

Selectivity of intramuscular stimulating electrodes in the lower limbs

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Abstract—Intramuscular (IM) electrodes have been used safely and effectively for decades to activate paralyzed muscles in neuroprosthetic systems employing functional electrical stimulation (FES). However, the response to stimulation delivered by these and any type of electrode can be limited by a phenomenon known as spillover, in which the stimulus intended to produce a contraction in a particular muscle inadvertently activates another muscle, causes adverse sensation, or triggers undesired reflexes. The purpose of this retrospective study was to determine the selectivity of monopolar intramuscular stimulating electrodes implanted in the lower limbs of individuals with motor and sensory complete paraplegia secondary to spinal cord injury (SCI) and to catalog the most common electrode spillover patterns. The performance records of 602 electrodes from 10 subjects who participated in a program of standing and walking with FES in our laboratory over the past decade were examined. Sixty percent (358) of these electrodes were “stable” (i.e., stimulated responses were consistent during the first 6 months postimplant), and 32% of all stable electrodes (113) exhibited spillover as noted in clinical and laboratory records. Common spillover patterns for eight muscle

groups were tabulated and analyzed in terms of their functional implications. The beneficial (activation of synergistic muscles) or deleterious (activation of compromising reflexes, antagonists, or adverse sensation) effects of spillover were highly context dependent, with several potentially useful spillover patterns in certain phases of gait becoming undesirable and limiting in others. Knowledge of the selectivity of intramuscular electrodes and the patterns of spillover they exhibit should guide surgeons and rehabilitationists installing lower-limb neuroprostheses during the implantation process and allow them to better predict the ultimate functional usefulness of the electrodes they choose.

Key words: *electrodes, functional electrical stimulation (FES), spinal cord injury (SCI).*

INTRODUCTION

For persons with paraplegia resulting from thoracic level spinal cord injuries (SCI), neuroprostheses using functional electrical stimulation (FES) can be powerful adjuncts to conventional therapies by providing the means to exercise, stand, and step through the active contractions of their otherwise paralyzed muscles. If the damage to the nervous system is confined to the upper motor neurons, small electrical currents can excite the intact peripheral nerves, which in turn cause the muscle fibers they innervate to contract. Coordinating the actions

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of many muscles by modulating stimulus timing, intensity, pulse duration, or frequency can result in useful movements from the entire limb. To be successful and truly functional, many lower-limb applications of FES require strong isolated contractions of single muscles or muscle groups.

The selectivity and recruitment properties of a stimulated response are related to the design and location of the stimulating electrode relative to the target nerve. Stimulation can be delivered to the nerve via different electrode technologies that are usually classified according to the location of their stimulating surfaces. *Surface electrodes* are placed on the skin surface and deliver electrical charge to the motor nerve transcutaneously. Such electrodes are practical alternatives for muscle conditioning, balance training, and initial functional evaluation of candidates for neuroprostheses (1–4). One commercially available FES system using two to six channels of surface stimulation allows individuals with injury levels of T4 or below to stand and take steps at speeds and physiologic costs similar to alternative mechanical systems (5–8). However, it is difficult or impossible to selectively activate individual muscles transcutaneously, especially deep muscles such as hip flexors (9,10). Large currents may be required to drive sufficient charge through the skin and intervening tissues between the electrode and the peripheral nerve. In many cases, cutaneous pain receptors are excited, and patients with preserved or heightened sensation may find it difficult to tolerate surface stimulation at the levels required to produce a functional motor response.

Muscle-based electrodes, on the other hand, bypass both the high resistance of the skin and the cutaneous sensory fibers. Because their stimulating surfaces lie closer to the motor nerve of the desired muscles, they can produce contractions more efficiently (with lower currents) and with greater selectivity than surface electrodes. For these reasons, muscle-based electrodes are preferable for situations that require independent control of several isolated muscles. The stimulating tips of *intramuscular (IM)* electrodes of various designs reside in the muscle tissue itself and generally include a barbing mechanism to resist movement until encapsulation occurs. Depending on their intended application, intramuscular electrodes can be introduced either percutaneously (11–13) or in an open surgical procedure (14). In addition to their selectivity, low current requirements, and ease of implantation, intramuscular electrodes allow access to deep nerves that are difficult to approach surgically. When used with percuta-

neous leads, they can also be removed easily and provide a means for safely producing strong and repeatable contractions on either an acute or longer term basis (15–21). Individuals with thoracic paraplegia using monopolar intramuscular electrodes with percutaneous leads have been able to stand and walk repeatably at speeds approaching two thirds of normal (22,23). With 16 to 32 channels of stimulation, subjects were able to sidestep (24), back step (25), climb and descend stairs (26), as well as perform selected one-handed reaching tasks while standing (27).

Selectivity refers to the ability of an electrode to activate the targeted nerve and produce an isolated contraction of the desired muscle without recruiting other muscle groups, producing adverse sensation or triggering reflexes. Although intramuscular designs tend to be more selective than surface electrodes, they can still “spill over” to unintended neural structures and produce responses other than those expected (28). For example, an intramuscular electrode near the femoral nerve intended to activate the vasti to extend the knee during quiet standing can spill over to recruit rectus femoris or sartorius at higher stimulus levels, which would flex the hip and be counterproductive to standing (29). “Spillover” usually refers to the situation in which the stimulus threshold of the secondary (unintended) nerve is reached before maximal recruitment of the primary (target) nerve and muscle. The action of the secondary muscle may be synergistic or antagonistic with respect to the primary muscle’s action, depending on the overall motion desired.

The purpose of this study was to investigate the selectivity of intramuscular electrodes in the major muscles of the lower limb and characterize the most common patterns of spillover produced by intramuscular stimulation. Knowing which spillover patterns to expect from intramuscular electrodes and their effects on standing and stepping with FES should assist surgeons and rehabilitation professionals during the implant process and should help predict the ultimate clinical utility and functional outcome of neuroprostheses using intramuscular stimulation.

METHODS

The monopolar intramuscular electrodes and percutaneous leads employed in this study have undergone extensive laboratory and animal testing (15), as well as clinical use in upper- (14) and lower-limb applications

(13,16), which are described in other previously cited publications. They were fabricated from multifilament (7 or 10 strand) Teflon-insulated type 316 LVM stainless steel wire, with a diameter of approximately 200 μm . The multistranded cable was then coiled to form the flexible open helical lead approximately 580 μm in diameter. Ten millimeters at the end of the electrode are deinsulated to create a conducting surface area of at least 10 mm^2 . A hook at the tip of the electrode formed by folding back the final 2 mm of the deinsulated segment promoted anchoring in the tissue until encapsulation is complete. Previous studies have shown that these types of electrodes can produce reliable and strong contractions and are well tolerated by the body. All electrodes were manufactured in a Class 1000 clean room at facilities at Case Western Reserve University and sterilized with ethylene oxide gas.

During testing and functional use, a large ($2 \times 2 \text{ in.}^2$) dispersive surface electrode was placed over a bony prominence away from excitable tissue, usually on greater trochanter, lateral epicondyle or anterior-superior iliac spine, to serve as a common anode. Biphasic, asymmetrical charge balanced stimulus currents of constant amplitude (20 mA) and frequency (20 Hz) were used to characterize the response of each electrode. Rectangular cathodic stimulating pulses with exponential recharge phases were delivered with 1- μs resolution via a microprocessor-controlled stimulator (30).

We collected data from the clinical and laboratory records of subjects who had participated in lower-limb FES programs using chronically indwelling intramuscular electrodes with percutaneous leads at the Motion Study Laboratory of the Louis Stokes Cleveland Department of Veterans Affairs Medical Center. Each subject's record contained information on every electrode implanted for the duration of its use, including the primary muscle targeted, any secondary actions it caused, and the presence of spillover or reflex activation. As part of routine laboratory practice, the recruitment properties of each electrode (muscle activation thresholds and saturation levels) were determined at regular intervals (nominally monthly). As illustrated in **Figure 1**, the activation threshold was defined as the lowest pulse duration that produced a just-noticeable contraction. Saturation was defined as that pulse duration above which no additional muscle force was generated or spillover (in terms of secondary muscle movement, sensation, or reflex activity) was observed. This information had been updated periodically throughout each electrode's lifetime, providing a

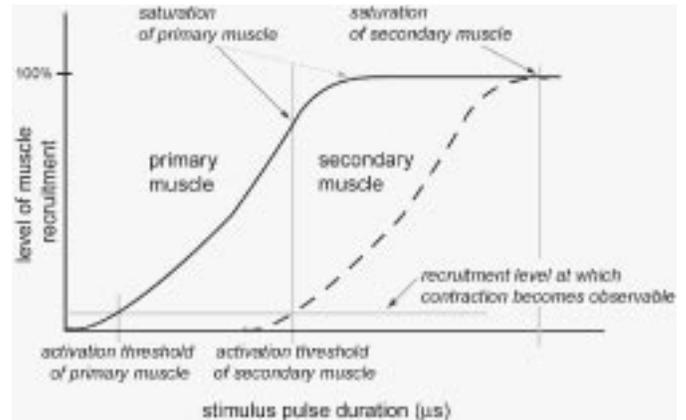


Figure 1.

Activation threshold, saturation, and spillover values of pulse duration for a stimulus of constant amplitude and frequency. Activation threshold is pulse duration at which a muscle's activity first becomes observable; saturation occurs at stimulus duration that maximally recruits a muscle (dashed arrow), activates a secondary muscle or triggers a reflex (solid arrow).

history in the laboratory record of its behavior and selectivity.

The records of 10 subjects implanted with percutaneous intramuscular electrodes during the 10-year period from January 1988 through December 1998 were examined. To ensure consistency of the data and avoid any confounding influences because of the mechanical properties of the electrode design, we included only electrodes showing stable recruitment properties in the analysis. An electrode was defined as being "stable" if it exhibited a consistent functional response during the entire 4-month window between the second and sixth month postimplantation. Excluding responses prior to 2 months postimplant eliminated electrodes showing signs of early movement away from the motor point because of the critical encapsulation period immediately after insertion. Similarly, excluding responses after 6 months postimplant eliminated electrodes showing altered responses caused by late movement, breakage, or removal upon completion of a laboratory research protocol. Thus, the data included in the analysis represented only the recruitment properties of stable intramuscular electrodes without artifacts introduced by the mechanical properties of various anchoring and lead wire configurations of different electrode designs.

The information from all the laboratory records was combined and used to establish the most common patterns of spillover for each muscle listed in **Table 1**. Entries in the records during the 10-year period under

Table 1.
Common spillover patterns of muscles.

Action	Primary muscles
Knee extension	Vasti of the quadriceps
Hip extension	Gluteus maximus Long hamstrings Posterior adductor magnus
Trunk extension	Erector spinae
Hip flexion	Illiopsoas Sartorius Tensor fasciae latae (TFL) Gracilis
Hip abduction	Gluteus medius
Ankle dorsiflexion	Tibialis anterior (TA)
Ankle plantarflexion	Gastrocnemius/soleus
Knee flexion	Short head of biceps femoris

examination were completed by different members of the Motion Study Laboratory staff, who employed different terminology and evaluation methods to describe the spillover patterns they observed. Some observers noted an undesired joint motion or action, while others explicitly identified the secondary muscle or neural structure activated by name. For the purposes of this analysis, spillover was identified if the clinical record indicated any of the following to describe the response during stimulation of a single electrode: (1) *a part of the body* (e.g., “foot”) that could not be directly affected by the target muscle, without specifying the observed motion or

Table 2.
Number of stable electrodes of targeted muscles.

Primary target muscle	Stable electrodes	Spillover electrodes (% per muscle)	Reflex electrodes (% per muscle)
Illiopsoas	12	8 (67%)	1 (8%)
Gluteus medius	24	11 (46%)	0
Long hamstrings	39	17 (44%)	2 (6%)
Short head of biceps femoris	14	6 (43%)	0
Gluteus maximus	40	17 (42%)	0
Vasti of quadriceps	74	23 (31%)	5 (7%)
Posterior adductor magnus	31	8 (26%)	0
Erector spinae	23	6 (26%)	0
Gracilis	16	4 (25%)	2 (12%)
Tensor fasciae latae (TFL)	18	3 (17%)	1 (6%)
Sartorius	25	4 (16%)	4 (16%)
Gastrocnemius	13	2 (15%)	4 (30%)
Tibialis anterior (TA)	29	4 (14%)	11 (38%)
Total	358	113 (32%)	30 (8%)

responsible muscle and nerve, (2) activation of a *particular secondary muscle* (e.g., “gastrocnemius”) other than the target, neither describing the resulting motion nor the associated nerve, (3) observation of a *specific joint motion* (i.e., “plantarflexion”) other than that caused by the target muscle, without naming the responsible nerve or muscle, or (4) stimulation of a *specific nerve* (e.g., “sciatic”) other than that innervating the target muscle without reference to the resulting motion or responsible muscle. Basic principles of lower-limb neuromuscular anatomy (31,32) were then applied to integrate these various methods of describing spillover and identify the most likely neural pathway to coherently explain the recorded observations. Finally, the possible advantages and disadvantages of each spillover pattern during standing and walking with FES were analyzed.

RESULTS

Six hundred and two electrodes were considered for inclusion in the study. Sixty percent (358) of the electrodes were stable. The number of stable electrodes included in the analysis for each targeted muscle is provided in **Table 2**. Almost one third (113) of all the stable electrodes exhibited at least one episode of spillover. Several electrodes spilled over to more than one nerve or muscle, and 30 of the stable devices (8 percent) caused reflex activation as previously noted with IM electrodes. Results for individual muscles grouped by function are presented below in their order of

importance for achieving standing and stepping with FES. Complex spillover patterns are illustrated graphically in terms of the nerves, muscles, or joint movements observed and noted in the clinical record.

Knee Extensors

Vasti of the Quadriceps (Figure 2): For the sake of this analysis, data from all individual heads of the vasti were pooled. Because the vasti are all uniaxial muscles innervated by the femoral nerve to extend the knee without flexing the hip, simultaneous activation of multiple components of the vasti was treated as the desired and targeted response. Seventy-four stable quadriceps electrodes were implanted into the vastus lateralis, medialis, or intermedius. Twenty-three (31 percent) showed evidence of spillover. A majority of these (22) spilled over through the femoral nerve to activate the rectus femoris or sartorius to flex the hip when the primary desired action was knee extension. Fourteen of the spillover electrodes (61 percent) activated the rectus femoris as noted by palpation of the proximal rectus tendon, either alone (11) or in combination with other muscles. A large number (11) of the spillover electrodes stimulated the sartorius, either in isolation (8) or together with rectus (3), causing noticeable abduction of the thigh. Internal rotation was noted as a secondary action of one electrode, possibly because of spillover to the tensor fasciae latae.

Hip Extensors

Gluteus Maximus (Figure 3): Of 40 stable electrodes in the gluteus maximus, 17 resulted in notable

spillover (42 percent). The most commonly observed spillover patterns involved the sciatic nerve (10), either alone or in combination with other muscles. Of these electrodes, three activated the hamstrings; one recruited the toe flexors (flexor digitorum longus and flexor hallucis longus); one caused plantarflexion (probably via gastrocnemius or soleus), and two caused unspecified motions at the foot. Neither the muscles nor the resulting actions of the three remaining cases of sciatic nerve spillover were recorded. Eight electrodes spilled over to the superior gluteal nerve to activate the gluteus medius, including the one previously mentioned case in which unspecified foot movement via the sciatic nerve was observed.

Long Hamstrings (Figure 4): The clinical record did not consistently distinguish between the individual muscles of this group (semimembranosus, semitendinosus, and biceps femoris), so data for this analysis were pooled for all long hamstrings that are innervated by branches of the sciatic nerve. There were 39 stable electrodes in the long hamstrings, 17 of which (44 percent) showed a variety of spillover patterns involving either the sciatic or gluteal nerves. Spillover to the distal components of the sciatic nerve was more common and observed in all but two cases. Thirteen electrodes activated other undesired structures innervated by the sciatic nerve alone, while one case each involved combinations of sciatic and inferior or superior gluteal nerves. The remaining two electrodes spilled over to the superior gluteal nerve exclusively, causing internal rotation (probably via tensor fasciae latae and/or gluteus minimus) and did not involve the sciatic.

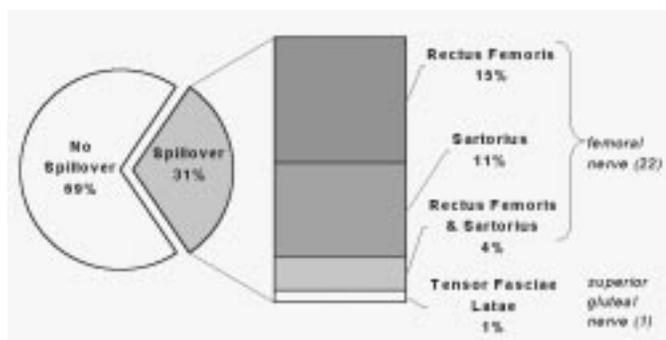


Figure 2.

Spillover patterns exhibited by intramuscular electrodes implanted in the vasti of quadriceps ($n = 74$). Vastus lateralis, medialis, and intermedius are innervated by femoral nerve and are targeted in FES systems to extend knee without flexing hip during quiet standing or stance phase of gait.

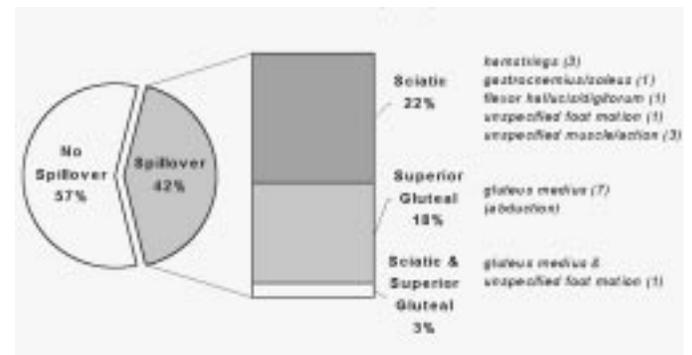


Figure 3.

Spillover patterns exhibited by intramuscular electrodes implanted in gluteus maximus ($n = 40$). Gluteus maximus is innervated by inferior gluteal nerve and is targeted in FES systems to extend hip during standing and stepping.

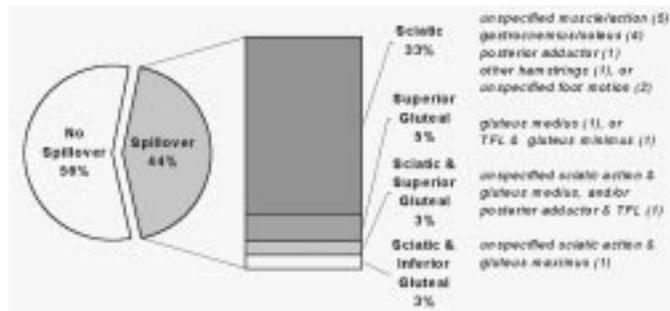


Figure 4.

Spillover patterns exhibited by intramuscular electrodes implanted in long hamstrings ($n = 39$). Long hamstrings (semimembranosus, semitendinosus, and long head of biceps femoris) are innervated by sciatic nerve and are targeted in FES systems to extend hip during standing and to decelerate shank in terminal swing during ambulation.

Seven of the spillover electrodes caused unspecified actions, while two others stimulated the posterior fibers of the adductor magnus. Four electrodes plantarflexed the ankle, presumably via the gastrocnemius and/or soleus, and two more caused an unspecified foot action.

Posterior Fibers of Adductor Magnus (Figure 5): Eight of the thirty-one stable electrodes (26 percent) in the posterior portion of adductor magnus, which extends and adducts the hip via a recurrent branch of the sciatic nerve, exhibited spillover. The sciatic and/or obturator nerves were involved in all eight cases caused by the dual innervation of adductor magnus. Six electrodes spilled over through the obturator nerve, causing adduction, hip flexion, and internal rotation, probably because of the actions of the anterior fibers of the adductor magnus and/or the gracilis. Five of these six electrodes activated the obturator alone, while the sixth included a contribution from the sciatic. Three electrodes caused spillover to the sciatic nerve. Two of these electrodes stimulated the hamstrings alone to flex the knee. The third electrode activated both the sciatic and obturator nerves simultaneously, causing contractions of the gastrocnemius and/or soleus muscles to plantarflex the ankle while flexing and adducting the hip via the anterior fibers of adductor magnus.

Trunk Extensors

Erector Spinae (Figure 6): The lumbar portion of the erector spinae was routinely implanted with intramuscular electrodes to extend the trunk and stabilize the pelvis during standing and walking with FES. Because these muscles are segmentally innervated and lack dis-

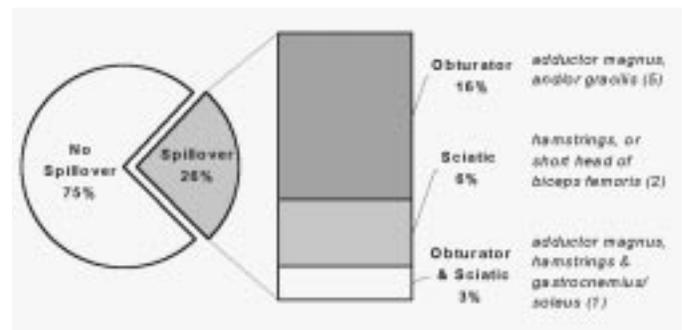


Figure 5.

Spillover patterns exhibited by intramuscular electrodes implanted in posterior fibers of adductor magnus ($n = 31$). Posterior adductor is innervated by sciatic nerve and is targeted in FES systems to extend and adduct hip during standing without flexing knee.

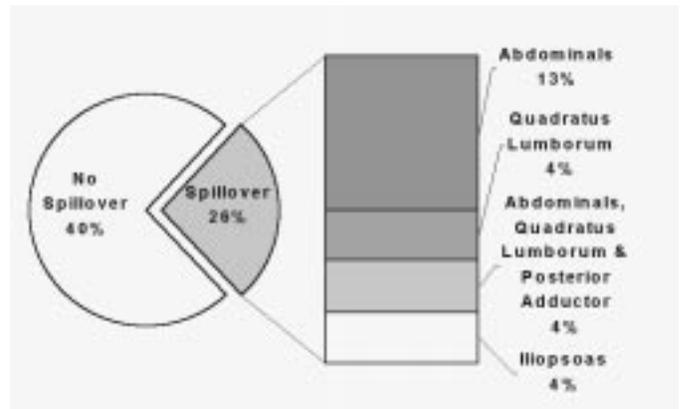


Figure 6.

Spillover patterns exhibited by intramuscular electrodes targeted for erector spinae $n=31$ at T12–L2 spinal roots. Erector spinae are segmentally innervated and are used in FES systems to extend trunk and stabilize pelvis during stance.

crete motor points, IM electrodes were inserted into or near the intervertebral foramen at T12 or L1 to excite the spinal roots and recruit as much of the erector spinae muscles as possible. Six out of twenty-three stable electrodes (26 percent) showed spillover to other structures receiving innervation by the T12–L1 spinal roots, with the most frequently observed spillover pattern involving the abdominal muscles. A total of four electrodes activated the abdominals, three in isolation and one in combination with the quadratus lumborum and adductor magnus. The other two cases of spillover involved the iliopsoas (see next paragraph) and the quadratus lumborum exclusively. The hip and trunk flexion caused by these spillover patterns would clearly be counterproductive to an erect upright posture during standing or walking.

Hip Flexors

Iliopsoas (Figure 7): In a manner similar to the erector spinae, the iliopsoas was commonly recruited for hip flexion during walking via intramuscular electrodes inserted in or near the L1 or L2 vertebral level. Electrodes in these locations could activate the spinal nerve roots innervating the psoas major and iliacus muscles, as well as many other muscles, which may explain their high rate of spillover. Out of the 12 stable electrodes examined, 8 spilled over to other structures innervated by the lumbar spinal roots (67 percent). Three electrodes resulted in activation of the erector spinae, either alone (1) or in combination with the abdominal muscles (1) or quadratus lumborum (1). Isolated spillover to the abdominal muscles alone was also observed in two cases. Two additional electrodes activated the rectus femoris through the femoral nerve, which is supplied by the L1/L2 nerve roots via the lumbar plexus. The final case involved simultaneous spillover to both the obturator nerve (gracilis) and the quadratus lumborum.

Sartorius: While intramuscular electrodes targeted for the quadriceps frequently spilled over to sartorius, electrodes in sartorius showed a relatively low rate of spillover. Of 25 stable electrodes, only 4 (16 percent) instances of spillover were noted. The pattern of spillover was consistent as all four electrodes activated quadriceps via the femoral nerve and produced knee extension rather than the intended hip flexion.

Tensor Fasciae Latae (TFL): Similar to the results for sartorius, spillover from electrodes in TFL occurred

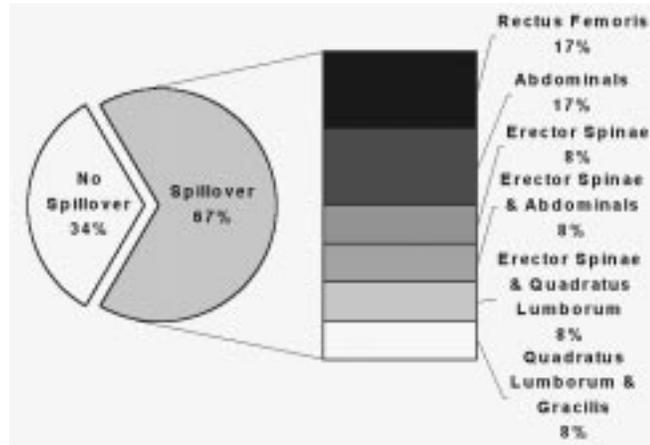


Figure 7. Spillover patterns exhibited by intramuscular electrodes targeted for iliopsoas at the L1–L2 spinal roots ($n = 12$). Iliopsoas (psoas major and iliacus) is segmentally innervated and is used to flex hip during stepping with FES systems.

relatively infrequently. Only 3 of 18 stable electrodes (17 percent) exhibited spillover. Two electrodes activated the gluteus medius and minimus via the superior gluteal nerve, while the third recruited sartorius.

Gracilis: Of 16 stable electrodes in the gracilis, 4 (25 percent) exhibited spillover. All cases of spillover involved activation of the adductor longus via the obturator nerve.

Hip Abductors

Gluteus Medius (Figure 8): Eleven out of twenty-four stable electrodes targeted for the gluteus medius caused spillover to other neuromuscular structures. The complex spillover patterns observed generally involved the sciatic or gluteal nerves, either individually or in various combinations. A total of six spillover patterns included the sciatic nerve. Three electrodes exhibited spillover to only the sciatic nerve as evidenced by unspecified foot movements and recruitment of the biceps femoris and gastrocnemius/soleus. Two electrodes simultaneously activated the sciatically innervated lower leg muscles (unspecified foot movements) and the inferior gluteal nerve as evidenced by spillover to the gluteus maximus. The last spillover pattern involving the sciatic nerve included plantarflexors and contributions from both the superior and inferior gluteal nerves by way of the TFL and gluteus maximus, respectively.

Five electrodes caused spillover to the superior gluteal nerve. In addition to the one mentioned above, three electrodes recruited the superior gluteal nerve alone as evidenced by activation of TFL or TFL in combination with gluteus minimus. One produced spillover to both superior and inferior branches of the gluteal nerve, causing both the gluteus maximus and gluteus minimus to contract.

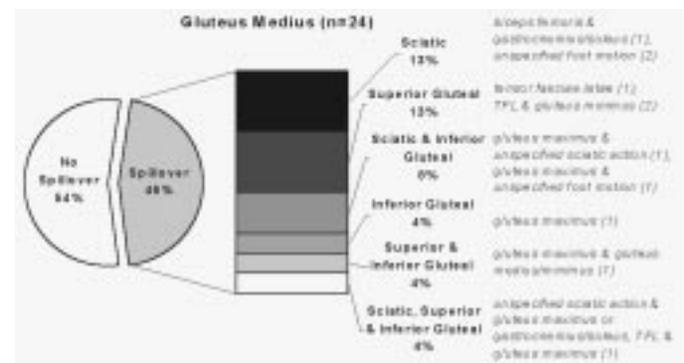


Figure 8. Spillover patterns exhibited by intramuscular electrodes implanted in gluteus medius $n=24$. Gluteus medius is innervated by inferior gluteal nerve and is targeted in FES systems to abduct hip and elevate pelvis during single-limb stance.

Finally, five electrodes exhibited spillover patterns that included the inferior gluteal nerve. In addition to the four cases already mentioned involving muscles innervated by the inferior gluteal nerve in combination with sciatic or superior gluteal nerves, one electrode caused spillover exclusively to the gluteus maximus via the inferior gluteal nerve.

Ankle Dorsiflexors and Plantarflexors

Analysis of the behavior of electrodes targeting the ankle plantarflexors and dorsiflexors was complicated by the fact that synergistic actions of multiple muscles, rather than isolated contraction of a single muscle, were often targeted as the desired response during implantation. For example, electrodes were positioned to coactivate the tibialis anterior and peroneal muscles in an attempt to balance their inversion and eversion components, respectively, and to maximize dorsiflexion moment with a single channel of stimulation. Similarly, electrodes that simultaneously recruited both soleus and gastrocnemius were actively sought during implantation to maximize plantarflexion. The degree to which this strategy to recruit synergistic muscles with a single electrode was successful was not always clear from the clinical record, and electrodes that recruited only one of the synergists targeted were always kept and used functionally during stepping with FES. Therefore, for the sake of this analysis, we assumed that the tibialis anterior and gastrocnemius were the primary muscles targeted and categorized the synergies as spillover, even though they were desirable.

Tibialis Anterior (TA): Of the 29 stable electrodes implanted in the ankle dorsiflexors (primarily tibialis anterior), 4 (14 percent) demonstrated spillover. The most common spillover pattern involved the peroneals (3), which tended to enhance dorsiflexion and counteract the inversion caused by the TA. One case of spillover to the short head of the biceps femoris was also reported.

Gastrocnemius: The 11 intramuscular electrodes targeted for the gastrocnemius for ankle plantarflexion during gait exhibited two cases of spillover (15 percent), both involving the soleus. In one case the soleus was recruited in isolation, which would serve to augment the plantarflexion provided by the primary target muscle. In the other case, spillover to soleus was combined with inversion and some unspecified action of the tibialis anterior.

Knee Flexors

Short Head of Biceps Femoris: Six of the fourteen stable electrodes (43 percent) in the short head of biceps

femoris resulted in spillover to other muscles innervated by the sciatic nerve. The patterns of spillover observed were variable and inconsistent and included dorsiflexion (2), posterior adductor alone (1) and in combination with unspecified foot movement (1), and two instances of spillover to sciatic nerve without comment on the muscles or actions observed.

Reflex Responses

Thirty stable electrodes elicited various reflexes, representing over 8 percent of those included in the analysis. Reflex activation and spillover were not mutually exclusive, and many of these electrodes also produced both spillover and reflex responses. The relative frequency of reflex activation is also summarized in **Table 2**. The electrodes most often triggering reflex activity were located in the tibialis anterior muscle, a location traditionally targeted to elicit a flexion withdrawal reflex (1–8). Thirty eight percent of all stable electrodes in this muscle resulted in some reflex activity that was not always clearly described in the clinical record but is likely to have exhibited characteristics of flexion withdrawal or crossed extensor reflex patterns. Less frequently, electrodes placed in the sartorius (16 percent), gracilis (12 percent) and quadriceps or long hamstrings (7 percent and 6 percent, respectively) produced reflexes when stimulated. It is noteworthy that fully half (15) of all electrodes that elicited reflexes were implanted in the lower leg muscles. Furthermore, one third (10) of all reflex electrodes were in a single subject, and a second subject contributed another 7 electrodes to the total. The remaining electrodes were distributed relatively evenly between five other subjects, and three volunteers exhibited no reflex activity whatsoever. This strongly suggests that a reflex response may be highly subject dependent.

DISCUSSION

Electrical stimulation delivered via intramuscular electrodes can be extremely selective and very effective in producing the strong isolated contractions of individual muscles needed for lower-limb neuroprostheses for standing and stepping. However, intramuscular electrodes can also activate neural structures near their stimulating tips other than those intended, thus recruiting muscles in addition to the ones targeted. The frequency and severity of the spillover exhibited by IM electrodes

appear to be a function of the complexity of the innervation near the target motor point. From this retrospective analysis, it is evident that IM electrodes intended to recruit the *iliopsoas* (Figure 7), *hamstrings* (Figure 4), and *gluteal muscles* (Figure 2 and Figure 8) are particularly susceptible to spillover and exhibit highly variable patterns of coactivation.

Intramuscular electrodes placed at the lumbar spinal roots to activate iliopsoas are proximal to the lumbosacral plexus, accounting for both the high rates (67 percent) and types of spillover patterns observed. Since the femoral nerve receives contributions from spinal nerves at these levels via the lumbosacral plexus, and the rectus abdominus, erector spinae, and quadratus lumborum are segmentally innervated, coactivation of these muscles is commonly observed with an electrode placed in the intervertebral foramen of T12–L1 or L1–L2. Similarly, electrodes intended to activate the hamstrings appear to produce motions caused by other muscles supplied by the sciatic nerve. The location of IM electrodes in the posterior upper thigh near the sciatic notch and the branching points of the gluteal and sciatic nerves also explains coactivation of gluteus maximus, medius, and minimus or TFL with electrodes targeting the hamstrings. The same anatomical consideration is probably responsible for coactivation of hamstrings and plantarflexors (as well as other gluteal muscles) by electrodes intended for the gluteus maximus.

In addition to anatomical considerations and the proximity of the stimulating surface to complex neural structures, the geometry of the intramuscular electrodes themselves can contribute to the lack of selectivity evident in many situations. Because the deinsulated stimulating tip is basically cylindrical in shape, the electric field that results from passing current through an IM electrode will be symmetrical and almost omnidirectional. Theoretically, the ability of such an electric field to bring an axon located a fixed radial distance from the stimulating tip to threshold should be equal in any direction. This symmetry in the electric field implies a lack of directional selectivity. With all other factors equal (nerve diameter, radial distance from the electrode, etc.) an IM electrode should be equally effective at activating any nerve located within 360° of the stimulating tip. In contrast, the electric fields generated by epimysial type electrodes (33,34) are more hemispherical and constrained by the insulating elastomer backing to which their flat stimulating surfaces are mounted. This configuration makes epimysial devices more directionally selective than IM designs, which is confirmed by studies reporting spillover in less than one third

of all epimysial electrodes implanted in the gluteus medius (35), as opposed to almost half of IM electrodes in that muscle included in this analysis. Surgically implanted intramuscular electrodes currently in use with implanted neuroprosthesis systems (14) were designed to replicate the recruitment characteristics of the open helix IM electrodes with percutaneous leads examined in this study and have similar deinsulated areas and insertion techniques. Although recruitment characteristics and spillover properties of epimysial or other electrode designs used in surgically implanted systems still need to be established, the results from this study should indicate what can be expected from most intramuscular monopolar stimulating electrodes, regardless of their lead configurations.

Whether the spillover exhibited by an electrode is synergistic or counterproductive depends upon the context in which the electrode is to be used and the nature of the spillover effect. For example, the spillover patterns observed for iliopsoas electrodes can assist or hinder the hip flexion required for ambulation or stair climbing. Care needs to be taken to avoid the knee extension caused by activation of the quadriceps via spillover to the femoral nerve when implanting electrodes in this location. Although coactivation of iliopsoas and rectus femoris may enhance hip flexion, the knee extension caused by the quadriceps will interfere with foot-floor clearance during gait initiation and swing phase of the gait cycle. Spillover from iliopsoas to abdominal muscles is equally common (Figure 7) and the trunk flexion they cause can also be counterproductive to gait progression by compromising erect posture. On the other hand, coactivation of erector spinae, quadratus lumborum, or gracilis by an iliopsoas electrode is observed less frequently but can enhance function by stabilizing the pelvis, hiking the hip, or generating additional hip flexion moment, all of which will enhance foot-floor clearance during swing or stair climbing.

As previously noted, almost one third of all IM electrodes in the vasti of the quadriceps intended to extend the knee during standing with FES were contaminated by rectus femoris, sartorius, or TFL. Spillover to any of these muscles could compromise erect standing posture by flexing the hip or anteriorly tilting the pelvis. This active hip flexion can cause FES users to adopt a lordotic posture and exert increased forces on an assistive device with their arms to keep the torso erect. In addition, with the knee extended by the quadriceps, the sartorius can externally rotate and abduct the thigh, thus making swing-to gait difficult and increasing the risk of hitting

the walker with the toes. All of these postural and ambulatory abnormalities have been observed in our subjects as they attempt to use their intramuscular FES systems functionally (28).

For the gluteal and hamstrings muscles, spillover to the plantarflexors and intrinsic muscles of the foot should be avoided by judicious placement of IM electrodes. In standing, selective activation of these muscles will prevent a posterior tilt of the thigh and shank that would require FES users to flex their trunks or hips forward and lean on an assistive device to keep from falling backwards. Timing of plantarflexor activity is crucial to forward progression during walking with FES. Changes as short as 50 ms in the temporal patterns of stimulation to the plantarflexors can severely compromise FES assisted walking (23), highlighting the need for independent control of the muscles separate from coactivation with the hamstrings, posterior adductor, and gluteals. For example, premature activation of the plantarflexors during early to mid-stance phases of gait with FES via spillover from the hip extensors can inhibit tibial advancement and push neuroprosthesis users backward, rather than contribute to forward progression. In addition, uncontrolled motions of the toes and unnatural postures of the fore- and midfoot resulting from similar spillover patterns can lead to skin breakdown and the development of other deformities (36,37).

Many spillover patterns exhibited by the hip muscles would be counterproductive to standing or stepping with FES. Although the posterior, sciatically innervated fibers of adductor magnus assist with hip extension during quiet standing and the stance phases of gait, spillover to the obturator nerve can recruit the anterior fibers or gracilis, thus compromising posture and forward progression by flexing the hip. During walking, the adduction component could also contribute to a Trendelenberg gait by counteracting any abduction provided by gluteus medius during single-limb stance. Similarly, activation of TFL with gluteus medius would internally rotate the thigh during stance and be antagonistic to hip extension.

Nevertheless, the majority of all IM electrodes analyzed in this study selectively recruited only the primary muscle or exhibited desirable synergistic spillover patterns that assisted with the desired motion. Synergistic spillover patterns can be useful and are often sought out during electrode implantation. Activating vastus lateralis and intermedius with a single electrode is extremely beneficial for standing and walking, since the recruitment pattern enhances knee extension without compromising hip extension. Coactivating posterior adductor with ham-

strings could also be desirable in most circumstances to stabilize and extend the hip during standing (although not necessarily during gait as noted above). Similarly, locating a single electrode to activate TA and peroneals simultaneously can be an effective strategy to increase the magnitude ankle motion and balance inversion/eversion with a minimum number of electrodes and stimulus channels. For similar reasons, coactivation of soleus and gastrocnemius with one electrode can also be useful and was often the recorded goal of implantation.

As attractive as this strategy is, attaining selective or beneficial spillover patterns with intramuscular electrodes is not easy in practice and requires a great deal of skill and patience during what can be a difficult, exacting, and time-consuming implantation process. There is a real and significant tradeoff between selectivity of a response (or ability to produce desirable synergies) with the time and effort exerted during the implant procedure. Maximizing beneficial spillover while avoiding the compromising and counterproductive patterns places increased demands on the surgeon or rehabilitation physician who chooses to deploy neuroprostheses based on intramuscular electrodes. Stimulating tips of intramuscular electrodes need to be located accurately and responses need to be tested frequently both intraoperatively and postoperatively to optimize function. The electrodes included in this analysis were installed by surgeons who were well-practiced and truly experts in the technique with years of experience implanting intramuscular electrodes, yet the results still indicate a high degree of spillover.

Frequently, the effects of undesired spillover can be minimized by manipulating the parameters of the stimulus waveform. Limiting stimulation levels to values below the threshold of spillover can be an effective strategy if the responses of the primary target muscles are adequate for function. For example, intramuscular electrodes at the lumbar roots targeted for erector spinae can selectively activate only the trunk extensors at lower pulse durations and are extremely useful for standing, while at higher pulse durations spillover to iliopsoas via the same electrodes can produce the hip flexion required to achieve stepping function (38). Even where the spillover pattern is undesirable, an electrode can still be useful if the primary target muscle is sufficiently strong at stimulus levels that do not recruit other structures. Since the spillover thresholds were not consistently reported in the laboratory clinical records, it is only possible to report the presence or absence of spillover, not whether or not it occurred at low enough threshold to interfere with the primary intended function of the electrode.

There are several limitations to this review of the recruitment properties of IM electrodes in the lower limbs that should be kept in mind when interpreting the results. First, the motor responses of the electrodes included in this study were already optimized, since electrodes that were nonfunctional or exhibited intolerable spillover patterns were usually withdrawn intraoperatively or explanted within the first 2 months of use. Therefore, these results do not reflect the performance of every intramuscular electrode implanted and may be skewed toward the best and most tolerable cases. In addition, the intramuscular electrodes examined were implanted by individuals with highly developed skills and specialized expertise in the field. Results from electrodes installed by less experienced individuals are unlikely to match those included in this analysis. In spite of these positive influences, anywhere from 15 to 67 percent of the intramuscular electrodes in this study (depending on the muscle targeted) still exhibited some form of spillover. Secondly, because some subjects had more electrodes than others did, any effects caused by variations in the anatomy of a few individuals may have affected a large portion of data. It should also be stressed that the results presented in this study are from percutaneous intramuscular electrodes and may or may not be applicable to other electrode designs (such as epimysial electrodes) developed for long-term implantation. Finally, as with any retrospective analysis, controls were applied after the data were collected to ensure unbiased and consistent results. With the clinical records available for analysis, there was no way to discern whether the action of the primary muscle was adequate for function before the spillover threshold was reached. In most cases, only the presence or absence of spillover was recorded rather than the degree to which it interfered with (or enhanced) function when incorporated into a neuroprosthesis. Although more confidence can always be placed in prospective, randomized, and well-controlled studies, this retrospective analysis can still provide insight into the behavior of intramuscular electrodes that may be valuable for predicting their functional performance and clinical utility in lower-limb neuroprostheses.

CONCLUSIONS

Intramuscular electrodes provide a safe and effective means to produce strong and isolated contractions of single muscles and can be a powerful tool for diag-

nosis, rehabilitation, or function after paralysis. Depending on the muscle targeted, monopolar IM electrodes in the lower limbs can be from 33 percent to 85 percent successful in selectively producing only the desired contraction. Even though they may be more selective than other methods of stimulation, intramuscular electrodes are not always perfectly selective and can exhibit spillover to other nearby nerves and muscles because of the proximity of another nerve or nerve branch to the stimulating tip.

In this review of over 350 stable intramuscular electrodes implanted in volunteers with spinal cord injuries over a 10-year period, consistent and repeatable patterns of spillover and reflex activation were identified in between 15 percent and 67 percent of the electrodes examined, depending on the primary muscle targeted. As expected, several spillover patterns emerged from this study that may be advantageous in standing and walking with FES, while others are undesirable and should be avoided by judicious placement of IM electrodes, selection of other electrode designs, or careful adjustment of stimulus levels. Surgeons and therapists using monopolar IM electrodes need to understand the nature of these spillover patterns and appreciate their frequency and complexity in order to successfully optimize the functionality of future applications of FES systems relying on intramuscular designs.

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