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Immediate versus delayed loading of single mandibular molars. One-year results from a randomised controlled trial



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Purpose: To compare the outcome of immediate non-occlusal loading and that of delayed implant loading in the bilateral replacement of single mandibular molars.

Materials and methods: This study was designed as a randomised, controlled, split-mouth trial. Twenty patients with bilaterally missing first mandibular molars had one of the sites to be restored randomly assigned to be treated with immediately or conventionally loaded single implants. A total of 40 implants were bilaterally installed. All the implants were inserted in healed healthy bone with an insertion torque between 35 and 45 Ncm. One molar was restored with a non-occluding temporary crown within 24 h after implant placement, while the contralateral molar was restored with a definitive crown 4 to 5 months later, according to a two-stage procedure. Final restorations were provided 4 to 5 months after implant placement for all implants. Outcome measures were implant survival, complications, radiographic marginal bone-level changes, PPD and BOP.

Results: No patients dropped out and no implant failed. Only minor prosthetic complications were observed (2 provisional acrylic crown fractures in the immediate loading group and 2 ceramic chipping in the delayed loading group). Mean marginal bone loss was 0.83 ± 0.16 mm (95% CI 0.75 to 0.91) in the immediate loading group and 0.86 ± 0.16 mm (95% CI 0.78 to 0.94) in the conventional loading group and no statistically significant differences between the two groups were observed ($P = 0.530$). Mean PPD and BOP values were, respectively, 2.76 ± 0.48 (95% CI 2.55 to 2.97) and 1.30 ± 0.73 (95% CI 0.98 to 1.62) in the immediate loading group, and 2.70 ± 0.37 (95% CI 2.54 to 2.86) and 1.40 ± 0.75 (95% CI 1.07 to 1.73) in the conventional loading group. Also, a statistical comparison of BOP and PPD did not show any significant difference ($P = 0.163$ and $P = 0.652$, respectively).

Conclusions: Within the limitations of this study, the present data seem to confirm the hypothesis that the clinical outcome of immediate versus delayed loading of implants in single mandibular molar sites is comparable.

Conflict-of-interest statement: *This study was partially supported by Nobel Biocare (grant 2007-646).*

■ Introduction

Single tooth replacement using implant therapy is a predictable and successful dental procedure¹⁻². Different surgical placement and loading protocols

have evolved in response to an increased demand for shortened treatment time³. Several terms are used to define the time of implant loading, such as immediate, early or conventional delayed loading. Immediate loading has been shown to be success-

ful, particularly for procedures involving multiple splinted implants in the parasymphiseal mandible or in the edentulous maxilla⁴⁻⁵. Reports and clinical studies have confirmed high success rates using immediate provisionalisation of single unsplinted implants³. A meta-analysis found neither clinical nor radiological differences in either aesthetic outcome or implant success among the various loading protocols⁶.

Several implant features, like geometry of the implant body specially designed for critical bone conditions and implant surfaces like TiUnite, which is an osteoconductive porous anodised surface promoting faster bone healing⁷, combined with high insertion torques during bone healing may have minimised the risk of early failure of immediately loaded implants⁸. Most data concerning the immediate provisionalisation of single implants derive from implants installed into fresh extraction sockets. Only a few studies have investigated the outcome of immediately loaded single teeth^{3,9-10}.

The present study tested the hypothesis that immediate non-occlusal loading and delayed loading would have different outcomes in single mandibular molars sites against the alternative hypothesis of no difference. This trial is reported according to the CONSORT statement (<http://www.consort-statement.org/>) for improving the quality of reporting of parallel-group randomised trials.

■ Materials and methods

This study was designed as a randomised, controlled, split-mouth trial. The study was approved by the local ethics board (MF2341) and was conducted at the Oral and Maxillofacial Surgery Unit of the University Hospital of Sassari, Italy between January 2009 and April 2011 in accordance with Helsinki Declaration guidelines. Patients were treated by the same oral surgeon (S.M.) following the same surgical and prosthetic protocol. Patients were recruited in three different centres (Surgical Microsurgical Medicine Department, University of Sassari and two different private offices) by offering bilateral replacement of the mandibular first molars.

Patients were selected according to the following main inclusion and exclusion criteria.

Inclusion criteria:

- missing bilateral mandibular first molars
- stable interocclusal contacts
- ≥ 18 years of age
- provided written informed consent
- residual bone height ≥ 10 mm
- residual bone thickness ≥ 6 mm with at least 5 mm of keratinised gingiva crestally.

Exclusion criteria:

- general contraindications to implant surgery
- lack of occluding dentition in the area intended for immediate loading
- periodontitis
- bruxism
- immunosuppression
- previous history of irradiation of the head and neck area
- uncontrolled diabetes
- heavy smoker (>10 cigarettes/day)
- poor oral hygiene
- current or past treatment with bisphosphonates
- substance abuse
- psychiatric disorder
- inability to complete follow-up ≥ 1 year
- requirement for bone augmentation (bone graft and membrane)
- pregnancy or lactation
- implant insertion torque less than 35 Ncm.

The study was thoroughly explained and all participants provided written informed consent prior to enrolment in the trial.

Thirteen out of 33 patients screened for eligibility did not meet the selection criteria: 4 were wary of receiving immediately loaded implants, 3 refused to adhere to a strict clinical and radiological follow-up, 4 had insufficient bone height, and 2 insufficient bone width. Since this study is intended to be preliminary to a larger clinical trial, an *a priori* sample size calculation was not performed. A total of 20 consecutive patients were enrolled. In each eligible patient, the mandibular right or left molar was randomly selected to receive either an immediate or delayed provisional crown. The randomisation code was created by a dedicated computer programme (Excel, Microsoft, Redmond, WA, USA) combining a sequence of randomised non-consecutive numbers matching the

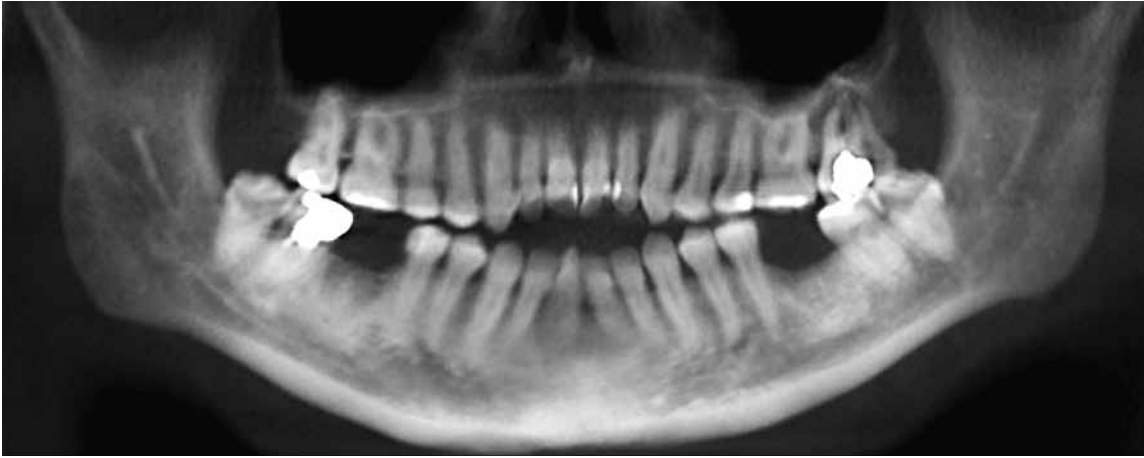


Fig 1 Preoperative panoramic radiograph.



Fig 2 Clinical lateral views.

two different procedures (immediate or delayed loading) with right or left molar, was assigned by an independent operator (R.P.) not involved in the trial, and was placed in envelopes. Data were collected in spreadsheets (Excel) by an independent medical doctor (D.S.) at the Department of Maxillofacial Surgery of the University of Sassari.

■ Clinical procedures

All patients were clinically evaluated and their medical history recorded. Preliminary screening, including the acquisition of intraoral and panoramic radiographs (Fig 1), was performed to evaluate potential patients' eligibility. Patients that met selection criteria (Fig 2) received oral hygiene instructions and debridement if required, after which bone volumes were analysed using cone-beam computed tomography (CBCT) (Imaging Sciences International, Hatfield, PA, USA).

All patients received amoxicillin + clavulanic acid (Augmentin, GlaxoSmithKline, Verona, Italy) 1 g twice daily from 1 hour before implant placement to 6 days post-surgery. Prior to implant placement, patients rinsed for 1 min with 0.2% chlorhexidine (Curasept, Curaden Healthcare, Saronno, Varese, Italy) mouthwash and local anaesthesia was induced using articaine with adrenaline (1:100,000) (Pierrel, Milan, Italy).

Implants were placed using a conventional approach: an intrasulcular and crestal incision was performed and a mucoperiosteal flap was elevated. Drills were used to prepare the recipient bed and all implants were installed with an insertion torque >35 Ncm and <45 Ncm measured with a manual torque wrench by the surgical operator. Both mandibular sites received tapered implants with an anodised surface (Nobel Replace Tapered Groovy; Nobel Biocare, Goteborg, Sweden), with diameters of

Fig 3 Right implant randomised to delayed loading.



4.3 or 5.0 mm and lengths of 10 or 8 mm. Flaps were sutured with Vicryl 4.0 sutures (Vicryl, Ethicon J&J International, St-Stevens-Woluwe, Belgium). The envelope containing a randomisation code to assign the immediate and the delayed site was opened only at this moment by a blinded independent medical doctor and the immediate loading site was assigned.

A silicone impression was then taken, and an acrylic crown was fabricated on the temporary titanium abutment and was placed the day after surgery in the immediate loading site, while a healing abutment was inserted on the delayed loading implant, immediately following surgery (Figs 3 and 4).

Care was taken that provisional crowns did not have any static or dynamic occlusion contacts.

Baseline intraoral radiographs were taken of both sides with the parallel technique at the time of surgery. When the bone levels around the study implants were inconclusive, a second radiograph was taken.

A total of 80 mg of ketoprofen (Oki; Dompe', Milan, Italy) 2 to 3 times daily was prescribed for as long as required. Patients were instructed to rinse with 0.2% chlorhexidine (Curasept) for 2 weeks and to stay on a soft diet regimen for 10 days. Sutures were removed after 1 week. After 3 to 4 months, implants were radiologically and manually checked (Figs 5 and 6) for stability and silicone

impressions were taken bilaterally. Customised cast models were then produced. After 3 to 4 weeks, definitive zirconia-ceramic or metal-ceramic crowns were cemented on individualised titanium-zirconia abutments (Procera CAD/CAM; Nobel Biocare). Intraoral radiographs of the study implants were taken at the time of definitive crown delivery and after 6 and 12 months (Figs 7 and 8). Patients were then enrolled in an oral hygiene program with monitoring every 3 months for 1 year following surgery.

■ Outcome measures

The following outcome measures were used:

Implant survival

The removal of implants was dictated by instability, progressive marginal bone loss, infection or implant fracture. The stability of individual implants was measured by the prosthodontist at the time of definitive crown delivery (4–5 months after implant placement) by applying 35 Ncm of removal torque. After 1 year of final crown delivery, implant stability was manually tested with two dental mirror handles.

Complications

Prosthetic complications, such as provisional or definitive crown fracture and abutment mobility or fracture, and biological complications such as wound or implant infection, mucositis, abscesses or peri-implantitis were recorded.

Marginal bone levels

Peri-implant marginal bone levels were evaluated on intraoral digital radiographs taken with the parallel technique at the time of implant placement, at 6 months and 1 year after definitive loading. If radiographs were inconclusive, they were repeated. A blinded radiologist (F.G.), unaffiliated with the study centre, interpreted all radiographs. The distances from the mesial and distal interproximal bone to the reference point (the horizontal interface between the implant and abutment) were measured with a software measurement tool (NIH Scion Image programme version 4.0.2, Frederick, MD, USA) calibrated against the

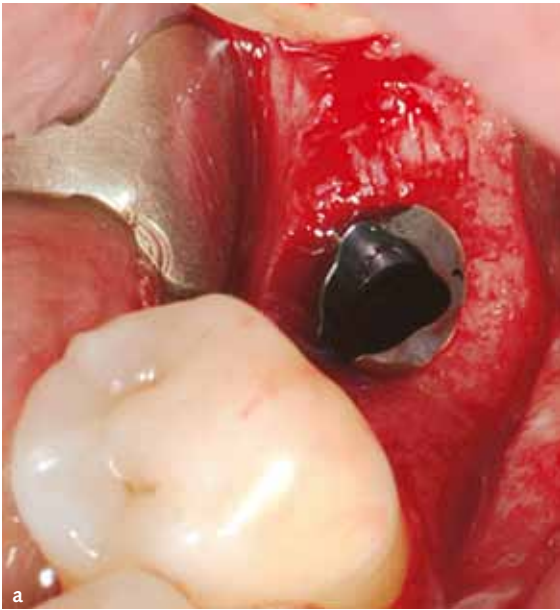


Fig 4 a) Left implant randomised to immediate loading; b) immediate provisional non-occluding crown in place.

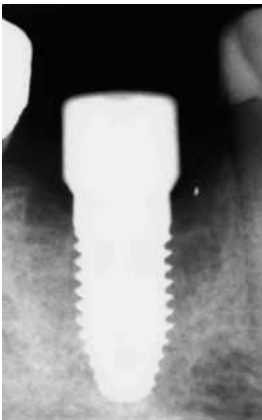


Fig 5 Intraoral radiograph 3 months after implant placement: delayed loading site.

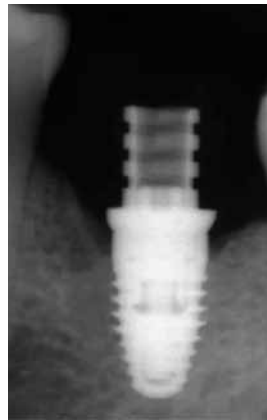


Fig 6 Intraoral radiograph 3 months after implant placement: immediate loading site.

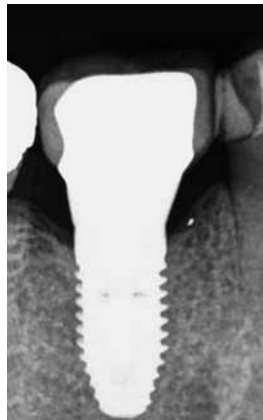


Fig 7 Intraoral radiograph 12 months after definitive crown loading: delayed loading site.



Fig 8 Intraoral radiograph 12 months after definitive crown loading: immediate loading site.

space between two threads to the nearest 0.1 mm, and the mean of these two measurements was calculated for each implant. The measurements were recorded with reference to the implant axis.

Peri-implant mucosal response

Probing pocket depth (PPD) and bleeding on probing (BOP) were measured by a blinded operator (A.D.) with a periodontal probe (PCP-UNC 15, Hu-Friedy Manufacturing, Chicago, IL, USA) at 6 months and 1 year after definitive crown delivery. Three vestibular and 3 lingual values were collected for every implant by the same dentist.

Statistical analysis

Statistical analyses were conducted using QI Macros SPC software (ver. 2010, KnowWare International, Denver, CO, USA) for Microsoft Office Excel. A paired *t* test was used to detect significant differences between immediate and delayed loading; the values included peri-implant bone level, PPD and BOP at each time point. Statistical significance was tested at the 0.05 probability level, and all values were presented as mean \pm standard deviation with 95% confidence intervals.

Table 1 Implant diameter and length between groups.

Implants	Immediate	Delayed
Diameter 5.0 mm	11	9
Diameter 4.3 mm	9	11
Length 8 mm	3	1
Length 10 mm	17	19

■ Results

Twenty consecutive patients, 8 males and 12 females, with a mean age of 46 years (range 28–70) were considered eligible and treated. No patient dropped out of the study within 1 year after initial loading. No deviations from the protocol occurred. Data were collected at baseline, 6 and 12 months after initial implant loading. A total of 40 implants were placed in sites healed for at least 2 months with an insertion torque between 35 and 45 Ncm (Table 1).

■ Implant survival

No implant mobility, infection or implant fracture occurred. All implants were stable at the end of the study.

■ Prosthetic and biological complications

Two provisional acrylic crowns fractured 2 months after immediate loading and were replaced with new acrylic crowns. Two zirconia-ceramic crowns of the delayed loading group had ceramic chipping at 10 and 11 months after loading, which were resolved with ceramic remodelling.

No major biological complications were recorded in both treatment groups. Two patients had bilateral peri-implant mucosal inflammation with BOP after 6 months. Improved oral hygiene reduced the peri-implant inflammation.

■ Peri-implant marginal bone level (Table 2)

The average change in interproximal marginal bone level was analysed for each implant. Mean marginal bone levels after 6 months were 0.66 ± 0.14 mm (95% CI 0.59 to 0.73) for immediately loaded implants and 0.69 ± 0.17 mm (95% CI 0.60 to

0.78) for two-stage delayed loaded implants, and no statistically significant differences between the two groups were observed ($P = 0.332$).

After 12 months, the mean marginal bone levels were 0.83 ± 0.16 mm (95% CI 0.75 to 0.91) for immediately loaded implants and 0.86 ± 0.16 mm (95% CI 0.78 to 0.94) for two-stage delayed loaded implants, and no statistically significant differences between the two groups were observed ($P = 0.530$).

■ Peri-implant mucosal response (Tables 3 and 4)

The mean PPD values were 2.76 ± 0.48 (95% CI 2.55 to 2.97) for immediate loaded implants and 2.70 ± 0.37 mm (95% CI 2.54 to 2.86) for two-stage delayed loaded implants, and no significant difference was found between groups after 12 months ($P = 0.652$).

The mean BOP values were 1.30 ± 0.73 (95% CI 0.98 to 1.62) for immediate loaded implants and 1.40 ± 0.75 (95% CI 1.07 to 1.73) for two-stage loaded implants, and no significant difference was found between groups after 12 months ($P = 0.163$).

■ Discussion

An adequate non-functional healing period has for a long time been considered a basic prerequisite for the osseointegration of dental implants. Due to differing osseous structures, this period was defined as being 3 months for the mandible and 6 months for the maxilla¹¹. During the last decade, implant loading protocols have undergone dramatic changes possibly because of enhanced implant surfaces and changes in implant thread design¹². Recently, the use of immediate loading for the restoration of fully or partially edentulous jaws with osseointegrated implants has gained popularity among clinicians^{5,6,13–15}. The use of prolonged healing periods has been questioned because they were determined empirically. Hence, one aim of clinical research in modern implant dentistry has been the validation of early and immediate loading protocols as viable therapeutic alternatives under certain circumstances.

The results of many studies have supported the use of immediate loading procedures to restore

Table 2 Mean marginal bone levels in mm: statistical analysis between groups.

	Immediate Mean \pm SD	95% confidence intervals	Delayed Mean \pm SD	95% confidence intervals	<i>P</i> value
Baseline	0.44 \pm 0.16	0.36–0.52	0.38 \pm 0.12	0.32–0.44	0.105
6 months	0.66 \pm 0.14	0.59–0.73	0.69 \pm 0.17	0.60–0.78	0.332
12 months	0.83 \pm 0.16	0.75–0.91	0.86 \pm 0.16	0.78–0.94	0.530

Table 3 Mean PPD values in mm: statistical analysis between groups.

PPD	Immediate Mean \pm SD	95% confidence intervals	Delayed Mean \pm SD	95% confidence intervals	<i>P</i> value
6 months	2.75 \pm 0.60	2.49–3.01	2.73 \pm 0.57	2.45–3.01	0.929
12 months	2.76 \pm 0.48	2.55–2.97	2.70 \pm 0.37	2.54–2.86	0.652

Table 4 Mean BOP values in mm: statistical analysis between groups.

BOP	Immediate Mean \pm SD	95% confidence intervals	Delayed Mean \pm SD	95% confidence intervals	<i>P</i> value
6 months	1.40 \pm 1.10	0.92–1.88	1.55 \pm 0.89	1.16–1.94	0.453
12 months	1.30 \pm 0.73	0.98–1.62	1.40 \pm 0.75	1.07–1.73	0.163

edentulous jaws with success^{16–18}. Some clinical studies^{19,20} have reported high 5-year survival rates in the maxilla (97%) and up to 10 years in the mandible (94.8%) when totally edentulous jaws were restored with splinted cross-arch prostheses.

Currently, a growing need exists for the rehabilitation of patients with a fixed, implant-supported prosthesis delivered just after surgery to minimise patient discomfort. This procedure restores patients' dental function and aesthetics, allowing them to resume normal work and social activities within a shorter period of time. For these reasons, many patients request the immediate loading of implants.

The ultimate goal of an immediate loading protocol is to reduce the number of surgical interventions and shorten the interval between surgery and prosthesis delivery, without compromising the success rate of the procedure. These new protocols will ultimately lessen patients' reservations, resulting in increased acceptance of implant therapy. Before the procedure is accepted as a routine treatment, it must be validated by a significant number of clinical cases, extended follow-up periods and a clear definition of limitations.

The clinical outcome of immediate loading of single oral implants has been studied in few clinical trials. In 2007, Rao and Benzi²¹ published a study on single, mandibular first-molar implants (Replace SelectTapered TiUnite) placed with flapless guided surgery and immediately loaded with pre-manufactured individualised abutments and crowns. All 51 tapered implants placed were stable and successful in function after 1 year, providing a 100% survival rate²¹. More recently, Schincaglia et al⁹ published the findings from a randomised controlled trial comparing immediate versus delayed loading of wide body implants (TiUnite Wide Platform MK III, Nobel Biocare) supporting single-unit restorations in the molar area. No implants were lost in the delayed group (0/15), whereas one implant failed (1/15) in the immediate loading group after a 1-year follow-up. In this study, the radiographic bone level change observed after 12 months of loading was statistically significantly less for immediately loaded implants than for implants with delayed loading. Meanwhile, Calandriello et al²² reported a high degree of success of single molar restorations after a 5-year follow-up.

The present authors know of only one study that has applied a randomised split-mouth design comparing different loading of single first mandibular molars, with a different prosthetic design and fewer number of patients²³, and only one other study²⁴ tested molar immediate loading in a split-mouth trial comparing two different implant surfaces. Thus, it was decided to study the outcome of immediate non-occlusal prosthetic loading in this clinical situation because single mandibular first molars are normally not immediately loaded by most clinicians due to a reticence to immediately load single unsplinted teeth that are subjected to high masticatory forces.

Taking into account the limitations of the present study (small number of patients), the findings seem to support that the immediate loading of single mandibular molar implants restored with non-occluding temporary crowns is a reliable option. This technique was shown to be comparable to the conventional two-stage delayed loading approach in native bone, when using modern rough implant surfaces inserted with good primary stability. Another trial has tested immediate loading in atrophic ridges with short implants (6.5 mm in length)¹⁰, therefore, we conclude that immediate loading of single posterior mandibular implants could be a reliable technique when certain parameters are respected (high primary stability and bone volumes sufficient to insert implants at least 8 mm long).

■ Conclusions

Acknowledging the limited number of patients, the present data seem to validate that the outcome of immediately loaded single mandibular molar implants is comparable to conventional loading.

■ Acknowledgements

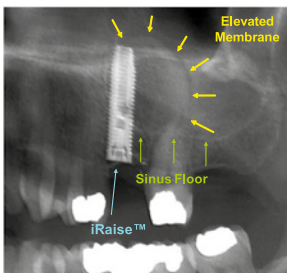
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