IMPACT OF MAXILLOMANDIBULAR ADVANCEMENT ON HEALTH-RELATED AND FUNCTIONAL OUTCOMES: THE DALHOUSIE EXPERIENCE

by

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ABSTRACT

Purpose: To determine the clinical effectiveness and safety of maxillomandibular advancement surgery (MMA) for the treatment of moderate to severe obstructive sleep apnea (OSA).

Methods: A prospective cohort study was designed to evaluate patients undergoing MMA for treatment of moderate to severe OSA with an apnea-hypopnea index (AHI) $\geq$ 15. Primary outcome measures included 1. Objective measures: AHI, high-sensitivity C-reactive protein (hsCRP), psychomotor vigilance task (PVT) reaction times (1/RT), blood pressure (BP) and body mass index (BMI) and 2. Subjective measures: sleepiness (Epworth Sleepiness Scale [ESS]) and quality of life (Functional Outcomes of Sleep Questionnaire [FOSQ]). Secondary outcome measures included surgical site infections (SSI), neurosensory disturbance and changes in facial appearance.

Results: Nine patients (55.6% men, age 48$\pm$6.4 years [mean$\pm$SD]) participated in the study with an average of 278.3 days (9.15 months) follow-up. Mean BMI was 30.9$\pm$5.95 and mean AHI was 31.14$\pm$13.56. AHI decreased from a mean of 31.14$\pm$13.56 to 7.12$\pm$10.97 events/h ($p<0.01$). PVT reaction times (1/RT) improved from 2.79$\pm$0.32 to 3.04$\pm$0.27 ($p<0.05$). ESS decreased from a mean of 13.22$\pm$4.09 to 4.33$\pm$3.04 ($p<0.01$). FOSQ increased from a mean of 13.38$\pm$3.2 to 17.8$\pm$2.9 ($p<0.01$). No major peri-operative adverse events were reported. Three post-operative infections were minor and managed with oral antibiotics and irrigation. 88.9% of patients (eight out of nine) felt the change in their facial appearance was either favourable or neutral. 66.7% (four out of six) of patients who experienced post-operative sensory numbness described the numbness as not a problem or a very mild problem. There were no statistically significant changes in hsCRP, BP or BMI.

Conclusion: The results of this study support MMA as being a highly effective surgical option for the treatment of moderate to severe OSA, for patients unable to adhere to CPAP therapy, and caries a low risk of adverse outcomes including numbness and infection.

LIST OF ABBREVIATIONS USED

AASM	American Academy of Sleep Medicine
Abx	Antibiotics
AHI	Apnea-Hypopnea Index
ANP	Atrial Natriuretic Peptide
BMI	Body Mass Index
BP	Blood pressure
BSSO	Bilateral sagittal split osteotomy
CIH	Chronic Intermittent Hypoxia
CPAP	Continuous Positive Airway Pressure
CRP	C-reactive protein
DBP	Diastolic blood pressure
DU	Dalhousie University
EDS	Excessive daytime sleepiness
ESS	Epworth Sleepiness Scale
FOSQ	Functional Outcomes of Sleep Questionnaire
hsCRP	High sensitivity C-reactive protein
IL-6	Interleukin 6
ISI	Inter-stimulus intervals
LDL	Low-density lipoprotein
LTAP	Long-term antibiotic prophylaxis
MMA	Maxillomandibular Advancement Surgery
nCPAP	Nasal Continuous Positive Airway Pressure
NF-κB	Nuclear Factor κB
NREM	Non-rapid eye-movement sleep
OHS	Obesity hypoventilation syndrome
OSA	Obstructive Sleep Apnea
PAP	Positive Airway Pressure
PSG	Polysomnography
PVT	Psychomotor Vigilance Task
RDI	Respiratory Disturbance Index
REM	Rapid eye-movement sleep
RERA	Respiratory effort-related arousal
R&K	Rechtschaffen and Kales
RT	Reaction Time
SBP	Systolic blood pressure
SD	Standard Deviation
SDB	Sleep disordered breathing
SSI	Surgical Site Infection
STAP	Short-term antibiotic prophylaxis
SWS	Slow wave sleep
TNF-α	Tumor necrosis factor-α
UPPP	Uvulopalatopharyngoplasty
VUMC	Vanderbilt University Medical Centre

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CHAPTER 1 INTRODUCTION

Humans spend almost one third of their lives sleeping. (1) Sleep disordered breathing (SDB) is characterized by abnormal respiration during sleep, and is estimated to occur in 1 of 20 adults. (2) OSA is the most common form of SDB and is highly prevalent and grossly underdiagnosed. (3, 4) OSA contributes to an increased risk for multiple co-morbidities and decreased quality of life. As a result, OSA patients have higher usage of healthcare resources, which can be mitigated with effective treatment. (5)

Sleep Disordered Breathing

SDB includes a wide spectrum of sleep-related breathing abnormalities. The spectrum includes obstructive sleep apnea (OSA), central sleep apnea, sleep-related hypoventilation disorders, and sleep-related hypoxemia disorder. (3, 6)

Diagnostic criteria have been recently updated in the International Classification of Sleep Disorders, Third Edition, 2014 (6) and the American Academy of Sleep Medicine Manual for Scoring Sleep and Associated Events, 2016. (7) Based on polysomnographic event scoring, the American Academy of Sleep Medicine (AASM) classifies sleep apnea syndromes as being obstructive or central. (7) Respiratory events are classified as apneas and hypopneas. Apneas are further subdivided into obstructive, central, or mixed. Obstructive apneas are episodes of complete upper airway collapse, defined as a greater than 90% drop in airflow/thermal sensor in the presence of continued respiratory effort lasting at least 10 seconds. Hypopnea is defined as a 30% or more drop in the nasal pressure signal lasting for at least 10 seconds, associated with a 3% or more oxygen

desaturation or an arousal (AASM-recommended definition) or 4% or more oxygen desaturation (AASM-acceptable definition, Centers for Medicare and Medicaid Services Definition). (7) Hypopneas are generally considered to be obstructive events representing partial upper airway collapse. In contrast, central apnea is defined as a greater than 90% drop in the airflow/thermal sensor accompanied by absent respiratory effort that lasts for at least 10 seconds. Mixed apnea is characterized by a greater than 90% drop in the airflow/thermal sensor lasting at least 10 seconds and associated with initial absence of respiratory effort that resumes despite continued airflow. (3, 6, 7)

Obstructive Sleep Apnea

Interestingly, obstructive sleep apnea was famously described in 1836 not by a clinician but by the novelist Charles Dickens. The term pickwickian was based on one of Dickens' characters, Fat Boy Joe, from a series of papers entitled the "Posthumous Papers of the Pickwick Club." Joe was described as a boy who was obese and always excessively sleepy, who was praised for his ability to fall asleep instantaneously after drinking alcohol. (8) The current terminology used to describe such an individual is the obesity hypoventilation syndrome (OHS). (9)

OSA is characterized by repetitive upper airway obstruction, with recurrent episodes of partial obstruction with reduced ventilation (hypopnea) or complete obstruction and cessation of breathing (apnea). (6) Diagnostic criteria include either an obstructive AHI of at least 15 per hour or at least 5 per hour when accompanied by at least one symptom of excessive daytime sleepiness; waking breath holding; gasping or choking; observer reports of loud snoring, breathing interruptions, or both; or a comorbid condition

including hypertension, mood disorder, cognitive dysfunction, coronary artery disease, or type 2 diabetes mellitus. (6) When OSA is defined by polysomnography and is associated with daytime symptoms such as excessive daytime sleepiness, then it is referred to as OSA syndrome. (3)

The severity of OSA is objectively characterized by the number of apneic and hypopneic episodes per hour of sleep, a measure called the apnea-hypopnea index (AHI). (10) The severity of OSA is further classified according to the number of apnea-hypopnea events per hour of sleep. Mild corresponds to an AHI of 5 - 14 events/h, moderate an AHI of 15 - 29 events/h and severe an AHI of $\geq$ 30 events/h. (11)

Another index used for the assessment of OSA is the respiratory disturbance index (RDI). RDI, like AHI, takes into account the number of apnea-hypopnea events, and it additionally includes the number of respiratory effort-related arousals (RERAs). A RERA is defined as an increase in respiratory effort for lasting for at least 10 seconds leading to an arousal, but does not meet criteria for an apnea or hypopnea due to less oxygen desaturation. (10)

Epidemiology of OSA

The prevalence of OSA is significant. In the United States, the most rigorous population-based study concerned with epidemiologic features of OSA is the Wisconsin Sleep Cohort Study. The Wisconsin-based cohort study of state employees younger than 65 years of age found a prevalence of SDB, defined as an AHI of 5/hr or greater (with hypopneas based on a definition of discernible change in airflow and 4% desaturation), to be 9% in women and 24% in men.(12) Sleep apnea syndrome, defined as the presence of

both SDB and self-reported sleepiness, was present in 2% of women and 4% of men. More recent data from the Wisconsin Sleep Study Cohort indicates that 10% of men and 3% of women 30 to 49 years of age and 17% of men and 9% of women 50 to 70 years of age have moderate to severe OSA. (13) Bixler et al. found a 17% prevalence of an AHI greater than 5/hr and a 7% prevalence of an AHI greater than 15/hr in men. (14) It is estimated that in Western countries, up to 5% of the population have an undiagnosed OSA syndrome (elevated AHI and symptoms). (15) Young et al. also published data showing that 93% of women and 82% of men with moderate to severe OSA were undiagnosed. (16)

There is also evidence that OSA severity can progress with time. Analysis of an 8-year follow-up of 282 participants of the Wisconsin cohort study showed a mean increase in the AHI from 2.6 events/hr to 5.1 events/hr. (16)

Clinical features of OSA

The dominant symptom of OSA is excessive daytime sleepiness (EDS). (17) Other daytime symptoms include excessive daytime sleepiness (EDS), fatigue, morning headaches, poor concentration, reduced libido, personality changes, depression, and/or insomnia. Nocturnal symptoms include restlessness, snoring, witnessed apneas, nocturnal choking, nocturia, diaphoresis, reflux symptoms, dry mouth, drooling, and/or bed partner sleep disruption. (17)

Stratification of patients with suspected sleep apnea may be based on the following four symptoms: habitual snoring, EDS, a body mass index (BMI) >35kg/m^2, and observed/witnessed apneas. Patients with all 4 of the above symptoms may be placed in a

high-risk group and have an approximately 70% likelihood of having an apnea-hypopnea index > 10 events/hour. (17) Other risk factors include male gender, post-menopausal women, age, race, obesity (BMI=28-35 kg/m^2), and craniofacial abnormalities. (17)

Abnormalities known to be associated with OSA should be targeted during physical examination. (18) This includes measurement of the patient's BMI and systemic blood pressure as well as careful examination of the nose, ears, and oropharynx. Observation of the oropharynx usually reveals a crowded upper airway, and examination of the patient's face in profile may reveal retrognathia. Measurement of neck circumference and observation of signs of right heart failure may also be revealing. A neck size of greater than 17 inches in men and 16 inches in women suggests the possibility of OSA. (18)

Sleep Architecture

Sleep architecture refers to the basic structural organization of normal sleep. (19) There are two types of sleep, non-rapid eye-movement (NREM) sleep and rapid eye-movement (REM) sleep. Until recently, the widely accepted standard for describing the human sleep process came from the manual of sleep classification by Rechtschaffen and Kales (1968) which divided NREM into stages S1, S2, S3 and S4. (20) However, according to the new guidelines of the American Academy of Sleep Medicine (AASM, 2007), sleep stages S1 to S4 are replaced by N1, N2 and N3. N3 reflects slow wave sleep (SWS) and corresponds to R&K stages S3 and S4. (21) A sleep episode begins with a short period of NREM which starts at N1 and progresses through N2, followed by N3 and finally by REM. Individuals do not remain in REM sleep as they cycle between stages of NREM

and REM throughout the night. NREM sleep constitutes about 75-80% of total sleep time and REM sleep constitutes the remaining 20-25%. The average length of the first NREM-REM sleep cycle is 70 to 100 minutes. The second and later cycles are longer lasting approximately 90 to 120 minutes. In normal adults, REM sleep increases as the night progresses and is longest in the last one-third of the sleep episode. (19) REM sleep is characterized by high-frequency irregular respirations, decreased tidal volume and minute ventilation, and reduced responsiveness to respiratory modulation. (22)

Repetitive obstructive respiratory events occur during sleep in patients affected by OSA. The upper airway in OSA is abnormally collapsible, with reduced genioglossus and upper airway dilator muscle activity, or is partially occluded because of upper airway or craniofacial pathology. (3) These events can result in reduction in oxyhemoglobin saturation and may be terminated by arousal, leading to sleep fragmentation. (3) The oxygen saturation level usually returns to baseline following resumption of normal breathing, but may remain low if the respiratory events are frequent or prolonged, or occur in the presence of underlying pulmonary pathology. Respiratory events occur more frequently in sleep stages N1, N2 and REM. Respiratory events in patients with OSA are often more frequent and longer in REM sleep, with more profound oxygen desaturation occurring than in any other sleep stage; yet at the same time events in REM sleep are more resistant to eliciting arousal than respiratory events in NREM sleep. REM OSA, in which respiratory events occur exclusively or predominately in this cycle, is estimated to constitute 14% to 36% of all OSA cases. (22) By contrast, sleep stage N3 is protective against OSA, with less frequent and severe desaturations.

Pathophysiology of OSA

The physiologic changes that occur in OSA are vast and involve complex mechanisms, which increase the risk of cardiovascular and metabolic adverse outcomes. (3) Recurring obstructive apneas lead to significant decreases in intrathoracic pressure as a result of forceful inspiratory effort against an occluded airway. (23) The decreased intrathoracic pressure leads to increased dilation in the right atrium. The heart perceives a false signal of fluid overload, and in response, the atria of the heart secrete atrial natriuretic peptide (ANP). (24) ANP results in increased sodium and water excretion, which causes nocturia, a symptom commonly seen in OSA patients. (23, 24)

The autonomic regulation of blood pressure is also affected. The hypoxemia, hypercapnia, and arousal response associated with recurrent obstructive events results in increased sympathetic activity, causing loss of the normal circadian rhythm of blood pressure dipping during sleep. (23, 25) Arousal at apnea termination is associated with a large increase in sympathetic tone and decreased vagal tone, which leads to increased blood pressure and heart rate. (18) High sympathetic tone is still present during wakefulness.(18)

OSA also has proinflammatory effects. Interruptions during sleep in OSA patients lead to chronic intermittent hypoxia (CIH). (26) In response to CIH, there is an activation of pro-inflammatory transcription factors, including nuclear factor κ B (NF-κ B). NF-κ B activation, in turn, leads to an increased expression of pro-inflammatory cytokines such as tumor necrosis factor-alpha (TNF-α), interleukin 6 (IL-6), C-reactive protein (CRP),

and adhesion molecules that lead to endothelial dysfunction and cardiovascular disease. (23, 27)

Polysomnography

The apnea-hypopnea index (AHI) is the main objective measurement for determining the severity of OSA. AHI is recorded by overnight polysomnographic studies conducted at sleep centres; also know as overnight sleep studies. Sleep studies are classified into 4 levels. A level I sleep study refers to overnight polysomnography (PSG) in a sleep laboratory with a trained health care professional (i.e. a sleep technician) in attendance, while the other sleep studies are unattended. (28) Level I sleep studies are considered the gold standard for diagnosing sleep disordered breathing. In a level I sleep study, multiple sensors are attached to the patient to capture neurological, cardiovascular, and respiratory data. A minimum of 7 parameters are measured including brain waves, eye movements, chin muscle movements, respiratory effort, oxygen saturation, airflow, and heart rate or rhythm. (29) In comparison, a level II sleep study is basically a level I study, using the same equipment and channels of data, but it is performed outside of a sleep laboratory and without a sleep technician in attendance. A level III study, however, uses a portable device that is typically used by the patient at home and without a healthcare professional in attendance. These devices measure a minimum of 4 parameters, including at least 2 respiratory variables (respiratory movement and airflow), a cardiac variable (heart rate or rhythm), and also oxygen saturation. (28, 29) A level IV sleep study measures a minimum of 1 parameter, including oxygen saturation, airflow, or chest movement.

Level III sleep studies are attractive alternatives to level I sleep studies, since patients can have them done in the comfort of their own homes. Level III studies thus avoid long waits associated with overnight sleep studies done in sleep labs. The question remains if they are as accurate as level I sleep studies. A systematic review and meta-analysis by El Shayeb at al. compared the accuracy of level III portable sleep tests to level I polysomnography. (30) They concluded that level III sleep studies are safe and convenient for diagnosing moderate to severe forms of OSA in patients with no comorbidities with high pre-test probability. However, level I sleep studies remain the preferred method for diagnosing patients suspected of having comorbid sleep disorders, unstable medical conditions or complex sleep disordered breathing. (30)

Psychomotor Vigilance Task (PVT)

Vigilance is a state of heightened readiness to perform efficiently, and it is thought to be impaired in patients with OSA. (31-33) The psychomotor vigilance task (PVT) is sensitive to sleep deprivation and is widely used as an objective tool to identify cognitive impairment in a variety of situations, such as sleep restriction, napping and sleepiness. (32-34) The PVT is one of the leading assays of sustained vigilant attention in sleep research. (35) Most early studies on sleep disordered breathing concentrated on quantifying excessive daytime sleepiness, while more recent studies have concentrated on impaired sustained vigilant performance. PVT is one of the most widely used tools to assess vigilant attention, which is defined as sustained attention and alertness. In sleep-deprived individuals, vigilance is the component of cognition that is most consistently and dramatically affected. (36) The PVT is a simple test of reaction time (RT) to a cue

that occurs at random inter-stimulus intervals (ISI). In the standard administration of the test the ISI varies randomly from 2 to 10 seconds. The standard test is 10 minutes long. During this time, subjects are seated comfortably in front of a computer screen. They are instructed to respond as quickly as possible by pressing on the spacebar whenever they perceive the appearance of a millisecond counter on the screen. Pressing the spacebar stops the counter and allows subjects to view their reaction times, which remain on the screen for 1 second. Pressing the spacebar when the counter is not displayed on the screen is counted as a false start, or an error of commission. Numerous outcome measures can be collected from a single 10-minute bout of PVT. These measures include median RT, errors of commission, variability in RTs, and number of lapses (i.e. responses greater than 500ms). PVT therefore allows the collection of a large amount of data in a relatively short period of time. These characteristics increase the sensitivity of the test to detect even small changes in vigilant attention. PVT is highly sensitive to sleep deprivation. Its reliability and validity have been demonstrated and the test shows virtually no learning curve and is independent of aptitude. (35, 36)

Subjective Assessment of OSA

The most identifiable symptom associated with OSA is hypersomnolence i.e. excessive daytime sleepiness (EDS). In 1993 Johns et al. developed the Epworth Sleepiness Scale (ESS), a questionnaire used as a tool to quantify EDS in patients with sleep apnea. ESS uses a series of eight questions measuring the probability of falling asleep in a variety of situations. Possible total scores range from 0 to 24, with scores > 10 indicative of clinically significant EDS. (37, 38) ESS is a validated clinical and research tool in

assessing daytime sleepiness with high test-retest reliability and internal consistency. (37-40)

Another instrument for measuring health-related quality of life in OSA patients is the Functional Outcomes of Sleep Questionnaire (FOSQ). (41) The FOSQ is used to evaluate the specific impact of excessive sleepiness or tiredness on multiple activities associated with everyday living. A total score is generated from responses concerning five domains: activity level, vigilance, intimacy, sexual relationships, general productivity, and social outcome. The FOSQ has been found to be capable of discriminating between non-apnea participants and untreated sleep apnea patients. (39, 41) In addition to its high test-retest reliability and internal consistency, FOSQ has very high content validity. A total score of less than 18 is considered to be clinically significant. (42)

Detrimental Health Effects of OSA

As a result of recurrent airway obstructions, OSA leads to chronic sleep disruption, hypoxemia and, detrimental health sequelae. (43) Left untreated, patients are at risk of developing hypertension, myocardial infarction, arrhythmias and strokes. (44-46) Patients suffering from OSA have impaired health-related quality of life when compared with healthy age- and gender-matched controls. (47) OSA patients are also at an increased risk of being involved in automobile accidents as a result of falling asleep at the wheel. (48) Studies have suggested up to a sevenfold increase in crashes in patients with OSA. (48, 49)

OSA patients suffer from impaired cognitive performance, decreased productivity, memory loss, poor concentration, irritability and reduced libido. (50, 51) A meta-analysis

by Beebe et al. demonstrated that OSA has a very significant effect on vigilance. This result indicates that OSA markedly impairs the sufferer's ability to sustain attention for extended periods. (52)

Not only are OSA patients negatively impacted by their symptoms, but their bed partners have also been shown to suffer. Treatment of OSA patients has been shown to improve quality of life in both OSA patients and their bed partners. For example, Parish et al. conducted a study in which 54 patients with OSA were treated with CPAP for 6 weeks. (53) The patients and their bed partners completed the same set of questionnaires before and after treatment. Following treatment, bed partners also showed significant improvement in quality of life.

OSA is considered to be a chronic disease that requires lifelong management and is associated with increased mortality in patients not receiving any treatment, making it a significant public health concern. (54) Therefore, chronic disease management strategies need to be developed to provide clinically effective treatment of OSA on a long-term basis.

Association of CRP with Cardiovascular Disease and OSA

The biomarker C-reactive protein (CRP) is an important serum marker of inflammation and has been associated with an increased risk of developing cardiovascular and cerebrovascular disease. (55, 56) It is synthesized from the liver and regulated by cytokines. (57) But unlike cytokines, CRP levels are quite stable in the same individual across 24 hours and may reflect the level of inflammatory response. (58) Epidemiological studies show that an elevated CRP level in the high normal range in apparently healthy

men and women is a strong predictor of cardiovascular disease. (59, 60) Higher CRP is also associated with future cardiovascular events in patients with acute coronary artery disease, stable angina, or a history of myocardial infarction. (61, 62)

CRP can be measured with high-sensitivity assays measured as high-sensitivity C-reactive protein (hsCRP). hsCRP is a classical acute phase reactant and a widely used inflammatory biomarker. (23, 63-68) Circulating levels of hsCRP have been used to assess changes in inflammation that may occur with treatment of OSA, and most studies show higher levels of hsCRP in individuals with OSA. (64)

Fragmented sleep and intermittent hypoxia in OSA patients leads to increased sympathetic activity and endothelial dysfunction with elevated CRP levels. (69-72) CRP has a direct role in cell adhesion molecular expression and opsonizes low-density lipoprotein (LDL) for uptake by macrophages in atherosclerotic plaque. (73-76) This suggests that CRP may have an important and direct role in the development of atherosclerotic lesions and in promoting cardiovascular morbidity. (71)

Non-Surgical Treatment of OSA

Mild OSA may be improved through behavioural interventions such as weight loss in obese patients and the avoidance of alcohol and sedatives. (77) Studies have demonstrated that weight loss, whether by medical or by surgical techniques, has a beneficial effect in a minority of obese OSA patients. (15, 78) However, long-term weight maintenance is difficult to sustain. Based on the definition of long-term weight

loss as losing at least 10% of initial body weight and maintaining the loss for at least 1 year, only around 20% of people in the general population are successful at long-term weight loss maintenance. (79)

It is important to note that substantial portions of patients with OSA are not obese. Data collected from more than 1,500 individuals in the Wisconsin sleep cohort indicate that, among the non-obese, almost 5% of men and 1% of women aged 30-49 years have moderate to severe OSA. (13, 80) A study by Gray et al. (80) collected data from 163 consecutive in-laboratory diagnostic sleep studies on participants referred for suspected OSA. 25% of the participants with a diagnosis of OSA had a BMI within the normal range of <25 kg/m^2 and 54% had a BMI of <30 kg/m^2 (and were hence non-obese). In addition, of the patients prescribed CPAP, more non-obese patients reported not using their CPAP machine at all at follow-up (36% vs. 13%, p=0.03). Interestingly, a recent review by Joosten et al. showed that long-term treatment of OSA with CPAP is associated with a small but significant weight gain. (78) They believe the weight gain is due to the elimination of increased work of breathing associated with OSA.

Positional therapy is another recognized effective behavioural treatment of OSA. (77, 78) Patients with OSA who sleep in the supine position experience prolonged respiratory events, greater oxygen desaturation, longer arousals from sleep, and louder snoring than those who sleep laterally. (77) Sleep posture can be altered during sleep to a more lateral position by using adjuncts such as pillows or body belts. This improves lung volume,

neuromuscular activity, and airway size, which enhances airway support and reduced collapsibility. (81)

Oral appliances have also been used in the treatment of OSA. Oral appliances advance the mandible and maintain a patent airway. The American Academy of Sleep Medicine (AASM) recommends oral appliances for the treatment of mild to moderate OSA in patients who prefer them to CPAP therapy or who do not respond to CPAP therapy. (82) Studies have demonstrated that oral appliances were effective in mild to moderate cases of OSA but less effective than CPAP in more severe cases. (83, 84) Adverse effects associated with oral appliances include excessive salivation, gagging, dryness of the tongue and throat, development of dental malocclusion, pain in the teeth and jaw, insomnia, and, in extreme cases, dislocation of the jaw. (77, 85, 86) Also, compliance with dental devices has been shown to diminish over time. A long-term study of 32 male patients with OSA showed that compliance dropped from 82% at 1 year to 62% at 4 years. (87) More importantly, it is difficult to determine which patients are eligible for oral appliance therapy since there are no standardized parameters to predict treatment success. (88)

CPAP has proven to be a very effective first-line therapy for patients with OSA. (89) Significant improvements in quality of life, neurocognitive function, and levels of inflammatory biomarkers (23, 63-68) have been demonstrated following the use of CPAP. (89) Effective treatment of severe OSA by CPAP reduces the risk of cardiovascular events. (45)

CPAP works by keeping the pharyngeal airway patent throughout the duration of sleep, thereby acting as a pneumatic splint.(90) This splint function alleviates symptoms resulting from upper airway obstruction that lead to inadequate sleep. A meta-analysis conducted by Patel et al. concluded that CPAP improves both objective and subjective measures of sleepiness, especially in patients with severe OSA (AHI $\geq$ 30) and severe sleepiness (ESS $\geq$ 11). (91) Although CPAP has been adopted as the gold standard for non-invasive treatment of OSA, poor tolerance of and compliance with the treatment have been the main drawbacks in its use. When CPAP adherence is defined as 4 hours or greater of nightly use, 29-83% of patients with OSA have been reported to be non-adherent to treatment. (92) This non-adherence is mainly due to mask discomfort, nasal drying, nasal irritation, and intolerance of pressure. It is estimated that 50% of patients discontinue the use of CPAP within 1 year after having it prescribed to them for treatment. (93, 94) This leaves OSA patients inadequately treated and at increased risk for cardiovascular events and diminished quality of life. (45)

Surgical Treatment of OSA

Several surgical techniques have been adopted for the treatment of OSA. In adults, surgical treatments aim to treat OSA by relieving the airway obstruction by bypassing the pharyngeal airway or increasing the overall volume of the airway.

A surgical option that is rarely used but is very effective is a tracheostomy. A tracheostomy bypasses the upper airway and is therefore very efficacious at treating

upper airway obstruction. It does however have several drawbacks. Most notably, it leads to patient dissatisfaction as a result of psychosocial implications of the surgery. (95) Tracheostomy is also associated with perioperative complications, recurrent bronchitis, granulation tissue, trachea-innominate fistula formation, and stoma stenosis. (95) It is therefore reserved for highly select cases: severe cases of OSA whose patients cannot tolerate CPAP or any other surgical intervention.

A common surgical technique that has been used for the treatment of OSA is the uvulopalatopharyngoplasty (UPPP). (96) UPPP is a surgical procedure that ideally enlarges the oropharyngeal airway lumen by excising redundant tissues from the soft palate, tonsillar pillars and uvula. As reported by Holty and Guilleminault, (97) several meta-analyses have reported surgical success rates (AHI < 20/h and a reduction in AHI of $\geq$ 50%) following UPPP for OSA to be between 40% and 60%, and a surgical cure rate (AHI <5/h) of only 16%. (98-100) This low success rate is due to the fact that a UPPP only addresses the obstruction of the palate and tonsils at a single level of the airway. Most patients with OSA have a multilevel expression of the disease with obstructions in the oropharynx and hypopharynx; therefore, the appropriate surgical treatment should be multilevel. (98) In 1984, Fujita initially recognized that half of the patients who underwent UPPP were non-responders, and were identified as having multilevel obstruction, with 36 out of 66 patients (54.5%) being found to have combined oropharyngeal and hypopharyngeal obstruction. (98, 101) In 1993, Riley et al. outlined a multilevel classification whereby patients were divided into three categories: Type 1 (oropharyngeal obstruction only), Type 2 (combination of oropharyngeal and

hypopharyngeal obstruction), and Type 3 (hypopharyngeal obstruction only). (98, 102) Out of 239 patients, 223 patients (93.3%) were found to have a Type 2 obstruction (combined oropharyngeal and hypopharyngeal obstruction). Studies have also shown recurrence of OSA following UPPP. In 2000, Boot et al. published results of their long-term follow-up of patients who underwent UPPP for the treatment of OSA. (103) The study included 58 patients with a follow-up period of 11 to 74 months (median 34 months). Following surgery, when comparing results at 6 months with long-term follow up at 11 to 74 months, excessive daytime sleepiness showed a relapse to preoperative levels. The initial improvement in oxygen desaturation index had also decreased significantly between 6 months and long-term follow-up.

Maxillomandibular Advancement (MMA) surgery, a specific type of orthognathic surgery, has emerged as the definitive treatment of OSA for patients not able to tolerate CPAP. It was first suggested as an alternative to tracheostomy for the treatment of OSA in 1979. (104) MMA is the most effective single stage surgery available for treatment of OSA with very high success rates (57-100%). (105) MMA has also been shown to eliminate the need for CPAP use in the majority of patients. (106) Obstruction at the levels of the nasopharynx, oropharynx and hypopharynx are a result of maxillomandibular deficiency, which leads to diminished airway dimension. (107) MMA has been shown to enlarge the pharyngeal and hypopharyngeal airway by physically expanding the facial skeletal framework. (105) Expansion of the upper airway by MMA is most commonly achieved by advancing the maxilla via a LeFort I osteotomy, and by advancing the mandible using a bilateral sagittal split osteotomy (BSSO). (43) These

procedures may also be performed in combination with an advancement genioplasty in patients with anterior mandibular deficiency. A genioplasty involves repositioning the oropharyngeal tongue base by advancing the tongue's attachment at the genial tubercle, further expanding the pharyngeal airway. The soft palate, tongue, hyoid bone and associated muscles are attached directly or indirectly to the maxilla and mandible. MMA leads to the anterior movement of the soft palate, tongue, and anterior pharyngeal tissues, resulting in an increase in volume of the nasopharynx, oropharynx and hypopharynx, therefore increasing the posterior airway space.(108)

Adverse functional outcomes following MMA surgery

Although MMA has proven to be a clinically effective and safe long-term treatment for OSA (109), the suitability of widespread MMA has been questioned because of its perceived lack of multicenter data and the potential for increased morbidity over other methods of treatment, as surgery is not without risk. (97)

The most frequently reported complication of MMA is sensory loss in the distribution of the mental nerve. (110) Following a BSSO, the inferior alveolar nerve is at particular risk of transection, compression, stretching, edema, and pressure from fixation screws. The incidence of neurosensory disturbance after a BSSO is reported to be between 9% and 85%. (111) A systematic review by Holty and Guilleminault found that facial paresthesia was common, occurring in 100% of patients who underwent a BSSO, but it resolved in 85.8% of patients 12 months post-operatively. (97) In another prospective study by Boyd et al. that included 30 patients, no patients exhibited anesthesia of the lips or chin. (109) 40% of MMA patients did perceive a subjective decrease in sensation. However, those

patients with decreased sensation rated the change as no problem to only a small to moderate problem.

Complications from MMA are infrequent. In a prospective long-term study by Boyd et al. that followed 30 patients who underwent MMA for OSA, no patient had adverse perioperative cardiac, respiratory or neurologic events. (109) 6.7% of patients (2 of the 30) experienced a wound infection and were effectively treated by local measures and oral antibiotics without the use of intravenous antibiotics or re-hospitalization. In a systematic review looking at 455 consecutive patients, no deaths were reported. (97) Only 4 major complications (1%) were reported (2 cardiac arrests, one dysrhythmia and one mandibular fracture).

A Cochrane review by Brignardello-Petersen et al. in 2015 (112) showed that long-term antibiotic prophylaxis (LTAP) decreases the risk of surgical site infection (SSI) compared to short-term antibiotic prophylaxis (STAP) in patients undergoing orthognathic surgery. The results of their review suggest that patients who receive long-term (compared with short-term) antibiotic prophylaxis experience a reduction in the absolute risk of developing a SSI (from 168 SSIs per 1000 surgeries with short-term antibiotics to 71 SSIs per 1000 surgeries with long-term antibiotics).

General orthognathic surgery and specialized MMA surgery to treat OSA are used to treat vastly different dental and skeletal irregularities and thus tend to focus on different patient demographics. Orthognathic surgery patients are often young in age, and experience good overall health. Patients undergoing MMA for the treatment of OSA are often older in age, obese, and suffer from additional medical conditions. (109) Currently

there is no study specifically looking at OSA patients to suggest that a similar duration of prophylactic antibiotics would reduce infections following MMA surgery.

A factor that might influence referring physicians as well as prospective MMA surgery patients is the possibility of a change in a facial appearance. In MMA surgery, since expansion of the upper airway is the primary objective, the advancement of the maxilla and mandible are usually greater than in traditional orthognathic surgery. Some have reported unfavorable changes in facial appearance; however, many patients feel that the esthetic changes following MMA surgery have been positive. (113) A study by Beranger at al. looked at 23 patients who underwent MMA for the treatment of OSA. (114) 91.3% of patients were satisfied overall following surgery, 78.3% considered that their faces were improved or unchanged, 39.1% found their faces to be slimmer, and 34.8% thought they looked more youthful. In another study by Goodday et al., 89% of patients (8 out of 9) reported a favorable change in facial appearance following MMA, and 100% of patients (9 out of 9) considered the surgery a worthwhile experience. (115)

When considering MMA as a definitive treatment over CPAP, it is important that the patient, the surgeon, and the referring clinician be aware of possible adverse effects following surgery. In this study, we aim to assess possible adverse outcomes following MMA, including post-operative surgical site infections, neurosensory disturbances, and a changes in facial appearance.

CHAPTER 2 PURPOSE

The purpose of this comprehensive prospective study is to determine the clinical effectiveness and safety of MMA for the treatment of moderate to severe OSA in patients unable to adhere to CPAP therapy.

In this study, we used subjective and objective measures to determine if the treatment of moderate to severe OSA (AHI $\geq$15 events/h) by MMA resulted in significant improvement on several important health-related and functional outcomes.

CHAPTER 3 METHODS

Study Design

A prospective cohort study was designed to recruit patients undergoing MMA for treatment of moderate to severe OSA (AHI $\geq$ 15). Patients were referred to the Department of Oral & Maxillofacial Surgery at Dalhousie University in Halifax for assessment of their OSA for possible MMA.

Inclusion criteria used for participation in the study included: 1) Adults 18-65 years of age, 2) diagnosis of moderate to severe OSA (AHI $\geq$ 15) as interpreted by overnight Level I polysomnography (PSG) and 3) failure of CPAP therapy due to inadequate adherence (<4 hours of use <70% of nights) or non-acceptance of lifetime use of CPAP therapy.

The following exclusion criteria were used: 1) central or complex sleep apnea not amenable to surgical correction, 2) individuals who would not consider MMA as an alternative treatment to CPAP therapy, 3) previous upper airway surgery for OSA or craniofacial surgery, 4) presence of a craniofacial syndrome, 5) significantly elevated perioperative risk as determined by the surgeon (e.g. previous severe cardiorespiratory illness, respiratory failure, acute renal failure), 6) unstable cardiovascular disease, pulmonary disease, diabetes or psychiatric disease (excluding mood disorders such as depression), and 7) inability or unwillingness to give written informed consent.

Pre-MMA Evaluation (see Appendix A, B, C)

Each patient who met the study inclusion criteria was approached prior to MMA surgery by the treating Oral and Maxillofacial Surgeon or their designee, who provided an explanation of the study in detail, including the aims, study protocol, and potential benefits and risks of participating in the study. After giving their informed consent in writing, eligible study subjects underwent the following baseline assessments prior to undergoing MMA surgery: 1) comprehensive clinical evaluation including: medical history, sleep history, general physical exam, facial esthetics, nasal function, temporomandibular function, trigeminal and facial nerve function, dental occlusion, and oropharynx examination, 2) administration of the Epworth Sleepiness Scale and FOSQ surveys, 3) computer-based administration of the PVT test and 4) blood taken for hsCRP analysis.

The comprehensive clinical evaluation included a general medical and sleep-specific history, as well as a detailed physical examination. As part of the physical examination, measurements of height and body weight, blood pressure, heart rate, and neck circumference were taken, and a routine medical examination was performed. The physical also included a subjective and objective evaluation of the facial structures including the nose, temporomandibular joints, muscles of mastication, trigeminal and facial nerves, dental occlusion, and oropharynx.

Subjects had blood drawn at the time of their baseline/pre-operative visit, which was repeated at their subsequent 6-month follow-up evaluation. The blood samples were

analyzed for the inflammatory biomarker high sensitivity C-reactive protein (hsCRP). The results were used to determine the changes in levels of the biomarkers that occur following MMA treatment.

Maxillomandibular Advancement Surgery (MMA) and Peri-operative Management Evaluation (see Appendix D)

A standardized surgical procedure was performed on all patients, as has previously been reported. (97, 116-121) Once a patient was diagnosed with OSA by polysomnography, Delaire cephalometric analysis was performed in order to plan for surgical advancement of the maxilla and mandible to maximize the enlargement of the nasopharyngeal, retropalatal and hypopharyngeal airways. (43, 122, 123) Maxillomandibular retroposition is then treated by a combination of Lefort I osteotomies in the maxilla and bilateral sagittal split osteotomies (BSSO) in the mandible followed by rigid internal fixation with miniplates and monocortical screws, with adjunctive genioplasties performed during the same surgery for those deemed suitable.

A comprehensive perioperative evaluation form, which measures specified surgical and anesthetic findings, was completed for each participating patient during the time of their hospitalization for MMA. This evaluation facilitates a systematic and standardized assessment of the type and severity of all perioperative adverse outcomes associated with MMA.

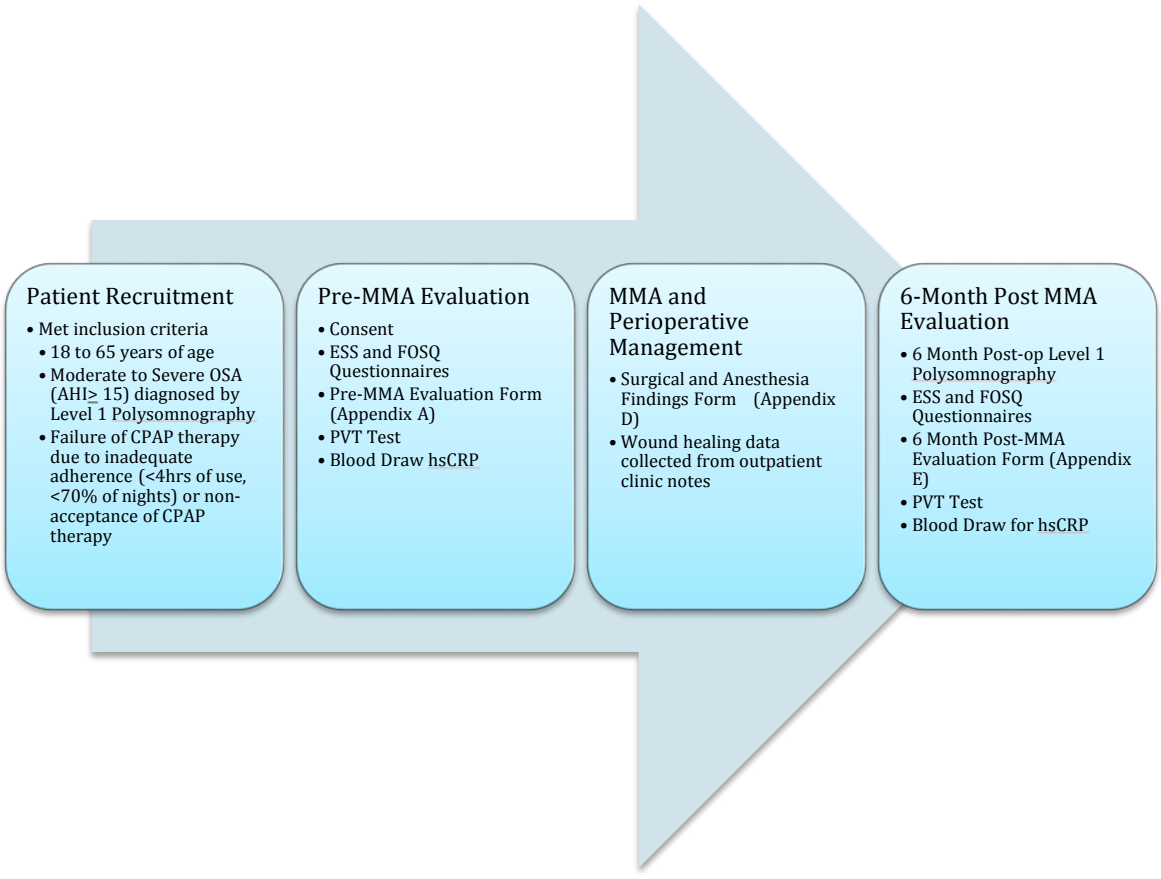
Additionally, a standardized assessment was completed at each post-operative clinic visit in order to assess any post-operative wound healing problems, neurosensory deficits of the trigeminal nerve, facial pain, malocclusion, mandibular mobility, and temporomandibular joint function.

Six-Month Post-MMA Evaluation (see Appendix E)

Patients who completed the pre-MMA evaluation, MMA surgery, and the perioperative evaluation, underwent a comprehensive 6-month post-MMA evaluation to determine the changes in all measured outcomes following MMA. This evaluation was essentially the same as the pre-MMA evaluation including the following assessments: 1) a comprehensive clinical evaluation including neurosensory testing, 2) administration of the Epworth Sleepiness Scale and FOSQ surveys, 3) computer-based administration of the PVT task neurocognitive test, 4) blood tests for inflammatory biomarker analysis of hsCRP, 5) post-MMA polysomnography, and 6) clinical assessment and recording of any adverse events or study-related problems since completion of MMA surgery. Patients who completed both the pre-MMA and 6-month post-MMA evaluations received compensation for their participation in the study in the amount of $100 Canadian dollars.

A flow chart depicting a summary of the study design is presented in Figure 1 below.

Figure 1 - Study Design Flow Chart



AHI: apnea-hypopnea index; CPAP: continuous positive airway pressure; MMA: maxillomandibular advancement surgery; ESS: Epworth sleepiness scale; FOSQ: functional outcomes of sleep questionnaire; PVT: psychomotor vigilance task test; hsCRP: high-sensitivity C-reactive protein

Sample Size Calculations

The sample size and power were calculated using an objective primary outcome measure and a subjective primary outcome measure. For our objective primary outcome measure, we calculated the sample size based on a previous study (124) that is similar to ours. The standard deviation (SD) of the difference in CRP between pre- and post-treatment was assumed to be similar to that study (i.e. SD=0.15), and a clinically meaningful difference

would be at least a half of the difference observed in that study (i.e. the assumed difference in the CRP = 0.09). Based on this finding, a total sample size of 30 would provide at least 90% power to detect clinically meaningful CRP differences before and after MMA surgery. For our subjective primary outcome measure, the primary outcome ESS was used to calculate the sample size. A range of the pre-surgical ESS score of 10 to 16 is typically considered as sleepy,(106) and we considered that at least an ESS score change of 3 would be clinically effective (from the median score of 13 as sleepy to the largest non-sleepy score of 10). With a conservatively inflated SD of 5 and a clinically meaningful pre- and post-surgical ESS score change of 3, a total sample size of 30 would provide at least 90% power to detect a clinically meaningful difference in ESS score pre- and post-MMA surgery. Thus, taking into account a drop-out rate of approximately 15% for patients lost to follow-up, a total sample size of 36 would provide at least 90% power to study the primary outcome measures.

Statistical Analysis

Descriptive statistical analysis was performed for all demographic and outcome variables for the pre-MMA and 6-month post-MMA data, and reported as mean ± standard deviation for continuous variables and frequency, and as a percent for categorical variables. In order to determine the treatment effect, the Wilcoxon signed rank test was used to test the null hypothesis that the change from the baseline in each outcome measured at the 6-month post-MMA would be zero. All analyses were performed with SPSS Statistics version 21 (SPSS, Inc., Chicago, UL, USA). A Shapiro-Wilk test was performed for the variables being compared to test for normality. Even though the sample

size was small, only 1 of the variables was not normally distributed. This was the post FOSQ variable. This comparison using non-normal data was analyzed using the Wilcoxon rank sum test, because one group in the comparison was not normally distributed. The Wilcoxon rank sum test normalizes non-normal data by assigning ranks to the raw data and comparing the ranks as opposed to the raw data. For the remaining variables, with normally distributed data, data was analyzed using t-tests. T-tests are used for parametric mean comparisons that assume normality. Significance was accepted as $p<0.05$.

Data Collection

Primary objective measures included the high-sensitivity C-reactive protein (hsCRP) biomarker which was analyzed in the lab, the Apnea-Hypopnea Index (AHI) measured by polysomnography, and the Psychomotor Vigilance Task (PVT) reaction times measured by computer-based neurocognitive testing. Using the PVT, the outcome measure used was the 1/RT, which is the mean reciprocal reaction time (RT) in $seconds^{-1}$. Blood pressure and BMI measurements were compared from the pre-MMA evaluation and at 6-month post-MMA evaluation.

Primary subjective measures included changes in the Epworth Sleepiness Scale (ESS) and Functional Outcomes of Sleep (FOSQ) questionnaires. Secondary measures included assessment of surgical site infections and how they were managed, changes in facial appearance, and post-operative numbness.

We assessed changes in facial appearance by asking our patients if they felt there was a change in their facial appearance following surgery. If they answered yes, we further asked whether they felt it was a favourable, unfavourable or neutral change.

Postoperative paresthesia was assessed by asking our patients if they experienced any post-operative numbness. If they did, the site of post-operative deficit was documented and the patients were asked how much of a problem it was, on a scale of 5 possible answers ranging from not a problem to a severe problem.

A summary of the primary and secondary outcome measures are listed below:

Summary of Primary Outcome Measures

1. Determine the changes in the following objective measurements following MMA for the treatment of OSA:

I. Apnea-Hypopnea Index (AHI): objective measure of OSA by polysomnography

II. Inflammatory biomarker high-sensitivity CRP (hsCRP) indicative of cardiovascular disease

III. Neurocognitive function as measured by the Psychomotor Vigilance Task (PVT) test

IV. Changes in Blood Pressure (BP)

V. Changes in Body Mass Index (BMI)

2. Determine the changes in the following subjective measurements following MMA for the treatment of OSA:

I. Changes in sleepiness measured by the Epworth Sleepiness Scale (ESS)

II. Changes in quality of life measured by the Functional Outcomes of Sleep Questionnaire (FOSQ)

Summary of secondary Outcome Measures

I. Assessment of rates of surgical site infections following MMA for OSA

II. Assessment of neurosensory disturbance as a result of MMA

III. Assessment of patient's attitudes towards a change in their facial appearance

A summary of the primary and secondary outcome measures are presented in Figure 2 below.

Figure 2 - Summary of primary and secondary outcome measures

Primary Outcome Measures

Objective

Apnea-Hypopnea Index (AHI)
High sensitivity C-reactive protein (hsCRP)
Psychomotor Vigilance Task (PVT)
Blood Pressure (BP)
Body Mass Index (BMI)

Subjective

Epworth Sleepiness Score (ESS)
Functional Outcomes of Sleep Questionnaire (FOSQ)

Secondary Outcome Measures

Rates of Surgical Site Infections (SSI)
Neurosensory disturbance
Change in facial appearance

CHAPTER 4 RESULTS

Patient Characteristics

Within the allotted timeframe provided for this study, twelve patients were recruited from February 2015 to March 2016 who met the inclusion criteria and were enrolled in the study. Nine patients completed all the pre-operative and post-operative assessments. Two patients did not complete the post-operative assessments due to loss to follow-up (i.e. they did not attend the follow-up appointment), and one patient's surgery was postponed due to illness and could not be included in the study.

The mean age was 48$\pm$6.4 [mean$\pm$SD] years of age. Five patients were male (55.6%) and four patients were female (44.4%). The average length of follow-up for post-operative assessment was 278.3 days (9.9 months). Due to the high demand and long waitlist of patients waiting to undergo sleep studies, adhering to the 6-month follow-up time frame was challenging. As soon as patients completed their post-MMA follow-up polysomnography, whether it was completed at 6 months or later, they were seen in clinic soon thereafter for their post-MMA evaluation.

Pre-operatively, the average patient was obese with a BMI of 30.9±5.95 and the average AHI was severe 31.1±13.56. The patients' pre-operative demographic data is presented in Table 1.

Table 1 - Patient Pre-Operative Demographics

Patient	Age (years)	Gender	BMI (kg/m^2)	AHI (events/h)	Length of Follow-up (days)
1	55	Female	18.3	27.3	271
2	50	Male	33.4	47.4	382
3	52	Female	35.8	16.9	349
4	50	Male	28.1	17.3	315
5	35	Female	38.3	41	230
6	47	Male	35.4	26.2	194
7	44	Male	31.3	21	203
8	55	Female	28.6	28.3	300
9	44	Male	28.5	54.9	261
Mean±SD	**48.0±6.4**	**M 55.6%, F 44.4%**	**30.9±5.95**	**31.1±13.56**	**278.3±64.26**

SD: standard deviation; M: male; F: female, BMI: body mass index, AHI: apnea-hypopnea index

Primary Objective and Subjective Outcome Measures

Complete lists of all patients' pre-operative and post-operative results are presented in the tables below. The primary objective outcome measures are divided into two tables, Table 2 shows the results of variables: AHI, hsCRP and PVT, and Table 3 shows the results of variables: systolic blood pressure (SBP), diastolic blood pressure (DBP), and BMI.

Table 2 – Primary Objective Outcome Measures (AHI, hsCRP, PVT)

Patient	Pre-AHI (events/h)	Post-AHI (events/h)	Pre-hsCRP (mg/L)	Post-hsCRP (mg/L)	Pre-PVT(1/RT) (seconds)	Post-PVT(1/RT) (seconds)
1	27.3	1.5	1	0.8	2.96	3.02
2	47.4	6.1	4.6	2.3	3.2	2.98
3	16.9	1.4	3.2	3.9	2.23	2.71
4	17.3	4.5	0.8	0.7	2.63	2.87
5	41	0.1	4.1	6	3.12	3.27
6	26.2	9.7	5.8	4.5	2.53	2.77
7	21	3.7	0.6	0.5	3.04	3.26
8	28.3	1.8	2.42	0.74	2.64	2.96
9	54.9	35.3	3.09	0.83	2.72	3.55
Mean	**31.1**	**7.1**	**2.85**	**2.25**	**2.79**	**3.04**
SD	**13.56**	**10.97**	**1.82**	**2.05**	**0.32**	**0.27**
Median	**27.3**	**3.7**	**3.09**	**0.83**	**2.72**	**2.98**

AHI: apnea-hypopnea index; hsCRP: high-sensitivity C-reactive protein, PVT: psychomotor vigilance task test; RT: reaction time; 1/RT: reciprocal reaction time in seconds; SD: standard deviation

Table 3 – Primary Objective Outcome Measures (SBP, DBP, BMI)

Patient	Pre-SBP (mmHg)	Post-SBP (mmHg)	Pre-DBP (mmHg)	Post-DBP (mmHg)	Pre-BMI (kg/m^2)	Post-BMI (kg/m^2)
1	106	94	67	59	18.3	19.1
2	149	144	96	81	33.4	32.7
3	116	118	72	75	35.8	32.5
4	113	107	78	70	28.1	28.9
5	112	137	78	86	38.3	38.5
6	115	110	84	73	35.4	30.5
7	139	133	86	85	31.3	29.1
8	140	134	82	78	28.6	26.8
9	165	154	100	106	28.5	28.9
Mean	**128.3**	**125.7**	**82.6**	**79.2**	**30.9**	**29.7**
SD	**20.47**	**19.51**	**10.57**	**13.00**	**5.95**	**5.21**
Median	**116**	**133**	**82**	**78**	**31.3**	**29.1**

SBP: systolic blood pressure; DBP: diastolic blood pressure; BMI: Body Mass Index; SD: standard deviation

Table 4 shows the results of the primary subjective outcome measures that include ESS and FOSQ.

Table 4 – Primary Subjective Outcome Measures

Patient	Pre-ESS Score	Post-ESS Score	Pre-FOSQ Score	Post-FOSQ Score
1	9	3	13.2	19.4
2	15	0	17.9	19.9
3	17	3	9.9	17.5
4	13	7	14.5	17.9
5	12	3	7.7	16.6
6	7	9	12.3	10.8
7	17	7	16.1	18.2
8	19	6	12.8	20
9	10	1	16	19.9
Mean	**13.2**	**4.3**	**13.4**	**17.8**
SD	**4.09**	**3.04**	**3.20**	**2.89**
Median	**13**	**3**	**13.2**	**18.2**

ESS: Epworth sleepiness scale; FOSQ: functional outcomes of sleep questionnaire; SD: standard deviation

A summary of the pre-operative and post-operative primary objective and subjective outcome measures is presented in Table 5.

Table 5 - Summary of Primary Objective and Subjective Outcome Measures

Outcome	Pre-MMA	Post-MMA	Mean Change	P value
Objective Outcomes				
AHI score, mean ± SD	31.14±13.56	7.12±10.97	-24.02±2.59	<0.01
Median	27.3	3.7		
hsCRP (mg/L), mean ± SD	2.85±1.82	2.25±2.05	-0.59±0.24	>0.05
Median	3.09	0.83		
PVT (1/RT), mean ± SD	2.79±0.32	3.04±0.27	0.26±0.05	<0.05
Median	2.72	2.98		
Systolic BP, mean ± SD	128.33±20.47	125.67±19.51	-2.67±0.96	>0.05
Median	116	133		
Diastolic BP, mean ± SD	82.56±10.57	79.22±13	-3.33±2.43	>0.05
Median	82	78		
BMI, mean ± SD	30.86±5.95	29.67±5.21	-1.19±0.74	>0.05
Median	31.3	29.1		
Subjective Outcomes				
ESS Score, mean ± SD	13.22±4.09	4.33±3.04	-8.89±1.04	<0.01
Median	13	3		
FOSQ Score, mean ± SD	13.38±3.2	17.8±2.9	4.42±0.31	<0.01
Median	13.2	18.2		

P values shown are based on Wilcoxon signed rank test and t tests for differences between baseline and post-operative measurements. MMA: maxillomandibular advancement surgery; AHI: apnea-hypopnea Index; hsCRP: high sensitivity C-reactive protein; PVT: psychomotor vigilance task; 1/RT: mean reciprocal reaction time (RT) in seconds; RT: reaction time; BP: blood pressure; BMI: body mass index; ESS: Epworth Sleepiness Scale; FOSQ: Functional Outcomes of Sleep Questionnaire.

Secondary Outcome Measures

From the nine patients, three patients did experience minor post-op infections, which were treated with oral antibiotics and local irrigation. All the three infections were in the mandible. Only one patient required removal of a mandibular fixation plate. The data collected regarding surgical site infections is presented in Table 6.

Table 6 - Surgical Site Infections

Patients	Wound infection	Days after MMA	Site of infection	Management of infection	Post-Op Antibiotics	Length of Post-Op Antibiotics (days)	Bone plate removed
1	**Yes**	27	Mandible	Oral Abx/local irrigation	Yes	1	No
2	**Yes**	18	Mandible	Oral Abx/local irrigation	Yes	1	Yes
3	No				Yes	1	No
4	**Yes**	14	Mandible	Oral Abx/local irrigation	Yes	1	No
5	No				Yes	1	No
6	No				Yes	1	No
7	No				Yes	3	No
8	No				Yes	1	No
9	No				Yes	1	No

MMA: maxillomandibular advancement surgery; Abx: antibiotics

All patients felt there was a change in their facial appearance. Five patients felt it was a favourable change, three answered that it was neutral, and one felt it was unfavourable. Results of patients' attitudes towards a perceived change in their facial appearance are presented in Table 7.

Table 7 – Changes in Facial Appearance

Patients	Was there a change?	Type of Facial Change
1	Yes	Favorable
2	Yes	Favorable
3	Yes	Favorable
4	Yes	Neutral
5	Yes	Neutral
6	Yes	Neutral
7	Yes	Unfavorable
8	Yes	Favorable
9	Yes	Favorable

Six out of nine patients experienced post-operative numbness. One patient felt it was not a problem, three felt it was a very mild problem, and one felt it was a fairly bad problem. The results of neurosensory deficits following MMA surgery are presented in table 8.

Table 8 –Neurosensory Deficits

Patients	Post-Op numbness	Site of Post Deficit	How much of a problem
1	Yes	LLL, RLL, Chin	Very mild problem
2	Yes	LLL, RLL, Chin	Moderate problem
3	Yes	LUL	Fairly bad problem
4	Yes	LLL, RLL, Chin	Not a problem
5	No		
6	No		
7	Yes	Chin	Very mild problem
8	No		
9	Yes	Chin	Very mild problem

LLL: left lower lip, LUL: left upper lip, RLL: right lower lip

CHAPTER 5 DISCUSSION

Objective Primary Outcome Measures (AHI, hsCRP, PVT, BP, BMI)

Apnea-Hypopnea Index (AHI)

Based on the criteria for treatment effectiveness which is defined as a post-operative AHI of <5 or an AHI of $\leq$15 with no significant symptoms of sleepiness as assessed by an ESS of $\leq$10, 100% of patients were treated effectively. The AHI in our cohort of patients went from a mean pre-operative AHI of 31.14$\pm$13.56 to a post-operative AHI of 7.12$\pm$10.97 ($p<0.01$), which was statistically significant.

It is worth noting that patient number 9 had a post-op AHI of 35.3, down from 54.9 pre-operatively (see Table 2). Their high post-operative AHI result increased the post-operative mean significantly. If this patient's AHI were excluded, the post-operative mean AHI would have been 3.2 instead of 7.1. Although there was not a significant drop in this patient's AHI, the patient's ESS dropped from 10 to 1, and their FOSQ improved from 16 to 19.9 (see Table 4). This signifies that although the objective measurement of their AHI did not have a significant drop, their symptoms of hypersomnolence and quality of life did greatly improve.

Six out of nine patients who had moderate to severe OSA with AHI's of $\geq$ 15 events/h, ended up with an AHI of <5 events/h post-operatively. Of the remaining three patients (patients 2,6 and 9) who had post-operative AHI's of >5 events/h, two of the three patients had a dramatic improvement according to their ESS and FOSQ. Patient number 2 had a drop in ESS from 15 pre-operatively to 0 post-operatively, and their FOSQ

improved from 17.9 pre-operatively to 19.9 post-operatively. Similarly, patient number 9's ESS dropped from an ESS of 10 pre-operatively to an ESS of 1 post-operatively. Both patients showed significant improvement in their symptoms of sleepiness and quality of life. One of the three patients who had a post-operative AHI >5 events/h, patient number 6, did not show any improvement in ESS which worsened from a pre-operative ESS of 7 to a post-operative ESS of 9, and their FOSQ also worsened from a pre-operative FOSQ of 12.3 to a post-operative FOSQ of 10.8, even though they did have a drop in their AHI from a moderate pre-AHI of 26.2 events/h to a mild post AHI of 9.7 events/h.

High sensitivity C-Reactive Protein (hsCRP)

A meta-analysis by Nadeem et al. (125) that looked at the association between multiple inflammatory markers and OSA, including CRP, found that the levels of systemic inflammatory markers were found to be higher in OSA patients compared to control subjects.

Shamsuzzaman et al. (64) studied 22 patients with newly diagnosed OSA who were free of other diseases, had never been treated for OSA, and were taking no medications. They then compared CRP measurements in these patients to measurements obtained in 20 control subjects who were matched for age and body mass index, and in whom occult OSA was excluded. They found that Plasma CRP levels were significantly higher in patients with OSA than in controls (median [range] 0.33 [0.09 to 2.73] versus 0.09 [0.02 to 0.9] mg/dL, $P<0.0003$). In multivariate analysis, CRP levels were independently

associated with OSA severity (F=6.8, *P*=0.032). The two novel findings presented in their study included firstly that OSA was associated with elevated levels of CRP, and secondly that the severity of OSA is proportional to the plasma CRP levels.

Another study assessed the effect that non-surgical treatment of OSA has on levels of CRP and was conducted by Yokoe et al. (65) The study looked at the effect of nasal continuous positive airway pressure (nCPAP) on serum levels of CRP and interleukin-6 (IL-6). After patients underwent polysomnography, blood was collected from 30 patients diagnosed with OSA and 14 obese control subjects. Patients with moderate to severe OSA were treated with 1 month of nCPAP. Serum levels of CRP and IL-6 were investigated in both groups of patients. Levels of CRP and IL-6 were significantly higher in patients with OSA than in obese control subjects. Also, treatment with nCPAP significantly decreased levels of both CRP and IL-6. In conclusion, the researchers found that levels of CRP and IL-6 are elevated in patients with OSA and are decreased by treatment of OSA, in this case using nCPAP.

Kezirian et al. (124) evaluated the impact that surgery had on multilevel obstruction in patients with OSA who were unable to tolerate CPAP. Patients underwent uvulopalatopharyngoplasty (UPPP), tonsillectomy, and genioglossus advancement, with or without hyoid suspension. All patients underwent pre-operative and post-operative blood testing for C-reactive protein as part of their assessments. Responders to the surgery were defined as patients who post-operatively had an AHI reduction of $\geq$ 50% compared to their pre-operative AHI, with an absolute AHI level of <15. These responders to the surgery demonstrated a decrease in CRP of -1.02$\pm$0.98mg/L (p=0.003),

that was independent of changes in body weight.

In contrast, a study by Taheri et al. (126) found no independent relationship between CRP levels and indices of SDB in 907 adults enrolled in the Wisconsin sleep cohort who underwent inpatient polysomnography. They concluded that lack of an independent association between CRP levels and SDB suggests that the reported relationship between these two variables may be primarily driven by their association with obesity.

In our cohort of patients, there was a drop in hsCRP from a pre-operative mean of 2.85$\pm$1.82mg/L to 2.25$\pm$2.05mg/L ($p>0.05$) post-operatively, with a mean change of -0.59$\pm$0.24mg/L ($p>0.05$). Although there was an observed decrease in hsCRP, it did not reach statistical significance. Our results are more consistent with Taheri et al.'s findings. In our cohort, there was no significant drop in BMI. The BMI went from a pre-MMA mean of 30.86$\pm$5.95kg/m^2 to a post-MMA of 29.67$\pm$5.21kg/m^2 ($p>0.05$). However, the drop in BMI was not statistically significant and so no evidence based conclusions can be drawn from the results. A larger cohort would have benefited the strength of the results.

Psychomotor Vigilance Task (PVT)

Batool-Anwar et al. (127) evaluated the effects of OSA on attentiveness and vigilance by conducting a cross-sectional study to examine the association between OSA and psychomotor vigilance task (PVT) performance. Patients attending sleep clinics for the evaluation of possible sleep apnea were recruited. The subjects underwent either a standard overnight laboratory polysomnography or a home sleep study. Subjective daytime sleepiness was assessed by the Epworth sleepiness scale, and vigilance was tested using a portable device. The participants were asked to respond to the PVT signals

using their dominant hand. Each PVT administration lasted 10 minutes, with stimuli signals appearing randomly at variable intervals of 2–10 seconds. The mean age of the participants was 46±15 years, and mean body mass index was 34.3±9.8 kg/m^2. Participants with higher ESS scores had worse PVT performance ($p<0.05$). In multivariate analyses, age, body mass index, and poor sleep efficiency were associated with worse PVT performance ($p<0.05$).

Lee et al. (33) conducted a study to examine the relationship between PVT performance (lapse and average response time) and fatigue. They demonstrated that the PVT count of lapses was significantly associated with physical symptoms of fatigue. Vigilance was assessed with the Psychomotor Vigilance Test (PVT).(128) From each PVT trial, reaction times (RTs) were collected. Two performance variables, average response time and number of lapses (i.e. failures to respond or RT > 500 msec), were extracted using a software program. 48 patients had their sleep monitored with polysomnography. Fatigue was assessed and the 10-minute PVT was administered. The main outcome variable was the PVT lapse count. The PVT lapse count was significantly associated with physical fatigue ($r=0.324, p=0.025$).

A study conducted by Kim et al. assessing the association between sleep-disordered breathing and vigilance performance in a large community-based sample using PVT showed a mean 1/RT of 3.97 in patients with AHI's of > 15. (129) Although there was no significant difference in 1/RT between mild (3.96), moderate (3.87) and severe (3.97) AHI categories in the study, there was a difference between gender and age groups. 1/RT in males was worse in older age groups, as seen with a drop in 1/RT in the older age

groups, hence a slower reaction time: 4.23 (ages 35-44), 4.08 (ages 45-54), 3.95 (ages 55-64) and 3.88 (ages 65-74). Similarly, females showed the same trend across age and also showed slower reaction times compared to the male groups: 3.98 (ages 35-44), 3.84 (ages 45-54), 3.77 (ages 55-64) and 3.76 (ages 65-74).

In our study, the PVT performance outcome was measured as a response speed defined as mean 1/RT, or reciprocal response time, during the 10-minute testing period. As 1/RT is the measurement of a reciprocal response time, a greater number translates to a quicker response time. The mean response time improved from 2.79 pre-operatively to 3.04 post-operatively ($p<0.01$), a change that was statistically significant.

A draw back that should be mentioned in this study is that there were no controls to compare with. The design of future research could be improved by introducing a control group. In addition, improvements in reaction time may also be in part attributed to practice effect, as it may be easier the second time a subject performs the test.

Blood Pressure (BP)

Previous studies have shown a decrease in blood pressure following MMA surgery for treatment of OSA. A study by Boyd et al. showed a decrease in SBP and DBP of -3.5 mmHg and -4.8 mmHg respectively in patients following MMA surgery. (109) A systematic review and meta-analysis by Schein et al. also showed drops of SBP -3.2 mmHg and DBP -2.9mmHg following CPAP treatment. (130)

In our study there was a decrease in both systolic and diastolic blood pressures, although it did not reach statistical significance. There was a mean drop in systolic blood pressure (SBP) from 128.3±20.47 mmHg to 125.7±19.51 mmHg ($p>0.05$) along with a drop in diastolic blood pressure (DBP) from 82.56±10.57 mmHg to 79.22±13 mmHg ($p>0.05$). The mean drop in SBP was -2.67±0.96 mmHg, while the mean drop in DBP was -3.33±2.43 mmHg.

Body Mass Index (BMI)

Although there also was a decrease in the mean BMI from 30.86±5.95 to 29.67±5.21, with a mean change of -1.19 ±0.74 it did not reach statistical significance ($p>0.05$).

The insignificant change in BMI suggests that the success of MMA could not simply be attributed to weight loss. As previously mentioned, 100% of our patients were treated effectively. Although obesity is a risk factor for OSA, it is important to address the site of functional obstruction in the upper airway. This emphasizes the importance of performing the appropriate investigations, in potential MMA surgery candidates, to correctly identify the etiology of upper airway obstruction.

Subjective Primary Outcome Measures (ESS, FOSQ)

Epworth Sleepiness Scale (ESS)

A meta-analysis by Crawford et al. (131) that showed high use of CPAP (>4 h average nightly use) was associated with a 4.2 ESS score reduction. Another study by Antic et al. (132) also reported that >7 hours of CPAP use resulted in normalization of ESS in 80.6% of patients with moderate to severe OSA. Another meta-analysis by Patel et al. (91)

showed that patients with severe OSA (AHI $\geq$ 30) and excessive daytime sleepiness (ESS $\geq$ 11) had a mean reduction in ESS scores of 4.75.

In our cohort, the mean ESS score dropped from 13.22$\pm$4.09 pre-operatively to 4.3$\pm$3.04 post-operatively, with a mean ESS score reduction of 8.89$\pm$1.04 and reached statistical significance ($p<0.01$). All nine patients enrolled in this study had normal ESS scores (ESS $\leq$ 10) following MMA.

Functional Outcomes of Sleep Questionnaire (FOSQ)

Changes in FOSQ scores reported by Lye et al. (133) showed a mean change of 4.5 in patients following MMA. Another study by Doff et al. reported a mean change in FOSQ score of 3.2 after two years of CPAP use. (134) Strollo et al. also showed a mean FOSQ score change of 2.9 following hypoglossal nerve stimulation. (135)

Our results showed an improvement of FOSQ from a pre-operative mean of 13.38$\pm$3.2 improving to 17.8$\pm$2.9 post-operatively, with a mean improvement of 4.42$\pm$0.31, and reached statistical significance ($p<0.01$).

Secondary Outcome Measures (SSI, Facial Appearance)

Surgical Site Infection (SSI)

Three of the nine patients (33.3%) experienced minor post-operative infections. All patients who did have a post-operative infection had received a 24-hour course of

intravenous antibiotics following MMA surgery. All three infections were treated with oral antibiotics and local irrigation. One patient (11.1%) who had a minor post-operative surgical site infection went on to have a mandibular plate removed. All three infections were in the mandible. This suggests that the mandible is more prone to having a SSI than the maxilla, and the risk of requiring a plate removed is greater in patients who experience a SSI.

These results correlate with findings that were made from another study assessing the rates of SSI's in OSA patients receiving short-term antibiotic prophylaxis (STAP) vs long-term antibiotic prophylaxis (LTAP). A two-center retrospective cohort study was conducted between Dalhousie University (DU) and Vanderbilt University Medical Center (VUMC). The study looked at the efficacy of STAP compared to LTAP for preventing infections in patients undergoing MMA for OSA. STAP was defined as antibiotic prophylaxis administered before and during surgery, and up to 24 hours after surgery. LTAP was defined as antibiotic prophylaxis administered before and during surgery, and longer than 24 hours after surgery. The results were presented as an abstract at the American Association of Oral and Maxillofacial Surgeons (AAOMS) annual meeting in September 2016. (136) The study included 216 patients who underwent MMA for the treatment of OSA at either DU or VUMC. All DU patients qualified for the STAP group (n=114), and all VUMC patients qualified for the LTAP group (n=76). The STAP group had significantly more SSI's than the LTAP group; STAP SSI rate, 37.8% vs. LTAP SSI rate, 10.7% ($p = <0.0001$). The mandible alone was the most frequent site of infection; STAP 72% vs. LTAP 75%. There was a significantly greater risk of fixation plate

removal in patients who experienced a SSI; SSI 41% vs no SSI 7.8% ($p<0.0001$), and most frequently mandibular plates were removed**.** A significantly greater percentage of STAP group patients underwent plate removal, compared to patients in the LTAP group; STAP 21.7% vs. LTAP 9.3% ($p=0.0225$). It was concluded that long-term antibiotic prophylaxis, compared to short-term antibiotic prophylaxis, decreases the risk of surgical site infections and fixation plate removal in patients undergoing MMA for the treatment of OSA.

Facial Appearance

As part of our follow-up evaluation, we also assessed the patients' perceived change in their facial appearance. All patients felt that there was a change in their facial appearance. More than half of the patients, five out of nine, felt the change in facial appearance was favourable. Almost all of patients, eight out of nine, said it was either favourable or neutral, while only one felt it was unfavourable.

A previous study was conducted at Dalhousie looking at objective and subjective outcomes following MMA for the treatment of OSA patients with severe OSA (AHI>100). The study included 13 patients with preoperative and postoperative PSGs.(115) Of the 13 patients, nine had completed pre-operative and post-operative questionnaires. Eight of the nine patients reported a favourable change in facial appearance after MMA surgery. All nine patients however considered the surgery to be worthwhile, and eight would recommend the surgery to others.

Major Adverse Events

There were no major adverse events reported. No patient had perioperative cardiac, respiratory or neurologic adverse events associated with MMA surgery. The airway was managed during surgery with intubation in all patients, and no tracheotomies were performed. No patient required re-intubation for perioperative control of the airway. No patient received any blood transfusion. No patients experienced complications requiring return to the operating room.

CHAPTER 6 CONCLUSION

The results of this study show that MMA is a highly effective surgical option for the treatment of moderate to severe OSA for patients unable to adhere to CPAP therapy. For participants in this study, MMA resulted in statistically significant objective improvements in AHI from 31.14±13.56 to 7.12±10.97 ($p<0.01$) and PVT reaction times (1/RT) from 2.79±0.32 to 3.04±0.27 ($p<0.01$). There was also a statistically significant improvement in subjective measures of sleepiness with ESS dropping from 13.22±4.09 to 4.33±3.04 ($p<0.05$) and quality of life with FOSQ improving from 13.38±3.2 to 17.8±2.9 ($p<0.05$).

Regarding secondary outcomes, the study also showed that MMA is a surgical option that caries a low risk of major adverse events with no major peri-operative adverse events reported. The three reported post-operative infections were minor and managed with oral antibiotics and irrigation, with only one patient requiring plate removal. Almost all (eight out of nine) patients felt that the change in their facial appearance was either favourable or neutral. Additionally, from the six out of nine patients who experienced post-operative sensory numbness, four out of those six patients described the numbness as not a problem or as a very mild problem.

There was, however, no statistically significant improvement in hsCRP, blood pressure, or BMI. This may be due to the small size of the cohort, and the strength of results may benefit from recruitment of a larger group of patients in future studies.

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APPENDIX A PRE-MMA EVALUATION FORM

Date of Pre-MMA exam: _____
Study Site: _____
Patient Age: _____
Gender: __Male __Female

MEDICAL HISTORY
Hypertension? __*Yes* __*No*
Coronary Artery Disease? __*Yes* __*No*
Cardiac Dysrhythmia? __*Yes* __*No* (If Yes, describe: _____
_____)
Myocardial Infarction? __*Yes* __*No*
Stroke? __*Yes* __*No*
Lung Disease? __*Yes* __*No* (If Yes, describe type of lung disease: _____
_____
_____)
Asthma? __*Yes* __*No*
Sinusitis? __*Yes* __*No*
Diabetes? __*Yes* __*No* (If Yes, indicate: __Type I __Type II)
Thyroid Disease? __*Yes* __*No*
Depression? __*Yes* __*No*
Major Psychiatric Disease? __*Yes* __*No* (If Yes, describe type of psychiatric disease:_____
_____)
Other conditions? __*Yes* __*No* (If Yes, describe other medical conditions:
_____)

SLEEP HISTORY
Excessive Daytime Sleepiness (EDS)? __*Yes* __*No*
Loud Snoring? __*Yes* __*No*
Witnessed Apneic Episodes? __*Yes* __*No*
Non-restorative Sleep? __*Yes* __*No*

Epworth Sleepiness Scale score: _____

GENERAL PHYSICAL EXAM
Blood Pressure: _____/_____
Weight: _____ lbs Height: _____ in. Neck Circumference: _____ in.

FACIAL ESTHETICS – Symptoms

Are you feeling self-conscious of your facial appearance? __*Yes* __*No*

If Yes, how much of a problem is this?

__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

FACIAL ESTHETICS – Exam

Normal facial appearance and symmetry: __Normal __Abnormal

(If Abnormal, describe abnormality:_____

_____

_____)

NASAL FUNCTION– Symptoms (NOSE SCALE)

Nasal stuffiness:

__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

Nasal blockage or obstruction:

__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

Trouble breathing through nose:

__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

Trouble sleeping:

__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

Unable to get air through your nose during exercise or exertion:

__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

NASAL FUNCTION – Exam

Nasal Septal Deviation? __*Yes* __*No*

(If Yes, indicate severity: __Mild __Moderate __Severe)

Inferior Turbinate Hypertrophy present? __*Yes* __*No*

(If Yes, indicate severity: __Mild __Moderate __Severe)

TEMPOROMANDIBULAR FUNCTION – Symptoms

Is there pain or aching in your jaw joints or jaw muscles? __*Yes* __*No*

(If Yes, how much of a problem is this symptom?)

__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

Is there popping or clicking of your jaw joints? __*Yes* __*No*

(If Yes, how much of a problem is this symptom?)

__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

Is there a limitation in your jaw opening? __*Yes* __*No*
(If Yes, how much of a problem is this symptom?)
__Not a problem __Very mild problem __Moderate problem __Fairly bad problem
__Severe problem

TEMPOROMANDIBULAR FUNCTION – Exam

Palpable TMJ Pain? __*Yes* __*No* (If Yes, site of pain: __Right TMJ __Left TMJ __Both joints)
Palpable Muscle Pain? __*Yes* __*No* (If Yes, number of sites with pain: _____)
Maximum Mandibular Opening: _____(mm)
Palpable/Audible TMJ Clicking? __*Yes* __*No* (If Yes, site: __Right TMJ __Left TMJ __Both joints)
Palpable/Audible TMJ Crepitus? __*Yes* __*No* (If Yes, site: __Right TMJ __Left TMJ __Both joints)
Imaging Evidence of Bony Changes? __*Yes* __*No* (If Yes, describe: _____
_____
_____
_____)
Muscle Disorder? (muscle pain ≥ 3 sites) __*Yes* __*No*
(If Yes, type: __Myofascial pain __Myofascial pain w/limited opening (<40mm)
Disc Displacement? __*Yes* __*No*
(If Yes, type: __Disc displacement w/reduction __Disc displacement w/o reduction, w/limited opening
__Disc displacement w/o reduction, w/o limited opening)
Arthralgia? (painful TMJ/no Crepitus) __*Yes* __*No*
Osteoarthritis? (painful TMJ/Crepitus or Bony changes) __*Yes* __*No*
Osteoarthrosis? (non-painful TMJ/Crepitus or Bony changes) __*Yes* __*No*

TRIGEMINAL and FACIAL NERVE FUNCTION-Symptoms

Is there numbness or pain of your lips and/or chin? __*Yes* __*No*
(If Yes, site(s): __Left Upper Lip __Right Upper Lip __Left Lower Lip __Right Lower Lip __Chin)
(If Yes, how much of a problem is this symptom?)
__Not a problem __Very mild problem __Moderate problem __Fairly bad problem
__Severe problem

TRIGEMINAL and FACIAL NERVE FUNCTION-Exam

Neurosensory deficit of CN V? (Any site Von Frey >1.65) __*Yes* __*No*
(If Yes, Von Frey Exam:
Left Upper Lip: _1.65 _2.36 _2.44 _2.83 _3.22 _3.61 _3.84 _4.08 _4.17 _4.31
Right Upper Lip: _1.65 _2.36 _2.44 _2.83 _3.22 _3.61 _3.84 _4.08 _4.17 _4.31

Left Lower Lip: _1.65 _2.36 _2.44 _2.83 _3.22 _3.61 _3.84 _4.08 _4.17 _4.31
Right Lower Lip: _1.65 _2.36 _2.44 _2.83 _3.22 _3.61 _3.84 _4.08 _4.17 _4.31
Chin: _1.65 _2.36 _2.44 _2.83 _3.22 _3.61 _3.84 _4.08 _4.17 _4.31

Motor deficit of CN VII? __*Yes* __*No*
(If Yes, describe site and severity of deficit:
_____)

DENTAL OCCLUSION – Symptoms
Is there aching in your teeth that lasts at least an hour? __*Yes* __*No*
(If Yes, how much of a problem is this symptom?)
__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem
Do your upper and lower teeth meet properly? __*Yes* __*No*
(If No, how much of a problem is this symptom?)
__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem
Is there discomfort, aching, or tenderness of your gums? __*Yes* __*No*
(If Yes, how much of a problem is this symptom?)
__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

DENTAL OCCLUSION – Exam
1st Molar Occlusion: __I __II __III
Canine Occlusion: __I __II __III
Dentition Status: __Full complement of teeth __Partially edentulous __ Completely edentulous
Is there an Open Bite present? __*Yes* __*No* (If Yes, magnitude: _____(mm)
Is there attrition of the Dentition? __*Yes* __*No* (If Yes, severity: __Mild __Moderate __Severe)
Oral Hygiene? __Good __Fair __Poor
Are Dental Caries present? __*Yes* __*No* (If Yes, severity: __Mild __Moderate __Severe)
Is Periodontitis present? __*Yes* __*No* (If Yes, severity: __Mild __Moderate __Severe; Site: _____)

OROPHARYNX – Exam

Tonsil Size: __0 (removed) __1 (within pillars) __2 (extend to pillars) __3 (extend past pillars) __4 (extend to midline)

Friedman Tongue Position / Modified Mallampatti:
__1 (visualization of entire uvula and tonsils) __2 (visualization of entire uvula, but not tonsils)
__3 (visualization of soft palate, but not uvula) __4 (visualization of hard palate only)

CPAP & ORAL APPLIANCE USE
Within 1 month of MMA surgery, have they/will they have used:
CPAP? Yes __ No __
If yes, how many hours a night? __
If yes, how many days a week? __

Oral Appliance? Yes __ No __
If yes, how many hours a night? __
If yes, how many days a week? __

APPENDIX B EPWORTH SLEEPINESS SCALE (ESS) QUESTIONNAIRE

EPWORTH SLEEPINESS SCALE (ESS)

Study ID _____ Date _____

The following questionnaire will help you measure your general level of daytime sleepiness. You are to rate the chance that you would doze off or fall asleep during different routine daytime situations. Answers to the questions are rated on a reliable scale called the Epworth Sleepiness Scale (ESS). Each item is rated from 0 to 3, with 0 meaning you would never doze or fall asleep in a given situation, and 3 meaning there is a very high chance that you would doze or fall asleep in that situation.

How likely are you to doze off or fall asleep in the following situations, in contrast to just feeling tired? Even if you haven't done some of the activities recently, think about how they would have affected you.

Use this scale to choose the most appropriate number for each situation:

0 = would never doze
1 = slight chance of dozing
2 = moderate chance of dozing
3 = high chance of dozing

It is important that you mark a number (0 to 3) for EACH situation.

Sitting and reading	□0	□1	□2	□3
Watching television	□0	□1	□2	□3
Sitting inactive in a public place (theater/meeting)	□0	□1	□2	□3
As a passenger in a car for an hour without a break	□0	□1	□2	□3
Lying down to rest in the afternoon	□0	□1	□2	□3
Sitting and talking to someone	□0	□1	□2	□3
Sitting quietly after lunch (with no alcohol)	□0	□1	□2	□3
In a car, while stopped in traffic	□0	□1	□2	□3

Total Score _____

APPENDIX C FUNCTIONAL OUTCOMES OF SLEEP (FOSQ) QUESTIONNAIRE

FUNCTIONAL OUTCOMES of SLEEP QUESTIONNAIRE (FOSQ)

Study ID _____ Date _____

This survey helps determine how sleepiness affects your quality of life. Some people have difficulty performing everyday activities when they feel tired or sleepy. In this survey, when the words "sleepy" or "tired" are used, it describes the feeling that you can't keep your eyes open, your head is droopy, that you want to nod off or that you feel the urge to nap. These words do not refer to tired or fatigued feeling you may have after you have exercised or worked strenuously.

There are 30 questions. Please fill out this form completely and *select only one answer* for each question.

1. Do you have difficulty concentrating on the things you do because you are sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

2. Do you generally have difficulty remembering things, because you are sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

3. Do you have difficulty finishing a meal because you become sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

4. Do you have difficulty working on a hobby (for example, sewing, collecting, gardening) because you are sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

5. Do you have difficulty doing work around the house (for example, cleaning house, doing laundry, taking out the trash, repair work) because you are sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

6. Do you have difficulty operating a motor vehicle for short distances (less than 100 miles) because you become sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

7. Do you have difficulty operating a motor vehicle for long distances (greater than 100 miles) because you become sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

8. Do you have difficulty getting things done because you are too sleepy or too tired to drive or take public transportation?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

9. Do you have difficulty taking care of financial affairs and doing paperwork (for example, writing checks, paying bills, keeping financial records, filling out tax forms, etc.) because you are sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

10. Do you have difficulty performing employed or volunteer work because you are sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

11. Do you have difficulty maintaining a telephone conversation, because you become sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

12. Do you have difficulty visiting with your family or friends in your home because you become sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

13. Do you have difficulty visiting with your family or friends in <u>their</u> home because you become sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

14. Do you have difficulty doing things for your family or friends because you are too sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

15. Has your relationship with family, friends or work colleagues been affected because you are sleepy or tired?

□ 1 = Yes, extremely
□ 2 = Yes, moderately
□ 3 = Yes, a little
□ 4 = No

16. Do you have difficulty exercising or participating in a sporting activity because you are too sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

17. Do you have difficulty watching a movie or videotape because you become sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

18. Do you have difficulty enjoying the theater or a lecture because you become sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

19. Do you have difficulty enjoying a concert because you become sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

20. Do you have difficulty watching TV because you are sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

21. Do you have difficulty participating in religious services, meetings or a group or club, because you are sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

22. Do you have difficulty being as active as you want to be in the evening because you are sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

23. Do you have difficulty being as active as you want to be in the morning because you are sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

24. Do you have difficulty being as active as you want to be in the afternoon because you are sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

25. Do you have difficulty keeping pace with others your own age because you are sleepy or tired?

□ 0 = I don't do this activity for other reasons
□ 1 = Yes, extreme difficulty
□ 2 = Yes, moderate difficulty
□ 3 = Yes, a little difficulty
□ 4 = No difficulty

26. How would you rate your general level of activity?

□ 1 = Very low
□ 2 = Low
□ 3 = Medium
□ 4 = High

27. Has your intimate or sexual relationship been affected because you are sleepy or tired?

□ 0 = I don't engage in this activity for other reasons
□ 1 = Yes, extremely
□ 2 = Yes, moderately
□ 3 = Yes, a little
□ 4 = No

28. Has your desire for intimacy or sex been affected because you are sleepy or tired?

□ 0 = I don't engage in this activity for other reasons
□ 1 = Yes, extremely
□ 2 = Yes, moderately
□ 3 = Yes, a little
□ 4 = No

29. Has your ability to become sexually aroused been affected because you are sleepy or tired?

□ 0 = I don't engage in this activity for other reasons
□ 1 = Yes, extremely
□ 2 = Yes, moderately
□ 3 = Yes, a little
□ 4 = No

30. Has your ability to have an orgasm been affected because you are sleepy or tired?

□ 0 = I don't engage in this activity for other reasons
□ 1 = Yes, extremely
□ 2 = Yes, moderately
□ 3 = Yes, a little
□ 4 = No

APPENDIX D SURGICAL AND ANESTHESIA FINDINGS

Date of MMA: _____

LeFort I: __*Yes* __*No*

BSSRO: __*Yes* __*No*

Genial Advancement: __*Yes* __*No* (If Yes, describe surgical technique: _____

Other surgery: __*Yes* __*No* (If Yes, describe other type of surgery: _____

Orthodontic appliances: __*Yes* __*No*

Arch bars: __*Yes* __*No*

Sequencing of MMA: __Maxilla-Mandible __Mandible-Maxilla

Interim splint: __*Yes* __*No*

Maxillomandibular fixation: __*Yes* __*No*

Length of maxillomandibular fixation: __*Yes* __*No*

Length of Case: _____(minutes)

Length of Hospitalization: _____(days)

Complications requiring return to OR during hospitalization? __*Yes* __*No*

(If Yes, describe reason and treatment: _____)

Hospital re-admission following discharge? __*Yes* __*No*

(If Yes, reason: _____ _____)

AIRWAY MANAGEMENT

Tracheotomy performed? __*Yes* __*No*
(If Yes, was tracheotomy: __planned __unplanned)

Complications with intubation? __*Yes* __*No*
(If Yes, describe: _____ _____)

Site of extubation: __OR __PACU __ICU
Was re-intubation required? __*Yes* __*No*

ANESTHETIC MANAGEMENT

Management of blood pressure: __Normotensive __Hypotensive
Total Estimated Blood Loss: _____(mL)

Unplanned transfusion of blood or blood products during or following surgery? __*Yes* __*No*

(If Yes, type of blood product transfused:

_____)

Amount of blood product transfused: _____(units)

Intraoperative total fluid administered: _____ (mL)
Intraoperative total urine output: _____ (mL)

MEDICATIONS

Prophylactic antibiotics? __*Yes* __*No*

(If Yes:Type of antibiotic: _____ Total dosage: _____

Intraoperative antibiotics? __*Yes* __*No*

(If Yes:Type of antibiotic: _____ Total dosage: _____

Prophylactic corticosteroids? __*Yes* __*No*

(If Yes:Type of corticosteroid: _____ Total dosage: _____

Intraoperative corticosteroids? __*Yes* __*No*

(If Yes:Type of corticosteroid: _____ Total dosage: _____

ANESTHETIC and PERIOPERATIVE COMPLICATIONS

Death associated with MMA surgery? __*Yes* __*No*

Respiratory event? __*Yes* __*No*
(If Yes, describe:

_____

_____)

Myocardial Infarction? __*Yes* __*No*

Stroke? __*Yes* __*No*

Severe/Uncontrolled Hypertension __*Yes* __*No*

Severe Tachycardia? __*Yes* __*No*

Significant PVCs? __*Yes* __*No*

Severe Bradycardia? __*Yes* __*No*

Asystole? __*Yes* __*No*

Atrial Fibrillation? __*Yes* __*No*

Deep Venous Thrombosis? __*Yes* __*No*

Clinically significant neurological deficit after MMA? __*Yes* __*No*
(If Yes, describe:

_____

_____)

Ocular injury during MMA surgery? __*Yes* __*No*
Describe any other anesthetic or perioperative complications:
_____

Other complications? __*Yes* __*No*
(If Yes, describe:

_____

_____)

LEFORT I – SURGICAL TECHNIQUE

LeFort I Osteotomy design: __Standard __Step-design __Other

(If Other, describe: _____)

Maxillary bone graft? __*Yes* __*No*

(If Yes, describe bone graft:
_____)

Method of LeFort Osteotomy fixation: __4 plates __Other

(If Other, describe: _____)

Size of plates/screws: _____(mm)

LEFORT I – COMPLICATIONS

Significant hemorrhage after LeFort I Osteotomy? __*Yes* __*No*

(If Yes, describe method used to treat hemorrhage:

_____
_____

Ischemia/Vascular compromise after LeFort I Osteotomy? __*Yes* __*No*

(If Yes, describe sites and characteristics
_____)
Dental injury during LeFort I Osteotomy? __*Yes* __*No*

(If Yes, describe:
_____)

Was a trigeminal vagal reflex observed following mobilization of the maxilla? __*Yes* __*No*

BSSRO – SURGICAL TECHNIQUE

Method of BSSRO fixation: __Positional screws __Monocortical plates and screws

Screw/Plate configuration:
_____)

BSSRO - COMPLICATIONS

Significant hemorrhage during BSSRO? __*Yes* __*No*
Inadvertent fracture during BSSRO? __*Yes* __*No*

(If Yes, describe:
_____
____)

Direct injury to the inferior alveolar nerve during BSSRO? __*Yes* __*No*

(If Yes, describe:
_____
__)

Dental injury during BSSRO? __*Yes* __*No*

(If Yes, describe:
_____
_____)

SURGICAL WOUND HEALING

Was there a postoperative wound infection? __*Yes* __*No*
(If Yes, when did the infection occur: _____ (days after MMA)
Site of infection: __Mandible __Maxilla
Management of Infection: __Oral antibiotics/local irrigation __I&D/oral antibiotics__ Hospitalization and IV antibioitics __Other (Describe:
_____)
Use of postoperative antibiotics? __*Yes* __*No*
(If Yes, type of antibiotic: _____
Length of postoperative antibiotic use: _____ (days)
Was a bone plate removed? __*Yes* __*No*

(If Yes, weeks after surgery plates removed: _____
Number of mandibular plates removed: _____
Number of maxilla plates removed: _____

APPENDIX E 6 MONTH POST-MMA EVALUATION FORM

Date of Post-MMA evaluation: _____
Length of Post-MMA follow-up: _____ (days)

MEDICAL HISTORY
Hypertension? __*Yes* __*No*
Coronary Artery Disease? __*Yes* __*No*
Cardiac Dysrhythmia? __*Yes* __*No* (If Yes, describe: _____
_____)
Myocardial Infarction? __*Yes* __*No*
Stroke? __*Yes* __*No*
Lung Disease? __*Yes* __*No* (If Yes, describe type of lung disease: _____
_____)
Asthma? __*Yes* __*No*
Sinusitis? __*Yes* __*No*
Diabetes? __*Yes* __*No* (If Yes, indicate: __Type I __Type II)
Thyroid Disease? __*Yes* __*No*
Depression? __*Yes* __*No*
Major Psychiatric Disease? __*Yes* __*No* (If Yes, describe type of psychiatric disease:__
_____)
Other conditions? __*Yes* __*No* (If Yes, describe other medical conditions:_____
_____
_____
_____
_____)

SLEEP HISTORY
Excessive Daytime Sleepiness (EDS)? __*Yes* __*No*
Loud Snoring? __*Yes* __*No*
Witnessed Apneic Episodes? __*Yes* __*No*
Non-restorative Sleep? __*Yes* __*No*

Epworth Sleepiness Scale score: _____

GENERAL PHYSICAL EXAM
Blood Pressure: _____/_____
Weight: _____ lbs Height: _____ in. Neck Circumference: _____ in.

FACIAL ESTHETICS – Symptoms
Are you feeling self-conscious of your facial appearance? __*Yes* __*No*
If Yes, how much of a problem is this?
__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

Has there been a change in your facial appearance after MMA? __Yes __No

If Yes, what type of change?

__Favorable (more attractive and/or youthful)__Neutral (no more attractive and/or youthful)__Unfavorable (less attractive and/or youthful)

FACIAL ESTHETICS – Exam

Normal facial appearance and symmetry: __Normal __Abnormal

(If Abnormal, describe abnormality:_____
_____
_____)

NASAL FUNCTION– Symptoms (NOSE SCALE)

Nasal stuffiness:

__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

Nasal blockage or obstruction:

__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

Trouble breathing through nose:

__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

Trouble sleeping:

__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

Unable to get air through your nose during exercise or exertion:

__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

NASAL FUNCTION – Exam

Nasal Septal Deviation? __*Yes* __*No*

(If Yes, indicate severity: __Mild __Moderate __Severe)

Inferior Turbinate Hypertrophy present? __*Yes* __*No*

(If Yes, indicate severity: __Mild __Moderate __Severe)

TEMPOROMANDIBULAR FUNCTION – Symptoms

Is there pain or aching in your jaw joints or jaw muscles? __*Yes* __*No*

(If Yes, how much of a problem is this symptom?)

__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

Is there popping or clicking of your jaw joints? __*Yes* __*No*

(If Yes, how much of a problem is this symptom?)

__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

Is there a limitation in your jaw opening? __*Yes* __*No*

(If Yes, how much of a problem is this symptom?)

__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

TEMPOROMANDIBULAR FUNCTION – Exam

Palpable TMJ Pain? __*Yes* __*No* (If Yes, site of pain: __Right TMJ __Left TMJ __Both joints)

Palpable Muscle Pain? __*Yes* __*No* (If Yes, number of sites with pain: _____)

Maximum Mandibular Opening: _____(mm)

Palpable/Audible TMJ Clicking? __*Yes* __*No* (If Yes, site: __Right TMJ __Left TMJ __Both joints)

Palpable/Audible TMJ Crepitus? __*Yes* __*No* (If Yes, site: __Right TMJ __Left TMJ __Both joints)

Imaging Evidence of Bony Changes? __*Yes* __*No* (If Yes, describe: _____ _____ _____ _____ _____)

Muscle Disorder? (muscle pain ≥ 3 sites) __*Yes* __*No*

(If Yes, type: __Myofascial pain __Myofascial pain w/limited opening (<40mm)

Disc Displacement? __*Yes* __*No*

(If Yes, type: __Disc displacement w/reduction __Disc displacement w/o reduction, w/limited opening

__Disc displacement w/o reduction, w/o limited opening)

Arthralgia? (painful TMJ/no Crepitus) __*Yes* __*No*

Osteoarthritis? (painful TMJ/Crepitus or Bony changes) __*Yes* __*No*

Osteoarthrosis? (non-painful TMJ/Crepitus or Bony changes) __*Yes* __*No*

TRIGEMINAL and FACIAL NERVE FUNCTION-Symptoms

Is there numbness or pain of your lips and/or chin? __*Yes* __*No*

(If Yes, site(s): __Left Upper Lip __Right Upper Lip __Left Lower Lip __Right Lower Lip __Chin)

(If Yes, how much of a problem is this symptom?)

__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

TRIGEMINAL and FACIAL NERVE FUNCTION-Exam

Neurosensory deficit of CN V? (Any site Von Frey >1.65) __*Yes* __*No*

(If Yes, Von Frey Exam:

Left Upper Lip:	_1.65	_2.36	_2.44	_2.83	_3.22	_3.61	_3.84	_4.08	_4.17	_4.31
Right Upper Lip:	_1.65	_2.36	_2.44	_2.83	_3.22	_3.61	_3.84	_4.08	_4.17	_4.31
Left Lower Lip:	_1.65	_2.36	_2.44	_2.83	_3.22	_3.61	_3.84	_4.08	_4.17	_4.31
Right Lower Lip:	_1.65	_2.36	_2.44	_2.83	_3.22	_3.61	_3.84	_4.08	_4.17	_4.31
Chin:	_1.65	_2.36	_2.44	_2.83	_3.22	_3.61	_3.84	_4.08	_4.17	_4.31

Motor deficit of CN VII? __*Yes* __*No*

(If Yes, describe site and severity of deficit:

_____)

DENTAL OCCLUSION – Symptoms

Is there aching in your teeth that lasts at least an hour? __*Yes* __*No*

(If Yes, how much of a problem is this symptom?)

__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

Has there been a change in the way your upper and lower teeth meet after MMA? __Yes __No

(If Yes, what type of change?)

__Favorable (improved occlusion)__Neutral (not significantly better or worse)

__Unfavorable (worsening of bite)

Do your upper and lower teeth meet properly? __*Yes* __*No*

(If No, how much of a problem is this symptom?)

__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

Is there discomfort, aching, or tenderness of your gums? __*Yes* __*No*

(If Yes, how much of a problem is this symptom?)

__Not a problem __Very mild problem __Moderate problem __Fairly bad problem __Severe problem

DENTAL OCCLUSION – Exam

Status of Occlusion: __Stable and unchanged from Pre-MMA __Correction of malocclusion by MMA __Malocclusion resulting from MMA (Describe: _____)

1st Molar Occlusion: __I __II __III

Canine Occlusion: __I __II __III

Dentition Status: __Full complement of teeth __Partially edentulous __Completely edentulous

Is there an Open Bite present? __*Yes* __*No* (If Yes, magnitude: _____(mm)

Is there attrition of the Dentition? __*Yes* __*No* (If Yes, severity: __Mild __Moderate __Severe)

Oral Hygiene? __Good __Fair __Poor

Are Dental Caries present? __*Yes* __*No* (If Yes, severity: __Mild __Moderate __Severe)

Is Periodontitis present? __*Yes* __*No* (If Yes, severity: __Mild __Moderate __Severe; Site: _____)

Periodontitis resulting from MMA? __Yes __No

(If Yes, describe: _____ _____)

Loss of teeth resulting from MMA? __Yes __No

(If Yes, describe: _____ _____)

OROPHARYNX – Exam

Tonsil Size: __0 (removed) __1 (within pillars) __2 (extend to pillars) __3 (extend past pillars) __4 (extend to midline)

Friedman Tongue Position / Modified Mallampatti:
__1 (visualization of entire uvula and tonsils) __2 (visualization of entire uvula, but not tonsils)
__3 (visualization of soft palate, but not uvula) __4 (visualization of hard palate only)

SURGICAL WOUND HEALING

Was there a postoperative wound infection? __*Yes* __*No*
(If Yes, when did the infection occur: _____ (days after MMA)
Site of infection: __Mandible __Maxilla
Management of Infection: __Oral antibiotics/local irrigation __I&D/oral antibiotics__ Hospitalization and IV antibioitics __Other (Describe: _____)

Use of postoperative antibiotics? __*Yes* __*No*
(If Yes, type of antibiotic: _____
Length of postoperative antibiotic use: _____ (days)

Was a bone plate removed? __*Yes* __*No*
(If Yes, weeks after surgery plates removed: _____ (months)
Number of mandibular plates removed: _____
Number of maxilla plates removed: _____

CPAP USE

Have you required to use CPAP after surgery? __ Yes __ No
If yes, how often? _____