A SECOND GENERATION NEUROPROSTHESIS FOR UPPER EXTREMITY SPINAL CORD INJURY

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Abstract

An advanced neuroprostheses has been developed for control of grasp-release, forearm pronation, and elbow extension in persons with cervical level spinal cord injury. The neuroprosthesis includes an implanted 10-channel stimulator-telemeter (IST) and an implanted joint angle transducer (IJAT). This system has completed pre-clinical testing and has been implanted fully in four persons and partially in an additional person, all with C5/C6 level spinal cord injury. The maximum follow-up time is 3.5 years. All subjects demonstrated increased grasp strength, range of motion, ability to grasp objects, and increased independence in the performance of activities of daily living. Each subject became a regular user of the neuroprosthesis, and has indicated satisfaction with it. The electrodes and sensors have been stable over time, and there were no medical complications. This study indicates that advanced neuroprosthetic systems are safe and can provide grasping and reaching ability to individuals with cervical level spinal cord injury.

Introduction/Background

Neuroprostheses use electrical stimulation of paralyzed muscles to produce controlled limb movement. The paralyzed individual obtains functional control of the stimulation through various means based on their remaining voluntary movement. The goal of our program is to provide hand and arm function for tetraplegic individuals. This is accomplished using a combination of implanted neuroprosthetic technology and surgical reconstruction techniques.

A first generation neuroprosthesis for C5 and C6 level tetraplegic individuals has been implemented in more than 150 individuals, having received FDA approval in 1997. The results of a multi-center clinical trial indicated improvement in pinch strength, grasp-release ability, and performance in activities of daily living. The complication rate has been low, and a high.level of user satisfaction has been reported. This device is now commercially available (NeuroControl Corp.).

A second generation neuroprosthetic system has now been developed which provides additional functions and improved ease of use. The primary feature of this new system is the implantation of the control source, which is accomplished either through implantation of a joint angle transducer in the wrist, or through myoelectric control obtained from wrist or neck extensor muscles. The second generation device also has additional channels of stimulation, which can be used to provide improved grasp opening, elbow extension, and/or forearm pronation.

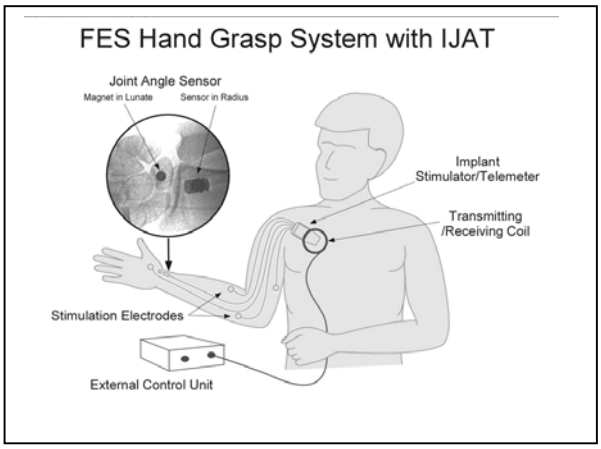

Figure 1: *Schematic of the 2nd generation system*

Methods

The second generation neuroprosthesis includes both implanted and external components, as shown in Figure 1. The implanted components are the IST, the IJAT and ten electrodes.The external components are the external control unit, which provides the power and intelligence for the system, a transmit/receive coil that is placed on the user's chest over the IST device, and an on/off switch typically placed on the user's wheelchair. The entire system is portable and, once donned, can be operated independently by the user throughout the day.

The operation of the second generation neuroprosthesis is based on that of the first generation, in which the stimulus to the paralyzed muscles is controlled through user-initiated movements. The sequence begins with the user hitting a switch, which turns the system on and selects an initial grasp pattern [1]. Movement of the wrist is sensed by the joint angle sensor. Wrist extension results in grasp closing and wrist flexion in grasp opening. Grasping action is active, generated by the stimulated muscles, and augments the tenodesis grasp, which is produced by the passive forces of the muscles as the wrist is moved. This control method has been shown to be efficient for the user. The user can over-ride stimulated wrist control by pressing a "hold" switch, which locks the stimulus at the level that was applied when the switch was hit.

Holding the switch down for a brief period (0.5-3 seconds) causes the system to "toggle" between the available grasping patterns. Holding the switch down for longer than three seconds turns off the system.

The primary "intelligence" of the neuroprosthesis resides externally in the external control unit (ECU). The ECU is programmable by the clinician from a personal computer to set the stimulation and control parameters, which must be customized for each individual user.

Communication and powering of the implanted components is accomplished by electromagnetic induction through radio frequency (RF) waves. To communicate with the implanted components, the external coil is placed over the implant and the system turned on. This transmits the radio frequency signal internally to power the IST and IJAT. Movements of the wrist are transduced and transmitted externally over the RF waves [2]. The transducer signal is used by the ECU to determine the appropriate stimulus levels for each electrode, and this information is transmitted back to the IST device

The implanted system was designed for installation in either a single or a staged procedure, using lead interconnections to join system components. When the installation is staged, the IST device and ten electrodes are implanted in a single procedure. The IJAT is implanted in a subsequent procedure and connected to the IST device by exposing the IST leads to the IJAT at a connector site on the lateral upper arm. Between the two stages, patients can operate their system using an externally mounted wrist position transducer. This control method works identically to the implanted control method.

Study Participants. All individuals who participated in this study were tetraplegic secondary to traumatic spinal cord injury at the C5 or C6 level and classified as motor complete, as shown in Table 1.

Surgical Procedure

The IST and electrodes were implanted in a single operation. Augmentative surgical procedures to the hand and arm were often performed in the same sitting. The installation of the implant device and electrodes followed the same procedures that have been employed in the first generation system. Electrode locations were mapped using a temporary epimysial or intramuscular electrode with direct stimulation of the muscle. Both epimysial and intramuscular electrodes were used. Typically, deep and small muscles were implanted with intramuscular electrodes.

The surgical installation of the IJAT followed the procedures described by Johnson [3]. The IJAT magnet was implanted in the lunate and the IJAT sensor in the radius, using a cannulated insertion procedure, modeled after orthopedic fracture surgery techniques. Guide wires were used to establish the location and depth for drilling and tapping holes for each component. X-ray guidance was used to establish the proper position of the magnet and sensor within the bone. The sensor leads were subcutaneously routed superiorly along the arm to the lateral connector site, and the sensor was tested to verify proper operation prior to wound closing.

Table I. Subjects with second generation neuroprosthetic systems.

	International Classification		Grasp Patterns							Tendon Transfers		
Subject	Implanted Arm	Non-Implanted Arm	Lateral	Palmar	Parallel	Pointer	Elbow	Pronation	Control Source	PD->Tri	Br->ECRB	ECU->ECRB
A	OCu:2	OCu:3	●	●	●	●	●		IJAT	●		
B	OCu:2	O:0	●	●	●		●		IJAT			
C	OCu:2	OCu:3	●	●	●			●	Ext Wrist	●		
D	OCu:1	OCu:X[1]	●	●	●		●		IJAT		●	●
E	O:2	O:3	●	●			●		IJAT	●		●

Table 1: *Subjects with 2nd generation system.*

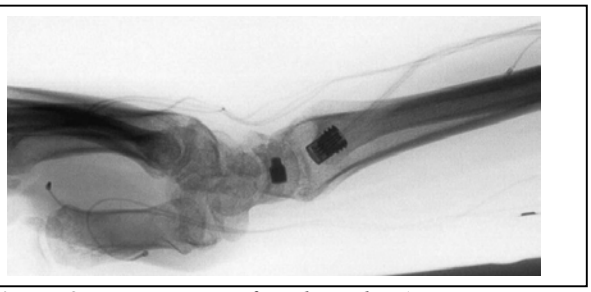

Figure 2: *XRay image of implanted IJAT.*

Results

The second generation neuroprosthesis was implemented in five subjects, as shown in Table I. Figure 2 shows a radiographic image of the implanted components in one of the subjects. The neuroprosthesis is operational in all five subjects, and has been implanted for a median of 43 months (range 35 to 49 months). The IJAT has been implanted for 3, 35 and 37 months. All subjects report using their system on a regular basis for activities such as eating, drinking and other ADL. Radiological evidence indicates that the bones have healed around the insertion holes for the IJAT, with no indication of bone resorption or breakage.

Every subject demonstrated an increased level of independence in activities of daily living when using the neuroprosthesis, as shown in Figure 3. Three of the subjects demonstrated an increased level of independence in at least five different activities when using the neuroprosthesis, and indicated a preference for using the neuroprosthesis in at least 8 activities. These activities included eating with a fork, drinking from a glass, writing, typing, and brushing hair. The need for

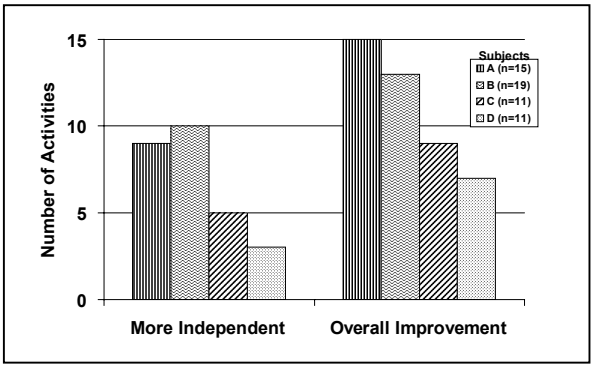

Figure 3: *Activities of daily living.*

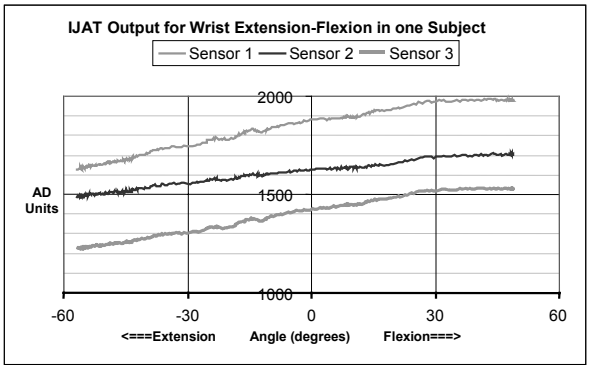

Figure 4: *IJAT output.*

adaptive equipment, such as an enlarged fork handle, was removed in seven activities among the three subjects. In addition, the need to use self-assistance, such as placing the object in the mouth to manipulate it, was removed in 14 activities. The fourth subject, although still showing improvement in two activities, had some voluntary hand function in his non-instrumented hand that enabled him to perform all tested activities with only self-assistance and the neuroprosthesis. This subject obtained additional function through the action of the stimulated triceps for overhead reach.

Device usage at home, as indicated by device datalogging and patient report, regularly averaged between 4 days and 7 days per week. Usage was affected by illness, with usage dropping when a subject was bed-ridden. One subject was able to don the neuroprosthesis independently due to voluntary hand function in his non-instrumented hand.

Figure 4 shows representative IJAT signals for a typical extension wrist displayed as IJAT signals versus wrist angle. This range is sufficient to allow approximately 30 command levels in the control scheme.

Discussion/Conclusions

The IJAT appears to be a practical sensor for implant applications. The installation procedure is modeled after similar orthopaedic surgical procedures, and can be performed successfully in the radio-lunate joint. The signal output of the IJAT has been shown to be adequate to be used for control of grasp opening and closing, and functions similarly to the external device. Previous studies [4] have demonstrated that the sensor is safe within the bone and does not migrate over time.

The ability of the IST device to transmit signals outside of the body provides the possibility of utilizing a wide array of implantable control sources, in addition to the IJAT. We have begun work on a device that is capable of utilizing myoelectric signals as an implemented control source. Other possible sources of implanted control include accelerometers, contact sensors and nerve and cortical recordings.

References

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