A 5- TO 6-YEAR RADIOLOGICAL EVALUATION OF TPS/SLA IMPLANTS: RESULTS FROM PRIVATE PRACTICE

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Running Title: Long Term Bone Level Evaluation Around Rough Surface Implants

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ABSTRACT

Objectives: The aim of this study was to determine bone level changes after 5-6 years of follow-up for a large group of one-stage dental implants consecutively placed in private practice. Potential confounding factors influencing crestal bone loss were also to be assessed.

Materials and Method: A total of 378 transmucosal Straumann® implants in 174 patients were examined radiographically. Half of the study population (189 implants) had a titanium plasma sprayed (TPS) surface, the other half (189 implants) were sand-blasted and acid etched (SLA). Mean crestal bone loss (CBL) was measured from 5-6 year post-operative radiographs on the basis of known implant landmarks. Correlations of increased CBL with various independent variables were also investigated. Statistical analyses were performed using generalized estimating equations.

Results: Radiographic measurements showed a CBL ≤ 1.5 mm for 65% of studied implants. A CBL ≥ 1.5mm was found for 28% of implants, while 7% of implants included in this study had a CBL ≥ 3mm. Three factors significantly influenced CBL ($p<0.05$): implant surface texture (TPS>SLA), smoking status (smokers>non-smokers), and implant location (anterior>posterior).

Conclusions: CBL was less than 1.5mm after 5-6 years for the majority of followed implants. For implants with a CBL ≥1.5, statistically significant correlations were found for TPS surface type, anterior jaw locations, and smoking. Implant length did not influence CBL.

Key words: clinical research, dental implants, bone-implant interaction, crestal bone loss, success rate, TPS, SLA, implant surface, rough surface, smoking, implant location, vestibular bone width, short implants, private practice.

INTRODUCTION

Implant therapy has long been proven to be a safe and reliable mode of treatment with limited biological and prosthetic postoperative complications (Lang et al. 2000). Since the early studies of Brånemark et al. (1985), osseointegrated implants have become the therapy of choice to rehabilitate fully and partially edentulous ridges (Adell et al. 1981 &1986, Buser et al. 1997; Weber et al. 2000; Romeo et al. 2006).

Success criteria for dental implants are conflicting in the literature (Papaspyridakos et al. 2012). Those proposed by Buser et al. (1997) and Cochran et al. (2002) did not include bone level measurements over time and consisted of: 1) absence of clinically detectable implant mobility, 2) absence of pain or any subjective sensation, 3) absence of recurrent peri-implant infection, 4) absence of continuous radiolucency around the implant.

Other authors recommended the use of mean crestal bone level changes as one of the criteria for success of dental implants (Albrektsson et al. 1986). Studies on rough surface implants reported a radiographic bone loss of approximately 0.5-1mm in the first year, and 0.05-0.2mm per year thereafter (Hämmerle et al. 1996, Weber et al. 2000, Peñarrocha et al. 2004, Ricci et al. 2004). Using this information, the evaluation of the crestal bone loss over a period of 5-6 years would result in a total average of ≥1.5mm for being considered 'normal'.

Several confounding factors affecting initial bone levels have been investigated in the literature. Parameters such as implant location, height of the smooth collar, implant diameter and length, implant surface texture, opposing occlusion, crown-to-implant ratio, type of superstructure, as well as patient related factors like periodontal status, smoking, bruxism, and hygiene control may affect CBL (Chung et al. 2007, Lindquist et al. 1997, Mericske-Stern.1997, 2000; Keller et al. 1998; Miyata et al. 2002; Nedir et al. 2004; Fransson et al. 2005). A thorough understanding of the physiological principles governing crestal bone remodeling around implants facilitates the distinction between an expected physiologic crestal bone remodeling, and a pathologic condition resulting in bone loss (Hermann et al. 1997, 2000, 2001a,b). One must distinguish between physiologic bone loss and bone loss as a consequence of the invasion of the biological width. The so-called “biological width” refers to a protective structure of about 3 mm above the bone at the tooth or implant interface and is made of a given thickness of soft tissue, a junctional epithelium and a sulcus. Once this structure has been altered (e.g. during implant crown insertion), bone moves apically as a mean to remain away from the local irritation caused either by bacteria, a biomechanical reason or micro-movements. This means that physiological bone loss because of biomechanical misuse is indeed limited to the rough-smooth boundary (Hänggi et al. 2005, Pilliar et al. 1991, Vaillancourt et al. 1996, Wiskott et al. 1999).

When the crown-implant junction is beneath the crest of the bone, this causes a non-physiological response or an irritation that initiates an additional bone loss on top of the physiological bone loss. This additional bone loss is the result of the re-establishment of the protective environment; namely the biological width. With tissue level Straumann® implants, and because of the existence of a smooth-rough surface interface on the implant itself, bone loss occurring up to that interface can be considered physiological remodeling; bone loss occurring apical to that point (around the rough surface) can hence be regarded as pathological bone loss. These findings were applied in crestal bone loss (CBL) measurements around implants in the current study.

The purpose of this study was to assess bone level changes adjacent to dental implants after 5-6 years in function for a large group of implants consecutively placed in private practice. Potential factors that may be correlated with peri-implant crestal bone loss of ≥ 1.5 mm after 5-6 years of follow-up were to be investigated as well.

MATERIALS AND METHODS

Patient enrollment

Subjects in the current study represent a subset of that of a previous study, in which an implant success rate of 99.4% for a total of 528 implants in 236 patients was reported (Nedir et al. 2004), using the mentioned success criteria by Buser et al. (1997).

Between January 1995 and December 2000, 528 dental implants (Straumann AG, Waldenburg, Switzerland) were inserted in 236 consecutive patients. These patients were treated in a private practice (Ardentis Clinique Dentaire SA, Vevey, Switzerland). All patients were initially selected for implant treatment based on standard diagnostic procedures including benefit/risk assessment. As outlined above, this patient pool has been published and reported on in the literature (Nedir et al. 2004). In summary, the patient population consisted of 145 females (61.4%) and 91 males (38.6%). Mean age at implant placement was 53.5 years. All patients were enrolled in the practice's hygiene maintenance program.

From this population, patients, who were eligible for radiographic examination, became part of the present radiographic study. A total of 378 implants, 71.6% of the initial total population, were available for a 5-6 year post-operative radiographic evaluation.

Reasons for drop-out and sample attrition from the original implant pool are summarized in table 1.

Surgical procedures and variables

All surgeries were performed by two surgeons (RN, MB). In the mandible, implant length was chosen from standard radiographs maintaining a 2-mm safety margin above the mandibular canal. In the maxilla, implant penetration of 1 to 2 mm into the sinus floor was tolerated. Standard insertion (without a prior sinus graft) was performed when 5 mm of bone height was available. Bone width prior to surgery was assessed according to the complexity of the situation by clinical palpation, bone mapping, or CB/CT radiographic imaging techniques (especially in cases of complete maxillary edentulousism). Implants placed before June 1999 were titanium plasma sprayed (TPS) implants, and those placed after June 1999 were sandblasted and acid-etched (SLA). Esthetic Plus implants were used when the esthetic situation required a deeper placement of the implant-crown junction in the peri-implant soft tissues. Surgeons paid attention to place all rough-smooth junctions at the level of the mesial and distal crestal bone level or deeper. No implant was placed with the rough-machined junction above the bone crest at any proximal site. A specific period between tooth extraction and implant placement was not observed. Few implants (2.3%) were placed immediately after tooth extraction, 34.9% after 3–6 months, 15.9% after 6–12 months and 47.0% after more than 1 year. Recommended healing times prior to loading were followed. For TPS implants, the mean time healing time was 3.9 months in the mandible and 4.5 months in the maxilla. For SLA implants it was 2.3 months in the mandible and 2.5 months in the maxilla were observed.

Radiographic analysis

All patients were recalled during the period from 2000 to 2005 in order to achieve the 5- to 6-year control including a conventional periapical radiograph, using the long cone paralleling technique. Radiographs prior to November 2005 were taken without long-cone and paralleling device. After November 2005, digital radiographic images were taken using the DBSWIN system® (Dürr Dental, Baden-Württemberg, Germany). All bent or otherwise non-diagnostic radiographs were excluded from the crestal bone level analysis. For a total of 378 implants (71.6% of the initial population), 5-6 year post-operative radiographs were eligible for CBL measurements (Table 1).

Conventional films were scanned in a digital format using a flatbed scanner (Epson Expression 1680 Pro, Wadenswil, Switzerland) with at least 600-1200 dpi resolution. Both conventional and digital radiographs were subsequently analyzed using an image analysis software (Digora, Soredex, Helsinki, Finland), allowing a measurement precision of 0.01 mm. To determine the magnification factor, an internal calibration was performed for each radiograph. The known implant inter-thread distance was 1.25 mm and used for internal calibration. In order to improve the image analysis, image enhancement operations including sharpness, brightness, contrast and gamma adjustments were done whenever deemed necessary.

The smooth-rough surface interface on the included implants was defined as the ® line. Its location depends on the height of the smooth implant collar; being 2.8mm on Standard implants, and 1.8mm on Esthetic implants (Fig.1). Once the ® line was identified on the periapical radiograph to be analyzed, CBL measurements were made from the ® line to a line perpendicular to the long axis of the implant at the most apical part of the proximal marginal bone (Fig. 2). Measurements were done by two different observers (HG and SA) on both mesial and distal sides of the implant, without a significant difference ($p>0.05$). Mean values were then calculated.

Outcome variable

The main outcome variable of this study was CBL at the end of the 5-6 year follow-up period. To be considered ‘within normal range’, an implant could exhibit a CBL of ≤ 1.5mm after the 5-6 year follow-up. This number was calculated as an average from proposed peri-implant bone loss values in the literature as described above (0.5-1mm in the first year following surgery and up to 0.2mm annually in subsequent years). Implants with a CBL ≥ 1.5mm were further investigated and assessed for correlations with the independent variables listed below.

Independent variables

Independent variables included the following:

- Implant surface texture (TPS versus SLA),
- Smoking status (smoker versus non-smoker),
- Implant location (anterior versus posterior),
- Implant length (6, 8, 9, 10, 11, 12 or 13mm),
- Jaw location (maxilla versus mandible),
- Height of implant smooth collar (standard versus esthetic implant),
- Opposing dentition (natural or fixed versus removable),
- Implant collar diameter (3.5, 4.8, or 6.5 mm),
- Implant prosthetic superstructure (fixed versus removable),

- Vestibular bone lamella (VBL) (≥ or < 1mm).

Statistical analysis

Descriptive statistics including mean, standard deviation, and percentage above 1.5 mm were used to assess the CBL. To account for dependence of data within a subject, bivariate and multivariate analyses were performed via generalized estimating equations (GEE). The outcome variable for every analysis was the presence or absence of CBL > 1.5 mm. Each independent variable that exhibited a statistically significant association with the outcome in a bivariate analysis was entered into the multivariate model. All statistical tests were two sided and p-value of < 0.05 was deemed to be statistically significant. Analyses were conducted using SAS Version 9.2 (SAS Institute Inc., Cary, NC).

RESULTS

From the total number of 411 implants available for radiographic caption, 33 implants were discarded from analysis because of unclear resolutions / film distortions or missing patient data. Ultimately, a total 378 implants (71.6% of the initial implant population) were eligible for radiographic bone level measurements (Table 1). At the time of the surgical intervention, the following variables were collected:

- Implant surface: of the 378 implants, 189 (50%) had a TPS surface, the other 50% had an SLA surface.
- Implant location: a total of 228 implants (60.3%) were placed in the mandible, and 150 implants (39.7%) were placed in the maxilla. A higher number of implants

(276) were placed in the posterior segments (73.0%) than the anterior segments (102 implants, 27.0%)

- Opposing dentition: the majority of fixtures (293) had a natural/fixed opposing dentition (77.5%); 85 (22.5%) had a removable opposing dentition.
- Height of implant smooth collar: only 64 implants (16.9%) had an Esthetic collar. The rest (314) had a Standard collar (83.1%).
- Implant prosthetic superstructure: the majority of implant prosthesis were fixed (298), representing 78.8% of implant superstructures and the remaining (80) were removable (21.2%).
- Smoking status: 72 (19.0%) of the implants were placed in smoking patients and 306 (81.0%) in non- smokers.
- VBL: at surgery, 273 (72.2%) of the implant beds presented a VBL≥1mm and 105 (27.8%) a VBL<1mm. Of the anterior implants, 72 (70.6%) had VBL≥1mm and 30 (29.4%) had a VBL<1mm.

The mean (SD) CBL was 1.08 (1.08) mm at the mesial aspect and 1.15 (1.11) mm at the distal. The median (inter-quartile range) was 0.86 (1.36) mm mesial and 0.89 (1.47) distal. A total of 104 implants (27.5%) exhibited a CBL ≥ 1.5mm.

Fig. 3 displays the percentage of CBL values ≥ 1.5mm for each implant length. In total, 236 implants (62.4%) were ≤ 10 mm in length. This percentage ranged from 22% (8mm) to 50% (6mm); however, it should be noted that the sample size for 6mm implants was very small (n=4). Among implant lengths with sample sizes of n ≥ 42, the percentage of CBL values > 1.5mm ranged from 22% (8mm) to 31% (10mm).

Three factors exhibited statistically significant associations with CBL > 1.5mm (Table 2):.

1. Implant surface texture; A higher percentage of TPS surface implants showed CBL > 1.5mm than SLA surface implants.
2. Smoking status; implants in smokers showed a higher percentage of CBL > 1.5mm than implants in non-smokers,
3. Anterior versus posterior location; implants in anterior sites showed a higher percentage of CBL > 1.5mm than implants in posterior sites.

Implant length did not exhibit a statistically significant association with CBL > 1.5mm ($p>0.05$), nor did the other studied factors (vestibular bone lamella, jaw location, implant collar diameter, implant prosthetic superstructure, height of implant smooth collar). The three aforementioned factors with significant bivariate associations (implant surface texture, smoking status, and implant location) were entered into a multivariate GEE model to predict the outcome (CBL > 1.5mm or CBL < 1.5 mm). Results are presented in Table 2 in the adjusted "GEE results columns". Each of the three factors was statistically significant in the multivariate model (all $p<0.05$). The direction of association for each factor was the same as had been observed in the bivariate analyses (TPS > SLA, smokers > non-smokers, and anterior > posterior).

DISCUSSION

In the present study, initial bone level was not measured on baseline (post-surgical) radiographs because the effective crestal bone loss was not the targeted variable. The experimental and clinical literature (Hämmerle et al. 1996, Hermann et al. 1997, 2001, Hänggi et al. 2005. Alomrani et al. 2005, Pilliar et al. 1991, Hartman & Cochran 2004) recognizes that implants with a smooth-rough boundary (the ® line) placed below the crest, are expected to experience a physiological crestal bone loss. The most coronal implant-bone contact is expected to get physiologically stabilized within 3-4 months along the ® line. This allowed us to introduce the ® line as an absolute baseline for implants in function; it discarded the need of getting initial baseline values measured at each implant site. Thus, the crestal bone loss that was measured here was the one measured beneath the ® line. This marginal crestal bone loss was correlated to the various independent variables described in the paper. This method has not only simplified the study methodology but has also reduced measurement errors and permitted the inclusion of an extremely wide range of patients.

Success criteria proposed by Buser et al. (1997) and Cochran et al. (2002) were applied on the initial population (Nedir et al. 2004). These include: 1) absence of clinically detectable implant mobility, 2) absence of pain or any subjective sensation, 3) absence of recurrent peri-implant infection, 4) absence of continuous radiolucency around the implant. Three implant failures in two patients were recorded. They occurred during the first year, none later. All controlled implants after 5 to 6 years were clinically stable and free of any symptoms, yielding to a success rate of 99.4 %.

Crestal bone loss (CBL)

Literature reports have recommended the radiographic evaluation of crestal bone levels at regular intervals and the calculation of mean bone loss over time as a criterion for success of an individual implant (Albrektsson et al. 1986). Crestal bone loss is an early manifestation of implant healing and the stability of the implant and implant abutment interface play an important early role in crestal bone levels. However, late marginal bone resorption has been attributed to biomechanical factors. Based on longitudinal radiographic observations of peri-implant bone remodeling, two distinct periods have been differentiated (Adell et al. 1981 &1986): a healing period and a follow up period. Depending on the study, mean crestal bone losses of 0.5-1mm in the first year, and mean annual bone loss of 0.05-0.2 in the follow up period were reported (Hämmele et al. 1996, Behnecke et al. 1997, Buser et al. 1999, Weber et al.1992, 2000, Astrand et al. 2004, Peñarrocha et al. 2004, Ricci et al. 2004, Zechner et al. 2004). These observations led to the recommendation for using mean crestal bone level changes as one of criteria determining the success of dental implants (Albrektsson et al. 1986, Weber et al. 1992, Buser et al. 1999). When applying such annual bone loss values to the current study, they would result in a total average CBL of ~1.5mm for the period of 5-6 years. Therefore, implants having CBL>1.5mm were identified and correlated to the several independent variables investigated.

Bone loss greater than 3mm was observed in 7 % of the implant population. Major conclusions cannot be made despite the increased radiographic loss in this group, since clinical parameters such as bleeding on probing and pocket depths, were not available. Further investigation of this group is warranted.

TPS/SLA surface effect

A significantly higher percentage of TPS surface implants showed CBL>1.5mm than SLA surface implants in the present study. Moreover, more TPS implants showed CBL>3 mm.

SLA implants were reported to have greater success and survival rates than TPS implants in animal and human studies (Cochran et al. 1998, 2002, Bornstein et al. 2005, Arlin 2007). SLA surface demonstrate enhanced bone apposition in histomorphometric studies and higher removal torque values in biomechanical testing (Cochran et al. 1998 and 2002)

Smoking effect

Many authors have shown that crestal bone loss in heavy smokers was higher than that of non-smokers (Lindquist et al. 1997, Esposito et al. 1998, Penarrocha et al. 2004, De Luca & Zarb 2006). Smoking is thought to interfere with early healing events in the process of osseointegration and hence the consequences are usually recognized in the first year following implant placement. The present study showed that CBL manifested approximately a 25% increase after at least 5 years in smokers. Implants in smokers showed a statistically higher percentage of CBL > 1.5mm than implants in non-smokers.

Implant location effect

Contradicting data has been reported on the effect of implant location on success and survival rates. Higher bone loss occurred in the anterior region (Weber et al. 2000), independent of the implant surface roughness (Zechner et al. 2004). It was also suggested that the more extensive bone loss around the anterior implants was a consequence of tensile forces, caused by loading of the posterior cantilever extensions and other biomechanical factors (Lindquist et al. 1996).

Present results showed that implants in anterior sites showed a higher percentage of CBL > 1.5mm than implants in posterior sites. Some of the anterior implants (32%)

exhibited VBL <1mm and an augmentation procedure was sometimes required. Furthermore, anterior implants are usually placed deeper for esthetic reasons; this leads to a more elaborate and complicated sequence of events that usually take place when implants are ready for restoration. They involve second stage surgery, tissue conditioning, provisional crown fabrication and removal, multiple impressions and trial of the definitive crown. All these procedures may lead to an increased irritation of the adjacent bone that may lead into an increased CBL, in order to re-establish the phenomenon of biologic width. Deeper implant placement may also result into the micro-gap situated deeper at the crown-implant connection and lead to an increased bone loss as documented by Hämmerle et al. (1996).

Vestibular bone lamella effect

It is recommended to maintain a minimum width of 1 mm around implants at placement to obtain optimum osseointegration and to prevent exposure of the implant threads following bone remodeling (Alberktsson et al. 1986). The effect of VBL on bone loss has not yet been reported in the literature.

Bone that is less than 1 mm wide was thought to be more susceptible to resorption after surgery or following function. This minimal bone would fail to provide a sufficient matrix for the surrounding mesio-distal bone remodeling process, and would even enhance its resorption (Brägger et al. 1998, Carlsson et al. 2000, Berglundh et al. 2002, Meijer et al. 2003). Such findings should alarm clinicians while placing implants in anterior regions with a VBL less than 1 mm, since it may cause higher peri-implant bone loss, provoke surgical recession, hence jeopardizing esthetic outcome.

Implant Length

Smoking, implant location and implant morphology have been demonstrated to influence marginal bone loss and are associated with an increased failure rate with short implants. (Penarrocha et al. 2004).

However, the introduction of textured implants has allowed a greater bone-to-implant contact; hence, higher success and survival rates with these implants were noted (Bernard et al. 2003). Mean marginal bone loss and gingival crevice probing depth associated with short or long implant lengths were statistically comparable (Romeo et al. 2006). Implants of 6 mm in length, with porous surface treatments, were introduced to avoid possible vertical augmentation and sinus lift procedures (Bernard et al. 2003, Nedir et al. 2004, Renouard & Nisand 2005).

Implant length did not influence crestal bone levels in the present study. Moreover, implants placed in the posterior area that tended to be shorter for anatomical reasons exhibited less bone loss than those placed in anterior areas. Short implant lengths could also be considered a valid predictable treatment option, especially in areas of reduced bone height. This was a significant finding which might not only simplify surgical and planning procedures, but also might drastically expand the applications of implant therapy.

That being said, the current study results and conclusions are subject to a few limitations. Only an association and not a cause and effect relationship was examined. In addition, the generalizability of the study findings cannot be established since the patients are drawn from one clinical setting. It should also be noted that only one cut off value (1.5mm) was used for the CBL variable over the 5-6 year period. However; this value was based on average findings from the literature as discussed above.

Conclusions made on implant length correlations with CBL≥1.5mm have to be interpreted with caution since implant numbers in the different length categories were not distributed evenly (e.g., few implants were of 6mm and or >12mm lengths). Limitations also include the lack of individualized and precise measurements of the initial bone level, and the assumption that bone stabilizes for all implants at the smooth-rough surface boundary, regardless of placement depth. While selection criteria in private practice may not be as strictly defined as in randomized prospective studies, patient selection was based on careful diagnosis and risk assessment nevertheless. This has rendered the results realistic and in accordance with outcome expectations for implant performance in clinical practice.

CONCLUSIONS

Mean CBL was less than 1.5mm after 5-6 years for the majority of followed implants. For implants with a CBL ≥1.5, statistically significant correlations were found for TPS surface type, anterior jaw locations, and smoking. Implant length did not influence CBL. The use of short implants may provide a beneficial alternative to bone augmentation prior to implant placement in sites with reduced bone height.

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