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TRANSVERSE INTRAFASCICULAR MULTICHANNEL ELECTRODE (TIME) SYSTEM FOR TREATMENT OF PHANTOM LIMB PAIN IN AMPUTEES

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AIM: Phantom limb pain (PLP) develops in the lost limb in 50-80% of amputees. Today, it is not completely understood why the pain occurs, and no effective treatments are available. The favorable effect of electrical stimulation on PLP has been demonstrated. Our aim is to develop a novel system for manipulation of sensations by application of multi-channel microstimulation to the nerve stump of an amputee and explore this method as a treatment for clinched fist PLP (see figure).
RESULTS: *1) Electrode design.* Non-corrugated TIME electrodes with different dimensions and 8-12 active sites have been manufactured and tested in vivo and in vitro in the rat and pig animal models. Methods for corrugated prototypes were developed and realized. *2) Electrode selectivity modeling.* A peripheral nerve model is under development to evaluate the electrode's selective stimulation properties and to optimize electrode design. Simulated currents and neural activity generated were qualitatively assessed using experimental data obtained from rat nerves. *3) Implant modeling.* To optimize the implantation procedure, a theoretical peripheral nervous tissue model and a 3D FEM was implemented. Both models closely reproduce the experimental peripheral nervous tissue behavior and simulate the insertion forces transmitted to the electrode during implantation. *4) Multi-channel stimulators and connectors.* A 12-pole bench-top, proto-type stimulator has been implemented and successfully tested in animal experiments. A high-count, implantable connector between stimulator and electrode has been designed. 5*) Biocompatibility.* Electrode materials were evaluated and did not induce immune rejection and significant inflammatory reaction after in vivo implantation in the rat. Electrode implantation will require an understanding of the fascicular characteristics of the target nerve. Morphological characteristics of the rat, pig and human nerves are currently evaluated and compared.*6) Animal testing.* First TIME electrodes test were carried out in the acute rat and acute pig animal models. Results indicated selective stimulation of different fascicles with graded recruitment. *7) C*linical *evaluation:* To quantify the location of artificially evoked sensations and evaluate the strength of artificially evoked sensations a psychophysical testing platform is under development. The main inclusion criteria for patient recruitment have been identified and protocols have been defined.
CONCLUSION: The feasibility of the corrugated version of the TIME electrode has yet to be explored. Further work designing, optimizing and testing the TIME electrode and all technological developments will be carried out including theoretical stimulations and animal experimental work before the optimal electrode for human implant will be chosen.
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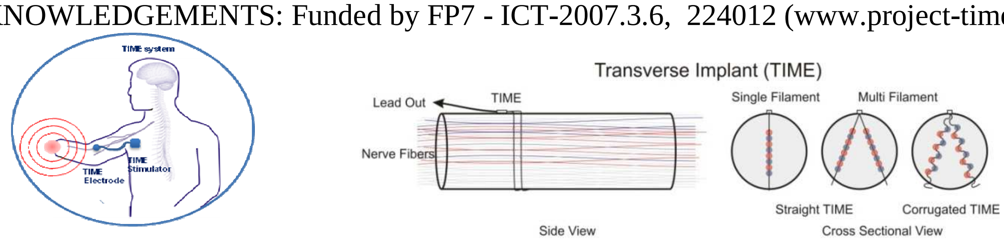

Figure 1: Concept of project TIME (left) and the concept of TIME electrode (right)