FiLaC™: The Latest Revolution in Anal Fistula Treatment-A Literature Review of Various Therapeutic Techniques

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Abstract

Anal fistula, an abnormal tunnel anal and rectal's mucosa to surrounding skin in anus or perianal region, has long been considered a complex clinical challenge. This condition often poses a threat in long-term treatment due to the recurrence high risk and incontinence. In this article, we narratively review a number of scientific literatures regarding new treatment techniques which been employed to address anal fistula in the past five years. We objectively evaluate the pros and cons of each technique according to clinical outcomes, and aim to explore the most effective treatment strategy for anal fistula. To date, surgery remains the primary method used to treat anal fistula. However, there has not yet been a single technique that is simple and capable of fully curing complex anal fistulas. In undertaking surgical treatment, both healing outcomes and the protection of anal function must be comprehensively considered.

***Keywords**: FiLaC™, Anal Fistula Treatment, Therapeutic Techniques.*

A. INTRODUCTION

Anal fistula is typically condition arises as the result of abscesses, ulceration, or drainage incisions occurring around the anus and rectum. It manifests as an abnormal channel connecting the anal canal and rectum to the skin surrounding the anus. Statistical analysis based on big population in UK data indicates there are roughly 1.69 anal incidences fistula per 10,000 individuals (García-Olmo et al., 2019). Anal fistula patients are generally adults aged among 30 to 40 years, where men is in higher prevalence than women (Tetsuo, 2018). Anal fistula can lead to several complications, including abscesses. These abscesses take various exit routes. Most descend to the anoderm (perineal abscess) or pass through the thickness of the external anal sphincter and end in the ischiorectal fossa. Some come to and end in the supralevator domain, where the anal fistula as the infection drainage pathway result that lined from epithelial tissue. After the remaining abscess drains either natural or surgical. The 60% of abscesses end in such a fate (García-Olmo et al., 2019);(Tetsuo, 2018).

Anal fistula significantly impacts the patients life quality and often effect negatively in the psychological condition of the patients, with many experiencing symptoms of depression or anxiety. Generally, anal fistula cannot be cured without therapeutic intervention. Surgical action is the primary method used for treating anal

fistula. The main criteria in determining treatment method are the removal of the infected lesion, creation of adequate drainage, and fistula closure, while minimizing damage to the anal sphincter.(Bleier & Moloo, 2011) The integrity of the internal and external anal sphincter is the most crucial element in maintaining normal anal function for the patient.

Anal fistulas could be classified in the basic or complex based on the lesions severe. The ASCRS or the American Society of Colon and Rectal Surgeons classifies it into simple types, that comprise < 30% of anal sphincter external and the low transsphincteric also the intersphincteric fistulas. For simple anal fistulas, especially those located distally, fistulotomy can be used to achieve optimal treatment outcomes (Alasari & Kim, 2014). Conversely, complex anal fistulas are among the conditions that are difficult to manage in colorectal surgery. Examples include the anal fistulas connected to the cancer, inflamammatory bowel dissease, radiation, diarrhea also the pre-existing fecal incontinence as the transsphinicteris fistulas which represent > 30% of the external anal sphincter.

The various causes and forms of complex anal fistulas often make their treatment accompanied by a high risk of recurrence and the potential for incontinence issues. To date, there is still no clinical consensus on the best surgical approach for this condition. Cutting seton (CS) is an early exploration of sphincter-sparing technology, working on the principle that gradual muscle release will result in fibrosis and necrosis, potentially maintaining sphincter complex integrity with minimal damage at the cutting edge. The sphincter portion managed with CS may result in sphincter injury, with outcomes that may be less controllable compared to simple open fistulotomy. Gradual total sphincter surgery is becoming the first choice for treating anal fistula.

In recent decades, numerous sparing sphincters methods have been improved, including endorectal advance flap (ERAF), ligation of the intersphincteric fistula tract (LIFT), fibrin glue, anal fistula plug, fistula-tract laser closure (FiLaC™), video-assisted anal fistula treatment (VAAFT), and the use of adipose-derived stem cells (ADSC) (Limura & Giordano, 2015). Based on these independent sphincter-sparing techniques, several new, innovative, combined, and modified therapies have been proposed and implemented in clinical studies to reduce recurrence rates, protect the anal sphincter, and achieve better postoperative outcomes. However, the variable results produced by various treatment methods and the inevitable heterogeneity of clinical trials often create confusion and misunderstanding.

B. METHODS

This literature review systematically evaluated various surgical techniques for the treatment of anal fistula, utilizing a narrative analysis approach. We conducted an extensive search of scientific databases, including PubMed, Embase, and Scopus, to gather articles published in the past five years, focusing on new developments in anal fistula treatment. The search terms used included "anal fistula," "surgical treatment,"

"sphincter-sparing techniques," and specific procedures such as "FiLaC™," "LIFT," and "OTSC®."

Articles were selected based on their relevance to surgical outcomes, innovation in treatment methodologies, and their focus on minimizing postoperative incontinence. Both retrospective and prospective studies were considered, with particular attention given to those providing comparative analyses of different techniques.

The data extraction included information on the type of study (randomized controlled trial, cohort study, case series), the number of patients, the type of fistula treated, the surgical technique employed, and the outcomes measured, which primarily focused on healing rates, recurrence rates, and incidence of incontinence.

Our review also included a qualitative assessment of the methodologies used in these studies to address potential biases and variability in outcome reporting. This was crucial in understanding the effectiveness and reliability of each technique. Further, the review considered the advancements in surgical tools and the incorporation of new materials, such as biomaterials used in fistula plugs or advancements in laser technology.

The methods of this review allowed for a comprehensive understanding of the current landscape of surgical treatments for anal fistula, highlighting the benefits and limitations of each technique and identifying areas requiring further research.

C. RESULTS AND DISCUSSION

1. FiLaC™ for the Treatment of Perianal Fistula

FiLaC™ utilizes diode laser energy to abrade the fistula tract from the inside, resulting in less tissue damage and preserving the function of the external sphincter (Garg et al., 2010; Gecse et al., 2014; Sileri et al., 2014; Wilhelm et al., 2017). A recent study combining FiLaC™ with autologous fat cell transplantation has shown that this combination can improve the success rate in managing complex and recurrent anorectal fistulas.(Gecse et al., 2014) Lay-open remains the optimal way to heal fistulas. The healing advantages must weighed against the danger of patients losing the continence through the fistula impact muscle. Several surgical procedures are encouraged to deal the issue because currently there is no technique which optimally removes the incontinence possibility. Although none of the methods ensure positive outcomes as the reason of new developed method (Dönmez & Hatipoğlu, 2018);(Wolicki et al., 2021). More than 600 patients reported in FiLaC and shown both the viability and safety. Effectiveness from the studies varies marginally, with fistula healing rates ranging from 20% to 89%. There are no fecal incontinence reports and the operation interesting in the sphincter-preserving setting fistula surgery since it could be repeated with some morbidity. Several success rate from study with FiLaC compare favorably with other sphincter-preserving techniques. A recent systematic review reported an accumulated healing rate of about 70% for the LIFT procedure in nearly 500 patients with perianal fistulas. For advancement flaps, an accumulated success rate of about 75% reported in nearly 800 patients analysis (De Hous et al.,

2019);(Alam et al., 2020). It is unclear if the high success initial rates which certain FiLaC surgery result recorded will hold true in some future years. Several studies shown even more limited advantages. Several striking dissimilarity among studies showed on FiLaC, especially regarding the addition of internal opening closure (with sutures or advancement flaps) used in some groups. The several previous studies analyze the combination, suggesting which combining two therapy techniques makes it more difficult to asses the FiLaC affects treatment result.(De Hous et al., 2019; Dönmez & Hatipoğlu, 2018; Wolicki et al., 2021) Moreover, some studies reporting on FiLaC without internal opening treatment reported better results, so the expressing doubt on the further closure necessity. Identifying target patients who would benefit from the procedure is challenging due to the heterogeneity in studies and outcomes achieved. Transsphincteric fistulas seen in the majority patients from the height and intricacy were not always documented optimally. The size, length and fistulas style variations suggestes as the reason the several numerous results (Giamundo et al., 2015);(Frountzas et al., 2020). Where this context the future study is being done to analyze the result collection core and to focuse to the variation in result reporting. Several series demonstrated that the FiLaC procedure is minimally invasive and possible in outpatient setting. The positive reviews or the result (main fistula healing) also the possibility of multiple applications with minimal impact on continence have emerged. However, this technique has significant cost implications compared to other techniques. Fistula tract anatomy can pose problems also the secondary extensions presence inaccesible at time for the fistula probel laser. In addition, pre-and post-operative MRI are rarely used in analysis to confirm the tract and susequent healing architecture. It could impacted on outcome technique because the majority of fistula procedures frequently fail due to concealed tracts and undected extensions. Furthermore, radiological healing does not in line with the clinical healing necessarily. The case frequently with Crohn's perianal fistual, that the radiological healing can take for years to heal (Giamundo et al., 2014). FiLaC need to used in another methods for fistula anatomy which is more complicated. In fact, the recent report shows its usages in conjuction with video-assisted anal fistula surgery (VAAFT). The FiLaC studies also limited from the retrospective designs that uses data from one institution as reperesentation of diverse population study. It reduces the external validity and findings repetability.

2. Other Surgical Techniques in the Management of Anal Fistula

a. Seton Modification In an effort to protect the uninvolved anal sphincter during anal fistula surgery with Seton, an early Seton drainage method has been proposed. This technique involves creating continuous drainage from the fistula using materials such as medical thread and rubber bands to prevent abscess formation (García-Olmo et al., 2019). Although Seton drainage successfully preserves sphincter function and reduces anal incontinence, previous research indicates that the long-term recurrence rate for the treatment of complex anal fistulas could reach 20-80% (Eitan et al., 2009). Techniques such

as cutting Seton, rerouting Seton, and rerouting Seton around the EAS in combination with mucosal advancement flaps have been found more efficient for the treatment of more complex anal fistulas compared to conventional Seton methods (Tetsuo, 2018).

b. Modified LIFT, introduced by Rojanasakul Md et al. (2007) is an effective and economical technique with a success rate of 94.4% without continence failure. However, healing outcomes with the LIFT technique can be unstable, with some studies showing a success rate of only around 50% (Bleier & Moloo, 2011). This technique has become popular worldwide and has inspired various other therapeutic innovations, such as LIFT-plug and BioLIFT, though the effectiveness of these modalities still needs further testing through prospective research (Alasari & Kim, 2014).
c. Over-the-Scope-Clip (OTSC®) Proctology Device OTSC® is an elastic nitinol closure clip used to close fistula tracts from the inside by placing the device at the internal opening of the fistula (Prosst et al., 2012). A study by Mascagni et al. (2018) showed a success rate of 93.3% (14/15 patients with anal fistula) treated with OTSC®, however, the effectiveness of this device requires further validation in large-scale research.
d. Fistulectomy and Primary Sphincteroplasty (FIPS) is a technique proposed by Parkash et al to reduce the high risk of incontinence and keyhole deformities as the two main drawbacks of traditional fistulotomy, a preferred technique for treating simple anal fistulas (Dango et al., 2017);(Parkash et al., 1985).
e. Filling Therapy. This technique was introduced by Bobkiewicz et al. [12], using acellular dermal matrix to create anal fistula plugs. Various other filling materials have also been reported to assist in the treatment of anal fistulas (Limura & Giordano, 2015).
f. Photodynamic Therapy (PDT). PDT is a treatment that combines light energy and a photosensitizer to induce photooxidative damage to target tissues or cells (Arroyo et al., 2017). Although clinical research related to PDT is still very limited, the effectiveness and costs of this technique require further evaluation (Arroyo et al., 2017).
g. Innovative tissue engineering techniques offer promising alternatives to support primary therapy, such as enhanced Seton placement through nanobiomaterials that provide better mechanical and biological properties in tissue growth. The use of adipose-derived stem cells (ADSCs) following the use of FiLaCTM in conjunction with internal opening repair in the treatment of complex perianal fistulas has also shown promising results, with healing rates reaching 70%.
h. Other Procedures, include proximal superficial cauterization, emptying regularly fistula tracts and curettage of tracts (PERFACT), transanal opening of the intersphincteric space (ROPIS), and tunnel-like fistulectomy plus draining seton combined with incision of internal opening of anal fistula (TFSIA). In 2015, the PERFACT technique was proposed for the treatment of complex high

anal fistulas. This technique relies on burning the mucosal surface around the internal opening of the fistula, as well as maintaining cleanliness of the fistula tract, branches, and cavities. Two years later, the same authors reported another new technique, TROPIS, for the same disease (Garg, 2017). This technique successfully increased the healing rate to 84.5%, with an overall healing rate exceeding 90%.

i. Non-surgical procedures have begun to be developed for the treatment of anal fistulas, however, the effectiveness of these methods is often limited and even ineffective, making them unsatisfactory alternatives to anal fistula surgery. Iqbal et al. (2019). proposed non-surgical therapy for the treatment of low perianal fistulas by washing the fistula with a 1% silver nitrate solution. The prospective observational trial proved that silver nitrate successfully healed 80% of patients with perianal fistulas.

j. As many as 76.3% of patients were reported with low perianal fistulas. This technique shows that this simple, easily realizable, and side-effect-free therapy is viable for the treatment of low perianal fistulas. On the other hand, previous research attempted to use ozone to treat chronic anal fistulas. Although this treatment has no side effects or complications caused by ozone injection, the healing rate only reached 25% among 12 patients participating in a prospective clinical trial. A third of the patients who healed relapsed, making this technique unreliable as a primary treatment method.

D. CONCLUSION

The treatment of patients with anal fistula often requires an individual and personalized approach, considering the patient's condition and the specific form of the fistula. Minimally invasive treatment techniques like FiLaC™ offer several advantages, such as smaller wound size, faster healing, and no postoperative incontinence found. However, the assessment of this technology is still hampered by the limited data available, which is a common challenge in this research field. Therefore, high-quality research and clinical trials remain necessary to determine the best treatment strategies for managing anal fistulas, with the aim of developing more effective and evidence-based therapies.

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