TITLE
Prospective trial of the TAP Oral Appliance (formerly known as the Nellcor Puritan Bennet, QuietKnight Appliance) in the management of Obstructive Sleep Apnea and Snoring

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INTRODUCTION
Supporting evidence for the efficacy of Oral Appliances \(^1\,^2\,^3\,^4\,^5\) in the management of sleep disordered breathing is growing rapidly.

Many Mandibular Advancement Appliances (MAAs) are currently available

A Survey by Loube et al\(^5\) of dentists belonging to the Sleep Disorders Society indicated that 25 different appliances were being used.

Most studies consist of case series with comparisons of conditions before and with treatment, with the interval between studies usually being brief.
There are few studies evaluating the characteristics of large population groups over extended periods. A recent study by Pancer et al examined the largest group of patients to date, with complete data available for 75 patients out of 134 in the study. Utilizing the Thornton Anterior Positioner (TAP) he found a significant reduction in AHI, RDI, ESS and snoring.

The TAP has undergone multiple design changes and modifications since its development. Up to date at least 14 modifications have been reported.

This study aimed to assess the efficacy of a custom fitted modification of the TAP (formerly known as the Nellcor Puritan Bennet QuietKnight Oral Appliance) in a large cohort of patients over a two year period evaluating sleep parameters, demographics, anatomical variations and both objective and subjective data.

Compliance, long term tolerance, side effects and patient rating were also evaluated.

A previous pilot study of 50 patients (paper presented at the 3rd International Congress on Orofacial Pain and Temporomandibular Disorders in Korea in 2000) had demonstrated the efficacy of this device.

**MATERIALS AND METHODS**

**Referral**
Patients were referred by 12 senior Respiratory Sleep Physicians from accredited sleep disorders centres from both general hospitals and private sleep centres.

Patients were referred for multiple reasons including primary treatment for Obstructive Sleep Apnea, snoring or Upper Airway Resistance Syndrome (UARS), as an adjunct or alternative to CPAP, and following failed upper airway surgery.

**Study design**
134 consecutive patients fulfilling the following criteria were included in the study.
PATIENT SELECTION

Inclusion criteria
1. Subjects have successfully completed an all-night PSG that demonstrated OSA, snoring or UARS.
2. Subjects are either gender aged 21-75 years.
3. Subjects have an AHI score greater than or equal to five per hour but less than 90.
4. Subjects should be in good health.
5. Subjects should have at least 7mm protrusive jaw movement from a position of maximum intercuspation

Exclusion criteria
Subjects must not have the following:
1. Central Sleep Apnea as the primary diagnosis.
2. Unstable angina, arrhythmias, renal, neurological or pulmonary disease, pregnancy, organ transplantation.
3. Less than 8-10 teeth per arch that were structurally sound.
4. Presence of partial or full dentures producing poor retention for a MAA or ‘clip on’ MAA.
5. Substantial evidence of periodontal disease or dental caries.
6. Substantial evidence of Temporomandibular Joint Disorder (TMD)
7. Previously failed Mandibular Advancement Appliance.

In essence, a broad as group as possible was included in the study with more generous selection criteria than in other studies.

Patient examination
This involved a comprehensive assessment of the teeth, dentures, periodontal condition, dental occlusal relationship, diagnostic study models any prostheses, TMJ evaluation, intraoral assessment, evaluation of oropharyngeal tissues e.g. tongue size, length of soft palate, size of uvula, crowding of palatopharyngeal area.

Imaging of the upper airway
An orthopantogram (OPG) and lateral cephalogram were routinely taken for every patient assessing the condition of the dentition TMJ, presence of bony pathology, posterior airway space, soft palate length, mandibular and maxillary deficiency, hyoid bone position and other cephalometric variables.
Oral Appliance
The Nellcor Puritan QuietKnight Oral Appliance was initially trialled in a pilot study. This was a boil and bite appliance.

As there were many problems associated with this device, including the limitation of the size of the trays for other than small to medium size dentitions with most teeth present, and its unsuitability for denture patients, the device was modified.

Impressions were taken and a custom made laboratory fabricated appliance using a bilaminar material (Proform Dual Dental Resources, Delano MN) retaining the lower shelf and hook with its adjusting Allen Key was constructed and fitted.

The device was composed of two separate arches, maxillary, incorporating the hook and mandibular incorporating the shelf which permitted a maximum of 15mm advancement of the lower jaw.

Initially a position was set at 70% of maximum protrusion for a few days to assess fit, comfort, pressure on teeth etc.

The MAA was then advanced to maximum protrusion or until the patient felt discomfort in the TMJ, facial muscles or teeth and then slightly stepped back so any discomfort was eliminated. The patients were instructed to advance the mandible gradually by turning the Allen Key up to a maximum protrusive position subject to patient comfort.

The patients were re-assessed by their sleep physician within two months of insertion of the MAA and advancement was continued to an optimal protrusive position.

A repeat sleep study was then carried out with the MAA in situ at about 3-6 months or at the sleep physician’s discretion, depending on the availability of the sleep centre. At times further sleep studies were carried out.

The patients were seen regularly initially two weeks after insertion and then on a monthly or two monthly basis.
Patients were instructed in use and care of appliance, told about possible side effects and given an Australian Dental Association brochure outlining the same.

A leaf gauge was recommended to be used each morning after removal of the OA and suitable exercises were recommended.

If TMJ problems or bite problems arose, the OA was wound back and physiotherapy was provided.

The MAA was used only at night and advanced the mandible to the maximum protrusive distance as measured from a position of maximum intercuspation.

**ASSESSMENT**
The patients were evaluated and treated by the primary author in his private office at the Melbourne Medical Centre Pain Clinic.

**Baseline data**
All patients had baseline polysomnography BMI, neck circumference and Epworth Sleepiness Scale (ESS) measurements.

**Polysomnography**
All subjects completed a preliminary sleep study.

Polysomnograms were performed in established sleep disorders clinics and included the following information:
Left and right electro oculogram, chin and leg electromyogram, electroencephalogram, electrocardiogram, nasal and oral air flow, thoracic and abdominal chest movements, pulse oximetry, body position.

Standard sleep parameter analysis included:
Total hours in bed, time asleep, time awake, sleep efficiency, initial sleep latency, REM latency, number of REM periods, minutes and percentage of stages 1 2 3 4 and REM, respiratory patterns, Apnea/Hypopnea index, overall, back and sleep state dependent, respiratory disturbance index, O₂ saturation, [minimum] mean sleep, percentage time with SaO₂ < 90%, snoring intensity and frequency.
Apneas were defined as complete episodes of cessation of breathing lasting ≥ 10s. Hypopneas were defined as episodes with > 50% reduction in respiratory airflow accompanied by oxygen desaturation of > 4%.

Arousals were defined as 3-15s of alpha and fast theta EEG frequency.

**Obesity Parameters**
At baseline the patient’s height and weight was used for calculation of the body mass index (BMI) (Kg/m²).

**Neck circumference (NC)** was measured in cm with a measuring tape placed around the neck below the prominence of the thyroid cartilage.

**INVESTIGATIONS**
A repeat study with OA in situ was carried out, assessing the whole range of sleep architecture when the MAA was optimally advanced.

**Subjective patient and partner reports**
The Epworth Sleepiness Scale (ESS) was scored before and after treatment. A partner report of snoring intensity and frequency before and after was recorded as none, mild, moderate and severe.

**FOLLOW UP**
The patients continued to be followed up for at least a two year period, with continuing assessment of their symptoms. Final subjective assessments were made at this time. Some had further repeat sleep studies and were changed to nCPAP surgery or nCPAP and MAA.

Currently the majority of these patients still receive regular assessment and maintenance of their OA. (Four to five years after commencement of study.)

Assessments by Respiratory Sleep Physicians are ongoing as necessary.
DATA ANALYSIS

The results were analysed using (t-tests and $\chi^2$ tests) to compare the difference of sleep variables before and with the Oral Appliance in situ.

All data analysis was performed using SAS software version 6.

Further statistical analyses which are currently underway include principal component analysis and multiple regression analysis.

Results

There were 134 patients in the study. 14 were lost to follow up and 20 had incomplete data. 100 patients had complete data.

Reasons for loss of follow up included total satisfaction with the appliance, dissatisfaction with the appliance, lack of time, further treatment with CPAP, surgery and unknown factors.

Details of the Study are shown in table 1.

Most patients were male (67%) married (66%) and of Australian origin (50%), with a wide spread of national origins (North and East European, Middle Eastern and Asian).

Patients were referred from Public Hospital Sleep Units (67%) and Private Respiratory Sleep Physicians (33%).

Reason for referral included obstructive sleep apnoea (40%), mixed central and obstructive sleep apnoea (8%), Upper Airway Resistance Syndrome (12%) and primary snoring (40%).

Snoring intensity was rated as mild (20%), moderate (40%) and severe (40%).

Snoring frequency was rated as mild (20%), moderate (48%) and severe (32%).

There were periodic limb movements in 64% and sleep bruxism in 48% of patients.

Hypersomnolence was present in 80%, fatigue/tiredness in 84% and headaches on awakening in 12%.
The main associated features were overweight (72%), hypertension (48%), poor job performance (34%), driving accidents (30%), occupational accidents (24%), impotence (22%), dry mouth on awakening (22%), depression (20%), anxiety (18%) and intellectual deterioration (14%).

Use of medication included alcohol (40%), nasal corticosteroid sprays (40%), anticonvulsants (30%), tranquillizers (18%), antihistamines (16%), anti Parkinsonian drugs (14%), other (12%), sedative hypnotics (12%) and antidepressants (10%).

A psychiatric disorder was present in 30% (treated) and 10% (untreated).

**Dental findings**
The majority of patients, 70% had their natural dentition, 10% were edentulous and had full dentures and 40% had their own teeth and dentures.

There was no Temporomandibular Joint Dysfunction in 86%, mild symptoms in 8%, moderate symptoms in 4% and severe symptoms in 2%.

Intraorally there were a range of anatomical variations ranging from anterior open bite (12%) macroglossia (32%) to narrow parallel arches (24%), high arched palatal vault (8%), elongated soft palate (40%), shallow pharyngeal wall (16%), oedematous uvula (24%).

Radiographic findings (OPG & lateral cephalogram) demonstrated various findings including retrognathia/mandibular deficiency (84%), maxillary deficiency (40%), reduced posterior airway space (80%), elongated soft palate (40%), inferiorly positioned hyoid bone (48%), maxillary deficiency (40%), steep mandibular plane (32%) high upper and lower facial height (30%) maxillary and mandibular discrepancy (30%).

**Apnea/Hypopnea Index (AHI)**
Baseline mean AHI was 39 ± 3 /hr range (6-92). Patients were rated as mild (36%), moderate (40%) and severe (24%). (Table 2)

Degree of improvement of AHI is indicated in table 3.
A t-test revealed a significant mean decrease in AHI (30 ± 3/hr) at $p < 0.001$. A $\chi^2$ test also revealed a significant improvement in AHI levels in 74% of patients at $p < 0.004$. t-tests also revealed a significant difference in mean AHI for patients after treatment with mild AHI (6 ± 2), moderate AHI (7 ± 3) and severe AHI (14 ± 4) at $p < 0.001$ (tables 3 & 4).

If we define that the response to the appliance as a reduction in AHI to <10 events/h, there was a response of 76%.

Alternatively if we define the response to the MAA as a reduction in AHI > 50%, we find that 85% were responders.

**Minimum Oxygen saturation ($\text{SaO}_2$)**
The level of improvement and baseline measurements are detailed in table 5.

The increases in mean minimum $\text{SaO}_2$ for the mild, moderate and severe group are detailed in Table 6.

**Snoring frequency**
The baseline data is detailed in table 7.

A $\chi^2$ test revealed a significant reduction in 80% of patients at $p < 0.001$ (Table 8).

20% were considered mild, 48% moderate and 32% severe.

**Snoring intensity**
The baseline data is detailed in table 7.

A $\chi^2$ test revealed a significant reduction in 80% of patients at $p < 0.001$.

20% were considered mild, 40% moderate and 40% severe.

**Hypersomnolence**

**Daytime sleepiness**

A $\chi^2$ test revealed a significant improvement in 80% of patients at $p < 0.001$. 
Fatigue/tiredness
A $\chi^2$ test revealed a significant improvement in 80% of patients at $p < 0.001$.

EES
A $t$-test revealed a significant reduction in mean EES values at $p < 0.001$.

Sleeping with bed partners

t-tests revealed that a significant amount of both male (70%) and female (73%) patients resumed sleeping with their partners after treatment, at $p < 0.001$.

There were no gender differences between men and women.
There was no interaction effects between gender and sleeping partners.

The MAA was found to work independently of any gender effects.
Patients rating of satisfaction with Oral Appliance
60% were very satisfied, 32% were satisfied, 4% were dissatisfied and 4% were very dissatisfied with the MAA.

Follow up
10% discontinued use, while 90% continued use of the MAA at two years.

Side effects of Oral Appliance
There were a variety of minor reversible side effects, predominantly excess salivation 30%, initial muscle discomfort 30% with 4% having permanent bite change. (Table 10)

DISCUSSION
This study consisting of a case series allowing comparison of conditions before and after treatment, has shown that the modified TAP Oral Appliance (formerly known as the Nellcor Puritan Bennet QuietKnight Oral Appliance) was highly effective in managing OSA, snoring and UARS over a two year period in a varied group of patients.

All the patients were adults mainly male, middle aged and overweight similar to OSA patients in other case studies, although considerable variation occurred.

The current study supports and expands the findings of the study with the largest group of patients to date by Pancer et al\textsuperscript{4} evaluating the efficacy of the TAP Oral Appliance. This study had the same number of patients (134) but more patients with complete data (100 compared to 75). This modified custom fitted TAP Oral Appliance (MAA) was effective in managing sleep apnea and snoring over a two year period in a varied group of patients.

The modified, custom fitted TAP device used in this study incorporated a bilaminar material which was easy to fabricate, easy to adjust, provided good retention and was well tolerated by the patients.

The hook device collected plaque, was difficult to clean and at times wound back in severe bruxists. The Allen Key was more difficult to use than the standard TAP adjusting device and the Allen Key was often lost or misplaced.
While this modified device has achieved good results, it is not as user friendly as the standard TAP device.

A continuing study of this cohort of patients not yet published demonstrated that the positive response over two years has continued at five years. Other patients who had previously shown only a mild response to the TAP have demonstrated significant objective and clinical improvement with the combined use of the TAP and CPAP therapy.

It is proposed that future cephalometric measurements are performed with the patient lying down to more closely simulate the night sleep position.

The successful response in a number of patients who were non obese, with a normal posterior airway space and other radiographic and clinical parameters, should be further investigated.

Cross over outcome studies utilising randomised controlled trials in selected subjects with specific polysomnographic, clinical and radiographic findings should be carried out to further evaluate the efficacy of the TAP appliance.

The incidence of the side effects with long term use need to be evaluated.

Further statistical analysis which is currently underway with the available data set includes principal components analysis and multiple regression analysis to further define the effectiveness of the TAP Oral Appliance.

* Statistical values are available from the authors on request.
CONCLUSION

Patients with mild, moderate and severe obstructive sleep apnoea and snoring responded to the TAP device, with generally minor reversible side effect and good tolerance to the appliance.

The patients improved over a wide range of sleep variables including AHI index, minimum SaO₂ saturation, snoring intensity and frequency, fatigue/hypersomnolence and return to sleep with their bed partner.

Long term effectiveness has been limited in the past in part due to issues with compliance. The TAP device had an excellent level of compliance allowing long term effectiveness to be evaluated.
REFERENCES
Oral appliances for the treatment of snoring and obstructive sleep apnoea. A Review.

Practice parameters for the treatment of snoring and obstructive sleep apnea.

3. Thornton WK, Roberts DH.
Nonsurgical management of the obstructive sleep apnoea patient.

4. Pancer J, Al-Faifi S, Al-Faifi M, Hoffstein V.
Evaluation of variable mandibular advancement appliance for treatment of snoring and sleep apnoea

5. Mehta A, Qian J, Petocz P, Darendeliler A, Cistulli P.
A Randomized Controlled Study of a Mandibular Advancement Splint for Obstructive Sleep Apnoea.

6. Loube DI, Strauss AM.
Survey of Oral Appliance Practice among dentists treating obstructive sleep apnea patients
### Table 1
Details of study

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No of Patients</td>
<td>100</td>
</tr>
<tr>
<td>Age (mean)</td>
<td>47 ± 3 years</td>
</tr>
<tr>
<td>(range)</td>
<td>30-73 years</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>male</td>
<td>67 (67%)</td>
</tr>
<tr>
<td>Female</td>
<td>33 (33%)</td>
</tr>
<tr>
<td>BMI kg/m2</td>
<td>31 ± 8</td>
</tr>
<tr>
<td>Epworth sleepiness</td>
<td></td>
</tr>
<tr>
<td>scale (ESS)</td>
<td>11 ± 4</td>
</tr>
<tr>
<td>Neck circumference (cm)</td>
<td></td>
</tr>
<tr>
<td>NC</td>
<td>42 ± 0.5 (30-49)</td>
</tr>
</tbody>
</table>
Table 2
Baseline AHI Index

<table>
<thead>
<tr>
<th>Apnea Hypopnea Index (AHI)</th>
<th>Overall/hr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild (&lt;20)</td>
<td>36 (36%)</td>
</tr>
<tr>
<td>Moderate (20-40)</td>
<td>40 (40%)</td>
</tr>
<tr>
<td>Severe (&gt;40)</td>
<td>24 (24%)</td>
</tr>
<tr>
<td><strong>Mean AHI</strong> 39 ± 3/hr</td>
<td><strong>Range</strong> 6-92</td>
</tr>
</tbody>
</table>
Table 3
Change in AHI on treatment

<table>
<thead>
<tr>
<th>AHI Index (N=100)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>no improvement</td>
<td>8</td>
<td>(8%)</td>
</tr>
<tr>
<td>mild improvement</td>
<td>18</td>
<td>(18%)</td>
</tr>
<tr>
<td>moderate improvement</td>
<td>24</td>
<td>(24%)</td>
</tr>
<tr>
<td>major improvement</td>
<td>50</td>
<td>(50%)</td>
</tr>
</tbody>
</table>

$\chi^2 (1, n = 100) = 13.56, \ p < 0.004$

mean AHI before treatment 39 ± 3/hr
mean AHI after treatment 9 ± 3/hr
mean reduction AHI 30 ± 3/hr

t-test was significant at $p<0.001$

Reduction in AHI < 10 events/hr
Response = 76%

Reduction in AHI > 50%
Response = 85%
**Table 4**

**Polysomnography Results**  
**Apnea Hypopnea Index (AHI) Overall/hr**  
**N = 100 patients**

<table>
<thead>
<tr>
<th>Severity</th>
<th>No. of patients</th>
<th>Mean AHI before treatment</th>
<th>Mean AHI after treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild &lt;20</td>
<td>36</td>
<td>16 ± 1</td>
<td>6± 2*</td>
</tr>
<tr>
<td>Moderate</td>
<td>40</td>
<td>32 ± 2</td>
<td>7± 3*</td>
</tr>
<tr>
<td>20-40</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>24</td>
<td>69 ± 4</td>
<td>14± 4*</td>
</tr>
<tr>
<td>&gt; 40</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N = 100</td>
<td></td>
<td>39± 3</td>
<td>9 ± 3*</td>
</tr>
</tbody>
</table>

* All t-tests were significant at p<0.001
**Table 5**

Minimum oxygen saturation (SaO\textsubscript{2})

N = 100

<table>
<thead>
<tr>
<th>Improvement</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>no improvement</td>
<td>10</td>
<td>(10%)</td>
</tr>
<tr>
<td>mild improvement</td>
<td>16</td>
<td>(16%)</td>
</tr>
<tr>
<td>moderate improvement</td>
<td>30</td>
<td>(30%)</td>
</tr>
<tr>
<td>major improvement</td>
<td>44</td>
<td>(44%)</td>
</tr>
</tbody>
</table>

\( \chi^2 (1, n = 100) = 13.56, \ p < 0.004 \)

mean min SaO\textsubscript{2} before treatment 86 ± 2%

mean min SaO\textsubscript{2} after treatment 94 ± 2%

mean increase in SaO\textsubscript{2} 8 ± 2%

\( t \)-test was significant at \( p < 0.001 \)
Table 6

Mean minimum oxygen saturation (SaO$_2$) before and after treatment.

<table>
<thead>
<tr>
<th>Severity of Desaturation</th>
<th>No. of Patients</th>
<th>Mean minimum SaO$_2$ before treatment</th>
<th>Mean minimum SaO$_2$ after treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild (&gt;90%)</td>
<td>28</td>
<td>91 ± 2</td>
<td>97 ± 1*</td>
</tr>
<tr>
<td>Moderate (85-90%)</td>
<td>40</td>
<td>87 ± 3</td>
<td>94 ± 2*</td>
</tr>
<tr>
<td>Severe (&lt;90%)</td>
<td>32</td>
<td>80 ± 4</td>
<td>91 ± 6*</td>
</tr>
<tr>
<td>N=100</td>
<td></td>
<td>86 ± 2%</td>
<td>94 ± 2%*</td>
</tr>
</tbody>
</table>

* All t-tests were significant at $p < 0.001$
<table>
<thead>
<tr>
<th>Snoring N = 100</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Snoring intensity</strong></td>
</tr>
<tr>
<td>no improvement</td>
</tr>
<tr>
<td>mild improvement</td>
</tr>
<tr>
<td>moderate improvement</td>
</tr>
<tr>
<td>major improvement</td>
</tr>
</tbody>
</table>

$\chi^2$ test was significant at $p<0.001$

<table>
<thead>
<tr>
<th><strong>Snoring frequency</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>no improvement</td>
</tr>
<tr>
<td>mild improvement</td>
</tr>
<tr>
<td>moderate improvement</td>
</tr>
<tr>
<td>major improvement</td>
</tr>
</tbody>
</table>

$\chi^2$ test was significant at $p<0.001$
<table>
<thead>
<tr>
<th></th>
<th>Before treatment</th>
<th>After treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sleeping with partner</td>
<td>Not sleeping with partner</td>
</tr>
<tr>
<td>Male</td>
<td>27</td>
<td>40</td>
</tr>
<tr>
<td>Female</td>
<td>18</td>
<td>15</td>
</tr>
<tr>
<td>Total</td>
<td>45 (45%)</td>
<td>55 (55%)</td>
</tr>
</tbody>
</table>

Table 8

Patient sleeping with bed partners
Due to snoring/sleep apnoea
N = 100
Table 9
Patient sleeping with bed partner
Due to snoring/sleep apnea
N = 100

Multiple $\chi^2$ tables analysis was not significant.
- There is no gender difference between men and women
- There are no interaction effects between gender and sleeping patterns

A significant amount of both male and female patients resumed sleeping with their partners after treatment.
$t = -44.9737, p < 0.001$ for males
$t = -18.4762, p < 0.001$ for females

The MAA works independently of any gender effects.
Table 10

Side effects of Oral Appliance

<table>
<thead>
<tr>
<th>Issue</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>slight tooth discomfort for first</td>
<td>30</td>
<td>(30%)</td>
</tr>
<tr>
<td>slight muscle discomfort initially</td>
<td>32</td>
<td>(32%)</td>
</tr>
<tr>
<td>excess salivation initially</td>
<td>36</td>
<td>(36%)</td>
</tr>
<tr>
<td>excess salivation</td>
<td>30</td>
<td>(30%)</td>
</tr>
<tr>
<td>temporary bite change</td>
<td>16</td>
<td>(16%)</td>
</tr>
<tr>
<td>permanent bite change</td>
<td>4</td>
<td>(4%)</td>
</tr>
<tr>
<td>taking appliance out at night</td>
<td>12</td>
<td>(12%)</td>
</tr>
<tr>
<td>TMJ dysfunction</td>
<td>8</td>
<td>(8%)</td>
</tr>
<tr>
<td>excess dryness</td>
<td>20</td>
<td>(20%)</td>
</tr>
<tr>
<td>difficult to sleep with appliance</td>
<td>8</td>
<td>(8%)</td>
</tr>
<tr>
<td>other</td>
<td>12</td>
<td>(12%)</td>
</tr>
</tbody>
</table>
ABSTRACT

Title:
Prospective trial of the TAP Oral Appliance (formerly known as the Nellcor Puritan Bennet, QuietKnight Appliance) in the management of Obstructive Sleep Apnea and Snoring

Authors and Institutions

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INTRODUCTION

Supporting evidence for the efficacy of oral appliances in the management of sleep disordered breathing is growing rapidly.

There are few studies evaluating the characteristics of large population groups over extended periods.

The TAP appliance has undergone multiple design changes and modifications since its development.

This study aimed to assess the efficacy of a custom fitted modification of the TAP (the QuietKnight oral appliance) using a bilaminar material, in a large cohort of patients over a two year period, evaluating sleep parameters, demographics, anatomical variations, and both objective results and subjective reports.

METHOD

134 consecutive patients, with varying degrees of obstructive sleep apnea and snoring referred by twelve respiratory sleep physicians, were evaluated over a two year period. Initial data included a PSG study, a panoramic and cephalometric radiograph, BMI, and ESS Score. Efficacy was assessed by changes in AHI, SaO₂, ESS changes, and subjective patient and partner reports.

A custom made laboratory fabricated version of the QuietKnight appliance was fitted, with instructions to the patient for gradual advancement up to a maximum protrusive position subject to patient comfort.
RESULTS

14 patients were lost to follow up
20 had incomplete data
100 patients had complete data

BASELINE DATA FOR 100 PATIENTS
Age: 47 ± 3 years (30-73 years)

Sex: Male 67 patients (67%)
Female 33 patients (33%)

BMI 31 ± 8 Kg/m² (29-43), ESS mean 11 ± 4

AHI 39 ± 3/hr, minimum mean SaO₂ 86 ± 2%

NC 42 ± 0.5cm (30-49)

Patients sleeping with bed partners - male 27 (27%), female 18 (30%)
Total 45%

Patients not sleeping with bed partners - male 40 (40%), female 15 (15%)
Total 55%

ASSESSMENT OF EFFICACY

Mean reduction of AHI: 30 ± 3/hr [9 ± 3/hr reduced to 9 ± 3/hr] (p < 0.004).
Mean minimum SaO₂ increase: 8 ± 2% [6 ± 2% increased to 94 ± 2%]
(p < 0.001).

ESS reduction 4 ± 1 (11 ± 4 reduced to 7 ± 3) (p < 0.001).

Snoring intensity: moderate to major reduction in 80% of patients (p < 0.001).
Snoring frequency: moderate to major reduction in 80% of patients (p < 0.001).
Fatigue/hypersomnia: moderate to major improvement in 80% (p < 0.001).

Sleeping with bed partner: 39/55 (71%) patients – male 28/40 (70%), female 11/15.
(71%) not sleeping with bed partners resumed sleeping with bed partners (p < 0.001).

Multiple χ² tables analysis was not significant.
• There is no gender difference between men and women
• There are no interaction effects between gender and sleeping patterns

A significant amount of both male (70%) and female (73%) patients resumed sleeping with their partners after treatment.
t = -44.9737 (P < 0.001) for males
t = -18.4762 (P < 0.001) for females

The MAA works independently of any gender effects.
Patient satisfaction: 92% were satisfied or very satisfied and continued use of appliance

Side effects: Common, but minor, mainly initial, tooth, jaw or muscle discomfort on waking, excess salivation, minor bite changes.

CONCLUSION

The modified custom fitted TAP appliance was highly effective in managing obstructive sleep apnea and snoring over a two year period in a varied group of patients.

Randomized placebo controlled trials in selected groups of patients are necessary to further define the utility of the TAP appliance.