Title

A histomorphometric analysis of bone formation following sinus augmentation with two different bone graft materials.

NCT 03059914

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PI- Dr. Jaime Lozada --- IRB # 5170069

CALIFORNIA EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in an experimental clinical procedure. Before you decide whether you want to participate in the experimental procedure, you have a right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of any signed and dated written consent form used in relation to the experiment.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

I have carefully read the information contained above in the "California Experimental Subject's Bill of Rights" and I understand fully my rights as a potential subject in a medical experiment involving people as subjects.

_____ _____

Date Signature of subject or Legally Authorized Representative

If signed by other than the subject, indicate: _____

Relationship to subject

_____

Name of subject

LOMA LINDA UNIVERSITY
School of Dentistry

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Study Title: A histomorphometric analysis of bone formation following sinus augmentation with two different bone graft materials.

Sponsor: Loma Linda University, School of Dentistry, Advanced Education Program in Implant Dentistry and Sigma Graft, Inc.

Principal Investigator: Jaime L. Lozada
Director for advanced education in Implant Dentistry
Department of Restorative Dentistry
Loma Linda University School of Dentistry

Purpose of the Study:

You are invited to participate in this study because you have missing posterior teeth in the upper jaw and you have requested implant therapy for replacement of the missing teeth. You would require the placement of bone graft material inside the maxillary sinus cavity to facilitate dental implant placement in the upper jaw. The purpose of this study is to compare new bone formation following the placement of specific types of bone graft material in the maxillary sinus cavity. The bone substitute graft material will be obtained from two different companies.

Augmenting the maxillary sinus cavity with bone graft materials is a well accepted and predictable surgical procedure that increases bone height in order to place implants in patients with insufficient bone. It is possible to use your own bone as a graft material, however, this requires a second surgical site, and increases the time of the procedure, and can increase post-treatment discomfort. The benefit of using a bone-substitute grafting material is that it may provide the same level of bone formation without introducing a second surgical site.

If you agree to participate, you will be placed into one of two randomly selected groups for each sinus cavity. We will use a computer software called quickcals to randomly assign participants into one of the two groups. The bone-substitute graft will be obtained from two different companies. The donor bone graft for both groups will be obtained from a cow donor. All graft materials utilized in this study are considered safe, are commercially available and FDA approved.

3-D CBCT scans will be obtained for the purpose of sinus augmentation and implant placement. This is considered a standard procedure. The first scan will be taken before the sinus augmentation and the second scan will be 8 months after the sinus augmentation in preparation for the implant placement.

If you decide to participate in this study, it is important to know that the length of the study for patient interaction is 8-9 months. 8 months after the initial surgery a second surgery will be performed for implant placement. At this second appointment a small portion of bone from the previously grafted site will be taken to analyze in a laboratory. The bone core will be taken using a small diameter trephine drill that will preserve the bone inside the drill for us to examine in the laboratory. There will be two sites from which the bone core will be taken. One of the site will be filled with the dental implant and the other site will be filled with bone graft material, similar to the bone graft material used in the first surgery. If you are having a graft of the sinus cavities on both sides, samples will be taken from each site. This act of taking a bone core is not standard procedure after bone grafting in the sinus and is specific to this study design. The procedure that will be followed in obtaining the bone core will follow standard of care practice for bone core biopsy.This procedure while it is done at the same appointment as the implant placement might increase postoperative discomfort, bruising, and healing time by about 1-2 days. The pain medication routinely prescribed for implant placement should be sufficient after this procedure. The postoperative instructions for you to follow and food restrictions are the similar to the recommendations after implant placement. This post operative care is considered standard procedure.

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

Follow-up Procedures and Patient Responsibilities:

Should you agree to participate in this study, you must be available for regular follow-up appointments until the completion of the study. The success of your treatment outcome can also be maximized through these follow-up appointments, as we will be able to identify any possible complications early on. The usual required follow up appointments are 2 weeks after surgery and 4 weeks after surgery. Follow up appointments will be required after the first and the second surgery. Other follow up appointments might be required based on individual requirements.

Possible Risks with the Study Procedure:

The committee at Loma Linda University that reviews human studies (Institutional Review Board) has determined that participating in this study exposes you to **minimal risk**.

You will be informed separately of all possible risks and complications associated with routine sinus augmentation surgery and asked to sign a separate informed consent form for that surgery.

Benefits:

You may or may not benefit from this research study. It is our hope that the information acquired from this study will benefit future patients who are candidates for sinus augmentation. You will be eligible for a fee reduction for the cost of sinus

augmentation. The fee reduction will be applied to your account in the form of a credit at the completion of the study.

Participants' Rights:

If you decide to participate in this study, it is your right to change your mind about participating in this study. However, once you remove yourself from the study, you will not be eligible for the fee reductions associated with this study. If you do change your mind about participating in this study you may communicate the same in writing to Dr. Sarat Ummethala or Dr. Jaime Lozada and submit your paperwork at the reception desk or center for implant dentistry and prosthodontics, Loma linda school of dentistry.

Alternative:

The alternative to not participating in this study would be that you can still be treated at the center for implant dentistry and prosthodontics to have one of the two bone graft materials mentioned above placed. You can continue to have future implants placed to support or retain a future prosthesis. You may receive any of grafts based on consultation with another dentist not participating in this study.

Confidentiality:

All medical records and research materials that would identify you will be held confidential to the extent possible. Any published information resulting from this study will not disclose your identity without your permission.

Your rights regarding permission to use your health information are described on the attached “Authorization for Use of Protected Health Information” form.

Costs:

The standard charge associated with the treatment has been determined to be $1,400 for each sinus cavity. The details of which are disclosed to you on the Treatment Summary Forms. As a consideration for your participation in this study, you will receive a credit refund of $750.00 for each sinus augmentation applied toward a total amount of your treatment. Your net clinical cost for each sinus augmentation will be $650.00.

You may use your credit of $750 towards any other treatment in the dental school. You will not be charged for the bone core biopsy, but you will be charged for the implant placement. You and/or your health insurance companies will pay for services, supplies, procedures, and care required for routine medical and dental care.You will be responsible for any co-payments and/or deductibles as required by your insurance. If you participate in this study, there may ne additional costs to you, such as travel for study visits. We will try to perform all study related activities at your routine pre-operative and post operative visits. If you have any questions about your insurance coverage or the items for which you might be required to pay, please contact Michelle Ojeda at financial services for information at 909-558-4983.

You will not be paid and compensated for any travel or the cost of lost work time resulting from your participation in this study. If you decide to participate in the study, but withdraw from the study, you will become responsible for all fees pertaining to follow-up care by your dentist.

The investigator is receiving financial support from the study sponsor to conduct the study.

Research related injury:

Your study doctors will be monitoring your condition throughout the study, and precautions will be taken to minimize the risks to you from participating. If you are injured or become ill while taking part in this study, please do the following:

- If the situation is a medical emergency, **call 911** or go to the nearest emergency room. Then, notify the study doctor as soon as you can.
- For a non-emergency injury or illness, notify your study doctor as soon as you can.
- To contact Dr. Sarat Ummethala or Dr. Jaime Lozada during regular business hours, dial 909-558-4983. After hours, call 909-558-4000 and ask for the resident on call in the implant dentistry department, and identify yourself as a subject in this study.

Appropriate medical treatment will be made available to you. If your injury or illness results from the sponsor's product or study procedures, the study sponsor (not Loma Linda University) has promised to pay the reasonable cost of necessary medical treatment for your injury or illness. You will not be billed and your insurance company will not be billed for such treatment. However, the sponsor's willingness to pay may depend on its judgment that the injury or illness is actually connected in some way to their product or procedures. If the connection is unclear, the sponsor might choose not to pay for treatment of your injury or illness. In that case, you and your insurance company could be billed for such treatment, and you might be asked to pay whatever your insurance does not pay, including all the cost if your insurance pays nothing.

Also, no funds have been set aside, nor any plans made (by either the sponsor or Loma Linda University) to compensate you for time lost from work, disability, pain, or other discomforts resulting from your participation in this research.

Impartial Third Party Contact:

If you have a question or complaint and wish to contact an impartial third party not associated with this study, you may contact the Office of Patient

You do not give up any legal rights by participating in this research.

Relations, Loma Linda University Medical Center, Loma Linda, CA 92354, phone (909) 558-4647 for information and assistance.

Informed Consent Statement:

I have read the above information and discussed the purposes, benefits, and risks of this clinical study with a study investigator. All my questions about this study have been answered to my satisfaction. If I have additional questions in the future, I may contact one of the investigators Joseph Kan, DDS, MS (909-558-8247), Sarat Chandra Ummethala DDS (937-409-0775), Jaime L. Lozada, DDS (909-558-4983), Aladdin Al-Ardah, DDS (909-558-8247) or Christopher Church, MD (909-558-8247) at Loma Linda University School of Dentistry, Loma Linda, CA 92350.

I understand that my study dentist has the right to remove me from the study at any time if he feels that it is in my best interest or if I fail to cooperate with the terms of the study. I understand that I may still be asked questions about my experience with the treatment I received and that I will be informed of any new findings about this procedure, developed during the study, which may relate to my willingness to continue to participate in the study.

I voluntarily agree to participate in the study. My signature acknowledges that I agree to the statements made herein and have been given a copy of this consent form. I also have received a copy of the California Experimental Subject's Bill of Rights and have had these rights explained to me.

Signature of Subject	Printed Name of Subject	Date

Investigator statement

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the participant has been provided with a copy of the California Experimental Subject's Bill of Rights, that I have discussed the research project with the participant and explained to him or her in nontechnical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

Investigator's Signature	Printed Name of Investigator	Date