Medical Engineering & Physics 33 (2011) 1254–1261

Contents lists available at ScienceDirect

Medical Engineering & Physics

journal homepage: www.elsevier.com/locate/medengphy

Modelization of a self-opening peripheral neural interface: A feasibility study

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ARTICLE INFO

Article history:
Received 7 September 2010
Received in revised form 6 April 2011
Accepted 5 June 2011

Keywords:
Neural interface
Peripheral nerve
Insertion procedure
Structural and FE analysis
Asymmetric kinematics

ABSTRACT

In this paper a self-opening intrafascicular neural interface (SELINE) has been modeled using both a theoretical approach and a Finite Element (FE) analysis. This innovative self opening interface has several potential advantages such as: higher selectivity due to its three-dimensional structure and efficient anchorage system. Mechanical, structural and micro-technological issues have been considered to obtain an effective design of the electrode, as a feasibility study of the self-opening approach. A simple framework has been provided to model the insertion and partial retraction into peripheral nerves, resulting in the opening of wings.

This integrated approach results in a rational procedure to optimize kinematics, geometry, and structural properties of peripheral interfaces. The design and feasibility study carried out in this work can potentially assure a correct behavior and dimensioning of the neural interface: in this way anomalous breakage should be avoided while mechanical and geometrical biocompatibility should increase.

1. Introduction

Neuroprosthetic systems are devices that could significantly improve the quality of life of impaired patients. The key issue of these devices is the development of an efficient and safe multichannel neural electrode that captures bioelectrical activity or applies current into the living neural tissue [1]. Electrodes that interface with the peripheral nervous system (PNS) can be classified either for their selectivity (ability of a neural interface to interact with a small groups of axons within a nerve fascicle) and their invasiveness (potential damage due to the insertion of the electrode inside the nerve).

Among the others, flexible intra-fascicular electrodes showed a good compromise between selectivity and invasiveness. The promising TIME [2] and tf-LIFE neural interfaces [3] belong to this group: they are polyimide-based electrodes implanted respectively transversally and longitudinally into the nerve. They are made of a looped polyimide thin film with electrical contacts on top: these electrodes could be implanted within nerve fascicles, by pushing a needle through the perineurium and pulling the electrode, until the active zone is centered in the fascicle [4]. The functionality and biocompatibility of these electrodes were tested in acute experiments with human volunteer [5,6] and in animal models [2,4]. Despite the great potential advantages, when subject's movements occur, intrafascicular electrodes can slip inside the nerve, changing the position of active sites as suggested by Goodall et al. [7]. Lastly, as the recorded signal amplitude falls off rapidly when the distance between the electrode and fibers increases, the spike becomes broader and it is harder to discriminate from the background activity and noise.

In order to overcome these problems, during the last years innovative electrodes have been proposed such as self-opening interfaces for CNS [8] and PNS [8]: they behave as an anchorage system reducing active sites shifts and moving them away from the most damaged area. The aim of this study was to propose an easy and reversible strategy to obtain a self-opening neural interface with a high degree of flexibility and increased degrees of freedom.

This work addresses the feasibility of a self-opening intrafascicular neural interface (SELINE) considering micro-technological and structural issues [9], theoretical models, and available experimental data of penetrating pressures of needles [10] and insertion forces of electrodes [11] inside porcine peripheral nerves. The interface has been obtained by mixing the advantages of the pre-existing solutions [8] such as the reversible insertion–extraction in one case and the presence of multiple active sites on lateral barbs in the other one. The electrode has a main body and lateral wings with active sites on both of them (Fig. 1). The proposed solution has several potential advantages such as: potential higher selectivity, as the wings of the electrode can move within fascicles exploiting the three-dimensionality of the structure; potential lower fibrotic encapsulation and lower electrical insulation around wings, as their size is smaller than the main body's one [12] and they drift away

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doi:10.1016/j.medengphy.2011.06.001

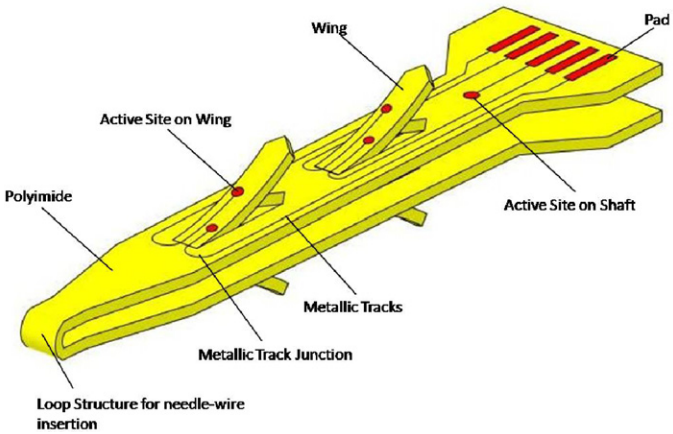

Fig. 1. SELINE, lateral view: looped polyimide structure composed of a main body with four lateral wings. There are two active sites on each wing and one active site on the main body, for each side (10 active sites).

during the opening from the most damaged area of insertion [2]; anchorage to the tissue due to the presence of wings [9].

2. Materials and methods

2.1. SELINE: layout and opening strategy

The proposed electrode is an evolution of TIMEs and tf-LIFEs. As those electrodes, SELINE's main structure is made of thin films of polyimide which is a lightweight, flexible, biocompatible polymer: it could be easily used in microfabrication processes and it has been widely employed even for neural interfaces [1,13,14] showing promising results in terms of biocompatibility [4,15,16]. Long term behavior of polyimide in body tissue is still unknown: however, in vitro evaluations over the course of 20 months showed good stability in PBS and no changes in the chemical structure at body temperature have been observed [17]. In addition to the main shaft, SELINE has two lateral wings for each side. The active sites will be positioned both on the main shaft and on the lateral wings as indicated in Fig. 1.

The working principle of SELINE is based on two main phases (Fig. 2): 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 (Fig. 3): a longitudinal implantation is not recommended since the device is actuated by a pulling force parallel to the direction of insertion, thus it would be technically difficult to pull wires to open wings. The system can be manually actuated by the surgeon or by an automated insertion tool. In order to reduce the chronic damage to the nerve, the device can be implanted transversally so that wings open perpendicularly to the longitudinal axis of the nerve (Fig. 4a): in this way the longitudinal drift is minimized and the electrode can move between fibers during its positioning. If the wings open parallel to the longitudinal axis of the nerve (Fig. 4b), invasiveness rises since fibers are transected during the insertion.

The geometry of the lateral wings has been designed to behave asymmetrically with respect to the insertion and the partial extraction needed for their outspreading into the tissue. 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 modeled as linked by a revolute joint. For this reason, all wings begin straight and parallel to the main body and end with a constant curvature.

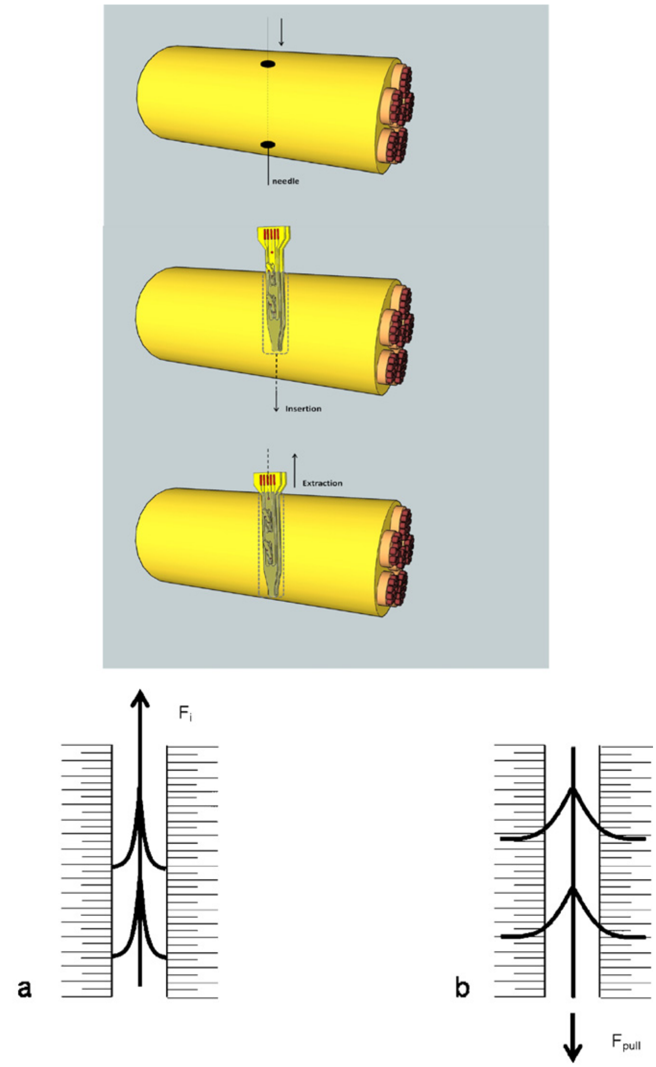

Fig. 2. The SELINE working principle: piercing of nerve; insertion of electrode inside the hole previously made by the needle; partial extraction of the electrode that allows the opening of the wings (the area inside the dashed rectangle represents the inner section of the nerve). (a) Zoom on phase of insertion (F_i corresponds to the insertion force); (b) zoom on phase of extraction (F_{pull} corresponds to the pulling force). The system can be manually actuated by the surgeon or by an automated insertion tool.

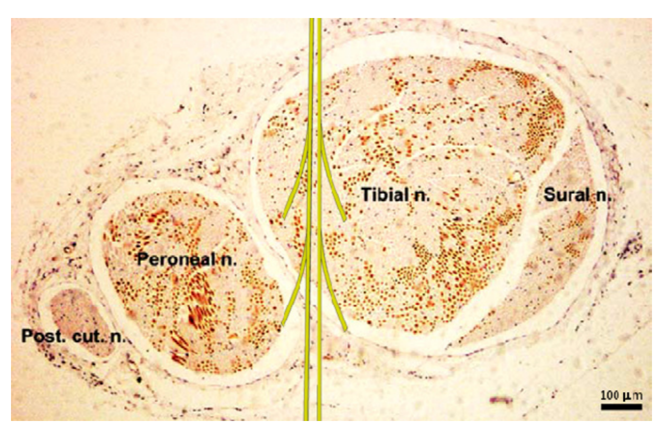

Fig. 3. Transversal implantation of the SELINE in a rat nerve section (nerve section was taken from Badia et al. [32]).