CLINICAL ORAL IMPLANTS RESEARCH

Robert Noelken
Fabienne Oberhansl
Martin Kunkel
Wilfried Wagner

Immediately provisionalized OsseoSpeed™ Profile implants inserted into extraction sockets: 3-year results

Authors' affiliations:
Robert Noelken, Fabienne Oberhansl, Private Practice for Oral Surgery, Lindau/Lake Constance, Germany
Robert Noelken, Department of Oral and Maxillofacial Surgery, University Medical Center, Johannes Gutenberg University of Mainz, Mainz, Germany
Martin Kunkel, Department of Oral and Maxillofacial Surgery, University Hospital of Bochum, Bochum, Germany
Wilfried Wagner, Department of Oral and Maxillofacial Surgery, Johannes Gutenberg University of Mainz, Mainz, Germany

Corresponding author:
Robert Noelken, Priv-Doz Dr Med Dent, MSc
Augustusplatz 2, D – 55131
Mainz (clinic) & Paradiesplatz 7-13,
D - 88131 Lindau / Lake Constance (practice)
Germany
Tel.: +49 8382 944030
Fax +49 8382 944031
e-mail: rnoelken@me.com

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Abstract

Objectives: A sloped shoulder might improve the congruence between extraction socket and dental implant and may add to a better circumferential support of the peri-implant structures. Therefore, this study evaluates the 3-year clinical outcome (survival and success rates, marginal bone levels, and Pink Esthetic Score (PES)) of immediately inserted and provisionalized OsseoSpeed™ Profile implants in the anterior maxilla.

Material and methods: Twenty-one implants were inserted in 16 patients. All implants were immediately placed into extraction sites with and without facial bone deficiencies. A flapless procedure was utilized, and the implants were provisionalized immediately. Facial gaps were grafted with autogenous bone chips from the mandibular ramus. Implant survival and success, the interproximal bone levels, the thickness of the facial bony wall, and the PES were evaluated.

Results: After a mean follow-up period of 43 months, 19 implants were still in function. One patient with 1 implant did not follow the study protocol (dropout) and 1 implant was lost at 10 weeks. Interproximal marginal bone levels measured −0.2 ± 0.4 mm (range, −1.0–0.4 mm) apical to the implant shoulder. The mean PES ratings were 11.9 ± 1.4 (range, 8–14) at the final examination.

Conclusions: Clinical and radiographic results provide evidence that sloped implants can preserve the marginal bone circumferentially and are able to maintain soft tissue esthetics when inserted and provisionalized immediately, even in the presence of facial bony wall defects.

Apart from the reduction of treatment time, the insertion of implants into extraction sockets focuses on the preservation of circumferential peri-implant hard and soft tissue structures to support a natural and esthetic contour. As an alternative to placement of implants in healed ridges, immediate insertion protocols and provisionalization concepts as well as flapless surgery approaches may show reasonable esthetic results with reduced treatment time, pain, and costs. Specifically, promising results have been reported for immediately inserted and provisionalized implants (Gelb 1993; Kan et al. 2003; Norton 2004; De Kok et al. 2006; Noelken et al. 2007, 2014b,c; Valentini et al. 2010; Mertens & Steveling 2011; De Bruyn et al. 2012; Cooper et al. 2014). In the extraction socket in the anterior maxilla, the main problem to overcome is the physiological height difference between the oral, interproximal and facial bone, and the respective soft tissue levels (Becker et al. 1997; Wöhrle 2003). Several years ago, the concept of scalloped implants was introduced to maintain the natural contour of the alveolar ridge and the peri-implant soft tissue contour by mimicking the scalloped shape of natural topography of the healthy marginal bone contour (Wöhrle 2003). The long-term results showed stable soft tissues around the scalloped implants in spite of some loss of marginal bone support in relation to the originally intended marginal bone level (Noelken et al. 2014b; Paul & Held 2013). Recently, a dental implant with a sloped marginal contour and a height difference of the implant shoulder of approximately 1.5 mm (OsseoSpeed Profile™, Dentsply Implants, Mölndal, Sweden, Fig. 1) has been developed to improve the congruence between implant and bone in extraction sites and sloped ridges. This bi-center prospective study evaluated the clinical and radiographic performance of immediately and flaplessly inserted and provisionalized OsseoSpeed™ Profile implants in the esthetic zone

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Fig. 1. The OsseoSpeed Profile implants design with a sloped implant shoulder and a height difference of 1.5 mm.

of the maxilla after a follow-up of at least 36 months.

Material and methods

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

Patients

In a prospective bi-center study, 21 patients received 29 OsseoSpeed Profile™ implants between February 2010 and February 2011. The implants were inserted in healed sites and extraction sockets in the esthetic zone and immediately restored with a temporary prosthetic restoration. 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, flap elevation and flapless), a subgroup treated according to a homogeneous treatment concept was extracted for this analysis. Inclusion criteria for this subgroup were as follows: hopeless tooth in the esthetic zone of the maxilla (15–25) deemed to be extracted, expectation of primary stability (≥15 Ncm insertion torque), immediate provisionalization requested, immediate and flapless insertion into extraction sockets, no connective tissue graft.

Exclusion criteria were as follows: known or suspected current malignancy, a history of radiation therapy in the head and neck region, chemotherapy within 5 years prior to surgery, uncontrolled diabetes mellitus, permanent immunosuppressive medication, bone modifier (e.g., bisphosphonate or rank ligand inhibitor) medication, present alcohol, and/or drug abuse. Deficiencies of the facial bone wall (fenestrations, dehiscences, total loss of facial bone wall) and smoking were not regarded as exclusion criteria.

Sixteen patients were included in this subgroup of this study. The average age of this population (8 women, 8 men) was 40.9 years (range, 19–74 years). Thirteen patients were nonsmokers, and three were moderate smokers. The indication for immediate implant insertion was a single-tooth replacement in 13 patients and a partial restoration in three patients. The reason for teeth removal was an endodontic failure in four, a long-axis root fracture in two, a nonrestorable decay in two, an external root resorption in one, and periodontitis in five sites. Seven teeth were lost due to a trauma.

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. Written informed consent was obtained from all patients prior to any examination carried out for study purposes. The study was supported by a grant from DENTSPLY Implants IH AB, Sweden to the Department of Oral and Maxillofacial Surgery, University Medicine of Mainz, Germany.

Pretreatment examination

At pretreatment examination, subjects in need of an immediate implant restoration were screened for eligibility to the study. A CB-CT was performed to evaluate the dimensions of the facial bony lamella. Twelve extraction sockets showed a pristine facial bone wall, seven sites partial defects, and two sites a total loss of the facial bone wall.

Surgical technique

The OsseoSpeed™ Profile implants were screw-shaped and self-tapping. The diameters used were 4.5 and 5.0 mm with a length of 15 mm. Surgery followed the guidelines outlined in the manufacturer's instructions. Under local anesthesia, the respective teeth were extracted atraumatically using the periotome technique. The extraction site was cleansed of granulation tissue using a chairside microscope. All procedures were performed without raising a flap even when a facial bone defect was observed. Single-use drills, undersized by 0.3 mm, were taken for final site preparation. Unstable implants (below 15 Ncm) were excluded from the study ($n = 4$). Healing abutments (Healing Abutment Uni 4.5/5.0; Dentsply Implants, Mölndal, Sweden) were inserted prior to the bone grafting procedure to avoid bone chips from getting into the inner surface of the implants. They were left in place during the short time of fabrication of the temporary restoration. Simultaneous grafting of the facial gap between implant surface and facial tissues was performed by condensing bone chips to the bottom of the defect for reconstruction of the facial contour. Autogenous bone grafts were harvested at the mandibular ramus by particulating a bone block in a bone mill (Quetin Bone-Mill, Leimen, Germany) or by collecting bone particles by a disposable filter (BoneTrap, Dentsply Implants). Additional connective tissue grafts to close the alveolar defects were not used. The patients received antibiotic prophylaxis (starting the day before surgery until 7 days postop; clindamycine 300 mg 3–4 times/day or a combination of metronidazol 500 mg and ciprofloxacin 500 mg each twice daily) and a prescription for chlorhexidine rinse 0.2%, for 10 days.

Immediate and final restorations

The healing abutments were replaced by titanium abutments (TiDesign™, Dentsply Implants) without disturbing the grafted bone chips. Immediate temporary restorations were manufactured by denture teeth, which were adjusted chairside to the implant site and cemented on top of titanium abutments using a temporary cement (Temp Bond, Kerr Hawe SA, Bioggio, Switzerland). Alternatively, temporary screw-retained restorations were fabricated using temporary abutments. The grafted bone was covered by the titanium abutments and the undercontured temporary crowns, which were in slight contact with the marginal tissues.

All restorations were inserted at the day of implant placement and adjusted to clear all contacts in centric occlusion and during excentric movements. The implants were splinted to neighboring teeth or to each other

using a cross-linked glass fiber ribbon (Ribbond THM, Seattle, WA, USA) for 8 weeks. The patients were advised to keep a soft diet for 8 weeks.

After a minimum of 3 months, an impression was made for fabrication of the definitive crown. The final zirconia crowns were cemented on top of zirconia abutments (Atlantis™ zirconia abutment or ZirDesign™, Dentsply Implants) using a temporary cement (Temp Bond™).

Follow-up and definition of outcome variables

The patients were examined preoperatively, at implant placement, at prosthetic delivery, and at 1-year, 2-year, and 3-year follow-up visits following implant insertion.

Evaluation of primary outcome parameter

The primary end point of this analysis was implant survival after a follow-up of at least 36 months following flapless implant insertion.

Evaluation of secondary outcome parameters

- The status of the interproximal marginal bone level was determined by digital periapical radiographs with paralleling technique using commercially available film holders (Dentsply/Rinn, Elgin, IL, USA). The vertical distances between the mesial and distal bone level and the first micro-thread (reference level) were measured. Attachment levels crestal to this reference level were designated as positive values and vice versa.
- 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. The thickness of the facial bone wall was measured 1 mm, 3 mm, and 6 mm apical to the reference level. The level of the facial bony wall was measured on CB-CT at teeth and implant sites as a distance between reference level and midfacial bone level. This reference level was determined by the level of the healthy facial and oral bony wall at the condemned teeth or the first micro-thread at implant sites (Fig. 2).
- The PES (Fürhauser et al. 2005) 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.
- Implant success was rated according to the criteria established by Buser et al. (1990). Additionally, implant success was estimated by combining these criteria with bone loss <1 mm circumferentially. An implant was considered successful when the implant was *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 were present and the marginal bone loss was less than 1 mm.

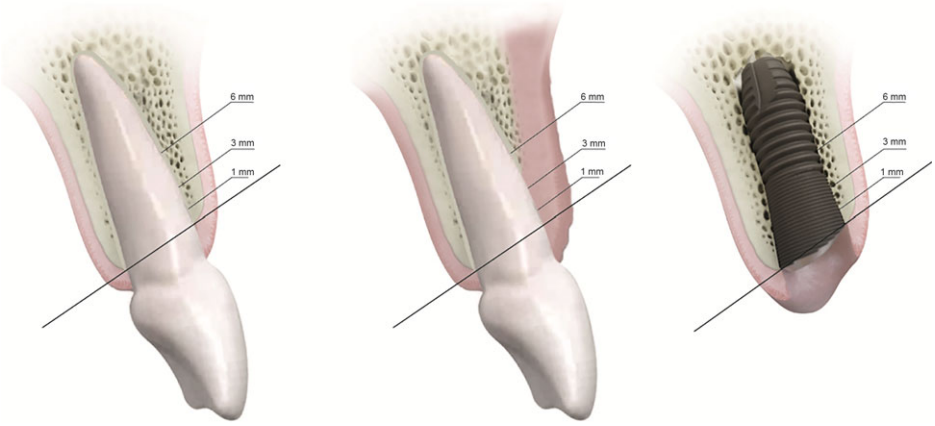

Fig. 2. Method of measurement of the facial bony wall thickness 1, 3, and 6 mm below reference level.

Statistical analysis

Survival probabilities were estimated by the Kaplan–Meier method for all implants and in addition on a per-patient basis using the most critical implant (regarding to PES and marginal bone level). The analysis exploring the linkage between marginal bone and PES utilized the Spearman's rank-based correlations. Subpopulations within the study group (single vs. multiple restorations, smokers vs. nonsmokers) were compared using the nonparametric *U*-test. All statistic evaluations were performed on a "per-patient" basis. In case of more than one implant per patient, the implant site with the worst result was selected for each parameter. The reported *p*-values are two-sided. For graphic description, boxplots are given (Fig. 3 & 4). All calculations were carried out using SPSS 22 (SPSS Inc., Chicago, IL, USA).

Results

Implant follow-up and implant survival

A total of 21 implants were placed in 16 patients. There was one implant replacing a premolar, three replacing canines, two replacing lateral incisors, and 15 replacing central incisors. Peri-radicular infection was present in 18 sites. The mean insertion torque was 24.4 ± 5.7 Ncm. One patient with 1 implant resigned from the study at 8 months (drop-out). One implant (replacing a canine) was lost at 10 weeks. All other patients attended the 3-year visit. Nineteen of 20 implants were still in function after a mean follow-up of 43.4 ± 3.5 months. The survival rate according to the Kaplan–Meier method was 95% for all implants and 93.3% when only the most critical implant per patient was evaluated.

Marginal bone level

Marginal bone levels in relation to reference level are presented in Table 1 and in Fig. 3. The mean interproximal bone level changed from 0.8 ± 0.6 mm at insertion to −0.2 ± 0.4 mm at 3-year follow-up. CB-CTs were recorded preoperatively (n = 18), at 1-year (n = 15), at 2-year (n = 12), and at 3-year postoperatively (n = 11). The thickness of the facial bony lamellae was measured at 1, 3, and 6 mm apical to reference level and showed increased thickness of the facial bone (Table 2, Fig. 4). The distance between the reference level and the facial level of bony wall (measured on the CB-CT) changed from preoperatively −3.8 ± 3.8 mm (range, −12.4–0.0 mm, n = 18) to 0.3 ± 1.0 mm (range, −1.6–2.4 mm, n = 17).

Esthetics

The pre- to 3-year postoperative changes of the PES (Fürhauser et al. 2005) are displayed in Table 3. Mean PES changed from 10.58 ± 2.39 preop to 11.89 ± 1.45 at 3-year follow-up. The most critical variable of the PES was the contour of the alveolar process, which decreased from 1.98 ± 0.32 preop to 1.61 ± 0.5 at 3-year follow-up (p = 0.059). An improved or stable score of the PES was noticed in 14 sites, in five sites the PES sustained moderately (Fig. 5 a, c & d).

Implant success

One implant showed a decrease of the interproximal, another implant of the facial mar-

Table 1. **Mean interproximal marginal bone level in relation to the reference level during the observation period**

	Implant insertion $n = 19$	Prosthesis delivery $n = 14$	1-year $n = 16$	2-year $n = 18$	3-year $n = 18$
Mesial mean ± SD	0.8 ± 0.7	0.1 ± 0.6	−0.2 ± 0.6	−0.2 ± 0.5	−0.1 ± 0.5
Distal mean ± SD	0.9 ± 0.7	0.4 ± 0.8	0.1 ± 0.6	−0.1 ± 0.7	−0.3 ± 0.6
Mean ± SD	0.8 ± 0.6	0.2 ± 0.6	−0.1 ± 0.5	−0.2 ± 0.5	−0.2 ± 0.4

Table 2. **Mean facial bone thickness (in mm) 1, 3, and 6 mm apical to reference level during the observation period**

	Preop $n = 18$	1-year $n = 15$	2-year $n = 12$	3-year $n = 11$
1 mm	0.1 ± 0.2	1.0 ± 0.6	1.0 ± 0.6	1.5 ± 0.9
3 mm	0.4 ± 0.3	1.1 ± 0.5	0.9 ± 0.3	1.3 ± 0.9
6 mm	0.5 ± 0.4	1.3 ± 0.6	1.2 ± 0.6	1.4 ± 1.0

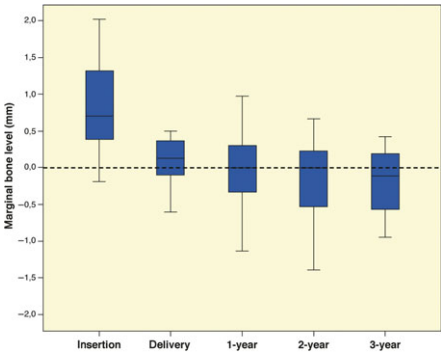

Fig. 3. Marginal bone level changes over the course of the 3-year follow-up in relation to the reference level (implant shoulder).

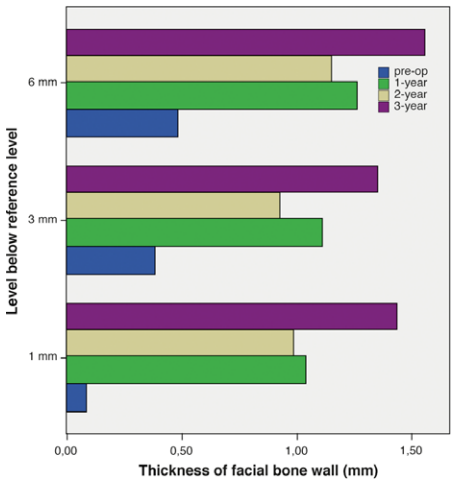

Fig. 4. Increase of the thickness of facial bony plate 1, 3, and 6 mm apical to the reference level over the course of the 3-year follow-up.

ginal bone level to more than 1 mm apical to the reference level. According to the second end point definition combining the success criteria established by Buser et al. (1990) with the criterion of at most 1 mm bone loss, 17 of 20 implants were classified successful. The success rate according to the Kaplan–Meier method was 90% for all implants and 86.7% when only the most critical implant per patient was evaluated.

Correlation results

The analysis exploring the linkage between marginal bone and PES did not reveal a significant correlation ($r = 0.444$; $p = 0.111$: Spearman's rank correlation coefficient). There were no significant differences when comparing the esthetic results or the marginal bone level of single vs. multiple implant restoration (median, single, PES 12.3 ± 0.91, multiple, PES 12.0 ± 2.1, $p = 0.66$; median, single 0.0 ± 0.33 mm, multiple −0.71 ± 0.68 mm, $p = 0.37$) and of smoker vs. nonsmokers (median, smokers, PES 12.0 ± 0.0, nonsmoker, PES 12.0 ± 1.3, $p = 0.79$; median, smokers −0.40 ± 0.43 mm, nonsmokers 0.0 ± 0.43 mm, $p = 0.38$).

Discussion

This bi-center prospective study analyzed implant success, peri-implant marginal bone and soft tissue esthetics around the sloped OsseoSpeed™ Profile implants after a follow-up of at least 36 months. After 3 years of follow-up, a reasonable success rate, a modest marginal bone loss, and largely stable esthetic ratings of the peri-implant soft tissues were found. CB-CT data revealed consolidation and yet thickening of the facial bone, even when the initial status of the facial bony lamella was substantially compromised. In spite of an initial reduction, the interproximal marginal bone level stabilized at 3 years at the level of the implant shoulder. This result is in line with the amount of −0.5 mm interproximal marginal bone loss around sloped implants placed in sloped healed sites after a one-year follow-up (Noelken et al. 2014a).

As 12 extraction sockets showed a pristine facial bone wall, 7 sites partial defects, and 2 sites a total loss of the facial bone wall, the level of the facial plate was not useful as a reference level for insertion depth. Successful techniques for flapless reconstruction of a defect or missing facial bony wall with autogenous bone chips (Noelken et al. 2011) or porcine bone grafting material (Covani et al. 2008) are described in the literature. Thereby, the focus of vertical implant alignment is not the level of the facial bone wall but the level of the natural oral bone wall and the desired facial soft tissue level. The documented gain of the vertical facial bone height (preop −3.8 mm, final 0.3 mm) to a level coronal of the sloped implant shoulder supports this concept.

Regarding the well-documented issue of a higher risk of recessions with the immediate

Table 3. **Mean score (SD) of the variables of the PES according to Fürhauser during the observation period**

	Preop	Delivery	1-year	2-year	3-year
Papilla mesial	1.32 ± 0.67	1.20 ± 0.56	1.50 ± 0.63	1.50 ± 0.51	1.33 ± 0.69
Papilla distal	1.11 ± 0.81	1.07 ± 0.59	1.31 ± 0.70	1.39 ± 0.70	1.44 ± 0.71
Soft tissue level	1.63 ± 0.5	1.80 ± 0.41	1.75 ± 0.45	1.83 ± 0.38	1.72 ± 0.46
Soft tissue contour	1.58 ± 0.61	1.80 ± 0.41	1.88 ± 0.34	1.78 ± 0.43	1.89 ± 0.32
Alveolar process	1.98 ± 0.32	1.80 ± 0.41	1.69 ± 0.60	1.72 ± 0.46	1.61 ± 0.50
Soft tissue color	1.42 ± 0.51	1.73 ± 0.46	1.94 ± 0.25	1.89 ± 0.32	1.89 ± 0.32
Soft tissue texture	1.63 ± 0.5	1.93 ± 0.26	1.94 ± 0.25	1.78 ± 0.43	2.00 ± 0.00
Sum PES	10.58 ± 2.39	11.27 ± 1.22	12.00 ± 1.67	11.94 ± 1.16	11.89 ± 1.45

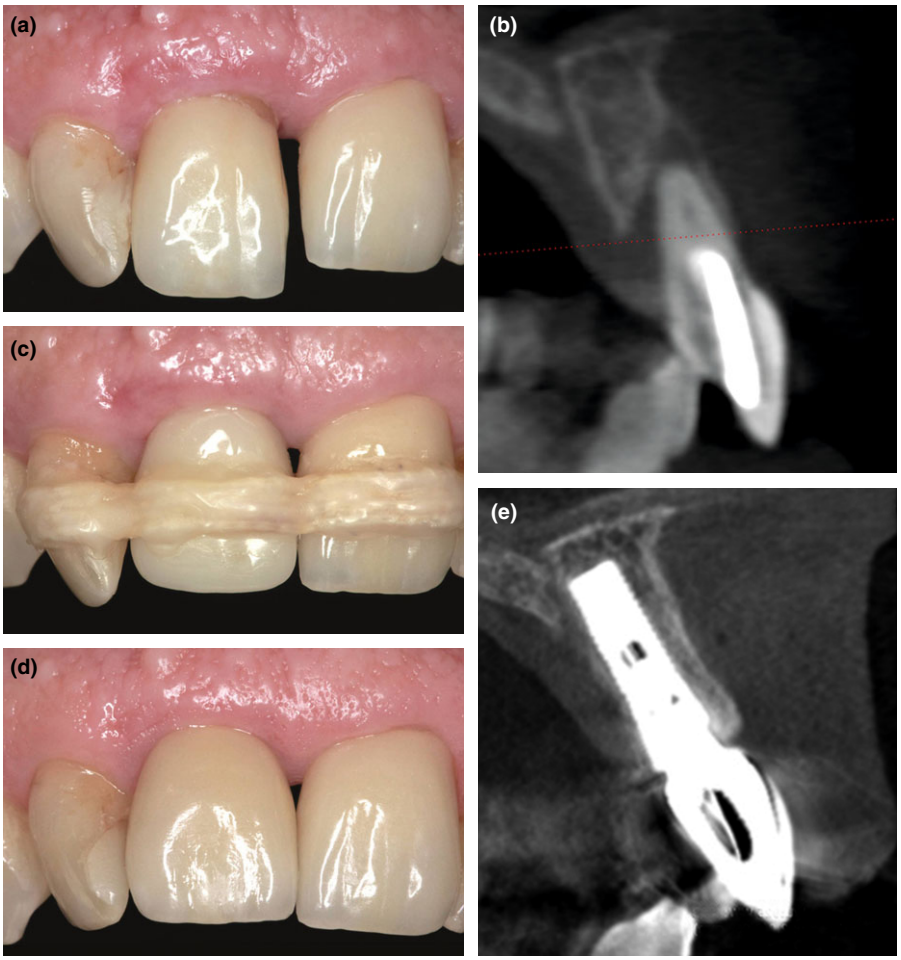

Fig. 5. Immediate implant insertion, reconstruction, and provisionalization in case of partial loss of the facial and oral bone wall. The right central incisor shows an endo-perio lesion and, because of elongation and mobility, was not worth re-treatment. (a) Preoperative aspect of the condemned central right incisor with elongation and severe mobility. (b) CB-CT at preoperative examination showing the dehiscence defect of the facial and oral bone wall at the right central incisor. (c) Immediate provisionalization without functional contacts at the day of surgery. To protect the implant against undesirable loading, a Ribbond splint was attached adhesively to the facial aspect of the neighboring teeth. (d) Matured and increased facial soft tissues without any signs of recession at 50 months. (e) CB-CT at 50 months showing the complete reconstruction of the facial and oral bone wall with a facial marginal bone level coronal to the implant shoulder.

insertion protocol (Chen & Buser 2009, 2014; Cosyn et al. 2012; Ross et al. 2014), we were able to show a stable facial soft tissue level in the PES (preop 1.63, 3-year follow-up 1.72). Prospective studies have described the factors influencing the resorption of the buccal bone wall in horizontal dimensions following immediate implant insertion 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 and even to enable reconstruction of the facial bone wall, the implants in this series were strictly aligned to the oral cortical lining, placed without elevating a flap, and grafted with autogenous bone chips at the facial aspect.

The implants had a smaller diameter than the extracted teeth, and the facial gaps were augmented with autogenous bone grafts. Therefore, the increased thickness of the facial bony wall may only be the result of the grafting procedure, the angulation and the more palatal positioning of the implant. It remains an open issue whether the specific implant design and surface or the surgical concept are the key to the support of the marginal contour and the reconstitution of the bony wall. Although, about 43% of the implant sites had preoperative extended defects of the facial alveolar bone wall, the clinical outcome parameters were in line with the results reported for immediate loading in favorable bone conditions (De Bruyn et al. 2013).

Although flat-top OsseoSpeed™ implants and a one-stage procedure in healed sites were used, Mertens and Steveling observed a −0.18 mm marginal bone level loss for immediate loading of OsseoSpeed™ implants at 5 years (Mertens & Steveling 2011), which is in line with our results. In a prospective multicenter study, De Bruyn et al. (2012) reported 94.6% implant survival following immediate insertion and provisionalization of OsseoSpeed™ implants at 3 years. Compared to our results, the De Bruyn study survival rate is comparable even though it excluded all cases with facial bone deficiencies. They also found a bone level of −0.7 mm apical to implant shoulder which is slightly below our results.

However, in spite of these promising results for the OsseoSpeed™ Profile implant design, some questions could not be answered in our study. Due to the limited number of patients, we could not perform a multivariate analysis to weigh additional parameters (periodontal disease, soft tissue type, age, etc.) that might contribute to a superior or inferior esthetic result. Although the reconstitution of facial bone and an increase of the PES were documented in this study, the contour of the alveolar process was slightly reduced (PES variable: alveolar process contour preop 1.98, 3-year 1.61). Until now, this reduction was below patient's perception, but will be followed critically in the future follow-ups.

Conclusion

This prospective bi-center 3-year follow-up study showed that OsseoSpeed Profile implants with a sloped implant shoulder inserted into extraction sockets in the esthetic zone of the maxilla and restored with a nonfunctional temporary crown at the day of surgery yielded a positive outcome in terms of implant survival and success, circumferential marginal bone level stability and soft tissue esthetics, irrespective of the presence of facial bone deficiencies. Due to the restriction to a fixed treatment concept in the esthetic zone, the number of subjects and thereby the scientific validity is limited. Further research with randomized controlled prospective studies comparing standard vs. sloped implant designs is necessary to prove this treatment modality.

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