Patient 1

Introduction:

Patient 1 was a 47 year-old Caucasian male (DOB: 29/01/1975) at the time of presentation with his main symptoms revolving around excessive daytime somnolence and sleep maintenance insomnia. He was referred to a respiratory & sleep physician who had the patient undergo a Type 2 ambulatory sleep study. The results of this sleep study was discussed with the patient and he was concluded to have moderate obstructive sleep apnoea (OSA). He trialled CPAP over the course of 2 months with technical improvement in his AHI however the patient found it disturbing and invasive with no significant improvement in his symptoms. After a follow-up consultation with the sleep physician, patient 1 was referred to me for consideration of a mandibular advancement splint (MAS) oral appliance as an alternative treatment option. He presented for his first consultation on 16/06/2022.

Chief Complaint:

Patient 1's chief complaint revolves around sleep maintenance insomnia which he believes contributes to his symptoms of excessive daytime somnolence and tiredness. He has no troubles initiating sleep at the start of the night however will tend to have frequent arousals from sleep every night which he has noticed for most of his adult life. On awakening during the night, he can take up to 1-2 hours to return back to sleep successfully. He has noticed this duration to return to sleep is reduced in the winter months. He reports occasional loud snoring that can be disruptive to his partner however believes this is infrequent and is not a major concern. He describes excessive daytime somnolence and tiredness during the day and awakening unrefreshed.

History & Diagnosis of Present Illness:

Patient 1 has noticed his issues with sleep maintenance insomnia and daytime somnolence for many years, however due to increasing severity of his symptoms, this triggered a consultation with his general practitioner (GP) and subsequent referral to the sleep physician for further investigations. He had been using a custom-made occlusal splint oral appliance for management of sleep bruxism for many years however it broke and he did not replace it. The Type 2 ambulatory sleep study he performed on 22/12/2021 showed overall moderate OSA with an overall AHI of 25.2 and lowest oxygen desaturation of 91%. There was no supine (supine AHI 21.8) or REM (REM AHI 25.4) predominance. Vast majority of sleep-disordered breathing events were hypopnoeas (162 hypopnoeas , 7 obstructive apnoeas, 3 central apnoeas). Epworth Sleepiness Scale recorded at this sleep study was 12/24 and BMI was 26.3. After these results were discussed, Patient 1 trialled CPAP therapy for 2 months but although it technically controlled his AHI and OSA well, Patient 1 did not find any improvement in his symptoms and he found the CPAP invasive and disturbing to his sleep. After review with his sleep physician, he was referred to trial MAS therapy as an alternative OSA treatment option.

Past Medical History:

Patient 1 weighs 97kg at the time of consultation and with a height of 190cm gave him a BMI of 26.9 which was only very slightly elevated to when he performed his sleep study. He is a non-smoker and drinks alcohol approximately 1-2 nights a week. He does not take any prescription medications. He does take supplements including multi-vitamin, magnesium, glucosamine, and calcium. He does not reportedly use recreational drugs. He does report seasonal hayfever/allergic rhinitis type symptoms but manages it conservatively. He does have a history of mental illness and depression but also manages this conservatively.

Clinical Examination:

Patient 1 is missing all 4 wisdom teeth due to previous extraction. He has a Class 2 Div 2 malocclusion, deep anterior overbite, anterior overjet and evident mandibular retrognathia. His maxillary and mandibular dental arches are narrowed with the appearance of a transverse deficiency. There is moderate-severe attrition wear, especially notable with the mandibular teeth with the anterior teeth the most severely affected. The only restorations present are composite veneers with teeth 11 & 21. Mallampati Score was class 2. Friedman Tonsils Grade 1. Uvula, tongue and soft palate are all within normal limits in size and shape. TMJ examination revealed bilateral clicking joint noises on lateral excursive movements when the patient performs it in a certain fashion which he has previously repetitively done as a habit. There are otherwise no signs of joint noises with all other TMJ movements, there is no pain to palpation of the masticatory muscles or TMJs, and there is no deviation or deflection on jaw opening or protrusion. There are no self-reported issues with nasal breathing or patency.

Treatment Plan:

Patient 1 had no contraindications to proceed with oral appliance therapy based on the examination results. A SomnoDent Avant MAS design was chosen due to comfort, ease of use and titration, and patient's preference with appliance design. He was able to understand the titration mechanism with changing bands in 1mm steps forwards and was also happy with the notion that the band would provide resistance to jaw opening during sleep. The acrylic material would allow ease of adjustment in future should he have any further restorative work however there was no such work planned at the current time. George Gauge bite registration was taken at approximately 55% maximum protrusion (maximally retruded -7mm, maximally protruded +4mm, registration taken at -1mm).

Results:

This SomnoMed Avant appliance was fitted on 07/07/2022 with excellent retention, balance of occlusal contacts, ability of patient to insert & remove the device, and provision of titration instructions. The titration instructions were to change up from band 0 up to a minimum of band 2 prior to having the sleep study or further if required to subjectively control his symptoms and snoring levels adequately. This was to be done in 1mm adjustments performed approximately once per 5-7 days. Patient did not respond to review attempts by our clinic prior to him seeing the sleep physician and having a repeat MAS efficacy Type 2 ambulatory sleep study on 16/01/2023 to assess it objectively. The repeat sleep study showed overall mild OSA with the MAS in-situ with an overall AHI of 10.9. There was a supine AHI of 26.7 and REM AHI of 13.6. Lowest oxygen desaturation was 90%. ESS recorded at this sleep study was 11/24 and BMI was 24.9. He had a follow-up consultation with the sleep physician on 06/02/2023 whereby MAS therapy was deemed suitable to use as a long-term OSA treatment option considering the results of the sleep study and that the patient had good subjective improvement in his symptoms, beyond what CPAP was providing him. There were no further scheduled visits with the sleep physician and the patient was discharged.

Follow-up appointments:

13/04/2023:

Patient 1 returned after responding to a recall attempt by clinic staff. Has been using the SomnoMed Avant at this stage for approximately 9 months. He reports using it every night for the full duration of his sleep with no self-reported side effects. His subjective results are that the snoring is completely resolved, his daytime somnolence symptoms have reduced, and that his sleep quality appears to be improved with deeper and more consolidated sessions. He reports previous insomnia complaints from work stress however he advises that his stress levels have reduced. He does ruminate on whether he is getting optimal sleep quality and finds this may initiate insomnia. A recent shoulder injury has been disturbing his sleep due to pain from certain positions in bed. His weight has remained stable since the sleep study.

He is currently at band 3 (3mm advanced and approximately 80% maximum protrusion) out of a maximum of 8 bands. He advises he has been at this level for a long time. The MAS is in excellent condition with no evidence of cracks or stress fractures. There have been no changes evident of teeth movement or bite changes with full arch occlusion noted on occluding in maximal intercuspation position (MIP). There are no TMJ concerns or changes to the bilateral clicking noises that the patient could perform prior to starting MAS therapy. There appears to be a slight increase his maximum protrusion with the patient able to protrude a further 1mm compared to his initial George Gauge measurements.

Recommendations at this appointment were to trial increasing the titration of the MAS considering there were some residual daytime tiredness symptoms and mild OSA identified on the sleep study. Patient 1 was also asked to seek a consultation with a trained sleep psychologist as CBTi was identified as something that may be able to help improve his insomnia. Patient was asked to return in 4 weeks to review his progress with titration.

17/05/2023:

Patient 1 returned as requested at the 4 week mark to re-assess his progress with MAS therapy and titration. He has now increased to band 5 (approximately 90% maximum protrusion) which he feels has improved his levels of daytime tiredness. He has made an appointment with a sleep psychologist and this is upcoming for the initial assessment. He has had some mild jaw discomfort and pain on awakening for the last 2 weeks however has noted that these symptoms are improving and becoming less frequent. There has been no evident teeth movement or bite changes similarly to last appointment. His TMJs are again in good condition with no evident dysfunctional issues. There is mild tenderness to palpation of the masseter muscles bilaterally but no other muscles with identified pain. Considering the high titration level, the patient was asked to return to the clinic in 3 months for re-assessment and review of his dental and jaw structures. Advised patient not to increase the titration and to continue wearing the MAS as it is currently. Considering the change in symptoms and titration, he could be considered for another sleep study to again objectively test the MAS and this decision was given for the respiratory & sleep physician and/or GP to make.

02/08/2023:

Patient 1 returned for 3 month review of his progress with MAS therapy. He has consistently been wearing the SomnoMed Avant MAS every night without any reported side effects or issues tolerating it. The mild jaw discomfort and pain reported from last appointment has completed resolved. He has continued with band 5 and his symptoms & snoring are still subjectively very well controlled. No follow-up sleep study was determined needed at this current stage by his GP. He has seen the sleep psychologist for 4 sessions of CBTi and this has helped reduce his insomnia episodes and given him healthier views on sleep. He is very happy with his current state in sleep disorder management. His weight has continued to be stable and no other medical issues have arisen. There have been no changes in medication status. The MAS is in excellent condition with no evidence of cracks or stress fractures. There is no evidence of teeth movement or bite changes with full arch occlusion noted in MIP. The TMJs had no issues noted on examination with no pain to palpation of them or the muscles of mastication. Jaw opening and excursive movements were not limited and there was no midline deviation or deflection. Considering the excellent subjective response, the patient was asked to return in 6 months for another review.

Diagnostic sleep study Page 1:

Queensland Sleep

ADULT RESPIRATORY/SLEEP PHYSICIANS

Dr S Bowler FRACP
Dr J Binder FRACP
Dr J Churton FRACP
Dr G Eather FRACP
Dr W Kelly FRACP
Dr A Rosentengel FRACP
Dr G Simpson MD FRACP
Dr A Thasneem FRACP
Dr S Vincent FRACP

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sleep NATA

Accredited for compliance with ASA Standard for Sleep Disorders Services

QUEENSLAND SLEEP

RE :
Study Type : Portable Diagnostic
Date of Birth : 29/01/1975 (46yrs)
Date of Study : 22/12/2021
Referring Dr :
Location : Brisbane

Referrals received via Medical Objects/ Fax. Detailed Statistical Report available on request.

Patient History: B.M.I. = 26.3 (95kg) Medications: nil listed

Mr. Bray presents with a history of snoring, excessive daytime sleepiness, insomnia, irritability, restless sleep, poor memory, poor concentration, dry mouth on waking and headache on waking. Epworth Sleepiness Score (ESS) = 12/24. Past medical history is unremarkable. Mr. Bray rated his quality of sleep on the study night as average, awakening feeling unrefreshed. No alcohol was consumed on the evening.

Sleep: Lights out @ 22.08hrs. Sleep onset = 34.5 mins. Latency to REM sleep = 81.0mins. Slow wave sleep proportion = 22.5% and REM sleep proportion = 23.7%. Sleep efficiency = 77.4%. The EEG arousal index = 13.5, most often spontaneous in nature.

Respiratory: There were 7 obstructive apnoeas, 3 central apnoeas and 162 hypopnoeas (average duration = 42secs; longest duration = 136 secs) recorded. The overall AHI = 25.2, supine AHI = 21.8, supine REM AHI = 20.5 and REM AHI = 25.4. A total of 178.5mins of supine sleep were recorded, with 20.5mins of supine REM. Occasional snoring was recorded. Mean awake SaO_2 = 95%, nadir SaO_2 = 91%. Total number of Limb movements = 0. Average heart rate = 58 bpm.

5th January 2022

SLEEP PHYSICIAN REPORT

Interpretation:
A diagnostic sleeps study was performed to investigate daytime sleepiness and insomnia.

Sleep latency was prolonged. Sleep efficiency was reduced, but REM duration was adequate. Occasional snoring was heard. Repetitive obstructive apnoeas and hypopneas occurred during sleep, associated with mild oxygen desaturation to a nadir of 91%. Arousal indices are within normal limits.

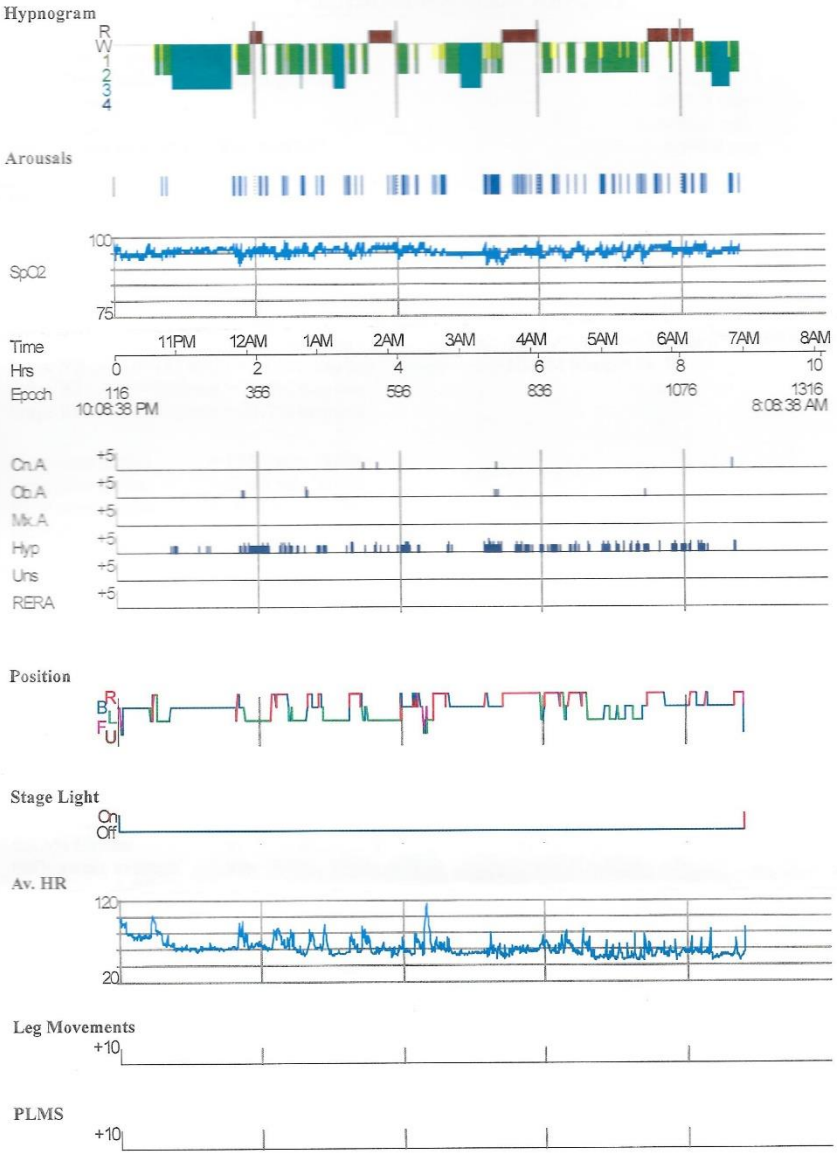
Summary: Moderate OSA. Recommend clinical review to discuss management options.

Patients who clinically have excessive daytime sleepiness should be advised of the risks of driving. They should restrict or cease driving until successful treatment of the underlying condition has occurred. Guidelines to assist health professionals in determining a person's fitness to drive are available on the AUSTROADS website (www.austroads.com.au). Additional clinical management advice may be obtained by emailing specific questions to our Accredited Sleep Physician on clinical@qsdu.com.au.

Date Transcribed: 9th January 2022
Physician Signature:

Diagnostic Sleep Study Page 2

Name:	**Study Date: 22/12/2021**
Sex: Male	DOB: 29/01/1975
Height: 190cm	Weight: 95 Kg



Name:	Study Date: 22/12/2021
Sex: Male	DOB: 29/01/1975

POLYSOMNOGRAM REPORT

Report time from 22:08:38 to 06:58:07	= 529.5 min
TRT - Time available for sleep (lights out)	= 528.5 min
Sleep Latency	= 34.5 min
REM latency	= 81.0 min
Sleep period from 22:43:38 to 06:57:37	= 494.0 min

Sleep Summary

Total Sleep Time = 409.0 min
Sleep Onset = 34.5 min
Sleep Efficiency = 77.4%

WASO = 85.0 min
No of Awakenings = 31
REM latency = 81.0 min

Stage N1 = 38.0min = 9.3% sleep time
Stage N2 = 182.0min = 44.5% sleep time
Stage N3 = 92.0min = 22.5% sleep time
Stage REM = 97.0min = 23.7% sleep time

Total Sleep = 409.0 min
NREM Sleep = 76.3%

Sleep time supine = 178.5 min 43.6%
Sleep non-supine = 230.5 min 56.4%
REM sleep supine = 20.5 min 21.1%
REM sleep non-supine = 76.5 min 78.9%

Arousal Statistics

Spontaneous Arousals	= 58	Index = 8.5/hr
Respiratory Arousals	= 34	Index = 5.0/hr
PLM Arousals	= 0	Index = 0.0/hr
Isolated Limb Movement Arousals	= 0	Index = 0.0/hr
Total Arousals	= 92	Index = **13.5/hr**

Respiratory/Saturation Statistics

Oxygen Saturations	NREM			REM		
	Back	Other	All	Back	Other	All
SaO_2% min average	94	94	94	95	95	95
SaO_2% Lowest	91	91	91	93	91	91

SaO_2 awake average 95%
Time Below 95%: 60.9 % sleep time
Time Below 90%: 0.0 % sleep time
Time Below 88%: 0.0 % sleep time
Time Below 85%: 0.0 % sleep time
Oxygen Desaturations (≥ 3%) = 17

Index	NREM			REM			**Total No**
	Back	Other	All	Back	Other	All	
Central Apnoea	0.4	0.4	0.4	0.0	0.8	0.6	3
Obstructive Apnoea	1.9	0.8	1.3	0.0	0.0	0.0	7
Mixed Apnoea	0.0	0.0	0.0	0.0	0.0	0.0	0
Hypopnoea	19.7	27.3	23.5	20.5	25.9	24.7	162
Apnoea+Hypopnoea	22.0	28.4	25.2	20.5	26.7	25.4	
Total AHI		**25.2**			**25.4**		

Supine AHI	= 21.8 events/hr	Apnoea Index	= 1.5/hr
Non-supine AHI	= 27.9 events/hr	Hypopnea Index	= 23.8/hr
REM AHI	= 25.4 events/hr	Mean Event Duration	= 40 secs
Supine REM AHI	= 20.5 events/hr	Longest Hypopnoea	= 136 secs
Total AHI	**= 25.2 events/hr**	Longest Apnoea	= 21 secs

RE	:	
Study Type	:	Portable Diagnostic
Date of Birth	:	29/01/1975 (47yrs)
Date of Study	:	16/01/2023
Referring Dr	:	
Location	:	Brisbane

Referrals received via Medical Objects/ Fax. Detailed Statistical Report available on request.

Patient History: B.M.I. = 24.9 (90kg) Medications: Nil

Mr. presents with a history of abnormal leg movements, excessive daytime sleepiness (EDS), insomnia, poor concentration, restless sleep and witnessed apnoeas. Epworth Sleepiness Score (ESS) = 11/24. Past medical history includes . Mr. rated their quality of sleep on the study night as above average, awakening feeling unrefreshed. No alcohol was consumed on the evening. Study conducted with MAS in use.

Sleep: Lights out @ 2133hrs. Sleep onset = 4.5 mins. Latency to REM sleep = 66.5mins. Slow wave sleep proportion = 5.0% and REM sleep proportion = 26.2%. Sleep efficiency = 89.6%. The EEG arousal index = 8.1, most often associated with respiratory events.

Respiratory: There were 27 obstructive apnoeas (average duration = 16 secs), 0 mixed apnoeas (average duration = 0 secs), 5 central apnoeas (average duration = 17 secs) and 54 hypopnoeas (average duration = 24secs) recorded. The overall AHI = 10.9, supine AHI = 26.7, supine REM AHI = 0.0 and REM AHI = 13.6. A total of 4.5mins of supine sleep were recorded, with 0.0mins of supine REM. Rare moderate snoring was recorded. Mean awake SaO_2 = 95%, nadir SaO_2 = 90%. Artefact persisted in leg input. Total number of Limb movements = 0, PLMS index = 0.0 with a PLMS arousal index of 0.0/hr and 0 isolated limb movement arousals. Average heart rate = 55 bpm.

25-Jan-23

SLEEP PHYSICIAN REPORT

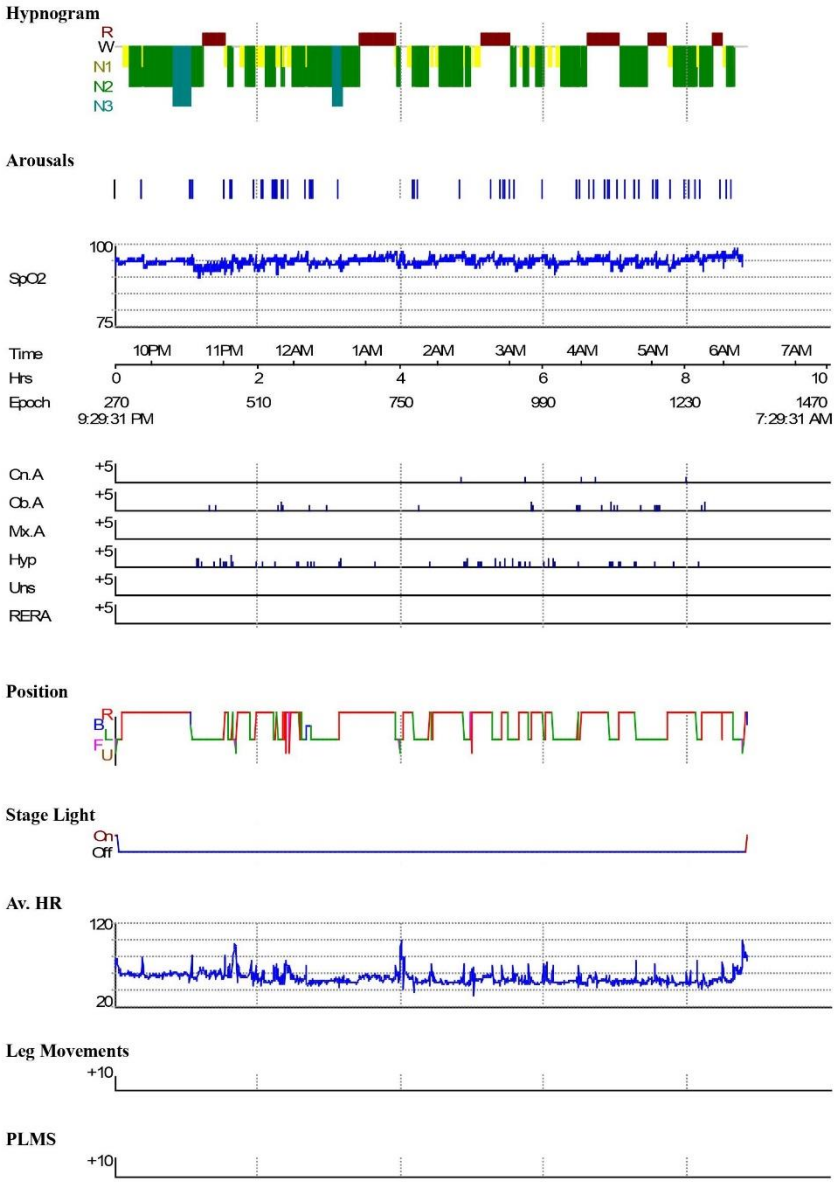
Interpretation: Normal sleep latency and latency to REM sleep onset. Over 7.5 hours of sleep was available for analysis, although near absence of supine sleep. Study was undertaken with oral appliance in-situ. Respiratory indices consistent with mild obstructive sleep apnoea. Arterial saturation remained >90%.

Management: Treatment options including trial of positive airway pressure therapy to be discussed with patient.

Patients who clinically have excessive daytime sleepiness should be advised of the risks of driving. They should restrict or cease driving until successful treatment of the underlying condition has occurred. Guidelines to assist health professionals in determining a person's fitness to drive are available on the AUSTROADS website (www.austroads.com.au). Additional clinical management advice may be obtained by emailing specific questions to our Accredited Sleep Physician on clinical@qsdu.com.au.

Date Transcribed: 1 February 2023
Physician Signature:

Name:	Study Date: 16/01/2023
Sex: Male	DOB: 29/01/1975
Height: 190cm	Weight: 90 Kg



Name:	**Study Date: 16/01/2023**
Sex: Male	DOB: 29/01/1975

POLYSOMNOGRAM REPORT

Report time from 21:29:31 to 06:20:00	= 530.5 min
TRT - Time available for sleep (lights out)	= 526.5 min
Sleep Latency	= 4.5 min
REM latency	= 66.5 min
Sleep period from 21:37:01 to 06:09:00	= 512.0 min

Sleep Summary

Total Sleep Time = 472.0 min		WASO	= 50.0 min
Sleep Onset	= 4.5 min	No of Awakenings	= 23
Sleep Efficiency	= 89.6%	REM latency	= 66.5 min
Stage N1	= 73.0min = 15.5% sleep time	Total Sleep	= 472.0 min
Stage N2	= 252.0min = 53.4% sleep time	NREM Sleep = 73.8%	
Stage N3	= 23.5min = 5.0% sleep time		
Stage REM	= 123.5min = 26.2% sleep time		
Sleep time supine	= 4.5 min 1.0%		
Sleep non-supine	= 467.5 min 99.0%		
REM sleep supine	= 0.0 min 0.0%		
REM sleep non-supine	= 123.5 min 100.0%		

Arousal Statistics

Spontaneous Arousals	= 62	Index	= 7.9/hr
Respiratory Arousals	= 2	Index	= 0.3/hr
PLM Arousals	= 0	Index	= 0.0/hr
Isolated Limb Movement Arousals	= 0	Index	= 0.0/hr
Total Arousals	= 64	Index	= **8.1/hr**

Respiratory/Saturation Statistics

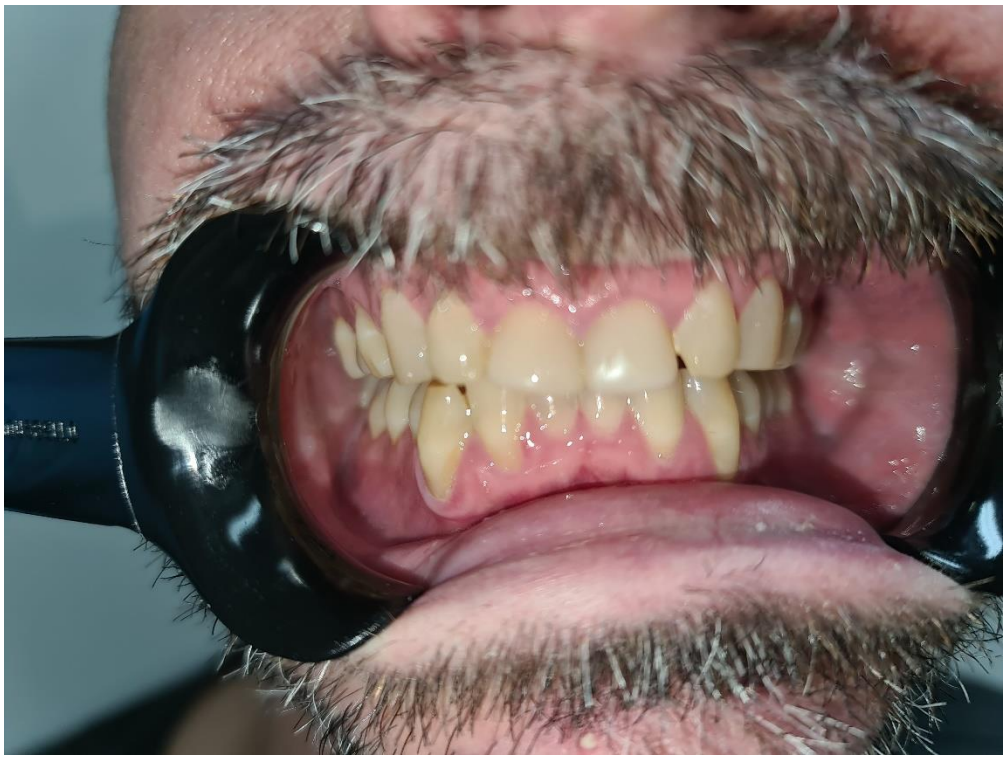
Oxygen Saturations	NREM			REM		
	Back	Other	All	Back	Other	All
SaO_2% min average	94	94	94	-	95	95
SaO_2% Lowest	92	90	90	-	91	91

SaO_2 awake average	95%
Time Below 95%:	69.3 % sleep time
Time Below 90%:	0.1 % sleep time
Time Below 88%:	0.0 % sleep time
Time Below 85%:	0.0 % sleep time
Oxygen Desaturations (≥ 3%) =	48

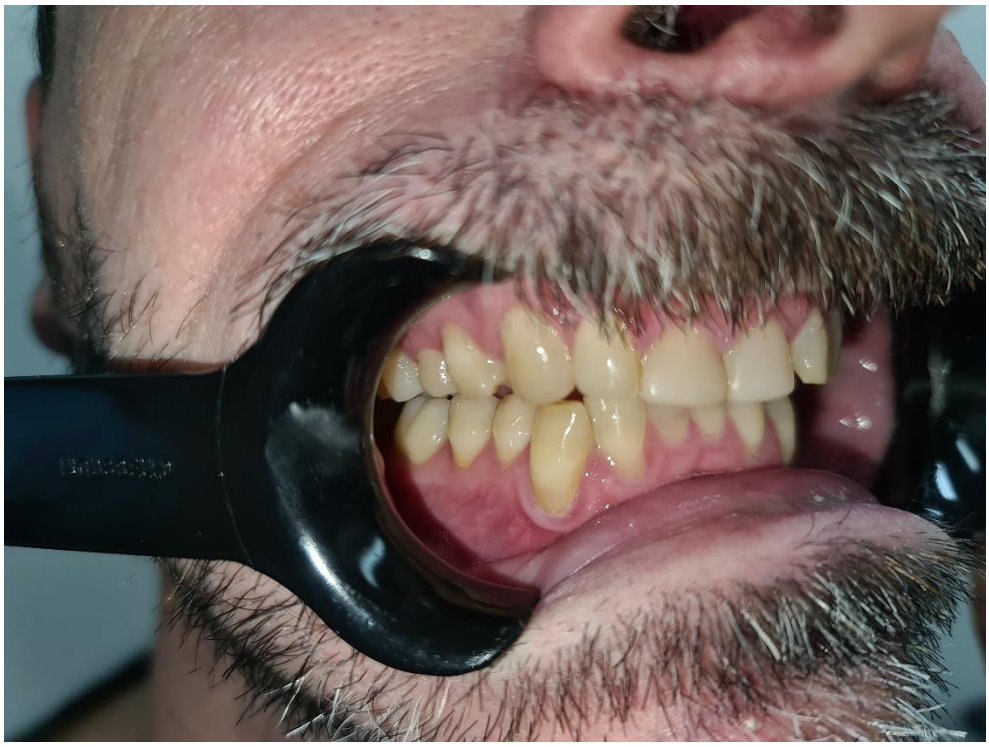
	NREM			REM			
Index	Back	Other	All	Back	Other	All	**Total No**
Central Apnoea	0.0	0.7	0.7	0.0	0.5	0.5	5
Obstructive Apnoea	13.3	2.6	2.8	0.0	5.3	5.3	27
Mixed Apnoea	0.0	0.0	0.0	0.0	0.0	0.0	0
Hypopnoea	13.3	6.5	6.5	0.0	7.8	7.8	54
Apnoea+Hypopnoea	26.7	9.8	10.0	0.0	13.6	13.6	
Total AHI		**10.0**			**13.6**		

Supine AHI	= 26.7 events/hr	Apnoea Index	= 4.1/hr
Non-supine AHI	= 10.8 events/hr	Hypopnea Index	= 6.9/hr
REM AHI	= 13.6 events/hr	Mean Event Duration	= 21 secs
Supine REM AHI	= 0.0 events/hr	Longest Hypopnoea	= 62 secs
Total AHI	= **10.9 events/hr**	Longest Apnoea	= 27 secs

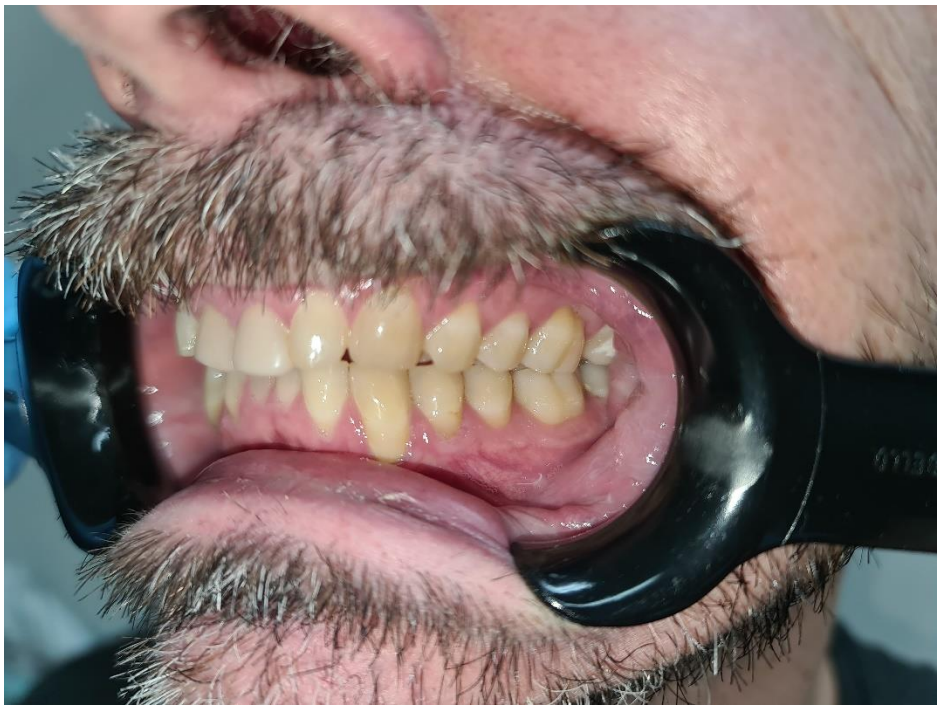
Anterior View in Occlusion:



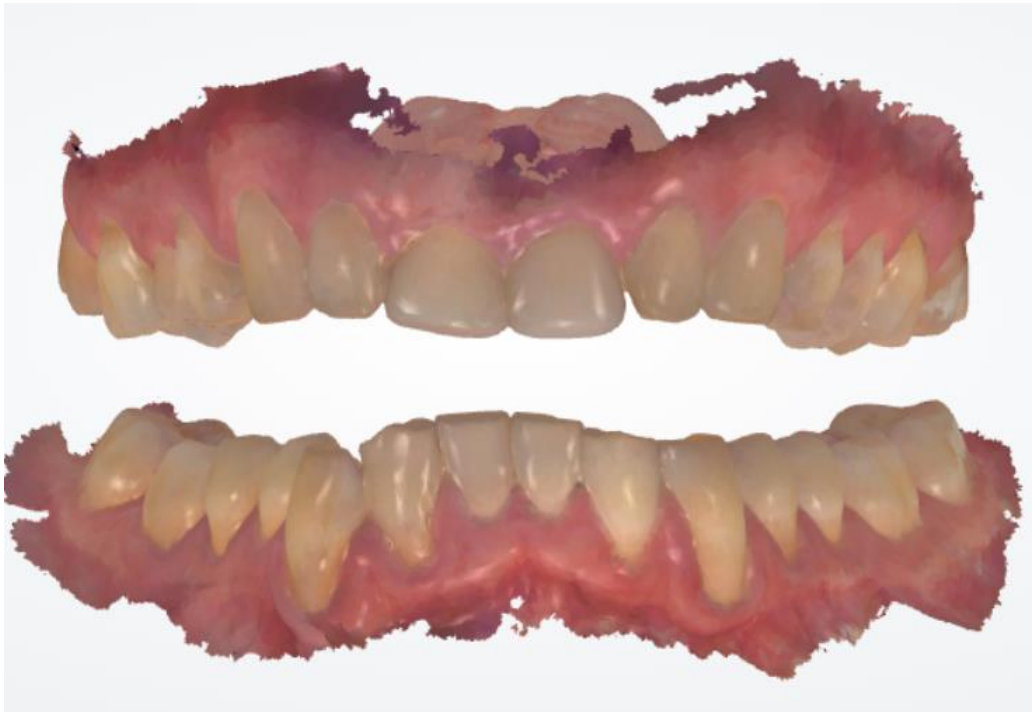
Right lateral view in occlusion:



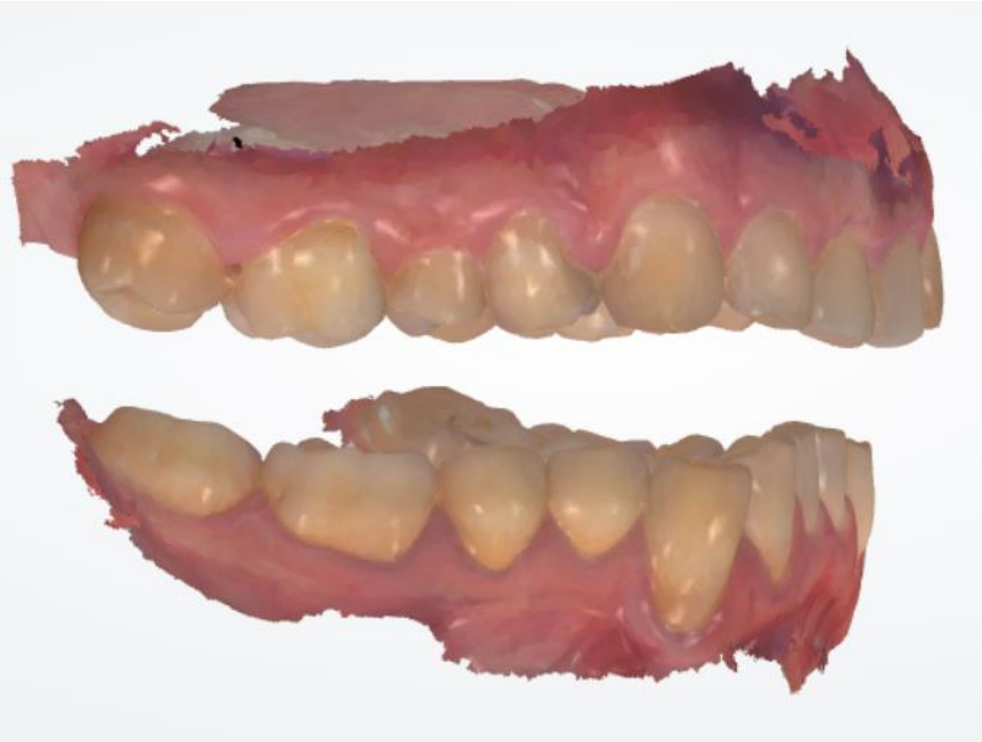
Left lateral view in occlusion:



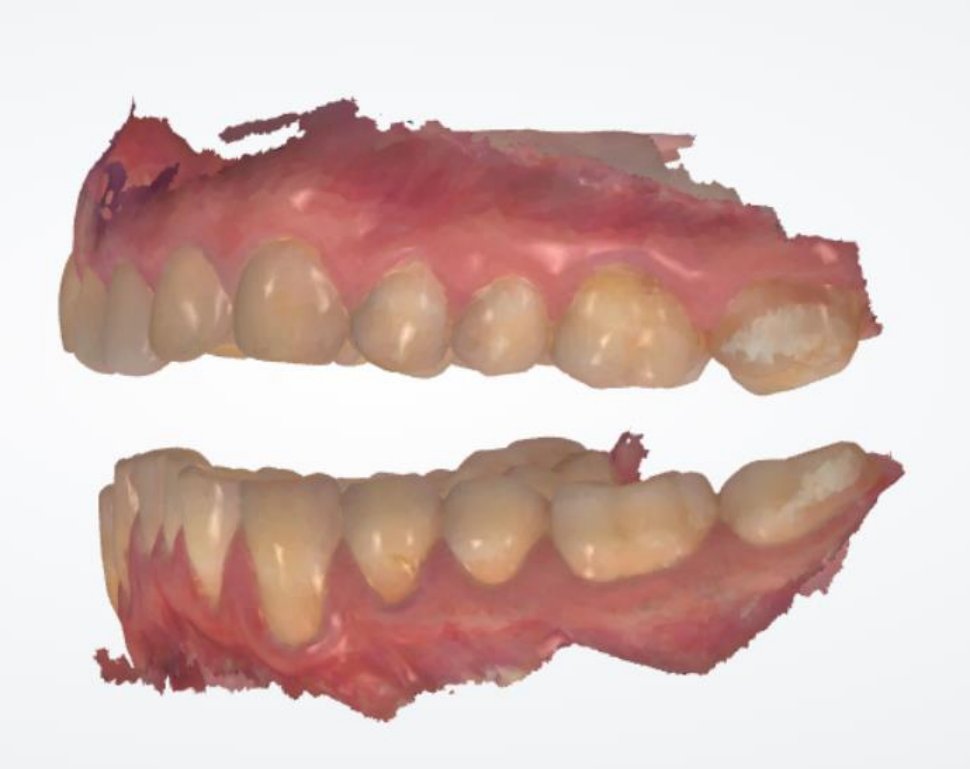
Anterior view intra-oral scans in bite position:



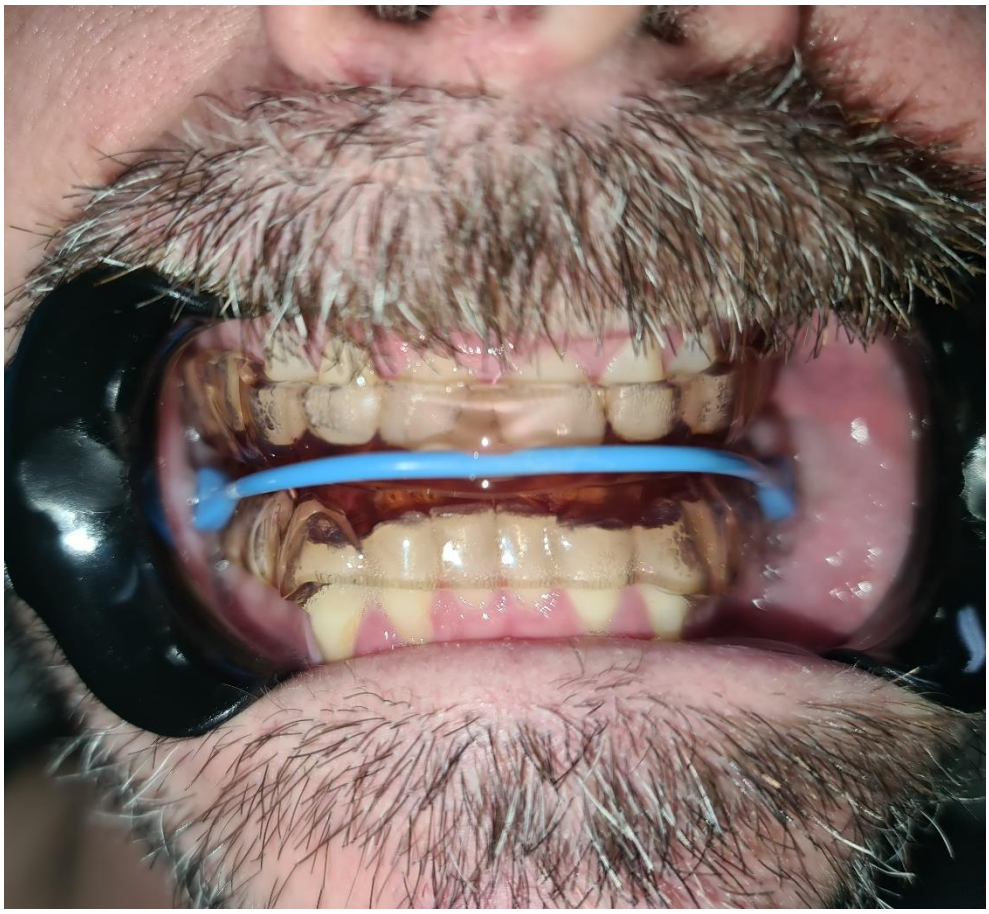
Right lateral view of intra-oral scans in bite position:



Left lateral view of intra-oral scans in bite position:



Anterior view with MAS in-situ:



Patient 2

Introduction:

Patient 2 was a 35 year-old Caucasian male (DOB: 14/11/1986) at the time of presentation with his main concerns revolving around loud disruptive snoring to his partner and witnessed apnoeas. He was referred to a respiratory & sleep physician who had the patient undergo a Type 1 in-lab sleep study. The results of this sleep study was discussed with the patient and he was concluded to have moderate to severe obstructive sleep apnoea (OSA). He had a discussion with the respiratory & sleep physician regarding these results and referred for MAS therapy as a frontline treatment option as the patient was not willing to consider CPAP therapy at this current time. He presented for his first consultation on 17/08/2022.

Chief Complaint:

Patient 2's chief complaint revolves around controlling loud snoring and witnessed apnoeas for his partner. He believes these episodes have actually reduced in recent times. He denies any significant symptoms of excessive daytime somnolence or tiredness and has no self-perceived issues with his own sleep.

History & Diagnosis of Present Illness:

Patient 2 does not report any significant history of sleep issues and/or snoring concerns. He was in the process of getting approval for an insurance claim and advises this prompted the process of having his sleep investigated due to the presence of loud snoring and witnessed apnoeas by his partner. He denies any excessive daytime somnolence or tiredness symptoms and has no self-perceived troubles with his sleep patterns, quality or quantity. The Type 1 in-lab diagnostic sleep study performed on 21/07/2022 showed overall moderate OSA with an overall RDI of 22.3 and minimum oxygen desaturation of 90%. There appeared to be a significant positional element with the supine RDI being 59.9 and non-supine RDI being 15.6. There was also a REM predominance with REM sleep RDI being 45.6 and NREM sleep RDI being 19.0. The vast majority of sleep-disordered breathing events were hypopnoeas (118 hypopnoeas, 7 obstructive apnoeas, 1 central apnoea). Epworth Sleepiness Scale recorded at this sleep study was 6/24 and BMI was 23.4. After the sleep study, Patient 2 had a follow-up consultation with the respiratory & sleep physician for discussion. He was referred for MAS therapy as a frontline treatment option and the patient was not willing to consider CPAP therapy as a treatment option at this current time.

Past Medical History:

Patient 2 weighs 84kg at the time of consultation and with a height of 192cm gave him a BMI of 22.8 which was only very slightly reduced to when he performed his sleep study. He is a non-smoker and drinks alcohol approximately 3-4 nights a week. He does not take any prescription medications and does not reportedly use recreational drugs. He does report seasonal hayfever/allergic rhinitis type symptoms and a history of mental illness, depression and anxiety but manages these conservatively. He had his palatine tonsils removed at age 10 and had childhood asthma which has since dissipated.

Clinical Examination:

Patient 2 has had all 4 wisdom teeth removed surgically under GA when he was about 21 years old. He has a Class 3 skeletal appearance due to what appears to be maxillary retrognathia and maybe some mandibular prognathism. His maxillary and mandibular dental arches are narrowed with the appearance of a transverse deficiency and a high arched palatal vault. There is mild attrition wear of the teeth with the anteriors most notable. There are no restorations present and all teeth are sound. He regularly has these examined and cleaned by his own general dentist. Mallampati Score was class 2 and Friedman Tonsils grade 0. The tongue appears to be enlarged with some lateral border scalloping notable. The uvula and soft palate are within normal limits in size and shape. TMJ examination did not reveal any concerning issues with normal jaw range of motion (jaw opening 46mm inter-incisally), absence of joint noises and pain, and no deviation or deflection from midline. The masticatory muscles were absent of any mobility or pain issues. There was no self-reported issues with nasal breathing or patency.

Treatment Plan:

Patient 2 had no contraindications to proceed with oral appliance therapy based on the examination results. A SomnoDent Avant MAS design was chosen due to comfort, ease of use and titration, and patient's preference with appliance design. He was able to understand the titration mechanism with changing bands in 1mm steps forwards and was also happy with the notion that the band would provide resistance to jaw opening during sleep. The acrylic material would allow ease of adjustment in future should he have any further restorative work however there was no such work planned at the current time. George Gauge bite registration was taken at approximately 60% maximum protrusion (maximally retruded -4mm, maximally protruded +6mm, registration taken at +2mm). There was an approximate 1-2mm midline shift to the left in the bite position noted which was corrected by the lab prior to splint construction.

Results:

This SomnoMed Avant appliance was fitted on 07/09/2022 with excellent retention, balance of occlusal contacts, ability of patient to insert & remove the device, and provision of titration instructions. The titration instructions were to change up from band 0 up to a minimum of band 2 prior to having the sleep study or further if required to subjectively control his symptoms and snoring levels adequately. This was to be done in 1mm adjustments performed approximately once per 5-7 days. The patient ended up titrating to band 6 (close to 100% maximum protrusion) prior to performing the repeat sleep study. This derived the best results in terms of snoring reductions and resolution of witnessed apnoeas although there was some snoring noted by his partner.

The MAS efficacy Type 1 in-lab sleep study was performed on 21/02/2023 to assess it objectively. The repeat sleep study showed overall mild OSA with the MAS in-situ with an overall RDI of 14.5. There was a supine RDI of 15.8 and REM RDI of 16.6. Lowest oxygen desaturation was 92%. ESS recorded at this sleep study was 6/24 and BMI was 22.8. He had a follow-up consultation with the sleep physician whereby MAS therapy was deemed suitable to use as a long-term OSA treatment option considering the results of the sleep study however he was asked to trial further protrusion/titration if possible. There were no further scheduled visits with the sleep physician and the patient was discharged.

Follow-up appointments:

27/09/2022:

Patient 2 returned for his 3 week review post-fitting of the SomnoMed Avant MAS. He has been using the device every night without any significant side effects or issues noted and for his full sleep duration. His partner has noticed reducing apnoea events and that snoring had reduced however it was still present. He is currently at band 2 (2mm advanced and approximately 70% maximum protrusion) out of a maximum of 8 bands and wishes to continue further titration to see whether his snoring and witnessed apnoeas can reduce further. The MAS is in excellent condition with no evidence of cracks or stress fractures. There have been no changes evident of teeth movement or bite changes with full arch occlusion noted on occluding in maximal intercuspation position (MIP). There are no TMJ concerns on examination with no dysfunctional signs or tenderness to palpation of the joints or masticatory muscles. There appears to be a slight increase his maximum protrusion with the patient able to protrude a further 1mm compared to his initial George Gauge measurements.

Recommendations at this appointment were to trial increasing the titration of the MAS considering the continuing snoring and witnessed apnoea events. Patient was asked to return in 4 weeks to review his progress with titration and reassess subjective markers.

28/10/2022:

Patient 2 returned as requested at the 4 week mark to re-assess his progress with MAS therapy and titration. He has now increased to band 6 (close to 100% maximum protrusion) which he feels has reduced his snoring a lot and completely eliminated any witnessed apnoeas. There is still some presence of snoring levels. He has had some mild jaw discomfort and pain since going up to these higher advancement levels but finds these are minor, dissipate within an hour after removal of the device and are becoming less frequent. There has been no evident teeth movement or bite changes similarly to last appointment. His TMJs did not show any concerns with good jaw opening range, mobility, and absence of joint noises or pain. There is mild tenderness to palpation of the masseter and temporalis muscles bilaterally but no other muscles with identified pain.

Recommendations at this point are to consider reduction of alcohol intake and also trial positional therapy in combination with MAS therapy to see whether absence of supine sleep may help reduce the remaining snoring levels. Patient scheduled for MAS efficacy PSG sleep study and so will also await these results to see what further interventions may be suggested by the respiratory & sleep physician. Patient put on a 6-month recall list for review and to contact earlier should any further assistance be needed prior to this appointment date.

12/04/2023:

Patient 2 returned for 6 month review of his progress with the SomnoMed Avant MAS. He has been continuing to use it every night without any troubles or side effects. The MAS efficacy sleep study was delayed due to patient becoming ill and then having the Christmas holiday period. He performed the sleep study on 21/02/2023 and had a review with the sleep physician to discuss the results. Considering the remaining mild OSA which no longer appears to have any positional predominance, patient was asked by the sleep physician to trial further MAS titration if able to and other lifestyle measures such as alcohol abstinence. He has therefore adjusted up to band 7 (7mm advanced from initial position) and has found this has reduced the snoring even further which his partner is happy with. He did attempt to trial band 8 but found it too uncomfortable and painful for his jaws to cope with.

His weight has continued to be stable and no other medical issues have arisen. There have been no changes in medication status. The MAS is in excellent condition with no evidence of cracks or stress fractures. There is no evidence of teeth movement or bite changes with full arch occlusion noted in MIP. The TMJs had no issues noted on examination with no pain to palpation of them or the muscles of mastication. Jaw opening and excursive movements were not limited and there was no midline deviation or deflection. On awakening, the patient feels his jaw and bite alignment is incorrect but resolves within an hour and with doing gentle jaw exercises along with the morning repositioner appliance. He does appear to have a further 2mm of protrusive range which correlates with the ability to titrate further than his initial George Gauge measurements and being close to 100% of his maximum protrusion with the MAS.

Considering his MAS is effectively fully titrated and he and his partner are happy with the subjective results, besides the lifestyle measures mentioned, no further changes are required to his case management. Informed patient that should his snoring and symptoms worsen, then he should consult with his sleep physician and other alternative treatment options may need to be considered such as CPAP therapy, combination therapy or ENT surgeon assessment. Patient 2 placed on a 6 month recall for review.

Diagnostic sleep study Page 1:

NORTH BRISBANE
SLEEP AND THORACIC

CLAYFIELD IN LAB DIAGNOSTIC

Patient Name:		**D.O.B:**	14/11/1986 (35 years)
Patient ID:	14916	**Study Date:**	21/07/2022
Sex:	Male	**Referring Doctor:**	
Height:	192.0 cm	**Weight:**	86.4 kgs
B.M.I:	23.4 kg/m2	**Waist Circumference**:	97cm

Indication for study: Snoring, witnessed apneoas
Epworth sleepiness score at referral: 6/24 (normal)
Relevant co-morbidities: Hay fever, tonsillectomy as a child
Blood Pressure: 121/89mmHg (Pre-study), 115/73mmHg (post study)
Alcohol intake: 10 per week
Medications: Restavit
Technical comments: Erroneous body position throughout – manually corrected during analysis.

Polysomnography Summary:
Sleep architecture: exhibited disrupted sleep architecture with decreased proportions of REM sleep (10.5%TST). There was a normal sleep efficiency measuring 83% and a normal sleep latency of 15.1 mins. REM latency was normal at 120 minutes. There was one brief period of REM sleep whilst supine recorded. Total arousals were 23.0/hr of which, spontaneous arousals were normal at 3.0/hr. Upon termination of the study, indicated that his sleep quality was slightly worse than usual.

Body Position: Supine- 51.1mins (15.07%), Non-supine: 287.90mins (84.93%)

Respiratory: **Total AHI = 22.3/hr**

	NREM sleep			REM sleep			All sleep		
	Supine	Nonsupine	Total	Supine	Nonsupine	Total	Supine	Nonsupine	Total
AHI /hr	58.1	11.72	19.0	50.0	45.14	45.6	59.9	15.63	22.3

Runs of respiratory events were recroded in REM and NREM sleep, increasing in frequency in supine and REM sleep. Respiratory events caused frequent cortical arousals (17.7/hr). There were 118 hypopnoeas and 8 apnoeas of which 7 were obstructive and 1 was central in nature. There was frequent inspiratory snoring of variable intensity, observed for approximately 62.8% of sleep time. The oxygen saturation was beneath 90 % for 0.0 minutes. Mean SpO2 was 95.10% and nadir SpO2 was 90% during TST. TIB SpO2 <89% was 0.0mins.
Cheyne-Stokes Respiration (CSR): None observed during study.
Periodic Leg Movements of Sleep: Total PLMI = 9.2/hr. Periodic Limb Movement Arousals = 0.0/hr.
ECG: Normal sinus rhythm. No sustained arrhythmias during sleep. Baseline HR was 63.2 bpm, maximal sleep HR 102 bpm

- Polysomnographer **- Sleep Scientist**

Conclusions:
1. There was evidence of moderate obstructive sleep apnoea, stable peripheral oxygen saturation and variable snoring.
2. There were no limb movement arousals.
3. The sleep architecture was disrupted, REM sleep was underrepresented.

Recommendations:
1. The patient is booked for follow up, please await my letter.

Thank you for referring this patient for testing,

Thoracic and Sleep Physician, MBBS, FRACP

Diagnostic Sleep Study Page 2

SLEEP ARCHITECTURE

Patient preparation clock time:	8PM	**Recording start clock time:**	10:04:23 PM
Patient set up clock time:	9:15PM	**Recording complete clock time:**	5:13:17 AM
Lights out clock time:	10:12:47 PM	**Sleep Efficiency:**	83.3 %
Lights on clock time:	4:59:53 AM	**Sleep Onset:**	15.1 minutes
Total Recording Time (TRT):	428.9 minutes	**WASO:**	53.0 minutes
Time In Bed (TIB):	407.1 minutes	**REM Latency (from Sleep Onset):**	120.0 minutes
Total Sleep Time (TST):	339.0 minutes	**REM Latency (from Lights Off):**	135.1 minutes

Sleep Staging	Duration	% TST	Latency (from Lights Off)	
N 1:	37.0 minutes	10.9 %	**N 1:**	15.1 minutes
N 2:	197.0 minutes	58.1 %	**N 2:**	17.6 minutes
N 3:	69.5 minutes	20.5 %	**N 3:**	27.6 minutes
REM:	35.5 minutes	10.5 %	**REM:**	135.1 minutes

Body Position	Duration	%TST
Supine:	51.1 minutes	15.07%
Non-Supine:	287.90 minutes	84.93%

RESPIRATORY DATA

Type of Event	Num	Index	Mean [sec]	NREM Supine Index	NREM NS Index	NREM Index	REM Supine Index	REM NS Index	REM Index	Supine index	Non-Supine Index
Apnoeas (OA+CA+MA)	8	1.4	14.7	8.8	0.23	1.6	0.0	0.00	0.0	8.2	0.21
Obstructive	7	1.2	13.4	8.8	0.00	1.4	0.0	0.00	0.0	8.2	0.00
Central	1	0.2	23.5	0.0	0.23	0.2	0.0	0.00	0.0	0.0	0.21
Mixed	0	0.0	0.0	0.0	0.00	0.0	0.0	0.00	0.0	0.0	0.00
Hypopnoea	118	20.9	23.3	49.3	11.48	17.4	50.0	45.14	45.6	51.7	15.42
RERAS	0	0.0	0.0	0.0	0.00	0.0	0.0	0.00	0.0	0.0	0.00
TOTAL AHI (apneas + hypopneas)	**126**	**22.3**	**22.8**	**58.1**	**11.72**	**19.0**	**50.0**	**45.14**	**45.6**	**59.9**	**15.63**
TOTAL RDI (apneas + hypopneas+ RERAs)	**126**	**22.3**	**22.8**	**58.1**	**11.72**	**19.0**	**50.0**	**45.14**	**45.6**	**59.9**	**15.63**

*Above Index Values Based on Total Sleep Time

Respiratory Event Index Summary (Total sleep time)

	NREM sleep			REM sleep			All sleep		
	supine	Non supine	Total	Supine	Non supine	Total	Supine	Non supine	Total
AHI /hr	***58.1***	***11.72***	***19.0***	***50.0***	***45.14***	***45.6***	***59.9***	***15.63***	**22.3**

Cheyne Stokes Respiration Summary

	REM	NREM	TIB
Total Duration (minutes)	0.00	0.00	0.00
Total Duration (% TST)	0.00	0.00	0.00

AROUSALS

	REM	NREM	Arousals	Awakenings	Ar + Aw	Ar + Aw Index
Respiratory:	23	69	100	0	100	17.7
Leg Movement:	0	2	2	0	2	0.4
Snore:	0	6	11	0	11	1.9
Spontaneous:	1	5	17	0	17	3.0
Total:	24	82	130	0	130	23.0
Arousal Index:	40.6	16.2	23.0	0.0	23.0	--

Patient Name: **- DOB: 14/11/1986. STUDY DATE- 21/07/2022**

OXYGEN SATURATION

	WAKE	NREM	REM	TST
Mean SpO2%:	95	95	96	95.10
Minimum SpO2%:	-	-	-	90
<89% (min):	0.0	0.0	0.0	0.00

	WAKE		NREM		REM		TIB	
	Time		Time		Time		Time	
	Min	%	Min	%	Min	%	Min	%
<95%:	12.0	2.9	161.7	39.7	5.1	1.3	178.8	43.9
<90%:	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<85%:	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<80%:	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<75%;	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<70%:	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<60%:	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
< 50%:	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

	minutes	Percentage
TIB SpO2 <89%	0.0mins	0.0%

Relative Desaturation

	W	R	NR	TOTAL
Average (%)	95	96	95	95
Number of desaturations	3	10	65	78
Desat Index ≥3%(#/hour)	2.7	17.0	12.9	**13.8**

LIMB MOVEMENTS

	Count	Index (#/h)
Total Leg Movement:	56	9.9
PLMS:	52	9.2
PLMS Arousals:	0	-

CARDIAC SUMMARY (BASED ON PULSE RATE CHANNEL)

Average Heart Rate During Sleep:	63.2 bpm
Highest Heart Rate During Sleep:	102 bpm
Highest Heart Rate During Recording (TIB):	121 bpm
Lowest Pulse Rate During Sleep (TST)	49 bpm
Lowest Pulse Rate (TIB)	49 bpm

POLYSOMNOGRAPHY RECORDING PARAMETERS AND ANALYSIS CRITERIA SUMMARY

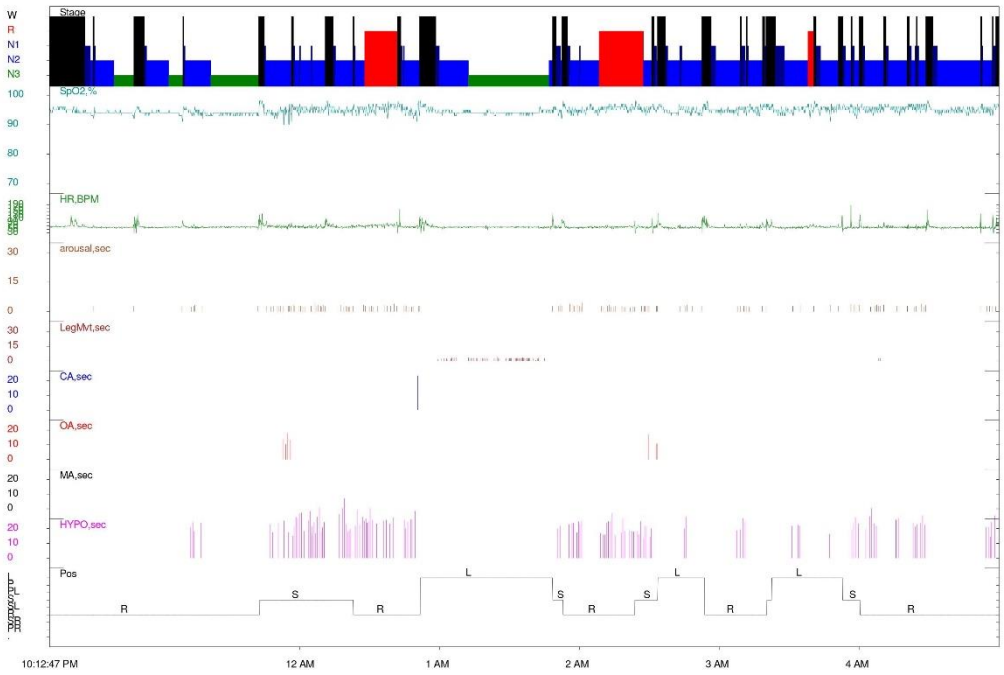
Philips Respironics Alice 6- EEG (F4-M1, C4-M1, C3-M2, O2-M1), EOG (ROC-M1, LOC-M2), EMG (Submental/Mental), ECG (Modified Lead II, Lead I, and Lead III), Saturation Pulse Oximetry, Respiratory Inductance Plethysmography(Thoracic, Abdominal and SUM), Nasal Pressure Transducer, Oral-Nasal Thermistor, Limb EMG (Anterior Tibialis Pair), Body Position, Pulse Rate and Plethysmography, Synchronised audio visual monitoring,

ANALYSIS CRITERIA

As per; The American Academy of Sleep Medicine manual for the scoring of sleep and associated events 2012 Version 2.0.2 – Hypopnoea Criteria 1A.

Diagnostic Sleep Study Page 4

All Night Hypnogram



NORTH BRISBANE SLEEP AND THORACIC: North Lakes | Clayfield | | **P**: 1300 391 820 **F**: 07 3036 6094 | **E**:reception@nbst.com.au

NORTH BRISBANE SLEEP AND THORACIC

CLAYFIELD IN LAB DIAGNOSTIC WITH M.A.S

Patient Name:		**D.O.B:**	14/11/1986 (36 years)
Patient ID:	14916	**Study Date:**	21/02/2023
Sex:	M	**Referring Doctor:**	
Height:	191.5 cm	**Weight:**	83.5 kgs
B.M.I:	22.8 kg/m2	**Waist Circumference:**	86.0 cm

Indication for study: Previous moderate OSA, severe in REM sleep (DxSS NBST July 2022). Subsequently had a MAS device fashioned by Dr Adam Teo. ?efficacy in controlling moderate OSA.
Epworth sleepiness score at referral: 6/24 (normal)
Relevant co-morbidities: Hayfever, tonsillectomy, ADHD/anxiety
Blood Pressure: 130/80 mmHg (Pre-study), 10/63 mmHg (post-study)
Alcohol intake: 3 standard drinks, 4 nights / week
Medications: Nil
Technical comments: Some manual body position corrections were required due to erroneous body position readings. Some artifacts on the naso-oral thermocouple.

Polysomnography Summary:

Sleep architecture: exhibited a disrupted sleep architecture in the first half of the recording with reduced proportions of REM sleep. There was a reduced sleep efficiency measuring 63.3% and a normal sleep latency of 21.8 minutes. REM latency was increased at 241.0 minutes. There were two periods of REM sleep recorded whilst supine. Total arousals were 31.9/hr of which, spontaneous arousals were increased at 14.9/hr.

Body Position: Supine: 148.0mins (47.67%), Non-supine: 162.50mins (52.33%)

Respiratory: **Total AHI = 14.5/hr**

	NREM sleep			REM sleep			All sleep		
	Supine	Non-supine	Total	Supine	Non-supine	Total	Supine	Non-supine	Total
AHI /hr	12.2	14.1	13.2	30.0	7.9	16.6	14.6	14.4	14.5

The study was performed with the patient's Mandibular Advancement dental Splint (MAS) in-situ throughout. Runs of obstructive hypopnoeas and occasional RERA events and apnoeas persisted during both NREM and REM sleep and caused cortical arousals (12.2/hr). There were 7 apnoeas of which 2 were obstructive and 5 were central in nature. There was occasional inspiratory snoring of soft intensity, observed for approximately 7.7% of sleep time. The oxygen saturation was beneath 90% for 0.0 minutes. Mean SpO_2 was 95% and nadir SpO_2 was 92% during TST. TIB SpO_2 <89% was 0.0mins.
Cheyne-Stokes Respiration (CSR): None observed during study.
Periodic Leg Movements of Sleep: None observed during study.
ECG: Normal sinus rhythm. No sustained arrhythmias during sleep. Baseline HR was 55.8 bpm, maximal sleep HR 91 bpm

- Polysomnographer **- Sleep Scientist**

Conclusions:

1. The patient was wearing a mandibular advancement splint.
2. There was evidence of mild obstructive sleep apnoea, occasional snoring, and stable peripheral oxygen saturation on room air.
3. There were no limb movement arousals .
4. The sleep architecture was disrupted; REM sleep was underrepresented.

Recommendations:

1. The patient is booked for follow-up; please await my letter.

Thank you for referring this patient for testing,

Thoracic and Sleep Physician, MBBS, FRACP

Patient Name: **- DOB: 14/11/1986. STUDY DATE- 21/02/2023**

SLEEP ARCHITECTURE

Patient preparation clock time:	8:00 PM	**Recording start clock time:**	9:04:00 PM
Patient set up clock time:	8:30 PM	**Recording complete clock time:**	5:35:06 AM
Lights out clock time:	9:08:42 PM	**Sleep Efficiency:**	63.3 %
Lights on clock time:	5:18:54 AM	**Sleep Onset:**	21.8 minutes
Total Recording Time (TRT):	511.1 minutes	**WASO:**	157.9 minutes
Time In Bed (TIB):	490.2 minutes	**REM Latency (from Sleep Onset):**	241.0 minutes
Total Sleep Time (TST):	310.5 minutes	**REM Latency (from Lights Off):**	262.8 minutes

Sleep Staging	Duration	% TST	Latency (from Lights Off)	
N 1:	17.0 minutes	5.5 %	**N 1:**	21.8 minutes
N 2:	180.5 minutes	58.1 %	**N 2:**	22.3 minutes
N 3:	62.5 minutes	20.1 %	**N 3:**	168.3 minutes
REM:	50.5 minutes	16.3 %	**REM:**	262.8 minutes

Body Position	Duration	%TST
Supine:	148.0 minutes	47.67%
Non-Supine:	162.50 minutes	52.33%

RESPIRATORY DATA

Type of Event	Num	Index	Mean [sec]	NREM Supine Index	NREM NS Index	NREM Index	REM Supine Index	REM NS Index	REM Index	Supine index	Non-Supine Index
Apnoeas (OA+CA+MA)	7	1.4	15.1	1.9	0.91	1.4	0.0	1.97	1.2	1.6	1.11
Obstructive	2	0.4	19.8	0.5	0.45	0.5	0.0	0.00	0.0	0.4	0.37
Central	5	1.0	13.2	1.4	0.45	0.9	0.0	1.97	1.2	1.2	0.74
Mixed	0	0.0	0.0	0.0	0.00	0.0	0.0	0.00	0.0	0.0	0.00
Hypopnoea	68	13.1	21.8	10.3	13.18	11.8	30.0	5.90	15.4	13.0	13.29
RERAS	15	2.9	13.2	1.4	5.45	3.5	0.0	0.00	0.0	1.2	4.43
TOTAL AHI (apneas + hypopneas)	**75**	**14.5**	**21.2**	**12.2**	**14.09**	**13.2**	**30.0**	**7.87**	**16.6**	**14.6**	**14.40**
TOTAL RDI (apneas + hypopneas+ RERAs)	**90**	**17.4**	**19.9**	**13.6**	**19.55**	**16.6**	**30.0**	**7.87**	**16.6**	**15.8**	**18.83**

*Above Index Values Based on Total Sleep Time

Respiratory Event Index Summary (Total sleep time)

	NREM sleep			REM sleep			All sleep		
	supine	**Non supine**	**Total**	**Supine**	**Non supine**	**Total**	**Supine**	**Non supine**	**Total**
AHI /hr	***12.2***	***14.09***	***13.2***	***30.0***	***7.87***	***16.6***	***14.6***	***14.40***	**14.5**

Cheyne Stokes Respiration Summary

	REM	NREM	TIB
Total Duration (minutes)	0.00	0.00	0.00
Total Duration (% TST)	0.00	0.00	0.00

AROUSALS

	REM	NREM	Arousals	Awakenings	Ar + Aw	Ar + Aw Index
Respiratory:	9	52	74	4	78	15.1
Leg Movement:	0	0	0	0	0	0.0
Snore:	0	6	6	1	7	1.4
Spontaneous:	12	60	77	3	80	15.5
Total:	21	118	157	8	165	31.9
Arousal Index:	25.0	27.2	30.3	1.5	31.9	--

Patient Name: **- DOB: 14/11/1986. STUDY DATE- 21/02/2023**

OXYGEN SATURATION

	WAKE	NREM	REM	TST
Mean SpO2%:	96	95	96	95.16
Minimum SpO2%:	-	-	-	92
<89% (min):	0.0	0.0	0.0	0.00

	WAKE		NREM		REM		TIB	
	Time		Time		Time		Time	
	Min	%	Min	%	Min	%	Min	%
<95%:	6.0	1.2	29.2	6.0	2.1	0.4	37.3	7.6
<90%:	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<85%:	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<80%:	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<75%;	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<70%:	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<60%:	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
< 50%:	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

	minutes	Percentage
TIB SpO2 <89%	0.0mins	0.0%

Relative Desaturation

	W	R	NR	TOTAL
Average (%)	96	96	95	96
Number of desaturations	0	8	27	35
Desat Index ≥3%(#/hour)	0.0	9.5	6.2	**6.8**

LIMB MOVEMENTS

	Count	Index (#/h)
Total Leg Movement:	0	0.0
PLMS:	0	0
PLMS Arousals:	0	-

CARDIAC SUMMARY (BASED ON PULSE RATE CHANNEL)

Average Heart Rate During Sleep:	55.8 bpm
Highest Heart Rate During Sleep:	91 bpm
Highest Heart Rate During Recording (TIB):	104 bpm
Lowest Pulse Rate During Sleep (TST)	43 bpm
Lowest Pulse Rate (TIB)	43 bpm

POLYSOMNOGRAPHY RECORDING PARAMETERS AND ANALYSIS CRITERIA SUMMARY

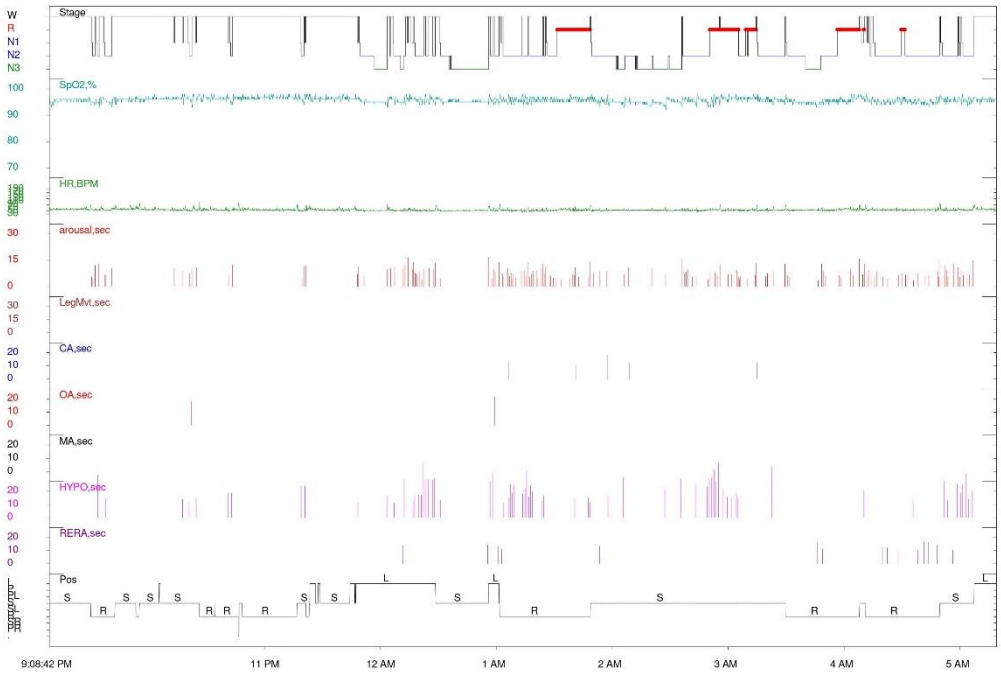
Philips Respironics Alice 6- EEG (F4-M1, C4-M1, C3-M2, O2-M1), EOG (ROC-M1, LOC-M2), EMG (Submental/Mental), ECG (Modified Lead II, Lead I, and Lead III), Saturation Pulse Oximetry, Respiratory Inductance Plethysmography(Thoracic, Abdominal and SUM), Nasal Pressure Transducer, Oral-Nasal Thermistor, Limb EMG (Anterior Tibialis Pair), Body Position, Pulse Rate and Plethysmography, Synchronised audio visual monitoring,

ANALYSIS CRITERIA

As per; The American Academy of Sleep Medicine manual for the scoring of sleep and associated events 2012 Version 2.0.2 – Hypopnoea Criteria 1A.

MAS Efficacy Sleep Study Page 4

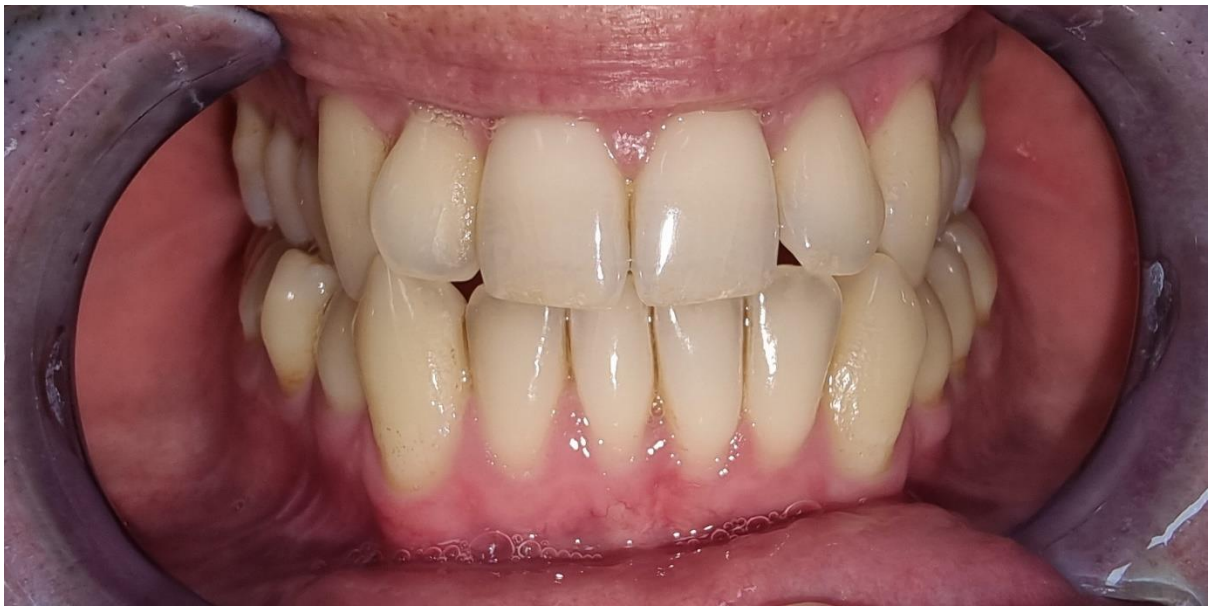
All Night Hypnogram



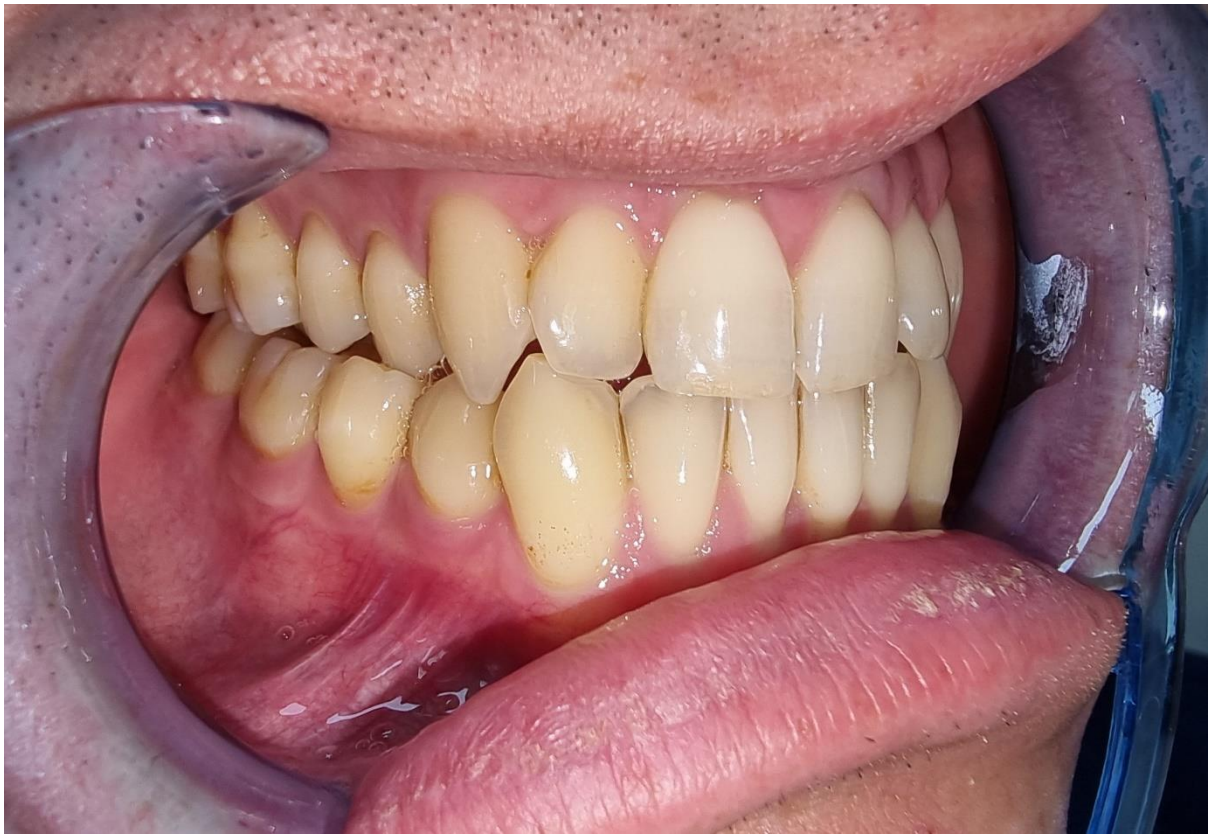
In-Laboratory Diagnostic- North Brisbane Sleep and Thoracic- Clayfield

NORTH BRISBANE SLEEP AND THORACIC: North Lakes | Clayfield | | **P**: 1300 391 820 **F**: 07 3036 6094 | **E**:reception@nbst.com.au

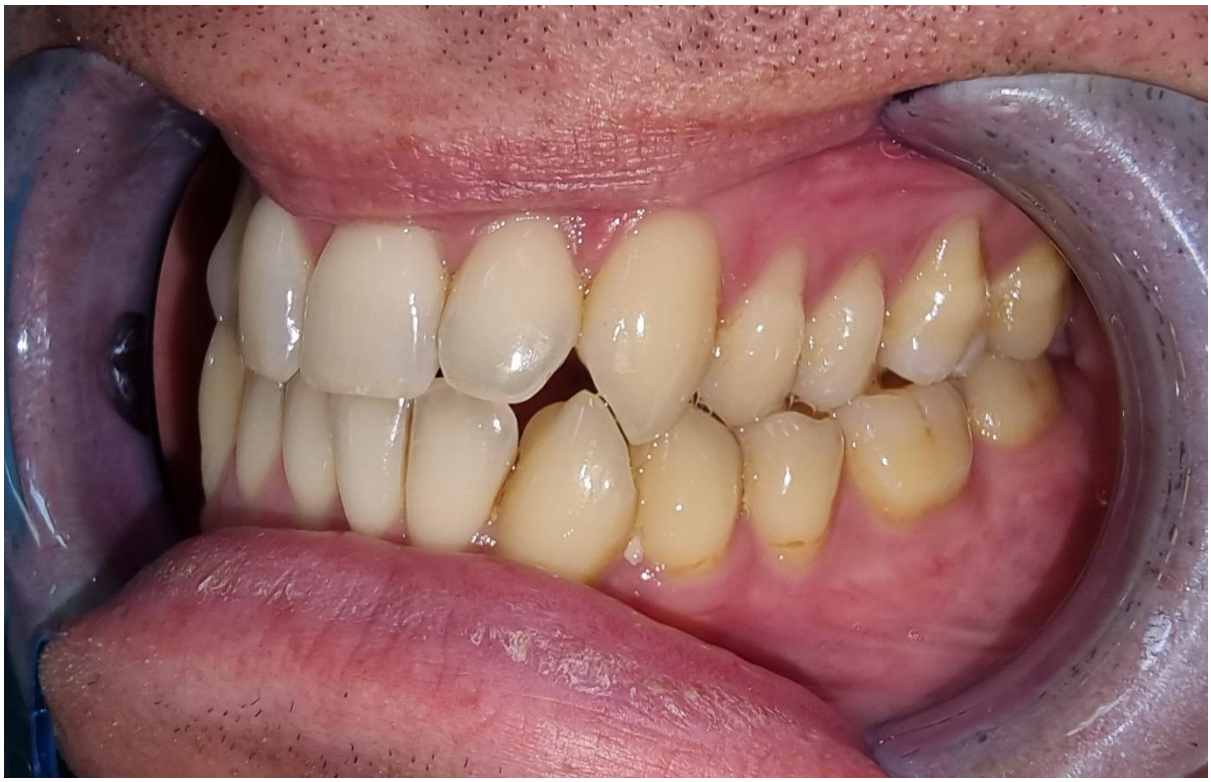
Anterior View in Occlusion:



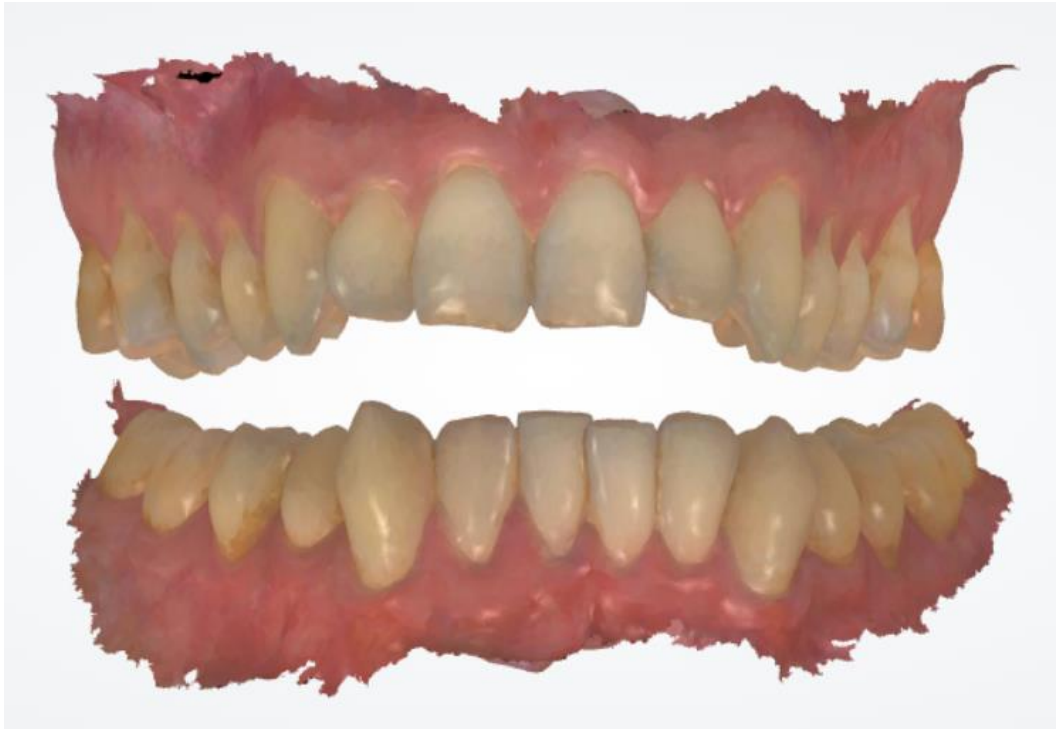
Right lateral view in occlusion:



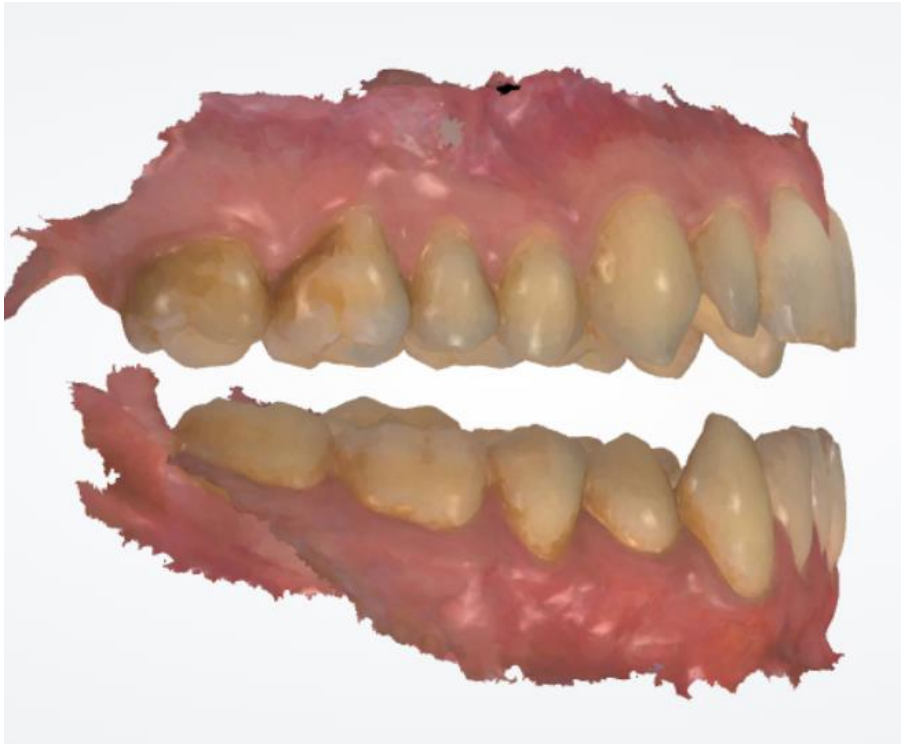
Left lateral view in occlusion:



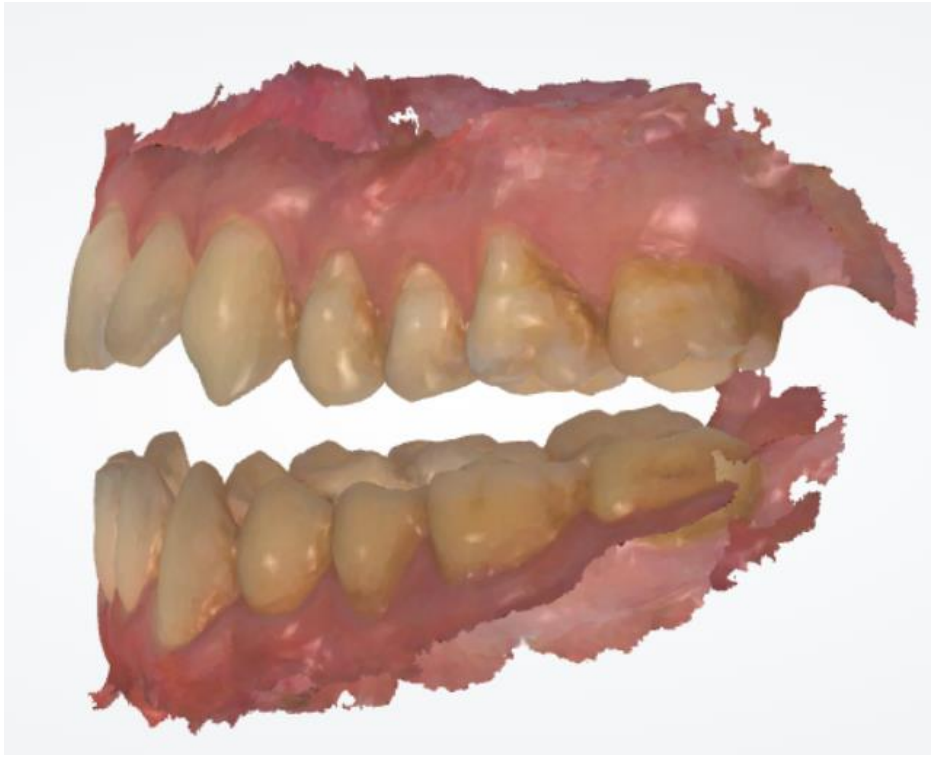
Anterior view intra-oral scans in bite position:



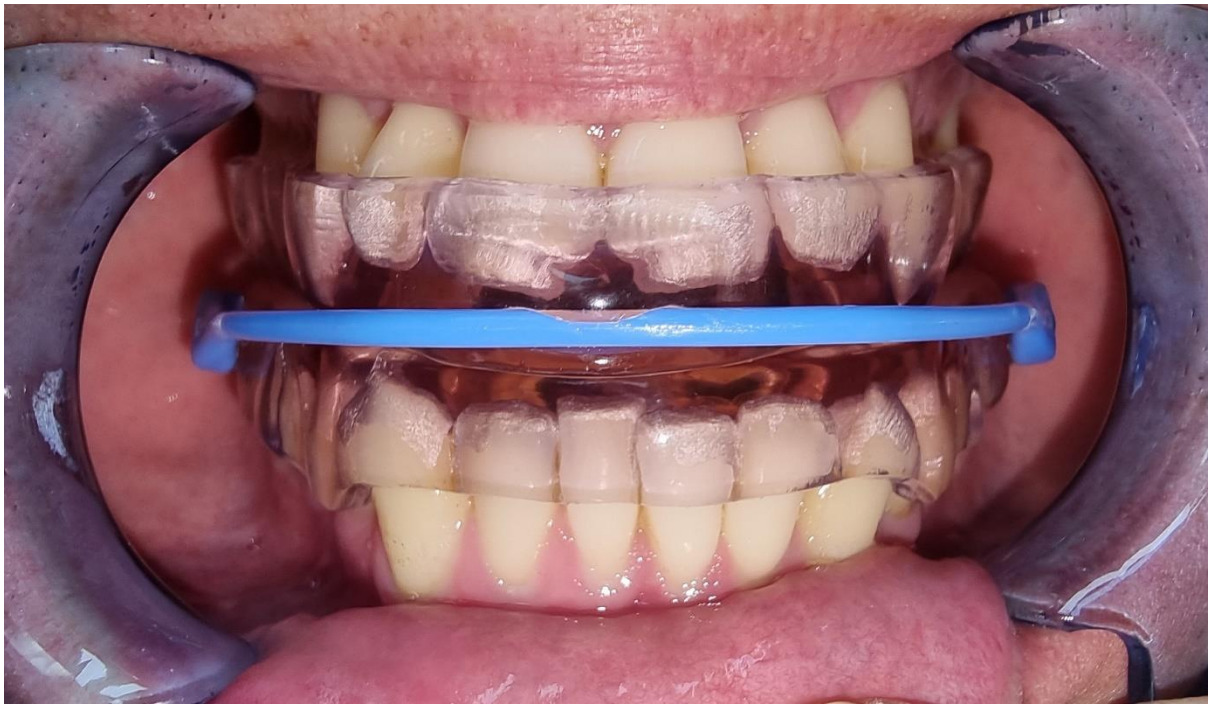
Right lateral view of intra-oral scans in bite position:



Left lateral view of intra-oral scans in bite position:



Anterior view with MAS in-situ:



Patient 3

Introduction:

Patient 3 was a 59 year-old Caucasian female (DOB: 12/02/1960) at the time of presentation with her main concerns revolving around loud disruptive snoring to her husband which was disrupting his sleep. She was referred to a respiratory & sleep physician from her GP for investigation and had a Type 2 ambulatory sleep study completed at home. The results of this sleep study was discussed with the patient and she was concluded to have moderate obstructive sleep apnoea (OSA). After discussion of the results with the respiratory & sleep physician and consideration of treatment options, she was referred for MAS therapy as a frontline treatment option her preferred option. She presented for her first consultation on 05/11/2019.

Chief Complaint:

Patient 3's chief complaint was around her loud snoring being disruptive for her husband's sleep. She denied any significant symptoms of excessive daytime somnolence or tiredness and had no self-perceived issues with her own sleep besides her husband waking her throughout her sleep if she was snoring loudly.

History & Diagnosis of Present Illness:

Patient 3 reports that her snoring has become more loud and disruptive to her husband in recent times however it had always been present to a degree. This prompted a consultation with her GP who screened her and found a moderate-high pre-test probability of obstructive sleep apnoea and so was referred to a respiratory & sleep physician for further assessment. She had also been referred and had a consultation with an ENT surgeon as she was aware of mouth breathing however it was concluded that no surgical interventions was needed nor significant nasal obstruction noted. She does not note any symptoms of excessive daytime somnolence or tiredness and was working without any significant stress as a registered nurse at a nearby hospital.

The Type 2 ambulatory diagnostic sleep study performed on 09/10/2019 showed overall moderate OSA with an overall RDI of 17.3 and minimum oxygen desaturation of 89%. There was no supine sleep recorded on this night and it was reported that the severity of OSA may be under-estimated due to this finding. There was a REM predominance with REM sleep RDI being 35 and NREM sleep RDI being 14.4. The vast majority of sleep-disordered breathing events were hypopnoeas (74 hypopnoeas, 5 obstructive apnoeas, 1 central apnoea, 1 mixed apnoea, and 24 respiratory effort related arousals - RERAs). Epworth Sleepiness Scale recorded at this sleep study was 2/24 and BMI was 27.2. After the sleep study, Patient 3 had a follow-up consultation with the respiratory & sleep physician for discussion. She was referred for MAS therapy as a frontline treatment option and was preferable over a CPAP therapy trial.

Past Medical History:

Patient 3 weighed 57kg at the time of consultation and with a height of 146cm gave her a BMI of 26.7 which was only slightly reduced to when she performed her sleep study. She is a non-smoker and rarely drinks alcohol. She does not take any prescription medications besides having an annual infusion of Aclasta (zoledronic acid) for osteoporosis management. She has coeliac disease and avoids gluten in the diet. She does feel her nasal airway obstructs however manages this with anti-histamine medications and/or intra-nasal sprays.

Clinical Examination:

Patient 3 has had 3 wisdom teeth (18, 28, 38) removed when she was in her early 20s. She appears to have a retrognathic maxilla & prognathic mandible with a Class 3 malocclusion. Her maxillary and mandibular dental arches are narrowed with the appearance of a transverse deficiency and a high arched palatal vault. There is very mild attrition wear of the teeth with the anteriors most notable. There is canine guidance on lateral excursions. There are no restorations present and all teeth are sound. She regularly has examinations and cleans with her general dentist. Mallampati Score was class 3. The tongue appears to be of a normal size but appears large due to the small oral cavity space. The uvula and palatine tonsils were of a normal size. TMJ examination did not reveal any concerning issues with normal jaw range of motion (jaw opening 42mm inter-incisally) and absence of joint noises and pain. There was noted deflection to the left on mandibular protrusion with no restriction. The masticatory muscles were absent of any mobility or pain issues.

Treatment Plan:

Patient 3 had no contraindications to proceed with oral appliance therapy based on the examination results. A 3DS Advance Nylon Dorsal MAS design was chosen due to comfort, ease of use and titration, patient's preference with appliance design, and increased comfort for probable mouth breathing with the dorsal design allowing freedom of movement. She was able to understand the titration mechanism with changing the clips in 1mm steps forwards. George Gauge bite registration was taken at approximately 55% maximum protrusion (maximally retruded -7mm, maximally protruded +5mm, registration taken at 0mm).

Results:

This 3DS Advance Nylon Dorsal MAS appliance was fitted on 03/12/2019 with excellent retention, balance of occlusal contacts, ability of patient to insert & remove the device, and provision of titration instructions. The upper plate had slightly suboptimal retention on the initial fitting however this was rectified by tightening the plate with heat due to its slight thermoplastic nature. The titration instructions were given to change up from clip 0 in the 1mm steps as required to subjectively control the snoring levels adequately for her husband. This was to be done in 1mm adjustments performed approximately once per 5-7 days. The patient ended up titrating to clip 2 (approximately 75% maximum protrusion) prior to performing the repeat sleep study. This reportedly completely controlled her snoring levels as reported by her husband.

The MAS efficacy Type 1 in-lab sleep study was performed on 30/03/2020 to assess the MAS objectively. The repeat sleep study showed the OSA was well controlled with the MAS in-situ with an overall RDI of 4.5. There was again no supine sleep recorded. Lowest oxygen desaturation was 92%. ESS recorded at this sleep study was 2/24 and BMI was 27.2. Patient 3 had a follow-up consultation with the sleep physician whereby MAS therapy was deemed suitable to use as a long-term OSA treatment option considering the results of the sleep study. There were no further scheduled visits with the sleep physician and the patient was discharged.

Follow-up appointments:

28/01/2020:

Patient 3 returned for a post-fitting review of the 3DS Advance Nylon Dorsal MAS. She has been using it every night and has not yet titrated the device at this stage. Snoring levels have significantly reduced as per her husband's reports however have not completely resolved. The upper part of the MAS has become loose again and can occasionally fall off her teeth during her sleep. There are no TMJ, muscle or teeth symptoms or side effects noted. Patient 3 has noticed hypersalivation as a side effect which has stayed pretty consistent since the initial fitting appointment but perseveres with using it.

MAS is in excellent condition with no evidence of cracks or stress fractures. There have been no changes evident of teeth movement or bite changes with full arch occlusion noted on occluding in maximal intercuspation position (MIP). There are no TMJ concerns on examination with no dysfunctional signs or tenderness to palpation of the joints or masticatory muscles. The upper part of the MAS was tightened again with heat to improve the retention further than last appointment. Patient 3 was happy with the end result with excellent retention with both the upper and lower parts.

Recommendations at this appointment were to trial increasing the titration of the MAS considering the continuing snoring. The clip was increased to 1mm advanced (65% maximum protrusion approximately). Patient advises that sleep study is scheduled and will titrate further to eliminate snoring prior to doing this sleep study.

21/04/2020:

Patient 3 has completed the MAS efficacy PSG sleep study on 30/03/2020. This report by the sleep physician advises OSA is well controlled with an RDI of 4.5 with the MAS in-situ. Clinical review between the sleep physician and the patient was also done and the patient was advised to continue with MAS therapy at the current titration settings and to continue focusing on weight loss as an additional strategy to reduce OSA severity and potentially prevent significant worsening with time. Patient advises that was titrated to clip 2 (2mm advanced and approximately at 75% maximum protrusion) at the time of performing the MAS efficacy sleep study.

Patient 3 has been continuing to use the MAS every night but has noticed mild bleeding in the upper part of the MAS in the 26/27 region. On examination noted gingivitis in this region due to an accumulation of plaque and calculus deposits. Minor adjustment done to the interproximal region of 26/27 to reduce pressure in this region. Advised patient to see general dentist to have further examination of this area and debridement to reduce the inflammatory swelling of the gingivitis which would be causing the bleeding complication. Lower part of MAS has become slightly suboptimal in retention and this was rectified by increasing its tightness using heat. Patient was happy with the end result after adjustment to the MAS.

There has been no evident teeth movement or bite changes similarly to last appointment. Her TMJs did not show any concerns with good jaw opening range, mobility, and absence of joint noises or pain. There was no tenderness to palpation of TMJs and muscle of mastication. Considering the excellent results from the MAS efficacy PSG and complete resolution of snoring as reported by the patient's husband, no changes are required to the MAS besides any adjustments for comfort. Patient advised to return for a 12 month review.

18/05/2021:

Patient 3 returned for 12 month review of her progress with the 3DS Advance Nylon Dorsal MAS. She has been compliant with using it every night without any side effects or issues noted. There have been no episodes of gingival bleeding as noted from the last appointment. Hypersalivation is still noted by the patient however she has adapted to this, and it does not concern her. Snoring is still well controlled with some rare occasions of mild breakout snoring noted by her husband however it is not frequent enough to concern him and warrant her considering further titration. The titration level is still at clip 2 (approximately 75% maximum protrusion) and the retention of both upper and lower parts of the MAS is excellent. A minor rough edge was noted on the upper anterior section and this was polished with a bur to the patient's satisfaction.

Her weight has continued to be stable and no other medical issues have arisen. There have been no changes in medication status. The MAS is in excellent condition with no evidence of cracks or stress fractures. There is no evidence of teeth movement or bite changes with full arch occlusion noted in MIP. The TMJs had no issues noted on examination with no pain to palpation of them or the muscles of mastication. Jaw opening and excursive movements were not limited and the same deflection to the left-side on protrusive movements was noted. Protrusive measurements are the same as the initial George Gauge measurements.

Considering the MAS is subjectively still controlling the snoring effectively, no further changes are required. The patient will continue to focus on weight loss and is looking to retire in the next year. Patient placed on recall for another 12 months.

Diagnostic sleep study Page 1:

SleepCare

Locations
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Sunnybank Private Hospital
St. Andrews Place, Spring Hill
Mater Private Hospital, Redlands
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www.sleepcare.com.au

Reporting Physicians
Dr Robyn O'Sullivan
Dr Allan Finnimore
Dr Rachel Thomson
Dr Katherine Semple
Dr Miriam Vassallo
Dr Sophie Williams
Dr Dinithi Samaratunga
Dr Tim Edwards

SLEEP STUDY REPORT

Ref: cc: c.c. SleepCare Greenslopes
c.c. Dr Adam Teo

Re: **UR:** **ESS: 2/24**
DOB: 12/02/1960 **Weight: 58 kg**
Site: Home **BMI: 27.2 kg/m^2**

An unattended level II diagnostic sleep study was performed as per AASM guidelines on the 9/10/2019 to investigate possible obstructive sleep apnoea. No medications likely to affect the sleep study were listed. No alcohol was consumed. No sedation was administered. Study set up was performed by a trained professional. Signal quality was good.

The patient slept for 375.5 minutes and rated her quality of sleep as worse than usual. Sleep efficiency was 87.7%. Sleep latency was 13.5 minutes. Sleep architecture showed all sleep stages with an increased REM latency (168.0 minutes) and reduced amount of REM comprising 13.7% of sleep total. Supine REM was not recorded and no supine sleep was recorded. Slow wave sleep was over-represented (35.0% of sleep total). EEG arousals occurred in increased numbers and were significantly associated with respiratory events. The arousal index was 26.4 per sleep hour. 32.6 periodic limb movements occurred per hour of sleep, contributing to 2.7 arousals per sleep hour.

Snoring was noted in all positions. Respiratory events occurred in moderate numbers, and included 7 apnoeas: 5 obstructive, 1 mixed, 1 central; 77 hypopneas and 24 respiratory effort related arousal events (RERA's). Central apnoeas clustered at sleep-wake transitions and did not have the typical morphology of Cheyne-Stokes respiration. The respiratory disturbance index including RERA's (RDI) was **17.3** events per hour (NR <5); in REM sleep was 35.0; and in NREM sleep was 14.4. The RDI during supine sleep was - and in the lateral decubitus position was 17.3. The mean apnoea / hypopnoea duration was 33 seconds, the longest apnoea was 57 seconds.

Baseline awake arterial oxygen saturation was 97%, minimum saturation 89%. 1.9 minutes (0.5 % of sleep total) were spent at an arterial oxygen saturation at or below 90%, and 0.0 minutes (0.0 % of sleep total) at or below 80%. ECG was sinus rhythm with mean heart rate 72 bpm.

CONCLUSION

1. Moderate obstructive sleep apnoea associated with mild sleep fragmentation and mild oxygen desaturation. Severity of obstructive sleep apnoea may have been underestimated due to the lack of supine REM sleep on the study night.
2. Severe periodic limb movements during sleep without associated sleep fragmentation.
3. Overweight: BMI 27.2 kg/m^2.
4. ECG within normal limits.
5. Normal Epworth Sleepiness Score 2/24.

RECOMMENDATIONS

1. Consider mandibular advancement splint or CPAP trial if symptoms warrant. Sleep physician review is required by Medicare prior to a CPAP titration study.
2. Weight reduction.
3. Assess for periodic limb movement disorder and treat if symptoms warrant.
4. Clinical review by referring sleep physician.

Reported by: **Scientist:** 18/10/2019
Respiratory & Sleep Physician
(Electronically reviewed and verified by

Diagnostic Sleep Study Page 2

SleepCare
SLEEP STUDY REPORT

Patient Name: [redacted] **UR:** [redacted] **Study Date:** 9/10/2019

Sleep Statistics[1]		NR
Study Length	11:43 hrs	
Total Sleep Time (TST)	375.5 min	
Sleep Onset	13.5 min	
Wake after sleep onset	39.0 min	
Sleep Efficiency	87.7%	>75%
Supine Sleep	0.0 min (0.0%)	
REM Latency	**168.0 min**	60-130 min
REM sleep	**51.5 min (13.7%)**	15-25%
REM Supine	0.0 min (0.0%)	
N1 sleep	30.0 min (8.0%)	
N2 sleep	162.5 min (43.3%)	
N3 sleep	131.5 min (35.0%)	1-30%

Epworth Sleepiness Score[2]
Mild 9-11
Moderate 12-15
Severe 16-24

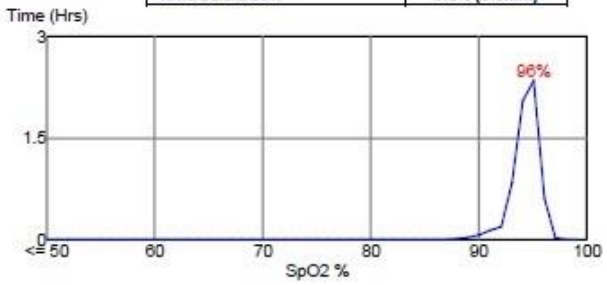
Severity grading of OSA[3]
Mild 5-14.9
Moderate 15-29.9
Severe 30+

Respiratory Statistics[4]	Events/hr
Total RDI	**17.3**
REM RDI	35.0
NREM RDI	14.4
Supine RDI	-
Non-Supine RDI	17.3

Arousal and PLM Statistics	Events/hr	NR [5]
Arousal Index (AI)	**26.4**	<20 <50yr <25 >50yr
Respiratory AI	13.1	< 5
PLM AI	2.7	< 5
PLM Index	**32.6**	<15

Distribution of Respiratory events				*Events/hr*		
	NREM			REM		
Parameters	Supine	Non-Supine	All	Supine	Non-Supine	All
Min SaO2 (%)	-	89	89	-	89	89
Apnoeas Total (A)	**0.0**	**1.3**	**1.3**	**0.0**	**0.0**	**0.0**
Obstructive apnoeas (ObA)	0.0	0.9	0.9	0.0	0.0	0.0
Central apnoeas (CnA)	0.0	0.2	0.2	0.0	0.0	0.0
Mixed apnoeas (MxA)	0.0	0.2	0.2	0.0	0.0	0.0
Hypopneas (H)	**0.0**	**9.3**	**9.3**	**0.0**	**31.5**	**31.5**
RERA's	-	3.9	3.9	-	3.5	3.5
AHI	0.0	10.6	10.6	0.0	31.5	31.5
RDI	-	**14.4**	**14.4**	-	**35.0**	**35.0**
Total AHI			**13.4**			
Total RERA'S			3.8			
Total RDI			**17.3**			
Mean A/H Duration		33 sec		**Longest Apnoea**		57 sec

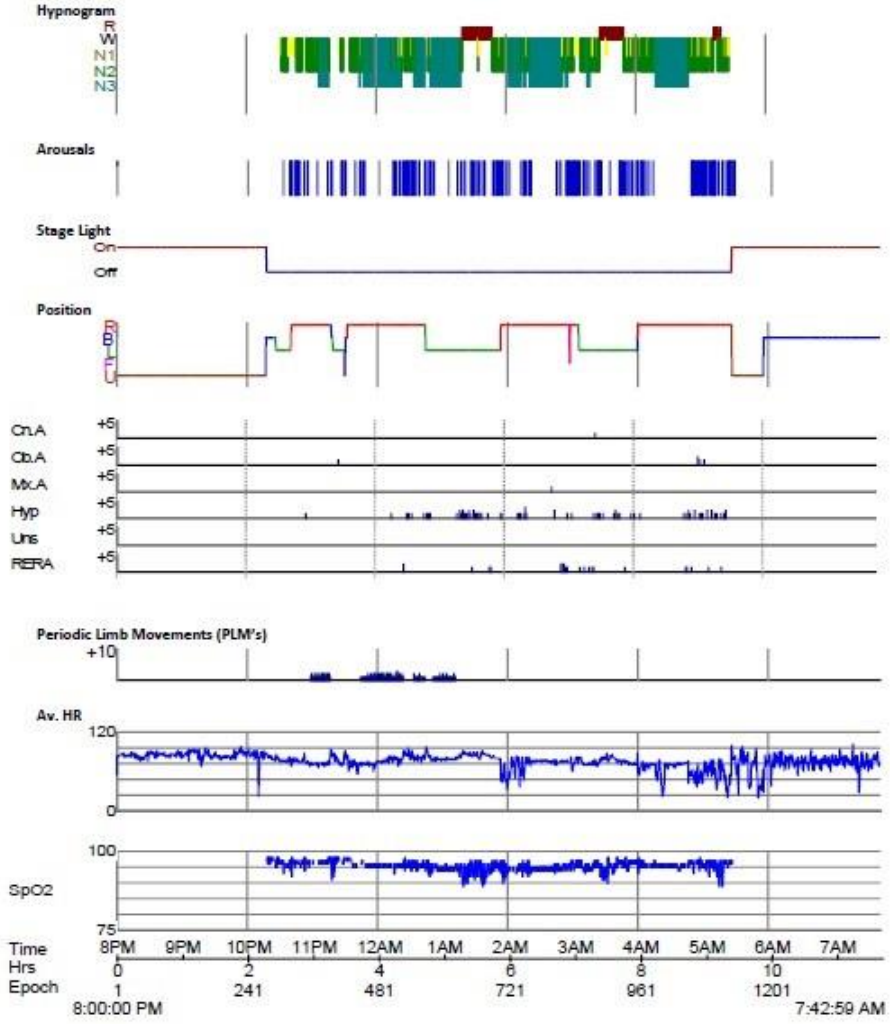
Oximetry Statistics	
Baseline SpO2	97 %
SpO2 Nadir	**89%**
Average SpO2 desaturation	3 %
Number of desaturations >=3%	13
Time below 90%	**0.5% (1.9min)**
Time below 80%	**0.0% (0.0min)**



SpO2	Time
91-100	6.23
81-90	0.03
71-80	0
61-70	0
51-60	0
<= 50	0

SleepCare
SLEEP STUDY REPORT

Patient Name:		**Study Date:**	9/10/2019
UR:		**Height:**	146 cm
Sex:	Female	**Weight:**	58 kg
Sleep pattern past 24hrs:	2235 – 0515 hrs. **Nap:** Nil	**BMI:**	27.2 kg/m^2



References:
1. Chayon. Sleep 2004:27(7):1255-73.
2. Johns. Sleep 1997;20(10):844-9.
3. Sleep. 1999; 22:667-89.
4. Iber. ASSM Scoring Manual 2012.
5. Bonnett. J Clin Sleep Med 2007 April 15; 3(3): 271-274.

MAS Efficacy Sleep Study Page 1

SleepCare

Locations
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Reporting Physicians
Dr Robyn O'Sullivan
Dr Allen Fitzsimons
Dr Rachel Thomson
Dr Katherine Semple
Dr Miriam Vassallo
Dr Sophie Williams
Dr Dinithi Senaratunga
Dr Tim Edwards

SLEEP STUDY REPORT

30th March, 2020

Ref: cc: c.c. SleepCare Greenslopes
c.c. Medical Records GPH

Re: UR:
DOB: 12/02/60
Site: Greenslopes

ESS: 2/24
Weight: 58 kg
BMI: 27.2 kg/m²

A diagnostic sleep study was performed on the 17/03/20 to objectively assess the efficacy of a mandibular advancement splint (MAS) to treat obstructive sleep apnoea. No medications likely to affect the sleep study were listed. No alcohol was consumed. No sedation was administered. Signal quality was good.

The patient slept for 281.5 minutes and rated her quality of sleep as the same as usual. She had a dry mouth but no headache on waking and she reported feeling rested. Sleep efficiency was 75.3%. Sleep latency was 9.0 minutes. Sleep architecture showed all sleep stages with an increased REM latency (182.0 minutes) and normal amount of REM comprising 17.9% of sleep total. Supine REM was not recorded. No supine sleep was recorded. Slow wave sleep was within normal limits (29.8% of sleep total). EEG arousals occurred in normal numbers. The arousal index was 7.9 per sleep hour. No periodic limb movements occurred.

Snoring ranging from soft to moderate was noted in all positions. Respiratory events did not occur in significant numbers, and included 0 apnoeas: 0 obstructive, 0 mixed, 0 central; 22 hypopneas and 0 respiratory effort related arousal events (RERA's). The respiratory disturbance index including RERA's (RDI) was 4.5 events per hour (NR <5); in REM sleep was 4.8; and in NREM sleep was 4.4. The RDI during supine sleep was - and in the lateral decubitus position was 4.5. The mean apnoea / hypopnoea duration was 37 seconds, the longest apnoea was - seconds.

Baseline awake arterial oxygen saturation was 97%, minimum saturation 92%. 0.0 minutes (0.0 % of sleep total) were spent at an arterial oxygen saturation at or below 90%, and 0.0 minutes (0.0 % of sleep total) at or below 80%. Blood pressure on retiring was 116/73 mmHg and on waking was 120/70 mmHg. ECG was sinus rhythm with mean heart rate 75 bpm.

CONCLUSION

1. Sleep apnoea is well controlled with the mandibular advancement splint.
2. No evidence for periodic limb movements during sleep.
3. Overweight: BMI 27.2 kg/m².
4. ECG within normal limits.
5. Normal Epworth Sleepiness Score: 2/24.

RECOMMENDATIONS

1. Continue mandibular advancement splint at same splint settings.
2. Weight reduction.
3. Clinical review by referring sleep physician.

Reported by: Scientist: 26/3/2020

Respiratory & Sleep Physician
(Electronically reviewed and verified by)

SleepCare
SLEEP STUDY REPORT

Patient Name: **UR:** **Study Date:** 17/03/20

Sleep Statistics[1]		NR
Study Length	10:09 hrs	
Total Sleep Time (TST)	281.5 min	
Sleep Onset	9.0 min	
Wake after sleep onset	83.5 min	
Sleep Efficiency	75.3%	>75%
Supine Sleep	0.0 min (0.0%)	
REM Latency	182.0 min	60-130 min
REM sleep	50.5 min (17.9%)	15-25%
REM Supine	0.0 min (0.0%)	
N1 sleep	10.5 min (3.7%)	
N2 sleep	136.5 min (48.5%)	
N3 sleep	84.0 min (29.8%)	1-30%

Epworth Sleepiness Score[2]
Mild 9-11
Moderate 12-15
Severe 16-24

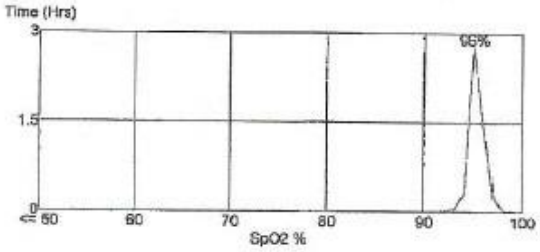
Severity grading of OSA[3]
Mild 5-14.9
Moderate 15-29.9
Severe 30+

Respiratory Statistics[4]	Events/hr
Total RDI	4.5
REM RDI	4.8
NREM RDI	4.4
Supine RDI	-
Non-Supine RDI	4.5

Arousal and PLM Statistics	Events/hr	NR[5]
Arousal Index (AI)	7.9	<20 <50yr <25 >50yr
Respiratory AI	1.5	<5
PLM AI	0.0	<5
PLM Index	0.0	<15

Distribution of Respiratory events				*Events/hr*		
	NREM			REM		
Parameters	Supine	Non-Supine	All	Supine	Non-Supine	All
Min SaO2 (%)	-	94	94	-	92	92
Apnoeas Total (A)	0.0	0.0	0.0	0.0	0.0	0.0
Obstructive apnoeas (ObA)	0.0	0.0	0.0	0.0	0.0	0.0
Central apnoeas (CnA)	0.0	0.0	0.0	0.0	0.0	0.0
Mixed apnoeas (MxA)	0.0	0.0	0.0	0.0	0.0	0.0
Hypopneas (H)	0.0	4.4	4.4	0.0	4.8	4.8
RERA's	-	0.0	0.0	-	0.0	0.0
AHI	0.0	4.4	4.4	0.0	4.8	4.8
RDI	-	4.4	4.4	-	4.8	4.8
Total AHI		4.5				
Total RERA'S		0.0				
Total RDI		4.5				
Mean A/H Duration		37 sec		Longest Apnoea		- sec

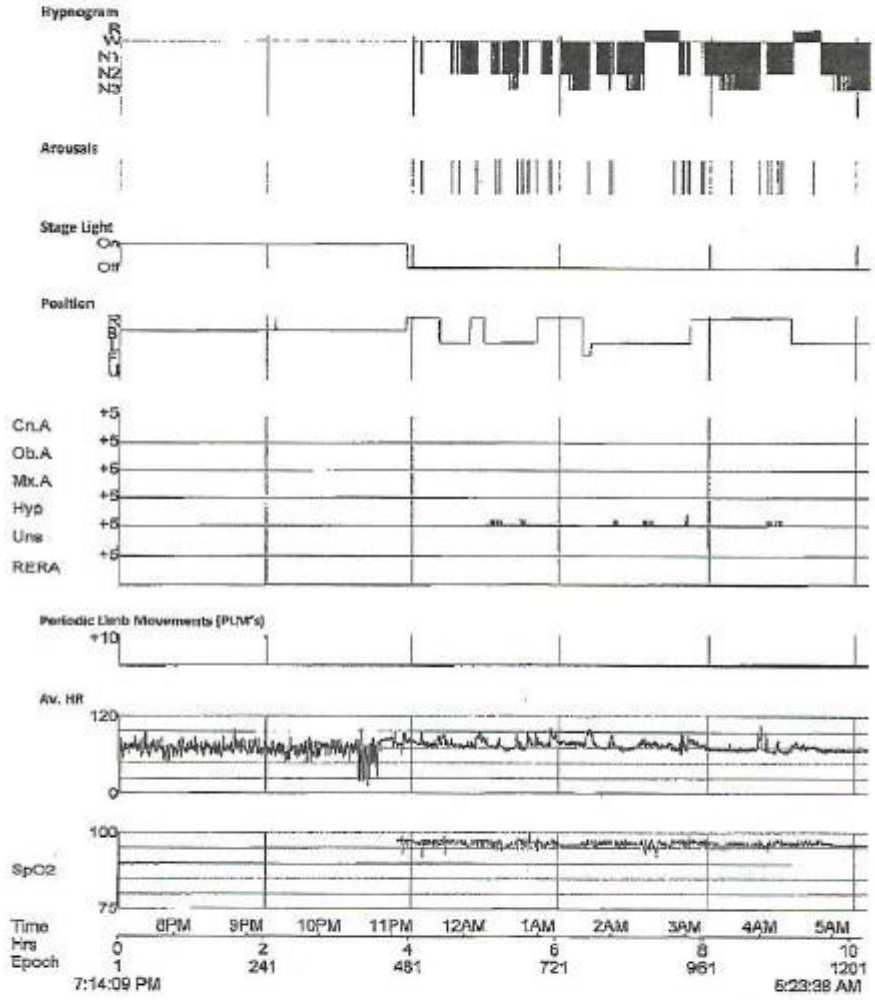
Oximetry Statistics	
Baseline SpO2	97 %
SpO2 Nadir	92%
Average SpO2 desaturation	3 %
Number of desaturations >=3%	7
Time below 90%	0.0% (0.0min)
Time below 80%	0.0% (0.0min)



SpO2	Time
91-100	4.69
81-90	0
71-80	0
61-70	0
51-60	0
<= 50	0

SleepCare
SLEEP STUDY REPORT

Patient Name:		**Study Date:**	17/03/20
UR:		**Height:**	146 cm
Sex:	Female	**Weight:**	58 kg
Sleep pattern past 24hrs:	2240-0520 hrs. **Nap:** Nil	**BMI:**	27.2 kg/m²



References
1. Chayen. Sleep 2004;27(7):1255-73.
2. Johns. Sleep 1997;20(10):844-9.
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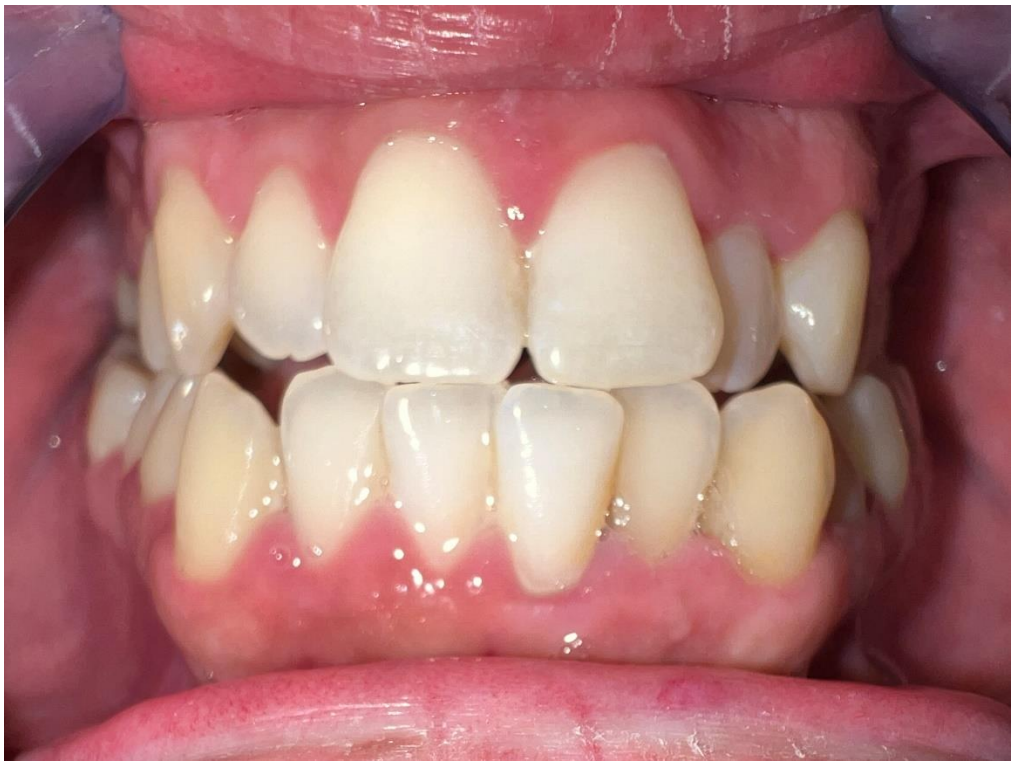
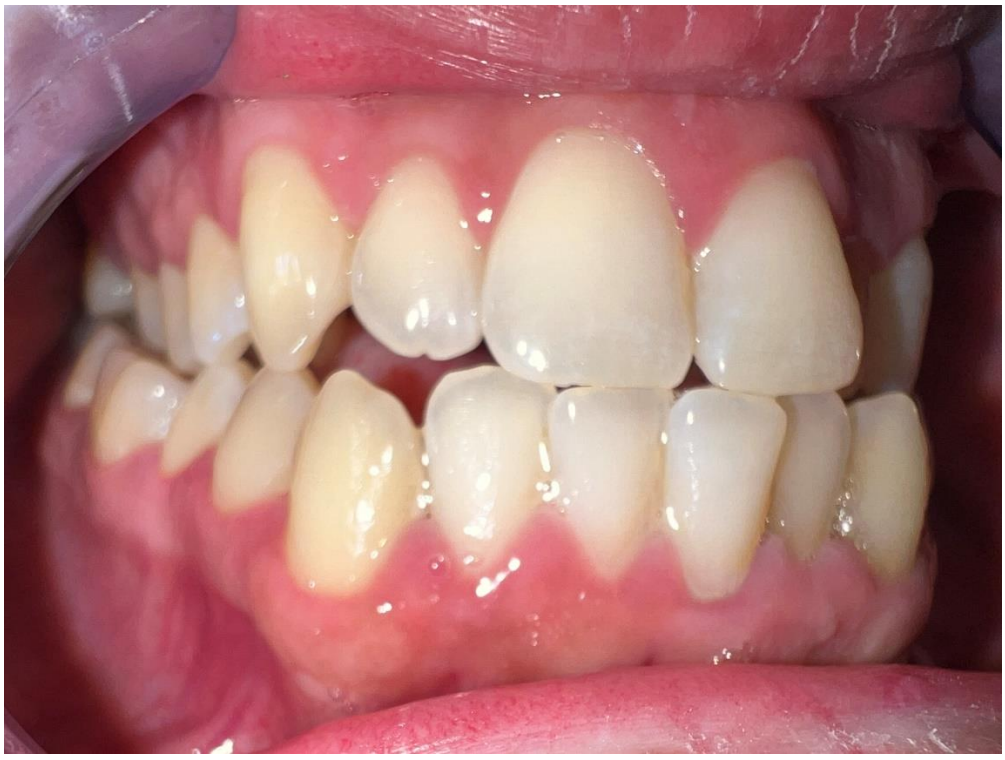
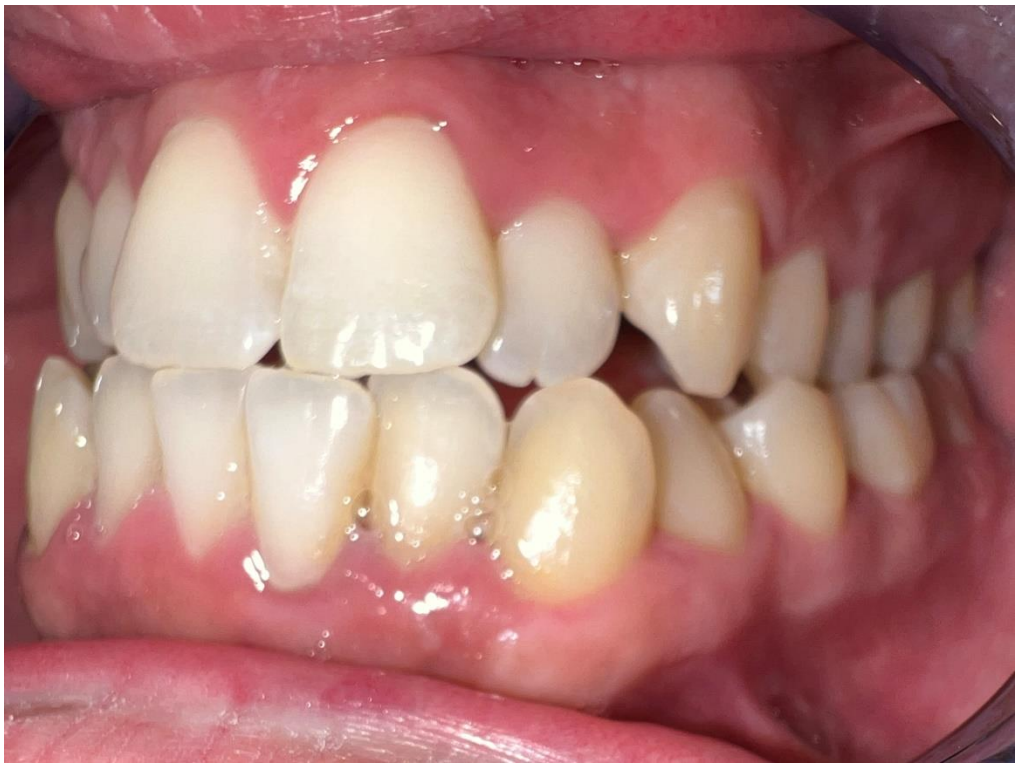
Anterior View in Occlusion:



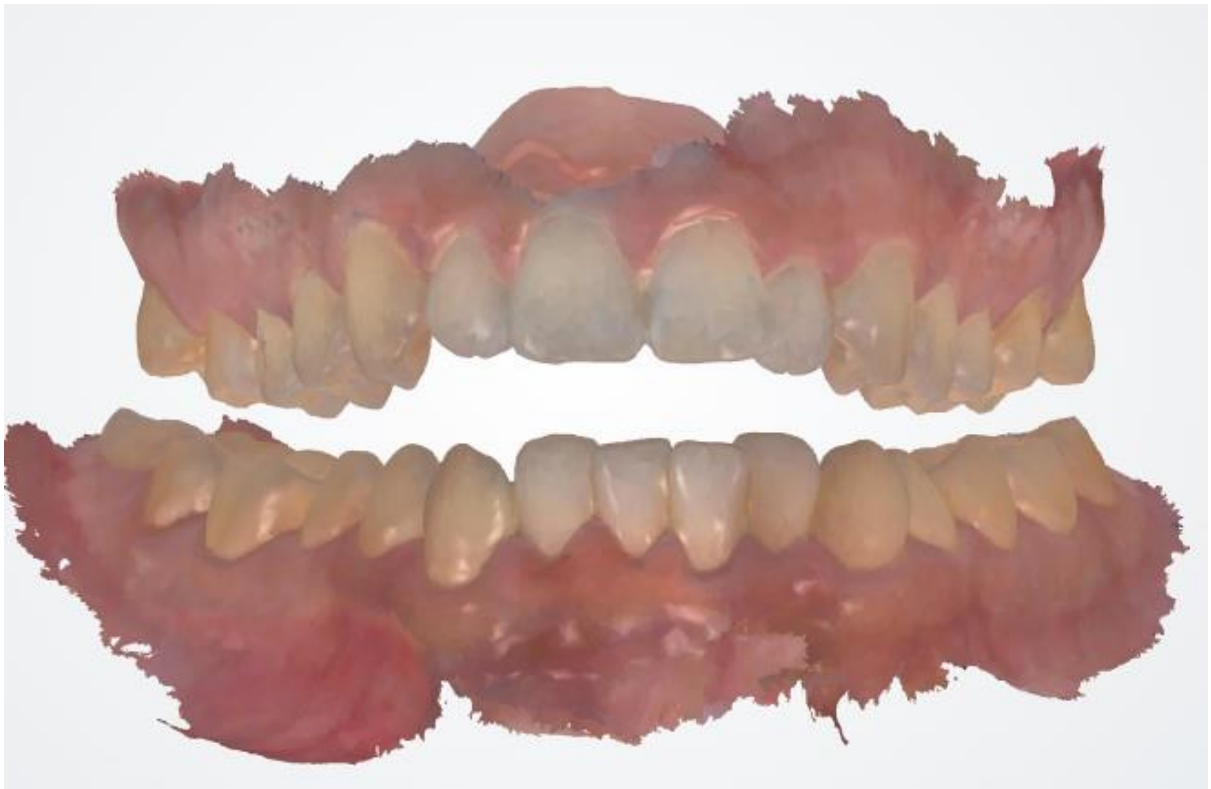
Right lateral view in occlusion:



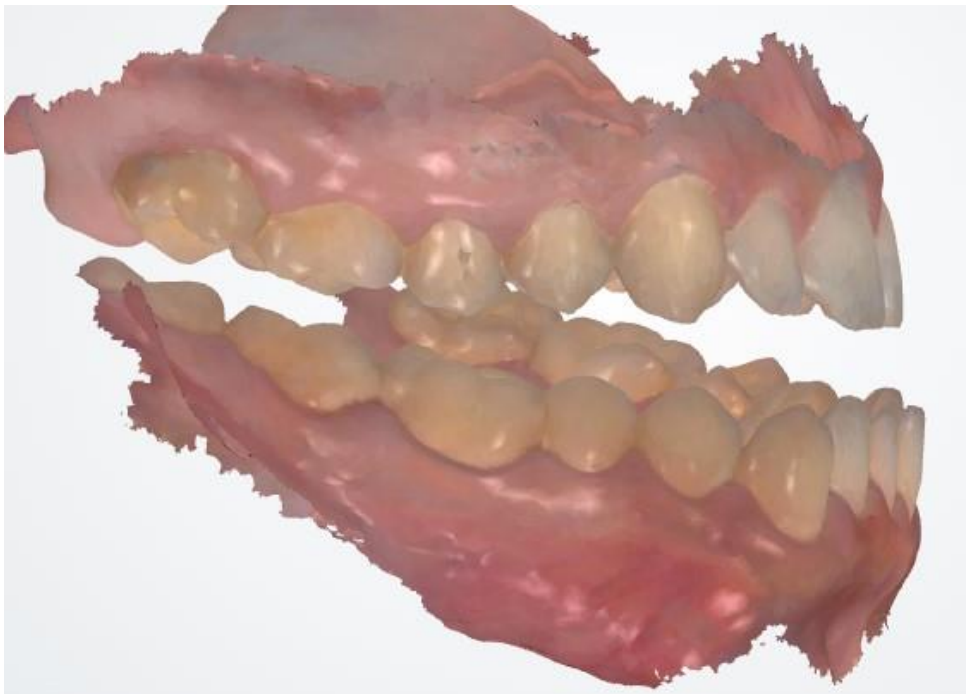
Left lateral view in occlusion:



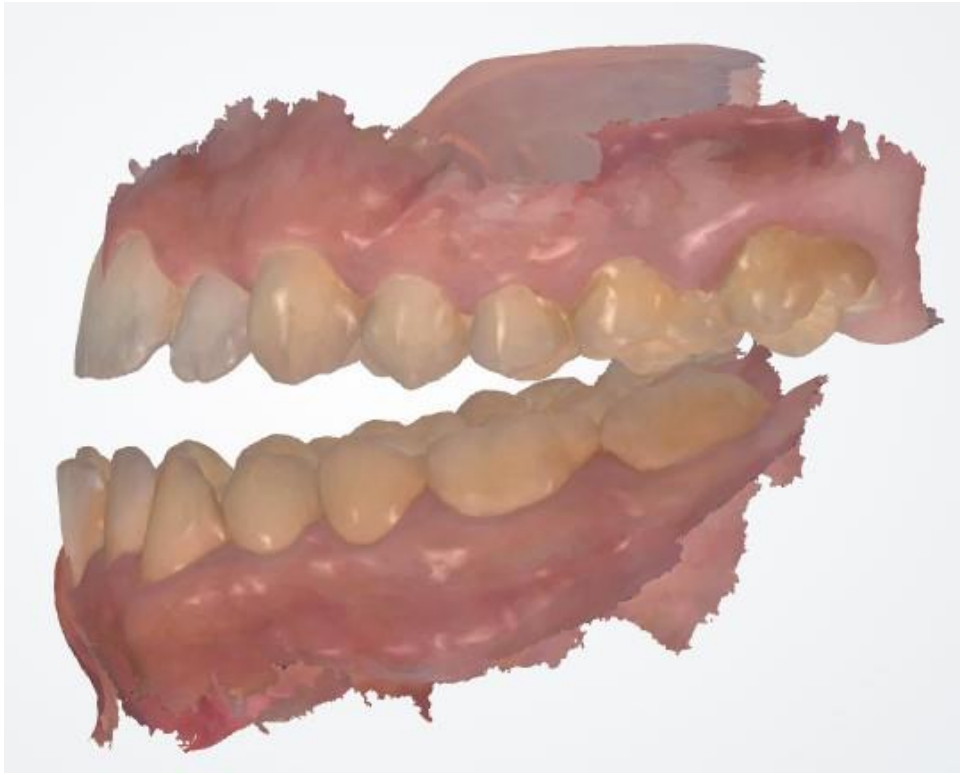
Anterior view intra-oral scans in bite position:



Right lateral view of intra-oral scans in bite position:



Left lateral view of intra-oral scans in bite position:



Anterior view with MAS in-situ: