Effects of Orthognathic Surgery on Quality of Life compared with Non-surgical controls in an American Population

Thesis

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

By
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ABSTRACT

There is inadequate data to determine if patients’ self-reported quality of life changes following orthognathic surgery result from the surgery itself or from other factors. **Objectives:** To determine the psychosocial effects of correcting facial skeletal mal-relationships on quality of life, depression, and anxiety in a group of surgically treated orthodontic patients compared with matched controls. **Methods:** Subjects were patients presenting to a graduate orthodontic clinic or dental faculty practice with facial skeletal mal-relationship whose proposed treatment plan included orthognathic surgery or who had previously received surgical correction of a facial skeletal mal-relationship. Sex, age, employment and educational level matched controls were surveyed in an identical manner. Instruments used to assess psychosocial impact included the Orthognathic Quality of Life Questionnaire (OQLQ), Beck Depression Inventory (BDI-II), Satisfaction With Life Scale (SWLS), and the State Trait Anxiety Index (STAI). Instruments were administered at initial consultation before any treatment and at post treatment, 6 to 24 months after appliance removal. Between group data was analyzed using multiple Mann-Whitney-Wilcoxon tests with p-values adjusted using the step-down
Bonferroni method of Holm. **Results:** A total of 149 subjects participated in the study, 44 subjects in the pre-treatment control group, 39 in the pre-treatment surgery group, 32 in the post-treatment control group, and 34 in the post-treatment surgery group. There was a significant increase in age, education and employment in both post-treatment groups compared with their respective pre-treatment groups. There were no significant differences in quality of life, depression, anxiety or overall satisfaction with life in orthognathic surgery patients compared with matched controls except in oral function. The third domain of the OQLQ, oral function, was found to be significantly different between the pre-treatment control and pre-treatment surgery groups and between the pre-treatment surgery and post-treatment surgery groups. **Conclusion:** Subjects with facial-skeletal mal-relationships who chose to have surgical correction on average are no different from controls relative to health related quality of life, depression, anxiety, and overall satisfaction with life. Patients selecting to have orthognathic surgery can expect to see an improvement in oral function but no other significant improvements in psychosocial parameters.
Dedicated to my loving and supportive family
ACKNOWLEDGEMENTS

I would like to thank my thesis advisor, Dr. Allen Firestone, for all of his guidance and encouragement throughout this process. It has truly been a pleasure to work with him over the years. I also thank my thesis committee members, Dr. Shiva Shanker and Dr. F. Michael Beck. Each of them made important contributions in different aspects of the study and I am very grateful for all of their direction and advice.

I thank Dr. Rashelle Delli-Gatti and Dr. Tariq Sayegh for their assistance in this study. Because of their hard work and efficiency both the data collection and data entry were completed.

Funding for this study was provided in part by Delta Dental Foundation. I would like to thank them for making this study possible through their financial support.

Finally, I thank my husband--I am grateful for all the love, support, and encouragement he has given me.
VITA

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CHAPTER ONE

INTRODUCTION

Along with the increasing acceptance of orthognathic surgery as a method to correct a dentofacial skeletal mal-relationship among adolescents and adults, the need to assess the psychological well-being of these patients after treatment has also grown (Rivera et al., 2000 and Kiyak et al. 1982). Combined orthodontic and orthognathic surgical treatment have as their goal providing the patient with a harmonious facial skeletal relationship and improved occlusal function. Patients’ primary motivation to pursue combined orthodontic and orthognathic surgical correction of their malocclusion is for esthetic facial and dental improvement, however, it is also suggested that they expect psychosocial benefits after treatment such as positive impact on their interpersonal relationships, self-confidence and self-image (Rivera et al., 2000, Hunt et al., 2001).

Currently, the evaluation of outcomes of clinical procedures has been expanded to include the patient’s perception of the effect of the condition and its correction on their quality of life and well-being (Rivera et al., 2000).

Previous research has shown high levels of satisfaction with outcomes of orthognathic surgery: the majority of participants believing they made the right decision in choosing to have surgery (Cunningham et al., 1996). Flanery et al. (1990) reported
significant positive effects in the subscales of self-concept: self-esteem, self-satisfaction, self-identify, physical self, family self, social self and total self-conflict two years after surgery. A positive impact on the quality of life of orthognathic surgery patients in the physical and social aspects was reported by Nicodema et al. (2008). Orthognathic surgery patients also reported general health-related quality of life, oral health-related quality of life, and psychosocial function improvements that were stable between 2 and 5 years post-surgery (Motegi et al., 2003).

Post-surgery, most patients reported high satisfaction, psychological and oral functional status, but some patients reported depression and dissatisfaction with the surgical outcome (Kiyak et al. 1982). Most of this decline was attributable to patients still in orthodontic treatment for months post-surgery. The patients with residual pain, paresthesia, and oral dysfunction were not more likely to report psychological dissatisfaction (Kiyak et al., 1982).

Cunningham et al. (1995) reviewed the literature on the psychological aspects of orthognathic surgery. They concluded that while patient satisfaction after orthognathic surgery is generally high, with most patients reporting they would re-elect to have surgery, the success of surgery may depend on careful patient selection (Cunningham et al., 1995). Orthognathic surgery is planned to improve the patients’ facial appearance. As a result, some authors report that patients’ exhibit improved psychological profiles; however, this result is not universal and other authors have not found an effect on psychological well-being (Kovalenko et al. 2012).
Kiyak et al. (1982) reported that orthognathic patients had higher body image scores before surgery than 9 months after surgery. This decline in self-esteem was later reversed with an increase at 24 months post-surgery but was still lower than the mean pre-surgery level (Kiyak et al., 1984). The areas identified as the main problems were concerning presurgical explanations and insufficient advice regarding side-effects. However, the majority of patients commented that persistent symptoms such as lip paresthesia and limited mouth opening had no effect on their daily life (Cunningham et al., 1996). Patients with elevated psychological distress prior to orthognathic surgery “reported significantly more discomfort or difficulty with symptoms, social/self-concerns, general health, and overall recovery after surgery” (Phillips et al. 2004).

Cunningham et al. (1996) found no significant difference in orthognathic surgery patients before and after surgery in depression, anxiety and self-esteem. Hatch et al. (1999) reported that orthognathic surgery patients are similar to the general population in psychological analysis. They reported that a short period of depression may follow the surgery but will likely be self-limiting and short-lived. Burden et al. (2010) evaluated whether orthognathic surgery patients should be routinely referred for psychological screening and concluded that this was not justified because these patients were similar to the control population.

Hunt et al. (2001) conducted a systematic review that confirmed that the psychosocial benefits that are likely occurring for orthognathic surgery patients have not yet been clearly defined in a meaningful scientific way. The authors identified an urgent need for well-controlled longitudinal studies to be conducted. They noted both a lack of
consistency in the methods used to measure psychosocial status in the articles which resulted in an inability to show a clear and precise psychosocial benefit and a lack of studies high in the hierarchy of evidence (Hunt et al., 2001).

OBJECTIVES

The aim of this study was to determine the effects of a facial skeletal mal-relationship and its subsequent correction on quality of life, depression, anxiety and overall satisfaction with life compared with a matched non-surgical control group.

NULL 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 before or after correction by means of orthognathic surgery.

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 before correction by means of orthognathic surgery.
H₃: 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 matched non-surgical controls after correction by means of orthognathic surgery.

H₄: There is no difference in the quality of life, depression, anxiety, or overall satisfaction with life between the two groups of non-surgical controls.
CHAPTER TWO

MATERIALS AND METHODS

Study Approval

This study was approved by the Ohio State University Institutional Review Board (study protocol #2011 H0195).

Selection of Subjects

Subjects were patients presenting to The Ohio State University College of Dentistry graduate orthodontic clinic and the College’s dental faculty practice with facial skeletal mal-relationship and whose proposed treatment plan included orthognathic surgery to correct the mal-relationship. Additionally, patients who had previously received surgical correction of the facial skeletal mal-relationship and whose appliances had been removed at least six months and up to two years earlier were recruited. Potential subjects were approached by staff and residents at the time of the orthodontic visit or via a telephone call. Matched control groups were recruited in the dental hygiene clinic at
the College of Dentistry and on The Ohio State University main campus. This was a convenience sample of available subjects.

**Inclusion/Exclusion Criteria**

i.) Surgical Group

a. Patients at least 12 years old

b. Patient, if under 18 years old, accompanied by a parent or guardian who could sign consent for research and treatment and had legal guardianship for at least one year

c. Patient and parent do not have any developmental disabilities or urgent medical conditions

d. Patient and parent able to communicate in English

e. Patient has been given or selected a combined orthodontic and surgical treatment plan that was not a sequelae of cleft lip and/or palate, trauma, or developmental syndrome

ii.) Control Group

a. The non-surgical control groups were matched to the surgical groups with the following variables: age, gender, education level, and employment status

**Data Collection**

This was a clinical study with a cross-sectional design. This study used questionnaires to collect data at two different stages of treatment from individuals who possessed a
facial skeletal mal-relationship. The earliest time period included subjects at the initial consultation, before any treatment was initiated. The second, later time period was post treatment (from 6 months to two years after removal of appliances). Data was collected to establish patients’ pretreatment level of anxiety, depression, overall satisfaction with life and their ‘condition specific’ quality of life. Then, the data was compared with that collected from post treatment patients. A control group completed the same questionnaires. The control was matched to the experimental group at both time periods for: 1. Education level, 2. Employment status, 3. Age, and 4. Gender. On completing the questionnaires the patients received a $10 gift certificate to a local restaurant or restaurant chain.

**Statistical Analysis**

There are two types of instruments that can be used to evaluate health-related quality of life: generic and condition specific. Generic surveys account for multiple conditions and measure a wider effect, making them more suitable for comparisons between different groups. Generic instruments have a greater potential to capture any unforeseen side effects. Condition specific, or focus instruments, have the potential to be more responsive or sensitive to clinically important changes and can reflect the areas considered to be of greatest importance specific to the particular disease, condition, or problem. Cunningham et al. (2000, 2002) developed a condition specific instrument to measure changes in health related quality of life in patients who have had orthognathic surgery, the Orthognathic quality of life questionnaire (OQLQ). The OQLQ is based on
the individual’s perceived impact of their dentofacial deformity on their daily life. They proposed its utility in investigating the outcome of orthognathic treatment. Their instrument was developed from a literature review and interviews with clinicians and patients. The OQLQ consists of 22 statements that contribute to four domains: social aspects, facial aesthetics, oral function, and awareness of dentofacial aesthetics. It is based on a four point scale, with 1 meaning “it bothers you little” to 4 meaning “it bothers you a lot”. There is also an option of “not applicable”. This instrument was found to be reliable in Great Britain and the United States (Cunningham et al., 2000 and Bedair et al., 2011).

Of the dependent variables in this study, OQLQ has the highest variability. Consequently, sample size determination was based on this variable. With a non-directional alpha risk of 0.05 and assuming a standard deviation of 20.3 (Bedair et al., 2011), a sample size of 35 subjects would be required to demonstrate a difference of ±15 units with a power of 0.86

Independent Variables:

- Group (treatment or control)
- Time period (pre-treatment or post-treatment)

Dependent Variables:

- Orthognathic Quality of Life (OQLQ) (Cunningham et al., 2000): The OQLQ, a validated condition specific questionnaire, consists of 22 questions with scores ranging from 1-4 and N/A. The minimum possible score is 0 and a maximum possible score is 88. A higher score indicates a reduced quality of life.
• Beck Depression Inventory II (BDI-II) (Children’s Depression Inventory-2 (CDI 2) for subjects under age 18) (Kumar 2002): There are 21 items with scores ranging from 0-3 with a minimum possible score of 0 and maximum of 63 in the BDI-II. The CDI 2 has a total of 28 items with scores ranging from 0-2 with a minimum possible score of 0 and maximum of 56. In both the CDI 2 and the BDI-II, a higher score indicates a greater number of symptoms of depression.

• State Trait Anxiety Inventory (STAI) (State Trait Anxiety Inventory for Children (STAIC) for subjects under age 18) (Spielberger et al., 1970): Both the STAI and STAIC consist of 40 questions with scores ranging from 1-3 and possible minimum score of 40 and maximum of 120. In both the STAI and STAIC a higher score indicates a greater amount of anxiety.

• Satisfaction with Life Scale (SWLS) (Diener et al., 1985): The SWLS consists of 5 items with scores ranging from 1-7 with a minimum possible score of 5 and maximum of 35. In the SWLS a higher score indicates higher life satisfaction.

A significance level of p<0.05 was established. Non-parametric statistics were used to analyze the data because the data were not normally distributed. All four dependent variables were analyzed using a multiple Mann-Whitney-Wilcoxon analysis (SAS Version 9.1.3, SAS Institute Inc., Cary, North Carolina) with group (treatment, control) and stage (pre-treatment, post-treatment) as the independent variables. The step-down Bonferroni method of Holm was used when comparing groups (Holm 1979).
CHAPTER THREE

MANUSCRIPT

Effects of Orthognathic Surgery on Quality of Life compared to Non-surgical controls in an American Population

ABSTRACT

Objectives: To determine the psychosocial effects of correcting facial skeletal mal-relationships on quality of life, depression, and anxiety in a group of surgically treated orthodontic patients compared with matched controls.

Design: Cross-sectional study

Patients/Setting: Subjects were patients presenting to a graduate orthodontic clinic or dental faculty practice with facial skeletal mal-relationship whose proposed treatment plan included orthognathic surgery or who had previously received surgical correction of a facial skeletal mal-relationship. Sex, age, employment and educational level matched control subjects were surveyed in an identical manner.

Main Outcome Measure(s): Instruments used to assess psychosocial impact included the Orthognathic Quality of Life Questionnaire (OQLQ), Beck Depression Inventory (BDI-II), Satisfaction With Life Scale (SWLS), and the State Trait Anxiety Index (STAI).
Instruments were administered at initial consultation before any treatment and at post treatment, 6 to 24 months after appliance removal. Between group data analyses were accomplished using multiple Mann-Whitney-Wilcoxon tests with p-values adjusted using the step-down Bonferroni method of Holm.

Results: A total of 149 subjects participated in the study, 44 subjects in the pre-treatment control group, 39 in the pre-treatment surgery group, 32 in the post-treatment control group, and 34 in the post-treatment surgery group. A significant increase was seen in age, education and employment when comparing the pre-treatment group with the post-treatment group. There were no significant differences in quality of life, depression, anxiety or overall satisfaction with life in orthognathic surgery patients compared to matched controls except in oral function. The third domain of the OQLQ, oral function, was found to be significantly different between the pre-treatment control and pre-treatment surgery groups and between the pre-treatment surgery and post-treatment surgery groups.

Conclusions: Subjects with a facial-skeletal mal-relationships do not differ from controls relative to overall health related quality of life, depression, anxiety, and overall satisfaction with life. However, subjects with a mal-relationship do report a significant functional impairment compared with those without an impairment. Patients selecting to have orthognathic surgery can expect to see an improvement in oral function but no other significant improvements in psychosocial parameters.

Key words: orthognathic surgery, quality of life
INTRODUCTION

Combined orthodontic and orthognathic surgical treatment have as their goal providing the patient with a harmonious facial skeletal relationship and improved occlusal function. Patients’ primary motivation to pursue this treatment of their malocclusion is for esthetic facial and dental improvement, however, it is also suggested that they expect psychosocial benefits after treatment such as a positive impact on their interpersonal relationships, self-confidence and self-image (Rivera et al., 2000, Hunt et al., 2001).

Currently, the evaluation of outcomes of clinical procedures has been expanded to include the patient’s perception of the effect of the condition and it’s correction on their quality of life and well-being (Rivera et al., 2000). Previous research has shown high levels of satisfaction with outcomes of orthognathic surgery: the majority of participants believing they made the right decision in choosing to have surgery (Cunningham et al., 1996). Flanery et al. (1990) reported significant positive effects in the self-concept: self-esteem, self-satisfaction, self-identify, physical self, family self, social self and total self-conflict two years after surgery (1990). A positive impact on the quality of life of orthognathic surgery patients in the physical and social aspects was reported by Nicodema et al. (2008). Orthognathic surgery patients also showed general health-related quality of life, oral health-related quality of life, and psychosocial function improvements that were stable between 2 and 5 years post-surgery (Motegi et al., 2003).
Post-surgery most patients reported high satisfaction, psychological and oral functional status; however, some patients reported depression and dissatisfaction with the surgical outcome (Kiyak et al. 1982). Most of this decline was attributable to patients still in orthodontic treatment for months post-surgery. The patients with residual pain, paresthesia, and oral dysfunction were not more likely to report psychological dissatisfaction (Kiyak et al., 1982).

Orthognathic surgery is planned to improve the patients’ facial appearance. As a result, some authors report that patients exhibit improved psychological profiles. However, this result is not universal and other authors have not found an effect on psychological well-being (Kovalenko et al. 2012).

Kiyak et al. (1982) reported that orthognathic patients had higher body image scores before surgery than 9 months after surgery. This decline in self-esteem was later reversed with an increase at 24 months post-surgery but was still lower than the mean pre-surgery level (Kiyak et al., 1984). The areas identified as the main problems were concerning presurgical explanations and insufficient advice regarding side-effects. Patients with elevated psychological distress prior to orthognathic surgery reported greater discomfort, self-concerns and overall recovery after surgery (Phillips et al. 2004).

Cunningham et al. (1996) found no significant difference before and after surgery in depression, anxiety and self-esteem. Hatch et al. (1999) reported that orthognathic patients are similar to the general population in psychological analysis. They reported that a short period of depression may follow the surgery but will likely be self-limiting and short-lived. Burden et al. (2010) evaluated whether orthognathic patients should be
routinely referred for psychological screening and concluded that this was not justified because these patients were similar to the control population.

Hunt et al. (2001) conducted a systematic review that confirmed that “despite the increasing use of orthognathic treatment, the psychosocial benefits likely to accrue to patients have not been clearly defined in a meaningful scientific way.” The authors identified an urgent need for well-controlled longitudinal studies to be conducted. They noted both a lack of consistency in the methods used to measure psychosocial status in the articles and this resulted in an inability to show a clear and precise psychosocial benefit and a lack of studies high in the hierarchy of evidence (Hunt et al., 2001).

The aim of this study was to determine the effects of a facial skeletal mal-relationship and its subsequent correction on quality of life, depression, anxiety and overall satisfaction with life compared with a matched controls.

MATERIALS AND METHODS

Participants / Subjects

This study was approved by the Ohio State University Institutional Review Board (study protocol #2011 H0195). Subjects were patients presenting to The Ohio State University College of Dentistry graduate orthodontic clinic and the College’s dental faculty practice with facial skeletal mal-relationship and whose proposed treatment plan included orthognathic surgery to correct the mal-relationship. Additionally patients who
had previously received surgical correction of the facial skeletal mal-relationship and whose appliances had been removed at least six months and up to two years earlier were recruited. Potential subjects were approached by staff and residents at the time of the orthodontic visit or via a telephone call. The matched control groups were recruited in the dental hygiene clinic at the College of Dentistry and on The Ohio State University main campus. This was a convenience sample of available subjects.

Data Collection

This was a clinical study with a cross-sectional design. This study used questionnaires to collect data from individuals who possess a facial skeletal mal-relationship at two different stages of treatment. Stage one included subjects at the initial consultation before any treatment was initiated and stage two was post treatment (from 6 months to two years after removal of appliances).

There are two types of instruments that can be used to evaluate health-related quality of life: generic and condition specific. Generic surveys account for multiple conditions and measure a wider effect making them more suitable for comparisons between different groups. Generic instruments have a greater potential to capture any unforeseen side effects. Condition specific, or focus instruments, have the potential to be more responsive or sensitive to clinically important changes and can reflect the areas considered to be of greatest importance specific to the particular disease, condition, or problem. Cunningham et al. (2000, 2002) developed a condition specific instrument to measure changes in health related quality of life in patients who have had orthognathic surgery, the
Orthognathic quality of life questionnaire (OQLQ). The OQLQ is based on the individual’s perceived impact of their dentofacial deformity on their daily life. The OQLQ consists of 22 statements that contribute to four domains: social aspects, facial aesthetics, oral function, and awareness of dentofacial aesthetics. It is based on a four point scale, with 1 meaning “it bothers you little” to 4 meaning “it bothers you a lot”. There is also an option of “not applicable”. This instrument was found to be reliable in Great Britain and the United States (Cunningham et al., 2000 and Bedair et al., 2011).

The following four questionnaires were used:

- Orthognathic Quality of Life (OQLQ) (Cunningham et al., 2000): The OQLQ is a validated condition specific questionnaire. The minimum possible score is 0 and the maximum 88. A higher score indicates a reduced quality of life.

- Beck Depression Inventory II (BDI-II) (Children’s Depression Inventory-2 (CDI 2) for subjects under age 18) (Kumar 2002): There are 21 items scored from 0-3 with a minimum possible score of 0 and maximum of 63 in the BDI-II. The CDI 2 has a total of 28 items scored from 0-2 with a minimum possible score of 0 and maximum of 56. In both the CDI 2 and the BDI-II, a higher score indicates a greater number of symptoms of depression.

- State Trait Anxiety Inventory (STAI) (State Trait Anxiety Inventory for Children (STAIC) for subjects under age 18) (Spielberger et al., 1970): Both the STAI and STAIC consist of 40 questions scored from 1-3 and possible minimum score of 40 and maximum of 120. In both the STAI and STAIC a higher score indicates a greater amount of anxiety.
- Satisfaction with Life Scale (SWLS) (Diener et al., 1985): The SWLS consists of 5 items scored from 1-7 with a minimum possible score of 5 and maximum of 35.

In the SWLS a higher score indicates higher life satisfaction.

The data collected was analyzed to determine patients’ pretreatment level of anxiety, depression, overall satisfaction with life and their ‘condition specific’ quality of life. Then, the data was compared with that from post treatment patients. Control groups completed the same questionnaires. The control was matched to the experimental group for: 1. Education level, 2. Employment status, 3. Age, and 4. Gender. On completing the questionnaires the participants received a $10 gift certificate to a local restaurant or restaurant chain.

**Statistical Analysis**

Of the dependent variables in this study, OQLQ has the highest variability. Consequently, sample size determination was based on this variable. With a non-directional alpha risk of 0.05 and assuming a standard deviation of 20.3 (Bedair et al., 2011), a sample size of 35 subjects would be required to demonstrate a difference of ±15 units with a power of 0.86

A significance level of p<0.05 was established. Non-parametric statistics were used to analyze the data because the data were not normally distributed. All four dependent variables were analyzed using a multiple Mann-Whitney-Wilcoxon analysis (SAS Version 9.1.3, SAS Institute Inc., Cary, North Carolina) with group (treatment,
control) and stage (pre-treatment, post-treatment) as the independent variables. The step-down Bonferroni method of Holm was used when comparing groups (Holm 1979).

RESULTS

A total of 149 subjects participated in the study, 44 subjects in the pre-treatment control group, 39 in the pre-treatment surgery group, 32 in the post-treatment control group, and 34 in the post-treatment surgery group. Demographic information on the groups and their age, gender, employment and education characteristics are presented in Table 3.1.

Table 3.1. Demographic Characteristics of subjects

<table>
<thead>
<tr>
<th></th>
<th>Pre-treatment Groups</th>
<th></th>
<th>Post-treatment Groups</th>
<th></th>
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<tbody>
<tr>
<td></td>
<td>Control</td>
<td>Surgery</td>
<td>Control</td>
<td>Surgery</td>
</tr>
<tr>
<td>Age, mean (±SD)</td>
<td>19.2 (7.2)</td>
<td>18.7 (7.0)</td>
<td>26.2 (11.9)</td>
<td>25.8 (11.5)</td>
</tr>
<tr>
<td>Gender n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>24 (55.5)</td>
<td>20 (51.3)</td>
<td>20 (62.5)</td>
<td>20 (58.8)</td>
</tr>
<tr>
<td>Male</td>
<td>20 (45.5)</td>
<td>19 (48.7)</td>
<td>12 (37.5)</td>
<td>14 (41.2)</td>
</tr>
<tr>
<td>Employment n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>14 (31.8)</td>
<td>10 (25.6)</td>
<td>20 (62.5)</td>
<td>24 (70.6)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>30 (68.2)</td>
<td>29 (74.4)</td>
<td>12 (37.5)</td>
<td>10 (29.4)</td>
</tr>
<tr>
<td>Education n (#)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1=0-12th grade, 2=completed HS or equivalent, 3=some college, 4=completed college, 5=graduate education</td>
<td>1.0 (1.5)</td>
<td>1.0 (2.0)</td>
<td>3.0 (1.5)</td>
<td>3.0 (3.0)</td>
</tr>
</tbody>
</table>
A multiple Mann-Whitney-Wilcoxon test was used along with the Chi-square test and the step-down Bonferroni method of Holm to evaluate the differences in demographics. There was no significant differences (p>0.05) between the pre-treatment control and surgery groups, or the post-treatment control and surgery groups for age, gender, education, and employment demographics. Significant differences were seen in age, education and employment between the pre-treatment control vs. post-treatment control groups and between the pre-treatment surgery vs. post-treatment surgery groups. The age, education and employment all increased from pre-treatment to post-treatment groups.

Summarized in Table 3.2 are the mean values for all four questionnaires for all four groups. Components of questionnaires that were not fully completed were excluded from analysis. In the pre-treatment control group one participant did not complete the anxiety inventory or the depression inventory and in the pre-treatment surgery group one subject did not complete the depression inventory. In the post-treatment control group and surgery group one subject did not complete the anxiety inventory.
Table 3.2. Mean score (±SD) for each group for each questionnaire (and domain).

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Pre-treatment Groups</th>
<th>Post-treatment Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control (n=44)</td>
<td>Surgery (n=39)</td>
</tr>
<tr>
<td></td>
<td>Mean (±SD)</td>
<td>Mean (±SD)</td>
</tr>
<tr>
<td>OQLQ: D1 Social Aspects</td>
<td>9.8 (7.0)</td>
<td>12.1 (9.4)</td>
</tr>
<tr>
<td>OQLQ: D2 Dentofacial aesthetics</td>
<td>6.9 (5.0)</td>
<td>10.2 (6.5)</td>
</tr>
<tr>
<td>OQLQ: D3 Oral function</td>
<td>4.4&lt;sup&gt;a&lt;/sup&gt; (3.9)</td>
<td>8.6&lt;sup&gt;a,b&lt;/sup&gt; (5.2)</td>
</tr>
<tr>
<td>OQLQ: D4 Awareness of dentofacial aesthetics</td>
<td>5.1 (4.4)</td>
<td>5.9 (4.5)</td>
</tr>
<tr>
<td>OQLQ Total score</td>
<td>26.0 (17.6)</td>
<td>36.8 (21.8)</td>
</tr>
<tr>
<td>SWLS</td>
<td>27.1 (5.3)</td>
<td>25.6 (6.8)</td>
</tr>
<tr>
<td>ANXIETY</td>
<td>60.4 (13.2)</td>
<td>63.7 (15.0)</td>
</tr>
<tr>
<td>DEPRESSION</td>
<td>6.8 (6.4)</td>
<td>7.4 (6.7)</td>
</tr>
</tbody>
</table>

<sup>a</sup>Some subjects did not complete all of the questionnaires. Means in a row with the same superscript differ significantly (p < 0.05)

Between group comparisons

Multiple between group comparisons were conducted using a multiple Mann-Whitney-Wilcoxon test with the step-down Bonferroni method of Holm. Comparisons were between: 1. Pre-treatment control and pre-treatment surgery groups, 2. Pre-treatment control and post-treatment control, 3. Pre-treatment surgery and post-treatment surgery, and 4. Post-treatment control and post-treatment surgery. The results are summarized in Table 3.2. There were statistical differences (p < 0.05) between the pre-
treatment control and pre-treatment surgery and the pre-treatment surgery and post-treatment surgery in domain 3, oral function, of the OQLQ. There were no other significant differences between groups (Table 3.2).

DISCUSSION

The results of this study indicate that there are no significant differences in quality of life, depression, anxiety or overall satisfaction with life in orthognathic surgery patients compared to matched controls except for oral function. The third domain of the OQLQ, oral function, was found to be significantly worse for the pre-treatment surgery group compared with the pre-treatment control group and significantly improved for the post-treatment surgery group compared with the pre-treatment surgery group.

Compared with the pre-surgery group in the current study, Cunningham et al. (2002) reported greater mean scores in the OQLQ for the pre-surgery subjects in their study. This indicates their subjects were bothered by their facial skeletal mal-relationship more than our sample. A validation study of the OQLQ by Cunningham et al. (2002) had significant differences to the current investigation. Their study did not include a control group to which they could compare the findings of the surgical group. They reported a significant difference in social aspects, dentofacial aesthetics, and oral function (domains one, two and three respectively) from T2 (prior to surgery) to T3 (6-8 weeks following removal of fixed orthodontic appliances). In the current study, omitting the control groups, when the pre-treatment and post-treatment surgery groups were compared using
the Mann-Whitney-Wilcoxon test (Table 4.1) no significant difference was seen in the SWLS, anxiety, depression or domain four of the OQLQ (awareness of dentofacial aesthetics). In this comparison, a statistical difference was found in the OQLQ total score (p=0.0083), domain one: social aspects (p=0.0277), domain two: dentofacial aesthetics (p=0.0033) and domain three: oral function (p=0.0014). These results closely mirror the results of Cunningham et al. (2002).

Table 4.1 Comparison of Pre-treatment surgery vs. Post-treatment surgery.

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Pre-treatment surgery vs. Post-treatment surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>OQLQ Total score</td>
<td>0.0083**</td>
</tr>
<tr>
<td>OQLQ: D1 Social Aspects</td>
<td>0.0277**</td>
</tr>
<tr>
<td>OQLQ: D2 Dentofacial aesthetics</td>
<td>0.0033**</td>
</tr>
<tr>
<td>OQLQ: D3 Oral function</td>
<td>0.0014**</td>
</tr>
<tr>
<td>OQLQ: D4 Awareness of dentofacial aesthetics</td>
<td>0.2275</td>
</tr>
<tr>
<td>SWLS</td>
<td>0.2421</td>
</tr>
<tr>
<td>ANXIETY</td>
<td>0.8079</td>
</tr>
<tr>
<td>DEPRESSION</td>
<td>0.0653</td>
</tr>
</tbody>
</table>

# Mann-Whitney-Wilcoxon test
* Significant difference

In the validation study of the OQLQ by Cunningham et al. (2002), the mean scores from T1 (before any active treatment starts) to T2 showed an increase in all domains. The results of a comparison of T1 to T3 were not reported. This current
investigation did not evaluate subjects prior to surgery (T2). This may explain the apparent discrepancy between the two sets of results.

Phillips et al. (1998) emphasize the importance of evaluating subjects who are seeking orthognathic surgery rather than those who have already started treatment. In the study reported here, the initial stage was prior to any initiation of treatment and was compared to the final stage, after removal of all fixed appliances. In their systematic review, Hunt et al. (2001) noted a consistent methodologic flaw: control groups in most previous studies included those who required orthognathic treatment and declined it. In the current study, the control group reflected the general population of individuals who do not have severe skeletal discrepancies. The control group adds value to the study design by taking into account secular changes that occur with time.

Consistent with the current study, Cunningham et al. (2000) did not find their dentofacial group to have higher levels of depression at the start of treatment compared to their controls. They measured state and trait separately and noted a significantly higher state anxiety level of the surgical group compared to the control. No difference was seen in the trait anxiety. Burden et al. (2010) reported no statistically significant difference between skeletal class II or III patients and the control group for anxiety.

Steca et al. (2013) reported patients’ life satisfaction was influenced by the patient’s cardiovascular disease severity, indicating the SWLS is sensitive to detecting overall life satisfaction. Ljotsson et al. (2007) saw improvement in overall life satisfaction in their post-treatment group of bulimia nervosa and binge eating disorder patients. 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. Satisfaction with life did not differ between the pre-surgery and post-surgery group.

Currently there are inadequate data available about whether the changes reported by patients in their quality of life after orthognathic surgery are a result of confounding variables such as natural progression of time, or a result of the corrective surgery. Orthodontic treatment in concert with orthognathic surgery can pose a large financial burden (Liu et al., 2009). It is important to offer patients clear and accurate information so they will be able to make autonomous decisions. An accurate description of what to anticipate the impact of orthognathic surgery will have on quality of life can offer valuable information to the patient during the consent process when choosing between a surgical and non-surgical alternative (Lee et al., 2008).

Currently there is no universally accepted approach for determining the clinical significance of quality of life data. Still, there is pervasive agreement that p-values do not indicate if a particular finding has clinical significance because statistical significance does not necessarily equate a meaningful difference or change in quality of life. Determining the amount of change in quality of life that is clinically important is complex and requires multiple perspectives (Wyrwich et al., 2005). One key component in identifying clinically meaningful change is a consideration of the initial severity of the quality of life impairment. A result of ‘no meaningful change’ differs for a patient who has notable impairment in quality of life at the baseline than compared with a patient who shows little to no impairment at baseline (Crosby et al., 2003). In this investigation the assigned value of 15 units of difference in the OQLQ total score for our power analysis
can be presumed to show a clinically significant difference in this population given that the baseline total scores were averaged at 36, so an improvement of nearly 50% could be assumed to be clinically significant.

**Study Limitations**

One of the limitations of this study is the study design. The study was a cross-sectional design. However, when compared to Cunningham’s longitudinal study, we do see similar trends.

In order to avoid sample selection bias, we used consecutive cases. All patients who were eligible for the study were approached within the time period of the study and controls were matched for age, gender, employment status, and education level.

Cultural influences may affect the impact that an oral condition has on quality of life (Abbott et al., 2001; Tsakos et al., 2001; Stahl et al., 2003). Perceptions of the causes of diseases, attitudes toward health and disease, the doctor-patient relationship, the role of the family, mechanisms of coping with disease, and psychological adjustment to illness have all been shown to be affected by culture (Abbott et al., 2001). To account for cultural differences, quality of life instruments should be validated cross-culturally (Ruperto et al., 2001). The OQLQ was recently validated in an American sample (Bedair et al. 2011).

Another limitation of the current investigation is the small sample size along with large standard deviations making it more challenging to show significance. The current orthognathic subjects were not identified based on the spectrum of severity or
classification of skeletal mal-relationship; however the subjects can be considered to be a representative sample of overall orthognathic patients.

CONCLUSIONS

1. Individuals seeking treatment for their facial skeletal mal-relationship do not differ from matched controls with normal facial skeletal relationships with regard to depression, anxiety and overall satisfaction with life.

2. The major effect of orthognathic surgery to correct facial skeletal mal-relationships on quality of life is an improvement in oral function.

ACKNOWLEDGEMENTS

We would like to thank Dr. Rashelle Delli-Gatti and Dr. Tariq Sayegh 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 Dental Master’s Thesis Award Program sponsored by Delta Dental Foundation, which is the philanthropic affiliate of Delta Dental of Michigan, Ohio and Indiana.
REFERENCES


CHAPTER FOUR

DISCUSSION and CONCLUSIONS

The results of this study indicate that there are no significant differences in quality of life, depression, anxiety or overall satisfaction with life in orthognathic surgery patients compared to matched controls except for oral function. The third domain of the OQLQ, oral function, was found to be significantly worse for the pre-treatment surgery group compared with the pre-treatment control group and significantly improved for the post-treatment surgery group compared with the pre-treatment surgery group.

Compared with the pre-surgery group in the current study, Cunningham et al. (2002) reported greater mean scores in the OQLQ for the pre-surgery subjects in their study. This indicates their subjects were bothered by their facial skeletal mal-relationship more than our sample. A validation study of the OQLQ by Cunningham et al. (2002) had significant differences to the current investigation. Their study did not include a control group to which they could compare the findings of the surgical group. They reported a significant difference in social aspects, dentofacial aesthetics, and oral function (domains one, two and three respectively) from T2 (prior to surgery) to T3 (6-8 weeks following removal of fixed orthodontic appliances). In the current study, when the pre-treatment and post-treatment surgery groups were compared using the Mann-Whitney-Wilcoxon...
test (Table 4.1) no significant difference was seen in the SWLS, anxiety, depression or domain four of the OQLQ (awareness of dentofacial aesthetics). In this comparison, a statistical difference was found in the OQLQ total score (p=0.0083), domain one: social aspects (p=0.0277), domain two: dentofacial aesthetics (p=0.0033) and domain three: oral function (p=0.0014). These results closely mirror the results of Cunningham et al. (2002).

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Pre-treatment surgery vs. Post-treatment surgery</th>
<th>P (unadjusted)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>OQLQ Total score</td>
<td><strong>0.0083</strong></td>
<td></td>
</tr>
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<td>DEPRESSION</td>
<td>0.0653</td>
<td></td>
</tr>
</tbody>
</table>

* Mann-Whitney-Wilcoxon test

In the validation study of the OQLQ by Cunningham et al. (2002), the mean scores from T1 (before any active treatment starts) to T2 showed an increase in all domains. The results of a comparison of T1 to T3 were not reported. This current
investigation did not evaluate subjects prior to surgery (T2). This may explain the apparent discrepancy between the two sets of results.

Similarly, Lee et al. (2008) using the OQLQ reported significant differences in social, facial esthetics, oral function (domains one, two, and three respectively) and the OQLQ total score from just prior to surgery to 6 months (T2) following surgery. It was not reported if the patients were no longer in fixed orthodontic appliances at the post-operative appointment. Lee et al. (2008) saw significantly different results in the facial esthetic domain only when looking at their baseline to 6 weeks post-operatively.

Consistent with the study design of both Cunningham et al. (2002) and Lee et al. (2008), Al-Ahmad et al. (2009) evaluated subjects just prior to surgery. Al-Ahmad’s post-surgery group had completed treatment for up to 21 months. This study also included a group that had been presented a surgical option and declined it, and a control group that consisted of patients with normal occlusion and good maxillomandibular relations. Al-Ahmad corrected for multiple comparisons. In comparing the pre-surgery and post-surgery groups they reported significant difference in all domains except the oral function. Pre-surgery and declined surgery groups showed significant differences in all the OQLQ domains as did the pre-surgery to the control group. No significant difference was seen after surgery compared to the declined surgery group and the control group. The authors attribute this apparent discrepancy to the possible attempt of the declined surgery group to deny the negative impact of their deformity on their quality of life. Thus the results of Lee et al. (2008) are consistent with the results of the current study.
To compare this current investigation to Cunningham et al. (2002) results, the unadjusted P-values should be used since the Cunningham study did not report any statistical corrections for multiple comparisons to their p-values. The values in Table 4 compared to those of Cunningham’s are consistent in that significance was seen in the social aspects, dentofacial aesthetics, and oral function domains.

Phillips et al. (1998) emphasize the importance of evaluating subjects who are seeking orthognathic surgery rather than those who have already started treatment. In the study reported here, the initial stage was prior to any initiation of treatment and was compared to the final stage which was after removal of all fixed appliances. In their systematic review, Hunt et al. (2001) noted a consistent methodologic flaw: control groups in most previous studies included those who required orthognathic treatment and declined it. In the current study, the control group reflected the general population of individuals who do not have severe skeletal discrepancies. The control group adds value to the study design by taking into account secular changes that happen with time.

Consistent with the current study, Cunningham et al. (2000) did not find their dentofacial group to have higher levels of depression at the start of treatment compared to their controls. They measured state and trait separately and noted a significantly higher state anxiety level of the surgical group compared to the control. No difference was seen in the trait anxiety. Burden et al. (2010) reported no statistically significant difference between skeletal class II or III patients and the control group for anxiety.

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shows little to no impairment at baseline (Crosby et al., 2003). In this investigation the assigned value of 15 units of difference in the OQLQ total score for our power analysis can be presumed to show a clinically significant difference in this population given that the baseline total scores were averaged at 36, so an improvement of nearly 50% can be assumed to be clinically significant.

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CONCLUSIONS

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2. The major effect of orthognathic surgery to correct facial skeletal mal-relationships on quality of life is an improvement in oral function.
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mediating role of illness perception and self-efficacy beliefs, Psychology & Health, DOI: 10.1080/08870446.2012.759223


APPENDIX A

Adult consent
The Ohio State University Consent to Participate in Research

Study Title: Effects of Orthognathic Surgery On Quality of Life In An American Population

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 (dento-facial problem) through jaw surgery has on a patient’s overall psychosocial health, quality of life, depression and anxiety level, and satisfaction with life.

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 six questionnaires regarding your dental problem and general health and send them back in provided envelopes or at the conclusion of your appointment, if you
have just begun treatment you will be asked to fill out the questionnaires on three other occasions and send them back in the provided envelopes or turn them in at the conclusion of your appointment.

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

You could be in this study for less than a month. That is if the questionnaires are filled out only on one occasion. However if you have just begun treatment, then you will be asked to fill out the questionnaires twice more during treatment, and once after the braces are removed. This could be a year or longer.

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 name, address, phone number and 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 personal information locked up in a file cabinet, by removing your name from 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.

If we find that you may be in danger of harming yourself, we will work with you to find someone who can help 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 for each completed set of questionnaires you return.

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.
Consent
Biomedical/Cancer

IRB Protocol Number: 2008H0203
IRB Approval date: 
Version: B

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.

<table>
<thead>
<tr>
<th>Printed name of subject</th>
<th>Signature of subject</th>
<th>AM/PM</th>
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<table>
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<tr>
<th>Printed name of person authorized to consent for subject (when applicable)</th>
<th>Signature of person authorized to consent for subject (when applicable)</th>
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</thead>
<tbody>
<tr>
<td>Date and time</td>
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</table>

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.

<table>
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<th>Signature of person obtaining consent</th>
<th>AM/PM</th>
</tr>
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<tbody>
<tr>
<td>Date and time</td>
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Witness(es) - May be left blank if not required by the IRB

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</table>

Page 5 of 6
APPENDIX B

Child assent and Parental consent
The Ohio State University Assent to Participate in Research

Study Title: Effects of Orthognathic Surgery on Quality of Life in an American Population
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, similar to yours, have on individuals’ overall mental health, self-esteem, quality of life, depression and anxiety level, and satisfaction with life.

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

We will ask you to fill out seven questionnaires regarding your dental problem and your general health, and return them by mail.

3. How long will I be in the study?

You could be in this study for less than a month, that is if the questionnaires are filled out only on one occasion. However if you have just begun treatment, then you will be asked...
to fill out the questionnaires twice more during treatment, and once after the braces are removed. This could be a year or longer.

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 a very small chance that someone might find out your answers to the questionnaires. However, your answers will be kept locked up with only a few investigators being able to see them. When your answers have been put in a computer it will no longer have your name on it and the computer will be protected by a password.

If we find that you might be in danger of harming yourself, we will talk to your parent (or guardian) about it.

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 for each completed set of questionnaires you return.

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

Date and time

AM/PM

This form must be accompanied by an IRB approved parental permission form signed by a parent/guardian.
The Ohio State University Parental Permission
For Child's Participation in Research

Study Title: Effects of Orthognathic Surgery on Quality of Life In An American Population
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 (dento-facial problem) through jaw surgery and straightening of teeth has on a patient’s overall psychosocial health, quality of life, depression and anxiety level, and satisfaction with life.

2. How many people will take part in this study?
Approximately 200

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

   Your child will fill out three questionnaires regarding their dental problem and general health and send them back in provided envelopes or at the conclusion of their appointment. We estimate it will take 30 minutes or less to complete the questionnaires.

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 name, address, phone number and 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 personal information locked up in a file cabinet, by removing their name from the questionnaire, and by placing the information into a computer using a code number so that no one will be able to connect your child to their responses.

   If we find that your child is at risk for harming themselves we will inform you of this and will work with you to find someone to help for your child.

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.

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.

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 child’s 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 your child is 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 parental permission form

I have read (or someone has read to me) this form and I am aware that I am being asked to provide permission for my child 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 permit my child 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.

Printed name of subject

Printed name of person authorized to provide permission for subject

Signature of person authorized to provide permission for subject

Relationship to the subject

Date and time

AM/PM

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.

Printed name of person obtaining consent

Signature of person obtaining consent

Date and time

AM/PM

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

Printed name of witness

Signature of witness

Date and time

AM/PM

Printed name of witness

Signature of witness

Date and time

AM/PM

Page 5 of 5

Form date: 12/15/05
APPENDIX C

OQLQ
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

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APPENDIX D

BDI-II and CDI2
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).

1. Sadness
   0  I do not feel sad.
   1  I feel sad much of the time.
   2  I am sad all the time.
   3  I am so sad or unhappy that I can’t stand it.

2. Pessimism
   0  I am not discouraged about my future.
   1  I feel more discouraged about my future than I used to be.
   2  I do not expect things to work out for me.
   3  I feel my future is hopeless and will only get worse.

3. Past Failure
   0  I do not feel like a failure.
   1  I have failed more than I should have.
   2  As I look back, I see a lot of failures.
   3  I feel I am a total failure as a person.

4. Loss of Pleasure
   0  I get as much pleasure as I ever did from the things I enjoy.
   1  I don’t enjoy things as much as I used to.
   2  I get very little pleasure from the things I used to enjoy.
   3  I can’t get any pleasure from the things I used to enjoy.

5. Guilty Feelings
   0  I don’t feel particularly guilty.
   1  I feel guilty over many things I have done or should have done.
   2  I feel quite guilty most of the time.
   3  I feel guilty all of the time.

6. Punishment Feelings
   0  I don’t feel I am being punished.
   1  I feel I may be punished.
   2  I expect to be punished.
   3  I feel I am being punished.

7. Self-Dislike
   0  I feel the same about myself as ever.
   1  I have lost confidence in myself.
   2  I am disappointed in myself.
   3  I dislike myself.

8. Self-Criticalness
   0  I don’t criticize or blame myself more than usual.
   1  I am more critical of myself than I used to be.
   2  I criticize myself for all of my faults.
   3  I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes
   0  I don’t have any thoughts of killing myself.
   1  I have thoughts of killing myself, but I would not carry them out.
   2  I would like to kill myself.
   3  I would kill myself if I had the chance.

10. Crying
    0  I don’t cry any more than I used to.
    1  I cry more than I used to.
    2  I cry over every little thing.
    3  I feel like crying, but I can’t.
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 $\square$ next to your answer. Put the mark in the box next to the sentence that you pick.

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

<table>
<thead>
<tr>
<th>Item 1</th>
<th>Item 2</th>
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<th>Item 7</th>
<th>Item 8</th>
<th>Item 9</th>
<th>Item 10</th>
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<tbody>
<tr>
<td>□ I am sad once in a while.</td>
<td>□ Nothing will ever work out for me.</td>
<td>□ I do most things O.K.</td>
<td>□ I have fun in many things.</td>
<td>□ I am important to my family.</td>
<td>□ I hate myself.</td>
<td>□ All bad things are my fault.</td>
<td>□ I do not think about killing myself.</td>
<td>□ I feel like crying every day.</td>
<td>□ I feel cranky all the time.</td>
</tr>
<tr>
<td>□ I am sad many times.</td>
<td>□ I am not sure if things will work out for me.</td>
<td>□ I do many things wrong.</td>
<td>□ I have fun in some things.</td>
<td>□ I am not sure if I am important to my family.</td>
<td>□ I do not like myself.</td>
<td>□ Many bad things are my fault.</td>
<td>□ I think about killing myself but would not do it.</td>
<td>□ I feel like crying many days.</td>
<td>□ I feel cranky many times.</td>
</tr>
<tr>
<td>□ I am sad all the time.</td>
<td>□ Things will work out for me O.K.</td>
<td>□ I do everything wrong.</td>
<td>□ Nothing is fun at all.</td>
<td>□ My family is better off without me.</td>
<td>□ I like myself.</td>
<td>□ Bad things are not usually my fault.</td>
<td>□ I want to kill myself.</td>
<td>□ I feel like crying once in a while.</td>
<td>□ I am almost never cranky.</td>
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Remember, for each group, pick out the sentence that describes you best in the PAST TWO WEEKS.

<table>
<thead>
<tr>
<th>Item 11</th>
<th>Item 20</th>
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<tbody>
<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>
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<tr>
<th>Item 12</th>
<th>Item 21</th>
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<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>
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<tr>
<th>Item 13</th>
<th>Item 22</th>
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<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>
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<tr>
<th>Item 14</th>
<th>Item 23</th>
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<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>
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<th>Item 15</th>
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<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>
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<th>Item 16</th>
<th>Item 25</th>
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<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>
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<th>Item 17</th>
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<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>
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<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>
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<th>Item 19</th>
<th>Item 28</th>
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<tr>
<td>I do not feel alone.</td>
<td>It is easy for me to remember things.</td>
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<tr>
<td>I feel alone many times.</td>
<td>It is a little hard to remember things.</td>
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<tr>
<td>I feel alone all the time.</td>
<td>It is very hard to remember things.</td>
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APPENDIX E

STAI and STAIC
SELF-EVALUATION QUESTIONNAIRE STA I Form Y-1

Please provide the following information:

Name_________________________ Date______

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
APPENDIX F

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 G

Demographic form
Age: __________ yr __________ mo

Gender: M F

Employment status: Y N

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

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