

## Introducing a Novel Micro-recorder for the Detection of Oral Appliance Compliance: DentiTrac®

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Adherence data for oral appliances (OA) typically rely on subjective reports with few studies reporting objective compliance data measurement. In contrast, CPAP compliance is routinely reported and is now required by insurance payers for continued CPAP funding. The need for objective OA compliance measurement is widely recognized. In the AASM OA practice parameters paper published in 2006<sup>1</sup>, Kushida et al. call for the development of objective OA measurement technology. Indeed, several attempts have been made to objectively measure OA adherence.

In 1974, Northcutt described an extra-oral orthodontic headgear with a timing gear mechanism to objectively measure wearing time.<sup>2</sup> This device had internal power, memory, and the ability to communicate the data to a reading station. When patients were informed they were being monitored, wearing time increased from about 45 hours weekly to 100 hours weekly. Another extra-oral orthodontic headgear was introduced and commercialized about 25 years later by Orthokinetics Corporation and called the Compliance Science System. This device also used internal power, internal memory and a reading station; however, additional PC software was included. In a study of 46 patients originally blind to the existence of the compliance monitor, Doruk et al. reported a statistically significant increase in usage time in the second four-month follow-up compared to the two-month baseline period.<sup>3</sup> Thus, patients' knowledge of OA compliance measurement is sufficient to significantly increase OA wearing time in patients. Despite these early remarkable attempts to obtain objective OA adherence data, issues were encountered. First, orthodontics was generally headed in a direction away from extra-oral headgear towards removable

intra-oral appliances making widespread application limited. Second, creative children discovered that placing the headgear on teddy bears or dolls could deceive the compliance monitor.

Also during the late 1990s, Lowe et al.<sup>4</sup> developed and reported the use of an intra-oral compliance device which used internal power and periodic sampling of temperature. A change in temperature from ambient room temperature towards human body temperature inferred wearing time of the OA. Intra-oral OA temperature monitoring was performed for two weeks in eight apnea patients and objective compliance data was recorded and reported. However, the technology suffered from limitations and was not introduced on a commercial basis.

A recent study by Vanderveken et al.<sup>5</sup> reported the successful recording of OA wearing time in 43 patients with a subject data attrition of just less than 16%. The technology employed in this study used a device embedded within an oral appliance which measured temperature only. In this prospective three-month study, overall average daily use was 6.6 hours ( $\pm$  1.3 hours) and no statistically significant difference was found between subjective wearing time reports and objective compliance data. An earlier study by Schott and Göz<sup>6</sup> examined the same OA compliance measurement technology and reported that temperature-only based OA compliance technology susceptible to water bath deception.

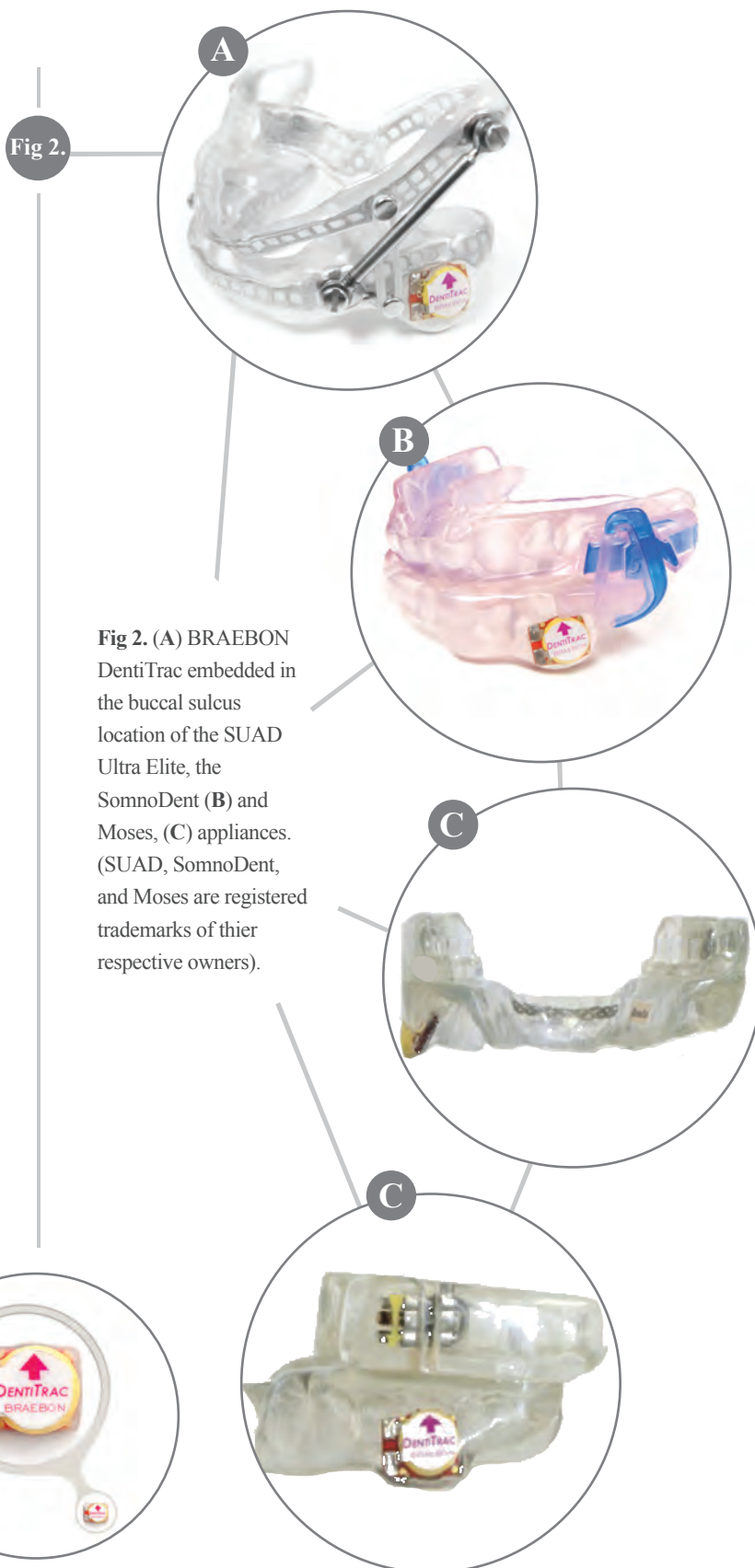
In the study by Schott and Göz<sup>6</sup>, a Büchi thermostatic water bath was set to turn on 14 hours daily. According to these authors, immersion in "thermostatic water bath simulated wear and non-wear times of orthodontic appliances with remarkable accuracy because the sensors' wear-time measurements are based on temperature." Thus, the opportunity exists for individuals motivated to deceive the

temperature-only based OA monitoring devices through the use of off-the-shelf technology. It is important to note that inexpensive aquarium water bath heaters are inadequate 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 Büchi water bath heater is designed specifically for precise laboratory thermostatic water heating and is the preferred method to replicate such testing. Therefore, no technology has heretofore been demonstrated to accurately, reliably, and objectively determine OA compliance while being simultaneously impervious to simple water bath immersion deception.

The extensive experience of BRAEBON Medical Corporation in the design and manufacture of biosensors and physiological recording technology, such as the MediByte®, spans decades and encompasses both sleep laboratory and home environments. BRAEBON has taken this knowledge and technology and miniaturized it to create a novel patent-pending micro-recorder, DentiTrac®, capable of being embedded into an OA for the objective measurement of patient treatment compliance (see Figures 1 & 2). The DentiTrac is actually a micro-recorder (or datalogger) and not a microsensor because sensors only transmit information downstream for amplification and permanent storage or recording. In comparison to a traditional home sleep testing recorder, such as the BRAEBON



**Fig 1.** Both the BRAEDON MediByte and BRAEDON DentiTrac are micro - recorders with internal battery, internal memory, internal sensors, and the ability to transmit the data out of the data logger



**Fig 2. (A)** BRAEBON DentiTrac embedded in the buccal sulcus location of the SUAD Ultra Elite, the SomnoDent (B) and Moses, (C) appliances. (SUAD, SomnoDent, and Moses are registered trademarks of their respective owners).



MediByte®, both DentiTrac® and MediByte® have an internal battery, internal sensors, internal memory storage, and a method to retrieve information from the datalogger. The DentiTrac® has internal memory capable of storing up to six months of data which would require a patient to see a dentist twice a year. DentiTrac® battery life expectancy is about two years or more and the micro-recorder uses extensive anti-deception algorithms based on collecting much more data than mere temperature. Our research has found that DentiTrac® is not susceptible to the aforementioned Büchi water bath deception precisely because more than temperature is being recorded and anti-deception algorithms are implemented.

In data collected comparing subjective OA wearing time with objective DentiTrac® compliance data, a paired t-test revealed no statistically significant difference, and a Pearson correlation of 0.90 was observed (see Figure 4). The DentiTrac® measures a mere 10.5 mm x 8.5 mm x 4 mm (L x W x T) with a weight of 0.5 grams and has a sampling rate of once per minute. It may be embedded into either new or old appliances and is as easy to insert as a label. The data is internally stored and uploaded to a web cloud portal using either the clinician base station or a read-only patient base station; the availability of the patient station permits busy patients to remotely and conveniently upload the compliance data from anywhere in the world.



87% Compliant (Everyday)

SUMMARY

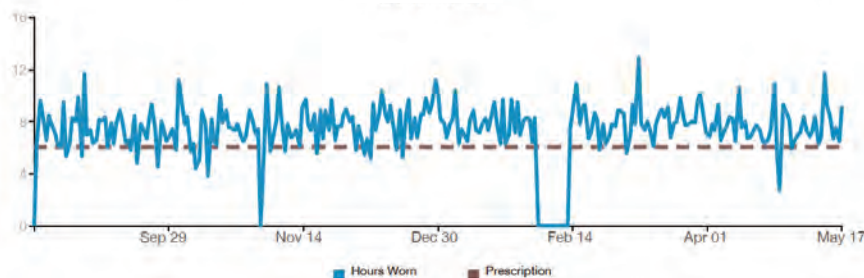


Fig 3. Two hundred and seventy-four days of DentiTrac® compliance data in a SUAD Ultra Elite appliance from August 17, 2012 through May 18, 2013. The dashed line represents prescription wearing time which is determined by the dentist or doctor in the cloud portal. November 1, 2012 and February 3 – 13, 2013 correctly show zero wearing time.

Fig 4.

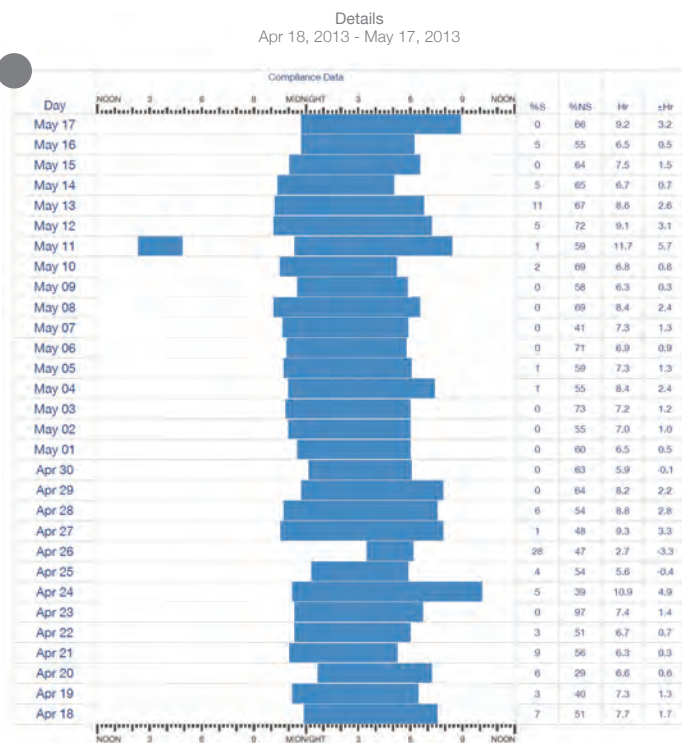


Fig 4. DentiTrac® detailed OA compliance graph indicating amount and time of daily OA usage. From top to bottom, daily usage from May 17 to April 18. Left to right indicates time from noon to noon. April 26 correctly indicates when the appliance was forgotten at the beginning of the night and subsequently inserted by the patient just prior to 0330. May 11 correctly shows a daytime nap. Data columns from left to right indicate percent supine head position, percent nonsupine head position, hours of use per 24-hour period, and time above or below prescribed wearing time. Data correctly indicate this person is predominantly a nonsupine sleeper.

Start Date: August 16, 2012  
 Prescribes daily use: 6 hours  
 Average daily use (when worn): 7.7 hours

In summary, the availability of the DentiTrac® micro-recorder levels the playing field with objective CPAP compliance measurement. This technology addresses the need for direct compliance measurement identified in orthodontics long ago and is also vital to the burgeoning field of dental sleep medicine. Insurance payers are anticipated to require objective OA compliance monitoring for OAT reimbursement analogous to the established CPAP compliance paradigm. DentiTrac® is currently being introduced into global markets and has been undergoing extensive validation by leading university dental schools and key dental luminaries throughout North America.

*Richard A. Bonato, Ph.D. and Donald C. Bradley are Co-Founders of BRAEBON Medical Corporation and have been involved in advancing the science of sleep for over 20 years with the development of the DentiTrac® micro-recorder, the MediByte® family of advanced home sleep testing equipment, numerous sleep sensor technologies, and PSG systems.*

*DentiTrac®, MediByte®, and BRAEBON® are registered trademarks of BRAEBON Medical Corporation.*

## References

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