Clinical and quantitative assessment of headgear compliance: A pilot study

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Introduction: This study was undertaken to evaluate the compliance of patients using headgear with a timing device and to determine the efficiency of the electronic module timer as a patient motivator. Methods: Twenty-one patients (average age, 14 years 10 months) were selected from the orthodontic clinic of Federal University of Paraná on the basis of headgear wear for anchorage. The patients were instructed to wear their headgear 14 hours a day for a given number of days. The headgears were equipped with recorders (Compliance Science System and Affirm smart headgear modules, Ortho Kinetics, Vista, Calif). The patients were not told about the recorders, but they were instructed to keep track of their wear times. At the end of the test period (T1), the patients’ reported wear times were compared with readings from the electronic modules. The patients were assigned a second period of headgear wear (T2) and told that their use would be monitored electronically. Again, the wear times reported by the patients were compared with the values from the electronic modules. Total time, number of hours accumulated between sessions, and quality time (uninterrupted use of headgear) were assessed.

Results: Patients reported wearing their headgear an average of 13.6 hours per day; the electronic modules detected 5.6 hours per day in T1 and 6.7 hours per day in T2. Quality time was 1.8 hours per day in T1 and T2. The mean actual hours of daily wear relative to the provider’s requirement was 56.7% in T1 and 62.7% in T2. Boys were more compliant than girls. After they learned of the electronic device, the girls’ compliance improved. Younger patients were more compliant than older ones. The compliance rate of older patients improved slightly in T2. Conclusions: Patients tend to overreport their headgear wear times. The mean actual hours of daily wear relative to the providers’ requirement was 56.7%. This increased to 62.7% when patients knew a recording device was being used. A monitoring system can provide feedback to the patient, facilitate parental involvement, and motivate patients to comply with headgear wear. (Am J Orthod Dentofacial Orthop 2006;129:239-44)

Headgear has been an effective treatment for the correction of Angle Class II malocclusions.1-4 The cooperation of children and adolescents plays a major role in achieving the desired results, but cooperation is often difficult to verify.

Laxity in following the instructions can lead to slow progress of treatment, loss of chair time, and compromised treatment results.5 Early identification of patients with poor compliance might help the orthodontist anticipate problems during treatment in time to establish alternatives to the initial treatment plans. In addition, techniques to improve the doctor-patient relationship could be used when problems are identified early.

The goals of this investigation were to determine the compliance rate of headgear use and the role of timing headgear as a motivator.

Several studies have examined patient cooperation in orthodontic treatment.5,7 Because compliance cannot be rated easily, test scales for evaluating cooperation have been developed.7 Nevertheless, few studies have considered the reliability of their patient cooperation measures.8 Other studies have relied on personality variables to predict compliance, and validated psychological inventories have been used to identify psychological variations in adolescents.9-15

Research findings show that patients can be selective concerning which aspect of the orthodontic regimen they follow.16 A patient who keeps appointments reliably might not take the prescribed medications as requested. Accurately predicting compliance is difficult.

Orthodontists often rely on the clinician’s judgment to assess compliance.15,17 This method is subjective and might include questioning the patient about the motivation for using the headgear, assessing oral hygiene, and identifying factors that might reflect on compliance.18 More direct methods include clinical
appraisal of molar mobility, cleanliness of headgear tubes, ease of placement by the patient, space created between teeth, molar positioning compared with pre-treatment models and cephalograms, and anchorage maintenance.\textsuperscript{11,16,19,20} Unfortunately, these methods are notoriously inaccurate, with clinicians tending to overestimate compliance. Treatment failures resulting from noncompliance often elude clinical recognition and are attributed to other causes.

The need to assess the level of headgear compliance between appointments has led to the development of timing devices built into the appliances.\textsuperscript{19,21-23} Northcutt\textsuperscript{21} introduced a timing headgear. Electronic approaches also have been used to measure compliance with intraoral appliances.\textsuperscript{6,24} Cureton et al\textsuperscript{25} studied headgear timers to determine the accuracy of 3 groups of investigators in clinically evaluating headgear compliance and found that no group accurately or consistently assessed headgear wear. Compliance was not different between the sexes. Patients 10 to 12 years of age were more compliant than those 12 to 14 years of age, who were more compliant than the over-16 age group. Patients reported wearing their headgear 11 hours a day, although their actual wear was 6.5 hours a day, or 54\% of the hours prescribed. Güray and Orhan\textsuperscript{26} described the Selçuk type of headgear timer and compared it with real-time measurements for 4 months. Ten patients were instructed to wear the extraoral appliance for 16 hours a day. After the timing mechanisms were introduced, compliance improved by 26\%.

Continued interest in measuring headgear use has led to more accurate timers.\textsuperscript{27-29} The reliability of this new technology, however, has been under scrutiny. Banks and Read\textsuperscript{29} performed in-vitro reliability tests on headgear timers and found that 9 of 14 timers were more than 70\% inaccurate. Only 4 of the 13 timing devices produced mean timing accuracy values exceeding 90\%. Informed clinical decisions require monitoring devices that can accurately assess headgear wear.

**MATERIAL AND METHODS**

The sample consisted of 21 patients (10 male and 11 female; age range, 11 years to 19 years 6 months) undergoing comprehensive orthodontic treatment in the graduate clinic at the Federal University of Paraná in Brazil. Headgear wear for anchorage support or growth modification was part of each patient’s treatment plan. The study started after 3 months of headgear use to minimize the confounding effects of novelty and initial enthusiasm.

All patients and their parents received instructions from the same operator (M.B.) to use the headgear for 14 hours daily. The importance of good headgear wear for treatment success was emphasized.

The Compliance Science System (CSS) and Affirm smart headgear modules, developed by Ortho Kinetics (Vista, Calif) in 1998, were used. This system records the duration of each “on” session in hours through an electronic chronometer tied to the cervical strap. A CSS reader transforms the information stored in the affirm modules into charts and reports of frequency and duration. Among the reports available in CSS, 3 types of information were selected: total time (number of hours between sessions), quality time (uninterrupted wear), and session duration. Quality time was defined as a session not less than 7 hours long but not longer than 14 hours. A daily goal of 10 hours with a break of 30 minutes was established. The break was programmed as a credit time for meals and tooth brushing to avoid interference in the quality-time evaluation.

Compliance rate was calculated as the mean actual hours of daily wear relative to the provider’s requirement stated in hours per day by using the formula suggested by Feinstein.\textsuperscript{30}

A questionnaire was used to monitor the patient’s understanding of the information given at the second and third visits before the study began. One month later, the study started, with record taking at every 2-week visit. At each visit, patients were requested to indicate the number of hours they were using the headgear.

The evaluation was done in 2 stages. In the first stage (T1), the patients were not told that the headgear included an electronic timing module. The modules were read at every visit to register the information about headgear use. The second stage (T2) began 70 days after the headgear was first placed. The patients were then informed that they were being monitored with electronic modules. Readings continued to be taken every 2 weeks to observe compliance rate changes from patient awareness of the monitoring.

Reliability was tested clinically to measure the accuracy of the electronic device in registering headgear wear and to determine whether head posture influenced the recordings. Reliability was assessed twice during a 24-hour period. Five patients were asked to use the monitoring headgear for 8 to 10 hours during the night (sleeping time) and to use it continuously for 3 to 7 hours during the day. The subjects were instructed to record the times the headgear was placed and removed. The data collected were compared with those registered by the software (Table I). Because more than 18 hours of uninterrupted wear is incompatible with everyday activities, any record of this amount was considered to represent either fraudulent behavior.
Reliability of each appliance was expressed as a percentage of the recorded time compared with the true time.

**Statistical procedures**

The mean and standard deviation were calculated for each variable. Associations between variables were assessed with the Pearson product moment correlation coefficients (r). Differences with probabilities of less than 5% (P < .05) were considered statistically significant.

**RESULTS**

The reliability test produced mean values for timing accuracy that varied depending on the period of use (Table I). Appliances used during the daytime had an accuracy rate of 92.7% (±12.8). The nighttime accuracy rate was 88.1% (±8.4).

Patients reported an average of 13.6 hours of daily use but the electronic module readings detected 5.6 hours during T1 and 6.7 hours during T2 (Table II). The mean actual hours of daily wear relative to the provider’s requirement were 56.7% in T1 and 62.7% in T2 (Table II).

In this study, quality of wear focused patient efforts on uninterrupted use of headgear. No one made continuous use of the appliance (Table II). The average quality time was 1.8 hours per day in T1 and T2, demonstrating many short sessions of use. The charts showed that most wear sessions were up to 3 hours in duration.

In T1 of the study, 1 girl had a single wear episode of more than 18 hours. This also occurred with 1 boy and 2 girls during T2; these patients were excluded from the cooperation rate comparisons. A correlation coefficient was used to evaluate whether knowledge of the electronic supervision by the patient would improve the compliance rate. For this purpose, the same patients were evaluated in T1 and T2. The high correlation demonstrated a positive influence of the timing device over patient behavior. The exclusion of 4 patients improved the correlation coefficient (from r = 0.65 to r = 0.79; P < .0001). During T1, boys were more compliant than girls. During T2, the compliance rate of girls improved (Table III).

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<th>Table I. Reliability test</th>
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<th>Table II. Descriptive statistics for total sample</th>
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<td>Total hours - T2</td>
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<td>Hours/day - T1</td>
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*High SD - median use is recommended.
When age was considered, it was observed that younger patients were more compliant than older patients. The high correlation coefficient between T1 and T2 in the younger group (r = 0.90; P = .0051) demonstrated the same wear patterns, ie, knowledge of the electronic device did not influence behavior. The oldest group improved compliance more after learning of the electronic device (r = 0.76; P = .01) (Table IV).

**DISCUSSION**

The use of timing headgears helps researchers assess compliance more accurately. Studies with these devices have demonstrated that patients usually overestimate their headgear wearing time and are consistent in the amount of misrepresentation.25,31 In a study with timing headgears, Mitchell22 reported readings showing an average of 4 hours of wear per day from patients who had been asked for 18 or more hours per day. Swetlik’s study31 subjects indicated 11.5 hours per day, but their average actual wearing time was 9.3 hours. Clemmer and Hayes7 reported that patients actually wore headgear 7.4 hours per day, or 55.8% of the recommended hours. Cureton et al,25 in a study to determine the accuracy of clinical evaluation of head-gear compliance by 3 groups of investigators, observed that patients reported 11 hours a day, although their actual wear was 6.5 hours a day or 54% of the hours prescribed. In our study, the patients indicated an average of 13.6 hours of daily use, but the electronic readings detected 5.6 hours in T1 and 6.7 hours in T2.
The large difference between actual and patient-reported hours shows that patients tend to say that they wore the headgear very close to the number of hours requested when, in fact, they did not. The advantage of a method like this is that, in slow-moving cases, compliance rather than mechanics can be designated as the cause of the problem. In addition, obtaining this information early in treatment might favor other treatment alternatives. Otherwise, a noncompliant patient who thinks he or she is successful in deceiving the doctor is unlikely to increase headgear wear.

Headgear wear has been recommended for 14 hours each day. This amount of wear generally produces satisfactory tooth movement with all types of headgear. According to Graber and Swain, the duration of force is the critical factor for clinical success. However, clinicians are unaware of the effect of partial compliance on the rate of Class II correction. According to Ramsay et al, the lack of an objective measure of compliance makes it difficult to describe the dose-effect relationship between headgear wear and Class II correction. Hence, when headgear wear effects are evaluated, it is more important to know the frequency and duration of use than the level of force applied.

One advantage of the CSS is its capacity to register the duration of each wearing session. The low quality-time average of 1.8 hours indicated that none of the patients wore the headgear continuously. The interrupted wear pattern might compromise treatment results.

In this study, the mean actual hours of daily wear relative to the provider’s requirement were 56.7% and 62.7% in T1 and T2, respectively. Because most orthodontists report satisfaction with the tooth-movement results from their headgear patients, it is possible that the orthodontic and orthopedic goals can be met with fewer hours of wear than usually recommended.

Sound clinical decisions require the availability of microelectronic monitoring devices that can accurately assess both time and force applications during headgear wear.

The degree of spring compression over time indicates head movement. Data have supported the observation that the spring compression of the right and left sides is frequently related (eg, as one side compresses, the other relaxes). According to Johnson et al, cervical headgear has a wider range of force, depending on head posture. In this study, as expected, data collected while the subject was awake had greater reliability than data collected during sleep.

The commercially available headgear timer made by Ortho Kinetics is not perfect. However, to create a long-term record of falsified wear data, a patient would need to adhere to a pattern of deceptive behavior over a long period (ie, remember to compress the spring before bed and allow the spring to relax on awakening).

A compliance change was expected after the timing mechanisms were introduced to the patients. Güray and Orhan, in a similar study with the Selçuk-type headgear timer, observed a compliance rate of 64% during the first stage (10 hours of wear of the 16 hours advised). At the second stage, compliance increased to 89% (14 hours). Northcutt claimed that his patients’ compliance increased from 35 to 50 hours per week to over 100 hours a week when they used headgear timers. In our investigation, the cooperation rate increased from 56.7% to 62.7%. The high correlation between before and after knowledge of the device demonstrates its positive influence on patient behavior.

A recent approach to the enhancement of compliance is based on the concept of self-regulation, a control process in which patients use a feedback mechanism (eg, microelectronic monitoring device) to learn to regulate their own behavior. One advantage of this method is that the adolescent’s responsibility for performing the activity is reinforced.

Some previous studies support the view that younger patients are more compliant with orthodontic treatment. Allan and Hodgson concluded that the best cooperators were 14 or younger. The results of this study demonstrated that younger patients were more cooperative than older ones, and they remained cooperative throughout the study. Older patients, however, increased their cooperation rate after learning of the electronic device. Several authors have suggested that girls are more compliant than boys in headgear wear. In our study, boys were more compliant than girls in T1, although the girls’ compliance rate improved during T2.

**CONCLUSIONS**

The use of a timing device was helpful in determining patient compliance. Patients generally overestimate or overreport their headgear wearing times. The mean actual hours of daily wear relative to the providers’ requirement was 56.7%. The knowledge that the wearing time was being monitored increased the cooperation rate to 62.7%. The evaluation of the continuity of wear showed many short sessions. The use of a monitoring system such as this can provide feedback to the patient, facilitate parental involvement, and serve as a motivator.
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REFERENCES