A Novel Device To Dislodge Fecal Impactions

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Abstract

Fecal impactions are a significant clinical complication often dealt with in the emergency room, and can have serious health effects if left untreated. The current standards of care are very painful and require multiple entries, maximizing discomfort and the length of the operation. Xerry Medical has designed a novel and unique fecal disimpaction device that will significantly reduce the discomfort of the operation by a novel ultrasonic vibration inside a device with a uniquie geometry designed for the anal cavity. Complete with a powerful aspiration hole, Xerry Medical seeks to significantly reduce the time and the discomfort of the overall operation.

1 Introduction

Fecal impactions are a significant clinical complication often dealt with in the emergency room. Left untreated, fecal impactions can be lethal, as the buildup of fecal matter can induce serious side effects, and significantly elevate blood pressure. A need exists for a way to easily treat fecal impactions.

2 Current Standard of Care

2.1 Digital Treatment

The most traditional method for treating fecal impactions at the hospital first entails taking mineral oil orally or via enema to soften the stool. An emergency room physician then uses his or her finger to gently dislodge stool in a process called "digital treatment". Additional enemas are used as required. The entire process requires care and is a rather uncomfortable process.

2.2 NuvoMed's DisImpactor

NuvoMed has designed a disimpactor tool for medical use. The device is pressed deep into the impacted feces and, when removed, generates enough force to dislodge small chunks of the feces. Multiple DisImpactors must be used for a single patient.

The tip of their device is designed to press deeply into the impacted impaction, while the ridges along the edges are designed to provide the traction by gripping the sides of the rectal cavity. The device in clinical testing had a 50% success rate, with one patient of the fourteen sampled ending up quitting due to pain and duress of the procedure.

3 Our Solution

3.1 Design 1: Ultrasonic Disimpactor

Design one is a fecal disimpaction device that will significantly reduce the discomfort of the operation by using ultrasonic wave propagation. Coupled with its customized geometry designed for the anal cavity, the device seeks to use the waves to loosen and break up stool in the area. An aspiration hole at the apical end and alongside the lateral edges allows the emergency-room physician to inject appropriate amounts of enema fluid to cleanly wash out the bowels.

The main advantages for this design compared to the current standard of care would be reducing the duration of the procedure, and thereby reducing the overall patient discomfort. Ultrasonic wave propagation is a safe, readily-available, and clinically-tested technology used elsewhere for a variety of

Figure 1: An image of NuvoMed's DisImpactor.

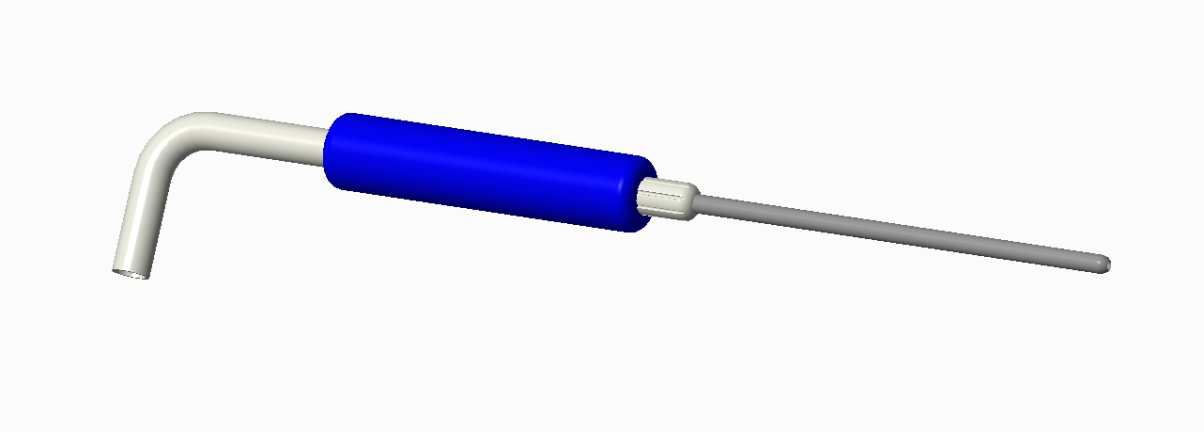

Figure 2: Design 1

purposes. The usage of ultrasonic waves may be able to significantly speed the duration of the procedure, to prevent multiple re-entries (as is required by the NuvoMed Disimpactor).

3.2 Design 2: Claw and Grip Disimpactor

Design two is a claw/grip disimpacting device that utilizes mechanical force to dislodge fecal matter. The length of the device and the small diameter of the device allows the surgeon to extend his/her reach into the cavity deeper than his/her own fingers allow. The claw/grip also includes an aspiration hole at the apical end, in order to maximize the effect of the enema fluid on the impacted feces.

The main advantages compared to the current standard of care are that this device is effectively an extension of the current digital treatment procedure. The device also includes an aspiration hole at the apical end to allow the direct application of enema fluid.

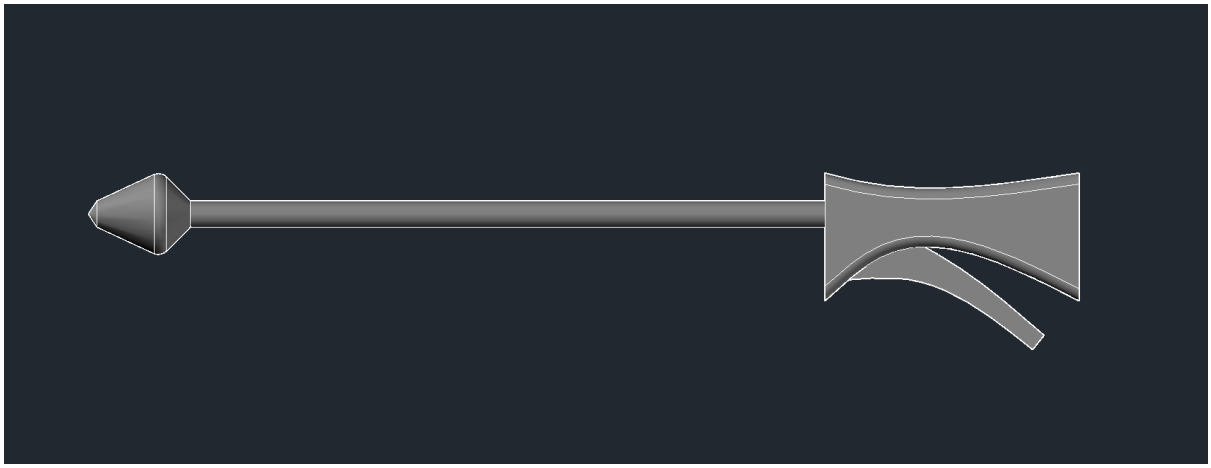

Figure 3: Design 2

4 Competing Patents

4.1 US Patent 4,243,037

Patent Abstract (1981); A device for breaking up impacted Fecal from the rectum comprising an outer hollow tube having an opening at one and for introducing an enema Solution in the tube cavity and having an opening at the other end allowing the enema solution to pass from the tube cavity into the rectum, and a plunger assembly shaped to slidingly fit in the tube cavity and having prongs attached at one end which can be used to digitally break up the impacted fecal matter.

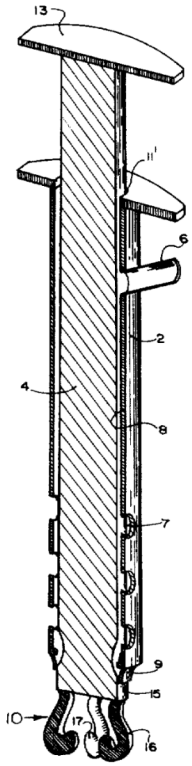

Figure 4: Patent 4,243,037

4.2 US Patent 5,730,726

Patent Abstract (1998); An apparatus for removing a fecal impaction from a patient's rectum is disclosed. The apparatus comprises a shaft which is inserted into the patient's rectum. Coupled to the shaft is a plurality of flexible spines. The apparatus also includes a mechanism for bowing at least one of the spines away from the shaft in order to cut through the fecal mass and define a volume that includes at least a portion of the fecal impaction to be removed. In one aspect, the mechanism for bowing at least one of the spines away from the shaft is a fixed collar which defines a plurality of flexible spine orifices. Each of the flexible spines passes a predeter mined length through one of the spine orifices. In another aspect, the mechanism for bowing the spines is a collar slideably mounted to the shaft. In this aspect. each one of the plurality of flexible spines is coupled to the slideable collar. In another aspect, the apparatus includes a sheath having an edge fixed to the closer end of the flexible spines and a movable edge which can be extended to cover the flexible spines and encapsulate the fecal mass. Once the fecal mass is encapsulated by extending the sheath over the bowed spines, the fecal mass can be flattened by straightening the spines and subsequently removed.

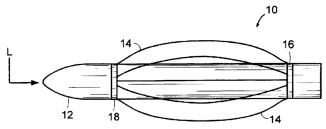

Figure 5: Patent 5,730,726

4.3 Patent 8,105,335 B1

Patent Abstract (2012, NuvoMed); A manually manipulatable tool for removing a fecal impaction, the tool is adapted for insertion into a patient's rectum to engage and penetrate the impaction. The tool is fitted With flexible, accurately configured elements collapsible at least partially during insertion into the rectum and penetration of the fecal impaction, Withdrawal of the tool deploying the elements to exert traction on the impaction thus facilitating Withdrawal of at least portions of the impaction. A body member of the tool is preferably elongated and can optionally be provided With a longitudinally extending lumen for introduction of an enema solution concurrently With or independently of impaction removal.

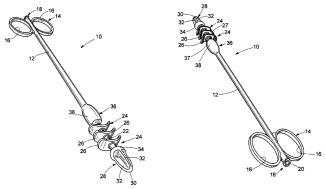

Figure 6: Patent 8,105,335 B1