A. Specific aims

A critical factor in determining the success of implant supported restorations in the anterior maxilla is the esthetics of the crown and surrounding soft tissues. New indices such as the Pink Esthetic Score (PES) and the White Esthetic Score (WES) provide practitioners and researchers a new method to objectively evaluate esthetics. However, patients often perceive esthetics differently than dental professionals. Therefore, the esthetic outcomes perceived by the dental professionals and the patients and their correlation need to be further investigated.

Our goal is to determine and improve the correlation between dentist-determined PES/WES and subjective patient satisfaction scores. In this project, we will examine the patient satisfaction scores using questionnaires with altered photographs of PES/WES. If high PES/WES scores can accurately predict patient satisfaction, then these indices provide a standardized method to compare the esthetic outcomes of different treatment modalities and biomaterials.

The following two specific aims are intended to test the hypothesis that patients/lay people value esthetic criteria in the Pink Esthetic Score (PES) and White Esthetic Score (WES) differently compared to dental professionals.

Aim #1: Improve the ability of the PES and the WES in predicting patient satisfaction of anterior implant supported restorations: altered photographs of maxillary anterior teeth with different PES/WES scores determined by dental professionals will be used for participants to assess the esthetic outcomes. This study will evaluate the importance of each PES/WES criterion from the patient's perspective.

Aim #2: Determine the minimum PES and WES thresholds to achieve patient satisfaction: altered photographs of maxillary anterior teeth will be given to the participants to rate satisfaction based on the esthetics outcome. This study will provide important information about the acceptable esthetic outcome from the patient's perspective.

If the effect size of each PES/WES criterion can be determined, then it is possible to improve these indices to better predict patient satisfaction by making important criteria weight more heavily. A new esthetic diagnostic tool may be developed to identify esthetically demanding patients. It is critical to carefully evaluate treatment options using mechanical, biological and esthetic factors to ensure patient satisfaction can be achieved. If the esthetic expectation of a patient is high in any specific PES/WES criterion, then the practitioner may be required to take additional steps to meet the patient demands.

B. Background and significance

Background: Advances in dental implant research, design and their clinical application have greatly changed dental care. Improved protocols in implant therapy over the last several decades have made implant supported restorations biologically and mechanically predictable.[1-3] The use of implants in the esthetic zone has increased and patients are becoming more esthetically demanding.[4]

Patient satisfaction is another important factor in predicting the success of implant therapy in the anterior maxilla.[5, 6] Despite the importance of esthetic outcomes, only few studies included in a systematic review evaluated the esthetics of implant supported single crowns.[7] In another systematic review, only 6 studies included esthetic criteria in determining implant success.[8] In addition, these studies had no standardized method to evaluate esthetics. Some studies asked their patients to rate their overall satisfaction of their implant supported crowns, while others were asked to rate only crown color and shape. Some studies had the practitioner, rather than the patient, evaluate the esthetics of the implant restoration. It is well known that the practitioner's perspective is different than that of the patient's.[9-11] Since less than 2% of publications on dental implants focus on patient-centered issues, outcomes such as esthetics and patient satisfaction of implant supported restorations need more focus in future dental research.[12]

There is a need for an objective and reproducible esthetic score for the restoration and the peri-implant soft tissues to drive dental implant research towards a more esthetic focus and to improve implant therapy for patients.[13] Furhauser and colleagues[13] developed the 7 criteria Pink Esthetic Score (PES) to objectively evaluate the peri-implant soft tissue (figure 1). The PES was shown to have a good intra-examiner agreement.[14] Belser and colleagues developed the White Esthetic Score (WES) to objectively evaluate implant supported restorations based on 5 criteria (figure 2). The authors combined a simplified 5 criteria PES with the WES to evaluate anterior implant supported restorations.[9] An arbitrary score of 6 was set to represent the minimum WES required for clinical acceptance[9] and a minimum PES was set at 8.[4] Correlations between PES and patient satisfaction determined on a visual analog scale have been reported.[15, 16] However, some other studies have reported poor to moderate correlation between PES/WES with patient satisfaction determined on the same scale.[4] There seems to be emerging evidence supporting the reproducibility of the PES and correlation with patient satisfaction[14-17] but similar evidence for the WES is scarce.

In order to compare esthetic results of different treatment modalities using the PES/WES for the future research, these indices *should* correlate with patient satisfaction. If this correlation is weak, then a more complex treatment resulting in a higher objective PES/WES may be rendered to patients when they may be equally satisfied with a more conservative but lower scoring treatment. If the objective indices are not correlated to a patient's esthetic perception, then the practitioner may be overlooking treatments and materials that are able to satisfy a patient, and overusing others that cannot meet patient expectations.

Significance: The expected outcome from this study includes determining the effect size of each PES/WES criterion, and to improve these indices to better predict patient satisfaction by making important criteria weight more heavily. A new esthetic diagnostic tool may be developed to identify esthetically demanding patients. It is critical to carefully evaluate treatment options using mechanical, biological and esthetic factors to ensure patient satisfaction can be achieved. If the esthetic expectation of a patient is high in any specific PES/WES criterion, then the practitioner may be required to take additional steps. Implant therapy may not be the treatment of choice altogether, if the patient's esthetic demand cannot be met.

C. Research design and methods:

Photograph preparation

A total of 36 photographs of the maxillary anterior 6 teeth will be used in this survey study (figure 3). One photograph in the series will have a perfect PES/WES of 24/24. The subsequent 35 photographs will be a digitally altered version of the initial perfect scoring photograph similar to the previous studies of altered dental esthetics.[18, 19] Twenty-four of these photographs will have one PES/WES criteria digitally altered to represent a score of 1 and 0 for that particular criterion. Eleven photographs will have total PES/WES of 20, 18, 16, 14, 12, 10, 8, 6, 4, 2, and 0 (figures 4 and 5). The degree of alteration for some criteria will be based upon previous research on noticeable thresholds.[18] Criteria that have no previous research on noticeable thresholds will be altered enough to be clinically relevant. The intended scores for each photograph will be verified in the pilot study. All photographs will be altered using a software program (Adobe Photoshop 5.0.2; Adobe Systems Inc, San Jose, CA) by an independent biomedical illustrator with a Masters of Science in Biomedical Communications (MScBMC). The researchers will have frequent meetings with the illustrator to ensure the photographic alterations meet the intent and purpose of the study. Sample photographs will also be used to communicate with the illustrator. All 36 photographs will be presented to patients in a randomized order so they are not grouped by criteria. The photographs will be in a 1:1 size ratio to simulate how patients view anterior implant supported restorations in real life. For this study, the lip is not included in the photographs.

Pilot study

The PES has been shown to have moderate to substantial intra-examiner agreement and fair to moderate inter-examiner agreement; however, there are differences in scoring between specialties.[4, 14] The WES has been shown to have fair to substantial intra-examiner and inter-examiner agreement.[4] To verify that the PES/WES for these altered photographs maintain intra and inter-examiner agreement, the survey will be taken by 5 board certified prosthodontists, 5 board certified periodontists and 5 prosthodontic residents at University of Illinois at Chicago, College of Dentistry (UIC COD). Intra-examiner repeatability and inter-examiner reproducibility will be determined by κ statistics. This pilot study will also determine whether the altered photographs actually depict the intended criteria scores. If the desired scores are not obtained, the degree of alteration will be increased or decreased accordingly.

Study population

Inclusion criteria for this study are that subjects must be 18 years or older to provide informed consent, and understand English. Exclusion criteria are those with known colorblindness, unwilling to participate on the colorblind test or do not pass the colorblind test. Colorblind individuals will be identified in this study by a simple Ishihara test at the beginning of the survey. Demographic data regarding year of birth, gender, education level, income level, ethnicity and occupation will be obtained from all participants (figure 6). Income level categories will be based on the current federally marked poverty level of $11,170 for a family of 1. Power analysis was used to determine the minimum sample size required and accept the outcome of the statistical test with a 95% confidence level. The power of the analysis with α=0.05 was 0.9. The power analysis reveled that a sample size of 200 participants is sufficient for the statistical evaluation. The experimental protocol has been submitted to the University of Illinois at Chicago Institutional Review Board office (IRB #2012-0396).

Institutional description

This study will consist of 2 parts, a photographic survey delivered on an iPad and a digital web-based survey. The iPad survey will be available to patients receiving dental care at the UIC COD in the

Advanced Prosthodontic Clinic (Room 361) and the Implant and Innovations Center (Room 330). Both clinics have uniform fluorescent lighting and patients will be completing the surveys in the dental chair. For the web-based survey, a digital high resolution copy of the photographs will be uploaded onto a web-site similar to a previous study.[19] The online survey program LimeSurvey will be used (http://www.limesurvey.org/). This web page will not be limited to dental patients but will also be made available to the general public. A link to the web-site will be sent out via email and a social network (Facebook Inc, Menlo Park, California, U.S.). Respondents are will be asked whether they are using an Apple machine (Mac) or a personal computer (PC). The web-site link will be available to the general public for a 5-month period.

Survey

Study participants will be asked to answer 2 questions for each photograph on a 100mm Visual Analog Scale (VAS) from 0 (very unsatisfied) to 100 (very satisfied).[4, 9] The first question asks the participant "how satisfied would you be with the aesthetic outcome of the gums surrounding these teeth if this were your mouth?" The second question asks the participant "how satisfied would you be with the aesthetic outcome of these crowns (teeth) if this were your mouth?" The questions do not direct the focus to any particular tooth but is intended to have the participant consider the esthetics of the entire photograph as a unit. Patients are instructed not to compare photographs and change their answers.

Data analysis

Since the web-based version of the photographs may have color differences depending on the computer monitors used, data collected from Mac users will be tabulated and analyzed separately initially from PC users. The Mac group and the PC group will be compared using the Mann-Whitney test. Likewise, iPad group and the web-based group will also be compared using the Mann-Whitney test. If no statistical difference is found between groups, the data may be pooled to increase the sample size and to expand the target population. The Spearman correlation coefficient will be used to assess any correlation between the objective scores (PES/WES) and the subjective score (patient satisfaction). The Kruskal–Wallis and Mann-Whitney tests will be used to determine if the change in scores for certain criteria in the PES/WES had an effect on patient satisfaction. If an effect exists, the effect size will be calculated from the data. All statistical analyses were performed using PASW Statistics 18.0 (SPSS Inc, Chicago, IL, USA). Statistical significance is defined as $p < 0.05$.

D. Time Table

Month	1	2	3	4	5	6	7	8	9	10	11	12
Photograph preparation	X	X										
Pilot study			X									
iPad collection				X	X	X	X	X				
Online data collection				X	X	X	X	X				
Data Analysis									X	X		
Report writing											X	X

E. Appendix

Figure 1: The 7 criteria of the Pink Esthetic Score developed by Fürhauser et al.

Table 1. **Variables of the pink esthetic score**

Variables		0	1	2
Mesial papilla	Shape vs. reference tooth	Absent	Incomplete	Complete
Distal papilla	Shape vs. reference tooth	Absent	Incomplete	Complete
Level of soft-tissue margin	Level vs. reference tooth	Major discrepancy >2 mm	Minor discrepancy 1–2 mm	No discrepancy <1 mm
Soft-tissue contour	Natural, matching reference tooth	Unnatural	Fairly natural	Natural
Alveolar process	Alveolar process deficiency	Obvious	Slight	None
Soft-tissue color	Color vs. reference tooth	Obvious difference	Moderate difference	No difference
Soft-tissue texture	Texture vs. reference tooth	Obvious difference	Moderate difference	No difference

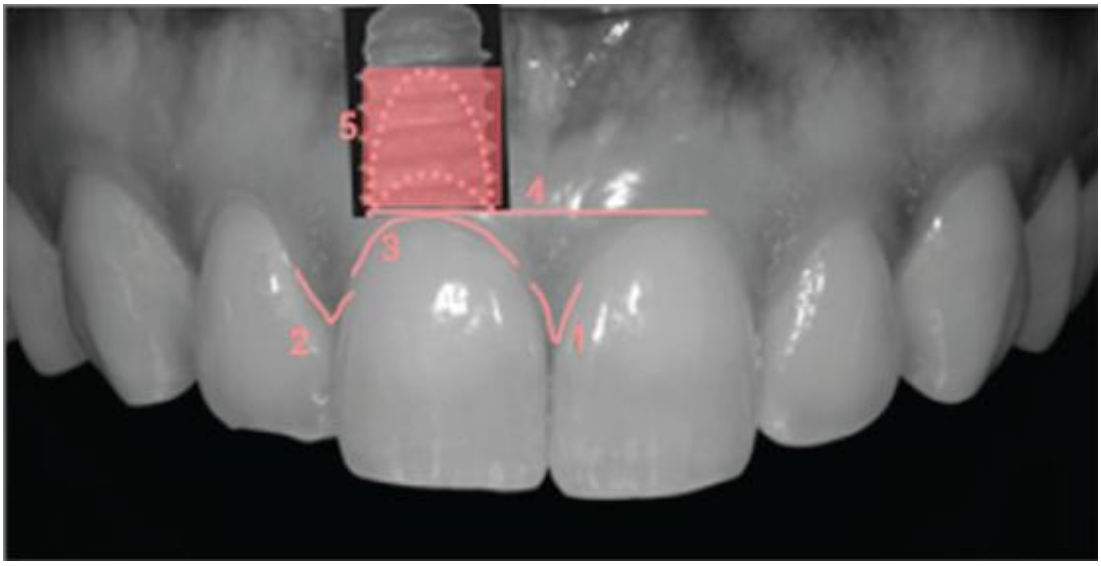


Figure 2: The 5 criteria of the White Esthetic Score developed by Belser et al.

WES			
Parameter	Major Discrepancy	Minor Discrepancy	No Discrepancy
Tooth form	0	1	2
Tooth volume/outline	0	1	2
Color (hue/value)	0	1	2
Surface texture	0	1	2
Translucency	0	1	2
Maximum total WES score			10

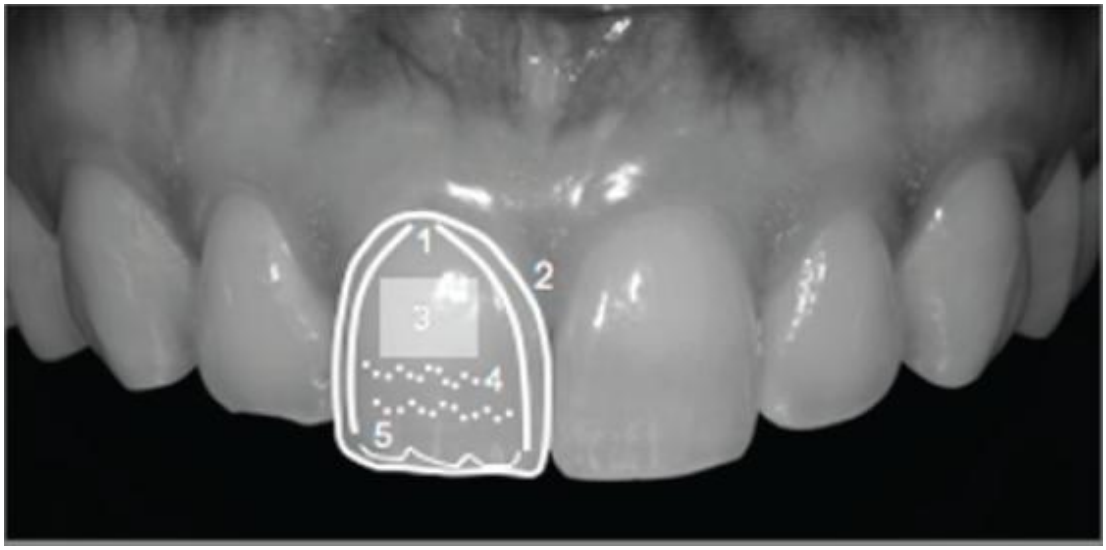


Figure 3: Flowchart of study protocol

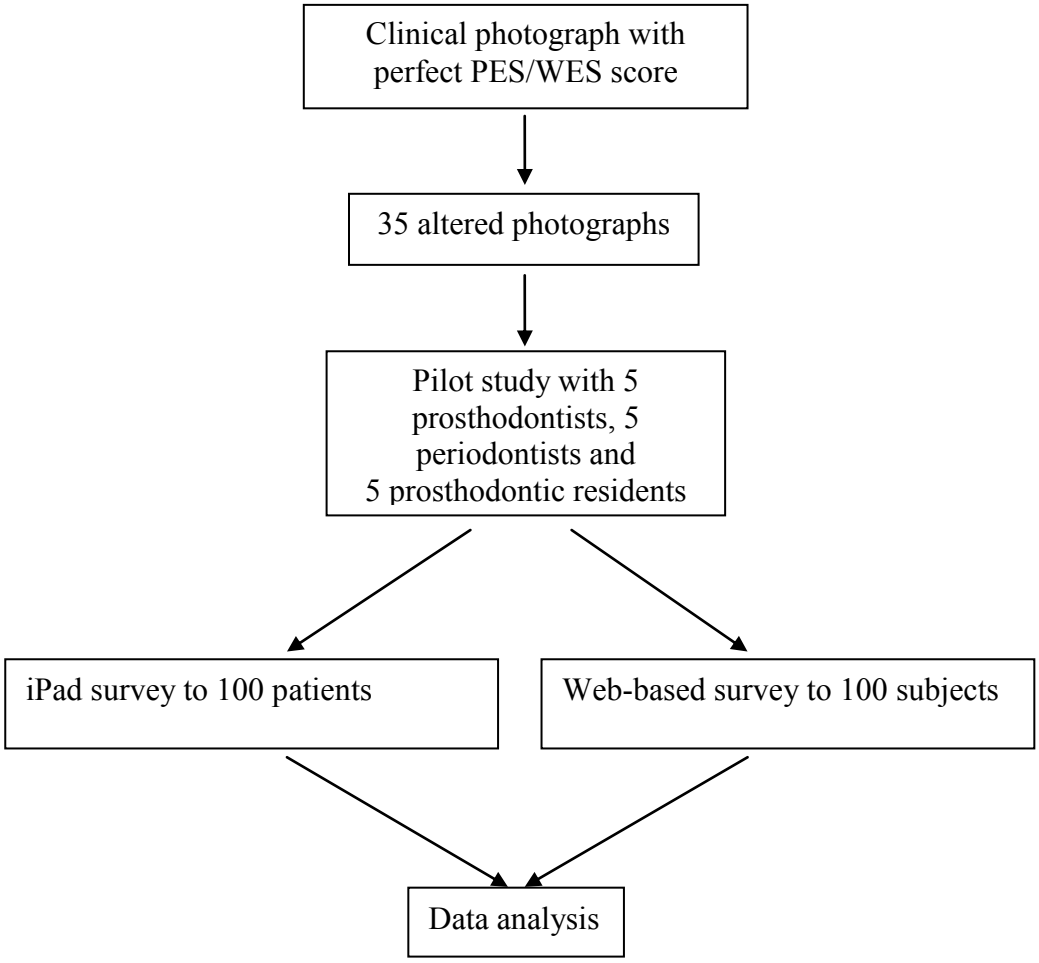
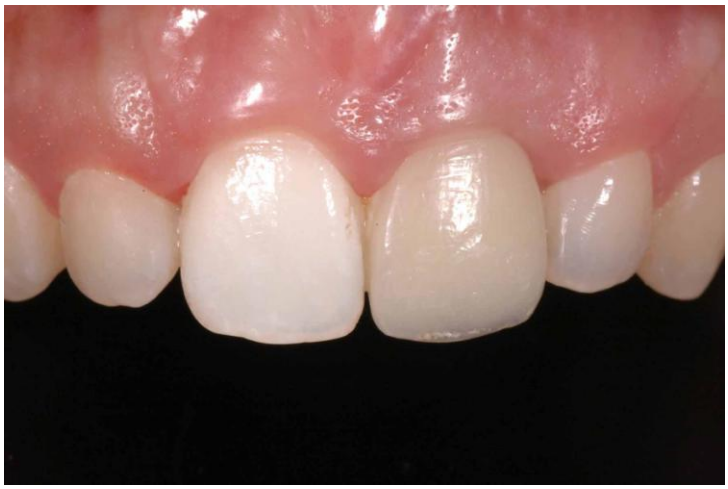
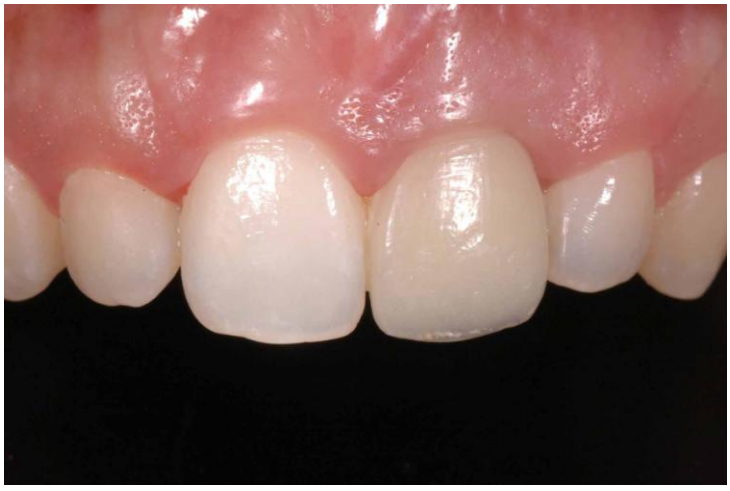


Figure 4: An example of the Tooth Color criteria altered to 0 (A), 1 (B) and 2 (C) respectively.

A



B



C

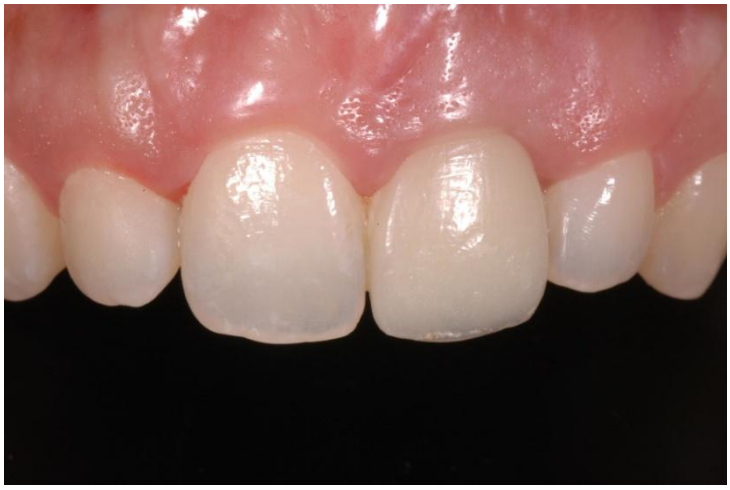
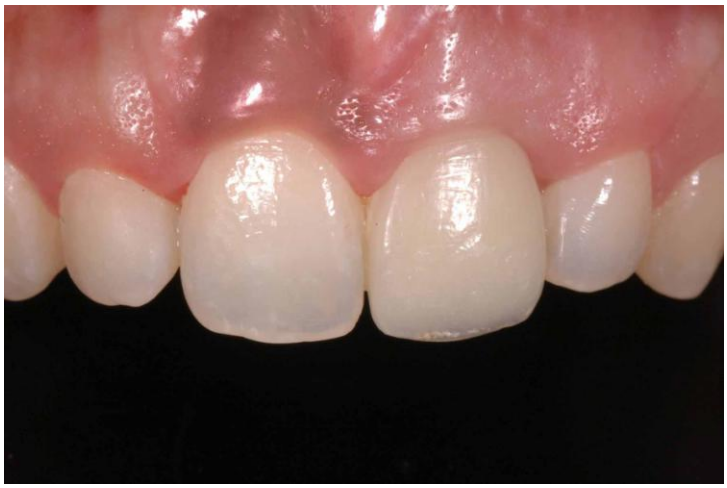
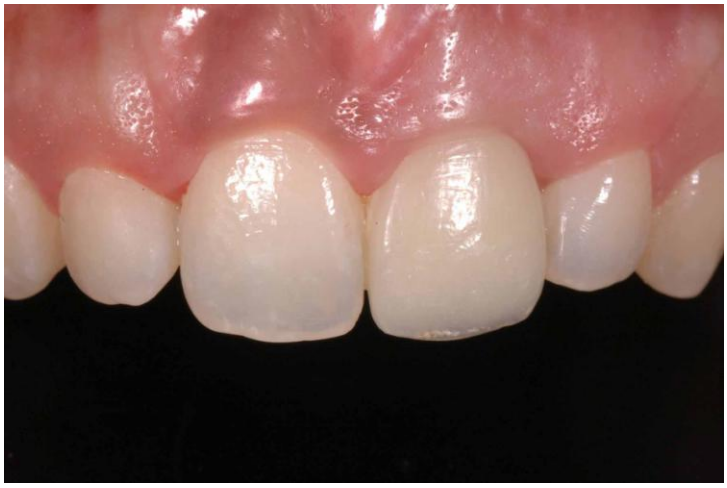


Figure 5: An example of 3 photographs with the Tissue Color criteria altered to 0 (A), 1 (B) and 2 (C) respectively.

A



B



C

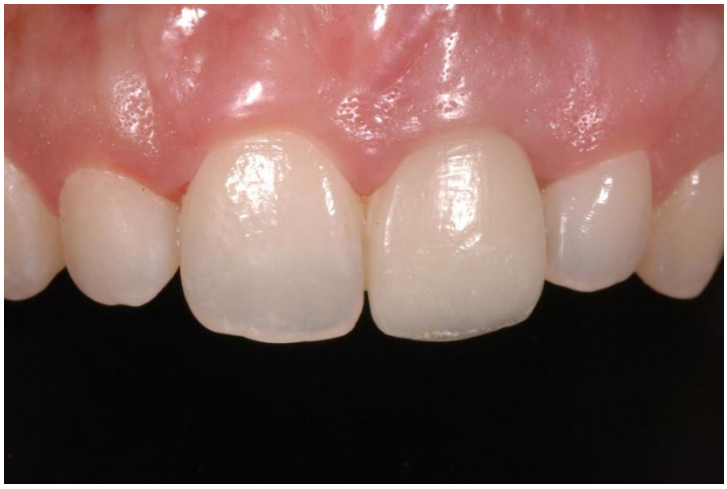


Figure 6: An example of the survey used for data collection (Pages 1 and 2)

Year of Birth _____ Gender: M F

Ethnicity:

a. American Indian or Alaska Native (origins in any of the original peoples of North, Central and South America
b. Asian (origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand and Vietnam.)
c. Black or African American (origins in any of the Black racial groups of Africa – includes Caribbean Islanders and other of African origin.)
d. Native Hawaiian or Other Pacific Islander (origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.)
e. White (origins in any of the original peoples of Europe, the Middle East, or North Africa.)

Education level:

a. Less than high school
b. High school
c. Bachelor's degree
d. Master's degree
e. Doctorate

Income level:

a. Less than $5,499
b. $5,500-$10,999
c. $11,000-$21,999
d. $22,000-$44,999
e. $45,000- $89,999
f. $90,000 or greater

Occupation:

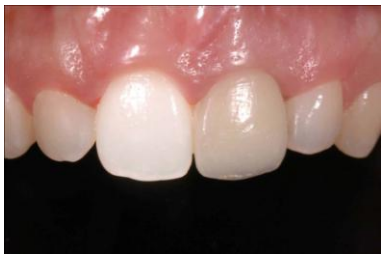
a. Dental professionals
b. Other

Please answer these 2 questions for each photograph by drawing a line between 0 (very unsatisfied) and 100 (very satisfied). For example:

Very unsatisfied Very Satisfied
0 |----------I----------| 100

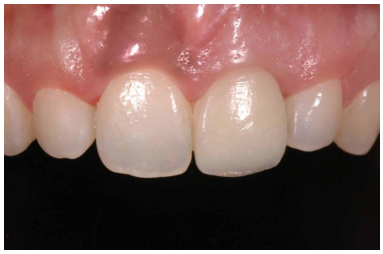
1. How satisfied would you be with the aesthetic outcome of the **gums** surrounding these teeth if this were your mouth?

2. How satisfied would you be with the aesthetic outcome of these **crowns (teeth)** if this were your mouth?



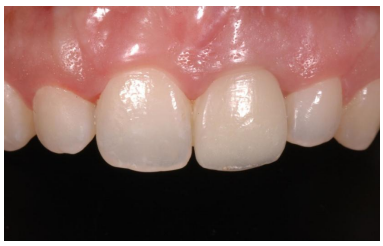
1.
Very unsatisfied Very Satisfied
0 |----------| 100

2.
Very unsatisfied Very Satisfied
0 |----------| 100



1.
Very unsatisfied Very Satisfied
0 |----------| 100

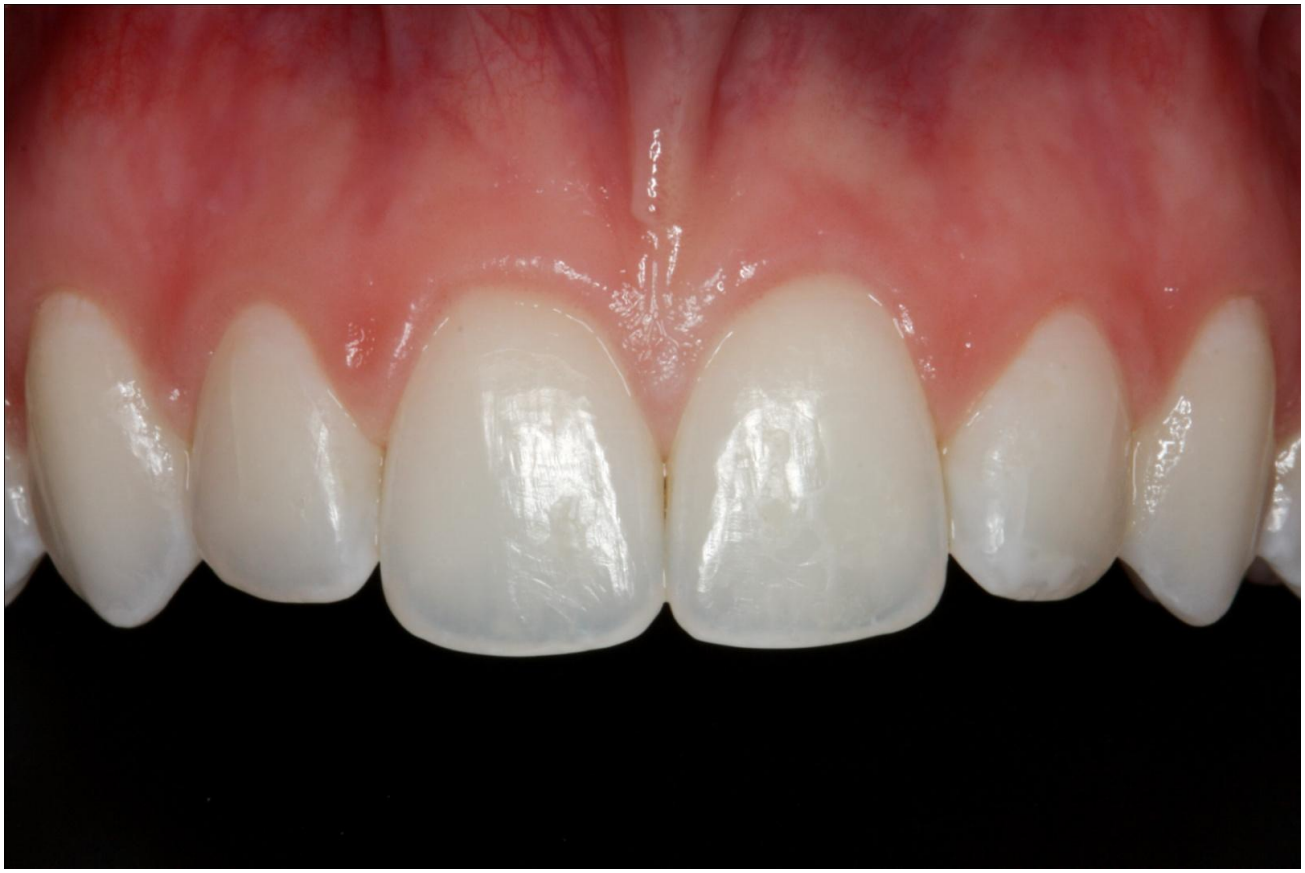
2.
Very unsatisfied Very Satisfied
0 |----------| 100



1.
Very unsatisfied Very Satisfied
0 |----------| 100

2.
Very unsatisfied Very Satisfied
0 |----------| 100

Figure7: Initial photograph to be altered



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G. IRB Approval

Exemption Granted

May 2, 2012

RE: Research Protocol # 2012-0396
"Improving the pink and white esthetic scores (PES/WES) in predicting patient satisfaction of anterior implant restorations"

Your Claim of Exemption was reviewed on May 2, 2012 and it was determined that your research protocol meets the criteria for exemption as defined in the U. S. Department of Health and Human Services Regulations for the Protection of Human Subjects [(45 CFR 46.101(b)]. You may now begin your research.

Exemption Period:	**May 2, 2012 – May 1, 2015**
Performance Site(s):	UIC
Subject Population:	Adult (18+ years) subjects only
Number of Subjects:	400

The specific exemption category under 45 CFR 46.101(b) is:
(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

You are reminded that investigators whose research involving human subjects is determined to be exempt from the federal regulations for the protection of human subjects still have responsibilities for the ethical conduct of the research under state law and UIC policy. Please be aware of the following UIC policies and responsibilities for investigators:

1. Amendments You are responsible for reporting any amendments to your research protocol that may affect the determination of the exemption and may result in your research no longer being eligible for the exemption that has been granted.

2. Record Keeping You are responsible for maintaining a copy all research related records in a secure location in the event future verification is necessary, at a minimum these documents include: the research protocol, the claim of exemption application, all questionnaires, survey instruments, interview questions and/or data collection instruments associated with this research protocol, recruiting or advertising materials, any consent forms or information sheets given to subjects, or any other pertinent documents.

3. Final Report When you have completed work on your research protocol, you should submit a final report to the Office for Protection of Research Subjects (OPRS).

4. Information for Human Subjects UIC Policy requires investigators to provide information about the research protocol to subjects and to obtain their permission prior to their participating in the research. The information about the research protocol should be presented to subjects in writing or orally from a written script. When appropriate, the following information must be provided to all research subjects participating in exempt studies:

   a. The researchers affiliation; UIC, JBVMAC or other institutions,
   b. The purpose of the research,
   c. The extent of the subject's involvement and an explanation of the procedures to be followed,
   d. Whether the information being collected will be used for any purposes other than the proposed research,
   e. A description of the procedures to protect the privacy of subjects and the confidentiality of the research information and data,
   f. Description of any reasonable foreseeable risks,
   g. Description of anticipated benefit,
   h. A statement that participation is voluntary and subjects can refuse to participate or can stop at any time,
   i. A statement that the researcher is available to answer any questions that the subject may have and which includes the name and phone number of the investigator(s).
   j. A statement that the UIC IRB/OPRS or JBVMAC Patient Advocate Office is available if there are questions about subject's rights, which includes the appropriate phone numbers.

Please be sure to:

→Use your research protocol number (listed above) on any documents or correspondence with the IRB concerning your research protocol.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact me at (312) 355-2908 or the OPRS office at (312) 996-1711. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.