Journal of the World Federation of Orthodontists xxx (xxxx) xxx

Contents lists available at ScienceDirect

Journal of the World Federation of Orthodontists

journal homepage: www.ejwf.org

Correlation of twin-block appliance efficacy and wear durationas assessed with a compliance indicator

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ARTICLE INFO

Article history:
Received 16 September 2021
Revised 22 November 2021
Accepted 22 November 2021
Available online xxx

Keywords:
Compliance
Twin block appliance
Wear time

ABSTRACT

Background: The aim of this study was to investigate the association between objective wear time and treatment efficacy of a twin block (TB) appliance.
Methods: A TB appliance incorporating a compliance indicator was delivered to 44 children in the age group of 11—14 years (25 boys and 19 girls). Participants were instructed to wear the appliance full time and were recalled at 3—4- week intervals. Cephalograms and study models were taken at baseline and after 6 months of appliance therapy.
Results: Data from 41 of the 44 participants were analyzed. A wide variation in daily wear time among participants was observed. Based on wear time, they were divided into full time (FT >17 h/d) and part time (PT < 12 h/d) wear groups. Mean wear durations were 20.86 hours in the FT-wear group and 9.55 hours in the PT-wear group. In skeletal changes, the ANB (A point, nasion, B point) angle was reduced by 2.69° in the FT-wear group, and 1.33° in the PT-wear group, and statistically significant increases were seen for the mandibular base measurement (Pg/OLp) in the FT-wear group (2.22mm), compared with those in the PT-wear group (0.44mm). . In dental changes, overjet were reduced by 3.91 mm and 2.0 mm in the FT-wear and PT-wear group, respectively. This difference was statistically significant.
Conclusions: Skeletal effects were pronounced in the FT-wear group, and dentoalveolar changes were comparable in the 2 wear groups. The maximum skeletal treatment effect of a TB appliance was found to occur with FT wear over a 6-month treatment period.

For treatment of Class II malocclusion with mandibular retrognathism, to correct the skeletal discrepancy, various removable and fixed myofunctional appliances have been used in order to redirect the growth . The most popular appliance used for correction of Class II malocclusion is the versatile, removable twin block (TB) appliance [1]. The TB appliance was designed for full-time wear, to take full advantage of all the functional forces applied to the dentition [2]. However, Proffit suggested that “extrinsic forces are effective when duration approaches 50%,” and a threshold of up to 6 hours has been proposed to permit orthodontic tooth movement as a result of either active appliances or habits [3]. Parekh et al. concluded that there is no difference in either the dental or skeletal changes achieved with full-time (FT) versus part-time (PT) wear of a TB appliance over a 12-month period. Less-onerous PT wear regimens may therefore be a viable alternative to FT wear of removable functional appliances [4].

The cooperation of children and adolescents plays an important role in achieving the desired treatment outcome with use of a TB appliance [5]. Various devices have been introduced to measure the objective wear time of removable appliances. Devices developed more recently have a thermal microsensor embedded in the appliance [6]. These microsensors can be embedded into the main construction material of the appliance and can identify temperature changes (e.g., a change from room temperature to “mouth temperature”), which are then transformed into wear-time information.

But in tropical countries, where most of the time the environmental temperature is higher than mouth temperature, these thermal sensors will give an incorrect result. The increased cost of these thermal microsensors, together with their reduced reliability and inadequate accuracy of measurement, has inhibited their use for research or clinical purposes in tropical countries. Hence arose

Funding: The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interest: Authors have completed and submitted the ICMJE Form for Disclosure of potential conflicts of interest. None declared.

Provenance and peer review: Not commissioned; externally peer reviewed.

Registration number: CTRI, CTRI/2020/03/023962. Registered 13 March 2020, http://ctri.nic.in/Clinicaltrials/regtrial.php?modid=1&compid=19&EncHid=86972.30391

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https://doi.org/10.1016/j.ejwf.2021.11.003

a need for a low-cost electronic timing device suitable for tropical countries in the application of wear-time recording of removable acrylic orthodontic appliances. We developed a sensor (electronic timing device) suitable for tropical countries that can sense the wear time by using the principle of infrared proximity detection. This sensor does not rely on temperature change and can be used in many places.

The null hypothesis of the study was that wear time does not affect the treatment efficacy of a TB appliance. Thus, the purpose of our study was to design and use a sensor suitable for tropical countries, to investigate the association between objective wear time and the treatment efficacy of a TB appliance.

1. Materials and methods

1.1. Sample size calculation

The study was approved by the institutional ethics committee. Epi Info software, and the formula $n = 2 (Z_\alpha + Z_\beta)^2 P^2 / d^2$, was used to calculate the sample size. Z_α was 1.96, at an α-error of 5%, and Z_β was 0.84 at a β-error of 20%, with the power of the study set at 90%. P_1 was 50.5% (the mean percentage of the compliance rate in the functional appliance); P_2 was 99% (the ideal percentage of the compliance rate); the significance level was $P < 0.05$; the total sample required was 40 patients. An additional 4 participants were recruited, based on an anticipated 10% attrition rate. Thus, a total of 44 participants were recruited.

1.2. Eligibility criteria

Clinical inclusion criteria were as follows: (i) a full-cusp class II or end-on molar relationship with a convex facial profile; (ii) an overjet > 5 mm; (iii) improvement in clinical visual treatment objective. Radiographic inclusion criteria were as follows: (iv) an ANB (A point, nasion, B point) angle > 4 degrees; (v) patients in the accelerated phase of the pubertal growth spurt (MP3-FG or MP3-G stage, as defined by Hägg and Taranger [7]). Those with a severe tooth-size arch-length discrepancy, a history of orthodontic treatment, or craniofacial syndromes were excluded.

1.3. Intervention

The wax construction bite was recorded with a sagittal advancement of up to 70% of the maximum protrusive movement, and a vertical opening of 2–3 mm beyond the postural rest position of the mandible. TB appliances were constructed according to the design described by W J Clark [1]. Each appliance was fitted with an electronic timing device (sensor) in the palatal aspect of the maxillary component, to allow objective assessment of wear durations (Fig. 1).

1.4. Mechanism of the sensor and measurement method

The sensor mechanism and measurement method were determined as follows:

1 The sensor was based on the infrared proximity-detection principle.
2 The sensor was placed, along with the battery, on the palatal surface of a maxillary cast in an appropriate location, so that an infrared light–emitting diode (IR LED) would come as close as possible to the palatal surface.
3 After the acrylic had set completely, the appliance was retrieved and the finished appliance was delivered to the patient.

Fig. 1. Intra-oral twin block appliance with embedded electronic timing device.

Fig. 2. Wear time after 1 week (1019×5 minutes = 5095 minutes, i.e., 84.91 hours total, or 12.1 h/d on average).

4 While the patient was wearing the appliance, the IR LED transmitted the infrared radiation pulse, which was reflected from the surface of mucosa and detected by the infrared photodiode (counted as the wear time of the appliance).
5 For appointments after the delivery of the appliance, wear time was recorded wirelessly by keeping the appliance with the IR LED of the sensor in close proximity to the receiver (Fig. 2).

A minor modification to the working model was made by painting the palatal surface with a nonreflective black paint. The patient was instructed to keep the appliance on the modified working model when it was not in use. The black color absorbed the infrared radiation from the sensor when it was placed over it, and thus prevented its reflection. Thus, an accurate assessment was made of wear time.

All patients were instructed to wear the appliance full time, including during eating, except while brushing teeth and during any sports activity. The patients were recalled after a week to check for sore spots and appliance fitting, and any other patient complaints. Following that visit, the planned visit frequency was every month for a study period of 6 months. At each visit, changes in occlusion and wear-time recording by the sensor were checked and recorded.

1.5. Cephalometric measurements

Lateral cephalometric radiographs were taken before appliance placement (T0), and after 6 months of treatment (T1), using the same machine (Planmeca ProMax S3 pan-ceph, Finland, Helsinki). Cephalometric tracings were performed by the same orthodontic trainee (NB) manually. The following landmarks were used: pogonion (pg); sella (s); A point; B point; condylion (co); inci-

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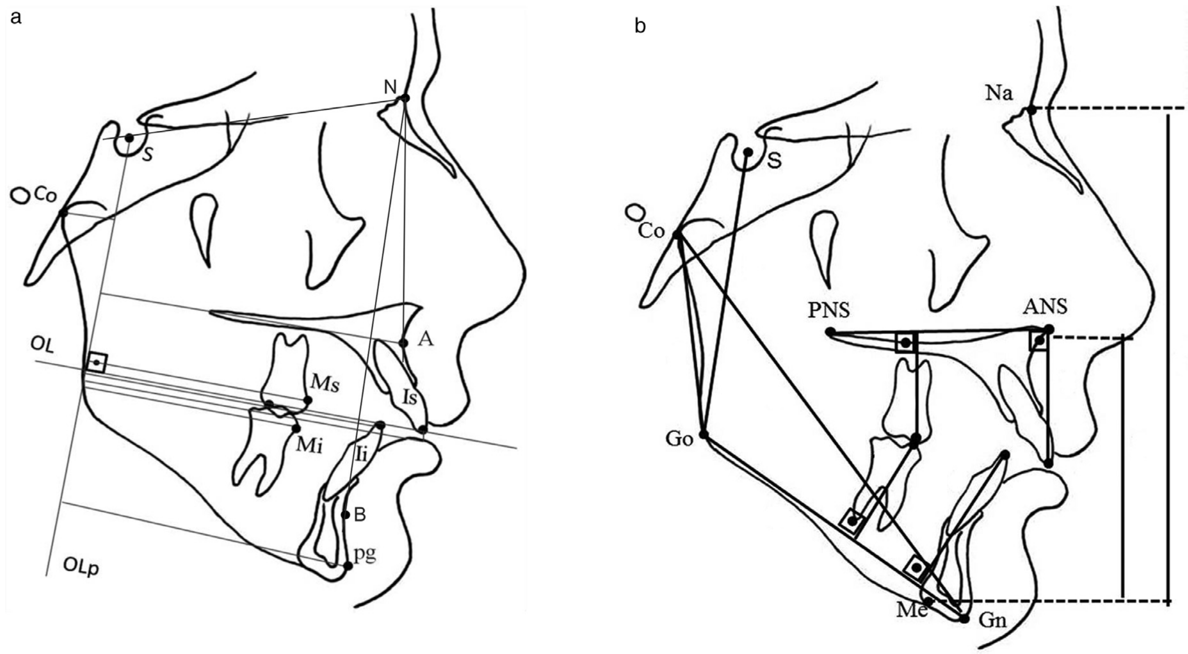

Fig. 3. (**A**) Cephalometric analysis (anteroposterior skeletal and dental parameters)..(**B**) Cephalometric analysis (vertical skeletal and dental parameters).

sion inferius (ii); incision superius (is); molar inferius (mi); molar superius (ms); anterior nasal spine (ANS); posterior nasal spine (PNS); menton (me); gnathion (Gn); and gonion (Go).

1.6. Pancherz's cephalometric analysis and superimposition procedure

A refined sagittal–occlusal Pancherz analysis was used [8]. The reference plane was composed of the occlusal line (OL) and a perpendicular-to-occlusal line (OLp) through the sella point. Pretreatment, and after 6 months of treatment, cephalograms were superimposed on the fixed bony structures of the anterior cranial base [9]. After superimposition, the reference grid was shifted to a post-6-month cephalometric radiograph. The cephalometric measurements are shown in Figure 3A and 3B (Table 1). Also, study models and clinical photographs were taken at baseline and after 6 months of appliance therapy.

The present study design was a nonrandomized interventional study (quasi-experimental design). Patients were allocated into FT- and PT-wear groups based on the duration of wear of the appliance. Patients wearing an appliance on average $<$ 12 hours per day were allocated to the PT wear group, and patients wearing the TB on average $>$ 17 hours per day were assigned to the FT-wear group.

1.7. Statistical analysis

Statistical analysis of data was performed using SPSS Chicago, IL (v. 26.0, IBM). The statistical significance level was set at $P < 0.05$. The Shapiro–Wilk test was used to evaluate normality of the data distribution. Intragroup comparison was made using a paired sample *t* test (up to 2 observations). Intergroup comparison (2 groups) was made using an unpaired sample *t* test. Differences in gender within groups were assessed using an independent sample *t* test. The differences were not statistically significant, and hence data were combined. Ten randomly selected cephalograms were traced again after 3 weeks from the first measurements, to assess the repeatability of the cephalometric measurements. Correlation of the 2 measurements was assessed using the paired *t* test, and the differences were found to be insignificant. Intra-operator reliability (method error) in cephalometric analysis was assessed using the intraclass correlation coefficient, which indicated a high level of agreement (0.96).

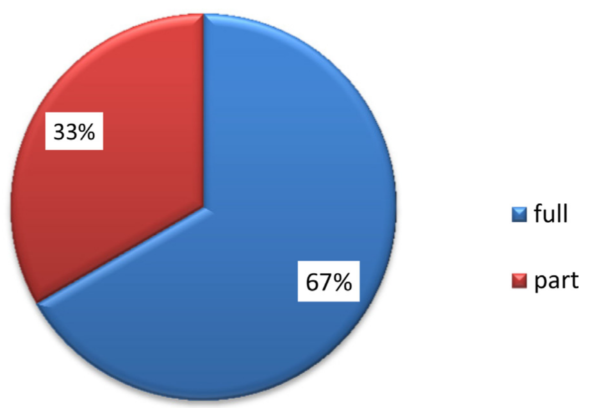

Fig. 4. Distribution of patients based on wear-time p (part time vs. full time).

2. Results

A sample of 44 participants consisted of 19 girls and 25 boys, with a mean age of 12.63 (standard deviation, 0.839) years. Data from 41 of the 44 participants were analyzed after 6 months of therapy. The average number of patient visits was 7 to 8 in 6 months of treatment. Monthly wear-time was assessed, with mean wear time of the TB appliance ranging from 15.17 to 17.96 hours per day, less than that prescribed (Table 2). Wear time of the TB appliance varied widely among patients, as recorded by an electronic timing device.

The frequency distribution for wear time for each group is depicted in Figure 4. There was a statistically highly significant difference in wear time between the 2 groups. In the FT group, the

Table 1
Comparison of baseline cephalometric measurements of full time– (FT) and part time– (PT) wear groups

Parameters	FT-wear group		PT-wear group	
	Mean, degrees/mm	SD	Mean, degrees/mm	SD
Skeletal anteroposterior				
Angle SNA	81.16	1.67	81.27	1.41
Angle SNB	74.44	1.57	74.5	1.96
Angle ANB	6.72	1.43	6.77	1.46
Mandibular base (Pg/ OLp)	75.51	3.32	72.27	3.14
Maxillary base (A Point/ OLp)	74.38	4.31	71.44	3.98
Condylar head (Co/ OLp)	13.11	3.21	11.27	3.58
Corpus length (Go-Gn)	72.25	3.82	70.87	3.88
Skeletal vertical				
Total anterior face height (Na-Me)	109.66	6.05	105.88	3.39
Lower anterior face height (ANS-Me)	59.27	4.97	57.22	3.79
Lower posterior face height (S-Go)	74.02	4.18	72.11	4.60
Effective mandibular length (Co-Gn)	103.08	3.77	102.55	4.20
Effective maxillary length (Co-ANS)	85.94	3.59	84.11	3.17
Ramus height (Co-Go)	51.55	2.50	52.61	4.01
Mandibular plane angle (angle SN-GoGn)	29.28	4.39	27.08	4.15
Dental anteroposterior				
Overjet (is/OLp minus ii/OLp)	9.83	1.36	10.27	1.50
Molar relation (ms/OLp minus mi/OLp)	2.55	0.92	1.94	1.01
Maxillary incisor (is/OLp minus A point/OLp)	10.19	1.40	10.22	1.14
Mandibular incisor (ii/OLp minus pg/OLp)	3.66	2.09	3.79	2.12
Dental vertical				
U1-PP	27.44	3.23	26.77	2.16
U6-PP	23.13	2.15	21.50	1.22
L1-MP	38.58	3.41	39.72	2.01
L6-MP	29.05	2.24	30.41	2.17
Soft tissue				
Upper lip with S line	4.44	2.07	3.88	1.29
Lower lip with S line	4.08	2.19	3.43	1.21

SD, standard deviation.

Table 2
Daily wear time of twin block appliance during treatment period of 6 months

Month	Wear time, h			
	Minimum	Maximum	Mean	SD
1	4.76	23.45	15.17	6.31
2	6.78	23.75	16.56	5.77
3	6.78	23.75	17.43	5.87
4	8.11	23.73	17.96	5.57
5	8.11	23.68	17.60	6.05
6	5.43	23.75	17.83	6.20

SD, standard deviation.

Table 3
Mean objective wear duration in full time– and part time–wear groups

Group	Mean wear time, h	SD	Proportion of recommended wear time, %
Full-time wear	20.86	2.79	86.91
Part-time wear	9.55	1.67	39.81

SD, standard deviation.

average wear duration was 20.86 hours a day, 86.91% of that prescribed; for the PT group, the mean wear time was 9.55 hours a day, 39.81% of that prescribed (Table 3).

2.1. Intergroup comparison

Comparison of the FT- and PT-wear groups after a treatment duration of 6 months is given in Table 4. TB treatment in the FT-wear group, compared with the PT-wear group, resulted in greater improvement in skeletal anteroposterior measurements, i.e., the SNB angle (between the sella/nasion plane and the nasion/B plane; $P = 0.010$), the ANB angle ($P = 0.003$), Pg/OLp, Co/OLp, and the corpus length ($P = 0.000$). However, no difference was found between the groups in the anteroposterior skeletal parameters such as the SNA angle (between sella, nasion, and subspinale point A; $P = 0.234$) and Point A/OLp ($P = 0.490$).

A greater increase in the total and lower anterior face height was observed in the FT group ($P = 0.001$), compared with the PT group. Slightly greater increases in posterior face height, ramus height, and mandibular plane angle were found in the FT-wear group than in the PT-wear group. However, these differences were not statistically significant. The FT-wear group had a greater increase in effective mandibular length, compared the change seen in the PT group ($P = 0.000$).

A significant decrease in the overjet, of 3.917 mm in the FT-wear group, compared with 2.0 mm in the PT-wear group, was observed. Overall, molar corrections of 4.694 mm in the FT group and 2.667 mm in the PT-wear group were noted. The difference between the groups was statistically significant ($P = 0.001$). The difference between the groups in the change in maxillary incisor inclination was less ($P = 0.397$), although a slightly greater mandibular incisor proclination was found in the PT-wear group (2.111° vs. 2.056°), but this difference also was not statistically significant ($P = 0.851$).

A statistically significant difference was found between the FT- and PT-wear groups in the lower molar to mandibular plane ($P = 0.010$). Changes in the other dental vertical measurements were not statistically significant. A minimal, nonsignificant difference in soft tissue changes was found between the groups.

Please cite this article as: N.R. Baheti et al, Correlation of twin-block appliance efficacy and wear duration, as assessed with a compliance indicator, Journal of the World Federation of Orthodontists, https://doi.org/10.1016/j.ejwf.2021.11.003

Table 4
Skeletal and dental changes with full time (FT) versus part time (PT) wear of a twin block appliance

Parameters	FT-wear group		PT-wear group		
	Mean, degrees/mm	SD	Mean, degrees/mm	SD	*P*
Skeletal anteroposterior					
Angle SNA	0.36	0.56	0.11	0.33	0.234
Angle SNB	2.33	0.92	1.33	0.79	0.010
Angle ANB	2.69	1.10	1.33	0.86	0.003
Mandibular base (Pg/ OLp)	2.22	0.75	0.44	0.52	0.000
Maxillary base (A Point/ OLp)	0.02	0.11	0.00	0.00	0.490
Condylar head (Co/ OLp)	2.22	0.75	0.44	0.52	0.000
Corpus length (Go-Gn)	1.50	0.51	0.44	0.63	0.000
Skeletal vertical					
Total anterior face height (Na-Me)	4.55	1.24	2.61	1.08	0.001
Lower anterior face height (ANS-Me)	3.55	1.24	1.83	0.66	0.001
Lower posterior face height (S-Go)	0.11	0.47	.00	0.00	0.490
Effective mandibular length (Co-Gn)	1.52	0.58	0.27	0.44	0.000
Effective maxillary length (Co-ANS)	0.27	0.54	0.00	0.00	0.145
Ramus height (Co-Go)	0.11	0.32	0.00	0.00	0.317
Mandibular plane angle (angle SN-GoGn)	1.58	1.06	1.50	0.79	0.837
Dental anteroposterior					
Overjet (is/OLp minus ii/OLp)	3.91	0.82	2.00	0.70	0.000
Molar relation (ms/OLp minus mi/OLp)	4.69	1.38	2.66	1.27	0.001
Maxillary incisor (is/OLp minus A point/OLp)	.139	0.47	0.00	0.00	0.397
Mandibular incisor (ii/OLp minus pg/OLp)	2.05	0.74	2.11	0.65	0.851
Dental vertical					
U1-PP	0.11	0.36	0.00	0.00	0.376
U6-PP	0.86	0.33	0.83	0.43	0.855
L1-MP	0.25	0.73	0.11	0.22	0.586
L6-MP	2.27	1.04	1.22	0.61	0.010
Soft tissue					
Upper lip with S line	.33	.66	.05	.16	.232
Lower lip with S line	1.47	.91	1.66	.43	.554

SD, standard deviation.

3. Discussion

Patient compliance plays an important role in achieving desired treatment results with a TB appliance. Many studies have shown that patients do not wear the removable orthodontic appliance for the recommended wear time [10,11]. A few studies have used microelectronic sensors, such as Smart Retainer, Scientific Compliance, Atlanta, Ga and TheraMon, MC Technology GmbH, Schmiedberg 10, 4483 Hargelsberg, Austria for measuring wear time. However, these thermal sensors work on the principle of temperature change from the mouth to the environment.

In tropical countries such as India where, most of the time, the environmental temperature is higher than mouth temperature, these thermal sensors will give an incorrect result. Therefore, we designed and patented a low-cost electronic timing device (sensor) suitable for use in tropical countries for recording wear time of removable acrylic orthodontic appliances.

This sensor does not rely on temperature change, as it operates on the principle of infrared proximity detection. A new electronic timing device was approved by The Centre of VLSI, Nanotechnology, and the institutional ethics committee. The battery life of the sensor was 14 months. The overall thickness of the appliance was 3–3.5 mm. The purpose of the current study was to use this new electronic timing device to investigate the association between objective wear time and treatment efficacy of TB appliances.

3.1. Wear time

A TB appliance incorporating the new electronic timing device to measure wear time was delivered to all the participants. All patients were prescribed a wear time of 24 hours per day, except while brushing teeth. Wear-time of the TB appliance was assessed monthly during the 6-month treatment period, using a data receiver.

Children were instructed to keep the appliance, when it was not in use, on a modified working model, to produce precise wear-time measurement and prevent distortion of the acrylic plate. The incorporated electronic timing device (sensor) would count wear time of the appliance exclusively when it was in contact with a reflecting medium such as water or intra-oral saliva. If the patient failed to keep the appliance on the working model, the reading of wear time was likely not affected, provided that the appliance was not near water. Also, parents of the children were instructed to oversee accurate appliance placement when it was not in use.

Our data showed a mean wear time of 15.17 to 17.96 hours per day. Similar findings were reported by Arponen et al. [12]. They found an average actual appliance wear time of half of that prescribed for patients with a TB appliance. In the present study, a large variation was observed in daily wear time among patients, ranging from 19.83% to 98.73% of that prescribed. Therefore, based on patients' amount of wear time of the appliance, they were broadly divided into an FT-wear group and a PT-wear group. Despite the fact that all the patients in both groups received a thorough education regarding the importance of wear time to motivate them, PT wearers remained in the PT-wear group and FT wearers remained in the FT-wear group.

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3.2. Skeletal and dental effects

To evaluate and compare the skeletal and dentoalveolar effects, Pancherz's cephalometric measurements were used in this study [8].

3.3. Skeletal anteroposterior changes

In terms of the maxillary restraining effect, the SNA angle was reduced by 0.36° in the FT-wear group, and 0.11° in the PT group. Functional appliances produce a distally directed force to maxilla (headgear effect), as the mandible is repositioned forward. Although the FT-wear group demonstrated slightly more maxillary restraint, the difference was not significant statistically. Similarly, the difference for the maxillary base measurement (point A/OLp) in both groups was not significant. The literature suggests that the effect of TB therapy on maxilla is controversial. A few studies have demonstrated restriction [13,14], whereas others have not [15,16].

However, the SNB angle increase was 2.33° and 1.33° in the FT- and PT-wear groups, respectively. Findings for the FT-wear group mirror those from previous research by Baysal and Uysal, who found a 2.1° increase in SNB angle during treatment with a TB appliance [2]. A significant difference was found among groups for the corpus length measurement (Go-Gn); statistically significant greater increases were seen for the mandibular base measurement (Pg/OLp) in the FT-wear group, compared with those in the PT-wear group. Studies have shown that a more retrognathic mandible tends to respond better to functional appliance treatment [17,18]. However, the pretreatment SNB angle was comparable in the 2 groups. Our findings suggest a significant effect of the TB appliance on the mandible with FT wear.

A reduction in the ANB angle, of 2.69°, was observed in the present study in the FT-wear group, whereas a less-significant decrease in the ANB angle, of 1.33°, was seen in the PT group. A comparable finding by Thiruvenkatachari et al. involving a meta-analysis of 2 studies, indicated that functional appliances led to a reduction in the ANB angle of 2.37° compared with that in untreated control subjects [19]. Analysis of inter-jaw relationsships showed that treatment effects were mainly produced by mandibular changes, because maxillary base measurements were not affected by TB therapy in either group.

3.4. Skeletal vertical changes

Increases in total anterior facial height (Na-Me) and lower anterior face height (ANS-Me) after TB therapy are consistent findings. A more-significant increase in the FT-wear group relative to the PT group was noted in both total face height (4.55 mm vs. 2.61 mm) and lower anterior face height (3.55 mm vs. 1.83 mm). Lund and Sandler found a 2.6-mm increase in total anterior face height after TB therapy, compared with that in a control group [20]. Mills and McCulloch noted a significant increase of 3.8 mm relative to that in a control group [21]. A smaller increase in facial height may relate to differences in growth patterns among participants.

A slight increase in posterior face height (S-Go) of 0.11 mm was found in the FT-wear group, whereas no increase was noted in the PT wear group in our study. Mills and McCulloch noted an increase of 2.9 mm relative to controls for posterior face heights [21]. A significant increase in the lower anterior face height and a slight increase in the posterior face height lead to a change in the mandibular plane angle [22]. Over a treatment period of 6 months, there was a significant opening of the mandibular plane angle (SN-GoGn), but when the FT-wear (1.58°) and PT-wear (1.5°) groups were compared, the difference was nonsignificant.

A significant difference in the effective mandibular length (Co-Gn) was found between the FT-wear (1.5 mm) and PT-wear groups (0.27 mm). Studies by Pancherz [23] and Valant and Sinclair [24] also found an increase of 1.3—3.4 mm in mandibular length. No significant change was observed in effective maxillary length (Co-ANS) in either the FT-wear or PT-wear groups in our study.

3.5. Dental anteroposterior changes

The reduction in overjet (is/OLp minus ii/Olp) was statistically significant between the FT-wear (3.91 mm) and PT-wear (2 mm) groups in the present study, over a duration of 6 months. These differences are significant and validate the efficacy of the appliance with FT treatment regimens. Studies by Baysal and Uysal [2] and Baccetti et al. [25] also reported a reduction in overjet of 4.48 mm and 3.73 mm, respectively. Findings suggested that both the skeletal and dentoalveolar components of overjet correction were due mainly to mandibular skeletal and dentoalveolar changes.

Correction of the molar relationship (ms/OLp minus mi/OLp) of 4.69 mm in the FT-wear group, and 2.66 mm in the PT-wear group, was observed. Findings for the FT-wear group mirror the findings of Baysal and Uysal, who reported a correction in the molar relationship of 5.05 mm with a TB appliance [2].

Our findings suggest that the nonsignificant change in the inclination of the upper incisor (is/OLp minus A point/OLp) in both the FT-wear and PT-wear groups (0.13 mm, and 0 mm, respectively) could be a result of the absence of labial bow. According to Jena et al., the labial bow contact with the upper incisors during sleep, and its headgear effect, could be a contributing factor to maxillary incisor retroclination [26].

In the present study, a low level of incisor proclination (ii/OLp minus Pg/OLp) was found in the FT-wear (2.0 mm) and PT-wear (2.1 mm) groups. Smaller values of proclination may be related to the acrylic capping of lower incisors with the TB appliance. Studies by Illing et al. [16], Lund and Sandler [20], and Tümer and Gültan [14] reported 2°–7.9° increases in lower incisor proclination after TB appliance therapy.

3.6. Dental vertical changes

Vertical eruption of upper molars (U6-PP) was not significantly affected by TB appliances in either the FT-wear or PT-wear group, as contact of acrylic was maintained. Lower molars (L6-MP) erupted 2.2 mm in the FT-wear group and 1.2 mm in the PT-wear group. This difference was statistically significant. The eruption of the lower molar was due to trimming of the appliance during treatment. Mills and McCulloch reported no change in upper molars, but lower molars erupted on average 4 times as much in the TB group as in the control group [21]. Lund and Sandler found mean differences of 0.9 mm in lower molar eruption in a TB group compared with a control group [20].

3.7. Soft tissue changes

Significant lower lip protrusion was observed in both groups (1.47 mm and 1.66 mm in the FT-wear and PT-wear groups, respectively). Protraction of the lower lip could be a result of lower incisor proclination. Upper lip retrusion was greater in the FT-wear group (0.33 mm) compared to the PT-wear group (0.05 mm). However, this difference was not significant.

The null hypothesis of the study was rejected, as wear time does affect the treatment efficacy of the TB appliance. Loss to follow-up rates of 10% to 33% have been seen in allied research by O'Brien et al. [27] and Lee et al. [28] involving the TB appliance.

In our study, the original calculated sample size was 40; in consideration of potential attrition, it was increased to 44. There were 2 dropouts, and 1 patient continued treatment only for 3 months. However, for a sample size of 40, the attrition rate in our study was 0%.

3.8. Limitations of the study

Limitations of the current study are as follows:

1. The new electronic timing device has a precision of 5 minutes.
2. Actual wear time measured can be affected if the appliance was kept in the vicinity of water when not in use.

4. Conclusions

Conclusions from the current study are as follows:

1. None of the patients involved in this study achieved the prescribed daily wear time of 23–24 hours. Based on accumulated wear time, 67% of participants were allotted to the FT-wear group, and 33% were allotted to the PT- wear group.
2. Patients were found to retain their initial wear behavior over the course of treatment. FT wearers remained FT wearers, and PT wearers remained PT wearers.
3. Skeletal effects were pronounced in the FT-wear group, and dentoalveolar changes were comparable in the 2 wear groups.
4. The maximum skeletal treatment effect of the TB appliance was found to occur with FT wear over a 6-month treatment period.

Authors Contributions

WB: conceptualization; NB: data curation; SC: formal analysis; NB: funding acquisition; NB: investigation; NB: methodology, project administration, resources, software; WB and SC: supervision, validation, visualization; NB : roles/writing of original draft; WB and NB: writing—review and editing.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.ejwf.2021.11.003.

References

[1] Clark W, Clark WJ. The twin block technique. A functional orthopedic appliance system. Am J Orthod Dentofacial Orthop 1988;93(1):1–8.
[2] Baysal A, Uysal T. Dentoskeletal effects of twin block and Herbst appliances in patients with Class II division 1 mandibular retrognathy. Eur J Orthod 2013;36:164–72.
[3] Proffit WR. Equilibrium theory revisited: factors influencing position of the teeth. Angle Orthod 1978;48:175–86.
[4] Parekh J, Counihan K, Fleming PS, Pandis N, Sharma PK. Effectiveness of part–time vs full-time wear protocols of twin-block appliance on dental and skeletal changes: a randomized controlled trial. Am J Orthod Dentofacial Orthop 2019;155:165–72.
[5] Al-Kurwi AS, Bos A, Kuitert RB. Overjet reduction in relation to wear time with the van Beek activator combined with a microsensor. Am J Orthod Dentofac Orthop 2017;151:277–83.
[6] Pauls A, Nienkemper M, Panayotidis A, Wilmes B, Drescher D. Effects of wear time recording on the patient's compliance. Angle Orthod 2013;83:1002–8.
[7] Hägg U, Taranger J. Maturation indicators and the pubertal growth spurt. Am J Orthod 1982;82:299–309.
[8] Pancherz H. The mechanism of Class II correction in Herbst appliance treatment: a cephalometric investigation. Am J Orthod 1982;82:104–13.
[9] Björk A, Skieller V. Normal and abnormal growth of the mandible. A synthesis of longitudinal cephalometric implant studies over a period of 25 years. Eur J Orthod 1983;5:1–46.
[10] Arreghini A, Trigila S, Lombardo L, Siciliani G. Objective assessment of compliance with intra- and extraoral removable appliances. Angle Orthod 2017;87:88–95.
[11] Al-Moghrabi D, Salazar FC, Pandis N, Fleming PS. Compliance with removable orthodontic appliances and adjuncts: a systematic review and meta-analysis. Am J Orthod Dentofacial Orthop 2017;152:17–32.
[12] Arponen H, Hirvensalo R, Lindgren V, Kiukkonen A. Treatment compliance of adolescent orthodontic patients with headgear activator and twin-block appliance assessed prospectively using microelectronic wear-time documentation. Eur J Orthod 2020;42:180–6.
[13] Toth LR, McNamara Jr JA. Treatment effects produced by the twin-block appliance and the FR-2 appliance of Fränkel compared with an untreated Class II sample. Am J Orthod Dentofacial Orthop 1999;116:597–609.
[14] Tümer N, Gültan AS. Comparison of the effects of monoblock and twin-block appliances on the skeletal and dentoalveolar structures. Am J Orthod Dentofacial Orthop 1999;116:460–8.
[15] Clark WJ. The twin block traction technique. Eur J Orthod 1982;4:129–38.
[16] Illing HM, Morris DO, Lee RT. A prospective evaluation of Bass, Bionator and twin block appliances. Part I—the hard tissues. Eur J Orthod 1998;20:501–16.
[17] Fleming PS, Qureshi U, Pandis N, DiBiase A, Lee RT. An investigation of cephalometric and morphological predictors of successful twin block therapy. Aust Orthod J 2012;28:190–6.
[18] Caldwell S, Cook P. Predicting the outcome of twin block functional appliance treatment: a prospective study. Eur J Orthod 1999;21:533–9.
[19] Thiruvenkatachari B, Harrison J, Worthington H, O'Brien K. Early orthodontic treatment for Class II malocclusion reduces the chance of incisal trauma: results of a Cochrane systematic review. Am J Orthod Dentofacial Orthop 2015;148:47–59.
[20] Lund DI, Sandler PJ. The effects of twin blocks: a prospective controlled study. Am J Orthod Dentofacial Orthop 1998;113:104–10.
[21] Mills CM, McCulloch KJ. Treatment effects of the twin block appliance: a cephalometric study. Am J Orthod Dentofacial Orthop 1998;114:15–24.
[22] Ruf S, Pancherz H. The effect of Herbst appliance treatment on the mandibular plane angle: a cephalometric roentgenographic study. Am J Orthod Dentofacial Orthop 1996;110:225–9.
[23] Pancherz H. Treatment of Class II malocclusions by jumping the bite with the Herbst appliance: a cephalometric investigation. Am J Orthod 1979;76:423–42.
[24] Valant JR, Sinclair PM. Treatment effects of the Herbst appliance. AmJ Orthod Dentofacial Orthop 1989;95:138–47.
[25] Baccetti T, Franchi L, Toth LR, McNamara Jr JA. Treatment timing for twin-block therapy. Am J Orthod Dentofacial Orthop 2000;118:159–70.
[26] Jena AK, Duggal R, Parkash H. Skeletal and dentoalveolar effects of twin-block and bionator appliances in the treatment of Class II malocclusion: a comparative study. Am J Orthod Dentofacial Orthop 2006;130:594–602.
[27] O'Brien K, Wright J, Conboy F, et al. Effectiveness of treatment for Class II malocclusion with the Herbst or twin-block appliances: a randomized, controlled trial. Am J Orthod Dentofacial Orthop 2003;124:128–37.
[28] Lee RT, Kyi CS, Mack GJ. A controlled clinical trial of the effects of the twin block and Dynamax appliances on the hard and soft tissues. Eur J Orthod 2007;29:272–82.