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SCIENTIFIC INVESTIGATIONS

Measurement of snoring and stertor using the Sonomat to assess effectiveness of upper airway surgery in children

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Study Objectives: The success of surgical treatment for pediatric sleep-disordered breathing is typically assessed using the mixed and obstructive apnea-hypopnea index (MOAHI). Although an important metric, previous work has shown that snoring and stertor are also associated with sleep disruption. Our aim was to assess the efficacy of surgery using the Sonomat (Sonomedical Pty Ltd), a noncontact sleep assessment system, that accurately records complete and partial upper airway obstruction. Methods: Forty children (< 18 years) had a Sonomat study, in their own beds, before and after surgery. As an MOAHI ≥ 1 event/h is considered abnormal, the

same threshold was applied to snore/stertor runs. Median (interquartile range) values are reported.

Results: Respiratory event–induced movements decreased from 12.0 (8.7–19.0) to 0.5 (0.1–3.2) events/h (P < .01), with no significant change in spontaneous movements: 12.8 (9.8–17.9) to 16.5 (13.7–26.1) events/h (P = .07). The MOAHI decreased from 4.5 (1.9–8.6) to 0.0 (0.0–0.4) events/h (P < .01). Snoring and/ or stertor runs decreased from 32.8 (23.4–44.4) to 3.0 (0.2–14.6) events/h (P < .01). Thirty-four children had an MOAHI < 1 event/h following surgery; however, 20 had snore and/or stertor runs ≥ 1 event/h and 11 had snore and/or stertor runs ≥ 5 events/h. Only 14 (35%) children had a postsurgery MOAHI < 1 event/h combined with snoring and/or stertor < 1 runs/h.

Conclusions: Although surgery is effective in improving breathing, success rates are overestimated using the MOAHI. Our results indicate that snoring and/or stertor are still present at levels that may disrupt sleep despite a normalization of the MOAHI and that when obstructed breathing was objectively measured, there was a large variation in its response to surgery.

Keywords: snoring, pediatric, upper airway surgery, snoring, stertor, sleep disruption, sleep-disordered breathing

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BRIEF SUMMARY

Current Knowledge/Study Rationale: Surgery for pediatric sleep-disordered breathing is assessed using the mixed and obstructive apnea-hypopnea index (MOAHI). Previous work has shown that snoring and stertor are also associated with sleep disruption. We aimed to assess the efficacy of surgery using the Sonomat, a noncontact sleep assessment system, that records complete and partial upper airway obstruction.

Study Impact: Of 40 children studied, 34 had an MOAHI <1 event/h following surgery; however, 20 had snore/stertor runs \geq 1 event/h and 11 had snore/stertor runs \geq 5 events/h. Only 14 (35%) children had a postsurgery MOAHI < 1 event/h combined with snoring and/or stertor < 1 runs/h. Although surgery is effective, success rates are overestimated using the MOAHI alone. Our results indicate that snoring and/or stertor are still present at levels that may disrupt sleep despite a normalization of the MOAHI.

INTRODUCTION

A history of snoring, disturbed sleep, enlarged adenoids/tonsils, and an array of daytime symptoms, including attention difficulties and hyperactivity, is common in children with sleep-disordered breathing (SDB).^{1–3} As the primary treatment option for pediatric SDB is adenotonsillectomy,⁴ a surgical procedure that is not without risk,⁵ it is preferential to ensure that a child does have a degree of SDB that warrants surgery.

Using supervised polysomnography (PSG) as an objective measure in children before and after surgery is recommended^{6,7} yet is rarely performed. PSG is associated with long waiting lists and is a time-consuming, labor-intensive process. Further, it is recognized that adult criteria using apnea-hypopnea indices (AHIs) alone do not adequately characterize childhood SDB⁸ and that other PSG measures of gas exchange and breathing may be better indices of upper airway obstruction (UAO).⁸ While standard PSG metrics report apneas and hypopneas, they do not adequately measure periods of partial UAO such as snoring and stertor that are characteristic of pediatric SDB. Snoring is a sign of UAO characterized by low-frequency sounds.⁹ In contrast, stertor consists of higher frequency sounds thought to be generated by high-velocity air moving through a very narrow rigid airway.¹⁰ Many PSG systems do use snore sensors but miss significant snoring as the recommended recording parameters¹¹ only permit capture of a small bandwidth of snore sounds.^{12–14} Other PSG signs of UAO, such as flow limitation, are difficult to score and signs of sleep disruption, such as body movements, are often not scored at all unless there is a concurrent electroencephalography (EEG) activation.¹¹

The Sonomat (Sonomedical Pty Ltd, Balmain, Australia) has been recently validated against PSG in children for measurement of PSG metrics such as total sleep time and the AHI, with sensitivity and specificity of 86% and 96%, respectively, at a threshold of 5 events/h.¹⁵ This system is a noncontact mattress overlay that also accurately records snoring and stertor,^{13–15} which are pathognomonic physical signs of partial UAO and may be associated with subtle forms of sleep disruption such as disturbance of slow-wave sleep.¹⁶ The aim of this study was to assess the efficacy of surgery using the Sonomat, a noncontact sleep assessment system, that accurately records complete and partial UAO.

METHODS

This single-center observational study was undertaken through the David Read Laboratory (University of Sydney, Camperdown, Australia) with the protocol approved by the University of Sydney Human Research Ethics Committee (HREC Ref: 10–2007/10229).

Participants

We have previously reported results of Sonomat studies in otherwise healthy children (n = 231) with a range of symptoms suggestive of SDB referred clinically to an otolaryngologist for assessment for adenotonsillectomy.¹³ Of these children, 40 had upper airway surgery and returned for a postsurgery recording, allowing this comparison of pre- and postsurgery Sonomat data. None of these 40 children had postsurgery PSG. The parent/caregiver managed a single overnight Sonomat recording in the child's bed, pre- and postsurgery. Participants, or the parents of participants, were provided with a brief education session on the placement and use of the Sonomat during the afternoon prior to their study.

Sonomat and scoring criteria

The Sonomat is a mattress overlay that does not require the physical attachment of sensors. It is placed on top of the mattress with bedclothes arranged as normal, separating the individual from the sensors. Care was taken to ensure that only a single sheet was placed between the sensors and the participant, with any thicker items such as mattress protectors not used for the night of recording. Each embedded sensor is composed of a piezo-electric material that records a duo of signals: breath sounds (similar to a digital stethoscope) and movement.^{13,14} All 4 sensors produce the same output and, due to their physical placement within the Sonomat, permit the individual to move around the bed while maintaining contact with at least 1 sensor^{13,14} (Figure 1). Analysis requires signals from only 1 sensor. Additionally, 2 room sound microphones are situated in the 2 upper corners of the Sonomat. These sensors record breath sounds and ambient sound.

Breath sound signals are analyzed visually and audibly as they can be replayed through audio speakers/headphones and analyzed using spectrographic methods (Figure 2) that allow visual display and measurement of the frequency components of breath sounds. Movement signals, similar to the thoracoab-dominal signals in PSG, are analyzed visually. Apneas, hypopneas, snoring, stertor, body movements, quiescent time (Qd), poor-quality signals, and instances of the child leaving the bed were scored manually, as described in detail previously.¹⁵ Recordings were scored by M.B.N. and reviewed by C.E.S. to ensure scoring consistency.

In summary, a movement arousal (MA) is an abrupt change in the regular breathing pattern (**Figure 1**); spontaneous MAs (minimum duration of 3 seconds) are preceded (within 5 seconds) by



Four Sonomat sensors (dashed circles) record sound and movement signals (output from only 1 sensor shown). Two room-sound microphones (open white circles) record breath and ambient sound. The 2 vertical lines bound a 30-second epoch of time. The figure shows 2 runs of 7 snoring breaths (green) on the breath sound trace associated with breathing movements (inspiration up) on the movement trace. A body movement (pink) follows the first run of snoring and consists of irregular patterns of larger-amplitude signals; this would be classified as a respiratory-induced MA due to its proximity to the run of snoring. MA = movement arousal.

Figure 2—Visual representations of breath sound events (30-second spectrograms).



The cooler colors indicate quiet sounds and the hotter colors indicate louder sounds. (A) Normal breathing: low-frequency white noise < 500 Hz. (B) Snoring: clear frequency bands starting \sim 100 Hz on inspiration. (C) Stertor: high-frequency white noise 1,200–2,000 Hz. (D) Mixed apnea: no breath sounds (apnea) on the spectrogram occurring simultaneously with a combination of no breathing movements followed by breathing movements during the apneic period (mixed apnea). This shows how obstructive and central events can be differentiated.

normal breath sounds and respiratory-induced MAs (no minimum duration) by apneas, hypopneas, snoring, or stertor. The periods of quiescence between movements were considered analogous to sleep. Normal breath sounds (Figure 2A) contain white noise <500 Hz. Snoring sounds contain frequency bands from 30 to ~300 Hz (Figure 2B), and stertor contains no clear frequency peaks but white noise from $> \sim300$ Hz (Figure 2C). A single snoring or stertor are collectively referred to as "obstructed breathing" as both are pathognomonic indicators of partial UAO. The numbers of obstructive breathing events per hour were calculated, as was the duration of obstructive breathing. Apneas present as an absence of breath sounds, with heart sounds maintained, and are classified

based on the presence or absence of breathing movements. **Figure 2D** shows an apnea (red rectangle) with central and obstructive components visible (mixed apnea). Hypopneas consist of a 30% change in the amplitude of the breathing movement signal and are classified as obstructive or central based on the presence or absence of obstructed breathing (a hypopnea with obstructed breathing is an obstructive hypopnea and a hypopnea without obstructed breathing is a central hypopnea). A minimum of 2 breaths' duration was required for scoring of apneas and hypopneas. The MOAHI was calculated by dividing the number of mixed and obstructive events by the Qd. As an MOAHI \geq 1 event/h is considered abnormal in children, the same threshold was applied to obstructed breathing runs.

Data analysis

All data were deidentified and the scorer blinded to the nature of the study (pre- or postsurgery). Statistical analysis was performed using GraphPad Prism 9 (GraphPad Software, Inc, La Jolla, CA, USA). Normally distributed data are presented as mean \pm SEM (standard error of the mean) and nonnormally distributed data as median and interquartile range (IQR). The significance of any differences was determined using paired *t* tests, Wilcoxon tests, and Mann-Whitney *U* tests. Correlation was performed using Spearman's rank-order method. All tests of significance were 2-tailed and a *P* value of < .05 was considered significant.

RESULTS

The median time from surgery to follow-up Sonomat study was 3 months, with the minimum of 1 month and the maximum of 26.1 months. Tonsillectomy accounted for 6 (15%), adenoidectomy for 3 (7.5%), and adenotonsillectomy for 31 (77.5%) of the 40 surgical procedures. Only 20 participants had paired height and weight data recorded before and after surgery and there was no significant change in body mass index (BMI) *z*-scores following surgery (BMI-*z* presurgery = 0.05 [-1.49 to 0.86], BMI-*z* postsusrgery = 0.27 [-0.59 to 1.01]) (**Table 1**). There was no difference in the recording time or the time available for analysis in the presurgery and postsurgery studies (**Table 2**).

All forms of snoring and obstructive breathing decreased significantly following surgery, with the MOAHI decreasing from 4.5 (1.8–8.7) to 0.0 (0.0–0.4) events/h (P < .0001) (**Table 2**). Obstructed breathing runs decreased from 32.8 (23.4–44.4) to 3.0 (0.2–14.6) events/h (P < .0001). The duration of obstructed breathing runs was brief at 12 (5–31) seconds on diagnostic and 8 (4–23) seconds following surgery, similar in duration to MOAHI event duration at 12 (9–17) seconds on diagnostic and 11 (8–14) seconds following surgery (**Table 2**). Respiratory event–induced movements decreased from 12.0 (8.7–19.0) to 0.5 (0.1–3.3) events/h (P < .001) following surgery, with no significant change in spontaneous movements: 12.8 (9.8–17.9) to 16.5 (13.7–26.1) events/h (P = .07) (**Table 2**).

Prior to surgery, all children were beyond at least 1 obstructed breathing threshold (\geq 10 minutes of snoring and/or stertor or \geq 5 snoring and/or stertor events/h) (Figure 3), regardless of their MOAHI. Thirty-four children (85%) had an MOAHI < 1 event/h following surgery but only 14 (35%) had a postsurgery MOAHI < 1 event/h combined with obstructed breathing runs < 1 event/h (Figure 3). The remaining 20 children with a postsurgery MOAHI < 1 event/h had obstructed breathing runs ranging from 1.1 to 36.6 events/h. The 6 children with an MOAHI \geq 1 event/h had obstructed breathing runs ranging from 2.8 to 144.3 events/h. Obstructed breathing runs were associated with body movements postsurgery (Figure 4), with the frequency of respiratory-induced MAs increasing with frequency of obstructed breathing.

DISCUSSION

In this study it was found that obstructive apneas and hypopneas decreased following upper airway surgery but were not always abolished and that snoring and/or stertor were still present in many children, at levels that may disrupt sleep despite a normalization of the MOAHI. Lack of objective measurements of partial UAO may explain why surgery often benefits children who do not meet the MOAHI criteria for obstructive sleep apnea (OSA) yet show marked clinical improvements following surgery.¹⁷

Recent work has shown that adenotonsillectomy is not associated with 80%–90% cure rates as previously published,^{18,19} with a multicenter investigation showing that although 90% of children had a reduction in their AHI following surgery, only 27% had complete resolution of their OSA (AHI < 1 event/h).²⁰ Moreover, 22% still had an AHI \ge 5 events/h.²⁰ A recent systematic review showed that the prevalence of persistent postsurgical OSA varied between 33% and 76% in obese children and 15% and 37% in nonobese children.²¹ Similarly, the current study shows that when obstructed breathing (snoring and/or stertor) is measured, runs of obstructed breathing persist in many children.

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| Table | 1—Characteristics | of | children | studied. |
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| Variable | Presurgery | Postsurgery | |
|---|----------------------|----------------------|--|
| Sex, M/F, n | 28/12 | 28/12 | |
| Age, mean (SEM), y | 4.6 (0.3) | 5.1 (0.3) | |
| Age range, y | 2.0–10.9 | 2.5–11.2 | |
| BMI z-score,* median (IQR) | 0.05 (-1.49 to 0.86) | 0.27 (-0.59 to 1.01) | |
| Surgery, number (% of total) | | | |
| Tonsillectomy | — | 6 (15) | |
| Adenoidectomy | — | 3 (7.5) | |
| Adenotonsillectomy, number (% of total) | — | 31 (77.5) | |
| Time since surgery, median (IQR), mo | _ | 2.9 (1.7–4.1) | |

*Paired BMI z-score data for 20 participants only. BMI = body mass index, F = female, IQR = interquartile range, M = male, SEM = standard error of the mean.

Table 2—Sonomat variables.

| Variable | Presurgery | Postsurgery | Р |
|--|--------------------|------------------|---------|
| Recording time, mean (SEM), min | 534 (14.2) | 546.7 (11.4) | .412 |
| Poor signal quality, median (IQR), min | 14.1 (0.0–93.0) | 32.2 (3.1–112.9) | .168 |
| Out of bed, median (IQR), min | 0.0 (0.0–0.4) | 0.0 (0.0–0.6) | .792 |
| Analysis time, mean (SEM), min | 475.8 (18.0) | 474.8 (13.9) | .958 |
| Spontaneous movements, median (IQR), /h | 12.8 (9.8–17.9) | 16.5 (13.7–26.1) | .07 |
| Respiratory movements, median (IQR), /h | 12.0 (8.7–19.0) | 0.5 (0.1–3.3) | < .001 |
| Quiescent time, mean (SEM), min | 438.9 (17.4) | 441.2 (13.8) | .892 |
| Quiescent time, mean (IQR), % recording time | 92.8 (89.9–94.0) | 93.6 (90.6–95.2) | .140 |
| MOAHI, median (IQR), events/h | 4.5 (1.8–8.7) | 0.0 (0.0–0.4) | < .0001 |
| MOAHI event length, median (IQR), s | 12 (9–17) | 11 (8–14) | < .0001 |
| Obstructed breathing runs, median (IQR), events/h | 32.8 (23.4–44.4) | 3.0 (0.2–14.6) | < .0001 |
| Obstructed breathing run length, median (IQR), s | 12.0 (5.0–31.0) | 8.0 (4.0–22.9) | < .0001 |
| Total obstructed breathing duration, median (IQR), s | 144.5 (85.4–202.3) | 2.7 (0.1–26.4) | < .0001 |

IQR = interquartile range, MOAHI = mixed and obstructive apnea-hypopnea index, SEM = standard error of the mean.

Despite imperfect cure rates in clinical practice, and the risks involved with surgery, laboratory PSG is reported to be requested only "sometimes" and home PSG "rarely" to "never" presurgery, with even fewer having a postsurgery study to assess the success of treatment.^{22–24} It has been reported that more than 80% of children have surgery based on clinical history alone despite multiple studies showing that approximately 45% do not actually have a level of OSA for which surgery is recommended.²⁵ However, as clinical guidelines for otolaryngologists recommend PSG before surgery only in the presence of certain comorbidities, or if the need for surgery is uncertain,²⁶ these numbers are likely to vary.

If PSG is performed pre- and postsurgery, it is the AHI and measures of oxygenation and sleep disturbance that are used to gauge the severity of disease and the degree of success achieved.^{20,27–35} Recording EEG is a precise means of measuring sleep disturbance and EEG changes also correlate with body movements³⁶; movement metrics have been shown to improve following surgery.^{37,38} Even though quantification of body movement is simple to perform within PSG, it is rarely done as the EEG-based measures of sleep disruption take precedence, with the exception being periodic limb movements and other movement disorders. Although most participants in this study had fewer respiratory movements following surgery, many children had continued obstructed breathing runs and a clear relationship was shown between obstructed breathing runs and body movements postsurgery. Additionally, in very few PSG studies is snoring, the dominant form of pediatric SDB, noted as being recorded. If snoring is recorded, it is often only mentioned as being present or absent²⁸ and typically not objectively quantified beyond this. This current study found that, when obstructed breathing was objectively measured, there was a large variation in its response to surgery. This indicates that snoring and stertor should be measured in any assessment of breathing during sleep. The quantification of obstructed breathing and the fact that all recordings were made unobtrusively in the child's own home, using the Sonomat, are novel.

There are several limitations to this study. Of the larger published study of children with symptoms suggestive of SDB,¹³ there were only a relatively small number of children studied pre- and postsurgery. We are unsure how many of the children who had diagnostic studies progressed to having surgery and not all of the children who had surgery returned for follow-up appointments or a postsurgery study. A common reason for not having a postsurgery study, given by several parents, was that surgery had "cured" their child and they did not feel a follow-up study was required. This may have skewed the postsurgery results toward children perceived by their parents as still having problems, so the partial success and failure rates may not be truly representative. Snoring results were probably the most likely affected by this possibility, being the symptom of SDB that is more likely to be noticed by the parent. Further, the children studied pre- and postsurgery were possibly not representative of a typical group of children with suspected OSA, as many with severe OSA may have been identified clinically and been referred for PSG and/or directly to surgery, bypassing the Sonomat recording. This possibility is likely as previous work has shown a presurgery MOAHI of 18.2 events/h and an obstructive apnea index of 6.0 events/h in presurgery children,²⁰ values that are much higher than those found in this study. As children with severe disease are more likely to have residual OSA following surgery, the failure rate in this study may have been greater had more children with severe OSA been included initially. The methods and practice of the single surgeon who operated on these children may have had some impact on the results. A relatively short period of time (3 months) occurred between surgery and the follow-up recording, but this period should have accounted for any benefits of surgery that were transient. Additional follow-up studies over the longer term would be valuable to determine if those who showed improvement maintained their improvement and if those who worsened following surgery continued to have significant

Figure 3—Bubble plot showing total duration (\log_{10} , *x*-axis) plotted against number of runs (\log_{10} , *y*-axis) of obstructed breathing with MOAHI (*z*-axis) for each child.



Blue circles are non-OSA children with hotter colors and larger circles indicating increasing severity of OSA (MOAHI values \geq 10 events/h have the same diameter). Red dashed lines indicate thresholds of 10 minutes (*x*-axis) and 5 events/h (*y*-axis). MOAHI = mixed and obstructive apnea-hypopnea index, OSA = obstructive sleep apnea.

OSA or if their problems improved with time. Additional measures of respiratory compromise and sleep disturbance, such as oximetry and EEG, were not recorded in this current study, but the nature of the Sonomat removed any disruption that may have been induced by sensors attached to the child. From this study we cannot say if the snoring and stertor measured are or are not associated with downstream effects other than body movements that indicate sleep disruption. Further investigations of any link Figure 4—Relationship between runs of obstructed breathing and body movements (sleep disruption).



between UAO and behavior, cognition, school performance, and daytime sleepiness are warranted.

When the MOAHI and runs of obstructed breathing were examined before and after surgery the data indicated that surgery was successful (**Figure 3**), but outliers were present. Individually, most children had substantial decreases in obstructed breathing and the MOAHI. However, there were some in whom very little change was observed and a minority in whom the MOAHI and obstructed breathing worsened after surgery. Although the MOAHI improved more consistently than did obstructed breathing, 3 children had an increased MOAHI following surgery, 2 of them markedly so. These 2 children with severe OSA postsurgery (MOAHI ≥ 10 events/h) had both adenoids and tonsils removed, indicating either that their upper airway was inherently more collapsible than the others or that their primary site of obstruction may have been elsewhere.

Most studies reporting the effects of surgery on pediatric OSA use the MOAHI as the metric of success or failure. Using MOAHI as the singular measure of success, 85% of participants in this study were cured. After the inclusion of obstructed breathing thresholds in tandem with the MOAHI, the cure rate dropped to 35%, suggesting that current PSG criteria may not be the best way to gauge overall success. Attempts have been made to quantify more subtle breathing events in PSG recordings using the respiratory disturbance index. The respiratory disturbance index is calculated as the number of apneas and hypopneas plus respiratory event-related arousal events that occur per hour of sleep. The respiratory event-related arousal event allows recognition of periods of breathing that are abnormal yet do not meet the criteria for being an apnea or hypopnea. The nasal pressure trace is used to identify flow limitation for the purpose of identifying partial airway obstruction and scoring respiratory event-related arousal events, but it is a signal that can be difficult to maintain, particularly in children. Many minutes of continuous and pronounced flow limitation, which may be associated with snoring or other sounds indicating a compromised airway, terminated by an EEG arousal can be scored as a respiratory event–related arousal. However, as this is a single event, a count of "1" is used to represent this prolonged period of disordered breathing, misrepresenting the severity of the problem. Perhaps identification of flow limitation during sleep requires that alternate measures of breathing be investigated and, although quantifying the downstream effects of abnormal breathing using EEG is useful and should be measured if possible, directly quantifying partial obstruction should also be considered. We found more children with persistent and continuing snoring and/or stertor following surgery than there were with persistent or continuing respiratory events.

Measurements of nocturnal respiration and sleep disturbance within Sonomat recordings change following upper airway surgery. In the majority of cases these changes signify an improvement in both breathing and sleep disturbance to levels that approach those observed in normal children, but surgery often only provides a partial cure or worsens SDB in some children. The Sonomat is a highly suitable tool for the diagnosis of pediatric SDB and the assessment of the efficacy of upper airway surgery in children as it directly measures both obvious and subtle breathing events, thus quantifying the dominant pathology in these children without the requirement of attached sensors, and it can be used in the child's own bed. Rather than waiting to see a sleep physician to order a PSG, and the subsequent waiting time involved before testing can be performed, the Sonomat could ideally be used prior to a visit to the physician. If severe SDB is found, the steps toward surgical treatment may be initiated immediately. If the Sonomat produces an equivocal result, then PSG may be required. If the Sonomat results are normal, then either a follow-up study or no treatment may be required. If no severe SDB is found and a PSG is deemed necessary, the physician and the parent can be confident knowing that the time spent waiting for a PSG will be unlikely to result in adverse consequences.

CONCLUSIONS

Although surgery is effective in improving SDB, success rates may be overestimated using the MOAHI alone. Sleep investigations in children that do not include PSG should include objective measurement of obstruction or partial obstruction, such as snoring, stertor, and body movement, especially when assessing outcomes of surgical intervention.

ABBREVIATIONS

AHI, apnea-hypopnea index BMI, body mass index EEG, electroencephalography IQR, interquartile range MA, movement arousal MOAHI, mixed and obstructive apnea-hypopnea index OSA, obstructive sleep apnea PSG, polysomnography SDB, sleep-disordered breathing SEM, standard error of the mean UAO, upper airway obstruction

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All authors have seen and approved this manuscript for submission. Work for this study was performed at the Faculty of Medicine and Health, University of Sydney. Professor Colin Sullivan is a director and co-owner of Sonomedical Pty Ltd, manufacturer of the Sonomat. Sonomedical provided the Sonomat devices for sleep investigations performed within this project, at no cost and with no financial benefit to Sonomedical. Dr Mark Norman is employed as a consultant with Sonomedical Pty Ltd. Other authors report no potential conflict of interest.