Comparison of Two Gingival Displacement Procedures: a Randomized Clinical Trial

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UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL
SCHOOL OF DENTISTRY
GRADUATE STUDENT MASTERS THESIS DEVELOPMENT PROGRAM

ABSTRACT OF RESEARCH PLAN

Date of submission: _____

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PROGRAM: _Prosthodontics___

TITLE OF PROJECT: _Comparison of Two Gingival Displacement Procedures; a Randomized Clinical Trial___

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Objective: The intent of this exploratory study is to compare two methods (cordless vs corded gingival displacement) currently used in clinical practice to displace sulcular tissues to facilitate an acceptable dental impression that accurately captures the prepared cervical finish line for the fabrication of indirect fixed prosthodontic restorations. The primary aims are to compare the two methods with respect to 1) the accuracy of the impression with respect to capturing the prepared cervical finish line for the fabrication of the indirect fixed prosthodontic restoration as assessed by two expert clinicians 2) the time required to prepare the impression and 3) the discomfort of the procedure as reported by the patient. Secondary aims are to estimate the effect of clinician experience (resident level vs faculty) and jaw of restoration placement (maxillary vs mandibular) on the outcomes of accuracy, time, and discomfort.

Background: Indirect fixed prosthodontic restorations are widely used for the restoration of teeth. The fabrication of a well-fitting indirect restoration requires an accurate impression which captures the cervical finish line. Dentists have a hard time making proper impressions, with a reported 56% of impressions sent to labs being inadequate. The most common deficiency is inadequate recording of the cervical finish line. The primary reason for this inadequacy is deficient gingival displacement technique.

The traditional procedure used to displace gingival tissue prior to making impressions is gingival retraction cord, with a reported 92% of dentists surveyed employing this procedure. (Ahmed 2014) For this procedure to work properly, it is time consuming (requires 7-10 minutes in the sulcus), technique sensitive, requires anesthetizing the patient, and causes patient discomfort both during and post operatively.

More effective and efficient gingival displacement procedure can lead to clinically improved fixed restorations, less patient chair time, and less patient discomfort.

Materials and Methods: One hundred (100) patients will be recruited from the University of North Carolina (UNC) School of Dentistry (SOD). A stratified block randomization will be used to randomize patient to impression technique: Aquasil Ultra Cordless, Dentsply International using Aquasil Ultra Polyvinyl siloxane (PVS) impression material versus Dentsply International, gingival displacement cord (Ultrapak, Ultradent Products International) hydrated with aluminum chloride hexahydrate (Hemodent, Premier Dental Products Company). Stratification will be based on the clinic where treatment is provided (Dental Faculty Practice, Graduate Operative Dentistry, Graduate Prosthodontic Clinic), A block size of 4 within each stratum will be used to maintain a balanced allocation to impression group. Patient inclusion criteria include: 1) requires indirect restoration 2) probing depths 4mm or less. 3) No bleeding on probing. 4) finish line 0-1mm sub-gingival.

Specific Aims

The intent of this exploratory study is to compare two methods (cordless vs corded gingival displacement) currently used in clinical practice to displace sulcular tissues to facilitate an acceptable dental impression that accurately captures the prepared cervical finish line for the fabrication of indirect fixed prosthodontic restorations. The primary aims are to compare the two methods with respect to 1) the accuracy of the impression with respect to capturing the prepared cervical finish line for the fabrication of the indirect fixed prosthodontic restoration as assessed by two expert clinicians 2) the time required to prepare the impression and 3) the discomfort of the procedure as reported by the patient. Secondary aims are to estimate the effect of clinician experience (resident level vs faculty) and jaw of restoration placement (maxillary vs mandibular) on the outcomes of accuracy, time, and discomfort.

Significance

Indirect fixed prosthodontic restorations are widely used for the restoration of teeth. The fabrication of a well-fitting indirect restoration requires an accurate impression which captures the cervical finish line. Dentists have a hard time making proper impressions, with a reported 56% of impressions sent to labs being inadequate. The most common deficiency is inadequate recording of the cervical finish line. The primary reason for this inadequacy is deficient gingival displacement technique.

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More effective and efficient gingival displacement procedure can lead to clinically improved fixed restorations, less patient chair time, and less patient discomfort.

The specific aims in this proposal explore whether a cordless gingival displacement procedure can properly displace sulcular tissues to facilitate an acceptable impression that accurately captures the prepared cervical finish line for the fabrication of indirect fixed prosthodontic restorations and thereby improve the efficiency of a traditionally technique sensitive procedure in dentistry.

Methods

A total of one hundred participants will be recruited from the University of North Carolina (UNC) School of Dentistry (SOD) Graduate Prosthodontics clinic, Graduate Operative clinic, and the Dental Faculty Practice. A stratified block randomization will be used to randomize patient to impression technique: Aquasil Ultra Cordless, Dentsply International using Aquasil Ultra Polyvinyl siloxane (PVS) impression material versus Dentsply International, gingival displacement cord (Ultrapak, Ultradent Products International) hydrated with aluminum chloride hexahydrate (Hemodent, Premier Dental Products Company). Stratification will be based on the clinic where treatment is provided (Dental Faculty Practice, Graduate Operative Dentistry, Graduate Prosthodontic Clinic), A block size of 4 within each stratum will be used to maintain a balanced allocation to impression group. The randomization schedule will be prepared by Dr. Ceib Phillips. Randomization allocations will be placed in sequentially numbered envelopes for ease of use by clinicians within the three clinics.

The treating clinician will open the allocation envelope after the tooth preparation is completed. This is to limit the potential bias of the clinician altering the tooth preparation design in anticipation of a known gingival displacement technique. Although the patient may require restorations on multiple teeth, only one tooth, the most posterior, will be included in the evaluation. The clinician will be instructed to

complete the impression for that tooth before proceeding to other teeth. The patient will be informed that participation, if multiple teeth are treatment planned, may increase the appointment time.

The gingival displacement procedures and impression procedures are described here:

Traditional Corded Impression Procedure:

1) The prepared tooth is washed and dried, and assure hemostasis.

2) Small diameter retraction cord, after it has been hydrated with Hemodent for 10 minutes, is tucked around the tooth in the space between it and its surrounding gum tissue. A second larger diameter retraction cord, also hydrated with Hemodent, will be placed over the first cord and tucked around the tooth. These cords will be left in place for a minimum of 8 minutes. These cords temporarily push the gum tissue back away from the tooth. (Before making the impression, the 2nd larger cord is removed, and the gums will stay back long enough for the impression material to seep around the tooth, thus allowing it to capture a copy of the entire tooth preparation.)

3) After a minimum of 8 minutes, the larger 2nd cord will be removed, and the tooth dried. Quickly, after confirmation of a dry field, the light body consistence impression material is syringed around the prepared tooth and across the occlusal surfaces of adjacent teeth.

4) An impression tray that has been filled with the heavy body consistency impression material is then placed over the arch of teeth, and gently pressed into place to ensure the teeth are completely covered with a uniform thickness of impression material. As the different impression material consistencies set, they fuse together into a single unit.

5) When removed from the mouth, the impression should contain a negative copy of both the prepared tooth and the teeth of that jaw.

Cordless Impression Procedure:

1) The prepared tooth is washed and dried, and assure hemostasis.

2) Apply B4 + surface optimizer.

3a) If 1 prepared tooth requiring an indirect restoration is being impressed, a single size (0.7mL) unit dose cartridge will be inserted into the digit power dispenser. If more than 1 prepared tooth requiring an indirect restoration is being impressed, a multi size (1.6mL) unit dose cartridge will be inserted into the digit power dispenser.

3b) Using the digit power dispenser, unit dose cartridge, and intrasulcular mixing tip, depress foot pedal and gently insert tip into the gingival sulcus of the prepared tooth, slightly apical to the preparation finish line. Material should flood the sulcus. Make sure to dispense material ahead of the intrasulcular tip, and completely around the prepared finish line, and then the tooth.

4) An impression tray that has been filled with the heavy body consistency impression material is then placed over the arch of teeth, and gently pressed into place to ensure the teeth are completely covered with a uniform thickness of impression material. As the different impression material consistencies set, they fuse together into a single unit.

5) When removed from the mouth, the impression should contain a negative copy of both the prepared tooth and the teeth of that jaw.

The clinician will record the impression technique, type of impression material used; whether tray adhesive was used; the tray material; the type of tray used; the number of units requested; the time required to obtain the first impression (start and end of impression taking is defined above for each procedure), and the total number of impressions produced until an adequate impression was made. Also recorded will be the clinic and resident year if placed in a graduate clinic and the subject's age and sex. Unique id numbers not related to clinical record will be used.

The impressions will be photographed, digitally scanned, saved in black and white, and then collectively evaluated at a later time based on a criteria evaluation form by two calibrated evaluators. The evaluators (also referred to as expert examiner) will assess each impression for errors in the finish line; in the tray/material; and errors with gingival displacement/hemostasis as primary outcomes. The number of errors can range from 0 to 13.

Patient discomfort will be assessed using the FACES visual picture pain scale rated from 1-10 based on the following question posed at 4 points during treatment; "How much discomfort are you experiencing at this point in treatment?" This question will be asked at the beginning of the treatment appointment, immediately before the impression procedure is initiated, immediately after the impression procedure is completed, and again at the completion of the treatment appointment. Each question will be rated on a scale of 1 to 10. The total score indicated by the sum of the 4 questions will be analyzed.

Patient consent will be obtained prior to treatment and the impression. This may occur at a prior treatment planning visit or at the treatment visit.

Inclusion Criteria:

- Patients must be adult males or females 18 years of age or older.
- Patients must be able and willing to follow study procedures and instructions.
- Patients must have read, understood and signed an informed consent form.
- Patients must be in good general health, (based on a review of the medical history, blood pressure and heart rate).
- Patients must have no health-realated contra-indications to dental treatment.
- Patient must require at least one indirect restorations (crowns).
- Probing pocket depths around the treatment tooth/teeth must be 4mm or less.
- There must be no bleeding on probing around the treatment tooth/teeth.
- The prepared finish line must be between 0 to 1mm sub-gingival (inclusive).

Exclusion Criteria:

- Individuals who have a chronic disease with oral manifestations.
- Individuals who exhibit gross oral pathology.
- Smokers
- Uncontrolled Diabetics (per review of medical history)
- Probing pocket depths around treatment tooth/teeth of greater than 4mm.
- Bleeding on probing around treatment tooth.teeth.
- The prepared finsh line is greater than 1mm sub-gingival.

The inclusion/exclusion criteria limit generalizability of the findings to patients without confounding periodontal or medical issues. However, the sample size of this study is not sufficient to extend to a consideration of the effect of these confounders on the comparison of the two impression techniques.

The proposed research study requires a total of 100 participants. Patients will be recruited from and will be treated in the Dental Faculty Practice, the Graduate Operative Clinic, and the Graduate Prosthodontic Clinic. The patient may seek other dental treatments in the above mentioned clinics or in other clinics in the School of Dentistry.

Study clinicians will be trained and calibrated on both the cordless and the corded gingival displacement procedures and impression procedures in a practice session. Clinical instruction protocols will be printed on laminated forms for all study clinicians to follow, for both the cordless and the corded procedures. These clinical protocol forms will be in the clinicians operatory during actual study treatment, and this protocol must be followed for the impression to be included in the study. The clinical instruction protocol is listed in Appendix A.

In addition to a signed Consent form, the study subject will be asked to complete the standard adult medical and dental health history questionnaire provided by the UNC SOD (Appendix 1) and will be provided with the UNC Chapel Hill Notice of Privacy Practices and the Consent for Purposes of Treatment, Payment and Health Care Operations (Appendix 2). Other than the research consent, these are standard practices followed by UNC SOD for all patients. The study is mandated to adhere to these protocols prior to treating a patient at the UNC SOD. After consent has been obtained, an oral examination will be performed by the treating dentist to confirm the patient meets inclusion criteria. The patient will be dropped from the study if inclusion/exclusion criteria are not met. The treating clinician will record the criteria that resulted in the patient being dropped (See Appendix B). If the inclusion criteria are not met, a clinically appropriate impression method will be performed at the clinician's judgment and will be made per case by the treating clinician, following standard of care.

Customary anesthesia and tooth preparation will be performed by the clinician as necessary for the particular indirect restoration. The gingival displacement procedure and impression will be made as described in this study protocol and as followed on the laminated clinical protocol sheet. If the clinician finds that the first impression is inadequate and chooses to make an additional impression, only the first impression will be evaluated for the study and a note will be indicated to record the number of impressions the clinician made to achieve an acceptable impression.

Patients will be given appropriate verbal and written post-procedure instructions; and appointments will be made for restoration try-in and delivery, as would happen as part of their regular treatment.

There are no potential direct benefits to the participant besides the fact that particularly close attention will be paid to the gingival displacement and impression procedures, and there will be close evaluation of impressions.

All of the impressions will be photographed and digitally scanned, and saved in black and white. These scans will be evaluated collectively on a later day, and will be critiqued based on a criteria form (See Appendix B). This evaluation will be performed by 2 calibrated expert examiners for all impressions, and will be completed independently. If a conflict exists in evaluations between examiners, the examiners will meet to form a consensus response. Impressions will be deemed acceptable or not acceptable, and the reasons for not acceptable impressions will be indicated. The evaluation criteria are listed in Appendix B.

In an effort to reduce bias in reviewing the impressions, all of the images will be black and white so not to clue the examiners into which color of impression material was used, which could be correlated with each technique.

The scientific knowledge to be gained will be the efficacy of a new gingival displacement procedure, and if it can be adopted to improve patient treatment and treatment outcomes.

The risks of the study are consistent with the current standard of care. Standard treatment protocols will be observed for the treatment of teeth which require indirect restorations. The risks will be minimized by

treatment evaluation and proper treatment technique.

Data monitoring

Research data management will involve collection, entry, processing, storage, retrieval, archival, distribution and documentation of information. Data collection will adhere to precise written forms. Data will be stored in a series of Microsoft Access data files, which will be accessible to the Investigators and their staff. Only project-related personnel will be able to access these files. Data collection forms will be kept in locked files. Quality assurance (QA) will occur as data is entered in order to check for data completeness and consistency prior to entry.

Statistical Analysis:

Descriptive statistics for all study variables will be computed by impression group and used to summarize the procedural materials used in the impression and the outcomes. The primary outcomes are the number errors of the impression in the finish line; in the tray/material; and errors with gingival displacement/hemostasis (number of errors can range from 0 to 13), the time to complete the impression, and patient discomfort (range from 0 to 40). Since the outcomes are unlikely to be normally distributed, the Wilcoxon rank sum test will be used as the primary statistical test to assess whether the quality of impressions, time, or patient discomfort made with a cordless gingival displacement procedure is different than with a corded technique. To adjust for additional covariates [clinic providing care, jaw, procedural materials], Poisson regression will be used to assess the relationship between the primary outcomes and the covariates of interest, including impression group with a primary interest in estimation using confidence intervals.

The lack of historical data comparing the proposed outcomes between the two impression groups makes a sample size calculation difficult. For this exploratory study which is time constrained as a thesis project, a sample size calculation was done using an effect size which may be larger than the clinically meaningful effect size. A sample size of 30 in each group will have 80% power to detect a probability of 0.709 that an observation (number of total errors) in the Cordless group is less than an observation in the Corded group using a Wilcoxon (Mann-Whitney) rank-sum test with a 0.05 two-sided significance level.

Budget

Materials	Amount needed	Estimated costs
Aquasil Ultra Cordless Pneumatic Power Dispenser Units (3)	3 systems	Included in normal clinic treatment
Aquasil Ultra Cordless PVS material	Enough for 30 impressions + 10 for practice callibration.	Included in normal clinic treatment
Aquasil Ultra Cordless B4 Pre-Impression Surface Optimizer	Enough for 30 impressions + 10 for practice callibration.	Included in normal clinic treatment
Aquasil Ultra Cordless Ultrathin intra sulcular tips	Enough for 30 impressions + 10 for practice callibration.	Included in normal clinic treatment
Aquasil Ultra PVS materials (heavy and light body)	Enough for 60 impressions + 10 for practice callibration.	Included in normal clinic treatment
GingiBraid retraction cord	12 containers- sizes: 00,0,1,2; (3) of each.	Included in normal clinic treatment
Hemodent	3 bottles + 1 for practice callibration	Included in normal clinic treatment
Viscostat	60 disposable vial/syringe	Included in normal clinic treatment
Impression trays	60 trays + 20 for practice callibration	Included in normal clinic treatment
Impression tray adhesive	3 bottles + 1 for practice callibration	Included in normal clinic treatment
Estimate Total:		

Timeline

The study is planned to last approximately 1.5 years to allow for recruitment and data collection and analysis. The study would ask the participants to come to 2 appointments; it might be possible to consent the patient and perform treatment on the same day, if the patient was scheduled for treatment that day already.

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Gingival Displacement with Impressions for Fixed Prosthodontics

TO BE COMPLETED BY TREATING CLINICIAN:

[ ] Patient did not meet inclusion / exclusion criteria and is dropped from the study

- *[} Medical / smoking*
- *[ ] Probing pocket depths around treatment tooth/teeth of greater than 4mm.*
- *[ ] Bleeding on probing around treatment tooth.teeth.*
- *[ ] The prepared finsh line is greater than 1mm sub-gingival*

[ ] Patient meets inclusion / exclusion criteria

Patient ID: _____

Impression Group: _____*Corded* _____*Cordless*

Clinic: _____*Dental Faculty Practice*

_____*Graduate Operative Clinic* _____*1st* ____*2nd* ____*3rd*

_____*Graduate Prosthodontic Clinic* _____*1st* ____*2nd* ____*3rd*

Patient Age: _____ *Gender :* _____*Male* ____*Female*

Type of impression material used: *Tray adhesive used:*

[ ] Aquasil Ultra Cordless [ ] Aquasil Ultra

[ ] Yes [ ] No

Tray material:

[ ] Metal stock [ ] Plastic stock [ ] Custom [ ] Plastic dual arch [ ] Metal dual arch

Type of tray used:

[ ] Ant quad [ ] Post quad [ ] Full arch

Number of units requested:

[ ] 2-3 FDP [ ] Onlay [ ] Single crown x _____

[ ] Anterior [ ] Canine [ ] Premolar [ ] Molar

Jaw: [ ] Maxillary [ ] Mandibular

Time Required for 1st Impression: _____ minutes and seconds

Number of Impressions Required to Obtain Adequate Impression: _____

Appendix B:

TO BE COMPLETED BY EVALUATORS

Evaluator: _____***ONE*** _____***TWO***

Patient ID: _____

Errors in the finish line:

[ ] Voids/Bubbles [ ] Lack of wash material [ ] Tearing

Errors in the tray/material:

[ ] Cotton roll attached [ ] Inadequate fusion of viscosity [ ] Lack of polymerization

[ ] Show through of occlusal/incisal edges

[ ] Inadequate retention [ ] Pressure of tray on soft tissue [ ] Void on the preparation

Errors with gingival displacement/hemostasis:

[ ] Tissue over finish line [ ] Retraction cord attached [ ] Blood on impression