Replacement of Mandibular Molars with Single-Unit Restorations Supported by Wide-Body Implants: Immediate Versus Delayed Loading. A Randomized Controlled Study

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Purpose: *This prospective randomized controlled trial aimed to compare single implant-supported mandibular molar restorations using either an immediate or a delayed loading protocol.* ***Materials and Methods:*** *Thirty subjects requiring single mandibular molar replacement were consecutively treated. One implant was placed in each patient. Fifteen subjects were assigned to delayed loading protocol and 15 to immediate loading protocol according to a randomization table. After insertion, the delayed loaded implants were connected to a healing abutment and restored after 3 to 4 months of healing without loading. The immediately loaded implants were loaded within 24 hours of surgery with a provisional restoration. The interim prosthesis was placed in centric occlusion. All contacts in lateral excursions were eliminated. At implant placement the maximum value of insertion torque was recorded. Radiographic bone level change was measured on periapical radiographs obtained at the time of implant placement and 12 months after loading. Means of the 2 groups were compared by Student* t *test and analysis of variance (ANOVA). The level of significance was set at .05.* ***Results:*** *No implants were lost in the delayed loading group (0/15), whereas 1 implant failed (1/15) in the immediate loading group. No differences were observed in relation to implant length or insertion torque between the groups. The average radiographic bone level change after 1 year of function was 1.2 ± 0.55 mm (range, 0.5 to 2.6 mm) and 0.77 ± 0.38 mm (range, 0.29 to 1.23 mm) for the delayed loaded and the immediately loaded implants, respectively. The difference in radiographic bone level change between the delayed and immediate loading groups was statistically significant (*P = .022; CI = −0.79 to −0.06; *Student* t *test).* ***Conclusions:*** *Immediate loading of wide-diameter implants supporting single restorations in mandibular molar sites seems to be a suitable clinical option. Moreover, the radiographic bone level change observed after 12 months of loading was significantly less for immediately loaded implants.* Int J Oral Maxillofac Implants 2008;23:474–480

Key words: *dental implants, immediate loading, randomized controlled trial*

The use of an implant-supported restoration for single molar replacement has been the subject of increasing interest among clinicians. Implant placement in the posterior regions of the dental arch may be limited by the bone anatomy. The edentulous ridge in the molar sites is often characterized by adequate width but reduced bone height and poor bone quality. To enhance the clinical performance of implants in molar regions, wide-body implants have been introduced. The use of a wide-body implant allows for higher mechanical stability as compared to the standard (3.75 to 4 mm) diameter implant. Also, wide-body implants may permit increased bone-implant contact due to the increase in implant surface area.[1,2] In addition, the wide-body implant is considered biomechanically more effective in counteracting occlusal forces of the magnitude that may be present in molar areas.[3] Despite encouraging data obtained from finite element analysis and animal studies, the initial experience with machined-surface

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wide-body implants showed lower success rates than those reported for standard-sized implants. Early clinical studies showed a failure rate ranging from 10% to 19% in the mandible and 9% to 29% in the maxilla.[4,5] Furthermore, an augmented marginal bone resorption was observed around wide-body implants placed in the posterior mandible as compared to standard-sized implants.[5] Those results were related to implant design, the learning curve for the surgical technique required, and the traumatic effect on the bone from the wide drills used during the osteotomy preparation.[4,5]

More recently, modified drilling techniques[6] along with the introduction of 1-stage (nonsubmerged) surgical protocols[7] have improved the clinical success of wide-body implants placed in the posterior regions of the dental arch. In addition, new implant surface configurations have contributed to the enhanced performance of wide-body dental implants. In in vitro and animal studies, recently introduced rough surfaces have shown reduced bone healing time and increased bone-implant contact and have demonstrated osteoconductive properties.[8–14] The clinical application of osteoconductive implant surfaces has allowed the introduction of protocols with early or immediate loading.

Immediate implant loading is considered a routine treatment option for edentulous mandibles.[15] Several prospective studies have presented encouraging results for the treatment of the edentulous maxilla.[16] However, only limited data are available for single-tooth applications or fixed partial dentures in the posterior regions of the dental arch.[16] Short-term prospective studies on the immediate loading of wide-body implants supporting single mandibular molars have been reported.[17,18] A cumulative survival rate of 96% to 100% has been observed. Furthermore, radiographic bone loss consistent with that seen with standard-sized implants inserted following a delayed loading protocol has been demonstrated.[17] These clinical results have been related to the quality of the new osteoconductive implant surfaces.[17,18] However, evidence that immediate loading may enhance bone healing and mineralization around dental implants has been obtained from in vitro and animal studies.[19–22] Thus, the emerging hypothesis that immediate loading may contribute to improve bone healing around dental implants should be assessed.

Only limited data are available regarding the effect of immediate loading versus delayed loading on bone healing around dental implants.[16] To better understand the potential of immediate loading, comparative studies with dental implants used in the same clinical conditions following either a delayed or an immediate loading protocol are needed. The purpose of this prospective randomized controlled study was to evaluate, clinically and radiographically, wide-body implants supporting single-unit mandibular molar restorations following either a delayed or an immediate loading protocol.

MATERIALS AND METHODS

All patients scheduled for single-unit mandibular molar implant-supported restorations at the Department of Fixed Prosthodontics at the University of Bologna School of Dentistry were asked to participate. The subjects were enrolled in the study for a period of 2 years, from 2002 to 2004. After signing the informed consent approved by the Ethical Committee at the University of Bologna, patients meeting the following inclusion criteria were enrolled:

1. Edentulous molar site in the mandible
2. Adequate amount of bone height for the placement of an implant with a minimum length of 8.5 mm
3. Adequate amount of bone width (7 mm) for the placement of a 5-mm-diameter implant
4. Opposing occlusion with natural dentition or fixed restorations
5. Healed bone sites (at least 4 months from the last extraction)
6. No need for bone augmentation
7. Sufficient implant primary stability; insertion torque of ≥ 20 Ncm

One implant was placed in each patient. Patients were allocated to either the immediate loading or the delayed loading group using a randomization table. The immediately loaded implants were restored with a screw-retained provisional restoration within 24 hours of implant placement. The implants in the delayed loading group were connected to a healing abutment and restored after 3 to 4 months.

Patients were excluded from the study if *(1)* Severe systemic diseases, ASA III status were reported; *(2)* local conditions at the implant site that could affect the treatment outcome were present (desquamative gingivitis, radiation therapy, bone and soft tissue pathosis); *(3)* the patient's cooperation appeared questionable; or *(4)* the patient did not give his or her consent to participate.

Surgical Protocol

One hour after the administration of prophylactic antibiotics (2 g amoxicillin; Pharmacia Italia, Milan, Italy), the implants were inserted under local anesthesia (mepivacaine 2%; Ogna Farmaceutici, Milan, Italy).

Following a crestal incision, a full-thickness flap was raised and the implant osteotomy site was prepared, with the 3.8-mm twist drill as the final drill. If a thick cortical bony crest was present, a 4.3-mm drill was utilized accordingly. The implant position was decided with a radiographic/surgical guide based on a diagnostic waxup and a computerized tomography (CT) scan evaluation. An Mk III WP TiUnite implant (Nobel Biocare, Göteborg, Sweden) was positioned without screw tapping. The peak insertion torque was measured during the seating of the most coronal 4 to 5 implant threads by means of an Osseocare surgical unit (Nobel Biocare), and recorded as being 20, 30, 40, or 50 Ncm. In cases of an insertion torque lower than 20 Ncm, the implant was not immediately loaded. The patient was excluded from the study, and implant treatment was completed following the standard protocol.[23] Whenever the torque needed for the insertion exceeded 50 Ncm, (the maximum torque allowed by the Osseocare machine), a manual wrench (Nobel Biocare) was utilized and IT was reported as > 50 Ncm. For the test group, following implant insertion, pickup impression copings were connected to the implants, and an impression was made using a polyether elastomeric material (Permadyne; 3M ESPE, St Paul, MN) according to the open-tray technique. To avoid contact of the impression material with the flap and the underlying bone, a portion of a sterile rubber dam sheet was adapted around the coping to isolate the surgical site during the impression making. Healing abutments were seated on the implants, and the flap was sutured with 5.0 suture material (Polysorb; USS-DG, Norwalk, CT). After surgery, the patient was asked not to brush the operated areas and to rinse instead with 0.12% chlorhexidine solution (Peridex; Procter & Gamble, Cincinnati, Ohio) twice a day for 1 minute for 14 days for plaque control. Pain control was provided with 400 mg ibuprofen (Brufen; Boots Healthcare, Milan, Italy) as needed. Sutures were removed after 7 to 14 days.

Prosthetic Procedure

Provisional restorations were connected by screws to the immediately loaded implants within 24 hours of implant placement. An interim prosthesis was custom made from a self-curing composite resin (Protemp; 3M ESPE) using a silicone index obtained from the diagnostic waxup. The occlusal scheme of the restorations was designed with contacts in maximum intercuspal position or centric relation; working and balancing contacts were carefully eliminated. Contacts were adjusted so that a 7-μm-thick articulating paper could be removed when the teeth were in contact but held when the patient exerted a maximum biting force.

Three months after the implants were placed, a final impression was made for both the delayed loading and immediate loading groups, and permanent porcelain-fused-to-metal, screw-retained, or cemented restorations were inserted. The screw-retained restorations were connected directly to the implant platform. The cemented restorations were made on customized abutments. The customized abutments were designed according to the profile of the peri-implant mucosa. The crown margin was positioned 0.5 to 1 mm into the peri-implant sulcus.

Follow-up Visit

The patients were recalled at 1, 2, 4, 12, and 24 weeks after surgery and 12 months after loading. For the test group, occlusion was checked at the postoperative visit. Standardized periapical radiographs were obtained for both the delayed and the immediately loaded implants at surgery (baseline) and after 12 months of loading with the paralleling technique using a Rinn film holder (Dentsply Rinn, Elgin, IL). The radiographs were made so that the platform and the threads were clearly visible both mesially and distally (Fig 1).

Radiographic Bone Level

Radiographic bone level change was measured on the periapical radiographs. A blinded examiner made the bone height measurements. Image analysis software (Digora for Windows 2.1; Soredex, Milwaukee, WI) was used to measure the distance between the implant platform and the most coronal level of the bone deemed to be in contact with the implant surface. The first bone-implant contact at surgery was defined as the baseline level. Mesial and distal bone height measurements were averaged for each implant. Radiographic bone level changes were calculated as the difference between the readings at 1 year and the baseline level.

Success and Failure Criteria

The success criteria for the implants were *(1)* no radiolucency around the implant, *(2)* no mobility, and *(3)* no suppuration, pain, or ongoing pathologic processes. Implants that did not fulfill the success criteria were considered failures.

Failed implants were removed. After 8 weeks of healing of the surgical site, another implant was inserted and, after 3 months of healing, loaded.

Statistical Analysis

The implant success rate was expressed as a percentage among the total number of implants placed and relative to the numbers of implants in the delayed loading and immediate loading groups. The patient was considered the statistical unit. Radiographic bone level change was the main response variable used in the study to evaluate the clinical perfor-

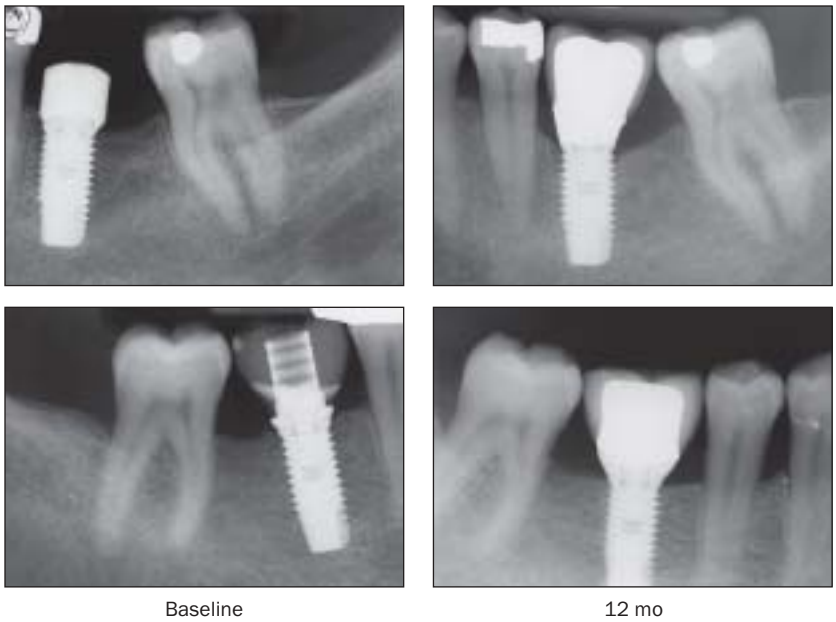

Fig 1 Radiographic images of a control implant (delayed loading) and an immediately loaded implant at baseline and after 12 months of loading.

mance of the two implant protocols. Radiographic bone level change of 0.3 mm was considered of clinical relevance.[24] Thus, the sample size analysis was calculated based on this variable for a Student *t* test based on an α error of 5% and a power of 80%. A minimum sample size of 14 implants for each group was necessary to detect a difference of 0.3 mm, with a standard deviation of the change of 0.4 mm (Primer of Biostatistics 4.02 statistical package; Stanton A. Glanz, McGraw-Hill, New York, NY).

Kolmogorov-Smirnov goodness-of-fit tests were computed for the response variable to assess whether the parameter was normally distributed. Radiographic bone level change was normally distributed and was considered a parametric variable. The means for the 2 groups were compared by a Student *t* test. Analysis of variance (ANOVA), followed by the Tukey highly significant difference (HSD) test for post-hoc comparisons, was used to test the overall effect of the implant length and restoration type (cemented versus screw-retained) on radiographic bone level change. Implant length and insertion torque were considered ordinal data. To compare insertion torque and implant length between the test and control groups, the Mann-Whitney rank-sum test for nonparametric variables was used. The level of significance was set at 5% for all statistical tests.

RESULTS

Thirty patients were consecutively treated. Ten women and 5 men with a mean age of 49.2 years (range, 35 to 68 years) were included in the delayed loading group, and 11 women and 4 men with a mean age of 51.87 years (range, 31 to 75 years) were included in the immediate loading group. Two subjects in the delayed loading group and 1 subject in the immediate loading group were smokers.

All patients participated until the end of the study. No clinical dropouts occurred. Patients healed with minor discomfort. No swelling or surgical complications were reported. All the implants placed fulfilled the study requirements. No implants were lost in the delayed loading group (0/15), whereas 1 implant failed (1/15) in the immediate loading group. The failed implant was 10 mm long; it was inserted with 50 Ncm torque in a mandibular right second molar position (47) in a 66-year-old woman. It was determined to be mobile after 3 months and was subsequently removed. After 8 weeks of healing, the implant was replaced and loaded successfully 3 months later.

All patients at the end of the study received restorations as planned. The types of restorations supported by delayed loaded and immediately loaded implants are reported in Table 1.

Implant Position and Length

Six implants in the immediate loading group and 5 implants in the delayed loading group were in the more distal position of the occlusal scheme. Implant positions relative to group allocation are reported in Table 2. Distribution of implant lengths for each group is reported in Table 3. No statistical difference was observed for the implant length between the delayed and immediate loading groups ($P = .289$; Mann-Whitney rank sum test). ANOVA was carried out to evaluate the radiographic bone level change

Table 1 Distribution of Cemented and Screw-Retained Restorations Between the Delayed Loading and Immediate Loading Groups

	Retention method	
Restoration type	Cemented	Screw-retained
Delayed loading	7	8
Immediate loading	5	10

Number of implants shown.

Table 2 Distribution of Implants by Position

	Delayed loading	Immediate loading
Mandibular left first molar	10	9
Mandibular left second molar	—	—
Mandibular right first molar	5	4
Mandibular right second molar	—	2

Number of implants shown.

Table 3 Distribution of Implants by Length

	Length (mm)		
Restoration type	8.5	10	11.5
Delayed loading	5	5	5
Immediate loading	3	4	8

Number of implants shown.

Table 4 Distribution of Implants by Peak of Insertion Torque

	Peak insertion torque (Ncm)				
Restoration type	20	30	40	50	> 50
Delayed loading	1	1	3	4	5
Immediate loading	_	1	3	3	8

Number of implants shown.

Table 5 Distribution of Implants by Radiographic Bone Level Change After 12 months of Loading

	Radiographic bone level change (mm)					
Restoration type	< 0.5	0.5 – 1	> 1 – 1.5	> 1.5 – 2	> 2 – 2.5	> 2.5
Delayed loading	0	5	6	3	0	1
Immediate loading	3	7	4	0	0	0

Number of implants shown.

in relation to implant length. No statistically significant difference was observed between the groups with respect to length (F = 1.05; *P* = .364)

Insertion Torque

No statistically significant difference was observed for insertion torque between the delayed loaded and immediately loaded implants (*P* = .358; Mann-Whitney rank-sum test). Insertion torque distribution among delayed loading and immediate loading groups is reported in Table 4.

Radiographic Bone Level

Radiographic bone level change for each group is reported in Table 5. The average radiographic bone level change after 1 year was 1.2 ± 0.55 mm (range, 0.5 to 2.6 mm) for the delayed loading group and 0.77 ± 0.38 mm (range, 0.29 to 1.23) for the immediate loading group. The difference of radiographic bone level change between the DL and IL groups was statistically significant (Student *t* test; *P* = .022; CI = –0.79 to –.06). The radiographic bone level change between implant-supported cement- or screw-retained restorations was also compared, and the difference was not statistically significant (ANOVA: *P* = .61; post-hoc comparison: Tukey 95% CI= –0.51 to 0.311).

DISCUSSION

In the present study, wide-body implants supporting single-unit mandibular molar restorations were compared, clinically and radiographically, following either a delayed or an immediate loading protocol. No failures were reported in the delayed loading group, whereas 1 implant failed in the immediate loading group.

Radiographic bone level change was the main response variable used in the study to evaluate the clinical performance of the 2 implant protocols. The radiographic bone level change observed for immediately loaded implants was significantly lower than that reported for delayed loaded implants. Similar findings were presented by Attard et al,[25] who compared implants supporting bar-retained overdentures loaded either immediately or following a 2-stage protocol. The implants loaded immediately showed a smaller radiographic bone level change than the implants left submerged under the oral mucosa and loaded after 3 months. However, this result may have been influenced by the different surfaces utilized by the 2 implant groups. The implants used for the 2-stage protocol had a machined surface, whereas those used for the immediate loading group had a titanium oxide surface.

In the present investigation, the same implant design and surface was used for both groups. In addition, the delayed loading and immediate loading groups were similar regarding patient age distribution and bone quality at the implant site (as quantified by the peak insertion torque). Also, no differences were showed relative to implant position or implant length distribution. However, the number of 8.5-mm-long implants was higher in the delayed loading group than in the immediate loading group. The effect of implant length on radiographic bone level change was statistically evaluated. According to the present data, radiographic bone level change for 8.5-mm implants was not significantly different from the amount of change observed with longer implants. This is consistent with previous studies. Renouard and Nisand[26] reported a radiographic bone level change of 0.44 ± 0.52 on short implants (6 to 8.5 mm) after 2 years of loading in the maxilla. Similarly, Friberg et al[27] presented the clinical outcome of 6- and 7-mm Brånemark implants placed in atrophic mandibles over a 10-year period. The marginal bone loss, measured after 1, 5, and 10 years of function, was comparable to the marginal bone loss observed on longer implants.

The distribution of cemented restorations was a clinical factor that differed between the delayed and immediate loading groups. The number of implants supporting cemented restorations was higher in the delayed loading group than in the immediate loading group. Nevertheless, no differences were shown on radiographic bone level changes in relation to the retention type (cemented versus screw-retained). These data are in agreement with previous reports. Vigolo et al[28] compared implant-supported single-unit restorations, either cemented or screw-retained, in a split-mouth design. Over a 4-year observation period, no difference in marginal bone remodeling was reported between the groups.

Apparently, the only clinical factor that may explain the different response in radiographic bone level change observed in the present study is the difference in loading protocol applied in the 2 groups. For a long time immediate loading of dental implants has been regarded as a detrimental factor for osseointegration. Early studies indicated that micromotion of 100 to150 μm was the maximum that could be tolerated by the bone-implant interface. Above this threshold, fibrous encapsulation may occur.[29] The loading of an implant leads to both micromotion at the bone-implant interface and the transfer of forces to the surrounding tissue. This has 2 main effects on the bone cells and extracellular components. First, micromotion can destroy the bone cells and thus bone-implant contact. Second, micromotion can lead to the deformation of bone cells connected to the implant surface in a strain-related manner. Loading of intact bone following an osteotomy during growth, fracture healing, and distraction osteogenesis results in a strain-related tissue response. Load and bending moments result in strains or changes in the length of a material (with a microstrain of 1,000 corresponding to a 0.1% change in length).[30,31] With physiologic bone loading, which ranges between 500 and 3,000 microstrain, leads to mature bone formation, higher peak strains result in immature bone mineral formation and a fibroblastic cell pattern.[32] It is well known that mechanical bone strain stimulation is a key factor in the regulation of bone remodeling.[32] Recent studies showed that mechanical strain stimulates osteoblasts to produce osteoprotegerin.[33] The osteoprotegerin enhances bone deposition and downregulates osteoclastic activity.[33] Animal studies showed results consistent with the positive effect on osteodeposition induced by mechanical strain stimulation observed at the cellular level. Experiments on primates and minipigs have demonstrated increased bone-implant contact and bone density on immediately loaded implants compared to implants that were loaded after 3 to 4 months of healing.[19,21,22] More recently, in an animal study, Vandamme et al[34] showed a significant increase of bone mineralization around implants loaded immediately as compared to unloaded implants. A controlled load with 30 μm of displacement was applied.

Therefore, although 100 to 150 μm of micromotion may jeopardize implant osseointegration, a certain amount of mechanical stimulation may be tolerated by the bone-implant interface and in some cases may be even beneficial to bone deposition. However, the force transfer between the implant and the surrounding bone is indeterminate during clinical application of immediate loading. Hence, the bone reaction may vary in relation to several variables related to the host, the surgical protocol, the implant, and the type of prosthesis.

CONCLUSIONS

Within the limits of the present trial, immediate loading of single wide-body implants in mandibular molar sites was found to be a suitable alternative treatment option. In addition, a reduced radiographic bone level change after 1 year of loading was observed in the immediately loaded implant group compared to implants placed according to a nonsubmerged protocol and loaded after 3 to 4 months. Further investigation is needed to confirm this result.

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