GRIFFITH UNIVERSITY ANIMALS ETHICS COMMITTEE

18-Jun-2012

Dear Prof Ivanovski

I write further to the additional information provided in relation to the conditional approval granted to your application for ethical clearance for your project "Regenerative Potential of Biomaterials for the treatment of peri-implants defects" (GU Ref No: DOH/02/12/AEC).

This is to confirm receipt of the remaining required information, assurances or amendments to this protocol.

Consequently, I reconfirm my earlier advice that you are authorised to immediately commence this research on this basis.

The standard conditions of approval attached to our previous correspondence about this protocol continue to apply.

Regards

David Rounsevell

Research Ethics Officer

Office for Research

Bray Centre, Nathan Campus

Griffith University

ph: 3735 6618

fax: 3735 7994

email: D.Rounsevell@griffith.edu.au

web:

Cc:

At this time all researchers are reminded that the Griffith University Code for the Responsible Conduct of Research provides guidance to researchers in areas such as conflict of interest, authorship, storage of data, & the training of research students.

You can find further information, resources and a link to the University's Code by visiting http://www62.gu.edu.au/policylibrary.nsf/xupdatemonth/e7852d226231d2b44a25750c0062f457?opendocument

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INFORMATION SHEET

ENAMEL MATRIX DERIVATIVE ON PERI-IMPLANT AND PERIODONTAL DISEASE

**Purpose of Study**

Griffith University is conducting research on the beneficial effect of enamel matrix derivative (EMDOGAIN) in the management of peri-implantiitis and periodontal recession. EMDOGAIN is a commercially available product used to help in improving clinical result in the treatment of gum recession and peri-implantitis. It is derived from baby teeth of mini-pigs. The active ingredient amelogenin is the same in mini-pigs and humans. EMDOGAIN does cause any allergic reaction. It is produced by a Swiss company Straumann.

Peri-implantitis is the inflammatory condition surrounding a dental implant. This can result in the loss of surrounding bone around an implant, consequently leading to the loss of the implant affected. The inflammation of the gum around the implant can also cause gum bleeding, gum tenderness, bad breath and unsightly exposure of the implant metal in the mouth.

Current treatment for peri-implantitis involves surgical access, resection and placement of widely acceptable bone graft called Bio-Oss-. Bio-Oss is calcium mineral produced Geistlich Company. It is derived from Australian cattle and approved by FDA for use in peri-implantitis. This method of treatment is till unpredictable and also does not produce the ideal tissue around the tooth or implant. The addition of EMDOGAIN with Bio-Oss bone graft during the treatment surgery may help to improve the predictability of the dental implant procedure by helping to induce more natural bone in the area.

Periodontal recession affects around 30-50% of the population where the gum margin around a tooth has gone down, leading to the exposure of the root of the tooth. This can lead to tooth sensitivity, unsightly “long-tooth” and root decay if left untreated.

Current treatment for periodontal recession involves surgical procedure where a gum graft is harvested from the palate (roof of the mouth). This is sutured into the affected tooth and the patient is given adequate instruction on how to look after both the palate and tooth surgical wounds. This treatment though predictable does not produce the right tissue under the newly grafted gum. The addition of EMDOGAIN may help to promote new tissue including gum, bone and ligament under the newly grafted gum.

The Purpose of this study are:

1. To see if the addition of EMDOGAIN may help control peri-implantitis by reducing inflammation measure by dental probe.
2. To see if addition of EMDOGAIN with Bio-Oss bone graft may help promote more new bone around diseased dental implant.
3. To see if addition of EMDOGAIN may control more bacteria after surgery in peri-implantitis.
4. To see if addition of EMDOGAIN may reduce pain and inflammation after surgery involving peri-implantitis and gum recession.
5. To see if addition of addition of EMDOGAIN may promote more bone marker at gum fluid measured after implant and gum surgery.

**What is involved**

The study will be conducted at Specialist Dental Centre Penrith NSW, located at 34 Castlereagh St Penrith, NSW. The principal investigator responsible for the study is Professor Saso Ivanovksi.

The study will commence in Dec 2016 and we expect to continue recruitment through to Nov 2019. The patients who are eligible for the study are private patients referred for management of peri-implantitis and periodontal recession, systemically healthy, non-smoker and between 18-70 years old. 100 referred patients are needed to participate in the study. Recruited patients will be divided into four groups:

1. Peri-implantitis/Ridge Management Group Bio-Oss - Control
2. Peri-implantitis Group/Ridge Management Bio-Oss and Emdogain- Test
3. Periodontal recession and Gum-graft- Control
4. Periodontal recession, gum-graft and Emdogain-Test

Eligible participants will be allocated to one of four above-mentioned groups after initial examination by a trained dental surgeon. A verbal explanation of the study will also be given before any surgery is done. All the patients who agreed to participate in the study are aware that Emdogain may or may not be used for their treatments The allocation of the treatments will decided by picking a sealed envelope with “control” or “test” word written on it. All the patients who agreed to participate in the study will need to sign a consent form. All the patients will be given a unique identifier number to maintain confidentiality throughout the data.

Clinical measurements normally taken at initial consultation and subsequent visits will be taken. This will include gum/implant probing depth, gum recession and keratinised tissue, plaque index and gingival inflammation index. Radiographs or X-rays will also be taken at initial consultation, 3rd month, 12 month and 24 months after the treatment period.

All treatment procedures will be routine procedures for the treatment of peri-implantitis and periodontal recession and are therefore the standard of care. The used of EMDOGAIN in Groups 2 and 4 are additional steps to see if this material will help in the improvement of existing treatment protocols.

At initial treatment visit, a sample of gingival crevicular fluid (GCF) will be collected. A collection of gingival crevicular fluid is not part of a routine examination. A small area of gingival tissue will be cleaned, isolated with sterile cotton to prevent contamination by saliva and dried with air syringe then a paper strip will be inserted in the space between the tooth and surrounding gingival tissue for 30 seconds to collect a fluid sample. The gingival crevicular fluid (GCF) samples will be used to measure the extent of inflammation localized to the mouth and the plaque samples will be analysed to determine the amount and type of bacteria present.

All participants will then undergo comprehensive routine periodontal treatment involving non-surgical removal of plaque and calculus and a sample of plaque will be collected from the pockets around affected teeth/implants. Dental plaque is the cause of peri-implantitis and while the collection of dental plaque for analysis is not a part of a routine dental examination, it represents collection of plaque that would otherwise be removed and discarded by the subject when cleaning their teeth or having them professionally cleaned.

After the first appointment, the participants will be given their appointments for next treatment visit intervals, according to the schedule below:

Baseline - Perio exam, Clinical Data collection, GCF and Plaque samples, Radiographic exam.

I week – Routine perio exam and clinical data collection, GCF and Plaque samples

2 weeks – Routine Perio exam and Clinical Data collection, GCF and Plaque samples

4 weeks – Routine Perio exam and Clinical Data collection, GCF and Plaque Samples

3 months – Routine Perio exam and Clinical Data collection, GCF and Plaque Samples

6 months – Routine Perio exam and Clinical Data collection, GCF and Plaque Samples

12 months – Routine Perio exam and Clinical Data, GCF and Plaque Samples, Radiographic exam

24 months – Routine Perio exam and Clinical Data collection, GCF and Plaque Samples, Radiographic exam.

Periodontal exams (including scaling and cleaning), will take place at every visits per the standard management protocol after periodontal surgery.

**Possible Risks**

The study involves collection of redundant gum and bone tissue and data collection as part of routine follow-up. The sampling process involving GCF and Plaque collection is non-invasive. All procedures will be carried out by qualified personnel and in accordance with strict OHS guidelines.

**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.

**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 sample will be your age and gender. You will be provided with a copy of your personal results and a summary of the research findings (if needed) after the completion of the study.

**Costs involved**

There are no additional costs involved in participating in this project since the treatment you receive is part of your normal peri-implantitis and periodontal recession management.

**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

**Contact Personnel**

The principal investigators of this project are:

Professor S Ivanovski

Contact working hours: 567 80741

Dr Stephen Hamlet

Contact working hours: 567 80843

Dr. Tino Mercado

Contact Working hours – 02-4721-2888

GRIFFITH UNIVERSITY HUMAN RESEARCH ETHICS COMMITTEE

**STANDARD CONSENT FORM**

**FOR PEOPLE WHO ARE PARTICIPANTS IN A RESEARCH PROJECT**

1. I, ………………………………………………………………(please print name)

consent to take part in the research project entitled: **Enamel Matrix Derivative for Peri-implant Disease and Periodontal Recession management.**

2. I acknowledge that I have read the attached Information Sheet entitled: **Volunteer**

**Information Sheet - Enamel Matrix Derivative for Peri-implant Disease and Periodontal Recession management.**

3. I have had the project, so far as it affects me, fully explained to my satisfaction by the researcher. My consent is given freely.

4. I also consent to the use of dental assessments made during the preceding periodontal examination wherein I was identified as a potential volunteer for the study.

5. Although I understand that the purpose of this research project is to improve the quality of medical care, it has also been explained that my involvement may not be of any benefit to me.

6. I have been given the opportunity to have a member of my family or a friend present while the project was explained to me.

7. I have been informed that, while information gained during the study may be published, I will not be identified and my personal results will not be divulged.

8. I understand that I am free to withdraw from the project at any time and that this will not affect medical advice in the management of my health, now or in the future.

9. I am aware that I should retain a copy of this Consent Form, when completed, and the attached Information Sheet.

…………………………………………………………………………………………...

*(signature) (date)*

**WITNESS**

I have described to …………………………………………………….. *(name of subject)* the nature of the research to be carried out. In my opinion she/he understood theexplanation.

Status in Project**:** ……………………………………………………………………….

Name: ……………………………………………………………………………….….

…………………………………………………………………………………………...

*(signature) (date)*