



Contents lists available at ScienceDirect

## International Journal of Surgery Case Reports

journal homepage: [www.casereports.com](http://www.casereports.com)

## The Gatekeeper™ for fecal incontinence: Another trial and error



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## ARTICLE INFO

## Article history:

Received 3 July 2014

Received in revised form 30 July 2014

Accepted 3 August 2014

Available online 12 October 2014

## Keywords:

Gatekeeper

Fecal incontinence

Bulking agents

## ABSTRACT

**INTRODUCTION:** The Gatekeeper™ is the most recent bulking agent used in the treatment of fecal incontinence with no reported complications. This case reports side effects similar to other bulking agents, namely migration of the prosthesis and perianal abscess.

**PRESENTATION OF CASE:** A 52 year old gentleman presented with a history of fecal soiling. He underwent uncomplicated surgery in 2012 for 6 Gatekeeper™ implantations with only temporary improvements. In 2013, endorectal ultrasound revealed prosthesis migration. In 2014, he presented with a perianal abscess which contained one of the prosthesis.

**DISCUSSION:** The Gatekeeper™, made of the inert Hyexpan, typically implanted in the intersphincteric region, has been used for the treatment of fecal incontinence since its discontinuation in the treatment of gastroesophageal reflux disease.<sup>5</sup> The Gatekeeper™ was implemented on a small number of subjects for which the typical side effects of bulking agents were not seen.

**CONCLUSION:** Larger studies need to be conducted to investigate the advantages or perhaps disadvantages of the Gatekeeper™ over other bulking agents.

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## 1. Introduction

Fecal incontinence can negatively affect a person's lifestyle in many ways, if not greatly psychological. The incidence has been difficult to acquire as the majority of people suffering from fecal incontinence are reluctant to get medical help. It has been suggested that between 2%<sup>1</sup> and 7% of the general population suffer from fecal incontinence but this is definitely a much lower percentage of the population than actually exists.

The Gatekeeper™, one of the latest agents used for the improvement or perhaps even treatment of fecal incontinence, has been named the "novel"<sup>2</sup> bulking agent. With only two studies currently available on the Gatekeeper™,<sup>2,3</sup> it was concluded that it was the 'ideal' bulking agent for many reasons including the fact that it has no known complications as of yet and in addition, maintains medium to long term results, unlike other agents.

Almost everything has complications. Clearly, more research is needed, and, for complications to be picked up by the radar, a bigger population needs to be studied.

## 2. Case presentation

A 52 year old Arab gentleman presented complaining of passive soiling since 2007 which mainly occurred post defecation. He

would have more than 10 episodes per week; however, he did not need to wear pads. He had no complaints of urinary incontinence, sexual dysfunction, constipation or any complaints of sensing incomplete evacuation at the time of presentation. The Cleveland Clinic incontinence score<sup>4</sup> was 4.

The patient is a known case of bipolar disorder diagnosed over 5 years ago, on Lithium, and has a past history of L5-S1 disc prolapse since 2002 for which microdiscectomy was done in 2008. He had no history of other surgeries or history of pelvic trauma.

In 2007, he was followed up by the urology team for voiding problems but when he attended the surgical clinic in 2009, the voiding issues were resolved. He was examined and advised physiotherapy as his anal sphincter tone was normal and no underlying pathologies were found; colonoscopy was unremarkable.

When the patient was reviewed again in 2010, it was diagnosed that he had a long anal canal, which was the basis of his fecal soiling. No intervention was planned apart from continued physiotherapy.

In 2012 he was reviewed again, still he was symptomatic and did not improve with physiotherapy. He underwent surgery for the Gatekeeper™ implantation; 6 implants were inserted at 1, 3, 5, 7, 9 and 11 o'clock positions. There were no complications during the implantation process. Post operatively he was advised to take rest for 1 week and to avoid any physical exercise for another 3 weeks.

He was reviewed 3 months post operatively and some improvements were noted with regard to the soiling which had decreased to 3 episodes per week. The Cleveland Clinic score<sup>4</sup> was then 3. One year post operatively, the patient reported that the frequency of soiling had returned to more than 10 episodes per week as

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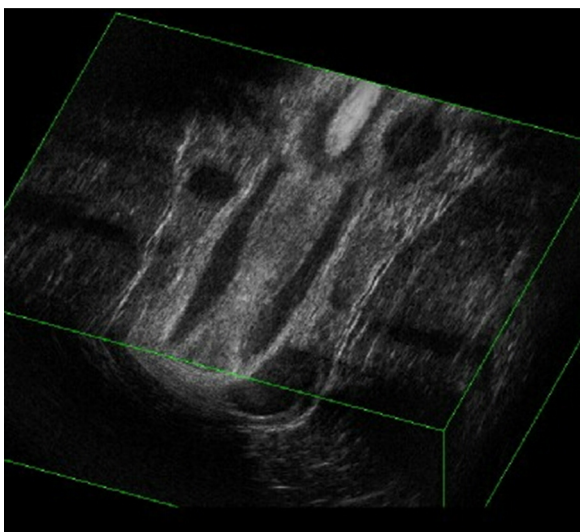


Fig. 1. Endorectal ultrasound showing the migrating gatekeepers.

was initially. Endorectal ultrasound was done and revealed the migration of the bulking agents from the intersphincteric region (Figs. 1 and 2).

In 2014, he presented with perianal pain and swelling and was diagnosed to have a perianal abscess, for which incision and drainage was done and one of the gatekeeper prosthesis popped out of the abscess cavity (Fig. 3).

### 3. Discussion

The Gatekeeper™ was first used in the treatment of gastroesophageal reflux disease.<sup>5</sup> After its use was discontinued, the Gatekeeper™ was implemented for the treatment of fecal incontinence. However, being an agent of the new generation of bulking agents, not enough subjects were studied to record side effects; and

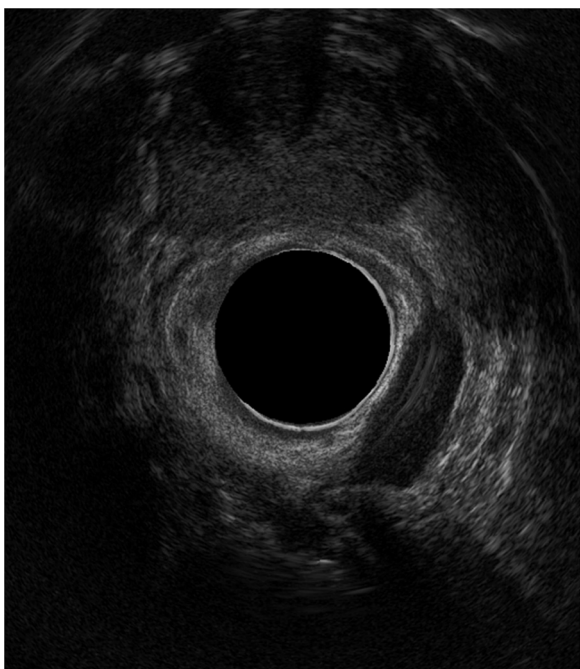


Fig. 2. Migrated Gatekeeper near the prostate level.



Fig. 3. Gatekeeper prosthesis obtained from incision site of perianal abscess.

of the few subjects that were operated on, no complications were found in the medium and long term follow ups.

The Gatekeeper™ is made of HYEXPAN™ (polyacrylonitrile), an inert and durable material that is implanted in the intersphincteric region and over time absorbs water and expands to the appropriate shape, size and consistency to act as an ideal bulking agent. The intersphincteric placement was preferred in order to reduce the risk of fistulas, ulcers or migration to other parts of the body as any foreign body would.

Generally, the complications of bulking agents include<sup>6</sup>: ecchymosis, inflammation, anal ulceration, perianal abscess, and sepsis. They may also include general symptoms like abdominal pain, post-operative proctalgia, fever, diarrhea and constipation.

### 4. Conclusion

Numerous trials have been carried out using various types of bulking agents but regrettably none of them have been able to maintain their success rates over long periods of time. The Gatekeeper™ was assumed to have done the trick – solving all the problems that other bulking agents had. However, with not many studies done on the product, it had not revealed its side effects.

Unfortunately, in this particular case, regardless of the intersphincteric placement of the prosthesis, migration had occurred along with the formation of a perianal abscess later on.

Larger studies and longer follow ups are needed to understand the possible side effects of the Gatekeeper™ more deeply.

### Conflict of interest

The authors declare that they have no competing interests.

### Funding

No source of funding or sponsor.

### Ethical approval

Written informed consent was obtained from the patient for publication of this case report and accompanying images. A copy of the written consent is available.

### Author contributions

Dr. Labib Al-Ozaibi: Study design; Dr. Yasmin Kazim: Writing; Dr. Wessam Hazim: Data collection; Dr. Alya Al-Mazroui, Dr. Faisal Al-Badri: Data analysis.

### Key learning points

- The bulking agents in treating fecal incontinence did not prove to be effective.
- The Gatekeeper™ which was assumed to solve the problems and side effects of the other bulking agents unfortunately has the same problems.
- It acts as a foreign body with subsequent risk of infection and fistula formation.

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