Effectiveness of part-time vs full-time wear protocols of Twin-block appliance on dental and skeletal changes: A randomized controlled trial

Jeet Parekh,[a] Kate Counihan,[a] Padhraig S. Fleming,[a] Nikolaos Pandis,[b] and Pratik K. Sharma[a]
London, United Kingdom, and Bern, Switzerland

Introduction: The aim of this 2-arm parallel study was to compare the dentoalveolar and skeletal changes achieved with Twin-block appliance therapy prescribed on either a part- or full-time basis for 12 months. **Methods:** Sixty-two 10- to 14-year-old patients were randomly allocated to either full-time (FT, 22 hours daily) or part-time (PT, 12 hours daily) wear of a modified Twin-block appliance. Participants were recruited from the Institute of Dentistry, Barts and the London School of Medicine and Dentistry, London, United Kingdom, and recalled at 6- to 8-week intervals. Electronic randomization was undertaken, with group allocation concealed using opaque, sealed envelopes. The outcome assessor was blinded; however, it was not feasible to blind either operator or patients. Study models and cephalograms were taken at baseline and after 12 months of treatment. **Results:** Data from 55 of the 62 participants were analyzed. Overjets were reduced by 7 mm (SD, 2.92) in the PT group and 6.5 mm (SD, 2.62) in the FT group, with no statistical difference between the groups ($P = 0.587$; 95% CI, −1.01, 1.78). Similarly, no clinical or statistical differences were noted for skeletal changes: ANB angle (PT, −1.51°; FT, −1.25°; $P = 0.828$; 95% CI, −0.68, 0.849), pogonion-sella vertical (PT, 3.25 mm; FT, 3.35 mm) or A-sella vertical (PT, 1.28 mm; FT, 1.06 mm). Mean wear durations were 8.78 hours a day in the PT group and 12.38 hours in the FT group. **Conclusions:** There was no difference in either dental or skeletal changes achieved with PT or FT wear of a Twin-block appliance over 12 months. Less onerous PT wear regimens may therefore be a viable alternative to FT wear of removable functional appliances. **Registration:** NCT02190630. **Protocol:** The protocol was not published before trial commencement. (Am J Orthod Dentofacial Orthop 2019;155:165-72)

The modified Twin-block is the most commonly used functional appliance in the United Kingdom.[1] Notwithstanding its popularity, its removability is a recognized impediment to optimal treatment outcomes, with failure rates between 9% and 34% reported in randomized studies.[2] Moreover, wear rates of approximately 4 to 5 hours less than that stipulated have been attributed to removable functional appliances.[3-5] Various approaches to enhance compliance have been developed; however, only the use of microelectronic timers has consistently shown a benefit, with the effect of recommendation of shorter wear durations on treatment outcomes not previously explored.[3]

The Twin-block appliance has been the subject of numerous clinical trials and systematic reviews with a mean increase in mandibular length of just 1 mm observed in 8- to 10-year-old subjects relative to matched untreated controls.[6,7] Most overjet correction (73%) comprised dentoalveolar changes.[8] Greater increments of mandibular length occur during the prepubertal growth spurt,[9] but differences in the underlying skeletal pattern appear to diminish after the subsequent fixed appliance phase, suggesting that any increase in mandibular growth is transient, and the underlying skeletal pattern may be immutable in the long term.[6] Consequently, because changes are predominantly

[a]Barts and the London School of Medicine and Dentistry, Queen Mary University of London, London, United Kingdom.
[b]Department of Orthodontics and Dentofacial Orthopedics, School of Dental Medicine, Medical Faculty, University of Bern, Bern, Switzerland.
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Address correspondence to: Pratik K. Sharma, Barts and The London School of Medicine and Dentistry, Orthodontics Turner Street, Whitechapel, London E1 2AD, United Kingdom; e-mail, p.k.sharma@qmul.ac.uk.
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dentoalveolar, it would be intuitive to expect that shorter wear durations may enhance compliance without compromising treatment responses, by reducing the impact of the intervention, assuming that a threshold wear duration to induce dental and transient skeletal changes is reached.

Previous studies examining the Twin-block have involved near full-time (FT) wear, in line with the originator's recommendations. However, Proffit[10] 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. Recent studies have demonstrated that use of a removable retainer on a part-time (PT) basis is as effective in preventing relapse as a FT wear regimen.[11] Furthermore, other orthopedic appliances including facemasks have been shown to elicit skeletal changes when worn on a less than FT basis.[12] Similar research relating to active removable or functional appliances has not yet been undertaken.

Specific objectives or hypothesis

We aimed to compare the dental and skeletal effects of modified Twin-block appliance wear when prescribed for either PT or FT wear. The null hypotheses tested were that there are no differences in either dental or skeletal effects induced with a Twin-block appliance prescribed for FT compared with PT wear.

MATERIAL AND METHODS

Trial design and any changes after commencement

This study was a parallel-group randomized controlled trial with a 1:1 allocation ratio. Ethical approval was obtained from the National Research Ethics Service, Queens Square London (13/LO/1512) and the Research and Development Department of the Barts and the London School of Medicine and Dentistry, London, United Kingdom.

Participants, eligibility criteria, and setting

Participants were recruited at the Institute of Dentistry, Barts and the London School of Medicine and Dentistry, from December 2013 to April 2016. Treatment was carried out by 2 specialist orthodontic trainees (J.P. and K.C.). The following inclusion criteria were applied: (1) Class II Division 1 incisor relationship, (2) overjet of 7 mm or more, (3) boys 12 to 14 years old at the start of treatment, (4) girls 11 to 13 years old at the start of treatment; and (5) willingness to participate in the study.

Fig 1. Modified Twin-block design with embedded TheraMon sensor.

Those with a history of orthodontic treatment or craniofacial syndromes were excluded.

Interventions

Participants in the PT group were asked to wear the appliance for 12 hours daily. Those in the FT group were asked to wear the appliance throughout the day and night, except for eating, brushing, and playing sports (22 hours per day). A standardized modified Twin-block design was used in both groups (Fig 1): (1) Adams clasps on all first premolars and permanent first molars, (2) ball-ended clasps in the mandibular anterior region, (3) midline expansion screws for the maxillary component, (4) blocks intersecting at 70° with block height of 6 mm in the premolar region, and (5) the Twin-block appliance had the bite recorded with maximal forward protrusion up to an edge-to-edge bite using a standardized bite gauge, with an anterior opening of 2 to 4 mm.

Each appliance was fitted with a temperature-sensitive TheraMon microsensor (Handelsagentur Gschladt, Hargelsberg, Austria, or Forestadent, Pforzheim, Germany) in the buccal aspect of the maxillary component to permit objective assessment of wear durations and was augmented with a self-completed wear chart. Patients were not informed that wear times

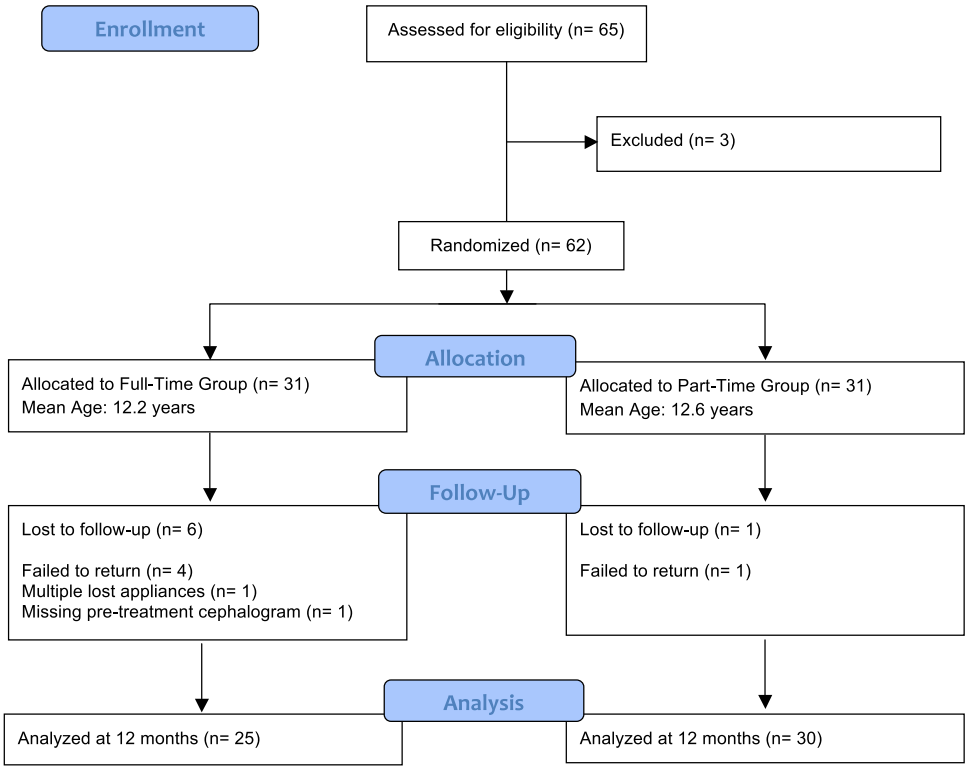

Fig 2. CONSORT flow diagram.

were being objectively recorded by the embedded microsensor.

Treatment was undertaken over 12 months, with standard recall intervals of 6 to 8 weeks. At each recall visit, subjective and objective estimates of compliance were obtained, allied to recording of occlusal changes including overjet, and canine and molar relationships. TheraMon data were taken as the measure of compliance in those not responding to treatment.

In case of loss or irreparable damage to the appliance or microsensor, a new appliance was made with a new TheraMon registered to allow continued data collection. Participants who did not attend an appointment were contacted to arrange a further appointment. All participants were free to withdraw from the study at any stage. A per-protocol analysis approach was used to treat dropouts (Fig 2).

Outcomes

The primary outcome was overjet reduction over the study period from baseline to 12 months of appliance therapy. Secondary outcomes included cephalometric assessment of anteroposterior skeletal changea. A lateral cephalogram, clinical photographs, and study models were taken at baseline and after 12 months of appliance therapy. Cephalograms were digitized using COG Soft Opal software 2.4 (Bristol, UK). The horizontal hard tissue measurements were calculated with reference to a line vertical to a constructed horizontal plane at 7° to the sella-nasion line.[13,14]

Sample size calculation

A clinically significant difference in overjet reduction was considered to be 2 mm. Based on previous clinical research, a standard deviation of 2.3 mm was used to calculate the standardized difference (2-2.3 mm = 0.86).[15] The power of the study was set at 90%, with a significance level of $P < 0.05$. A total sample of 56 patients (28 per group) was therefore required, although a further 6 participants were recruited to allow for potential attrition, based on an expected 10% dropout rate. A total sample of 62 participants was recruited.

Interim analysis and stopping guidelines

Compliant participants in the PT group who failed to respond to treatment (based on overjet readings) were to be withdrawn from the study and asked to wear the appliance on a FT basis. If participants in the FT group

were found to have significantly better occlusal outcomes, the study would be stopped prematurely.

Randomization (random number generation, allocation concealment, implementation)

Recruitment occurred at consultant-led new patient clinics, with patients fulfilling the selection criteria invited to take part in the study. Information leaflets were provided to both patients and parents. Those agreeing to participate were rebooked for consent and baseline records. Each subject was then randomly allocated to the PT or FT group based on electronic randomization by a statistician. Allocation was concealed from the participants and treating clinicians using sequentially numbered, tamper-proof, opaque sealed envelopes.

Blinding

It was not possible to blind the treating clinicians during the trial because of the need to monitor the response of the PT patients to the intervention. Therefore, to minimize bias, all outcome measures were taken from the lateral cephalograms at baseline and after 12 months of therapy. All tracings were completed by 1 practitioner (J.P.), who was blinded to any patient identifiable information or group allocation when digitizing the radiographs. The statistician was also blinded to group allocation.

Statistical analysis

Simple descriptive statistics only were used for baseline demographic and clinical data. The repeatability of the cephalometric measures was assessed on 10 randomly chosen radiographs redigitized 2 weeks apart. The intraclass correlation coefficient (ICC) showed a high level of agreement between groups (0.96- 0.99). Analysis of covariance was undertaken to detect between-group differences in relation to overjet reduction, intermaxillary relationships (ANB angle), and positions of the maxilla (A-point) and the mandible (pogonion) relative to the cranial base (sella vertical). Covariates included sex, age, overbite, SNB angle, and lower anterior facial height. Unpaired-samples *t* tests were used for the remaining cephalometric measurements. Statistical analyses used Stata software (version 14.0; StataCorp, College Station, Tex) with the level of statistical significance predefined at $P < 0.05$.

RESULTS

Participant flow

Overall, 62 patients were randomly allocated to PT or FT wear of the appliance, 31 per group (Fig 2). There were 37 girls and 25 boys with a mean age of 12.37 (SD, 0.95) years.

Table I. Demographic characteristics of the sample (n = 62) and both groups

	FT	*PT*	*Overall*
Mean age, y (SD)	12.16 (0.89)	12.58 (0.99)	12.37 (0.95)
Female, n (%)	22 (71.0)	15 (48.4)	37 (59.7)
Male, n (%)	9 (29.0)	16 (51.6)	25 (40.3)
Asian British, n (%)	16 (51.61)	22 (70.97)	38 (61.29)
Black British, n (%)	1 (3.23)	1 (3.23)	2 (3.23)
White, n (%)	14 (45.16)	7 (22.58)	21 (33.87)
Mixed, n (%)	0 (0)	1 (3.23)	1 (1.61)
Total, n (%)	31	31	62

Baseline data

The sex distribution was relatively balanced in the PT group, although there was a preponderance of girls (71%) in the FT group (Table I). Both groups had similar ages at baseline. The majority of the sample was of Asian British origin (61.29%). The PT group had more Asian British patients than did the FT group (71% vs 51.6%) and fewer white subjects (22.6% vs 45.2%). In terms of baseline cephalometric values (Table II), the PT group had an increased pogonion-sella vertical (53.7 vs 52 mm) measurement, suggesting that subjects in the FT group had slightly more retrognathic mandibles than those in the PT group at baseline. This corresponds with a slightly increased SNB angle in the PT group, although differences were minor (75.5° vs 74.7°). Vertical measurements and incisor inclinations were also broadly comparable between the groups (Table II).

Numbers analyzed for each outcome, estimation and precision, subgroup analyses

Data from 55 (30 in the PT and 25 in the FT groups) of the 62 participants were analyzed after 12 months of therapy. Overall, overjets reduced by means of 7 mm (SD, 2.92) in the PT group and 6.5 mm (SD, 2.62) in the FT group (Table III). The between-groups difference was not statistically significant ($P = 0.587$; 95% CI, −1.01, 1.78). When adjusted for sex, age, overbite, and lower anterior facial height, this difference was just 0.38 mm (Table IV).

Similarly, no statistical difference was found for anteroposterior skeletal changes between the groups with, eg, ANB angle decreases of 1.51° and 1.25° in the PT and FT groups, respectively ($P = 0.828$; 95% CI, −0.68, 0.849). In terms of mandibular changes, a marginally greater increase in horizontal mandibular projection of 0.036 mm was detected in the FT group, although this was neither clinically nor statistically

Table II. Baseline cephalometric characteristics of the sample

	FT (n = 31)		PT (n = 30)*	
Cephalometric value	*Mean*	*SD*	*Mean*	*SD*
Linear (mm)				
Pogonion-sella vertical	52.0	6.4	53.7	7.0
Articulare-gnathion	89.1	6.6	92.6	5.3
A-point–sella vertical	62.4	4.0	62.3	4.7
B-point–sella vertical	52.2	5.5	52.8	5.7
Angular (°)				
SNA	81.4	3.0	81.9	3.3
SNB	74.7	3.1	75.5	3.2
ANB	7.1	2.6	6.8	2.0
Vertical (mm)				
Total anterior face height	100.6	6.8	100.1	17.5
Lower anterior face height	53.6	4.8	55.1	3.6
Overbite	3.9	1.8	4.0	2.2
Dental measurements				
Overjet (mm)	10.3	1.9	11.1	2.1
Maxillary incisor to maxillary plane (°)	122.4	8.2	124.9	8.4
Mandibular incisor to mandibular plane (°)	95.2	7.8	97.1	7.1
Maxillary incisor-sella vertical (°)	67.4	5.7	69.4	5.9
Mandibular incisor-sella vertical (°)	58.5	5.3	59.7	5.1
Mandibular incisor–A-pogonion (°)	0.1	2.5	0.3	3.1

*There was a missing pretreatment cephalogram for 1 participant.

Table III. Dental and skeletal changes with PT vs FT Twin-block wear with unpaired-samples *t* tests of dental and skeletal changes

	PT group		FT group		
Cephalometric changes during treatment	*Mean*	*SD*	*Mean*	*SD*	P *value*
Angular (°)					
ANB	−1.51	1.49	−1.25	3.05	0.83
SNA	0.03	1.67	0.5	1.29	0.20
SNB	1.47	1.35	1.54	1.28	0.83
Pogonion-sella vertical	3.25	2.81	3.35	2.7	0.96
Vertical (mm)					
Lower anterior face height	4.6	2.33	3.67	2.47	0.17
Overbite	−2.17	2.22	−2.37	1.66	0.72
Dental measurements					
Overjet (mm)	−7	2.92	−6.5	2.62	0.59
Maxillary incisor to maxillary plane (°)	−8.81	5.62	−8.38	4.98	0.76
Mandibular incisor to mandibular plane (°)	4.43	3.83	6.02	4.18	0.15
Maxillary incisor to sella vertical (°)	−1.71	2.68	−1.59	2.16	0.86
Mandibular incisor to sella vertical (°)	4.62	3	4.19	4.07	0.67

significant ($P = 0.964$) after adjustment for age, sex, overbite, and lower anterior face height. This lack of difference was also reflected in B-point–sella vertical and SNB angle.

Reductions in overbite were similar (PT, −2.17 mm; FT, −2.37 mm) in both groups, with a slightly greater increase in lower anterior face height observed in the PT group (4.60 mm) compared with the FT group (3.67 mm). Neither change was statistically significant, however. Little difference was found between the groups for maxillary incisor inclination changes (PT, −8.81°; FT, −8.38°), although slightly more mandibular incisor proclination was noted in the FT group (4.43° vs 6.02°), but this difference was also not statistically significant ($P = 0.15$). Mean wear times for both groups were appreciably lower than those prescribed (Table V). In the PT group, mean wear duration was 8.78 hours a day, or 73.2% of that prescribed; in the FT group,

Table IV. Comparison of dental and skeletal changes with PT vs FT Twin-block wear based on analysis of covariance

Treatment change	*PT*		*FT*					
Variable	*Mean change*	*SD*	*Mean change*	*SD*	*Coefficient*	P *value*	*95% CI*	
Overjet (mm)	−7.00	2.92	−6.50	2.62	0.382	0.587	−1.01	1.78
Pogonion-sella vertical (mm)	3.25	2.81	3.35	2.7	−0.036	0.964	−1.64	1.57
A-sella vertical (mm)	1.28	1.78	1.06	2.04	0.228	0.664	−0.82	1.28
ANB (°)	−1.51	1.49	−1.25	3.05	0.083	0.828	−0.68	0.849

Table V. Mean objective wear durations in the groups based on microsensor (TheraMon) readings

Group	*Mean wear (h)*	*SD*	*Proportion of recommended wear time (%)*
PT	8.78	3.77	73.2%
FT	12.38	5.89	51.6%

mean daily wear of 12.38 hours, or 51.6% of that recommended, was observed.

DISCUSSION

Main findings in the context of the evidence, interpretation

This study was the first to demonstrate no significant differences in key dental and skeletal parameters between adolescent patients treated with a functional appliance prescribed for either PT or FT wear. This observation may have an important influence on clinical practice with PT wear protocols likely to induce less impairment in social interactions, functional effects, and quality of life. The implications of wear duration on objective wear levels and experiences of treatment are considered in a separate article involving the same sample.[16]

Overjet reductions between 6.5 and 7 mm were observed in both groups. These levels are significant and confirm the potency of the appliance with both treatment regimens but also reflect the magnitude of the baseline overjet (10.3-11.1 mm). This much overjet reduction compares favorably with a previous meta-analysis (−5.2 mm)[6] and mirrors findings by O'Brien et al,[2] who noted a reduction of 6.2 mm in patients treated with a Twin-block appliance for a mean period of 11 months. Although the descriptive data pointed to a residual overjet of 1.3 mm more at the end of the functional phase in the PT group, once covariates were accounted for, this difference declined to 0.4 mm and was neither clinically nor statistically significant. This lack of difference is interesting and potentially influential, since wear of a removable functional appliance can be associated with pain and embarrassment.[17] Other dental changes were also broadly similar between the groups, although there was slightly less mandibular incisor proclination in the PT group (4.4°) than in the FT group (6.0°). Whereas this risks slightly less stability in the FT group, the overall magnitude of proclination was similar to that reported in previous studies involving FT appliance wear with and without an upper labial bow,[18] and with conventional and streamlined Twin-block designs.[14]

No clinically or statistically significant differences between the PT and FT groups were noted with regard to skeletal changes. The pretreatment SNB angle was chosen as a potential confounding factor because studies have shown that a more retrognathic mandible tends to respond better to functional appliance treatment.[19,20] Therefore, the slightly more retrognathic mandibles in the FT group (pogonion-sella vertical, 52 mm, compared with 53.7 mm in the PT group) may have predisposed this group to greater mandibular change. However, between-group differences were negligible, with differences in B-point projection relative to sella vertical comparable (PT, 3.04 mm; FT, 3.22 mm). After 15 months of FT Twin-block treatment, Lee et al[21] reported an increase of 5.2 mm in pogonion-sella vertical, about 2 mm greater than that in our study. This larger increment in growth may relate to the extended treatment period in the latter study. In keeping with these findings, no statistical difference was found in changes in SNB angle between groups, with both increasing by approximately 1.5° over the 12-month period. This mirrors previous research; Baysal et al[22] noted a 2.1° increase in SNB angle during treatment with both Herbst and Twin-block appliances.

In terms of maxillary restraint, A-point to sella vertical increased by 1.1 mm in the FT group and 1.3 mm in the PT group. By comparison, Lee et al[13] noted minimal changes in patients with similar demographics. Negligible changes in SNA angle were noted in both groups (0.03°-0.5°) in our study, with the FT group demonstrating slightly more maxillary restraint. Slightly larger reductions in SNA angle of up to 1.4° have been noted in previous studies involving the Twin-block appliance, although A-point is susceptible to dental

changes, particularly maxillary incisor inclination change.[23,24]

The ANB angle was taken as the primary measure of assessment of anteroposterior skeletal changes since it is commonly used in trials and systematic reviews. A previous Cochrane review involving meta-analysis of 2 studies both at high risk of bias with younger patient cohorts showed that functional appliances led to a reduction in ANB angle of 2.37° compared with untreated control subjects.[6] Slightly less significant reductions in ANB angle (1.3°-1.5°) were observed in this study in both groups. Most studies broadly agree that functional appliance treatment with the Twin-block leads to a significant increase in lower anterior facial height. Similar changes were observed in both the PT (4.6 mm) and FT (3.7 mm) groups in our study, with both approaches equally potent in terms of overbite reduction. Previous studies have reported slightly smaller increases in lower facial height of 2.7 to 3 mm, most likely reflecting differences in growth patterns between the samples.[23,25]

Loss to follow-up rates of 10% to 33% have been seen in allied research involving the Twin-block appliance[2,13]; thus, the 9.7% failure rate in our study is reasonable. There were more dropouts in the FT (n = 5) than in the PT (n = 1) group. We assumed that these data were missing at random; an intention-to-treat analysis was therefore not considered appropriate. Further qualitative research into patient experiences during treatment was undertaken to explore the relative impact of the differing wear regimens. However, similar discrepancies were not observed in allied studies assessing PT vs FT wear of retainers.[26] The latter, however, may relate to more inconvenience associated with retainer wear as opposed to functional appliances, particularly since the latter are bulkier and involve pronounced anteroposterior and vertical postural changes.

The fact that both groups experienced similar levels of dental and skeletal changes is remarkable, since the PT subjects were asked to wear the appliance for 10 hours less per day than those in the FT group. It is clear from the compliance data that adherence to prescribed wear times was poor in the FT group (51.6% of recommended wear time) and much better in the PT group (73.2%). This variation questions the rationale for recommending FT wear, on the assumption that adherence appears to be better with a reduced wear regimen, yet still producing comparable and clinically meaningful changes. Although similar levels of potency may be attributable to wear patterns for each group based on the TheraMon readings, there was some heterogeneity in wear times among the groups, with the FT group typically wearing the appliances essentially at a PT basis.[16] This lends further credence to the hypothesis that PT wear of a Twin-block is sufficient to produce clinically significant dental and skeletal changes. However, 3 patients were asked to continue functional appliance wear after the trial period. Because the numbers were similar in both groups (PT, 2; FT, 1), these failures do not appear to be related to wear regimens but may reflect difficulty in obtaining consistent forward posture or measurement error inherent in the TheraMon readings, although the latter was mitigated against by placing the sensors in the buccal aspect of the maxillary component.[27]

Limitations

Randomization was undertaken to reduce the risk of selection bias and to balance potential confounders between groups. Notwithstanding this, there were more girls in the FT group, and the application of stratified randomization would have prevented this sex imbalance. Because girls have often been shown to be more compliant, this may have confounded the results in favor of the FT group. Sex was, however, incorporated as a confounder in the statistical analysis and did not appear to have an effect on the outcome. There was slightly greater attrition of the sample than was anticipated at the outset. Although this may have reduced the power of the study slightly, the mean differences between the groups in terms of the main outcomes were clinically insignificant, suggesting that the statistical inferences are robust. Finally, this study was undertaken in a hospital setting; consequently, these findings may not necessarily translate into private-practice settings. Notwithstanding this, the fact that short-wear durations are effective in producing skeletal and dental changes continues to pertain.

CONCLUSIONS

Based on this randomized controlled trial, there are no differences in dental and skeletal changes between prescribed PT and FT wear of a modified Twin-block applicance over a 12-month treatment period. Less onerous PT wear regimens may therefore be considered as a viable alternative to FT wear.

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