Maintenance of marginal bone support and soft tissue esthetics at immediately provisionalized OsseoSpeed™ implants placed into extraction sites: 2-year results

The main objective in modern implantology is to maintain and support peri-implant osseous and soft tissue structures to combine long-term osseointegration with an aesthetic and natural peri-implant mucosa. Both the patients' demands and the doctors' treatment objectives have changed over the decades. In the beginning of oral implantology, there was predominantly a functional focus to anchor prosthetic devices for full-arch rehabilitation. Today, an increasing number of patients demands highly esthetic rehabilitations in a very short time with minimal-invasive treatment protocols for single or multiple teeth replacements.

To meet the demand of faster and less invasive treatment protocols, immediate and early loading or provisionalization has been introduced. For implants placed in healed sites, these concepts have been reported as successful treatment protocol as long as the temporary restoration was cleared from...
occlusal and functional contact (Wöhrle 1998; Ericsson et al. 2000; Cooper et al. 2001; Andersen et al. 2002).

Moreover, immediate implant placement in extraction sockets may further decrease the time frame from extraction to final restoration of the implant. Although, there is still an ongoing and sometimes passionate discussion on the long-term results of immediate implant insertion into extraction sockets (Araújo et al. 2005, 2006; Chen & Buser 2009), there is growing evidence to support the concept of marginal tissue maintenance via immediate implant insertion protocols. There have been numerous systematic studies reporting the results of immediate implant placement (Gelb 1993) and implant placement in combination with immediate provisionalization (Kan et al. 2003; Norton 2004; De Kok et al. 2006; Noellken et al. 2007; Valentinelli et al. 2010; Mertens & Steveling 2011; De Bruyn et al. 2012). These have mainly presented similar results as immediate placement and delayed loading protocols. Prospective studies have described the factors influencing the significant resorption of the buccal bone wall in horizontal dimensions following immediate implant insertion in the extraction socket with and without facial bony deficiencies when using a flap procedure and no defect grafting (Paolantonio et al. 2001; Botticelli et al. 2004; Ferrus et al. 2010; Sanz et al. 2010). To counteract the resorption of the facial bone wall, the implants in this series were placed without elevating a flap and were strictly aligned to the oral cortical lining of the extraction socket to create a facial gap for autogenous bone grafting.

The aim of the study was to evaluate the success rate, the maintenance of marginal bone support, and the soft tissue esthetics after a follow-up of at least 12 months following flapless implant insertion of 37 OsseoSpeed™ (Astra Tech AB, Mölndal, Sweden) implants into extraction sockets and immediate provisionalization in the esthetic zone of the maxilla.

Material and methods

The primary outcome parameter of this study was to evaluate the peri-implant marginal bone stability. The secondary outcome parameters of the study were overall implant success and peri-implant soft tissue esthetics.

Patients

This communication describes a subgroup of a prospective bi-center study population of 37 patients, who have received 71 OsseoSpeed™ implants from February 2008 until May 2009.

The implants were inserted in both healed and extraction sites in the esthetic zone of the maxilla and the mandible followed by immediate provisionalization. As the variety of treatment modalities in the overall study group was rather high (implants placed in both maxilla and mandible, immediate and delayed insertion, with and without connective tissue or bone graft, flap elevation and flapless procedure), a subgroup of patients treated according to a homogeneous treatment concept was defined for this analysis.

Inclusion criteria were as follows:

- Teeth in the esthetic zone of the maxilla (15-25) deemed to be extracted.
- Immediate implant insertion into extraction sockets.
- Flapless procedure.
- Grafting of jumping gap with autogenous bone chips.
- No connective tissue graft.
- Immediate provisionalization.
- Expectation of good primary stability ($\geq 15$ Ncm insertion torque).

Exclusion criteria were as follows:

- Known or suspected current malignancy.
- History of radiation therapy in the head and neck region.
- Chemotherapy within 5 years prior to surgery.
- Uncontrolled diabetes mellitus.
- Permanent immunosuppressive medication.
- Present alcohol and/or drug abuse.

Deficiencies of the facial bone wall (fistulae, dehiscences, total loss of buccal bone wall) and smoking were not regarded as exclusion criteria.

Of the total study population of 37 patients, 20 patients fulfilled the above inclusion criteria. They received a total number of 37 implants. Additional implants placed simultaneously posterior to the premolar region were not evaluated. The average age of this study population (16 women, four men) was 47.3 years (range, 22-76 years). Seventeen patients were non-smokers, one moderate smoker (6-10 cigarettes per day), and two heavy smokers (more than 15 cigarettes per day).

The indication for immediate implant insertion was a single-tooth replacement in 10 patients, a partial restoration in eight patients (16 implants), and total tooth loss in two patients (11 implants). The reason for teeth removal was an endodontic failure in six sites (16.2%), a long-axis root fracture in six sites (13.5%), and periodontitis in 11 sites (29.7%). In 14 cases, an extended and non-restorable decay of the teeth was observed (37.8%). One tooth was lost by trauma (2.7%). Mean preoperative gingival recession of the condemned teeth was 1.54 mm (range 0-6 mm; standard deviation [SD] 1.26 mm).

Ethical approval

This study was approved by the Ethics committee of the county Rheinland-Pfalz, Germany (file no. 837.063.08 (6060)) and conducted according to the recommendations of good clinical practice. The study was supported by a grant from Astra Tech AB, Sweden to the Department of Oral and Maxillofacial Surgery, University Medicine of Mainz, Germany.

Pre-treatment examination

At the time of the pre-treatment examination, subjects in need of an immediate implant restoration were screened for eligibility to the study.

A cone beam computed tomography (CB-CT) was performed to evaluate the dimensions of the facial bony lamella prior to surgery (Figs 4e and 5c). Especially, the thickness of the facial lamella was measured in relation to a defined reference point. This reference point was determined by projecting the level of the healthy oral lamella perpendicular to the longitudinal root axis to the facial aspect. The thickness of the facial lamella was measured in distances of 1, 3, and 6 mm apical to this reference level.

Eight extraction sockets showed no recession and a pristine facial bone wall, 11 sites showed a combination of a pristine soft tissue condition and defects of the facial bone walls of various dimension, 18 sites showed a combination of facial recession and bone deficiencies. The gingival morphotype at four implant sites was thin, at 26 sites normal, and at seven sites thick.

Written Informed Consent was obtained from all patients prior to any examination carried out for study purposes.

Surgical technique

The OsseoSpeed™ implants (Astra Tech AB) used in this study were screw-shaped and self-tapping implants. The diameters used were 3.5, 4.0, 4.5, and 5.0 mm with implant lengths ranging between 11 and 17 mm. The implants had a conical implant-abutment interface, and a MicroThread™ (Astra Tech AB, Mölndal, Sweden) design characterizing the marginal part of the implant.

Surgery followed the guidelines outlined in the manufacturer’s instructions, modified to
Immediate implant placement and a one-stage surgical procedure. The surgical procedure was performed under local anesthesia. Pre-surgical radiographic findings of bone quality (Lekholm & Zarb 1985) were verified and documented during surgery. Clinical photos were taken prior to and immediately after implant installation (Figs 4a and 5a).

The respective teeth wereatraumatically extracted using the periotome technique maintaining the alveolar socket walls and gingival architecture, provided these bony structures were not destroyed by local inflammatory processes. The extraction site was cleansed of granulation tissue using a chairside microscope under 15× magnification (ProDent; Zeiss, Oberkochen, Germany). All procedures were performed without raising a flap even when a facial bone defect was observed.

Final site preparation was prepared using single-use drills in the standard drilling sequence and undersized by 0.3 mm to enable implant insertion with a high torque level. At this stage, any unstable implant (below 15 Ncm) was excluded from the study protocol. The implants were placed in contact with the oral lamella of the socket. Placement depth was determined by the interproximal and facial soft tissue and bone height. Healing abutments (Healing Abutment Uni 4.5/5.0; Astra Tech AB) were used during the short time of fabrication of the temporary restoration.

In all patients, simultaneous bone grafting of the facial gap between implant surface and facial tissues was performed by condensing bone chips to the bottom of the defect with a plugger for support or reconstruction of the facial bony contour. Autogenous bone grafts were harvested at the mandibular ramus by particulating a bone block in a bone mill [R. Quetin Bone-Mill, Leimen, Germany] or by collecting bone particles by a disposable filter [BoneTrap; Astra Tech AB]. Additional soft tissue grafts were not used.

Immediate restoration

In case of a single-tooth replacement, manufactured acrylic denture teeth were adjusted to the implant site and cemented on top of titanium abutments [n = 12] (TiDesign™; Astra Tech AB) using a temporary cement (Temp Bond; Kerr Hawe SA, Bioggio, Switzerland). In multiple teeth replacements, individual temporary screw-retained restorations were fabricated by a laboratory technician using temporary abutments [n = 25]. All temporary restorations were inserted at the day of implant placement and adjusted to clear all contacts in centric occlusion and during eccentric movements as long as natural teeth were present. For further stabilization against uncontrolled loading forces, the implants were splinted to neighboring teeth or to each other using a splint made of a cross-linked glass fiber ribbon (Ribbond THM; Ribbond, Seattle, WA, USA) for 8 weeks. To avoid excessive loading of the implants during the healing period, the patients were advised to keep a soft and liquid diet for 8 weeks.

The subjects received antibiotic prophylaxis (starting the day before surgery until 7 days postoperatively; clindamycin 300 mg 3–4 times/day) and a prescription for post-surgical chlorhexidine rinse 0.2%, for 10 days.

After implant placement, the subjects returned for a follow-up visit after 7–10 days for control of the implants, the temporary restoration, and the healing process.

Final restoration

After a minimum of 3 months, an impression was made for fabrication of the definitive crown. The final zirconia crowns or bridges were cemented on top of zirconia abutments [Atlantis™ zirconia abutment or ZirDesign™; Astra Tech AB] using a temporary cement (Temp Bond; Kerr Hawe SA) or a glass ionomer cement (Ketac-Cem; 3M Espe, Seefeld, Germany).

Follow-up and definition of outcome variables

The patients were examined at the time of implant placement, at prosthetic delivery, at 1-year, and at 2-year follow-up following implant insertion (Figs 4b and 5b). The primary outcome variables were as follows:

- The status of the interproximal marginal bone level was determined using digital periapical radiographs. To ensure reproducibility between the examinations, radiographs were taken with paralleling technique using commercially available film holders [Dentsply/Rinn, Elgin, IL, USA]. Specifically, the vertical distances between the mesial and distal bone level and the level of the implant shoulder (reference level) were measured.
- Attachment levels crestal to this reference level were designated as positive values and vice versa. The distance was recorded to the nearest 0.1 mm using 7× magnification (Figs 4c and d).
- The status of the facial bone level was determined by CB-CT data, specifically by the reconstruction according to the long axis of the teeth/implants at pre-treatment examination, at 1-year and/or 2-year follow-up. The thickness of the facial bone wall was measured 1, 3, and 6 mm apical to this reference level at the facial aspect of the implant (Figs 4e, f, 5c and d).

Evaluation of secondary outcome parameters

- Implant success was rated according to the criteria established by Buser et al. (1990).
- These success criteria are defined as:
  - The implant is in situ.
  - No persistent complaints such as pain, discomfort, or paresthesia.
  - No peri-implant infection with suppuration.
  - No mobility of the implant.
  - No peri-implant radiolucencies.

Additionally, implant success was estimated combining the criteria established by Buser with the criterion of bone loss <1 mm (mean of mesial and distal measurement).
- The Pink Esthetic Score according to Fürhauser (Fürhauser et al. 2005) [PES] was also measured prior to surgery and at each follow-up visit. This score consists of seven distinct items (configuration of the mesial/distal papilla, the vertical level, contour and symmetry of the soft tissue margin, and the texture and color of the soft tissue), which were each assessed as grade 0–2 on a rating scale.

Statistical analysis

Survival probabilities were estimated by the Kaplan–Meier method on a “per implant” basis. The endpoint of interest was implant

<table>
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<tr>
<th>Table 1. Mean inter-proximal marginal bone level in relation to the reference level during the observation period</th>
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<tr>
<td>Mesial</td>
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<td>Mean</td>
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<td>Distal</td>
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<tr>
<td>Mean (mesial + distal)/2</td>
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<td>Median</td>
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failure according to the criteria established by Buser et al. (1990). The analysis exploring the linkage between marginal bone level and the PES utilized the Spearman’s rank-based correlations.

Subpopulations within the study group (improved vs. decreased PES, single vs. multiple implant restoration, smokers vs. non-smokers) were compared using the non-parametric U-test. These comparisons were performed on a “per patient” basis. The reported P-values are two sided. For graphic description, scatter plots and box plots are given. All calculations were carried out using SPSS for Mac, Version 20 (SPSS Inc., Chicago, IL, USA).

Results

Implant follow-up
A total of 37 implants were placed in this study. There were five implants replacing premolars, six implants replacing canines, nine replacing lateral incisors, and 17 replacing central incisors.

According to the criteria of Lekholm & Zarb (1985), bone quality was 2 in 19% and 3 in 81% of the sites. 

Acute peri-radicular infection was present in two sites (5.4%), chronic infection in 19 sites (51.4%), while in 16 sites (43.2%) no infection was present. The mean insertion torque was 23.6 ± 7.9 Ncm (range, 15–45 Ncm).

One patient with three implants resigned from the study after final delivery of the prosthesis at 4 months. She moved to a foreign country and was not able to visit the follow-up examinations, but she reported by phone that the implants were still in function without any discomfort.

All other patients attended at least the 1-year visit, and five of them had already the 3-year follow-up control. All implants were still in function after a mean follow-up of 27 ± 5 months [range 16–40 months]. Hitherto, all implants fulfilled the success criteria according to Buser et al. (1990).

Three implants showed a decrease of the marginal bone level of more than 1 mm apical to the reference level. According to the second endpoint definition combining the success criteria established by Buser with the criteria of a bone loss less than or equal to 1 mm, the cumulative success rate according to this second endpoint was 87.4% [Kaplan–Meier analysis: Fig. 3].

Marginal bone-level alteration
Marginal bone height at the level of the implant shoulder averaged −0.1 ± 0.55 mm.
[range, −1.25 to 1.47 mm] at the final follow-up. Marginal bone-level alterations are presented in Table 1 and in Fig. 1. The mean interproximal bone level [as measured against the implant shoulder] changed from 0.82 ± 0.96 mm at implant insertion to 0.24 ± 0.58 mm at prosthesis delivery, and further to 0.14 ± 0.57 mm at the 1-year follow-up. Finally, at the 2-year follow-up, −0.07 ± 0.58 mm was recorded.

Cone beam computed tomographies were recorded preoperatively (n = 34), 1-year postoperatively (n = 32), and 2-year postoperatively (n = 33). The thickness of the facial bony lamellae at the condemned teeth as well as at the implants was measured at 1 mm [preop 0.05 mm, 1-year 1.22 mm, 2-year 1.29 mm], at 3 mm [preop 0.5 mm, 1-year 1.3 mm, 2-year 1.4 mm], and at 6 mm [preop 0.52 mm, 1-year 1.29 mm, 2-year 1.24 mm] apical to reference level and showed increased thickness of the facial bone dimension (Fig. 2).

**Esthetics**

The preoperative changes to 2-year postoperative changes of the PES according to Fürhauser et al. [2005] are displayed in Table 2. The mean PES changed from 10.65 ± 1.96 preop, to 11.94 ± 1.59 at 1-year, and to 11.3 ± 1.78 at the 2-year follow-up. The most critical variable of the PES was the contour of the alveolar process, which decreased from 1.95 ± 0.23 preop, to 1.82 ± 0.39 at 1-year, and to 1.61 ± 0.5 at the 2-year follow-up. An improved or stable score of the PES was noticed in 26 implant sites (76%). In eight sites (24%), the esthetic status sustained slight to moderate decrease on the esthetic rating scale. Thus, overall the “PES” was slightly improved with the surgical and prosthetic intervention.

The analysis exploring the linkage between marginal bone level and the PES was not able to reveal a significant correlation [Spearman’s rank-based correlation [two-tailed]; P = 0.698]. There were significant differences when comparing the esthetic results or the marginal bone level of single vs. multiple implant restoration (P = 0.028, Mann–Whitney U-test), however not for smokers vs. non-smokers (P = 0.958). The esthetic result for the thin biotype sites was 12.25 ± 0.5 [median 12.0], for normal sites 11.27 ± 1.93 [median 12.0], and for thick sites 11.57 ± 1.27 [12.0].

**Discussion**

This bi-center study analyzed the maintenance of the interproximal marginal bone level and the soft tissue esthetics around OsseoSpeed™ implants after a follow-up of at least 12 months following immediate implant insertion and provisionalization. The main result was a stably marginal bone levels and even sometimes improved esthetic ratings of the peri-implant mucosa were observed. This held true even when the initial facial bony

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**Table 2. Mean score (SD) of the variables of the PES according to Fürhauser during the observation period**

<table>
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<tr>
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<th>Preop</th>
<th>1-Year</th>
<th>2-Year</th>
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<tr>
<td></td>
<td>n = 34</td>
<td>n = 32</td>
<td>n = 33</td>
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<tr>
<td>Papilla mesial</td>
<td>1.38 ± 0.49</td>
<td>1.35 ± 0.54</td>
<td>1.12 ± 0.6</td>
</tr>
<tr>
<td>Papilla distal</td>
<td>1.27 ± 0.61</td>
<td>1.35 ± 0.49</td>
<td>1.15 ± 0.62</td>
</tr>
<tr>
<td>Soft tissue level</td>
<td>1.43 ± 0.65</td>
<td>1.76 ± 0.5</td>
<td>1.85 ± 0.36</td>
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<tr>
<td>Soft tissue contour</td>
<td>1.78 ± 0.42</td>
<td>1.79 ± 0.48</td>
<td>1.76 ± 0.44</td>
</tr>
<tr>
<td>Alveolar process</td>
<td>1.95 ± 0.23</td>
<td>1.82 ± 0.39</td>
<td>1.61 ± 0.5</td>
</tr>
<tr>
<td>Soft tissue color</td>
<td>1.43 ± 0.56</td>
<td>1.91 ± 0.29</td>
<td>1.94 ± 0.24</td>
</tr>
<tr>
<td>Soft tissue texture</td>
<td>1.38 ± 0.55</td>
<td>1.94 ± 0.24</td>
<td>1.88 ± 0.33</td>
</tr>
<tr>
<td>Sum PES</td>
<td>10.65 ± 1.96</td>
<td>11.94 ± 1.59</td>
<td>11.3 ± 1.78</td>
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PES, Pink Esthetic Score.

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lamella was substantially compromised. CB-CT data suggest consolidation and even thickening of the facial bone. Thus, not only uniform implant survival, but in addition a favorable esthetic outcome was achieved in the majority of the patients.

Especially, the maintenance or reconstruction of the facial bony lamella contrasts the mainstream findings of Chen and Buser, who stated that recessions of the facial mucosal margin are common with immediate implant placement [Chen & Buser 2009]. We are all well aware of the limitations of our study due to the hitherto small number of cases. However, we suppose that there are the following key factors which may explain the rather stable and constant results:

- The flapless procedure may preserve the blood supply of the facial lamella.
- The sole use of autologous bone without any bone substitutes and without membranes may prevent resorption due to foreign body reactions.
- The placement of the implants along with the oral cortical border of the extraction socket increases primary stability.

The clinical impact of flapless implant installation is discussed controversially for many years. Due to the large variety of operative techniques, flap designs, preoperative bone conditions, use of xenografts, membranes, types, and sizes of implants [Araújo et al. 2005, 2011; Blanco et al. 2008, 2011; Covani et al. 2008; Fickl et al. 2008; Araújo & Lindhe 2009, Hsu et al. 2012; Raes et al. 2011], it is highly unlikely, that mainstream results can be defined for a “flapless procedure” as such. However, the results of our study suggest a beneficial influence for bone stability and especially bone regeneration, when the gingival vascular architecture is preserved.

Although the validity of CB-CT for measurements of immediate peri-implant bone is limited by metal artifacts [Schulze et al. 2010, 2011], CB-CT has evolved as the method of choice for the assessment of the facial bone lamella [Miyamoto & Obama 2011], simply by the lack of alternatives. Fortunately, due to the nature of metal artifacts, CB-CT underestimates the dimension of the facial bone adjacent to an implant. This implies that we can rely on CB-CT data to represent the minimum of bone that is clinically available.

Although, there are considerable differences in terms of surgical protocol, time of implant insertion, implant-type, grafting procedure, and inclusion criteria, some findings of our study are in line with previous reports. Mertens and Steveling observed marginal bone-level changes for early and immediate loading of OsseoSpeed™ implants and found changes between −0.18 mm for immediate loading, 0 mm for early loading, and −0.24 mm (range −0.48 to 0.12 mm) for delayed loading after 5 years of function [Mertens & Steveling 2011]. Thus, the mean marginal bone-level changes of −0.31 mm (Table 1) for the time range from prosthesis delivery to the 2-year follow-up sound reasonable, taking into account, that bone grafting procedures to fill the vestibular gap have been performed in all of our cases. In a prospective multicenter study, De Bruyn et al. [2012] reported 3 years implant survival, bone and soft tissue changes following immediate non-functional provisionalization using single OsseoSpeed™ implants inserted in healed ridges or extraction sockets with an intact facial bone contour. Most interestingly, they found only minor differences between the survival rates of the extraction group and the healed group.

The results of our study provide further evidence for the support of marginal bone and soft tissues by means of immediate implant placement and immediate provisionalization and add that even the loss of the facial bony lamella is not an exclusion criterion for immediate implant placement, as long as primary stability can be secured. Moreover, this study provides longitudinal data on the esthetic outcome, which, to the best of our knowledge, has not been described in such detail yet.

However, in spite of these promising results, several questions remain to be addressed. Due to the limited number of patients, we could not perform a multivariate analysis to weight additional parameters (periodontal disease, soft tissue type, age, etc.) that might contribute to a superior or inferior esthetic result. Moreover, going into details of the PES, the contour of the alveolar process remains to be somewhat deficient in spite of our augmentation concept. At the moment, this phenomenon was below the threshold of the patient’s perception; however, a potential clinical relevance has to be scrutinized in the future follow-up.

Conclusion

Within the limitations of this pilot study, single- or multiple teeth rehabilitation patients can be treated with a favorable esthetic outcome and stable marginal bone levels using the immediate implant placement and provisionalization approach even when facial bony defects have to be reconstructed at the same time.
References


