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Dental Treatment Options for Snoring - A Pilot Study

Kainaz Khushrooh Byramjee

LOMA LINDA UNIVERSITY

Graduate School

Dental Treatment Options for Snoring – A Pilot Study

by

Kainaz Khushrooh Byramjee

A Thesis in Partial Fulfillment
of the Requirement for the Degree
Master of Science in Prosthodontics

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Each person whose signature appears below certifies that this thesis in his opinion is adequate, in scope and quality, as a thesis for the degree Master of Science.

Wayne V. Campagni, Professor, Advanced Education in Prosthodontics, Chairperson

Guillermo Bernal, Professor, Advanced Education in Prosthodontics

Jay Kim, Professor, Department of Bio-statistics

Carlos A. Munoz-Viveros, Professor and Director, Biomaterials Research Center

W. Patrick Naylor, Adjunct Professor, Department of Restorative Dentistry

DEDICATION

Dedicated to my late father

Khushrooh Pheroz Byramjee

ACKNOWLEDGEMENTS

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TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

ABSTRACT

Dental Treatment Options for Snoring – A Pilot Study

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Kainaz Khushrooh Byramjee

Master of Science, Graduate Program in Prosthodontics
Loma Linda University, December 2003
Dr. Wayne V. Campagni, Chairperson

This study compared the effectiveness of an anterior repositioning device, the Silent Nite®, to two new treatments in their ability to stop/reduce snoring. Comfort and side effects of each treatment were also evaluated.

Twenty-three subjects, in good medical condition along with their spouse/partner participated in the five-week study. A disposable sleep apnea screener, SleepStrip,™ was used to select only non-sleep apnea patients. The treatments tested were: (1) Silent Nite® (control – Treatment A), (2) Loma Linda Appliance (Treatment B), and (3) Snore Tape (Treatment C). Each participant received all three treatments separated by a one-week "wash-out" period of no treatments. The subjects and their spouse/partner completed a questionnaire at the beginning of the study and following each week of treatment. The data were statistically analyzed using a non-parametric technique at the significance level $\alpha = 0.05$ to detect significant differences in the effectiveness among the three treatments.

Overall treatment results showed no statistically significant difference among all three treatments ($p=0.6657$). According to the spouse/partner, 78.26% (18), 52.17% (12), and 73.91% (17) reported Treatment A, Treatment B, and Treatment C respectively, stopped/reduced the patient's snoring. This indicated a statistically significant difference

between Treatment A and Treatment B (p=0.0213), but not between Treatment A and Treatment C (p=0.3018) or Treatment B and Treatment C (p=0.3323). However, according to the patient, 65.23% (15), 43.48% (10), and 47.83% (11) reported that Treatment A, Treatment B, and Treatment C respectively, stopped/reduced their snoring. These values were not statistically significantly different (p=0.5558).

Overall side effects resulting from Treatment A were significantly greater than Treatment C (p=0.0135). Treatment A caused significantly greater tooth discomfort (p=0.0005), occlusal changes (p=0.0013), TMJ pain (p=0.0063), and TMJ noises (p=0.0361) than Treatment C.

Sleep habits (p=0.2382) and compliance with the instructions given at the start of the study (p=0.3942) were not statistically different for all treatment methods.

Despite the small sample size, the spouse/partner found the Silent Nite and the Snore Tape (patent pending) to be equally effective in reducing/stopping snoring. However, the patients found the Snore Tape (patent pending) to be more comfortable, have fewer side effects, and may be more cost-effective.

INTRODUCTION

Snoring is a clinical condition affecting millions of individuals throughout the world that has gained marked attention in dentistry. Teamed with medical professionals, many dentists are now providing patients with intraoral devices for the treatment of snoring and obstructive sleep apnea (OSA).

Definition

Snoring has been described in several different ways from an uncomplicated dictionary description to a more complex medical definition.

According to the Oxford's Dictionary, fourth edition, snoring is defined as "the act of breathing roughly and noisily while sleeping."[1]

In a 1968, Boulware,[2] conducted a survey of 100 physicians and found that 42% of the respondents accepted a simple definition, while 52% preferred the medical phrasing proposed by to Arnold.[3] The simple definition defined snoring as "any intense audible noise (of the sleeper) occurring while asleep."[3] Arnold, defined snoring "....as a sound made by vibrations of the soft palate and the posterior faucial pillars during sleep, but excludes sounds made by the tongue, cheeks, lips, nostrils, and laryngeal structures including the epiglottis."[3]

Arnold[3] also stated that snoring is "not a disease but a physiological phenomenon, which becomes a disorder only in the ears of those people who cannot tolerate it."

Epidemiology

Snoring is a common problem affecting many people. In North America, the number of habitual snorers among the population has been estimated to be as high as 80 million depending on the age, sex, and body weight.[4] According to a study by Lugaresi et al,[5] in northeastern Italy 30.9% of the population snored occasionally and an additional 19% were habitual snorers. There was a higher prevalence in males (40.9%) than in females (27.9%). Hicks et al[6] reported that men are 50.6% more likely to snore than women.

The frequency of snoring has been reported to increases with age. Up to 30 years of age, only approximately 10% of males and less than 5% of females are habitual snorers. As individuals those values change. In fact, once over the age of 30, these percentages increase more rapidly among males than among females. Between 60 and 65 years of age, more than 60% of the men and about 40% of the women are habitual snorers.[5]

Hicks et al[6] also reported that there was also an association between ethnicity and snoring. They found that the highest incidence of snoring was seen among Asian-Americans, followed by African-Americans, Mexican-Americans, and then Caucasians. Asian-Americans are 39.5% more likely to snore than Caucasians.[6]

Pathophysiology

Snoring is typically, a "noise" created by vibrations of the collapsible portion of the oral airway from the epiglottis to the chonae. Dr. Leonard Portnoy described this area as the "snore-way space."[7] The anatomic structures that have no rigid support and are

involved in the reduction of the airway are the soft palate, uvula, tonsillar pillars, base of the tongue, pharyngeal muscles, and the oral mucosa.

During sleep the musculature of these oral structures fail to maintain their normal tone during inspiration.[8] The soft tissues then collapse into the "snore-way space" causing partial or complete obstruction of the airway and the recognizable snoring sounds often result.

What is often not recognized is that there is more than one way to snore. People may snore through their mouth and nose, upon inspiration and expiration, while occupying every sleeping posture. These sounds may be generated in or by the buccal cavity, faucial pillars, relaxed velum, oral cavity, and other structures above the larynx.[2]

A cephalometric comparison of the airways and its associated structures between snorers and non-snorers demonstrated narrower airways, reduced oropharyngeal areas, shorter and thicker soft palates, and larger tongues among snorers than among non-snorers.[9]

According to the survey conducted by Boulware,[2] most physicians accepted the traditional medical classification of snoring as – organic or pathologic, nasal, and functional.

- Organic snoring is characterized by a nasal obstruction, or physiological and pathological changes in the nasopharynx and oropharynx, and retraction of the tongue.
- Nasal snoring is that which is produced, in part, by nasal resonant sounds.
- Functional snoring is a derangement in the central reflex governing the tone of the glossopharyngeal musculature during sleep.[2]

There are numerous factors that may cause someone to snore. Allergies, deflected nasal septum, infections in the nose, sinuses or pharynx, as well as nasal tumor, nasal polyps, and collapsed ale nasi affect snoring almost equally.[10] Smoking[11] and alcohol,[12] body mass index (BMI),[11,12] 'Mulberry' turbinates,[13] raised uric acid,[13] psychogenic stress,[13] debility and fatigue,[13] and family history,[13] are also all known to contribute to snoring. However, there is some debate as to whether or not the consumption of alcohol affects snoring as some studies have found no correlation between the two.[11,14] Nonetheless, it is now generally recommended that individuals not consume alcoholic beverages several hours prior to bedtime as a precautionary measure to reduce the likelihood of snoring.[12]

Sleeping position also plays a role in snoring. Non-apneic snorers have a lower snoring time and snoring intensity when sleeping on their side (lateral position) than on their back (supine position).[15,16] Medications like sedative-hypnotics, tranquilizers, and antihistamines can also exacerbate snoring.[13]

The most consistent sign that someone snores is excessive daytime sleepiness, and headaches.[40] Hypertension has also been seen more frequently among habitual snorers than among non-snorers.[11] This difference being particularly significant after age 40, where hypertension is twice as likely to affect habitual snorers than non-snorers.[5]

Treatment

The treatment for snoring can be divided into two main categories: surgical and non-surgical/medical/palliative. Surgical treatments include uvulopalatopharyngoplasty (UPPP), laser uvulopalatoplasty, and radio frequency ablation.[18] In a study conducted 20

years ago, surgical correction of anatomical anomalies have been shown to eliminate snoring in 72% of the cases, while non-surgical remedies eliminated snoring in only 5% of the cases after the first year.[17] However, today these success rates have changed markedly. Non-surgical treatments, which mainly include the intraoral appliances, have shown a significant increase in the success rates, ranging from 79% to 87%.[22,28,44,45,46] Surgery has a good success rate during the first year, but studies have shown a recurrence in approximately 29% to 40% of the cases.[41,42,48] Apart from being expensive and extremely painful, surgical intervention may result in complications such as excessive bleeding, dysphagia, infection, nasal regurgitation, dry mouth, and altered taste.[41,43] Therefore non-surgical treatment might be considered as an effective option for the treatment of snoring prior to surgery. Not only are success rates between surgical and non-surgical treatment comparable, non-surgical treatment is less invasive and safer for the patient. The non-surgical treatments also involve controlling the predisposing factors for snoring. It is important to maintain the body mass index [weight in kilograms divided by (height in meters)^2] below the overweight mark (27.3 for females and 27.8 for males).[36] Smoking and alcohol consumption should be discouraged.[11,12,13,14,18,19] Maintaining a lateral sleeping position and elevation of the head while sleeping has also been found to be beneficial for some patients.[15,16,19]

A study by Eckhart,[20] listed a number of dental appliances that have been developed and marketed for the treatment of snoring. While designs vary widely, these appliances generally are used to reposition the tongue, advance the mandible, and increase the airway space to facilitate breathing, and reduce obstructive breathing during sleep. By and large, most of the designs available today fall into one of the two

following categories: (1) the Anterior Repositioning Devices (ARD) and (2) the Tongue Advancers.

- *Anterior Repositioning Devices (ARD)* – This first group of appliances is intended to reposition the mandible anteriorly and maintain it in an opened position. Various authors have recommended that the mandible be opened 2 mm to 12 mm,[22,28,45,46] while the anterior repositioning range is from 3 mm to 16 mm,[29,37,44] depending on the appliance used. ARDs can either be one-piece, nonadjustable (fixed) designs or two-piece, adjustable devices. Nakazawa et al,[25] described a non-adjustable design in which maxillary and mandibular acrylic resin stents are fixed with the mandible positioned 3 to 5 mm anteriorly and 4 mm inferiorly to the normal closure position (Figures 1). The adjustable appliance allows for some limited lateral movement and changes to the device in the sagittal plane.
- *Tongue Advancers* – The second group of appliances captures and holds the tongue in the forward position. The Tongue Retaining Device (TRD) (Figures 2a and 2b) is an appliance that is fabricated by Professional Positioners (Racine, WI). These appliances can be used when the temporomandibular joints (TMJs) do not tolerate stretching or when there are insufficient teeth present to support an ARD.[20]

Appliances from both designs are intended to enlarge the retroglossal space thereby reducing the potential for of upper airway obstruction and pharyngeal collapse.[26]

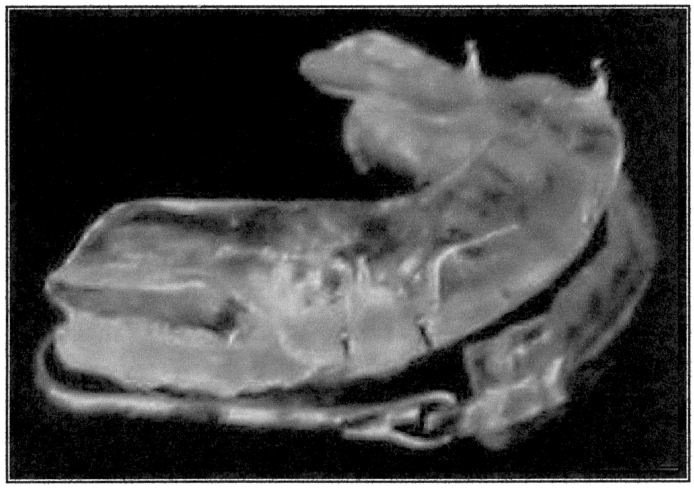


Figure 1

Anterior Repositioning Device (ARD) as described by Nakazawa. It is a non-adjustable design in which maxillary and mandibular acrylic resin stents are fixed with the mandible positioned anteriorly and inferiorly to the normal closure position.

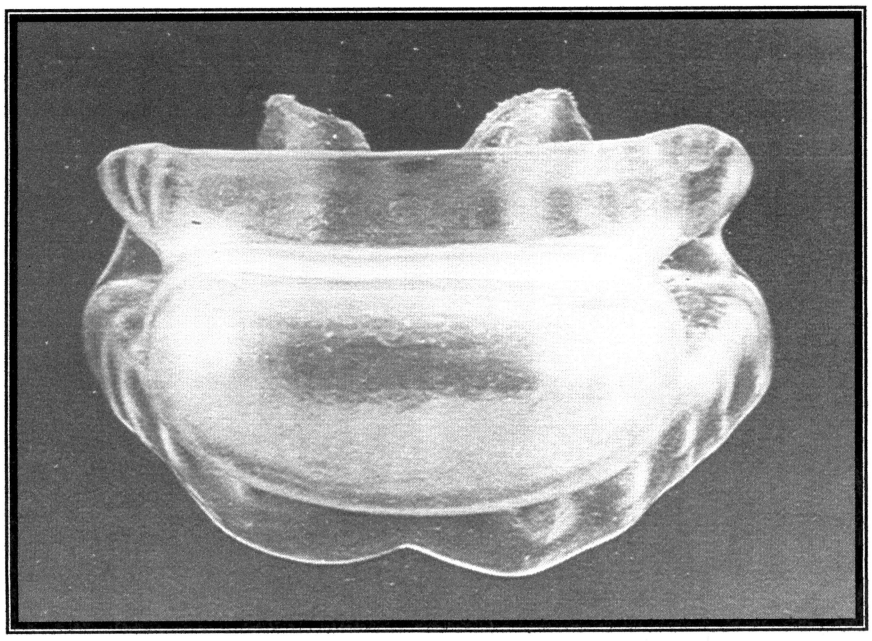


Figure 2a

Frontal view of Tongue Retaining Device (TRD) which captures and holds the tongue in the forward position.

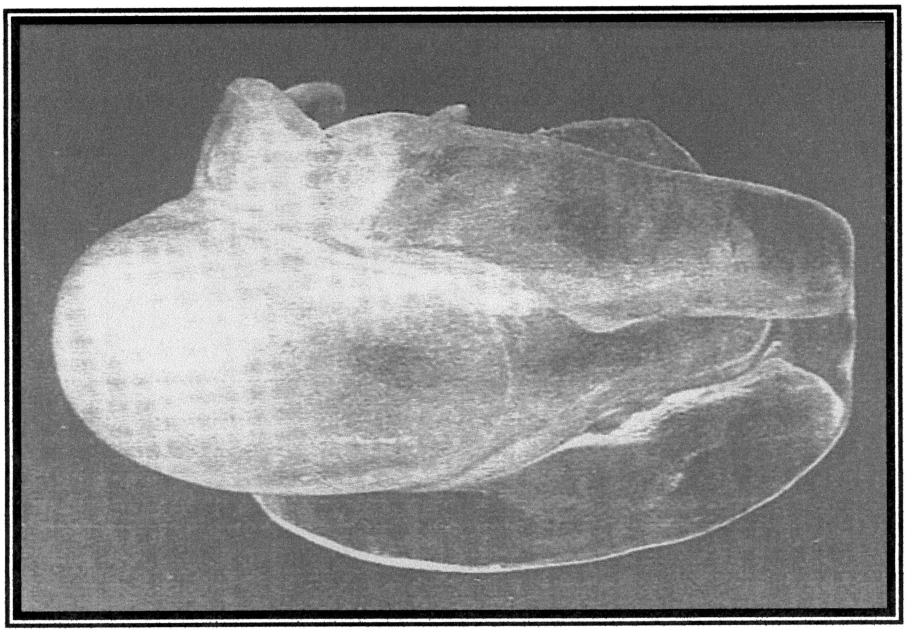


Figure 2b

Profile view of Tongue Retaining Device (TRD) which captures and holds the tongue in the forward position.

- *Tape* – In the 1950s, a Russian physician, Konstantin Buteyko,[30,31] first introduced the concept of using tape to keep the mouth closed as a breathing technique for the treatment of asthma. This treatment was intended to produce a conscious decrease in the depth of breathing. Buteyko stated that hyperventilation was directly related to the disease. The Buteyko breathing technique involved the placement of a tape vertically over the mouth to gently hold the patient's lips closed while they were asleep. This treatment prevents the mandible from dropping open, and forces the patient to breathe through their nose. Although, this technique was first described in the 1950s, the Soviet authorities did not officially recognize it as an acceptable treatment for asthma until 1981.[30,31] Unfortunately there were no illustrations of the tape used in the Buteyko technique available. Tape is used in a similar manner in this study to block the "snore-way space" and prevent the vibrations of the soft tissues, which produce snoring.

Recently two new treatments have been introduced. One is an intraoral device (Loma Linda Appliance) and the other is an extraoral treatment (Snore Tape), and they were both initially developed by Dr. Leonard L. Portnoy. Dr. W. Patrick Naylor later modified the design of the Snore Tape (patent pending). The principle behind the Snore Tape (patent pending) and the Loma Linda Appliances is to block the central airway or the "snore-way space" and to prevent vibrations of the soft tissue and resulting snoring.[7] The second intraoral appliance is the Silent Nite® and it's registered trademark are owned and marketed by Glidewell Laboratories, Inc. (Newport Beach, CA).

- *The Loma Linda Appliance* – is not unlike the Silent Nite®. It has a clear polypropylene form that covers the maxillary and mandibular teeth and part of the gingiva. But it has a small central tab, attached to the upper member, which is intended to block the central airway. The upper and lower members are joined by an adjustable, elastic band on each side. These elastic bands pull the mandible anteriorly (approximately 2 to 3 mm). Studies have shown success with a wide range of anterior repositioned positions[29,37,44] but no scientific reason was given by Dr. Portnoy[7] for repositioning the mandible 2mm to 3mm anteriorly. The polypropylene material used to fabricate the maxillary and mandibular members is a softer, more flexible material than the material used for the Silent Nite® appliance. The elastic bands and the softer material are intended to provide a more comfortable device for patients with fewer side effects.
- *Snore Tape* (patent pending) – is a modification of Buteyko breathing technique which involved placing a tape over the mouth to gently hold the lips closed during sleep. This prevents the mandible from dropping open and forces the patient to breathe only through their nose. The Snore Tape (patent pending) was designed in a similar manner, with the intention of making the patient breathe through the nose. It permits airflow at the corners of the mouth, but blocks the central airway or the "snore-way space" to prevent vibrations of the soft tissues that cause snoring. However, this does not prevent nasal snoring.

- *The Silent Nite®* – is a custom-made intraoral device that Glidewell Laboratories, Inc. (Newport Beach, CA) has been fabricating since 1997. It was first developed by Dr. Erich Kopp in Germany, almost two decades ago. It is intended to increase the airway space so that the air velocity is diminished, thereby reducing the soft tissue vibrations, which produce snoring noises. The device is fabricated from 2 mm clear double layer copolyester plates, Erkoloc-pro (Erkodent, Germany), which cover the maxillary and mandibular teeth. The double layer of the Erkoloc-pro plate consists of an outer hard layer and an inner soft layer. The maxillary and mandibular members of the appliance are linked by a pair of patented, hinged connectors that gently pull the mandible forward by a predetermined amount. According to the manufacturer, the mandible can be repositioned 3 to 8 mm anteriorly and 3 to 5 mm vertically, as these connectors are available in three different sizes. Glidewell Laboratories, Inc. contends that the patented Silent Nite® connectors prevent snoring by positioning the mandible and the airway in an opened position during sleep.[29] The Silent Nite® is recommended only for patients with complete dentition. The device covers the teeth and part of the gingiva, and is available in a transparent form or a yellow, blue, or ivory shade. The laboratory fee for the Silent Nite® is currently $89 and it is received by the treating dentist in a plastic box, which is also given to the patient to store the appliance when it is not in use.

  A study by Tan et al,[47] found that the Silent Nite® and nasal continuous positive airway pressure (nCPAP) were equally effective in treating mild to

moderate OSA. However, 80.9% of these subjects preferred the Silent Nite® appliance.[47] Occasionally this device may produce discomfort to the teeth or gingiva.[29] Transient changes in occlusion have also been observed.[29] Occlusal changes produced a decrease in the horizontal overlap of 1 to 3 mm. According to one report, the occlusal change that do occur are not related to the amount of protrusion produced by the ARD or the patient's existing occlusion.[37] However, the occlusal changes have been observed to increase with length of use of the appliance up to two years.[37] According to Glidewell Laboratories, Inc. these symptoms disappear soon after awakening or the patient found them tolerable. However, according to Pantin et al,[37] occlusal changes reportedly resolve within two weeks of treatment cessation.

The Loma Linda Appliance and the Snore Tape (patent pending) reportedly have been used in private practice with good results.[7] However, neither of these treatments have not been evaluated clinically in controlled clinical trials.

The purpose of this study was to compare the effectiveness of these two new treatments for snoring to the widely used Silent Nite®. The study also attempted to evaluate side effects, patient compliance, and patient preferences among all three treatment methods.

The hypothesis for the study was that the Snore Tape (patent pending) would be as effective as other intraoral appliances for the treatment of mild to occasional snoring.

MATERIALS AND METHODS

The investigation was conducted in the Clinical Research Facility of the Loma Linda University School of Dentistry.

Patient Selection

A total of 25 patients suffering from snoring were selected for participation in this study using the following inclusion and exclusion criteria.

Inclusion Criteria –

1) Patients with known snoring problems.

2) Epworth Sleepiness Scale < 8

3) Test negative for sleep apnea with the SleepStrip™

4) Otherwise normal medical condition.

The Epworth Sleepiness Scale is a simple questionnaire measuring a person's general level of daytime sleepiness. The Epworth Sleepiness Scale scores significantly distinguish patients who snore from those with obstructive sleep apnea syndrome.[32] Epworth Sleepiness Scale scores increase with the severity of the obstructive sleep apnea syndrome. A score between two and 10 represents a normal range, while six is considered an ideal score.[32] Although a score of 10 was considered normal, to be safe, a person with a score greater than eight was not included in the study.

The SleepStrip™ is a four-inch long, plastic, disposable, sleep apnea screener (Figure 3). It was developed at the Sleep Research Laboratory at the Technion-Israel Institute of Technology (Haifa, Israel) by two renowned sleep experts, Dr. Peretz Lavie and Noam Hadas. It is produced by S.L.P. LTD. Scientific Laboratory in Tel-Aviv,

Israel. In the United States, the product is distributed by Influent Medical (Concord, New Hampshire). In January 2001, the SleepStrip™ was approved by the FDA as an inexpensive and accurate home-screening device for sleep apnea. The patient fastens the SleepStrip™ to his/her upper lip (Figure 4). Three tiny sensors which are attached to the strip record when the patient stops breathing. In the morning, the patient removes the strip and returns it to the doctor who reads the results directly from the built-in display (Figure 5). Studies conducted to test the accuracy and the reliability of the SleepStrip™ have concluded that the SleepStrip™ is not intended to be a substitute for the polysomnograph, but it is a reliable tool for initial assessment of sleep apnea in high-risk populations.[33,34,35]

Exclusion Criteria –

1) Patients suffering from sleep apnea. (This may be known to the patient, diagnosed by a physician, or indicated by the SleepStrip™).
2) Inability to commit to the requirement of returning for recalls.
3) Spouse/partner unwilling to participate.
4) Single individual.
5) Patient not in good general health.

Of the 25 patients enrolled in the study, there were 19 males and six females. Age of the subjects ranged from 28 years to 69 years. Mean age was 46.65 years (Table 1). Of the initial 25 patients enrolled in the study, two had to be eliminated from the study due to non-compliance and inability to make the recall appointments.

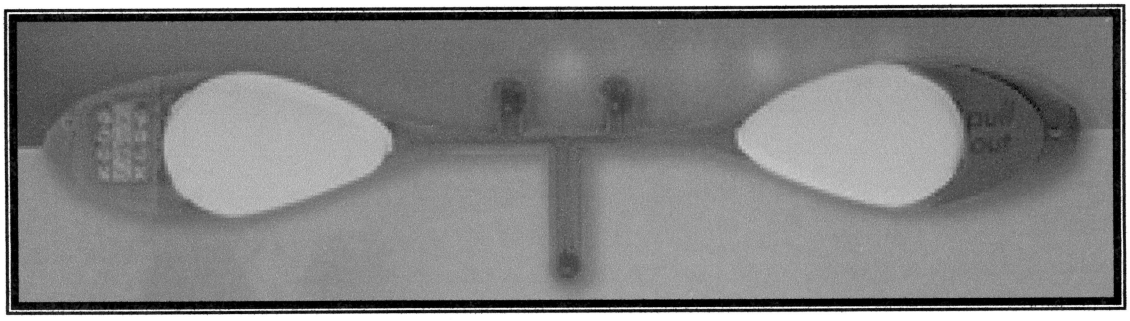


Figure 3

SleepStrip™ is a four-inch long, plastic, disposable, sleep apnea screener developed at the Sleep Research Laboratory at the Technion-Israel Institute of Technology (Haifa, Israel). It is produced by S.L.P. LTD. Scientific Laboratory in Tel-Aviv, Israel.

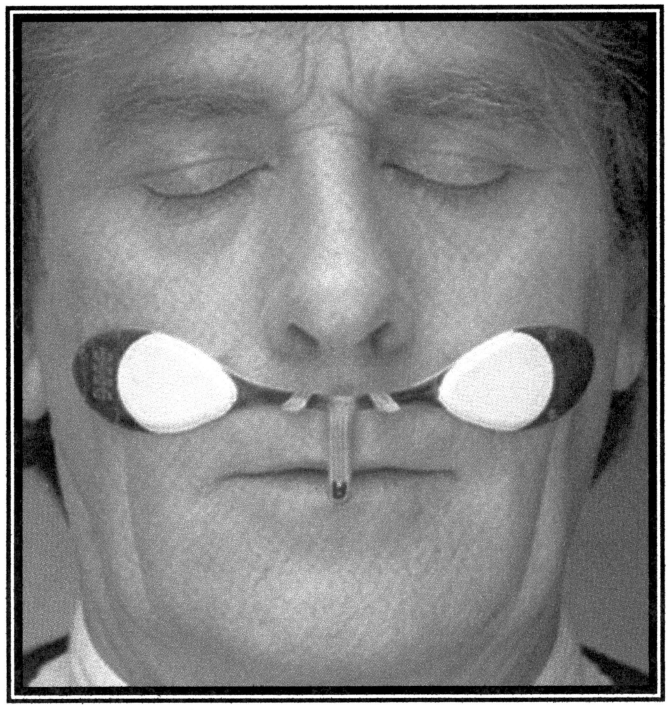
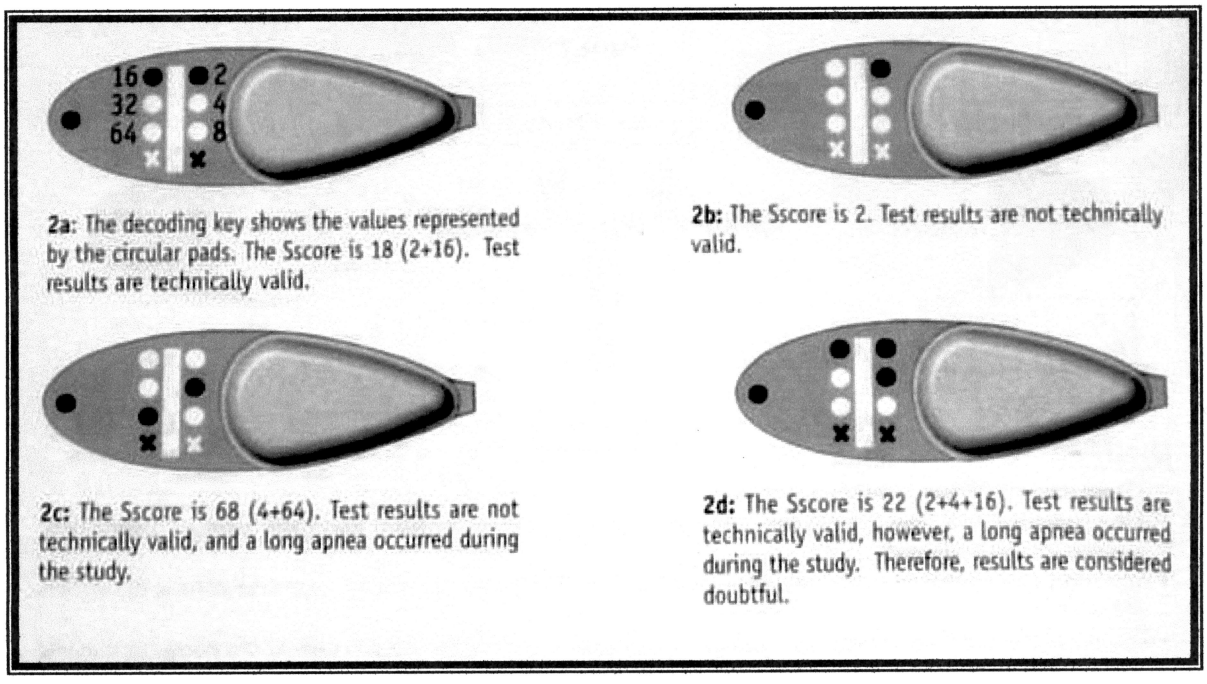


Figure 4

Application method for the sleep strip. Three tiny sensors which are attached to the strip record when the patient stops breathing.



2a: The decoding key shows the values represented by the circular pads. The Sscore is 18 (2+16). Test results are technically valid.

2b: The Sscore is 2. Test results are not technically valid.

2c: The Sscore is 68 (4+64). Test results are not technically valid, and a long apnea occurred during the study.

2d: The Sscore is 22 (2+4+16). Test results are technically valid, however, a long apnea occurred during the study. Therefore, results are considered doubtful.

Figure 5

Evaluation Of Sleep Strip

Table 1. Demographics of patients selected for the study

AGE (in years)	MALE	FEMALE	TOTAL
20-29	1	0	1
30-39	4	1	5
40-49	7 (1 lost)	2 (1 lost)	9
50-59	4	3	7
60-69	3	0	3
TOTAL	18	5	23

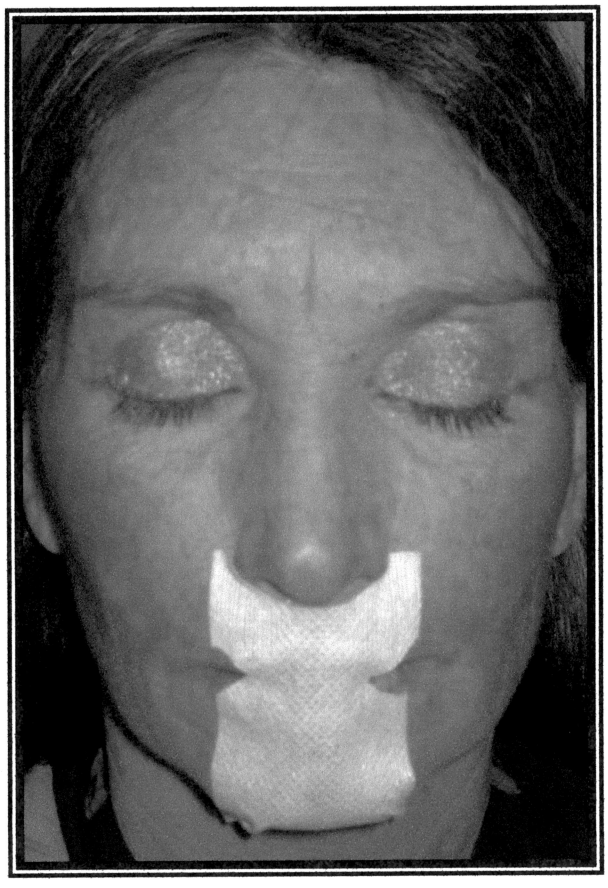


Figure 10

Application method for Snore Tape (patent pending).

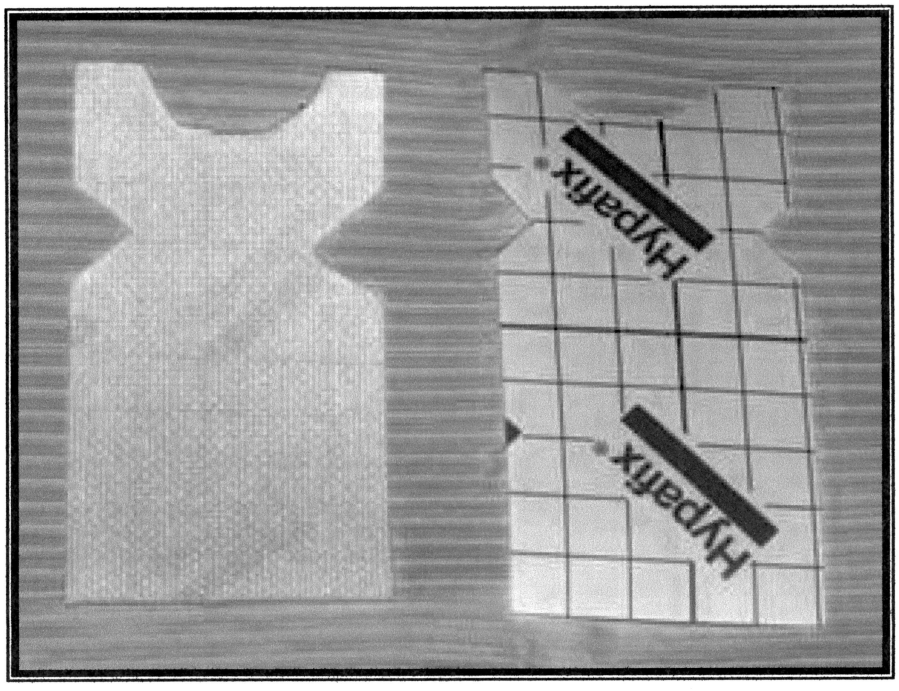


Figure 9

Snore Tape (patent pending) design. It is two inches wide and no less than four inches long.

Figure 8

Hypafix (Smith & Nephew Inc.) tape used for the Snore Tape (patent pending).

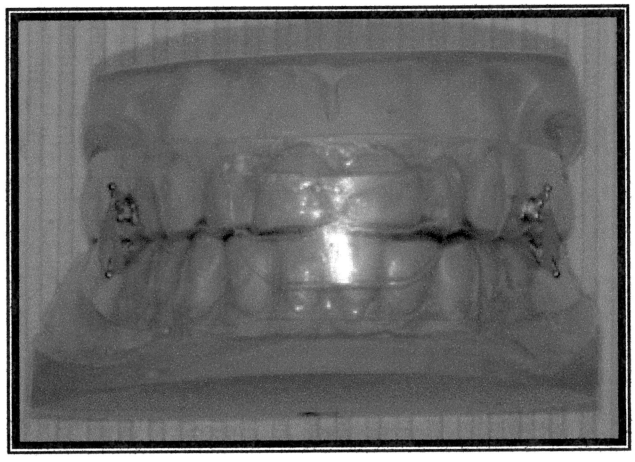


Figure 7a

Frontal View showing anterior tab that blocks the "snore-way space"

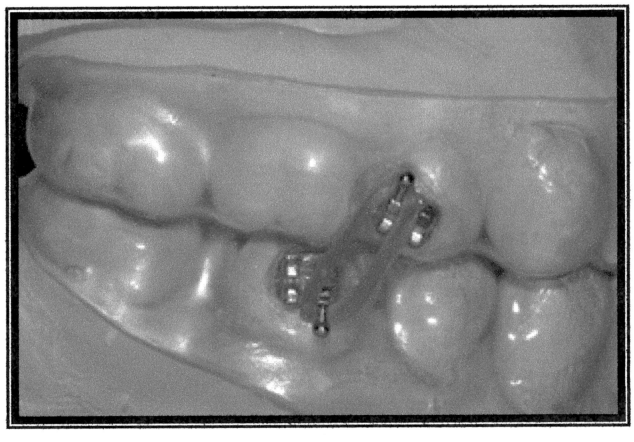


Figure 7b

Profile view showing the orthodontic brackets with the elastic bands

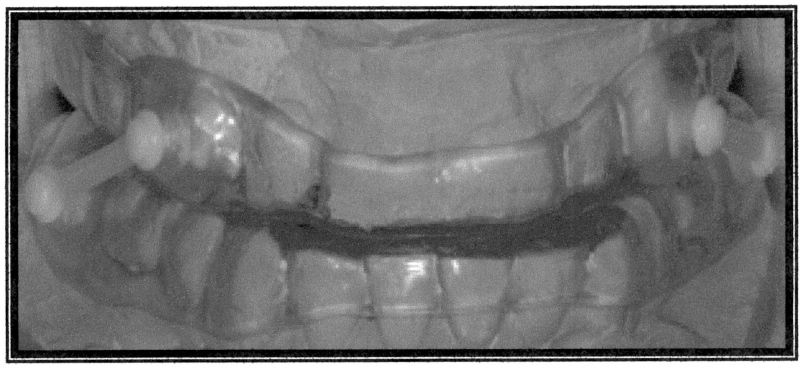


Figure 6a

Frontal view of the Silent Nite® appliance

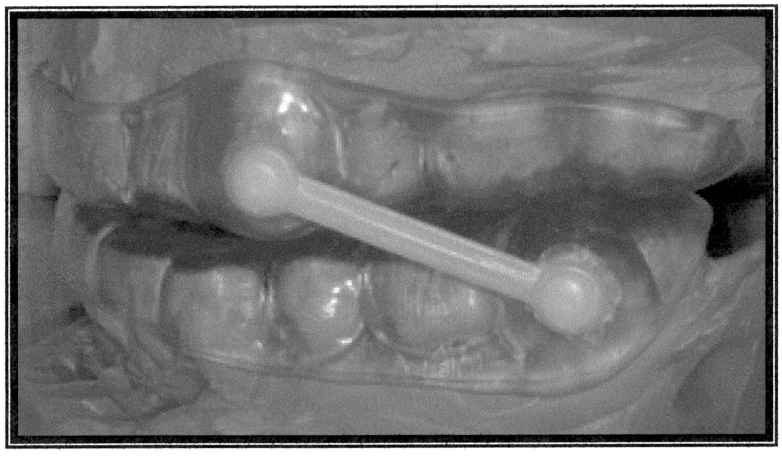


Figure 6b

Profile view of Silent Nite® appliance showing the inelastic, non-adjustable, patented plastic bands.

anterior repositioning simply by changing the strength of the elastic bands in accordance to the amount of anterior positioning required. Thinner bands with greater elasticity were selected for greater anterior repositioning and thicker bands with less elasticity were selected for lesser amounts of anterior repositioning. This design feature also allowed patients to gradually increase the anterior positioning of the mandible to a comfortable position without stressing the temporomandibular joints (TMJs) and the muscles of mastication. However, the mandible was positioned approximately 2 to 3 mm anterior and opened vertically approximately 4 mm from maximum intercuspal position. These measurements were not fixed and varied according to the patients' anatomic and physiologic conditions. The appliance also physically blocked the "snore-way space." A piece of coping material was attached to the maxillary component, but not to the mandibular component, using Orthodontic Resin. This allowed movement of the mandible, while still blocking the "snore-way space."

The aim of this device was two-fold: 1) to reposition the mandible anteriorly so as to increase the oral airway opening, and 2) to block the "snore-way space" to prevent snoring.

Treatment C – The Snore Tape (patent pending)

It involves the adaptation of a soft, non-woven polyester fabric tape that stretches for flexibility and has a non-irritating adhesive for patient comfort (Hypafix, Smith & Nephew Inc.) (Figure 8). The Snore Tape (patent pending) adheres to the skin ensuring a secure and lasting fit, yet it also allows some degree of mandibular movement.

manipulated according to the manufacturer's instructions, placed in a disposable plastic tray, sprayed with Hold Impression Tray Adhesive (Teledyne Waterpik, Newport Beach, CA), and alginate impressions were made. The alginate impression were made by the study investigator (KKB). The resulting impressions were poured in an ADA certified Type III dental stone (Microstone, Whip Mix Corporation, Louisville, KY) vacuum mixed according to the manufacturer's directions using a two-pour technique. Pre-weighed packages of Microstone and measured quantities of water were used to ensure the consistency of the material.

Forty-five minutes after pouring the impressions, the gypsum casts were separated from the alginate impression material, trimmed on a lathe, and allowed to dry overnight. One set of maxillary and mandibular casts was then sent to Glidewell Laboratories for the fabrication of the Silent Nite® appliance. The remaining set of maxillary and mandibular casts was used to fabricate the Loma Linda Appliance for each patient.

The Loma Linda Appliances were fabricated at Loma Linda University School of Dentistry by the study investigator (KKB). The maxillary and the mandibular components of the Loma Linda Appliance were fabricated by the vacuum press technique using 2 mm Polypropylene Coping Sheets (Ultradent, South Jordan, UT). Universal orthodontic brackets (Pyramid Orthodontics, Corte Madera, CA) were attached to the buccal surfaces of the maxillary and mandibular components, using autopolymerizing acrylic resin, Orthodontic Resin (Bosworth, Skokie, IL). The orthodontic brackets were attached in the maxillary first premolar and the mandibular first molar region (Figure 7b). These brackets were used to approximate the maxillary and mandibular components to one another via elastic bands. The patients were able to easily adjust the amount of

Once in place, the appliance repositions the mandible anywhere from 3 to 8 mm anteriorly and 3 to 5 mm vertically thereby increasing the airway space, to reduce or stop snoring. The patients were asked to rinse the appliance in warm water after its use, and store it in the provided plastic container, with no water or solution. Patients were advised not to use a brush or denture cleaning products in their cleaning protocol at home.

Treatment B – The Loma Linda Appliance

It is also an intraoral anterior repositioning device but with a major design modification. Unlike the Silent Nite®, it also has a central tab attached to the maxillary member (Figure 7a) to block the central airway and prevent vibrations of the soft tissue that cause snoring. The Loma Linda Appliance has elastic bands (Figure 7b) connecting the maxillary and mandibular components which allows the appliance to be adjusted both anteriorly and vertically. The patients were asked to rinse the appliance in warm water after its use, and store it in the plastic container provided, without any water or solution. Patients were advised not to use a brush or denture cleaning products during their cleaning protocol at home.

Fabrication Of The Silent Nite® And Loma Linda Appliances

To make both the Silent Nite® and the Loma Linda Appliances, two sets of irreversible hydrocolloid (alginate) impressions were made of the maxillary and the mandibular arches for all patients selected to participate in the study. Measured quantities of alginate impression material (Identic-Cadco, Oxnard, CA) were mixed mechanically in an Alginator (Identic-Cadco, Oxnard, CA) without vacuum and

Table 3. Patients' Body Mass Index Chart

Pt. #	Height (in inches/meters)	Weight (in lbs/kgs)	BMI	Classification
1	72 / 1.82	220 / 99.7	29.8	Overweight
2	72 / 1.82	220 / 99.7	29.8	Overweight
3	76 / 1.93	200 / 90.7	24.3	Normal
4	70 / 1.77	150 / 68.0	21.5	Normal
5	72 / 1.82	215 / 97.5	29.2	Overweight
6	71 / 1.80	205 / 93.0	28.6	Overweight
7	66 / 1.68	140 / 63.5	22.6	Normal
8	72 / 1.82	205 / 93.0	27.8	Overweight
9	72 / 1.82	185 / 83.9	25.1	Overweight
10	61 / 1.55	205 / 93.0	38.7	Obese
11	66 / 1.68	195 / 88.4	31.5	Obese
12	64 / 1.63	145 / 65.7	24.9	Normal
13	76 / 1.93	225 / 102.1	27.4	Overweight
14	63 / 1.60	206 / 93.4	36.5	Obese
15	75 / 1.91	197 / 89.3	24.6	Normal
16	68 / 1.73	155 / 70.3	23.6	Normal
17	64 / 1.63	140 / 63.5	24.0	Normal
18	72 / 1.82	210 / 95.2	28.5	Overweight
19	69 / 1.75	200 / 90.7	29.5	Overweight
20	67 / 1.70	158 / 71.6	24.7	Normal
21	68 / 1.73	155 / 70.3	23.6	Normal
22	73 / 1.85	178 / 80.7	23.5	Normal
23	69 / 1.75	180 / 81.6	26.6	Overweight

Table 2. Classification for Body Mass Index

Adults	Women	Men
Anorexia	< 17.5	< 17.5
Underweight	<19.1	<20.7
Normal range	19.1-25.8	20.7-26.4
Marginally overweight	25.8-27.3	26.4-27.8
Overweight	27.3-32.3	27.8-31.1
Very overweight or obese	>32.3	>31.1
Severely obese	35 – 40	35 – 40
Morbidly obese	40 – 50	40 – 50
Super obese	50 – 60	50 – 60

Formula for Body Mass Index

$$BMI = \frac{\text{Weight (in kgs)}}{\{\text{Height (in meters)}\}^2}$$

The body mass index (BMI) was calculated for all remaining 23 patients. According to the definition used by the World Health Organization, as its international standard,[36] a BMI between 25.8 and 31.1 is considered "overweight," and a score greater than or equal to 31.1 would indicate an individual is clinically "obese." As per this definition, 10 patients in the study were considered overweight and three were classified as obese. The remaining 10 patients were within the normal range of BMI (Tables 2 and 3).

Treatment Options

The treatments being compared were the Silent Nite® Appliance (Glidewell Laboratories, Inc.), the Loma Linda Appliance, and the Snore Tape (patent pending).

Treatment A (Control) – Silent Nite® (Glidewell Laboratories, Inc.)

It is one of the more popular dental devices used for the treatment of snoring available on the market today. It is a removable appliance in which the maxillary and mandibular components are made by a vacuum press technique using the Erkoloc-pro plates Erkodent, Germany). The appliance is custom made such that the maxillary and the mandibular components are held in a fixed position by an inelastic and non-adjustable plastic band (Figures 6a and 6b). For this study, appliances were ordered from Glidewell Laboratories to ensure consistency in fabrication for all patients.

It is available in two sizes – two-inch and four-inch width. The two-inch wide tape was cut in a specific design no less than four inches in length (Figure 9). Before going to bed each evening and after washing their face, patients first placed the tape on the upper lip then extended from under the nose to just under the chin (Figure 10). The tape was cut slightly longer for patients with facial hair (moustache, beard, goatee) for added support. The aim of this treatment method was to prevent snoring by blocking the "snore-way space" without having to reposition the mandible. Upon awakening, the patients were asked to slowly remove the tape to avoid any potential soft tissue irritation. Warm water could also be used to aid the removal of the tape, if necessary. Although the tape is non-irritating, patients were instructed to discontinue treatment and return for a re-evaluation if they experienced localized skin irritation or injury.

Study / Evaluation Method

Twenty-five patients, in good medical condition and not suffering from sleep apnea were enrolled in the study, in order to compare the effectiveness of the three appliances used in the study. Two patients were eliminated from the study due to non-compliance and inability to make recall appointments. At the beginning of the survey the patients were given a questionnaire (Questionnaire 1), to provide information about themselves and their snoring problems. This information served as the baseline data.

The 23 patients were divided randomly into three groups to form a cross-over design with three treatments. Group I, II and III. The treatment options tested were coded as Silent Nite® Appliance (Treatment A), Loma Linda Appliance (Treatment B), Snore Tape (patent pending) (Treatment C). Treatment B and C were the new treatments,

while Treatment A served as the control group. The patients in Group I were given Treatment A to use for the first week, Treatment B for the third week, and Treatment C for the fifth week. The patients in Group II were given Treatment B to use for the first week, Treatment C for the third week, and Treatment A for the fifth week. The patients in Group III were given Treatment C for the first week, Treatment A for the third week, and Treatment B for week five.

Table 4. Patient assignment for the three different treatment methods

WEEK #	TREATMENT		
	Group I	Group II	Group II
1	A	B	C
2	Wash-out	Wash-out	Wash-out
3	B	C	A
4	Wash-out	Wash-out	Wash-out
5	C	A	B

For the second and the fourth week, the patients did not wear any appliance or receive any treatment at all. This seven-day period of no treatment served as a "wash-out" to eliminate any "spill-over" effects from the previous week and to avoid biased results for the different treatments. In order to eliminate other potential biases, the patients were blinded as to which treatments they were receiving. At the end of the first, third, and fifth weeks the patients were given another questionnaire (Questionnaire 2) and their spouse/partner were also given a questionnaire (Questionnaire 3) to complete. The results from all the questionnaires were compiled and analyzed. All questionnaires were completed by the patient or their spouse/partner and were reviewed again with the study investigator (KKB).

Patient Instructions

In order to have control over the study and to minimize inter-subject variability in the effectiveness of the three treatments, patients were told to comply with the following instructions during the course of the study:

1) Do not consume alcoholic beverages for the length of the study.
2) Try to maintain a regular eating regime and avoid overeating. Do not eat at least three hours prior to bedtime.
3) Abstain from sedative-hypnotics, tranquilizers, or antihistamines (with their physician's approval).
4) Try to standardize their sleeping pattern i.e. time of retirement and duration of sleep.

The patient and their spouse/partner were required to maintain a diary to make daily notes. If the patient or the spouse/partner was not compliant with any of the above instructions, they were requested to make a record of an irregularity in the diary for later consideration. The diary notes were retrieved at the end of each week. The diary also helped indicate the compliance of the patient and their interest in the study.

Patient Evaluation

Questionnaire 1 was given to the patient at the beginning of the study. Questionnaire 2 was answered by the patient at the end of each week after treatment, while Questionnaire 3 was answered by the spouse/partner at the end of each week after treatment. The same criteria for patient evaluation were used before and after the use of the different treatments. Comparison of the pre-treatment and post-treatment results from questionnaires answered by patients and their spouse/partner were statistically analyzed.

Statistical Analysis

The data accumulated from the survey responses were subjective and based on a Leikert scale from zero to five or zero to seven. A scale of zero to seven was used for questions regarding the number of nights in a week during treatment that a symptom was experienced. A scale of zero to five was used for all other questions where zero indicated the absence of the symptom and five indicated the highest level of the symptom experienced by the patient. However, questions regarding the comfort and change in the sleep problem were graded on a scale from zero to seven where four indicated no change, five, six and seven indicated an improvement while all values below four indicated a deterioration of the sleep problem or comfort. The data collected through all the questionnaires, answered by the patients and the spouse/partner, at the end of the study period, were divided into four main categories prior to statistical analysis. The four main categories analyzed were treatment results, patient compliance, sleeping habits, and side effects of the various treatment methods. Each of these categories were further divided as follows:

1) *Treatment Results*

A) According to the Patient

- Whether or not the treatment stopped or reduced the patient's snoring problem.
- Evaluation of the overall comfort level of each of the treatment methods.
- Loudness of the patient's snoring.
- Number of nights (frequency) the patient snored.
- Number of nights the patient's snoring woke up their spouse/partner.
- Number of nights the snoring woke up the patients themselves.

- Number of nights the spouse/partner had to leave the room due to the snoring.
- Number of nights the spouse/partner woke up patient.
- Number of nights the patient made loud breathing sounds.

B) According to the Spouse/Partner

- Whether or not the treatment stopped or reduced the patient's snoring problem.
- Loudness of the patient's snoring.
- Number of nights (frequency) the patient snored.
- Number of nights the patient's snoring woke up their spouse/partner.
- Number of nights the spouse/partner had to leave the room due to the snoring.
- Number of nights the patient made loud breathing sounds.

2) *Patient Compliance*

A) According to the Patient

- Number of nights the patient was able to use the device.
- Whether or not the patient followed the pre-treatment instructions.

B) According to the Spouse/Partner

- Whether or not the patient followed the pre-treatment instructions.

3) *Sleeping Habits*

A) According to the Patient

- Quality of sleep
- Difficulty falling asleep
- Time patient went to bed
- Time spouse/partner went to bed
- Number of nights the patient and the spouse/partner went to bed at the same time.

- Number of nights the spouse/partner went to bed in a different room because of the snoring.
- Number of hours the patient was in bed.
- Number of hours the patient was asleep.

B) According to the Spouse/Partner

- Quality of sleep
- Difficulty falling asleep
- Time patient went to bed
- Time spouse/partner went to bed
- Number of nights the patient and the spouse/partner went to bed at the same time.
- Number of nights the spouse/partner went to bed in a different room because of the snoring.
- Number of hours the spouse/partner was in bed.
- Number of hours the spouse/partner was asleep.

4) *Side Effects of Various Treatment Methods*

A) According to Patient

- Temporomandibular joint (TMJ) pain
- Temporomandibular joint (TMJ) noises
- Daytime tiredness
- Degree to which tiredness affects daily activity
- Tooth discomfort
- Allergy/irritation to the material
- Excessive salivation

- Dry mouth
- Difficulty breathing
- Changes in occlusion

B) According to Spouse/Partner

- Daytime tiredness
- Degree to which tiredness affects daily activity

Comparisons of the responses given by the patients for the three treatment methods were analyzed using the Friedman Test in order to determine if a statistically significant difference existed. If a statistically significant difference was found, the Wilcoxon Sign Test was used to identify the differences. A similar analysis was carried out for a comparison of the responses given by the spouse/partner for the three different treatment methods.

Statistical analyses were carried out using Wilcoxon Sign Test to determine whether a statistically significant difference existed between the various responses given by the patients and their spouse/partner, for each treatment method. The McNemar's Test was used to analyze patient and spouse/partner compliance to the instructions given during the study.

Finally, an overall analysis for the four major categories, namely, treatment results, patient compliance, sleeping habits, and side effects of various treatment methods was carried out using one-way analysis of variance (ANOVA) fixed model, with an appropriately defined weight function to reflect the relative importance of the individual

variable within each category. If statistically significant differences were found the Tukey-Kramer Test was used for further analysis among the three treatment groups.

RESULTS

Of the 25 patients enrolled in the study, two were eliminated due to their inability to make the recall appointments. The remaining 23 patients and their spouse/partner were made to answer questionnaires after the use of each treatment method used in the study.

Only one of the 23 subjects had seen a physician for his snoring problem. None of the subjects had used over-the-counter products, ranging from medications to nasal sprays and nasal dilators. None of the patients had continued the use of these products , because they failed to stop their snoring.

None of the patients included in the study were known to suffer from sleep apnea, which was tested using the SleepStrip.^{TM} Only one of the subjects observed a gain or loss in weight in excess of 10 lbs.

The results of this study was divided into four categories, namely, comparison among three treatment methods according to the patient's responses, comparison among three treatment methods according to the spouse's/partner's responses, comparison of responses given by patient and spouse/partner, and overall analysis of the three treatment methods.

Comparison Among Three Treatment Methods According to Patient's Responses

The Friedman Test was used to compare the responses given by the patients for the three treatment methods to determine if statistically significant differences existed. If

a statistically significant difference was found, the Wilcoxon Sign Test was used for further analysis.

Overall Treatment Results

No statistically significant difference was found among the three treatments with respect to any of the variables for overall treatment results. Specifically, there was no significant difference for number of nights the snoring woke up the spouse/partner (p=0.6558), number of nights the spouse/partner had to leave the room (p=0.2765), number of nights the snoring woke up the patient (p=0.2717), number of nights the spouse/partner had to wake up the patient (p=0.8395), loudness of the snoring (p=0.1671), number of nights the patient snored (p=0.4020), number of nights the patient made loud breathing sounds (p=0.8463), whether or not the treatment stopped or reduced snoring (p=0.5558), or overall comfort level (p=0.7976). According to the patient, 65.23%(15) reported that Treatment A stopped or reduced their snoring problem, while Treatment B and Treatment C stopped or reduced snoring in 43.48% (10) and 47.83% (11) of the patients, respectively. These values were not statistically significantly different (p=0.5558).

Patient Compliance

No significant difference was observed among all three treatment methods for patient compliance. The Friedman Test detected no statistically significant difference for number of nights the treatments were used (p=0.6616) and Cochran's Q Test was employed to determine that there was no statistically significant difference with respect to instructions given to the patient and spouse/partner (p=0.5488).

Sleeping Habits

No significant difference in sleeping habits was detected, namely, difficulty falling asleep (p=0.1211) and quality of sleep (p=0.3826).

Side Effects

Unlike the previous outcomes, a statistically significant difference was observed for some of the side effects among the three treatment methods. Tooth discomfort (p=0.0005), occlusal changes (p=0.0009), temporomandibular joint (TMJ) pain (p=0.0041) and TMJ noises (p=0.0344) were all statistically different among the treatments.

The Wilcoxon Sign Test revealed that Treatment A caused significantly greater tooth discomfort when compared to Treatment B (p=0.0490) and Treatment C (p=0.0005). There was no significant difference with respect to tooth discomfort between Treatment B and Treatment C (p=0.0923). Tooth discomfort was reported by 73.91% (17) of the patients for Treatment A, 52.17% (12) for Treatment B, and only 17.39% (four) reported tooth discomfort for Treatment C.

For occlusal changes, Wilcoxon Sign Test revealed that there was no significant difference between Treatment A and Treatment B (p=0.0768), and between Treatment B and Treatment C (p=0.1094). However, Treatment A produced significantly greater occlusal changes when compared to Treatment C (p=0.0013). Occlusal changes were reported by 73.91% (17) of the patients for Treatment A, 43.48% (10) for Treatment B, and 8.70% (two) for Treatment C. The patients that did experience occlusal changes found that their posterior teeth were not contacting on awakening.

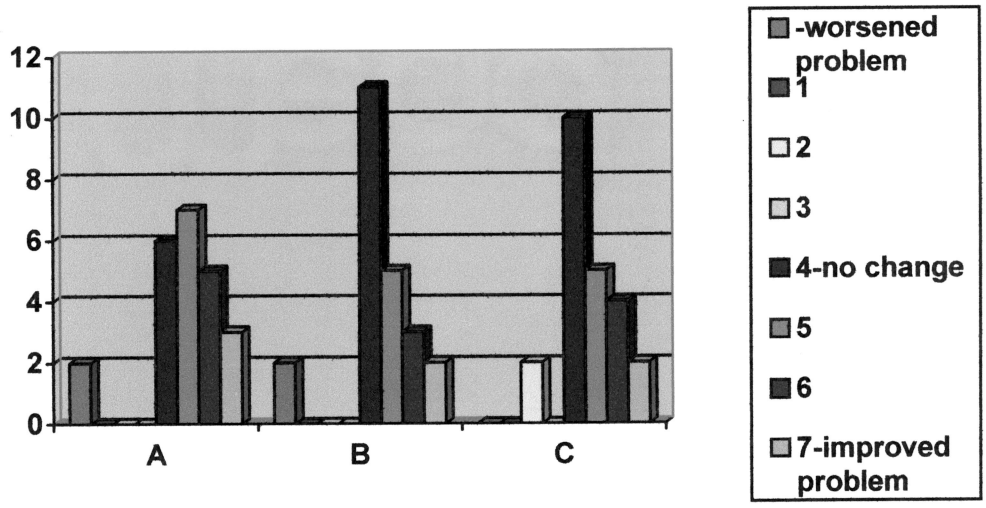


Figure 11. Change in Snoring According to the Patient

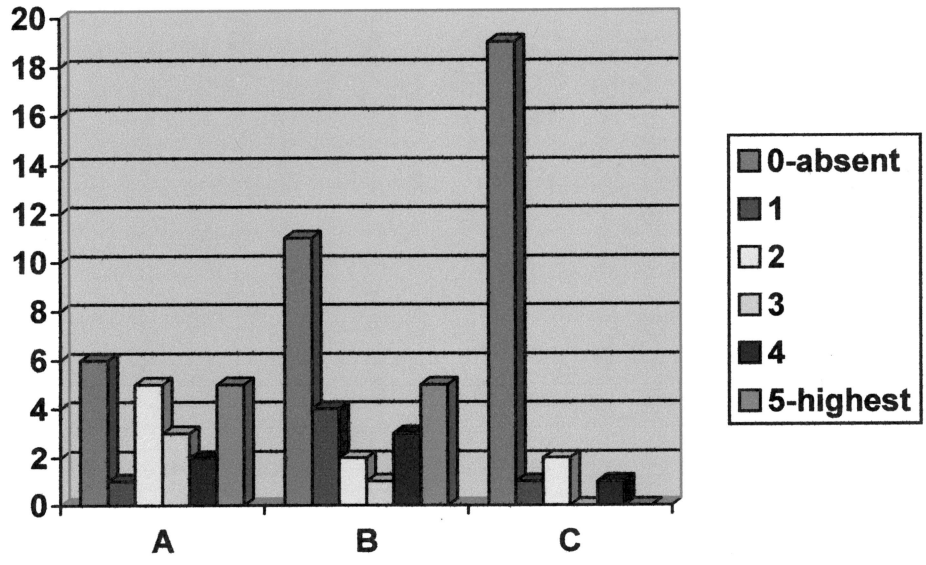


Figure 12. Tooth Discomfort Experienced by Patient Resulting From All 3 Treatments

However, these symptoms disappeared within 30 minutes to two hours after cessation of the treatment.

None of the patient experienced any TMJ pain while using Treatment C. However, 47.83% (11) of the patients and 34.78% (eight) of the patients experienced TMJ pain with Treatment A and Treatment B, respectively. Wilcoxon Sign Test revealed that there was no significant difference between Treatment A and Treatment B ($p=0.3877$). Treatment A caused significantly greater TMJ pain when compared to Treatment C ($p=0.0063$), and Treatment B caused significantly greater TMJ pain when compared to Treatment C ($p=0.0156$).

TMJ noises was reported by 21.74% (five) and 8.70% (two) of the patients for Treatment A and Treatment B, respectively. None of the patients experienced TMJ noises with Treatment C. Wilcoxon Sign Test revealed that there was no significant difference between Treatment A and Treatment B ($p=0.3750$), and between Treatment B and Treatment C ($p=0.2500$). However, Treatment A caused significantly greater TMJ noises when compared to Treatment C ($p=0.0361$).

No statistically significant difference were found for all the other side effects analyzed, namely, daytime tiredness ($p=0.1589$), level to which tiredness affected daily activities ($p=0.7733$), salivation ($p=0.0737$), dry mouth ($p=0.1801$), difficulty breathing, ($p=0.7115$) and allergy/irritation to material ($p=0.7396$).

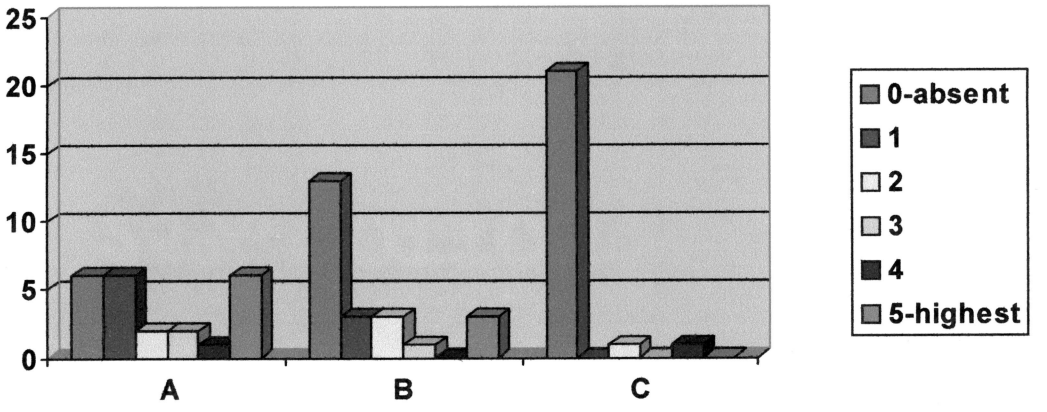


Figure 13. Occlusal Changes Experienced by Patient Resulting From All 3 Treatments

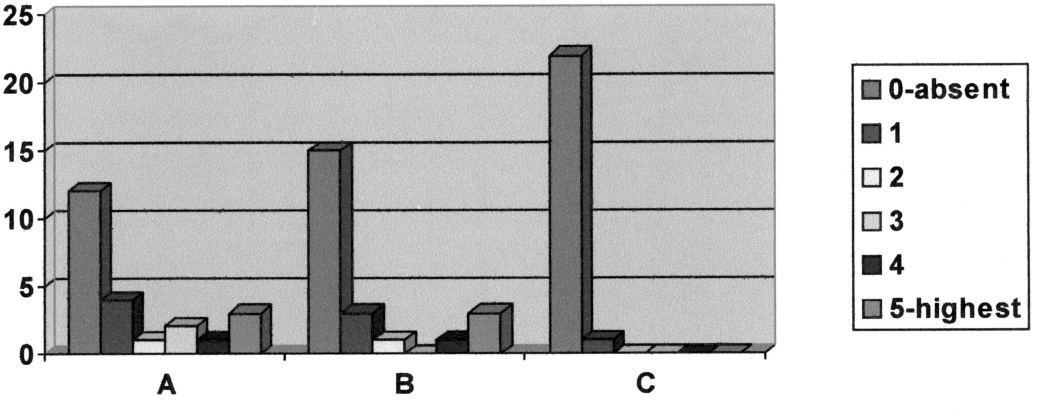


Figure 14. TMJ Pain Experienced by Patient Resulting From All 3 Treatments

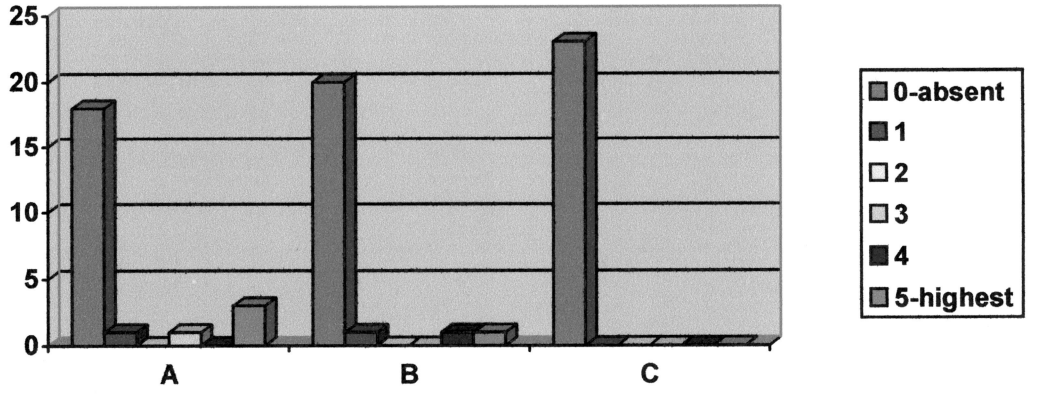


Figure 15. TMJ Noises Experienced by Patient Resulting From All 3 Treatments

Comparison Among Three Treatment Methods According to Spouse's/Partner's Responses

The Friedman Test was used to compare the responses given by the spouse/partner for the three treatment methods to determine if a statistically significant difference existed. If a statistically significant difference was found, Wilcoxon Sign Test was used for further analysis.

Overall Treatment Results

A statistically significant difference was found with respect to the level to which treatments stopped or reduced snoring (p=0.0348). According to the spouse/partner, Treatment A stopped or reduced snoring in 78.26% (18) of the patients, while Treatment B and Treatment C stopped or reduced snoring in 52.17% (12) and 73.91% (17) of the patients, respectively. Using the Wilcoxon Sign Test, Treatment A stopped or reduced snoring significantly more than Treatment B (p=0.0213). However, no significant difference existed between Treatment A and Treatment C (p=0.3018) or between Treatment B and Treatment C (p=0.3323).

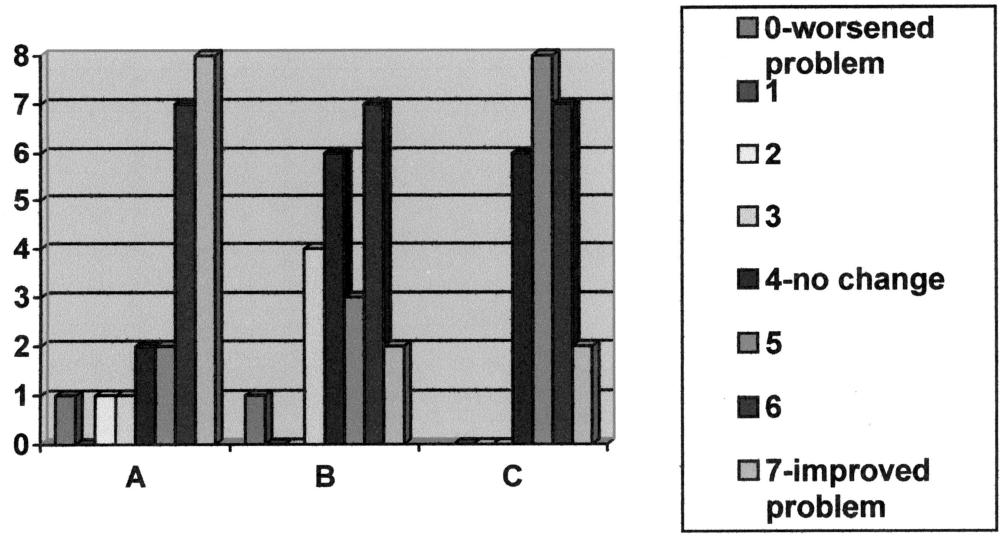


Figure 16. Change in Snoring According to Spouse/Partner

No statistically significant difference was found among the three treatments, with respect to, any other variables for overall treatment results. There was no significant difference for number of nights the snoring woke up the spouse/partner (p=0.9334), number of nights the spouse/partner had to leave the room (p=0.5647), loudness of the snoring (p=0.5861), number of nights the patient snored (p=0.4286), or number of nights the patient made loud breathing sounds (p=0.4724).

Patient Compliance

No significant difference was noted among all three treatment methods for patient compliance. The McNemar Test determined that there was no significant difference with respect to instructions given to the patient and spouse/partner, between Treatment A and Treatment B (p=0.6250), between Treatment A and Treatment C (p=0.2500), and Treatment B and Treatment C (p=1.00)

Sleeping Habits

No significant differences in sleeping habits were detected, among responses for difficulty in falling asleep (p=0.7974) and quality of sleep (p=0.8187) among the three treatments.

Side Effects

No statistically significant difference existed with respect to daytime tiredness (p=0.2725) among the three treatments.

Comparison of Responses Given by Patient and Spouse/Partner

Wilcoxon Sign Test was used to determine if a statistically significant difference existed between responses given by the patient and the spouse/partner, for the different variables for each treatment method.

Treatment A (Silent Nite®)

No significant difference existed between patient's and spouse's/partner's responses for any of the variables. Responses analyzed were number of nights the snoring woke up the spouse/partner (p=1.0), number of nights the spouse/partner had to leave the room (p=0.5000), loudness of the snoring (p=0.2188), number of nights the patient snored (p=0.2891), number of nights the patient made loud breathing sounds (p=0.1797), whether or not the treatment stopped or reduced snoring (p=0.0574), whether or not the patient and the spouse/partner experienced difficulty falling asleep (p=0.1094), quality of sleep (p=0.2668), and daytime tiredness (p=0.2668).

Treatment B (Loma Linda Appliance)

A statistically significant difference existed between patient's and spouse's/partner's response with respect to daytime tiredness (p=0.0042). Daytime tiredness experienced by spouse/partner was significantly greater than that experienced by the patient. Difficulty of falling asleep also showed a statistically significant difference (p=0.0018) with the spouse/partner experiencing a significantly greater difficulty falling asleep. No significant difference existed for number of nights the snoring woke up the spouse/partner (p=0.3438), number of nights the spouse/partner had to leave the room (p=1.00), loudness of the snoring (p=0.3438), number of nights the patient snored (p=1.00), number of nights the patient made loud breathing sounds

(p=1.00), whether or not the treatment stopped or reduced snoring (p=0.5078), and the quality of sleep (p=0.4807).

Treatment C [Snore Tape (patent pending)]

A statistically significant difference existed between patient's and spouse's/partner's response with respect to difficulty falling asleep (p=0.0034). The spouse/partner experienced a significantly greater difficulty falling asleep. No significant difference existed for number of nights the snoring woke up the spouse/partner (p=0.7266), number of nights the spouse/partner had to leave the room (p=1.00), loudness of the snoring (p=1.00), number of nights the patient snored (p=1.00), number of nights the patient made loud breathing sounds (p=1.00), whether or not the treatment stopped or reduced snoring (p=0.1796), daytime tiredness (p=0.4240), and the quality of sleep (p=0.5488).

McNemar's Test determined that there was no statistically significant difference (p=1.00) observed between compliance of patient and spouse/partner with respect to the instructions given before the start of the study, for all three treatments.

Overall Analysis for the Three Treatment Methods

Overall analysis was also carried out according to the four major categories. A one-way ANOVA fixed model was used to determine if a statistically significant difference existed among the three treatment methods. If a statistically significant difference existed, a Tukey–Kramer Test was used for further analysis.

Overall Treatment Results

No statistically significant difference was found for overall treatment results, among the three treatment methods (p=0.6657).

Patient Compliance

There was no statistically significant difference for patient compliance among the three treatment methods (p=0.3942).

Sleeping Habits

No statistically significant difference was found for sleeping habits, among the three treatment methods (p=0.2382).

Side Effects

There was a statistically significant difference for side effects, among the three treatment methods (p=0.0117). Further analysis using Tukey-Kramer Test revealed no statistically significant difference between Treatment A and Treatment B (p=0.8376), and between Treatment B and Treatment C (p=0.0543). However, there was a statistically significant difference between Treatment A and Treatment C (p=0.0135). Side effects caused by Treatment A were significantly greater than those caused by Treatment C.

DISCUSSION

The study enrolled 25 patients, of which two were eliminated. The results of this study were based on the findings of the remaining 23 patients and their spouse/partner. Each patient used all three treatment methods for a period of one week.

The Snore Tape (patent pending) and the Loma Linda Appliance have been used by Dr. Leonard L. Portnoy for the treatment of his patients suffering from snoring.[7] However, these treatments had never been evaluated and compared in controlled clinical trials. Therefore, this project was undertaken to compare the effectiveness of each treatment method with a device (Silent Nite®) that is currently commonly used. The Silent Nite® was selected as the control treatment, as it is one of the more popular devices currently used in the treatment of snoring. Common problems associated with this appliance and other anterior repositioning devices have been excessive salivation, TMJ pain, dental and myofascial discomfort, and transient occlusal changes.[37]

The Loma Linda Appliance is a simple modification to other anterior repositioning devices intended to minimize some of these side effects. The elastic bands make it easy for the patients themselves to adjust the amount of anterior positioning according to their comfort. The Snore Tape (patent pending) was included in the study because a number of patients in Dr. Portnoy's practice had experienced good results with it. Unlike the other treatments commonly used to reduce or stop snoring the Snore Tape (patent pending) is an extraoral treatment. It eliminates any possible side effects resulting from an intraoral appliance. No other treatment of its kind has been tested before in a controlled clinical trial. It also requires relatively less clinical time, is easily fabricated, and it is significantly less expensive than other treatment options. Dr. L. Portnoy used

the tape in many different ways from a single broad (two inch) or a narrow (one inch) tape extending from the upper lip to just under the chin, to two narrow (two inch) tapes in a cross design over the upper and lower lips. Dr. W. Patrick Naylor modified and standardized the original designs suggested by Dr. L. Portnoy after using the tape technique himself for over two and one half years.

The method of evaluation in this study entailed the use of extensive questionnaires both before and after each treatment. The patient and the spouse/partner answered these questionnaires. Although, this method of evaluation is subjective when compared to a polysomnograph, many studies in the past have used questionnaires for evaluations of snorers.[26,28,37] In order to do polysomnographs before and after the use of each appliance, it would require six polysomnographs for each patient in our study. Besides being very expensive, a polysomnograph is also very inconvenient for most patients who only have a snoring problem. Analysis of the responses to almost all the questions posted to the patient and the spouse/partner showed no significant difference for all three treatment methods in spite of the participants not being allowed to discuss their answers with each other. This finding suggests a certain level of accuracy of the responses given. This similarity between the responses of the patient and the spouse/partner is contrary to the findings of Wiggins et al[38] who reported that questionnaire data may be misclassified in part. They found that for men, the spouse (wife) reported a higher prevalence of snoring and other symptoms, while for women, the spouse (husband) reported a lower prevalence of snoring and other symptoms. However, in this study there was no statistically significant difference among most of the responses given by the patient and the spouse/partner. There was only a statistically significant

difference in the response between patient and spouse/partner for sleeping habits (daytime tiredness and difficulty falling asleep) for Treatment B and sleeping habits (difficulty falling asleep) for Treatment C. In both cases the spouse/partner experienced greater difficulty falling asleep or greater daytime tiredness, which is to be expected, given the patient's snoring problem.

This study included patients ranging from 28 years of age to 69 years of age. However, 74% of these patients were above the age of 40, which validates other literature that states that the incidence of snoring increases with age.[5,11] Only 25% of the patients were women, consistent with the findings of Hick et al that men are more likely to snore than women.[6] The study group also showed the majority (56.5%) of the snoring patients had a body mass index (BMI) consistent with someone who is overweight or obese. This finding is in accordance with the studies showing a direct relationship between snoring and a person's BMI. [11,12,13,15] Although, these findings with respect to age, sex, and BMI are consistent with other studies, no definite conclusion regarding the same can be drawn from this study due to the small sample size. It merely goes to show that the sample size though small in this study, is congruous in its demographic distribution when compared to other larger studies.

When evaluating the responses obtained from the patients themselves, it was apparent that they differed in their interpretation of the effectiveness of the three treatments. Even though 65.23%(15) of the patients reported that Silent Nite® stopped or reduced their snoring problem, compared to 43.48% (10) and 47.83% (11),for the Loma Linda Appliance and the Snore Tape (patent pending), respectively, these findings were not statistically different. It appears that the Silent Nite® was of more benefit to a

larger number of patients (15 compared to 10 and 11 for the Loma Linda Appliance and the Snore Tape (patent pending), respectively), when reporting these results in percentages. However, these evaluations were made on a scale from zero to seven. The percentages reported simply represent an improvement in the snoring problem without giving correct weight to each value in the scale. The small sample size may also be responsible for this discrepancy between the statistical significance and the percentage values.

What was clearly evident, and statistically significant, was the fact that the spouse's/partner's found that the Snore Tape (patent pending) was as effective as the Silent Nite® ($p=0.3018$) in stopping or reducing snoring. The Snore Tape (patent pending) reduced or stopped snoring in 73.91% (17) of the patients compared to 78.26% (18) for the Silent Nite®. We can safely say that these findings are more relevant as the spouse/partner is more accurate than the patient in reporting the effectiveness of the treatments.

The results from this study also demonstrate that patients experienced substantially more adverse side effects with the Silent Nite®. The side effects, namely, tooth discomfort, occlusal changes, TMJ pain, and TMJ noises produced by the non-adjustable device (Silent Nite®) were significantly greater than those produced by the Snore Tape (patent pending). The dentist should be aware of these possible side effects when selecting this appliance for the treatment of snoring. In most cases the occlusal changes and pain, disappear approximately two hours after the removal of the appliance in the morning. The dentist may also recommend the use of a leaf gauge to accelerate the recovery of the occlusion and reposition the mandible. A leaf gauge is a thickness of

mylar strips, which can be increased or decreased depending on the amount of incisal opening required.

Statistical analysis showed that there was no statistically significant difference in the overall side effects produced by the Silent Nite® Appliance and the Loma Linda Appliance. However, the patients did report having a higher level of tooth discomfort with the Silent Nite® than with the Loma Linda Appliance. Patients also found excessive salivation with the Loma Linda Appliance marginally more than with the Silent Nite®.

One patient could not use the Loma Linda Appliance, because the soft, flexible material could not provide adequate retention. As a result, the appliance would frequently lift off the mandibular teeth. Another patient had to discontinue the use of the appliance after two nights due to difficulty in breathing. Another problem with the Loma Linda Appliance was that the brackets that held the elastic bands frequently became detached from the upper or lower member of the appliance. An improved method of fastening these brackets to the polypropylene material needs to be evaluated.

The Silent Nite® Appliance was well accepted by other patients. There was no overall difference between the Silent Nite® and Loma Linda Appliance. Although, 4.37% (one) of the patients could not use the Silent Nite® as the anatomy of his mandibular teeth did not have sufficient undercut for retention of the appliance. This factor needs to be kept in mind when selecting this appliance for a patient. Unbearable pain in the teeth and jaws caused 8.74% (two) of the patients to discontinue using the appliance. One patient had to discontinue the use of the appliance after two nights due to difficulty in breathing.

Apart from the Snore Tape (patent pending) being more comfortable to use, it is less expensive for the patient, less time consuming for the clinician, and does not require laboratory support to fabricate. It can be used conveniently during travel as it is disposable. Also, cleanliness and maintenance are not concerns, as in the case of intraoral appliances. In an article by Tyler[39] in 2000, the author mentioned the importance of durability of intraoral appliances used for snoring. He stated that the prevalence of bruxism, clenching, and other parafunctional habits is higher in snorers who are commonly overweight or obese. Placing and removing an appliance that is to be used every night, causes stress and wear of the appliance. These intraoral appliances, therefore, require regular recall visits for their maintenance. The Snore Tape (patent pending) on the other hand, is a one-time-use (disposable) product that is replaced every time a patient goes to sleep.

The side effects anticipated with the use of the Snore Tape (patent pending) included reddening or irritation to the skin, difficulty with placement and removal on patients who had facial hair (mustache, beard and goatee), and inability to use in mouth breathers and patients with nasal blockages, claustrophobia, and psychological rejection. Although a non-irritant tape was used, one patient developed irritation on the skin. None of the patients with facial hair experienced any difficulty with the placement and removal of the tape. The use of warm water and removal of the tape along the direction of hair growth significantly decreased discomfort during removal. None of the patients experienced claustrophobia, but one female patient was unable to wear the tape more than two nights. She had difficulty adapting to it psychologically. Despite the absence of claustrophobia, difficulty in breathing or irritation, this patient was unable to accept the

idea of having a tape placed over her mouth. As with this patient, other patients needed time to get used to the tape method psychologically. Spending time to explain how the tape should be applied, worn, and removed helped patients accept this method of treatment more easily. Given adequate time, the patients also learned to place the tape with the correct tension for best results. They found a comfort zone for themselves, which allowed sufficient air exchange through the corners of their mouth should they need to breathe through their mouth. Patients also realized that if the tape was placed too loosely, its effectiveness was compromised. It was, therefore, observed in retrospect, that a "wash-in" period and longer treatment length (greater than one week) might also be necessary for the patients to get used to the appliance before they make their observation and comments on the treatment method. This might also translate into more accurate results in future studies.

The study also showed that there was no statistically significant difference among the three treatment methods for the overall treatment results, patient compliance, and sleeping habits.

The questionnaires also included information about medical problems and medications being taken by the patient. The percentage of patients that suffered from hypertension was 21.74% (five), while 4.35% (one) of the patients suffered from hypothyroidism, and another 21.74% (five) of the patients had other unrelated medical problems. The percentage of patients on anti-histaminics were 17.84% (four), while 26.22% (six) were on anti-hypertensive medication. However the sample size in this study was too small to form any conclusions from these findings.

The results of this study indicated that although the patient found that all three treatment modalities were not statistically significantly different in stopping or decreasing snoring, there were significantly fewer side effects with the Snore Tape (patent pending) compared to the intraoral appliances. The spouse/partner however found that the Snore Tape (patent pending) was as effective as Silent Nite® in stopping or reducing snoring. However the Loma Linda Appliance was significantly less effective than the Silent Nite® and the Snore Tape (patent pending), according to the spouse/partner. Therefore, the hypothesis for the study has been proved. The advantages in terms of cost, time, and convenience of use of the Snore Tape (patent pending) should not be overlooked. It is recognized that not all patients will benefit from this conservative, alternative treatment approach. However, this study has demonstrated that neither the Silent Nite® nor the Loma Linda Appliances are beneficial to all patients. Careful consideration needs to be given to the side effects and teeth anatomy, when selecting any intraoral appliances. The Snore Tape (patent pending) can be used in edentulous patient who would not otherwise be indicated for the Silent Nite® or the Loma Linda Appliance.

Therefore, the Snore Tape (patent pending) could be considered an initial treatment of choice to be considered prior to making an intraoral device. Although, it may not be beneficial for all patients, it appears to have the fewest side effects, is simple to use, requires the least patient preparation and clinic time, and needs no laboratory support. It is disposable and it is less expensive than any other intraoral treatment devices. Even if only a small percentage of patients can use the Snore Tape (patent pending) successfully, the potential benefits to them and their spouse/partner are

enormous. Clinicians can always recommend an intraoral device if the tape treatment is not successful or well accepted by patients.

However, additional studies with a larger sample size are necessary. It is also advisable to have the patients use the treatment modalities for a longer duration, so as to judge the long term effect, and also include a "wash-in" period in order to get more accurate results.

CONCLUSIONS

Within the limitations of this study the following conclusions can be made:

1) All three treatment methods help reduce or stop snoring.
2) The spouse/partner found that the Snore Tape (patent pending) reduced or stooped snoring in 73.91% (17) of the patients while the Silent Nite® reduced or stopped snoring in 78.26% (18) of the patients. This indicated that the Snore Tape (patent pending) was as effective as the Silent Nite® in reducing or stopping snoring, as these values were not statistically significantly different. The Loma Linda Appliance reduced or stopped snoring in 52.17% (12) of the patients.
3) The patients found that there was no significant difference in the effectiveness among all three treatments ($p=0.5558$).
4) The Silent Nite® had significantly greater overall side effects than the Snore Tape (patent pending). The Silent Nite® resulted in tooth discomfort, occlusal change, TMJ pain and TMJ noises in 73.91% (17), 73.91% (17), 47.83%(11), and 21.74% (five) of the patient, respectively. These values were significantly greater when compared to the Snore Tape (patent pending) which resulted in tooth discomfort, occlusal change, TMJ pain and TMJ noises in only 17.39% (four), 8.70% (two), 0% (0), and 0% (0) of the patients, respectively. Even the Loma Linda Appliance resulted in less tooth discomfort 52.17% (12), occlusal change 43.48%(10), TMJ pain 34.78% (eight), and TMJ noises 8.70% (two) when compared to the Silent Nite®.
5) There was no significant difference among all three treatment methods for overall treatment results (like effectiveness, comfort, loudness and frequency of snoring, etc.).

6) The responses given by the patient and the spouse/partner indicated no significant difference for most variables tested. There was a significant difference in the response between patient and spouse/partner only for sleeping habits (quality of sleep and difficulty falling asleep) for the Loma Linda Appliance and sleeping habits (difficulty falling asleep) for the Snore Tape (patent pending), which is to be expected, given the patient's snoring problem.
7) Patient and spouse/partner compliance to the instructions given at the start of the study showed no statistically significant difference for all treatment methods.
8) No statistically significant difference was observed by the patient for sleep habits (difficulty falling asleep and quality of sleep) for all three treatment methods.

Therefore the results of the study proved the hypothesis that the Snore Tape (patent pending) is as effective as intraoral appliances with fewer side effects for the treatment of mild to occasional snoring.

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APPENDIX 1 – PRE-TREATMENT QUESTIONNAIRE FOR PATIENT AND SPOUSE/PARTNER

Loma Linda, CA 92350

Snoring Study

Questionnaire 1

Contact:
Dr. Kainaz Byramjee

Clinic - (909) 558-8299
Study Coordinator Pager: (909) 558-1717, 1586

Thank you for agreeing to participate in this snoring study at the Loma Linda University School of Dentistry. If you have any questions, concerns, or problems during this evaluation, please call Dr. Byramjee at one of the phone numbers listed above.

PERSONAL DATA:

1. Participant #:_____
2. Age:_____
3. Sex:_____
4. Race:_____
5. Height: _____ Weight: _____
6. Do you snore? Yes / No
7. How long have you been snoring? (# of years) _____
8. How did you learn that you snore? _____
   _____
   _____
9. Have you ever been treated for snoring by a physician, dentist or other health professional? Yes / No .
   If "yes", then briefly explain the kind of treatment. _____
   _____
   _____
10. Have you ever used any over-the-counter products to stop your snoring? Yes / No
    If yes, what product or products did you purchase and use?
    _____

11. How long did you use that product or those products? (In months)

_____

12. Where did you purchase those products and how much did they cost?

_____

_____

13. Have you or your spouse / partner been given any advice on things to do before going to bed that would reduce or stop the snoring? Yes / No.
If "yes" then explain the advice given.

_____

_____

14. Do you and your spouse/partner go to bed at different times because of the snoring? Yes / No

15. How has your snoring been described?
Loudness [grade on a scale of 1 (softest) to 5(loudest)]_____
length of time you snore each night (in hours)_____
frequency (how many nights per week)_____

16. Have you been told about your sleeping position while snoring? Yes / No
Back ____, Right side ____, Left side ____, Stomach ____

17. Do you have difficulty breathing through your nose? Yes / No

18. Do you have sleep apnea (a condition where you stop breathing, gasp for air and resume breathing after a short interval, but remain asleep) ? Yes / No

19. Have you gained or lost more than 10 pounds in the last 6 months? Yes / No

20. If you answered "yes" to the question above, what was the change in weight and over what period of time did this change occur?

_____

_____

21. Would you consider yourself a light sleeper? Yes / No

22. Would you consider yourself to be a nervous person? Yes / No

23. Are you presently on any kind of medication? (Please list the names of the medication and the dosage)?
Sedative-hypnotics Yes / No _____
Tranquilizers Yes / No _____
Antihistamines Yes / No _____
Others _____

24. Are you aware of any medical problems that you might be suffering from? Yes / No

Hypertension	Yes / No
Angina	Yes / No
Any other cardiovascular disease	Yes / No
Hypothyroidism	Yes / No

Others_____

Special instruction: during the course of this study please try to go to bed at a set time each evening, do not drink alcohol or eat for 3 hours prior to bed time, and do not read in bed. Try to go to bed with the specific intent of going to sleep at this set time each evening. If for some reason these instructions cannot be followed at any stage during the study, please make a note of it in the questionnaire provided and in your diary.

APPENDIX 2 – POST-TREATMENT QUESTIONNAIRE FOR PATIENT

Questionnaire for Weekly Assessments
Questionnaire 2
(For Study Participants)

Participants' Study Number: _____

Date: _____ **Technique Used this Past Week**: A, B, or C (circle one)

Week Number: 1, 2, 3, 4, 5, or 6 (circle one)

Please answer all the following questions based on your experiences for the past 7 days:

1. In the past week, how many nights did you wear the appliance? 0 1 2 3 4 5 6 7

2. During the past week how many nights did you snore? 0 1 2 3 4 5 6 7

3. Did your snoring disturb or wake your spouse/ partner? Yes / No
   If you answered "Yes", please state how many nights? 0 1 2 3 4 5 6 7

4. Did your snoring cause your spouse/partner to leave the room and sleep elsewhere? Yes / No
   If you answered "Yes", please explain if your spouse had to sleep in another room or take some other action to avoid your snoring
   _____

5. Did your snoring wake you up? Yes / No
   If "Yes", how many nights? 0 1 2 3 4 5 6 7
   how many times per night? _____

6. What time did you go to bed each night? _____
7. What time did your spouse/partner go to bed each night? _____

8. In the past week, how many nights did you and your spouse/partner go to bed at the same time? 0 1 2 3 4 5 6 7

9. In the past week, how many nights did you and your spouse/partner go to bed in separate bedrooms because of the snoring? 0 1 2 3 4 5 6 7

10. How many hours did you remain in bed? _____

11. How many hours did you sleep, of the hours you were in bed? _____

12. How many times did your spouse/partner awaken you each night? _____

13. In the past week did you feel tired or sleepy at any time during the day? Yes / No
If *"Yes"* when did you feel tired/sleepy
_____

14. In the past week, has there been any change in your occlusion / bite? Yes / No
If *"Yes"* then explain the kind of change and how long it lasted?
_____
_____
_____

15. In the past week, were you able to comply with the instructions given to you at the beginning of the study? Yes / No
If "No",
explain_____
_____
_____

Answer the following question with in "yes" or "no" and / or grade your answer on a scale of 1 to 5.

16. Did you awake in the morning feeling tired? Yes / No

Not tired (0)				Very Tired/ Sleepy (5)	
0	1	2	3	4	5

17. Did the feeling of being tired and/or sleepy affect your daily activities? Yes / No

Did not affect (0)				Did affect (5)	
0	1	2	3	4	5

18. Did you have difficulty falling asleep? Yes / No

No Difficulty				Very Difficult	
0	1	2	3	4	5

19. In the past week, how would you rate the quality of your sleep each night? Yes / No

Not Rested (0)				Well Rested (5)	
0	1	2	3	4	5

20. In the past week, how would you rate the loudness of your snoring?

No Sounds (0)				Very Loud (5)	
0	1	2	3	4	5

21. In the past week, how frequently did you snore?

No Snoring (0)							Snored Every Night (7)
0	1	2	3	4	5	6	7

22. In the past week, how frequently did your own snoring awaken you?

Not At All (0)							Every Night (7)
0	1	2	3	4	5	6	7

23. In the past week, how frequently did you make loud breathing sounds?

Not At All(0)							Every Night (7)
0	1	2	3	4	5	6	7

24. In the past week, did you experience any of the following? (Please rank their intensity, where 0 = absent and 5 = highest)

Excessive Salivation	0	1	2	3	4	5
Dry Mouth	0	1	2	3	4	5
Difficulty in breathing	*0*	*1*	*2*	*3*	*4*	*5*
Irritation to the material used	0	1	2	3	4	5
Discomfort of teeth and jaws	0	1	2	3	4	5
Temporary change in occlusion/bite	0	1	2	3	4	5
Jaw pain	0	1	2	3	4	5
TMJ noise (area in front of the ear)	0	1	2	3	4	5

25. In the past week, do you think the treatment made a difference to your sleep problem? Yes / No

Worsened problem				No Change		Improved Problem	
0	1	2	3	4	5	6	7

26. How would you rate the general comfort of the treatment?

Not Comfortable							Comfortable
0	1	2	3	4	5	6	7

APPENDIX 3 – POST-TREATMENT QUESTIONNAIRE FOR SPOUSE/PARTNER

Questionnaire for Weekly Assessments
Questionnaire 3

(For Study Participants' Spouse or Partner)

Spouse/Partner Participant Number:_____

Date: _____ **Technique Used this Past Week**: A, B, or C (circle one)

Week Number: 1, 2, 3, 4, 5, or 6 (circle one)

Please answer all the following questions based on your experiences for the past 7 days:

1. During the past week (7 calendar days) how many nights did your spouse/partner snore? 0 1 2 3 4 5 6 7

2. Did your spouse / partner's snoring wake you up? Yes / No
   If "Yes" how many nights? 0 1 2 3 4 5 6 7
   how many times per night?_____

3. Did your spouse / partner's snoring cause you to leave the room and sleep elsewhere? Yes / No
   If "Yes", please explain if your spouse/partner had to sleep in another room or take some other action to avoid your snoring
   _____
   _____

4. What time did you go to bed each night?_____

5. What time did your spouse/partner go to bed each night?_____

6. How many hours did you remain in bed? _____

7. How many hours did you sleep of those hours you were in bed? _____

8. In the past week, how many nights did you and your spouse/partner go to bed at the same time? 0 1 2 3 4 5 6 7

9. In the past week, how many nights did you and your spouse/partner go to bed in separate bedrooms because of the snoring? 0 1 2 3 4 5 6 7

10. In the past week, did your spouse/partner's breathing stop while he was asleep?
    Yes / No
    If "yes" then how many nights? 0 1 2 3 4 5 6 7
    how many times per night?_____

11. In the past week did you feel tired or sleepy at any time during the day? Yes / No
    If "Yes" when did you feel tired/sleepy _____

12. In the past week, did your spouse/partner comply with the instructions given to him/her at the beginning if the study? Yes / No
    If 'No", explain_____
    _____

Answer the following question with in "yes" or "no" and / or grade your answer on a scale of 1 to 5.

13. Did you awake in the morning feeling tired? Yes / No

Not tired (0)					Very Tired/ Sleepy (5)
0	1	2	3	4	5

14. In the past week, how would you rate the quality of your sleep each night?

Not Rested(0)					Well Rested (5)
0	1	2	3	4	5

15. In the past week, how would you rate the loudness of your spouse/partner's snoring?

No Sounds (0)					Very Loud (5)
0	1	2	3	4	5

16. In the past week, how frequently did your spouse/partner's snore?

No Snoring (0)							Snored Every Night (7)
0	1	2	3	4	5	6	7

17. In the past week, how frequently did the snoring awaken you?

Not At All (0)							Every Night (7)
0	1	2	3	4	5	6	7

18. In the past week, how frequently did your spouse/partner make loud breathing sounds?

Not At All (0)							Every Night (7)
0	1	2	3	4	5	6	7

19. In the past week, did you have difficulty falling asleep, with your partner's snoring?

No Difficulty(0)					Very Difficult(5)
0	1	2	3	4	5

20. In the past week, do you think the treatment made a difference to your spouse/ partner's sleep problem?

Worsened problem(1)			No Change(4)			Improved Problem(7)
1	2	3	4	5	6	7

Spouse's/Partner's Responses to Questionnaire 3 for Treatment A

#	Grp	Qs1	Qs2	Qs3	Qs4	Qs5	Qs6	Qs7	Qs8	Qs9	Qs10	Qs11	Qs12	Qs13	Qs14	Qs15	Qs16	Qs17	Qs18	Qs19	Qs20
1	A	0	0	0	23	22	6	5	0	0	0	0	1	0	2	0	0	0	0	0	7
4	A	7	5	0	22	22	8	6	7	0	0	1	1	4	1	4	5	5	5	5	4
5	A	0	0	0	22	22	7	7	6	0	0	0	1	0	5	0	0	0	0	0	7
6	A	0	0	0	24	24	6	6	3	0	0	0	1	0	4	1	0	0	1	0	6
7	A	7	5	1	23	22	9	8	4	1	0	1	1	3	3	3	7	2	6	4	6
11	A	2	2	0	21	22	8	7	4	0	-	0	1	1	4	1	2	2	1	0	7
23	A	1	1	1	21	22	5	5	0	1	0	0	1	0	4	1	1	1	3	0	7
24	A	2	2	0	22	23	8	8	0	0	0	1	1	1	2	4	2	2	2	2	3
3	A	7	6	0	22	22	9	8	3	0	0	0	1	2	4	3	6	2	2	3	5
8	A	0	0	0	23	23	8	8	7	0	0	0	1	0	5	0	1	0	0	0	7
9	A	2	1	0	20	22	9	8	0	0	0	1	1	0	3	2	2	2	0	1	6
14	A	1	0	0	23	23	7	7	7	0	0	0	0	0	5	1	2	0	2	0	6
15	A	3	0	0	23	23	8	8	0	0	0	0	1	0	4	1	3	0	0	0	6
16	A	2	0	0	22	22	7	7	7	0	0	0	1	0	5	1	2	0	0	0	7
18	A	0	0	0	23	23	8	8	6	0	0	0	1	1	4	0	0	0	1	0	6
19	A	7	7	0	22	22	8	5	7	0	0	1	1	4	2	4	7	7	6	5	2
20	A	7	7	1	21	23	7	7	0	0	0	1	0	5	0	5	7	7	7	7	0
2	A	1	0	0	23	23	7	7	4	0	0	0	1	1	4	2	1	0	2	0	6
10	A	5	0	0	22	20	8	8	1	0	0	0	1	0	5	1	5	0	0	0	7
12	A	6	5	0	22	22	7	3	6	0	0	1	1	3	2	5	6	5	6	5	4
13	A	6	0	0	23	22	8	6	4	0	0	0	1	1	4	1	1	0	0	0	7
17	A	7	7	1	22	23	8	7	0	0	0	1	0	5	0	5	7	7	7	7	0
22	A	5	0	0	23	23	8	8	4	0	0	0	1	2	4	3	4	0	5	0	5
		3.4	2.1	0.17	22.3	22	7.6	6.8	3.5	0.1	0	0.35	0.87	1.43	3.3	2.09	3.09	1.83	2.43	1.7	5.26

Spouse's/Partner's Responses to Questionnaire 3 for Treatment B

#	Grp	Qs1	Qs2	Qs3	Qs4	Qs5	Qs6	Qs7	Qs8	Qs9	Qs10	Qs11	Qs12	Qs13	Qs14	Qs15	Qs16	Qs17	Qs18	Qs19	Qs20
2	B	1	0	0	23	24	7	7	4	0	0	0	1	0	4	1	1	0	2	0	6
10	B	7	2	0	22	20	8	8	1	0	0	1	1	0	4	3	6	2	3	1	3
12	B	5	5	0	22	22	8	4	7	0	0	1	1	3	2	3	5	5	4	4	4
13	B	4	4	0	21	23	9	7	0	0	0	1	1	3	3	4	4	4	2	3	4
17	B	1	1	0	23	22	8	7	3	0	0	1	1	3	3	1	2	2	5	2	6
22	B	2	0	0	22	22	8	8	4	0	0	1	1	1	4	1	2	0	2	0	6
1	B	0	0	0	23	22	7	7	0	0	0	0	1	0	4	0	0	0	0	0	6
4	B	5	5	0	22	22	9	8	7	0	0	1	1	3	4	5	5	5	5	4	3
5	B	0	0	0	22	22	7	7	7	0	0	0	1	0	5	0	0	0	0	0	6
6	B	1	0	0	23	23	6	6	5	0	1	0	1	2	2	1	1	1	1	0	5
7	B	7	4	1	24	23	8	7	4	2	0	1	1	4	4	4	7	2	7	2	6
11	B	6	6	1	22	23	8	5	1	2	-	1	1	3	3	3	7	7	7	5	5
23	B	0	0	0	21	22	8	8	0	0	0	0	1	0	5	0	0	0	0	0	7
24	B	4	0	0	22	21	8	8	2	0	0	0	1	2	3	3	4	3	4	2	3
3	B	6	6	1	22	22	6	6	4	0	0	0	1	2	2	4	6	6	2	2	4
8	B	7	7	0	23	23	8	8	5	0	0	0	1	0	5	4	7	6	7	0	3
9	B	1	1	0	20	22	9.5	9	0	0	0	0	1	0	4	2	1	1	2	1	6
14	B	3	0	0	23	23	7	7	5	0	0	0	1	0	5	2	3	0	2	0	5
15	B	6	6	0	23	23	9	7	7	0	0	1	1	4	1	4	6	6	6	4	4
16	B	0	0	0	22	22	7	7	7	0	0	0	1	0	5	1	1	0	0	0	7
18	B	6	3	0	23	23	7	7	7	0	0	1	1	3	2	3	6	6	3	4	4
19	B	7	7	1	22	22	8	5	7	0	0	1	0	5	0	5	7	7	7	7	0
20	B	5	3	0	21	23	7	6	0	0	1	1	1	3	3	3	5	3	2	3	4
		3.7	2.6	0.17	22.2	22	7.7	6.9	3.8	0.2	0.09	0.52	0.96	1.78	3.35	2.48	3.74	2.87	3.17	1.91	4.65

Spouse's/Partner's Responses to Questionnaire 3 for Treatment C

#	Grp	Qs1	Qs2	Qs3	Qs4	Qs5	Qs6	Qs7	Qs8	Qs9	Qs10	Qs11	Qs12	Qs13	Qs14	Qs15	Qs16	Qs17	Qs18	Qs19	Qs20
3	C	6	6	1	22	23	8	7	3	0	0	0	1	1	4	3	6	6	6	1	5
8	C	7	4	0	23	24	8	8	2	2	0	0	1	0	4	3	7	5	3	0	6
9	C	2	2	0	21	23	10	8	1	2	0	1	1	0	4	3	2	2	2	0	6
14	C	2	0	0	23	23	7	7	7	0	1	1	1	0	5	1	1	0	1	0	6
15	C	7	7	0	24	23	9	8	7	0	0	1	1	4	2	5	7	7	7	5	4
16	C	7	0	0	22	23	7	7	7	0	0	0	1	0	5	2	2	2	1	0	6
18	C	7	4	0	22	22	8	8	7	0	0	1	1	4	3	3	7	4	4	5	5
19	C	7	4	0	22	22	7	5	7	0	0	1	1	3	3	3	6	7	7	4	5
20	C	7	2	0	22	22	7	7	0	0	0	1	1	1	4	3	7	3	6	1	6
2	C	0	0	0	22	22	8	8	4	0	0	0	1	0	4	2	2	1	3	0	5
10	C	7	0	0	22	20	8	7	1	0	0	0	1	0	4	3	7	3	2	1	4
12	C	6	5	0	22	22	7	4	6	1	0	1	1	1	2	5	6	5	4	5	4
13	C	5	0	0	23	21	8	6	2	0	0	1	1	2	4	1	1	0	2	0	6
17	C	4	4	0	21	23	7	6	0	0	0	1	1	4	1	3	4	4	5	4	4
22	C	6	0	0	22	21	9	9	5	0	0	0	1	0	4	2	6	0	2	0	5
1	C	2	2	0	23	22	7	6	0	0	0	0	1	0	4	2	2	2	1	0	4
4	C	2	2	0	22	22	8	7	5	0	0	0	1	2	4	4	4	4	2	1	5
5	C	7	7	0	22	22	8	8	7	0	0	0	1	0	4	3	7	1	0	2	4
6	C	6	2	0	23	23	6	6	5	0	0	0	1	0	5	1	2	1	1	0	5
7	C	7	0	0	23	22	9	8	1	0	0	1	1	3	3	3	7	0	7	5	6
11	C	1	1	1	22	23	8	6	1	0	-	1	1	2	3	4	1	1	0	0	7
23	C	0	0	0	21	22	8	8	0	0	0	0	1	0	5	0	0	0	0	0	7
24	C	4	0	0	21	22	9	8	2	2	0	0	1	1	2	0	0	0	1	1	5
		4.7	2.3	0.09	22.2	22	7.9	7	3.5	0.3	0.05	0.48	1	1.22	3.61	2.57	4.09	2.52	2.91	1.52	5.22

Patient's Responses to Questionnaire 2 for Treatment A

#	Grp	Qs1	Qs2	Qs3	Qs4	Qs5	Qs6	Q7	Q8	Q9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24a	24b	24c	24d	24e	24f	24g	24h	25	26
1	A	7	0	0	0	0	22	23	0	0	7	6	0	0	1	1	0	0	0	5	0	0	0	0	1	0	0	0	2	3	0	0	4	3
4	A	7	5	3	0	3	22	22	7	0	7	6.5	2	0	1	1	0	0	0	3	4	3	3	7	3	0	0	0	5	5	5	0	5	0
5	A	7	0	0	0	0	22	22	7	0	8	7	0	0	1	1	0	0	0	4	0	0	0	0	4	1	0	0	3	1	0	0	6	5
6	A	3	0	0	0	0	24	24	3	0	6	6	0	0	1	1	0	0	0	5	1	0	0	0	3	0	0	4	5	4	4	0	5	6
7	A	7	6	6	1	0	22	23	1	5	7	7	0	1	2	1	3	0	0	3	3	6	0	6	0	3	1	0	2	2	0	0	5	5
11	A	7	2	2	0	0	22	22	4	0	7	6	1	0	0	1	0	0	0	5	-	2	0	-	1	2	0	1	2	0	1	0	7	4
23	A	7	1	1	1	0	22	21	0	1	10	10	0	1	1	1	3	0	0	3	-	1	0	3	0	0	0	0	5	5	2	5	7	6
24	A	2	4	2	0	0	22	21	0	0	7	7	0	0	0	0	0	0	0	3	3	2	0	0	0	0	0	5	0	0	0	0	4	2
3	A	7	5	5	0	0	22	22	7	0	8	7	0	0	0	1	1	0	3	4	3	6	0	5	0	0	0	0	4	3	3	3	4	2
8	A	7	0	0	0	0	23	23	7	0	8	8	0	0	0	1	0	0	0	5	0	0	0	0	0	0	0	0	0	1	0	0	6	7
9	A	6	2	2	0	0	22	20	0	0	6	6	2	0	1	1	0	0	0	4	2	2	0	2	3	0	0	5	4	5	3	0	6	3
14	A	6	1	0	0	0	23	23	7	0	8	8	0	0	0	1	0	0	0	5	1	1	0	1	0	0	2	0	5	1	1	0	4	0
15	A	7	2	2	0	1	24	24	1	0	7	7	1	1	1	1	4	3	1	2	3	3	3	3	0	0	0	0	3	2	0	0	5	4
16	A	7	0	0	0	0	22	22	7	0	7	7	0	0	0	1	1	1	2	5	0	0	0	0	5	1	1	1	1	1	1	1	6	1
18	A	7	0	0	0	0	23	22	6	0	6	6	0	0	1	1	0	0	0	4	0	0	0	0	0	0	0	0	2	1	1	0	6	5
19	A	7	-	-	0	0	22	22	7	0	7	7	0	0	0	1	0	0	0	2	2	2	0	0	0	4	0	4	3	1	0	0	4	2
20	A	2	7	7	7	7	22	21	0	0	7	6	7	1	1	0	5	5	5	5	5	7	7	7	5	5	5	5	5	5	5	5	0	0
2	A	7	1	0	0	0	23	23	3	0	7	7	0	0	0	1	0	0	0	4	1	1	0	0	0	0	0	1	0	0	0	0	5	4
10	A	7	7	0	0	0	20	22	0	0	7	6	0	0	1	1	0	0	0	4	1	7	0	0	0	0	0	0	0	5	0	0	7	7
12	A	5	-	4	0	0	22	22	6	0	8	7	4	0	0	1	3	0	0	4	4	6	0	5	3	1	0	0	2	0	0	0	4	4
13	A	6	2	0	0	0	24	23	4	0	5	5	0	0	0	1	1	1	0	4	1	1	0	0	0	0	0	1	0	0	0	0	5	5
17	A	0	7	7	7	7	22	23	3	0	7	6	7	1	1	0	5	5	5	5	5	7	7	7	5	5	5	5	5	5	5	5	0	0
22	A	7	5	0	0	0	23	23	4	0	7	7	0	0	0	1	0	0	0	4	3	5	0	7	0	0	0	4	0	0	0	0	5	4
		5.9	2.7	1.9	0.7	0.8	22	22	3.7	0.3	7.1	6.8	1	0	1	0.9	1.1	0.7	0.7	4	2	2.7	0.9	2.4	1.4	1	0.8	1.3	2.5	2.2	1.3	0.8	4.8	3.4

Patient's Responses to Questionnaire 2 for Treatment B

#	Grp	Qs1	Qs2	Qs3	Qs4	Qs5	Qs6	Q7	Q8	Q9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24a	24b	24c	24d	24e	24f	24g	24h	25	26
2	B	7	0	0	0	0	23	23	7	0	6	6	0	1	0	1	3	2	0	3	0	0	0	0	2	0	0	0	0	0	0	0	6	5
10	B	7	7	0	0	0	20	23	0	0	8	7	0	0	0	1	0	0	0	3	2	7	0	-	0	3	0	0	0	0	0	0	4	2
12	B	7	-	5	0	0	22	22	7	0	8	7	3	0	1	1	3	0	0	4	-	-	0	-	4	0	3	0	5	5	5	0	4	2
13	B	6	-	1	0	0	23	23	4	0	6	6	0	0	0	1	2	0	0	4	3	6	1	2	3	3	1	2	3	2	1	0	4	3
17	B	6	1	2	0	0	22	23	3	0	7	6	2	1	1	0	2	1	4	3	1	2	0	7	3	3	4	4	4	2	4	4	6	2
22	B	7	3	2	0	0	22	23	3	0	8	8	0	0	0	1	0	0	0	5	3	2	0	3	0	0	0	0	0	0	0	0	5	5
1	B	6	0	0	0	0	22	23	0	0	6	6	0	0	1	1	0	0	0	5	0	0	0	0	1	0	0	1	1	3	0	0	4	0
4	B	7	4	2	0	4	22	22	7	0	8	7	2	1	1	1	1	0	0	3	5	4	4	4	3	0	1	0	5	5	5	0	4	2
5	B	7	0	0	0	0	22	22	7	0	8	8	0	0	0	1	0	0	0	4	0	0	0	0	3	0	0	0	0	0	0	0	6	6
6	B	6	1	0	0	0	23	23	5	0	6	6	0	1	1	1	1	1	0	5	1	2	1	0	4	1	1	3	2	1	1	0	5	6
7	B	7	7	5	1	0	23	24	4	4	6	6	1	1	0	1	4	0	0	3	4	7	0	-	0	3	2	1	0	0	0	0	5	6
11	B	6	6	5	1	2	22	21	1	1	7	6	1	0	0	1	1	0	1	4	4	7	2	-	0	2	0	3	0	0	0	0	4	5
23	B	6	0	0	0	0	22	21	0	0	8	8	0	0	0	1	0	0	0	5	0	0	0	0	0	0	0	0	0	0	0	0	7	7
24	B	4	3	-	0	0	22	21	0	0	8	8	-	0	0	1	3	0	0	3	-	3	1	4	0	4	4	0	0	0	0	0	4	1
3	B	7	5	5	1	3	22	22	4	0	8	7	2	0	0	1	1	1	1	4	3	6	0	5	0	0	0	1	1	0	0	0	4	5
8	B	7	7	7	0	0	23	23	7	0	8	8	0	1	0	1	3	0	0	1	4	7	4	7	0	0	0	0	0	0	0	0	0	5
9	B	7	1	1	0	0	22	20	0	0	6	6	1	0	1	1	0	0	0	5	2	1	0	0	0	0	0	0	0	0	0	0	5	5
14	B	7	3	0	0	2	23	23	5	0	8	8	0	1	0	1	1	0	0	4	1	3	2	3	1	2	0	1	4	0	0	0	5	4
15	B	7	6	6	0	3	24	24	7	0	7	7	1	1	0	1	4	0	0	2	5	6	3	6	5	0	0	2	0	0	0	0	4	2
16	B	7	0	0	0	0	22	22	7	0	7	7	0	0	0	1	0	0	0	5	0	0	0	0	5	2	4	4	4	2	2	1	7	7
18	B	7	-	1	0	0	23	23	7	0	6	6	0	1	0	1	3	0	0	3	2	7	0	7	0	1	0	1	1	1	1	0	4	5
19	B	0	7	7	7	7	22	22	7	0	7	7	7	1	1	0	5	5	5	5	5	7	7	7	5	5	5	5	5	5	5	5	0	0
20	B	6	5	2	0	0	22	21	0	0	7	6	1	1	1	1	3	1	1	3	-	5	0	0	1	0	0	0	1	1	0	0	4	3
		6.3	3.3	2.3	0.4	1	22	22	4	0.2	7.1	7.1	0.9	0	0	0.9	1.7	0.5	0.5	3.7	2.3	3.7	1.1	2.9	1.7	1.3	1.1	1.2	1.6	1.2	1	0.4	4.4	3.8

Patient's Responses to Questionnaire 2 for Treatment C

#	Grp	Qs1	Qs2	Qs3	Qs4	Qs5	Qs6	Qs7	Qs8	Qs9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24a	24b	24c	24d	24e	24f	24g	24h	25	26
3	C	7	4	3	0	0	23	22	3	0	8	7.5	2	0	0	1	2	0	0	4	3	3	0	0	0	0	0	1	0	0	0	0	5	4
8	C	7	7	7	0	0	24	23	2	0	8	8	0	1	0	1	0	0	0	4	3	7	0	-	0	0	0	0	0	0	0	0	5	3
9	C	7	-	3	0	0	23	21	1	2	6	6	0	1	0	1	0	3	0	5	2	3	0	0	0	0	0	0	0	0	0	0	4	5
14	C	7	1	0	0	1	23	23	6	0	8	8	-	0	0	1	1	0	0	4	0	1	1	-	2	0	4	1	0	0	0	0	6	6
15	C	7	7	7	0	3	23	23	7	0	9	8	1	1	0	1	4	3	0	3	5	7	3	7	1	0	0	0	0	0	0	0	4	3
16	C	7	2	0	0	0	22	22	7	0	7	7	1	0	0	1	0	0	0	5	1	2	1	1	1	1	0	0	0	0	0	0	7	7
18	C	4	7	4	0	0	22	21	7	0	7	7	1	0	1	1	0	0	0	3	-	7	0	0	0	2	4	4	2	2	0	0	2	1
19	C	6	-	4	0	0	22	22	7	0	8	7	1	0	0	1	0	0	0	4	-	-	0	1	0	0	0	4	0	0	0	0	4	1
20	C	7	7	4	0	0	23	21	0	0	7	6	0	1	0	1	4	2	0	3	-	7	0	-	0	0	2	0	0	0	0	0	5	5
2	C	7	0	0	0	0	22	22	3	0	7	7	0	0	0	1	2	1	0	4	0	0	0	0	0	0	0	0	0	0	0	0	6	5
10	C	7	7	3	0	0	20	22	0	0	7	6	0	0	0	1	0	0	0	4	5	7	0	-	0	1	1	2	0	0	0	0	4	3
12	C	6	-	5	0	1	22	22	6	1	8	7	5	0	0	1	0	0	0	4	-	-	1	0	4	0	0	0	2	0	0	0	4	4
13	C	5	-	1	0	0	23	23	3	0	5	5	0	0	1	0	3	1	2	2	3	2	2	2	1	3	1	4	4	4	1	0	2	2
17	C	7	4	4	0	0	23	21	0	0	6	5	2	1	0	1	3	1	1	3	-	4	0	0	0	0	0	2	0	0	0	0	5	6
22	C	7	6	0	0	0	21	22	5	0	8	8	0	0	0	1	0	0	0	0	3	7	0	4	0	0	0	0	0	0	0	0	4	2
1	C	7	2	2	0	2	22	23	0	0	6	6	2	0	0	1	0	0	0	4	3	2	2	2	0	0	0	0	0	0	0	0	4	3
4	C	7	2	2	0	0	22	22	5	0	7	6	2	0	0	1	0	0	0	4	0	0	0	1	0	3	1	0	0	0	0	0	6	6
5	C	6	7	4	0	0	22	22	7	0	8	8	1	0	0	1	0	0	0	4	3	7	0	0	0	0	1	0	0	0	0	0	4	1
6	C	6	2	1	0	0	23	23	5	0	6	6	0	1	0	1	1	1	0	5	1	2	1	1	4	0	0	4	0	0	0	0	5	2
7	C	7	7	0	0	0	22	23	1	0	6	6	0	1	0	1	4	0	0	3	4	7	0	7	0	1	0	4	0	0	0	0	4	3
11	C	7	2	1	1	1	23	22	0	1	7	6	0	0	0	1	0	0	0	4	-	1	1	-	0	0	0	0	0	0	0	0	6	4
23	C	6	0	0	0	0	22	21	0	0	9	9	0	0	0	1	0	0	0	5	0	0	0	0	0	0	0	1	1	0	0	0	7	5
24	C	4	0	0	0	0	22	21	2	0	7	7	0	0	0	1	1	1	0	3	1	1	0	2	0	4	4	4	0	0	0	0	4	6
		6.4	3.9	2.4	0	0.3	22	22	3.3	0.2	7.2	6.8	0.8	0	0	1	1.1	0.6	0.1	3.7	2.2	3.7	0.5	1.6	0.6	0.7	0.8	1.3	0.4	0.3	0	0	4.7	3.8