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## Evaluation and Comparison of Child and Adolescent Mallampati Scores

Diana Bozner  
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EVALUATION AND COMPARISON OF CHILD AND ADOLESCENT  
MALLAMPATI SCORES

by

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A THESIS

Submitted to the graduate faculty of The University of Alabama at Birmingham,  
in partial fulfillment of the requirements for the degree of  
Master of Science

BIRMINGHAM, ALABAMA

2018

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2018

# EVALUATION AND COMPARISON OF CHILD AND ADOLESCENT MALLAMPATI SCORES

DIANA BOZNER

ORTHODONTICS

## ABSTRACT

**Objectives:** The purpose of this study is to investigate clinical assessments that may help to predict pediatric obstructive sleep apnea (OSA). These clinical tools include the Mallampati and Brodsky classifications, as well as the Epworth Sleepiness Scale for Children and Adolescents (ESS-CHAD). The specific aims of this study are to:

- 1.) Compare the Mallampati scores, Brodsky scores, and results of the ESS-CHAD of children versus adolescents in order to observe how these criteria change with age.
- 2.) Compare the Mallampati scores derived by a dental student, an orthodontic resident and a pediatric otorhinolaryngologist (ENT) to determine the accuracy of this assessment.
- 3.) Determine the relationships between these three clinical assessments.

**Methods:** This is a cross-sectional study of 33 children (ages 6-12) and 36 adolescents (ages 13-18). A photo was taken of each participant in order to evaluate his or her Mallampati score, which was assigned individually by a dental student, an orthodontic resident, and a pediatric ENT. All participants likewise received a Brodsky score based on tonsillar size. The ESS-CHAD questionnaire was also completed by each participant. Mallampati scores were then measured for reproducibility using the kappa statistic, along with the corresponding p-values and 95% confidence intervals. Correlations between the various assessments were explored using Spearman correlation analysis (these results were compared separately for each age group). Finally, assessment outcomes were

compared for the two age groups using the Wilcoxon rank-sum test. Statistical tests were two-sided and were performed using a significance level of 5%.

**Results/Conclusions:** The results of this study indicate that: 1.) In general, adolescents have a higher Mallampati score than children. 2.) There are no statistically significant differences in Brodsky and ESS-CHAD scores between children and adolescents. 3.) The Mallampati score is a reproducible clinical assessment. 4.) A statistically significant inverse correlation exists between the Mallampati and Brodsky scores of adolescents. However, this relationship is not statistically significant in the child age group. 5.) There are no statistically significant correlations between the Mallampati and ESS-CHAD scores or the Brodsky and ESS-CHAD scores.

Keywords: obstructive sleep apnea, Mallampati, Brodsky, Epworth Sleepiness Scale

## ACKNOWLEDGMENTS

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## LIST OF ABBREVIATIONS

ADHD	Attention-deficit / hyperactivity disorder
AHI	Apnea-Hypopnea Index
APK	Age-Phenomenon Knowledge Base
BMI	body mass index
CPAP	continuous positive airway pressure
ENT	otorhinolaryngologist
ESS	Epworth Sleepiness Scale
ESS-CHAD	Epworth Sleepiness Scale for Children and Adolescents
MAD	mandibular advancement devices
MeSH	Medical Subject Headings
NREM	Non-Rapid Eye Movement
OSA	Obstructive Sleep Apnea
REM	Rapid Eye Movement
RPE	rapid palatal expansion
TMD	temporomandibular joint disorder

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## CHAPTER 1

### INTRODUCTION

#### Health Screenings in the Dental Office

Obstructive Sleep Apnea (OSA) is often thought of as a condition which affects adults only. According to current estimates, 20% of American adults have OSA – of these, 6% have a moderate-to-severe form of the disease. Moreover, roughly 80-90% of Americans with OSA remain undiagnosed.<sup>1</sup> This prevalence has led to extensive research in the field of sleep medicine as well as a push for public awareness.

In contrast to the adult form of this disease, pediatric OSA remains a lesser-known disorder. Research suggests that 1-10% of children have some form of OSA.<sup>2</sup> This condition affects all ages, ranging from neonates to adolescents; however, it is most commonly seen in preschoolers.<sup>3,4</sup> Pediatric OSA results in numerous cognitive impairments, such as daytime sleepiness or difficulty focusing in school.<sup>3</sup> These issues have kindled a renewed interest in the diagnosis and treatment of OSA in children.

Today, dental professionals have the unique opportunity to screen patients for certain common diseases. This has led to the development of more robust standards in dentistry, such as checking blood pressure before treatment. By adopting this comprehensive systematic approach, orthodontists can look for and recognize signs of OSA in their pediatric patients. Proper referrals can then be made, helping to combat the problem of underdiagnosis. Through early detection, prompt referral, and timely

treatment of pediatric OSA, orthodontists can thus improve the quality of life for many of their young patients.

### Obstructive Sleep Apnea Syndrome

Obstructive sleep apnea is a multifactorial syndrome which consists of complete or partial obstruction of the upper airway despite respiratory effort.<sup>5</sup> This portion of the airway is bounded by many soft-tissue structures, such as the posterior aspect of the tongue and various cervical muscles. In other words, the upper airway is a muscular tube without any rigid structure to maintain patency. It is therefore collapsible at any level, including the nasopharynx, oropharynx, or hypopharynx.<sup>6</sup>

Airway obstruction is often caused by anatomical factors, such as the accumulation of submucosal fat. Obesity (as measured by neck circumference) is the most common cause of adult OSA.<sup>5, 7</sup> This is reflected in America's "obesity epidemic," which has contributed to a rising incidence of OSA as well as a host of other comorbidities.<sup>8</sup> Similarly, OSA can result from both pathological and physiological factors. The former of these concerns conditions like impaired breathing reflexes during sleep. This problem results in centrally-mediated OSA, which accounts for less than 3% of adult cases.<sup>9</sup> Physiological factors, on the other hand, concern findings like reduced pharyngeal muscle activity.<sup>5</sup> While asleep, the genioglossus muscle plays an important role in maintaining airway patency. Bilateral contraction of these muscles causes protrusion of the tongue, which enlarges and stabilizes the upper airway. Relaxation of the genioglossus (especially during Rapid Eye Movement (REM) sleep) is therefore a

common reason for airway obstruction. In fact, the genioglossus muscle is at least partially responsible for the gender difference seen in OSA. Somewhat paradoxically, men are more than *twice* as likely to suffer from OSA - despite having larger pharyngeal airways.<sup>1</sup> A possible explanation for this is the greater muscle tone of the genioglossus in women.<sup>10</sup>

In addition to the male sex, there are several prominent risk factors associated with OSA. These include obesity, age, and excess alcohol consumption.<sup>1, 11</sup> In a study by Park *et al.*, the authors identified OSA in 41% of patients with body mass index (BMI) of greater than 28.<sup>12</sup> Normal BMI measures 18.5-25, which places these patients in the mid-range of “overweight.” As previously discussed, this correlation is linked to increased neck circumference. Middle-age and older adults are also more susceptible to OSA due to the loss of pharyngeal muscle tone over the course of life.<sup>1</sup> Finally, excess alcohol intake has been shown to increase the risk of sleep apnea by 25%.<sup>11</sup> This is a function of depressing the central nervous system, which controls breathing rhythm and muscle tone. By considering social history as well as clinical presentation, providers can better assess someone’s overall risk profile.

Clinical manifestations of OSA vary from snoring to gasping to choking at night. Partners often report witnessed apneas, with intervals of more than 10 seconds between breaths.<sup>13</sup> These sleep disturbances result in morning headache, excessive daytime sleepiness, and cognitive impairment.<sup>14</sup> Consequently, untreated OSA is often associated with serious health problems, including hypertension, cardiovascular disease, type 2 diabetes, depression, stroke, and sudden death.<sup>5</sup> Individuals with OSA are even more likely to experience home or work related accidents and worsening quality of life.<sup>5, 14</sup>

According to an 18 year longitudinal study, patients with severe sleep apnea have *three times the mortality rate* compared to normal individuals and are *five times as likely to die* of cardiovascular complications.<sup>15</sup> These implications necessitate a greater emphasis on early diagnosis and treatment of OSA.

There are various treatment options for OSA, ranging from non-invasive to surgical. The choice of treatment often hinges on patient preference, as well as patient motivation to take the necessary steps to recovery. Perhaps the most benign treatment for overweight patients suffering from OSA is weight loss via diet and exercise. According to published randomized clinical studies, sustained weight loss results in significant improvements in patients with mild to severe forms of OSA, with marked reduction of the Apnea-Hypopnea Index (AHI).<sup>16, 17</sup> However, drastic lifestyle changes are difficult to maintain, and many patients need extra help in order to improve their breathing.

First described in 1981, continuous positive airway pressure (CPAP) is the current “gold standard” of treatment for OSA. This device delivers mild air pressure via the face mask and prevents the airway from collapsing. Although the CPAP is effective for all forms of OSA, its effectiveness is often diminished due to poor patient compliance. These patients frequently complain of noisy machines, skin irritation, dry mouth or nasal airways, claustrophobia, and epistaxis.<sup>18</sup> As a result, many OSA patients opt for dental devices are less noisy and less bulky. These include tongue repositioning devices (which hold the tongue in an anterior position via suction) and mandibular advancement devices or “MADs” (which serve to protrude the mandible). These oral appliances come in many different shapes and sizes; however, they have a common goal: to increase the volume of the pharyngeal airway space.



Some studies show that mandibular advancement devices are as effective as CPAP in decreasing AHI, blood pressure, and cardiovascular mortality rates and increasing quality of life.<sup>19, 20</sup> However, prolonged use of MADs can result in some notable side effects. One of the most common side effects is occlusal change, such as the development of a posterior open-bite and/or decreased overbite and overjet.<sup>21</sup> For this reason, the American College of Physicians recommends starting with the least-invasive treatment option (i.e. weight loss and behavior modification). CPAP should also be considered for initial therapy, while MADs can later be considered as an alternative treatment option.<sup>18</sup>

In addition to the conservative treatment modalities described above, the American Association of Sleep Medicine lists several surgical interventions for the adult OSA patient. These include advancement genioplasty, mandibular advancement, and maxillomandibular advancement.<sup>22</sup> Evidence in favor of the former two interventions comes largely from case reports; however, higher-level evidence in support of maxillomandibular surgery has led to this option becoming the preferred surgical-orthodontic treatment of OSA.<sup>23-28</sup> Maxillomandibular surgery with 10mm advancement has been shown to improve AHI scores of greater than 20 to less than 10.<sup>26</sup>

### Pediatric Obstructive Sleep Apnea

Pediatric OSA is commonly misconstrued as “adult OSA” in children. This viewpoint is incorrect. In contrast to adults, the most common cause of pediatric airway constriction is adenotonsillar hypertrophy.<sup>2, 3, 29</sup> However, not all children with enlarged

tonsils and adenoids have OSA. This is because pediatric OSA is thought to be a combination of both enlarged tonsils and/or adenoids *as well as* loss of neuromuscular tone.<sup>2, 29</sup> For this reason, pediatric OSA patients typically present with two or more risk factors.

There are specific facial and dental traits that accompany this condition. When large adenoids block nasal respiration, children will start to breathe predominantly through the mouth. This leads to development of the characteristic “adenoid face,” which involves an increased anterior facial height, posteriorly rotated mandible, and incompetent lips. Moreover, mouth breathers tend to have a lower resting tongue position, which leads to characteristic dental findings, including a “V-shaped” maxillary arch and a high palatal vault.<sup>30</sup> These are all easily-detectable signs that can be recorded during a clinical exam.

Certain craniofacial morphological characteristics have also been associated with OSA. These include a retrusive chin, steep mandibular plane, vertical direction of growth, and Class II malocclusion.<sup>31</sup> These features can appreciably reduce the size of the airway and lead to greater upper airway resistance. However, none of these craniofacial characteristics are considered pathognomonic due to the low sensitivity and specificity of studies that relied solely on lateral cephalograms to evaluate patients.<sup>31</sup> Moreover, it is not clear whether these characteristics are risk factors for OSA or whether they are the result of altered growth response due to OSA. Nevertheless, these characteristics can serve as red flags that should alert clinicians to inquire further into patients’ medical history and possibly refer them to an otorhinolaryngologist (ENT).

In addition to large tonsils and craniofacial features, there appear to be specific risk factors for pediatric OSA. Several studies have indicated that heavier children, boys, and African Americans show a predilection for the condition.<sup>3, 4, 29</sup> While the racial component is likely due to craniofacial differences, the reason for the difference in sex is less clear. In fact, one study reports that there is *no gender difference* when it comes to pediatric OSA.<sup>29</sup> These seemingly ambiguous results can make it difficult to know which evidence to follow. Some authors even suggest that childhood obesity is the primary cause of pediatric OSA (similar to adults).<sup>32</sup> Any element should thus be taken in its larger context, as there appears to be no single predictor of risk.

By disrupting the sleep cycle, pediatric OSA affects both daily behavior and overall development. The clinical manifestations of this disorder include snoring, labored breathing, apnea, and fragmented sleep. At night, these children may also experience diaphoresis, bruxism, as well as enuresis.<sup>2</sup> These experiences can impact a child's psychosocial development. The lack of a good night's rest has been shown to cause not only daytime sleepiness, but also behavior problems and poor school performance.<sup>3</sup> Cognitive deficits include decreased language and verbal skills, lower visual and auditory capabilities, and memory loss.<sup>33, 34</sup> Behavioral problems have been characterized as depression, aggression, and social maladaptation.<sup>33, 34</sup> Pediatric OSA has even been cited as a possible cause of Attention-deficit / hyperactivity disorder (ADHD).<sup>35</sup> These are all potential lifelong issues. Finally, there are physiological changes that are associated with pediatric OSA – failure to thrive, cor pulmonale, and hypertension, to name a few.<sup>3</sup> In the most extreme cases, cardiorespiratory failure may

lead to death.<sup>3</sup> These adverse outcomes are truly devastating and demonstrate why this condition demands the attention of the medical community.

Considering the range of etiologies, treatment of pediatric OSA will depend on case presentation. However, a majority of patients will require one of a few basic options. Adenotonsillar hypertrophy is the most common cause of pediatric OSA; therefore, it is no surprise that adenotonsillectomy is the first line of treatment for most patients, yielding significant improvements in polysomnographic measurements.<sup>3</sup> In otherwise healthy children, this surgical procedure resolves symptoms of OSA and is curative in 75-100% of patients (these findings are corroborated by sleep studies).<sup>3</sup> According to a meta-analysis by Becking *et al.*, adenotonsillectomy also affects further dentofacial development, resulting in more horizontal mandibular growth and increase in maxillary archwidth.<sup>36</sup> Thus, correction of tonsil- and/or adenoid-related OSA may redirect growth toward a normal direction, correcting the “adenoid face” appearance. These changes not only improve the child’s sleep, but can have a profound impact on later orthodontic treatment.

Alternative treatment options mirror those seen in adults – that is, mainly CPAP and weight loss. As expected, these options are met with the same hardships and lack of compliance. Moreover, the use of CPAP in young children may result in unwanted alterations of normal facial growth (not to mention a greater risk of childhood caries due to dry mouth).<sup>37, 38</sup>

While the American Academy of Pediatrics offers no formal endorsement of early orthodontic intervention, some clinicians prefer this approach as a means of treating pediatric OSA.<sup>39</sup> Treatment modalities include rapid palatal expansion (RPE), and some

evidence points to sagittal growth modification as an option.<sup>40</sup> Several studies have shown improvements in sleep study outcomes for children treated with RPE. This includes both short- and long-term follow up periods.<sup>41-43</sup> According to a meta-analysis, RPE is an effective means of reducing AHI by at least 50% and often up to 70% during a follow-up period of 3 years or less.<sup>41</sup> This orthodontic method can thus be used as a primary or secondary OSA treatment in children with maxillary transverse deficiency / small tonsils or in cases where adenotonsillectomy has failed.<sup>41</sup> Results from a 12 year study support use of RPE in the treatment of OSA and demonstrate the stability of maxillary expansion.<sup>42</sup> In this study, yearly orthodontic and otolaryngological examinations yielded normal findings, while a final follow-up sleep study produced normal results.<sup>42</sup> Based on these findings, orthodontic treatment via RPE *may* help a young child with OSA and maxillary transverse deficiency. However, this treatment must be initiated early, as the midpalatal suture closes during the teenage years. In this light, orthodontists can play a pivotal role in both screening and treating these patients.

According to a clinical trial by Villa *et al.*, both tonsillectomy and orthodontic treatment via RPE improve OSA. These authors recommend a multidisciplinary team approach to treatment.<sup>44</sup> Whether treatment involves orthodontics or surgical intervention, the benefits of timely intervention have been well documented. Between adenotonsillectomy and RPE, the chances of improving a child's AHI score are high, which highlights the importance of a multidisciplinary team approach when it comes to treatment of OSA.

## Polysomnography

In order to understand sleep disorders, it is first necessary to describe normal sleep patterns. There are two broad categories of sleep: Non-Rapid Eye Movement (NREM) and Rapid Eye Movement (REM). The latter of these is where dreams occur. Sleep patterns are furthermore grouped into five stages: Stage W (Wakefulness), Stage N1 (NREM 1 sleep), Stage N2 (NREM 2 sleep), Stage N3 (NREM 3 sleep), and Stage R (REM sleep).<sup>45</sup> These stages represent different levels of consciousness and metabolic output. During the course of a night, this five-stage cycle repeats an average of four to six times, each cycle lasting 90 minutes.<sup>46</sup>

Each sleep stage serves a unique role in rejuvenating the body. The first stage of sleep, Stage W, is a transitional phase that ranges from alert wakefulness to drowsiness. The duration of time spent in this stage varies from person-to-person but generally lasts between 10-20 minutes.<sup>47</sup> Stage N1 indicates sleep onset. It is the lightest stage of sleep, with brainwaves that are only slightly slower than during wakefulness. Breathing occurs at a regular rate, while skeletal muscles maintain muscle tone and may jerk. Approximately 3-6% of time asleep is spent in Stage N1.<sup>47</sup> Stage N2 follows with distinct brainwaves called “K-complexes” and occasional spikes of brain activity called “sleep spindles.”<sup>45</sup> Heart rate slows and body temperature decreases. Stage N2 comprises approximately half of the time spent asleep.<sup>47</sup> Progressively deeper sleep ensues in Stages N3 which is characterized by “slow wave sleep,” or brainwaves with slower frequency and higher amplitude called “delta waves.”<sup>45</sup> Blood pressure drops and breathing becomes slower and more rhythmic. Approximately 20% of sleep is comprised of slow wave sleep, although this duration decreases with aging.<sup>47</sup> These are the periods

from which it is most difficult to awaken. If aroused during this time, one may experience “sleep inertia,” or impaired mental performance, for up to half an hour.<sup>48</sup> Although the body is typically immobile in deep sleep, some children may sleepwalk in these stages. This is also when bedwetting and nightmares occur in youngsters.<sup>49, 50</sup> Studies have also shown that sleep deprivation results in a rebound in slow wave sleep, which points to the body’s need for this sleep stage.<sup>51</sup> Overall, slow wave sleep is essential for the body’s ability to restore itself.<sup>52</sup> For example, hormones that promote growth and control appetite are released during deep sleep and are crucial to development and maintenance of a strong body and healthy eating habits.<sup>45,52</sup>

The final stage of sleep – REM sleep – is distinctly different from the previous NREM stages. Stage R, or REM sleep, is the stage in which dreams occur. Brainwaves are similar to those seen in wakefulness, the heart rate increases, and breathing becomes more erratic. Transient muscle activity is also noted.<sup>45</sup> Adults spend 20-25% of time asleep in this stage, with increasing duration as sleep progresses.<sup>47</sup> REM sleep is positively associated with self-reported sleep quality and improved daily cognition.<sup>53</sup> As with slow wave sleep, time spent in REM sleep decreases with age.<sup>47</sup>

Indeed, sleep is a fascinating event during which the body undergoes many changes. Understanding the normal patterns of sleep allows clinicians to detect abnormal behaviors. Polysomnography (also known as “sleep study”) is a multi-parametric test used in sleep medicine to diagnose sleep disorders. Clinicians monitor sleep stages and cycles to identify *if* and *when* sleep is disturbed and the cause of the disturbance. During the session, the patient’s vital signs are recorded, including blood oxygen levels, heart rate, brain waves, breathing patterns, and body movements.<sup>54</sup>

Polysomnography is the current gold standard for OSA diagnosis, as it is the only means by which clinicians are able to distinguish between snoring and sleep apnea.<sup>3</sup> OSA occurs on a spectrum of severity, which is characterized by the Apnea-Hypopnea Index (AHI). This parameter represents the number of apneic or hypopneic events that occur per hour of sleep, and it is routinely measured during polysomnography. Normal adults have an AHI of less than 5, while individuals with mild OSA have an AHI between 5 to 14. Moderate OSA is characterized by an AHI of 15 to 29, whereas severe OSA is defined as having 30 or more events per hour of sleep. Notably, an AHI greater than 1 is diagnostic of OSA in a child.<sup>2</sup>

This clinical distinction highlights the fact that *children are not simply small adults*. In fact, children with OSA bear striking differences in their sleep patterns versus their adult counterparts. For example, in adults, apneas and hypopneas occur in both REM and NREM sleep. In children, NREM sleep is well-preserved, and apneas and hypopneas occur mostly in REM sleep. The reduction of NREM sleep in adult patients may explain why adults report more daytime sleepiness, morning headaches, and impaired memory than children.<sup>55</sup>

The importance of a proper diagnosis of OSA by a qualified physician is undisputable. However, the high cost and low accessibility of polysomnography contribute to the problem of underdiagnosis of this condition. Current data shows that a sleep study can cost between \$450 to \$1,100 per patient – a price that is prohibitively expensive for many patients seeking necessary medical care.<sup>56</sup> Moreover, there is a shortage of facilities that perform pediatric polysomnography.<sup>3</sup> Pediatric facilities require more specialized equipment and trained personnel to accommodate young



patients. These financial and logistical hurdles have led clinicians to seek out an alternative means of identifying at-risk children.

### Accuracy and Reliability of Clinical Assessments

In 1983, Dr. Seshagiri Mallampati – an American-Indian anesthesiologist – developed the Mallampati Score. This score represents a visual assessment used to predict the ease of endotracheal intubation. During this assessment, the patient is asked to open his mouth maximally while protruding his tongue as far as possible without producing any sound. The clinician then assigns a score based on the amount of airway that is visible. Scores are divided into four distinct classes: Class I: the entire soft palate and uvula are visible; Class II: the soft palate and a portion of the uvula are visible; Class III: only the soft palate or the base of the uvula is visible; Class IV: the soft palate is not visible. While Mallampati Classes I and II are associated with relatively easy intubation, Classes III and IV are associated with increased difficulty.<sup>57</sup>

In 1989, Dr. Linda Brodsky, an otorhinolaryngologist in New York, introduced the Brodsky classification, which has become the most well-known and accepted grading scale used to assess the size of tonsils.<sup>58</sup> In this assessment, the tonsils are graded from 0 to 4 based on the percentage of the oropharyngeal airway occupied by the tonsils. Scores are assigned as follows: Grade 0: surgically removed tonsils or no impingement on the airway; Grade 1: tonsils hidden within tonsillar pillars or less than 25% airway obstruction; Grade 2: tonsils extending to the pillars or 25 to 50% airway

obstruction; Grade 3: tonsils extending beyond the tonsillar pillars or 50 to 75% airway obstruction; Grade 4: tonsils extend to midline or more than 75% airway obstruction.<sup>59</sup>

Although polysomnography is the gold standard for OSA diagnosis, the difficulty of obtaining a sleep study has prompted clinicians to seek other means of evaluating OSA risk factors. With this goal in mind, several studies have identified a connection between the palate position / tonsillar size and AHI in children. For example, Kljajic *et al.* found a strong positive correlation between AHI and Mallampati score (standardized B = 0.51; partial correlation = 0.542,  $r = 0.631$ ) as well as AHI and tonsillar size (standardized B = 0.246; partial correlation = 0.295,  $r = 0.489$ ). These results were independent of confounding factors such as age, sex, BMI, and size of the adenoids.<sup>60</sup> Similarly, Kumar *et al.* were able to link together Mallampati, tonsillar size and AHI. For every point increase in the Mallampati score, the odds ratio of having OSA increased 6-fold (OR for 1-point increase was 6.75; 95% CI: 3.71–12.29;  $p < 0.01$ ). For every point increase in tonsillar size, the odds ratio of having OSA increased by more than 2-fold (OR for 1-point increase was 2.90, 95% CI: 1.69-4.15;  $p < 0.01$ ).<sup>61</sup> In a meta-analysis, Friedman *et al.* concluded that the Mallampati classification predicts the severity of OSA with a correlation of 0.351 (0.094-0.564,  $P = .008$ ).<sup>62</sup> These results agree with Wysocki's findings about the positive correlation between Mallampati and polysomnography results.<sup>7</sup> Finally, in a prospective study of adult patients, Nuckton *et al.* found that the Mallampati score was an independent predictor of both the presence and severity of OSA. Specifically, for every 1-point increase in Mallampati score, odds of having OSA with  $AHI \geq 5$  increased more than 2-fold (OR [per 1-point increase] = 2.5; 95% CI: 1.2-5.0;  $p = .01$ ). Moreover, for every 1-point increase in the Mallampati score, the AHI increased

by more than 5 events per hour (coefficient = 5.2; 95% CI: 0.2-10;  $p = .04$ ). These results were independent of more than thirty variables related to airway anatomy, body habitus, and history of snoring.<sup>57</sup> The authors concluded that the independent association between the Mallampati score and the presence and severity of OSA renders this scoring system clinically useful.

In addition to clinical evaluation, researchers have commonly used questionnaires in order to investigate pediatric OSA. These are typically administered to parents in order to determine whether children snore. In 1990 Dr. Murray Johns, founder of the Australasian Sleep Association, developed the Epworth Sleepiness Scale. This is a self-administered questionnaire consisting of eight questions which gauge the likelihood of one falling asleep while engaged in various activities. Responses are rated according to a 4-point scale, ranging from 0 to 3. Thus, the final score ranges from 0 to 24, where a higher score indicates greater daytime sleepiness. The questionnaire was named after the Epworth Hospital in Melbourne where Dr. Johns established the Epworth Sleep Center in 1988. Since its inception, the ESS has been used in numerous studies from obstructive sleep apnea to narcolepsy.<sup>63-65</sup> While the ESS is not a diagnostic tool by itself, it can be coupled with other clinical tests in order to draw useful conclusions about sleep patterns. Numerous studies have shown the ESS to be a valid and reliable means of assessing daytime sleepiness.

## Benefits of Timely Treatment

Orthodontics is a continuously evolving field with numerous advancements in technology, materials, and services. Like dentistry as a whole, the specialty of orthodontics has recently adopted a more comprehensive approach to treatment by focusing its attention on sleep apnea, especially in the case of children. Although an increasing number of adults are seeking orthodontic treatment today, currently 77% of orthodontic patients are children.<sup>66</sup> Due to the volume of young patients receiving orthodontic care, orthodontists are in a unique position to help their medical colleagues identify signs of potential breathing problems. Early identification, referral, diagnosis, and treatment of pediatric sleep apnea can ultimately improve a child's quality of life.

Although future research on pediatric sleep apnea will provide more insight into the best treatment modalities for children, the knowledge that is currently available has already spurred many clinicians to action. Identification of clinical risk factors is naturally the first step toward fighting pediatric sleep apnea.

## CHAPTER 2

### AIMS OF THE STUDY AND HYPOTHESES

#### Aims

The specific aims of this project are to:

1. Compare the Mallampati scores, Brodsky scores, and results of the Epworth Sleepiness Scale of children versus adolescents in order to observe how these criteria change with age.
2. Compare the Mallampati scores derived by a dental student, an orthodontic resident and an otorhinolaryngologist to determine the accuracy of this assessment.
3. Determine the relationships between three tools used to assess pediatric sleep apnea, including the Mallampati classification, the Brodsky assessment, and the Epworth Sleepiness Scale.

#### Hypotheses

The null hypotheses of this study are: (1) There are no differences between children and adolescents in terms of the Mallampati score, Brodsky assessment, and Epworth Sleepiness Scale. (2) There are no differences in the Mallampati scores given by a dental student, an orthodontic resident, and an otorhinolaryngologist. (3) There are

no correlations between the Mallampati classification, Brodsky assessment, and the Epworth Sleepiness Scale.

## CHAPTER 3

### MATERIALS AND METHODS

This cross-sectional study investigates the outcomes of three commonly used criteria in the assessment of pediatric obstructive sleep apnea. A total of 69 subjects aged 6-18 were recruited from the orthodontic clinic at the University of Alabama in Birmingham (UAB). Participants were divided into two groups based on age. Those aged 6-12 were considered “children,” and those aged 13-18 were considered “adolescents.” This delineation is based on standard age ranges defined by the Medical Subject Headings (MeSH), which is the National Library of Medicine’s controlled vocabulary thesaurus.<sup>67</sup> Meticulous research has been conducted in order to validate these commonly used age group definitions. In 2013, Geifman *et al.* sought to redefine age groups in the context of specific diseases. In light of this goal, researchers organized the “Age-Phenome Knowledge-base (APK),” a database that contains 35,000 entries that describe the relationship between age and certain diseases. These entries were mined from over 1.5 million PubMed abstracts. The availability of such organized information allows researchers to examine commonly accepted age-range definitions. The results of Geifman *et al.*’s study showed that age ranges defined by clustering of APK data closely resemble those defined by MeSH.<sup>67</sup> Thus, the MeSH definitions of “child” and “adolescent” were accepted for the purposes of this study.

Of the 69 total subjects, 33 were “children” and 36 were “adolescents,” resulting in approximately equal groups. This sample size mirrors that of a similar published study regarding pediatric obstructive sleep apnea.<sup>60</sup> The UAB Institutional Review Board for Human Use granted approval for this study.

### Subject Selection Criteria

In order to be considered for this study, subjects must be between the ages of 6 to 18 years old and willing/able to answer a survey themselves. Participants may either be awaiting orthodontic treatment, undergoing active treatment, or currently in post-treatment retention. Exclusion criteria includes any temporomandibular joint disorders (TMD) that limit maximum mouth opening.

### Data Acquisition

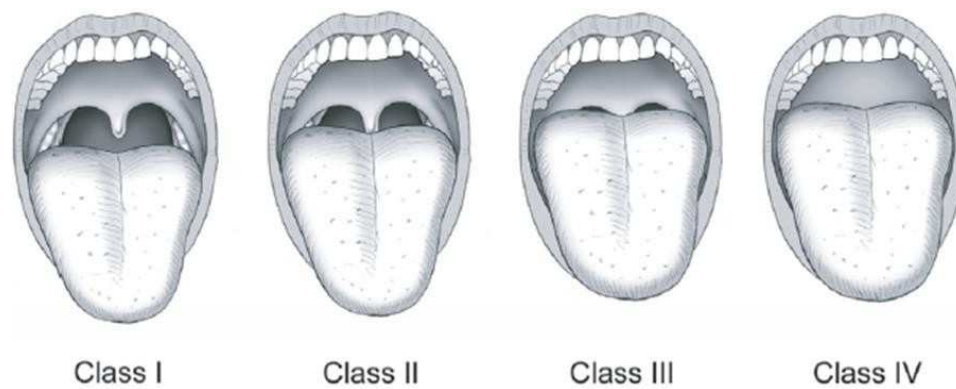
An orthodontic resident was the sole data collector for this study. The data obtained from each participant includes a photo used to assess the subject’s Mallampati score, a clinical assessment of tonsil size, and a survey. In order to obtain the photo, each participant was asked to sit in an upright position, open his/her mouth maximally, and protrude the tongue without producing any sound. The clinical assessment of tonsil size was performed in a similar way; however, a tongue depressor was also used to depress the tongue for better visualization of the tonsils. Finally, each subject independently completed the Epworth Sleepiness Scale for Children and Adolescents (ESS-CHAD).



## Scoring of Data

Each photo was assigned a Mallampati score by three individuals: a dental student, an orthodontic resident, and a pediatric ENT. The photos were rated according to the following classifications depicted in Figure 1: Class I: the entire soft palate and uvula are visible; Class II: the soft palate and a portion of the uvula are visible; Class III: only the soft palate or the base of the uvula is visible; Class IV: the soft palate is not visible.

Figure 1. Mallampati Classification

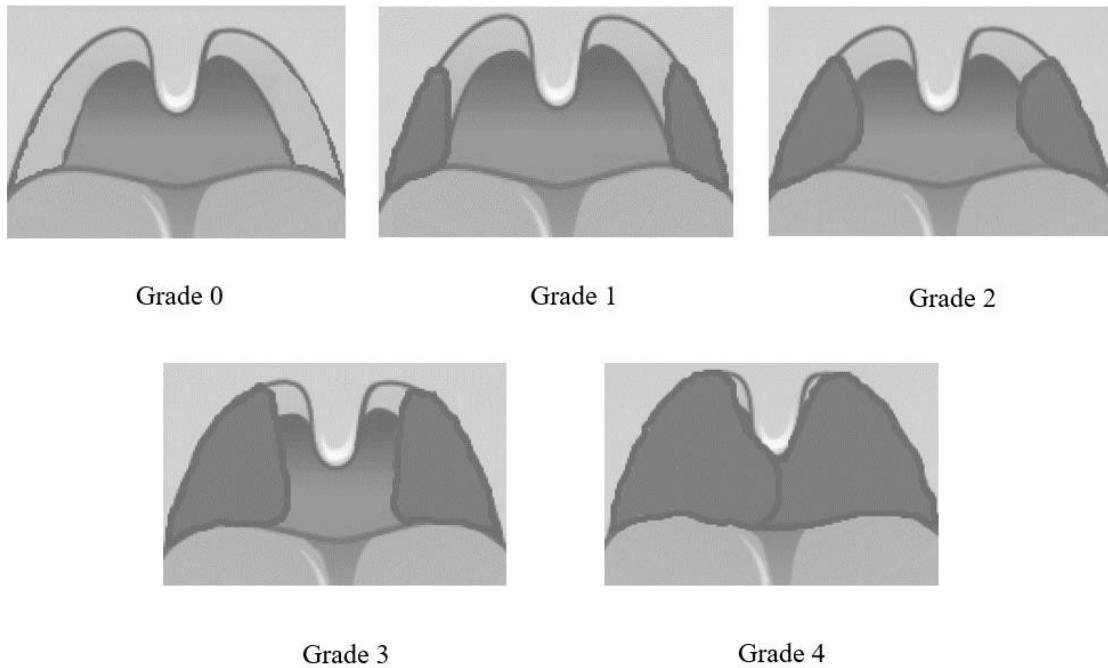


Note: From “Physical examination: Mallampati score as an independent predictor of obstructive sleep apnea” by T.J. Nuckton et al., 2006, SLEEP, 29, p. 904. Copyright 2006 by the American Academy of Sleep Medicine. Reprinted with permission.

The data collector assigned a Brodsky score based on clinical presentation, following the criteria depicted in Figure 2: Grade 0: surgically removed tonsils or no impingement on the airway; Grade 1: tonsils hidden within tonsillar pillars or less than 25% airway obstruction; Grade 2: tonsils extending to the pillars or 25 to 50% airway

obstruction; Grade 3: tonsils extending beyond the tonsillar pillars or 50 to 75% airway obstruction; Grade 4: tonsils extend to midline or more than 75% airway obstruction.

Figure 2. Brodsky Tonsillar Assessment



Finally, Figure 3 shows the ESS-CHAD questionnaire. Each participant completed this questionnaire independently. Participants responded to each question according to a 4-point scale (0-3), and the sum of these responses produced the final score which was recorded. The final score is evaluated based on the following scale: 0-5 Lower Normal Daytime Sleepiness; 6-10 Higher Normal Daytime Sleepiness; 11-12 Mild Excessive Daytime Sleepiness; 13-15 Moderate Excessive Daytime Sleepiness; 16-24 Severe Excessive Daytime Sleepiness.

Figure 3. Epworth Sleepiness Scale for Children and Adolescents

Use the following scale to choose one number that best describes what has been happening to you during each activity over the past month. Write that number in the box below.

**0 = would never fall asleep**

**1 = slight chance of falling asleep**

**2 = moderate chance of falling asleep**

**3 = high chance of falling asleep**

*It is important that you answer each question as best you can*

Activities	Chance of falling asleep (0 – 3)
Sitting and reading _____	<input type="text"/>
Sitting and watching TV or a video _____	<input type="text"/>
Sitting in a classroom at school during the morning _____	<input type="text"/>
Sitting and riding in a car or bus for about half an hour _____	<input type="text"/>
Lying down to rest or nap in the afternoon _____	<input type="text"/>
Sitting and talking to someone _____	<input type="text"/>
Sitting quietly by yourself after <i>lunch</i> _____	<input type="text"/>
Sitting and eating a meal _____	<input type="text"/>

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The three Mallampati scores given by the student, resident, and ENT were recorded in a Microsoft Excel spreadsheet, which also contained each patient's Brodsky tonsillar score and result of the ESS-CHAD. Patients were arranged in the spreadsheet according to age.

## Statistical Analysis

The Mallampati scores between the raters were assessed as follows: student scores vs. resident scores, student scores vs. ENT scores, and resident scores vs. ENT scores, using the kappa statistic, along with the corresponding P-values and 95% confidence intervals. The correlations of the mean Mallampati score (the mean score of the three raters) with the Brodsky score, the mean Mallampati score with the ESS survey score, the Brodsky score with the ESS survey score, the mean Mallampati score with the categorized ESS survey score, and the Brodsky score with the categorized ESS survey score, were determined using Spearman correlation analysis. The above analyses were then performed separately for the two age groups ( $<13$ ,  $\geq 13$ ). Comparisons of the mean Mallampati score, the mean Brodsky score, the mean ESS survey score, and the mean categorized ESS survey score between the two age groups were performed using the Wilcoxon rank-sum test. Statistical tests were two-sided and were performed using a significance level of 5%. SAS software (version 9.4; SAS Institute, Cary, NC) was used to conduct all statistical analyses.

## CHAPTER 4

### RESULTS

#### Clinical Assessments According to Age

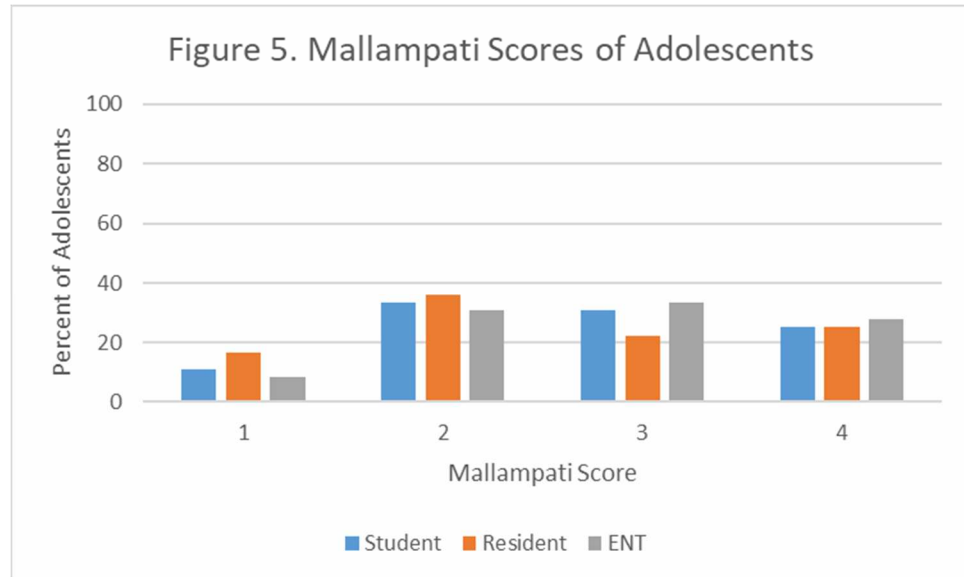
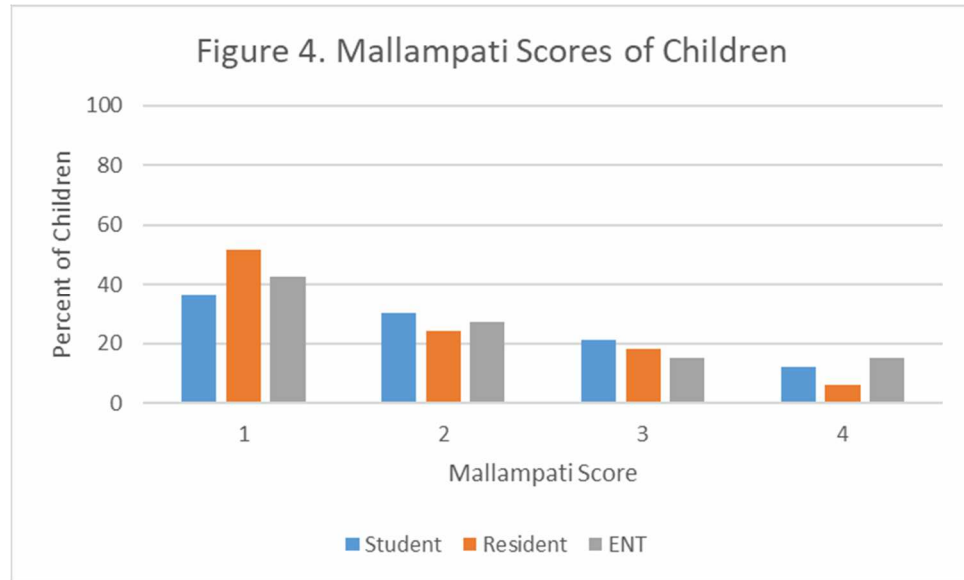
The mean Mallampati score for adolescents was significantly greater than the mean Mallampati score for children ( $p = 0.005$ ). Comparison of average Brodsky scores and average ESS-CHAD scores between the age groups showed no significant difference. These results are listed in Table 1.

<b>Table 1.</b> Comparison of Average Assessment Scores between Age Groups				
	All Participants (n=69)	Children (n=33)	Adolescents (n=36)	p-value
Age	13.4 $\pm$ 2.01	11.7 $\pm$ 1.20	14.97 $\pm$ 1.15	
Mallampati Score	2.34 $\pm$ 1.04	1.97 $\pm$ 1.00	2.69 $\pm$ 0.96	0.005
ESS Survey Score	8.23 $\pm$ 3.45	7.63 $\pm$ 3.87	8.72 $\pm$ 3.03	0.16
Brodsky Score	1.32 $\pm$ 0.90	1.51 $\pm$ 0.97	1.14 $\pm$ 0.80	0.12

Note: p-value applies only to children vs. adolescents

#### Mallampati Scores

Figures 4 and 5 show the distribution of Mallampati scores given by the three raters for children and adolescents, respectively. As depicted in these graphs, children received lower Mallampati scores compared to adolescents ( $p = 0.005$ ).



Comparisons of Mallampati scores assigned by the student, resident and ENT are listed in Table 2. The Mallampati scores showed good reproducibility between all raters. In particular, there is very good reproducibility of the adolescents' Mallampati scores between the student and the resident ( $\kappa = 0.734$ ,  $p < 0.001$ ). The student and ENT

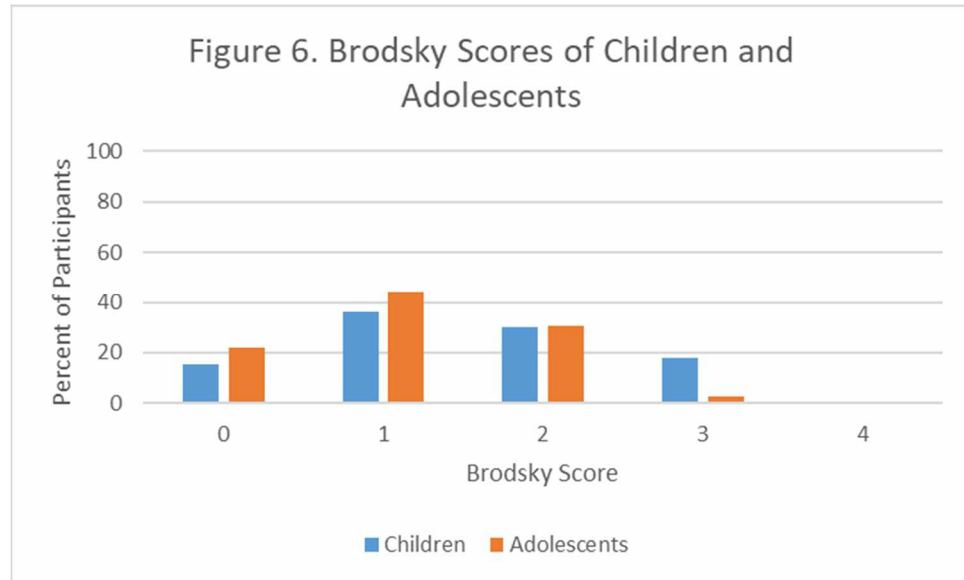
also showed very good reproducibility of Mallampati scores for adolescents ( $\kappa = 0.768$ ,  $p < 0.001$ ).

<b>Table 2.</b> Reproducibility of the Mallampati Score			
	All Participants (n=69)	Children (n=33)	Adolescents (n=36)
Student and Resident	0.668*	0.563*	0.734*
Student and ENT	0.728*	0.660*	0.768*
Resident and ENT	0.650*	0.554*	0.697*

\* $p < 0.001$

### Brodsky Scores

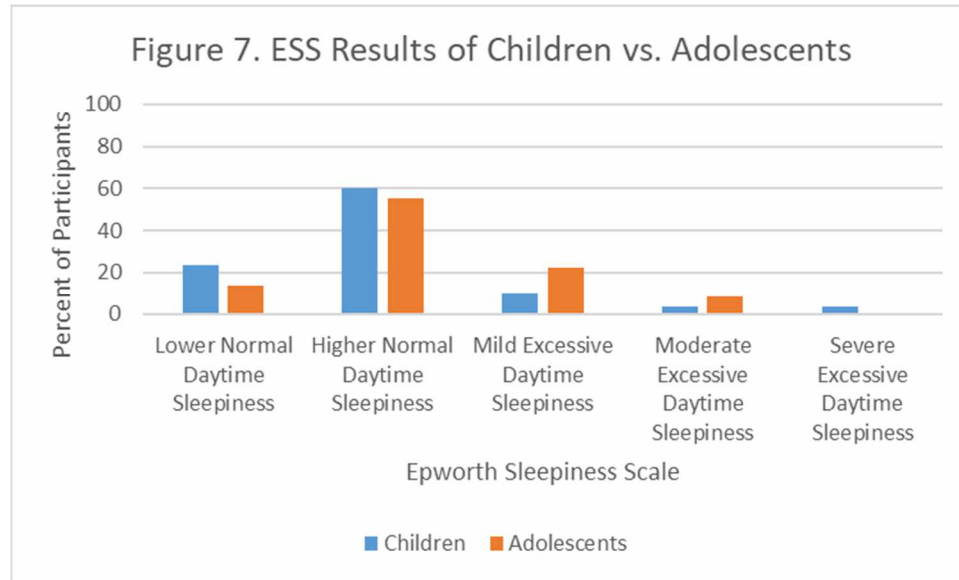
The distribution of Brodsky scores for children and adolescents is shown in Figure 6. However, there was no significant difference detected between the two age groups. The most frequent Brodsky score assigned to both children and adolescents was a score of 1.



#### Epworth Sleepiness Scale

The ESS-CHAD scores for children and adolescents are shown in Figure 6. As listed in Table 1, there is no significant difference between children and adolescents in this assessment. When the ESS-CHAD scores were categorized, the results showed that children and adolescents most frequently responded with “higher normal daytime sleepiness” according to the survey.





### Correlations of Clinical Assessments

Finally, all assessments were compared to determine the relationships between them. Comparison of the average Mallampati and Brodsky scores showed a statistically significant inverse correlation in adolescents ( $r = -0.39$ ,  $p = 0.020$ ) and for all participants as a whole ( $r = -0.36$ ,  $p = 0.003$ ). However, this comparison was not statistically significant in the child age group. Comparison of the average Mallampati and ESS scores showed no statistically significant correlation. No statistically significant correlation was found between the average Brodsky and ESS scores.

**Table 3.** Correlation of Average Assessment Scores According to Age

	All Participants (n=69)		Children (n=33)		Adolescents (n=36)	
	r	p-value	r	p-value	r	p-value
M vs. B	-0.36	0.003	-0.28	0.12	-0.39	0.02
M vs. ESS	0.058	0.64	0.015	0.94	-0.017	0.92
B vs. ESS	0.195	0.12	0.286	0.13	0.2	0.24

Note: “M” = Mallampati Score; “B” = Brodsky Score

## CHAPTER 5

### DISCUSSION

The aims of this study were to investigate the relationships between three clinical assessments that can be used to evaluate patients for risk factors of pediatric OSA, and to observe how these measures differ according to age. In addition, one of the assessments – the Mallampati classification – was tested for reliability by comparing scores given by three raters, including a pediatric ENT. Participants consisted of 69 orthodontic patients divided into approximately equal groups of 33 children under the age of 13 and 36 adolescents aged 13 to 18.

OSA has recently come to the forefront of dentistry and orthodontics as awareness of this condition is increasing among clinicians as well as patients. However, OSA is largely underdiagnosed, and proper diagnosis of pediatric OSA remains difficult due to financial and logistical obstacles. Given the various negative effects of OSA on a child's physical and cognitive development, researchers have aimed at identifying early signs of pediatric OSA in an effort to provide treatment to these patients in a timely manner.

While dentists and orthodontists may be able to offer treatment options – such as MADs or RPEs – the crucial step in combating OSA is identification of risk factors.

Orthodontists in particular are in a unique position to screen young patients for signs of potential breathing problems. Therefore, it is important to gain a better understanding of the clinical assessments used in these evaluations. The following discussion will focus

on three such assessments, including the Mallampati, Brodsky, and ESS scores which are used to classify palatal position, tonsillar size, and daytime sleepiness, respectively.

### Clinical Assessments According to Age

One of the ways to gain a better understanding of these three clinical tools is to observe how the outcomes change with age. The results of this study show that there was no significant difference in ESS scores between children and adolescents. Most scores were within the normal range, as expected since the participants were randomly chosen from an orthodontic clinic to represent a normal distribution of children and adolescents. This result agrees with Janssen *et al.*'s study which concluded that the ESS-CHAD is a valid and reliable way to assess daytime sleepiness.<sup>68</sup>

The results also showed no significant difference between the Brodsky scores of children and adolescents. Considering the changes in lymphatic tissue with age, one might expect children to have higher Brodsky scores compared to adolescents. For example, Scammon's growth curves depict the proliferation of lymphoid tissue in late childhood (around age 10) and involution of this tissue system as growth of the genital tissues accelerates at puberty (around age 13-14).<sup>69</sup> More recent research using magnetic resonance imaging (MRI) shows that in children without a history of snoring, the growing adenotonsillar tissue causes narrowing of the airway only during the first 8 years of life, mirroring the information found in Scammon's growth curves.<sup>70</sup> However, this difference in lymphatic tissue in age groups may not have been revealed in this study due to the low number of young child participants (the average age of children in this group

was  $11.7 \pm 1.2$  years). This points to one of the limitations of this study. Obtaining an adequate number of young children in an orthodontic clinic was difficult since most orthodontic treatment is begun at puberty. Nevertheless, the majority of participants in both age groups received low Brodsky scores, with the most frequently assigned score being a Brodsky score 1. In fact, no participants received a Brodsky score 4. These findings can be expected in a normal population of children and adolescents.

The mean Mallampati score for adolescents was significantly greater than the mean Mallampati score for children. This is an important finding for orthodontists seeking to identify OSA risk factors, since most orthodontic patients fall into the adolescent age group. The mean adolescent Mallampati score was  $2.69 \pm 0.96$ , which renders a subpopulation more susceptible to oropharyngeal obstruction. As previously mentioned, Kumar *et al.* reported that for every point increase in the Mallampati score, the odds ratio of having OSA increased 6-fold.<sup>61</sup> Similarly, Nuckton *et al.* reported that a 1-point increase in Mallampati score is linked to an increased AHI by more than 5 events per hour.<sup>57</sup> Moreover, it is important to remember that an AHI  $> 1$  is indicative of pediatric OSA.<sup>2</sup> These results therefore point to a greater risk of OSA in adolescent patients. To date, no other study has been identified that addresses this specific difference in Mallampati scores between age groups. However, the association between the Mallampati classification and the presence and severity of OSA has been well documented.<sup>7, 57, 60-62</sup>

## Reproducibility of the Mallampati Score

The Mallampati score showed good reproducibility between all three raters, indicating that this clinical assessment is reliable. This result is similar to that of other studies which also found good inter-observer reproducibility of the Mallampati score between the following: dental hygienists and a dentist, faculty members in dentistry and neurosurgery, and anesthesiology specialists and residents.<sup>71-73</sup> The adolescents' Mallampati scores, in particular, showed very good reproducibility between the student and resident ( $\kappa = 0.734$ ,  $p < 0.001$ ) and between the student and ENT ( $\kappa = 0.768$ ,  $p < 0.001$ ). Again, since adolescents are the typical age group that receive orthodontic treatment, this finding corroborates the validity and usefulness of this clinical tool in the orthodontic setting.

Interestingly, the agreement between the student and ENT ( $\kappa = 0.728$ ,  $p < 0.001$ ) was better than the agreement between the resident and ENT ( $\kappa = 0.650$ ,  $p < 0.001$ ). A possible explanation for this difference may be that the resident was biased in her assessment. While all raters assigned Mallampati scores based on photos of patients, the resident was the only rater who also saw the patient clinically. This clinical interaction may have influenced the resident's scoring, whereas the student and ENT relied solely on the photos. Nevertheless, the overall reproducibility of the Mallampati score renders it a useful assessment in communication among multidisciplinary team members.

## Correlations of Clinical Assessments

Finally, all three assessments were compared to determine the relationships between them. It is important to understand how these assessments are related in order to determine whether they can be used in conjunction to provide a more accurate or meaningful evaluation of OSA risk factors. Comparison of the average Mallampati and Brodsky scores showed a statistically significant inverse correlation in adolescents ( $r = -0.39$ ,  $p = 0.020$ ). However, this comparison was not statistically significant in the child age group. This inverse correlation between Mallampati and Brodsky scores differs from previous studies, which found a positive correlation between AHI and Mallampati score as well as AHI and tonsillar size. Interestingly, there was no reported association between Mallampati score and tonsillar size.<sup>60, 61</sup> Similarly, Nuckton *et al.* specifically concluded that there was an independent association of the Mallampati score and the presence/severity of OSA, and that there was no significant association between the Mallampati score and tonsil size.<sup>57</sup> Closer analysis of the data collected in this study may provide a possible explanation for the inverse correlation of the Mallampati and Brodsky scores of adolescents. For example, several adolescents with high Mallampati scores had had their tonsils previously removed, whereas fewer young patients had undergone tonsillectomy. Thus, the timing of this surgery may have influenced the association between the two clinical assessments in this study.

Comparison of the average Mallampati and ESS scores and the average Brodsky and ESS scores showed no statistically significant correlations. These results are in agreement with Nuckton *et al.*'s study, which also found no significant association between the Mallampati and ESS scores.<sup>57</sup> Although the ESS has been used to evaluate

subjective sleepiness in a number of studies, the American Academy of Pediatrics maintains that questionnaires alone cannot reliably be used to evaluate OSA due to low sensitivity and specificity.<sup>3</sup> The ESS survey is an easily administered assessment that reliably indicates daytime sleepiness; however, it may not be an accurate indicator of OSA risk factors.

### Limitations

This study was cross-sectional in nature, and as such, it presents with certain limitations. The findings presented are not the true results of aging as would be the case in a longitudinal study. However, a longitudinal study was not feasible under the current study's constraints.

A total of 69 participants were evaluated, of which 33 were children and 36 were adolescents. This was deemed an adequate sample size based on initial calculations and a similar study.<sup>60</sup> The recruitment of a sufficient number of child participants was a challenge, as most orthodontic patients are older than this age group. Orthodontic treatment is often initiated during peak height velocity, which occurs at age 12 for girls and age 14 for boys.<sup>74</sup> Thus, the majority of patients visiting the orthodontic clinic were at least this age or older. The average age of the “child” population in this sample was  $11.7 \pm 1.2$  years, indicating a larger number of older children. This may have masked some of the potential differences between children and adolescents found in this study.

As mentioned previously, the analysis of Mallampati score reliability may have been influenced by possible bias of one of the investigators who was not blinded. The



student and ENT graded the Mallampati scores based solely on photographs with no other information about the patients. However, the resident (who was also the data collector) could potentially recognize the photographs, which would reveal information such as patient age, etc. Although all photographs were cropped to avoid potential bias, the possibility of bias still remains.

Finally, there was only one rater (the resident) who evaluated the Brodsky score, which calls into questions the accuracy of this assessment. Visualization of the tonsils was difficult, and an accurate photo to capture the true tonsil size was not possible. Therefore, the tonsillar classification was conducted clinically by the data collector only. Other studies have used ultrasound and MRI to capture the size of the tonsils, but these means were not available for the current study.<sup>70, 75</sup>

### Future Research

Several studies have concluded that the Mallampati score is a reliable indicator of the presence and severity of OSA.<sup>7, 14, 60-62</sup> These studies were conducted in sleep centers where polysomnography was available to corroborate this association. In this study, the Mallampati classification showed to be an easily obtainable clinical measure. Moreover, clinicians from different disciplines were able to report the same Mallampati score with good reproducibility. These factors render the Mallampati score a good clinical tool to identify risk factors for OSA.

Future research can expand on these findings by using the Mallampati score to better understand whether certain orthodontic treatment modalities help reduce OSA risk

factors. Maxillomandibular surgery in adults and RPE treatment in young patients have been shown to improve AHI scores in OSA patients.<sup>26-28, 39, 41, 42, 44</sup> It would be interesting to see how these procedures affect the Mallampati score in undiagnosed patients. A significant reduction in Mallampati scores post-operatively can provide further evidence that these treatment modalities provide benefits in terms of reducing OSA risk factors.

As orthodontics continuously evolves to focus on the comprehensive care of patients, it will become increasingly important to work alongside other medical specialists, especially pediatric ENTs. Therefore, future research in orthodontics should continue to involve medical colleagues in the development of a systematic approach to identify patient with breathing problems.

## CHAPTER 6

### CONCLUSIONS

The following conclusions can be drawn from this study:

- Adolescents have a higher Mallampati score than children.
- There are no statistically significant differences in Brodsky and ESS-CHAD scores between children and adolescents.
- The Mallampati score is a reproducible clinical assessment.
- A statistically significant inverse correlation exists between the Mallampati and Brodsky scores of adolescents. However, this relationship is not statistically significant in the child age group.
- There are no statistically significant correlations between the Mallampati and ESS-CHAD scores or the Brodsky and ESS-CHAD scores.

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## APPENDIX

### INSTITUTIONAL REVIEW BOARD APPROVAL



Office of the Institutional Review Board for Human Use

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701 20th Street South  
Birmingham, AL 35294-0104  
205.934.3789 | Fax 205.934.1301 | irb@uab.edu

#### APPROVAL LETTER

**TO:** Souccar, Nada M

**FROM:** University of Alabama at Birmingham Institutional Review Board  
Federalwide Assurance # FWA00005960  
IORG Registration # IRB00000196 (IRB 01)  
IORG Registration # IRB00000726 (IRB 02)

**DATE:** 20-Jul-2018

**RE:** IRB-300001742  
Evaluation and Comparison of Mallampati Scores in Child and Adolescent Orthodontic Patients

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The IRB reviewed and approved the Initial Application submitted on 19-Jul-2018 for the above referenced project. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services.

**Type of Review:** Expedited  
**Expedited Categories:** 6, 7  
**Determination:** Approved  
**Approval Date:** 20-Jul-2018  
**Approval Period:** One Year  
**Expiration Date:** 19-Jul-2019

The following populations are approved for inclusion in this project:

- Children – CRL 1

**Documents Included in Review:**

- consent.clean.180718
- children.180718
- assent.clean.180718
- hsp.clean.180719
- surveyquest.180521