

VAAFT for treating anal fistulae

Medtech innovation briefing

Published: 20 April 2017

www.nice.org.uk/guidance/mib102

Summary

- The **technology** described in this briefing is VAAFT, or video-assisted anal fistulae treatment. It is a surgical kit used for treating anal fistulae.
- The **innovative aspects** are that VAAFT includes a video camera which allows the surgeon to see inside the anal fistula tract, and an endoscope light to help with locating the internal opening of the tract.
- The intended **place in therapy** would be as an alternative to other surgical techniques used to treat anal fistulae.
- The **key points from the evidence** summarised in this briefing are from 4 uncontrolled open-label studies including 838 patients. These studies suggest that VAAFT is safe and well tolerated.
- **Key uncertainties** around the evidence base, which is still developing, are that long-term healing and recurrence rates are unknown. VAAFT can be used to treat both simple and complex fistulae but it is currently unclear which subgroup would benefit the most.

- The **cost** of VAAFT is £7,988 per unit for the reusable surgical kit, plus around £20 in single-use consumables per procedure (exclusive of VAT). There is insufficient information to judge the overall **resource impact** of VAAFT compared with NHS standard care. Fistulotomy is the most common treatment for anal fistula and costs £1,169 per procedure.

The technology

VAAFT is a surgical kit for treating anal fistulae. The system comprises:

- A video telescope (fistuloscope) to allow surgeons to see inside the fistula tract.
- A unipolar electrode for diathermy of the internal tract. This is connected to a high frequency generator.
- A fistula brush and forceps for cleaning the tract and clearing any granulation tissue.

The VAAFT procedure is done in 2 phases, diagnostic and operative. Before the procedure, the patient is given a spinal or general anaesthetic and is placed in the lithotomy position (legs in stirrups with the perineum at the edge of the table).

In the diagnostic phase, the fistuloscope is inserted into the fistula to locate the internal opening in the anus and to identify any secondary tracts or abscess cavities. The anal canal is held open using a speculum and irrigation solution is used to give a clear view of the fistula tract. Light from the fistuloscope can be seen from inside the anal canal at the location of the internal opening of the fistula, which helps to locate the internal opening.

In the operative phase of the procedure, the fistula tract is cleaned and the internal opening of the fistula is sealed. To do this, the surgeon uses the unipolar electrode, under video guidance, to cauterise material in the fistula tract. Necrotic material is removed at the same time using the fistula brush and forceps, as well as by continuous irrigation. The surgeon then closes the internal opening from inside the anal canal using stitches and staples.

VAAFT can also be used for treating pilonidal sinus but this is beyond the scope of this briefing.

Innovations

VAAFT is claimed to be the only technique that allows the surgeon to see inside the anal fistula tract and locate the internal opening using an endoscope light. VAAFT is designed to only affect the fistula tract, preserving sphincter muscle function and faecal continence.

Current NHS pathway

Surgery is usually necessary to treat anal fistulae because they rarely heal spontaneously. Several techniques are currently used within the NHS; which one is used depends on the location of the fistula and the person's medical history. MRI scans are usually done before surgery to assess the extent and location of complex or transphincteric fistula tracts, and recurrent fistulae. The aim of surgery is to drain infected material so that the fistula can heal, while ensuring that the function of the anal sphincter is preserved. If the fistula does not heal properly it may reoccur and need another surgical procedure ([Dudukgian et al. 2011](#)).

Fistulotomy is the most common type of anal fistula surgery, used in 85% to 95% of cases ([Seow-Choen 2003](#)). This involves cutting open the whole length of the fistula, from the internal opening to the external opening, before the surgeon cleans out the contents and flattens it out. This leaves an open wound which must be cleaned and dressed while healing; after 1 to 2 months, the fistula will heal into a flat scar. This surgery is usually done as a day-case procedure under general anaesthesia. Depending on the position of the fistula, a fistulotomy may involve cutting the anal sphincter which can lead to faecal incontinence.

Seton placement is often used if the person is considered to be at high risk of developing faecal incontinence. This technique involves threading a stitch (the seton) through the fistula tract and back out through the anus where it is loosely tied. The anal sphincter is not cut. Two types of seton may be used: a silicone draining seton, or a silk or polyester cutting seton. A draining seton allows a fistula tract to drain for several weeks or months before a surgical procedure. A cutting seton is a non-absorbable stitch placed in the fistula tract and tightened periodically, to slowly cut through the fistula. Several seton procedures or a combination of seton and other techniques may be needed to treat a single fistula. Seton placement is done under general anaesthesia.

LIFT (ligation of inter sphincteric fistula tract) and mucosal advancement flap are alternative procedures that also avoid cutting the sphincter muscle. LIFT involves opening

the space between the muscles to access the fistula tract, whereas a mucosal advancement flap involves closing the internal opening of the fistula with a flap of tissue and cleaning out the fistula tract.

NICE has produced interventional procedures guidance on the [closure of anal fistula using a suturable bioprosthesis plug](#), made from porcine or human tissue. The guidance states that evidence of the efficacy for these is limited, and recommends that they should only be used with special arrangements for clinical governance, consent and audit or research.

Fibrin glue can be injected into the fistula tract in an attempt to seal it. Evidence for this procedure reports initial success rates of 50%, but long-term findings indicate that it may be associated with a high rate of recurrence ([Cirocchi et al. 2009](#)).

NICE is unaware of any CE-marked technologies which fulfil a similar function to VAAFT.

Population, setting and intended user

VAAFT is an option for adults and children with anal fistulae in place of current standard surgical approaches. It is used in secondary settings as a day-case procedure and is done by a surgeon trained in the VAAFT technique.

Costs

Table 1: Device costs

Description	Cost	Additional information
Indicative price of technology	£7,988 for reusable VAAFT equipment set (excluding VAT)	–
Consumables	£5.70 per single-use seal £15.00 per single-use fistula brush Irrigation fluid	–

Service/ maintenance cost and frequency	Ad hoc repairs when necessary £158 to £3,337 The manufacturer estimates this would amount to around £7,000 over the lifetime of the device	Lifespan is 10 years One kit can be used once per day (rest of day needed for sterilisation) Training provided at no charge to surgeons
Average cost per treatment	£26.40 (equipment costs) £1,195.40 total	Day-case procedure done under general anaesthetic £1,169 2014–15 national schedules (day-case FZ21C)

Costs of standard care

Fistulotomy is the most common treatment for anal fistula. It is usually done as a day-case procedure under general anaesthesia, costing £1,169. Additional costs are incurred if a draining seton is used before surgery.

Resource consequences

There could be a reduction in secondary care costs if VAAFT reduced or avoided the need for MRI scans. An MRI scan costs between £120 and £180 per person (enhanced tariff 2015/16). There may also be further potential savings from a reduction in the use of post-operative wound dressings (because after VAAFT wounds are not left open, unlike after fistulotomy) or from reduced fistula recurrence, although data to quantify these potential savings are not currently available.

VAAFT is currently used in 4 NHS hospitals in the UK.

Training is needed in the use of VAAFT but the manufacturer includes this in the purchase price. Adopting VAAFT may change the way services are delivered, because it can be done as a day-case procedure.

Regulatory information

VAAFT was CE marked in April 2015. The VAAFT fistuloscope is a class IIa device; all other items are class I.

A search of the Medicines and Healthcare Products Regulatory Agency website revealed that no manufacturer Field Safety Notices or Medical Device Alerts have been issued for this technology.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

People with anal fistulae are limited by pain and the management of their condition. If the condition is severe and has a significant and long-standing effect on their ability to carry out activities of daily living, they may be considered to have a disability. People with diseases that increase the risk of anal fistulae (for example, Crohn's disease) may also be considered to have a disability if the condition has similar effects on daily living. Disability is a protected characteristic under the Equality Act.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the published process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

This briefing includes 4 single-centre, non-controlled studies involving 704 patients with anal fistulae. These studies were selected because they represent the highest quality evidence and included the largest number of patients. The results indicate that VAAFT is safe, effective and associated with a low morbidity. In the studies VAAFT was mostly done

as a day-case procedure.

Treatment with VAAFT may lead to fistula recurrence rates of up to 30%. The study authors speculated that, in some of the studies, recurrence may have been because of the learning curve of the surgeons and the type of fistulae treated. Because of the relatively low morbidity resulting from the procedure, some patients had VAAFT several times.

The case study by [Liaqat et al. 2016](#) (not included in the table below) is the only report identified about the use of VAAFT in children and describes its successful use in a 6-year old girl. No recurrence was reported and the follow-up period is unknown.

Table 2 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The evidence base for VAAFT is still developing and comprises non-comparative and case studies. The total number of patients reported on is small in the context of a new procedure with a recognised learning curve.

The long-term healing rates for VAAFT are not addressed by the current evidence, because follow-up was either too short or completed in too few patients.

Most studies did not evaluate faecal continence; only Kochhar et al. (2014) used anal manometry to assess sphincter muscle strength before and after VAAFT.

All studies reported that pain scores and complication rates were low, suggesting that VAAFT is safe and well tolerated by patients.

All of the studies were done outside of the UK, which might limit their generalisability to NHS practice.

Table 2: Summary of evidence

Study	Details of intervention [and comparator]	Outcomes	Strengths and limitations

<p><u>Chowbey et al. 2015</u> n=580 Uncontrolled open-label study Single centre India</p>	<p>VAAFT (n=416), fistulotomy for superficial subcutaneous fistulae (n=114), LIFT with fulguration of distal fistula tract (n=21), incision and drainage of abscess only (n=29).</p>	<p>Internal fistula opening could not be found in 101 people and was too high to reach in 5 people. 391/416 procedures were done as day cases. 7 people were readmitted due to bleeding from the rectum or fistula tract. Mean VAS score (0–10) was 3.1 at discharge and 1.6 after 1 week. Discharge from the external fistula opening was found in 87% of people after 1 week. By 1 month this had reduced to 42%. 134 patients were available for 1-year follow-up and primary healing of the fistula was seen in 99 people. 35 people had recurrence; 20 with serous discharge, 9 with pus discharge and 6 with bloody discharge.</p>	<p>The study presents results for the 416 people receiving VAAFT only. Only 134 of these were followed up at 1-year. MRI was obtained for 150 patients with recurrent, multiple or high fistulae. This was used to assess the fistula anatomy. Faecal continence was not formally evaluated.</p>
---	--	--	--

<p><u>Kochhar et al. 2014</u> n=82 Uncontrolled open-label study Single centre India</p>	<p>82 fistulae (70 simple and 12 complex) were treated with VAAFT.</p>	<p>The mean VAS score immediately following the procedure was 4 which was reduced to nil after 24 hours and no pain was reported at 1-week follow-up. All patients had returned to work 5 days after the procedure.</p> <p>After 1 week, 28 patients (34.15%) had discharge from the wound. 13 patients (15.85%) had a recurrence during 6 month follow-up.</p> <p>Anal manometry showed that there were no statistically significant changes in the mean resting anal pressures and mean anal squeeze pressures before and after the procedure. None of the patients reported any problems with faecal continence.</p>	<p>People with Crohn's disease and existing faecal incontinence were excluded from the study.</p> <p>MRI scans were done for all participants.</p> <p>Faecal continence was assessed using anal manometry in the preoperative period and again at 1 month and 6 months postoperatively.</p> <p>The authors state that recurrence rates were lower than those observed in similar studies because the majority of fistulae treated in this study were simple rather than complex.</p>
--	--	---	--

<p><u>Meinero and Mori 2011</u> n=136 Uncontrolled open-label study Single centre Italy</p>	<p>136 complex fistulae were treated with VAAFT.</p>	<p>Primary healing was achieved in 72 people (73.5%) within 2 to 3 months. Of the 26 (26.5%) unsuccessful procedures, 19 people had a repeat VAAFT procedure, leading to another 9 fistulae being fully healed. Recurrence rate was 26.5%. No major complications, infection, incontinence or bleeding occurred as a result of treatment with VAAFT and all patients were discharged on the day of surgery. Mean VAS pain score in the first 48 hours following surgery was 4.5, no pain was reported after 1 week. All people had returned to work within 3 days.</p>	<p>All patients had complex fistulae which were defined as 'not treatable with fistulotomy'. The authors of this study developed the VAAFT technique and so a high level of proficiency and possible bias should be considered when comparing primary healing rates to those observed in other studies. Follow-up data for the entire cohort is only provided up to 3 months. The authors state that 62 people were followed up for at least 12 months and that in 54 (87.1%) of these primary healing had been achieved. Anal continence was not formally evaluated. This study was funded by the manufacturer.</p>
---	--	--	--

<p><u>Zarin et al. 2015</u> n=40 Uncontrolled open-label study Multicentre Pakistan</p>	<p>40 fistulae (16 simple and 24 complex) were treated with VAAFT.</p>	<p>Primary healing was achieved in 20 people at 6 weeks follow-up. Primary healing had been achieved in all 40 patients after 12 weeks of follow-up, however, 3 people had a repeat VAAFT procedure during this time.</p> <p>No major complications were noted. 17 people (42.5%) had minor discharge and itching before healing.</p>	<p>This study is reported in a brief paper and some key information (such as inclusion/exclusion criteria) is missing.</p> <p>40% of patients had simple, straight fistula tracts and 60% had complex fistulae. It is not explained how the fistula anatomy was assessed.</p>
---	--	---	---

Recent and ongoing studies

- ClinicalTrials.gov identifier [NCT02585167](https://clinicaltrials.gov/ct2/show/study/NCT02585167): Endoscopic treatment of complex anal fistulas. Status: recruiting (66 patients estimated). Estimated primary completion date: September 2017. Primary comparator: fistulotomy. Location: Denmark.
- ClinicalTrials.gov identifier [NCT02313597](https://clinicaltrials.gov/ct2/show/study/NCT02313597): VAAFT Vs SETON in the management of high peri anal fistula. Status: recruiting (60 patients expected). Study completion date: July 2016. Location: Pakistan.

Specialist commentator comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All specialist commentators were familiar with the technology and 1 stated that they used it on a regular basis.

Level of innovation

All specialist commentators stated that VAAFT is a novel technique, using existing equipment and methods in a way that has not previously been used to treat anal fistula. One noted that VAAFT was the only treatment that allowed visualisation inside the fistula, helping the surgeon locate and treat any secondary tracts. This could lead to improved healing rates compared with other techniques.

Potential patient impact

The potential patient benefits noted by the specialist commentators included a reduced risk of faecal incontinence, better understanding of the anatomy of the fistula and therefore full drainage of any pus or infection, reduction in post-operative pain and no loss of sphincter muscle function. They considered that VAAFT may be particularly useful for high fistulae and for people with recurrent fistulae due to Crohn's disease. One commentator stated that the use of VAAFT may mean fewer inpatient visits for these patients. Another was of the opinion that people having VAAFT may need more hospital visits than those having a fistula plug, but that this would be comparable to more invasive methods such as advancement flaps. All the specialist commentators felt that it is likely that patient benefits will be realised in practice. One noted that more studies are needed to provide evidence for the potential benefits, particularly long-term studies and patient questionnaires, ensuring that healing rates are measured.

Potential system impact

All the commentators agreed that use of VAAFT would require training, with 2 suggesting that this should be in the form of observation and mentoring with experienced users. One specialist commentator stated that VAAFT could reduce the need for MRI scans. Two felt that it would be a minimally invasive treatment option. Other benefits for the healthcare system cited by the specialist commentators included reduced follow-up and time to recovery and potentially fewer recurrences. One specialist commentator stated that use of VAAFT should be restricted to specialist units and should only be used as part of a clinical trial until more data are collected.

General comments

The specialist commentators were not aware of any safety issues associated with VAAFT.

They stated that it may lead to savings for the NHS but that more evidence was needed.

Patient organisation comments

The Crohn's in Childhood Research Association provided the following comments.

VAAFT could potentially offer benefits to children with complex and less complex fistula, but this should first be explored through appropriate studies. Any disadvantages are not yet known and must be investigated further.

Anal fistulae are associated with social stigma and can cause considerable pain and difficulty moving around and sitting. The association noted that any procedure which has the potential to heal internal fistula sites and lead to quicker recovery should be welcomed.

Specialist commentators

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

The following clinicians contributed to this briefing:

- Mr Janindra Warusavitarne, consultant colorectal surgeon, St Mark's Hospital, London. No conflict of interest declared.
- Mr James Francombe, consultant colorectal surgeon, Warwick Hospital. No conflict of interest declared.
- Mr Baljit Singh, consultant colorectal surgeon and honorary senior lecturer, University Hospitals Leicester. Received funding for speaking events from Medtronic regarding the Permacol surgical implant for anal fistula.
- Mr Terry Irwin, consultant colorectal surgeon, Belfast City Hospital. No conflict of interest declared.

Representatives from the following patient organisations contributed to this briefing:

- Crohn's in Childhood Research Association.

Development of this briefing

This briefing was developed by NICE. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

ISBN: 978-1-4731-2447-9