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Original Article

Establishing Dosimetric Foundations for Extraoral Photobiomodulation Therapy in Oral Mucositis Prevention

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ABSTRACT

Sexuality, which plays an essential and significant role in human life, is provided through healthy sexual organs. Therefore, any disease in the genital area, including vaginitis, can interfere with these tendencies and thus affect the quality of life of the individual. The researchers, therefore, conducted a study aimed at comparing sexual satisfaction in pregnant women with vaginal candidiasis. This is a cross-sectional study to evaluate the effect of Candida vaginitis infection on sexual satisfaction that should be considered in healthy individuals and comparative work. Therefore, in this study, 160 pregnant mothers referred to the gynecology clinic, Shahid Beheshti Hospital, Tehran were selected by convenience sampling method and divided into two groups of healthy pregnant women and vaginal candidiasis women (each group 80 people). Data were collected using the Larson Sexual Satisfaction Questionnaire. After data collection, data were analyzed in SPSS software and analyzed by independent t-test. The results showed that sexual satisfaction in healthy pregnant women was slightly higher than pregnant women with vaginal candidiasis, and there was a significant difference between the two groups regarding sexual satisfaction ($p < 0.05$). These results suggest that there is a relationship between sexual satisfaction and Candida infection. Regarding the difference of sexual satisfaction in the group of pregnant women with vaginal candidiasis and healthy pregnant women, it can be concluded that the rate of sexual satisfaction with the vaginal candidate will be effected and makes problems and disorders.

Keywords: Photobiomodulation therapy, Oral mucositis, Hematopoietic stem cell transplantation, Low-level light therapy, Monte Carlo simulation

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Introduction

Oral mucositis (OM) is a debilitating adverse effect of hematopoietic stem cell transplantation (HSCT), manifested by inflammation and ulceration of the oral mucosa [1]. Photobiomodulation therapy (PBMT), a safe and efficacious light-based modality, has demonstrated effectiveness in both preventing and managing OM among patients undergoing HSCT [2, 3]. Existing guidelines for PBMT predominantly employ intraoral application, which entails sequential, site-specific dose deliveries in a point-by-point fashion—a method that is technically demanding, labor-intensive, and dependent on substantial patient compliance **(Figure 1a)** [4].

a)

b)

Figure 1. Artistic representation of (a) intraoral and (b) extraoral photobiomodulation therapy.

Extraoral photobiomodulation therapy (PBMT) offers potential clinical benefits, including simpler administration and broader coverage of remote mucosal sites that are inaccessible via intraoral approaches. Nevertheless, extraoral application involves photon transmission through overlying orofacial tissues—such as skin, subcutaneous fat, and muscle—prior to reaching the target mucosal lining, resulting in substantial dose attenuation and necessitating intricate dosimetric adjustments **(Figure 1b)**. Moreover, no dedicated dosimetric investigations or validated protocols have been published to date. This review aims to critically evaluate the challenges associated with extraoral PBMT delivery and to advance the establishment of an evidence-based protocol for preventing oral mucositis (OM).

Challenges associated with extraoral PBMT for oral mucositis

Intraoral PBMT is applied directly to the mucosal surface, with the primary target being the submucosal connective tissue located at depths of approximately 100–700 μm [5]. The primary difficulties arising from extraoral PBMT stem from the intervening tissue layers that light must traverse to access the oral mucosa. These optically dense layers significantly diminish the delivered dose. Herein, we examine the fundamental anatomy of the orofacial region and highlight key photobiological implications.

Orofacial tissue layers

The tissues of the face and scalp are commonly categorized into five layers, progressing from superficial to deep: (1) skin, (2) subcutaneous tissue, (3) musculoaponeurotic layer, (4) loose spaces and retaining ligaments, and (5) deep fascia **(Figure 2**) [6]. Bone and periosteum are generally irrelevant in this context, as they can be avoided during extraoral PBMT application and would otherwise contribute to further dose reduction. From a photobiological viewpoint, the orofacial tissues may be simplified into three principal layers: skin, fat, and muscle, each possessing distinct optical characteristics. Among these, skin represents the most significant barrier to light penetration, primarily due to absorption and scattering by the chromophore melanin (predominantly eumelanin, though referred to here broadly as melanin) [7, 8]. Higher melanin concentrations in darker skin types result in greater optical attenuation.

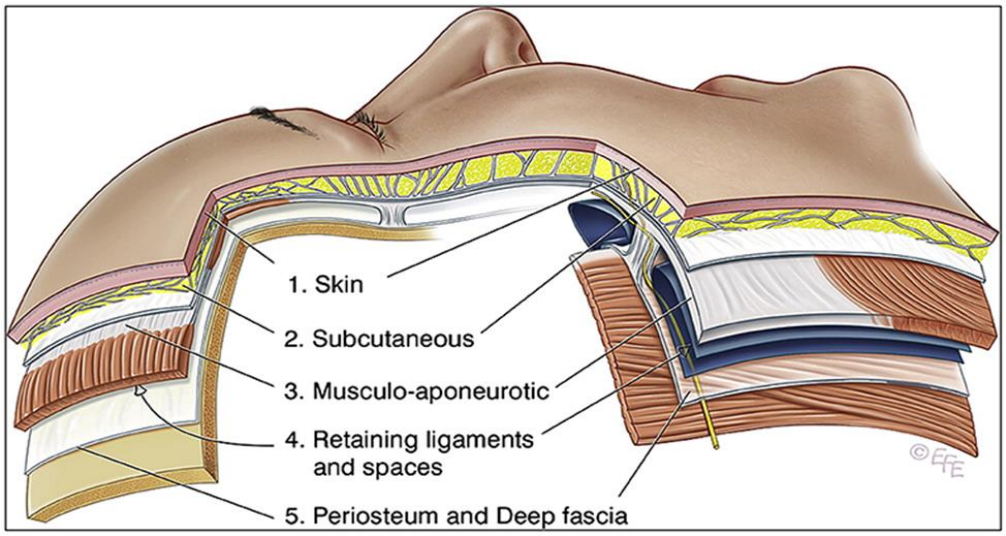

Figure 2. Layer model diagram of facial tissues. Adapted with permission from Mendelson *et al*.

Degree of attenuation

The extent of light attenuation by the skin, and to a lesser degree by subdermal tissues, is substantial. For instance, in skin with low melanin content, light at 600 nm wavelength is reduced to 37% of its initial intensity at a depth of just 550 μm beneath the surface; extending

the wavelength to 800 nm allows penetration to 1,200 μm before reaching the same level of attenuation [9]. Optical property analyses of human tissues have reported a scattering coefficient of 2.73 mm^{-1} at 633 nm in low-melanin dermis, which declines to 1.63 mm^{-1} at 900 nm. Although absorption and scattering coefficients in subdermal layers (fat and muscle) are lower, they remain noteworthy [7]. The typical thickness of the human cheek ranges from 6 to 7 mm [10]. Even though only a fraction of this comprises skin, a considerable portion of the incident energy is dissipated across these tissues en route to the oral mucosa. This has direct implications for treatment duration: a 90% loss in transmitted dose would necessitate a 10-fold prolongation of exposure time to achieve equivalent dosing at the target site. Enhancing penetration is thus beneficial for practical protocol implementation, and as evidenced, employing longer wavelengths reduces both scattering and absorption, thereby improving light transmission.

Variability in attenuation

Inter-patient variability arising from anatomical variations and skin pigmentation leads to inconsistencies in the dose reaching the oral mucosa. Such differences are difficult to predict and show no consistent association with sex or age. For example, ultrasonographic assessment of cheek thickness in 30 adults (aged 24–61 years) yielded a mean dermal thickness of 1,639.27 μm, accompanied by a substantial standard deviation of 531.53 μm [11]. No clear patterns emerged related to sex or age, indicating that stratifying patients into subgroups would not effectively mitigate this variability.

Skin classified under higher Fitzpatrick scales—which quantify skin color and tanning response—exhibits elevated melanin levels and consequently greater attenuation [7]. As a result, individuals with darker skin receive reduced mucosal dosing despite identical external application. Importantly, this disparity diminishes at longer wavelengths. One investigation of ex vivo dermal specimens from low- versus high-melanin skin types documented reduced scattering coefficients of 2.73 ± 0.54 mm^{-1} versus 3.21 ± 2.04 mm^{-1} at 633 nm, narrowing to 1.63 ± 0.25 mm^{-1} versus 1.81 ± 0.040 mm^{-1} at 900 nm [7]. Two in vivo studies encompassing Fitzpatrick types I–VI similarly observed elevated absorption coefficients in darker skin, with the gap narrowing over 600–800 nm and becoming insignificant at 850 nm [12, 13]. Additionally, skin pigmentation exerted a stronger effect on reflectance in the 460–700 nm range than at 800–850 nm [14, 15]. Collectively, these results indicate that longer wavelengths not only enhance overall penetration but also reduce dose discrepancies attributable to skin type.

Safety and feasibility

No toxicity has been documented in any investigations of photobiomodulation therapy (PBMT) for the prevention or treatment of oral mucositis (OM) [16]. Similarly, the few studies examining extraoral PBMT have reported no instances of cutaneous or oral adverse effects. Theoretically, PBMT might induce tissue heating, including skin warming during extraoral application; however, the American National Standards Institute (ANSI) provides safety guidelines defining the maximum permissible exposure (MPE) for laser irradiation of the skin (applicable across all skin types) [17], offering a valuable benchmark. One investigation involving patients with varying skin pigmentation and device settings compliant with ANSI standards evaluated the impact of melanin on skin surface temperature during PBMT exposure. The results indicated no notable temperature elevations across doses of 0 to 50 J, delivered using super-pulsed lasers combined with pulsed red and infrared LEDs at wavelengths of 810–904 nm [18].

Two studies have assessed the practicality of implementing extraoral PBMT in inpatient pediatric hematology-oncology settings, both achieving their primary objectives related to feasibility, tolerability, and safety. The initial study involved 10 patients aged 4 to 21 years and demonstrated successful delivery of prophylactic daily extraoral PBMT in 347 out of 355 sessions (97.7%), administered by 10 trained nurses, with no discontinuations due to pain or other issues [19]. The subsequent study utilized a therapeutic (rather than prophylactic) protocol combining intraoral and extraoral PBMT in 22 patients aged 3 to 18 years with WHO Grade ≥2 OM, achieving procedural success—defined as coverage of the entire oral mucosal surface at least three times within the first seven days of OM onset—in 77% of cases. The interventions were well-tolerated, with no adverse events attributable to the treatment [20].

Summary

These collective insights inform our strategy for designing an extraoral PBMT protocol. Primarily, given the considerable light attenuation by orofacial skin and underlying tissues, the regimen should prioritize penetration optimization to avoid prohibitively prolonged treatment times needed for therapeutic dosing. Additionally, identical protocols applied to different patients are likely to yield varying mucosal doses, underscoring the need for a uniform approach targeting the “average” patient—similar to

standardized dosing in pharmacology, despite inter-individual differences in pharmacokinetics and pharmacodynamics.

Established intraoral PBMT protocols for OM prevention advocate mucosal doses ranging from 1.0 to 6.2 J/cm², though the effective therapeutic window may extend further [4]. Since extraoral PBMT operates via identical mechanisms, the mucosal target dose should align accordingly. Several key considerations apply. First, inter-patient anatomical variations inevitably introduce dose heterogeneity at the mucosa. A fixed protocol designed for the "average" patient will thus result in some under- or overdosing. Fortunately, the relatively wide efficacious range suggests that most transmitted doses will retain therapeutic benefit, especially with a moderate target selection [21]. Second, prolonged treatment times pose a practical constraint for extraoral PBMT due to attenuation; excessively high target doses should therefore be avoided to ensure clinical feasibility, with emphasis placed on optimizing delivery rates through enhanced penetration (e.g., longer wavelengths) and higher power outputs. Third, regarding safety, no appreciable skin temperature increases were noted in subjects of diverse pigmentation exposed to PBMT at 640, 875, and 904 nm wavelengths with energies up to 50 J—far exceeding typical OM indications [18]. Consequently, the modest under- or overdosing arising from anatomical or pigmentary differences is unlikely to raise safety issues.

Wavelength selection

Standard intraoral PBMT regimens typically employ red-spectrum wavelengths, including 632.8 nm from helium-neon (He-Ne) lasers and 660 nm from diode lasers [4]. These are well-suited for shallow targets, such as when light is applied directly onto the oral mucosa. However, multiple advantages support choosing the longest wavelength proven effective for extraoral use, as outlined previously: (1) longer wavelengths experience lower levels of absorption and scattering in tissues like melanin, adipose, and muscle, thereby improving overall dose transmission and shortening required session times to practical levels; and (2) such wavelengths reduce inconsistencies in attenuation linked to varying melanin levels [7]. Supporting data from both animal models and human trials confirm the effectiveness of extended-wavelength PBMT in managing oral mucositis. A primary target chromophore, cytochrome c oxidase—widely regarded as central to PBMT's beneficial actions—exhibits multiple absorption "peaks" or optimal bands, implying comparable biological responses across this spectrum rather than restriction to a specific wavelength [22]. The most prominent of these lies within the near-infrared band, spanning 812.0–846 nm. Moreover, near-infrared PBMT has demonstrated clinical benefits in treating various other conditions involving inflammation or pain, including osteoarthritis, colitis, and temporomandibular joint disorders [23-30]. In contrast, wavelengths exceeding the near-infrared spectrum currently have no supporting data for therapeutic value [31].

Power density (Irradiance)

Compared to total energy density (fluence), power density appears to have a lesser impact on treatment outcomes and offers flexibility for improving protocol practicality. This is reflected in the wide variation seen in intraoral guidelines, which range from 24–31.25 mW/cm² for He-Ne systems to 417–1,000 mW/cm² for diode-based devices [4]. To align with efforts to accelerate effective dose accumulation at the target, power density should be set as high as possible without breaching ANSI safety guidelines. Such an approach ensures sessions remain manageable in length while addressing potential risks effectively.

Application sites and session structure

Primary oral cavity mucosal areas requiring attention encompass the cheeks (buccal surfaces), upper and lower lips, underside and sides of the tongue, floor of the mouth, and soft palate. Extraoral methods may additionally access farther regions, including oropharyngeal and even esophageal linings, consistent with research demonstrating regional or broader systemic benefits [32, 33]. A well-designed extraoral regimen should cover these zones efficiently, with limited redundancy in beam paths and deliberate bypassing of structures like teeth, bone, and cartilage to limit unnecessary light loss **(Table 1)**. This strategy relies on the premise that the mucosal layer is extremely thin and contributes minimally to attenuation, while the modest air volume inside the mouth is likewise optically irrelevant. Accordingly, beam paths targeting the buccal regions can simultaneously address the lateral tongue and soft palate, and those directed toward the floor of the mouth can concurrently treat the ventral tongue surface.

Table 1. Proposed protocol of treatment locations and trajectories and their target mucosal surface for use in extraoral delivery of photobiomodulation therapy for prevention of oral mucositis.

Treatment location and trajectory	Mucosal surface treated
Left cheek, transversely	Left buccal mucosa and lateral tongue

Right cheek, transversely	Right buccal mucosa and lateral tongue
Philtrum, anteroposteriorly	Upper lip and lower lip
Midline neck, vertically	Midline floor of mouth, ventral tongue, oropharyngeal mucosa, and esophageal mucosa
Left neck, transversely	Left floor of mouth, ventral tongue, oropharyngeal mucosa, and esophageal mucosa
Right neck, transversely	Right floor of mouth, ventral tongue, oropharyngeal mucosa, and esophageal mucosa

Treatment duration and delivery considerations

The duration of photobiomodulation therapy (PBMT) should be calculated to achieve the intended therapeutic dose on the oral mucosa. It depends directly on the energy fluence rate (J/cm²/s) and varies according to the specific treatment site. Accurate duration can only be established after a comprehensive dosimetric analysis that quantifies how much light is attenuated by bones, soft tissues, and other orofacial structures along each illumination pathway. Because of this attenuation, extraoral PBMT will almost certainly require substantially longer irradiation times than intraoral PBMT. Nevertheless, well-designed extraoral devices can enable hands-free, comfortable application and even simultaneous treatment of multiple sites, thereby improving practicality and patient tolerance.

Future directions

Several key obstacles remain before extraoral PBMT can be routinely used for oral mucositis (OM). Currently, no published dosimetric models exist for extraoral delivery — data that are indispensable for developing a rational and validated protocol. Essential components of such modeling include defining a "standard" or median patient anatomy, simulating light transmission to the oral mucosa along various beam trajectories for given device parameters, and confirming the model predictions in vivo. Once a protocol is proposed, its clinical effectiveness must be tested in a properly powered, randomized, sham-controlled trial that assesses outcomes such as the incidence, severity, and duration of severe OM.

Conclusion

Intraoral PBMT is a well-established, safe, and effective preventive and therapeutic intervention for oral mucositis in patients undergoing myeloablative conditioning before hematopoietic stem-cell transplantation. Extraoral PBMT offers potential advantages (non-invasive, better patient comfort, ability to treat multiple areas at once), but it currently lacks supporting efficacy data and requires separate dosimetric evaluation because light must traverse facial tissues before reaching the target mucosa. Consequently, parameters proven effective for intraoral PBMT cannot be directly transferred to extraoral use. Although extraoral treatments will inevitably be longer, thoughtful device design can reduce overall treatment burden and enhance convenience. This review has described the critical steps needed to create, dosimetrically validate, and clinically test a evidence-based extraoral PBMT protocol suitable for future randomized trials and eventual routine clinical adoption.

Acknowledgments: Figure 1 courtesy of THOR Photomedicine.

Conflict of Interest: JC is CEO of THOR Photomedicine. WL receives payment for service on Data and Safety Monitoring Boards for Merck and Jubilant Draximage. SS reports personal fees from Biomodels, LLC, personal fees from Primary Endpoint Solutions, LLC, outside of the submitted work. As an employee of Biomodels and PES, he is involved in assisting industry, government and academics in the study and enablement of drugs, biologicals and devices to treat patients for a broad range of indications including cancer and oral toxicities of cancer therapy. He does not have equity or receive payment from any of the companies' clients. NT serves as a consultant for MuReva Phototherapy Inc. The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Ethics Statement: None

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