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Efficacy of the combination of myofunctional therapy (lip exercises) and activator high-pull headgear in the closure of interlabial gap in long-face skeletal class II patients with lip incompetence: A 6–8-month longitudinal randomized clinical trial

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ABSTRACT

Background: Lip incompetence is an important issue in orthodontics. No study has evaluated the effects of the combination of headgear + lip exercises on lip incompetence. Therefore, this study was conducted.

Materials and Methods: This was a longitudinal randomized clinical trial on 29 subjects (16 controls and 13 experimental subjects). Both groups were treated with standardized activator high-pull headgear (and followed up monthly) for 6–8 months. In the experimental group, patients were also instructed to practice certain lip exercises 3 sessions a day, 5 times per session. Pre-/post-treatment interlabial gap, upper lip length and vermilion height, lower lip length and vermilion height, nasolabial angle, and profile convexity angle were measured clinically and photographically, immediately before treatment and after it. Data were analyzed using paired/unpaired *t*-tests (α = 0.025) and partial correlation coefficient controlling for the intervention type (α = 0.05).

Results: Lip exercise plus activator headgear significantly changed/improved all parameters ($P \leq 0.006$) over the 6–8-month course of treatment. Activator headgear alone changed/improved only 4 parameters: interlabial gap, upper and lower lip lengths, the lower lip vermilion height, and profile convexity ($P \leq 0.008$). Compared to the control (activator headgear alone), in the experimental group, the changes observed in the interlabial gap closure ($P = 0.011$), upper lip lengthening ($P = 0.002$), and upper lip vermilion lengthening ($P = 0.017$) were significantly greater. Convexity angle corrections were more successful in cooperative patients (R = 0.469, $P = 0.012$). Cases with smaller pretreatment nasolabial angles may experience more changes in this angle after treatment (R = 0.581, $P = 0.001$).

Conclusion: The addition of lip exercises to activator high-pull headgear can boost activator headgear's efficacy in treating lip incompetence.

Key Words: Extraoral traction appliances, myofunctional therapy, orthodontics, randomized clinical trial

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INTRODUCTION

Lip incompetence is a common and important problem in orthodontics.[1] It can disrupt esthetics, can negatively affect the growth and development of craniofacial complex,[2] and might severely prevent lip seal to below 30%,[1] causing halitosis, dry mouth, and periodontal problems.[3] Incompetent lips are usually seen in class II patients with long faces, which is an extremely common malocclusion.[4]

A common treatment for this problem is using a high-pull headgear or a functional device with a posterior bite block to control or limit the vertical growth.[5] However, the results in this regard were controversial: For example, some studies showed increased lip length after the application of an activator headgear appliance.[6] On the other hand, others could not find any changes in the height and thickness of the lips after such therapies.[7] Moreover, myofunctional therapies such as lip stretching and strengthening might be used to improve lip dimensions and reduce lip incompetence.[8,9]

There are very few studies regarding lip or facial changes as a result of headgear application or lip exercises. Moreover, when it comes to the combination of headgear and lip exercises, there is no study available. Studies on the efficacy of headgear have shown controversial results. According to Kirjavainen *et al*.,[10] treatment with cervical headgears could increase the nasolabial angle and reduce the interlabial gap (implying the retrusion of the upper lip) without altering the thickness of the lip thickness or chin depth. According to Bishara *et al*.,[11] Looi and Mills,[12] or Guo *et al*.,[13] orthodontic treatment involving bimaxillary premolars would result in the retrusion of the lower and upper lips. Combrink *et al*.[14] concluded that Class II intermaxillary elastics might advance the lower lip relatively more than the upper lip, resulting in an improvement in the interlabial relationship. Maetevorakul and Viteporn[6] asserted that several variables may complicate and confound the prediction of the alterations of soft-tissue profile after Class II Division 1 malocclusion treatment, including treatment types, demographics of the patient, and the patient's pretreatment anatomy. According to them,[6] the upper lip modifications in the horizontal direction may be less predictable than lower lip alterations. Maltagliati *et al*.[7] comparatively evaluates soft- and hard-tissue cephalometric alterations after Class II division 1 malocclusion treatment using activator-headgears and Bionator appliances. They failed to observe significant alterations in the growth path or modification of the vertical and sagittal position of the upper lip and the posterior inferior height by each appliance.[7] Their orthopedic appliances only slightly modified the soft mention and the lower lip; still, their experimental group showed a reduction in deepness of the mentolabial sulcus compared to the control group.[7] Hockenbury and Dana[9] observed that the length and strength of lips were improved in all subjects after 4 months of exercising to stretch, lengthen, and strengthen their upper lip, 3 times a day; after 4 months, 36 of their 56 subjects reported achieving lip competence both nocturnally and diurnally.[9]

This study was conducted because although each of these two methods (lip stretching exercises or headgear therapy) has been assessed before in few and mostly small studies, no study has evaluated effects of both of them combined on the improvements of lip incompetence. Moreover, only few studies on the effects of headgears on correction of lip incompetence have examined the vertical interlabial gap between the lips. Furthermore, most previous studies on the effects of headgears on lip incompetence had used cephalometric measurements (which is less relevant to real values, especially in vertical measurements), and none of them had clinically measured the lip positions, which is a more relevant method in soft-tissue assessments.[15] In addition, as mentioned above, the studies on the efficacy of headgears in lip incompetence treatment are controversial.[6,7] And finally, as mentioned above, the prevalence of class II disorders and lip incompetence is quite high, and the methods of their treatment are worth investigation. The null hypothesis was the absence of any difference in the vertical interlabial gap in rest position in long-face people with skeletal class II division 1 malocclusion who were treated with the activator high pull headgear appliance versus the combination of the activator high pull headgear and lip exercises.

MATERIALS AND METHODS

This randomized clinical trial was performed on long-face orthodontic patients with class II division 1 malocclusion attending the orthodontic department and two private orthodontic clinics in Tehran, Iran, in 2021. The sampling was performed through clinical examination of children in the age range of

9–12 years to find convex and elongated faces as well as the assessment of the records of previous patients with complete patient records and complete sets of photography.

The subjects were selected prospectively from attendees to the orthodontics department and 2 private orthodontic offices. The dropouts were replaced with new prospectively acquired participants.

Ethics

No unknown alterations were made to the routine treatments. The patients could leave the study anytime they wanted to, without any changes happening to their treatments. All patients signed written consents. The ethics of this study were approved by the research committee of the university (ethics code: IR. IAU. DENTAL. REC.1399.183). The study was also preregistered at and approved by an international randomized controlled trial register, before commencement of the study (RCT code: IRCT20200707048046N1).

Eligibility criteria

The patients had to be skeletal class II Div 1 (without any limits in overjet), long face, and lip incompetent (at least 3 mm interlabial gap in rest position[16]). Examinations of vertical facial thirds were done on profile photographs to detect the vertical growth patterns. To select long-face patients, the patients were examined in the frontal view clinically. For this purpose, the patient's face was divided into vertical thirds in the frontal view, which included a segment between the hair growth and glabella, the middle segment being from glabella to subnasal, and the lower third which was between subnasal and menton. In long-face patients, the lower third had to be taller than the upper two-thirds. To examine the class II skeletal relationship, we measured the degree of facial convexity (as detailed below). The angular measurements were all measured on standardized profile photographs. If the glabella-subnasale-pogonion angle was smaller than 165°, the patient would be considered to have a convex face and thus having a class II skeletal relationship.[17] All included patients needed to attend all the follow-up sessions, which were held every 1 month after the treatment. The other inclusion criteria were no history of orthodontic treatment, attendance before the age of physical maturity defined for girls as 9–11 years and for boys as 10–12 years.

Sample size

The sample size was predetermined using PASS 11 software as two groups of 16 patients, assuming α =0.05 and β =0.2.

Randomization and blinding

The study was not blind. Only the statistician was blinded to the grouping. The experimental and control groups were assessed by two observers not aware of the measurements in the other group (but aware of the grouping). The subjects were randomly assigned to the control or experimental groups using a random number generator program. The randomization was performed by the operator.

Photography

All patients were photographed immediately before beginning the treatment and after it using the same model of camera and in standardized situations, in natural head position, and in the three views of frontal, frontal while smiling, and profile.

The best extraoral dental images may be recorded at a distance of 30 cm with a magnification of 1:2. These images should be taken using a camera on autofocus and equipped with a ring flash light around the lens.[18] All the frontal-view images were taken while the camera was level with the patient's face and their eyes on a fixed tripod, and the patient was seated on a marked line that was 30 cm away from the camera. The image background was bright.

In the profile photographs, a mirror was installed in front of the patient with a distance of 1 meter, so that when taking the picture, the patient looked at their own eyes in the mirror and was in the natural head position. In addition, the teeth were in occlusion.

Interventions

Activator headgear (in both groups [control or experimental])

All patients (in both groups) were given an activator high-pull headgear. This device consists of two components, the activator and high-pull headgear. The headgear includes facebow and the head cap. The face bow has an outer bow and an inner bow. The inner bow is 10 mm larger than the intermolar distance and parallel to the occlusal surface, and 3 mm away from the incisor teeth in front. The external bow is attached to the headcap at an angle of 15 °; it applies a force equivalent to 450 g on each side to the teeth.[10,19] The activator component maintains the upper and lower jaw relations during the changes with two upper and lower acrylic plates.[20] At the time of impression taking for this appliance, the height of the bite wax was about 2–3 mm higher than the patient's free-way space. During the bite recording, the patient guided the mandible forward and the dental position was edge-to-edge. Finally, the activator component was connected to the retainer at the premolars.[19] We handed over the appliance to the patients and emphasized that they should use it 12–14 h a day, especially in the evening and night.

Lip exercises (only in the experimental group)

In addition to the activator headgear, the experimental group's patients were also taught the upper lip exercises. This exercise attempts to stretch the muscles of the orbicularis oris and the levator labii superioris. It comprised placing the thumb inside the upper lip vestibule and the other 4 fingers outside the lip under the nose and pulling the upper lip down for 20 s and also massaging the upper lip downward with the thumb for 20 s. This exercise needed to be done three sessions a day and 5 times each session.[9] The course of treatment in all control and experimental patients lasted between 6 and 8 months.

Outcomes

The primary outcomes were the vertical interlabial gap, the upper lip length and vermilion height, and the lower lip length and vermilion height, both before the treatment and after it. The secondary outcomes were the pre- and post-treatment nasolabial angle and facial profile convexity angle.

Then Inter-labial gap, upper and lower lip length, upper and lower lip vermilion were clinically calibrated using a caliper with a precision of 0.02 mm and the nasolabial angel and angel of convexity were measured using the images.

The pre- and post-treatment linear measurement (inter-labial gap, upper and lower lip length, and upper and lower lip vermilion) were clinically measured using a calibrated caliper at a precision of 0.02 mm (either before treatment or after its completion). For pre- and post-treatment clinical measurements, the patient was seated upright, slightly leaning on the chair and with relaxed lips and facial muscles. To measure the upper lip length, the distance from the subnasal to the upper lip wet line on the midline was vertically marked and measured (Sn-Sts). In addition, the followings were vertically marked and measured on the midline: The distance from the border of the upper lip vermilion to the wet line of the upper lip (Sts-Ls, the upper vermilion height), the distance between the wet line of the upper and lower lip (the vertical interlabial gap), and the distance from the wet line of the lower lip to the vermilion of the lower lip (Sti-Li, the lower vermilion height). To measure the length of the lower lip, the vertical distance from the lower lip wet line to the labiomental sulcus was measured on the midline (Sti-Ils).[21] The nasolabial angel and angel of convexity were measured on the photographs. To measure the pre- and post-treatment facial convexity, we determined the glabella-subnasal-pogonion angle (G-Sn-P). To mark the glabella point, we selected the most prominent point on the forehead in profile view. To mark the subnasal point, we marked the junction of the base of the nose to the upper lip. To determine the pogonion, we selected the most anterior point on the chin. Then we connected these three points in order and determined the angle between them using an image analysis program (Digimizer-5.4.7, MedCalc Software, Ostend, Belgium). To measure the pre- and post-treatment nasolabial angle, in the profile image, we drew a tangent line on the nasal columella and a tangent line on the upper lip and measured the angle between them using the Digimizer-5.4.7 software as the nasolabial angle.[21] The linear measurements were clinically measured on the face of the subjects.

Statistical analysis

Descriptive statistics and 95% confidence intervals (CIs) were calculated. A Kolmogorov–Smirnov test confirmed the normality of the sample. Patients' ages were compared using an independent-samples *t*-test. A paired *t*-test was used to compare the pretreatment versus posttreatment values of each of the orthodontic parameters (primary and secondary outcomes); this was done separately in the control and experimental groups. The extent of change in each of the orthodontic parameters in each patient was calculated by subtracting the pretreatment value from posttreatment value. These changes were compared between the control and experimental groups, using an independent-sample *t*-test. A partial correlation coefficient was used to examine the correlations across the variables, controlling for the role of grouping (experimental or control). The level of significance was set at 0.05 for the partial correlation coefficient and the *t*-test comparing patients' ages. It was adjusted to 0.025, using the Bonferroni method, for the paired and unpaired *t*-tests used to analyze the orthodontic parameters.

RESULTS

The study began after registration, on January 30, 2021. Two groups of 16 patients each were initially formed. However, 3 patients from the experimental group and 4 from the control group were dropped out of the study because of not attending the follow-up sessions regularly (mainly because of the COVID-19 pandemic). The 4 patients in the control group were replaced with new subjects. The trial ended when the sample size reached 16 patients in the control and 13 patients in the experimental group. A total of 29 subjects with a mean age (standard deviation) of 10.41 ± 1.086 years were included. The mean ages in females and males were 10.62 ± 1.044 and 10.25 ± 1.125 years, respectively. The *t*-test did not show a significant difference between the ages of the sexes (*P* = 0.377). There were 16 (9 females) patients in the control group and 13 (4 females) patients in the experimental group. The mean ages were 10.63 ± 0.957 years (range: 9–12) in the control group and 10.15 ± 1.214 years (range: 9–13) in the experimental group. The *t*-test did not show a significant difference between the mean ages of the control and experimental groups (*P* = 0.253). In the control and experimental groups, respectively 2 and 3 patients were poorly cooperative, but the rest were fully cooperative. None of the subjects had a history of orthodontic treatment in the past, and all of them had incompetent lip positions. The convexity of their faces was <165, which would be considered convex. No harm was identified with this study.

Were the changes (occurred over the 6–8-month course of treatment) significant?

Descriptive statistics and 95% CIs pertaining to clinical examinations are presented in Tables 1 and 2.

Experimental group

Comparing the pretreatment with posttreatment values in each of the experimental and control groups separately, it was found that all the parameters in the experimental group changed significantly after 6–8 months of treatment [paired *t*-test, all the 7 *P* ≤ 0.006, Tables 1, 2 and Figure 1].

Control group

In the control group, the changes observed in the following 2 parameters were insignificant: nasolabial angle (*P* = 0.088, α =0.025) and Sts-Ls (the upper lip vermilion height, *P* = 0.084, α =0.025). However, the following parameters had significant changes: interlabial gap, upper and lower lip lengths, and profile convexity [all the 4 *P* ≤ 0.001, Tables 1, 2 and Figure 1]. Furthermore, the change in Sti-Li (the lower lip vermilion height) of the control group was significant [*P* = 0.008, α =0.025, Tables 1, 2 and Figure 1].

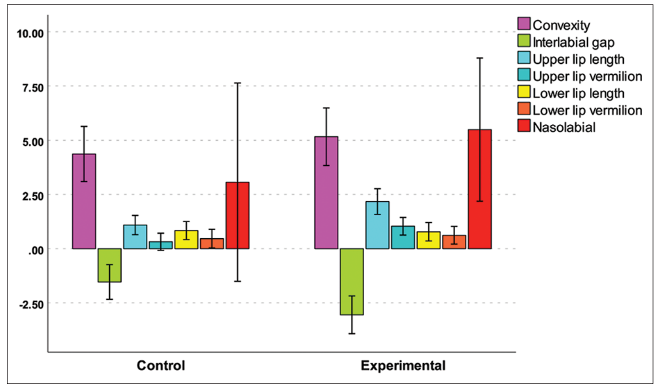

Figure 1: Mean and 95% confidence interval for the alterations occurred to the orthodontic parameters by the control and the experimental treatments. Negative values show reductions over the course of treatment, while positive values show increases over time.

Did "the extents of parameter alterations over time" differ between the intervention groups?

The independent-samples *t*-test showed that comparing the extent of treatment-induced changes observed in the experimental versus control groups, the extent of change in the interlabial gap closure was significantly greater in the experimental group compared to the control (*P* = 0.011, α =0.025); also the extents of the increase in the parameter Sn-Sts (the upper lip length, *P* = 0.002) and the extent of the increase in the parameter Sts-Ls (the upper lip vermilion height, *P* = 0.017) were significantly greater in the experimental group compared to the control. The extents of change in the rest of the 4 parameters were not significantly different between the control and experimental groups [all the 4 *P* ≥ 0.314, Table 2 and Figure 1].

Role of potentially associated factors

The partial correlation coefficient showed that sex was marginally significantly correlated only with the changes that happened to the upper lip length (Sn-Sts), so that females tended to show a slightly greater increase in their upper lip length [Table 3]. Patient cooperation was correlated with facial convexity correction, in a way that cooperative patients tended to show greater extents of convexity corrections compared to poorly cooperative patients [Table 3]. Age was correlated with the pretreatment nasolabial angle, but not with changes in nasolabial angle [Table 3]. Cases with smaller baseline

Table 1: Descriptive statistics and 95% confidence intervals for the orthodontic parameters evaluated at either interval in each group

Interval	Parameter	Group	*n*	Mean±SD	95% CI	Minimum	Maximum
Baseline	Convexity angle (°)	Control	16	155.83±4.03	153.68–157.97	148.6	161.4
		Experimental	13	155.88±3.63	153.68–158.07	150.7	163.4
		Total	29	155.85±3.79	154.41–157.29	148.6	163.4
	Interlabial gap (mm)	Control	16	7.80±2.69	6.37–9.23	4.5	13.0
		Experimental	13	7.95±2.55	6.40–9.49	5.4	13.3
		Total	29	7.87±2.58	6.88–8.85	4.5	13.3
	Sn-Sts (upper lip length) (mm)	Control	16	13.33±1.96	12.28–14.38	9.6	17.8
		Experimental	13	12.16±2.33	10.75–13.57	8.0	16.4
		Total	29	12.81±2.18	11.98–13.64	8.0	17.8
	Sts-Ls (upper lip vermilion) (mm)	Control	16	5.06±1.19	4.42–5.69	3.6	7.0
		Experimental	13	6.04±1.44	5.17–6.91	3.7	8.3
		Total	29	5.50±1.38	4.97–6.02	3.6	8.3
	Sti-Ils (lower lip length) (mm)	Control	16	9.38±1.61	8.53–10.24	6.7	11.9
		Experimental	13	11.08±1.52	10.17–12.00	9.0	13.5
		Total	29	10.14±1.76	9.47–10.82	6.7	13.5
	Sti-Li (lower lip vermilion) (mm)	Control	16	7.05±1.02	6.51–7.59	4.9	8.9
		Experimental	13	8.61±1.73	7.56–9.65	4.0	10.8
		Total	29	7.75±1.57	7.15–8.35	4.0	10.8
	Nasolabial angle (°)	Control	16	107.26±10.79	101.51–113.00	83.3	124.4
		Experimental	13	98.16±8.87	92.80–103.52	76.5	106.5
		Total	29	103.18±10.83	99.06–107.30	76.5	124.4
After treatment	Convexity angle (°)	Control	16	160.16±3.94	158.06–162.26	153.9	166.9
		Experimental	13	161.04±3.42	158.97–163.11	156.8	168.6
		Total	29	160.55±3.68	159.15–161.95	153.9	168.6
	Interlabial gap (mm)	Control	16	6.26±2.44	4.96–7.56	2.0	11.3
		Experimental	13	4.89±1.68	3.88–5.91	2.5	8.5
		Total	29	5.65±2.21	4.81–6.49	2.0	11.3
	Sn-Sts (upper lip length) (mm)	Control	16	14.39±2.04	13.30–15.47	11.8	19.5
		Experimental	13	14.33±2.06	13.09–15.57	10.7	18.7
		Total	29	14.36±2.01	13.60–15.13	10.7	19.5
	Sts-Ls (upper lip vermilion) (mm)	Control	16	5.41±1.01	4.87–5.95	3.8	7.5
		Experimental	13	7.07±1.31	6.28–7.86	5.4	8.9
		Total	29	6.15±1.41	5.62–6.69	3.8	8.9
	Sti-Ils (lower lip length) (mm)	Control	16	10.22±2.02	9.14–11.30	6.9	13.7
		Experimental	13	11.86±1.56	10.92–12.80	9.5	14.5
		Total	29	10.96±1.98	10.20–11.71	6.9	14.5
	Sti-Li (lower lip vermilion) (mm)	Control	16	7.62±0.87	7.16–8.08	6.2	8.9
		Experimental	13	9.22±1.89	8.08–10.36	4.0	11.7
		Total	29	8.34±1.61	7.73–8.95	4.0	11.7
	Nasolabial angle (°)	Control	16	110.63±9.45	105.60–115.66	86.0	121.6
		Experimental	13	103.65±6.19	99.90–107.39	90.1	110.4
		Total	29	107.50±8.76	104.17–110.83	86.0	121.6

SD: Standard deviation; CI: Confidence interval

nasolabial angles tended to show more changes in this measurement after treatment, while cases with more obtuse nasolabial angles tended to change less by the treatment [Table 3].

DISCUSSION

The findings of this study indicated that soft tissue changes in the vertical dimensions of the lips, especially the interlabial gap, were significant either using the activator high-pull headgear alone or the activator headgear together with lip stretching exercises. One of the most important results obtained in this study was the significant difference between the two groups in terms of reducing the distance between the lips and increasing the length of the upper lip, which shows the effect of the addition of lip exercises. The causes of changes might be a

Table 2: Descriptive statistics and 95% confidence intervals for the changes in orthodontic parameters after treatment (calculated as posttreatment minus pretreatment)

Parameter	Group	*n*	Mean±SD	95% CI	Minimum	Maximum
Convexity angle (°)	Control	16	4.33±2.14	3.19–5.47	1.4	9.3
	Experimental	13	5.16±2.20	3.83–6.49	2.7	9.1
	Total	29	4.70±2.17	3.88–5.53	1.4	9.3
Interlabial gap (mm)	Control	16	−1.54±1.52	−2.35–−0.73	−5.4	0.0
	Experimental	13	−3.05±1.44	−3.92–−2.19	−4.8	−0.7
	Total	29	−2.22±1.64	−2.84–−1.59	−5.4	0.0
Sn-Sts (upper lip length) (mm)	Control	16	1.06±0.81	0.62–1.49	−0.3	2.5
	Experimental	13	2.17±0.98	1.58–2.76	0.6	3.5
	Total	29	1.56±1.04	1.16–1.95	−0.3	3.5
Sts-Ls (upper lip vermilion) (mm)	Control	16	0.35±0.76	−0.05–0.75	−1.4	2.0
	Experimental	13	1.03±0.67	0.63–1.44	0.1	2.3
	Total	29	0.66±0.79	0.36–0.95	−1.4	2.3
Sti-Ils (lower lip length) (mm)	Control	16	0.84±0.77	0.43–1.25	0.2	3.3
	Experimental	13	0.78±0.70	0.35–1.20	−0.7	2.3
	Total	29	0.81±0.73	0.53–1.09	−0.7	3.3
Sti-Li (lower lip vermilion) (mm)	Control	16	0.57±0.75	0.17–0.97	−0.8	2.1
	Experimental	13	0.62±0.67	0.21–1.02	−0.2	1.9
	Total	29	0.59±0.70	0.32–0.86	−0.8	2.1
Nasolabial angle (°)	Control	16	3.38±7.40	−0.57–7.32	−19.8	10.5
	Experimental	13	5.48±5.46	2.18–8.79	−1.0	20.0
	Total	29	4.32±6.58	1.82–6.82	−19.8	20.0

SD: Standard deviation; CI: Confidence interval

combination of the following factors: The correction of patients' skeletal relationship with mandibular protrusion and prevention of the forward and downward growth of the maxilla in addition to the correction of patients' overjet due to the retroclination of the upper incisors and the proclination of the lower incisors and their uprighting helps reduce the gap between the lips. Furthermore, lip-incompetent patients do not have anterior seals and their upper lip may have hypofunction due to which muscle growth in this part occurs less than other parts. In patients receiving a functional device for the treatment of skeletal relationships, protruding the mandible helps to create some lip seal and closure. However, patients who also did lip exercises also helped to activate the orbicularis oris and superior levator muscles, thereby increasing the growth of these muscles. Various factors can cause lip incompetence, such as anterior open bite, excessive facial high, a lack of upper lip height, and excessive overjet,[22] some of which are commonly seen in class II Div1 individuals. According to Leonardo *et al*.[1] incompetent lips are more common in class II individuals with increased lower face height who have pogonion retrognathism.

The muscle that engages the lips is mainly the orbicularis oris, which is a striated muscle and surrounds the mouth opening. Decreased function of this muscle can cause the lips to not close completely.[8] This forces the patient to swallow while placing the tongue in contact with the lower lip to provide an anterior seal, which leads to hyperfunction of the lower lip and mentalis muscles.[23] Various exercises can improve the muscular strength of the lips; there are also various approaches for lip training, including hand exercises, oral screen, Iowa oral performance instrument, and JMS.[8] About 71.8% of orbicularis oris muscle fibers are type II, which are involved in rapid contractions, and 28.2% are type I muscle fibers, which are involved in slow contractions; the latter is suitable for continuous exercise and is more resistant to fatigue.[24] Type I fibers are found in conditioning muscles;[25] therefore, it is suggested that these muscles play a role in maintaining lip seal after exercise and that to maintain lip competence, the endurance of these muscles must be increased; such increases in the stamina of these muscles were shown after lip exercises.[26] In a study on lip muscle exercise, it was found that changes in the upper and lower lip dimensions were significant.[27]

In people with skeletal malocclusion Cl II Div1, overjet is increased; also, typically, these patients have a smaller mandible than those with class 1 skeletal relationship.[28] Therefore, one of the first

Table 3: Partial correlation coefficients (*r*) across the studied variables, controlling for control/experimental grouping

Variable	Parameter	Co-op	Age	Pretreatment measurements							Changes caused by treatment						
				Convex	Gap	Sn-Sts	Sts-Ls	Sti-Ils	Sti-Li	NL	Convex	Gap	Sn-Sts	Sts-Ls	Sti-Ils	Sti-Li	NL
Patients																	
Sex	*r*	−0.393	−0.121	0.209	0.342	0.154	0.054	−0.101	0.386	0.122	−0.112	0.022	−0.360	−0.096	−0.216	−0.012	−0.417
	P	0.039	0.539	0.286	0.075	0.434	0.783	0.609	0.042	0.535	0.570	0.910	0.060	0.628	0.269	0.950	0.027
Co-op	*R*		0.152	−0.072	−0.031	−0.181	−0.166	0.129	0.050	−0.056	0.469	−0.331	0.281	−0.014	0.156	−0.109	0.038
	P		0.441	0.715	0.874	0.356	0.399	0.513	0.801	0.775	0.012	0.085	0.148	0.942	0.429	0.580	0.849
Age (year)	*R*	0.152		−0.280	−0.107	0.120	−0.061	0.147	0.052	0.438	0.322	−0.246	0.166	−0.237	0.258	−0.035	−0.314
	P	0.441		0.148	0.588	0.543	0.757	0.455	0.794	0.020	0.094	0.207	0.400	0.225	0.184	0.861	0.104
Pretreatment																	
Convexity (°)	*r*	−0.072	−0.280		−0.216	−0.084	−0.006	−0.221	0.037	−0.499	−0.344	0.149	−0.002	0.287	−0.477	−0.030	0.220
	P	0.715	0.148		0.269	0.671	0.974	0.258	0.854	0.007	0.073	0.450	0.990	0.139	0.010	0.879	0.261
Interlabial Gap (mm)	*r*	−0.031	−0.107	−0.216		−0.184	0.034	−0.176	0.316	−0.060	−0.031	−0.582	0.198	−0.161	−0.076	0.014	−0.077
	P	0.874	0.588	0.269		0.348	0.865	0.372	0.101	0.762	0.875	0.001	0.313	0.412	0.699	0.945	0.696
Sn-Sts (mm)	*r*	−0.181	0.120	−0.084	−0.184		0.030	0.522	0.194	0.355	0.115	0.341	−0.309	0.029	0.093	−0.399	0.017
	P	0.356	0.543	0.671	0.348		0.880	0.004	0.323	0.064	0.559	0.076	0.109	0.882	0.636	0.035	0.933
Sts-Ls (mm)	*r*	−0.166	−0.061	−0.006	0.034	0.030		0.106	0.263	0.052	−0.094	0.117	−0.425	−0.479	0.158	−0.217	0.093
	P	0.399	0.757	0.974	0.865	0.880		0.591	0.177	0.794	0.633	0.552	0.024	0.010	0.421	0.268	0.637
Sti-Ils (mm)	*r*	0.129	0.147	−0.221	−0.176	0.522	0.106		0.211	0.202	0.344	0.241	−0.221	−0.064	0.152	−0.369	0.198
	P	0.513	0.455	0.258	0.372	0.004	0.591		0.281	0.302	0.073	0.217	0.259	0.748	0.439	0.053	0.313
Sti-Li (mm)	*r*	0.050	0.052	0.037	0.316	0.194	0.263	0.211		0.031	0.187	−0.343	−0.418	−0.065	−0.047	−0.212	−0.156
	P	0.801	0.794	0.854	0.101	0.323	0.177	0.281		0.877	0.342	0.074	0.027	0.744	0.811	0.279	0.427
Nasolabial (°)	*r*	−0.056	0.438	−0.499	−0.060	0.355	0.052	0.202	0.031		0.151	0.230	−0.124	−0.223	0.202	−0.110	−0.581
	P	0.775	0.020	0.007	0.762	0.064	0.794	0.302	0.877		0.442	0.239	0.529	0.253	0.302	0.577	0.001
Changes caused by treatment																	
Convexity (°)	*r*	0.469	0.322	−0.344	−0.031	0.115	−0.094	0.344	0.187	0.151		−0.232	0.125	−0.104	0.226	0.033	0.043
	P	0.012	0.094	0.073	0.875	0.559	0.633	0.073	0.342	0.442		0.235	0.525	0.597	0.248	0.866	0.827
Interlabial Gap (mm)	*r*	−0.331	−0.246	0.149	−0.582	0.341	0.117	0.241	−0.343	0.230	−0.232		−0.324	−0.013	−0.027	−0.269	0.192
	P	0.085	0.207	0.450	0.001	0.076	0.552	0.217	0.074	0.239	0.235		0.093	0.947	0.891	0.166	0.328
Sn-Sts (mm)	*r*	0.281	0.166	−0.002	0.198	−0.309	−0.425	−0.221	−0.418	−0.124	0.125	−0.324		0.245	−0.052	0.136	0.213
	P	0.148	0.400	0.990	0.313	0.109	0.024	0.259	0.027	0.529	0.525	0.093		0.208	0.793	0.490	0.278
Sts-Ls (mm)	*r*	−0.014	−0.237	0.287	−0.161	0.029	−0.479	−0.064	−0.065	−0.223	−0.104	−0.013	0.245		−0.255	0.228	0.055
	P	0.942	0.225	0.139	0.412	0.882	0.010	0.748	0.744	0.253	0.597	0.947	0.208		0.191	0.244	0.780
Sti-Ils (mm)	*r*	0.156	0.258	−0.477	−0.076	0.093	0.158	0.152	−0.047	0.202	0.226	−0.027	−0.052	−0.255		0.157	0.043
	P	0.429	0.184	0.010	0.699	0.636	0.421	0.439	0.811	0.302	0.248	0.891	0.793	0.191		0.424	0.827
Sti-Li (mm)	*r*	−0.109	−0.035	−0.030	0.014	−0.399	−0.217	−0.369	−0.212	−0.110	0.033	−0.269	0.136	0.228	0.157		−0.181
	P	0.580	0.861	0.879	0.945	0.035	0.268	0.053	0.279	0.577	0.866	0.166	0.490	0.244	0.424		0.357

Co-op: Cooperation; Convex: Convexity angle; Gap: The interlabial gap; NL: Nasolabial angle options for treating patients who are in growth age but have not entered their growth spurt is the use of functional devices, which have different types such as twin block, Herbst, Bionator, and activator, which improve the intermaxillary relations because of the anterior shift of the mandible and also the increase in the growth of its body.[29] However, long-term research has shown that after the complete eruption of permanent teeth, the length of the mandible is not much different from that in normal people, which might be due to the late growth of the mandible or the so-called "catch up" in these people.[30] Due to the removal of the mandible from the glenoid fossa in the activator device and the creation of a tensile force in the head of the condyle, after treatment with this device, growth changes are observed in addition to the base in the head of the mandibular condyle; this increases facial height.[29] This is undesirable in people with a longer lower face, so orthodontists use high-pull headgear to control vertical growth in such patients.

In addition to retruding the maxilla, the retainer prevents it from growing forward and vertically.[31] If the center of force exerted by this appliance is focused behind the maxilla base, it will cause the maxilla plane to rotate slightly clockwise, which helps prevent facial height increase. In addition, this appliance intrudes the maxillary molars and, in return, extrudes the mandibular molars.[32] Overall, it might be said that a functional device such as an activator with high-pull headgear is one of the best treatment plans for patients with class II Div1 occlusions and long faces.[33] After using the activator appliance, the vertical changes of the upper lip were significant, showing that this appliance might be effective in increasing the vertical height of the lips, especially the upper lip; this was in line with some previous studies.[19,34] However, such changes might not always happen.[7] The controversy might be attributable to different sample characteristics and other methodological variations. Besides, a considerable part of the corrections observed in the interlabial gap after using activator headgear can be due to retroclining the maxillary incisors.[8,19] Moreover, it is possible that this treatment protrudes the lower lip,[35] again contributing to the decrease in the interlabial gap.

Another factor contributing to the interlabial gap closure is the rectification of the intermaxillary relationship. The present study showed that the activator headgear appliance can influence facial convexity, which agreed with previous research and due to the correction of the class II relationship.[19] However, a study showed that despite the correction of the intermaxillary relationship, the profile convexity did not change significantly.[31]

Among the potentially associated factors, very few correlations were observed with any changes. Patient's cooperation could affect only profile convexity (i.e. more corrections seen in patients with cooperative patients). It is said that sex might affect the soft-tissue alterations, with girls showing greater changes.[6] However, this was not the case in the present study except in the case of the length of the upper lip.

This study was limited by some factors. Although the sample size had been calculated to obtain adequate powers, 3 experimental patients who had been lost to follow-up could not be replaced. Still, the sample was large enough to provide various significant results. Future studies should improve their methods noting our limited methodology: It would be better to also use other factors, such as the mandibular plane angle, to identify long-face patients. Moreover, although a rather strong correlation exists between the chronological and skeletal ages of patients,[36] it would still be better to also check the patients' skeletal age. It should be noted that these methods need radiography which is not always available, especially in many prospective cases. The generalizability of this study was limited to patients with skeletal class II malocclusions, long faces, and their demographics.

CONCLUSION

Within the limitations of this study, it could be concluded that without lip exercises, 6–8 months of treatment with the activator high-pull headgear can close the interlabial gap, increase upper and lower lip lengths, increase profile convexity, and increase the lower lip vermilion height. However, the addition of lip exercise to the activator high-pull headgear can cause significance changes in all the assessed 7 parameters over the 6–8-month course of the treatment (interlabial gap, the lengths of both lips and their vermilions, nasolabial angle, and profile convexity).

The extents of these changes observed in the lip exercise group were greater than the control group in terms of the interlabial gap closure, the upper lip length increase, and the upper vermilion height increase. Poor patient cooperation might reduce the extent of correction caused by treatment to facial profile convexity. Females might experience slightly greater increases in their upper lip length.

Women might show slightly better results in their upper lip length increase compared to men, although this finding is not conclusive and needs more evidence. Corrections to the convexity angle may be more successful in cooperative patients compared to poorly cooperative ones. Age was correlated with the pretreatment nasolabial angle, but not necessarily with changes in nasolabial angle caused by treatment. Cases with less obtuse pretreatment baseline nasolabial angles are more prone to changes in this measurement after treatment.

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Conflicts of interest

The authors of this manuscript declare that they have no conflicts of interest, real or perceived, financial or nonfinancial in this article.

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