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Headgear compliance as assessed by a temperature-sensitive recording device: a prospective clinical study

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Summary

Objective: To accurately describe compliance in headgear wearing time by using a temperature- and force-sensitive device over an 8 month period of use in a prospective clinical manner.
Materials and methods: Twenty children with Class II malocclusion aged 8–12 years were randomly selected for treatment with cervical headgear. The headgears were equipped with an electronic module, which measured temperature and force, and patients were instructed to wear the headgear 12 hours daily. The recorded values were analysed to determine the number of days the headgear was used, the number of hours per day it was worn, and the percentage of compliance (100 per cent corresponding to 12 hours daily).
Results: The average treatment period was 8.4 months with 5.8 months of effective use. When effectively used, headgear was worn 8.7 hours a day (compliance of 73 per cent). Including days where it was not worn, compliance was 6.4 hours (54 per cent). The appliance was used on average 0.5 hours during the day (8 am–8 pm) and 5.9 hours during the night (8 pm–8 am). Very low compliance was recorded during July and August.
Conclusion: The average compliance with cervical headgear use was 54 per cent of the 12 hour prescription. The headgear was effectively used only 5.8 months over the study period, with roughly 30 per cent of no use. Headgear was used almost exclusively during evening and night-time. During the summer period, compliance was particularly poor.

Introduction

Headgear appliances are still a popular choice for treating Class II malocclusion in children, being used by 62 per cent of American and Canadian orthodontists according to a recent survey (1).

Like every removable appliance, headgear is compliance dependent and patient cooperation is a key factor in achieving treatment goals. From the beginning of its use, clinicians felt the need to assess patient collaboration in order to understand the reasons for unsatisfactory treatment outcomes besides attributing failure to biological factors. In fact, the lack of an objective method of measuring cooperation makes it difficult to describe the 'dose–effect' relationship between headgear use and molar distalization.

In 1974, Northcutt introduced timing measurements, with a headgear timing device (2) being used as a tool to objectively measure patient compliance. He found that his patients self-reported 11 hours of daily use of headgear, while their actual wear time was only of 6.5 hours over the 12 hours per day prescribed (54 per cent compliance) when they were unaware they were being recorded. After revealing the recording tool to his patients, he reported a net increase in the use of headgear with a doubling of the weekly hours of use. Even though the precision of these specific headgear timers was called into question later (3) because of patients attempting to falsify results, Northcutt's input (2) highly influenced research into compliance behaviour.

Indeed, it revealed how indirect methods of compliance assessment are weak and unreliable. Orthodontists can simply deduce compliance from clinical parameters like fitting of the appliance, oral hygiene, appraisal of molar mobility, space created between teeth, and by comparing the treatment progress with initial treatment records (4). Orthodontists' predictions of effective compliance tend to overestimate actual wearing time by patients (5). Patients and parents are even worse judges of their actual cooperation level and tend to report that they wear headgear very close to the number of hours prescribed by the orthodontist (6,7), especially if they are unaware of being recorded (2,5). In particular, those patients who are not aware of being recorded, tend to report themselves as very compliant with the orthodontist's request. Indeed, they are generally the least honest about assessing actual wearing time and, as a consequence, the least compliant (4).

A recent systematic review reports 5.0 hours per day of difference between self-reported and objectively assessed removable appliance wear (8). Some authors affirm that knowledge of being recorded by a device may produce a positive influence on patient cooperation (9).

In the early 1990s, a new quartz-based timer to assess headgear compliance was developed by Cureton *et al.* (10) with similar results to those found by Northcutt (2). During the same period, microelectronic monitoring of wearing time was first applied to functional appliances (11). Results were very similar to headgear use in terms of absolute timing (7.7 hours of wear per day) and relative use (50–60 per cent of the time prescribed by the orthodontist). However, timing of prescribed use is not evidence-based and depends on the doctors' education and beliefs, ranging between 12 and 14 hours for most removable appliances (12).

Later, in the early 2000s, headgear equipped with modern recorders was used to assess collaboration. A Brazilian cohort of patients showed average compliance of 5.6 hours when unaware of being recorded, and 6.7 hours when made aware, out of the 14 hours prescribed by the orthodontist (4). The evidence regarding the role of awareness on compliance use is, by the way, uncertain as suggested by some authors (13,14).

A Dutch group of patients showed identical results, with 5.6 hours of average daily use over a 1 month observation period. By excluding the results from blank days, when headgear was not used at all (12 out of 29 on average), the wearing time increased to 7.6 hours (5). Al-Moghrabi *et al.* reported an average headgear use of 5.8 hours per day on a systematic review based on six studies (8).

More recently, a microelectronic sensor was developed to be embedded into removable appliances (15). It has been used to measure wearing time of functional appliances and active plates. Results of wearing time range from 8 to 10 hours on average, out of 14 to 16 hours of prescribed use, with the rate of actual wearing time versus prescribed wearing time ranging between 55 and 65 per cent (16–18).

Most of the studies in the literature have observation windows ranging from 1 to 3 months (4,17–19), with a few exceptions extending to 6–8 months (13,20). The aim of our study was to accurately describe compliance in headgear wearing time by using a temperature- and force-sensitive device over an 8 month period of use.

Material and methods

Study design

This is a prospective clinical cohort study assessing objective compliance over an 8 month observation period. The present study was approved by the local research ethics board (CER 12-250). All patients and their parents gave informed consent.

Setting

Patients were selected randomly and prospectively from the orthodontic clinic of the University of Geneva. The recruitment period lasted 9 months (from March to December 2016), and the observation period ended on September 2017.

Participants

Inclusion criteria were: 8–12-year-old children with a Class II malocclusion (at least edge-to-edge bilateral molar relationships and an overjet of 6 mm or more), a positive overbite, in the mixed dentition, with the maxillary second permanent molars not yet erupted, an A point–nasion–B point angle greater than 4 degrees, and non-extreme vertical skeletal patterns. Children with tooth agenesis, a compromised periodontium, previous orthodontic treatment, on systemic medication, or medically compromised were excluded from the study.

Variables and measurement

Children were instructed to use headgear for 12 hours a day over the study period of 8–9 months. The headgear was equipped with a temperature- and force-sensitive module (Smartgear, Swissorthodontics AG, Cham, Switzerland) that recorded data every 15 minutes (Figure 1). The triggering range of the force measured by the sensor is 100–500 g.

The patients were aware of being recorded since they were instructed about the recording module at the time of appliance delivery. A single operator (SA, postgraduate resident) adjusted the headgear and followed up the patients every month. The same set of instructions was given to every patient and their parents with regard to appliance wear, and motivational written reminders were also given to all patients at each appointment.

At the end of the treatment period, the recorded values were exported from the electronic modules into an Excel spreadsheet. They were then analysed to determine the number of days the headgear was used, the number of hours per day, and the percentage of compliance (100 per cent compliance representing 12 hours of use per day, as prescribed by the orthodontist).

The headgear was considered used when force was above zero (and temperature close to the human body temperature range of 35–37 degrees). Two investigators (LH and SA) indipendently examined the software outcomes in order to identify the sensor's possibly erroneous records (21). A full agreement was found between the two

Figure 1. Headgear–sensor combination on a patient (picture published with permission https://orthowalker-kieferorthopaedie.ch/produkt/smartgear/—last accessed 27 April 2019).

investigators in attributing the measures to the 'in use' or 'not in use' category.

Study size

A sample size of 20 patients was calculated based on the findings of a similar study (5). The power of the study was calculated to detect at least 1 mm of molar distalization. The results of this study are object of a different paper that also includes a control group. A control group is not applicable to the present study focussed on compliance only.

Statistical methods

Statplus (AnalystSoft Inc., Walnut, California, USA) was used to calculate box plots for compliance, effective compliance (compliance during days of effective use of the appliance, not including those where the appliance was not worn at all), monthly compliance, hourly compliance, weekday versus weekend compliance, and daily versus nightly hours of use. Spearman's correlation coefficient (non-parametric) was used to assess the relationship between the number of times per day the headgear was inserted and effective compliance, as well as to assess the correlation between days of non-use and effective compliance.

Results

Twenty Class II malocclusion children were included in the present prospective cohort study, 11 girls and 9 boys, with an average age of 10.2 years [standard deviation (SD) 1.2 years]. The average treatment period was 252 days (8.3 ± 0.6 months). All data from all participants during the observation period were analysed.

Actual headgear use (at least once per day) was on average 5.8 months (70 per cent of the time), whereas headgear was not used at all for 2.6 months (30 per cent of the time) on average (Figure 2).

The average daily compliance, including days of non-use, was 6.4 hours (54 per cent of the 12 hours prescribed wear; Figure 3), while when excluding blank days (days of no use), the daily effective wear of headgear was 73 per cent or 8.7 hours of daily usage (Figure 2). Patients who skipped most days of headgear use were also those who recorded the lowest effective compliance: Spearman's correlation between effective/net compliance and blank day of no use was –0.63 (Figure 2).

The appliance was used (inserted in the mouth) on average 1.8 (±1.0) times per day. Spearman's correlation between effective compliance and blank days of no use was 0.77 (Figure 3).

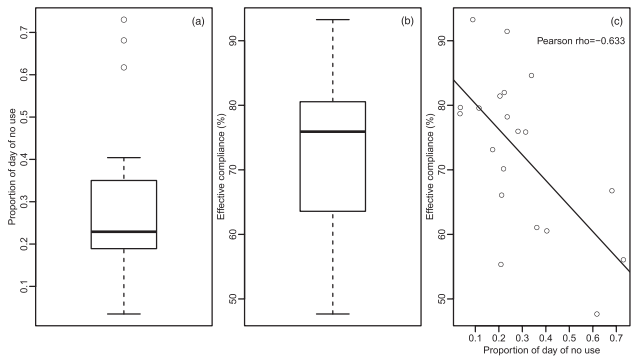

Figure 2. (a) Proportion of days of no use (percentage). (b) Effective compliance (percentage) excluding days of no use. (c) Correlation between days of no use and effective compliance.

The monthly compliance rate is reported in Figure 4. The compliance was consistent on months going from October to May (72 per cent of use on average) while it dropped from June to September with a minimum in July (33 per cent on average).

The hourly report of compliance is reported in Figure 5. Night hours going from midnight to 7 am showed an average compliance over 50 per cent. The compliance during day time was close to 0 especially in the period going from 11 am to 8 pm.

When defining daytime as 8 am–8 pm, the number of hours of use was 0.5 hours versus 5.9 hours of use at night-time as defined by 8 pm–8 am. When comparing weekdays (Monday–Friday) to weekends, there was virtually no difference (54 versus 51 per cent of average compliance, respectively).

Discussion

Quantifying the compliance in relation to headgear use has been a recurrent topic in orthodontic literature since Northcutt used his timing device (2). This question is still of interest as headgear represents a very common choice for orthodontists (1). It is indeed difficult to answer this question with conviction since numerous factors may determine patient cooperation. Our study focussed on a multiethnic pool of patients living in a large Swiss city, and our findings may be extended to similar demographic situations.

Previous investigations (2,4,5,10) reported an average use that ranged between 5 and 7 hours per day, following a prescribed recommended wear time of 12 hours. These values were registered despite the fact that patients were aware of being recorded. Our findings (6.4 hours corresponding to 54 per cent of the 12 hours prescribed time) were very close to the 50–55 per cent of compliance reported in the literature and to the 5.8 hours reported by Al-Moghrabi *et al.*'s

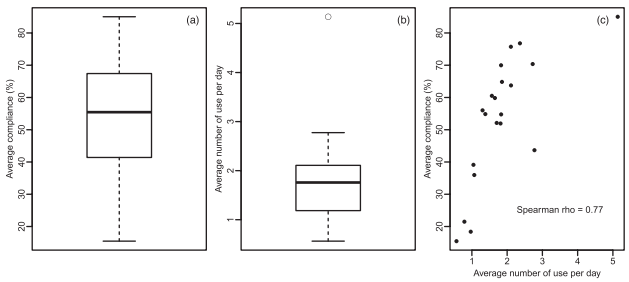

Figure 3. (a) Average compliance (percentage). (b) Average times of use of the headgear per day. (c) Correlation between times of use and compliance.

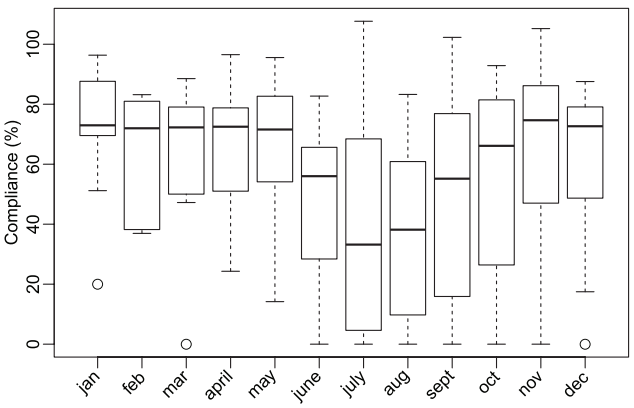

Figure 4. Compliance on a yearly basis over the 12 months.

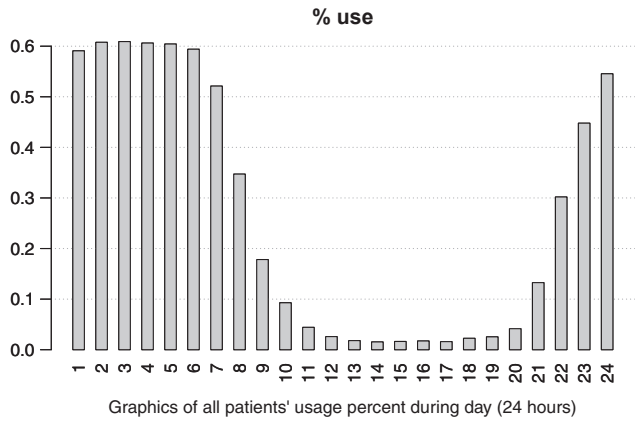

Figure 5. Compliance on an hourly basis over 24 hours.

systematic review (8). Values were higher (8.7 hours corresponding to 73 per cent of compliance) when considering effective compliance (excluding days of non-use). When patients remember or are willing to use their appliance, their compliance is fairly good, which is likely to take place during the evening and night-time.

In fact, by having recordings available every 15 minutes, we closely investigated the use behaviour on a daily basis over 24 hours. Daily use (8 am–8 pm) was negligible as it was only half an hour on average. This was significantly different from the 6 hours of average evening and night-time use (8 pm–8 am). The findings leave no doubt that patients wear their headgear at night only and that daily users are the exception. When looking for differences in use of headgear between week/schooldays and weekends, we found a very small (3 per cent) yet statistically significant difference, with more compliant use of the headgear during schooldays.

Patients did not wear their headgear for an average of 2.6 months during the treatment period, which represents 30 per cent of the total time of observation. As the observation period was evenly distributed throughout the year, it was possible to observe a typical drop of compliance during the warm summer period (from June to September in Switzerland). The months when the lowest compliance was recorded were July and August, which corresponds to the school holiday time for Swiss students. Not surprisingly, patients are far less motivated to cooperate during their relaxation and vacation time. Some of them completely forgot to wear their headgear during the entire vacation time (or more likely they simply forgot it at home).

We also tried to relate compliance and patient behaviour. Patients inserted their headgear on average 1.8 times per day (the moment of insertion and disinsertion could be detected thanks to the tensile force that was recorded). There was a high correlation between average compliance and number of times the headgear was inserted (Spearman's correlation coefficient = 0.77). Patients who wore headgear just once per day scored compliance values up to 40 per cent, while those using headgear two to three times per day scored compliance ranging from 50 to 80 per cent. Interestingly, the only outlier who inserted the headgear five times per day on average was also the most compliant patient (85 per cent), with an average use of more than 10 hours per day.

Compliance assessment is an important factor that needs to be assessed ideally any time a removable appliance is used. Data collected in the present study allow to better understand minor nuances of the attitude of patients when using headgear. The results are far from encouraging. Further investigations should try to identify the role of compliance in relation with clinical results of headgear use.

Limitations

A possible limitation of the study is the absence of a control group. A control group exists for evaluating the dental effect of headgear therapy but it is not possible to compare compliance between a group using an appliance and a control group out of therapy. A further limitation may be the cost of the sensor as it is proposed at 200 Swiss Francs, with a guaranteed durability of 1 year.

Conclusions

During 8 months of observation, average compliance of headgear use was 8.7 hours of wear per day (73 per cent of the 12 hours prescribed) on those days when the headgear was used. Indeed, the headgear was never used on 30 per cent of the days (it was effectively used only 5.8 months over the 8.4 months of the treatment period). By including these blank days, the average compliance dropped at 6.4 hours per day. Not surprisingly, during the summer period, compliance was particularly low. The compliance factor should be carefully considered when planning to correct a Class II malocclusion through headgear as the lack of compliance may play an important role on the clinical outcomes.

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Conflict of interest

The authors declare the absence of conflict of interest.

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