Effects of Orthognathic Surgery on Quality of Life Compared with Non-Surgical Controls in an American Population:
A Cross-Sectional Study

THESIS

Presented in Partial Fulfillment of the Requirements for the Degree Master of Science in the Graduate School of The Ohio State University

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ABSTRACT

Objectives: (1) To determine the psychosocial effects of a facial skeletal mal-relationship with its subsequent surgical correction in a group of patients treated using surgical orthodontics compared to a matched group of non-treated controls. (2) To conduct a preliminary assessment of the correlation between severity of malocclusion and patient’s quality of life (QoL) as measured by questionnaires evaluating depression, anxiety, satisfaction with life and oral function.

Methods: This study was approved by The Ohio State University IRB. Subjects were patients presenting with facial skeletal mal-relationships whose proposed treatment plans included orthognathic surgery, or who were currently in treatment, or who had previously completed surgical correction of a facial skeletal mal-relationship. This study utilized valid and reliable questionnaires: OQLQ, BDI (CDI), SWLS, and STAI-Y (STAI-C), administered at three different stages of treatment (Time 1=initial pre-treatment, Time 2= prior to oral surgery, and Time 3 = at completion of treatment). Matched controls completed the same questionnaires. Treatment subjects’ severity of malocclusion was assessed by recording ANB angle (º), overjet(mm) and amount of openbite (mm).

Results: A total 283 subjects were recruited to participate in this study. There were no significant differences between treatment and control groups in age, sex, education level or employment status at any of the three stages of treatment indicating that the controls were well matched. The randomization test was used to compare values for all outcome
variables between groups at the three stages of treatment. For the pre-treatment time period, T₁, there were significant differences between patients and controls in domains 1 (p=0.0093), 2 (p=0.0000), and 3 (p=0.0000) of the OQLQ (Social Aspects, Facial Esthetics and Oral Function respectively) as well as total OQLQ (p=0.0000). For the pre-surgery time period, T₂, there were significant differences between patients and controls in domains 2 (p=0.0136) and 3 (p=0.0001) of the OQLQ (Facial Esthetics and Oral Function) as well as total OQLQ (p=0.0291). Lastly, for the post-treatment time period, T₃, there was a significant difference between patients and controls only in domain 3 (p=0.0324) of the OQLQ (Oral Function). Although small, the Spearman Correlation Coefficient indicated significant inverse relationships between severity of ANB, \( \rho=-0.19 \) (P=0.0230), and overjet, \( \rho=-0.17924 \) (P=0.0322), with the Oral Function domain of the OQLQ. Another significant inverse correlation was between severity of ANB, \( \rho=-0.22936 \) (P=0.0407), with the STAI-Y.

**Conclusions:** The psychosocial profile of individuals with or who initially possessed facial skeletal mal-relationships does not differ from the general population in depression, anxiety, and overall satisfaction with life. However, these individuals do report a reduced quality of life based upon condition specific measures in social aspects, facial esthetics and oral function. The severity of the mal-relationship does not seem to play a major role in patient’s quality of life, depression, anxiety, or overall satisfaction with life.
Dedicated to my loving and supportive family and friends.
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CHAPTER 1

INTRODUCTION

Defining dentofacial deformity

A facial skeletal mal-relationship exists when an individual exhibits deviations from normal facial proportions and dental relationships due to an underlying skeletal discrepancy. According to Proffit et al, these deviations can be so severe that they are thought to be handicapping and then referred to as a dentofacial deformity.\(^1\) Jaw function, speech, and social interactions are often compromised within this population of patients. Data from the NHANES – III study reveals that approximately 2.5% of the United States population has severe malocclusion and facial disproportions constituting a dentofacial deformity\(^2\) and this represents an estimated 5% of patients seeking orthodontic treatment.\(^3\)

Treatment for these individuals requires a combined orthodontic and orthognathic surgical approach due to the severity of the mal-relationship where orthodontics and/or growth modification alone cannot provide an ideal result. Although functional impairment such as difficulty in chewing food, discomfort, and pain from temporomandibular joint dysfunction are important reasons for treatment, it is generally accepted that the majority of these patients are seeking treatment because of concerns
about their dentofacial esthetics and are motivated by self-image and social well-being.\textsuperscript{4,6} It has been shown that the more the patient perceives his or her problem as outside of normal, the more likely they will seek treatment.\textsuperscript{7,8}

Facial esthetics can strongly impact a person’s quality of life and therefore have a psychological impact on the individual that include making them feel inadequate or discontented because of their appearance. Cunningham et al reported that there are differences in the psychological profile of an orthognathic patient compared to the general population, specifically: higher levels of anxiety, a greater number of individuals in their social support network, a lower body-, and facial image and borderline lower self-esteem.\textsuperscript{9} Other investigators, however, have reported no differences in regards to psychosocial parameters\textsuperscript{10,11} and therefore do not recommend psychological screening of patients requiring orthognathic surgery.\textsuperscript{11} It has been suggested that most dentofacial patients have coping skills that keep them within the normal range on psychological testing, and this may conceal the true extent of their psychosocial distress.\textsuperscript{1}

The degree of psychological discomfort may be correlated with the severity of the facial skeletal mal-relationship. Kovalenko et al reported that the prevalence of psychological problems in patients with light and moderate facial deformity remained more or less the same when compared to controls but increased significantly in patients with a severe deformity.\textsuperscript{12} They found that patients with a severe facial mal-relationship had higher prevalence of emotional instability, introversion, anxiety, and unsociability.\textsuperscript{12}

A longitudinal study by Kiyak et al confirmed that the majority of patients with facial skeletal mal-relationships benefit from a psychological standpoint following
orthognathic treatment, demonstrating improved facial and dental appearance and an associated increase in self-confidence.\textsuperscript{13,14} The patients reported high levels of satisfaction following surgery and that they perceived considerable improvements in their facial appearance and body image, viewing themselves more positively after surgery. Some patients did report depression and dissatisfaction with the surgical outcome. However, most of this was attributable to prolonged time in orthodontics following surgery.\textsuperscript{13} Flanary et al also found high levels of post-operative satisfaction and a healthy psychological adjustment and concluded that orthognathic treatment appears to have a positive impact on quality of life.\textsuperscript{15} Positive effects were seen for self-concept including self-esteem, self-satisfaction, self-identity, physical self, social self and total self-conflict.\textsuperscript{15} It is possible that a portion of this satisfaction could result from the time, discomfort, and expense of treatment creating cognitive dissonance with an unsatisfactory outcome.

\textit{Quality of Life}

There has been a paradigm shift in the focus of health care which now includes health-related quality of life and evaluation of treatment based on its impact on the patient’s feelings and perceptions of treatment. According to the World Health Organization, quality of life can be defined as “an individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns.”\textsuperscript{16} Becker simplifies this
definition of quality of life as “a sense of well-being that stems from satisfaction or dissatisfaction with areas of life that are important to an individual.” 17

More specifically, health related quality of life (HRQoL) refers to the effect that a disease, condition, or treatment has on a patient’s ability to carry out the physical and social tasks of daily life. 18 HRQoL is used as an outcome measure in clinical trials and in 2000 Cunningham et al developed a condition-specific quality of life measure to be used in studies investigating the outcome of orthognathic treatment. 19 The instrument is known as the Orthognathic Quality of Life Questionnaire (OQLQ) and consists of 22 statements relating to the impact that a facial skeletal mal-relationship has upon a patient’s quality of life. These statements can be subdivided into four domains: social aspects of the deformity, facial esthetics, oral function, and awareness of facial deformities. Responses to each statement range from 0-4 points making the minimum possible score of 0 and a maximum possible score of 88, with a higher score indicating a reduced quality of life. Upon development, the OQLQ was found first to be reliable19, and then later tested for validity and responsiveness.20

In 1985, Diener, Emmons, Larsen, and Griffin developed and validated a scale to measure global life satisfaction as a cognitive-judgmental process known as the Satisfaction with Life Scale (SWLS).21 The SWLS consists of 5 items with a Likert-type scale ranging from 1-7 and a higher score indicating higher life satisfaction. Pavot and Diener reported a score of 4 as ‘neutral’, >6.2 indicating ‘extremely satisfied’ and <2 as ‘extremely dissatisfied’. 22 For any individual, a number of personality variables and situational or life circumstances can influence his or her judgment on life satisfaction,
therefore the SWLS can be used to assess change such as assessing the impact of a clinical intervention.\textsuperscript{22}

Depression and anxiety are other components involved with subjective well being affecting one’s quality of life. The Beck Depression Inventory (BDI) is a widely used instrument to assess severity of depression with a 21-question multiple choice self-report inventory.\textsuperscript{23} Similarly, the Children’s Depression Inventory (CDI) is a 27-item assessment that rates the severity of symptoms related to depression in children and adolescents.\textsuperscript{24} These instruments were found to be reliable with high internal consistency\textsuperscript{25,26} and high validity was also established.\textsuperscript{25,27} Both inventories are in their second edition (BDI-II & CDI-2)\textsuperscript{28,29} and a higher score indicates more severe depressive symptoms for the individual.

Anxiety can be classified as transitory, situational anxiety known as state anxiety, or as trait anxiety which is relatively stable feelings of worry or distress that one experiences on a day to day basis. In 1973, Spielberger et al developed the State-Trait Anxiety Inventory (STAI-Y) as well as an inventory for children (STAI-C) to investigate how strong a person’s feelings of anxiety are.\textsuperscript{30,31} These questionnaires were found to be valid and reliable\textsuperscript{32} with a higher score indicating a greater amount of anxiety.

\textit{Patient education and counseling}

Flood et al found that patient expectations can affect treatment outcomes through five fundamental mechanisms.\textsuperscript{33} They can (1) trigger a physiologic response, (2) motivate the patient to achieve a better outcome, (3) change the patient’s understanding
of the condition, (4) act in concert with anxiety to heighten or reduce symptoms, and (5)
condition the patient psychologically to observe certain types of symptoms and ignore
others.\textsuperscript{33} Therefore managing realistic patient expectations is critical for successful
outcomes, and it is important to build rapport with patients and communicate with them
throughout treatment so that they understand what is happening and why.

Quality of life issues are strong underlying motivators in the decision for a patient
to accept treatment that includes orthognathic surgery. Both the clinician and the patient
require a thorough understanding of the effects of treatment on HRQoL in order to
anticipate the changes that occur and to allow this type of treatment to be compared with
other procedures.\textsuperscript{34} This information allows clinicians to be able to give clear and
accurate information to patients as to what to anticipate the impact of surgical treatment
will have on their quality of life.

A systematic review conducted by Hunt et al identified an urgent need for well-
controlled longitudinal studies to be conducted to confirm psychosocial benefits
following orthognathic surgery.\textsuperscript{35} From the articles in the review, the authors noted both
a lack of high-level evidence as well as a lack of consistency in the methods used to
measure psychosocial status which resulted in an inability to show a clear and precise
psychosocial benefit.\textsuperscript{35}
OBJECTIVES

1. To determine the psychosocial effects of a facial skeletal mal-relationship and its subsequent surgical correction in a group of patients who are treated using surgical orthodontics compared with a matched group of non-treated controls.

2. To conduct a preliminary assessment of the correlation between the severity of a facial skeletal mal-relationship and patient’s quality of life as measured by questionnaires evaluating depression, anxiety, satisfaction with life and oral function.

HYPOTHESES

H₀1: There is no difference in the quality of life, depression, anxiety, or overall satisfaction with life of patients who possess a facial skeletal mal-relationship and non-surgical controls before initiation of surgical orthodontics.

H₀2: There is no difference in the quality of life, depression, anxiety, or overall satisfaction with life of patients who possess a facial skeletal mal-relationship and non-surgical controls just prior to correction by means of orthognathic surgery.

H₀3: There is no difference in the quality of life, depression, anxiety, or overall satisfaction with life of patients who initially possessed a facial skeletal mal-
relationship and non-surgical controls after removal of all appliances after correction of the mal-relationship by means of surgical orthodontics.

H₀₄: There is no relationship between the severity of a facial skeletal mal-relationship and quality of life, depression, anxiety or overall satisfaction with life of patients who possess a facial skeletal mal-relationship before, during or after correction.
CHAPTER 2

MATERIALS & METHODS

This study was approved by The Ohio State University Institutional Review Board (protocol #2011H0195). This prospective, observational study was a continuation from a previous study and the way in which data was collected was mixed, cross-sectional and longitudinal in nature. The results reported are strictly from the cross-sectional arm of the study.

Subjects were patients presenting to The Ohio State University College of Dentistry graduate orthodontic clinic and the College’s dental faculty practice whose proposed treatment plan included an orthognathic surgery option to correct a facial skeletal mal-relationship, or who were currently in treatment, or who had previously completed surgical correction of a facial skeletal mal-relationship. In order to reduce selection bias, all treatment subjects who were eligible to participate were consecutively recruited into the study from August of 2011 until November of 2015. Criteria for inclusion were: treatment subjects had to be at least 12 years old, be accompanied by a parent or guardian if under 18, not have any developmental disabilities or urgent medical conditions, be able to communicate in English, and been offered or selected a combined orthodontic and surgical treatment plan that was not a result of cleft lip and/or palate, trauma, or a developmental syndrome. A convenience sample of non-surgical controls
matched to age and sex of the treatment subjects was recruited from the Ohio State University College of Dentistry Hygiene Department, Pediatric Department and the Ohio State University main campus. This group of individuals was chosen to reflect the general population, and exclusion criteria included the presence of orthodontic fixed appliances or a marked dento-facial abnormality.

The questionnaires utilized in this study were the:

- Orthognathic Quality of Life Questionnaire (OQLQ)\textsuperscript{19,20}
- Satisfaction with Life Scale (SWLS)\textsuperscript{21}
- Beck Depression Inventory II (BDI-II)\textsuperscript{28}
  - Children’s Depression Inventory – 2 (CDI-2)\textsuperscript{29} for subjects under 18
- State Trait Anxiety Inventory (STAI-Y)\textsuperscript{30}
  - State Trait Anxiety Inventory for Children (STAI-C)\textsuperscript{31} for subjects under 18

These questionnaires were administered at three different stages of treatment:

- **T\textsubscript{1}: Pre-treatment** – prior to initiation of orthodontic appliances. This stage of treatment was chosen in order to compare quality of life parameters of untreated patients who possess a facial skeletal mal-relationship with controls representing the general population.

- **T\textsubscript{2}: Pre-surgery** – at completion of pre-surgical orthodontics, just prior to orthognathic surgery. This stage of treatment was included in order to evaluate if making the malocclusion worse by removing dental compensations affected quality of life.
• **T₃: Post-treatment** – 6 months to 2 years after orthodontic appliances have been removed. This stage of treatment was chosen to evaluate if correction by surgical orthodontics makes quality of life parameters of treatment subjects comparable with the general population. The time interval was selected to allow enough time to pass after removal of appliances so that responses weren’t a reflection of elation from being finished with treatment, and short enough so that other life events had not intervened and become the primary determinants of psychological state.

Questionnaires were either administered at the time of appointment or mailed to subjects who would return the questionnaires by mail or bring them to the following appointment. Although most of the data was collected at only one point in time, the questionnaires were de-identified and coded so that data could be collected for the same subject over the entire process of treatment in order for the study to be continued for future longitudinal analysis. Demographic information including age, sex, education level and employment status was recorded for all participants. To evaluate severity of the facial skeletal mal-relationship, treatment subjects’ digitized lateral cephalograms were assessed using the ‘Alabama’ analysis (Dolphin Imaging 11.7, Patterson Dental, St. Paul, MN) and the following measurements were noted: ANB angle in degrees along with its standard deviation, overjet in millimeters, and presence and amount of openbite in millimeters. Subjects and controls were given a $10 gift certificate each time a full set of questionnaires were administers as compensation for the time required to respond.
Sample size determination was based upon the dependent variable instrument with the highest variability, the OQLQ. With an alpha risk of 0.05, a sample size of 35 subjects per time period was required to demonstrate a difference of ±15 units with a power of 0.86. Descriptive statistics and inferential analyses were used to compare the independent variables (group and treatment stage) with the dependent variables (questionnaires). Tests included the Independent t-test, Chi-Square test, Wilcoxon test and Randomization test (SAS Institute Inc., Cary, NC). Correlation analyses were used to evaluate if a relationship exists between the severity of the facial skeletal mal-relationship and patient’s quality of life. Because the data were not normally distributed, the Spearman Correlation Coefficient was used. Statistical significance for all tests was set at p<0.05. Calculations were done using the Statistical Analysis System version 9.3 (SAS Institute Inc., Cary, NC).
CHAPTER 3

MANUSCRIPT

Effects of Orthognathic Surgery on Quality of Life compared to Non-surgical controls in an American population: A cross-sectional Study

ABSTRACT

Objectives: (1) To determine the psychosocial effects of a facial skeletal mal-relationship with its subsequent surgical correction in a group of patients treated using surgical orthodontics compared to a matched group of non-treated controls. (2) To conduct a preliminary assessment of the correlation between severity of malocclusion and patient’s quality of life (QoL) as measured by questionnaires evaluating depression, anxiety, satisfaction with life and oral function.

Methods: This study was approved by The Ohio State University IRB. Subjects were patients presenting with facial skeletal mal-relationships whose proposed treatment plans included orthognathic surgery, or who were currently in treatment, or who had previously completed surgical correction of a facial skeletal mal-relationship. This study utilized valid and reliable questionnaires: OQLQ, BDI (CDI), SWLS, and STAI-Y (STAI-C),
administered at three different stages of treatment (Time 1=initial pre-treatment, Time 2= prior to oral surgery, and Time 3 = at completion of treatment). Matched controls completed the same questionnaires. Treatment subjects’ severity of malocclusion was assessed by recording ANB angle (º), overjet(mm) and amount of openbite (mm).

**Results:** A total 283 subjects were recruited to participate in this study. There were no significant differences between treatment and control groups in age, sex, education level or employment status at any of the three stages of treatment indicating that the controls were well matched. The randomization test was used to compare values for all outcome variables between groups at the three stages of treatment. For the pre-treatment time period, T₁, there were significant differences between patients and controls in domains 1 (p=0.0093), 2 (p=0.0000), and 3 (p=0.0000) of the OQLQ (Social Aspects, Facial Esthetics and Oral Function respectively) as well as total OQLQ (p=0.0000). For the pre-surgery time period, T₂, there were significant differences between patients and controls in domains 2 (p=0.0136) and 3 (p=0.0001) of the OQLQ (Facial Esthetics and Oral Function) as well as total OQLQ (p=0.0291). Lastly, for the post-treatment time period, T₃, there was a significant difference between patients and controls only in domain 3 (p=0.0324) of the OQLQ (Oral Function). Although small, the Spearman Correlation Coefficient indicated significant inverse relationships between severity of ANB, ρ=-0.19 (P=0.0230), and overjet, ρ=-0.17924 (P=0.0322), with the Oral Function domain of the OQLQ. Another significant inverse correlation was between severity of ANB, ρ=-0.22936 (P=0.0407), with the STAI-Y.
**Conclusions:** The psychosocial profile of individuals with or who initially possessed facial skeletal mal-relationships does not differ from the general population in depression, anxiety, and overall satisfaction with life. However, these individuals do report a reduced quality of life based upon condition specific measures in social aspects, facial esthetics and oral function. The severity of the mal-relationship does not seem to play a major role in patient’s quality of life, depression, anxiety, or overall satisfaction with life.

**Key words:** orthognathic surgery, quality of life

**INTRODUCTION**

A facial skeletal mal-relationship exists when an individual exhibits deviations from normal facial proportions and dental relationships due to an underlying skeletal discrepancy. According to Proffit et al, these deviations can be so severe that they are thought to be handicapping and then referred to as a dentofacial deformity.¹ Jaw function, speech, and social interactions are often compromised within this population of patients.

Treatment for these individuals requires a combined orthodontic and orthognathic surgical approach due to the severity of the mal-relationship where orthodontics and/or growth modification alone cannot provide an ideal result. Although functional impairment such as difficulty in chewing food, discomfort, and pain from temporomandibular joint dysfunction are important reasons for treatment, it is generally accepted that the majority of these patients are seeking treatment because of concerns about their dentofacial esthetics and are motivated by self-image and social well-being.²⁻⁴
It has been shown that the more the patient perceives his or her problem as outside of normal, the more likely they will seek treatment.\textsuperscript{5,6}

Facial esthetics can strongly impact a person’s quality of life and therefore have a psychological impact on the individual that include making them feel inadequate or discontented because of their appearance. Cunningham et al reported that there are differences in the psychological profile of an orthognathic patient compared to the general population, specifically: higher levels of anxiety, a greater number of individuals in their social support network, a lower body-, and facial image, and borderline lower self-esteem.\textsuperscript{7} Other investigators, however, have reported no differences in regards to psychosocial parameters\textsuperscript{8,9} and therefore do not recommend psychological screening of patients requiring orthognathic surgery.\textsuperscript{9} It has been suggested that most dentofacial patients have coping skills that keep them within the normal range on psychological testing, and this may conceal the true extent of their psychosocial distress.\textsuperscript{1}

The degree of psychological discomfort may be correlated with the severity of the facial skeletal mal-relationship. Kovalenko et al reported that the prevalence of psychological problems in patients with light and moderate facial deformity remained more or less the same when compared to controls but increased significantly in patients with a severe deformity.\textsuperscript{10} They found that patients with a severe facial mal-relationship had higher prevalence of emotional instability, introversion, anxiety, and unsociability.\textsuperscript{10}

A longitudinal study by Kiyak et al confirmed that the majority of patients with facial skeletal mal-relationships benefit from a psychological standpoint following orthognathic treatment, demonstrating improved facial and dental appearance and an
associated increase in self-confidence.\textsuperscript{11,12} The patients reported high levels of satisfaction following surgery and that they perceived considerable improvements in their facial appearance and body image, viewing themselves more positively after surgery. Some patients did report depression and dissatisfaction with the surgical outcome. However, most of this was attributable to prolonged time in orthodontics following surgery.\textsuperscript{11} Flanary et al also found high levels of post-operative satisfaction and a healthy psychological adjustment and concluded that orthognathic treatment appears to have a positive impact on quality of life.\textsuperscript{13} Positive effects were seen for self-concept including self-esteem, self-satisfaction, self-identity, physical self, social self and total self-conflict.\textsuperscript{13} It is possible that a portion of this satisfaction could result from the time, discomfort, and expense of treatment creating cognitive dissonance with an unsatisfactory outcome.

There has been a paradigm shift in the focus of health care which now includes health-related quality of life and evaluation of treatment based on its impact on the patient’s feelings and perceptions of treatment. According to the World Health Organization, quality of life can be defined as “an individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns.”\textsuperscript{14} More specifically, health related quality of life (HRQoL) refers to the effect that a disease, condition, or treatment has on a patient’s ability to carry out the physical and social tasks of daily life\textsuperscript{15} and has been used as an outcome measure in clinical trials.
Flood et al found that patient expectations can affect treatment outcomes\textsuperscript{16}, therefore managing realistic patient expectations is critical for successful outcomes. It is important to build rapport with patients and communicate with them throughout treatment so that they understand what is happening and why. Quality of life issues are strong underlying motivators in the decision for a patient to accept treatment that includes orthognathic surgery. Both the clinician and the patient require a thorough understanding of the effects of treatment on HRQoL in order to anticipate the changes that occur and to allow this type of treatment to be compared with other procedures.\textsuperscript{17} This information allows clinicians to be able to give clear and accurate information to patients as to what to anticipate the impact of surgical treatment will have on their quality of life.

A systematic review conducted by Hunt et al identified an urgent need for well-controlled longitudinal studies to be conducted to confirm psychosocial benefits following orthognathic surgery.\textsuperscript{18} From the articles in the review, the authors noted both a lack of high-level evidence as well as a lack of consistency in the methods used to measure psychosocial status which resulted in an inability to show a clear and precise psychosocial benefit.\textsuperscript{18}

The aims of this study were (1) to determine the psychosocial effects of a facial skeletal mal-relationship and its subsequent surgical correction in a group of patients who are treated using surgical orthodontics compared with a matched group of non-treated controls and (2) to conduct a preliminary assessment of the correlation between the
severity of the facial skeletal mal-relationship and patient’s quality of life as measured by questionnaires evaluating depression, anxiety, satisfaction with life and oral function.

**MATERIALS AND METHODS**

This study was approved by The Ohio State University Institutional Review Board (protocol #20111H0195). This prospective, observational study was a continuation from a previous study and the way in which data was collected was mixed, cross-sectional and longitudinal in nature. The results reported here are strictly from the cross-sectional arm of the study.

Subjects were patients presenting to The Ohio State University College of Dentistry graduate orthodontic clinic and the College’s dental faculty practice whose proposed treatment plan included orthognathic surgery to correct a facial skeletal mal-relationship, or who were currently in treatment, or who had previously completed surgical correction of a facial skeletal mal-relationship. In order to reduce selection bias, all treatment subjects who were eligible to participate were consecutively recruited into the study from August of 2011 until November of 2015. Criteria for inclusion were: treatment subjects had to be at least 12 years old, be accompanied by a parent or guardian if under 18, not have any developmental disabilities or urgent medical conditions, be able to communicate in English, and been offered or selected a combined orthodontic and surgical treatment plan that was not a result of cleft lip and/or palate, trauma, or a developmental syndrome. A convenience sample of non-surgical controls matched to age and sex of the treatment subjects was recruited from the Ohio State University College of
Dentistry Hygiene Department, Pediatric Department and the Ohio State University main campus. This group of individuals was chosen to reflect the general population, and exclusion criteria included the presence of orthodontic fixed appliances or a marked dento-facial abnormality.

The questionnaires utilized in this study were the:

1. **Orthognathic Quality of Life Questionnaire (OQLQ)**: a condition-specific quality of life measure developed in 2000 by Cunningham et al. to be used in studies investigating the outcome of orthognathic treatment. The OQLQ consists of 22 statements relating to the impact that a facial skeletal mal-relationship has upon a patient’s quality of life. These statements can be subdivided into four domains: social aspects of the deformity, facial esthetics, oral function, and awareness of facial deformities. Responses range from 0-4 points making the minimum possible score of 0 and a maximum of 88, with a higher score indicating a reduced quality of life.

2. **Satisfaction with Life Scale (SWLS)**: a scale to measure global life satisfaction as a cognitive-judgmental process developed in 1985 by Diener et al. The SWLS consists of 5 items with a Likert-type scale ranging from 1-7 making the minimum possible score of 5 and a maximum of 35, with a higher score indicating higher life satisfaction.

3. **Beck Depression Inventory II (BDI-II)**: a widely used instrument to assess severity of depression first developed by Beck et al in 1961. The BDI consists of
21 items scored from 0-3 with a minimum possible score of 0 and a maximum of 63.

a. **Children’s Depression Inventory – 2 (CDI-2)**: a 27-item assessment that rates the severity of symptoms related to depression in children and adolescents. Scores range from 0-2 with a minimum possible score of 0 and maximum of 56.

With both inventories, a higher score indicates more severe depressive symptoms.

4. **State Trait Anxiety Inventory (STAI-Y)**: an inventory developed in 1973 by Spielberger et al to investigate how strong a person’s feelings of anxiety are. The STAI-Y consists of 40 statements scored from 1-4 with a minimum possible score of 40 and maximum of 160.

   a. **State Trait Anxiety Inventory for Children (STAI-C)** for subjects under 18. The STAI-C consists of 40 statements scored from 1-3 with a minimum possible score of 40 and maximum of 120.

With both inventories, a higher score indicates a greater amount of anxiety.

All questionnaires had previously been shown to be valid and reliable.19-21,28-30 These questionnaires were administered at three different stages of treatment:

- **T1: Pre-treatment** – prior to initiation of orthodontic appliances. This stage of treatment was chosen in order to compare quality of life parameters of untreated patients who possess a facial skeletal mal-relationship with controls representing the general population.
• **T₂:** Pre-surgery – at completion of pre-surgical orthodontics, just prior to orthognathic surgery. This stage of treatment was included in order to evaluate if making the malocclusion worse by removing dental compensations affected quality of life.

• **T₃:** Post-treatment – 6 months to 2 years after orthodontic appliances have been removed. This stage of treatment was chosen to evaluate if correction by surgical orthodontics makes quality of life parameters of treatment subjects comparable to the general population. The time interval was selected to allow enough time to pass after removal of appliances so that responses weren’t a reflection of elation from being finished with treatment, and short enough so that other life events had not intervened and become the primary determinants of psychological state.

Questionnaires were either administered at the time of appointment or mailed to subjects who would return the questionnaires by mail or bring them to the following appointment. Although most of the data was collected at only one point in time, the questionnaires were de-identified and coded so that data could be collected for the same subject over the entire process of treatment in order for the study to be continued for future longitudinal analysis. Demographic information including age, sex, education level and employment status was recorded for all participants. To evaluate severity of the facial skeletal mal-relationship, treatment subjects’ digitized lateral cephalograms were assessed using the ‘Alabama’ analysis (Dolphin Imaging 11.7, Patterson Dental, St. Paul, MN) and the following measurements were noted: ANB angle in degrees along with its standard deviation, overjet in millimeters, and presence and amount of openbite in
millimeters. Subjects and controls were given a $10 gift certificate each time a full set of questionnaires were administers as compensation for the time required to respond.

Sample size determination was based upon the dependent variable instrument with the highest variability, the OQLQ. With an alpha risk of 0.05, a sample size of 35 subjects per time period was required to demonstrate a difference of \( \pm 15 \) units with a power of 0.86. Descriptive statistics and inferential analyses were used to compare the independent variables (group and treatment stage) with the dependent variables (questionnaires). Tests included the Independent t-test, Chi-Square test, Wilcoxon test and Randomization test (SAS Institute Inc., Cary, NC). Correlation analyses were used to evaluate if a relationship exists between the severity of the facial skeletal mal-relationship and patient’s quality of life. Because the data were not normally distributed, the Spearman Correlation Coefficient was used. Statistical significance for all tests was set at \( p<0.05 \). Calculations were done using the Statistical Analysis System version 9.3 (SAS Institute Inc., Cary, NC).

**RESULTS**

A total of 283 subjects were recruited to participate in this study. Demographic information of the groups is presented in Table 1 along with statistical analysis for comparison. There were no significant differences between the treatment subjects and control subjects in age, sex, education level or employment status at all three stages of treatment indicating that the groups were well matched.
Table 1. Demographic Characteristics of Subjects

<table>
<thead>
<tr>
<th>Tx</th>
<th>Stage</th>
<th>Age Mean (+/- SD)</th>
<th>Indpndt T-Test</th>
<th>Sex</th>
<th>Chi-Square Test</th>
<th>Education Level</th>
<th>Wilcoxon Test</th>
<th>Employment Status</th>
<th>Chi-Square Test</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Tx C</td>
<td>Tx C</td>
<td>Tx C</td>
<td>Tx C</td>
<td>Tx C</td>
</tr>
<tr>
<td>Pre-Tx (T_1)</td>
<td>19.5 (6.7)</td>
<td>19.7 (7.0)</td>
<td>p=0.8537</td>
<td>41 F (51.9%)</td>
<td>38 M (48.1%)</td>
<td>41 F (54.7%)</td>
<td>34 M (45.3%)</td>
<td>46 ED 1 (58.2%)</td>
<td>47 ED 1 (62.7%)</td>
</tr>
<tr>
<td>Pre-Sx (T_2)</td>
<td>20.8 (5.1)</td>
<td>20.9 (5.2)</td>
<td>p=0.9192</td>
<td>12 F (54.5%)</td>
<td>10 M (45.5%)</td>
<td>9 F (47.4%)</td>
<td>10 M (52.6%)</td>
<td>7 ED 1 (31.8%)</td>
<td>5 ED 1 (26.3%)</td>
</tr>
<tr>
<td>Post-Tx (T_3)</td>
<td>25.2 (10.4)</td>
<td>25.2 (10.6)</td>
<td>p=0.9921</td>
<td>27 F (60.0%)</td>
<td>18 M (40.0%)</td>
<td>27 F (62.8%)</td>
<td>16 M (37.2%)</td>
<td>10 ED 1 (22.2%)</td>
<td>5 ED 1 (11.6%)</td>
</tr>
</tbody>
</table>

Tx = Treatment Subjects
C = Control Subjects
Summarized in Table 2 are the mean, median, and range of values for all outcome variables. The randomization test was used to compare treatment subjects versus controls at all three stages of treatment. Figure 1 illustrates significant differences noted between the treatment and control groups within the condition specific OQLQ instrument. At the pre-treatment time period, T1, there were significant differences between patients and controls in domains 1, 2, and 3, Social Aspects, Facial Esthetics and Oral Function respectively, of the OQLQ as well as total OQLQ. At the pre-surgery time period, T2, there were significant differences between patients and controls in domains 2 and 3, Facial Esthetics and Oral Function, as well as total OQLQ. Lastly, for the post-treatment time period, T3, there was a significant difference between patients and controls only in domain 3, Oral Function, of the OQLQ.

Assessment of the severity of treatment subjects’ facial skeletal mal-relationship as measured by ANB (°), overjet (mm), and amount of openbite (mm) at all three stages of treatment is summarized in Table 3. The Spearman Correlation Coefficient (Table 4) was used to examine if a relationship existed between severity and quality of life. Results revealed significant inverse correlations between severity of ANB, $\rho = -0.19$ (P=0.0230), and overjet, $\rho = -0.17924$ (P=0.0322), with the Oral Function domain of the OQLQ. Another significant inverse correlation was seen between severity of ANB, $\rho = -0.22936$ (P=0.0407), with the STAI-Y. P-values associated with these coefficients were not adjusted for multiple comparisons.
Table 2. Outcome Variables: Treatment Subjects vs Controls

<table>
<thead>
<tr>
<th>Tx Stage</th>
<th>Variable</th>
<th>Sample Size</th>
<th>Mean (+/- SD)</th>
<th>Median</th>
<th>Min-Max</th>
<th>R Test</th>
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<td></td>
<td></td>
<td>Tx</td>
<td>C</td>
<td>Tx</td>
<td>C</td>
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<tr>
<td>Pre-Tx (T1)</td>
<td>OQLQ (total)</td>
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<td>38.2(19.6)</td>
<td>25.7(16.8)</td>
<td>36</td>
<td>26</td>
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<tr>
<td></td>
<td>OQLQ 1</td>
<td>79</td>
<td>12.3(8.3)</td>
<td>9.7(7.1)</td>
<td>11</td>
<td>8</td>
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<tr>
<td></td>
<td>OQLQ 2</td>
<td>79</td>
<td>10.8(5.8)</td>
<td>8.6(4.8)</td>
<td>11</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>OQLQ 3</td>
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<td>8.9(5.4)</td>
<td>4.9(3.9)</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>OQLQ 4</td>
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<td>6.2(4.3)</td>
<td>5.1(4.1)</td>
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<td>4</td>
</tr>
<tr>
<td></td>
<td>SWLS</td>
<td>79</td>
<td>25.6(6.6)</td>
<td>26.7(6.2)</td>
<td>26</td>
<td>28</td>
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<td>30</td>
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<td>5.4(7.0)</td>
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<tr>
<td></td>
<td>CDI (total)</td>
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<td>8.0(6.6)</td>
<td>8.6(7.8)</td>
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<td>3</td>
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<td></td>
<td>CDI-F</td>
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<td>70.2(21.4)</td>
<td>68.0(21.0)</td>
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<td>STAI-C</td>
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<td>62.1(11.4)</td>
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<td>59</td>
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<td>26.7(15.9)</td>
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<td>26</td>
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<td>9.8(5.9)</td>
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<tr>
<td></td>
<td>OQLQ 2</td>
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<td>7.2(4.8)</td>
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<td>OQLQ 3</td>
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</tr>
<tr>
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<td>OQLQ 4</td>
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<td>6.5</td>
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<tr>
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<td>SWLS</td>
<td>22</td>
<td>25.1(5.7)</td>
<td>22.6(4.3)</td>
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<td>23</td>
</tr>
<tr>
<td></td>
<td>BDI</td>
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<td>5.0(6.0)</td>
<td>8.2(9.3)</td>
<td>2</td>
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</tr>
<tr>
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<td>CDI (total)</td>
<td>7</td>
<td>9.3(7.4)</td>
<td>10.3(7.0)</td>
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<td>10.5</td>
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<td>CDI-F</td>
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<td>5.0(4.4)</td>
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<td>5.5</td>
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<tr>
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<td>STAI-Y</td>
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<td>73.2(17.7)</td>
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<td>69</td>
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<td>62.2(10.9)</td>
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<td>60</td>
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<td>OQLQ (total)</td>
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<td>21.2(16.3)</td>
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<td>16</td>
</tr>
<tr>
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<td>OQLQ 1</td>
<td>45</td>
<td>6.5(6.6)</td>
<td>6.4(6.6)</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>OQLQ 2</td>
<td>45</td>
<td>5.5(4.7)</td>
<td>6.1(4.3)</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>OQLQ 3</td>
<td>45</td>
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<td>2.9(3.3)</td>
<td>4</td>
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</tr>
<tr>
<td></td>
<td>OQLQ 4</td>
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<td>4.5(4.2)</td>
<td>4.8(4.6)</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>SWLS</td>
<td>45</td>
<td>27.3(5.4)</td>
<td>25.7(6.1)</td>
<td>28</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>BDI</td>
<td>38</td>
<td>4.5(5.9)</td>
<td>6.9(8.5)</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>CDI (total)</td>
<td>7</td>
<td>6.7(3.8)</td>
<td>11.4(8.4)</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>CDI-E</td>
<td>7</td>
<td>3.1(2.1)</td>
<td>5.0(3.7)</td>
<td>3</td>
<td>4</td>
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<tr>
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<td>CDI-F</td>
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<td>3.6(2.9)</td>
<td>6.4(4.9)</td>
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<td>5</td>
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<tr>
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<td>STAI-Y</td>
<td>38</td>
<td>62.0(16.1)</td>
<td>70.5(20.5)</td>
<td>59</td>
<td>69</td>
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<tr>
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<td>STAI-C</td>
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<td>58.4(7.9)</td>
<td>66.0(23.8)</td>
<td>57</td>
<td>70</td>
</tr>
</tbody>
</table>

* OQLQ 1: Social Aspects  OQLQ 2: Facial Esthetics  OQLQ 3: Oral Function  OQLQ 4: Awareness  CDI-E: Emotional  CDI-F: Functional  * statistically significant results (p<0.05)
Figure 1. Orthognathic Quality of Life: Treatment Subjects vs. Controls

Statistically significant results (p<0.05)
Domains: 1 – Social Aspects; 2 – Facial Esthetics; 3 – Oral Function; 4 – Awareness
### Table 3. Occlusal Severity Measures for Treatment Subjects

<table>
<thead>
<tr>
<th>Group</th>
<th>Variable</th>
<th>Sample Size</th>
<th>Mean ( +/- SD)</th>
<th>Median</th>
<th>Min-Max</th>
</tr>
</thead>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-Tx (T₁)</td>
<td><strong>Angle's Class I</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ANB (°)</td>
<td>7</td>
<td>1.5 (0.9)</td>
<td>0.9</td>
<td>0.7 – 2.8</td>
</tr>
<tr>
<td></td>
<td>OJ (mm)</td>
<td>7</td>
<td>2.3 (4.9)</td>
<td>3.7</td>
<td>-4.2 – 9.6</td>
</tr>
<tr>
<td></td>
<td>OPENBITE (mm)</td>
<td>5</td>
<td>3.2 (2.3)</td>
<td>4.4</td>
<td>0.5 – 5.5</td>
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<tr>
<td></td>
<td><strong>Angle's Class II</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ANB (°)</td>
<td>35</td>
<td>7.2 (2.8)</td>
<td>6.8</td>
<td>3.3 – 15.6</td>
</tr>
<tr>
<td></td>
<td>OJ (mm)</td>
<td>35</td>
<td>7.6 (3.7)</td>
<td>7.9</td>
<td>1.1 – 16</td>
</tr>
<tr>
<td></td>
<td>OPENBITE (mm)</td>
<td>15</td>
<td>3.3 (2.4)</td>
<td>3.6</td>
<td>0.1 – 6.9</td>
</tr>
<tr>
<td></td>
<td><strong>Angle's Class III</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>ANB (°)</td>
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<td>-3.9 (3.1)</td>
<td>-3.3</td>
<td>-10.4 – 0</td>
</tr>
<tr>
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<td>OJ (mm)</td>
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<td>-2.8 (2.7)</td>
<td>-2.5</td>
<td>-8.4 – 4.3</td>
</tr>
<tr>
<td></td>
<td>OPENBITE (mm)</td>
<td>18</td>
<td>2.4 (2.1)</td>
<td>1.9</td>
<td>0.1 – 8.3</td>
</tr>
<tr>
<td>Pre-Sx (T₂)</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>ANB (°)</td>
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<td>1.9 (0.7)</td>
<td>1.9</td>
<td>1 – 2.8</td>
</tr>
<tr>
<td></td>
<td>OJ (mm)</td>
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<td>-1.5 – 8.8</td>
</tr>
<tr>
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<td>2.75 (0.8)</td>
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<td><strong>Angle's Class II</strong></td>
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<td>ANB (°)</td>
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<td>6.9 (3.1)</td>
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<td>OJ (mm)</td>
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<td>7.4 (2.1)</td>
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<td>4.1 – 10</td>
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<td>1.4 (0.7)</td>
<td>1.7</td>
<td>0.3 – 1.9</td>
</tr>
<tr>
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<td><strong>Angle's Class III</strong></td>
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<td></td>
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<td></td>
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<tr>
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<td>ANB (°)</td>
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<td>-4.1</td>
<td>-8.1 – 0.8</td>
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<tr>
<td></td>
<td>OJ (mm)</td>
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<td>-4.3 (3.6)</td>
<td>-5.3</td>
<td>-9.3 – 0.3</td>
</tr>
<tr>
<td></td>
<td>OPENBITE (mm)</td>
<td>3</td>
<td>2 (2.6)</td>
<td>0.8</td>
<td>0.2 – 5</td>
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<td>Post-Tx (T₃)</td>
<td><strong>Angle's Class I</strong></td>
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<tr>
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<td>1.9 (0.8)</td>
<td>1.9</td>
<td>0.4 – 3</td>
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<tr>
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<td>OJ (mm)</td>
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<td>2.6 (0.5)</td>
<td>2.6</td>
<td>1.6 – 3.3</td>
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<tr>
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<td>OPENBITE (mm)</td>
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<td><strong>Angle's Class II</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ANB (°)</td>
<td>22</td>
<td>4.4 (1.4)</td>
<td>3.9</td>
<td>3.1 – 7.6</td>
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<tr>
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<td>OJ (mm)</td>
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<td>3.0 (0.7)</td>
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<td>1.9 – 4.2</td>
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<td>0.6</td>
<td>0.1 – 1</td>
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<td><strong>Angle's Class III</strong></td>
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<tr>
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<td>ANB (°)</td>
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<td>-1.2 (1.1)</td>
<td>-0.8</td>
<td>-3 – 0.2</td>
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<td>OJ (mm)</td>
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<td>2.5 (0.8)</td>
<td>2.7</td>
<td>1.4 – 3.3</td>
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<tr>
<td></td>
<td>OPENBITE (mm)</td>
<td>0</td>
<td>0.2</td>
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Table 4. Spearman Correlation Coefficient: Severity and Quality of Life

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<tr>
<th>Occlusal Severity Measures</th>
<th>ANB (°)</th>
<th>Overjet (mm)</th>
<th>Overbite (mm)</th>
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<tbody>
<tr>
<td><strong>Outcome Variables</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>OQLQ (Total)</strong></td>
<td>-0.03257</td>
<td>-0.05543</td>
<td>-0.07895</td>
</tr>
<tr>
<td>n=143</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>OQLQ 1 Social</strong></td>
<td>0.04119</td>
<td>0.03462</td>
<td>-0.1182</td>
</tr>
<tr>
<td>n=143</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>OQLQ 2 Facial Esthetics</strong></td>
<td>-0.0642</td>
<td>-0.06022</td>
<td>-0.12764</td>
</tr>
<tr>
<td>n=143</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>OQLQ 3 Oral Function</strong></td>
<td>-0.19001*</td>
<td>-0.17924**</td>
<td>0.14193</td>
</tr>
<tr>
<td>n=143</td>
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<tr>
<td><strong>OQLQ 4 Awareness</strong></td>
<td>0.03205</td>
<td>-0.0507</td>
<td>-0.10367</td>
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<tr>
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<tr>
<td><strong>SWLS</strong></td>
<td>-0.08873</td>
<td>-0.08015</td>
<td>-0.0299</td>
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<td><strong>BDI</strong></td>
<td>0.03022</td>
<td>0.02224</td>
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<tr>
<td><strong>CDI (Total)</strong></td>
<td>0.14149</td>
<td>0.1624</td>
<td>0.12211</td>
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<tr>
<td>n=63</td>
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<tr>
<td><strong>CDI – E Emotional</strong></td>
<td>0.17948</td>
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<td>0.16876</td>
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<tr>
<td><strong>CDI – F Functional</strong></td>
<td>0.12776</td>
<td>0.21236</td>
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<tr>
<td><strong>STAI-Y</strong></td>
<td>-0.22936***</td>
<td>-0.2051</td>
<td>-0.01272</td>
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<td><strong>STAI-C</strong></td>
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<tr>
<td>n=63</td>
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</tbody>
</table>

Statistically significant results
*p=0.0230  
**p=0.0322  
***p=0.0407

**DISCUSSION**

The aim of this study was to evaluate the psychologic well being and quality of life of patients who possess a facial skeletal mal-relationship before, during and after
correction with orthognathic surgery in comparison with a control group that represented the general population. In addition, correlation between the severity of a facial skeletal mal-relationship and patient’s quality of life was assessed.

Care was taken to ensure that the control groups matched the treatment groups for age, sex, education level and employment status. Similar to previous studies\textsuperscript{4-5,9, 20, 32-34}, there was a wide age range of the treatment subjects with the majority of the patients being young adults. Sex distribution of the treatment subjects in the present study was similar between female and male patients, whereas, other studies have reported higher percentages of females.\textsuperscript{4-5,8-9,13,20,32-34}

The results reported no significant differences in measures of depression, anxiety, or overall satisfaction with life in patients with a facial skeletal mal-relationship compared with matched controls reflecting the general population at any of the three stages of treatment indicating that these patients are psychologically well-adjusted. However, significant differences were noted between subjects and controls in orthognathic quality of life as measured by the condition specific OQLQ instrument. The number of these differences decreased at each stage of treatment sampled. Prior to initiation of treatment, differences were present for total OQLQ and specifically in the domains of social aspects, facial esthetics and oral function. Just prior to surgery, however, the social aspect domain of the OQLQ for the treatment subjects was no longer significantly different compared with the controls. One hypothesis for this change could be the patients’ acceptance in social situations once they were in braces and clearly seeking treatment. At completion of treatment, the only difference noted between groups
was decreased quality of life related to oral function within the treatment group. Why this
difference persisted even after 6 to 24 months post treatment is puzzling. The oral
function domain of the OQLQ includes statements related to difficulties with biting or
chewing as well as facial and/or jaw pain. Lip paresthesia has been reported as a common
post-surgical complication among orthognathic patients, but as having no effect on
overall satisfaction with surgical outcomes which are typically high.\textsuperscript{12,35-36} We
hypothesize that persistent lip paresthesia was a potential reason for the subjects
indicating functional problems. One of the advantages of using a condition specific
HRQoL instrument such as the OQLQ is that it is responsive/sensitive to problems that
may not be registered on a more general survey of satisfaction with a medical procedure.

When examining Figure 1, there are trends seen in the domains of the OQLQ for
treatment subjects within the different stages of treatment. There seems to be an increase
in OQLQ scores and thus a decrease in quality of life for subjects just prior to surgery.
Following treatment, OQLQ scores are decreased indicating improvement in quality of
life. Examining specifically the oral function domain, there seems to be an improvement
in function of subjects following treatment (T\textsubscript{1} vs T\textsubscript{3}) even though the oral function
scores at T\textsubscript{3} are increased for the Treatment group compared with the Control group.
Another explanation for the post- treatment difference noted for oral function between
subjects and controls could be due to age as a confounding variable. Oral function scores
improved in both the Treatment group and the Control group from T\textsubscript{1} to T\textsubscript{3}. The scores
for the treatment subjects at T\textsubscript{3} had decreased to a level similar to that of the control
subjects at T\textsubscript{1}, while the control subjects’ scores for Oral Function at T\textsubscript{3} had decreased
further suggesting that age could be a confounding variable with oral function i.e., it seems to improve with age.

In this study, the severity of the mal-relationship of treatment subjects did not seem to play a major role in most aspects of quality of life, depression or overall satisfaction with life. It has been suggested that it is the perceived degree of disfigurement and not the objective severity of malocclusion that provides the greatest information about psychosocial parameters of orthognathic patients. Nevertheless, a small, but statistically significant relationship was seen between the severity of the mal-relationship and oral function and adult anxiety. Specifically, quality of life related to oral function decreased as the severity of both skeletal and dental Class III increased, and the amount of adult anxiety increased with a more severe skeletal Class III. Since the correlation coefficients in the study were not adjusted for multiple comparisons, care must be exercised in the interpretation due to inflation of the type I error rate. This does warrant further study.

Interpretation and comparison of previous research in this area is difficult because of the wide variety of psychological measures used. Studies done by Cunningham in 2000 and Burden in 2010 utilized the same instruments as this study to evaluate symptoms of depression and anxiety in an orthognathic patient population compared to controls, (i.e the BDI and STAI). Consistent with the current study, Burden found no differences in depression or anxiety between the groups, whereas Cunningham reported significantly higher anxiety levels of the surgical group, but found no differences in regards to depression. Neither study took place in the United States, however, and both
studies only looked at individuals at one time point, prior to initiation of treatment, whereas this study confirmed no difference within the entire process of treatment as well as after treatment was complete.

In reviewing the literature, this study seems to be the first to utilize the SWLS instrument to evaluate overall satisfaction with life in an orthognathic population. Unlike other scales, the SWLS leaves the respondent free to weight various domains such as health or material wealth, and various feeling states in whatever way he or she chooses.\textsuperscript{21} The SWLS has been used in previous studies to show the influence that illnesses such as cardiovascular disease or eating disorders have on overall life satisfaction\textsuperscript{39-40}, however, in the current study patients with facial skeletal mal-relationships do not seem to be affected in their overall satisfaction with life compared to controls.

The OQLQ is a condition specific instrument which has been utilized in previous studies to examine the effect that an orthognathic condition has on a patient’s quality of life as well as to determine changes in quality of life after surgical orthodontic treatment in patients with facial skeletal mal-relationships.\textsuperscript{20,34,41-42} These studies, however, have all taken place outside of the United States (England, Jordan, Hong Kong) and therefore differ from the present study evaluating an American population. Comparing the pre-treatment group, the current study appears to have similar mean scores in the OQLQ as a Chinese population\textsuperscript{41}, whereas both British and Jordanian populations were reported to have greater mean values and thus lower condition specific quality of life.\textsuperscript{20,34} Heterogeneous methodologies complicate comparison of current results with these previous studies. The longitudinal study done by Cunningham et al did not have a control
group for comparison, but instead looked at changes within the subjects between stages of treatment. In line with the current study, when comparing pre-treatment subjects to controls, Lee et al reported significant differences in the overall OQLQ as well as social aspects, facial esthetics and oral function. They also reported a significant difference in domain 4, Awareness of Facial Deformity, which was not found in the current study.

In their systematic review, Hunt et al noted a consistent methodologic flaw within most previous studies in this field whereby control groups used were those who required orthognathic treatment and declined it. In the current study, the well matched control group reflected the general population of individuals who do not have severe skeletal discrepancies. This control group adds value to the study design by taking into account secular changes that occur with time.

The cross-sectional study design is a limitation of the current study where treatment subjects were not compared throughout the three stages of treatment.

Sample size of the pre-surgery time period was smaller than indicated by the power analysis and therefore another limitation of the study. Although significant differences were reported for this time period, failure to find more differences may have been attributable to the reduced statistical power of the small sample size.

It’s been shown that cultural influences may affect the impact that an oral condition has on quality of life. While evaluating an American population, the study could be strengthened to include ethnicity when collecting demographic data for both treatment subjects and controls to account for cultural differences and enable the study of any existing ethnic effects which we did not in this study.
CONCLUSIONS

1. The psychosocial profile of individuals with or who had initially possessed facial skeletal mal-relationships does not differ from the general population in depression, anxiety, and overall satisfaction with life.

2. Compared to the general population, individuals with a facial skeletal mal-relationship report a reduced quality of life based upon condition specific measures in social aspects, facial esthetics and oral function.

3. The severity of the mal-relationship does not seem to play a major role in quality of life, depression, anxiety or overall satisfaction with life.

ACKNOWLEDGMENTS

We would like to thank Ruth Powderly and Lydia Lancaster for their assistance in data collection and entry. We are also grateful to the Ohio State University Division of Orthodontics and Dental Faculty Practice for their cooperation and participation. We would like to recognize financial support for this research provided by the Delta Dental Foundation.
REFERENCES


CHAPTER 4

CONCLUSIONS

1. The psychosocial profile of individuals with or who had initially possessed facial skeletal mal-relationships does not differ from the general population in depression, anxiety, and overall satisfaction with life.

2. Compared to the general population, individuals with a facial skeletal mal-relationship report a reduced quality of life based upon condition specific measures in social aspects, facial esthetics and oral function.

3. The severity of the mal-relationship does not seem to play a major role in quality of life, depression, anxiety, or overall satisfaction with life.


APPENDIX A

Adult Consent
The Ohio State University Consent to Participate in Research


Principal Investigator: Dr. Allen Firestone

Sponsor: OSU Department of Orthodontics

- This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

- Your participation is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

- You may or may not benefit as a result of participating in this study. Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.

- You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?
This study is to test the effects that treatment of upper and lower jaws that don’t line up correctly (dentofacial problem) through jaw surgery has on a patient’s overall quality of life, and psychological well-being.

2. **How many people will take part in this study?**

   Approximately 300

3. **What will happen if I take part in this study?**

   You will fill out four questionnaires regarding your teeth and face and psychological well-being and send them back in provided envelopes or at the conclusion of your appointment. You may be asked to participate in the study at a future time point where you would complete the same four questionnaires. Please check if interested in participating in the study in the future:

   - [ ] Yes, I agree to be re-contacted
   - [ ] No, I do not wish to be re-contacted to participate

4. **How long will I be in the study?**

   You will be in this study for approximately 20 minutes.

5. **Can I stop being in the study?**

   You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. **What risks, side effects or discomforts can I expect from being in the study?**

   There are no side-effects or discomforts to be expected from participating in the study. There is a small risk that your responses to the questionnaires could be seen by others not involved in the research (breach of confidentiality). We will lessen this
risk by not having your name on the questionnaire, and by placing the information into a computer using a code number so that no one will be able to connect your answers to you.

7. What benefits can I expect from being in the study?

There are no direct benefits from this study; however the knowledge gained by this study may benefit people who may be considering treatment similar to yours.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If the study involves the use of your protected health information, you may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form.
10. What are the costs of taking part in this study?
None

11. Will I be paid for taking part in this study?
Yes. You will receive a $10.00 gift certificate after completion of the questionnaires. By law, payments to subjects are considered taxable income. If asked to participate in the study again, you will receive an additional $10.00 gift certificate after completion of the questionnaires.

12. What happens if I am injured because I took part in this study?
If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my rights if I take part in this study?
If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.
You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact Dr. Allen Firestone at (614) 292 1172.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Allen Firestone at (614) 292 1172.
**Signing the consent form**

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study. I am not giving up any legal rights by signing this form. I will be given a copy of this form.

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**Investigator/Research Staff**

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

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<th>Signature of person obtaining consent</th>
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**Witness(es) - *May be left blank if not required by the IRB***

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APPENDIX B

Parental Permission Form
The Ohio State University Parental Permission
For Child’s Participation in Research

Effects of Orthognathic Surgery on Quality of Life
Compared with Non-Surgical Controls in an American
Population: A Mixed Cross-Sectional and Longitudinal
Study

Principal Investigator: Dr. Allen Firestone
Sponsor: Department of Orthodontics, OSU

- This is a parental permission form for research participation. It contains important information about this study and what to expect if you permit your child to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to permit your child to participate.

- Your child’s participation is voluntary. You or your child may refuse participation in this study. If your child takes part in the study, you or your child may decide to leave the study at any time. No matter what decision you make, there will be no penalty to your child and neither you nor your child will lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you or your child is a student or employee at Ohio State, your decision will not affect your grades or employment status.

- Your child may or may not benefit as a result of participating in this study. Also, as explained below, your child’s participation may result in unintended or harmful effects for him or her that may be minor or may be serious depending on the nature of the research.

- You and your child will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate. If you permit your child to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider permitting your child to participate in this study for the reasons explained below.

1. Why is this study being done?
This study is to test the effects that treatment of upper and lower jaws that don’t line up correctly (dentofacial problem) through jaw surgery and straightening of teeth has on a patient’s overall quality of life, and psychological well-being.

2. **How many people will take part in this study?**

Approximately 300

3. **What will happen if my child takes part in this study?**

Your child will fill out four questionnaires regarding their teeth and face and psychological well-being and send them back in provided envelopes or at the conclusion of their appointment. We estimate it will take 20 minutes to complete the questionnaires. Your child may be asked to participate in the study at a future time period for an additional 20 minutes to complete the same four questionnaires. Please check if interested in your child participating in the study in the future:

- [ ] Yes, I agree for my child to be re-contacted
- [ ] No, I do not wish for my child to be re-contacted to participate

4. **How long will my child be in the study?**

Your child will be in the study the duration of time required to complete the questionnaires.

5. **Can my child stop being in the study?**

Your child may leave the study at any time. If you or your child decides to stop participation in the study, there will be no penalty and neither you nor your child will lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. **What risks, side effects or discomforts can my child expect from being in the study?**

There are no side-effects or discomforts to be expected from participating in the study. There is a small risk that your child’s responses to the questionnaires could be seen by others not involved in the research (breach of confidentiality). We will lessen this risk by keeping your child’s name off of the questionnaire, and by placing the information into a computer using the code number so that no one will be able to connect your child to their responses.
7. **What benefits can my child expect from being in the study?**

There are no direct benefits from this study; however the knowledge gained by this study may benefit people who may be considering treatment similar to your child’s.

8. **What other choices does my child have if he/she does not take part in the study?**

You or your child may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. **Will my child’s study-related information be kept private?**

Efforts will be made to keep your child’s study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your child’s participation in this study may be disclosed if required by state law. Also, your child’s records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If the study involves the use of your child’s protected health information, you may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form.
10. What are the costs of taking part in this study?

None

11. Will I or my child be paid for taking part in this study?

Yes, your child will receive a $10.00 gift certificate after completion of the questionnaires. By law, payments to subjects are considered taxable income. If asked to participate in the study again, your child will receive another $10.00 gift certificate after completion of all questionnaires.

12. What happens if my child is injured because he/she took part in this study?

If your child suffers an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if your child should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my child’s rights if he/she takes part in this study?

If you and your child choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights your child may have as a participant in this study.

You and your child will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You or your child may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.
An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

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### Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study. I am not giving up any legal rights by signing this form. I will be given a copy of this form.

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<thead>
<tr>
<th>Printed name of person obtaining consent</th>
<th>Signature of person obtaining consent</th>
<th>AM/PM</th>
<th>Date and time</th>
</tr>
</thead>
</table>

### Witness(es) - *May be left blank if not required by the IRB*

<table>
<thead>
<tr>
<th>Printed name of witness</th>
<th>Signature of witness</th>
<th>AM/PM</th>
<th>Date and time</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Printed name of witness</th>
<th>Signature of witness</th>
<th>AM/PM</th>
<th>Date and time</th>
</tr>
</thead>
</table>
APPENDIX C

Child Assent
The Ohio State University Assent to Participate in Research

Study Title: Effects of Orthognathic Surgery on Quality of Life Compared with Non-Surgical Controls in an American Population: A Mixed Cross-Sectional and Longitudinal Study.

Researcher: Dr. Allen Firestone

Sponsor: OSU Department of Orthodontics

- You are being asked to be in a research study. Studies are done to find better ways to treat people or to understand things better.
- This form will tell you about the study to help you decide whether or not you want to participate.
- You should ask any questions you have before making up your mind. You can think about it and discuss it with your family or friends before you decide.
- It is okay to say “No” if you don’t want to be in the study. If you say “Yes” you can change your mind and quit being in the study at any time without getting in trouble.
- If you decide you want to be in the study, an adult (usually a parent) will also need to give permission for you to be in the study.

1. What is this study about?

This study is to examine how using surgery to correct problems with bite and with upper and lower jaws that don’t line up correctly, have on individuals’ overall quality of life, and psychological well-being.

2. What will I need to do if I am in this study?

We will ask you to fill out four questionnaires regarding your teeth and face and your psychological well-being, and return them by mail or in person at your appointment.
3. **How long will I be in the study?**

You will be in this study for approximately 20 minutes. You may be asked in the future to participate in this study again for an additional 20 minutes. Please check if interested in participating in the study in the future:

- [ ] Yes, I agree to be re-contacted
- [ ] No, I do not wish to be re-contacted to participate

4. **Can I stop being in the study?**

You may stop being in the study at any time.

5. **What bad things might happen to me if I am in the study?**

No bad things will happen to you in this study. There is no chance that someone might find out your answers to the questionnaires because the questionnaires will be coded and have no personal identifiable information.

6. **What good things might happen to me if I am in the study?**

There is no direct benefit to you, however the answers will help us to decide whether these questionnaires are good enough to be used in future and thereby help people who may be considering going through the same kind of treatment.

7. **Will I be given anything for being in this study?**

Yes, you will get a $10 gift certificate after completion of all the questionnaires. If you are asked to participate in this study again, you will be given an additional $10 gift certificate after completion of all the questionnaires. By law, payments to subjects are considered taxable income.

8. **Who can I talk to about the study?**

For questions about the study you may contact Dr. Allen Firestone at 614 292 - 1172.

To discuss other study-related questions with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.
Signing the assent form

I have read (or someone has read to me) this form. I have had a chance to ask questions before making up my mind. I want to be in this research study.

Signature or printed name of subject  Date and time

AM/PM

Investigator/Research Staff

I have explained the research to the participant before requesting the signature above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining assent  Signature of person obtaining assent

AM/PM

Date and time

This form must be accompanied by an IRB approved parental permission form signed by a parent/guardian.
Please read the following statements carefully. In order to find out how important each of the statements is to you. Please circle 1, 2, 3, 4 or N/A where:

- 1 means it bothers you a little
- 4 means it bothers you a lot
- 2+3 lie between these statements
- N/A means the statement does not apply to you or does not bother you

<table>
<thead>
<tr>
<th>Number</th>
<th>Statement</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I am self-conscious about the appearance of my teeth</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>2</td>
<td>I have problems biting</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>3</td>
<td>I have problems chewing</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>4</td>
<td>There are some foods I avoid eating because the way my teeth meet makes it difficult</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>5</td>
<td>I don’t like eating in public places</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>6</td>
<td>I get pains in my face or jaw</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>7</td>
<td>I don’t like seeing a side view of my face (profile)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>8</td>
<td>I spend a lot of time studying my face in the mirror</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>9</td>
<td>I spend a lot of time studying my teeth in the mirror</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>10</td>
<td>I dislike having my photograph taken</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>11</td>
<td>I dislike being seen on video</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>12</td>
<td>I often stare at other people’s teeth</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>13</td>
<td>I often stare at other people’s faces</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>14</td>
<td>I am self-conscious about my facial appearance</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>15</td>
<td>I try to cover my mouth when I meet people for the first time</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>16</td>
<td>I worry about meeting people for the first time</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>17</td>
<td>I worry that people will make hurtful comments about my appearance</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>18</td>
<td>I lack confidence when I am out socially</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>19</td>
<td>I do not like smiling when I meet people</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>20</td>
<td>I sometimes get depressed about my appearance</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>21</td>
<td>I sometimes think that people are staring at me</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>22</td>
<td>Comments about my appearance really upset me, even when I know people are only joking</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>N/A</td>
</tr>
</tbody>
</table>
APPENDIX E

BDI-II and CDI-2
Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the one statement in each group that best describes the way you have been feeling during the past two weeks, including today. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Pattern) or Item 18 (Changes in Appetite).

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0 I do not feel sad.</td>
<td>0 I am not discouraged about my future.</td>
<td>0 I do not feel like a failure.</td>
<td>0 I get as much pleasure as I ever did from the things I enjoy.</td>
<td>0 I don’t feel particularly guilty.</td>
<td>0 I don’t feel I am being punished.</td>
<td>0 I feel the same about myself as ever.</td>
<td>0 I don’t criticize or blame myself more than usual.</td>
<td>0 I don’t have any thoughts of killing myself.</td>
<td>0 I don’t cry any more than I used to.</td>
</tr>
<tr>
<td>1 I feel sad much of the time.</td>
<td>1 I feel more discouraged about my future than I used to be.</td>
<td>1 I have failed more than I should have.</td>
<td>1 I don’t enjoy things as much as I used to.</td>
<td>1 I feel guilty over many things I have done or should have done.</td>
<td>1 I feel I may be punished.</td>
<td>1 I have lost confidence in myself.</td>
<td>1 I am more critical of myself than I used to be.</td>
<td>1 I have thoughts of killing myself, but I would not carry them out.</td>
<td>1 I cry more than I used to.</td>
</tr>
<tr>
<td>2 I am sad all the time.</td>
<td>2 I do not expect things to work out for me.</td>
<td>2 As I look back, I see a lot of failures.</td>
<td>2 I get very little pleasure from the things I used to enjoy.</td>
<td>2 I feel quite guilty most of the time.</td>
<td>2 I expect to be punished.</td>
<td>2 I am disappointed in myself.</td>
<td>2 I criticize myself for all of my faults.</td>
<td>2 I would like to kill myself.</td>
<td>2 I cry over every little thing.</td>
</tr>
<tr>
<td>3 I am so sad or unhappy that I can’t stand it.</td>
<td>3 I feel my future is hopeless and will only get worse.</td>
<td>3 I feel I am a total failure as a person.</td>
<td>3 I can’t get any pleasure from the things I used to enjoy.</td>
<td>3 I feel guilty all of the time.</td>
<td>3 I feel I am being punished.</td>
<td>3 I dislike myself.</td>
<td>3 I blame myself for everything bad that happens.</td>
<td>3 I would kill myself if I had the chance.</td>
<td>3 I feel like crying, but I can’t.</td>
</tr>
</tbody>
</table>
11. Agitation
   0  I am no more restless or wound up than usual.
   1  I feel more restless or wound up than usual.
   2  I am so restless or agitated that it’s hard to stay still.
   3  I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest
   0  I have not lost interest in other people or activities.
   1  I am less interested in other people or things than before.
   2  I have lost most of my interest in other people or things.
   3  It’s hard to get interested in anything.

13. Indecisiveness
   0  I make decisions about as well as ever.
   1  I find it more difficult to make decisions than usual.
   2  I have much greater difficulty in making decisions than I used to.
   3  I have trouble making any decisions.

14. Worthlessness
   0  I do not feel I am worthless.
   1  I don’t consider myself as worthwhile and useful as I used to.
   2  I feel more worthless as compared to other people.
   3  I feel utterly worthless.

15. Loss of Energy
   0  I have as much energy as ever.
   1  I have less energy than I used to have.
   2  I don’t have enough energy to do very much.
   3  I don’t have enough energy to do anything.

16. Changes in Sleeping Pattern
   0  I have not experienced any change in my sleeping pattern.
   1a I sleep somewhat more than usual.
   1b I sleep somewhat less than usual.
   2a I sleep a lot more than usual.
   2b I sleep a lot less than usual.
   3a I sleep most of the day.
   3b I wake up 1–2 hours early and can’t get back to sleep.

17. Irritability
   0  I am no more irritable than usual.
   1  I am more irritable than usual.
   2  I am much more irritable than usual.
   3  I am irritable all the time.

18. Changes in Appetite
   0  I have not experienced any change in my appetite.
   1a My appetite is somewhat less than usual.
   1b My appetite is somewhat greater than usual.
   2a My appetite is much less than before.
   2b My appetite is much greater than usual.
   3a I have no appetite at all.
   3b I crave food all the time.

19. Concentration Difficulty
   0  I can concentrate as well as ever.
   1  I can’t concentrate as well as usual.
   2  It’s hard to keep my mind on anything for very long.
   3  I find I can’t concentrate on anything.

20. Tiredness or Fatigue
   0  I am no more tired or fatigued than usual.
   1  I get more tired or fatigued more easily than usual.
   2  I am too tired or fatigued to do a lot of the things I used to do.
   3  I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex
   0  I have not noticed any recent change in my interest in sex.
   1  I am less interested in sex than I used to be.
   2  I am much less interested in sex now.
   3  I have lost interest in sex completely.
Kids sometimes have different feelings and ideas.

This form lists the feelings and ideas in groups. From each group of three sentences, pick one sentence that describes you best for the past two weeks. After you pick a sentence from the first group, go on to the next group.

There is no right or wrong answer. Just pick the sentence that best describes the way you have been recently. Put a mark like this ☑ next to your answer. Put the mark in the box next to the sentence that you pick.

Here is an example of how this form works. Try it. Put a mark next to the sentence that describes you best.

Example:
☐ I read books all the time.
☐ I read books once in a while.
☐ I never read books.

Remember, for each group, pick out the sentence that describes you best in the PAST TWO WEEKS.

<table>
<thead>
<tr>
<th>Item 1</th>
<th>Item 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ I am sad once in a while.</td>
<td>☐ I hate myself.</td>
</tr>
<tr>
<td>☐ I am sad many times.</td>
<td>☐ I do not like myself.</td>
</tr>
<tr>
<td>☐ I am sad all the time.</td>
<td>☐ I like myself.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 2</th>
<th>Item 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Nothing will ever work out for me.</td>
<td>☐ All bad things are my fault.</td>
</tr>
<tr>
<td>☐ I am not sure if things will work out for me.</td>
<td>☐ Many bad things are my fault.</td>
</tr>
<tr>
<td>☐ Things will work out for me O.K.</td>
<td>☐ Bad things are not usually my fault.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 3</th>
<th>Item 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ I do most things O.K.</td>
<td>☐ I do not think about killing myself.</td>
</tr>
<tr>
<td>☐ I do many things wrong.</td>
<td>☐ I think about killing myself but would not do it.</td>
</tr>
<tr>
<td>☐ I do everything wrong.</td>
<td>☐ I want to kill myself.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 4</th>
<th>Item 9</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ I have fun in many things.</td>
<td>☐ I feel like crying every day.</td>
</tr>
<tr>
<td>☐ I have fun in some things.</td>
<td>☐ I feel like crying many days.</td>
</tr>
<tr>
<td>☐ Nothing is fun at all.</td>
<td>☐ I feel like crying once in a while.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 5</th>
<th>Item 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ I am important to my family.</td>
<td>☐ I feel cranky all the time.</td>
</tr>
<tr>
<td>☐ I am not sure if I am important to my family.</td>
<td>☐ I feel cranky many times.</td>
</tr>
<tr>
<td>☐ My family is better off without me.</td>
<td>☐ I am always never cranky.</td>
</tr>
<tr>
<td>Item 11</td>
<td>Item 20</td>
</tr>
<tr>
<td>---------</td>
<td>---------</td>
</tr>
<tr>
<td>I like being with people.</td>
<td>I never have fun at school.</td>
</tr>
<tr>
<td>I do not like being with people many times.</td>
<td>I have fun at school only once in a while.</td>
</tr>
<tr>
<td>I do not want to be with people at all.</td>
<td>I have fun at school many times.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 12</th>
<th>Item 21</th>
</tr>
</thead>
<tbody>
<tr>
<td>I cannot make up my mind about things.</td>
<td>I have plenty of friends.</td>
</tr>
<tr>
<td>It is hard to make up my mind about things.</td>
<td>I have some friends but I wish I had more.</td>
</tr>
<tr>
<td>I make up my mind about things easily.</td>
<td>I do not have any friends.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 13</th>
<th>Item 22</th>
</tr>
</thead>
<tbody>
<tr>
<td>I look O.K.</td>
<td>My schoolwork is alright.</td>
</tr>
<tr>
<td>There are some bad things about my looks.</td>
<td>My schoolwork is not as good as before.</td>
</tr>
<tr>
<td>I look ugly.</td>
<td>I do very badly in subjects I used to be good in.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 14</th>
<th>Item 23</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have to push myself all the time to do my schoolwork.</td>
<td>I can never be as good as other kids.</td>
</tr>
<tr>
<td>I have to push myself many times to do my schoolwork.</td>
<td>I can be as good as other kids if I want to.</td>
</tr>
<tr>
<td>Doing schoolwork is not a big problem.</td>
<td>I am just as good as other kids.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 15</th>
<th>Item 24</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have trouble sleeping every night.</td>
<td>Nobody really loves me.</td>
</tr>
<tr>
<td>I have trouble sleeping many nights.</td>
<td>I am not sure if anybody loves me.</td>
</tr>
<tr>
<td>I sleep pretty well.</td>
<td>I am sure that somebody loves me.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 16</th>
<th>Item 25</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am tired once in a while.</td>
<td>It is easy for me to get along with friends.</td>
</tr>
<tr>
<td>I am tired many days.</td>
<td>I get into arguments with friends many times.</td>
</tr>
<tr>
<td>I am tired all the time.</td>
<td>I get into arguments with friends all the time.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 17</th>
<th>Item 26</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most days I do not feel like eating.</td>
<td>I fall asleep during the day all the time.</td>
</tr>
<tr>
<td>Many days I do not feel like eating.</td>
<td>I fall asleep during the day many times.</td>
</tr>
<tr>
<td>I eat pretty well.</td>
<td>I almost never fall asleep during the day.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 18</th>
<th>Item 27</th>
</tr>
</thead>
<tbody>
<tr>
<td>I do not worry about aches and pains.</td>
<td>Most days I feel like I can't stop eating.</td>
</tr>
<tr>
<td>I worry about aches and pains many times.</td>
<td>Many days I feel like I can't stop eating.</td>
</tr>
<tr>
<td>I worry about aches and pains all the time.</td>
<td>My eating is O.K.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 19</th>
<th>Item 28</th>
</tr>
</thead>
<tbody>
<tr>
<td>I do not feel alone.</td>
<td>It is easy for me to remember things.</td>
</tr>
<tr>
<td>I feel alone many times.</td>
<td>It is a little hard to remember things.</td>
</tr>
<tr>
<td>I feel alone all the time.</td>
<td>It is very hard to remember things.</td>
</tr>
</tbody>
</table>
APPENDIX F

STAI-Y and STAI-C
SELF-EVALUATION QUESTIONNAIRE STAI Form Y-1

Please provide the following information:

Name_________________________ Date__________ S____

Age_________________________ Gender (Circle) M F T____

DIRECTIONS:
A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel right now, that is, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

1. I feel calm .......................................................... 1 2 3 4
2. I feel secure .......................................................... 1 2 3 4
3. I am tense .............................................................. 1 2 3 4
4. I feel strained ........................................................ 1 2 3 4
5. I feel at ease .......................................................... 1 2 3 4
6. I feel upset ............................................................ 1 2 3 4
7. I am presently worrying over possible misfortunes .............. 1 2 3 4
8. I feel satisfied ....................................................... 1 2 3 4
9. I feel frightened ..................................................... 1 2 3 4
10. I feel comfortable .................................................. 1 2 3 4
11. I feel self-confident ............................................... 1 2 3 4
12. I feel nervous ...................................................... 1 2 3 4
13. I am jittery ........................................................... 1 2 3 4
14. I feel indecisive .................................................... 1 2 3 4
15. I am relaxed ......................................................... 1 2 3 4
16. I feel content ....................................................... 1 2 3 4
17. I am worried ....................................................... 1 2 3 4
18. I feel confused ..................................................... 1 2 3 4
19. I feel steady ......................................................... 1 2 3 4
20. I feel pleasant ..................................................... 1 2 3 4

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SELF-EVALUATION QUESTIONNAIRE
STAI Form Y-2

DIRECTIONS
A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you generally feel.

21. I feel pleasant ......................................................... 1 2 3 4
22. I feel nervous and restless ........................................ 1 2 3 4
23. I feel satisfied with myself ........................................... 1 2 3 4
24. I wish I could be as happy as others seem to be .............. 1 2 3 4
25. I feel like a failure ...................................................... 1 2 3 4
26. I feel rested .............................................................. 1 2 3 4
27. I am “calm, cool, and collected” .................................. 1 2 3 4
28. I feel that difficulties are piling up so that I cannot overcome them ............................................... 1 2 3 4
29. I worry too much over something that really doesn’t matter ......................................................... 1 2 3 4
30. I am happy .............................................................. 1 2 3 4
31. I have disturbing thoughts .......................................... 1 2 3 4
32. I lack self-confidence ............................................... 1 2 3 4
33. I feel secure ............................................................ 1 2 3 4
34. I make decisions easily ............................................. 1 2 3 4
35. I feel inadequate ...................................................... 1 2 3 4
36. I am content ........................................................... 1 2 3 4
37. Some unimportant thought runs through my mind and bothers me ............................................. 1 2 3 4
38. I take disappointments so keenly that I can’t put them out of my mind ........................................... 1 2 3 4
39. I am a steady person ................................................. 1 2 3 4
40. I get in a state of tension or turmoil as I think over my recent concerns and interests ................. 1 2 3 4

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HOW-I-FEEL QUESTIONNAIRE
Developed by C.D. Spielberger, C.D. Edwards, J. Montuori, and R. Lushene
STAIC Form C-1

Name: ___________________________ Age: __________ Date: __________

DIRECTIONS: A number of statements which boys and girls use to describe
themselves are given below. Read each statement carefully and decide how you
feel right now. Then put an X in the box in front of the word or phrase which best
describes how you feel. There are no right or wrong answers. Don’t spend too
much time on any one statement. Remember, find the word or phrase which
best describes how you feel right now, at this very moment.

1. I feel................................................... ☐ very calm ☐ calm ☐ not calm
2. I feel................................................... ☐ very upset ☐ upset ☐ not upset
3. I feel................................................... ☐ very pleasant ☐ pleasant ☐ not pleasant
4. I feel................................................... ☐ very nervous ☐ nervous ☐ not nervous
5. I feel................................................... ☐ very jittery ☐ jittery ☐ not jittery
6. I feel................................................... ☐ very rested ☐ rested ☐ not rested
7. I feel................................................... ☐ very scared ☐ scared ☐ not scared
8. I feel................................................... ☐ very relaxed ☐ relaxed ☐ not relaxed
9. I feel................................................... ☐ very worried ☐ worried ☐ not worried
10. I feel................................................... ☐ very satisfied ☐ satisfied ☐ not satisfied
11. I feel................................................... ☐ very frightened ☐ frightened ☐ not frightened
12. I feel................................................... ☐ very happy ☐ happy ☐ not happy
13. I feel................................................... ☐ very sure ☐ sure ☐ not sure
14. I feel................................................... ☐ very good ☐ good ☐ not good
15. I feel................................................... ☐ very troubled ☐ troubled ☐ not troubled
16. I feel................................................... ☐ very bothered ☐ bothered ☐ not bothered
17. I feel................................................... ☐ very nice ☐ nice ☐ not nice
18. I feel................................................... ☐ very terrified ☐ terrified ☐ not terrified
19. I feel................................................... ☐ very mixed-up ☐ mixed-up ☐ not mixed-up
20. I feel................................................... ☐ very cheerful ☐ cheerful ☐ not cheerful

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HOW-I-FEEL QUESTIONNAIRE
STAIC  Form C-2

Name: ___________________________________ Age: _______ Date: _______

DIRECTIONS: A number of statements which boys and girls use to describe themselves are given below. Read each statement carefully and decide if it is hardly-ever, or sometimes, or often true for you. Then for each statement, put an X in the box in front of the word that seems to describe you best. There are no right or wrong answers. Don't spend too much time on any one statement. Remember, choose the word which seems to describe how you usually feel.

1. I worry about making mistakes .................. □ hardly-ever □ sometimes □ often
2. I feel like crying ..................................... □ hardly-ever □ sometimes □ often
3. I feel unhappy ........................................ □ hardly-ever □ sometimes □ often
4. I have trouble making up my mind ............... □ hardly-ever □ sometimes □ often
5. It is difficult for me to face my problems......... □ hardly-ever □ sometimes □ often
6. I worry too much ..................................... □ hardly-ever □ sometimes □ often
7. I get upset at home ................................... □ hardly-ever □ sometimes □ often
8. I am shy ................................................ □ hardly-ever □ sometimes □ often
9. I feel troubled ........................................ □ hardly-ever □ sometimes □ often
10. Unimportant thoughts run through my mind and bother me ........................................ □ hardly-ever □ sometimes □ often
11. I worry about school .................................. □ hardly-ever □ sometimes □ often
12. I have trouble deciding what to do ............... □ hardly-ever □ sometimes □ often
13. I notice my heart beats fast .......................... □ hardly-ever □ sometimes □ often
14. I am secretly afraid ................................... □ hardly-ever □ sometimes □ often
15. I worry about my parents ............................ □ hardly-ever □ sometimes □ often
16. My hands get sweaty ................................. □ hardly-ever □ sometimes □ often
17. I worry about things that may happen .......... □ hardly-ever □ sometimes □ often
18. It is hard for me to fall asleep at night .......... □ hardly-ever □ sometimes □ often
19. I get a funny feeling in my stomach .............. □ hardly-ever □ sometimes □ often
20. I worry about what others think of me .......... □ hardly-ever □ sometimes □ often

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APPENDIX G

SWLS
Below are five statements that you may agree or disagree with. Using the 1 - 7 scale below, indicate your agreement with each item by placing the appropriate number on the line preceding that item. Please be open and honest in your responding.

- 7 - Strongly agree
- 6 - Agree
- 5 - Slightly agree
- 4 - Neither agree nor disagree
- 3 - Slightly disagree
- 2 - Disagree
- 1 - Strongly disagree

_____ In most ways my life is close to my ideal.
_____ The conditions of my life are excellent.
_____ I am satisfied with my life.
_____ So far I have gotten the important things I want in life.
_____ If I could live my life over, I would change almost nothing.
APPENDIX H

Demographic Information Form
Age: __________ yr __________ mo

Sex:  M  F

Employment status:  Y  N

Education level: a. 0-12th grade
    b. Completed High School or equivalent
    c. Some College
    d. Completed College
    e. Graduate education
APPENDIX I

Participant suicide hotline letter
Dear Participant,

In the event that you have suicidal thoughts please contact the following national toll-free hotline:

1-800-273-8255

TTY: 1-800-799-4TTY (4889)

Or call the Franklin County Suicide Prevention Hotline at: 614-221-5445. Or go to the Ohio State University Department of Psychiatry for an evaluation.

OSU Harding Hospital
1670 Upham Drive
Columbus, OH 43210
Ph: 614.293.8283

Thank you again for your participation!

Best regards,

[Signature]

Dr. Allen Firestone