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Keratinized mucosa around implants in partially edentulous posterior mandible: 10-year results of a prospective comparative study

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SUMMARY

Objective: The aim of this research was to investigate the clinical conditions around dental implants placed in the posterior mandible of healthy or moderately periodontally compromised patients, in relation to the presence or not of keratinized mucosa.

Materials and methods: One hundred and twenty-eight patients who needed an implant in the posterior mandible were consecutively enrolled in a private specialist practice. Only one implant per patient was examined originally placed either within keratinized (KT) or alveolar (AM) mucosa. At 10 years, clinical and radiographic measures were recorded by a calibrated operator. The number of sites treated according to therapy modalities C and D (antibiotics and/or surgery) during the 10 years was also registered.

Results: Ninety-eight patients completed the 10-year study. The absence of KT was associated with higher plaque accumulation, greater soft-tissue recession, and a higher number of sites that required additional surgical and/or antibiotic treatment. Patient-reported outcomes regarding maintenance procedures presented major differences between the groups. In 11 of the 35 AM cases, additional free gingival graft (FGG) was successfully employed to reduce discomfort and to facilitate optimal plaque control.

Conclusion: Implants that are not surrounded by KT are more prone to plaque accumulation and soft-tissue recession, even in patients exercising sufficient oral hygiene and receiving adequate Supporting Periodontal Therapy (SPT). In selected cases, particularly in the edentulous posterior mandible, where ridge resorption leads to reduced vestibular depth and lack of keratinized mucosa, additional FGG can be beneficial in order to facilitate proper oral hygiene procedures

MATERIALS AND METHODS

All patients attending the principle investigator (M.R.), a specialist in periodontology, for dental implant therapy between December 1998 and December 2002 were screened for possible inclusion in the study. The criteria used for excluding patients were as follows: (1) mucosal diseases; (2) alcohol and drug abuse; (3) pregnancy or breast feeding; (4) uncontrolled metabolic disorders; (5) severe or aggressive periodontitis; (6) no interest in participating into the study.

In order to be incorporated in the study, patients had to present a treatment plan that included a site with one implant in the posterior mandible as a distal element, supporting either a single crown or a fixed dental prosthesis. The implant could be in the position of either a molar or a premolar, but no natural dentition could be present distally to it. The implant could not be placed in conjunction with an augmentation procedure or following Guided Bone Regeneration. No distal cantilevers were allowed. Only one implant per patient was selected for the examination. In case of 2 or more implants were placed at the same time, only the distal one was selected for the analysis.

Patients were informed that their data would be used for statistical analysis and gave their informed consent to the treatment. No ethical committee approval was sought to start this study, as it was not required by national law or by ordinance of the local inspective authority. The prospective study was performed in accordance with the principles stated in the Declaration of Helsinki and the Good Clinical Practice Guidelines.

Subjects were clinically and radiographically monitored at baseline. Full mouth plaque score (FMPS), full mouth bleeding score (FMBS), pocket depths (PD) were measured, at 4 sites of all teeth, by means of a periodontal probe (XP23/UNC 15, Hu-Friedy, Chicago, USA), and rounded off to the nearest millimeter. Following selection, all patients received appropriate initial therapy, consisting, depending on the cases, in motivation, oral hygiene instruction, scaling and root planning with the aim to reduce to a minimal level periodontal pathogens. No implant surgery was performed before the assurance of excellent motivation and compliance from each single patient (FMPS<20%; FMBS<20%).

One hundred and twenty-eight patients (52 males and 76 females; mean age: 52.4 + 10.2 years; 21 smokers) were consecutively treated, by means of SLA dental implants (Institut Straumann AG, Basel, Switzerland). Implants were placed, by the same operator (MR), with the border of the rough surface approximating the alveolar bone crest leaving the machined neck portion in the transmucosal area with a close adaptation of the wound margins to the implant shoulder. Abutment connection was carried out at 35 Ncm 6-10 weeks postsurgery to provide patients with cemented implant-supported fixed restorations. Therefore, each test implant supported either single crows, or the distal portion of a 3-4 unit bridge. All restorations were fabricated in order to facilitate both the oral hygiene procedures and the probing along their circumference. Baseline probing measurements were also recorded around the implants. Radiographic data were collected, after prosthesis installation, in order to establish a baseline reference for the following controls.

FOLLOW-UP

Patients were placed on an individually tailored maintenance care program (SPT), including continuous evaluation of their ability to perform proper plaque control. Motivation, re-instruction, instrumentation and treatment of sites with inflammation were performed as needed. Patients were asked to indicate if discomfort was present during oral hygiene procedures (1= YES, 0= NO). If AM patients showed insufficient plaque control due to soreness during oral hygiene procedures, they were given the option to receive an additional FGG around the implant. When a patient either expressed the desire not to attend follow-up examinations or was not able to attend the requested visits, he/she was classified as “dropout”.

FINAL CLINICAL EXAMINATION

After 10 years, an examiner (S.G.) with more than a dozen years of experience as hygienist, blinded to the initial classification of the patients, recorded, for each test implant, probing depth (PD) measured at four sites (mesial, buccal, distal and lingual) by means of a periodontal probe (XP23/UNC 15, Hu-Friedy, Chicago, USA) and rounded off to the nearest millimeter.

Soft tissue recession (REC) was measured from the implant shoulder to the coronal margin of the mucosa, by means of a Castroviejo Caliper Short, (Salvin Dental Specialties, Inc., U.S.A.) and rounded off to the nearest ½ millimeter.

The distance between the base of the implant shoulder and the most coronal visible bone-to-implant contact, measured in millimetres, both at the mesial and at the distal aspect of each implant, was calculated using standardized periapical intraoral films with a long cone technique and compared with the baseline values according to the technique previously described.

Furthermore, the following parameters were collected:

- Implant loss;
- Plaque score (presence/absence): total score for both teeth and implants (FMPS) and for the implant alone(PI), measured at four sites per implant and expressed as a percentage of examined sites;
- Bleeding on probing score (presence/ absence): total score for both teeth and implants (FMBS) and for the implant alone (BoP), measured at four sites per implant and expressed as a percentage of examined sites;
- Smoking habits;
- Number of sites which required, during the SPT, additional treatment with modalities C and D according to the Cumulative Interceptive Supportive Therapy (CIST);
- Presence of soreness / discomfort upon oral hygiene maintenance, evaluated by the patient (1= YES, 0= NO).

STATISTICAL ANALYSIS

Each patient contributed with one implant and was, therefore, regarded as the statistical unit. Data were expressed as mean ± SD and median (25-75 precentile) or counts and percentages. Since the statistical distribution of the quantitative measures, except the age, was found to be non-gaussian (tested by Shapiro-Wilk test), Kruskal Wallis rank test were used to assess between-group differences. The pairwise comparisons of the groups were performed by Mann-Whitney with Bonferroni's adjustment for multiple comparisons and $p<0.017$ were considered statistically significant. For categorical variables, the groups were compared using Chi-square or Fisher's exact test, as appropriate. A two-sided p value of less than 0.05 was considered to indicate statistical significance. All analyses were performed using STATA SE v13.1 (StataCorp, College Station, TX: StataCorp LP).

RESULTS

Of the initial 128 patients enrolled in the study, 3 patients lost their test implant during the observation period while 27 patients were lost to follow up: 8 died, 5 moved to other cities/countries, 2 developed severe health problems, and 16 refused the final follow-up visit.
The final 10-year analysis was therefore performed in 98 patients (38 males and 60 females).
During the entire 10-year observation time, KT patients needed in 12.7 % of the cases antibiotic or surgical therapy for the treatment of biological complications. The corresponding values for AM patients were 51.4%. The statistical analysis revealed a significant difference between the 2 groups ($p < 0.001$).
This difference is particularly significant from the clinical point of view, since both FMPS (18.40 ± 7.42 % vs. 19.57 ± 8.66 %, $p=0.48$) and FMBS (17.46 + 6.97 % vs. 18.26 + 8.33 %, $p=0.61$) revealed a good long-term compliance in both groups.
No patient reported pain or discomfort in oral hygiene procedures in KT group, while 15 out of 35 (42,9%) of the patients in AM group reported discomfort in performing oral hygiene ($p<0.001$). In 11 of these additional FGG was performed to facilitate plaque control.
At the end of the observation period, plaque was found on 21.0 ± 20.2 % of the 252 examined surfaces around implants placed in KT, on 37.5 ± 27.6 % of the 96 sites around implants in AM, and on 27.3 ± 26.1 % of the 44 surfaces around implants originally placed in AM with additional FGG, but only between the KT and AM group was found a significant difference ($p=0.007$).
Bleeding on probing was more frequent in the AM group than KT group, without reaching a statistical significant level among the 3 groups ($p=0.23$).
No significant differences were found with respect to mBL (0.34 ± 0.38 mm vs. 0.50 ± 0.38 mm vs. 0.56 ± 0.39 mm, $p=0.07$). Patients in AM group received a greater number of C or D interventions during the follow-up compared with the KT ones.
At the final examination, mean REC was 0.16 ± 0.39 mm in KT patients, 2.08 ± 0.71 mm in the AM group and 1.27 ± 1.17 mm in AM + FGG patients, with a statistical significant difference between the KT group both with the AM ($p=0.0001$) and the AM+FGG ($p=0.0001$) groups.

DISCUSSION

This is, to the best of our knowledge, the first 10-year prospective study that presents results on the influence of the quality of the mucosa on the long-term implant outcomes, recruited from a private clinic. The benefit, in accordance with the Consensus Report of 6th European Workshop on Periodontology (Lindhe & Meyle, 2008), is that subjects recruited from private or public dental clinics, rather than university clinics, provide information on the 'effectiveness' rather than 'efficacy' in implant therapy.

Several articles and consensus conferences were published in the literature since the present study was initiated. While some studies concluded that the presence of KT could significantly and positively impact tissue stability, others presented opposite results.

The European Association for Osseointegration (EAO) organized a consensus conference in 2006, in Zurich, Switzerland. For the meeting a systematic review was presented by Rompen et al. (2006) that concluded that in order to avoid bacterial penetration through this transmucosal piercing, the early formation of a long-standing effective barrier capable of biologically protecting the peri-implant structures is of paramount importance.

Cairo and coworkers (2008) presented at the 6th European Workshop on Periodontology a review based on several papers mainly expert opinions, case reports and case series. Literature analysis showed that (i) the width of KT did not influence the survival rate of dental implants; (ii) there was no evidence to recommend a specific technique to preserve/augment KT; and (iii) factors including bone level, KT and implant features have not been shown to be associated with future mucosal recession around dental implants. The only possible conclusion, approved by the Consensus Report (Palmer & Cortellini 2008), was that although scientific evidence in most part is lacking, soft tissue augmentation at implant sites may be considered in some clinical situations. However, the outcomes of these procedures have not been evaluated in prospective studies.

Three recent articles support the advantage of increasing KT. Yeung (2008) stated that even though available data so far suggest that with good oral hygiene, peri-implant soft-tissue health can be maintained irrespective if KT surrounding implant is present, good oral hygiene is, indeed, very difficult to achieve around dental restorations without the protection of a band of keratinized gingival tissue. Bouri et al. (2008) correlated the width of KT and the health status of the supporting tissues around dental implants. He found out that increased width of KT around implants is associated with lower mean alveolar bone loss and improved indices of soft tissue health. Kim et al. (2009) evaluated the peri-implant tissue response according to the presence of KT. He found out that in cases with insufficient keratinized gingival in the vicinity of implants, the risk of the increase of gingival recession and the crestal bone loss is present. Therefore, it is thought that from the aspect of long-term maintenance and management, as well as for the area requiring esthetics, the presence of an appropriate amount of KT is required.

Esposito et al. (2012) attempted a systematic review for the Cochrane collaboration group, but he was not able to find a single acceptable RCT in the world literature to evaluate if soft tissues augmentation improves the long-term prognosis of dental implants. According to the author, there is insufficient reliable evidence to provide recommendations on whether techniques to increase the width of keratinized mucosa are beneficial to patients or not. The review encouraged properly designed and conducted RCTs, with at least 6 months of follow-up, to provide reliable answer to this question. It must be noted, however, that it is unlikely that such a brief follow-up would show any significant difference even in a large population. Long-term, i.e. longer than 5 years, should instead be stimulated.

The most recent systematic review (Brito et al. 2014) aimed at evaluating the association between KM width and the periimplant tissue health, by selecting recent studies, with follow up greater than 12 months. Seven articles supported the conclusions that the presence of an adequate zone of keratinized tissue may be necessary because it was shown to be related to better peri-implant tissue health. The authors concluded that further randomized controlled trials are necessary to support this statement, even though it must be stated that practical and ethical reasons, however, make RCTs on this specific topic not easily feasible.

In our opinion, one of the reasons why it has not been possible so far to assess whether or not keratinized tissue is needed around implants, based on data of current literature, is that most studies present a cut off at 2mm KT. In particular, a major concern regards the possibility to make a precise recording when the reference point (such as the gingival margin) lies approximately near the 2 mm marking. For example, while recording the KT lies near the 2 markings, there may be the possibility that the case is registered as KT or AM. Therefore cases with a minimal clinical difference may be given to 2 different groups. In this way it is possible that implants with a minimal, but present KT, are pooled with those which are surrounded by AM. In order to avoid this problem in the present study, it was decided to dichotomously differentiate between implants either in KT or AM.

Smoking has been correlated to higher number of complications even in patients enrolled in a SPT (Aglietta et al. 2011). In the present study, even though the smoking habits of all patients were recorded, the relative number of smokers (11 out of 98) was limited and did not allow any powerful statistical analysis. Incidentally, it must be noted that all 3 patients who lost implants were indeed, smokers.

The results of this study seems to be in contrast with a recent retrospective evaluation of peri-implant diseases and KM width in patients with versus without mucogingival surgery (Frisch et al. 2013). Under supportive postimplant therapy in a private practice, 68 patients with peri-implant KM widths <1mm were identified between 1992 and 2011. Thirty patients rejected surgery and 30 patients agreed. After at least 1 year, low incidences of peri-implant diseases over long periods can be expected in patients attending SPT programs, independent of the absence or presence of KM. It must be noted that, because of the retrospective nature of this study, these results should be interpreted with caution.

The results of this research reveal that good oral hygiene is, indeed, more difficult to be achieved around dental implants without the protection of a band of KT. Moreover, increased width of KT around implants is associated with improved quality of soft tissues. In 11 of the 35 cases with a subjective problem by the patient, FGG was performed and the situation improved in a marked way. The fact that, despite a higher percentage of plaque found in the AM patients, there was no statistical difference in BOP between the 2 groups could possibly be related to the fact that recession, and therefore less pocket formation may be more common in areas without KT.

On the other hand, it must clarified that the results of the present investigation do not exclude the possibility that, even in the absence of KT, peri-implant health can be maintained for long-term, as it was demonstrated in several of the patients treated, but confirm the previous indication (EFP 1999) that proper oral hygiene procedures may be facilitated in the presence of an adequate band of KT.
An intriguing finding was that both FMPS and FMBS remained below the 20% threshold, both for KT and AM patients, implying that SPT was efficient. However, because in a portion of AM patients an adequate level of oral hygiene was achieved after additional FGG, it is not possible to draw definitive conclusions on how effective would have been the maintenance program should FGG had not be included. Indeed, one of the limits of the present investigation is that a number of patients have, in the 10-year observation period, changed their status (i.e. received additional FGG). Even though this could be considered a treatment bias, the patients treated referred a significant beneficial effect. On the other hand, the refusal to improve patients' conditions would be ideal from the statistical point of view, but would not be acceptable from obvious ethical reasons.

At this time, no conclusions can be drawn on the protective role of KT around implants in the maxilla and/or in the anterior part of the mandible, and/or in conjunction with GBR procedures. Similar prospective longitudinal controlled clinical trials will have to be performed to further elucidate the potential role of a sealing effect of masticatory mucosa on peri-implant stability.

One other limit of this study is that the mobility of the marginal soft tissue, i.e., lack of an attached portion of masticatory mucosa, was not registered as an independent variable. In this paper the presence of keratinized mucosa was dichotomously (yes or no) assessed regardless of its attached or unattached nature. It must be said, however, that in the presence of AM the mobility of the margin was observed at all implants.

In conclusion, this study represents a first important step forward in the definition of the outcomes to be searched in future studies. Moreover, the results of this 10-year study encourage continuous monitoring of the peri-implant tissue conditions to prevent peri-implant biological complications. Clinicians should keep in mind that soft tissue grafting seems beneficial in posterior mandibular sites especially when:

- patients complains of soreness during oral hygiene procedures;
- bone grafts and/or bone guided regeneration procedures are expected to stretch the mucosa;
- ongoing soft tissue recession is found, i.e. apical displacement of mucosal margin;
- plaque control is less than ideal and it may be facilitated by a better topography.

Owing to the impossibility to properly design and conduct RCTs on this specific topic for ethical reasons, new long-term multi-center observational studies in the various areas of the mouth, with at least 5-10 years of follow-up, are needed to provide a reliable final answer to the question.

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