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Activities on PNS neural interfaces for the control of hand prostheses

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***Abstract*—The development of interfaces linking the human nervous system with artificial devices is an important area of research. Several groups are working on the development of devices able to restore sensory-motor function in subjects affected by neurological disorders, injuries or amputations. Neural electrodes implanted in peripheral nervous system, and in particular intrafascicular electrodes, seem to be a promising approach for the control of hand prosthesis thanks to the possibility to selectively access motor and sensory fibers for decoding motor commands and delivering sensory feedback. In this paper, activities on the use of PNS interfaces for the control of hand prosthesis are presented. In particular, the design and feasibility study of a self-opening neural interface is presented together with the decoding of ENG signals in one amputee to control a dexterous hand prosthesis.**

I. Introduction

IN the last decades, several research groups started working on the development of new and more effective devices for the restoration and replacement of sensory-motor function in disabled people (e.g., spinal cord injured persons or amputees) [1, 2]. In order to develop reliable prosthetic or neuroprosthetic systems , a fast, intuitive, and robust flow of information must be exchanged between these devices and the nervous system of the user. For example, signals from efferent fibers can be recorded and used to control a prosthetic device whereas afferent fibers can be stimulated to deliver a variety of sensory feedback information to the amputee [3]. Similarly, kinematic and kinetic information for the closed-loop control of a neuroprostheses could be detected from signals originated from natural sensors intercepted by a neural interface with sufficient recording selectivity [4].

In recent years, several attempts have been carried out to restore this natural link in different ways by developing different types of interfaces with the central [1, 2] and peripheral system (CNS and PNS respectively) [1, 5-8]. Among the possible choices, interfaces with the PNS [6], and in particular longitudinal intrafascicular interfaces (LIFEs) [9, 10] seem to be particularly interesting for the control of hand prostheses. As a matter of fact, they could represent a trade-off between a potentially good ability to restore a natural link with the nervous system and a reduced invasiveness. This is particularly important for amputees who still retain many voluntary skills.

In this paper, research activities on intraneural electrodes for the control of hand prostheses are presented. In particular, two main aims are currently pursued: (i) development of a new interface with higher selectivity (SELINE, a self opening intrafascicular neural interface) and (ii) investigation of the decoding of ENG signals recorded in a patient recently implanted with LIFEs.

II. The SELINE Intraneural Interface

The proposed electrode is an evolution of TIMEs [11] and LIFEs: it has a main structure made of thin films of polyimide and, in addition to the main shaft, SELINE has two lateral wings for each side. This electrode has been obtained by mixing the advantages of pre-existing solutions [12, 13] such as the reversible insertion-extraction in one case and the presence of multiple active sites on lateral barbs in the other one. A feasibility study of a self-opening electrode has been done by considering micro-technological and structural issues [14], theoretical models, and available experimental data of penetrating pressures of needles [15] and insertion forces of electrodes [16]. The active sites will be positioned both on the main shaft and on the lateral wings (Fig. 1)

The working principle is based on two main phases: insertion of the electrode inside a hole previously made by a needle; partial extraction of the electrode so that wings can open through the tissue. This working principle is suitable for transversal implantations: a longitudinal implantation is not recommended since a pulling force parallel to the direction of insertion actuates the device. The system can be manually actuated by the surgeon or by an automated insertion tool. The geometry of the lateral wings has been designed to behave asymmetrically with respect to the insertion and partial extraction needed for the outspreading into the tissue.

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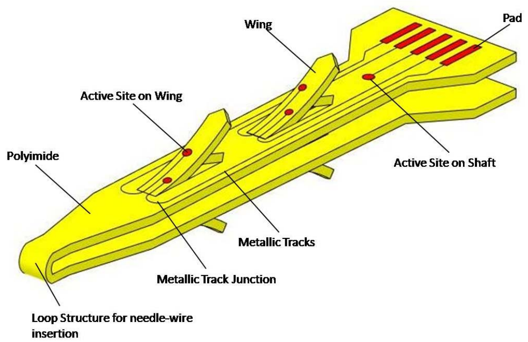

Fig. 1 SELINE lateral view: looped polyimide structure composed of a main body with four lateral wings. There are two active sites on each wing and one active site on the main body, for each side.

During insertion wings behave as linked to the main body by a built-up section, while during the partial extraction needed to achieve the opened configuration, wings can be modelled as linked by a revolute joint.

A. Design of the electrode

The insertion of SELINE inside the tissue is driven by needle and wire [17] and it occurs in an already existing circular hole.The electrode is made of a symmetric looped structure. The wing is 150 µm wide and 11 µm thick: these sizes are ruled by literature data in order to maximally reduce the bulk. The wing ends with a radius of curvature at the tip comparable to the mean interaxonal distance of peripheral nerves (r_t = 11 µm) [18]. Each wing is composed of a rectilinear part L_r and a curvilinear part L_c (Fig. 2).

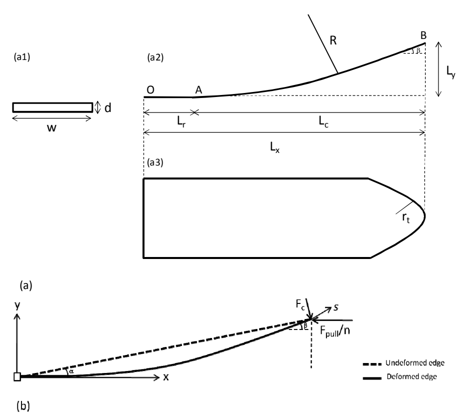

Fig. 2. Geometric profile of the wing: (a1) cross-sectional area, (a2) lateral view, (a3) top view; (b) Free Body Diagram of the profiles of the wing (rectilinear and mixed curvilinear-rectilinear) subjected to the contact force F_c and the reaction of the pulling force F_{pull}.

In order to characterize the shape of the wing in rest conditions, four parameters were chosen: L_x, L_y, L_r and R.

The electrode has been dimensioned by following geometric, microfabrication and mechanical constraints. L_y has been chosen in order to constrain all wings to the internal surface of the nerve. L_x has been estimated so that the maximum stress is lower than polyimide tensile strength, satisfying geometrical and biological constraints. L_r and R have been dimensioned in order to minimize strain energy density during insertion, thus avoiding the rising of high stresses in the surrounding tissue. To correctly size these parameters, theoretical assumptions have been made [19]. FE simulations are performed using a standard commercial software (Ansys ®): simulations are needed to deeply investigate complex secondary non-linear effects arising during insertion and extraction. Hence the insertion of the electrode has been modeled. Half electrode has been analyzed: the material properties are congruent with polyimide mechanical features and the simulation has been performed assuming an isothermal behavior. A 3D 10 node tetrahedral structural solid (SOLID92) has been used to model the whole structure. The mesh has been made by using 2521 tetrahedral-shaped elements. The structure is subjected to lateral compressive forces due to the interference between the electrode and the nerve. Compressive forces were assessed imposing the contact between the lateral sides of the main shaft and the internal wall of the hole. Moreover, in order to expand the theoretical study, lateral contacts dynamic friction (μ_d= 0.1) was assumed [20]. Finally, the maximum bearable insertion force has been determined (Fi = 380 mN).

B. Results

Considering the simulation of the electrode insertion (Fig.3), the stress state along the structure is analyzed while the electrode is pulled with the maximum tolerable insertion force (F_i = 380 mN). Results show that in the weakest area (near the loop with the pulling wire) the stress is 340.97 MPa. Thus, as in ex-vivo experiments the maximum insertion force is about F_i = 10 mN [16], the breakage of the electrode occurs for an insertion force much higher than the maximum one. Since the maximum stress at the sides of wings' slots varies between 197.61 and 233.45 MPa, this means that the frame of the slots does not break and the design succeeded. At this worst condition, maximum x-displacement at holes is about 3 µm: this means that theoretically, during insertion, holes do not collapse.

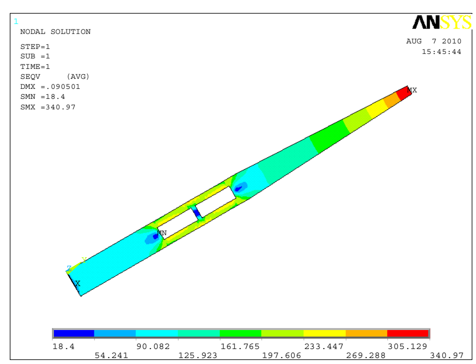

Fig. 3. Von Mises Stresses for the electrode during insertion. Maximum stresses are located on the tip of the electrode, because of the reduction of cross-sectional area. The maximum obtainable force is about 0.38 N: beyond this value, polyimide could break (as its tensile strength is 350 MPa). At this worst condition, maximum x-displacement at holes is about 3 µm: this means that theoretically during insertion holes do not collapse.

The feasibility of SELINE seems to be confirmed by the obtained results of simulations: no failure occurs in the main body of the electrode and at the wings. This electrode represents an innovative solution with several advantages such as: higher selectivity due to its three-dimensional structure and efficient anchorage system.

III. Decoding of ENG Signals

Decoding algorithms represent a critical point of ENG-based hand prosthesis control. In the last decades, several algorithms have been developed to decode ENG signals recorded with cuff electrodes for the closed-loop control of FES systems [4] or to decode afferent ENG signals recorded with LIFEs in animals [21]. However, relatively little work has been done to analyze and decode afferent signals in humans [22-25]. In the next part of this section, some results of the decoding of efferent ENG signals recorded with tfLIFE in one amputee are given.

A. Case study with one amputee – experimental setup

Recently, a multisite flexible version of LIFE (tf-LIFE) has been implanted in the median and ulnar nerves of an amputee's stump in a four-week chronic trial. Detailed information about the surgical procedure and clinical report can be found in [25].

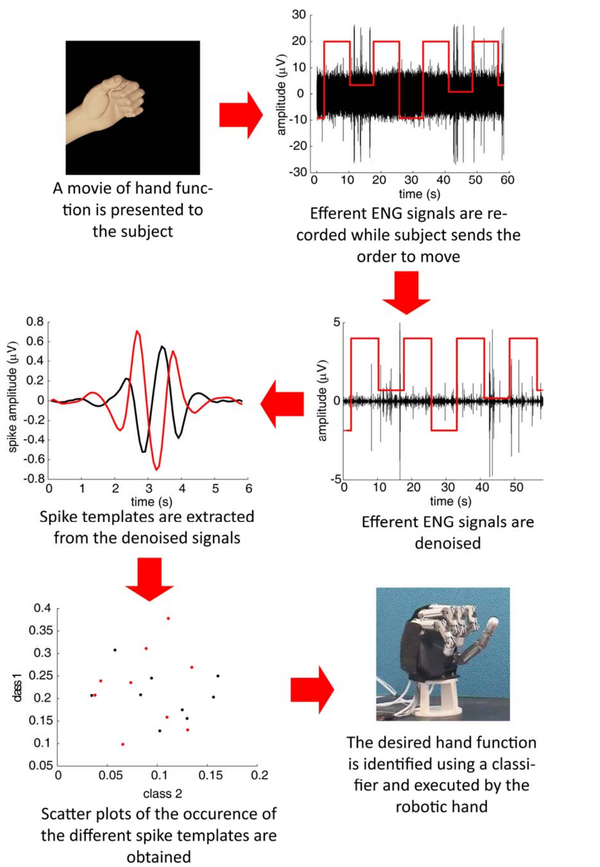

Fig. 4. A scheme of the decoding algorithm proposed for efferent ENG signals recorded with tf-LIFE (modified from [25]).

A scheme of the experiment protocol is shown in Fig.4. Subject was trained to perform three phantom limb movement (e.g., (a) palmar grasp, (b) pinch grasp, (c) flexion of the little finger), without activating stump muscles and using, as a trigger, a picture randomly representing one of the three grasps.

ENG signals from tfLIFEs have been amplified and recorded with a commercial amplifier (Grass QP511 Quad AC; amplification = x10.000; band pass filter = 100–10kHz; sampling frequency = 48 kHz).

Since the ENG signal has a low SNR, a denoising technique based on a translation-invariant wavelet transform decomposition scheme has been implemented [21, 26]. After the denoising, a spike detection and sorting technique based on template matching has been used [21]. Efferent signals have been classified in order to identify the dispatched motor commands. A SVM classifier [27] has been trained to classify feature vector made of the ratios between the number of spikes matching each spike template and the total number of spikes in the epoch [28]. Finally, the information (desired motor command) decoded from the motor LIFE signals was then used to remotely control a dexterous hand prosthesis [28].

B. Case study with one amputee – results

In Fig. 4 an example of the ENG signal recorded with tfLIFE before and after wavelet denoising is shown. Moreover in the same Figure, some examples of detected spikes are given.

The classification accuracy has been calculated as a function of the number of grips taking advantage of the use of a multichannel electrode (see Fig. 5).

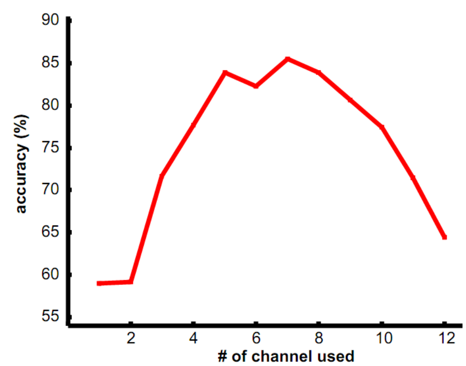

Fig. 5. Classification accuracy of the decoding algorithm proposed for efferent ENG signals recorded with tf-LIFE as a function of the number of channel (modified from [24]).

The accuracy of the classification significantly increased using features extracted from many channels up to a certain limit, ranging from less than 60% with 2 channels to 85% with 7 channels. The use of a larger number of electrodes did not provide a better classification result due to overfitting issues.

Moreover in Table 1 the accuracy obtained using the best combination of tfLIFE channels is given as a function of the number of grips. In case of 1 grip, a rest vs activity classification has been done (e.g., rest vs palmar, rest vs pinch grasp, rest vs flexion of the little finger) obtaining a mean accuracy of 96%. In case of two grips, a hierarchical discrimination has been carried out: (i) rest versus activities and then (ii) selection of grip type. Considering all the possible pairwise combination from the three grips, a mean accuracy of 89.67% has been obtained. Finally, the hierarchical approach has been used for the classification of the three grips (accuracy of 85% as also shown in Fig.5).

TABLE I
CLASSIFICATION ACCURACY AS A FUNCTION OF THE NUMBER OF GRIPS

# of grips	Accuracy (mean ± standard deviation)
1	96 ± 3.61%
2	89.67 ± 2.52 %
3	85 %

IV. DISCUSSION

Neural interfaces have a pivotal role in the control of hybrid bionic systems. Intra-fascicular PNS interfaces seem to be a good compromise between selectivity and invasiveness and they represent an interesting short-term solution. However, despite their great potential advantages, there are several aspects that limit their usage. In this manuscript, some experiments are presented in order to address these issues. Thanks to the results of these experiments, innovative neural interfaces can be developed so that: invasiveness decreases (for example by using smart materials and exploiting biomechanical models); the extraction of information improves (using advanced techniques); a sensory feedback is delivered (increasing the number of contacts in the interface) and a smart positioning is assured, optimizing the desired signal-to-noise-ratio. Extensive experiments will be carried out in the future to verify the potential of this approach

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