

Video-assisted anal fistula treatment combined with anal fistula plug for treatment of horseshoe anal fistula

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Abstract

Objective: Horseshoe anal fistula is a common anorectal disease, and there is no standard procedure for its treatment. In this study, we performed a modified surgical procedure for the treatment of horseshoe anal fistula and investigated its efficacy and adverse effects.

Methods: We retrospectively analyzed the outcomes of video-assisted anal fistula treatment combined with an anal fistula plug (VAAFT-Plug) in 26 patients with a horseshoe anal fistula. The follow-up period ranged from 6 to 18 months. Preoperative and postoperative data were collected to analyze the cure rate, anal sphincter function, and incidence of complications.

Results: The surgeries were successfully performed in all patients, 23 of whom were cured (effective cure rate of 88.46%). Three patients developed recurrence and were cured after traditional surgery. No patients developed severe complications or postoperative anal incontinence. The VAAFT-Plug protocol was performed with a small incision in the fistula that subsequently promoted fistula healing and preserved sphincter function.

Conclusion: Although randomized controlled trials will be needed to fully validate these findings, our results suggest that VAAFT-Plug represents a promising treatment strategy for horseshoe anal fistulas. This technique preserves normal anal function and achieves satisfactory outcomes in most patients.

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Keywords

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Introduction

Anal fistulas are one of the most common forms of benign anorectal disease. Despite the relatively common nature of this complication, treatment of the more complex fistulas, such as horseshoe anal fistulas, is challenging for clinicians. The main reason for the difficulty of treating horseshoe anal fistulas is that the fistula site is deep and involves the sphincter, with a large invasion range.¹ Surgeons must carefully select a surgical intervention appropriate to a given fistula; if an incorrect surgical procedure is chosen, the anal canal and sphincter can sustain intraoperative damage leading to potentially problematic complications including anal incontinence and anorectal deformities. Furthermore, if the fistula is not completely treated during the operation, it can easily recur because of inadequate drainage or incomplete treatment of lesions, leading to prolonged pain associated with this condition. Given these challenges, reports regarding the treatment of horseshoe anal fistulas are limited, and the current treatment strategies are generally conservative.²

Horseshoe anal fistulas are a relatively rare form of fistula, affecting roughly 5% of all patients with anal fistulas.^{3,4} These fistulas were initially reported in 1965 when Hanley⁵ described the performance of fistulotomy of a tract in the deep postanal space and drainage of the anterior extension. Based on this description, the modified Hanley⁶ procedure was developed, with the principle goal of using a seton to

gradually and chronically incise the sphincter. This approach offered several advantages over the more direct approach of directly cutting off the sphincter because it allows for control over the speed of incision; additionally, the inflammatory response and fibrosis at the incised site prevent continuous retraction during incision, thereby reducing the rate of fecal incontinence.⁷

Despite the use of this modified Hanley procedure, the treatment of horseshoe anal fistulas has remained difficult, and adverse outcomes including a high rate of recurrence, slow wound healing, and anal control disorder persist.² Because traditional surgical interventions will inevitably damage the function of the anal sphincter, increasing numbers of innovative surgeries and therapeutic strategies have been developed to improve upon the current standard of care and better preserve the integrity of the anal sphincter complex.

Exploration of the fistula is the first step toward confirming the shape of the fistulous tract and localizing the internal opening. Video-assisted anal fistula treatment (VAAFT)⁸ is a new technology based on a uniquely designed optical fistuloscope that is used to evaluate the internal structure (including any branches or abscess cavities) within the fistula via debriding and washing. Garg and Singh⁹ reported that VAAFT is a safe procedure for treating anal fistulas, with a total cure rate of 76%. The main advantages of this approach are the low associated risk of incontinence, short

length of hospital stay, and rapid patient recovery. Importantly, Emile et al.¹⁰ found that for highly complex anal fistulas, this technology can be used as an effective diagnostic tool and safe treatment method with few postoperative complications. The VAAFT approach can reduce the risk of intraoperative injury to surrounding structures, including the sphincter complex, and it offers key advantages as a means of interpreting the configuration of a complex anal fistula.

Anal fistula plugs act as a scaffold, allowing for infiltration of connective tissue into the fistula tract and thereby accelerating the healing process. Although these plugs are effective in many cases, the effective cure rates range widely among different reports. A recent meta-analysis of 20 studies involving 530 patients treated with anal fistula plugs showed that over a 3- to 40-month follow-up, the excretion rate of anal fistula plugs was 8.7%, while the cure rate ranged from 24% to 83% (average, 54%).¹¹ Another meta-analysis of 25 studies showed that the cure rate of complex fistulas using these plugs was approximately 24% to 92%.¹² In a randomized controlled trial assessing the use of anal fistula plugs for treating complex anal fistulas, the total success rate was 82.22% during an average follow-up period of 5.7 months.¹³ In a prospective study using acellular extracellular matrix with a follow-up period of 7 to 14 days, 10 of 30 patients achieved primary healing.¹⁴ A retrospective study of 114 patients in the same center with an average follow-up period of 19.5 months achieved a cure rate of 54.4%.¹⁵ Thus, although anal fistula plugs are an attractive treatment strategy, there is a clear need for further improvement of the implantation technique to ensure reliable and durable outcomes in patients with complex fistulas.

All of these techniques offer key advantages relative to more traditional surgical

approaches with respect to preserving normal sphincter function. However, long-term follow-up after treatment of complex conditions such as horseshoe anal fistulas often reveals unsatisfactory outcomes and lower than desirable success rates.¹⁶

Of the available treatment techniques, the imaging advantages of VAAFT make it an attractive strategy for the successful completion of complex operations such as those required for the treatment of horseshoe anal fistulas. Despite the promising nature of this technique, VAAFT has not yet demonstrated satisfactory outcomes for the treatment of this condition. Several reports have described successful application of fistula plugs in the closure of high anal fistulas, but all treatments were associated with varying degrees of incontinence. The findings of these studies were controversial, suggesting that further investigations are required to obtain conclusive evidence.¹⁷ Therefore, to increase the effectiveness of this technology and overcome limitations in the implantation of anal fistula plugs, we modified the VAAFT procedure by combining it with the anal fistula plug approach in an intervention we have termed "VAAFT-Plug." We used this surgical approach to treat patients with horseshoe anal fistulas and evaluated the efficacy and safety of this procedure in the present study.

Methods

Patients and assessments

Patients who underwent treatment for horseshoe anal fistulas from January 2016 to August 2017 were enrolled in this single-center, non-randomized, retrospective study. The inclusion criteria were normal anal function with no laxity, stenosis, infection, or deformity of the anus structure and good physical condition with cardiopulmonary function suitable for surgery.

Patients with diabetes, blood disease, tuberculosis, inflammatory bowel disease, or malignant tumors were excluded from this study.

The study was approved by the Ethics Committee of Beijing Erlonglu Hospital, China. After enrollment and before the start of the experiments, the main objectives and possible benefits and risks of the study were clearly explained to all participants. All patients then provided written informed consent to participate in this study.

Surgical interventions

Preoperative evaluation of the patients included a digital examination of the rectum, endoanal three-dimensional ultrasound or pelvic magnetic resonance imaging, and sigmoidoscopy or colonoscopy. All patients received oral polyethylene glycol for bowel preparation. The anesthesia methods included sacral anesthesia, lumbar anesthesia, and general anesthesia. The surgical position was determined according to the site of the external opening of the anal fistula and the specific fistula configuration in a given patient.

The surgery was performed in two stages. The first stage was an exploratory examination using a VAAFT device, and the second stage involved the placement of an acellular dermal matrix (ADM) anal fistula plug (Beijing Qingyuanweiye Bio-tissue Engineering Co., Ltd., Beijing, China).

First surgery: A VAAFT device (Karl Storz GmbH, Tuttlingen, Germany) was used to explore the fistula site. The optical fistuloscope was inserted through an external opening (Figure 1), and the fistula was stretched to be as straight as possible. The fistuloscope was then advanced along the tract, reaching the internal opening if possible. Given the typical contorted nature of horseshoe anal fistulas, great care was taken to avoid any violent or forceful movements of the fistuloscope and thus avoid

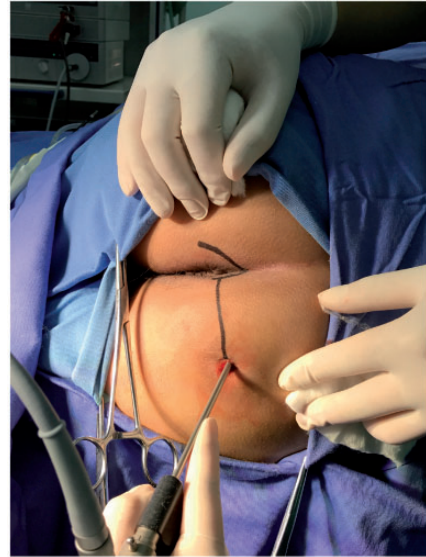


Figure 1. Insertion of the optical fistuloscope. The optical fistuloscope was inserted through an external opening and then advanced along the tract, reaching the internal opening if possible.

damaging the fistula tract. Next, an anal fistula brush was used to clean visible necrotic substances under direct vision. The configuration and site of the internal opening were then visually confirmed, and the fistula was explored to determine whether any branches or chronically infected cavities were evident. We then further visually assessed whether the incised and remaining fistulas were suitable for plug placement. Finally, an incision was made along the intersphincteric groove, and the internal sphincter was treated with a seton (Figure 2).

Because this procedure was rarely associated with postoperative pain, the patients were generally postoperatively discharged within 48 hours. The cutting seton was tightened every 2 weeks and removed at an average of 14 to 30 days postoperatively.

Second surgery: After the seton had been removed and most of the incised fistula had healed, the patients were readmitted.



Figure 2. Seton in the internal opening. During the first surgery, an incision was made along the intersphincteric groove, and the internal sphincter was treated with a seton.

The condition of the fistula was again observed by VAAFT to confirm the presence of any branches or infected lesions. The tract was completely cleaned and the plug was installed. Briefly, the plug was inserted into the fistula through the internal opening, resulting in its adherence to the fistula. The plug was fixed using 2-0 Polysorb (Medtronic, Dublin, Ireland) at both the internal and external openings. Excess plug ADM material at the external opening was trimmed. Complete closure of the external opening was avoided because this has been found to promote the outflow of autacoid from the fistula and liquefied plug (Figure 3).

All patients received an elemental diet for 72 hours postoperatively to control defecation and prevent plug contamination. The patients were also instructed to avoid strenuous activity during this time and were administered broad-spectrum antibiotics to prevent infection. Postoperative dressing



Figure 3. Placement of acellular dermal matrix. During the second surgery, the plug was inserted into the fistula through the internal opening and fixed using 2-0 Polysorb at both the internal and external openings. The excess plug at the external opening was trimmed.

changes were conducted daily; povidone iodine was used to clean the wound, and topical antibiotic cream was then applied.

The operation time, intraoperative blood loss, postoperative pain, healing time, length of stay, and time until the patient returned to employment were recorded. A visual analog scale was used to assess postoperative pain on the day of surgery and 7 days postoperatively. Satisfactory clinical healing was defined as closure of the internal and external openings, the absence of drainage, healing of the incision, and no evidence of abscess formation (Figure 4). If such healing was not achieved, the fistula was considered to be recurrent.

All patients underwent outpatient follow-up by physician appointment in the outpatient department or by telephone interview. Follow-up was performed at 3 and 6 months postoperatively and every 6 months thereafter. The Wexner



Figure 4. Satisfactory clinical healing. Satisfactory clinical healing was defined as closure of the internal and external openings, healing of incision, and the absence of drainage and abscess formation.

incontinence scale was used to evaluate anal function preoperatively and at 3 and 6 months postoperatively using a questionnaire. The Wexner score is used to evaluate continence and provides insight on the status of the sphincteric apparatus. On a scale of 0 to 20, 0 represents perfect continence and 20 represents complete incontinence.

Statistical analysis

All statistical analyses were conducted using IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp., Armonk, NY, USA). Continuous variables are expressed as median with range. The threshold of statistical significance was set as $P < 0.05$.

Results

Twenty-six patients were enrolled in the present study. They comprised 21 male and 5 female patients with a median age

Table 1. Patients' characteristics.

Variables	Patients (n = 26)
Age, years	39.7 ± 10.8
Sex	
Male	21 (81)
Female	5 (19)
Type of fistula	
High-transsphincteric	15 (58)
Suprasphincteric	7 (27)
Extrasphincteric	4 (15)
External openings	
Single	17 (65)
Multiple	9 (25)
Previous anorectal surgery	
No	12 (46)
Yes	14 (54)
Three or more interventions	2 (8)

Data are presented as mean ± standard deviation or n (%).

of 40 years (range, 15–64 years). The duration of their clinical condition ranged from 20 days to 20 years. Fourteen patients had undergone previous anorectal surgeries. Table 1 shows the patients' demographic information and basic clinical data. Both surgical operations were successfully performed in all 26 patients. As shown in Table 2, the median operation time was 48 minutes (range, 25–70 minutes), and the median intraoperative blood loss was 11 mL (range, 2–25 mL). The median healing time was 33 days (range, 20–60 days).

The median follow-up period was 8.3 months (range, 6–18 months). Based on our healing criteria, 23 patients were cured (effective cure rate of 88.46%). Three patients developed recurrence, and all three of these patients had a history of another anal operation. This previous anal surgery and the associated severe local scarring in these patients may have contributed to their suboptimal surgical outcomes. Local scarring can significantly impair VAAFT manipulation, thus hampering the surgeon's ability to accurately visualize the entire fistula tract. When these three

Table 2. Surgical outcomes.

Variables	Patients (n = 26)
Operation time, minutes	47.9 ± 13.7
Blood loss, mL	10.7 ± 4.6
VAS score (0–10)	
1 day postoperatively	2.4 ± 1.0
7 days postoperatively	0.9 ± 0.2
Postoperative hospitalization time, days	5.4 ± 1.4
Time until returning to work, days	6.3 ± 0.9
Healing time, days	33.0 ± 10.5
Prognosis at 6-month follow-up	
Healing	23 (88.5)
Recurrence	3 (11.5)

Data are presented as mean ± standard deviation or n (%). VAS, visual analog scale.

patients underwent the second-stage surgery, we determined that the residual fistula branch had not been adequately treated. All three patients' conditions were cured after a traditional incision was performed.

No patients developed postoperative fecal incontinence. The patients' mean preoperative Wexner score was 0.39 ± 0.64 , that at 3 months postoperatively was 1.23 ± 0.82 [significantly higher than the preoperative score ($P < 0.01$)], and that at 6 months postoperatively was 0.42 ± 0.58 (no significant difference relative to the preoperative score) (Figure 5).

Complications

We observed a few minor complications that were not clinically significant. Three (11.5%) patients developed postoperative urinary retention, two (7.7%) developed edema at the wound site, and three (11.5%) developed postoperative bleeding. The bleeding was stopped by local compression without further surgery, and no serious postoperative complications were observed.

Discussion

The primary goal of anal fistula treatment is to simultaneously preserve the anal

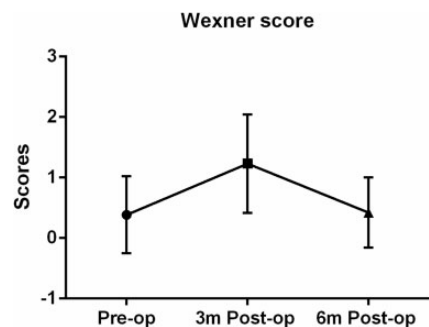


Figure 5. Wexner scores preoperatively and at 3 and 6 months postoperatively.

sphincter function while removing the fistula.¹⁸ Unfortunately, these two outcomes are often at odds with each other, particularly when treating complex fistulas such as the relatively rare horseshoe fistula, which accounts for only 5% of all anal fistulas.^{3,4} Traditional surgical approaches can achieve curative effects in patients with horseshoe fistulas; however, multiple operations are often required to achieve such outcomes, and the cure rates may be even lower in certain patient populations such as those with Crohn's disease.¹⁹ In particular, there is substantial concern regarding the potential for disrupting the normal anal sphincter

function when treating this form of fistula given its complexity,² necessitating the exploration of novel surgical techniques with the potential to reduce the complication rate associated with this disease.

VAAFT is a minimally invasive technique for treatment of complex anal fistulas, and even after repeated use it does not damage the fistula or anal sphincter.²⁰ Although the recently developed VAAFT and anal fistula plug implantation strategies alone offer attractive advantages as a means of treating anal fistulas, both suffer from certain deficiencies with respect to treating horseshoe fistulas. Indeed, necrotic substances in the fistulous tract can cause infections and lead to recurrence, and direct viewing of the fistula to facilitate cleaning using hydrogen peroxide is not possible. Thus, plug implantation is associated with the risk of persistent foreign matter resulting in infection and recurrence.^{21,22} By allowing for direct viewing of the fistula tract, which is not possible with other techniques, VAAFT makes it possible to clean the fistula and thus achieve a higher operative success rate. Our incorporation of the observational advantages of VAAFT with the practical value of the anal fistula plug-based procedure allowed us to explore the value of a novel VAAFT-Plug intervention as a means of reducing complication rates and bolstering sphincter function in patients with horseshoe anal fistulas.

In our study, 23 of 26 patients with horseshoe anal fistulas were cured using this VAAFT-Plug approach (overall cure rate of 88.46%). All three patients who did not achieve total success had undergone previous anal surgeries resulting in local scarring, which led to the presence of small branches in the fistula tract that were not readily observed using the VAAFT device. These tracts thus led to postoperative infection of the plug that required treatment with a subsequent incision. This finding emphasizes that although

VAAFT-Plug is a promising technique, the patient's surgical history should be considered when determining his or her suitability for this approach. After undergoing successful surgery, none of our patients developed severe postoperative complications or incontinence, suggesting that VAAFT-Plug is a potentially valuable means of relieving pain, shortening the disease course, and preserving anal function and appearance.

This study has certain limitations that must be considered when interpreting its results. First, this was a retrospective study of a novel procedure; hence, the sample size was relatively low and the follow-up times were variable. Caution is therefore warranted when generalizing these results to longer-term outcomes. Second, several additional factors have the potential to influence the outcomes of any surgical operation aimed at curing anal fistulas. Previous studies of patients with horseshoe anal fistulas have shown that the primary fistula tract is of a high trans-sphincteric conformation in 90% of cases, with the primary internal opening being posterior in 65% of cases.⁴ Among the 26 patients in the present study, the primary internal opening was posterior in 24 (92%) and anterior in only 2 (8%). Third, anal fistulas commonly affect patients with Crohn's disease, and treatment of fistulas in such patients can be more complex.²³ Whether the VAAFT-Plug approach will be as successful in these complex scenarios remains to be assessed. How these factors affect the surgical outcomes of VAAFT-Plug was not specifically assessed in the present study and will require future examination in the context of larger-scale multicenter randomized controlled trials. Similar to other surgeries, the VAAFT-Plug procedure involves incision of part of the fistula and internal opening, inevitably inflicting a certain amount of injury to the anal sphincter. However, the VAAFT-Plug procedure is considered safer than the

traditional methods. Apart from our report of two minor adverse events, a few minor complications have been reported by several other researchers, including urinary retention and perineal or scrotal edema.^{8,24} Therefore, the VAAFT procedure is feasible in patients with complicated perianal fistulas because of its low probability of complications; usually, the procedure can be easily performed before success is achieved. The video fistuloscope provides the surgeon more control over the operation because visualization of the tract and its branches helps to define the precise direction of the fistula and its internal opening. This helps prevent the development of a false tract or false internal opening when blindly and vigorously probing the tract with a fistula probe. In addition, visual feedback allows us to distinguish side divisions of the fistula that may otherwise be unobserved and omitted. A final limitation of this study is that we lacked a control group to demonstrate the advantage of combination therapy. Future studies should thus aim to further decrease or eliminate the amount of injury incurred by this or related procedures and evaluate the applications of combined therapy. Despite these limitations, our results provide a promising glimpse into the value of a novel procedure suitable for achieving satisfactory surgical outcomes in a majority of patients with horseshoe anal fistulas. This approach thus warrants further examination as a means of improving patient standards of care.

Conclusions

The two primary goals of anal fistula surgery are healing of the fistula and preservation of anal function; however, these goals can often conflict with each other. The recently developed VAAFT technique can assist with accurate intraoperative assessment of fistulas, facilitating complete

cleaning of necrotic tissues from the fistula and thereby improving the success rate of the ADM plug implantation without damaging the perianal muscle. VAAFT thus enables maximal preservation of normal anal function while simultaneously improving the success rate of ADM anal fistula plug placement. We found that the success rate of the VAAF-Plug procedure for the treatment of horseshoe anal fistulas was high and that the operation was relatively straightforward for surgeons, ensuring repeatable satisfactory outcomes. Although these results are promising, a randomized controlled trial and a longer follow-up period are still needed to confirm the effectiveness of this intervention. Further validation of this combined surgical approach has the potential to provide a higher standard of care to patients in need worldwide, making it a high-priority topic for future study.

Consent for publication

This manuscript has not been published and is not under consideration for publication elsewhere in whole or in part. No conflicts of interest exist in the submission of this manuscript, and the manuscript has been approved for publication by all listed authors.

Availability of data and material

The data used to support the findings of this study are available from the corresponding author upon request.

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Authors' contributions

Conceptualization: Yuru Zhang and Fei Li; methodology: Fei Li; software: Tuanjie Zhao;

validation: Tuanjie Zhao, Ang Li, and Feng Cao; formal analysis: Tuanjie Zhao and Feng Cao; investigation: Tuanjie Zhao; resources: Feng Cao; data curation: Tuanjie Zhao and Feng Cao; writing—original draft preparation: Yuru Zhang, Tuanjie Zhao, and Feng Cao; writing—review and editing: Yamin Zheng and Ang Li; visualization: Yamin Zheng and Feng Cao; supervision: Fei Li and Ang Li; project administration: Fei Li; funding acquisition: Yuru Zhang.

Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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