A Multilevel Analysis of Platform-Switching Flapless Implants Placed at Tissue Level: 4-year Prospective Cohort Study

Carlo Prati, MD, DDS, PhD\(^1\)/Fausto Zamparini, DDS, MEndo, PhD\(^2\)/Chiara Pirani, DDS, MEndo, PhD\(^2\)/Lucio Montebugnoli, MD, DDS\(^3\)/Luigi Canullo, MD, DDS\(^4\)/Maria Giovanna Gandolfi, D Biol, MBiol, PhD\(^2\)

**Purpose:** To evaluate the factors affecting peri-implant marginal bone level of single platform-switched implants with a smooth neck placed at gingival level (tissue level) using a flapless technique. **Materials and Methods:** Consecutive healthy patients requiring dental implant rehabilitations were enrolled in this study. Titanium implants with a zirconium-oxide-blasted surface and a platform-switch neck tulip configuration were used. Loading was performed 3 months after insertion with a provisional resin crown and after approximately 15 days with a definitive ceramic crown. Peri-implant marginal bone level (MBL) was measured on periapical radiographs at 1, 3, 6, 12, 24, 36, and 48 months by a blinded assessor. The following parameters were evaluated: location (maxillary/mandibular), position (anterior/posterior), sex (male/female), smoke (yes/no), implant placement timing (immediate, early, delayed), gingival thickness (thin/thick), endodontically treated adjacent teeth (yes/no), and diameter (3.8/4.25/5.0 mm). Multilevel analyses exploring factors associated with MBL at 36 and 48 months were performed. **Results:** A total of 76 patients (42 women, 34 men; mean age: 55.6 ± 10.7 years) received 128 implant rehabilitations. The survival rate was 98.4%. MBL displayed an initial increase during the first months from insertion (preload period). Cumulative mean MBL at T\(_{36}\) was 0.99 ± 0.68, which was not statistically significant from the values at T\(_{24}\) to T\(_{36}\) (P > .05). Mandibular location, delayed implants, and presence of adjacent endodontically treated teeth showed higher bone loss at 36 months (P < .05). Interestingly, at 48 months, only implant placement timing showed statistically significant differences. Delayed implants showed increased bone loss compared with both early and immediate groups (P < .05). Multilevel analysis confirmed the statistical significance of implant location (P = .031; 95% CI: 0.031 to 0.659), endodontically treated adjacent teeth (P = .001; 95% CI: –1.228 to 0.859), and implant placement (P = .045; 95% CI: 0.003 to 0.337) as factors affecting MBL at 36 months. All the investigated parameters, with the only exception being the implant placement group (P = .020; 95% CI: 0.334 to 1.432), were not statistically significant at 48 months (P > .05). **Conclusion:** Platform-switched implants placed nonsubmerged with a flapless approach showed a reduced bone loss progression in the first 4 years, as MBL remained stable at longer times (36 and 48 months). Implants placed with early and immediate timing showed reduced bone loss compared with delayed implants. Int J Oral Maxillofac Implants 2020;35:330–341. doi: 10.11607/jomi.7541

**Keywords:** best clinical practice, dental implants, flapless surgery, MBL, platform-switch

Although submerged dental implants show high and predictable long-term success,\(^1\)\(^2\) a growing interest in less-invasive protocols has been reported in the literature.\(^3\) Placement of implants in a nonsubmerged tissue-level approach has been proposed in different studies as a predictable technique with similar risks compared with the traditional submerged technique\(^4\)\(^–\)\(^6\) and high long-term survival.\(^7\) Nonsubmerged healing is usually achieved placing a bone-level implant and immediately positioning a healing screw, which remain exposed to the oral environment.\(^8\)

The platform-switching concept was reported by Lazzara and Porter in 2006.\(^9\) Through the repositioning of a cylindrical implant-abutment junction far from the crestal bone, platform switching
demonstrated reduced bone loss values. Implants with this configuration are usually positioned at bone level (submerged), with the neck at crestal bone height (equicrestally) or under (subcrestally). Platform-switched implants with a moderate tulip-shaped neck were tested in a recent study in an equicrestal position with a transmucosal healing screw with reduced marginal bone loss at 24 months.

Histologic findings, however, revealed that when tapered platform-switched implants are positioned subcrestally, greater bone remodeling occurs, as the removal of a great portion of the coronal bone during site preparation compromises blood supply of the remaining cortical bone. In this context, factors such as implant-abutment connection, micromobility, and associated tissue inflammation play an important role in relation to the crestal bone remodeling.

Moreover, the placement of a smooth/unroughened tulip-shaped–neck implant in a subcrestal position was found to not support crestal bone and may also be associated with initial bone loss. A low-invasive approach could be the placement of a flapless platform-switched implant with a moderate tulip-shaped neck in a supracrestal position.

Marginal bone level (MBL) differences represent an important analysis that may provide information on peri-implant bone health/disease. Indeed, the radiographic assessment of MBL at different endpoints gives important information regarding the hard and soft tissue modification that occurs in the early healing phases (preload period) or after the definitive restoration (postload period).

Numerous other conditions, as well as preoperative, intraoperative, and postoperative parameters may affect the peri-implant marginal bone morphology/environment and clinical-radiographic aspects.

Different statistical methodologies, such as multilevel analysis or linear logistic regressions, have been proposed and used to evaluate and correlate strategic-technical (ie, surgical) decisions with many factors associated with MBL, such as bone quality, implant diameter, implant surface, and type of prosthesis.

The aim of this consecutive, nonrandomized prospective cohort study was to investigate factors that may affect MBL around implants placed nonsubmerged.

The primary outcome measures were implant MBL variation at 1 and 3 months (preload time) and at 6, 12, 24, 36, and 48 months.

The secondary outcome measures were the success and survival rates of implant rehabilitations after 48 months.

MATERIALS AND METHODS

Study Setting and Patient Selection

The study design was a single-blind human longitudinal prospective cohort study comparing the clinical and radiographic outcomes after 4 years for the treatment of patients who had lost one or more teeth due to endodontic, root fracture, and deep-caries lesions.

The study was conducted in one University Endodontic Clinical Department and in two private dental offices between January 2011 and June 2018 by the same clinical team. Recruitment of patients was performed from October 2009 to June 2014. Once included in the study, patients were treated from January 2010 to July 2014.

All patients included in this investigation were treated according to the principles established by the Declaration of Helsinki as modified in 2013. Before enrollment, written and verbal information was given by the clinical staff, and each patient gave a written consent according to the aforementioned principles. An additional signed informed consent was obtained from all patients stating that they accepted the treatment plan and agreed to cover the costs and follow the maintenance hygiene program. This report was written according to the Consolidated Standards of Reporting trials guidelines for reporting clinical trials (STROBE) and respecting the guidelines published by Dodson in 2007.

The patients were considered eligible or noneligible for inclusion in the clinical protocol based on the following criteria:

Inclusion criteria:

- 18 to 75 years of age at the time of implant placement
- Partially dentate requiring dental implants
- Possibility of being included in a hygiene recall program and implant control for at least 4 years

Exclusion criteria:

- Medical and/or general contraindications for the surgical procedures (ASA score ≥ 3)
- Poor oral hygiene and lack of motivation
- Active clinical periodontal disease in the dentition expressed by probing pocket depth > 4 mm and bleeding on probing
- Smoking more than 20 cigarettes per day
- Uncontrolled diabetes mellitus
- Systemic or local diseases that could compromise postoperative healing and osseointegration
- Alcohol and/or drug abuse
- Pregnancy or lactating
- Malocclusion and other occlusal disorder (bruxism)
- Bisphosphonate therapy

MATERIALS AND METHODS

Study Setting and Patient Selection

The study design was a single-blind human longitudinal prospective cohort study comparing the clinical and radiographic outcomes after 4 years for the treatment of patients who had lost one or more teeth due to endodontic, root fracture, and deep-caries lesions.

The study was conducted in one University Endodontic Clinical Department and in two private dental offices between January 2011 and June 2018 by the same clinical team. Recruitment of patients was performed from October 2009 to June 2014. Once included in the study, patients were treated from January 2010 to July 2014.

All patients included in this investigation were treated according to the principles established by the Declaration of Helsinki as modified in 2013. Before enrollment, written and verbal information was given by the clinical staff, and each patient gave a written consent according to the aforementioned principles. An additional signed informed consent was obtained from all patients stating that they accepted the treatment plan and agreed to cover the costs and follow the maintenance hygiene program. This report was written according to the Consolidated Standards of Reporting trials guidelines for reporting clinical trials (STROBE) and respecting the guidelines published by Dodson in 2007.

The patients were considered eligible or noneligible for inclusion in the clinical protocol based on the following criteria:

Inclusion criteria:

- 18 to 75 years of age at the time of implant placement
- Partially dentate requiring dental implants
- Possibility of being included in a hygiene recall program and implant control for at least 4 years

Exclusion criteria:

- Medical and/or general contraindications for the surgical procedures (ASA score ≥ 3)
- Poor oral hygiene and lack of motivation
- Active clinical periodontal disease in the dentition expressed by probing pocket depth > 4 mm and bleeding on probing
- Smoking more than 20 cigarettes per day
- Uncontrolled diabetes mellitus
- Systemic or local diseases that could compromise postoperative healing and osseointegration
- Alcohol and/or drug abuse
- Pregnancy or lactating
- Malocclusion and other occlusal disorder (bruxism)
- Bisphosphonate therapy

The International Journal of Oral & Maxillofacial Implants
Clinical evaluations of periapical status were made by three experienced operators included as authors (C.P., Ch.P., F.Z.).

Treatment Procedures
The choice of implant placement timing was performed following the recommendations proposed by the Third ITI Consensus Conference. This classification was performed aiming to reflect the alveolar hard and soft tissue modifications occurring from the moment of tooth extraction (Type 1) to the complete maturation of the tissues (Type 4). Three different implant placement timings were performed:

- Immediate postextraction implant (Type 1 for ITI): when the implant was placed into a fresh extraction socket immediately after extraction of the root affected by chronic periapical disease and/or seriously damaged hopeless (or fractured) teeth. Only chronic periapical lesions were present and identified by periapical radiolucency.
- Early implant (Type 2 for ITI): when the implant was placed in healed bone after 8 to 12 weeks after extraction of root affected by acute periapical lesion and/or abscess, pus, and clinical symptoms.
- Delayed implant (Type 4 for ITI): when the implant was placed in edentulous mature bone 10 to 12 months after the tooth extraction for different reasons.

Therefore, no randomization was used aiming to follow the principles of the “best clinical practice.”

Surgical Procedures
Cylindrical implants (Premium SP, Sweden & Martina) with a zirconium-oxide–blasted surface; smooth machined collar of 0.5 mm; tulip-shaped platform-switching emergence profile of 0.3 mm; hexagonal internal connection; and 3.8-, 4.25-, or 5.0-mm-diameter (10.0-mm or 11.5-mm length) were used.

One single experienced surgeon performed all surgeries (C.P.). A careful occlusal and periodontal examination was performed on each patient, including presence of plaque, gingivitis, pocket depth, and radiographic bone loss of all remaining teeth. Oral hygiene instruction and periodontal therapy were performed when and where indicated.

Two days prior to the intervention, all patients were asked to comply with a pharmacologic regime that included amoxicillin/clavulanic acid 1 g tablet and application of chlorhexidine digluconate 0.20% gel (Corsodyl Gel, GlaxoSmithKline UK) twice a day, in accordance with a previous study. Antibiotic administration continued for 5 to 6 days after surgery.

All surgical procedures were conducted under local anesthesia with mepivacaine chloride 30 mg/mL (Carboplyina, Dentsply Italia). No computer-aided guide was used.

Implants were placed in order to obtain a nonsubmerged tissue-level healing, with the entire rough surface located in the bone tissue and the smooth neck surface immersed in gingival tissue (supracrestal placement).

The final insertion torque was measured using the W&H Implantmed motor (W&H Dentalwerk Bürmoos) and recorded. The values ranged between 20 and 70 N/cm². An adequate primary stability was obtained in all implants.

The thickness of the mucosa was carefully measured with a periodontal probe, and depending on this, a 1-mm or 2- to 3-mm-high cover-healing screw was selected, which emerged just over the gingival level.

Immediate Implant Placement
For immediate postextractive insertion, an atraumatic flapless root extraction was performed, and a careful inspection of the socket site was made. All granulation tissue was gently debrided from the apical portion of the socket.

Then, a 1.2-mm drill was used to prepare the intrasocket place, following the palatal bony walls as a guide. Twist and calibrated drills at 225 rpm were then used and irrigated with sterile saline solution.

Primary implant stability was obtained by anchoring the implant in the remaining apical portion of the socket at least 3 mm beyond the root apex area.

When necessary (four cases), a porcine corticocancellous bone substitute (Osteobiol MP3, Tecknoss Dental) was applied into the surgical site to fill the socket and to reduce any gaps between the implant and the residual bone.

The thickness of the mucosa was measured with a periodontal probe, and a 1-mm or 2- to 3-mm-high cover-healing screw was positioned following a nonsubmerged healing approach.

Early and Delayed Implant Placement
The surgical procedures were similar for the early and delayed placements. No flaps were reflected.

An initial 1.2-mm-diameter drill was used to mark the position, angle, and depth. The drill passed through the mucosa (transmucosal), cortical bone, and cancellous bone under copious saline irrigation. A twist and calibrated drill at 225 rpm was used, and a site of the adequate depth and diameter was created while irrigating with sterile saline solution.
The entire rough surface was located in the bone, and the smooth surface neck was immersed in gingival tissue (supracrestal placement). The thickness of the mucosa was measured with a periodontal probe, and a 1-mm or 2- to 3-mm-high cover-healing screw was positioned following a nonsubmerged healing approach (as mentioned earlier). No computer-aided surgical guides were used.

**Postoperative Procedures**

A surgical dressing (Coe-Pak, GC) was placed on the wound in all patients and removed at the first clinical control after 1 week.

Patients were instructed to follow a soft diet regime for 1 week, to rinse 3 times/day with 0.12% chlorhexidine gel for 3 weeks, and to perform oral hygiene on the Coe-Pak using a medium toothbrush for the first week and for 2 weeks after surgical pack removal. Thereafter, conventional brushing and flossing were permitted.

**Prosthetic Rehabilitation**

Prosthetic phases started after 3 months from implant insertion. No second surgeries to expose the implant neck were performed. Briefly, cover screws were removed, impression posts were placed, and impressions were made with polyether materials (Permadyne and Garand, 3M ESPE) in customized trays for the pick-up technique.

Customized definitive abutments were screwed on the implants after approximately 15 days, and provisional resin crowns were cemented with temporary zinc-oxide eugenol cement (Temp Bond, Kerr). Definitive prosthetic metal-ceramic rehabilitations, made by two equally experienced prosthodontists, were positioned on definitive abutments and fixed with polycarboxylate cement (Heraeus Kulzer) 12 to 15 days later.

The quantity of the extruded cement was reduced by filling the occlusal half of the crown and maintaining an occlusal space of the abutment screw channel to minimize the hydraulic pressure through slowing cement escape. Patients were instructed to bite on a cotton roll for 5 minutes. Subsequently, dental floss was used to remove the cement flow.

**Follow-up Implant Evaluation**

Active periodontal therapy consisting of motivation, instruction in oral hygiene practice, scaling, and root planing was performed during the entire time of observation; no bleeding on probing and pocket probing depth ≥ 3 mm were detected during the follow-up procedures. Routine follow-up visits were performed every 6 months from implant loading. Occurrence of endodontic treatments on implant-adjacent teeth was also recorded.

**Gingival Thickness Evaluation**

The soft tissue thickness around implants and their corresponding mesial neighboring teeth was determined at the 4-year follow-up. The soft tissue was pierced midfacially at 3 mm apical to the gingival margin with an endodontic file (K-file Nr. 20, Dentsply-Maillefer). The gingival biotype was defined as thick (soft tissue thickness > 2 mm) or thin (soft tissue thickness ≤ 2 mm).

**Radiographic Assessment**

Intraoral periapical radiographs of all implants were taken using a paralleling technique with Rinn-holders and analog films (Kodak Ektaspeed Plus, Eastman Kodak) after implant placement (baseline) and at 1, 3, 6, 12, 24, 36, and 48 months after implant insertion.

The following parameters were used, and a proper standardization was performed before the start of the study. The target-film distance was approximately 30 cm with the sample, 0.41 seconds exposure at 70 kV and 8 mA. The radiographs were developed in a standard developer unit at 25°C (Euronda), 12 seconds developing and 25 seconds fixing according to the manufacturer’s instructions. Patients were asked for a new radiograph when these characteristics were not fulfilled.

All radiographs were scanned with a slide scanner with a resolution of 968 dpi and a magnification factor of ×20.

Radiographic evaluation was performed in single-blind by one additional examiner (F.Z.). Before evaluating the radiographs, the examiner was calibrated using well-defined instructions and reference radiographs with different MBL measures. The crestal marginal bone and the bone-implant interface were examined to evaluate the marginal bone morphology. MBL was assessed at the mesial and distal implant surfaces by measuring the distance between the reference point of the implant platform to the most coronal bone-to-implant contact level using a scale divided into 0.1-mm steps according to previous studies.

ImageJ software (National Institutes of Health) was used to perform all the measurements. Length and diameter of implants were used to calibrate the measurement.

**Evaluated Variables**

MBL was measured and evaluated according to the following variables:

1. Preoperative parameters: Implant location (maxilla/mandible), implant position (anterior/posterior), sex (male/female), endodontically treated adjacent teeth (yes/no), smoke (yes/no), implant placement timing (immediate/early/delayed)
2. Intraoperative parameters: Implant diameter (3.8/4.25/5.0 mm)
3. Postoperative parameters: Gingival thickness (yes/no)

Statistical Analysis
Statistical analyses were performed using Stata 13.1 (StataCorp).

Linear regression models were fitted to evaluate the existence of any significant difference regarding endodontically treated adjacent teeth (yes/no), times (1, 3, 6, 12, 24, 36, and 48 months), and the interactions between endodontically treated adjacent teeth and time. To take into account the correlation in the data due to the presence of multiple implants per subject, the aforementioned regression models were estimated following a generalized estimating equation (GEE) approach. The estimates of coefficients’ standard errors and confidence intervals were adjusted using a robust variance-covariance estimator. The same analysis was performed for all the operative variables.

A multiple linear regression with stepwise selection was fitted to evaluate the relationship between MBL at 36 and 48 months and the following variables: sex (male/female), smoke (yes/no), location (mandible/maxilla), implant position (anterior/posterior), endodontic adjacent teeth (yes/no), adjacent teeth coronal restoration (direct/indirect/no restoration), implant placement timing (immediate/early/delayed), implant diameter (3.8/4.25/5.0 mm), and gingival thickness (thin/thick).

Boxplots were created using Sigma plot 12 software (Systat) to show the range and distribution of MBL (mm) as a function of implant placement timing (immediate, early, delayed) at 1, 3, 6, 12, 24, 36, and 48 months from implant insertion.

RESULTS

Study Population and Demographic Data
According to the inclusion/exclusion criteria, 76 patients (128 implants) were studied with a mean age of 55.6 ± 10.7 years (42 women and 34 men). Eight patients (17 implants) were identified as smokers, consuming from 10 to 20 cigarettes/day, and included in the study; these patients were distributed evenly across the three groups (three in immediate, two in early, and three in delayed group).

The survival rate was 98.4%, as two implants (delayed group) failed during the observational time.

Two nonsmoker patients dropped out after 6 and 36 months, respectively. The total dropout rate was 2.58%. No wound infection, osteitis, and bone graft sequestration occurred during the follow-up period.

The success rate was 97.65%. Mucositis was observed in one patient after 3 months and was caused by a recurrent unscrewing of the implant abutment. The abutment was removed, and the area was carefully treated with chlorhexidine 0.12%. After 1 month, a new abutment was screwed, and a new metal-ceramic crown was cemented.

Two series of periapical radiographs are reported in Figs 1 and 2.

MBL Assessment
MBL of implants and all the clinical parameters evaluated with linear logistic regression analysis are reported in Table 1.

Overall mean MBL showed progressive variation during the evaluation time (48 months). Bone MBL variation was observed at preload time (T1 and T3) with significant changes at T6, T12, and T24 (0.47 ± 0.57, 0.67 ± 0.78, and 0.89 ± 0.81 mm, respectively), as illustrated in Table 1.

No statistically significant differences (P > .05) with minimal variation were observed at T24, T36, and T48 (0.89 ± 0.81, 0.95 ± 0.85, and 0.99 ± 0.68 mm, respectively). The reduction of standard deviation values at T48 suggests a more stable MBL.

Linear logistic analysis of preoperative parameters revealed no statistical differences for implant position, sex, and smoke. In contrast, implant location, presence of endodontic adjacent teeth, and implant placement timing revealed significant differences (P < .05).

Concerning implant diameter as intraoperative and gingival thickness as postoperative parameters, no MBL significant differences were present (P > .05).

Considering implant location, implants placed in the maxilla showed reduced bone loss compared with those placed in the mandible (P < .05).

Implants placed in sites with adjacent endodontically treated teeth showed more bone loss at T36 (mean MBL was 0.70 ± 0.68 mm vs 1.16 ± 0.69 mm, respectively); the differences were statistically significant (P < .001).

Considering implant placement timing, all groups (immediate, early, and delayed) displayed significant variation (Table 1). Early implants showed the lowest bone loss at all the evaluation times. Immediate implants demonstrated a similar behavior up to T6, while delayed implants showed the highest bone loss and significant differences with other groups.

Multilevel mixed logistic regression analysis at T36 and T48 is reported in Tables 2 to 5.

The analysis confirms the significant influence of endodontically treated adjacent teeth (P < .0001), implant placement timing (P = .044), and implant location (maxilla/mandible) (P = .019) parameters. No statistical differences were observed for the other parameters (P > .05) (Table 2). Multiple linear regression after stepwise selection (Table 3) additionally confirms that all three variables statistically affected...
MBL at $T_{36}$ ($P$ value was .001 for endodontic treated adjacent teeth, .031 for implant location, and .044 for implant placement timing).

Multilevel mixed logistic regression analysis at $T_{48}$ is reported in Table 4. Interestingly, none of the evaluated parameters appear to significantly affect MBL at this time. Implant placement timing still appears to be a factor that significantly affects MBL only after stepwise logistic regression, confirming data shown in Table 1 ($P = .020$) (Table 5).

Boxplot representations concerning implant placement timing are shown in Fig 3. The delayed
<table>
<thead>
<tr>
<th>Table 1</th>
<th>Linear Regression Results for All Operative Parameters Using GEE with Robust Covariance Estimator to Account for Correlation in Data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preoperative parameters</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Implant location</strong></td>
<td>n</td>
</tr>
<tr>
<td>Maxilla</td>
<td>70</td>
</tr>
<tr>
<td>Mandible</td>
<td>58</td>
</tr>
<tr>
<td><strong>Implant position</strong></td>
<td>n</td>
</tr>
<tr>
<td>Anterior</td>
<td>16</td>
</tr>
<tr>
<td>Posterior</td>
<td>112</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td>n</td>
</tr>
<tr>
<td>Male</td>
<td>57</td>
</tr>
<tr>
<td>Female</td>
<td>71</td>
</tr>
<tr>
<td><strong>Endodontic adjacent teeth</strong></td>
<td>n</td>
</tr>
<tr>
<td>No</td>
<td>59</td>
</tr>
<tr>
<td>Yes</td>
<td>69</td>
</tr>
<tr>
<td><strong>Smoke</strong></td>
<td>n</td>
</tr>
<tr>
<td>Smokers</td>
<td>17</td>
</tr>
<tr>
<td>Nonsmokers</td>
<td>111</td>
</tr>
<tr>
<td><strong>Implant placement timing</strong></td>
<td>n</td>
</tr>
<tr>
<td>Immediate</td>
<td>24</td>
</tr>
<tr>
<td>Early</td>
<td>21</td>
</tr>
<tr>
<td>Delayed</td>
<td>83</td>
</tr>
<tr>
<td><strong>Intraoperative parameter</strong></td>
<td>n</td>
</tr>
<tr>
<td><strong>Implant diameter</strong></td>
<td>n</td>
</tr>
<tr>
<td>3.8</td>
<td>53</td>
</tr>
<tr>
<td>4.25</td>
<td>56</td>
</tr>
<tr>
<td>5.0</td>
<td>19</td>
</tr>
<tr>
<td><strong>Postoperative parameter</strong></td>
<td>n</td>
</tr>
<tr>
<td><strong>Gingival thickness</strong></td>
<td>n</td>
</tr>
<tr>
<td>Thin</td>
<td>73</td>
</tr>
<tr>
<td>Thick</td>
<td>55</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>128</td>
</tr>
</tbody>
</table>

The implant was used as the unit of analysis (MBL values expressed as mean ± SD). Different superscript letters represent statistically significant values (P < .05) in the same horizontal row (uppercase letters) or in the same column (lowercase letters).

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Multilevel Mixed Logistic Regression Exploring Factors Associated with MBL at 36 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Groups</strong></td>
<td>Coefficient</td>
</tr>
<tr>
<td>Preoperative parameters</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td>0.204</td>
</tr>
<tr>
<td>Location</td>
<td>0.373</td>
</tr>
<tr>
<td>Smoke</td>
<td>0.252</td>
</tr>
<tr>
<td>Position</td>
<td>−0.276</td>
</tr>
<tr>
<td>Endodontically treated adjacent teeth</td>
<td>0.501</td>
</tr>
<tr>
<td>Implant placement timing</td>
<td>0.181</td>
</tr>
<tr>
<td>Intraoperative parameters</td>
<td></td>
</tr>
<tr>
<td>Implant diameter</td>
<td>0.052</td>
</tr>
<tr>
<td>Postoperative parameters</td>
<td></td>
</tr>
<tr>
<td>Gingival thickness</td>
<td>−0.128</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 3</th>
<th>Multiple Linear Regression After Stepwise Selection for Factors Associated with MBL at 36 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Groups</strong></td>
<td>Coefficient</td>
</tr>
<tr>
<td>Implant placement timing</td>
<td>0.168</td>
</tr>
<tr>
<td>Location</td>
<td>0.335</td>
</tr>
<tr>
<td>Endodontically treated adjacent teeth</td>
<td>−0.57</td>
</tr>
</tbody>
</table>

© 2020 BY QUINTESSENCE PUBLISHING CO, INC. PRINTING OF THIS DOCUMENT IS RESTRICTED TO PERSONAL USE ONLY. NO PART MAY BE REPRODUCED OR TRANSMITTED IN ANY FORM WITHOUT WRITTEN PERMISSION FROM THE PUBLISHER.
The group showed the highest presence of outliers, in particular after $T_6$ from insertion (postloading period). The early group showed the most stable MBL values (less wide distributions) up to $T_6$ (preloading time) and at $T_{48}$.

The graph of final insertion torque values distributed into implant placement timing groups is reported in Fig 4. A high percentage (43.9%) of torque values > 50 N/cm$^2$ was observed in the delayed group, while the early and immediate groups revealed a similar final insertion torque distribution, with few discrepancies.

**DISCUSSION**

The present study aimed to investigate which clinical factors after 4 years may affect MBL around platform-switched implants with an enlarged neck placed with a nonsubmerged technique, confirming the results obtained from a 2-year prospective study.\textsuperscript{33}

Different preoperative variables have been analyzed in this study. Some of them were revealed to greatly affect MBL.

*Table 4* Multilevel Mixed Logistic Regression Exploring Factors Associated with MBL at 48 Months

<table>
<thead>
<tr>
<th>Groups</th>
<th>Coefficient</th>
<th>Robust SE</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preoperative parameters</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td>0.226</td>
<td>0.190</td>
<td>(–0.146; 0.598)</td>
<td>.234</td>
</tr>
<tr>
<td>Location</td>
<td>0.138</td>
<td>0.237</td>
<td>(–0.326; 0.604)</td>
<td>.559</td>
</tr>
<tr>
<td>Smoke</td>
<td>0.252</td>
<td>0.146</td>
<td>(–0.034; 0.137)</td>
<td>.084</td>
</tr>
<tr>
<td>Position</td>
<td>–0.186</td>
<td>0.308</td>
<td>(–0.792; 0.419)</td>
<td>.546</td>
</tr>
<tr>
<td>Endodontically treated adjacent teeth</td>
<td>0.329</td>
<td>0.172</td>
<td>(–0.009; 0.668)</td>
<td>.056</td>
</tr>
<tr>
<td>Implant placement timing</td>
<td>0.180</td>
<td>0.150</td>
<td>(–0.113; 0.475)</td>
<td>.229</td>
</tr>
<tr>
<td><strong>Intraoperative parameters</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implant diameter</td>
<td>0.075</td>
<td>0.121</td>
<td>(–0.161; 0.31)</td>
<td>.532</td>
</tr>
<tr>
<td><strong>Postoperative parameters</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gingival thickness</td>
<td>–0.224</td>
<td>0.186</td>
<td>(–0.254; 0.432)</td>
<td>.227</td>
</tr>
</tbody>
</table>

*Table 5* Multiple Linear Regression After Stepwise Selection for Factors Associated with MBL at 48 Months

<table>
<thead>
<tr>
<th>Groups</th>
<th>Coefficient</th>
<th>Robust SE</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant placement timing</td>
<td>0.231</td>
<td>0.998</td>
<td>(0.362; 0.427)</td>
<td>.020</td>
</tr>
<tr>
<td>Gingival thickness</td>
<td>–0.291</td>
<td>0.280</td>
<td>(0.334; 1.432)</td>
<td>.076</td>
</tr>
</tbody>
</table>

**Fig 3** Boxplot representation of placed implants at different evaluation times. Outliers are represented by circle points.

**Fig 4** Final insertion torque graph values distributed according to implant placement timing (immediate, early, and delayed). A greater percentage of insertion torque values < 50 N/cm$^2$ were observed in the delayed group.
Implant location, presence of endodontic adjacent teeth, and implant placement timing were significantly related to MBL at $T_{36}$; the latter remained significant at $T_{48}$.

In multilevel linear logistic regression, the implant location parameter was statistically different, as the maxilla reported lower bone loss. This trend was constant from $T_6$. Other studies reported similar results.41,42

The presence of endodontically treated adjacent teeth is rarely reported in implant clinical investigations.43–46 This parameter was included in the present analysis because it is a frequent clinical condition, particularly when single implant rehabilitations are considered. Indeed, 69 out of 128 implants presented at least one adjacent tooth with an endodontic treatment (53.9%). The presence of endodontically treated teeth adjacent to the implant was responsible for a marked, even significant only at $T_{36}$, marginal bone loss. A number of studies evidenced marginal bone loss in teeth adjacent to the implants with MBL values $> 1.0$ mm at $T_{48}$.47–50

Other investigations suggested and/or supported the negative influence of treated root canal on adjacent implants.45,51

Localization of dormant bacteria around asymptomatic endodontic treated teeth into the dentinal tubules or along accessory canals is well recognized.52–56

These bacteria may be able to maintain a persistent inflammatory state on adjacent sites, with the result of higher bone tissue being more susceptible to inflammation.55,56

For these reasons, a radiologic follow-up of endodontically treated teeth might be important to identify a critical condition that may affect bone architecture remodeling.

Implant placement timing was found to be the most significant factor affecting MBL in this study on nonsubmerged platform-switched tulip-shaped implants.

The delayed group (implant placement timing) revealed significant differences from $T_3$ to $T_{48}$, showing greater bone loss compared with both immediate and early implants. Indeed, boxplots (Fig 3) clearly evidence that delayed implants presented a wider distribution of implants with MBL values $> 1.0$ mm at $T_{48}$. These changes, although difficult to detect clinically, may provide important information to detect increased bone remodeling.

The presence of thicker cortical mature bone in the delayed group may be responsible for higher torque values (Fig 4) and higher stress on marginal tissue during drilling and insertion procedures. Drilling procedures at the implant site may be responsible for bone necrosis and bone smear layer formation, inducing the activation of osteoclasts and vascularization damage. Both of these conditions may be responsible for higher bone resorption of the mature cortical bone.57,58

Implant placement timing (immediate, early, and delayed) was not randomly decided, but made on the basis of several clinical criteria: presence of acute endodontic periapical lesion (with pain, fistula, exudate/pus, tenderness, and radiographic apical translucency, or all of them) and/or the presence of chronic periapical disease (Periapical Index 3–4).59

Considering sex, female patients showed an increased MBL after 3 years, compared with male patients (mean $T_{36}$ MBL was $1.08$ mm vs $0.83$ mm, respectively). These differences were not statistically significant and, subsequently, clinically irrelevant. From the literature, male patients seem to have higher risks of implant failure; however, these data are controversial, as it is difficult to correlate peri-implant bone loss and patient sex.60

In the present study, smoking was found to not significantly affect MBL in the medium term. The small sample size of smoking patients and the group discrepancies (17 implants in 8 patients vs 92 implants in 57 patients) may justify this finding. A limit of 20 cigarettes/day has been adopted in the present study following the distinction of moderate smokers found in a previous work, where significantly higher failure rates were found in patients smoking more than 20 cigarettes/day, whereas no differences were found between patients smoking 1 to 10 cigarettes/day (9.1%) and 10 to 20 cigarettes/day (12%).29

Implant position parameter did not significantly influence MBL at $T_{36}$ and at $T_{48}$ ($P > .05$). The group discrepancies may have influenced this result.

Gingival thickness was evaluated in all patients at the 48-month follow-up. Interestingly, even though thin biotype showed higher values of MBL, this parameter appears not to influence MBL at 36 and 48 months ($P > .05$), and this variation was clinically undetectable.

The enlarged neck was partially immersed along the soft tissue thickness, the entire 0.50-mm smooth machined neck surface was close to the most superficial gingiva, and the rough surface was just at supracrestal placement level.

Several benefits may be provided following the nonsubmerged technique. As cover screws (or healing screws, depending on the soft tissue thickness) were exposed at soft tissue levels, additional surgeries before the prosthetic phases are avoided. The implant-abutment connection, as well as the crown margins, were more distant from bone tissues, allowing a better control of cement flowing from the restoration and avoiding the risks for cement overflow and retention in proximity with the bone tissues.61

This risk was reported in several studies where subcrestal (submerged) or equicrestal implants were performed, considering that subgingival cement excess cannot be adequately controlled62–64 or considering...
the use of irritating methacrylate-based cements. A recent study evaluated clinical radiographic and immunologic parameters around platform-switched implants with cement-retained or screw-retained restorations. The conclusions were that the type of crown retention does not affect bleeding on probing, pocket depth, MBL, and levels of IL-1B. In contrast, in the present study, a nonirritating polycarboxylate cement was used as the luting agent.

MBL values follow a similar trend compared with those previously reported with other implant brands, neck, insertion depth, and surgical interventions. A previous randomized clinical trial evaluating bone-level implants placed submerged or with a transmucosal approach found similar MBL values at 36 months. Likewise, MBL remained stable after the first 12 months from insertion, where the greater bone-level changes occurred.

The study demonstrated that significant bone-level changes/remodeling during the preload period occur. This concept has also been reported with other implants and surgical approaches.

Indeed, in the present study, mean MBL at 3 months (preload) was statistically different compared with MBL at 6 months (postload) (P = .001), with the values being 0.28 ± 0.56 and 0.47 ± 0.57, respectively, thus corroborating this hypothesis.

Data on implant depth insertion are mostly from histologic studies. Implants with a tulip-shaped (flared) neck placed in a most-apical position revealed more bone loss compared with the same implants placed supracrestally. This was attributed to the removal of a great portion of the coronal bone, thus potentially compromising blood supply of the remaining cortical bone.

In accordance with these histologic findings, a recent randomized clinical trial concluded that the preparation of the implant site following a subcrestal approach may induce more stress on marginal bone, which can turn into greater bone resorption after implant placement.

It should be underlined that the radiographs in the present study were performed using a parallel technique with Rinn Holders. This technique may reveal drawbacks in terms of less precision or accuracy in determining crestal bone height compared with traditional three-dimensional computed tomography (CT); however, CT is still considered excessive for routine assessment of crestal bone heights. This is particularly true when aiming to assess MBL on single implant restorations. The use of a standard developer unit, with predefined operative parameters, the possibility to repeat the periapical radiographs, the use of standard software with proper magnification, and the calibration of the x-rays using known length and diameter helped to standardize the processes of x-ray acquisition, development, and analysis.

It must be taken into account that the reduced bone loss values reported may be influenced by the expertise of the operator who performed the surgeries and the possibility of patients being included in a hygienic recall program. Moreover, the insertion protocol was not standard, but out-of-label. In this way, this implant may behave as a Straumann Tissue level with a shorter smooth neck.

This protocol will be further validated with long-term follow-up.

CONCLUSIONS

Conclusions may be summarized as follows: (1) tulip-shaped neck platform-switched implants may be placed at tissue level (nonsubmerged) with a minimal-invasive flapless technique; (2) the present protocol demonstrated reduced bone loss in the early phases from implant placement and MBL stability at 36 and 48 months; (3) among all the evaluated parameters, only implant placement timing appears to significantly affect MBL before loading and during the entire period of observation; and (4) delayed implant placement was responsible for higher bone loss compared with early and immediate implants.

ACKNOWLEDGMENTS

The authors claim to have no financial interest, either directly or indirectly, in the products or information listed in the article.

REFERENCES


