ADHERENCE AND EFFECTIVENESS OF POSITIONAL THERAPY FOR OBSTRUCTIVE SLEEP APNEA SYNDROME

by

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ABSTRACT

The purpose of this investigation was to explore how adherence to a positional therapy intervention affected therapeutic outcome in participants with positional-related obstructive sleep apnea syndrome. Eighteen adult participants identified as having positional-related obstructive sleep apnea by an initial overnight polysomnography study were recruited. Participants were instructed to use a “tennis ball technique” positional device for three weeks at home and record their sleep habits and adherence before a final post-treatment polysomnography evaluation. A repeated measures MANOVA found significant effects of treatment between pre- and post-test on the objective polysomnography variables of Total Recording Time \[ F(1,17) = 5.21, p<.05, \eta^2 = .24 \], Total Sleep Time \[ F(1,17) = 8.59, p<.01, \eta^2 = .34 \], Sleep Efficiency \[ F(1,17) = 5.42, p<.05, \eta^2 = .24 \], Total REM sleep time \[ F(1,17) = 9.91, p<.01, \eta^2 = .37 \], and the Apnea-Hypopnea Index \[ F(1,17) = 14.28, p<.001, \eta^2 = .46 \]. Sleep onset latency was not statistically significant. There were significant effects of treatment on the subjective measures of the Functional Outcome of Sleep Quality \[ F(1,17) = 8.92, p<.01, \eta^2 = .35 \], Pittsburgh Sleep Quality Index \[ F(1,17) = 11.2, p<.01, \eta^2 = .39 \], Epworth Sleepiness Scale \[ F(1,17) = 6.69, p<.05, \eta^2 = .28 \], and the Brief Symptom Inventory \[ F(1,17) = 5.14, p<.05, \eta^2 = .23 \]. No significant interaction effects were found between treatment and adherence when participants were grouped post-hoc into an adherent or non-adherent categories based on their self-reported daily log data. In summary, the results of this study indicated that the positional device was efficacious for significantly improving both
objective polysomnography variables and subjective variables of sleep. The results also indicated even partially adherent participants reported significant improvements in nighttime sleep quality and quality of life after the three week treatment period. Mixed Linear Modeling demonstrated that significant improvements in sleep quality, time to sleep onset, and total sleep time were not seen until the last weeks of treatment. This study found very acceptable adherence rates with this positional device design; all participants were able to utilize the therapeutic device on at least a portion of every night during the three-week intervention.
AIMS OF STUDY

**General Purpose:** The purpose of this study is to explore the efficacy of positional therapy for obstructive sleep apnea syndrome and to investigate differential effects of adherence to this treatment over time. Additionally, the general aim is to identify existing and emerging factors that may influence adherence and the impact of these factors on therapeutic response and psychosocial outcomes.

*Specific Aims for Research Study*

**Primary Aim:** To evaluate the short- and long-term efficacy of a positional sleep apnea device that is based on the design standard described in the literature as “the tennis ball technique” and that is most often utilized in prescriptive practice.

**Secondary Aim:** To establish if increased adherence to this intervention results in improvements in nighttime sleep and daytime functioning.

**Tertiary Aim:** To provide descriptive data on what factors might impact positional therapy acceptance and adherence and to explore the differential effects of adherence over time.
CHAPTER I
INTRODUCTION AND LITERATURE REVIEW

I.) Introduction

Sleep disturbances are commonly reported around the world and can have potentially serious consequences if not treated properly. In the United States, 10-20% of adults report persistent sleep problems (Ancoli-Israel and Roth, 1991). One of the most prevalent causes of sleep disturbance fall within the broad category of sleep disordered breathing. All sleep disordered breathing syndromes are related phenomenon where a cessation or partial cessation of airflow while sleeping ends with a physiological arousal. The most common type of sleep apnea is obstructive sleep apnea which is caused by a complete or nearly complete collapse of the air passageways causing an obstruction in the upper respiratory tract. For many individuals, obstructive sleep apnea is a progressively worsening disorder. The repetitive respiratory event-related arousals and periods of reduced airflow associated with even mild obstructive sleep apnea cause the respective chronic sleep fragmentation and cerebral hypoxia that often results in excessive daytime sleepiness, neuropsychological impairment, mood and anxiety disorders, reduced quality of life, and increased risk for mortality (Kotterba, S., Rasche, Widdig, Duscha, Blombach et al., 1998; Quan, Wright, Baldwin, Kaemingk, Goodwin et al, 2006). The prevalence rate of obstructive sleep apnea varies as reported in the literature. The most conservative
estimates are that 2% of adult females and 4% of adult males meet minimal diagnostic
criteria for obstructive sleep apnea (Young et al., 1997). Several moderating factors can
substantially increase the risk and prevalence of obstructive sleep apnea. Obesity, family
history, male sex, being from certain racial groups and increased age have all been
identified as risk factors for obstructive sleep apnea (Kripke et al, 1997). Differences in
diagnostic criteria may also influence the reported prevalence of obstructive sleep apnea
in the literature. Another strong factor influencing the prevalence of obstructive sleep
apnea is the position or posture that individuals assume while asleep.

While awake, neuromuscular control of the pharyngeal muscles, tongue and other
structures of the upper airway maintain an open airway. As a result of the general
reduction in skeletal muscle tone that is witnessed throughout the body during sleep,
these structures can relax causing a decrease in airway apace and reduction in airflow
(Schwartz, O'Donnell, Baron, Schubert, Alam et al, 1998). The effect of gravity on the
upper airway while asleep in the supine posture is the predominant mechanism that
results in the anatomical and physiological changes of maintaining this posture. The
improvements in sleep disordered breathing that are reported in the lateral or prone
sleeping positions are thereby thought to be the result of reducing the tendency of the
tongue to relapse posteriorly which makes the collapse of the pharynx less to occur from
the reduction in this gravity effect. The supine sleep posture worsens the breathing
function during sleep in the majority of individuals identified as having sleep disordered
breathing (Oksenberg and Silverberg, 1998).
It is estimated that more than half of obstructive apnea patients have twice as many apnea events when in a supine position and thus are considered to be positional patients (Mador, Kufel, Magalang, et al., 2005; Oksenberg, Silverberg & Arons, 1997). For these patients, sleeping in a non-supine position decreases the frequency and severity of the obstructive respiratory events (Cartwright, 1984; Oksenberg, Khamaysi, Silverberg, & Tarasiuk, 2000. For a substantial proportion of these positional patients, avoiding the supine position during sleep can reduce their apnea-hypopnea index (a metric of severity that represents on average how many respiratory disturbances occur per hour during a diagnostic evaluation period/night) values to a level below the threshold that is considered to be pathological (Oksenberg & Silverberg, 1998). There are several other factors that seem to influence the degree of “positionality” in patients with sleep disordered breathing. Based on the comprehensive work of Oksenberg and Silverberg (1998) who studied 574 consecutive adult obstructive sleep apnea patients there has been some identification of those patients that are more likely to have a positional dependence associated with their diagnosis of obstructive sleep apnea. In general, they have Body Mass Index (BMI) scores below 30 and an overall apnea-hypopnea index below 40. Age appears to be a weaker predictor of the positional dependency where patients between the ages of 20 and 60 have approximately equal rates of positional dependence. However, they reported that older obstructive apnea patients above 60 years of age are less likely to be positional than younger obstructive apnea patients. Therefore, a positional patient is
more likely to be thinner, have a milder form of obstructive apnea and be below the age of 60 years old.

To establish a diagnosis of sleep disordered breathing, patients are most typically referred to a sleep laboratory for a nocturnal polysomnographic study that measures a wide variety of physiologic variables to assess the frequency and severity of sleep disordered breathing. The American Academy of Sleep Societies Standard of Practice (Martin et al., 1985) recommendations requires body positioning monitoring in all diagnostic sleep studies. However, not all diagnostic sleep facilities record and analyze their breathing abnormalities data, including apnea-hypopnea index, according to body position. Diagnostic procedures for the identification of sleep disordered breathing without recording body position changes or without having patients sleep in a variety of positions can result in inaccurate diagnoses. For example, false positive diagnoses may occur in the instance of a positional patient sleeping predominantly in the supine position during the diagnostic study where the severity of the apnea-hypopnea index is over-estimated. Conversely, false negative diagnoses may occur in the instance that positional patients sleep predominantly in the lateral or prone positions during a diagnostic study where the severity of the apnea-hypopnea index would be under-estimated. Diagnostic studies performed in a sleep laboratory facility are assumed to be representative of a normal night at home. However, studies investigating the difference between naturalistic settings and sleep laboratory settings in regards to sleeping posture have found that patients sleep significantly longer in the supine position and significantly less in the
prone position when they are in a diagnostic setting (Mertersky and Castriotta, 1996; Hartse, Logan, Branham, et al., 1996; Nau, Stuckey, Hedge et al, 1997). Sleep posture is therefore a critically important variable to consider when evaluating patients for obstructive sleep apnea.

II.) Interventional Studies

A.) Positional Therapy as a Primary Intervention

Despite the powerful influence of posture on obstructive sleep apnea, research studies aimed at focusing on interventions that prevent patients from sleeping in the supine position have been lacking. There have no reports in the literature of the incidence of positional therapy as a primary or adjunctive intervention for the treatment of obstructive sleep apnea. Anecdotal accounts seem to indicate that currently it is somewhat rarely used by most sleep clinicians. Research studies aimed at testing the efficacy and effectiveness of positional therapy as a primary treatment have been conducted on a comparatively small number of participants.

A variety of techniques have been utilized in research studies to date to assist patients in avoiding the supine position of sleep for treatment of their obstructive sleep apnea condition. The main goal of such an intervention is to provide or suggest a practical and inexpensive method that prevents a patient from sleeping in the supine position and thereby reducing their apnea-hypopnea index below a threshold that is considered to be clinically significant. The so-called tennis-ball technique is the method
most widely reported in the literature on positional therapy (Oksenberg and Silverberg, 1998 for a review). This technique involves attaching one or more pockets to the back of a shirt that will be worn at night. Tennis balls are then placed in the pockets that run along the spine and thereby help to prevent individuals from sleeping in the supine position. Perhaps the first mention of the tennis ball technique as a method of avoiding the supine posture was reported in an abstract by Kavey et al. (1982). They reported on the long-term outcomes of two patients that showed a significant decrease in objectively measured apnea events. Alarm systems that awaken a patient when they are in the supine position have been used successfully (Cartwright et al., 1985). The use of a head and shoulder pillow to elevate posture has been reported to be somewhat efficacious, but was not tested on patients identified as positional patients (Skinner, Kingshott, Jones, Homan & Taylor, 2004). Freebeck and Steward (1995) studied 21 consecutive patients identified by an initial diagnostic sleep study as being positional patients with a follow-up therapeutic positional barrier-like device consisting of a rectangular shaped foam material surrounding a hard cylindrical core, which was secured to the participant’s back. They reported that the device allowed 90% of participants to spend less than five percent of their total sleep in the supine position and 80% of patients reduced their apnea-hypopnea index to within normal limits (apnea-hypopnea index < 5). Jokic, Klimazewski, Crossley, Sridhar and Fitzpatrick (1999) conducted a study with 13 positional patients in a randomized, single-blind crossover comparison aimed at comparing continuous positive airway pressure therapy and positional therapy for two weeks each. While the apnea-hypopnea index was reported to be lower and minimum oxygen saturation was higher
during the continuous positive airway pressure therapy period compared to positional therapy period, there were no significant differences reported in Epworth Sleepiness Scale scores, sleep architecture, maintenance of wakefulness testing results, neuropsychological test performance, mood scales or quality-of-life measures. With similar gains seen in both subjective and objective sleepiness, mood, cognitive measures and quality of life, these authors concluded that positional therapy and continuous positive airway pressure therapy have similar efficacy in the treatment of patients with positional obstructive sleep apnea.

When tested, the techniques that utilize a barrier that is worn along the spine appear to be the most effective in preventing patients from sleeping in the supine position and it may be possible that avoiding the supine position could be learned after a trial period. There have been a few studies reported in the literature reporting on whether avoiding the supine position can be a learned and maintainable behavior. The interventions in these studies involving small sample sizes have been varied and have consisted of instructions to avoid the supine position without a device (Chaudhary, Chaudhary and Kolbeck, 1986), to use an alarm system (Cartwright, Lloyd, Lilie et al., 1985), or use positional barriers along the spine (Freebeck and Stewart, 1995; Hurry, Waters and Bruner, 1995). The results of these studies, taken together, is that approximately half of patients will successfully learn to avoid the supine posture with or without the use of a device but the other half will require the continuous use of some type of device in order to effectively avoid the supine position during sleep.
B.) Other Interventions for Obstructive Sleep Apnea

Obstructive sleep apnea is most frequently treated with continuous positive airway pressure with estimates that approximately 80% of individuals that receive a diagnosis of obstructive sleep apnea are treated with continuous positive airway pressure therapy (Guilleminault, Stoohs, & Clerk, 1993). Continuous positive airway pressure changes the air pressure in the upper respiratory tract by wearing a mask attached to a compressor over the nose. The change in air pressure acts as a pneumatic splint to maintain an open airway thereby effectively eliminating obstruction in the structures of the upper airway. This therapy must be used every night to gain full benefits but it is estimated that fewer than half of patients prescribed continuous positive airway pressure therapy maintain regular adherence one year later mostly due to reported discomfort (Reeves-Hoche, Meck, and Zwillich, 1995). The side effects of continuous positive airway treatment for obstructive sleep apnea patients, such as discomfort associated with the mask, noise and the need to wear it as a prosthetic every night certainly contribute to the lack of compliance seen with this intervention.

Another treatment for patients with obstructive sleep apnea is by surgical interventions such as uvulopalatopharyngoplasty, but the efficacy of this procedure is reported to be uncertain especially for patients with more severe forms of obstructive sleep apnea (Itasaka, Miyazaki, Tanaka, and Ishikawa, 2001). There is substantial
variability in the size, shape and orientation of the several possible anatomical structures of the upper respiratory airway that collude to cause sleep disordered breathing. As a consequence, most patients may not be suitable candidates for a surgical intervention due to the difficulty in identifying the structures that might be surgically altered or removed for a successful surgical outcome that improves respiratory functioning while asleep. For individuals with mild to moderate obstructive sleep apnea, oral devices such as tongue-retaining devices (Higurashi, Kikuchi, Miyazaki, and Itasaka, 2002) and mandibular advancement splints (Gostopoulos, Chen, Qian & Cistulli, 2002) have shown some promise as efficacious methods in reducing the apnea-hypopnea index and daytime sleepiness for almost half of patients that wear them regularly. Because of the strong positive correlation between obstructive sleep apnea and obesity, many clinicians recommend weight loss in addition to any other interventions. Weight loss has been demonstrated to reduce the severity and progression of obstructive sleep apnea (Peppard, Young, Dempsey & Skatrud, 2000) and has also been shown to reduce apnea-hypopnea index in some patients across the threshold from non-positional patients to positional (Oksensberg and Silverberg, 1997). Positional therapy as an adjunctive therapy has been shown to be complementary to all of these interventions (Cartwright, 1985; Katsantonis, Miyashiki and Walsh, 1990; Pervaginie and Shepard, 1992; Itasaka, Miyazaki, Tanaka, and Ishikawa, 2001).
III.) Research Problem

Despite some promising initial reports on positional therapy as a treatment for obstructive sleep apnea, there is a paucity of evidence attesting to the long-term effectiveness and adherence to this treatment. The research, to date, that has reported on positional therapy has differed in how positional therapy is prescribed in clinical settings. Research studies uniformly provide the actual positional device to research participants, but clinical settings rarely if ever provide the same service (Oksenberg and Silverberg, 1998). Since there are currently no manufacturers of positional devices in the United State, the clinician may request that a patient construct a device by themselves with the instructions that they continue to utilize the self-made apparatus. It is unknown whether patients that have been asked to create their own devices actually do so and whether these devices are as effective as those used in research studies. There are currently no clinical standardized guidelines of practice for positional therapy which may contribute to quite variable responses of this intervention for patients.

Even when prescribed by sleep specialists, some patients may not receive adequate information from their referring physicians. In a short report by Freebeck and Stewart (1995), the authors reported on the results of a follow-up phone survey for 31 of their patients whose sleep reports recommended instituting a positional device for their recent diagnosis of positional-related obstructive sleep apnea. They were interested in determining what therapy was recommended by the referring physician who received the report, what therapy was actually implemented and whether they remained compliant
with their therapy. Phone surveys to the patients indicated that 39% were informed by their physicians of the recommendation to institute a positional device for their obstructive sleep apnea treatment but only two attempted to wear a positional device and both of these patients reportedly discontinuing its use after a few weeks. Despite the clear recommendation for positional treatment in all 31 patients, surgery was recommended for 26% of the patients, continuous positive airway pressure therapy for 10% and 26% reported that had not received any recommendations. This study highlights the possibility that many referring physicians may never inform their patients of the recommendation for positional therapy by sleep specialists.

Presumably, most clinicians who utilize positional therapy will review a diagnostic study with a patient indicating that the results of their diagnostic sleep study suggest a strong positional dependence on the occurrence of any sleep-related breathing abnormalities. When indicated, a prescription for positional therapy is administered by providing a description of the device to be constructed with instructions for continued use. However, whether patients actually construct any form of positional therapy remains untested. Even if the patient constructs a device based on a description provided by their clinicians or are provided with such a device, there have been no reports in the literature as to whether this prescription is followed and there are no follow-up data available that might suggest if such a prescription is effective.
It may be only in combined clinical and research settings that positional devices are routinely provided for participants. Clinical patients are prescribed positional therapy by their clinicians and are advised to continue to use the devices indefinitely or in the instance of a specified research study protocol the patients are requested to wear the device for a specific amount of time. Okensenberg et al. (2006) reported on a “tennis ball technique” study where 76 consecutive patients with positional obstructive sleep apnea who chose to use positional therapy rather than CPAP therapy were asked about their use at a 6-month follow-up. Of the 50 patients that responded to a mailed self-reported questionnaire, 38% said they were still using the device nightly, 24% said they used it initially but were currently avoiding the supine position by will and 38% said they also used it initially but did not believe they were effective in avoiding the supine position while sleeping without it. They reported that patients that maintained adherence to the positional therapy reported significantly greater improvements in self-reported sleep quality, daytime alertness and snoring. Patient discomfort accounted for more than 60% of complaints that led to discontinuation of the therapy. The remaining two reasons for discontinuing therapy were the belief that the intervention was not effective for sleepiness and snoring (15%) or that it did not sufficiently prevent sleeping in the supine position (15%). A similar study by Bignold, Deans-Costi, Goldsworthy, Robertson, et al. (2009) investigated long-term adherence with the “tennis ball technique” positional device and reported substantially poorer compliance. A self-report questionnaire (Okensenberg et al., 2006) was completed by 67 patients that had been prescribed positional therapy over a four year period. The average time between the initial prescription and response was
approximately 30 months. Less than 10% of respondents reported that they were still using positional therapy mostly due to discomfort. The question of whether participants utilize their prescribed devices on a night to night basis and for what portion of the night has remained largely unanswered.

There is only a single research study that has reported adherence to positional devices when patients are in their home environment (Skinner, Kingshott, Filsell, & Taylor, 2008). Using a portable recording device, the authors measured supine and non-supine body positions with a three-dimensional gravity dependent sensor for one month. They reported that of the 19 participants involved in the study, 15 stayed supine <10% of the night, two stayed supine 10-14% of the night and the remaining two spent 15-20% of the study time in the supine position. These investigators utilized a “tennis ball technique” device and reported that only one participant in their cohort was unable to wear the device during the 1-month treatment period. They also reported that there were no differences in a subjective assessment of sleepiness and quality of life between the baseline and post-treatment periods.

However, there are no reports in the literature that have assessed patients over time to determine whether differential amounts of nightly adherence to positional therapy influences their outcomes at post-study. Also unknown is whether participants daily sleep estimates are influenced by the adherence or non-adherence to the treatment and
whether adherent and non-adherent individuals respond differently to the intervention over the course of treatment.
CHAPTER 2
METHODS

I.) Study Procedure

A.) Participant recruitment. Participants were screened from the results of previously obtained diagnostic sleep studies that were conducted at regional clinical sleep facilities. Participants were referred by local physicians specializing in sleep medicine that had reviewed potential participant diagnostic sleep data to ensure the appropriateness of participating in this clinical intervention trial. Under the supervision of the referring physicians, participants were referred concurrently or retrospectively from an analysis of previously recorded diagnostic sleep studies. Those participants that were deemed appropriate for the research study by a retrospective investigation of their diagnostic sleep reports were contacted for participation in the research study by the staff of the various local sleep disorders center and under the supervision of their sleep physician. Initial approval for contact by the experimenter was confirmed by the professional staff. Participants were selected for inclusion in the study based on the results of previously obtained diagnostic sleep data that indicate that they were candidates most likely to benefit from positional treatment as reported in the literature. Specifically, these inclusion criteria are

* Adults between the ages of 18 and 65

* A primary diagnosis of obstructive apnea
* An Apnea-hypopnea index profile indicating respiratory events evidenced during their baseline diagnostic sleep study were more than twice as likely to occur in the supine position as in the lateral or prone sleeping positions.

* An indication that that the participant had an apnea-hypopnea index of less than 5 events per hour while sleeping in the lateral position of sleep (i.e. patients must have a non-pathological apnea-hypopnea index in the lateral position).

**B.) Exclusion Criteria.** The participants did not have another primary medical or psychiatric disorder or sleep disorder that would interfere with the potential gains of adhering to positional therapy for the treatment of their sleep apnea disorder. Excluding criteria included: overt cardiopulmonary disease, coronary artery disease, respiratory disease, severe psychiatric disease, substance abuse, uncontrolled hypertension, and orthopedic or musculoskeletal disabilities that would preclude sleep in positions other than supine.

**II.) Study Design**

This study was a pre-test/post-test intervention study. All participants received the positional apnea device. Four weeks of data were collected: a one week baseline followed by a three-week intervention period. At the end of the intervention period all participants received a post-test nocturnal polysomnogram (diagnostic sleep) study and completed all remaining paperwork upon awakening before leaving the laboratory.
A.) Clinical Interview. After referral, participants were asked to come to the sleep research laboratory for an initial visit to sign an informed consent form for participation in the research study. They were asked to complete several baseline measures to establish their current and retrospective sleep habits. Participants completed three retrospective questionnaires (Pittsburgh Sleep Quality Index, Sleep Apnea Quality of Life Index, and the Functional Outcomes of Sleep Questionnaire) to obtain recent historical information regarding their sleep continuity status during the last month. They also completed a daytime sleepiness measure (Epworth Sleepiness Scale) and a single mood measure (Brief Symptom Inventory). An initial brief interview conducted by the principal investigator collected additional demographic and medical information. All participants provided information on their historical and current use of any interventions for their identified sleep apnea disorder. At the end of the interview and after completing the questionnaires, each participant received daily sleep logs to be completed each morning upon awakening. After the two week period of baseline assessment, patients returned to the sleep laboratory to return the completed sleep logs.

B.) Treatment. During this second visit, each participant received a brief intervention that attempted to approximate as closely as possible the standard prescription process for positional therapy of obstructive sleep apnea as practiced by clinical sleep specialists. Specifically, they received a brief review of the results of their initial nocturnal polysomnogram study that emphasized the positional nature of their apnea condition. This was conducted by the principal investigator. A review of nocturnal
polysomnogram results by a health care provider has been reported to improve patients’ acceptance and subsequent compliance of positional therapy (Oksenberg and Silverberg, 1998). A brief psycho-educational period provided discussion of the importance of treatment of their disorder and why positional therapy may be an effective treatment for their diagnosed disorder.

All participants received a fitted positional therapy device that had already been constructed and was completely ready to wear. The design of the positional device was a prototype model based on the information provided in the scientific literature on the topic of “tennis ball method” of treatment delivery (Hurry, Waters, & Bruner, 1995). The devices were purchased from the clinical research facility of one of the originators of this intervention, Dr. Rosalind Cartwright from Rush University Medical School.

The specific design was a simple construction that had a single long vertical cloth pocket sewn into the back of a plain white T-shirt. The participants were individually fitted with the T-shirts to insure a snug fit. They were each provided with three standard tennis balls and instructed to insert these into the pocket on the back of the shirt before going to bed each evening. The pocket was approximately 40cm in length and 10cm in width. It was carefully sewn onto the back of the T-shirt and was “flush” with the T-shirt. The pocket ran lengthwise along the area located between the shoulder blades to the lower lumbar region along the spine. At the top of each pocket an extra “fold” of cloth was sewn into the design and utilized to prevent the tennis ball from falling out of the
pocket during the night. This device was purposely designed to make it convenient to remove the tennis balls so that the sleep shirt could be laundered at the discretion of the participant. Participants were asked to wear the positional device for the next three weeks at home and to bring the device and the accompanying tennis balls to the final appointment. The participants were asked to complete daily sleep log information for the duration of the at-home intervention period and to return the sleep log data when they returned in three weeks.

At the end of the three-week intervention period, each participant returned to the laboratory for a nocturnal polysomnogram study. They were instructed to bring their positional devices with them to the lab and to utilize the apparatus during the nocturnal polysomnogram study. All participants wore the positional device for the entire night of the post-test polysomnography study. Upon awakening, participants were asked to fill-out the identical measures that were completed during the initial baseline assessment. The post-test nocturnal polysomnogram data was provided to the patient and to their referring physicians at the completion of the study.

III.) Measures

A.) Objective Measures

*PSG.* Polysomnography is considered the gold-standard of measurement in sleep research. The measurement of the nocturnal polysomnogram included:
electroencephalogram (C4-A1, C3-A2, O2-A1, O2-A1 derivations), electro-oculogram, sub-mental electromyogram, electrocardiogram, oral-nasal airflow measured with a thermocouple sensor (Pro-Tech services, Mukilteo, WA), ribcage and abdominal effort measured by piezoelectric belt sensors, snoring sensor, a calibrated body position sensor, continuous oxygen level monitoring (Ohmeda Box 3700 pulse oximeter, Boulder, CO) and audio/video monitoring. The participants were asked to sleep for a minimum of six hours during this overnight study. Sleep records were scored using American Academy of Sleep Medicine guidelines (Iber, Ancoli-Israel, Chesson, Quan, 2007) by an independent registered polysomnographic technologist (RPSGT) that had demonstrated 90% inter-rater reliability with other registered technologists. The following seven variables were utilized in the data analyses and were collected by polysomnography:

*Total Recording Time (TRT): amount of minutes that from lights out to lights on.

*Total Sleep Time (TST): amount of minutes asleep during the total recording time.

*Sleep Onset Latency (SOL): the time to first sleep entry episode defined as 30 seconds of stage 2 or sometimes 1 sleep.

*Total REM sleep time (REMtot): the total number of minutes of REM sleep during the study.
*Sleep Efficiency (SE): the proportion of time in bed actually asleep expressed as a percentage.

*Total Apnea-hypopnea index (AHI): the number of respiratory disturbances (hypopneas or apneas) per hour averaged over the total sleep time.

*Periodic Limb Movement Index (PLMI): the number of limb movements per hour averaged over the total sleep time.

B.) Subjective measures

ESS. The Epworth Sleepiness Scale (Johns, 1991) is a self-administered questionnaire measuring daytime sleepiness in adults. The Epworth scale is likely now the most commonly used paper-based rating of sleepiness in sleep disorders research. It asks participants to rate their likelihood of dozing in eight everyday situations associated with greater to lesser sleepiness from “watching TV” to “driving a car”. The instrument seeks ratings of recent sleepiness over the previous month. The Epworth scale yields typical mean scores of 5 in healthy working normal subjects on a scale of 0-24. The most widely used clinical cutoff for clinically significant sleepiness is 9 or greater. Patients with moderate to severe obstructive sleep apnea may typically have ratings 2 or more
standard deviations greater than normal sleepers (Johns, 1997). It has demonstrated very good psychometric properties for reliability and validity during the last 20 years.

**PSQI.** The Pittsburgh Sleep Quality Index (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989) has wide acceptance as a questionnaire that is useful for measuring overall sleep quality in a wide variety of sleep populations. It has demonstrated good reliability and validity for a variety both normal and sleep disordered populations (Backhaus, Junghanns, Broocks, Riemann, and Hohagen, 2002; Carpenter & Andrykowski, 1998). The PSQI has 24 items that contain questions about restless legs syndrome, sleep apnea, parasomnias, insomnia, sleep/wake rhythms and the frequency of common nighttime disturbances that may have occurred during the previous one month period (Buysse et al., 1989).

**Sleep Log (subjective sleep measure).** The sleep log was completed every morning upon awakening and provided estimates of bedtime hour, time to fall asleep, the number and duration of awakenings during the night, the time of the final awakening and the time the participant arose out of bed. From these variables the additional variables of number of total minutes awake during the night between sleep onset and sleep offset, sleep efficiency percentage, total sleep time, and total time in bed were calculated. Additionally, two items pertaining to estimate of position were utilized. For both the pre- and post-treatment portions the question “How many hours of the night did you sleep on your back?” was utilized and during the treatment phase only the question “How many
hours did you sleep wearing your sleep T-shirt?” was included. Sleep logs have been reported to be a reliable measure and to have good validity when compared with polysomnography (Coates, Killen, George, Marchini, Hamilton, S. & Thoresen, 1982; Rogers, Caruso, & Aldrich, 1993).

**FOSQ.** The Functional Outcomes of Sleep Questionnaire (Weaver, Laizner, Evans, et al., 1997) was developed to assess the impact of sleep disorders associated with excessive daytime sleepiness on activities of daily living and is reported to have acceptable reliability and validity. The FOSQ is a self-administered 30 item questionnaire that focuses on five domains that may be affected by sleepiness and fatigue: general productivity, social interaction, activity level, vigilance, and intimate relationships and sexual activity. Each item is scored on a four-point scale where the range of possible scores for each is 1 (most dysfunctional) to 4 (least dysfunctional). Higher total scores indicate less difficulty with a particular activity due to sleepiness.

**BSI.** The Brief Symptom Inventory (Derogatis & Spencer, 1982) was developed from its longer parent instrument, the Symptom Checklist 90-R (CL-90-R). It has been demonstrated by psychometric evaluation to be an acceptable shorter version that helps evaluate a broad range of psychological problems and symptoms of psychopathology. The questions focus on the past 7 days and participants are asked to indicate the extent to which they have been bothered by the symptom rather than the severity of the symptom. There are 48 items that are rated on a 5-point scale ranging from not at all (0) to
extremely distressed (4). Both test-retest and internal consistency reliabilities are shown to be very good for the primary symptom dimensions of the BSI and it correlated highly with the SCL-90-R. It is reported that the BSI has high convergent validity with the MMPI provide good evidence of convergent validity and factor analytic studies of the internal structure of the scale have contributed evidence of construct validity (Derogatis & Melisaratos, 1983).

SAQLI. The Calgary Sleep Apnea Quality of Life Index (Flemons & Reimer, 1998) was developed as an evaluative instrument to measure within-subject change in response to therapeutic intervention for sleep apnea. During its development these investigators demonstrated that the items in each of the four SAQLI domains of normal daily routine, social interactions, emotional functioning, and symptoms were similar across strata of disease severity and sex. Good test-test reliability and construct validity was determined by comparing this instrument with the Short Form -36 Health questionnaire, the Ferrans and Powers Quality of Life score and the global quality of life score (Flemons & Reimer, 2002).

IV.) Participants

A total of 89 sleep disorder center patients in the Tucson Arizona area were identified by their sleep center physician staff as potential participants in the current study. All 89 patients that were contacted or referred for the research study had received a diagnostic polysomnogram during the previous 12 months before entering the study.
All referred patients met criteria as a positional obstructive sleep apnea patient and were contacted by telephone by the center staff members. Of this initial group of 89 patients, 19 agreed to be in the research study. All 19 participants who met study criteria were recruited and fully completed the study. One participant was not included in any of the analyses due to irretrievably lost data. Five participants did not submit any daily sleep log diaries and were not included in the data analyses examining sleep log responses. These five participants were also not included in the statistical analyses examining adherence since the sleep logs were the primary indicator of adherence in this study. Finally, there were 18 participants that had data available for the pre- and post-test MANOVA analyses comparing whole group means. These 18 participants’ demographic and anthropometric data are shown in Table 1. There were four females and ten males; nine participants were married and five were divorced, widowed or single.

The cohort of 14 participants that had retrievable sleep diary data were divided into two groups post hoc. The first group consisted of participants that reported less than or equal to a single night of not wearing the device. Adherence, therefore, is defined in this study as any participant in this cohort that wore the device on every night of the three-week treatment phase of the study or any participant that wore the device on every night of the treatment period except one night. For that single night of not wearing the device the participant could have reported anywhere between the whole night or a portion of the night that they did not wear the positional device. This group, finally, consisted of eight participants defined as “adherent.” The second group of six participants consisted
of those that reported greater than a single night of non-adherence and are henceforth defined as “non-adherent.” This splitting of the entire cohort was done to break this breakdown into two groups resulted in nearly identical number of participants in each group: Adherent Group (N=8) and Non-Adherent Group (N=6). All participants completed at least seven days of baseline diary data and completed at least 14 days of treatment diary data. The distribution of the number of nights participants reported being non-adherent during the three-week treatment phase of the study is reported in Table 2.

V.) Statistical Analyses

A repeated measures multivariate analysis of variance (MANOVA) was utilized to examine the effects of treatment (pre-post) by adherence group (adherent – non-adherent) for several objective polysomnography variables (DV’s). The objective sleep measures of apnea-hypopnea index, sleep onset latency, total sleep time, sleep efficiency amount of REM sleep and total supine sleep time were used as dependent variables in the MANOVA analysis. An additional MANOVA analysis was conducted to determine treatment by adherence group effects for subjective daytime and sleep functioning. Self reports of sleep quality (Pittsburgh Sleep Quality Index), sleepiness (Epworth Sleepiness Scale) and quality of life (Sleep Apnea Quality of Life Index) data were used as dependent variables. These analyses were completed with the 14 participants that had intact sleep diary data since adherence here is measured by self-report on the daily sleep logs.
How individuals change and develop over a period of time is a very important question within the social sciences. When looking within the framework of an intervention, this question is of particular importance. How individuals responded differentially to positional therapy for sleep apnea syndrome was investigated. Specifically, changes in self-reported sleep throughout the course of the 35-day study period were investigated. Examinations of change in sleep over time included whether adherence to the provided device therapy effected changes in sleep over time.

Examination of change over time was done through specification of a Mixed Linear Model. A Mixed Linear Model contains both fixed effects and random effects. In order to look at possible changes in time the week was designated as the fixed (constant) variable compared with a dependent (random) variable of change. Each week of the two weeks of baseline and each week of three weeks of treatment were included for a total of the five separate weeks compared in pair-wise combinations. Each self-reported sleep variable (e.g., sleep quality, sleep onset latency, etc.) served as a different dependent variable. All effects were estimated via SPSS version 17.0 (SPSS Inc., Chicago, IL, USA), using Mixed Models procedures. Analyses of change using mixed models procedures has many benefits, including (1) use of all available data, (2) no list-wise deletion, and (3) ability to capitalize on the many repeated assessments (Singer & Willett, 2003).
Additional repeated measures multivariate analysis of variance (MANOVA) was utilized to examine the overall effects of the treatment on the mean values for several objective polysomnography variables and subjective self-report instrument measures. These analyses differed from the previous MANOVA in that all 18 participants were included and were not separated by any adherence criteria. The objective sleep measures of apnea-hypopnea index, sleep onset latency, total sleep time, total recording time, sleep efficiency, amount of REM sleep and were used as dependent variables in the MANOVA analysis. The subjective data included in the analyses were also analyzed with a repeated measures multivariate analysis of variance (MANOVA). The instruments included were retrospective measures of sleep quality (Functional Outcomes of Sleep Questionnaire, Pittsburgh Sleep Quality Index, Calgary Sleep Apnea Quality of Life Index), sleepiness (Epworth Sleepiness Scale) and a mood measure (Brief Symptom Inventory).
CHAPTER 3

RESULTS

A repeated measures multivariate analysis of variance (MANOVA) was utilized to examine the effects of adherence on treatment (pre-post) on the mean values of several objective polysomnography variables (DV’s). These initial analyses included only the 14 participants that had the retrievable sleep diary data necessary to assess adherence. The omnibus test was significant Pillai’s Trace = .91, $F(6, 8)=14.09, p<.001, \eta^2=.91$) Multivariate test assumptions were all met. There was no interaction effect between adherence and treatment. There was a significant main effect for treatment on the apnea hypopnea index, $F(1,13) = 17.98, p < .001, \eta^2= 0.58$. There was a significant main effect for treatment on total sleep time, $F(1,13) = 8.54, p < .05, \eta^2= 0.40$. There was another significant main effect for treatment on total amount of REM sleep, $F(1,13) = 8.43, p < .05, \eta^2=0.39$. There was a final significant main effect for treatment on amount of time spent asleep in the supine position, $F(1,13) = 15.88, p <0.001, \eta^2=0.82$. There were no main effect for treatment on sleep onset latency and sleep efficiency. For the significant effects of treatment, there were moderate to strong effects. There were statistically significant differences ($p = <.001$) in the amount of PSG recording time between baseline and post-test when using a t-test. The mean total recording time was significantly less total recording time at baseline (mean = 353.7, sd = 129.4) when compared with the post-test study (mean = 428.3, sd = 419.9). An additional statistical
analysis using total PSG recording time as a covariate found that this variable was not significantly mediating these results. Please refer to Figures 1 through 6 for a graphing of the means of these variables by adherence group at baseline and post-test.

Subjective measures were examined by MANOVA to determine the effect between adherence and treatment for the 14 participants that had the retrievable sleep diary data necessary to assess adherence. The omnibus test was significant for treatment Pillai’s Trace=.58, $F(3,10)=4.57$, $p<.05$, $\eta^2=.58$). There was no significant interaction between adherence and treatment. There was a significant main effect of treatment on quality of life, $F(1,12) = 15.89$, $p<.01$, $\eta^2=.57$. There was also a significant main effect of treatment on Sleep Quality $F(3,10)=6.92$, $p<.05$, $\eta^2 = .37$. There was no significant main effect of treatment on sleepiness.

The mixed linear models for each self-reported sleep variable are presented in Figures 7 through Figure 13. There were significant effects for week for all of the subjective variables: Sleep Quality [$F(4,60) = 3.52$, $p = .012$], Sleep Efficiency [$F(4,104) = 6.62$, $p < .001$], Total Sleep Time [$F(4,62) = 4.67$, $p = .002$], Time In Bed [$F(4,43) = 7.92$, $p = .001$], Time in Supine [$F(4,88) = 27.56$, $p = .001$], Wake After Sleep Onset [$F(4,48) = 17.48$, $p=.001$], and Sleep Onset Latency [$F(4,90) = 4.16$, $p = .004$].

Pair-wise comparisons demonstrated statistically significant mean differences between the first week of baseline and at least one of the three treatment weeks for all
measured subjective variables. For Sleep Efficiency, Time in Supine, and Wake After Sleep Onset Week 1 of baseline was significantly lower (p < .01) than all the treatment weeks 3 through 5. For these variables, there were no significant differences between the treatment weeks themselves. For Sleep Quality and Sleep Onset Latency, Week 1 of baseline was significantly lower (both p < .05) when compared with Week 4 and Week 5. For Total Sleep Time and Time in Bed, Week 1 was significantly lower (p < .001 and p < .05, respectively) than only the final week of treatment. The second week of baseline likely did not demonstrate these same effects due to incomplete data.

When comparing the overall effect of the device intervention on all 18 participants between the time points of baseline and the last day of treatment (pre- and post-test) several significant changes were observed. There were significant effects of treatment on the objective polysomnography variables of Total Recording Time \( [F(1,17) = 5.21, p<.05, \eta^2=.24] \), Total Sleep Time \( [F(1,17) = 8.59, p<.01, \eta^2=.34] \), Sleep Efficiency \( [F(1,17) = 5.42, p<.05, \eta^2=.24] \), Total REM sleep time \( [F(1,17) = 9.91, p<.01, \eta^2=.37] \), and the Apnea-Hypopnea Index \( [F(1,17) = 14.28, p<.001, \eta^2=.46] \). The variable of sleep onset latency was not statistically significant. When combined there was a significant effect of treatment over time across all included objective polysomnography measures, \( F(7,11) = 3.14, p<.05, \eta^2=.667 \). Please refer to Figures 15 - 19 for a graphing of the overall means of these variables at baseline and post-test.
There were significant effects of treatment on the subjective measures of the Functional Outcome of Sleep Quality \([F(1,17) = 8.92, p<.01, \eta^2=.35]\), Pittsburgh Sleep Quality Index \([F(1,17) = 11.2, p<.01, \eta^2=.39]\), Epworth Sleepiness Scale \([F(1,17) = 6.69, p<.05, \eta^2=.28]\), and the Brief Symptom Inventory \([F(1,17) = 5.14, p<.05, \eta^2=.23]\). The Sleep Apnea Quality of Life Index did not demonstrate clinical significance. When combined there was a strong trend significant effect of treatment over time across all included subjective measures, \(F(5,13) = 2.93, p<.055, \eta^2=.530\). Please refer to Figures 19 - 22 for a graphing of the overall means of these measures at baseline and post-test.

I.) Adverse Events

It was not expected that participants would experience any serious adverse events during the course of this research study. To date, there have been no reports in the literature about any serious side effects associated with positional therapy. However, due to the nature of the intervention, there were some subjective reports by three participants of temporary mild discomfort when participants wore the device and especially when they attempted to remain in the supine position. This was reported to occur when changing sleeping position during the night or when spending a greater percentage of time in the supine position than normal. Though the patients were carefully instructed to contact the P.I. immediately when any potential events occurred, none of the participants did so during the course of the study. This information was obtained during the exit interview after the final night of the study. Mild discomfort was subjectively reported to
be the principle reason for not using the positional device either for portions of the night or an entire night. The next most frequently provided reasons obtained during the exit interview for not wearing the device were forgetting to wear it or that it was too hot to wear. No participants reported any lasting discomfort and all were amenable to wearing the device for the full-night polysomnography study that marked the last night of treatment.
The results of the present study confirmed the efficacy of the so-called “tennis ball technique” in the management of position dependent obstructive sleep apnea syndrome. The mean apnea-hypopnea index was significantly reduced from 12.3 (sd = 7.9) to 4.6 (sd = 3.9). This last value of an apnea-hypopnea index of 4.6 represents a value that is considered below the threshold for clinically significant obstructive sleep apnea syndrome. Polysomnography data also indicated that the positional device was effective in keeping participants off their backs during the night. Eight participants did not have any recorded supine sleep during their post-test polysomnography. The remaining five participants did not sleep supine, as a whole, more than 30 minutes (Mean = 5.98, sd=9.09). This study also confirms previous research findings that when participants use a positional device during a polysomnogram study they have statistically significant improvements on the polysomnography sleep variables of total sleep time, sleep efficiency, total REM sleep time, total apnea-hypopnea index and the amount of time spent in the supine position. There were no significant improvements found with sleep onset latency. Sleep onset latency may have not demonstrated statistically significant improvements due to the environmental setting of the laboratory. Participants may have taken longer to acclimate to their surroundings before following asleep, but their subsequent sleep was better.
The results suggest that while there were several notable improvements in objective sleep in both the adherent and non-adherent groups, there was no differential effect between the groups when adherence was considered. Both groups in this pre/post design demonstrated similar improvements in apnea-hypopnea index, total sleep time, sleep efficiency, amount of REM sleep and a decrease in supine sleep time. However, there are two caveats to the polysomnography findings. It is possible that the significantly poorer baseline values of the objective sleep variables may have been the result of either a first-night effect, a clinical limit on the amount of time a patient was permitted to sleep, or there being relatively more uncontrolled environmental disturbance in a clinical sleep laboratory. First-night effects are a well-established phenomenon in polysomnography studies. This effect is characterized by substantial variability in sleep due to the laboratory environment and the novelty of the polysomnography procedure. Lorenzo & Barbonoj, M.J. (2002) reported on a study that concluded that there is a “very first night effect” and that post-test polysomnography generally does not occur if the initial night of polysomnography occurred within the same one month period. However, in the present study there was variability in the spacing of time between the baseline and post-test polysomnography studies and the laboratories were at different testing sites. This effect may have possibly influenced the outcomes of all of the reported sleep variables but it is not known to what degree. However, it is likely that the apnea-hypopnea index may have been possibly least affected since it is considered a relatively stable variable that can be determined with accuracy after even a few hours. The effect
sizes associated with the main effects for treatment on the five reported variables were from moderate to high. This seems to suggest that the polysomnography variables may not have been unduly influenced by the limited opportunity to sleep during the initial baseline polysomnography study nights.

The current study also confirmed previous subjective findings that, overall, participants self-reported that their quality of life living with apnea had improved with treatment. Sleep quality was also found to improve. Participants reported that they had experienced a substantial decrease in the severity and nature of their sleep disturbances over the course of their treatment. The overall statistical improvement in self-reported sleepiness may indicate that even after as little as three weeks of treatment participants can demonstrate greater alertness and vitality during the day. There were no significant interactions found between treatment and adherence. This suggests that the degree to which participants adhered to the intervention did not seem differentially effect subjective daytime and nighttime functioning. However, there was a strong trend for sleep quality to have an interaction with adherence where the adherent group demonstrated relatively greater improvement when compared with the non-adherent group.

Overall, the statistical analyses using a MANOVA did not predict any interaction effects where increased adherence would improve sleep and daytime variables. The number of variables that could be included in a MANOVA analyses were limited due to
the sample size of this study. The variables that were reported were selected for analysis due to their robust construct validity and that there were complete data for all participants included in the analysis. A multiple regression analysis was utilized to determine if scores at pre-test were able to predict post-test outcomes. The proposed models did not detect any significant predicted effects for any of the primary demographic and baseline descriptive data including: age, sex, body mass index, previous sleep treatment, number of medications, current number of health disorders, and use of alcohol or caffeine.

As with the PSG variable data, the subjective data suggests marked improvements in overall sleep. The subjective nightly adherence data indicates that there is a bimodal type of distribution between those that had complete adherence and those that had several days of adherence. It was this observation that led to the grouping of “adherent” and “non-adherent” participants. However, it must be kept in mind that the number of hours of adherence per night did not vary considerably for those that were in the non-adherent group. For instance, there was only a single participant that reported that they sometimes did not wear the device at all on a given night. The other five participants included in the non-adherent group did not report any nights where they did not wear the device at all. This may suggest a limit in the range of these two groups that might have hindered the observed between-group differences. These findings differ substantially from recent published data on adherence. In this study, participants overall had quite excellent adherence to the treatment. At least for a three-week time period, this cohort were adherent at a level that has not been reported elsewhere. It is unclear what the factors
may have influenced this somewhat unexpected result. These promising adherence findings seem to warrant further investigation into length of treatment and specific device design being possible mediating factors in treatment adherence. This study had less treatment time and a slightly different design than previous studies on adherence to positional device for sleep apnea.

The current study also provided findings about change over time through specification of mixed linear models with each self-reported sleep log variable (e.g., sleep efficiency percentage, sleep quality, wake after sleep onset, etc.) serving as dependent (random) variables and the particular week in the study (Weeks 1 through 5) as the fixed variable. There was a statistically significant fixed effect for week for each subjective sleep log variable. The first week of data in these analyses were likely to be more representative of the true baseline status of each participant. Though it was possible for all 14 participants to record up to 14 days of data, only half completed even more than 7 days before their first night of treatment. The mean value of days recorded of baseline data for these 14 participants was 8.71 (sd = 2.40). The second week of baseline data was necessary for statistical completeness. However, it is likely that Week 2 had inadequate data to be usefully compared with the other four weeks that are nearly completely full datasets.

Since this group of participants was largely adherent during the three weeks of treatment, the mixed linear model findings provide useful information about the dose
response of this positional device. Sleep Efficiency, Time Spent in Supine and Wake after Sleep Onset demonstrated rapid and sustained improvements over the course of the three week treatment period where there were significant gains seen even in the first week of use. Significant changes in the report of sleep onset latency and sleep quality were not seen until the second week of treatment and those improvements were maintained during the third week of treatment. Significant improvements in the total duration of sleep and its related variable total time in bed were not seen until the third week of treatment. This suggests that consistent wear and adherence are necessary in order for positional apnea patients to experience the types of benefits that they are seeking from this type of intervention. Overall benefits such as regaining more time asleep and better sleep quality would seem to be particularly salient features of sleep for patients presenting with sleep disorders. This study supports the finding that these benefits may only be realized for most patients after two or more weeks of nearly continuous use.

Two obvious limitations of this study were a lack of randomized control group and a small sample size. The study was originally designed as a randomized controlled trial. Due to the unexpected difficulty in participant recruitment, the study protocol was revised to allow all participants to receive the provided therapeutic device. What remains unanswered is whether patients that have been asked to construct a device of their own are able to do and if whether they are more or less adherent than those that receive already-constructed devices. Due to the lack of published data in this area and
the general lack of consensus on a standard of device design there are likely only a handful of health providers worldwide that actually prescribe positional devices for their patients. Those that make such prescriptions may be able to provide their patients with pre-constructed devices manufactured by their respective facilities in much the same fashion as those clinical researchers whose work is reported here. For example, the positional therapy T-shirts that were utilized in the present study were purchased from the clinical sleep research facility at Rush University Medical School in Chicago Illinois.

From the findings of this study and the few others that have measured adherence, a concern has emerged about the reported tendency that positional devices decrease sleep comfort in wearers. Currently, the adherence problems reported with positional devices have some similarities with nasal CPAP therapy. The primary reason that patients have not been able to tolerate nasal CPAP therapy is due to mask discomfort (McArdle, Devereaux, Heidarnojad, Engleman, Mackay, & Douglas, N.J. 1999). Patient discomfort has, as mentioned, been reported to be a vexing problem with positional therapies for obstructive sleep apnea syndrome and has resulted in reports of poor long-term adherence that often leads to complete non-use (Okenson et al., 2006; Bignold, Deans-Costi, Goldsworthy, Robertson, et al., 2009)). It seems, therefore, that is critically essential to find not only an effective positional device, but one that is practical and comfortable enough to be utilized every night to achieve the maximum therapeutic value.
Currently, there is tremendous variability in the types of positional devices that have been utilized in clinical and research settings. The “tennis ball technique” alone has had at least three derivations in the literature including: a tennis ball placed into the pocket of a cloth belt attached around the waist (Oksenberg, Silverberg, Offenbach, D. & Arons, 2006), a backpack-like apparatus (Bignold, Deans-Costi, Goldsworthy, Robertson, et al., 2009) and a harness-style device (Skinner, M.A., Kingshott, R.N., Jones, D.R., Homan, S.D.R., & Taylor, D.R, 2004). To date, there have been no studies on the direct comparison of different device designs to assess the efficacy and feasibility variability. Since there is no current scientific consensus concerning specific design there is likely doubt on the part of many clinicians to recommend positional therapy for their patients even though it might be beneficial to the patient. The lack of standardized and empirically tested designs may inadvertently be preventing the use of this effective therapy being utilized more widely. At this time there have been no two studies reported in the literature that have utilized a single common device design. This has made comparison of data between studies somewhat difficult to accurately interpret. There appears to be no simple solution to the problem of design consistency and standardization other than continued research efforts to gain a clear consensus. However, current researcher might become interested in seeking product approval with a governing body such as the Food and Drug Administration. The approval of a single device could perhaps increase confidence in its utility. Additionally, establishing a standardized and device model would invariably lead to free market interest. Like CPAP before it,
positional therapy devices could lead to home health care manufacturers and distributors being able to provide and distribute positional devices to the clinical population.

An additional difficulty facing this area of inquiry is the lack of an inexpensive objective measurement device to accurately record sleep position. Thus far, there has only been a single published article that reported using an objective at-home device to measure position on multiple nights. The positional device used was part of a larger acquisition system to diagnose and monitor obstructive sleep apnea that includes oximetry, airflow, and respiratory effort. Although the initial costs in purchasing such a system are somewhat prohibitive there is also the additional participant burden of wearing the entire apparatus at night in conjunction with a positional therapy device. There have been enormous efforts within the scientific and commercial sleep community to improve the technology and comfort of nasal CPAP therapy for apnea syndromes. This effort has occurred because CPAP, like positional therapy, is an exceptionally effective therapeutic intervention for obstructive sleep apnea syndrome. Since both therapies act essentially as a prosthetic device, they require that that the wearer have nearly continuous adherence to have adequate therapeutic effect. Currently, there are no single devices available on the world commercial market to measure sleep position in a long-term naturalistic setting. This has undoubtedly limited interest in this area of study since there has not been, to date, an economically feasible way to conduct the research that is both necessary and sufficient to expand scientific inquiry in the area of treatment adherence for positional therapies.
Due to the lack of data comparing the effectiveness of differential positional therapy device designs, patient acceptance and adherence has suffered. This lack of reliable data has may be substantially contributing to positional therapy not being adopted more widely as a viable therapy for positional apnea. This lack of information is especially important considering that epidemiological studies attesting to the high rate of positional dependence in the obstructive sleep apnea population clearly indicates that positional therapy has the potential to be an effective and popular therapy for obstructive sleep apnea. While continuous positive airway pressure is the first-line treatment for obstructive sleep apnea, there is a need to find other effective long-term treatments for obstructive sleep apnea. Though under-utilized based on epidemiological data, positional therapy is a simple, non-invasive, inexpensive and effective form of treatment for many positional obstructive sleep apnea patients with no reported serious side effects other than mild discomfort.

It has been estimated that this type of therapy alone might be all that is necessary and sufficient for treating almost 50% of all obstructive sleep apnea patients (Dyonzak and Cartwright, 1993). Such a therapy may ultimately have better compliance than other treatments for obstructive sleep apnea if investigation continues in this area. At the very least, positional therapy has been demonstrated to be useful as an adjunctive treatment with other interventions. Whether used as a main therapy or in conjunction with other devices, its continued use could possibly lessen the deleterious clinical consequences of
untreated obstructive sleep apnea. The prevalence of clinically significant obstructive sleep apnea is approximately 4% in men and 2% in women and estimates of prevalence increase substantially within certain sub-populations. In the United States alone, this means that there are potentially millions of individuals diagnosed with obstructive sleep apnea that could be treated successfully with this type of therapy. It is important that the small cohort of researchers in this area continue to research new methods of delivery with rigorous study so that more persons suffering from inadequate or absent treatment might still benefit from this promising therapy.
APPENDIX A: TABLES

Table 1. Baseline characteristics of all 18 study participants

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Table 2. Days non-adherent by 14 participants included in sleep diary analyses.

![Distribution of Days Non-adherent](image-url)
Figure 1. Apnea Hypopnea Index by Adherence Group

Note. Non-adherent (N = 6), Adherent (N = 8)
Note. *** p < .001.
Figure 2. Total Sleep Time by Adherence Group

Note. Non-adherent Group (N = 6), Adherent (N = 8)

Note. * p < .05
Figure 3. Total REM Sleep Time by Adherence Group

Note. Non-adherent Group (N = 6), Adherent (N = 8)
Note. * p < .05
Figure 4. Total Supine Sleep Time by Adherence Group

Note. Non-adherent Group (N = 6), Adherent (N = 8)
Note. ***p < .001.
Figure 5. Sleep Apnea Quality of Life Index (SAQLI) score by Adherence Group

Note. Non-adherent Group (N = 6), Adherent (N = 8)
Note. ** p < .01
Figure 6. Pittsburgh Sleep Quality Index (PSQI) score by Adherence Group

Note. Non-adherent Group (N = 6), Adherent (N = 8)

Note. * p < .05
Figure 7. Sleep Quality Rating by Week

Sleep Quality Rating (1 - 4)

Note: (N = 14), Standard Error bars, Baseline = Weeks 1 & 2, Treatment = Weeks 3 – 5. Note: *p < .05 between means of Week 1 and Weeks 4 & 5
Figure 8. Sleep Efficiency Percentage by Week

Sleep Efficiency Percentage

Note: (N = 14), Standard Error bars, Baseline = Weeks 1 & 2, Treatment = Weeks 3 – 5.
Note: p **<.01 between Week 1 and Weeks 3, 4, & 5.
Figure 9. Total Sleep Time in Minutes by Week

Total Sleep Time in Minutes

Note: (N = 14), Standard Error bars, Baseline = Weeks 1 & 2, Treatment = Weeks 3 – 5.
Note: ***p < .001 between Week 1 and Week 5.
Figure 10. Time in Bed in Minutes by Week

Time In Bed in Minutes

Note: (N = 14), Standard Error bars, Baseline = Weeks 1 & 2, Treatment = Weeks 3 – 5.
Note: *p < .05 between Week 1 and Week 5.
Figure 11. Minutes Spent in Supine by Week

Minutes Spent In Supine

Note: (N = 14), Standard Error bars, Baseline = Weeks 1 & 2, Treatment = Weeks 3 – 5. Note: ***p < .001 between Week 1 and Weeks 3, 4 & 5.
Figure 12. Wake After Sleep Onset in Minutes by Week

Note: (N = 14), Standard Error bars, Baseline = Weeks 1 & 2, Treatment = Weeks 3 – 5.
Note: **p < .01 between Week 1 and Weeks 3, 4 & 5.
Figure 13. Sleep Onset Latency in Minutes by Week

Sleep Onset Latency in Minutes

Note: (N = 14), Standard Error bars, Baseline = Weeks 1 & 2, Treatment = Weeks 3 – 5.
Note: *p < .05 between Week 1 and Weeks 4 & 5.
Figure 14. (PSG) Change in Total Recording Time for All Participants

Note. *p < .05 (N = 18)
Figure 15. (PSG) Change in Total Sleep Time for All Participants

Note. **p < .01 (N = 18)
Figure 16. (PSG) Change in Sleep Efficiency (%) for All Participants

Note. *p < .05 (N = 18)
Figure 17. (PSG) Change in Total Amount of REM Sleep Time for All Participants

Note. **p < .01 (N = 18)
Figure 18. (PSG) Change in Apnea-hypopnea Index for All Participants

Note. *** p < .001 (N = 18)
Figure 19. Change in Functional Outcome of Sleep Quality for All Participants

Note. **p < .01 (N = 18)
Figure 20. Change in Pittsburgh Sleep Quality Index for All Participants

Note. ** p < .01 (N = 18)
Figure 21. Change in Epworth Sleepiness Scale Score for All Participants

Note:* *p < .05 (N = 18)
Figure 22. Change in Brief Symptom Inventory Score for All Participants

Note. *p < .01 (N = 18)
REFERENCES


Martin, R.J., Chairman; Block, A.J., Cohn, M.A. et al. (1985). Committee members; indications and standards for cardiopulmonary sleep studies. *Sleep, 8*, 371-379.


