FIBICO – Decompressive Craniectomy Device

Technology

Neurological surgeries, such as craniectomy and cranioplasty, have an increasing incidence. Combined, they are the most frequently applied techniques for brain swelling. The first surgery, named craniectomy, requires the removal of a skull fragment called "bone flap". The extraction is temporary, until the brain inflammation is reduced, which commonly happens between a month and a year after the craniectomy. At this point, a second surgery, named cranioplasty, is required. This procedure consists in the relocation of the "bone flap" back on the patient's cranium, which is an invasive and complicated surgery.

The presented technology consists of a novel medical device with a new surgical technique to improve these procedures. The new procedure avoids the "bone flap" removal trough the implementation of an engineering system wherein the mechanism allows the suspension of the "bone flap" under the skin. The space created with this mechanism facilitates the decompression of the brain; and when the inflammation is reduced, the "bone flap" is relocated without surgery. Thanks to this device, this new procedure keeps the "bone flap" detached from the cranium at a constant distance under the skin, avoiding a second complex surgery and the maintenance of the bone in a tissue bank.

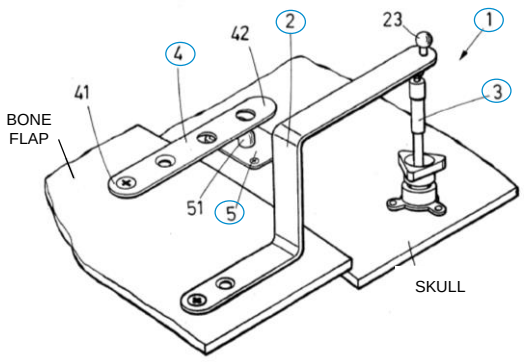
Engineering System

The invention (**1**) comprises *(see Figure 1)*:

- A **first elongated plaque** fixed to the "bone flap" (**2**).
- A **telescopic extensible component** (**3**) which has two configurations, extended (for "bone flap" suspension) and folded (natural position). This piece is anchored to the skull and has a mechanical system for external control; and a metal plaque (**2**) connected to the “bone flap”.
- A **second elongated plaque** (**4**) can be required if a definitive anchoring is needed, as a final step after the "bone flap" relocation. Each side is attached on the skull and on the "bone flap" respectively, and it is reinforced by a **fixing plate** (**5**).

The procedure starts with a cut on the skull to get access to it. Then, the system is installed, and the **telescopic extensible component (3)** is set *(see Figure 2)*. The extensible component mechanism (3) allows the "bone flap" to be raised to a fixed distance (until 25 mm between the "bone flap" and the skull). The distance depends on each patient and the pathology characteristics, in any case a manual control can be performed externally. Once the system has been set up, the skin is closed above the mechanism. After the brain decompression, the skull and the "bone flap" will be attached progressively.

Figure 1: Engineering system schematic



Benefits

This novel medical device application bring many benefits when compared with current techniques:

- From two difficult and invasive surgeries to just **one intervention**.
- **Easy application** for the surgeon.
- **Allows for external control** of the system.
- **The external anchoring** next to the surgical cut facilitates an **optimal skull reconstruction**.
- It **reduces the patient’s vulnerability** between both surgeries, when the brain is exposed without the "bone flap".
- **High-cost reduction,** as the maintenance in a tissue bank of the skull tissue between both surgeries is no longer required, and the cost and difficulty of the second surgery (cranioplasty) is highly reduced.
- Mechanism developed taking into consideration surface skull anatomy.

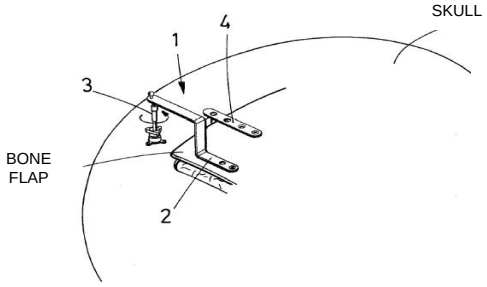
Stage of Development

The invention has been prototyped, and pre-clinical tests in pigs and corpses are being performed to evaluate its effectiveness and security.

The technology is protected by a Spanish Patent Application submitted in 2016 at the OEPM (Spanish Patent and Trademark Office), with priority date in December 2016; PCT application has been submitted in 2018.

This invention received several awards, including Biomedical Innovation Award from IMIBIC-ROCHE in 2017.

Figure 2: Detail of extended configuration applied



Represented Institutions and inventor:

The principal inventor behind the technology is Dr. Cristóbal J. Blanco Acevedo, neurosurgeon at the Reina Sofia University Hospital (HURS) in Córdoba (Spain). The invention has been co-developed with engineers from University of Córdoba (UCO), The Maimonides Biomedical Research Institute of Cordoba (IMIBIC) and the Foundation for Biomedical Research of Córdoba (FIBICO).

Objective of the collaboration

The represented institution is looking for a collaboration that leads to a commercial exploitation of the presented invention. The ideal scenario for the institution would be to reach an agreement in order to transfer the technology use by sale or a license (exclusive or non-exclusive). However, the form, terms, and conditions of the collaboration can be openly discussed if the presented technology is of interest.

Dossier visual elaborado en colaboración con la empresa ViromiiInnovationS.L en el ámbito del expediente de contratación FIB SE 01/2021