

# A New Means of Transcutaneous Coupling for Neural Prostheses

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**Abstract**— Neural prostheses are electronic stimulators that activate nerves to restore sensory or motor functions. Implanted neural prostheses receive command signals and in some cases energy to recharge their batteries through the skin by telemetry. Here we describe a new approach that eliminates the implanted stimulator. Stimulus pulse trains are passed between two surface electrodes placed on the skin. An insulated lead with conductive terminals at each end is implanted inside the body. One terminal is located under the cathodal surface electrode and the other is attached to a nerve targeted for stimulation. A fraction (10%–15%) of the current flowing between the surface electrodes is routed through the implanted lead. The nerve is stimulated when the amount of routed current is sufficient. The aims of this study were to establish some basic electrical properties of the system and test long-term stability in chronic implants. Stimulation of the nerve innervating the ankle flexors produced graded force over the full physiological range at amplitudes below threshold for evoking muscle contractions under the surface electrodes. Implants remained stable for over 8 months. The findings provide the basis for a new family of neural prostheses.

**Index Terms**— functional electrical stimulation, neural prostheses, passive implant

## I. INTRODUCTION

SENSORY and motor nerves may be activated by pulsatile electrical current delivered through electrodes applied to the skin. This method, first described in 1867 [1] is used clinically to this day, for example to relieve pain (TENS stimulators) and to activate muscles for therapeutic or functional purposes [2], [3].

A disadvantage of stimulation through skin electrodes is that non-targeted nerves may be co-activated along with targeted ones. This causes unwanted sensations or movements. Selectivity is improved by delivering stimuli to the target nerves with implanted wires. For short-term applications the wires may emerge through the skin and terminate in a connector, to which an external stimulator is attached [4], [5]. This mode of operation is referred to as percutaneous stimulation. In systems of this type, the

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connectors are vulnerable, inconvenient and require daily maintenance to avoid discomfort and infection.

For long-term applications such as cochlear stimulation [6]; dorsal column stimulation [7], [8], deep brain stimulation [9] and sacral root stimulation [10] the stimulator and leads are implanted. Implanted neural prostheses are usually battery-powered, receiving commands, and in some cases energy to recharge their batteries, through the skin by telemetry. Recently microstimulators have been developed that can be injected through a hypodermic needle [11]. In some devices the leads terminate in nerve cuffs [12]–[15].

Implanted stimulators are expensive as they require sophisticated electronics, hermetic sealing in corrosion-resistant casings and in most cases battery replacement every 4 or 5 years. Here we explore a new type of neural prosthesis that has no implanted active electronic components. A stimulator external to the body drives a train of electrical pulses between a pair of electrodes attached to the skin (Fig. 1). An implanted passive conductor with a “pick-up” terminal under the cathodal electrode and a “delivery” terminal on the target nerve diverts some of the current flowing between the surface electrodes to the target nerve. We will refer to this combination of components (external stimulator, surface electrodes and implanted conductor) as the stimulus router

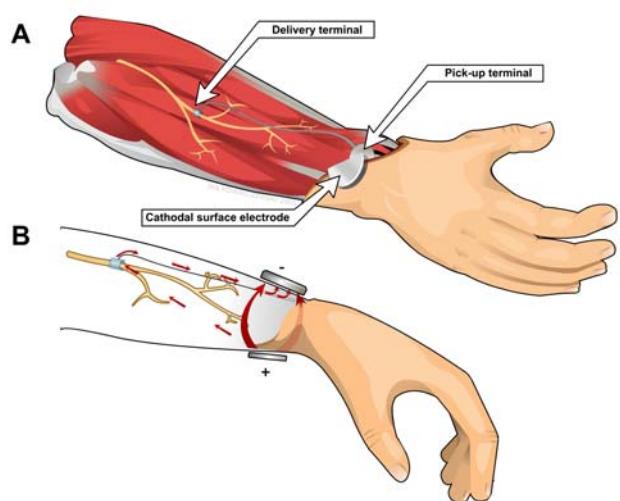


Fig. 1. Schematic of the stimulus router system. A) Cutaway view showing the cathodal surface electrode, implanted pick-up electrode, passive conductor and nerve cuff. B) Cross-section showing current flowing between the surface electrodes, some being diverted through the implanted conductor to the nerve cuff and returning via forearm tissues.

system (SRS).

The topics covered in this report include: 1) proportion of total current diverted through the implanted conductor; 2) effect of size and shape of electrodes on nerve activation thresholds; 3) effect of skin type and thickness on stimulus thresholds; 4) effect of misalignment of surface and pick-up electrodes; 5) graded control of muscle force; 6) changes in muscle contraction thresholds and maximal forces over time in chronic implants; 7) mechanism of charge transfer from the skin electrodes to the nerve via the implanted conductor.

## II. METHODS

As we were studying a completely new way of delivering stimulation to nerves, our study was exploratory in nature. To characterize the electrical and functional properties of the SRS across a variety of skin types, acute non-recovery experiments were performed in four cats, four rabbits and a Duroc piglet. In addition, passive conductors were implanted chronically in three cats and their operation as part of an SRS was monitored for several months. All experiments were performed with the approval of the University of Alberta Health Sciences Animal Policy and Welfare Committee. The human perceptual threshold measurements were carried out under a protocol approved by the University of Alberta Health Research Ethics Board.

*SRS designs:* External stimulators, surface electrodes and nerve cuffs are conventional components of the SRS that have been widely discussed in the literature [8]. The novel component of the SRS is the subcutaneous terminal that “picks up” some of the current flowing between a pair of surface electrodes and delivers it through an insulated wire to a nerve. In our study, we used conventional external components and nerve cuffs and explored various shapes and sizes of pick-up terminal.

*Surface electrodes:* these consisted of pairs of self-adhesive conductive gel surface electrodes, 34 mm x 23 mm with a 10 mm diameter central terminal (Kendall Soft-E; The Kendall Company, Mansfield, Massachusetts) affixed to the closely-shaved skin, well away from the target nerve and muscle, usually on the back. The anodal surface electrode was typically placed on the skin 30 to 50 mm away from the cathodal surface electrode.

*Implanted conductors:* In acute experiments, the pick-up terminals included discs or rectangles of stainless steel or bared lengths of Cooner AS814 lead wire coiled tightly around 2/0 prolene suture thread (Ethicon, Inc., Somerville New Jersey), similar to the termination of the “Peterson” electrode [16]. In chronic experiments, only stainless steel discs were used. Dimensions are given in Results. In all cases, delivery terminals (nerve cuffs) consisted of an 8 mm x10 mm piece of stainless-steel mesh (8 counts/mm; Stainless Mesh; Continental Wire Cloth Corp., Edmonton, Alberta) within a 12 mm long, longitudinally slit silastic tube (3.4 mm inside diameter, 4.7 mm outside diameter; Dow Corning Corp., MI). In acute experiments, pick-up terminals were

placed subcutaneously under the cathodal surface electrode through a small incision, usually about 10 mm away.

*Stimulators:* Depending on the experiment, one of two stimulators was used to deliver stimulus pulse trains (the independent variable) between the surface electrodes. The first was a custom stimulator that provided an amplitude-modulated train of biphasic, constant-current pulses (350  $\mu$ s primary phase duration, 45 pulses/s). The second was a Grass SD9 stimulator (Grass Instruments, Rhode Island) that produced voltage-controlled pulses (300  $\mu$ s duration, 60 pulses/s).

*“Internal” versus “total” current:* The current delivered through the surface electrodes (“total current”:  $I_{\text{total}}$ ) was measured indirectly by measuring the voltage across a 100 ohm resistor in series with the negative output of the stimulator and the cathodal surface electrode. In acute experiments only, the current in the implanted conductor (“internal” or “router” current,  $I_{\text{router}}$ ) was likewise measured: the pick-up and delivery terminals were supplied with separate insulated leads, which were brought out through the skin and attached to each end of the 100 ohm series resistor with miniature connectors.

*Amplifiers:* Three ISO-DAM8A differential amplifiers (World Precision Instruments Inc., Florida) were used to measure the voltage 1) between the surface electrodes, 2) across the 100ohm resistor in series with the cathodal surface electrode, 3) across the 100ohm resistor in series with the pick up and delivery terminals. All three signals were band-pass filtered (1Hz – 10KHz). The amplified signals were monitored with a Tektronix 5111 storage oscilloscope (Tektronix Inc., Texas) and digitized at 25,000 samples/sec with a CED 1401 laboratory computer interface (Cambridge Electronic Design Inc., Cambridge UK).

*Force transducer:* The force produced by the activated muscles was measured with a custom proving-ring strain gauge transducer attached by a Velcro loop around the metatarsophalangeal joint (Fig. 5C). The lower part of the animal’s leg was stabilized with respect to the transducer with a padded clamp fixed just above the ankle joint. During maximal muscle contractions the middle of the foot at the point of attachment of the loop moved by an estimated 2 to 3mm due to the compliance of the soft tissue and the loop. Torque was calculated from the force and the distance between the ankle joint and the point of application of the Velcro loop.

*Surgical procedures:* In all animals, the gaseous anesthetic isoflurane (Forane; Baxter Corp., Toronto, Ontario) was used to induce and maintain anesthesia. Respiration was monitored with a Beeper Animal Respiration monitor (Spencer Instrumentation, Irvine, Ca) and pulse rate was monitored with a SurgiVet V3404 pulse oximeter (SurgiVet, Waukesha, WI). A feedback-controlled heating pad under the animal was used to maintain body temperature. The depth of anesthesia was monitored periodically by checking respiratory rate, heart rate and motor responses to strong pinches applied to the toes.

In the case of the acute experiments, after deep anesthesia was achieved, a tracheotomy was performed and an endotracheal tube was inserted to allow automatic control of ventilation with a Model A.D.S. 1000 veterinary anesthesia delivery system (Engler Eng. Corp., Fl.). An intravenous cannula was inserted into the jugular vein. Acute experiments typically lasted 12 hours, after which the animal was euthanized with intravenous sodium pentobarbital.

Three cats were chronically implanted with passive conductors. The surgery, which lasted about an hour, was performed under aseptic conditions in a fully-equipped operating room. Pre-operatively the animals were sedated with intramuscular acetyl promazine (0.25mg/Kg) and atropine (0.04mg/kg). Isoflurane anesthesia was induced via a mask and maintained via a pediatric endotracheal tube. Respiration, heart rate and depth of anesthesia were monitored as described above. The legs and back were closely shaved, cleaned with soap and swabbed with iodine solution. An intravenous catheter was inserted into the cephalic vein and an intravenous drip of isotonic saline was implemented. About 10 mm of the common peroneal nerve was exposed proximal to the knee. The nerve cuff was placed on it and sutured closed at each end with 6/0 prolene monofilament sutures. The pick-up terminal and connecting lead were tunneled under the skin to a site over the sacrum. A small hole in the pick-up terminal allowed it to be sutured to the lumbodorsal fascia with 3/0 prolene monofilament suture. The two skin incisions were sutured with 3/0 prolene. Post-operative analgesia was provided with subcutaneous ketoprofen (Anafen, Merial Canada, Inc., Quebec City, Quebec) and a fentanyl patch (Duragesic 25, Janssen-Ortho, Inc., Toronto, Ontario). Post-operative recovery took place in an intensive care unit. Ampicillin was administered for 2-4 days after surgery, followed by Amoxil (50 mg tablets, 2/day) for 6 additional days.

In the weeks and months after recovery, stimulus thresholds and maximal force measurements were performed during brief periods of isoflurane anesthesia. Initially this was done at weekly intervals, then bi-weekly.

### III. RESULTS

#### A. Proportion of total current diverted and effect of shape of pick-up electrodes on nerve activation thresholds

As anticipated, the ratio of internal current  $I_{\text{router}}$  in the implanted conductor to total external current  $I_{\text{total}}$  depended on the surface area of the pick-up electrode. Fig. 2A shows data from an experiment performed in an 11.5 kg Duroc piglet. As above, two conductive gel electrodes were placed 5 cm apart on the closely shaved skin of the piglet's back at mid-thoracic level. A Grass SD9 stimulator was used to deliver stimulus pulse trains. Pick-up electrodes of different surface areas and designs were tested sequentially by slipping them subcutaneously under the cathodal surface electrode and connecting their lead wire to that of the 8 mm x 10 mm stainless steel mesh terminal in a cuff on the common peroneal nerve.

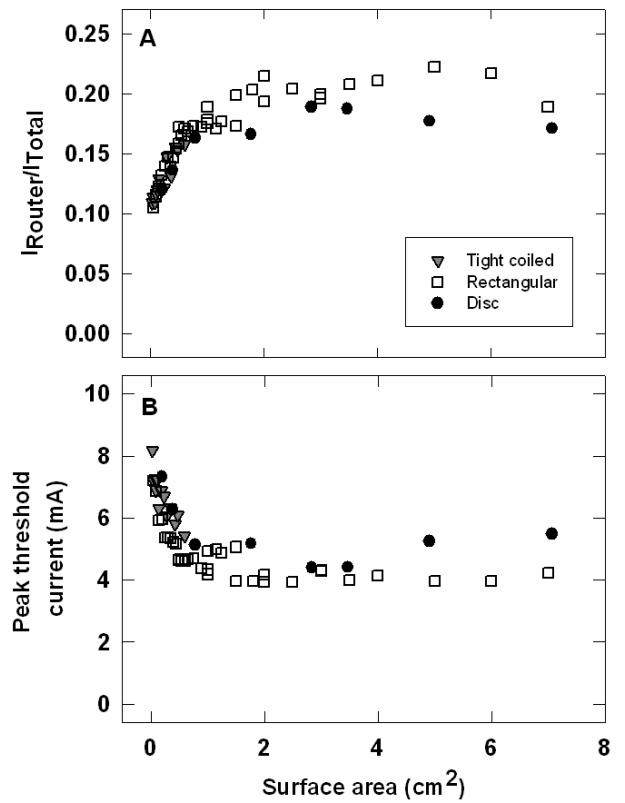


Fig. 2. Internal router currents and thresholds using various pick-up electrodes. A) The fraction of total current captured by the stimulus router versus surface area of pick-up electrodes of three different types (see Methods/Implanted Conductors) in an anesthetized piglet. B) Corresponding threshold currents measured between the surface electrodes.

Three types of pick-up terminal were tested: discs, rectangles and coils of bared lead wire wound tightly around a 2/0 prolene suture thread [16], [17]. We will refer to the latter as "Peterson-type" electrodes. Total external current and voltage between the surface electrodes as well as internal current flowing through the implanted conductor were monitored (Methods). Each data point in Fig. 2A shows the ratio of internal current to total current ( $I_{\text{router}}/I_{\text{total}}$ ) for a given area of pick-up electrode. The ratio was approximately 0.2 for surface areas greater than  $1 \text{ cm}^2$ . Thus in this case about 20% of the total current was diverted through the implanted conductor.

Fig. 2A also indicates that surface area rather than shape determined the current ratio. The results suggest that pick-up terminals as small as  $0.5 \text{ cm}^2$  in area could be used in a neural prosthesis, without significantly compromising the internal current. Peterson-type electrodes could in principle be implanted through a hypodermic needle [17]. Fig. 2B shows the relationship between the external current that just elicited ankle dorsiflexor muscle contractions and pick-up terminal area. Not surprisingly the curves in Fig. 2A and 2B are inversely related. With most sizes of pick-up electrode, the target nerves were activated at less than 40% of the stimulus strength needed to activate the muscles directly under the

TABLE I

TABLE 1. SUMMARY OF SURFACE AND INTERNAL CURRENTS ( $I_{\text{TOTAL}}$ ,  $I_{\text{ROUTER}}$ ) JUST ELICITING CONTRACTIONS OF TARGET MUSCLES WITH THREE STYLES OF PICK-UP ELECTRODE. IN ADDITION,  $I_{\text{TR}}/I_{\text{TL}}$ , THE RATIO OF SURFACE CURRENT JUST ELICITING TARGET MUSCLE CONTRACTIONS TO SURFACE CURRENT JUST ELICITING LOCAL MUSCLE CONTRACTIONS IS SHOWN. STANDARD DEVIATIONS ARE INCLUDED WHEN N IS 3 OR ABOVE.

	Cat			Rabbit			Piglet		
	Disk 1.8cm <sup>2</sup>	Rectangular 3.5cm <sup>2</sup>	"Peterson" 0.24cm <sup>2</sup>	Disk 1.8cm <sup>2</sup>	Rectangular 3.5cm <sup>2</sup>	"Peterson" 0.24cm <sup>2</sup>	Disk 1.8cm <sup>2</sup>	Rectangular 3.5cm <sup>2</sup>	"Peterson" 0.24cm <sup>2</sup>
$I_{\text{total}}$ (mA)	$0.7 \pm 0.2$ n = 93	$0.9 \pm 0.5$ n = 3	$0.9 \pm 0.4$ n = 3	$1.4 \pm 0.1$ n = 4	$1.7 \pm 0.4$ n = 4	$1.6 \pm 0.5$ n = 8	$5.0 \pm 0.1$ n = 2	4.0 n = 1	$6.3 \pm 0.6$ n = 2
$I_{\text{router}}$ (mA)	$0.1 \pm 0.01$ n = 2	$0.16 \pm 0.08$ n = 3	$0.11 \pm 0.01$ n = 2	$0.20 \pm 0.10$ n = 3	$0.19 \pm 0.08$ n = 3	$0.19 \pm 0.09$ n = 8	0.82 n = 1	0.84 n = 1	0.80 n = 1
$I_{\text{router}}/I_{\text{total}}$	$0.18 \pm 0.01$ n = 2	$0.19 \pm 0.01$ n = 3	$0.16 \pm 0.01$ n = 2	$0.15 \pm 0.08$ n = 3	$0.11 \pm 0.06$ n = 3	$0.11 \pm 0.02$ n = 8	0.16 n = 1	0.21 n = 1	0.12 n = 1
$I_{\text{total}}/I_{\text{local}}$	$0.2 \pm 0.09$ n = 21	$0.18 \pm 0.01$ n = 2	$0.21 \pm 0.01$ n = 2	$0.33 \pm 0.03$ n = 2	$0.41 \pm 0.08$ n = 2	$0.39 \pm 0.05$ n = 6	$0.30 \pm 0.01$ n = 2	0.24 n = 1	$0.38 \pm 0.03$ n = 2

increased by 31.9 %.

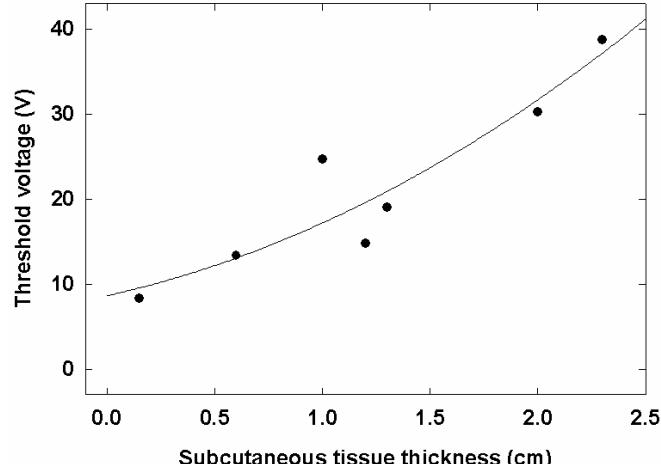


Fig. 3. Dependence of threshold voltage on thickness of skin and subcutaneous tissue between surface cathodal electrode and implanted pick-up electrode in an anesthetized rabbit.

surface electrodes (see Table 1). The Table shows the mean values of  $I_{\text{router}}/I_{\text{total}}$  ranging from 0.11 to 0.21 depending on the species and the type of pick-up electrode. The current ratios did not change significantly with increases in amplitude. In one experiment in a chronic cat, we varied the distance between the cathodal and anodal electrodes from 30 mm to 140 mm. The thresholds were fairly constant from 40 mm to 140 mm spacing, though about 20% higher at 30 mm spacing.

#### B. Effect of skin thickness and skin type on stimulus thresholds

In one cat experiment we found that stimulus thresholds varied less than 30% across a range of skin thicknesses from 1.0 mm to 5.0 mm. Similarly, in a rabbit experiment a Peterson-type pick-up electrode was placed under different thicknesses of subcutaneous fat and muscle tissue in the groin area (Fig. 3). The regression line fitted to these data ( $r^2=0.98$ ) indicated that in the range 1.0mm to 5.0 mm, the threshold

#### C. Effect of misalignment of surface and pick-up electrodes

It is to be expected that in clinical use, cathodal electrodes may not always be placed accurately over corresponding implanted pick-up electrodes. Furthermore, it is conceivable that systems with matching and accurately aligned arrays of surface and pick-up electrodes could stimulate several nerves independently with interleaved pulse trains. It was therefore of interest to determine the relationship between the surface current required to elicit a muscle contraction and the distance between the centres of the surface cathodal electrode and the underlying pick-up electrode. We explored this in two rabbits, two cats and a piglet anesthetized with isoflurane. Fig. 4 shows four such sets of measurements, two in an acute cat experiment, one in a chronically implanted cat and the other in an acute rabbit experiment. In the rabbit, the pick-up electrode was a 10 mm long Peterson-type terminal (0.24 cm<sup>2</sup> surface area), in the chronically implanted cat, it was a 15 mm diameter disk (1.8 cm<sup>2</sup> surface area), in the acute cat experiment both types of pick up electrode were used. The surface anodal electrodes were Kendall Soft-E self-adhesive conductive gel electrodes, 34 mm x 23 mm with a 10 mm diameter central carbon terminal. The same gel electrodes, cut down to a diameter of 15 mm, served as the surface cathodal electrodes. A fresh electrode was used for each cathodal position.

As anticipated, threshold current increased with increasing misalignment of the surface and implanted electrodes. U-shaped "spatial tuning curves" were obtained in all three animals and for both types of pick-up electrode. The curves from the acute cat experiments were lower than those in the rabbit and chronic cat. This was probably due to a more thorough cleansing of the skin with methyl alcohol prior to placing the surface electrodes in the acute cat trial. We were surprised that the spatial tuning curves were just as broad for the Peterson-type pick-up electrodes as for the disks. It may be that the width of tuning curves depends more on the size of

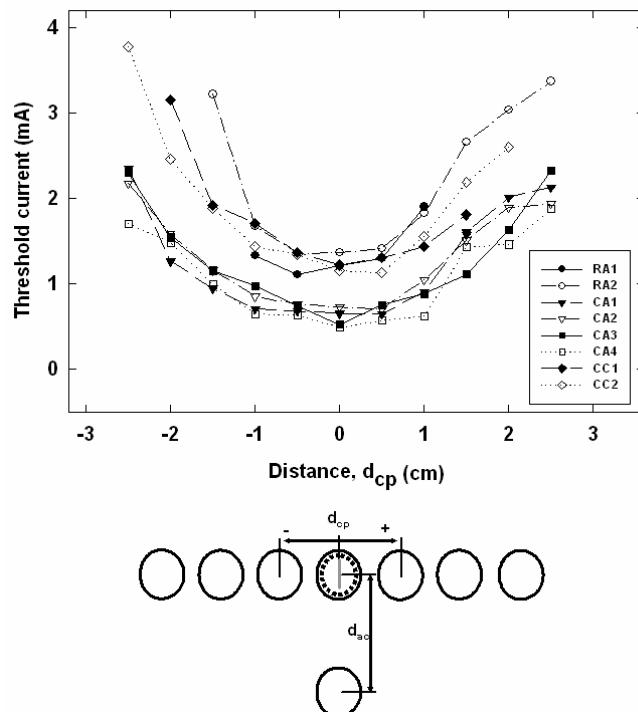


Fig. 4. Threshold current versus misalignment of surface cathodal electrode and subcutaneous pick-up electrode. Schematic below shows relative positions of anodal and cathodal surface electrodes (solid circles) and subcutaneous pick-up electrode (dashed and gray).  $d_{ac}$ : distance between centres of anodal and cathodal surface electrodes,  $d_{cp}$ : distance between centres of (surface) cathodal and (subcutaneous) pick-up electrodes. The graph shows measurements obtained with a Peterson-type pick-up electrode (10 mm long, 0.24 cm<sup>2</sup>) in an anesthetized rabbit (RA1, RA2) and cat (CA1, CA2) and a disk pick-up electrode (15 mm diameter, 1.8 cm<sup>2</sup>) in an anesthetized cat (CA3, CA4) and a chronically implanted cat (CC1, CC2). For each set of measurements  $d_{ac} = 6.5\text{cm}$  (solid symbols) and 10 cm (open symbols) respectively.

the surface electrodes than the implanted pick-up electrodes. The narrower the tuning curve, the closer the possible spacing of neighbouring electrodes in a multi-channel array.

#### D. Graded control of nerve activation levels

To be useful as a neural prosthesis, the system should allow graded activation of nerves over the full physiological range, ideally without activating nerves innervating non-targeted muscles directly under the surface electrodes. Fig. 5 shows the force developed by the ankle dorsiflexor muscles of a cat in response to an amplitude-modulated pulse train delivered by the custom stimulator through a pair of surface electrodes placed 5 cm apart. The cathodal electrode was located on the shaved skin of the sacrum over a subcutaneous pick-up electrode (15 mm dia. disc) connected by a lead wire to a nerve cuff implanted 23 weeks before on the common peroneal nerve. The force produced by the ankle dorsiflexor muscles was measured at the metatarso-phalangeal joint (Methods).

Force began to rise when the amplitude of the current pulses delivered through the surface electrodes reached 0.6 mA (Fig. 5A). We will call this parameter the threshold

current  $I_{th}$ .

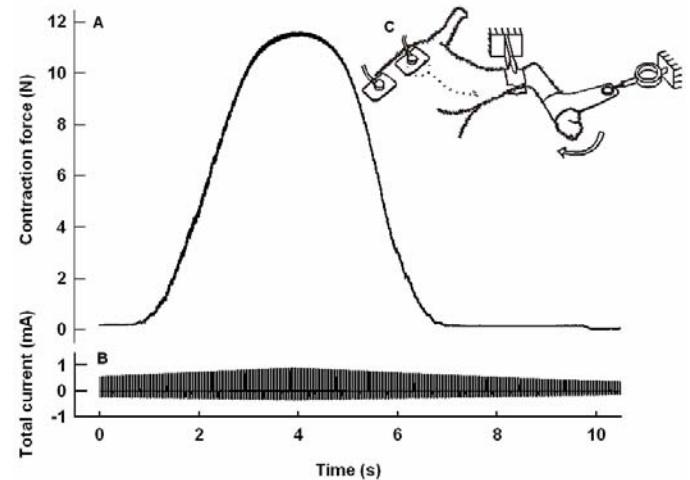


Fig. 5. Force and current measurements during router-elicited muscle contractions. A) Isometric ankle dorsiflexion force produced by amplitude-modulated stimulation through surface electrodes and a chronically implanted passive conductor in a deeply anesthetized cat. The force rose and fell smoothly as the amplitude of the stimulus pulses was ramped up, then down. B) The train of biphasic current pulses applied between the surface electrodes. C) The experimental arrangement. The surface electrodes were placed near the sacrum. The cathodal electrode (closer to the tail) was located over an implanted pick-up electrode with a subcutaneous insulated wire leading to a termination in a cuff on the common peroneal nerve. Force was measured with a proving-ring strain gauge transducer attached to a Velcro loop around the metatarsophalangeal joint. A padded clamp stabilized the leg.

With further increases in stimulus amplitude, force reached a maximum,  $F_{max}$  at a current of  $I_{max}$ . Between 0.65 mA and 0.8 mA amplitude, force increased monotonically, showing that the neural prosthetic requirement of *controlled gradation* of force is achievable. Close observation of the tissues under and around the surface electrodes indicated that no non-targeted muscle contractions occurred at any time during the recording. The ratio  $I_{max}/I_{th}$  (stimulus current eliciting maximal force/stimulus current just eliciting a contraction) was measured systematically over several months in 2 cats, each with two chronically implanted router systems. Mean  $I_{th}$  was  $0.72 \pm 0.20$  mA S.D. ( $n = 88$ ) and mean  $I_{max}$  was  $1.30 \pm 0.45$  mA S.D. ( $n = 82$ ), giving a  $I_{max}/I_{th}$  ratio of 1.8. Fig. 5 is typical of hundreds of measurements we have made in four different species, so we are confident in concluding that the system allows nerve activation to be graded over a useful range, in the absence of local muscle contractions.

#### E. Muscle contraction thresholds and maximal torques in chronic implants

In any clinical application, reproducibility and reliability of nerve activation are crucial. At the initial stage of the chronic implants, breakage of wires occurred within 2-3 weeks after implantation. These early prototype systems were fabricated with Cooner AS632 lead wires. They were then removed in an aseptic surgical procedure as described in Methods and replaced with implants made with Cooner AS632 lead wires reinforced with 4/0 prolene sutures, and in one case, a thicker

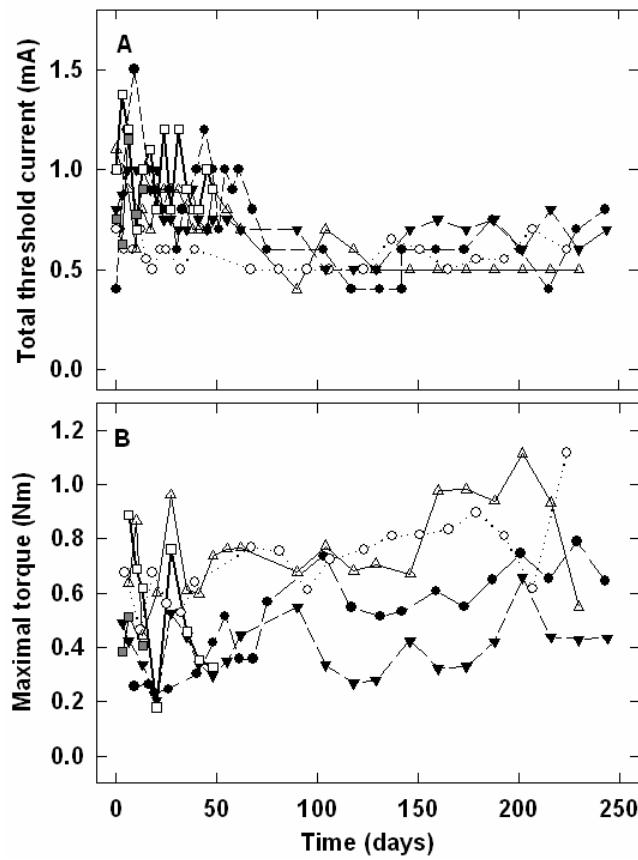


Fig. 6. Stimulus parameters monitored periodically over 250 days in 6 implanted stimulus router systems in 3 cats. Each system represented by a symbol with connecting lines. A) Current at muscle activation threshold  $I_{th}$ , B) Current at maximal torque  $I_{max}$ , C) Maximal isometric torque  $\tau_{max}$ . Two implants fabricated with thin lead wires failed 13 and 48 days after implantation respectively. Each plot has a superimposed thick line of best fit (exponential functions in A and B, linear in C).

Cooner AS814 lead wire. We measured  $I_{th}$ ,  $I_{max}$  and maximal torque ( $\tau_{max}$ ) in 3 cats implanted with a total of 6 router systems for up to 36 weeks (Fig. 6A, 6B and 6C). Interestingly,  $I_{th}$  and  $I_{max}$  gradually *decreased* over the first 50 or 60 days as reported in previous nerve cuff data [18] and  $\tau_{max}$  slightly *increased*. Two of the prolene reinforced AS632 router wires failed after a few weeks, while the rest remained functional for up to 8 months.

Consecutive torque values in any given animal in Fig. 6C varied substantially. We therefore did control measurements in which an anesthetized cat was placed into and removed from the force recording arrangement ten consecutive times. A force of 8N was applied with a spring gauge through a 4 mm diameter cord tied firmly around the foot 30 mm from the ankle joint (torque = 0.24 Nm). In each trial the 30 mm wide Velcro strap used in the force measurements of Fig. 6C was newly attached around the metatarsal phalangeal joint. The distance of the centre of this strap from the ankle joint was found to vary between 50 and 65 mm in these trials, a similar range as in the chronic measurements. The proving ring force transducer was attached to the Velcro strap as in Fig. 5. The

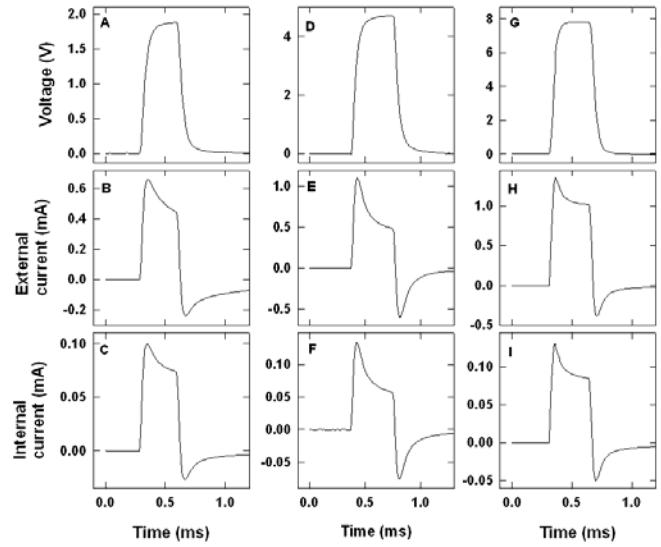


Fig. 7. Voltage (top), current between surface electrodes (middle) and current in implanted conductor (bottom) for cat (A, B, C), piglet (D, E, F) and rabbit (G, H, I) respectively. The voltage waveforms differ from their corresponding surface current waveforms. This indicates significant capacitive coupling through the skin. Surface and implanted current waveforms are very similar, indicating largely resistive coupling from tissue to and from the implanted conductor.

mean torque thus measured was  $0.31 \pm 0.03$  Nm S.D., which only partly explains the inter-trial variability in Fig. 6C. The additional variability was probably due to muscle fatigue, as the number of contractions needed to establish the stimulus level required to elicit peak force varied from day to day.

#### F. Mechanism of charge transfer via the implanted conductor

The question arose as to whether the current flowing in the implanted conductor is capacitively or resistively coupled. Also whether the electrical properties of different skin types (e.g. dry versus oily skin) influence charge transfer and therefore the viability of the system as a neural prosthesis. Fig. 7 shows voltage and current waveforms measured in cat, rabbit and piglet in the course of the experiments described above. The voltage profiles were damped rectangular waves. The current profiles show an initial peak, followed by an exponential sag towards an asymptotic level. The electrical properties of tissue are nonlinear, but to a first approximation, the greater the sag in current, the greater the ratio of capacitive to resistive current [19]. Although there were significant differences between corresponding voltage and current profiles, there was little difference between corresponding pairs of *current* profiles, indicating that most of the capacitance was at the interfaces between the surface electrodes and skin. In an additional experiment, voltage pulses were applied between a pick-up electrode and a separate delivery electrode placed subcutaneously a few cm from each other, with leads emerging percutaneously and connected to the anode and cathode of the stimulator respectively. The current in this case sagged by less than 5%, supporting the idea that the interfaces with subcutaneous

tissues are largely resistive.

It follows that the rise time of current delivered to the nerve will in general be similar to that delivered to the local subcutaneous tissues under the surface electrodes. This in turn means that the relative thresholds of activation of target and local nerves will be preserved, even in the face of variations in the capacitance of the skin interface. This was in fact borne out by the similar relative thresholds of local and targeted contractions we observed across different species, skin thicknesses, skin types and variations in thickness of subcutaneous fat.

#### IV. DISCUSSION

The aim of our study was to investigate the mechanisms underlying the percutaneous delivery of electrical stimuli to a target nerve via a passive implant. We found that up to 20% of the total current flowing between a pair of surface electrodes was diverted through the implanted conductor to the common peroneal nerve. This was sufficient to activate the ankle dorsiflexor muscles in a graded and controllable manner over their full physiological range. The effects of electrode size and shape, skin thickness and the relative positioning of internal and external electrode terminals on nerve activation thresholds were quantified. The reproducibility of muscle activation with chronically implanted systems was studied over several months. A comparison of external and internal current and voltage profiles led us to conclude that the skin interface had a large capacitive component of impedance, whereas the interfaces between the terminals of the implanted conductor and surrounding tissues were largely resistive. The results also indicated that although variations in skin impedance affected the rise times of current and voltage, in all cases the thresholds of activation of target motor nerves were lower than the thresholds for activating motor nerves directly under the surface electrodes. We did not attempt to monitor whether cutaneous nerves were activated in these experiments. It is possible in a human clinical application that some sensation would occur as a result of activation of cutaneous nerves under the surface electrodes, particularly with the large pulse amplitudes that may be required to activate the target nerves strongly. To explore this possibility, in a separate set of measurements we determined the sensory perceptual thresholds to surface stimulation with the same electrodes in five healthy human subjects (age range 23 to 59, 4 males, 1 female). After cleaning the skin with alcohol, the cathodal electrode was placed over the median nerve just proximal to the wrist crease and the anodal electrode was placed on the corresponding posterior surface of the wrist. Brief bursts of pulses (monophasic, 300  $\mu$ s duration, 60 pulses/s) were delivered by the Grass stimulator at varying amplitudes and subjects were required to report any sensations. The perceptual thresholds ranged from 3.8 to 4.4 mA (mean 4.1 mA). The motor thresholds across all the animal experiments

in Table 1 range from 0.7 mA to 6.3 mA. It remains to be seen whether the same range of stimulus amplitudes that produced appreciable muscle forces in the animals in our study is similarly effective in humans implanted with router systems. We have found that in human subjects using surface stimulators such as the Walkaide and Bionic Glove [20], [21], cutaneous sensations generally accompany muscle contractions, and they are usually well tolerated. Assuming that the levels of surface stimulation needed to activate target muscles with the SRS are lower than those required in conventional stimulation, it follows that SRS-evoked sensations should also be well tolerated.

The electrode configurations we explored were by no means exhaustive. Other shapes, materials and spatial arrangements of surface electrodes and implanted conductor terminations will presumably be developed to minimize tissue-conductor interface impedance and optimize contact with target nerves. In principle the method could be applied to treat any condition in which electrical stimulation of the peripheral or central nervous system is beneficial. Conditions in which neural prostheses have been applied include movement disorders (e.g. stroke, spinal cord injury, Parkinson's disease, tremor, cerebral palsy), incontinence, urinary retention, pain (e.g. migraine headaches, neck and back pain), epilepsy, sleep apnea, disorders of vision and hearing and psychiatric disorders such as depression.

The router system provides several potential advantages over existing neural prostheses. The surface electrodes are not positioned over the target nerves as they are in conventional surface stimulation, but rather over pick-up terminals implanted in anatomically convenient locations. Greater selectivity is possible compared to conventional surface stimulation, because the implanted conductor routes current only to the target nerve.

In relation to implantable stimulators, the external stimulator and implanted passive conductor are less costly. Battery replacement does not require repeat surgery. The surgical implantation is equivalent to implanting only the lead portion of a conventional implanted stimulator. We are currently testing a design of the passive conductor with terminals similar to those in the Peterson electrode [16] at each end that allow it to be implanted percutaneously with the use of a sheathed hypodermic needle and stylette [17].

On the other hand, the need for external electrodes and an external stimulator is also a drawback, as these components may be inconvenient to don and doff and to wear in daily life. It is worth pointing out that implanted neural prostheses requiring commands from outside the body also require external controllers and coil antennas. In applications requiring continuous long-term stimulation with pre-set pulse parameters, fully implanted neural prostheses will presumably remain the devices of choice.

Some existing implantable neural prostheses are able to activate several target nerves independently [11], so the question arises whether router systems could also have this capability. The spatial tuning curves of Fig. 4 show that

thresholds doubled for misalignments of surface and pick-up electrodes of around 2 cm. Given our finding that muscles were fully recruited at a mean stimulus current 1.8 times that at threshold, this suggests that surface electrodes could be spaced 2 cm apart without causing cross-talk. Two or three separate muscles could therefore be controlled independently using separate pick-up electrodes in the wristwatch-like configuration in Fig. 1. Larger numbers of independent channels might be feasible with larger matrices of surface electrodes and matching pick-up electrodes, though again this might be better done with conventional neural prostheses.

It should also be pointed out that if surface electrodes are not attached properly, or if they dry out, the current supplied by a constant-current stimulator flows through a reduced volume of skin, with an increase in the local current density and electric field such that cutaneous receptors including nociceptors may be activated, causing discomfort and pain.

In conclusion, this study is the first to explore in detail the electrical and functional properties of a new means of selectively activating nerves by transcutaneous coupling of stimulus pulses via an implanted passive conductor. We believe that the technique and the results reported here provide the basis for a new family of neural prostheses that will complement existing types.

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