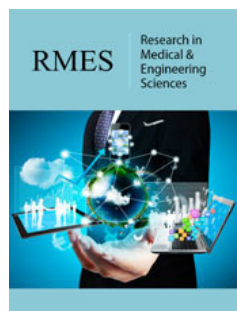


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Assessing the Clinical Potential of Low-Power Laser Irradiation for Post-Hysterectomy Reconstructive Care and Extended Module Design, Based on Clinical Outcomes in Genitourinary Syndrome of Menopause and Stress Urinary Incontinence

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Abstract

Hysterectomy, a common gynecological procedure performed for various indications such as uterine fibroids, cervical cancer, or other conditions impacting uterine health and pelvic integrity, often leads to significant post-operative genitourinary challenges resembling symptoms of Genitourinary Syndrome of Menopause (GSM) and Stress Urinary Incontinence (SUI). This paper explores the promising clinical potential of Low-Power Laser Irradiation (LPLI) as a non-invasive therapeutic approach for post-hysterectomy reconstructive care, drawing upon its established efficacy in treating GSM and SUI. Recognizing the delicate nature of post-operative tissues, this work proposes an extended LPLI module design focusing on critical enhancements. These include the development of an optimized fiber optic module with high flexibility and segmented adaptability, alongside a highly soft silicone end for patient comfort and minimal trauma. Furthermore, it emphasizes optimization of energy density and wavelength with increased options for lower basic output power to ensure optimal safety, and a compound light source design that integrates a bactericidal blue light LED module for enhanced therapeutic functions. The integration of biofeedback mechanisms, personalized treatment protocols, and potential for remote monitoring and home use are also highlighted. This comprehensive approach aims to precisely address the unique needs of post-hysterectomy patients, significantly enhancing their quality of life through safe, effective, and patient-centric rehabilitation.

Keywords: Primary pathology; Genitourinary Syndrome of Menopause; Genitourinary; Inflammation; Post-hysterectomy reconstructive care

Introduction

Hysterectomy remains one of the most frequently performed gynecological surgeries globally, indicated for a wide range of conditions including uterine fibroids, cervical cancer, adenomyosis, and severe uterine prolapse [1]. While critical for addressing primary pathology, the procedure frequently leads to various post-operative challenges, particularly affecting genitourinary health. Patients often experience symptoms such as vaginal atrophy,

dyspareunia, and urinary incontinence, which significantly impair their quality of life [1] and mirror the symptoms observed in Genitourinary Syndrome of Menopause (GSM) and Stress Urinary Incontinence (SUI) [1,2]. These genitourinary sequelae may have pre-existed or been exacerbated by the surgical intervention, highlighting an unmet clinical need for effective and patient-friendly rehabilitative interventions.

Low-Power Laser Irradiation (LPLI), also known as photobiomodulation therapy, has emerged as a well-established non-invasive therapeutic modality with proven efficacy in stimulating tissue repair, reducing inflammation, and promoting angiogenesis [2-4]. Its successful application in treating GSM and SUI [2], evidenced by improvements in tissue elasticity, lubrication, and pelvic floor support, provides a strong rationale for its potential extension into post-hysterectomy reconstructive care. The non-ablative, well-tolerated, and relatively cost-effective nature of LPLI makes it a particularly attractive option for individuals who have undergone extensive treatments, such as cancer survivors, minimizing further discomfort and risks [2-5].

This paper aims to assess the clinical potential of LPLI for addressing the specific post-operative genitourinary symptoms following hysterectomy. Drawing insights from the existing clinical evidence in GSM and SUI, we propose an extended design concept for the LPLI module tailored to the unique anatomical and physiological considerations of post-hysterectomy patients. A central focus of this proposed design is the acknowledgment of fragile post-operative tissues, necessitating innovations in probe design that include highly flexible and segmented light guides, options for lower basic output power to ensure optimal safety, and a compound light source which critically incorporates an auxiliary bactericidal blue light LED module [2-5]. By optimizing these design parameters and integrating advanced features, this work seeks to lay the groundwork for developing a comprehensive LPLI system that can precisely address the diverse rehabilitative needs of patients, ultimately enhancing their long-term genitourinary health and overall well-being. "Recognizing the delicate nature of post-operative tissues and the established efficacy of Low-Power Laser Irradiation (LPLI) in treating GSM and SUI, this paper proposes an extended LPLI module design. This design, with enhancements in fiber optics, energy parameters, and the integration of a bactericidal blue light, aims to precisely address the unique needs of post-hysterectomy patients, offering a safe, effective, and patient-centric approach to rehabilitation.

Clinical evidence from GSM and SUI

LPLI has demonstrated efficacy in both GSM and SUI by promoting tissue regeneration, improving angiogenesis, and reducing inflammation in the genitourinary tract [2-4]. The previous study, for instance, utilized a non-ablative laser applied in four sessions at 2-week intervals, demonstrating this approach's effectiveness. The GaAlAs laser diode with a wavelength of 660nm serves as the core light source in the designed medical device, delivering a fixed output of 30mW (Transverse Industries Co., Taiwan). This wavelength ensures effective vascular interaction

while minimizing thermal risk. For Genitourinary Syndrome of Menopause (GSM), studies show that LPLI can effectively alleviate symptoms such as vaginal dryness, dyspareunia (painful intercourse), itching, and burning [5]. Its mechanism of action includes stimulating collagen synthesis, increasing blood flow to vaginal tissues, and restoring the integrity of the vaginal mucosa, which helps improve tissue elasticity and lubrication, directly addressing the atrophic changes characteristic of GSM [5]. The study by Wu et al. [2] found that the SUI group showed significant improvements in the Urgency Severity Scale (USS) and Overactive Bladder Symptom Score (OABSS), and multiple domains of the King's Health Questionnaire (KHQ) also showed improvement. For Stress Urinary Continence (SUI), LPLI appears to strengthen pelvic floor muscles and connective tissues, thereby improving urethral support and closure mechanisms [2]. Clinical trials have reported a reduction in the frequency and severity of involuntary urine leakage, leading to an improved quality of life for patients [2]. The regenerative effect of LPLI on collagen and elastin is considered crucial in enhancing the structural support of the bladder and urethra.

Potential clinical applications in post-hysterectomy care

Given these confirmed benefits, LPLI holds multiple compelling application potentials in the rehabilitation of patients after hysterectomy. Firstly, LPLI helps alleviate vaginal atrophy and dyspareunia: Similar to its effects in GSM [2,5], LPLI can significantly improve vaginal dryness and painful intercourse, which are common issues after hysterectomy due to hormonal changes and surgical impact. By promoting tissue healing and regeneration, LPLI helps restore vaginal health and comfort, with all domains in the VHI showing significant improvement after LPLT. Secondly, LPLI can be used for managing urinary incontinence: post-hysterectomy patients, especially those who have undergone radical hysterectomies, often experience SUI due to pelvic floor muscle weakness or nerve damage. LPLI can strengthen the supportive structures around the bladder and urethra, potentially reducing or resolving incontinence episodes and improving bladder control. Although the primary mechanism of SUI involves structural aspects, LPLT has shown promise in addressing urinary urgency and overactive bladder symptoms, which often co-occur with LUTS. Furthermore, LPLI contributes to enhancing pelvic floor health: beyond specific symptoms, LPLI can promote overall pelvic floor rehabilitation by improving tissue quality and muscle function [6], leading to better long-term genitourinary health outcomes and a reduced incidence of related complications. Lastly, LPLI is non-invasive and well-tolerated: the non-invasive nature and low-power characteristics of the laser system make it a well-tolerated treatment option, minimizing discomfort and avoiding risks associated with more invasive procedures. Patients in the previous study [2,5], for example, reported only mild, transient discomfort or warmth during treatment, affirming its high tolerability. This is particularly beneficial for cancer survivors who may have already undergone extensive treatments; furthermore, LPLT is relatively cost-effective.

Translational Clinical Potential of Low-Power Laser Irradiation (LPLI) in Post-Hysterectomy Rehabilitation

Figure 1 provides a comprehensive illustration of the multifaceted effects of Low-Power Laser Irradiation (LPLI), directly connecting its diverse therapeutic applications to the critical needs of patients recovering from hysterectomy. At its core, LPLI acts as a catalyst, initiating a range of beneficial physiological improvements within the body. The central block, representing the “LPLI” application, branches out to detail six key areas of impact, each offering significant value for post-hysterectomy patients (Figure 1) [2-6]. Firstly, LPLI leads to increased collagen synthesis, which is vital for providing structural support and elasticity. For those who’ve undergone hysterectomy, this means crucial repair and strengthening of the vaginal vault and surrounding pelvic connective tissues that may have been stretched or otherwise affected by the surgery, aiding in the restoration of tissue integrity. Secondly, by promoting vasodilation and enhancing microcirculation, LPLI ensures increased blood flow to the treated area. This improved blood supply delivers more oxygen and essential nutrients, thereby accelerating the healing of surgical sites and improving the health of potentially atrophic vaginal tissues, a common concern after

hysterectomy due to hormonal shifts. Thirdly, LPLI significantly contributes to improved angiogenesis, the formation of new blood vessels. This fundamental process of capillary growth is essential for regenerating damaged tissue, directly assisting in reconstructing and revitalizing the vascular network in the pelvic region post-surgery to support overall tissue recovery. Fourthly, LPLI exhibits potent anti-inflammatory properties, effectively mitigating swelling, pain, and discomfort. For patients recovering from hysterectomy, this translates to alleviating post-surgical inflammation and discomfort, with the potential to reduce chronic pain often linked to pelvic floor issues. Furthermore, beyond direct tissue repair, LPLI also contributes to improved muscle endurance [6]. This benefit is particularly valuable for strengthening weakened pelvic floor muscles after hysterectomy, which is crucial for enhancing continence and overall pelvic support, directly addressing symptoms like stress urinary incontinence (SUI). Lastly, LPLI proves effective in fasciitis treatment by reducing inflammation in the fascia (connective tissue) and promoting its repair. This action can alleviate pain and improve mobility, directly tackling post-surgical fascial pain or adhesions that might develop in the pelvic area following hysterectomy.

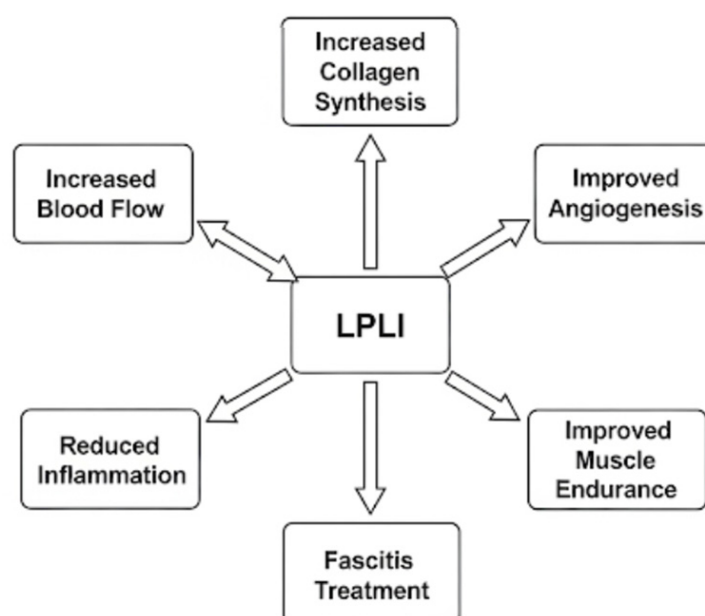


Figure 1: Clinical Potential of Low-Power Laser Irradiation (LPLI) in Post-Hysterectomy Rehabilitation.

In essence, this diagram articulates that LPLI is a remarkably versatile therapeutic tool. Its benefits extend beyond fundamental tissue repair to encompass enhanced muscle function and the resolution of inflammatory and pain conditions, making it a comprehensive and tailored approach for the diverse rehabilitation needs of post-hysterectomy patients.

Extended design of the LPLI core module and future prospects

To better meet the unique and delicate needs of post-hysterectomy rehabilitation, where tissue fragility is a significant

concern, the extended design based on the LPLI core module will focus on providing additional functionality, enhanced safety, and superior comfort. Key advancements include developing a highly flexible, low-contact stimulation light guide module that conforms precisely to the vaginal structure and fragile post-surgical tissues. For optimal safety, especially given the delicate post-operative state, the design will prioritize lower laser output options with precise control (Figure 2). Furthermore, it will integrate a compound light source with an auxiliary blue light bactericidal module to provide enhanced therapeutic functions, ensuring comprehensive and gentle care for patients recovering from hysterectomy.

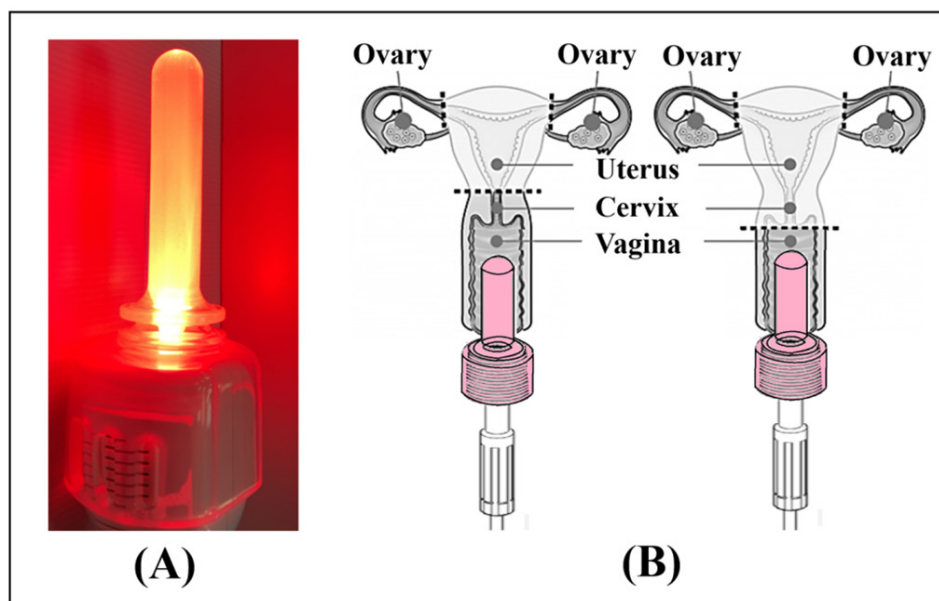


Figure 2: Translational Clinical Potential of Low-Power Laser Irradiation (LPLI) in Post-Hysterectomy Rehabilitation.
A. Low-Power Laser Irradiation (LPLI) in GSM and SUI and
B. Clinical Potential in Post-Hysterectomy Rehabilitation.

Secondly, optimization of energy density and wavelength is crucial. For clinical needs related to tissue repair and muscle endurance enhancement [2-6], especially considering the delicate nature of post-operative tissue, the focus should extend beyond mere time-adjusted dosage. It is imperative to increase the options for lower basic output power to cater to various physiological responses and ensure optimal safety. Furthermore, the integration of a compound light source design, specifically including a blue light option via an auxiliary LED module, is essential to provide both restorative and bactericidal functions. Future research can explore adjusting energy density and wavelength to achieve better structural improvement for urethral support issues that may arise after hysterectomy, without increasing side effects, thereby more effectively addressing common fascial and urethral support problems seen post-hysterectomy.

Laser and optical module combination

In the proposed LPLI extended module for post-hysterectomy care, the laser module and optical module aren't just separate parts but a meticulously integrated system (Figure 3). This combination is engineered to deliver precise, safe, and comfortable therapeutic light, specifically addressing the unique needs of patients recovering from a hysterectomy. The laser module, where the therapeutic light originates typically from laser diodes, will offer low laser output options with fine, precise control to ensure optimal safety and gentleness for delicate post-operative tissues, minimizing any risk of thermal damage while still achieving the desired therapeutic effects. Beyond the primary therapeutic wavelengths, this module integrates an auxiliary blue light LED module. This addition provides crucial bactericidal properties, significantly enhancing the overall functionality and cleanliness of the treatment, a vital consideration for healing tissues.

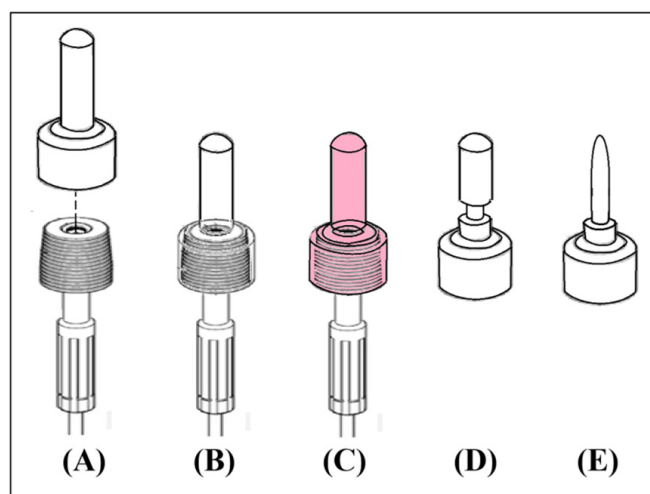


Figure 3: Optimized Optical Module for Low-Power Laser Irradiation (LPLI) in Post-Hysterectomy Rehabilitation.
A. Probe before use; B. Assembled laser and optical module; C. Assembled module with laser activated; D. Segmented flexible design; E. Highly flexible design.

The optical module encompasses the components responsible for guiding, shaping, and precisely delivering the light from the laser module to the target area. Its design is paramount for post-hysterectomy care, featuring an optimized fiber optic module that is a highly flexible, low-contact stimulation light guide. This ensures high flexibility to easily navigate the post-surgical anatomy and adapt to individual patient variations, maximizing comfort during both insertion and treatment. Its low-contact stimulation design actively minimizes harsh pressure or abrasion on sensitive, potentially fragile, or scarred tissues, achieved through a highly

soft silicone end or similar pliable materials, prioritizing patient comfort and safety during recovery. This module will also allow for various interchangeable tip diameters and lengths to ensure precise targeting for diverse patient anatomies and specific treatment areas within the vaginal vault. Lenses, fibers, and other optical elements within this module will ensure the laser light is delivered with the correct energy density and beam profile, optimizing therapeutic penetration and effectiveness in the healing tissues. In summary, this laser module and optical module combination forms a holistic, purpose-built system, merging a specialized, safe light source with a gentle, precise delivery mechanism, directly supporting enhanced functionality, safety, and comfort for post-hysterectomy rehabilitation.

Strategic VANGUARD medical device development framework for the LPLI extended module in post-hysterectomy care

To systematically develop and expand the LPLI extended module for post-hysterectomy care, particularly regarding the light guide module design, we will adopt a phased strategic framework. This framework emphasizes a user-centric, market-driven approach, ensuring the design effectively addresses clinical needs and achieves successful deployment in this specialized field. Our core focus for post-hysterectomy patients is on low stimulation, non-invasiveness, low dosage, and cleanliness. This process begins with the VAN Stage (Value Signal-Advantage Anchor-Niche Finding), focusing on foundational understanding. The Value Signal component prioritizes identifying the core value LPLI can bring to post-hysterectomy patients, particularly concerning their genitourinary recovery needs, requiring the light guide module to precisely deliver energy to their specific anatomical variations for optimal recovery. Low-Power Laser Irradiation (LPLI) has emerged as a well-established non-invasive therapeutic modality with proven efficacy in stimulating tissue repair, reducing inflammation, and promoting angiogenesis. Its successful application in treating Genitourinary Syndrome of Menopause (GSM) and Stress Urinary Incontinence (SUI) provides a strong rationale for its potential extension into post-hysterectomy reconstructive care. The Advantage Anchor confirms the laser-based design effectively targets relevant clinical pain points, with the light guide serving as the critical interface for precision and patient comfort. Recognizing the delicate nature of post-operative tissues, this design proposes critical enhancements including the development of an optimized fiber optic module with high flexibility and segmented adaptability, alongside a highly soft silicone end for patient comfort and minimal trauma.

Lastly, Niche Finding ensures the light guide design adapts to this underserved patient segment with unique post-surgical anatomies. This adaptation recognizes fragile post-operative tissues, necessitating innovations in probe design that include highly flexible and segmented light guides, and options for lower basic output power to ensure optimal safety. Next is the GUA Stage (Growth-User-Advantage Linking), connecting development with market potential and user experience. The Growth Leverage

component acknowledges the long-term demand for safe, anti-aging therapies, which means the light guide design must ensure durability and patient comfort for repeated use. The non-ablative, well-tolerated, and relatively cost-effective nature of LPLI makes it a particularly attractive option for individuals who have undergone extensive treatments, such as cancer survivors, minimizing further discomfort and risks. The Uniqueness Signal drives design for safety, comfort, and precise dose control, all directly influenced by the light guide's physical attributes. This includes optimization of energy density and wavelength with increased options for lower basic output power to ensure optimal safety. Furthermore, a compound light source design integrates a bactericidal blue light LED module for enhanced therapeutic functions, which is essential to provide both restorative and bactericidal functions. Furthermore, Advantage Validation confirms the LPLI extended module for post-hysterectomy care can enhance clinical value, further validating its precise application and efficacy. Given these confirmed benefits in GSM and SUI, LPLI holds multiple compelling application potentials in the rehabilitation of patients after hysterectomy, including alleviating vaginal atrophy and dyspareunia, managing urinary incontinence, and enhancing overall pelvic floor health. The next phase is the RD Stage (Realization & Deployment), focusing on practical implementation. Roadblock Breakthrough involves proactively addressing regulatory and usability hurdles, ensuring the light guide design complies with stringent medical device regulations and is intuitive for clinicians. The integration of biofeedback mechanisms, personalized treatment protocols, and potential for remote monitoring and home use are also highlighted. Concurrently, the Deployment Strategy adopts a modular format for scalability and consistency. The light guide itself can be a modular component, allowing for variations and easy replacement or adaptation based on different patient needs, leveraging the LPLI extended module's enhanced safety, comfort, and precision. This comprehensive approach aims to precisely address the unique needs of post-hysterectomy patients, significantly enhancing their quality of life through safe, effective, and patient-centric rehabilitation.

Conclusion

The potential of LPLI in post-hysterectomy reconstructive care is immense, particularly given the encouraging clinical evidence obtained from its use in GSM and SUI treatments. Through the refined design of the LPLI extended module, especially in the optimization of fiber optic modules and treatment protocols, and guided by a robust strategic development framework, the specific needs of post-hysterectomy patients can be more precisely addressed, thereby significantly enhancing their quality of life.

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