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Three-Dimensional Evaluation of Mandibular Changes following Treatment with a New Clear Mandibular Advancement Appliance

Ahmed Mostafa Zaky [a], Ibrahim Mazen Negm [b]

Abstract

Objectives: *This prospective clinical trial evaluates the skeletal and dental effects of a new clear mandibular advancement appliance (CMAA) based on the Twin-block design.* ***Materials and Methods:*** *Twenty-Five class II female patients aged 8-12 years (average 10) with mandibular deficiency (SNB≤78) were selected and fitted with the CMAA. The average follow-up period was 13 months. Cone Beam Computed Tomography scans of the patients pre and post operatively were obtained to evaluate the three-dimensional changes achieved with the use of the appliance.* ***Results:*** *There was significant increase in the effective mandibular length with an amount of 5.2mm ±2.58mm, a decrease in ANB angle by -1.88 ± 0.99 whereas SNB angle showed statistically significant increase by 1.92 degrees.* ***Conclusion:*** *The CMAA is an effective functional appliance for treatment of growing skeletal class II malocclusions due to retrognathic mandible, though the skeletal changes were not fully expressed due to the clockwise rotation of the mandible.*

This trial was registered on clinicaltrials.gov under the registration number NCT03824574.

Keywords: Twin-Block, Class II, Functional appliance, Deficient mandible, overjet

Introduction

Class II malocclusion occurs in a huge proportion of the population among different races [1,2,3]. Skeletal mandibular retrusion has been found to be the most common diagnostic finding associated with Class II malocclusion and thus an orthodontic therapy able to enhance growth of the mandible has long been aimed for during treatment of all growing Class II subjects.

Early correction of Class II malocclusion has been proven to reduce chances of incisal trauma. The timing of Class II correction is crucial and was found to be most efficient during or slightly after the onset of the pubertal peak in growth velocity [4].

The Twin-block appliance is by far the most common functional appliance used in the orthodontic office [5]. The Twin-block appliance was found to produce comparable skeletal and dental effects to the Herbst and Frankel II appliances [5,6]. Some studies proved that the Twin-block appliance produced significant skeletal and dental effects [7,8,9,10] while others did not show any noticeable effect [11]. Several modifications for the Twin block appliance were attempted during the years in order to make it more appealing or produce a better effect[12,13,14].

Transparent teeth positioners were previously used to correct minor tooth movements through modification of dental models. During the past decade teeth positioners or in other words dental aligners have been attempted for more and more complex cases from mild to severe crowding and they are now even being used for extraction treatments [14].

The development of this kind of orthodontic therapy and increasing patient

a Lecturer, Department of Orthodontics, Faculty of Dentistry, Ain Shams University, Cairo, Egypt.

b Associate Professor, Department of Orthodontics, Faculty of Dentistry, Ain Shams University, Cairo, Egypt.

demand for an esthetic appliance raised the question of whether we can combine a functional appliance and an aligner in one esthetic functional appliance which led to the development of the clear mandibular advancement appliance.

Material and Methods

Trial Design

This trial design is a longitudinal prospective clinical study. This study was approved by the research ethics committee (research ethics approval number RecD121312). After trial commencement no changes occurred in the methods.

Participants, Eligibility Criteria, and Settings

Subjects were selected from the outpatient clinic of the Orthodontic Department. Following a detailed explanation of the trial to the subjects and their guardians, a signed informed consent was obtained. Eligibility criteria included Twenty-Five female subjects aged between 8-12 years, skeletal class II malocclusion with normal maxilla and retruded mandible (SNB≤78), half to full unit Angle class II malocclusion, overjet 5-10mm, and growing subjects as revealed by cervical vertebral maturation method (CVMS) stage 2-3 [[15]]. Whereas the exclusion criteria included any systemic disease, dental anomalies, bad habits that might jeopardize the appliance, and previous orthodontic treatment.

Intervention and Outcomes

After clinical examination and obtaining full orthodontic records which confirmed the need for class II functional appliance therapy, alginate impressions were made (Major Prodotti Dentari S.P.A., Moncalieri, Italy). In addition, a protrusive wax bite (Cavex, Germany) was obtained by using the George Gauge to control the amount of protrusion required, which in our study was set so that the patient brings the mandible forwards to an edge-to-edge relationship. The impressions along with the protrusive bite were sent to the laboratory to construct the CMAA appliance. The fabrication of both the upper and lower Vacuum Pressed Positioners (VPPs) were accomplished via using a 1.5mm Essix plastic sheet (Dentsply Raintree Essix, Sarasota, Fla).

Bite ramps were then built on the VPPs using self-cured methyl methacrylate clear acrylic resin (Dentauram, Germany) to be at exactly 70 degrees angle to the occlusal plane.

After setting of the acrylic resin bite ramps, the appliance was removed from the models, finished, and polished (Fig. 1,2).

Figure 1 Finished and Polished CMAA

Figure 2 CMAA in place

Subjects were instructed to gradually increase appliance wear starting at 2 hours/day on the first day and increased by 4 hours daily reaching the desired wear time of 22 hours/day on the sixth day and discontinue appliance wear only during eating and tooth brushing. A wearing log was given for each subject to serve both as a reminder of appliance wear and as a method for monitoring the patient's compliance. The follow up visits were continued until the end of active functional appliance therapy (achieving edge to edge incisor relationship) or after twelve months whichever was closer (Fig. 3,4).

Figure 3 Pre vs post treatment profile

Figure 4 Pre vs post treatment side views

A pre and post treatment Cone Beam Computed Tomography (CBCT) scan for the subjects were obtained using the ICAT (GENDEX DENTAL SYSTEMS Hatfield, PA USA) with the following parameters: 15.4 mA, 120 Kv, FOV 12inch, exposure time 8.9 sec, and voxels size 0.3 (Fig. 5).

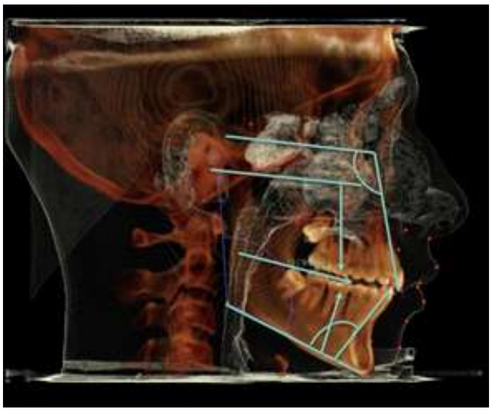

Figure 5 Pre vs post treatment side views

The primary outcomes were to evaluate the mandibular changes with the CMAA, whereas the secondary outcomes were the mandibular dental and soft tissue changes following CMAA.

Measurements

A standardized stepwise 3D Analysis was created through the 3D Analysis module of the InVivo Dental software (version 5.3; Anatomage, San Jose, CA, USA). Landmark identification (Table 1,2,3&4) was performed utilizing the slice locator utility of the software to localize each landmark on the axial, sagittal and coronal sections and confirmed on the 3D reconstruction of each subject. Data collection and analysis was performed by the second researcher.

Method Error

Ten pre and post CBCT scans were reanalyzed by both the principal researcher and second researcher a week after the primary analysis to assess the intra- and inter-observer reliability.

The Skeletal Mandibular Measurements:(Table 1)

	Measurement	Abbreviation	Definition
1	Effective Mandibular length (right and left)	Eff Man	Linear distance between Condylion and Gnathion (Cd-Gn).
2	Mandibular Body length (right and left)	Man body	Linear distance between Gonion and Menton (Go-Me).
3	Ramal length (right and left)	Ramal length	Linear distance between Condylion and Gonion (Co-Go).
4	Mandibular position	B-FP	Linear distance between B-point and frontal plane.
5	A-B difference projected on the Frankfurt Horizontal plane	A-B diff	Distance between points A and B projected of Frankfurt Horizontal plane.
6	Mandible to cranial base	SNB	Angle between points S, N and B.
7	Maxilla to mandible	ANB	Angle between points A, N and B.
8	Mandibular plane inclination	MP incl.	Angle between S-N line and Mandibular plane (MP-SN).
9	Maxillary-mandibular plane angle	MMP	Angle between Palatal line and Mandibular plane (PL-MP).
10	Rt and Lt Gonial angles	Go angle	Angle between Co, Go and Me (CoGo-GoMe).
11	Mandibular width	Mand width	Linear distance between right and left Gonion (Go R- Go L).

Lower Incisor Measurements:(Table 2)

	Measurement	Abbreviation	Definition
1	Lower incisors to mandibular plane	LR1, LL1 incl	Angle between the mandibular plane and the LR1 and LL1 long axes respectively as viewed from the sagittal view (LR1, LL1-MP).
2	Lower incisors antero-posterior position	LR1, LL1 AP position	Horizontal distance between the incisal edges of LR1 and LL1 and the frontal plane as viewed from the sagittal view (LR1, LL1 inc-FP).
3	Lower incisors vertical position	LR1, LL1 vert. position	Linear distance from the midroot of the LR1 and LL1 respectively to the mandibular plane as viewed from the sagittal view (LR1, LL1 mr-MP).
4	Overjet	L1-U1 H	Linear horizontal distance between incisal edges of the lower and upper central incisors.
5	Overbite	L1-U1 V	Linear vertical distance between incisal edges of the lower and upper central incisors.

Lower First Molar Measurements:(Table 3)

	Measurement	Abbreviation	Definition
1	Lower first molar vertical position	UR6-UL6 vert. position	Linear distance between the furcation area of the LR6 and LL6 respectively to the FHP as viewed form the sagittal view (UR6, UL6 F-FHP).
2	Lower first molar antero-posterior position (crown)	LR6, LL6 AP position C	Linear distance between the mesiobuccal cusp tip of the LR6 and LL6 respectively and the vertical plane as viewed from the sagittal view (LR6, LL6 tip-VP).
3	Lower first molar antero-posterior position (root)	LR6, LL6 AP. Position R	Linear distance between the mesiobuccal root apices of the LR6 and LL6 respectively and the vertical plane as viewed from the sagittal view (LR6, LL6 MB apx- VP).

Soft Tissue Measurements: (Table 4)

	Measurement	Abbreviation	Definition
1	Angle of facial convexity	N'Sn-SnPog'	Angle between soft tissue Nasion, Subnasale and soft tissue Pogonion.
2	Inter-labial gap	Sts-Sti	Vertical distance between Stomion superior and Stomion inferior.
3	Lower lip thickness	Li-inter L mx	Linear distance between Labrale inferior and the labial surface of the lower incisor.
4	Lower lip antero-posterior position to H line	Li-H line	Horizontal distance between Labrale inferior to H line.
5	Chin thickness	Pog-Pog'	Horizontal distance between soft and hard tissue Pogonion.
6	H angle	H line/N' Pog'	Angle between line joining soft tissue Nasion, soft tissue Pogonion and H line
7	Mento-labial sulcus	Li-Si/Si-Pog'	Angle between Labrale inferior, Sulcus inferior and soft tissue Pogonion.

Sample size Calculation

The sample size was calculated using G*Power software (Universty of Dusseldorf, Dusseldorf, Germany) for the primary outcome. Sample size calculation was based on the previous study conducted by Kirby A et al.[16], which examined the effect of the twin block appliance on the effective mandibular length change Co-Gn =6.5mm, SNB change=1.9 degrees. The calculation indicated that for a trial with a power of 80% and an alpha of .05 level of significance, 19 participants were required. To account for patient loss due to attrition, a sample of 25 subjects were recruited.

Blinding

Blinding of the researchers and subjects was not feasible due to the nature of this trial.

Statistical Methods

Descriptive statistics were calculated via the Statistical Package Social Science SPSS version 20 (SPSS Inc, Chicago, III). Data was explored for normality by utilizing Kolmogorov- Smirnov and Shapiro-Wilk tests. Data revealed a parametric distribution, a paired t-test was used to compare changes pre and post treatment. The significance level was set at P<.05. The Intra and Inter-observer reliability were measured via Intra-Class correlation coefficient (ICC).

Results

Baseline Data

Statistical Analysis of the collected data was performed, and the following results were obtained. The mean age of the subjects was 10 years with standard deviation of 9.6 months.

Intra and inter-observer reliability ranged from good to excellent for the measurements involving the selected landmarks. The following parameters should be considered when evaluating the results: ICC > 0.9 denotes excellent agreement or reliability, ICC > 0.8 denotes very good agreement and ICC > 0.7 denotes good agreement.

Anteroposterior skeletal measurements showed statistically significant increase in effective mandibular length, mandibular body length and increase in mandibular forward position, increase in the SNB angle, and decrease in ANB angle and linear A-B difference and increase in mandibular plane angle with SN plane. Transverse skeletal measurements revealed significant increase in mandibular intergonial width.

Table 5: Table showing pre and posttreatment changes in the anteroposterior linear and angular mandibular measurements

Variable	Pre		Post		MD	SD	P value	SE	95% Confidence Interval of the Difference	
	M	**SD**	**M**	**SD**					Lower	Upper
Effective Mandibular length	106.6	6.28	111.6	6.79	5.02	2.58	<0.001**	0.61	6.31	3.74
Mandibular body length	72.54	5.48	75.77	6.07	3.22	2.95	<0.001**	0.69	4.69	1.76
Ramal length	45.8	4.43	48.7	5.31	2.95	3.24	0.001*	0.76	4.56	1.34
Mandibular position	16.78	3.26	13.72	2.31	3.06	1.67	0.001**	0.75	-0.63	-2.49
A-B diff	14.60	3.55	12.98	4.21	-1.63	1.92	0.002*	0.45	-0.67	-2.58
SNB	73.47	4.08	75.38	5.06	1.92	1.79	<0.001**	0.42	2.80	1.03
ANB	7.70	2.66	5.82	3.02	-1.88	0.99	<0.001**	0.23	-1.38	-2.37
MP/SN	38.0	7.61	37.4	8.57	-0.65	2.32	0.002*	0.55	0.50	-1.81
MMP	28.3	9.21	27.5	10.1	-0.77	2.50	0.002*	0.59	0.48	-2.01
Gonial angle	129	6.51	129	6.55	0.58	2.72	0.377	0.64	1.93	-0.77
Mand. Width Go R-Go L	81.2	3.61	83.5	4.59	2.39	2.19	<0.001**	0.52	3.48	1.30

*: P<0.05: significant **: P <0.01: highly significant

The lower incisors showed statistically significant increase in its inclination in relation to the mandibular plane and NB line and significant increase in its vertical position in relation to the mandibular plane in addition to a decrease in overjet.

Table 6: Table showing pre and posttreatment changes in the lower incisors linear and angular measurements

Variable	Pre		Post		MD	SD	P value	SE	95% Confidence Interval of the Difference	
	M	SD	M	SD					Lower	Upper
L1 incl (L1-MP)	101.06	4.62	103.69	6.16	2.63	3.09	0.002*	2.12	4.95	-4.01
L1 AP position (L1 A Pog line)	4.69	2.89	5.05	1.57	0.36	2.47	0.542	0.80	-0.15	-3.53
L1 vertical position	25.25	2.11	27.02	3.45	1.77	1.87	0.001*	0.94	5.43	1.47
overjet	8.40	9.43	2.45	1.57	-5.95	2.33	<0.001*	3.07	-1.82	-14.85
overbite	6.26	5.38	5.25	8.26	-1.01	3.27	0.221	2.15	0.29	-8.84

*: P<0.05: significant **: P <0.01: highly significant

The lower molars showed statistically significant extrusion in relation to its vertical position in relation to the mandibular plane and significant mesial movement at both the crown and root level in relation to the vertical plane.

Table 7: Table showing pre and posttreatment changes in the lower molar linear measurements,

Variable	Pre		Post		MD	SD	P value	SE	95% Confidence Interval of the Difference	
	M	SD	M	SD					Lower	Upper
L6 vertical position	15.40	2.76	16.9	3.56	1.55	1.87	0.003*	1.28	4.36	-1.03
L6 AP position C	30.19	4.08	33.9	3.90	3.75	3.39	<0.001*	1.30	6.46	0.98
L6 AP position R	20.36	3.73	23.1	4.80	2.75	2.60	<0.001*	1.31	5.69	0.14

*: P<0.05: significant **: P <0.01: highly significant

The soft tissue measurements showed significant increase in soft tissue chin thickness decrease in the angle of facial convexity and Holdaway H-angle and increase in the mentolabial angle.

Table 8: Table showing pre and posttreatment changes in the mandibular soft tissue measurements

Variable	Pre		Post		MD	SD	P value	SE	95% Confidence Interval of the Difference	
	M	SD	M	SD					Lower	Upper
Angle of Facial convexity	26.7	4.78	22.2	4.21	-4.51	3.34	<0.01*	1.64	1.43	-5.49
Sts-Sti	4.35	2.82	4.42	3.93	0.07	5.12	0.956	1.04	1.78	-2.62
Li-inter L mx	11.6	4.47	14.1	1.79	2.52	5.49	0.069	1.13	4.48	-0.29
L lip - H line	2.65	1.03	3.31	1.72	0.66	1.43	0.067	0.41	1.31	-0.40
Pog-Pog'	10.1	1.79	12.2	2.31	2.15	2.31	0.01**	0.73	1.79	-1.27
H-angle	13.7	1.86	12.1	2.06	-1.60	1.24	<0.01*	0.71	3.11	0.13
Mento-labial sulcus	110	62.4	142	13.4	31.95	61.3	0.041*	16.3	63.55	-5.43

*: P<0.05: significant **: P <0.01: highly significant

Harms

No noticeable harms were reported other than two incidents of appliance breakage.

Discussion

Skeletal Class II malocclusion is one of the most common problems encountered in the orthodontic office and is a potential cause of psychological problems, bullying and teasing [17], airway problems [18], and increasing susceptibility to trauma. In addition, facial disfigurement has a negative impact on the child's social and physical development during his or her early years [7]. And since skeletal mandibular retrusion has been found to be the most common cause of skeletal class II malocclusion, an orthodontic therapy improving forward growth of the mandible has long been desired for growing Class II patients.

Orthodontists are still facing the dilemma of whether to start early functional appliance therapy or opting for camouflage or extraction therapy at a later stage. It always appeared more acceptable to prevent an abnormality or detect and treat it early rather than wait until it has become fully developed [13,14].

The choice to start a first phase of functional appliance therapy have been employed during the period of pubertal acceleration of skeletal growth. The sole purpose was to create the maximum possible impact on mandibular growth in the minimum amount of time and thus maximizing the efficiency of treatment. This improved the child profile and appearance during his early years and thus would have a positive impact on his life both psychologically and physically [13,14,15].

The major disadvantages of functional appliances were being bulky and inaesthetic interfering with patient's speech and functional development and affecting patient's compliance. The Twin-block functional appliance has been widely used in the orthodontic office [[19]], it consisted of separate upper and lower components; therefore, it was less conspicuous, less bulky and did not interfere with function. Despite these advantages, discontinuation rates with its use were still high; measuring between 9% and 15%. [14,15] This was attributed to patients demanding less bulky and less visible orthodontic devices. The Twin block appliance was used as the gold standard to which other functional appliances were compared to both old and new [[20],[21]].

Aligner therapy has become widespread during the past years. This esthetic treatment modality attracted both adolescents and adult patients; they were less bulky, did not involve complicated wire configurations, and could be removed during eating and oral hygiene measures. Therefore, it was appealing for orthodontists to adopt this widely demanded treatment strategy and implement it in a wide range of treatment options.

Accordingly, the incorporation of such esthetic appliance with a functional treatment modality was accomplished through adapting the original Clark Twin-block design with clear aligner therapy.

The efficiency of treatment of a retrognathic mandible strongly depends on the biologic responsiveness of the condylar cartilage [[22]]. During functional appliance treatment, changes in the mandibular condyle highly depend on the duration of functional therapy plus the direction, amount, and types of forces used. However, it is still undetermined whether growth modification enhances the total amount of mandibular growth or whether it only increases the rate of the genetically programmed amount of mandibular growth [[23]].

The results of the study revealed that most of the skeletal changes that occurred after the CMAA therapy were in the anteroposterior and vertical directions. There was a significant increase in the effective mandibular length with an amount of 5.2 mm $\pm$ 2.58 mm. These results were analogous to the amounts of effective mandibular length increase recorded by Toth et al.[24] and Jena et al.[25] reporting an increase of 5.7 and 5.4 mm respectively. In a comparative study, Giuntini et al.[17] reported an increase of 5.2mm with the Twin-block appliance compared to 3.2mm for the Forsus Fatigue resistant device and 2mm for the controls.

In our study, the increase in effective mandibular length was attributed to the increase in the length of the mandibular body of 3.2 mm and an increase in ramal length of 2.95 mm. These findings were corresponding to the results of Mills et al.[[26]] and Ajami et.al [[27]] both reporting an increase in the effective mandibular length. Similar changes were described by Yildrim et al.[[28]] who revealed growth of the condyle in an upward and backward direction resulting in an increase in condylar volume.

The SNB angle showed a statistically significant increase by 1.92 degrees. This little increase occurred despite the bigger increase in mandibular length which could be explained by clockwise rotation of the mandible masking the increase in effective mandibular length. The SNB angle only indicates positional rather than size change. Therefore, it should not be considered a sole indicator for measuring the effect of functional appliances on mandibular growth.

Several studies documented that in Class II subjects, there is a decrease in the Gonial angle with growth [29] Most studies involving functional appliance therapy documented an increase in the Gonial angle with therapy. This was mostly attributed to decreased muscle activity during functional appliance therapy which resulted in mild atrophic changes in the masticatory muscles and thus a decrease in muscle thickness. The transient muscle atrophy leads to a decrease in the mechanical stimuli required for the remodeling and development of the Gonial process of the mandible and thus leading to an increase in the Gonial angle [30].

In summary from a clinical standpoint, utilizing the CMAA resulted in enhancement in the soft tissue profile, reduction in overjet, and correction in molar and canine relationships. Even though the skeletal effects represented by the increase in the mandibular length was greatly camouflaged by the clockwise rotation of the mandible, it always will seem tempting to use our appliance among other functional appliances to get to a point with the second phase of therapy where the molars and canines are in a Class I relationship. Therefore, decreasing the complexity of phase 2 of orthodontic therapy leaving this phase with detailing final tooth positions and thus reducing the difficulty, invasiveness, and duration of that phase.

Limitations

The main limitation of this study was the absence of a control group. It was thought unethical to deny patients treatment during an important stage of their growth period. Another limitation was the absence of blinding for both the subjects and researchers, yet this did not affect the results since there was only one method of intervention. This study was limited to the first phase of treatment and conducted on female subjects only to benefit from their shorter period of pubertal growth acceleration.

Conclusion

The clear mandibular advancement appliance is an effective functional appliance for treating growing patients with skeletal Class II malocclusions due to retrognathic mandible and could be used as an alternative to the original Twin-block appliance.

The skeletal effects were not expressed fully due to the clockwise rotation of the mandible resulting from increase in ramal length and increase in the anterior facial height due to molars extrusion.

Disclosures

This study was self-funded by the principal researcher and thus there was no conflict of interest.

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