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THESIS APPROVAL PAGE FOR MASTER OF SCIENCE IN ORAL BIOLOGY

Title of Thesis: Intra-Examiner Reproducibility of Measuring Gingival Recession Using Three Techniques

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INTRA-EXAMINER REPRODUCIBILITY OF MEASURING GINGIVAL RECESSION USING THREE TECHNIQUES

by

Laura E. Kaye
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A thesis submitted to the Faculty of the
Periodontics Graduate Program
Naval Postgraduate Dental School
Uniformed Services University of the Health Sciences
In partial fulfillment of the requirements for the degree of
Master of Science
in Oral Biology
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ABSTRACT

Intra-Examiner Reproducibility Of Measuring Gingival Recession Using Three Techniques

Laura E. Kaye, DMD, 2022

Thesis directed by: Dr. Glen M. Imamura
Professor (ret), Research Department
Naval Postgraduate Dental School

Introduction: Gingival recession (GR) is typically measured using a periodontal probe (PP), but the measurements obtained with this device have inherent potential for variability. Using Castroviejo calipers (CC) or digital scanning software (DS) to measure GR may increase the preciseness and reproducibility of those measurements. **Purpose:** The primary goal of this study is to assess intra-examiner reproducibility of GR with the PP, CC, and DS. A secondary aim is to evaluate the practicality of DS as compared to manual alternatives. **Methods:** GR defects were measured by three different calibrated examiners using PP, CC, and DS. A subset of patients returned for a second appointment to have the same defects re-measured with each device. The intra-examiner reproducibility of each device was statistically evaluated using intraclass correlation with a 95% confidence interval. **Results:** To date, 8 patients with 44 sites of GR have been enrolled. 4 of those patients with 30 sites of GR returned for secondary assessment to determine intra-examiner reproducibility of each device. DS demonstrated an intra-examiner ICC of 0.98, which was higher than that of PP (0.88) and CC (0.88).

Conclusion: While clinically acceptable intra-examiner reproducibility may be obtained with any of the three devices studied, the digital scanner offers better reproducibility compared to the UNC-15 or calipers.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATONS

GR – Gingival Recession

PP– Periodontal Probe

CC– Castroviejo Calipers

DS– Digital Scanner

KT – Keratinized Tissue

FGM – Free Gingival Margin

CEJ – Cementoenamel Junction

ICC – Intraclass Correlation Coefficient

NPDS – Naval Postgraduate Dental School

STL – Stereolithography

CHAPTER 1: Introduction

The periodontium is comprised of hard and soft tissues that provide support to the teeth, including the gingiva, periodontal ligament, root cementum, and alveolar bone.[1] In health, the gingiva covers the alveolar bone and tooth root to a level just coronal to the cementoenamel junction (CEJ) of the tooth. However, in the case of gingival recession, the free gingival margin (FGM) shifts apically with respect to the CEJ. Gingival recession (GR) is associated with periodontal attachment loss and subsequent exposure of the root surface[2]. The precise etiology of recession is unknown; however, many risk factors have been found to be associated with this condition. Certain patient anatomic factors, such as a thin periodontal biotype, absence of attached gingiva at a given site, and reduced thickness of the alveolar bone have all been implicated in the etiology of recession[3]. Mechanical trauma to the gingiva due to toothbrushing habits, subgingival restorative margins in the presence of a thin periodontal biotype, and orthodontic treatment have also been found to increase the likelihood of GR.[3] With regards to recession following orthodontic treatment, risk of development may be related to thickness and width of keratinized tissue (KT) at a given site at the start of therapy.[3]

GR is a highly prevalent mucogingival deformity. A recent study found that 50 percent of people aged 18 to 64 possessed at least one site of GR; in populations 65 years of age or older, the prevalence increased to 88 percent.[4] GR is present in a variety of cohorts and prevalence generally increases with age.[5] The presence of GR may present as a clinical problem for a multitude of reasons. Patients may have esthetic concerns or experience root sensitivity because of GR. A recent systematic review found that sites with untreated recession are likely to worsen over time, regardless of the patient's oral

hygiene. Additionally, sites with no KT appear to be more susceptible to the development of further recession.[7]

Many periodontal soft tissue procedures have been developed to treat GR due to its clinical significance. The goal of treatment is to achieve complete root coverage and ultimately, gain attachment of the grafted tissue to the root surface.[8] Proper treatment planning and assessment of treatment outcomes relies on the ability to accurately measure the dimensions of the recession defect. GR should be measured as the distance from the CEJ to the FGM and is typically assessed using a periodontal probe (PP) with millimeter markings (Figure 1).[9]

Obtaining accurate, reproducible measurements of GR at a given site may be challenging for several reasons. Anatomic features such as dental abrasion, acid erosion, or cervical caries may obscure the CEJ, limiting its use as a reference point.[10] Additionally, measurements taken with a PP may only have precision to the nearest 0.5 to 1mm increment.[9] A previous report revealed that 90 percent of probe measurements are reproducible within 1mm, while 10 percent fall outside of this range.[11] To account for these limitations, devices such as calipers and digital scanners have been suggested for measuring GR with greater accuracy.[12] Castroviejo calipers (CC), which are of a movable-scale design, have been found to allow for measurements to the nearest 0.5mm.[13] A digital scanner (DS) can be used to capture optical impressions that allow for indirect measurements to the nearest hundredth of a millimeter.[14] Clinical utility of a given measuring device depends on a variety of factors, including ease of use for the practitioner and patient, preciseness, accuracy, and reproducibility of the measurements

obtained. Therefore, the purpose of this study was to determine the intra-examiner reproducibility of GR measurements using a PP, CC, and a DS.

CHAPTER 2: Materials and Methods

This study is the second part of a two-part comparative study of the reproducibility of recession defect measurements obtained with three different measuring devices (PP, CC, and DS). In the first part of the study, the inter-examiner reproducibility was assessed, while in this study, the intra-examiner reproducibility was assessed. This study was approved by the Walter Reed National Military Medical Center's Institutional Review Board.

Subject Population:

All eligible beneficiaries ages 18 or older evaluated at the Naval Postgraduate Dental School (NPDS) Periodontics Clinic and diagnosed with at least one gingival recession defect were eligible for enrollment in this study. To date, eight subjects have been consented and enrolled for the first part of the study. To conduct the second part of the study, a subset of four subjects returned for a second assessment. To date, a total of 44 sites have been measured to assess inter-examiner reproducibility, and a total subset of 30 sites were re-measured to assess intra-examiner reproducibility. The minimum number of sites established for each study objective (64 sites for the first objective and 30 sites for the second objective) were determined to estimate an inter-rater intraclass correlation coefficient (ICC) of 0.90 with a desired confidence interval width of 0.08 (+/- 0.04) and an intra-rater ICC of 0.90 with a desired confidence interval width of 0.14 (+/- 0.07). These estimates were derived from a recent study demonstrating high levels of inter-examiner agreement previously reported for related measurement methods.[12]

Study Procedures:

1. Initial phase:
    a. Subjects were referred to NPDS Periodontics for periodontal treatment.
    b. During the screening exam, subjects were provided a study brief by the staff member conducting the exam.
    c. Subjects were a given periodontal evaluation to determine if they met the criteria for the study. Those patients meeting study criteria were invited to participate in the study. The option to receive treatment at NPDS Periodontics without being part of the study was presented.
2. Data collection phase:
    a. If the patient agreed to be part of the study, consent and data collection was performed at the comprehensive periodontal evaluation appointment.
    b. Full written disclosure of the study protocol was presented to the subject by a Study Investigator. Consent and HIPAA forms were completed and signed (Appendix A).
    c. Once consent was obtained, the subjects were assigned a subject identifier, which was then populated into a Master List by a Study Investigator (Appendix B). Once the subject was enrolled, sites of GR that met eligibility criteria (single-rooted teeth with a clinically detectable CEJ) were selected for measurement by a Study Investigator. All measurements of the gingiva were performed by each

of three calibrated periodontists and entered onto a Data Collection sheet by a Study Investigator. The number of the tooth in the oral cavity with recession was recorded. Two direct clinical measurements of a subject's gingival recession were obtained parallel to the vertical long-axis of the tooth from the gingival margin to the CEJ (starting at the most apical portion of the defect), first using a UNC-15 probe (Figure 2), and then Castroviejo calipers (Figure 3). A CEREC Primescan was then used to take an intraoral optical impression following the manufacturer's guidelines. The optical impression included one tooth on either side of the tooth/teeth with recession. The acquisition was done in four consecutive sequences starting on the occlusal surface and moving to the buccal, lingual, and proximal surfaces. The scanner was moved in a distal direction and rotated 20 degrees toward the buccal or lingual direction. The optical impression was exported as a stereolithography (STL) file and converted to an image using Oracheck Dentstply digital software. Digital measurements were recorded from the image of the recession using the software's measurement tool (Figure 4).

d. Every other subject enrolled in the study was required to make a second appointment to have the above measurements repeated within 5 weeks of the first appointment, but before the initiation of any treatment in order to collect data for the second part of the study.

Statistical Analysis

Descriptive statistics (e.g., mean and standard deviations) were reported for gingival recession measurements for each combination of examiner and measurement method among the full cohort at the initial visit. Inter-examiner agreement among the three raters was estimated for each measurement method at the initial visit using a two-way ICC with observations from single rather than average ratings, and the ICC was evaluated as a measure of absolute agreement between examiners.[12] This analysis was repeated to evaluate intra-examiner agreement for each measurement method at initial versus follow-up visits. Agreement estimates were reported as the model-estimated ICC and its 95% confidence interval among the full cohort.

CHAPTER 3: Results

Table 1 shows the descriptive statistics for all measurement methods at the initial and follow-up visits for each examiner. Table 2 shows the intra-examiner ICC for each examiner for each measurement method. DS demonstrated the highest ICC (0.98 for each examiner) out of the three measuring devices. Table 3 shows the overall intra-examiner ICC for each measurement method, irrespective of examiner. The overall ICC for PP, DS, and CC were 0.88, 0.98, and 0.88, respectively.

CHAPTER 4: Discussion

In this study, the intra-examiner reproducibility of three different measuring devices was determined for three different examiners, as well as overall. DS demonstrated the highest intra-examiner reproducibility with an ICC of 0.98 for each examiner and an overall ICC of 0.98. These findings agree with previous studies that assessed similar outcomes.[15] In terms of interpreting the calculated ICC values, guidelines established by Koo and Li in 2016 were followed (Appendix C).[16] According to these guidelines, an ICC value less than 0.5 indicates poor reliability, a value of 0.5 to 0.75 has moderate reliability, a value less than 0.75 to 0.9 has good reliability, and a value greater than 0.9 has excellent reliability. Thus, the ICCs established by each examiner for each measuring device indicate that all devices demonstrated reliability that was good, if not excellent (Table 4). When assessing the intra-examiner ICCs calculated per examiner per instrument, all three examiners demonstrated excellent reliability with DS. Examiners 2 and 3 also demonstrated excellent reliability with PP; however, Examiner 1 demonstrated only good reliability with this device. Examiner 3 was the only examiner to demonstrate excellent reliability with all three devices. In terms of the overall ICC for each device, DS demonstrated excellent reliability, while PP and CC demonstrated good reliability (Table 5).

The results obtained in this study may be explained by several factors. First, obtaining direct intraoral measurements of a given site, regardless of device, may be challenging in terms of establishing site access. This factor is especially true of CC, a much bulkier device than PP. Furthermore, replicating the precise positioning and

angulation of a measuring device on a given tooth surface at two different time intervals may be difficult. Measuring a given site indirectly with DS bypasses potential access issues. Additionally, the examiner can magnify a given defect with the DS software, offering improved visibility over a direct measurement scenario. The precision of the measurements obtained by each device also likely impacts reproducibility. For instance, the smallest increment that can be measured with PP is 1mm, although estimations may be made up to 0.5mm. CC can measure up to 0.5mm increments, and DS can measure up to 0.01mm increments. In and of itself, measurement preciseness may not always impact reproducibility. However, for sites wherein the true value lies somewhere in between the smallest increment a device can measure, the impact of measurement preciseness is more appreciable. For example, if the true dimension of a given GR defect was 1.27mm, this value would fall in between the smallest increment that can be measured with PP or CC. Thus, it is possible that an individual may measure that defect to be 1mm at a given timepoint and 1.5mm at a different timepoint with either of these devices. When measuring with the DS, it is less likely that a discrepancy of this magnitude would occur between repeat measurements.

While DS demonstrated the highest intra-examiner ICC and was the only device to achieve excellent reliability overall, PP and CC also achieved high, clinically acceptable ICCs and good overall reliability. It is important to consider pros and cons of each device when establishing clinical relevance and practicality of these findings. For instance, PP is relatively inexpensive compared to DS, regularly implemented in dental and periodontal practices, and easy to use. CC is also relatively inexpensive compared to DS, but not as commonly implemented as PP. As previously mentioned, its bulky design

makes it less ideal for intraoral use than PP. DS offers certain benefits over PP and CC in terms of its precision, but it is also more expensive and requires an additional step in scanning the patient prior to measuring. Obtaining the scan may present its own challenges in terms of access and moisture control. Therefore, superior intra-examiner reliability may not alone justify DS use over alternative intraoral methods for measuring GR.

Several limitations exist in this study. Firstly, while the minimum sample size was evaluated, the size was still relatively small. A larger sample size would provide more reliable results. Additionally, while the examiners evaluated in this study were highly calibrated, increasing the number of examiners would also increase reliability of the results.

Chapter 5: Conclusion

Obtaining reliable, reproducible measurements of GR defects is important for proper diagnosis and treatment. Within the limitations of this study, all three of the measuring devices demonstrated clinically acceptable intra-examiner reproducibility, although the DS showed superior reproducibility compared to the PP and CC. Measuring GR indirectly with digital scanning technology may offer preferred clinical utility in certain scenarios, such as when the practitioner wishes to track changes in a patient's GR over time. Additionally, the precision that can be obtained with digital scanning protocol may render it a more desirable measurement tool for clinical research. Of note, this study did not seek to answer the question of which of these three devices best obtains the true value of a given GR defect measurement.

Table 1. Descriptive Characteristics of all Methods at Initial and Follow-up Measurement Visits

Measurement Method	Summary	EXAMINER			Test
		1	2	3	
UNC-15 (mm)	Min / Max	0.5 / 6.0	0.5 / 6.0	0.5 / 6.0	p value: 0.4339 (Kruskal-Wallis rank sum test)
	Med [IQR]	2.0 [1.0;3.0]	2.0 [1.5;3.0]	2.0 [1.4;2.5]	
	Mean (std)	2.1 (1.1)	2.3 (1.2)	2.1 (1.2)	
	N (NA)	44 (0)	44 (0)	44 (0)	
DIGITAL (mm)	Min / Max	0.3 / 5.4	0.5 / 5.6	0.4 / 5.6	p value: 0.1777 (Kruskal-Wallis rank sum test)
	Med [IQR]	1.6 [0.9;2.1]	1.9 [1.3;2.4]	1.8 [1.1;2.2]	
	Mean (std)	1.8 (1.2)	2.1 (1.1)	1.8 (1.1)	
	N (NA)	44 (0)	44 (0)	44 (0)	
CALIPER (mm)	Min / Max	0.5 / 6.0	0.5 / 5.0	0.5 / 5.5	p value: 0.1098 (Kruskal-Wallis rank sum test)
	Med [IQR]	1.5 [1.0;2.5]	2.0 [1.5;2.5]	1.8 [1.0;2.0]	
	Mean (std)	1.8 (1.0)	2.1 (0.9)	1.9 (1.0)	
	N (NA)	44 (0)	44 (0)	44 (0)	

Table 2. ICCs between Gingival Recession Measurements Comparing Initial and Follow-up Visits for Each Examiner

Examiner	Method	ICC	95% CI
1	UNC-15 (mm)	0.77	0.563, 0.888
	DIGITAL (mm)	0.98	0.955, 0.99
	CALIPER (mm)	0.87	0.652, 0.944
2	UNC-15 (mm)	0.93	0.854, 0.964
	DIGITAL (mm)	0.98	0.967, 0.992
	CALIPER (mm)	0.88	0.707, 0.944
3	UNC-15 (mm)	0.94	0.875, 0.97
	DIGITAL (mm)	0.98	0.95, 0.988
	CALIPER (mm)	0.92	0.826, 0.966

Table 3. Overall ICCs between Gingival Recession Measurements Comparing Initial and Follow-up Visits

Method	ICC	95% CI
UNC-15 (mm)	0.88	0.818, 0.917
DIGITAL (mm)	0.98	0.969, 0.986
CALIPER (mm)	0.88	0.766, 0.939

Table 4. Interpretation of ICC Reliability per Examiner per Instrument

Examiner	Method	Reliability
1	UNC-15 (mm)	Good
	DIGITAL (mm)	Excellent
	CALIPER (mm)	Good
2	UNC-15 (mm)	Excellent
	DIGITAL (mm)	Excellent
	CALIPER (mm)	Good
3	UNC-15 (mm)	Excellent
	DIGITAL (mm)	Excellent
	CALIPER (mm)	Excellent

Table 5. Overall Interpretation of ICC Reliability per Instrument

Method	Reliability
UNC-15 (mm)	Good
DIGITAL (mm)	Excellent
CALIPER (mm)	Good

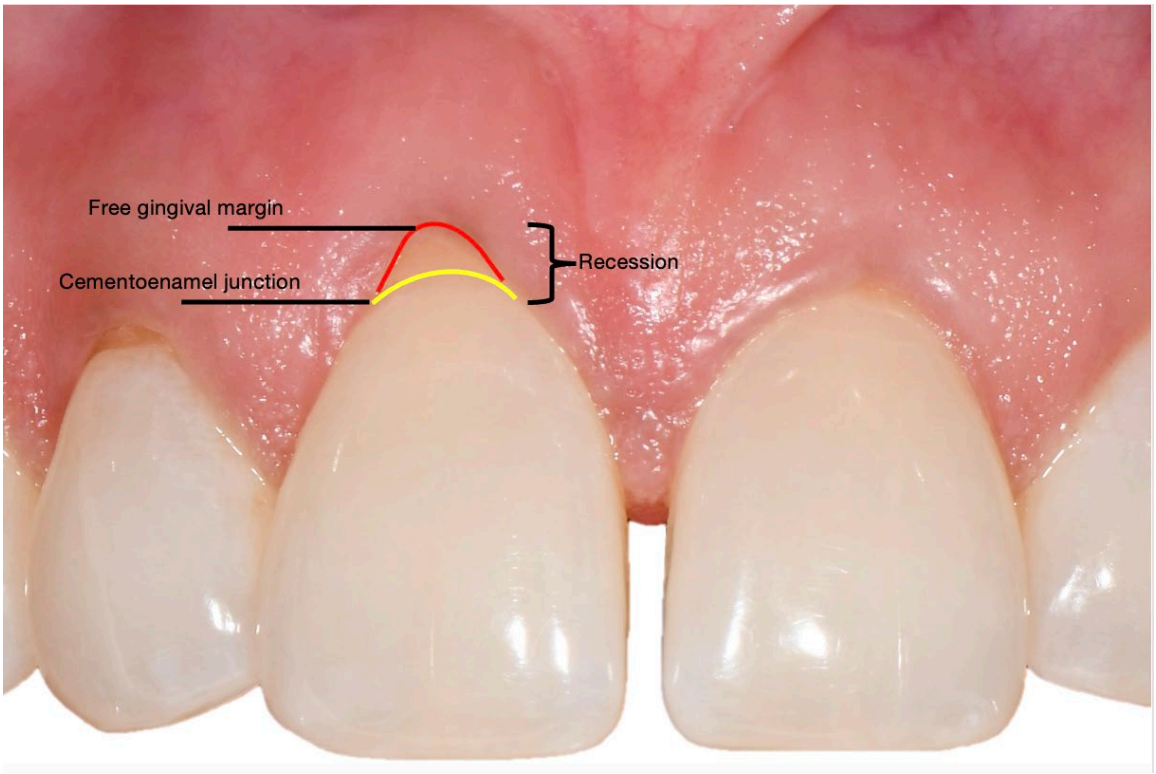

Figure 1. Gingival Recession Measurement Landmarks. GR is measured as the distance from the CEJ to the FGM.

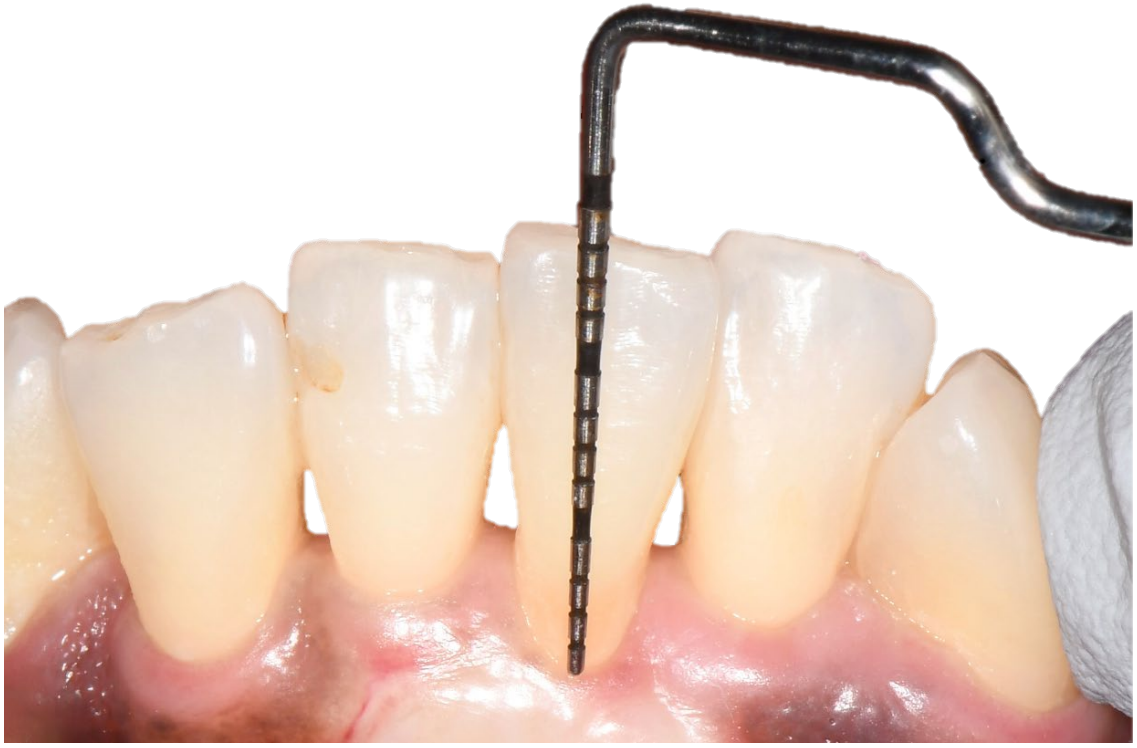

Figure 2. Measuring Gingival Recession Using a UNC-15 Periodontal Probe. A direct clinical measurement of a subject's gingival recession was obtained parallel to the vertical long-axis of the tooth from the gingival margin to the CEJ (starting at the most apical portion of the defect) using a UNC-15 probe.

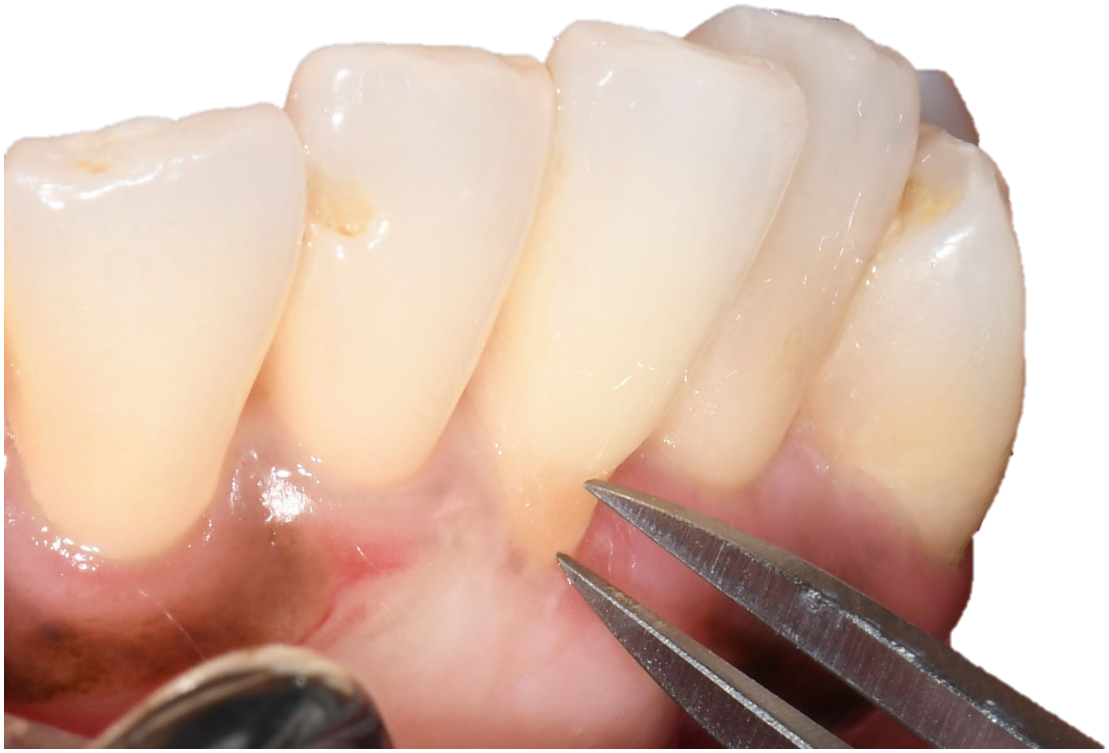

Figure 3. Measuring Gingival Recession Using Castroviejo Calipers. A direct clinical measurement of a subject's gingival recession was obtained parallel to the vertical long-axis of the tooth from the gingival margin to the CEJ (starting at the most apical portion of the defect) using Castroviejo calipers.

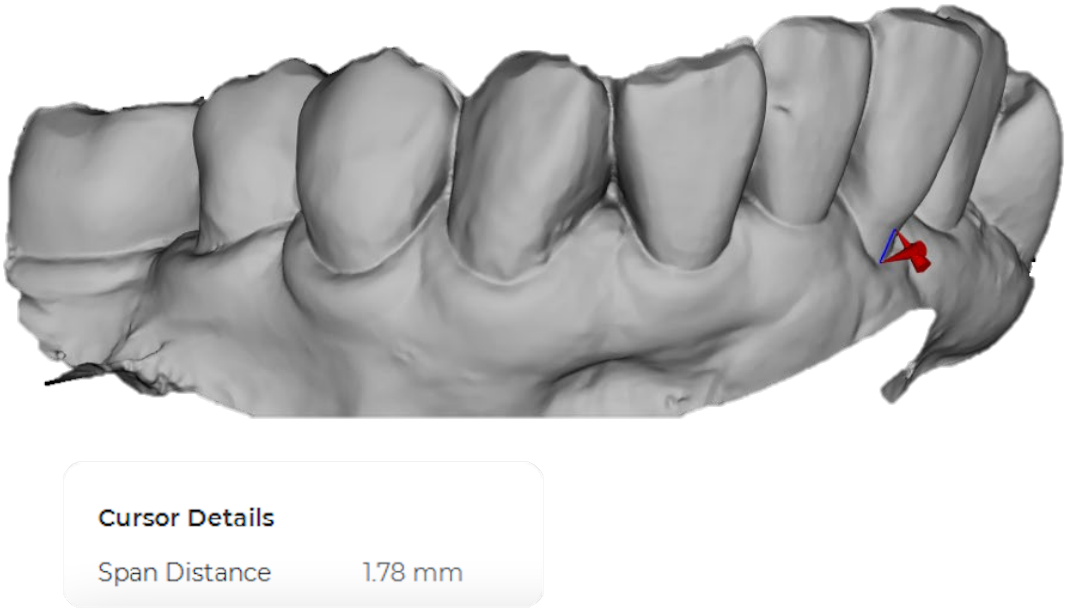

Figure 4. Measuring Gingival Recession Using Oracheck Dentsply Digital Software. The optical impression obtained from each patient was exported as a stereolithography (STL) file and converted to an image using Oracheck Dentstply digital software. Digital measurements were recorded from the image of the recession using the software's measurement tool.

APPENDIX A: Subject Consent

Walter Reed National Military Medical Center
CONSENT TO PARTICIPATE IN RESEARCH
Title: Inter- and Intra-Examiner Reproducibility of Measuring Gingival Recession Using Three Techniques
Principal Investigator: LT Bethany Brooks, DMD, MPH

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to carefully review this information. You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

1. KEY INFORMATION:

You are presenting to the Periodontal Clinic for an examination of your teeth, gums and the tissues surrounding and supporting these structures. Evaluating gingival or gum recession (receding gums) is part of the standard or care, and one of the items being evaluated by your provider. Your recession is evaluated by measuring the height of the gum to a fixed point on the associated tooth. If you do have gum recession, you will be asked to participate in this research study comparing the accuracy of three techniques used to measure gum recession as well as comparing the accuracy of the examiners taking the measurements. If selected, your participation will be needed for up to two appointments. Once your participation is completed you will continue your periodontal treatment. This study will not interfere with any treatment plans provided from your regular dental provider and may be completed at the same time as your regularly scheduled periodontal treatment visit. The potential benefit of this study is to help improve dental instrumentation and processes for measuring gum recession. There are no inherent risks to having the amount of your gingival recession measured.

Your consent is being sought and your participation is voluntary. Your decision will not affect your present, or future, care at Walter Reed National Military Medical Center. If you decide to take part, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you have gum recession. The purpose of this research study is to measure your gum recession using three different measuring instruments. From the measurements obtained, the reproducibility of each instrument will be assessed.

There will be about 30 subjects taking part in the study at Walter Reed National Military Medical Center, Naval Postgraduate Dental School, over a period of 1 year. All participants will be required to have measurements taken using 3 non-invasive diagnostic tools. This will take about 1 hour. Every other participant enrolled will need to make a second appointment and have the measurements repeated, within 5 weeks or less, of the first appointment. This will take about ¾ of an hour. Depending on which group you are assigned the time required to participate will be 1 appointment for about 1 hour or 2 appointments for about 1¾ hours total.

At the end of this research study the clinical results, including research results about you will not be shared with you.

3. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

Once you have been consented to participate in the study, you will have a series of non-invasive measurements taken within your mouth on teeth exhibiting gum recession. Documenting your gum recession is part of the standard of care. These measurements will be taken parallel to the long-axis of the tooth from the gum margin to a natural line on your tooth called the CEJ starting at the most apical (bottom) portion of the defect. Recession will be measured intraorally using 3 instruments approved for clinical use: a UNC-15 periodontal probe (similar to a ruler), Castroviejo calipers (similar to a drawing compass), and intraoral optical impressions (taking an oral image using a CEREC Primescan). For one-half of subjects, your participation in the study will be completed.

The remaining subjects will have been assigned to a group that will be asked to return to the clinic and have the measurements repeated. At the end of this appointment these subjects will have completed their study participation.

4. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

There are no inherent risks to measuring your gingival recession using the 3 methods used in this study. Every effort will be made to protect your research study records. However, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.

5. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

There are no direct benefits to you for taking part in the study. However, others may benefit in the future from the information learned during this study. The possible benefits to others are

opportunities to improve diagnostic instruments and criteria allowing for more accurate treatment protocols.

6. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

You are not disqualified from receiving periodontal treatment if you decided not to participate in this study. Routine treatment will not be denied if you decide not to participate. Choosing not to take part in this research study is also an option.

7. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

You will not receive any compensation for participating in this study.

8. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

There are no costs to you for taking part in this research study.

9. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):
Bethany Brooks, DMD, MPH
LT, DC, USN
Phone: 301 295-1364

10. SOURCE OF FUNDING:

This study has received no external funding.

11. LOCATION OF THE RESEARCH:

Naval Postgraduate Dental School – Periodontics Clinic

12. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

There are no financial interests or personal arrangements that financially support the research team members or their immediate family members in this study.

13. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at:
https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf

The research team will keep your research records. These records may be looked at by staff from the WRNMMC, the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to:

Minimizing the recording of any personal identifying information such as your name, DoD identification number and contact information. You date will be coded, hard copies of your information will be kept in locked cabinets in secure rooms of the study investigators, and on US Government, password protected computers. Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

Authorized members of the research team will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will de-identified.

AUTHORIZATION TO USE OR DISCLOSE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

I. Purpose of this Document
An Authorization is your signed permission to use or disclose your health information. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, as implemented by the Department of Defense (DoD), permits the Military Health System (MHS) to use or disclose your health information with a valid Authorization. The MHS is defined as all DoD health plans and DoD health care providers that are organized under the management authority of, or in the case of covered individual providers, assigned to or employed by, the Defense Health Agency (DHA), the Army, the Navy, or the Air Force. A valid Authorization must include the core elements and required statements as contained in this document.

Please read the information below and ask questions about anything you do not understand before deciding to give permission for the use and disclosure of your health information.

II. Authorization
The following describes the purposes of the requested use and disclosure of your health information:

The purpose of this study is to compare the accuracy of three instruments used to measure gingival or gum recession as well as compare the accuracy of the examiners taking the measurements. The study investigators are asking permission to review your health information to make sure you have no medical conditions that will prevent your participation in this study.

A. What health information will be used or disclosed about you?

Your medical history will not be used for the study or disclosed, it will only be reviewed by the study investigators. The only personal information collected will be your name, DoD ID#, phone # and e-mail address.

B. Who will be authorized to use or disclose (release) your health information?

Investigators from the Periodontics Dept. at the Naval Postgraduate Dental School will have access to your health information.

C. Who may receive your health information?

The principal study investigator, LT Bethany Brooks, DC, USN and associate study investigator, LT Laura Kaye, DC, USN, will access to your health information. The WRNMMC IRB or Data Safety and Monitoring Boards may also have access to your health information.

D. What if you decide not to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you will not be able to participate in the research study.

The MHS **will not** condition (withhold or refuse) treatment that is not part of this study, payment, enrollment, or eligibility for benefits on whether you sign this Authorization.

E. Is your health information requested for future research studies?

No, your health information *is not* requested for future research studies.

F. Can you access your health information during the study?

You may have access to your health information at any time, unless your identifiers are permanently removed from the data.

G. Can you revoke this Authorization?

• You may change your mind and revoke (take back) your Authorization at any time. However, if you revoke this Authorization, any person listed above may still use or disclose any already obtained health information as necessary to maintain the integrity or reliability of this research.

• If you revoke this Authorization, you may no longer be allowed to participate in this research study.

• If you want to revoke your Authorization, you must write to:

LT Bethany Brooks
Naval Postgraduate Dental School
Periodontics Department
8955 Wood Road
Bethesda, MD 20889

H. Does this Authorization expire?

No, it does not expire.

I. What else may you want to consider?

• No publication or public presentation about the research described above will reveal your identity without another signed Authorization from you.

• If all information that does or can identify you is removed from your health information, the remaining de-identified information will no longer be subject to this Authorization and may be used or disclosed for other purposes.

• In the event your health information is disclosed to an organization that is not covered by HIPAA, the privacy of your health information cannot be guaranteed.

J. Who should you contact if you have any complaints?

• If you believe your privacy rights have been violated, you may file a written complaint with the WRNMMC Privacy Officer, located at 8901 Wisconsin Ave, Bethesda, MD 20889, Telephone: 301-319-4775

K. Can your protected health information be disclosed to parties not included in this Authorization who are not under the HIPAA requirements?

• There is a potential that your research information will be shared with another party not listed in this Authorization in order to meet legal or regulatory requirements. Examples of persons who may access your protected health information include representatives of the DoD Higher Level Review, the Food and Drug Administration, the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP), and the DHHS Office for Civil Rights. This disclosure is unlikely to occur, but in that case, your health information would no longer be protected by the HIPAA Privacy Rule.

CONTACTS FOR QUESTIONS ABOUT THE STUDY:

• If you have questions about the study, or if you think you have a study-related injury you should contact LT Bethany Brooks at 301 295-1364.

• For questions about your rights as a research subject, contact the Human Protections Administrator, WRNMMC Department of Research Programs in Building 17B at 301-295-8239 or WRNMMC Staff Judge Advocate Office at 301-295-2215.

14. LONG TERM USE OF DATA

The information and data collected for this study will not be used in any future study.

15. INCIDENTAL FINDINGS

There is a possibility that while reviewing your test results we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding."

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away.

We will also give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious
- Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. If you are a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

16. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

You will be informed if significant new findings develop during the course of this research study

17. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must contact the study's principal investigator in writing stating your intent to withdraw. If you decide to no longer participate in this research study, the researcher may use your data that has already been collected.

If you are receiving treatment as part of this research study, you will no longer be eligible for such research-related treatment. Contact your personal physician to discuss medical treatment for your condition.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator of this research study may terminate your participation in this research study at any time if she determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

18. WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

If you think that you have a research-related injury, notify your Principal Investigator immediately using the contact information in the section below.

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active duty military, dependent of active duty military, retiree), you are authorized space-available medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary. This care includes, but is not limited to, free medical care at DoD hospitals or DoD clinics.

If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you are authorized space-available medical care for your injury at a DoD hospital or an DoD clinic; medical care charges for care at a DoD hospital or a DoD clinic will be waived for your research-related injury. If you obtain care for research-related injuries outside of a DoD or DoD hospital or clinic, you will not be reimbursed for those medical expenses.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: Transportation to and from hospitals or clinics will not be provided or paid for by DoD. Unless you are covered by TRICARE, no DoD reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights.

19. CONTACT INFORMATION:

Principal Investigator (PI)
The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: LT Bethany Brooks
Phone: (301) 319 - 1364

Mailing Address: Naval Postgraduate Dental School
Periodontics Department
8955 Wood Road
Bethesda, MD 20889

***Walter Reed National Military Medical Center* Human Research Protection Program (HRPP) Office**

The Human Research Protection Program Office Point of Contact and/or Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study.

WRNMMC Human Protection Program (HRPP) Office
Phone: 301 295-8239

Institutional Review Board (IRB) Office

If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Office at:

301 295-8239, 8901 Wisconsin Ave. Bldg. 17B, Floor 3, Suite C, Bethesda, MD 20889

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date

APPENDIX B: Data Collection Sheet

DATA COLLECTION SHEET

DATE	
SUBJECT ID	
EXAMINER ID	

Initial / Follow-up

(Circle One)

Measurements: CEJ to FGM	**Tooth #**	**Tooth #**	**Tooth #**	**Tooth #**	**Tooth #**	**Tooth #**
Periodontal Probe						
Calipers						
Intra-oral Scan						

APPENDIX C: Koo and Li Guidelines for Interpreting Reliability of Intra-Class Correlation Coefficients

Intra-Class Correlation Coefficient (ICC)	Reliability
<0.5	Poor
0.5-0.75	Fair
>0.75-0.9	Good
>0.9	Excellent

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