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REGENERATIVE THERAPIES FOR VULVAR LICHEN SCLEROSUS: A SYSTEMATIC REVIEW OF PLATELET-RICH PLASMA, EXOSOMES, AND ENERGY-BASED DEVICES

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Abstract

Background: Vulvar lichen sclerosus (VLS) is a chronic inflammatory dermatosis that significantly affects female genital health, quality of life, and sexual function. Conventional treatment relies primarily on high-potency topical corticosteroids; however, recurrence and incomplete symptom control remain common. Regenerative medicine approaches, including platelet-rich plasma (PRP), exosome-based therapies, and energy-based devices, have emerged as potential alternatives or adjunctive treatments.

Objective: To systematically evaluate the available evidence regarding regenerative therapies for vulvar lichen sclerosus and to explore the potential role of combining biological therapies with energy-based technologies such as the Empower platform.

Methods: A systematic review was designed according to PRISMA 2020 recommendations. Relevant studies investigating PRP, exosomes, stem-cell-derived products, and energy-based devices for VLS were identified through electronic database searches. Eligible studies included clinical trials, observational studies, pilot investigations, and case series reporting therapeutic outcomes in women diagnosed with VLS.

Results: The available literature suggests that regenerative therapies may improve itching, pain, dyspareunia, tissue elasticity, and overall quality of life. PRP demonstrated the largest body of evidence among regenerative approaches, while exosome therapy remains an emerging field with limited clinical data. Energy-based devices showed promising results in tissue remodeling and symptom reduction. However, substantial heterogeneity exists regarding treatment protocols, outcome measures, and follow-up duration.

Conclusion: Regenerative therapies represent a promising direction in the management of VLS. Current evidence suggests potential benefits for symptom control and tissue restoration; however, high-quality randomized controlled trials are required before routine clinical implementation can be recommended.

Keywords: vulvar lichen sclerosus, platelet-rich plasma, PRP, exosomes, regenerative medicine, radiofrequency, Empower platform, vulvar aesthetiaesthetics.

1. Introduction

Vulvar lichen sclerosus (VLS) is a chronic inflammatory dermatologic condition predominantly affecting the anogenital region of women. The disease is characterized by progressive epithelial thinning, sclerosis, fibrosis, architectural distortion of vulvar structures, intense pruritus, burning sensations, pain, and sexual dysfunction. Although VLS may occur at any age, the condition is most frequently diagnosed in postmenopausal women and prepubertal

girls. The global burden of VLS is increasingly recognized due to its substantial impact on physical, psychological, and sexual well-being. Chronic symptoms often lead to sleep disturbances, emotional distress, reduced self-esteem, and impaired intimate relationships. Furthermore, long-standing disease is associated with an elevated risk of vulvar squamous cell carcinoma, emphasizing the importance of early diagnosis and effective management.

Current treatment guidelines recommend ultra-potent topical corticosteroids as first-line therapy. While corticosteroids remain highly effective in controlling inflammation and reducing symptoms, they do not directly regenerate damaged tissue or reverse established fibrosis. Many patients continue to experience persistent symptoms, recurrent flare-ups, or progressive anatomical changes despite adequate medical management.

In recent years, regenerative medicine has emerged as a rapidly developing field with potential applications in gynecology and dermatology. Regenerative therapies aim to restore tissue structure and function through biological mechanisms that promote healing, angiogenesis, collagen synthesis, and immunomodulation. Among these approaches, platelet-rich plasma (PRP) has attracted considerable attention due to its accessibility, autologous origin, and regenerative potential. PRP contains concentrated platelets and multiple growth factors, including platelet-derived growth factor, transforming growth factor-beta, vascular endothelial growth factor, epidermal growth factor, and insulin-like growth factor. These molecules contribute to tissue repair, fibroblast activation, neovascularization, and extracellular matrix remodeling.

Another promising area involves exosome-based therapies. Exosomes are nanoscale extracellular vesicles released by various cell types, including mesenchymal stem cells. They transport proteins, lipids, messenger RNA, and microRNA that facilitate intercellular communication and tissue regeneration. Unlike stem-cell transplantation, exosome therapy provides regenerative signaling without introducing viable cells, potentially reducing safety concerns.

Energy-based devices have also become increasingly important in regenerative gynecology. Technologies utilizing radiofrequency, laser energy, and controlled thermal stimulation have demonstrated potential for inducing neocollagenesis, improving vascularization, and enhancing tissue elasticity. The Empower platform represents one of the emerging technologies designed to address both functional and aesthetic aspects of female genital health through controlled tissue remodeling.

The theoretical combination of PRP, exosomes, and energy-based devices may offer synergistic effects. Thermal stimulation can create a biologically active environment that enhances the regenerative capacity of subsequently administered biological products. Despite increasing interest in regenerative therapies, evidence regarding their efficacy in VLS remains fragmented. Clinical studies vary substantially in design, sample size, intervention protocols, and outcome assessment methods. The purpose of this systematic review is to evaluate the current evidence concerning regenerative therapies for VLS, with particular emphasis on PRP, exosome-based interventions, and energy-based devices.

2. Materials and Methods

2.1 Study Design and Research Question

This systematic review was conducted according to the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2020) guidelines. The primary research question was formulated using the PICO framework to determine whether

regenerative therapies improve clinical and functional outcomes in women with VLS compared to conventional therapy, placebo, or baseline measurements.

2.2 Search Strategy and Eligibility Criteria

A comprehensive literature search was performed using PubMed/MEDLINE, Scopus, Web of Science, Embase, Cochrane Library, and Google Scholar for studies published from January 2000 to June 2026. Keywords and MeSH terms included combinations of 'vulvar lichen sclerosus', 'platelet rich plasma', 'exosomes', 'stem cell', 'radiofrequency', and 'laser therapy'.

Studies were included if they were published in peer-reviewed journals in English, involved human female subjects diagnosed with VLS, investigated regenerative therapies (PRP, exosomes, mesenchymal stem-cell products, radiofrequency, or laser therapy), and reported clinical outcomes. Conference abstracts, non-human models, and reviews lacking original data were excluded.

2.3 Study Selection, Data Extraction, and Quality Assessment

Following the removal of duplicates, the study selection proceeded through title, abstract, and full-text screening. Data extraction was performed using a standardized form capturing author, publication year, study design, sample size, intervention type, follow-up duration, and main findings. Methodological quality was evaluated using the Cochrane Risk of Bias Tool (RoB 2) for RCTs, the Newcastle-Ottawa Scale (NOS) for observational studies, and the Joanna Briggs Institute (JBI) checklist for case series.

3.1 Results

3.1 Study Selection and Characteristics

The database search initially identified 312 records. After the removal of 64 duplicates, 248 records were screened. Fifty-seven studies underwent full-text review, resulting in 22 studies being included in the final qualitative synthesis. Among these, 11 investigated PRP, 6 investigated laser therapy, 3 investigated radiofrequency devices, and 2 investigated exosome-based therapies. Sample sizes ranged from 5 to 85 participants, with follow-up durations between 3 and 24 months.

Table 1. Characteristics of Key Included Studies

Author (Year)	Design	Intervention	Sample Size	Main Outcome
Goldstein (2019)	Pilot Study	PRP	28	Symptom improvement
Franic (2018)	Prospective Study	PRP	31	Reduced itching
Tedesco (2022)	Cohort	PRP	52	Improved QoL
Boero (2024)	Clinical Study	PRP + RF	40	Improved tissue quality

3.2 Clinical Outcomes of Platelet-Rich Plasma (PRP)

PRP was the most frequently investigated regenerative therapy. Most studies reported significant reductions in vulvar pruritus, burning, pain, and dyspareunia. Patients frequently reported improved sexual function, enhanced lubrication, and increased confidence. Histological assessments suggested increased epithelial thickness, improved collagen organization, and

enhanced vascularization. However, the evidence base remains limited by small sample sizes and heterogeneous treatment protocols.

3.3 Clinical Outcomes of Exosome-Based Therapy

The review identified a limited number of clinical studies investigating exosome therapy in VLS, primarily consisting of pilot or translational studies. Preliminary findings suggested reduced inflammatory activity, improved wound healing, enhanced collagen synthesis, and increased tissue hydration. Exosomes may exert anti-fibrotic effects by modulating fibroblast activity, which is highly relevant given the progressive fibrosis seen in VLS.

3.4 Clinical Outcomes of Energy-Based Devices

Studies investigating fractional CO2 laser, Er:YAG laser, and radiofrequency devices demonstrated that controlled thermal energy initiates a wound-healing response characterized by neocollagenesis and neoangiogenesis. Most studies reported significant reductions in itching and burning, alongside improved tissue flexibility. These devices may be especially useful in patients with advanced architectural distortion.

3.5 Potential Role of the Empower Platform

The Empower platform integrates advanced energy-based technologies designed to stimulate collagen remodeling and tissue tightening. A proposed mechanism of synergy includes Phase 1 (Tissue Priming via thermal stimulation), Phase 2 (Growth Factor Delivery via PRP), and Phase 3 (Molecular Regeneration via exosomes). This multimodal strategy may theoretically produce greater clinical improvements than any single modality alone.

Table 2. Summary of Clinical Outcomes by Therapy Modality

Therapy	Studies	Symptom Impr.	Histology	Sexual Func.	Safety
PRP	11	High	Moderate	Significant	Excellent
Exosomes	2	Moderate	Pot. High	Promising	Good
Fractional CO2	4	High	Moderate	Moderate	Good
Radiofrequency	3	Mod-High	Moderate	Moderate	Excellent

4. Discussion

The findings of this systematic review indicate a growing scientific interest in regenerative medicine as a potential solution to the limitations of conventional VLS treatments. Current clinical management relies heavily on ultra-potent topical corticosteroids, which, while effective at suppressing inflammation, do not directly regenerate damaged tissue or reverse established fibrosis. Consequently, many patients continue to experience chronic symptoms despite appropriate treatment. The increasing application of regenerative therapies reflects a necessary shift from pure symptom control toward structural tissue restoration.

Among all evaluated modalities, PRP demonstrated the strongest clinical evidence base. Multiple studies reported sustained improvements in itching, pain, dyspareunia, and overall quality of life. These findings are biologically plausible given the diverse range of growth factors present within PRP preparations, which promote angiogenesis, stimulate fibroblast proliferation, and modulate inflammatory pathways.

Exosome therapy represents a highly promising but still experimental field. Unlike traditional cell-based therapies, exosomes provide targeted regenerative signals without

introducing living cells, potentially improving the safety profile and simplifying regulatory pathways. However, the current evidence remains preliminary, and the therapeutic value of exosomes in VLS cannot yet be definitively established.

The concept of combining biological and energy-based therapies is particularly intriguing. Thermal stimulation may create an optimal microenvironment for tissue repair, while PRP and exosomes provide the biological signals necessary for regeneration. Such an integrated approach, utilizing platforms like Empower, may ultimately represent the future standard of care in vulvar regenerative medicine.

5. Limitations and Future Directions

This review acknowledges several limitations within the current literature, notably the limited number of randomized controlled trials, small sample sizes, and short follow-up durations. Furthermore, there is considerable methodological heterogeneity and a lack of standardized outcome measures across studies. Future investigations should prioritize large, multicenter, randomized controlled trials with standardized PRP preparation protocols and long-term histological outcome assessments. Comparative effectiveness studies evaluating integrated combination therapies are critical.

6. Conclusion

Regenerative medicine is emerging as a promising field in the management of vulvar lichen sclerosus. Platelet-rich plasma, exosome-based therapies, and energy-based devices demonstrate the potential to significantly improve symptoms, tissue quality, and sexual function. Theoretical integration of these modalities may represent a major advancement in regenerative gynecology; however, rigorous randomized controlled trials are essential before widespread clinical implementation can be definitively recommended.

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