Consensus Recommendations on the Diagnosis and Management of Noninflammatory and Inflammatory Nodules Secondary to Poly-L-Lactic Acid Injections

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Abstract

Background: Poly-L-lactic acid (PLLA) is a widely used biostimulatory injectable for face and body rejuvenation. Although uncommon, nodule formation secondary to PLLA injection remains one of the most challenging complications of PLLA treatment. Inconsistent terminology and variable management approaches have resulted in uncertainty regarding diagnosis and treatment, leading to unpredictable outcomes.

Objectives: The aim of this study was to develop international expert consensus recommendations for the clinical classification, prevention, and management of PLLA-associated nodules.

Methods: An international multidisciplinary panel of experienced aesthetic clinicians with expertise in PLLA treatment and complication management was convened to develop consensus recommendations for the classification, prevention, and management of PLLA-associated nodules based on the available literature and collective clinical experience.

Results: The panel developed a practical clinical classification distinguishing noninflammatory and inflammatory nodules, together with recommendations for prevention, diagnosis, and management. A practical treatment algorithm was produced to support clinical decision making.

Conclusions: These international expert consensus recommendations provide clinicians with a pragmatic, simple-to-follow, evidence-informed framework for the diagnosis, prevention, and management of PLLA-associated nodules in routine aesthetic practice.

Level of Evidence: 5 (Risk)

Poly-L-lactic acid, PLLA-SCA, marketed globally as Sculptra (Galderma, Uppsala, Sweden) is an injectable biostimulator for face and body rejuvenation. It is the earliest and most widely used biostimulator, approved in Europe in 1999 and the United States in 2004. Cosmetic applications for improving skin quality and restoring volume, and medical applications for the treatment of HIV-associated lipoatrophy have led to the widespread global use of PLLA.[1]

A fear of the development of localized masses, so-called nodules, post treatment has historically accompanied the use of PLLA. Historically, the rate of noninflammatory (product accumulation)

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nodule formation was high, between 6% and 44%.[2,3] More recent publications have reported nodule rates ranging from 0.004% to 0.4%, although these estimates are derived from different study designs, reporting systems and denominators and should therefore be interpreted cautiously.[4,5] The reduced rates of nodule formation have been associated with changes in reconstitution volume and injection technique.[3,4] Inflammatory nodules secondary to PLLA, commonly referred to as granulomas, are cited as 0.01% to 0.1%.[3]

Despite their prevalence, PLLA-associated nodule complications remain inconsistently defined, labeled, and managed across the global aesthetic practice. The terms "nodule" and "granuloma" have historically been used interchangeably, contributing to confusion among practitioners.

Histology is theoretically the diagnostic gold standard, but is rarely obtained in routine clinical practice because of the impracticality and invasiveness of facial biopsies. Without a clear pathological confirmation, many clinicians struggle to determine whether a lesion is a noninflammatory nodule resulting from technique-related product aggregation or an inflammatory nodule driven by a delayed host-immune reaction.

This consensus document was developed to offer clinicians a practical, clinically oriented framework for recognizing and managing PLLA-related nodules. The aims were to

1. establish clear and clinically useful definitions;
2. distinguish between inflammatory and noninflammatory nodules in a way that directly informs treatment;
3. propose a proportionate and defensible management strategy that is simple and effective.

By using clinical manifestations and features such as timing, symptoms, and ultrasound imaging, this paper aims to equip practitioners with a logical, stepwise approach to identifying PLLA complications in order to instigate the most appropriate treatment. This aims to minimize the risk of misdiagnosis or inappropriate intervention.

METHODS

To address inconsistencies in the management of PLLA nodule complications, a multidisciplinary international expert group comprising 9 international clinicians was formed. The consensus meeting was held February 2026, with the manuscript development review completed May 2026. All participants had extensive experience with PLLA and with managing aesthetic complications. The panel included members practicing in dermatology, plastic surgery, pharmacy, and aesthetic medicine representing the United Kingdom, Australia, Argentina, and the United States, to reflect a broad range of clinical expertise and regional variations in clinical practice.

Consensus questions were developed by the lead author in collaboration with the expert group based on areas of clinical uncertainty identified through the published literature and collective clinical experience. These questions were circulated to all members of the group before the consensus meeting to allow the participants time to review the topics and consider their responses in advance.

The consensus development was organized around 6 headline questions designed to clarify terminology, classification, and treatment pathways:

1. Definitions and clinical classification, including diagnostic tools: How should noninflammatory nodules and granulomatous inflammatory lesions be defined, and what practical clinical classification system should be adopted? What is the role of histology or imaging in aesthetic practice?
2. Timing: How should timing be related to diagnosis and management?
3. Prevention: What are the recommended minimum treatment standards to reduce the risk of nodule formation?
4. Noninflammatory nodule management: What is the appropriate treatment pathway for noninflammatory nodules?
5. Inflammatory nodule management: What is the appropriate treatment pathway for inflammatory nodules?
6. Escalation: When should escalation to surgical management or specialist referral be considered?

A structured consensus meeting was subsequently held during which each question was discussed. Recommendations were developed through open discussion until agreement was reached. Consensus was determined through group agreement rather than by a predefined numerical voting threshold. At the conclusion of the discussion for each recommendation, each panel member confirmed that the final wording accurately reflected their position before proceeding to the next topic.

Following the meeting, the agreed consensus statements were documented and circulated to all panel members for a further round of review and comment. Amendments arising from this review were incorporated where appropriate before the final manuscript was approved by all authors.

Ethics

IRB approval was not required because this study did not involve human participants, patient data, or patient interventions. Therefore, informed consent was not required.

RESULTS

Definitions and Clinical Classification

The panel recommended moving away from histological terminology and instead toward a pragmatic clinical classification based on inflammatory status to guide diagnosis and management in routine aesthetic practice.

A binary classification was agreed as most useful:

- Noninflammatory nodules (product-related)
- Inflammatory nodules (host immune-mediated reactions)

Noninflammatory nodules were defined as lesions most consistent with product accumulations. These lesions are usually early in onset, firm, well-defined, asymptomatic, and clinically "cold," with no signs of active inflammation.

Inflammatory nodules, historically referred to as granulomas, were defined as lesions most consistent with a host immune-mediated reaction. Histologically, these lesions show a dense inflammatory infiltrate with multinucleated giant cells. Clinically, they present as "hot" lesions with features such as tenderness, erythema, edema, and progressive enlargement.[6]

The group emphasized that although the term "granuloma" is widely used clinically, it is strictly a histological diagnosis and should be reserved for cases in which it has been confirmed by biopsy. The proposed classification is intended as a pragmatic clinical framework to support diagnosis and management rather than a validated pathological classification. Histology remains the gold standard for characterizing the underlying pathological process but is rarely practical or justified in routine aesthetic practice, particularly for facial lesions where patients may not consent to biopsy.

Instead, the panel supported ultrasound as the most practical adjunct, allowing clinicians to determine whether lesions are inflammatory or noninflammatory, without the need for invasive investigations. Noninflammatory nodules appear as hyperechoic, nonvascular product deposits. Inflammatory nodules present as irregular hypoechoic areas with peripheral vascularization on Doppler imaging.[7,8]

Bedside clinical features were considered central to the classification of both types of nodules, with the following identified as key differentiators:

- Tenderness or pain: typically absent in noninflammatory nodules and present in inflammatory nodules.
- Overlying skin changes: noninflammatory nodules present with normal overlying skin; inflammatory nodules demonstrate erythema, tenderness, and edema.
- Consistency and borders: noninflammatory nodules are usually firm and well demarcated; inflammatory lesions may be softer and more diffuse.
- Growth behavior: noninflammatory nodules tend to remain stable after initial appearance; inflammatory lesions may demonstrate rapid onset or progressive enlargement.

The group acknowledged that clinical overlap exists and that classification should always be interpreted in the context of timing, imaging (where available), and overall clinical presentation.

Timing

The panel agreed that timing is a useful but nondefinitive clinical indicator. It should be considered supportive rather than diagnostic and interpreted alongside clinical features and, where available, imaging.

The panel identified a clear temporal pattern that helps guide classification:

- Early-onset nodules are most commonly noninflammatory product accumulation without an associated inflammatory reaction.[9] They typically arise within 2 weeks to 3 months following treatment and are often related to technique factors, such as dilution, placement, or product distribution. They appear gradually, first as a product accumulation and become more clinically apparent over time as collagenesis occurs.
- Late-onset nodules are more likely to be consistent with inflammatory reactions occurring in response to foreign material that cannot be phagocytosed.[9] They generally occur after 3 months, and as late as 6 to 24 months or more after treatment.[10] They can appear rapidly once the inflammatory response has been triggered.

Late-onset nodules are less commonly clinically noninflammatory, and the likelihood of an inflammatory presentation increases with time. Most delayed presentations demonstrate clinical features consistent with an immune-mediated process, although timing alone should not be considered diagnostic.

Inflammatory reactions can also be triggered by secondary events occurring months or even years after the initial treatment. Although direct PLLA-specific evidence remains limited, the panel observed that delayed inflammatory nodules may follow systemic immune activation events, including acute infection, dental procedures, vaccination, autoimmune disease, and postpartum immune change, consistent with broader literature describing delayed inflammatory reactions in cosmetic fillers.[11,12]

A practical time-based threshold of ~3 months is a useful guide for distinguishing between early, likely noninflammatory, and late, likely inflammatory, lesions. However, this was not considered as absolute, and overlap between categories was acknowledged.

- Early-onset nodules are more likely to be product-related complications, and management should initially focus on mechanical disruption where clinical assessment supports this diagnosis.
- Late-onset nodules are more likely to be inflammatory processes and should be managed with anti-inflammatory or immunomodulatory therapies where supported by the overall clinical presentation.

Overall, timing was considered a helpful contextual factor that increases diagnostic probability. Table 1 summarizes the distinguishing features of noninflammatory and inflammatory PLLA-associated nodules.

Prevention

Prevention is primarily technique-dependent. Noninflammatory nodules can be largely prevented by modifying preparation and treatment techniques.

For the reconstitution of PLLA for injection, higher dilution volumes are recommended. For facial treatment, a total volume of ~9 to 10 mL (8 mL sterile water with 1-2 mL lidocaine) is advised. Lower dilution volumes have been associated with an increased risk of nodule formation.[3,13] The panel emphasized that adequate dilution is one of the most important modifiable factors in preventing noninflammatory nodules.

Regarding hydration time, variability in both historical and current practice was acknowledged. It has been shown that hydration is effectively immediate with adequate mechanical agitation, with no meaningful differences in particle distribution or viscosity between immediate and delayed use.[14,15] Immediate use following thorough reconstitution and vigorous mixing is therefore considered acceptable, and prolonged hydration is not necessary.

Injection plane was identified as critical. Consistent with the Sculptra Instructions for Use (IFU) published by the manufacturer, the group advised that PLLA should be placed in the subdermal or subcutaneous layer.[16] Superficial or intradermal placement should be avoided, because this has been consistently linked to early-onset, noninflammatory nodules, and papules due to concentrated product deposition. It was acknowledged that injection approaches may vary depending on indication and practitioner technique, with some clinicians using supraperiosteal placement in selected areas. The overall principle is to avoid superficial deposition and ensure even distribution within an appropriate tissue plane.

The group urged caution when considering PLLA injection into thin tissue or hyperkinetic areas such as the forehead and periorbital and perioral regions, where the risk of visible or palpable nodule formation is disproportionately high.[17,18] Beyond the face, the neck and hands have been identified as particularly high-risk sites.[2,19]

For posttreatment care, the group endorsed the “5-5-5” massage protocol (5 min, 5 times per day, for 5 days) as a simple and practical instruction for patients. This recommendation is consistent with the manufacturer’s IFU.[16] However, it was emphasized that the evidential basis for this specific regimen is limited, and compliance in real-world practice is variable. Immediate, thorough massage performed by the practitioner at the time of treatment was considered more important, with patient-led massage likely playing a supportive rather than critical role once the diluent has been absorbed.

These recommendations accord with the broader evidence base, which has identified injection depth, dilution, and product distribution as the main variables influencing the development of PLLA-related nodules.

Table 1 Quick Reference Guide Summarizing the Distinguishing Clinical Features and Initial Management Considerations for Noninflammatory and Inflammatory PLLA-Associated Nodules

Feature	Noninflammatory nodule	Inflammatory nodule
Underlying process	Product accumulation/clumping	Immune-mediated inflammatory reaction
Typical onset	Early (2 weeks to 3 months)	Delayed (from 3 months to years)
Common cause	Technical factors, such as superficial placement, inadequate dilution, or poor distribution	Host inflammatory response, sometimes triggered by systemic inflammatory events
Clinical appearance	Firm, well-defined, stable	Tender, erythematous, edematous, may enlarge rapidly
Pain/tenderness	Usually absent	Common
Skin changes	Normal overlying skin	Redness, warmth, swelling, discoloration
Consistency	Firm, discrete	Softer, ill-defined
Growth behavior	Usually static	May fluctuate or enlarge
Ultrasound appearance	Discrete hyperechoic, nonvascularized deposits	Poorly defined hypoechoic lesions with peripheral vascularity
First-line management	Observation or mechanical disruption	Anti-inflammatory/immunomodulatory therapy
Role of corticosteroids	Avoid	Recommended
Response to mechanical disruption	Improvement expected	Often ineffective or may worsen inflammation
Typical escalation pathway	Repeat mechanical disruption if required	Intralesional or systemic medical therapy; consider referral if persistent
Surgical management	Rarely required	Reserved for refractory or severe cases

The table is intended as a practical clinical aid and reflects the international expert consensus informed by the available published literature and collective clinical evidence.

Management of Noninflammatory Nodules

The panel agreed that early noninflammatory nodules primarily represent product-related accumulations and should therefore be managed by mechanical dispersion rather than anti-inflammatory therapy.

For asymptomatic, nonvisible nodules, a conservative approach of observation and reassurance was recommended. Palpable lesions may not require intervention unless they become visibly enlarged or cause significant distress to the patient. Unnecessary treatment should be avoided.

Where intervention is indicated, mechanical disruption is considered the recommended first-line treatment by the panel. This typically involves using a needle or cannula to disrupt the nodule, irrigating it with fluid and massaging it vigorously. The aim is to disperse the PLLA particles.

Both sterile water and saline were considered acceptable irrigation fluids. Important determinants of success are irrigation volume and amount of mechanical dispersion, rather than the specific solution itself. A theoretical advantage of sterile water was noted: as a hypo-osmolar solution, it may cause osmotic cell swelling or lysis, increasing local fluid volume and enhancing the dilution and dispersive effect on aggregated PLLA particles. In contrast, saline is isotonic and does not produce this effect. In practice, either solution is clinically effective, provided sufficient volume is used.

The group emphasized that small irrigation volumes are unlikely to be effective. Larger volumes (~10-20 mL, depending on nodule size and location) are required to adequately infiltrate and disperse the nodule.

Timing was also considered important. Early intervention is associated with improved outcomes before collagen deposition occurs around the PLLA accumulation. Although mechanical disruption can still be attempted at a later stage, results are less predictable in established lesions.

A minimum interval of 2 weeks between sessions for tissue recovery and nodule dispersal was suggested. Two to three treatment attempts were considered reasonable before escalation to alternative strategies. Where available, ultrasound should be used to measure nodule size and evolution over treatment attempts.

The panel agreed that corticosteroids should be avoided in noninflammatory nodules, because these lesions are not immune-mediated. Their use is unlikely to be effective and may carry a risk of local tissue atrophy, which may worsen cosmetic outcomes and make nodules more apparent.

Management of Inflammatory Nodules

The panel agreed that inflammatory nodules are immune-mediated and require a fundamentally different management approach from noninflammatory nodules. Treatment should focus on anti-inflammatory and immunomodulatory therapy; mechanical disruption is generally not appropriate.

Clinical presentation of inflammatory nodules may vary, with some patients developing discrete nodules and others presenting with multiple diffuse inflammatory nodules.

Based on available evidence and expert consensus, the panel recommended that the first-line management of single inflammatory nodules should be intralesional anti-inflammatory therapy. Intralesional corticosteroids (eg, triamcinolone 10 mg/mL or dexamethasone 4 mg/mL) suppress the local inflammatory response and reduce lesion size and associated symptoms.

Intralesional combination therapy with 5-fluorouracil (5-FU) was also supported. 5-FU, frequently used off-label in the treatment of hypertrophic scars and keloids, inhibits fibroblast proliferation and targets the underlying inflammatory process while reducing the risk of steroid-induced tissue atrophy.

Treatment is delivered through intralesional injection into the center of the nodule using small volumes (~0.1-0.5 mL per injection point). Various mixtures are described, typically combining 5-FU (50 mg/mL) with low-dose corticosteroid (triamcinolone 10 mg/mL), in ratios ranging from 1:1 to 9:1, favoring 5-FU. The addition of local anesthetic improves patient comfort.[20] The panel cautioned that the amount of 5-FU should be limited to <1 mL to prevent adverse effects of hyperpigmentation or possible tissue necrosis, which can occur with higher volumes. Hyaluronidase (150 units) may be added as a spreading agent to improve diffusion of the injected agents within the nodule. Hyaluronidase does not degrade PLLA. Ultrasound-guided targeting of intralesional injections additionally improves precision.

Clinical response should be assessed after a minimum of 6 weeks, with repeat treatment considered only if there is partial improvement at this point. Up to 2 to 3 treatment sessions were considered reasonable. Ultrasound can be used to measure treatment response where available.

In cases with multiple or widespread inflammatory nodules, the group agreed that systemic corticosteroid therapy may be more appropriate. A commonly used regimen is a tapered course of prednisolone in a dose of 40 mg reducing to 5 mg over 5 days.

If there is no meaningful response or if the diagnosis remains uncertain, referral for specialist review or surgical management may be indicated.

Escalation and Referral

Escalation should be guided by response to first-line treatment, assessed over appropriate intervals between sessions. For noninflammatory nodules, treatments are reviewed after >2 weeks. Inflammatory lesions are reviewed after a minimum of 6 weeks.

Treatment failure can be defined as the persistence of the nodule with minimal or no improvement after first-line treatment has been carried out over 2 to 3 sessions.

Referral to a specialist was considered appropriate in the following situations:

- Persistence despite repeated first-line treatment
- Symptomatic nodules
- Visible or cosmetically significant deformity
- Large or progressive nodules
- Significant patient distress
- Diagnostic uncertainty

Escalation may also be appropriate in cases when further evaluation, including ultrasound, is required. Surgical management was regarded as a last-line option, reserved for refractory or severe cases where first-line treatments have failed. Although excision may provide definitive resolution, it carries risks including scarring and contour irregularity and should be considered carefully.

DISCUSSION

The management of PLLA-related nodules has historically been limited by inconsistent terminology, variable treatment strategies, and the use of histological definitions that are not useful in routine aesthetic practice. This consensus sought to address these challenges by establishing a clinically pragmatic, evidence-informed framework for classification, prevention, and management.

Central to this consensus document is the adoption of clinical rather than histological classification, using the binary system of noninflammatory and inflammatory nodules. The term “granuloma” remains widely used. However, the group recognized that this histological definition limits its clinical utility. Focusing on clinical features instead, and supported by ultrasound where available, practitioners can make more consistent diagnoses without reliance on invasive diagnostics.

The consensus highlights the importance of timing in understanding the origin of PLLA-related nodules. Early-onset lesions are predominantly product accumulations, whereas late-onset lesions are more likely to result from immune-mediated reactions. This distinction is important for both diagnosis and management.

Noninflammatory nodules are largely because of technical factors. These include low dilution volume, superficial placement, and poor product distribution. Changes to reconstitution practices and manufacturer recommendations for appropriate injection planes have reduced the incidence of nodules, making PLLA a predictable and safe treatment when used appropriately.

PLLA exerts its biostimulatory effect through a controlled, macrophage-mediated foreign-body response, in which biodegradable microparticles provoke a sustained low-grade inflammatory response that drives neocollagenesis over a period of months. This controlled biological response underpins therapeutic mechanism of PLLA. The biological processes underlying product accumulation and inflammatory reactions are likely to exist along a spectrum rather than representing entirely distinct entities. However, from a clinical perspective, the panel considered that classifying nodules according to their predominant clinical presentation provides a more practical framework for diagnosis and management. Within this framework, noninflammatory lesions are most consistent with product accumulation, whereas inflammatory lesions are most consistent with dysregulation of the immune response.

Overtreatment with corticosteroids or surgical intervention in noninflammatory nodules has been historically common. The panel noted that such approaches may expose patients to unnecessary risks, including tissue atrophy and scarring. Noninflammatory nodules are most appropriately treated with mechanical disruption. Inflammatory nodules benefit from management with intralesional or systemic anti-inflammatory or immunomodulatory agents, depending on the number of nodules present.

Although the panel considered these approaches to represent the most appropriate first-line management strategies based on the available evidence and collective clinical experience, some nodules may prove refractory to treatment despite appropriate intervention, and complete resolution cannot be guaranteed. This highlights the importance of appropriate patient counseling, realistic treatment expectations and timely referral where the suggested first-line management strategies are unsuccessful.

The potential role of infection in delayed presentations was also discussed. The panel did not consider delayed-onset infection to be a significant contributor to PLLA-related nodules in routine practice. Acute infections may occur in the days following treatment as a result of a skin barrier breach, but these are typically early events occurring within days of the initial treatment. Biofilm formation has been proposed as a cause of delayed-onset filler nodules, especially with hyaluronic acid and other cohesive gel implants. PLLA is delivered as discrete biodegradable microparticles rather than a cohesive matrix capable of supporting bacterial colonization. This mechanistic distinction is important and supports the panel’s recommendation against routine empirical antibiotic therapy for delayed inflammatory PLLA nodule presentations. The panel emphasized that a misdiagnosis of delayed infection may lead to unnecessary polypharmacy with courses of antibiotics without clinical benefit.

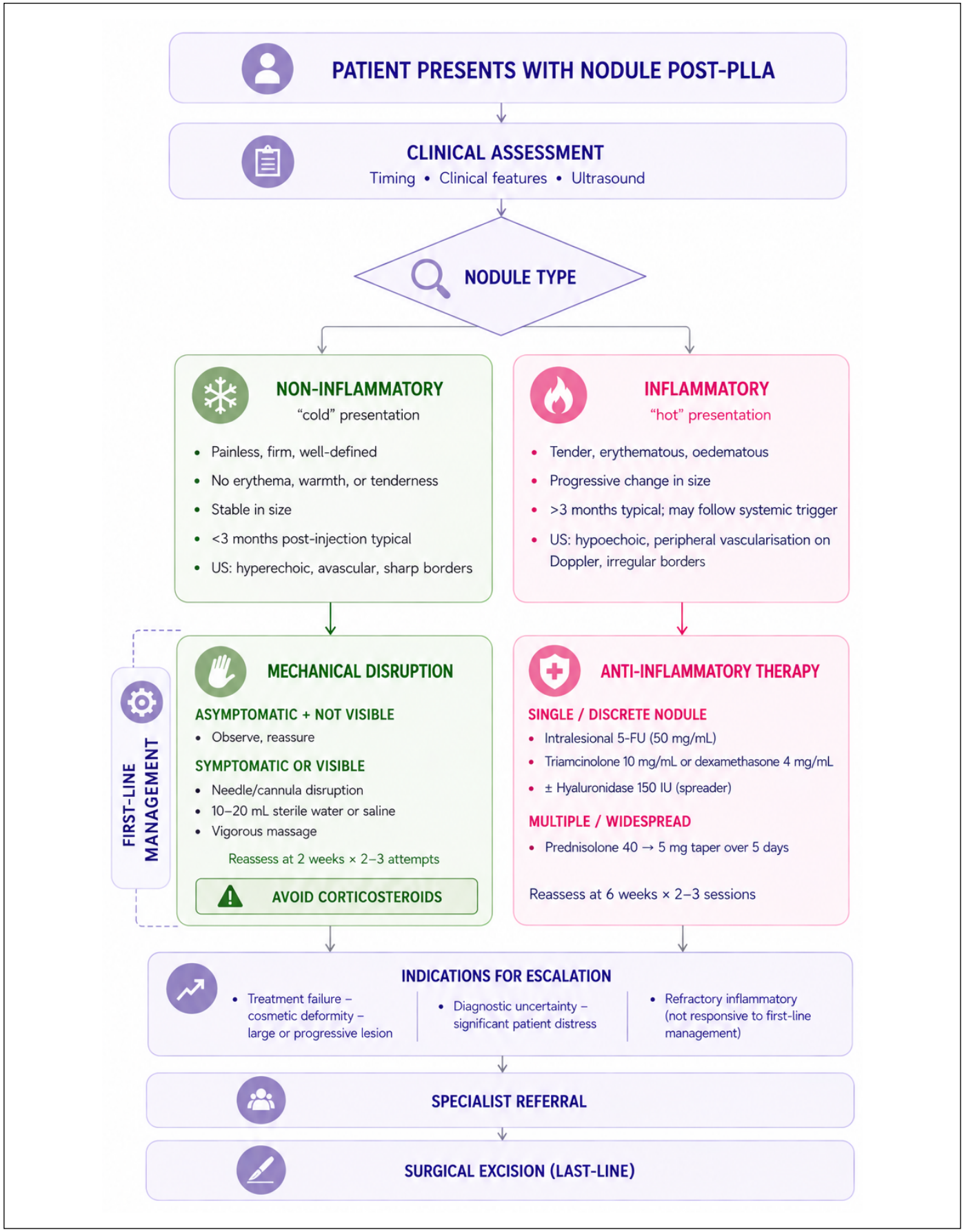


Figure 1. Proposed algorithm for the diagnosis and management of poly-L-lactic acid (PLLA)-associated nodules. The algorithm provides a stepwise clinical framework for distinguishing clinically noninflammatory and inflammatory PLLA-associated nodules and outlines the recommended management pathway based on international expert consensus. 5-FU, 5-fluorouracil.

There is a lack of publications to define optimal treatment protocols for PLLA nodule management, and complications are likely underreported. Histopathological confirmation is rarely obtained in routine aesthetic practice, meaning that most diagnoses rely on the integration of clinical assessment and, where available, ultrasound findings rather than tissue diagnosis. Although ultrasound can provide valuable diagnostic information, it cannot replace histological confirmation. In the absence of robust comparative data, this consensus offers a pragmatic framework derived from converging expert practice across multiple regulatory environments. Many of the treatment recommendations presented reflect international expert consensus informed by the available literature and clinical experience, rather than high-level comparative evidence.

Another limitation is the variability in global practice, including differences in injection techniques, access to ultrasound, medications such as 5-FU, and specialist referral pathways. Although this consensus aimed to provide internationally applicable guidance, local adaptation may be required depending on available resources, practitioner experience, and regulatory environments.

Finally, it is important to emphasize that patient communication remains central. A clear and informed consent process should specifically address: (1) the small but real risk of both noninflammatory and inflammatory nodule formation, (2) the importance of posttreatment massage and patient compliance, (3) the typical stepwise and often conservative management of PLLA nodules, including the possibility of multiple intervention sessions over weeks to months, and (4) the rare requirement for surgical excision in refractory cases.

The practical management strategies derived from this consensus are summarized in a stepwise algorithm outlining the assessment and treatment of both noninflammatory and inflammatory PLLA-associated nodules (Figure 1).

CONCLUSIONS

This consensus establishes a practical, evidence-informed framework for managing PLLA-related nodules in aesthetic practice. Prevention strategies are central to this, achieved through modifications to reconstitution and injection techniques.

Uncertainty around choosing the most appropriate management pathway has been reduced by adopting a binary classification of noninflammatory and inflammatory nodules supported by clinical assessment and ultrasound. This provides practitioners with a pragmatic stepwise approach to management and helps avoid unnecessary interventions and support consistent clinical decision making.

Supplemental Material

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Disclosures

Dr Rowland-Warmann is a speaker for Galderma (Zug, Switzerland) and consultant for GE (Chicago, IL). Mr Clague is a former employee and consultant for Allergan (Dublin, Ireland), speaker for Galderma, Alma Lasers (Caesarea, Israel), Hugel (Chuncheon-si, South Korea), Croma (Leobendorf, Austria), Cryomed (Alexandria, Australia), and Xytide (Sydney, Australia). Dr Desyatnikova is a speaker for Galderma, consultant for GE, and consultant for Fujifilm Sonosite (Bothell, WA). All remaining authors have nothing to disclose.

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