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INTERACTIONS BETWEEN SELF PENETRATING NEURAL INTERFACES AND PERIPHERAL NERVES

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Abstract: This work provides a simple framework to optimize the design of self penetrating neural interfaces. First, an assessment of interactions between electrodes and peripheral nerves is provided and related to the instantaneous elasticity of the tissue. Then, the elastic instability of electrodes is considered, because it is the main cause of failure of implants. The connection between the previous two sections, integrated with an assessment of a safety coefficient for in-vivo implants, allows to predict some important parameters of a reliable electrode: its maximum slenderness ratio (SR) and the minimum Young modulus of its main shaft.

1 INTRODUCTION

The use of neural interfaces with the peripheral nervous tissue (PNT) allows to develop neuroprosthetic devices and hybrid bionic systems [1]. These devices can create an intimate and selective contact with the PNT, recording and stimulating from different fascicles into the nerves to restore the efferent and afferent neural pathways in an effective way. Several research groups started investigating the possibility of develop neural interfaces characterized by self penetrating electrodes vertically or longitudinally inserted into the tissue [2,3]. This approach seems to be promising because a quite low invasiveness is combined with a quite good selectivity. Unfortunately, the high slenderness ratio of these structure can make difficult their insertion into the PNT: the success of this task is strongly dependent from the biomechanical properties of the tissue, the geometry and the mechanical characteristics of the neural interface. Indeed, while a stiff electrode is necessary to enter the tissue, it could increase both the invasiveness and the probability of provoking damages into the nerve. For this reason, the design of effective and low-invasive self penetrating interfaces is a crucial task which requires an integrate design accounting for the PNT biomechanics influencing the interactions with the electrode structures. In the first part of this work a macroscopic approach is used to study the interactions between peripheral nerves and structure with high slenderness ratio, in particular self penetrating electrodes. Simple mathematical models are used to quantify these interactions as explicitly depending from the tissue mechanics [4].

These models are able to account for experimental studies [5,6]. In the second part of this work, the previously achieved framework is used to improve and integrate the design of self penetrating [7] (e.g. needle-like and shaft) neural interfaces as far as the choice of structural materials, giving elements to optimize the geometry and to maximize the insertion ability.

2 METHODS

2.1 Simple assessment of superficial interactions between electrodes and peripheral nerves

Interactions between electrodes and external surface of the peripheral nerves are quite complex. In this work the attention will be focused only on the initial phase of contact between the electrode tip and the tissue. Moreover, the velocity of the local dimpling of the tissue under the electrode tip is assumed to have a characteristic time considerably shorter than the relaxation time of the tissue: this allows to neglect viscoelastic effects. With the previous assumptions, the tip force arising during the initial phase can be generally modelled using Equation (1):

$$F(z) = f(\alpha)M(E,z)\wp[n,z,g(\rho)] \tag{1}$$

where z is the dimpling of the tissue (which equals the electrode tip displacement), $f(\alpha)$ is a function of the half opening angle of the tip, $M(E,z)$ is a function of the Young modulus of nerve and z, $\wp[n,z,g(\rho)]$ is a polynomial of n degree in z and $g(\rho)$, finally $g(\rho)$ is a function the radius of curvature of the tip. To simplify the writing of Equation (1) some assumptions can be reasonably done. First, $f(\alpha)$ is constant for a selected type of electrode. Then, in spite of $M(E,z)$ could be non linear with z [4], it can be expanded in Taylor series around the point $z=0$ leading to $M(E,z) = E + o(E,z)$. Finally, $\wp[n,z,g(\rho)] = \wp[2,z,g(\rho)] = z^2 + k_2 z$ [8], where $k_2 \in \Re$ is a constant accounting for the real geometry. As a consequence, Equation (1) can be approximated with:

$$F(z) \approx k_1 E(z^2 + k_2 z) \tag{1.2}$$

Equation (1.2) models the first phase of interaction as an indentation, and can assess the instantaneous elasticity of the external layer of peripheral nerves starting from experimental data [5,6].

2.2 Basic elements of rational design of self -penetrating electrodes

Self-penetrating electrodes has to bear compressive forces arising in dimpling of external layer of nerves. Since the main macroscopic cause of implantation failure is elastic instability, the investigation of buckling of needle-like and shaft structures is crucial to their effective design. To this aim, since both the approaching velocity is low (for careful implantations ~ several mm/min), and the mass of the electrode is small, inertial effects can be neglected and the analysis can be performed in the quasi-static buckling framework. Moreover, since the main shaft is considerably longer than the tip high, the analysis will be focused on the first mode of buckling of the global structure. For slender electrodes the first buckling load can be generally written as [7]:

$$P_{cr} = \frac{\psi^2 E_n J}{(\omega L)^2} \tag{2}$$

where J is the minimum second area moment of the cross section, E_n is the Young modulus of the electrode material, ψ is the Legendre elliptic integral of the first kind, L the length of electrode, and ω the end-condition constant. In this case, since also small deflections result in a failure of implantation we have $\psi \to \pi$ and $\omega \to 0.7 \div 2$, depending from the boundary conditions (pin-fixed and free-fixed). In particular, introducing in Equation (2) the slenderness ratios $S_r = L/r$ for a circular shaft, and $S_h = L/h$ for a prismatic one (where h is the electrode depth), and dividing P_{cr} for the cross sectional area of the main shaft, it follows:

$$\sigma_{cr} = \frac{\pi^2 E_n}{\gamma_r S_r^2} \tag{2.1.1}$$

$$\sigma_{cr} = \frac{\pi^2 E_n}{\gamma_h S_h^2} \tag{2.1.2}$$

where Equations (2.1.1) and (2.1.2) holds respectively for circular and prismatic sections, and γ_r=1.96÷16 and γ_h=5.88÷48 respectively for pin-fixed and free-fixed boundary conditions. Therefore, the structural condition for which the main structure can bear the maximum dimpling force is:

$$P_{cr} \geq SF_{global} F(z_0) \tag{3}$$

where SF_{global} is the global safety factor that will be assessed in the next paragraph, and z_0 is the dimpling of the nerve when the piercing of the external layer happens. From Equations (1.2), (2.1), (2.1.1-2) and (3), an approximation of the maximum slenderness ratio for low z_0 can be written as:

$$S_r(m, k_2, k_1, z_0, X, SF_{global}, A, E, E_n) \approx \pi \frac{g(m, k_2, z_0)}{h\left(\frac{2m+1}{2}, k_2\right)} \sqrt{\frac{E_n A}{X SF_{global} k_1 E z_0}} \tag{4}$$

where X stands for γ_r or γ_h respectively for circular or shaft electrodes, $g(m,k_2,z_0)$ is a polynomial of m degree in k_2 and z_0, and $h\left(\frac{2m+1}{2},k_2\right)$ is a polynomial in k_2. The more m increases, the more S_r approximates the exact value of the minimum slenderness ratio for any value of local dimpling. As illustration of the case m=5, the values of $\wp(m,k_2,z_0)$ are listed and plotted below:

$$\begin{aligned} &g(5,k_2,z_0) = 63z_0^5 - 70k_2z_0^4 + 80k_2^2z_0^3 - 96k_2^3z_0^2 + 128k_2^4z_0 - 256k_2^5 \\ &h(11/2,k_2) = 256k_2^{11/2} \end{aligned} \tag{5.1}$$

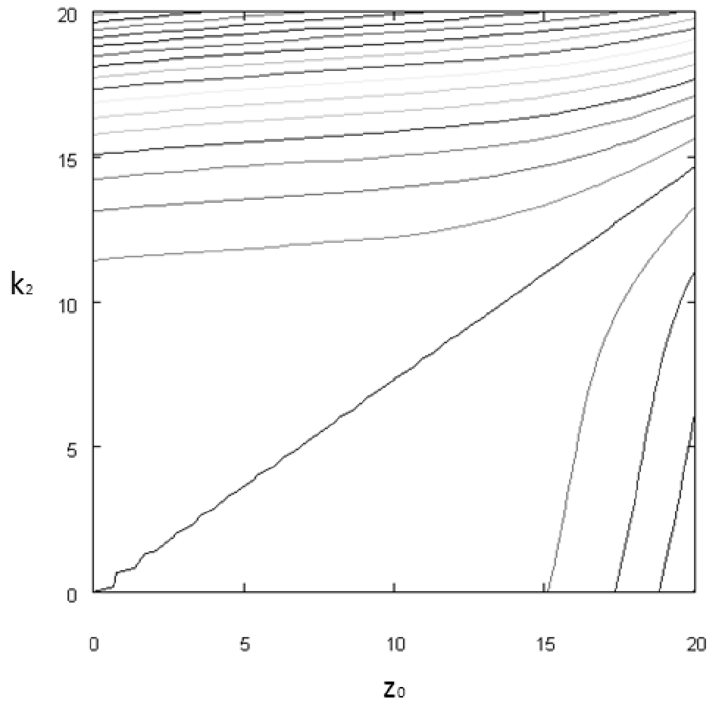

Figure 1: Contour plot of *g(5,k₂,z₀)*

2.3 Safety coefficient for in vivo insertions of self- penetrating electrodes

Self penetrating electrodes have to be implanted in living peripheral nerves. As a consequence, at least in this final phase, the implantation has to assure good performances and reliability in time without ethically unacceptable complications (sources of pain, need of several surgical operations, etc.). Moreover, the surgical procedure of insertion in living peripheral nerves has to be totally safe for the patients, but also without any risk of damages for the electrodes. Unfortunately, from a purely mechanical point of view, the in vivo insertion procedure is less studied and all possible causes of overloads are difficult to assess. Moreover, the range of mechanical stresses on the electrodes can largely change with the surgical set up. All these issues lead to the use of safety coefficients (SF) to assure the success of the implant without any damages of the electrodes in uncertain conditions. To approximate this coefficient some different factors have to be considered: the material properties (e.g. mechanical properties of the main shaft of the electrode), the knowledge of the loading-overloading conditions, the knowledge of the surgical environment. A possible way to assess the SF is to use the Norton's approach [9], where all the previous factors are involved.

Table 1: Coefficient of safety [9] as function of the material properties, loading conditions and working environment.

Coefficient of safety	SF1 - Material properties (from tests)	SF2 - Loading conditions (knowledge)	SF3 - Working environment
1.3	Well known / characteristic	Verified by testing	Same as material testing conditions
2	Well approximated	Well approximated	Checked, room temperature
3	Fairly approximated	Fairly approximated	Slightly demanding
5+	Roughly approximated	Roughly approximated	Extremely demanding

In our case self penetrating electrodes derive from well-known microtechnological processes, with conventional material, then the coefficient SF1, due to the material properties can be set to 1.3 (see Table 1). On the contrary, the surgical environment is in general unknown. Even if, with the use of special supports the stability of the insertion can be improved, nevertheless the contact conditions between the nerve and the surrounding environment are still quite indeterminate. Furthermore, the pushing forces given by the surgeon during a manual insertion are difficult to achieve and liable to large changes related to its specific ability and experience. As a consequence, for SF2 (considering the knowledge of the loading conditions) the value of 5+ can be chosen. Finally, at least for preclinical trials, the working environment is directly the body of a human being, and every damage to the residual nerve stump can further compromise the condition of the patient. Then, as well as ethically unacceptable, every damage can have a legal and financial impact. So, also for SF3 the value of 5+ can be set. Following the standard approach the global safety coefficient can be obtained using Equation (6):

$$SF = \max\{SF1, SF2, SF3\} \tag{6}$$

Therefore in our case *SF=5+* (that is, 5 or larger values).

3 RESULTS

The previous simple approach helps to rationalize the design of self penetrating electrodes: in this paragraph will be analyzed both the choice of the minimum Young's modulus of the electrode main shaft, once given its slenderness ratio, and the assessment of the maximum slenderness ratio for a given construction material. Figure (2) shows how the minimum Young modulus depends on the maximum slenderness ratio through experimental values of piercing forces. Indeed, σ_{cr} can be defined starting from both Equations (3) and (1.2). As a consequence, it is related to both the peripheral nerve biomechanics and the geometry of the electrode. Therefore, if technical constraints fix the electrode geometry (and then SR), the main shaft material can be chosen in order to ensure the bearing of the maximum dimpling force. In this way, the failure of the implantation procedure can be avoided.

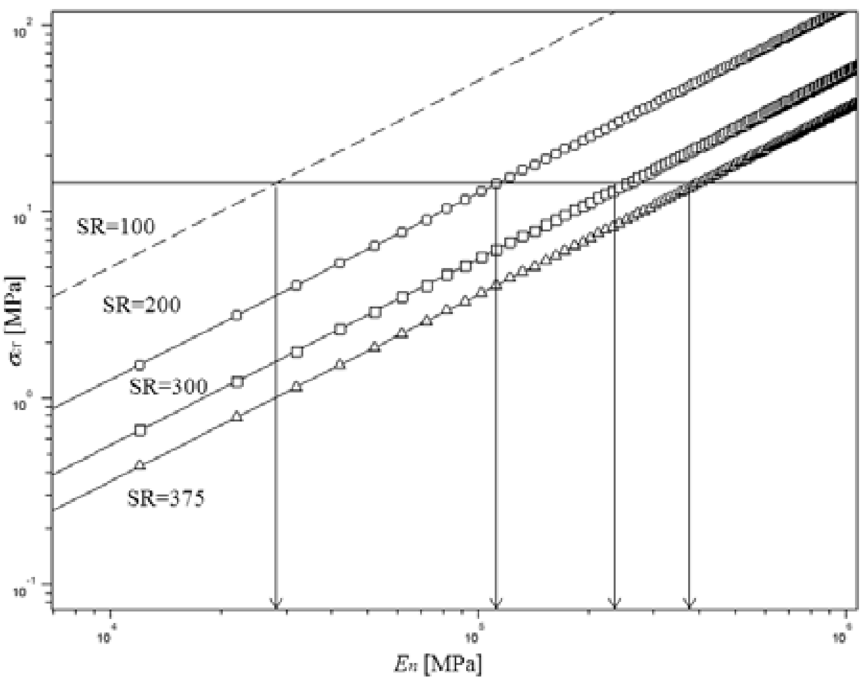

Figure 2: This log-log plot shows the usefulness of biomechanical inputs, deriving form the interaction phase (σ_{cr}), to rationally assess the minimum Young modulus providing a safe utilization with a given slenderness ratio. Figure (2) illustrates the case of electrodes with a circular cross sectional area and pin-fixed boundary conditions.

On the other hand, if biocompatibility issues constrain the choice of the material of electrodes, their SR can be chosen in order to avoid implantation failures. To this aim, Figure

(3) shows as starting from the Young modulus of a set material the maximum slenderness ratio can be found. Also in this case, the biomechanical input about the expected maximum forces (or dimpling) is crucial to univocally assess σ_{cr} and then the intersection points of interest. Both Figures (2) and (3) illustrate the procedure of choice for electrodes with circular section and pin-fixed boundary conditions.

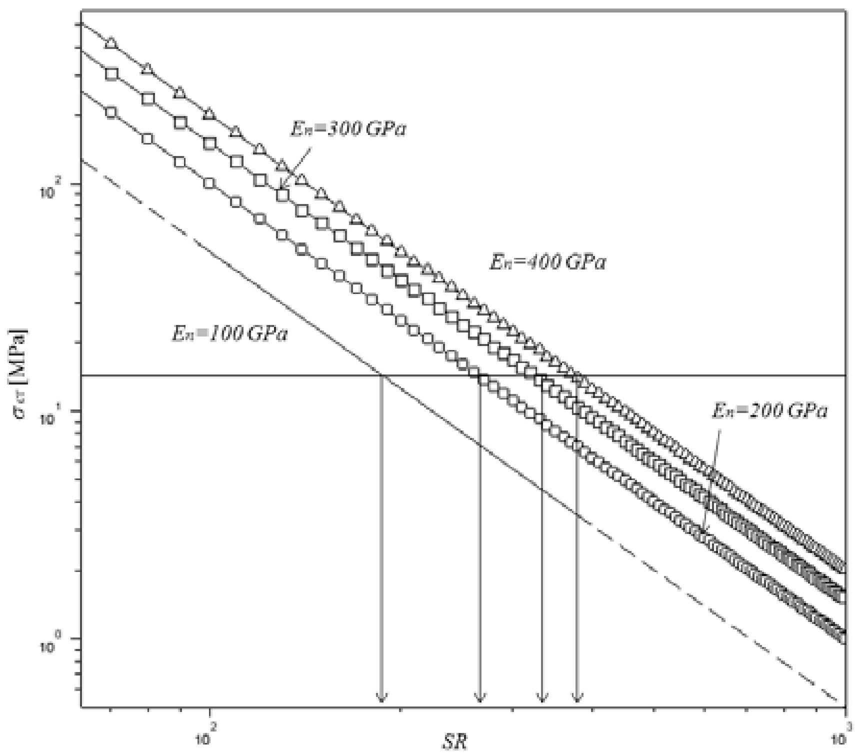

Figure 3: This log-log plot illustrates the importance of the biomechanical assessment of the interaction phase (σ_{cr}) to rationally found the maximum slenderness ratio providing a safe implant with a given material. Figure (3) shows how to choose parameters for electrodes with a circular cross sectional area and pin-fixed boundary conditions.

4 DISCUSSION

4.1 From biomechanics to design of self penetrating electrodes: a possible path for safe implantations

Several neural interfaces have been developed to control neuroprostheses and hybrid bionic systems . Among them, self penetrating electrodes seems to be promising because they represent an interesting trade-off between the needs for high selectivity and reduced invasiveness. However, no particular attention is usually paid to design their structures accounting for the biomechanical properties of the system to be interfaced. Furthermore, the implantation of electrodes in the peripheral nerves is a complex surgical task: a great experience in insertion is required to avoid tissue damages (which could result in pain) and electrode breakage. The sum of these factors results in failure of implantations, also with already tested and commercialized products, in significant increases of surgical times and number of attempts, risks of damages for nerves and waste of expensive electrodes. Therefore, to rationally design self penetrating electrodes the knowledge of the surrounding environment is necessary. Indeed, the choice of structural materials, the geometry, and also the procedure of implantation depends on the magnitude of the reciprocal interactions between tissue and electrode. To quantify these forces appears to be "strategic" to provide useful information about the design process. To this aim, in section (2.1) a simple framework to assess these interactions was provided. However, it is an approximation and the more it is valid, the more the characteristic time of tissue local reaction are shorter than the relaxation one. In other words, this approximated framework only consider the local instantaneous elastic response of peripheral nerves. This is, of course, a limitation but for many real surgical procedures it provides a suitable approximation. Moreover, a problem to be solved in electrode design is to balance the minimum stiffness able to enter the tissue and minimize the internal damages. A possible suitable solution is to minimize the stiffness considering all different designs having the first buckling load greater than a given force accounting for the maximum piercing force and the right safety factor. To this aim in section (2.2) the basic elements leading to a rational design of a self penetrating interface were provided, and in section (2.3) an assessment of a possible safety factor was presented. The synergistic use of these two parts allows to assess some useful design parameters of electrodes, as the SR and the Young modulus. This approach seems to be effective and is able to predict the outcome of real trials of surgical implantation [6].

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