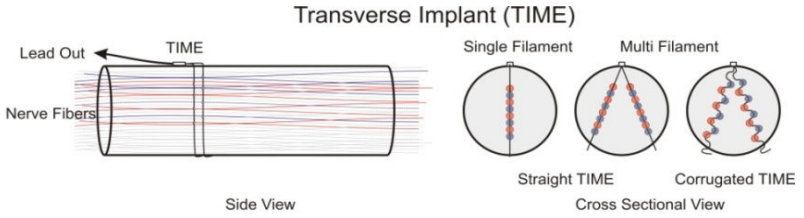
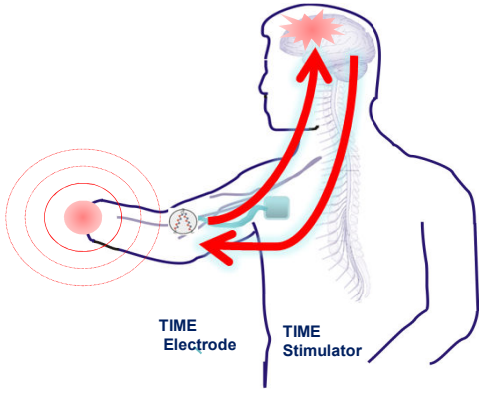
2013

Transverse Intrafascicular Multichannel Electrode (TIME) system for induction of sensation and treatment of phantom limb pain in amputees

Background and aim

The aim of project TIME is to develop a novel Human Machine Interface (HMI) for treatment of phantom limb pain. Amputation of a limb results from trauma or is a surgical intervention used as a last resort to remove irreparably damaged, diseased, or congenitally malformed limbs where retention of the limb is a threat to the well-being of the individual. The amputation traumatically alters the body image, but often leaves sensations that refer to the missing body part, the phantom limb. In 50-80% of cases, these sensations are painful and currently, there are no effective treatment modalities. We believe that given sufficient control over a large number of nerve fibers, a neural interface may be able to counteract the phantom limb pain





A novel micro-fabricated neural interface, the **T**hin-film **I**ntrafascicular **M**ultichannel **E**lectrode array and an implantable multichannel stimulator system will form the key core technological developments in the project.

- We will model, design, manufacture and characterize the multi-channel electrode (TIME) and design, manufacture and test an implantable, multi-channel stimulator.
- In vivo characterization phase will evaluate the TIME electrodes for biocompatibility, stability and chronic safety in animals and develop a psychophysical test platform for system integration.
- Finally, pre-clinical evaluation will test the system in short-term implants in amputee subjects.

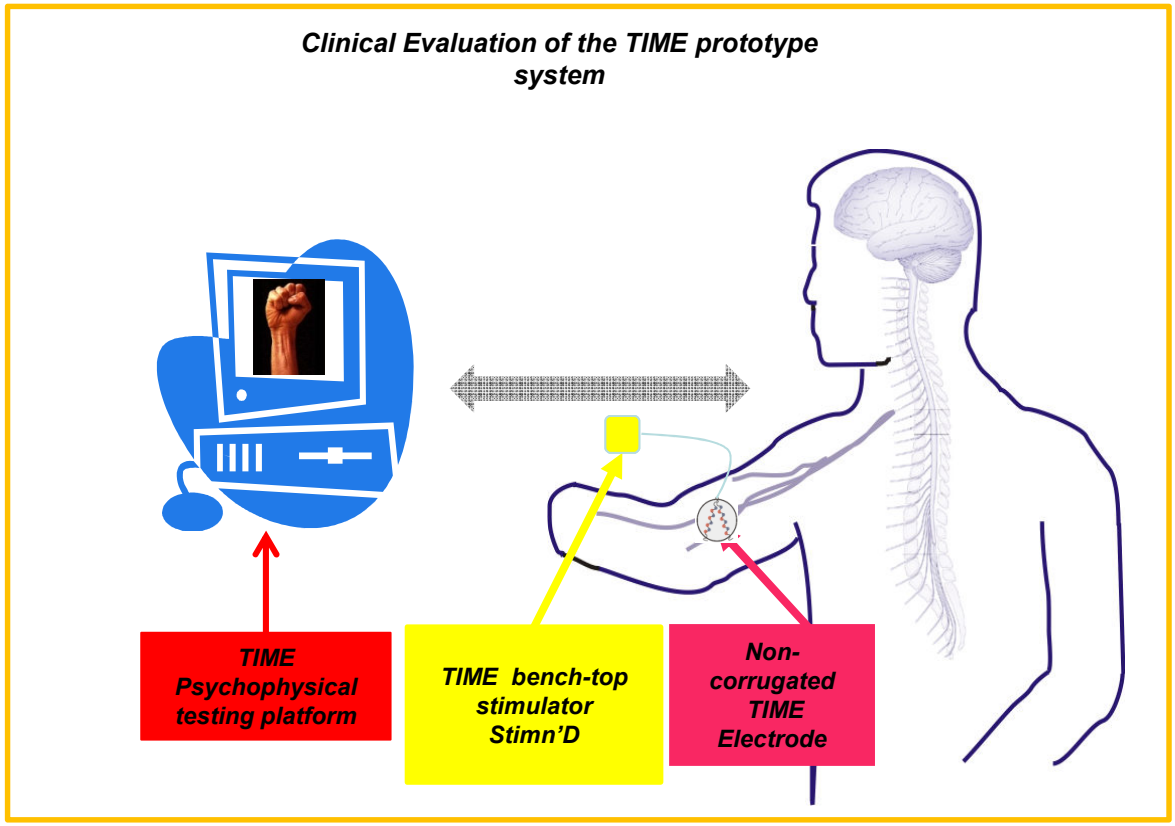
The application of these micro/nano technologies with functional electrical micro stimulation is expected to pave the road towards a treatment for phantom limb pain

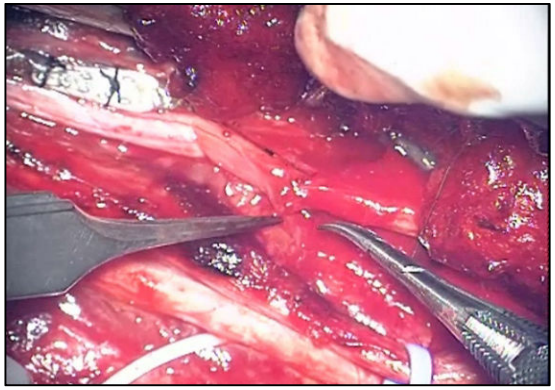
FP7 - ICT-2007.3.6 Micro/Nanosystems priority
project number 224012
www.project-time.eu
project-time@hst.aau.dk

2013

Transverse Intrafascicular Multichannel Electrode (TIME) system for induction of sensation and treatment of phantom limb pain in amputees

Clinical testing in volunteer amputee subject





The TIME system was tested in one human volunteer amputee subject in Jan 2013. The microsurgical technique of implantation of electrodes on an amputee was carried out without any complicaitons. Four electrodes were placed within the the ulnar and median nerves. The four implanted electrodes worked well during the entire implant period (30 days). Some channels, when stimulated, generated a movement sensation of the phantom hand (usually a pronation movements): this kind of sensation was always associated to an evident motor twitch of the stump. The two more common evoked sensation were vibration and touch. The anatomical distribution of this sensation was always congruent with the used electrode: electrodes inserted on median nerve generated sensation in the median nerve innervated part of the phantom hand and electrodes implanted on ulnar nerve evoked sensation on the ulnar innervated portion of the phantom hand. During the experiment the current threshold to generate a sensation increased progressively for each electrode and channel. However the current threshold never exceeded the safety threshold for the electrodes and the patient. During the stimulation session the patient described a significant decrease of his phantom limb pain.The effect lasted only some hours after therapy.

2013

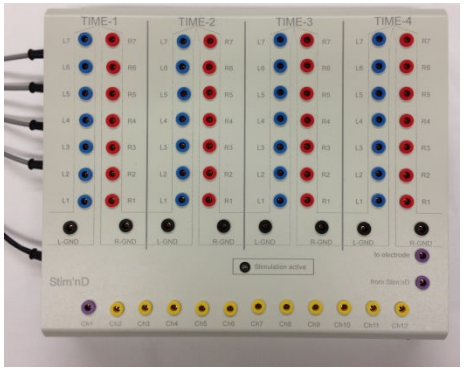
Transverse Intrafascicular Multichannel Electrode (TIME) system for induction of sensation and treatment of phantom limb pain in amputees

Tech development
TIME electrodes for human clinical trials

TIME have been manufactured for human clinical trials. Washing and sterilization validation has been performed in accredited laboratories. Documents for manufacturing according to quality management have been written as well as the technical dossier for the legal body and the ethical commission.

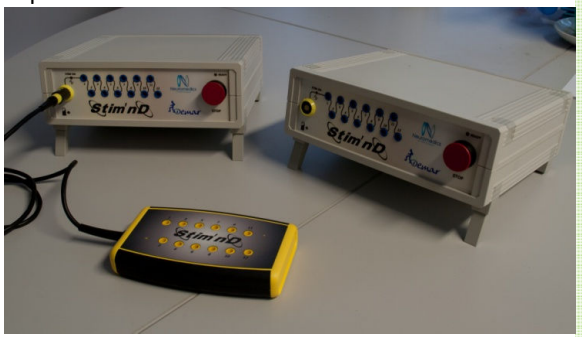
Tech development
Switchbox to connect up to four electrodes to one stimulator

A switchbox was designed that reduced the likelihood of confusion during connection of up to 12 sites from 4 devices to the 12 channel stimulator STIM'nD as recommended by the clinical team.



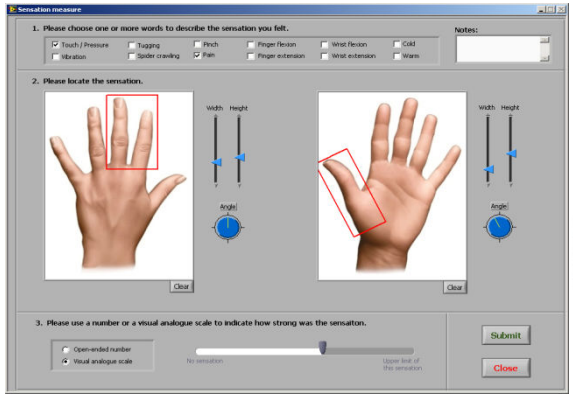
Tech development
Design and realization of multi-channel stimulator

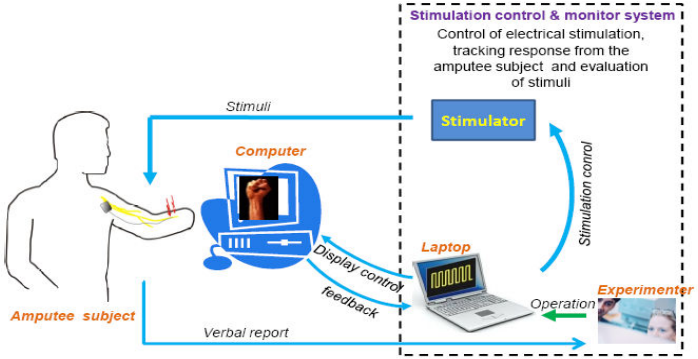
Stimulator prototypes - 12-pole bench-top stimulator - was manufactured, tested and delivered for use in human clinical trialAll designs include regulatory requirements of a future implantable device.



Clinical testing
Psychophysical testing platform

A psychophysical testing platform was designed to quantify the location of artificially evoked sensations and evaluate the strength of artificially evoked sensations.





FP7 - ICT-2007.3.6 Micro/Nanosystems priority, Project 224012
www.project-time.eu
project-time@hst.aau.dk