Original article

Quantifying patient adherence during active orthodontic treatment with removable appliances using microelectronic wear-time documentation

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Summary

Objectives: The aim of this study was to quantify the wear times of removable appliances during active orthodontic treatment.

Materials and methods: The wear times of 141 orthodontic patients treated with active removable appliances in different locations were documented over a period of 3 months using an incorporated microsensor. Gender, age, treatment location, health insurance status, and type of device were evaluated with respect to wear time. Significant associations between wear times and patient factors were calculated using non-parametric tests.

Results: The median daily wear time was 9.7 hours/day for the entire cohort, far less than the 15 hours/day prescribed. Younger patients wore their appliances for longer than older patients (7–9 years 12.1 hours/day, 10–12 years 9.8 hours/day, and 13–15 years 8.5 hours/day; \( P < 0.0001 \)). The median wear time for females (10.6 hours/day) was 1.4 hours/day longer than males (9.3 hours/day; \( P = 0.017 \)). Patients treated at different locations wore their devices with a difference of up to 5.0 hours/day. Privately insured patients had significantly longer median wear times than statutorily insured patients. No significant difference in wear time was noted according to device type.

Conclusions: The daily wear time of removable appliances during the active phase of orthodontic therapy can be routinely quantified using integrated microelectronic sensors. The relationship between orthodontist and patient seems to play a key role in patient adherence. Wear-time documentation provides the basis for more individualized wear-time recommendations for patients with removable appliances. This could result in a more efficient, shorter, and less painful orthodontic therapy.

Introduction

Removable appliances are commonly used in Europe during the active orthodontic treatment phase to achieve therapeutic targets (1, 2). In the USA, removable appliances are mainly used during the retention phase (3, 4). Depending on the severity of dysgnathia, the treatment plan might include the use of removable appliances either exclusively, or in combination with, a multi-bracket appliance.
In order to achieve successful orthodontic treatment results, patients are asked to wear their removable appliances for a prescribed period each day, and it is known that patient adherence in wearing their devices is particularly important for optimal therapeutic progress. In cases of poor treatment progress or an unsatisfactory treatment outcome, it is almost impossible for the orthodontist to evaluate to what extent non-adherence contributed, or whether the failure was due to biological factors, malconstruction of the removable appliance, or the treatment plan itself. The consequence is that treatment time and costs are increased, and suboptimal treatment alternatives have to be considered. This results in frustration for the orthodontist, parent, and patient. Orthodontists currently recommend ‘standard’ wear times with a broad deviation in practice ranging from night-only (5) to full-time wear (6–8). The choice of protocol is based on empiric parameters or personal experience and does not currently consider the individual circumstances of the patient (2, 9).

Due to the key role that removable appliances play in orthodontics, there have been many attempts to find a suitable method to objectively measure patient wear times. Several different strategies have been developed, most of which have been unsuccessful (10–15). However, with the development of new microelectronic devices to measure wear times, it is now possible to quantify patient adherence over the whole therapy period using methods that can routinely be performed by staff in an orthodontic office (16–22).

The purpose of this study was to quantify adherence to the use of active removable appliances in a large clinical cohort during the first 3 months of treatment. We sought to evaluate any associations between wear times and influencing factors including age, gender, type of device, location of treatment, and health insurance status.

**Subjects and methods**

One hundred and forty-one patients (88 males, 53 females) were recruited between January 2011 and June 2012 based on the following inclusion criteria: aged between 7 and 15 years, no syndromic illnesses, treated for the first time with a functional or active removable appliance with an incorporated microsensor, wear time of at least 3 months or more, and check-up appointments at least every 100 days. The mean patient age at the start of treatment was 10.95 ± 1.87 years (range 7–15 years). Patients were divided into three age categories: 7–9 years old, 10–12 years old, and 13–15 years old. Fifteen patients were treated at the Department of Orthodontics at the University Hospital of Tübingen, Germany, and 126 patients were treated in three private practices in Germany. There were no significant differences in the age, gender, or distribution of health insurance status of the patient groups treated at different locations. The health insurance status of the patients, however, was different. Statutory health insurance (SHI) from sickness funds is compulsory for workers and their families in Germany whose gross income does not exceed a certain threshold, for the unemployed, and for certain other population groups. Employees with incomes above the threshold may opt in to a voluntary sickness fund (‘private health insurance’), which is more expensive but offers additional benefits. Around 88 per cent of the population are covered by SHI (74 per cent obligatory and 14 per cent voluntarily) (23). Written consent was obtained from both patient and the legal guardian for the incorporation of the microsensor and subsequent data evaluation. The study was approved by the ethics committee of the University of Tübingen (project number 339_2012B01).

**Devices and wear-time documentation**

Seventy-one patients were treated with functional appliances (standard activator or Class III activator; Figure 1A) and 70 patients were treated with maxillary expansion plates (containing one or two expansion screws; Figure 1B). The devices were made of Orthocryl® (Dentaurum, Ispringen, Germany) according to standard procedures. The commercially available temperature-sensitive TheraMon® Sensor (approximately 30€ per sensor; Handelsagentur Gschladt, Hargelsberg, Austria or Forestadent, Pforzheim, Germany) was used to measure patients’ wear times. The microsensor was routinely inserted in the removable devices by the dental technician, as previously described (24). The sensor measured ambient temperature at 15 minute intervals, and data were saved to the integral memory of the sensor. Patients were instructed to wear their appliances for a minimum of 15 hours a day. At regular check-up appointments, stored data were transmitted to a computer via the TheraMon® Reader station using radio-frequency identification technology. The temperature data were transformed into wear and non-wear times and graphically displayed on the computer screen according to time and date (TheraMon® Software, Version 2.1.0.13; Figure 2). Unphysiological oral cavity temperatures were automatically identified by the software and regarded as possible artifact or manipulation by the patients, and conspicuous values were highlighted using the in-built detailed analysis (21). Wear-time data of the

![Figure 1. Removable appliances with integrated TheraMon® Sensors: (A) functional appliance and (B) expansion plate.](https://academic.oup.com/ejo/article-abstract/37/1/73/436300/531x531)
patients were documented during the first 3 months of their active therapy phase.

Statistical analysis
Descriptive statistical analysis of the collected wear-time data was performed using SPSS® for Windows (IBM® SPSS® Statistics 20, Chicago, Illinois, USA). Since the data were not normally distributed (Shapiro–Wilk test), the 25th percentile, median, and 75th percentile were used as statistical indices. For further evaluation of the data, the Mann–Whitney $U$-test and the Kruskal–Wallis $H$-test were performed to detect differences between groups. Median wear times were represented using box plot diagrams (Figures 3 and 4). The alpha level was set at 0.05.

Results
Wear-time graphs were generated based on the collected data to allow quantification of wear time with respect to the examined factors. In a representative segment of the graph shown in Figure 2, the blue horizontal line represents the prescribed daily wear time of 15 hours. The red dotted line illustrates the mean wear time of the corresponding patient over the examined time period. The purple line connects the

Figure 2. Characteristic patterns of wear behavior. Daily wear time is indicated by the purple line, prescribed wear time by the blue horizontal bar, and mean wear time by the red dotted line. Wear-time graphs illustrating an example of (A) regular and good adherence and (B) fluctuating wear times and poor adherence.
daily total number of hours that the appliance was worn. Figure 2A shows a wear-time graph of a patient who wore the removable appliance for a median of 15.0 hours over the examined 3 month period. It can be seen that the appliance was worn on a quite regular basis and the patient adhered to the target wear time of 15 hours. Figure 2B shows a wear-time graph of a patient with a high variance in the daily wear time, with a maximum of 22.5 hours/day and a minimum of 0 hours/day. Considering the overall median wear time of 9.7 hours/day (Figure 3), the proportion of actual wear time to instructed wear time was 64.7 per cent.

There were statistically significant differences in wear time according to gender, age, place of treatment, and health insurance status (Table 1 and Figure 4). Female patients wore their devices 1.3 hours/day longer than male patients over the first 3 months of treatment (10.6 versus 9.3 hours/day; \( P = 0.017 \)). The median monthly wear times for each of the first 3 months were 11.3 hours/day (month 1), 10.7 hours/day (month 2), and 10.7 hours/day (month 3) for female patients and 9.5 hours/day (month 1), 9.6 hours/day (month 2), and 9.5 hours/day (month 3) for male patients (Figure 4A).

Wear times decreased with increasing age (Table 1 and Figure 4B; \( P < 0.0001 \)). Over the first 3 months, patients aged between 7 and 9 wore their appliances for a median of 12.1 hours/day, patients aged between 10 and 12 years wore their appliances for a median of 9.8 hours/day, and patients aged between 13 and 15 years wore their devices for a median of 8.5 hours/day.

Wear times according to place of treatment were very variable and there were significant differences in median wear times both over the 3 month period (Table 1; \( P < 0.0001 \)) and for each month separately (\( P < 0.0001 \); Figure 4C). Over the 3 month period, patients treated at Private Practice 2 wore their devices for a median of 14.1 hours/day, and for each separate month these patients wore their devices for approximately 5 hours longer than patients treated either at the University Hospital or in private practices.

Wear times were significantly higher in patients with private health insurance, both when examined over the first 3 months and for each month separately (\( P = 0.033 \); Table 1 and Figure 4D).

As shown in the box plots in Figure 4E, significant differences in wear times according to the type of device were only seen in the first month (\( P = 0.04 \)). Over the 3 month period as a whole (Table 1), no significant differences in wear times were found (\( P = 0.148 \)), consistent with previous observations (18, 25).

Discussion

Here, we demonstrate that wear times can routinely be documented for different removable orthodontic appliances during the active therapy phase in a large patient cohort. This technology allows for accurate determination of daily patient wear times, as well as generation of additional useful data, including software-generated mean wear times over any chosen time period. The inexpensive, commercially available sensor can be inserted into the removable appliance by a dental technician as part of routine practice. For the entire cohort, the median daily wear time was only 9.7 hours/day, far less than the 15 hours/day prescribed. This unexpected low median daily wear time has also been reported by other groups that have used microelectronic wear-time documentation with the TheraMon® system, with median wear times similar to those seen in our study [8.1 hours/day (18), 8.3 hours/day (17), 9.0 hours/day (22)].

Due to the ability to perform detailed analysis of the data, the operator was able to check whether there was any suspicion of manipulation. Overall, the method was reliable and the monitoring protocol was easy to follow. According to the results of a questionnaire study describing the experiences of patients and parents during treatment with removable orthodontic appliances with electronic wear-time tracking, 86 per cent of patients stated that the comfort of the appliance was not affected by the installed sensor (26). Since the patients knew that their wear time was being monitored and recorded, this may have influenced behavior; indeed, it has been shown that patients aware of their monitoring are more motivated to wear their appliance than patients unaware of monitoring (27). Another study has indicated that wear-time monitoring does not alter the time that removable devices are worn by patients (18, 25). A possible increase in motivation may therefore be seen as an advantage of the monitoring process.

We limited our evaluation of wear times to the first 3 months of the active treatment phase with removable appliances. Based on our clinical experience and the evaluation of over 500 experimental wear-time documentation studies, patients generally retain their initial wear behavior over the entire course of treatment, and therefore the analysis of patients’ wear-time data over the first months of treatment is a useful proxy of their long-term wear behavior. The direct quantification of adherence at last allows for clarification of previously contradictory data on the factors that influence wear time based on indirect wear-time measurements. Female patients were more likely to wear their removable appliances than males, consistent with previous findings (3, 11, 28–32). Several other studies have failed to demonstrate a gender-related difference in wear behavior (18, 25, 33–37), and one even concluded that adherence was better in boys than in girls (17). We also showed that in the first 3 months of treatment, younger patients have longer wear times than older patients. Again, there are other contradictory data with several empirical studies and experimental studies also showing similar age-dependent differences (10, 22, 28, 33–35, 38), while others have failed to demonstrate that age influences wear time (11, 36, 39, 40). Early pilot studies using wear-time sensors revealed similar associations to ourselves between gender, age, and compliance, although these data need to be treated with caution since the technology at that time was known to be less reliable.
Figure 4. Grouped box plots of median wear times for the whole period of the first 3 months of treatment (wide box plot) and for each month separately (small box plots) with regard to (A) gender (female $n = 53$; male $n = 88$), (B) different age categories (7–9 years $n = 34$; 10–12 years $n = 72$; 13–15 years $n = 35$), (C) place of treatment (University Hospital $n = 15$; Private Practice 1 $n = 61$; Private Practice 2 $n = 29$; Private Practice 3 $n = 36$), (D) health insurance status (statutory $n = 98$; private $n = 43$), (E) the device type (functional appliance $n = 71$; expansion plate $n = 70$). Left: over entire study period; right: per month.
The conflicting results using microelectronic devices on gender [no effect (18, 22) and males more compliant than females (17)] can be explained as follows: these studies were very small [32 patients (18) and 45 patients (17, 22)] with a much higher age range [6.42–21.5 years (18), 7.2–21.5 years (22)], or the study was confounded by the mean age for boys being lower than that for girls (17); we show that younger children wear their devices for longer and therefore this might be responsible for the observed compliance of males in (17).

Previous studies measuring wear times of removable appliances have only been determined at a single location or institution. Our multi-centre study is novel and shows that both the place of treatment (i.e. University Hospital or independent private practice) and health insurance status also have an influence on patient adherence. This result was unexpected and has not yet been described in the literature. Treatment location is therefore an important parameter to consider and may introduce bias if not considered in the interpretation of previous studies, or the planning of future studies. The influence of the treatment location suggests that the practitioner may, either consciously or unconsciously, influence patient adherence. This may be due to several parameters, such as the patient/doctor relationship, therapy instructions given, or role of supporting staff; however, these factors were not evaluated in the present study but need to be included in future studies. The relationship between median daily wear time and therapeutic result when using removable appliances has yet to be quantified. It therefore remains to be determined whether practitioners whose patients have short wear times can achieve comparable therapeutic success to those practitioners who motivate their patients to wear their devices for longer.

Adherence is a multi-faceted behavior and difficult to predict. Various parameters, and the personal circumstances of the patients, including their social life, activities, personal preferences, and possible dissatisfactions regarding treatment, result in highly individual characteristics requiring individualized wear-time protocols. By identifying these influencing parameters, practitioners can start to model and predict the adherence and prognosis for orthodontic treatments using removable appliances. However, girls aged between 7 and 9 years, privately insured, and treated with removable appliances may have better adherence than older male patients with statutory insurance. The construction of predictive statistical models will require large-scale data from prospective studies.

The main clinical contribution of this study is the possibility of using objective knowledge of wear time and patient adherence in patient management. When planning treatment, the practitioner can only expect an average wear time of about 10 hours/day; the usual wear-time prescription of approximately 15 hours/day for removable appliances is simply not realistic in practice for the majority of patients. The practitioner may reasonably assume that the removable device type does not cause a significant difference in wear time, and health insurance status will only slightly influence patient adherence. However, adolescent patients are likely to have much worse adherence than younger children, and girls seem to wear their appliances longer than boys. The treatment site, and thus the practitioners themselves, have a significant influence on adherence. Using this information, the practitioner may be able to better judge the level of risk of non-compliance and whether, particularly in more complex cases, a fixed appliance may be more appropriate than a removable device.

Our results on the factors that influence wear time during the active phase are similar to our recently published data on factors influencing wear time during the retention phase (41); only the influence of health insurance status on wear time is different. Quantitatively, however, the most important difference is the significantly longer median wear time of active appliances (9.7 hours/day) compared to retention devices (7.0 hours/day), which may be related to the marked difference in prescribed wear time in these two settings (15 hours/day versus minimum 8 hours/day). During the active phase of treatment with removable appliances, the patients become familiar with orthodontic treatment and come to realize that adherence is crucial for therapeutic success, and therefore more closely follow the prescription. Following
the active treatment phase when corrections are complete, adherence is only required for stabilization of the results during the retention phase. However, it is also possible that the higher median wear time during the active phase might be due there being a larger proportion of younger children (who wear their devices for longer) in the current cohort compared to adolescents, who form a larger proportion of the retention phase cohort. These differences are important to highlight because a low median wear time during the retention phase, although effective in this setting, might be too short in the active treatment phase to achieve the desired therapeutic outcome.

The ability to estimate treatment adherence and predict wear behavior would be of great value in everyday practice. Ideally, practitioners would be able to adapt their treatment plans to the personal circumstances and needs of the patient; the result would be less frustration for both orthodontist and patient during the removable treatment phase, and ultimately shorter treatment periods and reduced therapy costs. Uniform and mandatory wear protocols are unlikely to be suitable for all patients and improve success in the active treatment phase. By using accurate and objective wear-time documentation, orthodontists can determine the most acceptable wear times and complement this with longer follow-up. Getting patients involved in treatment decisions and making them aware of their own responsibility for successful therapy is important for maintaining high levels of adherence (42). There is no doubt that orthodontists, through both effective communication based on wear-time documentation and practical ability, hold the key to optimizing and individualizing the course of treatment. A good relationship between orthodontist and patient seems to be crucial for good patient adherence; therefore, both parties have a role to play in enhancing adherence to improve therapeutic success.

Finally, the aim of microelectronic wear-time documentation is not to enforce the existing ‘standard’ wear times with their poor evidence base, rather to evaluate wear effects and therapeutical decisions and making them aware of their own responsibility for successful therapy is important for maintaining high levels of adherence (42). There is no doubt that orthodontists, through both effective communication based on wear-time documentation and practical ability, hold the key to optimizing and individualizing the course of treatment. A good relationship between orthodontist and patient seems to be crucial for good patient adherence; therefore, both parties have a role to play in enhancing adherence to improve therapeutic success.

Conclusions

Electronic wear-time documentation has, for the first time, allowed the accurate measurement of patient adherence to prescribed wear times. The technology allows orthodontists to study the wear times for the whole therapy phase at any time. A median wear time of about 9 hours was acceptable to the majority of patients for removable devices and was usually adhered to for several months. Quantification of adherence allows the assessment of the extent to which patients themselves contribute to the success of therapy, and whether changes to treatment plans are necessary. The argument that the ‘adherence was unknown’ can no longer be applied to explain failures of treatment using removable appliances when built-in wear-time sensors are used. The clinically relevant (but unresolved) problem of ‘what is the most optimal and effective length of wear time for optimal treatment outcomes’ can now be measured and be integrated into future investigations.

References


