Pneumatic device for somatosensorial and pain stimulation compatible with magnetic functional resonance (fMRI) and Magnetoencephalography (MEG) DISNESO-02

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Abstract:
A prototype has been developed to study the somatosensory activation using functional magnetic resonance imaging technologies (fMRI). The complete system is based on two pneumatic pressure valves that activate an applicator which is totally compatible with the magnetic resonance and magnetoencephalography, and is controlled by programmable software. The system provides stimulation on the tender points area with accuracy of 0.8cm², and it allows to determine the pain threshold in persons with different neuropathologies related with pain processes. It should be useful in the characterization and distinction of somatosensory, motor and pain areas.

1. Introduction
The location and characterization of the cerebral areas involved in the process of pain and their differentiation from other somatosensorial or motive stimuli is possible by means of the functional technologies for cerebral image (fMRI, RM-MEG), improving thus the knowledge and process of the information for some pathologies (Fibromyalgia, Headaches etc). Though some of the most recent studies use the CO2 laser for the stimulation (1), our study is focused on the mechanoreceptors and nociceptors activation (2). Till now the design of compatible stimulation equipments with these technologies has a limited characterization. Recent researches (2005) use pneumatic somatosensorial stimulators (3), with the aim of registering evoked motor potentials. There are also people who, by means of magnetic resonance, evaluate the response to Fibromialgia patients by comparing them with controls (R.H. Gracely (2002)) (4). It is necessary to design new programmable devices based on pneumatic systems fully compatible with functional image technologies. This will allow us to characterize with a major precision (in the time domain as well as space domain) the eloquent cerebral areas responsible for these processes by means of programming pulses compatible with the sequences of captation of fMRI (5).

2. Material and methods.
This device is a complete system. All components have been designed, developed and assembled by the authors of this study in the GBT group. A first prototype has been developed for the cerebral processing of the pain which allows for somatosensory stimulation by means of gradients of pneumatic pressures. The materials used must be diamagnetic in order to make this device compatible with fRM and MEG. This is the reason why materials are non conductive plastic polymers, which are suitable to avoid the influence of magnetic fields.

The stimulation system consists of three modules:

1. A programmable software unit located in the control room of the RM or MEG, which allows the control of the thresholds of pain and the sequences of pulses. This software offers the possibility of making two different stimulations. First, we have the experimental stimulation, which consists in defining a threshold of pressure between 0 % and 100 %, defining also the number of pulses which we want to apply, as well as the maximum and minimum time intervals between consecutive pulses. The second stimulation modality is called “thresholds detection”, which consists in increasing the pressure slowly, until the subject notices pain. By using this modality we can characterize the pain threshold for each of the subjects.

2. The second module is a mechanical subsystem able to generate the required pressure and is located in the machine room of the magnetic resonance. It consists of a compressor and two control valves.

3. The third module is a system that applies the pressure and it is placed inside the room for RM or MEG, in physical contact with the patient.
A 3 Teslas GE RM's system has been used for this application. The system is located at the premises of the Fundación Cien in the Queen Sofia Hospital devoted to Alzheimer's study and university research. It consists of a closed coil magnetic resonance machine.

This study consists of a characterization and process of painful signals in healthy patients plus its later, comparison with patients with neurological disorders in the processing of the pain (fibromyalgia etc). The following protocol was used for the patients' selection and for the application of the sequences of somatosensorial stimulation.

<table>
<thead>
<tr>
<th>FASE</th>
<th>DESCRIPCIÓN</th>
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<tbody>
<tr>
<td>1</td>
<td>Test of “tender points” of FD.</td>
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<tr>
<td>2</td>
<td>Anatomic analysis</td>
</tr>
<tr>
<td>3</td>
<td>Somatosensorial 60%</td>
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<tr>
<td>4</td>
<td>Motor activation</td>
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<tr>
<td>5</td>
<td>Sensitive stimulation</td>
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<tr>
<td>6</td>
<td>Somatosensorial 80%</td>
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The first phase consists of a medical examination on Tender Points to determine the validity of the controls. Afterwards a questionnaire is provided to the patient where he is informed about the voluntary character of this experiment as well as its environmental conditions and possible risks.

The second phase consists of an anatomical sequence (RM) that allows obtaining structural images of the brain. In the third phase a pulse train is applied on the epicondilo of the right arm by the stimulator device described before. The sequence of pulses in this phase reaches the 60 % of the maximum pressure.

The whole sequence of stimulations to the patient lasts five minutes and twelve seconds, from which, the first twelve are of preparation. Once finished the preparation, it begins another sequence, in which there are alternately applied thirty seconds of rest, and thirty seconds of stimuli, (fifteen pulses of a second of duration and a second apart between two consecutive ones). The synchronization with the clock of the magnetic resonance is realized manually.

The phases fourth, fifth and sixth, are used for comparing motor response (6), somatosensorial at simple contact (7) and somatosensorial painful (7).

In the fourth phase the patient is asked to move the right hand in order to being able to register the motor response. During this phase no sequence of pulses was sent from the stimulator device.

In the fifth phase the stimulation is realized by contact in the ipsilateral zone of the hand, and the use of the stimulator device will not be necessary. Finally, in the sixth stimulation phase is realized consisting of the application of the same sequence of pulses described in the third phase, this time applying 80 % of the available pressure of the stimulator device (5 Kg/cm2) with the aim to produce “pain”.

In order to analyze the results, the images are elaborated by means of diffusion tensors (4,5), where gradients are applied in the different planes of the space, to obtain information about the proton diffusion according to every plane of the space.

### 3. Results:

The initial results allows to identify the activated zones due to the difference in processing the three stimulation systems used, showing therefore its usefulness for the differential studies of the pain, which allows to classify the intensity and the trains of pulses to be used. New studies are necessary to be applied in patients with other processing techniques for the magnetic cerebral MEG signals.
The rapid developments of imaging methods over the past years have led to a decrease in variability in the description of central pain responses between different studies and have led a definition of a central pain matrix with specialized subfunctions in man. In the near future we will see studies where the systems perspective allows for a better understanding of the functional areas of central pain (8).


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