DOI 10.26724/2079-8334-2026-1-95-7-12
UDC 616.35-002-089+615.814

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MINIMALLY INVASIVE VERSUS SURGICAL SOLUTIONS FOR CHRONIC ANAL FISSURE

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Chronic anal fissure is a common anorectal disorder associated with considerable morbidity. Lateral internal sphincterotomy is regarded as the gold standard because of its consistently high healing rates, while botulinum toxin injection has been proposed as a less invasive alternative. This study evaluated 48 female patients with chronic anal fissure, divided equally into two groups: botulinum toxin injection (24 patients) and lateral internal sphincterotomy (24 patients). The mean age was similar between groups at approximately 37 years. At twelve months, healing was higher in the lateral internal sphincterotomy group (95.8 %) compared with the botulinum toxin injection group (75 %), though this difference did not reach statistical significance (p=0.0532). Repeat injection was required in 12.5 % of patients. Transient incontinence occurred in 12.5 % of botulinum toxin patients but resolved, whereas 8 % of surgical patients reported persistent incontinence at one year. Botulinum toxin offered faster recovery and fewer complications.

Key words: chronic anal fissure, botulinum toxin injection, lateral internal sphincterotomy, recurrence, incontinence.

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МІНІМАЛЬНО ІНВАЗИВНІ МЕТОДИ ЛІКУВАННЯ ХРОНІЧНИХ АНАЛЬНИХ ТРІЩИН ЗАМІСТЬ ХІРУРГІЧНОГО ВТРУЧАННЯ

Хронічні анальні тріщини є поширеними аноректальними станами, що супроводжуються значним погіршенням якості життя. Завдяки стабільно високим показникам загоєння, латеральна внутрішня сфінктеротомія вважається «золотим стандартом» лікування анальних тріщин, тоді як ін’єкції ботулінічного токсину розглядаються як менш інвазивна альтернатива. У дане дослідження було включено 48 пацієнток із хронічними анальними тріщинами, яких рівномірно розподілили на дві групи: ін’єкції ботулінічного токсину (24 пацієнтки) та латеральна внутрішня сфінктеротомія (24 пацієнтки). Середній вік в обох групах був порівнянним і становив близько 37 років. Через дванадцять місяців загоєння було вищим у групі латеральної внутрішньої сфінктеротомії (95,8 %) порівняно з групою ін’єкції ботулінового токсину (75,0 %), однак ця відмінність не досягла статистичної значущості (p=0,0532). Повторна ін'єкція була необхідною для 12,5 % пацієнток. Після введення ботулотоксину, у 12,5 % пацієнток відзначалося тимчасове нетримання калу, яке повністю зникло до кінця дослідження, тоді як у 8 % пацієнток після хірургічного втручання нетримання калу зберігалося навіть через рік після операції. Таким чином, ін'єкції ботулотоксину забезпечували швидше відновлення та меншу кількість ускладнень у пацієнток з анальними тріщинами.

Ключові слова: хронічні анальні тріщини, ін’єкції ботулотоксину, латеральна внутрішня сфінктеротомія, рецидиви, нетримання калу.

Funding. *This study received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors. The study was conducted at the authors’ primary place of work and was funded from their income there.*

Chronic bleeding from a damaged anus contributes to the development of anemia and significantly reduces quality of life and work capacity. Consequently, timely identification and management of bleeding-related conditions are of considerable clinical and public health importance [2, 3]. Chronic anal fissure (CAF) is a common proctologic condition characterized by a longitudinal mucosal tear in the distal anal canal, often accompanied by severe pain, bleeding, and sphincter spasm. The condition predominantly affects young adults and significantly impairs quality of life due to its persistent symptoms and recurrence risk. The pathogenesis is primarily attributed to hypertonia of the internal anal sphincter and ischemia, which hinder mucosal healing and perpetuate the fissure cycle [3, 4]. Lateral internal sphincterotomy (LIS) remains the gold standard treatment for chronic anal fissure, with healing rates exceeding 90 % and long-term efficacy demonstrated across diverse patient populations [4, 5]. However, LIS carries inherent surgical risks, including fecal incontinence and wound-related complications, particularly in women with an obstetric history and elderly patients [6, 7]. To address these limitations, minimally invasive approaches such as botulinum toxin injection (BTI) have been explored. BTI induces a temporary chemical sphincterotomy by inhibiting acetylcholine release at the neuromuscular junction, resulting in reversible sphincter relaxation and promoting fissure healing [9]. Although limited data exist in the literature on the novel therapeutic use of BTI, the findings are inconsistent, at times contradictory, and underscore the need for further research. Bonyad et al. (2024), in a meta-analysis of randomized clinical trials (RCTs) encompassing 489 patients, found that

LIS was associated with higher healing and lower recurrence, but BT was equally safe, with fewer incontinence complications [6]. Thippeswamy et al. (2025) in a systematic review of 35 RCTs with 1,532 patients reported a primary healing rate for BT, a low complication rate, and confirmed BT's favorable safety profile, though healing/recovery was inferior to LIS [12]. New spring 2024 SAS Meta-Analysis with analyses showed LIS superior in healing (pooled effect 0.77); authors highlight better safety and fewer side effects with BT – but note that long-term follow-up is still needed [6]. RCT comparing BT vs LIS found higher 3-month healing rates in LIS, while both had similar safety profiles – reinforcing BT's role as an initial or adjunctive therapy. Frontiers in Surgery, 2022, states that in recurrent post-LIS anal fissure, redo-LIS achieved better pain control and lower recurrence rates, with incontinence remaining stable; BT was less effective in this subgroup [1].

The purpose of the study was to compare the therapeutic efficacy, safety outcomes, and recurrence rates of botulinum toxin injection versus lateral internal sphincterotomy in the treatment of chronic anal fissure in a defined female patient cohort.

Materials and methods. This prospective cohort study included 48 female patients aged 19 to 45 years (mean age 37.1–1.04), diagnosed with chronic anal fissure and treated at Baku Therapeutic-Surgery Center between 2017 and 2022. Patients were evenly assigned to two treatment groups: botulinum toxin injection (BTI, n=24) and lateral internal sphincterotomy (LIS, n=24). Baseline characteristics, including fissure location, history of vaginal delivery, constipation, and bleeding at presentation, were recorded. Both groups were comparable in demographic and clinical parameters. Age comparability was ensured by stratified analysis (19–30; 31–40; 41–45 years). No statistically significant intergroup age differences were found ($p>0.05$). Tissue-related age bias was minimized by limiting inclusion to women under 45 years without prior anorectal surgery.

In the BTI group, each patient received 25 units of botulinum toxin (Allergan, AbbVie company, USA) injected into four quadrants of the internal anal sphincter. BTI was administered using sterile disposable insulin syringes (BD Micro-Fine™, USA). LIS was performed using electrosurgical unit ERBE VIO 200 D (ERBE Elektromedizin GmbH, Germany). Interventions were performed according to European Society of Coloproctology (ESCP) and American Society of Colon and Rectal Surgeons (ASCRS) guidelines, and all procedures were carried out in accordance with Institutional Clinical Protocols. The LIS group underwent electrocautery-assisted partial division of the internal sphincter at the 3 o'clock position. All patients were followed up for 12 months post-treatment.

Primary outcome measures included fissure healing at 6 and 12 months, while secondary outcomes encompassed recurrence, fecal incontinence, postoperative bleeding, and time to return to daily activities. Fissure healing was defined as the complete resolution of symptoms and epithelialization of the fissure on clinical examination. Statistical analysis was conducted using Fisher's exact test and other relevant comparative methods; p-values <0.05 were considered significant.

Patients in the BTI group who did not achieve initial healing were offered a repeat injection. All adverse events, including transient and persistent fecal incontinence, were documented and monitored throughout the follow-up period. Written informed consent was obtained from all participants. The study was approved by the Bioethics Committee of Azerbaijan Medical University (Protocol No. 2/17, dated June 25, 2017). The research complied with the Declaration of Helsinki (2013 revision) and Good Clinical Practice (ICH-GCP).

Results of the study and their discussion. The results of the present prospective cohort study provide a structured comparison of two commonly used surgical treatment modalities for chronic anal fissure. Particular attention was given to both therapeutic efficacy and postoperative functional outcomes in order to ensure a comprehensive evaluation of each intervention. Statistical analysis was performed to determine the significance of intergroup differences and to assess the clinical relevance of the observed findings.

This study compared the clinical outcomes of BTI and LIS in 48 female patients with chronic anal fissure. The baseline data of patients at admission to the clinics are presented in Table 1. The analysis focused on healing rates, recurrence, incontinence, and postoperative recovery. The results affirm previously published data on the relative efficacy and safety of each modality, while highlighting key considerations in selecting the optimal treatment approach.

Table 1

Basal clinical characteristics of patients (n=48)

Variable	BTI Group (n=24)	LIS Group (n=24)	p-value
Mean age (years)	37.2±1.1	37.0±1.0	>0.05
Posterior fissures (%)	70.8 % (17)	75 % (18)	>0.05
Anterior fissures (%)	29.2 % (7)	25 % (6)	>0.05
Vaginal delivery history (%)	25 % (6)	20.8 % (5)	>0.05
Constipation reported (%)	54.2 % (13)	62.5 % (15)	>0.05
Bleeding on presentation (%)	41.7 % (10)	45.8 % (11)	>0.05

In terms of fissure location, posterior fissures were more prevalent in both groups, found in 70.8 % (17 out of 24) of BTI patients and 75 % (18 out of 24) of LIS patients. Anterior fissures were less common, occurring in 29.2 % of BTI patients and 25 % of LIS patients. This distribution aligns with the known predominance of posterior midline fissures in chronic cases.

A history of vaginal delivery was reported in 25 % of BTI patients and 20.8 % of those in the LIS group, which may be relevant when assessing continence risks post-treatment, especially in surgical interventions. Constipation, a known contributing factor in anal fissure pathogenesis, was reported by 54.2 % of patients in the BTI group and 62.5 % in the LIS group. Rectal bleeding was noted at baseline in 41.7 % of BTI patients and 45.8 % of LIS patients, suggesting similar severity of presentation in both cohorts.

Overall, the baseline characteristics were well-matched between the two treatment groups, minimizing potential bias and ensuring comparability in outcome assessment.

After treatment, in BT group initial complete fissure healing was achieved in 18 out of 24 patients (75 %) (Table 2).

Table 2

12-month follow-up treatment outcomes

Outcomes	BTI Group (n=24)	LIS Group (n=24)	p-value
Inital healing (within 6 months) (%)	87.5 % (21)	95.8 % (23)	>0.05
Final healing rate (after one year) (%)	75.0 % (18)	95.8 % (23)	0.0532
Return to activities	1–3 days	~5 days	<0.01
Recurrence (%)	14.3 % (3 of 21)	4.1 % (1 of 24)	<0.05
Incontinence (%)	12.5 % (transient)	8.0 % (persistent)	<0.05 (severity)
Bleeding post-op (%)	0 %	12.5 %	<0.05

Among the six patients who did not initially respond to BTI, three declined further intervention, while the remaining three underwent a second BT injection, resulting in an improved cumulative healing rate of 87.5 % (21 out of 24) within six months. In contrast, the lateral internal sphincterotomy (LIS) group demonstrated a superior initial healing rate of 95.83 % (23 out of 24). However, one patient experienced recurrence, yielding an effective long-term healing rate of 95.83 % after 12 months.

At the one-year follow-up, although the healing rate in the LIS group remained significantly higher compared to the BT group (95.83 % vs. 75 %, respectively), nevertheless, the difference did not reach statistical significance (p=0.0532, Fisher's exact test). Nonetheless, the observed disparity underscores the consistent superiority of surgical intervention in producing durable outcomes, particularly in patients with long-standing or refractory fissures. Our year follow-up LIS superior healing rate is consistent with earlier studies reporting healing rates above 90 % with LIS [4, 5]. Superiority of one-year healing rates and lower recurrence in LIS vs. BTI (75 % healing, 14.3 % recurrence) is closely mirroring recent meta-analyses. A large-scale review encompassing 1,839 patients confirmed the advantage of LIS over BTI – with a pooled effect size of 0.77 (95 % CI 0.69–0.83) – reinforcing our findings [6].

Although the difference in healing rates approached statistical significance (p=0.0532), it did not reach statistical significance, possibly due to the limited sample size. Nonetheless, the trend supports LIS as a more definitive treatment for chronic anal fissure, particularly in long-standing or refractory cases. Notably, although healing differences approached statistical significance, the small cohort size may have limited statistical power. Still, consistent trends across studies underscore LIS as the more effective intervention for durable fissure resolution [11].

Notably, healing in the BT group required repeated administration in 12.5 % of patients, reflecting the reversible pharmacologic effect of botulinum toxin and its dependency on individual variability in neuromuscular junction responsiveness. This aligns with prior studies suggesting that the efficacy of BT is influenced by factors such as injection technique, dosage, and disease chronicity. Extended symptom duration likely correlates with advanced sphincter fibrosis and ischemia, which may attenuate the therapeutic effect of chemical denervation. Although BTI has been shown to be somewhat less effective in achieving complete healing, its value lies in its minimally invasive alternative. So, the healing rate of 75 % observed after 1 year in the BTI group increased to 87.5 % when repeat injections were administered to non-responders. This aligns with recent findings indicating that repeated or higher-dose BTI protocols can improve outcomes in patients with resistant fissures [7]. However, the temporary nature of botulinum toxin's effect means sustained efficacy remains a challenge, especially in patients with advanced fibrosis or ischemia of the internal sphincter. Recurrence was notably higher in the BTI group (14.3 %) compared to the LIS group (4.1 %), highlighting the transient pharmacologic action of BT. Previous systematic reviews and meta-analyses confirm similar trends, with recurrence rates for BTI ranging between 10 % and 20 %. The variability in response to BTI can be attributed to factors such as injection technique, anatomical distribution of toxin,

disease chronicity, and neuromuscular junction responsiveness [7]. This emphasizes the need for protocol optimization – particularly in patients with chronic anal fissure – through improved targeting, dosing, and possibly adjunctive therapies.

In terms of safety, transient fecal incontinence was reported in 3 BT patients (12.5%) within the first 2 months post-treatment. Importantly, all cases resolved spontaneously by the sixth month, highlighting the reversibility of BT-induced sphincter relaxation. Conversely, LIS was associated with a higher risk of persistent incontinence, as two patients (8 %) continued to exhibit symptoms at 12 months, indicative of permanent structural alterations in the internal anal sphincter mechanism. This means that regarding safety, the BTI group had a favorable profile. The safety contrast between interventions is stark. BTI-induced incontinence was purely transient, resolving within six months – reflecting its pharmacologic action. In contrast, LIS-associated persistent incontinence reflects structural sphincter compromise, corroborating long-term findings of 6–14 % incontinence rates post-LIS [11]. A 2023 RCT comparing closed and open LIS found pooled incontinence at 8.9 %, slightly lower than some reports, but still clinically relevant [5]. These data underscore that while LIS is highly effective, patient selection must account for the risk of incontinence, especially in multiparous women and elderly patients.

The findings of transient fecal incontinence, which resolved spontaneously after six months, are consistent with the known reversibility of the neuromodulatory effects of botulinum toxin. Despite the fact that the LIS group had a lower incidence of incontinence, yet the symptoms were persistent at 12 months, indicating structural compromise of the internal sphincter. This mirrors findings in the literature where LIS, although highly effective, has been associated with long-term continence risks, especially in women with a history of vaginal delivery or in elderly populations [4, 9].

Recurrence rates further illustrated the differential nature of the interventions: BT-treated patients had a recurrence rate of 14.28 % (3 of 21 healed cases), substantially higher than the 4.1 % noted in the LIS group. This disparity is consistent with the transient effect of BT on anal sphincter tone, which diminishes as neuromuscular function is restored. While this characteristic favors BT in high-risk populations (e.g., multiparous women, elderly), it poses a limitation in terms of sustained efficacy. Recurrence rates observed in the BTI group (14.3 %) align with literature reporting 10–20 % relapse, especially in chronic, fibrotic fissures [6]. This reaffirms that while BTI is appealing for its reversibility, its benefit is often transient and influenced by factors such as dosage, injection strategy, and fissure chronicity [14]. Repeated injections, as administered in two BTI patients (12.5 %) in our cohort, echo protocols recommended in guidelines for refractory cases [3]. These findings reinforce the principle that while LIS provides superior and more definitive outcomes, BT may offer a preferable risk-benefit profile in selected patient populations, particularly where preservation of continence is paramount. Long-term management strategies for chronic anal fissure should therefore be individualized, balancing efficacy with functional outcomes and recurrence risk. Future studies should aim to refine BT protocols – including dosage optimization, injection site selection, and combination with topical agents – to enhance therapeutic durability and minimize recurrence.

This study confirms that BTI offers a safer but slightly less effective treatment alternative to LIS for chronic anal fissure, particularly beneficial for women with risk factors for incontinence. While LIS remains more effective in achieving complete healing, it also carries greater long-term risks, particularly fecal incontinence, BTI allows for rapid recovery and repeatability, albeit with higher recurrence.

These findings underscore the importance of individualized treatment planning. While LIS offers a higher probability of definitive healing, it may not be appropriate for all patients. BTI is especially valuable in populations where continence preservation is paramount, such as multiparous women and elderly individuals. Additionally, BTI permits outpatient management with minimal recovery time – patients returned to daily activities within 1–3 days compared to approximately 5 days for LIS. The absence of post-injection bleeding and lower complication burden further enhances BTI's role in tailored, conservative care. Moreover, the use of BTI aligns with current trends favoring minimally invasive interventions with quicker recovery and fewer complications. Although LIS remains the gold standard, the need for safer, repeatable, and cost-effective alternatives has grown, particularly in health systems prioritizing patient comfort and outpatient care efficiency.

In light of the current findings and supporting literature, a pragmatic approach to chronic anal fissure management can be proposed. Patients with mild-to-moderate symptoms, short fissure duration, or continence risk factors may benefit most from BTI as a first-line therapy. Conversely, patients with long-standing, fibrotic fissures or prior BTI failure should be considered for LIS, provided that continence status is carefully evaluated. Additionally, exploring combined treatment strategies – such as fissurectomy followed by BTI, or BTI with topical agents – may yield further improvements in both efficacy and safety [9]. Recent advancements in the management of chronic anal fissure have led to refinement in both pharmacologic and surgical techniques. With regard to BTI, dosing strategies have evolved to favor higher doses (typically 80–100 units), as well as repeated administrations,

when necessary, both of which have demonstrated improved healing outcomes in chronic cases [8].

Injection techniques are also being optimized; while both unilateral and bilateral injections show equivalent efficacy, individualized approaches based on fissure location and severity may enhance therapeutic success [1]. Several clinical predictors have been identified to influence BTI outcomes, with chronic constipation and patient gender emerging as significant factors – particularly in males with long-standing constipation, who may exhibit reduced responsiveness to treatment [3]. In the surgical domain, technique variations in LIS) have been explored extensively. A 2023 meta-analysis concluded that both closed and open LIS techniques yield comparable healing rates; however, closed LIS appears to confer a slightly lower risk of postoperative incontinence and fewer wound-related complications [5]. Furthermore, minimal LIS techniques – which involve limited sphincter division – have shown promising results, with low rates of both recurrence and incontinence, thereby supporting sphincter-preserving approaches [13]. In cases of fissure recurrence, repeat or redo LIS remains an effective and reliable intervention, capable of providing symptom relief without significant detriment to continence [1]. Additionally, alternative surgical procedures such as fissurectomy with or without anoplasty have demonstrated high healing rates (~92.8 %) and minimal impact on continence, positioning them as valuable adjuncts or alternatives for patients unsuitable for conventional LIS [10].

Limitations. Ethical limitations included restriction to the adult female population, avoidance of vulnerable populations, and continuous adverse event monitoring. The study limitations must be acknowledged as well. The sample size, while balanced, was relatively small, which may limit generalizability and statistical power. Additionally, only female patients were included, which, although justified due to higher continence risk, limits the application of results to broader mixed-gender populations. The one-year follow-up duration, although sufficient for assessing healing and early recurrence, does not capture late-onset complications or recurrences beyond 12 months. Future research with larger cohorts, longer follow-up, and subgroup analysis (e.g., by parity or sphincter integrity) would provide deeper insight into long-term outcomes and patient-centered benefits of each modality.

Conclusion

Lateral internal sphincterotomy remains the most effective treatment for chronic anal fissure, offering the highest rates of initial and sustained healing. However, this benefit comes with an increased risk of persistent sphincter dysfunction, as a small but notable proportion of patients experience long-term incontinence. Botulinum toxin injection, while associated with lower overall healing and higher recurrence rates, provides significant advantages in safety, reversibility, and faster recovery. Its favorable complication profile, including minimal bleeding and transient, fully reversible incontinence, makes it particularly suitable for patients at elevated risk of postoperative sphincter compromise, such as multiparous women and the elderly. This study highlights the complementary roles of both therapies: lateral internal sphincterotomy as the gold standard for definitive resolution in otherwise healthy individuals, and botulinum toxin injection as a repeatable, minimally invasive alternative for those requiring continence preservation.

Prospects for further research. Future research focused on optimizing botulinum toxin techniques and dosing regimens may further enhance its effectiveness, enabling more tailored, patient-centered approaches to fissure management.

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Conflict of interest. The authors have no conflicts of interest to declare.

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Article received: 05.03.2025.

DOI 10.26724/2079-8334-2026-1-95-12-16
UDC 616.316.2-002.2-085

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CLINICAL AND LABORATORY OUTCOMES OF COMPLEX THERAPY IN PATIENTS WITH CHRONIC SIALADENITIS IN THE EXACERBATION STAGE

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Chronic sialadenitis is one of the most common recurrent salivary gland diseases, complicating treatment in maxillofacial practice due to its long course and frequent exacerbations. The purpose of the study was to evaluate the clinical and laboratory effectiveness of complex therapy combining conventional treatment with local immunotherapy using autologous leukocytes stimulated by a synthetic immunomodulatory peptide. Forty-five patients were examined: the control group received standard therapy, while the main group additionally underwent three intraductal administrations of stimulated leukocytes. Complex treatment led to faster symptom regression, improved salivary parameters, normalization of the cytokine profile, and a lower recurrence rate (12 % vs. 35 %). The findings suggest that the combined therapeutic approach improves both short-term clinical recovery and long-term disease control.

Key words: chronic sialadenitis, salivary glands, immunotherapy, cytokines, sialometry.

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КЛІНІКО-ЛАБОРАТОРНІ РЕЗУЛЬТАТИ КОМПЛЕКСНОЇ ТЕРАПІЇ ХВОРИХ НА ХРОНІЧНИЙ СІАЛОАДЕНІТ У СТАДІЇ ЗАГОСТРЕННЯ

Хронічний сіаладеніт – одне з найпоширеніших рецидивуючих захворювань слинних залоз у щелепно-лицьовій практиці, лікування якого ускладнюється тривалим перебігом та частими загостреннями. Метою дослідження стала оцінка клініко-лабораторної ефективності комплексної терапії, що поєднує традиційне лікування з місцевою імунотерапією аутологічними лейкоцитами, стимульованими синтетичним імуномодулюючим пептидом. Обстежено 45 пацієнтів: контрольна група отримувала традиційне лікування, основна група додатково отримала три внутрішньопротокові введення стимульованих лейкоцитів. Комплексне лікування призвело до швидшого регресу симптомів, поліпшення показників слини, нормалізації цитокінового профілю та зниження частоти рецидивів (12 % проти 35 %).

Ключові слова: хронічний сіаладеніт, слинні залози, імунотерапія, цитокіни, сіалометрія.

Funding. *This study received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors. The study was conducted at the authors' primary place of work and was funded from their income there.*

Chronic nonspecific sialadenitis (CS) is a long-standing inflammatory disease of the salivary glands, characterized by recurrent exacerbations, gradual fibrosis of the glandular parenchyma, and progressive secretory dysfunction [1–3]. It accounts for up to 40–50 % of all salivary gland pathologies and represents a significant burden in oral and maxillofacial practice [4, 5]. Despite widespread use of antibiotics, antiseptic irrigation, and physical therapy, recurrence remains frequent, and long-term remission is difficult to maintain [6].

The persistence of inflammation is closely linked with disturbances in local immunity, altered cytokine profiles, and accumulation of endotoxins [7]. Traditional therapies primarily target microbial agents but do not adequately restore immune homeostasis. Hence, immunomodulatory approaches are increasingly recognized as promising adjuncts [8–10].

Synthetic peptide immunomodulators has demonstrated immunoregulatory, anti-inflammatory,