ORIGINAL ARTICLE

The Rematee Bumper Belt[®] positional therapy device for snoring and obstructive sleep apnea: Positional effectiveness in healthy subjects

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The present study was designed to investigate body position changes resulting from wearing a Rematee Bumper Belt (Rematee, Canada) during sleep. The majority of obstructive sleep apnea (OSA) patients will experience up to two times as many apneas and hypopneas while supine relative to lateral or prone body positions during sleep. It has been suggested that a positional therapy device could reduce the number of apneas and hypopneas in such patients. The present study was conducted to determine whether the Rematee Bumper Belt positional therapy device could prevent healthy subjects from sleeping in the supine position. Test subjects wore the belt for one to two nights. Each belt was equipped with an accelerometer that was used to measure the orientation of the belt relative to the horizontal plane. The results suggest that the belt creates an exclusion zone approximately 80° wide centred near the supine orientation, where subjects are effectively prevented to enter. Results of the present preliminary study suggests that the Rematee Bumper Belt positional therapy device is effective at limiting healthy subjects from sleeping in a supine position. The device appears to be most effective between 150° and 230°. A device with this capability may provide an inexpensive and potentially effective alternative treatment option for patients with OSA. This device has the capacity for reducing snoring and the apnea-hypopnea index in individuals with positional OSA.

Key Words: Body position; Positional obstructive sleep apnea; Positional sensor; Rematee Bumper Belt; Snoring

An obstructive sleep apnea (OSA) event is defined as a >10 s cessation of breathing with continued breathing effort, during sleep (1). The most common cause of OSA is soft-tissue blockage of the upper airway (2). Gravity-dependant soft-tissue obstruction of the upper airway in the supine position is a common problem (2). This led Robert Bowles, in 1891 (3), to be the first to describe the recovery position solution. Muscle tone, gravity and a number of anatomical, physiological and pathophysiological processes can contribute to airway obstruction when consciousness is altered. Airway obstruction is usually preceded by snoring (4). This, in the absence of sleep arousal, can cause significant reduction of blood oxygen levels and elevation of blood carbon dioxide levels. The primary clinical manifestation of repetitive airway obstructions and sleep arousal is daytime sleepiness (5). OSA appears to be associated with hypertension, diabetes and cardiovascular disease (3). Although OSA can occur in any sleep position, the supine position can actually cause or, at least, exacerbate the condition (6).

Positional OSA has been described as having an apnea-hypopnea index (AHI) >5 that is reduced by >50% when in a nonsupine posture during sleep (6,7). The majority of OSA patients will experience up to two times as many apneas and hypopneas while supine compared with lateral or prone body positions during sleep (8,9). It has been determined that these 'positional patients' tend to be thinner and younger than 'nonpositional patients' (1). The upper airway of patients who experience positional exacerbation appears to be significantly different L'appareil de thérapie positionnelle Rematee Bumper Belt[®] pour les ronflements et l'apnée obstructive du sommeil : l'efficacité positionnelle chez des sujets en santé

La présente étude a été conçue pour examiner les changements de position corporelle découlant du port de la Rematee Bumper Belt (Rematee, Canada) pendant le sommeil. La majorité des patients présentant une apnée obstructive du sommeil (AOS) auront jusqu'à deux fois plus d'épisodes d'apnée et d'hypopnée en supination qu'en position latérale ou ventrale pendant le sommeil. Il a été avancé qu'un appareil de thérapie positionnelle pourrait réduire le nombre d'apnées et d'hypopnées chez ces patients. La présente étude a été menée pour déterminer si l'appareil de thérapie positionnelle Rematee Bumper Belt pouvait empêcher les sujets de dormir sur le dos. Les sujets à l'étude ont porté la ceinture une ou deux nuits. Chaque ceinture était munie d'un accéléromètre pour en mesurer l'orientation par rapport au plan horizontal. D'après les résultats, la ceinture créait une zone d'exclusion d'environ 80° centrée près de l'orientation de supination, où les sujets sont incapables de pénétrer. Selon les résultats de la présente étude préliminaire, l'appareil de thérapie positionnelle Rematee Bumper Belt empêche les sujets en santé de dormir sur le dos. L'appareil semble plus efficace entre 150° et 230°. Un appareil ayant cette capacité peut constituer un traitement peu coûteux au potentiel efficace pour les patients ayant une AOS. Il peut réduire le ronflement et l'indice d'apnée-hypopnée chez les patients présentant une AOS positionnelle.

than their nonpositional counterparts (4). It is postulated that, in individuals with positional OSA, sleep quality could be improved by avoiding the supine position (6). The significance of positional OSA goes beyond the issue of daytime sleepiness. It has been determined that severe stroke patients tend to sleep supine, which is known to exacerbate their sleep apnea (10,11). It is interesting to note that in an least one study (5), the lateral AHI correlated better with daytime sleepiness than did the supine AHI. Sleep studies continue to emphasize the significance of body position during sleep. It is also important to note that head and trunk position may be of equal importance when studying sleep quality in individuals with positional exacerbations of sleep apnea (12).

Devices have been designed to modify or control body position during sleep. Sewing a tennis ball into a pajama top or T-shirt is a technique that has been used for many years and has shown some efficacy (13). Unfortunately, for a variety of reasons, studies have shown very poor compliance with the tennis ball technique (<10% after 30 months) (13). While numerous other devices have been developed in an attempt to control or modify body position during sleep, most continue to demonstrate poor compliance rates (2). Although the effectiveness of some devices has been demonstrated in at least one small study (14), the longterm compliance and effectiveness of these devices needs more study. In one study involving patients with positional sleep apnea (15), preventing the patients from sleeping in the supine position was as effective as using continuous positive airway pressure for treating OSA.

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Figure 1) The Rematee Bumper Belt (Rematee, Canada) used in the present study. The belt includes shoulder straps with three inflatable bumpers. The rectangular outline of the accelerometer, located inside a pouch, is apparent in the centre of the photograph

In our sleep-disordered breathing outpatient clinic, we have encountered patients identified as having primarily positional OSA. Although we have many questions about devices and ideal body positions, we have studied one particular aspect and one device. This study was designed to investigate the effect of wearing a Rematee Bumper Belt (Rematee, Canada) on body position during the night.

Population

METHOD

In total, 15 subjects comprising students and faculty members from the university volunteered for the study; seven were male and eight were female, with age ranging from 18 to 56 years (mean $[\pm SD]$ 30±11 years). The volunteers reported that they were good sleepers and in good health. They all attended an information session during which the purpose of the study was explained, the use of the accelerometer-equipped Rematee Bumper Belt was demonstrated and they provided their informed consent. The study was reviewed and approved by the Thompson Rivers University (Kamloops, British Columbia) Ethics Committee.

The collection of positional data occurred in the homes of the volunteers. The belt shown in Figure 1 is equipped with with three inflatable bumpers. To assess its effectiveness at limiting subjects from sleeping in the supine position, volunteers slept with the bumpers inflated as well as not inflated. Of the 15 volunteers, six used the belt in both configurations. Of the remaining nine volunteers, three slept with an inflated belt and six slept with a noninflated belt. Each subject completed a diary that included age, sex, and the time in and out of bed while using the device. Subjects were also asked to complete a short postassessment of their experience with the belt. All participants indicated that it was comfortable to wear.

Instrumentation

A small accelerometer (Gulf Coast Data Concepts, model X6-2 mini, $63.5 \text{ mm} \times 25.4 \text{ mm} \times 12.7 \text{ mm}$, 18 g) was firmly inserted in a pouch located on the back of a Rematee Bumper Belt (Figure 1), placing the sensor midpoint between the shoulder blades of the subject.

The sensor recorded accelerations along three orthogonal directions shown in Figure 2A, with the negative y-axis pointing toward the head, the positive x-axis pointing toward the left shoulder and the plane formed by the x and y axes set parallel to the back of the subject. When stationary, the sensor measured the projections g_x , g_y and g_z of the gravitational acceleration vector g, and could be used as an inclinometer to measure orientation relative to g. For a subject lying horizontally (Figure 2B), the three outputs of the accelerometer were given by $g_x = -g \sin(\phi)$, $g_y = 0$, $g_z = \cos(\phi)$, in which $g=9.8 \text{ m/s}^2$ and ϕ is the angle between the positive z-axis of the sensor and the vector g. With this definition of angles, the prone, left, supine and right positions are equal to 0°, 90°, 180° and 270°, respectively, as illustrated in Figure 2C.

Just before bed time, the subject would activate the sensor and don the belt. Data-gathering sessions were between 2 h and 6 h in duration (mean 5.5 h). Once activated, the sensor would start recording at a rate of 10 Hz until turned off, or would automatically stop after 6 h. The acceleration values were stored in the internal memory of the sensor in individual files containing 1 h worth of data. Once the belt was returned, the data were immediately transferred to a personal computer for analysis.

The orientation of the torso was inferred from the sensor. For this method to be accurate, the position of the sensor relative to the subject must be constant (ie, the belt should not slip or fold during sleep). The accuracy of the approach was verified in a laboratory setting. Images of subjects continuously moving from prone to supine positions were recorded and later compared with the calculated orientations of the torso; in all cases, the agreement was excellent.

When a subject changes position during sleep (or while getting ready for sleep or getting up), accelerations are imparted to the sensor, and the values of g_x , g_y and g_z are no longer simply equal to the projection of the gravitational vector g. When this occurs, the calculated angle no longer reflects the spatial orientation of the sensor. However, the duration of these transitions are typically short (ie, seconds) compared with the duration of a measuring session (ie, hours), and they do not affect the results presented here in the form of histograms.

Analysis

Once a subject returned the belt, each file was analyzed using Excel (Microsoft Corporation, USA). The measured components of g were smoothed using a moving average of five data points, and the angle ϕ was calculated using the equation

$\varphi = \text{Tan}^{-1} (-g_x / g_z)$

A plot of φ versus time, an example of which is shown in Figure 3, was produced to assess to validity of the recorded data. Because the subjects were, for the most part, lying horizontally during their sleep, the value of

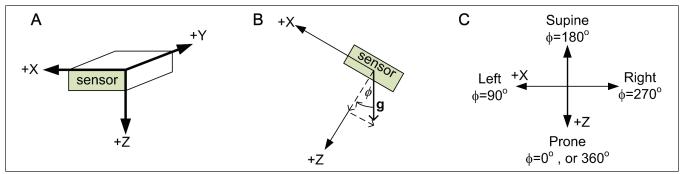


Figure 2) A The sensor measured acceleration along three orthogonal directions. B A subject lying horizontally places the y-axis of the sensor in the same direction. In this case, $g_x = -g \sin(\phi)$, $g_y = 0$ and $g_z = g \cos(\phi)$. C Correspondence between and sleeping positions for a subject lying horizontally

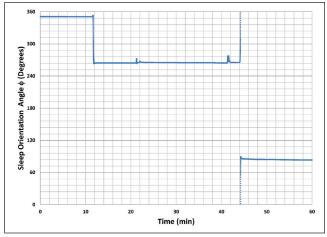


Figure 3) Evolution of the angle as a function of time for a subject wearing an inflated belt. For the first 12 min, the subject sleeps in a near prone position (\sim 350°). For the next 44 min, the subject sleeps on the right side (\sim 264°). At 44 min, the subject rolls to the right, briefly passing through the prone position. The subject remains on the right side (\sim 84°) for the final 12 min of the 60 min recording

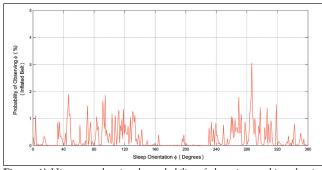


Figure 4) Histogram showing the probability of observing a subject sleeping in a given orientation while wearing an inflated Rematee Bumper Belt (Rematee, Canada). The histogram was obtained by measuring the sleep orientation of nine subjects for 44 h while wearing an inflated belt. The area under the curve between 150° and 230° is equal to 2.0%, indicating that the inflated belt is effective at preventing sleep in a supine position

g_y was typically equal to 0 and not used in the analysis presented here. In total, 67 1 h files obtained from 12 subjects sleeping with noninflated belts, and 44 1 h files obtained from nine subjects sleeping with inflated belts were analyzed and verified in this manner.

Subsequently, the effectiveness of the Rematee Bumper Belt was assessed by examining the distribution of angle as a function of sleep position. Two histograms were produced using the data analysis software IGOR (Wavemetrics, USA). The first histogram, shown in Figure 4, was obtained by combining in a single IGOR data file all values measured from subjects wearing inflated belts. The y-axis of the histogram is equal to the number of times a value of ϕ (within a range of $\pm 0.5^{\circ}$) was observed divided by the total number of observations present in the IGOR file. As such, the area under the curve (AUC) in the histogram represents the probability of observing a given range of angles ϕ . Similarly, the histogram shown in Figure 5 was obtained by combining the values of ϕ measured from all subjects wearing noninflated belts. For both histograms, it was verified that the total AUC was equal to 100%.

RESULTS

On comparing the two histograms, an important reduction in the AUC is observed between 150° and 230° in Figure 4, consistent with the hypothesis that the inflated Rematee Bumper Belt reduces the probability of sleeping near a supine position. In this range of angles, the AUC in Figure 4 is 2.0% while the AUC in Figure 5 is 24%.

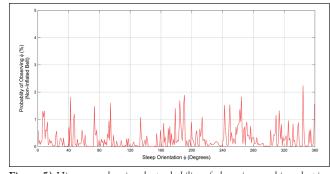


Figure 5) Histogram showing the probability of observing a subject sleeping in a given orientation while wearing a noninflated Rematee Bumper Belt (Rematee, Canada). The histogram was obtained by measuring the sleep orientation of 12 subjects for 67 h while wearing a noninflated belt. The area under the curve between 150° and 230° is equal to 24%, indicating that a noninflated belt is ineffective at preventing sleep in a supine position

TABLE 1 Comparison of the measured area under the curve (AUC) for the four basic sleep orientations of supine, left, right and prone

	AUC, %				
Sleep orientation	Inflated belt	Noninflated belt			
Left (45°< φ <135°)	43	17			
Supine (135°< φ <225°)	4.0	25			
Right (225°< φ <315°)	39	31			
Prone (315°< φ <45°)	14	28			

Results from all volunteers were used. With a noninflated belt, the AUC in the supine orientation was 25%; with an inflated belt, it was reduced to 4.0%

Dividing each histogram into four equal regions, each one centred on the supine, left, right and prone orientations, the AUC for each region was calculated (Table 1). The value of the AUC in the supine position is this time reduced from 25% to 4% when using the inflated belt. A *t* test for dependent samples was used to assess the statistical significance of the observed change in values of AUC, using the results obtained from six volunteers that used the belt in both modes (Table 2). It was determined that the use of the inflated belt significantly reduced the value of the AUC from an average value of 33% to 2.9% (t=-3.35, tc=2.57; P<0.05) and, therefore, reduced the probability of sleeping near a supine orientation. The inflated belt did not affect the AUC of the other sleep orientations in a statistically significantly manner (Table 2).

DISCUSSION

The objective of the present study was to assess the effectiveness of the Rematee Bumper Belt at significantly limiting volunteers from sleeping in a supine position. The results suggest that the Rematee Bumper Belt creates an exclusion zone approximately 80° wide centred near the supine orientation, where subjects are unlikely to sleep. The exclusion zone is illustrated in Figure 6. This range of angles is specific to the particular design of the Rematee Bumper Belt, and the range of effectiveness of other belts would need to be established.

More importantly, however, because of the location of the sensor, only the position of the torso was measured; the position of the head was not. The relationship between head and torso position has been determined to be a significant factor in airway occlusion (7). Future studies will include torso and head position. Despite our interesting findings, we are aware of several limitations to our study. Our subjects were self-reported healthy, good sleepers. Individual physical limitations and/or comorbidities could play a role in adaptation to this device during sleep. It is planned to continue collecting data to increase sample size and verify the effect of this device on a broader population base. Although the sensor and body position relationship was validated in a

TABLE 2

Measured area under the curve (AUC) for a group of six volunteers that used the Rematee Bumper Belt (Rematee, Canada) in both modes

	Orientation, AUC %								
	Left		Supine		Right		Prone		
	Inflated	Noninflated	Inflated	Noninflated	Inflated	Noninflated	Inflated	Noninflated	
Volunteer	belt	belt	belt	belt	belt	belt	belt	belt	
1	47	33	0.0	26	48	39	5.2	2.0	
2	100	25	0.0	70	0.0	5.5	0.0	0.0	
3	23	41	0.0	20	62	22	15	17	
4	6.5	0.2	1.5	40	53	50	39	10	
5	50	11	15	33	24	38	11	19	
6	47	33	0.5	8.9	52	31	0	27	
Mean	46	24	2.9	33	40	31	12	12	
t	1.68		-3.35		1.10		-0.0863		
tc	±2.57		±2.57		±2.57		±2.57		
Р	0.05		0.05		0.05		0.05		

At test for dependent samples indicates that the use of the inflated belt significantly reduces the value of the AUC (t=-3.35, tc=2.57; P<0.05) in the supine orientation from an average value of 33% to 2.9%, corresponding to a reduced probability of sleeping in a supine orientation

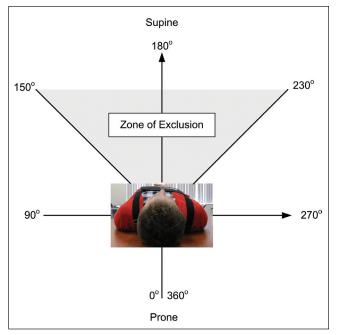


Figure 6) When inflated, the Rematee Bumper Belt (Rematee, Canada) creates an exclusion zone approximately 80° wide centred around the supine orientation, in which the subjects are effectively prevented to enter

laboratory setting, the application of this device was unattended. The absence of video recordings could call into question actual subject positions throughout the night. However, subjects did not identify issues with belt movement.

CONCLUSION

The present preliminary study suggests that the Rematee Bumper Belt positional therapy device is effective at limiting healthy subjects from sleeping in a supine position. The device appears to be most effective between 150° to 230°. A device with this capability may provide an additional, inexpensive and potentially effective treatment option for OSA patients. This device has the capacity for reducing snoring and the AHI in individuals with positional OSA.

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AUTHORSHIP: Les Matthews and Normand Fortier contributed to the conception and design of the experiment, the analysis and the interpretation of the results, the drafting and revision of the manuscript, and approval of its final version for publication.

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