Comparison of extra-short (4 mm) implants used as distal support of a maxillary full-arch FDPs vs. 10 mm implants installed after sinus floor elevation. A randomized clinical trial.

Brief title

Comparison of extra-short (4 mm) implants used as distal support of a maxillary full-arch FDPs vs. 10 mm implants installed after sinus floor elevation.

Authors

Fabio Rossi, Emanuele Ricci, Lorenzo Ferraioli, Lorenzo Tuci, Daniele Botticelli, Luca Cordaro, Claudio Marchetti

Authors' affiliations

Fabio Rossi, Emanuele Ricci, Lorenzo Ferraioli, Lorenzo Tuci, Claudio Marchetti, Unit Scholar, Department of Biomedical and Neuromotorial Science, University of Bologna, Bologna, Italy

Daniele Botticelli, BMBD, Dentist, PhD, ARDEC Academy, Rimini, Italy

Luca Cordaro, Head of the Department of Periodontology and Prosthodontics, Eastman Dental Hospital, Rome, Italy

Institution at which the work was carried out:

Department of Biomedical and Neuromotor Science, University of Bologna, Bologna, Italy

Corresponding author:

Dott. Fabio Rossi, DDS, Unit Scholar, Department of Biomedical and Neuromotor Science, University of Bologna, Bologna, Italy

Tel. +39 347 2549059 Fax: +39 051 6390234

E-mail: farossi@libero.it

Bologna, January 18th, 2017

Conflict of Interest Statement

Fabio Rossi and Luca Cordaro declare to be ITI fellows and to be involved in activities in favor of the Institute Straumann.

Daniele Botticelli declares that Ariminum Odontologica, of which is co-owner, is receiving contributions to perform research from different implant and biomaterial companies.

All the other authors declare no conflicts of interest.

Acknowledgements

Grant from ITI number 1049_2014

Abstract

Aim: to compare the survival and success rates of 4 mm implants used as distal support of a maxillary full-arch FDPs with standard (10 mm) implants placed in association with a bilateral sinus floor augmentation procedure.

Material and Methods: Two groups will be randomly prepared, the Short group and the Standard group. In the Short group, one 4 mm long and 4.1 mm in diameter implant (extra-short implant) will be installed in each side of the posterior region of the maxilla. In the Standard group, bilateral sinus floor elevations will be performed. After 4 months of healing, one 10 mm long and 4.1 mm in diameter implant (standard implant) will be installed into each augmented sinus. In the frontal region, four 10 mm long implants will be installed in both groups. Clinical assessments and x-rays will be taken at prosthesis delivering (6-8 weeks after implant installation), and after 6, 12, 18 and 24 months.

Introduction

Anatomical limitations to implant insertion in fully edentulous arches are frequently encountered in the posterior regions of the jaws, due to the presence of the mandibular canal and of the maxillary sinus. In such situations, the installation of standard implants (≥10 mm) could be impossible.

An alternative might be the use of the so-called “tilted implants” that might allow the use of standard implants.[1] Vertical augmentation[2] procedures or sinus floor elevation[3] might allow the installation of standard implants as well. Another alternative is the use of short implants, as recommended in a consensus conference[4] for the lower occurrence of complications of this treatment compared the use of longer dental implants installed in augmented sinus. Another consensus report concluded that the use of ≤6 mm long implants are a valid option to be used as alternative to augmentation procedures to reduce morbidity incidence.

A recent article reported a high survival rate (91.7%) after 10 years of loading of 6 mm long implants supporting single FDPs in the posterior regions of both jaws.[5] Recently, 4 mm long implants with a standard diameter have been used for the restauration of the posterior edentulous mandible with favorable results.[6,7] However, RCTs reporting the results from full-arch FDPs that included 4 mm long implants placed in the posterior regions of the maxilla have not been published yet.

Hence, the aim of the present study will be to compare the survival and success rates of 4 mm implants used as distal support of a maxillary full-arch FDPs with standard (10 mm) implants placed in association with a bilateral sinus floor augmentation procedure.

Material and methods

The Declaration of Helsinki was followed, and the protocol was approved by the Ethical Committee Interaziendale Bologna-Imola (protocol #15052; 9 September 2015).

All procedures, timing, and complications will be systematically explicated to the included patients and signed informed consents will be collected. The Consort checklist will be followed for this report (http://www.consort-statement.org/). The study will be registered in the ClinicalTrials.gov with the following identifier: xxxxxxx.

Study population

This study will be designed as an RCT study. Twenty patients have been planned to be included in the present RCT. Two parallel groups will be randomly arranged, the Short group that will include the 4 mm long implants, and Standard group that will include only 10 mm long implants installed 4 months after bilateral sinus floor elevation. Participants recruitment and all clinical procedures will be performed at the Department of Biomedical and Neuromotor Sciences, Dental Clinic, University of Bologna, RN, Italy.

The following inclusion criteria will be adopted:

• Edentulous maxilla

• Willing to receive a full arch fixed restoration in the maxilla.

• Latest extraction at least 8 weeks before implant insertion

• Sinus floor height included between 4 to 6 mm

• Bone width in the distal segments sufficient to allow the insertion of a 4 mm long implant of standard diameter.

• In the anterior maxilla (from first premolar to first premolar) bone width sufficient to allow the insertion of 10 mm long implants of standard diameter.

Minor horizontal augmentations with GBR procedures was allowed in the anterior maxilla.

Moreover, the opposing arch have to present one of the following conditions:

- natural dentition (at least 10 elements from 3.5 to 4.5)

- FPDs of at least 10 elements (from 3.5 to 4.5) supported by teeth or implants

- Implant supported or teeth supported overdentures

- Adequate partial removable prostheses.

Exclusion criteria:

Systemic exclusion criteria

• Presence of conditions requiring prophylactic use of antibiotics (e.g., history of rheumatic heart disease, bacterial endocarditis, cardiac valvular anomalies, prosthetic joint replacements).

• Major systemic diseases, or medical conditions requiring prolonged use of steroids, or alcoholism or chronically drug abuse.

• Current pregnancy or breastfeeding women

• Smokers > 10 cigarettes per day

• Physical handicaps that would interfere with the ability to perform adequate oral hygiene

• Immunocompromised patients including patients infected with HIV

• Conditions or circumstances, in the opinion of the investigator, which would prevent completion of study participation or interfere with analysis of study results, such as history of non-compliance, or unreliability.

• Patients with an ongoing or previous treatment with bisphosphonates (for at least 2 months for oral therapy or 6 months for IV injection)

Local exclusion criteria

• Local inflammation, including untreated periodontitis

• Pre-cancerous oral lesions

• History of local irradiation therapy

• Severe bruxism or clenching habits

• Patients with inadequate oral hygiene or unmotivated for adequate oral home care

• Previous GBR or GTR treatment at the implant site

• Total removable prosthesis in the lower arch

Randomization and assignment concealment

A statistician not involved in the study performed the randomization in blocks of four and the assignments will be sealed in coded and opaque envelopes.

Masking Procedure: The surgeon will be blinded about the assignment until the time of the surgery. The outcome assessor will be blinded about the protocol.

Implants and biomaterial used

The implants will be offered by Institute Straumann AG, Basel, Switzerland)

A natural bovine bone grafting material (Cerabone granules 1-2 mm, Botiss biomaterial GmbH, Zossen, Germany) will be used for sinus floor elevation.

A porcine dermis collagen membrane (Collprotect membrane, Botiss biomaterial GmbH, Zossen, Germany) will be used to cover the antrostomy.

Bone fillers and collagen membranes are distributed by Institute Straumann AG, Basel, Switzerland.

Surgical procedures in the Standard implant group

Bilateral sinus floor elevations using a lateral access will be performed using Cerabone as filler material and Collprotect to cover the antrostomy. After 4 months of healing, one bone level implant, 10 mm long and 4.1 mm in diameter, will be installed into each augmented sinus. In the frontal region (included between the second premolars), four bone level implants, 10 mm long and 4.1 mm or 3.3 mm in diameter will be installed. A non-submerged healing will be allowed.

Surgical procedures in the Short group

In each side of the posterior region of the maxilla, one tissue level implant, 4 mm long and 4.1 mm in diameter, will be installed. In the frontal region, four bone level implants, 10 mm long and 4.1 mm or 3.3 mm in diameter will be installed

Maintenance care of the patients

Amoxicillin and clavulanic acid will be administrated per os before and for the following 6 days. As painkiller, Ibuprofen 600 mg *per os* will be suggested if needed.

Prosthetic procedures

During the healing, a temporary removable prosthesis will be provided to the patients.

Six weeks after implant installation, impressions will be taken and a fixed metal ceramic full-arch screw-retained prosthesis will be fabricated and delivered within a week.

Clinical evaluation

Bone quality according to Lekholm and Zarb (1985) will be subjectively evaluated and the insertion torque will be assessed using a ratchet device (Institute Straumann AG, Basel, Switzerland), and categorized as follows: $0 \leq 15$, $15 < x < 35$, and ≥ 35 Ncm. Plaque Control record (O'Leary et al., 1972), Bleeding on Probing (Lang et al., 1986), and probing depths will be assessed around Short and Standard implants at prosthesis delivering and after 6, 12, 18, 24 months. The

highest probing depth will be recorded and categorized as follows: 1-3 mm, 4-5 mm, ≥6 mm.

PROMs were compiled by each patient regarding esthetics, function, and comfort satisfaction using a VAS scale.

Radiographic measurements

X-rays applying a parallel technique will be taken at implant installation, at prosthesis delivering (baseline) and after 6, 12, 18, 24 months. The measurements the digital x-rays will be carried twice by the same operator (LT) using the software Planmeca ROMEXIS® (Helsinki, Finland). The calibration of the measurements on the software will be obtained using the full length of the implant.

The distance between the implant margin and the first bone to implant contact will be measured at the mesial and distal aspects of the Short and Standard implants.

Data analysis

Mean values will be obtained from the double measurements made at the mesial and distal aspects of each implant. Mean values will be calculated between the distal and mesial measurements for each implant.

At the tissue level implants, the height of the polished neck (1.8 mm) will be subtracted to obtain the level of the coronal margin of the rough surface. The marginal bone levels reported in the present article will be related to the position of the coronal marginal rough surface. Marginal bone changes over time will be calculated and differences between groups will be evaluated at implant level using

the Mann-Whitney test included in the Statistics software SPSS (IBM Inc., Chicago, IL, USA) The level of significance will be set at α=0.05.

The primary variable will be the change of marginal bone level between the baseline and 1 and 2 years of follow-up.

Outcomes

PRIMARY OUTCOMES

TITLE: Survival rate of 4 mm implants

DESCRIPTION:

-To compare the survival rate of 4 mm implants used as distal support of a maxillary full-arch FDPs with standard (10 mm) implants placed in association with a bilateral sinus floor augmentation procedure.

TIME FRAME: 24 months

TITLE: Changes of crestal bone level

DESCRIPTION: Change of crestal bone level measured on intraoral x-ray applying a parallel technique from baseline (definitive prosthesis delivering) and 2-year follow-up. The distance between the implant margin and the first bone to implant contact will be measured in millimeters at the mesial and distal aspects of the Short and Standard implants.

TIME FRAME: 24 months

SECONDARY OUTCOMES

TITLE: Technical complications

DESCRIPTION:

Technical complications: any technical complications related to implants, abutments, screw loosening, prosthetic fracture or chipping of the veneer material expressed in number of occurrence.

TIME FRAME: 24 months

References

1. Apaza Alccayhuaman KA, Soto-Peñaloza D, Nakajima Y, Papageorgiou SN, Botticelli D, Lang NP. Biological and technical complications of tilted implants in comparison with straight implants supporting fixed dental prostheses. A systematic review and meta-analysis. Clin Oral Implants Res. 2018 Oct;29 Suppl 18:295-308.
2. Cucchi A, Ghensi P. Vertical Guided Bone Regeneration using Titanium-reinforced d-PTFE Membrane and Prehydrated Corticocancellous Bone Graft. Open Dent J. 2014 Nov 14;8:194-200.
3. Raghoebar GM, Onclin P, Boven GC, Vissink A, Meijer HJA. Long-term effectiveness of maxillary sinus floor augmentation A systematic review and meta-analysis. J Clin Periodontol. 2019 Jan 9. doi: 10.1111/jcpe.13055. [Epub ahead of print]
4. Thoma DS, Zeltner M, Hüsler J, Hämmerle CH, Jung RE. EAO Supplement Working Group 4 - EAO CC 2015 Short implants versus sinus lifting with longer implants to restore the posterior maxilla: a systematic review. Clin Oral Implants Res. 2015 Sep;26 Suppl 11:154-69.
5. 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 Dec;29(12):1212-1219
6. Slotte C, Grønningsaeter A, Halmøy AM, Öhrnell LO, Mordenfeld A, Isaksson S, Johansson LÅ. Four-Millimeter-Long Posterior-Mandible Implants: 5-Year Outcomes of a Prospective Multicenter Study. Clin Implant Dent Relat Res. 2015 Oct;17 Suppl 2:e385-95.

7. Esposito M, Zucchelli G, Barausse C, Pistilli R, Trullenque-Eriksson A, Felice P. Four mm-long versus longer implants in augmented bone in atrophic posterior jaws: 4-month post-loading results from a multicentre randomised controlled trial. Eur J Oral Implantol. 2016;9(4):393-409. PubMed PMID: 27990507.

.