Original Research Article

Photobiomodulation effects on the postoperative outcomes of surgically assisted rapid maxillary expansion: a double-blind randomized controlled pilot study

Abstract

The postoperative period following Surgically Assisted Rapid Maxillary Expansion (SARME) is often characterized by pain, edema, and paresthesia. Photobiomodulation (PBM) has been shown to effectively alleviate symptoms after minor oral surgical procedures; however, it has not yet been evaluated in the postoperative setting of SARME. This pilot study aimed to assess the effects of PBM on managing pain, edema, and paresthesia in patients post-SARME utilizing LED devices. A total of thirty-one cases performed by three surgeons were included, with pre- and postoperative evaluations conducted by two blinded examiners. Prior to surgery, facial measurements and sensitivity assessments were carried out. Subsequently, participants were randomly assigned to either the PBM group (n=15), receiving nine applications of PBM, or the control group, which underwent simulated irradiation. Data were collected for up to 120 days post-surgery. Although no significant differences were observed between the groups for any evaluated outcome, these findings underscore the need for further research to explore the optimal parameters and conditions for PBM application. Future investigations may reveal potential avenues for enhancing the efficacy of PBM in the postoperative management of patients following SARME.

Keywords: Photobiomodulation, Surgically Assisted Rapid Maxillary Expansion, Paresthesia, Edema, Pain.

Introduction

The treatment of transverse maxillary deficiency greater than 5 mm in adults is typically performed through the association of Surgically Assisted Rapid Maxillary Expansion (SARME) and expansion devices that can be attached to the teeth or through commercially available osteogenic distraction devices that act directly on the palatine bone (1,2).

The most common complications in the postoperative period of SARMEare epistaxis and pain, but they may also include edema, paresthesia, and other minor complications (3-5).

The treatment of the most common complications in oral surgeries is most commonly performed using analgesics and anti-inflammatories, and more recently, also through the use of photobiomodulation (6,7).

Photobiomodulation (PBM) has demonstrated favorable outcomes in the postoperative period of oral surgeries (8-10); however, there are currently no reported studies on the application of PBM specifically in the context of SARME. Most studies evaluating PBM in minor oral surgeries have utilized laser equipment. However, in surgeries that involve larger areas, devices incorporating multiple LEDs may offer enhanced ease and safety in their application (11,12).

In this pilot study, the effects of PBMusing LED devices during the postoperative period of SARMEwere evaluated. The study specifically focused on pain, edema, and paresthesia, with applications administered both intraorally and extraorally.

Materials and Methods

The protocol for this study was approved by the Research Ethics Committee of Nove de Julho University (03645518030015511) and the Mandaqui Hospital Complex (03645518000005551), registered on the Clinical Trials platform (https://clinicaltrials.gov/) under the number NCT03814525 and published (11).

Participants of both genders were selected who were referred to the Oral and Maxillofacial Surgery and Traumatology Service of the Mandaqui Hospital Complex (São Paulo, Brazil) and required SARME, being diagnosed with transverse maxillary deficiency greater than 5 mm and bilateral posterior crossbite, aged between 18 and 45 years (11). Participants were excluded if they had local or systemic conditions that contraindicated surgical intervention or complicated postoperative recovery; smokers; pregnant or lactating women; those with a history of photosensitivity; individuals with systemic diseases, chronic pain, or neurological and psychiatric disorders; as well as

those using anti-inflammatories, analgesics, or bisphosphonates in the 15 days prior to surgery (11).

In the preoperative assessment, facial measurements, extraoral and intraoral sensitivity tests, and anxiety analysis were conducted (11). The preoperative and postoperative evaluations were conducted by two examiners who were unaware of the group to which each participant was assigned.

Sample size calculation

The sample size calculation was based on the variability of the results from three articles that assessed the primary outcomes of this study in similar situations (13-15). The required sample size would be 72 individuals (unpaired t-test), considering a significance level of 0.05, an absolute error of 5%, and a loss of 10% (11). Unfortunately, it was not possible to recruit the entire sample because the Mandaqui Hospital Complex became a reference center for confronting the COVID-19 pandemic, resulting in the suspension of elective surgeries. Thus, 31 participants were operated on, and this trial can be considered a pilot study.

Surgical Procedure

As previously described (11), all patients received a Hyrax-type expander (Dentaurum 602-802, Ispringen, Germany) in the palate at least 24 hours prior to the surgeries. The surgical procedures were performed by three specialized surgeons following the SARME protocol of the Oral and Maxillofacial Surgery and Traumatology Department of the Mandaqui Hospital Complex, in accordance with prior publication (11).All patients underwent the same surgical protocol (11).

In the immediate postoperative period, participants administered cefazolin 1 g (intravenously, IV) every 8 hours, dexamethasone 10 mg IV every 8 hours, and dipyrone 1 g IV every 6 hours until hospital discharge (two days). The prescription after hospital discharge included amoxicillin 500 mg (tablet, orally) every 8 hours for 7 days, dexamethasone 4 mg (tablet, orally) every 8 hours for 3 days, dipyrone 500 mg (tablet, orally) every 6 hours for 3 days, and rinses with 5 mL of 0.12% chlorhexidine

digluconate solution, three times a day (11). The participant activated the Hyrax device one week postoperatively until the planned expansion was achieved during the preoperative assessment, at which point the device was locked for a period of 3 to 6 months (11).

Immediately following the surgeries, participants were assigned to their respective groups (Control or PBM) according to the randomization indicated in the prepared envelope, as described earlier (11).

Experimental groups

PBM Group: Participants received PBM after the surgical procedure.
Control Group: Participants received simulated PBM application by positioning the devices in the same locations as described for the PBM group; however, the equipment was kept turned off. To prevent participants from identifying the group to which they belonged, the activation sound of the devices was recorded and played during the application(11).

Application of Photobiomodulation (PBM)

PBM was administered in the immediate postoperative period and on days 1, 2, 7, 14, 30, 60, and 90 following the surgeries. A single researcher performed the applications and did not conduct any evaluations. An intraoral device in a rectangular shape was utilized for intraoral applications, while an extraoral mask was employed for external applications (11). The images of the devices are represented in Figures 1 and 2 and the dosimetric parameters of the equipment's are detailed in Tables 1 and 2(11).

Intraoral PBM

Participants received intraoral LED applications (Cosmedical, São Paulo, SP, Brazil) (Figure 1) with the parameters described in Table 1, during the periods previously mentioned(11).

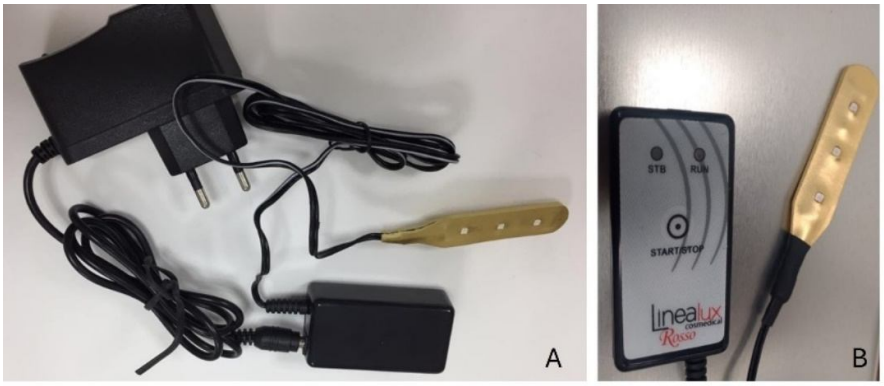

Figure 1: Overview of the intraoral device (A) and detailed view of the device and activation plug (B).

Table 1: Dosimetric parameters of the intraoral LED device

Parameter	
Wavelength (nm)	660
Spectral bandwidth (nm)	20
Operating mode	Continuous
Average radiant power (mW)	5
Polarization	Random
Aperture diameter (mm)	10±2
Beam profile	Multimode
Beam spot size at target (cm^2)	0.785
Exposure duration (m)	7
Radiant exposure per LED(J/cm^2)	2.7
Radiant energy per LED(J)	2
Device area (cm^2)	2.35
Application technique	Contact
Number of LEDs in the device	3
Number and frequency of sessions	1 /day

Extraoral PBM

Participants received extraoral LED applications (Cosmedical, São Paulo, SP, Brazil) (Figure 2) with the parameters described in Table 2, during the periods previously mentioned (11).

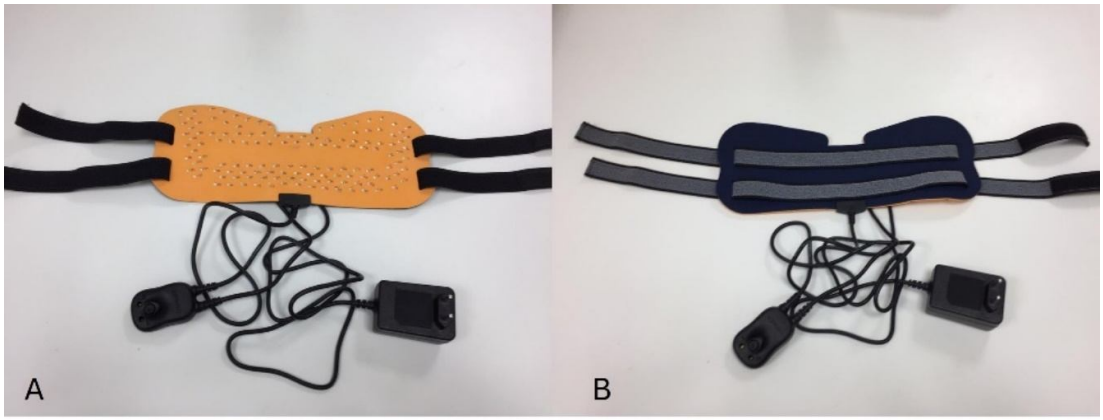

Figure 2: Internal view of the LED mask for extraoral PBM application (A) and external appearance of the mask (B).

Table 2:

Parameter	**Red**	**Infrared**
Wavelengt (nm)	660	850
Spectral bandwidth (FWHM) (nm)	20	20
Operating mode	Continuous	Continuous
Average radiant power (mW)	5	5
Polarization	Random	Random
Aperture diameter (mm)	10	10
Beam profile	Multimode	Multimode
Beam spot size at target (cm^2)	0.785	0.785
Exposure duration (m)	20	
Radiant exposure per LED (J/cm^2)	7.64	7.64
Radiant energy per LED (J)	6	6
Device area (cm^2)	15.7	
Application technique	Contact	
Number of LEDs in the device	57	74
Number and frequency of sessions	1 /day	

Dosimetric Parameters of the Extraoral LED Mask

Assessment of outcomes

Pain assessment

Pain was assessed using the numeric rating scale (NRS-101) after 1, 2, 7, and 14 days post-surgery as described previously (11,16).

Facial measurements (assessment of edema)

The comparison of the sum of five facial measurements (posterior tragus point to the most lateral point of the labial commissure; posterior tragus point to pogonium; posterior tragus point to the lateral corner of the eye; lateral corner of the eye to the lowest point of the jaw angle; lower point of the mandible angle -gonion- to the midpoint of the nasal bone) was performed by two calibrated examiners using a flexible plastic caliper, both before and 1, 2, 7, and 14 days post-surgery, to assess edema as previously described (11).

Assessment of paresthesia

The assessment of extraoral and intraoral sensitivity was conducted in six regions: below the lower eyelid, cheek, wing of the nose, upper lip, vestibular oral mucosa, and palatal oral mucosa on both sides (11,14). Four types of tests were performed, and the results were grouped into two indices: the Qualitative Global Sensitivity Index (QGSI) and the Quantitative Global Sensitivity Index (QGSI) (11,14).The QGSI was determined by summing the results of the light touch and

pinprick sensation tests, with a maximum score of 5 points per side per participant per evaluation period (11,14,17).

For the calculation of the quantitative GSI, the measurements obtained from the static two-point discrimination test (TPD) and the dynamic two-point discrimination test (DPD) at each assessment time were subtracted from those obtained during the preoperative evaluation. The difference between these measurements was classified as previously described (11,14). The sum of the scores obtained from the TPD and DPD tests at each assessment time was defined as quantitative sensitivity, ranging from 0 to 10 per participant per evaluation time (11,14).

Subsequently, the Global Sensitivity Index (GSI) was calculated by summing the qualitative sensitivity value with the quantitative sensitivity value, with a maximum score of 15 for each assessed anatomical area. In addition to analyzing individual areas, the total score was computed by summing all areas at each evaluation time (11,14).The sensitivity tests were repeated in all participants on both sides at 7, 30, 60, 90, and 120 days postoperatively (11).

Results

The data were analyzed for normality and described as mean and standard error for Gaussian distributions. Categorical data were expressed as absolute and relative frequencies (%). For comparison of sample characteristics between groups, the Mann-Whitney test was employed for ordinal categorical variables and non-parametric numerical data. The Pearson chi-square test was used to compare gender frequencies between the groups. For facial measurement variables (edema), pain and the Global Sensitivity Index, a two-way ANOVA was conducted. A significance level of 5% was adopted.

The study comprised 31 participants, with 16 (52.6%) in the control group and 15 (48.4%) in the PBM group. The majority were female (58.1%), with ages ranging from 18 to 49 years, and most had completed high school (48.4%). No significant

differences were observed between the groups regarding the assessed demographic characteristics ($p > 0.05$).

Pain assessment

Table 3 presents the average pain values measured by the NRS-101 scale across different groups and experimental time points, indicating that no significant differences were observed between the groups at any of the time periods.

Table 3: Mean ± standard error of pain as measured by the NRS-101 scale according to time and group.

Time	FBM (n=15)	Control (n=16)	p-value
1st Day	11.9 ± 5.9	21.9 ± 5.7	0.233
2nd Day	8.8 ± 5.0	15.3 ± 4.9	0.362
7th Day	8.7 ± 5.4	16.9 ± 5.2	0.284
14th Day	6.0 ± 5.0	7.5 ± 4.9	0.834

An analysis was also conducted categorizing the NRS-101 scale into "absent pain" when participants assigned a value of zero to pain and "present pain" when a value greater than zero was assigned. Table 4 presents the absolute number and relative frequency (%) of patients who reported the presence of pain, as measured by the NRS-101 scale, across evaluations according to group. No significant variation in the frequency of reported pain was observed throughout the evaluations in either group ($p > 0.05$), nor were there significant differences between the groups regarding the presence of pain in each evaluation ($p > 0.05$).

Table 4: Distribution of the absolute number of patients and relative frequency (%) with reported pain according to the NRS-101 scale by group at each evaluation time point.

Time	FBM (n=15)	Control (n=16)	p-value
1st Day	8 (43.3%)	7 (43.8%)	0.594
2nd Day	6 (40.0%)	6 (37.5%)	0.886
7th Day	5 (33.3%)	8 (50.0%)	0.347
14th Day	2 (13.3%)	3 (18.8%)	0.682

Assessment of edema

Figure 3 illustrates the progression of edema, determined by the sum of facial measurements from both hemifaces of participants, from the preoperative period to the 14th day post-surgery in each evaluated group. It is noteworthy that throughout the follow-up, the PBM group consistently exhibited a slightly lower average facial measurement compared to the control group. Table 3 presents the mean values for each evaluation.

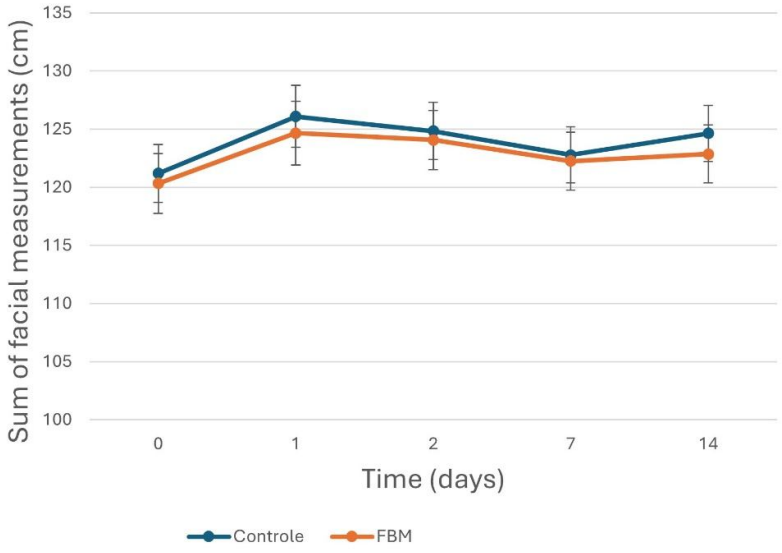

Figure 3: Sum of facial measurements

A two-way ANOVA revealed no significant interaction effect between time and group (p=0.958), indicating that both groups exhibited similar trends in facial measurements over time. Additionally, no significant group effect was observed (p =0.746), meaning that although the average facial measurement in the control group was slightly higher than that of the PBM group throughout the follow-up period, this difference was not statistically significant. There was, however, a significant time effect ($p < 0.05$), indicating a notable variation in average facial measurements over the monitoring period, which was evident in both evaluated groups, as detailed in Table 5.

Table 5: Mean ± standard error of the sum of facial measurements of participants according to time and group (PO refers to postoperative days)

Time	Pre	1st PO	2nd PO	7th PO	14th PO	p-value
PBM	120.3 ± 2.6	124.6 ± 2.7	124.0 ± 2.5	122.2 ± 2.5	122.9 ± 2.5	0.025
Control	121.2 ± 2.5	126.1 ± 2.6	124.8 ± 2.5	122.8 ± 2.4	124.6 ± 2.4	0.006
p-value	0.811	0.709	0.818	0.880	0.614	

No significant differences in the average facial measurements were observed between the two groups at any of the evaluated time points ($p > 0.05$). However, the variation in measurements over the follow-up period was significant for both groups ($p= 0.025$ and $p = 0.006$, respectively).

Assessment of paresthesia

The occurrence of paresthesia was assessed using the Global Sensitivity Index (GSI). Tables 6 to 11 represent the GSI values in the different anatomical areas assessed during all postoperative periods.

Table 6: Mean ± standard error of ISG Global for the eyelid according to time and group (PO refers to postoperative days).

Time	Group	FBM	Control	p-value
7th PO		8.0 ± 1.3 (n=15)	9.9 ± 1.1 (n=16)	0.282
30th PO		11.4 ± 0.98 (n=15)	12.6 ± 0.82 (n=14)	0.372
60th PO		11.0 ± 0.83 (n=11)	12.0 ± 0.69 (n=12)	0.369
90th PO		11.0 ± 0.90 (n=8)	11.6 ± 0.75 (n=12)	0.615
120th PO		12.4 ± 0.80 (n=7)	12.0 ± 0.67 (n=10)	0.688

Table 7: Mean ± standard error of ISG Global for the cheek according to time and group (PO refers to postoperative days).

Time	Group	FBM	Control	p-value
7th PO		9.0 ± 1.3 (n=15)	10.8 ± 1.1 (n=16)	0.297
30th PO		11.8 ± 0.79 (n=15)	12.4 ± 0.66 (n=14)	0.605
60th PO		10.4 ± 0.75 (n=11)	11.8 ± 0.63 (n=12)	0.182
90th PO		10.8 ± 0.88 (n=8)	11.4 ± 0.74 (n=12)	0.643
120th PO		12.6 ± 0.80 (n=7)	11.9 ± 0.67 (n=10)	0.528

Table 8: Mean ± standard error of ISG Global for the nasal alar according to time and group (PO refers to postoperative days).

Time	Group	FBM	Control	p-value
7th PO		8.1 ± 1.2 (n=15)	10.7 ± 1.0 (n=16)	0.127
30th PO		12.0 ± 0.80 (n=15)	11.9 ± 0.70 (n=14)	0.928
60th PO		10.7 ± 0.73 (n=11)	12.1 ± 0.61 (n=12)	0.167
90th PO		10.8 ± 0.75 (n=8)	11.6 ± 0.63 (n=12)	0.460
120th PO		12.3 ± 0.69 (n=7)	11.4 ± 0.58 (n=10)	0.340

Table 9: Mean ± standard error of ISG Global for the upper lip according to time and group (PO refers to postoperative days).

Time	Group	FBM	Control	p-value
7th PO		7.6 ± 1.1 (n=15)	10.7 ± 0.94 (n=16)	0.051
30th PO		11.7 ± 0.87 (n=15)	12.2 ± 0.73 (n=14)	0.674
60th PO		10.0 ± 0.64 (n=11)	12.1 ± 0.54 (n=12)	0.024*
90th PO		9.7 ± 0.91 (n=8)	12.1 ± 0.76 (n=12)	0.062
120th PO		11.8 ± 0.67 (n=7)	12.1 ± 0.56 (n=10)	0.786

The asterisk (*) indicates statistical significance

Table 10: Mean ± standard error of ISG Global for the vestibular mucosa according to time and group(PO refers to postoperative days).

Time	Group	FBM	Control	p-value
7th PO		3.3 ± 1.0 (n=15)	4.2 ± 0.86 (n=16)	0.506
30th PO		6.4 ± 2.0 (n=15)	7.1 ± 1.6 (n=14)	0.798
60th PO		5.4 ± 1.4 (n=11)	5.5 ± 1.2 (n=12)	0.970
90th PO		7.6 ± 1.5 (n=8)	7.8 ± 1.3 (n=12)	0.911
120th PO		7.7 ± 1.3 (n=7)	9.8 ± 1.1 (n=10)	0.242

Table 11: Mean ± standard error of ISG Global for the palatine mucosa according to time and group (PO refers to postoperative days).

Time	Group	FBM	Control	p-value
7th PO		5.8 ± 1.5 (n=15)	9.5 ± 1.22 (n=16)	0.075
30th PO		11.7 ± 1.1 (n=15)	11.2 ± 0.94 (n=14)	0.731
60th PO		10.0 ± 0.90 (n=11)	11.3 ± 0.75 (n=12)	0.283
90th PO		8.7 ± 1.4 (n=8)	11.0 ± 1.2 (n=12)	0.229
120th PO		11.1 ± 1.0 (n=7)	10.8 ± 0.85 (n=10)	0.799

Table 12 presents the sum of the GSI values across different anatomical regions. No significant differences in GSI were observed between groups at any experimental time points

Table 12: Mean ± standard error of the Global Sensitivity Index (GSI) for the sum of areas according to time and group (PO refers to postoperative days)

Time	Group	FBM	Control	p-value
7th PO		41.8 ± 5.9 (n=15)	55.8 ± 4.9 (n=16)	0.091
30th PO		65.1 ± 4.6 (n=15)	67.4 ± 3.8 (n=14)	0.712
60th PO		57.6 ± 3.4 (n=11)	64.8 ± 2.8 (n=12)	0.123
90th PO		58.7 ± 4.6 (n=8)	65.5 ± 3.8 (n=12)	0.271
120th PO		68.0 ± 4.2 (n=7)	68.0 ± 3.5 (n=10)	1.000

Discussion

In the examined sample, the two groups did not differ significantly regarding the assessed demographic characteristics.

In the assessment of pain using the NRS-101 scale, it was observed that the mean pain level in the control group was greater than that in the FBM group until the 14th day; however, this difference did not reach statistical significance. Similarly, there was no significant variation in the number of participants reporting pain between the groups. No studies were found comparing pain following SARME with the use of photonic therapies. The study by Gasperini et al. (2014), which evaluated the effect of laser therapy on pain after orthognathic surgery, reported that pain intensity was

lower on the irradiated side within 24 hours post-surgery (1.2 PBM vs. 3.4 control) and after three days (0.6 PBM vs. 2.1 control), although no pain was reported on either side seven days post-surgery. The authors employed red and infrared lasers for intraoral and extraoral applications with an energy output of 1.2 J per point, totaling 21.6 J per application, administered within 72 hours post-surgery, and 2.8 J per point totaling 50.4 J across ten sessions carried out after the fourth day post-surgery (18). In the present study, 2 J per point was applied intraorally and 6 J per point extraorally, with a lesser number of applications, resulting in lower pain intensity even within the first 24 hours and no significant difference between the groups. It is possible that had the planned sample size been achieved and/or had the patients experienced higher pain intensities, a significant difference between the groups might have been demonstrated, thereby highlighting the modulatory effect of PBM.

Regarding edema, throughout the follow-up, the PBM group exhibited a lower mean facial measurement compared to the control group, although this difference was not statistically significant. Considering the total sample, postoperative edema peaked within the first 24 hours, with the cumulative measurements increasing by an average of 4.9 cm, subsequently decreasing after 48 hours, which aligns with the typical pattern for oral surgeries. However, this response was below the expected standard for SARME cases, where edema is generally more pronounced in the initial postoperative days and may persist for three to eight weeks, affecting a larger facial area (19-23). No articles were found that assessed the use of PBM following SARME. Gasperini et al. (2014) reported significant differences favoring the PBM group (a difference of 1.73 cm less in the PBM group's measurements) in edema after orthognathic surgeries using red and infrared laser irradiations with the previously mentioned parameters (18). In this study, 2 J per point were applied intraorally and 6 J per point extraorally, with a lesser number of applications, resulting in an average difference of 1.5 cm between the groups in the immediate postoperative period, although no statistically significant difference was observed. It is believed that significant differences might have been observed had the planned sample size been achieved.

The sensitivity analysis, classified according to scores obtained on the Global Sensitivity Index (GSI), can be considered normal when the score exceeds 12, subnormal when the score ranges from 10 to 12, intermediate when the score ranges from 6 to 9, and reduced when the score is below 6. Tables 8 to 13 demonstrate that the groups did not differ at any of the assessment points for the lower eyelid, cheek, nasolabial fold, vestibular mucosa, and palatine mucosa. A significant difference between the groups was observed only at 60 days for the upper lip, with poorer outcomes in the PBM group, while no significant differences were noted at other assessment points. The sum of the GSI values for the different areas also did not reveal differences between the groups. Neurosensory deficits may persist for 6 to 12 months following SARME surgery (24). In the results obtained in this study, reduced sensitivity was noted in the vestibular and palatine mucosa even at the 120-day mark, whereas deficits in other anatomical areas resolved more rapidly. As previously reported, no articles were found that assessed the use of PBM following SARME for comparative sensitivity analysis.

In this pilot study, the novel application of PBM in SARMEwas explored using intraoral and extraoral LED devices, combining two wavelengths for the extraoral application. Compared to laser equipment, LED devices offer greater practicality for PBM therapy, as they can be applied to larger areas, thereby minimizing application time, and are safe for at-home use (11,12). Since SARME affects both superficial and deeper facial tissues, the use of two wavelengths aims to enhance treatment efficacy (12). Although significant differences between the groups have not yet been identified in the evaluated outcomes, this pilot study suggests that future investigations may incorporate daily PBM applications or other energy parameters to elucidate the modulatory effects of PBM in SARME.

Conclusion

Integrating the presented findings, it can be observed that both pain and edema exhibited mild intensity, with paresthesia resolving within a maximum of 90 days in the majority of the anatomical areas assessed. Although the effects of SARME

were not particularly pronounced and the sample size was small, it was possible to observe that PBM may have a minimizing effect on pain, edema, and paresthesia. These results suggest a potential avenue for future research that involves adjustments in the frequency of application and/or the energetic parameters utilized for photobiomodulation.

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Data availability statement

All data will be available for the readers.

Conflict of interest disclosure

All authors disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) this study.

Ethics approval statement

This study was approved by the Research Ethics Committee of Nove de Julho University (03645518030015511) and the Mandaqui Hospital Complex (03645518000005551).

Patient Consent Statement

The participants signed an Informed consent.

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Clinical trial registration

This trial was registered on the Clinical Trials platform (https://clinicaltrials.gov/) under the number NCT03814525 and published (11).