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A Prospective Randomized Clinical Trial to Assess the Performance of Microtextured Dental Implants With or Without a Machined Collar- 1 Year Results

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A PROSPECTIVE RANDOMIZED CLINICAL TRIAL TO ASSESS THE PERFORMANCE OF MICROTEXTURED DENTAL IMPLANTS WITH OR WITHOUT A MACHINED COLLAR – 1 YEAR RESULTS

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ABSTRACT

Aim: To assess the performance of microtextured dental implants with or without a machined collar at one year after placement. Material and Methods: Fifty-eight patients received dental implant therapy to restore missing teeth in one area of the maxilla or mandible at the UAB Department of Graduate Periodontology. Residents in the program placed microtextured implants with a microtextured collar with microgrooves (test group) and microtextured implants with a machined collar (control group). Sites were randomized to the test group or control group. Study visit protocol was followed and implants were restored by off-site dentists. Sixty-nine (69) implants were assessed at one year for a final study visit. The primary outcome was to determine the difference between crestal bone levels in the test versus the control group implants as measured by differences in radiographic crestal bone heights at baseline and one year. Data collected consisted of periapical radiographs and clinical photographs that were taken at specific time points throughout the study period. Statistical analyses using individual t-tests and ANOVA were performed to analyze the data. Results: Statistical analysis determined that a significant difference in marginal bone loss was present between the roughened collar (0.65±0.43) and machined collar (1.20±0.62) MTX implants at one year ($p<0.0001$). The mean differences of bone loss were (0.35±0.56) and (0.82±0.70), respectively ($p=0.0039$). Secondary analysis assessed implant survival, site-specific differences, pa-

tient-related factors, and esthetic considerations. The only significant secondary variable found associated with marginal bone loss was implant diameter (p=0.0194). This study also assessed implant placement by novice surgeons to determine if implant design characteristics had an affect. Conclusion: Microtextured implants with a roughened collar with microgrooves had less crestal bone loss at one year than ones with a machined collar. More studies with larger sample sizes should be performed to determine the significance of other local and systemic factors on MTX implants and crestal bone loss.

Keywords: microtextured surface, dental implants, collar, crestal bone loss, marginal bone loss

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TABLE OF CONTENTS

Page

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

ANOVA	Analysis of variance
BIA	Bone-to-Implant apposition
BIC	Bone-to-Implant contact
CCTS	Center for Clinical and Translational Science
HA	Hydroxyapatite
HbA1c	Glycated Hemoglobin
IA	Implant-Abutment
ICC	Intraclass Correlation Coefficient
ITI	International Team for Implantology
MTX	Microtextured
NHANES III	Third National Health and Nutrition Examination Survey
SLA	Sandblasted and acid-etched
TSV	Tapered, screw-vent
TSVT	Tapered, screw-vent textured
UAB	University of Alabama at Birmingham

INTRODUCTION

Within the past few decades, dental implants have become the gold standard for the replacement of single or multiple teeth to restore function and esthetics. Since the development of the dental implant, its design has seen constant evolution in order to enhance implant osseointegration, soft and hard tissue compatibility, biomechanical stability, and implant survival and success rates. In the 1980's, Albrektsson established criteria for successful integration of dental implants [1]. Since the adoption of Albrektsson's success criteria, implant design has evolved with the intent of minimizing bone loss around implants. The modalities for achieving this goal have differed between implant manufacturers. Some companies focus on the implant thread design, which can range in sharpness and thread depth depending on the self-tapping or non-cutting nature. Implant platform-switching, in which the prosthetic platform is set more internally than the outer diameter of the implant, has also been employed to prevent further crestal bone loss. Chrcanovic et al. shows in a recent meta-analysis that platform-switched implants maintain statistically better marginal bone levels than their platform-matched counterparts [2].

Implant body design may also influence overall stability and osseointegration. A tapered implant body, which allows for a "wedging" effect into the bone, may result in better initial stability[3]. Additional mechanical retention features include vent holes and surface textures. While dental implants initially had a screw-shaped design with a machined titanium surface with micro-irregularities, over time this has been substituted with

a roughened, threaded surface to improve osteoblast compatibility and implant surface area[4-6]. The majority of these implant designs were initially designed with a machined collar. This smooth machined collar was established to prevent microbial plaque accumulation and facilitate its removal in the gingival sulcus area, while the roughened implant body allowed for increased bone-to-implant contact during healing.

Success Criteria for Dental Implants

Albrektsson's success criteria were derived for implants that were predominantly machined in their entirety. Implant success included implants with initial bone loss extending to the first thread (1.0-1.5mm from the collar) of the implant during the first year of function and no more than 0.2mm of bone loss per year afterwards [1]. After one year, it was thought that bone levels would remain fairly stable over time unless affected by peri-implant inflammatory disease or other destructive trauma. This initial bone loss was thought to occur due to poorer osteocompatibility with the machined collar or the micromovement present at the implant-abutment interface[7, 8]. With advancements in technologies and evolving implant designs, however, these criteria may be outdated, and it may be no longer acceptable to expect this much bone loss around implants. In 2012, Papaspyridakos et al. reviewed success criteria for dental implants. He found that the absence of pain, no mobility, no radiolucencies, and bone loss less than 1.5mm were the most common indicators of implant-level success. Patient comfort with esthetics and prosthetic function in the absence of bleeding and suppuration were also indicators of success at five years[9]. Progressive bone loss of any amount is no longer considered successful. Though some crestal bone loss may still be seen around the top collar of the

implant due to micromotion at the implant-abutment (IA) interface, the surface characteristics of the implant collar have now changed expectations that bone levels can be maintained on the collar of the implant and should not extend to the first thread[5, 10, 11].

It has been hypothesized that the initial crestal bone loss may occur naturally as a form of "biologic width" between the abutment-implant interface and the attachment level to bone, mimicking the biologic width around natural teeth. Cochran examined the hypothesis that rough collars interfere with biologic width and cleaning procedures. In a study comparing rough collar and smooth collar implants, he suggested that the recent prevalence in peri-implantitis may be linked to the inability to prevent plaque buildup on rough collars[12]. However, he found that in a canine model, the connective tissue attachments around all implants were similar, but the junctional epithelium and biologic width measurements were statistically greater for the machined collar implants. He also found that there was slightly more bone and mature collagen formation on the rough collar implants, though inflammation scores were about the same[12]. There is still, however, a small amount of bone loss at the crest regardless of collar design, which may indicate that a minimum distance is needed from the implant-abutment (IA) interface to the level of the alveolar bone. King et al. investigated the need for a minimum distance between the bone level and the IA interface and if this distance was dependent on the size of the IA interface and/or the micromotion at this junction. The investigators found that the size of the gap at the IA interface did not affect crestal bone loss, but micromotion at the IA interface lead to significantly more bone loss compared to implants that had their interfaces laser-welded together[7].

The finding in the above mentioned study reinforces the attractiveness of platform-switched implants. In these implants, the IA interface has been moved laterally, allowing for more coronal bone levels around the outside margin of the implant since the micromotion at the IA interface is further away. Trammell et al. found that twenty-five platform-switched implants lost significantly less crestal bone than their conventional counterparts (0.99 +/-0.53 mm versus 1.19 +/- 0.58 mm)[13]. Atieh et al. reviewed ten studies including 1,239 implants and found that platform-switched implants had significantly less marginal bone loss than platform-matched implants. In that review, platform-switched implants lost between 0.055mm to 0.99mm, and the platform-matched implants lost 0.19 to 1.67mm of bone. The least crestal bone loss was found in groups in which the platform diameter was at least 0.4mm smaller than the implant diameter[14].

Another modifiable factor to improve bone maintenance around implants addresses bone-to-implant contact (BIC) through implant surface texturing. For the past two decades, different surface characteristics have been utilized on titanium implants in order to increase the amount of BIC, therefore maintaining better osseointegration. Additive surfaces have been created such as hydroxyapatite (HA) and titanium plasma spray. Subtractive surfaces including sandblasted, acid-etched (SLA) treatments and anodizing/oxidizing surfaces are also utilized. Zechner et al. found that when comparing osseointegration of HA-coated implants, machined-surface implants, and anodized titanium implants, that the HA-coated and anodized ones had much higher BIC than the machined surfaces [4]. However, it was also found that the HA-coated implants demonstrated slightly more crestal bone resorption, possibly because once the bacteria affect HA surface treatments, depending on the crystalline structure of the additive HA, the whole

coating is affected. If this is true, then a subtractive roughened surface would be more preferable to a chemically modified additive surface so that if initiated, a disease process affecting the implant surface could be arrested. Much research has been done in attempt to determine which surface treatments achieve the best osseointegration. Furthermore, some studies also examine what collar design allows the surface treatment to be maximized in maintaining the vulnerable crestal bone levels.

In an in vivo study, Botos et al. compared the effects of a laser-microtextured collar to those with a machined collar on crestal bone loss around prosthetically loaded and unloaded implants [15]. Laser-microtextured implants placed in the mandible exhibited shallower probing depths and less crestal bone loss than machined collar implants in both loaded and unloaded groups. This study also concluded that machined collars are not necessary to prevent plaque accumulation at the collar as the roughened collar implants did not increase plaque or bleeding indices [15]. Similarly, Weiner et al. demonstrated in a canine model that laser-microtextured collars hindered epithelial downgrowth, allowed for a connective tissue attachment in the laser-ablated grooves, and showed a better quality of remodeled bone near the implant-bone interface [16].

Valderrama et al. found that in a canine model chemically modified and acid-etched implants without a machined collar actually gained an average of 0.11mm of bone in one year as compared to those with machine-polished collars that lost an average of 1.00mm [11]. This gain was attributed to enhanced osseointegration from the chemically modified surface as well as the advantage of the acid-etched, “roughened” surface of the collar that provided the suitable characteristics for bone growth to the coronal portion of the implant [11].

Additional studies have focused solely on the collar design of implants as it relates to crestal bone loss [11, 15-18]. Stein et al. examined machined collars, roughened collars, straight collars, and stepped collars for differences in marginal bone loss at five years. It was found that though stepped collars had more crestal bone loss than straight collars, and roughened collars maintained crestal bone levels better than machined collars. Over five years, roughened collar implants lost an average of 0.19mm and had a final distance of 0.61mm from the crest to the IA interface, while the machine collared implant lost 0.36mm bone to have a final bone level of 1.55mm from the IA interface[5]. Alomrani et al. examined crestal bone loss on fully sandblasted and acid-etched (SLA) implants and machined collar implants in a canine model. The non-submerged SLA implants had less crestal bone loss and also had a shorter distance from the microgap at the IA interface to the bone-implant contact in comparison to the machined collar implants[17]. Similarly, Schwartz et al. found in a canine model that sandblasted, acid-etched implants with roughened collars had less crestal bone loss than those with a machined collar after 12 weeks healing [18].

Shin and colleagues evaluated the marginal bone loss of three different implant collars (a machined collar, a roughened collar, and a roughened collar with microgrooves) radiographically at one year. The study showed that the machined collar and roughened collar implants had comparable marginal bone loss levels of .76mm and 1.32mm, respectively. However, the roughened collar with microgrooves group had significantly less marginal bone loss with an average of 0.18mm. These authors suggested that this particular implant design might have the best resistance to marginal bone loss with functional loading[10].

Microtextured Surface Implants

Previous literature has compared multiple surface designs and treatments such as SLA and laser-ablated surfaces to the machined collar[11, 17, 18]; however, to our knowledge, no study has compared the microtextured (MTX) surface technology in maintaining crestal bone levels around implants with a full MTX treatment versus implants with MTX treatment and machined collar. The manufacturer of the implants used in this study has created a microtextured, tapered, screw-vent (TSV) implant that has been grit-blasted with hydroxyapatite particles to create a roughened surface. The MTX surface has no other coating on its titanium surface. After surface blasting, the implant is washed in non-etching acid and distilled water baths to ensure that there is no residue remaining on the implant. According to the manufacturer, this process does not weaken the titanium nor does it affect the implant threads, thereby allowing the sharp, self –tapping effects to remain present[19]. This MTX surface has been shown to have a greater bone-to-implant apposition (BIA) than the traditional machined surface [6]. In a human study, Trisi et al. found that MTX surfaces had an average BIA of 72% as compared to machined surfaces that had a BIA of 38% [6]. Mazor et al. also showed that MTX surfaces had a more uniform micro-pitted surface than the SLA control group, to which he attributed the 100% success rate of these implants after 4 years [20].

In light of the previous literature review, the current study focuses on evaluating the current MTX implant design to aid in maintaining crestal bone levels. Two commercially available implant designs were compared in this analysis: a full-length roughened surface with microgrooves at the collar and the traditional MTX tapered screw vent implant with a machined collar. The investigation seeks to determine the effects, if any, of

this implant collar design enhancement. The primary purpose of this study is to assess the maintenance of marginal bone levels around these implants at one year. Secondary outcomes of early implant failure, implant esthetics, and clinical experience will also be evaluated.

OBJECTIVES AND SPECIFIC AIMS

Since Albrektsson's criteria for implant success predict the majority of the crestal bone loss to take place during the first year, this study protocol dictated re-evaluation of radiographic implant bone levels at one year after implant placement. The goal of the alteration in implant collar design is to minimize or prevent initial marginal bone loss, thereby increasing the long-term success rate of this type of implant. The purpose of this study is to assess the crestal bone changes of microtextured (MTX) dental implants with and without a machined collar at one year after placement.

1. To assess the radiographic crestal bone loss in microtextured implants without a machined collar as compared to those with a machined collar

2. To assess differences in crestal bone height between the two implant types in terms of site specificity, prosthetic loading conditions, and implant diameter as well as patient factors including smoking, diabetes, and history of periodontal disease

3. To evaluate the survival of both types of implants placed by novice implant surgeons (specialty residents in their training program)

4. To determine the esthetic outcomes of microtextured implants with or without a machined collar

The hypothesis for this study is that fully textured dental implants will result in less crestal bone resorption than the microtextured implant with a machined collar during initial healing.

MATERIALS AND METHODS

This study was performed at the University of Alabama at Birmingham (UAB) School of Dentistry in the Periodontology Clinic. The participants were enrolled between May 2012 and January 2014. All follow-up visits were completed by January 2015. This study was reviewed and approved by the Institutional review board of UAB (F110412003).

Study Design

This study was a prospective, randomized, controlled study comparing bone healing and osseointegration between two microtextured implants made by the same manufacturer. The "Control" implant consists of a two-piece, tapered screw-vent dental implant with surface texturing and a machined collar. This MTX-TSV implant has a 1.0mm polished collar above a 1.5mm MTX surface followed by the implant threads with MTX technology. The "Test" implant is a two-piece, tapered screw-vent dental implant with a fully microtextured surface. The test MTX-TSVT implant has a roughened surface to the top of the collar with the first 0.5mm of MTX surface followed by 1.8mm fully textured microgrooves. The implant threads with MTX technology are the same on the apical portion of both implant designs. See Figure 1 for the differences in collar design.

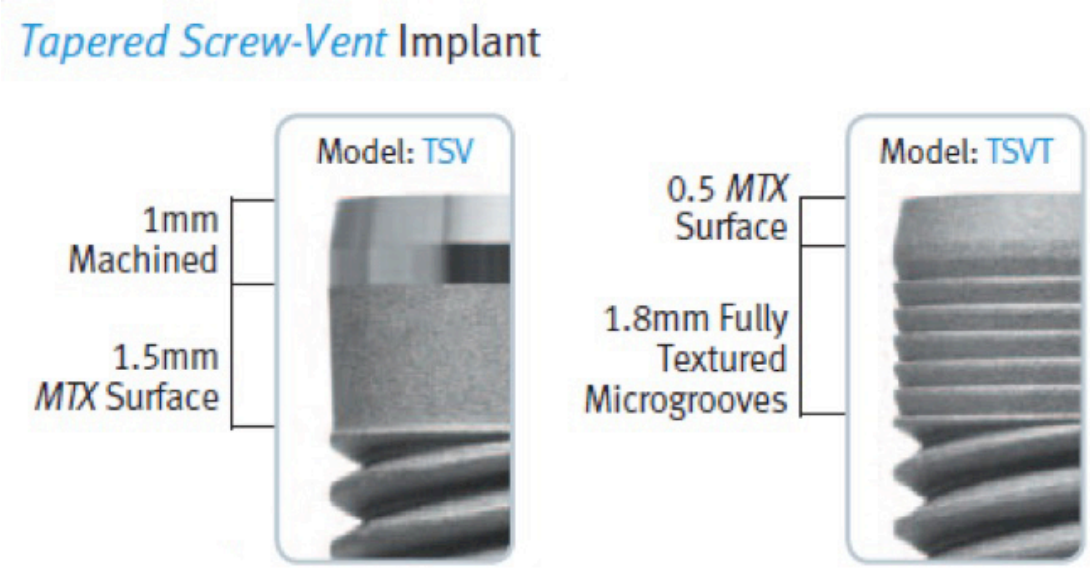

Figure 1. MTX-TSV and MTX-TSVT Implant Collars

Study Population

Sixty-nine patients (ages 19+) who were treatment planned to receive dental implant therapy were enrolled in this study and informed consent was obtained. All patients were seen for initial examination and treatment at the UAB Graduate Periodontology clinic. They received placement of microtextured implants to replace missing teeth. Pre-surgical assessments, surgeries, and follow-up visits adhered to established periodontal clinical guidelines. Inclusion criteria and exclusion criteria for participation in the study are noted in Table 1 and Table 2.

Table 1.

Inclusion Criteria for Participation in the Study

Inclusion Criteria
Existence of one or more missing teeth in one quadrant that are scheduled to be replaced with dental implants
Healthy enough to undergo the proposed therapy without compromise to existing health status
Demonstrated willingness to comply fully with protocol time-line and procedural requirements
At least 19 years old
Able to read and understand the consent form
Able to cognitively understand the proposed study therapy and possible prognosis
Able to consent for their own inclusion into the study

Table 2.

Exclusion Criteria for Participation in the Study

Exclusion Criteria
Any health condition that in the opinion of the clinical investigators may adversely affect bone healing
Any medication that in the opinion of the clinical investigators may adversely affect bone healing
Any indication of an inability to make autonomous decisions
Pregnancy at time of enrollment

Participants were asked to attend at least 6 visits in the periodontal clinic over the course of approximately thirteen months: 1) Pre-surgical assessment and consent; 2) surgical placement of implants; 3) 1 week follow-up; 4) 1 month follow-up; 5) pre-prosthetic evaluation; and 6) 1 year final study visit. Patients were informed that one to two visits would also be required for off-site restoration. A study visit flow chart is provided in Figure 2.

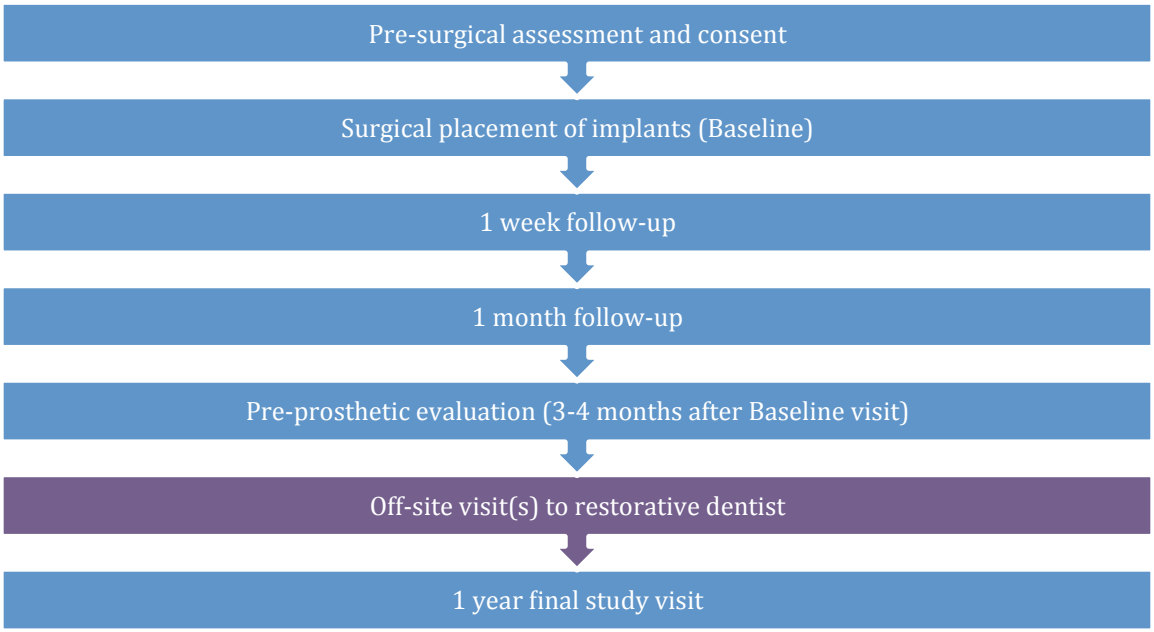

Figure 2. Study Visit Timeline

Study Protocol

All implants were placed by periodontal residents under the supervision of the study investigators serving as attending faculty within the UAB Graduate Periodontology clinic. Each "case" consisted of a single implant with a single restoration or several im-

plants with multiple restorative units that are joined together (i.e. 3-unit fixed partial denture). Cases were randomized to either "test" or "control" implants (*Tapered Screw-Vent*® implants, Zimmer Dental Inc., Carlsbad, CA) digitally by a research coordinator that was not present at the surgical visits. Patients could have one or more implant "cases" placed in one quadrant (as long as they can be captured on the same periapical radiograph) to restore missing teeth for function and esthetics. Multiple implants in the same participant may consist of a randomized combination of test and control implants. Patients were referred for restoration of implant(s) after implant osseointegration as determined by the surgeon and then returned for the final study visit at 12 months (+/- 7 days) post-placement. During this period, patients were seen for prophylaxis and maintenance care in the UAB Graduate Periodontology clinic. Patients were given the implants at a discounted price for participating in the study and were informed that the costs of restoration were not included.

Pre-surgical radiographs and photographs were taken of each site. Prior to surgery, the patient was given a loading dose of antibiotics based on his or her medical history and concomitant medications. Local anesthesia was provided by nerve blocks or infiltration. Patients were offered conscious sedation to manage anxiolysis. The facial area surrounding the oral cavity was disinfected with 0.12% chlorhexidine gluconate antimicrobial soap and a pre-procedural intraoral rinse (Acclean®, Henry Schein, Melville, NY) was performed for one minute.

Surgical incision design was dependent on the soft and hard tissue assessment in each case, and full thickness flaps were reflected in all surgeries. All sites were prepared according to the manufacturer's protocol, which was the same for both types of implants.

Implant dimensions were determined according to the surgeon's treatment planning, location, tooth anatomy, and bone volume. The following implant sizes were available for placement with either the MTX-TSVT or the MTX-TSV surface: implant lengths of 10mm, 11.5mm or 13mm and implant diameters of 3.7mm, 4.1mm, or 4.7mm. Osteotomy sites were prepared with a sequential drilling protocol and copious amounts of sterile water irrigation were used during osseous drilling procedures to prevent heating or thermal necrosis of the bone.

The pre-selected implant was placed in a sterile field. All implants were placed with their collars positioned at the level of the crestal bone. Depending on the measured level of primary stability, a cover screw or a healing abutment was placed on each implant and all sites were sutured using polyglactin 4-0 suture (Vicryl, Ethicon, Cornelia, GA). Initial implant placement radiographs were taken at this time. After the procedure, patients were given post-operative instructions and prescriptions for a seven-day course of antibiotics along with necessary analgesics.

If implant uncovery was necessary, it was initiated at least three months after placement for mandibular implants and four to six months following maxillary implant placement. The patient was then referred to the restoring dentist of their choice, who had been identified prior to implant placement. These restoring dentists were UAB dental students and prosthodontics residents (under faculty supervision) or private practice general dentists.

Data collection consisted of radiographic and photographic data at time of implant placement (baseline) and at one year following implant placement (final study visit). The majority of radiographs were taken with size 1 or size 2 digital sensors (Schick sensor,

Sirona Dental Inc., Long Island City, NY), though a small number of radiographs were taken with phosphor plate images. Care was taken to expose radiographs from the exact same position at each designated interval to reduce the possibility of geometric inaccuracy. A Rinn bite-block with aiming ring (XCP®, Dentsply Rinn, Elgin, IL) was used to aid in positioning. Fixed exposure times and standardized beam settings (milliamperage and kilovoltage) were used to increase accuracy of the analysis. Clinical photographs of the site were taken from the facial and occlusal views at the surgical visit (pre-operatively and after implant placement) and at the final study visit. Final study visits were to take place within one year +/- seven days of the baseline visit (surgical placement of the implants). See Figure 3 for examples of clinical photographs.

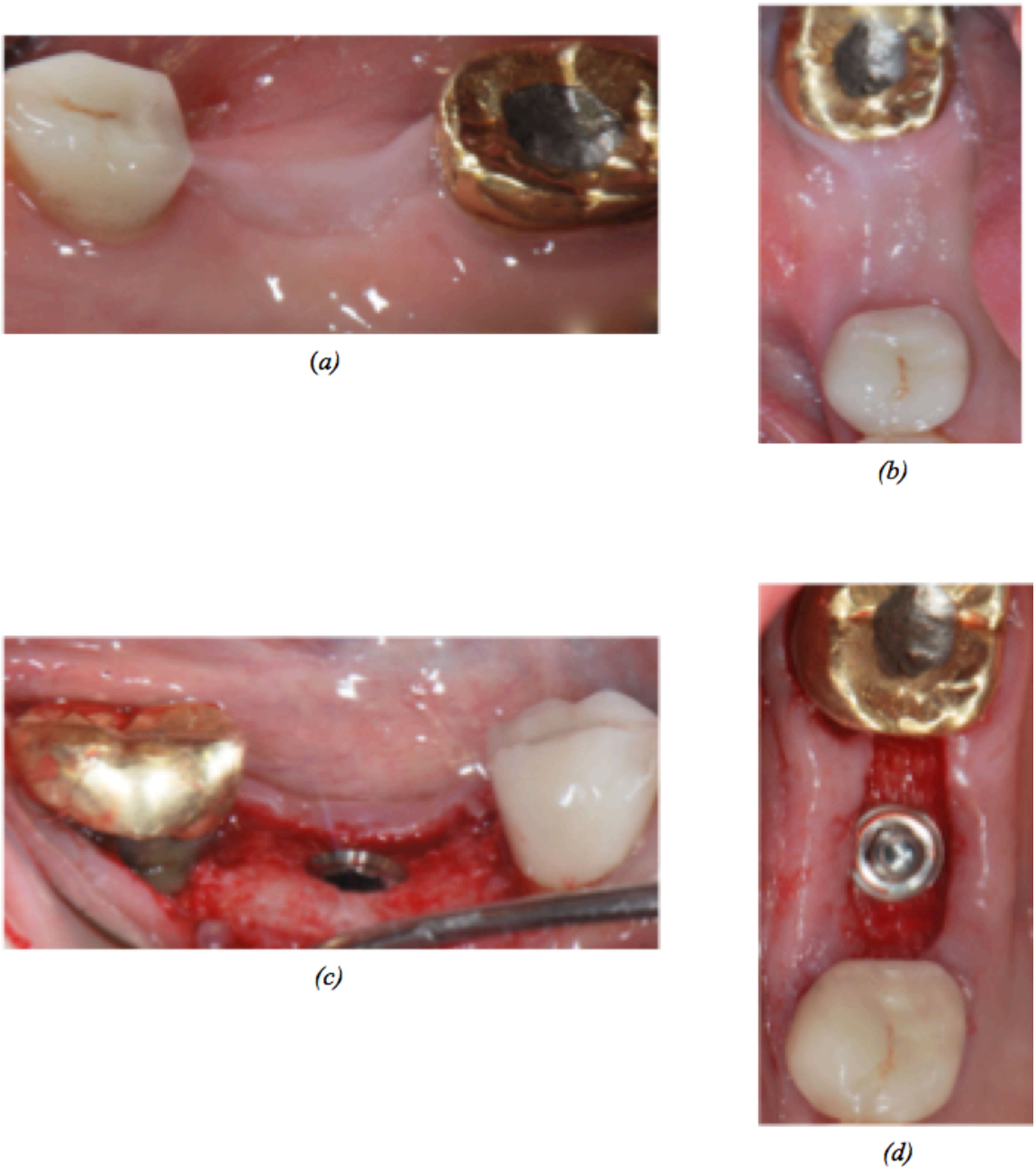

Figure 3. Clinical Photographs of a Z11 Study Implant (*a)* Pre-operative lingual view for Z11 study site *(b)* Pre-op occlusal view for Z11 study site *(c)* Occlusal view at placement *(d)* Buccal view at placement. Pictures courtesy of Dr. Britany Matin.

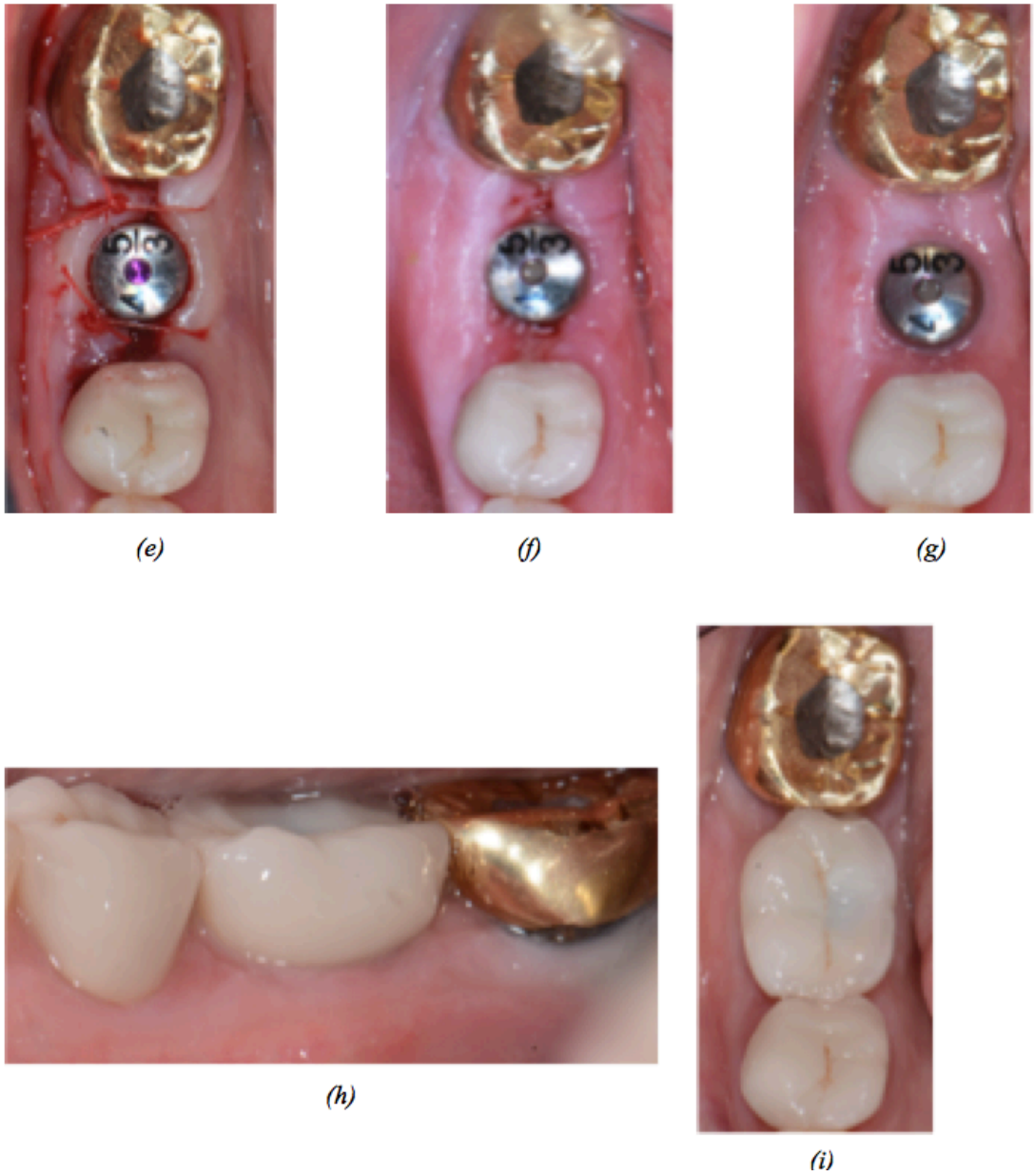

Figure 3. *(e)* Occlusal view at placement with healing abutment and sutures *(f)* One week post-operative healing *(g)* One month post-operative healing *(h)* Buccal view at one year with final restoration in place *(i)* Occlusal view at one year with final restoration in place. Pictures courtesy of Dr. Britany Matin.

Outcomes

The primary outcome in this study is to determine if there is a difference in radiographic crestal bone loss between the two types of implants. During data collection, several other local and patient factors were considered that might affect the crestal bone loss. The variables that were statistically analyzed in this data set are noted in Figure 4.

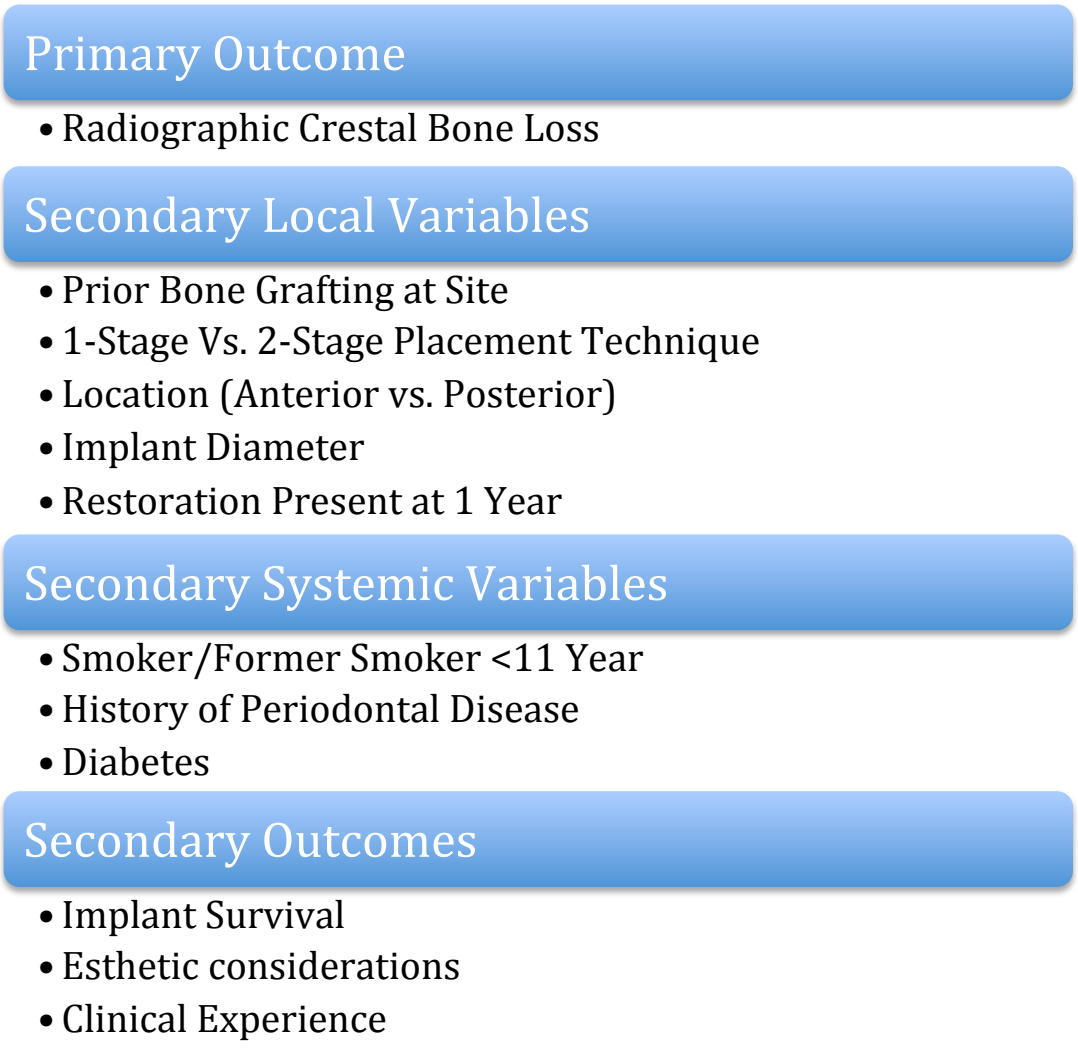

Figure 4. Specific Outcomes of Z11 Study

In addition to the type of implants being compared, esthetics, implant survival, and clinical experience may play a significant role in the patients' perceptions of success. One important element of this study is that novice clinicians in the Graduate Periodontology program at UAB School of Dentistry performed some of the procedures. The inclusion of novice surgeons may be of interest since more dentists are placing implants that have not had formal surgical training. As surgical expertise can affect implant success rates, a greater difference may be seen if the surgeons have less experience and therefore cannot overcome any design deficiency of the dental implant. Therefore, this study was designed to be performed by residents during training who have less experience than expert clinicians. In a study by Zoghbi, there was a significant difference in the success rates of implants based on the clinician's surgical experience. He found that practitioners placing their first 50 implants had a success rate of 84% and a success rate of 94.4% for all implants placed thereafter [21]. The additional aim of evaluating surgeon experience may be beneficial in determining if there is a specific implant that is more appropriate for novice clinicians with regards to early implant failure rates.

Radiographic Image Analysis

Each initial and final periapical radiographic image was uploaded into an image analysis software system (NIS-Elements, Nikon Corporation, Minato-ku, Tokyo). Radiographs were taken with care to recreate the original angulation and used a paralleling technique to accurately assess the crestal bone in relation to the implant. Refer to Figures 5 and 6 for radiographs of a Z11 implant assessed in the study.

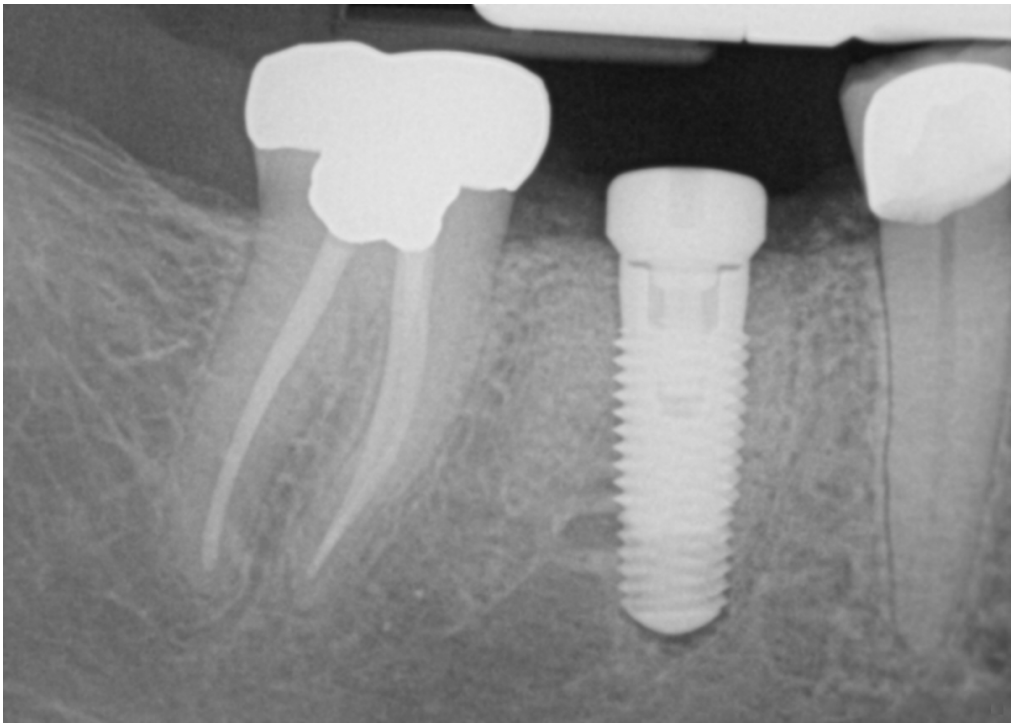

Figure 5. Initial Radiograph of a Z11 Study Implant

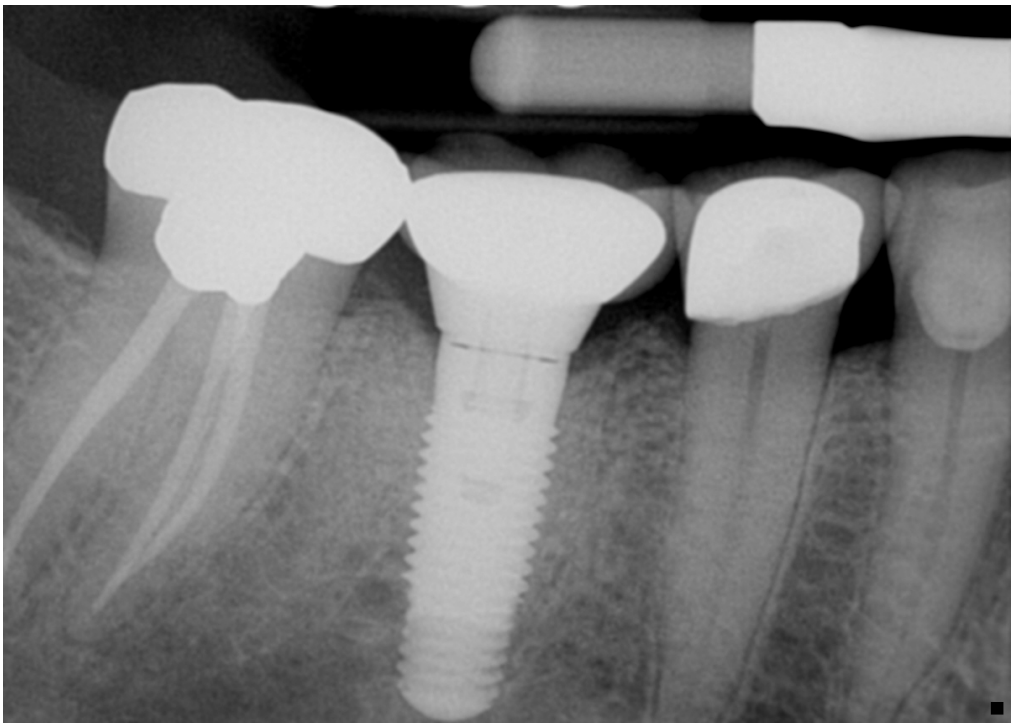

Figure 6. Final Radiograph of a Z11 Study Implant

Once all images were loaded into the Nikon Elements software system, each radiograph was adjusted to 1:1 magnification prior to analysis. Within each radiograph, linear measurements were made on the mesial and distal sides of each implant. Each measurement started from the top of the collar portion of each implant to the height of the crestal bone on each of the lateral surfaces.

A novel calibration technique was developed for this study analysis. Measurements were performed on the radiographic image of the implant itself to provide a known dimension to allow the pixels to be converted to millimeters. A table of known measurements is provided below in Table 3 [22]. Most commonly, a conversion using one or two of the manufacturer's triple lead threads were used, mainly because these were known landmarks in the same dimension as the bone loss was measured, and they were the most accurate of all when tested against the length of several particularly parallel images of an implant body.

The triple lead thread consists of three individual threads 120 degrees apart that are at a steeper angle than most conventional implant threads. Each 360-degree turn seats the implant 1.8mm. The consistent spread of these implant threads allow for them to be used as accurate, comparative measurements in the longitudinal dimension. This was important because it accounted for the same x-ray angulation errors (elongation or foreshortening) that would be otherwise unaccounted for with measurements like collar width, which are more perpendicular to the direction of marginal bone loss.

Once all dimensions were determined and converted into millimeters, the two measurements were then averaged per implant to find average bone loss per implant. This was performed for the initial radiograph and for the final radiograph. If the implant was

inadvertently placed below the crestal bone level initially or the implant was still covered by bone at the one-year evaluation, then the bone level was noted as zero. No positive bone-overgrowth measurements were recorded since 1) all implants were planned to be placed flush with the alveolar crest and 2) this bone loss or retention is not a reflection of the collar characteristics of the implants. A single examiner performed all measurements. Intra-examiner calibration was performed on 10% of the implants, selected at random.

Table 3.

Known Implant Dimensions

Implant Dimension	Measurements in Millimeters (mm)
Implant Length	10, 11.5, or 13
Implant Diameter	3.7, 4.1, or 4.7
1 Triple Lead Thread	1.8
2 Triple Lead Threads	3.6
Implant Collar Length (Rough Collar)	2.3
Implant Collar Length (Smooth Collar)	2.5

STATISTICAL ANALYSIS

Once the final number of implants was determined for analysis, all measurements were analyzed with the assistance of statistician Dr. Russell Griffen at the UAB Center for Clinical & Translational Science (CCTS). All tests were independent t-tests with the exception of one. A secondary variable, implant diameter, was estimated with an analysis of variance (ANOVA) due to the three collar diameter designations. The hypothesis tested was that the rough collar microtextured implants with microgrooves will have less marginal bone loss than the MTX implants with a machined collar at one year. The significance threshold was set at $p<0.05$.

One examiner measured all radiographs, and calibration was performed to assure reproducibility of the measurements by the same examiner. Intra-examiner calibration was accomplished by selecting 10% of the implants at random and performing all associated measurements on the radiographs a second time. Analysis was performed using an intraclass correlation coeffcient to ensure calibration. The intraclass correlation coefficient (ICC) is used to compare two continuous variables that are organized into groups. The closer the ICC is to one, the higher the agreement in the continuous measurements. The ICC for the length in pixels was 0.93, showing a high agreement in measurements performed by this examiner in this study.

RESULTS

Sixty-nine participants were screened in the study. Twenty-nine males and forty females between the ages of thirty-two and eighty-two were evaluated (two participants were screened twice). Fifty-eight participants were enrolled and had implants placed that qualified with all of the study criteria. The eleven patients that did not enroll were removed from the study at the day of the surgical visit due to the following reasons: patient opted out of study participation, site required specific implant size not included in the study, or additional grafting needed to be performed at the crestal portion of the site and/or implant. One of the patients that was initially removed from the study due to a smaller implant size being needed at one surgical site, was re-enrolled for another site, and implants were successfully placed that met all study criteria.

Three patients had early failures of their implants within the first month after placement. Four implants of the eighty-three total implants placed were removed due to early infections. One patient re-enrolled after grafting and another implant was placed in the site. One patient elected not to proceed with implant treatment and was removed from the study. A final patient had one implant removed due to infection from a Tal cover screw exposure but had another implant remain in the study [23].

Four of the remaining seventy-nine implants were excluded due to grafting around the crest of the implants that was performed between implant placement and uncovery (3-4 months post-placement). These implants had significant bone loss prior to

restoration and needed additional grafting prior to abutment and crown placement in order to maintain the implants in health and in function. Because these implants had crestal grafting performed before the one-year final study visit, they were not included in the analysis due to the alteration of crestal contours between the initial and final radiographic analysis. Of the seventy-five implants remaining up to the final study visit, six more were excluded in the final analysis. Five implants were lost to follow up at the one-year final study visit. Also, one final radiograph was determined to be of non-diagnostic quality following the last study visit. This implant was excluded from the study since the crestal bone levels could not appropriately be assessed, leaving sixty-nine implants eligible for final analysis. These implants had been randomized to rough (MTX-TSVT) and smooth (MTX-TSV) collar implants at initial implant placement. The flow chart below in Figure 7 accurately depicts the study population and implants included in the analysis. Table 4 shows the overall numbers of each type of implant that was placed.

One drawback of the study to note is that one year follow up appointments occurred over a much larger time span than intended. In general, very few patients actually returned within one week of exactly one year after the baseline study visit. The range of time from baseline to final study visit was 1 year less 8 days to 1 year, 11 months, and 14 days. Since the data was so stratified, no implant was excluded from the study for follow up visit being outside of the established evaluation period. This wide time span should not make a significant difference according to long-term implant success guidelines in Jimbo and Albrektsson 2015. They found that roughened surface implants do not have progressive yearly bone loss after the first year, so a span of one or two years should not make a difference in crestal bone levels measured [24].

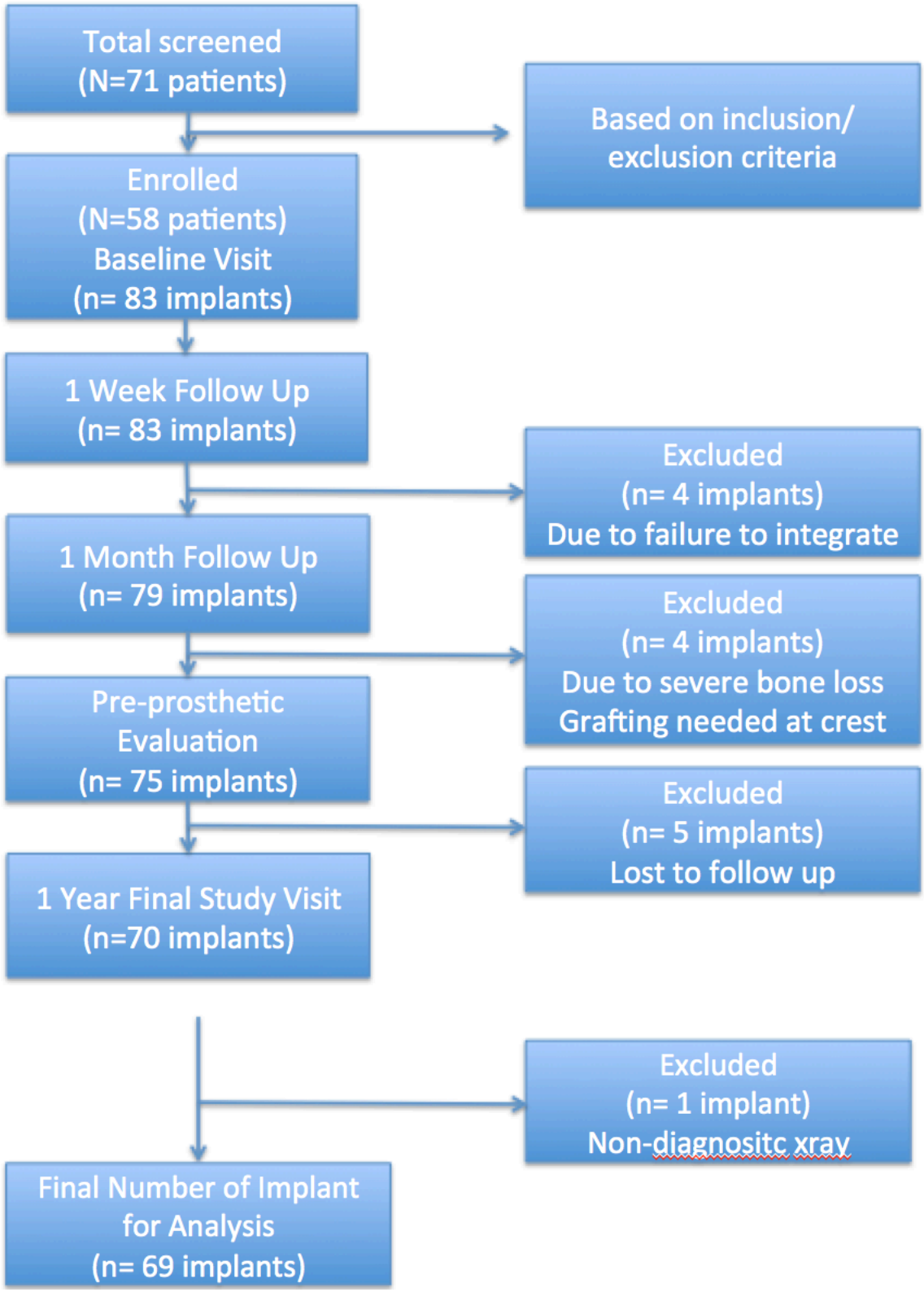

Figure 7. Patient Flowchart

Table 4.

Implants Placed in Z11 Study

Type of Implant	Number of Implants
Smooth Collar Implants (MTX-TSV)	38
Rough Collar Implants (MTX-TSVT)	31

Two sample independent t-tests were performed to determine if there was any difference in the amount of crestal bone loss on the smooth collar versus the roughened collar MTX implants. Analyses confirmed that there was no difference in baseline bone levels between rough (mean 0.30±0.63) and smooth (mean 0.38±0.40) implant types (p=0.5334). These comparisons can be found in Table 5. At one year, however, a difference was observed by implant type, with bone loss being greater among the smooth collar implants compared to the rough collar implants (p<0.0001). The smooth collar implants had an average bone loss from the top of the implant collar of 1.20±0.62 at one year, while the rough collar implants had an average of 0.65±0.43from the top of the implant collar at one year.

Table 5.

Comparison of Initial and One Year Bone Loss by Implant Collar Design

	Rough	Smooth	p-value*
Mean initial bone level at placement (mm)	0.30±0.63	0.38±0.40	0.5334
Mean 1-year bone loss (mm)	0.65±0.43	1.20±0.62	<0.0001
Mean difference in bone loss (mm)	-0.35±0.56	-0.82±0.70	0.0039

* Estimated from a two-sample independent t-test

Similarly, the difference in bone loss between one-year and initial measurements was greater among those with a smooth implant collar ($p=0.0039$). The smooth collar implants had an average first year bone loss of 0.82 ± 0.70, while the rough collar implants had an average loss of 0.35 ± 0.56 in the first year. Figure 8 provides an example of one implant radiographic image uploaded and analyzed in the Nikon NIS Elements imaging software.

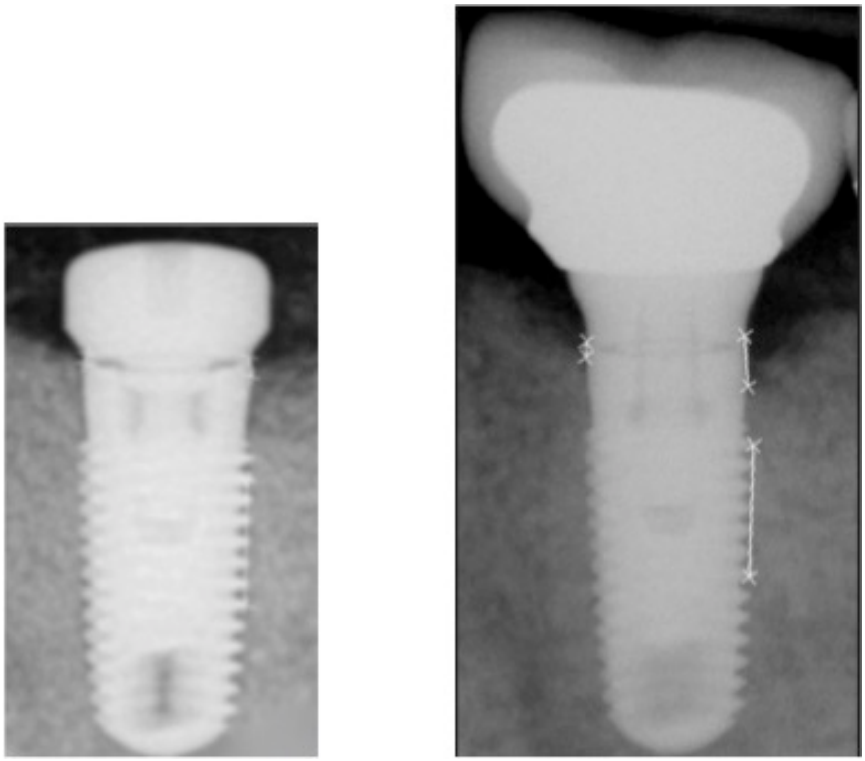

Figure 8. Initial and Final Radiographs of a Z11 Implant Uploaded in the Nikon NIS Imaging Software

In addition to analyzing the significance of collar surface characteristics, several secondary variables were examined to determine their effects on first year marginal bone loss. Local factors of prior bone grafting at the site, 1-stage versus 2-stage implant placement, anterior or posterior location in the oral cavity, implant diameter, and pres-

ence of a final restoration were all examined as potential confounding factors. Systemic variables included smoking (current or former <11years), history of periodontal disease, and diabetes. Table 6 shows the initial statistics for each variable.

All of the two-value variables were analyzed with an independent t-test at a 5% level of significance ($p<0.05$). Implant diameter had three options for which an ANOVA was used for comparison (see Table 7). Of the variables of interest, only implant diameter was significantly associated with the difference in bone loss between initial and one year measurements ($p=0.0194$). In particular, bone loss was greater among those with a 3.7mm diameter (mean 0.81±0.73mm) compared to those with a 4.7mm diameter (mean 0.25±0.61mm) ($p=0.0194$) (see Figure 9). In a model including both implant collar designs and diameter, both variables independently remained significantly associated with bone loss. Specifically adjusted for implant diameter, the estimated mean value for bone loss was significantly different between rough and smooth implant types (mean -0.32 and -0.75, respectively, $p=0.0051$).

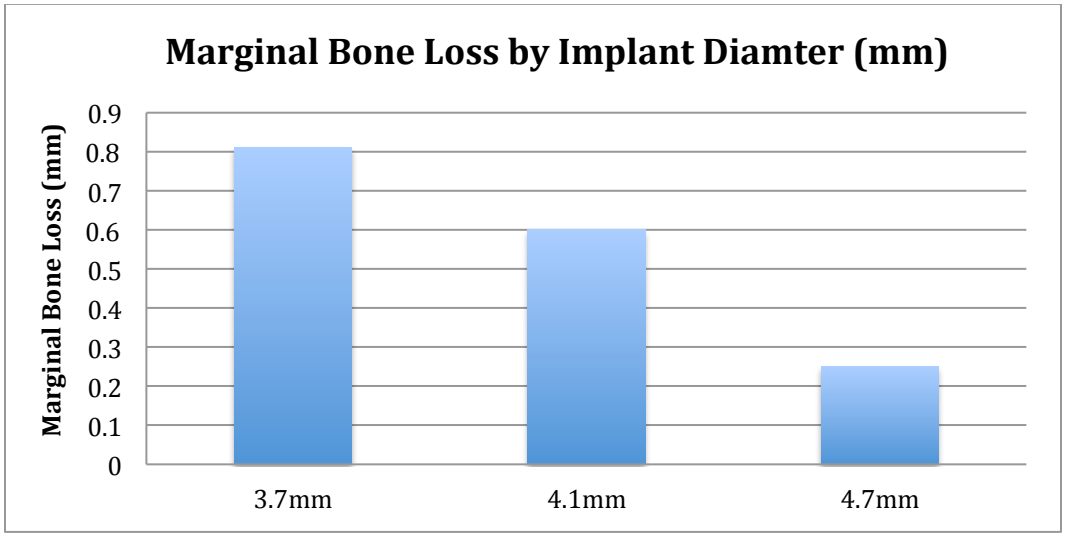

Figure 9. Average Marginal Bone Loss by Implant Diameter

Table 6.

Demographics of Variables

Variables	Total number of implants N=69 (%)
Prior bone graft	
Yes	48 (70%)
No	21 (30%)
Staging	
Single-staged	29 (42%)
Two-staged	40 (58%)
Location	
Posterior (premolars, molars)	59 (86%)
Anterior (canines, incisors)	10 (14%)
Implant diameter	
3.7mm	32 (46%)
4.1mm	19 (28%)
4.7mm	18 (26%)
Restoration	
Yes	20 (30%)
No	49 (70%)
Smoker	
Yes/Former smoker <11 years	9 (13%)
No	60 (87%)
History of periodontal disease	
Yes	24 (35%)
No	45 (65%)
Diabetes	
Yes	2 (3%)
No	67 (97%)

Table 7.

Correlation Between Difference in Initial and One-Year Bone Loss and Selected Variables of Interest

	Mean difference	p-value*
Prior bone graft		
Yes	-0.61±0.70	0.9636
No	-0.60±0.65	
Staging		
Single-staged	-0.65±0.65	0.5547
Two-staged	-0.55±0.73	
Location		
Posterior	-0.65±0.69	0.2173
Anterior	-0.36±0.58	
Implant diameter		
3.7mm	-0.81±0.73	0.0194†
4.1mm	-0.60±0.54	
4.7mm	-0.25±0.61	
Restoration		
Yes	-0.61±0.63	0.9743
No	-0.60±0.81	
Smoker		
Yes/Former smoker <11 years	-0.51±0.57	0.6434
No	-0.62±0.70	
History of periodontal disease		
Yes	-0.57±0.63	0.5075
No	-0.68±0.78	
Diabetes		
Yes	-1.04±1.15	0.3643
No	-0.59±0.67	

* Estimated from a t-test for all variables but implant diameter, which was from an analysis of variance

† P-value <0.05 statistically significant association with implant diameter

There was no association between the variables of interest and bone loss stratified by implant collar design. In Table 8, the p-value for interaction (the far right column) denotes whether the association between rough or smooth collar type and bone loss difference varies by the additional variable. None of these p-values were statistically significant, suggesting that the association between rough and smooth collars with bone loss was not significantly modified by any of the additional variables in this study.

Table 8.

P-values for the Association Between Bone Loss and Variables of Interest Stratified by Implant Collar Design

	Rough p-value*	Smooth p-value*	p-value†
Prior bone graft	0.9735	0.9628	0.9894
1-Staging vs 2-Staging	0.6140	0.9755	0.7283
Location	0.4483	0.5517	0.9538
Implant diameter	0.2646	0.0950	0.8429
Restoration	0.1473	0.3135	0.0926
Smoker	0.2489	0.1798	0.0773
History of periodontal disease	0.6947	0.3384	0.3423
Diabetes	0.8329	0.1372	0.2013

* Estimated from a t-test for all variables but collar width, which was from an analysis of variance

† P-value for interaction between variable of interest and rough/smooth implant type

DISCUSSION

Primary Outcome: Radiographic Crestal Bone Loss

The findings in the present experiment that the crestal bone levels at the implants with a microthreaded collar design remained stable during the first year of healing is consistent with observations reported in other clinical studies.[4, 10, 15-18, 25]. In this study, the results show that with implants having the same microtextured surface, those with a roughened collar as opposed to a longer machined collar had less crestal bone loss at one year after implant placement. According to the statistical analysis, both implant designs were placed at similar bone levels at the crest of the alveolar ridge. The control implants with the 1mm machined collar had one year bone levels at 1.20mm below the top of the implant, losing an average of 0.82mm over the course of a year. The test implants with MTX- surfaced collars and microgrooves had one-year bone levels at 0.65mm below the implant-abutment interface, losing an average of 0.35mm bone over the first year. These results show that the MTX collars with microgrooves developed less than half the amount of bone loss in the first year than their smooth-collared counterparts.

Shin et al. found that not only did the roughened collar implants have less marginal bone loss then the machined collars at one year of loading, but that the roughened collars with microthreads significantly reduced crestal bone loss[10]. The surface characteristics of MTX-TSVT implants are unique, and it is the first of its kind produced by this manufacturer. Another advantage to the rough collars is that the bone loss may stabilize

more quickly than for machined collar implants. Shin found that after three months of loading, crestal bone loss around the roughened collar implants stabilized, but those implants with machined collars did not achieve stability of crestal bone levels for six months [10].

Rasmusson and colleagues found that in a canine model, implants with grit-blasted with TiO_2 had significantly more bone-to-implant contact (BIC) and bone area in the threads compared with machined implants[26]. Abrahamsson and Berglundh also found in six beagle dogs that implants with microthreaded collars had a significantly greater BIC as compared to non-threaded collars, 81.8% and 72.8% respectively. This study found that though both surfaces were TiOblast, the test implants with the microthreads maintained twice as much marginal bone[25]. Similarly, Song et al tested microthreads at the top of the implant collar and 0.5mm below the implant collar. He found that the microthreads at the top of the implant collar stabilized the peri-implant bone levels better through one year of functional loading[27].

Hansson discusses that the roughened collars of implants have several biomechanical roles in addition to maintaining marginal bone levels. He found that retention elements in the collars of implants reduced the shear stresses, allowing for the implant to have a greater capacity to carry axial loads[28]. This finding is not pertinent to the one-year bone loss data, since no implant has been loaded for longer than a few months, but this biomechanical adaptation could aid in further long-term advantages of this design. Long-term studies will need to be performed to assess this theory.

The current study reinforces the findings in recent literature that there may be a significant advantage to not only having a roughened collar but also adding microgrooves

to the implant collar design to further minimize crestal bone loss around implants. Though there is no commercially available roughened collar MTX implant without microgrooves, findings in past literature show that this presently tested alteration in collar design may be the most effective at maintaining crestal bone levels[10]. More studies with larger sample sizes will be needed to assess the addition of microgrooves to the collar design and to which portion the microgrooves should be included, but this study clearly demonstrates that this collar design significantly prevents early crestal bone loss around MTX implants.

Secondary Local Factors

Prior Bone Grafting at Site

Some of the potential limitations of this study included the placement of implants into sites of grafted or non-grafted bone and the exclusion of cases where additional bone grafting would be required around the implant collar at time of placement (e.g. immediate placement in extraction sockets and placement in thin ridges). In this study, there was no significant difference in crestal bone loss at sites with prior grafts versus no grafting. Data collection was not specified for type of site preparation grafting that took place, for example, socket preservation, ridge augmentation, and/or sinus lift. It may also be important to note that all implant placements were delayed at least three months after grafting. Barone performed a similar study in which implants were placed into augmented and non-augmented sites seven months after grafting. No differences were found in marginal bone loss at these sites[29], indicating that grafted sites that have had an opportunity to heal sufficiently do not affect the crestal bone levels after implant placement.

One-Stage Versus Two-Stage Placement Technique

Single- staged implants (42%) had a healing abutment placed the day of surgery and were immediately exposed to the oral environment. Two-staged implants (58%) had a cover screw placed and were fully covered with tissue for period of several months prior to uncover and exposure to the oral environment. It has been hypothesized that the two-stage technique will allow for uninterrupted healing free from bacterial insult and unforeseen loading[30]. However, a one-staged technique allows for one less surgery with flap reflection and subsequent insult to the alveolar crestal bone, and it results in one less procedure involving movement at the implant-abutment interface. In a Cochrane Review, Esposito found that there was no difference in marginal bone levels between one and two-staged implants[31]. Tallarico also found that at one year there was no significant difference in peri-implant bone loss around one-staged and two-staged implants[32]. This study is in agreement with previous literature that does not show any statistical importance to one-staging or two-staging implants. It should be noted, however, that implants lacking adequate primary stability or requiring grafting or membrane placed in conjunction with the implant may be more successful with a two-staged approach.

Location

Implant location was analyzed for significance associated with crestal bone loss. Only ten (14%) of the implants were placed in the canine and incisor sites of the anterior region, and there was no notable importance associated with positioning in the jaw. Since

the sample size was so small, results should be regarded with caution. More studies with larger sample sizes should be performed to interpret results.

Implant Diameter

The only secondary variable that was significantly associated with marginal bone loss was implant diameter. The stratification of sizes was as follows: 46% were 3.7mm, 28% were 4.1mm, and 26% were 4.7mm. The smallest diameter implant was found to have the most significant amount of bone loss. The smallest diameter implants lost an average of 0.81mm of bone during the first year as opposed to the middle-sized implant losing 0.60mm and the largest diameter implant losing 0.25mm, a third of the bone loss of the narrower implant. Also, when the implant type was adjusted for diameter, the rough collar implants lost an average of 0.32mm of marginal bone while the smooth collar implant lost twice the amount at 0.75mm.

In the literature, the influence of implant diameter does not provide a clear-cut tendency. Negri examined marginal bone loss around 3.3mm, 3.8mm, 4.1mm, and 5mm diameter implants. He found that in the maxilla, larger diameter implants sequentially lost more bone than smaller diameter implants. The same was true in the mandible with the exception of the 4.1mm diameter implants losing less marginal bone than the smaller diameters[33]. On the other hand, Zweers et al performed a study comparing bone loss around narrow-neck and regular-neck implants. He found that narrow diameter implants (3.3mm) had double the marginal bone loss than the regular diameter implants (4.1mm) between one and three years, 0.32mm and 0.14mm respectively[34].

A possible explanation could be that the smaller diameter implants were placed in areas of thinner, more cortical bone. When the surgical mucoperiosteal flaps were reflected in combination with surgical site preparation, this trauma caused some crestal bone loss [35].. Ormiander shows that bone stress increases when bone thickness decreases around implants of all diameters[36]. Yet Yu shows in another stress/strain model that it is best to place wider implants that are at least half of the ridge width in narrow ridges to overcome peak stress in the cervical necks of implants[37]. However, these rationales only apply to loaded implants, which does not correlate with our results.

Restoration Present at One Year

Though one of the stipulations of the study was that the implant should be restored by an off-site dentist prior to the final study visit, only twenty of the sixty-nine implants (30%) were restored. This failure of the implants to all be restored is a major limitation to this study. Since study implants were offered at a reduced fee, it is thought that more patients that were financially compromised entered the study. Patients reported that they decided to proceed with implant therapy at the reduced fee while it was available and planned to get the restoration when they could afford it. Since the restoration fee was not included in the study and was not offered at a discounted rate, this became cost prohibitive within the same year for many of the patients. All patients do plan to have their implants restored in the near future. This finding helped identify that the restoration cost and placement should be included in future studies to better ensure compliance.

Restorations present showed no significant correlation with marginal bone loss, though it should be noted that no restoration was placed for longer than six months prior

to the final study visit. Since so few restorations were placed in the sample size, and a maximum of six months of loading were followed, these results should be interpreted with caution. Long-term follow up would be more appropriate to assess the effect of a restoration on marginal bone loss.

Secondary Systemic Factors

Smoking

It is commonly known that the effects of tobacco smoking have a negative impact on the periodontium and implant healing[38]. This study found no significant correlation with smoking and crestal bone loss in the first year following implant placement. Smokers were defined as current smokers or former smokers who quit less than eleven years ago. This chosen definition could have skewed the significant of the results because most studies define smokers as patients who smoke >10 cigarettes a day, though as shown in the Third National Health and Nutrition Examination Survey (NHANES III), effects can be seen for up to eleven years later[39]. Peñarrocha found that one year after loading 108 International Team for Implantology (ITI) implants, smokers (11-20 cigarettes per day) had significantly more peri-implant bone loss than non-smokers[40]. In general though, smoking effects are difficult to assess at shorter time intervals, since it is known to be a long-term risk factor for peri-implantitis. Smoking affects the tissues of the surrounding areas, making the sites more susceptible to bacterial insult and peri-implant bone loss over time[41]. The time period of this study is too short to appreciate these effects. Former smokers were included with current smokers in this study due to the small sample size of each group. Heavy smokers were largely excluded from this study due to the sur-

geon's discretion because of the exclusion criteria of that patient having any medical condition that may adversely affect bone healing. Larger sample size and more long-term studies are needed to assess the effects of cigarette smoking on crestal bone loss.

History of Periodontal Disease

One of the greatest risk factors for per-implant diseases is the history of periodontal disease. Karoussis et al. found that patients who lost teeth to chronic periodontitis had significantly lower implant survival and success rates[42]. However, history of periodontal disease has not been established as a factor in early implant bone loss. All patients with diagnosed periodontal disease received active treatment prior to implant placement and maintenance therapy post-operatively. Implant placement was only performed once active therapy was complete and local factors including inflammation were controlled. There was no significant difference in marginal bone loss at one year in patients with a history of periodontal disease. This finding does not imply that patients are not predisposed to the effects of chronic disease that may cause long-term issues with the implants; it simply demonstrates that there seem not to be increased crestal bone loss at implants after one year in treated patients. Chrcanovic performed a review finding that dental implant failure and marginal bone loss over time was higher in periodontally compromised patients in comparison to periodontally healthy patients[43]. More studies are necessary to determine the early bone loss around implants in periodontal susceptible patients.

Diabetes

Another risk factor for peri-implant bone loss is diabetes. Diabetes was not a significant factor in this study, mainly due to the extremely small sample size. Only one patient that attended the initial and final study visit had Type II diabetes. Even though the average bone loss for these two implants was 1.04mm compared to .59mm for the non-diabetic patients, the range was too large to find any correlation. The one patient with diabetes was under very good glycemic control (HbA1c<6.5). Due to the small sample size, no conclusions can be drawn with regards to the relationship between diabetes mellitus and implant crestal bone loss. One of the exclusions of this study was any health condition that may affect bone healing. Many previous studies have found links with peri-implant bone loss and poorly controlled diabetes. Aguilar-Salvatierra et al found that in the first two years following implant placement, peri-implant bone loss was related to higher glycated hemoglobin (HbA1c) levels[44]. It was at the discretion of the surgeons that many of these patients were not included in the study due to their glycemic control.

Secondary Outcomes

Implant Survival

Early implant failures were attributed to infection at the site of implant placement. One patient did not return for his initial follow-up visit and had purulence around the implant at his second follow-up visit. The implant was removed, the site was grafted, and a new implant was placed three months after grafting. The second patient had an early exposure above one of his implants. Upon early uncovery, it was found that the bone loss was significant and would affect the future survival of the implant, and the implant was

removed. The third patient had no signs of infection until one month post-operatively when a pustule appeared in the tissue over one of the implants. On uncovery, both implants were surrounded by fibrous tissue and completely non-integrated. The patient was suspected to potentially have either an early infection or an undiagnosed allergy to titanium. Sicilia found titanium allergies to occur in 0.6% of implant patients, and in five of eight unexplained implant failures, the patients tested positive for a titanium allergy[45]. This patient elected to discontinue implant therapy and decided to proceed with alternative treatment. Two of the implants that failed had the machined collar, and two had the MTX roughened collar. Therefore, each group had the same number of implant failures, thus no significant difference was observed.

With four of seventy-nine implants failing in one year, there was an overall 94.9% success rate. The American Academy of Periodontology (AAP) Academy Report states that implant success rates are generally reported as greater than 90% for maxillary and mandibular implants[46]. Therefore, this study seems to report similar findings as other studies. This is a positive finding, especially since periodontal residents placed these implants some of whom qualified as novice implant surgeons (less than 50 implants)[21].

Esthetic Considerations

According to Grunder, the limiting factor to the esthetic results of implants is the bone level at the site [47]. An identifiable amount of bone is lost immediately after placement in the horizontal and vertical dimensions. Since the soft tissue contours follow the bone levels in health, it is important to maintain marginal bone levels for proper esthetics. At one-year post-implant placement, there were no significant differences in re-

storative esthetics. All implants had at least 2mm of good quality keratinized tissue surrounding them. Unfortunately, only 30% (20) of the implants were restored at the one-year follow-up, so a very limited esthetic assessment was possible. It is the subjective assessment of the investigator that upon clinical and photographic examination, different implant collar designs cannot be visibly determined once restored. However, Shin et al. makes an important note when comparing machined collared implants versus roughened and microthreaded designs. He found that the machined implants continued to have bone loss over the first year of loading, and that this bone loss did not reach a steady state (defined by Albrektsson as bone loss of 0.2mm or less annually[1]) until six months of loading[10]. The effects of this finding were not applicable in this study since so few implants were restored at one year but had all implants been restored within six months of placement, clinical differences may have been seen at subsequent follow-ups. Further studies are needed to determine if a three to six month transitional temporary phase may benefit final esthetic outcomes. Additionally, sample sizes in this study were too small to allow for analysis of implants in site-specific areas to determine if particular implant collar designs are preferable in anterior areas due to gingival color change and/or gingival contour alterations. Further studies with additional follow-up and larger sample sizes may be necessary to determine the effects of these implant collar designs on esthetic assessment.

Clinical Experience

One aspect of the study is the skill of the operators, who range from first to third year periodontal residents having placed between one and over one hundred implants. Since there is no learning curve accounted for in this study, differences in experience

may be stratified. The importance of examining this variable is to see if this implant system is suitable for novice clinicians in practice. Zoghbi found that there is approximately a 10% difference in success rates of implant placement between operators placing their first 50 implants and their subsequent implants[21]. Since the success rate of 94.9% and considered acceptable for any group of surgeons, it can be summarized that both types of implants are suitable for placement by novice and experienced clinicians.

A limitation to this finding is that it cannot be confirmed which implants were placed by novice clinicians and which ones were not. Since residents in this program place implants over 100-200 dental implants throughout their three year tenure and no definitive tracking system was in place to evaluate where in the learning curve each of the resident that the implants were placed, there is no way to know if the failures can be associated with clinicians who had placed fewer implants. However, it should be noted that all failures occurred in surgeries performed by first and second year residents, though the residents could have easily already placed over 50 implants by the time of the surgery. Also, as the implants were placed as a part of a surgical training program, all residents were overseen by a faculty of experienced surgeons, which may have blunted the effect of the novice surgeon's learning curve. Furthermore, residents with less experience also receive more attention by very experienced faculty members, who can aid in surgical technique and decisions. This may be another reason why the success rate was as acceptable as it was for this study.

Nevertheless, it seems as though both microtextured implants are suitable for placement by clinicians of any skill level. Vandeweghe showed that placement of thirty-six implants by dental students under faculty supervision yielded a 94.4% success rate at

one year with mean crestal bone loss of 1.41mm. It was noted that guidance was viewed as necessary for future experience though the student and patient both agreed that it was overall a good experience[48]. With more dental professionals performing dental implant placement with and without formal training, it is beneficial to know what types of implants may respond more favorably, and microtextured implants appear acceptable in all of these situations.

CONCLUSION

In summary, microtextured implants with roughened collars with microgrooves maintained marginal bone better at one year than microtextured implants with a smooth, machined collar. On average, the MTX-TSVT implants with a roughened implant collar demonstrated less crestal bone loss over the course of the first year as well. Analyses for prior grafting, staging, location, and restoration yielded no significant differences although collar width did affect bone loss. Narrower diameter implants had significantly more bone loss than the larger diameter implants. Smoking, history of periodontal disease, and diabetes did not show any statistically significant correlations to bone loss, but heavy smokers and uncontrolled diabetics were excluded from the study. More studies should be performed to assess the effect of these local and systemic factors on marginal bone loss with MTX implants. Implant survival and success rates by novice and advanced clinicians proved this to be a good system for implant placement by all surgeons provided it is executed with attention to detail, following proper protocols. While the overall sample size of restored implants available for analysis was low, esthetic considerations for both implants designs were acceptable at one year, and no significant differences were noticed. Longer-term studies should be performed to determine the success and esthetics of MTX implants after the first year.

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APPENDIX

IRB APPROVAL- PROJECT REVISION/ AMENDMENT FORM

Project Revision/Amendment Form

Form version: June 26, 2012

OCT 10 2013

In MS Word, click in the white boxes and type your text; double-click checkboxes to check/uncheck.

- **Federal regulations require IRB approval before implementing proposed changes. See Section 14 of the IRB Guidebook for Investigators for additional information.**
- **Change means any change, in content or form, to the protocol, consent form, or any supportive materials (such as the Investigator's Brochure, questionnaires, surveys, advertisements, etc.). See Item 4 for more examples.**

1. Today's Date

October 10, 2013

2. Principal Investigator (PI)

Name (with degree)	Nicolaas C. Geurs, DMD, MS	**Blazer ID**	ngeurs
Department	Periodontology	**Division (if applicable)**	
Office Address	412 School of Dentistry	**Office Phone**	934-4984
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Contact person who should receive copies of IRB correspondence (Optional)

Name	Sandra J. Haigh	**E-Mail**	shaigh@uab.edu
Phone	934-7513	**Fax Number**	934-7901
Office Address (if different from PI)			

3. UAB IRB Protocol Identification

3.a. Protocol Number	F110412003
3.b. Protocol Title	A Prospective Randomized Clinical Trial to Assess Performance of Micotextured Dental Implants With or Without a Machined Collar

3.c. Current Status of Protocol—Check ONE box at left; provide numbers and dates where applicable

- ☐ **Study has not yet begun** — **No participants, data, or specimens have been entered.**
- ☒ **In progress, open to accrual** — **Number of participants, data, or specimens entered:** 54
- ☐ **Enrollment temporarily suspended by sponsor**
- ☐ **Closed to accrual, but procedures continue as defined in the protocol (therapy, intervention, follow-up visits, etc.)**
  - **Date closed:**
  - **Number of participants receiving interventions:**
  - **Number of participants in long-term follow-up only:**
- ☐ **Closed to accrual, and only data analysis continues**
  - **Date closed:**
  - **Total number of participants entered:**

4. Types of Change

Check all types of change that apply, and describe the changes in Item 5.c. or 5.d. as applicable. To help avoid delay in IRB review, please ensure that you provide the required materials and/or information for each type of change checked.

- ☐ **Protocol revision (change in the IRB-approved protocol)**
  In Item 5.c., if applicable, provide sponsor's protocol version number, amendment number, update number, etc.
- ☐ **Protocol amendment (addition to the IRB-approved protocol)**
  In Item 5.c., if applicable, provide funding application document from sponsor, as well as sponsor's protocol version number, amendment number, update number, etc.
- ☑ **Add or remove personnel**
  In Item 5.c., include name, title/degree, department/division, institutional affiliation, and role(s) in research, and address whether new personnel have any conflict of interest. See "Change in Principal Investigator" in the IRB Guidebook if the principal investigator is being changed.
  - ☒ **Add graduate student(s) or postdoctoral fellow(s) working toward thesis, dissertation, or publication**
    In Item 5.c., (a) identify these individuals by name; (b) provide the working title of the thesis, dissertation, or publication; and (c) indicate whether or not the student's analysis differs in any way from the purpose of the research described in the IRB-approved HSP (e.g., a secondary analysis of data obtained under this HSP).
- ☐ **Change in source of funding; change or add funding**
  In Item 5.c., describe the change or addition in detail, include the applicable OSP proposal number(s), and provide a copy of the application as funded (or as submitted to the sponsor if pending). Note that some changes in funding may require a new IRB application.

☐	**Add or remove performance sites** In Item 5.c., identify the site and location, and describe the research-related procedures performed there. If adding site(s), attach notification of permission or IRB approval to perform research there. Also include copy of subcontract, if applicable. If this protocol includes acting as the Coordinating Center for a study, attach IRB approval from any non-UAB site added.
☐	**Add or change a genetic component or storage of samples and/or data component—this could include data submissions for Genome-Wide Association Studies (GWAS)** To assist you in revising or preparing your submission, please see the IRB Guidebook for Investigators or call the IRB office at 934-3789.
☐	**Suspend, re-open, or permanently close protocol to accrual of individuals, data, or samples (IRB approval to remain active)** In Item 5.c., indicate the action, provide applicable dates and reasons for action; attach supporting documentation.
☐	**Report being forwarded to IRB (e.g., DSMB, sponsor or other monitor)** In Item 5.c., include date and source of report, summarize findings, and indicate any recommendations.
☐	**Revise or amend consent, assent form(s)** Complete Item 5.d.
☐	**Addendum (new) consent form** Complete Item 5.d.
☐	**Add or revise recruitment materials** Complete Item 5.d.
☐	**Other (e.g., investigator brochure)** Indicate the type of change in the space below, and provide details in Item 5.c. or 5.d. as applicable. Include a copy of all affected documents, with revisions highlighted as applicable.

▶

5. Description and Rationale

In Item 5.a. and 5.b, check Yes **or** No **and see instructions for** Yes **responses.**
In Item 5.c. and 5.d, describe—and explain the reason for—the change(s) noted in Item 4.

☐Yes ☒No	**5.a. Are any of the participants enrolled as normal, healthy controls?** If yes, describe in detail in Item 5.c. how this change will affect those participants.
☐Yes ☒No	**5.b. Does the change affect subject participation, such as procedures, risks, costs, location of services, etc.?** If yes, FAP-designated units complete a FAP submission and send to fap@uab.edu. Identify the FAP-designated unit in Item 5.c. For more details on the UAB FAP, see www.uab.edu/cto.

5.c. Protocol Changes: In the space below, briefly describe—and explain the reason for—all change(s) to the protocol.

Periodontal resident, Elizabeth Felts, DMD, Department of Periodontology, will use data collected under this protocol to develop a Master's Degree Thesis.

✓ The working title of Dr. Felts' thesis is: *A Prospective, Randomized Clinical Trial to Assess the Performance of Microtextured Dental Implants with or without a Machined Collar: 1 year results.*

Dr. Felts, will perform an analysis of data to compare peri-implant crestal bone levels around dental implants with a microtextured collar (rim at the top edge of the implant) and dental implants designed with a smooth polished collar one year after surgical placement. Dr. Felts' analysis does not differ from the intended purpose of the study as described in the IRB-approved human subjects' protocol.

5.d. Consent and Recruitment Changes: In the space below,
(a) describe all changes to IRB-approved forms or recruitment materials and the reasons for them;
(b) describe the reasons for the addition of any materials (e.g., addendum consent, recruitment); and
(c) indicate either how and when you will reconsent enrolled participants or why reconsenting is not necessary (not applicable for recruitment materials).

Also, indicate the number of forms changed or added. For new forms, provide 1 copy. For revised documents, provide 3 copies:
- **a copy of the currently approved document (showing the IRB approval stamp, if applicable)**
- **a revised copy highlighting all proposed changes with "tracked" changes**
- **a revised copy for the IRB approval stamp.**

Signature of Principal Investigator _____ Date 10/10/13

FOR IRB USE ONLY

☐ Received & Noted ☑ Approved Expedited* ☐ To Convened IRB

Leslie Cooper, CIP — Signature (Chair, Vice-Chair, Designee)

10/15/13 — Date

DOLA 3-6-13

Change to Expedited Category **Y / N / NA**

*No change to IRB's previous determination of approval criteria at 45 CFR 46.111 or 21 CFR 56.111