

Atta OLOUMI, Ph.D.



We've just received the tragic news that Dr. Atta Oloumi died in an automobile accident on 26 Nov 99. Our thoughts and prayers are with his family and all his many friends.

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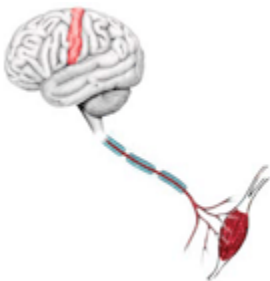
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Current Project

A HIGH DATA BANDWIDTH MAN-MACHINE INTERFACE :

Between the decision in the brain of an action and the final motion, the detection of information can be made at different levels :

- motor cortex
- transcortical electrodes placed directly on the surface of the cortex nerves
- muscles : ElectroMyoGram (EMG)



[Picture1](#)

Our approach : starting with EMG and migrating in the future, step by step, closer to the motor cortex.

To use the EMG as a control signal imposes:

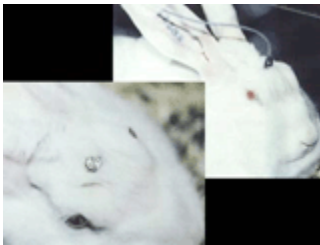
- to increase the quality of the signal
- to solve the calibration problem

But increasing the quality of the signal is also equal to increasing the calibration problems. The only solution to solve these two opposite needs is to use permanently implanted EMG.

However, this was confronted by a constriction: the impossibility to establish an electrical link, permanently and unlimited in the flow of energy and information between the interior of the body and the exterior.

A solution to this problem has been developed by Dr. Pierre Sabin (Clinique Saint-Antoine, Chirurgie Maxillo-Faciale, Bois Guillaume France), a French Maxillo-Facial surgeon [Ref : *Sabin P. et al.* , Permanent percutaneous electrical connection, Rev. Laryngol. Otol. Rhinol. 118 (1997) 335-342].

Dr Pierre SABIN has developed and tested out on animals, a revolutionary technology, the Percutaneous Electrical Plug (PEP) that will allow to extract the signals from EMGs. A first application on human is going on since feb 98.



[Picture2](#)

The PEP is a new desing of extra-oral implant.

It is a :

- permanent
- electric connector
- placed on through the skin (percutaneous)
- behind the ear (and quietly only there)
- without rejection
- without infection
- capable to pass, across 6 electric wires, current and data,
- in both directions (from the outside of the body to the inside and vice versa)
- nearly without limitations in the quantities of data and electrical power

For the practical implantation of the patients we consider 2 typical cases:

Tetraplegia C4 or higher and tetraplegia C5 to T1.

In the first case, only the muscles of the face can be used to command a computer

through EMG. The absolute necessity to avoid surgical risks dictate to choose easily accessible muscles :

- 2 implanted electrodes on the frontal belly of epicranium muscles
- 1 on the corrugator supercilli muscle
- 2 on the orbicularis oculi muscles
- 2 on the zygomaticus major muscles
- 2 on the levator anguli oris muscles
- 4 on the orbicularis oris muscles
- 2 on the depressor anguli oris muscles
- and 2 on the platysma muscles,
- i.e. a total of 17 electrodes implanted on 15 muscles of facial expression, and recording the EMG.



[Picture3](#)

The eye's muscles will not be used, because it would be too delicate and too dangerous, particularly for heavily disabled patients.

In addition, patients with stroke, Bell's palsy or acoustic neuroma can also profit from this implanted interface in the muscles of the face.

In the cases of tetraplegia C5 to T1, there is no active movement of upper limb but some traces of contraction, detectable by implanted EMG remain. According to Zancolli's classification, biceps, brachialis, brachioradialis or supinator can be used by a large part of this population.

The muscle grading system, defined by the British medical research council (1943), identifies 6 different levels for the muscle's state :

- level 0 : no contraction
- level 1 : trace of contraction
- level 2 : active movement, but not against gravity
- level 3 : active movement against gravity
- level 4 : active movement against resistance
- level 5 : normal

We propose to define a new level, between the level 1 and 2:

- level 1bis : conscious contraction, detectable by EMG

Even for tetraplegic patients, it must be possible to use some muscles of the arms, to produce detectable contractions. 10 to 20 muscles can be used per arm.

By assuming 2 to 3 muscular contractions per second and per muscle, the PEP can provide a high data bandwidth, include between 40 bits/sec and 120 bits/sec. It

means, 100 times the data bandwidth of an EEG-Based Brain-Computer Interface.

Some recent articles about the PEP and osseointegration :

Permanent percutaneous electric connection. General principles

Sabin, P; Labbé, D; Levillain, D; Cazin, L; Caston, J.

Revue de Laryngologie Otologie Rhinologie, 1997, 118(5):335-42.

Abstract: The Swedes for more than twenty years, and the Germans for over five years have been able to maintain inert or active prostheses with permanent percutaneous connections, thanks to the dependable and proven material and techniques of extraoral implants. The significant improvement extra-oral implants have brought about is not only in a new therapeutic approach to the treatment of important facial defects or transmission deafness; it is also because for some twenty old years now, the few millimeter wide cylinders of Titanium, the "abutment cylinders" affixed on the implants, have crossed the cutaneous barrier for extended periods without complications. The percutaneous abutment thus creates a permanent communication between the interior and the exterior of the organism. If the abutment, instead of simply carrying a Maxillo-Facial Prosthesis or an auditive prosthesis, is modified by placing an electric conductor inside it, the simple "percutaneous peg" will turn out to be, in a way, a "percutaneous electric plug". By adapting classic "mechanical" abutments and implants, authors have created a Permanent Percutaneous Electric Connection (PPEC) which has been successfully experimented on rabbits to record EEG. Clinical applications on humans would make it possible either to receive "bio-electrical information" coming from within the organism, or to send electrical energy into the organism. This last application opens vast perspectives of improvement both in diagnosis and therapy in many fields.

Implant-supported prosthesis. The significance of endosseous and juxta-osseous implants

Sabin, P; Labbé, D; Ferrand, JY; Kaluzinski, E; Compère, JF.

Revue de Stomatologie et de Chirurgie Maxillo-Faciale, 1997 Oct, 98(4):248-52.

Abstract: The new extra-oral of Farmand (EPITEC system) is a plate-implant. This concept is really different from the Brånemark's implant and the use of EPITEC system give the authors opportunity of a first assessment. It seems that if, of course, Brånemark system is still the reference, the EPITEC system certainly has a real interest in thin osseous implantation areas.

Bone-anchored implants: comparison of the techniques and values of endo- and juxta-bone implants

Sabin, P; Cadre, B; Ferrand, JY; Pacini, R; Labbé, D.

Revue de Laryngologie Otologie Rhinologie, 1997, 118(2):103-7

Abstract: Extra-oral implants have been used for well-defined application for nearly 20 years; for tupoorting maxillo-facial prostheses and for bone anchored

hearing aids (BAHA). In both of these applications, the bone-anchored prostheses support transcutaneous abutments. It is the junction between the implant and the abutment which ensures, given certain preconditions, the permanent percutaneous connection (PPC). The authors describe the two types of implants currently in use-intra- and juxta-osseous implants. They then give a brief description of the two techniques. The advantages and disadvantages of each system are summarised, as well as the conditions required for permanent survival of a PPC.

Some recent articles about biocompatibility of implanted recording electrodes :

Chronically implanted intrafascicular recording electrodes.

Lefurge T, Goodall E, Horch K, Stensaas L, Schoenberg A
Department of Bioengineering, University of Utah
Ann Biomed Eng 1991;19(2):197-207

Abstract : A newly designed intrafascicular electrode for chronic neural recording was studied by implanting 12 electrodes in the radial nerves of 6 cats for 6 months. Action potentials were monitored at specified intervals throughout the experiment. The number and size of the signals recorded suggest that this type of electrode provides information that is appropriate for feedback control in functional electrical stimulation (FES) systems. Histology of the nerve revealed that the implants are biocompatible and that little damage is caused by the presence of the electrode.

Single-fiber electromyography.

Sanders, DB; Stålberg, EV.
Muscle and Nerve, 1996 Sep, 19(9):1069-83

Abstract: Single-fiber electromyography (SFEMG) is a selective recording technique in which a needle electrode with a small recording surface in the side is used to identify action potentials from individual muscle fibers. The SFEMG parameters of greatest organization of muscle fibers within the motor unit; jitter reflects the safety factor of neuromuscular transmission at individual neuromuscular junctions. SFEMG can be of great value in demonstrating or excluding abnormalities in mild or questionable disease of nerve, muscle, or the neuromuscular junction. The neuromuscular jitter may be measured during nerve stimulation, which is particularly useful in uncooperative patients or when it is desirable to control the firing rate precisely, or during voluntary muscle activation, which is less subject to technical artifact. The SFEMG findings may not be specific to a particular disease, but they frequently increase understanding of the disease process by demonstrating abnormal neuromuscular transmission or rearrangement of muscle fibers within the motor unit, which complements information from more conventional EMG examinations.

Biocompatibility of silicon-based electrode arrays implanted in feline cortical tissue.

Schmidt S, Horch K, Normann R

Department of Bioengineering, University of Utah, Salt Lake City 84112.

J Biomed Mater Res 1993 Nov;27(11):1393-9

Abstract : The passive biocompatibility of silicon-based electrode arrays was studied in feline cortical tissue. Three types of arrays were used: uncoated, coated with polyimide, and coated with polyimide over an adhesion promoter. Fifteen arrays were implanted for 24 h to determine early tissue reaction to the implantation procedure, and twelve arrays were implanted for 6 months to determine structural and material biocompatibility. Edema and hemorrhage were present around the short-term implants, but involved less than 6% of the total area of the tissue covered by the array. With chronic implants, leukocytes were rarely present and macrophages were found around roughly one-third of the tracks. Remnants of foreign material from the electrodes could be identified in less than 10% of the tracks. Gliosis was found around all tracks, forming an annulus between 20 and 40 microns thick. A capsule was not always present, and never exceeded a thickness of 9 microns. These results suggest that the implantation procedure produces limited amounts of tissue damage, and that the arrays are biocompatible. However, the arrays insulated with polyimide over a primer had significantly greater involvement of macrophages, gliosis, and capsule formation than uncoated arrays and arrays insulated with polyimide without primer, perhaps indicating a reaction to aluminum oxide in the primer.

Evaluation of a thin-film peripheral nerve cuff electrode.

Walter JS, McLane J, Cai W, Khan T, Cogan S

Hines VA Hospital, Rehabilitation Research and Development Center, IL 60141, USA.

J Spinal Cord Med 1995 Jan;18(1):28-32

Abstract : This is a study of the reaction of large nerves to implantation using a flexible, thin-film cuff electrode. Cuff electrodes were implanted on the sciatic nerve of three cats. An implantation period of six weeks allowed sufficient time for any injury responses in the nerve and connective tissue sheath around the cuff to develop. The electrode came off the nerve in one of the cats. In the remaining two cats, gross observation following explantation of the electrodes revealed encapsulation of the cuffs without swelling of nerve tissue. Histological evaluation did not demonstrate nerve injury. The nerve cuff electrodes, which are comprised of titanium and iridium coatings on a fluorocarbon polymer substrate, appeared unaffected by the implantation, and connective tissue encapsulation did not adhere to either the polymer substrate or metallization. Evaluation of the electrodes using activated iridium oxide charge injection sites in more extended studies is now being undertaken.

Some recent articles about biocompatibility of stimulating

electrodes :

Stability of the input-output properties of chronically implanted multiple contact nerve cuff stimulating electrodes.

Grill WM, Mortimer JT

Case Western Reserve University, Cleveland

IEEE Trans Rehabil Eng 1998 Dec;6(4):364-73

Abstract : The objective of this investigation was to measure the input-output (I-O) properties of chronically implanted nerve cuff electrodes. Silicone rubber spiral nerve cuff electrodes, containing 12 individual platinum electrode contacts, were implanted on the sciatic nerve of seven adult cats for 28-34 weeks. Measurements of the torque generated at the ankle joint by electrical stimulation of the sciatic nerve were made every 1-2 weeks for the first 6 weeks post-implant and every 3-5 weeks between 6 weeks and 32 weeks post-implant. In three implants the percutaneous lead cable was irreparably damaged by the animal within 4 weeks after implant and further testing was not possible. One additional lead cable was irreparably damaged by the animal at 17 weeks post-implant. The three remaining implants functioned for 28, 31, and 32 weeks. Input-output curves of ankle joint torque as a function of stimulus current amplitude were repeatable within an experimental session, but there were changes in I-O curves between sessions. The degree of variability in I-O properties differed between implants and between different contacts within the same implant. After 8 weeks, the session to session changes in the stimulus amplitude required to generate 50% of the maximum torque (I50) were smaller (15+/-19%, mean +/- s.d.) than the changes in I50 measured between 1 week and 8 weeks post-implant (34+/-42%). Furthermore, the I-O properties were more stable across changes in limb position in the late post-implant period than in acutely implanted cuff electrodes. These results suggest that tissue encapsulation acted to stabilize chronically implanted cuff electrodes. Electrode movement relative to the nerve, de- and regeneration of nerve fibers, and the inability to precisely reproduce limb position in the measurement apparatus all may have contributed to the variability in I-O properties.

Quantification of recruitment properties of multiple contact cuff electrodes.

Grill WM Jr, Mortimer JT

Case Western Reserve University, Cleveland

IEEE Trans Rehabil Eng 1996 Jun;4(2):49-62

Abstract : Nerve-based stimulating electrodes provide the technology for advancing the function of motor system neural prostheses. The goal of this work was to measure and quantify the recruitment properties of a 12 contact spiral nerve cuff electrode. The cuff was implanted on the cat sciatic nerve trunk, which consists of at least four distinct motor fascicles, and the torque generated at the ankle joint by selective stimulation of the nerve was recorded in nine acute experiments. Comparisons of torques generated with the cuff to torques generated by selective stimulation of individual nerve branches indicated that the cuff allowed

selective activation of individual nerve fascicles. Selectivity was dependent on the relative location of the electrode contacts and the nerve fascicles, as well as the size and relative spacing of neighboring fascicles. Selective stimulation of individual nerve fascicles allowed independent and graded control of dorsiflexion and plantarflexion torques in all nine experiments. Field steering currents improved selectivity as reflected by significant increases in the maximum torques that could be generated before spillover to other fascicles, significant increases in the difference between the current amplitude at spillover and the current amplitude at threshold, and significant increases in the slope of the current distance relationship.

Effect of long-term implanted nerve cuff electrodes on the electrophysiological properties of human sensory nerves.

Slot PJ, Selmar P, Rasmussen A, Sinkjaer T

Center for Sensory-Motor Interaction, Aalborg University, Denmark.

Artif Organs 1997 Mar;21(3):207-9

Abstract : During a long-term implantation (307 days) of a tripolar split cuff electrode around the palmar digital nerve to the radial side of the left index finger, branching off the median nerve in a medullary lesioned C6 patient, the physiological state of the nerve was intensively monitored. The resulting sensory nerve action potential (SNAP) amplitude was recorded, using both near-nerve electrodes and the implanted cuff electrode. The SNAP amplitude declined within 10 days to approximately 50% of the first SNAP cuff amplitude measured on Day 2 after implantation and recovered to the initial amplitude within 3 months. The SNAP amplitude measurements made with near-nerve electrodes were consistent with the cuff results; the SNAP conduction velocity (CV) recorded by the near-nerve electrodes and the cuff electrode was constant during the whole implantation period. This is in agreement with the results from two other patients: one with a cuff implanted around the sural nerve, and the other with a cuff implanted around a branch of the tibial nerve. These results and animals studies show that the cuff electrode is an electrically stable neural-electrical transducer.

A method for evaluating the selectivity of electrodes implanted for nerve simulation.

Liang DH, Kovacs GT, Stormont CW, White RL

Department of Internal Medicine, Stanford University Medical Center

IEEE Trans Biomed Eng 1991 May;38(5):443-9

Abstract : The scale of stimulating electrodes possible for use in functional electrical stimulation to restore motor and sensory function is rapidly approaching that of individual neurons. Although the electrodes may approach the dimensions of single nerve cells, it is unclear if the region of excitation elicited by each electrode will be correspondingly small. Previous techniques for evaluating this have either been tedious or have lacked the resolution necessary. This paper describes a method that uses the refractory interaction of the compound action potentials elicited by a stimulus pulse pair, along with high-resolution recording of those potentials, to achieve measurements of the selectivity of stimulation down to the scale of a few axon diameters. The feasibility of this technique is demonstrated in sciatic nerves of frogs (*Rana Catesbiana*) acutely implanted with a sapphire

electrode array.

Comparison of 180-degree and 360-degree skeletal muscle nerve cuff electrodes.

Letsou GV, Hogan JF, Lee P, Kim JH, Ariyan S, Dewar ML, Baldwin JC, Elefteriades JA

Department of Surgery, Yale University, New Haven, Connecticut

Ann Thorac Surg 1992 Nov;54(5):925-31

Abstract : Use of skeletal muscle for cardiac augmentation is a promising technique for treatment of end-stage cardiac failure. An electrode woven through the latissimus dorsi that recruits nearby nerve fibers is commonly used to pace skeletal muscles both in clinical practice and in the laboratory. A proximally placed nerve cuff electrode offers potential advantages in improved recruitment of muscle fibers and low threshold for stimulation. We tested the effectiveness of a nerve cuff electrode passed directly about the proximal thoracodorsal nerve. Our report looks at the efficacy of nerve cuff electrode stimulation and compares electrical and histologic characteristics of a 180-degree wrap of the thoracodorsal nerve to a 360-degree wrap in dogs over 3 months. Threshold voltage at the commonly used pulse width of 200 microseconds was typically in the range of 400 to 600 mV for each electrode after 3 months. Statistical analysis revealed no significant difference ($p < 0.05$) in threshold voltage or current between the 180-degree and 360-degree nerve cuff electrode either at acute evaluation or after 3 months. Even contraction of latissimus dorsi was achieved with all implants. Adenosine triphosphatase staining revealed 100% conversion of type II to type I fibers in all stimulated muscles. Histologic examination of the thoracodorsal nerve and latissimus dorsi muscle revealed no abnormalities grossly or by light microscopy. Thus, a carefully applied nerve cuff electrode is an atraumatic, effective method for skeletal muscle stimulation. The 180-degree and 360-degree nerve cuff configurations are equally effective.

Some recent articles about electrostimulation of the optic nerve :

Visual sensations produced by optic nerve stimulation using an implanted self-sizing spiral cuff electrode.

Veraart C, Raftopoulos C, Mortimer JT, Delbeke J, Pins D, Michaux G, Vanlierde A, Parrini S, Wanet-Defalque MC

Neural Rehabilitation Engineering Laboratory, Universite Catholique de Louvain, Belgium

Brain Res 1998 Nov 30;813(1):181-6

Abstract : A blind volunteer with retinitis pigmentosa was chronically implanted with a self-sizing spiral cuff electrode around an optic nerve. Electrical stimuli applied to the nerve produced localized visual sensations that were broadly distributed throughout the visual field and could be varied by changing the

stimulating conditions. These results demonstrate the potential for constructing a visual prosthesis, based on electrical stimulation of the optic nerve, for blind subjects who have intact retinal ganglion cells.

Some recent articles about long term implantation of electrodes :

Long-term peripheral nerve and muscle recordings from normal and dystrophic mice.

Milner TE, Hoffer JA

J Neurosci Methods 1987 Jan;19(1):37-45

Abstract :A method for long-term recording of electrical activity from small mammalian nerves and muscles is described. Electrodes for stimulating and recording activity were implanted on nerves and muscles subserving ankle flexion and extension in normal and dystrophic mice. Activity was monitored on a regular basis for up to 200 days following implantation. Neural compound action potentials, compound EMG potentials and twitch tension were recorded. Shortly after implantation, evoked EMG and twitch tension declined, but recovered progressively to values measured at the time of implantation and subsequently remained steady in normal mice. However, while dystrophic mice did recover, with EMG levels reaching 50-60% of the values recorded at implantation, tension eventually dropped to 10% in flexor muscles and 25% in extensors.

Long-term implantation of platinum electrodes: effects on electrode material and nerve tissue.

Jonzon A, Larsson EN, Oberg PA, Sedin G

Med Biol Eng Comput 1988 Nov;26(6):624-7

Long-term results of nervous tissue alterations caused by epineurial electrode application: an experimental study in rat sciatic nerve.

Koller R, Girsch W, Liegl C, Gruber H, Holle J, Losert U, Mayr W, Thoma H
Second Surgical Clinic, University of Vienna, Austria.

Pacing Clin Electrophysiol 1992 Jan;15(1):108-15

Abstract :In order to evaluate the long-term effects of epineurial electrode application for functional electrical stimulation (FES) the left sciatic nerve of seven rats was exposed. Four ring-shaped stainless steel wire electrodes were sutured to the epineurium of each nerve in the same manner as performed clinically for carousel stimulation in man. The nerves were reexposed 1 year after implantation and the stimulation threshold to obtain a tetanic contraction in the lower limb was determined for each electrode.

Afterwards the animals were sacrificed. The electrodes were excised and cross sections of the sciatic nerve directly at site of the electrodes, 2-mm proximal and 2-mm distal to them were harvested for histologic and planimetric assessment of nerve lesions. The area of damaged neural tissue was expressed as a percentage of

the total cross-sectional area within the perineural sheath. The sciatic nerves of the right side served as controls. The values for the stimulation thresholds ranged between 0.1 and 1.0 mA (mean 0.43 mA). By morphometric examination five of seven nerves were seen altered, the altered areas captured between 1% and 4.8% of the total cross-sectional area of the nerves within the perineural sheath. Besides two specimens, all altered nerve segments exhibited distinct signs of nerve fiber regeneration. The clinical implications of the results for long-term electrical stimulation, such as phrenic pacing, are discussed.

Some recent articles about electrostimulation of the phrenic nerves :

Electrical stimulation to restore respiration.

Creasey, G; Elefteriades, J; DiMarco, A; Talonen, P; Bijak, M; Girsch, W; Kantor, C.

MetroHealth Medical Center, Department of Medicine, Cleveland, OH 44109, USA.
Journal of Rehabilitation Research and Development, 1996 Apr, 33(2):123-32.

Abstract: Electrical stimulation has been used for over 25 years to restore breathing to patients with high quadriplegia causing respiratory paralysis and patients with central alveolar hypoventilation. Three groups have developed electrical pacing systems for long-term support of respiration in humans. These systems consist of electrodes implanted on the phrenic nerves, connected by leads to a stimulator implanted under the skin, and powered and controlled from a battery-powered transmitter outside the body. The systems differ principally in the electrode design and stimulation waveform. Approximately 1,000 people worldwide have received one of the three phrenic pacing devices, most with strongly positive results: reduced risk of tracheal problems and chronic infection, the ability to speak and smell more normally, reduced risk of accidental interruption of respiration, greater independence, and reduced costs and time for ventilatory care. For patients with partial lesions of the phrenic nerves, intercostal muscle stimulation may supplement respiration.

Diaphragm pacing: clinical and experimental results.

Brouillette, RT; Marzocchi, M.

Department of Pediatrics, Montreal Children's Hospital, Canada.

Biology of the Neonate, 1994, 65(3-4):265-71

Abstract: Over the last 26 years diaphragm pacing has been used in over 400 adults and 70 children to support ventilation and oxygenation. Diaphragm pacing can be useful for conditions in which the brain stem respiratory centers provide little or no stimulation to the respiratory muscles, i.e. central hypoventilation syndrome, Arnold-Chiari malformation/brain stem dysfunction, and high quadriplegia. Because the pacing systems are so portable, the greatest advantages

accrue to those patients who require ventilatory support both while awake and asleep. Infants and children require tracheostomy to avoid upper airway obstruction and bilateral pacing to meet higher metabolic demands. The stimulus parameters most appropriate for pediatric patients have been characterized as low stimulus frequency, short inspiratory time, and moderate respiratory rate. Use of similar stimulus parameters in an immature animal model has resulted in preservation of diaphragmatic structure and function but transformation of the diaphragm from a mixed muscle to one with a uniform population of type 1, fatigue-resistant fibers (physiologic, histochemical, myosin isoform, and ultrastructural evidence). In 33 pediatric patients, representing 96 patient-years of use, there were 26 failures of the pacing systems requiring removal and/or replacement of the internal components. Mean time to failure was 56 months. Of our 36 patients who had diaphragm pacing systems implanted, 26 are alive and 22 are currently using the pacing systems. Two recent advances may further improve the long-term outcome of patients using diaphragm pacing. Smaller, better encapsulated receivers may improve system longevity and a new stimulus electrode may reduce the risk of diaphragmatic damage.

Some recent articles about functional electro-stimulation (FES) of limbs

Peripheral nerve stimulation for restoration of motor function.

Bhadra, N; Peckham, PH.

Department of Orthopedics, MetroHealth Medical Center, Cleveland, Ohio

Journal of Clinical Neurophysiology, 1997 Sep, 14(5):378-93

Abstract: This review paper discusses the use of electrical stimulation to restore function after upper motor neurone type of paralysis. It describes the basic physiology of electrical stimulation, the electrophysiology and biomaterials associated with using metal electrodes to deliver charge to living tissue, and also the adverse effects of stimulation.

The central concepts of electrode applications, stimulus parameters, muscle fatigue, and stimulation control are covered. Next, a survey of clinical applications is made with focus on upper and lower limb applications. A concluding section mentions the current status of commercial products available for stimulation.

Clinical use of percutaneous intramuscular electrodes for functional electrical stimulation.

Shimada Y, Sato K, Kagaya H, Konishi N, Miyamoto S, Matsunaga T

Department of Orthopedic Surgery, Akita University School of Medicine, Japan.

Arch Phys Med Rehabil 1996 Oct;77(10):1014-8

Abstract : 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, 1yr to 4yr 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, and 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.

Muscle selection and walking performance of multichannel FES systems for ambulation in paraplegia.

Kobetic R, Triolo RJ, Marsolais EB

Veterans Affairs Medical Center, Motion Study Laboratory, Cleveland, OH 44106, USA.

IEEE Trans Rehabil Eng 1997 Mar;5(1):23-9

Abstract : A minimal set of muscles (8 to 16) were identified as candidates for implantation in a clinical system to provide walking function to individuals with complete paraplegia using functional electrical stimulation (FES). Three subjects with complete motor and sensory paraplegia had percutaneous intramuscular electrodes implanted in all major muscles controlling the trunk, hips, knees, and ankles. Stimulation patterns for walking with FES were generated for different sets of eight and 16 muscles. The quality and repeatability of the resulting gait produced by walking patterns consisting of various combinations of muscles were determined. Most eight-channel stimulation patterns resulted in scissoring or insufficient hip flexion, preventing forward progression. One eight-channel system allowed a maximum speed of 0.1 m/s with a cadence of 22 steps/min and a stride length less than 0.3 m. Improved walking performance was observed with 16 channels of stimulation. This ranged from slow step- to gait at 0.1 m/s to smooth reciprocal gait at 0.5 m/s. In all three subjects, the favored combination of 16 channels included erector spinae for trunk extension; gluteus maximus, posterior portion of adductor magnus and hamstrings for hip extension; tensor fasciae latae and either sartorius or iliopsoas for hip flexion; vastus lateralis/intermedius for knee extension; and tibialis anterior/peroneus longus for ankle dorsiflexion. In one subject the 16-channel FES system provided repeatable day-to-day gait averaging 0.4 m/s, 58 steps/min and a stride length at 0.8 m. A maximum

repeatable walking distance with 16 channels was 34 m. Multiple 34-m trials were possible with minimal rests between walks. Fatigue of both the hip extensors and upper body was a limiting factor. The selection of target muscles for implantation is critical to the performance of FES systems. This study provides guidelines to muscle selection for walking with FES based on objective measures of gait performance. The findings indicate that a 16-channel FES system for total implantation is feasible for repeatable short distance, independent, walker-support walking in paraplegia.

Implantation of a 16-channel functional electrical stimulation walking system.

Sharma M, Marsolais EB, Polando G, Triolo RJ, Davis JA Jr, Bhadra N, Uhlir JP
Department of Veterans Affairs Medical Center, Cleveland, OH 44106-1702, USA.
Clin Orthop 1998 Feb;(347):236-42

Abstract :A 16-channel electrical stimulation system was implanted in a 39-year-old patient with T10 paraplegia to restore sit to stand, walking, and exercise functions. System implantation required two surgical sessions. In the first session, the posterior muscle set consisting of bilateral semimembranosus, adductor magnus, and gluteus maximus muscles were exposed and epimysial electrodes sutured at the point of greatest muscle contraction. Closed double helix intramuscular electrodes were implanted in the erector spinae. Two weeks later, epimysial electrodes were attached to the eight anterior muscles consisting of the tibialis anterior, sartorius, tensor fasciae latae, and vastus lateralis with all 16 electrode leads passed to the anterior abdominal wall. The electrodes were connected to two eight-channel stimulators placed in the iliac fossae, and the system was checked by activating the individual muscles.

The implanted stimulators received stimulation instructions and power via a radio frequency link to an external control. Stimulation patterns for standing, walking, sitting, and exercise functions were chosen from a preprogrammed menu via a finger key pad. After 3 weeks of restricted patient activity, all electrodes stimulated either the target muscle or had an acceptable spillover pattern. The patient is undergoing a 16-week rehabilitation course of stimulated exercises gradually increasing in intensity. At the conclusion, the goal is to discharge the patient with the system for spontaneous use. Although long term followup is required to determine system reliability, preliminary clinical results indicate that targeted, repeatable, functional muscle contractions in the lower extremity can be achieved with a system consisting of epimysial electrodes.

Reliability of closed double helix electrode for functional electrical stimulation.

Kagaya H, Sharma M, Polando G, Marsolais EB
Clin Orthop 1998 Jan;(346):215-22

Veterans Administration Medical Center, Cleveland

Abstract :The reliability of a closed double helix electrode in the lower limbs was studied. This electrode is an implanted intramuscular electrode and is used for a totally implantable functional electrical stimulation system. Eighty electrodes were evaluated retrospectively with a mean period of 15 months. The total implant time

was 1222 electrode months. The cumulative proportion surviving was 0.934 at 6 months, 0.855 at 1 year, 0.765 at 2 years, and 0.730 after 30 months. Fifteen of 80 electrodes failed, seven showed increasing electrode impedance, and eight had undesirable changes in recruitment. Of the failed electrodes, 2/3 failed during the first 10 months. The reliability was 0.91 at 6 months and 0.80 at 1 year after implantation in all muscle groups. The closed double helix electrode displayed an increased reliability when compared with the open double helix electrode at 6 months, and an equivalent reliability as compared with the electrodes developed by Handa and colleagues at 6 months and 1 year, using the chi squared test for independence. This study suggests that the closed double helix electrode has an acceptable reliability and can be used as a part of a totally implantable functional electrical stimulation system.

Urinary bladder control by electrical stimulation: review of electrical stimulation techniques in spinal cord injury.

Rijkhoff, NJ; Wijkstra, H; van Kerrebroeck, PE; Debruyne, FM.
Department of Urology, University Hospital Nijmegen, The Netherlands.
Neurourology and Urodynamics, 1997, 16(1):39-53

Abstract: Evacuation of urine in paraplegics without the need for catheters would be possible when voiding could be induced by eliciting a bladder contraction. A challenging option to obtain detrusor contraction is electrical stimulation of the detrusor muscle or its motor nerves. This article reviews the 4 possible stimulation sites where stimulation would result in a detrusor contraction: the bladder wall, the pelvic nerves, the sacral roots, and the spinal cord. With respect to electrode application, sacral root stimulation is most attractive. However, in general, sacral root stimulation results in simultaneous activation of both the detrusor muscle and the urethral sphincter, leading to little or no voiding. Several methods are available to overcome the stimulation-induced detrusor-sphincter dyssynergia and allow urine evacuation. These methods, including poststimulus voiding, fatiguing of the sphincter, blocking pudendal nerve transmission, and selective stimulation techniques that allow selective detrusor activation by sacral root stimulation, are reviewed in this paper.

Some recent articles about functional electro-stimulation (FES) in the control of pain

Stimulation of the central and peripheral nervous system for the control of pain.

Stanton-Hicks, M; Salamon, J.
Journal of Clinical Neurophysiology, 1997 Jan, 14(1):46-62

Abstract: After suffering some setbacks since its introduction in 1967, stimulation of the spinal and peripheral nervous systems has undergone rapid development in the last ten years. Based on principles enunciated in the Gate Control Hypothesis that was published in 1968, stimulation-produced analgesia (SPA) has been

subjected to intensive laboratory and clinical investigation. Historically, most new clinical ideas in medicine have tended to follow a three-tiered course. Initial enthusiasm gives way to a reappraisal of the treatment or modality as side-effects or unanticipated problems arise. The last and third phase proceeds at a more measured pace as the treatment is refined by experience. This review is divided into three parts as it traces the progress of spinal cord stimulation (SCS) and peripheral nerve stimulation (PNS). The review commences with a discussion of the theory of SCS and PNS, and is followed by early reports during which it became apparent that the modality is essentially only effective in the treatment of neuropathic pain. The last section describes the modern experience including efficacy in specific types of pain and concludes with recent accomplishments that dramatize the relief of pain which can be achieved in nonoperable peripheral vascular disease or myocardial ischemia. Over the years, a search for those transmitters that might be influenced by spinal cord stimulation focused on somatostatin, cholecystokinin (CCK), vasoactive intestinal polypeptide (VIP), neurotensin and other amines, although only substance "P" was implicated. More recently, in animal studies, evidence that GABA-ergic systems are affected may explain the frequent successful suppression of allodynia that follows spinal cord stimulation. During the past eight years, much attention has been directed to studies that use a chronic neuropathic pain model. While PNS held significant promise as a pain relieving modality, early electrode systems and their surgical implantation yielded variable results due to evolving technical and surgical skills. These results dramatically reduced the continued development of PNS, which then gave way to a preoccupation with SCS. Modern development of SCS with outcome studies, particularly in relation to failed back surgery syndrome (FBSS) and the outcome of peripheral nerve surgery for chronic regional pain syndromes, has earned both modalities a place in the ongoing management of patients with intractable neuropathic pain. The last section, dealing with pain of peripheral vascular and myocardial ischemia, is perhaps one of the more exciting developments in stimulation produced analgesia and as the papers discussed demonstrate, can provide a level of analgesia and efficacy that is unattainable by other treatment modalities. SCS and PNS has an important role to play in the management of conditions that are otherwise refractory to conservative or other conventional management.

Some recent articles about interaction between electrodes and tissues :

Electrical stimulation of neural tissue to evoke behavioral responses.

Tehovnik, EJ.

Journal of Neuroscience Methods, 1996 Mar, 65(1):1-17

Department of Brain and Cognitive Sciences, Massachusetts Institute of Technology

Abstract: This review yields numerous conclusions. (1) Both unit recording and behavioral studies find that current activates neurons (i.e., cell bodies and axons)

directly according to the square of the distance between the electrode and the neuron, and that the excitability of neurons can vary between 100 and 4000 microA/mm² using a 0.2-ms cathodal pulse duration. (2) Currents as low as 10 microA, which is considered within the range of currents typically used during micro-stimulation, activate from a few tenths to several thousands of cell bodies in the cat motor cortex directly depending on their excitability; this indicates that even low currents activate more than a few neurons. (3) Electrode tip size has no effect on the current density--or effect current spread--at far field, but tip size limits the current-density generated at near field. (4) To minimize neuronal damage, the electrode should be discharged after each pulse and the pulse duration should not exceed the chronaxie of the stimulated tissue. (5) The amount of current needed to evoke behavioral responses depends not only on the excitability of the stimulated substrate but also on the type of behavior being studied.

Tissue response to chronically stimulated implanted epimysial and intramuscular electrodes.

Akers JM, Peckham PH, Keith MW, Merritt K

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Abstract : Twenty-four epimysial and 16 intramuscular electrodes were implanted in five adult dogs for periods ranging from 11 to 50 months. Chronic stimulation was applied to half of the electrodes for eight weeks near the end of the implantation period. The tissue response was rated by the amount and appearance of the fibrous tissue and inflammatory cells seen in the capsule lining the region of the electrode. The encapsulation tissues were composed primarily of collagen and fibroblasts and some macrophages and few other inflammatory cells. The epimysial electrodes exhibited more variation between and within electrodes, but had more of the better scores than the intramuscular electrodes. No difference in the distribution of scores was measured between the control and stimulated groups for the epimysial electrodes. While the scores for the intra-muscular electrodes varied very little, variance was sufficient to indicate a trend for poorer ratings with the application of chronic stimulation. Fibrous capsules were generally thinner under the epimysial electrodes than around the intramuscular electrodes. For both electrode types, the thickness was not correlated with the application or level of chronic stimulation. Thickness was shown to be positively correlated to the degree of loss of the sutures used to anchor the epimysial electrodes.

A chronic intracortical electrode array: preliminary results.

Campbell PK, Normann RA, Horch KW, Stensaas SS

J Biomed Mater Res 1989 Aug;23(A2 Suppl):245-59

Department of Bioengineering, University of Utah, Salt Lake City 84112.

Abstract : Two sets of electrode arrays made of either 25- or 50-microns-diameter Teflon-insulated platinum-iridium wire and Teflon have been developed for chronic intracortical electrical stimulation. Cortical histological studies were performed following acute and chronic implantation in cats. While some neural damage resulted from the implantations of either array configuration, a unique set of problems was associated with each diameter wire. Arrays with 50-microns electrodes and lead wires tended to maintain interelectrode spacing upon

implantation, but the percutaneous leads retained residual stress which made array implantation difficult. Arrays with 25-microns electrodes and lead wires suffered from changes in interelectrode spacing upon implantation, but were much easier to manipulate during surgery. Both array configurations demonstrated some movement after implantation. It is concluded that a chronic intracortical stimulating electrode array of this geometry should have the following properties: 1) the penetrating electrodes and supporting substrate must be stiff (to maintain interelectrode spacings upon implantation), and 2) the percutaneous leads must be extremely flexible (to avoid array movement after implantation).

Electrical properties of implant encapsulation tissue.

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Ann Biomed Eng 1994 Jan-Feb;22(1):23-33

Abstract : The purpose of this study was to determine the electrical properties of the encapsulation tissue that surrounds electrodes chronically implanted in the body. Two four-electrode arrays, fabricated from either epoxy or silicone rubber, were implanted in each of six adult cats for 82 to 156 days. In vivo measurements of tissue resistivity using the four-electrode technique indicated that formation of the encapsulation tissue resulted in a significant increase in the resistivity of the tissue around the arrays. In vitro measurements of tissue impedance using a four-electrode cell indicated that the resistivity of the encapsulation tissue was a function of the tissue morphology. The tight layers of fibroblasts and collagen that formed around the silicone rubber arrays had a resistivity of 627 ± 108 $\Omega\text{-cm}$ (mean \pm SD; $n = 6$), which was independent of frequency from 10 Hz to 100 kHz, and was significantly larger than the resistivity of the epoxy encapsulation tissue at all frequencies between 20 Hz and 100 kHz. The combination of macrophages, foreign body giant cells, loose collagen, and fibroblasts that formed around the epoxy arrays had a frequency-dependent resistivity that decreased from 454 ± 123 $\Omega\text{-cm}$ ($n = 5$) to 193 ± 98 $\Omega\text{-cm}$ between 10 Hz and 1 kHz, and was independent of frequency between 1 kHz and 100 kHz, with a mean value of 195 ± 88 $\Omega\text{-cm}$. The results indicate that the resistivity of the encapsulation tissue is sufficient to alter the shape and magnitude of the electric field generated by chronically implanted electrodes.

Anchoring of deep brain stimulation electrodes using a microplate.

Technical note.

Favre J, Taha JM, Steel T, Burchiel KJ

Division of Neurosurgery, Oregon Health Sciences University, Portland .

J Neurosurg 1996 Dec;85(6):1181-3

Abstract : The authors report a new technique to anchor deep brain stimulation electrodes using a titanium microplate. This technique has been safely used to secure 20 quadripolar deep brain stimulation electrodes implanted for movement disorders (18 electrodes) and pain (two electrodes). Twelve electrodes were implanted in the thalamus, four in the subthalamic nucleus, and four in the pallidum. No electrode migration or rupture occurred, and all electrodes have been shown to work properly after internalization of the system.

Prevention of the rapid degradation of subcutaneously implanted Ag/AgCl reference electrodes using polymer coatings.

Moussy F, Harrison DJ

Department of Chemistry, University of Alberta, Edmonton, Canada.

Anal Chem 1994 Mar 1;66(5):674-9

Abstract : To assess the effect of the biological response to implanted Ag/AgCl reference electrodes on the electrode stability, uncoated and polymer-coated Ag/AgCl electrodes were implanted subcutaneously in rats. After 1 week of implantation, uncoated Ag/AgCl electrode potentials, measured in 0.1 M KCl, shifted by about -180 mV, and both voltammetry and electron microscopy showed that all the AgCl was removed. The electrodes could be significantly protected by coating with polyurethane or a perfluorinated ionomer (Nafion) cured at 120 degrees C for 1 h. Electron micrographs showed the 120 degrees C cured Nafion and polyurethane coatings remained intact over 2 weeks of implantation. Following 2 weeks of implantation the cured, Nafion-coated electrodes' potentials were shifted by 15 +/- 7 mV relative to the initial values. Voltammetry showed that they were still not polarizable. The current densities obtained with the coated reference electrodes are sufficient for their use as counter/pseudoreference electrodes with implantable two-electrode glucose sensor systems. The tissue response to coated electrodes was minimal in comparison to the response to uncoated reference electrodes.