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Soft Tissue Improvement by Fixed Functional Appliance in Class Ii Patients, Cbct Study

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Introduction

Skeletal Class 2 discrepancy had been one of the most encountered problems in the orthodontic practice. It affects about 19.56 of the patients seeking orthodontic treatment (1). Skeletal Class 2 could be due to maxillary excess, mandibular deficiency, or a combination of both. The mandibular skeletal deficiency was found to be the main feature or factor that attributed to the development of more than half of the Class II patients (2-4).

There is always controversy regarding the effectiveness of fixed functional appliances (FFAs) in stimulating mandibular growth; many studies have demonstrated the successful correction of skeletal Class 2 in adolescent patients through the use of FFAs. In addition, FFAs don't rely on patient compliance and shorten the treatment time as there is no need for two-phase treatment (5).

Power scope (American orthodontics corporation, Sheboygan, Wisconsin, USA) is one of the recently introduced hybrid fixed functional appliances. It has one size that fits all patients with right and left different assemblies. There is no need for any special laboratory work or special clinical steps as the appliance allows an intermaxillary wire to wire installation using a nut with a hexagonal screw. The ball and socket joint maximize the lateral movements provided by the appliance and improve patient comfort (6-8).

The evaluation of the treatment effects using Power scope appliance had been conducted in several previous studies using lateral cephalometric radiography which is a two-dimensional evaluation tool that is subjected to distortion, superimposing, and magnification (9). This study evaluated the effects of Power scope appliance using CBCT, which presents high accuracy and precision (10).

Material and Method

Study design: A prospective clinical study.

Study setting and population:

The current study was conducted on twelve female orthodontic patients. All patients received treatment at the outpatient clinic at Orthodontic Department, Faculty of Dental Medicine (Boys - Cairo), Al-Azhar University, Egypt.

Sample size calculation:

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To determine the effective sample size, a statistical power analysis was conducted according to a previous study (11) depending on an acceptable level of significance (alpha = 0.05) and power of the statistical test of 0.90 with an estimated effect size of 1.2137477, resulting in a sample size of ten patients and for the dropouts, twelve patients were enrolled in the study.

Ethical considerations:

Ethical approval of the study was obtained from the Ethical Committee of the Faculty of Dentistry, Al-Azhar University, (Cairo, Boys) with reference number [EC Ref No.99/110]. The patients and/or the guardians were informed about the nature and benefits of their participation in the study, and they signed informed consent before any further procedures.

Inclusion criteria:

(1) Healthy post-pubertal female patients with cervical vertebrae maturational stages 4, 5, and 6 according to Baccetti et al. (12). (2) Skeletal Class 2 patients of ANB angle greater than 4° due to deficient mandible with/without maxillary protrusion. (3) Angle Class II division 1 malocclusion with at least an end-on Class II molar relationship. (4) Presence of all permanent dentition excluding third molars. (5) Good oral hygiene.

Participants:

This study involved a single group of patients treated using fixed orthodontic appliances and Power scope as a fixed functional appliance. Due to the age difference of pubertal growth spurt peak and the amount of overall growth between males and females and to avoid any sexual dimorphism, only female patients were involved in the study to eliminate any gender-based difference that could affect the results. The patients were selected according to their skeletal maturation stages based on the modified cervical vertebrae maturation stages by Baccetti et al. (12). Twelve post-pubertal female patients with cervical stages 4, 5, and 6 (CS4, CS5, and CS6) were enrolled in the study.

Patient records:

For each patient, the following diagnostic records were taken before the orthodontic treatment: extraoral and intraoral photographs, orthodontic study model, digital panoramic radiograph, and digital lateral cephalometric radiograph. CBCT images were taken before and after the treatment using the Power scope appliance.

Operative procedures:

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Fixed orthodontic appliances: Transpalatal arch **(**TPA**)** was fabricated and cemented on the first maxillary molar, and that was to counteract the buccal forces exerted by the fixed functional appliance; TPA should be spaced from the palatal mucosa by 2 mm to avoid ulceration or impingement into the soft tissue as a result of the intrusive forces of the fixed functional appliance. Pre-adjusted Roth appliance **(**Dentaurum Discovery Smart Metal Brackets Kit, Dentaurum GmbH & Co, 75228 Ispringen, Germany**)** was bonded **(**Grengloo for metal brackets, Ormco Co 1717 West Collins Avenue, USA**)** on the upper and lower arches with a 0.022" x 0.028" slot. The buccal tube **(**M-Series mini buccal tubes, Dentaurum GmbH & Co, 75228 Ispringen, Germany**)** was bonded to the second permanent molar to ensure its stability with the arch form and prevent it from any rotation or deviation.

Levelling and alignment phase took place until reaching 0.019" x 0.025" stainless steel archwire **(**Dentaurum remanium ideal arches, Dentaurum GmbH & Co, 75228 Ispringen, Germany**)**. Its duration was 7.5 ±1.5 months.

Appliance activation:

After Power scope installation, initial activation of the appliance was done. The inner middle shaft of the telescopic system at the canine end has three activation lines spaced 2 mm apart, which reference the activation level of the NiTi spring, ranging from no activation to partial activation to full activation. After the appliance installation, the activation lines were observed. If there were no or partial activation, crimpable shims would be added until full activation. The appliance should be checked at each appointment **(**every month**)**, removed, and cleaned. The molar relation was observed, and then the appliance was reinstalled. Stepwise mandibular advancement activation is done by adding 2 mm Crimpable shims every two months, according to Aras et al. **(**13**)**, until reaching an edge-to-edge bite with an unstrained Angle Class I molar relationship. Hence, no further activation of the appliance was done**(**14-18**)**.

Appliance Removal:

After six months of the treatment using Power scope, the appliance was removed. Extraoral and intraoral photographs were taken as post appliance treatment records, and then the patient was sent to perform a cone-beam computed tomography. Finally, intermaxillary elastics **(**Wildlife Serie Elastomeric, American Orthodontics corporation, Sheboygan, Wisconsin, USA**)** were used to adjust the final occlusion.

Cone Beam Computed Tomography **(**CBCT**)** images were taken before **(**T1**)** and after **(**T2**)** treatment using the Power scope appliance. It was done using an I-Cat scanner **(**Imaging Sciences International, Hatfield, Pennsylvania, USA**)** under fixed parameters **(**120 KVP and 37 mA in 26.9 seconds**)** with an amorphous

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silicon flat-panel detector. Field of View **(**FOV**)** was 17x23 cm with voxel size 0.3 mm. The patients' heads were oriented with the Frankfurt Horizontal plane parallel to the floor and the mid-sagittal plane perpendicular to the floor. Instructions were given to the patients to maintain an upright standing posture and a natural head position with maximum intercuspation. The CBCT scans were acquired in a Digital Imaging and Communications in Medicine **(**DICOM**)** format. The images were imported into Invivo **(**Anatomage Inc., San Jose, CA, USA**)** dental software version 5.2 for the measurements**(**19,20**)**.

Measurements used in this study: 1- Soft tissue measurements.

Soft tissue measurements used in the study are explained as follows [Table **(**1**)**].

Measurement	Definition
Angular measurements	
Z-angle	The angle formed between the line from Pog` to the most protruded upper or lower lip to Frankfurt horizontal plane.
Soft tissue convexity (N`-Sn-Pog`)	The posterior angle formed by connecting 3 points: soft tissue nasion, subnasale and soft tissue pogonion.
Linear measurements	
Upper lip to E-line	The distance between the most anterior part of the upper lip **(**Ls**)** to E-line **(**Pn-Pog`**)**.
Lower lip to E-line	The distance between the most anterior part of the lower lip **(**Li**)** to E-line **(**Pn-Pog`**)**.
Upper lip thickness	The distance extending between a point 2 mm below point A to the outermost point of the upper lip.
Lower lip thickness	The distance extending between the most anterior dentoalveolar point to the outermost point of the lower lip.
Mentolabial sulcus depth	The perpendicular distance between the deepest point on the mentolabial sulcus to Li-Pog` line.

Table (1): Soft Tissue Measurements Used in The Study.

Result

Age distribution:

The mean age of the patients was 15.39 ± 1.25 years old **(**ranging from 13.8 to 16.9 years**)**.

Skeletal maturation distribution:

The cervical vertebrae skeletal stages for the twelve patients were distributed as follows: 4 patients in cervical stage 4, 4 patients in cervical stage 5, and 4 patients in cervical stage 6.

Dropouts: There were no dropouts. Therefore, the statistical analyses were performed on twelve patients.

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Reliability and error analysis:

Kolmogorov-Smirnov and Shapiro-Wilk tests were used to verify the normality of data distribution which showed normal distribution of all data. Parametric tests were used for statistical evaluation. Paired t-test was used for the normally distributed quantitative variables to compare the two periods (T1 and T2). Quantitative data were presented as mean and standard deviation with estimated upper and lower limits of the confidence intervals (CI) at a 95% confidence level. The significance of the obtained results was judged at the 5% level (P-value was considered significant at P ≤ 0.05). The reliability of the analyzed data was verified using the method of intra-observer error assessment. A paired t-test was used to compare the first and second readings of 5 randomly selected patients with pre-and post-treatment CBCT images measured by the same investigator after three weeks interval. The intra-observer ratability test results for all the studied variables revealed a non-significant difference between the first and second measurements, indicating high reliability of all measurements carried out by the same examiner.

Statistical and Descriptive Analysis:

Parameters	T₁		T₂		T₂ − T₁				T value	p. value	Sig.
	Mean	SD	Mean	SD	Mean	SD	95% CI				
							LL	UL			
Angular measurements											
Z-Angle	61.18	8.12	63.60	8.17	2.41	1.05	1.77	3.05	8.246*	<0.001*	S
N - Sn - Pog`	152.4	4.30	155.5	5.25	3.06	2.36	1.63	4.49	4.668*	0.001*	S
Linear Measurements (mm)											
U-lip to E-line	-0.14	2.10	-0.97	1.89	-0.83	0.75	-1.28	-0.38	3.999*	0.002*	S
L-lip to E-line	1.81	2.31	0.71	1.85	-1.10	0.95	-1.68	-0.53	4.188*	0.001*	S
U-lip thickness	11.86	1.19	11.06	1.59	-0.80	1.15	-1.50	-0.10	2.491*	0.028*	S
L-lip thickness	15.04	1.53	12.90	1.71	-2.14	1.44	-3.01	-1.27	5.367*	<0.001*	S
Mento-Labial Sulcus Depth	6.42	1.11	5.18	1.14	-1.24	0.82	-1.74	-0.75	5.454*	<0.001*	S

T1: Pre-treatment using Power scope appliance, T2: Post-treatment using Power scope appliance, SD: Standard deviation, CI: Confidence interval, LL: Lower limit, UL: Upper Limit, S (*): Statistically significant at p ≤ 0.05, NS: Non-significant.

Table (2): Descriptive statistics and comparison of the soft tissue measurements pre- (T1) and post-treatment (T2) using Power scope appliance.

II. Complications related to the appliance:

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1. Buccal mucosal irritation:

The incidence of buccal mucosal irritation was presented in two patients [Figure **(**1**)**], both showed a bilateral irritation for the right and left buccal mucosa. The degree of the irritation was variable as it was mild in one patient and moderate in the other. The resolution of the mild irritation happened spontaneously after 2 weeks of installing the appliance. For the moderate one, it didn't heal during the treatment with the appliance, but it transformed to a fibrous nodule or polyp **(**fibroma**)** due to the persistent long-standing irritation from the appliance. After the appliance removal, progressive resolving of the fibrous nodule happened.
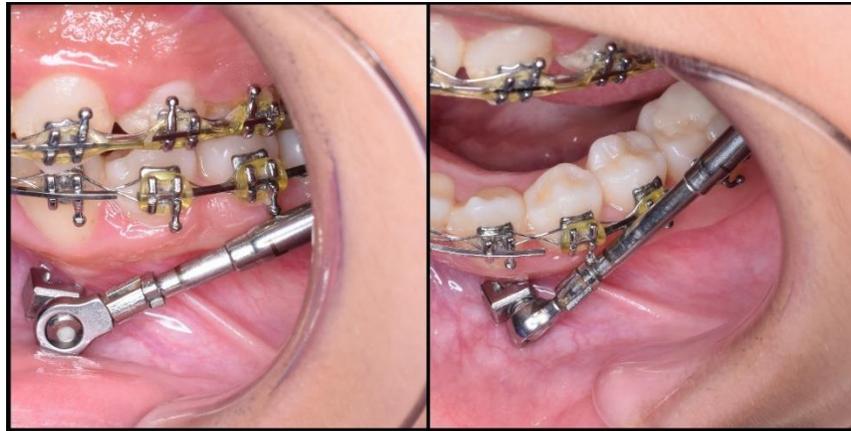

Figure (1): Buccal mucosal irritation during the treatment course with the Power scope appliance.

2. Arch wire breakage:

During the course of the treatment with the Power scope appliance, the main arch wire used was stainless steel 0.019"x0.025". The incidence of arch wire breakage was presented 3 times in two patients [Figure **(**2**)**]. One of them, the wire broke mesial to the upper right first molar tube 3 months after appliance delivery. The other one, the breakage happened twice at the same site, distal to the lower left canine with a month apart. This happened after 2 weeks of the appliance installation.

3. Orthodontic brackets debonding:

Orthodontic brackets debonding happened 4 times during the treatment course with the Power scope appliance which related to the arm ends of the appliance. Three of them were in the lower arch while only one was in the upper arch. Two of the lower arch bracket debonding happened to the same patient and to the same bracket which was the left canine bracket while the third one was to a right canine bracket. For the upper incidence of bracket debonding, it happened to the right second premolar bracket.

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Figure 2: Appliance breakage, and wire breakage.

Discussion

The present study included 12 orthodontic female patients with a mean age was 15.39 ± 1.25 years old. Only female patients were involved in the study to eliminate any sexual dimorphism that could affect the results of the study.

The duration of treatment using Power scope appliance in this study was 6 months, similar duration was reported by previous studies (21-24) using Power scope appliance. Other studies (25-29) reported a varied duration of Power scope treatment ranging from 5 to 9 months until reaching a Class I molar relationship. In this study, a specific duration was used for fixation of the treatment time and precise evaluation of the appliance.

Changes in the soft tissue measurements:

There were statistically significant changes in the soft-tissue relationship and facial profile after treatment with Power scope appliance regarding the Z-angle, N-Sn-Pog` angle, and the position of upper and lower lips to E-line measurements. This was agreed with the results of other Power scope studies in addition to a study using Forsus Fatigue-resistant Device which showed an improvement in the facial profile and the lips position(25,28,29). On the contrary, these findings disagreed with those reported by a Power scope appliance study (27) which showed no soft tissue changes and facial profile improvement after treatment with Power scope appliance.

Also, a minor contribution of the improvement of the soft tissue profile was due to the reduction in the upper and lower lip thickness also the reduction in the depth of the mento-labial sulcus. There was a statistically significant (p≤0.028, p≤0.001) decrease in the U-lip and L-lip thickness by -0.8 ±1.15 and -2.14 ±1.44 mm, respectively. These results were agreed with the results reported by studies (21,28) using Power scope appliance and opposite findings were reported by a Power scope appliance study (27).

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The mento-labial sulcus depth showed a statistically significant **(**p≤0.001**)** decrease by -1.24 ±0.82 mm and that agreed to the results of the following studies **(**11,26,27,29**)** using Power scope appliance.

Complications related to the appliance:

Limited clinical complications had been reported in the literature regarding the treatment using the Power scope appliance. In this study, the incidence of arch wire breakage was presented 3 times in two patients. One of them, the wire broke mesial to the upper right first molar, and the other one, the breakage happened twice to the same patient at the same site, distal to the lower left canine. This was agreed with two studies **(**22,29**)** with breakage to only the lower arch wire, but the frequency of breakage was not mentioned. The reason may be the wire-to-wire installation of Power scope that made it completely attached to the upper and lower arch wire and, thus, the total force is borne by the arch wire at the sites of attachment and then transmitted to the various structures.

A study **(**23**)** revealed the slippage of the Power scope out from the arch wire which didn't happen in this study but instead, the debonding of brackets related to the arm ends of the Power scope occurred and sliding of the appliance over the debonded brackets happened. The incidence of breakage was 4 times, three of them were in the lower arch while only one was in the upper arch. The rebonding of the brackets was done as soon as possible and was positioned passively through the arch wire then reinstallation of the appliance again in place.

Buccal mucosal irritation was presented bilaterally in two patients of this study. One was mild and resolved spontaneously and the other was moderate and didn't heal during the duration of treatment with the appliance, but it transformed fibroma and was healed later progressively after appliance removal. This happened due to the design of the appliance which had a ball and socket attachment permitting a wide range of movements of the appliance, especially lateral movements. During opening and closure, the appliance slides laterally to touch the buccal mucosa with its telescopic shaft or arm but when noticing the two patients with the buccal mucosal irritation incident, during opening and closing the appliance touched the buccal mucosa with its most apical part which is not fully smooth as it got an open end of the telescopic shaft enclosing the spring.

Previous studies using Power scope didn't report a buccal mucosal irritation that happened during the course of the treatment, instead, pain in the teeth and jaws, headaches, and sleep discomfort were mentioned by a study **(**22**)** which were greater at the first 7 days after Power scope appliance and then decreased over the following 30 days.

Conclusion

The following conclusions could be drawn: Power scope appliance provides an effective tool for the

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treatment of skeletal Class 2 adolescent patients with significant enhancement of the soft tissue profile and the mento-labial sulcus.

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