Cover Page

Official Title of the Study:

The Use of Intraoral Imaging at Clinical Crown Lengthening Procedures

NCT number:

NCT03064217

Date of the Document:

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Project Summary

Crown lengthening surgery is done when a tooth needs to be fixed with a crown. Sometimes, not enough of the tooth sticks out above the gum to support a crown. This can happen when a tooth breaks off at the gum line, or when a crown or filling falls out of a tooth and there is decay underneath. To place a crown, the dentist needs to expose more of the tooth. This is done by removing some gum tissue or bone. After surgery, the area will heal in about three months. Then, making a crown can begin. This healing period often delays the delivery a final crown. This study is investing a way to make the final impression at the surgery to expedite the delivery of a final crown.

General information

Title: The Use of Intraoral Imaging at Clinical Crown Lengthening Procedures

Funding Information

1. The department of Endodontics, Periodontics, and Prosthodontics (EPP) and the department of General Dentistry will partially support this study regarding supplies for procedures and participant compensation. The ADEA project pool fund will also partially support this study.

2. The American Dental Education Association
655 K Street NW, Suite 800
Washington DC, 20001, USA

The Principal Investigator

Se-Lim Oh, DMD, MS
Clinical Associate Professor
Division of Periodontics
University of Maryland School of Dentistry

650 West Baltimore Street, Room 4211
Baltimore, MD 21201

Office phone) 410-706-8061
Email: soh@umaryland.edu

Resources

The Principal Investigator is devoting 10% of her time to conducting and completing the research. There is sufficient time to conduct, oversee and complete research. Patients will have enough time to ask questions and to address their concerns before they participate in this research. Enough clinical times are allocated for each participant to conduct the procedures described in this protocol. A research coordinator and a certified dental assistant are working with the PI and research team members. All procedures in this protocol are performed with the separate room to secure the information. The University of Maryland School of Dentistry (UMSOD) is currently having many patients on its records. In addition, there are at least seven new patients to visit the clinics in each clinic session. All research team members completed CITI and HIPAA trainings. The research team members are responsible to recruit subjects. The PI and the research team members will perform all surgical procedures described in this protocol.

Sites where research activities will be conducted

This is a single site study. The study will be conducted at the UMSOD dental clinics.
650 West Baltimore Street, Baltimore, MD, 21201, USA

Clinical Trial Registration: NCT03064217

Rationale and background information

Dental caries is the most common oral disease, which affects the crown and/or the root surfaces of teeth. The prevalence of dental caries in permanent teeth among adults 20-64 years of age was approximately 92% during 1999-2004.[1] Overall root caries experience was 36% among the adult population.[1] When dental caries affects most tooth surfaces, a crown is recommended to protect the tooth. In cases that caries extends below the gingival margin, a clinical crown lengthening procedure (CLP), "a surgical procedure designed to increase the extent of supragingival tooth structure for restorative or esthetic purposes by apically positioning the gingival margin, removing supporting bone, or both"[2], is often required to fabricate a crown.

The conventional treatment protocol involving a CLP is as follows; 1) caries control with core build-up, 2) initial tooth preparation, 3) performing a CLP, and 4) making the final impression with elastomers using double gingival cords, and 5) delivering a crown. A healing period of 6 to 12 weeks after CLPs is recommended.[3, 4] Since packing two gingival cords could injure the soft tissue still in healing and the tooth preparation was not definitive at a CLP, the restorative treatment is generally initiated 3 months after CLPs. However, this waiting period delays the final crown delivery, which is often patient's chief complaint.

The technical developments have brought digital workflows, such as computer aided design/computer aided manufacturing (CAD/CAM) and intraoral imaging, to restorative dentistry. This technique allows fabricating the fixed restoration without taking impression via impression materials. Studies reported that digital impressions were equally or more accurate and precise than plaster models made by impression materials.[5-7]

Since intraoral imaging system allows us to take the impression without applying impression materials around teeth, the final impression could be made at the surgery without increasing any postoperative complications. If the final tooth preparation could be made at the surgery and making the final impression are performed at a CLP, a delivery of the final crown can be expedited.

Several studies[5-8] have reported the benefits of chairside intraoral imaging system and CAD/CAM from patient-centered outcomes and from technical and economic aspects. However, the use of intraoral imaging in conjunction with CLPs has not been examined. Furthermore, there is no systematic study investigating the influences of final prostheses on the soft tissue and the hard tissue around teeth when they are delivered before the 8 to 12 weeks healing period after CLPs.

Study goals and objectives

The purpose of this study is to evaluate clinical and radiographic outcomes of single unsplinted fixed restorations made with digital intraoral imaging in conjunction with CLPs, compared ones fabricated with digital intraoral imaging made at 8 to 12 weeks following CLPs.

Specific Aim 1: To evaluate the clinical outcomes between the experimental group (the digital impression taking at CLPs) and the control group (the digital impression taking at 12 weeks following CLPs)
Hypothesis: There will be no differences in clinical parameters around the teeth between the two groups.
Approach: We will conduct a prospective clinical study and will compare the changes in gingival recession, the width of keratinized gingiva, and pocket depths around the teeth between the two groups.

Specific Aim 2: To evaluate the radiographic outcome between the experimental group and the control group
Hypothesis: There will be no difference in crestal bone level around teeth between the two groups.
Approach: The study will investigate the difference in crestal bone level around the teeth at baseline and 12 months between the two groups.

The results from this study would give a better prediction of the healing after CLPs and scientific supports for making the final impression at the surgery to expedite the delivery of final prostheses. Thus, this study will achieve a sustainable impact on the interdisciplinary field, both periodontics and restorative dentistry.

Literature review

The biologic width around teeth includes both connective tissue and junctional epithelium attachment. Its average dimension is 2 mm, and it presents in all healthy dentitions.[9] Invasion of the biologic width with a restoration could result in crestal bone loss and persistent gingival inflammation.[10] Thus, a clinical crown lengthening procedure (CLP) is often required to treat a caries extended below the gingival margin. The apically positioned flap with osseous surgery is the most common procedure for CLPs. A few studies investigated healing after CLPs. Crown length gained from CLPs was significantly decreased at 6 months.[11] The coronal displacement of the gingival margin was observed during 12 months period of healing following CLPs.[12, 13]

The waiting period before initiating restorative procedures is still controversial.[14] Wagenberg et al.[15] recommended 12 weeks. Two to four mm of gingival recess was reported between 6 weeks and 6 months postoperatively.[3] The original biologic width was reestablished by 3 months.[4, 16] Therefore, a wide range from 6 weeks up to 6 months was recommended by literature based on the soft tissue healing.

However, beginning restorative procedures should not be predominantly based on the timing of restoring the biologic width only, since a long-term use of a temporary crown is not recommended. In fact, the dimension of biologic width is different from surface to surface even in the same tooth.[10] Therefore, another controversial issue regarding CLPs is the amount of bone reduction. Based on the concept of the biologic width, there is a necessary amount of root surface to be exposed for restoring this dimension. However, a limitation of bone reduction also exists due to the local anatomical factor, such as the furcation, and a crown to root ratio. Dibart et al.[17] reported that 40% of the mandibular molars developed a furcation involvement at 5 years after CLPs and the final crown delivery. Meanwhile, Diniz et al. reported no significant changes in the crestal bone level during 12 months period after removal of crestal bone at CLPs.[18] In summary, there is a little consensus among studies regarding the post-surgical changes following CLPs. The optimal timing of restorative treatments has not been systemically investigated.

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Preliminary findings

We have performed several cases, in which final impressions were made during crown lengthening procedures (CLPs) and final crowns were delivered at suture removal appointments and have observed favorable outcomes including shortening overall treatment time, reducing visits, no postoperative pain, and no crestal bone loss from the previous cases.

Figure 1 depicts one of our previous cases. A delivery of a final gold crown for #19 was planned. However, the crown margin was still on a core material evident on a bitewing radiograph (Fig. 1a). Therefore, a CLP was recommended to re-prepare the tooth and to place the crown margin on the sound tooth structure. At the CLP, buccal and lingual full thickness flaps were retracted and the surrounding soft tissue was removed (Fig. 1b) so that a restorative dentist was able to complete the tooth preparation. The final impression was made with Omnicam® (Fig. 1c). Osseous surgery was completed and sutures were placed (Fig. 1d). A temporary crown was cemented and Coe-pak™ was placed. No antibiotics were prescribed and over-the-counter ibuprofen was recommended for pain management. A final gold crown was delivered at 2 weeks following the surgery at the suture removal appointment (Fig. 1e). A postoperative radiograph confirmed the fitting of crown and the crown margin was placed on the sound tooth structure (Fig. 1f). This patient only took one 200 mg ibuprofen right after the CLP and did not experience any pain or any discomfort either after the CLP or after the delivery of the final crown.

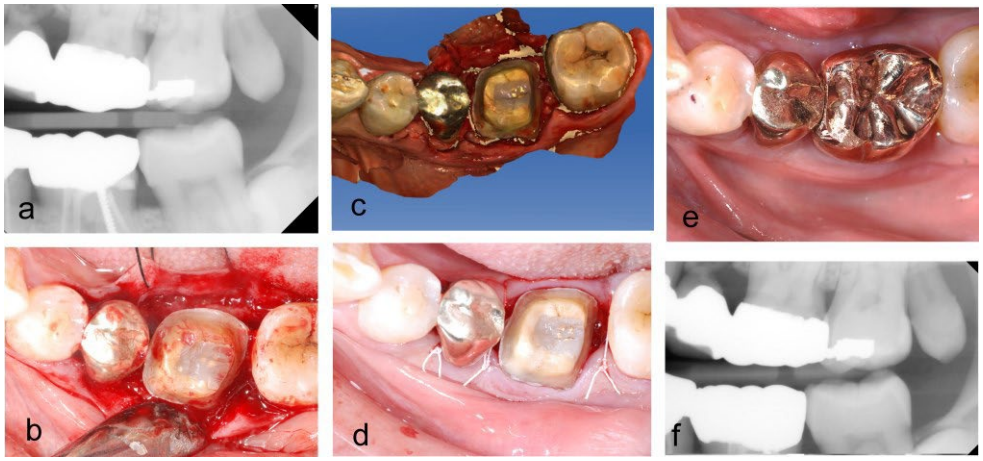


Figure 1. #19 gold crown fabricated with digital impression made during a CLP. (a) Delivery of a final crown was attempted but was not successful because the crown margin was still on a core. (b) Full thickness flaps were retracted during the CLP. Final preparation was performed. (c) Final impression was made with Omnicam®. (d) Sutures were placed to complete the surgery. (e) The final crown was delivered at 2 weeks after the surgery. (f) A bite-wing confirmed the fitting of crown margin.

The University of Maryland School of Dentistry (UMSOD) is now fully equipped with intraoral imaging and CAD/CAM (computer aided design/computer aided manufacturing) systems. A lithium disilicate crown can be

fabricated in house laboratory. Therefore, we are fabricating and delivering lithium disilicate crowns as final restorations in our study.

Study design

This is a prospective randomized controlled trial (RCT) to investigate the clinical and radiographic outcomes of lithium disilicate crowns made by digital technology following clinical crown lengthening procedures (CLPs). Figure 2 shows a flowchart of the study. The final preparation and the final impression are made at the CLP in the experimental group; the final preparation and the final impression are made after 8 weeks following the CLP in the control group. After the delivery of lithium disilicate crowns, all subjects will be followed at 12 months to perform periodic evaluation and oral prophylaxis.

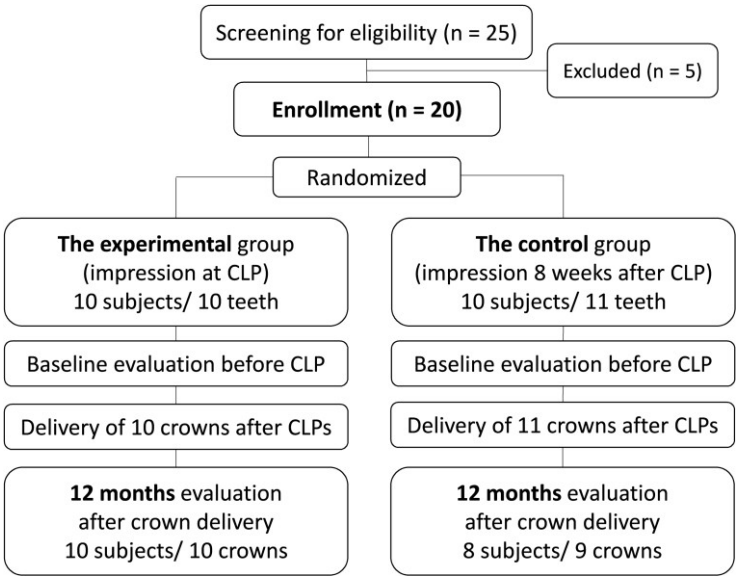


Figure 2. A flowchart of study.

Methodology

1) The Study population: the groups to be recruited are patients registered in dental clinics at the UMSOD.

Twenty subjects will be enrolled; the subjects will be randomly assigned to the experimental group (10 subjects) or to the control group (10 subjects) using a random number table. Subjects with the following conditions will be included: a) age >18 years, b) a single-unsplinted crown needed, c) a tooth must be in the area from the canine to the second molars, d) a CLP is required to fabricate a lithium disilicate crown. Exclusion criteria are as follows: a) uncontrolled hypertension, b) diabetes mellitus patients whose HbA1c level is 6.5% and above, c) subjects with a history of a long-term use of corticosteroid (> 6 months), d) subjects with a history of taking oral/IV bisphosphonates within the past 2 years, e) subjects taking anticoagulants, and f) smokers.

At the enrollment, if potential subjects are diabetic, the potential subjects are required to provide their A1c level verified by their primary care providers. The A1c level accepted needs to be within 3 months.

2) Clinical measurements: A Williams probe (Hu-Friedy) will be used to obtain the level of gingival margin (GM), the width of keratinized gingiva (KG), and pocket depths (PDs).

<u>The following measurements will be obtained at delivery of the crown.</u>
a) Gingival Margin (GM) will be measured from the cervical margin of the crown to the free gingival margin at the facial and lingual/palatal sites.
b) The width of keratinized gingiva (KG) will be measured from the free gingival margin to the mucogingival junction (MGJ) at the midfacial and the midlingual surfaces. The MGJ will be identified by the color contrast between gingiva (pink) and mucosa (red).

<u>The following measurements will be obtained at 12-month follow-up.</u>
a) Gingival Margin, b) The width of KG, c) Probing depths

3) Clinical photographs will be taken at each appointment. Obtaining intraoral photographs is the standard way to compare before and after the treatments.

4) Radiographic measurements: the radiographs will be exposed at baseline (the delivery of final prostheses; T_0) and 12-months follow-up (T_{12}). A blind evaluator will measure crestal bone loss from the crown margin to the most coronal aspect of the alveolar crest at the mesial and distal sides of the teeth on the bitewing radiographs. MiPACS® distal radiography system will be used to measure crestal bone level.

5) All procedures being performed for research purposes only
All procedures being performed in this research (except obtaining signatures on the consent form) would need to be done for those patients regardless of their participation in this study.

The clinical photographs will be taken at the evaluation appointments and scanning with intraoral imaging will be obtained for the final impression. Obtaining the intraoral images is the standard way to compare before and after the treatments. All procedures described in the protocol are in accordance with the standard protocol for each treatment.

The final impression will be made with intraoral imaging (intraoral camera) in both groups (the experimental group and the control group).

Two diagnostic radiographs need to be made in both groups (the experimental and the control group) at delivery of crown and 12 months follow-up. No additional x-ray in the control group will be exposed. The fees for radiographs are included in the crown delivery and in periodic oral evaluation. Therefore, no additional fees will be charged.

The following procedures are research procedures.
1) If potential subjects are diabetic from medical history taking, the potential subjects are required to verify their HbA1c levels confirmed by their primary care providers. The A1c level accepted needs to be within 3 months.
2) Obtaining signatures on the consent form at screening visit in the experimental and the control group.
The PI and/or research team members will follow the protocol in the approved IRB application while we are obtaining signatures from the potential subject. The information will be given to the potential subject in the separate room. The potential subject will be encouraged to ask the PI and/or research team members any questions regarding this protocol.
3) The final impression made with intraoral imaging system at the surgery in the experimental group
This is a research procedure. Since intraoral imaging system allows us to take the impression without applying impression materials around teeth (in the mouth), the final impression could be made at the surgery without increasing any postoperative complications. No materials will be contacting the flap and the tooth. The PI and research team members are experienced dental providers and will carefully monitor subjects.

6) The duration of an individual participant's participation in the study
An individual participant is expected to present from 7 to 10 appointments to complete his/her participation. The anticipated duration for an individual participant is approximately 18 months.

7) The research procedures at each appointment for **the experimental group** are as follows:
a) Appointment 1 (30-40 iminutes): A screening visit. Clinical examination and taking clinical photographs will be done.
b) Appointment 2 (60-90 iminutes): Cavity removal, filling and initial tooth preparation will be performed under local anesthesia.
c) Appointment 3 (120 iminutes): A clinical crown lengthening under local anesthesia will be performed. The final impression will be made with introral imaging (intraoral camera) at surgery.
d) Appointment 4(60-120 iminutes): Suture removal and a final crown delivery 2 weeks after the surgery will be performed. X-rays will be taken to veryify the fitting of a crown.
e) Appointment 5 (30 iminutes): Examination of bite and gum tissue 4 weeks after the delivery of a crown.
f) Appointment 6 (40-60 iminutes): 6 months after the crown delivery. Examination and cleaning will be performed.
g) Appointment 7 (40-60 iminutes): 12 months after the crown delivery. Examination, taking x-rays, and cleaning will be performed.

8) The research procedures at each appointment for the control group are as follows:
a) Appointment 1 (30-40 iminutes): A screening visit. Clinical examination and taking clinical photographs will be done.
b) Appointment 2 (60-90 iminutes): Cavity removal, filling and initial tooth preparation will be performed under local anesthesia.

c) Appointment 3 (120 iminutes): A clinical crown lengthening under local anesthesia will be performed.
d) Applintment 4 (30 minutes): Suture removal and postoperative follow-up
e) Apppointment 5 (30 minutes): Evaluation of gume tissue 4 weeks after the surgery
f) Appointment 6 (60-120 minutes): The final impression will be made with intraoral imaging (intraoral camera) at surgery 8 to 12 weeks after the surgery.
g) d) Appointment 7(60-120 iminutes): A final crown delivery. X-rays will be taken to veryify the fitting of a crown.
h) e) Appointment 8 (30 iminutes): Examination of bite and gum tissue 4 weeks after the delivery of a crown.
i) Appointment 9 (40-60 iminutes): 6 months after the crown delivery. Examination and cleaning will be performed.
j) Appointment 10 (40-60 iminutes): 12 months after the crown delivery. Examination, taking x-rays, and cleaning will be performed.

* All procedures described above are in accordance with the standard protocol for each procedure.

9) Audio or Video Recording/Photographs

1. What is the purpose of the recording
   1) To make digital dental impression for fabricating the final crowns
   2) To compare clinical parameters (such as gingival recession or keratinized gingiva) before, during, and after treatments

2. How will individuals' identities be protected?
The facial photography will not be made. Only intraoral dental images will be made. The digital impression can be stored only in the specific software that is password-protected. Intraoral photographs made by the investigators will be stored in the computer at the room 4211. The computer in the room 4211 is password-protected. The room 4211 will be locked at the end of the day. The photographs might be on the publication. However, no individual identification will be attached.

Safety considerations

1. Potential risks related to the study

Taking part in this study will expose participants to some potential risks from what they would have from routine crown lengthening surgery and crown placement.

Risks from gum surgery and crown placement in both groups:
• There might be bleeding after the surgery. Pressure dressing will be used to prevent bleeding.
• There might be some pain after the surgery. Pain medicine will be prescribed.
• Infection rarely occurs after the gum surgery. However, if infection develops, an antibiotic will be prescribed.
• You may feel some discomfort after the procedures. This discomfort will subside within two weeks.
• The crown may or may not need adjustments in both groups.
• The gum receding may or may not occur after the crown delivery in both groups.

Risks for the subjects assigned to the experimental group.
• There is a chance it might not be as successful as standard of care.

There is a potential for breach of confidentiality in both groups. Research data will be kept in a file cabinet in room 4211 at the UMSOD. The room 4211 will be locked at the end of each day. Only research team members listed on the protocol will have access to research data.

2. Potential benefits related to the study

The subjects may or may not get any benefits from participating in this study. They will receive the dental treatments that are indicated. The subjects assigned to the experimental group will get a crown earlier.
The results from this study would give a better prediction of the healing after CLPs and scientific supports for making the final impression at the surgery to expedite the delivery of final prostheses. Thus, this study will achieve a sustainable impact on the interdisciplinary field, both periodontics and restorative dentistry.
The surgical procedures and the dental restorative procedures in this study are in accordance with standard periodontal surgical procedures and standard restorative procedures. No more additional risk is encountered than at routine dental visits for periodontal surgery and restorative procedures. The PI and research team members will closely monitor all subjects in this study.

Participation is voluntary and the alternative is not to participate.

Follow-up

The study aims to follow participants up to 12 months after the delivery of the final crowns. Periodic oral evaluation, obtaining x-rays, and oral prophylaxis will be performed.

Data management and Statistical Analyses

1) Sample Size Determination
This study is the first clinical trial to determine the feasibility and safety of the proposed approach. Therefore, 10 subjects in each group are selected as a pilot study to clarify whether making the final impression at the surgery is acceptable or not.

2) Calibration for the Evaluator
SO will calibrate one investigator in terms of obtaining clinical parameters and radiographic crestal bone levels. SO and one investigator will measure GR, KG, PDs, BOP, and crestal bone levels and record Plaque Index separately for 10 patients. Pearson correlation coefficient (*r*) will be used to test the reliability.

3) Data Analysis: Descriptive statistics will be prepared for all outcome variables (mean ± standard deviation). To test the null hypothesis of no difference in level of GM, PDs and CBLs at each time point between the experimental and control groups, independent t-tests will be conducted. The confidence interval (CI) of the treatment difference in crestal bone loss between the two groups will be evaluated against the non-inferiority margin (0.5 mm). A $p \leq 0.05$ will be considered significant.

Recruitment

The research team members will recruit potential subjects through patients' screening, regular dental visits, and recall examinations. After the approval from IRB, the PI will present the brief summary of the study to the dental providers at the UMSOD. Dental providers who find a potential participant will introduce the study to a potential participant and will give the contact information to one of research team members upon patient's agreement. The PI and the research team members will ensure that all potential participants have a chance to talk and ask questions any time. The PI and the research team members will be sensitive to any signs of distress on the part of the participants. Individuals who refuse to participate will not be penalized in any way.

Eligibility Checklist

Inclusion/Exclusion Criteria (once the protocol is approved, this page must be copied, used as a checklist for screening subjects, signed by investigator, and inserted in research record for every subject screened):

Inclusion Criteria

Yes	No	Criteria .

□	□	age >18 years
□	□	a single-unsplinted crown needed
□	□	the tooth must be in the area from the canine to the second molar
□	□	a CLP (crown lengthening procedure) is required to fabricate a crown

Exclusion Criteria

Yes	No	Criteria .
□	□	uncontrolled hypertension
□	□	diabetes mellitus patients with whose HbA1c level is 6.5% and above
□	□	subjects with a history of a long-term use of corticosteroid (> 6 months)
□	□	subjects with a history of taking oral/IV bisphosphonates within the past 2 years
□	□	smokers

Quality assurance

Se-Lim Oh and Radi Masri perform quality monitoring. Se-Lim Oh is the principle investigator of the study. Radi Masri is not a research team member. He has conducted several clinical trials at the UMSOD.

The final DSMB report is attached (Appendix 1).

Expected outcomes of the study

Making the final tooth preparation and the final impression at CLP will significantly reduce the time between the CLP and the delivery of the final crown and show comparable clinical outcomes.

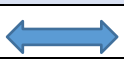
Dissemination of results and publication policy

Research data will be kept storing in a file cabinet in a locked office (4211). Only research team members in this study will have access to the research data. The data from the study may be published. However, the subjects will not be identified by their names. The personal information will not be given out unless required by law.

Duration of the project

This study will last about 3 years

Table 1. Study Period-Timetable for Completion of the Project

Research procedures	2 months	18 months	30 months	36 months
Calibration				

Recruitments			
The clinical procedures			
Data analysis			

Problems anticipated

All potential risks related to the study were addressed. If we cannot deliver a CAD/CAM crown as described in this study, we will deliver a PFM as an alternative solution.

Project management

1) Se-Lim Oh: obtaining CR from the IRB, recruiting participants, performing surgeries, data obtaining, data analysis with Dr. Yang
2) Luz Abrera-Crum: recruiting participants, performing restorative procedures, data obtaining
3) Seung Kee Choi: blind evaluator
4) Ji Seung Yang; analyzing data

Ethics

The study protocol was approved by the IRB at the University of Maryland, Baltimore (HP-00073913). The protocol is currently CR5. The approval letter is attached (Appendix 2).

The process of obtaining informed consent from the research participants is described as follows.
1) Before meeting with potential participants
The PI will verify that the consent form is approved by the IRB and is the most current version.

2) At the meeting with potential participants
A potential subject will be referred to the PI or research team members from dental providers at the UMSOD. The referral procedures are independent of the study.

The PI or research team members will explain that the nature of the study, its purpose, procedures, expected duration and the benefits and risks of participation in accordance with Federal regulations in a separate private clinic room at the UMSOD.

The potential participant will be informed of his/her rights to privacy. The potential participant is encouraged to ask questions. PI will ask the potential participant if questions have been answered to their satisfaction. The participant will be given the opportunity to review the consent alone or to review it with study personnel. The potential participants are encouraged to take the informed consent at home and discuss it with family and significant others.

3) Filing out the consent form
If the potential participant decides to enroll, he/she will sign and enter the date on the current approved consent form. The PI or a co-investigator who obtains the consent will sign and date the informed consent form. The PI will keep the original informed consent form with the participant's study file in a locked cabinet at the room 4211. The participant will keep a hard copy of the original informed consent form.

4) HIPAA
During the informed consent process the participant will also sign the research HIPAA form. The PI or a co-investigator who conducts the informed consent process will explain to the participant that by signing the HIPAA form he/she authorizes his/her medical information to be shared with those parties listed on the form for the purposes of the research study. If the participant does not agree to sign the HIPAA form, he/she cannot

participate in the study. The original HIPAA form will be kept with the original consent form in the participant's study file.

Potential participants will receive research information in a separate private room at the UMSOD clinics to secure priva

Participants will be given ample time to read and assess the consent form. They will also be given as much time as needed to ask questions. The questions will be answered to their satisfaction.

If a participant presents for each appointment, a participant is implicitly willing to be in the study. Therefore, we will not consider for ongoing consent.
However, re-consenting may be required for various reasons including but not limited to cases where:
1) The original consent form was not properly executed (missing date, time, checkboxes, etc)
2) The study has been amended (i.e. changes in the study procedures affecting current participants)

Informed consent forms

The research informed consent form is attached (Appendix 3).

Appendix 1

Data and Safety Monitoring Report

Protocol Title: The Use of Intraoral Imaging at Clinical Crown Lengthening Procedures
Principal Investigator: Se-Lim Oh
Co-monitoring person: Radi Masri

IRB#: HP-00073913
Date of the last IRB approval: 4/15/2020

The previous CR for the approved IRB protocol was obtained in April 2020. As of March 14, 2021, twenty-six subjects were enrolled and randomly assigned either to the experimental group or to the control group in this study.

Seven subjects were excluded from the study.
Five subjects were dropped out of the study. Three participants have withdrawn from the study without any specific reasons. No crowns have been delivered to these three subjects. Two participants received a porcelain-fused metal crown instead of a CAD/CAM crown because there was too much loss in tooth structure. Therefore, the two participants were excluded from the study.
Two subjects received crown lengthening surgeries and CAD/CAM crowns, but they did not present for any follow-ups.

The final e-max crowns were delivered for 19 subjects. No complications were observed in these subjects during the study period. No analysis was performed pending the completion of data collection.

The included information above were shared with the monitor (Dr. Masri), and no concerns or additional actions were recommended.

Se-Lim Oh
Clinical Associate Professor
University of Maryland School of Dentistry

Radi Masri
Professor
University of Maryland School of Dentistry

Appendix 2

University of Maryland, Baltimore
Institutional Review Board (IRB)
Phone: (410) 706-5037
Fax: (410) 706-4189
Email: hrpo@umaryland.edu

APPROVAL OF RESEARCH NOTIFICATION

OF NOTE: The Principal Investigator should review the University of Maryland Baltimore criteria for performing research during the current COVID-19 pandemic emergency. Understand that IRB approval of this research does not suggest that performance of this research under current guidelines is allowed. Failure to comply with the UMB President's directives would be considered non-compliance. The UMB Research directives can be found at https://www.umaryland.edu/coronavirus/ . If you need clarification or guidance please call the Human Research Protections Office at 410-706-5037.

Date: February 11, 2022

To: Se-Lim Oh
RE: HCR-HP-00073913-5
Type of Submission: Continuing Review
Type of IRB Review: Expedited

Approval for this project is valid from 2/11/2022 to 2/10/2023

This is to certify that the University of Maryland, Baltimore (UMB) Institutional Review Board (IRB) approved the continuing review report for the above referenced protocol entitled, "*The Use of Intraoral Imaging at Clinical Crown Lengthening Procedures*".

The IRB has determined that this protocol qualifies for expedited review pursuant to Federal regulations 45 CFR 46.110, 21 CFR 56.110, & 38 CRF 16.110 category(ies):
(8)(c) - Continuing review of research previously approved by the convened IRB where the remaining research activities are limited to data analysis. (For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever these conditions are satisfied for that site.)

The IRB made the following determinations regarding this submission:
- Written informed consent is required. Only the valid IRB-approved informed consent form(s) in CICERO can be used.
- A waiver of HIPAA authorization for release of the PHI identified in the CICERO application has been reviewed and approved for recruitment purposes only.

This study is approved to enroll 34 local participants.

This study is approved to enroll 34 worldwide participants.

Below is a list of the documents attached to your application that have been approved:
informed consent_hp00073913_hshsl (2).docx

informed consent_hp00073913_hshsl (3).docx
Eligibility Checklist for HP-00073913_2 v2-11-2018-1518365546057
The research protocol_3.pdf
HIPAA_CLP.docx

In conducting this research you are required to follow the requirements listed in the INVESTIGATOR MANUAL. Investigators are reminded that the IRB must be notified of any changes in the study. In addition, the PI is responsible for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103(4)(iii)). The PI must also inform the IRB of any new and significant information that may impact a research participant's safety or willingness to continue in the study and any unanticipated problems involving risks to participants or others.

DHHS regulations at 45 CFR 46.109 (e) require that **continuing review** of research be conducted by the IRB at intervals appropriate to the degree of risk and **not less than once per year.** The regulations make **no provision for any grace period extending the conduct of the research beyond 2/10/2023.** You will receive continuing review email reminder notices prior to this date; however, it is your responsibility to submit your continuing review report in a timely manner to allow adequate time for substantive and meaningful IRB review and assure that this study is not conducted beyond **2/10/2023**. Investigators should submit continuing review reports in the electronic system at least six weeks prior to this date.

Research activity in which the VA Maryland Healthcare System (VAMHCS) is a recruitment site or in which VA resources (i.e., space, equipment, personnel, funding, data) are otherwise involved, must also be approved by the VAMHCS Research and Development Committee prior to initiation at the VAMHCS. Contact the VA Research Office at 410-605-7000 ext. 6568 for assistance.

The UMB IRB is organized and operated according to guidelines of the International Council on Harmonization, the United States Office for Human Research Protections and the United States Code of Federal Regulations and operates under Federal Wide Assurance No. FWA00007145.

If you have any questions about this review or questions, concerns, and/or suggestions regarding the Human Research Protection Program (HRPP), please do not hesitate to contact the Human Research Protections Office (HRPO) at (410) 706-5037 or HRPO@umaryland.edu.

Appendix 3

UNIVERSITY of MARYLAND
THE FOUNDING CAMPUS

RESEARCH CONSENT FORM

Protocol Title: The Use of Intraoral Imaging at Clinical Crown Lengthening Procedures

Study No.: HP-00073913

Principal Investigator: Se-Lim Oh, DMD, MS / 410-706-3708

Sponsor: The American Dental Education Association and the department of Advanced Oral Sciences and Therapeutics

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You are invited to take part in a research study. Taking part in this study is voluntary. You do not have to take part. This consent form contains information about the study that will help you decide if you want to take part or not. Please read this form carefully. If you have questions, you may ask them any time.

PURPOSE OF STUDY

The purpose of this study is to test a new procedure that could shorten the time to fix a tooth with a crown for certain patients. The process of fixing a tooth with a crown can take longer if not enough of the tooth sticks out above the gum line. In such cases, the dentist needs to expose more of the tooth by removing some gum tissue or bone. The process of exposing the tooth in this way is called "crown lengthening surgery."

When a crown lengthening surgery is needed, the dentist typically performs this surgery first. The patient is then given about 3 months to heal before the dentist begins making a crown. This healing period often delays the delivery of a final crown.

In this study, we will test a method where we make the final impression for the crown during the surgery. We will compare the results of this method with the standard method where the impression is made 3 months after surgery. If the new method is effective, it could help patients receive a permanent crown sooner.

You qualify for this study because a crown lengthening surgery is required to make a crown.

PROCEDURES

If you are diabetic, your HbA1c must be below 6.5% in order to participate in this study. You are required to provide your HbA1c level verified by your primary care provider. The A1c level accepted needs to be within 3 months.

This study will last about 3 years. Your role in the study will last around 18 months. If you take part in this study, you will be placed in one of two treatment groups:

1. Group 1 (**the *experimental group***) will have crown lengthening surgery *with* ***a final impression made at the time of surgery***
2. Group 2 (**the *control group***) will have crown lengthening surgery *with* ***a final impression made about 3 months after surgery***. This is considered as the standard protocol.

The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an equal chance of being given each treatment. ***If you are placed in the control group, you will have three more visits compared to those in the experimental group. However, these are not research procedures. There will be no additional costs because of the three more visits. The final***

impression will be made by intraoral imaging (intraoral camera) in both groups.

We will take x-rays of your tooth when you get your crown(s), and at a follow-up visit after 12 months. These x-rays are standard care at UMB. You will not receive any additional radiation by participating in this study. Clinical photographs will be taken at baseline, surgery, delivery of crown(s), and each follow-up visit. These are also considered standard care at UMB.

The following procedures will be performed ***in the experimental group.***

1) Appointment 1(30-40 minutes): A screening visit. Clinical examination and taking clinical photographs will be done.
2) Appointment 2 (60-90 minutes): Cavity removal, filling and initial tooth preparation will be performed under local anesthesia.
3) Appointment 3 (120 minutes): A clinical crown lengthening under local anesthesia will be performed. The **final impression** will be made with **intraoral imaging (intraoral camera) at surgery**.
4) Appointment 4 (60 to 120 minutes): Suture removal and a final crown delivery 2 weeks after the surgery will be performed. **X-rays** will be taken to verify the fitting of a crown.
5) Appointment 5 (30 minutes): Examination of bite and gum tissue 4 weeks after the delivery of a crown.
6) Appointment 6 (40-60 minutes): 6 months after the crown delivery. Examination and cleaning will be performed.
7) Appointment 7 (40-60 minutes): 12 months after the crown delivery. Examination, **taking x-rays**, and cleaning will be performed.

The following procedures will be performed ***in the control group***.

1) Appointment 1(30-40 minutes): A screening visit. Clinical examination and taking clinical photographs will be done.
2) Appointment 2 (60-90 minutes): Cavity removal, core build-up and initial tooth preparation will be performed under local anesthesia.
3) Appointment 3 (90 minutes): A clinical crown lengthening under local anesthesia will be performed.
4) Appointment 4 (30 minutes): Suture removal and postoperative follow-up
5) Appointment 5 (30 minutes): Evaluation of gum tissue 4 weeks after the surgery
6) Appointment 6 (60-120 minutes): **The final impression will be made with intraoral imaging (intraoral camera) 12 weeks after the surgery**.
7) Appointment 7 (60-120 minutes): A final crown delivery. **X-rays** will be taken to verify the fitting of a crown.
8) Appointment 8 (30 minutes): Examination of bite and gum tissue 4 weeks after the delivery of crown.
9) Appointment 9 (40-60 minutes): 6 months after the crown delivery. Examination and cleaning will be performed.
10) Appointment 10 (40- 60 minutes): 12 months after the crown delivery. Examination, **taking x-rays**, and cleaning will be performed.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible to be present for each procedure and to follow the instructions of the research team.

POTENTIAL RISKS/DISCOMFORTS:

Taking part in this study will expose you to some potential risks from what you would have from routine crown lengthening surgery and crown placement.

Risks from gum surgery and crown placement *in both groups*:

- There might be bleeding after the surgery. Pressure dressing will be used to prevent bleeding.
- There might be some pain after the surgery. Pain medicine will be prescribed.
- Infection rarely occurs after the gum surgery. However, if infection develops, an antibiotic will be prescribed.
- You may feel some discomfort after the procedures. This discomfort will subside within two weeks.

- The crown may or may not need adjustments in both groups.
- The gum receding may or may not occur after the crown delivery in both groups.

Risks when you are placed *in the experimental group.*
- There is a chance it might not be as successful as standard of care.

Risk for loss of confidentiality *in both groups*: As with any study, there is a risk that your study data might not be kept confidential. We will be minimize this risk by storing data in a secure location, such as a locked office and locked cabinet. Electronic data will be password-protected.

POTENTIAL BENEFITS

You may or may not benefit by taking part in this study. There is no guarantee that you will receive direct benefit from your participation in this study. Knowledge gained from this study could help others in the future. *If you are placed in the experimental group, you will get a crown earlier.*

ALTERNATIVES TO PARTICIPATION

Standard of care/conventional treatment is available outside the study. You may also choose to receive temporary filling instead of a crown or receive no treatment. If you choose not to take part, your healthcare at UMB will not be affected.

COSTS TO PARTICIPANTS

1) You are responsible for the fees of a crown lengthening procedure ($451) and a final crown ($543).
2) Root canal therapy (RCT) may be indicated. RCT is not the procedure related to this study. You are responsible for the fee ($300 to $800) for RCT.
3) You are responsible for co-pays and deductible in cases that your dental insurance covers the aboveprocedures
4) You are responsible for parking fees.

PAYMENT TO PARTICIPANTS

The cost of cavity removal and filling ($100 to $150) will be waived. The fee for periodic oral exam ($37) and cleaning ($67) at 6-months and 12-months follow-ups will be waived.

CONFIDENTIALITY AND ACCESS TO RECORDS

To protect your privacy, study data will be stored in a file cabinet in a locked office. All electronic data will be password protected. Only research team members in this study and the Institutional Review Board (IRB) will have access to study data.

The data from the study may be published. However, you will not be named. Certain people from the institutions where the study is being done will be able to view sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. If you refuse to take part, or if you stop taking part in the study, you will face no penalty or loss of benefits to which you are entitled.

Please contact the investigator Dr. Se Lim Oh at 410-706-3708 if any of the following occur:
- You decide to stop taking part in the research.
- You have questions, concerns, or complaints about the research.
- You need to report a medical injury related to the research.

If you choose to withdraw from the research, there will be no adverse consequences. If you withdraw, you will continue to receive treatment as a regular patient.

If you decide to withdraw from the research, a written withdrawal is required to Dr. Se-Lim Oh.

If you withdraw from this study, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine dental care. If you agree, this data will be handled the same as research data.
You will be told if any significant findings develop during the study that could affect your choice to remain in the study.
If you are an employee or student, your employment status or academic standing at UMB will not be affected by your choice to take part or not take part in this study.

CAN I BE REMOVED FROM THE RESEARCH?
The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include failure to follow instructions from the research staff and if the person in charge decides that the research study is no longer in your best interest. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

DENTAL SCHOOL RESEARCH POLICY STATEMENT
It is the Dental School's policy that all research participants being seen at the Dental School must be registered in the School's patient records system. It is also the Dental School's policy that the care received by research participants can be reviewed by appropriate Dental School personnel under the Dental School's quality assurance program. These policies help the Dental School to verify that your dental care is appropriate, and to provide continued care when research participation has concluded. If you consent to participate in research, please understand that you are agreeing that your personal information will be entered in the Dental School's patient records, and that members of the quality assurance staff will have access to your dental information. The records concerning your dental care are confidential as required by law of Maryland and the U.S.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS
The University of Maryland, Baltimore (UMB) is committed to providing participants in its research the rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research subject.

Participating in research may result in an injury, as explained above. If you suffer an injury directly related to your participation in this project, UMB and/or one of its affiliated institutions or health care groups will help you obtain medical treatment for the specific injury and provide referrals to other health care facilities, as appropriate. UMB and/or its affiliated institutions or health care groups will not provide you with financial compensation or reimbursement for the cost of care provided to treat a research-related injury or for other expenses arising from a research-related injury. The institution or group providing medical treatment will charge your insurance carrier, you, or any other party responsible for your treatment costs. If you incur uninsured medical costs, they are your responsibility. The study staff can give you more information about this if you have a study injury.

By signing this Consent Form, you are not giving up any legal rights. If this research project is conducted in a negligent manner and you are injured as a direct result, you may be able to recover the costs of care and other damages from the individuals or organizations responsible for your injury.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland School of Medicine
Human Research Protections Office
620 W. Lexington Street, Second Floor

Baltimore, MD 21201
410-706-5037

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

_____	_____
Participant's Signature	Investigator or Designee Obtaining Consent Signature
Date:_____	Date:_____