Original Article

Comparative evaluation of treatment effects between two fixed functional appliances for correction of Class II malocclusion: *A single-center, randomized controlled trial*

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ABSTRACT

Objective: The objective of this study was to evaluate and compare the effects of PowerScope and Forsus in the treatment of Class II division 1 malocclusion.

Materials and Methods: This was a 2-arm parallel, double-blind, randomized, controlled trial. A total of 28 Class II division 1 malocclusion patients indicated for treatment with fixed functional appliances were randomized and equally divided (n = 14) among PowerScope (American Orthodontics, Sheboygan, Wis; mean age 14.11 ± 1.3 years) and Forsus (3M Unitek Corp, Monrovia, Calif; mean age 15.5 ± 1.1 years) groups. Skeletal and dentoalveolar effects of PowerScope and Forsus were compared. The secondary outcomes were evaluation of patient comfort and operator convenience. Randomization was accomplished with a 1:1 allocation ratio, and concealment was achieved by sealed opaque envelopes. The participants and data collectors were all blinded to study group allocation. Data were analyzed for 26 patients, 13 in each group, as one patient from each group discontinued treatment. Statistical comparisons were carried out using Student's *t*-tests and chi square tests ($P \leq .05$).

Results: A significantly greater mesial mandibular movement and improvement in sagittal skeletal relation were found in the Forsus patients ($P \leq .05$). The forward movement of the mandibular molar and incisors were greater in the PowerScope patients (2.3 mm and 2.80 mm) than in the Forsus patients (1.9 mm and 2.38 mm).

Conclusions: Both PowerScope and Forsus are effective in correcting Class II malocclusion. The percentage of dentoalveolar effects in correcting Class II malocclusion is more for PowerScope when compared with Forsus. Patient comfort was the same with both appliances. This trial was registered. (*Angle Orthod.* 2018;88:259–266.)

KEY WORDS: Pitchfork analysis; PowerScope; Class II malocclusion

INTRODUCTION

Among different dental and skeletal combinations that can create a Class II malocclusion, mandibular retrusion is one of the most common characteristics.[1] In such cases, to stimulate mandibular growth by the forward positioning of the mandible, various removable and fixed functional appliances are commonly used to alter the position of mandible.[2,3,4]

The stimulation of mandibular growth, distal movement of the upper dentition, and mesial movement of the lower dentition contributes to the correction of Class II malocclusion with the use of fixed functional appliances.[5] The Forsus Fatigue Resistant Device (3M Unitek Corp., Monrovia, Calif) is one of the various fixed functional devices commonly used by orthodontists. The appliance consists of a push rod that inserts into a telescoping cylinder and is attached to the mandibular arch wire distal to either the canine or first premolar bracket.[5,6] However, frequent breakage of canine brackets and soft tissue lacerations have been reported with Forsus.[7] It is available in various sizes, hence a large inventory must be maintained, and

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chairside application time is increased as size selection is needed. The PowerScope (American Orthodontics, Sheboygan, Wis) is a recent addition to the orthodontist's armamentarium. It is delivered as a one-size-fits-all appliance, preassembled with attachment nuts for quick and easy chairside application.[8] The appliance is a wire-to-wire installation with attachments placed mesial to the first molar in the maxillary arch and distal to the canine of the mandibular arch. Although there are a few case reports showing the treatment effects and clinical application, there is no previous study evaluating the effects of the PowerScope appliance, which has a different attachment mode than other fixed functional appliances. Thus, the purpose of this study was to determine the skeletal and dental changes produced by the PowerScope appliance and to compare these effects with those produced by the Forsus Fatigue Resistant Device. The null hypothesis was that there were no significant differences in treatment effects of PowerScope and Forsus.

Successful orthodontic treatment also depends on patient acceptance of the orthodontic technique being used. To minimize patient discomfort and maximize satisfaction during treatment, different modifications are made in various appliance designs. Therefore, the secondary objective of this study was to assess and compare patient comfort and operator convenience with the use of PowerScope and Forsus. This will assist clinicians in selecting the method of treatment that will be better accepted by their patients.

MATERIALS AND METHODS

The present study was a prospective, nonpharmacological, double-blind, randomized clinical study conducted in the Department of Orthodontics and Dentofacial Orthopedics, Postgraduate Institute of Dental Sciences, Rohtak, India.

Sample size was calculated with a type 1 error frequency of 5% and power of the statistical test set at 80% for a clinically significant difference for effect size of 0.6, resulting in sample size of 12 in each group.[9] Anticipating a dropout rate of 10%, 14 patients were enrolled in each group.

Ethical clearance from the institutional review board was obtained before starting the study (no. PGIDS/IEC/2015/76).

The study sample consisted of 28 patients selected from patients reporting to the department for fixed orthodontic treatment. The inclusion criteria were postpubertal boys and girls presenting with Class II malocclusion with the molars in at least an end-to-end relationship, retrognathic mandible, increased overjet not less than 5 mm, horizontal to average growth pattern, positive pretreatment visual treatment objective, and minimum crowding in the dental arches requiring no extraction of any permanent teeth (excluding third molars) and patients in the cervical vertebral maturation index stages 4 and 5.[10] Participants with a history of orthodontic treatment, severe proclination and crowding of anterior teeth, or any systemic disease affecting bone and general growth were excluded. The primary researcher explained the nature of study to the patients and their parents and written consent to participate in the study was obtained. The final sample of 28 patients fulfilling all the above criteria was randomly divided in one of the following two groups: PowerScope and Forsus.

Randomization and Allocation Concealment

Randomization was accomplished using a simple randomization method to ensure a 1:1 allocation ratio, and allocation concealment was achieved with similar-looking sealed opaque envelopes. The name of the groups "Forsus" and "PowerScope" appeared on 13 pieces of paper each, resulting in a total of 26 pieces of paper that were folded and shuffled in a box. They were removed and, without opening, placed in 26 opaque envelopes that were then sealed and replaced in the box. The envelopes were shuffled inside the box, and each patient was asked to pick one envelope from the box. The patient was then assigned to the group designated and recorded by an investigator who was not involved in the intervention or data analysis.

Interventions

All of the participants in both treatment groups were treated by the principal investigator (Dr Arora) with an MBT prescription 0.022-inch slot preadjusted edgewise appliance (Ortho Organizers, San Marcos, Calif). Both arches were leveled and aligned up to 0.019" $\times$ 0.025" stainless steel wires, and then the fixed functional appliance was installed as per the group chosen in the patient's envelope. A transpalatal arch in the upper arch was placed to control the transverse expansion of maxillary first molars. A lingual crown torque of 10° in the lower anterior segment was placed in both groups to minimize the anticipated side effect of flaring caused by the fixed functional appliances. Also, the mandibular archwire was consistently cinched distal to the molars in both groups.

For the Forsus Group, the measurement guide was used to determine the correct size of the appliance by measuring each side from the distal end of maxillary molar tube to the distal side of the mandibular canine with the patient in centric occlusion. An L-pin served to attach it to the maxillary headgear tube. A circular loop

was placed in the mandibular arch distal to the canine bracket for attachment of the push rod.[11] For the PowerScope group, the maxillary attachment screw was engaged mesial to the first molar on the maxillary rectangular stainless steel arch wire and the mandibular attachment screw onto the mandibular rectangular stainless steel arch distal to the canine wire using the driver provided. The patients were observed at 4-week intervals and appliances were activated as needed. The patients were asked to report to the department immediately in case they experienced any breakage of the appliance before the next follow-up visit. The patients underwent the functional appliance phase of treatment for a period of 6 months. No additional adjuncts (Class II elastics, etc.) were administered during the period of the study.

To check patient comfort, all patients were administered a questionnaire. The questionnaire was modified from that of Bowman et al,[12] who investigated patient experiences with the Forsus appliance. The questionnaire was designed in English and then verbally translated into the patients' and parents' native language at the installation appointment, although all of the patients and their parents could read and understand it in English.

Cephalometric Analysis

Lateral cephalometric radiographs were taken before starting fixed functional appliance therapy (T1), immediately (1–3 days) before placement of the fixed functional appliance (T2), and after removal of the fixed functional appliance (T3). All cephalometric radiographs were taken on the same cephalostat with a magnification of 8%, which was acceptable for the measurements. For evaluation of skeletal and dentoalveolar changes that contributed to the Class II correction, the pitchfork analysis[13] was used.

Intraexaminer Reliability

To determine repeatability of the method, 10 cephalograms were retraced by the investigator. The intraexaminer reliability was found to be 90%. All measures were within a 1-mm range, with an average discrepancy of 0.4 mm.

Blinding

Blinding of participants in each group was done. As the primary investigator who performed the intervention could not be blinded, both the coinvestigator who analyzed pre- and postfunctional lateral cephalograms of both groups and the statistician were blinded with regard to the group to which each lateral cephalogram belonged.

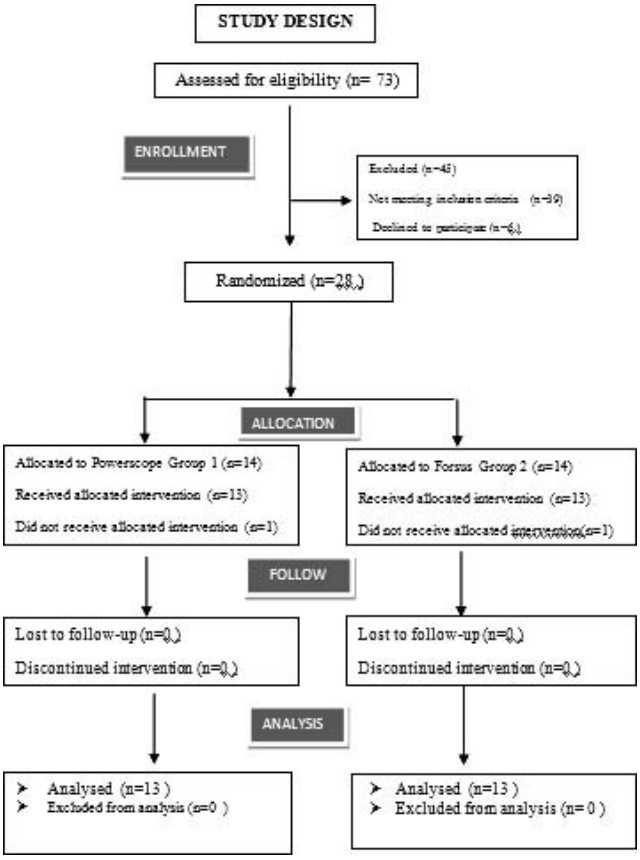

Figure 1. CONSORT - Consolidated standards of reporting trials flow diagram.

Statistical Analysis

A master file was created by entering data into a Microsoft Excel spreadsheet and was checked for any discrepancies. The data were analyzed using SPSS (version 21.0 SPSS, Chicago, Ill). The Shapiro Wilk test was used to check the normality of data. The data were subjected to descriptive analysis for proportion, mean, and standard deviation. Independent *t*-tests were used for parametric data to compare the means between groups. The Pearson chi-square test, *t*-test, and Mann-Whitney test were used to analyze patient and operator convenience. All statistical tests were performed at the .05 significance level.

RESULTS

Patient flow through the study is illustrated in the CONSORT - Consolidated standards of reporting trials flow diagram shown in Figure 1.).

A total of 28 participants were enrolled in the study that was randomly and equally distributed between the two groups. A total of 26 patients (13 in each group) completed the treatment protocol. Two patients dropped out from the study during the initial stages

Table 1. Comparison of Mean Age and Gender Distribution of the Participants in the Two Groups at the Start of Treatment (T1)[a]

Parameter	PowerScope Group	Forsus Group	*P* Value	Significance
Mean chronological age	14 years 11 months ± 1 year 3 months	15 years 5 months ± 1 year 1 month	.987	NS
Skeletal age				
CVMI 4	8	9	.800	NS
CVMI 5	5	4		
Gender				
Male	8	5	.130	NS
Female	6	9		

[a] CVMI indicates cervical vertebral maturation index; NS, nonsignificant.

as they could not complete the treatment because of personal reasons.

Baseline Data

The mean pretreatment age and gender distributions of the groups are shown in Table 1. The homogeneity between the two groups with respect to age and skeletal maturity at the start of treatment allowed for comparisons without annualizing the data. The statistical comparison of the baseline data (Table 2) between the two groups also did not reveal any significant difference for any cephalometric variable.

The comparisons of treatment changes for the skeletal and dentoalveolar measurements between the two groups are shown in Table 3 and Figures 2 and 3. Positive values are those that contributed to the correction of the Class II malocclusion, and negative values are those that worsened the Class II relationship.

Skeletal Changes

The forward movement of the maxilla was comparable between the two groups. However, mesial movement of the mandible was greater in the Forsus group participants (3.7 mm) than in the PowerScope group participants (2.9 mm), and the difference was statistically significant ($P < .05$). The apical base change (maxillomandibular differential change) was 3.0 mm in the Forsus participants and was significantly greater than in the PowerScope participants (2.2 mm).

Dentoalveolar Changes

The forward movement of the lower molars and the lower incisors were greater in the PowerScope participants than in the Forsus participants. The palatal movement of the upper incisors was 0.8 mm in the PowerScope participants and 1.26 mm in the Forsus participants, and the difference was statistically significant ($P < .05$). Molar correction and overjet correction in the Forsus group was significantly greater ($P < .05$) than in the PowerScope group.

Patient Comfort and Operator Convenience

Patient comfort was evaluated by responses to the questionnaire. Responses regarding the initial perceptions of PowerScope and Forsus regarding certain functions (speech and eating) are shown in Table 4. Patients in the PowerScope group had significantly more discomfort while eating when compared with those in the Forsus group. Discomfort while talking and soreness on the lip/cheek was comparable between the two fixed functional appliances (Table 5).

The mean time required for appliance insertion in the PowerScope participants was significantly less when compared with the Forsus participants ($P < .001$; Table 6).

DISCUSSION

The aim of the present study was to evaluate and compare the skeletal and dental changes produced by the PowerScope and Forsus appliances. Ethical

Table 2. Comparison of Baseline Data at the Time of Placement of Functional Appliance in the Two Groups (T2)[a]

Variable	PowerScope Group	Forsus Group	*P* Value	Significance
SNA	81.00 ± 1.47	80.84 ± 2.12	.832	NS
SNB	75.73 ± 1.11	74.84 ± 2.53	.261	NS
ANB	5.26 ± 0.90	6.00 ± 1.02	.065	NS
GoGn-SN	29.57 ± 3.21	31.57 ± 2.84	.106	NS
J-ratio, %	68.62 ± 3.50	64.23 ± 3.70	.075	NS
IMPA	101.26 ± 6.54	100.53 ± 4.66	.746	NS
U1-SN	104.42 ± 2.87	103.03 ± 4.43	.355	NS

[a] J-ratio indicates Jaraback ratio; U1, upper incisor; NS, nonsignificant.

Table 3. Comparison of Treatment Changes in All Measurements in Groups 1 (Powerscope) and 2 (Forsus)[a]

S.No	Variable	PowerScope Group	Forsus Group	*P* Value	95% Confidence Interval of the Difference		Significance
					Lower	Upper	
1	Maxilla	−0.66 ± 0.20	−0.60 ± 0.31	.51	−0.28067	0.14528	NS
2	Mandible	2.92 ± 0.52	3.76 ± 0.55	.01	−1.26999	−0.40386	*
3	ABCH	2.25 ± 0.37	3.08 ± 0.32	.01	−1.10847	−0.54537	*
4	U6	0.75 ± 0.18	0.77 ± 0.19	.75	−0.17609	0.12993	NS
5	L6	2.37 ± 0.34	1.94 ± 0.21	.01	0.18897	0.64949	*
6	Molar correction	5.37 ± 0.45	5.80 ± 0.51	.03	−0.82271	−0.03883	*
7	U1	0.86 ± 0.12	1.26 ± 0.31	.01	−0.596	−0.201	*
8	L1	2.80 ± 0.42	2.38 ± 0.33	.08	0.12496	0.73504	NS
9	Overjet correction	5.91 ± 0.47	6.63 ± 0.59	.02	−1.14881	−0.28503	*

[a] U6 indicates upper molar; L6, lower molar; U1, upper incisor; L1, lower incisor; ABCH, apical base change; NS, nonsignificant.
* $P < .05$.

principles precluded the use of an untreated control group. The significant features of this study were the skeletal and dental evaluation of patients treated by the PowerScope, which was not previously published. It adds to the existing literature by comparing two fixed functional appliances. The blind methodology employed in the analysis of the data reduced bias of the study.

Classifying participants by their skeletal age diminishes or even eliminates sex differences, which reduces influence of the possible confounding factor of sex.[14] The assessment of skeletal age was done from lateral cephalometric films to avoid the need for additional hand-wrist radiographs. Pitchfork analysis was used to evaluate dental and skeletal effects because it enabled a clear distinction between skeletal and dental changes in the sagittal dimension.

In this study, in both the PowerScope and Forsus groups, the maxilla moved mesially by 0.7 mm at the end of the functional phase. The effects of functional appliances on the maxilla are inconsistent in the literature, with many previous studies showing no restriction in the forward growth of the maxilla,[15,16] whereas others reported inhibition of maxillary growth. The current study also showed that neither of the appliances inhibited the forward growth of the maxilla, and there was no statistically significant difference in the effect of the two appliances on the maxilla.

The mandible moved mesially by 3.7 mm in the Forsus group, which is comparable to the effects reported in previous studies of Forsus over untreated controls.[16] The change in the sagittal position of the mandible in the PowerScope group was 2.9 mm and could not be compared because of the lack of previous studies with this appliance. However, the study showed that the Forsus displayed a statistically significant difference ($P < .05$) in mandibular mesial movement when compared with the PowerScope. The statistically significant difference in skeletal mandibular changes between the Forsus and PowerScope groups

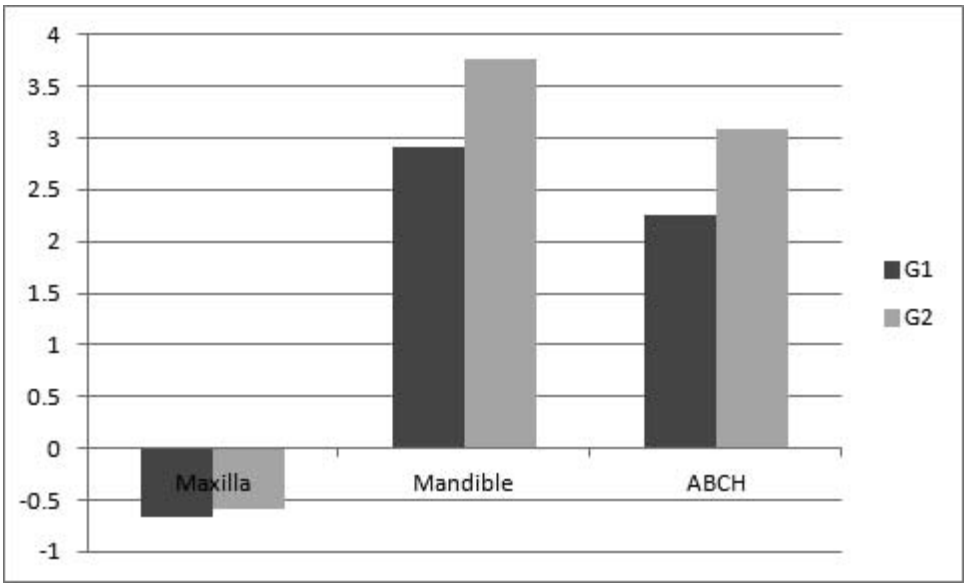

Figure 2. Comparison of skeletal changes between the PowerScope (G1) and Forsus (G2) groups.

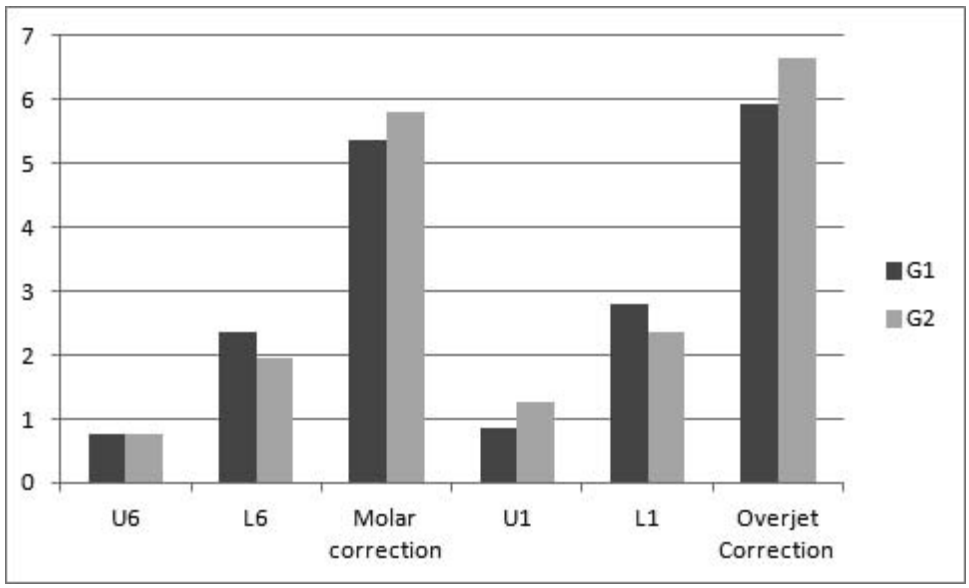

Figure 3. Comparison of dentoalveolar changes between the PowerScope (G1) and Forsus (G2) groups.

may have been a result of the difference in the sites of attachments of the two appliances. The greater dentoalveolar effects can be explained by the attachment of the PowerScope, which is completely on the archwires, making the appliance less rigid when compared with the Forsus. Also, an increased number of patient visits and more frequent breakage were reported with the PowerScope. The difference in effective treatment time for which the appliance was kept in the mouth for the Forsus was significantly more than for the PowerScope, and this may have allowed for more mandibular skeletal changes in the Forsus group than in the PowerScope group.

The apical base change value, which represents the maxillomandibular differential change, also showed a significant difference between the two groups ($P < .05$), with greater improvement in the Forsus group (3 mm) than in the PowerScope group (2.2 mm). In both groups, the value was positive, indicating that the mandible outgrew the maxilla. The significantly more mesial mandibular movement in the Forsus group contributed to the statistically significant difference in the maxillomandibular differential between the two groups.

The maxillary dentition moved distally with both of the appliances. The distal movement of the maxillary molars was similar in both of the groups (0.7 mm), whereas the distal movement of the maxillary incisors was significantly greater in the Forsus group (1.3 mm) when compared with the PowerScope group (0.8 mm). This shows that more reciprocal force acted distally on the maxillary dental arch when the mandible was postured forward by the Forsus compared to the PowerScope.

The dentoalveolar effects on the lower dental arch with both appliances were mesial movement of the lower molars and proclination of the lower incisors. These findings are in accordance with those reported in various other studies of fixed functional appliances[15,16] and were a result of the downward and forward application of force on the mandibular dentition. The mesial movement of the mandibular molar and incisors was greater in the PowerScope group (2.3 mm and 2.8 mm, respectively) when compared with the Forsus group (1.9 mm and 2.3 mm, respectively). As discussed, the difference in mode of attachment between the two appliances, with the PowerScope being completely attached on the archwires, may have led to more dentoalveolar changes. There was a 54.5% reduction of

Table 4. Comparison Between the Two Groups With Respect to Discomfort During Functional Activities

Question	Group	Not at All, n (%)	A Little, n (%)	A Lot, n (%)	Does Not Worry, n (%)	*P* Value	Significance[a]
Discomfort while talking	PowerScope	3 (23.1)	7 (53.8)	3 (23.1)	0	.187	NS
	Forsus	6 (46.2)	6 (46.2)	0	1 (7.7)		
Discomfort while eating	PowerScope	3 (23.1)	4 (30.8)	3 (23.1)	3 (23.1)	.027	*
	Forsus	6 (46.2)	7 (53.8)	0	0		

[a] NS, nonsignificant.
* $P < .05$.

Table 5. Tooth Pain, Jaw Pain, Muscle Pain, Headache, Sleep Discomfort at 7 Days, 14 Days, and 30 Days

	7 Days, n (%)			14 Days, n (%)			30 Days, n (%)		
Questionnaire	Not at All	A Little	A Lot	Not at All	A Little	A Lot	Not at All	A Little	A Lot
Tooth pain									
PowerScope Group	1 (7.7)	10 (76.9)	2 (15.4)	6 (46.2)	7 (53.8)	0	10 (76.9)	3 (23.1)	0
Forsus Group	6 (46.2)	6 (46.2)	1 (7.7)	9 (69.2)	4 (30.8)	0	11 (84.6)	2 (15.4)	0
Jaw pain									
PowerScope Group	1 (7.7)	8 (61.5)	4 (30.8)	9 (69.2)	4 (30.8)	0	9 (69.2)	4 (30.8)	0
Forsus Group	7 (53.8)	5 (38.5)	1 (7.7)	9 (69.2)	4 (30.8)	0	13 (100)	0	0
Muscle pain									
PowerScope Group	8 (61.5)	4 (30.8)	1 (7.7)	9 (69.2)	4 (30.8)	0	9 (69.2)	4 (30.8)	0
Forsus Group	7 (53.8)	6 (46.2)	0	10 (76.9)	3 (23.1)	0	13 (100)	0	0
Headache									
PowerScope Group	10 (76.9)	3 (23.1)	0	8 (61.5)	5 (38.5)	0	11 (84.6)	2 (15.4)	0
Forsus Group	11 (84.6)	2 (15.4)	0	12 (92.3)	1 (7.7)	0	13 (100)	0	0
Sleep discomfort									
PowerScope Group	0	7 (53.8)	6 (46.2)	3 (23.1)	9 (69.2)	1 (7.7)	7 (53.8)	6 (46.2)	0
Forsus Group	8 (61.5)	5 (38.5)	0	11 (84.6)	2 (15.4)	0	12 (92.3)	1 (7.7)	0

the overjet and 44.8% molar correction in the Forsus group as a result of dentoalveolar changes, whereas the corresponding amounts were 62.7% and 58.5%, respectively, in the PowerScope group. This shows less dentoalveolar and, hence, more skeletal mandibular changes produced by the Forsus appliance when compared with the PowerScope.

The PowerScope group experienced significantly more discomfort while eating when compared with the Forsus group. This might have been a result of the differences in the design of the two appliances. With both appliances, pain in the teeth and jaws, headaches, and sleep discomfort were greater at 7 days and decreased over 30 days; there was no difference between the two appliances. This is in accordance with other studies of fixed functional appliances, thus implying that orthodontic patients seem to accept a certain amount of initial discomfort and functional interference associated with their usage.[12]

Installation of the PowerScope was faster than the Forsus (10.18 minutes for PowerScope versus 18.5 minutes for Forsus), with the difference being statistically significant ($P < .001$). This was understandable as no size selection was needed with the PowerScope, and the claim of easy and quicker installation by the manufacturer of the PowerScope was supported by this study. However, an important finding was the reported increase in lower archwire breakage in the PowerScope group. This might have been because the PowerScope was completely attached to the archwires and, thus, the total force is borne by the archwire and then transmitted to the various structures. The breakage rate resulted in a highly significant difference ($P < .001$) between the groups in terms of the number of patient visits, being much greater in the PowerScope group (median = 9) when compared with the Forsus group (median = 5). The significant time efficiency during installation of the PowerScope appliance was negated by the need for more repair appointments for these patients.

Table 6. Comparison of Time Taken for Appliance Insertion (in Seconds) in the Two Groups

Group	Mean ± SD	*P* Value	Significance[a]
PowerScope	611.69 ± 185.64	<.001	NS
Forsus	1110.30 ± 120.43		

[a] NS indicates nonsignificant.

Limitations

The limitations of this study included the small sample size recruited for the trial and the relatively short follow-up period of 6 months. Further studies evaluating more parameters, incorporating a larger sample size and perhaps an untreated control group are required. Long-term follow-up is essential to study the stability of the corrections that were obtained.

CONCLUSIONS

- The treatment effects of the PowerScope in Class II correction were a combination of skeletal and dentoalveolar effects, similar to other fixed functional appliances.
- When compared with Forsus, the PowerScope had less skeletal effects on the mandible and more dentoalveolar effects, contributing to Class II correction.
- Patient comfort was comparable between the two appliances except while eating, in which the PowerScope group had more discomfort.
- The decreased chair time required for placement of the PowerScope was negatively affected by the need

for more frequent patient appointments as a result of wire breakage.

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