

Immediate Occlusal versus Non-Occlusal Loading of Implants: A Randomized Clinical Pilot Study

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ABSTRACT

Background: Immediate occlusal and non-occlusal loading protocols have been discussed and, despite varying success rates, are considered viable in selected cases. Preoperative implant planning and intraoperative transfer are essential to the success of implant-supported reconstructions in partially or completely edentulous jaws.

Purpose: This study was performed to compare clinical outcomes of immediate occlusal versus non-occlusal loading of posterior implants.

Materials and Methods: Of 19 patients with 52 screw-type implants replacing mandibular molars or premolars, nine patients with 21 implants were randomized to a study group that received immediate restorations with occlusal loading, whereas 10 patients with 31 implants were randomized to a control group that received provisional restorations without occlusal loading. Occlusal loading was defined as full loading in maximum intercuspitation. Single-tooth or splinted multiunit restorations were incorporated by screw retention or cementation. Marginal bone defects (MBD), implant survival, and implant success were evaluated 12 months after insertion.

Results: Both groups revealed similar MBD levels consistent with previous reports. No implants were lost (overall survival: 100%) or found to fail (overall success: 100%). No significant intergroup differences were noted for any of the evaluated parameters.

Conclusions: Immediate restorations in partially edentulous mandibles demonstrated successful clinical and radiographic 12-month results. Larger long-term prospective studies are needed to confirm the final evidence and predictability of immediate functional loading as a standard treatment concept for partially edentulous jaws.

KEY WORDS: computer-assisted, immediate loading, marginal bone loss, surgical guides, survival rate

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BACKGROUND

Recent treatment concepts in implant dentistry have been developed with the objectives of exposing patients to as few surgical interventions as possible and of sparing them postoperative discomfort. A major step in this direction has been to introduce concepts of immediate loading for use both in the mandible and in the maxilla. Immediate loading protocols have since been extensively discussed in the literature and found to be a viable treatment approach in selected cases¹⁻⁸ with implant survival rates of 95 to 98.8% in the posterior mandible.⁹⁻¹¹

Bruxism and severe clenching have been suspected to increase the risk of failure among immediately loaded implants.¹² To avoid complications of this type, non-functional protocols of immediate loading have been introduced with the objective of protecting newly inserted implants from exposure to any excessive

functional or parafunctional forces in partially dentate patients.¹³

The real problem, however, might be the current paucity of information on any effects of immediate functional provisionalization.¹⁴ Recent studies have reported lower implant survival rates after immediate functional loading than after both nonfunctional immediate restoration and delayed loading.^{15,16} Other authors, by contrast, did not note any differences between immediate functional and nonfunctional loading regarding implant survival, bone loss, or soft-tissue healing.^{7,8,11,17}

The aim of this prospective randomized pilot study was to assess changes in marginal bone levels, implant success, and implant survival after immediate functional versus nonfunctional loading of posterior implants in partially edentulous patients up to 12 months postoperatively.

MATERIALS AND METHODS

The study was conducted following the International Conference for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practice. Guidelines for Clinical Trials and the Declaration of Helsinki as revised in 2008. Institutional approval was obtained from the local ethics commission at the Medical University of Graz (ref: 23–202 ex 10/11).

Patients

Twenty patients were enrolled in this pilot study between March 2011 and April 2012, all of them giving their informed consent after being comprehensively informed about the study. A total of 59 implants were originally planned. All patients were treated at our center exclusively. Each patient was screened by reviewing his or her medical history, obtaining a panoramic radiograph, performing a clinical examination, and taking an alginate impression (Xantalgin® select; Heraeus Kulzer, Hanau, Germany). Only adult patients showing partial edentulism in posterior segments were included in the study. Patients were excluded if they presented with a smoking habit (>10 cigarettes a day), active inflammation in the target area, metabolic disease, previous irradiation or chemotherapy in the head-and-neck area, treatment with bisphosphonates, pregnancy, or parafunctional habits with evidence of severe bruxing or clenching. All restorations were planned by an experienced clinician using a prosthetic-

driven approach. Three-dimensional implant planning was prepared by fabricating a radio-opaque scan prosthesis for each patient from a self-curing resin (Paladur; Heraeus Kulzer) mixed with a barium-sulfate powder (mixing ratio 3:1).

Radiographic Examinations

A diagnostic orthopantomogram (Orthophos XG Plus; Sirona, Bensheim, Germany) was obtained during the screening visit. Three-dimensional imaging included a computed tomography (CT) scan in one patient and cone-beam computed tomography (CBCT) scans in 19 patients. A Somatom Sensation 16 unit (Siemens, Bensheim, Germany) was used for the CT scan (collimation: 16×0.75 mm; layer thickness: 0.75 mm; increment: 0.5 mm; 12 kV; 80 mAs; field of view: 105 cm; rotation time: 0.75 seconds; kernel: H60 sharp) and a Promax 3D unit (Planmeca Oy 00880, Helsinki, Finland) for the CBCT scans (kV: 8G; mA: 14; 12 seconds).

Implant Planning

Each restorative treatment plan was verified for consistency with patient anatomy and location of sensitive structures by using three-dimensional implant planning software (Simplant® Crystal; Materialise Dental, Leuven, Belgium). Implants were placed in a virtual environment to verify the restorative treatment plan (Figure 1), and a tooth-supported surgical guide was ordered online. To ensure a precise fit of this guide, the shipment also included a stone cast for direct correction of any inaccuracies.

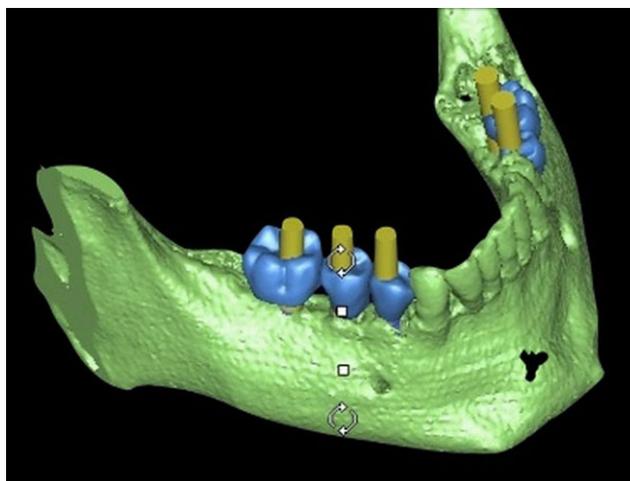


Figure 1 Three-dimensional computer-aided planning (Simplant Crystal) enabling optimal prosthetic-driven implant position.

Group Assignment and Medication

Patients were instructed to rinse with chlorhexidine digluconate 0.2% for 1 minute before surgery, which was conducted under local anesthesia (Ultracain dental forte®; Sanofis-Aventis, Vienna, Austria). Antibiotic treatment (Augmentin 1 g twice daily; Smithkline Beecham, Worthing, UK) was started 1 day before surgery and carried on for 5 days. Patients were randomized to a study group or a control group by an independent examiner prior to laboratory fabrication, using permuted blocks as randomization method within Randomizer for Clinical Trials provided by our Institute for Medical Informatics, Statistics, and Documentation (<http://www.randomizer.at>). Patients in the study group were to receive immediate restorations offering full occlusal loading (Hanel Shimstock, Coltène/Whaledent 89129, Langenau/Germany) while in the control group immediate restorations were adjusted to infraocclusion in maximum intercuspidation.

Implant Placement

Stereolithographic tooth-supported guides were implemented to transfer the three-dimensionally planned implant positions to the surgical situation (Figure 2, A and B). The same implant system (XiVE®; Dentsply Friadent, Mannheim, Germany) was used, and all implants were inserted in accordance with the drilling protocol recommended by the manufacturer. Primary stability was recorded in terms of insertion torque and Periotest values. Provisional splinted restorations were delivered to the implants on temporary abutments (TempBase®; Dentsply Friadent) not later than 72 hours after implant placement (Figures 3 and 4). Once the restorations were in place, any manipulations other than occlusal adjustment, retightening of loosened screws, or recementation were avoided.

Immediate Provisional Restorations

Using a standardized protocol, restorations included single-unit or splinted crowns in case of adjacent implants made from resin (SR Ivocron®; Ivoclar Vivadent, Schaan, Liechtenstein) and designed for immediate use on customized temporary abutments (TempBase) either with or without occlusal contacts as dictated by the group assignment. Restorations were screw retained or cemented to temporary abutments for immediate delivery within 72 hours.

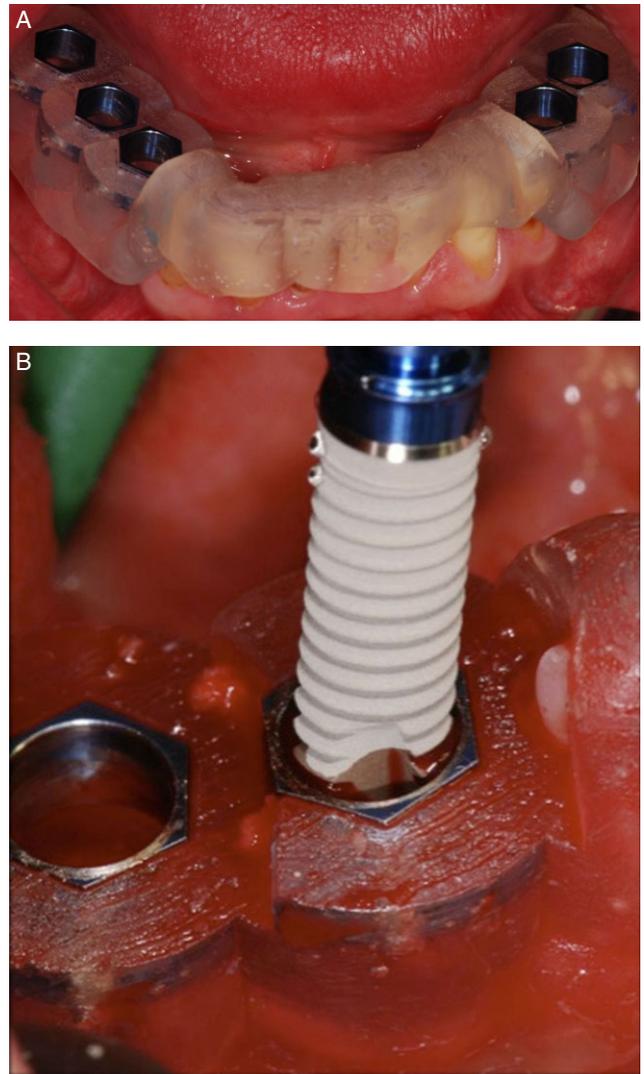


Figure 2 A, Tooth-supported stereolithographic surgical guide in situ. B, Guided implant placement (XiVE) via guide facilitating optimal position and angulation.

Follow-Up

One week after surgery, gingival¹⁸ and plaque¹⁹ scores were recorded, and the mucosa was examined for signs of inflammation, necrosis, dehiscence, or pyogenic infection. Follow-up visits were performed at 4-week intervals to examine the mucosa, verify the stability of the provisional restorations, and evaluate dental adverse events. Occlusal adjustments were made during the same visits, including adaptations as dictated by the randomization protocol. Marginal bone defects (MBD) were evaluated by obtaining digital perpendicular long-cone radiographs immediately after surgery (baseline) and 1, 2, 3, 6, and 12 months thereafter. Evaluations performed at the last follow-up included gingival and plaque scores, Periotest values, occlusal parameters, and



Figure 3 Minimal invasive flapless inserted implants plus temporary abutments (TempBase) immediately postop.

a radiographic assessment. The definitive functional restorations were delivered either splinted or as single-tooth restorations 6 to 8 months after the implant procedures (Figure 5, A and B). Success criteria defined by Misch and colleagues²⁰ were evaluated 12 months after implant insertion.

Radiographic Analysis

Marginal bone defects were assessed by an examiner (M.S.) not involved in the surgical and restorative

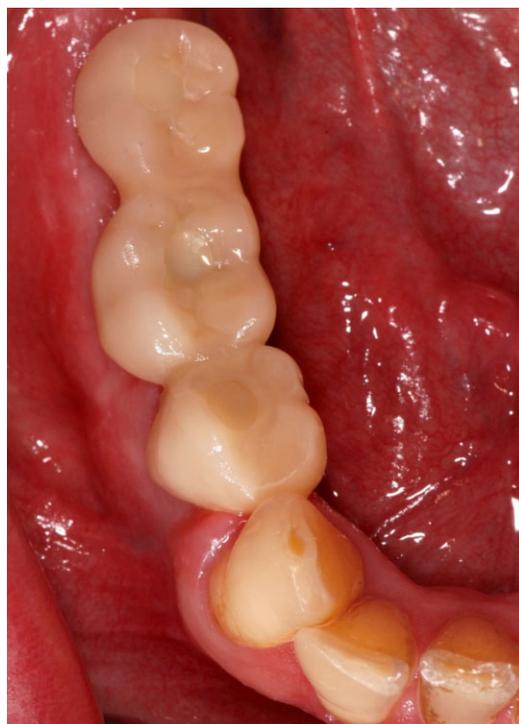


Figure 4 Immediate provisional three-unit restoration (acrylic resin, screw retained) 1 month postop.



Figure 5 A and B, Temporarily cemented permanent single-crown restorations on customized zirconia abutments 8 months postop.

procedures based on digital radiographs (Sidexis, Sirona; Orthophos plus DS) and displaying Sidexis software. Following calibration via implant diameter and implant length, the distance from the implant shoulder (reference line) to the point of first implant-bone contact was measured using $\times 2$ screen magnification (i.e. $\times 3.7$ magnification) on the mesial and distal aspect of each implant and rounded to the nearest 0.1 mm. At each consecutive follow-up visit, the distance from the crestal bone level to the reference line was reset to zero, and bone loss was calculated via measuring tool of the software by the same clinician (Figure 6, A–E).

Statistical Analysis

Data were analyzed using appropriate statistical software (SPSS 18.0; SPSS Inc., Chicago, IL, USA). A Kolmogorov–Smirnov test confirmed that the bone-level data were normally distributed. A general linear model with repeated measurements was used to assess bone-level changes between follow-up visits in both groups of patients. A Wilcoxon signed-rank test was

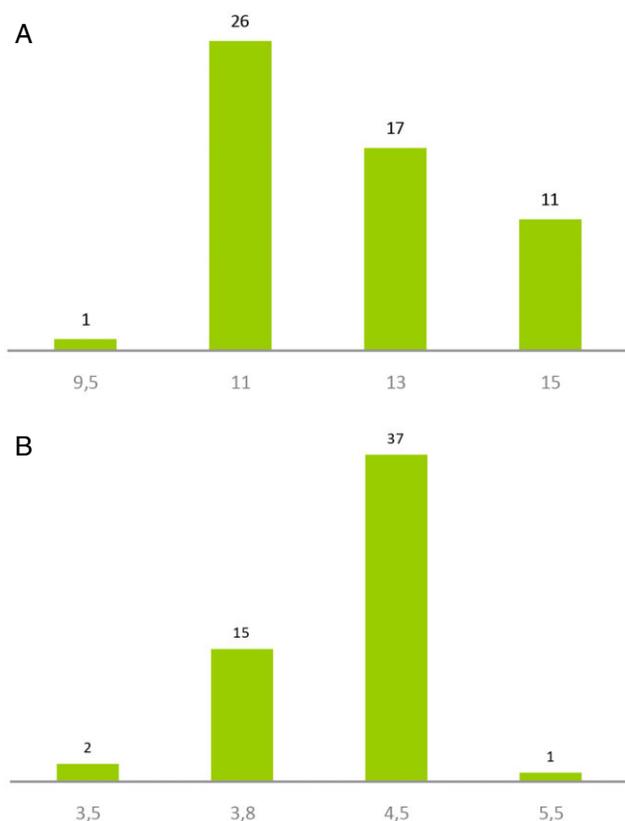


Figure 7 A, Distribution of implant lengths in mm. B, Distribution of implant diameters in mm.

(0 – 1.4 mm) in the control group of nonfunctionally immediately restored implants. Six months after surgery, they amounted to 0.4 ± 0.4 mm (0 – 1.2 mm) and 0.3 ± 0.4 mm (0 – 1.2 mm), respectively. At the final evaluation 12 months after surgery, the mean MBD was

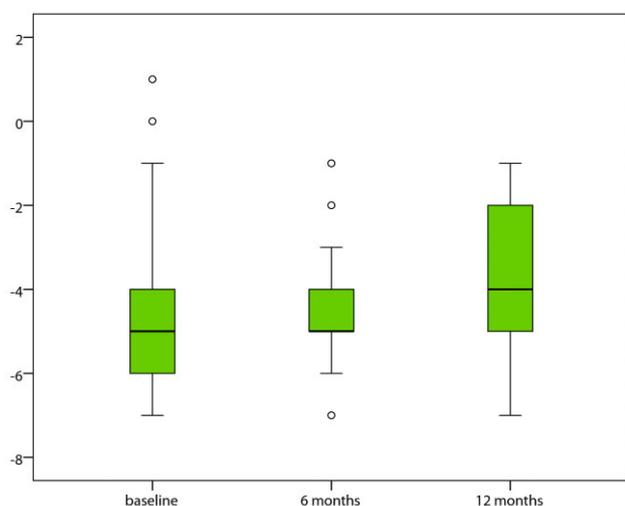


Figure 8 Boxplot analysis of Periotest values (PTV) at baseline, 6 months postop, and 12 months postop.

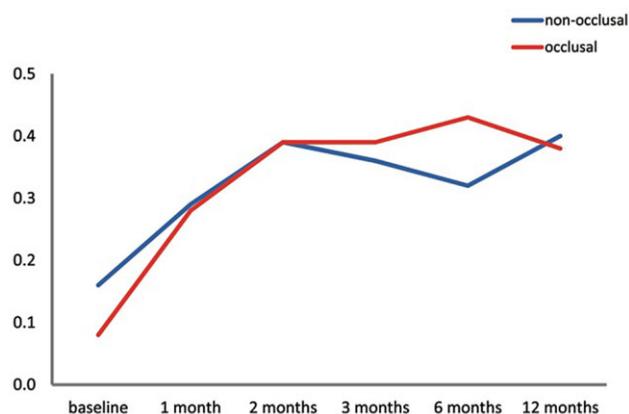


Figure 9 General linear model with repeated measurements for evaluation of marginal bone defects (MBD) in mm at baseline and up to 12 months after surgery.

0.4 ± 0.4 mm (0 – 1.2 mm) in the study group and 0.4 ± 0.5 mm (0 – 2.3 mm) in the control group. Adjacent implants were restored either as single-tooth crowns ($n = 32$) or as splinted restorations ($n = 20$; tooth-by-tooth) according to preferences of restorative dentists; because of the small sample size, no statistical comparison between single-tooth and splinted permanent restorations was performed. The majority of the patients (75%) presented with a plaque index of 1, and 63.2% showed a gingival index of 0 at the 12-month follow-up.

The Kolmogorov–Smirnov test confirmed a normal distribution of the data measured for MBD. A general linear model with repeated measurements was used to analyze the way in which the MBD would develop over time (Figure 9). Highly significant ($p < .001$) increases were noted both for the study group and for the control group, with the increases showing no significant differences between the groups ($p = .738$). Although the values in the study group were generally somewhat lower, this difference was not statistically significant ($p = .758$). None of the differences observed are considered to be clinically relevant. Friedmann test was used to compare Periotest values at baseline and 6 and 12 months after surgery, which did not yield a significant difference between the three measurements ($p = .471$).

DISCUSSION

This randomized clinical pilot study of two immediate provisional loading protocols in partially edentulous posterior mandibles was performed against the background that provisionalization with fixed partial

dentures is known to reduce treatment durations and to improve patient comfort. The 12-month data obtained in the sample of 19 patients rehabilitated with 52 implants yielded implant survival and success rates of 100% and MBD similar to or lower than the ones reported in previous studies.^{7,8,11,15,16,22–27}

Immediate loading in partially edentulous mandibles is today considered a viable treatment option in the hands of experienced clinicians.²⁸ Even the “high-load” scenario of the posterior mandible does not seem to affect the osseointegration of screw-type implants. Östman and colleagues⁸ demonstrated a cumulative survival rate of 99% following a 1-year period after immediate occlusal loading of 139 implants, with a mean marginal bone resorption of 1.01 mm. Cannizzaro and colleagues⁶ arrived at a 94% cumulative survival rate based on 143 immediately loaded implants after 1 year in function with mean crestal bone loss of 0.24 or 0.33 mm.

Various authors have stated that controlling occlusal forces is essential to successful immediate loading.^{12,29–31} Esposito and colleagues¹⁴ performed an extensive systematic review and meta-analysis without arriving at a conclusive statement about the impact of occlusal contacts during the healing phase of dental implants. Furthermore, a recent review by El Ghouli and colleagues³¹ reported disagreement about occlusal guidelines in immediate loading but recommended that occlusal centric contacts should be maintained only.

The opposing dentition might influence the performance of immediately delivered acrylic resin implant-supported provisionals. Suarez-Feito and colleagues³² in their study found a 4.7 times increased risk for fracture of metal-free provisionals with an opposing implant-supported restoration and a higher cumulative survival probability for provisionals in immediately loaded implants when occluding on full dentures or natural teeth. Because of the small sample size in the present pilot study, no scientifically relevant data with respect to the impact of opposing dentitions could be analyzed; several recent papers comparing occlusal and non-occlusal immediate loading did not report any data about the opposing dentition (Zembic and colleagues,¹⁵ Margossian and colleagues,¹⁶ Payer and colleagues,⁹ Degidi and colleagues¹¹).

Degidi and colleagues¹¹ performed a randomized clinical study of 100 implants that were immediately loaded either in full occlusal contact or in mild

infraocclusion and found no significant differences in survival rates, bone loss, or soft-tissue parameters. Based on 307 implants supporting two- to four-unit fixed partial dentures in 117 patients, Margossian and colleagues¹⁶ also investigated any effects of different loading protocols on implant survival, success, implant stability quotient, insertion torque, and marginal bone level changes over 2 years. Implant survival rates were 100% with immediate nonfunctional loading and delayed loading versus 93% with immediate functional loading due to failure of seven implants, most of them in two-unit restorations. Authors concluded that loading factors and the number of units might influence implant stability during healing. Given the sample size in our pilot project, no statistical comparison between different numbers of units could be performed. However, the fact that we detected no difference in survival/success rates is in contrast to the aforementioned findings.

Marginal bone levels might vary with load distribution patterns between natural teeth and implants, with access for hygiene instruments in splinted provisional restorations⁹ or with iatrogenic manipulation of the implant during initial healing.¹³ In our study, radiographic evaluation showed lower baseline bone levels of 0.1 and 0.2 mm, compared with 0.5 mm observed for the same implant type in a previous study by the same group (Payer and colleagues⁹) indicating an increased insertion depth for both groups in the present study. Moreover, less radiographic resorption in both groups was noted from baseline to 6 and 12 months in the present trial compared with Payer and colleagues.⁹ As higher bone density is supposed to decrease strain in marginal bone when loading implants immediately,^{33,34} it might be a contributing factor to less peri-implant bone loss in the present trial. Results reported by Degidi and colleagues¹¹ are very well in accordance with the present findings with no significant difference in survival/success rates and peri-implant tissue reaction between both loading protocols. Our data showed both significant increases in marginal bone resorption within the 12-month period without significant intergroup difference in the steepness of this curve and similar MBD at the end of this period (0.4 vs 0.4 mm).

In the present study, complications included restoration-specific problems (resin fractures, loosening, or inaccurate fit), mucositis, and imperfections of three-dimensional planning and the surgical guide. All of these could be easily managed and would in no way

jeopardize integration and radiographic appearance of the implants. Three implants were not evaluated as they were left to heal submerged during the 6-month period after showing rotational instability after insertion. Adjacent implants were splinted to optimize force distribution, similar to the approach reported by Zembic and colleagues.¹⁵ Insertion torques between 25¹¹ and 45 Ncm have been recommended for immediate loading, although five implants in our investigation (three in the study and two in the control group) showed insertion torques <35 Ncm without any notable effects on clinical outcomes 12 months after surgery. Splinting of the provisional restoration might have protected these implants from micromotion.

Our finding that occlusal and non-occlusal immediate restorations performed equally well in partially edentulous posterior mandibles is consistent with two recent studies^{8,11} but disagrees with others.^{15,16} Careful patient selection, preoperative three-dimensional planning and exact intraoperative transfer, exclusion of implants with reduced primary stability, accuracy in laboratory and restorative procedures, and a strict postoperative follow-up might have contributed to a 100% survival and success rate without any major complications compromising implant success. Plaque and soft-tissue parameters were well within the range of similar investigations,^{10,35} and within the limitations of our study, no different outcomes between single- and multiunit permanent restorations were noted.

CONCLUSION

No clinically relevant differences in radiographic 12-month results were observed between functionally loaded and nonloaded immediate restorations in partially edentulous posterior mandibles. Both types of restorations yielded 100% success and survival rates over observation periods of 12 months and can therefore be considered a viable treatment concept in selected patients.

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