# Effect of Three Different Mandibular Advancement Devices and Two Different Bite Techniques on the Resultant Sleep Metrics

*Shamshudin (Sam) Kherani, DDS, FAGD, MICCMO*

**Background**

It has been documented in the literature that nearly 20% of the American Population suffers from Sleep Apnea (Obstructive, Central and Mixed). Majority of the cases comprise of the Obstructive type of Sleep Apnea. As such, it is considered to be a major health hazard. Furthermore, it is documented that 85-90% of these patients have not been diagnosed yet. Therefore, this is an area that needs further research and study as to how to better serve our populations.

Most physicians prescribe the cPAP (continuous Positive Air Pressure) since it is the gold standard for the majority of the cases. The problem with this avenue of treatment is that over 70% of those with cPAPs do not wear them. Therefore, physicians are looking to the dentists to help with devices in the oral cavity that could help with improving the airway when the patient is asleep.

Mandibular Advancement Devices (MADs) are therefore gaining ground in their use as the first order treatment for many patients. Almost all MADs are made using an arbitrary bite technique where the mandible os protruded to 70% of maximum possible protrusion. By their very design, almost all MADs impinge upon the precious tongue space which pushes the tongue back resulting in further reduction in the airway volume. Therefore, MADs are either made to or further titrated to a highly protrusive position. In many instances, this protrusive position leads to TMJ problems, bite changes, etc

It is the belief of many physiologists that arbitrary bites promote further torquing of the mandible leading to torquing of the C1, C2 around the brain stem where the respiratory centre resides. Such resultant force on the respiratory center leads to Central Sleep Apnea (CSA). Many physiologists believe that many cases of Obstructive Sleep Apnea are actually a combination of both Central and Obstructive Sleep Apnea namely Mixed Sleep Apneas.

**Materials and Methods:**

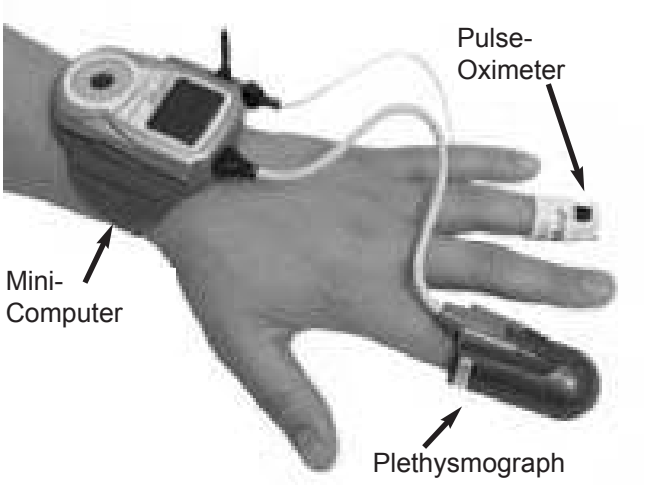
Participants were asked to participate in the study If interested. The following was accomplished on the first visit.

1. The Sleep Study was started with Medical and Dental History along with an Informed Consent Forms were filled out and signed.
2. A baseline CT scan was taken to record the airway and bony position information.
3. Participants were then given instructions on how to perform a sleep study at home (hotel) using the Watch PAT 200 "ambulatory" sleep devices.
4. Participants were asked to avoid alcohol as it further suppresses the autonomic system that helps maintain a patent airway during sleep.

The following diagnostic information was noted from the studies:

- Apnea-Hypopnea Index (AHI)
- Respiratory Disturbance Index (RDI)
- Oxygen Desaturation Index (ODI)
- Snoring (Frequency & Time)
- Body Position
- REM, Non-REM, Light or Deep Sleep

After this baseline data was obtained, the participants who were diagnosed from the sleep metrics as having some type of sleep apnea were asked to attend the clinic where a standard George Gauge bite was taken at 70% of maximum protrusion and 5 mm opening to allow enough room to construct the acrylic appliance. Subsequent to that the participant was hooked up to the TENS unit in order to TENS Cranial Nerves V, VII and XI. After 45 min to 1 hour of TENS, at a predetermined scheduled appt time, a TENS Sleep Appliance bite was taken which was very similar to a normal TENS bite except that the patient did not close as much as normal so as to allow more room for the acrylic. Generally, there was a 3mm clearance between the upper and lower anterior teeth. The models and bites (George Gauge bite and TENS bite) were sent to the lab for the fabrication of 3 different appliances for each participant.




- The evening prior to the second visit to the campus, 3 different appliances were delivered to each participant and Cone Beam CT scans were obtained with these appliances in the participant's mouth.
- The participant was instructed to wear the Protrusive SomnoDent (Appliance #3) on the first night and perform a sleep study using the Watch PAT that was given to him/her earlier that day.
- The next night the same thing was accomplished except that the participant wore the Protrusive Lingualless SomnoDent (Appliance #2) and performed the sleep study.
- The last night the participant wore the NM Lingualless (Appliance #1) and performed a sleep study.
- The participants then took all 3 appliances with them back home and continued the study and this portion of the study was named the "Longitudinal Portion".

**Materials and Methods**
**–Longitudinal Portion**

Appliance #3 was worn for 1 month every night and a sleep study was performed using a Watch PAT 2. Following that the patient was asked to titrate the appliance in the order of 3 turns every 3 days and when the participant felt good and was happy that the snoring had stopped as indicated

by the bed partner, or that one month had passed, another sleep study was performed. If snoring was still present or the sleep metrics as per the most recent sleep study showed that the patient still had sleep apnea, the participant was instructed to titrate the appliance even further and then another sleep study was performed.

The same procedure as mentioned above was then requested from the participant using Appliance #2 and finally with Appliance #1.

**The Study – Summary**

***2 variables***

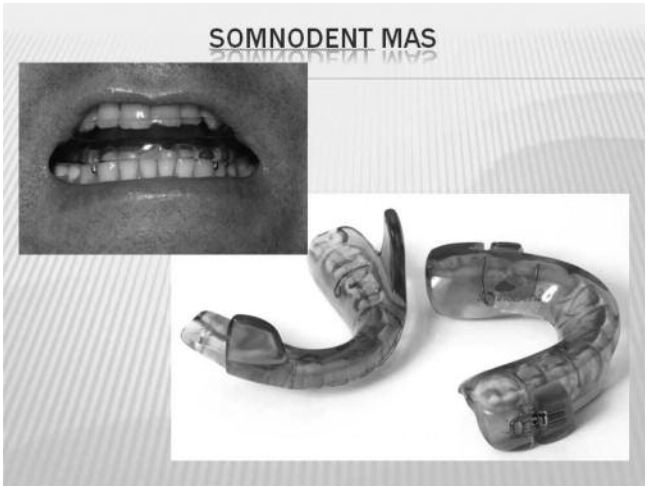
- Standard arbitrary George Gauge Bite vs TENS Bites
- Lingual Flange present vs Lingual-less design

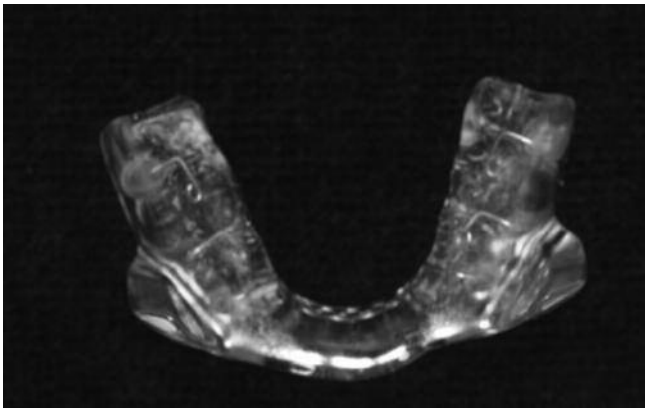
***10 different Sleep Studies***

- Base line
- George Gauge bite SomnoDent with Lingual Flange (App # 3)
- George Gauge bite Lingual-less SomnoDent (App # 2)
- NM Lingual-less SomnoDent (App # 1)
- 1 month study with Appliance # 3
- 1 month study with Appliance # 3 with titration every 3 days until snoring cessation
- 1 month study with Appliance # 2
- 1 month study with Appliance # 2 with titration every 3 days until snoring cessation
- 1 month study with Appliance # 1
- 1 month study with Appliance # 1 with titration every 3 days until snoring cessation

***Results:***

- Initial 3 days with each appliance worn 1 night each



Lingualless Somnodent

| | A | D | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V | W | X | Y | Z | AA | AD | AC | AD | AE | AF | AG |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | | BASELINE | | | | | | | | #3 - PS | | | | | | | | #2 PSL | | | | | | | | #1 NMLS | | | | | | | |
| 2 | | RDI | AHI | ODI | NADIRO | MEAN PULSE | REM | DEEP | LIGHT | RDI | AHI | ODI | NADIRO | MEAN PULSE | REM | DEEP | LIGHT | RDI | AHI | ODI | NADIRO | MEAN PULSE | REM | DEEP | LIGHT | RDI | AHI | ODI | NADIRO | MEAN PULSE | REM | DEEP | LIGHT |
| 3 | C | 21.0 | 18.0 | 9.6 | 91 | 57 | 23.8 | 11.9 | 64.2 | 63.5 | 63.5 | 45.0 | 71 | 56 | 0.5 | 12.2 | 78.4 | 0.0 | 5.5 | 0.8 | 94 | 53 | 13.7 | 16.1 | 70.3 | 10.3 | 1.6 | 0.4 | 93 | 49 | 19.3 | 13.3 | 67.4 |
| 4 | D | 16.8 | 11.4 | 3.6 | 91 | 58 | 22.6 | 13.8 | 63.6 | 14.2 | 8.2 | 2.2 | 91 | 65 | 34.6 | 17.7 | 47.7 | 12.0 | 9.4 | 2.0 | 91 | 72 | 17.7 | 14.4 | 68.0 | 18.4 | 17.3 | 4.9 | 90 | 67 | 18.1 | 19.9 | 62.0 |
| 5 | G | 12.0 | 1.4 | 0.2 | 93 | 57 | 25.0 | 16.3 | 58.7 | 15.1 | 0.5 | 0.0 | n/a | 51 | 21.5 | 13.5 | 65.1 | 13.6 | 4.3 | 0.6 | 94 | 57 | 15.7 | 22.1 | 62.1 | 15.9 | 6.6 | 0.9 | 94 | 59 | 26.2 | 22.2 | 51.7 |
| 6 | I | 24.2 | 22.2 | 12.6 | 90 | 63 | 38.5 | 14.0 | 40.5 | 14.9 | 6.7 | 2.9 | 92 | 67 | 30.0 | 19.0 | 51.0 | 11.0 | 11.0 | 4.2 | 93 | 63 | 9.4 | 18.3 | 72.2 | 17.4 | 14.3 | 5.5 | 92 | 60 | 13.8 | 14.7 | 71.5 |
| 7 | I | 47.7 | 46.1 | 28.2 | 88 | 80 | 27.9 | 18.3 | 53.8 | 28.5 | 19.2 | 10.8 | 89 | 82 | 35.6 | 22.3 | 42.1 | 26.2 | 22.6 | 11.6 | 89 | 74 | 31.0 | 16.9 | 52.7 | 20.1 | 18.4 | 7.6 | 87 | 96 | 28.6 | 17.9 | 53.5 |
| 8 | M | 30.9 | 35.1 | 22.5 | 90 | 79 | 10.3 | 10.3 | 79.5 | 29.5 | 27.4 | 14.3 | 92 | 72 | 28.3 | 19.5 | 52.2 | 27.4 | 26.2 | 14.6 | 91 | 79 | 32.1 | 22.0 | 46.0 | 34.4 | 32.6 | 20.5 | 91 | 77 | 23.7 | 14.1 | 62.2 |
| 9 | N | 27.5 | 20.2 | 4.9 | 92 | 54 | 26.5 | 18.8 | 55.8 | 19.5 | 16.0 | 4.5 | 91 | 62 | 25.6 | 13.1 | 61.3 | 24.8 | 20.9 | 4.4 | 91 | 64 | 31.1 | 11.4 | 57.6 | 25.7 | 23.8 | 4.4 | 92 | 65 | 26.6 | 15.2 | 58.2 |
| 10 | P | 21.9 | 14.5 | 6.0 | 93 | 60 | 5.8 | 22.7 | 71.5 | 26.2 | 22.0 | 7.9 | 93 | 66 | 15.8 | 25.3 | 59.0 | 20.9 | 17.0 | 9.6 | 92 | 70 | 24.6 | 23.5 | 51.9 | 21.2 | 15.2 | 3.9 | 91 | 74 | 10.6 | 16.9 | 72.5 |
| 11 | Q | 11.7 | 8.3 | 4.7 | 91 | 67 | 12.5 | 13.9 | 73.7 | 7.7 | 4.2 | 1.2 | 94 | 60 | 14.1 | 16.1 | 69.8 | 9.3 | 8.8 | 4.1 | 92 | 65 | 20.9 | 19.4 | 60.0 | 9.1 | 5.7 | 2.5 | 91 | 65 | 18.3 | 15.8 | 65.9 |
| 12 | R | 14.6 | 10.8 | 6.5 | 90 | 61 | 31.4 | 14.5 | 54.2 | 11.1 | 7.2 | 3.7 | 93 | 65 | 34.1 | 22.0 | 44.0 | 9.1 | 7.0 | 3.0 | 93 | 69 | 31.4 | 23.9 | 44.7 | 20.3 | 18.7 | 7.9 | 91 | 69 | 30.8 | 21.2 | 48.0 |
| 13 | S | 15.6 | 14.1 | 4.1 | 91 | 66 | 37.4 | 22.2 | 40.4 | 20.8 | 7.7 | 2.6 | 93 | 59 | 30.1 | 20.8 | 49.1 | 15.6 | 15.3 | 7.3 | 91 | 75 | 11.0 | 20.1 | 68.9 | 25.3 | 22.4 | 11.6 | 91 | 75 | 17.5 | 22.0 | 60.5 |
| 14 | T | 24.9 | 24.0 | 19.8 | 87 | 70 | 15.6 | 29.3 | 55.1 | 29.9 | 28.8 | 19.1 | 87 | 69 | 29.2 | 15.0 | 55.8 | 24.1 | 23.7 | 14.9 | 86 | 67 | 33.2 | 30.1 | 36.7 | 35.3 | 33.9 | 24.6 | 85 | 65 | 34.0 | 16.9 | 49.1 |
| 15 | V | 13.9 | 12.0 | 8.5 | 91 | 47 | 35.0 | 18.9 | 46.1 | 15.1 | 11.9 | 6.5 | 91 | 60 | 27.6 | 21.8 | 50.6 | 14.6 | 6.7 | 3.9 | 91 | 64 | 30.1 | 13.9 | 56.0 | 19.5 | 15.7 | 10.7 | 91 | 58 | 25.1 | 11.3 | 63.6 |
| 16 | W | 12.9 | 9.5 | 3.2 | 89 | 69 | 27.5 | 31.9 | 40.6 | 16.2 | 13.8 | 7.4 | 90 | 62 | 17.8 | 25.0 | 57.3 | 15.0 | 10.1 | 5.5 | 90 | 67 | 29.1 | 18.7 | 58.2 | 13.2 | 11.1 | 6.5 | 90 | 65 | 17.0 | 35.0 | 48.1 |
| 17 | Y | 22.8 | 22.0 | 14.3 | 87 | 66 | 16.1 | 10.6 | 73.0 | 27.6 | 26.1 | 14.9 | 91 | 68 | 18.3 | 10.0 | 71.7 | 22.1 | 21.1 | 8.5 | 90 | 62 | 26.6 | 15.1 | 58.2 | 29.4 | 28.0 | 18.2 | 89 | 68 | 20.7 | 5.9 | 73.4 |
| 18 | Z | 19.1 | 12.9 | 3.6 | 92 | 68 | 27.3 | 14.9 | 57.8 | 10.2 | 3.2 | 1.1 | 93 | 76 | 19.4 | 19.0 | 61.6 | 15.2 | 10.8 | 4.2 | 92 | 78 | 34.6 | 22.5 | 42.9 | 14.3 | 6.7 | 1.4 | 92 | 77 | 20.7 | 16.1 | 63.2 |
| 19 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

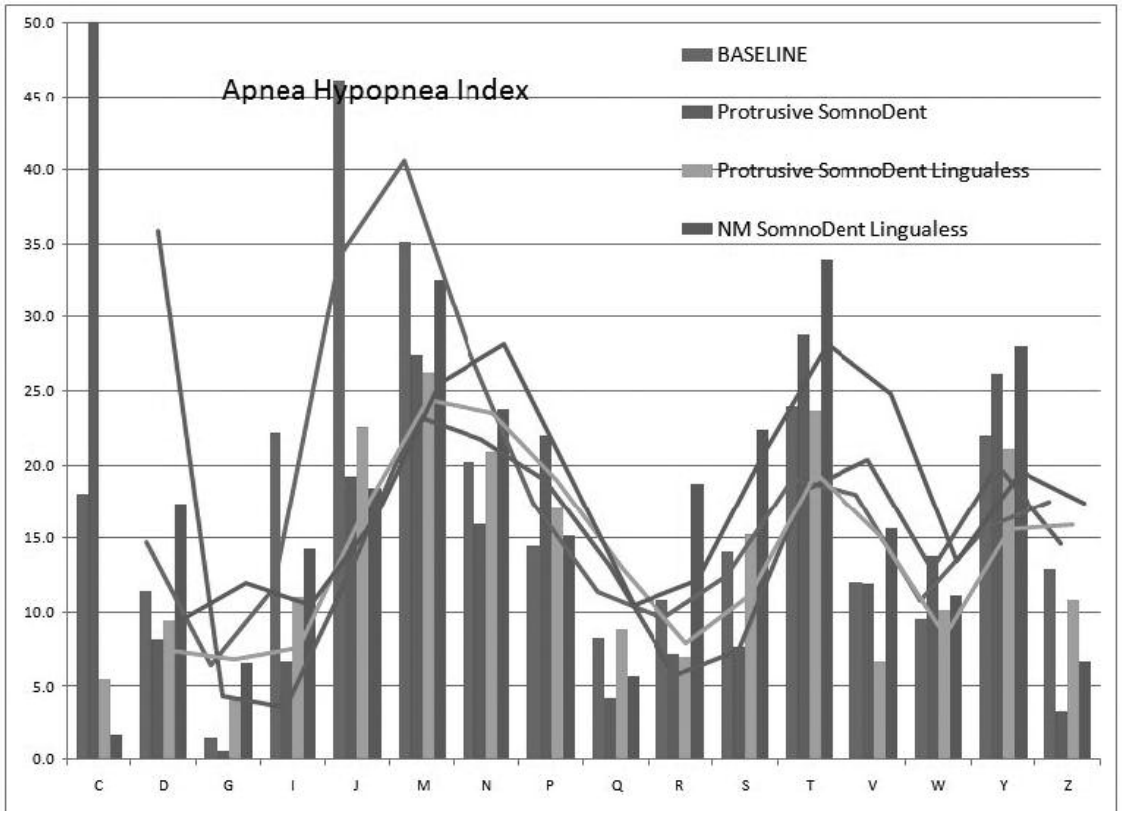



**Figure 1.** Results after 1 night wear

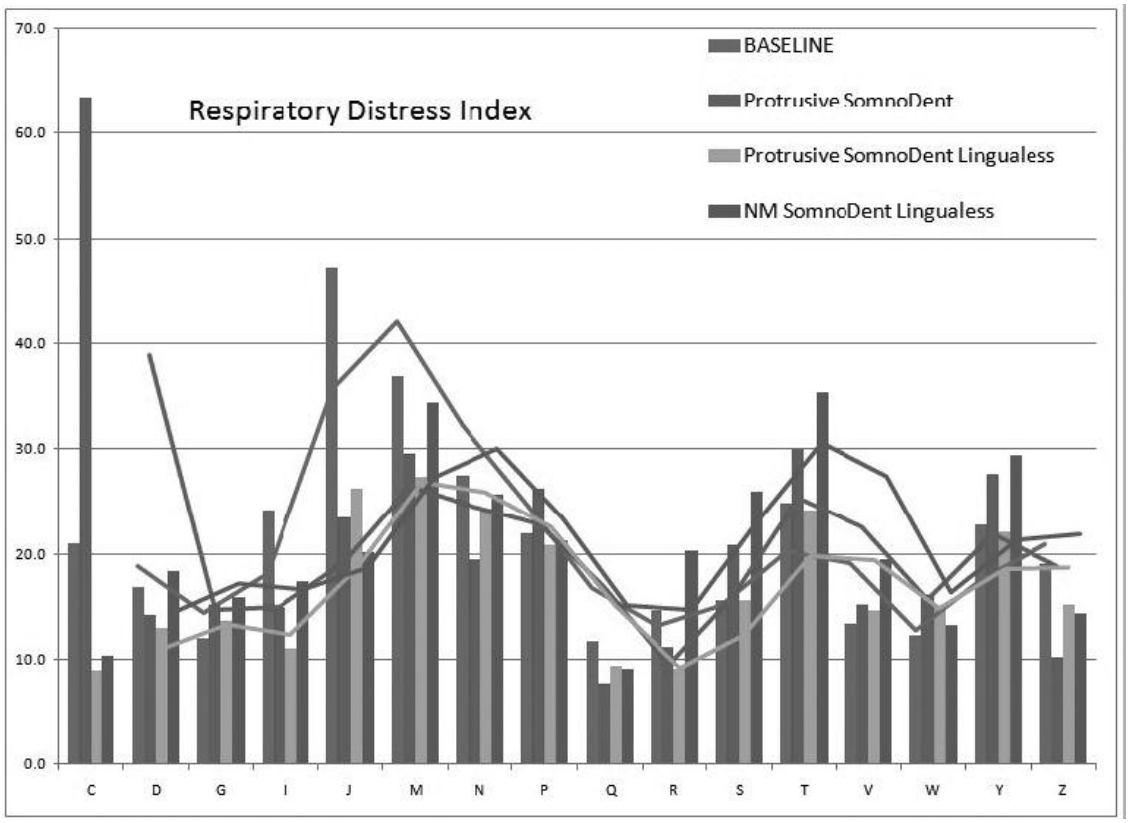



**Figure 2.** Results after 1 night wear

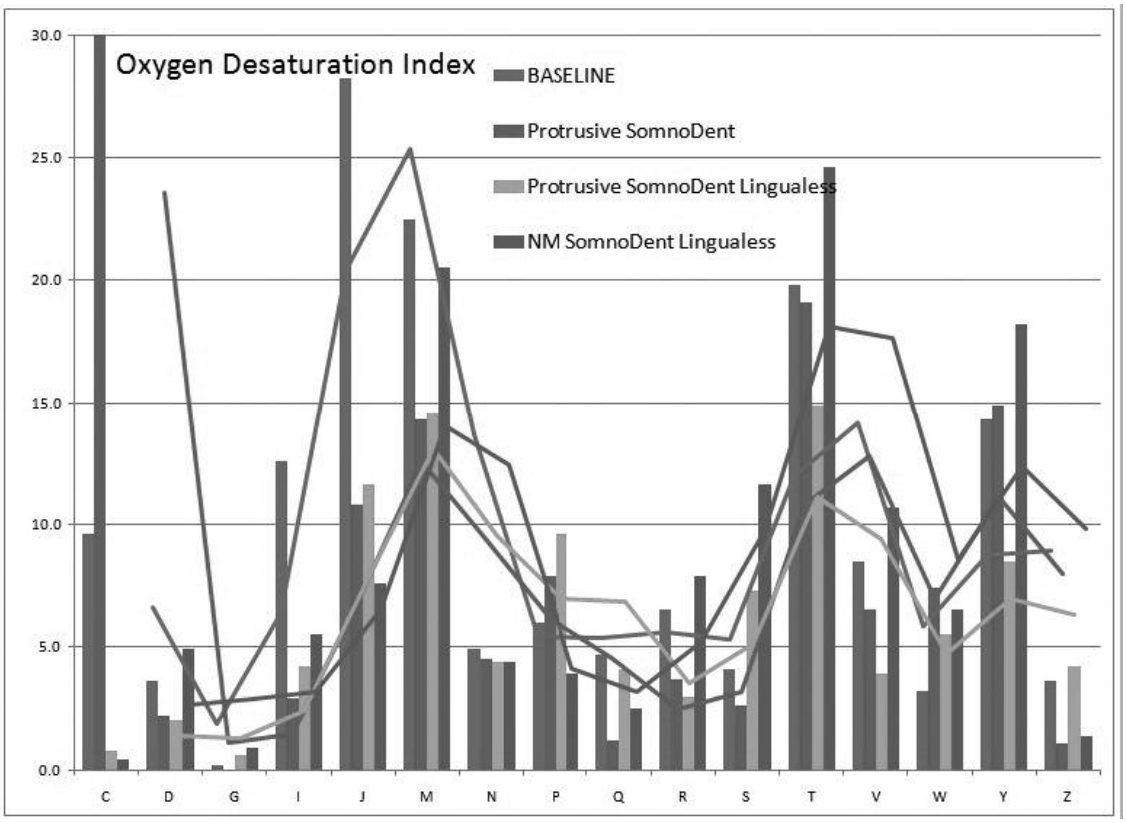



**Figure 3.** Results after 1 night wear

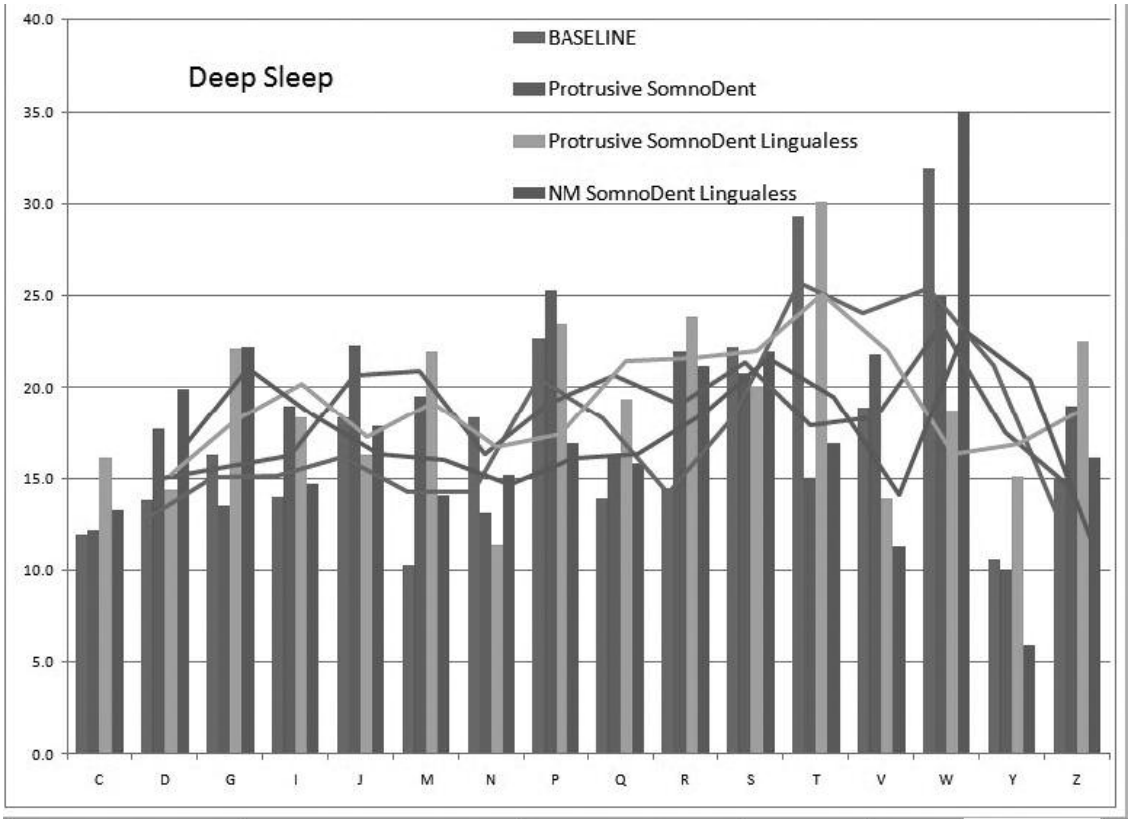



**Figure 4.** Results after 1 night wear

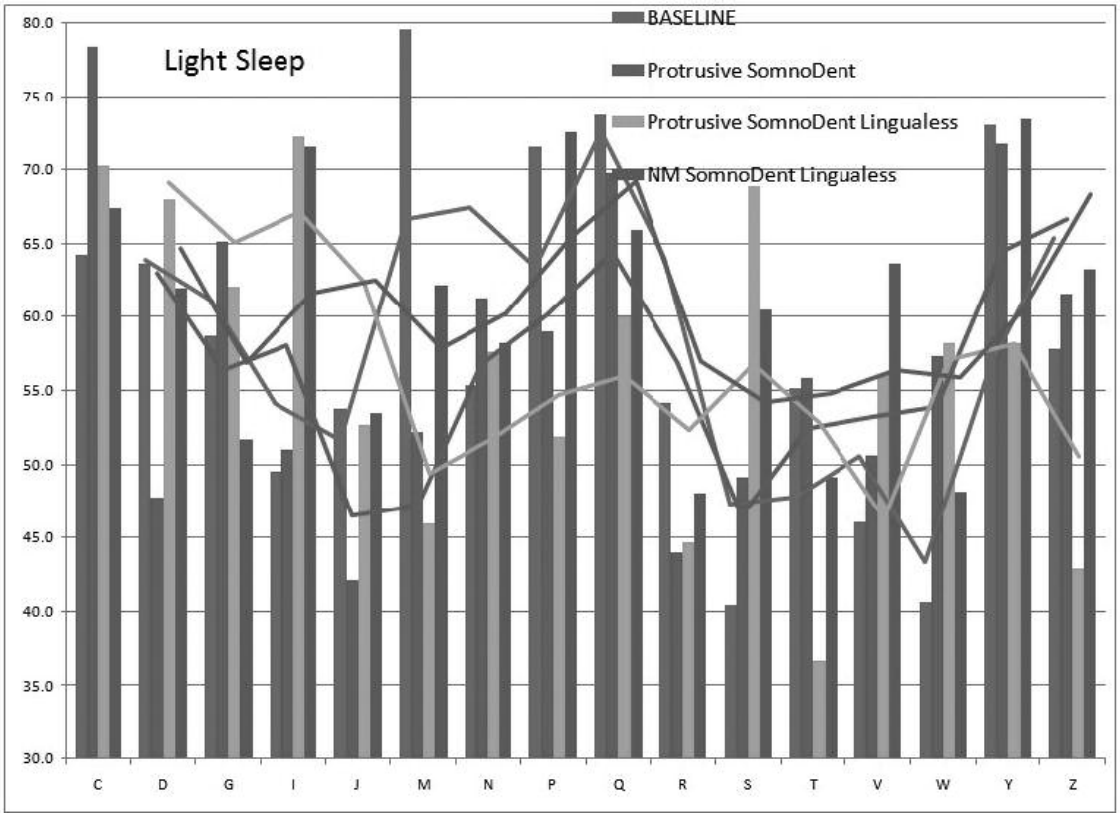
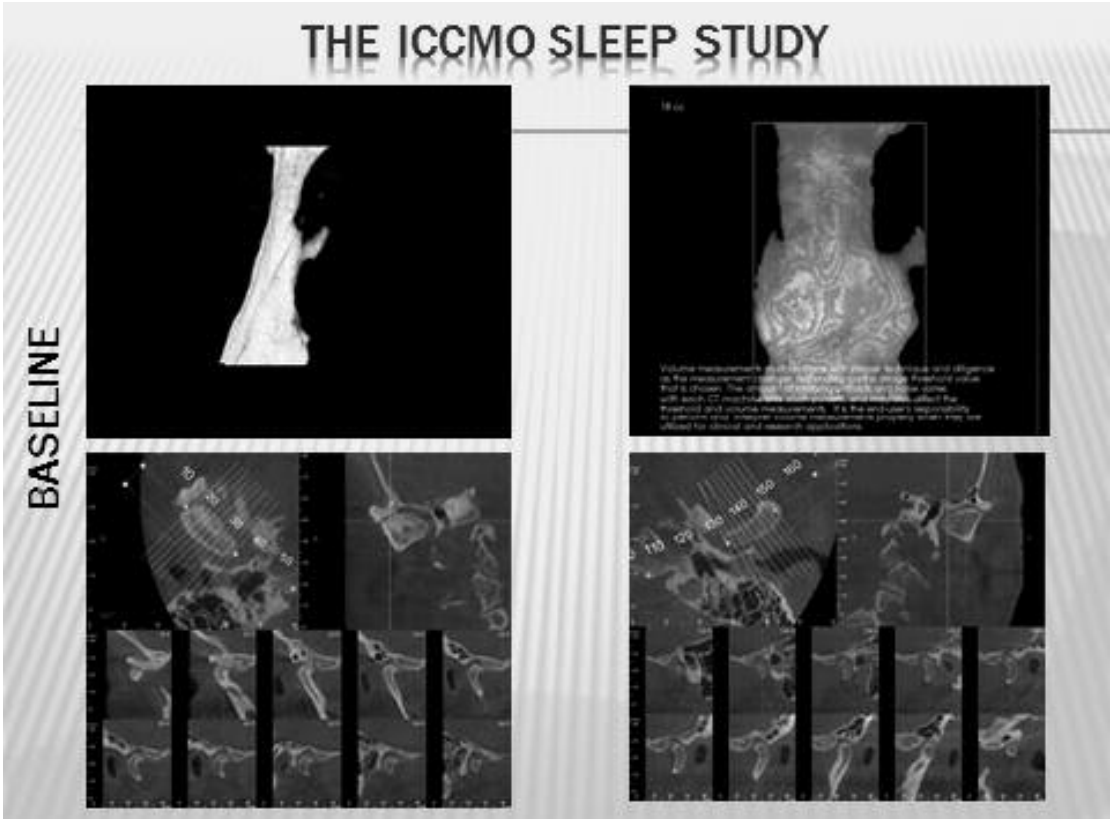
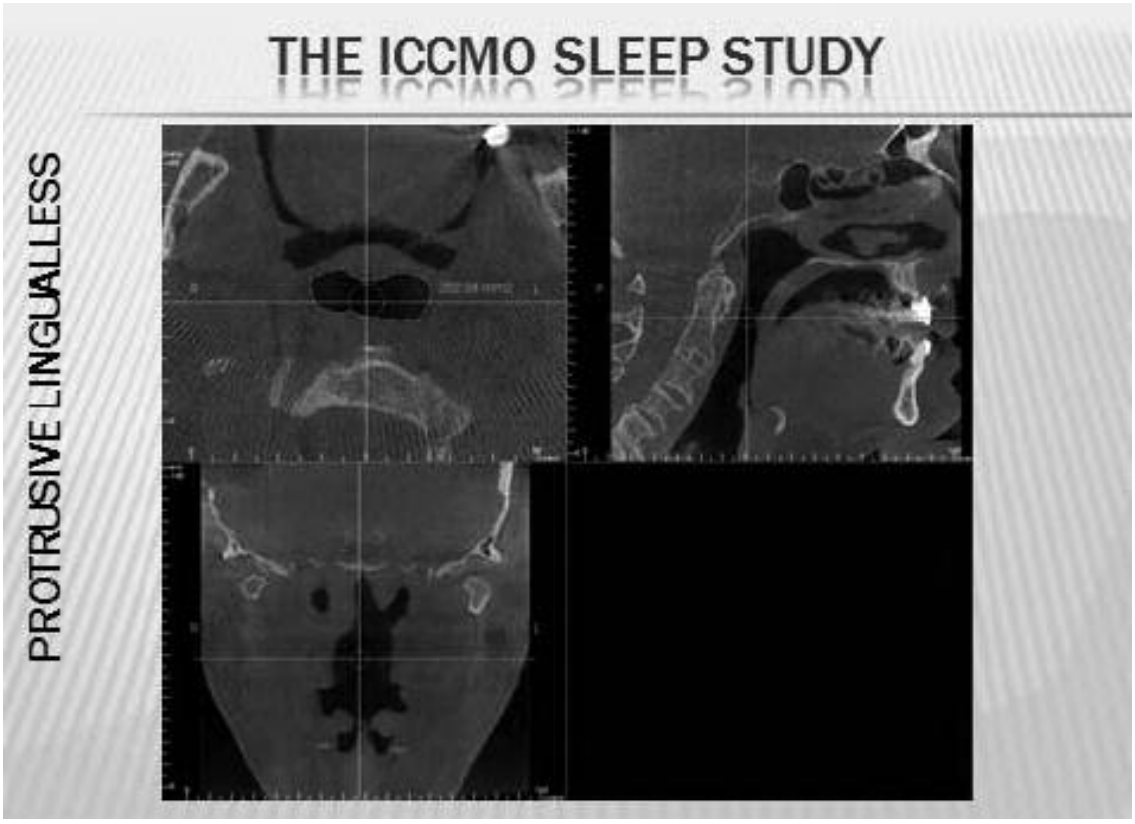
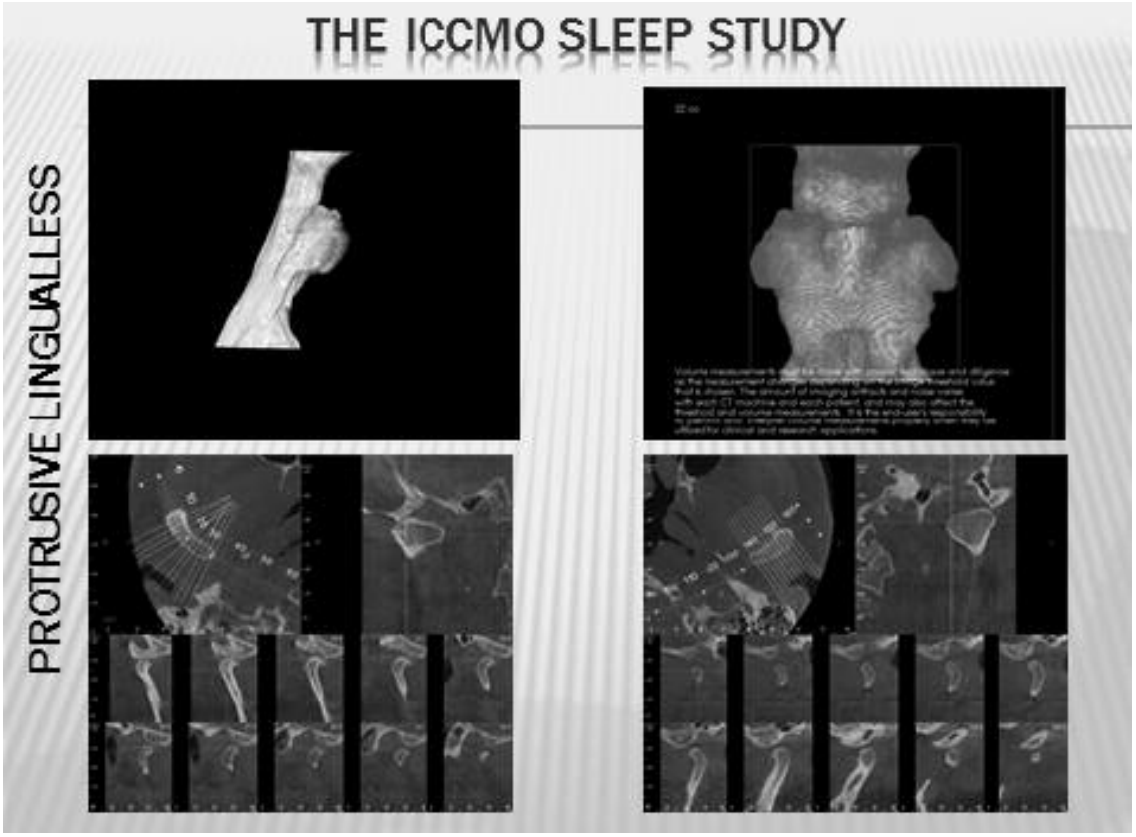


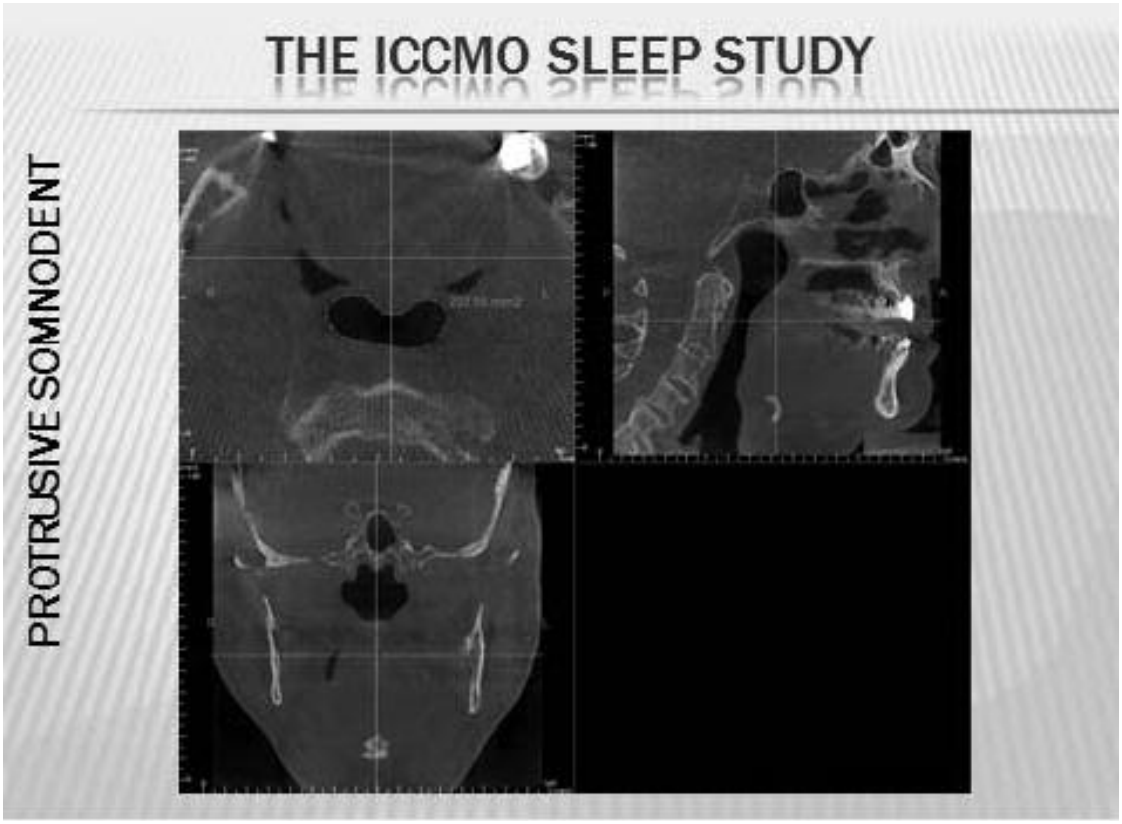

**Figure 5.** Results after 1 night wear

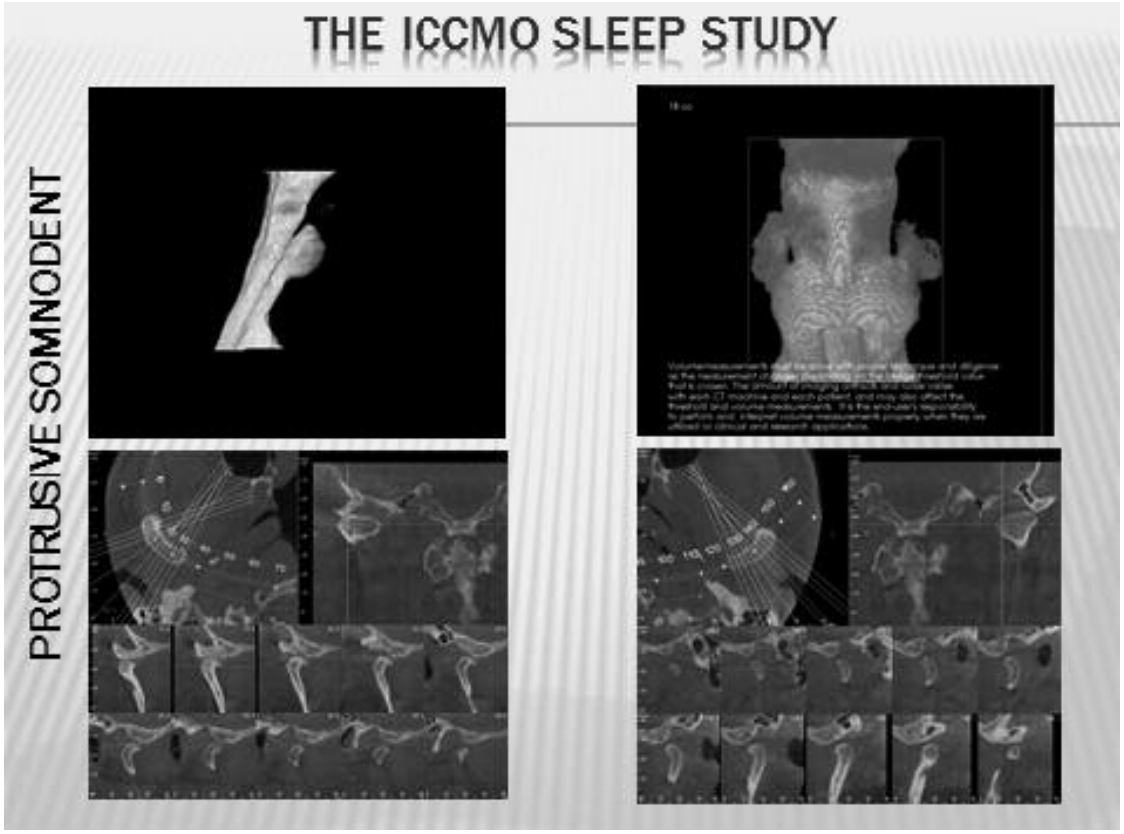
**2 and 3-dimensional airway measurement results using Cone-beam tomography**

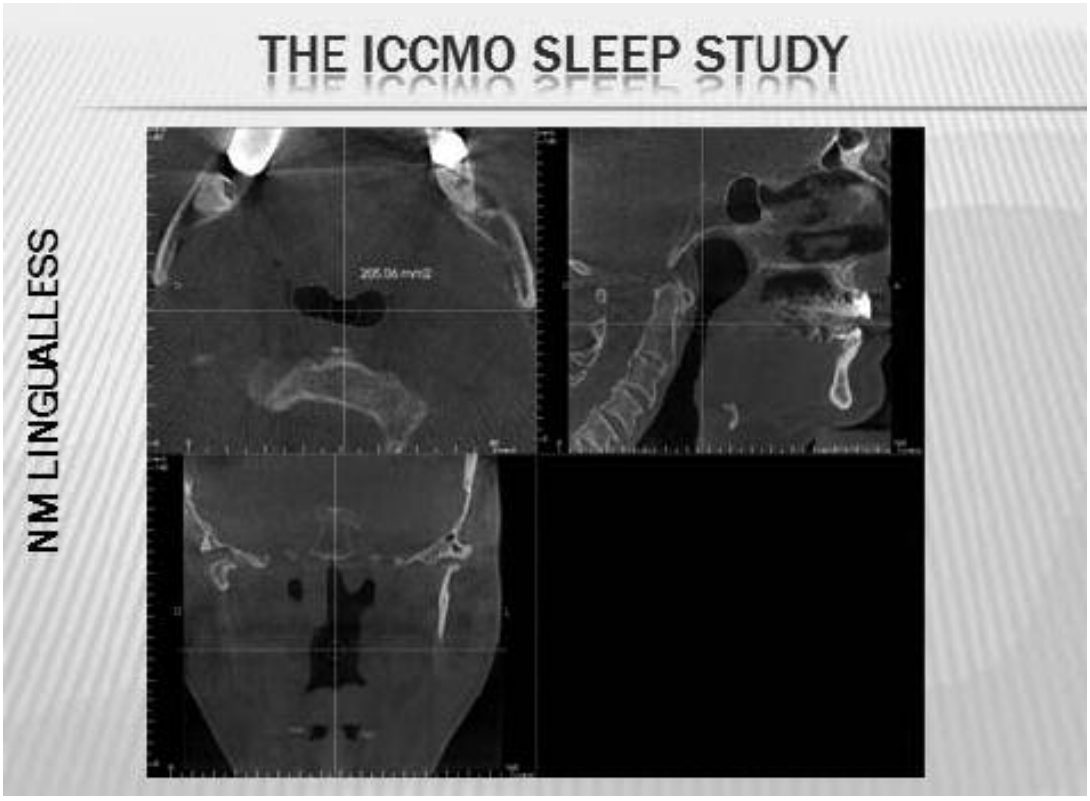



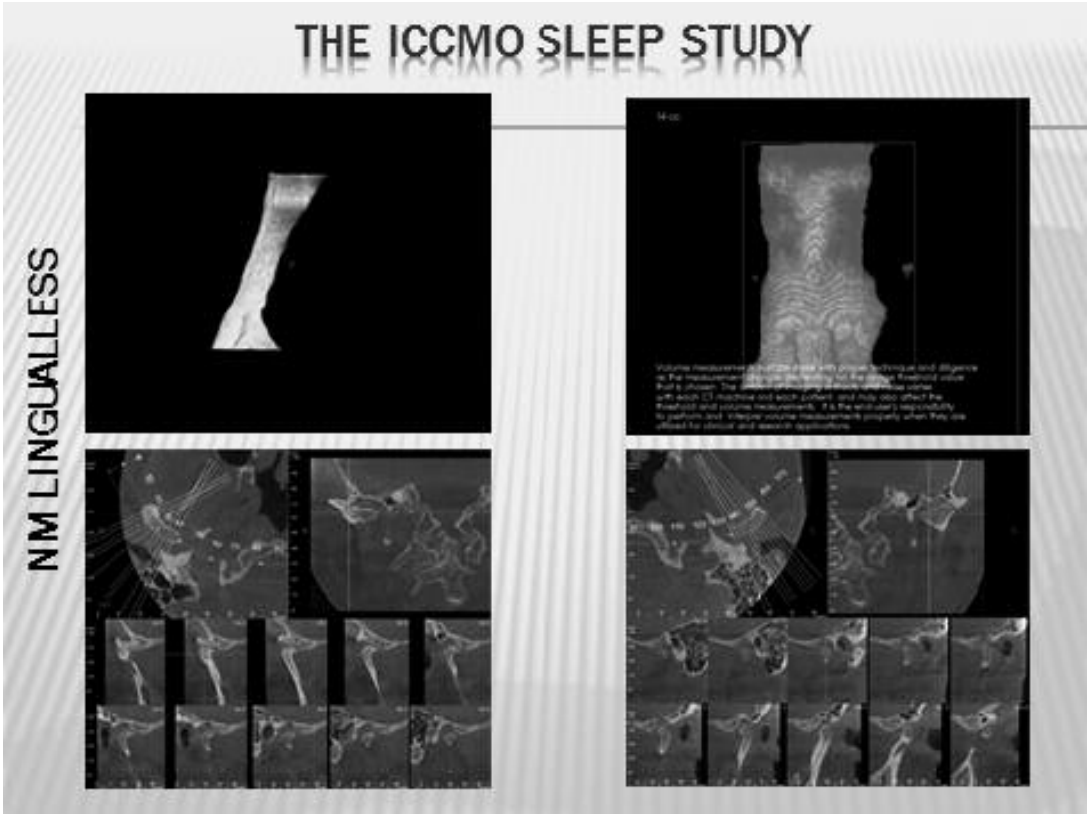

THE ICCMO SLEEP STUDY
PROTRUSIVE LINGUALLESS

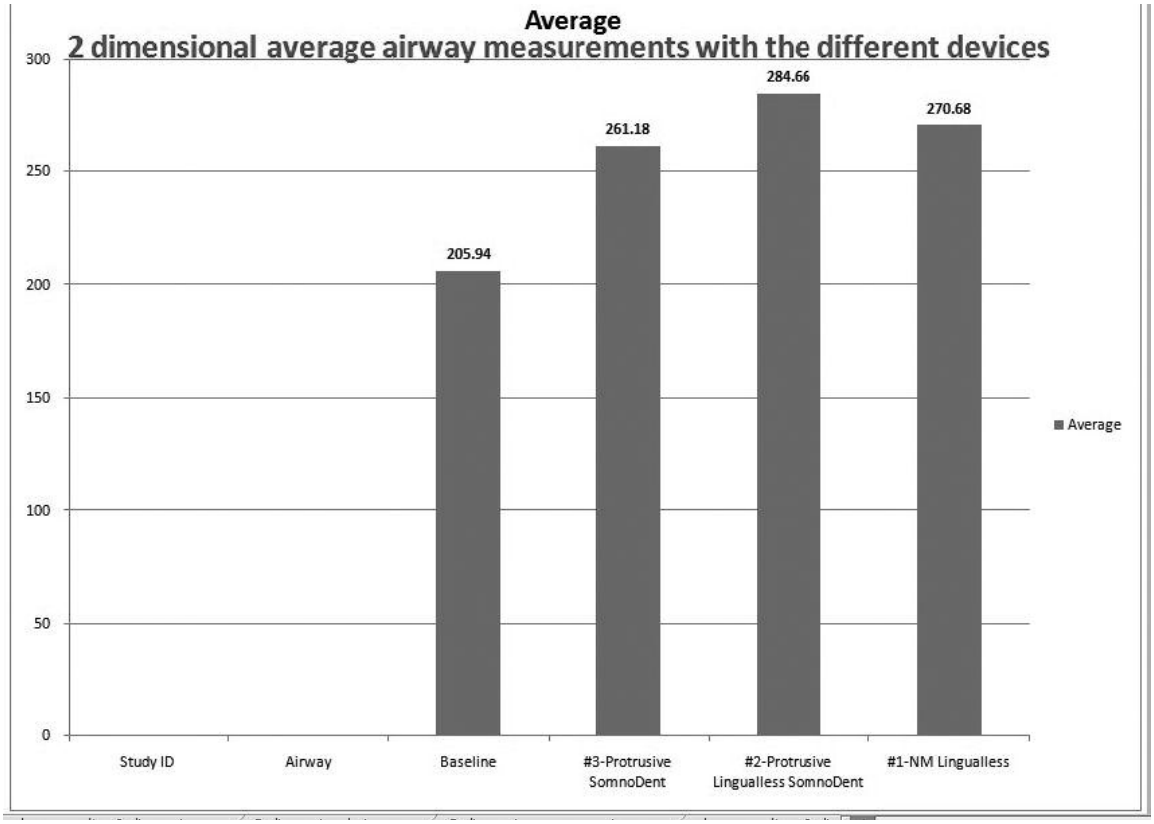

THE ICCMO SLEEP STUDY
PROTRUSIVE LINGUALLESS

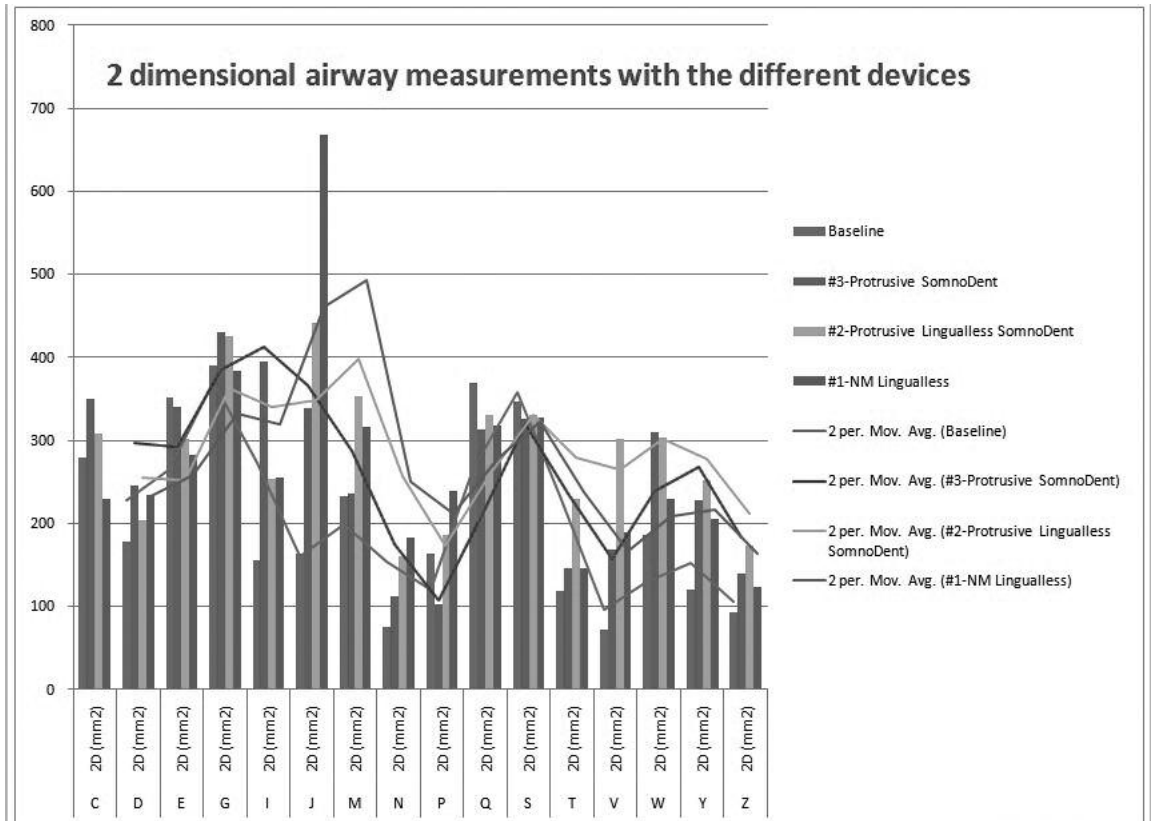

THE ICCMO SLEEP STUDY
PROTRUSIVE SOMNODENT

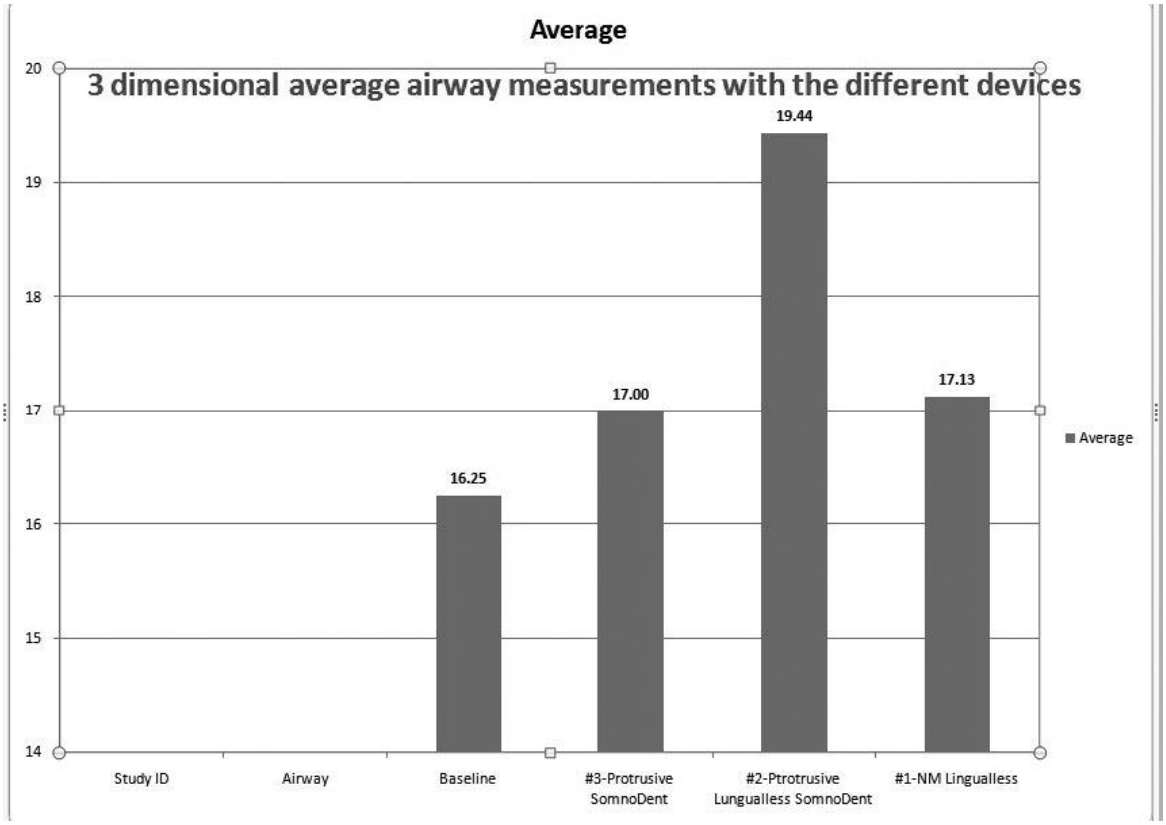

THE ICCMO SLEEP STUDY
PROTRUSIVE SOMNODENT

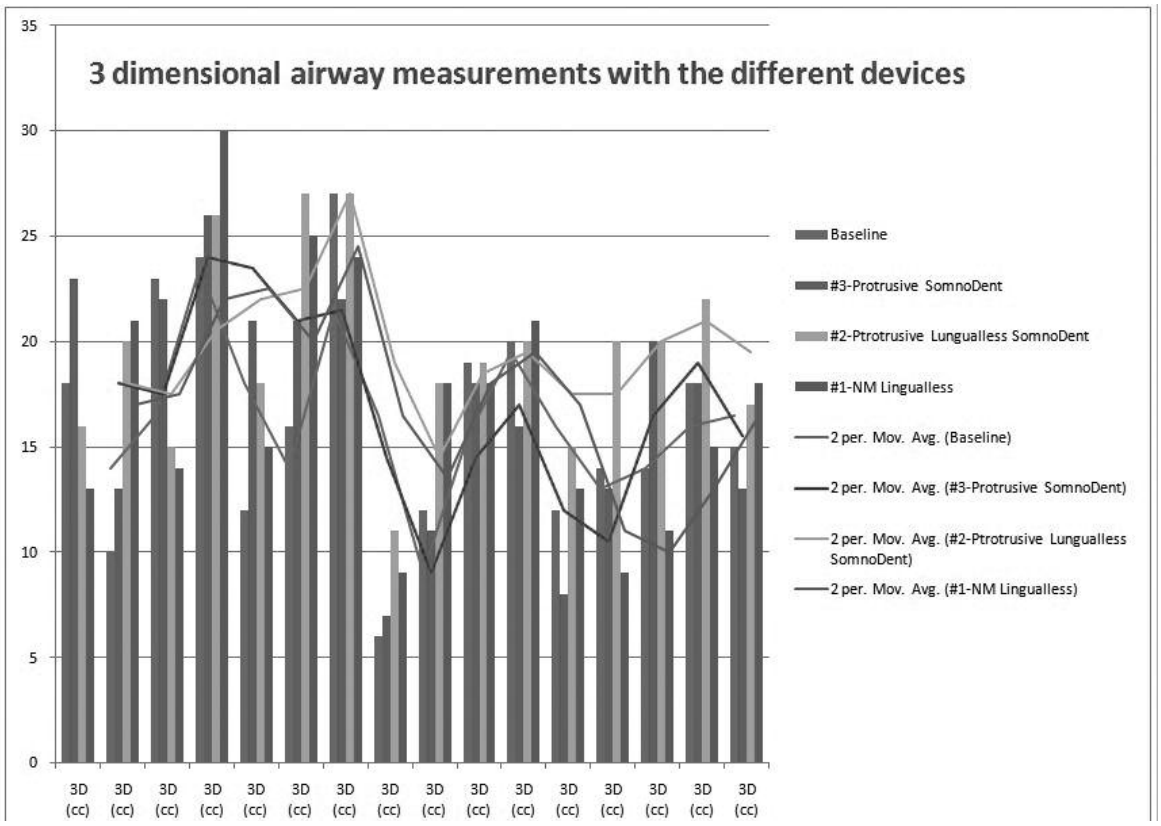

THE ICCMO SLEEP STUDY
NM LINGUALLESS


THE ICCMO SLEEP STUDY
NM LINGUALLESS


Average
2 dimensional average airway measurements with the different devices
300
250
200
150
100
50
0
205.94
261.18
284.66
270.68
Study ID
Airway
Baseline
#3-Protrusive SomnoDent
#2-Protrusive Lingualless SomnoDent
#1-NM Lingualless
Average


2 dimensional airway measurements with the different devices
800
700
600
500
400
300
200
100
0
2D (mm2)
C
D
E
G
I
J
M
N
P
Q
S
T
V
W
Y
Z
Baseline
#3-Protrusive SomnoDent
#2-Protrusive Lingualless SomnoDent
#1-NM Lingualless
2 per. Mov. Avg. (Baseline)
2 per. Mov. Avg. (#3-Protrusive SomnoDent)
2 per. Mov. Avg. (#2-Protrusive Lingualless SomnoDent)
2 per. Mov. Avg. (#1-NM Lingualless)


Average
3 dimensional average airway measurements with the different devices
20
19
18
17
16
15
14
19.44
17.13
17.00
16.25
Average
Study ID
Airway
Baseline
#3-Protrusive SomnoDent
#2-Ptrotrusive Lungualless SomnoDent
#1-NM Lingualless

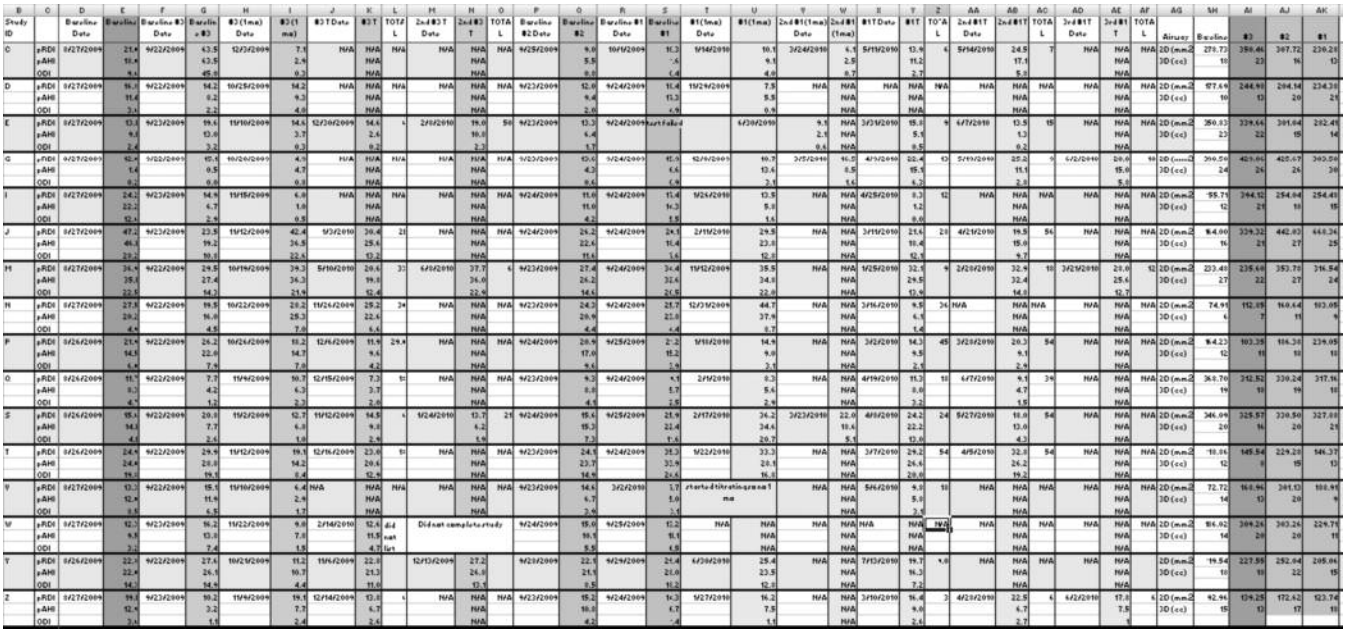

3 dimensional airway measurements with the different devices
35
30
25
20
15
10
5
0
3D (cc)
Baseline
#3-Protrusive SomnoDent
#2-Ptrotrusive Lungualless SomnoDent
#1-NM Lingualless
2 per. Mov. Avg. (Baseline)
2 per. Mov. Avg. (#3-Protrusive SomnoDent)
2 per. Mov. Avg. (#2-Ptrotrusive Lungualless SomnoDent)
2 per. Mov. Avg. (#1-NM Lingualless)

**Protrusion Analysis**

It was noted from the protrusion analysis that the mandible on average was protruded nearly 6.4 mm with an average titration of 2.0 mm for the Protrusive SomnoDent where as the mandible was titrated on average nearly 2.7 mm from the NM bite position. Therefore, the protrusion difference between these 2 appliances was in the order of nearly 5.7 mm minus the advancement of the mandible during the physiologic TENS bite.

| | | | in 10th of mm | Oxygen Desaturation Index (ODI) | | | | in 10th of mm | | | in 10th of mm |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Study ID | Baseline | Baseline #3 | PROTRUSION | Baseline #2 | Baseline #1 | #3 1 month | #3 T1 | TURNS | #1 1 month | #1 T1 | TURNS |
| J | 28.2 | 10.8 | 60 | 11.6 | 7.6 | 22.6 | 13.2 | 21 | 12.8 | 12.1 | 28 |
| M | 22.5 | 14.3 | 50 | 14.6 | 20.5 | 21.9 | 12.4 | 33 | 22.0 | 13.9 | 9 |
| N | 4.9 | 4.5 | 60 | 4.4 | 4.4 | 7.0 | 6.6 | 30 | 8.7 | 1.4 | 36 |
| P | 6.0 | 7.9 | 70 | 9.6 | 3.9 | 7.0 | 4.2 | 29 | 3.1 | 2.1 | 45 |
| Q | 4.7 | 1.2 | 60 | 4.1 | 2.5 | 2.3 | 2.0 | 18 | 2.9 | 3.2 | 18 |
| S | 4.1 | 2.6 | 80 | 7.3 | 11.6 | 1.0 | 2.9 | 6 | 5.1 | 13.0 | 24 |
| T | 19.8 | 19.1 | 70 | 14.9 | 24.6 | 8.4 | 12.9 | 18 | 16.8 | 20.0 | 54 |
| Y | 14.3 | 14.9 | 80 | 8.5 | 18.2 | 4.4 | 11.0 | | 15.0 | 12.8 | |
| Z | 3.6 | 1.1 | 50 | 4.2 | 1.4 | 2.4 | 2.6 | 6 | 1.1 | 2.6 | 3 |
| Average | 12.0 | 8.5 | 64.4 | 8.8 | 10.5 | 8.6 | 7.5 | 20.1 | 9.7 | 9.0 | 27.1 |

**The Longitudinal Results**

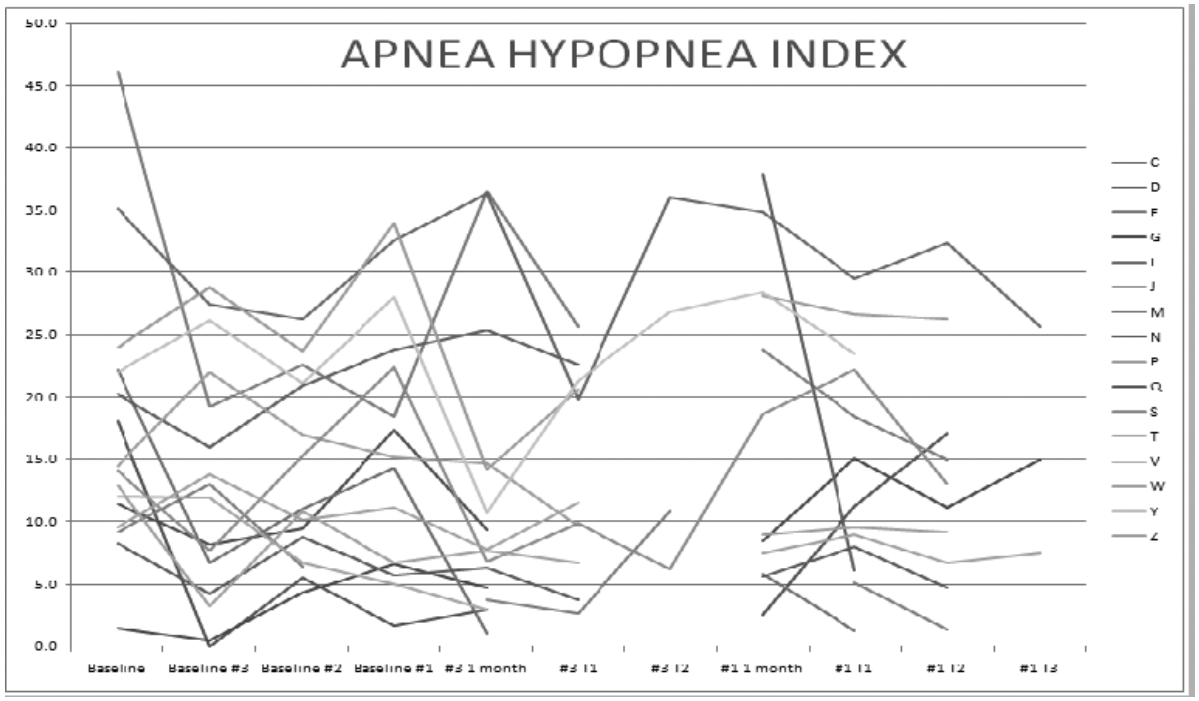


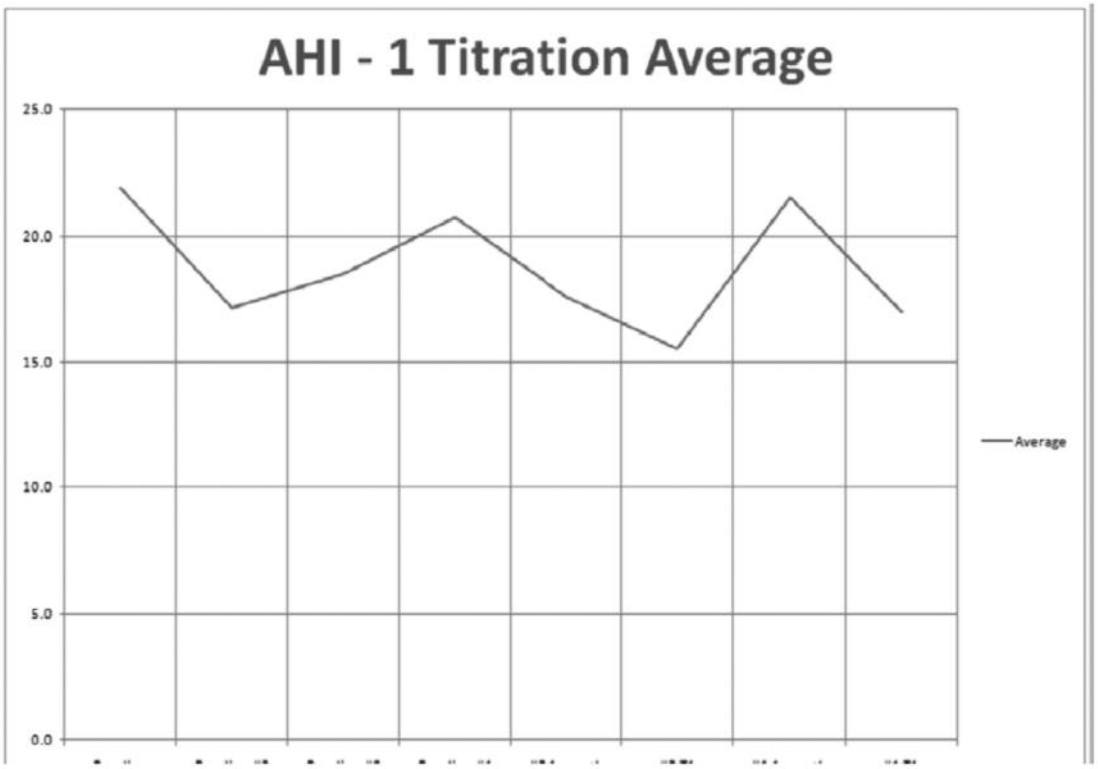
# THE ICCMO SLEEP STUDY

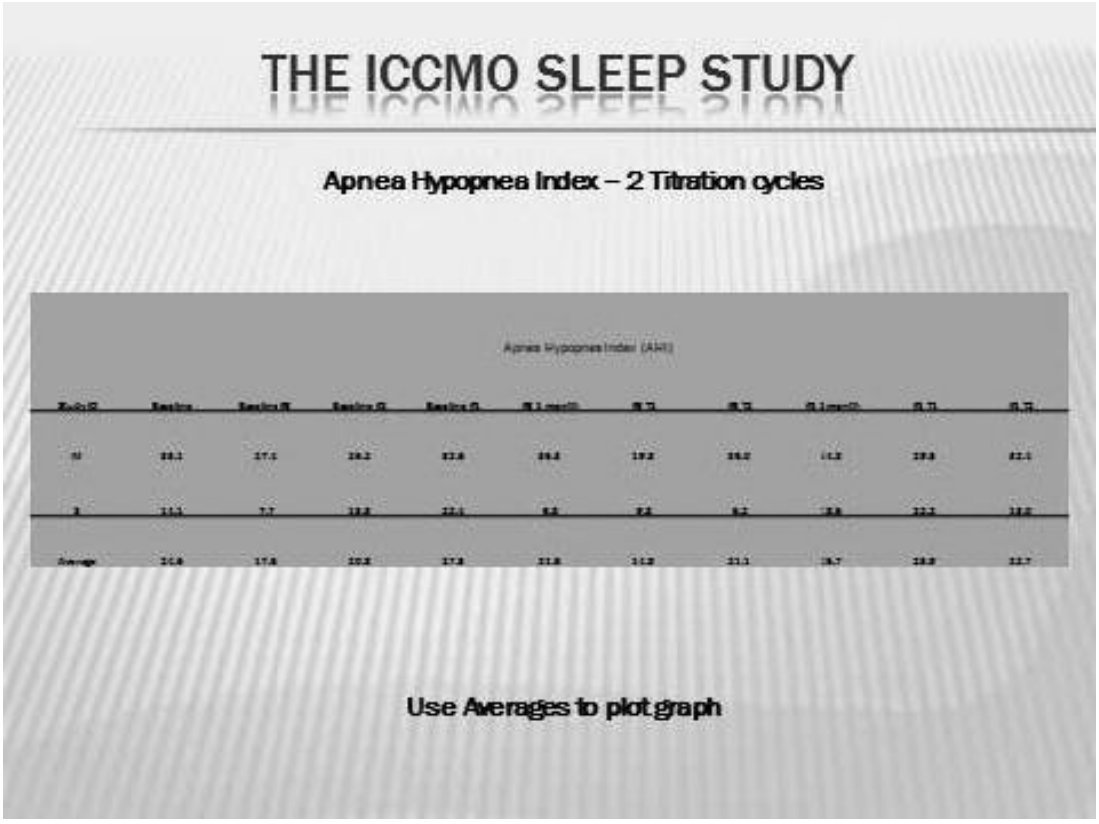
## Apnea Hypopnea Index

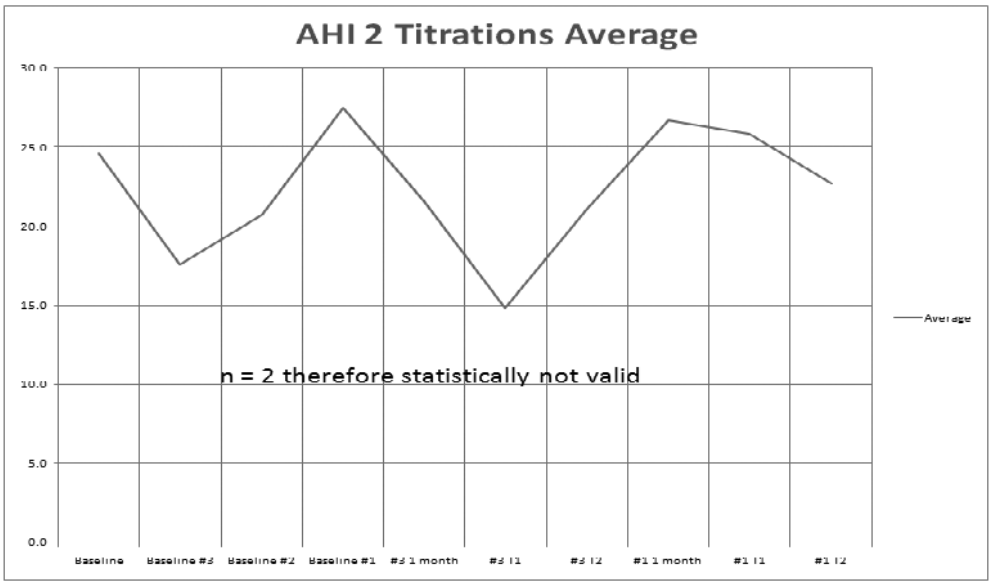
| Study ID | Baseline | Baseline #3 | Baseline #2 | Baseline #1 | #3 1 month | #3 f1 | #3 f2 | #1 1 month | #1 f1 | #1 f2 | #1 f3 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| C | 12.0 | | 8.8 | 1.6 | 2.8 | | | 2.8 | 11.2 | 17.1 | |
| D | 11.1 | 8.2 | 8.1 | 17.8 | 8.8 | | | 6.8 | | | |
| F | 8.1 | 12.0 | 6.1 | | 3.7 | 2.8 | 12.3 | | 8.1 | 1.8 | |
| G | 1.1 | 0.8 | 1.8 | 8.6 | 1.7 | | | 3.8 | 18.1 | 21.1 | 14.0 |
| I | 23.2 | 8.7 | 11.0 | 11.8 | 1.8 | | | 6.8 | 1.2 | | |
| J | 18.1 | 18.2 | 22.6 | 13.1 | 25.8 | 28.6 | | 23.8 | 13.1 | 18.8 | |
| M | 28.1 | 27.1 | 28.2 | 22.8 | 28.8 | 19.8 | 26.8 | 21.3 | 28.8 | 22.1 | 23.6 |
| N | 20.2 | 16.8 | 20.8 | 23.2 | 23.8 | 22.8 | | 27.8 | 6.1 | | |
| P | 11.8 | 22.8 | 17.8 | 18.2 | 11.7 | 8.8 | | 9.8 | 8.8 | 8.1 | |
| Q | 8.8 | 1.2 | 8.8 | 8.7 | 8.8 | 8.7 | | 8.8 | 3.8 | 1.7 | |
| S | 11.1 | 7.7 | 16.8 | 22.1 | 8.8 | 8.8 | 6.1 | 13.8 | 12.2 | 13.8 | |
| T | 21.8 | 23.8 | 28.7 | 28.8 | 11.2 | 20.8 | | 23.1 | 28.8 | 28.2 | |
| V | 12.8 | 11.8 | 8.7 | 8.8 | 2.8 | | | | 8.8 | | |
| W | 8.8 | 18.8 | 18.1 | 11.1 | 7.8 | 11.8 | | | | | |
| Y | 22.8 | 28.1 | 21.1 | 23.8 | 12.7 | 21.8 | 28.8 | 23.1 | 28.8 | | |
| Z | 1.8 | 8.1 | 18.8 | 8.7 | 7.7 | 8.7 | | 7.8 | 8.8 | 8.7 | 7.8 |
| Average | 17.8 | 16.8 | 18.7 | 18.2 | 11.8 | 11.8 | 20.8 | 16.8 | 18.7 | 18.7 | 16.8 |

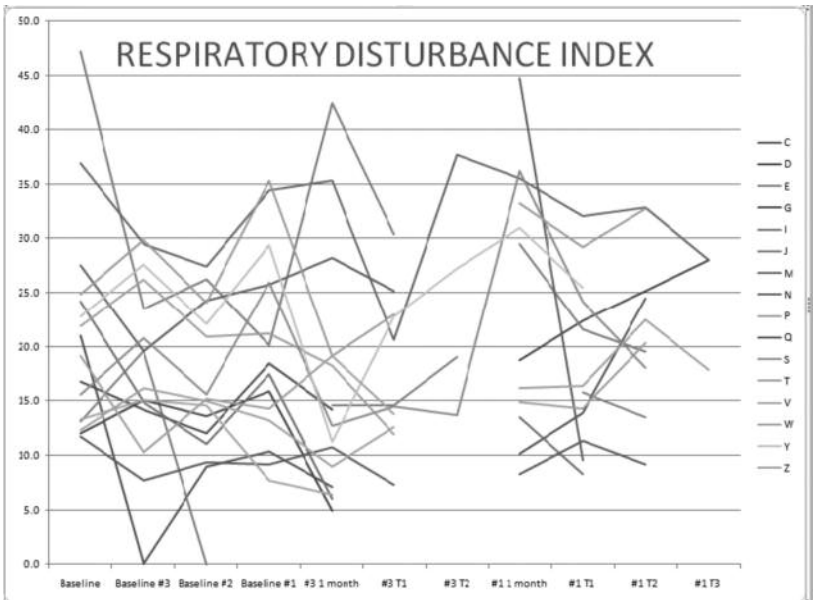
## Londitudinal Study Data

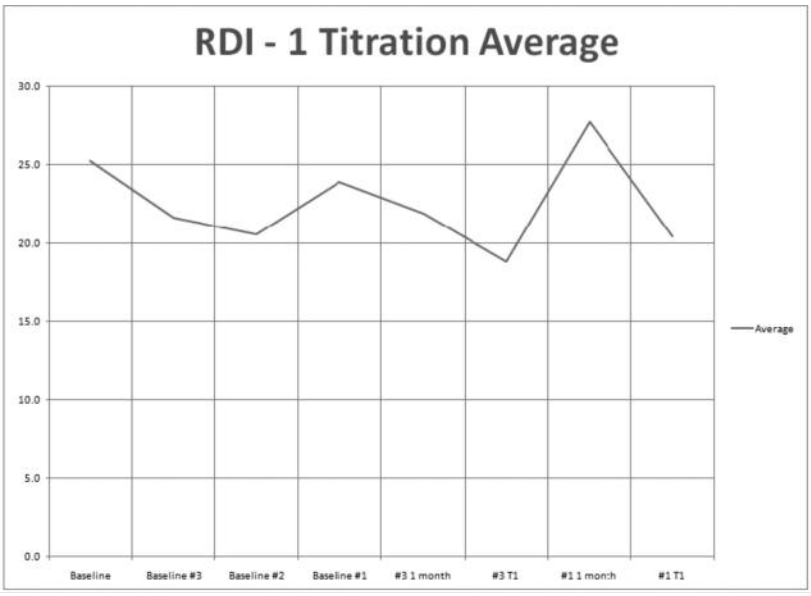


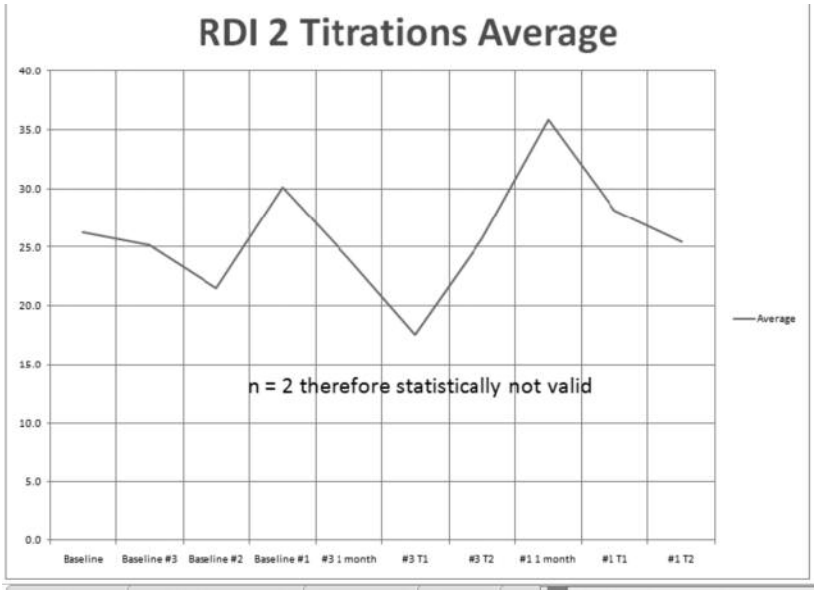

AHI - 1 Titration Average
25.0
20.0
15.0
10.0
5.0
0.0
Average

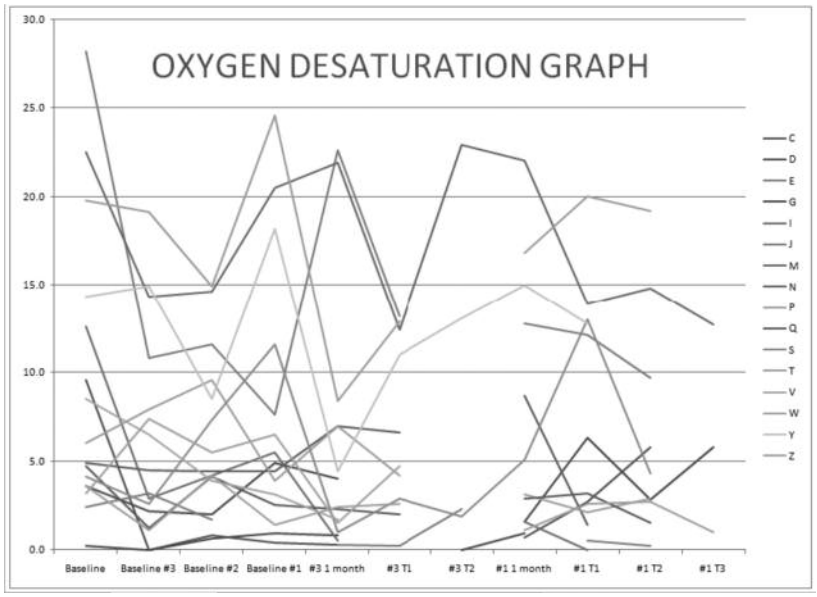

THE ICCMO SLEEP STUDY
Apnea Hypopnea Index – 2 Titration cycles
Use Averages to plot graph

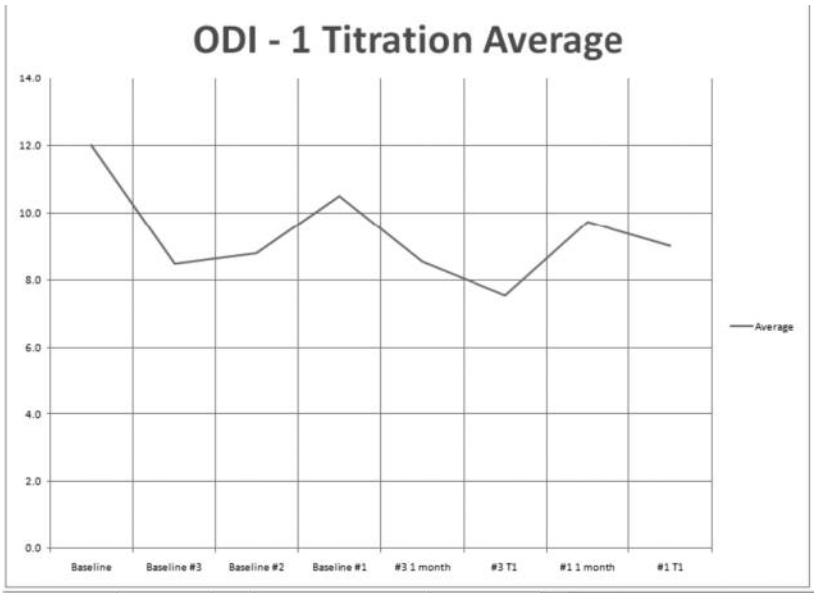

AHI 2 Titrations Average
30.0
25.0
20.0
15.0
10.0
5.0
0.0
n = 2 therefore statistically not valid
Average
Baseline
Baseline #3
Baseline #2
Baseline #1
#3 1 month
#3 T1
#3 T2
#1 1 month
#1 T1
#1 T2

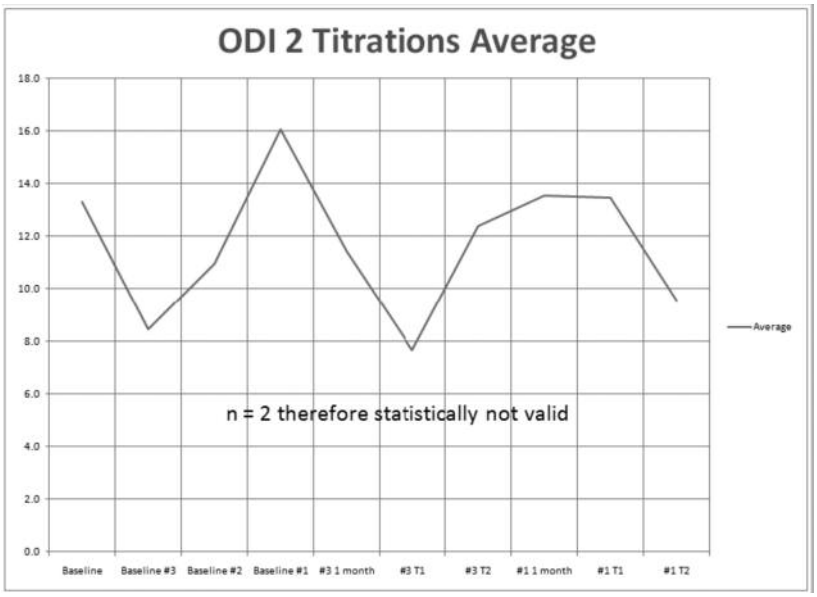

RESPIRATORY DISTURBANCE INDEX
50.0
45.0
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0.0
C
D
E
G
I
J
M
N
P
Q
S
T
V
W
Y
Z
Baseline
Baseline #3
Baseline #2
Baseline #1
#3 1 month
#3 T1
#3 T2
#1 1 month
#1 T1
#1 T2
#1 T3


RDI - 1 Titration Average
30.0
25.0
20.0
15.0
10.0
5.0
0.0
Average
Baseline
Baseline #3
Baseline #2
Baseline #1
#3 1 month
#3 T1
#1 1 month
#1 T1


RDI 2 Titrations Average
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0.0
n = 2 therefore statistically not valid
Baseline
Baseline #3
Baseline #2
Baseline #1
#3 1 month
#3 T1
#3 T2
#1 1 month
#1 T1
#1 T2
Average


OXYGEN DESATURATION GRAPH
30.0
25.0
20.0
15.0
10.0
5.0
0.0
Baseline
Baseline #3
Baseline #2
Baseline #1
#3 1 month
#3 T1
#3 T2
#1 1 month
#1 T1
#1 T2
#1 T3
C
D
E
G
I
J
M
N
P
Q
S
T
V
W
Y
Z


ODI - 1 Titration Average
14.0
12.0
10.0
8.0
6.0
4.0
2.0
0.0
Baseline
Baseline #3
Baseline #2
Baseline #1
#3 1 month
#3 T1
#1 1 month
#1 T1
Average




*Variables that were controlled in the study:*

- Bite taking (70% of max protrusion or TENS)
- Appliance design (Lingual or Lingualess)

*Variables beyond the control of this study:*

- Tongue Volume
- Body Mass Index
- Neck Size (Circumference)
- Mallampati Classification
- Tongue height
- Tonsils
- Adenoids
- Alcohol intake
- Other drugs taken
- Fatigued NM complex – leading to physiologic load on system**
- Other factors such as posture, sleep habits, emotional stress, lifestyle issues, etc.

**Observations:**

1. A single night wear of a sleep appliance does not give any obvious correlation to the sleep metrics obtained. Participants need to wear such appliances for a period of time before sleep metrics can be reliable to offer conclusive correlation between the appliance worn and the sleep metrics obtained.
2. There is generally an increase in the airway volume when any of these appliances were worn compared to standard.
3. The highest increase in airway volume was with the Protrusive SomnoDent with NO lingual flange.
4. It was interesting to note that the NM Lingual-less SomnoDent had a higher airway volume than the regular Protrusive SomnoDent underscoring the importance of the Lingual-less design.
5. The average Protrusion obtained using the George Gauge was in the order of approximately 6.4 mm. Furthermore, such appliances were titrated a further 2.0 mm
6. The average titration of the NM appliance was in the order of 2.7 mm. There was no arbitrary protrusion of the appliance.
7. In the Longitudinal portion of the study, the sleep metrics obtained after 2 months of titration were not statistically relevant for comparison since only 2 participants continued such titration since their sleep metrics were high enough to warrant such further titration.
8. In the Longitudinal portion of the study, the sleep metrics obtained after 1 month of titration showed the best sleep metrics with the Protrusive SomnoDent with the NM Lingualless trailing close behind. It should be noted that since there was no arbitrary protrusion of the NM Lingualless SomnoDent, there was much more room left to further titrate this appliance.

9. It is believed that the NM Lingual-less SomnoDent would bring about a balance within the stamatognathic system and therefore unload the NM complex leading to lower possibility of central sleep apnea.
10. The arbitrary nature of protrusion in the Protrusive SomnoDent and the Protrusive Lingual-less SomnoDent was cited by the participants as the reason for the discomfort and as such no one wanted to titrate the Protrusive Lingual-less SomnoDent. Therefore, this device was only worn for one month.
11. Certain variables cause a load on the physiologic system of the patient. Such a load can lead to NM fatigue which can further diminish the compensatory NM responses as discussed in the paper by Susheel P. Patil et al from Johns Hopkins University.

**Conclusions:**

1. The Lingual-less design has a significant positive impact on the sleep metrics and airway volume as it minimally impinges on the precious tongue room.
2. The Protrusive SomnoDent produced the best sleep metrics but this was at the expense of discomfort.
3. The NM design reduces Neuro Mechanical load on the patient.
   a. This allows the autonomic system (particularly the Parasympathetic system) to work optimally in maintaining a patent airway during sleep
   b. This can be accomplished by a NM orthotic or a NM reconstruction/ orthodontics/combination
4. It is obvious that there are many significant factors that need to be addressed when treating sleep apnea. Therefore, the use the "Medical Model" to treat the patient for sleep apnea is strongly indicated.
5. It is highly recommended that the most comfortable appliance is placed as a first course of action in the patient's mouth after diagnosis that also allows a significant improvement in the sleep metrics. This should be followed by the incorporation of all possible unique variables for each unique patient using the "Medical Model" that would involve other health practitioners from medical specialists to physiotherapists.
6. Finally, it should be understood that the airway in an ambulatory patient who is erect may be very different from the airway in a patient that is supine and asleep. Hence, the sleep metrics are more reliable predictor of sleep apnea that the cone beam airway volume analysis.