

人工肛門患者の社会復帰に貢献する高機能排便制御デバイスの開発

プロジェクト
責任者

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プロジェクト概要

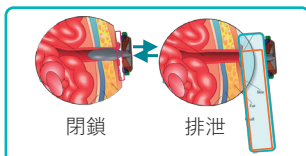
直腸癌治療による排泄トラブル

直腸癌術後の“人工肛門”“低位前方切除後症候群:LARS”の患者は術後日常的な便漏れトラブルをかかえる

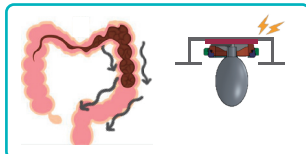
結腸内に溜まった便は、1日数回ランダムに発生する“大蠕動”と呼ばれる現象によって一気に溢れるが、術後患者は堰き止めることができず、漏れる
→直腸癌の治療をうけたが故に、当たり前の日常がおくれなくなる



開発機器の概要



①プラグによる便流出抑止
特殊形状のバルーン→愛護的な腸管閉鎖
ワンタッチで排泄、再開鎖が可能



②便意の事前予測
→排便前の前兆を検知
→前もって排泄の準備ができる



③排便誘発
事前に排泄一便が出ない時間を確保
ライフスタイルにあわせて
排泄時間をコントロール可能

想定するビジネスモデル

セグメント分析:医療分野の1stターゲット

医療機関で治療中の、特に症状の強い18万人
治療抵抗性のLARS

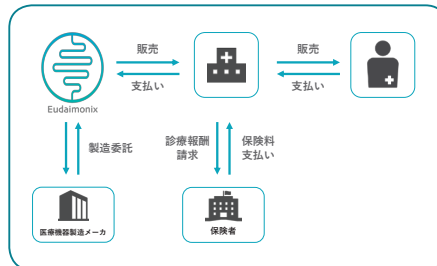
・・・1.8万人 (LARS全体の30%)

日常的な便漏れのある人工肛門

・・・1.2万人 (結腸人工肛門全体の23%)

切迫性素因のある難治性便失禁

・・・15万人 (難治性便失禁全体の10%) :



これまでの取り組み

下記2機能を開発した。

①閉鎖・排泄機能:バルーンプラグを用いて常時便をパウチ内に保持しなくなることで便漏れを抑止できる。またプラグを抜去後、排泄時にシームレスな手技で手を汚すことなく、簡単に便を破棄し、その後再度閉鎖できる。POC取得済み。特許出願済み。

②便意の事前予測;第一試作での動物実験検証から改良試作を作成。POC取得中。

③排便誘発機能;動物実験でのPOC取得済み。特許出願準備中。

今後の展望

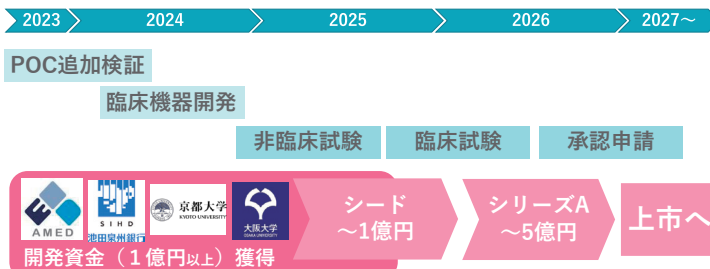
2024年度

臨床様機器開発、システムの統合

2025年度、2026年度

非臨床試験、臨床試験

2027年度 上市を目指す



Medical devices

Development of continence device for ostomy

Principal Investigator

Department of Gastrointestinal Surgery,
Graduate School of Medicine, Kyoto University

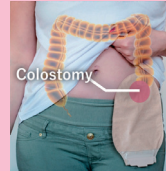
Professor Kazutaka OBAMA

Project Outline

Bowel leakage issues resulting from rectal cancer treatment.

After surgery for rectal cancer, patients with "Low Anterior Resection Syndrome (LARS)" or those with an "artificial anus" often face daily issues with bowel leakage. The stool accumulated in the colon overflows suddenly due to a phenomenon called "mass movements," occurring several times a day at random intervals. However, postoperative patients are unable to contain it and experience leakage.

→The patient's normal routine is disrupted due to receiving treatment for rectal cancer



Colostomy

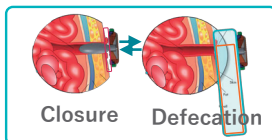
Unable to preserve the natural anus, a constructed alternative route is created. This results in a continuous flow of stool that needs to be collected in a pouch.



Low Anterior Resection Syndrome (LARS)

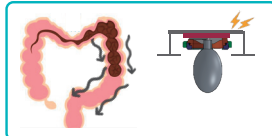
Defecation difficulties in patients with preserved anus.

The value of device



Containment of stool leakage with a plug.

"Special-shaped balloon → gentle intestinal occlusion. It allows for one touch excretion and reocclusion"



Anticipating the need to defecate in advance.

"Detecting pre-signals before defecation. Being prepared for defecation in advance."



Push the switch for 15 minutes: Easy operation, no mess.

Stimulation of bowel movements.

Pre-scheduled bowel movements to ensure time for evacuation, allowing control over the timing according to one's lifestyle.

Business model

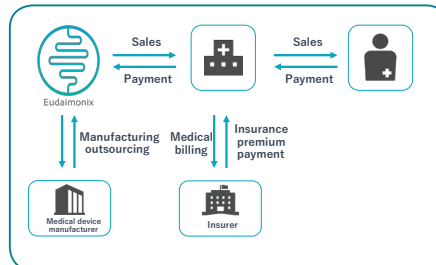
Primary target in the medical field

Patients with severe symptoms undergoing treatment at medical facilities : 180,000

•18,000 individuals with treatment-resistant LARS, accounting for 30% of all LARS cases.

•12,000 individuals with daily bowel leakage through an artificial anus, representing 23% of all colostomy cases.

•150,000 individuals experiencing intractable fecal incontinence due to urgency factors, constituting 10% of all cases of intractable fecal incontinence."



Our past initiatives.

We've developed the following two functions:

1. Closure and excretion function: Using a balloon plug, we're able to contain stool within a pouch, preventing leakage. After removing the plug, a seamless technique allows for easy disposal of stool during excretion without soiling hands, followed by re-closure. POC has been acquired through animal testing, and the patent has been filed.
2. Preceding defecation prediction: After initial animal experimentation and subsequent improvements in the prototype, we are currently obtaining proof of concept (POC).
3. Bowel movement induction function: POC has been acquired through animal testing, and preparing for patent application.

Next plan

In the fiscal year 2024, we aim to develop clinical-grade equipment, integrate the system. In 2025 and 2026, we plan to conduct non-clinical trials followed by clinical trials. By the fiscal year 2027, our goal is to pursue market approval.

