DURAL SEALING SYSTEM

DESCRIPTION OF THE TECHNOLOGY

Post-Dural Puncture Headache (PDPH) is a relatively frequent complication of neuraxial anaesthesia. The PDPH is generated by a cerebrospinal fluid (CSF) leak through a dural perforation caused by an intentional puncture (in intradural anaesthesia) or by an accidental puncture (in epidural anaesthesia) of the dura mater.

The PDPH usually appears at 24 to 48 hours post-puncture and it presents an intense headache that worsens with sedestation, increased abdominal pressure, standing and ambulation, and improves with supine position.

In cases in which the problem is not identified early and strict postural measures are not ordered together with the adjuvant therapy, PDPH can lead to serious problems that result in altered vision, balance and hearing. This is because the central nervous system accuses the loss of CSF which acts as a "protective cover/sheath" to neighbouring structures.

At present, there is not etiological treatment for PDPH, and all therapeutic efforts are aimed at reducing its symptoms. Palliative means are rudimentary and ineffective, besides are not free from risks. In this sense, Fisabio has developed a prevention system that pretends to avoid the establishment of the clinical problem and therefore, the onset of PDPH.

The invention is a biocompatible and resorbable system, conceived as a kit, which includes the implant and the necessary tools for its insertion through the puncture needle. The kit contains a millimetric dural implant that is applied at the time of the anesthetic act (when accidental CSF leak is detected), seals the dural perforation and blocks the persistent fluid leak.

Its application is carried out quickly and without losing the puncture site, so sealing can prevent the development of clinical Post-Dural Puncture Headache, taking advantage of the CSF's mechanical properties and avoiding the application of pharmacological measures or higher risk procedures in extreme cases.

MARKET APPLICATION SECTORS

Companies in the health technology sector focusing on application of biomedical engineering in research, design, manufacture, and sale of instruments or devices to manage chronic and acute pain.

Manufacturers specialized in medical devices or surgical implants.

TECHNICAL ADVANTAGES AND BUSINESS BENEFITS

The new implant has the following advantages regarding to the therapeutic arsenal currently available to combat PDPH:

- It is not necessary a new epidural puncture (with its consequent risk of a new dural pucture) to accomplish the therapeutic procedures. In many cases, after an accidental dural puncture with PDPH, the patient will undergo new epidural manipulations with a needle, but now with a therapeutic approach, in order to insert blood that "blocks" the leak – blood patch. It logically entails risks, such as another failed puncture.
- It results a prophylactic measure, since it's performed in the same anaesthetic act, not in two times nor according to the clinical course of the patient, which may not be favourable.
- Its application is less laborious and faster than alternatives such as the blood patch (current *gold standard*).
- It facilitates the maintenance of sterile conditions by not requiring the setup of a new sterile field (or of two new sterile fields in case the patch is applied).

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- It avoids the potential complications with the use of blood patch (infections, problems resulting from mechanic compression).
- It shorts the hospital stay, exclusively related to the headache, bringing with it a lower associated health spending.

CURRENT STATE OF DEVELOPMENT

Technical viability of the prototype has been tested in vitro – through synthetic and biological membranes – waiting for validation of the kit in/under real operating conditions.

INTELLECTUAL PROPERTY RIGHTS

The technology has been filed under patent application to the Spanish Patent and Trademark Office, with priority date 19/04/2017 and in co-ownership with the Instituto de Biomecánica of València (IBV). The international expansion is expected during the priority year through via the PCT.

COLABORATION SOUGHT

Licensing agreement with companies willing to manufacture and commercialize the technology.

Co-development agreement with companies specialized in Pain Medicine.

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