



Preclinical testing of a new radiofrequency ablation device in a porcine perianal fistula model

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Purpose: Anorectal fistulas present a treatment challenge, with conventional surgical methods potentially resulting in complications such as fecal incontinence. To improve patient outcomes, more effective and minimally invasive therapies are critically needed. In this study, an optimal porcine model for the creation of anorectal fistulas was developed and used to evaluate the efficacy of radiofrequency ablation (RFA) therapy.

Methods: Two distinct but related experiments were conducted. In the first experiment, a reliable and standardized porcine anorectal fistula model was developed. In the second, the healing process was assessed, and outcomes were compared between the RFA-treated group and the control group using the established porcine model.

Results: The results indicated that a 3.5-cm fistula tract length and a 14-day evaluation period following seton removal are optimal for the porcine anorectal fistula model. In the second experiment, the RFA group tended to exhibit better outcomes regarding fistula closure, although the differences were not statistically significant. Histopathologically, no significant difference in inflammation grade was observed between groups; however, scar tissue was more predominant in the RFA group.

Conclusion: The findings suggest that RFA therapy may offer potential benefits in the treatment of anorectal fistulas, as demonstrated using a porcine model. To validate these results and explore the mechanisms of action underlying RFA therapy for anorectal fistulas, further research involving larger sample sizes and a more robust study design is required.

Keywords: Radiofrequency ablation; Anorectal fistula; Minimally invasive therapy; Porcine model

INTRODUCTION

Low-lying anorectal fistulas can be successfully treated using traditional surgical methods such as fistulectomy or fistulotomy. However, for high-lying or complex fistulas, these approaches may lead to anal sphincter damage, resulting in fecal incontinence (FI) even after healing. These procedures involve the removal of infected tissue and the creation of an open wound that

heals from the inside out. Alternative surgical options, such as rectal advancement flap (RAF) [1], ligation of the intersphincteric fistula tract (LIFT) [2], and seton drainage followed by RAF or LIFT [3], aim to preserve the anal sphincter muscle. The success rates of these methods vary, ranging from 37% to 88%. Nonetheless, some degree of sphincter damage may be unavoidable with these procedures, and the reported incidence of FI varies from 0% to 51% [1–3].

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Anorectal fistula is a chronic and debilitating condition that meaningfully impacts patient quality of life, particularly when associated with FI. The pursuit of more effective and less invasive treatments is essential to improve patient outcomes and alleviate the burden of this condition. Thermal therapy for fistula tracts has recently emerged as a promising option due to its capacity to destroy fistula tissue and promote tract shrinkage. For instance, video-assisted anal fistula treatment (VAAFT) employs an endoscope to visualize the fistula tract, allowing for targeted treatment of complex fistulas, including those with secondary tracts [4]. VAAFT has demonstrated favorable results, with healing rates between 70% and 90% and low recurrence rates [5]. Another innovative, minimally invasive technique is Fistula-tract Laser Closure (FiLac; Biolitec Research), which uses a novel sphincter-preserving method. FiLac employs a radially emitting laser to obliterate the lumen of the fistula tract [4, 6–8]. Although healing rates have been observed to vary—81.8% with a previously inserted loose seton versus 40% without—no worsening of FI has been reported [6–8]. As radiofrequency ablation (RFA) therapy has been successfully used alongside laser therapy to close varicose veins, we hypothesized that RFA could be similarly applied to anorectal fistulas as an endofistula thermal therapy.

RFA therapy has demonstrated promising results in various medical applications, including varicose veins [9, 10], thyroid nodules [11], and hepatocellular carcinoma [12, 13]. RFA generates heat via high-frequency alternating current. While its mechanism of heat production is distinct from that of FiLac, both therapies employ thermal effects to damage the target tissue [11, 14, 15]. The potential efficacy of RFA in the treatment of anal fistulas merits further exploration. However, the available data on the effectiveness of RFA therapy for anal fistulas are sparse, highlighting the need for further research to clarify its benefits and drawbacks.

To address this gap in knowledge, we conducted 2 separate but related experiments. In the first experiment, we developed an optimal porcine model for anorectal fistula that mimicked the self-healing of an artificial anorectal fistula tract. A reliable and standardized animal model is essential for investigating novel treatments and comparing their effectiveness. In the second experiment, we evaluated the efficacy of RFA therapy using the established porcine model for anorectal fistula. Assessing the healing process and comparing outcomes between the RFA-treated group and the control group can elucidate the potential advantages of RFA therapy for treating anorectal fistula.

METHODS

Ethics statement

The study protocol was approved by the Institutional Animal Care and Use Committees of Cronex Inc (No. CRONEX-IACUC 202203001, No. CRONEX-IACUC 202207003). The criteria for anesthesia and euthanasia were established in accordance with the American Veterinary Medical Association's guidelines for animal euthanasia [16].

Study design

The present study was conducted in 2 parts. Initially, an optimal pig model for anorectal fistula was established, and subsequently, the efficacy of RFA therapy in this pig model was evaluated.

All pigs were sourced from the experimental animal center at Cronex Inc (Seoul, Korea) and were in good health, with an average weight of 48 kg (range, 46–59 kg). Each clinical examination and surgical intervention, including the creation of iatrogenic fistulas, seton insertion, and seton removal, was conducted under general anesthesia. The pigs received intramuscular injections of 0.5 mL/kg Zoletil 50 (Virbac) and 0.2 mL/kg Rompun (Bayer Animal Health), as well as intravenous injections of 0.3 mL/kg Zoletil 50 and 0.5 mL/kg Rompun. After intubation of the trachea, anesthesia was maintained with isoflurane. During the procedures, the pigs were positioned prone on the operating table.

Manufacturing and operation of the newly developed RFA device

RFA employs high-frequency alternating current, which is advantageous in medical applications because it minimizes stimulation to the human body and carries a low risk of electrocution. A coil element is rapidly heated to temperatures exceeding 100 °C and applied to the venous wall, resulting in ablation [9]. In the treatment of fistula, a comparable approach is anticipated, wherein heat exceeding 100 °C is applied to the fistula wall and causes ablation and occlusion.

Using their experience in developing RFA products, RF Medical Co Ltd has developed a product specifically for the treatment of perianal fistula (Fig. 1). Furthermore, by incorporating the benefits of VAAFT, they have designed a catheter equipped with an endoscopic camera, as well as a catheter fitted with a light-emitting diode (LED). Prior to preclinical testing with pigs, we conducted a simple *ex vivo* test using pork loin to better understand the ablation conditions. We ultimately chose to cauterize at 120 °C for 20 seconds, a standardized protocol in the treatment of venous insufficiency.

RFA therapy was administered under general anesthesia. Prior

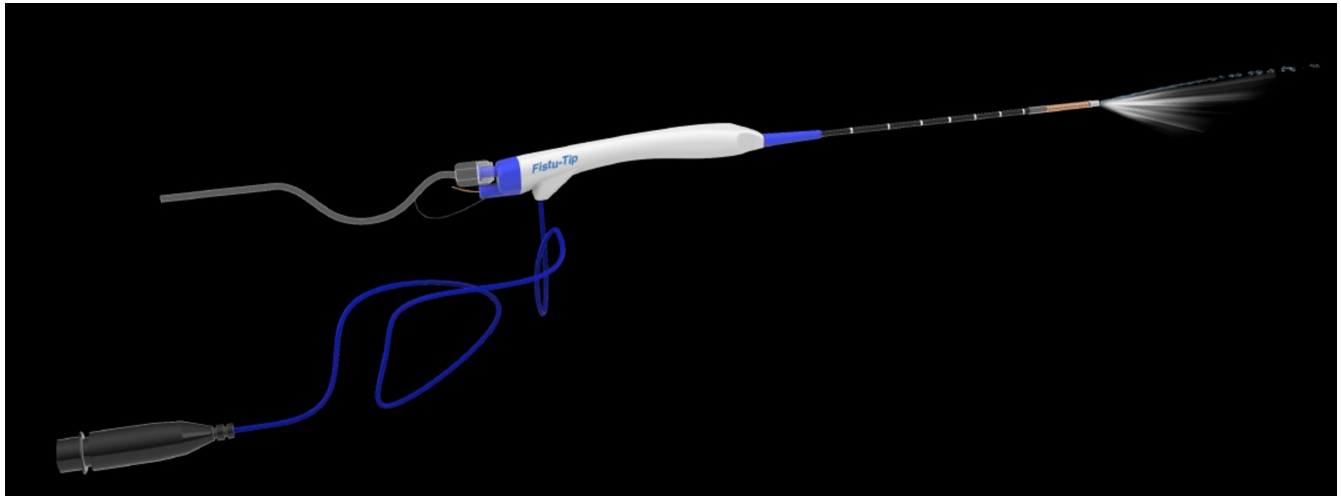


Fig. 1. Newly developed radiofrequency ablation device (RF Medical Co Ltd). The device can be used for segmental ablation and features an endoscopic camera to visualize the inside of the tract.

to the insertion of the RFA device into the fistula tract, the seton was removed, and the tract was delineated by inserting a dilator into the external opening. The end tip of the RFA device was then positioned in the anal canal via the fistula tract. The device's LED tip was utilized to pinpoint the location of the RFA device, providing accurate segmental ablation therapy within the tract (Fig. 2). Once the RFA device was placed, ablation was performed at 120 °C for 20 seconds, with the device remaining stationary due to its segmental heating capability.

Clinical and histopathological measures of fistula healing

The closure of internal and/or external fistula openings was considered a clinical indicator of fistula healing. For histopathologic examination of the fistula tract, all surgically removed fistula tracts were sectioned into 3 parts and stained with hematoxylin-eosin for microscopic analysis (Fig. 3). Two histological parameters were utilized to assess fistula healing. The first was the inflammatory response, which was graded based on the presence of inflammatory cells: grade 0, no inflammatory response; grade 1, a mild inflammatory response with low cell density in up to 25% of the analyzed area; grade 2, a moderate inflammatory response with medium cell density in 26% to 75% of the analyzed area; and grade 3, a severe inflammatory response with high cell density in over 75% of the analyzed area [17]. The second parameter was the predominant tissue type in the analyzed area, either granulation tissue or scar tissue. Wound healing encompasses 3 overlapping phases: inflammation, tissue formation, and tissue remodeling [18]. In this study, granulation tissue reflected tissue formation, while scar tissue indicated tissue remodeling. The

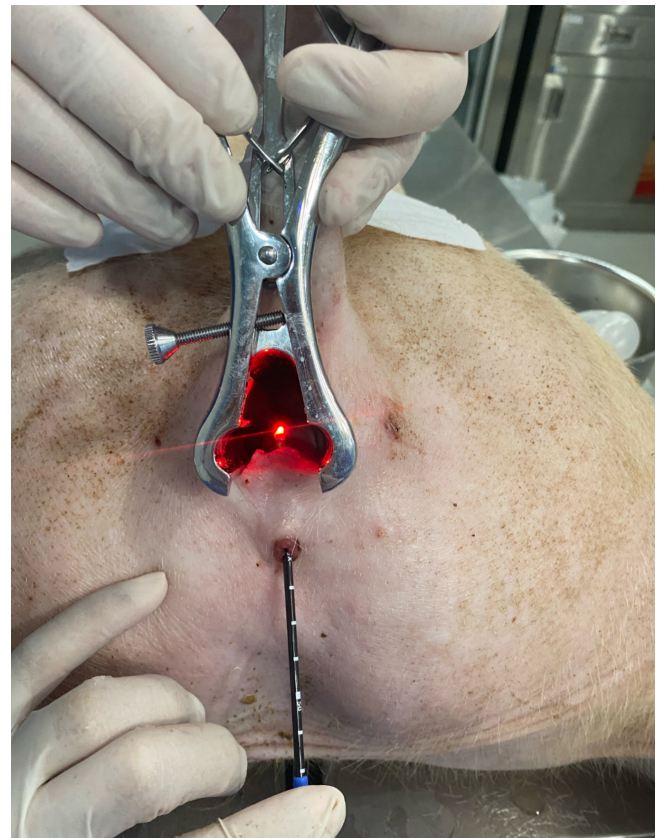


Fig. 2. Actual use of the radiofrequency ablation device in a porcine anorectal fistula. A small light-emitting diode is mounted at the end of the device to help pinpoint catheter placement.

predominance of scar tissue in the analyzed area was considered indicative of more advanced healing. All slides were examined by an experienced pathologist using an Olympus CX33 microscope

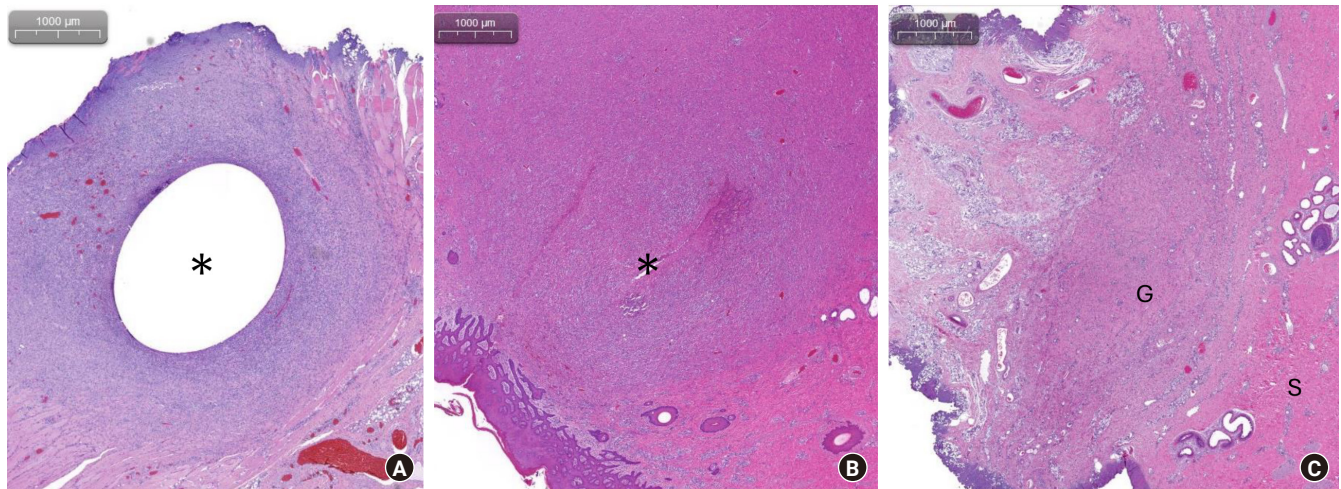


Fig. 3. Histological examination of the fistula tract in a porcine anorectal fistula model. Images show hematoxylin-eosin–stained ($\times 40$) sections of the fistula tract from a porcine anorectal fistula model at various time points. (A) Following seton removal, immediately after the procedure, the fistula is clearly visible at the center, with scar tissue present. (B) Fourteen days after seton removal, the fistula at the center appears smaller, with a greater amount of surrounding granulation tissue. (C) At 28 days post-seton removal, the fistula is no longer present. Granulation tissue (G) is visible at the center, and pinkish scar tissue (S) is seen in the outer regions. Asterisks indicate the location of the fistula in each image.

(Olympus Corp) at magnifications of $\times 40$, $\times 100$, and $\times 400$.

Experiment 1: creation of a porcine anorectal fistula model and observation of self-healing under different experimental conditions

The fistula created in this porcine model was iatrogenic and acute, in contrast to the chronic “conventional” fistula typically seen in humans. Furthermore, the self-healing mechanisms that lead to fistula tract closure can vary among species. Consequently, in this experiment, we examined the condition of the fistula tract across various tract lengths (1.5, 2.5, and 3.5 cm) and observation periods (0, 14, and 28 days) following seton removal to identify the most appropriate anorectal fistula porcine model.

Three healthy pigs were selected for this experiment. Under general anesthesia, a fistula probe with a rubber band seton was used to establish 3 iatrogenic fistula tracts for each pig, extending from the anal canal to the perianal skin, with the aid of an anoscope (Fig. 4A). The internal openings were located at the level of the pectineal line, and 3 external openings were created at the 3, 9, and 12 o'clock positions (Fig. 4B). The distance of the external opening from the anal orifice was 1.5 cm at the 12 o'clock position, 2.5 cm at 3 o'clock, and 3.5 cm at 9 o'clock. Setons were removed on the 28th day following insertion.

Each pig was clinically examined and sacrificed on day 0, 14, or 28 after seton removal. The clinical and histopathological characteristics of the fistula tracts were compared.

Experiment 2: efficacy of RFA in the porcine anorectal fistula model

The second experiment built upon the findings of the first, wherein a porcine anorectal fistula model was established. This model allowed for the observation of self-healing under various experimental conditions, as previously detailed.

Six healthy pigs, with an average weight of 48 kg (range, 46–52 kg), were selected and randomly assigned to either the control or the RFA therapy group. Under general anesthesia, fistula tracts were created, and rubber band setons were inserted at the 3, 9, and 12 o'clock positions. The distance from the external opening to the anal orifice was set at 3.5 cm in all cases. The setons were removed 28 days after insertion, again under general anesthesia. Immediately following seton removal, the RFA group received RFA therapy within the fistula tracts, while the control group had the RFA device inserted but did not receive treatment.

Clinical and histopathological evaluations were performed for both groups 14 days after seton removal.

Statistical analysis

The sample size was determined using G*Power (University of Düsseldorf) based on FiLaC treatment outcomes: 6 cases per group were initially calculated, with 9 allocated per group considering potential dropouts, while adhering to animal welfare ethics. The inflammatory grade was compared between groups using the Mann-Whitney U-test. The presence of an internal or external opening, as well as whether granulation tissue or scar tissue was

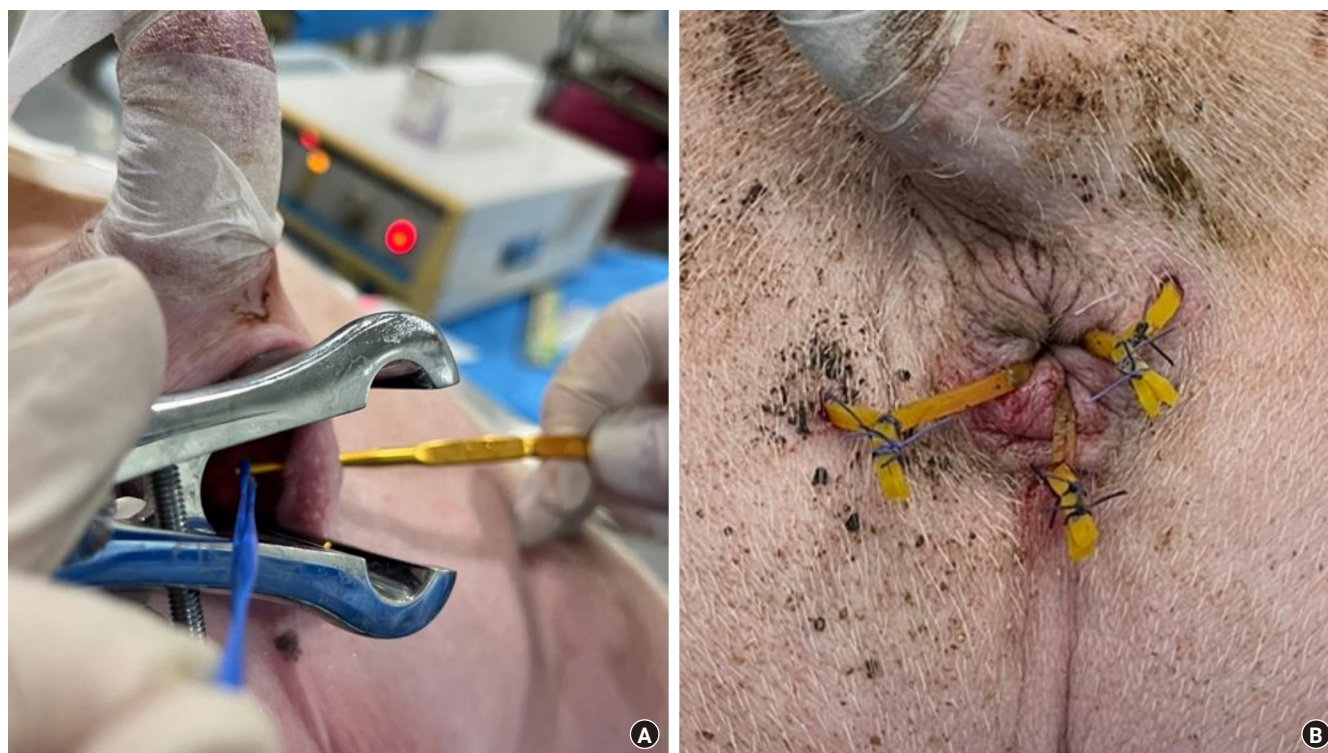


Fig. 4. Modeling and observation of self-healing in porcine anorectal fistulas under various experimental conditions. (A) Placement of a rubber band seton using a fistula probe. (B) Fistula tracts of various lengths: 1.5 cm at the 12 o'clock position, 2.5 cm at 3 o'clock, and 3.5 cm at 9 o'clock.

Table 1. Clinical and histological features of anorectal fistula tract healing in experiment 1

Pig no.	No. of days after seton removal	Length of fistula tract (cm)	Clinical feature		Histological feature	
			Internal opening	External opening	Inflammation grade	Predominant tissue
1	0	1.5	Opened	Opened	3	Granulation
		2.5	Opened	Opened	3	Granulation
		3.5	Opened	Opened	3	Granulation
2	14	1.5	Closed	Closed	2	Granulation
		2.5	Closed	Opened	2	Granulation
		3.5	Opened	Opened	2	Granulation
3	28	1.5	Closed	Closed	2	Scar
		2.5	Closed	Closed	2	Scar
		3.5	Closed	Opened	2	Scar

histologically predominant, were identified and compared between groups using the Fisher exact test. P-values of less than 0.05 were considered to indicate statistical significance. Data analysis was performed using IBM SPSS ver. 20.0 (IBM Corp).

RESULTS

Experiment 1

On day 28 following iatrogenic fistula formation, when the setons were removed, all 3 pigs exhibited well-demarcated internal and

external openings. One pig was sacrificed at that time for histopathological examination, while the remaining 2 pigs underwent clinical assessments 14 days and 28 days after seton removal, respectively.

In the study of 1.5-cm fistula tracts, 2 pigs exhibited closed internal openings, while 1 pig displayed an open external opening. Regarding the 2.5-cm tracts, 1 pig presented with an open internal opening, and 2 pigs had open external openings. For the 3.5-cm tracts, 1 pig had an closed internal opening, while 3 pigs had open external openings (Table 1).

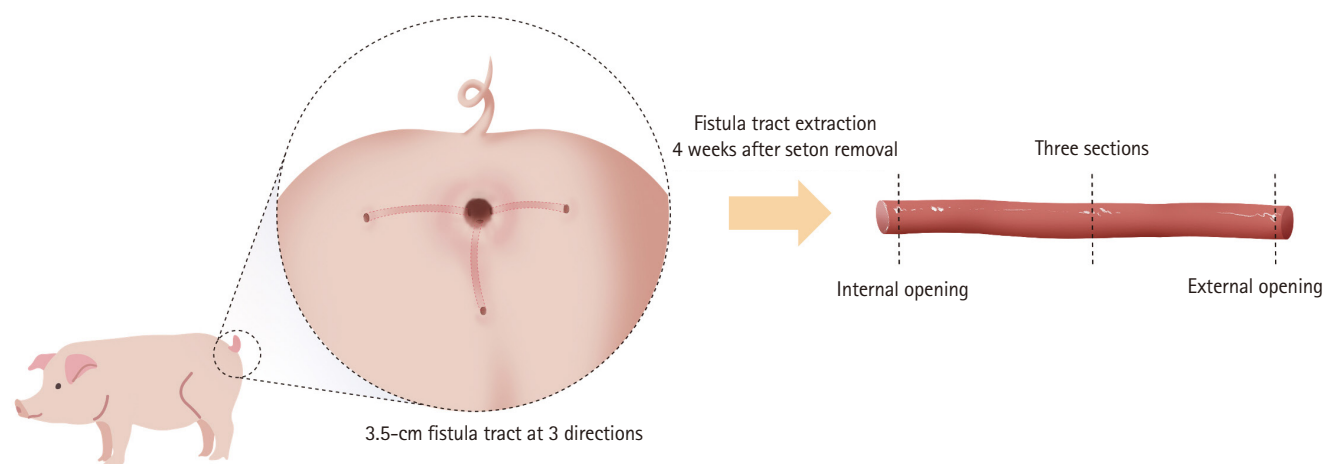


Fig. 5. Schematic view of the experimental setup for evaluating radiofrequency ablation (RFA) therapy in a porcine anorectal fistula model. Fistula tracts measuring 3.5 cm in length were positioned at 3, 6, and 9 o'clock. Rubber band setons were removed 28 days after insertion. Immediately after seton removal, the RFA group underwent RFA therapy in the fistula tracts, while the control group had the RFA device inserted but did not receive treatment. Both groups were subjected to clinical and histopathological examinations 14 days following seton removal.

A second pig was sacrificed for histopathological examination, and the remaining pig was clinically assessed 28 days after seton removal. For all fistula tract lengths, the internal openings were closed; however, the external opening of the 3.5-cm tract remained open.

Histopathological examinations were conducted at 3 distinct time points after seton removal for each of the 3 pigs (Fig. 5). On the day the seton was removed, all 3 sections, representing different tract lengths, were predominantly composed of granulation tissue and exhibited an inflammatory grade of 3. Fourteen days after seton removal, the number of granulation tissue-dominant sections increased in relation to the length of the tract: 1 section in the 1.5-cm tract, 2 sections in the 2.5-cm tract, and 3 sections in the 3.5-cm tract. A consistent inflammatory grade of 2 was noted across all tract lengths. By 28 days after seton removal, all tissue sections had transitioned to being scar tissue-dominant, irrespective of the fistula length, and maintained an inflammatory grade of 2 for all lengths (Table 1).

Based on these findings, the optimal fistula tract length in the present study was determined to be 3.5 cm; accordingly, clinical and histopathological examinations were performed 14 days after seton removal.

Experiment 2

Upon seton removal, 2 pigs in the RFA group had lost 1 seton each, resulting in a total of 2 setons lost. In the control group, 3 pigs had lost 1 seton each, totaling 3 setons lost. Most of the unintended seton removals occurred within the first 7 or 14 days after placement, when the pigs rubbed their hips. Consequently, the fi-

Table 2. Comparison of clinical and histological outcomes between the RFA group and the control group in experiment 2

Variable	Control group	RFA group	P-value
No. of pigs	3	3	-
No. of fistula tracts	6	7	-
External opening still open	5 (83.3)	3 (42.9)	0.135
Internal opening still open	1 (16.7)	0 (0)	0.261
Inflammation grade	1.61 ± 0.502	1.62 ± 0.498	0.961
Scar tissue dominance	11/18 (61.1)	16/21 (76.2)	0.309

Values are presented as number only, number (%), or mean ± standard deviation.

RFA, radiofrequency ablation.

nal sample comprised 7 tracts from 3 pigs in the RFA group and 6 tracts from 3 pigs in the control group.

The clinical outcomes were compared between the RFA group, which included 7 tracts, and the control group, which contained 6 tracts. The external openings remained open in 3 of the 7 tracts (42.9%) in the RFA group and in 5 of the 6 tracts (83.3%) in the control group ($P=0.135$). Regarding the internal openings, all tracts in the RFA group remained closed (0 of 7, 0%), while in the control group, 1 of the 6 tracts (16.7%) remained open ($P=0.261$) (Table 2).

Histopathological outcomes were compared across 21 sections from the 7 tracts in the RFA group and 18 sections from the 6 tracts in the control group. The inflammation grade was 1.62 ± 0.498 in the RFA group and 1.61 ± 0.502 in the control group ($P=0.961$). Scar tissue predominated in 16 of the 21 sec-

tions (76.2%) in the RFA group compared to 11 of the 18 sections (61.1%) in the control group ($P = 0.309$) (Table 2).

DISCUSSION

Anorectal fistula presents a treatment challenge, as conventional surgical procedures such as fistulectomy, fistulotomy, RAF, LIFT, or seton placement often lead to complications, including FI, fistula recurrence, and prolonged wound healing [3]. These complications can markedly impact patient quality of life and present difficulties for clinicians. In comparison, endofistula therapies, including RFA, represent minimally invasive alternatives that have the potential to supplant conventional surgery. Because thermal therapy is a relatively new approach, the effectiveness of RFA has not yet been conclusively established. Nevertheless, the exploration of thermal therapy techniques like RFA represents a promising avenue in the management of anorectal fistulas. The potential benefits of these minimally invasive therapies warrant further investigation and validation in clinical practice.

RFA is often compared to laser ablation techniques such as FiLac. Both RFA and FiLac are minimally invasive methods that use thermal energy to treat anorectal fistulas. While they share some similarities, their mechanisms and benefits differ. FiLac employs laser light, which is characterized by high directionality, coherence, collimation, and monochromaticity [6]. The biological effects of laser light are categorized into high-energy photochemical reactions, photomechanical reactions, photothermal reactions, and low-energy photochemical reactions. Collagen fiber contraction occurs at 50 °C, while necrosis is induced at temperatures between 70 and 100 °C [4, 6]. Furthermore, the FiLac laser probe should be retracted at a rate of 1 cm every 3 seconds to avoid unintended hyperthermal injury [4]. In a previous study, the mean anorectal fistula tract length was reported to be 3.2 cm [19]. Moving the probe slowly at the recommended rate over such a short distance can be challenging, potentially causing unintentional fast-tracking of the probe.

In the present study, a novel RFA therapy device was applied for the treatment of anorectal fistula. This approach offers several advantages that may address the shortcomings of existing treatments, such as FiLac, which depends on manual pullback, and laser ablation, which risks either underablation or overablation of the fistula tract. The RFA device provides a uniform distribution of thermal energy across the targeted tract, leading to more consistent ablation. Additionally, the device is equipped with a 20-mm heating wire and markers on the catheter shaft, which facilitate segmental ablation. Using these markers, clinicians can deliver thermal energy with precision and control, reducing the risks

of inadequate or excessive ablation. For fistula tracts exceeding 50 mm in length, at least 2 ablation rounds are necessary. The markers on the device are particularly useful during re-ablation, as they enable the operator to accurately retract the device by the appropriate distance, ensuring that subsequent ablation is performed at the desired location. This feature minimizes the likelihood of uneven treatment and promotes consistent coverage along the entire tract. Another benefit of the RFA device is the integration of a camera on the catheter, which can be particularly helpful in identifying secondary branches in complex fistulas. While this feature is similar to VAAFT, the RFA device offers greater versatility in treating a broader range of fistula tract sizes. Unlike VAAFT, which is not well-suited to treating thicker tracts, the RFA device accommodates catheters ranging from 2 to 3 mm in diameter, allowing clinicians to select the appropriate tool based on the tract size and ensuring more effective treatment across different fistula dimensions. However, the device does have a limitation concerning the integrated video scope. While it is feasible to equip the device with a video scope like that used in VAAFT, the electromagnetic field generated by the RFA device can introduce noise into the video images. This interference issue must be addressed to improve visualization and provide more accurate treatment guidance during the procedure.

In this study, we compared the outcomes of RFA therapy with those of a control group using a porcine anorectal fistula model. The results indicated generally better outcomes in the RFA group in terms of fistula closure, evidenced by lower proportions of open external openings (42.9% vs. 83.3%) and open internal openings (0% vs. 16.7%). However, these differences did not achieve statistical significance, possibly due to the small sample size and unintended removal of setons in both groups. Histopathological analysis revealed no significant difference in inflammation grades between the 2 groups; nonetheless, the RFA group exhibited a higher proportion of scar tissue, suggesting superior healing of the treated fistulas. These findings suggest potential benefits of RFA therapy for anorectal fistulas, but larger, more robustly designed studies are necessary to confirm these results and to better understand the mechanisms of action of RFA therapy in this context. In the present study, we employed an RFA treatment protocol derived from settings used for varicose vein treatments, which may not have been optimal for achieving the desired thermal effects in the management of anorectal fistulas. Future research should aim to determine the ideal settings specifically for anorectal fistula treatment with RFA therapy. Additionally, the sterilizing effect of ablation therapies like RFA may aid the healing process by reducing infection risk. A more detailed investigation of this aspect could support the optimization of RFA therapy for

anorectal fistula treatment and provide valuable insights into its mechanisms of action.

In the present study, we proposed an optimal pig model for the creation of anorectal fistulas. This model could represent a valuable tool for investigating novel treatments, including RFA therapy. Only a few studies have reported on animal models of anorectal fistula, and a standardized method has not been established. In a rat study, anorectal fistula models were created using steel wire; a lumen with surrounding granulation tissue was observed in all specimens, with 90% displaying at least some epithelialization [20]. The reported similarity in anal glands and their musculature between humans and pigs [21] informed our decision to use pigs rather than rats for our experiments. Additionally, a few pig studies have successfully used silicone tubes to construct fistula tracts [22–24]. A Ba-Bai-Ke-Re et al. [25] developed an experimental model of anorectal fistula in pigs using a rubber band, which was found to be a reliable method that caused comparatively little damage to the surrounding normal tissues. However, unlike in our research, previous studies did not vary the length of the fistula tract (1.5 cm vs. 2.5 cm vs. 3.5 cm). The timing for seton removal was approximately 26 to 28 days in those studies [20, 22–25], which is similar to the 28 days in the present report.

Based on the results, a fistula tract length of 3.5 cm and an evaluation at 14 days after seton removal were deemed optimal for a porcine anorectal fistula model. However, the findings from the second experiment indicated that a total of 5 setons—2 in the RFA group and 3 in the control group—were unintentionally removed as the pigs rubbed their hips, with these incidents occurring within 7 to 14 days after seton insertion. To ensure the secure placement of rubber band setons and the successful creation of iatrogenic anorectal fistulas, the rubber bands must be securely tied with more than 2 knots, and a short remnant of the band should remain outside the anal canal. In future experiments, reducing the seton placement duration from 28 days to 14–21 days may be beneficial for investigating the potential effects of a shorter duration on creating a porcine fistula model. We believe that the rubber band seton placement method for creating anorectal fistulas is reproducible and represents an optimal model. Furthermore, this method has been reported to simulate the pathophysiology of clinical anal fistula [25]. The development of a standardized and reliable porcine model is essential for advancing future research and for comparing the efficacy of different treatment modalities.

The present study had several limitations. First, the experiments were conducted with a limited number of animals, potentially impacting the generalizability of the findings due to the small sample size. Second, while porcine models are appropriate for studying

anorectal fistula treatments, differences exist between human and porcine anatomy and physiology that could impact the applicability of the results to human patients. Additionally, although the porcine model aimed to simulate conditions in humans, it could not fully replicate the cryptoglandular pathophysiology; thus, the study primarily reflected the acute stage of fistula development rather than the chronic stage. Another limitation is that the RFA treatment protocol was adapted from settings used for varicose vein treatments, which may not be ideal for achieving the desired thermal effects in anorectal fistula treatment. Further research is necessary to establish the optimal RFA therapy settings specifically for anorectal fistula treatment. These limitations should be considered when interpreting the study findings and their potential implications for human patients.

In conclusion, the results of this study offer a standardized porcine model for anorectal fistula and indicate that RFA therapy may be effective in this context. The establishment of a reliable animal model for researching treatments for anorectal fistulas, along with preliminary evidence supporting the effectiveness of RFA, could help further the advancement of minimally invasive and sphincter-preserving treatments for this condition.

ARTICLE INFORMATION

Conflict of interest

Kwang Dae Hong received the novel radiofrequency ablation device used in the experiment from RF Medical Co Ltd (Seoul, Korea). No other potential conflict of interest relevant to this article was reported.

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Author contributions

Conceptualization: KDH; Data curation: SY, JWC; Funding acquisition: KDH; Investigation: JWC, HSL; Methodology: YS, SY; Visualization: JWC; Writing—original draft: SY; Writing—review & editing: all authors. All authors read and approved the final manuscript.

REFERENCES

1. Balciscueta Z, Uribe N, Balciscueta I, Andreu-Ballester JC, García-Granero E. Rectal advancement flap for the treatment of complex cryptoglandular anal fistulas: a systematic review and meta-analysis. *Int J Colorectal Dis* 2017;32:599–609.

2. Hong KD, Kang S, Kalaskar S, Wexner SD. Ligation of intersphincteric fistula tract (LIFT) to treat anal fistula: systematic review and meta-analysis. *Tech Coloproctol* 2014;18:685–91.
3. Schulze B, Ho YH. Management of complex anorectal fistulas with seton drainage plus partial fistulotomy and subsequent ligation of intersphincteric fistula tract (LIFT). *Tech Coloproctol* 2015;19:89–95.
4. Wilhelm A. A new technique for sphincter-preserving anal fistula repair using a novel radial emitting laser probe. *Tech Coloproctol* 2011;15:445–9.
5. Emile SH, Elfeki H, Shalaby M, Sakr A. A systematic review and meta-analysis of the efficacy and safety of video-assisted anal fistula treatment (VAAFT). *Surg Endosc* 2018;32:2084–93.
6. Wilhelm A, Fiebig A, Krawczak M. Five years of experience with the FiLaC™ laser for fistula-in-ano management: long-term follow-up from a single institution. *Tech Coloproctol* 2017;21:269–76.
7. Lauretta A, Falco N, Stocco E, Bellomo R, Infantino A. Anal fistula laser closure: the length of fistula is the Achilles' heel. *Tech Coloproctol* 2018;22:933–9.
8. Terzi MC, Agalar C, Habip S, Canda AE, Arslan NC, Obuz F. Closing perianal fistulas using a laser: long-term results in 103 patients. *Dis Colon Rectum* 2018;61:599–603.
9. Proebstle TM, Vago B, Alm J, Göckeritz O, Lebard C, Pichot O. Treatment of the incompetent great saphenous vein by endovenous radiofrequency powered segmental thermal ablation: first clinical experience. *J Vasc Surg* 2008;47:151–6.
10. Proebstle TM, Alm BJ, Göckeritz O, Wenzel C, Noppeney T, Lebard C, et al. Five-year results from the prospective European multicentre cohort study on radiofrequency segmental thermal ablation for incompetent great saphenous veins. *Br J Surg* 2015;102:212–8.
11. Mauri G, Cova L, Monaco CG, Sconfienza LM, Corbetta S, Benedini S, et al. Benign thyroid nodules treatment using percutaneous laser ablation (PLA) and radiofrequency ablation (RFA). *Int J Hyperthermia* 2017;33:295–9.
12. Poon RT, Ng KK, Lam CM, Ai V, Yuen J, Fan ST. Radiofrequency ablation for subcapsular hepatocellular carcinoma. *Ann Surg Oncol* 2004;11:281–9.
13. Lau WY, Lai EC. The current role of radiofrequency ablation in the management of hepatocellular carcinoma: a systematic review. *Ann Surg* 2009;249:20–5.
14. Paravastu SC, Horne M, Dodd PD. Endovenous ablation therapy (laser or radiofrequency) or foam sclerotherapy versus conventional surgical repair for short saphenous varicose veins. *Cochrane Database Syst Rev* 2016;11:CD010878.
15. Sartori S, Di Vece F, Ermili F, Tombesi P. Laser ablation of liver tumors: an ancillary technique, or an alternative to radiofrequency and microwave? *World J Radiol* 2017;9:91–6.
16. Kirkwood J. AVMA Guidelines for the euthanasia of animals. *Anim Welf* 2013;22:412.
17. Galvão MO, Santos CH, Falcão GR. Evaluation of the inflammatory response induced by different materials in the treatment of perianal fistulas: experimental study in rats. *J Coloproctol* 2016;36:16–20.
18. Singer AJ, Clark RA. Cutaneous wound healing. *N Engl J Med* 1999;341:738–46.
19. Burney RE. Long term results of surgical treatment of anal fistula in a case series of 483 patients. *Int J Surg Open* 2021;33:100350.
20. Arakaki MS, Santos CH, Falcão GR, Cassino PC, Nakamura RK, Gomes NF, et al. Experimental model of anal fistula in rats. *J Coloproctol* 2013;33:135–8.
21. McColl I. The comparative anatomy and pathology of anal glands. Arris and Gale lecture delivered at the Royal College of Surgeons of England on 25th February 1965. *Ann R Coll Surg Engl* 1967;40:36–67.
22. Buchanan GN, Sibbons P, Osborn M, Bartram CI, Ansari T, Halligan S, et al. Experimental model of fistula-in-ano. *Dis Colon Rectum* 2005;48:353–8.
23. Han JG, Xu HM, Song WL, Jin ML, Gao JS, Wang ZJ, et al. Histologic analysis of acellular dermal matrix in the treatment of anal fistula in an animal model. *J Am Coll Surg* 2009;208:1099–106.
24. Aikawa M, Miyazawa M, Okada K, Akimoto N, Koyama I, Yamaguchi S, et al. A newly designed anal fistula plug: clinicopathological study in an experimental iatrogenic fistula model. *Int Surg* 2013;98:122–8.
25. A Ba-Bai-Ke-Re MM, Chen H, Liu X, Wang YH. Experimental porcine model of complex fistula-in-ano. *World J Gastroenterol* 2017;23:1828–35.