Biohybrid — Result In Brief

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Chitosan tubes help regenerate peripheral nerves

Peripheral nerve damage is a serious cause of disability. A European consortium successfully developed an artificial nerve implant to promote and support the repair of damaged nerves.

In contrast to the central nervous system, peripheral nerves have regenerative capacities. However, regeneration after substantial nerve loss is very poor and can lead to loss of function of the interacting muscle. This necessitates the development of innovative therapies for peripheral nerve injuries.

The EU-funded BIOHYBRID (Biohybrid templates for peripheral nerve regeneration) project worked to develop a graft device made of the biopolymer chitosan for long-distance repair of injured nerves. Obtained from crustacean shells, this device is designed to bypass the gap in the nerve tissue and activate regeneration between the proximal and distal nerve stumps. Their integrated experimental approach included prefabrication of a bio-hybrid nerve device, its transplantation into nerve gaps in an animal model and evaluation of the regenerative outcome.

After three years of work, BIOHYBRID partners tested 3D scaffolds based on chitosan hollow tubes. One comprehensive and one medium-scale in vivo study evaluating chitosan hollow tubes with different degrees of acetylation resulted in the Reaxon® Nerve Guide, approved as a medical device. These nerve conduits also supported regeneration across 15-mm gaps in animals.

In vitro studies of scaffold functionalisation showed that iron oxide nanoparticle-conjugated neurotrophic factors convey the necessary properties to the scaffolds, resulting in a patent application. In vivo evaluation revealed that seeding the scaffold with fibroblast growth factor-2 overexpressing Schwann cells promoted axonal regeneration. The differences in peripheral nerve regeneration between healthy and diabetic, male and female rats were also characterised.

BIOHYBRID developed a comprehensive clinical investigation plan for evaluating repair of median and ulnar nerve lesions in humans using an implanted Reaxon® Nerve Guide. The Reaxon® Nerve Guide was implanted in a few patients with peripheral nerve defects in Germany after its market entry in June 2014. The consortium completed preparation of a multicentre clinical trial on Reaxon® Nerve Guide in median and ulnar nerves and initiated FDA submission.

The results of the clinical trial will support future applications of advanced composite chitosan conduits. Clinical use of the developed innovative bio-engineered nerve device is expected to shorten recovery times and speed up return to quality of life for affected patients.

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