Study Title: A Prospective Randomized Study on the Immediate Loading of Mandibular Overdentures Supported by a Parallel Sided or Tapered Dental Titanium Implant

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Brief Title: Mandibular Overdenture Clinical Trial Comparing Parallel Sided and Tapered Dental Implants

Study Protocol

Recruitment process

Subjects will be recruited using flyers/posters on the University of Washington Campus. Brief information about the study including criteria for inclusion and contact information will be provided. Subject will be informed to contact the research coordinator to schedule a screening appointment.

Pre-screening procedure

The research coordinator will be providing oral information about the study including criteria for inclusion. If a subject is interested to participate, he/she will be scheduled for a screening appointment.

Screening Procedure

Part I

The screenings will be performed at the Regional Research Clinic, School of Dentistry at the University of Washington. Dr. Kronstrom and Dr. Shor will do all the screenings. These investigators will inform the patient about the screening procedures and collect information about the patient's medical and dental history. To be considered for inclusion the subject must:

Inclusion criteria

- Be between 20 and 75 years of age
- Be edentulous and have both upper and lower complete dentures
- Present with ASA I or ASA II and no medical contraindications to implant treatment
- Have adequate bone volume for placement of one (1) 4.0 mm diameter titanium dental implant with a minimum length of 10 mm in the symphyseal area (=midline) of the anterior mandible
- Show absence of pathology such as cysts, infections in the gum tissue or bone and remaining roots.
- Be able to understand the procedures and have a jaw opening range of 30 mm or more

Exclusion criteria

- Ongoing chemotherapy
- Previous radiation to head/neck
- Ongoing corticosteroid medication
- Ongoing blood thinner medication
- Ongoing medication with psychopharmacological drugs
- History of alcohol/drug abuse
- Remaining teeth/root tips

- Poor quality /fractured/severely worn dentures that cannot be modified to fit the implant
- Jaw opening range less than 30 mm

If a subject is found not to qualify after reviewing the dental and medical history, he/she will be informed about the reasons and all information collected up to that point will be immediately destroyed.

Subjects enrolled in the study will sign a consent which includes information about the costs for the treatment. The cost for the CBCT is $ 150 which will be charged to the subject at the time of the radiographic examination. There will be no charge to the subjects of the surgical implant placement procedure and denture modification. Further, the titanium dental implant and the attachment components will be provided free of charge to the subjects. Follow-ups will be done at no charge to the patient.

Part II

- Those who are eligible to participate in the study will have opportunity to ask the investigators and the research coordinator any question he/she might have about the study before signing the consent form. Once the subject has consented to participate, he/she will be scheduled for a clinical examination, including evaluation of the dentures and a panoramic radiograph (large size radiograph of the upper and lower jaw extending from the left to the right glenoid fossa) taken to evaluate bone height and to ensure absence of infections, cysts and root tips.
- Subjects who qualify for inclusion in the study will then be scheduled for the pre-surgical procedure. Subjects who have dentures with poor fit will be offered a reline (adding acrylic resin to the denture base) for improved denture fit/stability prior to implant surgery.
- The subject will be excluded if the clinical and radiographic examination reveals that bone grafting (adding bone to the site before implant surgery) or surgical removal of cyst/residual roots prior to implant surgery are necessary.
- Subjects who are excluded from the study due to poor denture quality or oral disease/cysts/remaining root tips/infections will be informed and recommended seeking treatment either with their regular dentist or referred to specialist. All information collected for study purposes up to that point will be destroyed.

Pre-surgical Procedure

- The pre-surgical procedures include having a Cone Beam Computed Tomography (CBCT) examination to evaluate the bone volume/width in the mandibular midline where the implant is being placed. This examination is considered standard of care and is used regularly when planning for surgical implant placement. The patient's denture will be duplicated and the denture replica will serve as a guide when placing the implant. A 2 mm diameter hole will be drilled in the denture replica acrylic in the ideal implant position and used during the surgical implant placement.

Surgical Implant Placement

- The surgical implant placement will be done at the Regional Research Clinic, School of Dentistry, at the University of Washington. Each subject will have a titanium dental implant placed in the midline of the lower jaw (mandible). The type of implant (parallel sided or tapered) will be determined using a computer random sampling program (Research Randomizer, JavaScript, and the patient will be informed what implant he/she will have the day of surgery. Each implant will have an attachment (metal coping to provide denture retention) connected immediately following placement. The subject will receive 2 g Amoxicillin as prophylactic antibiotics 1 hour before the surgical procedure to minimize the risk of infection. Those reporting allergy to Penicillin will have 600 mg Clindamycin orally 1 hour before the procedure. Local anesthetics (3.6 cc, 2% Lidocaine 1:100000 epi) will be used to numb the subject. The subject will receive post-op information and prescription of Chlorhexidine mouth rinse.

Prosthodontic Procedures

- Immediately following the surgical implant placement, the subject's lower denture will be modified to fit over the implant attachment. A metal housing (with a snap-on plastic insert) placed on the implant attachment will be secured to the denture base using fast setting acrylic. A non-latex rubber dam will be used to protect the gum tissue against resin monomer during the attachment pick-up procedure. The denture will be polished and inserted to assure correct fit. The subject will be instructed to keep the denture in the mouth for 24 hours to avoid post-operative swelling and scheduled for a follow-up visit the next day.

Follow-ups

- Subjects are scheduled for follow-up 6- and 12-months after implant placement and annually thereafter for 4 years. A periapical radiograph will be taken to evaluate peri-implant bone support. Implant stability will be assessed and soft tissue condition, denture fit, wear and occlusion (bite) will also be evaluated. Subjects will be asked to fill out the OHIP questionnaire at all follow-up appointments to evaluate oral comfort, chewing ability and oral health related quality of life.