

# Twenty Year Experience with Implanted Neuroprostheses

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**Abstract**—The long-term durability and safety of implanted devices is of great importance in the field of motor neuroprosthetics, where systems may possibly be utilized in excess of 50 years by some individuals. Neuroprosthetic systems have now been implanted in the upper extremity of spinal cord injured individuals for more than 20 years. The experience with these systems shows a high level of durability of the implanted components, particularly the stimulating electrodes and leads.

## I. INTRODUCTION

IMPLANTED neuroprostheses for upper extremity function in spinal cord injury have now been in use for over 20 years. These neuroprostheses provide individuals who have cervical level spinal cord injury with the ability to use their hands more independently for daily activities. The goal of this abstract is to present some of the results and lessons learned from that experience.

Three generations of upper extremity neuroprosthetic systems have been developed at the Cleveland Function Electrical Stimulation (FES) Center and implanted in spinal cord injured (SCI) subjects for at least five years, and summarize in Table 1. The first generation system [1] was first implemented in a human volunteer in 1986 [2]. This system became known as the Freehand System® (NeuroControl Corp., Elyria, OH) [3]. The Freehand neuroprosthesis used an eight channel receiver-stimulator (IRS-8), eight epimysial or intramuscular electrodes, leads, and connectors. The second generation system [4],[5], which was first implanted in 1997, consisted of a ten channel implanted stimulator with an implanted joint angle sensor [6]. This system, referred to as the implanted stimulator-telemeter (IST-10), was capable of bi-directional communication, allowing the implanted sensor information to be transmitted out of the body. The third generation system [7], referred to as the IST-12, was capable of twelve channels of stimulation and could acquire myoelectric

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signals from two different muscles. This system was first implanted in 2003. Over 240 cervical-level SCI individuals have received these systems at multiple sites worldwide, including 51 implanted and followed at the Cleveland FES Center.

Table 1. Implanted Upper Extremity Neuroprosthetic Systems in Cleveland

System Name	Functions	Features	Subjects Implanted	Years Implanted
IRS-8 (Freehand)	Grasp	8 stimulus channels, external shoulder position control	225	1986-2002
IST-10	Grasp, Reach	10 stimulus channels, implanted wrist position control	5	1997-2001
IST-12	Grasp, Reach	12 stimulus channels, 2 channels myoelectric signal acquisition	13	2003-2009

## II. NEUROPROSTHESIS DESIGN

All three generations of implanted systems utilized a similar design concept. The implanted stimulator was powered by a transcutaneous inductive link. An external control unit provided the power and signal processing for the system [8]. The Freehand System utilized an externally-worn shoulder position transducer for control of grasp opening and closing. The IST-10 and IST-12 systems incorporated implanted sensors, but still utilized powering through a transcutaneous inductive link and an external control unit.

A titanium capsule was utilized for all three generations of implanted devices. The capsule provides a hermetic encapsulation of the circuitry in a biologically compatible enclosure with sufficient connection density to accommodate leads for stimulation and control functions. The capsule size for the IST systems was 4.0 X 3.8 X 0.7 cm. Feedthrough assemblies were used to transmit electrical signals in and out of the titanium enclosure. The hermeticity of the feedthroughs and capsule welding was verified by conducting fine leak tests using a helium leak detector.

The electrode leads consisted of two teflon insulated multistranded wires helically wound in tandem and enclosed in silicone elastomer [1]. Each wire can be used as a separate conductor providing a two-conductor lead. For the IST-10 and IST-12 Systems, the two wires are separated and connected to individual feedthrough pins. At the distal end of the proximal lead, the two wires are again separated into single conductors (a Y-branch) and terminated in an in-line connector [9]. Connector marking was developed to enable lead identification post-surgery.

Two styles of stimulating electrodes were used by all three generations: epimysial electrodes, which are sewn to the muscle epimysium, and intramuscular electrodes, which

are inserted into the muscle belly. The electrodes utilize a closed helix design. Stimulating electrodes have a tandem conductor close coiled lead wire from the connector, covered with a silicone tube. The epimysial electrode terminates in a Pt-10 Ir disk mounted in a silicone backing reinforced with dacron. The intramuscular electrode has a stainless steel stimulating area wound around the distal end of the lead. A prolene-barb on the tip of the electrode serves to anchor the electrode in the muscle [10]. The intramuscular electrode was developed for use in small muscles of the hand, but the ease of surgical placement of this electrode has resulted in the use of the intramuscular electrode almost exclusively in later implanted systems.

The IST-10 utilized an implanted joint angle transducer (IJAT) to measure voluntary wrist angle in two degrees of freedom. [6]. The transducer consisted of two elements, a Hall-effect sensor array and a magnet, both packaged in titanium. The sensor design used three Hall-effect sensors arranged in an equilateral triangle for sensing the field produced by the magnet. The three sensors, two resistors, and a voltage regulator were assembled into a hybrid circuit and sealed in a titanium capsule. The sensor array was connected to the IST-10 via three Y-branch leads and connectors. The permanent magnet element design utilized a cylindrical Neodymium-Iron-Boron (NdFeB) magnet sealed in titanium. The outside of both capsules are threaded to enable simple insertion into bone using cannulated drills and taps to create precisely positioned threaded holes in two bones, one in the radius for the sensor capsule and one in the lunate for the magnet capsule. Special surgical tools were developed for the insertion of the capsules into the holes.

The IST-12 utilized two independent myoelectric signals (MES) for control of grasp. The MES was recorded through electrodes placed on muscles under voluntary control, and the signal processed within the IST-12 implanted device. The MES electrodes were bipolar epimysial electrodes surgically implanted on the fascia of the target muscle. They were made of two 4mm diameter Pt10Ir discs mounted on a medical grade Dacron reinforced silicone backing. The discs were positioned 10mm apart. The distal lead wires for the bipolar MES electrodes began with a Y-junction and ran together to the distal recording electrode pair, with an impedance of 2 Ohms/cm. Electrode access impedance is 1300 Ohms at 200 kHz.

The implanted systems are installed in a single surgical procedure under general anesthesia, typically lasting four to six hours [11], [12]. Electrodes are surgically placed on or in the paralyzed muscles of the hand, forearm, upper arm and shoulder. The implanted device is placed subcutaneously in the chest over the pectoralis muscle in the location typically utilized for pacemakers. Post-operatively, subjects were placed in a whole arm cast for three weeks to allow healing of the electrodes to the muscles. After the cast was removed, subjects began a four week period of exercise, followed by functional use of the neuroprosthesis.

Two grasp patterns were provided for functional activities: lateral pinch and palmar prehension [13]. The lateral pinch was used for holding small utensils such as a fork, spoon or pencil. In the open phase of this grasp, the fingers and thumb are extended. Palmar prehension was used for acquiring large objects, such as a glass or can.

To operate the first generation neuroprosthesis, the user depressed a switch on their chest that activated the system, and the user's hand opened into full extension in the lateral pinch mode. Graded elevation of the user's contralateral shoulder resulted in graded grasp closure [14]. A quick movement of the shoulder "locked" the hand so that it remained closed at the desired degree of closure, until another quick movement of the shoulder released the lock command. Depressing the chest switch briefly caused the system to switch to the palmar grasp. Depressing the switch for a longer time turns the system off. Second and third generation systems operate similarly, except that wrist angle (IST-10) or MES (IST-12) was used to generate the graded control signal for grasp opening and closing. In the IST-12 system, MES was also used to eliminate the need for an external switch for logic commands.

### III. LONG-TERM FUNCTIONAL OUTCOMES

A multi-center clinical trial was conducted with the Freehand System from 1992-1997 [3]. Fifty subjects were enrolled in this study, and the results indicated that subjects obtained greater strength of grasp, increased grasp range of motion, improved ability to manipulate objects and improved performance in activities of daily living with the neuroprosthesis. Across all three generations of implanted systems, functional results have been uniformly positive. Every subject tested in activities of daily living ability have demonstrated increased independence in at least one task. The first generation neuroprosthesis received FDA Premarketing approval (PMA) in 1997 and remains the only implanted neuroprosthesis approved for upper extremity functional restoration. The second and third generation systems are currently implanted under Investigational Device Exemptions (IDE) from the FDA.

Usage rates after long-term implantation of the first generation neuroprosthesis were recently evaluated. One hundred and fifty-five subjects were identified who were implanted with the Freehand System between 1986 and 2001 in the U.S.. There were 9 confirmed deaths. Direct contact was made with 65 of the remaining 146 subjects. Of the individuals contacted, 37 (56%) continued to be regular users of the Freehand System, despite the fact that the company marketing the device stopped providing technical support in 2006. Four subjects (6%) had had the device removed, and 24 (37%) reported to be non-users. Half of the non-users (12/24) reported some type of technical issue that caused their non-use, including failure of external components, need for additional programming and difficulties with wearing the external components. These issues are directly related to the lack of technical support from the marketing company. Seven of the 24 non-users did

not give a reason for non-use. These results, though preliminary, confirm our initial hypotheses regarding system usage. Specifically, the neuroprosthesis has a life-changing impact for many users. These individuals rely on the device daily and have made changes in their lifestyle based on the increased function they obtain with the system, including returning to work or school, or leaving long-term care facilities to live independently. On the other hand, there remain a cohort of neuroprosthesis recipients who are not users of the system. These individuals presumably did not receive sufficient benefit from the system to adopt regular usage. At present, there is no clear relationship between the functional outcome, as measured through a variety of clinical outcome measures, and eventual usage or non-usage of the device. The assumption is, therefore, that issues such as motivation and patient goals play a much bigger role in determining whether the system is used or not. Thus, it is not possible at present to predict *a priori* which candidates will become eventual regular users of the neuroprosthesis.

#### IV. LONG-TERM TECHNICAL OUTCOMES

The electrodes and leads have been very durable. We analyzed the performance of the electrode lead system in the first and second generation neuroprostheses [15]. Overall, 238 electrodes were implanted, with an average follow-up time of 7.1 years (Range: 3.2 - 16.4 years). There were 204 epimysial electrodes and 34 intramuscular electrodes. The performance of both types of electrode was excellent. There have been no cases where failure of a component of the neuroprosthesis resulted in the inability of the subject to use the neuroprosthesis for functional activities. Of the 238 electrodes in the series, 234 (98.3%) remained intact throughout the duration of the study. Three (1.3%) were broken and one (0.4%) was infected. Survival analysis using Kaplan-Meier showed that there was a 98.7% probability for an electrode to be intact at 16 years. At present, there are 53 electrodes older than 15 years and 198 electrodes older than 10 years. These results indicate that this device is biologically and electrically safe within the body.

Electrode threshold measurements indicate that the electrode response is stable over time, with no evidence of electrode migration or continual encapsulation in any of the electrodes studied. The leads and electrodes demonstrate excellent mechanical stability. The device-tissue interface consists of minimal encapsulation that is stable over time. In those cases where the implanted components have been replaced, the encapsulation layer has been found to be translucent and approximately 1mm thick. It would appear that the movements of the upper extremity do not stress the leads anywhere near their failure point, despite the fact that many of the leads cross three joints. None of the failures that have been analyzed appear to have been the result of fatigue failure.

The implanted stimulators have shown a higher overall rate of failure than the electrode leads. For the first generation system, the known overall failure rate was 8.4% in 2002, the last year accurate worldwide information is available. However, within this group of devices, there was a specifically identified lot of 22 implants that were

determined to have excessive moisture in the capsule due to inadequate bake-out during fabrication. These devices failure at a rate of 41% within the first six years of implantation. Excluding this specific batch of devices, the failure rate of the remaining devices was 4.4%. Most of these failures occurred within five years of implantation, and there is insufficient information at present to determine the long-term failure rate of these devices.

Second and third generation devices, the IST-10 and IST-12, have total subject numbers too small to identify a true failure rate. One of the five IST-10s failed after two years and was replaced, with no further incident. That failure was determined to be due to an inconsistent operation of an oscillator circuit in the device [4]. One of the 19 IST-12 devices failed after 3 years of operation and three of the remaining devices have developed a single channel failure that is unlikely to be due to an electrode failure. In all three of the latter cases, the system remains functional for the subject and therefore there are no immediate plans for device replacement surgery and explanted failure analysis.

#### V. LONG-TERM MEDICAL EVENTS

Infection is the primary medical concern regarding implanted devices, including neuroprosthetic systems. Among the 51 subjects that have been implanted and followed in Cleveland, there have been three confirmed system component infections requiring removal of a portion of the implanted system. In two subjects, the implant stimulator was infected and the device was removed, leaving all of the electrodes intact. In one case, the infection was localized to a suture near a single electrode termination and the electrode was removed with no further complication. There have been no infections in the immediate post-operative phase, but all infections occurred within 4 years of device implantation. There is insufficient evidence to determine the mode of infection in any of the three cases. In two of the three infections, the subject reported redness and swelling around the implanted component, but no other symptoms. In the third infection, the subject was asymptomatic, and the infection was only discovered during an unrelated surgical procedure in which the implant pocket was surgically exposed and cultured.

SCI individuals have depressed immune systems due to the nature of their injury, making infection an increased concern in this population [16]. Because these individuals utilize a bladder drainage device, they are prone to urinary tract infections (UTI). Pneumonia is a common problem for cervical SCI because of the difficulty in coughing. Pressure sores are also extremely common in SCI, and these remain a significant concern as a source of possible infection that could track to the implant. Despite such a high rate of organ and systemic infections, there are no reported cases that an infection which originated in an organ subsequently tracked to the implanted components, although one subject had five electrode leads removed prophylactically when he developed cellulitis in his forearm. In one early case in the multi-center trial of the Freehand, a subject developed a pressure sore on the elbow directly over the implanted leads. The subject failed to get treatment and ultimately the leads were exposed

through the sore and infected. The entire device was eventually removed in this subject [3].

We do not know of a confirmed infection of an implanted device that was successfully treated with oral or i.v. antibiotics alone. It is likely that the capsule that forms around the implant tends to trap the infection, with a minimal blood supply, thus eliminating the possibility of treating the infection through the bloodstream. As a result, removal of the infected component appears to be the only treatment remedy. It is possible, however, to successfully remove only the infected portion of the system if the infection is identified before it has spread to the entire system. In two patients with infected stimulator devices, the stimulator was removed while all of the electrode leads were left in place and no further infection of the electrode leads or implant pocket were encountered.

Other possible medical incidents include device migration, tissue erosion and host rejection. There have been no cases of rejection. In one subject, leads crossing the shoulder appeared close to eroding through the skin, so those leads were surgically repositioned. Two of the first five subjects to receive the Freehand System had their devices rotate inside the body. We now suture these devices to the underlying fascia so that they cannot rotate. One other case of migration required surgical correction. This latter case was the situation described earlier where an infection was discovered around the implant in a secondary surgical procedure. It is not possible to determine if the migration and infection were directly related.

## VI. SUMMARY

Implanted neuroprostheses have now been in use to provide upper extremity function to individuals with SCI for over 20 years. At present, there is no apparent increase in failure rate as a function of years post-implantation. In fact, nearly all of the incidents reported (lead failure, infection, migration) occurred within three years of implantation. To date, there has been no reports of an electrode failure or device infection between five and 23 years post-implant. Reported implant device failures have occurred within six years of implantation, although this may be due to insufficient data. In general, it appears that the 5-20 year time frame is in the trough of a bathtub failure curve. Exactly when, or if, late failures will occur in these systems remains unknown.

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