



EPIONE Call for Patients

During the course of 2015/2016 a study focused on the treatment of phantom limb pain and the development of a very advanced sensorized bionic hand will be held at the Policlinico Gemelli in Rome. This study is aimed at patients with unilateral upper limb amputation in the forearm who have developed a high intensity phantom pain with stable characteristics lasting for more than six months, and not responding to any type of pharmacological or non-pharmacological therapy.

The goal of the study is to test the effectiveness of a system composed by assembling various medical devices, including a prototype robotic hand, in the treatment of phantom limb syndrome. By means of this system, the patient will not only be able to voluntarily move the bionic hand but also to receive tactile sensations from the hand itself, and thereby control the closing force and recognize objects of different shape and texture without the aid of sight, in a similar manner to that of a natural hand.

In order to achieve this objective, 4 electrodes with the same tenuity of a hair will be surgically implanted into the stump (median and ulnar nerves) and which will then be connected to an electrical stimulator and a bionic hand prosthesis. In early 2013, a similar system had already been successfully tested for a period of 30 days on a Danish patient, Dennis Aabo Sørensen, who is an amputee of the left arm following the explosion of a firework during the New Year celebrations in 2004. A few months after the trauma Dennis had developed a phantom pain of high intensity. During the early stages of the study, the direct stimulation of the residual nerves of the amputee limb by means of implanted electrodes, brought about a marked reduction of phantom pain in a patient, who, it should be remembered, had previously tried various treatments without ever obtaining any tangible benefit.

During the second phase of the experiment, the patient was also made to try a prosthetic bionic hand. Dennis states, "the first thing that I was made to touch was a baseball, and I immediately felt that it was a round object, and it was a wonderful thing; I knew right away, without seeing it." Dennis continues, "This was a wonderful experience for me, to go back to feeling the different texture of objects, and to realize whether they are hard or soft and feel like I was holding them was incredible." After a short training period, Dennis was able to recognize the consistency of three different objects (hard, soft and intermediate) in over 78% of the tests and to define



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the size and position of objects relative to the hand in 88% of the cases. He also managed to accurately determine the strength to be applied in order to grasp objects with the same precision as with a natural hand, which is a decisive factor for a bionic prosthesis, as it allows the hand to modulate the grip on an object thus avoiding it slipping or being damaged, which is an essential factor in the creation of functional bionic hands. The results of the experiment were published and described in detail in the international scientific journal "Science Translational". By following the link <https://www.youtube.com/watch?v=QtPs8d4JbwY> it is possible to find a short video focused on the experiment.

The duration of the use of the bionic hand and treatment for phantom limb pain will be longer compared to that of the previous implant. In fact, it is foreseen to carry out an implantation of the duration of one year, in the course of which the patient will be engaged daily for the first six weeks of the study, excluding weekends. From the 7th to the 12th week the engagement will be limited to two consecutive days per week, while from the 13th week onwards until the end of the study the system will only be used one day a week. For the entire duration of the study, the use of the prosthetic system will be limited to the tests carried out with the experimenters and the patient cannot wear the prosthesis outside the research laboratory. In a first brief phase of the experiment, we will proceed to identify what kind of feelings are evoked by stimulating the nerves by means of the implanted electrodes. In practice, a kind of mapping of the contacts of the 4 electrodes and the best parameters for stimulation will be carried out. During the second phase of the study, this data will be used to operate the bionic hand prosthesis by combining the sensors with the different electrode contacts. In the course of this phase, the patient will be asked to perform a series of tests that require the use of the bionic hand, and includes tests aimed at dosing the force of contraction and recognizing the shape, size and texture of various objects. At the end of the experiment, the electrodes will be explanted. During the study, the patient will undergo various neurophysiologic tests and answer questionnaires in order to assess any possible modulation of the pain and relative changes to the central nervous system associated with this. None of the methods used during the neurophysiologic investigation are invasive. It is foreseen to study at least two of the patients among those recruited.

The study, which is part of a larger project funded by the European community called Epione (<http://project-epione.eu/>), will be carried out by Professor Paolo Maria



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Rossini and his team in Italy at the Institute of Neurology at the Policlinico Gemelli in Rome, upon the approval of the Ethics Committee and the health authorities of the Ministry of Health.

Contacts:

Prof. Paolo Maria Rossini: paolomaria.rossini@afar.it

Dr. Giuseppe Granata: granata.gius@gmail.com +39 3342108315; +390630156623)

Website: <http://project-epione.eu/>

We recommend that all those who are interested in participating send an e-mail, which should include a brief description of the site and the reason for the amputation. Photos of the amputated limb and specifically of the stump should be attached.