

# The Efficacy of a Novel Tongue-Stabilizing Device on Polysomnographic Variables in Sleep-Disordered Breathing: A Pilot Study

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## ABSTRACT

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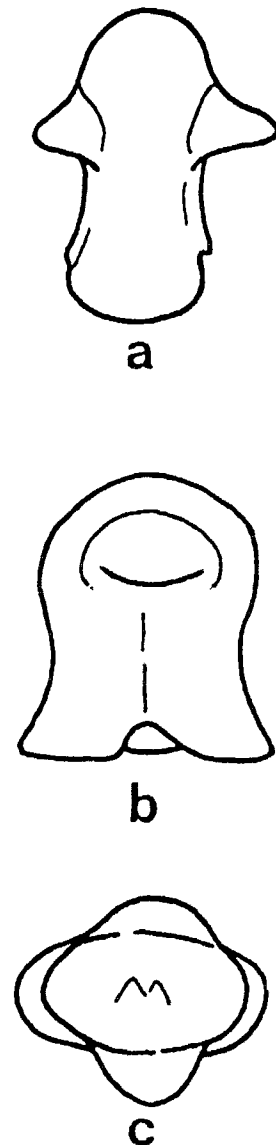
The polysomnographic efficacy of a novel tongue-stabilizing device (TSD) in the treatment of snoring and sleep-disordered breathing (SDB) was evaluated in this pilot study. Six current users of the TSD with SDB underwent polysomnography with and without the TSD in situ in a randomized crossover design. The TSD significantly lowered the frequency of snores per hour slept (61- to 70-dB range) (no TSD: mean = 41/h slept  $\pm$  52 SD; TSD: 8/h slept  $\pm$  16 SD;  $P = 0.046$ ) but did not alter snoring in the other decibel ranges (all  $P$ s  $> 0.1$ ). Trends were found for reductions in the frequency of apneas plus hypopneas (no TSD: 26/h slept  $\pm$  17/h slept; TSD: 15/h slept  $\pm$  13;  $P = 0.06$ ) and oxygen desaturations of 4% or more (no TSD: 10/h slept  $\pm$  10; TSD: 5/h slept  $\pm$  5;  $P = 0.09$ ). Significant improvements in microarousal frequency with the TSD were found (no TSD: 34/h slept  $\pm$  16; TSD: 22/h slept  $\pm$  14;  $P = 0.004$ ). Significant reductions in percentage of Stage 1 sleep with the TSD were also demonstrated (no TSD: 10  $\pm$  3%; TSD: 8  $\pm$  2%;  $P = 0.03$ ). The results of this small pilot study indicate that the TSD may be effective in reducing snoring severity and microarousals, with favorable trends for reducing SDB severity in selected individuals. Additional larger prospective studies are required to identify suitable candidates for TSD use in the treatment of snoring and SDB.

**KEYWORDS:** Oral appliances, tongue retainers, sleep-disordered breathing, snoring

Sleep-disordered breathing (SDB) ranges from snoring to severe obstructive sleep apnea (OSA).<sup>1</sup> Continuous positive airway pressure (CPAP) is the current treatment of choice for moderate to severe OSA.<sup>2,3</sup> Mandibular advancement splints have been used as an alternative first-line therapy for the management of SDB, in particular for snoring and mild sleep apnea. These intraoral devices hold the mandible in a forward position, thus potentially increasing upper airway dimensions.<sup>4-6</sup>

Less attention has been focused on a second type of oral appliance devised in the 1980s: tongue-retaining devices (TRDs).<sup>7</sup> These devices contain a plastic bulb into which the anterior part of the tongue is positioned. The bulb is depressed to create a negative suction pressure and hold the tongue in a forward position. TRDs have been shown to significantly reduce the frequency of breathing pauses and improve sleep quality.<sup>4,7,8</sup> The tongue protrusion created by a TRD increases oropharyngeal, hypopharyngeal, and velopharyngeal cross-sectional areas of the upper airway during awake states.<sup>9</sup> TRDs have also been shown to affect genioglossus muscle activity in a different manner in awake sleep apneics compared with controls.<sup>10</sup> Therefore, it is hypothesized that tongue protrusion alters the shape of the upper airway and is important in alleviating impaired upper airway function.

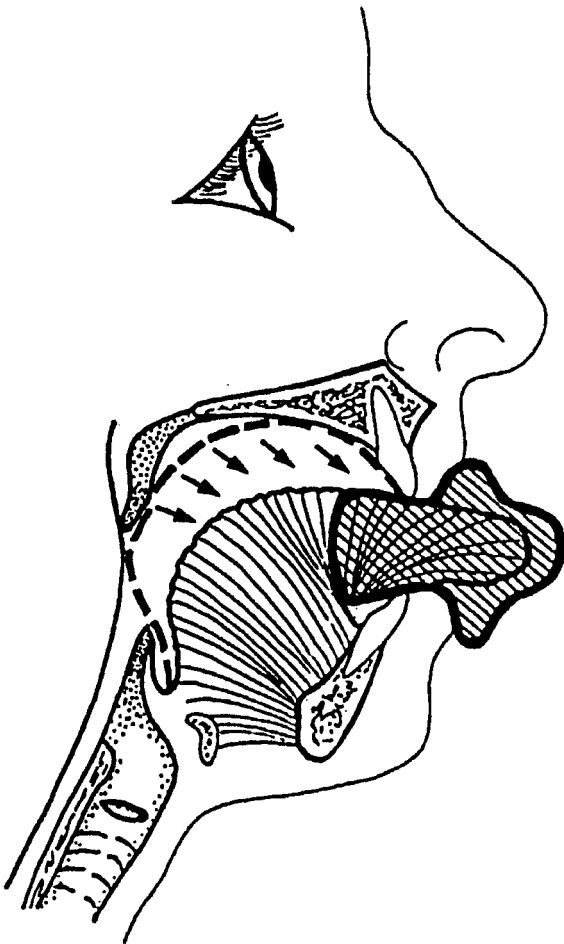
The tongue-stabilizing device (TSD) was developed by Christopher J. Robertson and manufactured in the United States (Great Lakes Orthodontics, Ltd., Tonawanda, New York) (Figs. 1 and 2). Based on the bulbous compartment of the TRD, this novel oral appliance incorporates a narrowed isthmus joined to the anterior bulbous compartment. The tip of the tongue is inserted into the bulbous compartment, which contains vertical external supports to hold the tongue in a forward position by negative pressure. TRDs incorporate some form of occlusal stop or grooving over the dentition and in doing so usually require the taking of dental impressions. In contrast to the TRD, the TSD only extends intraorally to incorporate the incisor teeth or, in edentulous patients, the alveolar ridge. The TSD is a non-adjustable universal device that is available in four



**Figure 1** Tongue-stabilizing device: (A) lateral view; (B) superior view; (C) anterior view.

different sizes. In addition, the TSD allows for oral breathing, has no moving parts, and is small and simple to use. As such, it was designed as an inexpensive "off-the-shelf" product for health professionals involved in the treatment of snoring and SDB.

Currently, the TSD is prescribed for the treatment of self- or partner-reported snoring. Treatment success is based on subjective reduction in snoring and daytime dysfunction. The objective effi-



**Figure 2** Tongue-stabilizing device in situ.

cacy of the TSD as a therapy for SDB is not known. The aim of the current pilot investigation was to examine the effect of the TSD on polysomnographic variables in patients with mild SDB who were already using the TSD.

## METHODS

### Patients

Suitable study patients had been medically referred from Sleep or Ear, Nose, and Throat Clinics to the University of Otago Orthodontic Outpatient Clinic for the treatment of snoring and had been fitted

with TSDs. Inclusion criteria were as follows: current TSD users (> 3 h/night, self-reported), use of TSD for more than 2 months, and willingness to stop using TSD for one night. Exclusion criteria were self-reported symptoms of OSA, which would constitute a referral to the Sleep Laboratory for polysomnography; taking medication known to affect muscle activity; previous upper airway surgery; and ongoing treatment for SDB.

Eight patients had been issued with the TSD and fulfilled the study criteria. Six male patients (mean age: 51 years  $\pm$  4 SD; mean body mass index: 30 kg/m<sup>2</sup>  $\pm$  3) agreed to participate. The remaining two patients were unable to take part because of family and work commitments.

The Otago Ethics Committee approved the study, and each study participant provided written informed consent. The TSD has Food and Drug Administration approval for the treatment of snoring (FDA No. K993381).

### Study Design

The pilot study was a single-center efficacy trial. Each patient attended the Sleep Laboratory on two consecutive nights: one night with the TSD in situ and one night without the TSD in situ. The order was randomized.

### Overnight Polysomnography

On both study nights, patients attended the Sleep Laboratory for full diagnostic polysomnography.<sup>11</sup> Before their arrival, patients were instructed to abstain from caffeinated beverages and alcohol for at least 4 hours. Sleep was monitored by electroencephalography (EEG; C3-A2 and O2-A1), electrooculography, and submental electromyography (EMG). Thoracic and abdominal respiratory movements were measured by inductance plethysmography and arterial oxygen saturation using pulse oximetry. Electrocardiogram, body position, and right and left leg movements were also monitored. In

addition, an integrated sound meter (NL-05, Rion Co., Ltd., Tokyo, Japan) monitored sound levels. The calibrated sound meter was situated at the side of the bed; the microphone was located 4 cm out from the wall at the head of the bed and 20 cm above the pillow. All signals were recorded onto a computerized system (Compumedics S, Victoria, Australia) using a 16-channel polygraph configuration. On the study night with the TSD in situ, patients were instructed to use their device all night.

**Off-Line Analysis** Sleep stages were manually scored using standard Rechtschaffen and Kales scoring guidelines.<sup>12</sup> Sleep stage values were expressed as a percentage of sleep period time. An apnea episode was defined as a complete cessation of airflow for a minimum of 10 seconds and hypopnea as a 50% reduction in thoracoabdominal movement for a minimum of 10 seconds.<sup>13</sup> The total number of respiratory events was divided by total sleep time to give the apnea-hypopnea index (AHI) per hours slept. Microarousals were scored using the definition of a return to alpha or theta waves on the EEG for a minimum of 3 seconds during non-rapid eye movement sleep, with the addition of a concurrent minimum 3-second rise in submental EMG tone during rapid eye movement sleep.<sup>14</sup> Both spontaneous and respiratory event-related arousals were included in the microarousal frequency. Oxygen desaturations of 4% or more of baseline were calculated from each overnight study using an automatic desaturation detection algorithm (Compumedics S) and divided by total sleep time to give a desaturation index per hour slept. The snore parameters were as follows: The background baseline value was set at 40 dB in each bedroom, a minimum deviation of 5dB from the sound baseline was required before a snore was detected, and the minimum time between snores was 1 second. Each peak snoring sound was then automatically counted and placed into a range of decibel bins using an automated program (Compumedics S) and divided by total sleep time to give a snore index for each decibel range. Each record was anonymous so

that the polysomnographer was unaware of whether the TSD was in situ or not.

## Statistical Analyses

Paired data were analyzed using mixed two-way analysis of variance for repeated measures, with treatment as a within-subject factor and treatment order as a between-subject factor. Order effects were seen for percentage of Stage 2 sleep and percentage of slow wave sleep. These data were, therefore, analyzed as suggested by Hills and Armitage<sup>15</sup> using an unpaired *t* test on first-limb data only. Snore indexes in the ranges of 51 to 60 dB and 61 to 70 dB displayed substantial heterogeneity of variance and were compared using Wilcoxon rank-sum tests for paired differences. A probability value of less than 0.05 was accepted as statistically significant. All data were analyzed using SPSS version 10 for Windows.<sup>16</sup>

## RESULTS

### Participants

All participants reported wearing their TSD for the complete duration of the study night.

### Efficacy Measures

**Snoring** Use of the TSD significantly decreased the snore frequency in the 61- to 70-dB range ( $P = 0.046$ ). However, no significant improvements in snoring levels were seen in the other decibel ranges or in the overall frequency of snores per hour slept with the TSD in situ (Table 1; Fig. 3).

**AHI** A nonsignificant trend was seen for a reduction in AHI with the TSD (Table 2; Fig. 4). The mean reduction in the AHI with the TSD in situ was 11/h slept  $\pm$  10 SD.

**Table 1 Treatment Differences in Sound Levels (N = 6)**

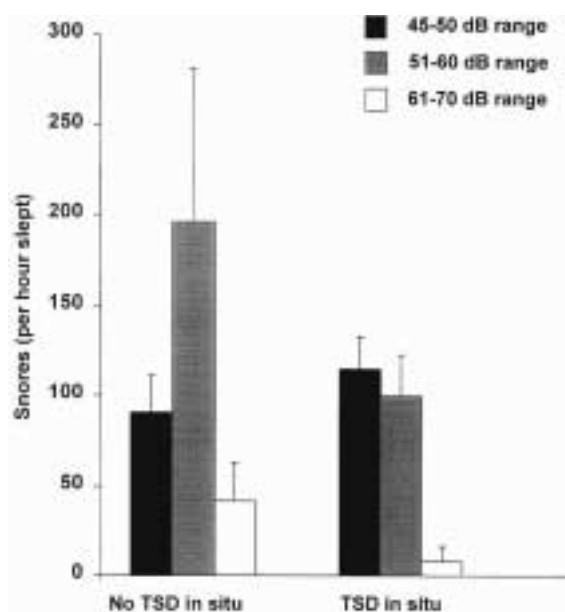
Snoring Index	Without TSD <sup>†</sup>	With TSD <sup>†</sup>	P
45–50 dB	90 ± 52	115 ± 4	0.16
51–60 dB	196 ± 208	100 ± 55	0.17
61–70 dB	41 ± 52	8 ± 16	0.046
>70 dB	1.3 ± 3	0.7 ± 1	0.35
Total snore peaks	329 ± 282	223 ± 106	0.31

TSD, tongue-stabilizing device.

<sup>†</sup>Values represent mean ± standard deviation.

**Oxygen Desaturations** There was a nonsignificant trend for a reduction in the frequency of oxygen desaturations of 4% or more when the TSD was in situ (see Table 2).

**Arousal Frequency** A significant decrease was noted in the arousal frequency with the TSD in situ (see Table 2; Fig. 5). The mean reduction in the arousal frequency with the TSD in situ was 12/h slept ± 5 SD.

**Figure 3** Comparison of snoring levels with and without the tongue-stabilizing device in situ.

**Sleep Stages** Use of the TSD significantly decreased the percentage of Stage 1 sleep ( $P = 0.03$ ); however, the TSD had no significant effect on any of the other sleep stages, including stage wake (see Table 2). Total sleep time was not significantly different ( $P = 0.7$ ) between the two study nights.

**Treatment Outcome** Of the six participants, three were recommended by the respiratory and sleep physician (D. Robin Taylor) to continue using the TSD as first-line treatment for SDB or snoring. The three remaining patients were recommended CPAP therapy, a mandibular advancement splint, and conservative therapy (alcohol avoidance and sleep position training), respectively, as first-line therapy.

## DISCUSSION

This study examined the effect of a novel TSD on polysomnographic variables in the treatment of SDB. In this pilot study, the TSD significantly reduced snoring and sleep fragmentation. The TSD did not significantly lower the AHI or frequency of oxygen desaturations of 4% or more, although trends were found. Findings indicate that the TSD may be an effective therapy in selected individuals with SDB and snoring. Further study is required to determine whether these statistically significant improvements correspond with any clinical benefit and which factors can predict TSD treatment success.

A significant reduction in snoring in the 61- to 70-dB range was found in the current study, in agreement with subjective snoring reports from a previous study using a TRD.<sup>17</sup> Significant reductions in objective snoring sounds have been demonstrated in an efficacy study using a mandibular advancement splint.<sup>18</sup> The TSD was not as effective as the mandibular advancement splint in reducing snoring in our population sample; no significant changes in the other decibel ranges were seen. One possible explanation for the lack of a greater reduction in snoring

**Table 2 Treatment Differences in Nocturnal Sleep and Respiratory Variables (N = 6)**

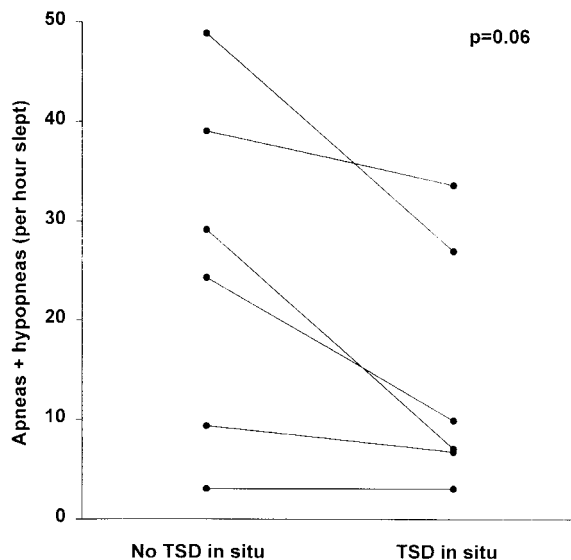
Variable	Without TSD*	With TSD*	P
Apnea-hypopnea index <sup>†</sup>	26 ± 17	15 ± 13	0.06
≥4% oxygen desaturations <sup>†</sup>	10 ± 10	5 ± 5	0.09
Arousal frequency <sup>†</sup>	34 ± 16	22 ± 14	0.004
Total sleep time (minutes)	400 ± 55	410 ± 70	0.72
% Awake	15 ± 6	14 ± 5	0.32
% Stage 1 sleep	10 ± 3	8 ± 2	0.03
% Stage 2 sleep	48 ± 4	43 ± 4	0.15
% Slow wave sleep	11 ± 1	15 ± 5	0.17
% REM sleep	18 ± 6	20 ± 5	0.16

TSD, tongue-stabilizing device; REM, rapid eye movement.  
 \*Values represent mean ± standard deviation.  
<sup>†</sup>Per hour slept.

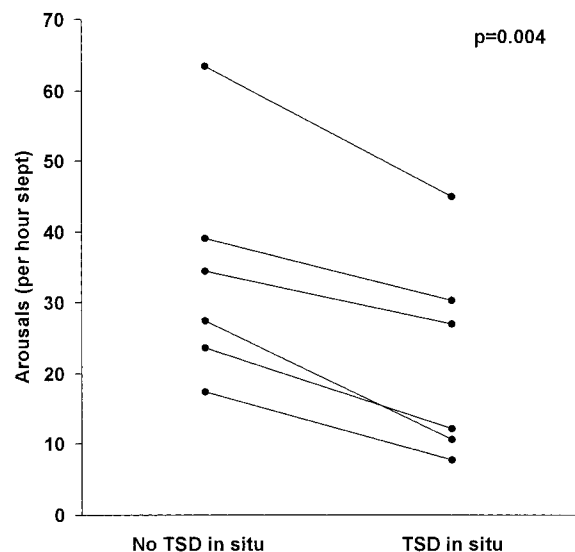
sounds in our study is that patients only snored intermittently; the snoring was frequently interspersed with hypopneas and occasional apneas. It is possible that the TSD reduced the AHI and replaced the silent airway obstruction with partial airway narrowing, thus increasing snoring sound.

Early studies demonstrated significant reductions in the apnea index with a TRD but were performed before the recognition of hypopneas.<sup>7,19</sup>

A later study using a TRD did find significant improvements in AHI with a TRD in situ.<sup>8</sup> The current study demonstrated similar improvements in AHI with the TSD, although significance in our smaller sample was not reached. Cartwright<sup>19</sup> also found that patients with a higher AHI in the supine position responded well to a TRD compared with those with no positional component. Although body position was measured in the current study,



**Figure 4** A comparison of the apnea-hypopnea frequency with and without the tongue-stabilizing device in situ.



**Figure 5** A comparison of the nocturnal arousal frequency with and without the tongue-stabilizing device in situ.

because of the small sample size, subdividing patients into positional and nonpositional SDB was not undertaken. Cartwright<sup>19</sup> also found a significant improvement in the minimum oxygen saturation with a TRD in place. A trend for a reduction in the frequency of oxygen desaturations of 4% or more with the TSD was found in the current study. The greater respiratory treatment success of a TRD could be attributable to the larger sample sizes and greater disease severity studied by Cartwright and Samelson.<sup>7,19</sup> However, it is worth noting that, although TRD studies have demonstrated significant reductions in apnea frequency, the on-treatment apnea indexes remain clinically high for these two studies (22.7 and 32.9/h slept, respectively).<sup>7,19</sup>

The current study found a significant improvement in the arousal frequency with the TSD. Early efficacy studies<sup>7,19</sup> of a TRD were performed before the routine scoring of microarousals; therefore, direct study comparisons cannot be made. However, in agreement with TRD studies,<sup>7,19</sup> the TSD significantly reduced the percentage of Stage 1 sleep. These results indicate that the TSD may reduce the sleep fragmentation associated with SDB.

Limitations to the current study include study power and study design. First, this is a pilot study with a limited sample size. The trends might have been statistically significant with a larger sample size. (Based on our data, if the effect we measured is the true effect, then 23 individuals would be required to detect a significant reduction in AHI and arousal frequency [at  $P < 0.05$ ] with a power of 80%.) Second, the study design has its limitations. Participants were all current users of the TSD who stopped using their devices for one night of polysomnography for the study. This night acted as a “diagnostic” nontreatment night. However, the TSD had been worn consistently for at least 2 months before. Therefore, treatment carryover effects of prior TSD use may have reduced potentially significant differences with and without the TSD in situ. One night without treatment is unlikely to be sufficient to allow the return of upper airway edema. Third, the patients recruited were highly selected; thus, patient acceptability and subjective outcomes

were not assessed in the current pilot. Fourth, the sample studied had a wide range of SDB severity. All were self-reported snorers without symptoms of sleep apnea. Yet results demonstrated that four of the six participants had a diagnostic AHI of more than 20/h slept. This highlights the importance of validated questionnaires, screening tools, or prior polysomnography to rule out moderate to severe OSA before fitting an orthodontic device. However, the primary purpose of this pilot was to assess the effect of the TSD on polysomnographic variables rather than predicting disease severity in non-symptomatic snorers.

The results of this pilot study indicate that the TSD may be an effective therapy in selected individuals with snoring and SDB. Further work on the efficacy and acceptability of the device is required to identify suitable candidates for this simple form of treatment. In addition, the role of the TSD as an alternative, adjunct, or temporary therapy for snoring and SDB needs to be determined.

#### FUNDING

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#### FINANCIAL DISCLOSURE

Christopher J. Robertson developed the TSD and has a small commercial interest.

#### ACKNOWLEDGMENTS

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