CLINICAL ORAL IMPLANTS RESEARCH

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Marginal masticatory mucosa dimensional changes in immediate post-extractive implants: a 2 year prospective cohort study

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Abstract

Objectives: The present two-year prospective cohort study was undertaken to evaluate marginal masticatory mucosa dimensional changes around immediate post-extractive implants positioned transgingivally with a non-submerged healing screw.

Material and methods: Twenty-one immediate post-extractive implants from 21 patients were enrolled, peri-implant gap was filled with bovine bone mineral, and soft tissue was allowed to heal around a non-submerged healing screw. Post-extractive socket dimension was recorded. Intraoperative (T0) vertical distances: bone margin level (BML) from the bone margin to the implant platform and mucosal margin height (MMH) from marginal mucosa to implant platform were taken; MMH measurement was repeated 4 months later (T4). Horizontal mucosal level (HML): from customized stent to marginal mucosa at 0, 4, 12, and 24 months postoperatively (T0, T4, T12, T24) and vertical mucosal level (VML): from the stent to marginal mucosa at T4, T12, T24 were registered.

Results: One implant failed at 3 weeks; in the remaining 20 cases the MMH, coronally positioned with respect to the BML ≅2 mm at T0, showed a statistically significant vertical contraction of the mucosa at T4. Other vertical mucosal measurements (VML) did not show further changes over time. HML measures showed a, statistically significant, shrinkage of the mucosa on the transverse plane between T0/T12 and T0/T24 and between T4/T12 and T4/T24.

Conclusions: Immediate post-extractive implant inserted transgingivally with a non-submerged healing screw and internal peri-implant gap filled with bovine bone mineral may favor an early and stable peri-implant soft tissue healing over 2 years.

Traditionally, the Branemark surgical protocol for implant insertion considers a healing time of 6–12 months after tooth extraction (Eckert et al. 2005). For a number of years, one of the developmental goals of this technique has been to reduce treatment time, the number of operations and patients stress. As a result, implant positioning immediately after extraction has been successfully experimented (Schulte et al. 1978; Lazzara 1989). Over a period of time, several different studies have validated the predictable and long-term clinical success, as well as histological osseointegration, obtained with this subsequently developed technique (Lang et al. 1994, 2012; Schwartz-Arad & Chaushu 1997).

Immediate post-extractive positioning is associated with various degrees of discrepancy between the three-dimensional space of the socket and the implant profile, the so-called peri-implant gap, and to a reduced amount of available peri-implant soft tissue; both of which require correction through osseous reconstructive or regenerative and/or oral plastic surgical techniques (Lang et al. 2012).

The type of approach to the treatment of the peri-implant gap depends on its dimension and on the morphology and number of the residual walls of the post-extractive socket (Salama & Salama 1993; Hammerle et al. 2004). Certain studies showed that a regenerative surgical procedure and soft tissue primary closure were absolute requirements for any peri-implant defect to heal satisfactorily (Lazzara 1989; Wilson et al. 2003). Other reports described complete osseous and soft tissue healing by grafting

bovine bone mineral without the use of barrier membranes (Schwartz-Arad & Chaushu 1997; Nemcovsky et al. 2000). Araujo et al. (2011) confirmed that filling the peri-implant gap with bovine bone mineral may substantially improve positive osseous remodeling, notwithstanding conflicting evidence produced by different Authors (Hsu et al. 2012). Tan et al. (2012) speculated, in a subsequent comprehensive review, that positioning grafts or barriers in between the external bone plate and the covering soft tissue might interfere with the vascular supply of the tissue itself.

Some single arm observational studies investigated mucosal changes around immediate dental implants with gap filling with bovine bone mineral (Valentini et al. 2010; Cosyn et al. 2011; Tsuda et al. 2011). A recent review paper (Slagter et al. 2014) summarized, from those and from an additional large number of studies similar to the abovementioned ones, the results of inter-proximal or mid-facial mucosal level changes around immediate implants, with and without site filling, the vast majority being represented by single arm observational studies with a maximum number of patients/implants from 9 to 40 followed for 1 year. The ranges for the two procedures, with filled and unfilled sites, appear, as reported, very close for the changes at the inter-proximal mucosal level, whereas the measures of spread of the data, both for the two surgical methods and overall described measurements, are very wide. The authors of the review (Slagter et al. 2014) finally report the loss in inter-proximal and mid-facial mucosal level after 1 year of follow-up in terms of a mean from the pooled data for sites with and without bovine bone mineral filling but they suggest a careful interpretation. Therefore, an implementation of the overall amount of followed immediate dental implants for a further meta-analytic review would be required.

The purpose of this 2-year single arm prospective cohort study was to evaluate marginal masticatory mucosa dimensional changes around immediate post-extractive implants positioned transgingivally with a non-submerged healing screw and internal peri-implant gap filled with bovine bone mineral without barrier membranes.

Material and methods

Study design/sample

Twenty-one patients were recruited, treated, and followed-up at the Clinical Department "Head and Neck", University "Federico II" of Naples, from July 2011 to November 2013, for the present prospective study.

The inclusion criteria were (1) the need for the extraction of one maxillary premolar for untreatable caries, endodontic treatment failure or root fracture and acceptance by the patient for replacement through an immediate osseointegrated post-extractive implant as per Type I procedure of the 2004 Consensus (Hammerle et al. 2004); (2) post-extractive sockets type 1 (Salama & Salama 1993); (3) adult patients (aged 18 or older) (Barone et al. 1997); (4) a good standard of oral hygiene, as determined by the registration of Plaque Index (LÖe & Silness 1963), and Gingival Index (Silness & LÖe 1964) and (5) no signs of active periodontal disease.

The exclusion criteria were (1) the presence of systemic or local factors which might interfere with implant osseointegration such as: hypertension, coagulation problems, osteoporosis, hypo-hyperthyroidism, chemotherapy, diabetes type I or II, Crohn's disease, scleroderma, Parkinson's disease, Sjogren's syndrome, HIV infection, pemphigus vulgaris, ectodermal dysplasia, long-term immune-suppression after organ transplantation, cardiovascular disease or bone quantity (Mombelli & Cionca 2006; Alsaadi et al. 2007, 2008; Toti et al. 2013); (2) the presence of bone dehiscence and fenestrations of the post-extractive alveolus (3) subjects who had undergone therapeutical radiation, and (4) patients who had been subjected to or who were under bisphosphonate therapy.

A custom-made acrylic stent was fabricated to allow accurate repositioning for measurements by a periodontal probe (Fig. 1).

Study was conducted in full accordance with ethical principles, including the World Medical Association Declaration of Helsinki.

Informed consent was obtained from the patients, and the study approved by the Ethical Committee of the University "Federico II" of Naples.

Surgical methods

The surgical procedure was performed on outpatients, under local anesthesia by the administration of 2% mepivacaine with epinephrine, 20 + 12.5 mg/ml. Prophylactic antibiotic administration consisted of 2 g of Amoxicillin, or 600 mg of Clindamycin when allergic to penicillin, 1 h before surgery.

Before extraction, the periodontal biotype was examined with a UNC periodontal probe (CP 15 UNC; Hu Friedy® Chicago, IL, USA) in each patient, related to the single tooth to be extracted, and scored as: flat-thick (F), thin-scalloped (S), or intermediate (I), (Pontoriero & Carnevale 2001) (Table 3). A probing depth (PD) over 3 mm was never registered around these teeth.

An envelope full thickness flap of minimal extension through horizontal intrasulcular incision extended to the line angle of the mesial and distal adjacent tooth without any vertical releasing incision was raised to perform a dental extraction with minimal trauma. After extraction, the root anatomy of the tooth and post-extractive socket dimensions were recorded. The current immediate implant surgical procedure to seek and reach primary stability in the apical portion beyond the alveolus fundus and/or through contact with the lateral bony wall was applied (Lang et al. 2012). Titanium dental implants – root-form, active surface screws – all from the same manufacturer (Biomet 3i, Palm Beach, FL, USA) were inserted.

The implant platform was positioned at the crestal bone margin level, or slightly below, and at a horizontal distance from the buccal plate of ≥2 mm; the buccal and palatal gaps, internal to the bone plate, were filled with bovine bone mineral (Bio-Oss®; Geistlich Pharma AG, Wolhusen, Switzerland).

A healing screw was immediately applied, so that the submerged type of implant would heal in a transmucosal manner; the elevated flap was released when needed, coronally re-positioned and tied with a suspended suture to obtain maximum soft tissue adaption in order to achieve all the criteria that would favor the best results (Vignoletti et al. 2012). No soft tissue graft or osseous surgical correction was performed, nor was a barrier membrane and/or an extra-alveolar (external to the socket walls) graft positioned between the soft tissues and the underlying external bone plate. Amoxicillin 1 g/bid per 5 days, or Clindamycin 600 mg/day per 5 days when allergic to penicillin, and an anti-inflammatory drug (Ibuprofen 600 mg/day) if needed, were prescribed together with a chlorhexidine mouth rinse bid/15 days.

The healing screw was left in place for the 4 months postoperative healing time.

A visual description of a case from surgery to the final restoration is reported in Fig. 2.

Postoperative controls and clinical data collection

Implants were checked postoperatively at 4 months and those non-mobile, without infection, without peri-implant radiolucency, and no elicitable pain at a forward torque

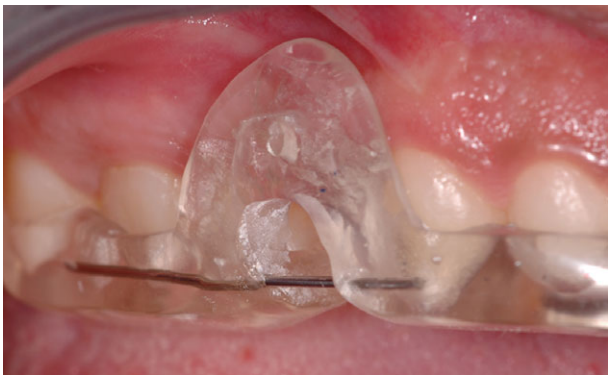

Fig. 1. Custom acrylic stent for measurements in position.

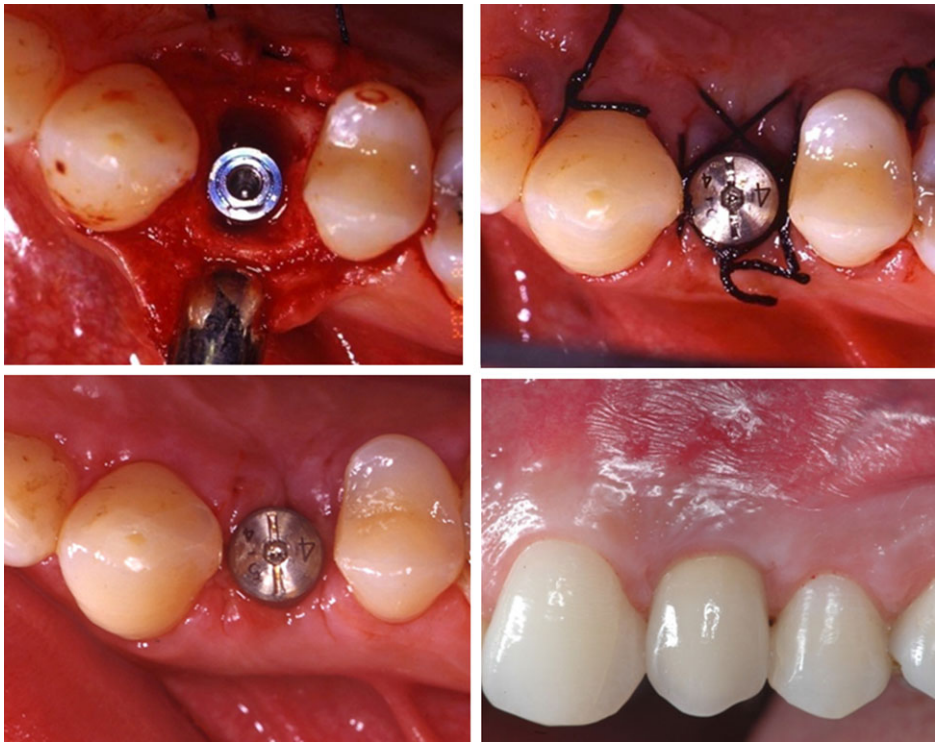

Fig. 2. Visual description of a case from surgery to the final restoration.

application of 10 to 20 Ncm (Sbordone et al. 2009a) were considered suitable for prosthetic restoration (Sbordone et al. 2009b).

At the 4 months post-implant insertion time, a temporary acrylic restoration was applied for the following 8 weeks. After that time, impressions were taken to prepare a metal ceramic crown for final restoration that was cemented over a custom metal abutment, simultaneously fabricated.

The following intraoperative osseous clinical parameters were registered at the time of surgery:

- Maximal and minimal vertical distance between the crestal bone margin and the bottom of the socket (Maximal and Minimal Post-Extractive Socket Vertical Measurement; M-MPESVM)
- Horizontal, mesial-distal and buccal-palatal, Post-Extractive Socket Diameters (HPESD)
- Bone Margin Level (BML): Axial distance from the crestal bone margin to the implant platform measured at six points around the implant (values may be negative when the implant platform is more apically positioned with respect to the bone margin)
- Horizontal distance between the palatal marginal bone (inner aspect) and the margin of implant platform (Palatal peri-implant gap)
- Maximum horizontal distance between the mesial and distal crestal bone margin (inner aspect) and the margin of implant platform (Max peri-implant gap)

The following soft tissue parameters were recorded:

- Mucosal Margin Height (MMH): Axial distance from the marginal mucosa to the implant platform measured at six points around the implants at time 0 and 4 months postoperatively (T0, T4), which may show negative values when the implant platform is more apical than the mucosal margin
- Vertical Mucosal Level (VML): Axial distance, buccally measured, between the central marginal mucosa and the custom-made stent (metal wire reference point) (Fig. 1) at 4, 12, and 24 months postoperatively (T4, T12, T24).
- Horizontal Mucosal Level (HML): buccally measured distance (on the transverse plane) between the central marginal mucosa and the custom-made stent through the drilled reference hole (Fig. 1) at all time points, from T0 to T24.

Clinical measurements were taken with a UNC periodontal probe (CP 15 UNC; Hu Friedy® Chicago, IL, USA) rounded to the next mm and reported in the text and Tables as single values, medians and means (*M*) and standard deviations (±SD).

A schematic drawing of the clinical measurements taken and of the landmarks is reported in Fig. 3.

Statistical analysis

For a more conservative analysis, a Wilcoxon signed-rank test for paired data was employed for the comparison of MMH between T0 and T4; the level of statistical significance was set at <0.05; the "Statistics Toolbox, MatLab 7.8" (The MathWorks, Natick, MA, USA) was used for the calculations.

A longitudinal analysis according to Brunner & Langer (2000) was run for longitudinal measurements (VML and HML) (Table 5, Figs 4 and 5). When the null hypothesis (or no time effect) was rejected a paired comparison as per Brunner & Langer (2000) and Lazić et al. (2014) was used, with the Bonferroni correction for multiple comparisons; the nparLD package (Noguchi et al. 2012) of the R language was used to run this last analysis.

Results

The age (years) and gender of the 21 patients included in the study are reported in Table 1; 13 patients were male and eight female with an overall average age of 39 years (30 ÷ 53). Of these patients, 13 were non-smokers

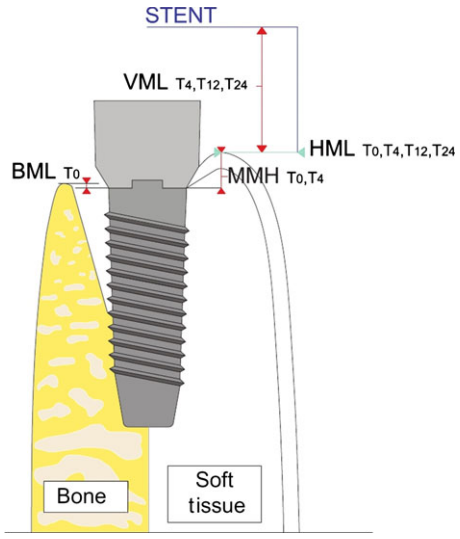

Fig. 3. Schematic drawing of the clinical measurements taken and of the landmarks.

while the remaining ones were smokers (Table 1).

The 21 implants inserted, one per patient, ranged from 11.5 to 15 mm in length and from 4 to 5 mm in diameter (Table 2) and were positioned in the post-extractive socket of the right and left first and second maxillary bicuspid (Table 2). Of the 21 extracted premolars, 13 were single-rooted and seven double-rooted (Table 3). Periodontal biotypes, registered before the extraction, were almost equally distributed in three main groups: thin-scalloped (6), flat-thick (6), and intermediate (9) exhibiting a slight prevalence in the last group (Table 3).

The level of periodontal health at the time of surgery was satisfactory as measured by the Plaque Index (0; median) and the Gingival Index (0.75; median) and was maintained satisfactorily throughout the study.

Case # 20, a female, smoking patient, showed clinical signs of implant failure represented by tissue inflammation and mobility 3 weeks after insertion. Therefore, the implant was removed and the patient withdrawn from the study. The remaining 20 implants met and maintained, for the entire observation period, the success criteria of Albrektsson et al. (1986), accounting for a Cumulative Survival Rate, at 2 years, of 95.24% (95% CI: 86.13–100%).

The mean values of intraoperative osseous clinical parameters of post-extractive sockets from the 20 successful cases were Maximal Post-Extractive Socket Vertical Measurement 10.1 ± 1.26 (mm ± SD); Mesio-Distal Diameter 5.95 ± 0.97 (mm ± SD), and Buccal-Palatal Diameter 8.5 ± 0.92 (mm ± SD). The mean peri-implant gap for the 20 successful cases was 2.1 ± 1.04 (mm ± SD) on the palatal site, while the mean of the largest gaps, that is the maximum chosen between mesial or distal gap in each single site, was 0.65 ± 0.48 (mm ± SD) (Table 3).

Implants were positioned at least 2 mm away from the buccal plate so the buccal gap had, as a minimum, that linear dimension.

The average distance on the axial plane between the bone margin (BML), the mucosal margin (MMH) and the implant platform, measured on six points and calculated on the 20 successful implants, were intraoperatively, at T0, respectively, −0.57 ± 0.87 (*M* ± SD) and −0.67(median) for BML and −2.57 ± 0.56 (*M* ± SD) and −2.67(median) for MMH. The last parameter (MMH) registered a value of −2.26 ± 0.65 (*M* ± SD) and −2.33(median) at 4 months postoperatively, with a statistically significant difference with the baseline when compared (Table 4).

The Vertical Mucosal Level (VML), buccally measured, was 3.65 ± 0.73 (*M* ± SD) and 4 (median) at T4; 3.75 ± 0.54 (*M* ± SD) and 4 (median) at T12; 3.9 ± 0.30 (*M* ± SD) and 4 (median) at T24, with the last two sets of measurements taken after prosthetic crown cementation. For the VML measurement, the null hypothesis, or no time effect, was not rejected (Table 5).

Horizontal Mucosal Level measurements on the transverse plane (HML) showed an average value of 0.9 ± 0.54 (*M* ± SD) and 1 (median) at T0, of 1.1 ± 0.89 (*M* ± SD) and 1 (median) at T4, of 1.5 ± 0.92 (*M* ± SD) and 2 (median) at T12 and of 1.7 ± 0.95 (*M* ± SD) and 2 (median) 24 months after surgery with a statistically significant difference, corrected as per Bonferroni, between T0 and T12, between T0 and T24, between T4 and T12, and between T4 and T24. Comparisons between baseline and 4 months postoperatively and between T12 and T24 registered no statistically significant difference.

Table 5 summarizes all the mucosal measurements from the customized stent.

In Figs 4 and 5 estimates of the relative treatment effect (RTE), along with 95% confidence intervals, for the variables VML and HML are displayed. The obtained result of 0.63 after 24 months (T24) for the variable HML, for example, can be interpreted as follows: a randomly chosen observation from the whole dataset results in a smaller value than a randomly chosen observation from the group at time T24 with an estimated probability of 63%.

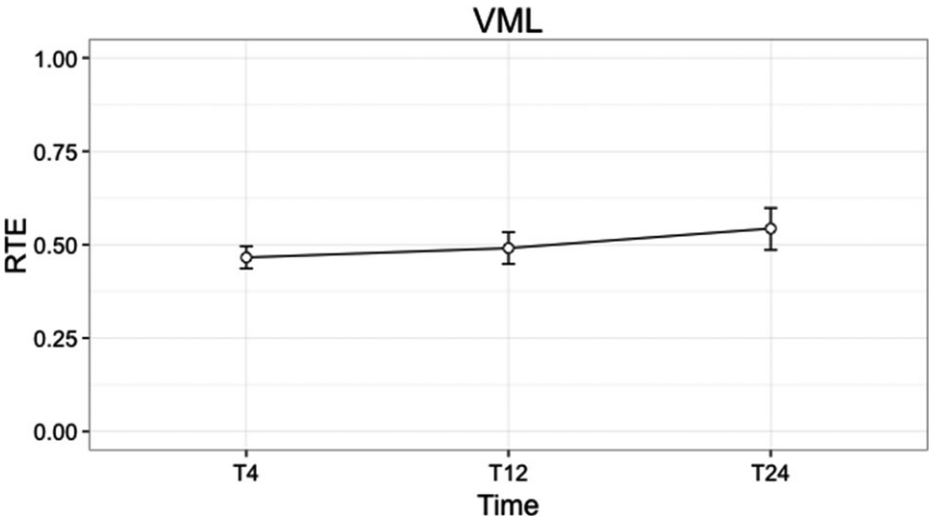

Fig. 4. Estimates of the relative treatment effect (RTE) at various time points (T0, T4, T12, T24), along with 95% confidence intervals, for the variable VML.

Discussion

The present study was conducted to monitor, over a 2-year span, the dimensional changes of marginal masticatory mucosa around immediate post-extractive implants positioned with a non-submerged healing screw.

Immediate post-extractive implant insertion is a currently established surgical procedure showing an implant Cumulative Survival Rate (CSR), with or without the application of regenerative techniques, of 98.5% (97.3–99%), as reported in a recent severely stringent review paper by Lang et al. (2012). It is similar to that which resulted after following the delayed protocol reported as a 5-year survival rate of 96% (CI: 93–98%) (Eckert et al. 2005) and is higher than the

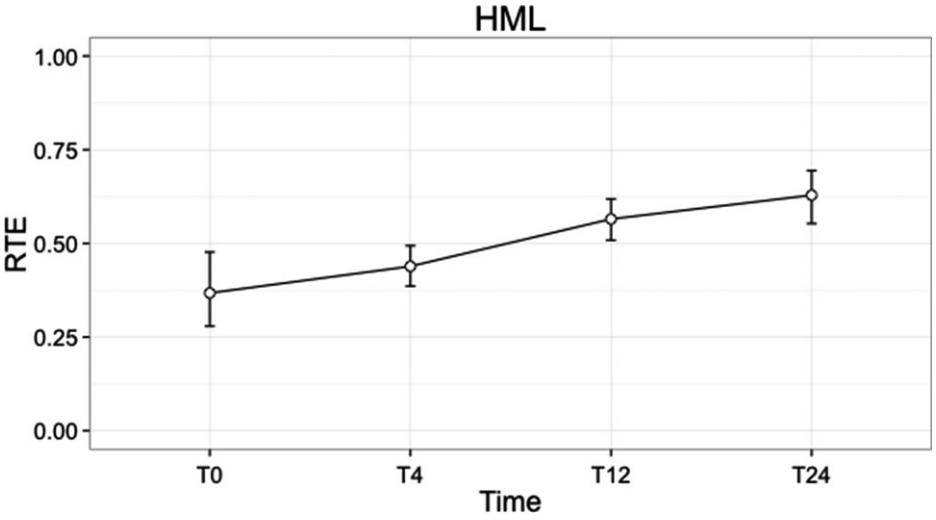

Fig. 5. Estimates of the relative treatment effect (RTE) at various time points (T0, T4, T12, T24), along with 95% confidence intervals, for the variable HML.

Table 1. **Age (in years), sex distribution, and smoking habits of patients at the time of surgery (mean *M* ± SD and max–min value)**

	All	Female	Male
No. pts	21	8	13
Age *M* ± SD	39.38 (±6.36)	40.25 (±6.08)	38.85 (±6.48)
Age max–min value	30 ÷ 53	33 ÷ 50	30 ÷ 53
Smokers	8	3	5
Non-smokers	13	5	8

Table 2. **Implant distribution in relation to anatomical position, length, and diameter and in relation to alveolar sites (*n* = 21 in 21 patients)**

	Length	11.5 mm	13 mm	15 mm	Total
Diameter (∅)					
4 mm		5	9	2	16
5 mm		2	3	Ø	5
Total		7	12	2	21
Tooth #	14	15	24	25	
No. of implants	5	5	8	3	

5-year CSR of 93.3% described for implants in autogenous bone graft in sinuses (Sbordone et al. 2013, 2014). In the present study, the CSR of 95.24% (95% CI: 86.13–100%), calculated at 2 years, appears to confirm such data.

Given this survival rate, the procedure offers different multiple advantages from a biological as well as a clinical viewpoint, such as a definite reduction in treatment time and the number of procedures and also aesthetic advantages as implant insertion can be made according to the existing periodontal contour (Lazzara 1989; Schwartz-Arad & Chaushu 1997; Lang et al. 2012; Tan et al. 2012). All these advantages were exploited in this study with the application of the "Type 1 protocol" of the 2004 Consensus Conference (Hammerle et al. 2004) and the insertion, at the same time, of a non-submerged healing screw of appropriate dimension. This allowed close adaption of the soft tissues to the implant emergence profile and a resultant stable healing in time. Consequently, total treatment time, the number of operations and patient stress were all reduced in addition to maintaining the mucosal contour. The disadvantage reported in the above-mentioned protocol regarding the issue that thin tissue biotype would be a risk for complete success cannot be properly evaluated in this study, as all the biotypes were almost equally represented in the observed sample. However, it is not possible to exclude that the thin biotype might represent a relevant factor in the outcome of the procedure, but in the present study the number of samples does not allow enough statistical power to prove this assumption.

In the healing process of a post-extractive socket, bone resorption proceeds in both directions, corono-apical, and buccal-lingual, and was calculated, as reported in the literature in the dog, as approximately 2.2 ± 0.2 mm for the former direction and as 1.9 ± 0.9 mm (around 56%) in the buccal side for the latter. Such a remodeling of the osseous profile, attributed to the resorption of the "bundle bone" internal to the socket, may cause an alteration of the soft tissue contour (Araujo & Lindhe 2005). In a review paper, Tan et al. (2012) reported a vertical variation between a bone resorption of 0.9 mm and an apposition of 0.1 mm at 6 months after extraction with an increased apposition at 12 months; horizontal decrease of combined hard and soft tissue was registered up to 5.1 mm in 6 months, thus demonstrating prominence on this plane. It would seem that the insertion of bovine bone mineral positively hampers bone resorption (Sbordone et al. 2011) particularly when employed in the immediate peri-implant gap, as it may augment the gap filling with hard tissue and supply extra volume of such tissue over the rim of the original socket (Araujo & Lindhe 2009; Araujo et al. 2011). Immediate post-extractive implant insertion alone does not seem to contain the bone remodeling phenomenon (Araujo & Lindhe 2005; Araujo et al. 2006; Evans & Chen 2008).

In the present study, the peri-implant gap resulting after the immediate post-extractive implant placement and due to the obvious discrepancy between the implant round section and the variable socket cross section, was always filled, internally to the socket, with bovine bone mineral and fully covered by the soft tissue with no interposition of membrane barriers. This was because this latter technique does not appear to improve the results but may interfere with the soft tissue healing process (Tan et al. 2012). The 2 mm gap from the buccal plate, surgically searched to allow for the circumferential osseous resorption resulting at the end of osseointegration time (Spray et al. 2000), was treated similarly.

A direct monitoring of osseous resorption was beyond the methods adopted in this study, but it was assumed that the measurements of the changes in the mucosal profile might also give reliable information. However, the data should be carefully considered because the vertical decrease of hard tissue may be compensated for, as reported by Tan et al. (2012), and therefore be masked in the clinical evaluation by the increase in soft tissue thickness. When comparing the

Table 3. **Alveolar site, periodontal biotype, extracted tooth root number, post-extractive socket dimension, residual peri-implant gap at the baseline (n = 21 in 21 patients). Mean and standard deviation (mm $M \pm$ SD) of post-extractive socket dimension, residual peri-implant gap at the baseline in 20 successful cases**

Implant case/ Patient #	Tooth #	Biotype S: thin-scalloped F: flat-thick I: intermediate	Extracted Root S: Single-rooted D: Double-rooted	Maximal Post-Extractive Socket Vertical Measurement (MPESVM) (mm)	Horizontal, mesial-distal Post-Extractive Socket Diameter (HPESD)	Horizontal, buccal-palatal Post-Extractive Socket Diameter (HPESD)	Implant dimension	Max peri-implant gap (mesial or distal) (mm)	Palatal peri-implant gap (mm)
1	24	S	D	8	5	8	4 × 13	0	0
2	24	F	S	9	6	6	4 × 11.5	1	1
3	25	S	S	10	7	9	5 × 11.5	1	2
4	14	I	S	10	6	9	4 × 11.5	1	2
5	14	I	S	10	6	9	4 × 13	1	3
6	14	I	S	12	5	8	4 × 13	0	3
7	25	S	S	9	4	8	4 × 13	0	2
8	24	F	S	13	7	8	4 × 15	1	2
9	24	S	D	10	5	9	4 × 13	0	4
10	15	F	S	11	4	10	5 × 13	0	3
11	24	I	D	10	6	8	4 × 13	1	3
12	24	I	D	10	5	8	4 × 13	0	0
13	25	I	S	11	7	8	5 × 13	1	2
14	15	I	S	10	6	10	5 × 11.5	0	3
15	14	S	D	8	6	8	4 × 11.5	1	1
16	15	F	S	10	7	9	4 × 11.5	1	3
17	24	F	D	9	7	9	4 × 13	1	2
18	14	F	S	9	6	8	4 × 13	1	2
19	15	S	S	12	7	8	4 × 15	1	1
20 (failed)	24	I	D	11	8	9	4 × 11.5	2	3
21	15	I	S	11	7	10	5 × 13	1	3
$M \pm$ SD				10.1 ± 1.26 Mean of 20 successful cases	5.95 ± 0.97 Mean of 20 successful cases	8.5 ± 0.92 Mean of 20 successful cases		0.65 ± 0.48 Mean of 20 successful cases	2.1 ± 1.04 Mean of 20 successful cases

Table 4. **Bone margin level (BML) and mucosal margin height (MMH) measured at six points around the implant from the Implant platform (mm $M \pm$ SD; median; n = 20)**

Time	BML $M \pm$ SD	BML Median	MMH $M \pm$ SD	MMH Median
T0	−0.57 ± 0.87	−0.67	−2.57 ± 0.56	−2.67
T4			−2.26 ± 0.64	−2.33

At the Wilcoxon signed-rank test the result is significant at $P < 0.05$ for MMH T0 vs. T4 ($P = 0.0082$; 95% CI: −0.500 to −0.085).

Table 5. **Vertical and horizontal parameter dimensional changes at different time points (mm $M \pm$ SD; median; n = 20)**

Time	VML $M \pm$ SD	VML Median	HML $M \pm$ SD	HML Median
T0			0.9 ± 0.54	1
T4	3.65 ± 0.73	4	1.1 ± 0.89	1
T12	3.75 ± 0.54	4	1.5 ± 0.92	2
T24	3.9 ± 0.30	4	1.7 ± 0.95	2

HML	T0 vs. T4	T0 vs. T12	T0 vs. T24	T4 vs. T12	T4 vs. T24	T12 vs. T24
P	1.0000	0.0214	0.0003	0.0171	0.0003	0.1758
Bonferroni correction	ns	s	s	s	s	ns

At the ANOVA type statistics (Brunner & Langer 2000), with the Bonferroni correction for multiple comparisons, the results are significant at $P < 0.05$ for HML: T0 vs. T12; T0 vs. T24; T4 vs. T12; T4 vs. T24.
At the ANOVA type statistics (Brunner & Langer 2000), with the Bonferroni correction for multiple comparisons, the results are NOT significant at $P < 0.05$ for HML: T0 vs. T4; T12 vs. T24.
VML did not show any time effect ($P \cong 0.14$).

vertical measurements, averaged on the six points evaluated around the implants: bone marginal level (BML) at T0 and MMH at T0 and T4, it is possible to argue that about 2 mm of the soft tissue surgical coronal positioning, over the bone margin at the time of surgery, was maintained in the following 4 months with only a slight (0.3 mm), statistically significant, shrinkage.

Observing the single point buccal vertical recordings from the custom-made stent (VML), it is possible to speculate that the soft tissue remains at the same level for 20 months, from T4 to T24, since the measurements, when longitudinally analyzed, showed a non-statistical significant difference in time (Table 5, Fig. 4). This may suggest complete healing in the first 4 months with no further rearrangement, when we also consider that the last two sets of measurements, at 12 and 24 months postoperatively, were taken after final prosthetic crown restoration. Horizontal measurements, on the transverse plane, of the buccal mucosal profile showed an average value of HML of 0.9 ± 0.54 ($M \pm$ SD) and 1 (median) at time 0 and of 1.7 ± 0.95 ($M \pm$ SD) and 2 (median) 24 months after surgery with a statistically

significant difference between those two time points, corrected as per Bonferroni. It is assumed that the soft tissue maturation, in the horizontal dimension, happened slowly between T0 and T24 with a sudden shrinkage between 4 and 12 months postoperatively (Table 5, Fig. 5).

An over debated topic about immediate post-extractive implants has been the need for soft tissue closure over the inserted implant. In the present study, submerged implants with a non-submerged healing screw were inserted in a transmucosal fashion to achieve close adaptation of the soft tissues to the implant profile in order to protect the blood clot and to enhance early tissue conditioning around the implant emergence profile. Such a type of approach seems to favor satisfactory tissue adaptation, particularly when considering the wide range of healing screws available when compared to the limited opportunities offered by non-submerged implants in terms of emerging profiles. Therefore, the appropriate choice of healing screw may enhance aesthetics and stabilize marginal soft tissue healing.

Conclusions

Immediate post-extractive implants inserted with peri-implant filling of bovine bone mineral and a contemporary non-submerged healing screw might have favored early and stable peri-implant soft tissue healing over the 2-year observation period. Although the results obtained in the reduced but homogeneous number of cases of the current study are promising, they would certainly require confirmation by a larger trial.

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