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Original Article

# Injection-based Interventions for Plantar Fibromatosis: A Clinical Evidence Review

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**Introduction:**
**Background:** Surgical management of plantar fibromatosis is commonly used for treatment in advanced or refractory cases; however, high recurrence rates and procedural morbidity have driven interest in non-operative strategies.
**Purpose**: This review critically examines current evidence on injection-based and adjunctive therapies to clarify their clinical utility. A systematic literature search of PubMed, Embase, and the Cochrane Library was conducted using the term plantar fibromatosis. Studies involving human participants and published in English were included. Evidence was critically appraised across domains of clinical effectiveness, safety, and practical application. Case series were only included when higher-level evidence was not available for a given modality. Twenty-six studies met inclusion criteria.
**Recent Findings:**

- Intralesional corticosteroids provided short-term symptom relief but were limited by recurrence.
- Extracorporeal shockwave therapy (ESWT) consistently improved pain and function across varied protocols with minimal adverse effects.
- Radiotherapy demonstrated the most robust clinical evidence, including a recent randomised controlled trial reporting significant improvements in pain, mobility, and quality of life at 12 months.
- Collagenase Clostridium histolyticum (CCH) showed biological activity but remains unreliable, with inconsistent outcomes and no role in current European practice.

**Conclusion:** Radiotherapy and ESWT offer the strongest outcomes, while corticosteroids may provide short-term symptom control. CCH remains experimental. Current evidence is limited by small sample sizes and heterogeneous protocols. A stage-based, individualised treatment algorithm may help guide conservative care. Future trials must define long-term effectiveness using objective pain metrics and imaging-based endpoints, while standardising delivery to guide clinical practice.

**Keywords:** Plantar fibromatosis, Ledderhose disease, corticosteroid injections, extracorporeal shockwave therapy, radiotherapy, collagenase

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## Introduction:

Plantar fibromatosis (Ledderhose's disease, LD) is a benign fibroproliferative disorder characterised by the development of firm nodules along the plantar fascia, typically in the medial longitudinal arch [1]. Although histologically similar to Dupuytren's disease, LD presents a unique challenge due to its weight-bearing location, often resulting in progressive pain, altered gait mechanics, and functional impairment in daily

ambulation [1,2].

The pathological progression of plantar fibromatosis is typically described as three stages. These stages reflect changes in cellular activity, clinical impact and tissue structure. The first, known as the proliferative stage, is marked by elevated fibroblast proliferation. The second, described as the involution or active stage involves the maturation of fibroblasts into myofibroblasts and increased collagen deposition. This marks the onset of nodule formation and fascial contraction. The third stage, known as the residual stage, is characterised by a decline in both collagen production and fibroblast activity; this final stage is associated with an increased likelihood of developing fibrotic contractures [3–5].

Surgical excision remains a last-line option for severe or refractory cases. Recurrence after surgery is extremely high, ranging from 60% to 86%, depending on the extent of resection. Complications may also occur, such as wound dehiscence, injury to nerves or painful scarring [6]. These limitations have prompted growing interest in non-operative strategies, especially those targeting the underlying fibroproliferative biology of the disease.

Multiple non-surgical treatments have emerged as potentially viable alternatives. These include:

- Intralesional corticosteroid injections, aiming to reduce fibroblast activity, collagen deposition, and reduce local inflammation [7,8].
- Collagenase Clostridium histolyticum (CCH), an enzymatic therapy that degrades matrix collagen, though its use remains off-label and is currently unavailable in Europe [9,10].
- Extracorporeal shockwave therapy (ESWT), a mechanotransducive modality hypothesised to alter fibroblast behaviour and promote neovascularisation [5].
- Radiotherapy (RT), which has proven effective in early-stage disease by inhibiting myofibroblast proliferation [11].

While none of these modalities are curative, each offers a potential way to manage symptoms, improve functionality, or defer surgery in well-selected patients. This clinical evidence review critically evaluates evidence on injection-based and adjunctive therapies for Ledderhose disease, with particular focus on clinical efficacy, safety, and practicality. Clinical efficacy was evaluated based on measurable outcomes such as pain reduction (e.g. VAS scores), functional improvement (e.g. FFI), and changes in nodule size or consistency. Safety was assessed by reported adverse effects, complications, and long-term tolerability. Practicality was determined by treatment accessibility, cost-effectiveness, and feasibility in routine clinical settings, including considerations such as treatment invasiveness and patient burden. Special attention was given to biologically plausible mechanisms and outcome domains relevant to the conservative management of LD. Other emerging pharmacological agents have been proposed for the treatment of plantar fibromatosis based on their anti-fibrotic properties. Tamoxifen, a selective estrogen receptor modulator, has been studied for its ability to inhibit fibroblast proliferation and TGF-β2 expression, but has no established role in clinical practice for Ledderhose disease. Imatinib mesylate (Gleevec®), a tyrosine kinase inhibitor originally developed for chronic myeloid leukaemia, has been investigated in related fibroproliferative disorders such as desmoid tumours and Dupuytren's disease, but lacks supporting evidence or defined protocols for plantar fibromatosis. Verapamil, a calcium channel blocker, is used topically in the United States for Dupuytren's and Peyronie's disease, but robust clinical data in Ledderhose disease is absent. As such, these agents are not discussed in detail in this review [1,2].

**Methods:**

A literature search was conducted across the Cochrane Library, Embase and PubMed using the single keyword "plantar fibromatosis", applied as a free-text search across multiple fields. A single-term strategy was used to maximise sensitivity and ensure inclusivity, particularly due to sparse and variably indexed literature on the condition. The search was limited to only two criteria; studies involving human participants and published in English. Subject headings (e.g. MeSH or Emtree) and intervention-specific filters were omitted to maintain the spread of the initial yield.

As this review focuses on assessing treatment for Ledderhose disease, preclinical or animal-based studies are considered outside the scope of this analysis. This review is written as a narrative-style clinical evidence review, aimed at

evaluating reported outcomes such as clinical efficacy, safety, and practicality across a broad range of clinical studies.

The primary search found 468 records. All retrieved records were first screened by title and abstract to assess relevance. Full-text review was then done for articles that potentially addressed treatment strategies, with a specific emphasis on injection-based or non-operative interventions. Studies focusing only on clinical presentation, imaging, or histopathology were omitted if no therapeutic discussion was present. Ultimately, a total of 26 studies were included. Case reports and small case series were included only when higher-level evidence (e.g. RCTs or cohort studies) were unavailable for a specific intervention, such as corticosteroid injections and extracorporeal shockwave therapy to ensure clinically relevant representation of available data.

Intralesional Corticosteroid Injections (CSI)

Intralesional corticosteroid injections (CSI) are used in plantar fibromatosis as they suppress fibroblast proliferation, decrease collagen synthesis, and reduce local inflammation. These mechanisms are supported by their broader usage in fibrosing disorders such as keloids and Dupuytren's disease [2,7,8].

As of 2025, evidence for its use in LD is restricted to small series and case reports. Pentland and Anderson described symptomatic and structural improvement following serial triamcinolone injections in bilateral plantar fibromatosis. Five monthly injections of 0.5-1.0ml triamcinolone acetonide (30mg/mL, diluted with lidocaine) were administered per lesion (1–2 cm at baseline). No precise volume reduction was reported, but lesions decreased in size at 4-month follow-up with functional recovery sufficient for the patient to resume recreational activity [12].

More recently, Flanagan et al.[13] reported two cases treated with ultrasound-guided fenestration and intralesional triamcinolone injection. Each patient received two injections of 20mg triamcinolone acetonide mixed with 1 mL mepivacaine, delivered with 20-30 fenestration passes per lesion. In case 1, the distal nodule decreased from 13.5 x 5.3 mm to 6 x 1.9 mm (approximately 68% volume reduction) and the proximal nodule from 7.9 x 2.8mm to 2.4 x 1.2 mm (approximately 87%) at 12 months, with complete resolution of pain (VAS 0/10). In case 2, a 24.1 x 7mm nodule significantly reduced in size with no palpable lesion and VAS 0/10 at one year, although post-treatment dimensions were not recorded due to pandemic-related limitations.

Reviews suggest that CSI may offer short-term pain relief, and they remain an accessible, low-cost option for patients who are unfit for surgery or seeking non-operative care [7,8]. Despite this, recurrence is frequent; Veith et al. report that up to half of patients experience relapse within three years, reflecting the need for multiple treatments to maintain symptom control [7].

Complications include local skin atrophy, fat pad thinning, hypopigmentation, and rarely, fascial rupture, particularly if injection technique is imprecise or over-aggressive [8,12]. CSI should be reserved for well-selected patients, with discrete, painful nodules unresponsive to conservative care, without deep fascial infiltration, and where surgery is undesirable. Ultrasound guidance is advised to ensure accurate intralesional deposition and minimise risk, particularly in small, superficially located nodules [7,12,13].

In summary, CSI serves to defer invasive management in early-stage plantar fibromatosis, especially in patients with well-circumscribed, symptomatic nodules ≤2 cm in diameter [13].

Collagenase Clostridium Histolyticum (CCH) Injections

Collagenase Clostridium histolyticum (CCH) is a bacterial-derived enzyme that hydrolyses types I and III collagen, the predominant collagen types within plantar fibromatosis nodules [2,10]. Although developed for Dupuytren's disease, its use in LD remains off-label, and from 2020 it has been unavailable in the UK [10].

The strongest evidence arises from a phase 2b, double-blind, randomised controlled trial of 166 patients [9]. CCH did not significantly improve foot pain ($p = 0.274$) but did show gains in global impression of change (CGIC+14. 8%, $p = 0.044$), nodule hardness ($p = 0.020$) and consistency ($p = 0.002$). Side effects were mild and localised. Case reports remain inconsistent: Lehrman et al. reported a patient symptom-free 84 months after injection, while Hammoudeh et al. described recurrence despite three sessions of CCH, hypothesising limited enzymatic diffusion in plantar fascia compared to superficial cords in the hand [14,15.]

Expert reviews are cautious. Carroll et al. and Espert et al. list CCH among injection options but emphasise the lack of standardised protocols [3,16]. Tersago and Constantin (2025) include CCH as promising but stress insufficient comparative data,[10] while Fuiano et al. concluded it offered no meaningful advantage over other conservative treatments [4]. Similarly, Young et al. highlight variability in outcomes and uncertainty around patient selection [2].

To summarise, CCH shows biological activity but inconsistent efficacy. With no standardised dosing, unclear selection criteria, and lack of availability in Europe, it remains experimental rather than a routine treatment for plantar fibromatosis.

Radiotherapy (RT)

Radiotherapy inhibits fibroblast and myofibroblast proliferation and is supported by the strongest evidence among conservative treatments [11,17].

The 2023 LedRad trial demonstrated that electron-beam radiotherapy (30 Gy in 2 courses of 5 x 3 Gy) significantly improved pain (NRS 2.5 vs 3.6, p = 0.003), barefoot walking and quality of life compared to placebo. Complete or partial pain response was achieved in 74% of treated feet, with only mild, self-limiting side effects such as erythema and dryness [11]. An economic analysis found RT to be cost-effective (€14,249 per QALY gained at 18 months) [18].

Retrospective series reinforce these findings. Schuster et al. reported 81% pain relief and stability or regression in 91% of sites, with no grade ≥2 late toxicity[19]. Heyd et al. observed remission or stability in nearly 90% of plantar sites, with pain relief in 68% and gait improvement in 73%.[20] Lloyd et al. also found favourable outcomes with minimal acute toxicity [21]. Long-term follow-up confirms safety, with mild dryness in approximately 15% of patients and no severe late effects [22].

Adjuvant RT after surgery has been tried but is discouraged: van der Veer reported impaired function in 43% of patients, and de Bree documented serious morbidity including amputation [6,23]. Thus, postoperative RT should be restricted to rare high-risk cases after multidisciplinary review.

In summary, radiotherapy offers durable benefits in early-stage disease, particularly in non-operated feet with intact fascia. Its use should be confined to specialist centres using orthovoltage or electron beam protocols, typically 30 Gy in 2 courses of 5 x 3 Gy with appropriate shielding. Careful patient selection is essential, with previously operated or scarred feet contraindicated [6,11,19–23].

Extracorporeal Shockwave Therapy (ESWT)

ESWT is a non-invasive treatment increasingly used in musculoskeletal conditions, thought to act via mechano-transduction pathways influencing fibroblast activity, collagen remodelling, and neovascularisation [5]. While direct mechanistic evidence in LD is lacking, small series suggest it can reduce pain, improve function, and soften nodules, particularly in early disease or postsurgical recurrence [5,20,24].

Knobloch and Vogt (2012) treated six patients with high-energy ESWT (2,000 impulses at 1.24 mJ/mm² over two weekly sessions) [24]. Mean baseline pain (VAS 6 ± 2) improved to 2 ± 1 after 14 days and 1 ± 1 at three months. All patients reported softening of nodules, though no imaging was used.

Frizzero et al. described two patients treated with low-energy focused ESWT (four weekly sessions, 1,600 impulses at 0.20 mJ/mm$^2$) [5]. Pain fell from 6-7 to ≤1 at six months, with marked improvement in Foot Function Index subscores. Ultrasound showed no change in nodule size, though softening was noted on palpation.

Hwang et al. retrospectively analysed 10 feet treated with low- to mid-energy ESWT (0.10–0.14 mJ/mm², up to 12 sessions)[25] At 34 months, pain scores decreased from 6.2 to 0.6 and Roles-Maudsley scores from 3.5 to 1.4. Ultrasound showed significant reduction in fibroma thickness (4.4 to 2.6 mm, p = 0.003), though length/width remained unchanged.

Zachariou et al. reported a patient with bilateral LD treated with three high-energy ESWT sessions (2,000 impulses, 3 Hz, 1.25 mJ/mm²) plus TECAR therapy and orthoses [26]. Pain improved from 6 to 1 on the right and 8 to 4 on the left at 12 months, with increased walking tolerance.

Across studies, ESWT consistently reduced pain and improved function, with nodule softening frequently observed. Structural change is less clear; only Hwang et al. demonstrated thickness

reduction [25]. Adverse events were minimal, limited to transient soreness

Table 1.

*Outcomes of ESWT in Ledderhose disease*

[1] Only patients with plantar fibromatosis included; other conditions excluded

| Study | Sample Size | ESWT Type | Energy Level (mJ/mm²) | Sessions | Functional Outcomes | Ultrasound Outcome | Pain Scores | Adverse Effects[1] |
|---|---|---|---|---|---|---|---|---|
| Knobloch & Vogt (2012) | 6 patients (feet not specified) | Focused, high-energy | 1.24 | 2 (weekly) | Subjective softening of nodules | Not assessed | VAS 6 ± 2 → 1 ± 1 (3 mo) | None |
| Frizziero et al. (2017) | 2 patients (3 feet) | Focused, low-energy | 0.20 | 4 (weekly) | FFI: Right foot 24/47/6 → 0/6/0; Left foot 25/19/3 → 0/3/0 | No size change; softening noted | VAS 6–7 → ≤1 (6 mo) | None |
| Hwang et al. (2020) | 10 feet | Focused, low- to mid-energy | 0.10–0.14 | Up to 12 (mean 7.8) | RMS 3.5 → 1.4 | Thickness: 4.4 → 2.6 mm (p = 0.003) | NRS 6.2 → 0.6 (34 mo) | None (mild transient soreness) |
| Zachariou et al. (2023) | 1 patient (2 feet) | Focused, high-energy | 1.25 | 3 | Improved walking tolerance | Not reported | VAS (right): 6 → 1; (left): 8 → 4 (12 mo) | Post-ESWT pain resolved with TECAR |

As shown in Table 1, ESWT consistently demonstrates pain reduction and functional improvement across a variety of energy settings and protocols. Whether delivered as low-energy regimens over multiple sessions or high-energy in only two to three treatments, all studies reported symptomatic benefit. Long-term results were

strongest in Hwang et al., who showed sustained pain reduction and decreased fibroma thickness at nearly three years [25].

Nodule softening was reported in every cohort, even when size remained unchanged, supporting a mechanism of altered tissue consistency or pain modulation rather than complete regression, Structural changes were inconsistently documented, with only Hwang et al. demonstrating a measurable reduction in thickness [25].

Treatment was well tolerated in all studies, with no serious adverse events and only transient soreness noted in some patients. In Zachariou et al., post-ESWT pain resolved following adjunctive TECAR therapy [26].

Overall, ESWT appears to be a safe and non-invasive modality with reproducible symptomatic benefit, though lack of standardisation and limited long-term data remain key limitations.

**Discussion:**

Corticosteroid injections have been investigated in small studies and case reports, showing short-term pain relief and nodule softening, Outcomes are inconsistent, and recurrence is common, often requiring repeat injections [12,13]. Complications such as skin atrophy and plantar fat pad thinning are especially significant in the weight-bearing foot [8]. CSI may be considered in selected patients unfit for or seeking to defer surgery, but expectations must remain modest.

ESWT has generated increasing interest. Across multiple studies it produced consistent reductions in pain and improved function [5,24–26]. Structural change was less reliable; many patients improved despite stable nodule dimensions, suggesting benefit arises from altered tissue consistency or pain modulation [5,25]. Treatment was well tolerated and particularly useful in early-stage disease [24–26]. However, variation in energy settings, frequency, and delivery limits reproducibility [5,25]. Standardised protocols and prospective trials are needed to clarify mechanisms, optimise dosing, and establish long-term outcomes.

CCH offers a mechanically logical approach, but results remain inconsistent. Case reports range from durable success to failure,[14,15] influenced by anatomy, scarring, or technique. Larger trials are required before routine use can be justified.

Among the reviewed therapies, RT provides the most robust evidence, supported by a randomised controlled trial demonstrating improved pain, mobility, and quality of life compared to placebo [11.] Retrospective series reinforce these findings with high satisfaction and minimal long-term toxicity [19,22]. RT is most effective in early disease, but concerns about irradiating benign tissue and functional impairment in scarred fascia restrict its wider use [23]. Where available, it should be considered in carefully selected patients under specialist guidance.

Overall, the evidence base for conservative treatments in plantar fibromatosis is limited by small sample sizes, heterogeneous protocols, and short follow-up. Few studies provide clear guidance on sequencing or combining therapies, and no standardised outcome framework exists. Future work should prioritise prospective studies, multicentre data collection, and validated outcome measures.

These findings support selective use of non-operative therapies, particularly for patients unfit for or seeking to delay surgery. CSI may provide short-term relief, ESWT appears safe and beneficial though not yet standardised, RT has the strongest evidence but limited access, and CCH remains experimental. Surgery remains appropriate for refractory or progressive cases, but treatment should be individualised to disease stage, comorbidity, and patient goals.

**Conclusion:**

Conservative options for plantar fibromatosis remain limited and variable in quality. Corticosteroid injections may offer short-term relief, but recurrence is common. ESWT is safe and consistently improves pain and function, though protocols differ and structural benefits are uncertain. Radiotherapy is the only modality supported by randomised evidence showing durable benefit in early-stage disease when delivered to intact fascia. Collagenase remains experimental and is currently unavailable in Europe.

Currently, no conservative treatment offers predictable or disease-modifying outcomes, and surgical intervention remains the most definitive option in refractory or progressive disease. However, the risks associated with surgery, such as recurrence and morbidity, illustrate the importance of conservative strategies in selected cases. Treatment decisions must remain individualised, guided by disease stage, patient

comorbidities, and functional goals. Further high-quality studies are needed to define the role of these therapies, standardise protocols and develop a rational treatment algorithm that balances efficacy, safety, and accessibility.

Proposed Management Protocol

Based on current clinical evidence, a pragmatic, stage-based approach may assist in the management of plantar fibromatosis (Ledderhose disease).

**Asymptomatic or Mild Disease**

- Conservative measures: analgesia, footwear modification, orthoses, and activity modification.

**Early Symptomatic Disease (painful nodule ≤2 cm)**

- First-line: Intralesional corticosteroid injection (triamcinolone acetonide 20mg with 1 mL mepivacaine or 0.5-1.0 mL of 30 mg/mL per lesion; up to 2-3 injections, 4-6 weeks apart; with or without fenestration)

**Steroid-refractory cases or Contraindication to Steroids**

Extracorporeal Shockwave Therapy (ESWT)

- *Low-energy:* 0.10–0.20 mJ/mm² over 4–8 sessions [5,25]
- *High-energy:* 1.24–1.25 mJ/mm² over 2–3 sessions [24,26]

**Progressive Disease or Bilateral Involvement**

- **Radiotherapy (RT):** Electron beam or orthovoltage, typically 30 Gy in two courses of 5 x 3 Gy; or 21 Gy in 7 fractions.[19] Best in early-stage, non-operated feet; avoid scarred or post-surgical fascia.

**Refractory or Late-Stage Disease**

- Surgery: Local fasciectomy considered only for disabling, refractory disease.
- Postoperative RT reserved for rare high-risk cases after MDT review.

**Summary of Management Pathway**

- **Mild/Asymptomatic:** Conservative care
- **Early symptomatic:** Corticosteroids
- **Steroid failure/contraindicated:** ESWT
- **Progressive/bilateral:** Radiotherapy
- **Refractory/contracted**: Surgery (consider post-op RT selectively)

Management should remain individualised, guided by stage, lesion size, comorbidities, and patient priorities. Ultrasound guidance and MDT input are recommended to optimise safety and outcomes.

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