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Exploring selective neural electrical stimulation for upper limb function restoration

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Abstract

This article introduces a new approach of selective neural electrical stimulation of the upper limb nerves. Median and radial nerves of individuals with tetraplegia are stimulated via a multipolar cuff electrode to elicit movements of wrist and hand in acute conditions during a surgical intervention. Various configurations corresponding to various combinations of a 12-poles cuff electrode contacts are tested. Video recording and electromyographic (EMG) signals recorded via sterile surface electrodes are used to evaluate the selectivity of each stimulation configuration in terms of activated muscles. In this abstract we introduce the protocol and preliminary results will be presented during the conference.

Key Words: electrical stimulation, neural selectivity, grasping function restoration

Prevalence of complete spinal cord injury (SCI), is estimated at 2 million people worldwide. SCI consequences are often devastating for patients. For trauma at cervical levels (tetraplegia), among many dysfunctions, one of the most impressive is the loss of use of four limbs. In complete SCI, sub-lesional peripheral nervous system (PNS), does not receive anymore commands from the central nervous system (CNS) because communication is impeded. Although some assistive devices allow them to palliate basic functions, recovery of grasp movements is still seen as a priority for these patients to regain autonomy. To restore hand movements, electrical stimulation remains almost the only solution. Indeed, applying an electrical current sufficient to excite cells (neurons or myocytes) allows the initiation of action potentials responsible for muscle contraction. Moving paralyzed limbs after such trauma becomes possible. Implanted systems, such as the Freehand System (Neurocontrol, USA) or the FESMate (Japan) use epimysial or intramuscular electrodes to activate directly muscles to restore movements of the upper limb, while in the non-implanted systems, such as the Bionic Glove (Canada) or the Handmaster (Israel), the stimulation is delivered through surface electrodes. In implanted systems, activation of each muscle requires the use of at least one electrode, complexity of the device and number of foreign bodies may be high, up to 12 channels for the Freehand for instance. Risks of failure, externalization of foreign bodies and infections spreading along wires are further increased. Moreover, the needed surgery involves multiple procedures and takes considerable time and care to be successfully achieved. In one study, it has been necessary to re-operate on four subjects over nine to make adjustments of the system while three other surgeries have been required to replace or remove broken electrodes or exchange an implant/receiver. However, patients become more independent of daily living activities, thus limiting the needs of a human aid. Although these devices have emerged as one of the most promising techniques for the restoration of hand function for SCI or stroke subjects, their use is still very limited in terms of acceptability, efficacy and trade-off between benefit / risk. Indeed, the higher the patient's lesional level is, the larger the number of muscles to be stimulated to achieve gripping movements is. A method which allows to activate more than one muscle by electrode becomes relevant. Another approach has been used for decades; functional surgery, which is mainly based on muscle-tendon transfers and opened a wide field of improvement of the functional potential of
tетраплегиков\textsuperscript{11,12}. В этих процедурах, дистальная часть функционального тендиномускульного комплекса отсоединяется от его естественного вставочного места и затем фиксируется на нон-функциональной прилегающей к нему тендине в целях восстановления исходной функции нон функциональной тендиномускульной пары. Например, перенос бицепса предплечья на трехцепочечную функциональную тендиномускульную пару может позволить восстановить активный разгибатель локтя, резidual elbow flexion being provided by the other flexors (brachialis and brachioradialis). Однако, этот тип подхода требует присутствия достаточно большого числа мышц в естественной контролируемой зоне, которое, как правило, недоступно. Кроме того, послеоперационная реабилитация не всегда позволяет восстановить доброта последней попытки восстановления\textsuperscript{13}. Китх и др.\textsuperscript{7} разработали эпимизиальный FES и тендиномускульный трансплантат в венце, но при этом их процедура была основана на эпимизиальных электродах, обеспечивающих распространение по системе всех используемых мышц. Поэтому, если мы объединим тендиномускульный трансплантат и эпимизиальный FES, пациенты с нон-функциональными движениями ко времени реабилитации, возможно, могут восстановить активный локтевой разгибатель, а также еще одну функцию мышц предплечья и плеча. Введение в активный локтевой разгибатель и движения плеча такого электрода, как электрод, может быть реализовано в принципе в виде множества электродов. Электроды, расположенные на медиальной и/или радиальной нервных ветвях, вблизи локтевого сустава. Эти 12 контактов позволяют независимо активировать 12 контактов. Каждый активный электрод (т.е. участвующий в электростимуляции) может служить катодом или анодом. Электросхема вычисления, реализованный на программном обеспечении (Lunatum разработано на MXM) и управляет электрическим стимулятором R&STIM 12 (Alexander, AXONIC и INRIA-DEMAR). Электроды были разработаны для оптимального положения на медиальной и радиальной нервных ветвях.

Электростимулятор

Одновременно с этой информацией, мы получаем информацию о том, что при проведении электрофореза в области отделов, включая область медиальной и/или радиальной нервных ветвей, возможно, могут быть использованы двенадцать электродов. Программа Lunatum MXM-AXONIC и INRIA-DEMAR разработаны для управления 12-ю электродами, адресуемыми одновременно. Всё это позволяет использовать 3D-iếuуляцию, которая позволяет независимо активировать 12 контактов. Синхронизация позволяет изменять частоту, а электрофорез позволяет изменять частоту, а электрофорез позволяет использовать эти параметры. Каждый активный электрод (т.е. имплантированный в электрод) может быть использован в качестве катода или анода. R&STIM 12 (Axonic, AXONIC и INRIA-DEMAR) разработаны на основе программного обеспечения Lunatum MXM-AXONIC, которая позволяет использовать различные конфигурации стимуляции. Основные характеристики R&STIM 12 следующие:

- Максимальный ток: I_{max} = 5mA,
- Текущее решение: \Delta I = 1.3 \mu A
- Временная разрешающая способность: \Delta t = 1 \mu s
- Максимальная ширина импульса: T_{max} = 2 ms.
Selective configuration design

After a simulation study, the more interesting combinations of poles from a selectivity performance point of view, were determined leading to up to 40 configurations to be tested on each nerve. When relevant, the same configurations of stimulation are reproduced on the 3 rings to investigate possible fascicular re-organization within the few millimeters which separate each ring (see Table 1).

Protocol and methodology

Cuff electrodes are placed around the median and/or radial nerves. Nerves are stimulated with increasing intensity. The protocol consists of the activation of one or more poles of the electrode. The stimulation pulse is biphasic, balanced but asymmetric, followed by a passive discharge to guaranty charge balance. Pulse width is fixed and intensity is modulated (up to 2.4 mA). For each configuration and intensity, a tetanic stimulus is induced for 2 seconds. For the first patient pulse width was 500 µs and stimulation frequency 25 Hz. Cuff electrode did not fit perfectly, shorter pulse widths did not produced any movements. Surface EMG electrodes are placed upon the ERCL or ERCB, EDP, EDS, FDS, FDS and FPL muscles to record EMG signals. This allows us to evaluate the selectivity capacity of our configurations. Nevertheless, because the radial and median nerves activate more muscles than the recorded ones, in particular deep muscles contraction may not be detected, a synchronized video recording with the stimulator is performed. The video analysis is used to assess the functional selectivity capacity of our different stimulation configurations based on hand and wrist movements analysis.

Judgment criteria

The primary judgment criterion is based on the quantification of the strength and the selectivity of muscle recruitment induced by the electrical stimulation of the median and/or radial nerves. The strength of recruitment and the selectivity are quantified for ECRL or ERCB, EDC, EPL, FPL, FDS and FDP muscles using electromyography.

For a given configuration C and intensity I, a signal which reflects muscle activation is obtained for each muscle. Amplitudes of compound muscle action potentials (CMAP) are measured from the reference to the highest magnitude of the M-wave negative voltage. Then, for each configuration, those signals are normalized to the maximal amplitude of the CMAPs. We note the normalized signal CMAP-EMGCI. CMAP-EMGCI below 0.05 are considered equal to 0. Intensities of stimulation corresponding to 20, 50 and 100% of EMGmax are determined for each configuration and for each of the 6 muscles. For each configuration, up to 18 series (6 muscles and 3 levels of activation) can be determined. For each series, an index of selectivity SI(I)% is defined as the ratio between the normalized signal CMAP-EMGCI of the m muscle whose nerve was stimulated with the optimal intensity I causing an activation of n6(µi) and the sum of normalized signal CMAP-EMGCI(µi) of the 6 muscles:

$$SI(I)_m\% = \frac{\mu_i}{\sum_{j=1}^{6} \mu_j}$$

SI(I)% corresponds to the selectivity index. SI(I)% is between 0 et 1, where 0 indicates no selectivity and 1 indicates that only the muscle m is activated. A selectivity index curve is plotted, from SI(I)%s. The surgeon also evaluates muscle strength produced by the electrical stimulation (MRC scale). Finally, we have developed a software to track hand movements in the recorded video in order to qualify the motion range and type.

Results

We included 2 patients. Selective activation of the flexor carpi radii and palmaris longus muscles was possible for the patient 1 from 600 µA with grade 3 on the MRC scale. Preliminary quantitative results will be presented at the 2016 IFESS Conference to be held June 7 – 9, 2016 at La Grande Motte, Montpellier, France.

Discussion

Currently, there is no more commercial implanted stimulation neuroprosthesis allowing to restore hand movements. If the results of this study will be positive, it could lead us to design a new neuroprosthesis based

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Table 1. - Examples of stimulation configurations

<table>
<thead>
<tr>
<th>Name of the configuration - Number of Pole</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
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<tbody>
<tr>
<td>Ring Longitudinal</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>-3</td>
<td>-3</td>
<td>-3</td>
<td>-3</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Tripolaire TransverseA</td>
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<td>0</td>
<td>0</td>
<td>6</td>
<td>-12</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Tripolaire TransverseB</td>
<td>6</td>
<td>-12</td>
<td>6</td>
<td>0</td>
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<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td>-12</td>
<td>6</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>1 Cathode Ring Anode</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>-12</td>
<td>0</td>
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<td>0</td>
<td>6</td>
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<td>0</td>
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<td>0</td>
<td>6</td>
<td>0</td>
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<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>-12</td>
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<td>6</td>
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<td>0</td>
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</table>
on nerve stimulation for grasp movements in high tetraplegic subjects recovery. Even if the results can not be conclusive to how well a cuff electrode will work in chronic condition to selectively activate a high number of muscle groups because in chronic condition the electrode-nerve interface will have different properties due to impedance changes for example, we expect that our number of contact and modification of stimulation parameters will selectively activate the same muscle groups. Thus, a device using such technology would, in combination with tendon transfer surgery, be materially lighter than those which existed, would require less time for its implementation, and less power for its operation. An interface for piloting the stimulation is studied in parallel.\textsuperscript{15}

**Contributions**

WT: protocol design, experimental setup implementation, data acquisition; DG: coordination of the technical and theoretical aspects of the study. Data acquisition and processing expertise; DA: technical expertise in stimulator design and programming; BC: neurosurgery and patient follow up; AG: patient recruitment, muscle mapping and patient follow up; CF: study design, expertise in FES applied to SCI rehabilitation; PM: stimulator design and stimulation pattern software programming; CP: experimental setup and data analysis support; OR: stimulation patterns definition and data processing; JT: neurosurgery and patient follow up; CA: coordination of the experimental aspects of the study. Protocol and setup design expertise.

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**Conflict of Interest**

The authors declare no potential conflict of interests.

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