## **Original Article**

## Three-Dimensional Evaluation of the Effect of Low-Level Laser Therapy on Facial Swelling after Lower Third Molar Surgery: A Randomized, Placebo-Controlled Study

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**Purpose:** This study aimed to evaluate the effect of a low-level laser therapy (LLLT) on pain, trismus, and swelling of patients whose impacted 3<sup>rd</sup> molar tooth was extracted compared to placebo or "sham" treatment and measure volumetrically the edema with a three-dimensional (3D) surface imaging device (3dMD face system). Materials and Methods: Forty-five patients over 17 years of age were included in the study. Patients were randomized to three groups; Group 1, the control group, received only routine management (ice application) (n = 15); Group 2, received single-dose LLLT immediately after surgery (n = 15); and Group 3, placebo group, received sham therapy immediately after surgery (n = 15). In this study, a gallium-aluminum-arsenide diode laser device was used. The laser was applied extraorally (0.3 W, 40 s, 4 J/cm<sup>2</sup>). The trismus, pain, and facial swelling were evaluated. A 3D surface imaging device (3dMD Photogrammetric System) was used to evaluate the volumetric changes of the swelling. The 3D morphology of the facial swelling was recorded using this imaging device immediately before surgery, the second day after surgery, and the 7th day after surgery. IBM SPSS statistics 22.0 program was used in the statistical assessment and P < 0.05 was considered statistically significant. Results: There was no statistically significant difference in the edema and trismus between the groups. The pain level in Group 2 was significantly lower than that in Group 3 at all-time points. Furthermore, the pain level in Group 2 was significantly lower than that in Group 1 on day 7. **Conclusions:** LLLT reduced the intensity of pain following third molar surgery by single dose. The results of this study revealed that LLLT reduced facial swelling, but no significant differences were found among the three groups. In addition, a 3D craniomaxillofacial imaging method provided insight into volume changes after 3<sup>rd</sup> molar surgery and the evaluation of facial swelling in an objective way.

**KEYWORDS:** 3dMD, low-level laser therapy, mandibular third molar surgery,

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### INTRODUCTION

The extraction of an impacted third molar is one of the most frequent procedures in oral and maxillofacial surgery and can lead to immediate postoperative pain, swelling, and restricted mouth opening due to muscle spasm.<sup>[1]</sup> It is a significant deterioration in oral health-related quality of life. Also economically, much fund is being spent on analgesics and antibiotics to reduce the postoperative morbidities.<sup>[2]</sup>

pain, swelling

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To prevent or reduce these complications, many studies have investigated the use of various drugs, biological

factors, surgical techniques, and laser therapies.<sup>[2-6]</sup>

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Craniomaxillofacial imaging plays a significant role in clinical examinations. Three-dimensional (3D) imaging devices and techniques are an important part of this. 3D imaging techniques can be broadly categorized as laser scanning, stereophotogrammetry, structured light techniques, and cone beam computed tomography scans. External soft tissues of the craniomaxillofacial regions can be recorded appropriately owing to these technologies.<sup>[12]</sup> The 3dMD face system (3dMD, Atlanta, GA) is an advanced stereophotogrammetry system which uses multiple cameras to capture an 180° image of a person's face from ear to ear in only 1.5 ms. Traditional methods have limitations for investigating craniomaxillofacial changes, but the 3dMD imaging system provides faster, noninvasive, and more accurate data, stored in digital format.<sup>[13]</sup> This 3dMD system has been applied in several studies such as variation in facial morphology,<sup>[14]</sup> assessment of facial anomalies,<sup>[15,16]</sup> changes in lip morphology following correction of functional anterior crossbite,<sup>[17]</sup> changes in facial soft tissues that occur after use of different rapid maxillary expansion appliances,<sup>[18]</sup> and assessment of nasolabial appearance in patients with complete unilateral cleft lip and palate.<sup>[19]</sup> To the best of our knowledge, up to date, the effect of LLLT on swelling has not been assessed with 3dMD imaging system except for our previous study.<sup>[20]</sup>

There are many studies which use LLLT in mandibular third molar extraction and had shown different and controversial results in pain, swelling, and trismus scores.<sup>[8-11,20-22]</sup> Our first objective was to determine whether LLLT reduces the morbidities of third molar surgery as compared to placebo and to contribute to literature associated with that ambiguous topic. Second, we aimed to determine objectively the effects of LLLT on facial swelling in three dimensions using a 3dMD imaging system.

#### **MATERIALS AND METHODS**

#### Patients and study design

The present prospective, single-center, randomized, double-blind pilot study was conducted on patients

recruited who required third molar extraction. This study was approved by the Human Ethics Committee and was performed in accordance with the Declaration of Helsinki.

A total of 45 healthy patients with a single impacted mandibular third molar in similar positions (Class II-III and position B, Pell and Gregory's classification)<sup>[23]</sup> along with the same degree of surgical difficulty were enrolled into the study. Patients were randomized into three treatment groups (n = 15); Group 1, the control group, received only routine management (ice application); Group 2, laser group, received single-dose LLLT immediately after surgery; and Group 3, sham group (negative control group), received sham LLLT immediately after surgery. Sample allocation was done by simple randomization. All subjects were informed of the risks of oral surgery and experimental treatment, and informed written consent was obtained from all patients and to participate in the clinical trial.

The 45 patients meeting the inclusion criteria had the following characteristics: male or female gender, healthy, asymptomatic, had no systemic disease, completely bone-impacted mesioangular lower third molars, and surgical difficulty Grades II to III. Exclusion criteria included contraindications to laser therapy, systemic disease, local infection, cigarette or tobacco use, penicillin/paracetamol/chlorhexidine allergy, oral contraceptives' use, pregnancy, lactation, and asymmetric or semi-impacted third molars.

#### Surgical procedure

All the operations were performed by the same surgeons using a standardized procedure: local anesthesia with 40 mg/mL of articaine (Ultracain<sup>®</sup>, Sanofi Aventis, Topkapı, Istanbul, Turkey) associated with 1:200,000 epinephrine was administered. A full-thickness three-cornered mucoperiosteal flap was raised, and bone removal and/ or tooth sectioning was performed. Lower third molars were extracted using round and fissure burrs under saline irrigation. The mucoperiosteal flap was repositioned and the surgical wound was closed using a 4-0 silk suture. The duration of the surgical procedure was noted.

After surgery, all patients were prescribed 1000 mg amoxicillin-clavulanic acid (2 times/1 day) and 500 mg paracetamol orally (2 times/1 day) and a 0.2% chlorhexidine mouth rinse (1 min, 3 times/1 day) for 1 week.

#### Laser therapy

A gallium-aluminum-arsenide (GaAlAs) diode laser device (CHEESE Dental Laser System, Wuhan Gigaa Optronics Technology Company, China) with a continuous wavelength of 810 nm was used, and laser therapy was applied extraorally at the insertion point of the masseter muscle using a 600- $\mu$ m handpiece. LLLT was performed on all patients of Group 2 and Group 3 by a different operator; measurements (mouth opening and swelling) were performed by another operator who was blinded to patient allocation. Parameters of the LLLT are summarized in Table 1.

#### **Postoperative evaluations**

A 10-cm Visual Analog Scale (VAS) ranging from 0 (absence of pain or discomfort) to 10 (maximum pain or discomfort) was used to evaluate postoperative pain intensity. The patient who received an explanation about how to measure pain intensity marked the scale to score the degree of pain with a number between 0 and 10 at 2 and 7 days after surgery.

Mouth opening was recorded by measurement of the maximal distance between the inter-incisor opening using manual calipers before the surgical procedure and  $2^{nd}$  and  $7^{th}$  days postextraction.

#### **3dMD evaluations**

Three-dimensional photographic images were captured by the 3D (3dMD Face<sup>®</sup>, Atlanta, GA) Photogrammetric System. The 3dMD system uses a synchronized digital multicamera configuration, with three cameras on each side (one color, two infrared) that capture photo-realistic quality pictures. The distance (patient to camera) was standardized to the duration of the study. The system can capture 180° facial images from ear to ear. 3D images were loaded in the 3dMD software 3dMD Vultus (3dMD, Atlanta, GA). T<sub>0</sub> and T<sub>1</sub> images were opened and superimposed on the forehead and bridge of nose as suggested by the manufacturer. The forehead and the bridge of the nose were not affected by swelling. After superimposition, the swelling was calculated by selecting the area of the swelling and subtracting the two images. A preoperative 3dMD image was taken immediately before surgery for comparison with the postoperative appearance. Postoperative 3dMD images were taken on the 2<sup>nd</sup> and 7<sup>th</sup> days [Figures 1 and 2].

#### **Statistical analysis**

The recorded data were analyzed using the SPSS 22.0 software (IBM SPSS, Istanbul, Turkey). The Shapiro–Wilk test was used to test for normal distribution of data of individual parameters. Differences in individual parameters among the groups were tested using the Tukey's honest significant difference test for normally distributed variables (trismus) and the Mann–Whitney U-test for abnormally distributed variables (swelling and pain). Kruskal–Wallis test was used to assess if a statistically significant relationship existed between two categorical variables. Wilcoxon signed-rank test was used

for intragroup evaluations for VAS and edema. Variance analysis was used for repetitive measures in the intragroup evaluations for the mouth openness, and Bonferroni test was used for the *post hoc* evaluations. Chi-square test was used for the comparison of qualitative data. P < 0.05 was considered statistically significant.

#### RESULTS

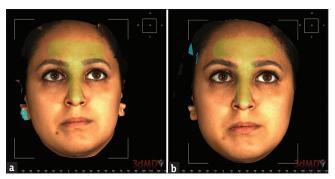
Twenty-five (55.6%) women and 20 (44.4%) men, aged between 17 and 29 years, were studied on a total of 45 cases. The mean age of the cases was  $21.11 \pm 4.15$  years. The cases were examined under three groups of 15 persons each. The mean operation time was  $15.27 \pm 5.85$  min in Group 1,  $14.03 \pm 3.77$  min in Group 2, and  $15.33 \pm 2.06$  min in Group 3. There was no statistically significant difference

#### Table 1: Parameters of the laser therapy performed in the current study

the current study			
Parameter	Value		
Wavelength	810 nm		
Beam area	$3 \text{ cm}^2$		
Output power	0.3 W		
Irradiation time	40 s		
Energy density	4 J/cm <sup>2</sup>		
Energy delivered	12 J		
Pulse rate	Continuous		
Application	Noncontact		

Table 2: Patient demographics and duration of surgery					
	Group 1	Group 2	Group 3	Р	
Age (mean±SD)	22.4±5.35	18.47±1.30	22.47±3.54	0.008*,a	
Duration of surgery (min) (mean±SD)	15.27±5.85	14.03±3.77	15.33±2.06	0.962ª	
Gender, <i>n</i> (%)					
Female	9 (60)	8 (53.3)	8 (53.3)	0.914 <sup>b</sup>	
Male	6 (40)	7 (46.7)	7 (46.7)		

<sup>a</sup>One-way ANOVA test, <sup>b</sup>Chi-square test, \**P*<0.05. Data are presented as the number of patients (%) or as the mean±SD. SD=Standard deviation



**Figure 1:** (a) Preoperative 3dMD image and (b) postoperative 3dMD image on day 2 after surgery

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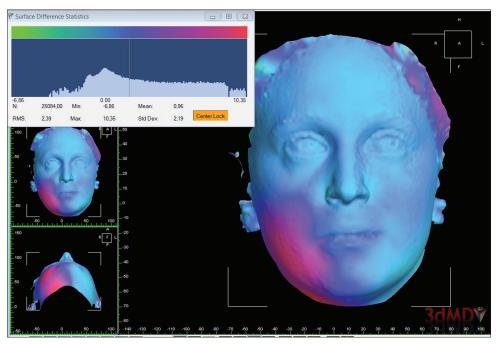


Figure 2: Histogram image obtained by superimposing two photographs (preoperative and postoperative 2<sup>nd</sup> day). Pink-shaded regions in the three-dimensional histograms define the regions of volume increase, while blue-shaded regions in the histograms define the areas of volume decrease

Table 3: Evaluation of the 2 <sup>nd</sup> and 7 <sup>th</sup> days' edema difference according to groups					
Edema differences	Mean±SD (median)				
	Group 1	Group 2	Group 3		
T0–T2 superimposition	20.33±11.85 (19.6)	15.47±5.41 (15.4)	18.91±10.99 (18.9)	0.385	
T0–T7 superimposition	6.56±8.16 (5.5)	2.31±1.81 (1.6)	4.21±3.26 (3.9)	0.396	
Pb	0.001*	0.001*	0.001*		

<sup>a</sup>Kruskal–Wallis test, <sup>b</sup>Wilcoxon signed-rank test, \*P<0.05. T0: Preoperative day 0, T2: Postoperative 2<sup>nd</sup> day, T7: Postoperative 7<sup>th</sup> day, SD=Standard deviation

Table 4: Evaluation of preoperative and 2 <sup>nd</sup> and 7 <sup>th</sup> days'mouth opening difference according to groups				
Mouth	Mean±SD (median)			Pa
opening	Group 1	Group 2	Group 3	
Preoperative	44.07±5.96	43.33±6.86	45.53±3.87	0.565
2 <sup>nd</sup> day	26.8±4.57	31.13±10.73	32.6±5.91	0.104
7 <sup>th</sup> day	37.2±6.92	37.07±9.67	41.07±4.44	0.248

0.001\*

<sup>a</sup>One-way ANOVA test, <sup>b</sup>Repeated-measures ANOVA, \**P*<0.05. SD=Standard deviation

0.001\*

 $\mathbf{p}b$ 

 Table 5: Evaluation of 2<sup>nd</sup> and 7<sup>th</sup> days' Visual Analog

 Scale values of pain level difference according to groups

 VAS
 Mean±SD (median)
 P<sup>a</sup>

	Group 1	Group 2	Group 3	
2 <sup>nd</sup> day	4.13±1.96 (4)	3.4±1.92 (3)	5.47±1.92 (5)	0.019*
7 <sup>th</sup> day	2.07±1.39 (2)	0.6±1.24 (0)	1.73±1.83 (1)	0.010*
$P^{\mathrm{b}}$	0.007*	0.001*	0.001*	

<sup>a</sup>Kruskal–Wallis test, <sup>b</sup>Wilcoxon signed-rank test, \*P<0.05. VAS=Visual analog Scale; SD=Standard deviation

between the groups in terms of mean duration of operation (P > 0.05) [Table 2].

Statistical analyses showed no significance in the differences between all groups for the edema and trismus results (P > 0.05). However, laser group had the lowest scores [Tables 3 and 4].

Regarding VAS scores, there was a significant difference only between laser and sham groups on postoperative day 2. At the 7<sup>th</sup> postoperative day, pain in the laser group was significantly less than that in the sham and control groups (P < 0.05); however, on day 7, the values were similar in the sham and control groups (P > 0.05) [Table 5].

#### **D**ISCUSSION

The mandibular third molar surgical extraction is often related to severe postoperative discomforts. Previously, Oikarinen<sup>[24]</sup> suggested that there may be a close relation between postoperative morbidities and operation time. In the present study, there was no difference between the groups in terms of operation time.

Preventive strategies for the management of postoperative morbidities of third molar surgery include

0.001\*

the use of local or systemic corticosteroids, nonsteroidal anti-inflammatory drugs, different flap techniques, and nonmedication methods such as compression, cryotherapy, ozone therapy, and LLLT.<sup>[2-6]</sup> Since some medications have side effects, we thought that a new nonmedication and comfortable treatment model is necessary. LLLT has been shown to modulate the inflammatory process without adverse effects. Thus, in the present study, the efficacy of LLLT was investigated in regard to pain, swelling, and trismus following mandibular third molar surgery.

In the last few decades, there has been a growing interest in investigating the physiological effects of LLLT and its various clinical applications in different medical and dental specialties. Since the LLLT has the ability to accelerate the regeneration of lymph vessels, decrease vascular permeability, and reduce hemorrhage, neutrophil infiltration, inflammatory cytokines, and enzymes, it may have a positive effect on postoperative morbidities of third molar surgery.<sup>[25-28]</sup> Many studies exist regarding the effect of LLLT on the morbidities of third molar surgery and have reported conflicting results.<sup>[8-11,20-22]</sup> These conflicting results may be due to difficulties in the measurement of variables related to postoperative sequelae, differences in study design or methods, differences in types of lasers and handpieces used, and differences in irradiation parameters.<sup>[3,8]</sup>

Some authors applied LLLT only extraorally<sup>[2]</sup> or only intraorally,<sup>[8,11,29-31]</sup> whereas a number of clinical trials have performed both extraorally and intraorally.<sup>[8,9,22,32]</sup> Aras and Güngörmüş<sup>[9]</sup> have reported that extraoral application of LLLT is more effective than intraoral use for the reduction of postoperative trismus and swelling. It may be that the extraoral laser application could directly have an effect on the masseter muscle. Oral surgery might cause spasm of some muscles, especially the masseter. However, intraoral laser therapy does not directly affect the masseter muscle. Therefore, in the current study, the LLLT was used extraorally.

There are many types of LLLT devices and these devices have different wavelength and doses. Ferrante *et al.*,<sup>[8]</sup> Aras and Güngörmüş,<sup>[9]</sup> Marković and Todorović,<sup>[29]</sup> and Kazancioglu *et al.*<sup>[2]</sup> reported beneficial results and they have applied values of "980-nm, 54 J," "808-nm, 12 J," "637-nm, 4 J/cm<sup>2</sup>," and "808-nm, 12 J," respectively. On the other side, López-Ramírez *et al.*<sup>[11]</sup> and Amarillas-Escobar *et al.*<sup>[22]</sup> reported inefficient results and they have used values of "810-nm, 5 J/cm<sup>2</sup>" and "810-nm, 4 J/cm<sup>2</sup>," respectively. It seems that there is no correlation between wavelength, doses, and success of LLLT therapy. However, there is no evidence of the effect of different doses on postoperative morbidities of third molar surgery.

The effect of LLLT on postoperative morbidities of third molar surgery is controversial. Ferrante *et al.*,<sup>[8]</sup> Kazancioglu *et al.*,<sup>[2]</sup> Aras and Güngörmüş,<sup>[32]</sup> and Marković and Todorović<sup>[29]</sup> reported that LLLT can reduce postoperative pain after mandibular third molar surgery, which is consistent with the findings of the current study. However, according to clinical studies by Escobar *et al.*<sup>[22]</sup> and López-Ramírez *et al.*,<sup>[11]</sup> there was no positive effect on pain with LLLT. The difference in the pain scores between the current study and that of Kazancioglu *et al.*<sup>[21]</sup> may be due to the sample of the studies, different flap technique, or difficulty levels of surgeries.

Mandibular third molar surgery may cause spasm of some muscles, especially masseter (trismus). To evaluate trismus, the maximum mouth opening was measured with manual calipers. According to the findings of the current study, there was no statistically significant difference between the trismus scores of the three groups, which is similar to the findings of López-Ramírez *et al.*<sup>[11]</sup> and Røynesdal *et al.*<sup>[33]</sup> However, Carrillo *et al.*<sup>[30]</sup> and Aras and Güngörmüş<sup>[9]</sup> reported that LLLT had positive effects on trismus.

Ferrante et al.,<sup>[8]</sup> Kazancioglu et al.,<sup>[2]</sup> and Aras and Güngörmüş<sup>[32]</sup> reported that facial swelling can be reduced with LLLT therapy. However, the results of the current study are not consistent with that conclusion. The current findings are supported by those of Carrillo et al.<sup>[30]</sup> who reported no statistically significant difference in swelling between study and placebo groups. Several techniques have been used to measure postoperative swelling including verbal response scales, mechanical (cephalostat, calipers, etc.), ultrasound, methods photographic techniques, computed tomography, and magnetic resonance imaging.<sup>[34-37]</sup> We used 3dMD face imaging system to evaluate postoperative swelling because 3dMD system measures changes in soft tissue three dimensionally and provides photo-realistic views and objective evaluation.[38,39]

Lack of evidences associated with different doses and application type (extraoral/intraoral) of LLLT on the postoperative indications to minimize pain, swelling, and trismus after surgical removal of mandibular third molar is the limitation of the present study.

#### CONCLUSIONS

This study has demonstrated that there is not enough evidence for considering LLLT therapy to be a useful and efficient treatment for the reduction of postoperative morbidities of mandibular third molar surgery. However, it was observed that single-dose LLLT reduced the intensity of pain following third molar surgery. The results of this study revealed that LLLT reduced facial swelling, but no significant differences were found among the three groups. The improvement of tools, methodology, and treatment plans is necessary to achieve this goal. In addition, a 3D craniomaxillofacial imaging method provided insight into volume changes after third molar surgery and the evaluation of facial swelling in an objective way.

#### **Declaration of patient consent**

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/ her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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#### **Conflicts of interest**

There are no conflicts of interest.

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