Original Article

Objective assessment of patient compliance with removable orthodontic appliances

A cross-sectional cohort study

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ABSTRACT

Objective: To assess objectively patient compliance with removable orthodontic appliances and the effect of possible influential factors.

Materials and Methods: Wearing times of 45 White patients were recorded with the aid of the TheraMon microsensor. Patient compliance was assessed relative to wear prescription and other parameters, such as age and sex.

Results: There was high individual variation in most measured variables and in all groups/subgroups. During a median observation period of 186 days (range, 55–318 days) the actual wear time was 9.0 h/d (range, 0.0–16.0 h/d) and did not differ between distinct prescriptions ($P = .49$). Eight patients wore their appliances less than 2 h/d, and six of them did not wear their appliances at all. Overall, the median wear per day relative to prescription was 62.5% (range, 0.0–89.3%) for the 14 h/d and 112.5% (range, 0.0–200.0%) for the 8 h/d prescription wear ($P = .01$) groups. There was a strong negative correlation of age (median: 12.5 years) with the daily percentage of actual wear time per day relative to wear prescription (14 h/d prescription: n = 21, rho = −0.61, $P = .00$; 8 h/d prescription: n = 24, rho = −0.73, $P = .00$), while sex did not exert a significant influence on compliance ($P = .58$).

Conclusions: Despite the fact that patients and parents were informed about wear time recording, compliance was insufficient with regard to functional treatment (14 h/d prescription), while it was sufficient for retention purposes (8 h/d prescription). Objective measures are necessary to assess compliance with removable orthodontic appliances since patient compliance is a highly variable issue. (*Angle Orthod.* 2014;84:56–61.)

KEY WORDS: Patient compliance; Removable orthodontic appliances; TheraMon

INTRODUCTION

Removable appliances have been widely used in orthodontics, either for correcting malocclusion problems or for retention of treatment results. Patient compliance is of crucial importance for successful outcomes in orthodontic treatment, especially when removable appliances are used.[1,2]

A great number of internal and external factors that potentially influence compliance have been reported in the literature. These include personal mentality and self-esteem of the patient and the doctor; optimal doctor-patient relationship; clear explanation of the purpose, risks, and costs of the therapy to the patient and his/her parents; maintenance of the regular control and recall appointments; and type of appliance used.[3–6]

The complexity of factors determining patient compliance makes the assessment of compliance for clinical or research purposes a quite difficult issue.[7] Recent evidence[7–9] suggests that subjective assessments of compliance, such as reports by patients, parents, or doctors, are usually not reliable. In order to overcome these limitations, various methods and devices have been introduced in the past decades in an attempt to objectively evaluate the level of patient

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Accepted: May 2013. Submitted: April 2013.
Published Online: July 8, 2013

 DOI: 10.2319/042313-315.1

compliance.[5,9–12] However, the increased cost, increased size, and complicated use together with reduced reliability and inadequate accuracy in measurements have inhibited the widespread use of these methods and devices for research or clinical purposes.

The even more recently developed electronic microsensors, such as the Smart Retainer[13] and the TheraMon,[14] seem quite promising since they are easy to use and because they have been proved reliable and accurate enough to measure wear time of removable orthodontic appliances.[13–15] The TheraMon chip offers more advantages as a result of its smaller size (9 × 13 mm) and its increased accuracy and reliability.[15,16] Both of these microsensors can be embedded into the main construction material of the appliance and identify temperature changes (eg, from "room temperature" to "mouth temperature"), which are then transformed to wear time information.

To our knowledge, there is only one recent study[16] that objectively evaluated compliance with removable orthodontic appliances in a group of patients, and this was a short-term (1-month) study with a limited sample (19 teenagers) that used the Smart Retainer for monitoring maxillary retention. A systematic evaluation of a reasonable group of patients regarding the objective assessment of compliance with removable orthodontic appliances in a considerable observation period is still missing from the literature. Thus, the present retrospective cohort study aimed to objectively assess the compliance of patients who wore various types of removable orthodontic appliances in the medium/long term. The influence of various parameters, including sex, age, and prescribed wear time, on compliance was investigated.

MATERIALS AND METHODS

This retrospective study was conducted in accordance with the ethical principles stated in the Declaration of Helsinki.

Wearing Time Measurement Device

In the present study the TheraMon chip (Handelsagentur Gschladt in 4483 Hargelsberg, Austria) was used for the objective documentation of removable appliance wear time. Although the TheraMon chip must be totally covered by the construction material, because of its small size it can be easily embedded to the acrylic of various orthodontic appliances, or even of plastic appliances, without compromising the size of the appliance and, thus, the comfort of the patient (Figure 1). The recorded data can be transmitted to a computer and presented as graphical curves (Figure 2). For the needs of this study, raw data were exported and organized in Excel spreadsheets (Microsoft Office Excel 2007, Richmond, Wash) in a standardized coded manner for further analysis.

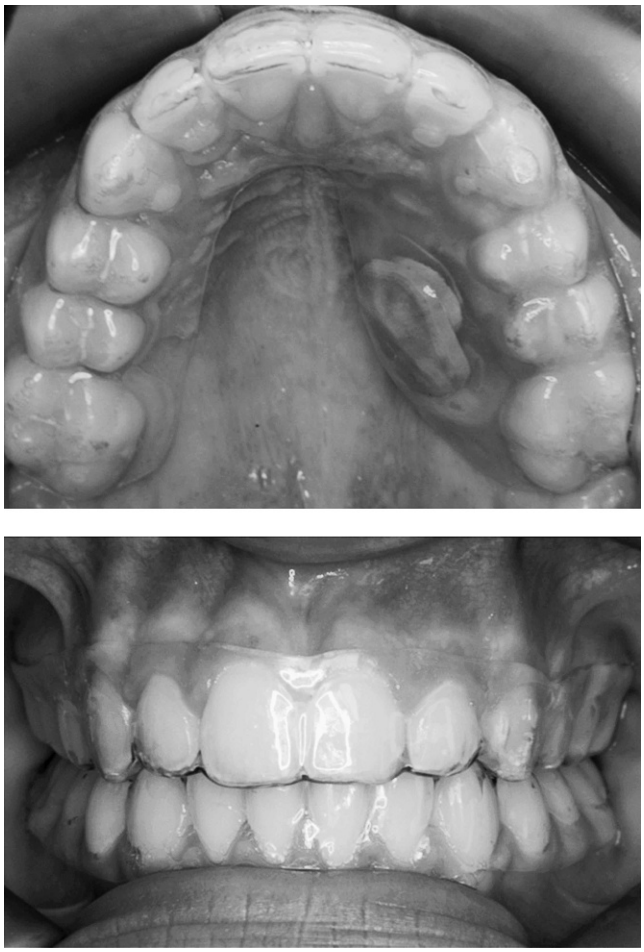

Figure 1. Intraoral image of a patient wearing a removable orthodontic appliance (Essix retainer) with the TheraMon microsensor embedded at the left posterior side of the palate.

TheraMon calculates the actual wear time by measuring temperature every 15 minutes and then transforms this information into wear time when the temperature ranges between two specific values. In the present study this range was defined as 28°C to 38°C, which includes the vast majority of intraoral temperature values observed in an individual under normal conditions.[17–19] The chip was placed at the posterior region of the mouth, buccally or palatally, which presents less variation in intraoral temperature when the chip is exposed to influential factors (eg, environmental temperature or consumption of hot or cold food/drinks).[18] In cases in which an appliance consisted of two parts, one for each jaw, TheraMon was always placed in the maxillary part.

Patients

All patients that were treated between October 2010 and June 2011 in a private orthodontic practice in

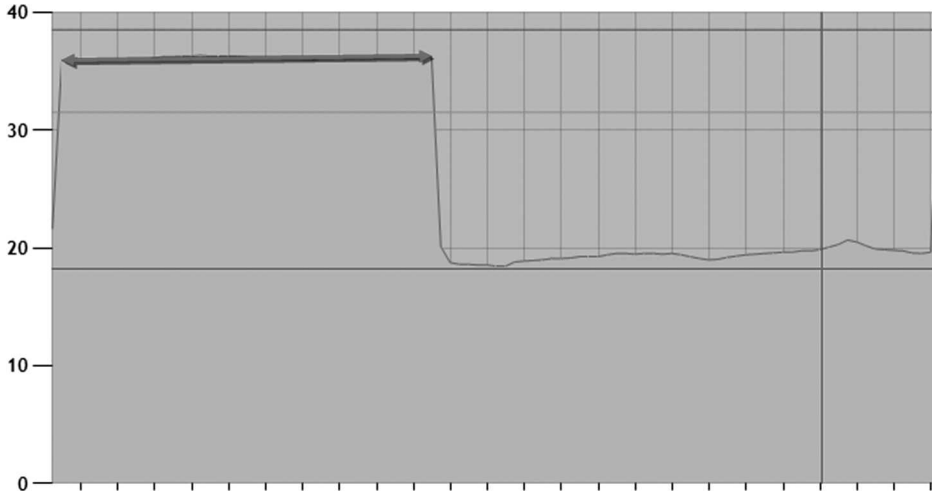

Figure 2. Graphical curve showing the temperature alterations in a patient's mouth, recorded over a 24-hour period. Numbers in the y-axis represent the measured temperature (°C). The horizontal arrow illustrates a 10-hour period when the measured temperature was approximately 36°C, indicating that the appliance was worn at that time.

Germany (BL), accepted the incorporation of TheraMon to their removable appliances, and had more than 30 days of appliance use at the time of sample selection were included in the study. The orthodontist suggested the incorporation of TheraMon in cases where compliance was considered important. Patients and their parents – if adolescent – were thoroughly informed about the presence and function of the TheraMon microchip at the start of treatment and verbal informed consent was obtained. The refusal rate was approximately 10%. The most common reasons included: 1. I can 100% trust my child, 2. I don't like to screen my child like "big brother is watching you", 3. It is too expensive.

Finally, 45 out of 49 patients were eligible for inclusion in the study. None of the patients was related to another in a close manner. Forty patients had a "clean" medical history, while five had a medical condition of weak to moderate severity. With regard to dental history, six patients had inadequate mouth hygiene (gingival inflammation and/or plaque accumulation evident by visual inspection), one had a finger sucking habit prior to treatment, and one was undergoing speech therapy. These medical and dental parameters were evenly distributed in the study groups. Since these cases are candidates for treatment in an orthodontic office and because their conditions were not considered severe enough to treat them as outliers we decided to include them all in the study sample in order to avoid selection bias.

Patients were instructed to achieve the prescribed wear time from the first day of appliance use, and they were not advised to remove the appliances while drinking or eating. The prescribed wear time was 8 or 14 hours per day, depending on the case. In order to remove variability generated by the exact time of starting or ending appliance use recordings during the first and last days of observation, the first and last days of recording at 22:00 hours were considered as the first and last time points, respectively, of the evaluation period for each case.

Parameters Evaluated

The potential influence of age and sex characteristics, function of the appliance (active or passive; Table 1), and prescribed appliance wear time on compliance was investigated.

Table 1. Description of the Type and Characteristics of the Removable Orthodontic Appliances Used in the Patient Sample

Type of Appliance	N	Wear Prescription, h/d	Location	Condition
Frankel II	4	14	Both[a]	Active
Frankel III	2	14	Both	1 Active 1 Passive
Sander II	14	14	Both	8 Active 6 Passive
Cow Catch	1	14	Both	Active
Hawley	19	8	18 Maxilla 1 Mandible	Passive
Essix	5	8	4 Maxilla 1 Both	Passive
Total	45	14 (n = 21) or 8 (n = 24)	22 Maxilla 1 Mandible 22 Both	14 Active 31 Passive

[a] Appliances placed either in one part including maxilla and mandible or in two parts, one placed in maxilla and the other in mandible.

Table 2. Description of the Results of the Study and Comparative Statistics Between the Two Groups With Different Prescribed Wear Time

	Whole Sample, n = 45, Median (Range)	14 h/d group, n = 21, Median (Range)	8 h/d group, n = 24, Median (Range)	*P*-Value[a]
Prescribed wear days	186 (55–318)	211 (96–318)	177 (55–293)	.195
Actual wear days	162 (16–279)	187 (51–279)	134 (15–270)	.052
Wear time per actual wear days (h/d)	9.2 (1.0–16.2)	9.7 (7.2–12.7)	9.1 (1.0–16.2)	.194
Wear time per prescribed wear days (h/d)	9.0 (0.0–16.0)	8.7 (0.0–12.5)	9.0 (0.0–16.0)	.494
Days of no wear	8 (0–201)	7 (0–109)	9 (0–201)	.882
Days of correct wear	19 (0–261)	3 (0–107)	91 (0–261)	**.000**
Percentage of wear time per day relative to prescription	75.00 (0.0–200.0)	62.5 (0.0–89.3)	112.5 (0.0–200.0)	**.009**

[a] Mann-Whitney *U*-test, 14 h/d group vs 8 h/d group; Level of significance: $P = .05$; Bold type indicates significant difference.

Statistical Analysis

All data were tested for normality through the Shapiro-Wilk test and for homogeneity of variances with the Levene's test. Variances were homogeneous in all cases examined, but most data were not normally distributed. Thus, nonparametric statistics were used. For descriptive purposes the median and range of examined variables are provided. The Spearman's rho correlation coefficient was used for assessing possible associations between the tested parameters. The Mann-Whitney *U*-test was used to test for differences between the two primary study groups (14 h/d vs 8 h/d prescribed wear time) and the Kruskal-Wallis test was used for more than two groups. The Chi-square test was also performed for testing distribution of subjects between tested groups according to specific variables, such as sex.

All data analyses were performed using SPSS (version 17.0, SPSS Inc, Chicago, Ill). The alpha level was set at .05.

RESULTS

All 45 included patients (20 female, 25 male) were of German ethnicity. The median age of patients with 14 h/d prescription wear was 11.8 years (range, 8.0–15.8 years), and that of the 8 h/d prescription wear group was 12.7 years (range, 7.2–21.5 years). Age was not significantly different in the two groups ($P = .072$). Patients' age showed a strong negative correlation with the daily percentage of actual wear time per day relative to wear prescription (rho = −0.731, $P = .000$ for the 8 h/d group; rho = −0.609, $P = .003$ for the 14 h/d group). Sex had also a similar distribution in the two groups (10 females, 11 males in the 14 h/d group and 10 females, 14 males in the 8 h/d group; $P = .161$). When the compliance of males was compared to that of the females the daily percentage of actual wear time relative to wear prescription did not differ significantly ($P = .585$).

From the 45 removable appliances assessed in the present study 14 were active and 31 were passive that were used for retention of treatment result. All of the 14 active appliances were instructed on 14 h/d wear. On the other hand, from the 31 passive appliances used as retainers, 24 were instructed on 8 h/d wear, while the remaining seven were instructed on 14 h/d wear. All of the latter were functional appliances that were used as retainers after the active phase of treatment (Table 1).

In a median observation period of 186 days (range, 55–318 days), patients' actual median wear time was 9.00 h/d (range, 0.00–16.00 h/d) and did not differ between the different prescription groups ($P = .494$). Overall, the median percentage of wear per day relative to prescription was 75.0% (range, 0.0–200.0%); 62.5% (range, 0.0–89.3%) for the 14 h/d prescription group and 112.5% (range, 0.0–200.0%) for the 8 h/d prescription group ($P = .009$). There was high individual variation in most measured variables and in all groups/subgroups. Eight patients wore their appliances less than 2 h/d, and six of them did not wear their appliances at all. Results accompanied by the relevant statistics are presented in detail in Table 2.

Regarding active appliances (n = 14), the median percentage of wear per day relative to prescription was 72.3% (range, 0.0–89.3%), while for passive appliances (n = 31) the median was 98.4% (range, 0.0–200.0%). This difference was not statistically significant ($P = .201$). However, since the prescribed wear time is different for active and passive appliances a more valid comparison would consider only the 14 h/d group. In this group, there was a tendency for increased median wear time for the active appliances compared to the passive appliances. The median wear time was 10.1 h/d (range, 0.0–12.5 h/d) for active (n = 14) and 8.1 h/d (range, 0.0–10.5 h/d) for passive (n = 7) appliances in this case ($P = .085$). This finding should be interpreted with caution since the two groups differed with regard to the stage of treatment and also with regard to age, with the first group being younger ($P = .048$).

DISCUSSION

The present study for the first time objectively assessed compliance with removable orthodontic appliances in a reasonable sample and for a considerable time period through accurate and reliable recordings of actual wear time. Within the limitations of the present study, mainly attributed to its retrospective nature, we concluded that despite the fact that patients and parents were informed about the recording of actual wear time, compliance was similar for the two distinct wear prescription groups (14 h/d vs 8 h/d). Namely, it was insufficient for functional appliance treatment, while it was sufficient for retention of treatment result. The extended variability in compliance in all tested groups emphasized the need for an objective measure of this important part of patient management.

In order to minimize the main source of bias in such kind of retrospective studies, the selection bias, we decided to include all patients that received TheraMon in the study and attempted to adjust for possible confounding factors. This was performed by testing for the effect of potential influential factors on patient compliance. This is also extensively analyzed for the first time in the literature using reliable and accurate objective measurements of removable appliance wear time. Previous attempts to assess compliance with removable appliances or to identify predicting factors were contradictory or inconclusive.[6,12,20] This inconsistency can be attributed to methodological issues such as sample size and composition considerations combined with the inability to accurately and reliably objectively assess compliance. These factors together with the high complexity of the issue are quite likely to skew or add noise to the results and to lead to misleading conclusions.

In our study, age was identified as an important factor that affected compliance negatively by increasing from middle childhood to early adulthood. A similar finding was reported by a study[9] involving monitoring of headgear wear time, in which patients younger than 13 years of age wore their appliance approximately 3 hours more than did older patients. Larger samples are needed in order to investigate in further detail the influence of age on compliance and to provide more specific guidelines for treatment with removable appliances. On the other hand, sex did not seem to have a significant influence, as was also observed in the study regarding headgear wear.[9]

A clear difference between patients' compliance with active compared to passive removable appliances was not evident under the present setup. There was a tendency for increased wear time of active appliances but this should be further investigated (see also "Results"). The effect of specific type of appliance was not tested in the present study because of sample size considerations. Patients wore their appliances approximately 9 h/d independent of wear prescription. Thus, compliance was considered sufficient for retention purposes where patients were instructed on 8 h/d wear[21] and insufficient for functional treatment where patients were instructed on 14 h/d prescribed wear time, indicating that the latter approach/wear regime might be unrealistic. However, it should be mentioned that although the 14 h/d regime is widely accepted for effective functional orthodontic treatment, there is no solid evidence regarding the optimal wear time for a successful treatment result.

Recording of wear time can be beneficial since it can help the doctor to promptly identify and overcome potential problems with compliance and may thus lead to more efficient and effective treatment approaches. The doctor should be able to instruct and control an individualized wearing program for each patient that will meet his/her needs and expectations.

Further research is needed to determine the proper use of these appliances in everyday clinical practice in order to motivate patients and exert a positive effect on compliance. A previous short-term pilot study[16] that used the Smart Retainer for recording wear time showed that patients who were informed about the recording of wear time were more compliant compared to those who were not informed, although detailed information is not provided. However, another pilot study[8] monitoring headgear wear time did not confirm this finding. In our study, even though patients were all informed about the presence of TheraMon, the majority still failed to wear their appliances according to their prescription, especially in the functional treatment group (14 h/d prescription). Of course, things might have been worse if patients were not informed about the presence of TheraMon, but this remains to be tested.

Future studies can test for possible correlations between wear time and several parameters, such as sex, age, type and character of appliance, and treatment outcome, in larger samples by using multivariate analysis models to determine the influence of different parameters on patient compliance and treatment result. The high variability observed in most tested variables and in all groups/subgroups indicate that compliance is a multifactorial issue and is thus quite difficult to study and to safely predict without the use of objective measures. Thus, there is strong need for well-designed prospective studies that will provide more useful information for valid assessment/prediction of patient compliance with removable appliances in clinical practice, prior to treatment. Then treatment approaches could be adjusted accordingly, thereby

avoiding failures attributed to poor compliance and burnout of patients sometimes caused by treating them for a certain period of time with ineffective treatment plans.

CONCLUSIONS

- Overall, despite the fact that patients and parents were informed about the recording of wear time, compliance was insufficient regarding functional treatment (14 h/d prescription), while it was sufficient for retention purposes (8 h/d prescription).
- Patients wore their appliances for a median of 9.00 h/d regardless of the wear time prescribed by the doctor. This indicates that the wear prescription given by the doctor may sometimes be unrealistic, since none of the 21 patients in the 14 h/d group could achieve the optimal wear time, while for the 24 patients in the 8 h/d group, 17 presented optimal wear.
- Age was recognized as a significant influential factor, indicating reduced compliance with increasing age from middle childhood to early adulthood.
- Sex did not exert a significant influence on compliance.
- Compliance is a highly variable, multifactorial issue that requires objective measures to be safely addressed in research designs and in clinical practice.

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