

**COMPARISON OF TWO GINGIVAL DISPLACEMENT PROCEDURES;
A PILOT STUDY**

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ABSTRACT

Anthony P. Prudenti: **Comparison of Two Gingival Displacement Procedures; a Pilot Study**
(Under the direction of Sumitha N. Ahmed)

Objective: The primary objective was to examine if a cordless gingival displacement procedure displaces sulcular tissue to facilitate acceptable impressions for fixed prosthodontic restorations.

Materials and Methods: Fifteen (15) patients were recruited; cordless impressions (n=7) and conventional corded impression (n=8) were made during routine treatment for fixed dental prostheses.

Results: Fisher's exact tests, Wilcoxon rank sum tests, and an unpaired t-test were used to compare variables between (CD) and (CL) groups, and to compare variables between acceptable and unacceptable impressions. Level of significance was set at 0.05 for all analysis. Within this small sample size, the 2 groups (CD and CL) are significantly similar in relation to most variables. Only TEAR and EVAL were significantly different between CD and CL, and VOID was significantly different between acceptable and not acceptable impression groups.

Conclusions: Within the limitations of this study, marginal tearing statistically affected the acceptance of impressions made using the cordless procedure.

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PREFACE

I would like to acknowledge the previous work completed in 2015 by Clayton T. Rau, for his master's degree thesis titled, "THE QUALITY OF FIXED PROSTHODONTIC IMPRESSIONS: AN ASSESSMENT OF CROWN AND BRIDGE IMPRESSIONS RECEIVED AT COMMERCIAL LABORATORIES." It was much of his work, and that of his mentor Dr. Terry Donovan, that outlined, defined, and guided this project.

Rau C, Donovan T, Boushell L, Delgado A, Ritter A. The Quality of Fixed Prosthodontic Impressions: An Assessment of Crown and Bridge Impressions Received at Commercial Laboratories. ProQuest 2015; UMI 1589096.

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LIST OF ABBREVIATIONS

PE	Polyether
PVS	Poly-vinyl siloxane
VPS	Vinyl polysiloxane
UNC	University of North Carolina
SOD	School of Dentistry
CL	Cordless Impression Group
CD	Corded Impression Group
VOID	Voids or bubbles on the finish line
WASH	Lack of wash material on the finish line
TEAR	Tearing of material at the finish line
TISSUE	Tissue over the finish line
FUSION	Inadequate fusion of viscosity

CHAPTER 1: LITERATURE REVIEW

Introduction

The success of any fixed prosthesis starts with the accuracy of the impression. Obtaining an impression that accurately captures the prepared margin and cervical finish line is paramount in the fabrication of well-fitting indirect restorations. A vital component in impression making is retraction of gingiva. Atraumatic gingival displacement allows access for impression material to accurately record the finish line and provides sufficient thickness of impression material in the gingival sulcus to prevent tearing during removal.¹ Making an optimal impression for indirect restorations remains one of dentistry's most challenging procedures.^{2,3} Clinicians must be able to properly select gingival displacement procedures and impression materials, as well as evaluate the quality of their impressions.⁴⁻⁷ These play a critical role in the success or failure of the final restoration.^{4,5}

Modern impression materials have improved the accuracy of impression making.^{8,9} Despite these improvements, many studies have reported that impressions sent to dental laboratories for fabrication of indirect restorations still remain inadequate.^{4,5,10,11,12} To date all impression materials require control of the gingival tissues adjacent to the preparation, adequate placement of the material around the finish line, and the use of an appropriate impression tray.³ Stewardson in 2005 recognized that a lack of impression making principles is one of the major causes of unacceptable indirect restorations.¹³

1.1. A History of Impression Quality

Historically, studies have shown that clinicians consistently make inadequate impressions.¹⁴ In 1984, Aquilino and Taylor¹¹ recognized the discrepancy between dental education, private practice, and what was being sent to dental laboratories. The study expresses concerns that recent graduates are gaining less laboratory experience and exposure in school, and that they quickly abandon the sound principles they were taught in school once they get out into private practice.

Winstanely *et al.*¹⁰ evaluated 290 impressions from four commercial dental laboratories. They reported that an acceptable restoration could be fabricated on 57% of the impressions evaluated, and that 20% of the impressions would be impossible or doubtful to fabricate an acceptable final restoration. In this study, the major cause of defective impressions was indiscernible recording of the finish line. Irreversible hydrocolloid was the material used for most all of the impressions evaluated in this study.

Albashaireh *et al.*¹⁵ evaluated 136 impressions sent to commercial laboratories for fabrication of fixed restorations. They studied the quality of impressions made and found that 50% of impressions/dies to be unsatisfactory or unusable.

Samet *et al.*⁴ evaluated 193 impressions from 11 different laboratories. Using a more detailed evaluation criterion they found that 89% of all impressions evaluated had at least one detectable error. This study also found that 51% of the defects involved the cervical finish line.

In 2007 Beier *et al.*² evaluated 1,466 impressions and found a remarkably low unacceptable rate of 3%. An explanation for this low unacceptable rate may be due to the strict protocol the clinicians followed, using retraction cord and controlling for moisture. Findings in other studies clearly demonstrates that a similar attention to detail does not occur constantly in

most practices.

1.2. Impression Materials

Today most impressions are made with polyether (PE) and polyvinyl siloxane (PVS). Digital impression techniques (optical scanning) have become popular and are promoted as the future of dentistry. This review focuses on PVS impression material because it is most applicable to the study design.

Poly-vinyl siloxane, also known as vinyl polysiloxane, polyvinyl, and addition silicone have been used as an impression material since the mid-1970s. The major advantages to the material is that its superior reproduction of fine details and elastic recovery.⁸ PVS materials set by way of an addition reaction, which involves the linking of a vinylsiloxane with a hydrogen siloxane via a platinum catalyst. Hydrogen is produced as a byproduct of this reaction, and is then scavenged by platinum. Silica fillers are used to control viscosity and rigidity of the material.^{9,16,17} Another major advantage of PVS impression materials are that their dimension stability over time. This material can be stored for weeks without losing accuracy.⁸ The major disadvantages of PVS impression material is its hydrophobic nature. This quality makes it sensitive to blood, saliva, and crevicular fluids in the unset phase.^{8,9,16,17}

Chai *et al.* describes three mechanical properties of impression materials that are clinically relevant: *yield strength* determines the ability of a material to withstand stress without permanent deformation, *strain at yield point* indicates the amount of undercut that the impression material can overcome without permanent elastic deformation, and *tear energy* indicates the resistance to tear of impression material.¹⁸ Perakis *et al.* suggest that the ideal impression material will absorb the most energy prior to the point of permanent deformation, without tearing.¹⁹ Laufer *et al.* in 1996 verified that PVS and PE impression materials can capture the finish line without distortion

when the sulcular space allows a sufficient thickness of material of 0.2 mm or greater.²⁰

1.2.1. Effects of Moisture

The way impression materials interact with moisture is described as the material's hydrophilic or hydrophobic nature. The hydrophilicity of a material is measured by the angle a standardized droplet of water makes with the material. Materials forming angles less than 90 degrees are defined as hydrophilic and those forming angles greater than 90 degrees as hydrophobic.¹⁵ PVS materials are principally hydrophobic because they contain hydrophobic aliphatic hydrocarbon groups around the siloxane bond.^{9,16,21,22}

Peutzfeldt and Asmussen²² evaluated how the hydrophilicity and viscosity affect the ability of impression materials to displace water and replicate surface detail. Their results found that materials with contact angles below 70 degrees performed better at displacing water as the hydrophilicity increased. Materials that were more hydrophobic (contact angles over 70 degrees) showed a propensity to displace water more readily with increases in viscosity. When water was omitted all impression materials achieved 100% reproduction of detail.

Johnson *et al.*²³ evaluated the ability of PE and PVS materials to replicate surface detail of a standard pattern metal plate. They evaluated three variables: material (PE and PVS), surface conditions (wet and dry), and technique (mono- and dual-phase). They found that PE was superior to PVS, monophasic was superior to a dual viscosity, and dry conditions were superior to wet conditions in replication of preparation details. It was noted that the pattern used in the study contained ridge heights of 10 μ m, while ISO specification for fine detail reproduction is 20 μ m. Considering this, all of the PE and PVS samples except one dual-phase PVS, produced acceptable detail to meet the current ISO standards for fine detail reproduction.

Petrie *et al.*²⁴ published similar findings also in 2003. This study created dry, wet, and “moist” surfaces to evaluate the detail reproduction of two PVS materials. Stainless steel dies fabricated to ADA specification no. 19 were used in to evaluate these impression materials. This study found that as the moisture level increased the ability to reproduce surface detail for PVS materials significantly decreased. In 2005, Walker *et al.*²⁵ repeated the study with PVS and PE materials under dry and moist conditions. The PE materials achieved complete reproduction of surface details on the dies in both dry and moist conditions, while the PVS materials were not able to reproduce the details in moist condition.

Rupp *et al.*^{26,27} showed that improved PVS materials with the addition of surfactants failed to achieve a similar hydrophilicity to PE materials. It was shown that the surface tension improved over 60 minutes, and that the addition of surfactants may be beneficial during the pouring of the impression, and not during the impression making process itself.²⁸

Nagrath *et al.*²⁹ evaluated four hydrophilic VPS impression materials. They found that the dimensional stability remained intact in all conditions (wet, moist, and dry), but the best surface detail results were obtained only under dry conditions for all the four materials.

Basapogu *et al.*³⁰ compared hydrophilic and hydrophobic VPS impression materials in a moist environment. Using stainless steel die prescribed to ADA specification no. 19 for elastomeric impression materials they concluded that hydrophilic vinyl polysiloxane was more dimensionally accurate than hydrophobic vinyl polysiloxane in monophase, one step and two step putty wash impression techniques under moist conditions.

Manufacturers have attempted to address problems with material wettability by the addition of surfactants. These products are labeled as “improved,” “hydrophilic,” or “smart wetting” vinyl polysiloxane. Despite the addition of surfactants, the above studies have shown that PVS materials do not readily interact with moist surfaces as well as they do dry surfaces. For this reason, moisture

control is still paramount on the final quality of the impression.

1.2.2. Interactions With Other Materials

It has been reported that PVS impression materials can have interactions with many items commonly used during restorative procedures.^{8,9,13,17,31,32,33} Interactions with sulfur or sulfur containing compounds and the PVS catalyst can inhibit the contaminated surface from completing the setting reaction. This can occur by direct or by indirect contact with the PVS materials.⁹

It has been reported that polymerization inhibition of PVS materials can be caused by direct contact with 96% of latex products like gloves and rubber dams, and be indirect contact by hands that had previously been wearing latex gloves or intraoral tissues that had come in contact with latex products.^{8,17,33} It is hypothesized that the chloroplatinic acid catalyst reacts with unreacted sulfur in these latex products.³⁴ It has been a belief that latex-free vinyl products do not cause this inhibition reaction,^{8,17} however, Amaya-Pajaras recently showed in 2014 that two light body PVS materials can be inhibited by direct contact with several latex and latex-free products.³⁵

It has been suggested that compounds in hemostatic agents may interfere with the setting of PVS. In 1993 the research by Camargo *et al.*³⁶ evaluated 3 latex samples, 5 retraction cords and 4 medicaments during PVS setting. The retraction cords nor the medicaments inhibited the setting reaction, as opposed to latex control samples. It was concluded that the medicaments and retraction cords were not the cause of the polymerization inhibition reported in previous studies, but that handling of the cords with latex gloves caused the contamination effect. In 2011, Machado and Guedes³⁷ found no inhibitory affect with any combination of gloves or hemostatic agents they evaluated. It is possible that improvements in materials have made them less or non-reactive to excess sulfur in latex products.

The oxygen inhibited layer has an inhibitory effect on the polymerization of PVS materials.

When used around a preparation that has been restored with fresh composites, or a veneer prep with immediate dentin sealing, unset material may result.^{9,38} This interaction can be avoided if the inhibition layer is removed by surface polishing with instruments or flour of pumice, air-particle abrasion, or by curing through a glycerin gel.^{8,9,17,38}

1.3. Impression Trays

Impression tray selection is often overlooked as a criterion for successful impression making. Gordon *et al.*³⁹ stated that dentists are regularly using less expensive prefabricated plastic trays because of the time and cost associated with fabricating custom impression trays. Research studies from 1980-2009 show a trend in tray selection,^{4,10,11,40,41} where the use of stock trays has increased from 75%⁴¹ to nearly 100%,^{11,40} and the use of quadrant trays has increased from 35%⁴¹ to 88%.⁴⁰

1.3.1. Stock Trays

Rigid trays are preferred in order to resist deformation from pressure during the impression, after removal from the mouth, and when pouring. A difference in rigidity exists between commercially available disposable plastic trays, custom trays, and metal stock trays. Cho and Chee in 2004⁴² found a statistically significant difference between the mean cross arch change of metal and plastic stock trays, and raised concerns for the use of plastic impression trays with high viscosity materials potentially leading to discrepancies in the final restorations.

Carrotte *et al.*⁴³ evaluated rigid, semi-rigid, and flexible tray systems based on the approximate thickness of the plastic tray material and presence of a reinforcing border. They found that with a high viscosity putty wash impression, the rigid metal and rigid plastic trays were identical, but the semi-rigid and flexible trays produced castings with greater marginal openings. When a softer putty was used, the marginal openings decreased but the rigid metal and rigid plastic

trays were still performed lower than the semi-rigid and flexible trays.

1.3.2. Custom Trays

The major advantages of custom trays are rigidity, ability to resist deformation, and the ability to provide a uniform thickness of impression material.⁴⁴ The uniform bulk of material for optimal PVS impressions has been demonstrated to be 2 mm.^{16,45,46} The ideal characteristics of a custom tray should include: 1) good adhesion to the impression material, 2) dimensional stability, 3) allowing even thickness of impression material, and 4) sufficient rigidity to resist deformation.^{8,32,42,45,47} Christensen (1994)⁴⁷ recognizes that many dentists think custom trays are too expensive, but he points out that stock trays require three to four times more material than proper custom trays, and the savings in material will offset the cost. Many researchers and clinicians still recommend the use of custom trays^{3,8,13,18,32,43,45,46,47,49}, while some others believe there is no clinical difference between stock and custom.^{39,50,51}

1.3.3. Dual Arch Trays

Dual arch, “closed bite” impressions have been in use in dentistry since the early 1980’s when they were described by Wilson and Werrin.⁵² They are designed to efficiently obtain impressions of the prepared teeth, opposing dentition, and intercuspal relationship simultaneously, while using less material than full arch impressions.⁵³ The indications and requirements for their accurate use are limited to the following: 1) a maximum of two prepared teeth, 2) unprepared stops both anterior and posterior to the preparations, 3) stable, reproducible intercuspal position, 4) the patient must be able to close into maximum intercuspal position with the tray in place, 5) existing anterior guidance, 6) the canine must be recorded in the impression, 7) the tray must not impinge on any teeth or soft tissue, and 8) the provider must be familiar with the procedures being performed.^{8,13,54,55,56} Contraindications for the utilization of dual arch trays are 1) group function

occlusal pattern, 2) unstable maximum intercuspal position, and 3) a planned alteration of the vertical dimension of occlusion.⁵⁷

A series of studies from 2002-2009⁵⁸⁻⁶² showed no clinically significant difference in dies from dual arch trays compared with those made in custom trays, and Parker⁵⁷ showed dual arch impressions had less horizontal contact error than custom full arch trays. Metal dual arch trays were shown to be superior to plastic dual arch trays by Cox *et al.*⁶¹ and Wostmann *et al.*⁶³ Wostmann points out that impression distortion from the impression tray is due to the elastic recovery from how the tray resets when it is removed from the mouth.⁶³ Small *et al.*⁵⁶ recommends that the trays have sidewalls that extend just to the gingival margin of the preparation to maintain material at this level, but it is advised to avoid large sidewalls that can cause soft tissue impingement, risking tray distortion.

Johnson *et al.*⁶⁴ studied 116 dual arch impressions in 2010 and showed that 64% of impressions were successful, but that PVS produced significantly more successful impressions compared with PE, 70% and 58% respectively. The most common errors pertained to the finish line and inadequate gingival displacement, and is consistent with previous impression studies.^{4,10,11}

In 2003, Lane *et al.*⁵³ showed that the double arch impression technique is faster, more comfortable, uses less material, and is preferred by 80 percent of patients.

1.4. Margin Design and Placement

Although clinicians should make decisions for margin design and margin location based on factors such as material, access, and esthetics, it was noted by Hunter *et al.* in 1990 that most dentists probably have a “preferred” design they feel comfortable preparing.⁶⁵ No matter what margin is chosen, the advantages of improved control of contours, esthetics, structural rigidity, ease of evaluating preparations, and clearer impressions allowed by wider margins must be considered.^{2,65} Donovan and Chee⁶⁷ in 2004 state that the following criteria for margin selection

should be considered: 1) the selected margin must provide a predictable level of integrity, 2) to minimize plaque accumulation, the selected margin must present smooth materials to the gingival sulcus, and 3) in some situations, the margin also must provide acceptable esthetics.

1.4.1. Subgingival Margins

It is crucial to consider the proper placement of the gingival margin in relation to the free gingival margin, the epithelial attachment, and the alveolar crest.^{67,68} It has been shown that a supragingival position is best to place a margin, however, clinical practice recognizes that subgingival margins are sometimes needed. Retention and resistance form must be obtained, and this sometimes requires extending preparations subgingivally.⁶⁹ Caries, extent of previous restorative margins, root sensitivity, cervical defects, and esthetics are factors that sometimes dictate subgingival placement of a margin.^{69,70,71}

When a subgingival margin is indicated, current recommendations indicate placing margins 0.5 mm apical to the free gingival margin, or sounding of the alveolar crest to make sure the biologic width is not violated.^{67,72,73} Kois in 1994 mentions the relationship of the margin location to the bone as being more critical than the distance below the free gingival margin.⁷³

1.4.2. Biologic Width

In 1961, Gargiulo *et al.*⁷⁴ first described the concept of biologic width when he measured the average length of the gingival attachment to the root, the junctional epithelium, and the sulcus depth in human cadavers. When Loe⁷⁵ published his article in 1968 on the reaction of gingival tissues to restorative procedures, the iatrogenic biologic response to the periodontium was revealed.⁷² Most consider the total biologic width to be approximately 2-3 mm to maintain normal gingival and osseous health, with 1 mm of gingival attachment, 1 mm of junctional epithelium, and 1mm of sulcus depth. This is an average measurement though, as junctional epithelium

measurements vary.^{72,74} Sounding the osseous crest has been recommended as the most accurate way to determinant how far subgingival margins can be placed without violating the biologic width.⁷³

Newcomb,⁷⁶ in 1974, showed increasing levels of inflammation in anterior teeth with direct correlation to the distance between the crown margin and the base of the sulcus. Felton *et al.*⁷⁷ in 1991 showed a strong correlation between the amount of marginal discrepancy and periodontal health, by measuring gingival index and crevicular fluid flow rates. They maintained that current methods for evaluating subgingival margin discrepancies are inadequate, and Christensen⁷⁸ in 1966 indicated that dentists do not detect subgingival margin discrepancies until they are larger than 120 μm .

Reeves⁷⁹ review in 1991 on subgingival margins stated that the degree of inflammation is influenced by a combination of four factors: 1) failure to maintain proper emergence profile, 2) inability to adequately finish subgingival margins, 3) placement of the margin in an area with minimum to no attached gingiva, and 4) violation of biologic width. When subgingival margins are needed, attention must be paid to ensure proper location and accurate recording of these margins to ensure well-fitting restorations and periodontal health.

1.5. Gingival Displacement

Gingival displacement is defined as “the deflection of the marginal gingiva away from the tooth,” according to *The Glossary of Prosthodontic Terms*.⁸⁰ In 1984, Nemetz *et al.*⁸¹ described the basic criteria for acceptable gingival displacement as: 1) the creation of sufficient lateral and vertical space between the finish line and gingival tissues to allow the preparation margin to be recorded in an impression medium, 2) provide absolute control of gingival fluid seepage and hemorrhage, 3) no significant, irreversible soft or hard tissue damage resulting from the procedure, and 4) not produce any potentially dangerous side effects. To accomplish proper gingival

displacement, techniques classified as mechanical, chemical, surgical, or a combination of these methods are used.^{6,81,82}

1.5.1 Gingival Retraction Cords and Medicaments

The most traditional method, and most frequently utilized,^{83,84} is the chemicomechanical technique for gingival displacement described by Schillingburg.⁶⁹ This technique utilizes 1 or 2 retraction cords placed in the gingival sulcus, with the addition of a hemostatic medicament. The two main types of gingival retraction cords being used by clinicians are braided and knitted retraction cords.^{6,41,83,84} Braided retraction cords are made by weaving a tight pattern that resists fraying during placement, and can be placed with smooth or serrated edge packing instruments.⁸⁵ Braided cords may not absorb medicaments as easily as knitted retraction cords, and knitted cords should be placed with non-serrated instruments to prevent fraying. Knitted cord has the ability to increase in size after placement in the sulcus, adding to the retraction of the gingiva. There has been an increase in the popularity of knitted cord.⁸⁶ The selection of cord type being used is mainly a selection based on provider preference, as there has been no substantial evidence supporting a difference in performance. There is also a lack of standardization in cord size and efficacy between manufacturers.^{6,82}

There are a number of medicaments that can be used along with retraction cord during the gingival displacement procedure. Medicaments that are currently available in solution or impregnated in cord are: aluminum chloride, aluminum sulfate, aluminum potassium sulfate, ferric sulfate, ferric subsulfate, and epinephrine.^{6,87} These medicaments do not seem to have a reported effect on the polymerization of PVS or PE materials.^{8,36,37} Epinephrine, however, has been linked to adverse clinical side effect such as anxiety, tachycardia, and increased respiratory rate.^{41,87-90} There is research which shows a spike in epinephrine levels in blood upon

placement of retraction cord which contains epinephrine.⁹¹ Safer medicaments, such as aluminum chloride, have shown similar clinical abilities to displace gingiva as epinephrine containing cord.^{92,93} In the dental materials course given by Dr. Terry Donovan, he presents evidence to support that the routine use of epinephrine in conjunction with gingival displacement procedures is not recommended.

1.5.2 Classical Displacement Methods

Shillingburg⁶⁹ in his text “*Fundamentals of Fixed Prosthodontics*,” describes the chemico-mechanical technique for gingival displacement. It is taught as the most traditional method of gingival displacement in dental institutions. This technique utilizes 1 or 2 cords placed in the gingival sulcus, with the addition of a hemostatic medicament. The *single-* or *double-* cord techniques, are the methods utilized by 98% of prosthodontists.⁸⁴ The single cord technique has been recommended with margins less than 0.5mm subgingival and when there is no hemorrhage.^{6,81,82} The technique was described to place the largest diameter cord that fits in the sulcus, and then to remove the cord just prior to making the impression. Some believe this technique is overused and under delivers due to the frequent presence of blood and fluids which are expressed when the cord is removed.³ A variation that has been used is to leave the single cord in place during impression making, and this can be a valid technique if the margins are clearly exposed with the cord in-place.

The double cord technique utilizes a small diameter cord which is first placed into the sulcus, followed by a second, larger diameter cord. This technique can be used in all situations, but is especially recommended for situations with deeper subgingival margins, less than ideal soft tissue health, and when a single cord does not provide sufficient lateral tissue displacement.^{6,81,82} Immediately before the impression material is introduced, the second (larger diameter) cord is removed from the sulcus, while leaving the smaller cord in place. With the smaller cord in place,

it maintains the ability to absorb gingival crevicular fluid, control hemorrhage, and maintain the gingival tissues in a displaced position.^{6,81} This technique has been referred to as the standard by which all other methods should be compared, and is the method of choice for 43% of prosthodontists surveyed.^{7,88}

In 1994, Laufer *et al.*^{20,94} demonstrated that there was an increased incidence of voids along the margins and greater impression material distortion when the sulcular width was less than 0.2 mm. In 2008, Finger *et al.*⁹⁵ showed that a 0.2 mm sulcus width could be fully reproduced with all types of impression materials, but for sulcular widths of less than 0.2 mm, the use of a light body wash along with a higher viscosity tray material produced more accurate recording than monophasic techniques. In 1997, Baharav *et al.*⁹⁶ showed that retraction cord needs to be left in place for a minimum of 4 minutes in order to maintain a sulcular width of 0.2 mm for up to 20 seconds after the cord is removed, but that the sulcular width would remain above the 0.2 mm width for nearly twice as long when the cords were left in place for 8 minutes. In the dental materials course given by Dr. Terry Donovan, he presents the evidence to support the double cord technique where the second cord is left in place for a minimum of 8 minutes before it is removed and impression made. Dr. Donovan also presents the evidence supported by Csempeš *et al.*,⁹⁷ where they calculated the optimal 20 minutes of soak time for retraction cords to become completely hydrated with a medicament. It is recommended that retraction cord be placed into the gingival sulcus with gentle pressure. However, Loe and Silness⁹⁸ noted tissue reactions to retraction cord when packed into the supra-alveolar connective tissue attachment, stating that excessive pressure is often used.

1.5.3 Alternative Methods

The most common method used to displace gingival tissue is the use of retraction cords. There are alternative gingival displacement methods currently available. Electrosurgery is a

technique used to reduce excessive tissue, expose gingival margins and control intra- operative hemorrhaging by removing several layers of epithelial cells. Baba *et al.*⁶ reported that when used correctly, has no adverse effects on healing. Contraindications to electrosurgery include patients with pacemakers and/or implanted cardioverter defibrillators, and should be used with caution around metallic restorative materials and implants. Electrosurgery does remove tissue, and the effects of its use can change soft tissue contours.^{7,13,99}

Soft tissue lasers have been used in a similar fashion as electrosurgery, where gingival tissues are removed.^{7,13,99} Less inflammation, reduced hemorrhage, and faster and painless healing have been reported with this method.^{99,100} However, the amount of time taken to complete the procedure with lasers has been reported to be much longer than electrosurgery.⁷

Cordless techniques for gingival retraction have been introduced recently with the promise of many advantages, such as the reduction in chair time, less invasive, greater patient comfort and requiring little to no additional anesthesia.^{6,101,102} Clinical trials which have evaluated the effects of cordless gingival displacement techniques compared to traditional corded techniques have shown varying results.¹⁰³ Shrivastava, *et al.*¹⁰⁴ showed that three evaluated displacement systems produced significant horizontal gingival displacement above the acceptable value needed for impression accuracy of 0.2 mm, where retraction cord soaked in 15% aluminum chloride produced maximum displacement (0.74 mm), followed by expasyl paste (0.48 mm), and magic foam cord produced the least displacement (0.41 mm). Another study showed that the same three techniques caused temporary gingival inflammation, but the cordless techniques did not induce bleeding during or after gingival displacement.^{103,105} Cordless systems have been documented to be more comfortable to patients and user-friendly to the operator.^{101,106} Compared to mechanochemical methods, however, cordless techniques have shown a compromised ability of these materials to move vertically in the sulcus and displace deeper gingival margins.^{101,107}

Acar, *et al.*¹⁰⁸ showed that when medicament impregnated cord, displacement paste, and pressure cap were all used simultaneously, better results for gingival displacement were achieved, but it was time consuming and clinically difficult.

1.6. Conclusion

Accurate impressions that capture the prepared margin and finish line are paramount to achieve successful, well fitting indirect restorations. A vital component in impression making is atraumatic gingival displacement. We know that making an optimal impression for indirect restorations remains one of dentistry's most challenging procedures,^{2,3} and that most impressions sent to dental laboratories have flaws.^{4,5,10,11,12}

Modern impression materials and techniques have improved the accuracy of impression making, however, the fundamentals for all current techniques still require control of the gingival tissues adjacent to the preparation, moisture control, adequate placement of the material around the finish line, and the use of an appropriate impression tray.^{3,8,9}

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CHAPTER 2: MANUSCRIPT

COMPARISON OF TWO GINGIVAL DISPLACEMENT PROCEDURES; A PILOT STUDY

2.1 Introduction

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 prepared margin and cervical finish line. Making an optimal impression for indirect restorations remains one of dentistry's most challenging procedures.^{1,2} Rau *et al.*³ reported that 86% of the evaluated impressions sent to dental laboratories for fabrication of indirect restorations had at least one detectable error. The most common deficiency was inadequate recording of the cervical finish line with a reported 55% of the evaluated impressions having at least one detectable error in the cervical finish line area. The primary reason for this inadequacy was identified as deficient gingival displacement technique.³ Thus, a vital component in impression making is retraction of gingiva. The goal of gingival retraction is to atraumatically displace gingival tissues to allow access for impression material to record the finish line, and to provide sufficient thickness of material in the gingival sulcus so that the impression does not tear during removal.⁴

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.⁵ For this procedure to work properly, it is time consuming, technique sensitive, requires anesthetizing the patient, and causes patient discomfort both during and post operatively.

Cordless techniques for gingival retraction have been introduced recently with the promise

of many advantages, such as the reduction in chair time, less invasive, greater patient comfort and requiring little to no additional anesthesia.^{6,7,8} Clinical trials which have evaluated the effects of cordless gingival displacement techniques compared to traditional corded techniques have shown varying results.⁹ Cordless systems have been documented to be more comfortable to patients and user-friendly to the operator.^{7,10} Compared to mechanochemical methods, however, cordless techniques have shown a compromised ability of these materials to move vertically in the sulcus and displace deeper gingival margins.^{7,11}

Gingival displacement is defined as “the deflection of the marginal gingiva away from the tooth,” according to *The Glossary of Prosthodontic Terms*.¹² In 1984, Nemetz *et al.*¹³ described the basic criteria for acceptable gingival displacement as: 1) the creation of sufficient lateral and vertical space between the finish line and gingival tissues to allow the preparation margin to be recorded in an impression medium, 2) provide absolute control of gingival fluid seepage and hemorrhage, 3) no significant, irreversible soft or hard tissue damage resulting from the procedure, and 4) not produce any potentially dangerous side effects. If newly developed cordless gingival displacement procedures can accomplish this outlined criteria, the goals of improved clinical effectiveness, efficiency, clinical outcomes, and patient comfort may be achieved.

Hypothesis and Specific Aims

The hypothesis for this study is that 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. Our objective was to identify if a new procedure can improve the efficiency of a traditionally technique sensitive, and poorly executed procedure in dentistry.

In an effort to evaluate the effectiveness of this cordless gingival displacement procedure, the following specific aims were explored:

- 1) To examine if a cordless gingival displacement procedure can properly displace sulcular tissue to facilitate acceptable impressions that accurately capture the prepared cervical finish line for the fabrication of indirect fixed prosthodontic restorations. These impressions were evaluated for acceptability based on a set of criteria, by 2 calibrated examiners.
- 2) To determine if a cordless gingival displacement procedure facilitates impressions that are at least as good as the traditional corded gingival displacement procedure. The impressions were evaluated and then a comparison was made between the 2 groups of impressions.
- 3) To determine if a cordless gingival displacement procedure is more time efficient than the traditional corded procedure. The procedures were timed, starting when the gingival displacement procedure commenced and ended when the impression was removed from the patient's mouth.
- 4) To determine if a cordless gingival displacement procedure causes less discomfort to the patient than the traditional corded procedure. Patient discomfort was evaluated with a 4 question written survey (0-10 FACES scale answers).

2.2 Materials and Methods

The study was conducted at the University of North Carolina, School of Dentistry, where all study clinicians were licensed dentists. The study clinicians were part of the graduate Prosthodontics residency program, the graduate Operative Dentistry residency program, or were faculty in these departments. Although these clinicians are already trained to perform clinical impression procedures, maintaining consistency of treatment for the purpose of this study was desired. For this reason, the study clinicians were part of a calibration session for both the cordless and the corded gingival displacement and impression procedures in a practice session. The practice procedures were performed on prepared typodonts, while clinicians followed instructions on a printed Clinical Instruction Protocol sheet (Figure 3.) for both the cordless and the corded procedures. This clinical protocol was printed and included in all study packets for each study impression, for the clinician to follow during the procedures.

Fifteen (15) adult patients who were treatment planned for indirect restorations were recruited from the UNC School of Dentistry. Participants were randomized to receive either the cordless (CL) gingival displacement procedure using Aquasil Ultra Cordless, or the traditional corded (CD) technique using Aquasil Ultra poly-vinyl siloxane (PVS) impression material along with gingival displacement cord (Ultrapak, Ultradent Products Inc., South Jordan, Utah) hydrated with aluminum chloride hexahydrate (Hemodent, Premier Dental, Plymouth Meeting, PA). The study clinicians were blinded from the impression group until after the preparation and margin placement was completed, and the clinician was ready to start the impression procedure. This was done to avoid potential preparation and margin bias based on prior knowledge of the impression technique to be used. Seven participants were included in the CL group, and eight participants were included in the CD group. Patient inclusion criteria included: 1) requires indirect restoration/s, 2) probing depths 4mm or less, 3) no bleeding on probing, and 4) prepared finish line 0-1mm sub-gingival.

Informed consent for the research study was obtained prior to the conduct of any research procedures. (Figure 1. and Figure 2.) A clinical evaluation was completed for inclusion criteria, however, only the data specified in the clinician impression form was recorded for research purposes. Customary anesthesia and tooth preparation was performed by the clinician per standard of care for the particular indirect restoration, and when completed, the finish line was evaluated for inclusion criteria [must be between 0 to 1mm sub-gingival (inclusive), using a periodontal probe, measured circumferentially around the preparation finish line].

A computerized randomization was used for the allocation, and once the preparation was finalized, the sealed study envelope was open to disclose which impression technique would be employed. The designated gingival displacement procedure and impression was then made as described in the Clinical Instruction Protocol sheet. If the clinician found that the first impression was inadequate and chose to make additional impressions, only the first impression was evaluated for the study and a note was made to record the number of impressions the clinician made to achieve an acceptable impression.

The gingival displacement procedures and impression procedures are described here, and can be seen in Figure 3. Clinical Instruction Protocol:

Corded Impression Procedure:

- 1) The prepared tooth was rinsed with water and dried, and assured hemostasis. Timing started.
- 2) Small diameter retraction cord, after it has been hydrated with Hemodent, was placed in the sulcus. A second larger diameter retraction cord, also hydrated with Hemodent, was be placed over the first cord and placed in the sulcus. These cords were left in place for a minimum of 8 minutes.
- 3) After a minimum of 8 minutes, the larger 2nd cord was removed, and the tooth dried. Quickly,

after confirmation of a dry field, the light body impression material was syringed around the prepared tooth and across the occlusal surfaces of adjacent teeth.

4) An impression tray filled with the heavy body impression material was 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.

5) When the impression was removed from the mouth, the time required to complete the procedure was recorded and the impression was inspected by the provider to ensure acceptability.

Cordless Impression Procedure:

1) The prepared tooth was rinsed with water and dried, and assured hemostasis.

2) Apply B4 + surface optimizer.

3) Using the digit power dispenser, unit dose cartridge, and intrasulcular mixing tip, the foot pedal was depressed and the tip gently inserted into the gingival sulcus of the prepared tooth, slightly apical to the preparation finish line. Material was allowed to flood the sulcus. The material was dispensed 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 impression material was 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.

5) When the impression was removed from the mouth, the time required to complete the procedure was recorded and the impression was inspected by the provider to ensure acceptability.

At the end of the dental appointment, the patient was asked to complete a discomfort questionnaire (Fig. 4), which illustrates the FACES scale. The questionnaire posed the following question: “In the appropriate box, record the number that represents how uncomfortable you are at each point during this visit.” Beside each of 4 boxes were the following statements: “At the start of the treatment appointment; immediately before the impression procedure was initiated; immediately after the impression procedure was completed; at the completion of the treatment appointment.” The patient had the ability to rate each statement on a scale of 0 to 10. The scores of the 4 questions were analyzed.

The clinician completed the clinician impression form (Fig. 5), recording variables such as: the research group (CL vs. CD); tooth number; whether tray adhesive was used; the tray material; the type of tray used; the number of units requested; the number of impressions required to obtain an acceptable impression; time required to make the study impression; patient age and gender; and the department and year of resident provider making the impression.

The impressions were disinfected with spray disinfectant (CaviCide, Desident), sealed in a biohazard bag, and sent to be evaluated. All evaluations were performed by 2 calibrated examiners for each impression using an impression evaluation form (Fig. 6), and were completed independently. In cases which had multiple prepared teeth, only the distal most prepared tooth was evaluated. The evaluators recorded criteria for errors in the finish line, errors in the tray/material, and errors with gingival displacement/hemostasis. The evaluation criteria were borrowed and modified from the previous impression evaluation study by Rau *et al.*, and are listed in Table 1. If a conflict existed in evaluations between examiners, the examiners met to form a consensus. Impressions were deemed acceptable or not acceptable. There were no attempts to evaluate the poured casts or the fabricated restorations specific to these impressions. Two

secondary outcomes were also analyzed. 1) The time required to perform the impression procedure, and 2) Patient discomfort assessed using the FACES visual scale.

2.3 Statistical Analysis

The Fisher's exact tests were used to compare the corded (CD) versus cordless (CL) groups for all nominal variables as well as to compare the major and minor error variables between the acceptable and unacceptable impressions. Wilcoxon rank sum tests were used to compare the corded and cordless groups for all continuous variables except age, for which an unpaired t-test was used. Level of significance was set at 0.05 for all analysis.

2.4 Results

With the randomization of all minor variables to the 2 groups (CD and CL) without any statistical significance detected, we can say the minor variables did not have an effect on the evaluation outcomes (acceptable or not acceptable). (Table 2.) Thus, the two groups (CD and CL) are similar. We can say this with statistical confidence, but due to the small sample size, we cannot definitively exclude the effect that these minor variables may have once the sample size meets a more powerful number.

Of the 4 critical variables, voids and bubbles at finish line (VOID), lack of wash material at finish line (WASH), tear at finish line (TEAR), and tissue over finish line (TISSUE), only TEAR was significantly different between CD and CL groups. The cordless group had statistically significant more finish line tears of the impression material. (Table 2.)

Of the 4 critical variables, only VOID was significantly different between acceptable and not acceptable impression groups. The not acceptable group had statistically significant more voids and bubbles at the finish line of the evaluated impressions. (Table 3.)

The evaluation of acceptable or not acceptable impressions had a statistically significant

difference between CD and CL. The cordless group had statistically significant more unacceptable impressions. (Table 2.)

Patient age (Table 4.) did not have statistical significance, nor did gender, tooth type (molar, premolar, anterior) or location (maxilla, mandible). The clinical department and the provider year in training did not have statistical significance, nor did the type of impression tray.

The amount of time recorded for corded impressions was median of 15 minutes and for cordless a median of 7 minutes, however this was not detected statistically. (Table 5.)

2.5 Discussion

Background

Gingival displacement is defined as “the deflection of the marginal gingiva away from the tooth,” according to *The Glossary of Prosthodontic Terms*.¹² In 1984, Nemetz *et al.*¹³ described the basic criteria for acceptable gingival displacement as: 1) the creation of sufficient lateral and vertical space between the finish line and gingival tissues to allow the preparation margin to be recorded in an impression medium, 2) provide absolute control of gingival fluid seepage and hemorrhage, 3) no significant, irreversible soft or hard tissue damage resulting from the procedure, and 4) not produce any potentially dangerous side effects. To accomplish proper gingival displacement, techniques classified as mechanical, chemical, surgical, or a combination of these methods are used.^{6,13,14}

Gingival Retraction Cords and Medicaments

The most traditional method, and most frequently utilized,^{5,15} is the chemicomechanical technique for gingival displacement described by Schillingburg.¹⁶ It is taught as the most traditional method of gingival displacement in dental institutions. This technique utilizes 1 or 2 cords placed in the gingival sulcus, with the addition of a hemostatic medicament. The *single-* or

double-cord techniques, are the methods utilized by 98% of prosthodontists surveyed.¹⁵ The *single-cord* technique has been recommended with margins less than 0.5mm subgingival and when there is no hemorrhage.^{6,13,14} The *double-cord* technique, however, can be used in all situations, but is especially recommended for situations with deeper subgingival margins, less than ideal soft tissue health, and when a single cord does not provide sufficient lateral tissue displacement.^{6,13,14} The *double-cord* technique utilizes a small diameter cord which is first placed into the sulcus, followed by a second, larger diameter cord. Immediately before the impression material is introduced, the second (larger diameter) cord is removed from the sulcus, while leaving the smaller cord in place. With the smaller cord in place, it maintains the ability to absorb gingival crevicular fluid, control hemorrhage, and maintain the gingival tissues in a displaced position.^{6,13} This technique has been referred to as the standard by which all other methods should be compared, and is the method of choice for 43% of prosthodontists surveyed.^{17,18} This study made use of the *double-cord* technique for the corded group.

The two main types of gingival retraction cords being used by clinicians are braided and knitted retraction cords.^{5,6,15,19} Knitted cord has the ability to increase in size after placement in the sulcus, adding to the retraction of the gingiva. There has been an increase in the popularity of knitted cord.²⁰ This study used knitted retraction cord for the corded procedures.

There are a number of medicaments that can be used along with retraction cord during the gingival displacement procedure. Medicaments that are currently available in solution or impregnated in cord are: aluminum chloride, aluminum sulfate, aluminum potassium sulfate, ferric sulfate, ferric subsulfate, and epinephrine.^{6,21} These medicaments do not seem to have a reported effect on the polymerization of PVS or PE materials.^{14,22,23} Epinephrine, however, has been linked to adverse clinical side effect such as anxiety, tachycardia, and increased respiratory rate.^{18,19,21,24,25} There is research which shows a spike in epinephrine levels in blood

upon placement of retraction cord which contains epinephrine.²⁶ Safer medicaments, such as aluminum chloride, have shown similar clinical abilities to displace gingiva as epinephrine containing cord.^{27,28} For the corded group in this study, aluminum chloride was utilized as the medicament to hydrate the retraction cord.

In 1994, Laufer *et al.*^{29,30} demonstrated that there was an increased incidence of voids along the margins and greater impression material distortion when the sulcular width was less than 0.2 mm. In 2008, Finger *et al.*³¹ showed that a 0.2 mm sulcus width could be fully reproduced with impression materials. In 1997, Baharav *et al.*³² showed that retraction cord needs to be left in place for a minimum of 4 minutes in order to maintain a sulcular width of 0.2 mm for up to 20 seconds after the cord is removed, but that the sulcular width would remain above the 0.2 mm width for nearly twice as long when the cords were left in place for 8 minutes. For the corded group in this study, retraction cord was left in place for a minimum of 8 minutes.

Statistically, when considering the 4 critical variables tested in this study, only TEAR showed an increased incidence in the cordless group. (Table 2.) This was not a surprising outcome, as the tear strength of the flash of material that remains in the sulcus is directly related to the thickness of that material. The above studies showed us that we need a minimum of 0.2mm of material thickness, and it was clear that we were not accomplishing this material thickness in the sulcus area in many of these cordless impression.

Alternative Methods

The most common method used to displace gingival tissue is the use of retraction cords. There are alternative gingival displacement methods currently available. Electrosurgery is a technique used to reduce excessive tissue, expose gingival margins and control intra- operative hemorrhaging by removing several layers of epithelial cells. Baba *et al.*⁶ reported that when used correctly, has no adverse effects on healing. Contraindications to electrosurgery include patients

with pacemakers and/or implanted cardioverter defibrillators, and should be used with caution around metallic restorative materials and implants. Electrosurgery does remove tissue, and the effects of its use can change soft tissue contours.^{17,33,34,35}

Soft tissue lasers have been used in a similar fashion as electrosurgery, where gingival tissues are removed.^{17,33,34} Less inflammation, reduced hemorrhage, and faster and painless healing have been reported with this method.^{34,35} However, the amount of time taken to complete the procedure with lasers has been reported to be much longer than electrosurgery.¹⁷

Cordless techniques for gingival retraction have been introduced recently with the promise of many advantages, such as the reduction in chair time, less invasive, greater patient comfort and requiring little to no additional anesthesia.^{6,7,8} Clinical trials which have evaluated the effects of cordless gingival displacement techniques compared to traditional corded techniques have shown varying results.⁹ Shrivastava, *et al.*³⁶ showed that three evaluated displacement systems produced significant horizontal gingival displacement above the acceptable value needed for impression accuracy of 0.2 mm, where retraction cord soaked in 15% aluminum chloride produced maximum displacement (0.74 mm), followed by expasyl paste (0.48 mm), and magic foam cord produced the least displacement (0.41 mm). Another study showed that the same three techniques caused temporary gingival inflammation, but the cordless techniques did not induce bleeding during or after gingival displacement.^{9,37} Cordless systems have been documented to be more comfortable to patients and user-friendly to the operator.^{7,10} Compared to mechanochemical methods, however, cordless techniques have shown a compromised ability of these materials to move vertically in the sulcus and displace deeper gingival margins.^{7,11}

Acar, *et al.*³⁸ showed that when medicament impregnated cord, displacement paste, and pressure cap were all used simultaneously, better results for gingival displacement were achieved, but it was time consuming and clinically difficult.

Previous studies have shown the percentage of unacceptable impressions for indirect restorations sent to laboratories by private practitioners to be 55%, and by dental students to be 25.7%.³ This study evaluated only the first impression attempted by institutional clinicians (graduate residents and faculty), and found 53% of these impressions to have critical errors considering them unacceptable. If additional impressions were made to obtain an acceptable impression, these additional impressions were not evaluated in this study, only a record was kept of how many attempts were made until an acceptable impression was made. It was reassuring to find that 75% of the impressions that were unacceptable, had been reattempted at least 1 more time by the clinician. This shows that the clinician self-evaluated the impression and determined it to be inadequate. On 8 of the 15 occasions, the study clinician made an additional impression; in 6 cases they made 2 impression, and in 2 cases they made 3 impressions. We don't know however, if the final impression that the clinician accepted would be evaluated with an acceptable criteria by the study evaluators.

Even though the difference in time required for each procedure was not statistically different, the median time for the cordless procedure was 7 minutes and the median time for the corded procedure was 15 minutes. The cordless system takes less time to perform an impression procedure.

The patient based discomfort data did not show significance with this small sample size. One thought is that this may be due to the questionnaire being administered to the patient at the end of the appointment, where they then answered all the questions retroactively. This may have had an impact on the discomfort values and perceived discomfort that they were recording, because the patient did this based on recall, rather than at the instant the impression procedure was started and when the impression was removed from the patient's mouth.

Of the 4 critical variables, only VOID at finish line was significantly different between acceptable and not acceptable impression groups. The not acceptable group had statistically significant more voids and bubbles at the finish line of the evaluated impressions, and this make sense, as voids and bubbles in the finish line are critical factors that make an impression not acceptable. (Table 3.) There is a trend that TISSUE over the finish line (p-value = 0.0513), may appear to have significance once the sample size increases. This also is reasonable outcome, as tissue over the finish line means that gingival tissue is not properly being displaced.

The evaluation of acceptable or not acceptable impressions had a statistically significant difference between CD and CL. The cordless group had statistically significant more unacceptable impressions. (Table 2.) This correlates with the other statistically significant TEAR at finish line outcome.

In summary, accurate impressions that capture the prepared margin and finish line are paramount to achieve successful, well-fitting indirect restorations. A vital component in impression making is atraumatic gingival displacement. We know that making an optimal impression for indirect restorations remains one of dentistry's most challenging procedures,^{1,2} and that most impressions sent to dental laboratories have flaws.^{3,39-42}

Modern impression materials and techniques have improved the accuracy of impression making, however, the fundamentals for all current techniques still require control of the gingival tissues adjacent to the preparation, moisture control, adequate placement of the material around the finish line, and the use of an appropriate impression tray.^{2,14,43}

Cordless systems have been documented to be more comfortable to patients and user-friendly to the operator,^{7,10} however, clinical trials which have evaluated the effects of cordless gingival displacement techniques compared to traditional corded techniques have shown varying results.⁹

2.6 Limitations

- None of the study clinicians had ever used the Cordless impression system before this study. At the start of the study, before patient treatment, study clinicians had a practice session where they became acquainted with the cordless system, and practiced the procedure on prepared typodonts. The clinical environment may have proved different, or more training may have been advised needed.
- All of the study clinicians had used a corded technique in practice previous to this study. To make a direct correlation between techniques, it would be ideal to have clinicians with equal experience using both the cordless and the corded techniques. This ideal may not be possible, however, a positive learning curve could be established. A minimum number of patient impressions using the cordless system could be set, for example 10, before study clinicians could move forward and start making impressions to be evaluated for the study.
- When preparing a tooth for indirect restoration, it is very common for the clinician to place gingival retraction cord in the sulcus to assist with gingival displacement to define and position the margin. For this study, if the provider placed any cord prior to the impression, the tooth was excluded from the study. This limited the recruitment of study patients.
- If clinicians had a challenging experience when using the study impression materials for an impression, they were less likely to recruit additional patients for the study impressions. This limited the recruitment of study patients.
- The Department of Prosthodontics and the Department of Operative Dentistry are small departments, and the residents and faculty interact regularly. When study impressions were made, it was common for others in the department to ask the clinician about their experiences with the impression materials. When a challenging experience was had when using the study impression material, this deterred others from recruiting their patients to use this study procedures.

- Criteria was set for this study to evaluate impressions which were made for the fabrication of no more than 3 restorations. This was due to the increased difficulty when impressions are made for multiple units, and also due to the Cordless system limitation of being able to express enough light body/wash material for up a maximum of 3 units a single use. In the graduate prosthodontics clinic, it was not common to impress 3 teeth or less with the inclusion criteria. This limited the recruitment of study patients.

2.7 Conclusions

Within the limitations of this study, marginal tearing statistically affected the acceptance of impressions made using the cordless procedure. Trends are visible in the limited sample size. When the number of impressions evaluated gets to a more powerful sample size, there is reason to believe that more statistically significant relationships will be revealed. This pilot study has opened the door for larger sample studies with modified criteria. More extensive clinician training with defined minimum clinical experience using the cordless system should be included.

Table 1. Impression Evaluation Criteria Descriptions

Criteria	Description of Error
Finish Line, Void/Bubble	Detectable void on the cervical finish line of a preparation $\geq 0.20\text{mm}$.
Finish Line, Lack of Wash Material	Cervical finish line recorded in heavy body material with no wash above or below the finish line.
Finish Line, Tear of impression material flash	Tearing of impression material flash beyond the cervical finish line.
Tray, Inadequate Retention of Material	Impression material pulling away from tray or not engaging tray retention features.
Tray, Pressure of Tray On Soft Tissue	Vertical tray flanges exposed by displacement of impression material. Any occurrence within 2 teeth of preparation(s) or on the preparation(s).
Tray, Show Through of Occlusal/Incisal Edges	Horizontal tray areas visible by displacement of impression material. Any occurrence within 2 teeth of preparation(s) or on the preparation(s).
Material, Inadequate Fusion of Viscosity	Lack of complete fusion between body and wash materials.
Material, Void on Preparation	Voids not located on the finish line greater than 1 mm in size
Material, Lack of Polymerization	Impression material visibly unset or tacky to the touch.
Gingival Displacement, Tissue Over Finish Line	Lack of flash beyond the cervical finish line, detected by change of reflection or visible horizontal bur marks on the preparation for ill-
Gingival Displacement, Blood On Impression	Blood, coagulant, or any foreign materials around the cervical finish line.

Table 2. Acceptability, Major Errors, and Minor Errors vs. CD or CL

Variable (affirmative response)	Corded		Cordless		p-value
	N	(%)	N	(%)	
VOID/BUBBLE FINISH LINE	3	(37.50)	6	(85.71)	0.1189
LACK OF WASH FINISH LINE	3	(37.50)	2	(28.57)	1.0000
TEAR FINISH LINE	1	(12.50)	5	(71.43)	0.0406
TISSUE OVER FINISH LINE	1	(12.50)	3	(42.86)	0.2821
LACK OF FUSION	1	(12.50)	4	(57.14)	0.1189
LACK OF POLYMERIZATION	0	(0.00)	1	(14.29)	0.4667
PRESSURE ON TISSUE	1	(12.50)	0	(0.00)	1.0000
VOID ON PREP	8	(100.00)	6	(85.71)	0.4667
SHOW THROUGH INCISAL	2	(25.00)	0	(0.00)	0.4667
BLOOD	3	(37.50)	0	(0.00)	0.2000
COTTON	1	(12.50)	0	(0.00)	1.0000
EVALUATION	6	(75.00)	1	(14.29)	0.0406

Table 3. Major Errors vs. Acceptability

Variable (affirmative response)	Acceptable		Not acceptable		p-value
	N	(%)	N	(%)	
VOID/BUBBLE FINISH LINE	1	(14.29)	8	(100.00)	0.0014
LACK OF WASH FINISH LINE	1	(14.29)	4	(50.00)	0.2821
TEAR FINISH LINE	1	(14.29)	5	(62.50)	0.1189
TISSUE OVER FINISH LINE	0	(0.00)	4	(50.00)	0.0513

Table 4. Age

Variable	Corded		Cordless	
	mean	(sd)	mean	(sd)
AGE	65.0000	(9.0370)	56.2856	(15.0190)

Table 5. Descriptive statistics for continuous variables comparing corded and cordless groups

Group	N	Variable	Label	25th Pctl	Median	75th Pctl
Corded	8	BEGIN	How uncomfortable: beginning of the appointment	0.0	0.0	0.5
		BEFORE	How uncomfortable: immediately before impression	0.0	0.0	1.5
		AFTER	How uncomfortable: immediately after impression	1.0	2.0	3.5
		END	How uncomfortable: end of the appointment	0.0	0.0	1.5
		UNITS	Number of Units Requested from this Impression	1.0	1.0	2.0
		TIME	Time Required for 1st Impression	10.0	15.0	17.5
		NUMBER	Number of Impressions Required Until Acceptable	1.0	1.0	1.5
		Cordless	7	BEGIN	How uncomfortable: beginning of the appointment	0.0
BEFORE	How uncomfortable: immediately before impression			0.0	1.0	2.0
AFTER	How uncomfortable: immediately after impression			0.0	2.0	3.0
END	How uncomfortable: end of the appointment			0.0	0.0	1.0
UNITS	Number of Units Requested from this Impression			1.0	2.0	3.0
TIME	Time Required for 1st Impression			5.0	7.0	12.0
NUMBER	Number of Impressions Required Until Acceptable			2.0	2.0	2.0

Figure 1. HIPAA Authorization: (page 1 of 2)

University of North Carolina at Chapel Hill
HIPAA Authorization for Use and Disclosure of Health Information for Research Purposes

IRB Study # 15-1787

Title of Study: Comparison of Two Gingival Displacement Procedures; a Randomized Clinical Trial.

Principal Investigator: Sumitha Ahmed

Mailing Address for UNC-Chapel Hill Department: CB: 429 Brauer Hall, Chapel Hill, NC 27599, USA

This is a permission called a "HIPAA authorization." It is required by the "Health Insurance Portability and Accountability Act of 1996" (known as "HIPAA") in order for us to get information from your medical records or health insurance records to use in this research study.

1. If you sign this HIPAA authorization form, you are giving your permission for the following people or groups to give the researchers certain information about you (described below):

Any health care providers or health care professionals or health plans that have provided health services, treatment, or payment for you such as physicians, dentists, clinics, hospitals, including but not limited to the UNC Health Care System and the UNC School of Dentistry.

2. If you sign this form, this is the health information about you that the people or groups listed in #1 may give to the researchers to use in this research study:

Any information in your medical records that relates to your participation in this research. These records might include information about mental health, drug or alcohol use, HIV/AIDS or other communicable diseases, or genetic testing. Other information includes the number of impressions required to make your crown.

3. The HIPAA protections that apply to your medical records will not apply to your information when it is in the research study records. Your information in the research study records may also be shared with, used by or seen by collaborating researchers, the sponsor of the research study, the sponsor's representatives, and certain employees of the university or government agencies (like the FDA) if needed to oversee the research study. HIPAA rules do not usually apply to those people or groups. If any of these people or groups reviews your research record, they may also need to review portions of your original medical record relevant to the situation. The informed consent document describes the procedures in this research study that will be used to protect your personal information. You can also ask the researchers any questions about what they will do with your personal information and how they will protect your personal information in this research study.

All research records will be coded with a subject ID number instead of your name, dental record number, or other identifying information.

Figure 1. (continued) HIPAA Authorization: (page 2 of 2)

4. If this research study creates medical information about you that will go into your medical record, you may not be able to see the research study information in your medical record until the entire research study is over.

5. If you want to participate in this research study, you must sign this HIPAA authorization form to allow the people or groups listed in #1 on this form to give access to the information about you that is listed in #2. If you do not want to sign this HIPAA authorization form, you cannot participate in this research study. However, not signing the authorization form will not change your right to treatment, payment, enrollment or eligibility for medical services outside of this research study.

6. This HIPAA authorization will not stop unless you stop it in writing.

7. You have the right to stop this HIPAA authorization at any time. You must do that in writing. You may give your written stop of this HIPAA authorization directly to Principal Investigator or researcher or you may mail it to the department mailing address listed at the top of this form, or you may give it to one of the researchers in this study and tell the researcher to send it to any person or group the researcher has given a copy of this HIPAA authorization. Stopping this HIPAA authorization will not stop information sharing that has already happened.

8. You will be given a copy of this signed HIPAA authorization.

Signature of Research Subject

Date

Print Name of Research Subject

For Personal Representative of the Research Participant (if applicable)

Print Name of Personal Representative: _____

Please explain your authority to act on behalf of this Research Subject:

I am giving this permission by signing this HIPAA Authorization on behalf of the Research Participant.

Signature of Personal Representative

Date

Figure 2. Adult Consent to Participate in a Research Study: (pages 1 of 4)

**University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants**

Consent Form Version Date: April 11, 2016

IRB Study # 15-1787

Title of Study: Comparison of Two Gingival Displacement Procedures; a Randomized Clinical Trial.

Principal Investigator: Sumitha Ahmed

Principal Investigator Department: Operative Dentistry

Principal Investigator Phone number: 9195373146

Principal Investigator Email Address: snahmed@dentistry.unc.edu

Research Personnel: Terry Donovan, Kevin Lim, Hugh Murphy, Anthony Prudenti, Leslie Trippe, Eduard Epure, Hector Saenz de Viteri Tejada, Kimberly Schlam, Lauren Katz, Sarah Lee, Kent Healey, Ceib Phillips, Caroline Nguyen-Ngoc, Islam Abd Alraheam, Alex Yarborough, Pooja Saha.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.

You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to compare two different methods used to make an impression.

You are being asked to be in the study because you have decided to have a crown placed in your mouth and this treatment requires that we make an impression.

Are there any reasons you should not be in this study?

You should not be in this study if you are a smoker or have uncontrolled diabetes.

Figure 2. (continued) Adult Consent to Participate in a Research Study: (pages 2 of 4)

How many people will take part in this study?

There will be approximately 100 people in this research study.

How long will your part in this study last?

Your part in this study only includes this consult and consenting time, plus about 1 hour during your treatment visit. During the time during the treatment visit, the study portion only includes the time that it takes to make the impression, and for you to respond to a few questions.

What will happen if you take part in the study?

A well-fitting crown requires an accurate impression. Making an accurate impression involves being able to get the impression material slightly below the gum line.

Both methods that we are comparing are FDA-approved and commonly used in dental practice. One method involves wrapping a thin cord around the base of the tooth to allow the impression material to reach below the gum line. The second method involves using a device with a small tip that can be inserted into the space between the tooth and the gum tissue. The device dispenses impression material directly around the tooth and below the gum line.

- You will be assigned by chance (randomized) to one of these methods. Like flipping a coin, you have a 50/50 chance of receiving either method. This means that 50 participants will receive the corded process and 50 participants will receive the cordless process.
- We will remove the impression from your mouth.
- The impression will be digitally photographed and scanned.
- Two members of the research team will evaluate the impression. They will not know which method was used to make your impression.
- You will be asked to indicate your pain level at three different times during your visit.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study.

What are the possible risks or discomforts involved from being in this study?

You may feel mild discomfort during the process of making the impression. Mild discomfort that comes from everything involved in your treatment, including the impression making, may last for 1-3 days.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

If you choose not to be in the study, what other treatment options do you have?

You do not have to be in this research study in order to receive treatment. You can receive a crown here at the School of Dentistry or at an outside practice. All procedures will be the same as if you were in the research study, except that your doctor will choose which method to use to make your impression and you will not be asked to rate your pain.

Figure 2. (continued) Adult Consent to Participate in a Research Study: (pages 3 of 4)

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?

You will be assigned a study ID number, which will be used on all research materials instead of your name, medical record number, or any other identifying information. This consent form will be kept securely in a locked cabinet. Only research personnel will have access to your research information.

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?

You will not receive anything for your participation.

Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study, complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Figure 3. Clinical Instruction Protocol: (pages 1 of 3)

IRB 15-1787

Instructions to clinician:

- **Clinical Protocol Operatory Instructions: Must be followed**
- The treating clinician will open the allocation envelope **after** the tooth preparation has been completed.
- Regardless of the number of restorations needed, **only one tooth per arch and the most posterior tooth that meets the inclusion criteria, will be included** in the evaluation.
- The patient will be informed that if multiple teeth are treatment planned and a separate impression will be made first for the study tooth, then this may increase the appointment time.

Please carefully follow the gingival displacement procedures and impression techniques described on the next pages

The impressions will be digitally photographed and digitally scanned by the research study investigator, Anthony Prudenti, and then returned to the clinician within 24 hrs, for laboratory fabrication.

Figure 3. (continued) Clinical Instruction Protocol: (pages 2 of 3)

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Traditional Corded Impression Procedure:

- The prepared tooth is rinsed and dried
- Assure hemostasis
- Start timing of the procedure
- Pack small diameter retraction cord hydrated with Hemodent
- Pack a 2nd larger diameter retraction cord, also hydrated with Hemodent, over the first cord
- Leave cords in place for a minimum of 8 minutes
- Prior to making the impression, remove the large diameter cord
- Dry the tooth and confirm a dry field
- Extrude the Aquasil Ultra PVS wash impression material around the prepared tooth and across the occlusal surfaces of adjacent teeth
- Carry impression tray filled with the Aquasil Ultra PVS tray impression material into the mouth and place over the arch of teeth
- Remove impression after 5 minutes and record the length of time for procedure
- Note to clinician: **Please have patient record FACES discomfort levels, and clinician to complete the impression form.**

The impressions will be digitally photographed and digitally scanned by the research study investigator, Anthony Prudenti, and then returned to the clinician within 24 hrs, for laboratory fabrication.

Figure 3. (continued) Clinical Instruction Protocol: (pages 3 of 3)

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Cordless Impression Procedure using Aquasil Ultra Cordless: Do not prepack a cord during preparation

- Insert unit dose cartridge into intrasulcular mixing tip and then into the digit power dispenser. For 1 prepared tooth use a single size (0.7mL) unit dose cartridge (pink), for more than 1 prepared tooth use a multi size (1.6mL) (blue).
- The prepared tooth is rinsed and dried
- Assure hemostasis and confirm a dry tooth and field
- Start timing of the procedure
- Apply B4 + surface optimizer to the study tooth and gingival sulcus
- Depress foot pedal and gently insert intrasulcular mixing 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.
- Carry impression tray filled with the Aquasil Ultra Cordless tray impression material into the mouth and place over the arch of teeth
- Remove impression after 5 minutes and record the length of time for procedure
- Note to clinician: **Please have patient record FACES discomfort levels, and clinician to complete the impression form.**

The impressions will be digitally photographed and digitally scanned by the research study investigator, Anthony Prudenti, and then returned to the clinician within 24 hrs, for laboratory fabrication.

Figure 4. Patient Discomfort Scale Questionnaire (FACES):

Faces Discomfort Scale-Revised IRB #15-1787

Instructions: In the appropriate box, record the number that shows how uncomfortable you are at each point during this visit.

0 1 2 3 4 5 6 7 8 9 10

At the beginning of the appointment:


Immediately before the start of the impression procedure:

Immediately after the impression procedure is completed:

At the end of the appointment:

Subject ID: _____

Figure 5. Clinician Impression Form:

	THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL	Gingival Displacement with Impressions for Fixed Prosthodontics
TO BE COMPLETED BY TREATING CLINICIAN:		
<input type="checkbox"/> Patient meets inclusion criteria		
<input type="checkbox"/> Patient meets exclusion criteria and is dropped from the study because:		
<input type="checkbox"/> Chronic disease with oral manifestations		
<input type="checkbox"/> Gross oral pathology		
<input type="checkbox"/> Smokers		
<input type="checkbox"/> Uncontrolled diabetics (per review of medical history)		
<input type="checkbox"/> Bleeding on probing around treatment tooth		
<input type="checkbox"/> The prepared finish line is greater than 1mm sub-gingival		
<input type="checkbox"/> Probing pocket depths around treatment tooth of greater than 4mm		
Patient Study ID: _____		
Tooth #: _____ <input type="checkbox"/> Incisor <input type="checkbox"/> Canine <input type="checkbox"/> Premolar <input type="checkbox"/> Molar		
Impression Group: _____ Corded _____ Cordless		
Clinic: _____ Dental Faculty Practice		
_____ Graduate Operative Clinic _____ 1 st _____ 2 nd _____ 3 rd		
_____ Graduate Prosthodontic Clinic _____ 1 st _____ 2 nd _____ 3 rd		
Patient Age: _____		
Gender: _____ Male _____ Female		
Type of Impression Material Used:		
<input type="checkbox"/> Aquasil Ultra <input type="checkbox"/> Aquasil Ultra Cordless		
Tray Adhesive Used:		
<input type="checkbox"/> Yes <input type="checkbox"/> No		
Tray Material:		
<input type="checkbox"/> Metal stock <input type="checkbox"/> Metal dual arch <input type="checkbox"/> Custom		
<input type="checkbox"/> Plastic stock <input type="checkbox"/> Plastic dual arch		
Type of Tray Used:		
<input type="checkbox"/> Ant quad <input type="checkbox"/> Post quad <input type="checkbox"/> Full arch		
Jaw:		
<input type="checkbox"/> Maxillary <input type="checkbox"/> Mandibular		
Number of Units Requested from this Impression: _____		
Time Required for 1 st Impression: _____ minutes		
Number of Impressions Required to Obtain Adequate Impression: _____		

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