The Durability of Implanted Electrodes and Leads
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Abstract
Implanted neuroprosthetic systems have been successfully utilized to provide upper extremity function for over 15 years. A critical aspect of these implanted systems is the safety, stability and reliability of the stimulus delivery components. These components are: 1) the stimulating electrode itself, 2) the electrode lead, and 3) the lead-to-device connector. A failure in any of these components results in the direct loss of the ability to activate a muscle in a consistent manner, usually resulting in a decrement in the function provided by the neuroprosthesis.

The results indicate that the electrode, lead and connector system are extremely durable. Over 250 electrodes have been implanted with at least a two year follow-up time. Over 98% of these electrodes produce the desired output and were used as part of a functional neuroprosthetic system. There have been only three electrode/lead failures and only one electrode infection. Electrode threshold measurements indicate that the electrode response is stable over time. There is no evidence of electrode migration or continual encapsulation in any of the electrodes studied.

These results have impact on the design of implantable neuroprosthetic systems. The electrode/lead component of these systems should no longer be considered a weak technological link.

1. Introduction
Electrodes and leads are common components of implanted systems, such as pacemakers, cochlear implants, respiratory assist devices and bladder/bowel stimulators. The use of implanted systems to provide joint movement, however, puts added requirements on the electrode/lead. First, multiple leads are typically required, because multiple muscles are activated and are spread out over a relatively large area of the body. Second, the leads are required to cross many joints to reach some of the more distal muscles. Third, fine control over the degree of contraction is required in order to produce highly coordinated movements.

In this abstract, we report on the reliability and stability of electrode/lead systems used in a neuroprosthesis providing upper extremity function. This system requires at least eight functioning electrodes, requires some leads to cross the shoulder, elbow and wrist joints and generally requires that all muscles must be activated in a graded fashion. We believe that this system provides a stringent test for implanted electrode/lead systems.

2. Methods
Neuroprosthetic System Description:
The implanted neuroprosthetic system used in this study consists of an implanted stimulator, electrodes, leads and connectors, as well as external components [1,2,5]. A radio frequency inductive link is used to provide the communication and power to the implanted device. The implanted stimulator has eight to ten leads connected to electrodes. An in-line connection is used to connect the implant device to each lead intraoperatively. Each electrode is implanted in a separate location, typically in the muscles of the hand, forearm and upper arm. In some cases, an electrode is placed in the

Figure 1. Electrodes used for implanted neuroprosthetic systems. Top: intramuscular (Membreg) electrode. Bottom: epimysial electrode.
supraclavicular region to provide sensory feedback. Muscle activation is accomplished through electrical stimulation. Stimulus pulses consisted of a constant current balanced charge waveform. The stimulating phase was a square cathodic pulse of 0-200μs in duration and 20mA in amplitude. In rare cases, a stimulus amplitude of less than 20mA was used. Stimulus frequency was 12-16Hz for all muscle-based electrodes. For sensory feedback, frequency varied from 4-64Hz.

Two styles of electrodes have been utilized in implanted upper extremity neuroprosthetic systems: epimysial and intramuscular (Membrog) [3,4]. Epimysial electrodes consist of a Pt-Ir disk embedded in a silastic backing. The electrode is sutured to the surface of the muscle. Intramuscular electrodes is inserted directly into the muscle belly. The stimulating tip of the electrode is created by winding the deinsulated wire around the outside of the tubing for a length of 2mm. An anchor, consisting of a polypropylene barb at the tip of the electrode, holds the electrode in place within the muscle.

**Monitoring of System Integrity:**

The implanted neuroprosthetic system is monitored to verify the biological safety and integrity of the implanted components. The mechanical and electrical integrity of the implanted components are also monitored. These tests include: intra-operative verification, X-rays, electrode thresholds, surface potential measurements, and patient/staff reports of system or medical incidents.

### 3. Results

Data was collected regarding neuroprostheses implanted in 29 arms in 28 patients. The follow-up time ranges from a minimum of two years to a maximum of fifteen years. A total of 253 electrodes have been implanted in this series of patients.

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.

**Functional Stability.** Nearly all of the electrodes (98.5%) recruit their target muscle at the lowest threshold of stimulation. These responses do not change over time. In two cases, an electrode was repositioned in a revision surgery to try to obtain improved function.

**Mechanical Durability.** Across all 253 electrodes, there have been a total of three electrode-lead mechanical failures. Each of these incidents occurred within two years post implant. We have identified that repeated use is the most likely cause of failure in only one of the three breakages. There have been no failures of the lead more than a few centimeters proximal to the electrode tip, and there have been no failures or separations of the connectors. None of the mechanical failures have been the result of the lead being flexed across the joint.

**Infection/Rejection Response.** There have been no cases of component rejection across the subjects studied. In one electrode, a local infection developed around the suture holding the electrode in place approximately one year after implant. The electrode was removed, but the lead left in place with no further incident. There have been no cases of tissue erosion over the implanted components.

**Device-Tissue Interface.** There is a direct electrical connection between the device and living tissue at the implant anode and at each electrode termination. There have been no cases where the encapsulation around the implant anode has compromised function in any way. We have been able to observe the tissue encapsulation around the implanted components in the few cases where an implant device or electrode has been moved or upgraded. The encapsulation is typically 1mm or less thick and well-formed. No indication of ongoing inflammatory response has been identified.

Electrode threshold measurements have been taken at various intervals on all electrodes implanted.
The results indicate that the electrode thresholds do not increase over time. There is typically a decrease in threshold over the first two or three months after the electrode is implanted, and thereafter it is stable. There is no evidence of a slowly increasing threshold that might indicate increased encapsulation or migration. There has been no evidence that any of the electrodes implanted have moved, either during the time of initial encapsulation or over long term usage.

Worldwide, over 1500 of these electrodes have now been implanted in over 200 quadriplegic individuals [5].

4. **Summary and Conclusions**

   The durability of implanted components, especially long leads, has been described in the literature as a major source of failure in neuroprosthetic systems. However, our results demonstrate that long leads crossing multiple joints are not a source of failure. Our results further indicate that complications due to electrode/lead breakage and infection/rejection are extremely low and do not pose a major limitation in the deployment of implanted neuroprosthetic systems. We believe that these results have implications regarding the future design of neuroprosthetic systems, demonstrating that elimination of leads does not need to be a major design criteria from the perspective of system durability.

**Acknowledgment**

This research has been supported by the Dept. Veterans Affairs Rehabilitation Research and Development Service and by the National Institutes of Health.

**References**


