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Comparing Titanium and Gold-Coated Abutment Screws for Immediate Loading of Dental Implants in Partially Edentulous Patients.
Four-year post-loading results from a randomised controlled trial

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ABSTRACT

Aim To compare the clinical outcome of titanium versus gold-coated abutment screws for immediately loaded implants in partially edentulous patients.
Materials and Methods One-hundred implants inserted with a torque superior to 25 Ncm in 59 partially edentulous patients were randomly allocated to receive titanium (49 implants) or gold-coated abutment screws (51 implants). Implants could be placed also as immediate post-extractive implants and were loaded immediately with single screw-retained crowns, replaced after 4 months by definitive ones. Outcome measures were crown and implant failures, and peri-implant marginal bone loss.
Results At four years after loading 49 patients remained in the study with 77 implants rehabilitated with 39 titanium and 38 implants with gold-coated abutment screws. No implant or crown failed. Peri-implant mean marginal bone loss from implant placement was 0.67 ± 1.30 mm at titanium screws and 0.46 ± 1.62 mm at gold-coated screws with no statistically significant differences between the two screw types (mean difference = 0.21 mm, 95%CI -0.46 to 0.88, p = 0.53).
Conclusions Within the limitations of this study, it can be concluded that the type of implant-abutment screw does not significantly affect peri-implant crestal bone. In addition, immediate implant placement and loading seems to be viable treatment alternatives.

KEYWORDS: abutment screw, dental implants, immediate loading

INTRODUCTION

Dental implants are a predictable treatment option to replace missing teeth. Implant survival and success rates are high, yet sometimes progressive crestal bone loss occurs(1). The latter increases the risk of implant exposure, aesthetic problems, and implant failure. Following implant placement, crestal bone remodeling can occur due to the establishment of the biological width. Initial crestal bone loss happens within the first months after implant placement and is described in the literature as initial bone remodeling. It is a physiological process that may depend on the soft tissue thickness, implant and abutment design and the vertical implant position(2-4). Crestal bone loss that occurs after the initial bone remodeling is more often associated with peri-implant pathology(5). Several risk indicators such as poor oral hygiene, a history of periodontitis, diabetes and smoking can contribute to this phenomenon. Peri-implant mucositis is an infection limited to the mucosa, whereas peri-implantitis also affects the supporting bone(6). According to the European workshop criteria by Lindhe et al.(6) peri-implantitis is characterized by mucosal inflammation with additional bone loss after the first year of loading, including increasing pocket depths and bleeding on probing (BoP) or suppuration. However, there is no real consensus on the thresholds for crestal bone loss and inflammatory parameters to define peri-implantitis. Klinge et al. (7) proposed a bone loss of at least 2 mm, compared to baseline radiographs, with bleeding on probing and/or suppuration to define disease.
As aforementioned, implant and abutment design as well as surface roughness may affect crestal bone loss. An additional factor which may affect peri-implant bone loss is the presence of a small microgap at the implant abutment junction. Bacteria can colonize the micro-gap, initiating a chronic inflammation which may induce peri-implant bone loss. The micro-gap size can be affected by the preload

or clamping force. The latter is defined as the force holding the abutment onto the implant and is exercised by the abutment screw. A higher preload results in a better fit between implant and abutment, better abutment stability and a smaller micro-gap and microleakage, which could affect crestal bone loss(8-10). In order to obtain a higher preload, abutment screws with a gold coating have been developed(11,12). An in vitro study by Byrne et al.(13) compared three different abutment screws and concluded that the use of a gold-coated abutment screw induces a significantly higher preload than its uncoated analogues due to the lubricating effect of the gold coating. Therefore a higher preload might result in less crestal bone loss due to a better fit between implant and abutment, better abutment stability and less microleakage(9).

Historically, implants were loaded 3 to 6 months after implant placement(14). With immediate loading a provisional restoration can provided few hours after implant placement(15). Immediate loading, however, cannot be applied, if a sufficient primary implant stability is not obtained. Ottoni et al.(16) performed immediate loading on implants with limited primary stability and found a higher failure rate. A systematic review by Esposito et al.(15) compared the marginal bone loss around implants for different loading protocols 1 year after placement and showed that immediate loading is a viable treatment alternative.

The aim of this randomized controlled trial was to compare the clinical outcome of titanium versus gold-coated abutment screws for immediately loaded implants in partially edentulous patients.

MATERIALS AND METHODS

Study Design

This was a single-centre randomised controlled trial (RCT) comparing the clinical outcome of screw-retained implant-supported crowns using titanium (control group) or gold-coated abutment screws (test group). Implants were randomly allocated using closed envelopes, which were opened just before implant placement.

Patients were recruited and treated in one private dental clinic located in Falun, Sweden, by a single operator having extensive experience with immediate placement and immediate loading procedures.

Inclusion and exclusion criteria

Any partially edentulous patient requiring at least one implant supported crown, who was 18 years of age or older, was eligible for inclusion in this trial. Both patients who were already partly edentulous and patients in need of tooth extraction were included. Only patients allowing placement of one or more implants with minimal length of 8.5 and of a minimal diameter of 4.1 mm were included.

Patients were not accepted into the study if any of the following exclusion criteria was present:

- Active infection or severe inflammation in the areas intended for implant placement.
- Uncontrolled diabetes mellitus.
- Uncontrolled metabolic bone disease where there is a diagnosis of osteomalacia, primary or secondary hyperparathyroidism, renal osteodystrophy, or Paget's disease of bone.
- History of therapeutic radiation to the head within the past 48 months.
- Need of bone grafting at the site of the intended study implant.
- Patients who are known to be pregnant at the screening visit.
- Severe para-functional habits such as bruxing or clenching.
- Implant insertion torque inferior to 25 Ncm and/or ISQ value below 60.
- Smoking more than 10 cigarettes per day.

Clinical procedures

All patients received prophylactic antibiotic therapy at the dental practice: 2g amoxicillin and diazepam (0.3 mg/kg body weight) given one hour before implant placement.

Based on the clinical situation, namely a healed ridge or extraction socket the protocols for delayed or immediate placement was followed. After local anesthesia with lidocaine-adrenaline 2% (Xylocaine-Adrenaline 2%, Dentsply Sirona, USA) and in case of a healed ridge, a midcrestal incision was made and the mucosal flap was reflected. In case of immediate placement, flapless implant placement was performed. Before proceeding with implant placement, the soft tissue thickness was measured. Based on the measured thickness, crestal or subcrestal implant placement was determined. The vertical position of the implant was adjusted according to the soft tissue thickness respecting the biological width. The drilling protocol was performed in accordance with the manufacturer guidelines, except that countersinking was not performed.

In all cases, T3 implants from Zimmer Biomet 3i (BNPT variant, Palm Beach Gardens, Florida, USA) were placed. This is a tapered implant that features an internal implant-abutment connection and an integrated platform-switch. This implant has a hybrid implant surface. The coronal 1.5 mm is a dual acid-etched surface which is minimally rough (Sa = 0.48 µm). The remaining part is moderately rough (Sa = 1.39 µm). This surface was first sandblasted with a resorbable calcium phosphate and then treated with dual acid etching (DAE). Finally, the entire implant surface was also treated by means of discrete crystalline deposition (DCD) of calcium phosphate (CAP), resulting in a nanoscale topography (10-100 nm). The following implant lengths were used: 8.5, 10.0, 11.5, and 13.0 mm and diameters: 4.1, and 5.0 mm.

Implants placed in fresh extraction sockets were anchored in the palatal wall of the socket. In case of a buccal gap of 2 mm or more, Endobon Xenograft (Zimmer Biomet 3i) was applied to fill up the space.

After final implant placement, torque values were record-

ed on the drilling unit (Elcomed, W&H Dentalwerk, Bürmoos, Austria) and resonance frequency analysis (RFA) was performed (Integration Diagnostics, Osstell, Gothenburg, Sweden). To be suitable for immediate loading, a minimum insertion torque of 25 Ncm and an ISQ > 60 was required. If the latter was not achieved, the implant was excluded from the study.

Temporary restorations were fabricated chair-side using a gold colored titanium abutment with nitride coating (GingiHue abutments, IAPP, IWPP, Zimmer Biomet 3i). A strip crown or a prefabricated translucent mold was used and filled with acrylic resin to fabricate the temporary crown. All restorations were screw-retained. Single crowns were torqued at 15 Ncm and placed out of occlusion. The abutment screws used were a titanium screw in the control group and the GoldTite screw (UNISG, IUNIHG, UNIHG: stainless steel screw with a gold coating) in the test group, both produced by Zimmer Biomet 3i (Fig. 1) and were placed according to the random scheme.

Baseline periapical radiographs of the study implants were taken with the paralleling technique.

Postoperatively, patients were advised to use a 0.1% chlorhexidine mouth rinse (Hexident, Carex Sweden, Löddeköpinge, Sweden) for one minute three times a day for the first 10 days. In addition, a diet consisting of soft foods was recommended for the same period. After 3 to 6 months, final impressions were taken, and final crowns were placed at 35 Ncm.

Recall visits were scheduled at 3, 6, and 12 months after implant placement. Thereafter, patients were seen annually. Oral hygiene was evaluated and adjusted as needed. Professional cleaning was performed according to the needs of the patient. Periapical radiographs or vertical bitewings were also taken during these appointments to evaluate the crestal bone loss.

FIG. 1 The abutment screws used in the present trial

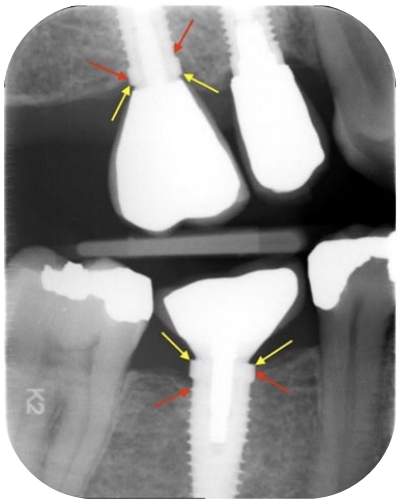

FIG. 2 Radiograph showing reference point (yellow) and crestal bone level (red)

Outcome measures

Primary outcome measures were:

- Crown failure: loss of the crown secondary to implant failure or replacement of the definitive crown for any reasons.
- Implant failure: implant failure was defined as implant mobility and/or any infection dictating implant removal or any mechanical failure rendering the implant unusable, such as implant fracture or deformation of the implant-abutment connection. The stability of each implant was measured manually by tightening the abutment screw at definitive crown delivery. The stability of single implants at the 1- and 4-year controls was checked by attempting to rock the crown with the handles of two metal instruments. Rotating implants were considered failures.

Secondary outcome measure was:

- Peri-implant marginal bone levels changes evaluated on periapical radiographs or vertical bitewings taken with the paralleling technique at implant placement (baseline), 1- and 4-year after loading. Measurements were performed by two masked investigators (MA & MR) using the ImageJ (National Institutes of Health, Bethesda, Maryland, USA) software. Bone level was described as the distance from the reference point (implant neck) to the crestal bone (Fig. 2). The mesial and distal bone level were rounded off two decimal. As a reference to calibrate the measurements, the size of the implant neck (1.17 mm) was used. Bone loss was calculated by taking the difference of the bone level at time X and baseline. Then the average crestal bone loss per implant was calculated and reported. These measurements were recorded in a dataset. The intraclass correlation coefficient (ICC) was determined by a third investigator (VC).

Sample size and statistical procedures

The sample size was calculated on marginal bone loss.

A power analysis was performed using SAS Power and Sample Size (SAS Institute Inc., Cary, North Carolina, USA). Sample size was calculated using a Satterthwaite t-test. In the absence of comparable studies, a clinically relevant mean difference in crestal bone loss of 0.5 mm was assumed. Based on a study by Chen(17), the SD was set at 0.9 mm. The statistical significance level was set at 5% and the power at 80%. This resulted in a sample size of at least 42 implants per group. Considering a drop-out rate of 10%, there should be a total sample size of 92 implants at the start of the study. The data was analyzed using SPSS Statistics version 26 (IBM, Armonk, New York, USA). The implant was the statistical unit of the analyses. Descriptive statistics were performed, and a Kolmogorov-Smirnov test was used to check for normality. Overall, the data was normally distributed. Only bone loss measured at 4 years of follow-up for the implants with a GoldTite abutment screw was not normally distributed (p=0.027). For titanium versus GoldTite abutment screws, mean crestal bone loss after 1 year of follow-up and mean difference in crestal bone loss (4y - 1y) were compared by means of an unpaired t-test with a statistical significance level of 5% and a Mann-Whitney U test with a statistical significance level of 5% was used to compare the difference in crestal bone loss after 4 years of follow-up.

RESULTS

One-hundred implants inserted with a torque superior to 25 Ncm in 59 partially edentulous patients were randomly allocated to receive titanium (49 implants: 27 with delayed placement and 22 with immediate placement) or GoldTite abutment screws (51 implants: 27 with delayed placement and 24 with immediate placement). At 1 year follow-up, 45 implants remained in each group (51 patients). After 4 years 39 implants in the titanium and 38 in GoldTite abutment screws (49 patients) could be evaluated. Poor quality of periapical radiographs, relocation or death were the reasons for drop-outs.
The follow-up focused on the time between implant placement and 4-year after loading.
Prosthesis failures: None occurred.
Implant failures: None occurred.
Marginal bone level changes (Table 1): The ICC for the measurements of 1 and 4 years of follow-up was 0.81 (95%CI 0.72 to 0.87, $p < 0.001$) and 0.87 (95%CI 0.80 to 0.92, $p < 0.001$), respectively. According to the guidelines of Koo and Li(18), the interrater reliability of the measurements of 1-year and that of 4-year follow-up were rated as "good". At implant placement, bone levels were 0.97 ± 1.07 mm (CI95% 0.47 to 1.12) at titanium, and 1.04 ± 1.50 mm (CI95% 0.60 to 1.47) at GoldTite abutment screws, with no statistically significant differences between the groups (mean diff = -0.24; CI95% -0.78 to 0.30, p = 0.37).
One year after loading, there was no statistically significant difference between the two groups for peri-implant bone loss: 0.56 ± 0.92 mm (CI95% 0.28 to 0.84) at titanium, and 0.55 ± 1.65 mm (CI95% 0.05 to 1.04) at GoldTite abutment screws (mean diff = 0.01; CI95% -0.55 to 0.57, p = 0.97).
Four year after loading, there was no statistically significant difference between the two groups for peri-implant bone loss: 0.67 ± 1.30 mm (CI95% 0.25 to 1.09) at titanium, and 0.46 ± 1.62 mm (CI95% -0.07 to 0.99) at GoldTite abutment screws (mean diff = 0.21; CI95% -0.45 to 0.88, p = 0.53).

DISCUSSION

The present trial was designed to evaluate whether the use of stainless steel abutment screw with a gold coating compared to conventional titanium screw could affect peri-implant marginal bone loss over time. No implant failures were reported, and no difference in peri-implant marginal bone loss was observed, therefore, both screw types work very well, and it would be up to clinicians to choose the one they prefer.
Since, there are no other RCTs testing our same hypothesis, it is not possible to compare our findings with those of other authors. Nevertheless, the clinical results of this study are exceptionally good considering that all implants were immediately loaded and that almost half of them were placed as immediate post-extractive implants. It has been reported that immediate post-ex-

	Implant placement	Difference placement – 1 year	Difference placement – 4 year
	N Mean±SD (95% CI)	N Mean±SD (95% CI)	N Mean±SD (95% CI)
Titanium screw	49 0.97±1.07 (0.47; 1.12)	45 0.56±0.92 (0.28; 0.84)	39 0.67±1.30 (0.25; 1.09)
GoldTite screw	51 1.04±1.50 (0.60; 1.47)	45 0.55±1.65 (0.05; 1.04)	38 0.46±1.62 (-0.07; 0.99)
Difference	-0.24±0.27 (-0.78; 0.30)	0.01 ± 0.28 (-0.55; 0.57)	0.21 ± 0.34 (-0.46; 0.88)
P-value intergroup	0.37	0.97	0.53

TABLE 1: Mean radiographic peri-implant marginal bone level changes between groups and time periods up to 4-year post-loading

traction implants have a probability of failing two to three times higher than delayed placed implants(19-23). Also immediate loading procedures are considered at higher risks for failures, especially at single implants, but this has not been clearly established yet(15). The most relevant factor which may explain the good results obtained in this trial is the high insertion torque at implant placement. To qualify for the immediate loading, implants had to be inserted with torque superior to 25 Ncm. This hypothesis is supported by the findings of two studies(16, 24). In a non-randomised controlled study of split-mouth design, single implants were either immediately non-occlusally loaded or conventionally loaded. The authors found a strong correlation between low implant insertion torque and implant failures for immediately loaded implants. In fact, out of ten single implants placed with an insertion torque of 20 Ncm, nine failed, whereas only one implant failed out of 10 implants inserted with a torque of at least 32 Ncm(16). The other split-mouth RCT included 50 patients who received two single immediately loaded implants, one randomly inserted with a torque between 25 and 35 Ncm, and the other with a torque superior to 80 Ncm. Seven implants inserted with a torque between 25 and 35 Ncm failed versus none of those implants placed with insertion torque superior to 80 Ncm(24). The difference was statistically significant.

The main limitations of this trial are the unproper randomization procedure and lack of allocation concealment, the lack of complication reporting, the limited sample size, the relative short follow-up, an unclear reporting of drop-outs and of unreadable radiographs. Randomized trials should designed according to a parallel group design or to a within-subject (split-mouth) design. According to the type of study design the correct statistics is chosen. In the present case, implants were randomized in a mixed parallel group and split-mouth design creating a statistical nightmare. Random allocation was done prior to implant placement, so the surgeon knew in advance which type of screw the abutment was receiving, while the randomization should have been made at the time of screwing the abutments, therefore no allocation of the procedure was attempted. Complications were not reported and they might have been affected by the screw type choice. The number of included patients was too low to detect a significant difference of 0.5 mm already at 4 years after loading and ideally a follow-up to 10 years would be very useful to study the effect of the screw type over time. Finally, the reasons for drop-out were not given in details and unreadable radiograph were accounted as drop-outs instead to be taken again at the time of data acquisition. The latter procedure further decreased the already small sample size. It is unfortunate that only implants which were loaded immediately were included in this trial since this reduces the generalisability of the results to other loading times. All these limitations, put the results of this study at a very high risk of bias, therefore other studies better designed with larger sample sizes and longer follow-ups, would be needed to confirm or reject these preliminary findings.

With respect to the generalisability (external validity) of these findings, it should be recognized that these procedures were tested in real clinical conditions and that patient inclusion criteria were relative broad with the exception of heavy smokers; therefore, results can be generalised to a wider population, keeping in mind that the operator was highly experienced with immediate placement and immediate loading procedures

CONCLUSIONS

Within the limitations of this study, it can be concluded that the type of implant-abutment screw does not significantly affect peri-implant crestal bone loss. In addition, immediate implant placement and loading seems to be viable treatment alternatives.

Conflict of interest notification

This work was supported by Zimmer Biomet by means of material support. There are no other conflicts of interest to disclose.

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