****

**INFORMATION SHEET**

**Research Project: Ridge preservation in prevention of sinus augmentation**

**Purpose of Study**

University of Queensland is conducting a research on the benefits of ridge preservation, also known as socket grafting, carried out at the time of extraction of an upper molar or premolar tooth to minimize the bone loss of the jaw ridge and the need for further sinus surgery should you decide to replace the tooth with a dental implant in the future. Bone loss occurs following tooth removal; over time the height and thickness of the bone diminishes due to the natural healing process and lack of mechanical loading. A sufficient amount of bone is essential to ensure the long-term stability of your teeth or dental implants. It can also be critical for ensuring the esthetic appearance of your teeth and gums.

Bone substitute material have been widely used for socket graft for more than 30 years. Geistlich Bio-Oss® / Bio-Oss Collagen® and Geistlich Bio-Gide® support the body’s own bone regenerative processes extremely effectively and helps to minimize bone and gum loss of the jaw ridge following tooth extraction. Both are naturally derived products. Bio-Oss® is currently derived from an Australian bovine herd around Melbourne. The bones are transported to Switzerland for treatment either by heat, chemicals or both to remove all organic components. Bio-Gide® is membrane from porcine collagen; both are made under strictly controlled manufacturing process. Due to the great similarity to human tissue, these materials are optimally suited and widely used clinically to promote new bone formation and tissue healing in the human body.

Current treatment following an extraction involves healing by blood clot with or without placement of sutures to stabilize the blood clot. Recent evidence suggests that the application of Bio-Oss® or Bio-Oss Collagen® and Bio-Gide® membrane might help preserve more soft and hard tissues around an extracted tooth socket.

**We are interested in whether socket grafting with Bio-Oss® or Bio-Oss Collagen® with Bio-Gide® membrane will help maintain bone height in the upper back jaw to prevent the need for sinus surgery should an implant is placed in that region compared to conventional therapy.**

**What it involves**

The study will be conducted in the University of Queensland Oral Health Center (288 Herston Road, Herston 4006) or in the private periodontics specialist practice Brisbane City Periodontics and Implants (11/141 Queen St. Brisbane 4000). The principal investigators responsible for the study are Prof. Saso Ivanovski, Dr. Ryan Lee and Dr. Lisetta Lam. The study will commence in May 2017 and we expect to continue recruitment through to Nov 2018. To be eligible for the study, participants is one that requires an upper molar or premolar tooth extracted.

The table below shows the eligibility criteria for the study;

***Participants and Groups:***

|  |  |
| --- | --- |
| **Inclusion Criteria**   * Aged >20 years * Need to have an upper molar or second premolar extraction; these teeth display a reduced bone height (between 6-8mm) under the sinus on a 2-D plain X-ray. * Systemically healthy * Non-smoker | **Exclusion Criteria**   * Person considered by the investigator to be unwilling, unlikely or unable to comprehend or comply with the study protocol * Smokers and ex-smokers within the last 2 years * Anticoagulant therapy * Taking other anti-platelet agents; bleeding disorders. * Gastrointestinal disease, including peptic ulcers * Pregnant or breastfeeding |

As the upper molar and second premolar teeth are typically very close to the sinus, prior to the extraction appointment, a 3D scans will be taken to visualize the relationship between the tooth roots and the sinus in order to plan for the extraction to minimize the risk of sinus complications. After tooth extraction, eligible participants will be randomly allocated (i.e. by chance) to one of 3 treatment groups as follows:

1. **Extraction with suture closure**
2. **Application of Bio-Oss® and Bio-Gide® and sutures**
3. **Application of Bio-Oss Collagen® and Bio-Gide® and sutures**

All participants will be asked to follow the usual post-operative instructions after an extraction. This might include the prescription of antibiotics, if indicated. Participants will then need to attend 2 follow-up appointments at 2 weeks and 4 months after extraction in which they will be examined and a 3D scans taken (max appointment duration 20 minutes). **All 3D scans, consultation and review appointments and treatment in the study (both extraction and grafting materials) will be free of charge for study participants.**

You have been identified during your recent appointment as a suitable candidate for this study. If you agree to participate, you will be enrolled in the study, allocated to a treatment group:

Review healing

CBCT scan

Optional treatment: implant, biopsy of extraction site

Review healing

Extraction group

**4 months after extraction**

**2 week after extraction**

Examination

CBCT scan

Review healing

CBCT scan

Optional treatment: implant, biopsy of grafted site

Extraction & socket grafting group

Review healing

Suture removal

**Possible Risks**

All procedures will be carried out by experienced dentist in accordance with strict Occupational Health and Safety and Infection Control Guidelines set by University of Queensland. However, to assist you in making an informed decision, the risks associated with procedures are set out below:

**Tooth Extraction and ridge preservation:** The associated risks inherent to any tooth extraction or socket grafting are:

pain or discomfort, redness, bleeding, swelling, bruising, and stiff jaws, all of which may last for several days. It is possible for an infection to occur in the extraction/grafted site and indicating the need for antibiotics and/or other procedures to treat the infection. Less common complications include: dry socket (lost blood clot); loss or loosening of dental restorations; loss or injury to adjacent teeth and soft tissues; jaw fractures; sinus exposure (upper teeth); swallowing or aspiration of teeth and restorations.

**Bio-Oss, Bio-Oss Collagen, Bio-Gide:** As Geistlich Bio-Oss Collagen® and Bio-Gide® contains collagen, in very rare circumstances cases of allergic reactions may occur.

**CT Dentascan/Cone Beam CT scan:** There is no known risks associated with the CT/CBCT scan. The CT/CBCT acquisition settings has been developed in consultation with a dental radiologist to incorporate a low radiation dose protocol to minimize patient’s radiation dose exposure. Vital structures such as the orbit and salivary glands will be excluded from the CT/CBCT field of view.

**Your Privacy**

All information collected as part of the study will remain confidential and no information that could lead to identification of any individual will be released. Personal details will be kept confidential and the data will be stored securely. Research data will be stored for up to 5 years before deletion. You will not be identified in any way in any report/publication. Only the researchers will have access to the information you provide except as required by law. You can access a convenient, plain language summary of results via email request to the investigators.

**Withdrawal from Study**

Participation in this study is voluntary. You may withdraw from participating in this study at any time and this will in no way jeopardize your dental treatment of relationship with The University of Queensland.

Should you decide to withdraw from the study after the procedure, attendance to the 2-week postoperative review appointment is still advised to review healing. Research results will be destroyed if the participants withdraw half way through the post procedure period.

**Confidentiality**

Your confidentiality is respected at all times. All material collected will be de-identified. There will be no reference made to your name. You will not be identifiable from the sample. The only information collected regarding the scan sample will be your age and gender.

**Costs involved**

There are no additional costs involved in participating in this project since the treatment you receive is part of your normal extraction management. There will be no cost to the patient for CT scans, consultation/review appointments and management of any adverse reactions due to extraction and ridge preservation with Bio-Oss/Bio-Oss Collagen and Bio-Gide.

**Adverse Events**

In the unlikely event that you suffer an unanticipated adverse reaction to the procedure every effort will be made to see you immediately and deal with whatever problem has risen at the surgical site.

**Ethics approval**

University of Queensland conducts research in accordance with the National Statement on Ethical Conduct in Human Research.  If you have any concerns or complaints about the ethical conduct of this research project, you are encouraged to contact the Ethics Coordinator on 33653924 or email [humanethics@research.uq.edu.au](mailto:humanethics@research.uq.edu.au) .

**Contact Persons**

This research is conducted as part of Dr Lisetta Lam’s DClinDent in Periodontics program.

The principal investigator:

Dr Lisetta Lam, [lisetta.lam@uq.net.au](mailto:lisetta.lam@uq.net.au)

Postgraduate student for DClinDent (Periodontics) Year 3

The clinical and research supervisors of this project is:

Prof Saso Ivanovski, +61 7 336 58064 or [s.ivanovski@uq.edu.au](mailto:s.ivanovski@uq.edu.au)

Professor, **School of Dentistry**

**University of Queensland**

Dr Ryan Lee, +61 7 336 58013 or [r.sblee@uq.edu.au](mailto:r.sblee@uq.edu.au)

**Senior Lecturer, School of Dentistry**

**University of Queensland**