


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

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FP7 - ICT-2007.3.6 Micro/Nanosystems priority project number 224012

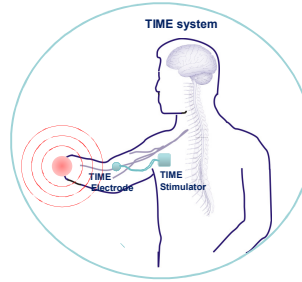


**Project objective**  
**Concept of project TIME**

The ultimate aim is to develop a Human Machine Interface (HMI) to manipulate phantom limb sensations in volunteer amputee subjects by the application of multi-channel microstimulation

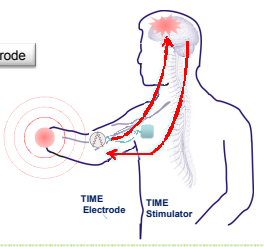
Advanced microfabricated electrode-structures will form the neural interfaces to:

- Provide sensory feedback
- Explore the possibility of treatment of phantom limb pain



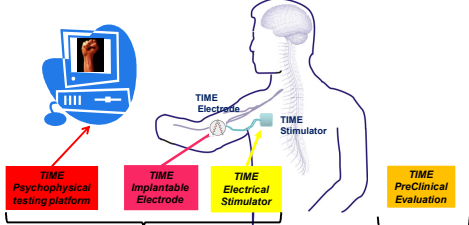
**Project Objective**  
**TIME hypothesis**

*By providing adequate patterns of stimulation to the transected afferent nerves central reorganization may be restored, and a normal processing of sensory signals recovered.*



Stimulation of afferent nerves through TIME electrode  
 ↓  
 Creating artificial, appropriate sensations  
 ↓  
 Restoring CNS changes  
 ↓  
 Reducing phantom limb pain

**R&D**  
**TIME prototype system for pre-clinical evaluation in amputee subjects**

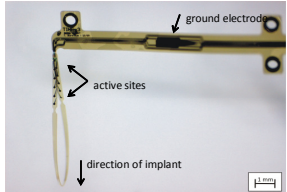


**PHASE I: Technological developments**  
 Implantable technology: electrode, connector, stimulator  
 Psychophysical testing platform

**PHASE II: In-vivo characterization**  
 Evaluation of biocompatibility, safety and selectivity in animal models

**Phase III: Clinical evaluation**  
 System test in human subject

Phase I: Technological developments  
**Electrode realization: Design of 3<sup>rd</sup> generation for chronic use**

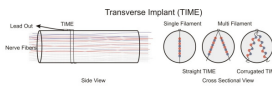


**3<sup>rd</sup> generation electrode characteristics**

- Scalable for small nerve and large nerves
- Iridium oxide (IrOx) for active sites
- Sufficient charge injection for human
- platinum tracks
- notches for decreased tensile stress
- anchors for nerve fixation

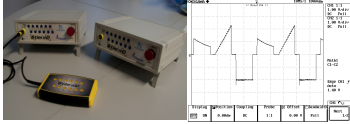
**Challenges within project life-time:**

- Mechanism to control corrugation after implantation
- Long-term stability of devices >30 days



WPA: Electrode realization  
 Thomas Stieglitz

Phase I: Technological developments  
**Multichannel stimulator: Moving from bench-top to implantable version**



**Bench-top**

- 12 independent channels
- Fully programmable stimulation parameters
- Flexible electrode configuration
- Real-time modulation of parameters
- Monitoring of injected charge
- Max amplitude of 5 mA (steps of 1.3 µA)

**Towards implantable stimulator**

- Architecture designed
- Analog part: stimulus generation (ASIC CAFE 12)
- Digital part: communication, stimulus generation, safety monitoring
- Same features as STIM'nD in a highly miniaturized hardware
- Patient-specific/optimal micro-stimulation patterns

**Towards implantable multichannel connector**

- Prototype high-density, multi-channel connector

**Challenges within project life-time:**

- Miniaturation of stimulator architecture
- Integration of HW components

WPS: Multi-channel stimulators  
 Jean-Louis Divoux, David Guiraud

Phase I: Technological developments  
**Modeling: electrode selectivity**

The model can be used to gather information on:

- Optimal electrode geometry and insertion procedure (e.g. number of active sites and their dimension and positions, shape of electrode...)
- Optimal stimulation parameters (e.g. amplitude, frequency, shape of waves for stimulation...)

**Challenges within project life-time:**

- Modeling of Electrode-Tissue interaction when the TIME is inside the nerve
- Biotribological analysis of friction origin
- Integration of frictional data in FEM simulations for optimization of TIME electrodes design

WP2: Electrode Selectivity Model  
 Susanna Ripstein, Peter Årnes, Silvestro Micera

Phase I: Technological developments  
**Modeling: Mechanical implant**

FE models were improved with anatomical features

The model can be used for:

- Characterization of TIME electrodes
- pushing force on peripheral nervous
- Evaluate different electrode dimensions
- Evaluate electrode shapes
- Evaluate thickness of materials

**Challenges within project life-time:**

- Modeling of Electrode-Tissue interaction when the TIME is inside the nerve, integration of frictional data
- Biotribological analysis of friction origin

WP2: Electrode Selectivity Model  
 Susanna Ripstein, Peter Årnes, Silvestro Micera

Phase II: In-vivo characterization  
**Biocompatibility, safety and electrode selectivity**

**Challenges within project life-time:**

- Test of TIME HW in chronic animal preparations

WP6: Biocompatibility and Safety  
 Youker Mawardi

WP7: Large Nerve Characterization  
 Aalborg University, Winnie Jensen

Phase III: Clinical testing  
**Psychophysical testing platform**

**Progress**

- Identify system and software use-case and specifications
- Development of psychophysical protocol
- Low-level integration of stimulator with computer

**Challenges within project life-time**

- Efficient and/or automatic selection and evaluation of optimal, patient-specific stimulation sequences
- Translation of surface stimulation to intra-fascicular stimulation

WP8: Psychophysical testing platform  
 Ken Yoshida, Winnie Jensen

Phase III: Clinical testing  
**Clinical testing**

**Progress**

- Protocols for recruitment of potential human volunteer subject has been defined
- Patient inclusion criteria has been defined
- Time-line and procedure for ethical approval has been outlined

**Experience from EU project 'SmartHand' - knowledge transfer to project TIME**

For the first time in Europe, a sub-acute implant of 4 t-LIFES in median and ulnar nerves (two for each nerve) in one volunteer amputee subject was carried out in December 2008 at UCBM with the aim of controlling a cybernetic hand prosthesis.

**Challenges within project life-time:**

- Knowledge transfer from EU project 'SmartHand' to current project 'TIME'
- Recruitment of suitable human volunteer amputee subject

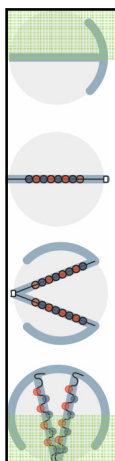
WP9: Clinical testing  
 GM Roscini

**Technological challenges beyond project life-time**

- Further clinical testing
- To develop a smart robotic support for a safer and less invasive electrode implantation
- Exploitation of R&D results – putting technology to market
- Biocompatibility
  - Life-long system life-time

**Future cluster collaborations?**

- Patient-specific tech design and manufacturing
- Wire-less connection to the electrode/TIME system
  - Transmission of control signals to the stimulator
  - Possible transmission of signals out of the body (high bandwidth, multiple channels)
  - Providing power (self-powered systems?)



**TIME**

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