

Supplement Article

Erbium:YAG Laser Combined With Plant-Derived Exosomes (ASCEplus IRLV) for Genital Rejuvenation

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Abstract

Background: Genitourinary syndrome of menopause (GSM) is a condition affecting peri and postmenopausal women. Er:YAG vaginal laser has been reported to improve symptoms through thermal remodeling, without tissue ablation. Exosomes are emerging biological mediators with regenerative and anti-inflammatory effects. Their use in combination with Er:YAG laser has not yet been extensively studied.

Objectives: The aim of this study was to evaluate safety and clinical efficacy of combining Er:YAG vaginal laser with topical intravaginal application of plant-derived exosomes (ASCEplus IRLV) for GSM symptoms.

Methods: Twenty women aged 45–63 years with GSM were enrolled between June and December 2023. Inclusion criteria were GSM symptoms, exclusion criteria included active infection, hormone therapy, or pelvic malignancy. Patients underwent 4 sessions of Er:YAG laser (4 J, 3600 pulses, 4 weeks apart), followed by intravaginal topical intravaginal application of 4 mL ASCEplus IRLV. Outcomes were assessed at baseline, 3 and 6 months with the Vaginal Health Index (VHI) and Female Sexual Distress Scale–Revised.

Results: Vaginal Health Index Scores improved significantly at 3 and 6 months. Female Sexual Distress Scale–Revised scores decreased significantly at 3 and 6 months and stabilized thereafter. Subgroup analysis showed consistent benefit across different baseline VHI ranges. Patients reported improvements in vaginal dryness, dyspareunia, and mild urinary incontinence. No adverse events occurred.

Conclusions: Combined Er:YAG laser and plant-derived exosomes is a safe, non-hormonal, regenerative option for GSM. The treatment improved vaginal symptoms, sexual function, and urinary complaints with durable effects. Larger controlled studies are needed to confirm these preliminary findings.

Level of Evidence: 4

Genitourinary syndrome of menopause (GSM) is characterized by vulvovaginal atrophy, dryness, dyspareunia, and urinary symptoms, significantly impairing quality of life. Conventional therapies include local estrogen, moisturizers, and energy-based devices. The Erbium:YAG (Er:YAG) laser has demonstrated efficacy in stimulating collagen remodeling and improving vaginal function through non-ablative thermal effects.^{1,2} Exosomes derived from stem cells, such as ASCEplus IRLV, offer regenerative properties, via delivery of microRNA, cytokines, and growth factors.^{3,4} ASCEplus IRLV is an exosome-based formulation specifically designed for the intimate area. It contains exosomes derived from *Rosa damascena* stem cells, enriched with bioactive molecules including growth factors (VEGF, EGF, FGF), cytokines, peptides, and microRNAs. These components promote fibroblast stimulation, angiogenesis, and extracellular matrix synthesis. In addition, the formulation exhibits strong antioxidant and anti-inflammatory properties, contributing to improved tissue hydration, elasticity, and mucosal regeneration. Their combination with Er:YAG laser may provide synergistic effects in vulvovaginal rejuvenation.

The aim of this pilot study was to evaluate the safety and efficacy of Er:YAG laser combined with ASCEplus IRLV exosomes in women with GSM.

METHODS

Twenty postmenopausal women (age range 45–63 years, mean age 53 years) with GSM were enrolled between June and December 2023. Exclusion criteria included active genital infection, previous vaginal surgery within 6 months, and systemic estrogen therapy. Participants received four sessions of non-ablative Er:YAG laser (4 J, 3600 pulses, one session every 4 weeks). Immediately after each session, 4 mL of ASCEplus IRLV (vial 1 + vial 2; ExoCoBio, Inc., Seoul, South Korea) was applied via topical intravaginal application over the vaginal mucosa via a 5 cc syringe. Patients remained supine for 10 minutes post-application.

Clinical evaluations were performed at baseline, 3 months, and 6 months post-treatment. Outcomes included the Vaginal Health

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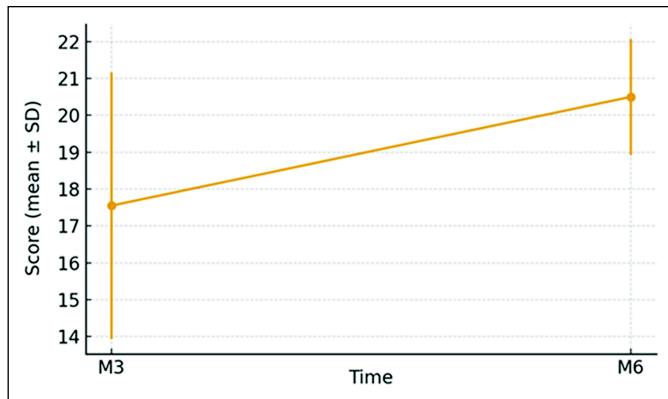


Figure 1. Evolution of vaginal health index scores.

Index (VHI) and the Female Sexual Distress Scale–Revised (FSDS-R). Adverse events were recorded.

RESULTS

All 20 women completed the protocol. The mean VHI score increased significantly at 3 months and at 6 months. Similarly, FSDS-R scores improved at 3 and 6 months, maintaining stable values thereafter (Figures 1, 2). Improvement was particularly noted in vaginal dryness and dyspareunia. Women with mild to moderate urinary incontinence experienced significant improvement, with some reporting complete resolution of symptoms.

No adverse events were reported. In addition to the improvement observed in VHI, analysis of the Female Sexual Distress Scale (FSDS) confirmed a progressive and sustained reduction in sexual distress. At baseline (M0), mean FSDS scores were high, reflecting substantial impairment. By 3 months (M3), scores had decreased markedly (mean 17.4 ± 4.0), and at 6 months (M6) the decline was even more pronounced (mean 10.9 ± 2.4). This reduction was both statistically and clinically significant, demonstrating a robust therapeutic effect of the combined Er:YAG laser and exosome therapy. The standard deviation narrowed over time, suggesting a consistent improvement across most participants. These results indicate not only efficacy but also homogeneity of treatment response, reinforcing the potential of this combined approach to improve sexual wellbeing in women with GSM (Tables 1, 2).

DISCUSSION

The present pilot study shows that combining non-ablative Er:YAG laser with exosome therapy (ASCEplus IRLV) can significantly improve symptoms of GSM, particularly vaginal dryness, dyspareunia, and mild to moderate urinary incontinence. These findings are consistent with prior studies that showed Er:YAG laser alone could stimulate neocollagenesis and improve vaginal health,^{1,2} while exosomes have been increasingly recognized for their regenerative capacity in tissue repair and cell to cell communication.^{3,4} The novelty of this study lies in showing a synergistic effect between energy-based therapy and exosome based bioregeneration.

From a mechanistic perspective, the Er:YAG laser promotes controlled thermal injury to subepithelial connective tissue, inducing fibroblast activation and collagen remodeling.² The addition of

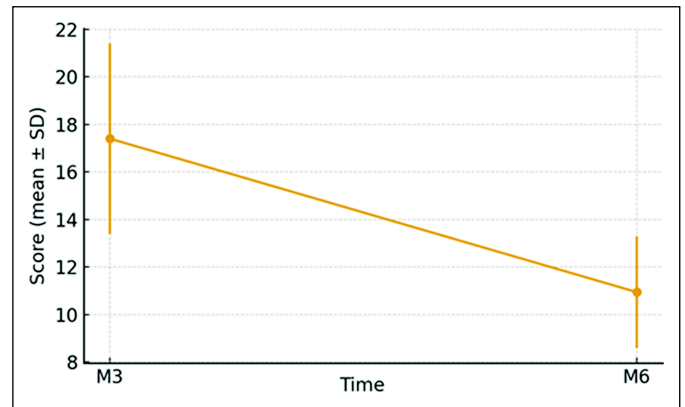


Figure 2. Evolution of female sexual distress scale–revised scores.

exosomes, containing growth factors, cytokines, and microRNAs, may enhance these regenerative processes by modulating inflammation, promoting angiogenesis, and stimulating fibroblast proliferation and extracellular matrix synthesis.^{3,5} Together, these effects contribute to greater tissue hydration, elasticity, and overall vaginal mucosal health compared with monotherapy.

Clinically, patients reported not only improvement in GSM related symptoms, but also better sexual satisfaction, and reduced urinary complaints. Improvement in urinary incontinence is of particular interest, as this expands the potential therapeutic scope of this combined approach beyond vulvovaginal atrophy, to include mild urogenital dysfunction. This supports previous evidence linking laser based therapies with improvement in stress and urgency incontinence,⁶ though the role of exosomes in modulating urothelial regeneration remains largely unexplored.

Limitations of this study must be acknowledged. The sample size was small ($n = 20$) and the trial was not randomized nor controlled, raising the risk of bias. The absence of a placebo group makes it impossible to fully distinguish treatment effects from placebo response, which is known to be substantial in sexual function studies. Moreover, the follow-up period, although extended to 6 months, is still relatively short to evaluate the durability of effects. Histological confirmation of tissue remodeling and biomarker analysis of inflammatory or regenerative processes was not performed, limiting mechanistic insight. Additionally, the study population included only healthy postmenopausal women, results may not be generalizable to women with comorbidities or different ethnic backgrounds.

Despite these limitations, this study provides important preliminary evidence supporting the safety and efficacy of combining Er:YAG laser with exosome therapy for GSM. Importantly, no adverse events were reported, supporting the tolerability of the combined approach. The results add to the growing body of literature positioning exosomes as a promising, cell free therapeutic platform in regenerative gynecology.

Future directions should include larger multicenter randomized controlled trials comparing laser alone, exosomes alone, and the combined therapy, with longer follow-up to assess long-term safety and efficacy. Incorporating objective measures such as histological analysis, imaging of vaginal mucosa, and biochemical markers would help confirm tissue level effects. Exploring the role of exosomes in urinary incontinence and other pelvic floor disorders could broaden their clinical application.

Table 1. Patient-reported Outcome Responses to Vaginal Health Index Questionnaire

	Pretreatment score	Score 3 months post	Score 6 months post
Patient 1	7	14	20
Patient 2	10	20	21
Patient 3	6	12	18
Patient 4	15	20	22
Patient 5	11	20	22
Patient 6	4	10	17
Patient 7	8	16	21
Patient 8	13	19	23
Patient 9	9	18	20
Patient 10	12	22	22
Patient 11	7	14	20
Patient 12	5	12	18
Patient 13	16	23	23
Patient 14	13	21	21
Patient 15	8	16	20
Patient 16	10	20	20
Patient 17	11	18	21
Patient 18	12	18	20
Patient 19	10	21	21
Patient 20	8	17	20

If validated, this combined treatment could represent a paradigm shift in managing GSM: a nonhormonal regenerative therapy that not only alleviates symptoms but also addresses underlying tissue degeneration. Such an approach would be especially valuable for patients contraindicated for estrogen therapy, including women with hormone sensitive cancers.

The clinical findings are further supported by quantitative analysis of both FSDS and VHI scores. Female Sexual Distress Scale results demonstrated a significant and progressive reduction in sexual distress from baseline to 6 months, while VHI scores showed marked improvement, reflecting mucosal regeneration and enhanced vaginal health. These consistent trends across both subjective and objective measures and reinforce the efficacy of the combined treatment. The narrowing of standard deviations in both scales suggests not only a strong therapeutic effect but also a homogeneous response among participants, highlighting the reliability and reproducibility of the intervention.

CONCLUSIONS

Er:YAG laser combined with ASCEplus IRLV exosomes appears safe and effective for GSM-related symptoms, improving vaginal health and sexual wellbeing. Exosome therapy represents a promising

Table 2. Patient-reported Outcome Responses to Female Sexual Distress Scale-Revised

	Pretreatment score	Score 3 months post	Score 6 months post
Patient 1	35	20	10
Patient 2	40	18	12
Patient 3	28	17	8
Patient 4	25	16	10
Patient 5	28	15	11
Patient 6	40	20	13
Patient 7	45	22	15
Patient 8	38	25	14
Patient 9	27	14	11
Patient 10	39	20	12
Patient 11	26	13	8
Patient 12	33	15	10
Patient 13	47	25	14
Patient 14	36	18	10
Patient 15	18	10	7
Patient 16	22	15	8
Patient 17	29	12	10
Patient 18	33	15	10
Patient 19	36	18	11
Patient 20	38	20	15

new frontier in genital rejuvenation. Further randomized controlled studies with larger populations and longer follow-up are needed.

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