Validation of a Short-form Measure for Oral Health-Related Quality of Life: The Relationship between Patients' Self-Perception of the Impact of Oral Health on Quality of Life and the Oral Condition

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Abstract

Objectives: To validate a new four-question instrument as an outcome assessment tool for oral health-related quality of life (OHRQoL) and compare its results to the Oral Health Impact Profile 14 (OHIP-14). We also tested the relationship between subjects' chief complaints and perceived impact of their oral health on their quality of life.

Methods: One hundred and two new patients (55 females and 47 males; age 19-79 years) at Tufts University School of Dental Medicine filled out the investigational survey instrument and underwent a clinical examination. Spearman rank correlation was used to analyze the relationship between the investigational questions and the OHIP-14. Reliability was assessed using Cronbach's alpha. Sensitivity and specificity were calculated and odds ratios computed using generalized estimating equations. Analyses were performed using SPSS (Chicago, Ill) and SAS (Cary, NC).

Results: Domain-specific correlations of the new measure with OHIP-14 were moderate to high 0.5-0.8 (all $p<0.001$). The reliability coefficient was high in all domains ($\alpha >0.7$). Sensitivity and specificity analyses showed that the new question in the 3 domains have a range of good to excellent discriminative ability in measuring the impact of oral problems on quality of life in comparison to the OHIP-14 questions within the same domain. In the psychological domain, the sensitivity was 86% (95% CI: 73% - 94%), in the social domain it was 86% (95% CI: 77% - 92%) while in the physical domain, it was 67% (95% CI: 56% - 76%). Those who presented with pain had an odds of it influencing their quality of life that was 21 times the odds for those presenting for routine visit ($p=0.006$).

Conclusion: The new oral health related quality of life measure has an acceptable validity and reliability in testing the impact of oral health on quality of life and is a valid tool in clinical settings.

Dedication

To everyone, who provided me with advice or support and became a mentor or a friend. I doubt that I will ever be able to convey my appreciation fully to all, but I owe my eternal gratitude to all.

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INTRODUCTION

Oral diseases have a substantial impact on the well-being of individuals and populations because of several special features of the structure and function of the mouth. From an early age, the mouth and face have powerful influences on psychological well-being and social interactions. In addition, the ability of dental decay to cause excruciating pain has been recognized since ancient times, and toothache continues to be a highly prevalent and disabling condition, even in an era of modern dental care. Although conditions such as dental decay, gum disease, dry mouth and tooth loss have much more subtle impacts on well-being, they are highly prevalent and hence contribute to a substantial burden of oral disease.

A positive relationship between dental problems or dental treatment and quality of life is well-established and reported in many studies: the pattern of missing teeth shows a higher impact on quality of life than the number of missing teeth [1]. Periodontal disease has a significant impact on quality of life since it interferes with the ability to chew and talk [2]. Implant therapy has a significant impact on the quality of life compared to conventional denture as treatment of missing occlusal units [3]. In addition, the effects of different oral conditions on the quality of life among geriatric patients have been investigated in many studies [4-6].

The term Oral Health Related Quality of Life (OHRQoL) has been defined as the extent to which oral disorders affect functioning and psychological well-being [7]. In comparison to the five general domains for measuring health-related quality of life [8], in

dentistry, the three dimensions of OHRQoL have been identified and used to measure OHRQoL: perception of well-being; physical symptoms; and physical function [9]. Subdivisions within these domains have been evaluated and described in the literature. Examples of these include: eating and chewing; presence or absence of pain or discomfort; the social aspects of appearance; speaking and communicating; satisfaction with the biologic health of the oral cavity; the psychological burdens associated with poor esthetics and function; and the inability to perform daily work.

In clinical practice, the areas or domains that may be of greatest importance to patients regarding their outcome of care are esthetics (appearance); comfort (physical and psychological); function (speech and eating); and the impact of these on their daily lives. To ensure the best quality of service to the patient, knowledge about the patient's self-perception of oral health status and expectations for treatment outcomes is important.

BACKGROUND

Oral Health-Related Quality of Life (OHRQoL)

The concept of oral health-related quality of life is based on the idea that oral health is an integral part of general health and that oral health contributes to overall health-related quality of life [8]. It has been noted that the oral cavity contributes to overall health-related quality of life through its role in protecting from systemic infection, the functions of swallowing, chewing, communication, and in contributing to facial appearance [10,11]. It has also been determined that the oral impact on quality of life can be important for both the individual and society [12,13]. This derives from the approach that when oral health is compromised, overall health and quality of life may be diminished.

An early definition by Locker of oral health-related quality of life was concerned with the functioning of the oral cavity and with subjectively perceived symptoms, such as pain and discomfort [14]. A later definition offered by the same author was both more specific and more comprehensive: "when talking about oral health, our focus is not on the oral cavity itself but on the individual and the way in which oral disorders, diseases and conditions threaten health, well-being and quality of life" [15]. In later contributions, oral health-related quality of life was defined in relatively simple terms as the extent to which oral disorders affect functioning and psychosocial well-being [7] and the symptoms and functional and psychosocial impacts that emanate from oral diseases and disorders [16].

Kressin [17] defined oral health-related quality of life as a broad conception of health, encompassing traditional definitions of health, as well as an individual's subjective impact of health on well-being and functioning in everyday life, and as the impact of oral conditions on daily functioning. Clearly, some of these definitions suggest that health-related quality of life equate with health, while others imply that it is something more than health, encompassing broader dimensions of human experience.

Domains

The increased awareness of the importance of quality of life in the field of dentistry and the need to evaluate the effect of oral problems on the quality of life have contributed to the development of numerous oral health-related quality of life instruments. Oral health-related quality of life instruments are questionnaires composed of a number of items or questions. These items are contained within a number of domains or dimensions. A domain or dimension refers to the area of behavior or experience that one is attempting to measure.

The concept of oral health-related quality of life is deceptive and multidimensional without clear distinctions between its different components [15]. As oral health-related quality of life is a part of health-related quality of life, the same domains identified as most appropriate for measuring the effects of health on quality of life have been used to measure oral health-related quality of life. Five domains are conceptualized through the literature: opportunity/resilience, health perception, functional status, impairments/diseases, and duration of life (survival) [8]. The effect of most perceived

signs and symptoms on individuals' oral health-related quality of life is not fully understood. Many indicators of perceived oral health and perceived treatment needs have been used to evaluate an individual's satisfaction with oral health and appearance, which are related to self-confidence and social interaction [8]. Few studies have examined the opportunity/resilience domain in relation to oral health-related quality of life.

The interaction between two or more domains in any single measure was reported in many studies. For example, having a few remaining teeth (illness domain) is associated with more impairment (functional domain) than being totally edentulous. Sensory perception (physical domain) declines in the presence of complete denture (illness domain), affecting food acceptability and potentially dietary intake (opportunity domain) [18].

Oral Health-Related Quality of Life (OHRQoL) Measures

Different indices have been constructed in medicine as well as dentistry to measure quality of life, the outcome of clinical trials comparing the efficacy of different treatments, evaluating the cost-utility and cost-effectiveness of health-care programs, assisting quality assurance, and for the marketing and regulation of drugs [19].

The fact that oral conditions affect the full scope of health, including patients' functioning and well-being [20], limited the use of many dental clinical assessment indices i.e.: DMF, Community Periodontal Index of Treatment Need (CPITN) [21], in measuring the effects of oral conditions on quality of life because they measure the end-point of the disease. Hence, the need for specified oral health-related quality of life measures has emerged within the last twenty-five years. In dentistry, measures for oral health-related quality of life have been used in surveys related to various issues of dental care in geriatric, special needs and implant populations [22-25]. Their use in clinical practice and clinical decision-making has yet to be reported.

In order to develop oral health-related quality of life measures, a multidimensional model of oral health was developed and validated by Gilbert, et al. [26] by adapting Locker's conceptual model for measuring oral health status [27], which in turn was adapted to the oral health context by World Health Organization [28] (Figure.1). This model postulates a sequential causal process comprising five dimensions of oral health and oral health-related quality of life. These dimensions are oral disease and tissue damage, oral pain and discomfort, oral functional limitation, oral disadvantage, and self-rated oral health.

Studies were conducted to identify the most important domains in measuring oral health-related quality of life. Bagewitz, et al. [9] found three dimensions of oral impact on daily performance: physical and social disability; psychological discomfort and disability; and functional limitation and physical pain. These match the domains used in oral health impact profile (OHIP) [29] and oral impact on daily performance (OIDP) [30]. A framework with four primary dimensions was hypothesized during validation of a brief measure for oral quality of life [31]. These dimensions are physical function, psychosocial functioning (with three sub-dimensions: role function, distress, and worry), impairment or disease, and perceptions. The dimensions derived from the OHIP-G (German national study) indicated that psychosocial impact, orofacial pain, oral functions, and appearance might serve as a parsimonious set of dimensions for OHRQoL in general [32].

Frequently Used Oral Health-Related Quality of Life Instruments

Along with several clinician-based assessments [33,34], numerous patient-based measures of oral quality of life [17,23,29,35] have been developed and evaluated (Table.1). These measures vary in their theoretical bases and in their sensitivity to clinical changes. Subject-based measures have shown to be more informative of how oral diseases affect the daily life of individual and population than are the clinical-based measures [23,29,36]. Table 1 presents a list of currently available oral specific health status measures as listed by Allen in a chorological order [19].

1. Social Impact of Dental Disease

As one of the first socio-dental indicators, this measure was developed in the early 1980s [37]. Three perspectives were adopted while developing this measure: physical (which is measured from a dentist perspective), social (which is measured from a social perspective in terms of task and role performance as a base), and psychological (which is measured from individual's general satisfaction and happiness). Four categories of impact were the basis for this measure development: eating restrictions; communication restrictions; pain and discomfort; and esthetic dissatisfaction. This measure aims to detect the impact of the dental problems on the quality of life without any attempt to measure the severity of the impact [38]. The impact of oral problems on health-related quality of life is calculated by assigning an overall score to indicate the extent of the impact, which is the summation of each statement score.

2. Geriatric and General Oral Health Assessment Index

Assessment of the effectiveness of dental treatment on individuals and populations of elders was the purpose of developing this 12-item measure of patient's self-reported oral functional problems and psychosocial impacts associated with oral diseases [23]. Three hypothesized dimensions: physical function; psycho-social functions; and pain and discomfort are intended to be measured by this measure. The impact of oral problems on health-related quality of life is calculated by assigning an overall score to indicate the extent of the impact, which is the summation of each statement score.

3. Oral Health Related Quality of Life Measure

Oral Health Related Quality of Life is an early measure developed in 1991 as part of the Veteran's Administration longitudinal health survey to assess the impact of oral conditions on health-related quality of life (HRQOL) [17]. Its three items assess how problems with teeth or gums might influence daily activities, social interactions, or avoidance of conversations. It was also an early tool used to evaluate the importance of comfort and health for elderly or demented persons [39].

4. Dental Impact Profile

The Dental Impact Profile is a 25-item, self-reported instrument developed to measure how quality of life is affected by oral health and oral structures [40]. It evaluates patients' perception toward important events as positive or negative effect covering four sub-scales: eating, health and well-being, social relations and romance. The overall score is the proportion of the positive or the negative responses among all items.

5. Oral Health Impact Profile

The Oral Health Impact Profile (OHIP) was developed to examine the effects of individuals' oral problems on their daily lives [29] and to ascertain the difference between individuals' subjective perceptions of having oral problems, and the objective information derived from clinical examinations [41]. It is a self-perceived oral health measure intended to assess the social and psychological impacts of oral disorders, that is, the dysfunction, discomfort and disability caused by these conditions. The purpose of the measure is broad, assessing priorities of care by documenting social impact among

individuals and groups, understanding oral health behaviors, evaluating dental treatment and providing information for promoting good oral health [29]. Validation of the OHIP as a measure of oral health status has been provided by numerous investigators; scores distinguish between the dentate and edentulous [3] and show moderate correlations with a wide range of clinical indicators and self-perceived oral conditions, such as xerostomia [42].

The original OHIP-49 was developed in Australia by Slade and Spencer [29]. It contains 49 questions that capture seven conceptually formulated dimensions based on Locker's theoretical model of oral health [27] which in turn was adapted from the World Health Organization's framework used to classify impairments, disabilities and handicaps. Slade developed the OHIP-14 as a shorter version of the OHIP-49, for situations where the use of 49 questions is less likely to be effective [43]. The Oral Health Impact Profile for edentulous (OHIP- EDENT) is also a modified, shortened, 20 items version of the original 49-item scale. This modified version may be more appropriate for use in edentulous patients than the short version OHIP-14 since it has shown to be comparable with the full 49-item version [44]. This measure has been developed by grading the impact of the outcome. It measures the frequency, by summing the reported negative impact across the statements, and the severity of oral problems, by using statements weight on functional and psychological well-being.

6. Subjective Oral Health Status Indicators

A collection of indicators was developed to describe functional, social and psychological outcomes of oral disorders and conditions, composed of four indices and one scale. The indices are a six-item index of chewing capacity, a three-item index of ability to talk clearly, a nine-item index of oral and facial pain symptoms and a ten-item index comprising other oral symptoms. The scale of social and psychological impact of oral problems is divided into four subscales: a three-item scale for eating problems, a four-item scale for communication and social relation, a six-item scale for limitation in daily activities and a two-item scale for worry and concern about oral health [45]. The impact of oral problems on health-related quality of life is calculated by assigning an overall score to indicate the extent of the impact, which is the summation of each statement score.

7. Dental Impact on Daily Living

The Dental Impact on Daily Living (DIDL) is a 36-item socio-dental measure which assesses five domains of quality of life: comfort, pain, appearance, performance, and eating restrictions [35]. It measures the frequency and the severity of oral problems on functional and psychological well-being. Impacts were coded +1 for the positive impact, 0 for not totally negative impact and -1 for negative impact. Weight for each dimension was calculated on an individual basis by dividing the summation of each dimension scores by total scale score. Over all DIDL score is the summation of all weighted dimension scores.

8. Oral Impact on Daily Performances

The Oral Impact on Daily Performances (OIDP) measure was developed in the early 1990's to assess overall population dental needs in conjunction with other measures to facilitate the planning of dental services[46]. Its nine items measure the behavioral impacts of oral disorders ignoring their effects on physical, psychological and social performances. In assessing the validity of the OIDP, associations were examined with clinical oral health indicators, such as the number of missing teeth. Its validity was assessed by means of the associations between OIDP scores and subjects' "overall perception of trouble from oral conditions". It was developed by grading the impact of the outcome (hierarchy of outcomes)[30]. It measures the frequency and the severity of oral problems on functional and psychological well-being by multiplying the frequency and severity scores for each item then summing them.

9. Oral Health-Related Quality of Life Inventory

Oral Health-Related Quality of Life (OH-QoL) Inventory is a 15-item dental specific measure that assesses individual's satisfaction with oral health and functional status [47]. It is intended to complement the existing oral health-related quality of life measures by adding subjective well-being statements.

Effects of Oral Problems on Quality of Life

The U.S. Public Health Service classifies oral diseases into six major categories: dental and periodontal infections; mucosal disorders, oral and pharyngeal cancer; developmental disorders; injuries; and certain chronic and disabling conditions including orofacial pain. Oral diseases such as caries or periodontal disease are pervasive and their consequences are not just physically disabling. They seriously impair quality of life in a large number of individuals affecting many aspects of life, including oral function, appearance and interpersonal relationships by creating economic, social and psychological problems [48].

Epidemiological studies have indicated that factors including gender, age, tooth retention [49], clinical condition, dental attendance, socio-economic status, cultural background, dental anxiety [50], and smoking may influence oral health-related quality of life. When evaluating oral health-related quality of life in the elderly, a study found a consistent correlation between oral health-related quality of life and somatization [51]. There are also indications that significant variations in oral health-related quality of life exist between socioeconomic groups; low educational level has an independent negative impact on oral health-related quality of life in older people, which is not explained by differences in income or denture wearing between educational groups [52].

Several researchers [53,54] believe that having poor oral health status or oral disease might impact quality of life. However, only certain issues were addressed in these articles; for example, the self-awareness of needing dental treatment or self-evaluation of being orally healthy. However, only one study found that the relationship between oral

health and living quality is weak [55]. Independently of sex and socioeconomic inequalities in oral health, OHIP-14 scores were significantly associated with oral health status indicators (dental caries, tooth loss and periodontal status) [56].

Chewing ability was related to oral health- related quality of life and general health, indicating the importance of oral health to general well-being [57]. Tooth loss impacts eating and speaking. This impact is somehow related to the number of remaining teeth as stated in a study that 25% of an elderly sample reported a severe impact on their life [58]. Patterns of the missing occlusal units are likely to be related to oral health-related quality of life from impairment in subjects with shortened dental arch subjects, with the presence of first molar contact having a particularly important positive role [59]. Examining the relationship between numbers of pairs of occluded teeth and oral health-related quality of life was the focus of some studies [60,61], which showed the number of pairs of occluding teeth is more relevant than the number of remaining teeth in affecting the chewing ability in a group of elderly subjects [5].

A study to measure the effect of xerostomia on day-to-day life showed that xerostomia has marked and consistent negative effects on the quality of life of those subjects [42]. Numerous studies have examined the impact of oral health status on OHRQoL in the elderly, focusing on the effects of general dental condition and oral dryness. Oral dryness and fewer numbers of remaining teeth were found to be associated with poorer oral health-related quality of life in a community of independently living elderly [62,63]. However, a study by Locker on a sample of institutionalized elders identified a

significant impact of oral dryness, but not tooth loss, on the oral health-related quality of life [64].

Effects of Dental Treatment on Quality of Life

Many dental interventions have been associated with improved oral health-related quality of life including implant-retained dental prostheses [65-68], conventional fixed prosthodontic [69,70], third molar removal [71], orthodontic treatment [72], orthognathic surgery [73,74], occlusal splints in therapy for temporomandibular disorder [75], teeth whitening [76] and surgery for oral cancer [77].

Third molar removal surgery has shown a significant effect on the oral health-related quality of life both preoperatively and postoperatively [78]. Implant therapy had a positive effect on the oral health-related quality of life [3]. Implant treatment provides significant short-term improvement over conventional treatment in oral health-related quality of life [68]. Mandibular over-dentures retained by two implants provide elderly patients with better oral health-related quality of life [69].

Although periodontal diseases are not life threatening, they can affect daily activities such as the ability to eat, speak and socialize, therefore impacting the quality of life [2]. A study comparing the effects of different periodontal treatment modalities on oral health-related quality of life has indicated that patient perceptions during the immediate post-operative period were significantly better in the non-surgical group when compared with the group that had surgery [79].

Subjects with temporomandibular disorders (TMD) have significantly diminished oral health-related quality of life. Subjects with pain-associated conditions have shown more

impaired oral health-related quality of life than subjects with no pain associated conditions [80]. Another study reported the increase of impairment in functional limitation domain among TMD patients [81]. A further study stated that orofacial pain had a negative impact on the quality of life of individuals with TMD in both men and women. The presence of muscular disorders and osteoarthritis was related to greater impact but not observed for diagnoses of disc displacement. A correlation between severity of TMD and decreased quality of life was clear. [82]

Orthodontic treatment has shown different effects on oral health-related quality of life during the first 6 months of treatment with first week and first month as the greatest change periods during the treatment [83,84]. Deterioration of general oral health-related quality of life was reported during the treatment compared with pretreatment. However, emotional well-being observed to be better during treatment compared with pretreatment. A study by Hassan [85] reported an association between the need for orthodontic treatment and some functional and social disability among a sample of adolescents.

PURPOSES AND HYPOTHESES

In this study, we validated a new four-question survey questionnaire by testing it against one of the most widely used of the oral health-related quality of life survey instruments, the OHIP-14, to develop an OHRQoL instrument that can be used with efficiency and accuracy in clinical practice to measure the patients' self-perception toward oral health treatment outcomes. In addition, we examined the relationship between subjects' self-perception toward the impact of oral health on the quality of life and the patients' chief complaint.

We hypothesize that the proposed four-question survey instrument is as valid an instrument for measuring oral health related quality of life, as is the pre-existing OHIP-14. We also hypothesized that patients' self-perception of the impact of their oral conditions on their quality of life is related to their chief complaints.

RESEARCH DESIGN AND METHODS

This cross-sectional study consisted of a health impact survey and data extracted from the electronic health record (axiUm) at Tufts University School of Dental Medicine (TUSDM), Boston, MA. The study was approved by the Tufts University Health Science Campus Institutional Review Board (IRB), Boston, MA.

Participants in the study were adult, aged 18 years or older, attending pre-doctoral clinics at TUSDM. Subjects were recruited at their first visit for screening.

Each subject signed a consent form, a research authorization form for limited release of protected health information form and answered the study questionnaire. Complete dental assessment for each subject was done by the subject's assigned dental student under supervision of dental school faculty members.

Oral Health Impact Survey

The survey questionnaire is an 18-item, oral health-related quality of life (OHRQoL) instrument, consisting of the Oral Health Impact Profile 14 (OHIP-14) and four randomly distributed new questions, which are under-investigation. The four questions were invented after reviewing the literature and determining which domains are the most important to be evaluated during oral health-related quality of life and outcome assessment evaluation.

The four questions to be tested are:

1. Have you been bothered by the comfort of your mouth, tongue, teeth or denture? (Psychological domain including perception and comfort).
2. Have you had a problem with speech or chewing your food because of problems with your teeth or denture? (Physical domain).
3. Have you had to make changes to your behavior based upon problems with your face, teeth or denture? (Social domain).
4. Have you been concerned with the appearance of your face, teeth or denture? (Esthetic domain).

The items were grouped into three domains: physical or functional domain, psychological or behavioral domain, and social domain including appearance. Each item was designed to measure the frequency of an event, as applied to the teeth, mouth, or denture. Responses were given on a five-point Likert scale ("Very often", "Fairly often", "Occasionally", "Hardly ever", "Never", or "Don't know"). Anumerical value was assigned to each of the answers: very often = 4, fairly often = 3, occasionally = 2, hardly ever = 1, and never = 0. Subjects who answered one or more questions with "Don't know" were excluded from the study.

Prevalence of impact of oral health on quality of life was measured as the percentage of people reporting one or more items 'fairly often' or 'very often', and the severity by summing all the ordinal responses and could range from 0 to 56 for the OHIP-14

responses and from 0 to 16 for the new questions. Higher scores indicate worse OHRQoL. Age, gender, and educational background were collected to test their potential associations with both outcome and explanatory variables.

Data Extraction

Utilizing subjects' clinical data from the electronic health record system (axiUm) at TUSDM, data about subjects' chief complaint were collected.

Statistical Analysis

All statistical tests were two-sided and p-values less than 0.05 were considered statistically significant. PASW statistics 18.0 (SPSS, inc., Chicago, IL) and SAS (Cary, NC) were used for all analyses. Data analyses included descriptive statistics and multivariate analyses.

Sample size:

The sample size was calculated based on data from a previously conducted pilot study using the same project methodology. The program nQuery Advisor (Version 7.0) was used to assess the anticipated precision of the correlation between the new and old questions, given 100 subjects would be recruited. Assuming a correlation of .911, which was observed in the pilot study, a half width of 95% confidence interval would be .082.

Statistics:

Counts and proportions were calculated for age, gender and education background. Descriptive statistics for subjects' chief complaints and responses were calculated.

Age, gender and educational background were considered potential confounders for the presence of the perceived impact of oral problems on the quality of life among different domains. So, independent associations between the presence of the impact of oral problems on the quality of life in each domain and our potential confounders were tested using generalized estimating equations (GEE).

Hypotheses testing

To test the hypothesis that the new four-question survey instrument is as valid instrument for measuring oral health-related quality of life as is the pre-existing OHIP-14, multitrait-multimethod (MTMM) scaling analysis was used to validate and test the reliability of the new instrument. The procedure involved examining item frequencies and descriptive statistics (e.g., mean, standard deviation, and variance); correlations among scales; and internal consistency estimates.

Percentage agreement analysis using two-way 5x5 contingency tables and Spearman's correlation were conducted to determine if the four new questions cluster with the components of their respective domains from the OHIP-14. Inter-item reliability and internal consistency were measured using Cronbach's alpha statistics. A value of (α = 0.80) or higher was considered be reliable.

Each question's responses were coded into binary data using a conceptual model that defines subjects' response with "very often", "fairly often" and "occasionally" as an

impact. Then, sensitivity and specificity of each of the new questions were calculated and odds ratios were reported for each question.

Logistic regression was used to measure the association between the presence of the impact of oral health on quality of life and subjects' chief complaints while controlling for confounders.

RESULTS

One hundred and fifteen (N=115) subjects signed the consent form, filled the survey and underwent the clinical examination. 13 subjects were excluded because of answering 1 or 2 questions with “don’t know”.

Females represented a larger proportion of the sample (n = 55; 53.9%) than males (n = 47; 46.1%). The mean age was 45.47 years and the standard deviation was 16.95 years. The age distribution was bimodal; the median was 52 years. The response rate to the education level question was 93.1% since 7 subjects had this information missing. The most common education level was college graduate (n = 40; 39.2%), followed by some college (n = 17; 16.7%), Master degree holder (n = 16; 15.7%), high school graduate (n = 14; 13.7%), subjects with doctorate degree (n = 5; 4.9%) and 3 subjects reported their educational status as “other” (n = 3; 2.9%) (Table.2).

In all domains, “never” was the highest prevalence response for all questions, while “very often” showed the lowest prevalence (Tables.3-6, Figures.2-5).

Prevalence of impact was high in the concern about appearance, moderate in both physical and psychological domains and low in the social domain. A moderate number (52%) of the subjects reported concern about their appearance and 40% of the subjects reported physical limitation related to problems with mouth, tongue, teeth and dentures. Psychological limitation was reported by 38.2% of the subjects while social domain impact showed only 23.5% impact (Table.7).

The impact showed to be severe in 5 subjects (4.9%), moderate in 19 subjects (18.6%) and mild in 78 subjects (76.5%) using OHIP-14 as indicator. Using the new instrument, 9 subjects (8.8%) showed a severe impact, 19 subjects (18.6%) with moderate impact and 74 subjects (72.5%) with mild impact (Table.8).

The highest percentage of the sample (n=55; 54%) was visiting the dental school seeking restorative treatment (filling or replacement of missing occlusal units); pain was the second reason for visiting the dental school (n=27; 26.3%), while only (n=20; 19.7%) of the sample presented for regular check up (Table.9, Figure.6).

In the generalized estimating equation model predicting the effect of age, gender and educational level on oral health-related impact perception, all were statistically significant. Females in general showed to have more impact compared to males ($p < 0.0001$) in all domains.

In the psychological domain, high school and some college female graduates showed a higher possibility of impact compared to the females with doctorates with odds of 5.2 ($p= 0.0012$) and 3.8 ($p= 0.0044$) respectively (Table.10).

In both social and physical domains, while females showed no significant difference between different educational categories, males showed a significant difference between high school, college graduates and doctorates ($p < 0.0001$) (Tables.11,12).

In regard to the appearance, there was no significant difference between females and males. Within the female group, high school and college graduates showed higher impact compared to the female doctorates ($p < 0.0001$) (Table.13).

Validity of the New Instrument against Oral Health Impact Profile 14

Three out of the four new questions were tested against the OHIP-14 questions for validity purposes. The fourth question about concern and perception of appearance presents a forth domain we intended to test but there was no corresponding domain in the OHIP-14.

Within the psychological domain, the new question, "Have you been bothered by the comfort of your mouth, tongue, teeth or denture?" showed a moderate agreement with the psychological domain's questions from OHIP-14. This agreement was the highest with the question about feeling tense because of a problem with mouth, tongue, teeth or denture with 65% agreement and Spearman correlation of 0.76 ($p<0.001$) and the lowest with the question about being embarrassed because of a problem with mouth, tongue, teeth or denture with 43% agreement and Spearman correlation of 0.51 ($p<0.001$). The agreement with the question about difficulty relaxing because of a problem with mouth, tongue, teeth or denture had the second best agreement with 62% agreement and Spearman correlation of 0.70 ($p<0.001$) followed by life in general is being less satisfactory with 59% agreement and Spearman correlation of 0.66 ($p<0.001$), painful aching in the mouth had 57% ($p<0.001$) agreement and Spearman correlation of 0.62 ($p<0.001$), while being uncomfortable with eating 50% agreement and Spearman correlation of 0.62 ($p<0.001$), and self-conscious 45% agreement and Spearman correlation of 0.58 ($p<0.001$) (Table.14, Figure.7a-b).

Testing for agreement between the new question "Have you had to make changes to your behavior based upon the health of your mouth or teeth?" and the corresponding questions from OHIP-14 in the social domain showed strong agreement that the new question agree by 69% and a Spearman correlation of 0.69 ($p<0.001$) with the question about difficulty doing regular job because of a problem with mouth, tongue, teeth or denture. Interrupting meals has an agreement of 67% and correlation of 0.72 ($p<0.001$), the question about irritability because of problem with mouth, tongue, teeth or denture has an agreement of 66% and correlation of 0.63 ($p<0.001$), total inability to function has an agreement of 64% and correlation of 0.61 ($p<0.001$) and diet being unsatisfactory has an agreement of 62% and a correlation of 0.64 ($p<0.001$) (Table.15, Figure.8a-b).

The question "Have you had a problem with speech or chewing your food because of problems with your teeth or denture?" showed less than a moderate agreement with the physical domain questions from OHIP-14 questionnaire. It has only 40% agreement with the question about trouble pronouncing words and a correlation of 0.40 ($p<0.001$). It showed a 40% agreement with deterioration of sense of taste due to problem in mouth, tongue, teeth or denture and a correlation of 0.39 ($p<0.001$) (Table.16, Figure9).

Reliability:

Inter-item reliability Cronbach's alpha was high ($\alpha = 0.93$, Mean= 1.2, SD= 1.19), which indicates high reliability of the questions in the psychological domain. Internal consistency showed to be high in this domain with Cronbach's alpha (α=0.91, Mean=

0.8, SD= 1.14). A lower internal consistency was seen within the questions in this domain with Cronbach's alpha (α= 0.70, Mean= 1.52, SD = 1.45) (table.17).

Diagnostic Ability

The question "Have you been bothered by the comfort of your mouth, tongue, teeth or denture?" had a good to excellent discriminative ability against the OHIP-14 questions in measuring the impact of oral health on quality of life within the psychological domain. The highest sensitivity, 86% (95% CI: 74-93%), was when compared to the question about being painful aching because of a problem in the mouth, tongue, teeth or denture and for being uncomfortable while eating, 86% (95% CI: 73-94%), while the lowest 76% (95% CI: 63-86%) was to detect the embarrassment due to an oral problem. Against the questions about difficulty relaxing or feel tense because of problem with mouth, tongue, teeth or denture, the new question showed 85% sensitivity (95% CI: 73-93%) and slightly lower sensitivity against life is less satisfactory for subjects with problems in the mouth, tongue, teeth or denture 82% (95% CI: 75-99%), followed by being self-conscious because of oral problems with 78% (95% CI: 65-88%).

However, specificity was modest with 57% (95% CI: 42-71%) ability to detect true negative responses in relation to question about being self-conscious, embarrassment because of oral problems 59% (95% CI: 41-71%), being uncomfortable with food was 62% (95% CI: 47-74%), 69% for painful aching (95% CI: 53-81%), difficulty relaxing 75% (95% CI: 73-93%), and feeling tense 85% (95% CI: 68-94%). While the highest

specificity 93% (95% CI: 75-99%) was against the question about the life being less satisfactory because of oral problem (table.18).

In the social domain, the new question concerned with change in behavior because of problem with the mouth, tongue, teeth or denture showed an excellent sensitivity in comparison to the OHIP-14 social domain questions. It ranged from 81 to 86%. The new question's discriminative ability was 86% (95% CI: 76-92%) against the questions about diet being unsatisfactory, meals being interrupted and irritability due to oral problems (95% CI: 76-92%). An 82% (95% CI: 73-89%) was for inability to function and 81% (95% CI: 72-88%) for difficulties doing regular job.

Specificity was good for all the questions in the social domain. It was 100% (95% CI: 52-100%) against questions about inability to function and having difficulties doing regular job. A 75% (95% CI: 47-92%) against the question evaluating the presence of irritability due to oral problems and 67% (95% CI: 41-86%) for the question about diet being unsatisfactory. The least, 63% (95% CI: 39-83%), for the question about meals interruption (table.19).

The new physical domain showed an acceptable sensitivity compared to the physical domain's questions from OHIP-14. A 66% (95% CI: 55-75%) was the sensitivity to detect difficulties with pronunciation and 67% (95% CI: 56-76%) was for change of taste. On the other hand, the ability to detect true negative responses was excellent to both

questions about pronunciation difficulties and change of taste 100% (95% CI: 63-100%) and 92% (95% CI: 60-99%), respectively (table.20).

The relationship between subject's chief complaint and the perceived impact of oral problems on quality of life

The relationship between the chief complaint and the perceived impact of oral health on quality of life is assessed using logistic regression analysis. All chief complaint types showed a positive correlation with the presence of psychological impact but only pain is showed as a significant predictor for the impact on psychology with 21 times the odds of having the impact, compared to subjects who visited for check-up (p=0.006).

In the social domain, all the chief complaints showed almost the same level of non-significant impact.

Measuring for the relationship in the physical domain, pain showed higher odds of disability that is 13.5 times that for regular visit's subjects, while needs for restoration had non-significant impact compared to the regular check-up (p=0.001).

Appearance was of more concern among subjects who presented with pain or restoration compared to the ones who presented for the regular check-up. Subjects with pain have 8 times the odd of having concerns about their appearance (p=0.003) while subjects sought restoration have 5.2 the odd of having the concern about the appearance (p=0.008).

DISCUSSION

We adapted the World Health Organization's model [86] and Locker's model [27] for health-related quality of life to adopt a new model for measuring oral health-related quality of life. We hypothesized a framework with four primary dimensions: 1) physical limitation including the impairment and disease; 2) psychosocial limitation (with three sub-dimensions: role function, distress, and worry); 3) social interaction including self-perceptions; and 4) esthetic and concern about appearance. We chose to list concern about appearance as a distinct domain and not to include it in the psychological domain as in the original OHIP- 49 instrument because esthetic or appearance is a two-dimension perception, psychologically by the person and a perception of others.

Multiple approaches may be used to produce short-form measures of health-related quality of life, including item impact studies, factor analysis, and stepwise regression analysis approaches, the approach used to reduce the OHIP-49 instrument to OHIP-14 [43]. In this study, we chose to use the multitrait-multimethod (MTMM) scaling analysis [87] because we were testing a new instrument validity and reliability against a currently valid and reliable instrument OHIP-14.

The sample was randomly collected from patients attending the outpatient clinics at the dental school. Hence, the data collected was limited to a group with access to dental care and cannot necessarily be generalized to the entire population. The mean (SD) age of our sample was 45 (16.9) years and the median was 52 years, which is similar to other work in this field that showed a better OHIP scores with increasing age [49]. The educational

level showed an impact on quality of life, which coincide with the results from a previous study that found that low educational level has an independent negative impact on OHRQoL in older people [52]. The socioeconomic information was not collected although it might have an effect on the result.

Both measures presented similar results in measuring the severity of the impact. Women generally reported poorer OHRQoL compared to men for both OHIP-14 and the new measure, which is consistent with previous findings [88]. The lower the educational level, the more impact on quality of life was shown in all domains.

Most of the subjects were visiting the dental school for restorative reasons like anterior restorations and replacing missing units and this might explain why concerns about appearance showed a higher prevalence among different oral health-related quality of life domains.

Validation of the new instrument:

Convergent validity [89] was assessed by testing the agreement and the correlation between the new instrument and the OHIP-14 questionnaire. The new measure has shown an acceptable validity among all domains. In the psychological domain, the new question showed moderate correlation with the OHIP-14 questions about feeling tense, difficulty relaxing and loss of life satisfaction and showed the ability to replace this question. The correlation with the questions about discomfort with food and painful aching was modest and it might be justified by the fact that these questions were originally part of the

physical pain domain and got assigned to the psychological domain. The weak correlation to the questions about embarrassment or being self-conscious because of oral problems would lower the possibility of excluding these specific questions from the new instrument. Further investigations might be needed to see if the subjects have misinterpreted the word “bothered” used in the new questions. Hence, it didn’t reflect their responses to the later questions.

Change in behavior, which is the new question in the social domain, has strong agreement ability with the answers about difficulty handling job, meal interruption and feelings of irritability and a moderate correlation with questions about inability to function and diet being unsatisfactory. Hence, the new question might be able to replace the OHIP-14 questions in the social domain.

Although the new question in the physical domain is asking about difficulty with speech, it was weakly correlated to the OHIP-14 question about pronunciation difficulties. The new physical question that specifies speech and chewing difficulties showed a weak correlation with the OHIP-14 question about change in taste, which is a different problem with the mouth and cannot replace it.

Reliability:

A reliability of 0.70 is advocated as the standard appropriate for the clinical trials and 0.90 as a minimum standard for the measurement designed at the individual level [90].

The high internal consistency showed among the new instrument questions proved its reliability in measuring oral health-related quality of life.

Diagnostic ability:

Testing the ability of the new questions to detect the true positive and the true negative answers showed a high discriminative ability of these questions. The new question in each domain had shown high sensitivity and specificity while only moderate correlation was detected in most of the domains. This can be justified by the statistical methods used to test each of the correlation and the diagnostic ability. For the correlation the analysis was done using the 5-point Likert scale and tests each possible response against the same exact response of the OHIP-14 question while for the sensitivity and specificity, multiple responses were combined to achieve the binary data needed for the analysis.

The associations between quality of life and clinical oral status are weak but some were significant. Pain was a significant predictor for psychological impact and physical limitation related to oral problems among subjects. Appearance was of a significant importance among all subjects.

Issues with oral health-related quality of life measures (Instrument Weight):

A further consideration in measuring oral health-related quality of life is the use of item weights. The use of weights could improve the responsiveness of a measure, by allowing the full impact of a designator to be portrayed [91]. However, it has been suggested that weighting of statements doesn't improve the performance of a measure consisting of

more than 40 items [92]. Weights increase the complexity of scoring, and this is likely to discourage clinician from using the measure. Also, it has been suggested in some studies that weighting provided only limited benefits as compared to un-weighted studies [93-95].

CONCLUSION

The new oral health related quality of life measure has an acceptable validity and reliability in testing the impact of oral health on quality of life and is a valid tool in clinical settings.

However, more work should be conducted to overcome and correct for the limitation of the project. The instrument should be tested on a larger, more variable sample to reduce the possibility that the results are solely due chance. In order to use the instrument in clinical settings, it should be tested in both pre-treatment and post-treatment settings to examine its ability to test the difference in between. Moreover, testing the new instrument against other valid oral health-related quality of life instruments and possibly other health related instrument like SF-36 would provide more information about its validity.

TABLES

Table 1: Examples of currently available oral specific health status measures

Authors	Name of the Measure
Cushing, et al., 1986	Social Impact of Dental Disease
Atchison and Dolan, 1990	Geriatric Oral Health Assessment Index
Kressin N, 1991	Oral Health Related Quality of Life Measure
Strauss and Hunt, 1993	Dental Impact Profile
Slade and Spencer, 1994	Oral Health Impact Profile
Locker and Miller, 1994	Subjective Oral Health Status Indicators
Leao and Sheiham, 1996	Dental Impact on Daily Living
Adulyanon and Sheiham, 1997	Oral Impacts on Daily Performances
McGrath and Bedi, 2000	OH-QoL Inventory

Table 2: Sample Characteristics

	Frequency	Percentage
Gender		
Female	55	53.9
Male	47	46.1
Total	102	100
Educational level		
High school	14	13.7
Some college	17	16.7
College graduate	40	39.2
Master degree	16	15.7
Doctor/doctorate	5	4.9
Other	3	2.9
Total	95*	93.1

* Data for 7 subjects were missing.

Table 3: Frequency of psychological domain responses

	Response Count n (%)				
	Never	**Hardly ever**	**Occasionally**	**Fairly often**	**Very often**
Bothered by comfort (New question)	38 (37.3)	25 (24.5)	26 (25.5)	7 (6.9)	6 (5.9)
Difficult to Relax	35 (34.3)	27 (26.5)	30 (29.4)	3 (2.9)	7 (6.9)
Painful aching	27 (26.5)	30 (29.4)	34 (33.3)	8 (7.8)	3 (2.9)
Embarrassment	40 (39.2)	18 (17.6)	19 (18.6)	10 (9.8)	15 (14.7)
Self-conscious	37 (36.3)	18 (17.6)	23 (22.5)	4 (3.9)	20 (19.6)
Uncomfortable with food	27 (26.5)	23 (22.5)	26 (25.5)	15 (14.7)	11 (10.8)
Felt tense	52 (51.0)	16 (15.7)	20 (19.6)	7 (6.9)	7 (6.9)
Life less satisfactory	64 (62.7)	10 (9.8)	16 (15.7)	6 (5.9)	6 (5.9)

Table 4: Frequency of social domain responses

	Response Count n (%)				
	Never	**Hardly ever**	**Occasionally**	**Fairly often**	**Very often**
Behavioral change (New question)	59 (57.8)	19 (18.6)	15 (14.7)	4 (3.9)	5 (4.9)
Inability to function	68 (66.7)	27 (26.5)	3 (2.9)	2 (2.0)	2 (2.0)
Unsatisfactory diet	62 (60.8)	22 (21.6)	9 (8.8)	5 (4.9)	4 (3.9)
Meal interruption	59 (57.8)	24 (23.5)	13 (12.7)	3 (2.9)	3 (2.9)
Irritability	71 (69.6)	15 (14.7)	11 (10.8)	3 (2.9)	2 (2.0)
Difficulty doing job	78 (76.5)	18 (17.6)	3 (2.9)	2 (2.0)	1 (1.0)

Table 5: Frequency of physical domain responses

	Response Count n (%)				
	Never	**Hardly ever**	**Occasionally**	**Fairly often**	**Very often**
Speech or chewing problems (New question)	32 (31.4)	29 (28.4)	15 (14.7)	8 (7.8)	18 (17.6)
Pronunciation problem	84 (82.4)	9 (8.8)	3 (2.9)	1 (1.0)	5 (4.9)
Bad sense of taste	74 (72.5)	16 (15.7)	11 (10.8)	0 (0.0)	1 (1.0)

Table 6: Frequency of esthetic domain responses

	Response Count n (%)				
	Never	**Hardly ever**	**Occasionally**	**Fairly often**	**Very often**
Concern about appearance (New question)	33 (32.4)	16 (15.7)	29 (28.4)	9 (8.8)	15 (14.7)

Table 7: Prevalence of perceived impact of oral health on quality of life (new instrument)

Item description	N	Very often	Fairly often	Occasionally
Psychological limitation	39	6 (15.4%)	7 (18%)	26 (66.6%)
Social limitation	24	5 (20.8%)	4 (16.7%)	15 (62.5%)
Physical limitation	41	18 (44%)	8 (19.5%)	15 (36.5%)
Concerns about appearance	53	15 (28.3%)	9 (17%)	29 (54.7%)

Table 8: Severity of the impact

Severity of Impact (total score)	N (%)
OHIP-14	
Mild (0-18)	78 (76.5)
Moderate (19-36)	19 (18.6%)
Severe (37-56)	5 (4.9%)
New instrument	
Mild (0-4)	74 (72.5)
Moderate (5-8)	19 (18.6%)
Severe (9-12)	9 (8.8%)

Table 9: Distribution of the chief complaint

Chief Complaint	N (%)
Problem or pain	27 (26.3)
Restoration	55 (54%)
Regular visit	20 (19.7%)

Table 10: Psychological domain- Generalized Estimating Equation

Parameter	Standard Estimate	95% Confidence interval		Significance
		Lower limit	Upper limit	
Age	0.0148	0.0048	0.0247	< .0001
Gender				
Female	22.3780	21.6178	23.1381	< .0001
Male	0.0000	0.0000	0.0000	
Educational level				
Female				
High school	1.6538	0.6547	2.6528	0.0012
Some college	1.3340	0.4168	2.2512	0.0044
College graduate	0.0189	-0.8396	0.8775	0.9656
Master degree	0.7526	-0.1566	1.6619	0.1047
Doctor/doctorate	0.0000	0.0000	0.0000	
Educational level				
Male				
High school	19.1199	17.8562	20.3837	< .0001
Some college	21.7561	20.7284	22.7839	< .0001
College graduate	22.4720	21.5830	23.3611	< .0001
Master degree	21.3761	21.3761	21.3761	
Doctor/doctorate	0.0000	0.0000	0.0000	

Table 11: Social domain- Generalized Estimating Equation

Parameter	Standard Estimate	95% Confidence interval		Significance
		Lower limit	Upper limit	
Age	0.0161	0.0009	0.0313	0.0374
Gender				
Female	20.1741	18.7164	21.6317	< .0001
Male	0.0000	0.0000	0.0000	
Educational level				
Female				
High school	2.1013	-0.0352	4.2377	0.0539
Some college	1.7742	-0.3349	3.8832	0.0992
College graduate	0.7214	-1.3880	2.8308	0.5027
Master degree	0.5986	-1.6020	2.7992	0.5939
Doctor/doctorate	0.0000	0.0000	0.0000	
Educational level				
Male				
High school	17.5823	15.4214	19.7432	< .0001
Some college	20.1267	18.4005	21.8529	< .0001
College graduate	20.8944	19.2584	22.5304	< .0001
Master degree	19.8686	19.8686	19.8686	
Doctor/doctorate	0.0000	0.0000	0.0000	

Table 12: Physical domain- Generalized Estimating Equation

Parameter	Standard Estimate	95% Confidence interval		Significance
		Lower limit	Upper limit	
Age	0.0422	0.0121	0.0722	0.0059
Gender				
Female	23.2287	20.6337	25.8236	< .0001
Male	0.0000	0.0000	0.0000	
Educational level Female				
High school	1.2346	-1.7298	4.1991	0.4143
Some college	-0.2783	-2.7105	2.1539	0.8226
College graduate	-1.5188	-3.8175	0.7798	0.1953
Master degree	-0.3752	-2.8145	2.0642	0.7631
Doctor/doctorate	0.0000	0.0000	0.0000	
Educational level Male				
High school	20.7673	17.0179	24.5167	< .0001
Some college	23.0424	19.7546	26.3302	< .0001
College graduate	23.6904	20.7572	26.6236	< .0001
Master degree	24.2055	24.2055	24.2055	
Doctor/doctorate	0.0000	0.0000	0.0000	

Table 13: Esthetic domain- Generalized Estimating Equation

Parameter	Standard Estimate	95% Confidence interval		Significance
		Lower limit	Upper limit	
Age	0.0159	-0.0034	0.0351	0.1064
Gender				
Female	-0.0535	-1.4299	1.3228	0.9393
Male	0.0000	0.0000	0.0000	
Educational level Female				
High school	24.1972	22.8155	25.5788	< .0001
Some college	24.2935	23.0589	25.5280	< .0001
College graduate	23.2851	22.1119	24.4584	< .0001
Master degree	23.6508	23.6508	23.6508	.
Doctor/doctorate	0.0000	0.0000	0.0000	
Educational level Male				
High school	-0.9714	-3.0124	1.0697	0.3509
Some college	0.1394	-1.6837	1.9624	0.8809
College graduate	0.1783	-1.5185	1.8751	0.8368
Master degree	0.2750	0.0000	0.2750	
Doctor/doctorate	0.0000	0.0000	0.0000	

Table 14: Psychological Domain Percentage Agreement and Correlation

Item	**Percentage Agreement (%)**	**Spearman correlation**	
		Observed Value (r_s)	Significance level p (2-tailed)
Difficulty relaxing	62	0.70	0.000
Painful aching	57	0.62	0.000
Embarrassment	43	0.51	0.000
Self conscious	45	0.58	0.000
Uncomfortable with food	50	0.62	0.000
Feel tense	65	0.76	0.000
Life is less satisfactory	59	0.66	0.000

Table 15: Social Domain Percentage Agreement and Correlation

Item	Percentage Agreement (%)	Spearman correlation	
		Observed Value (r_s)	Significance level p (2-tailed)
Inability to function	64	0.61	0.000
Unsatisfactory diet	62	0.64	0.000
Meals interruption	67	0.72	0.000
Irritability	66	0.63	0.000
Difficulty doing regular job	69	0.69	0.000

Table 16: Physical Domain Percentage Agreement and Correlation

Item	Percentage Agreement (%)	Spearman correlation	
		Observed Value (r_s)	Significance level p (2-tailed)
Pronunciation difficulties	40	0.40	0.000
Change of taste	40	0.39	0.000

Table 17: Reliability of the new instrument

Domain	Cronbach's Alpha (α)
Psychological	0.93
Social	0.91
Physical	0.7

Table 18: Psychological domain sensitivity and specificity

		Estimated Value %	95% Confidence Interval	
			Lower Limit	Upper Limit
Difficulty relaxing	Sensitivity	85	73	93
	Specificity	75	58	87
Painful aching	Sensitivity	86	74	93
	Specificity	69	53	81
Embarrassment	Sensitivity	76	63	86
	Specificity	59	41	71
Self conscious	Sensitivity	78	65	88
	Specificity	57	42	71
Uncomfortable with food	Sensitivity	86	73	94
	Specificity	62	47	74
Feel tense	Sensitivity	85	74	92
	Specificity	85	68	94
Life is less satisfactory	Sensitivity	82	71	90
	Specificity	93	75	99

Table 19: Social domain sensitivity and specificity

		Estimated Value %	95% Confidence Interval	
			Lower Limit	Upper Limit
Inability to function	Sensitivity	82	73	89
	Specificity	100	56	100
Unsatisfactory diet	Sensitivity	86	76	92
	Specificity	67	41	86
Meals interruption	Sensitivity	86	76	92
	Specificity	63	39	83
Irritability	Sensitivity	86	77	92
	Specificity	75	47	92
Difficulty doing regular job	Sensitivity	81	72	88
	Specificity	100	52	100

Table 20: Physical domain sensitivity and specificity

		Estimated Value %	95% Confidence Interval	
			Lower Limit	Upper Limit
Pronunciation difficulties	Sensitivity	66	55	75
	Specificity	100	63	100
Change of taste	Sensitivity	67	56	76
	Specificity	92	60	99

FIGURES

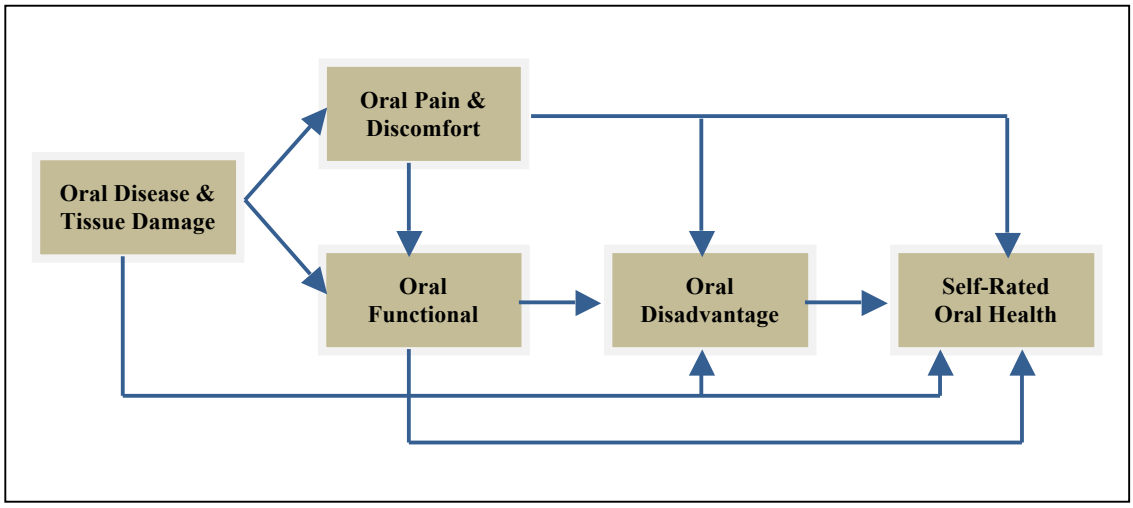

Figure.1. Multidimensional conceptual model of oral health specifying relations between dimensions of oral health.

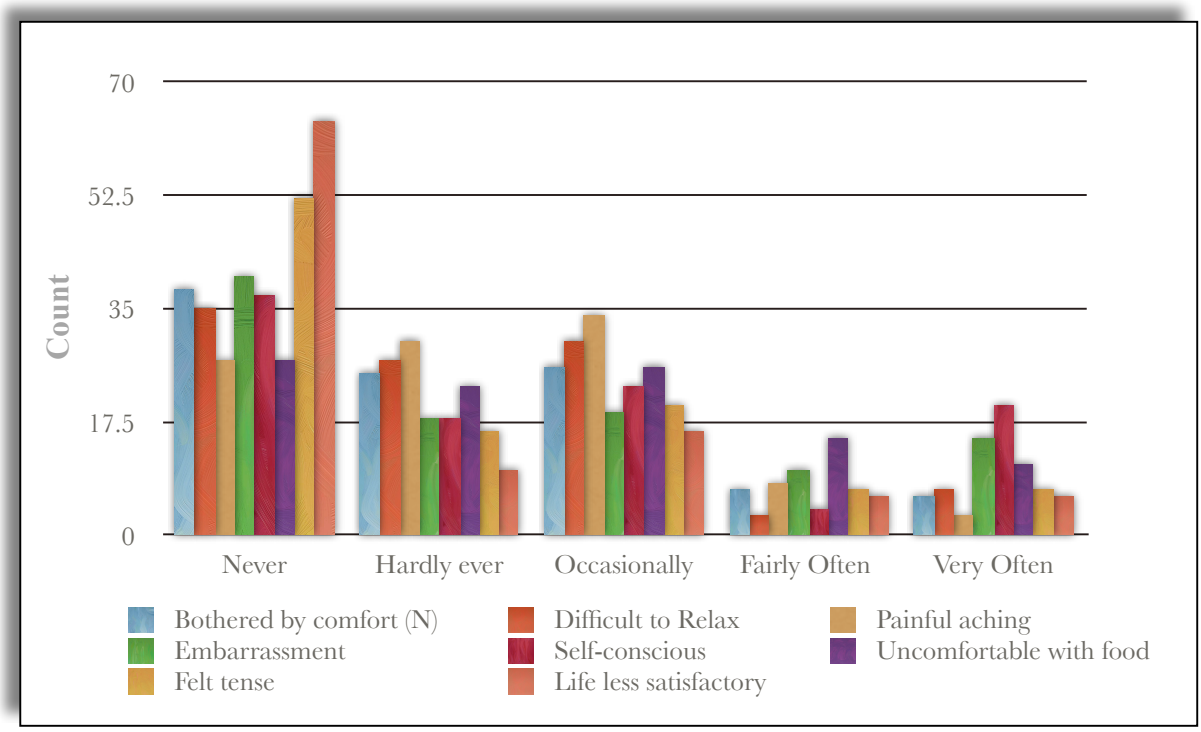

Figure 2: Frequency of psychological domain responses

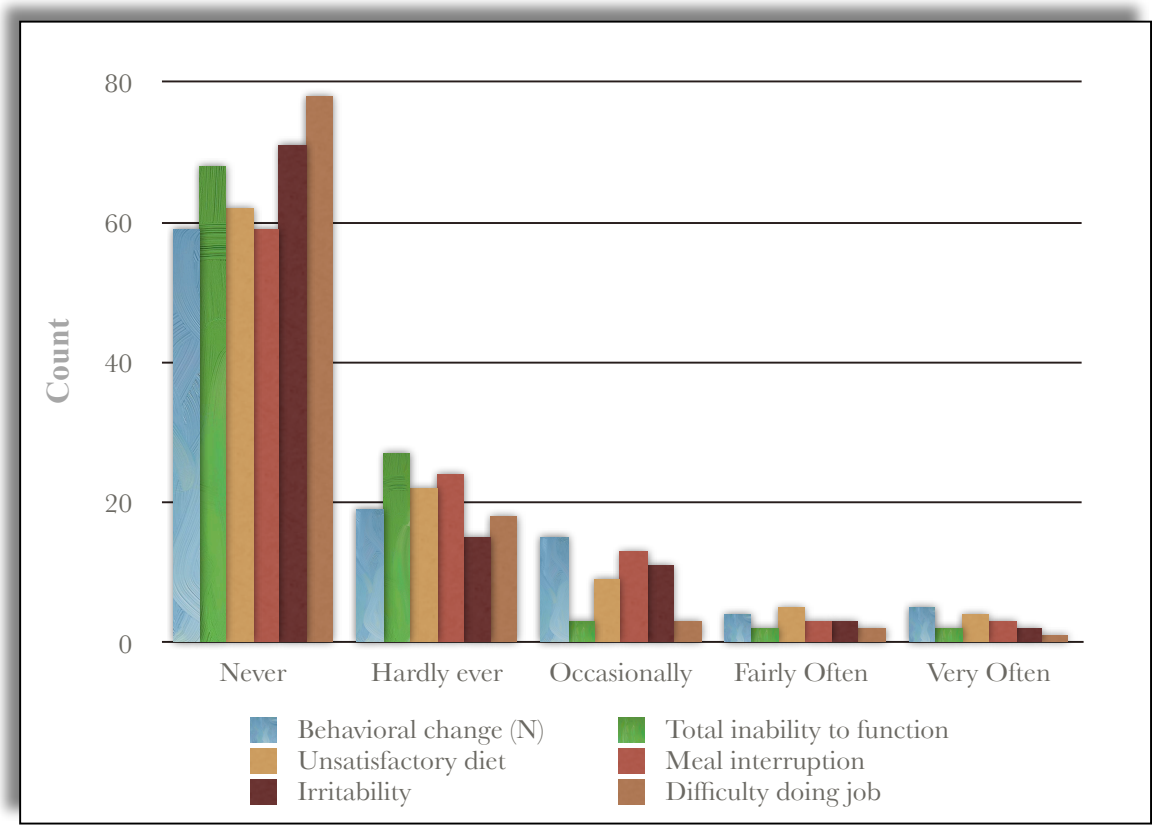

Figure 3: Frequency of social domain responses

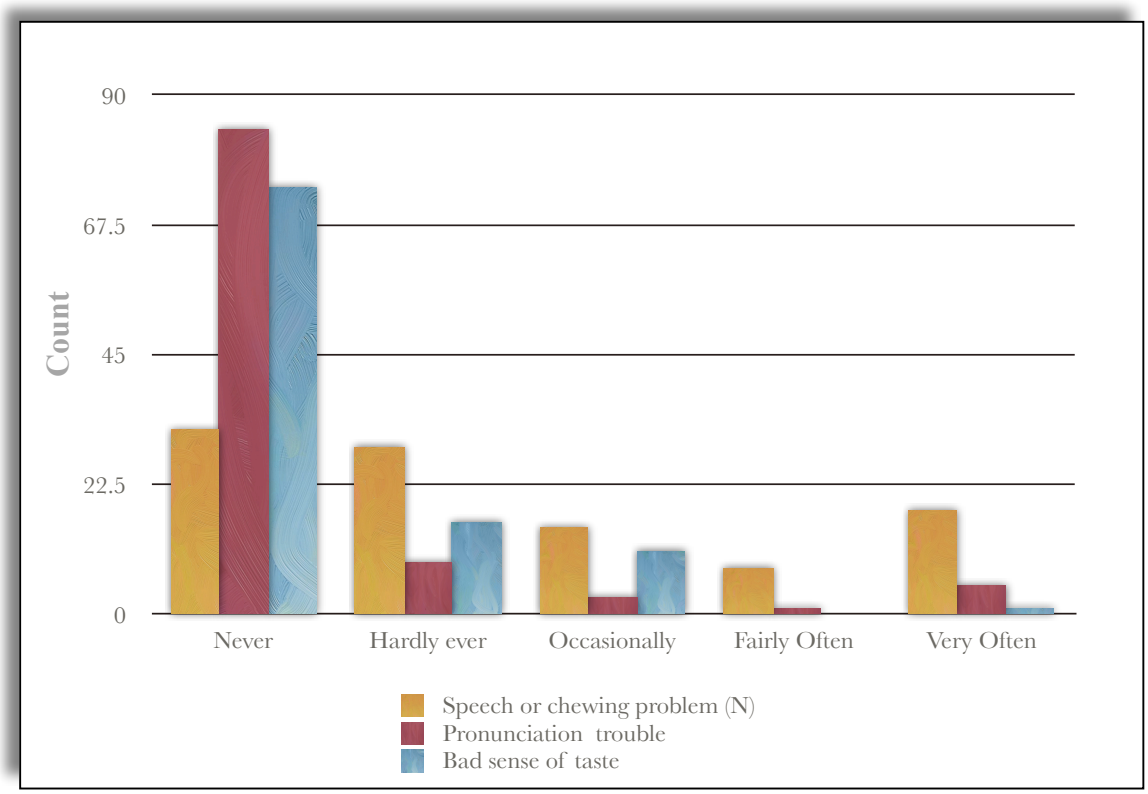

Figure 4: Frequency of physical domain responses

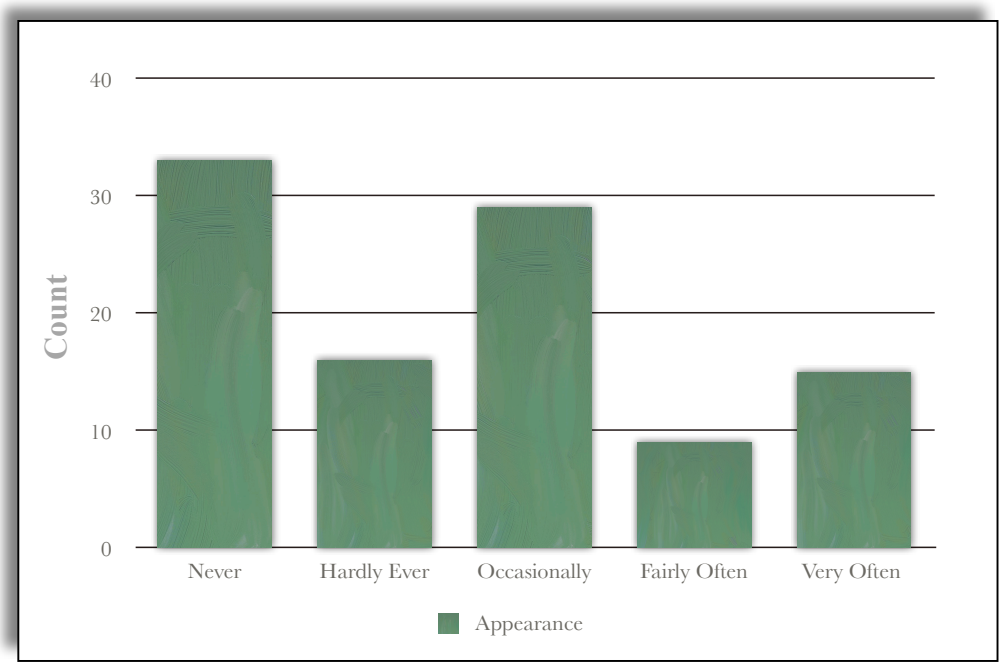

Figure. 5: Frequency of esthetic domain responses

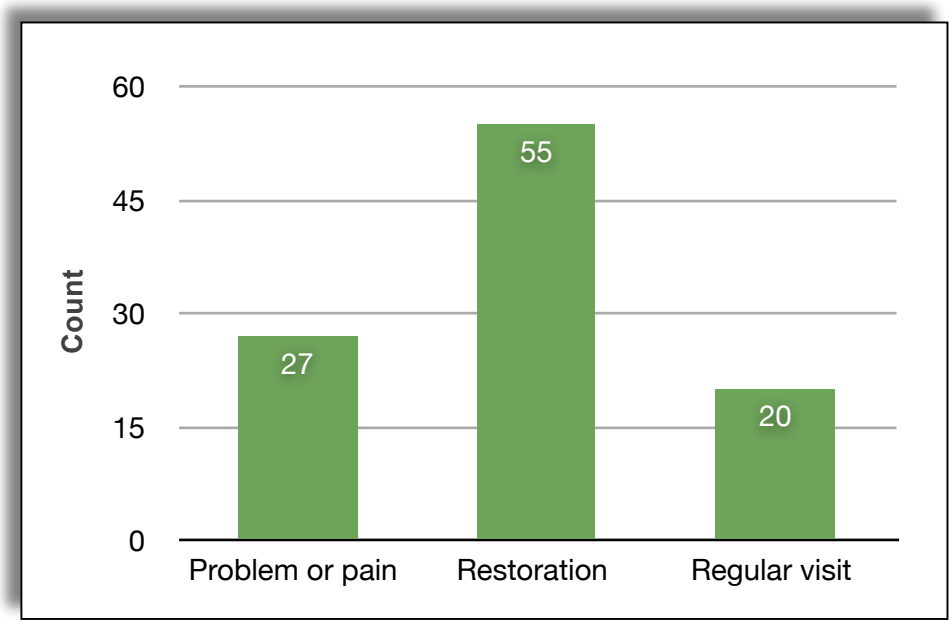

Figure 6: Frequency of chief complaints

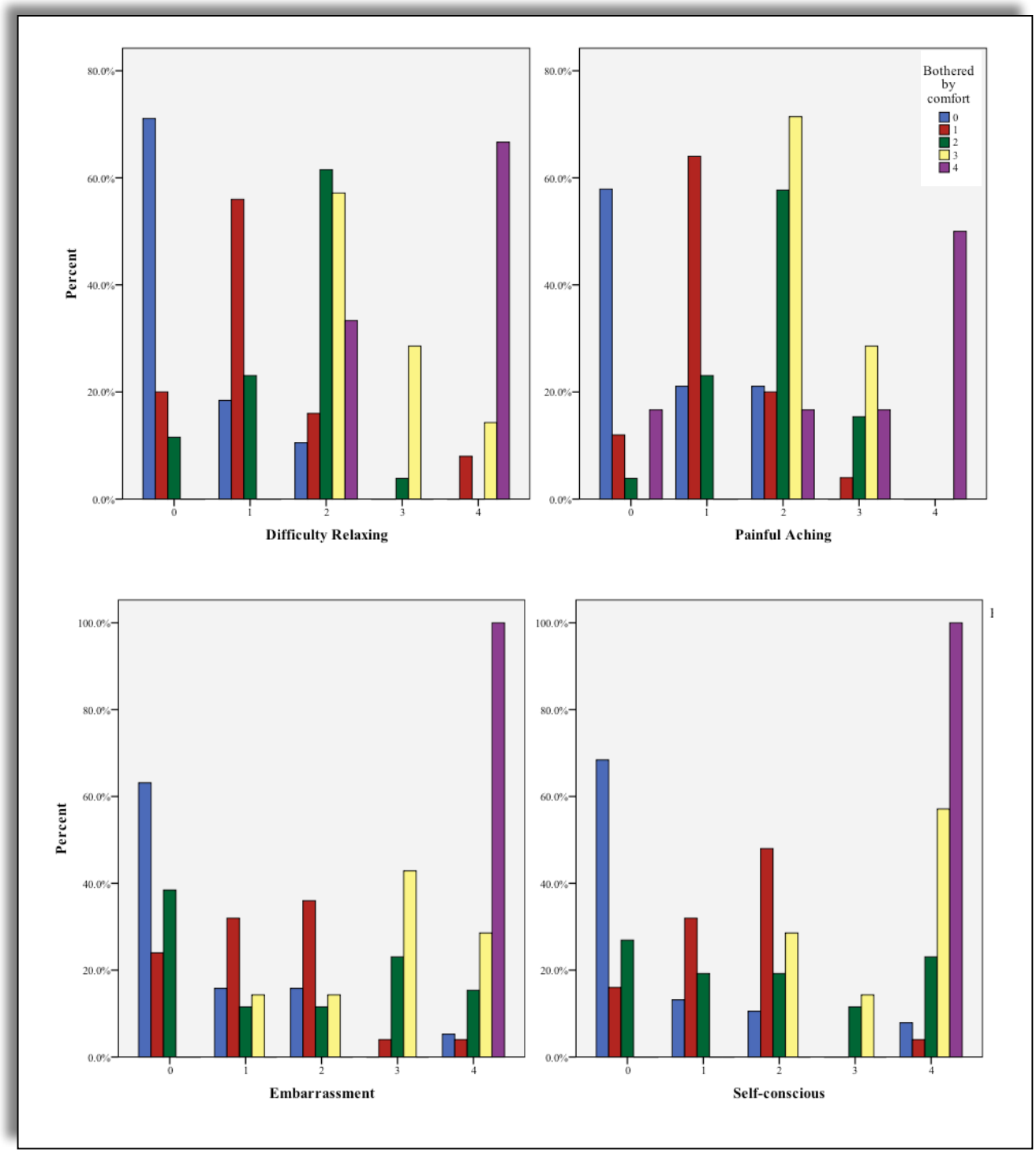

Figure 7-a: The correlation between the new question and OHIP-14 questions in the psychological domain

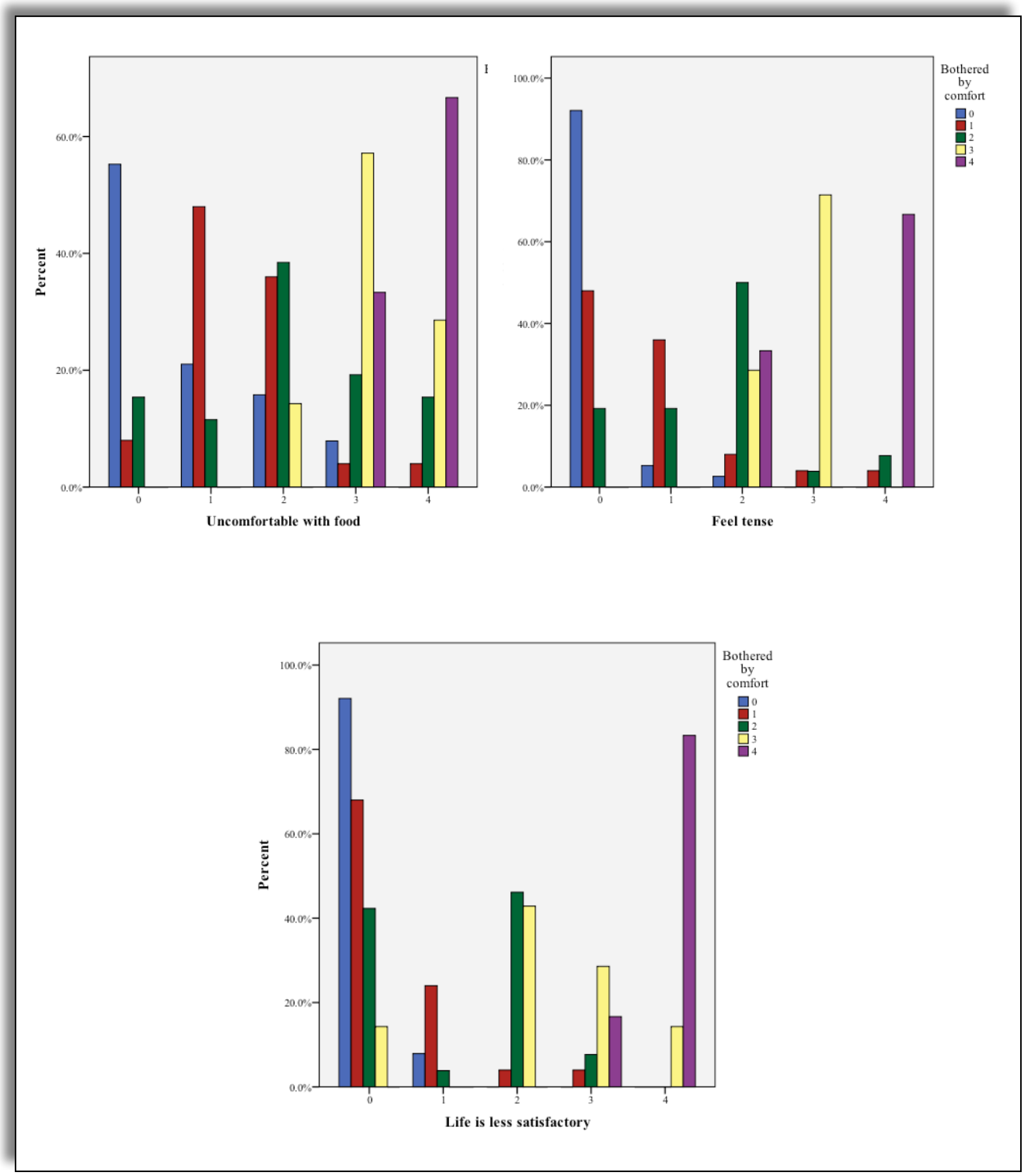

Figure 7-b: The correlation between the new question and OHIP-14 questions in the psychological domain

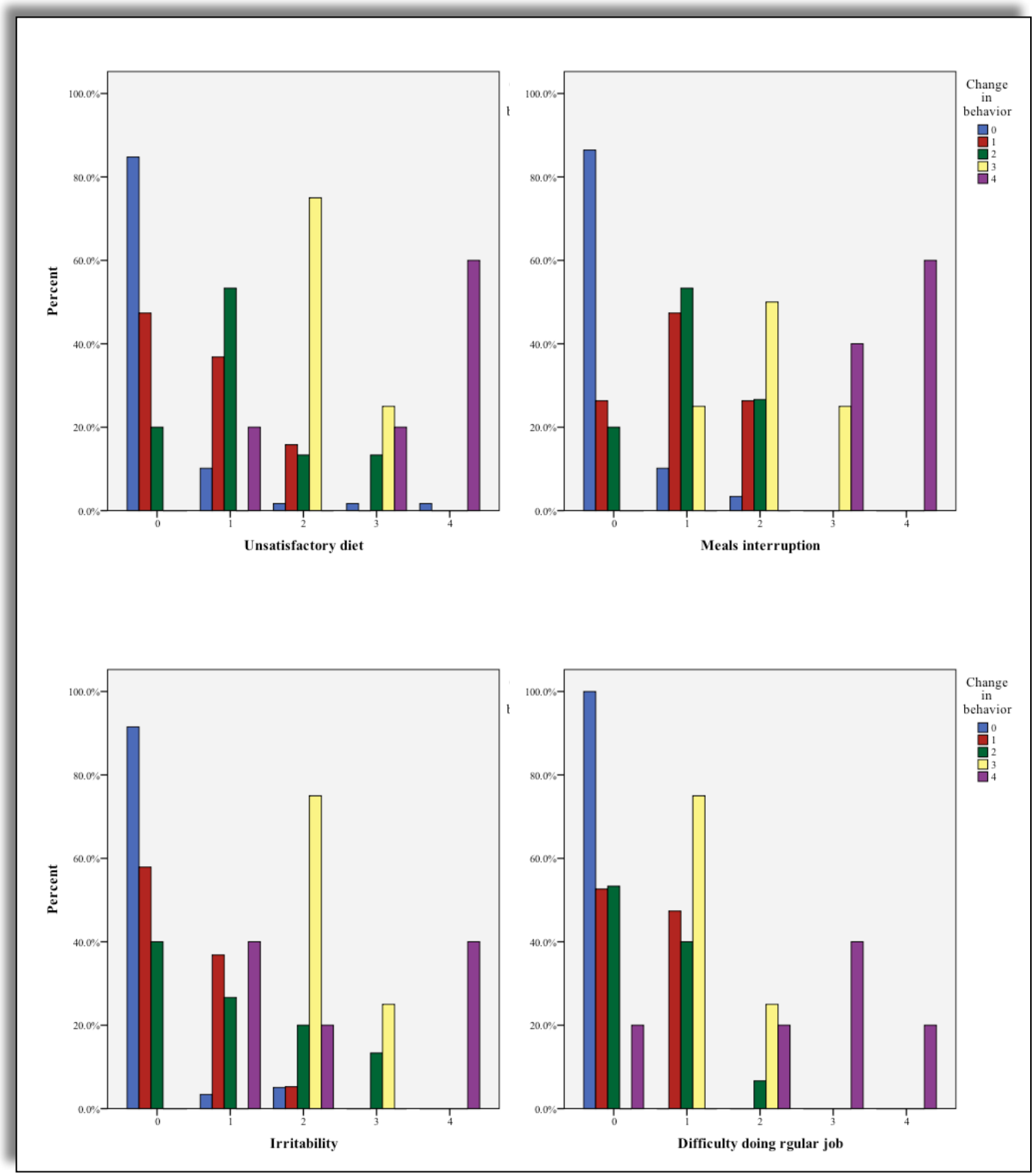

Figure 8-a: The correlation between the new question and OHIP-14 questions in the social domain

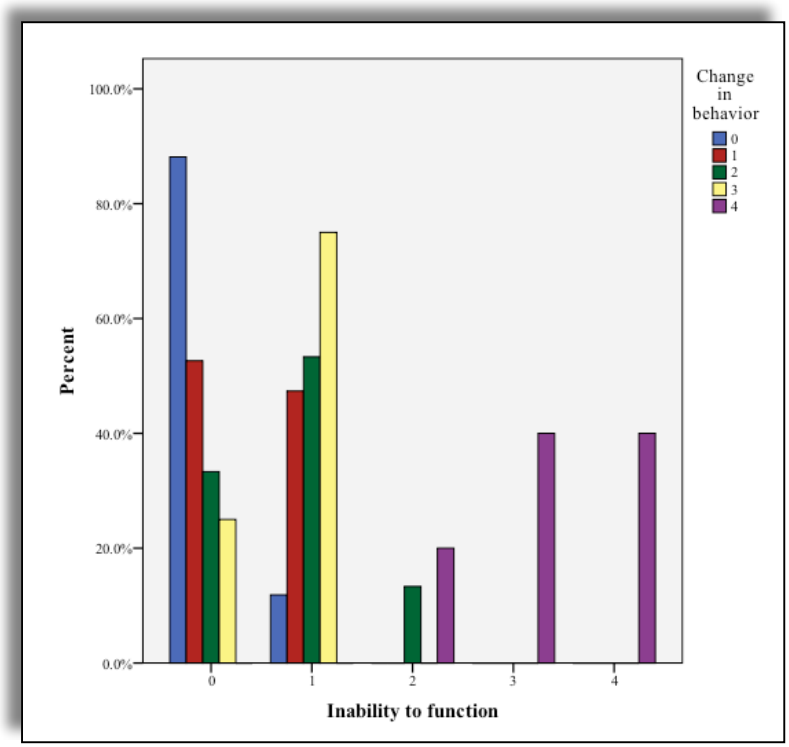

Figure 8-b: The correlation between the new question and OHIP-14 questions in the social domain

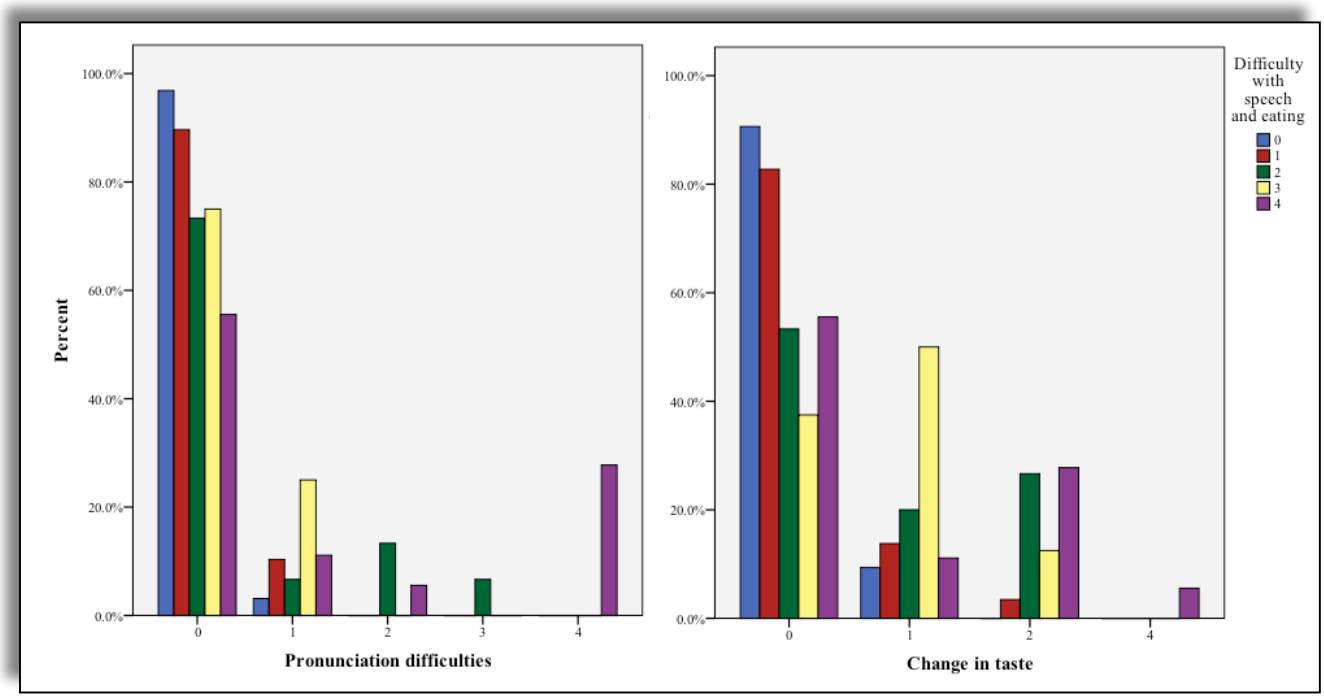

Figure 9: The correlation between the new question and OHIP-14 questions in the physical domain

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APPENDICES

Appendix A: Survey questionnaire

Appendix B: Informed consent Form

Appendix C: Research authorization form for limited release of protected health information form

APPENDIX A: Survey Questionnaire

Oral Health Impact Profile

Age:

Gender: Female Male

Highest education level: High school Some College

College graduate Master Degree

Doctorate degree/Doctor Other:

Please select the most applicable answer:						
1. Have you found it difficult to relax because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
2. Have you had painful aching in your mouth?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
3. Have you had a problem with speech or chewing your food because of problems with your teeth or denture?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
4. Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
5. Have you been totally unable to function because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
6. Have you been self conscious because of your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
7. Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
8. Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know

9. Have you had to interrupt meals because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
10. Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
11. Have you felt tense because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
12. Have you been bothered by the comfort of your mouth, tongue, teeth or denture?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
13. Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
14. Have you been concerned with the appearance of your face, teeth or denture?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
15. Have you had to make changes to your behavior based upon the health of your mouth or teeth?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
16. Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
17. Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
18. Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know

Appendix B: Informed Consent Form

TUFTS UNIVERSITY SCHOOL OF DENTAL MEDICINE

INFORMED CONSENT TO PARTICIPATE IN RESEARCH PROJECT TITLED:

Validation of a Short-form Measure for Oral Health-Related Quality of Life and the Relation Between Patients' Self-Perception to the Impact of Oral Health on Quality of Life and the Complexity of Oral Conditions

Principal Investigator: **Paul C. Stark,** MS, ScD
Research Coordinator: **Tofool A. Alghanem**, DDS
Co-Investigators: **Robert J. Chapman,** DMD
Matthew D. Finkelman, PhD
James B. Hanley, DMD

This research study is designed to try to figure out a new way to assess the quality of your oral health. In addition, we will study the relationship between how bad your oral health is and your overall quality of life.

Taking part in this research study is totally your choice. You can decide to stop taking part in this research study at any time for any reason. If you decide not to participate or stop being in this research study, it will not affect how you are treated at Tufts University School of Dental Medicine.

Please read all of the following information carefully. Ask Dr. Alghanem to explain any words, terms, or sections that are unclear to you. Ask any questions that you have about this research study. Do not sign this consent form unless you understand the information in it and have had your questions answered to your satisfaction.

If you decide to take part in this research study, you will be asked to sign this form. You will be given a copy of the signed form. You should keep your copy for your records. It has information, including important names and telephone numbers, to which you may wish to refer in the future.

PURPOSE OF STUDY

Because of the role the mouth plays in eating and communicating, oral diseases can impact your well-being. From an early age, the mouth and face have powerful influences on psychological well being and social interactions. The effects of different oral conditions on the quality of life among old patients and have been investigated in many studies but the correlation between the severity of the oral disease and patients' perceptions toward the disease and its effect on their quality of life have been not looked at yet.

We plan to discover a new way to measure the impact of oral health on the quality of life and to study the relationship between the severity of the oral condition and its impact on quality of life.

There will be 300 subjects enrolled in this study at Tufts University School of Dental Medicine.

PROCEDURES TO BE FOLLOWED

Subjects visiting Tufts University School of Dental Medicine for dental treatment will be asked to participate in the study. Subjects who agree to participate in the study will be interviewed by Dr. Alghanem for this project to sign an enrollment informed consent, Research Authorization Form for Limited Release of Protected Health Information form, and to fill out a questionnaire.

To document your specific medical or dental history, we will ask for your permission to extract your information from the electronic health record system using your medical record number. The total duration of your participation in this study should not exceed one hour.

RISKS OF PARTICIPATION

There are no known medical or physical risks associated with this study. This study will protect the confidentiality of your research records. All the data collected for the study will be coded and any personal data or information that could be used to identify you will not be disclosed. The research team will not share the research data with your hospital, insurance, employer, family or any other party. We will take precautions and put systems in place to keep data confidential. However you should be aware that every security system has its limitation.

BENEFITS OF PARTICIPATION

No direct benefits are expected. Knowledge gained from the study might benefit the dental practice by providing a tool that can be used clinically to ensure dentists provide the best quality of service to patients.

ALTERNATIVES

Taking part in this study is voluntary, if you decided not to participate; it will not affect the care you receive at Tufts in any way. Not taking part in this study is an alternative to you.

WITHDRAWAL

Your participation in the study is voluntary. If you choose not to participate, this decision will not result in the loss of any benefits to which you would otherwise be entitled. You may withdraw from the study at anytime without losing any of the benefits to which you would otherwise be entitled.

COST

There will be no research costs to you for your participation in the research.

PAYMENT

There will be no payments to you for your participation in the research.

PRIVACY AND CONFIDENTIALITY

No personal information or any data that may lead to your identity will be collected for this study. Every effort will be made to ensure that your participation in this study and all your records will remain confidential. However, confidentiality cannot be absolutely guaranteed. For example, some governmental and regulatory agencies (Office for Human Research Protections, Department of Health and Human Services, Food and Drug Administration, National Cancer Institute, etc) and the Institutional Review Board of Tufts Medical Center and Tufts

WHOM TO CONTACT

In case of any question regarding the conduct of the study, or research-related injury, please contact: Dr. Paul Stark at (617) 636-3753 or his representative, Dr. Tofool Alghanem: at (617) 636-6817.

If you have questions about your rights as a research study subject, call the Tufts Medical Center and Tufts University Health Sciences Institutional Review Board (IRB) at (617) 636-7512.

The Institutional Review Board is a group of doctors, nurses, and non-medical people who review human research studies for safety and protection of people who take part in the studies. Federal law requires the Institutional Review Board to review and approve any research study involving humans. This must be done before the study can begin. The study is also reviewed on a regular basis while it is in progress.

PARTICIPANT'S STATEMENT

I have read (or had read to me) this consent form and have discussed with Dr. Stark or his representative, Dr. Alghanem, the procedures described above. I have been given the opportunity to ask questions, which have been answered to my satisfaction. I understand that any questions that I might have will be answered verbally or, if I prefer, with a written statement.

I understand that I will be informed of any new findings developed during the course of this research study that may affect my willingness to stay in this research study.

I understand that my participation is voluntary. I understand that I may refuse to participate in this study. I also understand that if, for any reason, I wish to discontinue participating in this study at any time, I will be free to do so, and this will have no effect on my future care or treatment by my physicians or this hospital.

If I have any question concerning the study, I may contact Dr. Stark or his representatives at (617) 636-3753. And if I have any question concerning my rights as a research subject in this study, I may contact the Institutional Review Board at (617) 636-7512.

I have been fully informed of the above-described study with its risks and benefits, and I hereby consent to the procedures set forth above.

I understand that as a participant in this study my identity and my medical records and data relating to this research study will be kept confidential, except as required by law, and except for inspections by the U.S. governmental agencies, and the study sponsor. I have been given a copy of this consent form for my records.

_____ _____

Date Participant's Signature

I have fully explained to _____ the nature and purpose of the above-described study and the risks that are involved in its performance. I have answered all questions to the best of my ability.

_____ _____

Date Principal Investigator or Representative's Signature

APPENDIX C: Research Authorization Form for Limited Release of Protected Health Information Form

Tufts Medical Center
Tufts University Health Sciences
Research Authorization Form for Limited Release of Protected Health Information

Title of study: Validation of a Short-form Measure of Oral Health-Related Quality of Life. The Relation Between Patients' Self-Perception to the Impact of Oral health on Quality of Life and the Complexity of Oral Conditions

Principal Investigator: Paul C. Stark, MS, ScD
IRB #: 9299

Subject's Name: _____ **ID Number:** _____

We know that information about you and your health is private. We are dedicated to protecting the privacy of that information. Because of this promise, we must get your written authorization (permission) before we may use or disclose your protected health information or share it with others for research purposes. This form gives that permission. It also helps us make sure that you are correctly told how this information will be used or disclosed. Please read the information below carefully before signing this form. Please ask any questions you may have about this form or its uses. You can decide to sign or not to sign this form. However, if you choose not to sign this authorization, you will not be able to take part in the research study. Whatever choice you make about this research study, it will not have an effect on your access to medical care.

USE AND DISCLOSURE COVERED BY THIS AUTHORIZATION

DO NOT SIGN A BLANK FORM. *You or your authorized representative should thoroughly read the information below before signing this form.*

Who will disclose, receive, and/or use the information? This form will authorize the following person(s), class(es) of persons, and/or organization(s) to disclose, use, and receive the information*:

- Every research site carrying out this study. This includes Tufts University School of Dental Medicine. It also includes each site's research staff.
- Health care providers who provide services to you as part of this research study.
- The United States Food and Drug Administration (FDA) and other groups that have the right to use the information as required by law.
- The members and staff of any Institutional Review Board (IRB) that oversees this research study.
- The Principal Investigator: Dr. Paul C. Stark
- Study Coordinator: Dr. Tofool A. Alghanem

- Other Investigators and members of the research team: Dr. Robert J. Chapman, Dr. Matthew D. Finkelman and Dr. James B. Hanley

[*] If, during the course of the research, one of the companies or institutions listed above merges with, or is purchased by, another company or institution, this authorization to use or disclose protected health information in the research will extend to the successor company or institution.

What information will be used or disclosed?

Clinical and radiographic examination results including: endodontic, periodontal, prosthetic evaluation and the medical history data will be extracted for the electronic health record system at TUSDM.

SPECIFIC UNDERSTANDINGS

By signing this research authorization form, you give permission for the use and/or disclosure of your protected health information described above. The purpose for the uses and disclosures you are authorizing is to carry out the research study explained to you during the informed consent process. It is also to ensure that the information relating to the research is available to all parties who may need it for research purposes. Your protected health information may be used as necessary for your research-related treatment or to collect payment for your research-related treatment (when applicable). It may also be used to run the business operations of the institution.

This information may be redisclosed or used for other purposes if a recipient described in this form is not required by law to protect the privacy of the information.

You have a right to refuse to sign this authorization. While your health care outside the study, the payment for your health care, and your health care benefits will not be affected if you do not sign this form, you will not be able to take part in the research study described in this authorization if you do not sign this form.

If you sign this authorization, you will have the right to cancel it at any time, except to the extent that Tufts University School of Dental Medicine has already taken action based upon your authorization or needs the information to complete analysis and reports of data for this research study. This authorization will never expire until and unless you cancel it. To cancel this authorization, please contact the HIPAA Privacy Officer for Research: Janet Markel at phone # 617-636-0373 or at One Kneeland Street, Room # 334, Boston, MA 02111.

You have a right to receive a copy of this form after you have signed it.

SIGNATURE

I have read this form and all of my questions about this form have been answered. By signing below, I acknowledge that I have read and accept all of the above.

_____
Signature of Subject or Authorized Representative

_____
Print Name of Subject or Authorized Representative

_____
Date

_____
Relationship of the person signing as Subject or Authorized Representative above to the Subject

_____
Print Name of Individual Explaining this Research Authorization Form

CONTACT INFORMATION

The contact information of the subject or authorized representative who signed this form should be filled in below.

Address:

_____

_____

_____

_____

Telephone:

_____ (daytime)

_____ (evening)

E-mail Address (optional):

_____