TEXAS A&M UNIVERSITY HUMAN RESEARCH PROTECTION PROGRAM

INFORMED CONSENT DOCUMENT

Title of Research Study: Comparison of Gingival Flap Procedure Using Conventional Surgical Loupes vs. Videoscope for Visualization. A Pilot Study.

Investigator: Carlos Parra, Mirali Pandya and Yael Breziner

Funded/Supported By: This research is supported by the Department of Periodontics at Texas A&M University College of Dentistry. Dr. Harrel (study consultant) owns the patent for the Microsight videoscope that will be used in this study.

Why are you being invited to take part in a research study?

This study is being performed to compare different methods of visualization during routine gum surgery. The gum surgery is standard of care. This study will compare the use of a small camera in conjunction with magnification glasses during surgery vs. surgery only using magnification glasses. The small camera is a device which allows us to see the area under high magnification and projects live video feed on a computer screen.

What should you know about a research study?

- Someone will explain this research study to you and answer your questions.
- Whether or not you take part is up to you.
- You can choose not to take part and it will not affect your treatment.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research advisor:

Carlos Parra, DDS
3000 Gaston Avenue
Dallas TX 75246
(214) 828 – 8369
cparra@tamu.edu

This research has been reviewed and approved by the Texas A&M Institutional Review Board (IRB). You may talk to them at 1-979-458-4067, toll free at 1-855-795-8636, or by email at irb@tamu.edu., if

- You cannot reach the research team.

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Why is this research being done?

This study is being done to see if the use of a small camera in conjunction with loupes during surgery, as compared with the current routine approach of only using loupes, has better outcomes on gum surgery. The study will evaluate the effects of residual tartar left behind and determine if the small camera increases the success of surgery by better visualization.

If we find better surgical outcomes with the addition of the small camera, we could recommend using the small camera in addition to traditional loupes for all gum procedures.

How long will the research last?

We expect that you will be in this research study for the duration of the surgical procedure (2-4 hours), along with 1-2 hours at each of 3 follow-up appointments (3 months, 6 months, 1 year). See timeline below for more information. From the date you start the study to the end of the study will be approximately 1.5 years.

Surgery appointment	*Gum surgery (one side with loupes, one side with loupes & small camera), bacterial sample collected*
3 month follow-up appointment	*Routine dental cleaning (at no cost), gum measurements taken, bacterial sample collected*
6 month follow-up appointment	*Routine dental cleaning (at no cost), gum measurements taken, bacterial sample collected*
1 year follow-up appointment	*Routine dental cleaning (at no cost), gum measurements taken, bacterial sample collected*

*All dental cleanings are standard of care

How many people will be in the research?

We expect about 20 people to participate in this research at our site (Texas A&M School of Dentistry).

Inclusion Criteria:

This study will only include patients that have been diagnosed with the need for gum surgery before being considered for the study. In other words, the surgery portion of the study will be a routine procedure that was treatment planned prior to you being included in the study

and necessary for your periodontal condition. No surgery will be performed that is not necessary.

Other inclusion criteria include: age 18 years old or older, gum disease diagnosis, treatment planned prior to entering the study for 2 or more areas of gum surgery.

Exclusion Criteria:

The exclusion criteria include: diabetes, systemic disease affecting bone metabolism, previous or current bisphosphonate use, current smokers, recent joint replacement requiring prophylactic antibiotics (6 months), pregnant or lactating females. Teeth that need and will have bone reshaping will be excluded.

What happens if I say yes, I want to be in this research?

- Dental measurements around your gums will be made to assess the condition of your gums. This is routine and standard of care. We will review these measurements as part of this research.
- You will undergo gum surgery that is part of your standard of care. For this research study we will use two different techniques on your gums that are typically used at the School of Dentistry and not considered investigational. On one part of your mouth that requires surgery, called a quadrant, we will use a small camera in conjunction with magnification glasses. On the other quadrant we will only use the magnification glasses. We will compare these techniques as part of the research.
- Fluid from just underneath your gums will be collected using a paper strip placed just underneath your gums for bacterial sampling. The strip will be analyzed for bacteria. This is considered a research-only procedure since it is not routinely performed at the School of Dentistry. We will collect these samples 4 times during this study, initially at your surgical visit and again at your follow-up visits.
- You will attend follow-up visits as part of your standard of care. These visits will be at no cost to you or your insurance due to your participation in this research.
- Data will be taken from your dental records including x-rays, periodontal charting, photographs, and videos to analyze for research purposes.

What are my other options if I do not want to be in this research?

You do not have to be in this study. If you decide not to be in the research now or later, it won't be held against you. You can still receive comprehensive care at the Texas A&M University School of Dentistry.

What happens if I say yes, but I change my mind later?

You are free to leave the study at any time. There are no penalties and you do not lose any benefits to which you are otherwise entitled. Data that we have already used will stay in the study database and cannot be removed. This allows us to maintain the integrity of the research.

If you decide to leave the study, we may ask you if we can contact you for safety reasons or to follow your health. We may also ask you if we can collect data from your medical records and your routine medical care. You are under no obligation to grant us permission for this information.

What are the risks of being in this study?

The risk of being in this study is that your personal information (name, age, date of treatment) could be lost or exposed. This is very unlikely to happen, and we will do everything we can to make sure that your information is protected.

There are no risks associated with the fluid collection procedure that is for research-only purposes.

What are the costs of being in the research?

Costs that you may incur by participating in this study are travel to and parking at the clinic, as well as your time. You or your insurance will be responsible for routine care procedures that includes your dental consultation (ranging from $61-$96) and your surgery (ranging from $360 to $565).

You will not be billed for any procedures that are for research purposes only such as the bacterial sampling. If you are unsure of your financial responsibility, please discuss this with your insurance or your provider.

If you enroll in this study, you will receive at no cost to you or your insurance periodontal maintenance at your 3-month, 6 month, and 1-year follow-up visits at $98/per visit totaling $294.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research.

What happens to the information collected for the research?

Confidentiality will be maintained to the extent allowed by law. Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include the TAMU HRPP/IRB and other representatives of this organization.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

The sponsor, monitors, auditors, the TAMU HRPP, the US Office for the Protection of Human Research Protections (OHRP) and the Food and Drug Administration (FDA) may be granted direct access to your records to conduct and oversee the research. By signing this document you are authorizing this access.

Federal law provides additional protections of your health-related records and information. These are described in the HIPAA Authorization.

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

What else do I need to know?

If you become ill or get injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury. Texas A&M University has no program to pay for medical care for research-related injury. This does not keep you from seeking to be paid back for care required because of a bad outcome.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	