that the wire bundle connected to the array ran within it. By removing the passer, the array remained adjacent to the exposed median nerve at the point of the first incision, with the wire bundle running subcutaneously and exiting at the second incision, where it linked to an electrical connector pad that remained external to the arm.
The median nerve fascicle selected was estimated to be approximately 4 mm in diameter; however, an incision into the perineurium was necessary to ensure adequate electrode penetration depth. After dissection of the perineurium under a microscope, the array was pneumatically inserted into the radial side of the median nerve, allowing the array to sit adjacent to the nerve fibers with the electrodes penetrating into the fascicle.

With the use of the neural interface, it was possible to transmit neural signals directly to a computer from the peripheral nervous system by means of a hard-wire connection from the connector pad or through a digital radio transmitter attached to the pad. In this way, a range of cybernetic devices could be controlled by the neural activity when appropriately translated by the computer. In addition, signals sent from the computer to the implant could trigger stimulation of the nerve fibers, thereby enabling the closure of a feedback loop.

Neural signals associated with muscle contraction could be generated by finger movements and detected by the array. By monitoring and subsequently processing these analog signals in conjunction with a proportional in-time controller, the movement could be used to control devices through the computer via a bidirectional digital radio link. The microelectrodes allow the action potentials from small subpopulations of axons that surround each of the sensitive tips to be detected. With a typical action potential duration of 1 millisecond, it is reasonable to assume that the small subpopulation extracellular neural activity of interest occurs below a frequency of 3.5 kHz. Ideally, only the band of frequencies that contain signals of interest (as specified by a lower f_l and higher f_h cutoff frequency) would be linearly amplified, with any frequency outside this range completely suppressed. However, practical limitations mean that a completely sharp cutoff is not realizable. Instead, filter design dictates that the further out of the band of interest a frequency is, so the more it is attenuated. The sharpness of cutoff is then given by the order of the filter, with higher order filters realizing a sharper cutoff at the expense of increased complexity. As a result, the hardware interface for the array implant amplified each channel using a fifth-order Butterworth filter stage, where the gain of the filter was 5000, the lower cutoff frequency (f_l) was 250 Hz, and the higher cutoff frequency (f_h) was 7.5 kHz. This minimizes the distortion of the extracellular action potentials while aggressively rejecting extraneous noise. This is then digitized to 10-bit resolution by means of an onboard microcontroller and made available to the controller and radio link.

A constant current stimulator was implemented to stimulate the same subpopulations of axons with charge-balanced, biphasic rectangular pulses with an interphase delay of 100 microseconds and typical pulse duration of 200 microseconds. It was therefore possible to create artificial sensation, giving the subject feedback from the connected systems.

Stimulation was attempted for the first time 6 weeks after implantation by using currents up to 100 µA. During experimentation, we found that currents below 80 µA had little perceivable effect, although at that magnitude the electrodes showed good electrical characteristics, implying that current was being passed in the locality of the nerve fibers. During initial tests at 80 µA, with the subject blindfolded and the stimulation applied randomly, the subject achieved a mean correct identification of stimulation of 70%. By the end of the study, a 95% perception rate was being achieved. Electromyographic (EMG) recordings suggest that the stimulation resulted in muscular excitation of the first lumbrical muscle and that the associated sensation of this movement was perceived by the subject.

ARTICULATED HAND

The type of articulated hand prosthesis used in this study has multiple degrees of freedom and can be controlled...
in a hierarchical manner, with the aim to mimic the control mechanisms apparent in a human hand. This SNAVE (named after Mervyn Evans, its original designer) prosthesis\(^5\) (Figure 3) contains force and slip sensors in the fingers and palm and uses a microcontroller to coordinate the operation. Joint flexion sensors allow for adaptation of the grip shape and for the force applied to the object to be modified. The microcontroller can then ensure that the lightest possible touch is applied. If the microcontroller detects that the object is slipping, the tension can be automatically adjusted to prevent further slippage. As a result of this, the hand can be controlled by means of voluntary opening and involuntary closing, whereby the user need only tell the hand to relax for it to grasp the object in the most appropriate manner. At present, this prosthesis is undergoing clinical assessment in Oxfordshire.

In this experiment, processed signal data from the neural implant was used with the onboard intelligence of the SNAVE hand to control the hand-grasp function. This was achieved in a manner more closely associated with the operation of a human hand (compared with articulated hands controlled by means of surface EMG signals).

Subsequently, the touch force control in the prosthesis was disabled, and the control was changed to voluntary opening and voluntary closing, so the subject had to control the grip force himself. The sensory data from the hand’s fingertips were fed back to the operator, and the grip force and hand flexion were recorded. The subject was asked to open and close the hand by applying the lightest touch to the object with and without the implant’s force feedback and with and without visual feedback. As more force was applied to an object, the amount of neural stimulation was increased. After 6 hours of learning to operate the hand in this fashion, the subject was able to grip an unseen object while minimizing required force. In 12 days, the subject’s ability to judge the closing force and stop in a timely manner improved more when he had force and visual feedback than when he had either alone.

**TELECONTROL**

On May 20, 2002, with the subject in a laboratory at Columbia University, New York, NY, a link was established between the implanted device in New York and the SNAVE hand at Reading University. The processed signals from the neural implant were transmitted across the Internet to control the articulated hand at its remote location, and stimulation feedback information was sent back via the Internet to the implant. Taking into account the slight transmission delay across the Internet, the subject was again able to operate the articulated hand in a controlled manner.

**WHEELCHAIR CONTROL**

In the applications discussed herein, data collected via the neural implant were directly used for control purposes, thereby removing the need for any other external control devices. To control an electric wheelchair, a sequential-state machine was implemented, with a command signal decoded in real time from the neural signals being used to halt the cycle at the intended action. In this way, the overall control of the wheelchair was made to be as simple as possible.

Initial experiments involved selective processing of the signals obtained from several of the electrodes on the array over time to produce the discrete direction control outputs. With a small amount of learning time, the subject was able to control the direction and velocity of a fully autonomous mobile robot platform. Onboard sensors allowed the robot to override commands from the user to safely navigate local objects in the environment. The technique was further implemented on an electric wheelchair (Figure 4), with the command signal from the implant controller received by the wheelchair’s driver mechanism via a short-range digital radio link. The command signal, essentially obtained by the user closing his hand,
A further concern was the possibility of implant rejection by the body. The implant was finally removed on June 18, 2002, 96 days after implantation. At the time of extraction, no signs of rejection were observed; indeed fibrous scar tissue had grown around the implant site, holding it in position. The implant array did not appear to have lifted or tilted from the nerve trunk in that time, with the electrodes still embedded.

It is well documented that abnormal healing after even minimal trauma to a major mixed peripheral nerve (such as the median nerve) can result in conditions such as complex regional pain syndrome type II (formerly known as causalgia, a type of reflex sympathetic dystrophy). It is theorized that sympathetic nerve fibers form connections with the injured peripheral nerve, which can then cause aberrant sensory stimulation. For this reason, the subject performed the Southampton Hand Assessment Procedure® before, during, and after the implantation, and the subject’s ability to perform 2-point discrimination was regularly assessed for signs of neuropathy. No perceivable loss of hand sensation or motion control was experienced by the subject, and regular testing after extraction has not indicated any measurable long-term defects other than minor scarring.

Perhaps one of the most important issues in the endurance study was the robustness of the array. After implantation, all 20 active electrodes and 2 reference wires were fully functional, and distinct neural and EMG signals could be measured on each channel after appropriate muscular movement.

During the study, some of the electrodes became high impedance (implying discontinuity) and thus were no longer functional. By the end of the 96-day study, only 3 electrodes remained functional, one of which was used as a reference because of the failure of both implanted reference wires by this stage. Postextraction examination of the silicon electrodes showed them to be intact, and the cause of failure instead was mechanical fatigue of the connection wires at the point of exit from the arm. The gradual decline in functional channels was one of the main reasons the implant was extracted at this time.

The use of implant technology for the purpose of directly measuring neurological signals and of stimulating nerve fibers offers opportunities for the treatment of neurological problems and the amelioration of physical or neurological impairment. In this report, we describe an application study on a healthy individual.

The wheelchair study demonstrated how individuals with a restricting paralysis could, with this type of implant, control their movement in the real world. It was also possible to restore a small measure of sensation by means of the implant, using signals from tactile transducers on a prosthetic hand. This technique could in practice be used with an artificial limb to stimulate sensory axons that remain in the remnant stump of an amputee.

It is recognized that this study could be criticized on the basis of investigator bias, because the subject was also one of the researchers. However, many of the results such as biocompatibility, reliability, neuropathy, and infection stand independent of subject bias. In addition, independent observers were present to witness different stages of the experiment according to their individual interest. Video documentary footage was also obtained at each stage for later independent analysis.

One negative aspect of the trial was the gradual degradation of the implant wire bundle. However, the next development phase is toward a long-term fully implanted solution designed for longevity by including all electronics and power supply, which will circumvent these percutaneous issues. A further issue is that of the stimulation currents being nearly an order of magnitude larger than expected. This, together with low-amplitude neural recordings, suggests that the electrode filaments may have remained or become slightly superficial to the fascicle. Since the pneumatic insertion technique has been proved in previous animal studies to adequately drive the electrodes through the perineurium, a method of secur-

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**RESULTS**

One of the aims of the study was to examine the possibilities of using an implant of this type on a much wider scale, particularly to help those with an acquired injury (eg, spinal lesion) or a congenital abnormality (eg, some forms of blindness). The study has therefore been used to provide information to assess the long-term endurance of the technology.

Before the study, one of the main concerns was the possibility of infection occurring. For this reason, the tissue around the wounds, especially at the percutaneous site, was monitored closely for efflorescence. To reduce the probability of infection, only 20 of the 100 electrodes on the implant array were connected, thus reducing the diameter of the wire bundle exiting the arm. No indication of infection was observed during the study period.

![Figure 5. Sequential-state machine mounted on the wheelchair.](Image)

Figure 5. Sequential-state machine mounted on the wheelchair.
ing the array firmly in position, such as medical adhesion, may be adopted in subsequent implantations. This trial has demonstrated how such an implant has the potential to be beneficial to recipients and allow them to have abilities they would otherwise not possess. The response to stimulation improved considerably during the trial, suggesting that the subject learned to process the incoming information more effectively and adapted to exploit the input signals.

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