RESEARCH PROTOCOL

Title

Ridge preservation for the prevention of sinus augmentation

Investigators & Responsibilities

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Introduction

Alveolar bone undergoes a remodeling process after tooth extraction that results in an overall reduction in bone volume (Pietrokovski and Massler, 1967). In addition, maxillary sinus pneumatization after tooth extraction results in an increase of the sinus volume at the expense of the edentulous alveolar ridge. The rate and degree of the pneumatization process after tooth loss may be influenced by the protrusion of tooth roots into the sinus cavity (Kilic et al., 2010, Wehrbein and Diedrich, 1992).

It was reported that post-extraction pneumatization occurs within a period of 4 to 6 months post-extraction (Sharan and Madjar, 2008). Pneumatization of the sinus after extractions can have serious treatment planning implications including a reduction of the alveolar bone height available for implants. When implant placement is delayed in the maxillary posterior region, especially in cases with reduced vertical ridge height, a sinus augmentation procedure is usually required to increase the alveolar bone height. Hence it is necessary to consider regenerative procedures at the time of extraction to prevent three-dimensional bone loss (Cardaropoli and Cardaropoli, 2008, Iasella et al., 2003).

Current alveolar ridge preservation (ARP) techniques are based on the guided bone regeneration (GBR) technique in order to minimize the dimensional changes in soft and hard tissues after tooth extraction. Barrier membranes such as collagen membrane, Geistlich Bio-Gide® are used to create space and exclude soft tissue ingrowth, and are combined with dimensionally stable grafting materials which are placed within the socket at the time of extraction (Cardaropoli and Cardaropoli, 2008, Engler-Hamm et al., 2011, Barone et al., 2008). A previous clinical study proposed the use of anorganic bovine bone particles (Geistlich Bio-Oss®) as an acceptable grafting material in fresh extraction sockets for ridge preservation (Artzi et al., 2000). Clinically and histologically, Bio-Oss particles have been shown to be an effective biocompatible filler agent in extraction sockets for ridge preservation prior to titanium fixture implantation (Artzi et al., 2000, Darby et al., 2008, Darby et al., 2009).

Nevins and co-authors evaluated alveolar bone resorption of maxillary anterior post-extraction defects augmented with Bio-Oss (Nevins et al., 2006). Using computed tomography, it was demonstrated that 79% of augmented sites showed less than 20% buccal plate loss, and 71% of non-augmented sites demonstrated more than 20% buccal plate loss. These findings clearly demonstrated significant benefit from ARP at the time of extraction in minimizing alveolar bone resorption and preserving the ridge morphology. Geistlich Bio- Oss Collagen® is a relatively new material used in periodontal regeneration. It consists of 90% Geistlich Bio- Oss® granules and 10% porcine collagen, resulting in a structure similar to human cancellous bone and also enhances its handling characteristics. In a recent randomized control trial on ARP using Bio-Oss Collagen® immediately after tooth extraction, the grafted sites demonstrated significantly less reduction in cross- sectional ridge dimension compared to control (non-grafted) sites on CBCT evaluation 4 months after extraction (Araújo et al., 2015).

In the posterior maxillary region, Rasperini et al. compared the dimensional and histologic changes of Bio- Oss Collagen–Bio-Gide membrane augmented extraction sockets at first or second molars site to non- augmented sites and evaluated the need for sinus floor elevation (Rasperini et al., 2010). The authors reported a trend of an increase in sinus augmentation procedures in the group without grafting as a result of the increased loss in vertical dimension (Rasperini et al., 2010). However, the study finding should be cautiously interpreted as no standardized radiographic analysis of the dimensional changes of the residual or augmented alveolar ridge was performed and the inclusion criteria was not clearly defined.

A recent clinical and radiographic study investigated the changes in the position of the maxillary sinus floor using fixed anatomic structures on panoramic radiographs before and after posterior maxillary tooth extraction (Sharan and Madjar, 2008). Significant inferior expansion of the maxillary sinus floor in sites of extracted teeth (1.83 to 2.18mm) was observed both when comparing an edentulous site to its contralateral dentate site and when comparing the same site before and after extraction. Such sinus pneumatization after the extraction of maxillary posterior teeth and that sinus expansion was considerably larger in cases of extractions of teeth enveloped by a superiorly curving sinus floor as identified on pre-extraction radiographs. The authors concluded that there is increased probability for sinus pneumatization in teeth surrounded by a superiorly curving sinus floor, tooth roots shown to protrude into the sinus cavity, extraction of maxillary second molars and extractions of several adjacent posterior teeth or extraction of a tooth with missing adjacent teeth (Sharan and Madjar, 2008)

If dental implant placement is planned in these cases, immediate bone grafting at the time of extraction by means of ridge preservation techniques should be considered in order to preserve alveolar bone height (Fugazzotto, 1999, Sharan and Madjar, 2008). These procedures may also help maintain the 3-dimensional architecture of the thin sinus floor in the extraction site until complete healing of the socket, thus preventing or decreasing pneumatization (Sharan and Madjar, 2008, Hatano et al., 2004).

One of the major limitations of these studies is the use of either clinical measurement of the residual alveolar ridge or panoramic radiographs to analyze the relationship of tooth roots to maxillary sinus floor and to measure the vertical ridge height. Clinical measurements do not provide specific data on the dimensional changes in the alveolar bone and the distance between the alveolar crest to sinus floor. Panoramic radiographs only allow for a 2-dimensional evaluation of the edentulous ridge, and the assessment of the true distance between relevant anatomic landmarks may be affected by magnification and distortion. True topographic relation between the tooth and the maxillary sinus and changes in vertical ridge height can only be accurately assessed using 3-dimensional (3D) imaging such as conventional computed tomography (CT) or cone beam computed tomography (CBCT). With the revolutionary advances in 3D imaging technologies, together with low radiation protocols, it is now considered a routine imaging techniques for treatment planning for dental implant and ridge augmentation procedures.

To date, randomized controlled trials have examined the effect of ridge preservation with the use of 3D imaging to accurately document the alveolar ridge dimensional changes and sinus pneumatization following extraction of posterior maxillary teeth. The comparison between the use Bio-Oss and Bio-Oss Collagen is also of important clinical consideration, as both products are widely used in ARP procedures. The goal of this study is to investigate benefits of the use of ridge preservation immediately after extraction of posterior maxillary teeth, in which sinus pneumatisation and ridge dimensional changes could be minimized. This in turn will prevent the need for more complex and invasive sinus augmentation procedures, ultimately reducing patient morbidity and cost of the treatment.

Aims:

1) To compare the horizontal and vertical dimensional alterations of the alveolar ridge and changes in sinus volume 4 months following extraction with or without ridge preservation.

2) To compare the need for sinus lift augmentation for implant placement at the maxillary premolar and molar sites 4 months following extraction with or without ridge preservation.

3) To compare patient-centred outcomes between extraction with or without ridge preservation.

4) To compare histological and histomorphometric outcomes between extraction with or without ridge preservation sites.

Project Design

Subjects

Patients attending the Oral Health Centre, Herston, Metro North Hospital and Health Service (288 Herston Road, Herston QLD 4006) for dental treatment requiring extractions maxillary molars and second premolars will be invited to participate in the study.

Inclusion criteria

* 20 years of age or over
* Extraction of maxillary second premolars, first molars and second molars
* Vertical bone height from alveolar bone crest to maxillary sinus floor minimal of 6-8mm
* All indications (periodontal, endodontic, restorative) for extraction
* Non-smoker

Exclusion criteria

* History of smoking
* Presence of a systemic disease or metabolic bone disorder
* Currently pregnant
* History of malignancy, radiotherapy, or chemotherapy for a malignancy in the past 5 years
* Taking steroids, bisphosphonates, or chemotherapeutic drugs

An information sheet describing the aim and methodology of the study will be provided to all eligible subjects. Informed consent will be obtained from all subjects who agree to participate in the study

Randomization and group assignment

The treatment regimens will be assigned randomly to the subjects via computer-generated numbers and will be communicate to the operator immediate after tooth extraction. To reduce the chance of unfavorable differences between test and control groups in terms of potential confounding factors, the randomization process will take into account the following variables: molar and premolar sites and the presence of adjacent teeth.

Subjects will be randomly divided into:

-Control group (n=25)– tooth extraction without ridge preservation

-Grafting group (Bio-Oss) (n=25) – tooth extraction with ridge preservation with large particle Geistlich Bio- Oss® or Bio-Oss Collagen® into socket and covered by Geistlich Bio-Gide®

Pre-extraction data collection

Before extraction, all patients will receive professional oral hygiene care and instructions to minimize any infective complication. The following clinical parameters will be recorded:

* The tooth or teeth that are present in posterior maxilla
* The tooth or teeth to be extracted in the posterior maxilla
* Reason for the extraction: periodontal, endodontic, prosdodontic, restorative, orthodontic etc.
* Presence of associated pathologies: periodontal disease, periapical lesions, root fractures, endodontic-periodontic combined lesions

Pre-extraction 3D imaging (CBCT) will be taken using a standardized radiographic protocol evaluate the tooth in order to assess the root anatomy and plan the extraction procedure and to measure the horizontal and vertical ridge dimensions in relation to the maxillary sinus floor. The image acquisition settings have been developed in consultation with a specialist Dento-Maxillofacial Radiology 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 field of view. All 3D imaging will be taken at the same radiology clinic with the same machine.

Interventions/Procedures:

Tooth extraction and ridge preservation will be performed by calibrated clinicians using a minimally traumatic approached aimed to preserve an intact buccal bony cortex. If necessary, roots will be sectioned with a bur and removed separately to minimize damage to the bony cortex. Careful curettage of the socket will be performed to remove all bony and tooth debris and infective tissue. After debridement, the integrity of the buccal cortex will be inspected and recorded as intact, completely absent or presence of dehiscence of fenestrations.

In test group 1 sites, the alveolar socket will be grafted with large granules Bio-Oss firmly compacted to fully fill the socket to about 1mm above the alveolar crest and covered with Geistlich Bio-Gide® membrane. In test group 2, Geistlich Bio-Oss Collagen® will be place into socket and covered with Geistlich Bio-Gide® membrane. All test sites will be sutured using a Criss-cross internal horizontal mattress suturing technique with 5/0 prolene sutures. In control sites, the extraction sockets are left to heal naturally. Periosteal flaps will not be raised for primary closure.

Postoperatively, a one week course of amoxicillin 500mg every 8 hours daily (TID) will be prescribed for 7 days. For subjects that are allergic to penicillin, a one week course of clindamycin 300mg every 6 hours daily will be prescribed. Both oral and written postoperative care instructions will be given. Subjects will be instructed to avoid rinsing and spitting for the first 24 hours. Subjects will be advised to use 0.2% chlorhexidine mouth wash for rinsing twice daily and to avoid brushing directly on the surgical site for 1 week. Subjects will be advised to maintain a soft diet for 2 weeks. Patients will be reviewed in 2 weeks and sutures will be removed. Any incidence of postoperative complications and visual analog scale for pain, swelling, bleeding ad bruising will be recorded and can be compared between control and test groups.

Post-extraction measurements

At 4months, a post-operative 3D imaging (CBCT) will be taken to analyze post-extraction healing, graft integration and alveolar ridge dimensions at the site of tooth extraction and available bone for implant placement. Based on the post-extraction scan, the changes in alveolar ridge height and sinus volume before and after extraction/ridge preservation is compared within groups and between groups. The need for sinus augmentation is investigated on the postoperative scan using the implant planning software Simplant. The need for sinus augmentation is determined based on the mid-ridge height on the post-extraction CT scan. Lateral sinus augmentation would be required when the residual mid-ridge height was <5mm (Pjetursson and Lang, 2014, Thoma et al., 2015b, Schincaglia et al., 2015, Shanbhag et al., 2014, Pramstraller et al., 2011, Avila‐Ortiz et al., 2012). Histological core sample at the extraction site will be taken at implant surgery.

Endpoints:

The number of patients requiring subsequent sinus augmentation and patient-related outcomes (pain, bleeding, swelling, bruising and adverse events) will be compared between control and the two test groups. Additionally, the changes in horizontal and vertical ridge dimension within each group and between the control and both test groups.

Study plan:

Patients attending the Oral Health Centre, Herston, Metro North Hospital and Health Service (288 Herston Road, Herston QLD 4006) for dental treatment requiring extractions maxillary molars and second premolars will be invited to participate in the study. Patients seen by or referred to the researcher by other dental students or staff will be invited to participant in the project and be given the information sheets and consent materials. Patients that meet the inclusion criteria of the study are eligible to participate will be given information sheet detailing the aim and the method of the research project. The following will be explained in details (verbally and in written form):

* Aim and expected benefit of the project
* Method and material used:
* Random assignment into control group (extraction only) or one of the test group (extraction with ridge preservation)
* Why does the tooth need extracting
* How are the tooth extracted
* Information required in the form of CBCT before and 4 months after extraction
* Nature of the biomaterial used and method for ridge preservation
* Risks and complications of the procedure for extraction and ridge preservation depending on group assignment
* Duration of the project and follow up period: review at 2 week and 4 months after extraction/ridge preservation
* Risks and complication of taking a histological sample should patient decide to proceed with implant treatment (which is optional)
* Confidentiality is protected and participation is voluntary and potential participants are free to withdraw from the study at any time

Analysis:

Data collection method: CT scans will be taken at the Qscan or Queensland XR radiology clinics, and the data will be stored on a CD for each patient. The CT data will be analyzed by a single researcher who will be blinded to the group assignment of the participants and results will be stored on a designated laptop which is password protected.

Location: all data will be analysed at the School of Dentistry University of Queensland

Duration: all data will be kept for entire period of the research.

Analysis: data from the CT scans will be analysed using the Simplant® on the designated laptop. Statistical analysis will be done on the same laptop.

Data storage and disposal: At all times, patients’ identity and information will be kept secured at all times on Queenland Health clinic computers. All CT scans and patient consent forms will be securely stored in a locked drawer in the Periodontology department at the School of Dentistry University of Queensland. Only the researchers will have access to the drawer. At the end of the project, all research data and CT scans will be returned to the Oral Health Centre, Herston, Metro North Hospital and Health Service as part of patients’ record keeping. Patient/research data will be stored and accessed through Queensland health clinic computers. CT scan data will be accessed and stored on a CD in Oral Health Centre, Herston, Metro North Hospital and Health Service.

Ethical issues:

Dental students, supervisors and professional staff will be under no obligation to advise or refer their patients to enroll in the project if they deed the proposed treatment is not in the best interest for their patients. Patients seeking treatment Oral Health Centre, Herston, Metro North Hospital and Health Service will be under no obligation to participate in the research project and their treatment will not be affected in any way should they decline to participate. The researchers will not have access to the treatment carried out or the participatory status of the patients seen by students or professional staff in the dental clinics.

Should patient require oral sedation, they can obtain the necessary medication (recommended Diazepam (Valium) 5-10mg 1 hr prior to surgical procedure) from their GP. After the procedure, patients will be prescribed a suitable oral antibiotic for a 7-day course (Amoxicillin 500mg TID or Clindamycin 150mg QID if patient is allergic to Amoxicillin), which they will commence taking 1 day prior to the extraction to minimize the risk of post-operative infection. Patients will also be prescribed a suitable analgesic (Paracetamol 500mg, per required need). Standard post-extraction care instructions will be given both verbally and in written form. After 2 weeks, all patients will be reviewed and sutures will be removed. Any complication during the healing phase will be documented. Patients will be reviewed at 4 months both clinical and radiographically to assess level of wound healing and degree of ridge resorption and sinus pneumatization.

Postoperative discomfort, pain and swelling will be similar between extraction only and extraction with ridge preservation. Patients can expect mild-moderate postoperative pain for the first few days, which will be controlled by regular intake of oral analgesic. Possible postoperative complications may include bleeding, dry socket, perforation of the sinus floor and infection of the graft material. Ridge preservation will be contraindicated if there is perforation of the sinus floor; in which case, the socket will be closured completely and patient will be given specific instructions to protect the sinus. In cases of graft infection, graft material will be thoroughly removed and socket cleaned to allow for natural healing.

Participants can be accompanied by a family member to all consultations/visits and that any questions they may have will be addressed by members of the research team in an appropriate setting.

Resource requirements:

This project is the research project for postgraduate training in DClinDent Periodontics for Dr Lisetta Lam for graduation at the end of 2018. Formal patient recruitment will be completed in March 2018. Final patient reviews will be completed in July 2018 to allow for data analysis. The biomaterials for ridge preservation (Geistlich Bio-Oss®, Bio-Oss Collagen® and Bio-Gide®) are donated by Geistlich Pharma Australia.

Supervision:

All stages of this research project will be supervised by Dr Ryan Lee (Clinical and research supervisor; Senior Lecturer in Department of Periodontology at School of Dentistry, University of Queensland; Specialist Periodontist)

Dissemination of Findings:

Findings of the research will be dissemination in thesis form as part of the postgraduate training program requirement for DClinDent (Periodontology) and journal article submission to a peer review journal towards the end of 2018.

None of the patient identifiable information will be published. Radiographic images and clinical photos of the treatment procedure may be published only in de-identified form. Non-disclosure privacy statement – non-disclosure will be provided to the patient as part of the inform consent process.

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