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Quality of Life and Subjective Outcomes Following Maxillomandibular Advancement Surgery for the Treatment of Obstructive Sleep Apnea

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Abstract

Objective: The aim of this study was to assess outcomes related to general quality of life, daytime sleepiness and functional sleep outcomes, functional outcomes of orthognathic surgery, and facial aesthetics in patients undergoing maxillomandibular advancement (MMA) surgery for the treatment of obstructive sleep apnea (OSA).

Materials and Methods: This was a cross-sectional self-report study. A questionnaire was constructed using questions drawn from previously validated questionnaires. The survey was distributed to 25 patients who underwent MMA surgery for the treatment of OSA at LHSC in London, Ontario by a single surgeon between 2002 and 2013.

Results: The survey results showed that MMA patients responded positively with respect to quality of life, snoring, functional sleep outcomes and daytime sleepiness, and facial aesthetics. Nineteen (86.4%) indicated that their sleep apnea symptoms have improved since the surgery. Eighteen (81.8%) reported neutral or positive changes with respect to facial attractiveness. Nineteen (86.4%) indicated that their overall quality of life has become better since having MMA. Most patients indicated that the surgery was worthwhile and would recommend it to others suffering from OSA.

Conclusions: MMA surgery for the treatment of OSA appears to have an overall positive effect on quality of life, sleep outcomes, and aesthetic outcomes. The majority of patients found the surgery worthwhile. Orthodontic treatment in conjunction with MMA appears to enhance the subjective aesthetic outcomes of treatment.

Keywords

Obstructive Sleep Apnea (OSA), Maxillomandibular Advancement (MMA), Orthognathic Surgery, Orthodontics, Quality of Life (QoL), Aesthetics, Facial Appearance, Questionnaire, Survey, Subjective Outcomes

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List of Abbreviations

AHI: Apnea-Hypopnea Index

BMI: Body Mass Index

CPAP: Continuous Positive Airway Pressure

ESS: Epworth Sleepiness Scale

FOE: Facelift Outcomes Evaluation (Questionnaire)

FOSQ: Functional Outcomes of Sleep Questionnaire

GBI: Glasgow Benefit Inventory

GERD: Gastro-Esophageal Reflux Disease

MMA: Maxillomandibular Advancement

MSLT: Multiple Sleep Latency Test

OQLQ: Orthognathic Quality of Life Questionnaire

OSA: Obstructive Sleep Apnea

OSAS: Obstructive Sleep Apnea Syndrome

QoL: Quality of Life

RDI: Respiratory Disturbance Index

RERA: Respiratory Effort-Related Arousal

SF-36: Short Form-36 (Questionnaire)

STOP-BANG: Snoring, Tiredness, Observed Apnea, Blood Pressure, BMI, Age, Neck Circumference, Gender (Questionnaire)

UPPP: Uvulopalatopharyngoplasty

VAS: Visual Analogue Scale

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Epidemiology

Obstructive sleep apnea (OSA) is a sleep disorder in which complete or partial airway obstruction causes disruptive sleep and excessive daytime sleepiness. The result of airway obstruction may be characterized as hypopneas, where airflow into the lungs is reduced and blood oxygen saturation decreases, or apneas, where airway patency is completely absent for a period of time and breathing stops. The primary measure of the severity of a patient's OSA is the apnea-hypopnea index, or AHI, which is defined as the total number of apneic plus hypopneic episodes, divided by the time slept in hours. For a diagnosis of OSA, 5 or more episodes of apnea and/or hypopnea per hour must be observed in a controlled sleep study (AHI=5).[1] In addition to the AHI, the respiratory disturbance index (RDI) is sometimes used. The RDI takes into account the number of apneas and hypopneas, but also includes RERAs, or respiratory effort-related arousals, which are defined as increases in respiratory activity leading to arousal from sleep that do not qualify as apneas or hypopneas.[2]

The term obstructive sleep apnea syndrome (OSAS) may be applied when increased AHI is accompanied by excessive daytime sleepiness.[3] The Epworth sleepiness scale (ESS), a simple questionnaire, is currently the most commonly used measure to assess daytime sleepiness.[4] The gold standard test for daytime sleepiness is the multiple sleep latency test (MSLT), which is a laboratory-administered full-day test that is meant

to objectively assess daytime sleepiness.[5] Due to the high cost and low convenience to patients, the ESS is typically used instead.

OSA is a common, but often unrecognized disorder with a prevalence of 2% in middle aged women, and 4% in middle-aged men.[6] It has been proposed that due to the increasing average body mass index (BMI), this prevalence could be increasing. It has been estimated that up to 82% of men and 93% of women with OSA have not been clinically diagnosed.[7] Individuals with OSA have disrupted sleep patterns due to reduced activity of the muscles of the pharyngeal wall, decreased oxygen saturation, and increased arousal, which leads to insufficient rapid eye movement (REM) sleep.[8] This irregular sleep pattern manifests as daytime sleepiness and fatigue, which have been shown to have a number of negative sequelae, including hypersomnolence, cognitive dysfunction, impaired work performance, increased risk of cardiovascular disease, type II diabetes, and metabolic syndrome.[9] Individuals with OSA are at increase risk of accidents, particularly when driving,[10] indicating the urgent need to detect and diagnose OSA patients.

Obesity is a major comorbidity associated with OSA, as well as a predisposing factor. A 10% weight gain increases the risk of OSA by six times.[11] This is particularly a problem in North America, where approximately one third of the adult population is obese.[11] In addition to contributing to the pathophysiology of the disease, excess body fat also acts as a contributing factor to various comorbidities of OSA, including diabetes mellitus[12], metabolic syndrome,[13] and cardiovascular disease.[14] Several studies have demonstrated that weight reduction by caloric restriction and exercise reduced the

symptoms of OSA in the majority of cases, and these observations were consistent at long term follow up.[15] Therefore, weight loss may be considered as a low-cost, first line treatment for OSA, ideally before more invasive treatments are rendered.

Pathophysiology

The pathophysiology behind OSA involves several potential sites of airway obstruction in the head and neck region, involving both anatomic structures and neuromuscular forces. The human pharynx can be thought of a tube with no rigid skeletal support. When the extraluminal pressures from the surrounding soft tissues exceed the forces provided by the muscles of the pharyngeal wall, apneas and/or hypopneas are prone to occur.[1] During wakefulness, increased muscle tone generally compensates for the narrowed airway, but these reflexes are less active during sleep.[16]

The retropalatal (posterior to the soft palate) and retroglossal (posterior to the tongue base) areas are the most important potential sites of obstruction. It is essential to diagnose each patient on an individual basis, as one or both of these sites may be obstructed, and the prescribed treatment may depend on which sites are affected.[17] Excessive body fat can cause excessive narrowing in these regions, but other anatomical features are associated with OSA, including retrognathia, micrognathia, long face syndrome, increased cranial base flexion, and elongation of the soft palate.[17,18] Other features, such as reduced midface length, a retrusive upper lip, inferior hyoid bone, and reduced pharyngeal airway patency are commonly observed on cephalograms, and these features are also associated with smaller airway dimensions.[19] Lateral cephalograms may be taken quickly and at low cost, and are available in most orthodontic clinics, making

them useful adjuncts for OSA diagnosis and treatment. However, due to a number of shortcomings associated with 2-dimensional cephalometry, 3-dimensional dynamic imaging modalities would be more useful in assessing airway function.

Reductions in airway volume lead to a number of clinical features typical of patients with OSA. These include snoring, snorting, gasping, and choking during periods of sleep, as well as intermittent awakenings, insomnia, and headaches. Patients are more likely to complain about symptoms present during periods of wakefulness, which include sleepiness, fatigue, and hypersomnolence. Indeed, many patients are unaware of their nocturnal symptoms, which makes detection and diagnosis of these patients difficult.[1]

Treatment Options

Various treatment modalities exist for patients with OSA, which may or may not involve surgical procedures. Before any treatment can be recommended, it is imperative that the patient be properly diagnosed in concordance with a physician via a polysomnographic sleep study.[2] This is so that the severity and etiology of the patient's OSA can be determined. As mentioned previously, many OSA patients are overweight or obese, and weight reduction protocol should be considered a first line treatment for OSA. A BMI of 28 or higher has shown to increase the likelihood of developing moderate to severe OSA 5-fold.[20]

Several non-surgical interventions exist. The current gold standard is continuous positive airway pressure (CPAP). A machine is used to increase pressure within the pharynx, thus maintaining airway patency during inhalation and exhalation. Studies have shown that CPAP treatment can be greatly successful in reducing snoring, daytime

sleepiness, and other OSA symptoms, especially in patients with severe OSA.[21] The positive effects on patients with milder forms of OSA are not as dramatic.[22] Indirect effects from the use of CPAP include reduced susceptibility to cardiovascular disease, increased alertness, reduced motor vehicle accidents, and reduction in nocturnal GERD.[2]

One of the largest barriers to successful CPAP treatment is patient compliance. Compliance from nasal CPAP has been reported as ranging from 50% to 89%.[23] Lack of compliance often arises as patients find the treatment intolerable for one reason or another. Common complaints from patients who use CPAP include nasal congestion, dryness of the oral and pharyngeal tissues, skin rash from the mask, irritation, and pain. Less commonly, anxiety, claustrophobia, gastric distension, and ear/sinus infections have been reported.[1]

Oral appliances that reposition the mandible anteriorly, along with the tongue and hyoid bone, may be considered in patients with mild to moderate OSA as an alternative to CPAP. In advancing the mandible and its associated structures during sleep, the retroglossal airway patency is increased. Typically, the mandible is temporarily advanced up to 80% of its maximum protrusive capability while the appliance is worn. Before and after polysomnographic sleep studies are recommended to gauge the effectiveness of the treatment. Currently, oral appliances are not quite as effective as CPAP in reducing AHI scores below 5 and improving other symptoms.[24] This may be due to oral appliances addressing only the retroglossal site of obstruction. However, there are several advantages to using these appliances over CPAP, including low cost, less noise, less bulk, and greater acceptance by patients and their partners.[2] Due to the active nature of these

appliance, tooth movement and TMJ pain are common complaints,[25] so each patient should be monitored regularly by an appropriately trained dental professional.

Historically, the terms stage I and stage II surgery have been used to categorize the surgical techniques to treat OSA, with stage I being soft tissue resective surgery and stage II being hard tissue surgery (for example, maxillomandibular advancement or MMA). In the past, stage I surgery was considered first-line treatment, with MMA being considered only after soft tissue surgery had first failed to adequately reduce OSA symptoms. However, modern orthognathic techniques are able to produce predictable results with low morbidity, and there are several marked negative sequelae associate with soft tissue resection. Thus, MMA is increasingly being considered as a first-line surgical treatment for OSA.

Stage I, or soft tissue surgery aims to increase upper airway patency by removal of soft tissues in the oral, nasal, and pharyngeal cavities. While it is often insufficient to perform in isolation, nasal surgery may be considered as an adjunct to other surgeries.[26] Partial glossectomy may be considered only if it is determined that macroglossia is a contributing factor to a patient's OSA. This surgery is rarely indicated, as the associated morbidities, including dysphagia, odynophagia, loss of taste, and reduced mobility of the tongue, are difficult for patients to tolerate.[2]

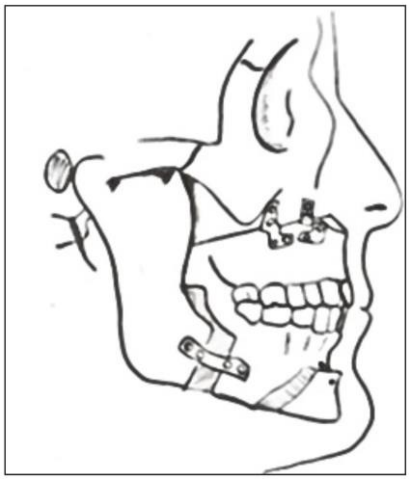
While tracheostomy was the first surgery developed for treatment of OSAS (and perhaps the most effective), it is poorly tolerated by patients and is rarely offered as a long term treatment for OSA.[27] A major development was the uvulopalatopharyngoplasty, or UPPP, modified by Fujita et al[28] to treat OSA. In this

procedure, the uvula posterior soft palate, and pharyngeal tonsils are resected in one surgery in order to increase the retropalatal airway. Unfortunately, reduction in AHI observed in most studies is modest at best (about 50% success), and the technique is best used in conjunction with other surgical procedures.[29] The limited success is due in part to the fact that the procedure addresses one area of obstruction only. Velopharyngeal insufficiency is sometimes present after UPPP, which may cause hypernasal speech, speech difficulties, and nasal reflux. Nasal airway obstruction secondary to scar tissue formation from the surgery may also develop.[2] UPPP is very effective in reducing snoring, however, and may be considered as a primary therapy for patients whose main complaint is snoring in the absence of other OSA symptoms.[30] Therefore, patient selection for this procedure is of critical importance, and must be limited to those who possess enough excessive retropalatal soft tissue to resect without causing velopharyngeal insufficiency.

Maxillomandibular advancement is more effective than UPPP surgery, and is accepted as the most successful surgical technique for the treatment of OSAS.[31] Traditionally, a phased approach to surgical treatment has been followed, with more so-called conservative surgeries like UPPP being performed first, while MMA was performed as a last resort. However, some authors now suggest that due to the high success rate and low morbidity of MMA surgery, as well as the low success rate of stage I surgery, MMA can be considered a first line surgical treatment for OSA.[32] Furthermore, MMA is a multi-site surgery that addresses the often multi-site problem that is OSA. Cephalometric and 3-dimensional computed tomographic analysis has shown that retropalatal, retroglossal, and total airway volume increases in both antero-posterior and

lateral dimensions following MMA surgery.[16,33] The surgery accomplishes this by physically expanding the facial skeletal framework, and along with it the associated soft tissues of the pharyngeal walls.

MMA is described as a "telegnathic" surgery, as both the maxilla and mandible are typically advanced to large degrees. The surgery consists of a LeFort I osteotomy of the maxilla, along with bilateral sagittal split osteotomies of the mandible, after which both jaws are advanced and rigidly fixated in their new, anterior positions. Genioplasty may or may not be performed. The hyoid, soft palate, tongue, and other pharyngeal tissues are brought forward along with the maxilla and mandible, which results in a total increase in the velo-orohypopharyngeal airway.[34]



<u>Figure 1.</u> Maxillomandibular advancement (MMA) plus genioplasty, profile view (Reprinted from Ronchi et al[35])

MMA has been shown to be more effective than UPPP in the treatment of OSA. In addition, MMA preformed in conjunction with UPPP has lower rates of success than

MMA performed in isolation.[31] This suggests that MMA may be considered the surgical treatment of choice for patients unable to tolerate CPAP for treatment of moderate to severe OSA. Critics of the MMA technique propose that the surgery is too invasive to be recommended for routine use. However, modern orthognathic surgery has been shown to be a very safe procedure with low frequency of serious complications.[36] It has been demonstrated that facial skeletal deformities need not be present pre-surgically for OSA patients to benefit from MMA,[35] as telegnathic lengthening of the jaws consistently produces an increase in upper airway volume by advancing the pharyngeal soft tissues, as well as raising the hyoid bone.[37]

Objective Outcomes of MMA for Treatment of OSA

When referring to objective outcomes of MMA for treatment of OSA, the changes in AHI (or sometimes RDI) are the primary outcomes considered. In recent years, many studies have arisen that demonstrate the efficacy in MMA surgery for the treatment of OSA. A retrospective study by Varghese et al[38] demonstrated that 71% of patients in their sample (n=24) had reduction of AHI below 10, with 42% of subjects reaching AHI<5. Smatt et al[39] studied a group of 18 patients who underwent MMA and defined success as having a post-operative AHI of less than 15, with at least a 50% reduction from initial AHI. Using these parameters, the success rate was 84%. Using a staged surgical approach, Li et al[40] demonstrated a high (>95%) success rate for the patients who underwent MMA surgery (with success defined as post-operative RDI<20) after previous soft tissue resection.

A retrospective study was conducted at The University of Western Ontario in 2015[41] that examined the clinical outcomes of patients, treated by one surgeon in London, Ontario, who underwent MMA for treatment of OSAS. Twenty-two patients (11 males and 11 females) were included in the sample. In this study, 86.4% of the patients were determined to have had a successful result, with 36.4% of the sample obtaining a cure of their OSAS after treatment, as determined by analysis of pre-treatment and post-treatment AHI scores. Daytime sleepiness was significantly reduced in 88.9% of patients. Due to the relatively small sample size, no gender, surgical, anatomical, physiologic, or cephalometric predictors of successful treatment were found in this patient population.

A systematic review conducted by Pirklbauer et al[42] found success rates for MMA ranging from 65% to 100%, depending on the criteria for success used, which varied widely among the studies. Strict target success rates are helpful in qualifying success or cure, and the authors recommend further follow-up studies to gauge the long-term success of the treatment. Another review conducted by Holty et al[43] found MMA to be a highly effective treatment, with a combined surgical success rate of 86% (success defined as AHI<10), and a cure rate of 66.7% (cure defined as AHI<5).

There is currently limited data on the long-term stability and success of MMA surgery as a treatment for OSAS. This is concerning, given the tendency for skeletal relapse following orthognathic surgery, particularly in cases where large skeletal movements have been achieved. Most data regarding outcomes for MMA surgery focus on the first year following the surgery. A study by Riley et al[44] followed 40 patients for a mean follow up period of 50.7 months (range 12-146 months). At long term follow up, 90% of patients had maintained reduction of their RDI to clinically successful levels

(<20). Four patients (10%) did not experience the same success, but it is noteworthy that these four patients experienced significant weight gain from the time of surgery to the time of follow up. Also, the authors found that the reduction in RDI to be proportional to the extent of the surgical movements; i.e. a larger advancement generally resulted in a greater reduction in RDI post-surgically and in long-term follow up.

Another study of 6 patients by Jaspers et al[45] examined the success of MMA surgery for OSA treatment 8 years post surgically. Five of the 6 maintained a markedly reduced AHI, although two remained above 5 and have been re-diagnoses with mild OSA. The sixth patient relapsed from an AHI of 2 at six month post-surgery to an AHI of 42 at 8 years. This patient had an AHI greater than 80 initially. The main drawback of this study is small sample sizes. Further studies examining the success of OSAS should focus on long-term analysis of surgical success.

Subjective Outcomes of MMA for Treatment of OSA

Measures of success of MMA treatment for OSA must not only include the objective parameters examined during polysomnography, but must also take into account subjective measures, such as patient satisfaction. In patients considering MMA, it is ideal if there are reasonable assurances that their quality of life will improve, and that they will achieve a reasonable aesthetic result. It has been shown that in patients seeking routine orthognathic surgery for treatment of dentofacial deformities, their levels of happiness were significantly lower pre-surgically when compared with controls. This was especially true in female, Class II patients.[46] Following surgery, patients are known to experience negative psychological changes in the immediate post-surgical period, such as

depression, but in the long term the enhanced sense of aesthetic satisfaction seems to mitigate this short-term depressive effect.[47] It is likely that the transient deterioration of quality of life can be attributed to surgical morbidities, which are generally temporary.[48] Long-term, these patients generally remain satisfied with their treatment.[49] Lye et al[50] reported that 93.3% of their sample of patients who underwent MMA for the treatment of OSA (n=15) had a successful quality of life change. Goodday and Bourque[51] reported that 89% of their sample (n=116) found the procedure to be worthwhile, and 95% would recommend the procedure to others.

There have been a limited number of studies examining the objective outcomes of MMA with respect to facial esthetics. It is important to note that while it is the hard tissues that are moved by telegnathic surgery, it is the soft tissues that form the basis for an aesthetic evaluation. In general, the soft-tissue to hard-tissue ratio of movement in the upper lip, lower lip, and chin of patients undergoing MMA is about 0.9:1.[52] Furthermore, the goal of surgery is not simply to correct a dentofacial disharmony. It is typically desirable to maximize the surgical movements to their greatest limits, so that maximum anterior movement of the maxillomandibular complex is achieved and, thereby maximally expanding the airway.[53]

A small number of studies have been published that specifically address facial aesthetic outcomes of MMA surgery. Liu et al[54] found that over 90% of patients in a Chinese population responded favourably to their facial appearance after MMA surgery for OSAS treatment. One hundred laypersons were also surveyed, and the aesthetic scores given to 11 of the 12 patients were significantly higher for the post-operative pictures. However, the sample size of this study was small (n=12), the sex distribution of

the sample skewed (11 M, 1 F), and the photos assessed were unaltered save for blocking out the eyes to protect the patients' identities. It is possible that this may have introduced confounding variables with respect to facial appearance that are difficult to control for.

Cohen-Levy et al[55] looked at assessment of patients' profiles by three groups: lay persons, art students, and orthodontists. Fourteen out of fifteen patients were satisfied with the aesthetic changes after surgery. The person who was dissatisfied noted worsened appearance of the nose and upper lip. Eighty-five percent of post-operative profiles were viewed as having changed favourably by the panel members, with no significant differences amongst the three groups. The profiles that were assessed as being worsened by surgery shared several common characteristics: prochelia of the lips (exceeding the E-line), visible closure of the nasolabial angle, a small-appearing nose, and short faces pre-treatment. Profiles assessed as the most attractive had an obtuse nasolabial angle, with marked labial retrusion. The authors suggest that retrocheilia and an open nasolabial angle in the pre-operative profile may be predictors of successful MMA treatment from an aesthetic perspective. They propose that this effect may be enhanced orthodontically by adjusting the antero-posterior position of the incisors, and thus the upper lip, prior to surgery.

A number of negative aesthetic sequelae have been reported following MMA, including excessive maxillomandibular protrusion, bulging upper lip, prominent upper incisors, and widening of the nose.[56] It is therefore crucial to optimize surgical treatment planning and execution to avoid incurring any of these effects, and to identify patients in which particular caution must be employed. Though these difficulties sometimes occur, high patient satisfaction with respect to post-surgical patient aesthetics has been

reported.[54] In a study by Li et al[53], it was found that 90% of patients who underwent MMA for treatment of OSAS reported neutral or positive changes to their facial appearance. This was despite significant maxillomandibular protrusion as determined by cephalometric analysis post-surgery. The authors used a visual analogue scale (VAS) for the patients' self-assessment. It was noted that while non-obese, younger patients with thin facial soft tissues were at the greatest risk of adverse facial change, each case must be assessed and diagnosed individually during surgical planning to avoid creating unfavourable changes.

Patient Reported Outcome Measures

Positive patient outcomes are paramount to the success of any surgical procedure. When discussing patients who undergo MMA for treatment of OSA, we are particularly interested in outcomes relating to overall health and general quality of life, snoring, daytime sleepiness, functional sleep outcomes, functional outcomes relating to orthognathic surgery, and facial aesthetics. Currently, there is no single questionnaire available that has been developed that addresses each of these domains for patients undergoing MMA for treatment of OSAS specifically. Development of such a tool may prove useful in not only assessing patient outcomes after treatment, but also to provide patients with sound data to manage their own expectations, as well as to provide more thorough informed consent prior to the treatment. There are a number of previously validated health-based questionnaires that address each of these domains on their own.

The most commonly used generic health status measure that can be used to measure outcomes in many different patient groups is the SF-36 short-form

questionnaire, along with its abbreviated version, the SF-12. These questionnaires, developed and validated in the United States, have been adopted as some of the main standard outcome measures in America and around the world.[57,58,59] The majority of the questionnaire relates to the status of the patient's life with respect to physical, emotional, and social health. While most questions are too general to ascertain outcomes of MMA in OSA patients, several of the questions regarding general health in well-being, especially those comparing health now and before the operation, could be useful in determining the patient's perception of overall health in a question format that has been previously validated.

There are a number of questionnaires that have been previously developed and repeatedly validated that assess various sleep outcomes in OSA patients, with different academic centers preferring to use specific ones. Several validated screening questionnaires include the STOP and STOP-BANG Questionnaires,[60,61] the Sleep-50 Questionnaire,[62] and the Sleep Disorders Questionnaire.[63] More commonly used screening measures are the Berlin Questionnaire and the Epworth Sleepiness Scale.

The Berlin Questionnaire is the most widely used questionnaire specifically developed for OSA patients.[64] In addition to assessing daytime sleepiness, the Berlin Questionnaire takes the patient's age and weight into account, and includes measures for snoring, hypopneas/apneas, and whether or not the patient has high blood pressure, which has been positively associated with OSA.[65] The patient's height and weight allow the investigator to calculate Body Mass Index (BMI). Snoring is not only correlated with apneic events, but also may serve as indicator for surgical success, as enlargement of the nasopharyngeal airway in theory will reduce the patient's tendency to snore.

The Epworth Sleepiness Scale is an 8-question questionnaire in which the subject is asked to rate his/her likelihood of falling asleep during various scenarios, on a scale from 0-3. An overall score is derived from the answers, with a score of 10 or higher indicating excessive daytime sleepiness.[4]

The Functional Outcomes of Sleep Questionnaire (FOSQ)[66] is a self-reported measure intended to assess the functional outcomes of daytime sleepiness. It was developed to determine how disorders of excessive sleepiness affect patients' abilities during daily activities. It consists of 30 questions, which ask the subject to rate the effect their sleepiness has on various daily activities on a scale of 0-4. Along with the Epworth Sleepiness Scale, it is one of the most commonly used self-reported measures to assess daytime sleepiness. It was not developed for MMA patients, but several questions in the FOSQ may be useful in assessing patients' daytime sleepiness during normal activities such as socializing with friends, exercising, and relaxing around the house.

The Orthognathic Quality of Life Questionnaire (OQLQ)[67] was developed specifically to assess quality of life in patients who are candidates for orthognathic surgery, primarily those with dentofacial deformities. The questionnaire assesses patients' perceptions of their teeth and face, jaw function, and the social impact of these variables. While it was not specifically designed for OSAS patients who are candidates for MMA, it can easily be applied to assess QOL outcomes in these patients, especially since older patients may be particularly sensitive to facial changes.

Other questionnaires that were not developed for orthognathic patients may also be of value. The Glasgow Benefit Inventory (GBI)[68] is a measure designed to assess the

impact of otorhinolaryngological interventions such as tonsillectomy and rhinoplasty on patients' quality of life. The questions examine the impact of such procedures on overall quality of life, self-confidence, and self-consciousness. The GBI uses factor analysis (a technique involving the grouping of question responses to demonstrate overall trends) as a defining feature, however this technique is not used in the present study. The validated question forms from the GBI may be drawn upon to assess QoL in MMA patients.

The change in facial appearance following MMA surgery must be addressed as part of informed consent. The literature about measures that assess subjective outcomes is limited in orthognathics. The OQLQ contains some questions that measure aesthetic satisfaction. The plastic surgery literature is more developed in this regard, and several validated and widely used questionnaires exist that assess cosmetic outcomes after facial surgery.

The FACE-Q Questionnaire is a very detailed measure that allows the patient to express their opinions about every aspect of the face, such as their skin, lips, eyebrows, etc. While it is very useful when assessing the aesthetic outcomes of plastic surgeries, it is far too detailed for use in orthognathics because the surgery itself has a relatively limited effect on external structures. The Facelift Outcomes Evaluation (FOE)[69] is a 6-question validated measure that is meant to screen patients for facelift procedures. The first question, which is an assessment of overall facial appearance, may be applied to patients undergoing MMA for treatment of OSAS, as well as a modified version of the same question assessing patient satisfaction with the appearance of the facial profile. Since MMA surgery is indeed often described as a "reverse facelift" due to soft tissue

stretch over expanded skeletal structures, the use of a modified form of the FOE may be useful in assessing aesthetic outcomes in MMA patients.

The Derriford Appearance Scale (DAS59)[70] is a comprehensive general questionnaire to measure the spectrum of psychological distress associated with having a physical deformity or disfigurement. It was developed with far less severe deformities in mind than those associated with dentofacial dysplasia, but nonetheless several measures in the questionnaire may prove useful in orthognathics. In particular the questions assessing the patients' feelings of attractiveness and masculinity/femininity would be of interest to MMA patients. In telegnathic MMA surgery, we are by definition lengthening the jaws. Societal interpretations of a "strong jaw" are inherently masculine in nature, so prospective female MMA patients in particular may be interested in whether or not the surgery will make them "too masculine".

With the increasing understanding of the health implications of OSA, it is likely that the number of patients seeking MMA for treatment of their sleep apnea will increase in the future. It would be useful to develop an outcomes measure specifically for these patients. As patients considering this treatment have to consider the implications with respect to multiple facets of their well-being, the questions in such a questionnaire would need to address general quality of life, daytime sleepiness and functional sleep outcomes, snoring, cosmetic facial outcomes, as well as functional outcomes of orthognathic surgery. By using a composite of questions from the previously mentioned validated questionnaires as a starting point, it may be possible to devise a measure that adequately assesses patient-reported outcomes in such a way that will be useful to screen future OSA

patients for MMA, as well as to assess the outcomes of MMA in the treatment of OSA and assess overall patient satisfaction with the treatment.

Introduction

Obstructive Sleep Apnea (OSA) is a common but often unrecognized disorder that has a significant detrimental effect on patient quality of life.[1] OSA is associated with a number of other conditions, such as diabetes,[12] metabolic syndrome,[13] and cardiovascular disease.[14] There is a strong correlation between OSA and Body Mass Index (BMI).[11] Other sequelae like hypersomnolence, cognitive dysfunction, impaired work performance, and increased irritability are also seen in individuals with OSA.[9]

Various treatment modalities are available to OSA patients. Overweight patients are typically recommended to lose weight. The gold standard treatment is continuous positive airway pressure, or CPAP, in which a machine blows air into the nose, increasing the pressure within the pharynx, thus maintaining airway patency during sleep. While CPAP has been shown to be an effective treatment,[22] patient compliance is often an issue as nasal congestion, oral and pharyngeal dryness, skin rash, and complaints from partners are often cited as reasons for not wearing the machine. Oral appliances to advance the mandible may be effective in mild to moderate OSA cases, although they address only the retroglossal site of airway obstruction and may have deleterious dental side effects.[25]

For many years, pharyngeal soft tissue (Stage I) surgery was the most common method of dealing with OSA surgically, with the uvulopalatopharyngoplasty (UPPP) being the most commonly employed technique.[28] It has been shown that UPPP is, at best, 50% successful,[29] and that common negative sequelae include hypernasal speech, nasal reflux, and nasal airway obstruction due to scar tissue formation from the surgery itself.[2]

Maxillomandibular advancement (MMA) has been traditionally designated a second stage surgery due to its perceived invasiveness, however it is becoming more popular as a first-line surgical treatment as its apparent advantages come to light. It has been shown to be a more effective OSA treatment with UPPP,[31] as it addresses both the retopalatal and the retroglossal areas of potential airway obstruction. Because of this, MMA is often referred to as "telegnathic" surgery, as both jaws are effectively lengthened.

MMA has shown to be an effective treatment that leads to an objective improvement in OSA symptoms.[38-43] A study conducted at the University of Western Ontario's in 2015[41] found that of 22 OSA patients treated with MMA by a single surgeon at LHSC, 86.5% had successful treatment with significant AHI reduction as well as reduced daytime sleepiness. However, the literature dealing with subjective outcomes of MMA in OSA patients is limited.

With any treatment procedure, subjective measures of success must be considered, in particular those that pertain to the patient's quality of life (QoL). Any procedure that has the potential to have a detrimental effect on QoL must be approached with caution. Uncovering predictors of post-treatment QoL in these patients has the potential to be helpful in screening patients who are candidates for MMA surgery, as well as to provide the opportunity for appropriate informed consent.

When considering MMA for treatment of OSA, we must consider the patient's perceptions when it comes to sleep outcomes such as daytime sleepiness and restfulness, as well as snoring and apneic events during sleep. The latter outcomes are usually

assessed by assessing the patient's partner, or someone else who can observe the patient while he/she is sleeping.

While the functional outcomes of orthognathic surgery have been well documented among patients with dentofacial deformities, there is little literature available that examines these outcomes with respect to OSAS patients specifically. The previously mentioned article by Phee[41] concluded that the procedure may be completed while avoiding any major complications, but data regarding quality of life in the peri-operative period for MMA patients specifically is limited. Goodday et al[51] found that most patients are satisfied with the procedure in the long term and would recommend it to others. It may be useful to explore this area to determine if patients undergoing MMA for treatment of OSAS deem the surgical process as being "worth it". Potential long-term considerations for those undergoing orthognathic surgery include numbness, jaw and/or facial pain, and difficulties with mastication.

Facial esthetic change is an outcome that has the potential to greatly affect a patient's self esteem and confidence. While facial change is expected and often desired in conventional orthognathic patients who are receiving treatment to correct an underlying dentofacial deformity, it is often desirable to minimize facial changes in adult patients. It is reasonable for an adult patient to inquire as to what they will look like after surgery. The majority of patients who undergo orthognathic surgery are satisfied with the changes in their facial appearance.[71] However, since in most cases, patients undergoing MMA for OSA treatment are concerned with aesthetics only secondarily to their sleep disorder, these patients may be more sensitive to large changes in facial appearance.[51] Therefore,

an effort must be made to optimize aesthetics in MMA cases, while ensuring enough advancement is performed as to allow for improvement in OSA symptoms.

As MMA becomes increasingly common for the treatment of OSA, it is of critical importance patients understand the effects the results of the surgery may have on their quality of life not only generally, but specifically with respect to facial aesthetics, snoring, daytime sleepiness, and functional sleep outcomes. Functional outcomes of orthognathic surgery, such as masticatory function, should also be assessed. There are already validated measures that assess these areas specifically. For example, the Functional Outcomes of Sleep Questionnaire (FOSQ)[66] and Epworth Sleepiness Scale[4] address daytime sleepiness and its effect on daily activities, the Berlin Questionnaire[65] addresses snoring, and the Orthognathic Quality of Life Questionnaire (OQLQ)[67] deals with subjective facial appearance after orthognathic surgery, among other functional surgical outcomes. By using a modified composite of these and other measures, it may be possible to construct a questionnaire that is able to assess subjective patient outcomes for OSA patients undergoing MMA in the areas mentioned above.

Purpose of the Study

There is clearly a need for more study into subjective patient outcomes in OSA patients following MMA. Therefore, the aim of this study is to assess general quality of life, snoring, daytime sleepiness and functional sleep outcomes, functional outcomes of orthognathic surgery, and facial aesthetic outcomes in a group of patients who underwent MMA surgery for the treatment of OSA.

Materials and Methods

Ethics Approval

Ethics approval was obtained from both the Health Sciences Research Ethics Board (HSREB) at Western University (approval number R-15-286), as well as the Lawson Institute at the London Health Sciences Center (LHSC)(file number 106869) (Appendix I).

Study Participants

The potential participants in this study were 32 patients who underwent maxillomandibular advancement surgery by a single oral and maxillofacial surgeon at LHSC between the years 2002 and 2013. The inclusion criteria included having a pre-surgical AHI greater than 5 as determined by a sleep study, that they underwent the procedure during the aforementioned time frame, and that they were able to be contacted to participate in the survey. Exclusion criteria included patients who could not be contacted prior to distributing the survey, patients with other sleep disorders other than OSA, or patients whose pre-surgical AHI was less than 5, and thus could not be diagnosed with OSA.

Development of the Questionnaire

A review of the literature was conducted to examine validated measures that assess general quality of life, quality of life related to orthognathic surgery, sleep-related quality of life and outcomes, as well as facial cosmetic and aesthetic outcomes. A

questionnaire was devised using modified questions from several previously validated measures including the SF-36[57], the Orthognathic Quality of Life Questionnaire (OQLQ)[67], the Epworth Sleepiness Scale (ESS)[4], the Functional Outcomes of Sleep Questionnaire[66], the Berlin Questionnaire[65], Derriford Appearance Scale[70], and the Facelift Outcomes Evaluation.[72] A number of original questions that were designed to assess subjective patient outcomes not touched on the above measures were included as well. (Appendix III). The majority of the questions were constructed using five categories, from most positive to most negative outcome, with the middle (third) outcome being interpreted as neutral. Several questions had two potential responses (yes/no, for example). The Epworth Sleepiness Scale was included in its original format. A number of questions provided text space for the patients to elaborate on their answers, if desired. For all questions, an option of "I don't know" was provided for the patients to select should one of the other provided answers not apply to them.

The first series of questions were meant to assess the patients' overall state of health and well-being. Question one was derived form the SF-36 questionnaire, while questions two, three, four, and five were original questions added by the author. Question six is the Epworth Sleepiness Scale in it's original, unaltered format. Questions seven and eight were added to determine the patients' current height and weight, so that current BMI values could be calculated. Questions nine through 14 were derived from the Berlin questionnaire, and were included to assess snoring outcomes. Questions 15 through 22 were intended to assess functional sleep outcomes, and were derived from the functional outcomes of sleep questionnaire (FOSQ).

Questions 23, 24, 26, 27, 28, and 29 were derived from the Orthognathic Quality of Life Questionnaire (OQLQ), and were added to address functional surgical outcomes. Question 25 was an original question added by the author to assess the extent of persistent numbness present after surgery.

The next series of questions addressed facial aesthetic outcomes, and were derived from the OQLQ, the Facelift Outcomes Evaluation (FOE), the Derriford Appearance Scale, as well as some original questions. Questions 30, 31, and 32 were derived from the OQLQ. Questions 33 and 34 were derived from the FOE, and question 35 was derived from the Derriford Appearance Scale.

The final series of questions (36 through 40) were intended to address the patients' overall quality of life, as well as their satisfaction with the treatment. All were original questions added by the author, as the variables addressed by these questions could not be retrieved from an existing validated questionnaire.

Content Validation

The questionnaire was pre-tested by distributing it to five individuals, none of who had a diagnosis of sleep apnea, to verify the clarity of the questions. The testers were asked to provide feedback regarding the wording and clarity of the questions, as well as feedback regarding the overall format of the survey. Minor grammatical and structural changes were applied to the survey after feedback from these individuals.

Distribution of the Questionnaire

The participants were initially contacted by the surgeon who provided their treatment. Up to date e-mail and home addresses were obtained over the phone. The survey as well as the informed consent form was distributed to the participants either by e-mail or standard mail, according to their preference. After one week, non-responders were sent a reminder e-mail with an additional link to the survey. This process was repeated once more for persistent non-responders, so the maximum number of times the patients could be sent a survey was three, as per the Dillman methodology[73] for online surveys. If after three attempts the patients did not respond, they were deemed non-responders and were not sent any additional surveys.

The survey was created and distributed using Qualtrics® survey software (Qualtrics, Provo, UT). The data from the returned questionnaires was stored within the Qualtrics® software on encrypted servers at The University of Western Ontario. For the participants who requested to be sent the questionnaire via regular mail, an addressed return envelope with postage to the department of Oral and Maxillofacial Surgery at University Hospital (LHSC) was provided. The data from these questionnaires was then entered manually by the author into the Qualtrics® software.

Informed Consent

An informed consent form was created using guidelines from the Health Sciences Research Ethics Board (HSREB) at The University of Western Ontario (Appendix II). An electronic version of this form was made available to the respondents before completing the survey electronically, or it was sent along with the survey for those patients who

requested to complete the survey via standard mail. In the electronic copy, the respondents were asked to click a box to indicate they have given informed consent for the study. Participants who were mailed the form along with the questionnaire were asked to send the signed and dated informed consent form back along with the completed questionnaire.

Statistical Methods

Data analysis was completed using SPSS statistical software program (Released 2014. IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY:IBM Corp). Descriptive statistics were generated along with tables for each question in the survey. Chi-square tests and ANOVAs were performed to assess any potential associations between the questionnaire responses and various demographic and other respondent variables. Fisher's exact test was used when the assumptions for chi-squared tests were not met. The responses for several question groups, such as daytime sleepiness and functional sleep outcomes, snoring outcomes, and facial aesthetic outcomes were condensed and combined in SPSS. Chi-square tests were run to look for significant associations between these outcomes and overall quality of life. Statistical significance for all tests was set at a P-value $<.05$.

Results

Patient Demographics

Of the 32 potential participants, two were excluded from the study because they could not be contacted. One patient was not included as he was diagnosed with CSA in conjunction with OSA, making him unsuitable for a surgical correction. A further four patients were excluded as their AHI scores were not high enough for a diagnosis of OSA, and thus did not satisfy the inclusion criteria. Out of the 25 surveys distributed, 22 (88%) were returned. No significant differences with respect to sex or age were found between responders and non-responders ($p>.05$). Eleven (50%) of responders were female and 11 (50%) were male (Table 1). The mean age at the time of survey completion was 48.8 (+/- 13.2) years, with a range of 19.4 to 65.5 years (Table 2). All surveys were completed in October of 2015. The mean time from the surgery date to the time of survey completion was 6.4 (+/- 3.5) years with a range of 1.8 to 13.4 years (Table 2).

	Frequency	Percent
Sex:		
Male	11	50.0
Female	11	50.0
Total	22	100.0
Ortho:		
Yes	17	77.3
No	5	22.7
Total	22	100.0
AHI success:		
Yes	15	68.2
No	2	9.1
Total	17	77.3
Missing	5	22.7
Pre AHI:		
Mean	48.4	
Range	11.5-120.0	
Post AHI:		
Mean	12.5	
Range	1.0-59.4	
AHI change:		
Mean	-36.1	
% AHI change:		
Mean	-68.2	

Table 1. Sex demographics of the survey responders, as well as the number that did and did not have orthodontic treatment, and those that did and did not have successful AHI reduction after surgery. The mean pre and post-surgical AHI values, as well as the mean AHI change is demonstrated.

Of the 22 responders, 17 (77.3%) had orthodontic treatment in conjunction with their surgery, while 5 (22.7%) did not (Table 1). The average BMI at the time of survey completion was 28.8 (+/-6.6), with a range of 20.2 to 46.1 (Table 2).

Age (years):	
Mean	48.8
Std. Deviation	13.2
Range	19.4-65.5
Current BMI:	
Mean	28.8
Std. Deviation	6.6
Range	20.2-46.1
Time Since Surgery (years):	
Mean	6.4
Std. Deviation	3.5
Range	1.8-13.4

Table 2. Current age, BMI, and time since surgery for the 25 survey respondents

Of the 22 participants, only 17 had post-surgical AHI scores, so AHI success (defined as a post-surgical AHI of 15 or less, or a post-surgical AHI reduction of 50%) could only be determined for these patients. Of the 17 participants with available post-surgery AHI scores, only 2 (9.1%) did not have a successful result with respect to AHI reduction. Thus, the success rate for this sample was 90.9%. The mean pre-surgical AHI was 48.4, the mean post-surgical AHI was 12.5, and the mean AHI change was -36.1 (-68.2%)(Table 1).

Questionnaire Results

Please refer to Appendix IV for detailed tables and results for all questions.

Questions one through three were meant to assess the general health of the patients. Sixteen (72.7%) of participants rated their health as “excellent” or “very good”, while the rest rated themselves as “good” or “fair”. Nineteen (86.4%) of participants rated their health as either somewhat or much better than the time before surgery, two (9.1%) rated their health as about the same, while one (4.5%) participant rated their current health as worse than the time before their surgery. Several of the participants were diagnosed with new medical conditions since the time of surgery, including ADHD (n=1), hypertension (n=2), and Celiac disease (n=1). One patient indicated that they are being investigated for Parkinson’s disease, but that they do not yet have a definitive diagnosis.

Twenty-one (95.5%) of the patients reported their sleep apnea got better since having the surgery, while none reported worsening of their OSA symptoms (Question four). Twenty-one (95.5%) of the participants report wearing a CPAP machine “never or nearly never”, while one (4.5%) reported continued nightly CPAP wear (Question five). The mean Epworth Sleepiness Scale value for the participants was 4.0 +/- 3.3 with a range of 0-14, with one patient (4.5%) having an ESS score above 10, which indicates clinically significant daytime sleepiness (Question six). Questions seven and eight asked the participants to provide their current height and weight so that BMI scores could be calculated.

Questions nine through 14 addressed snoring outcomes. Nine (40.9%) of the participants report snoring rarely, or never (Question nine). Most participants report that their snoring is not as loud as the time before surgery, and that it bothers other people less than it did before having surgery (Questions 10, 13, and 14). Eleven (50.0%) participants

reported that they experienced cessations in breathing during sleep rarely or never (Question 11), while 15 (68.1%) of participants claim to snore less than they did before surgery (Question 12). More participants selected "I don't know" as an answer option in this section than in other sections, indicating that they are not aware of their sleep behavior. The responses from 12 through 14 we combined to demonstrate the percentage of positive, negative, and neutral responses recorded for snoring variables (Table 3).

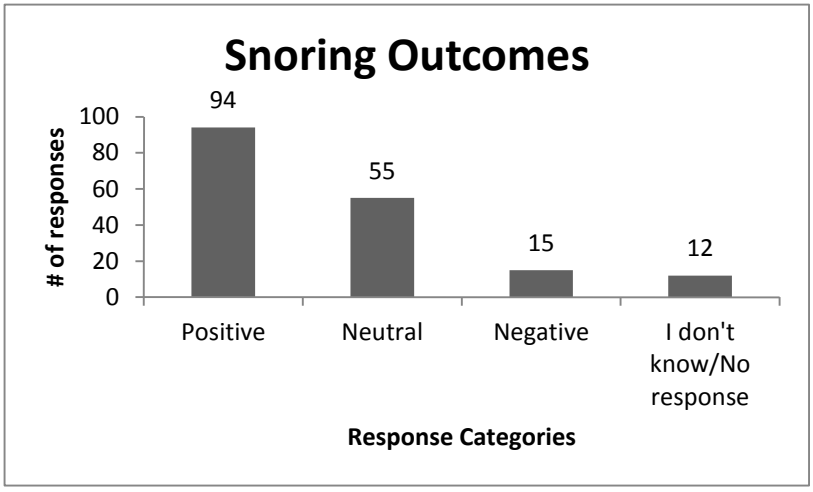
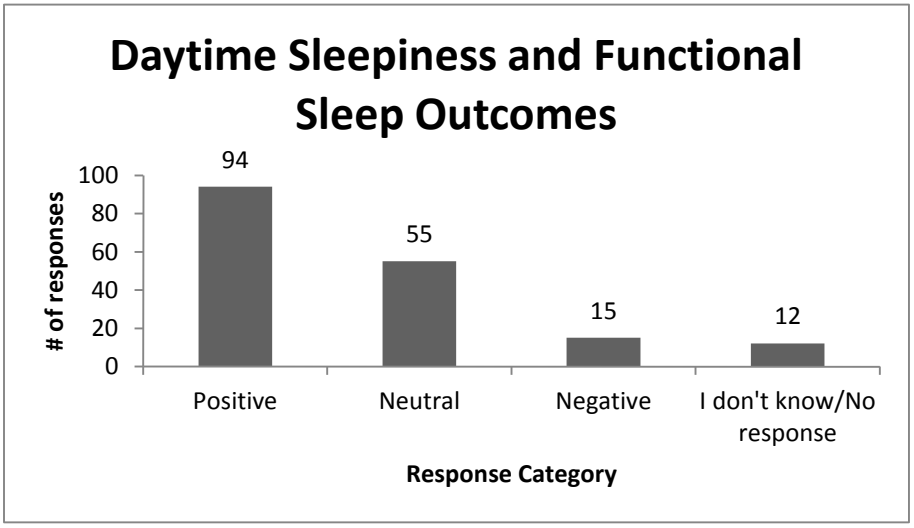


Table 3. Percentage of Negative, Neutral, and Positive Responses in the Questions That Addressed Snoring Outcomes (12 through 14)

Questions 15 through 22 assessed daytime sleepiness, as well as the effect of sleepiness on daily functioning. Nineteen (86.4%) of responders reported feeling more refreshed in the morning compared to the time before surgery (Question 15), 19 (86.4%) participants reported feeling less tired during the daytime (Question 16), and 20 (90.9%) reported that the quality of their sleep is better compared to the time before surgery (Question 17). Fifteen (68.2%) reported having less difficulty socializing compared to the time before surgery, 17 (77.3%) report having less difficulty concentration or remembering things, 19 (86.4%) reported less difficulty doing chores or exercising, and

19 (86.4%) reported less difficulty sitting through movies or lectures without difficulty (Questions 18 through 21). Sixteen (72.7%) of the participants reported their mood being less affected by sleepiness compared to the time before surgery. The results from questions 15 through 22 were compiled to demonstrate the percentage of positive, negative, and neutral responses recorded for daytime sleepiness and functional variables (Table 4).



<u>Table 4.</u> Percentage of Negative, Neutral, and Positive Responses in the Questions That Addressed Functional Sleep Outcomes (15 through 22)

Questions 23 through 25 address specific aspects of the participants' quality of life as it pertains to the orthognathic surgery itself. Eleven (50.0%) reported having fewer problems with biting and chewing than the time before surgery, while five (22.7%) reported more problems (Question 23). There was no significant relationship between problems with chewing and/or bite and orthodontic therapy ($P>0.05$). Seven (31.8%) reported less TMJ and facial pain than before surgery, seven (31.8%) reported more pain, while 6 (27.3%) reported no difference (Question 24). Eighteen (81.8%) of participants

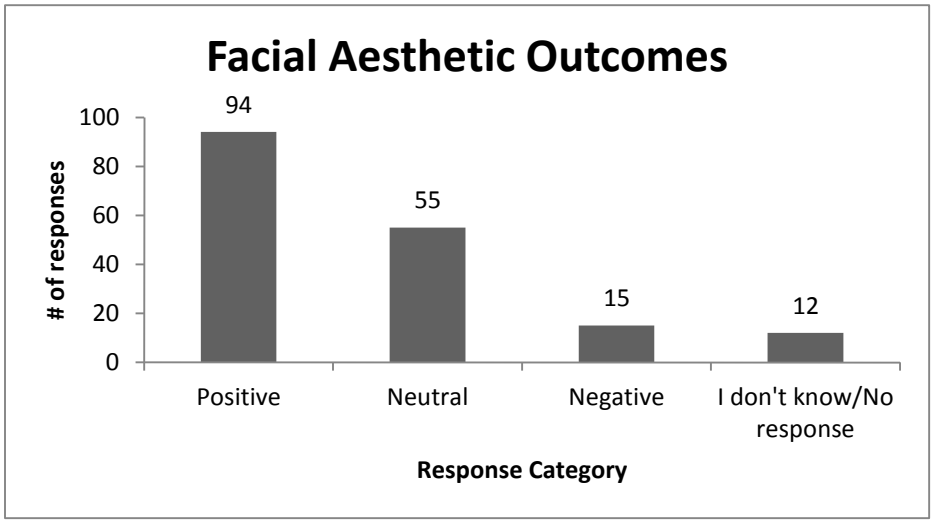
reported partial or complete resolution of numbness from the time of surgery (Question 25).

Questions 26 through 35 assessed the aesthetic facial outcomes of the surgery, as well as the psychological and social impact of these outcomes. Nine (40.9%) reported having more confidence when out socially, while two (9.1%) reported having less confidence (Question 26). Eleven (50.0%) reported feeling less self-conscious about their facial appearance than before surgery (Question 27), and 11 (50.0%) reported feeling less self-conscious about the appearance of their teeth and smile (Question 28). Six (27.3%) of participants reported spending more time studying their face in the mirror than the time before surgery (Question 29).

Twenty (90.1%) reported liking their frontal facial appearance the same or more than the time before surgery (Question 30), while one (4.5%) liked it less. Seventeen (77.3%) reported liking their appearance in profile the same or more (Question 31), while 17 (77.3%) believed that their family and friends like their facial appearance as much or more than the time before surgery (Question 32).

Nine (40.9%) respondents believed that the surgery made them look younger, while two (9.1%) believed that it made them look older (Question 33). Fourteen (63.6%) believed that the surgery made them look more attractive, four (18.2%) believed it had no effect on attractiveness, and two (9.1%) believe the surgery made them look less attractive (Question 34). One (4.5%) participants thought the surgery made them look more feminine, 4 (16%) thought the surgery made them look more masculine, while 15 (68.2%) reported no difference with respect to masculinity/femininity (Question 35).

Broken down by sex, four (18.2%) men found the surgery made them appear more masculine, while none indicated that the surgery made them look more feminine. Similarly, one (4.5%) female thought the surgery made her look more feminine, while no females indicated that the surgery made them appear more masculine. Questions 26, 27, 28, and 30 through 34 were combined to demonstrate the percentage of positive, negative, and neutral responses collected with respect to facial aesthetic outcomes (Table 5).



<u>Table 5.</u> Percentage of Negative, Neutral, and Positive Responses in the Questions That Addressed Facial Aesthetic Outcomes

The remaining questions were meant to assess the effect the surgery had on the participants' overall quality of life. Nineteen (86.4%) of the participants reported that their quality of life is better now than the time before the surgery (Question 36). Eighteen (81.8%) said their experience with the treatment was worthwhile (Question 37). Sixteen (72.7%) of the patients reported that they would go through the procedure again, while two (9.1%) reported that they wouldn't (Question 38). Seventeen (77.3%) reported that

they would recommend the procedure to their family and friends, if needed (Question 39).

Chi Square testing revealed positive associations between question 36 (subjective assessment of overall QoL) and snoring outcomes (p=0.001) and functional outcomes of sleep (p=0.003). Functional sleep outcomes were not significantly associated with snoring outcomes (p=0.084). Facial aesthetic outcomes were not found to be significantly related to overall QoL (p=0.818) and snoring outcomes (p=0.723), but were found to be significantly associated with functional sleep outcomes (p=0.046) (Table 6).

	QoL Improved?	Snoring	Functional Sleep	Aesthetics
Quality of life improved? Q36	X	0.001*	0.003*	0.818
Snoring Outcomes	0.001*	X	0.084	0.723
Functional Sleep Outcomes	0.003*	0.084	X	0.046*
Facial Aesthetic Outcomes	0.818	0.723	0.046*	X

Table 6. Associations between general QoL, snoring outcomes, daytime sleepiness and functional sleep outcomes, and facial aesthetic outcomes along with corresponding p values. *p<.05

Sex

There were statistically significant differences in several question responses with respect to patient sex. Females preferred their appearance in profile after surgery to males (p=.049), and females also felt significantly more attractive compared to males post-surgery (p=.043)(Table 7).

Question		Male	Female	p-value
Q31: Since having surgery, how do you like the appearance of your face from the side (profile)?	Less	0	2	0.049*
	Same	4	0	
	More	7	8	
Q34:Do you feel like having orthognathic surgery has made you more, or less attractive?	Less	0	2	0.043*
	Same	4	0	
	More	6	8	

Table 7. Statistically significant associations relating patient sex to various survey question responses. *p<.05

Orthodontic Treatment

More than twice as many patients were treated orthodontically in conjunction with the surgery than those who weren't (Table 1). Patients who were treated orthodontically reported to be significantly les self-conscious about their facial appearance (p=.009) and about the appearance of their teeth and smile (p=0.001). Patients who had orthodontics also liked their frontal facial appearance (p<.001) and their appearance in profile (p<.001) more than the patients who did not undergo orthodontics. Orthodontically treated participants also felt more attractive post-surgery than those who did not receive orthodontics (p<.001), and orthodontically treated patients also felt that their family and friends approved of their post-surgical facial appearance when compared to patients who did not receive orthodontics (p=0.033)(Table 8).

Question		Yes	No	p-value
Q27:Since having your surgery, are you more, or less self-conscious about your facial appearance?	More	3	2	0.009*
	No diff.	3	5	
	Less	11	0	
Q28: Since having your surgery, are your more, or less self-conscious about the appearance of your teeth and smile?	More	3	1	0.001*
	No diff.	3	5	
	Less	11	1	
Q30: Since having your surgery, how do you like the appearance of your face from the front?	Less	1	0	<0.001*
	Same	1	7	
	More	15	0	
Q31: Since having surgery, how do you like the appearance of your face from the side (profile)?	Less	1	2	<0.001*
	Same	0	5	
	More	16	0	
Q32: Do you feel that your family and friends like your facial appearance more, or less since having surgery?	Less	1	1	0.033*
	Sane	1	5	
	More	12	1	
Q34: Do you feel like having orthognathic surgery has made you look more, or less attractive?	Less	1	2	<0.001*
	Same	1	4	
	More	14	1	

Table 8. Statistically significant associations relating whether or not the respondents had orthodontic treatment to various survey question responses. *p<.05

AHI Success

There were no statistically significant associations found between AHI success/failure and other patient reported outcome variables.

Discussion

Obstructive sleep apnea is an increasingly common condition among people of all age groups, and has a potentially serious detrimental effect on quality of life for these individuals. While many treatments are available for OSA, none are as effective as maxillomandibular advancement (MMA) surgery as a definitive treatment to reduce AHI.[44] The facial aesthetic outcomes have also been shown to be generally positive.[53] It is important for patients considering MMA to have reasonable expectations with respect to their quality of life after the procedure. General QoL outcomes, daytime sleepiness, functional sleep outcomes, snoring outcomes, functional surgical outcomes and facial aesthetic outcomes must all be considered for these patients. Therefore, this study was done to assess patient quality of life after MMA for the treatment of OSA.

The World Health Organization (WHO) defines health not only in terms of the absence of disease, but must include a state of mental and social well-being[74].Thus, when assessing outcomes of any medical intervention, it is important to consider subjective patient outcomes, in addition to objective outcomes. With respect to MMA for the treatment of OSA, it is the patient's own quality of life we are seeking to improve, thus this is what we must seek to measure with our survey. Objective measures for assessing OSA include AHI and RDI scores, however positive outcomes with respect to these measures do not necessarily translate to positive outcomes as perceived by the patient. It is conceivable that even if a person has a successful treatment with respect to objective measures like AHI, that they may perceive an overall negative experience due to unwanted facial changes, surgical complications, etc. It is therefore necessary to include subjective patient outcomes in the parameters by which we define successful treatment.

Maxillomandibular advancement for the treatment of obstructive sleep apnea appears to have an effect on the quality of life for patients who undergo MMA for treatment of OSA. The outcomes regarding daytime sleepiness, as well as functional sleep outcomes are consistent with the literature. Most patients report never needing to use CPAP (n=21, 95.5%), which is typical in patients who undergo this procedure.[51] It is worth noting that the patient who still relies on CPAP nightly experienced significant weight gain, going from a BMI of 38.7 post-surgery to 46.1 at the time of survey completion, which may have resulted in a relapse of his OSA. He had a successful reduction in AHI after his surgery, as well as a successful reduction in ESS score in the time after his surgery. Since he is still using CPAP, his current ESS score was 0. It would be interesting to ascertain what his ESS score is in the absence of CPAP use, although it may not be an ethical to do so.

Patients who had successful surgical results reported that in addition to having improvement in their OSA symptoms, their overall health was better now than before having surgery. The association between OSA and other comorbidities is well documented.[12-14] It is possible that by ameliorating the OSA symptoms, the risk of developing these comorbidities went down in the successful patients, although a more detailed assessment of each patient's health today would be required as there are a large number of contributing factors to overall health. The effect that MMA has in OSA patients in decreasing blood pressure was demonstrated by Islam[75] in a 2015 study. A marked decrease in blood pressure was observed, especially in those patients who had established hypertension before surgery. This suggests that MMA may have the potential to reduce the severity of other comorbidities associated with OSA. Further studies should

focus on the long-term effects that MMA has on conditions like diabetes mellitus, metabolic syndrome, and cardiovascular disease.

One patient was not included in the study because he was diagnosed with central sleep apnea (CSA) in conjunction with OSA, and thus was not a good candidate for surgical correction. This participant was the only patient in the sample to have a diagnosis of CSA, indicating that his apneic events are not caused by upper airway obstruction, but rather a centrally mediated lack of respiratory effort. CSA is present in up to 10% of patients with sleep disorders, and is commonly found in elderly men and in those with poorly-controlled heart failure.[76] CSA is often difficult to diagnose because true apneas often mask CSA-related episodes during sleep studies.

The questions regarding snoring were derived in modified form from the Berlin Questionnaire.[65] Nine (40.9%) of the patients reported that currently they do not snore at all, and the ones that do still snore report doing so much less than they did before having surgery. The patients who still snore also report their snoring as much quieter than it was before surgery, and that it bothers other people less. The effect that MMA has as a telegnathic procedure effectively increases the volume of the oropharynx as the soft palate is carried anteriorly with the maxilla, and this effect on the reduction of snoring is well documented.[39] There were more respondents who selected “I don’t know” or did not respond to the questions in the survey that dealt with snoring (Questions 9-14). This may be due to the fact that those people do not sleep in the same room with others, or their partners might be deep sleepers. It is not known from the survey data which participants have sleeping partners on a regular basis, and it may be useful to ascertain this information in future surveys.

The following questions addressed functional outcomes of sleep (daytime sleepiness), and were mostly derived from the Functional Outcomes of Sleep Questionnaire,[66] in addition to the Epworth Sleepiness Scale[4]. The mean ESS score from the survey was 4.0+/-3.3, and only one respondent scored above 10, which is the threshold for clinically significant daytime sleepiness. Despite this, this patient reported positive or neutral outcomes in the other questions addressing functional outcomes of sleep, including Question 16, which directly addresses daytime sleepiness. This patient would benefit from a sleep study to ascertain the current status of their OSA. The majority of patients did have positive or neutral responses regarding these outcomes, including feeling more refreshed in the morning, less sleepy during the daytime, and better quality of sleep.

The majority of respondents reported less difficulty in social situations, less difficulty remembering things and concentrating on tasks, and less difficulty doing various forms of physical activity (Questions 18 through 20). These findings are similar to those of Lye et al[50], which noted that 93.3% of patients in their sample had positive QoL outcomes after MMA for the treatment of OSA when using the FOSQ as their primary measure. The original FOSQ uses a 0-4 Likert scale and includes 5 sections meant to assess various domains of day-to-day life, including general activity levels, vigilance, intimacy and sexual relationships, general productivity, and social outcomes. When designing this questionnaire, an effort was made to include at least one question type from each of those domains. The questions selected for use in this survey were modified to a standardized 5 category (plus one “I don’t know” category) scaled multiple-choice format.

In their raw forms, the ESS and FOSQ should produce agreeable results with respect to daytime sleepiness. It is possible that in changing the format of the questions, they may have lost some validity, but this is likely not the case. The questions used were constructed using blunt and straightforward wording, keeping with the original wording from the various source questionnaires as much as possible. Therefore, the questions may be said to have a degree of face validity, so formal validation may not be required as the questions are very close to their original formats.

If a formal validation process was desired, a number of steps would be undertaken, starting with establishment of face validation by having experts in the field evaluate the questions for clarity. Then, a pilot test of the questionnaire is performed on a sample of the intended population. This would be extremely difficult when assessing OSA patients undergoing MMA, as there aren't many of these patients to begin with. After pilot testing, the gathered statistical data is cleaned and entered, principle component analysis is performed to combine or eliminate questions that assess the same outcome, and a number of statistical tests (e.g. Cronbach's Alpha) are run to determine the consistency of the questions in assessing their intended variables. Pilot testing is then performed again and the process is repeated as needed.[78]

There were no statistically significant associations found between whether or not the respondents had successful reduction of their AHI scores after surgery and the other patient reported outcome variables considered in this study. One would think that successful AHI reduction would be associated with positive sleep and snoring outcomes, however this could not be demonstrated statistically in our population. This is likely due to the small sample size in this study and the low number of reported failures with respect

to AHI (n=2). In other words, there is significant risk of type II error, i.e. false negative results in this study. Future research should utilize larger populations for increased study power, and to minimize risk of beta-error.

The Orthognathic Quality of Life Questionnaire[79] is a widely used measure to assess patients' qualities of life who have undergone orthognathic surgery. It has traditionally been used to assess individuals who have undergone orthognathic surgery as part of routine combined orthognathic/orthodontic therapy to address dentofacial deformity and malocclusion.[80] The primary motivation for treatment for OSA patients is generally different from conventional orthognathic patients. While those suffering from OSA may or may not have an underlying dentofacial deformity, their primary motivation for treatment is typically to seek improvement of their OSA symptoms. Nevertheless, these patients should have reasonable expectations of the experience and outcomes of having orthognathic surgery as part of informed consent. It was deemed worthwhile to address several variables that relate to the experience of orthognathic surgery to our sample. The OQLQ has four components. Component one deals with social aspects of deformity, for example self-consciousness. Component two deals with facial aesthetics, component three addresses function, and component four addresses awareness of the facial deformity. An additional original question was added in this section to address the issue of persistent facial numbness after surgery. Questions 23, 24, and 26 through 31 are derived from the OQLQ.

The functional variables assessed included potential problems with mastication, facial pain, and numbness. Eleven (50.0%) reported fewer problems with mastication than before surgery, while five (22.7%) reported more problems (Question 23). This is

somewhat contrary to previous research that has demonstrated a strong positive effect of orthognathic treatment on mastication,[81] however the small sample size in this study makes it difficult to draw any definitive conclusions. Interestingly, there was no significant association found between orthodontic treatment and chewing/bite issues after surgery. It would have been expected that those receiving orthodontics had less discomfort associated with their bite, however this was not the case.

Seven (31.8%) reported more pain in their face, jaws, and TMJs after surgery, while seven (31.8%) reported less pain (Question 24). This is consistent with the literature[82], which shows that orthognathic surgery is neutral with respect with TMD, i.e. it is not known to improve nor worsen TMD symptoms. In a 2013 study, Sanders et al[83] demonstrated a link between TMD and OSA, as patients with 2 or more signs of OSA were found to have a 73% greater incidence of TMD than in the control group. Although the physiology underlying this association is not yet clear, it has been hypothesized that OSA patients have high rates of nocturnal bruxism which may lead to TMD symptoms. It is been hypothesized that these patients posture their mandible forward during sleep to maintain airway patency,[84] and that stress secondary to OSA leads to an increase in bruxism and TMD symptoms. However, there is currently no strong evidence that clearly defines the association between OSA and TMD.

Question 25 addressed facial numbness as a result of the surgery. Only three patients (13.6%) reported significant persistent numbness in their face at the time of survey completion. This is consistent with previous research that reports that significant long-standing numbness occurs in as low as 3% of orthognathic cases.[36]

One participant who was very disappointed with the results of her surgery cited persistent numbness as a major reason why. She reported that the numbness causes her to be uncomfortable in social situations, especially when eating. She also cited jaw "cracking" and pain while functioning. Due to these factors, she indicated that she would not undergo the procedure again. Despite this, she had overall positive sleep and snoring outcomes.

The data from Questions 26 and 27 indicate that the majority of participants had positive or neutral responses with respect to social confidence and self-consciousness. A single respondent, mentioned above, indicated that she has "much less confidence" in social situations, while nine (40.9%) reported an increase in self-consciousness regarding their facial appearance and smile. Of these nine, only two were dissatisfied with their facial appearance, so it may be that going through MMA treatment has simply made these individuals more aware of their facial appearance. The data from Question 29 show that six respondents spend more time studying their face in the mirror, so it may be that undergoing MMA causes an increase in self-awareness regarding dentofacial appearance. This has been demonstrated in patients seeking conventional orthognathic surgery,[85] but hasn't been observed in OSA undergoing MMA.

The great majority of patients reported either positive or neutral changes with respect to frontal facial and profile appearance, with 20 (91.0%) of respondents reporting improvement or no change in the former and 17 (77.3%) reporting improvement or no change in the latter. The majority of respondents also believed that their friends and family have positive or neutral feelings regarding their facial appearance after surgery. This is consistent with the current body of evidence regarding subjective facial self-

assessment after MMA, which indicates that most patients perceive the facial change that occurs as positive.[53,54,86] The patient mentioned above who cited persistent numbness and jaw pain also reported that her facial appearance became much worse after surgery, and cited negative changes in her nose as her main complaint. She indicated in the survey comments that she is considering plastic surgery to fix it, but is apprehensive about undergoing another surgical procedure after her unpleasant experience with MMA.

The responses from Questions 33 reveal that nine (40.9%) of respondents felt that the surgery made them look more youthful, while two (9.1%) thought it made them appear older. No significant associations with age or sex were noted. It has been documented that MMA has a "reverse face lift" effect, as advancing the facial skeleton improves soft tissue support resulting in a rejuvenation of the face.[87] It may also be possible that these patients are more rested due to improvement of their OSA symptoms. 14 (63.6%) felt the surgery made them more attractive, which is consistent with data from the previous question. With the data from our sample suggesting that the facial changes resulting from the surgery are positive in most patients, and that the patients mostly perceive the changes as making them appear more attractive and youthful, it appears that MMA surgery may have an additional benefit of improving facial aesthetics in addition to treating the OSA symptoms.

Several statistically significant associations between sex and variables that relate to facial aesthetics were noted. Females felt significantly more attractive than did males after the surgery ($p=0.043$), and females preferred their profiles more ($p=.049$). As mentioned above, the current literature that examines esthetics in MMA patients have had relatively few females in their samples, so finding associations between sex and MMA

variable outcomes has been difficult.[51,54,55,86] The respondents to the current survey were 50% male (n=11) and 50% female (n=11), which is a more evenly distributed demographic than is presented in the current literature. However, due to the small population size in our study (n=22), it is difficult to make confident associations between sex and the outcome variables examined. Future studies should focus on larger sample sizes with a more even gender distribution.

While it has been reported that the facial changes following MMA for the treatment of OSA are perceived as positive by the patients despite sometimes extreme jaw protrusion,[54] societal bias often causes us to perceive mandibular protrusion as masculine, while the typical feminine profile has more convexity and slight mandibular retrognathia. Question 35 was derived from the Derriford Appearance Scale,[70] and was included to determine if the facial changes following MMA are perceived by patients as masculine or feminine. Most respondents reported a neutral response to the question, indicating they observed no difference with respect to masculinity/femininity (n=15, 68.2%). Interestingly, the one respondent who felt more feminine after the surgery was female, and the four who felt more masculine were male. This is interpreted as a positive finding, as while the majority of patients perceived no change with respect to masculinity/femininity, those that did perceived the changes as being appropriate for their respective genders. This is a novel topic in orthognathic surgery, and further studies may be warranted to assess the effect that MMA has on perceived masculinity/femininity of the face, both subjectively and objectively.

The patients who had orthodontic treatment as part of their treatment plan (n=17, 77.3%) were significantly more likely to report higher satisfaction with esthetic and

social outcomes as a result of their treatment, in comparison to those who did not receive orthodontic treatment (n=5, 22.7%). The reasons for not having orthodontics are variable, from high cost to social stigma. It appears as though orthodontic treatment has a positive effect on the self-image in the patients in our sample. It has been demonstrated that in general, patients who undergo orthodontics in conjunction with conventional orthognathic surgery are satisfied with treatment[71,88,89]. It may reasonable to recommend orthodontic therapy for all eligible patients considering MMA surgery to improve the subjective aesthetic outcome, as well as the overall perceived success of the treatment. Patients with skeletal discrepancies in addition to OSA would benefit from orthodontics to decompensate the dentition to allow for maximum surgical movements. A mandibular retrognathic patient with a skeletal Class II malocclusion would benefit from upper incisor proclination, as well as lower incisor uprighting to create the space needed to sufficiently advance the mandible to correct the underlying skeletal discrepency. This is less of a concern in patients with Class I skeletal patterns, where it may be desirable to maintain the patient's original maxillomandibular relationship.

The final series of questions were meant to assess the patients' quality of life overall, as well as to ascertain their overall satisfaction with the surgery. The data from Question 36 indicate that 19 (86.4%) of respondents have a better quality of life now than they did before surgery, and one respondent reported no change. No patients reported a worse quality of life compared to the time before surgery. This is consistent with studies by Lye et al[50] and Goodday[51] which suggest an improved quality of life in OSA patients who undergo MMA. Although the patients were not asked directly about QoL in those studies, the authors from their data infer it.

Quality of life improvements have been reported with a number of other interventions for OSA, including CPAP,[90] UPPP,[91] and oral appliances.[92] It was not possible to compare the results of these studies (or others) to ours for several reasons. First, the measures to assess quality of life in these various studies are not the same ones used to construct the questionnaire used in this study, so comparisons between them would not be valid. Second, the questionnaire used in this study is specifically tailored towards MMA patients, so a large number of questions regarding the experience of surgical treatment would not apply to other treatment modalities. In particular, the questions regarding facial aesthetics used in this study would not be applicable to the other treatments as they do not have a large effect on facial aesthetics. To make valid comparisons between QoL outcomes for different treatment modalities would require the use of a questionnaire that is broad enough to be applicable to all potential treatments for OSA.

Eighteen (81.8%) of respondents felt like the surgery was worthwhile, while none indicated that they did not. This is similar to the findings of Goodday[51] which found that 89% of patients in their sample were satisfied overall with their treatment. Sixteen (72.7%) respondents claimed that they would go through the procedure again if they had to, while two (9.1%) said that they would not. Of the two that said they wouldn't, one cited poor facial appearance and invasiveness of the procedures as her primary reasons, while the other cited persistent jaw numbness and discomfort while eating. The same two respondents reported that they would not recommend the procedure to family and friends who may benefit from it, citing similar reasons, while the majority (n=17, 77.3%) indicated that they would recommend the procedure to others.

The study of MMA outcomes in OSA patients is a relatively novel area of research, and there is a need for more study in this area. Studies with larger sample sizes that potentially draw from multiple centers would be useful in producing more confident conclusions, as well as potentially uncovering more associations between the question outcomes and patient variables like sex and age. Although the questionnaire introduced here could be used in further studies, it is a cross-sectional survey in the sense that the participants were asked to compare their experiences now with their experiences before surgery. Ideally, such a questionnaire would be distributed in a prospective manner before and after MMA surgery so that the change can be analyzed. The questions in the survey were worded so that the respondents were asked to compare how they feel currently with a prior state of health, i.e. before surgery. These types of questions are called "transition" questions, and are a common format in many health-related quality of life measures like the OQLQ[93], however they do pose some difficulties when they are used. For example, it may be difficult for patients to recall their previous state of health accurately if significant time has passed since the intervention, and how the patients currently feel introduces bias in the responses. If patients are currently feeling well, they are likely to report that they have improved, and if they are feeling ill or poor, they tend to report that they have worsened[94]. Future versions of the questionnaire used in this study should be able to be applied before and after the intervention so that the two time points can be compared to each other.

Conclusions

This study had the aim of assessing subjective patient outcomes related to general quality of life, snoring, daytime sleepiness and functional sleep outcomes, functional surgical outcomes, and facial aesthetics in a group of patients who underwent MMA surgery for the treatment of OSA. A patient outcomes questionnaire was developed to meet this objective. The following conclusions were derived:

1. MMA surgery for the treatment of OSA appears to have an overall positive effect on patient quality of life.
2. MMA surgery appears to lead to subjective improvement of various sleep outcomes including snoring, daytime sleepiness, and functional outcomes of sleep. Most patients were able to discontinue CPAP after MMA surgery.
3. The subjective facial outcomes of MMA surgery appear to be overwhelmingly neutral or positive, with patients feeling overall more youthful and attractive after surgery. Females felt significantly more positive about their post-surgery facial appearance than males.
4. Orthodontic treatment in conjunction with MMA appears to have a positive effect on subjective post-treatment facial outcomes.
5. The experience of orthognathic surgery appears to be well tolerated in these patients. Most would go through it again if they had to, and would recommend it to others suffering from OSA.

Suggestions for Future Research

1. The methodology in this study may be repeated in the future with a larger sample size to increase study power and decrease risk of type II error. More participants would reduce false negative findings and potentially uncover more associations between patient variables (age, sex, AHI success, orthodontic treatment) and outcome variables. Using data from multiple centres may be considered.

2. Future version of the questionnaire may be modified so that they can be administered before and after treatment. This would eliminate the use of transition questions, which may be unreliable in determining a past state of being.

3. Studies examining the perception of facial changes following MMA for the treatment of OSA, including the perceived changes (if any) in the masculinity/femininity of the changes.

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Appendix I

LAWSON FINAL APPROVAL NOTICE

LAWSON APPROVAL NUMBER: R-15-286

PROJECT TITLE: Quality of life after maxillomandibular advancement surgery for the treatment of obstructive sleep apnea.

PRINCIPAL INVESTIGATOR: Dr. Ali Tassi

LAWSON APPROVAL DATE: September 28, 2015

Health Sciences REB#: 106869

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 Approval Officer, Lawson Health Research Institute, 750 Baseline Road, East, Suite 300.

cc: Administration

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

Review Type: Delegated
HSREB File Number: 106869
Study Title: Quality of Life After Maxillomandibular Advancement Surgery for the Treatment of Obstructive Sleep Apnea
Sponsor:

HSREB Initial Approval Date: September 10, 2015
HSREB Expiry Date: September 10, 2016

Documents Approved and/or Received for Information:

Document Name	Comments	Version Date
Instruments	Study Questionnaire	2015/08/10
Letter of Information & Consent		2015/09/08
Recruitment Items	Phone Script	2015/09/08
Recruitment Items	Email Invitation Script	2015/09/08
Recruitment Items	Email Invitation Script - 1st Reminder	2015/09/08
Recruitment Items	Email Invitation Script - 2nd Reminder	2015/09/08
Recruitment Items	Email Invitation Script - Final Reminder	2015/09/08
Western University Protocol		2015/09/08

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.

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.

Appendix II

Quality of Life After Maxillomandibular Advancement Surgery for the Treatment of Obstructive Sleep Apnea

Letter of Information/Consent

Principle Investigator

Dr. Ali Tassi Assistant Professor, Division of Graduate Orthodontics Schulich School of Medicine and Dentistry The University of Western Ontario University Hospital – Department of Dentistry

Co-Investigators

Dr. Michael Shimizu Assistant Professor, Division of Oral and Maxillofacial Surgery Schulich School of Medicine and Dentistry The University of Western Ontario University Hospital – Department of Dentistry

Dr. Andrew Emanuele Orthodontic Resident, Division of Graduate Orthodontics Schulich School of Medicine and Dentistry University of Western Ontario

Introduction

You are being invited to participate in a research study directed by Dr. Michael Shimizu and Dr. Ali Tassi along with their resident Dr. Andrew Emanuele, to evaluate outcomes related to sleep and overall quality of life for patients who have undergone maxillomandibular advancement surgery for treatment of obstructive sleep apnea syndrome (OSAS). As you have undergone this treatment with Dr. Michael Shimizu for treatment of sleep apnea, you qualify to participate in this study, if you wish. We have provided this consent form for you to read carefully, and will answer any questions you may have regarding the information it contains.

Purpose of Study

The purpose of the study is to assess patient outcomes with respect to sleep, aesthetics, and quality of life after maxillomandibular advancement (MMA) surgery for the treatment of obstructive sleep apnea. This information may help clinicians in their case selection when considering MMA treatment. Dr. Andrew Emanuele, a resident in the Graduate Orthodontics Program at the University of Western Ontario, will administer the study. The study will consist of a questionnaire to be filled out online.

Procedures

The patients who will be invited to complete the survey are patients of Dr. Michael Shimizu (UWO) who have undergone maxillomandibular advancement surgery for treatment of obstructive sleep apnea. Participation in the study is completely voluntary, and participants are able to withdraw their participation at any time. This letter of information and consent describes the study so you can make an informed decision on participating. Please take the time to make a decision and if necessary, discuss this proposal with your family and friends as you feel inclined. Please feel free to ask questions if anything is unclear or if there are phrases or words you do not understand. You have been asked to participate because you have undergone maxillomandibular advancement jaw surgery for treatment of obstructive sleep apnea. If you agree to participate, you will be asked to click on a link to fill out a questionnaire online. We will address any questions you may have as needed.

Number of Participants

There are 60 potential patients who may participate in this study.

Participant Inclusion and Exclusion Criteria

Participants will be included if they have undergone maxillomandibular advancement for treatment of obstructive sleep apnea by Dr. Michael Shimizu, an oral and maxillofacial surgeon on faculty at Western University's Schulich School of Medicine and Dentistry. Participants who are unable to give informed consent will be excluded.

Description of the Research

As a participant in the study, you will be asked to fill out an online questionnaire. This will take approximately 10-15 minutes and will consist of questions related to your history of sleep apnea, the jaw advancement surgery you underwent for this problem, as well as your satisfaction with this treatment and its effect on your overall quality of life. Dr. Emanuele will examine and analyze the data collected to draw conclusions regarding patient outcomes following maxillomandibular advancement surgery for the treatment of obstructive sleep apnea. The only information that will be used from your past medical records are the outcomes of your past polysomnographic sleep studies. After completing the survey, no follow up is required with respect to this research project specifically. This research project will not interfere with normal scheduled follow-ups with Dr. Shimizu.

Time Requirements

The completion of the questionnaire should take approximately 10-15 minutes.

Risks

It is possible that unpleasant memories of the period of time surrounding your surgery may be revisited while completing the survey online.

Benefits

Participants in the study will be given an opportunity to express their opinions and concerns pertaining to the results of their maxillomandibular advancement surgery for treatment of obstructive sleep apnea.

Right to Refuse

Your participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or you may withdraw from the study at any time with no effect on the results of your treatment. You do not waive any of your legal rights by signing the consent form.

Compensation for Participation

There is no compensation for the study.

Use of Data

Data collected via the questionnaire will be secured via encrypted, and password protected software and hard drives, and locked in appropriate University servers and storage facilities.

New Findings

If, during the course of this study, new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the investigator.

Confidentiality

Your privacy will be respected. If the results of this study are published, your name will not be used and no information that discloses your identity will be collected or released.

To monitor the conduct of research, the research team, authorized study personnel, Western University Health Science Research Ethics Board and the Lawson Health Research Institute may require access to your study-related records. Additionally, representatives of the Research Ethics Board may follow up with you directly for the same purpose.

All participants will be given a study number. Only that number will be used on any study analysis related documents.

By signing the consent form you allow Dr. Emanuele to review the questionnaire you will fill in.

Contacts

If you have any questions during the study, or wish to withdraw from the study at any time, you may contact Dr. Michael Shimizu, Dr. Ali Tassi at or Dr. Andrew Emanuele. If you have any questions or concerns about your rights as a research participant or the conduct of this study you may contact Dr. David Hill, Scientific director, Lawson Health Research.

Consent

I have read and understand the consent form for this study. I have been given sufficient time to consider the above information and to seek advice if so desired. I have had the opportunity to ask questions which have been answered to my satisfaction. I am voluntarily agreeing to participate in this study. I will print a copy of this consent form for my own information, if I wish.

By signing below, I am agreeing to participate in this survey.

Signature: _____

Date: _____

Appendix III

Jaw Surgery for Obstructive Sleep Apnea Outcomes Questionnaire

Please read each question carefully and checkmark what you feel is the most correct answer:

Q1 In general, would you say your health is:

- ❍ Excellent
- ❍ Very Good
- ❍ Good
- ❍ Fair
- ❍ Poor
- ❍ I don't know

Q2 Compared to the time before your jaw surgery, how would you rate your health in general now?

- ❍ Much better than before
- ❍ Somewhat better than before
- ❍ About the same
- ❍ Somewhat worse than before
- ❍ Much worse than before
- ❍ I don't know

Q3 Have you been diagnosed with any new medical conditions since having jaw surgery? If yes, what condition(s) have you been diagnosed with?

- ❍ Yes _____
- ❍ No

Q4 Since having orthognathic surgery, do you feel like your sleep apnea has gotten better or worse?

- ❍ Much better
- ❍ A little better
- ❍ No change
- ❍ A little worse
- ❍ Much worse
- ❍ I don't know

Q5 On average, how often are you still using a CPAP machine at night?

- ❍ Every night or almost every night
- ❍ 3-4 times a week
- ❍ 1-2 times a week
- ❍ 1-2 times a month
- ❍ Never or nearly never

Q6 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 have not 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 = no chance of dozing

1 = slight chance of dozing

2 = moderate chance of dozing

3 = high chance of dozing

	0	1	2	3
Sitting and reading	❍	❍	❍	❍
Watching TV	❍	❍	❍	❍
Sitting inactive in a public place (e.g. a theatre or 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 traffic	❍	❍	❍	❍

Q7 What is your current weight (in pounds)?

Q8 What is your height (in feet/inches)?

Q9 According to what others have told you, do you currently snore?

- ❍ Yes, nearly every night
- ❍ Yes, 3-4 nights a week
- ❍ Yes, 1-2 nights a week
- ❍ Yes, 1-2 nights a month
- ❍ Never or nearly never
- ❍ I don't know

Q10 If you still snore, how loud have others said your snoring is?

- ❍ Slightly louder than breathing
- ❍ As loud as talking
- ❍ Louder than talking
- ❍ Very loud - can be heard in adjacent rooms
- ❍ I do not snore
- ❍ I don't know

Q11 How often, if ever, has anyone noticed that you quit breathing during your sleep?

- ❍ Never or nearly never
- ❍ 1-2 times a month
- ❍ 1-2 times a week
- ❍ 3-4 times a week
- ❍ Nearly every night
- ❍ I don't know

Q12 Since having your surgery, do you snore more, or less than before?

- ❍ Much more
- ❍ A little more
- ❍ About the same
- ❍ A little less
- ❍ Much less
- ❍ I don't know

Q13 How loud is your snoring now, compared to before surgery?

- ❍ Much louder
- ❍ A little louder
- ❍ About the same
- ❍ A little quieter
- ❍ Much quieter
- ❍ I don't know

Q14 Since having your surgery, does your snoring bother other people more, or less?

- ❍ Much more
- ❍ A little more
- ❍ About the same
- ❍ A little less
- ❍ Much less
- ❍ I don't know

Q15 Compared to the time before your surgery, do you feel more, or less refreshed after your sleep (i.e. when you wake up in the morning)?

- ❍ Much more refreshed
- ❍ A little more refreshed
- ❍ About the same
- ❍ A little less refreshed
- ❍ Much less refreshed
- ❍ I don't know

Q16 Compared to the time before your surgery, do you feel more, or less tired or sleepy during the daytime?

- ❍ Much more tired
- ❍ A little more tired
- ❍ About the same
- ❍ A little less tired
- ❍ Much less tired
- ❍ I don't know

Q17 In comparison to before surgery, has the quality of your sleep become better or worse?

- ❍ Much better quality
- ❍ A little better quality
- ❍ About the same
- ❍ A little worse quality
- ❍ Much worse quality
- ❍ I don't know

Q18 Since having surgery, have you had more, or less difficulty socializing with your family and friends because you become sleepy or tired?

- ❍ Much more difficulty
- ❍ A little more difficulty
- ❍ No difference
- ❍ A little less difficulty
- ❍ Much less difficulty
- ❍ I don't know

Q19 Since having your surgery, do you have more, or less difficulty concentrating or remembering things because you are sleepy or tired?

- ❍ Much more difficulty
- ❍ A little more difficulty
- ❍ No difference
- ❍ A little less difficulty
- ❍ Much less difficulty
- ❍ I don't know

Q20 Compared to the time before your surgery, do you have more, or less difficulty doing housework, exercising, or other forms of physical activity because you are sleepy or tired?

- ❍ Much more difficulty
- ❍ A little more difficulty
- ❍ No difference
- ❍ A little less difficulty
- ❍ Much less difficulty
- ❍ I don't know

Q21 Compared to the time before your surgery, do you have more, or less difficulty watching television, or sitting through a movie or lecture because you are sleepy or tired?

- ❍ Much more difficulty
- ❍ A little more difficulty
- ❍ No difference
- ❍ A little less difficulty
- ❍ Much less difficulty
- ❍ I don't know

Q22 Since having surgery, has your mood been more, or less affected because you are sleepy or tired?

- ❍ Much more affected
- ❍ A little more affected
- ❍ No change
- ❍ A little less affected
- ❍ Much less affected
- ❍ I don't know

Q23 Since having surgery, do you have more, or fewer problems with biting or chewing?

- ❍ Much more problems
- ❍ Slightly more problems
- ❍ No difference
- ❍ Slightly fewer problems
- ❍ Much fewer problems
- ❍ I don't know

Q24 Compared to the time before your surgery, do you experience more, or less pain in your face, jaws, or jaw joints?

- ❍ Much more pain
- ❍ A little more pain
- ❍ No difference
- ❍ A little less pain
- ❍ Much less pain
- ❍ I don't know

Q25 Compared to the time immediately after surgery, to what extent has your facial numbness improved?

- ❍ Completely improved and back to normal
- ❍ Improved a lot, almost back to normal
- ❍ Improved a little, still some numbness
- ❍ Barely improved at all, still very numb
- ❍ No improvement, numbness is the same as the time immediately after surgery
- ❍ I don't know

Q26 Since having your surgery, do you have more, or less confidence when you are out socially?

- ❍ Much more confidence
- ❍ A little more confidence
- ❍ No difference
- ❍ A little less confidence
- ❍ Much less confidence
- ❍ I don't know

Q27 Since having your surgery, are you more, or less self-conscious about your facial appearance?

- ❍ Much more self-conscious
- ❍ A little more self-conscious
- ❍ No difference
- ❍ A little less self-conscious
- ❍ Much less self-conscious
- ❍ I don't know

Q28 Since having your surgery, are you more, or less self-conscious about the appearance of your teeth and smile?

- ❍ Much more self-conscious
- ❍ A little more self-conscious
- ❍ No difference
- ❍ A little less self-conscious
- ❍ Much less self-conscious
- ❍ I don't know

Q29 Since having jaw surgery, do you spend more, or less time studying your face in the mirror?

- ❍ Much more time
- ❍ A little more time
- ❍ No difference
- ❍ A little less time
- ❍ Much less time
- ❍ I don't know

Q30 Since having surgery, how do you like the appearance of you face from the front?

- ❍ Much more than before
- ❍ A little more than before
- ❍ About the same
- ❍ A little less than before
- ❍ Much less than before
- ❍ I don't know

Q31 Since having surgery, how do you like the appearance of your face from the side (profile)?

- ❍ Much more than before
- ❍ A little more than before
- ❍ About the same
- ❍ A little less than before
- ❍ Much less than before
- ❍ I don't know

Q32 Do you feel that your family and friends like your facial appearance more, or less since having surgery?

- ❍ Much more than before
- ❍ A little more than before
- ❍ About the same
- ❍ A little less than before
- ❍ Much less than before
- ❍ I don't know

Q33 Do you feel like having orthognathic surgery has made you look younger or older?

- ❍ Much older
- ❍ A little older
- ❍ About the same
- ❍ A little younger
- ❍ Much younger
- ❍ I don't know

Q34 Do you feel like having orthognathic surgery has made you more, or less attractive?

- ❍ Much more attractive
- ❍ A little more attractive
- ❍ About the same
- ❍ A little less attractive
- ❍ Much less attractive
- ❍ I don't know

Q35 Do you feel like having orthognathic surgery has made you look more masculine or feminine?

- ❍ Much more masculine
- ❍ A little more masculine
- ❍ No difference
- ❍ A little more feminine
- ❍ Much more feminine
- ❍ I don't know

Q36 Have the results of your operation made your overall quality of life better, or worse?

- ❍ Much better
- ❍ A little better
- ❍ No change
- ❍ A little worse
- ❍ Much worse
- ❍ I don't know

Q37 Overall do you feel like your experience with orthognathic surgery for the treatment of your sleep apnea was worthwhile?

- ❑ Yes
- ❑ No
- ❑ I don't know

If not, why?

Q38 If you had to, would you go through the procedure again?

- ❍ Yes
- ❍ No
- ❍ I don't know

If not, why?

Q39 Would you recommend orthognathic surgery to family and friends who are suffering from sleep apnea?

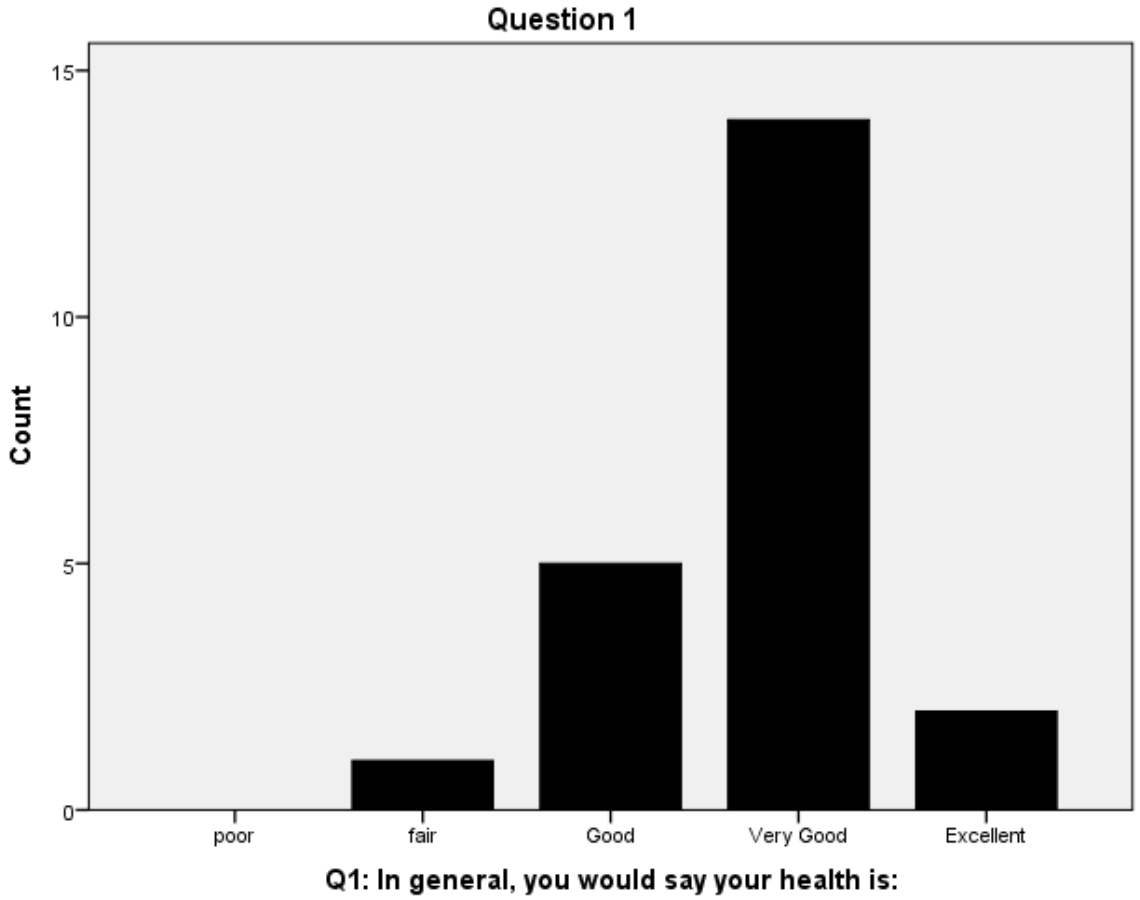
- ❍ Yes
- ❍ No
- ❍ I don't know

If not, why?

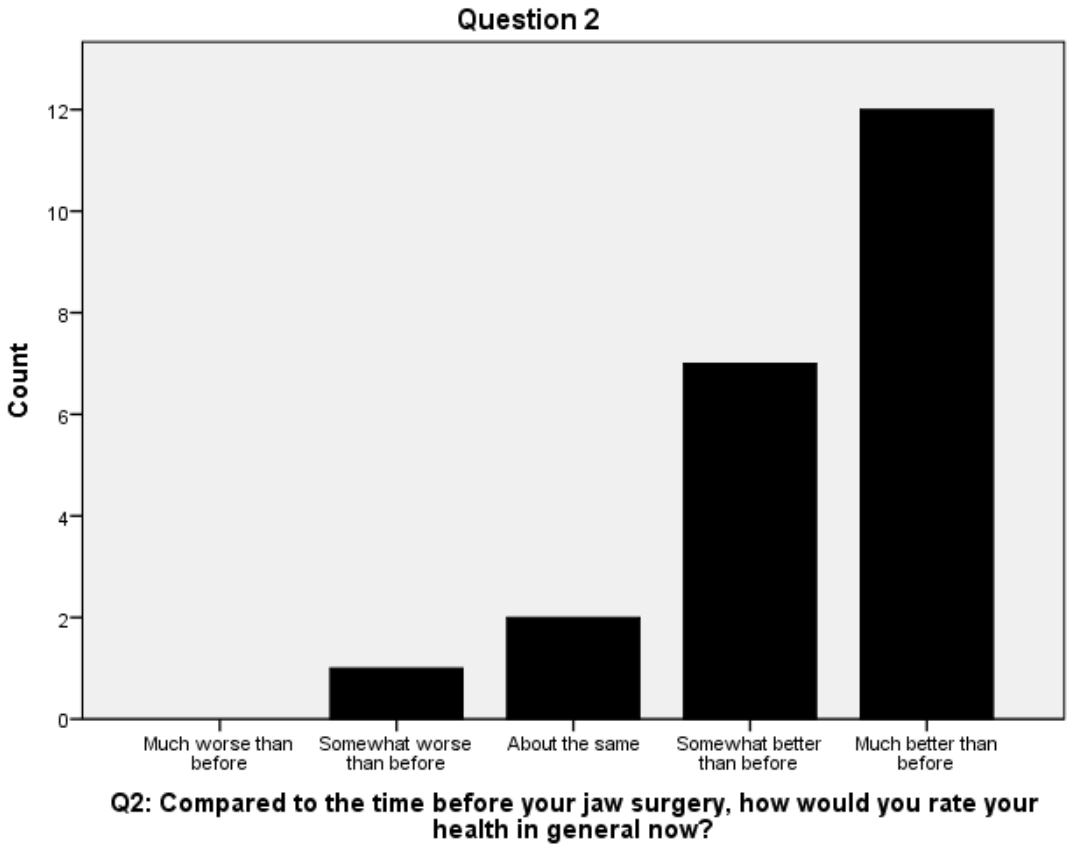
Q40 If you wish, feel free to provide additional feedback about your experiences and outcomes with respect to jaw surgery for the treatment of obstructive sleep apnea.

Appendix IV

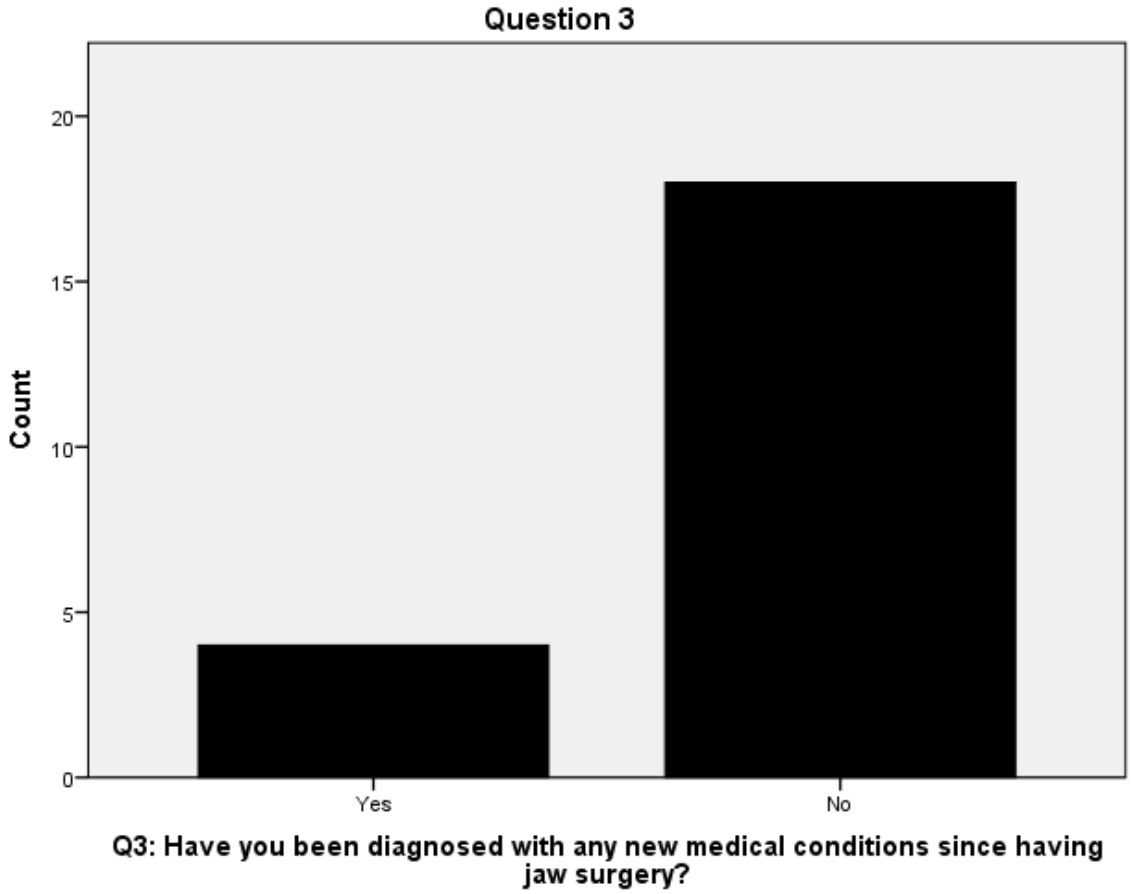
Data from the collected questionnaires, presented according to question number.



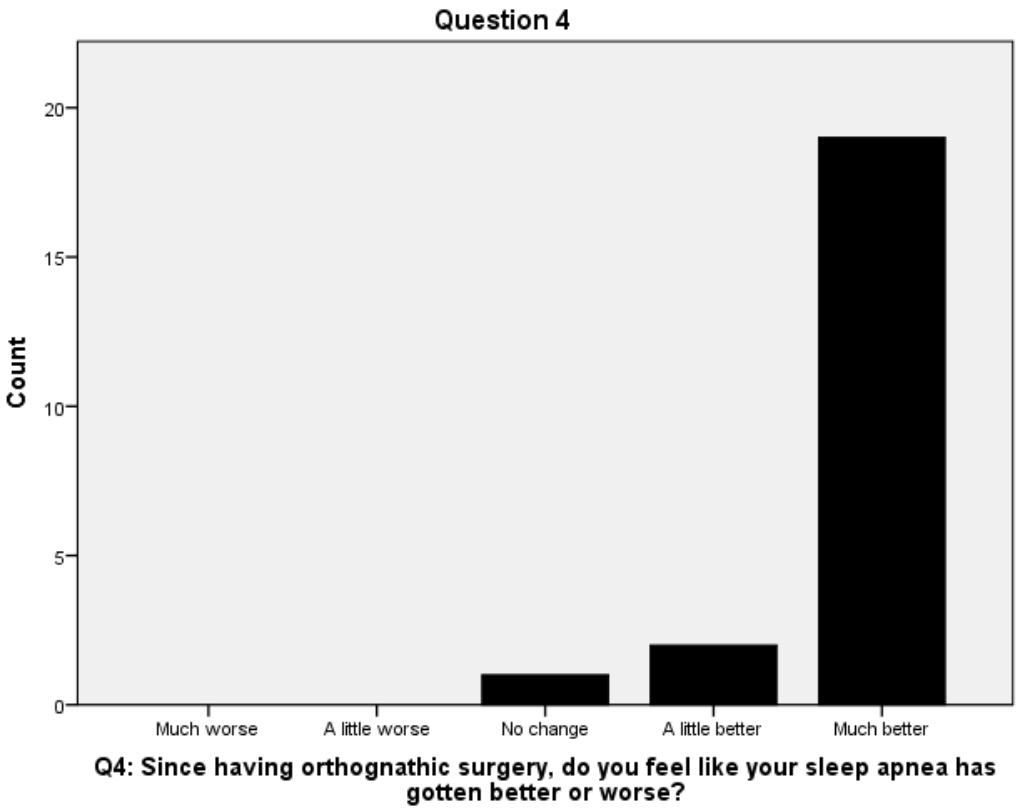
	Frequency	Percent
fair	1	4.5
Good	5	22.7
Very Good	14	63.6
Excellent	2	9.1
Total	22	100.0



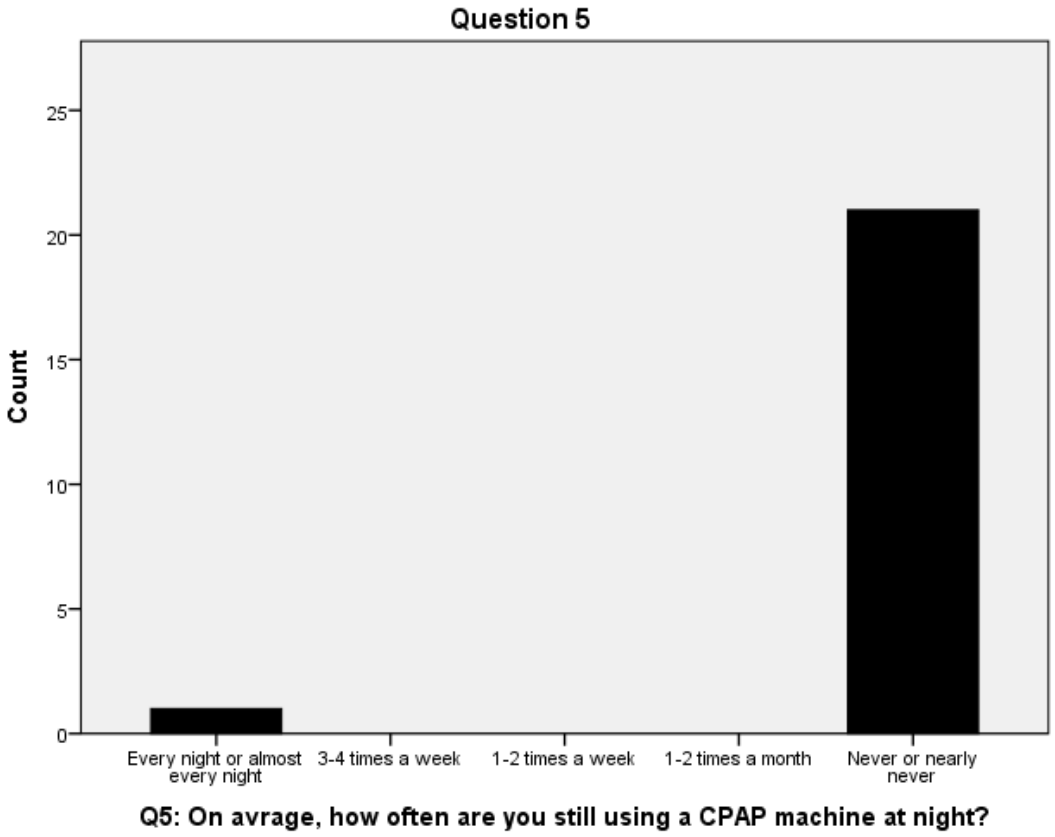
	Frequency	Percent
Somewhat worse than before	1	4.5
About the same	2	9.1
Somewhat better than before	7	31.8
Much better than before	12	54.5
Total	22	100.0



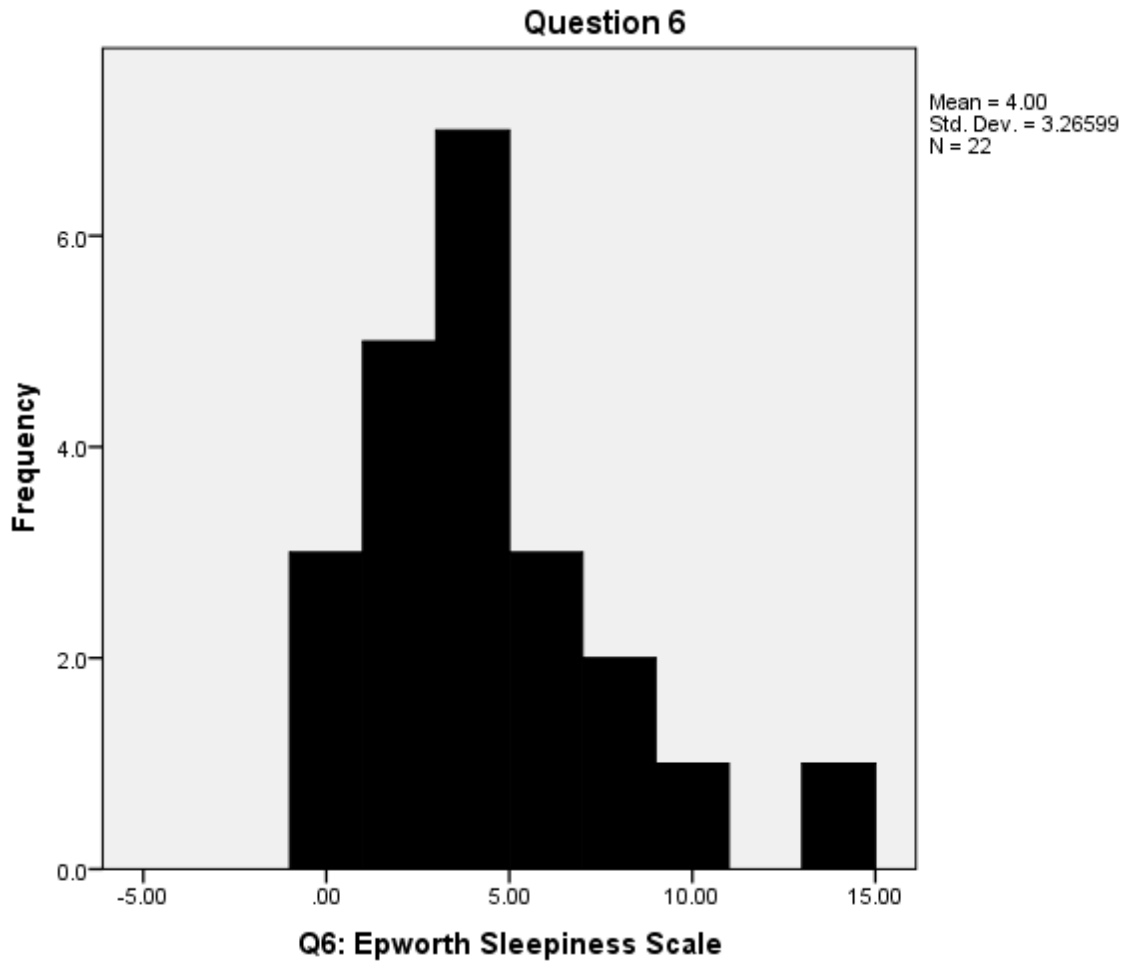
	Frequency	Percent
Yes	4	18.2
No	18	81.8
Total	22	100.0



	Frequency	Percent
No change	1	4.5
A little better	2	9.1
Much better	19	86.4
Total	22	100.0

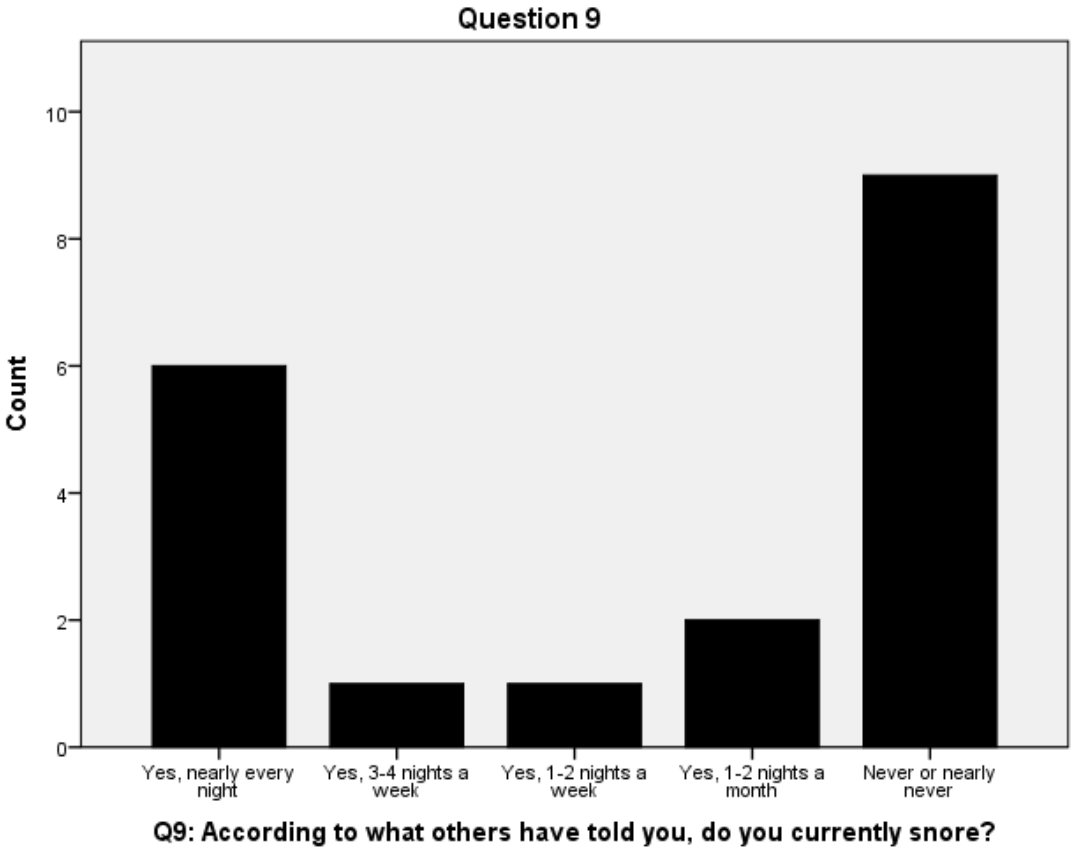


	Frequency	Percent
Every night or almost every night	1	4.5
Never or nearly never	21	95.5
Total	22	100.0

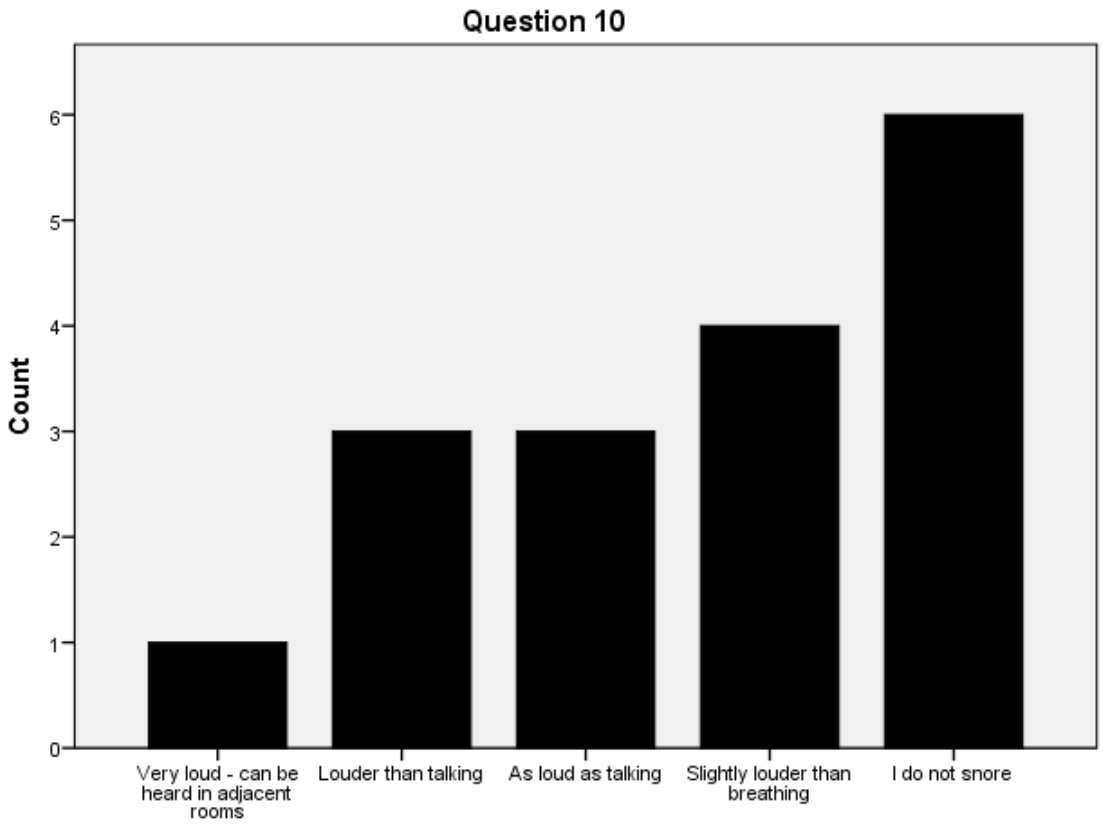


Questions 7 and 8

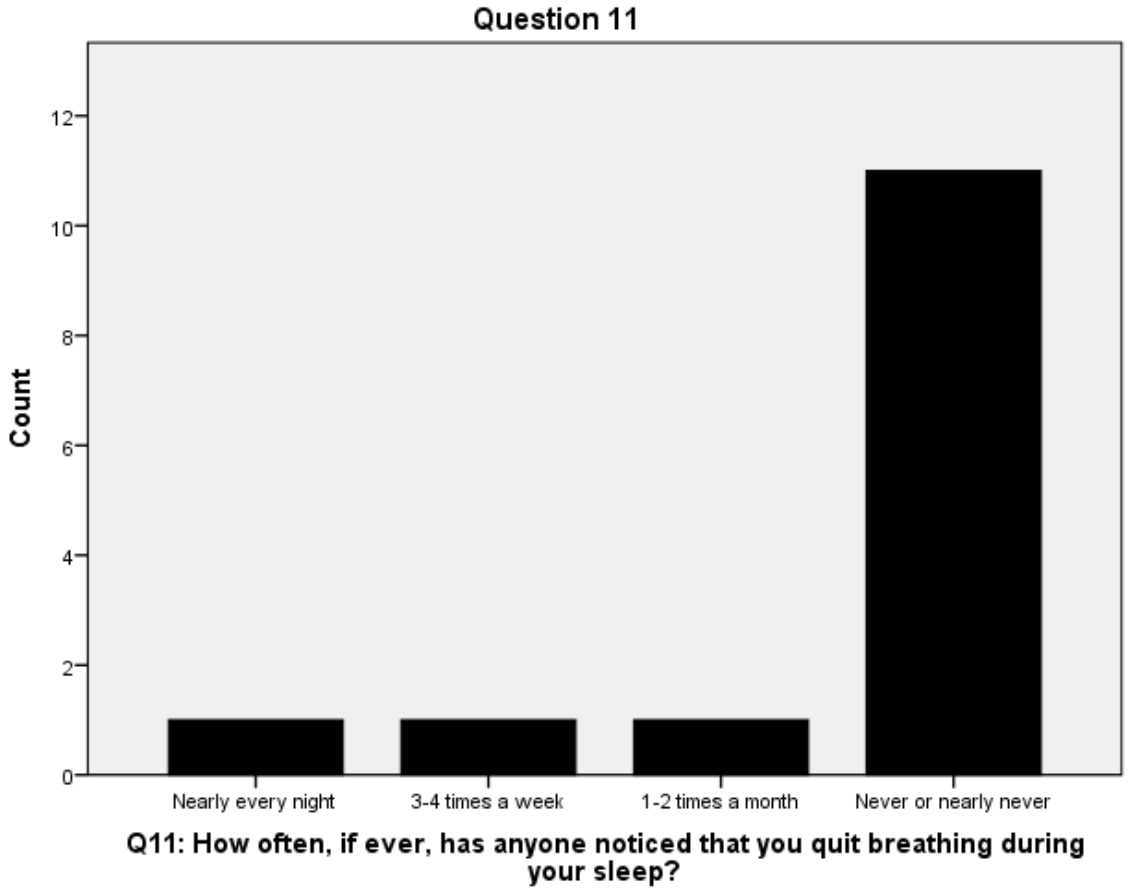
	N	Minimum	Maximum	Mean	Std. Deviation
Q7: What is your current weight (in pounds)?	22	125.00	379.0	195.0	55.9
Q8: What is your height (in cm)?	22	160.00	193.4	174.4	9.3
N	22				



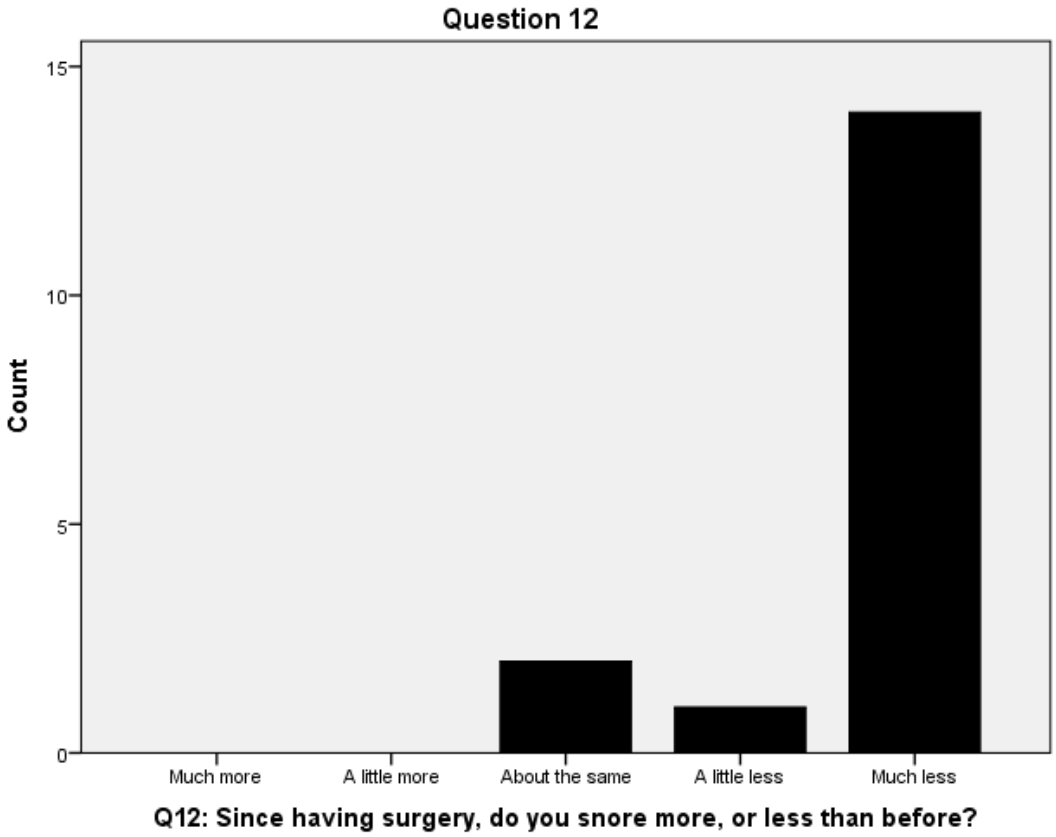
		Frequency	Percent
Valid	Yes, nearly every night	6	27.3
	Yes, 3-4 nights a week	1	4.5
	Yes, 1-2 nights a week	1	4.5
	Yes, 1-2 nights a month	2	9.1
	Never or nearly never	9	40.9
	“I don’t know”	2	9.1
	No response	1	4.5
Total		22	100.0



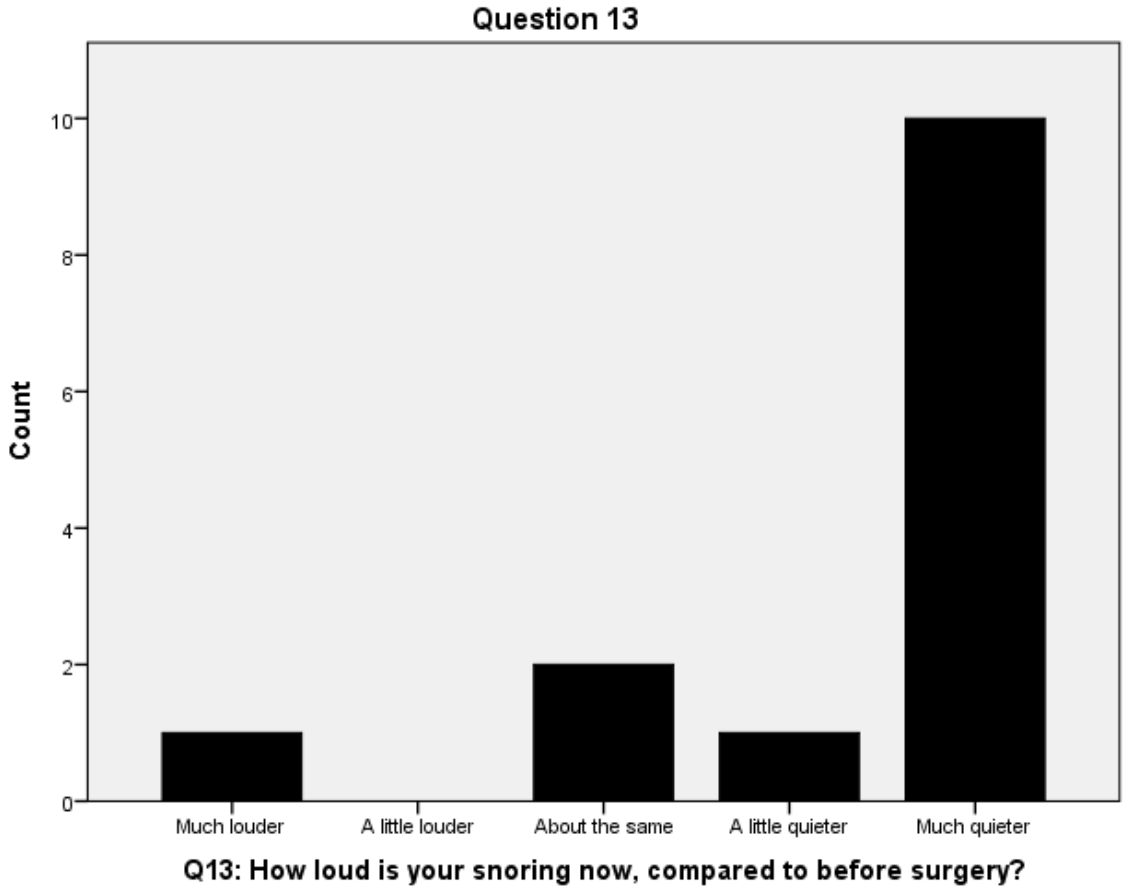
		Frequency	Percent
Valid	Very loud - can be heard in adjacent rooms	1	4.5
	Louder than talking	3	13.6
	As loud as talking	3	13.6
	Slightly louder than breathing	4	18.2
	I do not snore	6	27.3
	“I don’t know”	4	18.2
	No response	1	4.5
Total		22	100.0



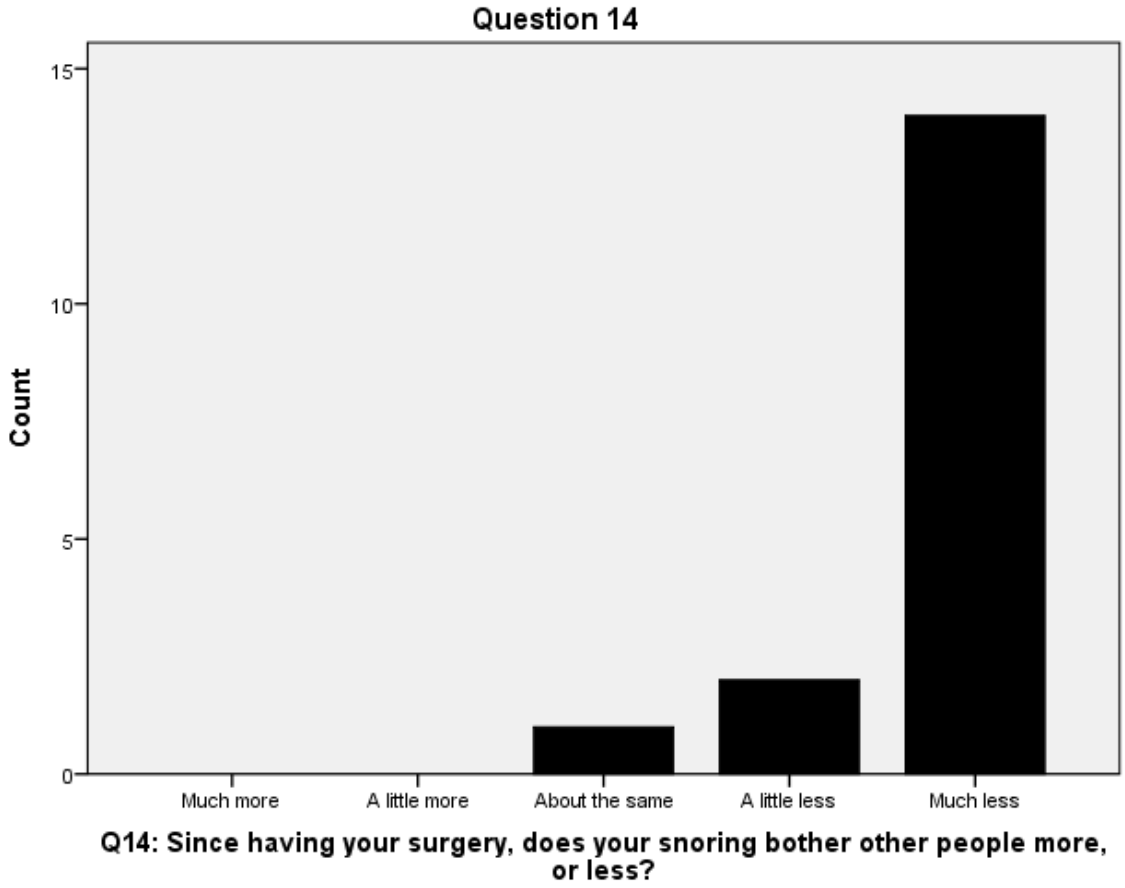
		Frequency	Percent
Valid	Nearly every night	1	4.5
	3-4 times a week	1	4.5
	1-2 times a month	1	4.5
	Never or nearly never	11	50.0
	“I don’t know”	7	31.8
	No response	1	4.5
Total		22	100.0



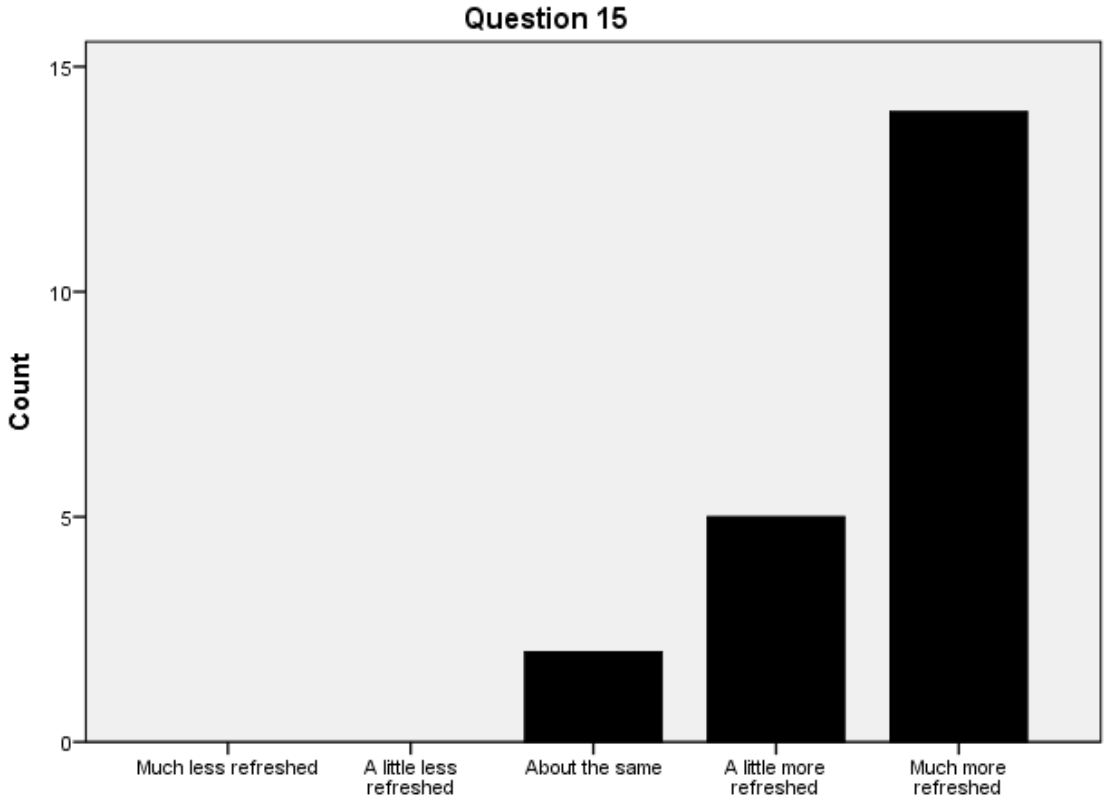
		Frequency	Percent
Valid	About the same	2	9.1
	A little less	1	4.5
	Much less	14	63.6
	“I don’t know”	4	18.2
	No response	1	4.5
Total		22	100.0



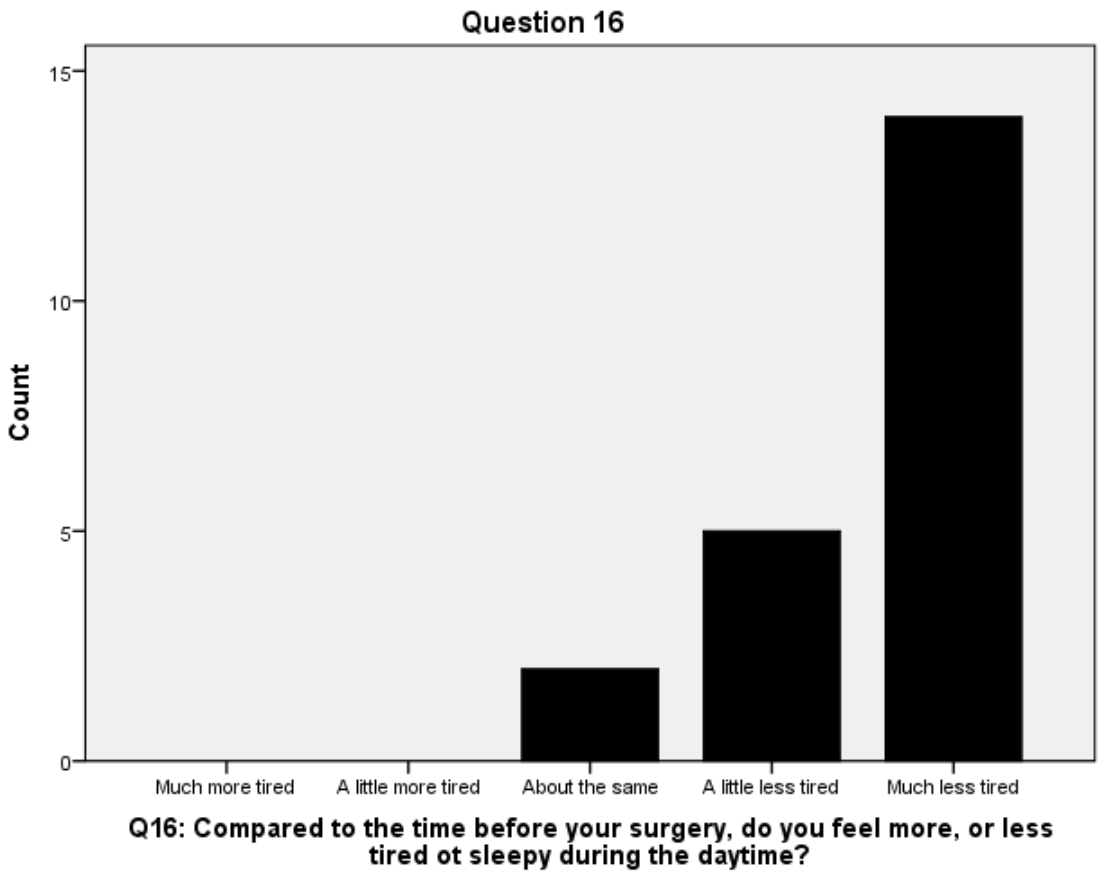
		Frequency	Percent
Valid	Much louder	1	4.5
	About the same	2	9.1
	A little quieter	1	4.5
	Much quieter	10	45.5
	“I don’t know”	7	31.8
	No response	1	4.5
Total		22	100.0



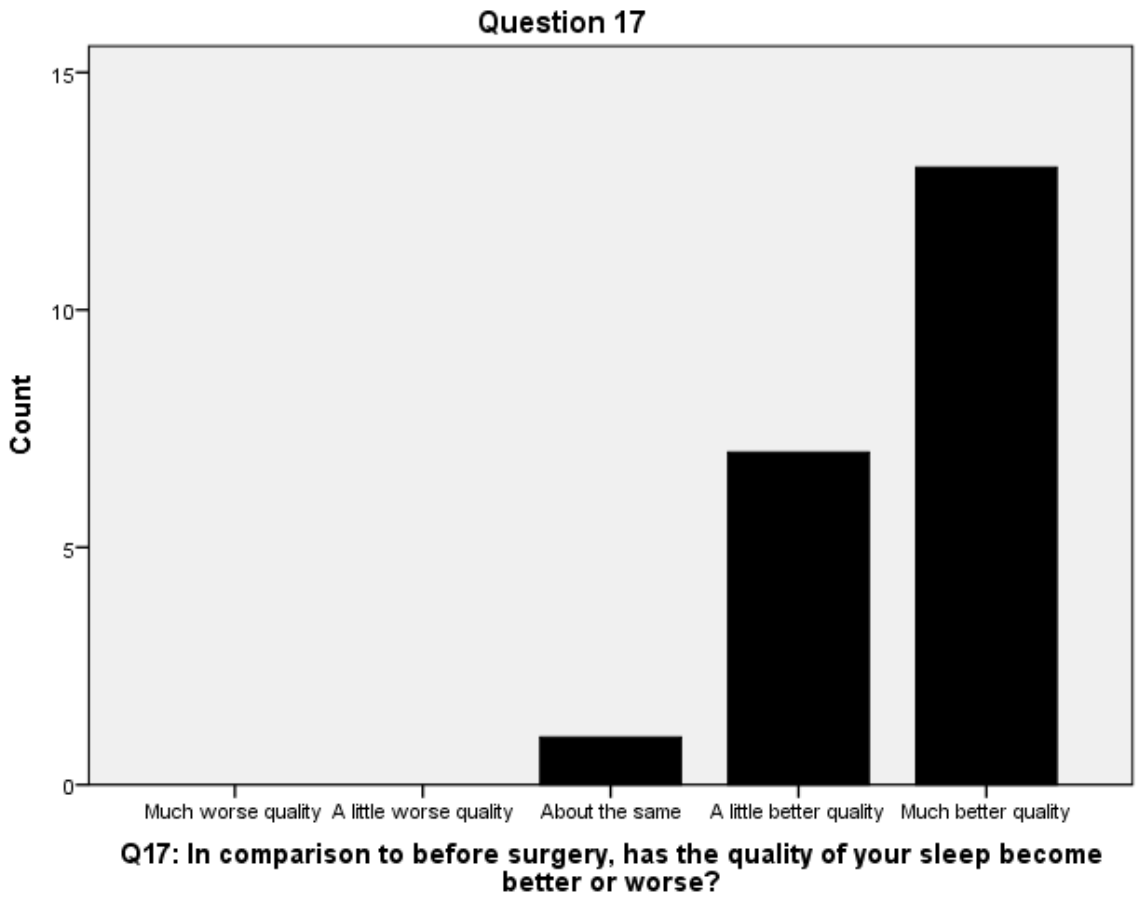
		Frequency	Percent
Valid	About the same	1	4.5
	A little less	2	9.1
	Much less	14	63.6
	“I don’t know”	4	18.2
	No response	1	4.5
Total		22	100.0



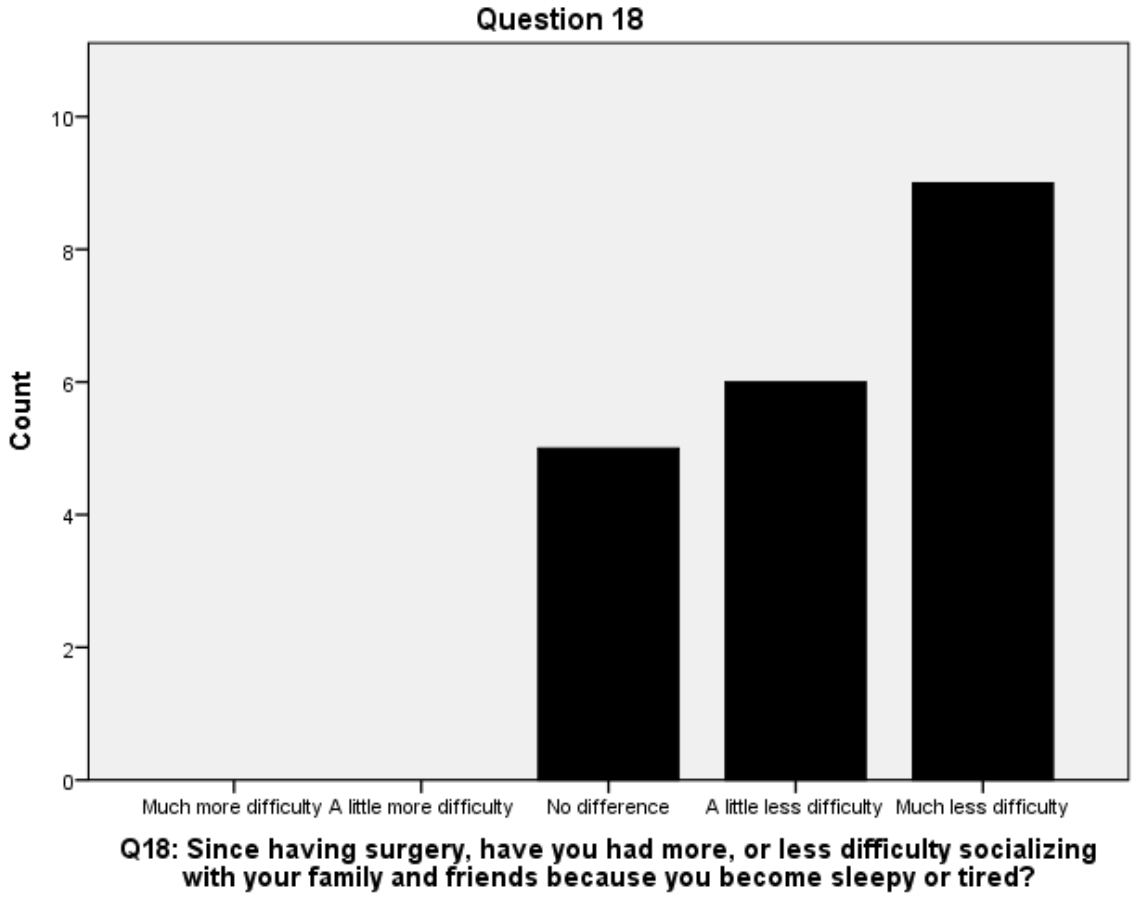
		Frequency	Percent
Valid	About the same	2	9.1
	A little more refreshed	5	22.7
	Much more refreshed	14	63.6
	No response	1	4.5
Total		22	100.0



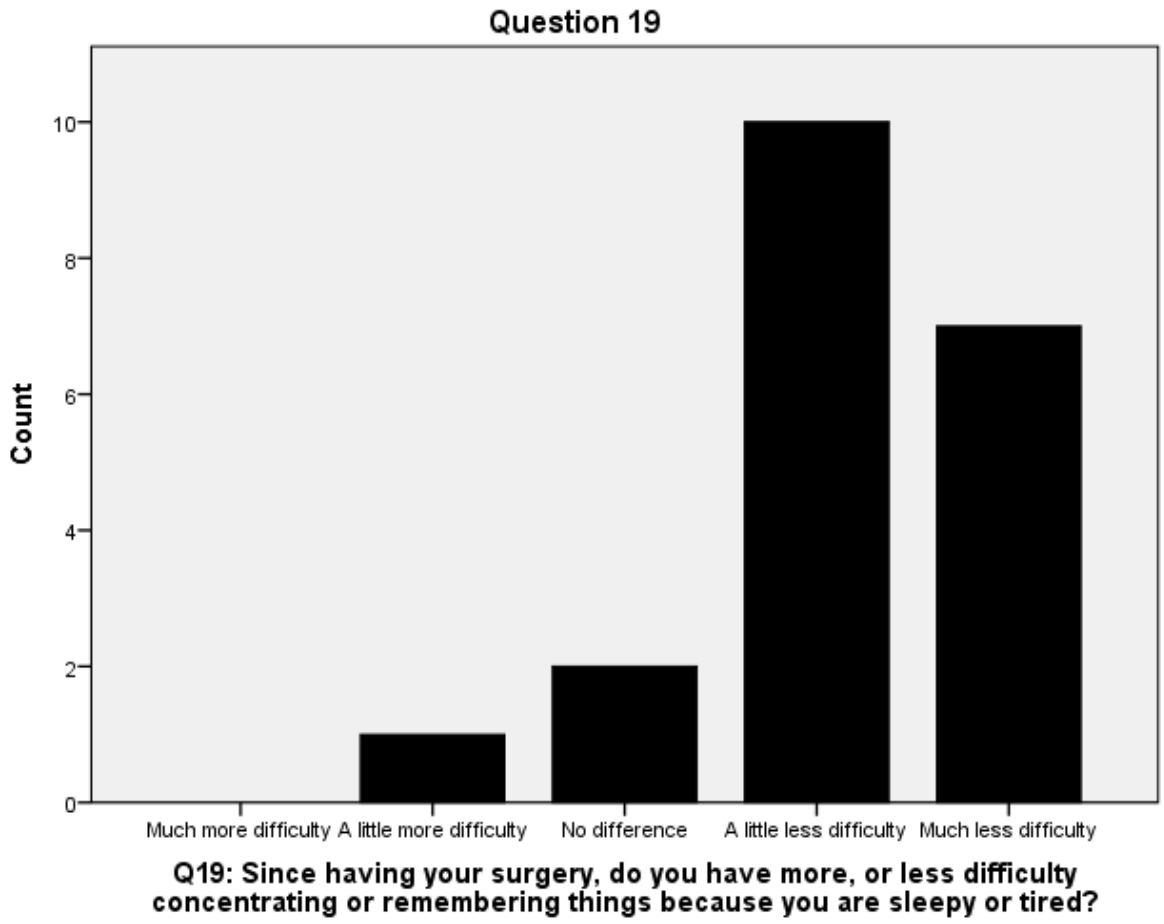
		Frequency	Percent
Valid	About the same	2	9.1
	A little less tired	5	22.7
	Much less tired	14	63.6
	No response	1	4.5
Total		22	100.0



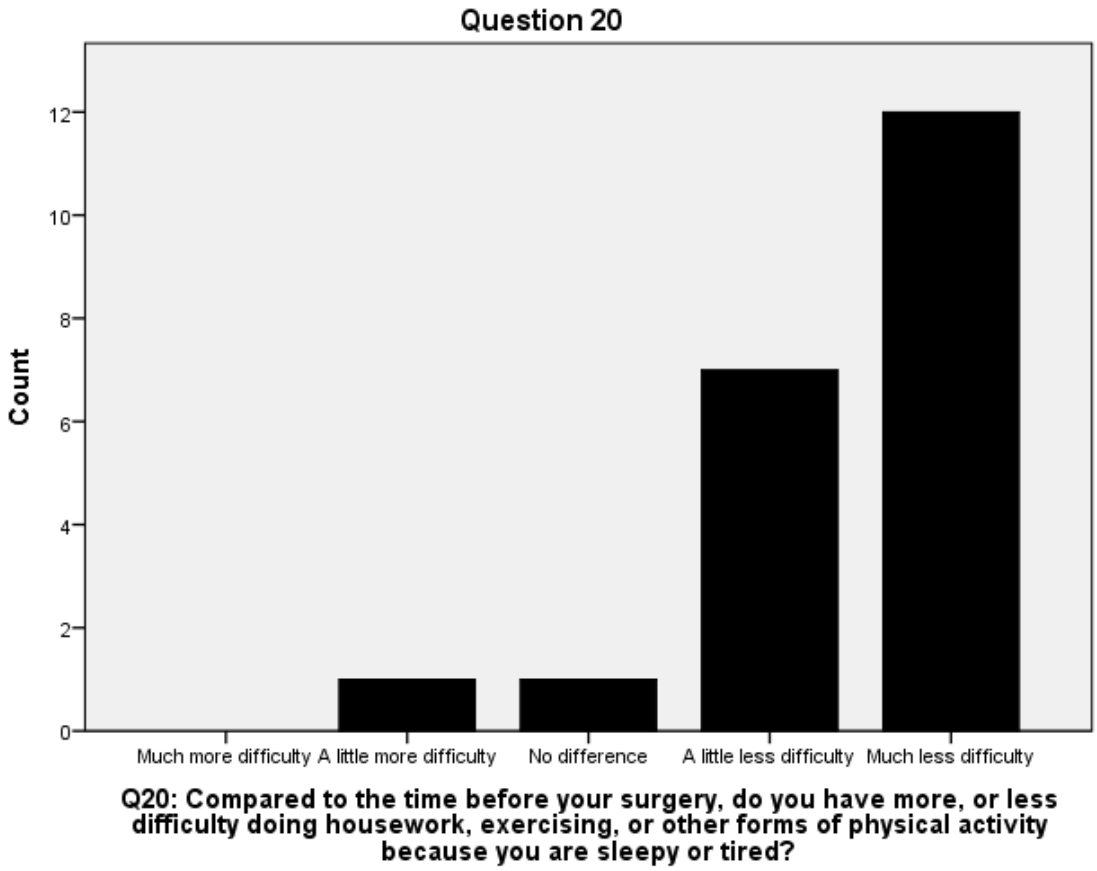
		Frequency	Percent
Valid	About the same	1	4.5
	A little better quality	7	31.8
	Much better quality	13	59.1
	No response	1	4.5
Total		22	100.0



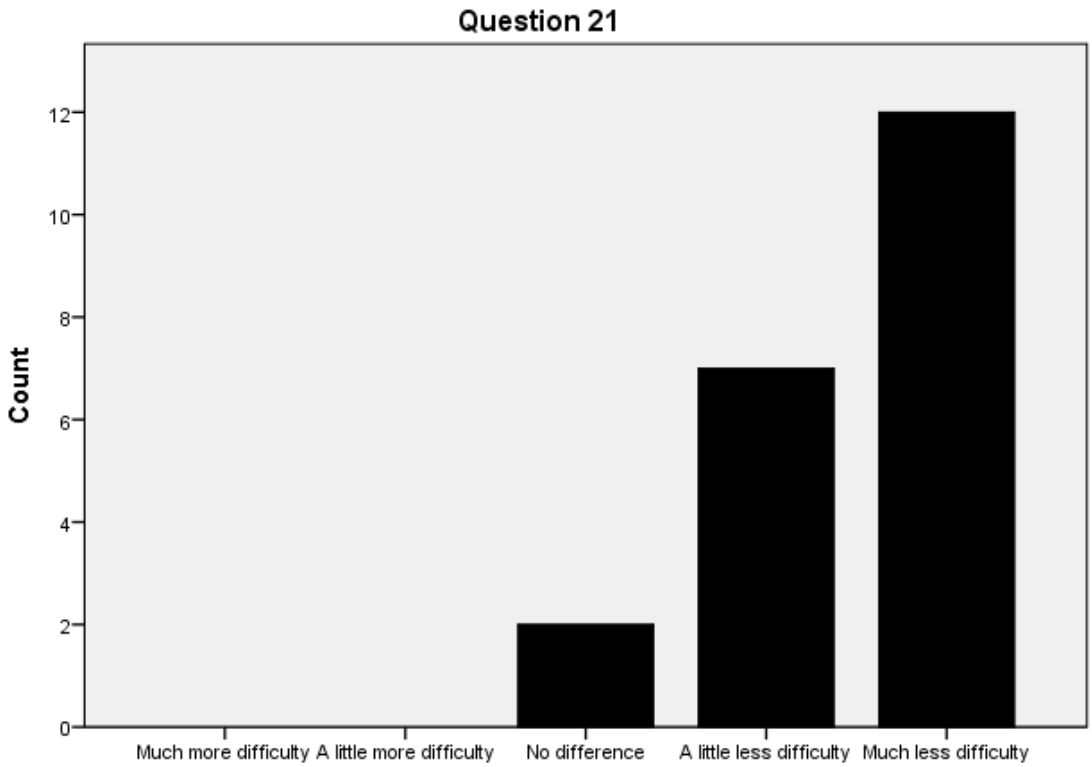
		Frequency	Percent
Valid	No difference	5	22.7
	A little less difficulty	6	27.3
	Much less difficulty	9	40.9
	No response	2	9.1
Total		22	100.0



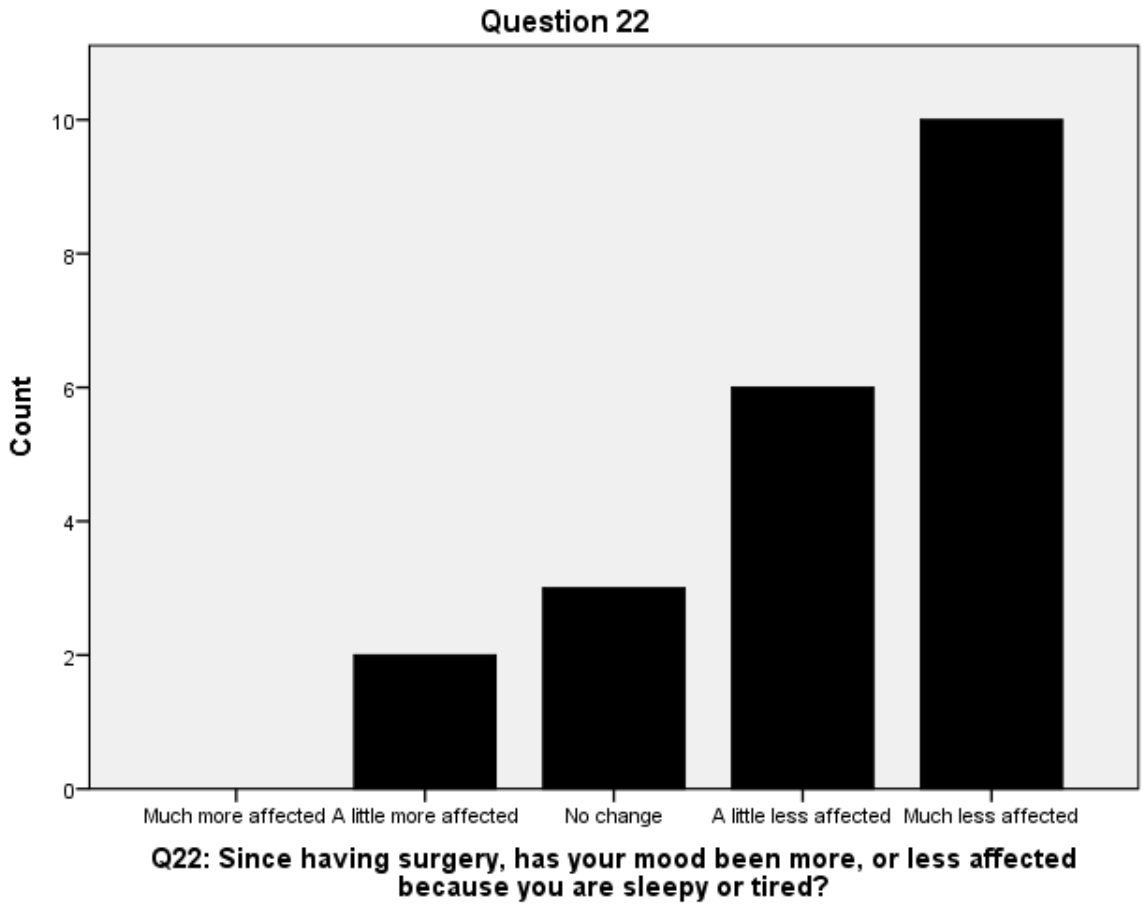
		Frequency	Percent
Valid	A little more difficulty	1	4.5
	No difference	2	9.1
	A little less difficulty	10	45.5
	Much less difficulty	7	31.8
	No response	2	9.1
Total		22	100.0



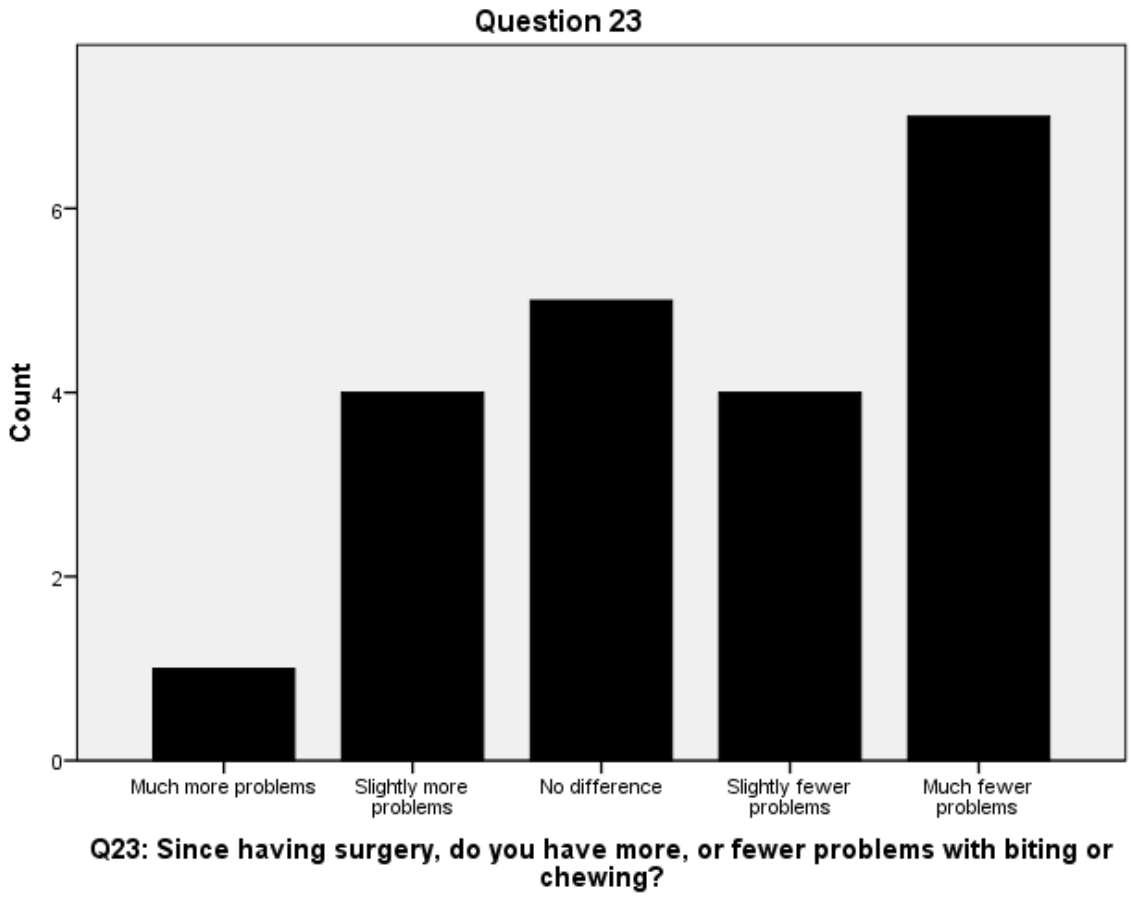
		Frequency	Percent
Valid	A little more difficulty	1	4.5
	No difference	1	4.5
	A little less difficulty	7	31.8
	Much less difficulty	12	54.5
	No response	1	4.5
Total		22	100.0



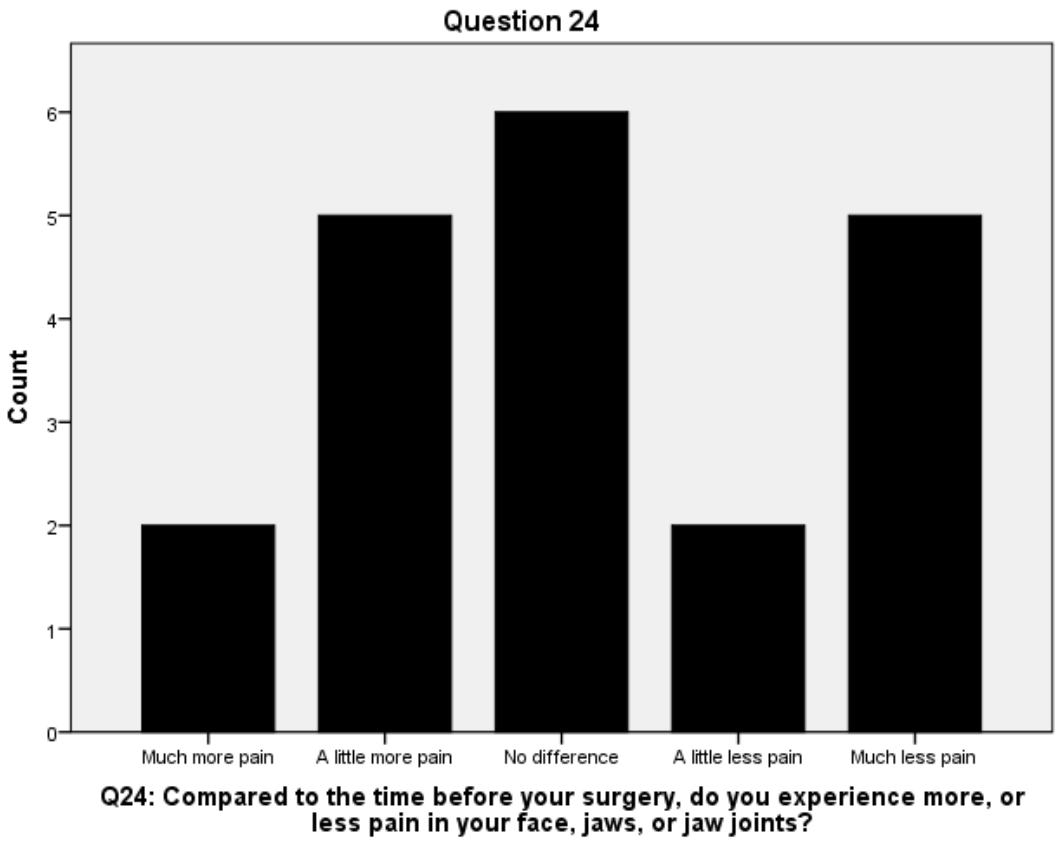
		Frequency	Percent
Valid	No difference	2	9.1
	A little less difficulty	7	31.8
	Much less difficulty	12	54.5
	No response	1	4.5
Total		22	100.0



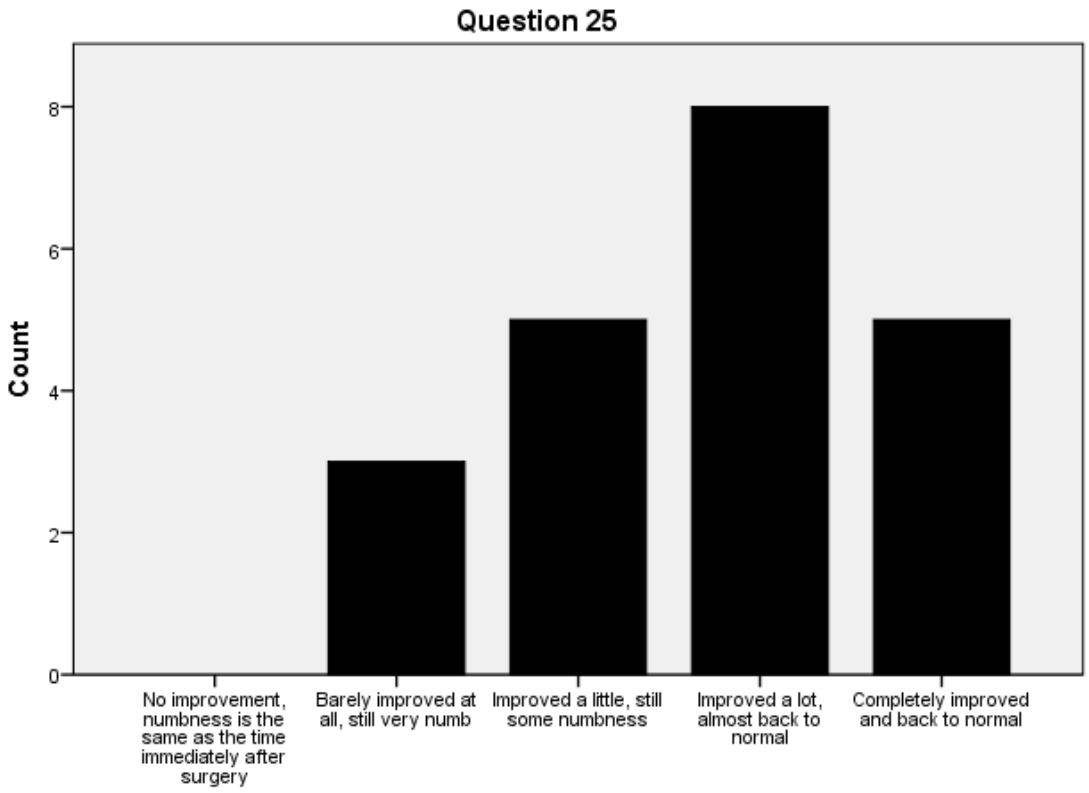
		Frequency	Percent
Valid	A little more affected	2	9.1
	No change	3	13.6
	A little less affected	6	27.3
	Much less affected	10	45.5
	No response	1	4.5
Total		22	100.0



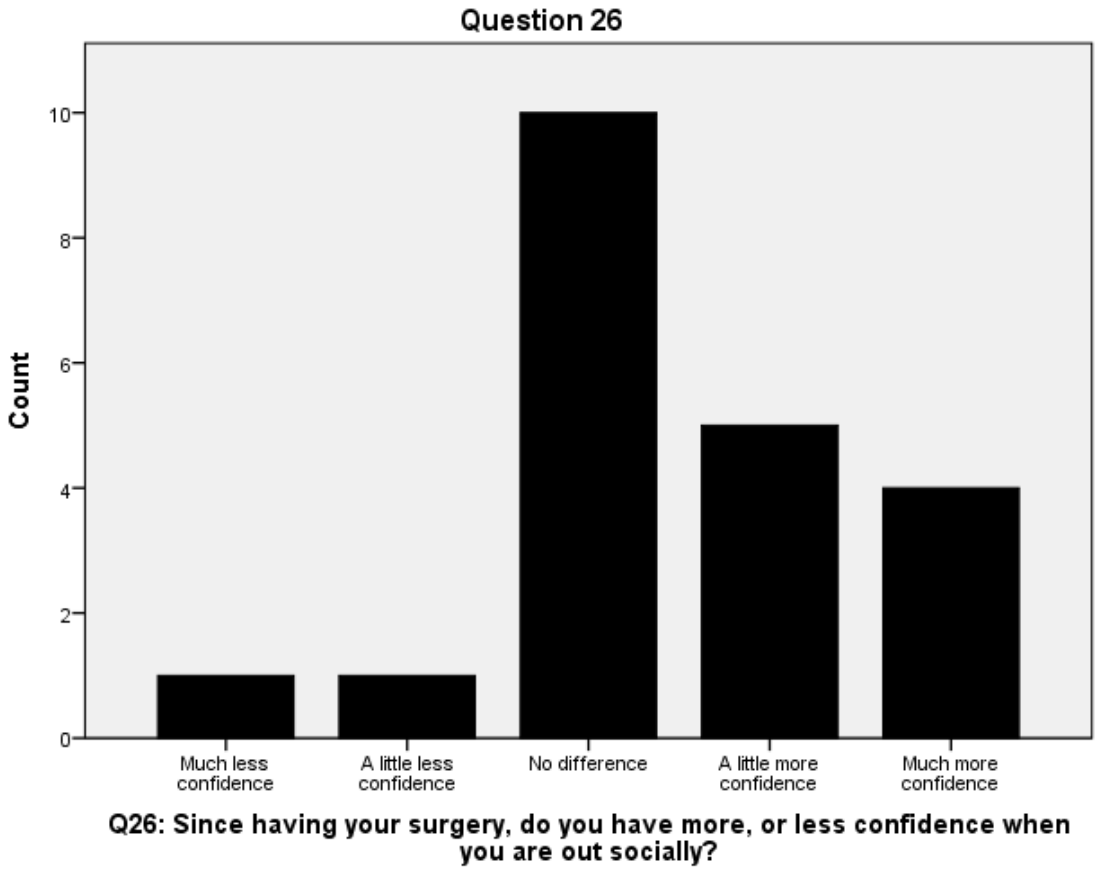
		Frequency	Percent
Valid	Much more problems	1	4.5
	Slightly more problems	4	18.2
	No difference	5	22.7
	Slightly fewer problems	4	18.2
	Much fewer problems	7	31.8
	No response	1	4.5
Total		22	100.0



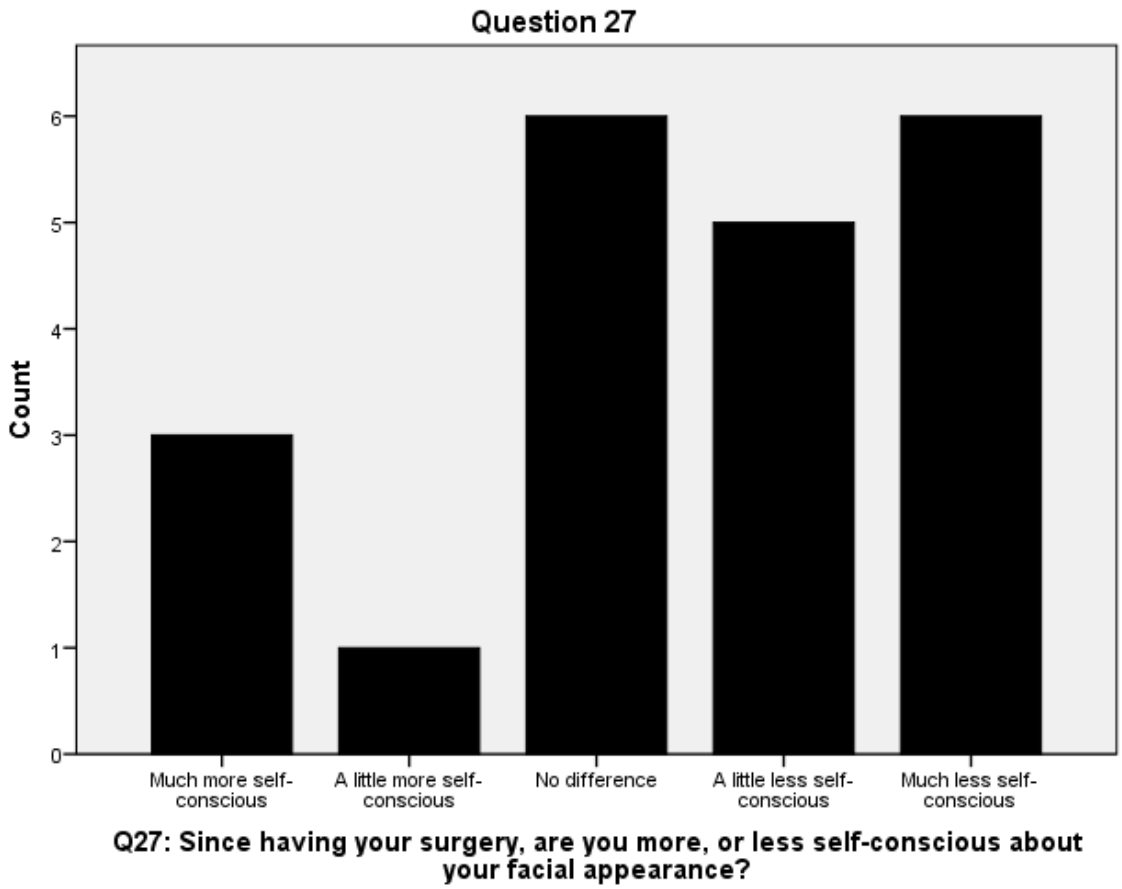
		Frequency	Percent
Valid	Much more pain	2	9.1
	A little more pain	5	22.7
	No difference	6	27.3
	A little less pain	2	9.1
	Much less pain	5	22.7
	“I don’t know”	1	4.5
	No response	1	4.5
Total		22	100.0



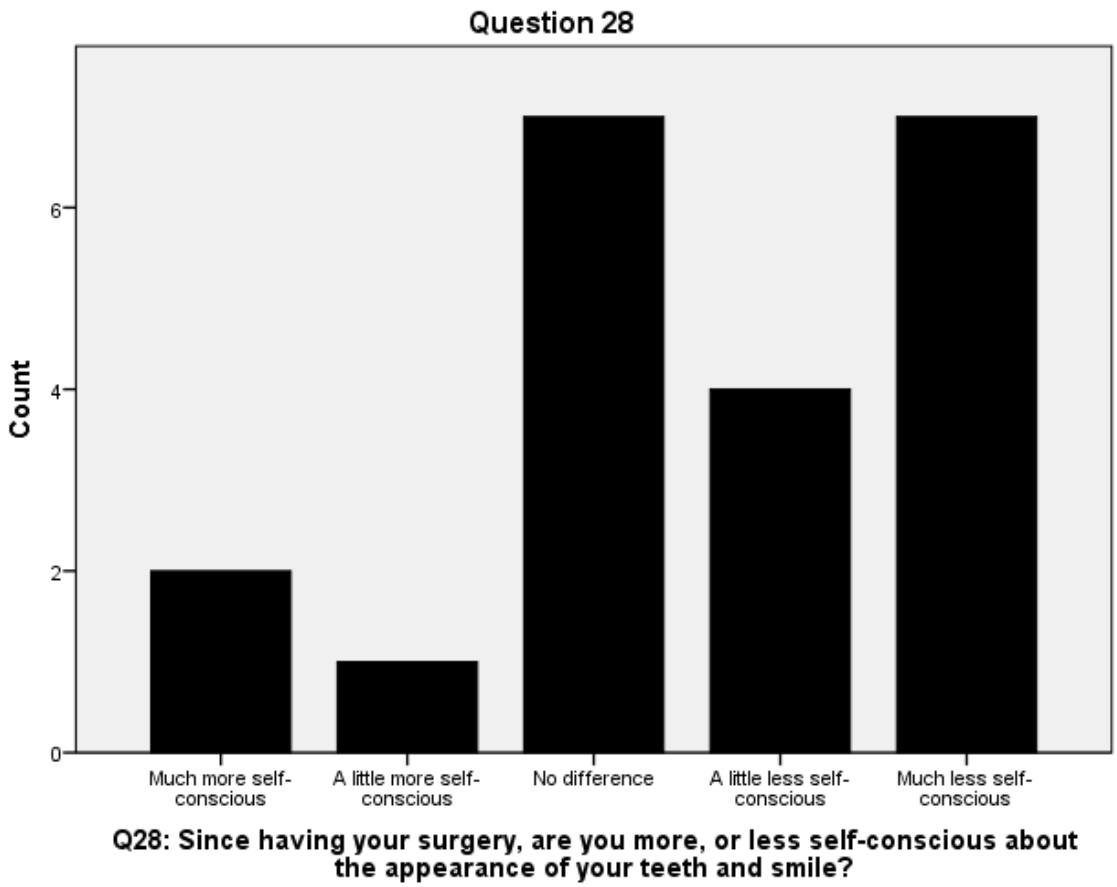
		Frequency	Percent
Valid	Barely improved at all, still very numb	3	13.6
	Improved a little, still some numbness	5	22.7
	Improved a lot, almost back to normal	8	36.4
	Completely improved and back to normal	5	22.7
	No response	1	4.5
Total		22	100.0



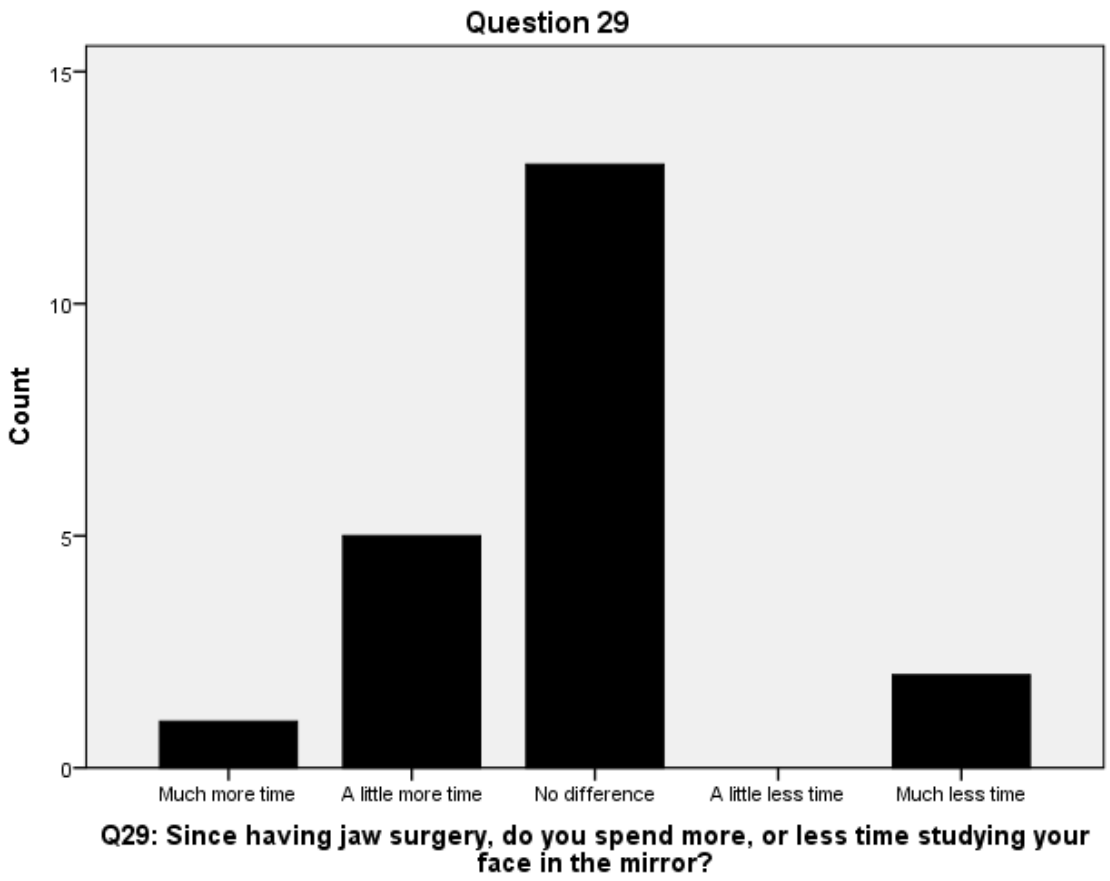
		Frequency	Percent
Valid	Much less confidence	1	4.5
	A little less confidence	1	4.5
	No difference	10	45.5
	A little more confidence	5	22.7
	Much more confidence	4	18.2
	No response	1	4.5
Total		22	100.0



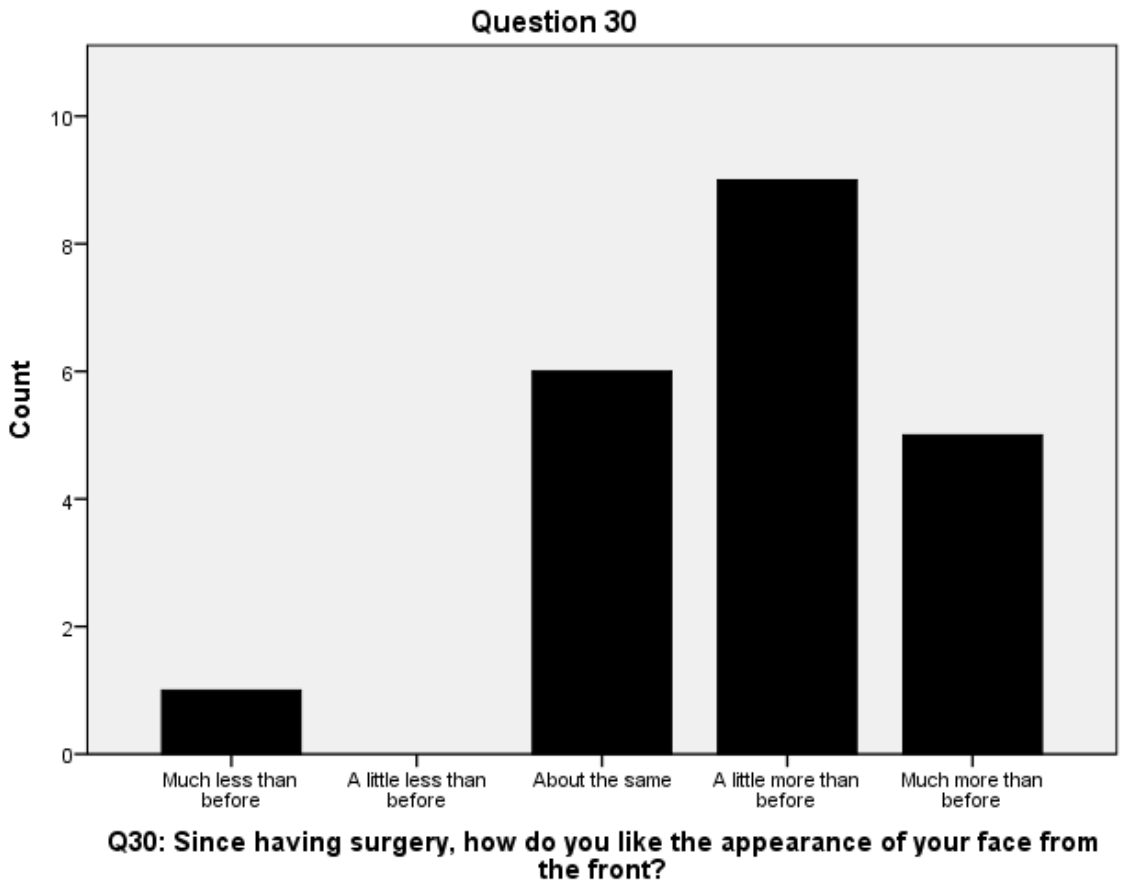
		Frequency	Percent
Valid	Much more self-conscious	3	13.6
	A little more self-conscious	1	4.5
	No difference	6	27.3
	A little less self-conscious	5	22.7
	Much less self-conscious	6	27.3
	No response	1	4.5
Total		22	100.0



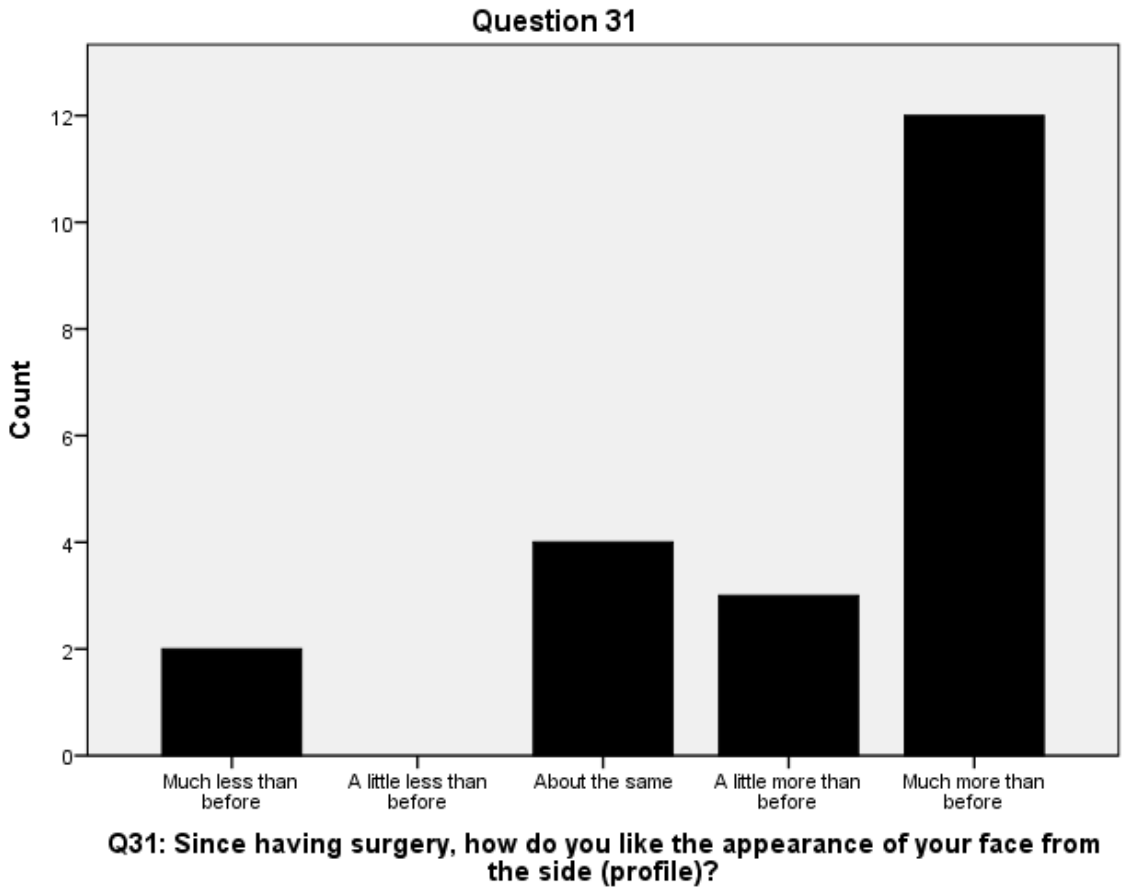
		Frequency	Percent
Valid	Much more self-conscious	2	9.1
	A little more self-conscious	1	4.5
	No difference	7	31.8
	A little less self-conscious	4	18.2
	Much less self-conscious	7	31.8
	No response	1	4.5
Total		22	100.0



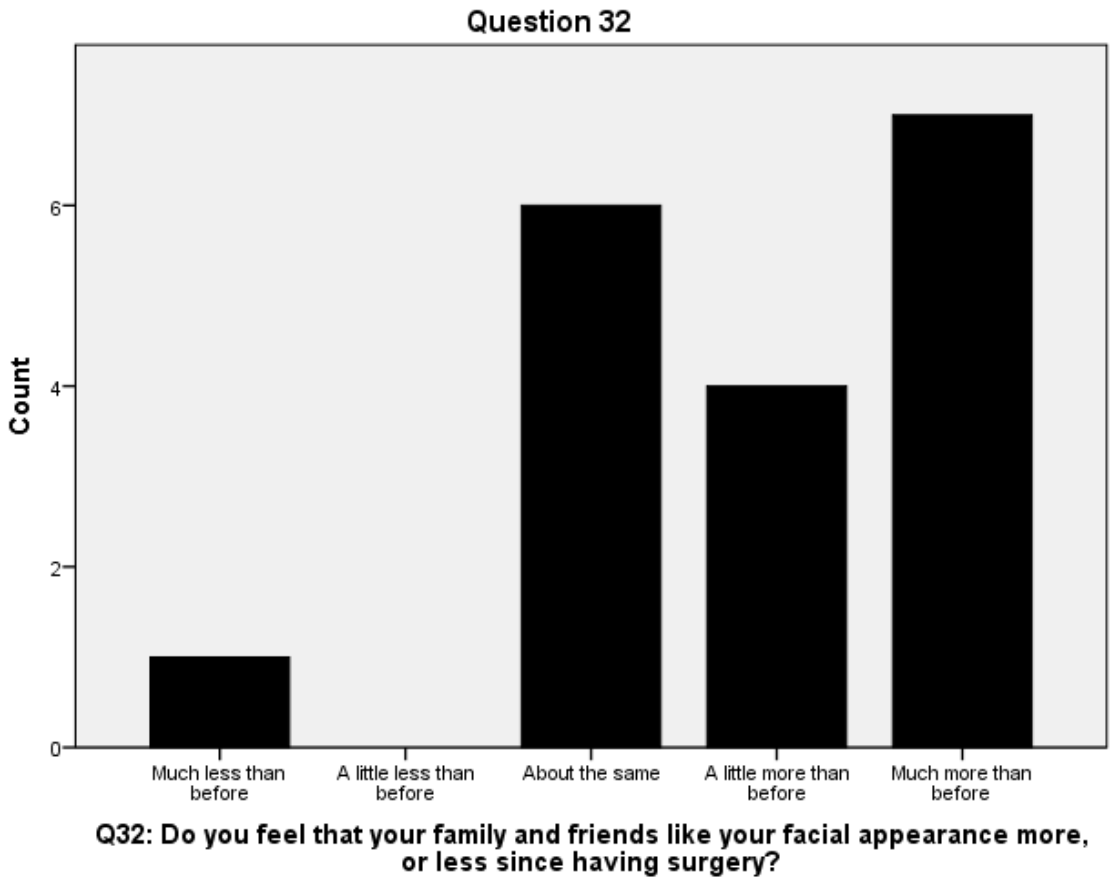
		Frequency	Percent
Valid	Much more time	1	4.5
	A little more time	5	22.7
	No difference	13	59.1
	Much less time	2	9.1
	No response	1	4.5
Total		22	100.0



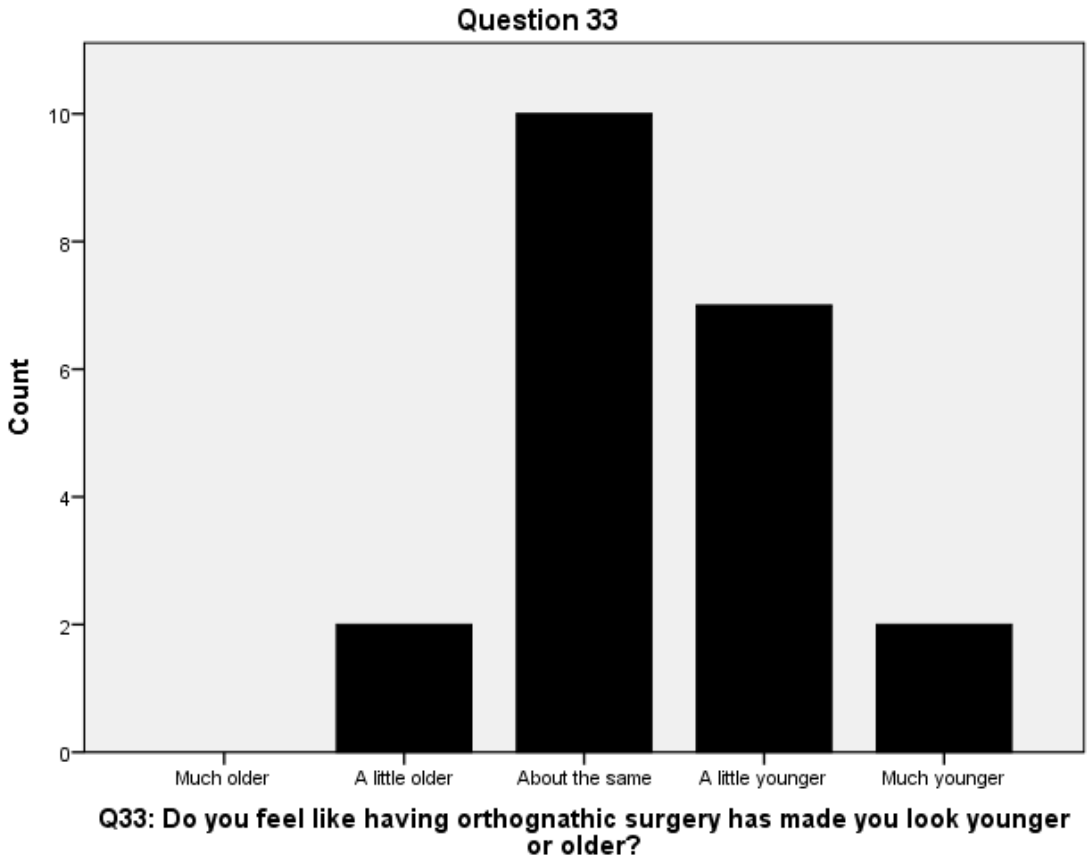
		Frequency	Percent
Valid	Much less than before	1	4.5
	About the same	6	27.3
	A little more than before	9	40.9
	Much more than before	5	22.7
	No response	1	4.5
Total		22	100.0



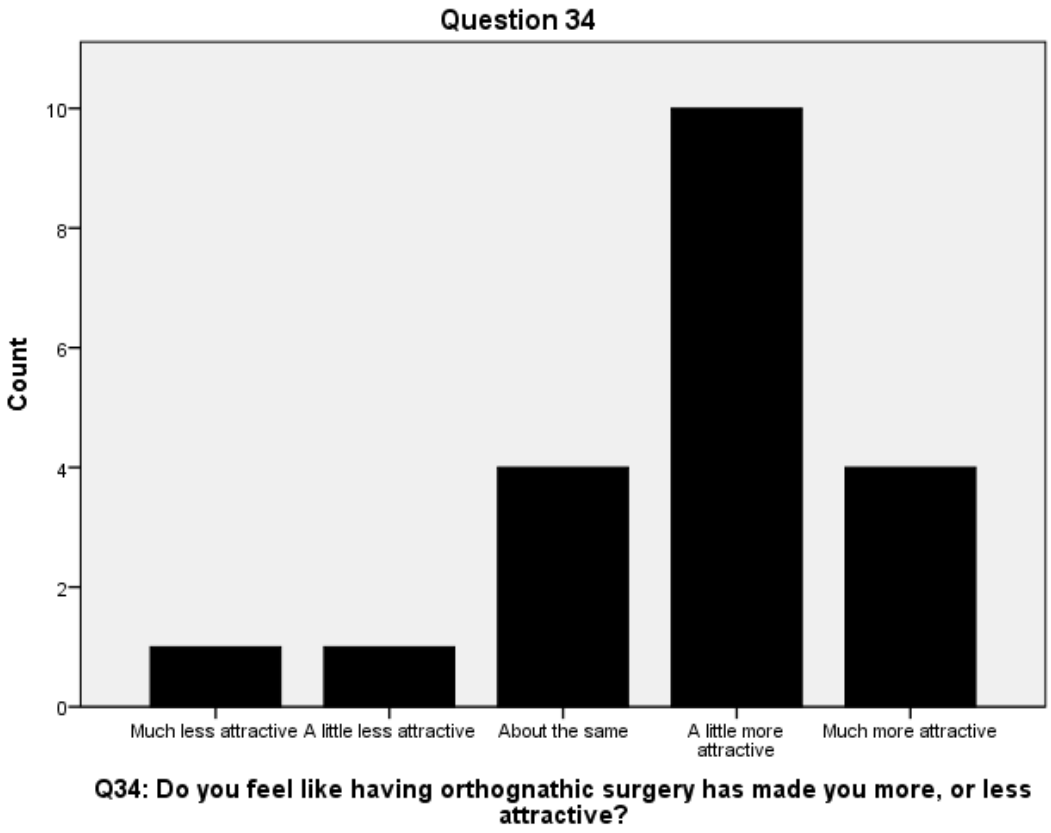
		Frequency	Percent
Valid	Much less than before	1	4.5
	About the same	6	27.3
	A little more than before	4	18.2
	Much more than before	7	31.8
	“I don’t know”	3	13.6
	No response	1	4.5
Total		22	100.0



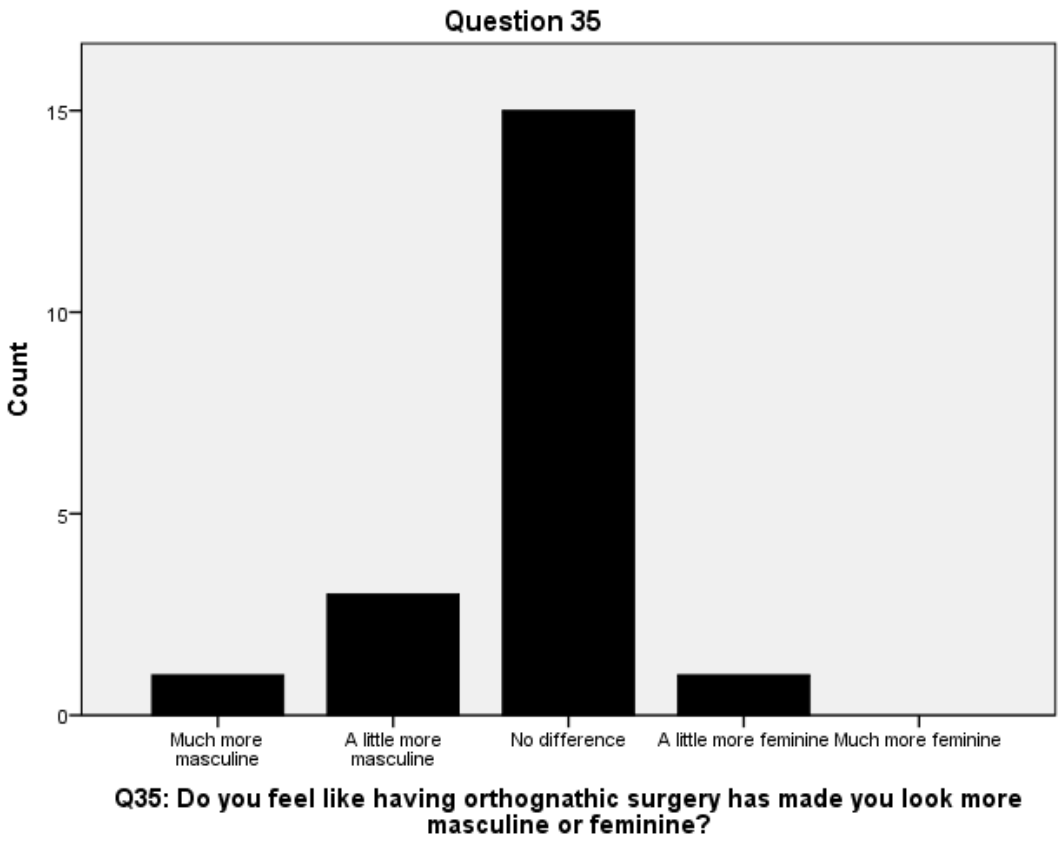
		Frequency	Percent
Valid	Much less than before	1	4.5
	About the same	6	27.3
	A little more than before	4	18.2
	Much more than before	7	31.8
	“I don’t know”	3	13.6
	No response	1	4.5
Total		22	100.0



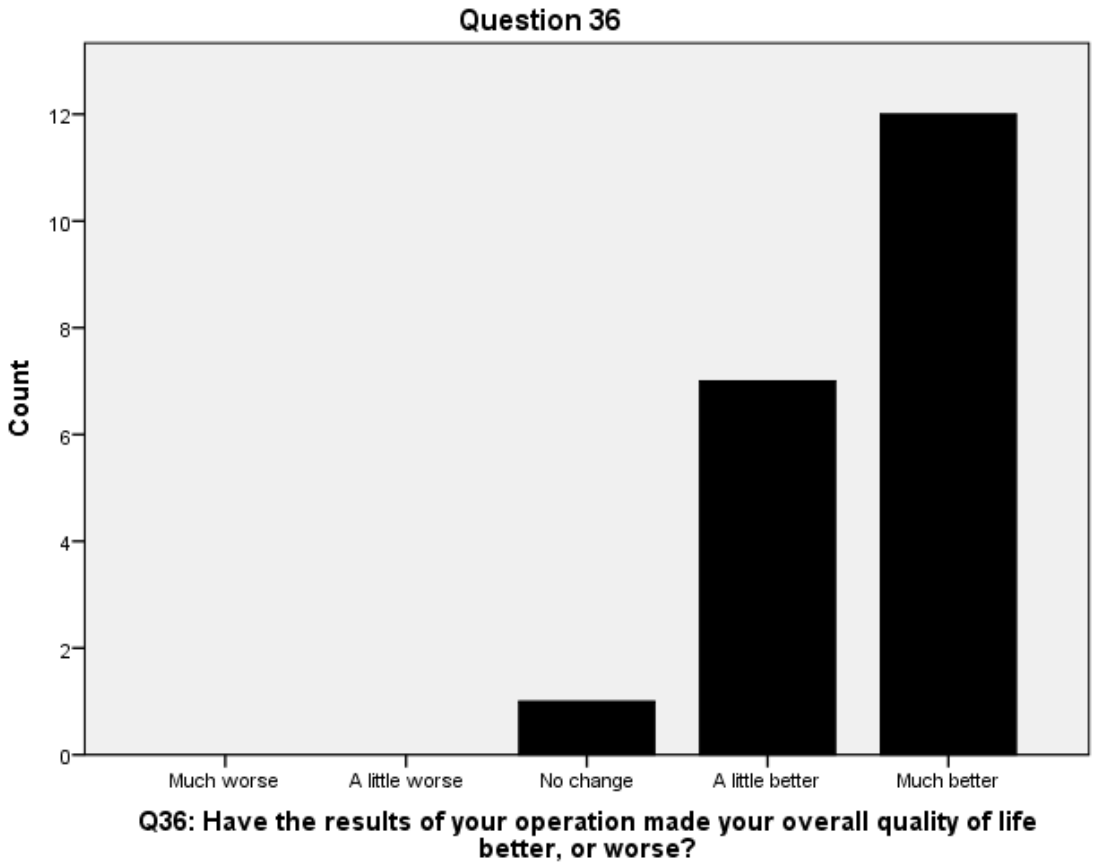
		Frequency	Percent
Valid	A little older	2	9.1
	About the same	10	45.5
	A little younger	7	31.8
	Much younger	2	9.1
	No response	1	4.5
Total		22	100.0



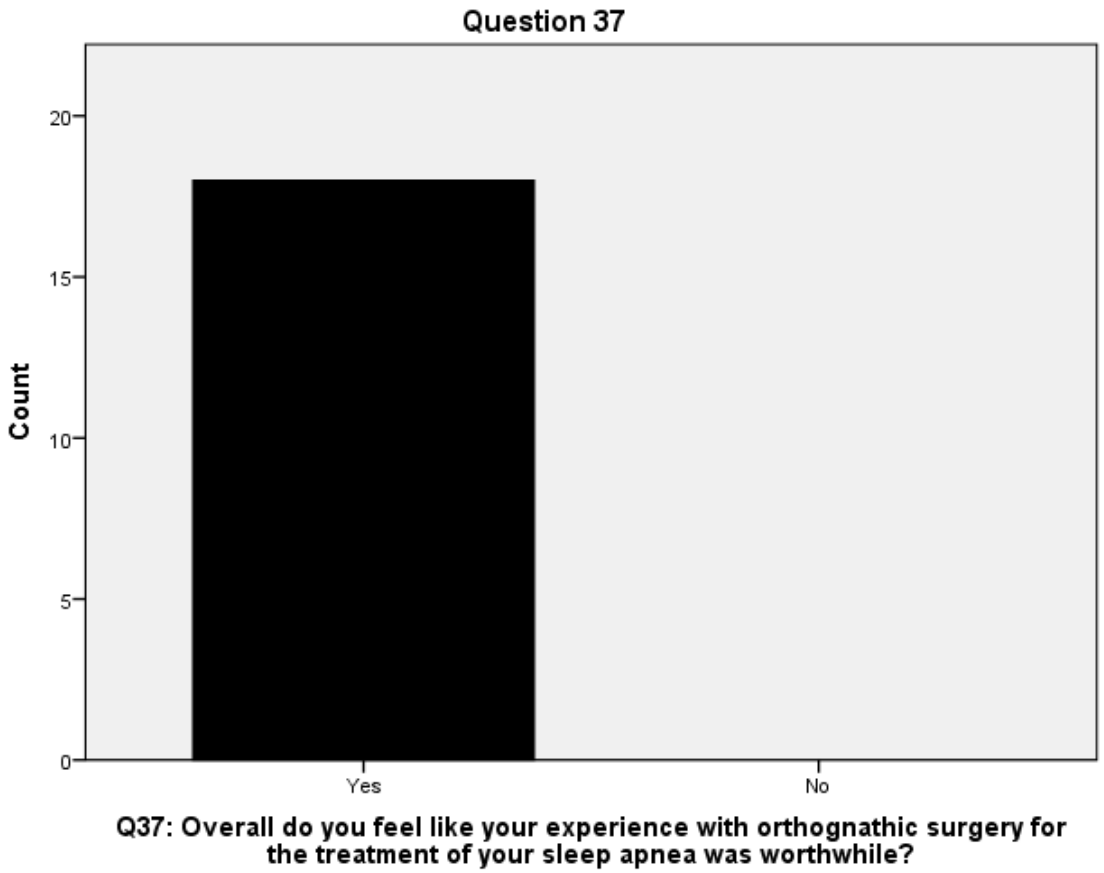
		Frequency	Percent
Valid	Much less attractive	1	4.5
	A little less attractive	1	4.5
	About the same	4	18.2
	A little more attractive	10	45.5
	Much more attractive	4	18.2
	I don't know"	1	4.5
	No response	1	4.5
Total		22	100.0



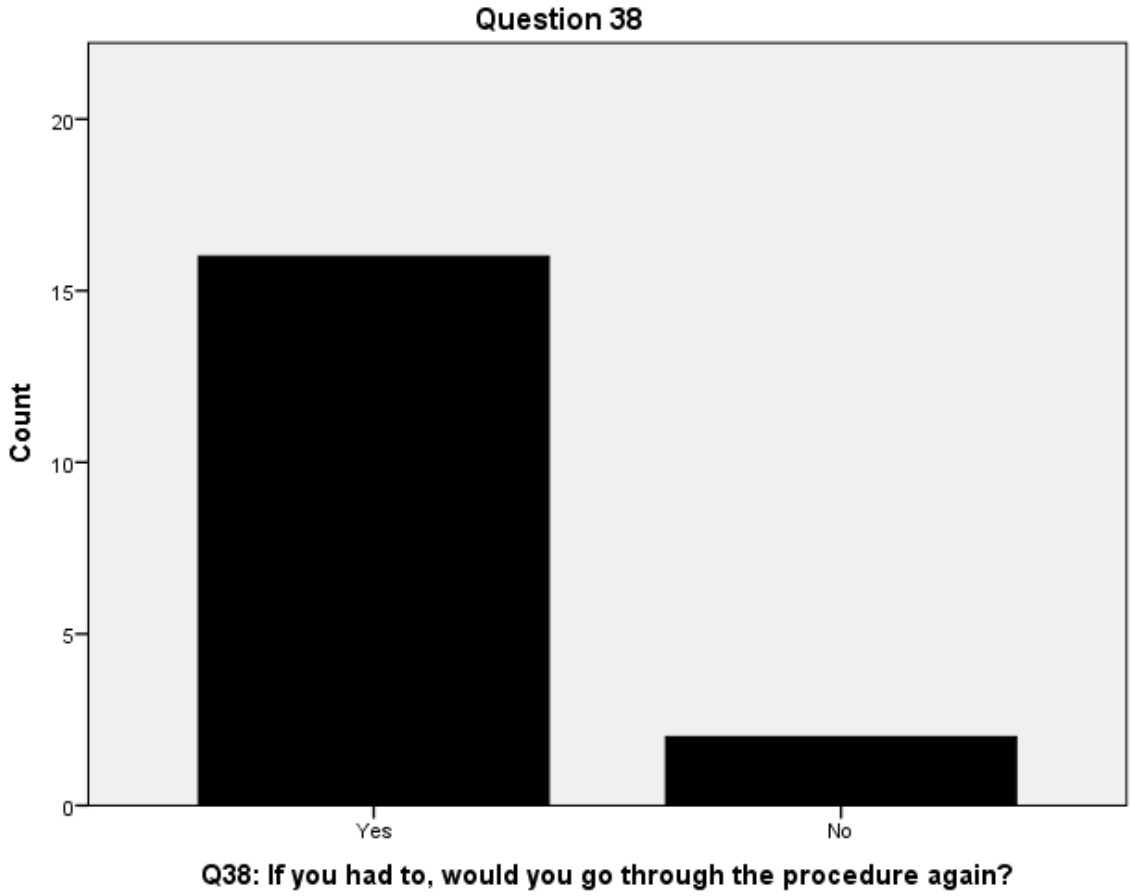
		Frequency	Percent
Valid	Much more masculine	1	4.5
	A little more masculine	3	13.6
	No difference	15	68.2
	A little more feminine	1	4.5
	“I don’t know”	1	4.5
	No response	1	4.5
Total		22	100.0



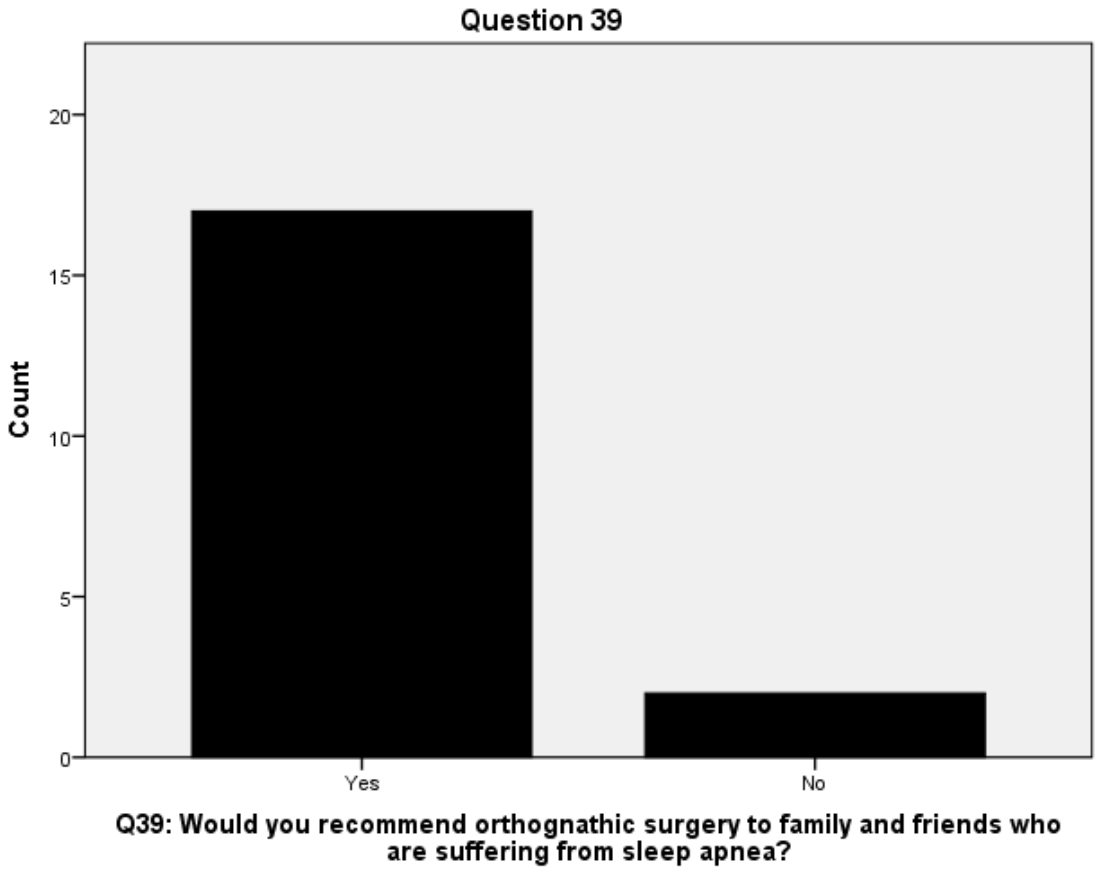
		Frequency	Percent
Valid	No change	1	4.5
	A little better	7	31.8
	Much better	12	54.5
	No response	2	9.1
Total		22	100.0



		Frequency	Percent
Valid	Yes	18	81.8
	"I don't know"	1	4.5
	No response	3	13.6
Total		22	100.0



		Frequency	Percent
Valid	Yes	16	72.7
	No	2	9.1
	“I don’t know”	2	9.1
	No response	2	9.1
Total		22	100.0



		Frequency	Percent
Valid	Yes	17	77.3
	No	2	9.1
	No response	3	13.6
Total		22	100.0

Curriculum Vitae

Name:	Andrew Emanuele
Post-secondary Education and Degrees:	Dalhousie University Halifax, Nova Scotia, Canada 2004-2007 BSc Dalhousie University Halifax, Nova Scotia, Canada 2007-2011 DDS Western University London, Ontario, Canada 2013-2016 MClD
Related Work Experience	General Practice Residency Western University and the London Health Sciences Centre London, Ontario, Canada 2011-2012 Private Practice General Dentistry London, Ontario, Canada 2012-2013