DEVICE FOR THE RELEASE OF BIOACTIVE AGENTS IN THE GASTROINTESTINAL TRACT

DESCRIPTION OF THE TECHNOLOGY

Inflammatory bowel diseases (IBD), such as ulcerative colitis and Crohn's disease, are a series of chronic and recurrent infectious disorders of the intestinal tract. Their incidence continues to increase worldwide and their specific etiology is still unknown, so that there is currently no possible cure. About 70% of IBD patients will require one or more intestinal resection surgeries during the course of the disease.

After the postoperative period, dysbiotic processes associated with IBD usually appear, where patients suffer an affectation and/or loss of some of the microorganisms that make up the intestinal microbiome. This aspect is considered to have a determining influence on the development of disease recurrence.

The most commonly used therapy at present is fecal microbiota transplantation (FMT) which, although it has demonstrated clinical efficacy, presents two main problems: on the one hand, due to the antibiotics administered after surgery, most of these fecal microorganisms administered in FMT do not survive, and on the other hand, the route of administration through colonoscopy can be aggressive. Another therapeutic tool is the use of oral probiotics, but their use is not very effective due to the high doses of tablets necessary to achieve the effective oral bacterial dose and their lack of efficacy at the colonic or terminal ileum level.

Researchers from the Universitat Politècnica de València and the Fundación para el Fomento de la Investigación Sanitaria y Biomédica de la Comunitat Valenciana (Fisabio) have developed a biodegradable polymeric device for the controlled release of bacteria in the intestine. It consists of two different polymeric coatings that store specific bacteria of the human microbiota. Its use is related to the improvement of the microbiome after intestinal resection surgeries in IBD with the aim of improving postoperative processes and preventing the appearance of intestinal dysbiosis and other comorbidities. The device will be implanted during the intestinal resection procedure and the bacterial load will be released in the colon between 1 and 3 months after the procedure. The delay between implantation and release of the bacterial load is intended to prevent the prophylactic (antibiotic) treatment given to the patient after surgery, which lasts approximately 1 month, from affecting the viability of the released bacterial load.

The application of the developed device will contribute greatly to the improvement of the quality of life of patients with IBD, allowing its use in hospitals and being able to extend its application to the treatment of other digestive diseases.

MARKET APPLICATION SECTORS

Surgical equipment and material commercialization companies.

TECHNICAL ADVANTAGES AND BUSINESS BENEFITS

The system has the following advantages over the currently most commonly used therapies, fecal microbiota transplantation (FMT) and oral probiotics:

- The device is implanted during the intestinal resection intervention with which, unlike TMF, it does not require subsequent colonoscopies for the introduction of the bacterial load.
- The device is implanted in the area of the colon where the intervention takes place, so that the bacterial load is released in the environment where it is required. In current treatments by oral administration, the loss of bacterial load along the digestive tract can make it difficult to adequately concentrate it in the area of the colon where it is required.
- It does not require the patient to follow a treatment. The patient's adherence to oral treatment is not controllable; on many occasions the patient himself/herself stops following it or does not do it properly, reducing its efficacy.

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- The device is adaptable in its design for specific applications and makes possible new therapeutic developments, by releasing the bacteria in a novel and very localized way in the area where the resection has been performed.

CURRENT STATE OF DEVELOPMENT

A prototype of the device has been developed from biodegradable polymeric materials for medical use. The bacterial load that can be released from the device will be encapsulated either in the form of lyophilized bacteria or in the form of spores.

The morphology of the device allows it to be fitted to the surgical stapler used in the intestinal resection procedure, so that the device will be fixed to the walls of the intestinal tube during the surgical procedure itself. The dimensions of the release device can be modified to fit the dimensions of the stapler required for the surgical procedure.

INTELLECTUAL PROPERTY RIGHTS

The technology has been registered at the Spanish Patent and Trademark Office with application number P202130457 and priority date 20/05/2021.

COLLABORATION SOUGHT

License agreement with companies willing to commercialize the technology.

RELATED IMAGES

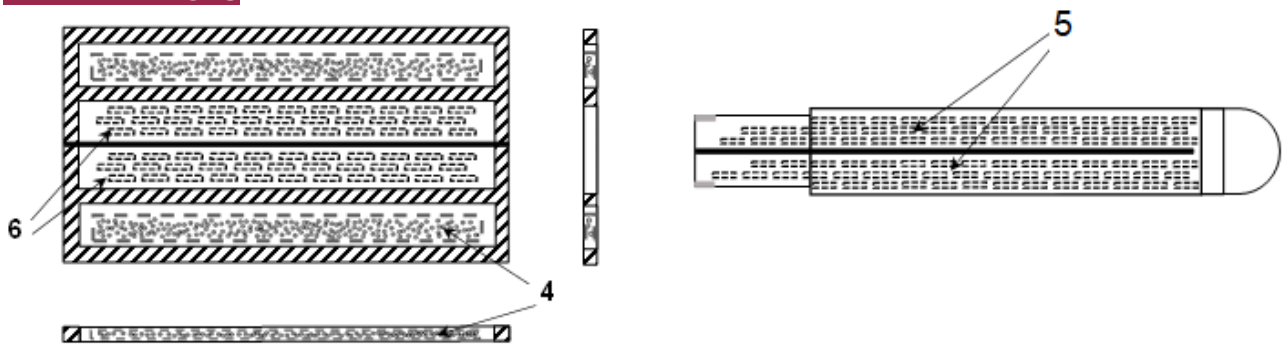

Figure 1: Detail of device attachment to the surgical stapler. Left: Position of the stapling area and cutting area of the stapler blade. Right: schematic representation of a part of the surgical stapler clamp (upper or lower part). (5) Surgical stapler clamp, (6) Stapling zone on the device, (4) Bioactive agent.

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