



## Original research

# Simultaneous Delorme's procedure and inter-sphincteric prosthetic implant for the treatment of rectal prolapse and faecal incontinence: Preliminary experience and literature review<sup>☆</sup>



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## HIGHLIGHTS

- A combination of techniques to treat rectal prolapse and incontinence is described.
- To date, there are no published data on a similar approach.
- Simultaneous treatment of prolapse and incontinence seems safe and feasible.
- Treating Incontinence during surgery for rectal prolapse should be always considered.

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## ABSTRACT

**Aim:** Rectal prolapse is a distressing condition affecting mostly elderly patients and females. Delorme's procedure is frequently performed since it offers good results and is burdened by a particularly low morbidity. Faecal Incontinence is associated with prolapse in a large percentage of patients, due to the sphincter damage caused by the prolapsed rectum through the anal canal. Prolapse resection is often ineffective in treating incontinence, and further specific procedures are frequently required. At present, no data are available on combined Delorme's procedure with the implant of Bulking Agents for the simultaneous treatment of rectal prolapse and faecal incontinence.

**Method:** Three patients affected by complete external rectal prolapse underwent simultaneous Delorme's procedure with application of six polyacrylonitrile prosthetic cylinders in the inter-sphincteric space (Gate Keeper™, THD, Correggio Italy). Follow up was at 3, 6 and 12 months.

**Results:** Gate Keeper procedure required a short operative time; no morbidity or complications were experienced. Prolapse was successfully treated in all patients and the mean Vaizey's incontinence score value dropped from pre-operative 19.3 to 9.3 after 3 months. All patients experienced a reduction of incontinence episodes and an improvement in daily activities and lifestyle.

**Conclusion:** Gate Keeper implant is feasible and safe when associated to surgical procedures like Delorme's prolapse resection. Preliminary results are positive even if a study with a larger numbers of patients is needed to confirm the efficacy. A simultaneous treatment of faecal incontinence should be always considered when performing surgery for rectal prolapse.

**Short statement:** The present manuscript describes a simultaneous combination of two surgical techniques to treat rectal prolapse and faecal incontinence. To date, there are no published data on a similar approach. The paper underlies the importance of treating faecal incontinence when performing surgery for rectal prolapse.

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## 1. Introduction

Full thickness rectal prolapse is a distressing condition that usually affects elderly patients. The disease is more frequent in

females, and the incidence is increased after 50 years of age, with a peak in the seventh decade [1]. Other anatomical defects are frequently associated with rectal prolapse: diastases of the levator ani, a deep pouch of Douglas, a redundant sigmoid colon, a lack of normal fixation of the rectum with a mobile mesorectum and a stretching of the anal sphincters with a progressive lack of muscular competence and continence ability [2]. This explains why patients with rectal prolapse suffer from not only a prolapsed rectum but also associated dysfunction. A large percentage of patients suffering from rectal prolapse also complain from faecal incontinence (FI), obstructed defecation and chronic constipation; in this patients the frequent straining during defecation induces an injury of the rectal mucosa, often leading to rectal ulcer development [3]. FI in external rectal prolapse has two different components: the prolapsed mucosa generates a continuous secretion that causes a soiling that can be serous-mucous as well as serous-haematic in case of mucosal ulcers and erosions; the stretching of the muscles induces a progressive weakness of the sphincters affecting their resting tone and reducing their contractile strength. While the soiling from the external mucosa tent to resolve after the surgical treatment of the prolapse since no mucosa is left outside the anus, the damage on the sphincters, if left untreated, causes an incomplete resolution of incontinence even if the prolapse has been successfully cured. There are several different surgical techniques available to treat rectal prolapse, including abdominal rectopexy with or without prosthetic materials (Ripstein anterior rectopexy, Frykman-Goldberg resection rectopexy, Wells posterior rectopexy) performed open or laparoscopically as well as perineal approach of the disease as is in Delorme's and Altemeier's procedure. The perineal approach seems to be more indicated in elderly patients in order to avoid the complications of pelvic surgery and the risks of an intra abdominal bowel resection and anastomosis [4]. The purpose of treatment for rectal prolapse is correction of the prolapsed rectum as well as recovery and prevention from defecation dysfunction postoperatively; despite the common association between rectal prolapse and FI, only few studies assessed the possibility to treat the two symptoms simultaneously with the adoption of combined procedures. Only two studies reported a series of cases where Delorme's procedure was associated with a post-anal repair to reduce the post-operative incidence of FI. To date, no published data are available on the association between Delorme's procedure and the application of Bulking Agents (BA) to treat FI and rectal prolapse.

Aim of the study is to establish the efficacy and safety of a simultaneous rectal prolapse resection with the inter-sphincteric implant of six polyacrylonitrile prosthetic cylinders (Gate Keeper™, THD, Correggio Italy) for the management of FI.

## 2. Materials and methods

Three patients (3 females) with complete rectal prolapse and faecal incontinence were treated by using a combined Delorme's technique followed by the application of implantable prosthesis in the intersphincteric space. One patient had a recurrent rectal

prolapse after a stapled transanal rectal resection, while 2 patients underwent their first rectal prolapse repair. Moderate to severe faecal incontinence was reported at the time of clinical examination and assessed with the Vaizey's FI score (0–24). Preoperative diagnostic tests included physical examination, colonoscopy, anal manometry and anal ultrasound. In all patients a visible complete rectal prolapse of at least 5 cm was present. Patient's characteristics are described in Table 1. Bowel preparation was based on 2–3 enemas the night before and the morning of the operation. An antimicrobial prophylaxis with Metronidazole (500 mg/ev) and Cefazoline (2 gr/ev) was applied. An experienced colorectal surgeon performed the procedure in all patients. The mean follow-up period was 8 months (range, 12 to 6 months). Follow up was at one week after discharge, and then at 1, 3, 6 and 12 months post operatively.

## 3. Surgical technique

All patients were treated under general endotracheal anaesthesia, in lithotomy position. Using a 1:200,000 epinephrine solution injection into the submucosal plane, a circular incision was made through the mucosal and the submucosal layers about 1 cm above the dentate line; a sleeve of mucosa was dissected, revealing the rectal circular muscular layer up to the prolapse vertex. Ten to twelve absorbable stitches with longitudinal sutures were applied to plicate the rectal musculature in order to reduce the prolapse. After the dissected mucosa had been excised, the prolapse was pushed back through the anal canal and the sutures tied. Following the Delorme's procedure, 6 polyacrylonitrile prosthetic cylinders with memory shape were inserted in the intersphincteric space using a dedicated device (Gate Keeper™, THD, Correggio Italy) according to the original technique as is described elsewhere [10]. In brief, the application begun with 2-mm skin incisions at the 1, 3, 5, 7, 9 and 11 o'clock positions in the perianal area, about 1–2 cm from the anal margin. With the surgeon's index finger placed into the anal canal to ensure a correct position of the cylinder and to avoid any damage of the mucosa, the dedicated introducer of the prosthesis was advanced through the skin incision up into the intersphincteric space until the upper part of the external sphincter was reached; at this point, by pressing the proper button on the device, the polyacrylonitrile cylinder was released in the intersphincteric space, and the wound skin incision sutured with a absorbable 2-0 stitch. The same procedure was repeated for all six positions. The thin cylinders (length 21 mm, diameter 1.2 mm) of polyacrylonitrile are designed to change shape and volume in 1–2 days after implantation, becoming thicker (diameter 7 mm), shorter (length 17 mm) and softer in order to offer a radial additional compression within the muscular complex to improve patient's continence ability.

## 4. Results

Mean operative time was 107.6 min (range 98–125) where mean time of Gate Keeper implant was 27.6 min (range 20–35), mean blood loss was less than 200 ml. No intra operative complications occurred with a mean mucosal resection length of 17.6 cm (16–19). Post-operative course was uneventful in all cases, with a mean post-operative stay of 3.5 days (3–4). First defecation occurred after 48 h in all cases stimulated by oral administration of Lactulose and fibres supply. Pain management required mild oral analgesic (Acetaminophen 1 gr/twice a day and/or Ibuprofen 500 mg/twice a day) for no more than 72 h from surgery. No bleeding, local or systemic infections were experienced at immediate and late follow-up. Intra muscular prosthesis were well tolerated and no chronic pain or discomfort was reported. At 3

**Table 1**  
Patients characteristics.

Patient/ age	Manometry rest/squeeze (mmHg)	Anal EUS internal sphincter (mm)	Anal EUS external sphincter (mm)	Anal EUS sphincter damage	Previous anorectal surgery
82	22/65	1	4.1	No	Haemorrhoids
76	35/80	<2	5.2	No	Prolapse
74	42/70	<2	5.9	No	None

**Table 2**  
Comparison between Vaizey Score pre and post operatively.

Vaizey parameters	Solid stools pre/post	Liquid stools pre/post	Gas pre/post	Lifestyle pre/post	Pad/plugs pre/post	Costipating medicines pre/post	Defer defecation pre/post	Total pre/post
Pt. 82 y.o.	3/1	3/2	4/2	4/2	2/2	2/0	4/4	22/13
Pt. 76 y.o.	2/0	3/1	4/1	4/2	2/2	0/0	4/4	19/10
Pt. 74 y.o.	2/0	2/1	4/1	3/1	2/2	0/0	4/0	17/5

months follow up the Vaizey's score questionnaire for FI was administered to assess FI results. Mean values of the Vaizey's score dropped from 19.3 to 9.3 (patient 1: 22 to 13; patient 2: 19 to 10; patient 3: 17 to 5) with a significant improvement in lifestyle and frequency of incontinence episodes. Urgency was the parameter that seemed to be less affected by the Gate Keeper application (Table 2). Endo-anal US scan at 30 days confirmed the presence of the six cylinders in the intersphincteric space in all patients with no misplacing or migration. No prolapse recurrence was experienced and results for FI were stable at follow up of 6 months in two and 12 months in one patient.

## 5. Discussion

Faecal Incontinence is often associated in patients with external rectal prolapse, and the treatment of the latter condition not necessarily resolves both symptoms. After prolapse resection, when a stable reduction of the redundant tissue above the anal canal is performed, patients often experience a reduction of serous and mucus soiling that it is mainly maintained by the presence of an external rectal mucosa. On the other hand, when no prolapse is longer acting as a lid through the anal canal, the weak sphincteric complex loses its ability in maintaining an adequate continence especially for liquid stools and gas; in those patients usually the prolapse reduction ameliorates the sero-haematic soiling making incontinence for stools definitely worse. This is why patients with rectal prolapse often complain for both obstructed defecation symptoms and incontinence and this is why, following prolapse resection, an adequate treatment of FI should also be planned. The first report of a combined procedure for rectal prolapse and FI dates back to 1987, when Delorme's procedure was associated to retro-anal plication in a small number of patients [5]. Since then, only two studies were published on the same topic. In a recent study from Youssef et al. [6] on 82 patients undergoing Delorme's procedure with or without post anal repair and levatorplasty, there was a significant improvement of FI in patients treated with sphincter repair compared to the ones receiving a prolapse treatment alone. Elgadaa et al. [7] reported similar results in a series of 20 patients treated with simultaneous Delorme's prolapse resection and post anal repair, with a follow up over 65 months. Recently, new minimally invasive techniques to treat FI have been developed, including the use of several Bulking Agents injected in the submucosal area just above the dentate line or in the inter sphincteric space. Among them a new method called Gate Keeper (THD, Correggio, Italy), based on the injection of up to six cylinders of polyacrylonitrile, seemed to show promising results in reducing incontinence and improving quality of life. Gate Keeper technique uses a dedicate disposable device designed to implant in the inter sphincteric space an hydrophilic material that within 1–2 days after operation increases its thickness while reducing its length; the prosthesis augment the volume of the whole sphincteric complex increasing the continence ability of the muscular system. The placement of the bulking agents in the area limited by the two muscles seems also to reduce dissipation and migration of the prosthetic material, both representing important limits of other Bulking Agents efficacy, especially in the long time period [8,9]. In a

study by Ratto et al. [10] 14 patients were treated with the Gate Keeper and followed up to 48 months (Median 33.5) after surgery. Results of this study showed a significant reduction of episodes of incontinence in the majority of patients, with a mean Vaizey's score value dropping from 15.4 to 6.9 at three months follow up and an increasing in patients physical function, general health, social function, emotional and mental health when compared to the pre operative assessment. In our limited study on an elderly population, we experienced the same trend in reduction of incontinence episode and gain in quality of life. Another important aspect to consider is that the application of Bulking Agents performed just after the mucosal prolapse resection do not add any adjunctive difficulty to the whole operation since the inter sphincteric space is not violated during Delorme's procedure and the Gate Keeper application can be easily done in the same manner as it would be without any previous procedure. For the same reason, the efficacy of the prolapse resection is not impaired by the bulking agents application, as it was in our series of patients. Since the main risk of any foreign body implant is infection, in our experience extra care was made to avoid any faecal contamination before starting the Gate Keeper procedure: at the end of the Delorme's operation the perineal area was cleaned with antiseptic solution and all the instruments and scrubs previously used were changed with new sterile ones. The combined procedure, in our series was not burdened by any complication or morbidity, with all patients having an immediate return to their normal activity and a limited hospital stay considering their age range.

Accepting the idea that treating FI just after prolapse resection should always be considered when technically feasible, the choice of a minimally invasive technique to add to the Delorme's procedure might have several advantages especially in the elderly population and in patients with significant co-morbidity when compared to more complex surgical options [11,12].

## 6. Conclusions

In the era of new Bulking Agents and modern strategies in treating FI, we tried to assess the feasibility and the efficacy of the association between the Gate Keeper placement and the Delorme's procedure in a small series of elderly patient. Our preliminary results seem to be positive; no complications and morbidity were experienced, prolapse treatment was effective and the expected results of Delorme's resection were not negatively affected by the adjunctive procedure aimed to treat FI. Regarding Incontinence, there was an improvement in lifestyle and a reduction in time and severity of FI episodes. Urgency (within 15 min) seemed the most difficult symptom to control with a sensible reduction of this symptom in only one on three patients. Larger number of patients is required to validate the preliminary data.

## Ethical approval

None required.

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**Author contribution**

All authors substantially contributed to the paper from data acquiring to drafting and editing.

**Conflicts of interest**

None.

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