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ORIGINAL ARTICLE

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The ProTect device in the treatment of severe fecal incontinence: preliminary results of a multicenter trial

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Abstract Background Patients suffering from severe fecal incontinence (FI) in whom surgical treatment has either failed or is inappropriate due to high operative risks and those who refuse to undergo surgery are condemned to living with their embarrassing symptoms, often responsible for progressive social isolation. ProTect is a new, relatively simple, medical device intended for selected patients suffering from severe FI. It consists of a pliable, silicone catheter with an inflatable balloon that seals the rectum at the anorectal junction, acting like an anal plug. The proximal part of the catheter incorporates two contacts that monitor the rectum for the presence of feces. The patient is alerted to an imminent bowel movement and, hence, a potential fecal accident, through a beeper. **Methods** A multicenter trial has been set up to assess the reliability of the device in preventing episodes of FI and to evaluate its impact on quality of life. Patients with significant FI (CCF>10) were prospectively entered into this 14-day study. Two quality of life questionnaires and a daily log of bowel activity and incontinent episodes were completed before and during the study. **Results** Currently, the study enrolled 17 patients and 11 patients (9 women, 2 men) with a mean age of 66 years (range, 46–85) completed the trial. In these 11 subjects, there was an overall significant improvement in the quality of life ($p<0.05$) and a significant reduction in incontinence scores ($p<0.001$) while using ProTect compared to baseline. **Conclusions** The ProTect is a safe non-surgical device that is able to prevent episodes of FI. It is unique because it can be used according to a patient's needs without interfering with activities of daily living.

Key words Fecal incontinence • Non-surgical device • Anal plug • Alerting system

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Introduction

Patients suffering from severe fecal incontinence (FI) unresponsive to medical and surgical treatments and unwilling to accept a permanent stoma are condemned to living with their embarrassing condition, which is often responsible for progressive social isolation.

ProTect (DignityProducts, Dodge City, USA) is a new medical device that is indicated for selected patients suffering from severe FI, as an alternative to diapers, when surgery and other treatments have failed or are not appropriate. The device can be implanted without a surgical procedure, and it can be independently managed by patients or caregivers.

In order to assess the reliability, safety and efficacy of the device in preventing episodes of FI, a multicenter trial has been set up. Additional goals of our study were to evaluate the impact of the device on patients' quality of life. Preliminary results of the ongoing trial are reported.

Materials and methods

The Protect device

The ProTect device consists of a pliable, cuffed, silicone catheter (Fig. 1a). The distal part of the catheter incorporates two metallic contacts that are partially covered by a sleeve, held in position by a sleeve-holder. The two contacts generate a signal when they encounter fecal matter. Approximately 2 cm proximal to the contacts, the catheter has an inflatable cuff (or balloon) which is similar to that on a Foley bladder catheter and is inflated with approximately 30 cm^3 air. Moreover, 4 cm proximal to the balloon there is a "wedge" that is left outside the anal canal in contact with the skin of the anal orifice (Fig. 1b). The wedge regulates the introduction of the catheter into the anal canal and blocks the inflated balloon at the anorectal junction. By doing this, the balloon seals the rectum, acts as a plug, and creates a barrier to the passage of stool from the rectum to the anal canal. A disposable absorbing disk placed on the wedge creates an additional barrier to leakage of liquid fecal matter, preventing staining of underwear. The proximal end of the device consists of a cuff fill valve and a notification box connector. The notification box, which resembles a common beeper, can easily be worn at the waistline. It converts the signal sent by the two contacts into either a prolonged sound or to a vibration movement according to the patient's preference. When feces enter the rectum and reach the two contacts, a signal is sent to the beeper alerting the patient of an imminent bowel movement and, hence, a potential fecal accident. Due to the mechanical barrier created by the inflated balloon, patients are allowed sufficient time to reach a toilet thus precluding any fecal accident. Voluntary evacuation is accomplished after the balloon is deflated and the catheter is removed from the rectum. Once the rectum is emptied, the catheter can be washed with soapy water, a light detergent or a soft cloth, and reinserted.

Study protocol

Seven centers are participating in this multicenter trial, which is being conducted according to the principles of human research established in Helsinki. The selection criteria for study entry are: age ≥18 years, severe FI (CCF score ≥10) [1] interfering with lifestyle, work and social activities; ability to provide written informed consent; and ability to comply with the research protocol. Patients with acute inflammation of the anal canal or recent (less than 3 months) low- rectal or anal anastomosis are excluded.

Patients' medical and surgical histories are thoroughly recorded at study entry. An anoscopy is performed before and after the trial to exclude acute inflammation of the anal canal.

Patients are requested to use the device for 14 consecutive days during waking hours, and to record their symptoms and personal acceptance of the device in a daily diary. The CCF score [1] and the AMS incontinence scores [2] are calculated for each participant at day "zero" before using the device (baseline) and then, again, at day "14" of the trial with reference to the previous 14 days with the device on.

Quality of life was assessed on the FIQOL questionnaire [3] and on the GIQOL questionnaire [4]. In addition, patients were asked, both before and during treatment, to subjectively evaluate quality of life by assigning a score on a scale from 0 to 10, where 0 represents the worst imaginable and 10 the best imaginable quality of life.

Statistical analysis

The paired *t* test is used to compare baseline results with those obtained during use of the device.

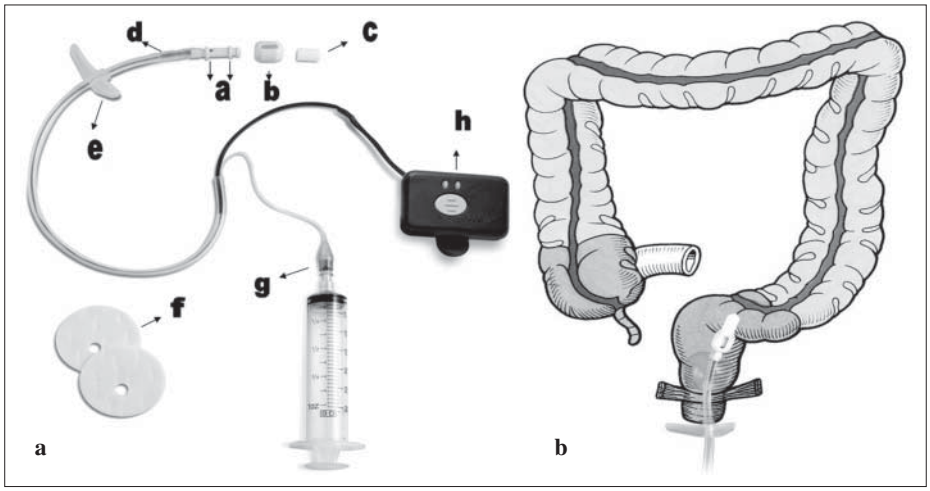

Fig. 1a, b The ProTect device (Dignity Products). **a** Components of the device: *a*, contacts; *b*, sleeve; *c*, sleeve-holder; *d*, inflatable balloon; *e*, wedge; *f*, absorbing disks; *g*, cuff fill valve; *h*, beeper. **b** Use of the device in the anal canal

Results

To date, a total of 40 patients (32 women and 8 men) of age ranging from 42 to 85 years with suffering from FI were screened in seven centers as candidates for this trial. However, 23 patients refused to enter the trial for various reasons: 8 patients considered the device too big, 6 were unable to follow instructions for correct use, 5 had severe arthritis hindering manual dexterity, and 4 refused for personal reasons. Therefore, 17 patients entered the study and 11 of these completed the 14-day trial. All patients who entered the study were either not candidates for surgery or had undergone surgical procedures and refused any further surgical treatment. In most of these patients (14 out of 17), biofeedback or several different minimally invasive procedures (sacral nerve stimulation, regular rectal emptying with enemas, anal plugs) had failed. The 11 patients who completed the trial included 9 women and 2 men, with an average age of 66 years (range, 46–85 years). The etiology of FI was idiopathic in five cases, neurological in two cases and a sphincter defect in four cases (two congenital and two iatrogenic). The withdrawal of 6 patients was motivated by the inability to follow the study protocol (one case), non-compliance and lack of motivation (two cases), and frequent alarm system activation due to continuous presence of liquid stool in the rectum (three cases).

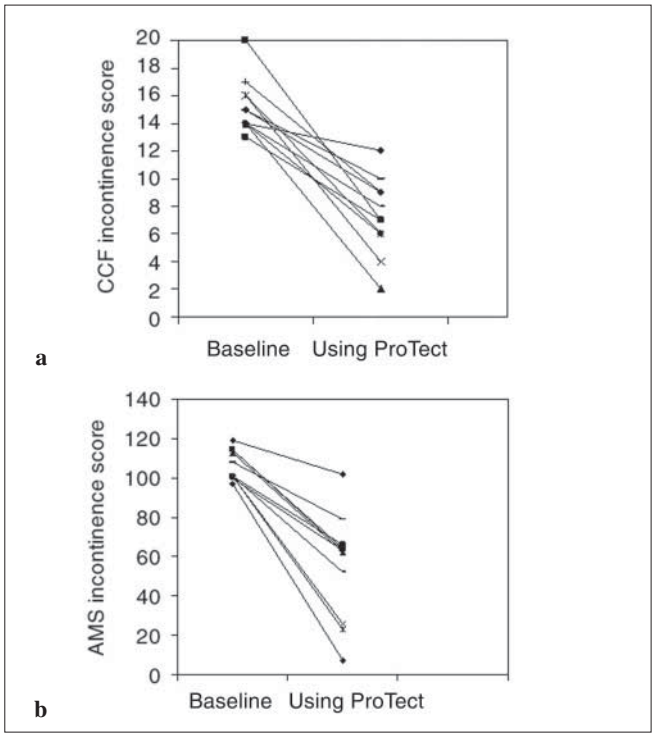

Fig. 2a, b *Incontinence score evaluation*. **a** CCF incontinence scores. **b** AMS incontinence scores

Of the 11 patients who completed the 14-day trial, 7 (64%) reported personal satisfaction and an overall positive experience regarding the efficacy of ProTect in preventing fecal accidents. The CCF incontinence score (Fig. 2a) significantly decreased with the use of ProTect, from a mean of 15.3 (range, 13–20) to 7.2 (range, 2–12) ($p<0.001$). Similarly, the AMS incontinence score decreased from a mean of 107 (range, 100–119) to 60 (range, 7–102) ($p<0.001$) (Fig. 2b).

The mean weekly number of accidents drastically decreased from several daily episodes to none or one weekly episodes in 7 patients. In addition, a reduction in the use of pads or diapers was reported from several day to

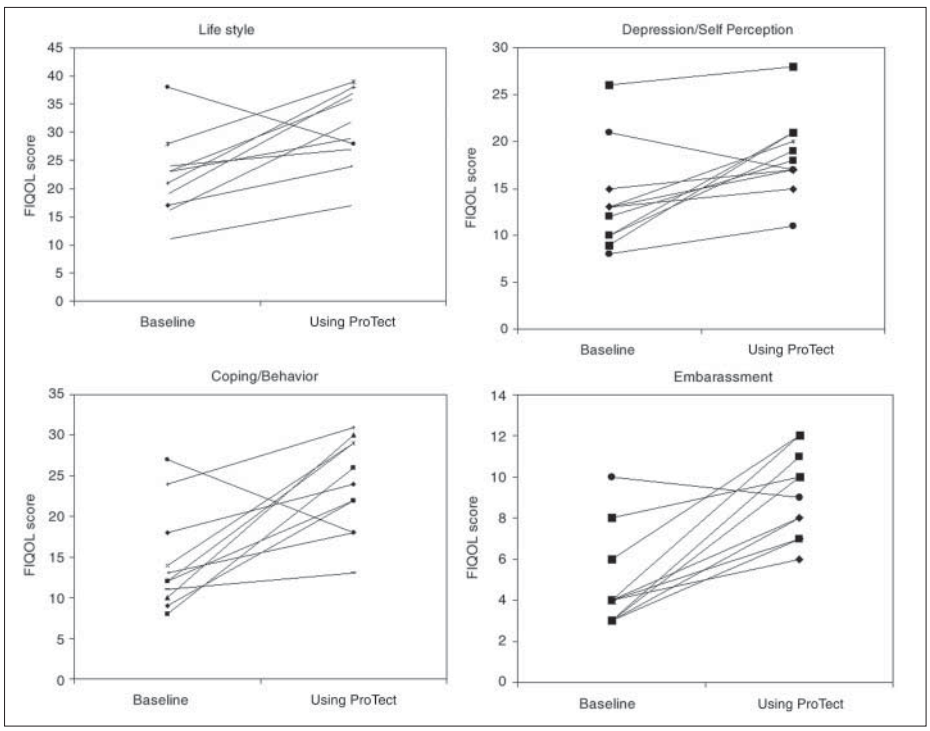

Fig. 3a-d *FIQOL questionnaire scores*. **a** Lifestyle domain. **b** Depression and self-perception domain. **c** Coping and behavior domain. **d** Embarrassment domain

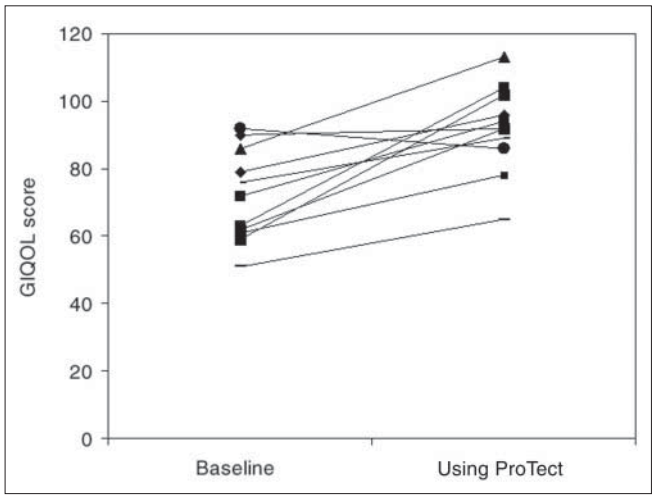

Fig. 4 Gastrointestinal quality of life (GIQOL) scores

one or two weekly in the same number of patients. However, voluntary control over gas was not improved in most cases.

Significant improvement in quality of life was observed for all four domains analysed on the FIQOL scale (Fig. 3a-d). In particular, the FIQOL lifestyle score increased from a mean of 22.4 (SD=7.6) to 31.0 (SD=6.9) (p=0.02). The depression and self-perception score increased from 13.6 (SD=5.4) to 18.3 (SD=4.3) (p=0.034). The coping and behavior score increased from 14.4 (SD=6.1) to 23.8 (SD=5.8) (p=0.0018). Finally, the embarrassment score changed from 4.7 (SD=2.3) to 9.0 (SD=2.0) (p=0.0002). Only one male patient with idiopathic incontinence showed a worsening of scores, due to anxiety in copying with the device and following the instructions. Nevertheless, even this patient reported fewer episodes of fecal incontinence while using the device. Increased quality of life was also recorded with the GIQOL score, which changed from a mean of 71.9 (SD=13.7) to 91.9 (SD=12.9) (p=0.002). Overall patients' subjective evaluation of quality of life significantly improved with the use of the device: baseline mean, 3.72 (range, 0–8); using the ProTect, 7.36 (range, 4–10) (p=0.0004).

Not all patients were able to continue to use the device since it is not yet available on the market. The 5 patients who continued to use the device responded to a telephone interview at a median time of 6 months after the trial (range, 3–11). In all cases, identical results in terms of reduction of episodes of incontinence were reported.

Discussion

Current medical and surgical procedures intended for the cure of severe fecal incontinence have variable and often unpredictable results [5–9]. In particular, the long-term follow-up of most surgical treatments shows an inevitable decrease in the success rate [10–13]. As a consequence, a considerable number of patients suffering from fecal incontinence must use diapers or other appliances and live with embarrassing symptoms often responsible for progressive social isolation and psychological impairment.

Anal plugs have been used to prevent episodes of fecal incontinence [14]. However, the pressure of the fecal stream, intraluminal gas and rectal peristalsis may easily cause an involuntary expulsion of the plug, regardless of its size. Timing and modality of plug expulsion are totally unpredictable. In addition, a high rate of intolerance and discomfort to anal plugs has been reported [15].

The ProTect is the latest version of a non-surgical device that has already been tested in a pilot study at the Cleveland Clinic Florida [16]. Its indications include patients suffering from severe fecal incontinence impairing their quality of life, who are motivated enough to manage their own treatment. When compared with a simple anal plug, the ProTect device has the advantage of including an alert system that notifies the patient when it is time to evacuate, thus preventing the natural expulsion of the plug and, consequently, a fecal accident.

Compared to the first generation of the device, the current ProTect has a different sensor (with metallic contacts) and an easier-to-use beeper controlled by different software. Other new features include: the protective sleeve that prevents false alarms due to mucous, the wedge that regulates the introduction of the device into the rectum, the absorbing disk that creates an additional protection against leakage, and a newly shaped balloon that seals the rectum at the anorectal junction. These changes were made in order to improve the efficacy and reliability of the first device and to facilitate its use.

The preliminary results of our multicenter trial showed that the ProTect is well tolerated and can be easily used by any individual with a good manual dexterity and mental capability. In fact, when the device was correctly used, a significant reduction in frequency and severity of symptoms of fecal incontinence was reported. The ProTect showed better results in patients with formed or semi-formed stool. In some patients, the constant presence of watery diarrhoea caused a frequent activation of the alert system. This was considered unacceptable by some patients and was reported as the reason for withdrawal from the trial in three cases. In fact, the alert system of the device is able to detect the presence of stool in the rectum but cannot "quantify" it. As a consequence, patients may be alerted even in presence of small quantities of feces in the rectum. However, despite the few episodes of inappropriate alarming reported by some cases, the reduction in frequency and severity of episodes of FI due to the mechanical barrier component cannot be underestimated.

The patients' motivation to overcome their embarrassing symptoms and improve social life played a crucial role

in the acceptance of the device. This explains why many who were screened for the study declined to participate: some expressed that the device was "too complicated" or admitted of being "too anxious" to follow instructions. With regard to these issues, as with all self-administered treatments and modalities, strong psychological support and encouragement offered by physicians and nurses and, above all, adequate patient training play a major role in improving the understanding of the device and compliance. By using the device, most patients (7 out of 11, 64%) in our study described themselves as more confident to overcome their social isolation and to resume normal activities. However, a larger group of patients is needed in order to better define the ideal group of patients who may gain major benefits by the use of the device.

Because the device is usable for 28 days, it is potentially more cost-effective than other devices or appliances used to treat FI. What makes the ProTect device unique among other devices is that it can be used according to each patient's needs without interfering with activities of daily living. In this regard, even intermittent or occasional use can potentially improve a patient's quality of life, restore dignity and provide an acceptable and productive social life.

We predict that the device will be largely used in the elderly population. Another potential application is in bed-ridden patients. In these cases, a telemetry system could be used to alert caregivers, who would respond by placing the patient on a bedpan, thus preventing the incontinence episode.

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