

CLINICAL AND RADIOGRAPHIC EVALUATION OF SINGLE TANTALUM DENTAL IMPLANTS: A PROSPECTIVE PILOT CLINICAL STUDY

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SUMMARY

Objective. The aim of this prospective pilot clinical case series report was to evaluate, through a clinical and radiographic analysis, the peri-implant bone resorption of the tantalum dental implants (TMT) (Zimmer TMT, Parsippany, NJ, USA) one year after prosthetic rehabilitation.

Methods. Twenty tantalum dental implants were placed in both maxillas and mandibles of 20 patients. Patients were asked to attend a radiographic and clinical follow-up and their previous clinical records and X-rays were assessed. Bone levels were calculated by digitally measuring the distance from the implant shoulder to the first bone-to-implant on periapical radiographs taken at surgery and after 6 and 12 months of functioning. The Pearson correlation analysis was performed to assess if there was a correlation between the measurement of the marginal bone loss (MBL). The Anova Test with a post-hoc analysis using Bonferroni's test was used to compare the three groups (0, 6 months and 12 months).

Results. The mean total MBL for the group 0 months was 0.84 mm (SD 0.21), 6 months was 0.87 mm (SD 0.22) and for 12 months was 0.89 mm (SD 0.23). The values of the Pearson's coefficients showed that the data measurement were positively correlated. The Anova test showed a statistically significant difference between the groups.

Conclusion. The statistically significant difference in marginal bone loss can be considered physiological. Within the limits of this study it can be concluded that TMT implants have an excellent bone crest's stability, however, to have most accurate information, will be necessary extend the sample.

Key words: dental implant, edentulous, marginal bone loss.

Introduction

Osseointegrated implants have become a viable option for replacing missing teeth in totally and partially edentulous patients, as established by systematic reviews, especially in the case of single tooth gaps (1). The success of implant therapy is influenced by various factors: implant biocompatibility, fixture design, surface characteristics, surgical techniques, state of host, biomechanical status and time (2-4). An alternate avenue for improving osseointegration has been implant surface technology. The material of choice in the manufacture of implants is titanium: commercially pure (cp Ti), or associated with other elements in the form of alloys which often offers better mechanical properties compared to the pure form (3, 1)

(5). Implant features significantly influence the formation and maintenance of bone at implant surfaces. Osseointegration is attained by cellular processes that contribute to bone formation at the alloplastic surface (6-8). Bone maintenance depends on continuous adaptation to functional loading and repair of damage subsequent to overload at the implant-bone interface (9, 10). In literature there are many studies on the properties of the metal surfaces and the molecular dynamics that come into play at the level of the bone-implant interface (11-15). In dentistry Boyan (16) concludes that an increase in the roughness of the implant surface also increases osseointegration. In the orthopaedic field they have shown that the existence of various porous coatings improves the osseointegration properties (17) and the degree of bone growth obtainable is widely variable, depending on the pore

size and the thickness of the coating (18). From these conclusions it developed a new surface called TMT (trabecular metal material, Zimmer TMT, Parsippany, NJ, USA). TMT is a biomimetic structure that simulates the texture of trabecular bone macro and microscopically and with an elastic modulus similar to that of spongy bone and cortical bone than titanium or other alloys (19). This structure composed of a skeleton in carbon, tantalum and an alloy of titanium has been developed and extended in the dentistry and implantology field (20) with the aim of obtaining a three-dimensional growth around the implant thanks to the dodecahedrons structure which enables a rapid endothelial response and a significant growth by interacting with the institution (21). In addition, the advantages of TMT seem to be related to a modulus of elasticity similar to bone and to an excellent mechanical properties, this is translated into a lower stress and resulting in less loss of bone in the short-medium-long term (22). The purpose of this pilot study was to evaluate, through a clinical and radiographic analysis, the peri-implant bone resorption of the TMT's implants one year after prosthetic rehabilitation.

Material and methods

Study design and patients

This pilot clinical study was designed as a prospective case series study with a 1-year follow-up after

prosthetic rehabilitation (Figure 1). The study was performed in compliance with Good Clinical Practice, the Declaration of Helsinki and local legal and regulatory requirements. All patients provided written informed consent before entry into the study. The patients were generally healthy (classified as ASA I). Male or Female > 18 years of age with whom were partially edentulous in the mandible or the maxilla with a buccolingual ridge width of at least 5.3 mm and at least for 11 millimetres (mm) long implant evaluated by juxta-gingival radiographs and clinical control, and with opposing dentition of natural teeth or tooth- or implant-supported fixed reconstructions were eligible for the study. Implants were placed at least 8 weeks after any tooth extraction at the proposed implant site (Figure 1). The alveolar ridge in the site maxilla or the mandible had to be of sufficient width to allow the insertion of at least one 4.5 mm diameter implant in any position between the first premolar to the second molar. The inclusion criteria were: good general health at the time of surgical procedure; absence of local inflammation and absence of mucosal disease; implant distribution according to opposing teeth or prostheses was considered: implants opposing mobile partial or total prostheses were excluded from the study. The exclusion criteria were: tobacco abuse, i.e., more than 10 cigarettes/day; history of radiotherapy in the head and neck region; leukocyte diseases at the time of surgical procedure; uncontrolled diabetes; severe clenching or bruxism; non compliant patients; bone grafts or local guided bone regeneration (GBR) before implant placement.



Figure 1
Clinical and radiographic evaluation of single dental implant in posterior maxilla.

Implants

The devices used in this study were TMM trabecular metal material (Zimmer, Parsippany, NJ, USA) diameter 4,1 mm, length 10 mm. The implants were used according to the manufacturer's instructions and the standard protocol for TMM implants.

Surgical procedures

All the surgeries were performed in the operation room in a protocol of complete asepsis through infection control. The subjects rinsed their mouth with a mouthwash containing 0.2% chlorhexidine for 1 minute preoperatively. Next, troncular anesthesia of the inferior alveolar nerve was obtained, followed by plexus anesthesia of the buccinator nerve with mepivacaine in the mandible surgical site, and with direct infiltration into the maxillary surgical site. A full-thickness intrasulcular flap was fashioned. After detaching the flap, the surgical site was exposed. Using a round burs, the sites of implant insertion were marked. A twist drill was used to drill the primary socket and the implants were inserted according to the instructions of the manufacturer. After implantation, the implant was closed with a closure screw or healing cap. The procedure was then completed with repositioning of the flap, and suturing with Vicryl 4-0 thread (Vicryl Ethicon, Johnson & Johnson, Somerville, NJ). The two-stage approach was completed after 4 to 6 months of healing, with surgical re-entry, when an appropriate transmucosal healing abutment was screwed to the implant.

Post-operative procedures

All subjects completed the same postoperative protocol. The protocol included antibiotic therapy (amoxicillin 50 mg/kg in 2 daily doses for 6 days) and analgesics (nimesulide 50 mg every 8 hours) as necessary for pain control, associated with a chlorhexidine 0.2% mouthwash (3 times daily for 6

days) (23). All subjects were advised to use cold compresses immediately after surgery. The stitches were removed at the first follow-up visit 10 days after the procedure. The patients were instructed to irrigate their mouth with chlorhexidine solution (24) once a day for another week, and to revisit the clinician after 1 month. Removable prostheses or interim fixed bridges (Maryland bridge) were adjusted if necessary. After a healing phase of 4 months, successfully integrated implants received cement- or screw-retained definitive ceramo-metal fixed reconstructions (25).

Imaging and radiographic assessment

Digital periapical radiographs were taken from any potential implant sites. Before the surgery, the surgical sites were thoroughly evaluated regarding their height, bone quality, possible pathologies, and their distance from the critical anatomies. The method used to obtain the intraoral periapical radiographs and upload them in the computer was consistent with other reports in the literature (26). No customized X-ray holder was provided for any of the patients. A standardized measurement protocol was used the reference measurement was the implant neck diameter; the measurement system considered the perpendicular distance from the implant shoulder (IS) to the first visible bone-to-implant contact (C) along an ideal line running parallel to the fixture's longitudinal axis; measurements were taken on the mesial and distal sides of each implant. To correct for any dimensional distortion in the X-ray, the apparent size of each implant (measured directly on the radiograph) was compared with the known implant neck diameter (at the most coronal level of the prosthetic interface), and the following equation:

$$\text{Implant neck diameter on X-ray} \div \text{True implant neck diameter} = \text{MBL on X-ray} \div \text{True MBL}$$

was used to establish reasonably accurately the extent of any vertical bone loss on the mesial and distal sides of the implant. Marginal bone loss (MBL) measurements were obtained by two operators (D.N. and

M.D.F.) blinded to each other's findings. Radiographs were taken at the time of loading (time zero), 6 months, and 12 months; the X-ray images were stored on a PC and analyzed with suitable software to measure peri-implant bone resorption (marginal bone loss, MBL) by comparing intraoral periapical radiographs obtained at the baseline (at the time of loading) and at latest follow-up evaluation (26).

Clinical assessment

Peri-implant tissues and implant health were assessed using the following parameters: (i) suppuration (presence/absence) (28); (ii) plaque index (score 0-3) according to Mombelli & Lang (29); (iii) probing pocket depth and probing attachment level (28); (iv) bleeding on probing (score 0-3) (25); (v) percussion with evidence of metal (functional ankylosis) or dull sound (fibrous integration in the area of implant placement); (vi) persistent pain or paresthesia. All cases showing peri-implant inflammation were treated according to the Mombelli and Lang guidelines (29).

Implant success and survival

The implant success was defined as the absence of: (i) tactile implant mobility at the final prosthesis placement, (ii) continuous peri-implant radiolucency, (iii) recurrent peri-implant infection, (iv) continuous or recurrent pain, (v) structural failure of the implant or (vi) probing depth no more than 3 mm for each implant site (mesial, distal, buccal, lingual-palatal) (vii) bone resorption in measurement areas no more than 1 mm during the first year after implant placement, and 0.2 mm a year thereafter (26, 27). The implant survival was defined as the present: (i) implants showing clinical and radiographic signs of peri-implantitis; (ii) implants supporting functional, symptom-free prostheses and 0.2 mm a year thereafter.

Statistical methods

This pilot study (open, non-controlled, single group pilot study) was conducted to generate data on the

expected effect size and standard deviation to allow for power calculations in future study. Based on previous experience from studies with similar implants, a sample size of 8-15 implants was considered sufficient to generate data. The implant was considered as the statistical unit. The primary variable was MBL as the average of bone loss mesial and distal for each group. Descriptive statistics recorded were the mean and standard deviation of the bone-level changes from baseline (implant loading, time zero) to 6 and 12 months after loading. However, although the study does not have the correct number of sample, a comparative statistical analysis was performed. The Pearson correlation analysis was performed to assess if there was a correlation between the measurement of the MBL. The one-way longitudinal analysis of variance (Anova Test) with a post-hoc analysis using Bonferroni's test was used to compare the three group (time 0, time 6 months, time 12 months). The level of statistical significance was set as $\alpha=0.05$ and statistical power of 80%. All testing was performed by the use of SPSS 16.0 software package (SPSS inc, Chicago, Illinois, USA).

Results

Twelve implant TMM Zimmer (Parsippany, NJ, USA) from 12 patients were analysed. The mean MBL was 0.89 mm (SD 0.2 mm) on the mesial side of the fixture to time 0, and 0.79 mm (SD 0.24 mm) on the distal side. The mean total MBL for the group time 0 months was 0.84 mm (SD 0.21). The mean MBL was 0.93 mm (SD 0.20 mm) on the mesial side of the fixture to time 6 months, and 0.82 (SD 0.26 mm) on the distal side. The mean total MBL for the group time 6 months was 0.87 mm (SD 0.22). The mean MBL was 0.96 mm (SD 0.22 mm) on the mesial side of the fixture to time 12 months, and 0.82 (SD 0.26 mm) on the distal side. The mean total MBL for the group time 12 months was 0.89 mm (SD 0.23). Since MBL measurements were obtained by two operators blinded to each other's findings. The Pearson's coefficient correlation was $r=0.992$ with a p-value = 0.001 (time 0 *versus* time 6); $r=0.978$ with a p-value=0.001 (time 0 *versus* time 12) and $r=0.995$ with a p-value=0.001 (time 6 *versus* time

12). The values of the Pearson's coefficients showed that the data measurement were positively correlated, thus allowing for paired statistical test. The Anova one-way was used to compare three groups (time 0, 6, 12 months). The three paired groups showed a statistically significant difference ($p < 0.05$). The post-hoc Bonferroni's test showed that the statistically significant difference was between the group time 0 months and the group time 12 months ($p\text{-value} = 0.017$) and between the group time 0 months *versus* the group time 6 months ($p\text{-value} = 0.036$), however between the group time 6 months and the group 12 month ($p\text{-value} = 0.173$) were not present statistically significant differences.

In terms of the clinical appearance of the perimplant tissues, signs of suppuration, bleeding on probing, percussion with evidence of metal (functional ankylosis) or dull sound (fibrous integration in the area of implant placement) and persistent pain or paresthesia were not present (Figure 1).

Discussion

The statistically significant difference in marginal bone loss between time 0 group and 6 month group and between time 0 group and the 12 month group can be considered physiological. The significant marginal bone reabsorption occurred within 6 months from the surgery, in fact, between the 6 month group and the 12 month group there are no statistically significant difference, this drives to the deduction that the marginal peri-implant bone reabsorption is due to physiological factors. This pilot study was conducted to estimate accurately the number of sample to be used to obtain statistically significant results with a power statistic in 80%, and a significance level of 0.05. The comparative statistical analysis was performed to evaluate the trend of the collected information.

With the expansion of the survey sample and the continuation of the prospective longitudinal study it can be possible get more reliable results. The obtained data in line with Schlee et al. (29) shows that although the sample is relatively small there is an optimal response of the peri-implant tissues. Furthermore, the particular circumferential microtexture of the cervical

area of the implant in accordance with Hartog et al. (30) seems to help the stabilization of the peri-implant tissues and consequently the reabsorption of bone levels. In a literature's review in contrast with Bateli et al. (31) they have shown that there are no reliable data on the actual efficacy of different implants configurations or better, they shown that further studies are still required. Within the limits of this study, TMM's implants results are reliable, with a valuable level behaviour of the marginal bone. Information are equal or better compared with similar literature studies that have been used by other types of implants (32).

Conclusion

The statistically significant difference in marginal bone loss between time 0 group and 6 months group and between time 0 group and the 12 months group can be considered physiological. Within the limits of this study it can be concluded that TMM implants have an excellent bone crest's stability, however, to have most accurate information, will be necessary extend the sample.

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