CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:
Treatment of localized gingival recession defects at lower mandibular incisors using a modified-free gingival graft: A Randomized Clinical Trial.

Institution responsible for this research project:
Department of Periodontology, Institute of Odontology, Sahlgrenska Academy, University of Gothenburg, Sweden.

Names, degrees, and affiliations of the principal investigator and study coordinator:

Principal Investigator: Olivier Carcuac, DDS, Specialist in Periodontics, PhD
Department of Periodontology, Institute of Odontology, Sahlgrenska Academy, University of Gothenburg, Sweden / ConfiDent ® Dental Surgery Clinic, Dubai, UAE

Study Coordinator: Olivier Carcuac, DDS, Specialist in Periodontics, PhD
Department of Periodontology, Institute of Odontology, Sahlgrenska Academy, University of Gothenburg, Sweden / ConfiDent ® Dental Surgery Clinic, Dubai, UAE

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies have different kinds of risks and risk levels, depending on the type of the study. You may need to think about other requirements for being in the study. This may require you to change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

Human Clinical Intervention Study

This research will help provide information on treating gum recession. Your health-related information will be collected for this research study.

Data collection

This research collects health-related information to better understand the wound healing following root coverage procedures. This research will evaluate the efficacy of a new modified surgical technique in the treatment of gum recessions.

Randomization
Sometimes because we do not know which way of treating patients is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer which has no information about the individual – i.e. by chance (like the flip of a coin). That is what is called randomization. Patients in each group then have a different treatment and these are compared. This means that whether you get or do not get the modified surgical technique in the study is not chosen by you or Dr Olivier Carcuac.
If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include not achieving the complete coverage of the recessions, prolonged bleeding following the surgery, and infection of the surgical area. More detailed information will be provided later in this document.

This study may offer some benefit to you now or others in the future by correcting the gum recessions and improving the quality and the thickness of your gum.

We expect the amount of time you will participate in the study will be 7 visits (30 minutes-2 hours each) over 1 year.

Even if you decide to join the study now, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive now or in the future.
More information about this study continues in Section 2 of this document.

Who has reviewed the study?
The research project, conducted by Dr Olivier Carcuac affiliated to the *Department of Periodontology, Institute of Odontology, Sahlgrenska Academy, University of Gothenburg, Sweden*, has been reviewed by the ***Dubai Scientific Research Ethics Committee, DHA***

2. PURPOSE OF THIS STUDY

2.1 Study purpose:
Evaluate the efficacy of a modified surgical technique for the treatment of multiple gum recessions.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely voluntary. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

To take part in this study you must:

- Age ≥ 18 years
- Periodontally and systemically healthy
- Good oral hygiene
- At least one lower front tooth with gum loss (with at least 3 mm or deeper)
- No bone loss between the teeth
- No prior experience of root coverage procedures within 1 year.

You can't take part of this study if:

- Contraindications for periodontal surgery
- Patient's pregnant or attempting to get pregnant (self-reported)
- Have been treated for dental bone loss
- Are unable to correct traumatic brushing technique
- Have teeth in the wrong position
- Self-reported current smoking more than 10 cigarettes/day or pipe or cigar smoking

3.2 How many people are expected to take part in this study?

30 subjects (15 for each treatment group) will be enrolled at ConfiDent ® Dental Surgery Clinic, Dubai – UAE.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

This is a randomized trial in which subjects will be selected at random (flip of a coin) to receive one of two methods of treatment. If you qualify for the study, you will be randomly selected to be in one of two groups (1:1). The control group will be treated with a gum graft using a conventional surgical technique, while the test group will be treated with a gum graft using a modified surgical technique.

The modified gum graft technique, introduced by Carcuac & Derks and accepted for publication in 2020 in the International Journal of Periodontics and Restorative Dentistry, will be applied at test sites. Thus, it has been demonstrated that the use of this novel modified surgical technique enhanced the gum healing and the percentage of root coverage at challenging gum recessions at lower front teeth.

- *Screening (Visit 1)*

If you decide to take part in this study, Dr Olivier Carcuac will go over the inclusion criteria for your participation in this study. We will review your medical history and check your vitals. A dental exam of your teeth and gums will be completed and we will take photos (no one will be able to tell it is you) of the inside of your mouth. We will also take

some measurements around the teeth with gum recessions. This visit will take approximately 30 minutes.

- *Surgery (Visit 2)*

We will review your medical history and check your vitals. You will receive the surgery for correcting the gum recessions, which involves opening the gums and placing the gum graft over the treatment area. The gums will be sutured together in a better position. Post-operative instruction and prescriptions for a mouth rinse and pain medications will be provided at the end of the surgery. This visit will take approximately 2 hours.

- *2-week post-op (Visit 3)*

We will review your medical history and check your vitals. Your sutures will be removed and photographs of the inside of your mouth will be taken. Oral hygiene instructions will be reinforced. This visit will take approximately 30 minutes.

- *1-month post-op (Visit 4)*

We will review your medical history and check your vitals. Photographs of the inside of your mouth will be taken. Oral hygiene instructions will be reinforced. This visit will last approximately 30 minutes.

- *3-month post-op (Visit 5)*

We will review your medical history and check your vitals. Photographs and clinical measurements will be taken of the surgical site. Oral hygiene instructions will be reinforced. This visit will take approximately 30 minutes.

- *6-month post-op (Visit 6)*

We will review your medical history and check your vitals. Photographs and clinical measurements will be taken of the surgical site. Oral hygiene instructions will be reinforced. This visit will take approximately 30 minutes.

- *1-year post-op (Visit 7)*

We will review your medical history and check your vitals. Photographs and clinical measurements will be taken of the surgical site. Oral hygiene instructions will be reinforced. This visit will take approximately 30 minutes.

4.2 How much of my time will be needed to take part in this study?

The study includes 7 visits over 1 year (that are each expected to last from 30 minutes to 2 hours).

4.3 When will my participation in the study be over?

Your participation in the study is voluntary. You may stop at any time. Your participation in the study will end after visit 7.

4.4 What will happen with my information used in this study?
With appropriate permissions, your collected information may also be shared with other researchers, here and around the world.
Your identifiable private information will be stripped of identifiers and may be used for future research studies without additional informed consent.
It is possible that the Medical Research Committee (DSREC) may view this study's collected data for auditing purposes. The DSREC is responsible for the oversight of the protection of human subjects involved in research.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
The known or expected risks are:
In this study, you will be randomly assigned, like with a flip of a coin, to receive either the standard of care treatment, gingival graft with conventional surgical technique, or the test treatment, gingival graft with modified surgical technique. Thus, there is a chance that you may receive a treatment that will result in better or worse root coverage, and the cosmetic/aesthetic results may be better or worse depending on the group to which you are assigned.

Risks associated with surgery
The likelihood that you will be assigned a treatment that will be less effective than other study treatments or other available treatments is unknown. Other risks may include: not achieving the complete coverage of the recessions, prolonged bleeding following the surgery, and infection of the surgical area. Infection is a rare complication following root coverage procedure. All of these risks are possible for any gum surgery and are standard of care risks. Dr Olivier Carcuac will try to minimize these risks by performing the surgery with microsurgical instruments and in a sterile environment according to standard of care.

Risk of infection
There is no increase in the risk of infection whether you are treated either with the conventional or the modified surgical technique.

Risk of loss of confidentiality
Additionally, there may be a risk of loss to confidentiality or privacy because your chart will be used and photographs will be taken. All of your information will be in a computer that cannot be accessed without a code. All paper documentation will be in a folder labeled "confidential" and stored in a locked office that only Dr Olivier Carcuac has access to. See Section 9 of this document for more information on how Dr Olivier Carcuac will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
Dr Olivier Carcuac has taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when Dr Olivier Carcuac is careful to avoid them. Please tell Dr Olivier Carcuac about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors.

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
We hope that the treatment that you will receive will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future patients with gum recessions better.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, Dr Olivier Carcuac will tell you if he learns of important new information that may change your willingness to stay in this study. If you decide to withdraw, Dr Olivier Carcuac will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
Taking part in this study is strictly voluntary. You do not need to participate if you do not want to. In addition, your care will not be affected by not taking part in this study. The other option includes monitoring the gingival recessions over time.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell Dr Olivier Carcuac why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.
If you withdraw from the study, we will destroy all your identifiable information, but we will need to use the data collected up to your withdrawal.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

No, there would be no harm to you if you decide to leave this study before it is finished.

7.3 Could the researcher take me out of the study even if I want to continue to participate?

Yes. There are many reasons why Dr Olivier Carcuac may need to end your participation in the study.

Some examples are:

- Dr Olivier Carcuac believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from Dr Olivier Carcuac.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of my surgery?

How much you will have to pay depends on whether or not you have insurance and what costs your insurance will cover. Thus, insurance coverage cannot be guaranteed for tests and treatments related to this study. You or your insurance carrier will be responsible for covering the cost of the gum grafting surgery, the cost of the prescriptions that will be given to you and the cost of any non-research related care that you might need during the study.

8.2 Will I be paid or given anything for taking part in this study?

If you decide to take part in this study, you will not receive any incentives, compensation or special treatment.

8.3 Who could profit or financially benefit from the study results?

No company or individual would profit or financially benefit from the study results.

Research can lead to new discoveries, such as new surgical techniques, tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

All information which is collected about you during the course of the research will be kept strictly confidential. All research records will be kept in a locked room in a locked cabinet with limited access and or in a password protected computer program. Only Dr Olivier Carcuac will have access to the research records and password.

Any information about you which leaves the ConfiDent ® Dental Surgery Clinic will have your name and address removed so that you cannot be recognized from it.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by the World Medical Association (WMA, 13th October 2013). This Web site 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.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact Dr Olivier Carcuac to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

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Study Coordinator: Olivier Carcuac, DDS, Specialist in Periodontics, PhD
Mailing Address: ConfiDent ® Dental Surgery Clinic, P.O.Box 215177, Dubai – UAE
Telephone: + 971 55 6275575
e-mail: olivier.carcuac@gu.se

If you are concerned about a possible violation of your privacy or concerned about the research project you may contact Professor Tord Berglundh, Chairman of the Department of Periodontology, University of Gothenburg, Sweden, listed below:
Department of Periodontology, Institute of Odontology, Sahlgrenska Academy,
University of Gothenburg
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SE 405 30 Gothenburg
Sweden
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When you call or write about a concern, please provide as much information as possible, including the name of the researcher, and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you can contact **Dubai Scientific Research Ethics Committee, DHA** on +971 4219 1961/1965 or email on DSREC@dha.gov.ae

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following
documents:

- This "Consent to be Part of a Research Study" document. *(Note: In addition to the copy you* receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular ConfiDent ® Dental Surgery Clinic medical record.)

12. SIGNATURES

PARTICIPANT CONSENT FORM

Prospective Research Subject: you are requested to read the patient information sheet carefully before you sign this consent form. You are free to ask questions at any time before, during or after your participation in this research.

Project Title: Treatment of localized gingival recession defects at lower mandibular incisors using a modified-free gingival graft: A Randomized Clinical Trial.	
Project Number: 202101	
Patient Identification Number (for this trial) :	
Principal Investigator: Dr Olivier Carcuac	**Organization**: University of Gothenburg
Location: ConfiDent ® Dental Surgery Clinic Dubai	**Phone**: +971 55 6275575

1. I confirm that I have read and understand **the information sheet/contents of the consent form** dated ..... for the above study
2. I have had the opportunity to ask questions and have received answers.
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.
4. I understand that sections of any of my medical notes may be looked at by responsible individuals from Gothenburg University or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.
5. I agree to take part in the above study.
6. A copy of this consent form will be provided to me after I sign it.

Participant:

Name: _____

Signature: _____ Date: _____

Witness

Name: _____

Signature: _____ Date: _____

Person obtaining the consent:
(I have read this patient information sheet/consent form to the subject and/or the subject has read this form. I have provided the subject with a copy of the form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's information. A copy of the signed consent form has been provided to the participant).

Name: _____

Signature: _____ Date: _____

Investigator **Signature** **Date**

Copies: *1 for participant; 1 for researcher; 1 to be kept in hospital notes*

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