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The impact of mucosal phenotype on marginal bone levels around tissue level implants: A prospective controlled trial

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The Influence of Mucosa Tissue Thickness on Marginal Bone Loss of Implants with Smooth Collars: A Prospective Controlled Trial

Principal Investigators:

Hom-Lay Wang, DDS, MSD, PhD

Co-Investigators:

Hsun-Liang Chan, DDS, MS

Gustavo Mendonça, DDS, MSc, PhD

Study Coordinator:

Alice Ou, RDH, MS

Study Site:

Graduate Periodontics

Department of Periodontics and Oral Medicine

University of Michigan School of Dentistry

1011 N. University Ave., Ann Arbor, MI 48109-1078

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Introductory Statement

The influence of mucosal thickness was shown to be related to marginal bone stability around implants. Several investigators suggested that a minimum of 2 mm peri-implant mucosa thickness was required to prevent peri-implant crestal bone loss on rough surface implants.[1, 2] However, other factors such as implant surfaces may also play a significant role on peri-implant crestal bone level. While previous studies showed the advantages of completely rough implants from machined surface implants (such as faster healing periods and lesser crestal bone loss), its comparable survival rate has been documented.[3] Whether an initial two millimeters mucosal thickness is needed to obtain marginal bone stability around implants with different types of surfaces is still unknown.

General Investigational Plan

A single center, prospective controlled clinical trial is planned to investigate the effect of mucosa tissue thickness upon implant marginal bone changes on implant with smooth collar. Twenty eight adult patients who fulfill the inclusion criteria will be divided into 2 groups based upon the mucosa thickness (<2 mm and ≥2 mm). A signed written informed consent will be obtained from all subjects. Subjects will not be screened or treated until an informed consent has been obtained. Patient information will be protected according to the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

The enrolled patients will receive implants with polished collar. Implants will be restored at 4 (±1) months after placement. Outcome analyses will be performed until 1 (±1 month) year after loading and clinical and radiographic parameters will be evaluated to compare clinical outcomes between groups. The primary outcome is implant marginal bone loss and probing depth from clinical and radiographic measurements.

Study Protocol

I. Introduction

The thickness of the gingiva (i.e. gingival biotype) varies between subjects. In 1969, Ochsenbein and Ross proposed two main types of gingival biotype ("pronounced scalloped" and "flat") and their relationship with the contour of the osseous crest.[4] Subjects belong to pronounced scalloped biotype have thinner soft buccal tissues and more advanced soft tissue recession than subjects who had the flat biotype.[5] Claffey & Shanley (1986) defined thin tissue biotype as a gingival thickness < 1.5 mm and thick tissue biotype as tissue having thickness ≥ 2 mm.[6]

Several pre-clinical studies have examined how mucosal thickness affects marginal bone loss around implants.[1, 7] Abrahamsson et al. (1996) showed that sites with thin mucosa had an angulated pattern bone defects, whereas sites with an even pattern of the alveolar crest, the adjacent mucosa was consistently thick.[7] Another study by Berglundh and Lindhe (1996) suggested that certain width of the peri-implant mucosa is required to protect osseointegration.[1]

They showed when ridge mucosa was thin (≤ 2 mm), more bone resorption and angular bony defect were noted.[1]

A human prospective clinical trial reported that tissue/mucosa thickness may affect crestal bone stability around implants.[2] Implants with a thick tissue biotype (>2 mm) had significantly less bone loss when compared to implants with thin tissue thickness (≤2 mm). Implants with initially thin tissue had bone loss up to 1.45 mm that occurred within the first year of function. Whereas thick tissues only had 0.2 mm bone loss that was noted.[2] It was observed that thick mucosa formed an epithelial – connective tissue attachment to the titanium surface that protected and preserved the osseointegration. If this soft tissue dimension is not achieved, bone resorption might occur to establish a biological width of the epithelial – connective tissue attachment. Thus, it is suggested that a certain minimum width of peri-implant mucosa is required.[7]

Recently, researches have shown implant surfaces may play a critical role for long-term implant success.[8] Bacteria pathogens have been proposed as the main etiology factor of peri-implantitis leading to implant failure.[9] Therefore, implant design that can help reduce plaque retention is important to facilitate good oral hygiene. Originally, smooth/polished collar implants were developed because it is easier to clean and harbors less plaque than rough surface implant.[10] Concurrently, this has been changed to predominantly rough-coated surface to enhance osseointegration as well as a shortened waiting time.[11] However, a study that compared the implant survival rate of smooth- and rough-surfaced implants showed similar survival rate (94%).[3]

To date, the influence of mucosa tissue thickness upon implant crestal bone loss on implant with smooth surface collar has not been determined yet. Hence, the aim of this study is to test the effect of mucosa tissue thickness upon implant marginal bone changes on implant with smooth collars.

II. Objectives

The primary objective of this study is to compare the amount of implant marginal bone loss radiographically and probing depth in between thin and thick mucosa group that will receive a machined collar implant.

III. Treatment

A. Patient selection

The use of human subjects in this project will be submitted for approval by the Institutional Review Board (IRB) at the University of Michigan prior to conducting the study. Patients requiring an implant to replace a missing tooth in the premolar or 1st molar area will be recruited for this prospective controlled trial. A total of up to 40 subjects will be recruited with the goal of enrolling a minimum of 28 subjects divided into 2 groups (14 in each group) based upon the mucosa thickness (<2 mm and ≥2 mm). A prospective design will be applied and implants with a polished collar will be placed.*

* Biohorizons Tapered Internal Implant, Laser-Lok, RBT

Potential patients will be carefully screened according to the inclusion and exclusion criteria as follows:

Inclusion Criteria
• Male or Female • Aged ≥18 • In need of one dental implant in the Maxillary or Mandibular area, premolar, or 1st molar tooth • Natural adjacent teeth • Bone height of ≥10mm • Bone width of ≥5mm • Good oral hygiene • Stable periodontium • Willingness to fulfill all study requirements
Exclusion Criteria
• Need bone augmentation • Need one dental implant that is anterior, a 2nd or 3rd molar tooth • Current smoker or quit smoking less than one year • Pregnant or plan to get pregnant • Uncontrolled diabetes (HbA1C > 7) • Medical conditions that may influence the outcome of the study (neurologic or psychiatric disorders, systemic infections) • Current use of oral bisphosphonates • History of IV bisphosphonates • History of radiation therapy in the head and neck area within 4 years • Poor oral hygiene (plaque score more than 40% based on O'Leary plaque score) • Once a group has been filled, subjects who meet the criteria of that group will be excluded

B. Clinical assessments

Clinical measurements (probing depth, clinical attachment level and bleeding on probing) will be recorded using a UNC (University of North Carolina) manual probe. These measurements will be taken at two weeks post-operatory (V4), one month post-operatory (V5), crown impression (V6), crown restoration (V7), 6 months (V8), and 12 months (V9) after crown restoration. A tension-free caliper will be used to measure mucosa thickness at the time of surgery. Clinical photographs will be taken at each appointment as well as standardized radiographs. In addition, bone sounding procedure under local anesthesia will be performed on the mid buccal and lingual side of the implant sites at 12 month follow-up to assess the level of the underlying bone. Subjects will also be receiving a cleaning at no charge to them at their 6 and 12 month visits.

C. Radiographic assessment

Intraoral radiographs will be taken using a paralleling technique with a Rinn-type film holder at the initial appointment (V1), implant placement (V3), Crown impression (V6), crown delivery (V7), and at 6 (V8) and 12 (V9) months after crown restoration. The CBCT scan will be taken at the pre-implant surgery visit (V2) and the 12 month follow up (V9). Custom-made stents will be fabricated to ensure reproducibility and standardized radiographs. All assessments will be made by one examiner. Intra-examiner calibration will be performed.

D. Surgical protocol

Preliminary alginate impressions will be taken at the screening appointment for the purpose of making study models to then be able to fabricate a reference stent and surgical guide. On the

implant surgery visitvital signs will be taken. Local anesthesia will be performed by using local infiltration technique with 2% Lidocaine with 1:100k epinephrine or 1:50k epinephrine. Intrasulcular and crestal incision design will be made along the crest of the ridge, bisecting the existing zone of keratinized mucosa. Full-thickness flaps are raised on the buccal and lingual/palatal side up to or slightly beyond the level of the mucogingival junction, exposing the alveolar ridge of the implant surgical sites. Once the flaps are reflected and the bone is prepared, a surgical guide will be inserted and a series of drills are used to prepare the osteotomy site incrementally. All implants will be placed according to the manufacturer's protocol (Biohorizons Tapered Internal Implant, Laser-Lok, RBT) and the rough-smooth junction will be placed to the bone crest. The buccal mucosal thickness will be measured at different levels. Implants with 9-13 mm length and 3-5 mm width will be used. After implant placement a healing abutment will be connected and interrupted sutures will be placed to close the flaps. After suturing, standardized radiographs will be obtained. Other radiographs will be taken during the surgery to check implant angulation, these will not be standardized. The surgery is being done as part of standard of care. Subjects will be instructed to rinse with warm salt water once a day every day for two weeks. All subjects will be prescribed 500mg of amoxicillin to take 3 times a day for ten days. If the subject is allergic to Amoxicillin, they will be prescribed 250 mg of Zithromax 6 tablets total /sig. 2 tablets the 1st day and Q.D. (1 x per day) until gone. In addition, the subject will be prescribed 600 mg of ibuprofen, taken as needed, for pain control. The sutures will be removed in 2 weeks.

E. Prosthodontic protocol

All patients will have two (possibly more) visits to receive the permanent restoration. The crown impression will be performed 4(±1) months after implant placement and the final restoration 3+ weeks after that. Custom abutment and screw retained implant crown will be used. Proper occlusion, crown contours, and crown margins will be confirmed in the final restoration. The subject may have to return for more than one visit for the final restoration. This is to ensure the color, contours, and margins are correct.

F. Schedule of events

Event	Screening	CBCT visit	Implant Surgery	2 weeks PO	1 month PO	Crown impression	Crown delivery	6m	12m
Visit number	V1	V2	V3	V4	V5	V6	V7	V8	V9
Timeline			Baseline (BL)	2 (±1 day) wks	1 (± 1 wks) months	4 (±1) M after BL	3+ weeks after crown impression	6(±1)M after crown delivery	12(±1)M after crown delivery
Informed consent	SIGN		X	X	X	X	X	X	X
Medical history	X		X	X	X	X	X	X	X
Adverse Events			X	X	X	X	X	X	X
Vitals (BP and HR)	X		X						
Dental Exam	X								
Impressions	X Alginate					X			
CBCT Scan		X							X
Implant placement			X						
Clinical measurements				X	X	X	X	X	X
Periapical Radiograph *S (standardized)	X(S)		X and X(S)			X	X(S)	X(S)	X(S)
Clinical photographs	X		X	X			X	X	X
Cleaning								X	X
Patient compensation payment									X

IV. Outcome analysis

The measurement variables and correspondent measurement time points are summarized in the Table.

Measurement time	***Measurements***
Clinical outcomes	
Baseline (V3)	Mucosa thickness
At two weeks post-operatory (V4), one month post-operatory (V5), crown impression (V6), and at crown delivery (V7),	Probing depth, bleeding on probing, clinical attachment level
6 (V8) and 12m (V9) after crown placement	Probing depth, bleeding on probing, clinical attachment level
Radiographic outcome	
At screening (V1), implant/surgery baseline (V3), crown impression (V6), crown delivery (V7), 6m (V8), and 12m (V9) after crown placement.	Marginal bone level

V. Statistical analyses

Sample size

In this present study, test significance level (α) that is used is 5% and the power analysis is 80%.

Sample size for each group is calculated using a computer program with two sided equivalence

for difference of proportions in two group design.[†] According to the previous study[2] mean bone loss of implant placed in thin tissue biotype (μ_1) was 1.450 mm and mean bone loss of implant placed in thick tissue biotype (μ_2) was 0.170 mm. The difference in means in between two groups ($\mu_1 - \mu_2$) was 1.280 mm and common standard deviation was (σ) was 1.160 mm. Therefore, the sample (n) needed in each group in this present study is 14 patients.

Hypothesis

Null hypothesis is mucosa thickness does not affect implant marginal bone loss on implant with smooth collar.

Statistical analysis

One way ANOVA will be used to detect any differences in between groups and student *t* test analysis will be conducted to assess mean differences between the groups.

[†]nQuery Advisor®, version 7.0., Los Angeles; Statistical Solutions Inc., 2007

VI. Experimental flow chart:

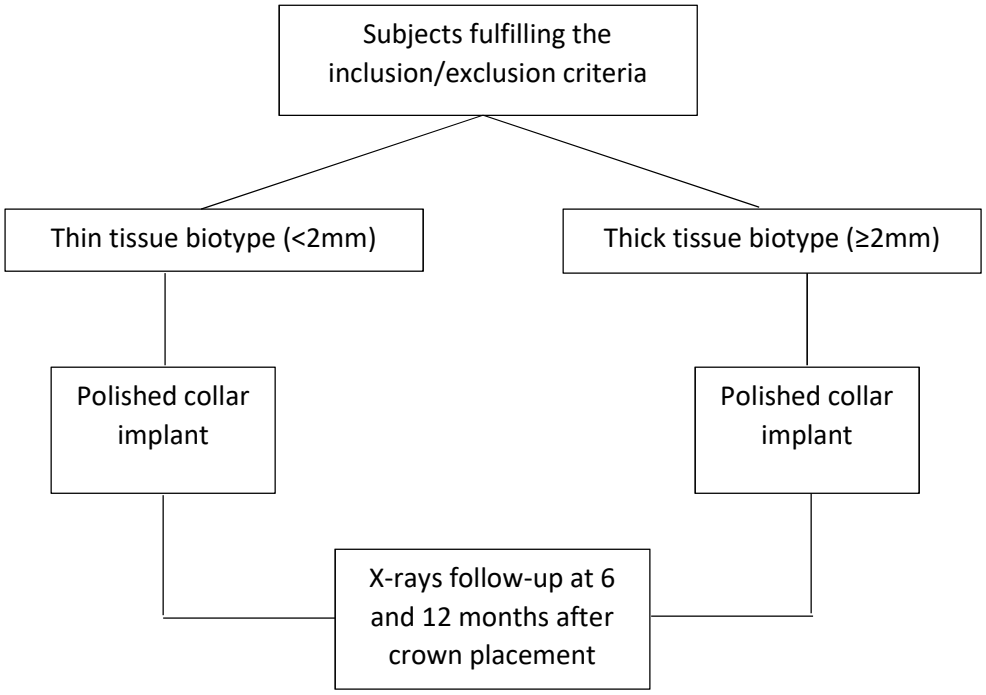

Fig. 1 Schematic drawing of the study design

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