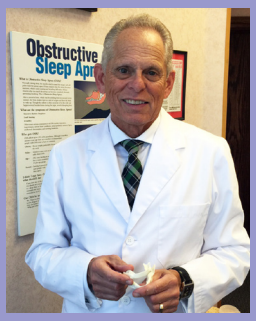

Dr. Les Priemer

DENTAL SLEEP MEDICINE UPDATE 2016

Dr. Les Priemer
SNORING AND SLEEP APNEA THERAPY

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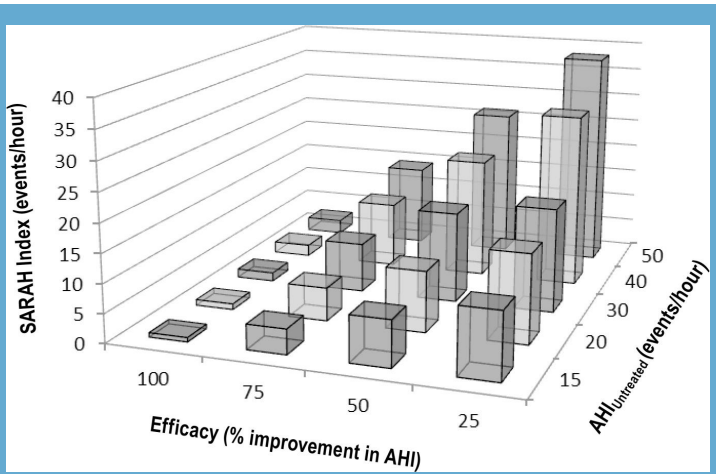
AMERICAN ACADEMY OF DENTAL SLEEP MEDICINE DIPLOMATE

COMPARISON OF AHI AND SLEEP ADJUSTED RESIDUAL AHI (SARAH INDEX) IN CPAP AND ORAL APPLIANCE TREATMENT

We have previously published a large cross-over study (108 completers) of one month each of optimized CPAP and oral appliance treatments. This study found that oral appliances were non-inferior to CPAP across a range of health outcomes in predominantly moderate-severe patients. There were no between-treatment difference in cardiovascular (24-hr blood pressure, arterial stiffness), neurobehavioral (subjective sleepiness, driving simulator performance), or quality of life outcomes. In a subgroup of hypertensive patients, blood pressure during sleep reduced from baseline with both treatments, but more importantly, with no difference between them. In comparing the efficacy profiles of the two treatments, as expected, polysomnography confirmed OSA resolution on CPAP, whereas residual mild OSA was evident with oral appliance treatment (AHI 4.5 ± 6.6 vs. 11.1 ± 12.1/hr). However, self-reported compliance favored oral appliances at an average 1.3 h more usage per night than CPAP. These efficacy and compliance profiles of CPAP and oral appliance treatment suggest that superior CPAP efficacy may be offset by greater oral appliance usage. We now use real data from this trial to compare AHI and SARAH Index between CPAP and oral appliance treatments across the spectrum of OSA severity.

Median treatment AHI on CPAP from this trial was 4.7/hr (i.e., elimination of OSA). We have used AHITreatment of 4.7/hr to calculate the SARAH Index at different levels of treatment usage hours for an 8-h sleep period (healthy sleep time range44). Figure 3 shows the results from calculation of SARAH Index across a range of OSA severity (AHIUntreated). If CPAP is used for the total 8-hr sleep, OSA is indeed resolved (AHI = 4.7) for all levels of OSA severity. However, it is recognized that as many as 50% of CPAP treated patients are using their treatment < 4 hr of total sleep time.15 Using this example of an 8-hr sleep period, the graph demonstrates that patients using their device for 4 and 2 h per night have at least mild OSA assessed by the SARAH Index, with much higher levels in those with more severe OSA. As total sleep time decreases, the SARAH Index reduces; however, for an average 8-h sleep period, the majority of CPAP users would be effectively under-treated based on known compliance rates. As CPAP usage further declines long term, CPAP treatment effectiveness may additionally become worse over time. This graph illustrates that when taking into consideration CPAP hours used over sleep time, OSA may not be well controlled, and even moderate-severe OSA may still be present in more severe and less compliant patients who sleep for longer periods. The SARAH Index calculation raises the possibility that despite high efficacy, CPAP users may not be effectively treated in practice.

Oral appliance usage data from this same trial found median reported usage time to be 95% of total sleep time. We have used this 95% compliance rate to assess oral appliance treatment effectiveness by the SARAH Index. With good self-reported usage of nearly 100% of sleep time the influencing factor on treatment effectiveness for oral appliances is their efficacy, expressed as a percentage improvement in OSA from baseline levels. We show SARAH Index for different OSA severities across different levels of oral appliance efficacy of 25%, 50%, 75%, and 100% improvement in the chart below. Oral appliance treatment effectiveness expressed by SARAH Index varies with efficacy and OSA severity. We have shown in a large audit of oral appliance treated patients that the majority (70%) will have ≥ 50% improvement in OSA using an oral appliance. If we compare CPAP and oral appliance treatment effectiveness measured by the SARAH Index, conceptually we can see that many patients may be effectively undertreated with either treatment. However, with half of all CPAP treated patients using it < 4 hr per night and two-thirds of oral appliance treated patients reducing OSA by at least half, theoretically many patients with incomplete efficacy on oral appliance may be no worse off than when on fully efficacious CPAP in terms of treatment effectiveness.



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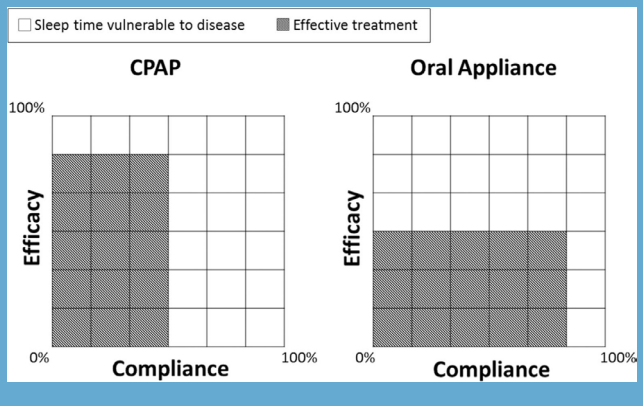
SLEEP ADJUSTED RESIDUAL AHI (SARAH INDEX) FOR ASSESSMENT OF TREATMENT EFFECTIVENESS

Evidence of equivalent health outcomes between oral appliances and CPAP suggest that real-world treatment effectiveness is not captured by the efficacy measure $AHI_{Treatment}$. However this is the metric on which clinical decisions are primarily made, although it is well recognized that CPAP is not used for all hours of sleep. The different treatment profiles of CPAP (high efficacy/low adherence) and oral appliances (moderate efficacy/high adherence) may conceptually result in similar profiles of treatment effectiveness. In the schematic in Figure 1, two identical sleep periods in which OSA can occur is represented by a grid (white boxes) for which CPAP and oral appliance are applied. Treatment effectiveness is a composite of efficacy (represented on the y axis of the grid) and hours of treatment usage (represented on the x axis). In this example MAS is only half as efficacious as CPAP, but compliance is twofold greater. Despite these different treatment profiles, both treatments have similar overall effectiveness in relieving OSA (shaded area). This conceptual example likely reflects many patients in the real world, for whom CPAP is highly efficacious but treatment usage is modest, while oral appliances may have more modest efficacy but are used for relatively more of the sleep period. Potentially a more representative measure of treatment effectiveness than $AHI_{Treatment}$ should also take into account hours ON treatment ($AHI_{Treatment}$) and hours OFF treatment ($AHI_{Untreated}$) for the TOTAL sleep period. We adopt the formula of Ravesloot and colleagues,12 which accounts for these additional factors in order to assess a more accurate measure of treatment effectiveness, which we have called the Sleep Adjusted Residual AHI or SARAH Index. Potentially such an index which incorporates these currently overlooked factors could be a more accurate measure of treatment effectiveness and will better align with downstream health benefits.

The formula is expressed below:

$$\text{Sleep Adjusted Residual AHI (SARAH Index)} = \frac{[AHI_{Treatment} \times Hours_{Treatment}] + [AHI_{Untreated} \times Hours_{Untreated}]}{Hours_{Total\ Sleep\ Time}}$$



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