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ORIGINAL ARTICLE

Effect of low-level laser therapy on condylar growth in children treated with functional appliance: a preliminary study

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Abstract

Purpose This study aimed to evaluate the skeletal and dentoalveolar changes achieved by combining low-level laser irradiation applied on the condyle area with twin-block therapy in growing class II malocclusion patients.

Methods Fourteen patients (9 males, 5 females; mean age, 11.4 ± 2 years) with skeletal class II mandibular deficiency were recruited. They were divided into two groups (G 1: twin-block + low-level laser therapy, G 2: twin-block only). A semiconductor diode laser with a wavelength of 940 nm was applied on the condyle area (100 mW, 2.5 J, 3.9 J/cm^2). The laser was applied twice a week in the first month and once a week in the second and third months, totalizing 16 sessions. Skeletal, dental, and soft-tissue cephalometric parameters were measured and compared at different treatment points.

Results Mandibular length (Co-Gn) was significantly increased by 3.6 mm in the experiment group (3.16 SD) and 4.3 mm (4.4 SD) in the control group, with no significant difference between groups at every time point (*P*-value 0.949 at T2). Similarly, a statistically significant positive effect of treatment was found in both groups on ramus height (Co-Go), upper lip to E-Line, SNA angle, ANB angle, and U1/SN angle with no significant difference between groups.

Conclusion Based on the results of this preliminary study, low-level laser irradiation with the used parameters seems to have no synergetic impact on the skeletal and dental outcomes of twin-block therapy over 9 months. However, more studies are needed to investigate the effect of low-level laser therapy on condylar growth during functional orthodontic treatment.

Keywords Low-level light therapy · Mandibular condyle · Orthodontic appliances · Functional · Retrognathia

Introduction

Class II malocclusion was found to be the second most prevalent malocclusion in mixed and permanent dentitions [1]. The most consistent etiological factor in class II malocclusion is mandibular deficiency. Growing children with underdeveloped mandibles can have severe psychological and social impacts. It also can lead to life-threatening complications due to severe airway constriction, as seen in non-positional obstructive sleep apnea [2].

A therapy able to enhance mandibular growth is indicated in these patients. A variety of functional appliances aimed to stimulate mandibular growth by forward posturing the mandible is available to correct this skeletal and occlusal disharmony. The mandibular condyles have a significant role in the development and growth of the mandible. Accordingly, deficient growth of the condyles may result in mandibular retrognathia. One of the significant roles of functional appliances during the mandibular advancement process is to increase condylar cellular activity. Such activity

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is characterized by increasing the thickness of cartilage on the posterior aspect of the condyle, leading to an increase in total mandibular length [3].

Lasers have gained popularity in most dentistry fields for many years and have recently been widely used in orthodontic practice. Dental lasers can be categorized as soft and hard tissue lasers according to their applicability to tissues. Soft lasers can be used in a nonsurgical mode for biostimulation, rapid wound healing, and pain relief. At the same time, soft lasers can be termed low-level laser therapy (LLLT) [4].

The LLLT, currently called photobiomodulation therapy (PBMT) due to its photochemical effect, in which light is absorbed, promotes a chemical change known as photobiostimulation, which influences cellular activities, including the release of several growth factors responsible for the formation of epithelial cells, fibroblasts, collagen, and vascular proliferation [5].

Based on the stimulatory effects of the low-level laser therapy and the role of the mandibular condyle in the growth of the mandible, it has been hypothesized that applying low-level laser on condyle will stimulate mandibular growth and increase mandibular length subsequently.

Material and methods

Study design

This trial was a two parallel-group randomized, blinded controlled trial with a (1:1) allocation ratio. Ethical approval was obtained from the Research Ethics Committee, Faculty of Dentistry, Suez Canal University, Ismailia, Egypt (number 111/2018). The study flow chart is shown in (Fig. 1).

Sample size calculation

Based on the study of Mills et al. [6], the aid of IBM™ SPSS™ Sample Power™ Version 3.0.1 sample size calculation was achieved. With a total sample size of 14 (7 for each group), the study had the power of 73.6% to yield a statistically significant result. This computation assumes that the mean difference is 1.60 (corresponding to means of 1.90 versus 0.30). The common within-group standard deviation is 1.06 (based on SD estimates of 1.20 and 0.90) for a significance level of 5%.

Participants, eligibility criteria, and settings

Participants were recruited from the outpatient clinic, Faculty of Dentistry, Suez Canal University, from 5\2019 to 3\2020. The intervention was carried out by one operator (Mohamed E. Amer). The inclusion criteria were (1) subjects ranging in age between 9.5 to 14 years old, (2) skeletal class II cases where ANB angle is greater than 5° with a mandibular deficiency that the SNB angle is less than 76°, (3) growing patients with cervical vertebrae maturation stage at CS3 or CS4, and (4) subjects should be free from any systemic disease. Patients who had previous orthodontic and/or craniofacial surgical interventions were excluded.

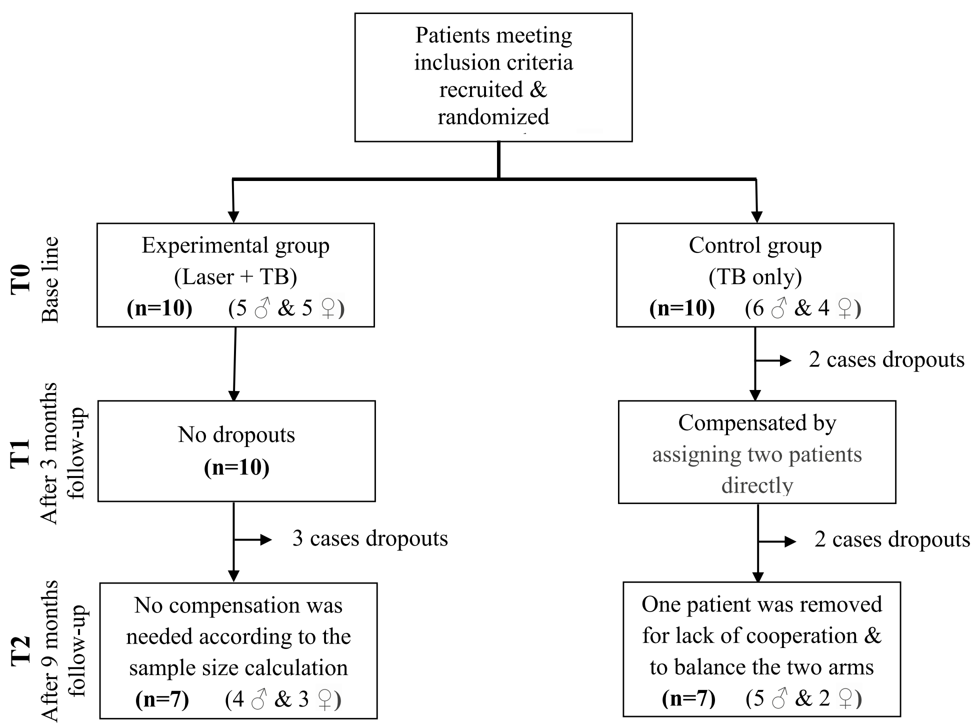

Fig. 1 Study flow chart

Randomization (random number generation, allocation concealment, implementation)

Twenty patients were included in this study to compensate for dropouts during the study. Patients were equally distributed into laser and non-laser groups (10 patients in each group). Randomization has been done using an excel sheet[1] through the Excel RAND function to assign every patient number in laser group or non-laser group through the following steps. Microsoft Excel sheet was created and used for the randomization process. Then, in the 1st column, numbers from 1 to 20 were written, representing the 20 patients included in this study. In the 2nd column, the laser and non-laser groups were equally assigned for ten numbers each: first ten samples as laser and the next ten as non-laser. In the 3rd column, a randomization formula had been added, which is between 0 and 1. A function called "RAND" had been inserted in the 1st row of the 3rd column. Accordingly, Excel has added a random number to the cell. Random numbers had been added to the entire column. After that, a filter was added to column 2 and column 3 as we wanted to randomize column two. Then, column 3 content has been sorted smallest to largest from the filter function to randomize it. Finally, all the contents in column 2 were randomized, and all patient numbers were randomized to either laser or non-laser groups.

During recruitment of patients, every patient was allocated in a group according to his number in the Excel sheet without concern to the dropouts. After recruiting 20 patients, every group strictly consisted of 7 patients according to the sample size calculation. More than three dropouts in each group were compensated by assigning a patient directly to the incomplete group.

Blinding

Due to the nature of the intervention, it was impossible to blind the operator during the study because the intervention included applying low-level laser therapy on the condyle by the operator. For this reason, to minimize bias, all cephalometric tracings and measurements were completed by two investigators (M. Salah and A. Kadry), who were blinded to any patient information or group allocation. Moreover, the statistician was also blinded to group allocation.

Cephalometric analysis

Lateral cephalograms were obtained for every patient before the beginning of treatment (T0), after 3 months of beginning treatment (T1), and after 9 months from the beginning of treatment (T2). All cephalometric films were taken by the same machine (Sirona ORTHOPHOS XG 5 DS/Ceph). All the cephalometric radiographs were taken in natural head position. The patients were instructed to stand upright and look straight ahead to a point at eye level on a mirror in front of them [7]. Cephalometric tracing was done on the digital cephalogram with Dolphin imaging software version 11.5.04.36 premium.

Cervical vertebrae maturation was assessed to ensure that patients were still at CS3 or CS4 stage. The assessment was done following Baccetti et al. guidelines [8].

Landmarks used for cephalometric tracing are shown in Table 1 and Fig. 2. The linear and angular measurements are shown in Table 2 and Figs. 3 and 4.

Bite registration

An alginate impression was taken for every patient on the upper and lower arches. Then, a protrusive construction bite was obtained by softened pink wax. The patients were asked to protrude their mandible and close their mouth trying to get the anterior teeth in edge-to-edge relation. This technique allowed an overjet correction up to 10 mm with a single advancement.

Maxillary and mandibular labial frenums were used as a guide to assure that skeletal midlines were adequately aligned and no mandibular shift during protrusive movement. The patients were instructed to practice opening wide and moving the mandible straight and forward to ensure that the lines on the incisors stay adequately aligned. They were trained on these movements until assured they could do it on wax.

Twin-block fabrication

The protrusive construction bite registered the relation between upper and lower arches, and they were mounted on a simple hinge articulator.

The general design of the twin block involved the following:

- Adams clasps on first permanent molars or premolars in both arches (0.7 mm stainless steel)
- Ball-ended clasps on the mandibular incisors (0.7 mm stainless steel)
- A midline screw placed in the upper block to expand the upper arch
- Upper and lower acrylic blocks with inclined planes at 70° to the occlusal plane and at least 5 to 6 mm thick.
- Passive upper labial bow extending from the canine-to-canine tooth (0.7 mm stainless steel).

The twin-block appliance was checked for comfort fit on the delivery appointment, and minor clasps adjustments

[1] Microsoft® Excel ® 2016 MSO (16.0.9226.2114) 32-bit.

Table 1 Landmarks used for cephalometric tracing

Landmark	Definition
S point	Center of sella turcica
Nasion	Most anterior point of the frontonasal suture that joins the nasal part of the frontal bone and the nasal bones
A point	Deepest point on the anterior contour of the maxillary alveolar process
B point	Deepest point on the outer contour of the mandible
Pogonion	Most anterior point of the bony chin
Menton	Most inferior point of the outline of the symphysis
Gnathion	Most anterior and inferior point of the bony outline of the chin, situated equidistant from pogonion and menton
Gonion	Point at the angle of the mandible determined by the intersection of the ramus' posterior border tangent and the lower border of the mandible
Articulare	Point on the intersection between the posterior border of the ramus and lower border of the cranial base
Condylion	Highest point on the head of the condylar process
Porion	Highest point of the opening of the external auditory canal
Orbitale	Lowest point on the lower margin of the orbit
SN line	Connecting line between point sella (S) and nasion (N)
Frankfort horizontal plane	Plane connecting porion with orbitale

were made. All the patients were instructed to wear the appliance full time except for eating and brushing. They were also instructed to turn the upper midline expansion screw once a week (0.2 mm) until the necessary transverse expansion was achieved [9]

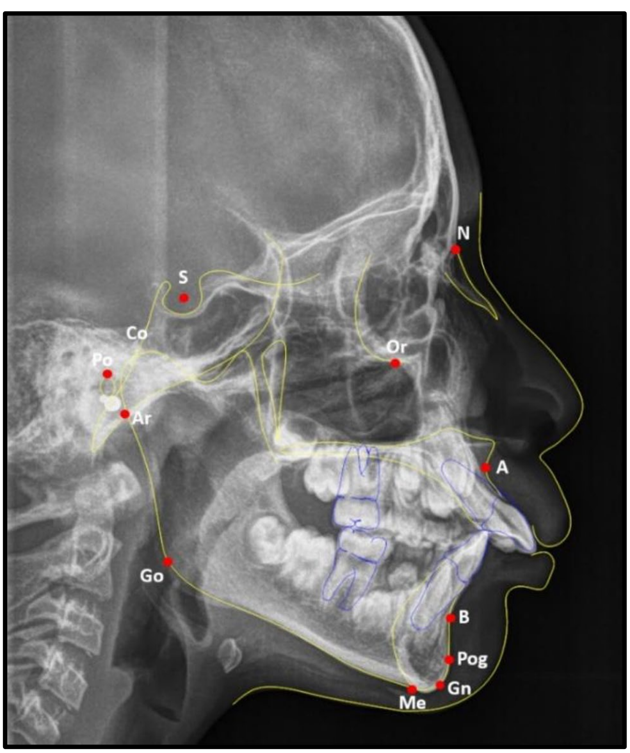

Fig. 2 Landmarks used for cephalometric tracing

- **Laser application protocol**

For the laser group, the following protocol was used.

- Laser radiation was done by a semiconductor diode laser near-infrared 940 nm (EPIC X™ by BIOLASE®, USA). The deep tissue handpiece by BIOLASE® was used for laser delivery with a laser beam diameter of 9 mm with an irradiation area of 0.635 cm^2.
- The following laser parameters and settings were used: power (100 mW), irradiation time (25 s), energy (2.5 J), energy density (3.937 J/cm^2), in contact mode [10].
- The points of laser application were marked on the skin according to the method suggested by Laskin [11]. A line was drawn from lateral canthus of the eye to the tragus of the ear, and the point was placed 2 mm below this line and 10 mm forward of the midtragus.
- The laser application was done with the twin block in mouth and the patient was asked to close his mouth while upper and lower inclined planes are in touch.
- The laser was applied twice a week in the first month and once a week in the second and third months, totalizing 16 sessions [12].
- The device tip was protected with plastic wrap according to the biosafety standards. During the laser application, both the operator and the patient were wearing filter glasses (Fig. 5).

Statistical analysis

Intra- and inter-observer reliability was measured using Cronbach's alpha reliability and intra-class correlation coefficients (ICC). Cronbach's alpha reliability coefficient

Table 2 Cephalometric linear and angular measurements

	Measurement	Description
Linear measurements	Mandibular length	Distance between condylion and gnathion
	Ramus height	Distance between articulare and gonion
	Mandibular plane length	Distance between gonion and gnathion
Angular measurements	SNA angle	Angle formed by the intersection of the line nasion-point A with the SN line
	SNB angle	Angle formed by the intersection of the line nasion-point B with the SN line
	ANB angle	The included angle between point a, nasion, and point B
	U1/SN	Angle formed by the intersection of the long axis of the upper central incisor and the SN line
	L1/Mp	Angle formed by the intersection of the long axis of the lower central incisor and mandibular plane from gonion to menton
	Gonial angle	The included angle between articulare, gonion, and menton
	Y-axis angle	Angle formed by the intersection of sella-gnathion line with the Frankfort horizontal plane
	Frankfurt/mandibular plane angle	Angle formed by the intersection of Frankfurt horizontal plane and mandibular plane from gonion to menton

normally ranges between 0 and 1. Cronbach's alpha values indicated an excellent agreement 0.980 and 0.965 respectively. When appropriate, data presented as mean, standard deviation (SD), and median (Mdn). Data explored for normality using Kolmogorov–Smirnov and Shapiro–Wilk tests.

Cephalometric measurements showed a parametric distribution. Multiple comparisons were achieved with Bonferroni adjustment for linear and angular measurements. Change in cephalometric measurements showed a nonparametric distribution. So, the Mann–Whitney test was used to compare between different groups. The significance level was set at $P<0.05$.

Statistical analysis was performed with IBM® SPSS® (SPSS Inc., IBM Corporation, Armonk, NY, USA) Statistics Version 26 for Windows.

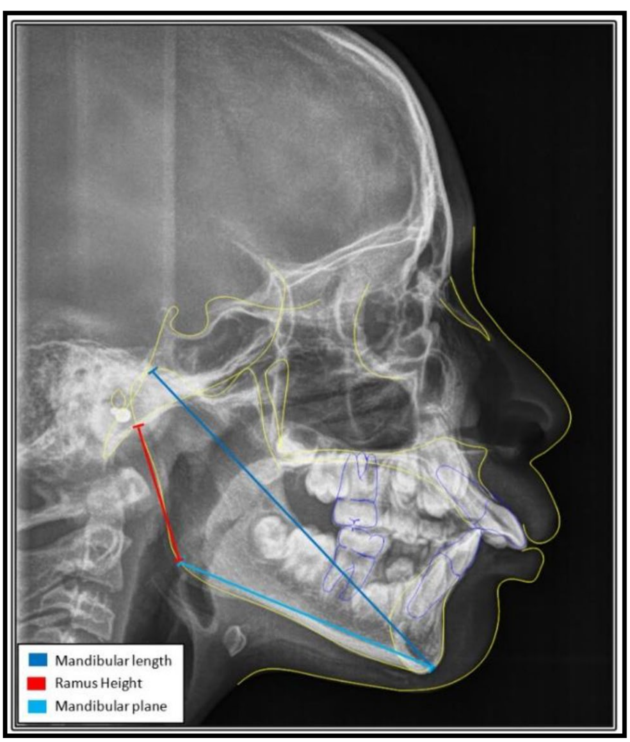

Fig. 3 Linear measurements

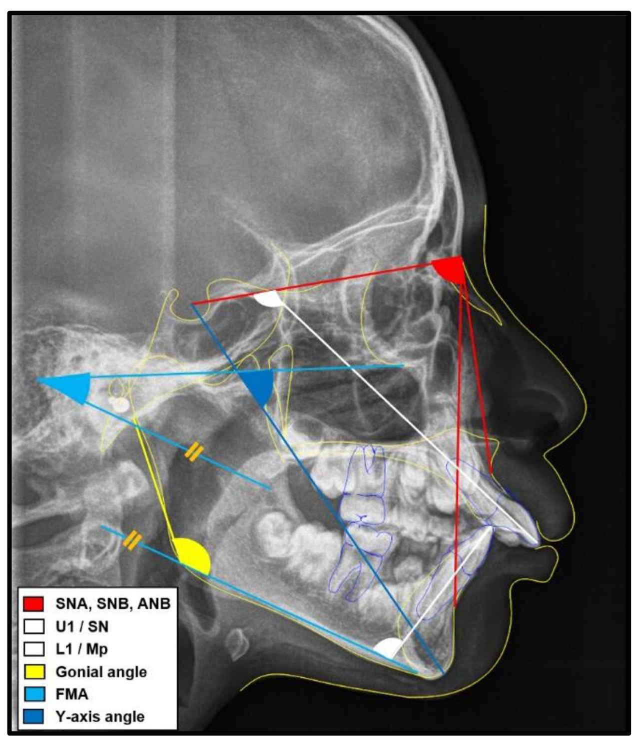

Fig. 4 Angular measurements

Fig. 5 Laser application

Results

Comparison of cephalometric measurements between tested groups at the beginning of treatment

There was an insignificant difference in cephalometric measurements at the beginning of treatment (T0) between both groups except for the *Y*-axis angle (FH/S-Gn), which increased significantly in the laser group compared to the non-laser group (Table 3).

Effect of twin-block with laser application

Different follow-up periods in the laser-treated group showed a significant increase in mandibular length (Co-Gn) and gonial angle (Ar-Go-Me) at T2 compared to the baseline measurement (T0). Also, there was a significant decrease in ANB and U1/SN angles at T2 compared to the baseline measurement (T0) ($p > 0.05$) (Table 4).

Effect of twin-block with no laser application

Different follow-up periods in the non-laser-treated group showed a significant increase in mandibular length (Co-Gn) and ramus height (Ar-Go) at T2 compared to the baseline measurement (T0). Also, there was a significant decrease in ANB angle at T2 compared to the baseline measurement (T0) ($p > 0.05$) (Table 5) (Figs. 3 and 4).

Comparison between the change in cephalometric measurements in the laser and non-laser groups

Change from T0 to T1

Insignificant difference between the change from T0 to T1 in laser and non-laser groups for all the cephalometric measurements ($p > 0.05$) except for Frankfurt/mandibular plane angle (Go-Me) angle (Table 6).

Change from T0 to T2

Insignificant difference between the change from T0 to T2 in laser and non-laser groups for all the cephalometric measurements ($p > 0.05$) (Table 7).

Table 3 Mean and standard deviation for the cephalometric measurements at T0

		Laser		Non-laser		*p*-value
		Mean	SD	Mean	SD	
T0	Mandibular length Co-Gn	104.43	3.77	103.9	6.4	0.85
	Ramus height Ar-Go	37.04	3.49	37.1	3.7	0.983
	Mandibular plane Go-Gn	70.34	3.36	69.3	6.6	0.721
	SNA	81.39	2.86	81.2	5.6	0.929
	SNB	73	2.88	73.9	4.8	0.687
	ANB	8.34	1.45	7.3	1.4	0.199
	U1/SN	107.47	2.76	111.4	5.2	0.106
	L1/mandibular plane (Go-ME)	98.61	6.94	99.5	5.5	0.796
	Gonial angle Ar-Go-Me	126.96	11.5	125.9	6	0.837
	Frankfurt/mandibular plane (Go-Me)	27.63	6.11	23.4	3.3	0.137
	Y-axis angle FH/S-Gn	60.93	3.43	57.1	2.1	0.028*

*The last measurement of Y-axis angle has a significant difference between both groups (p<0.05)

Table 4 Mean and standard deviation for all linear and angular measurements data for laser group

	Cephalometric measurements	Laser group						p-value
		T0		T1		T2		
		Mean	SD	Mean	SD	Mean	SD	
Linear	Mandibular length Co-Gn	104.4_a	3.8	107.3_{ab}	3.9	108.1_b	4.1	0.047*
	Ramus height Ar-Go	37.0	3.5	37.7	3.7	38.1	3.3	0.612
	Mandibular plane Go-Gn	70.3	3.4	70.9	6.1	69.8	4.3	0.766
Angular	SNA	81.4	2.9	80.5	2.5	79.4	2.6	0.083
	SNB	73.0	2.9	73.9	4.0	73.1	3.1	0.234
	ANB	8.3_a	1.4	6.5_b	2.6	6.4_b	1.5	0.029*
	U1/SN	107.5_a	2.8	102.3_b	7.1	102.0_b	5.2	0.046*
	L1/mandibular plane (Go-ME)	98.6	6.9	99.5	7.5	98.1	7.0	0.595
	Gonial angle Ar-Go-Me	127.0_a	11.5	131.4_b	12.5	132.1_b	10.0	0.025*
	Frankfurt/mandibular plane (Go-Me)	27.6	6.1	29.5	6.9	29.3	7.0	0.119
	Y-axis angle FH/S-Gn	60.9	3.4	60.1	3.8	60.0	4.0	0.842

*Significant. Different letters indicate significant differences within each row ($p < 0.05$)

Table 5 Mean and standard deviation for all linear and angular cephalometric measurement data for non-laser group

	Cephalometric measurements	Non-laser group						p-value
		T0		T1		T2		
		Mean	SD	Mean	SD	Mean	SD	
Linear	Mandibular length Co-Gn	103.9_a	6.4	107.5_b	5.3	108.2_b	7.2	0.028*
	Ramus height Ar-Go	37.1_a	3.7	38.9_a	5.9	40.5_b	6.8	0.011*
	Mandibular plane Go-Gn	69.3	6.6	69.5	4.6	71.0	6.0	0.363
Angular	SNA	81.2	5.6	80.5	4.7	80.0	4.4	0.407
	SNB	73.9	4.8	75.0	5.1	74.9	4.3	0.338
	ANB	7.3_a	1.4	5.5_{ab}	1.5	5.0_b	1.6	0.012*
	U1/SN	111.4	5.2	107.9	6.0	105.9	7.9	0.051
	L1/mandibular plane (Go-ME)	99.5	5.5	102.9	7.7	101.9	6.7	0.224
	Gonial angle Ar-Go-Me	125.9	6.0	127.6	5.9	125.5	5.9	0.651
	Frankfurt/mandibular plane (Go-Me)	23.4	3.3	22.2	2.9	22.9	2.8	0.301
	Y-axis angle FH/S-Gn	57.1	2.1	55.6	1.8	57.1	2.8	0.180

*Significant. Different letters indicate significant differences within each row ($p < 0.05$)

Table 6 Median, mean, and standard deviation for the change in all measurements from T0 to T1

		Laser			No llaser			p-value
		Median	Mean	SD	Median	Mean	SD	
Linear	Mandibular length Co-Gn	3.7	2.91	2.34	4.4	3.6	4.1	0.7494
	Ramus height Ar-Go	1.0	0.69	1.72	1.3	1.9	2.6	0.4803
	Mandibular plane Go-Gn	0.9	0.60	5.97	0.4	0.2	4.4	0.8478
Angular	SNA	−0.5	−0.93	2.28	−0.8	−0.7	1.9	0.848
	SNB	1.5	0.91	2.04	1.4	1.1	1.7	0.8981
	ANB	−1.8	−1.80	1.67	−2.1	−1.8	1.8	0.9491
	U1/SN	−4.5	−5.14	6.29	−2.4	−3.5	6.3	0.5224
	L1/mandibular plane (Go-ME)	1.1	0.84	4.37	3.3	3.4	4.9	0.3056
	Gonial angle (Ar-Go-Me)	6.0	4.46	5.78	−0.1	1.6	3.4	0.0845
	Frankfurt/mandibular plane (Go-Me)	2.9	1.91	2.17	−1.2	−1.3	2.1	0.021*
	Y-axis angle FH/S-Gn	0.7	−0.80	5.07	−1.3	−1.5	2.0	0.2774

*$P<0.05$

Table 7 Median, mean, and standard deviation for the change in all measurements from T0 to T2

		Laser			No laser			p-value
		Median	Mean	SD	Median	Mean	SD	
Linear	Mandibular length Co-Gn	4.8	3.63	3.16	4.5	4.3	4.4	0.9491
	Ramus height Ar-Go	1	1.04	1.77	2.6	3.5	3.3	0.2248
	Mandibular plane Go-Gn	0.4	−0.51	3.38	0.8	1.7	3.4	0.4817
Angular	SNA	−1.9	−1.96	2.99	−1.8	−1.2	1.5	0.4803
	SNB	0.6	0.09	2.07	1.6	1.1	1.7	0.37
	ANB	−2.6	−1.96	1.22	−1.4	−2.3	1.9	0.7005
	U1/SN	−3.9	−5.49	4.55	−4.3	−5.5	5.3	0.9491
	L1/mandibular plane (Go-ME)	0.3	−0.50	4.15	2.7	2.4	4.9	0.2248
	Gonial angle (Ar-Go-Me)	3.3	5.17	6.28	−2.4	−0.4	3.3	0.0842
	Frankfurt/mandibular plane (Go-Me)	1.6	1.63	3.62	−0.4	−0.6	1.3	0.1248
	Y-axis angle FH/S-Gn	0.6	−0.89	5.00	−0.1	0.0	2.0	0.7494
	Overjet	−5.20	−5.40	1.36	−5.20	−5.30	2.05	0.848

Discussion

It was found through experimental studies that appliances used to position the mandible anteriorly stimulate significant mandibular growth. This increase is achieved mainly by condylar remodeling [13] and extra elongation in total mandibular length [14]. Twin-block appliance is one of the most commonly used functional appliances clinically because of its excellent results [6, 14–17].

Low-level laser therapy (LLLT) was found to produce stimulatory effects on fibroblastic and chondral proliferation [5]. Evaluation of the effect of low-level laser therapy on condylar growth has been a point of interest for researchers and clinicians in the last few years. Several experimental studies [18–23] have shown that low-level laser irradiation can be used for further improvement of mandibular retrognathism. The current study aimed to evaluate the effect of low-level laser therapy on condylar growth in skeletal class II mandibular deficiency patients treated with twin-block appliances.

Choosing the most appropriate wavelength is crucial when using a laser. Laser penetration of the tissues depends mainly on the wavelength. Infrared laser has a low absorption coefficient in hemoglobin and water and a high penetration depth in the irradiated tissue. A wavelength between 780 and 940 nm presents the deepest penetration, reaching the cortical, alveolar bone tissues and, in our case, able to reach the mandibular condyle. On the other hand, red laser (620 and 670 nm) has weaker penetration, mainly due to the high absorption tendency by the biological tissue; it is therefore indicated for superficial lesions, such as tissue repair (healing and local drainage) [24]. A semiconductor diode laser near-infrared with a wavelength 940 nm was used in the current study. This wavelength was also used in previous experimental studies [25, 26] and clinical studies [10, 27, 28]

Low-level laser therapy effects depend on the total amount of irradiation, frequency, and duration of application. There is a dose-related response; at relatively low doses of laser radiation, there can be photobiostimulation which could be helpful in healing enhancement. On the other hand, at higher levels of laser radiation, photobioinhibition occurs, optimal for pain relief [29]. Laakso et al. [30] recommended that the therapeutic window of laser doses may exist between energy densities of 0.5 J/ cm^2 and 4 J/cm^2. They recommended that doses above these may result in bio-inhibition.

Moreover, Kubasova et al. [31] stated that the saturation of cells towards the biostimulative effects induced by polarized light occurring is at 4 J/cm^2. Cells cannot absorb any more energy above this level. According to these findings, the energy density used in the study was 3.9 J/cm^2 which was calculated from the given parameters: energy density = energy (J) 2.5 J/area (cm^2) 0.635 cm^2. These parameters were used by Sedky et al. [10]. Furthermore, they found a positive effect of low-level laser therapy on RANKL level and bone remodeling during orthodontic tooth movement.

It has reported that the optimum treatment timing for twin-block therapy of class II malocclusion appears to be during or slightly after the onset of the pubertal peak of mandibular growth (between CS3 and CS4) [14, 32]. In the current study, we recruited growing patients aged 9.5 to 14 years old with cervical vertebrae maturation stage at CS3 or CS4. Skeletal age assessment was performed via evaluation of the cervical vertebral maturation method, following the technique of Baccetti et al. [8]. The advantage of this version is that the skeletal maturity can be evaluated on a lateral cephalogram. The cervical vertebrae maturation method analyzes only the second, third, and fourth cervical vertebrae and comprises six maturational stages (CS1 to CS6).

The most common method to analyze mandibular length in the clinic is the lateral cephalogram. Linear measurements of mandibular length have been observed to have high reproducibility between different measurement times. They are not dependent on whether the patient is positioned in habitual occlusion or centric relation. Skeletal effects of functional treatment seen at the mandibular level consist mainly of increasing mandibular length and ramus height [32]. However, other studies recommended that linear measurements are susceptible to magnification bias [17]. Accordingly, linear and angular cephalometric measurements were used to analyze and compare the treatment groups of the current study.

In the current study, an improvement in mandibular retrognathism was achieved in all the patients. These results were presented clinically by improving the facial profile and statistically by skeletal and dentoalveolar changes. A significant change in the ANB angle and overjet (<0.001) was seen in all cases, explaining the tremendous change in the facial profile in all treated subjects. Although most studies that examined the effect of twin-block therapy found the same results, the difference between these studies explained how this took place. Several studies attributed these changes to skeletal or dentoalveolar changes or combinations.

Regarding the skeletal effect of twin-block therapy on the mandible, we found an increase in the effective mandibular length (Co-Gn) and ramus height (Ar-Go) in both laser and non-laser groups in the current study. These are desirable outcomes of treatment with functional therapy, and these results are in accordance with Sharma et al. [33], Saikoski et al. [34], and the systematic review by Ehsani et al. [15]. After 9 months of twin-block therapy, the mean increase in the mandibular length (Co-Gn) was 3.7 mm in the laser group and 4.3 mm in the non-laser group.

Moreover, regarding the skeletal effect of twin-block therapy on the maxilla, controversial outcomes are reported for the restraining effect on the maxilla. In the current study, maxillary forward growth restriction could be explained by the twin-block's distal reciprocal force exerted on the maxilla (headgear effect). These results were also emphasized by Elfeky et al. [16] and Sharma et al. [33]. However, the current findings are incompatible with those of Saikoski et al. [34]**.**

Regarding the dentoalveolar effect of the twin-block therapy, there was a significant decrease in the inclination of the maxillary incisors in the current study. Again, this could be attributed to the headgear effect of the incorporated labial arch in the twin-block appliance. These resulted in palatal tipping of the maxillary incisors by 5.5° at the end of treatment. On the other hand, no significant effect was found on mandibular incisors' inclination. These dentoalveolar findings were in accordance with studies reported by Koretsi et al. [17] and Trenouth et al. [16], who stated that removable functional appliances caused significant dentoalveolar changes (predominantly retroclination of the upper incisors). Nevertheless, Ehsani et al. [15] found consistent reports of proclination of lower incisors and retroclination of upper incisors with twin-block therapy in their systematic review.

So, from our results, the changes following twin-block therapy are a net result of skeletal and dentoalveolar changes. This finding is in accordance with Elfeky et al. [16] and Sharma et al. [33]. On the other hand, O'Brien et al. [35] stated that most of the correction was due to dentoalveolar change.

Consequently, the current results recommended no significant difference between laser and non-laser groups regarding mandibular growth in class II mandibular deficiency patients treated with the twin-block appliance. The current study results comply with Mohamed et al.'s (2020) [36] clinical study. They found that low-level laser therapy has no considerable effect on mandibular condylar volume and position following the twin-block functional orthopedic treatment of skeletal class II malocclusions. On the other hand, several experimental studies have shown that low-level laser irradiation can further improve mandibular retrognathism [18–23]. This conflict in results between clinical and experimental studies recommends that low-level laser therapy could effectively stimulates mandibular growth but with different parameters than used in the current study.

Limitation

The results reported in this study should be considered in the light of some limitations. The first limitation is the relatively small sample size. However, our approach was relatively new in the orthodontic practice, including applying low-level laser therapy on condyles of growing subjects. So, our ethical committee limited the recruitment of our sample in the low-level laser group. Moreover, the evaluation was on a short-term basis. However, it was hard for us to accomplish a longer term investigation due to the high dropout rate of the patients because of the Covid-19 pandemic crisis in the middle of our study.

In this study, randomization was performed as described in the material section to minimize the risk of selection bias, more importantly, to balance potential confounding factors between the two groups (laser vs. non-laser group). Notwithstanding this, patients in the laser group were characterized by a vertical growth pattern evidenced by the *Y*-axis angle measurements at baseline. The use of stratified randomization would have sabotaged this baseline imbalance. Because changes in the vertical dimension have often been shown to affect the response to the functional appliance therapy, this may have confounded the results by showing a significant difference between the two groups regarding the vertical dimension.

Conclusion

From the results of the current preliminary study, it could be concluded that:

1. Low-level laser irradiation with the used parameters seems to have no synergetic impact on the skeletal and dental outcomes of Twin-block therapy over 9 months.
2. Twin-block therapy is effective in growing patients with skeletal class II mandibular deficiency.
3. The changes following twin-block therapy result from skeletal and dentoalveolar changes.

However, more studies are needed to investigate the effect of different low-level laser therapy parameters on condylar growth during functional orthodontic treatment.

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Author contribution All authors contributed to the study conception and design. Material preparation, data collection, and analysis were performed by Mohamed E. Amer. The analyzed data were revised by Mohamed Nadim and Abbadi Elkadi. The laser device was calibrated by Youssef Sedky. The first draft of the manuscript was written by Mohamed E. Amer and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Declarations

Ethics approval This study was conducted in accordance with all the provisions of the local human subjects' oversight committee guidelines and policies of Research Ethics Committee, Faculty of Dentistry, Suez Canal University, Ismailia, Egypt. The approval code for this study is: 111/2018.

Consent to publish The authors affirm that human research participants provided informed consent for publication of the images.

Consent to participate Written informed consent was obtained from the parents.

Informed consent Informed consent was obtained from all individual participants included in the study.

Conflict of interest The authors declare no competing interests.

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