



# Three-dimensional skeletal and pharyngeal airway changes following therapy with functional appliances in growing skeletal Class II malocclusion patients

## A controlled clinical trial

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### Abstract

**Introduction** To three-dimensionally analyze the skeletal and pharyngeal airway changes induced by Twin Block (TWB) and Forsus Fatigue Resistance Device (FFRD) in skeletal Class II female patients compared with untreated controls.

**Materials and methods** The study comprised 62 growing female patients with skeletal Class II malocclusion due to mandibular retrusion treated with either TWB ( $n=23$ ) or FFRD ( $n=21$ ), or neither ( $n=18$ ; controls). Pre- and posttreatment/observational cone beam computed tomography images were used to evaluate the treatment changes.

**Results** TWB induced more obvious mandibular skeletal changes and caused significant retrusive effects on the maxilla. Similarly, the sagittal and vertical jaw relationships were affected more obviously with TWB ( $P < 0.001$ ) compared to FFRD. Changes in oropharyngeal volume and minimal axial area were more obvious with TWB.

**Discussion** The TWB functional appliance induced significant skeletal and pharyngeal airway changes. These changes were more obvious relative to the slight changes induced by FFRD or by natural growth.

**Keywords** Twin Block · Pharyngeal airway · Cone-beam computed tomography · Functional appliance · Mandibular skeletal changes

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## Dreidimensionale Veränderungen der skelettalen und pharyngealen Atemwege nach Therapie mit funktionellen Geräten bei heranwachsenden Patienten mit einer skelettalen Klasse-II-Malokklusion

Eine kontrollierte klinische Studie

### Zusammenfassung

**Einführung** Dreidimensional untersucht werden sollten TWB(Twin Block)- und FFRD(Forsus Fatigue Resistance Device)-induzierte Veränderungen der skelettalen und der pharyngealen Luftwege bei weiblichen Klasse-II-Patienten im Vergleich zu unbehandelten Kontrollen.

**Material und Methoden** Die Studie umfasste 62 heranwachsende weibliche Patienten mit skelettaler Klasse-II-Malokklusion bei mandibulärer Retrusion, die entweder mit TWB ( $n=23$ ) oder FFRD ( $n=21$ ) behandelt wurden. Eine weitere, nicht behandelte Gruppe ( $n=18$ ) diente der Kontrolle. Zur Beurteilung der therapiebedingten Veränderungen wurden DVT(digitale Volumentomographie)-Aufnahmen vor und nach der Behandlung bzw. während der Beobachtungsphase analysiert.

**Ergebnisse** Der TWB führte zu deutlicheren skelettalen Veränderungen der Mandibula und es kam zu signifikanten retrusiven Effekten auf die Maxilla. Auch die sagittalen und vertikalen Kieferrelationen wurden durch den TWB stärker verändert ( $<0,001$ ) im Vergleich zum FFRD. Änderungen des oropharyngealen Volumens und der maximalen Engstelle des Atemweges waren bei TWB deutlicher zu erkennen.

**Diskussion** Das TWB-Funktionsgerät führte zu signifikanten skelettalen Veränderungen und zu Veränderungen der pharyngealen Atemwege. Diese Veränderungen waren offensichtlicher im Vergleich zu den leichten Veränderungen, die durch die FFRD oder das natürliche Wachstum hervorgerufen wurden. .

**Schlüsselwörter** Twin Block · Pharyngealer Atemweg · Digitale Volumentomographie · Funktionelle Apparatur · Skelettale Veränderungen der Mandibula

### Introduction

Class II malocclusion is one of the most common problems in orthodontic practice accounting for approximately one-third of the patients seeking orthodontic treatment [1]. Like other types of malocclusion, Class II malocclusion causes esthetic, functional, and psychological problems, the severity of which depends on the amount of anteroposterior discrepancy and its interaction with the surrounding soft tissue structures. Various factors contribute to the development of Class II malocclusion, but mandibular retrognathism is the most common factor [2]. This mandibular positioning pattern can be corrected during the growth period using functional appliances that can aid in enhancing and/or redirecting mandibular growth in a favorable direction [3].

In this context, the Twin Block (TWB) is the most popular functional appliance during the last few decades [4]. Recent systematic reviews concluded that TWB is the most efficient removable functional appliance in producing skeletal changes [5, 6]. In contrast, other systematic reviews reviewed the effects of fixed functional appliances (e.g. Forsus Fatigue Resistance Device [FFRD]) and concluded that though the appliances cause dentoalveolar changes, there is no or minimal skeletal effect [7, 8]. Interestingly, a recent systematic review evaluated the skeletal effects of removable and fixed functional appliances and concluded that there was little evidence concerning the comparative effectiveness of the two types of appliances [9].

Moss and Simon [10] developed the functional matrix theory which states that “most of the growth and development of the craniofacial region is under the control of functional activity of the surrounding soft tissues.” Hence, a direct relationship does exist between pharyngeal airway spaces and craniofacial configuration; any abnormality in these spaces might affect the position of the surrounding skeleton and vice versa. Indeed, it is argued that skeletal Class II malocclusion may play a role in the development of obstructive sleep apnea syndrome owing to the reduced oropharyngeal dimensions [11, 12].

Many studies have evaluated the effects of removable and fixed functional appliances on the pharyngeal airway spaces with conflicting results [13–18]. These studies relied upon two-dimensional evaluation using lateral cephalometry with its inherent limitations, such as distorted images, enlarged images in some areas and reduced in others, superimposition, and inaccurate landmark localization [19]. Two recently published systematic reviews [20, 21] retrieved and analyzed five studies that used cone beam computed tomography (CBCT) [22–26]. Of these, two studies used two-dimensional cephalometry extracted from CBCT images for measurements [23, 25], one had no control group [26], another one included samples with both males and females [22], and the last one [24] did not compare the effects of both types of appliances. Hence, no single study so far has compared both types of appliances with each other and

with a control group using three-dimensional (3D) measurements of CBCT images.

Based on the above argument, the aim of this study was to evaluate the 3D treatment effects, in term of skeletal and pharyngeal airways changes, in skeletal Class II female patients treated by either TWB or FFRD in comparison with untreated controls.

## Materials and methods

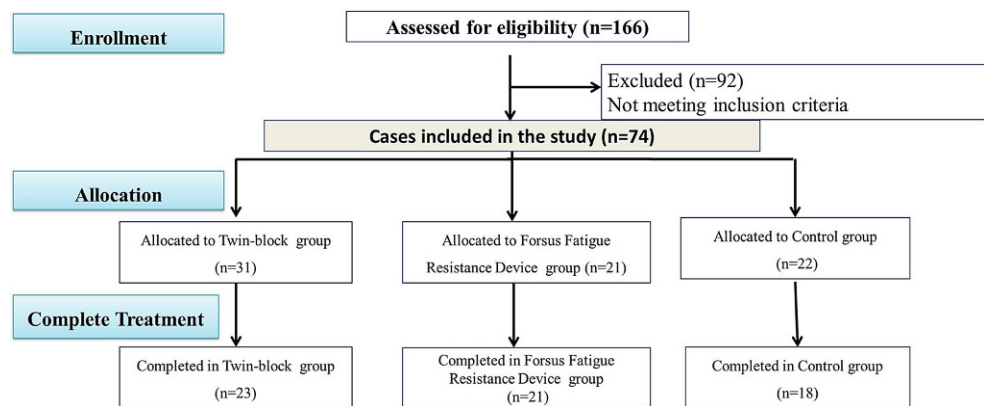
This was a controlled clinical study conducted at the outpatient clinics, Department of Orthodontics, Faculty of Oral and Dental Medicine, Cairo University, Egypt, and it was

approved by the relevant Research Ethics Committee (1/13-8-2011), Faculty of Oral and Dental Medicine, Cairo University, Egypt. All parents were informed about the study procedure and written informed consents were obtained.

Patients were included if they fulfilled the following criteria: (1) growing females in stage 3–4 as assessed using the cervical vertebrae maturational indicators (CVMI) [27], (2) mandibular deficiency (convex profile with retruded mandible), (3) normal or protruded maxilla, (4) overjet:  $\geq 5$  mm, (5) buccal segment relationship:  $\geq \frac{1}{2}$  unit Class II molar and canine relationship. All participants in the control group were treated using FFRD after completion of the observation period, upon achieving their turns in the waiting list.

**Fig. 1** Flow chart of the sample inclusion and allocation

**Abb. 1** Selektion und Allokation der Stichprobe, Flussdiagramm



**Fig. 2** Intraoral photos of the Twin Block (TWB) during treatment

**Abb. 2** Twin Block (TWB) während der Behandlung, intraorale Fotos



**Fig. 3** Intraoral photos of the Forsus Fatigue Resistance Device (FFRD) during treatment

**Abb. 3** Forsus-Apparatur (FFRD) während der Behandlung, intraorale Fotos

**Table 1** Definitions of skeletal and pharyngeal airways measurements in the study**Tab. 1** Skelettale und pharyngeale Luftwege, in der Studie verwendete Definitionen

Measurements	Definition
<i>Maxillary base measurements</i>	
<i>A-Nv (mm)</i>	The linear distance measured between point A and Nv line, measuring the anteroposterior position of the maxilla relative to the nasion vertical line
<i>SNA°</i>	The angle between 3 point landmarks S, N and A point, determining the anteroposterior position of the maxilla relative to the cranial base
<i>ANS-PNS (mm)</i>	The linear distance between points ANS and PNS measuring the maxillary base length
<i>Co-A (mm)</i>	The average of the bilateral linear distance between point Co and A point, measuring the effective mid facial length
<i>Mandibular base measurements</i>	
<i>B-Nv (mm)</i>	The linear distance measured between point B and Nv line, determining the anteroposterior position of the mandible relative to the nasion vertical line
<i>Pg-Nv (mm)</i>	The linear distance measured between point Pg and Nv line, determining the anteroposterior position of the chin relative to the nasion vertical line
<i>SNB°</i>	The angle between 3 point landmarks S, N and B point, determining the anteroposterior position of the mandible relative to the cranial base
<i>Sagittal jaw relation</i>	
<i>ANB°</i>	The angle between 3 point landmarks, A point, N and B point, determining the anteroposterior relation between maxilla and the mandible relative to the cranium
<i>AB diff (NV) mm</i>	The linear distance between point A and point B relative to Nasion-vertical line, measuring the anteroposterior millimetric jaw relation relative to the cranium
<i>Vertical jaw relation</i>	
<i>S-Go: N-Me%</i>	The ratio between the posterior facial height and the anterior facial height
<i>SN/GoMe</i>	The angle between the line S-N and the mandibular plane, measuring the mandibular base tipping relative to the cranium
<i>Pharyngeal airway spaces</i>	
<i>Naso-pharyngeal volume (mm<sup>3</sup>)</i>	The volume of air bordered by a vertical and horizontal lines passing through the posterior nasal spine perpendicular to the midsagittal plane and the posterior nasopharyngeal wall
<i>Oro-pharyngeal volume (mm<sup>3</sup>)</i>	The volume of air bordered by horizontal line passing through the posterior nasal spine perpendicular to the midsagittal plane, horizontal line passing through the most inferior point of the third cervical vertebrae perpendicular to the midsagittal plane and the posterior oropharyngeal wall
<i>Min-axial-area (mm<sup>2</sup>)</i>	The minimal axial area (maximum constriction) throughout the naso- and oropharyngeal airway area

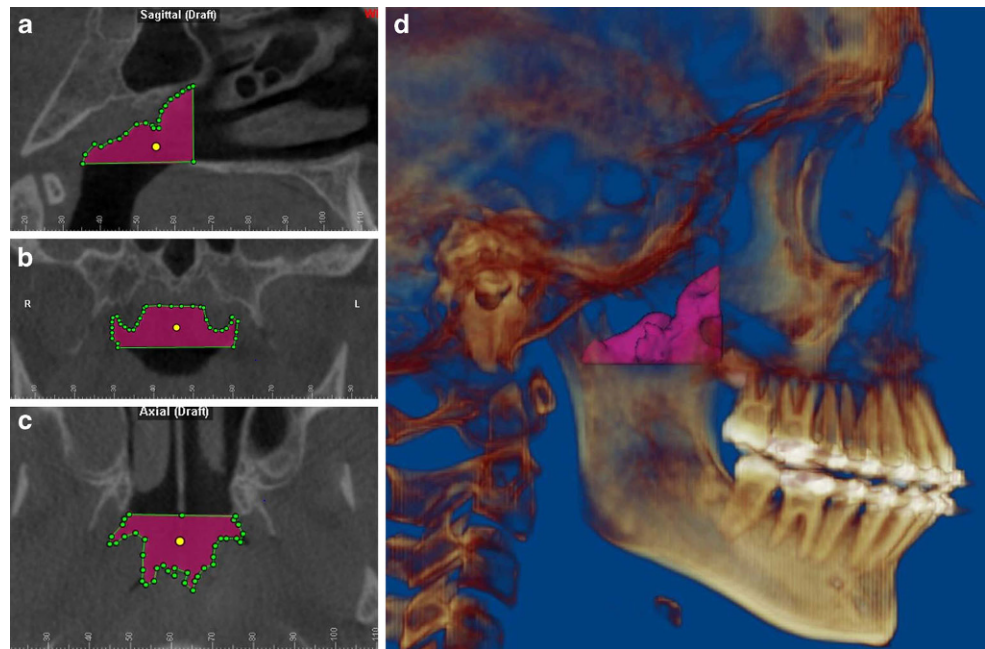
The sample size was calculated with an alpha value of 0.05 and a power of 80% based on the study conducted by Rizk et al. [25], in which the mean treatment difference in airway volume was  $5537.38 \pm 4849.72 \text{ mm}^3$  in the fixed functional appliance group and  $2220.47 \pm 1310.07 \text{ mm}^3$  in the control group. The resultant sample size was 20 in each group. For the TWB group, the sample size was calculated based on the above criteria and the study by Elfeky et al. [24], in which the mean treatment difference in oropharyngeal airway space was  $3052.45 \pm 1281.2 \text{ mm}^3$  in the TWB group and  $738.17 \pm 507.11 \text{ mm}^3$  in the control group. The resultant sample size was 5 in each group. Accordingly, it was decided that 20 participants would be included in each of the groups accounting for a total sample size of 60 participants. This number was increased to 74 participants to compensate for any potential dropouts. Of the 52 patients allocated to the treatment groups, 31 were treated with TWB and 21 with FFRD, while 22 patients were observed as untreated controls (Fig. 1).

CBCT images were obtained using the i-Cat CBCT machine (Imaging Sciences International, Hatfield, PA, USA). The source to detector distance was 67.5 cm. The voxel dimension selected was 0.3 mm and slice thickness was 2.00 mm. The image detector was a flat panel measuring  $20 \times 25 \text{ cm}$ ; images were acquired at 14 bits in a single  $360^\circ$  rotation [28]. These images were used for pretreatment/observational measurements (T1).

Participants in the TWB group were treated using a standard TWB appliance according to the procedure described by Clark ([4]; Fig. 2). The patients were instructed to wear the appliance continuously (24 h/day), including at meal-times, and were followed up once every 4 weeks. The anteroposterior dental arch relationship was assessed, with and without the appliance, at each appointment. The active treatment period was complete when there was no difference, with and without the appliance, and the mandible could not be retruded. Retention period with the appliance continued for another 3 months.

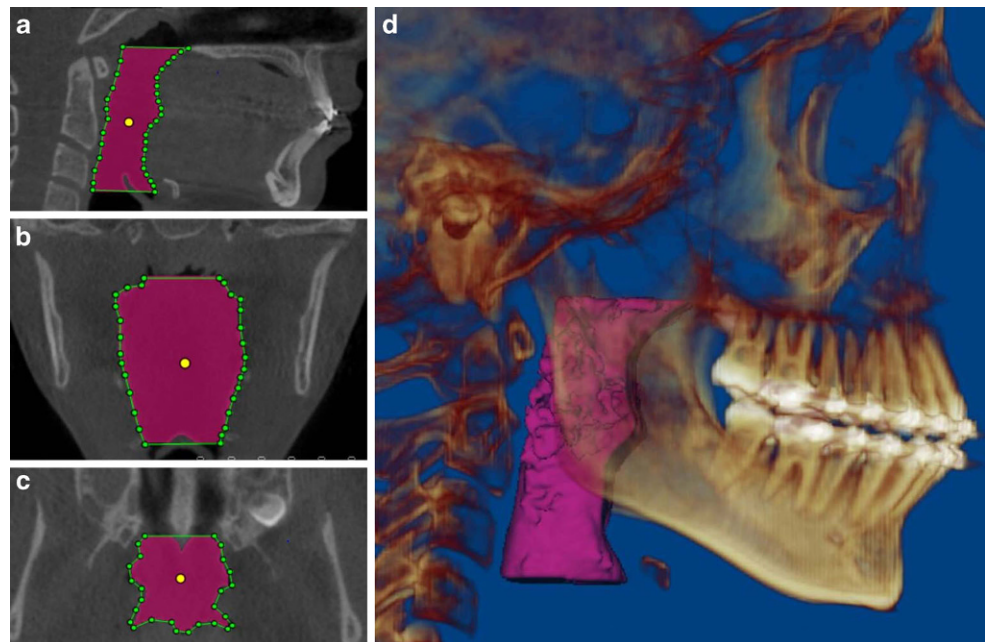
**Fig. 4** Nasopharyngeal airway space: **a** surface area (sagittal view), **b** surface area (coronal view), **c** surface area (axial view), **d** airway volume (volumetric view)

**Abb. 4** Nasopharyngealer Luftweg, Raum: Bereich der Oberfläche, **a** sagittal, **b** koronal, **c** axial; **d** Luftwegvolumen (volumetrische Ansicht)



**Fig. 5** Oropharyngeal airway space: **a** surface area (sagittal view), **b** surface area (coronal view), **c** surface area (axial view), **d** airway volume (volumetric view)

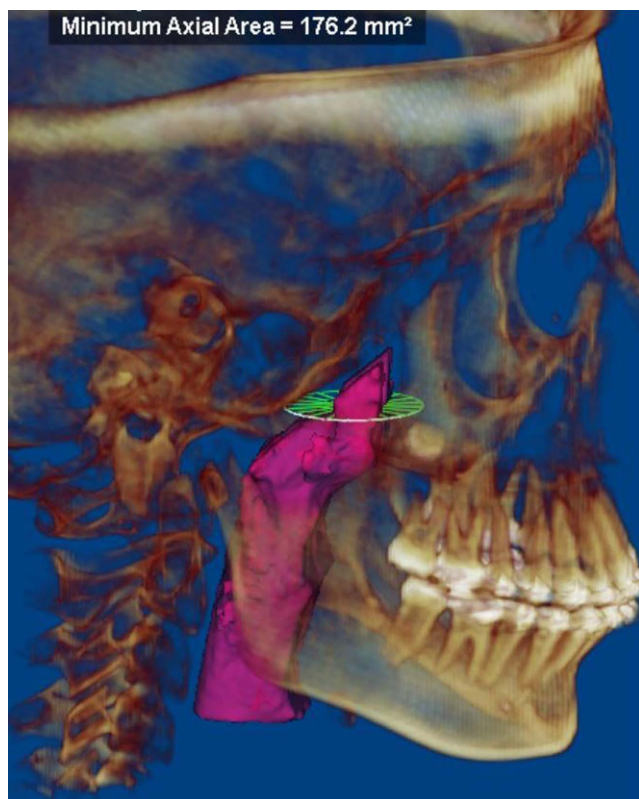
**Abb. 5** Oropharyngealer Luftweg, Raum: Bereich der Oberfläche, **a** sagittal, **b** koronal, **c** axial; **d** Luftwegvolumen (volumetrische Ansicht)



Participants in the FFRD group were treated with fixed appliances as follows: MBT prescription brackets (3M Unitek, St. Paul, MN, USA) with 0.022 inch slot were bonded to the upper and lower teeth. A soldered passive transpalatal arch (TPA) was fitted to the maxillary first molars. Alignment and leveling proceeded until 0.019×0.025 inch stainless-steel arch wires were engaged. The FFRD was fitted according to the manufacturer's instructions (3M Unitek). Follow-up visits were scheduled every 4 weeks for assessing the changes, provisioning maintenance, and activation (Fig. 3). The active phase continued until Class II

occlusion was overcorrected to an edge-to-edge incisal relationship. Thereafter, the fixed appliance was retained to finalize the occlusion. Upon completion of the treatment period, the second CBCT image was obtained for each participant and used for posttreatment/observational measurements (T2).

Three-dimensional skeletal measurements were performed using Anatomage 5.02 software (Anatomage, San Jose, CA, USA), while 3D pharyngeal airway measurements were obtained using Dolphin 11.5 software (Dolphin Imaging and Management Solutions, Chatsworth, CA,



**Fig. 6** Minimal axial area (volume rendering view)

**Abb. 6** „Minimal axial area“ (Volumen-Rendering-Ansicht/Ansicht zur Volumendarstellung)

USA) with a saturation level of 72 [24, 29, 30]. Descriptions of these measurements are listed in Table 1.

The three-dimensional (3D) upper pharyngeal airway measurements included: (1) nasopharyngeal airway volume (Fig. 4), (2) oropharyngeal airway volume (Fig. 5), and (3) minimal axial area (Fig. 6).

Fourteen pre- and posttreatment/observation CBCT images were selected randomly and measured independently by two examiners on two occasions with a 2-week interval to assure reliability of the measurements.

### Statistical analysis

Data were input and analysed using the statistical package for social sciences (SPSS) software, Version 21 (IBM Corp., Armonk, NY, USA) for windows. Intraclass correlation coefficients (ICCs) were calculated to assess the reliability and reproducibility of the measurements. Descriptive statistics, including mean and standard deviation for each variable, were calculated and presented. Data were checked for normal distribution using Kolmogorov–Smirnov test. Comparison of pre- and posttreatment/observational measurements was accomplished using the paired t-test (or Wilcoxon signed-rank test). Between the groups, both pre-

and posttreatment/observational comparisons were conducted using one way analysis of variance (ANOVA) (or Kruskal–Wallis test) followed by Bonferroni correction (or Mann–Whitney U test) whenever one way ANOVA (or Kruskal–Wallis test) revealed a statistical significance. A *P* value of <0.05 was considered statistically significant.

### Results

Out of the 74 patients included in this study, 62 patients completed the treatment (23 TWB patients, 21 FFRD patients, and 18 controls). Most of the patients who dropped out were in the TWB group (Fig. 1).

Intraclass correlation coefficients with regard to intra- and interexaminer measurements ranged from 0.789 and 0.984 for nasopharyngeal volume and ANB, respectively, to 0.788 and 0.995 for oropharyngeal volume and B-NV, respectively, indicating a high degree of reliability.

With regard to T1 measurements, there were statistically significant differences between the TWB and FFRD groups in many mandibular skeletal linear measurements, sagittal jaw relationships, and mandibular plane inclinations. The mandibular plane inclination and naso-pharyngeal airway volume were significantly different between the control group and the FFRD and TWB groups (Table 2).

Differences between T1 and T2 were more obvious in the TWB group. These differences were in terms of mandibular skeletal measurements, sagittal and vertical jaw relationships, and pharyngeal airway spaces. Although to a very small extent, the second obvious difference was seen in the control group, more specifically in the vertical skeletal jaw relationship. There was no difference between the T1 and T2 measurements in the FFRD group (Table 3).

The changes induced by treatment/growth are presented in Table 4. No differences were recorded in all the maxillary skeletal measurements, neither between the TWB and FFRD groups nor between the FFRD group and control group. Only change of the maxillary base position (SNA) was significantly higher in the TWB group than the control group. For all other measurements, the TWB group demonstrated more significant posttreatment changes compared to the FFRD and control groups. Changes in the FFRD and control groups were not significantly different.

Table 5 presents the correlations between the changes of measurements in skeletal and pharyngeal airways. There were significant direct correlations between the oropharyngeal airway and SNA, and Po-NV and SNB ( $r=0.481$ ,  $0.490$  and  $0.712$ , respectively) in the TWB group. There was also an inverse correlation between the minimal axial area and ANB in that group ( $r=-0.422$ ). The minimal axial area in the control group showed a significant inverse correlation with SNA ( $r=-0.612$ ) and a significant direct correlation

**Table 2** Pretreatment/observation skeletal and pharyngeal measurements (T1)  
**Tab. 2** Skelettale und pharyngeale Messungen vor der Behandlung bzw. vor der Beobachtung (T1)

Measurements	Twin Block (A)		FFRD (B)		Control (C)		<i>P</i> -value A vs. B	<i>P</i> -value A vs. C	<i>P</i> -value B vs. C
	Pretreatment measurements		Pretreatment measurements		Preobservation measurements				
	Mean	SD	Mean	SD	Mean	SD			
Age	11.89	1.85	13.45	1.12	11.27	1.19	0.01	0.05	0.001
<i>Maxillary measurements</i>									
A-NV	1.03	2.55	3.63	4.34	1.68	1.44	0.02 <sup>a</sup>	1 <sup>a</sup>	0.156 <sup>a</sup>
SNA	81.25	3.39	79.72	2.83	81.38	2.9	0.147		
Co-A	82.68	3.68	83.71	4.87	81.88	4.19	0.169		
<i>Mandibular measurements</i>									
B-NV	-10.4	3	-4.58	6.49	-8.04	2.62	0.001	0.278	0.08
Pg-NV	-10.63	3.85	-1.61	7.38	-7.55	3.98	0.001 <sup>a</sup>	0.217 <sup>a</sup>	0.003 <sup>a</sup>
SNB	72.84	2.99	72.78	3.04	73.9	2.24	0.494		
<i>Sagittal jaw relation</i>									
ANB	8.42	1.14	6.76	1.56	7.24	1.23	0.001	0.014	1
AB Diff (NV)	11.29	1.8	8.21	3.25	9.67	2.19	0.001 <sup>a</sup>	0.130 <sup>a</sup>	0.213 <sup>a</sup>
<i>Vertical jaw relation</i>									
SGo: NMe	0.56	0.04	0.6	0.05	0.6	0.036	0.017	0.026	1
SN/GoMe	43.69	3.38	30.62	2.78	38.9	4.5	0.001	0.051	0.001
<i>Pharyngeal airway spaces</i>									
Naso-pharyngeal airway volume (mm <sup>3</sup> )	3612	692.2	4196	841.93	4832.8	1185.15	0.111 <sup>a</sup>	0.001 <sup>a</sup>	0.1 <sup>a</sup>
Oro-pharyngeal airway volume (mm <sup>3</sup> )	12939.22	3036.35	12875.71	1955.33	15289.11	3562.38	0.055		
Min-axial-area (mm <sup>2</sup> )	174.48	81.85	167.33	42.95	201	78.13	0.267		

<sup>a</sup>One way analysis of variance (ANOVA) followed, whenever significant, by Bonferroni correction test. When not indicated, the test is by Kruskal–Wallis test followed, whenever significant, by pairwise comparison using Mann–Whitney test  
*SD* standard deviation, *FFRD* Forsus Fatigue Resistance Device

with Pg-NV ( $r = -0.602$ ). No single correlation was found in the FFRD group.

## Discussion

In this study, use of TWB revealed the most obvious skeletal treatment effects in terms of maxillary, mandibular, sagittal, vertical, and pharyngeal airway 3D measurements compared to natural growth in controls and even to the skeletal treatment effects induced by FFRD. The latter is known to induce camouflage dentoalveolar effects and since those measurements were not included in this study, its real effects were not evident. In other words, the current study revealed no obvious skeletal effects with FFRD, when the changes induced by this appliance were compared with the natural growth effects in controls.

All the subjects who participated in the study were females. This was to rule out the gender effect, as mandibular growth is sex- and age-dependent [31].

The results of randomized and controlled clinical trials (RCT, CCT) [32–36] were analysed in a recent systematic review [9] that compared the efficacy of fixed versus removable functional appliances in children with Class II malocclusion. Of the reviewed studies, one reported soft tissue changes [33], two compared the TWB and the Herbst appliances [32, 35], and two compared the activator with FFRD [34] and Twin Force appliances [36]. Although these studies used two-dimensional imaging techniques, the review indicated that these studies currently represent the highest available level of evidence [9].

It is well recognized that orthopaedic/orthodontic therapy using functional appliances has maximum effects when performed during the mandibular growth spurt period. The greatest skeletal effects have been found in patients treated within the peak pubertal growth period [27]. Hence, in this study, participants in the TWB and control groups were selected in pubertal growth stage 3, based on CVMI [27], as it is the optimum treatment period to achieve maximum skeletal effects, either through natural growth or induction by therapeutic functional intervention. In the FFRD group,

**Table 3** Pre- and posttreatment/observation skeletal and pharyngeal measurements (T2)  
**Tab. 3** Skelettale und pharyngeale Messungen vor Behandlung bzw. vor Beobachtung und danach (T2)

Measurements	Twin Block				FFRD				Control				P-value		
	Pretreatment measurements		Posttreatment measurements		Pretreatment measurements		Posttreatment measurements		Pretreatment measurements		Posttreatment measurements				
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD			
<i>Maxillary skeletal measurements</i>															
A-NV	1.03	2.55	0.26	2.56	0.002 <sup>a</sup>	3.63	4.34	3.34	4.7	0.096 <sup>a</sup>	1.68	1.44	1.75	1.79	0.472
SNA	81.25	3.39	80.89	3.06	0.006	79.72	2.83	79.1	2.71	0.165 <sup>a</sup>	81.38	2.9	81.31	2.74	0.579
Co-A	82.68	3.68	83.61	4.38	0.011	83.71	4.87	84	4.95	0.329 <sup>a</sup>	81.88	4.19	81.99	4	0.689
<i>Mandibular skeletal measurements</i>															
B-NV	-10.4	3	-8.55	2.75	0.001	-4.58	6.49	-4.52	6.78	0.566	-8.04	2.62	-8.36	2.5	0.005 <sup>a</sup>
Pg-NV	-10.63	3.85	-8.93	3.48	0.001 <sup>a</sup>	-1.61	7.38	-3.07	6.4	0.09 <sup>a</sup>	-7.55	3.98	-7.78	3.09	0.123 <sup>a</sup>
SNB	72.84	2.99	74.44	2.51	0.001	72.78	3.04	72.48	3.4	0.149	73.9	2.24	73.85	2.15	0.720 <sup>a</sup>
<i>Sagittal skeletal jaw relation</i>															
ANB	8.42	1.14	5.93	1.57	0.001	6.76	1.56	6.72	1.75	0.856 <sup>a</sup>	7.24	1.23	7.53	1.52	0.019 <sup>a</sup>
AB Diff (NV)	11.29	1.8	8.75	1.94	0.001 <sup>a</sup>	8.21	3.25	8.04	3.58	0.635 <sup>a</sup>	9.67	2.19	9.84	2.3	0.073 <sup>a</sup>
<i>Vertical skeletal jaw relation</i>															
SGo: NMe	0.56	0.04	0.58	0.04	0.001	0.6	0.05	0.6	0.05	0.429	0.6	0.036	0.59	0.04	0.001
SN/GoMe	43.69	3.38	43.5	3.67	0.412 <sup>a</sup>	30.62	2.78	30.9	2.87	0.243 <sup>a</sup>	38.9	4.5	39.32	4.31	0.003 <sup>a</sup>
<i>Pharyngeal airway spaces</i>															
Naso-pharyngeal volume (mm <sup>3</sup> )	3612	692.2	4119.2	691.42	0.001 <sup>a</sup>	4196	841.93	4110.22	845.12	0.170	4832.8	1185.15	4725.48	989.21	0.408 <sup>a</sup>
Oro-pharyngeal volume (mm <sup>3</sup> )	12939.22	3036.35	16208.96	4394.11	0.001	12875.71	1955.33	12891.38	1597.27	0.951 <sup>a</sup>	15289.11	3562.38	15649.29	2946.67	0.231
Min-axial-area (mm <sup>2</sup> )	174.48	81.85	331.64	223.72	0.001	167.33	42.95	162.38	22.82	0.540 <sup>a</sup>	201	78.13	222.96	83.53	0.005 <sup>a</sup>

<sup>a</sup>Paired t-test. When not indicated, the analysis was conducted using Wilcoxon signed-rank test  
SD standard deviation, FFRD Forsus Fatigue Resistance Device



**Table 4** Treatment/observation skeletal and pharyngeal changes  
**Tab. 4** Behandlung bzw. Beobachtung: skeletale und pharyngeale Veränderungen

Measurements	Twin Block (A)		FFRD (B)		Control (C)		P-value A vs. B	P-value A vs. C	P-value B vs. C
	Mean	SD	Mean	SD	Mean	SD			
<i>Maxillary skeletal measurements</i>									
A-NV	-0.77	1.04	-0.29	0.77	0.08	0.48	0.217	0.001	0.242
SNA	-0.36	0.55	-0.26	0.83	-0.07	0.51	0.826	0.032	0.028
Co-A	0.94	1.63	0.3	1.4	0.11	1.1	0.306		
<i>Mandibular skeletal measurements</i>									
B-NV	1.48	1.11	0.06	1.34	-0.032	0.42	0.001 <sup>a</sup>	0.001 <sup>a</sup>	0.815 <sup>a</sup>
Pg-NV	1.7	0.61	-1.46	3.75	-0.23	0.6	0.001	0.001	1
SNB	1.59	0.98	-0.29	0.93	0.05	0.56	0.001 <sup>a</sup>	0.001 <sup>a</sup>	1 <sup>a</sup>
<i>Sagittal skeletal jaw relation</i>									
ANB	-2.49	0.74	-0.03	0.79	0.29	0.48	0.001	0.001	0.621
AB Diff (NV)	-2.63	0.84	-0.17	1.59	0.16	0.36	0.001	0.001	0.242
<i>Vertical skeletal jaw relation</i>									
SGo: NMe	0.03	0.01	-0.001	0.01	-0.01	0.01	0.001	0.001	0.445
SN/GoMe	-0.19	1.09	0.28	1.07	0.42	0.52	0.132		
<i>Pharyngeal airway spaces</i>									
Naso-pharyngeal volume (mm <sup>3</sup> )	507.2	641.16	-86.73	253.5	-107.32	536.4	0.004	0.025	1
Oro-pharyngeal volume (mm <sup>3</sup> )	3269.74	2297.51	15.66	1160.53	360.18	299.55	0.001	0.001	1
Min-axial-area (mm <sup>3</sup> )	157.16	206.25	-4.96	36.47	22.01	29.02	0.001	0.001	0.157

<sup>a</sup>One way analysis of variance (ANOVA) followed, whenever significant, by Bonferroni correction test. When not indicated, the test is by Kruskal–Wallis test followed, whenever significant, by pairwise comparison using Mann–Whitney test  
SD standard deviation, FFRD Forsus Fatigue Resistance Device

however, participants were selected in the later stage of growth so as to minimize the time before installation of the fixed functional appliance.

With regard to skeletal changes in the maxilla, neither appliance induced noticeable effects. When their effects were compared separately with the growth effect in the controls, TWB showed a significantly greater net retrusive effect than FFRD. The effective maxillary length was not affected by normal growth or any of the functional appliances. Accordingly, it can be concluded that TWB is effective in inhibiting forward growth of the maxilla. This finding is similar to that in the study by Bilgic et al. [34]. A recent systematic review concluded that “removable functional appliances in Class II growing patients have a slight inhibitory effect on the sagittal growth of the maxilla in the short term” [37]. In contrast to this study’s results, Dalci et al. [36] found an insignificant effect of TWB on the maxillary base. Otherwise, effective maxillary length was not affected in all the groups in this study; this implies that neither these appliances nor normal growth has an effect on the anteroposterior maxillary position (point A) or vertical growth of the condyle (Co).

Besides the restricting effects on the maxilla, TWB revealed growth-enhancing effects on the mandible compared with both FFRD and controls. Otherwise, the skeletal ef-

fects of FFRD on the mandible were not different compared to the natural growth increments reported in controls. These findings were similar to those reported by Bilgic et al. [34], Dacli et al. [36] and many recent systematic reviews [5, 7, 9]. This can be attributed to the mechanism of action of the TWB which relies on skeletal and dentoalveolar anchorage unlike the FFRD which relies only on dentoalveolar anchorage.

These minor restricting changes of the maxilla and major growth enhancing changes of the mandible were probably responsible for the evident reduction of sagittal jaw discrepancy, more specifically in the TWB group. Such sagittal changes have been reported in many CCTs [34, 36]. It is worth noting that both appliances successfully corrected the Class II molar relationship, overjet, and overbite malocclusion with varying degrees of skeletal changes. This correction can be attributed to the inhibiting effect on the maxilla and the growth-stimulating effect on the mandible in the TWB group, and to maxillary incisor retrusion and mandibular incisor protrusion in the FFRD group.

With regard to the vertical jaw relationship, inclination of the mandibular plane was not affected significantly in all groups unlike the posterior to anterior facial height, which was significantly increased in the TWB group compared to both the FFRD and control groups. Similar findings were

**Table 5** Correlations (Pearson correlation coefficients) between the skeletal and the pharyngeal-airway changes of measurements in each of study subgroups  
**Tab. 5** Korrelationen (Pearson-Korrelationskoeffizient) zwischen skeletalen und pharyngealen Veränderungen der Luftwege in jeder der untersuchten Gruppen

Measurements	Twin Block (A)				FFRD (B)				Control (C)				Overall			
	Naso-pharyngeal volume (mm <sup>3</sup> )	Oro-pharyngeal volume (mm <sup>3</sup> )	Min-axial-area (mm <sup>3</sup> )	Naso-pharyngeal volume (mm <sup>3</sup> )	Naso-pharyngeal volume (mm <sup>3</sup> )	Min-axial-area (mm <sup>3</sup> )	Oro-pharyngeal volume (mm <sup>3</sup> )	Naso-pharyngeal volume (mm <sup>3</sup> )	Min-axial-area (mm <sup>3</sup> )	Oro-pharyngeal volume (mm <sup>3</sup> )	Naso-pharyngeal volume (mm <sup>3</sup> )	Min-axial-area (mm <sup>3</sup> )	Oro-pharyngeal volume (mm <sup>3</sup> )	Naso-pharyngeal volume (mm <sup>3</sup> )	Min-axial-area (mm <sup>3</sup> )	Oro-pharyngeal volume (mm <sup>3</sup> )
<i>Maxillary skeletal measurements</i>																
A-NV	0.045	-0.362	-0.147	-0.085	-0.085	-0.095	-0.036	0.384	0.384	-0.095	0.172	-0.068	-0.377**	-0.120	-0.068	-0.264*
SNA	-0.129	0.481*	0.393	-0.424	-0.424	0.007	0.260	-0.274	-0.274	0.007	-0.322	-0.612**	0.180	-0.174	-0.612**	0.164
Co-A	0.252	-0.390	0.224	0.281	0.281	0.009	0.037	0.117	0.117	0.009	0.228	-0.072	0.033	0.303*	-0.072	0.247*
<i>Mandibular skeletal measurements</i>																
B-NV	-0.054	-0.177	0.153	-0.076	-0.076	-0.203	-0.209	-0.177	-0.177	-0.203	0.086	0.252	0.304*	0.260*	0.252	0.341**
Pg-NV	0.392	0.490*	0.175	-0.012	-0.012	-0.192	-0.400	0.099	0.099	-0.192	0.390	0.602**	0.296*	0.285*	0.602**	0.263*
SNB	0.356	0.718***	0.118	-0.205	-0.205	-0.139	-0.024	0.243	0.243	-0.139	0.289	-0.062	0.710***	0.481***	-0.062	0.399**
<i>Sagittal skeletal jaw relation</i>																
ANB	-0.334	-0.328	-0.422*	0.088	0.088	0.104	0.206	-0.081	-0.081	0.104	-0.104	0.160	-0.627***	-0.514***	0.160	-0.532***
AB Diff (NV)	0.279	-0.413	-0.257	0.091	0.091	0.202	0.233	-0.320	-0.320	0.202	0.007	0.315	-0.545***	-0.340**	0.315	-0.422**
<i>Vertical skeletal jaw relation</i>																
SGo: NMe	-0.156	0.260	0.076	-0.102	-0.102	-0.182	-0.210	-0.390	-0.390	-0.182	-0.283	-0.505	0.550***	0.341**	-0.505	0.357**
SN/GoMe	0.243	-0.049	-0.163	0.141	0.141	0.173	-0.107	0.165	0.165	0.173	0.173	0.208	-0.200	0.017	0.208	-0.200

FFRD Forsus Fatigue Resistance Device

reported by Bilgic et al. [34] and Dacli et al. [36]. Although the increase in the posterior to anterior facial height was statistically significant in the TWB group, it seems to be insignificant from a clinical point of view.

So far, to the best of available knowledge, no single study has compared the effect of removable versus fixed functional appliances on oropharyngeal airways. Furthermore, the studies that evaluated oropharyngeal airways in Class II patients using a single functional appliance did so based on two-dimensional images of CBCT scans [23, 25], included participants of both sexes [22], or did not consider the effect of natural growth [26] (no controls included).

The findings in this study indicated a significant increase in the nasopharyngeal airway in the TWB group compared to both the FFRD and control groups. These changes might be attributed to the maxillary skeletal changes produced by TWB relative to FFRD and natural growth amongst controls. This contradicts the results of Li et al. [22] who did not report a significant change in the nasopharyngeal volume; however, it is also similar to the conclusions of many systematic reviews and meta-analyses [20, 21].

The major changes were observed in the oropharyngeal airway in the TWB group compared to both FFRD and control groups. The anteroposterior positional changes of the mandible, and possibly, a forward movement of the hyoid bone owing to the direct connection between them, may be responsible for such a volumetric increase of the oropharyngeal airway. This finding is in line with that reported by Li et al. [22] and other systematic reviews [20, 21]. In the current study, FFRD had no skeletal effect on the mandible, and subsequently, on the oropharyngeal volume. Such a result contradicts the findings of Temani et al. [26] who evaluated the effect of FFRD on the oropharyngeal airway; however, natural growth changes were not considered in that study (no control group).

In the TWB group, the more obvious the changes exerted on the mandible and sagittal jaw relationship, the more obvious were the changes in oropharyngeal airway volume. This correlation was mostly due to the increased distance between the posterior limits of the maxillary and mandibular bases and the posterior pharyngeal wall. Erbas and Kocadereli [23] concluded that anterior repositioning of the mandible with the Xbow appliance resulted in an increased oropharyngeal airway volume. This correlation was not found in the FFRD group owing to the lack of skeletal effects, as the effects of FFRD are purely dentoalveolar [7].

Generally, the changes in the naso- and oro-pharyngeal airways and in the minimal axial areas were observed after short term evaluation. The long-term effects (after 2–3 years following treatment) need to be addressed. Moreover, growth has its own effects on these airway measurements, irrespective of being positive or negative.

Once those two factors are considered, a more obvious conclusion can be drawn.

## Conclusions

The Twin Block functional appliance induced significant skeletal and pharyngeal airway changes compared to the effects induced by FFRD or by natural growth.

## Compliance with ethical guidelines

**Conflict of interest** M.S. Alhammadi, H.Y. Elfeky, M.S. Fayed, R.A.R. Ishaq, E. Halboub and A.A. Al-mashraqi declare that they have no competing interests.

**Ethical standards** All procedures performed in studies involving human participants or on human tissue were in accordance with the ethical standards of the institutional and/or national research committee and with the 1975 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

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