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Effect of Low-Level Laser Therapy on Patients With Class II Mandibular Deficiency Treated with Farmand Functional Appliance

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Abstract

Introduction: Considering the positive effects of a low-level laser on new bone formation, we aimed to investigate the effects of a low-level laser in the treatment of patients with class II mandibular deficiency treated with Farmand functional appliance.

Methods: Twenty-two growing patients aged 10-14 years were randomly divided into "Farmand" and "Farmand+Laser" groups. All patients were treated with Farmand functional appliance. Patients in the "Farmand+laser" group were exposed to laser irradiation (980 nm, 100 mw, 4 points around temporomandibular joints, 100 seconds each point) weekly for three months after 3-4 weeks of using the appliance. Lateral cephalometry radiographs were taken from all patients before and after the treatment period, and changes in skeletal and dental parameters were measured.

Results: The association of the particular laser irradiation with the functional appliance led to a greater increase in the effective length of the mandible (Co-Gn, $P=0.048$), the anterior sagittal position of the mandible (SNB, $P=0.029$), and the length of the ramus (Co-Go, $P=0.028$), and it showed a further decrease in the discrepancy between the jaws (ANB, $P=0.000$) compared with the functional appliance alone.

Conclusion: The application of the laser with the chosen parameters and protocol in conjunction with the functional appliance improved the effects of the functional appliance and reduced the discrepancy between the two jaws.

Keywords: Low-level light therapy; Functional orthodontic appliance; Micrognathia; Cephalometry.

Introduction

Laser irradiation has different effects on tissues, varying from photobiomodulation to photodisruption depending on the time of radiation and energy density.[1] Recently, low-level lasers have been used for strengthening bone repair after a fracture[2,3] and distraction osteogenesis of the mandible,[4,5] bone formation in the mid-palatal suture after the rapid expansion of palate,[6-8] acceleration of dental movements during orthodontics[9] stimulation of the growth of epiphyseal plates,[10] and also stimulation of cartilage growth.[11]

The most common skeletal problem among orthodontic patients is class II malocclusion[12,13] because of mandibular retrognathism.[14,15]

In the treatment of class II malocclusion, the ability to change the facial growth pattern is of particular importance, which can be achieved by the functional appliance.[16,17] The best treatment for adult patients is obtained with orthosurgery, but it has been well established that in growing patients, the use of a functional appliance stimulates the growth of the condyle,[18-20] increases the size of the mandible[21,22] and consequently changes the skeletal pattern of the patient, and minimizes the need for future surgery. Therefore, the treatment of patients with class II mandibular deficiency depends on the ability of the functional appliance to stimulate cartilage growth.

Farmand II (Fa-II) is a passive tooth-borne functional appliance that was designed and introduced by Faramand S.M and registered in Loyola university in 1972. This appliance which is used by many Iranian orthodontists consists of flexible arches, tongue bow and stop bow at the mesial part of the first molars (Figure 1).

This appliance has been shown to be effective in the forward movement of the mandible[23,24]and to cause significant anterior displacement of the hyoid bone and tongue position,[25] and significantly increases pharyngeal airway dimensions[26] and improve soft tissue profile in the Treatment of Class II Division1 malocclusion patients.[27]

Mandibular cartilage is classified as secondary cartilage. Many in vitro and in vivo studies have shown that biomechanical stimuli are necessary for the growth of secondary cartilage. A helpful stimulus is a low-level laser.[28,29]

In a study on rabbits, irradiation of low level laser (LLL) (KLO3) during mandibular advancement increased bone formation in the condylar region compared to

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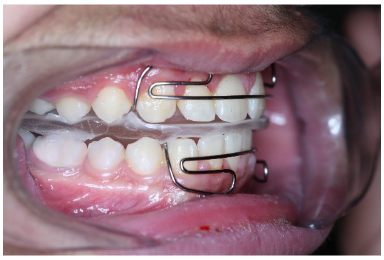

Figure 1. Farmand Functional Appliance

mandibular advancement without laser radiation.[30]

Another study showed that an intraoral appliance could stimulate condylar growth and increase mandibular protrusion in rats if combined with low-power laser treatment (8 J/cm^2).[31]

Two clinical studies have recently evaluated the simultaneous treatment of functional appliance and low-level laser, and their results showed that the combination of laser and functional appliance did not significantly increase the effectiveness of the functional therapy.[32,33]

Considering the positive effects of the low-level laser on new bone formation, we aimed to evaluate the effect of the low-level laser in the treatment of patients with class II mandibular growth deficiency treated with Farmand functional appliance.

Materials and Methods

This study was designed as a randomized controlled clinical trial. A total of 22 patients (8 girls & 14 boys) aged 10-14 years were recruited with the following criteria after their recall from the waiting list for orthodontic treatment from the Orthodontic Department of Yazd Dental School, Yazd, Iran.

A minimum of 8 patients per group were required to detect a clinically significant difference of 5 mm in mandibular efficient length (Co-Gn) between the two groups based on the previously reported standard deviations of 2.9[23] for a significant level of 5% (power = 0.9). We selected 11 patients for each group to consider possible dropouts.

$$n = \frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2 (\sigma_1^2 + \frac{\sigma_2^2}{r})}{(\mu_1 - \mu_2)^2}$$

Inclusion Criteria

1. Age range of 10-13 years for girls and 11-14 years for boys (before or at the beginning of the pubertal growth spurt)[27]
2. Mandibular retrognathia (so the patient will have a more balanced profile after bringing her/his mandible forward)
3. Class II canine and molar dental relationship
4. No history of diseases affecting the growth
5. No history of jaw surgery
6. No history of trauma to the skull and face

Exclusion Criteria

1. Lack of cooperation in using the appliance
2. Refusing to continue the treatment

All patients were in the pubertal stage (Cs2 and Cs3) according to cervical vertebral maturation.

To prepare the construction bite for making the Farmand appliance, we placed the wax between the patient's teeth. We guided the patient's mandible forward so that the tip-to-tip relationship of the incisors was achieved with a 2-3 mm opening of the bite between the molars.

Then lateral cephalometry radiographs were obtained from the patients. All radiographs were prepared in the radiology department of Yazd Dental School by PM-2002 EC (Planmeca, Finland) and Agfa film (made in Belgium) and in standard conditions (teeth in occlusion, lips at rest, and natural head posture). The cephalometry of each patient was traced twice by one person using the manual method, and if there was a difference in measurements, their mean value was calculated and selected.

The patients were instructed to use the appliance 24 hours a day, except when eating, exercising, and brushing their teeth. They were followed up weekly until the end of the active phase of using the appliance (Figure 1).

At this stage, we randomly divided the patients into two groups of 11. The files containing the patients' information, which had the same appearance and were closed and numbered from 1 to 22, were prepared. Then, with the help of the site "www.graphpad.com", the numbers were placed in one of the two groups, so that each group included 11 patients. The first group of patients used only the functional appliance. The second group of patients underwent laser irradiation in addition to the functional appliance.

The laser used in this study was a diode (gallium-aluminum-arsenide laser, GaA1As) (A.R.C. Laser, Deutschland, Nurberg) with a wavelength of 980 nm; the output power was 100 mW, and radiation was done continuously by a contact method for 100 seconds at each point.

The laser treatment protocol was selected according to the website https://energy-laser.com/guide-lines-for-treatment-with-laser-therapy/ and previous studies.[33,34]

In the first group of patients, after 3-4 weeks of using the appliance, a laser with the above characteristics was irradiated once a week (12 sessions).

This interval was created due to the evaluation of the patient's cooperation and also because of the coincidence of beginning the treatment with maximum cell activity according to the studies.[35,36]

Radiation was performed accurately and continuously at four points around the temporomandibular joint

(TMJ) (upper, anterior, posterior, and lower posterior). These points were determined by first determining the location of the TMJ by opening and closing the patient's mouth and then marking the mentioned points around that area for radiation (Figure 2). The patients in the second group were placed in the same situation, but we only placed the laser applicator in the mentioned places without laser radiation.

After completing the period of functional appliance treatment (6 months), lateral cephalometric radiographs were taken again from all the patients. Then, the distances of Co-Gn, Co-Me, Co-Go, Ar-Gn, Ar-Pg, Go-Me, Go-Pg, N-Pg, S-Go, Ar-Go, Overjet, Overbite, Upper lip to Eline, Lower lip to Eline and the angles of SNA, SNB, ANB, U1toSN, IMPA were measured in the lateral cephalograms before and after the treatment, and the results of the two groups in the pre- and post-treatment stages were compared (Figure 3).

In this study, the patients were unaware of which group they were in (Farmand group or Farmand + laser group) because all the patients were in the same situation with the difference that in the "Farmand group" the laser applicator was placed in the specified points but without laser radiation. In this study, except for the researcher who was aware of radiation or no radiation, the second researcher (who was also responsible for treating the patients and collecting data) and also the statistical consultant who was responsible for data analysis did not know which group each patient belonged to.

Figure 2. laser Radiation

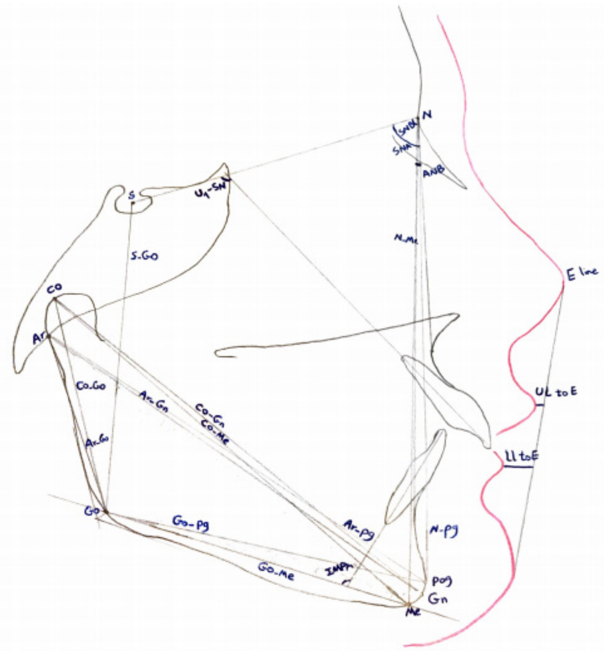

Figure 3. Angles and Distances Measured in This Study

Results

During the study period, one patient from each group was excluded from the study because of a lack of cooperation. However, the rest of the patients (20 patients: 6 girls and 14 boys) completed the study period.

The mean age of the participants at the beginning of the study (Farmand group = 12.06 ± 0.83, Farmand + laser group = 11.51 ± 1.27), sex distribution (3 girls and 7 boys in each group), and initial overjet (Farmand group = 6.80 ± 2.47, Farmand + laser group = 7.00 ± 2.14) did not differ between the two groups (*P* value of age = 0.54, *P* value of sex = 1.00, and *P* value of overjet = 0.20).

Kolmogorov-Smirnov and Shapiro-Wilk tests showed that the data had a normal distribution. Accordingly, parametric tests were used for statistical evaluation. To analyze the data and determine statistically significant changes, paired and independent *t* tests were used, and $P < 0.05$ was considered statistically significant. Table 1 shows the mean and standard deviation values of each of the variables in both groups before and after the treatment, as well as the P-values obtained from the paired *t* test. The mean and standard deviation of the differences between the two groups as well as the *P* values obtained from the independent *t* test are also shown in Table 2.

Skeletal Changes

Anterior-posterior maxillary discrepancy (ANB) was significantly reduced in both groups. The rate of this reduction was significantly higher in the laser group than in the Farmand group.

SNA values decreased in both groups, but this decrease was significant only in the Farmand + laser group. SNB also increased in both groups, but this increase was significant only in the Farmand + laser group. Moreover, the rate of increase of the SNB angle, which indicates the position of the mandible relative to the base of the cranium, was significantly higher in the Farmand + laser group than in the Farmand group.

The effective length of the mandible (Co-Gn) and other variables that show the overall length of the mandible (Co-Me, Co-Go, Ar-Gn, Ar-Pg) increased significantly in both groups. The effective length of the mandible (Co-Gn) increased significantly more in the Farmand + laser group than in the Farmand group.

Table 1. Mean Values of Variables Before and After the Treatment in the Two Groups

Variables	Farmand Group Mean ± SD Before Treatment	Farmand Group Mean ± SD After Treatment	*P* value	95% CI	Farmand + Laser Group Mean ± SD Before Treatment	Farmand + Laser Group Mean ± SD After Treatment	*P* value	95% CI
Skeletal maxilla and mandible								
SNA	80.30 ± 3.09	79.25 ± 4.36	0.235	-2.91-0.81	81.95 ± 3.94	80.65 ± 3.93	0.009	-2.19-(-40)
SNB	74.55 ± 3.16	75.25 ± 4.19	0.319	-.80-2.20	74.45 ± 3.57	77.05 ± 2.89	0.000	1.57-3.62
Co-Gn	101.43 ± 6.08	106.15 ± 5.79	0.000	3.53-5.90	101.21 ± 6.64	107.50 ± 7.45	0.000	5.11-7.46
Co-Me	93.99 ± 6.02	104.95 ± 5.96	0.000	3.77-6.26	100.41 ± 7.13	106.05 ± 7.39	0.000	4.96-6.31
Co-Go	48.81 ± 4.14	51.8 ± 3.51	0.000	1.80-4.17	48.44 ± 3.40	53.55 ± 4.79	0.000	3.49-6.72
Ar-Gn	92.8 ± 7.76	98.05 ± 6.17	0.000	3.44-7.05	93.11 ± 5.92	99.15 ± 5.98	0.000	4.77-7.30
Ar-Pg	92.54 ± 7.18	97.95 ± 5.98	0.000	3.82-6.99	93.15 ± 6.01	98.95 ± 5.98	0.000	4.74-6.85
Maxilla relative to mandible								
ANB	5.75 ± 1.62	4.00 ± 1.92	0.000	-2.28-(-1.21)	7.50 ± 1.64	3.60 ± 1.42	0.000	-4.52-(-3.27)
Dental maxilla								
U1 To Sn	105.05 ± 11.94	101.40 ± 11.07	0.027	-6.78-(-0.51)	106.95 ± 8.95	105.00 ± 4.69	0.380	-4.52-(-3.27)
Dental mandible								
IMPA	98.25 ± 9.40	103.20 ± 7.82	0.065	-.30-8.20	100.50 ± 7.72	102.80 ± 5.63	0.175	-1.23-5.83
Mandible Body								
Go-Me	63.15 ± 4.52	67.10 ± 4.07	0.000	2.79-5.10	5.69 ± 63.59	67.35 ± 6.38	0.000	2.77-4.74
Go-Pg	66.79 ± 4.42	70.75 ± 4.54	0.000	3.14-4.77	66.70 ± 5.72	70.45 ± 6.40	0.000	2.97-4.52
Interdental								
Overjet	6.80 ± 2.47	2.95 ± 1.32	0.000	-5.24-(-2.45)	7.00 ± 2.14	3.25 ± 1.32	0.000	-4.67-(-2.82)
Overbite	4.10 ± 2.97	2.45 ± 1.60	0.029	-3.09-(-.20)	3.70 ± 1.35	2.65 ± 1.41	0.017	-1.86-(-.23.0)
Vertical								
N-Pg	102.04 ± 6.48	107.35 ± 6.73	0.001	2.98-7.63	103.47 ± 4.41	108.80 ± 6.30	0.000	3.18-7.47
S-Go	66.41 ± 4.77	70.30 ± 4.56	0.000	2.57-5.20	67.02 ± 4.32	73.40 ± 6.64	0.000	4.12-8.63
Ar-Go	41.88 ± 4.85	45.40 ± 4.85	0.000	2.30-4.73	42.49 ± 4.30	47.25 ± 4.63	0.000	3.31-6.20
Soft tissue								
Ulip To E Line	0.45 ± 1.36	-0.45 ± 1.92	0.156	-2.21-0.41	1.60 ± 1.32	0.30 ± 1.25	0.001	-1.86-(-.73)
Llip To E Line	1.10 ± 2.50	0.85 ± 1.87	0.644	-1.43-0.93	1.40 ± 2.50	0.45 ± 1.81	0.046	-1.88-(-.19)

The mandible body length (Go-Pg, Go-Me) increased significantly in both groups; however, other indicators showing the total length of the mandible and the body length of the mandible did not show a significant difference between the two groups.

Dentoalveolar changes, vertical changes, and soft tissue changes are also shown in Tables 1 and 2.

Discussion

The aim of this study was to evaluate the effects of a low-level laser in the treatment of growing patients with class II mandibular deficiency treated with Farmand functional appliance. We found that the association of the laser with the functional appliance led to a further increase in the effective length of the mandible, the anterior sagittal position of the mandible, and the length of the ramus, and it showed a further decrease in the discrepancy between the two jaws compared with the functional appliance alone.

Photobiomodulation therapy is a type of light therapy that uses non-ionizing forms of light sources, including lasers, LEDs, and broadband light, in the visible and infrared spectrum. This process leads to beneficial therapeutic results that include relieving pain or inflammation, modulating the immune system, and improving wound healing and tissue regeneration.[37] Recent studies have shown that laser radiation has stimulatory effects in active areas such as bone fractures, mandibular osteogenesis distractions, bone lesions, and silent extractions.[38-40] In this study, we focused on TMJ as the active growth region of the laser.

Among the different types of lasers, in the present study, we selected the GaAlAs, which is known for its high penetration depth compared to other types of lasers and is, therefore, a highly efficient tool.[41] The World Association of Laser Therapists (WALT) has provided

Table 2. Mean differences between the two groups

Variables	Farmand Group	Farmand + Laser Group	*P* Value	95% CI
	Mean ± SD	Mean ± SD		
SNA	-1.05 ± 2.60	-1.30 ± 1.25	0.788	-2.17-1.67
SNB	0.7 ± 2.09	2.60 ± 1.42	0.029	0.21-3.58
Co-Gn	4.72 ± 1.66	6.29 ± 1.63	0.048	0.19-3.12
Co-Me	5.02 ± 1.74	5.64 ± 0.94	0.337	-0.70-1.94
Co-Go	2.99 ± 1.65	5.11 ± 2.66	0.028	0.25-3.98
Ar-Gn	5.25 ± 2.51	6.04 ± 1.76	0.428	-1.25-2.83
Ar-Pg	5.41 ± 2.21	5.80 ± 1.48	0.649	-1.38-2.16
ANB	-1.75 ± 0.75	-3.9 ± 0.87	0.000	-2.91-(-1.38)
U1 to Sn	-3.65 ± 4.38	-1.95 ± 6.77	0.514	-3.66-7.06
IMPA	3.95 ± 5.94	2.30 ± 4.94	0.508	-6.78-3.48
Go-Me	3.95 ± 1.61	3.76 ± 1.37	0.780	-1.59-1.21
Go-Pg	3.96 ± 1.14	3.75 ± 1.08	0.678	-1.25-0.83
Overjet	-3.85 ± 1.94	-3.75 ± 1.29	0.894	-1.45-1.65
Overbite	-1.65 ± 2.01	-1.05 ± 1.14	0.423	-0.93-2.13
N-Pg	5.31 ± 3.25	5.33 ± 3.00	0.989	-2.92-2.96
S-Go	3.89 ± 1.83	6.38 ± 3.14	0.044	0.06-4.91
Ar-Go	3.52 ± 1.69	4.76 ± 2.02	0.154	-.51-2.99
Ulip to E line	-0.90 ± 1.83	-1.30 ± 0.78	0.535	-1.72-0.92
Llip to E line	-0.25 ± 1.65	-0.95 ± 1.30	0.307	-2.09-0.69

guidance on the dosage range and treatment protocol for laser treatment and biological stimulation[42], based on which the laser therapy protocol of the present study was selected.

One study showed that irradiation to bone at infrared wavelengths (700 to 1000 nm) increased osteoblastic proliferation, collagen formation, and new bone formation.[43] The wavelength we used in our study was in the same range. According to another study, the highest rate of new bone formation in the posterior condyle during mandibular advancement was observed on day 30[36]. For this reason, and also because of the one-month evaluation of the patient's cooperation, we started laser irradiation after 3-4 weeks of using the appliance.

In the present study, skeletal age assessment was performed by examining CVMS, as in the modified method of Baccetti et al.[44] The selected patients of both groups were in the SC2-CS3 stage. According to Baccetti et al, maximum therapeutic effects were obtained when the course of treatment included a growth spurt of puberty, and it was suggested that the best time to treat with a functional appliance was during or shortly after the onset of puberty.[45]

One of the functional appliances currently used in private offices and dental schools in Iran is the modified bionator Farmand appliance. In 1967-1970, Farmand introduced the FAII appliance by modifying the wired components of the bionator. Skeletal changes in condylar growth and dental changes have been proven with this appliance.[24]

In orthodontic articles, CBCT and lateral cephalogram have been used to evaluate the length of the mandible. Comparing CBCT and lateral cephalometry in assessing mandibular growth, studies have shown that CBCT has no precedence over cephalometry and that bi-dimensional lateral radiographs remain the method of choice in evaluating mandibular body growth.[46] Therefore, lateral cephalometry was selected as the most efficient, least time-consuming, most economical, and most accessible method for this study.

Skeletal Changes

Maxilla

It is claimed that functional appliances apply a distal force to the maxilla while moving the mandible forward (headgear effect).

In the present study, the SNA did not change significantly in the Farmand group. This result agrees with the results of previous studies.[47-51]

Although the SNA reduced significantly in the laser group, the difference between the two groups was not statistically significant. This result was in agreement with another study, where the association of the laser with the functional appliance did not have a significant positive effect on the SNA angle and maxillary sagittal position.[33]

Mandible

In the present study, after functional therapy in both groups, the mandibular sagittal position (SNB), effective mandibular length (Co-Gn), and ramus length (Co-Go and S-Go) improved. This improvement was significantly greater in the laser group.

This is consistent with another study on albino mice, which observed the growth of the mandible in the group that received a laser with an energy of 8 J/cm^2 in conjunction with the bite jumper appliance, showing the highest growth of the mandible. They concluded that laser radiation could stimulate condylar growth and increase mandibular growth.[31]

The result of the present study was consistent with another study that examined the clinical and histological effects of a low-level laser on condylar growth in rats. The researchers concluded that mandibular growth was greater in the group to which the laser was applied in combination with the mandibular advancing appliance than in the group with the appliance alone.[11]

On the other hand, Amer et al showed in their study that low-level laser irradiation had no synergetic impact on the outcomes of twin-block therapy.[32] The wavelength (940 nm) and laser power (100 mW) were similar to those of our study. However, the difference in their results compared to our study may be related to the difference in the points of radiation (1 point vs 4 points), time of irradiation (25 seconds vs 100 seconds each point), and type of functional appliance (twin block vs Farmand).

Also, this result was not consistent with Amer and colleagues' study on growing patients. They concluded that although these indicators increased in both groups with functional appliance therapy (with and without a laser), there was no difference between the two groups.[33] This may be related to differences in the properties of the GaAlAs laser used in this study (635 nm wavelength) or a different functional appliance (Twin block). This difference may also be attributed to darker skin types in the Egyptian population than in Iran. As shown in one study, at each wavelength of the laser, darker skin absorbs more laser energy, leaving less laser to act in the deeper layers of the skin.[52]

According to the results of the present study, an ANB difference of 2.15 degrees and an effective mandibular length difference of 1.57 mm can be considered clinically significant; however, more studies should be done to evaluate the cost-benefit of this treatment.

One of the limitations of the present study was the lack of a control group without treatment to consider normal growth. However, because of ethical issues, including a group without treatment is problematic. In addition, the evaluation period of our study was short.

It is recommended that more clinical trials with a larger sample size and for a longer period of time be carried out to further explore the effectiveness of low-level laser therapy during functional treatment.

It can also be hypothesized that with lower laser power and even the use of visible light, similar effects can be achieved in this study to increase mandibular length. To test this hypothesis, we can use an appliance similar to a headphone that emits light around the TMJ while advancing the mandible by means of a functional appliance.

Conclusion

The application of a laser with the parameters and protocol used in this study in conjunction with the functional appliance positively affected the effective length of the mandible (Co-Gn), the anterior sagittal position of the mandible (SNB), the length of the ramus (Co-Go), and the discrepancy between the jaws, and it enhanced the effect of the functional appliance on improving the skeletal profile and reducing the discrepancy between the two jaws.

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Competing Interests

The authors declare no conflict of interest.

Ethical Approval

The study protocol was approved by the Ethics Committee of Shahid Sadoughi University of Medical Sciences (license number: IR.SSU.REC.1398.025) and registered at Iranian Registry of Clinical Trials (identifier: IRCT20210221050435N1).

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