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Clinical Outcomes of Maxillomandibular Advancement Surgery for the Treatment of Obstructive Sleep Apnea

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Clinical Outcomes of Maxillomandibular Advancement Surgery

for the Treatment of Obstructive Sleep Apnea

(Thesis format: Monograph)

by

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The School of Graduate and Postdoctoral Studies

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Abstract

Objective: To evaluate clinical and radiographic treatment outcomes after maxillomandibular advancement (MMA) surgery on subjects suffering from obstructive sleep apnea (OSA).

Materials and Methods: This was a retrospective cohort analysis. Subjects underwent pre- and post-surgical polysomnography (PSG) studies and were also asked to complete a subjective self-assessment via the Epworth Sleepiness Scale (ESS) questionnaire. Twenty-two patients (11 male, 11 female) met the inclusion criteria.

Results: The mean pre-surgical apnea-hypopnea index (AHI) score was 48.4 (+/-31.3) and mean ESS score was 11.6 (+/-4.6). After surgery, the mean AHI reduced to 14.0 (+/-15.0) and ESS reduced to 5.7 (+/-3.5). Treatment success was observed in 19 of 22 (86.4%) patients and 8 of 22 (36.4%) met the criteria for treatment cure.

Conclusions: MMA surgery is an effective treatment for patients suffering from OSA. Subjective sleepiness levels were significantly reduced after surgery. There were no pre- or post-surgical variables that acted as predictors of successful treatment.

Keywords

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List of Abbreviations

AHI	Apnea-Hypopnea Index
ANB	A-Point-Nasion-B-Point
BMI	Body Mass Index
CPAP	Continuous Positive Airway Pressure
ESS	Epworth Sleepiness Scale
IAS	Inferior Airway Space
MMA	Maxillomandibular Advancement
OSA	Obstructive Sleep Apnea
PSG	Polysomnography
SNA	Sella-Nasion-A-Point
SNB	Sella-Nasion-B-Point
SV-Ii	Sella Vertical-Incisor Inferiorus
SV-Is	Sella Vertical-Incisor Superiorus

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Introduction

Obstructive sleep apnea (OSA) is a syndrome that was first recognized in the medical literature in 1965.[1] It is characterized by partial or complete blockage of the airway during sleep referred to as hypopnea or apnea.[2] Apnea is identified by the complete inability to breath for at least ten seconds, despite an effort to breathe, whereas hypopnea is associated with a 30% reduction in thoraco-abdominal movement or airflow (when compared to a baseline), lasting at least ten seconds with 4% or more oxygen desaturation.[1] "Obstructive" sleep apnea can be differentiated from "central" sleep apnea by observing that, in an obstructive sleep apnea patient, a physical effort to inhale is made but the airway is blocked, preventing inspiration. In the case of central sleep apnea, there is no signal sent from the brain to make an effort to breathe, therefore the patient stops breathing even though the airway remains unobstructed.[3]

Obstructive sleep apnea has a range of severity, which is measured via the apnea-hypopnea index (AHI). This index is used to identify the number of episodes that occur per hour of sleep. To be considered as suffering from obstructive sleep apnea, a patient must obtain a minimum AHI score of five or greater and also report having excessive daytime sleepiness. Scores of five to 14 are classified as mild sleep apnea, 15 to 29 are termed moderate and patients who obtain scores of 30 or greater are categorized as suffering from severe obstructive apnea.[1,2,4]

This condition has been reported to affect 4% of men and 2% of women aged 50 years or older.[2] Estimates of the effect on the middle age population, who may be asymptomatic and therefore undiagnosed, are as high as 30%.[5] Almost 80% of these

undiagnosed cases are likely to be apneas that are of the moderate to severe forms.[2, 4-6]
Postmenopausal women are determined to be at greater risk for development than those
that are premenopausal and individuals of African American descent are more likely to
develop the syndrome at an earlier age than are Caucasians.[7]

Those who are at greatest risk for developing the syndrome are characterized as being
male, obese and aged 65 or older.[2] Studies indicate that body weight is by far the greatest
contributing factor and that a 10% gain in body mass increases one's risk for developing
OSA by six times.[8] It has been suggested that the mechanism for the age- and weight-
related increase in incidence is derived from anatomic changes surrounding the pharynx,
such as deposition of fat in the parapharyngeal area and lengthening of the soft palate.[5]

There are a number of skeletal and soft tissue anatomical variations that predispose a
person to OSA. Having a maxilla or mandible that is retropositioned, enlarged
parapharyngeal fat pads, thick lateral parapharyngeal musculature, an enlarged soft
palate, enlarged tongue, or a narrow posterior airway space can lead to the development
of both apneas and hypopneas. [2, 9-11]

Neuromuscular factors are also important in the development of OSA. The pharynx
does not have skeletal support and is essentially a collapsible column, which must resist
numerous stresses during speech, respiration and swallowing. Maintenance of the airway
is achieved by tonic and phasic contractions of the pharyngeal dilator muscles. It has
been observed that patients who suffer from OSA have hyperactive muscles during
wakefulness to compensate for poor pharyngeal anatomy; however, during sleep the tone
in these muscles is eliminated as reflex mechanisms from both chemoreceptors and

mechanoreceptors are reduced during rapid eye movement (REM) sleep, contributing to airway collapse.[2]

The size and position of the tongue are also influential. When awake and in a supine position, the tongue falls posteriorly. Normally, this is counteracted by the anterior pull of the genioglossus muscle. However, during REM sleep, the genioglossus also loses tone and allows the tongue to fall to a posterior position of obstruction.[1,2]

Clinical features of OSA typically include snoring, snorting, gasping and choking with increased likelihood of repeated awakenings and insomnia.[2] Nocturia, chronic fatigue, daytime sleepiness and frequency of falling asleep during daytime activities are also common with the severity of symptoms increasing with increased body mass and age. Those who are afflicted may also experience morning headaches, dry mouth, chronic fatigue syndrome, fibromyalgia, irritable bowel syndrome, and migraine headaches.[2,12] There is also research indicating that the risk of motor vehicle accidents involving OSA patients is 1.3 to 7 times that of the national average.[1,2,13]

If left untreated, these symptoms may have a life threatening impact and are linked to the development of hypertension, coronary artery disease, stroke, depression, diabetes and glaucoma.[1,14] Studies estimate that daytime sleepiness results in loss of productivity valued at $150 billion annually in addition to another $48 billion in medical costs related to motor vehicle accidents (American research data).[15]

OSA diagnosis is done in a clinical setting by obtaining a full medical history, including a subjective self-assessment via the Epworth Sleepiness Scale (ESS), physical exam, imaging studies and polysomnography. The Epworth Sleepiness Scale (Appendix

I) is a written questionnaire that asks for a subjective ranking of eight situations to determine a score out of a possible 24 points to assess the patient's perceived level of sleepiness.[16] This test can be used both to assess pre-treatment sleepiness and to assess if the patient believes that improvement has been achieved during or after treatment.

Polysomnography involves the use of an electroencephalogram, electrooculogram, electromyogram, electrocardiogram, pulse oxymetry, respiratory inductance plethysmography, airflow measurement, recordings of body movement via infrared imaging and microphone measurements of snoring. It is considered the "gold standard" of analysis when diagnosing sleep apnea.[1, 2, 17]

Treatment options for obstructive sleep apnea involve both non-surgical and surgical management. Non-surgical approaches include loss of excessive body weight, fabrication of oral appliances and the use of continuous positive airway pressure (CPAP). Removing excess body fat can have a major impact on the reduction of OSA symptoms. Losing mass equivalent to 10.7 kilograms was correlated with a decreased AHI of 40% in patients who had been categorized as having mild OSA.[18-20]

Oral appliances can be used successfully by patients with mild to moderate OSA. These appliances are designed to either retain the tongue or reposition the mandible. Patients who are edentulous or suffer from macroglossia can utilize tongue-retaining appliances. They act to position the tongue anteriorly via negative pressure. The mandibular repositioning devices move the mandible forward thereby repositioning the attached musculature anteriorly, which increases the dimensions of the airway. Success of these appliances is dependent upon design and patient compliance.[20]

CPAP is recognized as the most effective non-surgical method of managing OSA. This treatment places a constant pressure along the upper airway during breathing. It causes enlargement of the lateral pharyngeal walls and supports the tone of the dilator muscles, which in turn reduces the likelihood of collapse. The success rate of CPAP has been estimated at up to 78% with patients achieving increased cardiac output, decreased systemic vascular resistance, reduced cardiovascular mortality, increased alertness and improved daytime functioning. [15] Compliance however can be anywhere from 50-89% as patients complain of dry mouth, conjunctivitis, rhinorrhea, skin irritations, pressure sores, nasal congestion, epistaxis, claustrophobia and anxiety. [20, 21]

Phase I surgical procedures are considered site specific. These include nasal surgery (septoplasty or turbinectomy) to improve airway intake, surgery on the tongue to reduce the soft tissue volume thereby reducing airway blockage, and uvulopalatalpharyngoplasty (UPPP) to remove soft tissue in the oropharynx. Of these procedures, uvulopalatopharyngoplasty is the most common and involves adenoidectomy, tonsillectomy, and uvulectomy along with excision of redundant lateral pharyngeal wall mucosa. [1, 20]

The primary goal of the UPPP procedure is to shorten the palate, which results in increased airway dimension. Complications of the surgery may include changes in voice (nasal tone), dysphagia, nasal reflux and velopharyngeal insufficiency. [1, 21] Studies indicate that improvement is seen in as few as 50% of cases and this already poor prognosis may fall to 35% after four years. [21] The procedure is described as being painful with an extended recovery time. Goodday [22] reports that only one out of 14 patients that had the UPPP surgery would undergo the procedure again due to the painful recovery. [22]

Perhaps the most significant reason for the poor success of the UPPP surgery lies in the location of the obstruction site(s) in the apnea patients. Rama et al.[23] studied available research published between 1980 and 2002 to determine the most common sites of obstruction in patients with obstructive sleep apnea. The authors note a variety of techniques utilized to identify the sites including nasopharyngoscopy, fluoroscopy, pressure measurements, CT scanning, and MRI. The search identified that the most common site of obstruction was at the level of the oropharynx with extension to the laryngopharynx also observed. However, in more recent studies it has been reported that multiple sites of obstruction were present.[23] Therefore a possible explanation for why the UPPP procedure has such a poor chance of success is that it targets only one specific site, and that area is not known to be one of the primary sources of obstruction.[22, 23]

Phase II surgical treatments include maxillomandibular advancement (MMA), tracheostomy and bariatric surgery. Bariatric surgery is used to facilitate weight loss to decrease sites of obstruction whereas tracheostomy is reserved as an emergency, life-saving surgery for those patients who have not had success with other treatments.[20] Tracheostomy can be a very successful treatment but the quality of life for the patients after surgery is questionable. In contrast, the quality of life is greatly improved with the use of MMA surgery, which has rapidly become one of the most sought after surgical treatments for those afflicted with obstructive sleep apnea.[1, 2, 6, 17, 20]

MMA surgery may be referred to as a *telegnathic* (lengthening of the jaws) surgery as opposed to *orthognathic* surgery (straightening of the jaws) and some patients may opt to forego the additional orthodontic treatment traditionally carried out with most orthognathic procedures. Telegnathic MMA surgery involves the advancement of the

maxilla, mandible, genial tubercles and hyoid, which results in a surgically stable enlargement of the posterior airway. Kuo et al [24] first used this surgical technique to address sleep apnea in 1979 as an alternative to tracheostomy in the most severely affected patients.

Most orthognathic patients are young and otherwise healthy whereas the average OSA patient undergoing telegnathic MMA is likely to be older with additional dental/periodontal concerns as well as excess body weight, hypertension, intellectual and physical impairment, erectile dysfunction and depression. [25] Therefore the surgical management of OSA patients can be more challenging than the typical orthognathic patient. [17]

The rationale of MMA surgery is to increase both the lateral and the antero-posterior dimensions of the airway at all levels. At the same time, tension and tone of the suprahyoid and velopharyngeal musculature are improved due to movement of the hyoid to a more anterior and superior position. [26] These MMA movements are ideal to counteract the physiological problems identified by Gungor et al. [27] who recognized OSA patients as having significantly reduced mid-face length and inferiorly placed hyoid bones in conjunction with smaller airway dimensions when compared to controls.

The success of MMA surgery has been repeatedly demonstrated using a variety of study designs. [28-34] Abramson et al. [35] reported on three-dimensional computed tomographic airway analysis of OSA patients that had undergone MMA treatment. This retrospective cohort study compared pre-treatment and post-treatment three-dimensional computed tomography (CT) scans from the hard palate to the base of the epiglottis. All

subjects underwent MMA surgery including genial tubercle advancement (GTA). The results of the comparison of the 3D scans demonstrated that the MMA and GTA treatments provided significant increases in antero-posterior and lateral airway diameter, increased airway volume, increased surface area, and greater uniformity in airway shape. In addition, subjects reported decreased daytime sleepiness, reduced fatigue, less snoring and improvements in memory.[35]

Ronchi et al.[21] postulated that the use of MMA could be as effective in patients without any skeletal anomalies as it was in those patients that did have a craniofacial anomaly. Two groups with differing skeletal patterns were evaluated before and after surgery. The first group had severe OSA as well as maxillomandibular hypoplasia. Group II also had severe OSA but did not have maxillomandibular hypoplasia or deformity. The final analysis included the apnea hypopnea index (AHI), posterior airway space (PAS), SNA and SNB angles, Epworth sleepiness scale, body mass index and subjective standardized questionnaire regarding esthetic appearance. After statistical evaluation, it was noted that the results of both groups were comparable and included significant improvements in OSA symptoms along with remission of subjective symptoms as recorded by evaluation of the Epworth Sleepiness Scale. Thus, the authors concluded that MMA surgery could be encouraged for use in all patients suffering from OSA, not just those who could also benefit from improving adjacent skeletal deformity.[21]

Prinsell[15] published an extensive literature review on the use of MMA for primary and secondary telegnathic surgery in 2012. The purpose of the review was to establish the roll, surgical doctrines, and efficacy of *primary* MMA treatment (when MMA surgery was the first surgical treatment rendered to the patient) and *secondary* MMA treatment

(when other surgical treatment(s) had been undertaken prior to the MMA procedure). Surgical treatments such as distraction osteogenesis, tracheostomy, uni-level procedures (except for UPPP) and pediatric surgeries were excluded. AHI data from all cited cases were tabulated to calculate a mean percentage reduction in AHI. It was noted that a true definition of treatment success was not universally accepted at the time of publication. However traditional success rates, such as AHI reduction of at least 50% and/or a reduction to below a score of 20, was an acceptable benchmark. [15] MMA was separated from other multilevel operations and divided into four categories including primary MMA, primary MMA with extra-pharyngeal procedures, primary MMA with intra-pharyngeal procedures, and secondary MMA. Additional recorded data included lowest arterial oxyhemoglobin saturation levels (LSAT), blood pressure, Epworth sleepiness scale scores, length of hospital stays, and lateral cephalometric analysis.

The results of the review showed a mean reduction in AHI of 92.1% for primary MMA with extra-pharyngeal procedures, 88.4% for primary MMA and 86.6% for secondary MMA surgery. A 79.4% success rate was observed for MMA with intra-pharyngeal procedures and only 53% success was determined for non-MMA multilevel surgery. Uvulopalatopharyngoplasty had the poorest prognosis with only 31.3% of surgeries meeting the defined expectations of success. The conclusions from this literature review stress that regardless of whether or not MMA surgery is applied as a primary or secondary surgery, it is highly therapeutic in comparison to non-MMA procedures. However, the authors caution that a definition for long-term success of MMA surgery has yet to be identified and that more research in this area is desired. [15]

Research by Riley et al.[36] attempted to address the lack of long-term data available. Their publication studied outcome data of forty patients who underwent soft tissue and skeletal surgery. Evaluation methods included polysomnography, respiratory disturbance index (RDI), oxygen desaturation, body mass index, quality of life assessments, roentgenograhic analysis and surgical complications (RDI is defined as including apneas, hypopneas and any respiratory event-related arousals and is sometimes reported in lieu of AHI). The mean follow up was 50.7 months. They determined that 36 of the 40 patients displayed long-term clinical success. They also noted that a positive correlation was found between the amount of skeletal advancement and the likelihood of successful clinical outcome.[36]

Another long-term outcome study was completed by Jaspers et al.[37] The sample size was small, consisting of only 6 patients, however, the authors were able to complete an eight year follow up study on OSA patients who had undergone MMA surgery. Records were obtained for ESS, polysomnography and AHI. Six-month post-operative figures showed significant mean reductions in AHI, and ESS scores. At the eight-year follow-up, there had been only one patient with significant relapse. This patient still had a reduced ESS score, but his AHI was back up to 43 episodes per hour. Two other patients also had AHI values above 5, indicative of mild OSA. The authors recognized that the sample size was small, but cite that the mean statistical improvements were encouraging.[37]

Improved quality of life is a key goal of surgical treatment. Therefore measurement of treatment success should also include the patient's subjective opinion of the surgical result. As such, research was done by Robertson et al.[38] via a patient questionnaire that included the Epworth Sleepiness Scale. Patients who had undergone MMA surgery for

OSA were questioned an average of 31.8 months after surgery and their recorded opinions demonstrated that daytime sleepiness, snoring, and witnessed apnea events were significantly reduced with 90% indicating that they would undergo the surgery again and 100% would recommend the treatment to other sufferers of OSA. Of these patients, 70% had achieved an AHI of less than 10 postoperatively.[38]

A patient-centered quality of life study was done by Lye et al.[39] In addition to correlating findings from polysomnography and physical examinations, they used the *functional outcomes of sleep questionnaire* (FOSQ) developed by Weaver et al.[40] The group emphasized that quality of life in clinical medicine was often neglected and the aim of their study was to assess quality of life in patients undergoing MMA surgery. All patients had tried and failed to be able to use CPAP therapy prior to MMA. Pre-operative functional outcomes of sleep questionnaires were completed and compared to post-surgery FOSQ answers. The improvement in FOSQ scores was statistically significant for all domains including general productivity, social outcomes, activity level, intimacy and sex.[39] The group encouraged the use of FOSQ for all surgical-based treatment in the assessment of patient satisfaction.

Relative safety must be considered with any surgical procedure. Panula et al.[41] reviewed 655 consecutive orthognathic surgeries for complications and problems. During a 13-year period, 655 MMA patients in Finland were observed for surgical complications. The patients were examined one week post-op, followed through their orthodontic treatment, and then again seen for a one-year post-operative assessment. There were some significant surgical concerns including 12% of patients requiring blood transfusions (usually red blood cells only), and one patient who had major bleeding from the

maxillary artery. Twelve patients had "bad splits" (referring to the bilateral sagittal split osteotomy of the mandible) and eleven had tears or cuts to the inferior alveolar nerve. Sixteen patients required re-operations due to loose screws/plates and severe post-op bleeding or swelling was observed in six patients. Five patients suffered from temporary localized acne and ten teeth were injured/damaged when struck by a bur during osteotomy. The most common problem was neurosensory injury involving the inferior alveolar nerve, which was mild in 32% of cases, and severe in only 3% of those affected. The most serious complication was severe bleeding. However, there were no deaths, no tooth loss, or loss of any bony segments. The authors concluded that orthognathic surgery is safe with severe complications being exceedingly rare.[41]

Obstructive sleep apnea has become an ever-increasing problem in North American society as the incidence of obesity increases and diagnostic technology becomes more advanced and readily available. An increasing financial burden to society combined with the debilitating health risks affecting those who are afflicted has led to increased interest in effective treatment strategies. The use of maxillomandibular advancement surgery has been proven to be a surgically stable approach when addressing the primary sites of obstruction found in OSA patients. The current literature has demonstrated that MMA has the potential to be an exceptionally effective surgical treatment method and should be considered a primary surgical technique for treatment of this debilitating disorder.[15, 22, 25, 42] It is also one of the few curative treatments available for this pathology. However, further studies are required to confirm the probability of success of this surgical technique, and to ascertain the effect of various patient and surgical variables on this success rate.

The use of MMA as a surgical technique to treat OSA has been performed at the University of Western Ontario (UWO) for over 15 years. However, there has never been a retrospective analysis to determine the level of treatment success. Therefore, in an effort to further contribute to the current body of evidence, the purpose of this study was to evaluate the outcome of MMA surgery at UWO in patients suffering from obstructive sleep apnea syndrome. In addition, the authors sought to identify any pre or post-surgical parameters that might be predictive of MMA treatment success.

Materials and Methods

Study Sample

This study was a retrospective cohort analysis. The data for this study was collected from the charts of patients who underwent maxillomandibular advancement surgery for the treatment of obstructive sleep apnea at the University of Western Ontario between the years 2002 and 2013. Patient charts were obtained from the London Health Sciences Centre Division of Oral and Maxillofacial Surgery at University Hospital, which is a teaching hospital affiliated with UWO. Ethics approval was obtained from the Health Sciences Research Ethics Board (HSREB), which manages the approval and monitoring of all research at the University of Western Ontario and its affiliated hospitals (Health Sciences REB File Number 104784 and Lawson Health Research Institute Approval Number R-14-047; Appendix II).

Subjects were chosen retrospectively by selecting consecutively treated patients who fulfilled the following inclusion criteria:

1) Diagnosis of obstructive sleep apnea syndrome (OSAS) by a sleep physician based on the patient's polysomnography results from an overnight sleep study

2) Treatment via maxillomandibular advancement surgery by the oral and maxillofacial surgeon on the Dental Sleep Apnea Team at London Health Sciences Centre (Dr. M. Shimizu)

3) Completion and availability of both a pre-surgical and post-surgical overnight sleep study (polysomnography), which included records of the patient's apnea-hypopnea index (AHI) scores and Epworth Sleepiness Scale (ESS) scores.

4) Good quality pre-surgical and post-surgical lateral cephalometric radiographs

The original sample size consisted of 32 patients (15 males, 17 females) collected from the records of Dr. Shimizu at the Department of Oral and Maxillofacial Surgery, London Health Sciences Centre. After scrutinizing the records of the original sample and applying the inclusion criteria, 10 patients (31.3%) were rejected from the study due to incomplete records, leaving 22 patients (11 females, 11 males) that were accepted as the sample population.

Surgical Procedure

All lateral cephalometric radiographs were evaluated via the Delaire analysis [41, 42] to determine the direction and amount of surgical movement desired for each patient. The maxilla was sectioned at the level of Le Fort I, advanced according to the treatment analysis via a pre-fabricated splint and fixated with plates and screws. Maxillomandibular advancement included bilateral sagittal split osteotomy of the mandible in the posterior body, angle and inferior ramus. The proximal segment (including condyles) was left in the original seated position, while the distal segment (alveolar bone and teeth with the body of the mandible) was advanced into a position, which has been pre-determined and captured, via an occlusal splint. The distal segment was then fixated with bicortical screws and/or miniplates and screws.[43] An additional osseous genioplasty procedure was performed on some subjects to allow for even greater advancement of the genial tubercles and adjacent musculature (geniohyoid, genioglossis, mylohyoid and digastric).[43]

Data Collection

The following data was recorded from patient charts:

1) Pre-surgical and post-surgical apnea-hypopnea index scores (recorded during overnight sleep studies via polysomnography)

2) Pre-surgical and post-surgical body mass index (BMI) scores

3) Pre-surgical and post-surgical Epworth Sleepiness Scale (ESS) scores

4) Pre-surgical and post-surgical radiographic films (lateral cephalograms) digitally scanned into Dolphin® imaging software (Version 11.7)

5) Estimated blood loss during surgery and any associated intra or post-surgical sequelae and complications

1) Apnea-Hypopnea Index (AHI)

AHI scores were recorded from the pre and post-surgical overnight sleep studies. These sleep studies were completed by the patients prior to being referred for a consult for surgical treatment on average 49.3 (+/-27.1) months prior to MMA and then again after completion of treatment with a mean follow up period of 15.7 (+/-9.4) months after MMA. Each subject's AHI scores were recorded and indexed into the following categories [15]:

AHI Scores below 5 = *Normal* levels of sleep (below threshold for OSA)

AHI Scores of 5-14 = *Mild* forms of sleep apnea

AHI Scores of 15-29 = *Moderate* sleep apnea

AHI Scores greater than or equal to 30 = *Severe* form of sleep apnea.

Surgical treatment was considered successful if the pre-surgical AHI score was reduced post-surgically to a score below 15 and/or an overall reduction of the pre-surgical AHI score by 50% or greater. A reduction of the AHI score to a value of less than 5 was indicative of the surgical treatment having resulted in a cure of that patient's obstructive sleep apnea. The difference between pre- and post-surgical AHI values was reported both numerically and as a percentage change.

2) Body Mass Index (BMI)

$$BMI = weight\ (kg)\ /\ height^2\ (m^2)$$

Pre-surgical and post-surgical body mass index scores were recorded and classified into the following 3 categories according to the Health Canada Body Mass Index Nomogram[44]:

BMI 18.50 – 24.99 = Healthy Weight

BMI 25.00 – 29.99 = Overweight

BMI 30.00 or greater = Obese

Change in BMI was also calculated as this is known to be a factor in severity of obstructive sleep apnea.[8]

3) Epworth Sleepiness Scale

Pre-surgical and post-surgical Epworth Sleepiness Scale scores were recorded from patient questionnaires and classified according to the following established categories [42]:

Score of 0 – 9 = *Normal* (Patient is getting sufficient sleep or has an acceptable amount of daytime sleepiness)

Score of 10 or greater = *Excessive* (Patient exhibits excessive/abnormally high levels of daytime sleepiness)

Pre and post-surgical scores were examined for changes and as evidence for a subjective evaluation of treatment success.

4) Radiographic Analysis

All cephalometric images were taken at London Health Sciences Centre on the same cephalostat (Siemans Orthophos O.P, Salzburg Germany). The protocol for capturing lateral cephalometric images included positioning the patient into the cephalostat with the sagittal plane of the head upright and parallel to the film and the Frankfurt plane parallel to the horizontal. The horizontal X-ray beam was positioned perpendicular to the sagittal plane and the film. The patients were directed to swallow and keep their tongue positioned at the roof of the mouth immediately prior to radiographic exposure.

Two lateral cephalometric radiographs were analyzed from each patient chart. The pre-surgical lateral cephalogram was taken within one week prior to surgery. The post-surgical lateral cephalogram was taken at the patient's first post-operative assessment, which was approximately one week later, and prior to any post-surgical orthodontic treatment being initiated (Appendix III). All radiographs were scanned into Dolphin® 11.7 imaging software (Dolphin Imaging Version 11.7.05.66, Chatsworth, CA) via digital scanner (Epson Expression 1680, Seiko Epson Corporation Markham, ON).

A custom cephalometric analysis was constructed in Dolphin® 11.7 imaging and used to trace all cephalograms in this study (Figure 1). The custom analysis used both linear and angular measurements (Figures 2 and 3 respectively).

A horizontal reference plane was constructed by subtracting 7 degrees from Sella-Nasion (SN-7°) and passing through Sella. This constructed Frankfurt horizontal line was utilized as the X-axis. A line running 90° perpendicular to this constructed horizontal line, that also passed through Sella point, was used as the Y-axis and referred to as *Sella-vertical* (Sv). Sella-vertical was used as the vertical reference line to calculate changes in horizontal surgical movements (Figure 2).

Three linear measurements were used in the radiographic analysis (Figures 1 and 2).

1) Inferior Airway Space (IAS): A measurement taken at the most narrow point in the inferior airway space of the oropharynx. The distance from the posterior wall of the oropharynx, labelled posterior inferior airway (PIA), to the base of the tongue, labelled anterior inferior airway (AIA) was recorded (all measurements in millimetres).

2) Sella-vertical to Incisor superiorus (Sv-Is): A linear measurement taken on the horizontal plane from Sella-vertical to the incisor superiorus (incisal tip of upper incisor) representing the surgical movement of the maxilla. Measurement was made in millimeters (mm).

3) Sella-vertical to Incisor inferiorus (Sv-Ii): A linear measurement taken on the horizontal plane from Sella-vertical to the incisor inferiorus (incisal tip of lower incisor) representing the surgical movement of the mandible. Measurement was made in millimeters (mm).

The use of Sv-Is (maxillary movement) and Sv-Ii (mandibular movement) to measure linear skeletal tissue movements was indicated due to difficulty in locating skeletal landmarks (A-point and B-point) in the post-surgical radiographs where the placement of surgical plates and screws may have distorted or covered the location of these points. This was deemed acceptable as no orthodontic movement occurred in the time period between the pre and post-surgical cephalograms.

Three angular measurements were also used in the radiographic analysis (Figure 3).

1) <u>Sella-Nasion-A-point (SNA):</u> Position of maxilla in reference to the cranial

base. Measured in degrees.

2) <u>Sella-Nasion-B-Point (SNB)</u>: Position of mandible in reference to the cranial

base. Measured in degrees.

3) <u>A-point-Nasion-B-point (ANB):</u> Position of maxilla in reference to the position

of the mandible. Measured in degrees.

These three angular measurements were utilized to categorize the skeletal patterns of the

patient population prior to surgery.

<u>5) Estimated Blood Loss:</u>

Surgical and post-surgical treatment notes were reviewed to gather the estimated

volume of blood loss per surgical procedure and identify the development of any

surgically related sequelae. Mean blood loss was calculated for the patient population and

any intra or post-surgical complications were recorded.

<u>Statistical Methods</u>

Data analysis was completed using SPSS statistical software program (Released

2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp).

Descriptive statistics were calculated for all study variables before and after surgery as

well as any changes between them. The assumption of normality for statistical tests was assessed graphically. Paired t-tests were utilized to detect statistically significant changes between pre and post-surgical continuous variables. Fisher's exact tests were utilized to assess the differences between successful and failure groups with regards to categorical predictor variables. An independent t-test was utilized to assess differences between successful and failure groups with regards to continuous predictor variables. The relationship between the pre and post-surgical change in AHI versus the change in ESS, BMI, IAS, Sv-Is and Sv-Ii was determined by calculating Pearson's product-moment correlation coefficient (r). Statistical significance for all tests was set at a P-value < .05.

Measurement errors in tracing and digitizing were assessed by re-tracing and re-measuring all 22 lateral cephalograms and re-digitizing them approximately three weeks later. All tracings and re-tracing were done by the same researcher. The formula of Dahlberg[45] was used to calculate the method of error. Measurement error and reproducibility of measurements were calculated (Appendix IV). In this study, a reproducibility of at least 90% was considered to be acceptable.[45]

Results

Radiographic Reproducibility and Error Analysis

The measurement error and reproducibility of cephalometric variables are shown in Appendix IV. The Dahlberg reproducibility error ranged from 0.91 to 0.96. These values met the minimum acceptable limit of 0.90. [45] The measurement errors for the linear measurements ranged from 0.41 mm to 1.06 mm, and for angular measurements the range was 0.50 to 0.98 degrees.

Patient Demographics

Of the 22 patients who met the criteria for inclusion, 11 (50.0%) were female and 11 (50.0%) were male (Table 1). The average age at the time of surgery was 44.0 (+/- 13.9) years with a range from 16.0 to 71.4 years. Surgeries were performed between January of 2002 and September of 2013. Orthodontic treatment (Ortho) was initiated prior to surgery in 16 of 22 (72.7%) patients.

Subjects (N=22)	Age (Years)	Male	Female
Mean	44.0	11/22	11/22
Range	16.0-71.4		
S.D.	13.9		

Table 1. Patient Demographics including age, number of males, and number of females in sample.

The mean pre-surgical BMI of all patients was calculated to be 28.2 (+/- 4.2) with a range of 19.0 to 36.4 (Table 2). There was a mean post-surgical BMI of 29.2 (+/- 5.4) with a range of 19.2 to 38.7. Therefore the average change in BMI for the entire patient population was an increase of 1.0 (+/-3.2) with a range in BMI change of -3.1 to 9.5. The change between pre- and post-surgical BMI was not statistically significant (P >.05). Appendix V contains numeric and categorical BMI data for all patients.

Subjects (N=22)	Pre-BMI	Post-BMI	BMI Change	% Change	P-Value
Mean	28.2	29.2	1	3.5	P=.165
Range	19.0-36.4	19.2-38.7	(-3.1)-(9.5)	(-8.6)-(33.9)	
S.D.	4.2	5.4	3.2	11.5	

Table 2. Data for pre-surgical body mass index (Pre-BMI), post-surgical body mass index (Post-BMI), change in body mass index (BMI Change), percent change (% Change) and P-value between pre and post-surgical BMI scores.

Success of Treatment

Prior to surgery, the mean AHI score was 48.4 (+/-31.3) episodes per hour with a range of 11.5 to 120.2 (Table 3). After surgery, the overnight sleep studies produced a mean AHI score of 14.0 (+/-15.0) events per hour with a range of 0.2 to 59.4. This indicated a mean reduction in the AHI of 34.3 (+/-29.4) episodes per hour, which translated to a 67.9% mean reduction in AHI post-surgically. For the entire patient population, the difference between pre and post-surgical AHI was found to be statistically significant (P<.001). (Appendices VI, VII, and VIII list all AHI values and OSA categories for both the successfully and unsuccessfully treated patients).

Nineteen of the 22 (86.4%) patients met the criteria for successful treatment with a reduction of the AHI to levels below 15 and/or a 50% overall reduction in score. Of those patients who met the criteria for success, 8 of 22 (36.4%) had their AHI levels reduced below a score of 5, indicating a cure from the OSA identified pre-surgically.

Subjects (N= 22)	Pre-AHI	Post-AHI	AHI Change	% Change	P-Value
Mean	48.4	14.0	-34.3	-67.9	P<.001
Range	(11.5)-(120.2)	(0.2)-(59.4)	(-104.1)-(8.4)	(-99.3)-(46.2)	
S.D.	31.3	15.0	29.4	39.1	

Table 3: Pre-surgical apnea-hypopnea index scores (Pre-AHI), post-surgical apnea-hypopnea scores (Post-AHI), change in score (AHI Change), percent change in score (% Change), and P-Value for difference between Pre-AHI and Post-AHI scores.

At time of data collection, 18 of 22 patient charts recorded both a pre- and post-surgical Epworth Sleepiness Score questionnaire (Table 4). The mean pre-surgical Epworth Sleepiness Scale score was 11.6 (+/- 4.6) with a range of 3.0 to 18.0. The post-surgical mean ESS score was reduced to 5.7 (+/- 3.5) with a range of 1.0 to 14.0. The reduction of the ESS scores after surgery was determined to be statistically significant from the pre-surgery scores (P<.001). Appendix IX contains data for all pre-surgical and post-surgical Epworth Sleepiness Scores as well as categorical information.

Subjects (N=18)	Pre-ESS	Post-ESS	ESS Change	P-Value
Mean	11.6	5.7	-5.7	P<.001
Range	3.0-18.0	1.0-14.0	(-14.0)-(10.0)	
S.D.	4.6	3.5	5.5	

Table 4. Data for pre-surgical Epworth sleepiness scale scores (Pre-ESS), post-surgical Epworth sleepiness scale scores (Post-ESS), change in Epworth sleepiness scale scores (ESS Change), and P-Value between pre and post-surgical ESS scores.

Predictors of Treatment Success

Variable	% Success (86.4%)			% Cure (36.4%)		
Age (N=22)	Above 45 (N=11)	Below 45 (N=11)	P-value	Above 45 (N=11)	Below 45 (N=11)	P-value
	72.7	100.0	.107	36.4	36.4	.670
Gender (N=22)	M (N=11)	F (N=11)	P-value	M (N=11)	F (N=11)	P-value
	81.8	90.9	.534	27.3	45.5	.375
Genioplasty (N=22)	Yes (N=13)	No (N=9)	P-Value	Yes (N=13)	No (9)	P-value
	92.3	77.8	.358	38.5	33.3	.584
Orthodontics (N=22)	Yes (N=16)	No (N=16)	P-value	Yes (N=16)	No (N=16)	P-Value
	87.5	83.3	.636	43.8	16.7	.255
Pre-ESS (N=18)	Normal (N=6)	Excessive (N=12)	P-Value	Normal (N=6)	Excessive (N=12)	P-Value
	100.0	75.0	.515	33.3	25.0	.561
Post-ESS (N=18)	Normal (N=16)	Excessive (N=2)	P-Value	Normal (N=16)	Excessive (N=2)	P-Value
	81.3	100.0	.502	31.3	0.0	.352

Table 5. The success and cure rates of Age, Gender, Genioplasty (Genio), Orthodontics (Ortho) and pre and post-surgical Epworth Sleepiness Scale scores (Pre-ESS, Post-ESS) were compared. None of these variables were statistically significant factors on treatment success or cure (P >.05).

Age

Median age of the patients in the study was calculated to be 45.5 years (Table 5). When those above and below the median age were compared to success and cure measures, no statistically significant difference could be found between either age group with regards to treatment success or cure (P >.05).

<u>Gender</u>

There were 11 females (50.0%) and 11 males (50.0%) in the sample population of this study. For the female patients, 10 of 11 (90.9%) were treated successfully and 5 of 11 (45.5%) met the standards for cure, whereas 9 of 11 (81.8%) males met the criteria for success and 3 of 11 (27.3%) could be categorized as cured after treatment (Table 5). No statistically significant association could be found between a patient's gender and likelihood of success or cure (P>.05)

<u>Genioplasty</u>

Thirteen of the 22 (59.1%) patients in the study underwent the additional surgical step of functional genioplasty. Of the 13 patients who underwent the procedure, 12 (92.3%) had success and 5 (38.5%) qualified as cured. In the non-genioplasty group, 7 out of 9 (77.8%) were successfully treated and 3 of 9 (33.3%) were cured (Table 5). However, neither the genioplasty nor non-genioplasty group were statistically more likely to achieve success or cure (P >.05).

<u>Orthodontics</u>

During treatment 16 of 22 (72.7%) patients underwent orthodontics in addition to MMA surgery. For the orthodontic group, 14 of 16 (87.5%) had surgical success with 7 of 16 (43.8%) being cured. For the non-orthodontic group, 5 of 6 (83.3%) qualified for success and 1 (16.7%) for cure (Table 5). No statistical significance could be found for either the orthodontic or non-orthodontic treatment group in regard to likelihood of treatment success or cure (P >.05).

Epworth Sleepiness Scale

The pre-surgical average self-reported score of the ESS was 11.6 (+/- 4.6), which included 6 of 18 (33.3%) patients scoring below 9 (normal), and 12 of 18 (66.6%) patients scoring above 9 (excessive). All 6 patients (100%) who had pre-surgical ESS scores in the normal category were observed to have met the criteria for success after treatment. Of those patients who had pre-surgical ESS scores in the excessive category, 9 out of 12 (75.0%) also met the criteria for surgical success (Table 5). Two of the 6 (33.3%) patients in the normal category and 3 of the 12 (25.0%) patients in the excessive category met the criteria for cure. No significant association was found between a subject's pre-surgical ESS score and their likelihood of surgical success or cure (P >.05).

For the post-surgical ESS scores, 13 of 16 (81.3%) from the normal category and both of the 2 (100.0%) patients who were in the excessive category had surgical success while 5 of 16 (31.3%) of those in the normal category and 0 out of 2 in the excessive category achieved a cure (Table 5). No significant statistical association could be found between a subject's post-surgical ESS score and treatment success or cure (P >.05).

The pre to post-treatment change in ESS was compared against the pre to post-treatment change in AHI (Table 9). A mild negative correlation was detected (Appendix X). However there was no statistically significant relationship (r = -.461; P = .054).

Variable	% Success (Total = 86.4%)				% Cure (Total = 36.4%)			
Pre-BMI (N=22)	Healthy (N=3)	Overweight (N=13)	Obese (N=6)	P-value	Healthy (N=3)	Overweight (N=13)	Obese (N=6)	P-Value
	66.7	84.6	100.0	.280	33.3	38.5	33.3	.970
Post-BMI (N=22)	Healthy (N=6)	Overweight (N=7)	Obese (N=9)	P-Value	Healthy (N=6)	Overweight (N=7)	Obese (N=9)	P-Value
	83.3	71.4	100.0	.154	66.7	28.6	22.2	.188
Pre-AHI (N=22)	Mild (N=2)	Moderate (N=6)	Severe (N=14)	P-Value	Mild (N=2)	Moderate (N=6)	Severe (N=14)	P-Value
	100.0	66.7	92.9	.247	100.0	50.0	21.4	.070
Pre-SNA (N=22)	Retro (N=8)	Normal (N=4)	Prog (N=10)	P-value	Retro (N=8)	Normal (N=4)	Prog (N=10)	P-Value
	75.0	87.5	90.0	.756	50.0	25.0	40.0	.662
Pre-SNB (N=22)	Retro (N=12)	Normal (N=10)		P-Value	Retro (N=12)	Normal (N=10)		P-Value
	83.3	90.0		.571	41.7	30.0		.454
Pre-ANB (N=22)	<7.7° (N=11)	> 7.7° (N=11)		P-Value	<7.7° (N=11)	> 7.7° (N=11)		P-Value
	81.8	90.9		1.0	27.3	45.5		.156

Table 6. Variables in relation to treatment success and cure including: Pre-surgical BMI (Pre-BMI), Post-surgical BMI (Post-BMI), pre-surgical apnea-hypopnea index (Pre-AHI), pre-surgical sella-nasion-A-point (Pre-SNA), pre-surgical sella-nasion-B-point (Pre-SNB), and pre-surgical A-point-nasion-B-point (ANB). Associated P-Values are reported.

Pre and Post-surgical BMI

When evaluating a patient's pre-surgical BMI classification versus success of treatment, the healthy category had 2 of 3 (66.7%) successful with 1 of 3 (33.3%) meeting the standards for cure (Table 6). The overweight category had 11 of 13 (84.6%) successfully treated and 5 of 13 (38.5%) were cured. Of those in the obese category, 6 of 6 (100%) were treated successfully and 2 of 6 (33.3%) met the criteria for cure. There was no statistical significance between a patient's pre-surgical body mass index score and treatment success or cure (P >.05)

After surgery, 6 patients were in the healthy BMI category and 5 of 6 (83.3%) were successfully treated with 4 of 6 (66.7%) having been cured. Of the 7 in the overweight category, 5 (71.4%) were successful and 2 (28.6%) were cured. The obese category increased to 9 patients with all 9 (100%) being successfully treated and 2 (22.2%) being cured. There was no statistical significance between a patient's post-surgical BMI category and success of treatment or cure (P >.05).

The change in BMI was plotted against the change in AHI (Table 9) and a moderate negative correlation was detected (Appendix XI). This correlation was determined to be statistically significant (r = -.661; P= .001).

Pre-surgical AHI

Prior to surgery, 2 patients were classified as being in the mild category (AHI of 5-15) for their apnea-hypopnea index scores (Table 6). Both of these patients met the standards for treatment success (100%) and cure (100%). Of the 6 patients in the moderate OSA category, 4 (66.7%) were successfully treated and 3 (50.0%) were cured. For the 14 patients in the severe category, 13 (92.9% were treated successfully and 3 (21.4%) were cured. There was no statistical significance found between a patient's pre-surgical apnea-hypopnea index and treatment success or cure (P >.05).

Pre-Surgical SNA

The mean pre-surgical SNA for all patients was calculated to be 83.8 (+/-3.9) degrees, which is categorized as normal. [46] Pre-surgical SNA groups in Table 6 are reported as retrusive (retro), normal and protrusive (prog). In the group of patients where

SNA was in the normal (82 +/- 2°) category, 7 of 8 (87.5%) were successfully treated with 2 of 8 (25%) achieving cure. The retrusive (less than 80°) category had 3 of 4 (75%) successful and 2 of 4 (50%) who were cured while the protrusive (greater than 84°) category had a 90% (9 of 10) success rate with 4 of those (40%) achieving the criteria for cure. All pre-surgical SNA values are reported in Appendix XII. No statistical significance was found between the value of a patient's pre-surgical SNA angular measurement and likelihood of successful treatment or cure outcome (P >.05).

Pre-surgical SNB

The mean value of the SNB for the entire sample was 76.5 (+/- 4.0) degrees, which is considered to be retrusive. [46] Pre-surgical SNB values in Table 6 are reported to be either retrusive (retro) or average (norm). Of the patients who had a retrusive SNB angle (pre-surgical value of less than 78°), 10 of 12 (83.3%) were treated successfully and 5 (41.7%) met the criteria for cure. In those patients who had average SNB values, 9 out of 10 (90.0%) had treatment success with 3 (30.0%) achieving cure. All pre-surgical SNB values are reported in Appendix XII. No statistical significance was found between a patient's pre-surgical SNB angle and the likelihood of treatment success or cure (P>.05).

Pre-Surgical (ANB)

The median value of the entire group was 7.7°. Of the patients who were below the median ANB value, 9 out of 11 (81.8%) had successful treatment and 3 (27.3%) were

in the cure group (Table 6). For those above the median ANB value of 7.7°, 10 out of 11

(90.9%) had successful treatment and 5 (45.5%) of them were classified as cured. All

pre-surgical ANB values are reported in Appendix XII. There was no statistical

significance found between pre-surgical ANB value and treatment success or cure (P >

.05).

IAS

For the entire population, the pre-surgical inferior airway space (IAS)

measurement had a mean of 8.1 (+/- 4.1) mm with a range of 2.7 to 19.2mm (All pre and

post-surgical values for IAS are reported in Appendix XIII). Post-surgical IAS

measurements averaged 14.6 (+/- 3.9) mm with a range of 9.3 to 20.1 mm. The average

change from pre-surgery to post-surgery was 6.6 (+/-4.5) mm, which equated to a mean

increase of 123.3% (Table 7). This change in IAS from pre-surgery to post-surgery was

found to be statistically significant (P<.001).

Subjects (N= 22)	Pre-IAS (mm)	Post-IAS (mm)	IAS Change (mm)	% Change	P-Value
Mean	8.1	14.6	6.6	123.3	P<.001
Range	2.7-19.2	9.3-20.1	0.7-17.3	7.1-302.3	
S.D.	4.1	3.9	4.5	143.9	

Table 7. Measurements of the inferior airway space including pre-surgical airway space (Pre-IAS), post-surgical airway space (Post-IAS), change in airway space (IAS Change), percent change in airway space (% Change), and P-Value. All measurements are in millimeters (mm).

The average pre-surgical IAS measurement of only those patients who had surgical success was 8.3 (+/- 4.4) mm whereas those that did not have successful treatment had an average IAS measurement of 6.3 (+/-1.8) mm (Table 8). When the two group means were compared, there was no statistical significance between them regarding treatment success (P >.05). The pre-surgical mean of those who met the criteria for cure was 7.0 (+/-2.5) mm and 8.6 (+/- 4.8) mm for those who did not fulfill the criteria. The difference between these two means was also not statistically significant (P >.05).

Treatment Variable (N=22)	Success (mm)	Non-success (mm)	P-Value	Cure (mm)	Non-Cure (mm)	P-value
Pre-Surg IAS	8.3 (+/-4.4)	6.3(+/-1.8)	.444	7.0(+/-2.5)	8.6(+/-4.8)	.399
Post-Surg IAS	14.3(+/-3.6)	16.2(+/-6.4)	.466	12.6(+/-2.5)	15.8(+/-4.2)	.058
Sv-Is	9.2(+/-3.6)	6.7(+/-5.1)	.314	9.5(+/-3.8)	8.4(+/-3.9)	.531
Sv-Ii	12.4(+/-4.5)	11.6(+/-4.6)	.780	14.0(+/-5.8)	11.3(+/-3.4)	.181

Table 8. Means, standard deviations, and P-values of pre-surgical inferior airway space (Pre-Surg IAS), post-surgical inferior airway space (Post-Surg IAS), maxillary horizontal movement (Sv-Is), and mandibular horizontal movement (Sv-Ii). No surgical variables were found to be statistically significant in relation to treatment success or cure (P >.05).

The average post-surgical IAS measurement of successfully treated patients was 14.3 (+/- 3.6) mm and the unsuccessful patient mean measured 16.2 (+/- 6.4) mm while the mean post-surgical IAS measurement for the cure group was 12.6 (+/-2.5) mm and the non-cure group mean was 15.8(+/-4.2) mm. There was no statistically significant correlation between the mean post-surgical IAS measurement and likelihood of treatment success or cure (P>0.05). The mean amount of change in the AHI was compared to the

mean amount of change in the IAS score (Table 9). No significant correlation could be drawn between the two variables (Appendix XIV, r = .079; P = .725).

AHI Change Vs.	BMI * (N=22)	ESS (N=18)	IAS (N=22)	Sv-Is (N=22)	Sv-Ii (N=22)
r	-.661*	-.461	.079	-.260	-.176
P-Value	.001*	.054	.725	.242	.434

Table 9. The change in the apnea-hypopnea index score was compared to the change in the body mass index (BMI), change in Epworth sleepiness scale (ESS), change in inferior airway space (IAS), change in horizontal movement of the maxilla (Sv-Is), and change in horizontal movement of the mandible (Sv-Ii), (r and P-values are both reported).

Maxillary Movement (SV-Is)

For the entire population, the surgical movement of the maxilla (Sv-Is) on the horizontal plane had a mean of 8.8 (+/- 3.8) mm with a range of 0.9-16.4 mm. Patients who had successful treatment averaged an increase of 9.2 (+/- 3.6) mm, whereas patients who had unsuccessful treatment had an average increase of 6.7 (+/-5.1) mm after surgery (All pre and post-surgical Sv-Is values are reported in Appendix XV). Those that were cured had a mean movement of 9.5 (+/- 3.8) mm and those who were not cured averaged 8.4 (+/- 3.9) mm (Table 8). No statistically significance was calculated between the amount of maxillary movement on the horizontal plane and likelihood of successful treatment or cure (P> .05). The change in AHI score and the change in maxillary movement (Sv-Is) were compared (Table 9) and there was no significant correlation (Appendix XVI, r = -.260; P= .242).

Manidibular Movement (Sv-Ii)

The surgical movement of the mandible (Sv-Ii) on the horizontal plane had a

mean of 12.3 (+/- 4.4) mm among the entire patient population with a range of 5.0 to 23.3

mm (all distances for mandibular advancement are reported in appendix XVII). Patients

who experienced treatment success had an average movement of 12.4 (+/-4.5) mm of

movement and those who did not meet the criteria of success had an average of 11.6 (+/-

4.6) mm of movement (Table 8). Those who met the criteria for cure had a mean

movement of 14.0 (+/- 5.8) and the non-cure group averaged 11.3 (+/-3.4). No statistical

significance was found between the amount of mandibular movement (Sv-Ii) and

treatment success or cure (P>.05). Table 9 contains data for comparison of the change in

AHI and the change in horizontal advancement of the mandible (Sv-Ii). No significant

correlation was detected (Appendix XVIII, r = -.176; P = .434).

Surgical Blood Loss and Sequelae:

The amount of estimated blood loss (Table 10) during surgery was recorded in the

surgical treatment notes to have an average of 386.4 (+/-114.6) cubic centimetres (cc). A

complete list of significant medical conditions, estimated blood loss during surgery, and

surgical-related complications is found in Appendix XIX.

All Patients	Estimated Blood Loss During Surgery (CC)
Mean	386.4
Range	(200.0)-(750.0)
S.D.	114.6

Table 10. Estimated blood loss during surgery (measured in cubic centimetres).

There were no deaths, no loss of bony segments, and no loss of teeth. Surgical sequelae included one patient who developed pneumonia requiring five days in hospital (full recovery), non-union of a Le Fort osteotomy which required a second surgery (full recovery), removal of a broken plate (no further treatment required, full recovery) and one patient required root canal therapy followed by internal bleaching on a central incisor.

Discussion

Patients who suffer from obstructive sleep apnea syndrome can develop serious medical conditions that have a negative effect on quality of life. [1, 13, 15] There are a variety of treatments currently being implemented for those who suffer from this condition including various surgical approaches. [1] The use of maxillomandibular advancement surgery has been proposed as the most effective craniofacial surgical treatment for OSA sufferers. [42] The purpose of this study was to evaluate the success of maxillomandibular advancement surgery at the University of Western Ontario when treating patients suffering from OSA and to identify if there were any demographic or treatment variables that had an effect on the success of treatment.

The definition of treatment *success* that was selected for use in this study was based upon the standards and precedents of recently published literature. [15, 25, 47] The majority of the MMA literature uses a definition of success that shows a post-operative AHI < 20 (or <15 or <10) and /or a 50% reduction. [15] At present, there remain a variety of study methodologies and the literature indicates that there is no universally accepted definition of success when surgically treating OSA. [15] The definition utilized by this study (a post-surgical reduction of the AHI to a score below 15 and /or an overall AHI decrease of 50%), achieved a standard of having the patient's OSA reduced to the level of *mild* sleep apnea (AHI between 5 and 14 episodes per hour) or below, where the symptoms and associated conditions are less severe. There is likely a benefit for patients treated with MMA surgery even when OSA is not completely cured. [42, 48] Li suggests that OSA is similar to other chronic illnesses in that complete elimination may not be possible and

therefore the goal of any treatment that is implemented is to control or improve the symptoms by reducing the severity of the syndrome. [49]

The definition of a *cure* from OSA does appear to be universally accepted throughout the published literature and is indicated by an AHI level that is reduced to below 5 episodes per hour. This is the minimum number of apneas per hour required to qualify as having any form of sleep apnea. [2, 42] Therefore this definition of cure was utilized in the present study and is easily comparable to the current body of literature.

The results observed in this study, which included 19 of 22 patients (86.4%) achieving surgical success along with 8 of 22 patients (36.4%) achieving a cure from their OSA symptoms, are very similar to the levels of success that have been reported in the published literature. [11, 15, 22, 25, 42, 47, 49] Dekeister et al. [11] reported data on a retrospective study of 25 males with a mean age of 48.0 (+/-7.0) years. The mean pre-surgical BMI of the group was 28.0 (+/-3.4) and the mean apnea-hypopnea index was determined to be 45.0 (+/-15.0) episodes per hour prior to MMA. After surgery, the success rate of the study was 84% with a cure rate of 48%.

Varghese et al. [50] completed research on 24 patients (75% male) with a mean age of 48.3 (+/-10.8) years who underwent MMA for treatment of OSA. All 24 patients had pre- and post-surgical AHI values recorded via overnight polysomnography with a pre-surgical mean of 45.4 (+/- 26.4) and post-surgical mean of 7.8 (+/- 10.5). An 83% reduction in AHI was produced and the difference from pre- to post-surgical values was statistically significant. Only 18 patients had both pre- and post-surgical BMI values recorded and the difference in the BMI values was not statistically significant. The

Epworth Sleepiness Scale was completed before and after surgery by 14 of the 24

patients with a mean pre-surgical ESS score of 13.6 (+/- 5.4) and a mean post-surgical

ESS score of 8.8 (+/- 3.3), which equated to a 35% reduction in ESS score after surgery.

In regards to success rate, this study showed 87.5% of patients had achieved an AHI

reduction of 50% and/or an AHI score less than or equal to 20 events per hour. These

results are very similar to those found in the present study.

Holty and Guilleminault [42] performed a systematic review and meta-analysis to

estimate the clinical efficacy of treating obstructive sleep apnea with MMA surgery.

After scrutinizing the literature they included 22 unique patient populations that were

studied between 1989 and 2009. Among the 22 studies a total of 627 patients were

observed with a range of study sample sizes from 2 patients to 175 patients with a mean

of 28.5 patients per publication. The average success rate of all studies investigated was

86.0% with an average cure rate of 43.2%. This reported level of success and cure was

very comparable to the results achieved in this study.

There are a variety of methodologies among the current literature for assessing

subjective, self-reported improvement in sleepiness. Authors have used second-person

reports of snoring and restlessness from spouses and family members, personalized

patients questionnaires, the Functional Outcomes of Sleep Questionnaire and the Epworth

Sleepiness Scale. [15, 22, 42] Patients involved in this retrospective study were given the

Epworth Sleepiness Scale and the mean pre-surgical ESS score was 11.6 (+/- 4.6). The

post-surgical mean ESS score was reduced to 5.7 (+/- 3.5). This represented a mean

reduction in subjective levels of sleepiness of 37.8%. This post-surgical reduction level

was comparable to that of Holty [42], which reported that patients who had completed the

Epworth Sleepiness Scale as part of their sleep studies had a mean pre-treatment score of 13.2 (+/- 5.5) with post-treatment scores averaging 5.1(+/- 3.6).

Goodday[51] also showed comparable results in his study, which evaluated the subjective outcomes of 116 patients who underwent MMA surgery for OSA syndrome from 2000 to 2010. Preoperatively only 28% of patients scored below 10 (normal levels of sleep) on the Epworth Sleepiness Scale. After surgery 90% had reduced their ESS score to less than 10. In the present study, only 27.3% patients recorded a pre-surgical score of 10 or less on the ESS, whereas post-operatively 77.3% of patients had reduced their score down to the normal category.

Johns[52] reported that the Epworth Sleepiness scale is both reliable and consistent. However, it must be recognized that the ESS is the patient's own subjective rendering of how they recall their levels of sleepiness at the time that they are reporting it. It would be expected that there might be multiple external factors that would affect ones recording of sleepiness levels on any given day. For example, some patients may be required by law to reduce their levels of sleepiness in order to maintain employment or to qualify for a drivers licence. In the present study, one patient (patient # 6, Appendix VII) had a post-surgical AHI decrease of 90.5 episodes per hour, yet his reported ESS scores increased from 4 pre-surgically to 14 after surgery. This patient was suffering from bipolar disorder and was taking multiple psychoactive medications at the time of surgery. Perhaps the mood altering effect of the bipolar disorder may have had an influence on that patient's reporting of sleepiness levels in either a positive or negative way.

Interestingly, for the 3 patients in this study who did not meet the criteria for surgical success, there was a pre-surgical mean ESS score of 13.3 +/- 3.5 (excessive sleepiness) and a post-surgical mean of 5.0 +/-1 (normal levels of sleepiness). Therefore even though these 3 patients did not meet the AHI standard for successful treatment, they reported a mean subjective reduction in daytime sleepiness of 63.8%. Additionally, all 3 of these unsuccessful patients had their reported amount of sleepiness reduced down to normal levels (ESS score of 9 or less), which may be indicative of a successful outcome from the patient's perspective.

Some publications have reported finding treatment variables that have been predictive of surgical success. These variables included younger patient age, decreased pre-operative weight, greater maxillary advancement and greater increases in SNA and SNB after surgery. [42, 53] In the present study, multiple variables were examined for predictors of success, with the goal of determining what patient characteristics may be best suited for MMA surgery, and also which specific treatment protocols would enhance the surgical outcome. However, for all variables examined, no statistically significant associations were detected (P>.05). This is likely attributable to the limited sample size in this study (n = 22), and the even smaller sample size of the surgical failure group (n = 3), which decreases the power of the study and makes it difficult to detect a significant correlation between variables.

Patient gender was compared to the likelihood of treatment success and no statistical significance was found (P>.05). This is in agreement with previous studies that found no association between gender and treatment success. [25, 42] However, this study did provide a unique sample population, as 11 of the 22 patients (50.0%) that met the

inclusion criteria were female. Two systematic reviews reported the percentage of males in the studies that were included: the Stanford group [42] had a range of 65%-100% with an average of 88% male, while Pirklbauer et al. [25] had a range of 61.9%-100% and averaged 86.3% males. Therefore, the present study appears to be unique in that it may be the first to have an equal population of male and female patients who have undergone MMA surgery to treat obstructive sleep apnea.

Mean age of the patients in this study was calculated to be 44.0 (+/- 13.9) years, which again was comparable to the mean age of the 22 studies reviewed by Holty[40] that reported an average age of 44.4 (+/- 9.4) years. [42] Age was not found to be a predictor of treatment success in the present study (P>.05), however it is notable that the mean age of those patients who did have treatment success was 41.0 (+/-12.2) years, whereas the mean age of the unsuccessful patients was 63.1 (+/-7.9) years. Age was reported to be a predictor of success by Holty et al. [42] Their research indicated that patients who were younger at the time of their surgeries had an increased likelihood of successful MMA treatment.

Some patients in this study underwent two adjunctive procedures in addition to the MMA surgery. The first was orthodontic treatment, with or without extractions of teeth, to allow for maximal surgical movement. The second adjunctive procedure, a functional genioplasty, may be expected to further increase the volume of the airway as the genial tubercles and associated musculature (geniohyoid, mylohyoid, genioglossus, digastric) is pulled even further anteriorly than what is observed with mandibular advancement alone. This would be expected to increase the likelihood of maximizing the positive airway change. In the present study, neither the orthodontic nor genioplasty

procedures produced a greater likelihood of treatment success (P >.05), which is in agreement with the current literature where no studies found either of these procedures to be predictive of success.

The average body mass index (BMI) of patients in this study remained relatively constant. Pre-surgically the mean BMI was 28.2 (+/-4.2) and post-surgically the BMI average was very similar at 29.2 (+/- 5.4). There was no significant association found between a patient's pre-surgical BMI or post-surgical BMI and likelihood of success (P>.05), which is contrary to findings in other studies that indicated a lower pre-surgical BMI could be a predictor of greater surgical success. [42] However, there was a small negative correlation (r = -.661) between the change in BMI and change in AHI that was not observed in other studies. This indicated that, as the patient's BMI went up (gained weight after surgery), their AHI episodes decreased. This finding was unexpected and would warrant further study with a larger sample to determine if it could be used as a predictor of successful treatment.

The Epworth Sleepiness Scale was used in this study because it is the most widely used analysis to report excessive daytime sleepiness. [51] The ESS was used to divide the patients into those who had acceptable levels of sleepiness (scores of 9 and below) and those with excessive sleepiness (scores of 10 and above). Pre-surgical and post-surgical classifications were compared with treatment success and no statistically significant correlations were found (P>.05). Therefore the ESS scores from both pre- and post-surgery were not predictors of success and this is consistent with other published research. [25, 42, 50]

The radiographic analysis in this study included measurements of the horizontal dimension of the Inferior Airway Space (IAS), linear hard tissue movements of the maxilla (Sv-Is) and mandible (Sv-Ii) and also calculations of the angular relationships of the maxilla to the cranial base (SNA), mandible to cranial base (SNB) and maxilla in reference to the mandible (ANB). It should be recognized that, while lateral cephalometric radiographs are an excellent method of assessing hard tissue (skeletal) position, they are a static image of soft tissue that is dynamic in real time. Therefore using a lateral cephalometric image to trace/measure a soft tissue landmark, such as the inferior airway space, may have limitations. Measurements of soft tissues may change if taken at different time points or if taken with the patient in a different postural position. The measurements obtained from the radiographs can be used as part of a patient record to guide treatment and assess surgical results, but cannot be considered alone as diagnostic, and must to be corroborated with a polysomnography study and subjective self-assessment (ESS) in order to provide a diagnosis of OSA.

For the inferior airway space, neither the pre-surgical nor post-surgical mean values were shown to be predictors of treatment success (P >.05). This was consistent with the findings of other research.[25, 42, 50] However, the pre-surgical measurements of the IAS indicated that the successful patients had a mean of 8.3 (+/-4.4) mm whereas the 3 patients who did not have success were shown to have a mean IAS of only 6.3 (+/- 1.8) mm. Therefore the unsuccessful group had a 24.4% smaller airway measurement prior to surgery. Also of interest was the finding that after surgery, the unsuccessful group had a larger mean IAS measurement (16.2+/-6.4mm) compared to the successful group (14.3+/-3.6mm). This indicates that a larger increase in airway space was achieved for those 3

unsuccessful patients, but they still recorded more apnea events per hour than the successful group.

For the skeletal movements, the difference in the average advancement of the maxilla (Sv-Is) and mandible (Sv-Ii) for both the successful and unsuccessful groups was not statistically significant (P >.05). In the present study, the mean maxillary advancement was 8.8 (+/-3.8) mm and mean mandibular advancement was 12.3 (+/-4.4) mm. These advancements are very similar to reported movements in other publications where MMA is performed for OSA treatment.[53] However, it was noted that the mean horizontal movement of the maxilla in the unsuccessful group was only 6.7 (+/-5.1) mm compared to 9.2 (+/-3.6) mm in the successfully treated group. This indicates that the 3 patients who were not treated successfully had approximately a 27.7% shorter horizontal advancement of the maxilla during surgery. The amount of maxillary advancement was found to be correlated with treatment success in other studies, as the anterior skeletal movement pulled the associated soft tissue with it, resulting in an increase in airway dimensions and volume.[42]

For the angular skeletal measurements, neither the pre-surgical SNA, SNB, nor ANB were seen to act as predictors of successful treatment (P >.05). These measurements did however provide some indication of the skeletal pattern of the study population. Only 4 patients in this study had a retrusive maxilla (SNA less than 80 degrees). This indicated that most patients in the study had a maxilla that was positioned normally (8 patients), or slightly protrusively (10 patients), in relation to the cranial base prior to surgery. This is similar to the findings of Ronchi et al.[21], whereby MMA surgery was found to be effective in OSA patients, even if no skeletal anomalies were present.

In reference to the SNB values recorded prior to surgery, 12 of 22 patients had a value that was retrusive and the remaining 10 patients had values in the normal range. This indicated that the majority of the patient population of this study had a retrognathic mandible in relation to the cranial base prior to surgery and no patients were observed to have prognathic mandibles. The published literature indicates a variety of pre-surgical skeletal patterns are possible for OSA patients and the present sample population is similar to those reported in other studies [15, 30, 32, 42]

The mean pre-surgical ANB value for the group was 7.3 (+/-2.6) degrees, which is greater than that of the average found in orthodontic control group populations (reported as 2.6 (+/-2.0) mm). [46] This elevated ANB value demonstrates that the patient population of the present study had a large skeletal discrepancy between the relationship of the maxilla and the mandible, which again is reported in other studies. [15]

The estimated blood loss for the study sample had a mean value of 386.4 (+/-114.6) cc. This amount is similar to that reported by Pineiro-Agular [54] in a review of seven studies of orthognathic surgeries that included Le Fort I, BSSO or both and found a mean volume of blood loss of 436.1 (+/- 207.89) ml. Panula et al [41] also produced similar results in reviewing 655 patients who underwent orthognathic surgery consisting of BSSO advancement, BSSO setback, Le Fort I or a combination of BSSO and Le Fort I. For all procedures an average blood loss of 451 ml was reported.

For the present study, there were no fatal complications, no loss of any bony segments, and no tooth loss. Again, these results are similar to those in the published

literature and indicate that MMA surgery is safe with very few complications related to surgical procedure (Appendix XIX). [15, 41, 42, 51, 54]

Historically, surgical treatments for obstructive sleep apnea have been categorized by medical professionals as *phase I* and *phase II* procedures with the intention that a phased approach would allow for the least amount of surgical intervention to be implemented. [55] However, this phased approach has been shown to be ineffective in many patients who do not benefit from the "less invasive" phase I surgical procedures. [49] Surgeons are now aiming for a more patient-specific approach with individualized treatment plans designed to increase the likelihood of success by choosing an appropriate surgical technique that will address the site of obstruction. [20, 22] Therefore a phased approach should no longer be the standard of care and authors in recent publications have stopped using the phase I/phase II terminology to avoid the implication that procedures which were previously considered as *phase II* should only follow *phase I* treatments. [15, 22, 49]

The sample population from which this study has been constructed is dependent upon referrals from physicians specializing in sleep medicine and therefore is inherently biased. These physicians conduct the polysomnography studies and then, based on their analysis, interpretation, and discussion with the patient, must decide whether or not the patient could benefit from surgery. Then the sleep physician must propose the surgical option to the patient and allow the patient to decide if they wish to pursue a consult with an oral surgeon to discuss the risks and benefits of the procedure. Therefore, the population that proceeds to the surgical consult is heavily controlled by the sleep physicians and patients deemed to have too low of an AHI, too high of a BMI, or those

with only moderate motivation, may never get consulted regarding surgery. Also, it is possible that patients may be given a surgical option but have success with other treatments, including CPAP or oral appliances. It is also likely that in some circumstances patients may only be referred for MMA surgery as a last resort after less invasive treatments have failed. It was therefore apparent that the patients selected for the sample population of this study had complex medical histories spanning numerous years, and were therefore not selected from a random sample.

This study included patients with AHI levels that were mostly moderate and severe, however, the investigators also chose to include 2 patients who had AHI scores in the mild category prior to surgery. This acted to lower the mean AHI of the pre-surgical population and also, as previously mentioned, these patients already met one of the two criteria that could qualify a patient as being successfully treated (AHI score of below 15). Therefore to be considered as successful, these 2 patients had to meet the other criteria of a 50% AHI reduction after surgery. Both patients achieved this standard and were included in the study to demonstrate that patients in the mild category of OSA can also exhibit significant improvements from MMA surgery. This was demonstrated by their AHI reductions of -92.5% and -90.7% and also their improved subjective ESS scores of 83.3% and 42.9%.

Dates listed in Appendix XXI indicate that for some patients there was a large range of time between the pre-surgical polysomnography (PSG) study and the date of surgery (mean number of months prior to surgery was 49.3 +/- 27.1). Post-surgical polysomnography studies had a much smaller mean of 15.7 (+/- 9.4) months after surgery. The large spans of time between the pre-surgical PSG study and the surgery date

may not account for any changes in AHI (worsening or improvement) that could have occurred in this time span and therefore comparing the post-surgery PSG to the original PSG may not be as accurate of a comparison if a large amount of time has occurred between the two studies. Patient availability, willingness to participate, surgical scheduling conflicts, and variations in wait list times for the overnight sleep studies may all contribute to the likelihood of having a sleep study done at a time closer to the surgical date. None of the previously published studies that were examined reported the dates of the pre or post-PSG studies in reference to surgical dates and therefore a comparison to the literature was not possible.

The surgical movements that were recorded in this study were done on radiographs taken immediately pre and post-surgically so there would have been only skeletal movements with no orthodontic movement between radiographs. However, the surgical movements were only measured on the horizontal plane. It is expected that some vertical movement also occurred during the surgical procedures, but this was not accounted for in the horizontal measurements that were reported. Additional investigation into the effect of the vertical surgical movements on success and cure of treatment should be considered for future study of this sample population.

The reliability of both the person scoring the sleep study and the reproducibility of sleep studies may also be discussed as a limitation of the study. The scoring variability between polysomnography technologists was investigated by Collop.[56] Eleven technologists in nine laboratories all utilized the same scoring system (Oxford Medilog SAC) to evaluate the same eleven sleep studies for evaluation of OSA. The results indicated that there was significant variability in scoring of respiratory events. Four

studies had a range of scores from *none* to *moderate* and one study had a range from *none* to *severe*, depending on which technologist scored the test. The researcher concluded that there could be large variations in scoring, depending on the technologist's interpretation of the rules for testing.

The test-retest reliability of overnight polysomnography was investigated by Levendowski et al.[57] The purpose of the research was to evaluate the reliability of laboratory polysomnography at an interval of at least one month (mean of 40 +/- 11.9 days between tests). The results of the study indicated that there was variation between the two PSG studies with an average increase of 7 events per hour during the second study. Twenty-five percent of the patients tested produced an increase of 20 events per hour on the consecutive study with only forty-five percent of patients tested having a variation of less than 5 events per hour in consecutive studies. Similar variations in sequential studies were observed by Chediak[58] and Carlile.[59] Therefore having multiple sleep centres where each patient only has a single study completed, which is interpreted by a variety of technologists and/or physicians, may lead to bias in the scoring of the study.

Conclusions

This retrospective study examined the pre- and post-surgical polysomnograms and radiographs of patients suffering from obstructive sleep apnea to evaluate the treatment effects of maxillomandibular advancement surgery. The following conclusions were derived:

1. Maxillomandibular advancement surgery is a safe and effective treatment for obstructive sleep apnea with 86.4% of patients experiencing a successful result, and 36.4% obtaining a cure.

2. Subjective self-assessment of sleepiness levels was reduced by an average score of 5.7 on the Epworth Sleepiness Scale, which placed 88.9% of patients below a score of 10.

3. Among the small sample group tested, AHI, BMI, ESS, IAS, SNA, SNB, gender, age, maxillary advancement and mandibular advancement could not be considered predictors of successful treatment for this patient population.

Suggestions for Prospective Research Studies:

1) To allow for a more direct comparison between the study populations, it would be ideal to have all patients referred from the same sleep clinic and to have their PSG studies interpreted by one standardized sleep physician both before and after surgery.

2) If possible, polysomnography studies should be conducted at a standard time point prior to and after surgery and it may be beneficial to have multiple studies done to confirm or average the scores.

3) An accepted definition of successful surgical treatment should be established for obstructive sleep apnea patients treated at London Health Sciences Centre.

4) Epworth Sleepiness Scale scores should be reported for all patients before and after sleep studies at all participating sleep laboratories. Functional Outcomes of Sleep Questionnaires could also be given to patients in addition to the Epworth Sleepiness Scale to allow for a more detailed subjective analysis and to allow for comparison to other published literature.

5) Cone Beam Computed Tomography could be considered for method of airway assessment before and after surgery to allow for airway volume calculation and comparisons to other published literature.

6) Long-term follow up studies of this patient population should be completed to establish the long-term prognosis for treatment (very few long-term studies currently available in the published literature).

7) All patients should be asked at follow-up appointments if they have completely eliminated the need for CPAP and/or any other sleep appliances.

Figure 1

Cephalometric landmarks included: 1. Sella 2. Nasion 3. Anterior Nasal Spine 4. A-point 5. Incisor Superiorus (upper incisal tip) 6. Incisor Inferiorus (lower incisal tip) 7. B-point 8. Pogonion 9. Menton 10. Gonion 11. Basion 12. Posterior Nasal Spine 13. Incisor Inferiorus (root apex) 14. Incisor Superiorus (root apex) 15. Articulaire 16. Anterior inferior airway (AIA) 17. Posterior inferior airway (PIA).

Figure 2

Linear Measurements:

Constructed Frankfurt horizontal: labelled as the x-axis (SN-7°).

Sella-Vertical (Sv) : labelled as the y-axis.

Sella-Vertical to Incisor Inferiorus (Sv-Ii): representation of the horizontal position of the mandible.

Sella-vertical to Incisor Superiorus (Sv-Is): representation of the horizontal position of the maxilla.

Inferior airway space (IAS): measured from AIA to PIA at the most occluded point of the oropharynx.
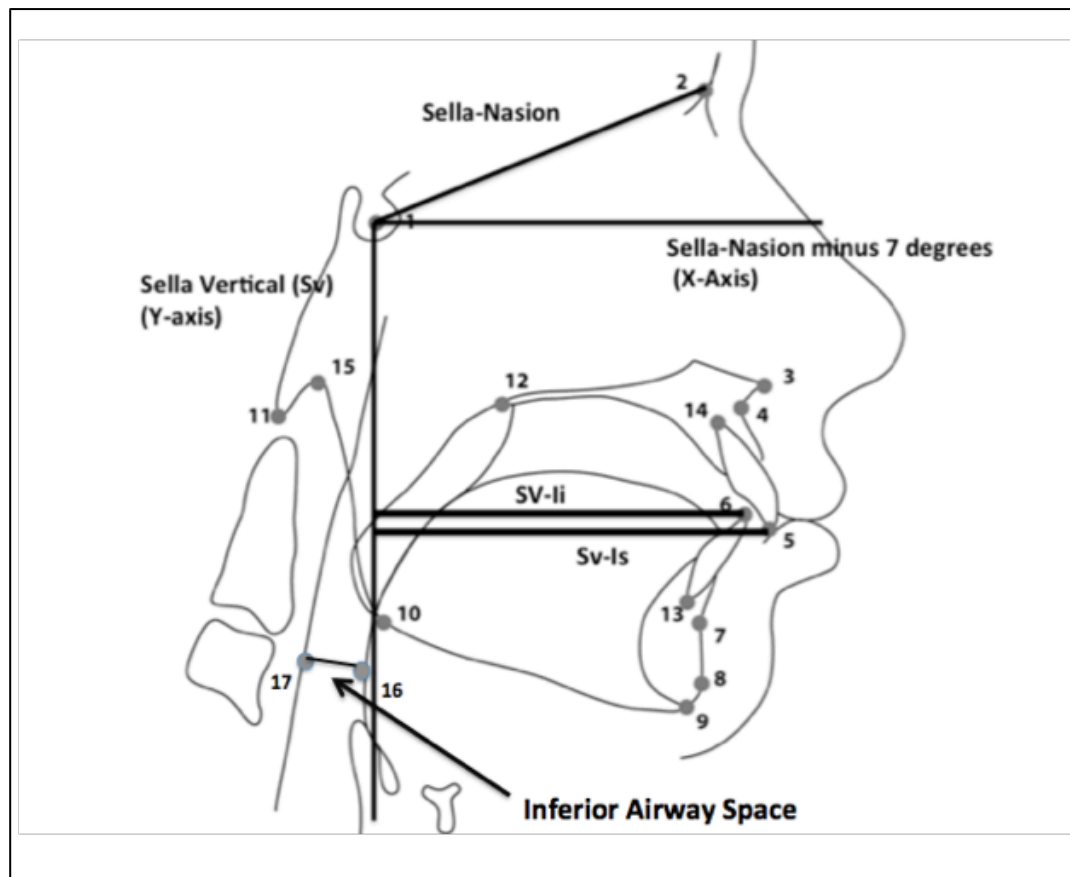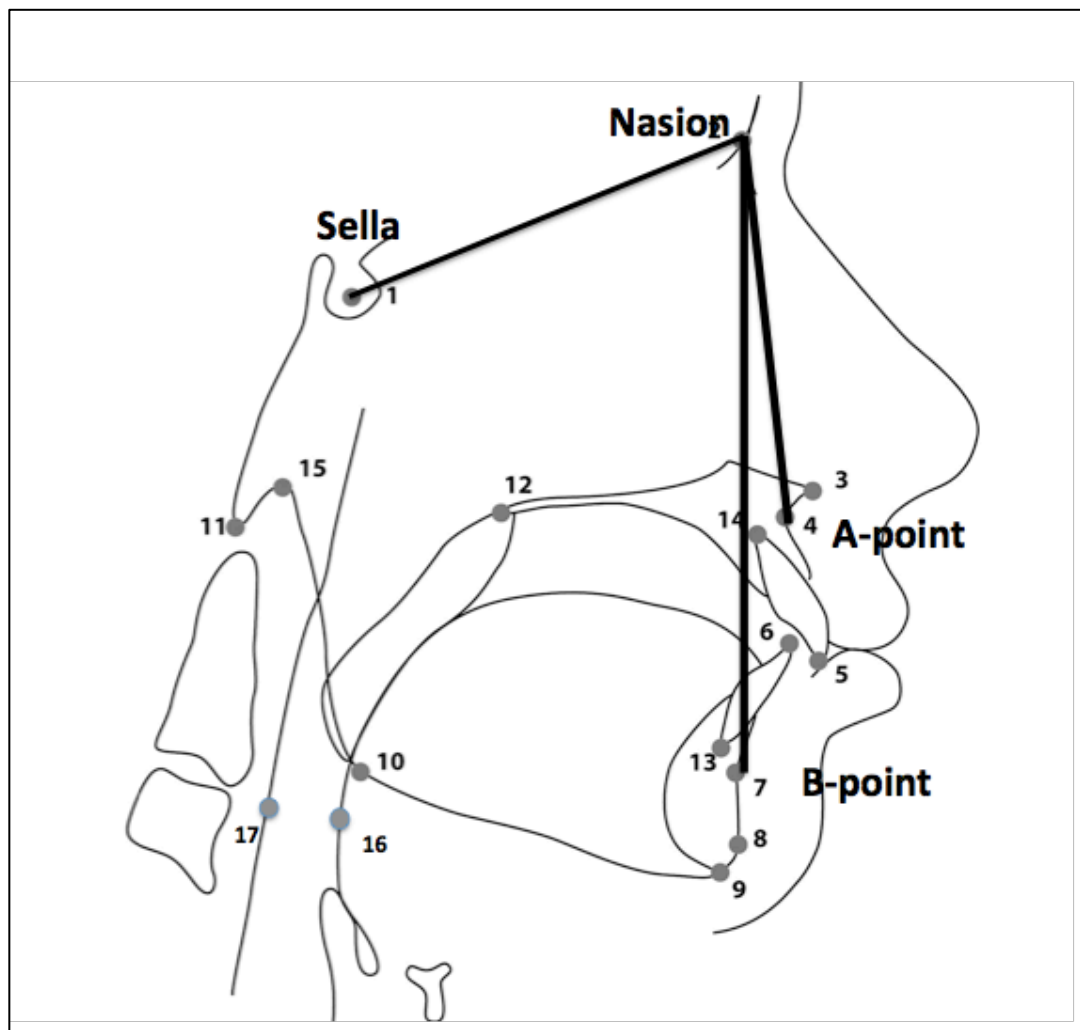
Figure 3

Angular Measurements:

Sella-Nasion-A-point (SNA): Position of maxilla in reference to the cranial base. Measured in degrees.

Sella-Nasion-B-Point (SNB): Position of mandible in reference to the cranial base. Measured in degrees.

A-point-Nasion-B-point (ANB): Position of maxilla in reference to the position of the mandible. Measured in degrees.

Appendix I

The Epworth Sleepiness Scale [16]

Epworth Sleepiness Scale

Name: _____ Today's date: _____

Your age (Yrs): _____ Your sex (Male = M, Female = F): _____

How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired?

This refers to your usual way of life in recent times.

Even if you haven't done some of these things recently try to work out how they would have affected you.

Use the following 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 answer each question as best you can.

Situation   **Chance of Dozing (0-3)**

Sitting and reading   _____   ___

Watching TV   _____   ___

Sitting, inactive in a public place (e.g. a theatre or a meeting) _____   ___

As a passenger in a car for an hour without a break   _____   ___

Lying down to rest in the afternoon when circumstances permit _____   ___

Sitting and talking to someone _____   ___

Sitting quietly after a lunch without alcohol _____   ___

In a car, while stopped for a few minutes in the traffic _____   ___

THANK YOU FOR YOUR COOPERATION

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Appendix II

Ethics Approval

Western Research

Research Ethics

Western University Health Science Research Ethics Board
HSREB Delegated Initial Approval Notice

Principal Investigator: Dr. Ali Tassi
Department & Institution: Schulich School of Medicine and Dentistry\Schulich School of Medicine & Dentistry, Western University

HSREB File Number: 104784
Study Title: Assessment of Orthognathic Surgery as a Treatment for Obstructive Sleep Apnea
Sponsor:

HSREB Initial Approval Date: June 25, 2014
HSREB Expiry Date: June 30, 2016

Documents Approved and/or Received for Information:

Document Name	Comments	Version Date
Data Collection Form/Case Report Form	Received June 20, 2014	
Western University Protocol		

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above named study, as of the HSREB Initial Approval Date noted above.

HSREB approval for this study remains valid until the HSREB Expiry Date noted above, conditional to timely submission and acceptance of HSREB Continuing Ethics Review. If an Updated Approval Notice is required prior to the HSREB Expiry Date, the Principal Investigator is responsible for completing and submitting an HSREB Updated Approval Form in a timely fashion.

The Western University HSREB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice Practices (ICH E6 R1), the Ontario Personal Health Information Protection Act (PHIPA, 2004), Part 4 of the Natural Health Product Regulations, Health Canada Medical Device Regulations and Part C, Division 5, of the Food and Drug Regulations of Health Canada.

Members of the HSREB who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Ethics Officer, on behalf of Dr. Joseph Gilbert, HSREB Chair

Ethics Officer to Contact for Further Information

Erika Basile ebasile@uwo.ca	Grace Kelly grace.kelly@uwo.ca	Mina Mekhail mmekhail@uwo.ca	Vikki Tran vikki.tran@uwo.ca

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LAWSON
HEALTH RESEARCH INSTITUTE

LAWSON FINAL APPROVAL NOTICE

LAWSON APPROVAL NUMBER: R-14-047

PROJECT TITLE: Assessment of Orthognathic Surgery as a Treatment for Obstructive
Sleep Apnea

PRINCIPAL INVESTIGATOR: Dr. Ali Tassi

LAWSON APPROVAL DATE: June 26, 2014

Health Sciences REB#:   104784

Please be advised that the above project was reviewed by the Clinical Research Impact
Committee and Lawson Administration and the project:

Was Approved

**Please provide your Lawson Approval Number (R#) to the appropriate
contact(s) in supporting departments (eg. Lab Services, Diagnostic
Imaging, etc.) to inform them that your study is starting. The Lawson
Approval Number must be provided each time services are requested.**

Dr. David Hill
V.P. Research
Lawson Health Research Institute

*All future correspondence concerning this study should include the Lawson Approval Number
and should be directed to Sherry Paiva, Research Administration Officer, Lawson Approval,
Lawson Health Research Institute, 750 Baseline Road, East, Suite 300.*

cc: Administration

Appendix III

Dates of pre- and post-surgical radiographs.

Patient	Pre-Surgical Radiograph	Post-Surgical Radiograph
#1	Jan, 2011	Jan, 2011
#2	Sept,2009	Sept,2009
#3	March, 2013	March, 2013
#4	Nov, 2008	Dec, 2008
#5	Dec, 2006	Dec,2006
#6	Sept,2008	Oct,2008
#7	March, 2009	March, 2009
#8	Jan, 2013	Jan, 2013
#9	Feb, 2013	April, 2013
#10	Sept, 2013	Sept, 2013
#11	Sept,2007	Oct, 2007
#12	Dec,2002	June, 2003
#13	Feb,2010	March, 2010
#14	Feb,2013	March, 2013
#15	March, 2003	May, 2003
#16	April, 2005	May, 2005
#17	Feb, 2006	Feb, 2006
#18	July,2007	July, 2007
#19	Jan,2002	March,2002
#20	Jan, 2012	Jan, 2012
#21	March, 2009	April, 2009
#22	Sept,2006	Sept,2006

Appendix IV

Measurement Error and Reproducibility of Cephalometric Variables

Measure	Measurement Error	Dhalberg Reproducibility
SNA	0.95 degrees	0.91
SNB	0.50 degrees	0.96
ANB	0.57 degrees	0.92
IAS	0.41 mm	0.91
Sv-Ii	0.62 mm	0.96
Sv-Is	1.06 mm	0.91

Appendix V

Body Mass Index before surgery (BMI Pre), after surgery (BMI Post), change in Body Mass Index (BMI Change), classification before surgery (Pre-Class), after surgery (Post-Class) and if the patient was successfully treated (Y= yes, N= no).

Patient	BMI Pre	BMI Post	BMI Change	Pre-Class	Post-Class	Success
#1	22.0	22.6	0.6	Healthy	Healthy	Y
#2	27.4	30.2	2.8	Overweight	Obese	Y
#3	26.5	25.4	-1.1	Overweight	Overweight	N
#4	25.2	23.6	-1.6	Overweight	Healthy	Y
#5	28.0	37.5	9.5	Overweight	Obese	Y
#6	26.8	32.4	5.6	Overweight	Obese	Y
#7	36.4	33.3	-3.1	Obese	Obese	Y
#8	19.0	19.2	0.2	Healthy	Healthy	N
#9	29.1	28.1	-1.0	Overweight	Overweight	N
#10	36.0	38.7	2.7	Obese	Obese	Y
#11	25.5	23.5	-2.0	Overweight	Healthy	Y
#12	29.2	29.6	0.4	Overweight	Overweight	Y
#13	26.4	26.4	0.0	Overweight	Overweight	Y
#14	33.2	34.7	1.5	Obese	Obese	Y
#15	25.1	29.8	4.7	Overweight	Overweight	Y
#16	33.1	36.5	3.4	Obese	Obese	Y
#17	29.8	29.5	-0.3	Overweight	Overweight	Y
#18	28.0	33.6	5.6	Overweight	Obese	Y
#19	26.7	24.4	-2.3	Overweight	Healthy	Y
#20	32.1	33	0.9	Obese	Obese	Y
#21	24.2	22.5	-1.7	Healthy	Healthy	Y
#22	30.3	27.3	-3.0	Obese	Overweight	Y
MEAN	**28.2**	**29.2**	**0.99**			**19/22**
Range	**19.0-36.4**	**19.2-38.7**	**(-3.1)-(9.5)**			
S.D.	**4.2**	**5.4**	**3.2**			

Appendix VI

AHI data for the entire treatment population including: patient number, apnea-hypopnea index prior to surgery (AHI pre), apnea-hypopnea index after surgery (AHI post), change in apnea-hypopnea index (AHI change), percent change in apnea-hypopnea index (% Change), classification prior to surgery (Pre-Class), classification after surgery (Post-Class), those who were successfully treated (Success) and those who were classified as cured (Cure).

Mean, range and standard deviation (S.D.) are also reported.

Patient (N=22)	AHI Pre	AHI Post	AHI Change	% Change	Pre-Class	Post-Class	Success	Cure
#1	13.3	1	-12.3	-92.5	Mild	Normal	Y	Y
#2	35	6.1	-28.9	-82.6	Severe	Mild	Y	N
#3	29	35.8	6.8	23.8	Mod	Severe	N	N
#4	11.5	0.8	-10.7	-90.7	Mild	Normal	Y	Y
#5	99.8	17.2	-82.6	-82.8	Severe	Mod	Y	N
#6	120.2	29.7	-90.5	-75.3	Severe	Mod	Y	N
#7	27	1.5	-25.5	-94.4	Mod	Normal	Y	Y
#8	18.2	26.6	8.4	46.2	Mod	Mod	N	N
#9	62.5	59.4	-3.1	-5	Severe	Severe	N	N
#10	52.6	18.9	-33.7	-64.1	Severe	Mod	Y	N
#11	29.6	0.2	-29.4	-99.3	Mod	Normal	Y	Y
#12	73.6	17.1	-56.5	-76.8	Severe	Mod	Y	N
#13	49.4	24.2	-25.2	-51	Severe	Mod	Y	N
#14	40	6.2	-33.8	-84.5	Severe	Mild	Y	N
#15	21.5	5.9	-15.6	-72.6	Mod	Mild	Y	N
#16	80.3	28.2	-52.1	-64.9	Severe	Mod	Y	N
#17	30.3	3.3	-27	-89.1	Severe	Normal	Y	Y
#18	107.5	3.4	-104.1	-96.8	Severe	Normal	Y	Y
#19	46.8	1.2	-45.6	-97.4	Severe	Normal	Y	Y
#20	64.1	13.2	-50.9	-79.4	Severe	Mild	Y	N
#21	32.5	5.1	-27.4	-84.3	Severe	Mild	Y	N
#22	19.1	3.9	-15.2	-79.6	Mod	Normal	Y	Y
MEAN	**48.4**	**14.0**	**-34.3**	**-67.9**			**19/22**	**8/22**
RANGE	**11.5-120.2**	**0.2-59.4**	**104.1-8.4**	**-99.3-46.2**				
S.D.	**31.3**	**15.0**	**29.4**	**39.1**				

Appendix VII

AHI data for only those patients in the treatment population who met the criteria of success (Defined as AHI reduction to below score of 15 or a 50% reduction in AHI).

Data presented includes success, Patient #, age of patient measured in years (Age Yrs), pre-surgical AHI score (AHI Pre), post-surgical AHI score (AHI Post), change in AHI score (AHI Change), percent change in AHI score (% Change), pre-surgical OSA classification (Pre-class), and post-surgical OSA classification.

*Note that for the category of Post-Class, the term "Normal" represents a cure from OSA

Success	Patient #	Age (Yrs)	AHI Pre	AHI Post	AHI Change	% Change	Pre-Class	Post-Class
YES	#1	45.7	13.3	1	-12.3	-92.5	Mild	Normal
YES	#2	35.6	35	6.1	-28.9	-82.6	Severe	Mild
YES	#4	44.3	11.5	0.8	-10.7	-90.7	Mild	Normal
YES	#5	16	99.8	17.2	-82.6	-82.8	Severe	Mod
YES	#6	49.9	120.2	29.7	-90.5	-75.3	Severe	Mod
YES	#7	52.7	27	1.5	-25.5	-94.4	Mod	Normal
YES	#10	36.6	52.6	18.9	-33.7	-64.1	Severe	Mod
YES	#11	42.1	29.6	0.2	-29.4	-99.3	Mod	Normal
YES	#12	44.4	73.6	17.1	-56.5	-76.8	Severe	Mod
YES	#13	59.9	49.4	24.2	-25.2	-51.0	Severe	Mod
YES	#14	36.8	40	6.2	-33.8	-84.5	Severe	Mild
YES	#15	29.1	21.5	5.9	-15.6	-72.6	Mod	Mild
YES	#16	57.6	80.3	28.2	-52.1	-64.9	Severe	Mod
YES	#17	52.3	30.3	3.3	-27	-89.1	Severe	Normal
YES	#18	19.2	107.5	3.4	-104.1	-96.8	Severe	Normal
YES	#19	31.1	46.8	1.2	-45.6	-97.4	Severe	Normal
YES	#20	29.3	64.1	13.2	-50.9	-79.4	Severe	Mild
YES	#21	47.6	32.5	5.1	-27.4	-84.3	Severe	Mild
YES	#22	48.4	19.1	3.9	-15.2	-79.6	Mod	Normal
MEAN		41.0	50.2	9.8	-40.4	-82.0		
Range		(16.0)-(59.)	(11.5)-(120.2)	(0.2)-(29.7)	(104.1)-(-10.7)	(-51)-(-97.4)		
S.D.		12.2	32.5	9.8	26.8	12.7		

Appendix VIII

AHI data for only those patients in the treatment population who did not meet the criteria of success (Defined as AHI reduction to below score of 15 or a 50% reduction in AHI).

Data presented include success, Patient #, age of patient measured in years (Age Yrs), pre-surgical AHI score (AHI Pre), post-surgical AHI score (AHI Post), change in AHI score (AHI Change), percent change in AHI score (% Change), pre-surgical OSA classification (Pre-class), and post-surgical OSA classification.

*Note that for the category of Post-Class, the term "Normal" represents a cure from OSA

| Success	Patient #	Age (yrs)	AHI Pre	AHI Post	AHI Change	% Change	Pre-Class	Post-Class
NO	#3	62.3	29	35.8	6.8	23.8	Mod	Severe
NO	#8	55.7	18.2	26.6	8.4	46.2	Mod	Mod
NO	#9	71.4	62.5	59.4	-3.1	-5	Severe	Severe
MEAN		63.1	36.6	40.6	4	21.7		
RANGE		(55.7)-(71.4)	(18.2)-(62.5)	(26.6)-(59.4)	(-3.1)-(8.4)	(-5)-(46.2)		
S.D.		7.9	23.1	16.9	6.2			

Appendix IX

Pre-surgical Epworth Sleepiness Scale scores (Pre ESS), post-surgical Epworth Sleepiness Scale scores (Post ESS), pre-surgical classification (Pre-Class), post-surgical classification (Post-Class) and change in score on the Epworth Sleepiness Scale (ESS Change). Mean, range and standard deviations are reported where appropriate.

*Note: For Pre-Class and Post-Class Columns, Normal ≤ 9, Excessive ≥ 10

Patient	Pre ESS	Post ESS	Pre-Class	Post-Class	ESS Change	% ESS Change
#1	6	1	Normal	Normal	-5	-83.3
#2	3	2	Normal	Normal	-1	-33.3
#3	17	4	Excessive	Normal	-13	-76.5
#4	14	8	Excessive	Normal	-6	-42.9
#5	15	3	Excessive	Normal	-12	-80.0
#6	4	14	Normal	Excessive	10	+250.0
#7	9	4	Normal	Normal	-5	-55.6
#8	10	5	Excessive	Normal	-5	-50.0
#9	13	6	Excessive	Normal	-7	-53.8
#10	18	4	Excessive	Normal	-14	-77.8
#11	14	5	Excessive	Normal	-9	-64.3
#12	7	4	Normal	Normal	-3	-42.9
#13	15	7	Excessive	Normal	-8	-53.3
#14	12	7	Excessive	Normal	-5	-41.7
#15	15	14	Excessive	Excessive	-1	-6.7
#16	7	5	Normal	Normal	-2	-28.6
#17	15	3	Excessive	Normal	-12	-80.0
#18	N/A	N/A	N/A	N/A	N/A	
#19	N/A	N/A	N/A	N/A	N/A	
#20	15	6	Excessive	Normal	-9	-60.0
#21	N/A	N/A	N/A	N/A	N/A	
#22	N/A	N/A	N/A	N/A	N/A	
MEAN	11.6	5.7			-5.7	-37.8
RANGE	(3)-(18)	(1)-(14)			(-14)-(10)	(-83.3)-(250.0)
S.D.	4.6	3.5			5.5	74.7

Appendix X
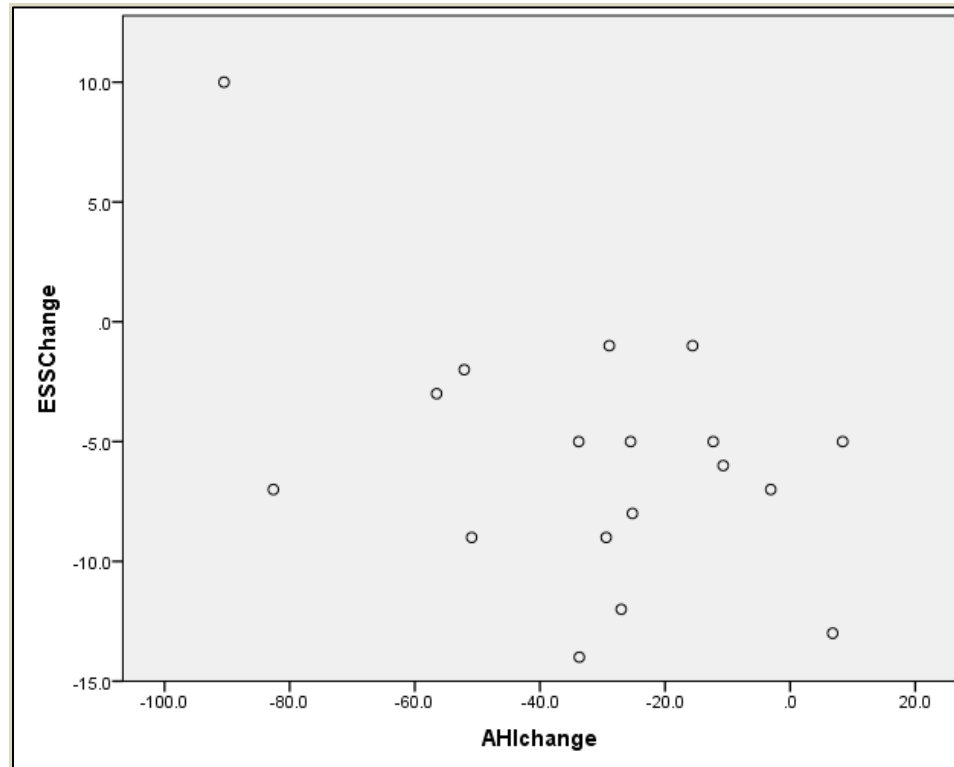
Graph 1: Pre to post-treatment changes of AHI vs. pre to post-treatment changes of ESS. A mild negative correlation was detected, however there was no statistically significant relationship. (r = -.461; P =. 054).

Appendix XI
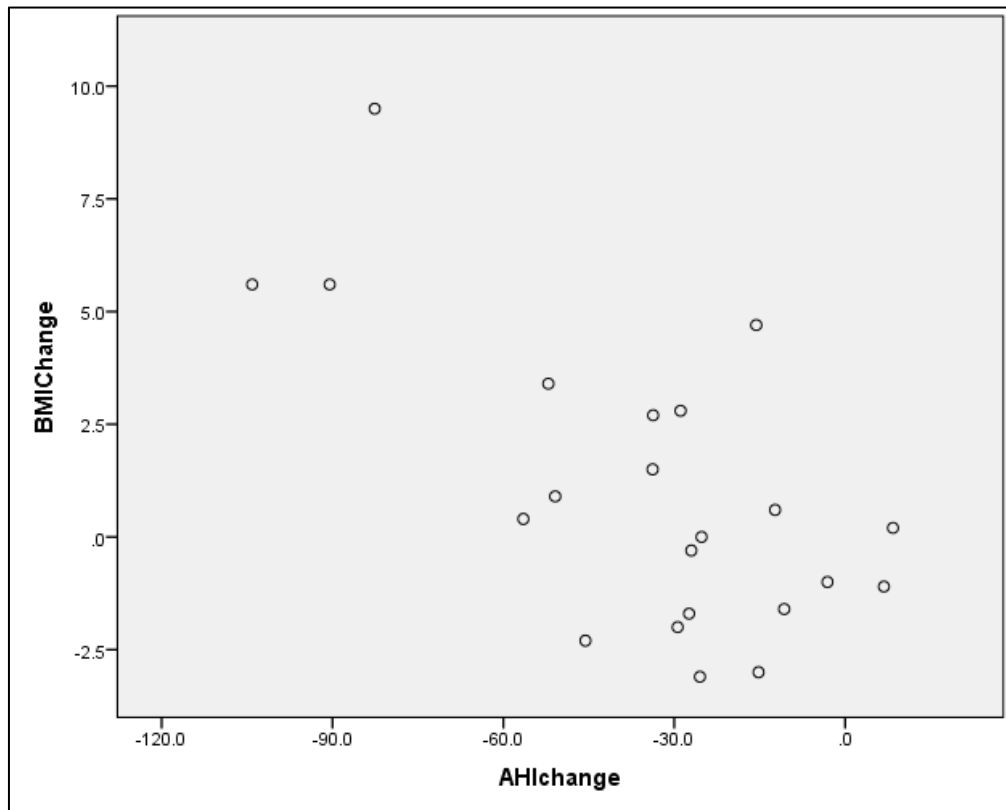
Graph 2. Change in BMI compared to change in AHI score. A moderate negative correlation was detected (r = -.661, P< .001).

Appendix XII

Values for pre-surgical Sella-Nasion-A-Point (SNA), pre-surgical Sella-Nasion-B-Point

(SNB), and pre-surgical A-point-Nasion-B-Point (ANB).

| Patient	Pre-SNA (deg)	Pre-SNB (deg)	Pre-ANB (deg)
#1	90.5	79.0	11.5
#2	81.8	70.0	11.8
#3	81.3	73.6	7.7
#4	78.3	70.6	7.8
#5	81.7	76.2	5.5
#6	83.7	73.4	10.4
#7	86.8	79.0	7.9
#8	76.6	70.8	5.8
#9	90.3	82.7	7.6
#10	82.0	80.6	1.4
#11	81.7	76.6	5.1
#12	77.8	72.6	5.2
#13	85.2	80.9	4.3
#14	86.5	79.5	7.0
#15	87.0	81.5	5.5
#16	86.0	78.1	7.8
#17	87.1	79.1	8.0
#18	82.1	71.9	10.2
#19	79.7	76.4	3.3
#20	88.4	80.9	7.5
#21	82.0	72.1	9.9
#22	86.4	77.7	8.7
MEAN	83.8	76.5	7.3
RANGE	77.8-90.5	70.0-82.7	1.4-11.8
S.D.	3.9	4.0	2.6

Appendix XIII

Lateral cephalometric measurements of the pre-surgical Inferior Airway Space (IAS Pre), post-surgical IAS (IAS Post), change in airway space size (IAS Change), percent change in airway space (% Change) and treatment success (Yes = Y, No = N).

Patient	IAS Pre (mm)	IAS Post (mm)	IAS Change (mm)	% Change	Success
#1	5.7	12.5	6.8	119.3	Y
#2	5.0	17.1	12.1	242	Y
#3	6.8	9.3	2.5	36.8	N
#4	3.7	11.0	7.3	197.3	Y
#5	9.8	10.5	0.7	7.1	Y
#6	2.7	20.0	17.3	640.7	Y
#7	5.4	13.3	7.9	146.3	Y
#8	4.3	17.3	13.0	302.3	N
#9	7.8	22.0	14.2	182.1	N
#10	19.2	20.1	0.9	4.7	Y
#11	9.3	13.0	3.7	39.8	Y
#12	6.4	9.9	3.5	54.7	Y
#13	4.8	16.8	12.0	250.0	Y
#14	15.3	18.9	3.6	23.5	Y
#15	7.8	14.0	6.2	79.5	Y
#16	10.8	16.5	5.7	52.8	Y
#17	4.7	8.1	3.4	42.0	Y
#18	10.0	16.3	6.3	63.0	Y
#19	10.1	14.7	4.6	45.5	Y
#20	14.8	17.9	3.1	20.9	Y
#21	5.3	11.0	5.7	107.5	Y
#22	7.4	11.5	4.1	55.4	Y
MEAN	8.1	14.6	6.6	123.3	
RANGE	2.7-19.2	9.3-20.1	0.7-17.3	4.7-640.7	
S.D.	4.1	3.9	4.5	143.9	

Appendix XIV
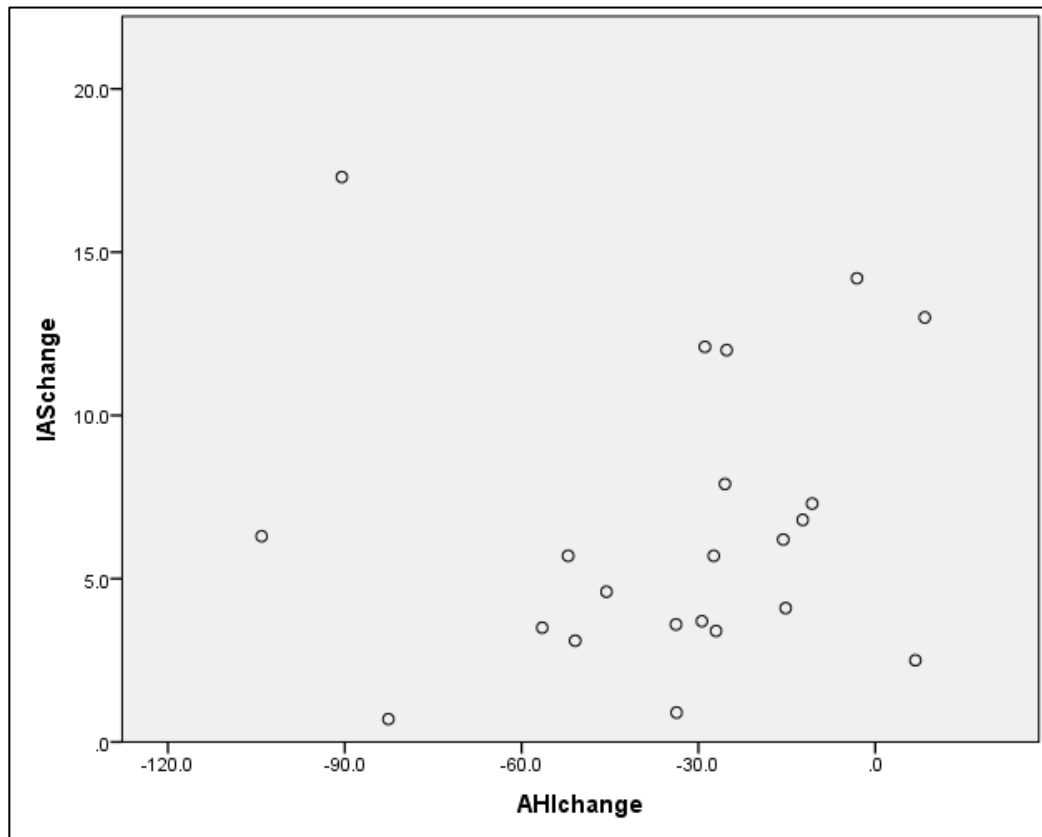
Graph 3: The change in inferior airway space in reference to change in the apnea-hypopnea index produced virtually no correlation and was not statistically significant (r =.079; P =.725).

Appendix XV

Maxillary advancement distance:

Pre-surgical Sella-Vertical to Incisor Superiorus (Pre-Sv-Is)

Post-surgical Sella-Vertical to Incisor Superiorus (Post-Sv-Is)

Change from pre- to post-surgery (Change SV to Is).

Patient	Pre-SV-Is (mm)	Post-SV-Is (mm)	Change SV to Is (mm)
#1	84.8	94.7	9.9
#2	67.4	75.7	8.3
#3	75.5	76.4	0.9
#4	66.3	74.3	8.0
#5	62.8	69.7	6.9
#6	74.2	82.9	8.7
#7	74.9	88.9	14.0
#8	63.5	73.3	9.8
#9	81.0	90.5	9.5
#10	76.8	90.3	13.5
#11	68.2	74.0	5.8
#12	64.3	72.7	8.4
#13	69.8	80.6	10.8
#14	87.1	90.8	3.7
#15	81.7	88.0	6.3
#16	81.9	86.1	4.2
#17	78.6	85.6	7.0
#18	65.9	82.3	16.4
#19	68.8	75.5	6.7
#20	74.5	86.5	12.0
#21	67.7	82.7	15.0
#22	75.1	83.4	8.3
MEAN	**73.2**	**82**	**8.8**
RANGE	**62.8-87.1**	**69.7-94.7**	**0.9-16.4**
S.D.	**7.2**	**7.1**	**3.8**

Appendix XVI

Graph 4. The change in AHI score and the change in maxillary movement (Sv-Is) were compared and there was no significant correlation (r = -.260; P = .242)

Appendix XVII

Mandibular advancement distance:

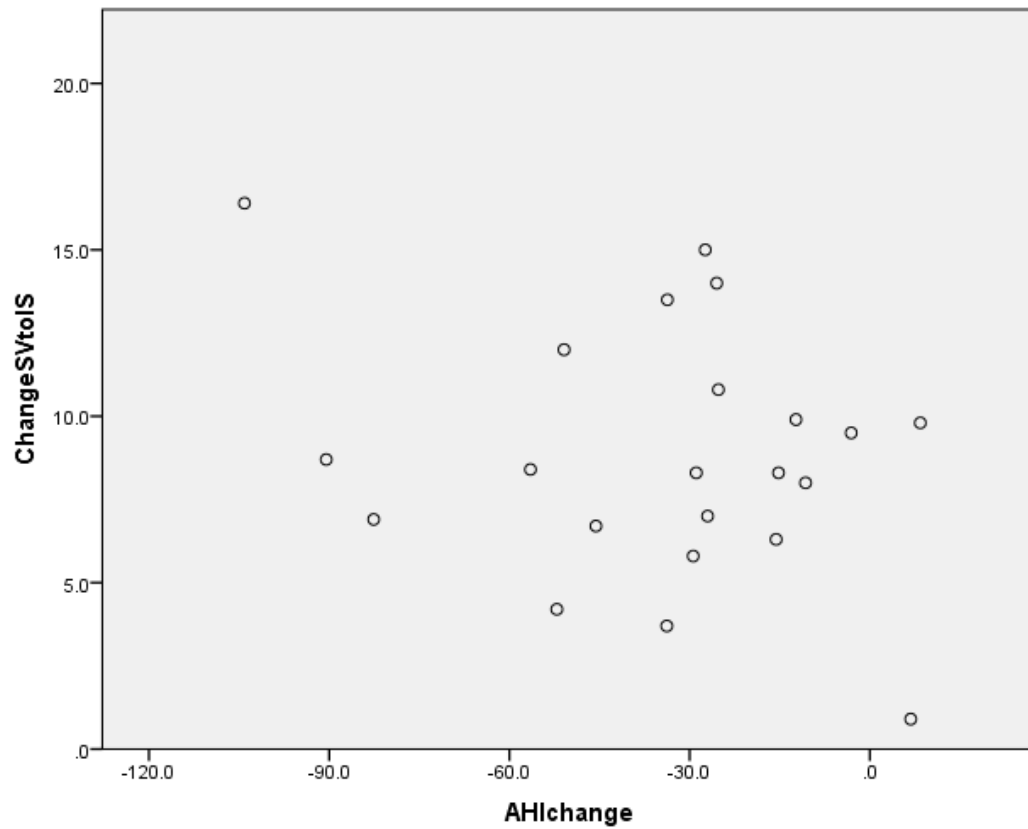Pre-surgical Sella-Vertical to Incisor Inferiorus (Pre-Sv-Ii)

Post-surgical Sella-Vertical to Incisor Inferiorus (Post-Sv-Ii)

Change from pre to post-surgery (Change Sv-Ii).

Patient	Pre-Sv-Ii (mm)	Post-Sv-Ii (mm)	Change Sv-Ii (mm)
#1	76.8	92.1	15.3
#2	62.5	74.5	12
#3	65.8	73.8	8
#4	57	72.3	15.3
#5	62.8	67.8	5
#6	65.6	81.1	15.5
#7	68.9	86	17.1
#8	60.2	70.1	9.9
#9	69.4	86.2	16.8
#10	73.8	86.3	12.5
#11	65.2	70.3	5.1
#12	59	69.6	10.6
#13	64.8	75.3	10.5
#14	75.9	87.8	11.9
#15	77.5	84.3	6.8
#16	73.5	84	10.5
#17	69	81.8	12.8
#18	56.8	80.1	23.3
#19	65.4	72.4	7
#20	71.7	83.8	12.1
#21	64.2	80.1	15.9
#22	65.9	81.7	15.8
MEAN	**66.9**	**79.2**	**12.3**
RANGE	**57.0-77.5**	**67.8-92.1**	**5.0-23.3**
S.D.	**6.1**	**6.9**	**4.4**

Appendix XVIII
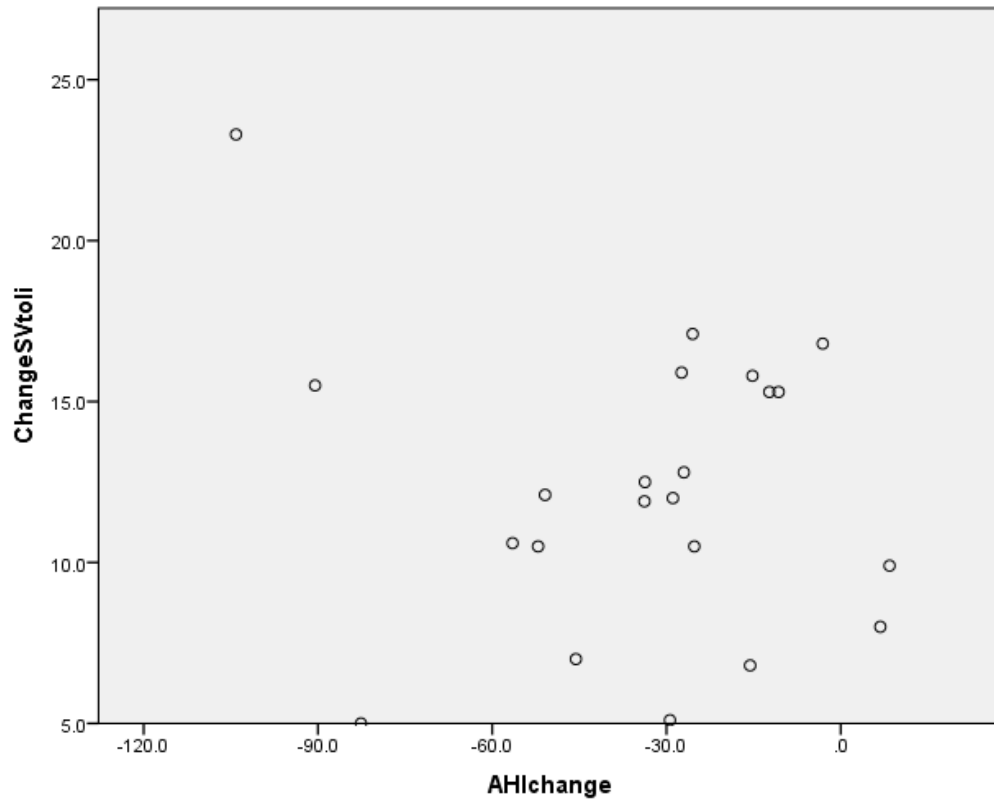
Graph 5. The change in mandibular advancement versus change in AHI was compared and there was no significant correlation detected (r = -.176; P = .434).

Appendix XIX

Estimated Blood Loss During Surgery and Associated Surgical Complications

Patient	Estimated Blood Loss (cc)	Surgically related complications
#1	300	N/A
#2	300	N/A
#3	400	Maximum Advancement not achieved, patient declined second surgical procedure immediately after surgery
#4	300	N/A
#5	400	Developed pneumonia in hospital, complete recovery (extended hospital stay for 5 days)
#6	500	N/A
#7	400	N/A
#8	300	N/A
#9	400	N/A
#10	400	N/A
#11	300	N/A
#12	200	Non-union of Le Fort, 2nd surgery 6 months later with full healing
#13	350	N/A
#14	400	N/A
#15	400	Dec. 2006 broken plate removed, no further treatment required
#16	300	N/A
#17	300	N/A
#18	400	N/A
#19	500	N/A
#20	550	N/A
#21	750	Surgeon felt advancement was too much, returned for 2nd surgery 3 weeks later to reduce the advancement
#22	350	Root canal therapy and internal bleaching on #21
Mean	386.4	
Range	200.0-750.0	
S.D.	114.6	

Appendix XX

Significant Medical History From Pre-Surgical Evaluations

Patient	Confirmed cPAP User Prior to Surgery	Significant Prior Medical History (excluding obesity)
#1	Y	Rheumatoid Arthritis
#2	Y	Depression
#3	Y	TMD, GERD, Scoliosis
#4	Y	Panic attacks, Hypertension, Hypoglycaemia, Mitral Valve Prolapse
#5	Y	Suspicion of syndrome-Pierre Robin (unconfirmed)
#6	Y	Bipolar, fatigue, patient taking multiple psychoactive medications
#7	Y	N/A
#8	Y	Hypothyroidism
#9	Y	Prostate cancer, Previous Myocardial Infarct
#10	Y	N/A
#11	N	N/A
#12	Y	N/A
#13	Y	Deviated septum, Asthma, Hepatitis A, Hypothyroid, GERD
#14	Y	History of sleep walking
#15	Y	Previous UPPP surgery
#16	Y	N/A
#17	N	N/A
#18	Y	Prior Surgery to remove adenoids
#19	Y	Depression
#20	Y	N/A
#21	Y	N/A
#22	N	N/A
	19/22	

Appendix XXI

Table below indicates dates of pre-surgical polysomnography, dates of surgery, dates of post-surgical polysomnography, and number of months after surgery that the post-surgical PSG was completed for each patient in the study.

Patient	Pre-Surg PSG	Months Pre-Surg	Date of Surgery	Post-Surg PSG	Months post-Surg
#1	8/4/2005	66	1/24/2011	6/26/2012	15.00
#2	10/8/2005	47	9/29/2009	8/21/2012	35.00
#3	2/2/2007	73	3/5/2013	4/28/2014	13.00
#4	9/12/2003	63	12/8/2008	9/30/2010	21.00
#5	2/7/2003	46	12/12/2006	10/26/ 2008	22.00
#6	9/26/1999	108	10/10/2008	1/11/2010	15.00
#7	9/11/2002	77	3/23/2009	4/7/2011	25.00
#8	4/24/2008	57	1/14/2013	11/26/2013	10.00
#9	9/8/2008	55	4/15/2013	5/1/2014	13.00
#10	4/27/2008	65	9/16/2013	5/8 2014	8.00
#11	1/3/2003	56	9/4/2007	10/29/2008	13.00
#12	5/28/2002	12	5/26/2003	9/17/2003	4.00
#13	4/23/2001	107	3/2/2010	3/1/2011	12.00
#14	2/1/2011	24	2/25/2013	11/30/2013	9.00
#15	4/2/ 2002	13	5/2/2003	12/7/ 2007	43.00
#16	6/12/2002	35	5/10/2005	N/A	N/A
#17	9/18/2003	29	2/13/2006	12/6/ 2006	10.00
#18	3/18/ 2004	39	7/19/2007	9/19/ 2008	14.00
#19	5/19/2000	19	1/18/2002	5/26/2002	4.00
#20	8/12/2009	29	1/16/2012	4/16/2013	15.00
#21	4/1/2005	48	4/6/2009	7/8/2010	15.00
#22	3/13/ 2005	17	9/22/2006	11/23/2007	14.00
MEAN		**49.3**			**15.71**
Range		**12-107**			**4.0-43.0**
S.D.		**27.1**			**9.4**

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