RESEARCH PROTOCOL OUTLINE

Title of Project: Alveolar Ridge Expansion by Osseodensification and Its Impact on Implant Survival and Success: A Case Series

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Abstract

Alveolar bone remodeling after tooth extraction may result in significant ridge resorption and inadequate bone volume for implant placement. Several methods have been designed for ridge augmentation, among which is the new technique of osseodensification, using the Densah® burs by Versah® (Versah®, LLC, Jackson, MI, USA). This method compresses the trabecular bone to periphery of the osteotomy site and has shown up to 80% ridge expansion in animal histological studies[i,ii,iii,iv,v,vi]. Apart from being an animal model with a short follow-up, another limitation of these studies is the lack of three-dimensional evaluation of the change in morphology of the ridge. Human clinical studies[vii,viii,ix,x,xi] have reported similar results, but they do not evaluate if this bone volume is retained during osseointegration and loading periods. No standardization method or long-term evaluation of peri-implant health was reported.

Although promising improvements in bone density and volume have been reported, there is a lack of clinical evidence in humans with adequate follow-up period. Our research is motivated by this gap and our objective is to further investigate this phenomenon. We propose a human case series to evaluate the implant survival and success rates when using the osseodensification technique for osteotomy preparation.

Approximately 40 implants from patients seeking treatment at the University of Oklahoma, College of Dentistry will be recruited for this study. Osteotomies will be prepared using the osseodensification technique and implants will be placed immediately after. The implants will be from a single manufacturer (Roxolid® SLA® Bone Level Tapered; Straumann®, Institut Straumann AG, Basel, Switzerland). Volumetric analysis of alveolar ridge will be studied using intra-surgical direct measurements and CBCT imaging. A custom stent will be fabricated to standardize the clinical and radiographic measurements. The stent will have positions for a Weiss modified curved bone caliper (Hu-Friedy®, Chicago, IL, USA) to be inserted at buccal and lingual and measure ridge width at~~, at~~ 2mm and 4~~, 3, 4~~ mm apical to edentulous alveolar ridge. These holes will be filled with gutta-percha and CBCTs will be taken with this stent in place, to standardize the measurements on CBCT. ~~-~~Changes in peri-implant bone density will be analyzed on standardized ~~periapical and~~ bitewing radiographs, using the ImageJ software (National Institute of Health, Bethesda, Maryland, USA). Implant stability quotient (ISQ) values will be recorded with a resonance frequency analysis system (Osstell®, Gothenburg, Sweden).

Calibrated examiners will assess implant survival and biological or restorative complications and failures. Sites will be evaluated throughout osseointegration and one year after final restoration is delivered.

1. Specific Aims

Primary Aim:
Evaluate the efficacy of osseodensification technique in regards to increase in alveolar bone volume and density at time of implant placement and retention of this volume throughout osseointegration and loading.

Secondary Aim:
Evaluate the osseodensification technique for preparation of implant osteotomy, in regards to implant stability, survival and failure rate, probing pocket depth, plaque index, bleeding index, gingival index, interproximal crestal bone level changes, biological complications (i.e. peri-implant mucositis, peri-implantitis), and restorative complications (i.e. screw loosening, porcelain fracture). These outcomes will be evaluated from the time of implant placement until 1 year after final restoration is delivered.

2. Background and Significance

Alveolar bone remodeling after tooth extraction may result in up to 50% ridge resorption within the first 3 months[xii]. This remodeling may result in inadequate bone volume for implant placement. Several methods have been designed for ridge augmentation, among which are guided bone regeneration, ridge splitting, and osteotome expansion technique. Recently the new technique of osseodensification has been proposed, by the use of non-subtracting drills, to compress the trabecular bone to periphery of the osteotomy site rather than removing it[xiii]. This simple method will expand the alveolar ridge without the additional need for bone augmentation.

Densah® burs by Versah® use the osseodensification technique to compact and auto-graft the osteotomy. These drills are designed with more than 4 lands for more precise movement and less potential chatter. The clockwise rotation can cut the bone and the counterclockwise direction will densify the bone. The cutting mode can be used in hard, trabecular bone. It is recommended by the manufacturer to avoid densifying xenografts, prepare the osteotomy 1.0 mm deeper than the final implant length, and to use this technique in areas with ≥ 2mm of trabecular bone and ≥ 1/1 trabecular/cortical bone ratio. Therefore, the ideal minimum ridge to expand is 4mm (2mm trabecular core + 1mm cortex on each side)[xiv].

Histological studies on sheep[i,ii,iii] and porcine[iv,v,vi] have shown an increase in primary stability, bone mineral density, and percentage of bone-to-implant contact with the osseodensification technique, when compared to conventional drilling. Although promising results were recorded by the above-mentioned studies, they present with multiple limitations as well. In the two studies on porcine model[iv,v], the osteotomies were performed on extracted tibial bone, which did not allow evaluation of healing over time. The osteotomies on sheep models[i,ii,iii] were either on ilium or vertebral body, with up to a 2-month follow-up. The extraoral animal model cannot be directly translated to human oral cavity and the short follow-up does not fully evaluate implant success. Furthermore, these studies did not

evaluate the effect of osseodensification on implant survival and success when loaded with restoration.

In a study**Error! Bookmark not defined.** on porcine oral alveolar bone, 80% ridge expansion was recorded immediately after osseodensification. After 4 weeks of healing, the animals were euthanized and samples were processed for histological evaluation. This was the first study to evaluate the amount of ridge expansion in atrophic mandibular ridge. Apart from being an animal model with a short follow-up, another limitation of this study is the method of recording the expansion. Transverse dimension of the ridge was measured with a periodontal probe, immediately before and after osseodensification. Measurements were only at one dimension, without three-dimensional evaluation of the change in morphology of the ridge. Also, there is no record if this bone volume is retained during osseointegration and loading.

A few human case reports[vii,viii,ix] and case series[x,xi] have reported significant ridge expansion immediately before and after osseodensification. They evaluated the expansion by measuring the ridge width at a crestal and an apical point, which again lacks an evaluation of ridge morphology in a three-dimensional view. Using the same methodology, a recent retrospective study[xi] on 28 implants found a mean expansion of 1.8±1.1mm at the crest and 0.9±0.8mm at 10mm mark apical to the crest, immediately after expansion. They reported greater expansion at narrow ridges. None of the mentioned studies report on retention of this volume over time, nor was standardization methods or evaluation of peri-implant health reported.

Although promising improvements in bone density and volume have been reported, there is a lack of clinical trial in humans with adequate follow-up period. Our research is motivated by this gap and our objective is to further investigate this phenomenon. We propose a human case series to evaluate the amount of ridge expansion and the survival and success rates of implants placed by using the osseodensification technique.

Calibrated examiners will evaluate implant survival rate, peri-implant pocket depth, plaque index, bleeding index, gingival index, interproximal crestal bone level changes on standardized ~~periapical~~ bitewing radiographs, biological and restorative complications. Volumetric analysis of alveolar ridge will be studied using cone-beam CT imaging and intra-surgical direct measurements. These outcomes will be evaluated from the time of implant placement until 1 year after final restoration is delivered.

3. Research Design and Methods

This case series will assess the efficacy for alveolar ridge expansion and change in peri-implant density when prepared by the osseodensification technique. The retention of this volume throughout osseointegration and loading will be evaluated. The changes in bone volume will be recorded by CBCT and intra-surgical direct measurements. A standardizing stent will be used to for direct measurements with a caliper. Radiopaque markers on this stent will guide the measurements on the CBCT. CBCT will be taken before and after osseodensification, and 1 year after delivery of final restoration. Standardized ~~periapical and~~ bitewing radiographs will be taken as well to evaluate marginal bone loss and peri-implant bone density. Calibrated examiners will evaluate implant survival and failure rate, ISQ value,

peri-implant pocket depth, plaque index, bleeding index, gingival index, biological and restorative complications.

All the surgical interventions and follow-up appointments will be conducted at the University of Oklahoma, Graduate Periodontics clinic. Restorative interventions will be scheduled with the restorative dentist of the patient's choosing. Approximately 10 visits are anticipated for each patient. Additional appointments may be needed depending on surgical or restorative complications that need attention or intervention. Following the completion of the study, the participants are placed on appropriate recall schedule either at the Graduate Periodontics clinic or referred to their dentist of choosing.

Informed consent will be obtained from the patients. Appropriate steps will be taken to protect collected data and de-identify it before data analysis. Identifiers will be removed and the de-identified information may be used for future research without additional informed consent from the subjects. Patient information will be protected according to the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

* *Research specific procedure*

Planned Visits:

1. Pre-screening
    a. Preliminary review of eligibility criteria*
2. Screening
    a. Confirm eligibility*
    ~~a.~~b. Informed consent*
    c. Diagnostic casts
3. Fabrication of measurement stents
    a. Fabrication of custom stent for measurement of alveolar ridge width*
        i. The stent will have positions for a Weiss modified curved bone caliper (Hu-Friedy®, Chicago, IL, USA) to be inserted at buccal and lingual, and measure ridge width at 2mm and 4mm apical to edentulous alveolar ridge.
    b. Fabrication of custom stent for measurements on CBCT*
        i. Gutta-percha will be inserted into the holes created in the measurement stent to serve as a guide for the CBCT measurements. Patient will be wearing this stent when taking each CBCT.
    c. Fabrication of custom radiographic stent*
        ~~b.~~i. A custom bite registration will be attached to the sensor holder to take standardized bitewing radiographs, using the long-cone technique.

~~3.~~4. Pre-surgical data
    a. Standardized CBCT
    b. Standardized ~~, periapical and~~ bitewing radiograph
    c. Non-standardized periapical radiograph
    ~~a.~~d. ~~s, diagnostic casts, I~~intraoral photos
    ~~b.~~e. Surgical and restorative treatment planning
    ~~c. Fabrication of surgical guide~~

~~d. Fabrication of custom stent for measurement of alveolar ridge width*~~

~~i. The stent will have positions for a Weiss modified curved bone caliper (Hu-Friedy®, Chicago, IL, USA) to be inserted at buccal and lingual, at 2, 3, 4 mm apical to edentulous alveolar ridge.~~

~~ii. Next to each of the 2, 3, 4mm insertion points, gutta-percha will be attached to serve as a guide for the CBCT measurements. Patient will be wearing this stent when taking each CBCT.~~

~~e. Fabrication of custom radiographic stent*~~

~~i. To take standardized periapical and bitewing radiographs, using the long-cone technique, a custom bite registration will be attached to the sensor holder.~~

~~4.~~5. Surgical intervention
   a. Achieve appropriate anesthesia
   b. Reflect a full thickness flap
   c. Measure alveolar ridge width by using the custom stent and bone caliper*
   d. Use the Densah® osseodensification drills (Versah®, LLC, Jackson, MI, USA), according to the manufacturer's recommendations, to create the appropriate osteotomy diameter for the planned implant size*
   e. Measure alveolar ridge width by using the custom stent and bone caliper*
   ~~e.~~f. Take standardized ~~periapical and~~ bitewing and non-standardized periapical radiographs~~, using the custom stent~~
   ~~f.~~g. Place the appropriately sized implant (Roxolid® SLA® Bone Level Tapered; Straumann®, Institut Straumann AG, Basel, Switzerland)
   ~~g. Take standardized periapical and bitewing radiographs, using the custom stent~~
   h. Measure ISQ by using Osstell Beacon (Osstell®, Gothenburg, Sweden)
   i. Hand torque the appropriately sized cover screw or healing abutment
   j. Measure alveolar ridge width by using the custom stent and bone caliper*
   k. Take standardized bitewing and non-standardized periapical radiographs
   ~~k.~~l. Use xenograft if bone grafting at the time of implant placement is indicated
   ~~l.~~m. Sutures~~s~~ the area
   ~~m.~~n. Give Appropriate post-operative instructions
   ~~n.~~o. Prescribe appropriate anti-inflammatory and antibiotics medications

~~5.~~6. 2-week follow-up after implant placement
   a. Evaluate wound closure, epithelialization, and any complications
   b. Take standardized CBCT, limited to the implant site*
   c. Perform localized prophy
   d. Take intraoral photos

~~6.~~7. 6-week follow-up after implant placement
   a. Evaluate wound closure, epithelialization, and any complications
   b. Perform localized prophy
   c. Take intraoral photos

~~7.~~8. 3-4-month follow-up after implant placement
   a. Evaluate wound closure, epithelialization, and any complications
   b. Evaluate pocket depth, plaque index, bleeding index, and gingival index
   c. Measure ISQ by using Osstell Beacon (Osstell®, Gothenburg, Sweden)
   d. Take standardized ~~periapical and~~ bitewing and non-standardized periapical

radiographs
e. Perform localized prophy
f. Take intraoral photos
g. Uncover the implant, if needed (and 2-week follow-up after uncovery)

~~8.~~9. Restoration by the restorative dentist

~~9.~~10. 2-week follow-up after implant restoration
a. Evaluate pocket depth, plaque index, bleeding index, and gingival index
b. Evaluate biological (i.e. peri-implant mucositis, peri-implantitis) and restorative complications (i.e. screw loosening, porcelain fracture)
c. Take standardized ~~periapical and~~ bitewing and non-standardized periapical radiographs
d. Perform localized prophy
e. Take intraoral photos

~~10.~~11. 1-year Follow-up after implant restoration
a. Evaluate pocket depth, plaque index, bleeding index, and gingival index
b. Evaluate biological (i.e. peri-implant mucositis, peri-implantitis) and restorative complications (i.e. screw loosening, porcelain fracture)
c. Take standardized bitewing and non-standardized periapical radiographs
~~c. Take standardized periapical and bitewing radiographs~~
d. Take standardized CBCT, limited to the implant site*
e. Perform localized prophy
f. Take intraoral photos

~~11.~~12. Data analysis
a. Evaluation of change in peri-implant bone density, using the ImageJ software (National Institute of Health, Bethesda, Maryland, USA)*
b. Statistical analysis of changes in the parameters throughout the study period*

4. Inclusion / Exclusion Criteria

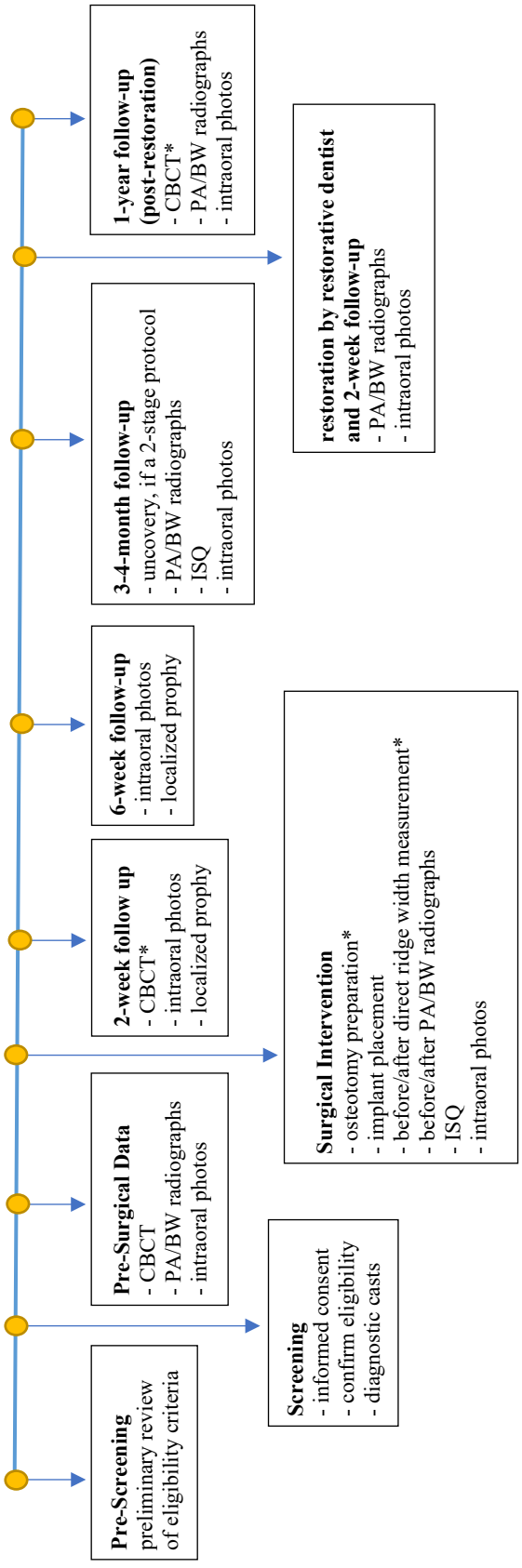
The inclusion criteria include:
1. Adult patients ≥18 years old
2. Able to understand and sign a written informed consent form and willing to fulfil all study requirements
3. Healed edentulous ridge that is planned for an implant restoration.
4. Experimental site has not been previously augmented with xenograft
5. Experimental site has at least 2 mm of cancellous bone

The exclusion criteria include:
1. Uncontrolled systemic disease
2. Currently smoking >10 cigarettes/day
3. History of head/neck radiotherapy within the past five years
4. Current use of oral bisphosphonates or history of IV bisphosphonate use
5. Pregnant, expecting to become pregnant, or lactating women
6. Presence of active periodontal disease
7. Poor oral hygiene
8. Previous history of implant failure at the site

The early termination criteria include:
1. The researcher believes that it is not in the patient's best interest to stay in the study

2. Based on the exclusion criteria, the patient becomes ineligible to participate
3. Patient's medical condition requires interventions which preclude involvement in the study (radiation therapy, chemotherapy, etc)
4. Patient does not follow study related instructions
5. The study is suspended or canceled

If subjects do not qualify or decide not to be part of this study, same treatments can be performed but without being part of this study. If subjects decide not to receive the treatments, consequences and probable outcomes will be explained.



5. Gender/Minority/Pediatric Inclusion for Research

There will no exclusion on the bases of race or gender. A translator will be provided to those that do not speak English, including Spanish speaking subjects. Patients under 18 years old will be excluded. Placement of implant is not indicated in children due to ongoing growth potential of alveolar bone at younger age.

6. Recruitment and Enrollment

This investigation will be conducted at the University of Oklahoma, College of Dentistry, Department of Graduate Periodontics. Potential participants will be selected from the new and established patients of the College of Dentistry and will be contacted by the study coordinator by telephone for information regarding the participation in the study. Subjects that may qualify based on the inclusion and exclusion criteria will be scheduled for a screening examination appointment. Patient and the intervention site will be further evaluated at the screening appointment to confirm that patient qualifies to participate in the study.

Study personnel will provide each study candidate with a written informed consent form at the screening appointment at Graduate Periodontics clinic, prior to administration of any research related procedures. The protocol, procedures and objectives of the study and the patient's role in the study will be explained to each subject and/or legal guardian/authorized representative, before obtaining consent. Subjects will be given the opportunity to read the informed consent. Study personnel will answer all questions that the subject may have and ensure that the subject understood all aspects of the study. When the subject (or legal guardian/authorized representative) understands and is willing to (have the subject) participate in the clinical trial, he/she (or the legal guardian/authorized representative) must sign and date the Institutional Review Board (IRB) approved Informed Consent Form.

A translator will be provided for the participants that do not speak English. A witness that can speak both English and the patient's language will be present and will sign the Consent Form.

7. Risks and Benefits

In preparation of the dental implant osteotomy, the osseodensification technique uses non-subtracting drills to compress the trabecular bone to periphery of the osteotomy site rather than removing it. As a result, there will be more bone available at the site for primary stability of the implant. This technique also expands the alveolar ridge and allows for placement of wider implants without the additional need for bone augmentation. By avoiding bone augmentation, this technique will not only be more cost effective, but also reduces treatment time and morbidity.

Animal studies and human case reports have reported significant ridge expansion, but there is a lack of randomized controlled clinical trial in humans. Because of this gap in knowledge, we do not know if the implants prepared with osseodensification technique, using the Densah® burs by Versah®, will be successful in the long term and if the expanded bone is retained or resorbed. A retrospective study[xi] observed 92.8% survival rate of the implants and high implant stability quotient value 6 weeks after placement. Details about marginal bone loss or status of peri-implant health or inflammation were not reported. Based on the

available data, the risk of implant failure is low when using the Densah® burs by Versah® to create the osteotomy and the risk of adverse events is similar to conventional techniques. We would like to further investigate if peri-implant health is maintained in long-term.

As with any surgery, there are risks involved, some common risks include, but are not limited to:

- Swelling and/or bruising and discomfort in the surgical area.
- Possible damage to adjacent teeth.
- Possible damage to nerves which causes numbness or altered feeling in the teeth. In rare cases the numbness is permanent.

Complications that do occur are often minor and can be treated. Every possible effort will be made to minimize the risks involved.

For volumetric assessment of the peri-implant bone, we propose to take a series of CBCT. The radiographs will be limited to the area of the implants to reduce the radiation exposure. Lead apron with thyroid collar will be used to limit radiation exposure to radiosensitive organs.

8. Statistical Methods

The biostatistics department at OUHSC will be utilized to review the data and perform statistical evaluation. Mean values, standard deviations, and medians will be calculated for clinical measurements. We will compare the bone volumetric changes before ridge expansion to different time points throughout healing. In addition, we will determine the implant survival and success rates by evaluating the probing pocket depth, bleeding index, gingival index, interproximal crestal bone level changes, biological and restorative complications of implants placed by the osseodensification technique. A fixed-effects regression model can account for correlations between repeated measures taken at each implant over time. This model can estimate a regression equation that describes the within-group changes.

Approximately 40 implants from patients seeking treatment at the University of Oklahoma, College of Dentistry will be recruited for this study. It is estimated that this sample size will provide 90% power of the test.

9. Data and Safety Monitoring Plan

The investigators will periodically audit the study records of each participant to evaluate the progress of the study, verify its accuracy and completeness, and resolve any inconsistencies in the study records. The Principal Investigator may stop the study if it is observed that the protocol or sound clinical practices are not being followed. The Principal Investigator may exclude subjects from the study if review of their records indicates violations of the protocol or if there are other reasons to believe that their inclusion would jeopardize the validity of the study. Subjects discontinued due to adverse events will not be replaced.

The investigator will make an accurate and adequate written progress reports to the IRB at appropriate intervals, not exceeding one year, and a final report to the IRB within 3 months after completion or termination of the study. The investigator will make an accurate and adequate special report to the IRB on any serious, unexpected, or life-threatening adverse

event or death occurring in relationship to the study whether regarded as study-related or not.

Any adverse event, including both observed or volunteered problems, complaints, or symptoms, are to be recorded as mild, moderate or severe as follows:

- MILD: events are usual transient, requiring no special treatment, and do not interfere with the subject's daily activities.
- MODERATE: events traditionally introduce a low level of inconvenience of concern to the subject and may interfere with daily activities, but are usually ameliorated by simple therapeutic measures.
- SEVERE: events interrupt a subject's usual daily activity and traditionally require systemic drug therapy or other treatment.

When intensity changes occur more frequently than once a day, the maximum intensity for the event should be listed. If the intensity category changes over a number of days, then these changes should be recorded separately (i.e. having distinct onset days).

The investigator will determine the relationship of the adverse event to the study test material. One of the following determinations will then be used to document the relationship of the adverse event to the study test material:

- NOT RELATED
- POSSIBLE
- PROBABLE

10. <u>Confidentiality</u>

Patient information is kept within the University of Oklahoma. Paper records will be maintained in a locked fireproof storage room and electronic records will be stored on an encrypted hard drive, which meets the University IT Security requirements. Patient records will be protected by the Health System's privacy policies and according to the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

These records will be available to copying and inspection if requested by a properly authorized employee of the Department of Health and Human Services, under the supervision of the investigator or a designated representative and in accordance with federal regulations.

The investigators understand that the office and hospital records of subjects entered in this study will be required to be available under the supervision of the investigator or a designated representative for inspection by the FDA. All subject related information provided to the FDA will be done so without subject names or other identifying information.

11. Literature Cited

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