STUDY PROTOCOL

Subcrestal placement of PRAMA implants with convergent neck incorporating Ultrathin Threaded Microsurface: A randomized controlled clinical trial

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Subcrestal placement of PRAMA implants with convergent neck incorporating Ultrathin Threaded Microsurface. A randomized controlled clinical trial.

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Introduction

Subcrestal implant placement has been indicated as a method capable of better maintaining the volume and height of hard and soft tissues compared to implants placed at the level of the alveolar bone crest (Hermann et al. 2001, Novaes et al. 2009; Barros et al. 2010; Degidi et al. 2011; Huang et al. 2012). A systematic review with meta-analysis concluded that platform-switching implants placed subcrestally show less marginal bone level change compared to crestally placed implants (Valles et al. 2018). In an experimental study in dogs (Cesaretti et al. 2014), similar results were reported, with the bone crest and coronal bone contact with the implant in a more coronal position in the subcrestal group compared to the crestal group. However, when the data were related to the original bone level, subcrestal implants showed more loss of buccal marginal bone and greater soft tissue recession than crestal implants.

In that experiment, the neck surface was polished, and this configuration may have influenced the results. These findings are consistent with a clinical study in which

two implants with a 2.8 mm polished neck were placed in eleven patients (Hämmerle et al. 1996). One implant was placed with the rough margin at the bone crest level, while the other was placed with that margin 1 mm subcrestally. Greater bone loss was observed in the subcrestal implants. Again, the neck surface was polished, suggesting that surface treatment of the neck might be necessary.

The characteristics of the abutment surface may influence marginal bone level if the implant is placed subcrestally. In a dog experiment (Welander et al. 2009), the rough margin of the implant was placed 2 mm subcrestally. Abutments with standard or rough surfaces were applied to the control and test sites, respectively. After four months of healing, the marginal bone level was more coronal in the subcrestal implant compared to the crestal ones. About 40% of the test implants exhibited bone apposition coronal to the abutment/fixture junction. Two-piece implants were used in this experiment. In another dog study (Hermann et al. 2011), bone and soft tissue levels were evaluated in one-piece non-submerged implants and two-piece submerged or non-submerged implants. One-piece implants with a rough neck surface exhibited more coronal peri-implant mucosa and less marginal bone loss compared to implants with a polished surface. Furthermore, conical abutments with a convergent transmucosal morphology showed less marginal bone loss compared to divergent configurations (Agustín-Panadero et al. 2019). Conical abutments applied with the platform-switching concept have shown circular fibers that could contribute to the long-term stabilization of marginal peri-implant soft and hard tissues (Rodríguez et al. 2016). Moreover, an in vitro study (Doyle et al. 2009) showed that unidimensional surface patterns favor cell migration and phenotype expression.

The effect of subcrestal implant positioning on hard and soft tissues remains controversial, and using an implant that incorporates three features—one-piece design, convergent (conical) neck, and micro-threads across the entire surface—could provide important clinical insights. Therefore, the aim of this RCT is to compare longitudinal changes in peri-implant hard and soft tissue levels around one-piece implants with conical necks and micro-threads placed juxtacrestally or subcrestally.

Materials and Methods

The protocol will be submitted for approval to the Ethics Committee of the local research center, and the Declaration of Helsinki on medical protocols and ethics will be applied. Patients will be informed about procedures and possible complications and asked to sign informed consent. The study will follow the CONSORT checklist (http://www.consort-statement.org/). This RCT will be registered at ClinicalTrials.gov to obtain an identification number xxxxxxx.

Study Population

In this parallel randomized controlled trial, patient recruitment, surgeries, and follow-ups will be carried out at the University of Medical Sciences of Havana.

Inclusion criteria: 1. Edentulous area allowing placement of two implants in the posterior maxilla or mandible (premolars and molars); 2. Alveolar bone height allowing insertion of implants at least 6 mm deep (minimum total of 10 mm); 3. Need for implant-supported prosthetic restoration; 4. ≥21 years old; 5. Good general health without contraindications for oral surgical procedures; 6. Not pregnant; 7. Patients

who agree to participate and sign informed consent.

Exclusion criteria: 1. Presence of uncontrolled systemic disease; 2. History of chemotherapy or radiotherapy; 3. Smokers declaring >10 cigarettes per day; 4. Previous bone regeneration procedures at the target site.

Implants Used

The PRAMA implant, 6 mm in length and 3.8 mm in diameter (Sweden & Martina, Due Carrare, Padua, Italy), is a one-piece implant (Agustín-Panadero et al. 2019) with a ZirTi surface (Caneva et al. 2016). The neck has three different configurations: short type (1.8 mm high with hyperbolic convergent coronal portion), standard type (0.80 mm cylindrical portion and 2.00 mm convergent portion), and long type (0.80 mm cylindrical portion and 3.00 mm convergent portion). The entire neck surface contains parallel micro-threads (Ultrathin Threaded Microsurface - UTM).

Study Design

This is a parallel randomized controlled trial. Two implants per patient will be used to restore edentulous posterior ridges of the maxilla or mandible with 2- or 3-unit bridges. Three patient groups will be included, each receiving randomly assigned implants with short (short group), standard (standard group), or long necks (long group). Implants will be placed with the coronal margin of the rough surface at the bone crest for the short group; 1 mm below the crest for the standard group; and 2 mm below the crest for the long group.

Additionally, one of the implant-supported crowns will have a false root shape

apically, while the other will have a traditional shape adapted to the mucosal margin.

Sample Size

Sample size was calculated based on a preclinical experimental study in dogs that showed statistically significant differences in soft and hard tissue levels using six animals (Cesaretti et al. 2015). Given the parallel design and potential dropouts, 30 patients will be included, ten per group (n=10).

Randomization and Allocation Concealment

Randomization will be conducted electronically by one author not involved in surgical procedures (DB). Assignments will be sealed in opaque envelopes opened at the clinic. Treatment allocation will be revealed to the surgeon after flap elevation and before site preparation. The distribution of differently shaped crowns will also be randomized and concealed as described above, and operators will only know at the time of prosthesis delivery.

Clinical Procedures

Clinical procedures will be performed by an experienced clinician (MCM). All surgeries will be performed applying a digital workflow. Both implants will be placed according to random assignment (see study design). Healing screws of sufficient length will be applied to ensure non-submerged healing. Sutures will be placed to adapt the flaps around the healing screw. Sutures will be removed after approximately 1 week. After three months of healing, digital impressions will be taken, and customized 2- or 3-unit zirconia bridges will be provided. Except for

complications, antibiotics will not be prescribed.

Maintenance

After surgery, patients may take analgesics if needed. 0.12% chlorhexidine mouth rinses will be used three times daily until suture removal (7-10 days). Patients will be enrolled in a maintenance program throughout the study. They will be followed for at least 3 years, and data will be reported annually.

Clinical and Radiographic Evaluations

At prosthesis installation (Baseline), probing depth will be recorded. Clinical photographs, standardized intraoral radiographs, CBCT, and digital impressions will be taken.

-After 6 months, plaque index, bleeding on probing, and probing depth will be assessed. Clinical photos, intraoral radiographs, and digital impressions will be repeated.

-Annually: plaque index, bleeding on probing, and probing depth will be evaluated. Clinical photos, intraoral radiographs, CBCT, and digital impressions will be collected.

Calibration for Measurements and Blinding Procedures

Radiographic image analysis will be performed by an experienced evaluator blinded to treatment groups, although implant types may be recognizable in images. For 3D image analysis, the evaluator will be blinded to treatment allocation.

Imaging Analysis

Bone tissue levels will be evaluated on intraoral radiographs and CBCT images. Peri-implant volumes will be assessed using 3D images obtained from digital impressions.

Interventional Study Model

Parallel Assignment (with a split-mouth design within subjects)

Number of Arms

3

Arm Descriptions and Interventions

Short Neck Implant (Crestal Placement)

Arm Type: Experimental

One-piece PRAMA implant with a 1.8 mm short convergent neck placed at the bone crest.

Intervention: Device: Short Neck PRAMA Implant – Crestal Placement

Standard Neck Implant (1 mm Subcrestal Placement)

Arm Type: Experimental

One-piece PRAMA implant with a 0.8 mm cylindrical and 2.0 mm convergent neck placed 1 mm below the bone crest.

Intervention: Device: Standard Neck PRAMA Implant – 1 mm Subcrestal Placement

Long Neck Implant (2 mm Subcrestal Placement)

Arm Type: Experimental

One-piece PRAMA implant with a 0.8 mm cylindrical and 3.0 mm convergent neck placed 2 mm below the bone crest.

Intervention: Device: Long Neck PRAMA Implant – 2 mm Subcrestal Placement

Outcome Measures

Type	Outcome Title	Description	Time Frame
Primary	Change in Peri-Implant Bone Height Over Time	Vertical changes in marginal bone levels at each implant site using radiographs, CBCT, and scans.	Baseline, 6 months, annually up to 3 years
Secondary	Volumetric Change in Peri-Implant Tissues	3D volumetric changes measured through digital scan overlays.	Baseline, 6 months, annually up to 3 years
Secondary	Effect of Crown Emergence Profile on Peri-Implant Tissue Volume	Comparison of tissue volume changes between two crown emergence profiles.	6 months, annually up to 3 years
Secondary	Changes in Clinical Parameters	Probing depth, plaque index, and bleeding on probing.	6 months, annually up to 3 years

Statistical Analysis

Data distribution for each parameter and group will be assessed using the Shapiro–Wilk test. Depending on the results of the normality assessment, group comparisons will be performed using either one-way ANOVA (for normally distributed data) or the Kruskal–Wallis test (for non-normally distributed data).

Post-hoc pairwise comparisons will be conducted using the Tukey HSD test (following ANOVA) or the Mann–Whitney U test with Bonferroni correction (following Kruskal–Wallis). A corrected p value < 0.05 will be considered statistically significant.

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