Chapter

Anal Injectable and Implantable Bulking Agents for Faecal Incontinence

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Abstract

Faecal incontinence (FI) is a common condition, the prevalence of which increases with age. It is associated with a negative impact on the quality of one's life. The aetiology is multifactorial; hence, both the diagnosis and the treatment of faecal incontinence may be challenging. A variety of surgical treatments for faecal incontinence have emerged over the years. One of these is the use of anal bulking agents. Anal bulking agents have been available for over 25 years, with various studies being published. Initial results were disappointing, mainly due to lack of efficacy and reliability as well as concerns about safety. Great strides have been made recently with the introduction of the anal implants Gatekeeper (GK) and Sphinkeeper (SK). This chapter explores the evolution of anal injectables and implants, discusses operative techniques and provides a critical analysis of the results of the various studies to date.

Keywords: faecal incontinence, anal sphincter, anal implants, anal injectables, anal bulking agents, gatekeeper, Sphinkeeper

1. Introduction

Faecal incontinence (FI) may be defined as an impaired ability of the control of the release of flatus or faeces. It is a socially stigmatising condition that may have an adverse effect on one's quality of life. From the financial point of view, the investigation and treatment of faecal incontinence may add to a significant cost to the health systems of most countries. In fact, the annual treatment cost of patients in the UK with urinary and faecal incontinence is of about £500 million.

Many factors may be involved in the pathophysiology of FI. A thorough clinical assessment of the patient is therefore mandatory. This starts with a full history, which may include a cognitive assessment if necessary. The characteristics of the faeces and the type and frequency of incontinence should be noted. Urge incontinence is suggestive of poor external anal sphincter (EAS) function, whilst passive and post-defaecatory incontinence indicates that internal anal sphincter (IAS) function is weak. Various questionnaires that enable the clinician to quantify the degree of incontinence and the impact on quality of life are available. These include symptom-specific questionnaires, such as the ones developed by Vaizey et al. [1] and Wexner et al. [2]

and the faecal incontinence quality of life (FIQOL) scale developed by Rockwood et al. [3], and also generic questionnaires such as the Short Form 36 (SF 36) [4].

A full examination of the patient, including the abdomen and perineum and a neurological examination in some cases, is necessary. Beneficial investigations include a flexible sigmoidoscopy, anal manometry (resting and squeeze pressure), rectal compliance, pudendal nerve terminal motor latency (PNTML) and endoanal ultrasound (EAUS). Clinicians, however, need to be able to determine which test to perform, and when, as well as be able to correctly interpret the results.

The management of FI is complex and multidisciplinary, involving the general practitioner, continence nurse, physiotherapist, gastroenterologist, urologist and colorectal surgeon. Conservative measures, which include patient education and support, improvement in diet and bowel habit, judicious use of anti-diarrhoeal medication and pelvic floor exercises, are used in the first instance. This is, in fact, recommended in the UK by the National Institute for Clinical Excellence (NICE) guideline 'CG49 Faecal Incontinence' [5]. If these measures fail, surgical intervention may be necessary. A variety of surgical options are available, with the appropriate therapy being selected depending on the cause of the incontinence and the patient's cognitive function and general physical condition (**Table 1**). One of the surgical options available is the use of anal bulking agents.

1. **Restoration and improvement of residual sphincter function**
a. Correcting a defective external anal sphincter
Sphincteroplasty (end-to-end repair; overlap repair)
b. Correcting a defective pelvic floor:
Levatorplasty
Postanal repair
Total pelvic floor repair
c. Correction of anorectal deformities
d. Sacral nerve stimulation (SNS)
e. Posterior tibial nerve stimulation (PTNS)
2. **Increasing the outlet resistance of the anal sphincter**
a. Augmentation of the anal sphincter and anal cushions (anal bulking agents)
b. Anal submucosal fibrosis (SECCA)
c. Anal encirclement (Thiersch procedure)
d. Non-dynamic graciloplasty
3. **Dynamic sphincter replacement**
a. Dynamic graciloplasty
b. Artificial anal sphincter
4. **Antegrade continence enema (ACE)**
5. **Faecal diversion**
a. Colostomy
b. Ileostomy

Table 1.
Surgical options in the management of faecal incontinence.

2. Anal bulking agents

Anal bulking agents have emerged as a treatment for FI, following the success of bulking agents for urinary stress incontinence in females. In the urology setting, bulking agents have been employed to augment the bladder neck and increase urethral resistance [6]. Therefore, the aim of anal bulking agents is to prevent FI by closing the anal canal or increasing the pressure within the anal sphincter.

The ideal characteristics of a bulking agent have been described in the literature [7]. The injected or implanted substance should be biocompatible, non-migratory, non-allergenic and noncarcinogenic. The substance should also be easy to inject or implant and should produce an improvement in continence, both in the short term and in the long term.

2.1 The evidence for anal bulking agents

Anal injectables and implantables have been used to manage faecal incontinence for over 20 years. It may be useful to chart their development over the years and to classify this development into three phases. The first phase consists of the initial experimental studies that took place in the 1990s. The second phase, from about the year 2000 onwards, encompasses an increase in the number of studies using a wide variety of agents and injection techniques. The third phase features the latest generation of anal bulking agents, the implantable polyacrylonitrile, available as Gatekeeper (GK) and Sphinkeeper (SK) devices.

2.2 Initial studies: The first phase

Anal bulking agents were first described in 1993 by Shafik [8]. Shafik, an Egyptian surgeon, is considered to be a pioneer in this field. In his first study, he described the outcomes following the injection of 5 ml of PTFE (polytef/Teflon) paste in 11 patients, 7 of whom had incontinence following a lateral internal sphincterotomy for anal fissure. In another study, the same author used 60 ml of abdominal wall fat as a submucosal injection into the rectal neck at 3 and 9 o'clock in 14 patients with partial faecal incontinence [9]. Pescatori's group from Rome, Italy, reported the use of anal injection of autologous buttock fat to restore continence in one patient who had poor results following a sphincteroplasty. This patient's continence improved following repeated injections [10].

The indications for injection of the anal bulking agents in these studies were various. Most patients had passive FI, but some had urge incontinence, indicating EAS disruption. The results of these initial studies showed that continence was improved in the short term. However, the medium- and long-term results were poor, probably because of the resorption or migration of the injected material. Reinjection was necessary in order to maintain continence.

A number of safety issues were raised with these studies. Teflon could potentially cause granuloma formation and sarcomas. The injection of autologous fat as a bulking agent in urology has been implicated in fatal fat embolism and stroke.

2.3 The second phase

The second phase in the development of anal bulking agents consisted of a wide variation in the types of materials used, surgical technique and clinical indications [11]. Some of the materials used to bulk the anal sphincter were being used in urology to augment the bladder neck. Nine different types of injectable bulking agents have been used in these studies (**Table 2**).

Type of bulking agent	Commercial name(s)	Injection site	Injection route	Published studies	No. of patients
Silicone biomaterial. Polydimethylsiloxane elastomer particles suspended in a biocompatible hydrogel made of poly-N-vinyl-pyrrolidone	PTQ; Bioplastique	Intersphincteric; within IAS	Transsphincteric	21	619
Carbon-coated zirconium beads, comprised of pyrolytic carbon-coated beads suspended in a water-based carrier gel containing β-glucan	Durasphere	Submucosal	Transmucosal; transsphincteric	7	187
Spherical particles of calcium hydroxylapatite, suspended in a gel	Coaptite	Submucosal	Transsphincteric	1	10
Dextranomer microspheres and stabilised sodium hyaluronate in phosphate-buffered 0.9% sodium chloride solution	NASHA Dx, Zuidex, Solesta	Submucosal	Transmucosal	5	192
Glutaraldehyde cross-linked collagen	Contigen	Submucosal	Transmucosal	2	90
Synthetic non-particulate hydrogel consisting of water (97.5%) and cross-linked polyacrylamide (2.5%)	Bulkamid	Intersphincteric	Intersphincteric	1	5
Cross-linked porcine dermal collagen matrix	Permacol	Submucosal; intersphincteric	Transmucosal; intersphincteric	5	172
8% ethylene vinyl alcohol copolymer dissolved in dimethyl sulfoxide. A spongy solid mass forms from the solidification of the hydrophobic copolymer when the solvent diffuses away on contact with tissue fluid	Onyx34	Intersphincteric	Intersphincteric	1	21
Expandable silicone microballoons filled with a biocompatible hydrogel made of poly-N-vinyl-pyrrolidone		Submucosal	Transmucosal	1	6

Table 2.
Injectable materials used in the second phase of studies.

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2.3.1 Indications

The clinical indications for which these bulking agents were used varied from study to study. These were:

- Failure of conservative management of faecal incontinence.
- Structurally intact but weak internal anal sphincter. This would be due to either primary idiopathic degeneration of the IAS or degeneration secondary to tissue disorders such as scleroderma.
- IAS damage (childbirth, haemorrhoidectomy, anal stretch, sphincterotomy) (**Figure 1**).
- Defect in the external anal sphincter.

The main indication was IAS dysfunction or disruption. Unlike the EAS, the IAS is not amenable to surgical repair.

2.3.2 Surgical procedure and technique

The bulking agents may be inserted under local, regional (anal or pudendal nerve block) or general anaesthesia. The type of anaesthesia used depends on the preference of the patient and the surgeon. The patient may be positioned in the prone (jackknife), lithotomy or left lateral positions, although the latter position may not give a satisfactory view of the anorectum to enable accurate injection. A phosphate enema is usually administered preoperatively. The procedure is usually covered by prophylactic antibiotics, such as intravenous (IV) co-amoxiclav 1.2 g, cefuroxime 750 mg and metronidazole 500 mg or gentamicin 1.5 mg/kg and metronidazole 500 mg at induction.

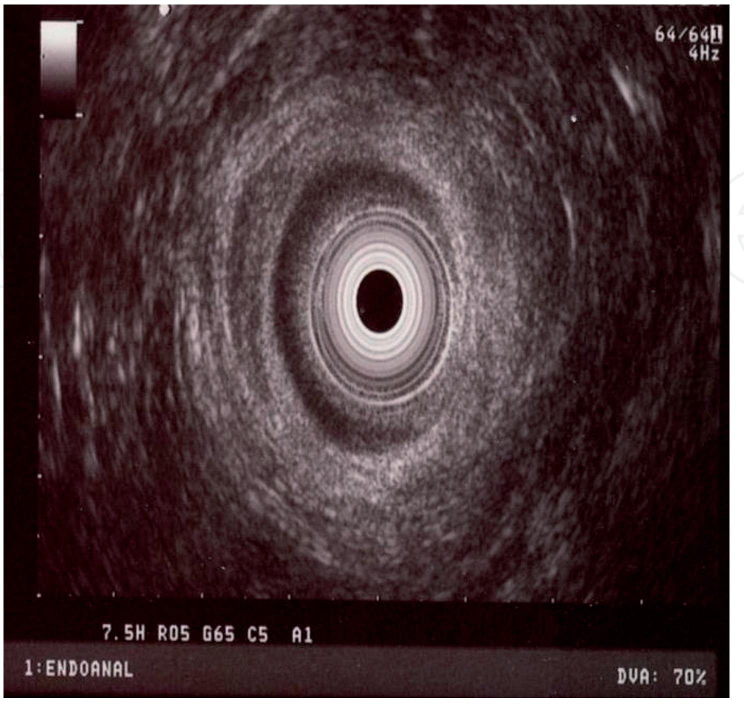

Figure 1.
Endoanal ultrasound scan showing a defect in the IAS of a 57-year-old lady with passive faecal incontinence following haemorrhoidectomy. The defect is present between the arrows from the 3 to the 5 o'clock positions.

The injection of the bulking agent varies depending on the type of substance used and the clinical indications. Three different routes of needle insertion were mentioned in the literature: transmucosal, transsphincteric or intersphincteric. The bulking agent was placed submucosally, within the intersphincteric space or within the IAS itself. For example, porcine dermal collagen (Permacol) may be injected via the transmucosal or transsphincteric route using a disposable 19G needle [12] (**Figure 2**). In patients with an intact IAS, 2.5 ml of Permacol is equally injected into the submucosal space at the 3, 7 and 11 o'clock positions above the dentate line. In cases of an IAS defect, 5 ml of Permacol may be injected at the site of the defect, with 2.5 ml of the substance injected diametrically opposite. With silicone biomaterial (PTQ or Bioplastique), four doses of 2.5 ml of silicone are used, using an 18G needle [13, 14]. Patients with an intact IAS have the silicone injected transsphincterically into the intersphincteric space at the 2, 4, 8 and 10 o'clock positions. In patients with an IAS defect, for example, after a lateral internal sphincterotomy, a total of three doses of 2.5 ml of silicone are injected into the defect. A fourth dose is injected into the intersphincteric space contralateral to the IAS defect, to provide symmetry. With carbon-coated beads (Durasphere), a total of 10 ml is injected in four divided doses in the submucosal plane using an 18G needle [14].

It is of utmost importance to ensure that the anal mucosa is not breached during injection, since that would allow intra-anal leakage of the substance. Intravascular injection must also be avoided.

Once the injection is completed, it is a good practice to leave the needle and syringe in place for a few seconds. As the needle is being withdrawn, pressure on the needle track by the index finger may prevent leakage of the bulking agent [12].

The bulking agent may be injected freehand, with an anal retractor such as Eisenhammer used to identify the IAS and intersphincteric groove. A finger placed within the anal canal may be useful to guide the needle to its correct position. However endoanal ultrasound has been recommended to guide the needle to an optimum position [13], especially if the agent is to be injected into the intersphincteric space or adjacent to a defect in the IAS.

2.3.3 Results

The majority of studies in this second phase of development were mainly case series and observational studies. Most of these studies reported either an improvement in the faecal continence scores or less frequent episodes of incontinence over time. Anorectal manometry testing is featured in some studies, with some showing an improvement in resting or squeeze pressures. Others studies showed no such improvement. Clinical improvement was not always associated with an increase in

Figure 2.
Porcine dermal collagen (Permacol) in a 2.5 ml syringe.

these pressures. Quality of life was formally assessed in some of these studies. The majority reported an improvement across various domains such as physical and social function.

To date there have been 6 randomised trials using anal bulking agents, with more than 400 patients. Two trials compared a bulking agent with a sham or saline injection. Siproudhis et al. in 2007 [15] compared a silicone biomaterial (PTQ) with a normal saline injection (control) into the intersphincteric space. PTQ did not demonstrate any appreciable clinical benefit when compared to the control. The trial was however deemed to be too small to detect any differences in continence. Graf et al. in 2011 [16] compared the injection of dextranomer (NASHA Dx) against sham injection (no substance injected). Continence was better in the short term (6 months) in the active intervention group, although interestingly about 30% of patients in the control group had an improvement in their continence. This same group, the NASHA Dx study group, published the results of a prospective multicentre trial in 2014, showing that 'submucosal injection of NASHA Dx provided a significant improvement of FI symptoms in a majority of patients and this effect was stable during the course of the follow-up and maintained for 3 years'.

A small study with 10 patients by Maeda et al. in 2008 [17] revealed significant improvement at 6 weeks postinjection using injection of Bulkamid and Permacol. Continence decreased slightly in the Permacol group at 6 months. However there was no reported difference between the two agents. The numbers were too small to detect a difference. Tjandra et al. in 2009 reported the results of a randomised study comparing PTQ with carbon-coated beads (Durasphere) [14]. PTQ injection was associated with better continence scores and quality of life and was safer than Durasphere.

Tjandra et al. in 2004 reported the short-term benefits from ultrasound-guided injection of silicone biomaterial (PTQ) compared with digital guidance [13].

The follow-up for the majority of patients in studies was less than a median of 3 years. A question on the term durability and effectiveness of these agents is therefore raised. The majority (97%) of patients were only followed up once or twice. No long-term evidence on outcomes was available, and further conclusions were not warranted from the available data. None of the studies reported patient evaluation of outcomes, and thus it is difficult to gauge whether the improvement in the continence scores matched the practical symptom and quality of life improvements that mattered to the patients.

The majority of patients did not report any complications. The complications described were mainly pain, anal bruising and leakage of injected material [11, 12]. Less common complications were anal ulceration and infection (local cellulitis and abscess formation). There were two reported cases of local giant cell foreign body reaction after injection of silicone (PTQ) [18]. Durasphere has been associated with skin rashes and arthritis. Skin patch testing is therefore recommended before using this agent [14].

2.4 The third phase: The implantable gatekeeper and Sphinkeeper

A relatively new and innovative development in anal bulking technology is the Gatekeeper and Sphinkeeper (THD S.p.A., Correggio, Italy). The material used is polyacrylonitrile (Hyexpan). Polyacrylonitrile is an inert, non-allergenic, nondegradable material that is also non-immunogenic and noncarcinogenic. First developed by Medtronic in Minneapolis, USA, it was originally used as an implant in the oesophagogastric junction for the management of gastro-oesophageal reflux disease.

The main indications for the use of the GK and SK are passive faecal incontinence, secondary to IAS dysfunction or damage, where conservative measures or injection of other bulking agents such as PTQ or Permacol has failed. However, the use of GK and SK in patients with other causes of FI is being explored.

The following are contraindications to the use of the GK and SK. Similar contraindications have also been described by the product manufacturers of other anal bulking agents:

- Perianal sepsis
- Inflammatory bowel diseases with anorectal involvement (Crohn's disease, ulcerative colitis)
- Anal, rectal or colon cancer undergoing active treatment
- Rectal bleeding of unknown or undiagnosed origin
- Rectal prolapse
- Uncontrolled blood coagulation disorders
- Pelvic radiotherapy
- Immunosuppression
- Pregnancy or planned pregnancy in the next 12 months.

2.4.1 Surgical apparatus, procedure and technique

Whereas the anal bulking agents that were developed in phases 1 and 2 are injected into or around the anal canal by means of a hypodermic syringe, the Hyexpan prostheses are implanted into the intersphincteric space using a custom-made gun (**Figure 3**).

The difference between GK and SK lies in the size of the prostheses. The dehydrated GK prostheses consist of thin solid cylinders, 22 mm long and 2 mm in diameter. The success of this material depends on its hydrophilic properties.

Figure 3.
The gatekeeper gun, made of the dispenser that houses one prosthesis and the delivery system. The Sphinkeeper delivery system and dispenser are similar but slightly larger.

Within 48 hours after implantation in the human tissue, the Hyexpan cylinders absorb water to become thicker and shorter. The in vitro maximum diameter is 6.5 mm and the length is 17 mm (**Figure 4**). The volume of each individual implant increases from approximately 70 mm^3 to 500 mm^3, a 750% increase. The implant also becomes much softer in consistency. On the other hand, the SK prostheses in the dehydrated state are thin, solid cylinders, 29 mm long with a diameter of 3 mm, changing their size to a length of 23 mm and a diameter of 7 mm within 48 h of contact with fluids.

The technique of implantation of the GK and SK is identical. The operation is performed under regional or general anaesthesia. Intravenous antibiotics are given at induction. The author's patients receive gentamicin 1.5 mg/kg and metronidazole 500 mg IV. The patient is placed in the lithotomy position. A strict sterile technique is used. The IAS and intersphincteric groove are identified by the placement of an anal retractor (e.g. Eisenhammer). The author's preference is a THD surgy Mini-light proctoscope, a self-illuminating anal and rectal retractor that gives a very good view of the anorectum without causing trauma to the anal sphincter (**Figure 5**). A 2 mm incision is made in the perianal skin, 2 cm from the anal verge (**Figure 6**).

Having attached the dispenser to the delivery system, the needle is inserted through the incision and tunnelled to the intersphincteric margin and introduced into the intersphincteric space. The needle is then positioned so that the tip would lie just beyond the dentate line. When the needle is identified in the correct position, by direct vision and palpation and/or by endoanal ultrasound, the prosthesis is released into the intersphincteric space (**Figure 7**).

The steps may be repeated to insert up to 10 prostheses, equidistant from each other. The GK has been originally described with the insertion of between 4 and 6 prostheses, whereas the SK has been described with the use of 10 prostheses. The choice of inserting 4 as opposed to 6 or 10 prostheses is arbitrary. The use of 10 prostheses enables the formation of a circumferential or quasi-circumferential intersphincteric ring, akin to an artificial anal sphincter. The prostheses self-fix in the desired position, thereby preventing displacement and migration in the majority of cases.

The wounds are closed with a single absorbable suture (**Figure 8**). At the end of procedure, EAUS imaging will show the location of all prostheses. The procedure takes about 30 to 40 minutes to complete and is done as a day case. Oral metronidazole 400 mg tds is prescribed for 5 days postoperatively. Oral laxatives such as lactulose are prescribed to minimise the risk of constipation. The patients are advised to avoid any anal trauma as well as anal intercourse for at least 72 h after implant insertion. The patients are followed up after 6 weeks and 3 months thereafter. The material remains identifiable both by palpation and by endoanal ultrasonography in the postoperative period (**Figures 9** and **10**).

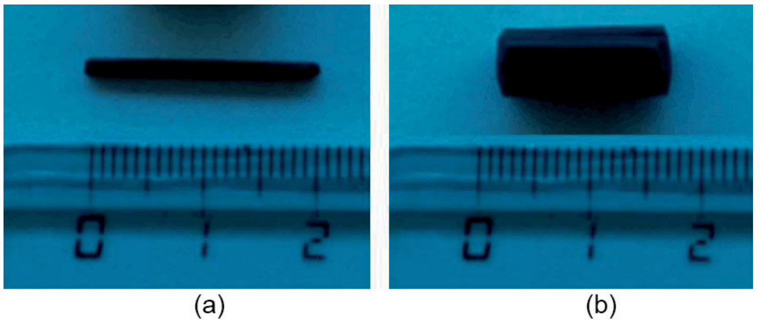

Figure 4.
(a) Shape of Hyexpan gatekeeper cylinder at insertion. (b) Fully expanded Hyexpan gatekeeper cylinder following contact with water.

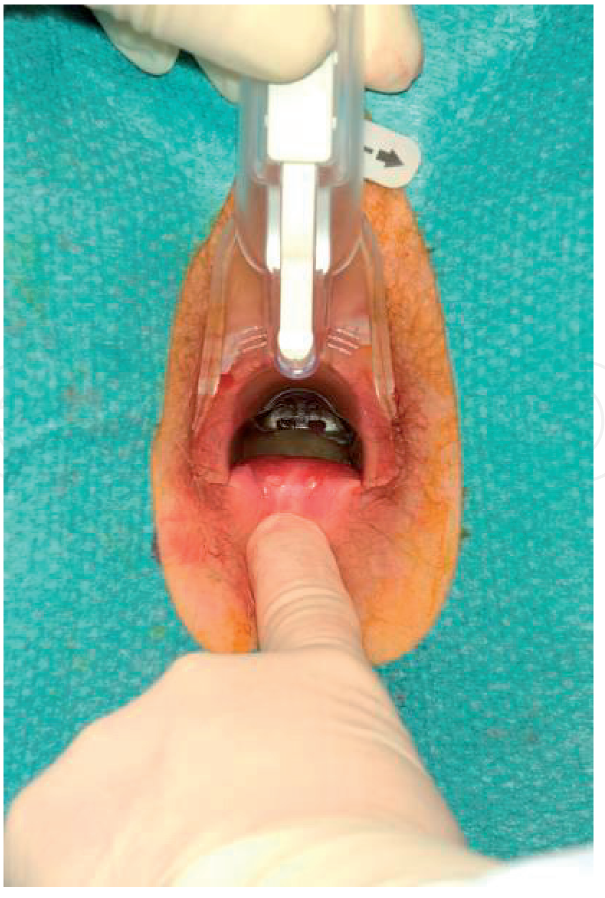

Figure 5.
Palpating the IAS and the intersphincteric groove at the 6 o'clock position with a THD surgy mini-light proctoscope in position.

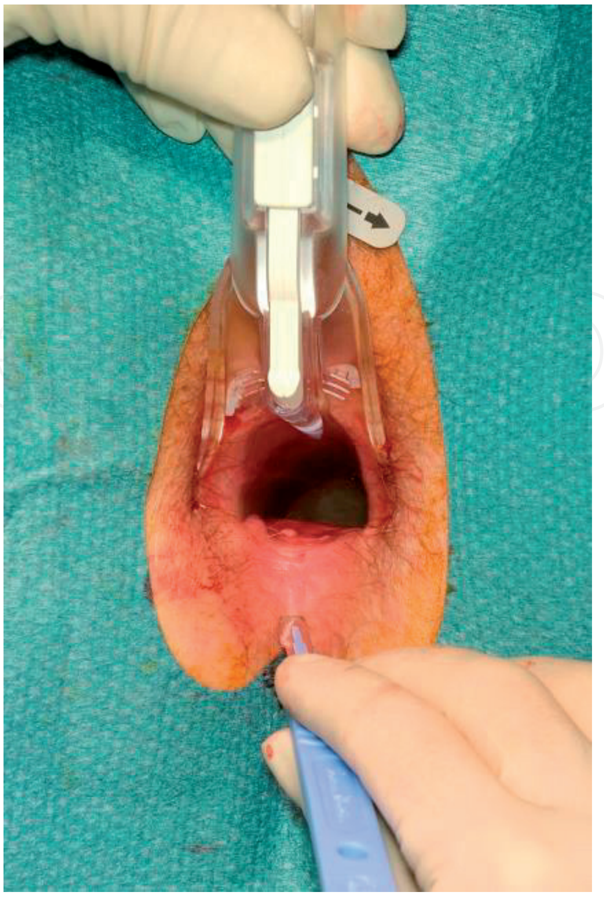

Figure 6.
Making an incision, 2 cm away from the anal verge, at the 6 o'clock position.

Figure 7.
The gatekeeper needle at the 9 o'clock position, with the endoanal ultrasound probe in place to determine correct placement.

Figure 8.
Up to 10 equidistant circumferential perianal wounds, each closed with an absorbable suture (Monocryl 3/0).

Figure 9.
Endoanal ultrasound scan (Aloka) at 6 weeks following the implantation of six gatekeeper prostheses in a 72-year-old male with idiopathic passive faecal incontinence.

2.4.2 Results

The first reported experience with the Gatekeeper was by Ratto et al. in 2011 [19]. This was a study with 14 patients. Eight had idiopathic FI, four had an IAS defect, and two had combined IAS and EAS defects. The median follow-up was of 12 months (ranging from 5 to 48 months). The authors reported a clinically significant improvement in continence in 13 patients, a sustained significant improvement in the Wexner and Vaizey scores and in the SF36 and FIQOL scores. No complications have been reported.

The second study was a comparative retrospective study by Parello et al. in 2012 [20]. Seven patients who had the Gatekeeper implanted were compared to six patients who underwent sacral nerve stimulation. The median follow-up was of 18 months in the Gatekeeper group and 20 months in the SNS group. The authors reported a sustained improvement in the Wexner continence scores with both modalities of treatment.

Fabiani et al. [21] used Gatekeeper for a group of patients affected by minor faecal incontinence. Four out of seven patients complained of passive incontinence prior to the procedure. After an average follow-up of 6 months, 6 patients reported a Wexner incontinence score under the value of 4, meaning that they rarely experienced symptoms (0 = perfect incontinence and 20 = complete incontinence). Only one patient who suffered mixed incontinence failed to respond.

Biondo et al. [22] concluded that Gatekeeper is a safe and effective procedure in more than 50% of patients for at least a year after implantation. They found that no patients had postoperative or long-term complications. Forty-eight per cent of patients were classed as responders, and significant differences were found between baseline mean Vaizey scores at 6 months, 12 months and last follow-up. At long-term follow-up (2.7 years), those patients that responded were found to have maintained an improvement more than 50% of their baseline Vaizey score.

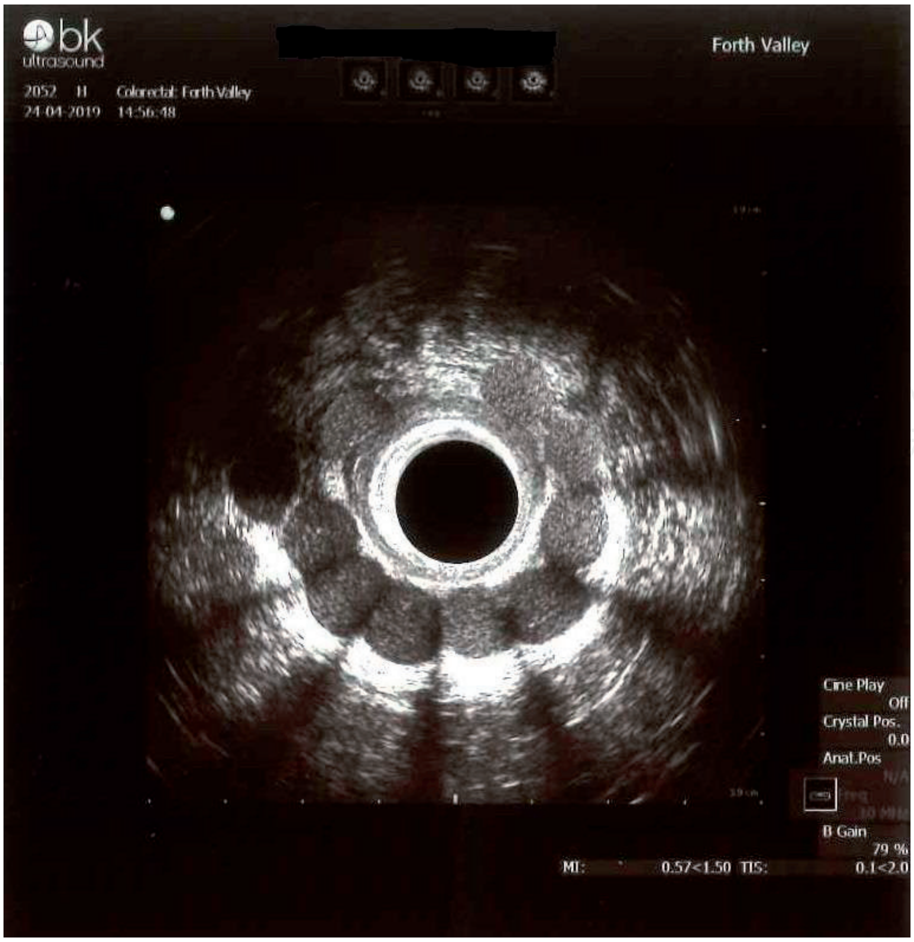

Figure 10.
Endoanal ultrasound scan (B&K) at 6 weeks following the implantation of 10 Sphinkeeper prostheses in a 68-year-old female with passive faecal incontinence and previous episiotomy.

In a multicentre study involving 54 patients and a clinical follow-up for a year, Ratto et al. [23] noted that after Gatekeeper implantation, incontinence to gas, liquid and solid stool improved significantly, soiling was reduced and the ability to defer defaecation was enhanced. All faecal incontinence severity scores were significantly reduced, and patients' quality of life improved. At 12 months, 30 patients (56 per cent) showed at least 75 per cent improvement in all faecal incontinence parameters, and 7 (13 per cent) became fully continent. Dislodgement of a few prostheses was reported, but this made no difference to postoperative continence.

The author has carried out more than 40 GK procedures in a single centre since 2012. The main indications were idiopathic FI and passive incontinence following surgery (anal stretch for anal fissure and haemorrhoidectomy). All patients had failed conservative management. There was a significant sustained improvement in the median Vaizey scores. The median (range) Vaizey scores improved from 16 (12–17) preoperatively to 5 (3–9), 4 (3–7), 4 (3–5), 4 (3–5), 5 (3–6) and 5 (3–6) at 6 weeks and at 3, 6, 12, 24 and 36 months, respectively ($p < 0.01$, Wilcoxon test). There was also an improvement in the Rockwood quality of life scores. The author reports no complications apart from minor pain that is managed by paracetamol.

Publications on the Sphinkeeper are limited. Ratto et al. [24] treated 10 patients with SK and followed them up for 3 months. The study demonstrated that the SK, with its larger prostheses than that of GK, is safe and effective. The Pelvic Floor Society of the Association of Coloproctology of Great Britain and Ireland is currently collecting prospective data on the SK from multiple centres in the UK.

3. Discussion

The development of anal injectable and implantable technology over the past 20 years has taken great strides forwards. Starting with the pioneering efforts of Shafik with autologous fat, more materials have been tried and used, the most popular being collagen (Permacol) and silicone (PTQ or Bioplastique). These agents were associated with variable and inconsistent results. Injections were frequently repeated to maintain continence in the long term. The latest generation of anal bulking agents is the implantable Hyexpan (Gatekeeper and Sphinkeeper). This material fits the criteria for the 'ideal' bulking agent. It overcomes most limitations of other bulking agents, and its use has shown very promising results.

The choice to implant the GK and SK prostheses into the intersphincteric space of the anal canal plays a key role. This location potentially avoids extrusion or migration of prostheses (different to what could happen if implanted into the submucosa). Moreover, thanks to the rapid increase of their volume, the prostheses self-fix and are unlikely to move after deployment.

The mechanism of action of anal bulking agents is a subject of debate. Most of the resting anal pressure is the function of the IAS, with some contribution from the EAS and anal cushions. Studies of faecal incontinence in patients who have undergone a traditional Milligan-Morgan haemorrhoidectomy lend support to the concept that anal cushions play an important part in the maintenance of the normal mechanism of continence. It is thought that the mechanism of action of a bulking agent injected into the submucosal space is an increase in the size of the natural anal cushions. On the other hand, a bulking agent injected or implanted into the intersphincteric space would bulk up the size of the anal sphincter. The end result would be an improvement in the seal of the lumen of the anal canal at rest and potentially an increase in resting anal pressure and in the length of the anal high pressure zone. When the injection is placed adjacent to an identifiable IAS defect, a better degree of anal canal sealing may be obtained through improvement in the configuration and symmetry of the anal canal [7]. Ratto argues that GK and SK, being embedded within the intersphincteric space, thereby pushing the EAS outwards and the IAS inwards, 'may improve sphincter contractility by increasing sarcomere length as well as increase the length of the anal canal and provide a powerful "bulking effect"' [24].

It is acknowledged that more research is required in this field. Most studies are case series with very few randomised trials. The Gatekeeper and Sphinkeeper, the latest generation of anal bulking agents, show promising results. Whether these results are maintained in the longer term or not awaits to be seen. The key factor however remains that correct patient selection is extremely important to achieve good results.

Larger series with longer follow-up and randomised controlled trials are therefore necessary. Further development on existing and emerging technology is also warranted.

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