Original Article

Comparison of objective wear time between monoblock and twin-block appliances measured by microsensor

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ABSTRACT

Objectives: To assess the objective compliance levels in skeletal Class II patients with mandibular retrognathia wearing monoblock and twin-block appliances.

Materials and Methods: A prospective clinical study was conducted with 30 patients between 10 and 15 years old who were equally divided into two study groups. Group 1 was treated with monoblock, and group 2 was treated with twin-block appliances. The patients were instructed to wear their appliance for 15 hours per day. Wear times were monitored by a microsensor. (TheraMon; MCTechnology, Hargelsberg, Austria) for an average of six appointments. Patients were also instructed to record their wear times on a chart, and this record was admitted as subjective wear time. Statistical analysis was performed with the data derived from both the patients' charts and the monitoring records.

Results: The mean wear time by the patients was 10.67 $\pm$ 3.93 hours, which was less than the 15 hours prescribed by the orthodontist, with no difference between the two appliances ($P > .05$). The regular use rate, which included the days with a wear time of 8 hours or more per day, was 75%. Compliance levels decreased by 35% throughout the six control appointments. Patients declared that their wear time was more than their objective wear time by an average of 3.76 hours.

Conclusions: Despite their different designs, there was no significant difference between the monoblock and twin-block appliances in terms of compliance. (*Angle Orthod.* 2021;91:749–755.)

KEY WORDS: Monoblock; Twin-block; Microsensor; Compliance; Orthodontics

INTRODUCTION

All types of orthodontic treatment require some degree of compliance, but removable-appliance treatment can only succeed with optimal compliance.[1–3] Functional removable appliances (FRAs) are used by orthodontists during the growth spurt to correct mandibular retrognathia and help to stimulate mandibular growth. Better profile esthetics, along with improved function, is the main goal of functional treatment, but success and long-term stability have not be proven in the literature.[4,5]

It has been reported that the usage rates of different functional appliances can vary from country to country. In general, removable functional devices are used by orthodontists in Europe while fixed functional devices are used in the United States. Use of the monoblock is common in Turkey, whereas twin-block is widely used in the United Kingdom.[5–7]

Although minimum wear time of FRAs to achieve an orthopedic effect has not been precisely determined, their prescribed wear time ranges from 8 to 15 hours per day.[8–11] Alternatively, fixed functional appliances can be used to reduce required compliance, but they are rarely the first choice.[12] Removable appliances have many advantages in terms of simplicity, cost, oral hygiene, and chair time. It is important to clarify the factors affecting compliance during functional orthopedic treatment in order to catch the timing of the pubertal peak. If the patient's growth is over, orthognathic surgery may be the only option to correct the mandibular retrognathia.[13]

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Figure 1. Monoblock appliance.

Objective assessment of compliance levels is required to identify the influencing factors. Indirect methods are relatively subjective, which makes them less reliable.[13–15] The use of thermal microsensors, which are capable of measuring ambient temperature, has proven to be a reliable method for evaluating the objective wear time of removable appliances. The TheraMon microsensor system (TheraMon; MCTechnology, Hargelsberg, Austria) has been reported to produce results with a 30-minute error margin per day.[16] It is a versatile device due to its small dimensions and ability to distinguish attempts to deceive the microsensor.[17]

Using microsensors, many factors influencing compliance can be identified, such as age, gender, and psychological parameters related to the patient. Age seems to be an important factor, with younger patients being more compliant, while the influence of gender has had conflicting results.[14–18] There are also treatment-related factors, such as appliance type,[11,18–21] prescribed wear time,[10] doctor-patient relationship,[22] and monitoring awareness.[19] Clinicians have more control over treatment-related factors as they can be modified. Many studies have been conducted on the assessment of compliance levels with various removable appliances, but most of them did not report significant differences.[18–21] However, to date there have been no studies designed with the main objective of comparing two different types of Class II functional activators.

The monoblock appliance is a simple yet effective functional appliance introduced by Pierre Robin in 1902.[23] Clark's twin-block appliance was proposed in 1988 and is widely accepted and still used by many orthodontists.[24,25] The twin block consists of two pieces and allows patients to function while the appliance is in the mouth. Some authors claim that patients are more likely to wear their appliance due to the functional advantage,[25] but this claim has not been quantified.

This prospective study aimed to compare the objective compliance levels between the monoblock and twin-block appliances and test the null hypothesis that there would be no significant difference in objective wear time between the monoblock and twin-block appliances.

MATERIALS AND METHODS

Ethical approval was obtained from the Human Ethics Committee of Istanbul Medipol University (approval number: 10840098-604.01.01-E.21937). Fifteen patients were found to be sufficient to achieve power over 80% with a 95% confidence interval (CI) and an α of 0.05 to find a meaningful difference of 1.3 standard deviation (SD) units between the groups, as reported previously.[26] Therefore, 30 patients between 10 and 15 years old were recruited who were seeking orthodontic treatment at Istanbul University Orthodontics Clinic. Inclusion criteria were; skeletal Class II division I patients with mandibular retrognathia and convex profile, without systemic disease or syndrome and no history of previous removable appliance therapy.

A patient pool of 30 incoming patients in need of functional treatment was created according to the inclusion criteria. Then, patients were randomly assigned to two equal groups by using a table of random numbers. The first group was treated with the monoblock appliance (Figure 1) while the second group was treated with the twin-block appliance (Figure 2). The monoblock group had 7 boys and 8 girls with a mean age of 12.73 years, while the twin-block group had 9 boys and 6 girls with a mean age of 12.27 years (Table 1). All impressions were taken by the same clinician (Dr Kutay), and appliances were fabricated by the

Figure 2. Twin-block appliance.

same technician. After the appliance fit was checked in the mouth, a TheraMon microsensor was embedded in the appliance and activated according to the manufacturer's instructions. The temperature around the microsensor was measured every 15 minutes, with an accuracy of ±0.1°C, and recorded in 96 data points per day; the microsensor was in sleep mode between recordings. Microsensors were placed on the palatal side of the monoblock laterally and the lingual side of the twin block's mandibular piece centrally.

Patients were not informed about microsensors and monitoring. Appliances were given to the patients, and instructions on how to use their appliances were read to each patient from a standard text. Printed versions of the text were given to each patient. The recommended wear time was a minimum of 15 hours per day. Patients were also given a chart to note their own daily wear time (subjective wear time). Patients were recalled every 4 weeks during 6 months of the study. At every appointment, stored wear-time data in the microsensors were transferred to the TheraMon reader station connected to a computer, which had an active Internet connection. The records were loaded to the TheraMon software and system server. Researchers were blinded to the wear-time data until the end of treatment; therefore, patients did not receive any additional motivational support during treatment. Objective wear-time data were extracted from TheraMon servers as monthly/total mean wear time and percentage of wear time to prescribed wear time. Also, the regular wear rate, which showed the percentage of days above 8 hours of appliance use per day, was calculated. There were no patient dropouts or technical problems with the sensors in the study.

Statistical Analysis

All data were transferred to a Microsoft Excel for Windows 10 spreadsheet and statistical analysis was performed with Statistical Package for the Social Sciences (SPSS version 25.0, IBM Corp, Armonk, NY). The Kolmogorov-Smirnov test was done to check the normal distribution of data. Normally distributed data were compared with Student's *t*-test, while others were compared with the Mann-Whitney U test. The χ^2 and Student's *t*-tests were also performed to check the distribution of age, gender, and observation period between tested groups. The level of significance was set at $P < .05$.

Table 1. Distribution of Parameters in the Appliance Groups[a]

	Monoblock Group	Twin-Block Group, Mean ± SD	*P* Value*
No. of patients	15	15	
Age (y), mean ±SD	12.73 ± 1.38	12.27 ± 0.96	.293[b]
Gender, boy:girl	7:8	9:6	.714[c]
Data acquisition time (d)	210.80 ± 28.90	198.53 ± 24.01	.216[b]

[a] SD indicates standard deviation.
[b] Student's *t*-test.
[c] Chi-square test.
* $P < .05$.

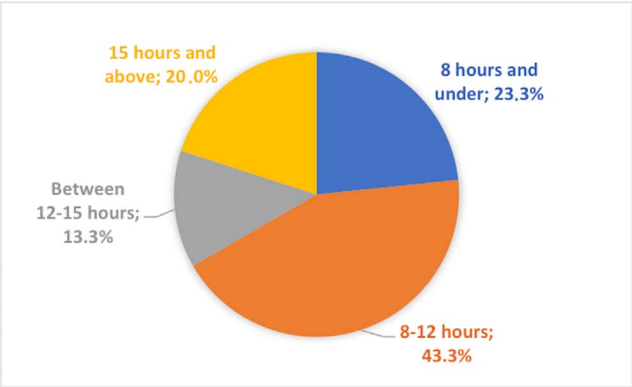

Figure 3. Distribution of patients according to objective and prescribed use times.

RESULTS

The demographic data and data acquisition time are given in Table 1. The distribution of the patients according to their objective and prescribed wear times is shown in Figure 3. Only 20% of the samples achieved prescribed wear times, while 23.3% exhibited less compliance than 8 hours/day. Compliance levels decreased steadily throughout the observation period. From the first month to the sixth month, a 35% decrease was calculated (Figure 4). Subjective patient-reported wear times were compared with objective sensor-based data. The patient-reported wear times were 15.6% more optimistic than those recorded by the microsensors (Table 2).

The distributions of age, gender, and observation period between the monoblock and twin-block groups were homogeneous. Although the monoblock group had a better mean wear time, 0.69 hours more per day than the twin-block group, the difference was not statistically significant. Table 3 shows the intergroup comparisons of objective wear time over months. A greater decrease was detected in the objective usage data of the monoblock group over the 6-month period; however, the difference was not statistically significant. No statistically significant difference was found between the monoblock and twin-block groups in the monthly objective use time changes ($P > .05$).

Comparisons of objective, subjective, and regular wear time of the appliances are given in Table 4. No statistically significant difference was found between the monoblock and twin-block groups in the reference usage data ($P > .05$).

Table 2. Evaluation of Objective Wear Times of the Appliances

Appliance Type	N	Mean Wear Time (h/d), Mean ± Standard Deviation	*P* Value*
Monoblock	15	11.02 ± 4.40	.636
Twin block	15	10.33 ± 3.51	
Total	30	10.67 ± 3.93	

* $P < .05$, Student's *t*-test.

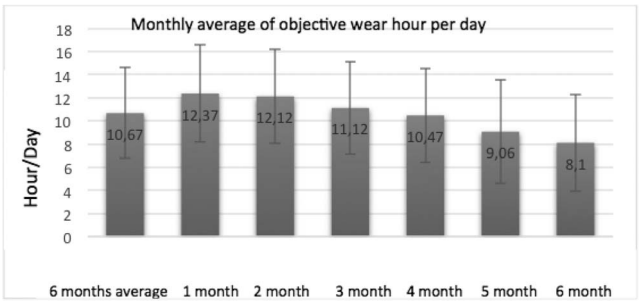

Figure 4. Overall and monthly average wear (hours per day).

DISCUSSION

Time-dependent patient compliance is especially important in treatment with removable appliances. Compliance has an unpredictable pattern over time but may be increased by clinical intervention.[27]

If cooperation with a pediatric patient with a skeletal problem cannot be achieved, a functional orthopedic treatment appliance will not be used. The use of fixed functional appliances can be an option for growth modification treatment. In contrast to noncompliant fixed functional appliances, the wearing period of removable functional appliances is the most important determining factor of the orthopedic effect and treatment success, and internal motivation of the patient is necessary.

Generally, patients state that they wear their functional appliances for the period recommended by an orthodontist; however, they usually do not actually achieve the prescribed wear time of the appliances. Orthodontists cannot manage the compliance level if they cannot measure the wearing time of removable appliances. TheraMon microsensors are very useful for determining the objective wear time of appliances; therefore, these sensors were used in this study.[21] Previous studies have shown that patients who knew that the usage time of their appliances was being recorded tended to wear their appliances for a longer period of time.[19,28] Since the aim of this study was to determine the adherence problem that was actually encountered and to determine the difference between what patients actually did and what patients said they did, the patients were not informed about the presence of the microsensors.[28]

Variable wear times of functional appliances were reported previously.[29] In addition, functional appliances were found to be effective when the wear time was lower than the full-time (22–24 hours) wear regimen.[29] Proffit[30] reported that external forces were effective even though their duration was nearly half. Parekh et

Table 3. Intergroup Comparison of Objective Wear Time Over Months

Observation Period	Group	Mean Compliance Decrease Over the Specified Period, Mean (%)	*P* Value*
1–3 months	Monoblock	12.31	.539[b]
	Twin block	7.57	
	Total	10.06	
3–6 months	Monoblock	32.30	.505[a]
	Twin block	22.24	
	Total	27.17	
1–6 months	Monoblock	40.64	.552[b]
	Twin block	28.31	
	Total	34.50	

[a] Independent samples *t*-test.
[b] Mann-Whitney U test.
* $P < .05$.

al.[29] observed no skeletal or dental changes between the full- or part-time wear regimens of functional appliances in their study. Therefore, a standard of 15 hours of appliance use was found to be more realistic in this study, as noted previously.

A recent systematic review reported that the study group showed 5 hours less overall wear time than was prescribed by an orthodontist.[14] The ratio of objective appliance wear time to the prescribed appliance wear time ranged between 52% and 73% in the literature.[14,18,19] In this study, the overall wear time of patients was 4.33 hours/day less than prescribed by orthodontist, while the objective wear rate was 71%, which was compatible with previous data.[14,18,19]

In this study, 23% of patients were calculated to have an objective wear time of less than 8 hours per day, while similar results have suggested that 25% of patients failed to comply with a wear time of 7–9 hours per day as prescribed by an orthodontist.[9,10]

The prescribed wear time goal was achieved by 20% of the sample group in the current study, which was greater than that presented in a similar study in which only 8% of the participants had achieved their wear-time goal.[20] Compliance levels with both the monoblock and twin-block functional appliances gradually decreased over time from the first month to the last month, with a reduction of 35% observed over the 6-month period in contrast to other studies,[20,31] which may have been due to a lack of re-motivation after the first visit.

In the literature, the time intervals in which the total objective wearing data were measured ranged from 5 to 8 months.[9,10,18,19] Some studies applied the data of the first 3 months and reported that this period was sufficient; therefore, we decided to use a 6-month evaluation period in this study.[20,31]

Similar to the main purpose of this study, many studies have been conducted to compare various types of removable appliances; however, no significant differences were found between Hawley retainers and activators[10,11,15,19–21] or between intraoral appliances and extraoral appliances.[18] Although the clinical results were similar in studies comparing the skeletal effects of the monoblock and twin-block devices,[23] there were no studies that compared the effects of these two devices on ease of use and patient compliance. It has been reported that children who used one-piece or twin-block functional devices were bullied in the community, which affected treatment compliance.[2]

The focus of this study was on the effect of appliance type on compliance levels between two equally divided groups of participants within a limited age range (10–15 years). Post hoc comparisons showed that the groups were homogeneous in terms of age and gender. All other factors were standardized; the same technician produced the appliances, and the same clinician carried out the clinical applications. Since larger temperature ranges are observed in microsensors placed in the upper jaw after food intake at various temperatures, all microsensors were placed in the lingual region of the lower piece of the appliances.[31]

Table 4. Comparisons of Objective, Subjective, and Regular Wear Times of the Appliances

	Appliance Type	N	Mean ± Syandard Deviation	*P* Value*
Subjective wear time (h/d)	Monoblock	15	14.08 ± 2.94	.534[a]
	Twin block	15	14.78 ± 3.16	
	Total	30	14.43 ± 3.02	
Objective wear time (h/d)	Monoblock	15	11.02 ± 4.40	.636
	Twin block	15	10.33 ± 3.51	
	Total	30	10.67 ± 3.93	
Objective-subjective wear time difference (h/d)	Monoblock	15	-3.06 ± 3.03	.234[a]
	Twin block	15	-4.45 ± 3.27	
	Total	30	-3.76 ± 3.17	
Regular wear rate (% of days with >8 wear time)	Monoblock	15	78.29 ± 23.58	.624[b]
	Twin block	15	72.76 ± 25.62	
	Total	30	75.52 ± 24.36	

[a] Independent samples *t*-test.
[b] Mann-Whitney U test.
* $P < .05$.

The same clinical motivation was given to all of the patients in this study to avoid affecting compliance levels. A significant difference was not detected between the objective wear times of monoblock appliances and those of twin-block appliances, supporting the findings of studies that suggested that appliance type did not affect patient compliance.[20,26]

As presented in a recent systematic review, subjective compliance data derived from patients tended to be 5–6 hours more optimistic than that of the objective wear-time data.[14] All of the patients in the current study, all of whom noted their wear time daily on a chart, overestimated their wear time by an average of 3.76 hours, which was 15.6% higher than that of the real daily compliance levels. While the monoblock group was 12.75% more optimistic, this rate was 18.54% in the twin-block group.

Solely analyzing the average daily wear time to assess patient compliance could be misleading in patients with irregular wear patterns.[9,20,32] A patient who had irregularly worn the appliance in equal days of 0 hour/day wear time and 20 hours/day wear time in a month would have the same average wear time as a patient who had a regular daily wear time of 10 hours/day. Thus, a regular wear-rate calculation was determined because it was well known that irregular wear would hinder clinical success. The rate was calculated as the percentage of days that a patient had wear times above the suboptimal wear time, which was accepted as 8 hours/day.[9]

Functional orthopedic appliances have a great importance in clinical orthodontics.[33] but it is not possible to achieve successful treatment without patient cooperation. Microsensors can measure the objective wear time of removable appliances and can help treatment progress, but further studies should focus on other factors that may affect patient adherence.

CONCLUSIONS

- There was no significant difference in objective wear time between the monoblock and twin-block groups. Thus, the null hypothesis could not be rejected.
- Compliance levels gradually decreased over the 5-month study period.
- Regular wear rate is a reliable measure that can be used to assess the compliance of patients with removable appliances, even in the presence of irregular wear patterns.

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