NEURIMP

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UNIVERSITY

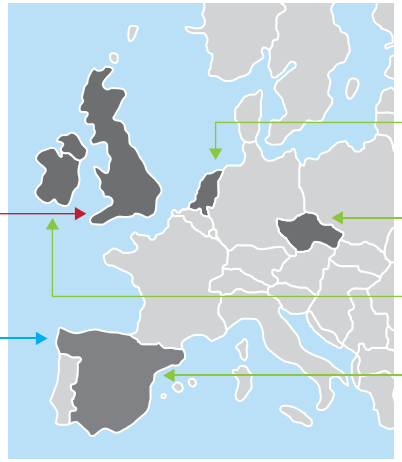
UNIVERSITY OF WESTMINSTER

The University Of Sheffield.

RESEARCH ORGANIZATION

IK4 TEKNIKER
Research Alliance

FUNDACIÓN del HOSPITAL NACIONAL de PARAPLÉJICOS
FUNHNPAIN



SME

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ORNIA BIOMATERIALS

histocell INGENIERÍA DE TEJIDOS

Novel combination of biopolymers and manufacturing technologies for production of a peripheral nerve implant containing an internal aligned channels array

TOPIC:

NMP2013.2.2.1 Biomaterials for advanced therapies and medical devices in the neurological/ neuromuscular cardiovascular fields.

EXECUTION:

January 1, 2014 - December 31, 2017

PROJECT COORDINATOR:

Dr. Santos Merino (IK4-TEKNIKER)

FP7
European Union Funding
for Research & Innovation
FP7-NMP-2013-SME-7
G.A. 604450

ABSTRACT

Peripheral nerves are basic communication structures guiding motor and sensitive information from CNS to effector or receptor units. Severe nerve injuries include axon bundles section and Schawnn cells destruction, which results in loss of motion control and sensorial perception. After the lesion, cells present in damaged nerves activate spontaneously self-regeneration programs that might facilitate further treatment. Nerve autograft is the "gold standard" surgical intervention that demands autologous tissue extraction and corresponding function loss.

The goal of the project is the validation of biomaterials structural plasticity and those compatible manufacturing technologies that will enable the generation of a tubular structure containing an intraluminal microstructure based on an array of aligned channels or fibers. The regenerative properties of this prototype will be also validated in vivo in a sciatic nerve section animal model.

The NEURIMP project will take advantage of partners' experience in the design of medical devices composed of natural and synthetic biomaterials and in scaled-up production micromanufacturing technologies for the generation of the most effective peripheral nerve implant.

OBJECTIVES

01 **Develop advanced synthetic-natural biohybrid materials** with improved biocompatibility and biodegradability regenerative capacity and mechanical properties **required by biomimetical endoneural tubes.** Scale - up biomaterial production to industrial levels.

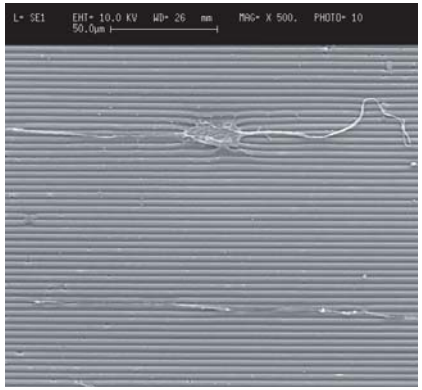
02 **Develop advanced manufacturing technologies for the generation of biomimetic endoneural tubes** with precise morphologies and sizes (intraluminal microchannels or fibers with high aspect ratio). Scale - up manufacturing technologies to industrial levels.

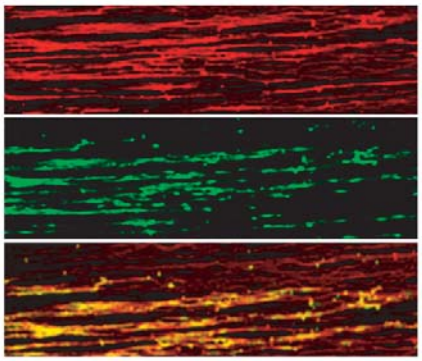
03 Understand the interplay between scaffolds and the endothelial cells, the Schwann cells and neurons (via **in vitro assays) to promote the generation of Bands of Büngner and revascularization** inside the Implantable nerve guidance conduits (INGCs).

04 Design, fabricate and optimize a **new generation of Neural Guides** composed of two clearly differentiated parts: i) An outer wall with selective porosity for nutrient exchange and providing physical stability that avoids the INGC collapse while regeneration progresses; ii) An inner endoneural-like microstructure to provide a topographical axonal regeneration.

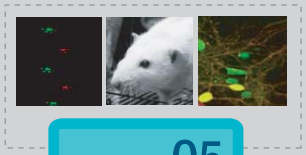
05 **Characterize, in** a clinically relevant **animal model** of sciatic nerve injury, **the performance of the produced INGCs** for key parameters such as the maximum gap length that can be repaired, their ability to promote the regeneration of both motor and sensory axons, and their ability to pave for precise target reinnervation with as resulting in improved functional recovery.

06 **Scaled up production** of the new generation of INGCs taking into account standards, regulatory affair and economical issues.





RELATIONSHIP BETWEEN THE DIFFERENT OBJECTIVES DEFINED IN NEURIMP



SYNTHETIC
PGA/PLA/PCL

NATURAL
HA/PHA/PHB

BIOHYBRID
SYNTHETIC / NATURAL

02 MICRO-STRUCTURES FABRICATION

05 IN VIVO ANALYSIS

01 MATERIAL DESIGN & SYNTHESIS

04 PROTOTYPE MANUFACTURING PROTOCOLS

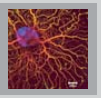
06 REGULATORY, TECHNICAL & ECONOMICAL EVALUATION

06 SCALE-UP PRODUCTION

06 EXPLOITATION PLAN

03 IN VITRO ANALYSIS

BIOCOMPATIBILITY



DEGRADATION
CELL ACTIVITY