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Development and Application of a Technique to Measure Soft Tissue Changes Following Noncarious Cervical Lesion Restorations

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ABSTRACT

Non-carious Cervical lesions (NCCL) often encountered in clinical practice, is tooth structure loss at the cemento-enamel junction unrelated to dental caries. NCCL is mostly associated with gingival recession. Restoration of NCCL is challenging due to close periodontal relationship.

OBJECTIVE: To develop a non invasive, highly reproducible technique to measure the soft tissue changes and apply the technique to measure the gingival margin position changes after restoration of NCCL.

MATERIALS & METHODS: Forty one patients participated in the study. 3 resin composite (Filtek Supreme Plus) restorations were done per patient. GI(Loe & Sillness), PI (Loe & Sillness) , digital images and elastomeric impressions (Aquasil heavy & extra low viscosity) were collected from the three visits (restoration, 10-15 days first recall, 6 month recall).Gingival phenotype is classified as thick or thin from the photographs. Casts (Fuji Rock type IV die stone) were prepared and a mold was made with putty impression material to hold the cast for imaging. Linear measurements (VHX 600 Keyence digital microscope) were recorded. Follow up visits were also recorded using the same molds as position guides.

RESULTS: Intraclass correlation of 0.9963 was seen for the reproducibility of the technique done on 40 samples repeated 8 times. Generalized mixed model analysis of variance was used to evaluate the gingival margin position changes over time and by phenotype. Generalized estimating equations were used to account the GI and the PI. No statistically significant difference in gingival height ($p=0.6993$), gingival height by phenotype ($p=0.9102$), and in plaque index ($p=0.3092$) was noted at the three time intervals. A significant difference was seen in the mean length between the phenotypes ($p=0.0211$), with thick phenotype having shorter mean length than thin phenotype and in GI ($p<0.0001$) between GI 1and GI 2 and between GI 1 and GI 3.

CONCLUSION: Within the limits of this study it can be concluded that placement of restoration in a NCCL restoration would not change the gingival margin position by time and by phenotype. Resin Composite restoration did not have an effect on plaque accumulation but, it would cause inflammation of the gingiva.

Key words: Non-carious cervical lesions, linear gingival margin position change measurement.

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TABLE OF CONTENTS

Page

ABSTRACT iii

ACKNOWLEDGMENTS v

LIST OF TABLES viii

LIST OF FIGURES ix

LIST OF ABBREVIATIONS xi

INTRODUCTION 1

HYPOTHESIS AND AIMS 16

MATERIALS AND METHODS 18

RESULTS 37

DISCUSSION 39

LIMITATIONS 44

CONCLUSION 45

FUTURE DIRECTIONS 46

LIST OF REFERENCES 47

APPENDICES

A WIRB APPROVAL 57

B 3M ESPE Protocol 58

C Research subject information and consent form 75

LIST OF TABLES

Tables		Page
1	Inclusion criteria	18
2	Exclusion criteria	19
3	Study design	20
4	Measurements taken and used	20
5	Loe & Sillness gingival index (GI)	21
6	Loe and Sillness plaque index (PI)	21
7	Gingival phenotype	22
8	Materials used to measure the gingival margin position	23
9	Keyence features	28
10	Reproducibility of the technique	33
11	The data from the non-carious cervical lesions Class V study	36

LIST OF FIGURES

Figure		Page
1	Tooth showing non-carious cervical lesions at the cervical area along with gingival recession	1
2	Biologic width of a natural tooth	9
3	Conventional impressions made of the maxillary and mandibular arches using elastomeric impression materials	24
4	Mold made with putty impression material used to hold the diagnostic cast in the same position during patient visits	26
5	A diagnostic cast with a mold	27
6	A maxillary and a mandibular cast positioned with the help of mold and ready for imaging	27
7	Keyence VHX-600 digital microscope	29
8	Keyence VHX- 600 series digital microscope, with VH-Z05R platform and a 0-40 X magnification lens. A cast is in position for scanning	30

9 Step 1 Straight line drawn by selecting 2 points on the left margin 31

10 Step 2 The cursor is moved to the right side of tooth and a point is selected creating a perpendicular line 32

11 Step 3 The cursor is again moved to the center of the tooth and a midpoint is selected creating a center line 32

12 Step 4 A two point tool is selected from the main menu and the incisal edge and the gingival margin are marked on the midline 33

13 Tooth # 19 with non-carious cervical lesion and gingival recession. Note that the gingival floor of the lesion is apical to the gingiva.....34

14 Tooth with rubberdam stabilized and gingival tissue retracted with no. 212 clamp.....34

15 VHX 600 Keyence digital microscope image at baseline 35

16 VHX 600 Keyence digital microscope image at first recall 10-15 days after restoration 35

17 VHX 600 Keyence digital microscope image at second recall -6 months after restoration 35

LIST OF ABBREVIATIONS

NCCL	Non-Carious Cervical Lesion
CEJ	Cemento Enamel Junction
GI	Gingival Index
PI	Plaque Index
PVS	PolyVinyl Siloxane
REML	Restricted or Residual Maximum Likelihood

INTRODUCTION

A noncarious cervical lesion (NCCL) [1] is tooth structure loss at the cemento-enamel junction (CEJ) unrelated to dental caries.

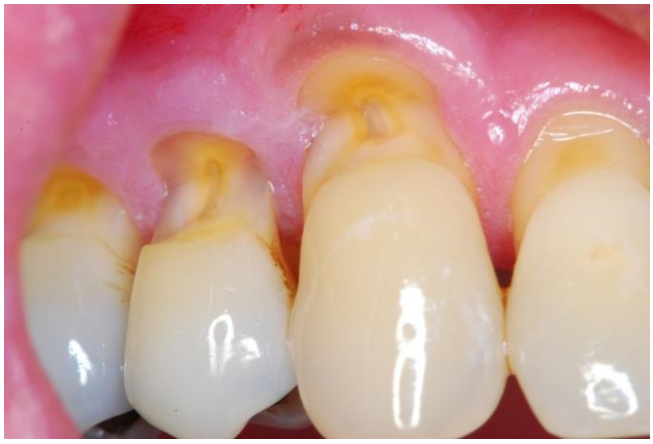

Figure1. Tooth showing non-carious cervical lesions at the cervical area along with gingival recession.

The etiology[2] of NCCL can be classified as: abrasion, erosion and abfraction.

Friction between a tooth and an exogenous agent causes wear called abrasion. Abrasion[3] can be a result of overzealous tooth brushing, improper use of dental floss, tooth picks, chewing tobacco, habits such as biting on hard objects such as pens, pencils or pipe stems, biting finger nails, opening hair pins, clasps of partial dentures or occupational who hold their instruments with teeth like tailors, cobblers, instrument players.

Tooth surface destruction caused by chemical or electrochemical[4] actions is termed erosion. Bulimia causes endogenous erosion and can be seen mostly on the palatal surface of maxillary anterior tooth. Gastroesophagial reflux disease [5, 6] also causes cupped or invaginated surfaces on exposed dentin due to the combined action of hydrochloric acid and proteolytic enzyme pepsin. According to Bodecker[7] gingival crevicular fluid can be acidic and may be erosive when in contact with teeth in the cervical region. Biocorrosion[8] can be due to corrodents produced by the resident bacterial plaque which also produce caries. Exogenous sources of erosion [9-11] can be due to any food with a critical pH value of less than 5.5 as is seen with mangoes, citrus fruits, carbonated soft drinks, sucking sour candies or pickles, acidic mouth washes. The citrate may be particularly destructive because of the chelating action[12] of the citrate on calcium. The citric and phosphoric acid in carbonated drinks[13] is corrosive due to the formation of carbon dioxide. The corrosive potential [3] of an acidic drink is dependent on the buffering capacity, chelating properties of the acid, frequency and duration of consumption of the drink along with the pH.

McCoy [14] proposed bruxism as the primary cause of angled notches at CEJ and postulated that tooth flexure from tensile stresses[15-17] lead to cervical tooth break down and class V amalgam restoration failure. Eakle[18] hypothesized, tensile stress from mastication and malocclusion as the primary etiologic factor in wedge- shaped cervical erosions. According to Grippo abfraction[3] is the pathological loss of tooth structure caused by biomechanical loading forces that result in flexure and failure of enamel and dentin at a location away from loading. It is the micro structural loss of tooth substance in areas of stress concentration seen most commonly in the cervical areas of the teeth, where

flexure may lead to fracture of the thin layer of enamel rods, cementum and dentin. Cervical lesions have a crescent form along the cervical line, where this brittle and fragile enamel layer exists. Hanaoka and colleagues [19] stated that mechanical microcracks on cementum and dentin may act as the initial contributor to the formation of cervical defects. Abfraction has the possibility of being the initial factor [20] and the dominant progressive modifying factor in producing cervical lesion. Occlusal loading forces are transmitted to the periodontal supporting tissues, which may cushion and dissipate the resultant stresses. Kuroe and colleagues [21] showed a positive correlation between cervical tooth surface lesions with tooth stability and periodontal support. Thus mobile teeth are less likely to have abfraction.

Morphological types [22] of NCCL can be described as two types: one is a concave shaped small defect with no sharp interior angles and little tooth damage and the other is a v-shaped angular lesion with a flattened floor associated with deep lesions. NCCLs may result[22] from two different mechanisms: a more common and destructive process for v-shaped NCCL and a less severe process for concave-shaped NCCL. The form of cervical lesion depends on the type and severity [23] of etiological factor, and not all lesions require restorations.

In an abfraction lesion, mechanical stress [24] at the center of the lesion increases faster resulting in a notch-shaped structure leading to a rapid progression of the lesion. The factors in deciding to restore [25] noncarious cervical lesions are based on the desire to strengthen tooth, decrease theoretical stress concentration, flexure, halt lesion progression, prevent hypersensitivity, pulp involvement, improve oral hygiene and enhance esthetics. The pronounced Wedge-shaped defects that are not indicated for soft

tissue coverage can be treated [26-28] using bonding-composite materials after minimal tooth preparation. Restorative treatment options include resin based composites, glass ionomers or a combination of the techniques. Other possibilities [29, 30] are metal restorations for posterior teeth, dentin bonding agents, copal varnishes, fluoride therapy and desensitizing agents, night guard and occlusal adjustments, dietary modification and cessation of oral habits.

A bonded restoration can halt or at least slow the spiral. The stress [31] will not be completely eliminated, but the distribution will change so there's much less concentration at the bottom of the lesion. The rapid progression will stop and will protect the vulnerable surfaces from the corrosive environment and toothbrush abrasion. Prior to placing restorations, careful evaluation of the occlusion and the other contributing factors should be completed.

Cervical lesions are a restorative challenge [3] due to their proximity to the periodontal tissues. Free gingiva frequently obstructs access to these restorations. Oral fluids commonly contaminate the surgical site, often complicated by bleeding [25] if the gingival tissue is diseased. Direct esthetic restorative materials are technique sensitive [32]and poor moisture control reduces their clinical success. Resin-based composites [33] are popular choice for cervical restorations and their clinical effectiveness [34] depends on the successful use of bonding agents. These materials are retained by adhesives which are sensitive to contaminants [35] and must provide enough retention to retain the restoration and also overcome the stress created by polymerization shrinkage of the composite. The polymerization shrinkage [36] results in marginal and interfacial gaps, loss of retention, clinical symptoms of sensitivity and secondary caries if the resin-based composite does

not adhere to enamel and dentin. The heterogeneous composition of dentin tissue, its hydrophilicity and the presence of a smear layer after cutting makes it a more difficult substrate to bond to dentin than to enamel tissue. The highest bond strength values are obtained with controlled conditions in the laboratory settings. Clinical experience suggests that there is a high risk of contamination [37] during placement of restorative materials or other errors caused by limited visibility and access, if the gingival wall is located within the gingival crevice. The form, function, esthetics and longevity of a restoration is affected by the conditions under which a restoration is placed in addition to the choice of material, operator skill, and patient factors, such as lesion size and caries risk status. The ultimate goal of isolation is to reduce the risk of procedural errors [38] that may affect restoration serviceability. In the oral cavity it is often difficult to achieve a dry environment, whereas moisture control is necessary for most dental materials, and it is critical with adhesive dentistry.

Tissue management [39] during cervical restoration placement varies and all cases cannot be managed in the same way. Isolation of many teeth can be managed by using conventional isolation methods (cotton rolls, absorbent wafers, gingival retraction cord) while others require sophisticated approaches like mechanical retraction device in conjunction with the rubber dam. The choice of retraction depends on the amount of retraction necessary. Finishing of a gingival margin can be attained by optimal retraction. The most commonly utilized technique [33] is the mechanical retraction achieved by rubber dam along with retraction clamps. Mechano-chemical retraction is achieved by using gingival retraction cords and surgical retractions by miniflap technique or electro surgery are also used when a simple mechanical retraction cannot expose a cervical lesion

adequately. The relative predictability, effectiveness, and safety of retraction cords [39] (mechanical or chemo mechanical) compared with rotary gingival curettage [40] and electrosurgery makes it well established. However, the use of retraction cord can be laborious, time-consuming and can cause gingival bleeding and may cause direct injury and gingival recession [41-43] when inappropriately manipulated. Aluminium potassium sulphate (Alum), aluminium chloride, epinephrine, zinc chloride, ferric sulphate and sympathomimetic amines are few of the haemostatic agents that are available. They have varying degrees of safety and effectiveness. Advantages with cordless techniques are time-saving and enhanced patient comfort while being minimally invasive. Expasyls (Kerr Corp., Orange, CA, USA) is a paste-like gingival retraction material that has the haemostatic properties of aluminium chloride and the hygroscopic expansion of kaolin. In about 2 min Expasyls [44] provides mild displacement of the gingiva upon contact with the crevicular fluid causing mild displacement of the gingiva. Aluminium chloride has been reported to be irritant in moderate concentrations and caustic in high concentrations. It is a stable acidic buffer, resulting in an etched dentine [45, 46]. Mechanically inaccessible areas can be accessed by surgical retraction using a limited soft tissue surgery called mini flap technique.

Rubber dam is considered as the gold standard [47] for isolation, and so it is advisable to use when the risk of contamination is greatest, such as on cervical lesions that extend below the margin of gingiva. The advantages [48] of using a rubber dam are the patient is protected from ingestion or aspiration of small instruments and fragments, opportunity to work in a clean surgical site, retraction and protection of soft tissues from the cutting action of bur, reduction of delays, better visibility, dentists and dental assistants can be

protected from the infections from the patients, better tactile sensitivity and patient comfort that the operator is not keeping their hands in the patients mouth. Rubber dam is ideally retained and stabilized so that it will not impinge on the surrounding tissues. The Ivory No. 212 gingival retraction clamp [49] is specially designed to displace free gingiva on the facial surface of premolars, canines and incisors and with limited use on molars. While seating a rubber dam clamp facial jaw of the retractor should contact the tooth in a more apical position than the lingual jaw (212SA is designed with different jaws). With 2 pairs of pliers, the jaws can be bent to accommodate subgingival facial lesions. While placing the gingival retractor first the lingual jaw is seated against the tooth and facial jaw is rolled apically against the tooth facially, pressing against the free gingiva for maximum apical displacement. Avoid trapping or tearing facial gingival attachment. Clamping can produce 1.5- 2 mm of gingival retraction. It is necessary to have atleast 1mm of healthy tooth structure for restoration. Later, when the rubber dam is in place, additional retraction of the papillary gingiva near the proximal margins of the lesion can be expected. Mark Meraner recommends a heavy rubberdam to provide a greatest potential for soft tissue retraction.

Careless dental treatment may cause iatrogenic damage [50]to the periodontium. The most effective tool for providing isolation of a bonded restoration is a rubber dam. Finally, the rubber dam clamp is often difficult to place without some discomfort for the patient when not using anesthesia. The clamp will also often create some damage to gingival tissue in the area where it was placed.

The Gingival index [51] is a valuable tool in assessing gingival condition which is probably the most widely used index in clinical trials, and provide a more objective assessment of gingivitis.

Along with the cervical restoration, gingival recession and mucogingival defects may be corrected by root coverage procedures [52] free and connective tissue grafts, rotational and coronally advanced flaps, guided tissue regeneration or a combination of these techniques.

In areas with no keratinized tissue gingival inflammation may result in gingival recession. Treating or not treating [53] mucogingival problems before or after recession has occurred remains controversial. The importance of attached and keratinized gingiva [54] adjacent to restorative margins is clear, while the need for these tissues in maintaining health around the natural dentition and dental implants can be debated. Specifically, attached gingiva is needed to reduce the probability of gingival recession in esthetic areas of margin placement, [55] to facilitate impressions, and in some cases, to increase patient comfort. Aesthetic or retentive demands often make it necessary to extend the margins [56, 57] of some restorations into the gingival sulcus. The extension of any restorative margin into the gingival sulcus should be considered as a compromise.

For the reason that margins in aesthetic areas must be camouflaged or concealed, any gingival recession that occurs following final placement of the restoration can compromise aesthetics. To reduce[58] the probability of recession, the gingival tissues should be clinically healthy before beginning restorative procedures, and also there should be an ‘‘adequate’’ band of keratinized and attached gingiva. An adequate band of attached gingiva in thicker tissues with 2 mm of keratinized gingiva and 1 mm of

attached gingiva provide adequate protection against recession provided that the health of the tissues is maintained. Restorative margins should not extend into the sulcus more than 0.5 mm, a traumatic retraction, impression procedures, and the optimal contours and marginal fit of final restoration [51] should be followed.

The biologic width is defined as the combined dimension of the epithelial attachment and connective tissue attachment, which is attached to the portion of the tooth coronal to the crest of the alveolar bone. Based on the work by Gargiulo et al. Dr. D. Walter Cohen coined the term biologic width. The biologic width should be maintained by controlling the gingival marginal form around the restorations. An understanding of the biologic width in preserving healthy gingival tissues and control of the gingival form around the restorations is essential to comprehend restorative procedures and their impact on restorations. The biologic width is said to be 2.04 mm, which represents the sum of epithelial and connective tissue attachment measurements. The optimal function of natural dentition is dependent on the surrounding hard and soft tissues. Careless dental therapy [51] may aggravate periodontal disease.

Figure 2. Biologic width of a natural tooth.

Periodontal changes [59] produced by dental restorations range from minor gingival alterations to pocket formation with bone loss and increased tooth mobility. Gingival injury may be due to crown preparation, impressions, retraction, electro surgery, temporary restorations, cavity preparation, placement of matrix, subgingival margins, overhangs, sub gingival debris, over contoured restorations, relation of pontic adaptation to periodontal health, design of the removable partial dentures, exodontic procedures that affect the periodontium, orthodontic therapy, implants and occlusal trauma.

Sub gingival restorative margins not only invade the attachment apparatus but also produce unwanted tissue effects [60] regardless of the depth of sulcus penetration. Orkin et al. demonstrated a greater chance of bleeding and gingival recession with sub gingival margins. A study by Valderhaug & Birkeland [56] with 329 sub gingival crowns in 114 patients revealed that only 32% remained below the gingival margin after 5 years. Based on the findings it is highly likely that sub gingival margins will eventually become supragingival.

Another important consideration in the gingival health and recovery is the periodontal biotype. It is widely accepted that a number of gingival/ periodontal problems are likely to occur in patients with a thin biotype. Treatment planning of restorative procedures [61, 62] and dental implants must take into account the periodontal biotype. A few classifications [63] of the periodontal/gingival biotype have been proposed in the literature. Unfortunately, these classifications are relatively subjective and observational. Generally, upon clinical examination the periodontal biotype [64] is considered to be thin scalloped or thick-flat. A third medium type [65] has also been reported. Muller and Eger [66] used an ultrasonic device to measure gingival thickness and to group individuals into three different gingival

phenotypes. This device appears to be an effective method to assess gingival thickness but, an overall overview [67] of the gingival/periodontal structures and their relationship were not obtained.

Numerous techniques have been used to measure tissue changes with different crown preparations and tissue grafting techniques. The techniques used include clinical measurement of the gingiva with a periodontal probe, radiographic or photographic measurement and imaging analysis software.

Hefti [68] described the errors seen when using a periodontal probe to record gingival recession. These errors were described in detail, and he divided them into physical, systematic error, random error, and consistency. Several physical problems were mentioned in this study, but the one most frequently mentioned was the force applied to the probe. Higher forces cause the tip of the probe to sink more deeply into the gingival tissue. Even small force differences produce significant variation in the depths recorded. This is further complicated by different brand and style probes having different tips. Tip diameters of the probe tips further complicated measurements since the force applied is directly related to the area of the probe. The same force applied to a smaller diameter probe would cause the probe tip to sink more deeply into the tissue and alter the study data. Hefti [68] examined the systematic error introduced by the periodontal probe. In Hefti examination repeatability was a major factor in producing errors. If a trained examiner measured a deep periodontal pocket depth to the nearest millimeter and repeated the measurement one day later, the two measurements will not be identical. Since the depth of a pocket does not measurably change daily, the discrepancy must be due to measurement error. Sources of error may be the instrument used, the measurement

technique, the examiner, and/or the examined object. Digit preference errors were also reported. Those errors occurred when examiners using a Williams periodontal probe tend to bias their readings toward an odd number, especially 5 mm, if the measured value falls anywhere between 3 and 7 mm. The Williams probe has markings at 1, 2, 3, 5, 7, 8, 9, and 10 mm, but no markings at 4 and 6 mm. These investigators reported that this type probe caused investigators to bias their measurements to the markings on the probe missing markings generally were not used. Standardization [69] was another problem which limited accuracy of the recorded measurement. Millimeter markings [69] on probes with identical design, made by the same manufacturer, on the same production line were not always accurate and these deviations lead to measurement errors [70] of up to 1 mm, assuming that the readings were made to the nearest marking.

Duplicate measurements are an attempt to cancel out causes of error due to systematic errors. Duplicate measurements are time-consuming for both the examiner and the patient. Patients experience pain [71] during probing and multiple probing can cause random involuntary patient movements that can influence the measurement process. The precise location of the probe tip during probing is critical to the measuring process.

Hefti also examined the random error involved in these measurements. Random errors are defined as measurement errors that lead to inconsistent measured values when repeated measures are taken. The word random indicates that they are inherently unpredictable errors. Examples of random error are examiner training and experience, having multiple examiners used in the study. The examiner skills, the probe design, and tissue condition. Variations in the readings increased with the severity of the periodontal disease. The probe must be placed in the same position, angle, and inclination for every

measurement. Measurements can also vary due to the angle of the examiners eye to the probe and tissues.

Many studies have attempted to overcome the problems seen with soft tissue measurements in the oral environment. Singh[72] described a personal bias error which can be introduced by human habits, which are not conducive for accurate measurement. This measurement relies on reading from an inappropriate distance and from an oblique direction habit of a person. The measurement, therefore, includes error on account of parallax.

An electronic periodontal probe has been evaluated by several evaluators with mixed reviews. Yang et al [73] used an electronic Florida Stent Probe and discovered that single measurement errors were observed. The error size increased with severity of disease and instrument error accounted for a large part of total variation, especially in periodontitis patients. Unfortunately, similar data are still not available for manual probes.

Grossi et al [74] used a Florida probe to study the comparison of random error to the probing measurement reliability and concluded that the pattern of variability for intra-examiner variance of probing measurements performed with either electronic or conventional probes by trained or calibrated examiners is mostly random error.

Santamaria et al [75] used a pair of dividers and a digital caliper with 0.01- mm precision to measure gingival recession associated with non-carious cervical lesions treated by a coronally advanced flap (CAF) alone or in combination with a resin-modified glass ionomer restoration.

Other methods that have been used in gingival measurements include 3-D laser scanners and reference-free automated 3-D superimposition software [76], Ultrasonic determination [77, 78], and soft tissue cone-beam computed tomography [79]. These are proved to be excellent for volumetric analysis, but a linear measurement is required to calculate the height or gingival length changes. Several studies have been tried to use probes with force feedback transducers to eliminate that variability, but still retain the in-vivo problem concerning training, alignment and parallax.

Accuracies of measurements of X-rays and photographs involve many considerations. One conceivable sources of error with photographs [80] could be due to the resolution of the image which depends upon the size of the aperture and the shutter speed when the photograph is taken, as well as the sensitivity of the film to light, which is related to the size of the image sensor. In addition, distortion effects introduced by the lens can also be a contributing factor. Digitizing also introduces errors due to variations in the scanner or camera used to digitize the images. The major problem in analysis of X-rays or photographs is the error in the system due to parallax. Parallax is defined as an apparent displacement or difference of orientation of an object viewed along two different lines of sight. A slight difference in angle of the camera to the angle of the object photographed can influence scanned measurements strongly. Ideal measurements mean that the camera or scanner must be at exactly at a right angle to the object to be measured. Since this measurement is in two dimensions and all oral objects are in three, alignment for scanning or photographing is extremely important. This is not always possible clinically. This may be better controlled on measurements of objects outside of the clinic such as of castings, but still requires much detail applied to strictly aligning the

object to insure this. Alignment jigs are critical when multiple castings are compared. This is further complicated by scanning pours made from impressions, which offer more opportunities for human and material errors.

HYPOTHESIS AND AIMS

Non-carious cervical lesions are at the interface of hard and soft tissue. Restoration of NCCL is essential to control the progression of the lesion. Restorative procedure involves soft tissue retraction. Objective of this study is to develop a non invasive, highly reproducible (precise) technique to measure the soft tissue changes and apply the technique to measure the gingival margin position changes after restoration of NCCL.

Study I- Evaluation of reproducibility of technique.

The aim of study I is to develop an *in vitro* reproducible technique to measure the linear gingival margin position changes.

Study II- Evaluation of soft tissue changes of non-carious cervical lesions restored clinically.

The aim of study II is to compare the gingival margin position changes before and after restoration of NCCL by time, tissue phenotype, gingival index, plaque index.

The following hypothesis will be considered from study II to compare gingival margin position changes before and after restoration of NCCL.

Null Hypothesis:

1. There is no statistically significant change in linear measurement of gingival margin position before and after restoration of a NCCL at three time periods.

   Length of the tooth will be measured from gingival margin to the apex during the three visits and the means will be compared. Differences in lengths across time will be compared by mixed model analysis of variance to account for correlations among multiple measurements made on the same patient.

2. There is no significant change in gingival healing between the two thick and thin gingival phenotypes.

   Gingival phenotype was classified as thick or thin based on the surface features from photographs. Differences in lengths across time by phenotype will be compared by mixed model analysis of variance to accept or reject null hypothesis.

3. There is no change in gingival index before and after restoration of a non carious cervical lesion.

   GI will be scored from 0-3 based on Loe &Sillness scale. Differences in GI measurements across time will be evaluated using generalized linear models.

4. There is no change in PI before and after restoration of a non-carious cervical lesion.

   PI will be scored from 0-3 based on Loe & Sillness scale. Differences in PI measurements across time will be evaluated using generalized linear models.

MATERIALS AND METHODS

This study received approval from the University of Alabama at Birmingham Institutional Review Board with a protocol number of CR-07-009. Subjects were informed of the study methods and the procedure. After the subject's questions were answered they were asked to participate in the study. Their verbal acceptance was followed by a signed informed consent process. Only subjects meeting the inclusion criteria were enrolled in the study.

Table1: Inclusion criteria.

	Inclusion criteria
1	19 years of age and older
2	Have a minimum of three noncarious Class V lesions requiring restoration that are >1.5 mm in depth
3	Be a regular dental attendee who is able to return for assessments
4	Be in good medical health and able to tolerate the dental procedure.
5	Must not have rampant caries
6	Must not have chronic periodontitis or carious lesions which could compromise tooth retention.
7	Must be able to tolerate the dental procedure.
8	Have normal salivary function

Table2: Exclusion criteria.

	Exclusion criteria.
1	They are enrolled in an evaluation of other restorative materials
2	Have fewer than 3NCCL lesions or have lesions less than 1.5 mm deep
3	Are not able to tolerate the time required to place the restorations
4	There is a history of an adverse reaction to any materials used in the study
5	They are irregular dental attendees.
6	They maintain an unacceptable standard of oral hygiene.
7	They have chronic periodontitis or rampant caries.
8	There is severe salivary gland dysfunction
9	They are unable to return for recall appointments

Noncarious lesions in anterior and premolar teeth requiring Class V restoration can be included in the study. Teeth must be vital, that is, free of signs and symptoms of periapical pathology both clinically and radiographically.

Table 3: Study design

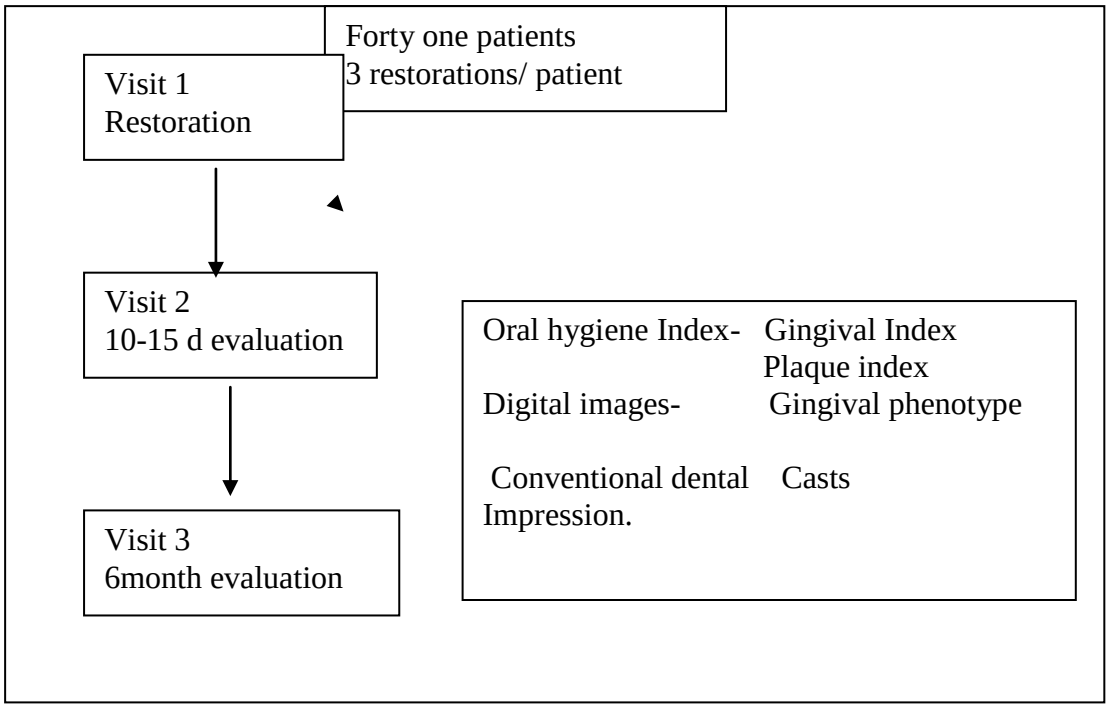

Table 4: Measurements taken and used

Measurements taken and used
Gingival index
Plaque index
Gingival phenotype.
Addition silicon impressions and casts
Digital images
Keyence VHX-600 series digital microscope

Table 5: Loe & Sillness gingival index (GI)

Appearance	Bleeding	Inflammation	Score
Normal	no bleeding	None	0
Slight change in color and mild edema with slight change in texture	no bleeding	Mild	1
Redness, hypertrophy, edema and glazing	bleeding on probing /pressure	Moderate	2
Marked redness, hypertrophy, edema and ulceration	spontaneous bleeding	Severe	3

Table 6: Loe and Sillness plaque index (PI)

Score	Criteria
0	No plaque in gingival area.
1	No plaque visible by unaided eye, but plaque is made visible on the point of a probe after it has been moved across surface at entrance of gingival crevice.
2	Gingival area is covered with a thin to moderately thick layer of plaque; deposit is visible to the naked eye.
3	Heavy accumulation of soft matter; the thickness of which fills out niche produced by gingival margin and tooth surface: interdental area is stuffed with soft debris.

Gingival phenotype: A board certified periodontist classified gingiva as thin (highly scalloped) or thick (flat) from the surface features visualized from the photographs.

Table 7: Gingival phenotype

Thin gingiva	Thick gingiva
Mimics the underlying bone	Does not mimic the underlying bone.
Exaggerated rise and fall of marginal gingiva (gingival scallop)	Flat gingival scallop with not more than 3-4 mm in the anterior and 1-2 mm in the posterior.
Often reveals undulating contours of the prominent roots of the teeth and bone alternating with the interdental bone (interdental sluiceway)	The contours over the roots are less pronounced, and often the roots are not prominent.

Method

A. The patient was appointed for a restorative appointment. At that time the GI and PI was recorded. During the restorative procedure digital images were taken before tooth was prepared, after the tooth was prepared and after it was restored. A conventional impression of the tooth before and after the restoration was made using addition silicone impression material.

B. The tooth to be restored was isolated with a rubber dam. Flour of pumice was used to clean the NCCL and the tooth surface is rinsed thoroughly. Adper

Scotchbond SE, Adper Easy Bond or Single Bond Plus adhesive was applied to the beveled preparation and the restorations were restored using Filtek Supreme Plus composite resin. All restorations were contoured with polishing instruments (Soft-Lex disks) and polished.

C. Aquasil addition silicone Impressions were disinfected using Biotrol and stored in a coded bag in lab under dry climatic conditions.

D. First recall evaluation was 10-15 days after restoration placement. During that appointment gingival index and plaque index was recorded and a PVS impression of the teeth was made.

E. The second recall evaluation occurred six months after the restoration was placed. The GI and PI were recorded and another PVS impression made.

Table 8: Materials used to measure the gingival margin position

Material	Manufacturer
Self adhesive Directed Flow Impression Tray	3M ESPE
Aquasil Ultra Heavy: Type 2: Medium bodied consistency	DENTSPLY Caulk
Aquasil Ultra XLV: Type 3: Light-bodied	DENTSPLY Caulk.
Fujirock Type 1V Die & model stone	GC America
Putty impression material	3M ESPE
Biotrol disinfectant solution	Biotrol International

PVS impression protocol:

The patient was comfortably seated in the dental chair. The dental assistant placed the loaded the Self adhesive Directed Flow Impression Tray (3M ESPE St. Paul, MN 55144) with Aquasil (DENTSPLY) impression material starting from left molar area to the right molar area avoiding air entrapment. The impression material was dispensed from Pentamix 2 (3M ESPE St. Paul, MN 55144) an automated machine. An air spray was used to dry the teeth while the assistant loaded the impression tray. The facial surfaces of the teeth of interest were covered with Aquasil Ultra XLV prior to tray insertion. The light viscosity impression material was inserted from the left side and rotated into the mouth while retracting the cheek. The impression tray was seated slowly, using the central incisors as guidance. The tray was positioned using the subject's nose as the reference point. Three and half minutes after seating the tray, the impression was removed and disinfected.

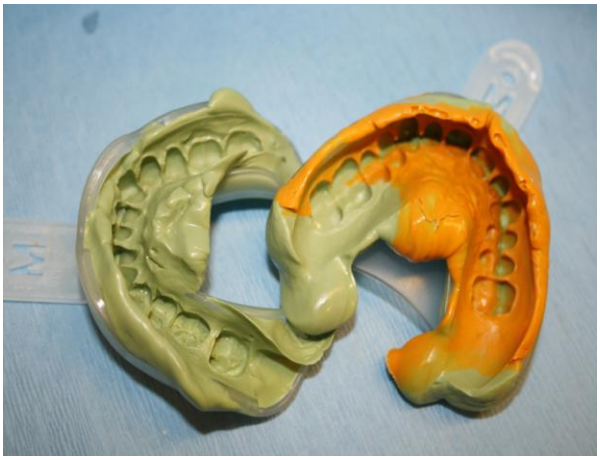

Figure3. Conventional impressions made of the maxillary and Mandibular arches using elastomeric impression materials.

Disinfection.

Biotrol disinfectant solution (Biotrol International, N Salt lake City, UT 85054) was sprayed on the impression. The impression was then placed in a plastic bag with the code written on it. The impressions were stored in a dry area.

Making a cast

The impressions were washed thoroughly with tap water, to remove any remaining disinfectant and dried with air water syringe to ensure no excess liquid remained. A 200mg pack of Fujirock (GC America 3737 W. 127th Street, Alsip, IL 60803) Type 1V Die & model stone was spatula mixed for 10 sec and followed by vacuum mixing (Whip Mix Corporation, Model # 6500, Louisville, US) under 27 psi/ hg for 30-40 sec with 40ml of tap water measured in a measuring cylinder at 23 ± 2 º C. The impression was poured at an ambient temperature of 23 ± 2 º C and humidity of 34 ±1 %. All the impressions were poured in the order they were made from the patients. Using the stone vibrator set in slow mode the mixed stone was slowly poured into the impression with the heel of the impression tray touching the vibrator. Care was taken not to touch the impression but the tray on the vibrator to prevent distortion. A small amount of the stone was vibrated through the impression to provide a thin wash of stone in the impression covering the depressions. Subsequent stone was slowly added in small increments to fill the impression while vibrating the impression. The impressions were not inverted. The casts were separated from the impression trays after setting for 30 to 40 minutes. Each cast was trimmed to a desired shape. No base was made since casts were to be placed in a

mold and measured under Keyence digital microscope. Patient codes were written on the casts and they were stored on a bench overnight.

Making a mold:

Molds were made with putty impression material on the occlusal surface of the opposite side. The impression materials positioned the cast in the same position to allow repeated impressions of the same patient at the same angle in Z axis. The impression materials positioned the cast in the same position to allow repeated impressions of the same patient at the same angle in Z axis. The impression material fixtures were wide enough to hold and position the cast with no movement of the cast during measurements. Occlusal surfaces of 3-4 teeth were covered with putty impression material, extending lingually and bucally. While the putty is still in working range, a straight base on the buccal side of the mold was created using a flat surface.

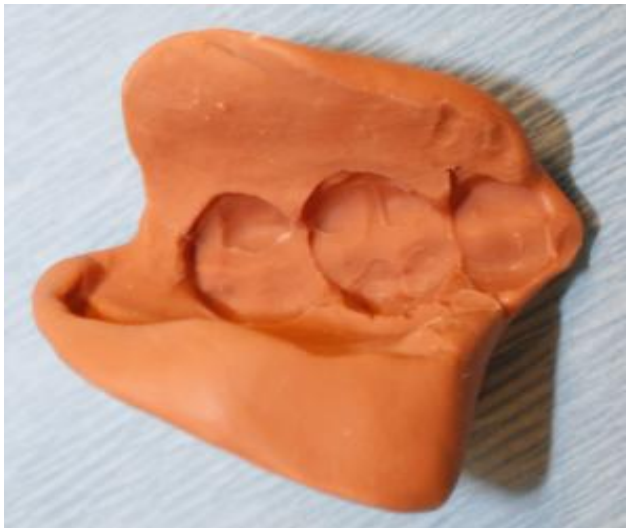

Figure4. Mold made with putty impression material used to hold the diagnostic cast in the same position during patient visits.

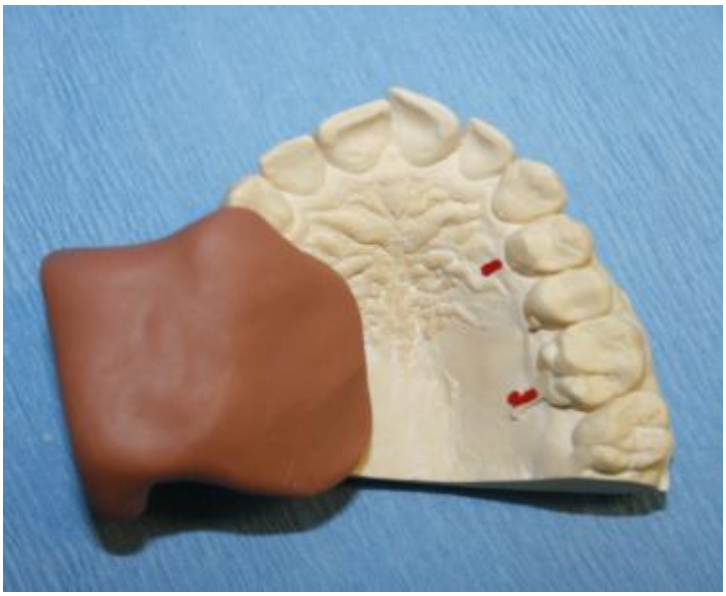

Figure5. A diagnostic cast with a mold.

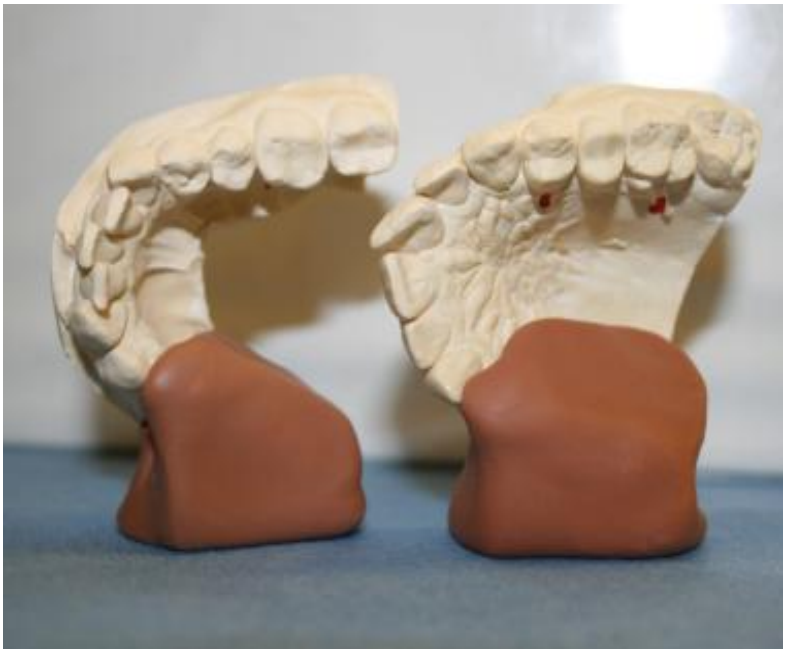

Figure6. A maxillary and a mandibular cast positioned with the help of mold and ready for Imaging.

Imaging

Keyence VHX-600 series digital microscope was used to do the necessary imaging.

Table9: Keyence features.

	Features of Keyence VHX-600 series digital microscope
1	Observation to 3D display.
2	54 million pixel, high-resolution 3CCD a built-in actuator enables accurate, complex movement.
3	High Resolution real zoom Lens can correct chromatic aberration.
4	Long Working Distance Lenses can help to View clearly at high magnification, even from long range.
5	Has an excellent balance of high resolution, brightness, observation distance, aberration and depth of field.
6	Accurate images with overall focus can be obtained even for a sample with a depth that exceeds the depth of field.
7	Integrated illumination simplifies setup
8	Images and text data can be saved in the digital microscope
9	UXGA-compatible, high-resolution 15"LCD monitor with 1600(H)x1200(V) resolution

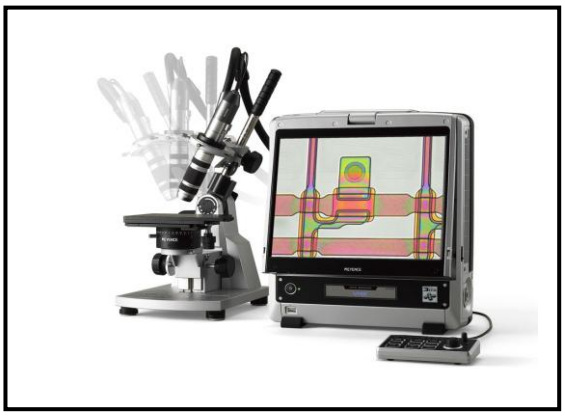

Figure7. Keyence VHX-600 digital microscope.

The Keyence VHX-600 series digital microscope was used with a VH-Z05R a 0-40 X magnification zoom lens. It was set up at a fixed height with the help of VH-S1 transmission/reflection base, so that the position of the lens was the same at all times.

The cast was placed under the microscope with the point of interest tooth being perpendicular to the field of vision.

Magnification of Keyence digital microscope is set at 2 places. The lens magnification is set depending on the size of the object and detail required. Then the magnification on the digital microscope is set same as the external magnification. The magnification on the digital microscope is selected from the LCD monitor. The measurement scale automatically adjusts with the internal lens set up to give the real time measurement value. Magnification of 15X-20X was selected depending on the size of the tooth. The aim of the magnification selection was to see the entire tooth with the gingival margin in the field of magnification. To achieve the goal of selecting the same points all the times, surface features were selected and the casts were aligned to these. This helped to reduce the error in the XY axis.

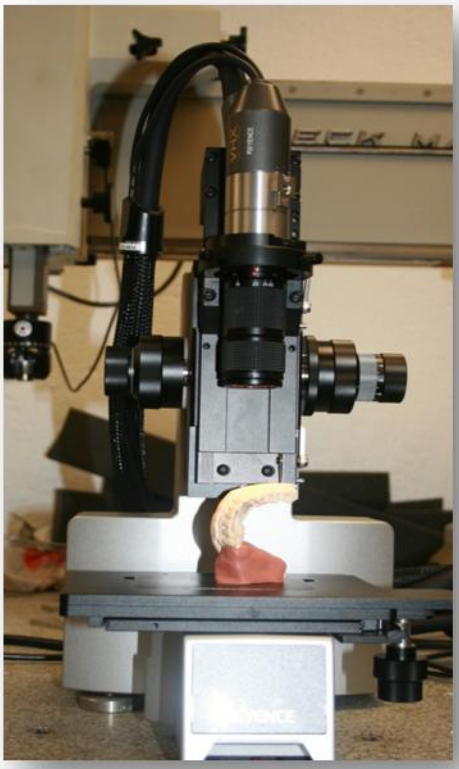

Figure8. Keyence VHX- 600 series digital microscope, with VH-Z05R platform and a 0-40 X magnification lens. A cast is in position for scanning.

Main measure scale was selected from the menu. From the measurement menu the parallel line tool was picked. This tool allows the operator to draw a line passing through two points which were selected on the distal side of tooth. A third point was selected on the mesial, creating a parallel line to the first line and also a horizontal line through the tooth. A mid-point between the parallel lines was used for the length measuring points. These points are picked at random from land marks, and used in each measurement of the same tooth. The distance between the apex of the tooth and the apical gingival margin was measured from the linear distance measurement tool on the midline measurement.

The recorded image was viewed on a laptop for subsequent measurements of the casts of the same patients. The magnification of the microscope was changed and the cast removed and replaced for subsequent measurements to measure operator repeatability.

The same parallel points and center perpendicular lines were created referencing the previous image for each cast. The same points on the incisal edge and the gingival margin are measured. These measurements were repeated eight times on the same tooth and recorded to check the operators' reliability. Each of these casts was positioned carefully to be able to reproduce the same axis orientation and magnifications.

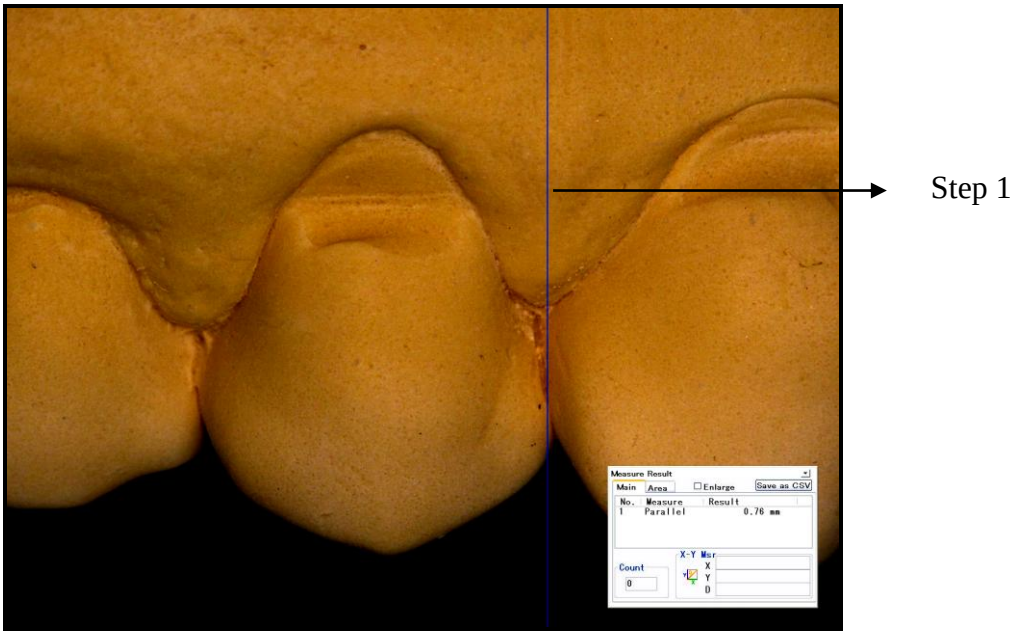

Figure 9 Step 1 Straight line drawn by selecting 2 points on the left margin

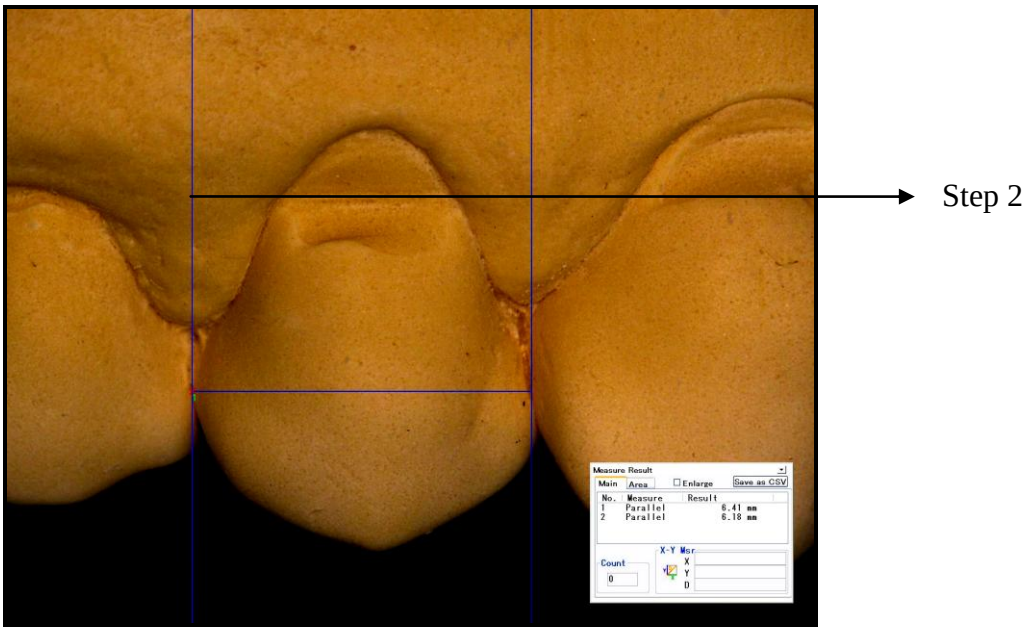

Figure10 Step 2 The cursor is moved to the right side of tooth and a point is selected creating a perpendicular line

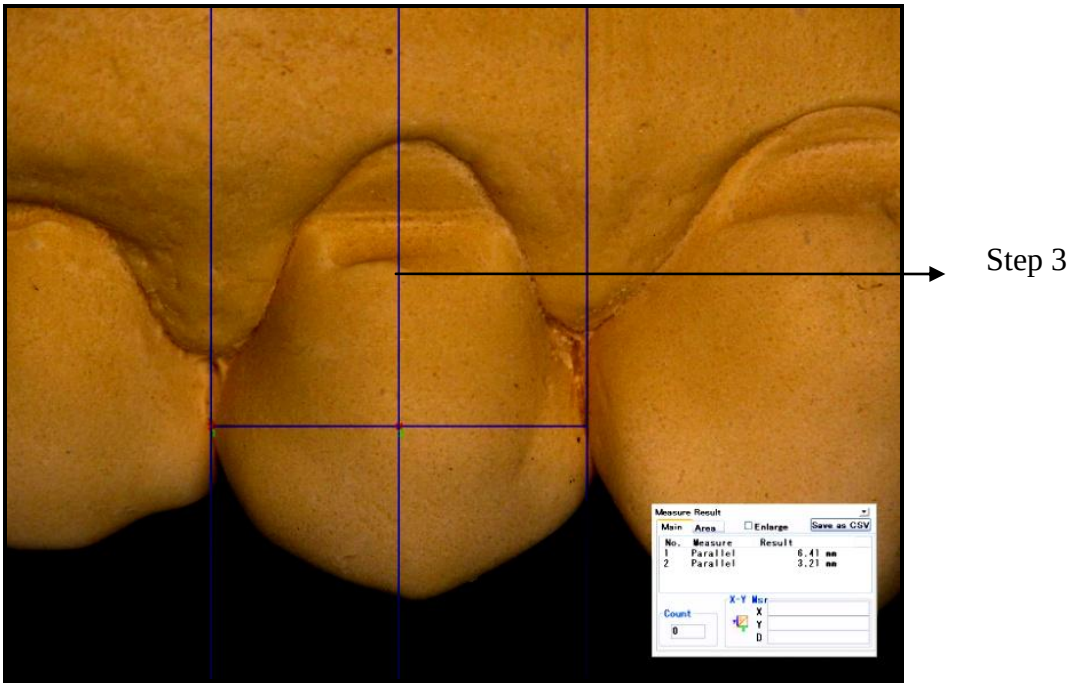

Figure11. Step 3 The cursor is again moved to the center of the tooth and a midpoint is selected creating a center line.

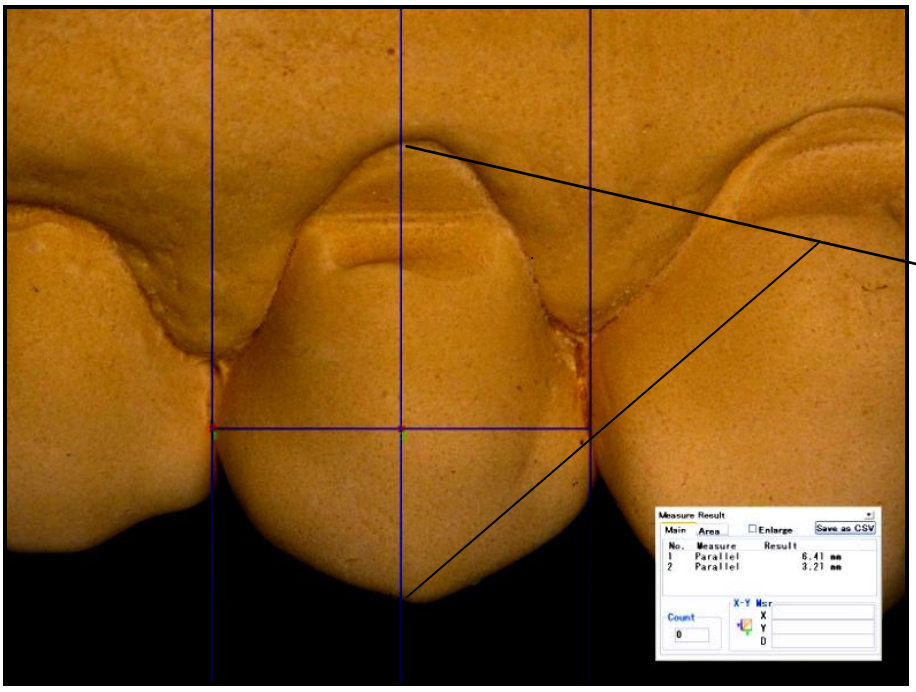

Figure12. Step 4 A two point tool is selected from the main menu and the incisal edge and the gingival margin are marked on the midline.

The reproducibility of the technique was measured by measuring 40 teeth each eight times. Results are tabulated as below:

Table10: Reproducibility of the technique

Reproducibility								
Identification No.	Tooth length from the incisal tip to the gingival margin measured on Keyence digital microscope-mm.							
	1	2	3	4	5	6	7	8
2/6/V3	12.81	12.88	12.83	12.77	12.81	12.73	12.84	12.79
10/4/V3	6.24	6.34	6.28	6.26	6.25	6.32	6.3	6.41
10/5/V3	8.13	8.06	8.03	7.93	7.9	8.11	8.03	7.98
10/12/V3	7.76	7.84	7.67	7.78	7.76	7.75	7.63	7.86
11/19/V3	6	6.41	5.99	5.98	6.42	6.32	6.09	6.17
11/20/V3	6.77	6.33	6.51	6.37	6.34	6.42	6.49	6.56
11/21/V3	7.76	7.58	7.78	7.51	7.59	7.63	7.45	7.69
12/2/V3	8.52	8.19	8.52	8.29	8.36	8.45	8.37	8.33
12/6/V3	7.21	7.2	7.26	7.16	7.14	7.34	7.19	7.15
13/3/V3	6.13	6.05	6.23	6.18	6.29	6.32	6.06	6.18
13/4/V3	8.32	8.29	8.33	8.28	8.31	8.35	8.27	8.24
13/6/V3	10.21	10.18	10.16	10.18	10.17	10.24	10.29	10.13

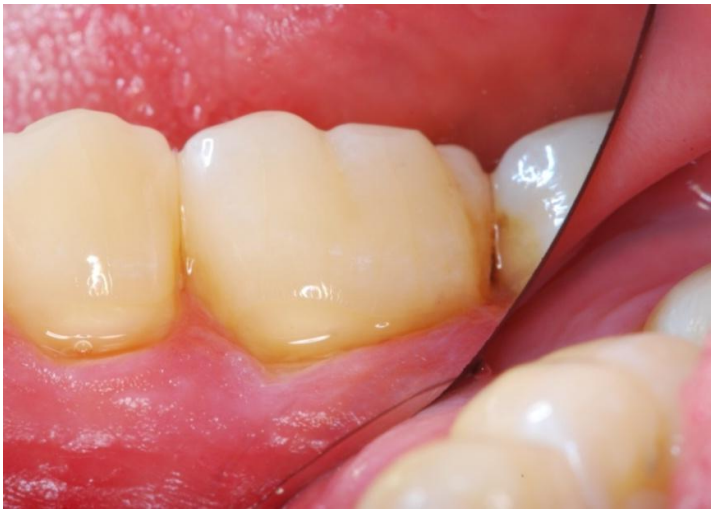

Figure13. Tooth # 19 with non-carious cervical lesion and gingival recession. Note that the gingival floor of the lesion is apical to the gingiva.

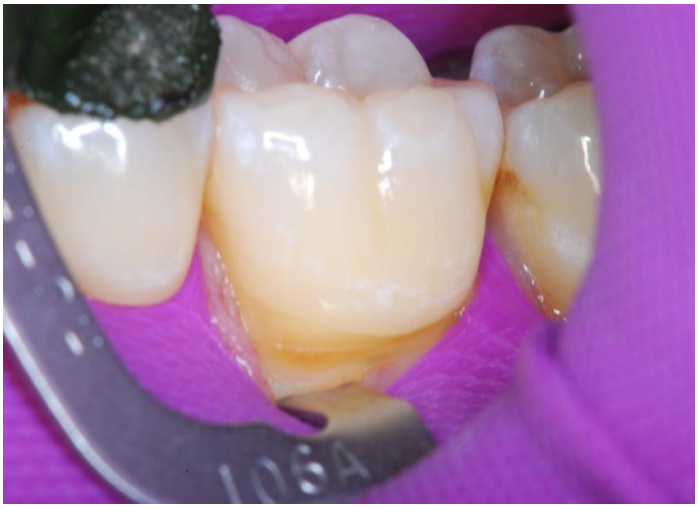

Figure14. Tooth with rubberdam stabilized and gingival tissue retracted with no. 212 clamp.

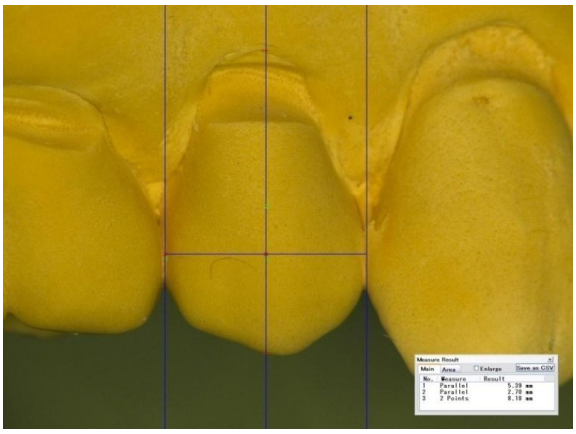

Figure15. VHX 600 Keyence digital microscope image at baseline.

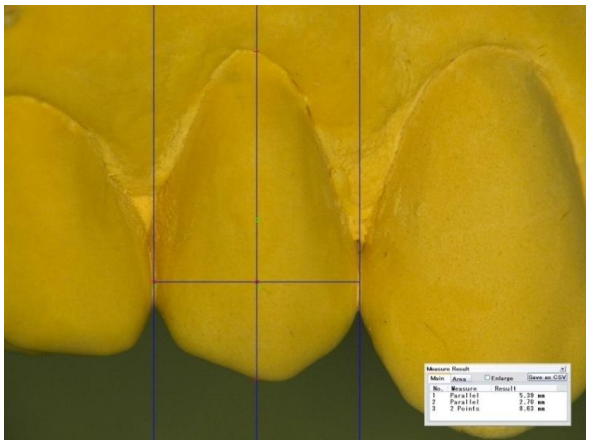

Figure16. VHX 600 Keyence digital microscope image at first recall 10-15 days after restoration.

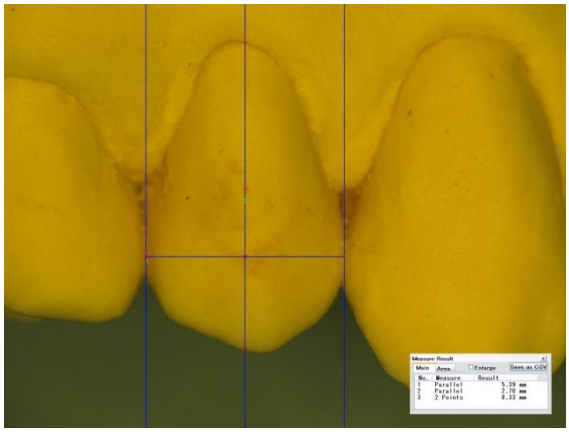

Figure17. VHX 600 Keyence digital microscope image at second recall -6 months after restoration.

Table 11: The data from the non-carious cervical lesions Class V study

Patient code	Tooth	L1	L2	L3	G.I 1	G.I 2	G.I 3	P.I 1	P.I 2	P.I 3	Biotype
3MPD04	10	12.51	12.61	12.54	1	0	1	1	0	1	Thick
3MPD04	11	13.92	14.03	14.34	1	1	1	1	1	1	Thick
3MPD04	13	9.27	9.73	9.2	1	0	0	1	1	1	Thick
3MRS05	5	8.58	8.3	7.53	0	1	0	0	0	0	Thin
3MRS05	6	9.12	9,08	8.99	0	0	0	0	0	1	Thin
3MRS05	11	10.63	10.97	10.89	0	1	0	0	0	0	Thin
3MDS06	3	6.67	6.57	6.58	0	1	1	1	1	1	Thin
3MDS06	4	7.33	7.59	7.52	0	1	0	1	0	1	Thin
3MDS06	12	8.66	8.37	8.27	0	0	0	1	1	1	Thin
3MRG10	5	7.58	7.77	7.88	0	0	1	0	1	0	Thick

L1 length of the tooth from the incisal tip to the gingival margin before restoration placement.

L2 length of the tooth from the incisal tip to the gingival margin at first recall.

L3 length of the tooth from the incisal tip to the gingival margin at second recall.

GI1 Gingival index before restoration placement.

GI2 Gingival index at first recall.

GI3 Gingival index at second recall.

PI1 Plaque index before restoration placement.

PI2 Plaque index at first recall.

PI3 Plaque index at second recall.

Results

Study 1-Measurement of the reliability of the measurement model.

Intraclass correlation was calculated as a measure of reliability of the measurements. Based on 8 replicate measurements on each of 40 teeth, the observed intraclass correlation was 0.9957.

Study II- Measurement of gingival margin position changes.

1. Mixed-model analysis of variance (REML) was used to measure the differences in lengths across the three time points in order to account for multiple observations on the same patients and teeth. Models included patient as a random effect, and tooth time and biotype as fixed effects. There was no significant difference between the mean lengths by time ($p=0.6993$). Hence we failed to reject the null hypothesis stating that there is no change in linear measurement of gingival margin position before and after isolation and restoration of a non-carious cervical lesion.

2. Mixed-model analysis of variance was used to measure the differences in lengths across the three time points by biotype, in order to account for multiple observations on the same patients and teeth. Models included patient as a random effect, and tooth time and biotype as fixed effects. There was no significant difference in length across time by biotype. ($p=0.9102$).Hence we failed to reject the null hypothesis stating that there is no significant change in gingival healing between the two thick and thin gingival phenotypes.

3. Differences in G.I measurements at three time intervals were evaluated using generalized estimating equations to implement generalized mixed model analysis of variance to account for multiple observations within individual patients.

Subject was included as a random effect, tooth as a within-subject effect, and time as a fixed effect.

There is a significant difference in GI across time ($p<0.0001$). GI at time 1 differed significantly from that at times 2 and 3 ($p<0.0001$) but times 2 and 3 were not significantly different ($p=0.7237$).

The null hypothesis stating that there is no change in gingival index before and after restoration of a non carious cervical lesion was rejected.

4. Differences in PI measurements across time were evaluated using generalized estimating equations to implement generalized mixed model analysis of variance to account for multiple observations within individual patients.

Subject was included as a random effect, tooth as a within-subject effect, and time as a fixed effect. There is no significant difference in PI over time ($p=0.3092$).

The null hypothesis stating that there is no change in PI before and after restoration of a non-carious cervical lesion was accepted.

DISCUSSION

The primary goals of this study were achieved after looking at the information obtained from how:

1. The outcome of VHX Keyence digital imaging is a reliable, reproducible method to evaluate the gingival marginal positional changes.

2. The technique was used to measure the linear gingival marginal position changes after restoration of NCCL.

Gingival marginal positional changes are measured to evaluate and compare outcome of root coverage techniques and effects of restorations on gingival margins. The techniques to measure the gingival marginal position changes can be intraoral and extra oral. Intraoral techniques use manual periodontal probe, electronic periodontal probe [81]or stents [82]. Extra oral techniques use photographs with image analysis software, radiographs [83], image J analysis [84].

Periodontal literature discusses many procedures for measuring the effectiveness of root coverage procedures. A literature review between the years 1982 and 1997 by Harry et al [85] demonstrated that many papers did not accurately measure attachment level changes. Studies using periodontal probes have shown differences in the probe tip geometries and diameters, calibration marks, and force application during probing all of which will affect the measurements. A technique that allows reproducibility of information would allow an accurate evaluation of the soft tissue gain from different

techniques. This would allow accurate comparison of grafting procedures to evaluate treatment outcome of the soft tissue gained from different techniques.

The method used here was evaluated for repeatability. Based on 8 replicate measurements on each of 40 samples, the observed intraclass correlation was 0.9957 on the measurement of reliability of the measurement model. The correlation was high in our study compared to a report that used volumetric changes on radiographs for fit and percentage bone loss showed a correlation of 0.68 and r=0.59respectively. Kerner et al.[84] reported image J analysis with reliability of 0.93. The principle disadvantage of this technique is the errors due to angulation of camera, and possible lens distortion.

The Keyence VHX-600 microscope system (Keyence Corporation of America, Rolling Meadows, IL) uses direct digital translation of scale to the computer as the microscope is calibrated to the camera that it uses. When the object that is being examined is in focus, the software is calibrated to know exactly what scale the measurements are taken at. The microscope comes with a sophisticated measurement system involving point, parallel, perpendicular measurements of distance between two features allowing the tooth to be precisely aligned, and eliminating inaccuracies in the X plane. To control the alignment in the Y and Z planes, a jig was manufactured that fit the teeth on the opposing side. The jig was manufactured from impression material and carefully formed to align the tooth being measured in as level a plane as possible. As the tooth is a rounded surface, a perfectly flat plane is not possible but care was taken to get this as close as possible. By using the jig and this system distance and parallax were minimized as much as possible.

There are several advantages with using this system. The largest is that it creates a method of tracing the progress of a patient over time. Differing treatments may be directly compared to see which worked better. UAB also has a large collection of historic casts, and the casts of the same patient taken at differing times may also be directly compared by this method. This also offers the possibility of doing two different treatments on the same patient and monitoring which treatment has the best outcome. Measurements taken are less subject to the observer's judgment because the software guaranties that all measurements are taken in the same place and at the same angle to the tooth axis. The major advantages with this technique are using diagnostic casts which are a part of standard clinical requirement, reducing the additional clinical time and or Volunteer time. Since this is an in-vitro procedure it has the advantage of standardizing the measuring technique which allows comparing different grafting procedures.

The linear measurement of gingival margin position change in NCCL was used to evaluate early changes caused by isolation and restoration. Mean lengths of the tooth from the incisal tip to the gingival margin in our study did not statistically differ by time ($p=0.6993$). A similar study was done by Schaizle et al in 2000 [86] over a period of 26 years. Their findings showed that a change in the gingival margin could be detected clinically 1-3 years after fabrication and placement of the restorations. The tool used to measure the linear margin changes was not explained. A two year clinical study by Santamaria et al [75] reported a gingival margin position change of 1.31 ± 0.37 mm for a comparison between two treatments options of only grafting or grafting and restoration. The probable cause which can explain the lack of difference in measurements in our

study can be the absence of grafting and using a very reliable technique to measure gingival margin position.

Another important consideration in non-carious cervical lesions defects is the gingival phenotype [64]. Weisgold considered long, tapered teeth more prone to recession, whereas those with a flat form presented larger bands of keratinized gingiva and seemed to be more resistant to recession. A possible suggestion was that thin phenotype may compromise the collateral blood supply to the underlying osseous structures [87,88] whereas in a thick phenotype it may be enhanced. Out of the 41 subjects who participated in the study 16 (39%) had thick gingiva. Muller HP [88] measured gingival thickness and discovered that subjects with thin narrow gingiva had more gingival recession and a higher bleeding/ plaque ratio. However, phenotype did not seem to have an outcome in healing of the gingival trauma in our study. There was a significant difference in mean length between the biotypes ($p=0.0211$), with thick biotype having shorter mean length (Ismean=8.10, se=0.27) than thin biotype (Ismean=8.95, se=0.23). The difference in means by biotype was consistent across the time points, resulting in a non-significant change in biotype by time ($p=0.9102$).

Loe and Sillness Gingival Index was used in this study as it is considered the gold standard and is the mostly frequently used index. GI remained low during the entire study. Mild inflammation was seen during the first recall visit presenting trauma. GI remained 0-1 during the study, except for one elderly female patient who received a score of 2 during the 6 month visit. This could be trauma or hormone changes. A statistically significant difference in GI across time ($p<0.0001$) between the first and second visit and first and third visit showed that there is significant amount of trauma and inflammation

after the restoration and the inflammation persisted even at 6 month visit. Another important finding is that, based on change in GI between the first and third evaluations: 22 patients (53.7%) had no teeth that increased in GI. As, over 50% had no change in GI the clinical significance is probably not large. 8 patients (19.5%) had 1 tooth with increased GI. 4 patients (9.8%) had 2 teeth with increased GI and 7 patients (17.1%) had 3 teeth with an increased GI.

Loe and Sillness Plaque index was used in this study as it is considered the gold standard and is the mostly frequently used index. PI also remained between 0-1 throughout the study except for 2 patients. Their PI was 2, but did not change from the start of the study to the end of the study which was over a period of 6 months. PI did not show any significant difference over time ($p=0.3092$). In a similar study the PI and GI increased significantly for the test sites between 2-4 yrs and remained consistent. The increase in plaque around the overhanging class II restoration margins [89] led to an increase in the bacterial count leading to increase in GI. In our study we did not observe any significant difference in 6 month time period. In our NCCL restorations the increase in GI would have been due to the subgingival margins causing trauma on the gingiva or due to the microfilled composite used for restoring the lesions.

The strengths of this study are that it involves a single operator in measuring the linear measurement changes. Despite the fact that this is a 6-month follow up study, longer periods of observation are recommended to assess the rate of success and the possible complications.

LIMITATIONS

- Texture of the soft tissue cannot be observed and sulcular periodontal attachment levels cannot be measured.
- This technique relies on stability, tipping of teeth can be difficult to measure.
- Limited number of patients.
- Six months is a limited time period to assess the possible side effects of restorations.
- The GI, PI, tissue phenotype are subjective measurements.
- Change in gingival margin was measured at one point dimension only.

CONCLUSIONS

- The method developed is a reproducible technique to measure gingival margin position changes.
- It can be used to follow gingival margin changes after crown preparations, root coverage procedures.
- Imaging followed in this technique may be a valuable research tool.
- Isolation and restoration of NCCL did not lead to gingival recession.
- Teeth with thin gingiva had longer clinical crown length.
- NCCL restored with composite resin have gingival inflammation scores that are higher than before restoration.
- Interestingly, no plaque changes were observed.

FUTURE DIRECTIONS

- Longer periods of observation are recommended to assess the possible complications.
- Include more parameters like

  Different gingival retraction methods

  Different crown margins and crown design
- Multicenter retrospective studies aiming to evaluate the outcomes of soft tissue grafting procedures eliminating the examiner bias.

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BOARD ACTION DATE: 12/5/2008
PANEL: 6
STUDY APPROVAL EXPIRES: 12/21/2009
STUDY NUM: 1095223
WIRB PRO NUM: 20072058
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PROTOCOL NUM: CR-07-009
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TITLE:
Clinical Evaluation of Three Dental Adhesive Systems in Class V Restorations

APPROVAL INCLUDES:
Study and Investigator for an additional continuing review period. This approval expires on the date noted above.

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PROTOCOL

Clinical Evaluation of Three Dental Adhesive Systems in Class V Restorations

Sponsor: 3M™ ESPE™, St Paul, MN, USA
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Study Objectives

The purposes of this clinical trial are to evaluate two new self etching dental adhesives in the restoration of Class V cavities in teeth of adults and to measure the occlusal forces generated during biting by individual teeth to examine the effect of occlusal forces on efficacy of class 5 restorations. The study will be a randomized, controlled, prospective clinical trial.

Ethical standards

The study will be conducted in accordance with the Declaration of Helsinki (1964) as revised in Venice in 1983. Institutional Review Board approval will be obtained prior to commencing the study. Informed written consent will be obtained from all patients prior to registration for participation in the evaluation. Implicit in giving informed written consent, each patient will reserve the right to withdraw from the study at any time. Patients' information sheet, informed consent form, and HIPAA form are given in Appendices 1, 2 and 3.

Study Design

The study will be a randomized, controlled clinical evaluation of three Class V restorations placed in a single patient using Filtek™ Supreme Plus composite as the esthetic restorative material which will be bonded with either a one bottle or two bottle self etching adhesive system or a control. The study will be conducted in the Department of Prosthodontics, University of Alabama at Birmingham (UAB), School of Dentistry. The study will be of one year's duration and may be renewed. 45 adult patients aged 19 years or older will be recruited into the study for the evaluation of the Class V restorations, to obtain a total of 135 Class V restorations at one year. Based previous clinical trials, the average attrition of subjects at the one year recall are approximately 10%. Therefore 135 restorations will be placed assuming a 10% drop out rate which will allow 40 patients to be evaluated at the end of year one.

Investigators

Dr Burgess will act as the Principal Investigator. Four experienced operators will place the tooth colored restorations in the study (Drs Belinda Waldo, Maureen Pezzementi, Dan Given and Ramtin Zadeh); two dentists will complete the occlusal force measurements: Drs Keith Kinderknecht and John Burgess; and Drs Muna Anabtawi, B. Waldo and John Burgess will complete the baseline, 6 month and 1 year recall examination of the restorations. Dr. Jampani will scan the impression and do the imaging for the Class V restorations. Baseline evaluations will be conducted one week after the restorations are placed.

Literature review and statement of the problem

Cervical lesions at the gingival of the tooth can be carious or noncarious (Fig 1).

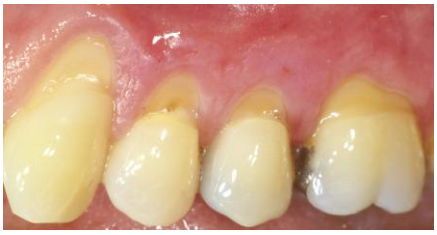

Figure 1. Noncarious cervical lesions

Noncarious lesions begin as a notch at the gingival area and slowly progress. The tooth is divided into a crown, which extends from the gingiva to the top of the tooth and the root which extends from the gingival crest to the bottom of the tooth. A non-carious cervical lesion (NCCL) is a loss of tooth tissue at the cervical or junction of the tooth between the crown and the root that is not produced by tooth decay. Such lesions are common and have frequently been investigated. However the etiology of the NCCL is complex with erosion, abrasion and tooth flexure from occlusal factors contributing at various times in the initiation and progression of the lesion. An excellent critical review of these lesions has recently been authored by Barlett and Shah, 2006.

Clinical observation has shown that non carious lesions are most often found on the facial surface seldom on the lingual surface, are more frequent on the incisors, canines and premolars and are more prevalent on the maxillary arch (Kitchen, 1941). These lesions frequently involve enamel but dentin is involved to a smaller degree (Borcic et al, 2004) indicating their progressive nature. In general the lesion progresses very slowly and may arrest. Treatment ranges from no treatment to placing an adhesive restoration if symptoms are present. The controversy over the etiology of the noncarious cervical lesion (NCCL) has centered on three possible etiologies.

Erosion

Erosion is the loss of hard dental tissues by a chemical process without bacterial interaction. Smooth surfaces of anterior and premolar teeth are particularly vulnerable to acid attack during the consumption of acidic foods and drinks. Posterior teeth are subject to erosion in patients who regurgitate gastric acid. The PKa of the acid is a greater contributor than pH in tooth tissue erosion. A high PKa demonstrates that more of the acid can be ionized producing the hydrogen ion than is indicated by the pH. For example, orange juice causes more erosion than colas although orange juice has a more alkaline pH than cola. Although occupational exposure to air-borne acids in the workplace used to be common now industrial exposure to acid is uncommon and is no longer a frequent cause of erosive NCCL. Other activities may produce acid exposure such as frequent swimming in chlorinated swimming pools which is a cause of tooth erosion as well as the erosion produced on enamel by professional wine

tasters. Acid erosion from environmental or internal sources such as gastric reflux is one possible mechanism for producing NCCL (Eccles, 1982). Bulimia produces another chemical attack on the teeth and while most lesions are found on the lingual of maxillary teeth some individuals regurgitate and hold gastric contents in the mouth until they are able to expectorate. This produces buccal lesions on cervical tooth surfaces adjacent to the retained vomit in lower premolar and permanent molar teeth.

Lesions caused primarily by erosion are classically described as smooth disc-shaped rounded lesions, concave and with no sharp edges, grooves or ridges. The prevalence of such cervical erosion lesions is not well documented, although Zipkin and McClure in 1949 reported that 27 percent of the 83 subjects studied had loss of tooth tissue on facial surfaces of teeth attributable to erosion. These workers found that the prevalence and severity of erosion lesions increased with age, with more lesions being found in maxillary teeth with first premolar teeth most commonly affected.

Abrasion

Toothbrush abrasion, the abnormal wearing away of a substance or structure by a mechanical process, was described by Zsigmondy in 1894 as angular defects and later by Miller in 1907 as a wasting of tooth structure. It was demonstrated *in vitro* by Manly in 1944. Piotrowski, et al. noted that many factors are involved in the rate of abrasion including tooth brushing technique, brush force, brushing frequency, bristle stiffness and toothpaste abrasiveness. Increased cervical lesions were reported in a large cross-sectional study in subjects who brushed twice daily compared with those who brushed less frequently. Horizontal brushing produces more tooth loss than longitudinal brushing. A greater number of NCCL are seen on the left side of patients who are right-handed, and areas brushed initially have been shown to have more abrasive lesions, perhaps due to increased brushing force and duration in that area. Boric et al noted that abrasion lesions increase in incidence with age.

Abrasive lesions typically have well defined, sharp margins and may be wedge-shaped or grooved with scratched surfaces and sharp line angles. In two cross-sectional studies the incidence of abrasive lesions has been shown to vary from 31-45 percent and to increase with age. Loss of tooth structure is accelerated when acid softening precedes tooth brushing (Attin et al,1997 and Davis & Winter, 1980). It has been noted that a delay of one hour can increase tooth resistance to abrasion and lessen the defects created by brushing in bovine teeth (Attin et al, 2000) and in an in situ study (Jaeggi & Lussi,1999). Erosion and abrasion probably act synergistically to differing degrees at different times *in vivo*, and it is difficult to determine the specific etiology of a NCCL at a specific point. While the abrasive effects of tooth brushing have been recognized as a major cause of NCCLs (Pinborg 1970), some lesions are difficult to explain by tooth brushing. These etiologies may be combined and one etiology may dominate at any one time. Accurate diagnosis of non carious lesions is probably multifactorial and is difficult to pinpoint at any one point in time.

Tooth flexure

A number of authors have suggested that factors other than abrasion and chemical erosion may be important in the pathogenesis of the NCCL. Grippo proposed that occlusal loading deforms the tooth especially at the cervical area disrupting the enamel crystals at the cervical area forming a NCCL. He called this occlusal generated lesion an abfraction lesion.

Cervical enamel has a weak mechanical bond to the underlying dentin due to a lack of the normal scalloped pattern of the enamel-dentin junction in this area. Enamel has high compressive strength but its ability to withstand tensile forces is poor. Therefore, tensile forces acting on a tooth are more likely to disrupt bonds between

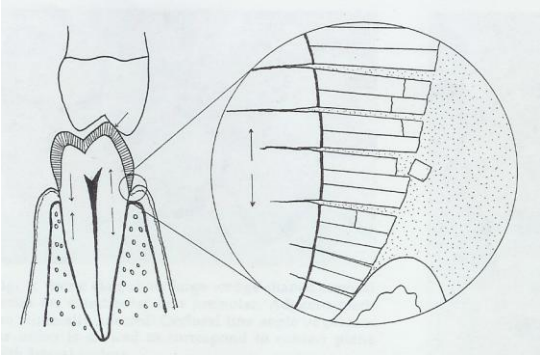

Figure 2: Stress corrosion showing enamel rod fracture and the beginning of the abfraction lesion from Lee and Eakle.

hydroxyapatite crystals. Lee and Eakle proposed (Fig 2) that a lesion created as a result of these tensile forces would be wedge-shaped and located at the fulcrum, the region of maximum stress. In an ideal occlusion functional loads are directed along the long axis of the tooth, while in eccentric movements the side towards which the tooth is bending is under compressive stress and the opposite side is under tension. These tensile forces break bonds between the enamel hydroxyapatite crystals and the ruptured enamel may then break away causing the exposure of the underlying dentin. Secondarily toothbrush abrasion and erosion may cause further tooth substance loss and enlarge the NCCL. Stress corrosion in teeth is the physicochemical cracking of the cervical area stressed by loading in the presence of a corrosive agent. This can occur and contribute to the etiology of NCCL when food and wine are consumed simultaneously. Tooth brushing after consuming acidic food or drink may have a similar corrosive/abrasive effect. Abfraction lesions as described by Grippo are typically wedge-shaped with sharp margins although secondary erosion or abrasion may alter the appearance of the lesion.

To have strong evidence for the occlusal etiology for NCCL heavy occlusal forces must be applied to the occlusal surface during excursive movements. A recent study examined 1974 teeth from 77 participants (Madani and Ahmadian-Yazdi, 2005) 167 teeth had a NCCL, while an additional 167 teeth with no cervical lesions were selected from the same population as controls. A through

occlusal examination was completed and centric occlusion and eccentric movements observed. The direction and magnitude of a slide from centric relation to maximum intercuspation was recorded as were premature contacts in eccentric movements. The relationship between NCCLs and premature contacts was examined using linear regression. The frequency of NCCLs differed significantly, most often seen in the first premolars followed by the canine teeth. The greatest number of premature contacts occurred in first premolars followed by canines. The total number of premature contacts was significantly greater in the NCCL group than in the control group. While this controlled clinical study defined NCCL inclusion criteria, the observation of centric occlusion and eccentric contacts intraorally by the use of occlusal marking paper creates less than compelling evidence of the magnitude of the prematurity. Although this study demonstrated a highly significant positive relationship between the presence of premature contacts and the number of teeth with NCCL, the study methodology results in a low level of evidence. Estafan et al 2005 evaluated the relationship between noncarious cervical lesions and occlusal (or incisal) wear. 299 casts were mounted on a Hanau semi-adjustable articulator (Waterpik Technologies, Newport Beach, Calif) without a dental facebow. Mandibular casts were hand articulated and the condylar inclination arbitrarily set at 25 degrees. Data collected included the presence and contour of noncarious cervical lesions (NCCLs) and the presence, location, and severity of any occlusal/incisal wear facets. Also included were Angle's classification, occlusal guidance patterns, midline, reverse articulation (cross bite), open occlusal relationship, and posterior excursive contacts where present. Following calibration, 2 evaluators made independent observations on the casts. The first evaluator recorded for each tooth in each subject: presence and severity of NCCLs, presence and extent of occlusal/proximal restorations, and presence of reverse articulation and open occlusal relationship. Following the first evaluation red rope wax was placed at the cervical margins of each tooth for the purpose of blinding the second evaluator from NCCL observations. The second evaluator recorded severity and location of occlusal/incisal wear, presence or absence of posterior excursive contacts, Angle's classification, occlusal guidance pattern, any midline discrepancy, and presence or absence of tori. 99 of the 299 casts demonstrated at least 1 NCCL, 99% of them on the buccal surface. The study found no correlation between NCCLs and occlusal wear in the well-defined population. Posterior excursive contacts and occlusal guidance schemes also did not correlate with NCCLs. There was no relationship between noncarious cervical lesions and occlusal/incisal wear. While this study presented interesting data, it cannot be considered definitive evidence in the controversial area of the etiology of the NCCL. The homogeneity of the participant population, the arbitrary nature of the mounting process, and the lack of a precise relationship between tooth wear and cervical flexure is not thoroughly established. While occlusal wear was demonstrated on every cast, NCCLs were only evident in 33% of the casts. The conclusions of this study are well founded but the precise depth of evidence relating to the true etiology of the NCCL remains less well defined.

Whereas most authors attempt to ascribe a single etiology to NCCL, a number of factors indicate the multi-factorial etiology of the NCCL including: the occurrence of NCCL on the lingual areas of teeth on teeth where access with a toothbrush is limited, the occurrence of NCCL in animals, the progress of NCCL around restorations, mobile teeth do not display NCCL as frequently as non-mobile teeth, an increased incidence of NCCL in bruxism, many NCCL appear below gingiva, the increased prevalence of NCCL in teeth of patients whose teeth demonstrate eccentric occlusal contacts in function, some clinical trials correlate a non-ideal occlusion with early loss of restorations of NCCL

Restoration of NCCL

Treatment of NCCL may be limited to palliative therapy if the causative factors have been eliminated and the patient is prepared to have the unrestored lesion monitored regularly. In many cases no treatment is indicated if the lesion is small and asymptomatic. Fluoride and bonding agents have been successfully applied to NCCL as palliative treatment. However, clinical evidence suggests that the restoration of NCCL may be necessary to prevent their enlargement. Primary indications for treatment of NCCL are sensitivity, poor aesthetics and plaque retention. However, when pulpal exposure is likely, where the position of the NCCL may compromise the design of a partial denture, where the structural integrity of the tooth is threatened, to arrest or delay the lesion's development, and perhaps to improve gingival health by facilitating better plaque control the NCCL should be restored. Nevertheless, an appreciation of the etiology and cessation of lesion progression should precede treatment and elimination of aggravating factors such as potentially harmful eccentric occlusal contacts should be adjusted. Kuroe et al 2000 advocated the evaluation of occlusal stresses on affected tooth/teeth and the reduction of heavy lateral forces. Ideally, restoration of NCCL is by the use of an adhesive material, generally a glass-ionomer or a composite resin and a dentin bonding system. New treatments to restore the NCCL without invasive techniques need to be developed this protocol will examine a newly developed adhesive designed to bond to tooth structure. It has been suggested that when NCCL are restored the flexure of the teeth under load would be reduced, thereby strengthening the teeth and perhaps slowing the progression of the NCCL.

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Preclinical testing of the New Dental Adhesive

The two new adhesives from 3M ESPE Adper Scotchbond SE and Adper Easy Bond (Self etching adhesives) have 510k approval and has been CE marked. The 510 K FDA approval process is common for dental restorative materials and designates that the material is safe for human use since the new formulation does not differ substantially from the previous various. As a control a total etch single bottle adhesive Single Bond Plus dental adhesive will be used. 3M ESPE's Filtek Supreme Plus dental composite resin restorative material will be used as the restorative for all adhesives and is commercially available in both Europe and North America. 3M ESPE Adper Scotchbond SE and Adper Easy Bond are not currently on the market. Its predecessors, Adper Single Bond Plus and Scotchbond™ Multi-Purpose Plus are both commercially available.

Risk Assessment

A Diplomate of the American Board of Toxicology has assessed the safety of 3M ESPE Adper Scotchbond SE and Adper Easy Bond as safe for their intended use.

Objectives of clinical investigation

To evaluate the performance of two self etching adhesives used in the restoration of Class V cavities in the teeth of adult patients compared to a total etch bonding agent which serves as the control since it has a significant history of success. A secondary goal is to quantify the number of teeth with NCCL with heavy occlusal forces and compare them to teeth with no NCCL and to measure the progression of the lesion over the time periods of this study.

Primary end points:

- Retention of the restoration
- Marginal integrity

Secondary end points:

- Post-operative sensitivity
- Color match
- Marginal Staining
- Surface roughness
- Secondary caries

Two hypothesis are to be tested. The first one is that the two self adhesive bonding agents (3M ESPE Adper Scotchbond SE and Adper Easy Bond) produce clinical results (primary and secondary end points) which are the same as that produced with a successful well established total etch (3M ESPE Single Bond Plus) dental adhesive system when used in combination with the restorative material Filtek Supreme Plus to restore Class V cavities in adults patients' teeth. The second hypothesis is that the occlusal force on teeth with noncarious cervical lesions has the same occlusal forces as adjacent teeth with no lesions and that the lesion with heavy occlusal forces does not progress.

Patient population

Subjects recruited for this investigation will be selected from patients attending Dr Burgess' clinic and recruited from advertisements (Attached). A total of approximately 45 patients aged 19 years and older will be recruited into the study to give 135 Class V restorations. With 135 restorations at baseline 120 restorations teeth are expected at the one year recall. Current clinical studies conducted in the dental clinical research area have shown about 10% loss in recalls at one year. We anticipate that subject retention in this study will be no different than previous clinical trials.

Inclusion and Exclusion criteria

To be considered appropriate for inclusion in the study a patient must:

- Age 19 years and older
- Have a minimum of three noncarious Class V lesions requiring restoration that are >1.5 mm in depth
- Be a regular dental attendee who is able to return for assessments
- Be in good medical health and able to tolerate the dental procedure
- Must not have rampant caries
- Must not have chronic periodontitis or carious lesions which could comprise tooth retention.
- Must be able to tolerate the dental procedure.
- Have normal salivary function.

Patients will be excluded from participating in the study if:

- They are taking part in an evaluation of other restorative materials / systems
- They do not have three noncarious lesions or have lesion that are less than 1.5 mm deep
- Are not able to tolerate the time required to place the restorations
- There is a history of a adverse reaction to any materials used in the study
- They are irregular dental attendees
- They maintain an unacceptable standard of oral hygiene.
- They have chronic periodontitis or rampant caries.
- There is severe salivary gland dysfunction
- They are unable to return for recall appointments

Noncarious lesions in anterior and premolar teeth requiring Class V restoration can be included in the study. Teeth must be vital, that is, free of signs and symptoms of periapical pathology both clinically and radiographically.

Test materials

The self etching adhesive bonding agents included in this protocol (3M ESPE Adper Scotchbond SE and Adper Easy Bond) are from 3M ESPE. The control material is 3M ESPE Single Bond Plus. The restorative composite resin Filtek Supreme Plus will be used with all dental adhesive systems.

Instructions for use

1. Adper Scotchbond SE, A rubber dam is used to isolate the tooth, flour of pumice is used to clean the NCCL and the tooth surface is rinsed thoroughly. The tooth is lightly dried – still glistening- and a drop of solution A is applied to one well and B is applied in another well. Apply A to the entire NCCL and observe the red color over the surface. Discard the brush. Wet another brush with solution B and apply to the tooth. The red color should disappear meaning that the etching components have been activated. Scrub for 20 seconds with moderate finger pressure. Air dry the solution for 10 seconds to evaporate the water solvent. The surface should be shiny. Recoat the brush with solution B and coat the tooth bonding surface again. Lightly air thin to increase the thickness of the film. Light cure for 10 seconds.
2. Adper Easy Bond: A rubber dam is used to isolate the tooth, flour of pumice is used to clean the NCCL and the tooth surface is rinsed thoroughly. The tooth is lightly dried – still glistening- and the enamel is etched with phosphoric acid for 15 seconds and rinsed. A drop of Easy Bond is applied to one well and the adhesive is applied wit a scrubbing motion over the entire bonding surface for 20 seconds. Rewet the surface

as needed during the 20 seconds scrubbing time. Air dry the solution for 5 seconds until the film no longer moves indicating that the solvent has been evaporated. Light cure for 10 seconds.

3. Single Bond Plus: A rubber dam is used to isolate the tooth, bevel enamel caviosurface margins, flour of pumice is used to clean the NCCL and the tooth surface is rinsed thoroughly. The tooth preparation enamel is etched with phosphoric acid for 15 seconds and rinsed. Blot excess water- tooth should be glistening with no water pools. Immediately after blotting apply 2-3 consecutive coats of adhesive to the etched enamel and the dentin for 15 sec with gentle agitation. Air thin for 5 seconds to evaporate the solvent. Light cure for 10 seconds.
4. Filtek Supreme: Select shade and opacity of the composite resin most will be in the dentin or body opacity range. Apply to the bonded area in increments no greater than 2 mm and light cure for 40 seconds. Contour with polishing instruments (Sof-Lex disks) and polishing paste for the final polish.

Randomization procedure

Restorations will be randomly allocated to teeth on the basis of equal distribution of the three materials being evaluated, one tooth of the three selected will be randomly allocated to receive one of the three adhesives while the other tooth of the remaining pair receives the second adhesive and the last tooth receives the remaining adhesive. All teeth will be restored with the same composite resin. A computer generated random numbers table will be used for the randomization procedure. All study treatments will commence with the patient's upper right, followed by upper left, lower right and lower left. The most distal tooth in each quadrant will be treated first. Each sequential random number in the random numbers Table will indicate the adhesive to be used, the second and the third cavity receiving the alternate materials.

Method of evaluation

Four trained operators will place the restorations; and two trained and calibrated examiners will complete the evaluation process.

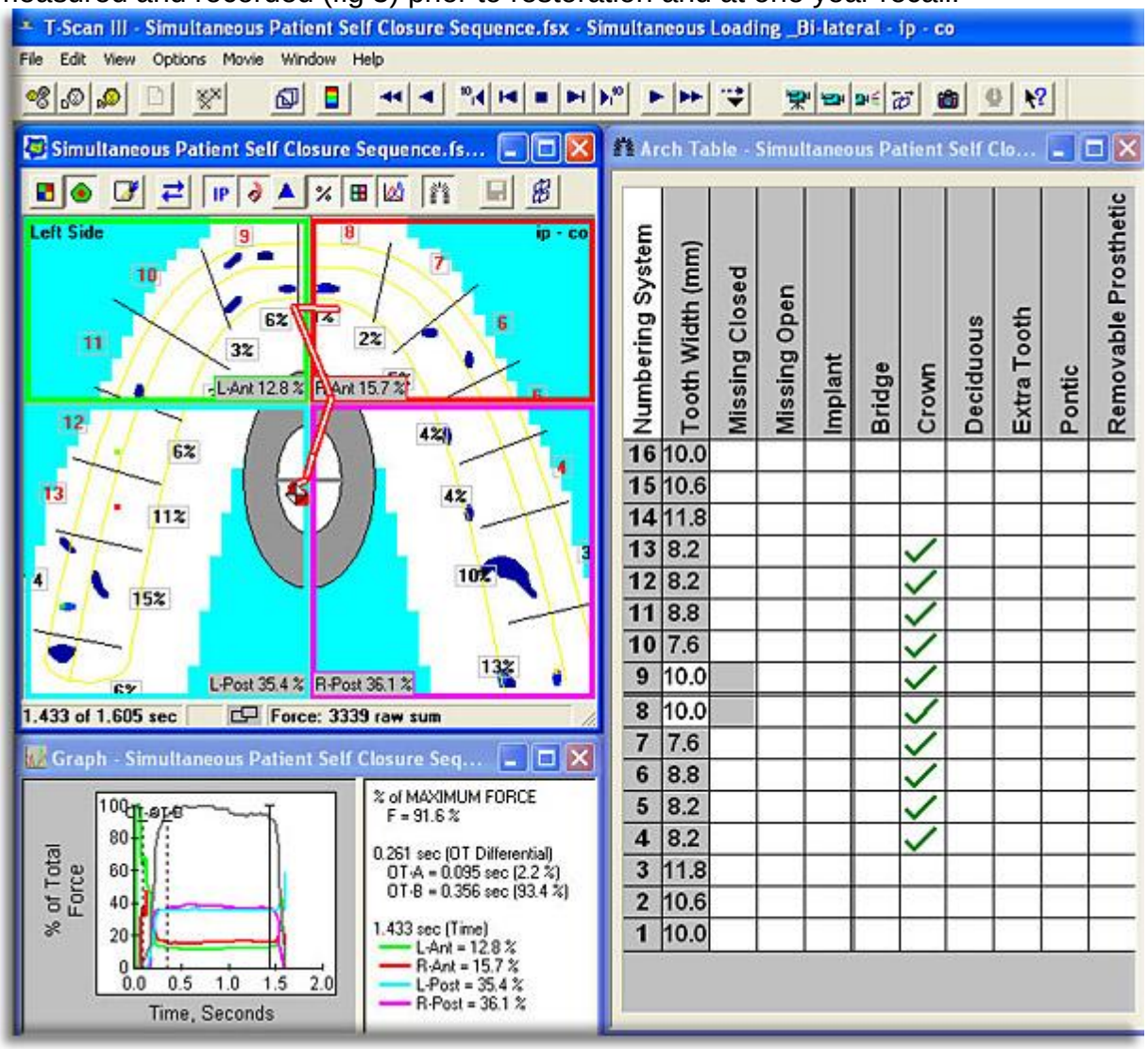
Pre-operative procedures

After an opportunity to read and consider the patient's consent form and having received satisfactory answers to any questions concerning the evaluation, each subject will be asked to complete and sign a consent form. Appropriate vitality and radiographic assessments will be completed and any pathology noted and recorded. A facial impression will be made of all noncarious cervical lesions which will be scanned using the Proscan 2000 (Scrantron, England) to measure the depth and the volume of the lesions. This non contact profiling device is accurate to 5 nm and will provide preliminary information as to the depth and ultimately the progress of the non carious lesion (control) which will not be restored. After scanning the impression will be poured in dental stone to aid in

locating the margins of the restorations placed in the lesion at each recall examination.

Operative procedures

After consent has been obtained, the occlusion of each subject will be analyzed with the T Scan III. The occlusal forces generated for each tooth will be measured and recorded (fig 3) prior to restoration and at one year recall.



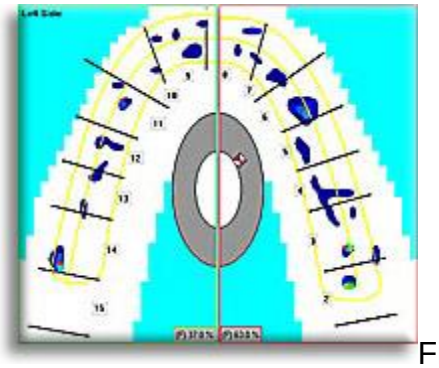


Figure 3: Views of the T Scan III showing the mandibular movement, percent of total bite force recorded for each tooth.

The T Scan technology can not measure absolute force as it can not describe occlusal forces in Newtons/cm sq. or lbs/sq. in. It has the advantage of gathering data output from teeth occluding across its recording sensor and is very precise, dynamically changing (in .003 -.005 second increments) relative applied load per occluding tooth. It also produces a variable "percentage of force" at each tooth that changes with each passing.003-.005 second time increment. This data is recorded sequentially as the occlusal contacts apply variable load to each occlusal surface in functional mandibular movements.

The data that can be gathered with this instrument include:
1) Changing % of applied force on abfracted teeth in both mandibular closure and excursive function (right, left, protrusive, clenching, grinding etc.)
2) Changing relative color-coded variable applied load on abfracted teeth in both mandibular closure and excursive movements
3) Length of time abfracted teeth have prematurities in both contact sequence time and in load in a closure movement
4) Length of time an abfracted tooth is involved in excursive functional contact.

The patient will then be appointed for a restorative appointment. Where clinically indicated and with the approval of the patient appropriate local anesthesia will be used. The lesion depth of the NCCL should be at least 1.5mm deep as measured with a periodontal probe. The teeth to be restored will be prepared using conventional instruments and techniques. Teeth will be isolated with a rubber dam and appropriate retainers carefully contoured to isolate the quadrant being restored. Each lesion will be cleaned with flour of pumice applied with a prophylaxis cup applied with a slow speed handpiece (NSK, Japan). After rinsing the cavity preparation, the occlusal enamel of the preparation will receive a short bevel made with an OS 2 bur (Brasseler, GA) and high speed hand piece (NSK, Japan). An adhesive will be applied to the preparation following the manufacturer's directions. Application times will be measured with a stop watch. The proper shade will be selected for the final restoration. The composite resin (Filtek Supreme, 3M ESPE) will be placed in increments according to manufacturer's instructions and cured using a G Light (GC America, Chicago, IL). Output will be measured daily to ensure high output (> 700mW/Cm^2) Finishing

will be completed using an established protocol. Gross reduction will be removed with finishing burs (7901 and OS 2, Brasseler, Savannah, GA). Polishing will be completed with polishing disks and rubber points, cups and disks. Digital images will be made before preparation, after preparation, at baseline and at each recall.

Recalls and Review procedures

Subjects are expected to participate for the initial screening and placement visits, the baseline evaluation, and six month and one year follow-up recalls. All restorations will be inspected and assessed according to the codes and criteria set out in Appendices 4, 5 and 6, which are based on the criteria established by Ryge. The assessment will include evaluation of anatomic form, margin adaptation, surface roughness, color match, post-operative sensitivity / discomfort, and presence or absence of secondary caries. In addition, photographic records and elastomeric impressions will be taken of the restorations at baseline, 6-month and 1-year recalls. Baseline assessment (Appendix 4) will be carried out one week after placement of the restoration by two evaluating dentists who did not restore the tooth. At the six month and 1 year recalls (which are to be completed within $\pm$2 months of the date of the recall interval) (Appendices 5 and 6 respectively). In addition, photographic records will be taken of the restorations at baseline, 6 months and 1 year. The recalls will be done by two calibrated examiners who were not involved in the restoration of the teeth. When decisions of assessors differ, a consensus opinion will be agreed before the patient is dismissed. In the event of a restoration being unsatisfactory, details of the mode of failure will be documented (Appendix 6) and the necessary replacement / remedial work done. An addition silicone impression will be made of the restored and control (non restored) lesions to determine the depth, volume and progression of the lesions around the restoration and in the unrestored tooth. This data will be used to correlate whether the occlusal force applied to the tooth is related to the progression of the lesion. This data is preliminary only and will be used to provide pilot data which will lead to a larger investigation to more fully understand the occlusal factors involved in noncarious cervical lesion progression.

Patient Compensation

All restorations performed for the study will be at the usual cost to the patient. Patients will receive $30 financial compensation per pair of restorations for each recall visit (six and 12 months). The compensation paid per subject at each recall visit will be $30.00.

Monitoring

The study will be monitored by Vicki B. Kolb, (651) 736-7779), 3M ESPE, 260-2A-10, 3M Center, St Paul, MN 55144-1000 [vbkolb@mmm.com] or a monitor designated by her.

Confidentiality

Each patient recruited into the study will be given a unique identifying code number. Computer files will be password protected and placed on a computer with no internet access. Paper records will be maintained in a locked cabinet in the clinical research area.

Analysis of results

Tables of percentages will be prepared to summarize the demographic characteristics of the subjects, the distribution of restorations and the baseline data, and to illustrate the recall and data analysis findings. Results from the comparison of the two dental adhesive systems will be evaluated by means of non-parametric statistics.

Problem cases

Where a study restoration has failed this will be recorded on the "Failed Restoration Form" (Appendix 7). An alternative treatment (of a different composite resin restorative and bonding system, or other direct restorative system, at the discretion of the clinician,) will be offered to the patient and a record made in the patient's notes. Neither the patient, nor the clinician will pay for this further treatment however the contact person at 3M ESPE (Vicki Kolb, 651-736-7779) must be notified that an alternative treatment has been necessary and requires payment by the sponsor.

Adverse Events

Any adverse reaction to the treatment provided as part of the study will be fully investigated and recorded on the Adverse Event Record Form (Appendix 8), including details of the appropriate clinical action taken, and promptly reported to the Investigational Review Board**,** Ms. Sheila Moore, Director of the Office of the UAB Institutional Review Board (IRB). Ms. Moore may be reached at (205) 934-3789 or 1-800-822-8816, press the option for operator/attendant and ask for extension 4-3789 between the hours of 8:00 a.m. and 5:00 p.m. CT, Monday through Friday. In addition the contact person at 3M ESPE (Vickie Kolb, telephone number 651-736-7779) will be contacted.

In the event of an adverse reaction to the 3M ESPE adhesive or Filtek Supreme Plus restorative material, any indemnity will be borne by 3M ESPE, in accordance with the research contract. Any decision as to whether to prematurely stop the study will be taken jointly by the PI, IRB and 3M ESPE. The

IRB will be kept updated by the PI regarding adverse events according to the IRB reporting guidelines.

Reports to sponsor

The PI will prepare and submit a report to the sponsors following completion of the 6 month and 1 year reviews.

Publication of findings

The investigators will be entitled to publish the findings of the evaluation; the data may also be presented as an abstract or oral presentation at an appropriate Dental Research meeting.

The investigators will be entitled to publish the findings of the evaluation; the data may also be presented as an abstract or oral presentation at an appropriate Dental Research meeting. Any manuscript, abstract or other communication prepared for submission or public presentation should be submitted to the sponsors for comment as stated in the contract. The data will also be communicated internally in 3M ESPE to appropriate members of the Business Team and Professional Services, Marketing, Regulatory and R & D personnel by Vickie Kolb or her designee.

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: **"Clinical Evaluation of Three Dental Adhesives**

in Class V Restorations"

PROTOCOL NO: CR-07-009

SPONSOR: **3M ESPE**

INVESTIGATOR: Dr. John O. Burgess

SITE: UAB School of Dentistry

STUDY RELATED PHONE NUMBER(S): 205-996-5795

SUMMARY

You are being asked to volunteer as a participant in a research study. This written material is designed to provide you with the information about this study and to answer any related questions or concerns you might have. If you decide to be in this study then change your mind, you can leave the study at any time. You will be in this study for about 1 year and have 4 study visits. The consent form may contain words or language you do not understand. Please ask the study doctor or the study staff to explain any words or information you do not clearly understand.

PURPOSE OF THE STUDY The purpose of this study is to evaluate the efficacy and the clinical success of adhesives used to bond tooth colored fillings placed in notched out areas on the sides of your teeth. This study will compare three adhesives used to hold white tooth colored filling materials on teeth.

DESCRIPTION OF THE STUDY AND PROCEDURES This study will recruit 45 patients to place 135 dental restorations using signs posted in the dental school and from newspaper advertisements. To be eligible for the study you must need a filling on the sides of three teeth. This study will place a filling on the side of your tooth next to the gum of your tooth. We will measure the biting force you can make on your teeth using a small piece of plastic which slips between your teeth.

You will be instructed to bite on this material and after making several jaw movements the plastic will be removed. The fillings will be placed like other fillings you may have had. You will be given a shot in the mouth to numb the teeth. The teeth to be filled will be isolated with a square piece of rubber, which slips around the tooth and is clamped to the tooth to prevent saliva from contacting the filling. Some drilling with a high-speed drill will be necessary to remove the decay and prepare the tooth. Then the tooth colored filling material will be placed into the cavity. The filling will then be polished. These filling appointments will last about two hours and normally one appointment will complete the fillings. Sometimes a second appointment may be necessary if the fillings are very large. You will be asked to return for an evaluation of these fillings one week after placement at 6 months and 1 year. These recall appointments will last about 30 minutes and include making an impression (or mold) of your teeth, completing a data sheet, testing the filled teeth with an ice stick to see if restoration is sensitive and taking photographs and x-rays of the fillings.

RISKS AND DISCOMFORTS

You may have discomfort from these dental procedures since some drilling will be done, but the discomfort should not be greater than you would have with any filling. There is also a possibility that you may be allergic to a local anesthetic (the solution used in the numbing shot) given to you. Although a true allergy is very rare it is possible.

NEW FINDINGS

You will be told about any new information that might change your decision to be in this study.

BENEFITS

The new composite filling material is bonded in three ways. Two of these adhesives are new and use fewer steps than the older but very successful adhesive. The manufacturer wants to know if one of these adhesives materials provides a better more long lasting filling. It may be that they are the same. While these fillings will be placed into teeth needing a filling, there are no guarantees that any subject will benefit from these procedures.

COSTS There will be no costs for the fillings placed in this study.

PAYMENT FOR PARTICIPATION

You will receive a dental exam and three dental fillings for participating in this study. In addition you will receive 30 dollars at each recall examination (6 and 12 months) for partial reimbursement of traveling and parking expenses. If you are injured as a result of being in the study, medical care will be provided. You will be responsible for all charges and we will not be able to give you money if you are injured.

ALTERNATIVE TREATMENT

If you do not wish to take part in this study, you may seek treatment of defective teeth at your own cost through a private office or you can elect not to have your teeth filled. If you elect not to have your teeth filled, the lesion may get worse with time.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you. If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health including:

- Past and present medical records
- Records about your study visits

Information about your health may be used and given to others by the study doctor and staff. The dental records related to this study are also available to the sponsoring agency (3M ESPE), the Food and Drug Administration, and the IRB.

Information about you and your health, which might identify you, may be given to:

- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- The University of Alabama at Birmingham - The physicians, nurses and staff working on the research protocol (whether at UAB or elsewhere); other operating units of UAB, the UAB IRB and its staff.
- The Western Institutional Review Board® (WIRB®)
- The billing offices of UAB and UAB Health Systems affiliates

Why will this information be used and/or given to others?

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. The will follow how the study is done, and they will be reviewing your information for this purpose.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

The information may be reviewed by WIRB®. The WIRB is a group of people who perform independent review of research as required by regulations.

Information may be shared with the UAB or UAB Health System affiliates billing services. This would be done so that the sponsor or your insurance can be appropriately billed for certain study activities.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review of copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

COMPENSATION FOR INJURY
If you are injured as a result of a research procedure used in this study you will be treated. In the event of such injury, treatment is provided, but is not provided free of charge. You or your medical insurance will be billed for the cost of such treatment.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Participation is voluntary. Subjects may choose not to participate or may discontinue participation at any time without penalty or loss of benefits and without affecting your future medical care at this facility. The study doctor or the sponsor may, without your consent, terminate your participation in this study at

any time. If significant new findings develop during the course of the research which may relate to the subject's willingness to continue participation that information will be provided to the subject.

SOURCE OF FUNDING FOR THE STUDY

The study doctor (investigator) is being paid by 3M ESPE to conduct this research.

QUESTIONS

If you have any questions about this study or your participation in it, or if at any time you feel you have experienced a research-related injury contact *Dr. John O. Burgess* at *205-996-5795 or e mail at JBurgess@UAB.edu. Or you can contact Dr. Muna Anabtawi at 996-6639 or e mail munaanab@uab.edu*

If you have questions about your rights as a research subject, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789.

or

Ms. Sheila Moore, Director of the Office of the UAB Institutional Review Board for Human Use (IRB). Ms. Moore may be reached at (205) 934-3789 or 1-800-822-8816, press the option for operator/attendant and ask for extension 4-3789 between the hours of 8:00 a.m. and 5:00 p.m. CT, Monday through Friday.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT

I have read the information in this consent form (or it has been read to me). All my questions about the study and my participation in it have been answered. I freely consent to participate in this research study.

I understand that by signing this form I am agreeing to participate in this dental fillings study and the required follow up visits at 6 months and 12 months after the first (baseline) appointment.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form I have not waived any of the legal rights that I otherwise would have as a subject in a research study.

_____
Subject Name

CONSENT SIGNATURE:

Signature of Subject	Date
Signature of Legally Authorized Representative (when applicable)	*Date*
Authority of Subject's Legally Authorized Representative or Relationship to Subject (when applicable)	
Signature of Person Conducting Informed Consent Discussion	Date
Witness	Date

----------Use the following only if applicable ----------

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to participate in the research study.

Signature of Impartial Witness	***Date***

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.