Clinical Use of Percutaneous Intramuscular Electrodes for Functional Electrical Stimulation

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Objective: To evaluate the clinical use of the percutaneous intramuscular electrode in functional electrical stimulation (FES).

Design: Randomized and controlled study.

Setting: A referral center and institutional practice providing outpatient care.

Patients: Seventeen patients (12 men, 5 women) who had implanted percutaneous intramuscular electrodes for more than 1 year were examined. The average follow-up time after implantation of electrodes was 2.2 years (range, 1 yr to 4 yr 10mo). Overall, there were 327 electrodes (83 upper extremities and 244 lower extremities).

Intervention: The indwelling electrode was composed of helically coiled Teflon-coated rope stranded from 19 hard drawn wires of SUS 316L stainless steel (SES 114).

Main Outcome Measures: The rates of breakage, movement, infection, and the number of electrodes that needed reimplantation were evaluated.

Results: Only one electrode broke (0.3%) in the iliopsoas muscle at 12 weeks after implantation. Eight electrodes (2.4%) were removed because of loss of sufficient contraction force caused by movement of the electrodes. Movements occurred at 9 weeks in 6 electrodes and at 5 months in two. The failure rate of electrodes in the lower extremities was 3.7%. No failures occurred in the upper extremities. Ten electrodes (3.1%) required reimplantation. Although ten superficial infections (3.1%) were seen around the site of electrode insertion, no removals of electrode were needed. All electrodes in one patient were removed, however, because of generalized methicillin-resistant Staphylococcus aureus infection complicated with renal disease. Electrodes were reimplanted after improvement of the infection.

Conclusions: The ultrafine percutaneous intramuscular electrode was considered practical for long-term FES use.

ADVANCES IN ELECTRONICS have made it possible to restore paralyzed muscles by functional electrical stimulation (FES). One principal difference among the various approaches to restoration of paralyzed muscles is that the use of surface versus internal electrodes for stimulation. Surface electrodes have disadvantages that include the potential to come loose, skin irritation, and poor cosmetic appearance. In addition, surface electrodes cannot stimulate deep muscles. Reliability is also a problem with surface electrodes because small differences in electrode placement create large differences in response, and habituation of the reflex occurs. Percutaneous or implantable electrodes offer the potential advantages of selective activation of individual paralyzed muscles for controlling fine and precise movements with high reliability and reproducibility, ease of use when left inside the body, and stimulation of deep muscles.

When functional loss due to breakage or movement of the electrodes occurs, the implantable system has a disadvantage in requiring additional surgery. In addition, a closed-loop control system is used to minimize muscle fatigue caused by electrical stimulation and to prevent falling has thus far been difficult to connect with an implantable system in the lower extremities, because there is no appropriate connector between implantable electrodes and the closed-loop control system. Percutaneous intramuscular electrodes are easy to change when problems arise, and they are easy to connect with a closed-loop control system; accordingly, we have used them since 1990.

The requirements for percutaneous intramuscular electrodes are high mechanical strength, flexibility, corrosion resistance, negligible tissue reaction, and chemical stability. However, they have been plagued with high infection and failure rates. This article describes the results of clinical use of ultrafine percutaneous intramuscular electrodes in the Akita FES Projects.

SUBJECTS AND METHODS

Subjects

The subjects included 17 patients (12 men, 5 women) who had implanted percutaneous intramuscular electrodes for more than 1 year. Patients included 6 with complete paraplegia, 3 with incomplete parapareses, 2 with incomplete tetraparases, and 6 with hemipareses. There were no subjects with complete tetraplegia because of the difficulties to restore the functional function by FES. The average patient age was 43.3 years (range, 19 to 68 years). The average time since injury was 3.9 years (range, 3 months to 15 years) and the average follow-up time since implantation of the electrodes was 2.2 years (range, 1 year to 4 years 10 months). Overall, 327 electrodes were implanted (83 upper extremities and 244 lower extremities) (table 1).

Methods

We used an indwelling electrode composed of helically coiled Teflon-coated rope stranded from 19 hard drawn wires of SUS 316L stainless steel (fig 1). The outermost diameter of the
PERCUTANEOUS ELECTRODES FOR FES, Shimada

Table 1: Details of Subjects

<table>
<thead>
<tr>
<th>Paralysis</th>
<th>Number of Patients</th>
<th>Site</th>
<th>Number of Electrodes</th>
<th>Breakage</th>
<th>Movement</th>
<th>Infection</th>
<th>Reimplantation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete paraplegia</td>
<td>6</td>
<td>LE</td>
<td>188</td>
<td>1</td>
<td>2</td>
<td>10</td>
<td>8</td>
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<tr>
<td>Incomplete paraparesis</td>
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<td>LE</td>
<td>44</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
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<tr>
<td>Incomplete tetraparesis</td>
<td>2</td>
<td>UE</td>
<td>36</td>
<td></td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Hemiparesis</td>
<td>6</td>
<td>UE</td>
<td>47</td>
<td></td>
<td></td>
<td>10</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>LE</td>
<td>22</td>
<td></td>
<td></td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>17</td>
<td></td>
<td>327</td>
<td>1 (0.3%)</td>
<td>8 (2.4%)</td>
<td>10 (3.1%)</td>
<td>10 (3.1%)</td>
</tr>
</tbody>
</table>

Abbreviations: UE, upper extremity; LE, lower extremity.

electrode was .48mm. The tip of the electrodes was deinsulated to apply stimulus current to each muscle.

Electrodes were implanted percutaneously into the motor point of the muscles under local or general anesthesia. Probing was done with a pointer needle to identify the motor point. Once a suitable contraction occurred with stimulation of the probe, a percutaneous electrode was inserted parallel to the pointer needle. The pointer needle was then removed. The electrode was not attached with skin. The localization of electrodes was verified by plane X-ray after implantation. We chose a common body-entry point for electrodes located at lateral upper arms in upper extremities and anterior proximal thighs in the lower extremities (fig 2). Following implantation, the electrode sites were dressed with dry sterile gauzes until oozing stopped after approximately a week. When the sites were dry, the only dressing was a Silkyapore patch. In the bath, a Tegaderm was used to prevent wetting. Electrical exercise commenced 2 weeks after implantation to allow time for tissues to heal. In therapeutic electrical stimulation (TES), stimulation of the muscles was conducted for 10 minutes three times daily at the beginning, and was increased by 10 minutes every 2 weeks. After 10 weeks, stimulation was applied for 60 minutes three times daily. After exercising with TES for more than 3 months, FES training started. The autonomic hyperreflexia during FES training was not seen in our series.

We evaluated the rates of breakage, movement, and infection, and the number of electrodes that needed reimplantation. Breakage of the electrode was indicated by an ohmic impedance component over 10 kilohms. Electrodes were most likely to move away from the motor point; these showed a normal impedance measurement but failed to produce the desired muscle response.

RESULTS

Only one electrode broke (0.3%) in a T6 completely paraplegic patient at a site deep in the iliopsoas muscle 12 weeks after implantation. Eight electrodes (2.4%)—3 in common peroneal nerves, 2 in femoral nerves, and 1 each in the iliopsoas muscle, vastus lateralis muscle, and gluteal medius muscle—were removed for loss of sufficient contraction force due to movement of the electrodes. Movements occurred at 9 weeks in 6 electrodes and at 5 months in 2. All failures of electrode were seen in the lower extremities. The failure rate of electrodes in lower extremities was 3.7%. No failures occurred in the upper extremities. Ten electrodes (3.1%) required reimplantation (table 1). On ten occasions (3.1%), superficial infection developed at the site of electrode insertion (fig 3). These infections were treated by topical sterilization of the skin using povidone iodine and oral antibiotics. Removal of the electrode was not required for superficial infection in any case. However, all electrodes in a T5 completely paraplegic patient were removed for treating generalized methicillin-resistant Staphylococcus aureus infection complicated with renal disease and these required reimplantation after improvement of the infection. Dermatitis around the site of electrode insertion caused by the Silkyapore was seen in an L1 incompletely paraparetic patient and was cured with an ointment (fig 4).

DISCUSSION

In FES, an electrode is the interface conducting programmed electrical signals to neuromuscular system of the extremities.8

Fig 1. Percutaneous intramuscular electrode (SES114√): An indwelling electrode composed of helically coiled Teflon-coated rope stranded from 19 hard drawn wires of SUS 316L stainless steel.

Fig 2. Body-entry points for electrodes located at anterior proximal thighs in the lower extremities.
Percutaneous electrodes for FES, Shimada

Fig 3. Superficial infection developed at the site of electrode insertion.

To allow selective stimulation of as many muscles as are necessary to provide patients with a standing, gait, feasible motion of the upper extremities, we implanted subjects with percutaneous intramuscular electrodes.

Development of practical percutaneous intramuscular electrodes for FES in the USA has been mainly performed at Case Western Reserve University (CWRU). Peckham et al.9 developed percutaneously indwelling intramuscular electrodes for transient FES usage. Their electrode consists of type-316 stainless steel wires arranged in a multistrand configuration creating a cable with a 250μm diameter. The cable is coated with Teflon and arranged in a helical configuration. Ten millimeters of insulation is removed at one end to form the stimulating surface with the last 2mm of the insulated tip bent to form a barb. Silastic is used at the insulated/deinsulated transition to dissipate the stress configuration. Membarg et al.10 reported the most recent analyses of this electrode and included 710 percutaneous electrodes implanted in 38 adults with C5 and C5-6 injuries. The probability of electrodes surviving for 6 months was 88%, while the 1-year survival probability was 80%, the 3-year survival probability was 60%, and the 5-year survival probability was 48%. Smith and colleagues11 reported the results of multicenter study conducted by CWRU to assess the benefits of its functional neuromuscular stimulation hand system. Of the 177 electrodes analyzed, 113 were removed. One hundred electrodes were nonfunctional at removal (breakage, altered response, adverse sensation) and 13 were explanted for other reasons (accidental removal, redundant function, site changed). Of all electrodes removed, breakage accounted for 38%, altered response 48%, and adverse sensation 3%. Compared with the results from CWRU, the cumulative electrode survival in the study by Smith12 was considerably lower. These results were mediocore for use in upper extremities, but the electrode failure rate in the CWRU study was still high as compared with that in our series (0% in the upper extremities).

In the lower extremities, Marsolais and his coworkers316 used percutaneous intramuscular electrodes to control the gait of paraplegic patients. Their electrodes are made from 76-micrometer, 10-strand, stainless steel Teflon-coated wire; each strand is 25 micrometers in diameter. Approximately 35mm of the wire is deinsulated at one end, and the bared wire is wound over a .15mm mandrill. The final 5mm of the deinsulated portion was fashioned into a hook to anchor the electrode in the muscle. Of 1,025 electrodes, 35% failed within the first 4 months and 38% of those implanted over a 38-month period continued to function for 1 year, while 28% survived for 2 years. Since the result of clinical use of this coil electrode was frustrating because of the frequent need to replace implanted electrodes that became dysfunctional, Scheper and associates17 developed a double helix electrode. The materials they used were chosen because of good electrical properties, biocompatibility, toughness, strength, and durability in vivo. Stainless steel, Teflon-insulated wire was wound into a helical lead around a polypropylene core and then rewound into a double helix configuration for stress relief during muscle contractions. The electrode tip was augmented with stainless steel barbs to increase anchoring strength. A ten-stranded braid with a 76μm strand diameter 316LVM stainless steel wire insulated with extruded FEP Teflon was used for lead wire. The diameter of the wire cable with insulation is .28mm. Anchoring barbs were fabricated from 0.1mm diameter 316LVM stainless steel wire. A total of 22 paralyzed patients received implants of 775 double helix electrodes, 453 of which (65%) continue to produce strong and stable muscle contractions. The oldest implanted electrode has remained functional for 4.5 years. The main causes for failure of double helix electrodes have been: (1) inability to locate a suitable site for stimulation and properly place the electrode (28%; 4%); (2) unwanted changes in muscle response to stimulation (91%; 12%); (3) increase in electrode impedance (74%; 10%; assumed breakage); (4) intolerable pain during stimulation (8%; 1%); and (5) infection (4%; 0.5%). This double helix electrode design has proven practical for achieving chronic stimulation of selected muscles as compared with that by the coil wire electrode. However, the failure rate of the double helix electrode remains high (35%) for use in daily living.

During the time that the SUS316 soft wire electrode, which was a helical coil wound from a Teflon-insulated seven strand stainless steel wire,18 was initially being used for FES and TES in Japan, 40% of the electrodes implanted into the bulky muscles with vigorous contraction broke within 4 months after implantation.4 Handa et al.4 developed a new electrode based on

Fig 4. Dermatitis around the site of electrode insertion caused by the Silkypore.
the same electrode as we used and reported that the breakage rate in this electrode was only 1.3% in 457 electrodes in the upper and lower extremities. Our results supported that SES114 electrode was well tolerated as a percutaneous intramuscular electrode for long-term clinical use in FES compared with other designs (fig 5).

Marsolais and colleagues\(^\text{10}\) reported that breakage of the coil wire electrode was often caused by the presence of inclusions within the wire and that half of the failures occurred at the insulated portion and the rest at the deinsulated portion or at the junction of the insulated and deinsulated portions. In our electrode, however, we have not found many inclusions in the fractured surface in SEM data and none of the nonfunctional electrodes showed electrode failure in the deinsulated portion or at the insulated-deinsulated boundary. Since the failure in the insulated portion occurred at the portion where electrodes penetrated the fascia and no corrosion was observed, breakage of our electrode appears to be mainly induced by large mechanical stress in the fascial plane. Therefore, high flexibility, elasticity, and tensile strength are required to prevent breakage of the percutaneous intramuscular electrode. Since the CWRU electrode was manufactured with vacuum melting method (VM), nonmetallic inclusions were not removed (fig 6). Our electrode was manufactured with an electroslag remelting process (ESR) that could remove most nonmetallic inclusions. The Ingot of our electrode was produced with double ESR (fig 7). In this respect, our electrode has greater mechanical strength compared with that of other designs.

Scheiner et al\(^\text{17}\) reported that success in achieving strong and stable muscle contractions varied with the area of implant. The best results were obtained from electrodes in the tibialis, gastrocnemius, quadriceps, and gluteal muscles. Poor results were seen from implants in the trunk (erector spinae, iliopsoas) and hamstrings areas. In our series, however, electrode failures were seen even in the quadriceps, gluteal muscles, and femoral nerve. Results will differ with implantation technique. Scheiner et al\(^\text{17}\) reported that unwanted changes in muscle response to stimulation after implantation were caused by distortion of the electric field during implantation due to fluid build up and swelling around the implant site, encapsulation of the electrode that was a layer of reactive fibrous process, and movement of the electrode relative to the stimulated nerve. As solutions, they recommended reducing trauma during surgery by decreasing the amount of probing needed to locate the implant site and the degree of encapsulation. However, the extent to which encapsulation of the electrode will change the field distribution around the implant site after implantation has not yet been determined. In addition, the electrode will still move relative to the stimulated nerve because of increases in muscle mass, fat, or connective tissue between the electrode and target nerve after fixation of the electrode in the soft tissue.

Medical complications from the implantation of intramuscular electrodes were infrequent. Pekham\(^\text{10}\) reported that only three minor infections were suspected in the implantation of nearly 500 electrodes. Membre\(^\text{11}\) also reported that granulomas and infections around CWRU electrodes accounted for 1.1% and 0.4%, respectively, and local antibiotic treatment or cautery generally cleared the reaction, although removal of the electrode was sometimes necessary. In our series, ten superficial infections (3.1%) were seen at the site of electrode insertion. However, these infections were treated by topical sterilization of the skin using povidone iodine and oral antibiotics without need to remove of the electrodes. Although superficial infections can be treated without removal of the electrode, the electrodes sometimes must be removed as a foreign material in severe generalized infections. This would be a serious problem in percutaneous and implantable electrodes.

Stimulus threshold levels were found to vary the most during
the initial few weeks after implantation, corresponding to maximal tissue response to the insertion and to the foreign material, which resulted in the encapsulation and stabilization of the electrode within a sheath of connective tissue. Handa reported that impedance of our electrode between active and reference electrodes fluctuated until 10 weeks after implantation and became almost constant thereafter. The threshold value then increased for 5 weeks after implantation and became stable thereafter. This electrical stability reduced the failure rate of electrodes and facilitated long-term stable electrical stimulation.

Thus, our results suggest that the SES114 percutaneous intramuscular electrode is practical for long-term FES use.

References

Suppliers
a. SES114; Nippon Seisen Co., Ltd., 4-17-1 Ikenomiya, Hirakata, Osaka 753, Japan.
b. 3M Health Care, St. Paul, MN 55144-1000.
c. A-M Systems Inc., 11627-A Airport Road, Everett, WA 98204.