Original Article

A prospective controlled evaluation of Class II division 1 malocclusions treated with fixed lingual mandibular growth modificator

Osama H. Alali[a]

ABSTRACT

Objective: To assess the net dentofacial effects of the fixed lingual mandibular growth modificator (FLMGM).

Materials and Methods: The study sample comprised 38 patients with Class II/1 malocclusion and retrognathic mandible. All were in the pubertal growth spurt. Whereas FLMGM was applied to the treatment group (n = 21, mean age = 13.2 years), no treatment was performed on the control group (n = 17, mean age = 12.5 years). Skeletal and dentoalveolar changes were assessed on digital lateral cephalograms obtained at the beginning and end of the treatment/observation period of 8 months. Paired and independent *t*-tests were used to assess the differences within and between groups.

Results: Maxillary growth was not affected by FLMGM treatment, which resulted in a significant overjet reduction of 4.1 mm, an increase in total mandibular length (Co-Gn) of 2.3 mm, chin advancement of 1.6°, and upper incisor retroclination of 4.0°. A reduction of 2.4° in ANB was largely due to an increase of 1.8° in SNB. Favorably, the lower incisors were obviously retroclined by 4.5°. The changes in the vertical skeletal relationships were negligible.

Conclusion: FLMGM was effective in treating growing Class II/1 patients and produced favorable dentofacial effects, with the matched untreated sample showing minimal changes. Lower incisor retroclination was a benefit of FLMGM treatment. (*Angle Orthod.* 2014;84:527–533.)

KEY WORDS: Fixed lingual mandibular growth modificator (FLMGM); Class II division 1 malocclusion; Mandibular retrusion; Dentofacial effects

INTRODUCTION

Mandibular retrusion is the most common component of Class II division 1 (Class II/1) malocclusion.[1] A wide range of functional appliances have been introduced that aim at mandibular growth modification by forward posturing of the mandible.[1] Some are removable, such as the activator,[2] double-plate,[3] and twin-block[4] appliances; others are fixed,[5] such as the Herbst[2] appliance, mandibular anterior repositioning appliance (MARA),[6] and functional mandibular advancer (FMA).[5]

The removable double-plate appliance, also referred to as the Bite Jumping Appliance (BJA),[3,7,8] was first introduced by Schwarz in the early 1940s[9] and subjected to numerous modifications.[7–10] The original design and all its modifications, however, incorporate an inclined plane in the mandible and guide bars in the maxilla as the mechanism of action.[11]

Numerous studies[3,7,8,12–15] have verified the effectiveness of the double-plate system in treating Class II/1 malocclusions. A recent randomized, controlled trial carried out by Martina et al.[15] concluded that BJA effectively corrects Class II malocclusions and produces a significant increase in mandibular length, reduction in dental overjet, and improvement in molar relationship. This effectiveness prompted the author to develop a fixed double-plate system for the correction of skeletal Class II malocclusions in growing patients, termed fixed lingual mandibular growth modificator (FLMGM).[16] This novel functional appliance is esthetic, cost effective, and clinically easy to handle.[16]

The effects of FLMGM in consecutively treated Class II/1 malocclusion patients have not yet been

[a] Assistant Professor, Department of Orthodontics, School of Dentistry, University of Aleppo, Al-Shahbaa, Aleppo, Syria.

Corresponding author: Dr Osama H. Alali, PO Box 10256, Aleppo, Syria
(e-mail: osama-alali@hotmail.com)

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Table 1. Study Sample: Sex Distribution, Withdrawals, and Chronological Age (Years) of the Final Sample[a]

	FLMGM Group			Control Group			Total Sample		
	Male	Female	Total	Male	Female	Total	Male	Female	Total
Initial sample									
n	11	14	25	8	10	18	19	24	43
Dropouts									
n	1	3	4	1	0	1	2	3	5
Final sample									
n	10	11	21	7	10	17	17	21	38
Start age	13.3 ± 1.1	13.1 ± 0.8	13.2 ± 0.9	12.9 ± 2.1	11.8 ± 2.3	12.5 ± 2.1	13.2 ± 1.4	12.9 ± 1.3	13.0 ± 1.3

[a] FLMGM indicates fixed lingual mandibular growth modificator.

investigated, and the literature pertaining to this novel corrector is restricted to a single case report[16] in which the efficacy was three-dimensionally quantified and displayed.

The current trial was, therefore, designed to investigate the possible initial net skeletal and dental effects of treatment with FLMGM by a comparative evaluation of treated and untreated Class II/1 malocclusion subjects. The null hypothesis stated that there were no significant differences in dentofacial changes between the FLMGM group and the control group.

MATERIALS AND METHODS

The current study was a prospective, controlled clinical trial conducted at the University of Damascus, Department of Orthodontics between May 2009 and June 2011. The protocol of study was approved by the council of scientific research and postgraduate studies.

The original study sample included 43 patients (25 treated, 18 untreated). Each patient fulfilled the following criteria:

- Class II/1 malocclusion with (overjet $>$ 4 mm).
- Mild to moderate skeletal Class II (ANB $>$ 4° and APg/NL $<$ 80°) with retrognathic mandible (SNB $<$ 76°).
- Somatic maturation. The Fishman method was used to assess the hand-wrist radiographs, and only patients in the pubertal growth spurt peak, which occurs between stages 4 and 7,[17] at the beginning of the treatment/observation period were invited.

All subjects were randomized by the author at the beginning of the study to either the treatment or control group. Of the 43 patients initially enrolled, 38 completed this trial and constituted the final sample, and five (four treated, one untreated) were excluded (Table 1); the five excluded patients were unable to return for final records because of change of residence to a different area. Treatment group patients (n = 21, mean age = 13.2 years) were treated with FLMGM. After a period of 8 months, the FLMGM was removed to record posttreatment findings, then the treatment was continued beyond this time point if the Class II malocclusion was not fully corrected and clinical objectives were not achieved. On the other hand, no orthodontic treatment was performed during the same period for the subjects of the control group (n = 17, mean age = 12.5 years), and most of the control subjects were offered suitable treatment at a later date.

All patients and parents gave prior informed consent to their inclusion in the investigation. The observation period of 8 months was chosen in agreement with other articles studying fixed functional appliances.[5,6,18,19]

Sample Size Considerations

Clinical and statistical significance in mandibular length change was defined, in the literature, as at least a +2-mm difference between Class II treated and untreated groups.[20] Based on that difference and standard deviation from previous investigations, a power analysis determined that, for a two-sided 5% significance level and a power of 80%, a sample size of 16 per group would be required. Accordingly, assignment continued until 25 patients had enrolled in the treatment group to compensate for any unexpected dropouts. In the control group, the enrollment continued until the minimum number of patients required to satisfy the statistical power was reached.

The Appliance

FLMGM consists of two separate and fixed parts (Figure 1). The maxillary part has four components (Figure 1A,D): (1) an acrylic button similar to the Nance button, (2) two retention wires (1 mm) running posteriorly to enter into the headgear tube, (3) two retention hooks (0.8 mm) directed anteriorly and welded to the retention wire before entering the headgear tube, and (4) advancing loops (1 mm) consisting of two consecutive, long U loops.

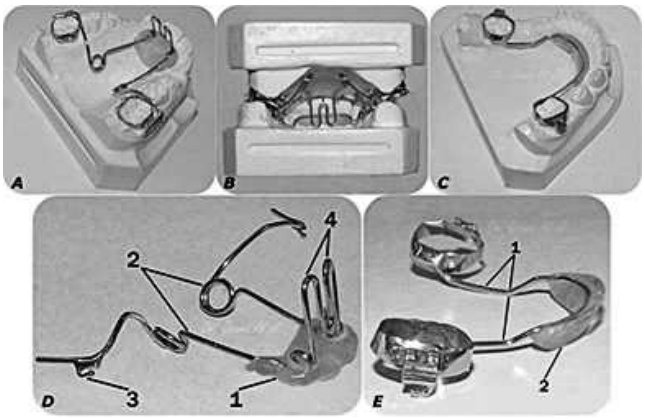

Figure 1. Fixed lingual mandibular growth modificator (FLMGM).

The mandibular part (Figure 1C,E) is similar to a standard lingual arch and welded to the lingual aspect of the molar bands. It includes an acrylic, anterior, inclined guiding plane seated on the lingual alveolar mucosa below the incisors; the plane is smooth to allow sliding against the advancing loops during mandibular closing movement to reach its anterior position.

A construction bite registration was taken with the incisors in an edge-to-edge relationship where achievable. If this position was not attainable, then the bite was recorded in a comfortable anterior position, and, during treatment, the advancing loops were reactivated when necessary at the chair side. Once the patient's mouth begins to close, the inclined plane and the advancing loops will come in contact in the anterior area of the mouth. Continued mouth closing will force the inclined plane to slide against the loops, and eventually the mandible will take a predetermined forced anterior position.

All appliances were fitted by the same orthodontist within 2 weeks of the patient's initial records. After fitting, all treated patients were instructed to bite in the therapeutic anterior position, to keep their lips in touch as much as possible, and to return at 6-week intervals until the end of treatment duration.

Analyses of Lateral Cephalograms

For each subject, a direct digital lateral cephalogram was taken pre- and posttreatment/observation period using PAX 400 (Vatech Co, Hawseong, Gyeonggi, Korea) with the same settings. Cephalograms were digitized on screen and analyzed in a blind manner by the same orthodontist using cephalometric software (Viewbox, version 3.1.1.13; dHal Software, Kifissia, Greece). Cephalometric landmarks and lines used in the cephalometric analysis are illustrated in Figure 2. Measurements are shown in Table 2. All linear measurements were reduced to life size (enlargement: 7.54%).

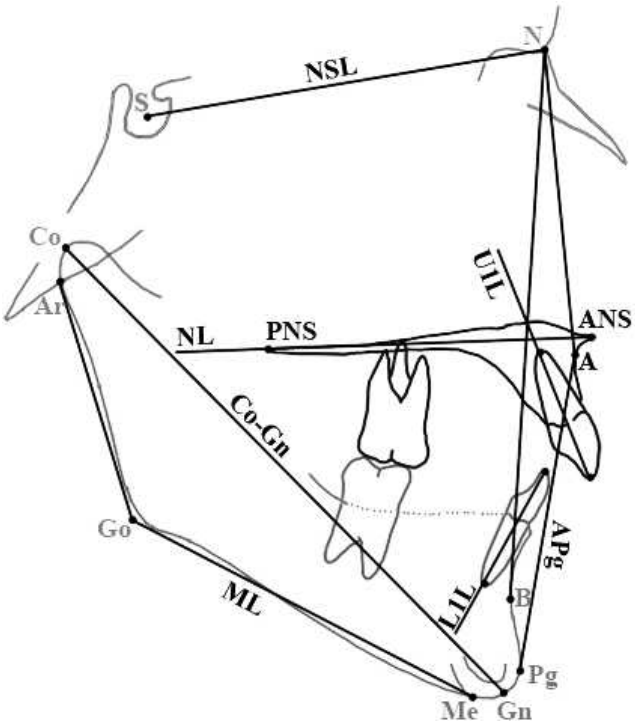

Figure 2. Landmarks and lines used in the cephalometric analysis.

Statistics

Pretreatment equivalence, changes occurring during the examination period in each group, and comparison of changes observed in both groups were tested for significance with *t*-tests using SPSS (ver.16.0; SPSS Inc, Chicago, Ill). $P < .05$ was considered statistically significant. To assess the method error, 20 cephalograms were randomly picked from both groups and redigitized and analyzed by the same orthodontist after 1 month, and the method error was calculated by the Dahlberg formula. The error ranged between 0.13–0.45 mm and 0.16–0.56° for the linear and angular measurements, respectively.

RESULTS

Both groups showed pretreatment equivalence for sex distribution and starting age. Cephalometrically, of the measured variables, four angular variables showed differences between the two test groups (Table 2).

Dentofacial effects for each group and net FLMGM effects are presented in (Table 3), and these net effects would all be expected outcomes of FLMGM treatment. Changes in a Class II/1 patient representative of the FLMGM treatment group are shown in (Figure 3).

Table 2. Pretreatment Equivalence of the Treatment Group Before Fitting the Appliance and the Control Group at the Start of the Examination Period[a]

Measurements	FLMGM Treatment Group (n = 21) Mean ± SD	Class II Control Group (n = 17) Mean ± SD	95% CI	*P* Value
Sex and age				
Sex (male/female)	10/11	7/10	–	.501*
Chronological age, y	13.2 ± 0.9	12.5 ± 2.1	−1.03 to +2.46	.372
Cephalometric analysis				
Mandibular length and configuration				
Co-Gn, mm	103.1 ± 4.5	101.5 ± 6.7	−6.18 to +2.92	.467
ArGoMe, °	122.5 ± 5.9	127.4 ± 7.3	−0.46 to +10.28	.071
Sagittal jaw relation				
SNA, °	80.7 ± 2.4	77.5 ± 3.4	−5.82 to −0.85	.011
SNB, °	73.5 ± 2.7	71.6 ± 2.3	−3.39 to +1.46	.413
SNPg, °	74.9 ± 3.0	72.1 ± 2.4	−5.19 to −0.43	.023
ANB, °	7.2 ± 1.6	5.9 ± 1.7	−1.65 to +1.12	.693
APg/NL, °	77.6 ± 2.9	79.0 ± 2.1	−0.67 to +3.50	.174
Profile convexity				
NAPg, °	193.3 ± 3.7	192.5 ± 4.1	−4.00 to +2.35	.614
Vertical jaw relation				
NL/NSL, °	9.7 ± 3.4	12.5 ± 3.2	−0.07 to +5.19	.076
ML/NSL, °	31.5 ± 3.7	37.1 ± 3.6	+1.95 to +9.29	.005
ML/NL, °	23.6 ± 2.9	24.8 ± 3.2	−1.53 to +3.91	.372
Face height index				
S-Go/N-Me, %	64.7 ± 2.0	63.7 ± 3.1	−3.64 to +1.56	.407
Dental relation				
Overjet	7.7 ± 3.3	6.7 ± 2.8	−3.44 to +1.42	.399
Incisor angular relation				
U1L/NL, °	113.6 ± 4.8	113.5 ± 4.1	−3.56 to +3.49	.984
L1L/ML, °	103.7 ± 6.3	96.2 ± 7.2	−12.81 to −2.10	.008
U1L/L1L, °	118.7 ± 5.7	122.0 ± 5.2	−1.13 to +7.73	.137

[a] FLMGM indicates fixed lingual mandibular growth modificator; 95% CI, 95% confidence interval; SD, standard deviation.
* Chi-square tests.

In the maxilla, there were no statistically significant differences between groups in skeletal measurements. The upper incisors were retroclined overall by 4.0° ($P < .001$).

In the mandible, there were great and significant differences observed for the sagittal mandibular skeletal measurements. Total mandibular length (Co-Gn) increased by 2.3 mm. With the chin moved forward, SNB and SNPg increased by 1.8° and 1.6°, respectively. Unexpectedly, the lower incisors of the FLMGM group retroclined significantly by 4.5° as a net effect.

Overall, FLMGM treatment produced an overjet reduction of 4.1 mm. The sagittal relation was significantly enhanced: ANB decreased by −2.4°, APg/NL increased by 4.3°, and the profile convexity (NAPg) improved by −3.9°. Face-height index change was not statistically significant.

DISCUSSION

The present trial aimed at evaluating the dentofacial effects of a novel functional appliance, FLMGM, in relation to growth. The results showed that FLMGM induced significant dentofacial changes in adolescent Class II/1 patients (Figure 3) when compared with untreated Class II/1 control patients, who showed minimal changes due to growth alone.

Changes in the treatment group reflect the combined effects of FLMGM and individual growth. Ideally, a matched or at least comparable control group should be included for identifying the changes due to growth.[2] A concurrent control group consisting of records obtained from untreated subjects exhibiting the same malocclusion was used in the present trial. Overall pretreatment comparison showed that the groups were reasonably well matched (Table 2). However, groups were not equivalent with respect to four variables. This difference is difficult to explain in a trial in which the group assignment was by random allocation. A possible explanation is that the random allocation of patients can lead to chance fluctuations between groups; therefore, there is no guarantee that the groups will be similar with respect to all variables.[21,22]

Table 3. Changes in the Cephalometric Variables at the End of the Examination Period and the Net Effects of FLMGM Treatment[a]

	FLMGM Treatment Group Change (n = 21)	Class II Control Group Change (n = 17)	Net Effects		
Measurements	Mean ± SD	Mean ± SD	Mean Treatment − Mean Control	95% CI	*P* Value
Mandibular length and configuration					
Co-Gn, mm	3.5 ± 1.4 *** [b]	1.2 ± 1.1 ** [b]	2.3	−3.35 to −1.30	.000 [c]
ArGoMe, °	0.4 ± 1.5 NS [b]	−0.6 ± 1.3 NS [b]	1.0	−1.79 to +0.50	.254 [c]
Sagittal jaw relation					
SNA, °	−0.4 ± 0.7 NS [b]	0.2 ± 0.8 NS [b]	−0.6	+0.08 to +1.22	.058 [c]
SNB, °	1.7 ± 1.1 *** [b]	−0.2 ± 0.7 NS [b]	1.8	−2.81 to −1.30	.000 [c]
SNPg, °	1.5 ± 0.9 *** [b]	0.0 ± 0.8 NS [b]	1.6	−2.36 to −0.99	.000 [c]
ANB, °	−2.0 ± 0.9 *** [b]	0.4 ± 0.7 NS [b]	−2.4	+1.75 to +3.11	.000 [c]
APg/NL, °	3.9 ± 2.0 *** [b]	−0.4 ± 1.5 NS [b]	4.3	−5.48 to −2.67	.000 [c]
Profile convexity					
NAPg, °	−3.9 ± 1.8 *** [b]	0.9 ± 1.9 NS [b]	−4.7	+3.24 to +6.19	.000 [c]
Vertical jaw relation					
NL/NSL, °	0.2 ± 0.6 NS [b]	0.2 ± 0.7 NS [b]	0.0	−0.53 to +0.50	.959 [c]
ML/NSL, °	0.4 ± 1.1 NS [b]	0.2 ± 1.4 NS [b]	0.2	−0.93 to +1.15	.823 [c]
ML/NL, °	0.2 ± 0.9 NS [b]	0.1 ± 1.3 NS [b]	0.2	−0.78 to +1.05	.763 [c]
Face height index					
S-Go/N-Me, %	0.5 ± 1.0 NS [b]	−0.2 ± 1.1 NS [b]	0.7	−1.21 to +0.54	.437 [c]
Dental relation					
Overjet	−3.3 ± 2.9 *** [b]	0.7 ± 0.9 * [b]	−4.1	+2.35 to +5.77	.000 [c]
Incisor angular relation					
U1L/NL, °	−3.1 ± 2.8 *** [b]	0.9 ± 2.7 NS [b]	−4.0	+1.80 to +6.18	.001 [c]
L1L/ML, °	−4.1 ± 4.7 ** [b]	0.4 ± 1.4 NS [b]	−4.5	+1.69 to +7.28	.004 [c]
U1L/L1L, °	7.1 ± 4.5 *** [b]	−0.9 ± 3.1 NS [b]	8.0	−11.33 to −5.21	.000 [c]

[a] FLMGM indicates fixed lingual mandibular growth modificator; SD, standard deviation; 95% CI, 95% confidence interval.
[b] Paired-samples *t*-test.
[c] Independent-samples *t*-test.
* $P < .05$; ** $P < .01$; *** $P < .001$; NS $P \geq .05$ (not significant).

A prospective design was used in the present trial so that treatment protocol could be standardized between all patients and the rate of treatment discontinuation could be accurately measured.[18] The discontinuation problem was reported with a rate of 27.7%, 15.8%, and 12.9% for the Bass,[4] twin-block,[4] and Herbst[18] appliances, respectively. The rate for FLMGM in this trial was 11.6%, and this figure compares favorably with reported rates. As long as there are dropouts from clinical trials, there is a natural increase in treatment effects.[23] To measure the true effectiveness of the treatment, an intention-to-treat analysis should be used.[24] In other words, the data analysis should include the results of treatment on all the patients

Figure 3. A 13.4-year-old girl treated with FLMGM. (A) Before. (B) Treatment beginning. (C) After 8 months, acceptable posterior interdigitation was established.

who initially entered the study, regardless of completion of the treatment. In fact, the data on the patients who dropped out of the current trial are not collected, as the patients failed to return at the end of the study period. For this reason, this approach was not performed.

The present trial, in agreement with the findings of other clinical studies using MARA,[6] FMA,[5] and twin-block applicances,[25] was not able to find evidence for headgear effect on the growth of the maxilla, probably because the maxillary part of the FLMGM does not convert the entire maxilla into a rigid unit (Figure 1A). In contrast, several clinical studies concluded that double-plate systems exert a growth-inhibiting effect on the maxilla.[7,8,13,14] A possible explanation of this effect is that the upper plate, which is anchored right on all erupted teeth, continuously transfers the inhibitory force originating from the mandibular retracting musculature to the maxilla via the guide bars.

In the current trial, which was started during the peak of the pubertal growth spurt, all mandibular skeletal variables measuring the changes in the mandibular growth were significantly different between groups (Table 3). Current mandibular position changes were similar to those reported in which SNB and SNPg decreased significantly using a double-plate system.[7,8,13,14] Moreover, there was an increase in mandibular length, and this increase was associated with significant chin advancement. These outcomes are in agreement with the findings of previous clinical studies using the MARA,[6] FMA,[5] BJA,[15] and twin-block appliance,[4] but they contradict the findings of studies by Lund and Sandler[25] and McNamara et al.[26] in which functional treatment led to an increase in the mandible length with no significant chin advancement. In principle, the clinical significance of a recorded increase in mandibular length needs to be considered in terms of forward chin positioning and must be assessed in relation to changes in the gonial angle.[27] When the gonial angle expands, it leads to a clockwise rotation of the mandible and consequently to a displacement of the chin posteriorly and to possible negation of the increase in mandibular length. In this trial, however, changes observed in the gonial angle were slight and not statistically significant. The increase in mandibular length, therefore, is due to the increase of the gonial angle only to an extremely minor extent.

The skeletal sagittal Class II relation was effectively enhanced (APg/NL significantly increased), and the profile convexity was improved (NAPg significantly decreased). This effect of FLMGM and other functional appliances, such as MARA[6] and twin block,[25] is not the result of an inhibitory effect on the maxilla but of a pronounced forward growth stimulation of the mandible. Otherwise, the double-plate system achieves the sagittal treatment goal through its almost exclusive effect upon the maxilla, with relatively limited influence on the mandibular position.[8,12–14] It has been reported that the pubertal growth spurt is the most suitable period in which growth modification can achieve pronounced skeletal effects.[28] The timing of FLMGM therapy, therefore, played a crucial role: the mandibular growth potential was successfully enhanced.

Increased vertical face height and opening rotation of the mandibular line has been commonly reported with functional treatment.[2,4,29] In the present trial, in agreement with the results of the Martina et al.[15] trial using the BJA, it is interesting to note that no significant modifications in the inclinations of the maxillary and mandibular lines were seen, thus avoiding the undesirable tendency toward clockwise mandibular rotation during treatment. However, the initial divergence of the jaws should be taken into account in any future studies using FLMGM.

The uprighting of the incisors, which is considered quite surprising in the mandible, was favorable and accounted for the increased interincisal angle. This can be attributed to two causes: (1) there is no mesial force acting on the lower teeth, because the acrylic inclined plane does not contact the lower anteriors,and (2) there is a mechanism of ''muscular equilibrium breaking'' between the tongue and lips. While the vertical advancing loops work as a shield to relieve tongue pressure on the incisors, only lingually directed functional forces generated by the sealed lips affect the incisors and cause lingual crown tipping. It is proven that palatal cribs eliminate the tongue/incisors contact, improve lip posture, and subsequently produce significant lingual incisor inclination.[30]

The double-plate system,[7,15] and most functional appliances[2,25] in general, frequently cause upper incisor retroclination and lower incisor proclination, which are usually considered unfavorable effects and should be limited, as they reduce the potential for orthopedic change.[31] The FLMGM appeared to be advantageous in terms of lower incisor retroclination, and this is somehow in accordance with the results of Cura et al.,[29] who found the Bass appliance to have little effect on the lower incisors, and Sander and Lassak,[7] who observed a minimal/clinically insignificant increase of the labial inclination of lower incisors as a result of the double-plate appliance. So, one can conclude that initial lower incisor proclination may no longer be a contraindication to FLMGM treatment as with Herbst and other intermaxillary functional appliances.[19]

From a clinical prospective, as with any appliance, FLMGM has clinical disadvantages. Swallowing, eating, and speaking could be cumbersome. Oral hygiene

is somewhat difficult in the lower lingual anterior area but has not been a problem. Lastly, it must be stressed that the present trial reported the short-term FLMGM effects, and no conclusions can be drawn about long-term stability.

CONCLUSIONS

- FLMGM was effective in treating Class II/1 growing patients and produced favorable and measurable dentofacial changes.
- Overjet reduction was achieved by a combination of upper incisor retroclination and increase in total mandibular length associated with forward chin repositioning.
- FLMGM appeared to be advantageous in terms of lower incisor retroclination.
- Horizontal maxillary growth and vertical jaw relations were not statistically different.

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