Title: Long-term dimensional changes in single-unit crowns supported by short (6 mm) transgingival implants with a divergent or convergent neck profile in the esthetic zone. A randomized controlled clinical trial.

NCT: xxxxxx

Study Protocol date: January 1, 2023

Long-term dimensional changes in single-unit crowns supported by short (6 mm) transgingival implants with a divergent or convergent neck profile in the esthetic zone. A randomized controlled clinical trial.

Summary

The objectives of the present randomized clinical trial are to evaluate the clinical and radiographic changes over time of hard and soft tissues around implants with a convergent or divergent collar. Twenty volunteer participants with two edentulous regions in the maxillary esthetic zone (from the right second premolar to the left second premolar) will be included in the study. Two implants will be randomly installed, one with a convergent collar and one with a divergent collar. After 3 months of healing, individual crowns will be installed. At each visit the following parameters will be evaluated: plaque index, probing depth, bleeding on probing, recession of the mucosal margin, intraoral radiographs, likewise control CBCT and impressions will be performed. The visit will take place at 6 and 12 months and then annually for a minimum of 3 years. Changes at the level of the marginal bone will be assessed over time on the radiographs. Dimensional changes will be clinically evaluated during control evaluations and later through digital impressions.

Keywords: Peri-implant marginal bone; digital impression; bone volume; bone loss; mucosal recession

Introduction

The use of 6 mm long implants to support single crowns or fixed dental prostheses (FDP) has become a widely used approach in the rehabilitation of the posterior region of both jaws. This method allowed the installation of implants without performing bone augmentation procedures, decreasing the number of surgeries, time spent on treatment, and costs. Several recent reviews have evaluated the results of short implants. In fact, short implants are a predictable choice, showing fewer biological complications and less marginal bone loss than longer implants, according to a comprehensive review and meta-analysis (Ravidà et al. 2019a). however, the length of implants in the maxilla, but not the mandible, had a substantial effect on the implant survival rate, according to a second thorough research with meta-regression analysis (Ravidà et al. 2019b). A different review and meta-analysis of randomized controlled studies found that the outcomes were similar but that short implants had a greater incidence of biological complications than longer implants. (Bitaraf et al. 2019). In addition, another comprehensive review with meta-analysis that included 10 randomized controlled studies came to the conclusion that after 1–5 years of functioning, short implants (6 mm) showed greater variability and a greater risk of failing than longer implants (>6 mm). Several studies have been performed with short transgingival implants with diverging profile necks supporting single crowns (Rossi et al. 2018; 2016) or bridges (Rossi 2017; Storelli 2018).

In a prospective study involving 21 patients (Agustín-Panadero et al. 2019), two one-piece transgingival implants, one with a converging collar and the other with a diverging collar, were installed in the posterior regions of the maxilla or mandible. After three months, the implants were loaded with fixed prostheses. Subsequently, after 24 months of operation, less peri-implant bone loss was found in implants with convergent collars (0.29 mm) compared to those with a divergent collars (0.60 mm). In a human histology study, platform-switch tapered abutments were shown to have circular fibers. It is speculated that these fibers could contribute to the stabilization over time of peri-implant marginal soft and hard tissues (Rodríguez et al. 2016).

The characteristic of the abutment/neck surface also influences the level of the marginal bone if it is placed subcrestally . (Welander et al. 2009) In an experimental

study in dogs (Hermann et al. 2011), one-piece implants with a neck featuring a rough surface had less marginal bone resorption compared to similar implants with a smooth neck. Furthermore, surfaces with a one-dimensional pattern seem to favor cell migration and phenotype modification (Doyle et al. 2009).

In the aforementioned mentioned study (Agustín-Panadero et al. 2019), the dimensional changes of the alveolar process on the two implants with different neck conformation at long term were not evaluated. In another clinical study (Szathvary et al. 2015), a new method was applied to elaborate three-dimensional changes of the alveolar process in implants installed immediately after long-term tooth extraction, which provided interesting and reproducible data.

However, a randomized controlled clinical trial comparing the clinical, dimensional, and radiographic results of short (6 mm) one-piece transgingival implants with a converging collar with microthreads or a diverging polished collar in esthetic regions is still lacking.

Therefore, the aim of the present study is to assess the long-term osseous and peri-implant soft tissue changes as well as the success rate of short implants (6 mm) with a converging collar with microthreads or a diverging polished collar placed in the esthetic zone of the maxilla.

Description of the problem

The literature frequently discusses how both hard and soft tissue around implants decreases over time. A convergent collar's conformation provides for better control of the conformation of the buccal portion of the crown in addition to providing a wider base of connective tissue than a non-convergent collar. It has been hypothesized that the crown's shape may enable the preservation or even the growth of the peri-implant mucosa.

General objective

The overall objective of this randomized clinical trial is to assess long-term soft and hard tissue changes around implants with a convergent or divergent collar.

Specific objectives

To assess changes in marginal soft tissue levels, marginal bone levels, and bone volume around implants with long-term converging or diverging collars.

Material and methods

The protocol will be submitted to the approval of the research and ethics unit of the Faculty of Stomatology of the National University of Trujillo and the Declaration of Helsinki on medical protocols and ethics will be applied. Patients will be informed about the procedures and possible complications and will be asked to sign the informed consent. The Consort checklist (http://www.consort-statement.org/) will be followed for this study. This RCT (Randomized Clinical Study) will be registered with ClinicalTrials.gov (https://clinicaltrials.gov/) to receive the registration number.

Study Population

In this randomized clinical trial, the recruitment of patients, surgeries and follow-ups will be carried out at the facilities of the Moche Stomatology Clinic- Faculty of Stomatology of the national university of Trujillo.

The inclusion criteria are as follows:

1. Presence of at least two edentulous areas in the esthetic region of the maxilla (from right to left from second premolar to premolar, preferably first premolars and incisors)
2. alveolar bone ≥ 8 mm in height and ≥ 5 mm in thickness assessed on CBCT.
3. Age of ≥ 21 years
4. Need for an implant-supported prosthetic restoration
5. Be in good general health with no contraindications to oral surgical procedures.
6. Not be pregnant.
7. Patients who agree to participate in the study and sign the informed consent.

The exclusion criteria are as follows:

1. presence of any uncontrolled systemic disease.
2. History of past or ongoing chemotherapeutic or radiotherapeutic treatments.
3. Heavy smokers (>10 cigarettes per day).

4. Previous bone regeneration procedures in the area of interest.

implants used

Two one-piece transgingival implants, one with a convergent hyperbolic collar (PRAMA, Sweden & Martina, Due Carrare, Padua, Italy), and one with divergent profile collar (TG, Sweden & Martina, Due Carrare, Padua, Italy) with ZirTi surface (Caneva et al. 2016) will be used. The length of the intraosseous portion is 6 mm.
The convergent hyperbolic collar (PRAMA, Sweden & Martina, Due Carrare, Padua, Italy) implant (Agustín-Panadero et al. 2019) will have a 2.8 mm long neck, characterized by a 0.80 mm cylindrical path and a 2.0 mm high convergent hyperbolic coronal portion. The entire surface of the collar contains parallel micro-threads (Ultrathin Threaded Micro-surface - UTM). The divergent profile collar (TG, Sweden & Martina, Due Carrare, Padua, Italy) implant has a 2.2mm high polished neck.

Study design

The study is a split-mouth randomized controlled trial. One implant with a converging collar with microthreads (PRAMA) or a diverging polished collar (TG) will be installed in each patient according to the site randomization in the esthetic region of the upper jaw (between the second premolars). It will be restored with individual crowns after three months of healing. Both implants will be placed with the rough margin ~1 mm subcrestally.

Sample size

To calculate the sample size, data from a clinical study (Agustín-Panadero et al. 2019) were previously evaluated. In that study, a difference in marginal bone loss of 0.31 mm was found between the two implant groups. Using a type I error probability of 0.05, with a power of 0.9, and an estimated standard deviation of the mean differences of 0.35, fifteen patients are needed to reject the null hypothesis that this differencein response is zero. Taking into account possible dropouts or complications, twenty patients are considered as an adequate sample.

Randomization and allocation concealment

Randomization will be performed electronically by one of the authors, who will not participate in the surgical procedures. Treatment assignments will be sealed in opaque envelopes that will be opened during the surgery. The treatment assignment will be disclosed to the surgeon after elevation of the alveolar mucosal flaps and prior to the preparation of the recipient sites.

Clinical procedures

The clinical procedures will be performed by an expert clinician. After the local anesthesia will be applied, the mucoperiosteal flaps will be elevated and the alveolar bone will be exposed. The preparation of the sites will be prepared according to the manufacturer's instructions. Both implants will be installed with the coronal margin of the rough surface approximately 1 mm deeper (subcrestal). Healing caps of sufficient length will be placed over the implants to ensure non-submerged healing. Sutures will be performed to adapt the flaps around the healing screw. Except for complications, antibiotics will not be provided. The sutures will be removed after approximately 1 week.

After three months of healing, digital impressions will be taken, and patients will be provided with a unique zirconia crown.

Maintenance

After surgery, patients will be administered pain relievers if necessary. Mouth rinses with 0.12% chlorhexidine three times a day until the suture is removed, which will be done after 7-10 days. All the participants will be enrolled in a maintenance program throughout the study. All participants will be followed for at least 3 years and data will be reported annually.

Clinical, radiographic and digital evaluations

- At the time of the prosthesis installation (baseline time) the depth of the probing will be recorded. Clinical photographs, standardized intraoral radiographs, CBCT, and digital impressions will be taken.

- After 6 months, the plaque index, bleeding on probing, and probing depth will be evaluated. Clinical photographs, standardized intraoral radiographs and digital impressions will be taken.
- The plaque index, bleeding on probing, and probing depth will be evaluated annually. Clinical photographs, standardized intraoral radiographs, CBCT, and digital impressions will be taken.

Calibration for assessment and blinding procedures

Analysis of the radiographic images will be performed by an experienced evaluator, unaware of treatment group assignment, although implant types will be recognized on the images. For three-dimensional image analyses, the evaluator will be blinded to the treatment allocation.

Imaging Analysis

Bone tissue levels will be assessed on both intraoral radiographs and CBCT images. The peri-implant volumes will be evaluated on the three-dimensional images obtained from digital impressions.

Data analysis

The main study variables will be the dimensional changes over time in the height of the peri-implant bone tissues, evaluated in the intraoral radiographic images, CBCT, and the peri-implant volumetric changes over time evaluated in the three-dimensional images obtained from the digital prints. Clinical data will be used as secondary variables. Additionally will be evaluated the implant surivival and success rate at 1y and 3y follow up and the criteria will be if there was no persistent and/or irreversible signs or symptoms such as pain, infection, neuropathies, or paresthesia, no peri-implant infection with suppuration, no mobility, and no continuous radiolucency around the implant. (Buser D et al. 2002)

The differences between groups will be evaluated by applying the Wilcoxon test. The significance level will be set at $\alpha = 0.05$.

References

- Agustín- Panadero R, Martínez-Martínez N, Fernandez- Estevan L, Faus -López J, Solá -Ruíz MF. Influence of Transmucosal Area Morphology on Peri-Implant Bone Loss in Tissue-Level Implants. Int J Oral Maxillofac Implants. 2019;(34):947–952. doi:10.11607/jomi.7329
- Altaib FH, Alqutaibi AY, Al-Fahd A, Eid S. Short dental implant as alternative to long implant with bone augmentation of the atrophic posterior ridge: a systematic review and meta-analysis of RCTs. Quintessence Int. 2019;50(8):636-650. doi:10.3290/j. qi.a 42948
- Bitaraf T, Keshtkar A, Rokn AR, Monzavi A, Geramy A, Hashemi K. Comparing short dental implant and standard dental implant in terms of marginal bone level changes: A systematic review and meta-analysis of randomized controlled trials. Clin Implant Dent Relat Res. 2019;21(4):796-812. doi:10.1111/cid.12774.
- Buser D, Ingimarsson S, Dula K, Lussi A, Hirt HP, Belser UC. Long-term stability of osseointegrated implants in augmented bone: a 5-year prospective study in partially edentulous patients. Int J Periodontics Restorative Dent. 2002 Apr;22(2):109-17. PMID: 12019706.
- Caneva M, Lang NP, Calvo Guirado JL, Spriano S, Iezzi G, Botticelli D. Bone healing at bicortically installed implants with different surface configurations. An experimental study in rabbits. Clin Oral Implants Res. 2015;26(3):293-299. doi:10.1111/clr.12475
- Doyle AD, Wang FW, Matsumoto K, Yamada KM. One-dimensional topography underlies three-dimensional fibrillar cell migration. J Cell Biol. 2009;184(4):481-490. doi:10.1083/jcb.200810041
- Hermann JS, Jones AA, Bakaeen LG, Buser D, Schoolfield JD, Cochran DL. Influence of a machined collar on crestal bone changes around titanium implants: a histometric study in the canine mandible. J Periodontol. 2011;82(9):1329-1338. doi:10.1902/jop.2011.090728.
- Papaspyridakos P, De Souza A, Vazouras K, Gholami H, Pagni S, Weber HP. Survival rates of short dental implants (≤6 mm) compared with implants longer than 6 mm in posterior jaw areas: A meta-analysis. Clin Oral Implants Res. 2018;29 Suppl 16:8-20. doi:10.1111/clr.13289
- Ravidà A, Majzoub J, Alassadi M, Saleh MH, Askar H, Wang HL. Impact of Implant Length on Survival of Rough-Surface Implants in Nonaugmented Posterior Areas: A

Systematic Review and Meta-Regression Analysis. Int J Oral Maxillofac Implants. 2019;34(6):1359-1369. doi:10.11607/jomi.7509.

- Ravidà A, Wang IC, Sammartino G, et al. Prosthetic Rehabilitation of the Posterior Atrophic Maxilla, Short (≤6 mm) or Long (≥10 mm) Dental Implants? A Systematic Review, Meta-analysis, and Trial Sequential Analysis: Naples Consensus Report Working Group A. Implant Dent. 2019;28(6):590-602. doi:10.1097/ID.0000000000000919.
- Rodríguez X, Navajas A, Vela X, Fortuño A, Jimenez J, Nevins M. Arrangement of Peri-implant Connective Tissue Fibers Around Platform-Switching Implants with Conical Abutments and Its Relationship to the Underlying Bone: A Human Histologic Study. Int J Periodontics Restorative Dent. 2016;36(4):533-540. doi:10.11607/prd.2580.
- Rossi F, Botticelli D, Cesaretti G, De Santis E, Storelli S, Lang NP. Use of short implants (6 mm) in a single-tooth replacement: a 5-year follow-up prospective randomized controlled multicenter clinical study. Clin Oral Implants Res. 2016;27(4):458-464. doi:10.1111/clr.12564
- Rossi F, Lang NP, Ricci E, Ferraioli L, Baldi N, Botticelli D. Long-term follow-up of single crowns supported by short, moderately rough implants-A prospective 10-year cohort study. Clin Oral Implants Res. 2018;29(12):1212-1219. doi:10.1111/clr.13386
- Rossi F, Lang NP, Ricci E, Ferraioli L, Marchetti C, Botticelli D. 6-mm-long implants loaded with fiber-reinforced composite resin-bonded fixed prostheses (FRCRBFDPs). A 5-year prospective study. Clin Oral Implants Res. 2017;28(12):1478-1483. doi:10.1111/clr.13015
- Storelli S, Abbà A, Scanferla M, Botticelli D, Romeo E. 6 mm vs 10 mm-long implants in the rehabilitation of posterior jaws: A 10-year follow-up of a randomized controlled trial. Eur J Oral Implantol. 2018;11(3):283-292.
- Szathvary I, Caneva M, Caneva M, Bressan E, Botticelli D, Meneghello R. A volumetric 3-D digital analysis of dimensional changes to the alveolar process at implants placed immediately into extraction sockets. J Oral Science Rehabilitation. 2015 Sep;1(1):62–9.
- Welander, M., Abrahamsson, I. & Berglundh, T. (2009) Subcrestal placement of two-part implants. Clinical Oral Implants Research 20: 226-231.