# Randomized controlled trial comparing a variable-thread novel tapered and a standard tapered implant: Interim one-year results

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**Statement of problem.** A tapered implant with continuously changing threads purported to provide stable tissue support and allow immediate function has been developed. Treatment success and stabilization of supporting tissues over time require documentation.

**Purpose.** The purpose of this prospective, randomized, controlled, multicenter study was to evaluate changes in bone level and soft tissue behavior between the novel implant (NobelActive/NA) and a standard tapered implant (NobelReplace Tapered Groovy/NR) with regard to immediate function.

**Material and methods.** A total of 177 patients randomly allocated to 3 treatment groups (2 different test implant groups: NA Internal (n=117; internal connection) and External (n=82), and 1 standard treatment group, NR (n=126)) received 325 implants. Implants were placed into healed sites, and all but 6 implants were immediately nonocclusally loaded. Clinical and radiographic evaluations of treatment success, crestal bone levels, and soft tissue changes were

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performed at the time of placement and after 3, 6, and 12 months. Log-Rank test was used to analyze the differences in survival rate. Marginal bone level was compared using the Kruskal-Wallis test and Mann-Whitney U-test ($\alpha$=.05).

**Results.** One-year cumulative survival rates were comparable (96.6% for NA Internal; 96.3% for NA External; 97.6% for NR; *P*=.852; Log-Rank). Mean (SD) change in bone level was -0.95 mm (1.37) for NA Internal, -0.64 mm (0.97) for NA External, and -0.63 mm (1.18) for NR (*P*=.589; Kruskal-Wallis). Stable soft tissues and significantly increased papilla scores (*P*<.001; Wilcoxon signed-rank) were observed for all implant types.

**Conclusions.** The novel implants showed high survival rates as well as stable bone and soft tissue levels after 1 year, and may be recommended for clinical use, even under immediate function. (J Prosthet Dent 2009;101:293-305)

## CLINICAL IMPLICATIONS

The interim 1-year results of this clinical study demonstrate that the variable-thread design implant (NobelActive) may be used in clinical practice.

Osseointegrated dental implants have been shown to be predictable options for treatments ranging from the replacement of single teeth to complete arch restorations.[1-4] Historically, a 2-stage treatment protocol was used in which the implants were submerged for a healing period of 3 to 6 months before the prosthesis was inserted.[3,4] The rationale for the 2-stage procedure was to avoid loading of the implants during the healing period to ensure proper osseointegration. However, patient demand as well as technique and material developments have driven the field of dental implantology towards 1-stage treatment and immediate loading, with simplified treatment procedures, reduced surgical invasion, shorter treatment time, and reduced costs constituting some of the benefits for the patient and the clinician.[5] Provided that occlusal loads are controlled and sufficient initial stability is reached, it has been shown that predictable and successful results can be obtained for implants that are placed into function immediately after insertion.[6-14]

Implant surface chemistry and topography have been shown to affect the osseointegration process of implants. The use of an oxidized, highly crystalline, phosphate-enriched titanium dioxide surface (TiUnite; Nobel Biocare AB, Göteborg, Sweden), compared to a machined surface, has been demonstrated to preserve primary implant stability and shorten the time needed for the achievement of secondary stability, thereby reducing the time at risk when using 1-stage procedures and immediate function protocols.[15-20] Both the long- and the short-term success of this surface have been demonstrated in clinical studies.[21-23] In addition, it has been shown that placement of macroscopic grooves on the flanks of the implant thread stimulates bone formation along the implant surface.[24]

It has been demonstrated that placing an abutment with a smaller diameter on wider diameter platforms, a concept called platform shifting, can have beneficial effects on the bone remodeling around the implant.[25-27] Platform shifting may reduce the risk of soft tissue recession often seen around dental implants.[28,29] Two different mechanisms have been hypothesized to contribute to the success of platform shifting: (1) the increased length of the soft tissue-to-implant interface stabilizes the connective tissue adhesion and, in turn, the marginal bone[28]; and (2) crestal bone height is stabilized by increasing the distance between the abutment-implant interface and the bone-implant interface. The risk of local inflammation may be reduced when compared to implants restored conventionally with prosthetic components with matching diameters.[30,31]

An implant (NobelActive; Nobel Biocare AB) was recently developed which has a tapered implant body and a variable-thread design. From the apical to the coronal part of the implant, the thread design is continuously changing, in that the bottom of the thread becomes shallower and the tip of the thread becomes wider. This thread design continuously reduces the space between the threads, therefore allowing axial and radial bone compression, a feature that is purported by the manufacturer to be beneficial with cancellous bone. An inward tapered collar and built-in platform shifting should allow for marginal bone maintenance and soft tissue stabilization. This implant design makes it possible to place the implant into narrow osteotomies; additionally, it allows the surgeon to slightly change the direction of the implant during insertion to obtain an optimal position. These advantages should be beneficial for patients; however, clinical data regarding this new implant are lacking.

The primary objective of this randomized, controlled, multicenter trial was to evaluate treatment success, differences in bone level, and soft tissue responses between a novel implant (NobelActive; Nobel Biocare AB) and a standard tapered implant (NobelReplace Tapered Groovy; Nobel Biocare AB) in immediate function. The null hypothesis was that the novel implant design would not differ

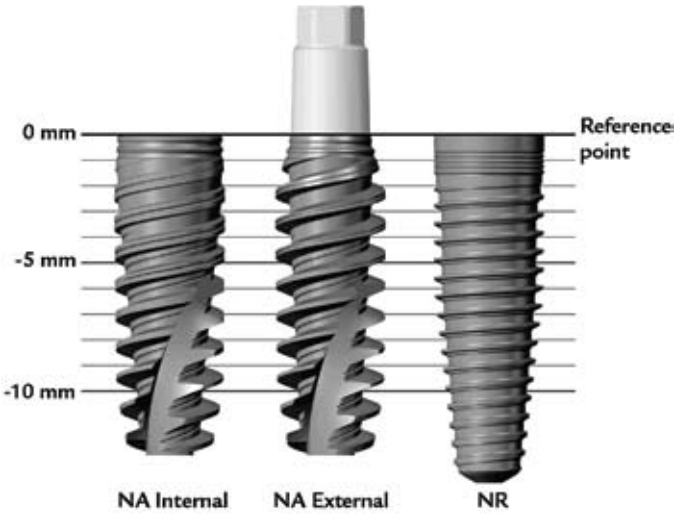
with regard to the marginal bone level when compared to a standard tapered implant after 1 year when subjected to immediate function, and the null hypothesis was tested against the alternative hypothesis of a difference.

## MATERIAL AND METHODS

This was a prospective, randomized, controlled, multicenter study in which subjects missing 1 or more teeth in either the maxilla or the mandible were consecutively included to receive 1 of the following 3 implant options: (1) a tapered implant with variable-thread design (NobelActive, NA Internal; Nobel Biocare AB); (2) a transmucosal tapered implant with variable-thread design (NobelActive, NA External; Nobel Biocare AB); or (3) a standard tapered implant (NobelReplace Tapered Groovy, NR; Nobel Biocare AB). All implants had the same surface (TiUnite; Nobel Biocare AB). The implant types used in the present study are shown in Figure 1. All patients requesting oral rehabilitation in 1 of the 12 study centers were candidates for inclusion in the study.

The study protocol called for consecutively included patients, with implants placed in healed sites with immediate provisional restoration. The following inclusion criteria were used: (1) the patient should request implant therapy, and be evaluated by the treating dentist if treatment with an implant-supported fixed restoration could be performed; (2) the patient should have an osseous architecture in the planned implant placement region sufficient to host implants with a diameter of at least 3.5 mm and a length of at least 10 mm, assessed radiologically and clinically; (3) adequate primary implant stability should be obtained to allow for immediate loading and suitable design of a provisional restoration to be connected to the implant within 24 hours after implant placement; (4) the implant sites should be completely healed (for at least 6 months after extraction) without infection.

A patient was not admitted to the study if any of the following criteria existed: (1) alcohol or drug abuse as noted in patient records or in patient history; (2) health conditions that would preclude surgical procedures (such as uncontrolled diabetes); (3) any pathological conditions such as previous tumors, chronic bone disease, or previous irradiation in the area planned for implant placement; (4) severe bruxism or clenching habits; (5) psychiatric disease or related problems as noted in patient records or in patient history; (6) inability of the patient to provide informed consent; (7) the need for bone augmentation to obtain an ideal position of the implant(s). However, a minor augmentation procedure to cover exposed threads or interproximal and/or buccal grafting due to deficient sites was not an exclusion criterion; (8) placement of the implant immediately after extraction; and (9) residence outside the city of the respective study center, insufficient contact information for follow-up, or foreseeable inability to return for follow-up. All patients had the right to withdraw from the study, at any time and with no explanation required, without any consequences to their future care.




**1** Study implant designs with reference points.

The study design was in accordance with the Helsinki Declaration of 1964 (as revised and amended in its sixth version in 2002). Approval for the study was obtained by the Ethical Review Committees at each of the 12 study centers. All patients were provided oral information about the study, and those who fulfilled the inclusion criteria and expressed interest in participating signed the informed consent and were included in the study.

All participants who met the criteria for inclusion underwent a pretreatment examination in which patient data and medical history were recorded. Patient inclusion was accomplished between April 2006 and May 2007 in the following 12 different study centers: (1) Charité - Universitätsmedizin Berlin, University School of Dental Medicine, Department of Operative Dentistry and Periodontology, Berlin, Germany; (2) University of Seville, Department of Prosthodontics, Seville, Spain; (3) Hebrew University, Hadassah Medical Center, Department of Periodontology, Jerusalem, Israel; (4) Medical University of Vienna, Department of Oral Surgery, Vienna, Austria; (5) University of Rome Tor Vergata, Department of Odontostomatology, Rome, Italy; (6) University Witten/Herdecke, Department of Oral Surgery, Witten, Germany; (7) University of Freiburg, Department of Prosthodontics, Freiburg, Germany; (8) Med-

ical University of Graz, Department of Dentistry and Maxillofacial Surgery, Graz, Austria; (9) University of Milano, Department of Implantology, Milano, Italy; (10) University of Bern, Department of Prosthetic Dentistry, Bern, Switzerland; (11) University Liége, Department of Periodontology, Liége, Belgium; (12) University Complutense of Madrid, Faculty of Odontology, Madrid, Spain. Prior to surgery, patients were randomized into 1 of the 3 treatment groups using sealed, numbered, opaque envelopes prepared in advance by the sponsor. The envelopes were prepared from a random-number table using a blocking method of 12 assignments per block. Following 12 assigned patients, 4 patients were assigned to each treatment group. The details of the randomization procedure were unknown to all of the investigators. Thus, a complete separation of the individuals involved in the generation and implementation of assignments was guaranteed. Due to the nature of the treatment, neither the study personnel nor the patients could be blinded to treatment assignment.

Pre- and postoperative medication (including type of analgesics or antibiotics, if appropriate) was administered according to the protocols of the respective study center. The clinical procedure was performed according to the manufacturer's guidelines for the respective implant systems. All implants were placed by dentists experienced in the field of implantology who had participated in 2 extensive calibration sessions and thorough training with the test implants. The implants were placed in healed sites, and bone quality and quantity at each implant site was assessed according to the Lekholm and Zarb classification.[32] In short, bone quality was assessed as one of the following: (1) almost the entire jaw is comprised of homogeneous compact bone; (2) a thick layer of cortical bone surrounds a core of dense cancellous bone; (3) a thin layer of cortical bone surrounds a core of dense cancellous bone of favorable strength; (4) a thin layer of cortical bone surrounds a core of low density cancellous bone. Bone quantity was assessed as one of the following: (A) most of the alveolar ridge is present; (B) moderate residual ridge resorption has occurred; (C) advanced residual ridge resorption has occurred and only basal bone remains; (D) some resorption of the basal bone has begun; (E) extreme resorption of the basal bone has occurred. Insertion torque was measured for all implants using a special torque wrench able to measure torques up to 150 Ncm (150 Ncm manual torque wrench; Nobel Biocare AB).

In all but 3 patients, an immediate provisional restoration was placed within 24 hours of implant insertion. In the remaining 3 patients (6 implants), the provisional restorations were placed 48, 72, and 96 hours after implant insertion due to logistical reasons. All patients were restored with definitive restorations during the first year.

Following implant placement, the patients were provided with home-care maintenance instructions and mouthrinses (chlorhexidine; GlaxoSmithKline, Bühl, Germany; or AmF/$SnF_2$ mouthrinse; GABA Intl, Therwil, Switzerland) as an adjunct to routine oral hygiene, if appropriate, and scheduled for postoperative follow-ups at 3 months, 6 months, and 1 year after implant placement. The following parameters were investigated at the follow-up visits. Implant stability was clinically assessed as stable, having rotational mobility, or requiring removal. Soft tissue esthetics were assessed through shape of the papillae and soft tissue remodeling. The papilla was evaluated using the Jemt papilla score.[33] In short, the papilla was assessed as: (0) no papilla is present; (1) less than half of the height of the papilla is present; (2) half or more of the height of the papilla is present; (3) the papilla fills the entire proximal space; (4) the papilla is hyperplastic. The soft tissue remodeling was evaluated by measuring the distance from the top of the implant-supported restoration down to the gingival margin (the height of the crown) at different time points using a periodontal probe. Measurements from implant insertion served as baseline records for evaluation of the soft tissue remodeling over the study period. Double measurements, both with the provisional restoration and the definitive prosthesis, were conducted at the time of definitive prosthesis insertion to allow for comparisons of soft tissue levels throughout the study. The status of the periimplant mucosa was evaluated and registered as either normal periimplant mucosa (score of 0), bleeding on superficial probing or discoloration (score of 1), or spontaneous bleeding of mucosa (score of 2). Plaque was assessed as no visible plaque or visible plaque. Due to prosthesis design, soft tissue parameters were not applicable for all implant sites.

Crestal bone levels around the implants, a surrogate outcome for treatment success,[34] were assessed by evaluation of intraoral radiographs. Radiographs were made using a long-cone paralleling technique at the time of implant insertion (baseline measurement)[35] and at the 3-month, 6-month, and 1-year follow-up visits. The different centers used different radiographic receptors, film or digital, with the exposure time appropriate for each system. Film radiographs were scanned using a flatbed scanner (Scanmaker i900; Mikrotek, Cerritos, Calif), and all radiographs were digitally evaluated. The marginal bone level, that is, the position of the most apical bone-to-implant contact point as compared to a reference point on the implant, was evaluated. Radiographs were displayed in software (Adobe Illustrator CS3 version 13.0.2; Adobe Systems, San José, Calif) on a 24-inch LCD screen (iMac; Apple, Cupertino, Calif) and evaluated under standardized conditions. The screen resolution was 1920 x 1200 pixels. The measuring tool of the software was used to calculate the measure-

ments, with magnifications taken into account. The reference points used for the readings were the top of the rough surface part of the implant for NA External and the top of the implant for NA Internal and NR (Fig. 1). The distance from the reference point to the bone level was recorded both mesially and distally (with mean values calculated for each implant). Two independent radiologists at Göteborg University, Göteborg, Sweden, assessed the radiographs. As in other studies of different implants, it was not possible to blind the outcome assessors to the interventions, since, in all patients, the different shapes of implants and abutments were easily recognizable.

The primary endpoint with respect to efficacy was the marginal bone level after 1 year. An additional analysis was performed on bone remodeling during the first year. The marginal bone levels and remodeling of the 2 test groups (NA Internal and NA External) were combined into 1 group, the test group, and compared to the control group (NR) using the Mann-Whitney U-test. In a subanalysis, individual differences in marginal bone levels and remodeling between all 3 treatment groups were compared using a Kruskal-Wallis test with a post hoc analysis using multiple Mann-Whitney U-tests with Bonferroni correction (factor of 3). The Kruskal-Wallis test was used to analyze the differences in soft tissue remodeling between the 3 treatment groups. Analysis of change in papilla score was done using the Wilcoxon signed-rank test. Implant sites with papilla score 4 (hyperplastic) were not included in the statistical analysis, since this would falsely improve the papilla score results due to a limitation in the score design. For scores 0 to 3, each step represents a gradual improvement in papilla status, whereas scores from 3 to 4 indicate an impairment. The Log-Rank test was used to analyze the differences in survival rate between the 3 treatment groups. Commercially available statistical software (SPSS 15.0; SPSS, Inc, Chicago, Ill) was used for the statistical analyses.

For the comparison of marginal bone levels, the calculation of sample size was performed based on the Mann-Whitney U-test with a difference in marginal bone height of 0.5 mm and a standard deviation of 0.9 mm. The alpha (Type I) error level was set to .05, with a power of 80%. The sample size calculation resulted in 55 patients per treatment group. The number of patients per group was set to 60 patients to allow for a patient withdrawal rate of up to 10%, resulting in 180 patients in total. A priori sample size calculation was performed with dedicated software (SAS; SAS Institute, Cary, NC).

## RESULTS

Twelve centers consecutively treated 177 patients; 92 women and 85 men. The NA Internal group had 37 women and 27 men, while the NA External group consisted of 21 women and 32 men. There were 34 women and 26 men in the control (NR) group. The flow of patients through the stages of the study is shown in Figure 2. Data up to the time of withdrawal of patients were included in the analysis; 3 patients in the NR group withdrew due to poor compliance; all others (1 NA Internal, 3 NA External, and 1 NR) withdrew due to loss of the study implant.

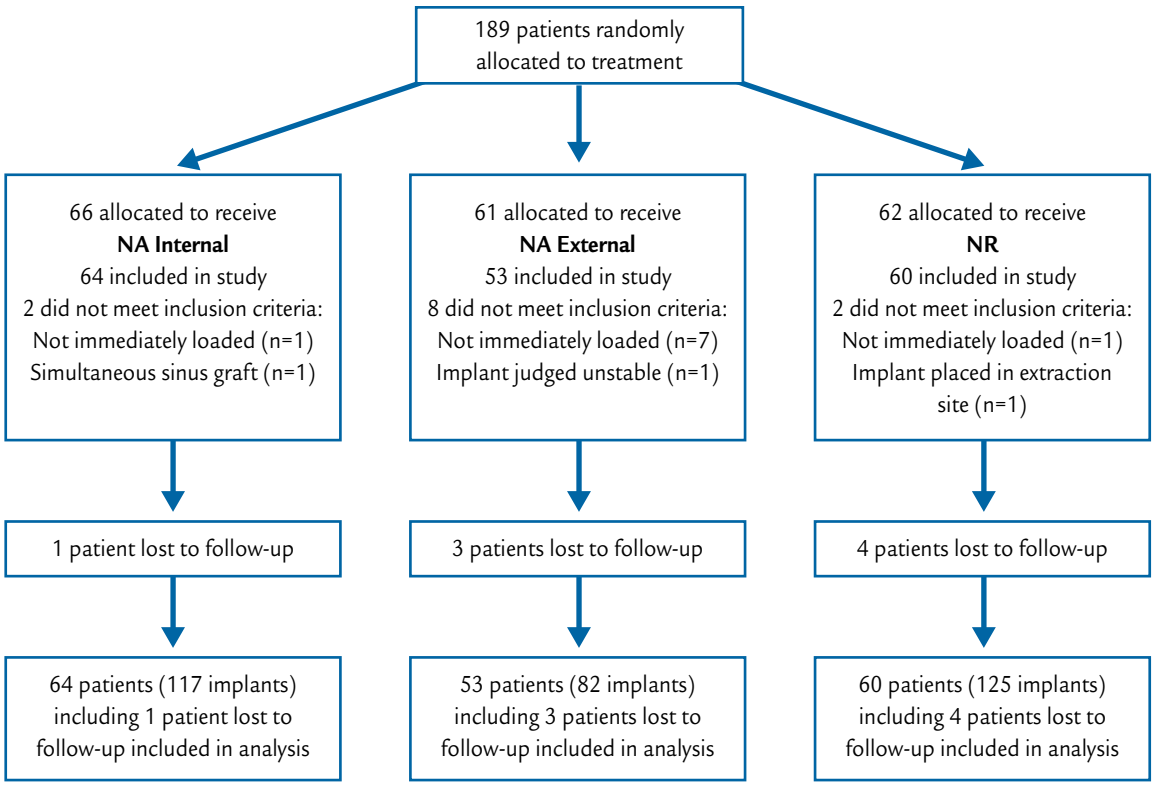
Patient age at time of surgery ranged from 17 to 79 years with a mean (SD) age of 48.7 (13.7) years for all groups. Mean (SD) age was 49.5 (13.1) years for NA Internal, 49.9 (13.6) years for NA External, and 46.9 (14.6) years for NR. The mean age of women and men was 47.4 and 50.3 years, respectively. A total of 325 implants (117 NA Internal, 82 NA External, and 126 NR) were placed. Two hundred and twenty-two implants (68.3%) were placed in the mandible and 103 implants (31.7%) were placed in the maxilla (Fig. 3). The implants were available in 2 diameters (3.5 and 4.3 mm) and 6 different lengths (Table I).

The majority of the implants (86.8%) were placed in bone quality of type II and III. Bone quantity was assessed as type A and B in 82.8% of the implants (Table II). For 18 implant sites (5 NA Internal, 8 NA External, and 5 NR), minor bone augmentation was performed to cover exposed threads or interproximal/buccal grafting. The mean (SD) insertion torque was 51.6 (18.4) Ncm for NA Internal, 50.4 (21.0) Ncm for NA External, and 41.3 (11.6) Ncm for NR (Fig. 4).

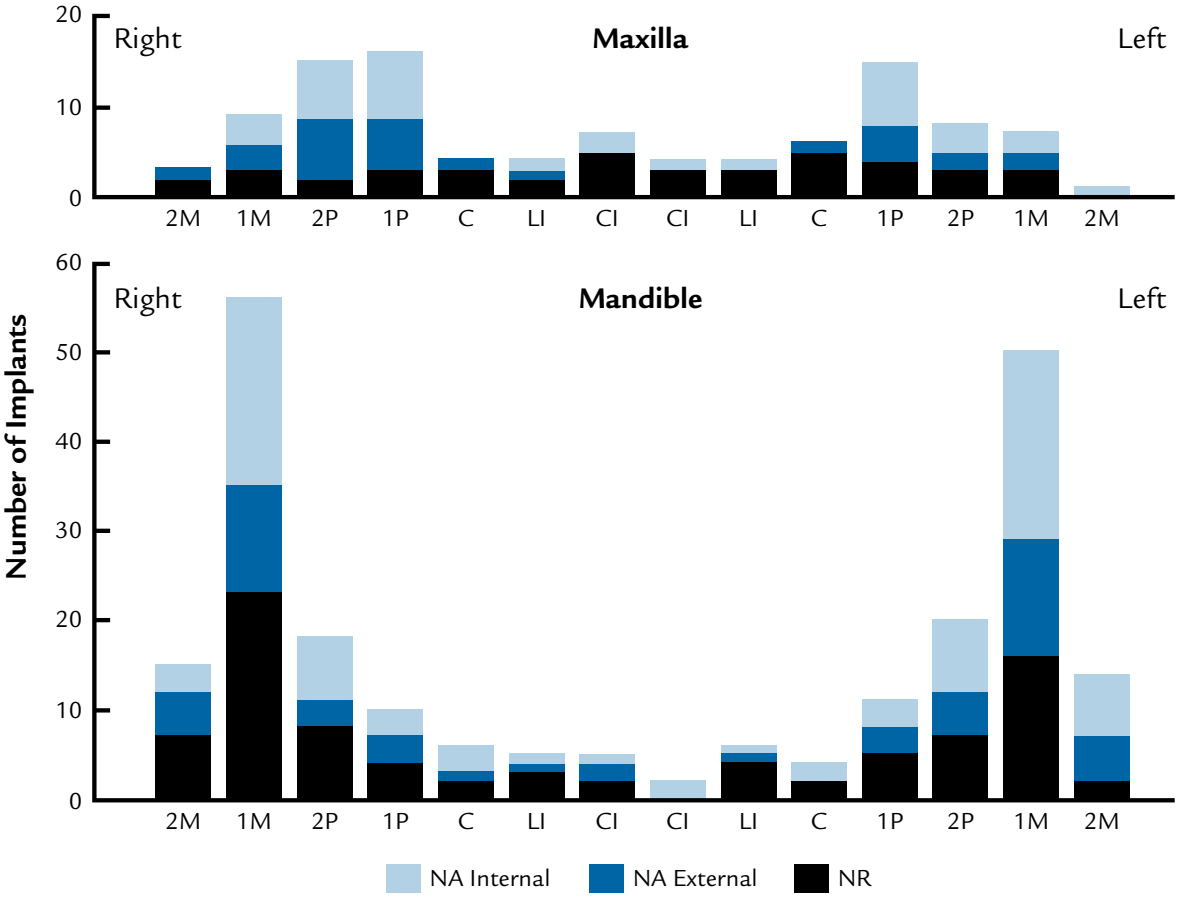
About half of the implants (52.3%) were provisionally restored with a single crown, while the other implants were restored with either a fixed dental prosthesis (35.7%) or with fixed dentures (12.0%, Table III). Fifteen implants that were initially splinted and restored with a fixed provisional multi-unit fixed prosthesis were later restored with definitive single crowns, resulting in 55.6% of the implants being restored with a single crown. In all, 33.1% implants were restored with multi-unit fixed prostheses and 11.3% with a fixed complete arch restoration (Table III).

Ten of the 325 implants failed and had to be removed before or at the 1-year follow-up (Table IV). Of the failed implants, 4 were from the NA Internal group, 3 from the NA External group, and 3 from the NR group, thus resulting in implant survival rates of 96.6%, 96.3%, and 97.6%, respectively, after 1 year. Five implants from the NR group were not followed up because the patients did not return for further evaluations. Statistical analysis comparing survival data between the 3 treatment groups demonstrated no significant difference after 1 year ($P$=.852; Log-Rank). Pairwise comparison of the 3 groups demonstrated no differences between any groups after 1 year ($P$>.853; Log-Rank adjusted for multiple comparisons using Tukey-Kramer test).

The marginal bone remodeling from implant insertion to the 1-year follow-up is presented in Table V. Negative numbers indicate bone loss.




**2** Graphic depiction of flow of participants through each stage of randomized trial.



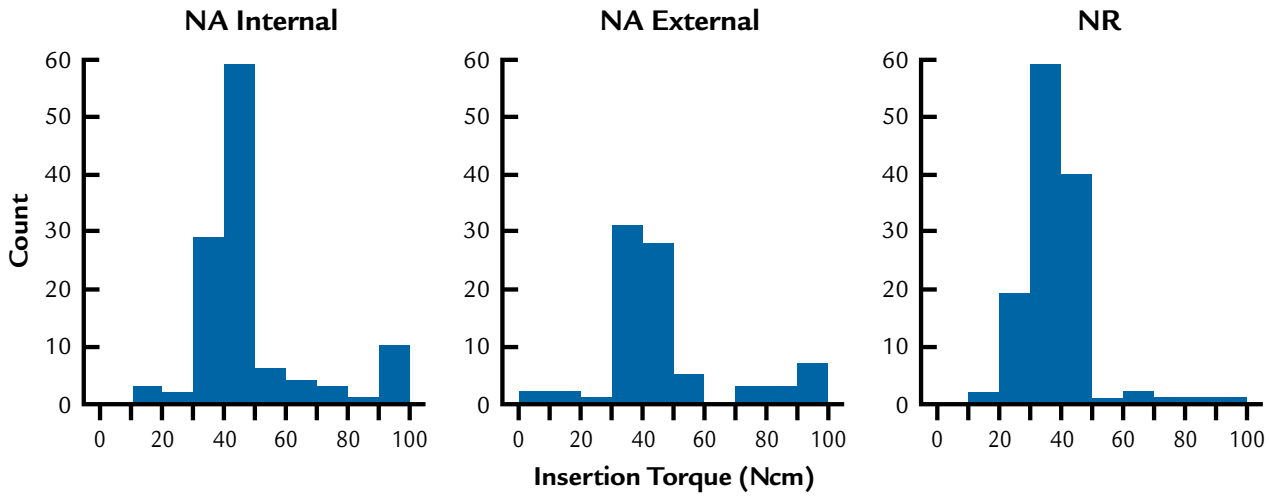

**3** Distribution of implant positions (CI: central incisor; LI: lateral incisor; C: canine, P: premolar; M: molar).

Table I. Implant sizes evaluated

| Implant Type | Implant Length | Implant Diameter | | Total |
|---|---|---|---|---|
| | | 3.5 mm | 4.3 mm | |
| NA Internal | 10 mm | 4 | 20 | 24 |
| | 11.5 mm | 13 | 32 | 45 |
| | 13 mm | 11 | 32 | 43 |
| | 15 mm | 2 | 3 | 5 |
| | Total | 30 | 87 | 117 |
| NA External | 10 mm | 4 | 12 | 16 |
| | 11.5 mm | 3 | 22 | 25 |
| | 13 mm | 6 | 33 | 39 |
| | 15 mm | 1 | 1 | 2 |
| | Total | 14 | 68 | 82 |
| NR | 8 mm | 0 | 1 | 1 |
| | 10 mm | 10 | 31 | 41 |
| | 13 mm | 27 | 51 | 78 |
| | 16 mm | 1 | 5 | 6 |
| | Total | 38 | 88 | 126 |
| Grand total | | 81 | 244 | 325 |

Table II. Bone quality and quantity (for definitions of 1-4 and A-E, see text)

| Implant Type | | | Quality | | | | Total |
|---|---|---|---|---|---|---|---|
| | | | 1 | 2 | 3 | 4 | |
| NA Internal | Quantity | A | 4 | 26 | 12 | 1 | 43 |
| | | B | 10 | 21 | 27 | 2 | 60 |
| | | C | 2 | 3 | 7 | 0 | 12 |
| | | D | 0 | 1 | 1 | 0 | 2 |
| | | Total | 16 | 51 | 47 | 3 | 117 |
| NA External | Quantity | A | 1 | 19 | 12 | 0 | 32 |
| | | B | 1 | 16 | 23 | 3 | 43 |
| | | C | 0 | 2 | 4 | 1 | 7 |
| | | Total | 2 | 37 | 39 | 4 | 82 |
| NR | Quantity | A | 7 | 25 | 8 | 1 | 41 |
| | | B | 1 | 24 | 23 | 2 | 50 |
| | | C | 0 | 5 | 19 | 1 | 25 |
| | | D | 4 | 0 | 2 | 0 | 6 |
| | | E | 2 | 2 | 0 | 0 | 4 |
| | | Total | 14 | 56 | 52 | 4 | 126 |




**4** Distribution of insertion torques in various groups.

TABLE III. Type of restoration

| Implant Type | NA Internal | | NA External | | NR | |
|---|---|---|---|---|---|---|
| | Provisional | Definitive | Provisional | Definitive | Provisional | Definitive |
| Single | 71 | 71 | 43 | 38 | 56 | 49 |
| Partial | 41 | 27 | 39 | 36 | 36 | 31 |
| Complete arch | 5 | 5 | 0 | 0 | 34 | 27 |
| Total | 117 | 103* | 82 | 74* | 126 | 107* |

*Information missing for definitive prosthesis

TABLE IV. Data for nonintegrated implants

| Treatment Group | Implant Position | Type of Restoration | Bone Quality | Bone Quantity | Insertion Torque (Ncm) | Time to Failure (Days) | Suspected Reason for Implant Loss |
|---|---|---|---|---|---|---|---|
| NA Internal | Max P | Single crown | 1 | B | 50 | 336 | Occlusal overload |
| NA Internal | Mand M | Single crown | 2 | A | 50 | 365 | Periimplantitis |
| NA Internal | Max P | Single crown | 2 | A | 50 | 35 | Mobility |
| NA Internal | Mand M | Single crown | 3 | B | 75 | 85 | Mobility |
| NA External | Mand M | Single crown | 1 | A | 32 | 118 | Mobility |
| NA External | Mand M | Single crown | 3 | C | 35 | 100 | Mobility |
| NA External | Mand P | Single crown | 3 | B | 40 | 22 | Mobility |
| NR | Mand M | Single crown | 2 | B | 50 | 56 | Mobility |
| NR | Mand P | Single crown | 1 | A | 35 | 152 | Mobility |
| NR | Mand P | Single crown | 3 | C | 30 | 23 | Mobility |

Mand: mandibular; Max: maxillary; P: premolar; M: molar

Table V. Marginal bone remodeling, mean values, and standard deviation (SD). Negative numbers indicate bone loss

| | | NA Internal | NA External | NR |
|---|---|---|---|---|
| Implant insertion | Mean | -0.95 | -0.64 | -0.63 |
| to 1 year | SD | 1.37 | 0.97 | 1.18 |
| | Number | 87 | 69 | 85 |
| | Bone remodeling (mm) | n | n | n |
| | >0 | 14 | 14 | 19 |
| | 0 | 2 | 2 | 3 |
| | -1.0 – -0.1 | 38 | 26 | 32 |
| | -2.0 – -1.1 | 19 | 22 | 25 |
| | -3.0 – -2.1 | 9 | 4 | 3 |
| | -4.0 – -3.1 | 3 | 0 | 3 |
| | < -4.0 | 2 | 0 | 0 |

Statistical analysis of the bone remodeling from implant insertion to the 1-year follow-up demonstrated no significant difference either when comparing NA (Internal and External combined to 1 group) to NR ($P$=.729; Mann-Whitney), or when comparing all 3 treatment groups separately ($P$=.589; Kruskal-Wallis).

One serious procedure/device-related adverse event (hypesthesia, in the NR group) was reported. All adverse events are presented in Table VI. Other procedure/device-related events were considered nonserious (according to the protocol, any undesirable clinical occurrence in a subject, whether it was considered to be device related or not, was recorded), and were predominantly related to the suprastructures. Eighteen of the 23 suprastructure-related adverse events, mostly the result of loosening or debonding of cemented crowns/fixed dental prostheses or of abutment screws, occurred in provisional restorations.

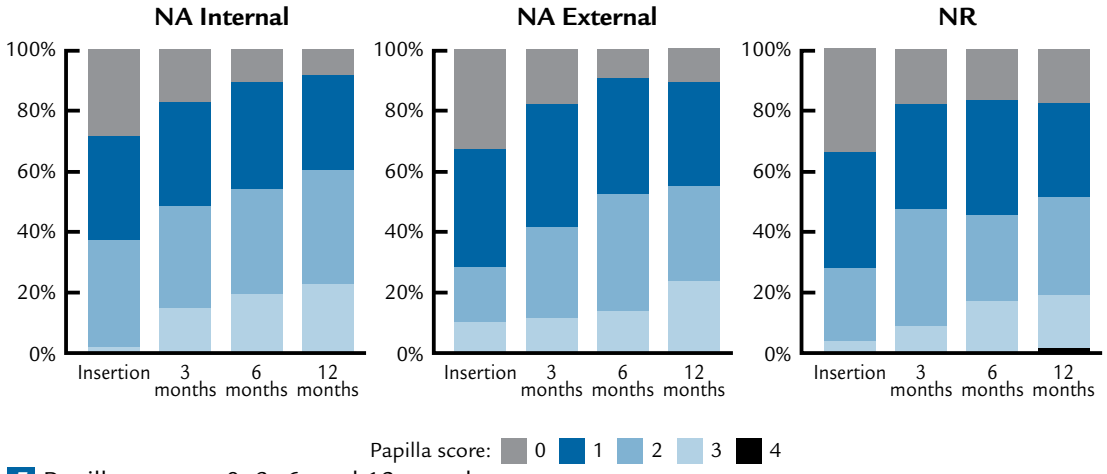
The distribution of papilla scores at different time points is shown in Figure 5. All 3 implant types show a similar distribution of papilla scores and the same trend in increasing papillae over time. At the 1-year follow-up, 1 NR implant site had a hyperplastic papilla (score 4). An increase in the papilla score was seen in 57.0% of evaluated papillae (57.9% for NA Internal, 53.2% for NA External, and 59.2% for NR), whereas a decrease in the papilla score was only seen in 7.6% of the papillae (5.6% for NA Internal, 7.8% for NA External, and 10.1% for NR). A significantly increased papilla score during the first year ($P$<.001; Wilcoxon signed-rank) was observed for all implant types.

Statistical analysis of the soft tissue remodeling from implant insertion to the 1-year follow-up demonstrated no significant difference between the treatment groups ($P$=.437; Kruskal-Wallis). Mean (SD) values for soft tissue changes from implant insertion to the 1-year follow-up were 0.16 (1.13) mm for NA Internal (n=83), -0.18 (1.69) mm (recession) for NA External (n=69), and -0.02 (1.71) mm (recession) for NR (n=66), respectively. The percentage of implant sites with no visible plaque was stable for all treatment groups throughout the first year (Fig. 6).

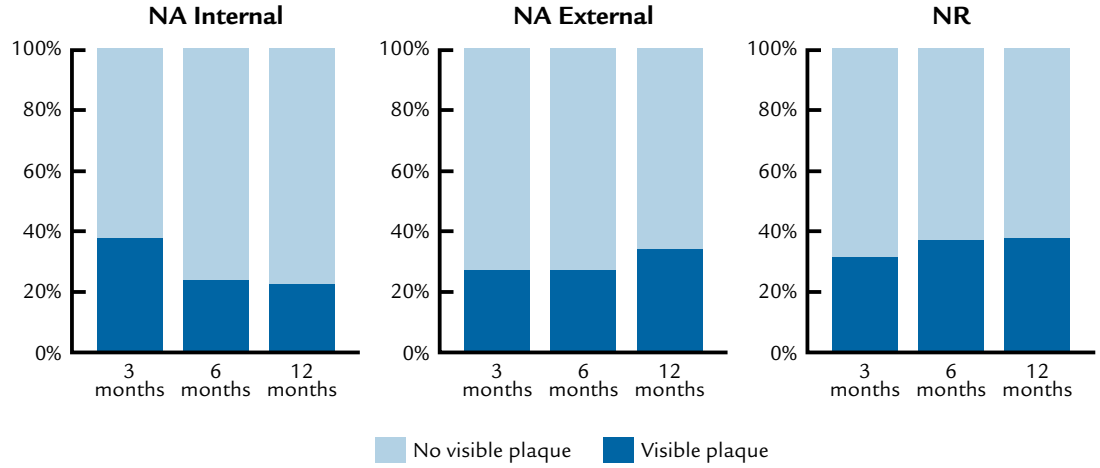
The number of implant sites with healthy periimplant mucosa exceeded 75% at the 3-month follow-up and was about 90% at the 1-year follow-up for NA Internal. For the NA External group, more than 90% of the implants showed healthy mucosa at the 3-month follow-up, and this increased to 95% at the 1-year follow-up. For the NR group, healthy mucosa was observed in more than 75% of the implant sites at the 3-month follow-up, and this increased to more than 80% at the 1-year follow-up. All other values corresponded to bleeding on superficial probing (with 1 implant site showing spontaneous bleeding in the NA External group).

TABLE VI. Number of adverse events at patient level

| Adverse Event | NA Internal | NA External | NR |
|---|---|---|---|
| Serious | | | |
| Hypaesthesia (device related) | 0 | 0 | 1 |
| Acute leukemia (not device related) | 0 | 0 | 1 |
| Squamous cell cancer (not device related) | 1 | 0 | 0 |
| Nonserious | | | |
| Suprastructure complications | 9 | 6 | 8 |
| Implant mobility | 3 | 2 | 1 |
| Implant fracture during insertion | 0 | 0 | 2 |
| Pain | 1 | 0 | 0 |
| Swelling/sore gingiva | 0 | 2 | 0 |
| Periimplantitis | 1 | 0 | 0 |
| Soft tissue recession | 0 | 0 | 1 |
| Buccal exostosis | 0 | 1 | 0 |
| Sinus perforation | 0 | 1 | 0 |




5 Papilla score at 0, 3, 6, and 12 months.




6 Plaque accumulation.

## DISCUSSION

No significant differences in bone remodeling between the different treatment groups were found. The present study revealed the same or less bone remodeling when compared to results from previous studies on the standard implant design (NR) used in the present study.[5,21,23] Measurement of crestal bone levels can be defined as a measure of treatment success, and has been classified as a surrogate outcome (a prognostic factor intended to capture the treatment effect on the clinical endpoint, but not directly measuring the main clinical benefit of the intervention).[34] Surrogate endpoints may be useful diagnostic tools for the early detection of potential problems, thus allowing for early treatment to preserve healthy conditions. Moreover, surrogate endpoints are considered sensitive predictors for true outcomes.[34] The marginal bone level was stable, and this was in contrast to other studies reporting on a gradual loss of periimplant bone during the first year.[6,22,23] Eight implants (5 NA Internal, 3 NR) lost more than 3 mm of bone during the first year in function. In total, mean crestal bone level outcomes between the NA groups and the NR group were comparable. Thus, the null hypothesis was not rejected.

Despite randomization and proper group allocation concealment, the treatment groups were not equally distributed with respect to all of the different parameters, such as implant position and type of indication. These subgroups were too small to allow for a proper analysis of the influence the group constitution might have had on the primary variable. To compare the effect of different implant characteristics, the present study was designed in such a way that only the characteristic of interest (the new implant design) was different for the test versus standard treatment group, whereas all of the other parameters (material and surface) were identical.

In the present study, 10 implants (4 NA Internal, 3 NA External, and 3 NR) were lost during the first year in function, resulting in favorable cumulative survival rates in the different treatment groups. The novel implant performed well in a wide variety of situations, from single tooth to fixed complete denture restorations, and in all positions and all bone qualities. No significant differences in survival rate between the treatment groups were observed. The survival rates were within the range of survival rates reported in clinical studies of immediate function and loading of dental implants.[8,10]

Soft tissue remodeling and interdental papillae dimensions near the test implants, both the NA Internal and the NA External, were comparable to those of the NR standard treatment implants. Almost no soft tissue remodeling was observed in the study, and the mean papilla score significantly increased in all treatment groups during the first year (Fig. 5). This was in agreement with a recent investigation, in which concave, gingivally converging abutments were used, allowing for above-average soft tissue outcomes.[28] These results might be attributed to the surface of the implants used in the present study, and are likely also due to the favorable crestal bone height. Thus, the present results revealed stable periimplant soft tissue architecture and less tendency for recession of the labial soft tissue. Results from previous studies with conventional implants indicate a mean soft tissue recession of 0.6 mm after 1 year in function using a 2-stage surgical protocol.[9,29]

The novel implant has a number of features that lead to an altered surgical protocol compared to standard implant types. The reverse cutting flutes of the NA implant allow for a gradual widening of the osteotomy; therefore, the additional number of drilling procedures that are required with standard implants are reduced. The expanding tapered body acts like a threaded osteotome, and high primary stability can be achieved, even in compromised bone situations. The back-tapered coronal region (built-in platform shift) allows for a maximum of alveolar bone volume around the implant, which should improve soft tissue support. Finally, manual insertion protocols enable active directional changes during the surgical procedure, and an optimal restorative position can be achieved in both vertical and transversal dimensions.

The NA implants were placed using a higher mean insertion torque than that used for the NR group (Fig. 4). This increase in insertion torque can be explained by the implant design. NA implants have a 1.2-mm thread spacing with a double-lead thread, which means that the implant advances 2.4 mm with each rotation of the implant (as purported by the manufacturer), compared to 0.7 mm for the NR implant. Theoretically, an implant with higher thread pitch (NA) requires more torque for insertion than a comparable implant with lower thread pitch (NR), since the implant is inserted in fewer turns. However, this higher insertion torque does not necessarily result in higher pressure to the surrounding bone. Furthermore, a high degree of primary stability (achieved by a sufficient insertion torque) at the time of implant insertion is generally considered a prerequisite for a successful immediate or early loading procedure. In the present study, no correlation was seen, either between insertion torque and bone remodeling, for any implant system (Pearson correlation; $P>.317$ for all implant types; r=0.036 for NA Internal, 0.016 for NA External, and -0.110 for NR), or between insertion torque and failure rates (Table IV). However, it should be emphasized that this study was not designed to investigate associations between insertion torques and outcomes.

For 15 implants, splinted provisional restorations were placed initially, while definitive restorations were separate (single) crowns. It is possible that the results of the present study could have been influenced

by this inconsistency. Indeed, this regimen could have affected force distributions and loading conditions. However, distribution over the study groups was comparable, and, thus, possible effects should have leveled out. As with all multicenter studies, there might be some bias due to varying study center characteristics and routines. Differences between centers were minimized by the use of a standardized surgical protocol and strict follow-up routines. Some freedom was given in the surgical protocol regarding soft tissue, and in the pre- and postsurgical medication, and this lack of completely standardized conditions may affect study conclusions. However, it should be emphasized that the present multicenter study design provides a platform for generating data that resembles normal clinical use of a product.

The recently introduced implant showed stable supporting bone and soft tissue levels after 1 year in function. The results revealed 1-year survival rates that were comparable to a standard tapered implant. This outcome is promising, particularly when considering the strict multicenter study protocol. Nonetheless, continued follow-up is indicated to confirm the preliminary results of this study.

## CONCLUSIONS

Within the limitations of the present study, the results show stable bone and soft tissue levels after the first year in function for this novel variable-thread design implant. From the results, it can be concluded that the novel implant may be used with immediate function. However, long-term follow-ups are important when evaluating new implant systems and needed to evaluate function over time.

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## Noteworthy Abstracts of the Current Literature

# The use of 3 different imaging methods for the localization of the mandibular canal in dental implant planning

Peker I, Alkurt MT, Michcioglu T.
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**Purpose:** The purpose of this study was to investigate the efficiency of panoramic radiography, conventional (cross-sectional) tomography, and computerized tomography for location of the mandibular canal before implant placement in the posterior region of the mandible.

**Materials and Methods:** Edentulous mandibles from 6 dry adult human skulls were used in this study. Four measurements ($D_1$, $D_2$, $D_3$, $D_4$) were made of 12 areas, one on each side of each mandible. Panoramic radiographs, conventional tomograms, and computerized tomograms were obtained. On each image, measurements were made for localization of the mandibular canal by one researcher. All measurements were repeated 3 times within a period of 3 weeks. Upon completion of imaging, the mandibles were surgically sectioned to provide direct measurements. The measurements obtained from the images were compared with direct measurements. Pearson correlation coefficients were calculated to detect statistical correlations between repeated measurements. The Dunnett t test was performed for statistical comparison of measurements from images and direct measurements.

**Results:** Pearson correlation coefficients showed strong linear correlation for all measurements ($P < .01$). No statistically significant difference was observed between direct measurement and $D_1$, $D_2$, or $D_4$ ($P < .05$), but a statistically significant difference for $D_3$ (buccolingual width 5 mm under mandibular crest; Dunnett t test; $P > .05$) between measurements was obtained from the images and direct measurements.

**Conclusion:** The measurements obtained from computerized tomographic images were more consistent with direct measurements than the measurements obtained from panoramic radiographic images or conventional tomographic images.