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LONG TERM (>10 YEARS) EFFECTS OF AIRWAY OBSTRUCTION TREATMENT ON DENTO-FACIAL MORPHOLOGY

by
ANNIE ARDASH BABAKHANIAN

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ANNIE ARDASH BABAKHANIAN

Approved by:

Dr. Anthony T. Macari, Associate Professor — Advisor
Orthodontics and Dentofacial Orthopedics

Dr. Joseph G. Ghafari, Professor and Head — Co-Advisor
Orthodontics and Dentofacial Orthopedics

Dr. Randa Al Barazi, Assistant Professor — Member of Committee
Otorhinolaryngology- Head and Neck Surgery

Dr. Abdo Jurjus, Professor — Member of Committee
Anatomy, Cell Biology and Physiological Sciences

Date of thesis defense: November 2nd, 2021

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ABSTRACT
OF THE THESIS OF

Annie Ardash Babakhanian for Master of Science
Major: Orthodontics

Title: Long term (>10 years) effects of airway obstruction treatment on dento-facial morphology.

Background
Airway obstruction, particularly when chronic, has been shown to lead to dento-facial dysmorphogenesis such as the long-face syndrome also known as “adenoid facies”. Despite the available evidence highlighting the importance of diagnosis of mouth breathing early in life, this condition remains widely misdiagnosed or underestimated among different medical specialists. The severity and the extent of the reported morphological changes depend on age, duration, and gravity of airway obstruction. Possibly confounding the issue are the facts that airway obstruction appears to be more acute at a younger age, but the amount of facial adaptation may allow regaining airway clearance. Consequently early examination (before age 6) is important to detect the problem and possibly reverse a negative effect on dentofacial development. Early intervention to promote nasal respiration has been shown to reverse such a course. The extent of normalization highly depends on the timing as well as the type of treatment.

Aims
1. To evaluate, at 10 years follow up, the craniofacial changes of a unique study population, who presented to pediatric Otolaryngologist for consultation during 2006-2008, with history of mouth breathing at the initial visit.
2. To recognize guidelines for airway obstruction treatment in relation to age and severity.
3. To observe the long term results of different treatment modalities on facial morphology.

Methods
Upon IRB approval, a total of 57 patients (35 males and 22 females; age 19.09 years (range 15.1 - 25.2 years), who were previously enrolled in a study conducted at AUBMC (2006-2008), accepted to enroll in this study.
Following a written consent at the initial visit, a clinical examination of the face and oral cavity was performed, medical history pertaining details about treatment of mouth breathing was recorded; moreover a lateral cephalogram, intra-oral and extra-oral photographs, and oral scan were taken. In addition two sets of questionnaires (Epworth sleepiness scale and STOP-BANG) were filled out to assess the risk of obstructive sleep apnea (OSA) in these individuals. The sample was divided into different groups based on surgical status, gender, breathing status and orthodontic treatment. Cephalometric and dental measurements, as well as OSA questionnaire scores, including the shortest adenoid distance (SAD) were compared between groups as well as at two time points.

Results

Most of the variables revealed significant changes from T1 to T2. ANB and SNA angles in the surgical group normalized to controls, whereas in the non-surgical group they remained statistically significant (p=0.03 and 0.02). The Ar-Go-Me (p=0.01), PP/MP (p=0.02) and MP/SN (p=0.00) had smaller values than controls due to more extensive changes after surgery, the non-surgical group on the other hand normalized to controls. The surgical group revealed more proclination of maxillary and mandibular incisors, while in the non-surgical group the mandibular incisors were more protruded compared to controls. The patients who had surgery above age 6 showed a trend towards proclined and protruded mandibular incisors whereas in the younger age group the values were similar to controls. Patients who had their adenoids removed after the age of 6 (p=0.00) as well as mouth breathing patients (p=0.04) developed more mandibular crowding. The surgical group had significantly larger SAD measures than that of controls (p=0.01), in contrast the non-surgical group had significantly smaller SAD measurements when compared to controls (p=0.00). Orthodontic treatment and age at T2 were strong predictors for SAD measurement (r=0.57). Analysis of questionnaires could not delineate a connection between the severity of scores and the SAD measurements.

Conclusion

The outcome of adenoidectomy and increased airway dimensions appear to be stable and permanent. Adenoidectomy to regain nasal patency results in normalization of dento-facial growth as well as corresponding bony bases, specifically of the mandible, enhancing better chin projection in the surgical group. Surgical treatment, specifically surgery before age of 6, helps in more horizontal mandibular growth direction. Adenoidectomy before age 6 leaves more growth potential to regain facial harmony. Nasal breathing must be ensured after treatment in order to benefit from the surgical procedure to the full extent. It is important that children with mouth breathing are diagnosed early and evaluated both from medical and dento-facial points of view. This demands interdisciplinary approach between pediatricians, otolaryngologists, orthodontists, and pediatric dentists.

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ABBREVIATIONS

Cl II/1	Class II, division 1
Cl III	Class III
LFS	Long face syndrome
LFH	Lower face heigh
RME	Rapid maxillary expansion
Mm	Millimeter
OSA	Obstructive sleep apnea
T&A	Tonsillectomy and adenoidectomy
SAD	Shortest distance between adenoid and soft palate
CAD	Distance between maximum convex point and soft palate
N	Nasion
S	Sella
Ba	Basion
Po	Porion
Pt	Pterygoid point
Or	Orbitale
ANS	Anterior nasal spine
PNS	Posterior nasal spine
A	A point
B	B point
Pog	Pogonion
Gn	Gnathion
Me	Menton
Co	Condylion
Ar	Articulare
Go	Gonion
ANS-PNS	Length of maxilla
Co-Gn	Length of mandible
Ar-Go-Me	Gonial angle
LFH/TFH	Lower to total face height ratio
PP	Palatal plane
MP	Mandibular plane
SN	Length of anterior cranial base
N-S-Ar	Saddle angle
U1	Most proclined maxillary incisor
L1	Most proclined mandibular incisor

CHAPTER I

INTRODUCTION

In the late eighteenth century, George Catlin, a well-known American artist, wrote about the noxious effects of mouth-breathing in his publication titled “Mal-respiration or the Breath of Life”. Dr. Edward Angle reprinted the document in 1925, and referred to the artist and stated, “In his belief that some forms of malocclusion of the teeth and facial deformity are due to mouth breathing we only too well know Mr. Catlin to be entirely correct, and, doubtless, he is one of the first, if not the first, in this country to direct attention to this combination, which often sadly can disfigure human face for life”(Goldsmith & Stool, 1994).

The effect of mode of breathing on dentofacial growth and development has been a controversial issue within orthodontics and otolaryngology for decades (Clark, 2005). Despite the evidence emanating from abundant studies and scientific data and highlighting the importance of diagnosis of mouth breathing early in life, the latter is still widely misdiagnosed and underestimated among different medical specialists.

According to Moss’s functional matrix theory, nasal breathing allows proper growth and development of craniofacial and dentofacial complex (Moss & Salentijn, 1969). This theory is based on the principle that normal nasal respiration favors harmonious growth and development of craniofacial structures by adequately interacting with mastication, swallowing and other components of the head and neck region (Yamada et al., 1997).

Studies on mouth breathing children do not point out the range of effectiveness of treatment and lack large population groups as well as long follow up periods; the

assessments are based on few isolated landmarks. The longest post-adenoidectomy follow up has been for 5 years and on a group of 38 children (Linder-Aronson, 1970). Therefore, the lack of evidence-based protocol for diagnosis and corresponding treatment modalities complicates decision making and might decrease the efficiency of treatment outcome. While early treatment to regain nasal respiration may help to reverse the facial features caused by mouth breathing, the amount of normalization depends mostly on the timing and type of treatment.

In conclusion, and because of the lack of clear-cut guidelines for the early versus late treatment of mouth breathing, a long-term study on a large sample size is necessary to evaluate the nature and amount of redirection of the dentofacial growth..

The focus of the present research is to highlight the optimal timing for treatment of airway obstruction in mouth-breathing children in an attempt to reverse and/or decrease the severity of malocclusion and related facial features. Ideal timing of treatment can prevent the future need for orthognathic surgery to resume the facial harmony and balance. In addition, this study can shed light on the changes in facial morphology in relation to age and treatment modality.

CHAPTER II

LITERATURE REVIEW

Edward Angle (1907) emphasized, in his malocclusion classification, not only the peculiarities of the occlusion and the relations of the jaws, but also the condition of the throat, nose and habits of the patients. Angle accounted for mouth breathing in his classification of two opposite malocclusions (Fig. 1). He described Class II division 1 malocclusion as “always accompanied and, at least in early stages, aggravated, if not indeed caused by mouth breathing due to some form of nasal obstruction”. Also, regarding the etiology of Class III, his only explanation was that: “deformities under this class begin at about the age of eruption of the first permanent molars, or even much earlier, and are always associated at this age with enlarged tonsils and the habit of protruding the mandible, the latter probably affording relief in breathing”.

Animal experiments have shown that induced nasal obstruction in healthy Rhesus monkeys can lead to oral respiration and dentofacial changes. The response to nasal obstruction differed considerably among the animals. The animals did not develop the same type of dental malocclusion, even though their noses were blocked by the same method and at the same age. It appears that, each animal would find its own most convenient way to secure the oral airflow and then develop a dental malocclusion in accordance with this new function (Fig. 2) (Harvold, 1968; Harvold et al., 1973).; However, traits such as increased face height, steeper mandibular plane, and larger gonial angle were common among the animals (Harvold et al., 1981).

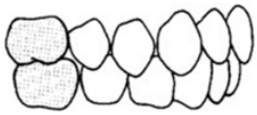
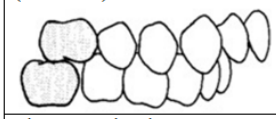
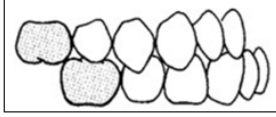
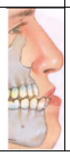
OCCLUSION DEFINED BY EH ANGLE	ASSUMED CORRESPONDING FACIAL PROFILE	RELATION BETWEEN MAXILLA AND MANDIBLE
Class I occlusion 	"Straight" (absence of protrusion or retrusion of middle face or mandible) 	Orthognathic
Class II malocclusion (division 1) 	Convex 	Maxillary prognathism of bone and/or dentoalveolus, mandibular retrognathism of same, or a combination.
Class III malocclusion 	Concave 	Maxillary retrognathism of bone and/or dentoalveolus, mandibular prognathism of same, or a combination

Figure 1: Edward Hartley Angle defined a Class I normal occlusion when the mesiobuccal cusp of the permanent maxillary first molar occludes in the mesiobuccal groove of the permanent mandibular first molar. In a Class II (division 1) malocclusion, mandibular teeth are distal to the maxillary teeth, and an overjet is present between the anterior teeth. The opposite relationship with an anterior crossbite defines a Class III malocclusion (Table by Ghafari J. 2008).

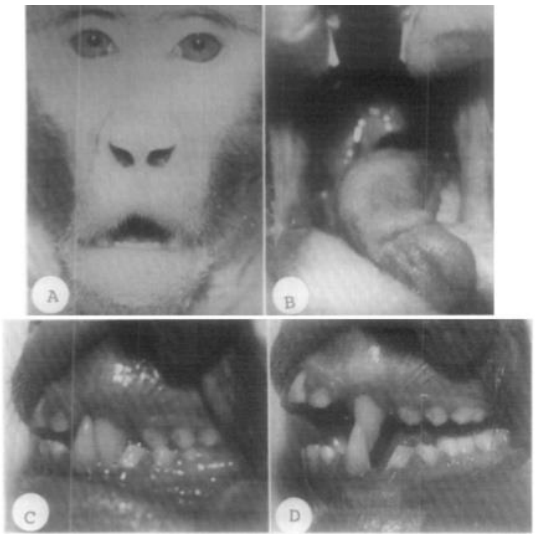


Figure 2: Three years of oral respiration in a rhesus monkey, displaying a notch in the upper lip and an open mouth posture (A), long slender tongue with a midline groove and development of malocclusion (B) as well as a dual bite (C & D) (From Harvold 1981).

A. Etiology of mouth breathing

Mouth breathing is multifactorial in origin and may be related to genetic factors, hypertrophy of the adenoids and palatine tonsils, as well as nasal obstruction of variable severity and duration due to septum deviation, nasal polyps, turbinate hypertrophy, respiratory allergies and sinusitis (Abreu et al., 2008; Jm et al., 2006, 2010).

The risk of nasal obstruction is not only related to the severity of the obstacle in the airways, but also airways anatomy plays an important role in making one person more disposed to obstruction than others. Massler and Zwemer (1953) stated that in the broad-faced individuals (brachyfacial), the nasal passages usually are ovoid and wide, therefore a considerable space is present between the middle turbinate and the septum. In contrast in the narrow-faced individuals (dolichofacial), the nasal passages usually are only a very thin slit, the turbinates frequently making actual contact with the septum, leaving practically no patent airway. Such airways are easily "stopped-up" by any form of obstruction or enlargement (Fig. 3).

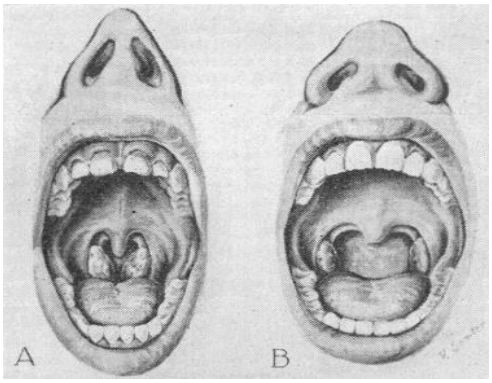


Figure 3: The size and the form of the nasal passages, oral cavity and oropharynx in a narrow-faced child (A) vs. a broad-faced child (B). Note how easily nasal passages could be occluded by minor obstructions (From Massler et al, 1953).

Mouth breathing can be classified into two groups: habitual, with adequate nasal patency, and enforced, through nasal resistance or obstruction. Obstruction can occur

anywhere along the airway or in multiple locations. The greatest resistance in the anterior airway is in the nasal part and therefore this region is more prone to obstruction (Timms, 1981).

1. Nasal obstruction

Nasal obstruction can occur anywhere along the pathway and often in multiple locations. The underlying cause of most cases of mouth breathing is an obstructed (completely or partially blocked) nasal airway.

a. Nasal septum

The nasal septum is composed of bone and hyaline cartilage and divides the nasal cavity into right and left nostrils. Septal deviation is considered one of the major causes of airway obstruction. Deviation in the nasal septum can be genetic or inherited, but the condition can also be caused by environmental factors such as trauma (Fig. 4) (Hassanpour et al., 2014).

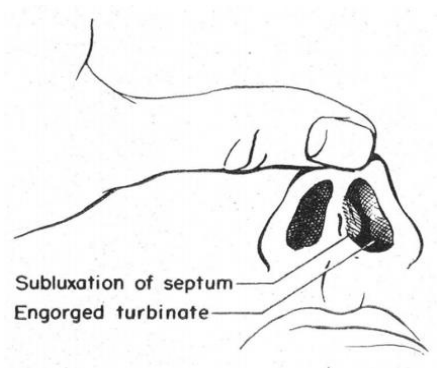


Figure 4: The condition of the turbinates (normal or engorged); and the position of the septum (deviated or subluxated to right or left) assessed during clinical examination (After Massler et al, 1953).

b. Nasal turbinates

The turbinates are covered with mucosa, and help filter, warm, and humidify the air before it reaches the lungs. Each nasal cavity consists of three pairs of turbinates: superior, middle and inferior.

The inferior turbinates are the largest ones and are responsible for the majority of airflow direction, humidification, heating, and filtering of air inhaled through the nose (Kotrannavar & Angadi, 2013). Turbinate hypertrophy refers to an excessive growth or enlargement of the turbinates which in turn can cause nasal airway obstruction (Fig. 5 A-B) (Orhan et al., 2014).

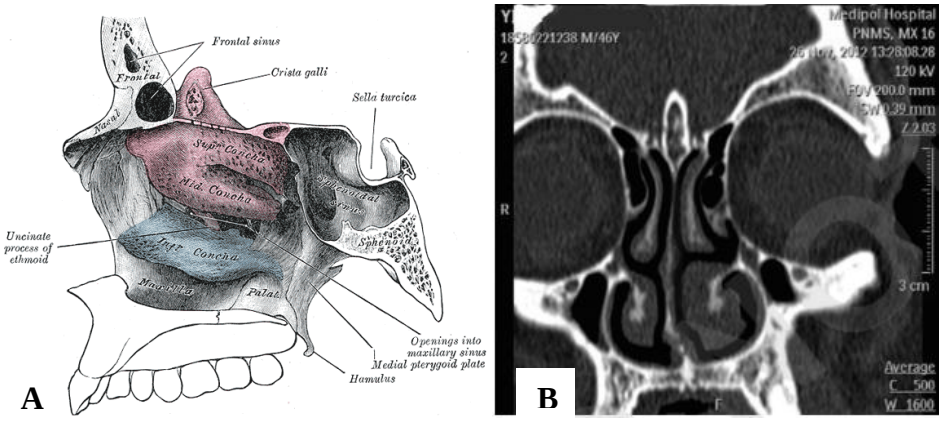


Figure 5: Superior, middle and inferior nasal turbinates (A) (From Henry Gray, 1918). Deviated nasal septum and enlarged left inferior turbinate on CT imaging (B).

2. Lymphoid tissues

Adenoids and tonsils are the lymphoid tissues located in the nasopharynx. They play an important role in the body's immune response.

a. Adenoids

The adenoids, also known as the pharyngeal tonsils are a mass of lymphatic

tissue located behind the nasal cavity, in the roof of the nasopharynx, where the nose blends into the throat. Their hypertrophy is a major cause of nasal obstruction (Fig. 6A).

b. Tonsils

The palatine tonsils are located between the palatoglossal and palatopharyngeal arch of the soft palate and are considered to be the "gate keepers" of the oropharynx. Their hypertrophy can cause bulging masses that can obstruct the airways (Fig. 6B).

Enlarged adenoids and tonsils are common obstructive agents of the posterior pharyngeal airway (Fig. 7 A-B).

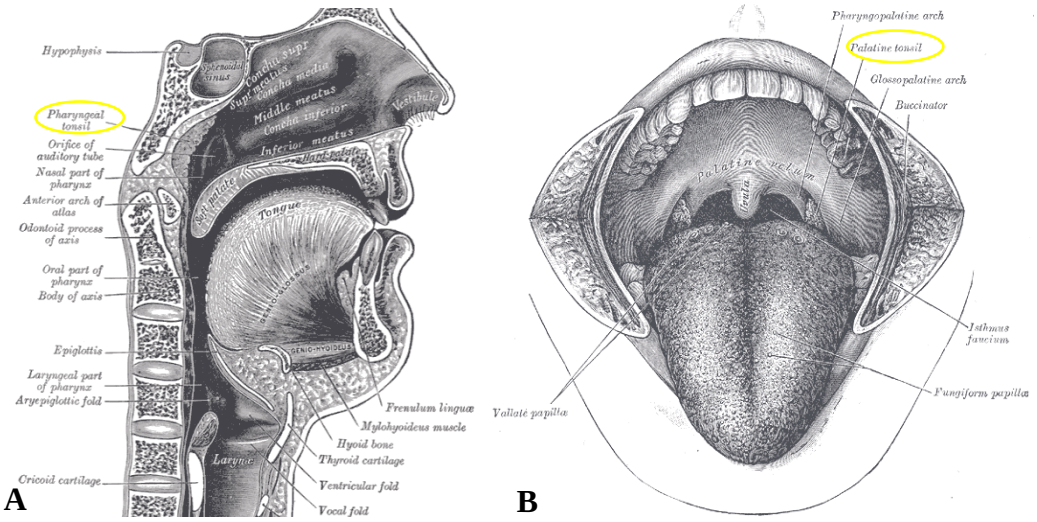


Figure 6: Adenoids (pharyngeal tonsils) highlighted on the Sagittal section of nose, mouth, pharynx, and larynx (A). Palatine tonsils displayed in the mouth cavity (B) (After Henry Gray, 1918).

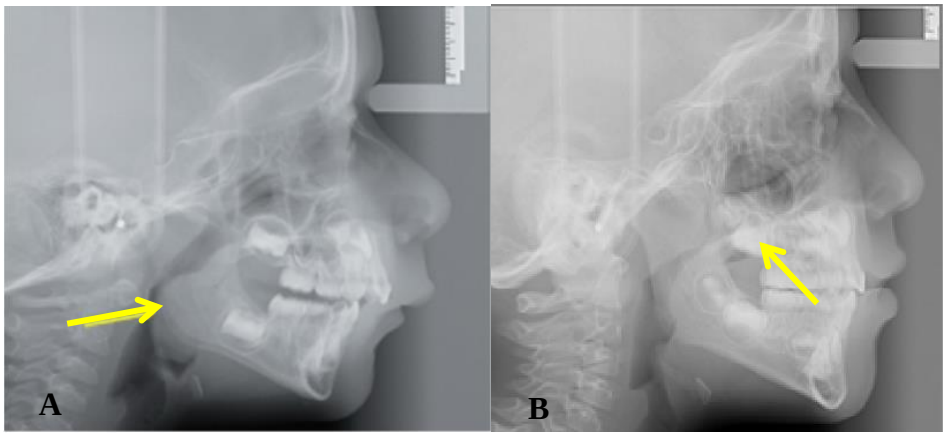


Figure 7: lateral cephalogram of a patient showing enlarged tonsils (arrow) (A). Lateral cephalogram of a patient showing enlarged adenoids (arrow) (B).

3. Respiratory allergies

Rhinitis is inflammation and swelling of the mucous membrane of the nose, usually caused by the common cold or a seasonal allergy. Rhinitis is classified as allergic or non-allergic, acute or chronic. The nose is the most commonly infected part of the upper airways.

The classic signs and symptoms of allergic rhinitis are nasal obstruction, watery rhinorrhea, sneezing, nasal itching and mouth breathing. Symptoms are often reversible either spontaneously or with treatment (Bezerra et al., 2014).

The treatment of allergic rhinitis includes combination of patient education, allergen avoidance, pharmacotherapy, and immunotherapy (Bousquet et al., 2001). The treatment modality is based on symptoms, severity and age (Sur & Scandale, 2010).

4. Sinusitis

The maxillary sinus is the largest of the paranasal sinuses, and drains into the middle meatus of the nose. Maxillary sinus volume reaches nearly adult size between the ages of 12 and 15 which coincides with the completion of maxillary growth (Fig. 8) (Tikku et al., 2013).

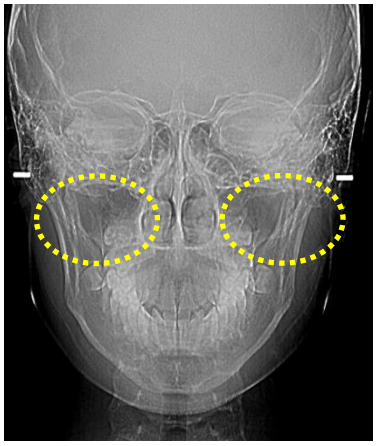


Figure 8: Maxillary right and left sinuses shown on postero-anterior x-ray.

Chronic sinusitis is defined as the inflammation of the sinuses that lasts more than 12 weeks. When sinusitis is associated with nasal polyps; as polyps swell or get larger, they start to fill the nose and cause nasal blockage or obstruction. According to the American Rhinologic Society (ARS) the sinus inflammation and swelling caused by sinusitis can force the patient to breathe through their mouth.

The chronic inflammation causes thickening of bony wall of the sinus, thereby reducing its volume. Moreover, mouth breathing individuals are more prone to developing chronic inflammation due to poorly growing sinuses which is evident in these individuals, therefore defining sinusitis as one of the causes of mouth breathing is hard since these factors are often interrelated (Tikku et al., 2013).

Treatment of sinusitis can include medications (nasal corticosteroids, antihistamines) or surgery (endoscopic sinus surgery) depending on extent and severity of the symptoms.

A study on 2,490 Brazilian children concluded that the main causes of mouth-breathing were: allergic rhinitis (81.4%), enlarged adenoids (79.2%), enlarged tonsils (12.6%), and obstructive deviation of the nasal septum (1.0%). The main clinical manifestations included sleeping with the mouth open (86%), snoring (79%), itchy nose (77%), drooling on the pillow (62%), nocturnal sleep problems or agitated sleep (62%), nasal obstruction (49%), and irritability during the day (43%) (Abreu et al., 2008).

In summary a combination of anatomic predisposition (narrow airway) plus nasal obstruction (enlarged pharyngeal tonsils, engorged nasal mucosa, deviated nasal septum) must be present to cause mouth breathing to be established on habitual basis (Emslie et al., 1952).

B. Obstructive sleep apnea (OSA)

OSA is the most common sleep-related breathing disorder and is characterized by recurrent episodes of complete or partial obstruction of the upper airway leading to reduced or absent breathing during sleep.

Lavie et al (1983) investigated the influence of partial and complete mechanical obstruction of the nasal passages in 10 young adults (5 males and 5 females, aged 20 to 27) without any ENT abnormalities. The protocol included five polysomnographic recordings (a baseline and four experimental recordings). On the 4 experimental nights, subjects slept in the laboratory for 2 nights with one nostril occluded either the left or the right, and 2 nights with both nostrils occluded by an adhesive tape. During the

baseline recordings, subjects had only a few occasional central apneas mostly associated with gross body movements (mean=1.4±1.9). The number of apneas during the nights with unilateral occlusion increased to 3.1±3.5, and to 7.9±12.2 during the nights with bilateral occlusion (p<0.03). It is conceivable, then, that increased nasal resistance and lack of nasal airflow greatly amplifies the tendency of the respiratory system to oscillate in sleep, which results in apneas in some individuals.

Reduction of muscular tonus in children with large adenoids and tonsils, or abnormal upper airway anatomy, may lead to airway obstruction and eventually to obstructive sleep apnoea (OSA). Interestingly, these children have similar craniofacial characteristics as adenoid face (Guilleminault et al., 1996). The first treatment of choice of OSA children is removal of adenoids and tonsils which in turn normalizes the hormone levels in these individuals, and is postulated to have a role in increased mandibular growth (Peltomäki, 2007). It can thus be postulated that some children with a clinical diagnosis of an adenoid face could nowadays be diagnosed as having OSA.

C. Facial growth adaptation to mouth breathing

According to Moss's functional matrix theory "All growth changes in size, shape, spatial position, and the maintenance of all skeletal units are always secondary to specific functional matrices" (i.e. capsular and periosteal matrix). The capsular matrix includes oral, pharyngeal and nasal cavity. Whenever the function carried out by capsular matrix is hampered subsequently the growth of skeletal units will be affected (Moss, 1968). Therefore, nasal breathing allows proper growth and development of the craniofacial complex interacting with other functions such as mastication and swallowing (Moss & Salentijn, 1969). Moreover, if we consider the

doctrine of functional matrices, the obstruction of nasal airways may have an impact on growth direction of facial structures (Subtelny, 1975).

Despite the evidence present in all the studies and scientific data that highlight the importance of diagnosis of mouth breathing early in life, this condition is still widely misdiagnosed or underestimated among different medical specialists. The severity and the amount of these morphologic changes depend on the age, duration, and severity of airway obstruction (Subtelny, 1975). The study conducted in the University of Toronto on 1000 consecutive patients showed that children with obstruction are significantly shorter and weigh less than children without obstruction.

Furthermore airway obstruction appears to be more severe in earlier ages so is the amount of facial adaptation to regain airway clearance (Bitar et al., 2010; Linder-Aronson et al., 1986; Macari & Haddad, 2016).

In a previous study conducted by Macari et al (2012), it was reported that facial dysmorphism is observed as early as the second year of life. The maxilla displays a posterior-inferior tilt, to preserve an open airway, the length of both arches (ANS-PNS and Co-Gn) is associated with the degree of airway obstruction, hyperdivergent growth pattern (increased palatal to mandibular plane angle; increased lower face height), incompetent lips at rest, dark under-eye circles, steep mandibular plane angle, antegonial notching, increased gonial angle, and elongated and thinner symphysis were the findings of this as well as many other studies (Hepper et al., 1990; Macari, 2008). No specific kind of malocclusion accompanies this condition, the occlusion can be ranging from normal to different types of malocclusions including: narrow maxillary arch, posterior crossbite, increased overjet, Class II molar relationship, anterior open bite and anterior crossbite (Linder-Aronson, 1970; Paul & Nanda, 1973; Subtelny, 1975;

Woodside, S, et al., 1991). Retroclined mandibular incisors and protruded maxillary incisors were also reported by some articles (Behlfelt et al., 1989; Woodside, Linder-Aronson, et al., 1991).

The shift from nasal breathing to oral mode of respiration induces a cascade of processes in the orofacial region (Fig. 9) (Solow & Kreiborg, 1977). The most severe outcome of this adaptation is named “adenoid facies” or long face syndrome (LFS) or high angle morphology, which is characterized by incompetent lips at rest, narrow width of the nose base, dark under eye circles and increased lower facial height (LFH).

Intraorally, the clinician might expect to find a narrow maxillary arch with a high palatal vault and a posterior cross bite with a Class II dental malocclusion (Basheer et al., 2014; Hernández-Alfaro, 2016; Tamkin, 2020).

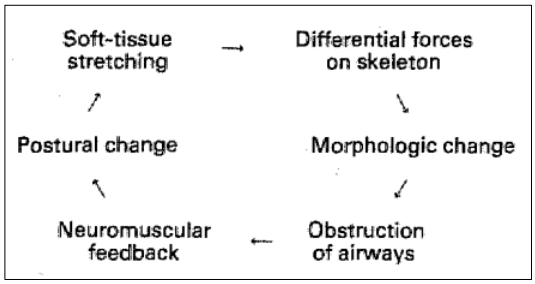


Figure 9: Suggested chain of factors relating head posture and craniofacial morphology to each other. In principle each factor may be the site of a primary affliction triggering the cycle (After Solow, 1977).

Mouth breathing during development of dentition seems to be highly correlated to the severity of malocclusion, the extend of which is determined by individual’s specific pattern of adaptation to mouth breathing, as it can also have a drastic impact on the facial morphology (J. G. Ghafari & Macari, 2013). Macari et al (2012) reported that airway measurements were smallest in children below the 6 years of age as well as in

those presenting severe hyperdivergent pattern, which denoted the most severe airway obstruction. These findings suggest airway clearance before age 6 in the most severely affected children. Therefore the emphasis on early examination no later than 5 years of age is of tremendous importance in order to detect treatable causal factors (Macari, 2008).

D. Diagnosis of mouth breathing

Diagnosis of mouth breathing is made on the basis of patient history, clinical examination and diagnostic tests. A detailed history regarding the development of the habit, duration, frequency and associated symptoms must be recorded. Patients are asked if, in their opinion, they are mouth breathers, and also whether they have dry mouth in the morning. This should be followed by a clinical examination (Nadaf et al., 2018).

1. The diagnostic tests

A reliable diagnostic test is mandatory to evaluate treatment needs. However, diagnosing an obstructed posterior airway is not always simple due to its location; no agreement has emerged on the gold standard procedure for diagnosis.

The following diagnostic tests are performed for diagnosis of mouth breathing.

a. <u>The mirror test</u>

Also called the fog test is performed when a double-sided mirror is held between the nose and the mouth. Fogging on the nasal side of the mirror indicates nasal breathing while fogging on the oral side is indicative of mouth breathing.

b. Massler's water holding test

Approximately 15 ml of water is placed in the patient's mouth and they are asked to hold it for 3 minutes (Pacheco et al., 2015; Singh, 2007).

c. Rhinometry

The total airflow through the nose and mouth can be quantified using inductive rhinometry. This allows the percentage of nasal and oral respiration to be calculated (Retory et al., 2016).

d. CT scanning, cone beam CT, and MR imaging

Three-dimensional view of the airway is an ideal imaging process. Reconstruction of the airway and surrounding soft tissue structures can be performed by these methods. These diagnostic tools provide an important role by clarifying the lateral pharyngeal walls, tongue and soft palate in modulating changes at the upper airway level (Schwab, 2001; Schwab & Goldberg, 1998).

e. Cephalometrics

Radiographs can be used in different angles to evaluate the skeletal pattern of the patients, size of the adenoids and tonsils, nasal septum and turbinates as well as the position of the hyoid bone which tends to be higher in mouth breathing children (Chung Leng Muñoz & Beltri Orta, 2014). The lateral cephalometric radiograph is a standardized sagittal radiograph of the head and neck and is the most used one for diagnosis of the upper airway obstruction. It is a simple, readily available and economical way to image the upper airway obstruction.

The cephalometric airway analysis as described by McNamara (1984) is measured from a point on the anterior half of the posterior outline of the soft palate to the closest point on the posterior pharyngeal wall (Fig. 10). McNamara considered a measurement of 5 mm or less, which he later modified to less than 3 mm (J. A. J. McNamara & Brudon, 1993), to be an indicator of possible airway obstruction. Schulhof (1978) analyzed the airway based on the percentage of nasopharynx occupied by adenoid tissue. This is determined by first constructing a trapezoid shaped area considered to represent the nasopharynx (Fig. 10) (Kluemper et al., 1995). The four sides of this area are defined as follows:

1. A line representing the palatal plane extended posteriorly beyond the skeletal atlas
2. A line perpendicular to the palatal plane that is tangent to the anterior surface of the skeletal atlas
3. A line tangent to the lower border of sphenoid registered on basion
4. A line perpendicular to the palatal plane that intersects with the palatal plane at the pterygomaxillary fissure.

Contained within the resulting trapezoid are the adenoid-pharyngeal wall area and the nasopharyngeal airway space. According to this airway analysis, the greater the percentage of this total area that is represented by the adenoid-pharyngeal wall, the less that remains for nasal airflow, and consequently the more predisposed the individual is to chronic mouth breathing.

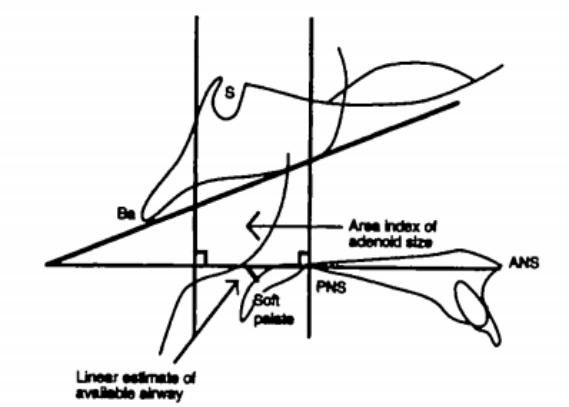


Figure 10: Illustration of area index of adenoid size by Schulhof and linear estimate of available airway by McNamara (after Kluemper et al).

Several authors have tried to determine the accuracy of airway measurements on lateral cephalographs. Maw et al (1981) attempted to correlate clinical degrees of nasal obstruction due to adenoid enlargement measured radiologically with the volume of the tissue removed during adenoidectomy, and found that there was reasonable correlation, especially between the adenoid area and the adenoid volume (r = 0.71). Conversely, they found little value in linear measurements of the superior nasopharynx (r = - 0.28) (Fig. 11).

According to Holmberg and Linder-Aronson (1979) the 3 most useful comparisons were correlating subjectively graded adenoid size during rhinoscopy with lateral cephalometric measures of subjectively graded adenoid size (r=0.71), a linear measure of the adenoid (r=0.57), and an area measure of the adenoid (r=0.60).

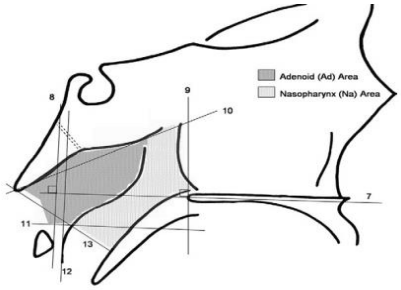


Figure 11: Adenoid (dark grey) and nasopharynx (light grey) areas, described by Maw et al. (after Major et al 2006)

Jeans et al (1981) also correlated cephalometric measurements of adenoid size to the volume of lymphoid tissue removed during adenoidectomy. Their most important measure was correlating nasopharyngeal soft-tissue area on a lateral cephalogram to adenoid volume. Using 2 observers, they found r values of 0.70 and 0.74. Furthermore, they found correlations of 0.66 and 0.67 between McNamara's line and adenoid size.

Major et al (2006) conducted a systematic review to evaluate the capability of lateral cephalograms in diagnosing hypertrophied adenoids and obstructed posterior nasopharyngeal airways. A total of 11 articles were included in this review and they concluded that both quantitative measures of adenoid area and subjective grading of adenoid size on lateral cephalograms had reasonable correlations to actual adenoid size (range of r = 0.60 to 0.88).

In summary cephalograms seem to reliably image the adenoids but are less dependable for diagnosing nasopharyngeal size. Clinicians should look for several abnormalities in adenoid and nasopharyngeal size rather than one definitive measure.

E. Treatment approaches

Mouth breathing does not invariably persist throughout life if it is not corrected during childhood. Mouth breathing and the open-mouth habit occur much less

frequently in adults. In many instances, the mouth breathing habit is self-corrected after puberty. this theory is presented by otolaryngologists stating that adenoids grow in size in pre and primary school years and then start to decrease during pre- and early adolescence (Linder-Aronson & Leighton, 1983).

The lymphoid tissue reaches nearly twice the final size before shrinking and obtaining adult size during pre-pubertal phase (Fig. 12) (Scammon et al., 1930). Nasopharynx maintains the patency of airway by corresponding increase in dimension. Otolaryngologists justify delayed removal of adenoids and tonsils based on these findings, not taking into account, that any disharmony in growth between the airway and adenoids may result in nasal obstruction or resistance (Diamond, 1980).

Mouth breathing is not physiologic and whenever discovered, should be corrected. Treatment of mouth breathing depends on the underlying cause and age of the patient. In addition, an otolaryngologist's examination is advised to determine whether the cause of obstruction is present in the tonsils, nasal septum or adenoids. If the habit continues even after the removal of cause then it is habitual.

Actual treatment can be divided into three parts: removal of nasal or pharyngeal obstructions, interception of the habit and correction of the dental effects.

1. Removal of the cause:

Etiology of mouth breathing should be treated first. Removal of nasal or pharyngeal obstruction by surgery or local medication should be sought. Allergic rhinitis is treated with either medication (nasal steroids) or surgery (reduction or excision) (Bousquet et al., 2001).

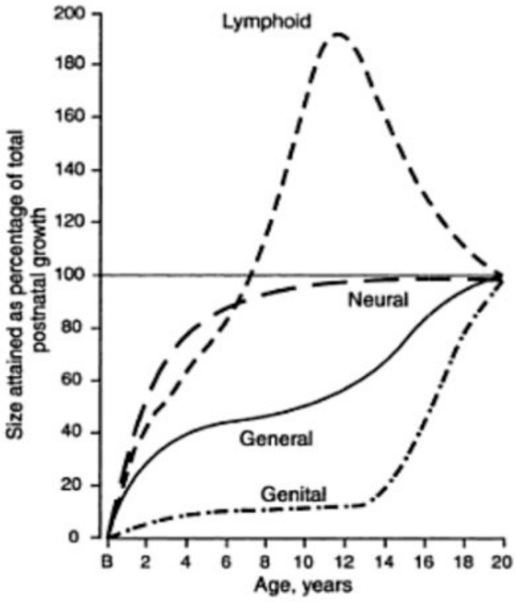


Figure 12: Postnatal growth curves of the lymphoid, neural, general and genital organs, from birth to 20 years. The lymphoid growth curve increases rapidly during infancy and childhood, and peaks before puberty to nearly twice the final size before reaching the adult volume (After Scammon, 1930).

a. Mandibular growth modification therapy

Harvold et al (1972) suggested that in patients with skeletal Class II malocclusion caused by a retrognathic mandible, the reduced space present between the cervical column, and the mandibular body may lead to posterior positioning of the tongue and soft palate causing impairment in the airway. Therefore in Cl II children with deficient mandibles generating differential growth by means of orthopedic appliances can have a positive influence on the upper airways (J. Ghafari et al., 1998; Kannan et al., 2017; Kiely et al., 1998; Tulloch et al., 1998).

Twin block treatment in patients with Cl II/1 malocclusion can result in enlargement of the oropharynx region as well as displacing the hyoid bone to an anterior position (Ghodke et al., 2014; Jena et al., 2013; Li et al., 2014). Other functional appliances, such as activator, Frankel II and bionator, have been reported to

have a positive influence on the pharyngeal airway dimensions as well (Gao et al., 2003; Hänggi et al., 2008; Ulusoy et al., 2014).

b. Maxillary appliances

i. Facemask therapy

The use of facemask in Class III patients with maxillary retrognathism can influence the upper airway dimensions. Himaya et al (2002) evaluated a total of 25 patients (mean age: 9.8 years) with Cl III malocclusion using lateral cephalograms, and concluded that maxillary protraction had a positive effect on the upper airway. Moreover Seo and Han (2017) reported significantly greater increase in airway dimensions using skeletally anchored face mask compared to tissue borne face mask therapy, and that the skeletal anchorage can improve both the superior and inferior pharyngeal airways as opposed to the conventional facemask therapy which targets the superior part mostly.

ii. Rapid maxillary expansion (RME)

RME is indicated in treatment of transverse maxillary deficiencies. This appliance can be combined with facemask therapy to increase the magnitude of protraction by reducing bony resistance.

Available information related to the ideal timing of RME treatment consists of studies of the growth and maturation of the intermaxillary sutural system. Melsen (1975) used autopsy material to histologically examine the maturation of the mid-palatal suture at different developmental stages. In the ‘‘infantile’’ stage (up to 10 years of age), the suture was broad and smooth, whereas in the ‘‘juvenile’’ stage (from 10 to 13

years) it had developed into a more typical squamous suture with overlapping sections, during the ‘‘adolescent’’ stage (13 and 14 years of age) the suture was wavier with increased interdigitation. And finally in the ‘‘adult’’ stage synostoses and numerous bony bridge formations across the suture was noted (Melsen & Melsen, 1982). The inference from these histologic data is that patients who show an advanced stage of skeletal maturation at the midpalatal suture may have difficulty undergoing orthopedic maxillary expansion. Therefore, patients treated before the pubertal peak exhibit significant and more effective long-term changes at the skeletal level in both maxillary and circum-maxillary structures. When RME treatment is performed after the pubertal growth spurt, maxillary adaptations to expansion therapy shift from the skeletal to the dentoalveolar level, (Baccetti et al., 2001) which in turn can reduce the effect of the treatment on airway dimensions.

Hershey et al (1976) evaluated the records of 6 boys and 11 girls (age 11-14) over a period of 3 months after RME treatment, and observed that expansion is not only an effective method for increasing the width of the maxillary arch but also reduces nasal resistance to levels compatible with normal nasal respiration. In addition, reduction in nasal resistance achieved with the expansion procedure was not lost after 3 months of retention.

c. Surgical approaches

i. Tonsillectomy and adenoidectomy (T&A)

Tonsillectomy is a surgical procedure in which both palatine tonsils are fully removed from the back of the throat. The procedure is mainly performed for treating

mouth breathing caused by enlarged tonsils, recurrent throat infections and OSA. In children with OSA this procedure results in improved quality of life (Mitchell et al., 2019; Venekamp et al., 2015).

Adenoidectomy is the surgical removal of the adenoid due to impaired breathing, chronic infections, or recurrent otitis media. The procedure is often combined with tonsillectomy (called an "adenotonsillectomy" or "T&A").

As mentioned earlier enlarged adenoids and tonsils are the leading cause of mouth breathing. Surgical intervention is considered in cases of severe obstructions or when other conservative treatments have failed. Early removal of adenoids and/or tonsils is indicated to resume nasal breathing. Interdisciplinary treatment done at an early age (surgery, orthodontics and orthopedics) can help to arrest or reverse development of LFS.

Bahadir et al (2006) reported that adenoidectomy caused significant relief of mouth breathing symptoms, 53 of 60 children (88.3%) completely recovered from their preoperative symptoms.

Tonsillectomy is also associated with a long-lasting improvement of health and quality of life, as well as lower utilization of medical resources. The number of visits to the doctor, the intake of analgesic drugs and antibiotics, and the number of medical absences from work also decline significantly after this surgical procedure in adults (Senska et al., 2015).

ii. Turbinectomy, septoplasty and polypectomy

Deviated nasal septum, enlarged turbinates and nasal polyps alone or in combination with enlarged adenoids and tonsils, increase the nasal resistance and therefore increase the chances of mouth breathing. Surgical correction or removal may

improve breathing. Septoplasty is not advised in growing children, because of the possible adverse effects that the procedure may have on the nose and midface region. However in number of severe cases where surgery is indicated the growth centers of the nose have to be avoided if possible (Kopacheva-Barsova & Nikolovski, 2016).

iii. Orthognathic surgery

Orthognathic surgery is the best treatment approach for adult patients with severe skeletal discrepancies whose main concern about the treatment is the esthetic outcome.

The maxillary advancement, through LeFort I osteotomy, to treat Class III patients with maxillary retrognathism leads to anterior movement of the soft palate therefore increasing the volume of the pharyngeal airway space (PAS), especially the nasopharynx (Chen et al., 2007; Sayinsu et al., 2006). In addition Hernandez-Alfaro et al (2011) reported that single-jaw mandibular advancement osteotomies, for treatment of Cl II patients with mandibular retrognathism, leads to larger pharyngeal airway spaces (78.3%) in comparison with single-jaw maxillary advancement surgeries (37.7%).

2. Interception of the habit:

Removal of obstructions usually permits normal nasal breathing. In fact, nasal breathing is resumed during daytime in almost all cases. However, in some patients, mouth breathing will persist during sleep even after the obstruction has been removed, especially in people with narrow airways. In such instances, the habit must be corrected. The correction can be done by methods such as myofunctional therapy and oral screen appliance.

First introduced by Newell in 1912, the oral screen is a piece of fitted material which rests in the labial and buccal vestibule and thus prevents the passage of air through the mouth. It usually is worn at night to correct the tendency to habitual nocturnal mouth breathing (Fig. 13) (Dickin, 1934).

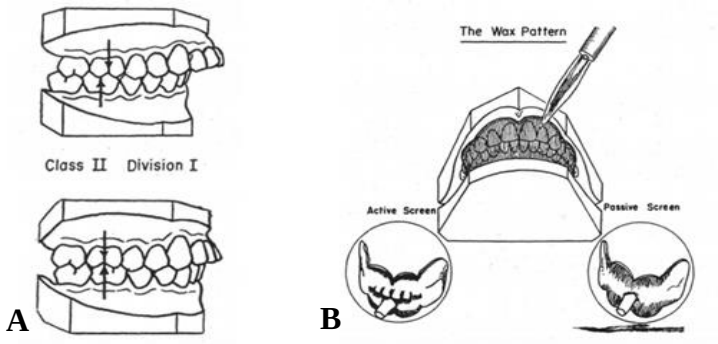


Figure 12: Orientation of casts in order to reduce overjet, when present, prior to making wax pattern for construction of plastic oral screen (A). Wax pattern. Note impression of the teeth to be moved in the active screen (B). (After Massler, 1939)

F. Reversal to nose breathing

Enlarged tonsils may necessitate an anterior tongue posture, depression of the mandible, and an open bite formation. With anterior tongue posturing and some degree of mouth breathing, it is conceivable that steepness of the lower border of the mandible may occur with continued growth and development. This, in conjunction with potential eruption of posterior teeth, may lead to increased lower facial height, as seen in adenoid cases studied by Sten Linder-Aronson.

In many instances after surgical removal of enlarged tonsils in growing children, a change in tongue posture and occlusion can be observed. The posterior repositioning of the tongue can enhance further eruption of anterior teeth, therefore an anterior open

bite may self-correct with continued growth and development of the jaws (Subtelny, 1975).

The first follow up study about the effect of adenoidectomy on mode of breathing, was conducted by Linder-Aronson (1970) which included 80 children who underwent adenoidectomy and 80 controls. The results show that 1 year after adenoidectomy, the incidence of mouth breathing had fallen from 90% to 20 ± 5.7. In most cases the result of the operation was permanent. Moreover, there was a better agreement between the 2 groups 1 year after adenoidectomy than before. In addition, the improvement in nasal airflow after adenoidectomy persisted throughout the year immediately after the operation.

Linder-Aronson et al (1986) reported changes in mandibular form and position after adenoidectomy in a 5-year longitudinal study on 38 children. They reported more anterior direction of growth in symphysis, counter-clockwise rotation of the mandible, increased mandibular growth but no change in the direction of maxillary growth. Additionally, the labial inclination of mandibular incisors was significantly increased.

Adenoidectomy does not always results in nose breathing, some studies reported that 20% of the original sample did not resume nasal mode of breathing (Kerr et al., 1989; Subtelny, 1975; Woodside, S, et al., 1991). Furthermore, no compromise of humoral and cellular immunity have been reported in any studies (Kaygusuz et al., 2009).

In terms of dental arch width, malocclusion, palatal height, overjet, overbite, dental arch perimeter, and arch length, a tendency toward normalization is evident following adenoidectomy or tonsillectomy, with no significant differences present between the surgical and control groups (Zhu et al., 2016).

Woodside et al (1991) also reported about growth magnitude and direction stating that the adenoidectomy improves nasal airflow in children with severe nasal obstruction. Greater downward and forward chin displacement is observed in surgical children than in controls for both sexes (approximately 3.0 mm). At the same time, the midface showed a small increase in growth (1.2 mm) at subnasale in the boys. In addition after adenoidectomy the mandibular growth direction in girls was more horizontal than in controls ($p < 0.02$). More anterior direction of symphyseal growth after adenoidectomy and significant relief of mouth breathing symptoms have also been reported in other publications (Bahadir et al., 2006; Kerr et al., 1989).

Paradise et al (1984) conducted a parallel non-randomized and randomized clinical trial in which the efficacy of tonsillectomy, or tonsillectomy combined with adenoidectomy procedures were evaluated over a 3 year period in 187 children. 91 of the children were assigned randomly to either surgical or nonsurgical treatment groups, and 96 were assigned according to parental preference. As a result in both intervention groups, the effects of tonsillectomy alone and of tonsillectomy with adenoidectomy were similar, furthermore the incidence of throat infection during the first two years of follow up was significantly lower ($P \leq 0.05$) in the surgical groups than in the corresponding nonsurgical groups. Third-year differences, although in most cases not significant, also consistently favored the surgical groups.

Woodside et al (1991) compared cephalometric and dental casts of 30 male and 20 female children, 8 to 13 years old, with chronic nasal mucosal swelling, to those of controls. The subjects selected had significantly more mandibular incisor crowding, significantly smaller mandibular arch widths, and smaller maxillary arch widths than

the controls. The male subjects had significantly smaller mandibular arch widths than the male controls ($p < 0.01$).

Cephalometric comparison of 33 mouth breathing children who restored to nasal breathing after surgery with 22 controls, age between 3 and 6, by Mattar et al (2011) 24 months after surgery, concluded that After dolichofacial pattern persisted, even though there was a significant normalization in the growth direction of the mouth breathing group. There was a decrease in the inclination of the mandibular plane, in the gonial angle, and an increase in the posterior facial height. The difference between the studied groups reached a significant similarity after respiratory correction.

Hultcrantz et al (1991) investigated the influence of tonsillectomy on facial growth and dental arch morphology on dental casts and lateral cephalograms of 20 children, age of 3.4-5.8 years, before and 2 years after surgery, and reported that 2 years after surgery, 77% of the open bites and 50-65% of the crossbites were corrected. The best results were seen in children operated before the age of 6.

These findings reinforce the results of Linder-Aronson (1970) that mouth breathing is particularly common among children with enlarged adenoids and a small nasopharynx. Generous removal of adenoid tissue is, therefore, justified in these children in order to promote a change from mouth to nose breathing. Although, some proportion of persistent mouth breathers is likely to remain even after surgery (9-31%) (Linder-Aronson, 1973).

G. Research Significance

Findings from this study demonstrate the long-term effect of treatment of mouth breathing in normalization of facial growth in children and the importance of diagnosis

of impaired nasal breathing by pediatricians and pediatric otolaryngologists early in childhood. The adverse effect of enlarged adenoids and tonsils and other etiologic factors leading to nasal obstruction or resistance must be recognized and treated as soon as diagnosed in order to increase the chances of complete reversal of growth process. Comparing these individual in two different time points, can help the physician in better understanding of best timing of interventions. The longitudinal aspect of the research over 10 to 14 years after diagnosis, the longest follow-up period to be studied, is an element of strength, particularly considering that many of the patients would be evaluated after puberty and after orthodontic treatment. In this context, the success of this treatment will be measured against the perceived need for surgery at the time of early diagnosis and subsequent surgical intervention. In addition, changes in facial morphology will be delineated relative to treatment approach.

H. Specific Aims

1. To evaluate, at 10 years follow up, the craniofacial changes of a unique study population, who presented to pediatric Otolaryngologist for consultation during 2006-2008, with history of mouth breathing at the initial visit.
2. To recognize guidelines for airway obstruction treatment in relation to age and severity.
3. To observe the long term results of different treatment modalities on facial morphology.

I. Hypothesis

1. Less severe to absence of dentofacial abnormalities in posttreatment follow up examination.
2. Airway clearance is more beneficial in early versus late childhood regarding the growth of the dentofacial structures.
3. The more severe the obstruction the less normalization of dentofacial features will be expected in the 10 year posttreatment follow up.

CHAPTER III

MATERIAL AND METHODS

A. Material

1. Subjects

The subjects enrolled in this current follow up investigation were previously recruited in a study conducted at AUBMC (2006-2008), investigating the effect of mouth breathing on dentofacial structures. The initial study included a total of 280 patients with a mean age of 6.0 years, ranging between 1.7 and 12.6 years(Macari, 2008). Those 280 children were referred by pediatric otolaryngologist to the orthodontic clinics at the American University of Beirut-Medical Center to evaluate adenoid hypertrophy on cephalometric radiographs. .

Out of the 280 children, a total of 57 individuals (35 males and 22 females) with a mean age of 19.09 years and ranging between 15.1 and 25.2 years agreed to participate, and were enrolled in this current study only if they met the following inclusion and exclusion criteria:

a. Inclusion criteria:

   Patients diagnosed with mouth breathing between 2006 and 2008 with an existing lateral cephalogram at the time of diagnosis.

b. Exclusion criteria:

   Pregnant women.

2. Recruitment strategy

After obtaining Ethical approval from the Institutional Review Board (IRB) at the American University of Beirut, the patients were contacted by phone calls, and were introduced to the follow up study. after receiving their oral agreement to participate, an appointment was scheduled, during which a written consent form was obtained from the participant or the legal guardian at the division of Orthodontics and Dentofacial Orthopedics at the American University of Beirut.

3. Records

The patient's medical and dental history, including history of Adenoidectomy and/or tonsillectomy (T&A) and persistence of mouth breathing was assessed and noted. All follow-up cephalometric radiographs were taken in the radiology unit in the division of Orthodontics and Dentofacial Orthopedics in the same machine the cephalographs were taken in the initial study of 2006-2008. Patients wore a lead apron before radiation exposure. The patient's head was positioned in the cephalostat (GE, Instrumentarium, Finland) in natural head position (Lundström et al., 1995) with midsagittal plane perpendicular to the machine platform. Subjects were asked to keep their teeth in occlusion and in retruded contact position with the lips gently closed. The radiographs were stored and saved spontaneously in the radiology unit's computer.

Dental and facial photographs were taken using one specific camera (CANON, EOS 1300D, Taiwan). The facial photographs included: Two anterior views – one with lips relaxed and slightly touching and one smiling. Patient's head was oriented accurately, head leveled, not tilted and parallel with the Frankfort horizontal plane, chin up; the ears were exposed for purpose of orientation, eyes were looking straight ahead.

Lateral views were taken when the patients were looking directly ahead of themselves. The intra-oral photographs included one frontal view with the teeth in maximum intercuspation, two lateral views (right and left) with the teeth in occlusion, overjet and maxillary and mandibular occlusal views with the use of the mouth mirror were taken as well; the teeth and mouth were dried with the air gun present in the dental unit and the use of suction, the cheeks were held away from the dentition with the use of cheek retractors. All photos were stored in a digital folder named “photographs”.

The oral scan was taken using a single intra-oral scanner device (3Shape, Trios 3, Denmark), the mandibular and maxillary dentition and the bite were registered. Before each arch was scanned the patient was asked to swallow to reduce the amount of saliva present. The scan was then compared to the actual bite of the patient to ensure accuracy. The files were stored within the same computer that was used for scanning purposes.

In addition, a series of questions, to assess the risk of OSA taken from STOP-BANG and Epworth Sleepiness Scale were answered by the patients. These questionnaires are of importance since the severity of sleep apnea is a major determinant of the time spent breathing orally and oronasally (Koutsourelakis et al., 2006).

B. Methods

1. Cephalometric measurements

One investigator (AB) imported the lateral cephalometric radiographs, taken in the two different time points (the original study timepoint T1 and the current follow-up timepoint T2), into the Dolphin Imaging® program, and after orienting them in natural

head position, digitized them. Definition of the soft and hard tissues landmarks are listed in Tables 1 and 2, their locations on lateral cephalograms are shown in Figs. 14 and 15.

Angular and linear measurements (Table 3) were computed to evaluate the sagittal and vertical positions of the maxilla, mandible and their corresponding dental components, relative to the cranial base, to each other and between the two x-rays to evaluate the direction as well as the amount of the growth of each individual. A sample of the digitized data is shown in Figs. 16 and 17.

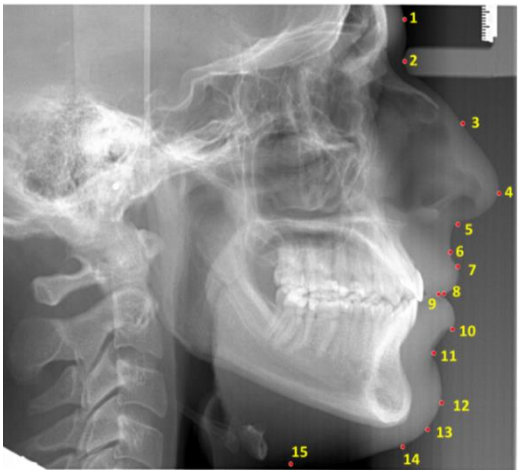


Figure 14: Soft tissue landmarks: 1. glabella; 2. soft tissue nasion; 3. bridge of nose; 4. tip of nose; 5. subnasale; 6. soft tissue A point; 7. upper lip; 8. stomion superius; 9. stomion inferius; 10. lower lip; 11. soft tissue B point; 12. soft tissue pogonion; 13. soft tissue gnathion; 14. soft tissue menton; 15. throat point.

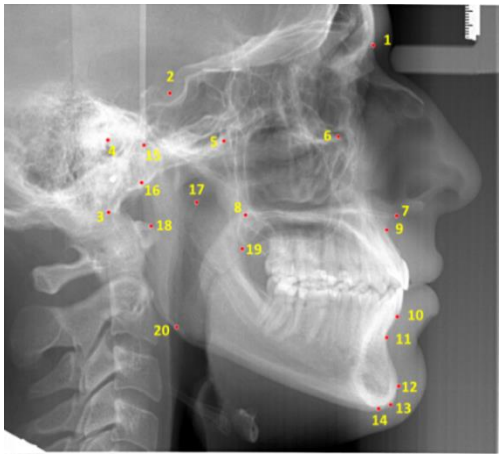


Figure 15: Hard tissue landmarks: 1. nasion; 2. sella; 3. basion; 4. porion; 5. pterygoid point; 6. orbitale; 7. anterior nasal spine; 8. posterior nasal spine; 9. A point; 10. infradentale; 11. B point; 12. pogonion; 13. gnathion; 14menton; 15. condylion; 16. articulare; 17. sigmoid notch; 18. ramus point; 19. mid ramus; 20.gonion.

Table 1: Definition of soft tissue landmarks

Nb	Landmark	Definition
1	Glabella	The most prominent or anterior point in the midsagittal plane of the forehead at the level of the superior orbital ridges
2	Soft tissue nasion	The point of intersection of the soft-tissue profile with a line drawn from the center of sella turcica through nasion
3	Bridge of the nose	The mid-point from soft tissue nasion to tip of nose
4	Pronasale (tip of the nose)	The most prominent or anterior point of the nose tip
5	Subnasale	The midpoint of the columella base where the lower border of the nasal septum and the surface of the upper lip meet
6	Soft tissue A point	The deepest point on the upper lip contour determined by an imaginary line joining subnasale with the laberale superius
7	Upper lip	The midpoint of the upper vermilion line
8	Stomion superius	The most inferior point traced on the upper lip
9	Stomion inferius	The most superior point traced on the lower lip
10	Lower lip	The midpoint of the lower vermilion line
11	Soft tissue B point	The point at the deepest concavity between laberale inferius and soft-tissue pogonion
12	Soft tissue pogonion	The most prominent or anterior point on the soft-tissue chin in the mid-sagittal plane
13	Soft tissue gnathion	The midpoint between soft-tissue pogonion and soft-tissue menton

14	Soft tissue menton	The most inferior point on the soft-tissue chin
15	Throat point	The intersection of lines tangent to the neck and the throat line

Table 2: Definition of hard tissue landmarks

Nb	Landmark	Abbreviation	Definition
1	Nasion	N	The intersection of the most anterior point of the nasofrontal suture
2	Sella	S	The center of Sella Turcica, as seen in the lateral radiograph and located by inspection
3	Basion	Ba	The most inferior point on the anterior margin of the foramen magnum in the midsagittal plane
4	Porion	Po	The highest point on the roof of the external auditory meatus
5	Pterygoid point	Pt	The most posterior point on the outline of the pterygopalatine fossa
6	Orbitale	Or	The lowest point on the lower margin of the orbit
7	Anterior nasal spine	ANS	The most anterior point of the nasal floor; tip of premaxilla on midsagittal plane
8	Posterior nasal spine	PNS	The most posterior point on the contour of the bony palate
9	A point	A	The deepest point on the premaxilla between anterior nasal spine and dental alveolus
10	Infradentale	ID	The most anterior superior point on the mandibular alveolar process
11	B point	B	The deepest midline point on the mandible between infradentale and pogonion
12	Pogonion	Pog	The most convex point on the mandibular symphysis
13	Gnathion	Gn	The lowest point of the mandibular symphysis
14	Menton	Me	The most inferior point on the symphysis of the mandible in the midsagittal plane
15	Condylion	Co	The most posterior superior point on the condyle of the mandible
16	Articulare	Ar	The point of intersection posterior margin of the ramus and the outer

			margin of the cranial base
17	Sigmoid notch	SIG	The deepest point on the sigmoid notch of the mandible
18	Ramus point	Rp	The most posterior point at the border of the ramus
19	Mid ramus	mR	The most concave point on the anterior border of the ramus
20	Gonion	Go	The point at the intersection of lines tangent to the posterior border of the ramus and the lower border of the mandible

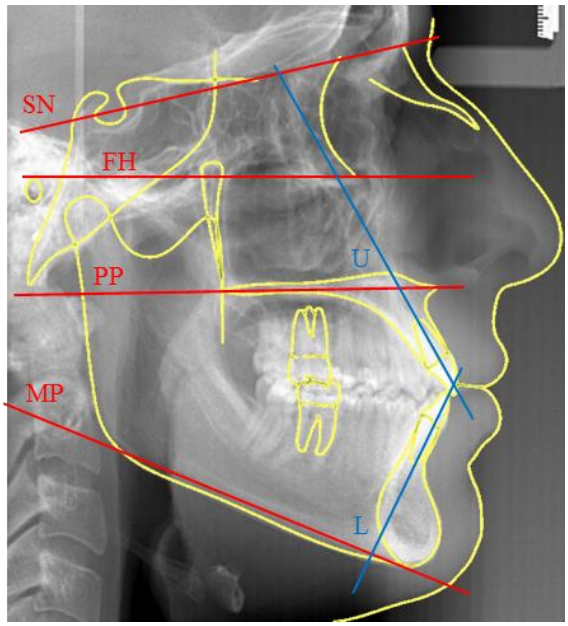
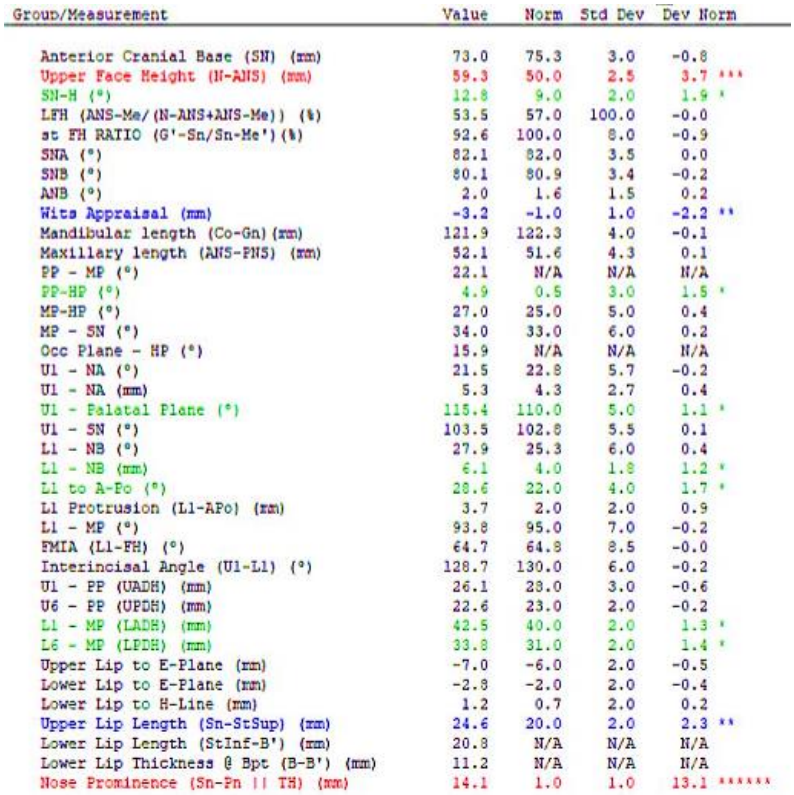


Figure 16: A sample of the outcome tracing and lines after landmarks digitization. Skeletal planes (red): MP. Mandibular; PP. Palatal; FH. Frankfort Horizontal; SN. Anterior cranial base. Dental incisors long axis (blue): U. Maxillary incisor; L. Mandibular incisor.



Group/Measurement	Value	Norm	Std Dev	Dev Norm
Anterior Cranial Base (SN) (mm)	73.0	75.3	3.0	-0.8
Upper Face Height (N-ANS) (mm)	59.3	50.0	2.5	3.7 ***
SN-H (°)	12.8	9.0	2.0	1.9 *
LFH (ANS-Me/(N-ANS+ANS-Me)) (%)	53.5	57.0	100.0	-0.0
st FH RATIO (G'-Sn/Sn-Me') (%)	92.6	100.0	8.0	-0.9
SNA (°)	82.1	82.0	3.5	0.0
SNB (°)	80.1	80.9	3.4	-0.2
ANB (°)	2.0	1.6	1.5	0.2
Wits Appraisal (mm)	-3.2	-1.0	1.0	-2.2 **
Mandibular length (Co-Gn) (mm)	121.9	122.3	4.0	-0.1
Maxillary length (ANS-PNS) (mm)	52.1	51.6	4.3	0.1
PP - MP (°)	22.1	N/A	N/A	N/A
PP-HP (°)	4.9	0.5	3.0	1.5 *
MP-HP (°)	27.0	25.0	5.0	0.4
MP - SN (°)	34.0	33.0	6.0	0.2
Occ Plane - HP (°)	15.9	N/A	N/A	N/A
U1 - NA (°)	21.5	22.8	5.7	-0.2
U1 - NA (mm)	5.3	4.3	2.7	0.4
U1 - Palatal Plane (°)	115.4	110.0	5.0	1.1 *
U1 - SN (°)	103.5	102.8	5.5	0.1
L1 - NB (°)	27.9	25.3	6.0	0.4
L1 - NB (mm)	6.1	4.0	1.8	1.2 *
L1 to A-Po (°)	28.6	22.0	4.0	1.7 *
L1 Protrusion (L1-APo) (mm)	3.7	2.0	2.0	0.9
L1 - MP (°)	93.8	95.0	7.0	-0.2
FMIA (L1-FH) (°)	64.7	64.8	8.5	-0.0
Interincisal Angle (U1-L1) (°)	128.7	130.0	6.0	-0.2
U1 - PP (UADH) (mm)	26.1	28.0	3.0	-0.6
U6 - PP (UPDH) (mm)	22.6	23.0	2.0	-0.2
L1 - MP (LADH) (mm)	42.5	40.0	2.0	1.3 *
L6 - MP (LPDH) (mm)	33.8	31.0	2.0	1.4 *
Upper Lip to E-Plane (mm)	-7.0	-6.0	2.0	-0.5
Lower Lip to E-Plane (mm)	-2.8	-2.0	2.0	-0.4
Lower Lip to H-Line (mm)	1.2	0.7	2.0	0.2
Upper Lip Length (Sn-StSup) (mm)	24.6	20.0	2.0	2.3 **
Lower Lip Length (StInf-B') (mm)	20.8	N/A	N/A	N/A
Lower Lip Thickness @ Bpt (B-B') (mm)	11.2	N/A	N/A	N/A
Nose Prominence (Sn-Pn || TH) (mm)	14.1	1.0	1.0	13.1 ******

Figure 17: A sample of the measurements colored according to deviation from norm.

Table 3: Angular and linear measurements.

Category		No	Landmark	Definition
Cranial base		1	SN	Length of anterior cranial base
		2	S-Ar	Length of posterior cranial base
		3	N-S-Ar	Saddle angle
Relationship between jaws and cranial base	Sagittal	4	SNA	Angle between anterior cranial base and point A
		5	SNB	Angle between anterior cranial base and point B
	Vertical	6	PP/H	Angle between palatal plane and the true horizontal
		7	MP/H	Angle between mandibular plane and the true horizontal
		8	MP/SN	Angle between anterior cranial base and mandibular plane
Relationship between jaws	Sagittal	10	ANB	Angle between point A and B
		11	AoBo	Distance between the lines drawn from points A and B perpendicular to the occlusal plane
	Vertical	12	PP/MP	Angle between palatal plane and

				mandibular plane
		13	LFH/TFH	Ratio between lower facial height and total facial height
Jaw specific measurements	Maxilla	14	ANS-PNS	Maxillary length
	Mandible	15	Go-Me	Mandibular body length
		17	Ar-Go	Ramus height
		18	Co-Gn	Mandibular length
		19	Ar-Go-Me	Gonial angle
Relationship between jaws and teeth	Maxilla	20	U1/NA	Angle between maxillary incisor long axis and the line joining nasion to point A
		21	U1-NA	Distance between maxillary incisor long axis and the line joining nasion to point A
		22	U1/PP	Angle between maxillary incisor long axis and palatal plane
		23	U1/SN	Angle between maxillary incisor long axis and anterior cranial base
	Mandible	24	L1/NB	Angle between mandibular incisor long axis and the line joining nasion to point B
		25	L1-NB	Distance between mandibular incisor long axis and the line joining nasion to point B
		26	L1/Apo	Angle between mandibular incisor long axis and the line joining pogonion to point A
		27	L1-Apo	Distance between mandibular incisor long axis and the line joining pogonion to point A
		28	L1/MP	Angle between mandibular incisor long axis and mandibular plane
Relationship between teeth		29	U1/L1	Angle between Maxillary and mandibular incisor long axis
		30	OB	Overbite
		31	OJ	Overjet

2. Airway assessment

Two linear measurement methods were used to quantify the amount of airway clearance (Fig. 18).

a- Shortest distance between adenoid and soft palate (SAD)

b- Distance between the maximum convexity point and the soft palate (CAD)

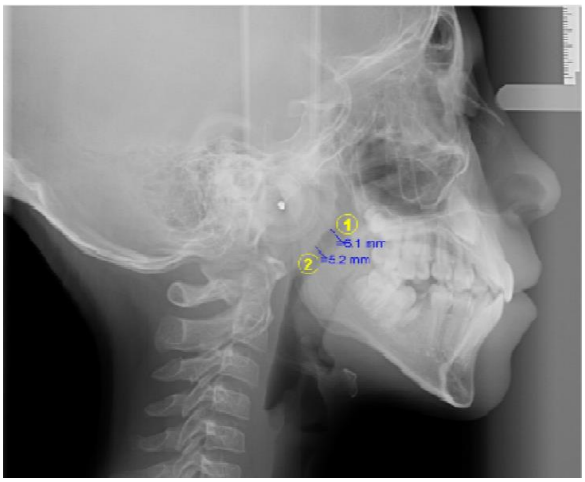


Figure 18: Linear measurements of airways: 1. Distance between adenoid most convex point and soft palate (CAD); 2. The shortest distance between adenoid and soft palate (SAD).

3. Dental measurements

All intraoral scans were imported into the 3Shape Ortho Analyzer software. The mesiodistal width of each tooth in both arches was measured. The arch length discrepancy was computed by the software (Fig. 19).

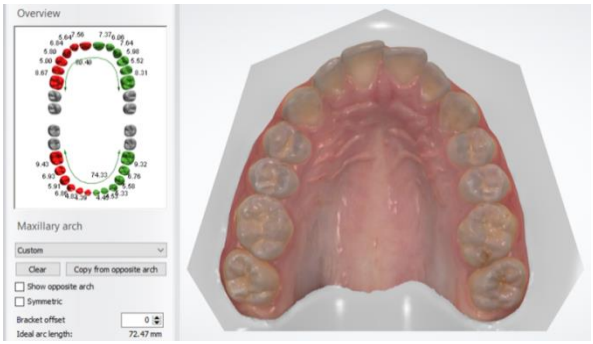


Figure 19: A sample of maxillary arch scan as well as the arch length discrepancy analysis.

4. Photographs

All dental and facial photographs were centered, cropped and imported to a file dedicated to the study. The photographs in combination with the oral scan and lateral

cephalogram were used to distinguish different occlusions among different treatment modalities (Fig. 20,21).

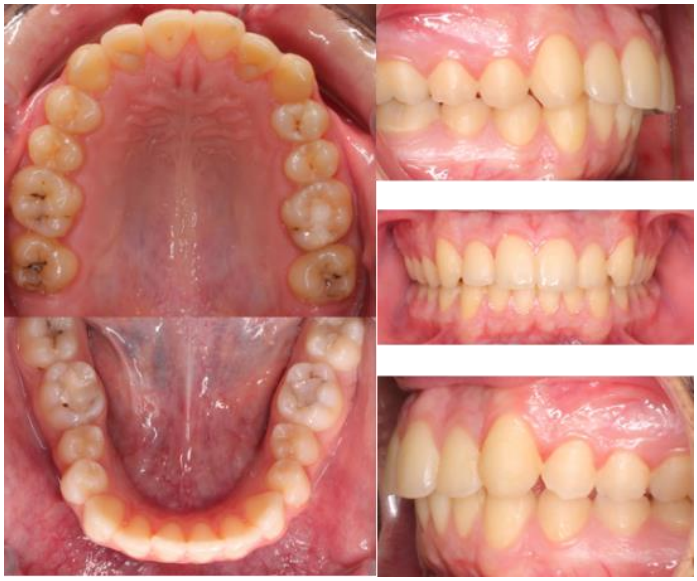


Figure 20: Sample of intra-oral photographs.

Figure 21: Sample of extra-oral photographs.

5. Questionnaires

One investigator (AB) imported the data and computed the cumulative values of each questionnaire in order to define the OSA risk of each participant. The list of questions included in each questionnaire is listed in Figs. 22 and 23.

STOP BANG Questionnaire

Height _____ inches/cm Weight _____ lb/kg
Age _____
Male/Female
BMI _____
Collar size of shirt: S, M, L, XL, or _____ inches/cm
Neck circumference* _____ cm

1. *S*noring
Do you *s*nore loudly (louder than talking or loud enough to be heard through closed doors)?
Yes No

2. *T*ired
Do you often feel *t*ired, fatigued, or sleepy during daytime?
Yes No

3. *O*bserved
Has anyone *o*bserved you stop breathing during your sleep?
Yes No

4. Blood *p*ressure
Do you have or are you being treated for high blood *p*ressure?
Yes No

5. *B*MI
*B*MI more than 35 kg/m2?
Yes No

6. *A*ge
*A*ge over 50 yr old?
Yes No

7. *N*eck circumference
*N*eck circumference greater than 40 cm?
Yes No

8. *G*ender
*G*ender male?
Yes No

Figure 22: STOP-BANG questionnaire for OSA, contains questions regarding the snoring, fatigue, stopped breathing during sleeping, high blood pressure, BMI index, age, neck circumference and gender of the patient. Answering yes to 3 or more items results in high risk of OSA.

Epworth Sleepiness Scale[11]

How likely are you to nod off or fall asleep in the following situations, in contrast to feeling just tired? This refers to your usual way of life in recent times.

Even if you haven't done some of these things recently, try to work out how they would have affected you. It is important that you answer each question as best you can.

Use the following scale to choose the most appropriate number for each situation.

	Would never nod off 0	Slight chance of nodding off 1	Moderate chance of nodding off 2	High chance of nodding off 3
Sitting and reading				
Watching TV				
Sitting, inactive, in a public place (e.g., in a meeting, theater, or dinner event)				
As a passenger in a car for an hour or more without stopping for a break				
Lying down to rest when circumstances permit				
Sitting and talking to someone				
Sitting quietly after a meal without alcohol				
In a car, while stopped for a few minutes in traffic or at a light				

Figure 23: Epworth sleepiness scale. Evaluates the risk of a person falling asleep in different situations by categorizing them into: no chance (0), slight (1), moderate (2) and high chance of nodding off (3). The points are added up to calculate the total score. A score of 10 or more suggest that the person may need more sleep, needs to change sleep practices or needs medical evaluation to find out the cause of the sleepiness.

6. Statistical methods

Descriptive statistics were computed for all the variables at T1 and T2 time points. The difference (T2-T1) was calculated for all the variables and descriptive statistics were also generated for the differences. The Shapiro Wilk normality test was used to evaluate the distribution of the data prior to any statistical analysis. Paired samples t test, or its equivalent for non-parametric data (The Wilcoxon test), were conducted to compare the means of the different variables between the 2 time points

(T1 and T2). Independent samples t tests, or its equivalent for non-parametric data (The Mann Whitney U test), were performed to compare the means of the variables between surgical and non-surgical groups, as well as between different genders, mouth breathers and nose breathers, and between patients who underwent orthodontic treatment and the untreated group. Furthermore, the surgical group was divided according to the age at which the surgery was performed (below or over 6 years) and an independent samples t test was conducted to evaluate any significant differences. The Paired t test was also used to compare surgical and non-surgical groups to their matched controls.

The Pearson product moment correlation coefficient was computed for associations between age and different cephalometric measures.

For measurements that were significantly different at a bivariate level, multiple linear regressions were performed to highlight possible predictors for the outcome variables.

Univariate analysis of covariance (ANCOVA) was performed to compare the means of the main outcomes between surgical and non-surgical groups, adjusting for the effect of age and time.

General linear model (GML) for repeated measures was used to generate graphs representing the difference of the main outcomes between surgical and non-surgical groups over time.

Finally, independent samples t tests were used, along with ANOVA to compare the SAD variable at T2 between the surgical/non-surgical groups and the questionnaires based on the severity scores.

SPSS *27.0* statistical software was used to perform all tests and the level of significance was set to < 0.05.

CHAPTER IV

RESULTS

A. Sample characteristics

A total of 57 patients (35 males and 22 females) with a mean age of 19.09 years and ranging between 15.1 and 25.2 years, were enrolled in this study.

1. Medical and dental history

Thirty four participants had adenoidectomy performed to remove nasal airway obstruction and restore normal breathing mode, whereas the remaining 23 individuals were treated with medications only. Mouth breathing at night was reported by 20 patients in total. Moreover 17 patients reported having orthodontic treatment during the past 10 years.

Subjects were classified into surgical group if they had adenoidectomy done and non-surgical group if they were treated with medication only. Subgroupings on age at which surgery was performed (above or below 6 years of age), breathing status (through nose or mouth), gender and orthodontic treatment were done. In addition, the two main groups were compared to class I control groups which were matched to each subject according to age and gender.

2. Intra-examiner reliability

The intra-class correlation coefficients (ICC) gauging intra-examiner reliability of repeated measurement was higher than 0.9 for all cephalometric measurements with a p-value of <0.000.

B. Comparison of surgical and non-surgical groups

The surgical group included 34 subjects (21 males and 13 females) who underwent surgical removal of adenoids; the non-surgical group included 23 participants (14 males and 9 females). The mean age of the surgical group at T1 was 5.31±1.99 while the mean age of non-surgical group was 7.24±3.17, at T2 the ages were 18.4±2.03 and 19.4±3.07 respectively (Table 4).

1. Cephalometric measurements

The cephalometric measurements of surgical and non-surgical groups at T1 and T2 and the analysis of their mean difference are displayed in Tables 4 and 5. Comparison between surgical group at T1 and T2, and surgical group to the corresponding matched controls are presented in tables 6 and 7. In tables 8 and 9 results of the comparison between the non-surgical group at T1 and T2, and non-surgical group to matched controls are shown.

a. Skeletal measurements

Statistically significant difference in mandibular length and facial height existed between the two groups at T1, Go-Pg (p= 0.04), Co-Gn (p=0.04) (Fig. 24) and N-Gn (p=0.02), with the surgical group exhibiting shorter mandibular length and face height. However these parameters were no longer significantly different at T2. There were more extensive changes in these measurements in the surgical group over time which helped this group to have similar parameters with its non-surgical counterparts at T2.

The mean differences of SN-Me (p=0.03), and N-Gn (p=0.02) were statistically significantly different. In the surgical group, SNA decreased from 86.06° to 83.43°

while in the non-surgical group no statistically significant changes were observed (84.67° to 84.57°) (p=0.02) (Fig. 25). When comparing to corresponding controls, SNA was significantly larger than controls (82.50°) in the non-surgical group (p=0.02), while in the surgical group it was similar (82.13°).

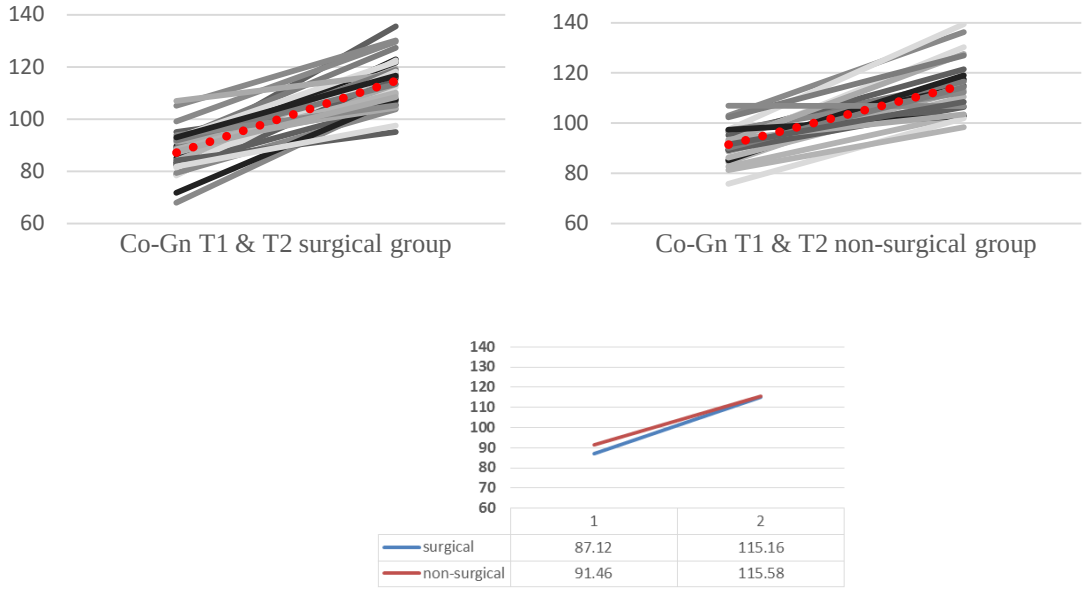


Figure 24: Graphs representing the Co-Gn measures from T1 to T2 in surgical and non-surgical groups and the difference between the means. Each line in the top graphs represents 1 patient; the dotted red lines as well as the bottom graph represent the mean of the sample.

The gonial angle (Ar-Go-Me) was significantly improved in both groups but more changes were observed in the surgical group (137.69° to 125.31°) as opposed to the non-surgical group (133.90° to 126.66°) which resulted in more gonial angle closure in the surgical group (p=0.01) (Fig. 26). The gonial angle was also smaller in the surgical group (125.31°) compared to controls (129.03°) (p=0.01) (Fig. 27).

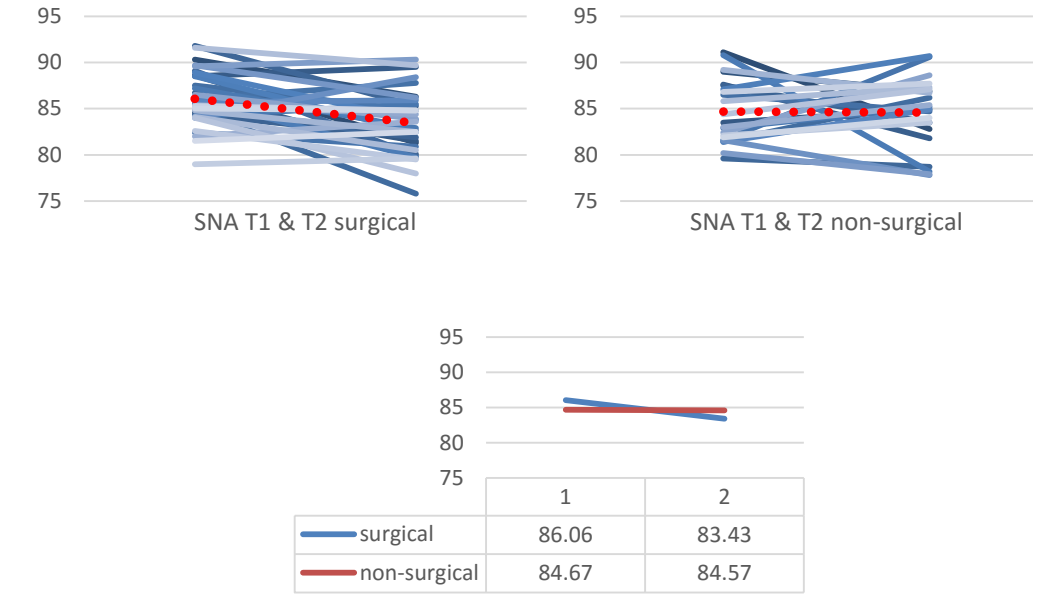


Figure 25: Graphs representing the measures of SNA from T1 to T2 in surgical and non-surgical groups and the difference between the means. Each line in the top graphs represents 1 patient; the dotted red lines as well as the bottom graph represent the mean of the sample.

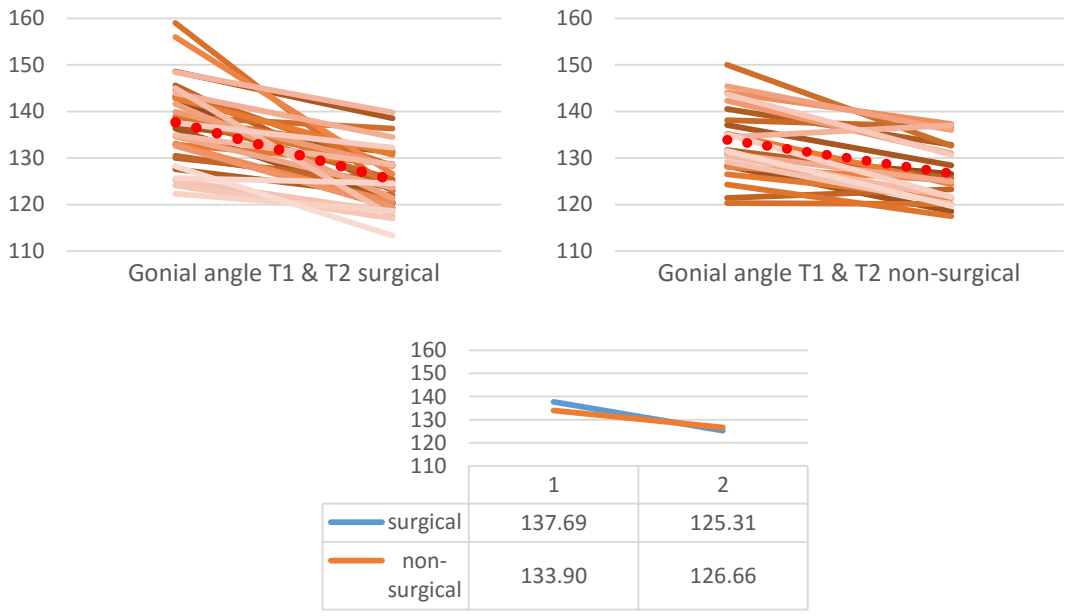


Figure 26: Graphs representing the measures of Ar-Go-Me from T1 to T2 in surgical and non-surgical groups and the difference between the means. Each line in the top graphs represents 1 patient; the dotted red lines as well as the bottom graph represent the mean of the sample.

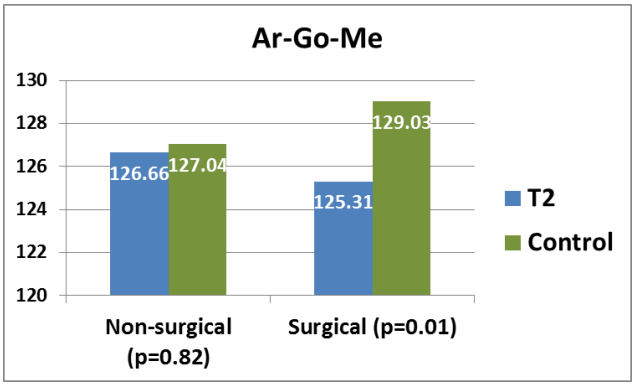


Figure 27: Graph representing the Ar-Go-Me measurements of surgical and non-surgical groups to their matched controls at T2.

When comparing each group within their corresponding time points, significant differences were observed in all the measurements except for AoBo, and SNB in the surgical group. As for the non-surgical group N-S-Ar, ANB, AoBo, and SNA measurements did not show any significant changes over time. As mentioned earlier, no changes occurred in SNA angle with time in the non-surgical group, nevertheless, it was larger (84.57°) than the controls (82.50°) projecting a more protruded maxilla (p= 0.02) (Fig. 28).

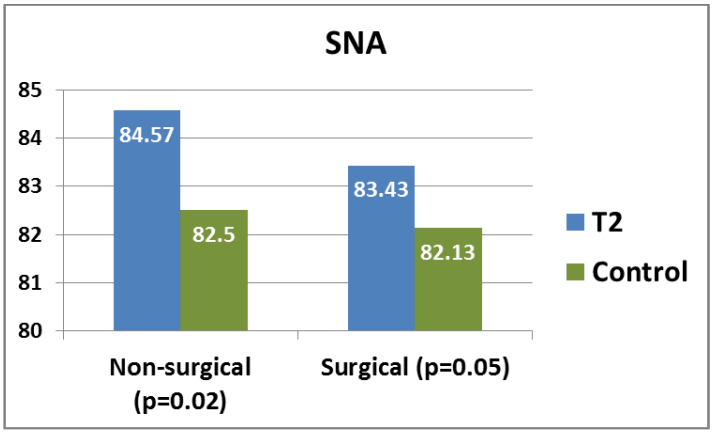


Figure 28: Graph representing the SNA measurements of surgical and non-surgical groups to their matched controls at T2.

The inter-jaw relationship (PP/MP) improved more with time in the surgical group (5.56°) than the non-surgical group (4.34°). However the changes were not statistically significant (p=0.41). It is noteworthy that the value of PP/MP (p=0.02) was 23.80° in the surgical group as opposed to 26.84° in the controls, in the non-surgical group this value was higher (25.66°) than the controls (24.03°) (p=0.37) (Fig. 29).

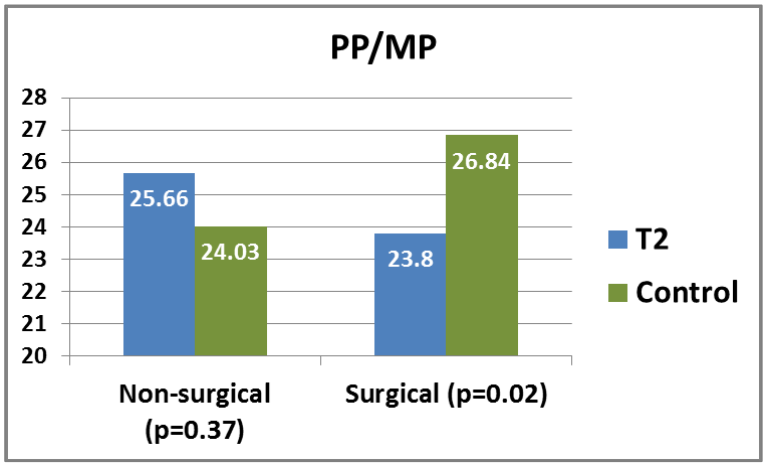


Figure 29: Graph representing the PP/MP measurements of surgical and non-surgical groups to their matched controls at T2.

b. Dental measurements

The maxillary incisors (U1/PP) (p=0.03) were more proclined in the surgical group than the non-surgical one at T2 (115.59° compared to 111.98°) as well as in comparison to controls (112.23°). All measurements for both groups were statistically significant when comparing T1 to T2 expect for overjet in the surgical group (p=0.34), as well as overjet and overbite in the non-surgical group (p= 0.37 and 0.25 respectively) but the amount of the overbite in the latter (1.24mm) was shallower when compared to controls (1.63mm) (p=0.03). In addition, the occlusal plane in the non-surgical group (OP/H) showed statistically significant differences when compared to controls (p=0.00).

c. Airway measurements

The shortest adenoid distance (SAD) at T1 for the surgical group was 2.96±2.49mm, whereas in the non-surgical group it was 4.39±2.95mm (p=0.05). Later on at T2 the significance increased even more but favoring the surgical group, measuring 16.25±2.94mm as opposed to 11.84±2.81mm (p=0.00) (Fig. 30). Moreover, the SAD measure of controls was also smaller by about 1.5mm (14.61mm) (p=0.01) from the surgical group. In contrast, the non-surgical group had narrower airways than the controls (15.63mm) (p=0.00) (Fig. 31).

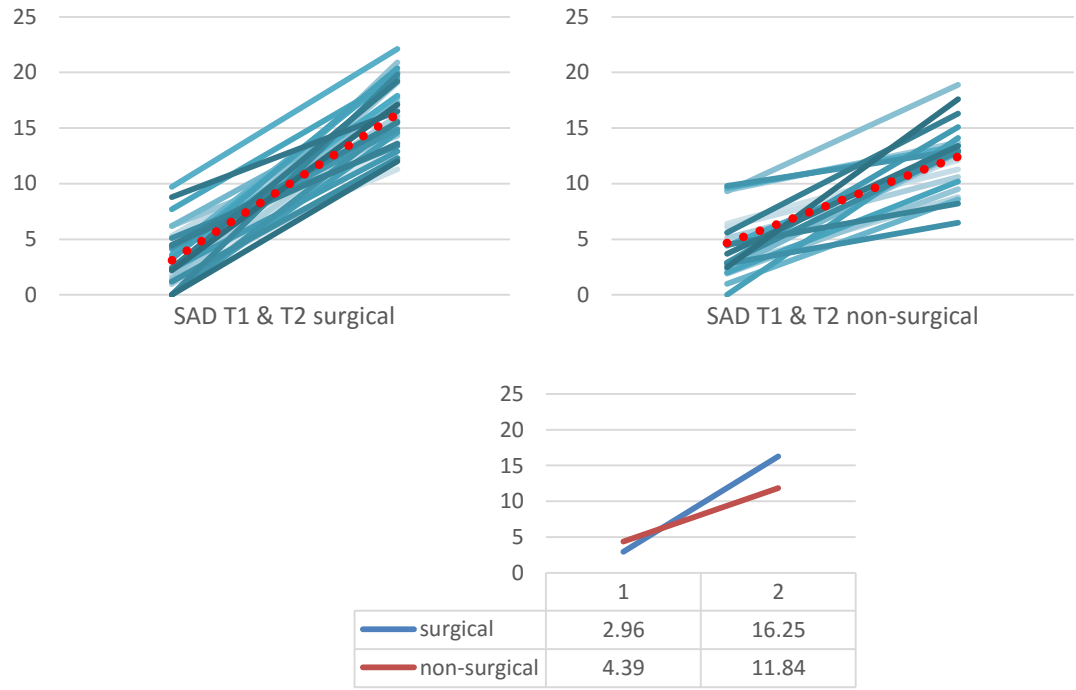


Figure 30: Graphs representing the measures of SAD from T1 to T2 in surgical and non-surgical groups and the difference between the means. Each line in the top graphs represents 1 patient; the dotted red lines as well as the bottom graph represent the mean of the sample.

SAD was also statistically significant for changes between T1 and T2 as well as the analysis of the mean difference (p=0.00).

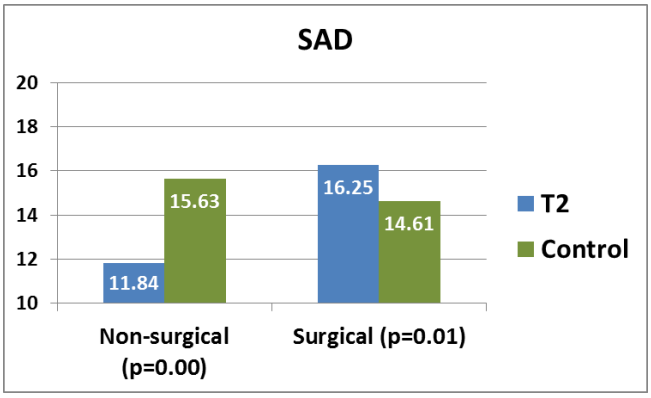


Figure 31: Graph representing the SAD measurements of surgical and non-surgical groups to their matched controls at T2.

2. Analysis of arch length discrepancy

Arch length discrepancy was not statistically significantly different between the 2 groups at T2 (Table 10). The non-surgical group had more crowding in both arches (-1.60mm and -2.55mm in the maxilla and mandible respectively), whereas the surgical group had more spacing in the maxillary arch (1.32mm) and the crowding in the mandibular arch was similar to the non-surgical group (-2.67mm).

Table 4: Independent samples t test comparing the cephalometric measurements between surgical and non-surgical groups at T1 and T2.

	T1					T2				
	Non-surgical		Surgical			Non-surgical		Surgical		
	Mean	SD	Mean	SD	Sig.	Mean	SD	Mean	SD	Sig.
Age	7.24	3.17	5.31	1.99		19.4	3.07	18.4	2.03	
Cranial base										
SN	61.02	2.73	60.04	2.84	0.20	68.76	4.72	68.04	4.72	0.58
N-S-Ar	121.75	7.32	121.53	6.14	0.90	124.17	6.03	125.89	4.59	0.23
S-Ar	27.93	3.84	26.19	3.23	0.07	34.60	4.02	33.78	3.25	0.40
Relationship between jaws										
ANB	4.40	2.88	4.47	2.39	0.92	3.61	3.54	2.61	1.82	0.17
Ao-Bo	-0.53	2.69	-0.69	2.99	0.83	-0.19	4.19	-1.00	3.32	0.42
PP-MP	30.00	4.81	29.37	4.39	0.61	25.66	7.18	23.80	5.72	0.28
LFH/TFH	56.84	2.27	57.43	2.05	0.32	55.52	2.08	56.07	2.15	0.34
Maxilla										
SNA	84.67	3.45	86.06	2.94	0.11	84.57	3.73	83.43	3.43	0.24
ANS-PNS	43.41	3.52	42.01	3.04	0.12	52.83	3.93	52.07	3.84	0.48
PP-HP	-5.20	4.40	-5.23	5.76	0.98	2.47	2.60	2.23	2.53	0.73
Mandible										
SNB	80.26	3.13	81.71	3.66	0.13	80.97	3.49	80.85	3.57	0.91
MP-HP	31.47	4.74	32.21	5.65	0.60	28.83	6.79	27.33	6.48	0.41
MP-SN	34.16	5.38	34.29	2.59	0.91	31.14	5.07	31.75	5.21	0.66
SN-Me	57.37	4.84	55.02	5.15	0.09	63.80	4.12	64.85	3.48	0.30
Go-Pg*	59.22	4.88	55.90	6.49	0.04	75.07	6.24	74.49	6.22	0.73
Ar-Go	38.69	5.59	37.18	4.56	0.27	47.44	5.95	47.63	4.52	0.89
Co-Gn*	91.46	7.48	87.12	8.01	0.04	115.58	10.63	115.16	8.36	0.87
Ar-Go-Me	133.90	7.83	137.69	8.66	0.10	126.66	6.42	125.31	6.43	0.44
N-Gn*	98.82	8.55	93.30	8.96	0.02	119.49	8.76	120.06	7.29	0.79
Dental Measures										
U1/NA	15.06	7.58	13.90	7.52	0.57	22.37	8.77	25.52	5.56	0.10
U1-NA	1.00	2.31	0.55	2.21	0.46	4.38	3.12	5.37	2.36	0.18
U1/PP*	102.87	7.54	102.78	7.45	0.97	111.98	6.82	115.59	5.64	0.03
U1/SN	99.84	6.20	100.37	6.57	0.76	106.38	6.63	108.83	5.24	0.13
L1/NB	23.86	6.20	23.39	3.18	0.71	26.44	7.15	27.09	5.83	0.71
L1-NB	3.67	1.97	3.16	1.34	0.25	6.30	3.56	5.66	1.92	0.38
L1/Apo	19.45	4.78	17.18	3.90	0.06	25.82	3.33	25.71	3.73	0.91
L1-Apo	1.80	2.21	1.61	2.06	0.75	3.06	2.71	3.57	1.91	0.40
L1/MP	89.90	6.73	89.01	4.52	0.55	93.64	8.81	94.92	7.62	0.56
OP/HP	15.63	3.82	16.08	4.59	0.70	12.21	6.14	9.72	4.95	0.10
U1/L1	136.36	10.82	137.72	8.52	0.60	127.76	8.96	124.97	6.73	0.19
OB	0.49	2.45	0.39	1.77	0.86	0.97	1.79	1.24	1.61	0.56
OJ	2.93	2.26	2.88	2.18	0.94	3.33	1.64	3.34	1.74	0.99
Airway measures										
SAD*	4.39	2.95	2.96	2.49	0.05	11.84	2.81	16.25	2.94	0.00
CAD	4.98	3.31	3.37	2.79	0.05	13.04	2.98	.	.	

*Statistically significant at $p<0.05$

Table 5: Independent samples t test comparing the difference of the cephalometric measurements (T2-T1) between surgical and non-surgical groups.

	Non-surgical		Surgical		Sig.
	Mean diff	**SD**	**Mean diff**	**SD**	
Cranial base					
SN	7.74	4.28	8.01	4.99	0.84
N-S-Ar	2.42	6.87	4.36	5.30	0.23
S-Ar	6.67	3.05	7.59	3.96	0.35
Relationship between jaws					
ANB	-0.79	2.84	-1.86	2.00	0.10
AoBo	0.34	3.48	-0.31	2.93	0.45
PP-MP	-4.34	5.39	-5.56	5.48	0.41
LFH/TFH	-1.32	3.06	-1.35	2.51	0.97
Maxilla					
SNA*	-0.10	4.81	-2.63	3.31	0.02
ANS-PNS	9.42	4.95	10.06	4.08	0.59
PP-HP	7.66	4.75	7.46	5.40	0.89
Mandible					
SNB	0.70	4.48	-0.86	3.56	0.15
MP-HP	-2.64	3.94	-4.88	5.51	0.10
MP-SN	-3.03	4.70	-2.54	4.64	0.70
SN-Me*	6.44	4.73	9.84	6.32	0.03
Go-Pg	15.86	6.42	18.59	6.35	0.12
Ar-Go	8.75	6.90	10.45	5.44	0.30
Co-Gn	24.12	10.15	28.04	9.55	0.14
Ar-Go-Me*	-7.24	4.97	-12.38	8.25	0.01
N-Gn*	20.67	8.21	26.76	10.07	0.02
Dental Measures					
U1/NA	7.31	12.09	11.62	9.61	0.14
U1-NA	3.39	4.21	4.82	3.29	0.16
U1/PP	9.11	11.48	12.80	9.50	0.19
U1/SN	6.54	9.87	8.47	8.72	0.44
L1/Apo	6.37	6.25	8.52	5.41	0.17
L1-Apo	1.26	2.52	1.96	2.22	0.28
L1/MP	3.73	6.79	5.91	7.57	0.27
OP/HP	-3.42	5.26	-6.36	5.42	0.05
U1/L1	-8.60	13.43	-12.75	11.17	0.21
OB	0.49	2.00	0.85	2.18	0.52
OJ	0.40	2.12	0.46	2.73	0.94
Airway measures					
SAD*	7.45	3.31	13.29	3.22	0.00

*Statistically significant at $p<0.05$.

Table 6: Paired t test for comparison of the cephalometric measurements of the surgical group at T1 and T2.

	T1		T2		Sig.
	Mean	**SD**	**Mean**	**SD**	
Age	5.31	1.99	18.4	2.03	
Cranial base					
SN*	60.04	2.84	68.04	4.72	0.00
N-S-Ar*	121.53	6.14	125.89	4.59	0.00
S-Ar*	26.19	3.23	33.78	3.25	0.00
Relationship between jaws					
ANB*	4.47	2.39	2.61	1.82	0.00
AoBo	-0.69	2.99	-1.00	3.32	0.55
PP-MP*	29.37	4.39	23.80	5.72	0.00
LFH/TFH*	57.43	2.05	55.96	2.66	0.00
Maxilla					
SNA*	86.06	2.94	83.43	3.43	0.00
ANS-PNS*	42.01	3.04	52.07	3.84	0.00
PP-HP*	-5.23	5.76	2.23	2.53	0.00
Mandible					
SNB	81.71	3.66	80.85	3.57	0.17
MP-HP*	32.21	5.65	27.33	6.48	0.00
MP-SN*	34.29	2.59	31.75	5.21	0.00
SN-Me*	55.02	5.15	64.85	3.48	0.00
Go-Pg*	55.90	6.49	74.49	6.22	0.00
Ar-Go*	37.18	4.56	47.63	4.52	0.00
Co-Gn*	87.12	8.01	115.16	8.36	0.00
Ar-Go-Me*	137.69	8.66	125.31	6.43	0.00
N-Gn*	93.30	8.96	120.06	7.29	0.00
Dental measures					
U1/NA*	13.90	7.52	25.52	5.56	0.00
U1-NA*	0.55	2.21	5.37	2.36	0.00
U1/PP*	102.78	7.45	115.59	5.64	0.00
U1/SN*	100.37	6.57	108.83	5.24	0.00
L1/NB*	23.39	3.18	27.09	5.83	0.00
L1-NB*	3.16	1.34	5.66	1.92	0.00
L1/Apo*	17.18	3.90	25.71	3.73	0.00
L1-Apo*	1.61	2.06	3.57	1.91	0.00
L1/MP*	89.01	4.52	94.92	7.62	0.00
OP/HP*	16.08	4.59	9.72	4.95	0.00
U1-L1*	137.72	8.52	124.97	6.73	0.00
OB*	0.39	1.77	1.24	1.61	0.03
OJ	2.88	2.18	3.34	1.74	0.34
Airway measures					
SAD*	2.96	2.49	16.25	2.94	0.00

*Statistically significant at $p<0.05$.

Table 7: Paired t test for comparison of the cephalometric measurements at T2 between the surgical group and its matched controls.

	Surgical		Control		Sig.
	Mean	**SD**	**Mean**	**SD**	
Age	18.75	2.29	18.99	2.39	0.67
Cranial base					
SN	68.04	4.72	68.80	5.02	0.52
N-S-Ar*	125.89	4.59	122.73	6.06	0.02
S-Ar	33.78	3.25	33.10	3.24	0.39
Relationship between jaws					
ANB	2.61	1.82	2.09	0.94	0.14
AoBo	-1.00	3.32	-0.73	1.48	0.67
PP-MP*	23.80	5.72	26.84	4.74	0.02
LFH/TFH	55.96	2.66	55.96	1.18	0.73
Maxilla					
SNA	83.43	3.43	82.13	1.45	0.05
ANS-PNS*	52.07	3.84	50.30	3.27	0.04
PP-HP	2.23	2.53	-1.30	3.35	0.49
Mandible					
SNB	80.85	3.57	80.04	1.50	0.23
MP-HP	27.33	6.48	28.29	4.72	0.49
MP-SN*	31.75	5.21	35.26	3.62	0.00
SN-Me*	64.85	3.48	71.87	6.01	0.00
Go-Pg*	74.49	6.22	70.55	5.82	0.01
Ar-Go	47.63	4.52	46.69	4.31	0.39
Co-Gn*	115.16	8.36	119.03	6.22	0.03
Ar-Go-Me*	125.31	6.43	129.03	5.62	0.01
N-Gn	120.06	7.29	121.98	6.38	0.25
Dental Measures					
U1/NA*	25.52	5.56	22.70	5.20	0.03
U1-NA	5.37	2.36	4.37	1.67	0.05
U1/PP*	115.59	5.64	112.23	5.17	0.01
U1/SN*	108.83	5.24	104.70	5.63	0.00
L1/NB	27.09	5.83	25.91	4.79	0.36
L1-NB	5.66	1.92	5.66	1.92	0.11
L1/Apo*	25.71	3.73	23.41	5.37	0.04
L1-Apo	3.57	1.91	3.24	4.20	0.68
L1/MP*	94.92	7.62	91.12	6.58	0.03
OP/HP*	9.72	4.95	6.27	4.36	0.00
U1/L1*	124.97	6.73	129.22	7.65	0.02
OB	1.24	1.61	1.63	1.30	0.28
OJ*	3.34	1.74	2.55	1.27	0.04
Airway measures					
SAD*	16.25	2.94	14.61	2.31	0.01

*Statistically significant at $p<0.05$.

Table 8: Paired t test for comparison of the cephalometric measurements of the non-surgical group at T1 and T2.

	T1		T2		Sig.
	Mean	**SD**	**Mean**	**SD**	
Age	7.24	3.17	19.4	3.07	
Cranial base					
SN*	61.02	2.73	68.76	4.72	0.00
N-S-Ar	121.75	7.32	124.17	6.03	0.11
S-Ar*	27.93	3.84	34.60	4.02	0.00
Relationship between jaws					
ANB	4.40	2.88	3.61	3.54	0.20
AoBo	-0.53	2.69	-0.19	4.19	0.65
PP-MP*	30.00	4.81	25.66	7.18	0.00
LFH/TFH	56.84	2.27	55.52	2.08	0.05
Maxilla					
SNA	84.67	3.45	84.57	3.73	0.92
ANS-PNS*	43.41	3.52	52.83	3.93	0.00
PP-HP*	-5.20	4.40	2.47	2.60	0.00
Mandible					
SNB	80.26	3.13	80.97	3.49	0.46
MP-HP*	31.47	4.74	28.83	6.79	0.00
MP-SN*	34.16	5.38	31.14	5.07	0.01
SN-Me*	57.37	4.84	63.80	4.12	0.00
Go-Pg*	59.22	4.88	75.07	6.24	0.00
Ar-Go*	38.69	5.59	47.44	5.95	0.00
Co-Gn*	91.46	7.48	115.58	10.63	0.00
Ar-Go-Me*	133.90	7.83	126.66	6.42	0.00
N-Gn*	98.82	8.55	119.49	8.76	0.00
Dental measures					
U1/NA*	15.06	7.58	22.37	8.77	0.01
U1-NA*	1.00	2.31	4.38	3.12	0.00
U1/PP*	102.87	7.54	111.98	6.82	0.00
U1/SN*	99.84	6.20	106.38	6.63	0.00
L1/NB*	23.86	6.20	26.44	7.15	0.03
L1-NB*	3.67	1.97	6.30	3.56	0.00
L1/Apo*	19.45	4.78	25.82	3.33	0.00
L1-Apo*	1.80	2.21	3.06	2.71	0.03
L1/MP*	89.90	6.73	93.64	8.81	0.02
OP/HP*	15.63	3.82	12.21	6.14	0.01
U1-L1*	136.36	10.82	127.76	8.96	0.01
OB	0.49	2.45	0.97	1.79	0.26
OJ	2.93	2.26	3.33	1.64	0.37
Airway measures					
SAD*	4.39	2.95	11.84	2.81	0.00
CAD*	4.98	3.31	13.04	2.98	0.00

*Statistically significant at $p<0.05$.

Table 9: Paired t test for comparison of the cephalometric measurements at T2 between the non-surgical group and its matched controls.

	Non-Surgical		Control		Sig.
	Mean	**SD**	**Mean**	**SD**	
Age	19.60	2.99	19.84	3.03	0.79
Cranial base					
SN	68.76	4.72	67.07	5.43	0.27
N-S-Ar	124.17	6.03	124.11	5.74	0.97
S-Ar	47.44	5.95	45.45	3.79	0.88
Relationship between jaws					
ANB*	3.61	3.54	1.87	1.15	0.03
AoBo	-0.19	4.19	-0.43	1.63	0.80
PP-MP	25.66	7.18	24.03	4.64	0.37
LFH/TFH	55.52	2.08	54.60	2.65	0.20
Maxilla					
SNA*	84.57	3.73	82.50	1.76	0.02
ANS-PNS*	52.83	3.93	49.79	3.96	0.01
PP-HP*	2.47	2.60	0.11	4.22	0.03
Mandible					
SNB	80.97	3.49	80.63	1.90	0.69
MP-HP	28.83	6.79	26.49	5.40	0.20
MP-SN	31.13	5.07	33.67	3.54	0.06
SN-Me*	63.80	4.12	72.56	9.11	0.00
Go-Pg	75.07	6.24	71.04	8.29	0.07
Ar-Go	47.44	5.95	45.45	3.79	0.18
Co-Gn	115.58	10.63	116.26	7.93	0.81
Ar-Go-Me	126.66	6.42	127.04	5.00	0.82
N-Gn	119.49	8.76	120.23	6.79	0.75
Dental Measures					
U1/NA	22.37	8.77	24.83	5.98	0.27
U1-NA	4.38	3.12	4.99	2.47	0.47
U1/PP	111.98	6.82	114.81	6.26	0.15
U1/SN	106.38	6.63	106.98	5.38	0.74
L1/NB	26.44	7.15	22.54	6.83	0.06
L1-NB*	6.30	3.56	3.88	2.59	0.01
L1/Apo	25.82	3.33	23.61	6.25	0.14
L1-Apo	3.06	2.71	2.66	5.11	0.74
L1/MP	93.63	8.81	89.83	7.71	0.13
OP/HP*	12.21	6.14	6.70	3.81	0.00
U1/L1	127.76	8.96	130.32	10.23	0.37
OB*	0.97	1.79	1.94	1.15	0.03
OJ	3.33	1.64	3.39	1.01	0.89
Airway measures					
SAD*	11.84	2.81	15.63	2.44	0.00
CAD*	13.03	2.98	16.82	2.20	0.00

*Statistically significant at $p<0.05$.

Table 10: Independent t test for comparison of arch length discrepancy between the surgical and non-surgical groups.

	Non-surgical		Surgical		Sig.
	Mean	SD	Mean	SD	
Maxilla	-1.60	2.94	1.32	3.97	0.50
Mandible	-2.55	3.59	-2.67	2.53	0.46

*Statistically significant at $p<0.05$.

C. Comparison of surgical groups below and above 6 years of age

From the total of 34 patients with history of adenoidectomy, 18 (12 males and 6 females) had undergone surgery below the age of 6 (mean age of 4.26±0.90), and the remaining 16 (9 males and 7 females) had their adenoids removed after the age of 6 (mean age of 6.40 ± 2.22).

1. Cephalometric measurements

The cephalometric measurements between the surgical groups below and above age 6 are displayed in Tables 11 and 12. In tables 13 and 15, the comparison of the surgical group below age 6 at T1 and T2 and to its matched controls is presented. The same comparisons for the group who had adenoidectomy after age 6 are shown in tables 14 and 16.

a. Skeletal measurements

Comparing the mean differences between the 2 groups showed that the palatal plane (PP/HP) and gonial angle (Ar-Go-Me) had more improvement in patients who underwent surgery below age 6. The mean difference in the PP/HP was 9.35° in patients who had surgery before 6 (from -7.07° to 2.28°), whereas in children who underwent surgery above the age of 6 this difference was only 5.34° (from -3.16° to 2.18°)

(p=0.03) (Fig. 32). Ar-Go-Me decreased by 15.11° in the below 6 age group (from 141.20° to 126.09°), whereas in the other group this difference was only 9.31° (from 133.74° to 124.44°) (p=0.04) (Fig. 33).

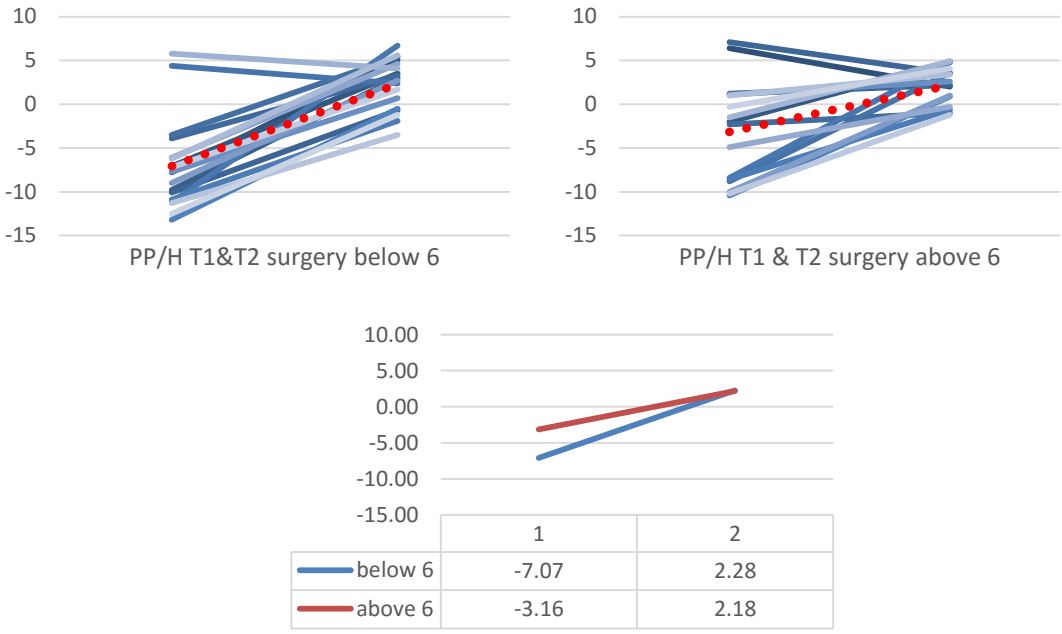


Figure 32: Graphs representing the measures of PP/H from T1 to T2 in below and above 6 surgical groups and the difference between the means. Each line in the top graphs represents 1 patient; the dotted red lines as well as the bottom graph represent the mean of the sample.

Both groups showed statistically significant changes between T1 and T2, except for AoBo and SNB which improved in the "below 6 years" surgical group and stayed the same for the "above 6 years" group. LFH/TFH improved in the below 6 surgical group but stayed the same for the opposing group. The MP/SN angle for the younger age group and LFH/TFH for the older one did not show significant changes from T1 to T2. However, the MP/SN angle when compared to controls was significantly smaller for below 6 surgical group, whereas in the older group this value was not significant.

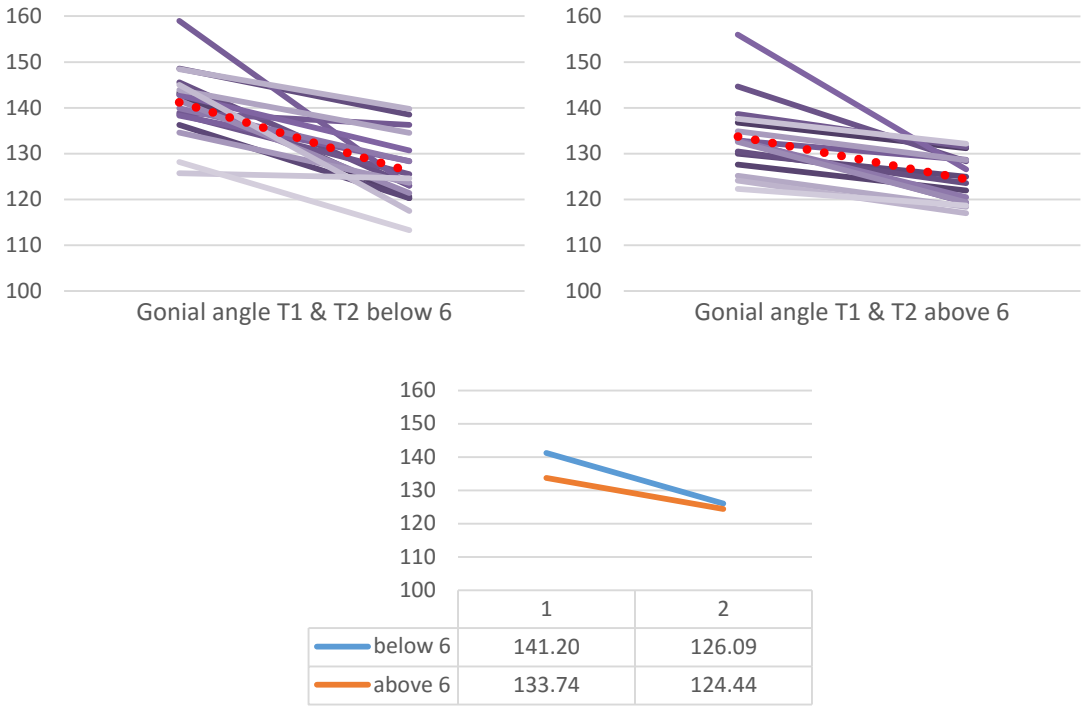


Figure 33: Graphs representing the measures of Ar-Go-Me from T1 to T2 in below and above 6 surgical groups and the difference between the means. Each line in the top graphs represents 1 patient; the dotted red lines as well as the bottom graph represent the mean of the sample.

The saddle angle (N-S-Ar) in patients who had surgery below age 6 normalized to the corresponding controls (p=0.43), whereas for the older age group this difference was still statistically significant (Fig. 34).

Both SNA and SNB in the younger age group were more protruded compared to controls (p= 0.02 and 0.04 respectively) (Fig. 35).

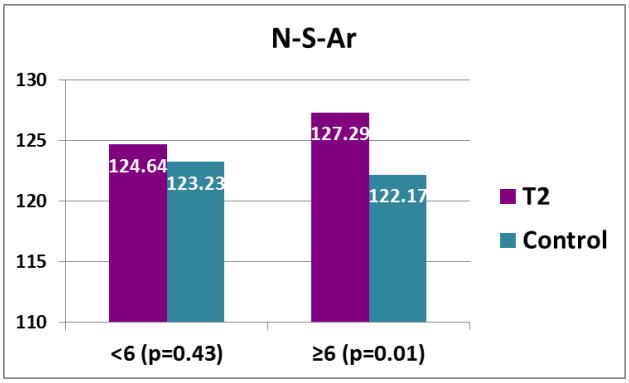


Figure 34: Graph representing the N-S-Ar measurements of below and above 6 years of age surgical groups to their matched controls at T2.

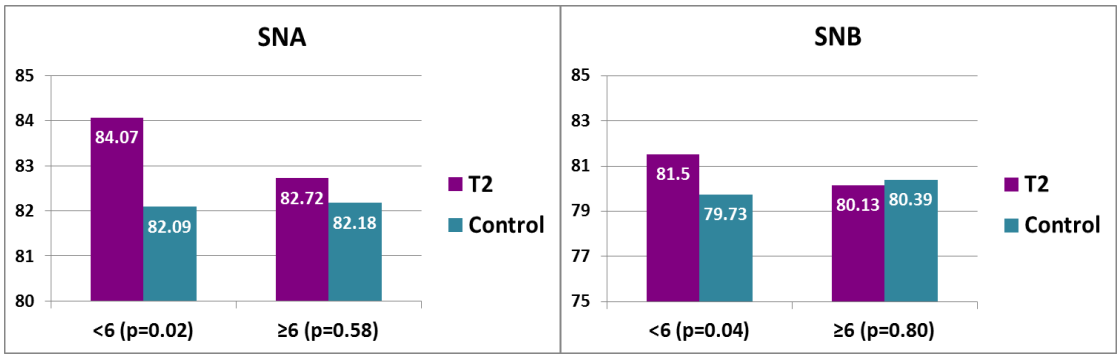


Figure 35: Graphs representing the SNA (left) and SNB (right) measurements of below and above 6 years of age surgical groups to their matched controls at T2.

b. Dental measurements

Statistically significant changes were observed in all dental measurements except in the amount of overbite and overjet at T1 and T2 for both groups.

When comparing the two groups at T2, the only significant difference was in the mandibular incisor's inclination; the patients who had surgery above age 6 had more proclination of the mandibular incisors, compared to both younger age and control groups. L1/APo was 24.30±2.91° in the below 6 age group and 27.29±3.99° in above 6 age group (p=0.02), and 23.65° in the control group (p=0.02).

c. Airway Measurements

Both groups showed great improvement of SAD after surgery (p=0.00), and the inter-group difference was not statistically significant. The patients who had the surgery below age 6 had significantly larger SAD than their corresponding controls at T2 (16.23mm and 14.09mm) (p=0.02), the airway dimension of the older age group was similar to controls (Fig. 36).

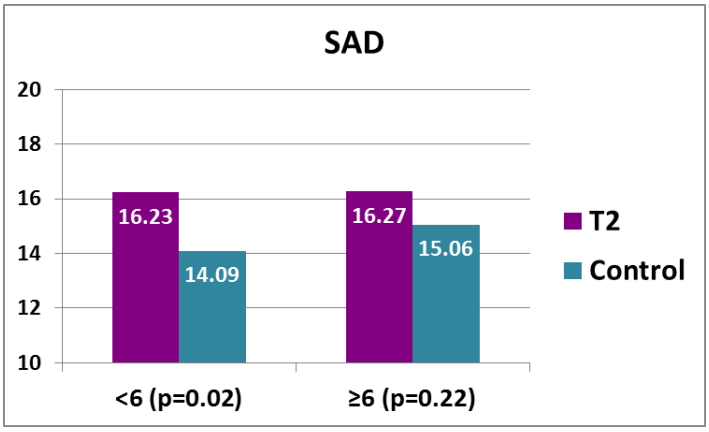


Figure 36: Graphs representing the SAD measurements of below and above 6 years of age surgical groups to their matched controls at T2.

2. Analysis of arch length discrepancy

The only statistically significant measurement in this category was the mandibular crowding which was -3.92mm in patients who had surgery above age 6 and only -1.56mm in the other group (p=0.00). The values of both maxillary and mandibular dental arch measurements are shown in Table 17.

Table 11: Independent samples t test comparing the surgery below 6 years and the surgery above 6 years groups at T2.

	<6		≥6		Sig.
	Mean	**SD**	**Mean**	**SD**	
Surg. age	4.26	0.90	6.40	2.22	
Cranial base					
SN	67.27	3.83	68.91	5.56	0.32
N-S-Ar	124.64	3.66	127.29	5.22	0.09
S-Ar	34.06	2.04	33.46	4.28	0.60
Relationship between jaws					
ANB	2.57	1.67	2.66	2.04	0.89
AoBo	-1.14	3.27	-0.84	3.48	0.80
PP-MP	23.87	4.39	23.73	7.07	0.94
LFH/TFH	55.94	1.65	56.23	2.66	0.71
Maxilla					
SNA	84.07	3.19	82.72	3.65	0.26
ANS-PNS	51.96	2.73	52.21	4.90	0.85
PP-HP	2.28	2.90	2.18	2.15	0.91
Mandible					
SNB	81.50	3.30	80.13	3.82	0.27
MP-HP	27.63	5.04	27.00	7.95	0.78
MP-SN	31.91	4.97	31.58	5.63	0.86
SN-Me	65.09	3.65	64.59	3.38	0.68
Go-Pg	73.34	5.95	75.79	6.46	0.26
Ar-Go	46.97	3.78	48.37	5.26	0.38
Co-Gn	114.37	6.64	116.04	10.11	0.57
Ar-Go-Me	126.09	7.41	124.44	5.23	0.46
N-Gn	119.83	7.10	120.31	7.72	0.85
Dental Measures					
U1/NA	25.28	5.49	25.79	5.80	0.79
U1-NA	4.79	2.26	6.03	2.37	0.13
U1/PP	115.98	6.08	115.14	5.27	0.67
U1/SN	109.43	5.53	108.16	4.99	0.49
L1/NB	25.45	3.45	28.94	7.37	0.08
L1-NB	5.22	1.34	6.16	2.37	0.16
L1/Apo*	24.30	2.91	27.29	3.99	0.02
L1-Apo	3.10	1.68	4.10	2.06	0.13
L1/MP	92.48	6.07	97.66	8.42	0.05
OP/HP	9.99	5.37	9.41	4.59	0.74
U1/L1	126.59	6.25	123.15	6.98	0.14
OB	1.27	1.38	1.21	1.88	0.92
OJ	3.22	1.74	3.46	1.79	0.70
Airway measures					
SAD	16.23	2.85	16.27	3.13	0.97

*Statistically significant at $p<0.05$.

Table 12: Independent samples t test comparing the difference of the cephalometric measurements (T2-T1) between the above and below 6 years of age surgical groups.

	<6		≥6		Sig.
	Mean diff.	**SD**	**Mean diff.**	**SD**	
Cranial base					
SN	8.10	4.15	7.90	5.93	0.91
N-S-Ar	4.31	5.48	4.42	5.26	0.95
S-Ar	8.18	2.58	6.93	5.10	0.37
Relationship between jaws					
ANB	-2.23	2.01	-1.44	1.97	0.25
AoBo	-0.58	3.20	0.00	2.67	0.57
PP-MP	-5.29	5.50	-5.87	5.61	0.76
LFH/TFH	-1.39	2.40	-1.31	2.70	0.92
Maxilla					
SNA	-3.01	3.09	-2.20	3.60	0.48
ANS-PNS	10.81	3.24	9.22	4.83	0.26
PP-HP*	9.35	4.77	5.34	5.41	0.03
Mandible					
SNB	-0.93	3.36	-0.78	3.88	0.90
MP-HP	-4.25	5.49	-5.59	5.63	0.49
MP-SN	-1.74	4.70	-3.43	4.55	0.30
SN-Me	11.39	5.23	8.09	7.13	0.13
Go-Pg	19.38	5.33	17.70	7.41	0.45
Ar-Go	8.76	5.37	12.35	5.01	0.05
Co-Gn	28.72	8.22	27.28	11.08	0.67
Ar-Go-Me*	-15.11	8.77	-9.31	6.58	0.04
N-Gn	29.64	9.57	23.51	9.90	0.08
Dental Measures					
U1/NA	14.06	10.03	8.87	8.60	0.12
U1-NA	4.94	3.10	4.69	3.59	0.82
U1/PP	15.10	9.91	10.22	8.59	0.14
U1/SN	10.24	9.05	6.48	8.15	0.21
L1/NB	2.39	4.62	5.17	7.37	0.19
L1-NB	2.42	1.59	2.60	2.31	0.79
L1/Apo	8.26	5.23	8.82	5.77	0.77
L1-Apo	2.15	2.32	1.74	2.17	0.60
L1/MP	4.02	5.99	8.03	8.74	0.13
OP/HP	-5.91	5.10	-6.87	5.88	0.61
U1/L1	-13.77	10.96	-11.59	11.65	0.58
OB	0.98	2.22	0.71	2.20	0.72
OJ	0.15	3.09	0.80	2.29	0.50
Airway measures					
SAD	14.09	2.91	12.39	3.40	0.12

*Statistically significant at $p<0.05$.

Table 13: Paired t test comparing the cephalometric measurements of the surgical group below age 6 between T1 and T2.

	T1		T2		Sig.
	Mean	**SD**	**Mean**	**SD**	
Age	4.26	0.90	17.91	1.25	
Cranial base					
SN*	59.17	2.22	67.27	3.83	0.00
N-S-Ar*	120.33	6.50	124.64	3.66	0.00
S-Ar*	25.88	2.31	34.06	2.04	0.00
Relationship between jaws					
ANB*	4.80	2.60	2.57	1.67	0.00
AoBo	-0.56	3.51	-1.14	3.27	0.45
PP-MP*	29.16	4.06	23.87	4.39	0.00
LFH/TFH*	57.33	2.06	55.94	1.65	0.03
Maxilla					
SNA*	87.08	2.95	84.07	3.19	0.00
ANS-PNS*	41.14	2.49	51.96	2.73	0.00
PP-HP*	-7.07	5.20	2.28	2.90	0.00
Mandible					
SNB	82.43	3.55	81.50	3.30	0.26
MP-HP*	31.88	5.24	27.63	5.04	0.00
MP-SN	33.65	1.84	31.91	4.97	0.13
SN-Me*	53.70	3.46	65.09	3.65	0.00
Go-Pg*	53.96	4.49	73.34	5.95	0.00
Ar-Go*	38.21	5.10	46.97	3.78	0.00
Co-Gn*	85.65	4.83	114.37	6.64	0.00
Ar-Go-Me*	141.20	7.57	126.09	7.41	0.00
N-Gn*	90.19	7.14	119.83	7.10	0.00
Dental measures					
U1/NA*	11.22	8.34	25.28	5.49	0.00
U1-NA*	-0.16	2.19	4.79	2.26	0.00
U1/PP*	100.88	8.02	115.98	6.08	0.00
U1/SN*	99.19	7.17	109.43	5.53	0.00
L1/NB*	23.06	3.06	25.45	3.45	0.04
L1-NB*	2.79	1.05	5.22	1.34	0.00
L1/Apo*	16.04	3.50	24.30	2.91	0.00
L1-Apo*	0.95	2.28	3.10	1.68	0.00
L1/MP*	88.46	4.83	92.48	6.07	0.01
OP/HP*	15.91	5.28	9.99	5.37	0.00
U1-L1*	140.37	8.04	126.59	6.25	0.00
OB	0.28	2.10	1.27	1.38	0.08
OJ	3.07	2.43	3.22	1.74	0.84
Airway measures					
SAD*	2.14	1.57	16.23	2.85	0.00

*Statistically significant at $p<0.05$.

Table 14: Paired t test comparing the cephalometric measurements of the surgical group above age 6 between T1 and T2.

	T1		T2		Sig.
	Mean	**SD**	**Mean**	**SD**	
Age	6.40	2.22	19.70	2.81	
Cranial base					
SN*	61.01	3.20	68.91	5.56	0.00
N-S-Ar*	122.88	5.62	127.29	5.22	0.00
S-Ar*	26.53	4.09	33.46	4.28	0.00
Relationship between jaws					
ANB*	4.09	2.14	2.66	2.04	0.01
AoBo	-0.84	2.37	-0.84	3.48	1.00
PP-MP*	29.59	4.85	23.73	7.07	0.00
LFH/TFH	57.53	2.11	56.23	2.66	0.07
Maxilla					
SNA*	84.92	2.56	82.72	3.65	0.03
ANS-PNS*	42.99	3.37	52.21	4.90	0.00
PP-HP*	-3.16	5.80	2.18	2.15	0.00
Mandible					
SNB	80.90	3.72	80.13	3.82	0.44
MP-HP*	32.59	6.23	27.00	7.95	0.00
MP-SN*	35.01	3.15	31.58	5.63	0.01
SN-Me*	56.50	6.35	64.59	3.38	0.00
Go-Pg*	58.09	7.75	75.79	6.46	0.00
Ar-Go8	36.02	3.67	48.37	5.26	0.00
Co-Gn*	88.76	10.45	116.04	10.11	0.00
Ar-Go-Me*	133.74	8.28	124.44	5.23	0.00
N-Gn*	96.80	9.70	120.31	7.72	0.00
Dental measures					
U1/NA*	16.92	5.22	25.79	5.80	0.00
U1-NA*	1.34	2.01	6.03	2.37	0.00
U1/PP*	104.93	6.32	115.14	5.27	0.00
U1/SN*	101.69	5.77	108.16	4.99	0.01
L1/NB*	23.77	3.36	28.94	7.37	0.01
L1-NB*	3.56	1.54	6.16	2.37	0.00
L1/Apo*	18.47	4.04	27.29	3.99	0.00
L1-Apo*	2.36	1.51	4.10	2.06	0.01
L1/MP*	89.63	4.20	97.66	8.42	0.00
OP/HP*	16.28	3.85	9.41	4.59	0.00
U1-L1*	134.74	8.28	123.15	6.98	0.00
OB	0.51	1.36	1.21	1.88	0.22
OJ	2.66	1.91	3.46	1.79	0.18
Airway measures					
SAD*	3.88	3.03	16.27	3.13	0.00

*Statistically significant at $p<0.05$.

Table 15: Paired t test for comparison of the cephalometric measurements at T2 between the surgical group below age 6 and its matched controls.

	T2		Control		Sig.
	Mean	**SD**	**Mean**	**SD**	
Age	17.91	1.25	18.06	1.44	0.73
Cranial base					
SN	67.27	3.83	69.55	4.46	0.11
N-S-Ar	124.64	3.66	123.23	6.52	0.43
S-Ar	34.06	2.04	33.14	2.34	0.22
Relationship between jaws					
ANB	2.57	1.67	2.35	0.99	0.64
AoBo	-1.14	3.27	-1.01	1.51	0.88
PP-MP	23.87	4.39	26.94	5.30	0.07
LFH/TFH	55.94	1.65	55.79	1.99	0.81
Maxilla					
SNA*	84.07	3.19	82.09	1.52	0.02
ANS-PNS	51.96	2.73	50.66	3.08	0.19
PP-HP*	2.28	2.90	-0.41	3.40	0.02
Mandible					
SNB*	81.50	3.30	79.73	1.34	0.04
MP-HP	27.63	5.04	29.40	4.93	0.29
MP-SN*	31.91	4.97	35.79	3.29	0.01
SN-Me*	65.09	3.65	71.57	6.02	0.00
Go-Pg	73.34	5.95	69.93	6.82	0.12
Ar-Go	46.97	3.78	46.07	3.06	0.44
Co-Gn*	114.37	6.64	119.34	5.71	0.02
Ar-Go-Me	126.09	7.41	130.18	5.38	0.07
N-Gn	119.83	7.10	122.51	6.41	0.24
Dental measures					
U1/NA	25.28	5.49	21.83	5.25	0.06
U1-NA	4.79	2.26	4.20	1.64	0.38
U1/PP	115.98	6.08	112.33	5.85	0.08
U1/SN*	109.43	5.53	103.96	5.85	0.01
L1/NB	25.45	3.45	22.54	6.83	0.06
L1-NB	5.22	1.34	3.88	2.59	0.07
L1/Apo	24.30	2.91	23.20	6.24	0.50
L1-Apo	3.10	1.68	3.92	5.44	0.55
L1/MP	92.48	6.07	90.68	6.39	0.39
OP/HP	9.99	5.37	7.59	3.63	0.13
U1-L1	126.59	6.25	129.56	8.04	0.22
OB	1.27	1.38	1.37	1.35	0.83
OJ	3.22	1.74	2.51	1.59	0.21
Airway measures					
SAD*	16.23	2.85	14.09	1.65	0.02

*Statistically significant at $p<0.05$.

Table 16: Paired t test for comparison of the cephalometric measurements at T2 between the surgical group above age 6 and its matched controls.

	T2		Control		Sig.
	Mean	**SD**	**Mean**	**SD**	
Age	19.70	2.81	20.03	2.84	0.74
Cranial base					
SN	68.91	5.56	67.96	5.62	0.63
N-S-Ar*	127.29	5.22	122.17	5.65	0.01
S-Ar	33.46	4.28	33.06	4.10	0.79
Relationship between jaws					
ANB	2.66	2.04	1.79	0.82	0.12
AoBo	-0.84	3.48	-0.42	1.43	0.66
PP-MP	23.73	7.07	26.72	4.19	0.16
LFH/TFH	56.23	2.66	56.76	1.84	0.52
Maxilla					
SNA	82.72	3.65	82.18	1.41	0.58
ANS-PNS	52.21	4.90	49.91	3.53	0.14
PP-HP*	2.18	2.15	-2.30	3.09	0.00
Mandible					
SNB	80.13	3.82	80.39	1.64	0.80
MP-HP	27.00	7.95	27.05	4.29	0.98
MP-SN	31.58	5.63	34.68	3.99	0.08
SN-Me*	64.59	3.38	72.21	6.18	0.00
Go-Pg*	75.79	6.46	71.25	4.56	0.03
Ar-Go	48.37	5.26	47.39	5.40	0.61
Co-Gn	116.04	10.11	118.67	6.91	0.40
Ar-Go-Me	124.44	5.23	127.73	5.77	0.10
N-Gn	120.31	7.72	121.38	6.50	0.67
Dental measures					
U1/NA	25.79	5.80	23.68	5.13	0.28
U1-NA	6.03	2.37	4.57	1.73	0.06
U1/PP	115.14	5.27	112.11	4.46	0.09
U1/SN	108.16	4.99	105.54	5.44	0.17
L1/NB	28.94	7.37	21.32	6.75	0.05
L1-NB	6.16	2.37	3.07	2.59	0.07
L1/Apo*	27.29	3.99	23.65	4.38	0.02
L1-Apo*	4.10	2.06	2.49	2.01	0.03
L1/MP*	97.66	8.42	91.61	6.97	0.03
OP/HP*	9.41	4.59	4.78	4.73	0.01
U1-L1*	123.15	6.98	128.84	7.43	0.03
OB	1.21	1.88	1.93	1.21	0.21
OJ	3.46	1.79	2.60	0.80	0.09
Airway measures					
SAD	16.27	3.13	15.06	1.73	0.22

*Statistically significant at $p<0.05$.

Table 17: Independent samples t test comparing arch length discrepancy between surgical groups below and above age 6.

	<6		≥6		Sig.
	Mean	**SD**	**Mean**	**SD**	
Maxilla	3.34	4.66	-0.96	4.94	0.42
Mandible*	-1.56	2.33	-3.92	2.18	0.00

*Statistically significant at p<0.05.

D. Comparison of patients based on breathing status

This category consisted of 20 patients who were still breathing through their mouth while the other 37 individual were nose breathers.

1. Cephalometric measurements

In table 18, the comparison between mouth breathers to nose breathers are displayed, and that of mean differences in table 19.

a. Skeletal measurements

The mouth breathing group had significantly higher ANB angle (4.12°) compared to nose breathers (2.42°) (p=0.02). LFH/TFH ratio was significantly larger in mouth breathing group as well (56.88% compared to 55.30%) with significance level of 0.01.

In addition, while comparing the mean differences of the 2 groups, both ANB and LFH/TFH remained statistically significantly different.

b. Dental measurements

More proclination of maxillary incisors to palatal plane (U1/PP) in nose breathing group (115.55±5.90°) than in the mouth breathers (111.50±6.42°) with significance level of 0.02 was reported.

c. Airway measurements

Mouth breathers had smaller airway dimensions (13.41±3.12mm) compared to nose breathers (15.43±3.75mm). In addition, the amount of increase in SAD in patients who resumed nose breathing was 11.65±3.92mm, whereas in mouth breathers SAD was increased only by 9.61±4.82. Although clinically significant, SAD did not demonstrate statistical significance with p values of 0.10 and 0.09 respectively.

2. Analysis of arch length discrepancy

Table 20 displays the degree of discrepancy of the maxillary and mandibular arches between the mouth breathing and nose breathing individuals. Mouth breathers had crowding of -3.84±3.33mm in the mandible whereas in the normal breathing individuals this amount was only -1.96±2.57mm (p=0.04). The crowding in the maxillary arch was not significantly different.

Table 18: Independent t test comparing patients based on breathing status at T2.

	Nose breathing		Mouth breathing		Sig.
	Mean	**SD**	**Mean**	**SD**	
Age	18.74	2.79	19.05	2.47	
Cranial base					
SN	68.39	4.68	68.23	4.83	0.90
N-S-Ar	124.64	4.70	126.23	6.10	0.28
S-Ar	34.45	3.55	33.48	3.61	0.33
Relationship between jaws					
ANB*	2.42	2.24	4.12	3.08	0.02
AoBo	-1.13	3.62	0.18	3.73	0.20
PP-MP	23.57	6.58	26.37	5.62	0.11
LFH/TFH*	55.30	2.02	56.88	1.94	0.01
Maxilla					
SNA	83.87	3.46	83.94	3.84	0.95
ANS-PNS	52.31	4.07	52.50	3.54	0.86
PP-HP	2.29	2.60	2.40	2.48	0.88
Mandible					
SNB	81.45	3.20	79.88	3.88	0.11
MP-HP	27.00	6.38	29.67	6.77	0.15
MP-SN	30.87	5.26	32.68	4.76	0.21
SN-Me	63.70	3.60	65.78	3.74	0.05
Go-Pg	74.35	6.15	75.43	6.33	0.53
Ar-Go	47.59	3.92	47.48	6.89	0.94
Co-Gn	115.19	8.71	115.58	10.42	0.88
Ar-Go-Me	126.62	6.79	124.44	5.49	0.22
N-Gn	119.42	7.83	120.59	8.02	0.60
Dental Measures					
U1/NA	25.56	5.78	21.82	8.77	0.06
U1-NA	5.44	2.54	4.10	2.87	0.07
U1/PP*	115.55	5.90	111.50	6.42	0.02
U1/SN*	109.23	4.94	105.28	6.78	0.02
L1/NB	26.58	5.46	27.29	7.84	0.96
L1-NB	27.29	7.84	6.09	2.93	0.73
L1/Apo	25.77	3.41	25.72	3.87	0.96
L1-Apo	3.56	2.11	3.00	2.52	0.37
L1/MP	94.38	7.99	94.44	8.43	0.98
OP/HP	10.38	5.54	11.36	5.65	0.53
U1/L1	125.66	6.91	126.92	9.26	0.56
OB	1.18	1.56	1.05	1.90	0.79
OJ	3.09	1.67	3.79	1.67	0.14
Airway measures					
SAD	15.43	3.75	13.41	3.12	0.10

*Statistically significant at $p<0.05$.

Table 19: Independent t test comparing for the mean difference between patients based on breathing status.

	Nose breathing		Mouth breathing		Sig.
	Mean diff	**SD**	**Mean diff**	**SD**	
Cranial base					
SN	7.94	4.60	7.82	4.93	0.92
SN-Ar	3.11	6.30	4.44	5.44	0.43
S-Ar	7.84	3.88	6.08	2.82	0.08
Relationship between jaws					
ANB*	-2.04	1.92	-0.29	2.83	0.01
Wits	-0.51	3.21	0.82	2.92	0.13
PP-MP	-5.84	5.35	-3.64	5.40	0.15
LFH/TFH*	-2.01	2.60	-0.10	2.55	0.01
Maxilla					
SNA	-1.79	4.33	-1.27	3.85	0.65
ANS-PNS	9.91	4.31	9.60	4.73	0.80
PP-HP	7.80	5.27	7.07	4.89	0.61
Mandible					
SNB	0.15	4.25	-0.93	3.47	0.34
MP-HP	-4.43	4.76	-3.14	5.52	0.36
MP-SN	-3.60	4.77	-1.13	3.98	0.05
SN-Me	8.48	5.80	8.43	6.32	0.97
Go-Pg	17.57	6.24	17.34	7.02	0.90
Ar-Go	9.64	5.37	10.00	7.34	0.84
Co-Gn	26.48	9.32	26.43	11.14	0.99
Ar-Go-Me	-10.81	7.08	-9.38	8.33	0.50
N-Gn	25.16	10.23	22.70	8.86	0.37
Dental Measures					
U1/NA*	12.43	9.96	5.17	10.92	0.01
U1-NA*	5.05	3.58	2.75	3.60	0.02
U1/PP*	13.74	9.51	6.83	10.74	0.02
U1/SN*	10.01	8.05	3.41	9.74	0.01
L1/NB	3.34	5.36	3.07	6.58	0.87
L1-NB	2.66	2.37	2.37	2.12	0.65
L1/Apo	8.70	5.33	5.73	6.30	0.07
L1-Apo	1.97	2.42	1.13	2.16	0.20
L1/MP	5.66	7.14	3.87	7.59	0.38
OP/HP	-5.45	4.97	-4.66	6.49	0.61
U1/L1	-13.33	11.21	-6.91	13.10	0.06
OB	0.88	2.21	0.38	1.89	0.39
OJ	0.41	2.57	0.48	2.36	0.92
Airway measures					
SAD	11.65	3.92	9.61	4.82	0.09

*Statistically significant at $p<0.05$.

Table 20: Independent samples t test comparing arch length discrepancy based on breathing status at T2.

	Nose breathing		Mouth breathing		Sig.
	Mean	**SD**	**Mean**	**SD**	
Maxilla	0.97	3.20	-1.41	4.58	0.17
Mandible*	-1.96	2.57	-3.84	3.33	0.04

*Statistically significant at p<0.05.

E. Comparison of patients based on gender

Gender grouping revealed 35 males (mean age of 18.51±2.59) and 22 female subjects (mean age of 19.32±2.56).

1. Cephalometric measurements

Tables 21 and 22 report measurements between males and females at T2, and the mean difference between the 2 groups respectively.

a. Skeletal measurements

The mandibular measurements namely, Go-Pg (=0.01), Ar-Go (p=0.00), Co-Gn (p=0.00) were significantly larger in males than in females.

Analysis of mean difference, revealed more reduction in ANB angle in males (1.96° from T1 to T2), whereas in females this amount was 0.57° (p=0.03). In contrast Ao-Bo changes in females were greater compared to males, with increase of 1.64mm in females and reduction of 1.11mm in males (p=0.00).

b. Dental measurements

No significant differences were observed when analyzing dental measurements between the genders. When comparing the mean differences, females showed more proclination of mandibular incisors over time (L1/NB and L1/MP) but neither of those measurements were significant when comparing males to females.

c. Airway measurements

No statistically significant differences were reported regarding SAD values in comparison to gender.

2. Analysis of arch length discrepancy

The amount of crowding in the maxillary arch for female participants was -1.75±3.43 mm, whereas for males more spacing was observed (1.32±3.69mm). Similarly, in the mandibular arch the females had more crowding than males, -3.15±3.66mm and -2.29±2.44mm respectively. Nevertheless, none of the differences were to a statistically significant level (Table 23).

Table 21: Independent samples t test comparing cephalometric measurements based on gender at T2.

	Males		females		Sig.
	Mean	**SD**	**Mean**	**SD**	
Age	18.51	2.59	19.32	2.56	
Cranial base					
SN*	70.16	4.50	65.42	3.37	0.00
N-S-Ar	124.66	5.07	126.05	5.50	0.33
S-Ar*	35.52	3.40	31.86	2.57	0.00
Relationship between jaws					
ANB	2.55	2.41	3.76	2.95	0.10
AoBo	-1.27	4.00	0.29	2.94	0.12
PP-MP	24.00	5.17	25.43	7.94	0.42
LFH/TFH	56.20	1.85	55.30	2.43	0.12
Maxilla					
SNA	83.70	3.61	84.20	3.57	0.61
ANS-PNS*	53.72	3.69	50.24	3.15	0.00
PP-HP	2.13	2.86	2.64	1.95	0.47
Mandible					
SNB	81.15	3.62	80.50	3.36	0.50
MP-HP	27.24	5.24	29.04	8.32	0.32
MP-SN	31.60	4.31	31.34	6.31	0.85
SN-Me	64.95	3.01	63.60	4.66	0.19
Go-Pg*	76.50	6.92	71.90	3.26	0.01
Ar-Go*	50.29	4.18	43.20	2.94	0.00
Co-Gn*	120.07	8.28	107.78	4.46	0.00
Ar-Go-Me	125.28	6.44	126.77	6.38	0.40
N-Gn*	123.18	5.58	114.49	8.07	0.00
Dental Measures					
U1/NA	25.33	5.93	22.52	8.58	0.15
U1-NA	5.43	2.61	4.24	2.77	0.11
U1/PP	115.17	5.43	112.47	7.41	0.12
U1/SN	108.62	4.86	106.60	7.23	0.21
L1/NB	25.52	5.60	28.91	7.00	0.05
L1-NB	5.94	2.87	5.89	2.46	0.94
L1/Apo	25.21	3.49	26.62	3.52	0.14
L1-Apo	3.41	2.43	3.29	2.01	0.85
L1/MP	93.23	7.46	96.27	8.82	0.17
OP/HP	10.95	5.77	10.38	5.29	0.71
U1/L1	126.68	6.55	125.17	9.46	0.48
OB	1.10	1.70	1.18	1.66	0.86
OJ	3.28	1.91	3.41	1.28	0.78
Airway measures					
SAD	14.87	3.82	13.83	3.20	0.29

*Statistically significant at $p<0.05$.

Table 22: Independent samples t test comparing the difference of the cephalometric measures based on gender.

	Males		females		Sig.
	Mean diff	**SD**	**Mean diff**	**SD**	
Cranial base					
SN*	9.19	4.69	5.85	3.93	0.01
N-S-Ar	3.46	6.16	3.77	5.89	0.85
S-Ar	7.66	4.16	6.51	2.46	0.25
Relationship between jaws					
ANB*	-1.96	2.26	-0.57	2.45	0.03
AoBo*	-1.11	3.11	1.64	2.44	0.00
PP-MP	-5.64	4.94	-4.15	6.13	0.32
LFH/TFH	-1.06	2.54	-1.79	2.99	0.33
Maxilla					
SNA*	-2.48	4.66	-0.22	2.68	0.04
ANS-PNS*	11.03	4.62	7.85	3.32	0.01
PP-HP	7.31	5.48	7.91	4.54	0.67
Mandible					
SNB	-0.60	4.48	0.37	3.07	0.38
MP-HP	-4.66	4.76	-2.89	5.35	0.20
MP-SN	-2.09	4.59	-3.76	4.60	0.19
SN-Me	7.73	5.60	9.64	6.38	0.24
Go-Pg*	19.07	6.15	14.97	6.28	0.02
Ar-Go*	11.58	5.44	6.87	6.01	0.00
Co-Gn*	30.26	8.76	20.41	8.64	0.00
Ar-Go-Me	-11.46	7.89	-8.47	6.60	0.14
N-Gn	26.23	10.18	21.22	8.39	0.06
Dental Measures					
U1/NA	10.71	9.55	8.56	12.63	0.47
U1-NA	4.66	3.56	3.58	3.97	0.29
U1/PP	12.11	8.85	10.05	12.62	0.47
U1/SN	7.55	7.57	7.91	11.45	0.89
L1/NB*	1.90	5.32	5.38	5.90	0.03
L1-NB	2.51	2.60	2.64	1.68	0.83
L1/Apo	6.66	5.69	9.24	5.78	0.10
L1-Apo	1.77	2.60	1.54	1.93	0.72
L1/MP*	3.46	6.48	7.53	7.93	0.04
OP/HP	-4.20	5.12	-6.73	5.85	0.09
U1/L1	-9.94	11.51	-12.88	13.27	0.38
OB	0.40	2.28	1.20	1.71	0.16
OJ	0.15	2.69	0.89	2.09	0.28
Airway measures					
SAD	10.96	4.32	10.90	4.44	0.96

*Statistically significant at $p<0.05$.

Table 23: Independent samples t test comparing length discrepancy based on gender at T2.

	Males		Females		Sig.
	Mean	**SD**	**Mean**	**SD**	
Maxilla	1.32	3.69	-1.75	3.43	0.30
Mandible	-2.29	2.44	-3.15	3.66	0.63

*Statistically significant at $p<0.05$.

F. Comparison of patients based on orthodontic treatment

This group consisted of 17 participants (11 males and 5 females) who have had orthodontic treatment between the 2 time points (mean age 17.81±1.88 years). The remaining 40 subjects were never treated orthodontically (24 males and 17 females; mean age 19.25±2.80 years).

1. Cephalometric measurements

Tables 24 and 25 display differences at T2 between orthodontically treated and untreated groups and the mean difference between the 2 groups respectively.

a. Skeletal measurements

Analyzing the mean differences showed that the ANB angle had significant reduction of 2.54° reaching 2.83° at T2 in the patients who had orthodontic treatment, whereas in the untreated group this value decreased by 0.96° only reaching 3.09° at T2 (p=0.02). As for SNA angle the reduction in the orthodontic group was 3.46°, whereas in the untreated group had reduction of only 0.82° (p=0.03).

b. Dental measurements

The only statistically significant value reported was maxillary incisors inclination relative to SN (U1/SN) with p value of 0.04. The maxillary incisors appeared to be more proclined in the orthodontically treated group 110.33°±5.96 relative to the untreated counterparts (106.79°±5.63).

c. Airway measurements

The population with history of orthodontic treatment had significantly wider SAD dimensions (16.04±3.55mm) compared to the non-treated group (13.81±3.45mm).

2. Analysis of arch length discrepancy

The amount of arch length discrepancy of maxillary and mandibular arches was statistically significantly different between the 2 groups (Table 26). The orthodontically treated group had significantly less crowding; 0.11±3.09mm in the maxilla (p=0.02) and -1.25± 1.46mm in the mandible (p=0.01), whereas in the untreated group these values were -1.15±3mm and -3.20±3.26mm respectively.

Table 24: Independent samples t test comparing the cephalometric measurements based on orthodontic treatment at T2.

	Untreated		Treated		Sig.
	Mean	**SD**	**Mean**	**SD**	
Age	19.25	2.80	17.81	1.88	
Cranial base					
SN	67.72	4.92	69.79	3.83	0.13
N-S-Ar	125.51	6.04	124.45	2.49	0.49
S-Ar	33.71	3.83	35.05	2.75	0.20
Relationship between jaws					
ANB	3.09	2.92	2.83	2.02	0.74
AoBo	-1.12	3.57	0.38	3.82	0.16
PP-MP	24.47	6.64	24.76	5.79	0.88
LFH/TFH	55.62	2.22	56.39	1.81	0.21
Maxilla					
SNA	83.96	3.61	83.73	3.56	0.83
ANS-PNS*	51.61	3.75	54.19	3.60	0.02
PP-HP	2.67	2.36	1.51	2.83	0.12
Mandible					
SNB	80.88	3.40	80.95	3.85	0.94
MP-HP	28.06	7.02	27.65	5.63	0.84
MP-SN	31.61	5.05	31.26	5.43	0.82
SN-Me	64.57	3.84	64.09	3.63	0.67
Go-Pg	74.48	6.29	75.31	6.05	0.65
Ar-Go	47.37	5.57	47.98	3.88	0.68
Co-Gn	115.14	10.56	115.77	5.23	0.82
Ar-Go-Me	125.99	6.42	125.53	6.56	0.81
N-Gn	119.08	8.36	121.60	6.34	0.27
Dental Measures					
U1/NA	23.25	7.06	26.60	6.94	0.11
U1-NA	4.73	2.75	5.55	2.62	0.30
U1/PP	113.62	6.09	115.34	6.94	0.35
U1/SN*	106.79	5.63	110.33	5.96	0.04
L1/NB	27.00	7.16	26.42	3.91	0.76
L1-NB	5.76	2.67	6.30	2.81	0.49
L1/Apo	25.68	3.61	25.93	3.48	0.81
L1-Apo	3.29	2.33	3.55	2.15	0.69
L1/MP	94.23	8.83	94.81	6.16	0.81
OP/HP	11.48	5.14	8.95	6.22	0.12
U1/L1	126.86	8.37	124.31	5.90	0.26
OB	1.11	1.84	1.20	1.22	0.85
OJ	3.24	1.73	3.55	1.60	0.54
Airway measures					
SAD*	13.81	3.45	16.04	3.55	0.03

*Statistically significant at $p<0.05$.

Table 25: Independent t test comparing the difference of the cephalometric measures based on orthodontic treatment.

	Untreated		Treated		Sig.
	Mean diff	**SD**	**Mean diff**	**SD**	
Cranial base					
SN	7.18	4.73	9.59	4.19	0.07
N-S-Ar	4.02	6.60	2.55	4.26	0.40
S-Ar*	6.56	3.75	8.78	2.81	0.03
Relationship between jaws					
ANB*	-0.96	2.42	-2.54	2.06	0.02
AoBo	0.03	2.85	-0.23	3.86	0.78
PP-MP	-4.65	5.33	-6.05	5.69	0.38
LFH/TFH	-0.93	2.69	-2.31	2.60	0.08
Maxilla					
SNA*	-0.82	3.66	-3.46	4.70	0.03
ANS-PNS	9.10	4.46	11.47	3.99	0.06
PP-HP	6.80	5.08	9.29	4.87	0.09
Mandible					
SNB	0.05	3.81	-0.87	4.45	0.44
MP-HP	-3.80	4.90	-4.39	5.44	0.69
MP-SN	-2.69	4.42	-2.84	5.23	0.92
SN-Me	8.43	6.46	8.54	4.63	0.95
Go-Pg	16.77	6.33	19.17	6.67	0.20
Ar-Go	9.42	6.61	10.57	4.64	0.52
Co-Gn	25.37	10.14	29.02	9.07	0.21
Ar-Go-Me	-9.08	5.35	-13.20	10.69	0.06
N-Gn*	22.32	9.67	28.97	8.54	0.02
Dental Measures					
U1/NA*	7.76	9.81	14.87	11.62	0.02
U1-NA	3.69	3.48	5.55	4.06	0.09
U1/PP	9.48	9.64	15.64	11.15	0.04
U1/SN	6.25	8.58	11.09	9.85	0.07
L1/NB	3.32	6.27	3.07	4.49	0.38
L1-NB	2.39	1.98	2.97	2.87	0.20
L1/Apo	7.01	5.91	9.18	5.42	0.20
L1-Apo	1.45	2.25	2.21	2.57	0.27
L1/MP	4.73	7.69	5.74	6.41	0.64
OP/HP	-4.60	5.13	-6.52	6.26	0.23
U1/L1	-9.41	12.05	-15.00	11.95	0.11
OB*	0.32	2.19	1.61	1.58	0.03
OJ	0.37	2.52	0.58	2.47	0.77
Airway measures					
SAD	10.19	3.97	12.68	4.76	0.05

*Statistically significant at $p<0.05$.

Table 26: Independent samples t test comparing arch length discrepancy between orthodontically treated and untreated individuals at T2.

	Untreated		Treated		Sig.
	Mean	SD	Mean	SD	
Maxilla*	-1.15	3.00	0.11	3.09	0.02
Mandible*	-3.20	3.26	-1.25	1.46	0.01

*Statistically significant at p<0.05.

G. Obstructive sleep apnea risk assessment

In analysis of Epworth Sleepiness Scale, 9 participants were categorized in the high risk group (16%) (Fig.37). The 9 patients included 5 females and 4 males, among which 8 had history of adenoidectomy. When assessing the breathing status 3 out of the 9 patients were still mouth breathers.

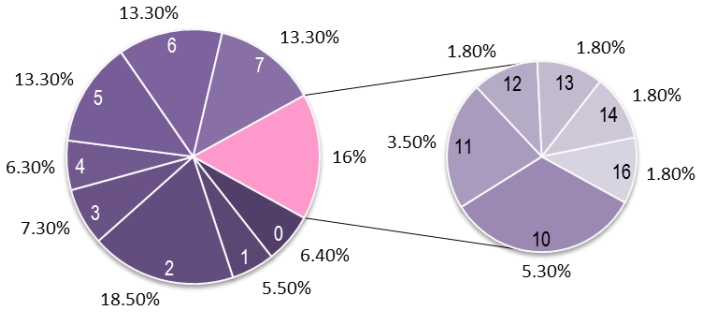


Figure 37: Scores of the patients in Epworth Sleepiness scale. A score of 10 or more suggest that the person may need more sleep, needs to change sleep practices or needs medical evaluation to find out the cause of the sleepiness (16% of the population).

According to the results from the STOP-BANG questionnaire, 12 people were at high risk of developing OSA (21%) (Fig. 38), among which 10 were males and 9 had a history of surgery in the past. From the total of 12 patients 6 reported to be mouth breathers to this date.

Combining the results from both questionnaires, 5 participants scored high in both questionnaires (2 females and 3 males). Four patients have had surgery in the past and 3 reported current mouth breathing.

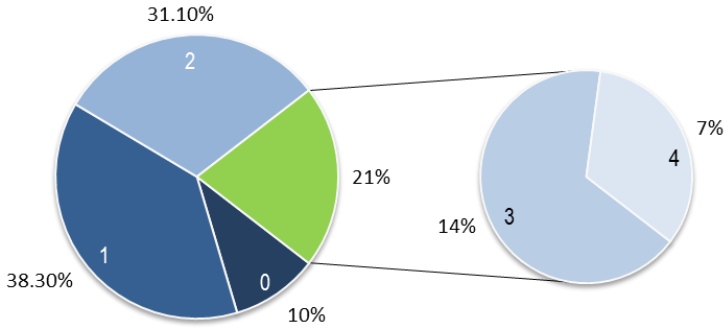


Figure 38: Scores of the patients in STOP-BANG questionnaire. Scores of 3 and 4 project a high risk of OSA (21% of population).

Further grouping based on the scores from the questionnaires is displayed in Figures 39 and 40. The patients were grouped based on the severity of their scores (severe and not severe). Moreover each group was divided into surgical and non-surgical subgroups; the SAD value was then compared among them by one way ANOVA which showed significant difference between the groups (p=0.00); further analysis of data did not reveal any significant connection between the severity of scores of the questionnaires and the dimensions of SAD by Chi Square and Bonferroni correction tests.

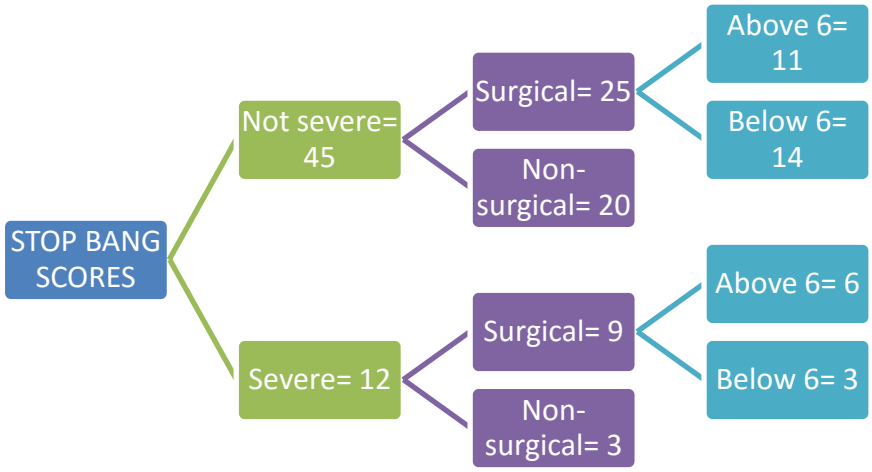


Figure 39: Grouping of the patients in STOP-BANG questionnaire based on severity scores and the surgical status.

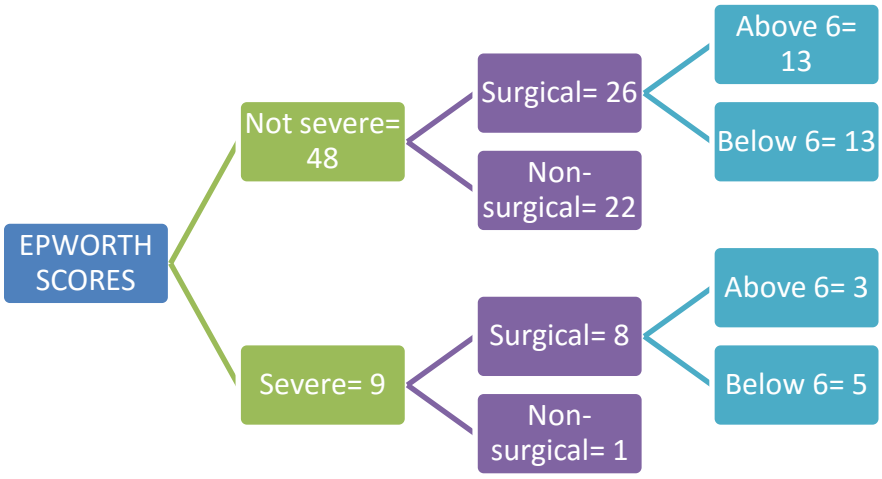


Figure 40: Grouping of the patients in Epworth questionnaire based on severity scores and the surgical status.

H. Correlations between cephalometric measurements

Cephalometric measurements were computed in a correlation matrix that covered all skeletal and dentoalveolar measures at 3 time points (T1, T2 and T2-T1) relative to age at T2 for all patients as well as age at the time of surgery. Only some selected correlations greater than $r \geq 0.3$ are shown in Tables 27 and 28 to represent the scope of measurements computed.

Table 27: Selected correlations with r ≥ 0.3 between age at T2 and cephalometric measurements.

R ≥ 0.5		CoGn	N-ANS	Go-Pog	N-Gn
		T1	T1	T1	T1
age T2	R	0.58	0.60	0.58	0.54
	P-value	0.00	0.00	0.00	0.00

R ≥ 0.4		LFH		ANB	AoBo	PP/MP	GoPog	SAD		N-ANS	U1/PP	L1/Apo	OB	SN-Me	Go-Pog	N-Gn
		T1	T2-T1	T2-T1	T1	T2-T1	T2-T1	T1	T2-T1	T2-T1	T2-T1	T1	T2-T1	T1	T2-T1	T2-T1
age T2	R	-0.47	0.46	0.43	-0.43	0.40	-0.42	0.47	-0.45	-0.49	-0.40	0.41	-0.42	0.49	-0.45	-0.49
	P-value	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

R ≥ 0.3		ANB	CoGn	ANS-PNS	SN	U1/NA		U1-NA		U1/PP	L1/Apo	L1-Apo	U1/L1	U1-PP	L1-MP	Sn-Npog	OB	SN-ME	S-Ar		Ar-Go	
		T1	T2-T1	T2-T1	T1	T2	T2-T1	T1	T2-T1	T2	T2-T1	T1	T2	T1	T1	T2-T1	T1	T2-T1	T1	T2-T1	T1	T2-T1
age T2	R	-0.39	-0.36	-0.32	0.38	-0.31	-0.34	0.37	-0.32	-0.35	-0.39	0.35	0.33	0.39	0.38	-0.34	0.33	-0.35	0.34	-0.39	0.37	-0.32
	P-value	0.00	0.01	0.02	0.00	0.02	0.01	0.01	0.02	0.01	0.00	0.01	0.01	0.00	0.00	0.01	0.01	0.01	0.01	0.00	0.00	0.02

Table 28: Selected correlations with r ≥ 0.3 between age at the time of surgery and cephalometric measurements.

R≥0.3		SAD		ANS-PNS	SN	GoPog	U1/PP	
		T1	T2-T1	T1	T1	T1	T2	T2-T1
age at surgery	R	0.53	-0.38	0.42	0.34	0.37	-0.38	-0.38
	P-value	0.00	0.03	0.01	0.05	0.03	0.03	0.03

I. Association between different cephalometric measurements with group comparisons

1. Multiple linear regressions

Multiple linear regression models were tested to predict the effect of surgery, orthodontic treatment, age and gender on mean difference of the cephalometric measures (T2-T1).

Shortest adenoid distance (SAD): Surgery, orthodontic treatment and age at T2 were strong predictors for SAD difference. Predicting the SAD depending on the

surgical status of the patients showed that, moving from non-surgical to surgical group the value of SAD difference increases by 5.26mm (95% Cl:0.60;6.55) (adjusting for orthodontic treatment and age at T2). Moreover each year increase in age decreases the SAD difference by 0.54 mm (95% Cl: -0.32;-3.45) adjusting for the other variables. These predictors in addition to orthodontic treatment could explain 57% of the variation of SAD in the population (Table 29).

Table 29: Multiple linear regression model for the prediction of SAD.

Predictors	ß	SE	95% Cl	*p*-value	R2
Surgery	5.26	0.80	0.60;6.55	0.00	0.57
orthodontic tx.	0.90	0.88	0.10;1.02	0.31	
age T2	-0.54	0.16	-0.32;-3.45	0.00	

Upper facial height (N-ANS): As shown in Table 30, age at T2, orthodontic treatment and gender were strong predictors of N-ANS, each year increase in age decreased the N-ANS difference by 0.76mm (95% Cl: -0.41;-3.53) and moving from males to females reduced this measurement by 2.65mm (95% Cl: -0.27;-2.39), also adjusting for the other variables. Both these measures in addition to orthodontic treatment account for 35% of the variation in N-ANS in the population.

Table 30: Multiple linear regression model for the prediction of N-ANS.

Predictors	ß	SE	95% Cl	*p*-value	R2
age T2	-0.76	0.22	-0.41;-3.53	0.00	0.35
orthodontic tx.	1.78	1.21	0.17;1.48	0.15	
gender	-2.65	1.11	-0.27;-2.39	0.02	

Lower Facial height (LFH): Both mouth breathing and age at T2 were strong predictors of lower face height, accounting for 30% of variation in LFH (Table 31).

Table 31: Multiple linear regression model for the prediction of LFH.

Predictors	ß	SE	95% Cl	*p*-value	R2
mouth breathing T2	1.676	0.646	0.30;2.60	0.01	0.30
age T2	0.452	0.12	0.43;3.78	0.00	

Total face height (N-Gn): Surgery, orthodontic treatment and age at T2 were strong predictors of N-Gn, each year increase in age reduced the N-Gn difference by 1.54mm (95% Cl: -0.41;-3.48) adjusting for other values. Surgery, orthodontic treatment and age together accounted for 32% of variation in population (Table 32).

Table 32: Multiple linear regression model for the prediction of N-Gn.

Predictors	ß	SE	95% Cl	*p*-value	R2
Surgery	4.26	2.27	0.22;1.88	0.07	0.32
orthodontic tx.	3.78	2.49	0.18;1.52	0.13	
age T2	-1.54	0.44	-0.41;-3.48	0.00	

Maxilla (SNA): Surgery, gender and orthodontic treatment were strong predictors of SNA, moving from the non-surgical to surgical group reduced the SNA difference by 4.26° (95% Cl: -0.27;-2.17) adjusting for other variables. These variables accounted for approximately 21% of variation in the population (Table 33).

Table 33: Multiple linear regression model for the prediction of SNA.

Predictors	ß	SE	95% Cl	*p*-value	R2
Surgery	-2.24	1.03	-0.27; -2.17	0.03	0.21
gender	2.00	1.04	0.24;1.93	0.06	
orthodontic tx.	-2.03	1.11	-0.23;-1.81	0.08	

Relationship between maxilla and mandible ANB: as shown in Table 34, mouth breathing, gender, orthodontic treatment and age at T2 were strong predictors for the

ANB angle. Moving from nose breathers to mouth breathers increased the ANB difference by 1.34° (95% Cl: 0.27;2.29), in addition each year of increase in age increased the ANB difference by 0.32° (95% Cl: 0.34;2.89). These predictors accounted for 21% of variation in the population.

Table 34: Multiple linear regression model for the prediction of ANB.

Predictors	ß	SE	95% Cl	*p*-value	R2
mouth breathing T2	1.34	0.59	0.27;2.29	0.03	0.21
gender	0.95	0.57	0.19;1.67	0.10	
age 2	0.32	0.11	0.34;2.89	0.01	
orthodontic tx.	-0.67	0.63	-0.13;-1.07	0.29	

Gonial angle (Ar-Go-Me): Moving from non-surgical to surgical group reduced the Ar-Go-Me angle by 4.65° (95% Cl: -0.31;-2.44) adjusting for other predictors. Surgery, gender and age at T2 together accounted for 19% of variation in the population (Table 35).

Table 35: Multiple linear regression model for the prediction of Ar-Go-Me.

Predictors	ß	SE	95% Cl	*p*-value	R2
Surgery	-4.65	1.90	-0.31;-2.44	0.02	0.19
Gender	2.53	1.91	0.17;1.33	0.19	
age T2	0.55	0.37	0.19;1.50	0.14	

2. Univariate analysis of covariance (ANCOVA)

ANCOVA covariance analysis was tested for different cephalometric measurements in relation to surgery and age. The only significant correlation found was in SAD and Ar-Go-Me difference. Surgery remained significantly associated with SAD (p=0.00) and Ar-Go-Me (p=0.02) difference after adjusting for age (Tables 36 and 37).

Table 36: Analysis of ANCOVA correlating surgery and SAD.

Dependent variable	**SAD diff.**	**P. value**
Independent variable	**Surgery**	
Covariate1:	Age diff.*	0.000
Covariate2:	Age T2*	0.000

*Statistically significant at p<0.05.

Table 37: Analysis of ANCOVA correlating Ar-Go-Me and SAD.

Dependent variable	**Ar-Go-Me diff.**	**P. value**
Independent variable	**Surgery**	
Covariate1:	Age diff.*	0.020
Covariate2:	Age T2*	0.020

*Statistically significant at p<0.05.

CHAPTER V

DISCUSSION

Despite the presence of evidence-based indications for tonsils and adenoids (T&A) removal, physicians tend to postpone surgery in young mouth breathing children because adenoids and tonsils gradually undergo reduction in time, and the concern about surgical complications. Considering that a significant amount of facial growth occurs early in life, sustained mouth breathing throughout years of growth can contribute to a more severe dentofacial abnormality.

The findings of this study indicated a clear relationship between adenoidectomy and timing of surgery with subsequent normalization of dentofacial morphology, supporting our hypothesis.

A. Skeletal findings

Most of the variables revealed significant differences between T1 and T2 when comparing the surgical and non-surgical groups. However ANB and SNA did not decrease in the non-surgical group and remained significantly different from the controls at T2, indicating that the sagittal relationship between maxilla and mandible did not improve and the maxilla remained protruded in the non-surgical group. In contrast greater improvement was observed in the surgical group in both ANB and SNA angles which were not statistically significant from the control values. This finding contradicts the results from Linder-Aronson et al (1986) who reported no changes in maxillary growth direction after adenoidectomy.

The mandibular measurements (Go-Pog, Co-Gn) were statistically significantly different between the surgical and non-surgical groups at T1, but the surgical group showed more extensive growth and similar measures to the non-surgical group at T2. This finding may be attributed to the younger age of the surgical group at T1, and to the fact that removal of the obstacles favored more efficient growth in this group. Moreover the non-surgical group received medicaments to treat enlarged adenoids, possibly because the SAD measurement was not severe enough to necessitate surgery or the parents had rejected surgery and therefore improvement in this group was expected as well but not to the extent of the surgical group.

More significant changes in the gonial angle (Ar-Go-Me) in the surgical group resulted in a more acute angle at T2. This angle was even smaller in the surgical group than the controls ($p=0.01$), whereas the non-surgical group normalized to control values. This finding suggests that the major effect from adenoids removal is the gonial angle closure. Both findings on Co-Gn and Ar-Go-Me are concomitant with the results reported by Kerr et al (1986), and Linder-Aronson et al (1989) who reported counter clockwise rotation of the mandible and increased mandibular growth after adenoidectomy. Dunn et al (1973) compared the cephalometric measurements between the monozygomatic twins of different adenoid dimensions and reported that the gonial angle decreases with increasing dimensions of the nasopharyngeal airway ($p< 0.01$). The reduction in the gonial angle was also reported by Mattar et al (2011) who compared 33 mouth breathing young children (age between 3 and 6) who restored to nasal breathing after surgery with 22 controls of corresponding ages, during a period of 28 months.

Of important clinical significance and therapeutic implication is the fact that the gonial angle showed more changes with time in patients who underwent surgery below age 6 (reduction of 15.11°±8.77) than the older age group (reduction of 9.31°±6.58) (p=0.04).

The saddle angle S-N-Ar in children below age 6 in the surgical group normalized to their corresponding controls whereas in the older group this value was higher than that of controls (p=0.01), indicating that surgery at a younger age may have influenced the cranial base development.

All measurements related to the divergence pattern (PP/MP, PP/H, MP/SN) reduced significantly with time (p=0.00) in both groups. PP/MP was not significantly different between controls and the non-surgical group (p=0.37), whereas the surgical group (23.80°±5.72) presented a less divergent pattern compared to controls (26.84°±4.74) (p=0.02). There was no significant difference in PP/MP between children above and below age 6 in the surgical groups and their corresponding controls. PP/H was not statistically significant from controls in the surgical group, whereas in the non-surgical group this value remained different from controls (p=0.03). Moreover the PP/H angle underwent more extensive changes in the younger surgical group compared to the above 6 surgical group (mean difference of 9.35°± 4.77 and 5.34°± 5.41 respectively) (p=0.03). MP/SN showed a similar pattern to that of PP/MP: closer to controls in the non-surgical group and more closure than controls in the surgical group. However, when comparing the below 6 age group to controls, MP/SN was significantly smaller in the younger surgical group (p=0.01); no significant difference was observed between the older surgical group and the corresponding controls.

Souki et al (2010) investigated lateral cephalograms of 39 surgical patients with 31 untreated mouth breathing controls, ranging from 3 to 10 years of age, at baseline before surgery, and then at approximately 1 year post-operatively. The patients were divided into deciduous and mixed dentition groups to aid in distinguishing whether the age at which adenoidectomy was performed had an effect on treatment outcome. They observed that the deciduous dentition treatment group showed a statistically significant reduction in PP/MP ($p=0.03$), whereas the untreated control group had an increase in the divergence ($p=0.54$) during this period of time. Because the PP/MP measure was the only significant difference between the groups, the authors could not generalize the results based on this single finding. Nevertheless they did not rule out that early intervention might be beneficial in patients with severe skeletal pattern.

Arun et al (2003) investigated 93 lateral cephalograms of 3 groups of patients. The first group (n=12, age: 11.16±2.08 years) had adenoidectomy between 1.5-4 years of age. The second group (n=54, age: 12.18±2.6 years) had surgery after age 4. The third group (n=27, age: 11.18±2.35 years) with clear airway served as controls. The only significant difference among age groups was in the ratio of LFH/TFH ($p<0.05$), which was higher in the less than 4 age group (58.46±2.51%) than in the older age group (56.90±2.14%). This result coincides with our finding a significant reduction in LFH in the below 6 age group ($p=0.03$) compared to the older age group ($p=0.07$). Arun et al also reported that when the surgerized groups were compared with controls, the MP/SN ($p<0.01$), PP/MP ($p<0.01$), and LFH/TFH ($p<0.05$), had significantly greater parameters in the surgical group, indicating greater vertical growth in the adenoidectomy group. This finding contradicts the results from our study, especially

taking into account that the measurements presented in control groups of both studies are similar to each other.

Linder-Aronson (1979) reported an actual difference of 0.4° in MP/SN angle during the first year, which was not significant. However, during the 5 year observation period, a significant change was noted in the operated children. They also reported that the LFH was reduced with reduction of PP/MP angle, as well as association between adenoidectomy with changed mode of breathing and the establishment of more horizontally growing mandibles than those of the control group (Linder-Aronson, Woodside and Lundström, 1986). In our study the only significant difference in the LFH/TFH was between mouth breathers and nose breathers; LFH in mouth breathers (56.88±1.94) was significantly longer compared with nose breathers (55.30±2.02) ($p=0.01$). A decrease in the inclination of the mandibular plane and an increase in the posterior facial height were also reported by Mattar et al (2011).

B. Dental findings

The majority of dental measurements were significantly different between T1 and T2 in all groups. The surgical group had more proclined maxillary incisors than the non-surgical group when comparing the U1/PP measurements ($p=0.03$). Also, the surgical group had more proclination of the maxillary and mandibular incisors than the control group; in the non-surgical group the mandibular incisors were more protruded. The patients who had surgery before age 6 had similar measures to their matched controls except for U1/SN (more proclination in the surgical group). In contrast the older age group showed a trend towards proclined and protruded mandibular incisors.

Other authors reported a significant increase in labial inclination of maxillary and mandibular incisors (Linder-Aronson, 1973, 1979), more proclination of maxillary (U1/PP) and mandibular (L1/MP) incisors of surgical group relative to controls (p=0.49 and 0.99 respectively) (Zettergren-Wijk, Forsberg and Linder-Aronson, 2006).

Regarding arch length discrepancy, the patients who had their adenoids removed after the age of 6 exhibited more mandibular crowding (p=0.00). Mouth breathers also had more crowding at T2 in the mandibular arch compared to nose breathers (p=0.04). As expected patients with a history of orthodontic treatment had significantly less crowding in both maxillary (p=0.02) and mandibular (p=0.01) arches. Woodside et al (1991) compared cephalometric and dental casts of 30 male and 20 female children, 8 to 13 years old, with chronic nasal mucosal swelling, to those of controls. The affected subjects had significantly more mandibular incisor crowding, confirming our findings regarding the mouth breathing group.

C. Airway findings

The SAD measurements of surgical (2.96mm±2.49) and non-surgical (4.39mm ± 2.95) groups at T1 were not statistically significant, however this value gained significance after adenoidectomy (p=0.00).

Both groups had significantly greater SAD measurements between T1 and T2. When comparing both groups with their respective controls, the values were still statistically significant; however the surgical group had significantly greater SAD distances than those of controls (16.25mm ± 2.94 compared to 14.61mm±2.31) (p=0.01). The non-surgical group had significantly smaller SAD measurements

(11.84mm±2.81 compared to 15.63mm±2.44) (p=0.00). Moreover the timing of surgery did not have an effect on outcome SAD at T2, a reasonable finding because the adenoid tissue was fully removed in both groups. Linder-Aronson (1973) compared the size of the adenoids in the adenoidectomy and control groups 1 year after surgery, and reported a better agreement between the 2 groups, and that the improvement in nasal airflow after adenoidectomy persisted throughout the year immediately after the operation.

Our data revealed that surgery, orthodontic treatment and age at T2 were strong predictors of the SAD measurement (r=0.57). In addition, the correlation between SAD at T1 and age at the time of surgery (r=0.53) was statistically significant.

D. OSA and mouth breathing findings

Analysis of the STOP-BANG and Epworth questionnaires did not disclose a connection between the severity of the scores and the SAD dimensions. Nevertheless the general trend was a high score in patients who underwent surgery after the age of 6.

Reversal to nose breathing was reported by 70.59% of the patients who had undergone surgery, a result that joins the findings of Linder-Aronson (1973) that some proportion of persistent mouth breathers is likely to remain even after surgery (9-31%). Bahadir et al (2006) reported 88.3% (53 of 60 children) relief of mouth breathing 2 months after adenoidectomy as relayed by the parents.

E. Clinical implications

This study adds further confirmation to the body of evidence present in the literature that many malocclusions and facial characteristics previously thought to be

inherent or skeletal may be the result of environmental factors and associated epigenetic influence.

Hultcrantz et al (1991) stated that the best results after tonsillectomy in children with OSA were observed when surgery was performed before age 6, possibly because prior to this age, the compensatory changes of the dentoalveolar development from tonsillar obstruction have not become permanent. In contrast during the mixed dentition stage, a spontaneous correction is less likely. The results of this study confirm the hypothesis provided by Macari et al (2012) who suggested performing airway clearance before age 6 in the most severely affected children to maximize the reversal of the affected craniofacial features.

1. Otolaryngology

The findings emphasize the need for pediatricians and pediatric otolaryngologists to examine children early on for diagnosis of enlarged adenoids and tonsils which are the most common obstacles for nasal breathing. Moreover, sustained interactions are needed with orthodontists regarding the impact of mouth breathing on craniofacial morphology.

The lymphoid tissue reaches nearly twice the final size during the pre-pubertal phase before shrinking to adult size (Scammon et al., 1930). Otolaryngologists justify the delayed removal of adenoids and tonsils based on these findings, underestimating the potential disharmony in growth between the airway and adenoids (Diamond, 1980).

The morphological changes over time reported in our study would justify the removal of hypertrophied adenoids in the first 6 years of life to increase the potential of normal growth of the dento-facial complex.

The obstruction of airways by adenoids should be treated as soon as diagnosed, especially in patients whose airway clearance is less than 2mm. Nasal breathing after treatment enhances the optimal growth potential. Interdisciplinary treatment with evidence based practice can help the patients and parents to weigh the cost to benefit ratio of early versus late removal of the hypertrophied adenoids.

2. Orthodontics

This study indicates that the environmental impact on the cranial and dental development can be reversible. Combining more horizontally growing mandibles and less divergent facial patterns after adenoidectomy together with simultaneous correction of the inclination of the teeth and normalization of lower facial height, due to corrected balance between pressure exerted by the lips and tongue (Linder-Aronson, 1970), would support the removal adenoids to intercept their harmful effect on craniofacial morphology.

Before the initiation of orthodontic treatment the patency of the patient's nasal airways should be addressed. Otherwise, the functional factors associated with abnormal respiration may counteract the orthodontic treatment and increase the risk of relapse. Mouth breathing has been considered a risk factor in relapse after orthognathic surgery, also emphasizing the management of mouth breathing in conjunction with orthognathic surgery (Ousterhout, Vargervik and Miller, 1983).

F. Reseach considerations

Our findings contribute to the knowledge on the interaction between adenoidectomy and normalization of dentofacial features over time. Additional studies

with larger samples following the same methodology would help the formulation of generalized guidelines for timing of adenoidectomy. The epigenetic and environmental factors contributing to the development of craniofacial disharmony should be emphasized in more details taking into account all factors (such as septal deviation, turbinates hypertrophy, sinusitis and allergic rhinitis) that would hinder adequate nasal patency during growth.

G. Strengths and limitations

The longitudinal aspect of this study between over 10 to 14 years after diagnosis, the longest follow-up period to be studied, as well as the largest (yet modest) sample size in relation to the time interval are the main elements of strength in this study. In addition the patients evaluated were past their puberty, therefore the full growth potential was expressed. Stratification of patients based on treatment, age at the time of surgery and gender helped determine the optimal timing for removing the enlarged adenoids.

One limitation of this study was the inability to recruit more patients, which could have enhanced the confidence of statistical computations. The recruitment of more patients was compromised by the long follow up period, but importantly by the COVID-19 pandemic that kept the potential participants from visiting hospital settings.

The absence of sufficient evidence in the literature with large sample size and long follow up periods also compromised comparison of the results with previous studies. The lack of a contemporary longitudinal matched control group during the study period was another limitation of the study, but was not possible since taking x-rays on such a young population would have not been possible for ethical reasons.

CHAPTER V

CONCLUSIONS

1- Adenoidectomy to regain nasal patency results on average in long term normalization of dento-facial growth in bony bases, specifically in the mandible, enhancing better chin projection in the surgical group.

2- Surgical treatment helps in more horizontal direction of mandibular growth and closure of the gonial angle, resulting in normalization of lower face height.

3- Surgery at a younger age (before age 6) results in better gonial angle closure and chin projection as well as more significant changes in the lower face height.

4- Adenoidectomy before age 6 allows enough time and growth potential to regain facial harmony, possibly because the improper growth tract has not completely settled in yet. As a result improved facial harmony can be expected in the future even when the skeletal features appear to be more severe initially.

5- Restoration of nasal patency and nasal breathing after treatment enhance the morphological improvements.

6- The outcome of adenoidectomy in terms of increased airway dimensions appears to be stable with time.

7- Children with mouth breathing should be diagnosed early and evaluated both from a medical and dentofacial perspectives through interdisciplinary cooperation between pediatricians, otolaryngologists, orthodontists, and pediatric dentists.

APPENDIX I

Minor's Initials ____

Institutional Review Board
American University of Beirut
Faculty of Medicine
Bliss Street
Beirut, Lebanon
Tel: (01) 350-000 ext. 5445

CHILD PARTICIPANT ASSENT FORM

(approximate ages 7-12)

Project Title: **Long term (>10 years) effects of airway obstruction treatment on dento-facial morphology**

Protocol Number:
Principal Investigator(s): Dr Anthony MACARI
Address: American University of Beirut Medical Center
Phone: (01) 350 000 ext: 5702
Site where the study will be conducted: Division of Orthodontics and Dentofacial Orthopedics, 6th floor, AUBMC

We want to tell you about a research study we are doing. A research study is a special way to find out about something. We are trying to find out more about the changes that mouth breathing can cause in the development of face and dentition, and the benefits that early treatment can have on facial features when mouth breathing is treated early in life. You are being asked to join the study because you were first referred to our department, almost 10 years ago, for a diagnostic radiograph when mouth breathing was diagnosed by the pediatric ENT physician. After which you were enrolled in Dr. Joseph Ghafari's study entitled "Relationship between severity of malocclusion and timing of Adenoidectomy and Tonsillectomy" in which 282 participants were enrolled. Accordingly, the corresponding treatment has been done and now we want to see what effect the treatment has caused on your facial features. After being contacted by Dr. Anthony Macari, you showed interest in participating in this follow up study.

If you decide that you want to be in this study, this is what will happen:

1- Any update in medical history will be filled out.
2- The orthodontist will look at your teeth and will take one x-ray of your profile, some photos from your teeth and face and an oral scan from your teeth.
3- You will be positioned in the x-ray machine, wearing a lead apron to reduce the risk of irradiation, which will move next to your face, for about 2 minutes.
4- An image of your profile will appear on the screen, showing your teeth and face. This is done to find out where are your jaws and teeth positioned and to compare it with the x-ray that was taken initially 10 years ago. An airway assessment on the image will be done and also compared to the findings from your previous xray.

Minor's Initials ____

5- The treatment for your mouth breathing condition will be assessed through your file present at the ENT Department.
6- Even if you do not want to participate in the research study, this x-ray, photographs and oral scan would be needed if you decide to undergo an orthodontic evaluation and treatment. In case an abnormal finding was present on the X-ray, further investigation will be performed accordingly. You will benefit from free diagnosis and treatment will be suggested.

This will require you to pass by AUBMC for 45mins: During which Dr. Annie Babakhanian will explain the project in detail, sign this consent form, have a clinical examination, photos from teeth and face, scanning of your teeth and a lateral cephalometric x-ray.

Can anything bad happen to me?

We want to tell you about some things that might hurt or upset you if you are in this study. There is the radiation risk from the X-ray, however there are no proven harmful effects from irradiation levels that you will be exposed to during the study. The risk however, will be more decreased by wearing a lead apron which will minimize the useless radiation to your body.

Can anything good happen to me?

The X-ray, photos and oral scan that will be taken from you will help us to tell you if you need any type of orthodontic treatment or not. We also hope to learn something that will help other people some day.

Do I have other choices?

You can choose not to be in this study

Can you be removed from the study without your consent?

You will not be removed from this study by the study team without your consent. However, the investigator may end your participation at any time.

Will anyone know I am in the study?

We will not tell anyone you took part in this study. When we are done with the study, we will write a report about what we found out. We will not use your name in the report.

What happens if I get hurt?

AUBMC will cover the cost of treating, on its premises, medical adverse events resulting directly from the medication and/or medical procedures of this research study. Otherwise, it will not cover for the costs of medical care for any medical condition or issue. But you should know that this risk is minimal.

Before you say yes to be in this study; be sure to ask Dr. Annie Babakhanian to tell you more about anything that you do not understand.

Minor's Initials ____

What are your rights as a research subject?

Being in this study is voluntary. You do not have to be in this study if you don't want to or you can stop being in the study at any time. Your decision will not result in any penalty or loss of benefits that you have now. If you have questions about your rights you may call:

Institutional Review Board on 01-350000 ext. 5445

You will be told about any new information that may affect your health, welfare, or willingness to stay in this study.

What if I do not want to do this?

You do not have to be in this study. It is up to you. If you say yes now, but you change your mind later, that is okay too. All you have to do is tell us.

Investigator's Statement:

I have reviewed, in detail, the informed consent document for this research study with _____ _____ (name of patient, legal representative, or parent/guardian) the purpose of the study and its risks and benefits. I have answered to all the patient's questions clearly. I will inform the participant in case of any changes to the research study.

_____ _____

Name of Investigator or designee **Signature**

_____

Date & Time

Patient's Participation:

I have read and understood all aspects of the research study and all my questions have been answered. I voluntarily agree to be a part of this research study and I know that I can contact Dr. _____Anthony Macari_____ at ____5702_____or any of his/her designee involved in the study in case of any questions. If I feel that my questions have not been answered, I can contact the Institutional Review Board for human rights at ___5445___. I understand that I am free to withdraw this consent and discontinue participation in this project at any time, even after signing this form, and it will not affect my care or benefits. I know that I will receive a copy of this signed informed consent.

_____ _____

Name of Patient or Legal Representative or Parent/Guardian **Signature**

_____

Date & Time

Minor's Initials ____

Witness's Name
(if patient, representative or parent do not read)

Witness's Signature

Date & Time

All the pictures taken if planned to be used in any publication will have their eyes and eyebrows covered in order to secure your identity.

Do you agree that your pictures may be shared in academic publications?

☐ Yes, I agree ☐ No, I don't want my pictures to be published

أحرف القاصر:
لجنة الأخلاقيات
الجامعة الأميركية في بيروت
كلية الطب
شارع بلس
بيروت، لبنان
هاتف: 350000 -(01)

الموافقة للإشتراك في البحث العلمي للمشترك القاصر

الأطفال ذو العمر الذي يتراوح بين 12- 7

"الآثار الطويلة (>10 سنوات) لأجل علاج انسداد مجرى الهواء على التشكيل الأسنان والوجه"

الباحث: د. انطوني مكاري

العنوان: الجامعة الاميريكية في بيروت
شارع بلس
بيروت – لبنان

هاتف: 000 350-01- مقسم : 5707

هدف الدراسة:

نريد أن نخبرك عن دراسة بحثية نقوم بها. الدراسة البحثية هي طريقة خاصة للتعرف على شيء.

نحاول معرفة المزيد عن التغييرات التي يمكن أن يسببها التنفس الفموي على نمو الوجه والأسنان ، والفوائد التي يمكن أن يحدثها العلاج المبكر للتنفس الفموي على ملامح الوجه.

يُطلب منك الانضمام إلى الدراسة لأنك أُحيلت أولاً إلى قسمنا ، منذ ما يقارب العشر سنوات ، لإجراء تصوير شعاعي تشخيصي بعدما تم تشخيص التنفس لديك عن طريق طبيب أخصائي لأمراض الأنف، الأذن والحنجرة لدى الأطفال.

بعد ذالك تم الحاقهم بدراسة ال دكتور جوزيف غفري بعنوان :العلاقة بين شدّة سوء إطباق الأسنان و توقيت إستئصال اللحميّة و اللوز حيث تم مشاركة 282 فرداً. وفقًا لذلك ، تم إجراء العلاج المطابق ونريد الآن معرفة التأثير الذي أحدثه العلاج على ميزات الوجه.

بعد الإتصال بك من قبل الدكتور إنتوني مكاري, أبديت أنت و طفلك إهتماماً في المشاركة في الدراسة المتابعة.

1. ماذا تشمل هذه الدراسة؟

إذا قررت الإشتراك في الدراسة، إليك ما سيحصل:

سيتم استكمال أي تحديث في التاريخ الطبي.

أحرف القاصر:

- سينظر طبيب تقويم الأسنان إلى أسنانك وسيأخذ صورة بالأشعة السينية في حال وجود علامات الحالة عند معاينتك بالإضافة إلى Oral scan و صور بالكاميرا للأسنان و الوجه.
- سيتم وضعك في جهاز الفحص بالأشعة السينية الذى سيتحرك حول وجهك لمدة دقيقتين مرتديا مريلة الرصاص لتخفيض مخاطر الأشعة.
- ستظهر على الشاشة صورة الجانبيّة تظهر فيها أسنانك ووجهك.
- سيتم ذلك لمعرفة ما هي وضعيّة الفك لديك وأسنانك ومقارنتها بالأشعة السينية التي تم التقاطها في البداية قبل عشر سنوات. سيتم إجراء تقييم للمجرى الهوائي على صورة الأشعة و كذلك أيضاً مقارنة بالنتائج التي توصلت إليها الأشعة السينيّة السابقة.
- سيتم تقييم طريقة العلاج المستخدمة لحالة تنفس الفم من خلال ملفك الموجود في قسم الأنف والأذن والحنجرة.
- حتى إذا كنت لا ترغب في المشاركة في الدراسة البحثية، إلا أن الأشعة السينية هذه قد تلزمك في حال قررت الخضوع لعلاج تقويم الأسنان. في حال وجود إكتشاف غير طبيعي على الأشعة السينية، سيتم إجراء المزيد من التحقيقات وفقا لذلك. ستستفيد من تشخيص مجاني وسيتم إقتراح العلاج المناسب.

سيتطلب منك أن تقوم بزيارة AUBMC مرّة (لمدة 45 دقيقة)، لنشرح لك المشروع بالتفصيل، لتقوم بإمضاء إستمارة الموافقة هذه، و لمعاينة أسنانك و أخذ صورة بالأشعة السينية الجانبيّة.

ستقوم الدكتورة آني باباخانيان بشرح المشروع بالتفصيل ، والتوقيع على نموذج الموافقة هذا ، وإجراء فحص

سريري وأشعة رأسية جانبية.

2. هل من الممكن أن يصيبني أي خطر؟

نريد أن نخبرك ببعض الأشياء التي قد تؤذيك أو تزعك إذا كنت في هذه الدراسة. هناك خطر الإشعاع الناجم عن الأشعة السينية ، ولكن لا توجد آثار ضارة مثبتة من مستويات التشعيع التي ستتعرض لها أثناء الدراسة. سوف ترتدي مريلة الرصاص لتخفيض مخاطر الأشعة.

3. هل هناك فوائد من المشاركة في الدراسة؟

الصور الشعاعيّة التي تم أخذها بالإضافة إلى الصور بالكاميرا و ال oral scan سوف تساعدنا للتحقيق ما إذا كنت بحاجة الى علاج تقويم للأسنان أم لا.

4- هل لدي خيار اخر؟

يمكنك إختيار عدم المشاركة في الدراسة.

5- هل يمكن اخرجك من الدراسة بدون موافقتك؟

لن يتم إخراجُك من الدراسة من قبل الفريق المختص بالدراسة من دون موافقتك. غير أنه يحق للباحث الرئيسي إنهاء مشاركتك في الدراسة في أي وقت.

6- ماذا يحدث إذا تعرضت للأذى؟

إن المركز الطبي في الجامعة الأمريكية في بيروت سوف يغطي تكاليف العلاج في المركز للعوارض الطبية السلبية الناجمة مباشرة عن الأدوية و/أو الإجراءات الطبية الخاصة بهذه

أحرف القاصر:

الدراسة البحثية. فيما عدا ذلك، لن يقوم المركز الطبي بتغطية تكاليف العناية الطبية لأية حالة أو مشكلة مرضية. ولكن يجب أن تعلم أن هذا الخطر ضئيلٌ جدا .
قبل أن توافق على المشاركة في هذه الدراسة ؛ تأكد من مطالبة الدكتورة آني باباخانيان بإطلاعك على أي شيء لا تفهمه.

7- ما هي حقوقك كموضوع للبحث؟

مشاركتك في الدراسة أمرٌ طوعي. لست مجبر على المشاركة في الدراسة إذا لم تريد ذلك، كما أنه يمكنك الإنسحاب من الدراسة في أي وقت. قرارك هذا لن يؤدي إلى أي عقوبة أو خسارة المزايا التي تملكها الأن. إذا لديك اسئلة تتعلق بحقوقك ، يمكنك الاتصال ب:
لجنة الأخلاقيات على 01/350 000 مقسم 5445

سيتم اعلامك عن أي معلومات جديدة قد تؤثر على صحتك أو رغبتك في البقاء في هذه الدراسة .

8- ماذا لو كنت لا أريد القيام بذلك:
لست مجبر أن تكون في هذه الدراسة. الأمر يعود إليك. إذا قلت نعم الآن ، لكنك غيرت رأيك لاحقًا ، فهذا جيد أيضًا.

موافقة الباحث:

لقد شرحت بالتفصيل للمشترك في البحث الطبي ل_____ (اسم المشترك او ممثله القانوني أو وليه الجبري أو وصيه اذا كان المشترك قاصرا أو غير قادر على التوقيع) طبيعته ومجرياته وتأثيراته السلبية. ولقد أجبت على كل أسئلته بوضوح على خير ما أستطيع. وسوف أعلم المشترك بأي تغييرات في مجريات هذا البحث أو تأثيراته السلبية أو فوائده في حال حصولها أثناء البحث.

_____ _____

إسم الباحث او الشخص المولى الحصول على موافقة المشترك

توقيع الباحث او الشخص المولى الحصول على موافقة المشترك

_____

التاريخ و الساعة

موافقة المشترك:

لقد قرأت استمارة القبول هذه وفهمت مضمونها. تمت الأجابة على أسئلتي جميعها. وبناء عليه فأنني، حرا مختارا، أجيز إجراء هذا البحث و أوافق على الإشتراك فيه، وإني أعلم ان الباحث الدكتور _____ انطوني مكارى **_____ وزملاءه ومعاونيه او مساعديه سيكونون مستعدين للإجابة على أسئلتي، وأنه باستطاعتي الإتصال بهم على الهاتف**

أحرف القاصر:

_____5702_____ . واذا شعرت لاحقا ان الأجوبة تحتاج الى مزيد من الإيضاح فسوف أتصل بأحد اعضاء لجنة الأخلاقيات (01- 350000 5445 المقسم). كما أعرف تمام المعرفة بانني حر في الإنسحاب من هذا البحث متى شئت حتى بعد التوقيع على الموافقة دون ان يؤثر ذلك على العناية الطبية المقدمة لي. أعلم أني سوف أحصل على نسخة طبق الأصل عن هذه الموافقة.

إسم المشترك _____ **توقيع المشترك او ممثله القانوني او وليه الجبري أو وصيه** _____

إسم الممثل القانوني او الولي الجبري أو الوصي _____

التاريخ و الساعة (بيد المشترك او ممثله القانوني أووليه الجبري أو وصيه) _____

إسم الشاهد (إذا كان المشترك أو الوصي أميا) _____ **توقيع الشاهد** _____

التاريخ و الساعة _____

جميع الصور التي تم التقاطها, إذا تم التخطيط لإستخدامها في أي منشور, سيتم تعطية أعينكم و حواجبكم لتأمين هويتكم.
هل توافق على مشاركة صوركم في المنشورات الأكاديمية ؟

☐ نعم, أوافق
☐ كلا, لا أوافق

APPENDIX II

Minor's Initials: _____

Institutional Review Board
American University of Beirut
Faculty of Medicine
Bliss Street
Beirut, Lebanon
Tel: (01) 350-000 ext. 5445

ADOLESCENT PARTICIPANT ASSENT FORM

(approximate ages 13-17)

Project Title: **Long term (>10 years) effects of airway obstruction treatment on dento-facial morphology**

Protocol Number:
Principal Investigator(s): Dr Anthony MACARI
Address: American University of Beirut Medical Center
Phone: (01) 350 000 ext: 5702
Site where the study will be conducted: Division of Orthodontics and Dentofacial Orthopedics, 6th floor, AUBMC

We want to tell you about a research study we are doing. A research study is a special way to find out about something. We are trying to find out more about the changes that mouth breathing can cause in the development of face and dentition, and the benefits that early treatment can have on facial features when mouth breathing is treated early in life. You are being asked to join the study because you were first referred to our department, almost 10 years ago, for a diagnostic radiograph when mouth breathing was diagnosed by the pediatric ENT physician. After which you were enrolled in Dr. Joseph Ghafari's study entitled "Relationship between severity of malocclusion and timing of Adenoidectomy and Tonsillectomy" in which 282 participants were enrolled. Accordingly, the corresponding treatment has been done and now we want to see what effect the treatment has caused on your facial features. After being contacted by Dr. Anthony Macari, you showed interest in participating in the follow up study.

WHAT IS INVOLVED IN THE STUDY?

This is what will happen if you are in this study:

1- Any update in medical history will be filled out.
2- The orthodontist will look at your teeth; will take one x-ray of your profile, oral scan from your teeth and photos from your face and teeth.
3- You will be positioned in the x-ray machine, wearing a lead apron to reduce the risk of irradiation, which will move next to your face, for about 2 minutes.
4- An image of your profile will appear on the screen, showing your teeth and face. This is done to find out where are your jaws and teeth positioned and to compare it with the x-ray that was taken initially 10 years ago. In addition airway assessment on the image will be performed and also compared to the findings from your previous xray.
5- The treatment modality used for your mouth breathing condition will be assessed through your file present at the ENT Department.

Minor's Initials: _____

6- Even if you don't want to participate in the research study, this x-ray, oral scan and photos would be needed if you decide to undergo an orthodontic evaluation and treatment. In case an abnormal finding was present on the X-ray, further investigation will be performed accordingly. You will benefit from free diagnosis and treatment will be suggested.

7- **"You may not participate in this study if you are pregnant or in doubt of being pregnant.**

This will require you to pass by AUBMC for 45mins: During which Dr. Annie Babakhanian will explain the project in detail, sign this consent form, have a clinical examination, photos from your teeth and face, oral scan and a lateral cephalometric x-ray.

WHAT ARE THE RISKS OF THE STUDY?

Radiation risk: Although there are no proven harmful effects from irradiation levels that you will be exposed to during this study, long-term effects on your health cannot be ruled out with certainty. The effective dose of a single cephalogram is only 1.7mrem, which is minor compared to the average annual dose that a person receives from environmental radiation (~300 mrem). The risk however, will be further reduced by wearing a lead apron which will minimize the useless radiation to your body.
For female participants if pregnant or in doubt of being pregnant xrays will not be taken.
For more information about these risks and side effects, ask your study doctor.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

a) The direct benefit is an instant evaluation of the patient's profile and to assess whether orthodontic treatment is needed or not.
b) The indirect benefit of this study is that it will allow us to better understand the correct timing of treatment of mouth breathing so that the reversibility of the facial features can be maximized. This knowledge can lead to a better treatment planning of mouth breathing and encouraging the parents and ENT specialists to propose adenoids and tonsils removal as early as possible when other treatment alternatives do not help to minimize the blockage. Early prediction of the condition would lead to: 1. Earlier treatment that can reduce the severity of the condition and possibly avoidance of surgery OR 2. More importantly, forego earlier interventions in favor of facial and dental disharmony or even later orthognathic surgery in severe cases when orthodontic treatment alone cannot solve the facial imbalance. Please note that refusal of participation will not lead to a loss of benefits.

WHAT OTHER OPTIONS ARE THERE?

This is not a treatment study so the only alternative is not to participate in the study.

CAN YOU BE REMOVED FROM THE STUDY WITHOUT YOUR CONSENT?

You will not be removed from this study by the study team without your consent. However, the investigator may end your participation at any time.

Minor's Initials: _____

WHAT ABOUT CONFIDENTIALITY?

Every reasonable effort will be made to keep your records confidential. The radiograph, photographs and -oral scan will be taken in the division of Orthodontics and Dentofacial Orthopedics, AUBMC. Radiogrpahs stored in the bank of radiographs generated and housed in the corresponding radiologic software (CLINIVIEW). The oral scans will be taken and stored in Ortho-analyzer software. The x-rays and oral scans will be placed in a separate digital folder on a computer in our division and codes will be applied so that the folder can be accessed only by the research group members. Dental and facial photographs, will be taken by one specific camera dedicated to the study, after taking the photos they will be stored in a digital folder named "photographs" on the same computer as with the radiographs and oral scans. All the pictures taken if planned to be used in any publication will have their eyes and eyebrows covered in order to secure the identity of the participants.

However, while you are in this study we do have to let some people look at your records. These people can see your records: the study doctor and designee, the ethics committee and inspectors from governmental agencies. We will keep your records confidential unless we are required by law to share any information.

Depending on your request, your individual results will be disclosed to you and to your family members as soon as the study is completed (approximate date: April 2021).

☐ I want to be informed of the results of the study .
☐ I don't want to be informed of the results of the study.

The study doctor can use the study results as long as you cannot be identified.

WHAT IF YOU ARE INJURED IN THE STUDY?

AUBMC will cover the cost of treating, on its premises, medical adverse events resulting directly from the medication and/or medical procedures of this research study. Otherwise, it will not cover for the costs of medical care for any medical condition or issue. But you should know the risk is minimal.

WHAT ARE THE COSTS?

There are no costs associated with participation. The study will cover the costs of the procedures done for its purpose which includes the X-ray, photos and oral scans that are taken from you, along with an initial consultation for the need of an orthodontic treatment. On the other hand, in case of abnormal findings that require further investigation or treatment, related costs will not be covered.

WILL YOU GET PAID TO BE IN THIS STUDY?

You will not be paid to participate in this study.

WHAT ARE YOUR RIGHTS AS A RESEARCH SUBJECT?

Being in this study is voluntary. You do not have to be in this study if you don't want to or you can stop being in the study at any time. Your decision will not result in any penalty or loss of benefits that you have now. If you have questions about your rights you may call:

Minor's Initials: _____

Institutional Review Board on 01-350000 ext. 5445

You will be told about any new information that may affect your health, welfare, or willingness to stay in this study.

Investigator's Statement:

I have reviewed, in detail, the informed consent document for this research study with _____ _____ (name of patient, legal representative, or parent/guardian) the purpose of the study and its risks and benefits. I have answered to all the patient's questions clearly. I will inform the participant in case of any changes to the research study.

_____ _____
Name of Investigator or designee **Signature**

_____
Date & Time

Patient's Participation:

I have read and understood all aspects of the research study and all my questions have been answered. I voluntarily agree to be a part of this research study and I know that I can contact Dr. _____Anthony Macari_____ at ____5702_____or any of his/her designee involved in the study in case of any questions. If I feel that my questions have not been answered, I can contact the Institutional Review Board for human rights at ___5445___. I understand that I am free to withdraw this consent and discontinue participation in this project at any time, even after signing this form, and it will not affect my care or benefits. I know that I will receive a copy of this signed informed consent.

_____ _____
Name of Patient or Legal Representative or Parent/Guardian **Signature**

_____
Date & Time

_____ _____
Witness's Name (if patient, representative or parent do not read) **Witness's Signature**

_____
Date & Time

Minor's Initials: _____

All the pictures taken if planned to be used in any publication will have their eyes and eyebrows covered in order to secure your identity.

Do you agree that your pictures may be shared in academic publications?

☐ Yes, I agree ☐ No, I don't want my pictures to be published

Institutional Review Board
American University of Beirut
23 JUN 2020
APPROVED

Institutional Review Board
American University of Beirut
Faculty of Medicine
Bliss Street
Beirut, Lebanon
Tel: (01) 350-000 ext. 5445

الموافقة للإشتراك في البحث العلمي

المراهقين ثو العسر يتراوح بين 17- 13

"الآثار الطويلة (<10 سنوات) لأجل علاج انسداد مجرى الهواء على التشكيل الأسنان والوجه"

الباحث: د. انطوني مكاري

العنوان: الجامعة الاميريكية في بيروت
شارع بلس
بيروت – لبنان

هاتف: 01-350 000- مقسم : 5707

هدف الدراسة:

نريد أن نخبرك عن دراسة بحثية نقوم بها. الدراسة البحثية هي طريقة خاصة للتعرف على شيء.
نحاول معرفة المزيد عن التغييرات التي يمكن أن يسببها التنفس الفموي على نمو الوجه والأسنان ، والفوائد التي يمكن أن يحدثها العلاج المبكر للتنفس الفموي على ملامح الوجه.
يُطلب منك الانضمام إلى الدراسة لأنك أُحيلت أولاً إلى قسمنا ، منذ ما يقارب عشر سنوات ، لإجراء تصوير شعاعي تشخيصي بعدما تم تشخيص التنفس لديك عن طريق طبيب أخصائي لأمراض الأذن والحنجرة لدى الأطفال. بعد ذلك تم تسجيلك في دراسة الدكتور جوزيف عقاري بعنوان "العلاقة بين شدة سوء إطباق الأسنان وتوقيت استئصال اللحمية و اللوزتين" حيث تم تسجيل 282 مشاركًا.
وفقًا لذلك ، تم إجراء العلاج المطابق ونريد الآن معرفة التأثير الذي أحدثه العلاج على ميزات الوجه.
بعد الاتصال بك من قبل الدكتور أنتوني ماكاري ، أبديت اهتمامًا بالمشاركة في هذه الدراسة.

ماذا تشمل هذه الدّراسة؟

إذا قررت الإشتراك في الدراسة، إليك ما سيحصل:

1. سيتم استكمال أي تحديث في التاريخ الطبي.
2. سينظر طبيب تقويم الأسنان إلى أسنانك وسيأخذ صورة بالأشعة السينية في حال وجود علامات الحالة عند

معاينتك. بالإضافة إلى أخذ صور داخل الفم باستخدام الة التصوير و إستخدام تقنية الماسح الفموى "oral scan"

3. سيتم وضعك في جهاز الفحص بالأشعة السينية الذى سيتحرك حول وجهك لمدة دقيقتين. . سوف ترتدي مريلة للرصاص لتقليل خطر التعرض لإشعاع

4. ستظهر على الشاشة صورة جانبيّة تظهر فيها أسنانك ووجهك .سيتم ذلك لمعرفة ما هي وضعيّة الفك لديك وأسنانك ومقارنتها بالأشعة السينية التي تم التقاطها في البداية قبل عشر سنوات. بالإضافة إلى ذلك ، سيتم إجراء تقييم لمجرى الهواء على الصورة ومقارنتها بالنتائج التي توصلت إليها الأشعة السينية السابقة.

5. سيتم تقييم طريقة العلاج المستخدمة لحالة تنفس الفم من خلال ملفك الموجود في قسم الأنف والأذن والحنجرة.

6. حتى إذا كنت لا ترغب في المشاركة في الدراسة البحثية، إلا أن الأشعة السينية هذه قد تلزمك في حال قررت الخضوع لعلاج تقويم الأسنان. في حال وجود إكتشاف غير طبيعي على الأشعة السينية، سيتم إجراء المزيد من التحقيقات وفقا لذلك. ستستفيد من تشخيص مجاني وسيتم إقتراح العلاج المناسب.

7. لا يجوز لك المشاركة في هذه الدراسة إذا كنت حاملاً أو إذا كنت على شك من أنك حامل.

8. سيتم مقارنة الأشعة السينية لمعرفة التغيرات التي نجمت عن النمو بعد إجراء علاج التنفس في الوقت الذي تم فيه أخذ الأشعة السينية الأولية. سيتم مقارنة مدى انعكاس ميزة الوجه.

سيتطلب منك أن تقوم بزيارة AUBMC مرّة (لمدة 45 دقيقة)، لنشرح لك المشروع بالتفصيل، لتقوم بإمضاء إستمارة الموافقة هذه، و لمعاينة أسنانك و أخذ صورة بالأشعة السينية الجانبيّة.

(ستقوم الدكتورة آني باباخانيان بشرح المشروع بالتفصيل ، والتوقيع على نموذج الموافقة هذا ، وإجراء فحص سريري وأشعة راسية جانبية.)

ما هي مخاطر هذه الدراسة ؟

على الرغم من أنه ليس هناك أي آثار ضارة ثابتة تنتج عن مستويات الإشعاع التي ستتعرض لها أثناء هذه الدراسة، إلا أنه لا يمكن استبعاد آثار طويلة الأمد على صحتك. الجرعة الفعالة لصورة واحدة لمعرفة عدد الأسنان هي 1.7 ميلي ريم فقط وهي نسبة ضئيلة مقارنةً بمعدّل الجرعة السنوية التي يتلقاها الشخص من (الإشعاع البيئي) ما يقارب 300 ميلي ريم. سوف ترتدي مريلة للرصاص لتقليل خطر التعرض لإشعاع. لا يجوز لك المشاركة في هذه الدراسة إذا كنت حاملاً أو إذا كنت على شك من أنك حامل.
للمزيد من المعلومات حول هذه المخاطر، إسأل الطبيب المسؤل عن الدراسة. يرجى ملاحظة أنه قد تكون هناك مخاطر غير متوقعة.

1. هل هناك فوائد من المشاركة فى الدراسة؟

- الفائدة المباشرة هي إجراء تقييم فوري لملف المريض وتقييم ما إذا كانت هناك حاجة إلى علاج تقويم الأسنان أم لا.
- الفائدة غير المباشرة لهذه الدراسة في أنها ستسمح لنا بفهم التوقيت الصحيح لعلاج التنفس الفموي بشكل أفضل بحيث يمكن تحقيق انعكاسات ملحوظة على ماتمح الوجه. يمكن أن تؤدي هذه المعرفة إلى تخطيط

معالجي أفضل للتنفس الفموي وتشجيع الوالدين والأخصائيين على اقتراح إزالة الغدانيات واللوزتين في أقرب وقت ممكن عندما لا تساعد أساليب العلاج الأخرى على تخفيف الانسداد التنفسي. التنبؤ المبكر بالحالة سيؤدي إلى:

1- العلاج المبكر الذي يمكن أن يقلل من شدة الحالة وربما تجنب الجراحة في وقت لاحق.

أو

2- الأهم من ذلك، التشخيص المبكر يسهل تأسيس خطة معالجة مناسبة، و التأكد ما اذا كان علاج تقويم الأسنان اساسي للعلاج ام لا.

يرجى ملاحظة أن رفض المشاركة لن يؤدي إلى فقدان الفوائد.

3- **<u>هل هناك طرق بديلة للوصول إلى الهدف المرجو؟</u>**

هذه ليست دراسة مخصصة للعلاج، فالوسيلة الوحيدة البديلة هي عدم مشاركتك في هذه الدراسة.

4- **<u>هل يمكن اخراجك من الدراسة بدون موافقتك؟</u>**

لن يتم اخراجك من الدراسة من قبل الفريق المختص بالدراسة من دون موافقتك. غير أنه يحق للباحث الرئيسي إنهاء مشاركتكم في الدراسة في أي وقت.

5- **<u>السرّية</u>**

يتعهد الباحثون بعدم الإفصاح عن نتائج البحث أو إعطائها إلا لك. في حال وافقت على المشاركة في هذه الدراسة، سيبقى اسمك طي الكتمان . لن يكون لأي شخص، ما لم ينص القانون على ذلك، حق الإطلاع على ملفك الطبي باستثناء الطبيب المسؤول عن الدراسة ومعاونيه، ولجان الأخلاق المهنية المستقلة، و مفتشين من الإدارات الحكومية المنظمة.
ستؤخذ الصورة بالأشعة السينية و بالآلة التصويرية في قسم تقويم الأسنان وتأهيل الفكين في المركز الطبي في الجامعة الأميركية في بيروت وتحفظ في بنك الصور الشعاعية (CLINIVIEW). الصور المأخوذة بطريقة "oral scan" سيتم حفظها في برنامج "ORTHO-ANALYZER". كل الصور سيتم احداثها وضمها في البرنامج الشعاعي المطابق سيتم وضعها في ملف رقمي منفصل على كومبيوتر في قسمنا، وسيتم تطبيق رموز بحيث لا يمكن لأحد اللجوء إلى الملف إلا أعضاء فريق البحث وحسب.
سيتم التقاط صور الأسنان والوجه بواسطة كاميرا واحدة مخصصة للدراسة ، بعد التقاط الصور التي سيتم تخزينها في مجلد رقمي باسم "الصور" على نفس الكمبيوتر كما هو الحال مع الصور الشعاعية والمسح الضوئي. جميع الصور التي تم التقاطها إذا تم التخطيط لاستخدامها في أي منشور ستغطي الأعين والحواجب لتأمين سرية هوية المشاركين.

بناءً على طلبك، سيتم الكشف عن النتائج الشخصية لك ولأفراد عائلتك بمجرد الانتهاء من الدراسة. التاريخ المتوقع: (نيسان 2021).

☐ **أريد أن أبلّغ بنتائج الدراسة.**

☐ **لا أريد أن أبلّغ بنتائج الدراسة.**

6- ماذا لو حصل لي أي عارض سلبي؟

إن المركز الطبي في الجامعة الأمريكية في بيروت سوف يغطي تكاليف العلاج في المركز للعوارض الطبية السلبية الناجمة مباشرة عن الأدوية و/أو الإجراءات الطبية الخاصة بهذه الدراسة البحثية. فيما عدا ذلك، لن يقوم المركز الطبي بتغطية تكاليف العناية الطبية لأية حالة أو مشكلة مرضية. ولكن يجب أن تعلم أن هذا الخطر ضئيلٌ جدا .

7- هل هناك تكاليف من خلال المشاركة في هذه الدراسة؟

ليس ثمة أي تكاليف مرتبطة بالمشاركة. ستغطي الدراسة تكاليف الاجراءات المطلوبة لتحقيق اهدافها: الأشعة السنينية , الصور الفموية و ال oral scans بالإضافة إلى الاشعة الأولية للحاجة إلى علاج تقويم الأسنان . لن تتم تغطية أي تكاليف أخرى تتعلق بالعثور على نتائج غير طبيعية و تستوجب المزيد من الفحوصات و العلاج.

8- هل ستتقاضى أي مردود مالي مقابل المشاركة في الدراسة؟

لن تحصل على أي مردود مالي مقابل مشاركتك في الدراسة.

9- ما هي حقوقك كموضوع للبحث؟

مشاركتك في الدراسة أمرٌ طوعي. لست مجبراً على المشاركة في الدراسة إذا لم تريد ذلك، كما أنه يمكنك الإنسحاب من الدراسة في أي وقت. قرارك هذا لن يؤدي إلى أي عقوبة أو خسارة المزايا التي تملكها الأن. إذا لديك اسئلة تتعلق بحقوقك، يمكنك الاتصال ب:
لجنة الأخلاقيات على 01/350 000 مقسم 5445

سيتم اعلامك عن أي معلومات جديدة قد تؤثر على صحتك أو رغبتك في البقاء في هذه الدراسة .

موافقة الباحث:

لقد راجعت ، بالتفصيل ، وثيقة الموافقة المستنيرة لهذه الدراسة البحثية الطبية مع _____ (اسم المشترك او ممثله القانوني أو وليه الجبرى أو وصيه اذا كان المشترك قاصرا أو غير قادر على التوقيع)عن طبيعتها ومجرياتها وتأثيراتها السلبية. ولقد أجبت على كل أسئلته بوضوح على خير ما أستطيع. وسوف أعلم المشترك بأي تغييرات في مجريات هذا البحث أو تأثيراته السلبية أو فوائده في حال حصولها أثناء البحث.

إسم الباحث او الشخص المولى الحصول على موافقة المشترك	توقيع الباحث او الشخص المولى الحصول على موافقة المشترك

التاريخ و الساعة

موافقة المشترك:

لقد قرأت استمارة القبول هذه وفهمت مضمونها. تمت الأجابة على أسئلتي جميعها. وبناء عليه فأنني، حرا مختارا، أجيز إجراء هذا البحث و أوافق على الإشتراك فيه، وإني أعلم ان الباحث الدكتور _____ انطوني مكارى _____ وزملاءه ومعاونيه او مساعديه سيكونون مستعدين للإجابة على أسئلتي، وأنه باستطاعتي الإتصال بهم على الهاتف _____5702_____ . واذا شعرت لاحقا ان الأجوبة تحتاج الى مزيد من الإيضاح فسوف أتصل بأحد اعضاء لجنة الأخلاقيات (01- 350000 5445 المقسم). كما أعرف تمام المعرفة بانني حر في الإنسحاب من هذا البحث متى شئت حتى بعد التوقيع على الموافقة دون ان يؤثر ذلك على العناية الطبية المقدمة لي. أعلم أني سوف أحصل على نسخة طبق الأصل عن هذه الموافقة.

إسم المشترك	توقيع المشترك او ممثله القانوني او وليه الجبري أو وصيه

إسم الممثل القانوني او الولي الجبري أو الوصي

التاريخ و الساعة (بيد المشترك او ممثله القانوني أووليه الجبري أو وصيه)

إسم الشاهد (إذا كان المشترك أو الوصي أميا)	توقيع الشاهد

التاريخ و الساعة _____

جميع الصور التي تم التقاطها. إذا تم التخطيط لإستخدامها في أي منشور، سيتم تغطية أعينكم و حواجبكم لتأمين هويّتكم.
هل توافق على مشاركة صوركم في المنشورات الأكاديمية ؟

- ☐ نعم، أوافق
- ☐ كلا، لا أوافق

Institutional Review Board
American University of Beirut
23 JUN 2020
APPROVED

APPENDIX III

Institutional Review Board
American University of Beirut
Faculty of Medicine
Bliss Street
Beirut, Lebanon
Tel: (01) 350-000 ext. 5445

ADULT PARTICIPANT CONSENT FORM

Project Title: **Long term (>10 years) effects of airway obstruction treatment on dento-facial morphology**

Protocol Number:
Principal Investigator(s): Dr Anthony MACARI
Address: American University of Beirut Medical Center
Phone: (01) 350 000 ext: 5702
Site where the study will be conducted: Division of Orthodontics and Dentofacial Orthopedics, 6th floor, AUBMC

You are being asked to join the study because you were first referred to our department, almost 10 years ago, for a diagnostic radiograph when mouth breathing was diagnosed by the pediatric ENT physician. after which you were enrolled in Dr. Joseph Ghafari's study entitled "Relationship between severity of malocclusion and timing of Adenoidectomy and Tonsillectomy" in which 282 participants were enrolled. Accordingly, the corresponding treatment has been done and now we want to see what affect the treatment has caused on your facial features. After being contacted by Dr. Anthony Macari, you showed interest in participating in the follow up study.

Please take time to read the following information carefully before you decide whether you want to take part in this study or not. Feel free to ask the doctor if you need more information or clarification about what is stated in this form and the study as a whole.

AIM OF THE STUDY

The aims of the study are to explore if the nasal obstruction had a long term effect on your facial features, comparing the age at which the treatment was done along with the type of the treatment. The study will include participants who were enrolled initially in the research conducted in our division between 2006 and 2008. Your enrolment is not obligatory. If you participate, you will commit to go through the following steps:

1- Any update in medical history will be filled out.
2- The orthodontist will look at your teeth, will take one x-ray of your profile, oral scan from your teeth and photos from your face and teeth.
3- You will be positioned in the x-ray machine, wearing a lead apron to reduce the risk of irradiation, which will move next to your face, for about 2 minutes.
4- An image of your profile will appear on the screen, showing your teeth and face. - This is done to find out where are your jaws and teeth positioned and to compare it with the x-ray that was taken initially 10 years ago. In addition airway assessment on the image will be performed and also compared to the findings from your previous xray.

5- The treatment modality used for your mouth breathing condition will be assessed through your file present at the ENT Department.
6- Even if you don't want to participate in the research study, this x-ray, oral scan and photos would be needed if you decide to undergo an orthodontic evaluation and treatment. In case an abnormal finding was present on the X-ray, further investigation will be performed accordingly. You will benefit from free diagnosis and treatment will be suggested.
7- "**You may not participate in this study if you are pregnant or in doubt of being pregnant**.
8- Superimposition of the x-rays will be done to compare the changes that were caused by growth after the corresponding treatment for mouth breathing was conducted by the ENT specialist at the time when the initial x-ray was taken and the extent of reversibility of the facial feature will be compared according to age and type of treatment.

This will require you to pass by AUBMC for 45mins: During which Dr. Annie Babakhanian will explain the project in detail, sign this consent form, have a clinical examination, photos from your teeth and face, oral scan and a lateral cephalometric x-ray.

WHAT ARE THE RISKS OF THE STUDY?

Radiation and other unforeseeable risks: Although there are no proven harmful effects from irradiation levels that you will be exposed to during this study, long-term effects on your health cannot be ruled out with certainty. The effective dose of a single cephalogram is only 1.7mrem, which is minor compared to the average annual dose that a person receives from environmental radiation (~300 mrem). The risk however, will be further reduced by wearing a lead apron which will minimize the useless radiation to your body.
For female participants if pregnant or in doubt of being pregnant xrays will not be taken
For more information about these risks and side effects, ask your study doctor.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

a) The direct benefit is an instant evaluation of the patient's profile and to assess whether orthodontic treatment is needed or not.
b) The indirect benefit of this study is that it will allow us to better understand the correct timing of treatment of mouth breathing so that the reversibility of the facial features can be maximized. This knowledge can lead to a better treatment planning of mouth breathing and encouraging the parents and ENT specialists to propose adenoids and tonsils removal as early as possible when other treatment alternatives do not help to minimize the blockage. Early prediction of the condition would lead to: 1. Earlier treatment that can reduce the severity of the condition and possibly avoidance of surgery OR 2. More importantly, forego earlier interventions in favor of facial and dental disharmony or even later orthognathic surgery in severe cases when orthodontic treatment alone cannot solve the facial imbalance. Please note that refusal of participation will not lead to a loss of benefits.

WHAT OTHER OPTIONS ARE THERE?

This is not a treatment study so the only alternative is not to participate in the study.

CAN YOU BE REMOVED FROM THE STUDY WITHOUT YOUR CONSENT?

You will not be removed from this study by the study team without your consent. However, the investigator may end your participation at any time.

CONFIDENTIALITY

Every reasonable effort will be made to keep your records confidential. The radiograph, photographs and oral scan will be taken in the division of Orthodontics and Dentofacial Orthopedics, AUBMC. Radiogrpahs stored in the bank of radiographs generated and housed in the corresponding radiologic software (CLINIVIEW). The oral scans will be taken and stored in Ortho-analyzer software. The x-rays and oral scans will be placed in a separate digital folder on a computer in our division and codes will be applied so that the folder can be accessed only by the research group members. Dental and facial photographs, will be taken by one specific camera dedicated to the study, after taking the photos they will be stored in a digital folder named "photographs" on the same computer as with the radiographs and oral scans. All the pictures taken if planned to be used in any publication will have their eyes and eyebrows covered in order to secure the identity of the participants.
However, while you are in this study we do have to let some people look at your records. These people can see your records: the study doctor and designee, the ethics committee and inspectors from governmental agencies. We will keep your records confidential unless we are required by law to share any information.

Depending on your request, your individual results will be disclosed to you and to your family members as soon as the study is completed (approximate date: April 2021).
☐ I want to be informed of the results of the study
☐ I don't want to be informed of the results of the study

The study doctor can use the study results as long as you cannot be identified.

WHAT IF YOU ARE INJURED IN THE STUDY?

AUBMC will cover the cost of treating, on its premises, medical adverse events resulting directly from the medication and/or medical procedures of this research study. Otherwise, it will not cover for the costs of medical care for any medical condition or issue. But you should know the risk is minimal.

WHAT ARE THE COSTS?

There are no costs associated with participation. The study will cover the costs of the procedures done for its purpose which includes the X-ray, oral scans and photos that are taken from you, along with an initial consultation for the need of an orthodontic treatment. On the other hand, in case of abnormal findings that require further investigation or treatment, related costs will not be covered.

WILL YOU GET PAID TO BE IN THIS STUDY?

You will not be paid to participate in this study.

WHAT ARE YOUR RIGHTS AS A RESEARCH SUBJECT?

Being in this study is voluntary. You do not have to be in this study if you don't want to or you can stop being in the study at any time. Your decision will not result in any penalty or loss of benefits that you have now. If you have questions about your rights you may call:

Institutional Review Board on 01-350000 ext. 5445

You will be told about any new information that may affect your health, welfare, or willingness to stay in this study.

Investigator's Statement:

I have reviewed, in detail, the informed consent document for this research study with _____ _____ (name of patient, legal representative, or parent/guardian) the purpose of the study and its risks and benefits. I have answered to all the patient's questions clearly. I will inform the participant in case of any changes to the research study.

_____ _____
Name of Investigator or designee **Signature**

_____
Date & Time

Patient's Participation:

I have read and understood all aspects of the research study and all my questions have been answered. I voluntarily agree to be a part of this research study and I know that I can contact Dr. _____Anthony Macari_____ at ____5702_____ or any of his/her designee involved in the study in case of any questions. If I feel that my questions have not been answered, I can contact the Institutional Review Board for human rights at ___5445___. I understand that I am free to withdraw this consent and discontinue participation in this project at any time, even after signing this form, and it will not affect my care or benefits. I know that I will receive a copy of this signed informed consent.

_____ _____
Name of Patient or Legal Representative or Parent/Guardian **Signature**

_____
Date & Time

_____ _____
Witness's Name (if patient, representative or parent do not read) **Witness's Signature**

_____
Date & Time

Institutional Review Board
American University of Beirut
23 JUN 2020
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All the pictures taken if planned to be used in any publication will have their eyes and eyebrows covered in order to secure your identity.

Do you agree that your pictures may be shared in academic publications?

☐ Yes, I agree ☐ No, I don't want my pictures to be published

أحرف القاصر:

Institutional Review Board
American University of Beirut
Faculty of Medicine
Bliss Street
Beirut, Lebanon
Tel: (01) 350-000 ext. 5445

الموافقة للإشتراك في البحث العلمي

الراشدين

عنوان البحث

"الآثار الطويلة (<10 سنوات) لأجل علاج انسداد مجرى الهواء على التشكيل الأسنان والوجه"

الباحث: د. انطوني مكاري

العنوان: الجامعة الاميريكية في بيروت
شارع بلس
بيروت – لبنان

هاتف: 000 350-01- مقسم : 5707

نحاول معرفة المزيد عن التغييرات التي يمكن أن يسببها التنفس الفموي في تطور الوجه والأسنان ، والفوائد التي يمكن أن يحدثها العلاج المبكر للتنفس الفموي على ملامح الوجه.

يُطلب منك الانضمام إلى الدراسة لأنك أُحيلت أولاً إلى قسمنا ، منذ ما يقارب العشر سنوات ، لإجراء تصوير شعاعي تشخيصي بعدما تم تشخيص التنفس لديك عن طريق طبيب أخصائي الامراض الأذن والحنجرة لدى الاطفال. عد ذلك تم تسجيلك في دراسة الدكتور جوزيف غفاري بعنوان "العلاقة بين شدة سوء إطباق الأسنان وتوقيت استئصال اللحميّة و اللوزتين" حيث تم تسجيل 282 مشاركًا.

وفقًا لذلك ، تم إجراء العلاج المطابق ونريد الآن معرفة التأثير الذي أحدثه العلاج على ميزات الوجه.

بعد الاتصال بك من قبل الدكتور أنتوني مكاري ، أبديت اهتمامًا بالمشاركة في هذه الدراسة.

يرجى قضاء بعض الوقت في قراءة المعلومات التالية بعناية قبل أن تقرر ما إذا كنت ترغب في المشاركة في هذه الدراسة أم لا. لا تتردد في سؤال الطبيب إذا كنت بحاجة إلى مزيد من المعلومات أو توضيح حول ما هو مذكور في هذا النموذج والدراسة ككل.

أحرف القاصر:

1. أهداف الدراسة:

تهدف الدراسة إلى استكشاف ما إذا كان انسداد الأنف كان له تأثير طويل المدى على ملامح وجهك ، ومقارنة العمر الذي تم فيه العلاج مع نوع العلاج. ستشمل الدراسة مشاركين تم تسجيلهم في البداية في البحث الذي أجري في قسمنا بين عامي 2006 و 2008. التسجيل الخاص بك ليس إلزاميًا. إذا شاركت ، فسوف تلتزم بالقيام بالخطوات التالية:

1. سيتم استكمال أي تحديث في التاريخ الطبي.
2. سينظر طبيب تقويم الأسنان إلى أسنانك وسيأخذ صورة بالأشعة السينية في حال وجود علامات الحالة عند معاينتك. بالإضافة إلى أخذ صور داخل الفم باستخدام آلة التصوير و إستخدام تقنية الماسح الضوئي "oral scan"
3. سيتم وضعك في جهاز الفحص بالأشعة السينية الذي سيتحرك حول وجهك لعدة دقيقتين. . سوف ترتدي مريلة للرصاص لتقليل خطر التعرض لإشعاع
4. ستظهر على الشاشة صورة جانبيَّة تظهر فيها أسنانك ووجهك. سيتم ذلك لمعرفة ما هي وضعيَّة الفك لديك وأسنانك ومقارنتها بالأشعة السينية التي تم التقاطها في البداية قبل عشر سنوات. بالإضافة إلى ذلك ، سيتم إجراء تقييم لمجرى الهواء على الصورة ومقارنتها بالنتائج التي توصلت إليها الأشعة السينية السابقة.
5. سيتم تقييم طريقة العلاج المستخدمة لحالة تنفس الفم من خلال ملفك الموجود في قسم الأنف والأذن والحنجرة.
6. حتى إذا كنت لا ترغب في المشاركة في الدراسة البحثية، إلا أن الأشعة السينية هذه قد تلزمك في حال قررت الخضوع لعلاج تقويم الأسنان. في حال وجود إكتشاف غير طبيعي على الأشعة السينية، سيتم إجراء المزيد من التحقيقات وفقاً لذلك. ستستفيد من تشخيص مجاني وسيتم إقتراح العلاج المناسب.
7. لا يجوز لك المشاركة في هذه الدراسة إذا كنت حاملاً أو إذا كنت على شك من أنك حامل.
8. ستتم مقارنة الأشعة السينية لمعرفة التغيرات التي نجمت عن النمو بعد إجراء علاج التنفس في الوقت الذي تم فيه أخذ الأشعة السينية الأولية. سيتم مقارنة مدى انعكاس ميزة الوجه.

سيتطلب منك أن تقوم بزيارة AUBMC مرَّة (لمدة 45 دقيقة)، لنشرح لك المشروع بالتفصيل، لتقوم بإمضاء إستمارة الموافقة هذه، و لمعاينة أسنانك و أخذ صورة بالأشعة السينية الجانبيَّة.

(ستقوم الدكتورة آني باباخانيان بشرح المشروع بالتفصيل ، والتوقيع على نموذج الموافقة هذا ، وإجراء فحص سريري وأشعة رأسية جانبية)

2. ما هي مخاطر هذه الدراسة ؟

على الرغم من أنه ليس هناك أي آثار ضارة طويلة تنتج عن مستويات الإشعاع التي ستتعرض لها أثناء هذه الدراسة، إلا أنه لا يمكن استبعاد آثار طويلة الأمد على صحتك. الجرعة الفعالة لصورة واحدة لمعرفة وضعيَّة الأسنان و الفك هي 1.7 ميلي ريم فقط، وهي نسبة ضئيلة مقارنةً بمعدَّل الجرعة السنوية التي يتلقاها الشخص من (الإشعاع البيئي) ما يقارب 300 ميلي ريم. سوف ترتدي مريلة للرصاص لتقليل خطر التعرض لإشعاع. لا يجوز لك المشاركة في هذه الدراسة إذا كنت حاملاً أو إذا كنت على شك من أنك حامل.

للمزيد من المعلومات حول هذه المخاطر، إسأل الطبيب المسؤل عن الدراسة. يرجى ملاحظة أنه قد تكون هناك مخاطر غير متوقعة.

3. هل هناك فوائد من المشاركة في الدراسة؟

الفائدة المباشرة هي إجراء تقييم فوري لملف المريض وتقييم ما إذا كانت هناك حاجة إلى علاج تقويم الأسنان أم لا.

أحرف القاصر:

الفائدة غير المباشرة لهذه الدراسة في أنها ستسمح لنا بفهم التوقيت الصحيح لعلاج التنفس الفموي بشكل أفضل بحيث يمكن تحقيق انعكاسات ملحوظة على منحنى الوجه. يمكن أن تؤدي هذه المعرفة إلى تخطيط علاجي أفضل للتنفس الفموي وتشجيع الوالدين والأخصائيين على اقتراح إزالة الغدانيات واللوزتين في أقرب وقت ممكن عندما لا تساعد أساليب العلاج الأخرى على تخفيف الانسداد التنفسي. التنبؤ المبكر بالحالة سيؤدي إلى:

- العلاج المبكر الذي يمكن أن يقلل من شدة الحالة وربما تجنب الجراحة في وقت لاحق.

أو

- الأهم من ذلك، التشخيص المبكر يسهل تأسيس خطة معالجة مناسبة، و التأكد ما اذا كان علاج تقويم الأسنان اساسي للعلاج ام لا.

يرجى ملاحظة أن رفض المشاركة لن يؤدي إلى فقدان الفوائد.

4. <u>هل هناك طرق بديلة للوصول إلى الهدف المرجو؟</u>

هذه ليست دراسة مخصصة للعلاج، فالوسيلة الوحيدة البديلة هي عدم مشاركتك في هذه الدراسة.

5. <u>هل يمكن اخراجك من الدراسة بدون موافقتك؟</u>

لن يتم اخراجك من الدراسة من قبل الفريق المختص بالدراسة من دون موافقتك. غير أنه يحق للباحث الرئيسي إنهاء مشاركتكم في الدراسة في أي وقت.

6. <u>السرّية</u>

يتعهد الباحثون بعدم الإفصاح عن نتائج البحث أو إعطائها إلا لك. في حال وافقت على المشاركة في هذه الدراسة، سيبقى اسمك طي الكتمان . لن يكون لأي شخص، ما لم ينص القانون على ذلك، حق الإطلاع على ملفك الطبي باستثناء الطبيب المسؤول عن الدراسة ومعاونيه، ولجان الأخلاق المهنية المستقلة، و مفتشين من الإدارات الحكومية المنظمة.
ستؤخذ الصورة بالأشعة السنية و بالآلة التصويرية في قسم تقويم الأسنان وتأهيل الفكين في المركز الطبي في الجامعة الأميركية في بيروت وتحفظ في بنك الصور الشعاعية ال(CLINIVIEW). الصور المأخوذة بطريقة "oral scan" سيتم حفظها في برنامج "ORTHO-ANALYZER". كل الصور سيتم احداثها وضعها في البرنامج الشعاعي المطابق سيتم وضعها في ملفٍّ رقميٍّ منفصل على كومبيوتر في قسمنا، وسيتم تطبيق رموز بحيث لا يمكن لأحد اللجوء إلى الملف إلا أعضاء فريق البحث وحسب.
سيتم التقاط صور الأسنان والوجه بواسطة كاميرا واحدة مخصصة للدراسة ، بعد التقاط الصور التي سيتم تخزينها في مجلد رقمي باسم "الصور" على نفس الكمبيوتر كما هو الحال مع الصور الشعاعية والمسح الضوئي. جميع الصور التي تم التقاطها إذا تم التخطيط لاستخدامها في أي منشور ستغطي الأعين والحواجب لتأمين سرية هوية المشاركين.

أحرف القاصر:

بناءً على طلبك، سيتم الكشف عن النتائج الشخصية لك ولأفراد عائلتك بمجرد الانتهاء من الدراسة. التاريخ المتوقع: (نيسان 2021).

☐ **أريد أن أبلّغ بنتائج الدراسة.**
☐ **لا أريد أن أبلّغ بنتائج الدراسة.**

7. **ماذا لو حصل لي أي عارض سلبي؟**

إن المركز الطبي في الجامعة الأمريكية في بيروت سوف يغطي تكاليف العلاج في المركز للعوارض الطبية السلبية الناجمة مباشرة عن الأدوية و/أو الإجراءات الطبية الخاصة بهذه الدراسة البحثية. فيما عدا ذلك، لن يقوم المركز الطبي بتغطية تكاليف العناية الطبية لأية حالة أو مشكلة مرضية. ولكن يجب أن تعلم أن هذا الخطر ضئيلٌ جدا .

8. **هل هناك تكاليف من خلال المشاركة في هذه الدراسة؟**

ليس ثمة أي تكاليف مرتبطة بالمشاركة. ستغطي الدراسة تكاليف الاجراءات المطلوبة لتحقيق اهدافها: الأشعة السنينية , الصور الفموية و الscans oral بالإضافة إلى البنشرة الأولية للحاجة إلى علاج تقويم الأسنان . لن تتم تغطية أي تكاليف أخرى تتعلق بالعثور على نتائج غير طبيعيّة و تستوجب المزيد من الفحوصات و العلاج.

9. **هل ستتقاضى أي مردود مالي مقابل المشاركة في الدراسة؟**

لن تحصل على أي مردود مالي مقابل مشاركتك في الدراسة.

10. **ما هي حقوقك كموضوع للبحث؟**

مشاركتك في الدراسة أمرٌ طوعي. لست مجبراً على المشاركة في الدراسة إذا لم تريد ذلك، كما أنه يمكنك الإنسحاب من الدراسة في أي وقت. قرارك هذا لن يؤدي إلى أي عقوبة أو خسارة المزايا التي تملكها الآن. إذا لديك اسئلة تتعلق بحقوقك، يمكنك الاتصال ب:
لجنة الأخلاقيات على 01/350 000 مقسم 5445

سيتم اعلامك عن أي معلومات جديدة قد تؤثر على صحتك أو رغبتك في البقاء في هذه الدراسة .
في حال قرّرت الإنضمام لمجموعة الراشدين الذين يشاركون في هذه الدراسة عليك أن توقّع على هذه الورقة. و في حال قرّرت أنك لا تريد ان تشترك فلا توقّعها، و هذا حتما لن يؤثر على اهتمام الاطباء بك. تذكر الإنضمام للدراسة قرارك و لا أحد يجبرك على التوقيع او سوف يستاء من عدم إشتراكك. يمكنك تغيير رأيك في أي وقت. بامكانك طرح الأسئلة المتعلّقة بالدراسة متى شئت.

موافقة الباحث:

لقد شرحت بالتفصيل للمشترك في البحث الطبي ل_____ (اسم المشترك او ممثله القانوني أو وليه الجبرى أو وصيه اذا كان المشترك قاصرا أو غير قادر على التوقيع) طبيعته ومجرياته وتأثيراته السلبية. ولقد أجبت على كل أسئلته بوضوح على خير ما أستطيع.

أحرف القاصر:

وسوف أعلم المشترك بأى تغييرات في مجريات هذا البحث أو تأثيراته السلبية أو فوائده في حال حصولها أثناء البحث.

إسم الباحث او الشخص المولى الحصول على موافقة المشترك	توقيع الباحث او الشخص المولى الحصول على موافقة المشترك

التاريخ و الساعة

موافقة المشترك:

لقد قرأت استمارة القبول هذه وفهمت مضمونها. تمت الأجابة على أسئلتي جميعها. وبناء عليه فانني، حرا مختارا، أجيز إجراء هذا البحث و أوافق على الإشتراك فيه، وإني أعلم ان الباحث الدكتور _____ انطوني مكارى _____ وزملاءه ومعاونيه او مساعديه سيكونون مستعدين للإجابة على أسئلتي، وأنه باستطاعتي الإتصال بهم على الهاتف _____5702_____ . واذا شعرت لاحقا ان الأجوبة تحتاج الى مزيد من الإيضاح فسوف أتصل بأحد اعضاء لجنة الأخلاقيات (01- 350000 5445 المقسم). كما أعرف تمام المعرفة بانني حر في الإنسحاب من هذا البحث متى شئت حتى بعد التوقيع على الموافقة دون ان يؤثر ذلك على العناية الطبية المقدمة لي. أعلم أني سوف أحصل على نسخة طبق الأصل عن هذه الموافقة.

إسم المشترك	توقيع المشترك او ممثله القانوني او وليه الجبري أو وصيه

إسم الممثل القانوني او الولي الجبري أو الوصي

التاريخ و الساعة (بيد المشترك او ممثله القانوني أووليه الجبري أو وصيه)

إسم الشاهد (إذا كان المشترك أو الوصي أميا)	توقيع الشاهد

التاريخ و الساعة _____

أحرف القاصر:

جميع الصور التي تم التقاطها, إذا تم التخطيط لإستخدامها في أي منشور, سيتم تغطية أعينكم و حواجبكم لتأمين هويتكم.
هل توافق على مشاركة صوركم في المنشورات الأكاديمية ؟

☐ نعم, أوافق
☐ كلا, لا أوافق

APPENDIX IV

Institutional Review Board
American University of Beirut
Faculty of Medicine
Bliss Street
Beirut, Lebanon
Tel: (01) 350-000 ext. 5445

Project Title: **Long term (>10 years) effects of airway obstruction treatment on dento-facial morphology** Parental consent

Protocol Number:

Principal Investigator(s): Dr Anthony MACARI

Address: American University of Beirut Medical Center

Phone: (01) 350 000 ext: 5702

Site where the study will be conducted: Division of Orthodontics and Dentofacial Orthopedics, 6th floor, AUBMC

Your child is being asked to join the study:

Your child was first referred to our department, almost 10 years ago, for a diagnostic radiograph when mouth breathing was diagnosed by the pediatric ENT physician, after which he/she was enrolled in Dr. Joseph Ghafari's study entitled "Relationship between severity of malocclusion and timing of Adenoidectomy and Tonsillectomy" in which 282 participants were enrolled. Accordingly, the corresponding treatment has been done and now we want to see what effect the treatment has caused on your facial features. After being contacted by Dr. Anthony Macari, you and your child showed interest in participating in the follow up study.

Please take time to read the following information carefully before you decide whether you want to take part in this study or not. Feel free to ask the doctor if you need more information or clarification about what is stated in this form and the study as a whole.

AIM OF THE STUDY

The aims of the study are to explore if nasal obstruction had a long-term effect on your child's features, comparing the age at which the treatment was done along with the type of the treatment. The study will include participants who were enrolled initially in the research conducted in our division during 2006-2008. Your child's enrolment is not obligatory. If your child participates, they will commit to go through the following steps:

1- Any update in medical history will be filled out.
2- The orthodontist will look at your child's teeth; will take one x-ray of profile, oral scan from their teeth and photos from their face and teeth.
3- Your child will be positioned in the x-ray machine, wearing a lead apron to reduce the risk of irradiation, which will move next to his/her face, for about 2 minutes.

4- An image of your child's profile will appear on the screen, showing his/her teeth and face. - This is done to find out where are his/her jaws and teeth positioned and to compare it with the x-ray that was taken initially 10 years ago. In addition airway assessment on the image will be performed and also compared to the findings from the previous xray.
5- The treatment modality used for your child's mouth breathing condition will be assessed through their file present at the ENT Department.
6- Even if your child does not want to participate in the research study, this x-ray, oral scan and photos would be needed if your child decides to undergo an orthodontic evaluation and treatment. In case an abnormal finding was present on the X-ray, further investigation will be performed accordingly. Your child will benefit from free diagnosis and treatment will be suggested.
7- Superimposition of the x-rays will be done to compare the changes that were caused by growth after the corresponding treatment for mouth breathing was conducted by the ENT specialist at the time when the initial x-ray was taken and the extent of reversibility of the facial feature will be compared according to age and type of treatment.

This will require you and him/her to pass by AUBMC for 45mins: During which Dr. Annie Babakhanian will explain the project in detail to you and your child, sign this consent form, he/she will have a clinical examination, photos from your teeth and face, oral scan and a lateral cephalometric x-ray.

WHAT ARE THE RISKS OF THE STUDY?

Radiation risk: Although there are no proven harmful effects from irradiation levels that you will be exposed to during this study, long-term effects on your health cannot be ruled out with certainty. The effective dose of a single cephalogram is only 1.7mrem, which is minor compared to the average annual dose that a person receives from environmental radiation (~300 mrem). The risk however, will be further reduced by wearing a lead apron which will minimize the useless radiation to your child's body.

For more information about these risks and side effects, ask your study doctor and please note that there may be unforeseeable risks.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

a) The direct benefit is an instant evaluation of the patient's profile and to assess whether orthodontic treatment is needed or not.
b) The indirect benefit of this study is that it will allow us to better understand the correct timing of treatment of mouth breathing so that the reversibility of the facial features can be maximized. This knowledge can lead to a better treatment planning of mouth breathing and encouraging the parents and ENT specialists to propose adenoids and tonsils removal as early as possible when other treatment alternatives do not help to minimize the blockage. Early prediction of the condition would lead to: 1. Earlier treatment that can reduce the severity of the condition and possibly avoidance of surgery OR 2. More importantly, forego earlier interventions in favor of facial and dental disharmony or even later orthognathic surgery in severe cases when orthodontic treatment alone cannot solve the facial imbalance. Please note that refusal of participation will not lead to a loss of benefits.

WHAT OTHER OPTIONS ARE THERE?

This is not a treatment study so the only alternative is not to participate in the study.

CAN YOUR CHILD BE REMOVED FROM THE STUDY WITHOUT YOUR CONSENT?

Your child will not be removed from this study by the study team without your/their consent. However, the investigator may end their participation at any time.

CONFIDENTIALITY

Every reasonable effort will be made to keep your child's records confidential. The radiograph, photographs and oral scan will be taken in the division of Orthodontics and Dentofacial Orthopedics, AUBMC. Radiogrpahs stored in the bank of radiographs generated and housed in the corresponding radiologic software (CLINIVIEW). The oral scans will be taken and stored in Ortho-analyzer software. The x-rays and oral scans will be placed in a separate digital folder on a computer in our division and codes will be applied so that the folder can be accessed only by the research group members. Dental and facial photographs, will be taken by one specific camera dedicated to the study, after taking the photos they will be stored in a digital folder named "photographs" on the same computer as with the radiographs and oral scans. All the pictures taken if planned to be used in any publication will have their eyes and eyebrows covered in order to secure the identity of the participants.
However, while your child is in this study we do have to let some people look at their records. These people can see their records: the study doctor and designee, the ethics committee and inspectors from governmental agencies. We will keep your child's records confidential unless we are required by law to share any information
Depending on your request, your child's individual results will be disclosed to them, you and to your family members as soon as the study is completed (approximate date: April 2021).

☐ I want to be informed of the results of the study
☐ I don't want to be informed of the results of the study

The study doctor can use the study results as long as you cannot be identified.

WHAT IF YOUR CHILD IS INJURED IN THE STUDY?

AUBMC will cover the cost of treating, on its premises, medical adverse events resulting directly from the medication and/or medical procedures of this research study. Otherwise, it will not cover for the costs of medical care for any medical condition or issue. But you should know the risk is minimal.

WHAT ARE THE COSTS?

There are no costs associated with participation. The study will cover the costs of the procedures done for its purpose which includes the X-ray, oral scans and photos that are taken from your child, along with an initial consultation for the need of an orthodontic treatment. On the other hand, in case of abnormal findings that require further investigation or treatment, related costs will not be covered.

WILL YOU GET PAID TO BE IN THIS STUDY?

Your child will not be paid to participate in this study.

WHAT ARE YOUR CHILD'S RIGHTS AS A RESEARCH SUBJECT?

Being in this study is voluntary. Your child does not have to be in this study if he/she does not want to or they can stop being in the study at any time. Their decision will not result in any penalty or loss of benefits that they have now. If your child has questions about their rights they may call:

Institutional Review Board on 01-350000 ext. 5445

Your child will be told about any new information that may affect your child health, welfare, or willingness to stay in this study.

Investigator's Statement:

I have reviewed, in detail, the informed consent document for this research study with _____ _____ (name of patient, legal representative, or parent/guardian) the purpose of the study and its risks and benefits. I have answered to all the patient's questions clearly. I will inform the participant in case of any changes to the research study.

_____ _____

Name of Investigator or designee **Signature**

_____

Date & Time

Patient's Participation:

I have read and understood all aspects of the research study and all my questions have been answered. I voluntarily agree to be a part of this research study and I know that I can contact Dr. _____Anthony Macari_____ at ____5702_____or any of his/her designee involved in the study in case of any questions. If I feel that my questions have not been answered, I can contact the Institutional Review Board for human rights at ___5445___. I understand that I am free to withdraw this consent and discontinue participation in this project at any time, even after signing this form, and it will not affect my care or benefits. I know that I will receive a copy of this signed informed consent.

_____ _____

Name of father **Signature**

_____

Date & Time

Institutional Review Board
American University of Beirut

23 JAN 2020

APPROVED

_____ _____

Name of mother **Signature**

_____
Date & Time

_____ _____
Witness's Name **Witness's Signature**
(if patient, representative or parent do not read)

_____
Date & Time

All the pictures taken if planned to be used in any publication will have their eyes and eyebrows covered in order to secure your identity.

Do you agree that your child's pictures may be shared in academic publications?

☐ Yes, I agree ☐ No, I don't want their pictures to be published

أحرف القاصر:
لجنة الأخلاقيات
الجامعة الأميركية في بيروت
كلية الطب
شارع بلس
بيروت، لبنان
هاتف: 350000 -(01)

الموافقة للإشتراك في البحث العلمي للمشترك القاصر
موافقة الاهل

"الآثار الطويلة (<10 سنوات) لأجل علاج انسداد مجرى الهواء على التشكيل الأسنان والوجه"

الباحث: د. انطوني مكاري

العنوان: الجامعة الإميركية في بيروت
شارع بلس
بيروت – لبنان

هاتف: 000 350-01- مقسم : 5707

نحاول معرفة المزيد عن التغييرات التي يمكن أن يسببها التنفس الفموي في تطور الوجه والأسنان لدى إبنكم/إبنتكم ، والفوائد التي يمكن أن يحدثها العلاج المبكر للتنفس الفموي على ملامح الوجه لديهم.

يُطلب من طفلكم الانضمام إلى الدراسة لأنه/ها أُحيل/ت أولاً إلى قسمنا ، منذ ما يقارب العشر سنوات ، لإجراء تصوير شعاعي تشخيصي بعدما تم تشخيص التنفس لديه/ها عن طريق طبيب أخصائي لأمراض الأنف الأذن والحنجرة لدى الأطفال, بعد ذلك تم الحاقهم بدراسة ان دكتور جوزيف عقري بعنوان :العلاقة بين شذة سوء إطباق الأسنان و توقيت إستئصال اللحميّة و اللوز. وفقًا لذلك ، تم إجراء العلاج المطابق ونريد الآن معرفة التأثير الذي أحدثه العلاج على ميزات الوجه.

بعد الإتصال بك من قبل الدكتور إنتوني مكاري, أبديت أنت و طفلك إهتماماً في المشاركة في الدراسة المتابعة.

يرجى قضاء بعض الوقت في قراءة المعلومات التالية بعناية قبل أن تقرر ما إذا كنت ترغب في مشاركة طفلكم في هذه الدراسة أم لا. لا تتردد في سؤال الطبيب إذا كنت بحاجة إلى مزيد من المعلومات أو توضيح حول ما هو مذكور في هذا النموذج والدراسة ككل.

أحرف القاصر:

1- هدف الدراسة:

تهدف الدراسة إلى استكشاف ما إذا كان انسداد الأنف كان له تأثير طويل المدى على ملتحم وجه ابنك/ابنتك، ومقارنة العمر الذي تم فيه العلاج مع نوع العلاج. ستشمل الدراسة مشاركين تم تسجيلهم في البداية في البحث الذي أجري في قسمنا بين عامي 2006 و 2008. التسجيل الخاص بابنك/ابنتك ليس إلزاميًا. إذا شاركو ، فسوف يلتزمون بالقيام بالخطوات التالية:

- سيتم استكمال أي تحديث في التاريخ الطبي.
- سينظر طبيب تقويم الأسنان إلى أسنان ابنك/ابنتك وسيأخذ صورة بالأشعة السينية في حال وجود علامات الحالة عند معاينتهم بالإضافة إلى Oral scan و صور بالكاميرا لأسنان و الوجه.
- سيتم وضع ابنك/ابنتك في جهاز القحص بالأشعة السينية الذي سيتحرك حول وجههم لمدة دقيقتين مرتديا مريلة الرصاص لتخفيض مخاطر الأشعة.
- ستظهر على الشاشة صورة جانبية تظهر فيها أسنانهم ووجههم.
- سيتم ذلك لمعرفة ما هي وضعيّة الفك والأسنان لدى ابنك/ابنتك ومقارنتها بالأشعة السينية التي تم التقاطها في البداية قبل عشر سنوات.
- سيتم تقييم طريقة العلاج المستخدمة لحالة تنفس الفم من خلال ملف ابنك/ابنتك الموجود في قسم الأنف والأذن والحنجرة.
- حتى إذا كنت لا ترغب في مشاركتهم في الدراسة البحتية، إلا أن الأشعة السينية هذه قد تلزمكم في حال قررتم اخضاع لدى ابنك/ابنتك لعلاج تقويم الأسنان. في حال وجود إكتشاف غير طبيعي على الأشعة السينية، سيتم إجراء المزيد من التحقيقات وفقا لذلك. ستستفيد من تشخيص مجاني وسيتم إقتراح العلاج المناسب.
- سيتم تراكب صور الأشعة السينية قبل و بعد العلاج لمقارنة التغيرات الناجمة عن النمو التابع لعلاج التنفس الفموي الذي قام به الأخصائي في أمراض الأنف، الأذن و الحنجرة. سيتم مقارنة مدى نسبة إرتداد ملتحم الوجه السابقة تبعاً للعمر و نوع العلاج.

سيتطلب منك أن تقوموا بزيارة AUBMC مرّة (لمدة 45 دقيقة)، خلال هذا الموعد سنشرح لكما الدكتورة التي بإباخانيان المشروع بالتفصيل، لتقوم بإمضاء إستمارة الموافقة هذه، و لمعاينة أسنانك و أخذ صورة بالأشعة السينية الجانبيّة بالإضافة إلى صور الكاميرا للوجه و الأسنان و صور بـOral Scan.

نرجو منكم قراءة المعلومات الواردة بتأني وهدوء، كما بإمكانكم طلب إيضاحات او معلومات إضافية عن أي شيء مذكور في هذه الا ستمارة أو عن هذه الدراسة ككل من طبيبكم.

2- ما هي مخاطر هذه الدراسة ؟

على الرغم من أنه ليس هناك أي آثار ضارة ثابتة تنتج عن مستويات الإشعاع التي ستتعرض لها أثناء هذه الدراسة، إلا أنه لا يمكن استبعاد آثار طويلة الأمد على صحة ابنك/ابنتك. الجرعة الفعالة لصورة واحدة لمعرفة وضعيّة الأسنان و الفك هي 1.7 ميلي ريم فقط، وهي نسبة ضئيلة مقارنة بمعدّل الجرعة السنوية التي يتلقاها الشخص من (الإشعاع البيئي) ما يقارب 300 ميلي ريم.
لتخفيض المخاطر الشعاعية، سوف يرتدي طفلكم مريلة الرصاص.
للمزيد من المعلومات حول هذه المخاطر، إسألو الطبيب المسؤل عن الدراسة. يرجى الملاحظة أنه قد تكون هناك مخاطر غير متوقعة.

أحرف القاصر:

3- ما هي فوائد هذه الدّراسة؟

الفائدة المباشرة هي إجراء تقييم فوري لملف طفلكم وتقييم ما إذا كانت هناك حاجة إلى علاج تقويم الأسنان له أم لا.
الفائدة غير المباشرة لهذه الدراسة هي أنها ستسمح لنا بفهم التوقيت الصحيح لعلاج التنفس الفموي بشكل أفضل بحيث يمكن تحقيق انعكاسات ملحوظة على ملامح الوجه. يمكن أن تؤدي هذه المعرفة إلى تخطيط علاجي أفضل للتنفس الفموي وتشجيعكم كوالدين والأطباء الأخصائيين على اقتراح إزالة الغدانيات واللوزتين لأبنك/ابنتك في أقرب وقت ممكن عندما لا تساعد أساليب العلاج الأخرى على تخفيف الانسداد التنفسي. التنبؤ المبكر بالحالة سيؤدي إلى:

- العلاج المبكر الذي يمكن أن يقلل من شدة الحالة وربما تجنب الجراحة في وقت لاحق.

أو

- الأهم من ذلك، التشخيص المبكر يسهل تأسيس خطة معالجة مناسبة، و التأكد ما اذا كان علاج تقويم الأسنان اساسي للعلاج ام لا. يرجى ملاحظة أن رفض المشاركة لن يؤدي إلى فقدان الفوائد.

4- هل هناك طرق بديلة للوصول إلى الهدف المرجو؟

هذه ليست دراسة مخصصة للعلاج، فالوسيلة الوحيدة البديلة هي عدم مشاركة إبنكم/ إبنتكم في هذه الدراسة.

5- هل يمكن اخراج إبنكم/إبنتكم من الدراسة بدون موافقتكم؟

لن يتم اخراج إبنكم/ إبنتكم من الدراسة من قبل الفريق المختص بالدراسة من دون موافقتكم/هم. غير أنه يحق للباحث الرئيسي إنهاء مشاركتهم في الدراسة في أي وقت.

6- المزيّة

يتعهد الباحثون بعدم الإفصاح عن نتائج البحث أو إعطائها إلا لكم. في حال وافقتم على مشاركة إبنكم/إبنتكم في هذه الدراسة، سيبقى اسمهم طي الكتمان . لن يكون لأي شخص، ما لم ينص القانون على ذلك، حق الإطلاع على ملفهم الطبي باستثناء الطبيب المسؤول عن الدراسة ومعاونيه، ولجان الأخلاق المهنية المستقلة، و مفتشين من الإدارات الحكومية المنظمة.
ستؤخذ الصورة بالأشعة بالإضافة إلى الصور بالكاميرا و ال Intra-oral scan في قسم تقويم الأسنان وتأهيل الفكين في المركز الطبي في الجامعة الأميركية في بيروت وتحفظ في بنك الصور الشعاعية (CLINIVIEW). الذي تم احداثها وضعها في البرنامج الشعاعي المطابق سيتم وضعها في ملفٍ رقميٍ منفصل على كومبيوتر في قسمنا، وسيتم تطبيق رموز بحيث لا يمكن لأحد اللجوء إلى الملف إلا أعضاء فريق البحث وحسب.

أحرف القاصر:

سيتم التقاط صور الأسنان والوجه بواسطة كاميرا واحدة مخصصة للدراسة ، بعد التقاط الصور التي سيتم تخزينها في مجلد رقمي باسم "الصور" على نفس الكمبيوتر كما هو الحال مع الصور الشعاعية والمسح الضوئي. جميع الصور التي تم التقاطها إذا تم التخطيط لاستخدامها في أي منشور ستغطي الأعين والحواجب لتأمين سرية هوية المشاركين.
مع ذلك، أثناء وجود طفلكم في الدراسة يتعين علينا السماح لبعض الأشخاص بمراجعة سجلاتهم. يمكن لهؤلاء الأشخاص رؤية ملفاتهم: طبيب الدراسة و المعيّن, لجنة الأخلاقيات و المفتشون من الجهات الحكومية.

بناءً على طلبكم، سيتم الكشف عن النتائج الشخصية لإبنكم/ إبنتكم بمجرد الانتهاء من الدراسة التاريخ المتوقع: (نيسان 2020).

- ☐ **أريد أن أبلّغ بنتائج الدراسة.**
- ☐ **لا أريد أن أبلّغ بنتائج الدراسة.**

7- <u>ماذا لو حصل لطفلكم أي عارض سلبي؟</u>

إن المركز الطبي في الجامعة الأمريكية في بيروت سوف يغطي تكاليف العلاج في المركز للعوارض الطبية السلبية الناجمة مباشرة عن الأدوية و/أو الإجراءات الطبية الخاصة بهذه الدراسة البحثية. فيما عدا ذلك، لن يقوم المركز الطبي بتغطية تكاليف العناية الطبية لأية حالة أو مشكلة مرضية. ولكن يجب أن تعلم أن هذا الخطر ضئيلٌ جدا .

8- <u>هل هناك تكاليف من خلال المشاركة في هذه الدراسة؟</u>

ليس ثمة أي تكاليف مرتبطة بالمشاركة. ستغطي الدراسة تكاليف الإجراءات المطلوبة لتحقيق أهدافها: الأشعة السينية التي ستؤخذ ال Intra-oral scan و الصور بالكاميرا لطفلكم بالإضافة للكشف الأولي للتحقق ما إذا كان طفلكم بحاجة لعلاج تقويم الأسنان. لن تتم تغطية أي تكاليف أخرى تتعلق بالعثور على نتائج غير طبيعية و تستوجب المزيد من الفحوصات و العلاج.

9- <u>هل ستتقاضون</u> أي <u>مردود مالي مقابل المشاركة في الدراسة؟</u>

لن تحصلون على أي مردود مالي مقابل مشاركة إبنكم/ إبنتكم في الدراسة.

10- <u>ما هي حقوق طفلكم كموضوع للبحث؟</u>

مشاركة إبنكم/ إبنتكم في الدراسة أمرٌ طوعي. لستم مجبرون على المشاركة في الدراسة إذا لم تريدون ذلك، كما أنه يمكنكم الإنسحاب من الدراسة في أي وقت. قراركم هذا لن يؤدي إلى أي عقوبة أو خسارة المزايا التي تملكوها الآن. إذا لديكم اسئلة تتعلق بحقوق إبنكم/ إبنتكم ، يمكنكم الإتصال ب:
لجنة الأخلاقيات على 01/350 000 مقسم 5445

سيتم اعلامكم عن أي معلومات جديدة قد تؤثر على صحة إبنكم/ إبنتكم أو رغبتكم في البقاء في هذه الدراسة .

أحرف القاصر:

في حال قرّرتم ضم إبنكم/ إبنتكم لمجموعة القاصرين الذين يشاركون في هذه الدراسة عليكم أن توقّعوا على هذه الورقة. و في حال قرّرتم أنكم لا تريدون ان يشاركوا فلا توقّعوا، و هذا حتماً لن يؤثر على اهتمام الاطباء بإبنكم/إبنتكم. تذكّروا، الإنضمام للدراسة قراركم و لا أحد يجبركم على التوقيع او سوف يستاء من عدم إشتراككم. يمكنكم تغيير رأيكم في أي وقت. بامكانكم طرح الأسئلة المتعلّقة بالدراسة متى شئتم.

موافقة الباحث:

لقد شرحت بالتفصيل للمشترك في البحث الطبي ل_____ (اسم المشترك او ممثله القانوني أو وليه الجبري أو وصيه اذا كان المشترك قاصرا أو غير قادر على التوقيع) طبيعته ومجرياته وتأثيراته السلبية. ولقد أجبت على كل أسئلته بوضوح على خير ما أستطيع. وسوف أعلم المشترك بأي تغييرات في مجريات هذا البحث أو تأثيراته السلبية أو فوائده في حال حصولها أثناء البحث.

_____ _____

إسم الباحث او الشخص المولى الحصول على موافقة المشترك

توقيع الباحث او الشخص المولى الحصول على موافقة المشترك

_____

التاريخ و الساعة

موافقة المشترك:

لقد قرأت استمارة القبول هذه وفهمت مضمونها. تمت الأجابة على أسئلتي جميعها. وبناء عليه فانني، حرا مختارا، أجيز إجراء هذا البحث و أوافق على الإشتراك فيه، وإني أعلم ان الباحث الدكتور _____ انطوني مكارى _____ وزملاءه ومعاونيه او مساعديه سيكونون مستعدين للإجابة على أسئلتي، وأنه باستطاعتي الإتصال بهم على الهاتف _____5702_____ . واذا شعرت لاحقا ان الأجوبة تحتاج الى مزيد من الإيضاح فسوف أتصل بأحد اعضاء لجنة الأخلاقيات (01- 350000 5445 المقسم). كما أعرف تمام المعرفة بانني حر في الإنسحاب من هذا البحث متى شئت حتى بعد التوقيع على الموافقة دون ان يؤثر ذلك على العناية الطبية المقدمة لي. أعلم أني سوف أحصل على نسخة طبق الأصل عن هذه الموافقة.

_____ _____

إسم المشترك

توقيع المشترك او ممثله القانوني او وليه الجبري أو وصيه

_____

التاريخ و الساعة

أحرف القاصر:

إسم الممثل القانوني او الولي الجبري أو الوصي

التاريخ و الساعة (بيد المشترك او ممثله القانوني أووليه الجبري أو وصيه)

إسم الشاهد (إذا كان المشترك أو الوصي أميا) **توقيع الشاهد**

التاريخ و الساعة

جميع الصور التي تم التقاطها, إذا تم التخطيط لإستخدامها في أي منشور, سيتم تغطية أعين و حواجب طفلكم لتأمين هويتهم.

هل توافق على مشاركة صور طفلكم في المنشورات الأكاديمية ؟

☐ نعم, أوافق
☐ كلا, لا أوافق

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