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Review Article

New Design and preclinical evaluation of Non-Invasive Multi-Spot Positioning Transcutaneous On-Venous Laser System for Metabolic and Chronic Care Management

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Abstract:

This study presents the design and preclinical evaluation of a novel, clinically oriented personalized non-invasive laser system. Engineered for transcutaneous on-venous laser irradiation of blood (TOLIB) and laser-simulated moxibustion (LSM), the system integrates a programmable dosing and positioning interface with modular components to enhance treatment precision and personalization. Central to the design is a low-power laser module (635 nm, 5-10 mW), significantly below the output of typical LPLI or LPLI devices, prioritizing safety, reproducibility, and suitability for extended sessions. The system addresses key limitations of conventional devices, including inadequate dose control and limited adaptability to individual needs. Its primary clinical modes, transcutaneous venous blood-cleansing and low-dose laser stimulation of acupoints, are supported by real time feedback and intelligent control. The device's architecture supports scalable deployment across diverse healthcare settings, including long-term and home-based care, offering a promising platform for chronic disease management and adjunctive non-invasive fat reduction for metabolic health. The integration of TOLIB and Laser-Simulated Moxibustion (LSM) within a single precision system also enables synergistic therapeutic effects. This work provides foundational evidence for expanding non-invasive photobiomodulation into personalized and sustained therapeutic applications.

Key words: transcutaneous on-venous laser irradiation of blood; laser-simulated moxibustion (lsm); personalized laser therapy; non-invasive device; programmable dosing; chronic care; photobiomodulation; medical device design

1.Introduction

Photobiomodulation (PBM) therapy is a non-invasive technique that utilizes low power light irradiation (LPLI) to modulate biological functions like tissue regeneration, inflammation control, and cellular metabolism [1-15]. These effects are largely attributed to interactions with mitochondrial cytochrome c oxidase (CcO), leading to increased ATP production and improved oxidative balance [1-6]. Recent evidence suggests broader systemic effects may arise through bioelectromagnetic and neuroimmune mechanisms, expanding PBM's potential into chronic care interventions. Transcutaneous on-venous laser irradiation of blood (TOLIB) delivers low level laser energy to superficial veins, modulating circulating blood components to achieve systemic therapeutic effects. Studies such as Benevento et al. have demonstrated metabolomic changes following transcutaneous blood irradiation, suggesting broad physiological impact. However, existing TOLIB systems often lack dosing precision and positioning control, limiting their clinical adoption [8]. This study addresses these gaps by introducing a programmable, personalized system that improves usability, precision, and therapeutic reproducibility [8]. Laser simulated moxibustion replaces traditional thermal stimulation with laser-based acupoint irradiation. Compared to traditional moxibustion, laser simulated moxibustion offers significant advantages, including being smoke free, providing precise and reproducible dosing, and enhancing safety by eliminating the risk of burns. Currently, clinical application of high dose laser irradiation at acupoints is widespread, but its high-power design typically involves short operating times and carries potential clinical operational risks, making it unsuitable for home care [5]. By applying low power laser with longer exposure durations, the present system offers a safer, scalable alternative for integrative therapy. Most existing LPLI systems are limited to treating localized lesions, which constrains clinical treatment approaches as they often fail to consider individual patient differences in symptom severity, physiological holism, and tissue response, often leading to limited or suboptimal therapeutic outcomes. This study aims to address this unmet need by introducing a clinically oriented personalized laser system with a programmable dosing interface that can integrate holistic medical strategies (such as blood purification and acupoint stimulation). The developed system is designed to facilitate scalable, non-invasive, and truly clinically oriented interventions that can dynamically adjust to individual patient needs for superior therapeutic results [16]. TOLIB and laser simulated moxibustion within a single, precise system also hold the potential for synergistic therapeutic effects, addressing a wider range of physiological dysfunctions and contributing to overall metabolic health. Its primary clinical application modes will focus on transcutaneous venous blood purification and low dose laser irradiation for acupoints. The use of this non-invasive laser therapy for use in patients with chronic diseases may assess its effects on the activation versus inactivation of anti-aging genes that are critical to the metabolic health [17-19]. The anti-aging gene Sirtuin 1 is important to the prevention of the metabolic syndrome and multiple organ disease syndrome. Non-invasive laser therapy patients may need to consume Sirtuin 1 activators versus Sirtuin 1 inhibitors to improve chronic disease and metabolic health. The design adopted fixed power with quantitative time-based dose management. Through clinical feedback, the evolved design will focus on a programmable interface, clinical experience-based protocol adjustment, and personalized medical order settings, providing clinicians with the flexibility for customized adjustments [16].

2. System Design and Development [16]

2.1. Design Philosophy with Clinically Driven Personalization

The system's architecture is founded on real world clinical demands, prioritizing personalized treatment protocols for both systemic and local stimulation [16]. Designed for both institutional and home-based use, it aims to balance safety, flexibility, and therapeutic reproducibility.

2.2. Core Laser Module and Optical Architecture

The GaAlAs laser diode with a wavelength of 635 nm serves as the core light source in designed non-invasive multi-spot positioning synchronous irradiation laser system for transcutaneous on-venous laser irradiation of blood (TOLIB), laser simulated moxibustion, and metabolic health, delivering a fixed output of 5-10 mW (TRANSVERSE INDUSTRIES CO., LTD.) (Figure 1). This wavelength ensures effective vascular interaction while minimizing thermal risk. This relative low power unit output design enhances the system's safety and versatility in clinical applications, making it particularly suitable for long term, repetitive treatment modalities, and differentiating it from the short duration, high power designs of high dose laser acupuncture. Furthermore, it aligns with the low stimulus, extensible nature of laser-simulated moxibustion (LSM)'s clinically observed feedback. Our design applies special designed multi-spot positioning synchronous irradiation (MPSI) laser modules for precise small area targeting [Figure 1(C)]. Critically, these modules can also be configured to enable large area irradiation through expandable multi-spot assembling irradiation module combining multiple single-spot laser units [Figure 2(A)], providing versatile application across different body regions. This relatively low power unit output design (5-10 mW) allows for precise dose control through time modulation of irradiation duration, effectively achieving the desired energy delivery while avoiding the tissue cell damage risks potentially associated with higher base powers, such as 50-1000mW. The system includes multiple transcutaneous irradiation modules and a dedicated venous laser module, optimized for consistent energy delivery in long duration applications [16].

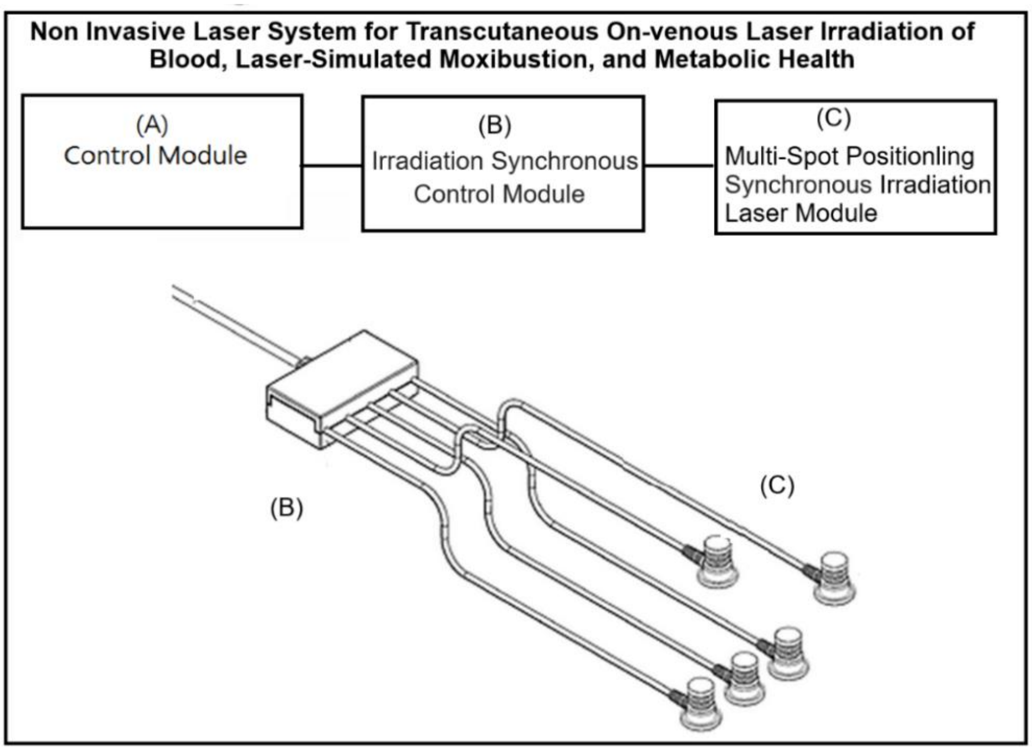

Figure 1: Conceptual design of the personalized non-invasive laser system caption[16]: (A) control module, (B) irradiation synchronous control module, and (C) the special designed multi-spot positioning synchronous irradiation laser module.

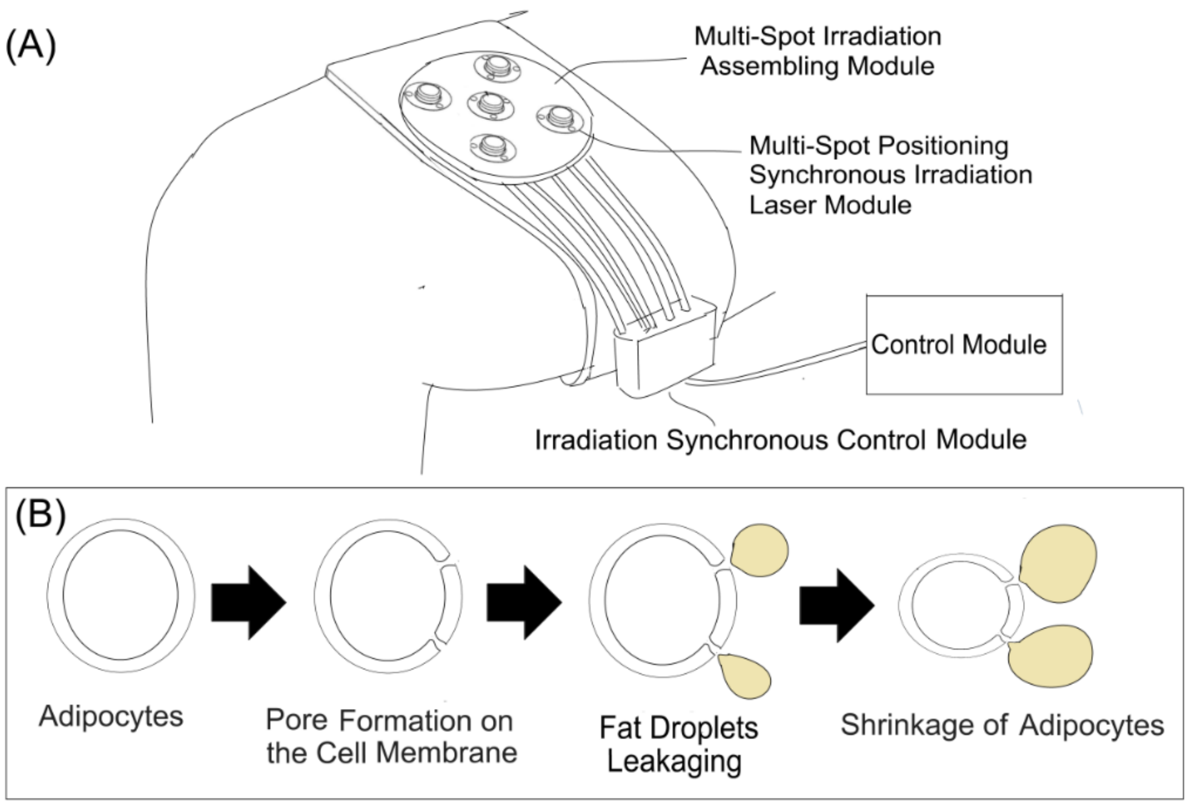

Figure 2: Illustration of (A)User Scenario Map[16] and (B) mechanism of adipocytes with 635 nm irradiation[13].

2.3. Programmable Dosing and Positioning Interface

The user interface supports time-based dose modulation through programmable controls, enabling treatment personalization without varying laser output. Anatomical alignment aids enhance placement precision for both veins and acupoints [16]. Positioning is achieved by a dedicated adhesive patch design that ensures fixed and accurate placement of the laser modules. When the laser module's positioning alignment reduces offset, LPLI remains well focused, ensuring consistent and targeted energy delivery. The energy delivery mechanism is based on dosing time controlled photobiomodulation. The product evolution strategy, through validated clinical data, involves structured hierarchical analysis of clinical data, directly correlating symptom severity with treatment dose intensity. This hierarchical logic enables algorithm driven prescription of treatment duration while maintaining fixed photophysical parameters, ensuring device safety, regulatory compliance, and enhancing treatment reproducibility.

2.4. Integration of Auxiliary Modules and Future Expansion

The system allows for the integration of AI based modules for adaptive treatment logic and physiological data interpretation. Remote monitoring via cloud connectivity is supported, enabling future development into a connected, home use phototherapy platform. This integration of auxiliary modules is strategic to enhance safety and efficacy. Specifically, an Artificial Intelligence (AI) module analyzes physiological monitoring data from each session, along with the laser treatment application site and time, treatment parameters, patient responses, and regular biochemical test data. Through this analysis, AI dynamically adjusts treatment parameters and provides patient specific feedback. The product evolution strategy will advance the system to AI assisted dosing and integrated home care, processing sensor data through a secure cloud platform to generate personalized treatment recommendations. This data recording capability is crucial for long term clinical research and personalized medicine.

2.5. Safety Engineering and Compliance

Designed in accordance with IEC 60601-1 standards, the system integrates thermal control, relative low power unit output design, and multiple hardware safety interlocks. Its passive safety profile supports use in fragile populations and chronic care environments [16].

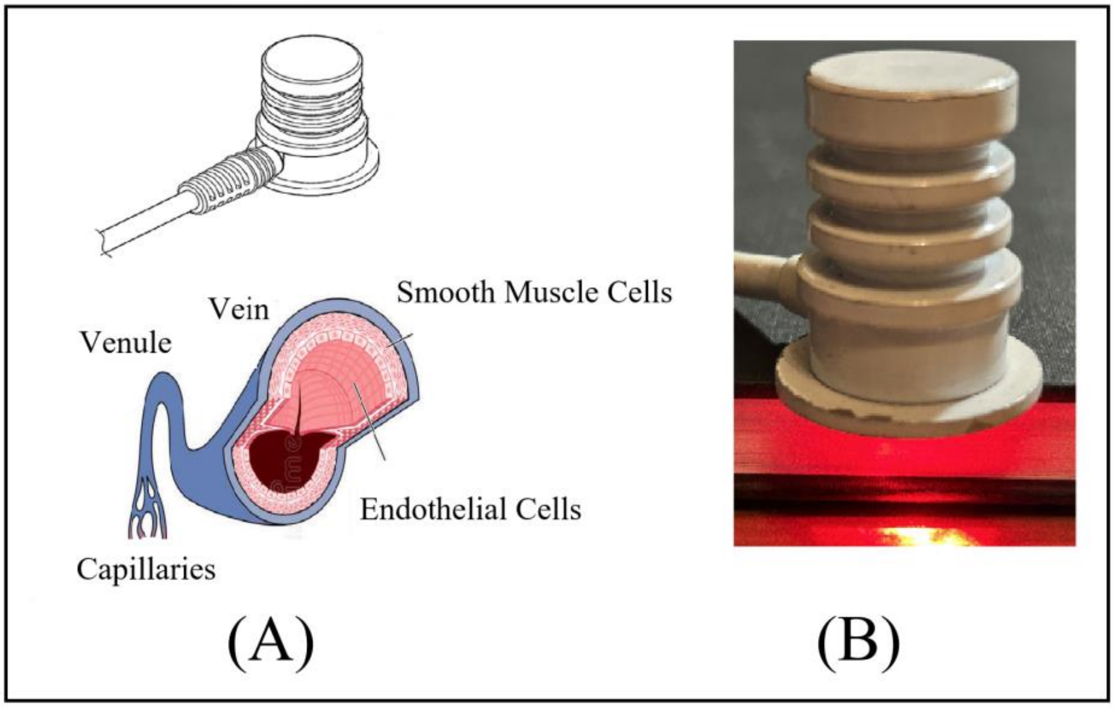

Figure 3: Illustration of (A) non-invasive laser system for transcutaneous on-venous laser irradiation of blood (TOLIB) and (B) irradiation of single-spot laser unit.

3. Preclinical Evaluation and Stratified Dosing Model

3.1. Interpretation of Results and Clinical Relevance

Preclinical testing confirmed the system's ability to deliver safe, reproducible LPLI with therapeutic relevance. Its unique combination of blood irradiation and moxibustion stimulation within a programmable framework suggests systemic and targeted benefits, with potential synergistic outcomes (Figure 3).

3.2 Comparison with Existing Laser Therapeutic Systems

Compared to static, lesion based LPLI systems or short duration, high power acupoint lasers, this platform offers superior personalization, lower risk, and expanded therapeutic flexibility. Its integrated design and modular control interface elevate it to a next generation tool for individualized phototherapy. This system's remarkably low base power (10 mW) not only significantly enhances safety but also expands its applicability to a wider range of clinical scenarios, especially for long term, frequent or high energy sensitive treatment needs. Compared to high dose laser acupuncture's short duration, high power design, this system's relatively low base power avoids the potential operational risks associated with high power lasers, making it more suitable as a home care solution. Through precise time control, our system can achieve energy delivery comparable to high dose treatments while maintaining high safety.

3.3. Therapeutic Mechanisms and Diverse Applications of 635nm LPLI in the System

The 635nm wavelength is central to the diverse therapeutic capabilities of our system, underpinning its efficacy in blood irradiation, moxibustion stimulation, and fat reduction. Understanding its underlying mechanisms is crucial for appreciating the system's broad clinical utility.

3.3.1. Mechanisms in Photobiomodulation (PBM) and Blood Irradiation.

At a fundamental level, 635 nm LPLI's therapeutic effects are attributed to its interaction with mitochondrial cytochrome c oxidase (CcO), a key photoacceptor. This interaction initiates a cascade of intracellular events, including increased ATP production, modulation of reactive oxygen species (ROS), and activation of signaling pathways [1–6]. In the context of TOLIB, photons penetrate the skin to interact with circulating blood components, a process proposed to lead to systemic physiological responses through various mechanisms. Research into Intravascular Laser Blood Irradiation (ILBI), often utilizing a laser at 632.8 nm (closely comparable to 635 nm), has revealed significant positive influences on blood components and systemic processes. Regarding blood cells, ILBI favorably alters peripheral blood, showing increases in red cell count, reduced erythrocyte sedimentation rate (ESR), and enhanced functions of lymphatic and macrophage cells. Studies on ischemic heart disease (IHD) patients indicate increased activity of energy enzymes in peripheral blood lymphocytes and normalization of neutrophilic granulocytes [8]. Clinically, ILBI has improved outcomes in unstable steno cardia, notably reducing platelet self-aggregation (up to 67%) and erythrocyte aggregation (up to 17%) [8]. Experimental studies further demonstrated reticulocytosis, increased erythrocyte count and resistance, and transient increases in specific white blood cell types (e.g., band neutrophils, eosinocytes, basophils, lymphocytes) within an hour, alongside a decrease in monocytes and segmented neutrophils, indicative of leucopoiesis stimulation and cell migration [9-12]. While white blood cell responses varied with irradiation modes, repeated treatments consistently led to stable lymphocytosis and a sharp reduction in segmented leukocytes [9-12]. The influence extends to blood enzymes, where numerous studies report a positive ILBI effect on lipid peroxidation (POL) [8-9], showing significant increases of enzymes, kinins, and POL products in plasma within post irradiation (while POL decreased in erythrocytes) [9-12]. ILBI enhances catalase activity, which has an absorption spectrum near the laser wavelength, and generally boosts major intracellular bioenergetics enzymes [9-12]. Laser radiation activates neural mitochondrial bioenergy processes and stimulates other key enzymes like dehydrogenase, cytochrome c oxidase, and acidic/alkaline phosphatase.

Characteristic changes in carbohydrate metabolism enzymes, such as a decrease in sodium lactate and increased pyruvate, suggest preferential activation of the henose monophosphate shunt [9-12]. Furthermore, LPLI promotes biosynthetic activity in blood serum, increasing carbohydrates, proteins, and nucleic acids [9-12]. It also contributes to the saving of failing skin grafts [9-12]. Regarding the blood coagulation system, ILBI demonstrates hypocoagulation effects, increasing blood fibrinolytic activity, reduced thrombocyte and erythrocyte aggregation, and improved blood flow properties and vasodilation [7]. Fibrinogen levels significantly decrease after ILBI procedures, accelerating fibrinolysis and lowering the prothrombin ratio, thereby enhancing peripheral blood circulation [7]. Beyond blood components, laser treatment has been determined to stimulate the division of both hepatocytes and fibroblasts, indicating broader tissue regenerative potential. Recent metabolomic studies following transcutaneous blood irradiation further support these broad systemic impacts [11-14].

3.3.2. Mechanisms in Acupoint Stimulation (LSM).

For laser simulated moxibustion (LSM), the 635nm LPLI is applied to specific acupoints. While the exact mechanisms of acupoint stimulation are still being elucidated, LPLI is thought to exert effects through local cellular activation and modulation of neuroimmune pathways, consistent with Traditional Chinese Medicine (TCM) principles. The low penetration characteristics of 635nm light make it particularly suitable for superficial acupoints, allowing for targeted stimulation without significant thermal effects, which differentiates it from traditional moxibustion's heat.

3.3.3. Mechanisms in Adipose Tissue and Potential for Cell Level Fat Sculpting.

The mechanism by which 635nm LPLI impacts adipose tissue and facilitates fat reduction is a key area for expanding the system's potential in non-invasive fat sculpting and reduction, particularly at a cellular level, and critically, for its role in chronic care management. Adipose tissue accumulation, especially visceral fat, is a key contributor to metabolic syndrome, type 2 diabetes, cardiovascular diseases, and systemic inflammation. Therefore, effective and safe non-invasive fat reduction can serve as a valuable adjunctive therapy in managing these chronic conditions. One prominent theory, initially put forth by Neira et al., posits that 635nm LPLI induces the formation of transitory micropores in adipocytes, which can be visualized using scanning electron microscopy (SEM) [8]. This micropore formation is believed to enable the release of intracellular lipids from the adipocytes. Benevento et al. suggested that LPLI (635 nm, with a reported 10W intensity for 6 minutes irradiation, though other studies by them specify a 10 mW diode laser with specific fluence values [8]) could facilitate the release of up to 99% of stored fat for subsequent removal. Further support for the transient nature and viability of cells after irradiation comes from Caruso Davis et al., who observed re cultured adipocytes regaining their native cellular conformation and confirmed their viability via live dead assays post irradiation [11]. The formation of these transitory micropores has been hypothetically linked to an increase in reactive oxygen species (ROS) following LPLI, potentially leading to lipid peroxidation within the cell membrane [12-14]. Another proposed mechanism for intracellular lipid release from adipocytes involves the activation of the compliment cascade, which is thought to induce adipocyte apoptosis [11]. Caruso Davis et al. conducted experiments exposing differentiated human adipocytes to plasma, with one group receiving laser intervention and a control group receiving none, to investigate the feasibility of this theory [11,12]. Furthermore, LPLI's ability to stimulate an increase in cyclic AMP (cAMP) levels has been suggested [13,14]. cAMP is known to activate protein kinases, which in turn activate enzymes responsible for the breakdown of triglycerides into fatty acids and glycerol, both capable of penetrating the adipocyte membrane [13,14]. However, findings from Caruso Davis et al.'s studies on in vitro human adipocyte cell cultures treated with LPLI (635 nm for 10 min) did not show an increase in glycerol and fatty acid levels, suggesting that fat liberation in their experiments was not primarily due to lipolytic stimulation of adipose tissue [13]. Interestingly, the presence of triglycerides in the supernatant during these cellular component examinations rather supported the theory of transient pore formation in adipocytes [11]. Clinical observations also highlight the synergistic effects of LPLI with other methods. Neira et al. demonstrated that the tumescent method facilitated laser penetration and intensity in lipectomy samples from patients exposed to a 10-mW diode laser (635 nm) with total fluence values ranging from 1.2 3.6 J/cm^2 for 0 to 6 minutes, leading to enhanced fat liquefaction [15]. A clinical setup involving 12 female patients undergoing lipectomy confirmed this synergy, showing effective fat removal when LPLI was combined with the tumescent technique. Without laser irradiation, fat tissue and cells maintained their original spherical shape [15]. The supplementary effect of the tumescent method on LPLI is thought to be due to either the stimulation of epinephrine induced cAMP production via adenyl cyclase or enhanced penetrative ability and intensity facilitated by the tumescent solution itself [15]. This body of evidence strongly supports the potential of 635nm LPLI for non-invasive fat reduction. The system's special designed multi spot positioning synchronous irradiation laser modules, combined with precise dose control and customizable positioning, offer a significant advantage in this application area. Such a design could enable more targeted and uniform irradiation of adipose tissue, potentially optimizing micropore formation or other cellular responses across a larger or more specific treatment area, leading to more effective and predictable cellular fat sculpting outcomes [16]. The modularity also extends to large area applications via expandable accessories, enhancing its versatility for various fat reduction needs. The relatively low base power output (10mW) is a key feature; it ensures a safe profile for extended and potentially frequent applications necessary for sustained aesthetic results or the management of localized fat accumulation, as it allows for precise dose control through time modulation, effectively mitigating the tissue cell damage risks potentially associated with higher base powers (e.g., 50-1000mW). This safety and convenience are paramount for integrating fat reduction as a component of long-term chronic care management. By allowing patients to safely perform regular, low intensity treatments at home, the system directly aligns with the VANGUARD framework's “Niche Finding” by targeting the specific patient demographic requiring safe, home-based adjunctive therapies. Furthermore, this capability provides significant “Growth Leverage” by contributing to sustained weight management and improved metabolic parameters within the expanding market for decentralized and digitally integrated chronic care solutions [16].

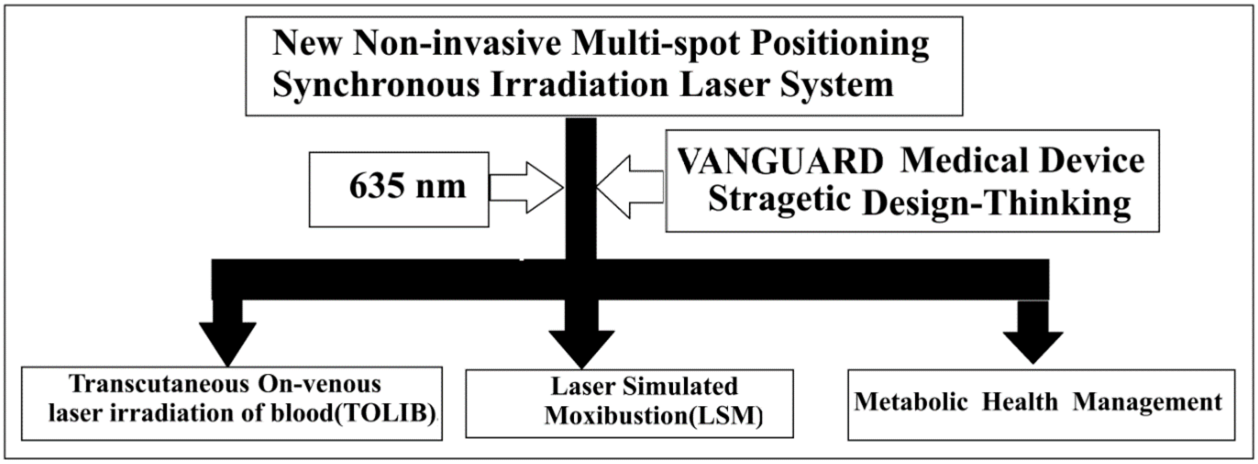

Figure 4: Application of the non-invasive multi-spot positioning synchronous irradiation laser system though VANGUARD medical device strategic design-thinking.

3.4. Integration into Chronic Care and Strategic Design Evaluation

The integration of this system into chronic disease management paradigms is not merely a matter of technical compatibility but a result of structured translational design thinking. To assess the long-term value and evolution potential of the platform, we applied the VANGUARD medical device strategic innovation framework (Figure 4), which includes eight interrelated dimensions (Table 1): "Value Signal", "Advantage Anchor", "Niche Finding", "Growth Leverage", "Uniqueness Signal", "Advantage Validation", "Roadblock Breakthrough", and "Deployment Strategy" (Table 1). This approach provided a comprehensive lens to analyze how the current system design aligns with unmet clinical needs, user expectations, and system level scalability.

In the "Value Signal" dimension, chronic care was identified as a growing unmet domain, particularly for non-invasive interventions addressing systemic inflammation, microcirculation disorders, and stress related autonomic dysfunction. Current therapeutic options often lack personalization, repeatability, or safety for long term home use. This system was fundamentally envisioned as a comprehensive solution, designed from inception to deliver low intensity photobiomodulation safely and precisely across repeated sessions, directly targeting these long-term care needs and signaling clear value to patients and providers [16].

Stage	Focus	Key Design Relevance
Stage 1	VAN Stage	Visioning–Assessing–Niche Finding Stage
	V: Value Signal	Focused on genitourinary recovery needs
	A: Advantage Anchor	Laser-based design targets clinical pain points
	N: Niche Finding	Epidemiology confirms underserved user segment
Stage 2	GUA Stage	Growth–User–Advantage Linking Stage
	G: Growth Leverage	Long-term demand for safe, aging-friendly therapies
	U: Uniqueness Signal	Design for safety, comfort, smart dosing control
	A: Advantage Validation	Sensor modules boost clinical value
Stage 3	RD Stage	Realization & Deployment Stage
	R: Roadblock Breakthrough	Regulatory and usability hurdles addressed proactively
	D: Deployment Strategy	Modular format ensures scalability and consistency

Table 1: Application of the VANGUARD Medical Device Design Thinking Framework to New Non-Invasive Laser System for TOLIB and Photo-Moxibustion[16]**.**

The "Advantage Anchor" component involved mapping user pain points across existing TOLIB and laser acupuncture devices. Common issues such as difficulty in maintaining consistent dose delivery, operator dependent variability, lack of session feedback, and mismatch with real world treatment environments were repeatedly reported. The system's core design elements – including the programmable time dose interface, ergonomic laser module, and potential for AI driven adjustment – were developed as direct responses to these identified deficiencies, serving as strong anchors for practical clinical utility. From a Niche Finding perspective, the system targets patients with moderate to severe chronic conditions requiring gentle but frequent systemic support. These include elderly populations, individuals with diabetes, inflammatory syndromes, or autonomic imbalance, for whom thermal, ablative, or pharmacological therapies are not suitable or well tolerated. The system's unique low power, modular design positions it distinctly within this niche, offering a safe and adaptable tool for these sensitive patient groups. The potential for safe, home based fat reduction perfectly complements this niche by addressing a critical aspect of metabolic health in chronic care. In the Growth Leverage analysis, we observe alignment with major demographic and policy trends including global aging, the decentralization of care, and the rise of home-based therapeutics. These trends forecast increasing demand for intelligent, safe, and repeatable non-invasive interventions that can be integrated into daily routines, without requiring hospital infrastructure. The system's inherent design features, such as its low power for extended use and modularity for home settings, directly capitalize on these projected growth areas. The system's capacity for adjunctive fat reduction further bolsters its market growth potential within the chronic care segment. The system's "Uniqueness Signal" was validated through preclinical user trials and mock deployment scenarios, demonstrating its distinctive value proposition. Results indicated that users prioritized simplicity, preloaded protocols, safety indicators, and anatomical guidance. These user priorities were meticulously translated into tangible design features, implemented through tactile interface modules, visual positioning aids, and the fixed low energy design, which collectively minimize training burden and maximize adoption likelihood in real world settings. In "Advantage Validation", benchmarking against existing LPLI and TCM inspired laser devices highlighted the platform's unique configuration: fixed relative low power, integrated transcutaneous blood and acupoint modes, modular expansion capability, and future AI compatibility. This combination, which is not seen in current commercial devices, directly stems from our design philosophy to create a truly versatile and safe personalized phototherapy solution, offering a distinct competitive and therapeutic positioning. Addressing the "Roadblock Breakthrough" component, potential barriers to innovation adoption and market entry were proactively considered. The platform's versatile product design, applicable across diverse clinical specialties (e.g., blood purification, pain management, metabolic health), combined with accumulating clinical evidence across these different uses, is key to building confidence and overcoming the inherent skepticism or "confidence threshold" associated with novel medical products. This cross-disciplinary validation is designed to accelerate product acceptance and broader market penetration. The platform was also designed in alignment with IEC 60601 1 and CE mark requirements from the outset, and the choice of fixed low power simplifies safety validation and supports broader deployment. Furthermore, its capacity for cloud-based treatment monitoring and data feedback directly addresses compliance and supervision challenges in decentralized use. The "Deployment Strategy" follows a phased approach: initial in clinic use for selected indications, followed by controlled expansion into home-based applications. Future models may incorporate adaptive feedback algorithms, wearable integration, or even digital twin modeling for predictive dosing. This modular roadmap is a direct manifestation of our design's inherent scalability, ensuring the system can evolve into a fully personalized therapeutic infrastructure capable of delivering safe, effective care for complex, long term conditions[16]. Some functional polymeric materials could be possible applied with the system for additional applications [20-24].

4. Conclusion

This study presents a clinically oriented, programmable, and highly safe non-invasive laser therapy platform optimized for both TOLIB and laser-simulated moxibustion. Its modular architecture, ultra-low power output, and intelligent control interface support long-term, personalized applications. Preclinical validation confirms its technical feasibility and biological relevance, laying the foundation for expanded use in chronic disease management, including adjunctive fat reduction for metabolic health, and home-based digital therapeutics. This study not only validates a novel technical platform but also demonstrates a structured innovation pathway using the VANGUARD framework, which guided the identification of clinical opportunities, technical gaps, and strategic directions for chronic care expansion.

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