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## A prospective, randomized, controlled study using OsseoSpeed™ implants placed in maxillary fresh extraction socket: soft tissues response

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**Key words:** gingival zenith, immediate implant placement, Papilla Index

### Abstract

**Purpose:** The aim of this work was to study the peri-implant soft tissues response, by evaluating both the recession and the papilla indexes, of patients treated with implants with two different configurations. In addition, data were stratified by tooth category, smoking habit and thickness of buccal bone wall.

**Materials and methods:** The clinical trial was designed as a prospective, randomized-controlled multicenter study. Adults in need of one or more implants replacing teeth to be removed in the maxilla within the region 15–25 were recruited. Following tooth extraction, the site was randomly allocated to receive either a cylindrical or conical/cylindrical implant. The following parameters were studied: (i) Soft tissue recession (REC) measured by comparing the gingival zenith (GZ) score at baseline (permanent restoration) with that of the yearly follow-up visits over a period of 3 years (V1, V2 and V3). (ii) Interdental Papilla Index (PI): PI measurements were performed at baseline and compared with that of the follow-up visits. In addition, data were stratified by different variables: tooth category: anterior (incisors and canine) and posterior (first and second premolar); smoking habit: patient smoker (habitual or occasional smoker at inclusion) or non-smoker (non-smoker or ex-smoker at inclusion) and thickness of buccal bone wall (TB):  $TB \leq 1$  mm (thin buccal wall) or  $TB > 1$  mm (thick buccal wall).

**Results:** A total of 93 patients were treated with 93 implants. At the surgical re-entry one implant was mobile and then removed; moreover, one patient was lost to follow-up. Ninety-one patients were restored with 91 implant-supported permanent single crowns. After the 3-year follow-up, a mean gain of 0.23 mm of GZ was measured; moreover, 79% and 72% of mesial and distal papillae were classified as >50%/ complete, respectively. From the stratification analysis, not significant differences were found between the mean GZ scores of implants with  $TB \leq 1$  mm (thin buccal wall) and  $TB > 1$  mm (thick buccal wall), respectively ( $P < 0.05$ , Mann–Whitney *U*-test) at baseline, at V1, V2 and V3 follow-up visits. Also, the other variables did not seem to influence GZ changes over the follow-up period. Moreover, a re-growth of the interproximal mesial and distal papillae was the general trend observed independently from the variables studied.

**Conclusions:** Immediate single implant treatment may be considered a predictable option regarding soft tissue stability over a period of 3 years of follow-up. An overall buccal soft tissue stability was observed during the GZ changes from the baseline to the 3 years of follow-up with a mean GZ reduction of 0.23 mm. A nearly full papillary re-growth can be detectable over a minimum period of 2 years of follow-up for both cylindrical and conical/cylindrical implants. Both the interproximal papilla filling and the midfacial mucosa stability were not influenced by variables such as type of fixture configuration, tooth category, smoke habit, and thickness of buccal bone wall of  $\leq 1$  mm (thin buccal wall).

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In spite of the fact that the changes occurring in the alveolar ridge after tooth extraction cannot be preserved by placing dental implants in fresh extraction sockets (Botticelli et al. 2004; Araujo & Lindhe 2005; Sanz et al. 2010), the immediate implant place-

ment remains an extensively used therapeutic protocol for the replacement of missing teeth. Among the clear advantages that may justify this treatment option are the reduced treatment times and surgical interventions, although aesthetic risks have been reported

by some authors (Ryser et al. 2005; Chen et al. 2007; Evans & Chen 2008), although conversely other studies have reported optimal aesthetic outcomes (Garber et al. 2001; Kan et al. 2003, 2011). This discrepancy lies in the occurrence of recession of the peri-implant mucosa when this treatment option is carried out in the anterior maxilla. While some authors report a one-year mean gingival recession between 0.5 and 1.5 mm (Chen et al. 2007; Evans & Chen 2008), others have reported minimal changes in the position of the gingival margin (Cooper et al. 2010; Kan et al. 2011). These controversial results have been explained by differences in the three-dimensional implant positioning, in the patient's mucosal biotype and whether an immediate provisional restoration is placed at implant placement (Kan et al. 2011; Cosyn et al. 2012). Most of these studies are, however, short-term, reporting one-year outcomes with few studies with follow-ups longer than 3 years (Kan et al. 2011; Cosyn et al. 2012).

Other important factor in the aesthetic outcome of implant supported restorations is the presence or absence of interdental papilla. Factors such as the implant to tooth distance and the distance between the bone and the contact point have been reported as predictors of papilla fill. In fact, when the horizontal distance between the implant and the adjacent tooth of  $\geq 1.5$  mm and a vertical distance between the bone peak and the contact point is  $\leq 5$  mm the probability of complete papilla fill is very high (Ryser et al. 2005; Lops et al. 2008, 2013; Kwon et al. 2009; Chow & Wang 2010; Nisapakultorn et al. 2010; Cosyn et al. 2011, 2012 and Koh et al. 2011; Vela et al. 2012). There are other implant and patient-related factors, such as the implant macro-design or the position in the arch, or whether the patient smokes that influence on the interdental papilla is not well understood.

It is, therefore, the aim of this clinical trial to study the 3-year aesthetic outcomes of immediately placed implants in the maxilla, by reporting the peri-implant soft tissue changes and secondarily to assess the factors that may intervene in these outcomes.

## Materials and methods

### Study design

The study was designed as a prospective, randomized-controlled parallel-group multicenter study evaluating the response of two implants with different configurations immediately placed after tooth extraction in the

maxilla. The details on the experimental design and patient selection criteria have been detailed in two preceding publications reporting the short-term outcomes (Sanz et al. 2010) and the 3-year clinical outcomes (Sanz et al. 2013). In brief, healthy adult patients scheduled for a single tooth extraction in the anterior maxilla (between 15 and 25) were selected in three clinical centres, Department of Periodontology and fixed Prosthodontics, University of Berne, Switzerland, Department of Periodontology, Universidad de Complutense, Madrid, Spain and Institute Franci, Padova, Italy. The study protocol as well as the informed consent forms were approved by the local ethics review boards. This clinical trial was registered at (ClinicalTrials.gov.: <http://clinicaltrials.gov/show/NCT00711282>).

### Treatments

Before implant placement, the selected tooth was carefully extracted and provided the extraction socket met the inclusion criteria (Sanz et al. 2010), the site was allocated to either treatment group A (cylindrical; 3.5 or 4.0 mm) or B (conical/cylindrical; 4.5 or 5.0 mm) by an independent randomization schedule generated for each centre in blocks and designed to ensure a balanced distribution of treatments. In each centre, the randomized treatment code was available in closed non-transparent envelopes (Fig. 2).

Each patient received an endosseous dental implant (Osseospeed, DENTSPLY Implants, Mölndal, Sweden) in accordance with the guidelines described by the manufacturer without additional soft- or hard-tissue grafting. Healing abutments were then installed (Healing Abutment Zebra, DENTSPLY Implants, Mölndal, Sweden), and the soft tissues were adapted and sutured to allow semi-submerged healing. After 16 weeks, the surgical re-entry was performed, the healing abutment was removed and a full-thickness flap was elevated. Implant stability was examined, and the detailed anatomy of the alveolar crest surrounding the implant was studied as described by Sanz et al. (2010).

Prosthetic restorations were delivered at 22 weeks after implant placement, where peri-apical radiographs were taken to record baseline interproximal bone levels (PR visit). Each patient was placed in a 3-year follow-up programme, including examinations at 12 (V1), 24 (V2) and 36 (V3) months, respectively, including various soft tissue and bone-level parameters. The radiographic and clinical outcomes of this clinical trial at 3 years have been reported in a separate pub-

lication (Sanz et al. 2013). This manuscript reports the long-term soft tissue changes and aesthetic outcomes, as well as the critical factors intervening in these changes.

### Measurements and outcome variables

In both groups of implants, the following parameters were evaluated and recorded (Fig. 1):

- Soft tissue recession (REC) by comparing the gingival zenith (GZ) score at baseline with that of the follow-up visits. This GZ score measures by means of a periodontal probe (Hu-Friedy Diagnostic Probe UNC, UNC15 Qulix, Hu-Friedy Mfg. Co Inc., Chicago, IL, USA) to the nearest millimetre, the distance between the soft tissue margin to the crown incisal edge.
- Interdental soft tissue by comparing the Papilla Index (PI) at baseline with that of the follow-up visits. This PI defined by Jemt (1997) scores from 0 to 4 depending on the degree of papilla filling the embrasure (absent, <50%, >50%, complete and overgrowth, respectively).

These parameters were then evaluated after stratification:

- Tooth category (anterior, including incisors and canines vs. posterior, including first and second premolars).
- Patient's smoking habits
- Thickness of buccal bone wall (TB) at implant placement: TB  $\leq 1$  mm (thin) or TB > 1 mm (thick).

### Statistical analysis

A power calculation was carried out to determine the sample size. This was described in detail in the first publication from this clinical trial (Sanz et al. 2010). Continuous variables were described by the number of observations ( $n$ ), minimum (min), median, maximum (max), mean, and standard deviation (SD) values and discrete variables by frequencies and percentages. Within-group and between-group comparisons were calculated using non-parametric statistics (Mann-Whitney  $U$ -test and Wilcoxon signed-rank test, respectively, using SPSS version 18.0.0; IBM Corporation, Armonk, NY, USA). A two-sided  $P$ -value of  $P < 0.05$  was considered as being statistically significant.

## Results

### Patient population

A total of 93 patients (48 men and 45 women, mean age of 51 years with a SD of 13 and range of 19–80 years) were treated

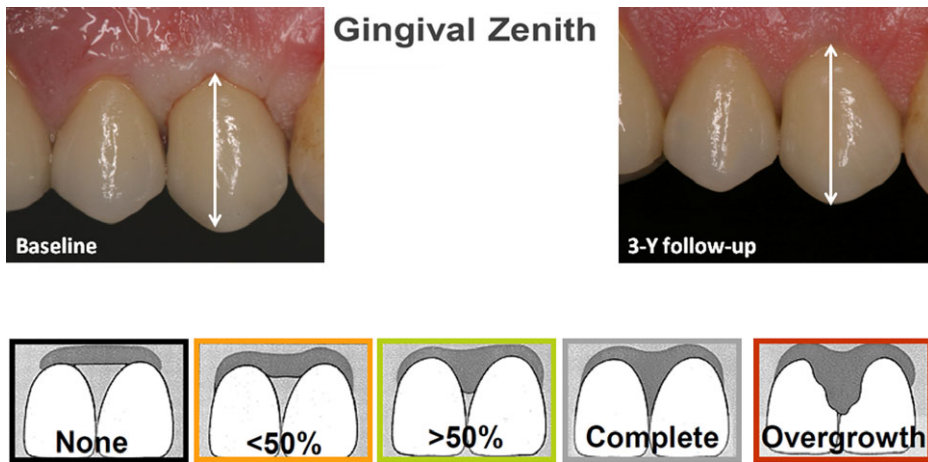


Fig. 1. Clinical parameters investigated over the follow-up period: soft tissue recession measured by means of Gingival Zenith (GZ) scores; interdental soft tissue measured by means of Papilla Index (PI) scores.

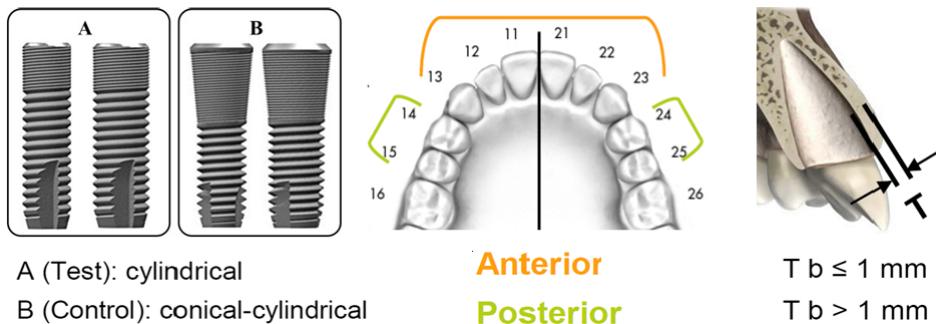


Fig. 2. Variables submitted to GZ and PI stratification: Fixture geometry (Cylindrical vs. Conical-Cylindrical); Anterior vs. Posterior; Thickness of buccal bone wall (TB) ≤ 1 mm vs. > 1 mm.

Table 1. Implant features

| Diameter (mm)                     | n  | Group               | Length (mm) | n (%) | %  |
|-----------------------------------|----|---------------------|-------------|-------|----|
| 3.5                               | 1  | Cylindrical         | 8           | 0 (0) | 0  |
| 4.0                               | 44 | Cylindrical         | 9           | 3     | 3  |
| 4.5                               | 42 | Conical/Cylindrical | 11          | 19    | 20 |
| 5.0                               | 6  | Conical/Cylindrical | 13          | 42    | 45 |
| Cylindrical = 45 implants         |    |                     | 15          | 21    | 23 |
| Conical/Cylindrical = 48 implants |    |                     | At least 17 | 8     | 9  |

with 93 implants (Table 1). Fifty-nine patients were classified as ‘non-smoker’, and 34 were classified as ‘smoker’.

The teeth extracted were central incisors (10), lateral incisors (19), canines (10) and premolars (54); the reason for the tooth extraction was: caries/endodontic (63), periodontitis (16); trauma (10) and other (4).

At the surgical re-entry, one implant was mobile and then removed; moreover, one patient was lost to follow-up. Both the implants were placed in anterior area. Ninety-one patients were restored with 91 implant-supported permanent single crowns. The restorations were as follows: metal ceramic (73) and all ceramic (18). Fourteen zirconia, 72 tita-

nium and two gold and three unknown abutments were used to support the prostheses.

Two patients were lost to before the baseline measurements. Seven patients were lost to follow-up during the 3 years of observation and were classified as ‘drop-out implants’.

**Gingival Zenith (GZ) changes**

GZ changes from the baseline to the 3-year follow-up visit (V3) are reported in the Table (2); after 3 years of observation, a mean GZ reduction of 0.23 mm was observed. The difference between the baseline and the V3 mean values was not statistically significant ( $P > 0.05$ , Wilcoxon signed-rank test). Moreover, for 80% of the implant-supported resto-

rations (65 of 81), no soft tissue recession was observed between baseline and V3.

GZ index by treatment group (cylindrical vs. conical/cylindrical conical fixture configuration) GZ changes from the baseline to the 3-year follow-up visit (V3) are reported in the Table (3). No significant differences were found between the two groups of implants ( $P > 0.05$ , Mann–Whitney *U*-test), regarding mean GZ scores and GZ changes from the baseline. No soft tissue recession was observed between baseline and V3 for 72% and 89% of restorations supported by cylindrical and conical/cylindrical implants, respectively.

GZ index by tooth category (anterior vs. posterior) GZ changes from the baseline to the 3-year follow-up visit (V3) are reported in the Table (4). Significant differences were found between the mean GZ scores of the two groups both ( $P < 0.05$ , Mann–Whitney *U*-test) at baseline and at V1, V2 and V3 follow-up visits. No significant differences in GZ changes from the baseline were found between the anterior and the posterior group of implants ( $P > 0.05$ , Mann–Whitney *U*-test). No soft tissue recession was observed between baseline and V3 for 83% and 78% of anterior and posterior restorations, respectively.

GZ index by patient’s smoking habits (nonsmoker vs. smoker)

GZ changes from the baseline to the 3-year follow-up visit (V3) are reported in the Table (5). No significant differences were found between the two groups of implants ( $P > 0.05$ , Mann–Whitney *U*-test), regarding mean GZ scores and GZ changes from the baseline. No soft tissue recession was observed between baseline and V3 for 82% and 77% of the implant-supported restorations in non-smoker and smoker patients, respectively.

GZ index by thickness of buccal bone wall (TB)

GZ changes from the baseline to the 3-year follow-up visit (V3) are reported in the Table (6) for implants with TB ≤ 1 mm (thin buccal wall) and TB > 1 mm (thick buccal wall), respectively. Significant differences were found between the mean GZ scores of the two groups ( $P < 0.05$ , Mann–Whitney *U*-test) at baseline, at V1, V2 and V3 follow-up visits. Nevertheless, no significant differences in GZ changes from baseline were found between the two groups of implants ( $P > 0.05$ , Mann–Whitney *U*-test). No soft tissue recession was observed between

**Table 2. Gingival Zenith (GZ) and GZ changes (mm)**

| GZ          | Baseline | V1 (1y-visit) | V2 (2y-visit) | V3 (3y-visit) | Change from Baseline to V1 | Change from Baseline to V2 | Change from Baseline to V3 |
|-------------|----------|---------------|---------------|---------------|----------------------------|----------------------------|----------------------------|
| <i>n</i>    | 89       | 88            | 83            | 82            | 87                         | 82                         | 81                         |
| Mean (mm)   | 10.6     | 10.5          | 10.2*         | 10.5          | 0.15                       | 0.49                       | 0.23                       |
| SD          | 2.3      | 2.2           | 2.1           | 2.1           | 1.3                        | 1.3                        | 1.2                        |
| Median (mm) | 10       | 10            | 10            | 10            | 0                          | 0                          | 0                          |
| Min (mm)    | 6        | 7             | 6             | 7             | -4                         | -2                         | -2                         |
| Max (mm)    | 18       | 17            | 15            | 15            | 6                          | 6                          | 5                          |

GZ was measured to nearest whole mm with periodontal probe. For GZ Change from Baseline, negative values are loss, positive values are gain.  
SD, Standard Deviation.  
Baseline: time of permanent restoration installation.  
\*Significant within group difference from baseline ( $P < 0.05$ , Wilcoxon signed-rank test).

baseline and V3 for 84% and 70% of implants with thick and thin buccal walls, respectively.

**Papilla Index (PI) changes**

PI changes from baseline to the 3-year follow-up visit (V3) are reported in the Table (7). After 3 years of observation, the proportion of mesial and distal papillae classified as ‘complete’ or ‘>50%’ improved. At baseline, 30% and 31% of the mesial and distal papillae were >50% complete and at 3 years these proportions changed to 79% and 72%, respectively. Of the 54 mesial papillae categorized as No or <50% at baseline, 16 remained within these categories at the 3-year follow-up visit. Similarly, from the 54 distal papillae categorized as No or <50% at baseline, 21 remained in these categories at 3-year follow-up visit.

PI changes by treatment group (cylindrical vs. conical-cylindrical fixture configuration)

These changes are reported in the Table (8). The proportion of >50% complete papilla improved from baseline to V3 in both the cylindrical (75% for mesial and distal papillae at V3) as well as conical/cylindrical implants (84% and 69% for mesial and distal papillae at V3).

PI changes by tooth category (anterior vs. posterior) These changes are reported in the Table (9). The proportion of >50%/complete papilla improved from baseline to V3 in both anterior (81% and 71% for mesial and distal papillae at V3) and posterior implant-supported reconstructions (78% and 72% for mesial and distal papillae at V3).

PI changes by Patient’s Smoking Habits (non-smoker vs. smoker)

These changes are reported in the Table (10). Similarly to the trends observed for the other parameters previously reported, the proportion of >50%/complete papilla improved from the baseline to V3 in both non-smoker (86% and 78% for mesial and distal papillae at V3) and smoker patients (69% and 63% for mesial and distal papillae at V3).

PI by thickness of buccal bone wall (TB)

These changes are reported in the Table (11) for implants with TB ≤ 1 mm (thin buccal wall) and TB > 1 mm (thick buccal wall), respectively. The proportion of >50%/complete papilla improved from the baseline to V3 both for implants with TB ≤ 1 mm (79% and 69% for mesial and distal papillae at V3)

and with TB > 1 mm (80% for mesial and distal papillae at V3).

**Discussion**

The results from this clinical trial demonstrate that the buccal soft tissues surrounding an immediate single tooth implant restoration remained stable over 3 years of follow-up in the majority of the patients. These soft tissue outcomes were not significantly different when implants with different configuration (cylindrical vs. conical/cylindrical) were placed in fresh extraction sockets. This finding agrees with the results from a similar 3-year prospective study Cosyn et al. (2011) that reported a mean buccal recession of 0.34 mm, with only two implants (8%) demonstrating more than 1 mm recession. Similar results have been reported in other prospective studies on immediate implants (Gallucci et al. 2011; Cabello et al. 2012; Finne et al. 2012; Jung et al. 2012; Lops et al. 2013; Raes et al. 2012). In clinical trials comparing immediate vs. conventional implant treatment, the timing of implant placement did not seem to affect the stability of buccal soft tissues (Galindo-Moreno et al. 2012; Raes et al. 2012). Other studies and systematic reviews, however, have reported a mean buccal marginal recession between 0.5 and 1 mm when implants were placed immediately in fresh extraction sockets (Kan et al. 2003; Ryser et al. 2005; Chen et al. 2007; and systematic reviews, Chen & Buser 2009; Sornibroeker et al. 2009). These contradictory results may be explained by differences in the study design (prospective or retrospective), in the surgical implant placement and the method for assessing the outcome measurements (use of fixed reference point methods). In the present investigation, GZ scores were measured to the nearest millimetre with a periodontal probe (Hu-Friedy Diagnostic Probe UNC, UNC15 Qulix, Hu-Friedy Mfg.

**Table 3. Gingival Zenith (GZ) and GZ changes (mm) by fixture configuration**

| GZ       | Cylindrical |      |      |      | Conical-Cylindrical |      |      |      | Cylindrical                 |                             |                             | Conical-Cylindrical         |                             |                             |
|----------|-------------|------|------|------|---------------------|------|------|------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
|          | Base-line   | V1   | V2   | V3   | Base-line           | V1   | V2   | V3   | Change from Base-line to V1 | Change from Base-line to V2 | Change from Base-line to V3 | Change from Base-line to V1 | Change from Base-line to V2 | Change from Base-line to V3 |
| <i>n</i> | 44          | 43   | 40   | 43   | 45                  | 45   | 43   | 39   | 43                          | 40                          | 43                          | 44                          | 42                          | 38                          |
| Mean     | 10.3        | 10.3 | 10.2 | 10.3 | 10.9                | 10.6 | 10.2 | 10.6 | 0.0                         | 0.1                         | 0.0                         | 0.3                         | 0.8                         | 0.5                         |
| SD       | 2.2         | 2.2  | 2.1  | 2.1  | 2.3                 | 2.2  | 2.1  | 2.0  | 1.0                         | 0.9                         | 1.1                         | 1.6                         | 1.4                         | 1.2                         |
| Median   | 10.0        | 10.0 | 10.0 | 10.0 | 11.0                | 10.0 | 10.0 | 10.0 | 0.0                         | 0.0                         | 0.0                         | 0.0                         | 0.0                         | 0.0                         |
| Min      | 7           | 7    | 7    | 7    | 6                   | 7    | 6    | 8    | -3                          | -2                          | -2                          | -4                          | -1                          | -2                          |
| Max      | 15          | 15   | 15   | 15   | 18                  | 17   | 15   | 15   | 1                           | 2                           | 2                           | 6                           | 6                           | 5                           |

GZ was measured to nearest whole mm with periodontal probe. For GZ Change from Baseline, negative values are loss, positive values are gain. No significant between group difference ( $P < 0.05$ , Mann-Whitney U-test).



**Table 4. Gingival Zenith (GZ) and GZ changes (mm) by tooth category**

| GZ       | Anterior |       |       |       | Posterior |      |      |      | Anterior                   |                            |                            | Posterior                  |                            |                            |
|----------|----------|-------|-------|-------|-----------|------|------|------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
|          | Baseline | V1    | V2    | V3    | Baseline  | V1   | V2   | V3   | Change from Baseline to V1 | Change from Baseline to V2 | Change from Baseline to V3 | Change from Baseline to V1 | Change from Baseline to V2 | Change from Baseline to V3 |
| <i>n</i> | 35       | 34    | 31    | 31    | 54        | 54   | 52   | 51   | 33                         | 30                         | 30                         | 54                         | 52                         | 51                         |
| Mean     | 11.6*    | 11.7* | 11.4* | 11.5* | 10.0*     | 9.7* | 9.5* | 9.8* | -0.1                       | 0.3                        | 0.2                        | 0.3                        | 0.6                        | 0.3                        |
| SD       | 2.2      | 2.3   | 2.2   | 2.1   | 2.1       | 1.8  | 1.7  | 1.7  | 1.4                        | 0.8                        | 0.9                        | 1.3                        | 1.4                        | 1.3                        |
| Median   | 11.0     | 11.0  | 11.0  | 11.0  | 9.5       | 9.0  | 9.0  | 10.0 | 0.0                        | 0.0                        | 0.0                        | 0.0                        | 0.0                        | 0.0                        |
| Min      | 6        | 9     | 8     | 8     | 7         | 7    | 6    | 7    | -4                         | -2                         | -2                         | -2                         | -2                         | -2                         |
| Max      | 16       | 17    | 15    | 15    | 18        | 15   | 14   | 14   | 4                          | 2                          | 2                          | 6                          | 6                          | 5                          |

GZ was measured to nearest whole mm with periodontal probe. For GZ Change from Baseline, negative values are loss, positive values are gain.  
\*Significant between group difference ( $P < 0.05$ , Mann-Whitney *U*-test).

**Table 5. Gingival Zenith (GZ) and GZ Changes (mm) by patient's smoking habits**

| GZ       | Non-smoker |      |     |      | Smoker   |      |      |      | Non-smoker                 |                            |                            | Smoker                     |                            |                            |
|----------|------------|------|-----|------|----------|------|------|------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
|          | Baseline   | V1   | V2  | V3   | Baseline | V1   | V2   | V3   | Change from Baseline to V1 | Change from Baseline to V2 | Change from Baseline to V3 | Change from Baseline to V1 | Change from Baseline to V2 | Change from Baseline to V3 |
| <i>n</i> | 58         | 56   | 53  | 50   | 31       | 32   | 30   | 32   | 56                         | 53                         | 50                         | 31                         | 29                         | 31                         |
| Mean     | 10.4       | 10.2 | 9.9 | 10.2 | 11.0     | 10.8 | 10.6 | 10.8 | 0.18                       | 0.51                       | 0.28                       | 0.10                       | 0.45                       | 0.16                       |
| SD       | 1.9        | 2.0  | 1.9 | 1.9  | 2.8      | 2.5  | 2.3  | 2.2  | 0.96                       | 0.85                       | 0.97                       | 1.80                       | 1.78                       | 1.46                       |
| Median   | 10         | 10   | 10  | 10   | 11       | 11   | 10   | 11   | 0                          | 0                          | 0                          | 0                          | 0                          | 0                          |
| Min      | 6          | 7    | 6   | 7    | 7        | 7    | 7    | 7    | -4                         | -1                         | -2                         | -3                         | -2                         | -2                         |
| Max      | 16         | 17   | 15  | 15   | 18       | 16   | 15   | 15   | 4                          | 3                          | 2                          | 6                          | 6                          | 5                          |

GZ was measured to nearest whole mm with periodontal probe. For GZ Change from Baseline, negative values are loss, positive values are gain.  
No significant between group difference found ( $P < 0.05$ , Mann-Whitney *U*-test).

**Table 6. Gingival Zenith (GZ) and GZ changes (mm) by thickness of buccal bone wall (TB)**

| GZ       | TB ≤ 1 mm (thin buccal wall) |       |       |       | TB > 1 mm (thick buccal wall) |      |      |      | TB ≤ 1 mm                  |                            |                            | TB > 1 mm                  |                            |                            |
|----------|------------------------------|-------|-------|-------|-------------------------------|------|------|------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
|          | Baseline                     | V1    | V2    | V3    | Baseline                      | V1   | V2   | V3   | Change from Baseline to V1 | Change from Baseline to V2 | Change from Baseline to V3 | Change from Baseline to V1 | Change from Baseline to V2 | Change from Baseline to V3 |
| <i>n</i> | 63                           | 61    | 57    | 58    | 26                            | 27   | 26   | 24   | 61                         | 57                         | 58                         | 26                         | 25                         | 23                         |
| Mean     | 11.0*                        | 10.8* | 10.6* | 10.8* | 9.6*                          | 9.6* | 9.3* | 9.6* | 0.2                        | 0.6                        | 0.3                        | 0.0                        | 0.3                        | 0.0                        |
| SD       | 2.3                          | 2.2   | 2.1   | 2.1   | 1.8                           | 1.9  | 1.9  | 1.9  | 1.5                        | 1.4                        | 1.2                        | 0.6                        | 0.9                        | 1.0                        |
| Median   | 11.0                         | 10.0  | 10.0  | 11.0  | 9.0                           | 9.0  | 9.0  | 9.0  | 0.0                        | 0.0                        | 0.0                        | 0.0                        | 0.0                        | 0.0                        |
| Min      | 6                            | 7     | 7     | 7     | 7                             | 7    | 6    | 7    | -4                         | -2                         | -2                         | -1                         | -1                         | -2                         |
| Max      | 18                           | 17    | 15    | 15    | 14                            | 15   | 14   | 14   | 6                          | 6                          | 5                          | 1                          | 3                          | 1                          |

GZ was measured to nearest whole mm with periodontal probe. For GZ Change from Baseline, negative values are loss, positive values are gain.  
\*Significant between group difference ( $P < 0.05$ , Mann-Whitney *U*-test).

Co Inc.), while in other studies, computerized analysis of digitized images has been used (Kerner et al. 2007; Weinländer et al. 2009; Lops et al. 2013), in order to verify any significant difference in measurements procedures.

In the present study, soft tissue recession ( $\geq 0.5$  mm change between the placement of the final restoration and 3 years) occurred around 17% of the anterior and 22% of the posterior single tooth implant restorations, although these differences were not statistically significant. This slightly higher percentage of soft tissue recession in the anterior implant restorations correlates with the significant buccal bone crest resorption between

**Table 7. Papilla Index (PI)**

| PI Index              | Baseline |    | V1       |    | V2       |    | V3       |    |
|-----------------------|----------|----|----------|----|----------|----|----------|----|
|                       | <i>n</i> | %  | <i>n</i> | %  | <i>n</i> | %  | <i>n</i> | %  |
| <b>Papilla mesial</b> |          |    |          |    |          |    |          |    |
| No papilla            | 5        | 6  | 1        | 1  | 2        | 2  | 2        | 2  |
| <50%                  | 57       | 64 | 30       | 34 | 16       | 19 | 15       | 18 |
| >50%                  | 24       | 27 | 34       | 39 | 39       | 47 | 42       | 51 |
| Complete              | 3        | 3  | 21       | 24 | 25       | 30 | 23       | 28 |
| Overgrowth            | 0        | 0  | 2        | 2  | 1        | 1  | 0        | 0  |
| <b>Papilla distal</b> |          |    |          |    |          |    |          |    |
| No papilla            | 3        | 3  | 2        | 2  | 1        | 1  | 4        | 5  |
| <50%                  | 58       | 65 | 35       | 40 | 17       | 21 | 19       | 23 |
| >50%                  | 25       | 28 | 35       | 40 | 46       | 55 | 41       | 50 |
| Complete              | 3        | 3  | 16       | 18 | 19       | 23 | 18       | 22 |
| Overgrowth            | 0        | 0  | 0        | 0  | 0        | 0  | 0        | 0  |

Grey boxes indicate how the papilla increased at visit 3 compared to baseline.

**Table 8. Papilla Index (PI) and PI changes by fixture geometry**

|                       | Cylindrical (Test group) |    |    |    |    |    |    |    | Conical-cylindrical (Control group) |    |    |    |    |    |    |    |
|-----------------------|--------------------------|----|----|----|----|----|----|----|-------------------------------------|----|----|----|----|----|----|----|
|                       | Baseline                 |    | V1 |    | V2 |    | V3 |    | Baseline                            |    | V1 |    | V2 |    | V3 |    |
|                       | n                        | %  | n  | %  | n  | %  | n  | %  | n                                   | %  | n  | %  | n  | %  | n  | %  |
| <b>Papilla mesial</b> |                          |    |    |    |    |    |    |    |                                     |    |    |    |    |    |    |    |
| No papilla            | 2                        | 5  | 0  | 0  | 1  | 3  | 2  | 5  | 3                                   | 7  | 1  | 2  | 1  | 2  | 0  | 0  |
| <50%                  | 27                       | 61 | 14 | 33 | 6  | 15 | 9  | 21 | 30                                  | 67 | 16 | 36 | 10 | 23 | 6  | 15 |
| >50%                  | 14                       | 32 | 17 | 40 | 20 | 50 | 20 | 47 | 10                                  | 22 | 17 | 38 | 19 | 44 | 22 | 56 |
| Complete              | 1                        | 2  | 10 | 23 | 13 | 33 | 12 | 28 | 2                                   | 4  | 11 | 24 | 12 | 28 | 11 | 28 |
| Overgrowth            | 0                        | 0  | 2  | 5  | 0  | 0  | 0  | 0  | 0                                   | 0  | 0  | 0  | 1  | 2  | 0  | 0  |
| <b>Papilla distal</b> |                          |    |    |    |    |    |    |    |                                     |    |    |    |    |    |    |    |
| No papilla            | 3                        | 7  | 2  | 5  | 1  | 3  | 2  | 5  | 0                                   | 0  | 0  | 0  | 0  | 0  | 2  | 5  |
| <50%                  | 26                       | 59 | 15 | 35 | 5  | 13 | 9  | 21 | 32                                  | 71 | 20 | 44 | 12 | 28 | 10 | 26 |
| >50%                  | 14                       | 32 | 18 | 42 | 26 | 65 | 21 | 49 | 11                                  | 24 | 17 | 38 | 20 | 47 | 20 | 51 |
| Complete              | 1                        | 2  | 8  | 19 | 8  | 20 | 11 | 26 | 2                                   | 4  | 8  | 18 | 11 | 26 | 7  | 18 |
| Overgrowth            | 0                        | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0                                   | 0  | 0  | 0  | 0  | 0  | 0  | 0  |

Grey boxes indicate how the papilla increased at visit 3 compared to baseline.

**Table 9. Papilla Index (PI) and PI changes by tooth category**

|                       | Anterior |    |    |    |    |    |    |    | Posterior |    |    |    |    |    |    |    |
|-----------------------|----------|----|----|----|----|----|----|----|-----------|----|----|----|----|----|----|----|
|                       | Baseline |    | V1 |    | V2 |    | V3 |    | Baseline  |    | V1 |    | V2 |    | V3 |    |
|                       | n        | %  | n  | %  | n  | %  | n  | %  | n         | %  | n  | %  | n  | %  | n  | %  |
| <b>Papilla mesial</b> |          |    |    |    |    |    |    |    |           |    |    |    |    |    |    |    |
| No papilla            | 1        | 3  | 1  | 3  | 2  | 6  | 1  | 3  | 4         | 7  | 0  | 0  | 0  | 0  | 1  | 2  |
| <50%                  | 25       | 71 | 14 | 41 | 5  | 16 | 5  | 16 | 32        | 59 | 16 | 30 | 11 | 21 | 10 | 20 |
| >50%                  | 9        | 26 | 12 | 35 | 17 | 55 | 18 | 58 | 15        | 28 | 22 | 41 | 22 | 42 | 24 | 47 |
| Complete              | 0        | 0  | 6  | 18 | 7  | 23 | 7  | 23 | 3         | 6  | 15 | 28 | 18 | 35 | 16 | 31 |
| Overgrowth            | 0        | 0  | 1  | 3  | 0  | 0  | 0  | 0  | 0         | 0  | 1  | 2  | 1  | 2  | 0  | 0  |
| <b>Papilla distal</b> |          |    |    |    |    |    |    |    |           |    |    |    |    |    |    |    |
| No papilla            | 1        | 3  | 1  | 3  | 0  | 0  | 0  | 0  | 2         | 4  | 1  | 2  | 1  | 2  | 4  | 8  |
| <50%                  | 24       | 69 | 14 | 41 | 7  | 23 | 9  | 29 | 34        | 63 | 21 | 39 | 10 | 19 | 10 | 20 |
| >50%                  | 10       | 29 | 14 | 41 | 18 | 58 | 18 | 58 | 15        | 28 | 21 | 39 | 28 | 54 | 23 | 45 |
| Complete              | 0        | 0  | 5  | 15 | 6  | 19 | 4  | 13 | 3         | 6  | 11 | 20 | 13 | 25 | 14 | 27 |
| Overgrowth            | 0        | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0         | 0  | 0  | 0  | 0  | 0  | 0  | 0  |

Grey boxes indicate how the papilla increased at visit 3 compared to baseline.

**Table 10. Papilla Index (PI) and PI changes by patient's smoking habits**

|                       | Non-Smoker |    |    |      |    |    |    |    | Smoker   |    |    |      |    |    |    |    |
|-----------------------|------------|----|----|------|----|----|----|----|----------|----|----|------|----|----|----|----|
|                       | Baseline   |    | V1 |      | V2 |    | V3 |    | Baseline |    | V1 |      | V2 |    | V3 |    |
|                       | n          | %  | n  | %    | n  | %  | n  | %  | n        | %  | n  | %    | n  | %  | n  | %  |
| <b>Papilla mesial</b> |            |    |    |      |    |    |    |    |          |    |    |      |    |    |    |    |
| No papilla            | 2          | 3  | 1  | 2    | 1  | 2  | 1  | 2  | 3        | 10 | 0  | 0    | 1  | 3  | 1  | 3  |
| <50%                  | 45         | 78 | 19 | 34   | 9  | 17 | 6  | 12 | 12       | 39 | 11 | 34   | 7  | 23 | 9  | 28 |
| >50%                  | 10         | 17 | 23 | 41   | 29 | 55 | 29 | 58 | 14       | 45 | 11 | 34   | 10 | 33 | 13 | 41 |
| Complete              | 1          | 2  | 11 | 20   | 13 | 25 | 14 | 28 | 2        | 6  | 10 | 31   | 12 | 40 | 9  | 28 |
| Overgrowth            | 0          | 0  | 2  | 4    | 1  | 2  | 0  | 0  | 0        | 0  | 0  | 0    | 0  | 0  | 0  | 0  |
| <b>Papilla distal</b> |            |    |    |      |    |    |    |    |          |    |    |      |    |    |    |    |
| No papilla            | 1          | 2  | 0  | 0    | 0  | 0  | 3  | 6  | 2        | 6  | 2  | 6    | 1  | 3  | 1  | 3  |
| <50%                  | 41         | 71 | 23 | 41   | 11 | 21 | 8  | 16 | 17       | 55 | 12 | 37.5 | 6  | 20 | 11 | 34 |
| >50%                  | 15         | 26 | 21 | 37.5 | 29 | 55 | 28 | 56 | 10       | 32 | 14 | 44   | 17 | 57 | 13 | 41 |
| Complete              | 1          | 2  | 12 | 21   | 13 | 25 | 11 | 22 | 2        | 6  | 4  | 12.5 | 6  | 20 | 7  | 22 |
| Overgrowth            | 0          | 0  | 0  | 0    | 0  | 0  | 0  | 0  | 0        | 0  | 0  | 0    | 0  | 0  | 0  | 0  |

Grey boxes indicate how the papilla increased at visit 3 compared to baseline.

implant placement and 4 months reported by Ferrus et al. (2010) in this same population at the anterior teeth. In this investigation, 81% of the implants were placed in the posterior region (premolars) with a thickness of buccal bone of >1 mm. This fact may explain the

mean high long-term stability of the soft tissues reported in this study. When comparing implants placed in thin vs. thick buccal bone walls, the differences in the 3-year soft tissue recession were non-significant, although almost double of the implants placed in thin

buccal crests had recession when compared with those in thick buccal bone crests (30% vs. 16%, respectively). This high correlation between arch position and thickness of buccal bone crest has been reported in many studies (Huynh-Ba et al. 2010; Januário et al.

**Table 11. Papilla Index (PI) and PI changes by thickness of buccal bone wall (TB)**

|                       | TB ≤ 1 mm (thin buccal wall) |    |    |    |    |    |    |    | TB > 1 mm (thick buccal wall) |    |    |    |    |    |    |    |
|-----------------------|------------------------------|----|----|----|----|----|----|----|-------------------------------|----|----|----|----|----|----|----|
|                       | Baseline                     |    | V1 |    | V2 |    | V3 |    | Baseline                      |    | V1 |    | V2 |    | V3 |    |
|                       | n                            | %  | n  | %  | n  | %  | n  | %  | n                             | %  | n  | %  | n  | %  | n  | %  |
| <b>Papilla mesial</b> |                              |    |    |    |    |    |    |    |                               |    |    |    |    |    |    |    |
| No papilla            | 4                            | 6  | 1  | 2  | 2  | 4  | 1  | 2  | 1                             | 4  | 0  | 0  | 0  | 0  | 1  | 4  |
| <50%                  | 41                           | 65 | 23 | 38 | 10 | 18 | 11 | 19 | 16                            | 62 | 7  | 26 | 6  | 23 | 4  | 17 |
| >50%                  | 16                           | 25 | 27 | 44 | 26 | 46 | 32 | 55 | 8                             | 31 | 7  | 26 | 13 | 50 | 10 | 42 |
| Complete              | 2                            | 3  | 9  | 15 | 18 | 32 | 14 | 24 | 1                             | 4  | 12 | 44 | 7  | 27 | 9  | 38 |
| Overgrowth            | 0                            | 0  | 1  | 2  | 1  | 2  | 0  | 0  | 0                             | 0  | 1  | 4  | 0  | 0  | 0  | 0  |
| <b>Papilla distal</b> |                              |    |    |    |    |    |    |    |                               |    |    |    |    |    |    |    |
| No papilla            | 3                            | 5  | 2  | 3  | 1  | 2  | 3  | 5  | 0                             | 0  | 0  | 0  | 0  | 0  | 1  | 4  |
| <50%                  | 41                           | 65 | 27 | 44 | 14 | 25 | 15 | 26 | 17                            | 65 | 8  | 30 | 3  | 12 | 4  | 17 |
| >50%                  | 17                           | 27 | 25 | 41 | 31 | 54 | 32 | 55 | 8                             | 31 | 10 | 37 | 15 | 58 | 9  | 38 |
| Complete              | 2                            | 3  | 7  | 11 | 11 | 19 | 8  | 14 | 1                             | 4  | 9  | 33 | 8  | 31 | 10 | 42 |
| Overgrowth            | 0                            | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0                             | 0  | 0  | 0  | 0  | 0  | 0  | 0  |

Grey boxes indicate how the papilla increased at visit 3 compared to baseline.

2011) may justify the higher recession percentages reported in anterior teeth and in those with thin buccal bone crests. The obtained results, however, demonstrated minimal buccal mucosal recession even in these anterior, thin buccal bone crest sites. In similar studies, other authors have reported the gingival biotype measured before the tooth extraction was the higher predictor of the marginal soft tissue stability (Nisapakultorn et al. 2010; Kan et al. 2011) being a thin gingival biotype, a significant factor in determining the facial marginal mucosal level. In contrast, other authors such as Cabello et al. (2012) and Cosyn et al. (2012) in similar studies, were not able to demonstrate a correlation between the soft tissue changes and the periodontal biotype of the patient.

In this investigation, we did not measure the biotype as we estimated that the thickness of the buccal bone wall was a more stable parameter, because a thin biotype can be replaced by an implant-supported reconstruction with a thick marginal mucosa if the implant is positioned palatally. In fact, when we performed a multilevel multivariate analysis to assess the critical factors for the reported buccal bone crest resorption between implant placement and 4 months, the significant factor was not the tooth position or the thickness of the buccal bone, but the implant positioning (Tomasi et al. 2010). These results agree with those of Cosyn et al. (2012) that reported a significant association

(OR = 17.2) between the position of the implant shoulder and the midfacial recession or with those of Cooper et al. (2010) reporting minimal changes in the position of the marginal tissues after 1 year, at immediate implants always placed palatally.

The second outcome measurement analyzed in this study was the behaviour of the interproximal soft tissues over the 3 years of follow-up. We utilized the Papilla Index (PI) by Jemt (1997) and analysed the results according to implant configuration, implant location, patient's smoking habits and thickness of the buccal bone wall. In most of the interproximal sites, the position of the interdental papilla improved along the evaluation time with most of these sites (around 75%) demonstrating more than 50% or complete papilla fill after 3 years. This tendency towards high percentages of papilla fill with time was not influenced by the studied factors (implant configuration, implant position, smoking habit or the thickness of the buccal bone crest), what agrees with the results reported by Kan et al. (2011) that reported an increased papilla height at each trial time point between 2 and 8 years of follow-up.

Other investigators have evaluated other factors that may affect the degree of papilla fill, such as the distance between the contact point to the bone crest (CPB), the distance between an implant and the adjacent tooth (ITD) and the gingival biotype. A CPB of <5 mm has been associated with a complete

papilla fill (Choquet et al. 2001; Ryser et al. 2005; Lops et al. 2008; Romeo et al. 2008; Nisapakultorn et al. 2010). Similarly, distances between an implant and the adjacent tooth of ≤3 mm may also have an effect on the papilla fill (Gastaldo et al. 2004; Lops et al. 2008; Romeo et al. 2008; Chow & Wang 2010). The role of the gingival biotype on the presence or absence of the interproximal papilla is still unclear, probably because the prevalence of a thin biotype around implants is likely to be less than that of natural teeth; however, the association between a thin biotype and less papilla fill did not reach statistical significance for some authors (Romeo et al. 2008; Nisapakultorn et al. 2010; Kan et al. 2011).

In conclusion, the results from this investigation indicate that the surgical protocol of immediate single implants may be considered a predictable option in regards to implant survival and soft tissue stability over a period of 3 years of follow-up, because an overall soft tissue stability and minimal marginal mucosa recession was observed (mean GZ reduction of 0.23 mm). Similarly interdental soft tissues increasingly filled the interdental embrasures over time with 75% of complete or nearly complete papilla fill at 3 years. The implant configuration, the implant position, the patient's smoking habits and the buccal bone crests did not influence these highly aesthetic outcomes.

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## Supporting Information

Additional Supporting Information may be found in the online version of this article:

**Appendix S1.** CONSORT 2010 checklist of information to include when reporting a randomised trial.