CLINICAL ORAL IMPLANTS RESEARCH

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# Immediate vs. delayed loading in the posterior mandible: a split-mouth study with up to 15 years of follow-up

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**Abstract**

**Purpose:** The aim of this study was to evaluate the long-term clinical and radiographic outcomes of implants that were immediately loaded in a prospective, randomized, split-mouth clinical trial in the posterior mandible.

**Materials and methods:** Patients with alveolar ridges that were bilaterally edentulous distal to the canines were enrolled to participate. On one randomly selected side of each patient's jaw, three implants (control group) with platform switching and a progressive thread design were placed, allowed to heal for 3 months, uncovered, and loaded occlusally using resin-splinted crowns, which then were replaced 6 weeks later by final prostheses. Three additional implants (test group) of the same size and design were placed on the contralateral side of each patient in symmetrical locations. The test implants were connected to their final abutments immediately after placement and immediately loaded. Periodontal indices and bone loss were evaluated at regular intervals.

**Results:** After a mean loading period of 12.14 (±0.89) years for the test group and 12.40 (±0.89) years for controls, differences between the immediately and delayed loaded implants were not statistically significant ($P > 0.05$). The crestal bone loss was (mesial) 0.70 (±1.09) mm (test group) and 1.17 (±1.27) mm (control group) and the distal bone loss was 0.43 (±1.02) mm (test group) and 1.06 (±1.33) mm (control group) ($P > 0.05$). The maximum crestal bone loss was 3.12 mm for the test group and 3.78 mm for the controls after 10.125/10.397 years, respectively.

**Conclusion:** Immediate loading does not negatively influence the long-term prognosis of dental implants in the posterior mandible, improves the implant stability, and is associated with minimal crestal bone loss when platform switching and a one-abutment concept with a Morse-tapered connection are used.

Over the last few decades, maxillary and mandibular implants placed in fully edentulous patients have been successfully immediately loaded using different types of prosthetic restorations (Babbush et al. 1986; Ledermann 1996; Balshi & Wolfinger 1997; Chiapasco et al. 1997; Tarnow et al. 1997; Testori et al. 2004; Romanos & Nentwig 2009; Degidi et al. 2010; Maló et al. 2012; Romanos et al. 2011, 2013a,b,c). Successes have also been reported for splinted crowns with no occlusal contacts delivered early or immediately to partially edentulous patients (Testori et al. 2007; Merli et al. 2008; Cannizzaro et al. 2010). However, in the partially edentulous jaw, cross-arch stabilization is not possible, and therefore, loading forces cannot be as well distributed, increasing the risk of bending moments (Rangert et al. 1995) and subsequent implant failures, especially when implants are loaded immediately after placement.

Previous studies performed by Degidi et al. (2006) and recent studies by Margossian et al. (2012) showed high success rates of immediately loaded implants placed in good bone quality with resonance frequency analysis (RFA) values > 60 implant stability quotient (ISQ) at the time of implant insertion and implant insertion torque (IT) >25 N or 30 N cm.

The implant failure under immediate loading compared to delayed loading was evaluated in seven randomized clinical trials (RCTs) (Chiapasco et al. 2001; Romeo et al. 2002; Assad et al. 2007; Shibly et al. 2010; Barewal et al. 2012; Elsyad et al. 2012; Margossian et al. 2012). For the immediate loading group, the implant failure rate was 2.87% (11/383) compared to 1.8% (5/278) in the delayed loading group. Overall, there was no difference in implant failure rate between these two groups.

Some success has been demonstrated for implants placed in the edentulous mandible

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and immediately loaded with splinted crowns. When such implants were compared in a split-mouth study to implants that were submerged for 3 months before being loaded, 100% of the immediately loaded implants survived after 2 years, and more crestal bone loss was found in the delayed loaded implants (Romanos & Nentwig 2006). While 2-year implant survival is high according to Romanos & Nentwig (2006), it is still important to evaluate implant performance over the long term and compare the peri-implant soft and hard tissues with delayed loaded implants in the same patients.

The present investigation was undertaken to evaluate the long-term clinical and radiological outcomes of posterior mandibular implants that were immediately loaded with splinted crowns and compare them with delayed loaded implants healed in a submerged mode.

## Material and methods

This clinical prospective and descriptive study was approved by the ethics committee of the Johann Wolfgang Goethe University, Faculty of Medicine Frankfurt, Germany, and conformed to the Declaration of Helsinki (1964) (no. 91/99). Patients at the university were invited to participate if they were seeking implant-supported restorations and met the following inclusion criteria:

- Bilateral mandibular edentulism distal to the canines or first or second premolars;
- Sufficient bone to accommodate implants that were at least 9.5 mm long.

Exclusion criteria were as follows:

- Use of alcohol, drugs, or other medications;
- Recent treatment with radiation or chemotherapy;
- Pregnancy.

A comprehensive clinical and radiological examination was performed before surgery. Three implants with a progressive thread design (Ankylos®; Dentsply Implants, Waltham, MA, USA) were placed on each side of each patient's partially edentulous posterior mandible. These implants have a Morse-tapered conical implant/abutment connection, and the design incorporates platform switching. In areas where anatomical limitations required the use of shorter implants (9.5 mm long), the implant diameter was 4.5 mm. Otherwise, 11-mm-long and 3.5-mm-diameter implants were placed. On the contralateral (control) side, implants with identical diameters and lengths were placed in the symmetrical positions. All implants were placed at the level of the alveolar crest.

Control group implants healed submerged for 3 months. Second-stage surgery was then carried out, and the cover screws were removed (the cover screws were incorporated in the implant design) for abutment connection. Implants with mobility during the cover screw removal were considered as "failures" due to lack of osseointegration. Abutments were connected to all control implants, and the implants were loaded with provisional restorations. No occlusal contacts in the lateral movements of the mandible were allowed during the provisionalization stage. An effort was made to achieve group function.

Test implants were inserted, and the cover screws were removed for immediate connection to the final abutment (one-abutment concept) and loaded with provisional restorations (with central occlusal contacts in the maximal intercuspation, ICP) (Romanos 2003).

Test implants having mobility during the removal of the cover screws were considered as not primarily stable and were excluded from the study.

The final torque for abutment connection using straight abutments was 20 N cm. For angulated abutments, it was 15 N cm, according to the manufacturer's guidelines.

Final metal-ceramic restorations were delivered 6 weeks after surgery when impressions were taken without removing the abutments using a closed tray and prefabricated impression caps to make impressions from the abutment level. Impregum® (Espe, Seefeld, Germany) was the impression material.

All implants were examined clinically and radiographically at regular intervals (3, 6, 9, 12, 18, and 24 months after loading and thereafter annually). Clinical assessments included the Plaque Index (PI; Silness & Löe 1964), Sulcus Bleeding Index (SBI; Mühlemann & Son 1971), probing pocket depth (PPD) in mm using a PCP 12 periodontal probe (Hu Friedy, Chicago, IL, USA), width of the keratinized mucosa (KG) in mm, and gingival recession (Rec) measured from the crown margin to the gingival margin (in mm). Implant stability (PV) was assessed using the Periotest® device (Medizintechnik Gulden, Modautal, Germany) (Olivé & Aparicio 1990) on the day of surgery and after 3, 6, 9, 12, 18, and 24 months of loading, as well as at the most recent follow-up visit. At each assessment, for both test and control implants, the provisional and final restorations were removed because they were cemented with provisional cement material. The handpiece of the Periotest device was then placed over the definitive abutment (after final torque of the abutment). Panoramic radiographs were used to evaluate marginal bone levels (mesially and distally) around both the test and control implants.

In an effort to eliminate any distortion, traditional panoramic radiographs were taken using the same panoramic unit for all assessments, and identical methods were used to develop each patient's radiographs. Bone levels were recorded by a clinician familiar with the Sidexis® software (Next Generation® Viewer 1.51; Sirona, Bensheim, Germany; Gomez-Roman et al. 1999) and unaware of which group each patient belonged to (test or control). Later values were compared with those obtained at baseline.

### Statistical analysis

The 10 patients were evaluated in the latest follow-up examination and were part of the initial clinical prospective and descriptive study including 12 patients. The patient was the statistical unit. Six values were clustered within each patient. The test and the control implants were 30 implants per group (60 in total) placed in the 10 patients (six implants per patient, three test and three control group implants).

A descriptive analysis of the clinical parameters of the patients for the test and control group implants was carried out. The non-parametric multivariate comparison Brunner–Langer (longitudinal model) test was used for the comparison of the data. Significance level was set as $P < 0.05$. The R-Package nparLD software (http://www.jstatsoft.org/v50/i12/) was used for this statistical evaluation.

## Results

Seven male and five female patients with a mean age of 50.75 (±7.95) years were enrolled initially to participate in this prospective clinical study. Four patients had removable maxillary prostheses, and eight patients had periodontally healthy teeth or fixed prosthetic reconstructions. Six of the 12 patients were occasional smokers. Of the total 72 implants placed, 66 implants were 11 mm long and 3.5 mm in diameter, and 6 were 9.5 mm long and 4.5 mm in diameter. After 2 years, two of the patients relocated and were not available for follow-up evaluation. Therefore, 10 patients were included in the final clinical and radiological evaluation.

***Table 1.*** **Descriptive statistics for periodontal parameters on immediately loaded (test) and delayed loaded implants (control)**

| | PV test | PV control | RC test | RC control | KG test | KG control | PI test | PI control | SBI test | SBI control | PPD test | PPD control |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mean | −3.066 | −1.3 | 0.3 | 0.2 | 1.733 | 2.00 | 0.566 | 0.433 | 0.066 | 0.00 | 2.53 | 2.6 |
| Standard deviation (SD) | 3.2582 | 3.7522 | 0.8366 | 0.48423 | 1.362 | 1.2318 | 0.935 | 0.626 | 0.253 | 0.00 | 0.63 | 0.498 |
| Sample size (*N*) | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 |
| Standard error mean (SEM) | 0.5948 | 0.68506 | 0.1527 | 0.08840 | 0.248 | 0.22489 | 0.1707 | 0.1143 | 0.046 | 0.1143 | 0.11 | 0.0909 |
| Lower 95% conf limit | −4.2832 | −2.7010 | −0.0123 | 0.0192 | 1.224 | 1.5401 | 0.2174 | 0.1995 | −0.028 | 0.1995 | 2.30 | 2.414 |
| Upper 95% conf limit | −1.8502 | 0.10095 | 0.6123 | 0.3808 | 2.24 | 2.4599 | 0.9158 | 0.667 | 0.161 | 0.667 | 2.78 | 2.786 |
| Minimum | −8.00 | −7.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 1.00 | 2.00 |
| Median (50th Percentile.) | −3.00 | −1.500 | 0.00 | 0.00 | 2.00 | 2.00 | 0.00 | 0.00 | 0.00 | 0.00 | 3.00 | 3.00 |
| Maximum | 3.00 | 7.00 | 3.00 | 2.00 | 4.00 | 4.00 | 4.00 | 2.00 | 1.00 | 2.00 | 4.00 | 3.00 |

The mean loading period for the remaining 10 patients was 145.72 (±10.73) months for the test group and 148.82 (±10.77) months for the control group. No visible implant mobility was observed in any of the observation periods in either group after removal of the prosthetic restorations (100% survival rate). Descriptive statistics of the periodontal parameters are demonstrated in the Table 1. Using the Brunner and Langer comparison, we found no statistically significant difference between the test and control subjects in the clinical parameters assessed ($P > 0.05$); only the Periotest values showed a statistically significant difference ($P < 0.05$) between the immediately loaded group and the delayed loaded group with better mean values (greater implant stability) for the immediately loaded implants. All presented values, indicating no pathology. Table 2 displays those values after Brunner and Langer comparison.

Mean values for radiological crestal bone loss were (mesial) 0.70 (±1.09) mm for the test group and 1.17 (±1.27) mm for the control group. The distal bone loss values were 0.43 (±1.02) mm for the test group and 1.06 (±1.33) mm for the control group ($P > 0.05$). The maximum bone loss in the test group was 3.12 and 3.78 mm in the control group after 121.5/124.77 months, respectively (Figs 1–4). The differences of crestal bone loss between the two groups were not statistically significant ($P > 0.05$) (Table 3).

## Discussion

Anatomical considerations in the posterior mandible include limitations on the available bone (width and density), the common need to undersize osteotomies in order to improve primary stability, and use of bone grafting, narrow diameter, and/or short implants. All these may pose additional risks. Biomechanical factors such as the increased loading forces in this area also may be associated with higher failure rates (Jemt & Lekholm 1993), and there is evidence of a higher prevalence of peri-implantitis in the posterior parts of the jaws (Esposito et al. 1998; Montes et al. 2007; Doan et al. 2014).

***Table 2.*** **Brunner and Langer, non-parametric multivariate comparison for the periodontal parameters with or without immediate loading**

| Periodontal Parameter | Group | Adjusted means (%) | *P*-value | Significance |
|---|---|---|---|---|
| PV | Delayed loaded | −1.23 | **0.04232*** | **<0.05** |
| | Immediately loaded | −3.172 | | |
| RC | Delayed loaded | 0.192 | 0.0921 | >0.05 |
| | Immediately loaded | 0.286 | | |
| KG | Delayed loaded | 1.873 | 0.4587 | >0.05 |
| | Immediately loaded | 1.629 | | |
| PI | Delayed loaded | 0.418 | 0.9123 | >0.05 |
| | Immediately loaded | 0.551 | | |
| SBI | Delayed loaded | 0.007 | 0.0631 | >0.05 |
| | Immediately loaded | 0.0643 | | |
| PPD | Delayed loaded | 2.565 | 0.7216 | >0.05 |
| | Immediately loaded | 2.498 | | |

Bold letters are showing statistical significant differences between delayed loaded and immediately loaded groups. The PV was significant higher in the immediately loaded group (better implant clinical stability) compared to the delayed loaded group. Statistical significance was set as $^*P < 0.05$.

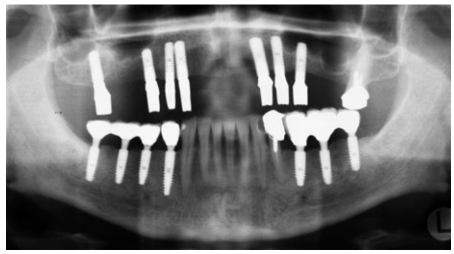

*Fig. 1.* Postoperative radiograph presenting immediately loaded implants (left side) and delayed (right side) after 15 years of loading. Observe the crestal bone loss around the implants in the maxilla, which were placed later and were loaded for only 2 years.

The present study demonstrates comparable long-term (up to 15 years) success for dental implants placed in the posterior mandible and functionally loaded both immediately and after a 3-month healing period. Maintenance of crestal bone around the platform-switched implants was similar for both groups and not apparently influenced by the loading protocol. A better implant stability was found for the immediately loaded implant group compared to the group with the conventional loading protocol.

This long-term study confirms previous findings that crestal bone maintenance may be associated with platform switching (Romanos et al. 2002; Lazzara & Porter 2006; Romanos & Nentwig 2009), when the abutments are not removed and restorations are fabricated using impression copings directly over the abutments. This protocol has also been extensively evaluated using the same implant design with crestal or subcrestal implant placement and the one-abutment concept after long-term clinical and radiological evaluation (Romanos et al. 2013a). The minimal crestal bone loss around the implants in the control group of the present study was associated with the implant uncovering (second-stage surgery), in which the implant platform was exposed

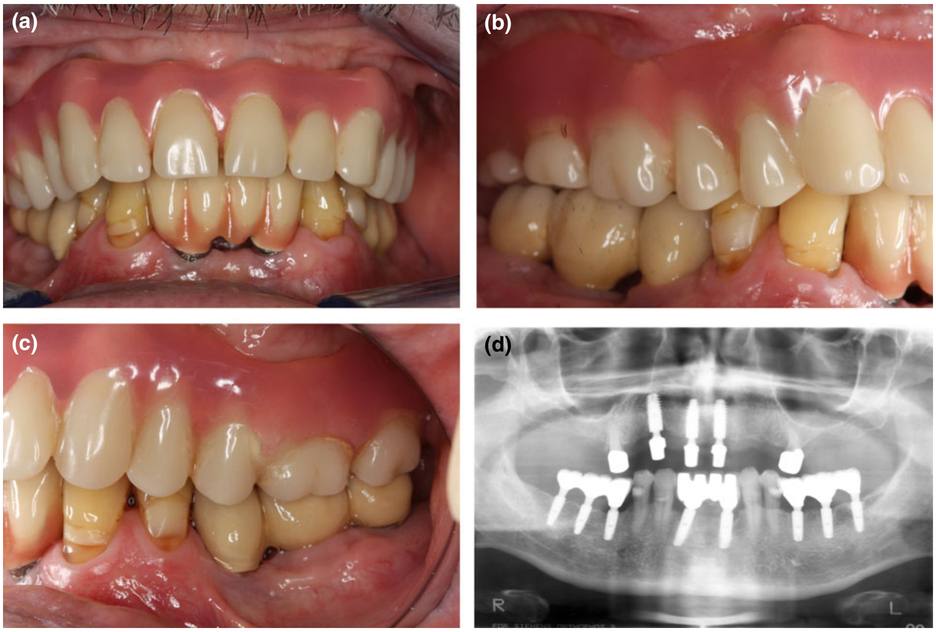


*Fig. 2.* Clinical photograph of the patient 15 years after rehabilitation in the posterior mandible (a). The right side implants with splinted crowns after delayed loading (b) and at the left side after immediate loading (c) after 15 years of loading. (d) Postoperative radiograph presenting immediately loaded implants (left side) and delayed (right side) after 15 years of loading showing crestal bone maintenance.

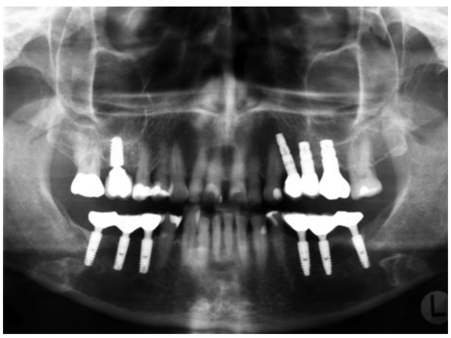

*Fig. 3.* Postoperative radiograph presenting immediately loaded implants (right side) and delayed (left side) after 12 years of loading. Observe the crestal bone loss around the implants in the left maxilla having another implant design and conventional butt joint connection.

after periosteal elevation. This phenomenon leads to bone resorption, a physiological phenomenon. Minimally invasive techniques are therefore recommended, especially when platform-switched implants are used, to avoid extensive periosteal elevation and possible removal of bone covering the implant platform.

Previous studies have demonstrated long-term success for implants placed in the posterior maxilla and non-occlusally loaded immediately after surgery (Testori et al. 2007). The present study confirms that long-term success also is possible for immediately loaded implants placed in the posterior mandible, where in most cases, the bone is structurally spongious (soft) compared to the anterior mandible (Qu 1994). In addition, the results show no significant long-term differences in peri-implant soft tissue quality and tissue response.

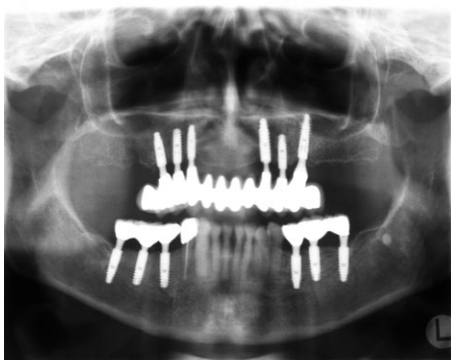

*Fig. 4.* Postoperative radiograph representing crestal bone maintenance for immediately loaded (left side) and delayed (right side) implants after 12 years of loading. The patient was a heavy smoker. The maxillary implants were loaded immediately as well.

*Table 3.* **Crestal bone loss of the test and control group at the final evaluation**

| Assessment measure | Test group ($n$ = 30) | Control group ($n$ = 30) | $P$-value |
|---|---|---|---|
| Crestal bone loss (mesial) | 0.70 (±1.09) mm | 1.17 (±1.27) mm | 0.84 |
| Crestal bone loss (distal) | 0.43 (±1.02) mm | 1.06 (±1.33) mm | 0.90 |

The risk of rotary movements (bending moment) in the posterior part of the jaws is high (Rangert et al. 1995). Therefore, an excellent implant–abutment connection in conjunction with high primary stability appears to be a key to success (Romanos 2009). A recent *in vivo* study comparing the implant–abutment interface in patients who had two implant designs in their mandibles – one incorporating a Morse-tapered implant–abutment connection and the other an internal butt joint connection – showed that the butt joint connections contained periodontopathogenic bacteria, which may be related to peri-implant crestal bone loss, independent from the presence or the absence of platform switching (Romanos et al. 2013c, 2014). An excellent seal between the implant and abutment appears to be essential for preventing crestal bone loss (Romanos 2009).

Additional factors also may contribute to maintaining the crestal bone level, including implant immobilization (Degidi et al. 2010; Romanos et al. 2013b), platform switching (Lazzara & Porter 2006; Romanos & Nentwig 2009), and the use of a roughened surface at the implant top (Calvo-Guirado et al. 2014). Guidelines for fostering the maintenance of the crestal bone have recently been described (Romanos 2014). Biological factors such as tissue preservation and gentle bone preparation also are associated with less bone resorption. The negative effect of crestal bone loss due to bone planing around platform-switched implants placed in the anterior mandible was demonstrated recently in a clinical study with two implant designs (Romanos et al. 2013c). Therefore, gentle bone preparation is significant for the stability of the bone crest around dental implants with delayed or immediate loading.

## Conclusion

The study demonstrates the long-term success of platform-switched implants with a Morse-tapered connection at the implant–abutment junction for which abutments were never disconnected using delayed or immediate loading protocol. It appears that the immediate loading protocol in the posterior mandible can enjoy long-term success similar to that achieved with the traditional delayed protocol, when some basic requirements are considered.

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