



Evaluation of a Novel Device for Measuring Patient Compliance with Oral Appliances in the Treatment of Obstructive Sleep Apnea

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Keywords

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Abstract

Purpose: The purpose of this study was to evaluate a novel intraoral monitor for measuring patient compliance of oral appliances for the treatment of obstructive sleep apnea.

Materials and Methods: A clinical trial was conducted to compare objective recording by an intraoral compliance monitor and self-reporting by participants using a mandibular repositioning device (MRD). Ten participants were fitted with a Thornton Adjustable Positioner (TAP III) with an embedded compliance monitor. The participants were asked to wear the test appliance for seven nights and to record their usage of the appliance and any adverse effects in a treatment journal. The data were downloaded to a dedicated computer using radio-frequency identification (RFID) technology, and the information was compared to the data in the participant's journal.

Results: The mean objective wearing time, as detected by the compliance monitor, was found to be 6.6 ± 1.6 hours/night. The mean subjective wearing time, as recorded by the participants, was 6.5 ± 1.5 hours/night. The correlation between subjective and objective times was 0.9985. The use of the test appliance by this sample population was 68.7% with a range of 24% to 100%. Participants reported a range of adverse outcomes related to the MRD consistent with those reported in the literature and were found to be transient in nature.

Conclusions: This study supports previously reported usage times and adverse outcomes. The compliance monitor showed a very high linear correlation between subjective and objective data, validating its use in future compliance studies.

Obstructive sleep apnea (OSA) is a common disorder caused by an obstruction of the pharyngeal airway during sleep. Various treatment modalities are available for the management of OSA. The decision for surgical or nonsurgical therapy is determined by the etiology of the pharyngeal obstruction, severity of symptoms, and magnitude of clinical complications. In patients with mild to moderate OSA, oral appliances are more likely to maintain an apnea/hypopnea index (AHI) of ≤ 5 after 1 year when compared to uvulopalatopharyngoplasty (UPPP).¹ Oral appliances, such as mandibular repositioning devices (MRD), have been found to be less effective at improving oxygen saturation and reducing AHI when compared to continuous positive airway pressure (CPAP) therapy.²⁻⁴ Oral appliance therapy is less likely to be successful in patients with severe OSA (AHI > 30)³ and for those with a higher body mass index (BMI).^{5,6} Studies evaluating CPAP and oral appliance effectiveness in improv-

ing daytime sleepiness, as defined by the Epworth Sleepiness Scale, have demonstrated comparable results in patients with mild to moderate OSA.⁷ Patient preference for oral appliances as an alternative to CPAP is well documented.⁸ The indications for oral appliance therapy for patients with mild to moderate OSA include patient preference of oral appliances to CPAP, a history of failed CPAP therapy, candidates not appropriate for CPAP, and CPAP nonresponders.^{2,4,9}

Treatment efficacy requires that a patient receiving an oral appliance will faithfully use it according to the practitioner's instructions. As with other chronic diseases, patient compliance with prescribed treatment can be problematic. Many investigators have studied patient compliance based on self-reporting. Studies evaluating weekly use report an average of 68% of patients use the device every night, 23% several nights a week, and 8% less than several nights per week.³ Research evaluating

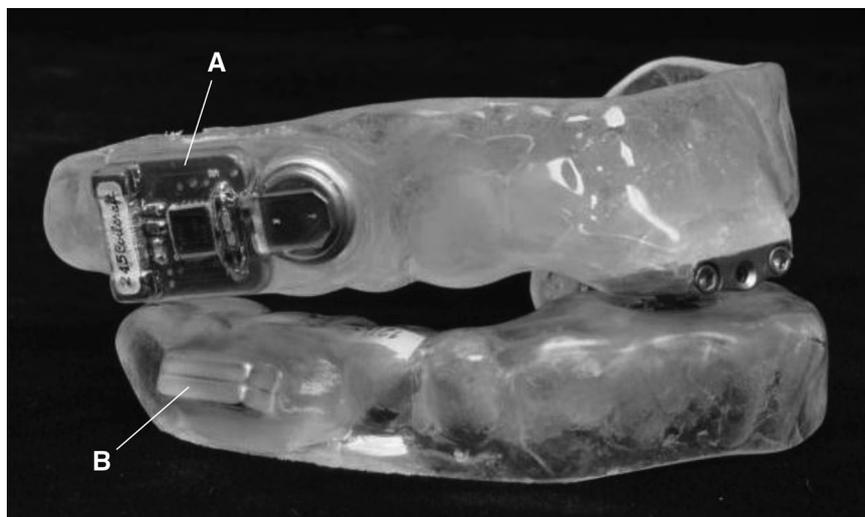


Figure 1 MRD with the compliance monitor (A) and magnet (B).

patient compliance over a period of less than 1 year found a median use of 77% of nights.³ Adherence rates have been shown to decline over time with one study reporting 48% adherence at 2 years,¹⁰ and another study reporting an adherence of 32% at 4 years.⁵ It has been suggested that long-term compliance with oral appliances is comparable to that of CPAP.¹¹

Studies comparing subjective reporting of CPAP compliance with objective data reveal that patients generally overestimate their CPAP usage and may in fact be poorly compliant with their self-reporting.^{12,13} Subjective reporting, therefore, is not the most ideal method of evaluating patient compliance. To date, three studies have attempted to objectively evaluate patient compliance with oral appliance therapy. Lowe et al¹⁴ used a monitor imbedded into the MRDs of 12 patients over a 2-week period. The investigators found a mean compliance of 6.8 hours/night with a range of 5.6 to 7.5 hours/night. Inoko et al¹⁵ evaluated data gathered from a covert monitor from 6 patients over the course of 1 month and reported objective compliance rates ranging from 20% to 100%. Finally, Vanderveken et al¹⁶ found objective usage of a covert monitor from 43 patients to be 6.7 ± 1.3 hours/night over a 3-month period.

These studies relied on monitors that regularly and continuously sampled ambient temperature as the means of measuring patient compliance. A fundamental tradeoff exists between accurately reconstructing temperature data and performance metrics such as memory life and power consumption. A high polling rate improves a sensor's ability to detect rate dependent information, which improves accuracy and precision of measurements as well as filtering against noise. High polling rates also require more memory to store sampled data, and the microprocessor draws more power due to the frequency of activity. This study evaluated the concept of using a companion sensor in conjunction with a temperature sensor, to improve monitor efficiency and effectiveness when measuring patient compliance with MRDs. The purpose of this study was to compare subjectively reported usage of an MRD with objective recordings obtained by a novel intraoral compliance monitor.

Materials and methods

The monitor

The compliance monitor consists of five components: a microprocessor (with built-in thermocouple), a nonvolatile flash memory, a battery, a crystal oscillator (for timekeeping), and a magnetic reed relay (companion sensor). The final dimensions of the monitor were $13 \times 25 \times 5$ mm³ (Fig 1).

The monitor was encased within a pressure-vacuum-formed sheet of 0.75 mm thermo-formable polyethylene terephthalate glycol (Splint Biocryl; Great Lakes Orthodontics, Tonawanda, NY) and attached to the maxillary, buccal portion of the MRD with poly(methyl methacrylate) (Orthodontic Resin; Great Lakes Orthodontics) (Fig 1A). The same process was used to attach a rare-earth magnet to the mandibular portion of the MRD (Fig 1B). The monitor functions in two modes: idle and active (Fig 2). The idle state is the time when the monitor's ambient temperature is relatively stable, i.e., the monitor is either in or out of the mouth. The time-constant and bandwidth of the system at this time are very long, on the order of many hours. During this state, the microprocessor has been programmed, via RFID, to sample ambient temperature at the slowest rate allowed by the monitor, in this case once every 18 hours. The active state is the time when the device is being inserted or removed from the mouth. During this time, temperature (as detected by the temperature sensor) is changing by a time-constant τ .¹⁷ In the active mode, the bandwidth of the system must be known to sample the temperature at a rate that will avoid distortion of the reconstructed frequency. This distortion is known as aliasing.¹⁸

The magnetic reed relay functions as the companion sensor to change the mode of operation of the monitor at the appropriate time. When the MRD is connected in the proper orientation and proximity, the magnet's field engages the monitor's reed relay (Fig 3). This event triggers the microprocessor to the active mode, increasing the temperature polling rate. After a fixed period of time, the device transitions back into idle mode

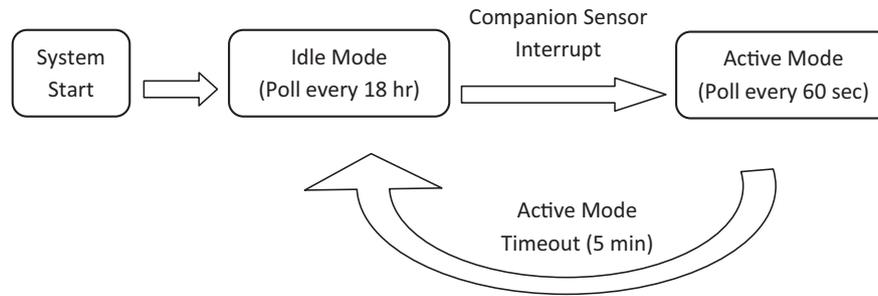


Figure 2 Diagram of monitor program.

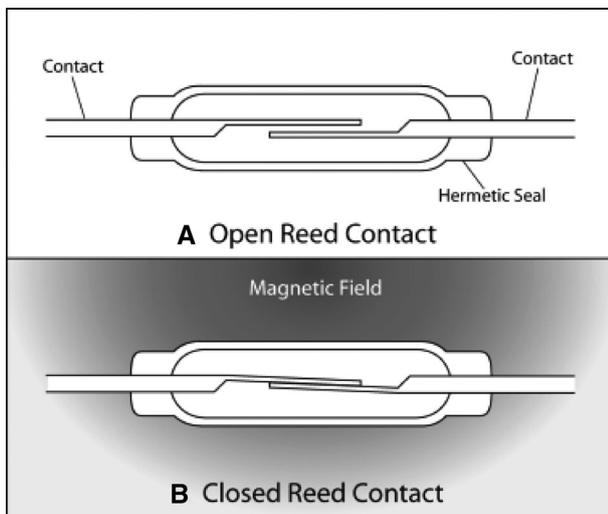


Figure 3 Diagram of the magnetic reed relay. The presence of a magnetic field induces the leads to come into contact, signaling increase in temperature sampling rate.

where temperature sampling is performed at a slow rate. When the two members are separated, the absence of the magnetic field again triggers a change to the active mode, increasing the polling rate. Following the period of high polling, the monitor returns to the low sampling rate. The data are stored on the flash memory, and a full history of appliance use is recorded.

Participants

This study was approved by the University of Texas Health Science Center at San Antonio (UTHSCSA) Institutional Review Board (#HSC20120069H). Ten participants (8 men, 2 women) between the ages of 27 and 65 were recruited from within the Advanced Education in Prosthodontics Program at UTHSCSA. Two of the participants had been previously diagnosed with mild/moderate sleep apnea and were experienced MRD users. The remaining eight participants had not received polysomnogram evaluations prior to inclusion in the study, and were using an MRD for the first time. The aim of this study was to evaluate the compliance monitor; therefore, a reduction in sleep apnea measures, such as AHI, was not determined. Participants were informed of risks associated with

MRD use, and informed consent was obtained. The inclusion criteria applied during selection of the participants were: age > 18 years. The exclusion criteria included inadequate tooth support to retain a TAP III (Thornton Adjustable Positioner) appliance.

Laboratory procedures

Maxillary and mandibular impressions of each participant were made with irreversible hydrocolloid (Jeltrate Plus; Dentsply, York, PA), and poured in Type III dental stone (Microstone; WhipMix, Louisville, KY). Interocclusal records were made with poly(vinyl siloxane) (PVS) impression material (Regisil PB; Dentsply) at 60% of maximum protrusion using a George gauge (Great Lakes Orthodontics).

Stone casts and interocclusal records were sent to AirWay Labs (Carrollton, TX) for fabrication of 10 TAP III oral appliances. Compliance monitors were developed and fabricated by an independent developer (San Jose, CA). The completed oral appliances and compliance monitors were sent to the Graduate Prosthodontic laboratory at the University of Texas Health Science Center at San Antonio for imbedding the compliance monitor and magnet into the MRD.

Clinical procedures

During the delivery appointment, the treatment appliances were fitted and the participants received usage and homecare instructions. The appliances were initially set at the protrusive position corresponding to that of the interocclusal record. Participants were instructed to wear the MRD for seven nights and to increase the amount of mandibular protrusion by adjusting the screw 0.25 mm per night as far as comfort permitted. A treatment journal was given to each participant to record the time of insertion and the time of removal of the oral appliance, as well as any side effects experienced. After having worn the test appliance for seven nights, the participants returned the treatment appliance and the treatment journal. The treatment appliances were de-identified, and the information was downloaded onto a dedicated computer using radio-frequency identification (RFID) technology.

Determination of bandwidth in active mode

The bandwidth in the active mode was determined experimentally. A monitor was programmed to sample temperature once

per second. One participant was asked to insert the test MRD intraorally for 10 minutes, and then to remove the appliance and wait 10 minutes before reinserting the appliance. This was repeated three consecutive times. The recorded temperature consistently showed an exponentially rising function fitting to the solution of an ordinary differential system:

$$T_{\text{meas}} = T_{\text{max}} - T_{\text{amp}}e^{-t/\tau}$$

where T_{meas} is the best fit to an ordinary differential equation, T_{max} is the maximum temperature value, T_{amp} is the difference between the maximum and minimum temperature value (amplitude), e is the exponential functional constant, t is the independent variable (time), and τ is the time constant.

The time constant, τ , was extrapolated from the data to be approximately 50 seconds. In the frequency domain, this translated to a bandwidth of 0.003 Hz. Therefore, following Nyquist criterion (sampling at least twice the bandwidth of the original signal), the minimal sampling in the active mode to avoid aliasing in the reconstruction of temperature is 0.006 Hz or 166 seconds.¹⁸ To ensure accurate temperature reconstruction in the active mode, the monitor was programmed to sample every 60 seconds for 5 minutes, before returning to the idle mode.

Data analysis

The subjective reporting of compliance by the participants in this study served as the control to compare the results of the objective data recorded by the compliance monitor. A Pearson correlation coefficient was employed to evaluate the relationship between objective and subjective elapsed times. Means and standard deviations of objective and subjective elapsed times were determined along with the percent nightly usage of the test appliance by each participant over the period of time in which he/she was in possession of the appliance. Finally, the percentage of participants reporting various adverse effects while wearing the MRD was examined.

Results

By using appropriate sampling rates at transition periods (insertion/removal), usage time can be determined without the need for calibrating monitors for absolute temperature accuracy. Mathematica Software (Wolfram Research, Champaign, IL) was used to filter the temperature data based on slopes and time constant to extract the objective insertion and removal times (Fig 4A). Filtering the data in this manner is more robust against false positives than filtering by a temperature threshold (Fig 4B). Objective usage times by each participant were compared to the times indicated in their treatment journals (Fig 4C). The correlation between subjective times as recorded by the participants and objective times as recorded by the monitor was 0.9985 (Fig 5). The mean objective wearing time, as detected by the compliance monitor, was 6.6 ± 1.6 hours/night. The mean subjective wearing time, as recorded by the participants, was 6.5 ± 1.5 hours/night (Fig 6). The mean usage of the MRD by participants in this study was 68.7%, with a range of 24% to 100% (Fig 7). Table 1 shows the percentage of participants reporting adverse effects while wearing the MRD.

Discussion

Modern processors operate at the lowest power by remaining in a deep sleep mode as long as possible. Awakening a processor to take a data point draws a fixed amount of charge from its power source. In the case of an intraoral monitor, the power source is a battery, which can only carry a certain amount of charge. The goal is to maximize the amount of time a dental sensor processor spends in idle. Furthermore, an intraoral monitor's ability to effectively function is dependent on the amount of data storage available. By limiting the number of data points recorded, the effective memory life of the monitor can be lengthened.

Conversely, high sampling rates allow for detection of time constants, derivatives, time delays, phasing, and other rate information, which is much more robust against noise and error than amplitude alone.¹⁷ The increase in activity of the microprocessor and analog-to-digital converter (ADC) results in an increased power draw from the battery. To support a higher sampling rate, a larger battery would be required, or the investigation duration must be shortened. Increasing battery size results in a larger form-factor, making the device more challenging for intraoral use. The cost of the device is also increased to account for the extra hardware required to accommodate the increased sampling rate.

A novel monitor has been developed to resolve the tradeoff between conservation of memory and battery life and the capture of fast-moving signaling. A magnetic reed relay operates as a companion sensor, which is passively activated to modulate the temperature sampling period to a bandwidth-appropriate rate. The data are then committed to nonvolatile memory and recovered using RFID. The processor can therefore idle for a maximum amount of time and still reconstruct rate-dependent information.

The goal of a sampling system is to convert a continuous time signal into discrete sampled signals such that the continuous time signal can be fully reconstructed through its samples.¹⁸ In this study, we seek to sample and reconstruct temperature data so that a history of the monitors' intraoral use can be evaluated. Alone, a sample set cannot fully reconstruct continuous temperature input because of the unknown signal values between samples. By setting bandwidth constraints on the input signal, that is, by limiting the input signal's rate of change between samples and by setting appropriate sampling rate, accurate reconstruction can be approached. In other words, the rate of temperature change of the temperature sensor must be known to determine the sampling rate, thereby enabling reconstruction of the original temperature signal.

A temperature step function was forced upon the temperature sensor by having a patient insert and remove a test appliance at specific intervals (10-minute). The experiment revealed the time-constant τ for the monitor to be about 50 seconds. This translates to a bandwidth of 0.003 Hz in the frequency domain. The results of the experiment demonstrate that the bandwidth-limiting function is the temperature sensor, and that the system is a linear time-invariant with a single dominant pole.¹⁸ Nyquist's criteria states that minimum sampling rate to avoid aliasing of the reconstructed signal is twice the bandwidth.¹⁸ Sampling below the Nyquist rate would distort the reconstructed signal frequency from the actual signal

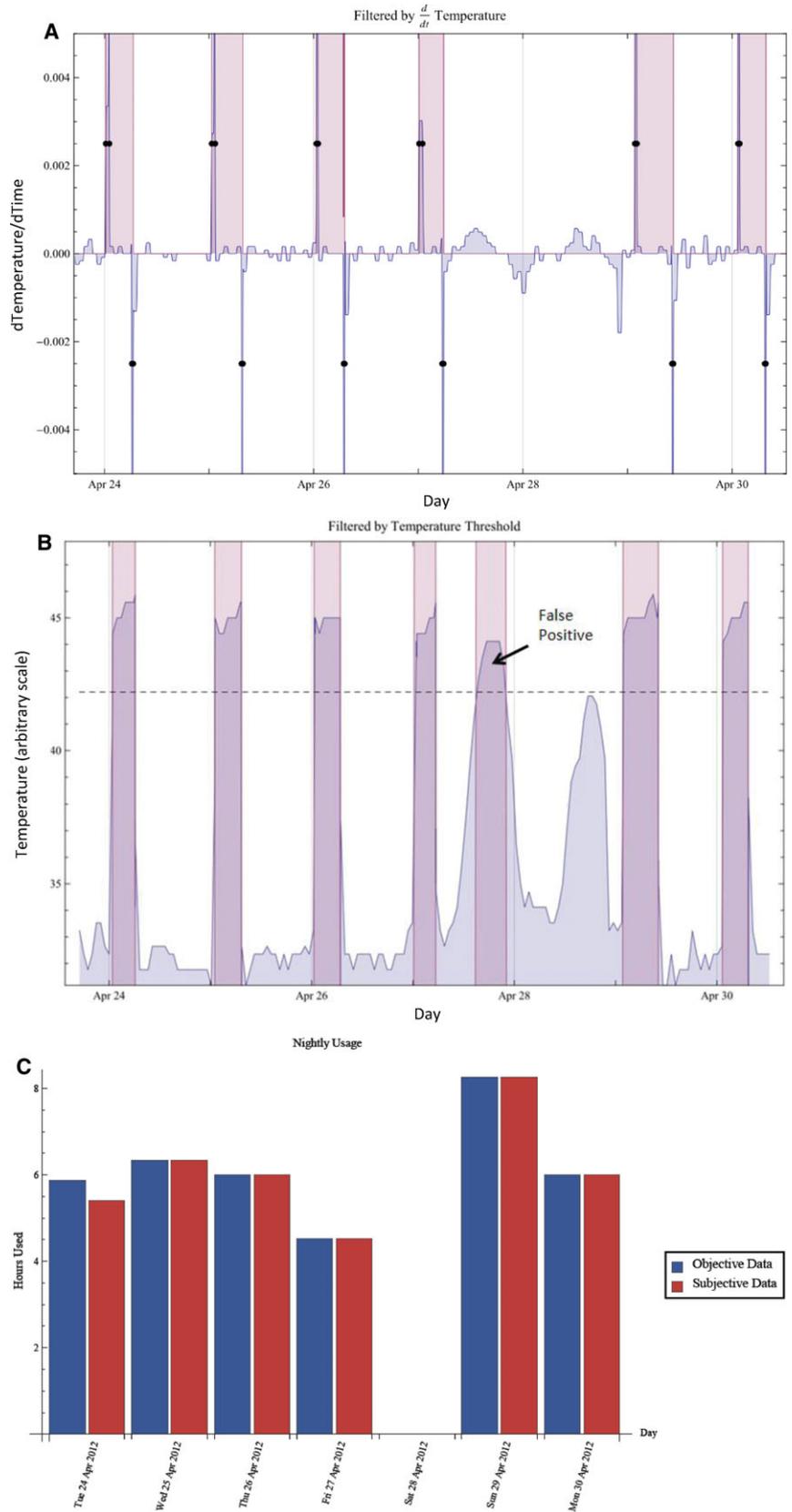


Figure 4 Sample data from a participant. A. Filtering data based on slopes and time constant. Areas in pink represent usage time. B. Filtering data using a threshold value. Areas in pink represent usage time. A false positive is noted for April 28. C. Results of objective and subjective data. Note that the MRD was not used on April 28.

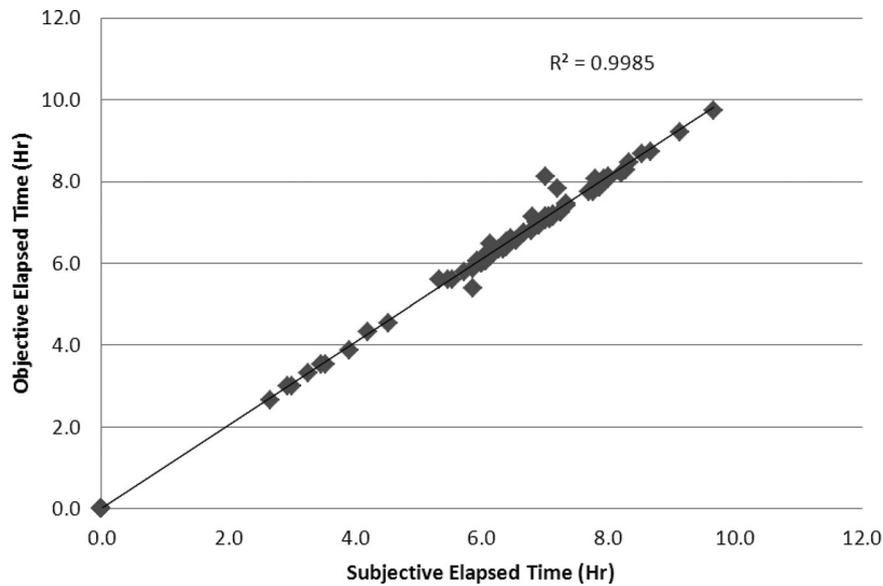


Figure 5 Correlation between subjective and objective elapsed times.

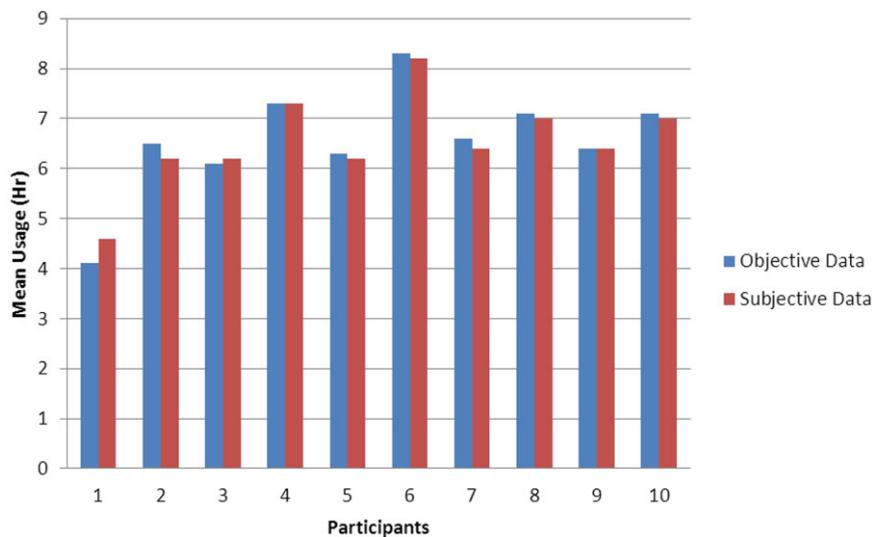


Figure 6 A comparison of objective and subjective mean usage by each participant.

frequency (aliasing), resulting in a change that is unrecoverable by downstream filtering techniques. Since the bandwidth of the system is 0.003 Hz, the sampling system must operate at a minimum sampling rate of 0.006 Hz (166 seconds). A sample rate of 60 seconds for 5 minutes was selected to ensure that aliasing of the temperature data during insertion and removal of the test appliance would be avoided.

Although the patients were asked to wear the appliances for a total of seven nights, they were given no restriction on the amount of time they could take to complete the trial. In Figure 4C, the data from the monitor demonstrate that the patient did not wear the test appliance on the fifth night, which was confirmed by the patient’s subjective reporting. This provides a

method for identifying the percentage of time the patients used the MRD over the time period in which they were in possession of the appliance. The patients’ use of the MRDs ranged from 7/7 consecutive nights (100% usage) to 7/29 nights (24% usage). The mean usage by patients in this study was 68.7%. Although the study was not intended to be an evaluation of compliance, it demonstrated the monitor’s capability of identifying and quantifying nightly usage of an MRD. Over a longer investigation period, use could be evaluated on a weekly and monthly basis.

The mean objective wearing time, as detected by the compliance monitor, was found to be 6.6 ± 1.6 hours/night. The mean subjective wearing time, as recorded by the patients, was

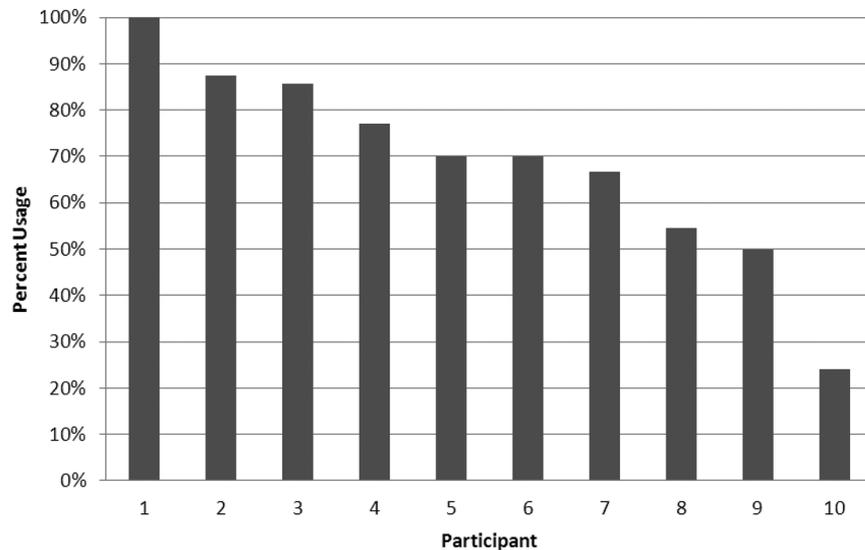


Figure 7 Percent nightly usage of the test appliance by each participant over the period of time in which they were in possession of the appliance.

Table 1 The percentage of participants reporting adverse effects while wearing the MRD

Adverse effects	% of participants
Transient, altered occlusion upon removal	21%
TMJ pain	21%
Disengagement of device	21%
Dry mouth	16%
Tooth pain	11%
Headache	5%
Excess salivation	5%

6.5 ± 1.5 hours/night. The usage time of MRDs by patients in this study corroborates similar times reported by Lowe et al¹⁴ and Vanderveken et al.¹⁵ The high correlation ($r^2 = 0.9985$) between subjective and objective data validates this monitor's use as a means of measuring patient compliance in future studies and applications.

Since poor compliance with MRD therapy is generally related to side effects,^{10,19} the participants were requested to indicate in their treatment journal any adverse effects they experienced over the course of the study. Adverse effects reported by the patients included transient altered interocclusal relationship upon removal, TMJ pain, unintentional disengagement of the maxillary and mandibular members of the MRD, dry mouth, tooth pain, headaches, and excess salivation. With the exception of separation of the appliance during sleep, these side effects and their frequency are consistent with those reported in the literature.^{20,21} The maxillary and mandibular members of the TAP III are allowed to engage and disengage through the use of a hook attached to the maxillary member. It is possible that disengagement of the MRD members was due to inadequate protrusion of the mandible, allowing the patient's mandible to inadvertently unhook from the maxilla during sleep. Initial interocclusal records for this study were made at 60% of maximum

protrusion. It is also possible that given the relatively short evaluation period, participants did not have sufficient time to optimally adjust the protrusion of the MRD. Studies have described a reduction in AHI with appliances set at 50% to 75% of maximum protrusion.⁶ Some studies have shown a relationship with increased side effects, such as occlusal changes, and an increase in protrusion.^{22,23}

Reported side effects were considered minor and temporary by the participants, and did not prevent use of the appliance. One patient experienced increasing TMJ pain over the course of the first three nights. The position of the hook was retruded, decreasing the amount of mandibular protrusion, after which the patient no longer experienced TMJ discomfort. It should be noted that the adverse effects reported by the patients only pertained to the effects of the MRD, and not to the presence of the compliance monitor. This suggests that the volume of space taken up by the monitor and magnet did not seem to be objectionable to the patients.

A limitation of this study was the use of subjective reporting by the participants as the control to evaluate the validity of the monitor. As no gold standard currently exists for objectively recording compliance, this method represented the most practical means of evaluating the device. Patients received a thorough explanation of the purpose of the study, and were instructed to subjectively record MRD usage as accurately as possible. Given the inherent weakness of subjective recording, the high correlation between the subjective and objective data demonstrated little variability between the two methodologies. Other limitations of this study were the small sample size and short evaluation period. Future studies with larger sample sizes and longer evaluation periods will be necessary to further validate the use of the device for objective monitoring of MRDs.

Compliance monitors have served to validate subjective reporting of compliance in a limited number of studies.^{14,15} Widespread use of compliance monitors is needed to evaluate

the effectiveness of oral appliances relative to other treatment options as well as to adverse effects. Efficiency of the monitor in terms of power consumption, memory life, and form factor will become increasingly important as long-term compliance studies are pursued.

Conclusion

Objective recording by a novel compliance monitor was found to strongly correlate with self-reporting by patients using an MRD. The mean elapsed time during which patients wore the MRDs in this study corroborates the times described by other investigators. Adverse effects reported by the participants were transient in nature and were found to pertain to the MRD and not to the presence of the compliance monitor. This study offers the first validation for the use of the monitor in future evaluations of objective compliance of patients wearing MRD for the treatment of OSA.

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