Implant Primary Stability and Ridge Dimensional Changes Utilizing the Osseodensification Protocol

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Protocol Title:	**Implant Primary Stability and Ridge Dimensional Changes Utilizing the Osseodensification Protocol**
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Population:	Twenty patients, 22 years or older, that are not systemically compromised and nonsmoking.
Number of Sites:	One
Study Duration:	24 weeks
Subject Duration:	24 weeks

General Information

Implant stability is critical for the success of osseointegration and for immediate loading protocols. Surgical instrumentation techniques, implant macrogeometric design, bone quantity and quality all affect implant primary stability. In contrast to standard drilling for implant placement, osseodensification drilling compacts and auto-grafts bone at the osteotomy walls resulting in increase of ridge dimension, higher insertion torque, and in increased temporal bone to implant contact even in low density bone.

Background Information

Studies conducted comparing standard drilling (SD) with osseodensification drilling (OD) show significant increase in implant primary and secondary stability with OD. Through surgical compaction of bone into marrow space, OD has been found to increase the insertion torque values regardless of the type of implant surface (machined versus acid-etched implant surfaces).[1] In another study, significantly lower insertion torques have been noted when SD was utilized.[2] Additionally, through histomorphometric analysis, greater bone-to-implant contact (BIC) and bone area fraction occupancy (BAFO) has been demonstrated with OD.[2] Autologous bone chips have been recorded with greater frequency in the OD group compared to the SD group.[3] The autologous bone chips acted as nucleating surfaces promoting new bone formation resulting in greater implant stability and bone density.[3] Another study verified the infrequent presence of bone chips in the SD group compared to the commonly observed presence of bone chips in the OD groups.[4] When clockwise (CW) and counterclockwise (CCW) OD was compared, higher volume of bone chips was observed in the CCW OD group. Further research has demonstrated increase in ridge dimensions with the OD method. Specifically, narrower ridges measuring 1-3 mm at the crest demonstrated the greatest increase in width accounting for 2.83± 0.66 mm increase. Greater changed in ridge width were noted at the crest versus 10 mm from the crest.[5]

Hypothesis:

- Bone Densification protocol does not increase implant primary and secondary stability values in 0-6 wks as compared to standard drilling protocol.
- Bone Densification does not increase ridge dimensions as compared to standard drilling protocol.
- Bone densification does not increase bone volume and density as compared to standard drilling protocol.
- There is no significant difference between bone densification and standard drilling protocols.

Objectives

The aim of this study is to compare ridge dimensional changes between densification and standard drilling protocols. Additionally, primary and secondary stability of implants placed by bone densification and standard drilling protocols will be compared. A comparison of the insertion torque values (measured in Ncm) and temporal (immediate, 3, 6, and 12 weeks) implant stability quotients at osteotomies prepared with standard drilling procedures or when subjected to osseodensification surgical instrumentation will be performed. Dimensional changes will be measured before and after completion of the implant osteotomy, and compared between standard and osseodensification surgical instrumentation. Finally, volumetric changes and ridge dimensional changes will be evaluated between initial CBCT and 6 months follow-up CBCT.

Study Design

Twenty patients (we will try to balance male and female population sample if it is possible) in need to receive at least 2 dental implants in single-unit or larger span edentulous spaces will be selected. Nonsmoking and not systemically compromised patients will be selected. The following scenarios will be chosen to rehabilitate the anterior and posterior regions in this study.

- **If maxilla**:
  - split-mouth, implant insertion to replace anterior or posterior teeth: one side will receive osseodensification drilling instrumentation and the other standard drilling. Site selection is randomized by coin toss.
  - same side, adjacent teeth: Site selection will be randomized by coin toss.
- **If mandible**:
  - split-mouth or same side surgical instrumentations will be performed, as described for maxilla.

Surgical technique

Final implant (NobelReplace® Conical) and respective bur diameter for either osseodensification instrumentation and conventional drilling will be either 3.5 mm, 4.3 mm or 5.0 mm. Implant lengths will be from 8.0 up to 13.0 mm. Versah (Fig. 2) and NobelReplace ® Conical implant surgical kit (Fig. 1) present burs with identical diameter and instrumentation will be performed so last bur diameter matches with chosen implant diameter. When using Versah, counterclockwise drilling will be performed in maxilla, and in mandible clockwise drilling. Before surgery, all patients will receive intraoral scans and will be subjected to tomographic examination of the edentulous site for virtual implant planning, surgical planning, implant selection, and fabrication of a surgical guide with a mark on the buccal aspect identifying the middle of the osteotomy. The osseodensification technique will be used for comparison with conventional drilling regarding ridge dimensional changes measured with a ridge caliber (Krekler Sliding Caliper Round Gauge Dental Instrument) at

implantation (T0); and insertion torque (IT) values and implant stability quotients (ISQ) at implantation (T0), 3 (T1,) 6 (T2), and at 12 weeks (T3). ISQ will be measured with Osstell ISQ meter. Data will be evaluated with paired t-tests. After T0, patients will receive a healing abutment which will be removed and repositioned for T1, T2, and T3 evaluations. After 12 weeks patients will be prosthetically restored if insertion torque was 35 Ncm and/or ISQ values are 68. After 6 months, follow-up tomographic examination will be completed for volumetric analysis.

Study Population

Patients of the Graduate Periodontology clinic requiring implant therapy will be screened and selected to participate in the study based on the following inclusion and exclusion criteria:

Inclusion Criteria

- Adults aged 22 years and older.
- Patients who understand and agree to this study.
- Adequate Oral hygiene
- One or more edentulous spaces, which are 10 weeks or longer after extractions
- Patients requiring signature from a Legally Authorized Representative (LAR) will be eligible to participate in the study

Exclusion criteria:

- Grafted extraction socket or ridge augmentation procedure utilizing xenogenic bone graft material.
- Pregnancy as checked via medical history
- Smoking of more than 5 cigarettes/day.
- History of alcoholism or drug abuse during the last 5 years.
- Uncontrolled Hypertension or diabetes.
- Patient with malignant tumor.
- Patients on daily dose of steroids.
- Patients with history of chemotherapy or radiation for the last 12 months.

Study Procedures

Forty implants will be paired and placed in 20 patients using OsseoDensification (OD) protocol as test, and using standard drilling (SD) protocol as control. Sites will be randomly assigned in comparative patients prior to flap reflection.

Primary Outcome Measures:

All ridge dimensions will be measured immediately after flap reflection and after final osteotomy preparation: at crest, 5 mm and 10 mm apical from the crest. A surgical guide will be fabricated for the implant surgery which will also be marked on the buccal indicating the middle of the osteotomy and the ridge dimensions will be measured using the mark as a standard reference. The measurements will be completed the day of surgery only.

Secondary Outcome Measures:

1. All implants' primary stability will be measured by insertion torque values and by resonance frequency analysis (ISQ) immediately after implant placement (T0). Resonance frequency analysis will be measured at three weeks (T1), six weeks (T2), and twelve weeks (T3) post implant placement.
2. At 6 months all patients with receive CBCT for volumetric analysis.

Digital radiographs (periapical radiographs PA) will be taken prior to implant placement, post placement, and at 6 weeks. Cone beam computer tomography (CBCT) will be obtained prior to implant placement for implant planning and fabrication of a surgical guide, and at 6 months post-implantation for volumetric analysis.

In any incidence of less than 1 mm buccal plate thickness has resulted after bone preparation, bone grafting will be done post implant placement and complete implant coverage will be achieved for two-stage healing protocol. Cases requiring bone grafting will be excluded from the CBCT analysis at 6 months and from 3-week (T1) and 6-week (T2) ISQ readings. Cases requiring two-stage healing will also be excluded from 3-week (T1) and 6-week (T2) ISQ readings, but will be included in 12-week (T3) ISQ readings at second stage surgery.

At 12 weeks all patients will receive dental restorations. Implants' restorative phase will be initiated at any time resonance frequency analysis become equal or more than ISQ 68.

Why 3 weeks, 6 weeks, and 12 weeks ISQ measurements:

The lowest value of implant stability is at three weeks after implant placement and it is most pronounced in type IV bone. (Barewal et al, Int. JOMI 2003. Sep-Oct; 18 (5) 641-51)
Implant Stability increases greatly between week 0 and week 6 and showed slow increase between week 6 and 6 months. (Jae-Min Kim et al, J. Adv. Prosthodont 2009. March; 1 (1) 31-36).
Implant stability starts declining after first week and reach its lowest value at three week to start increasing in the fourth week. (Markovic et al, OOOOE 2011. November; 112, (5) 557-63) ISQ is obtained at 12 weeks to ensure implant stability prior to having implants restored.

Data and Safety Monitoring

Implant therapy, either with standard drilling or osseodensification, has some inherent possible complications such as post-operative discomfort, infection, pain, implant failure, swelling and bleeding. All clinical protocols currently in effect in the Graduate Periodontology clinic will be followed in order to minimize these risks. Currently, all patients, undergoing implant therapy at the Graduate Periodontology, receive antibiotics prophylactically, pain medications for management of pain and discomfort, steroids as needed to help with edema, and chlorhexidine mouthrinse to maintain the surgical sites clean as possible by reducing the bacterial load. In the event of implant failure, the implant will be removed, and the site will be grafted for future repeat of the implant therapy at the specific area.

Statistics & Computer tomography analysis

Data will be evaluated with paired T-tests. The total number of subjects enrolled in the study will be twenty and all eligible subjects will be provided with the opportunity to participate. Termination of the trial will be considered only when unexplained implant failures are observed, excluding implant failures associated with systemic conditions, infections or other well documented contributing factors in the literature.

1. **2-D Linear CBCT analysis:** we will superimpose the pre- and post- surgical CBCTs. Then determine a cross-sectional plane that goes through the long axis of the placed implant and is as perpendicular as possible to the buccal/lingual walls for consistent reproduction. We will use the selected cross-sectional plane to measure the overall buccolingual width of the ridge and assess any ridge dimensional changes. The software automatically finds the best fit for superimposition of the CBCT scan which allows for accurate reproducible measurements.
2. **3-D Volumetric CBCT analysis:** Superimposition of the CBCTs, as previously explained, will be completed first. A box will be used as the region of interest which will encompass the implant and the adjacent cortical plates. The shape of the box will be kept the same for consistency. The segmented ridge volume within the box will be used to get actual volumetric differences. The term segmentation is a radiology term and refers to the inclusion of voxels (in this case, alveolar process) that falls within a specified range of CBCT gray scale values determined by an operator.

Ethics

At the time of initial consult, all eligible subjects will be provided with the opportunity to decide if they want to participate in the study. A description will be provided as well as all that will be required by

the patient. If they agree to participate, a written consent form will be obtained, and the subject will be provided with a copy of the signed consent form. All consent forms will be kept by the Primary Investigator in a locked and secured place.

Data handling and record keeping

All participants will be identified by a number and all identifying information will be kept confidential. All the data will be collected in a spreadsheet (excel document) under the participant's specific number. Only the Primary Investigator will have access to the identifiable information linked to the subject's specific number which will be kept in a locked and secured cabinet in room 6477 in the Department of Periodontics and Dental Hygiene.

Quality control and assurance

The primary investigator and all co-investigators participating in the study will be calibrated in order to ensure proper use of the Ostell ISQ meter and Mitutoyo Digimatic Caliper. The Ostell ISQ meter is a device that is used in everyday clinical practice and does not require special training. The Mitutoyo Digimatic Caliper is a digital caliper that measures ridge dimensions with accuracy of two numbers after the decimal point and does not require special training. The surgical techniques and procedures are used on a daily basis and follow all standards of care thus, no special training or calibration is necessary.

Publication Plan

All results from our site will be combined and published in a peer review journal as part of a multicenter study.

ATTACHMENTS

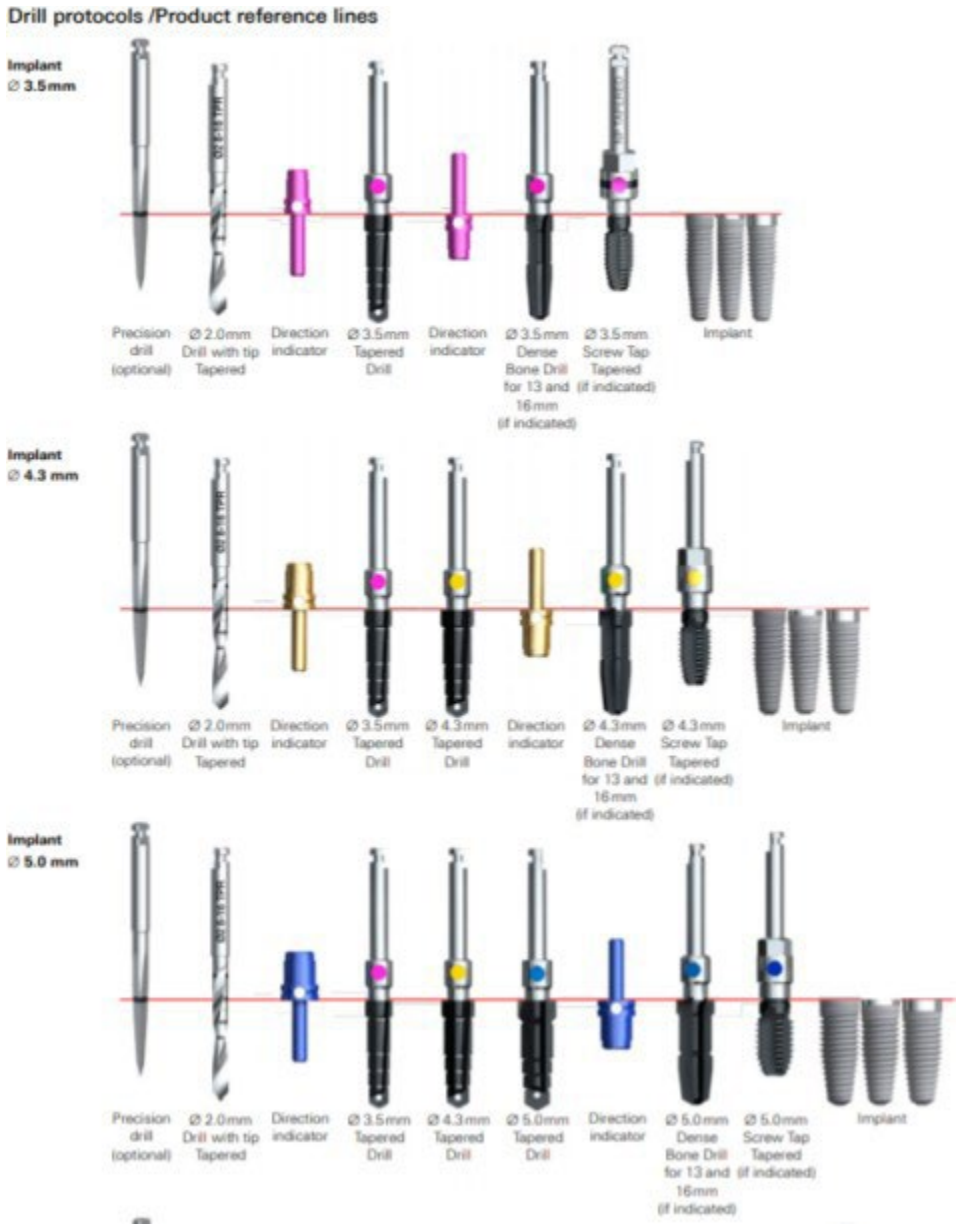

Figure 1: Burs from the NobelReplace® Conical implant surgical kit. The corresponding 3.5, 4.3 or 5 mm diameter bur from Versah kit will be used for sites where osseodensification will be performed.

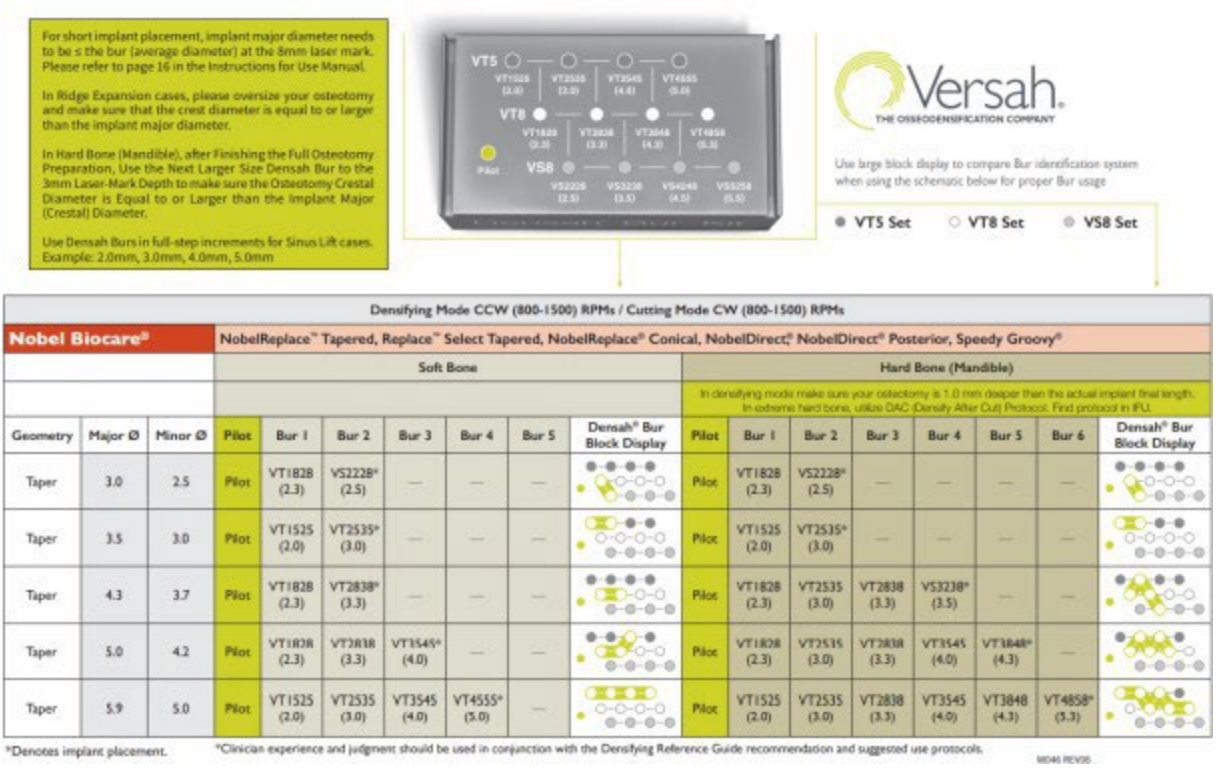

Figure 2: Versah burs to be used per implant diameter for soft and hard bone.

Products to be used in this project.

Product	Quantity	Check if Requested from Versa h
Osseodensification drills - kit	4	X
Osstell ISQ	1	X
Krekler Sliding Caliper Round Gauge Dental Instrument	1	
NobelReplace® Conical implants and healing abutments	40	
Computed Tomographic scans	20	

PTFE 4.0	20	
Lidocaine	1 package (50)	

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