ORAL APPLIANCE COMPLIANCE MEASUREMENT

By Richard A. Bonato, PhD, MA, RST, RPSGT

A previous article published in *A2Zzz*[1] discussed fundamental features and issues concerning successful oral appliance therapy (OAT) for the treatment of snoring and obstructive sleep apnea (OSA). Conspicuously absent from that discussion, but central to successful OSA therapy, is the concept of therapeutic compliance measurement. For OAT, compliance is the extent to which a person follows professional advice and wears the oral appliance the prescribed number of hours when sleeping. The terms adherence, cooperation, concordance or wearing time may also be used. Continuous Positive Airway therapy (CPAP) routinely measures compliance (wearing time) and is now a typical requirement for ongoing CPAP insurance reimbursement. However, the vast majority of OAT published research has relied on questionnaire data to establish subjective compliance levels. Indeed, the AASM OAT Practice Parameters paper[2] clearly states the need for objective OAT compliance measurement.

Objective compliance (wearing time) measurement has long been a desired feature in the fields of functional orthodontics and dental sleep medicine. Research has generally found that adherence increases substantially when patients are aware they are being monitored.[3,4] Lowe at al.[5] conducted a study on the use of an intra-oral compliance device for the treatment of sleep apnea. Their device periodically sampled temperature to infer wearing time when the ambient room temperature moved towards human body temperature. Subjects wore the oral appliance containing the internal compliance device for about two weeks and the device was found to be clinically useful. Unfortunately, commercial viability issues were encountered and the technology never entered routine clinical practice.

More recently, Vanderveken et al.[6] published research involving 43 patients who underwent OAT for three months while simultaneously wearing an intra-oral compliance device. No statistically significant difference was found between subjective and objective wearing time and overall daily use was 6.6 hours (± 1.3 hours). Unfortunately, the technology employed in this study only measured temperature. An earlier study by Schott and Göz[7] using the same oral appliance compliance technology reported that temperature-only based oral appliance compliance technology is susceptible to water bath deception. According to these authors[7] immersion in "thermostatic water, bath simulated wear and non-wear times of orthodontic appliances with remarkable accuracy because the sensors' wear-time measurements are based on temperature." An inexpensive aquarium water heater cannot be used to replicate this finding because such heaters frequently oscillate temperature and it is much easier to identify attempts at deception. In contrast, the more sophisticated thermostatic water bath heater is designed specifically for precise laboratory water heating and is the preferred method for replication. Therefore, no technology has been published in a peer-reviewed journal which has been demonstrated to accurately, reliably, and objectively determine OAT compliance while being simultaneously impervious to simple water bath immersion deception. The solution to this technical and clinical challenge was found in a technique common to polysomnography (PSG).

Polysomnography is a unique field involving the simultaneous electrographic recording of various physiological parameters. The term is a hybrid combination of Latin and Greek and translates as multiple parameter picture of sleep. The advantage of this multiple approach is the ability to more accurately measure the phenomenon of interest because many relevant signals are being measured at the same time. With this perspective, a decision was made to approach oral appliance compliance measurement from a multiple parameter micro-recorder perspective. Interestingly, features required for superior oral appliance compliance measurement overlap with certain PSG amplifier characteristics and virtually all home sleep apnea recorder requirements: low power consumption, small physical size, small patient data files, and sampling rates sufficient to accurately capture desired signals. Essential oral appliance micro-recorder design features include battery longevity, small footprint, memory optimization, anti-deception algorithms, and an adequate sampling rate. The result is the DentiTrac® oral appliance compliance micro-recorder.

Continued on Page 16

Continued from Page 15

Figure 1
From top to bottom: A DentiTrac® micro-recorder embedded within a SomnoMed G2, a SUAD Ultra-Elite (SUE), The Moses appliance side view followed by rear view (SomnoMed G2, SUAD/SUE, and The Moses appliances are trademarks of their respective owners).

Figure 2
Compliance data from a SomnoDent® oral appliance uploaded through the DentiTrac base station to the cloud portal.

The patent pending DentiTrac® micro-recorder may be embedded into virtually any oral appliance for the objective measurement of patient treatment adherence (see Figure 1). The DentiTrac® is sealed within biocompatible epoxy and is further sealed within the acrylic of the custom-made oral appliance. The preferred location of placement is the left or right buccal sulcus, though some micro-recorders have been placed in functional orthodontic appliances slightly lateral to the midline of the hard palate. Some individuals will refer to an oral appliance compliance recorder as a chip or sensor; however, this term is a poor technical descriptor and is a disservice to the technological sophistication of such a device. From a technological perspective, a device such as the DentiTrac® is actually a micro-recorder or datalogger. It is not a microsensor because sensors only transmit information downstream for amplification and permanent storage or recording, such as sleep sensors used nightly during PSG recordings. Analogous to unattended home sleep apnea recorders, the DentiTrac® has an internal battery, internal sensors, internal memory storage, and a method to retrieve information from the datalogger. A clinical base station is used to upload the data from the oral appliance to the web portal for permanent storage (see Figure 2). The data is usually uploaded in two minutes or less. This permits busy patients to remotely and conveniently upload the compliance data from anywhere in the world and is particularly relevant to forthcoming Department of Transportation legislation. Moreover, the web portal facilitates vastly improved exchange of information between sleep centers and dental sleep practitioners. A patient base station is available for home use which only reads data from the recorder and does not allow the patient to configure micro-recorder settings. For sleep appliances, the DentiTrac® has internal memory capable of storing up to six months of data which would require a patient to see a dentist at least twice a year (i.e., routine clinical practice or more frequently if desired). The internal battery will last about two years. The micro-recorder uses extensive anti-deception algorithms based on collecting much more data than mere temperature and our research has found that DentiTrac® is not susceptible to the aforementioned thermostatic water bath deception. Our internal research has found no statistically significant difference between subjective and objective compliance measurement when using paired t-test calculations. Figure 3 shows 200 nights of

consecutive compliance data. Periods showing zero wearing time are correctly recorded. A detailed compliance graph is a standard feature which provides precise daily wearing time duration, percentage supine and non-supine head position, and time above or below prescription wearing time (see Figure 4). Naps wearing the appliance are correctly shown as separate blocks on the left. Figure 5 is the compliance data of an individual who has repeatedly demonstrated 100 percent adherence.

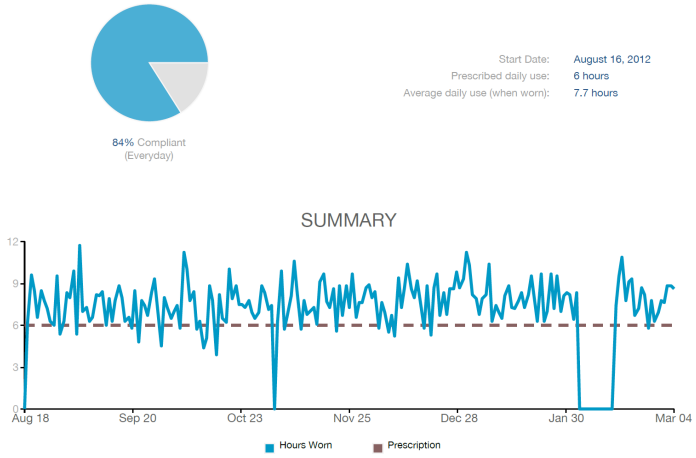

Figure 3

Consecutive compliance data for 200 nights of OAT for the treatment of snoring and sleep apnea using a SUAD Ultra Elite (SUE). The dashed line represents prescription wearing time (i.e., six hours) established by the clinician on the web portal. Periods showing zero wearing time are correctly recorded. Time above the dashed line indicates treatment adherence. Time below the dashed line shows noncompliance. Overall everyday treatment compliance is 84 percent.

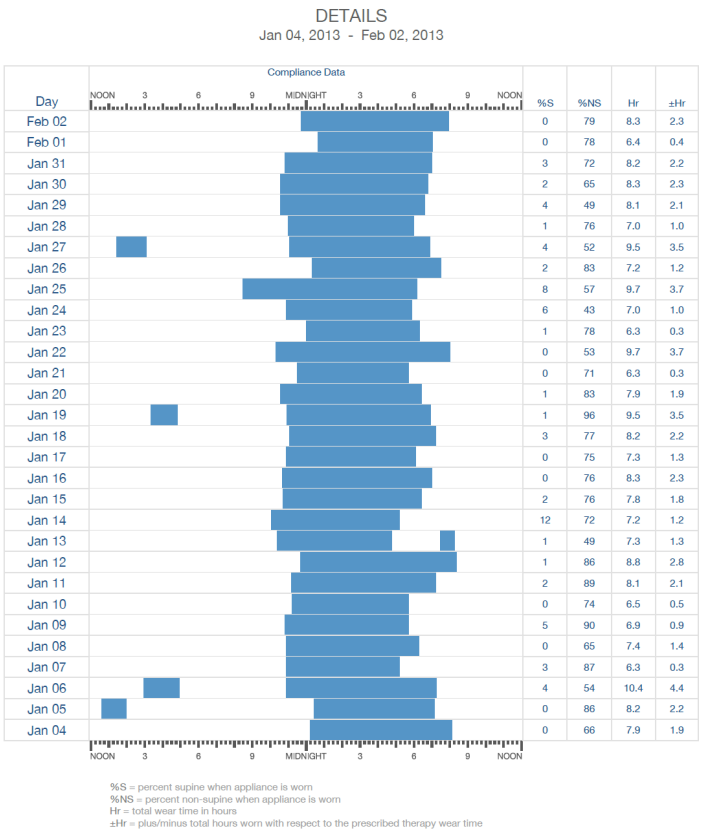

Figure 4

Detailed compliance information for 30 days of 200 day recording period. From left to right: date, bar graph indicating wearing time from noon to noon, percentage of supine head position, percentage of nonsupine head position, hours of use per 24-hour period, hours above or below (positive or negative) prescribed wearing time.

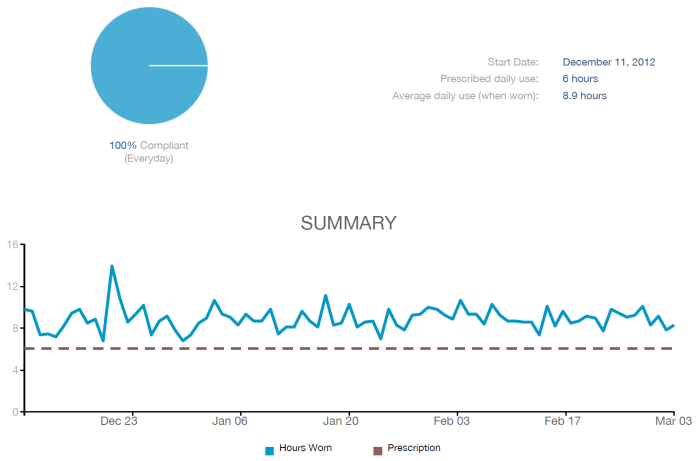

Figure 5

Eighty-three days of patient compliance data wearing a SomnoDent® oral appliance. The patient averages 8.9 hours of daily use resulting in 100 percent compliance, which is defined as time above the prescription usage of six hours daily.

Kushida et al.[2] call for the "development of similar [CPAP adherence] capabilities for OAT [which] should be pursued for both research and clinical purposes." One of the challenges in addressing this recommendation is that OAT adherence (compliance) may be defined in a variety of ways. For example, one could use various CPAP definitions. Historically adherence to CPAP has been defined, as ≥ four hours of nightly use at least five nights per week. More recently, CPAP compliance is frequently defined as the percentage of days worn ≥ four hours daily, > 70 percent of the time, in a 30-day period during the initial 90-day trial. Alternatively, OAT compliance may be defined in a very straightforward manner as the number of days exceeding the prescribed wearing time. However, this definition omits the concept of intent. In Figure 3 above, the patient intentionally did not wear the appliance for the zero days indicated to the right of January 30, but rather, the patient opted to wear a temporary appliance while traveling. To address these various definitions, all of which may be considered legitimate at some level or another, all four definitions are offered to the clinician thus permitting direct OAT compliance comparison *vis a vis* the established CPAP treatment paradigm. It is anticipated that insurance payers will require utilization information consistent with existing CPAP compliance data.

In summary, adherence technology which addresses a crucial need identified by the AASM now exists. This technology permits micro-recorders to be safely embedded within oral appliances for long-term use. Compliance information regularly available to CPAP providers will soon be available to those practicing OAT and to those combining the two therapies. The

Continued on Page 18

Continued from Page 17

DentiTrac® oral appliance compliance system will be introduced into the Canadian marketplace in the spring of 2013 and is pending US FDA clearance. It continues to undergo further long-term validation by leading dental schools and dental practitioners.

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Richard A. Bonato, PhD, MA, RST, RPSGT has been involved in the study of sleep and its disorders since 1986 and has been an author, co-author, reviewer, sessional lecturer and examiner in various educational organizations within the sleep field, including the AAST. He is the CEO and Co-Founder of BRAEBON® Medical Corporation.