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Immediate vs. Delayed Loading of Mandibular Mini-Implant Overdentures: A 12-Month Comparative Randomized Controlled Trial

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ABSTRACT

Background and Aim: While mini-dental implants (MDIs) provide a minimally invasive surgical solution for prosthesis stabilization, the optimal timing for functional loading remains highly contested in the scientific literature. This clinical trial sought to evaluate the effects of immediate versus delayed loading protocols on marginal bone level (MBL) changes and peri-implant mucosal health around MDIs supporting mandibular overdentures.

Methods: Twenty completely edentulous patients experiencing mandibular atrophy were randomly allocated (1:1 ratio) to either an Immediate Loading Group (n=10) or a Delayed Loading Group (n=10). Each participant received four one-piece mini-implants in the interforaminal region utilizing a flapless surgical approach. Implants in the immediate cohort were functionally loaded on the day of surgery via O-ring attachments. The delayed cohort received functional loading after a stringent three-month unloaded healing period. The primary outcome measure was MBL change, quantified via standardized digital periapical radiographs. Secondary outcomes included the Gingival Index (GI) and Probing Depth (PD). Statistical analysis was executed using repeated measures ANOVA and independent t-tests with a significance threshold set at α=0.05.

Results: A total of 80 implants were placed, achieving a 100% cumulative survival rate at the twelve-month follow-up. Both groups exhibited progressive, physiological crestal bone remodeling. At twelve months, the Immediate Loading Group demonstrated a mean MBL of 0.87 ± 0.22 mm (95% CI: 0.79, 0.95), whereas the Delayed Loading Group exhibited a mean MBL of 1.01 ± 0.25 mm (95% CI: 0.92, 1.10). While this 0.14 mm variance was statistically significant ($p = 0.042$), it remains clinically negligible. GI scores were transiently lower in the immediate group at three and six months ($p < 0.05$) but converged completely by twelve months (Immediate: 1.88 ± 0.41; Delayed: 2.13 ± 0.52; $p = 0.18$). PD showed no statistically significant divergence between the cohorts across any observation interval.

Conclusions: The immediate functional loading of 1.8 mm MDIs for the stabilization of mandibular overdentures resulted in highly comparable and predictable twelve-month clinical and radiographic outcomes when juxtaposed against a conventional delayed protocol. The immediate application of controlled functional forces did not precipitate adverse peri-implant tissue responses or pathological osteolysis, thereby validating the protocol as a predictable and patient-centric clinical modality.

Keywords: *Mandibular overdenture, mini-dental implants, immediate loading, marginal bone loss, flapless surgery, randomized controlled trial.*

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1. INTRODUCTION

The irreversible, chronic, and progressive resorption of the residual alveolar ridge following total tooth extraction represents one of the most formidable challenges in contemporary restorative dentistry. Severe horizontal and vertical mandibular atrophy frequently eradicates the anatomical foundations required for the retention and stability of conventional acrylic prostheses [1].

This anatomical degradation profoundly impairs masticatory efficiency, alters phonetic capability, and severely diminishes the psychological well-being and overall quality of life of the edentulous patient. Recognizing these profound functional deficits, the McGill and York consensus statements unequivocally established that a mandibular overdenture retained by endosseous dental implants should serve as the absolute minimum standard of care for the fully edentulous mandible [2,3]. While conventional standard-diameter implants (typically exceeding 3.5 mm in width) exhibit exceptional long-term predictability, their surgical placement in severely atrophied mandibular ridges often necessitates complex, invasive, and costly hard tissue augmentation procedures. To circumvent these surgical morbidities, narrow-diameter mini-dental implants (MDIs), defined by diameters ranging from 1.8 mm to 2.9 mm, have emerged as a highly viable and scientifically validated alternative. Engineered from high-tensile titanium alloys such as Ti-6Al-4V ELI, MDIs are specifically designed to be inserted utilizing a minimally invasive, flapless surgical technique. This flapless approach preserves the critical periosteal microcirculation, dramatically reduces postoperative edema and morbidity, and significantly accelerates the initial phases of soft tissue healing [4,5].

Despite the extensive literature documenting the high cumulative survival rates of MDIs—frequently exceeding ninety-five percent over five to ten years of functional service—the optimal timing for the prosthetic loading of these narrow fixtures remains a subject of intense academic and clinical debate [6]. The traditional two-stage Brånemark surgical protocol dictates an unloaded, quiescent healing period of three to four months in the dense mandibular symphysis to prevent deleterious micromovements at the dynamic bone-implant interface [7]. Extensive biomechanical research indicates that implant displacement exceeding a critical threshold of 100 to 150 micrometers during the early healing phase disrupts angiogenesis, inevitably triggering fibrous encapsulation rather than true osteoblastic osseointegration [8].

Conversely, contemporary biomechanical theories derived from Wolff's Law postulate that controlled, low-amplitude micro-strains induced by immediate functional loading provide a necessary mechanical stimulus to the surrounding bone. This functional stimulus is theorized to upregulate localized osteoblastic activity, optimize the density of the trabecular bone network, and actively mitigate the crestal disuse atrophy that is occasionally observed during prolonged unloaded healing periods [9].

Recent systematic reviews and meta-analyses exploring the clinical efficacy of immediate versus delayed loading protocols for narrow-diameter implants present highly conflicting benchmarks [10-12]. Given this distinct lack of scientific consensus, there is a clear necessity for further high-quality, meticulously controlled clinical investigations. Therefore, the primary objective of this prospective, randomized controlled trial was to evaluate and compare the twelve-month effects of immediate versus delayed loading protocols on marginal bone level alterations and peri-implant mucosal health around 1.8 mm mini-implants supporting mandibular overdentures. The null hypothesis tested was that there would be no clinically or statistically significant difference in marginal bone loss or peri-implant soft tissue parameters between the two distinct loading protocols over a twelve-month observation period.

2. MATERIALS AND METHODS

Study Design and Ethical Adherence

This investigation was designed as a prospective, randomized, comparative, parallel-group clinical trial. The clinical research protocol fully complied with the ethical principles established by the Declaration of Helsinki for medical research involving human subjects. Full ethical clearance was granted by the institutional Human Research Ethics Committee prior to the initiation of patient recruitment. Comprehensive written informed consent, detailing the surgical risks, prosthetic timeline, and required follow-up regimens, was secured from all participants.

Participant Eligibility and Selection

Participants were systematically recruited from the university hospital's prosthodontic outpatient clinic based on strict, predefined eligibility criteria. To be included in the trial, patients were required to be completely edentulous individuals aged between 50 and 80 years, with a history of wearing conventional mandibular complete dentures for a minimum of six months. Additionally, participants were required to have sufficient bone volume in the mandibular alveolar ridge to accommodate an implant measuring 1.8 mm in width and 10 mm in length. All participants were required to be in good general systemic health.

Exclusion criteria were rigorously applied to eliminate confounding biological and biomechanical variables. Patients with a history of head and neck radiotherapy, current intravenous bisphosphonate therapy, uncontrolled diabetes mellitus, or severe systemic osteoporosis were excluded. Furthermore, heavy smokers (consuming more than ten cigarettes per day) and individuals exhibiting unresolved temporomandibular joint disorders or severe parafunctional habits, such as severe bruxism, were denied entry into the trial to prevent uncontrolled mechanical overloading of the narrow-diameter implants [13].

Sample Size Determination and Randomization

An a priori power analysis was executed to determine the precise sample size required to ensure statistical validity. To detect a minimum clinically significant difference of 0.20 mm in Marginal Bone Loss between the two loading cohorts, assuming an estimated standard deviation of 0.22 mm, an alpha level of 0.05, and a desired statistical power of 80%, nine participants per group were deemed mathematically necessary. To aggressively account for a potential ten percent participant attrition rate over the twelve-month follow-up period, a total of twenty participants were formally enrolled, yielding ten participants per experimental arm[14].

Following successful enrollment, participants were randomly assigned in a 1:1 ratio to either the Immediate Loading Group or the Delayed Loading Group. The specific randomization sequence was generated by an independent, off-site biostatistician utilizing computer-generated block randomization with a block size of four. To ensure strict allocation concealment and prevent selection bias, the assignment details were secured within sequentially numbered, completely opaque, sealed envelopes. These envelopes were only opened by a non-operative surgical assistant within the operating theater immediately after the administration of local anesthesia.

Surgical Intervention Protocol

To mitigate the risk of postoperative surgical site infections, a standardized prophylactic antibiotic regimen was implemented. All participants were administered 625 mg of Amoxicillin/Clavulanic Acid every eight hours, commencing three days prior to the surgical intervention and continuing for seven days postoperatively. Additionally, a 0.12% Chlorhexidine gluconate oral rinse was prescribed for use twice daily, initiated twenty-four hours before surgery.

All surgical procedures were performed under profound local anesthesia utilizing bilateral mental nerve blocks and localized crestal infiltrations of Mepivacaine Hydrochloride 4% with 1:100,000 epinephrine. A transparent radiographic acrylic surgical stent, previously fabricated and modified by removing radiopaque markers and creating circular guide openings, was seated intraorally to dictate the precise three-dimensional positioning of the four implant osteotomies. These sites corresponded anatomically to the bilateral mandibular central incisors and canines.

A minimally invasive flapless surgical technique was exclusively employed. Transmucosal osteotomies were initiated directly through the keratinized gingiva utilizing a sharp 1.1 mm diameter pilot drill (10 mm length) operating at 800 RPM under copious, chilled sterile saline irrigation. This created a precise, undersized osteotomy at each predetermined site. Four one-piece mini-dental implants (1.8 mm diameter, 10 mm length, Ti-6Al-4V ELI; 3M ESPE MDI System, Seefeld, Germany), featuring an aggressive self-tapping thread design and a highly polished O-ball prosthetic head, were selected for insertion [15].

Initial implant insertion was performed manually, utilizing the manufacturer's proprietary plastic carrier to ensure the correct trajectory. Final osseous seating was completed utilizing a calibrated manual ratchet torque wrench. The acquisition of primary mechanical stability was an absolute prerequisite for trial continuation; therefore, an insertion torque exceeding 35 Ncm was strictly mandated for all implants allocated to the immediate loading cohort. The implants were meticulously threaded until the entire 10 mm intraosseous length was fully engaged within the surrounding cortical and trabecular bone, ensuring that only the smooth transmucosal collar and the O-ball retention head projected above the mucosal surface.

3. PROSTHETIC LOADING PROTOCOLS

Immediate Loading Group: Immediately following the completion of the surgical phase (Day 0), the patient's existing conventional mandibular denture was comprehensively relieved at the mucosal surface corresponding to the four projecting implant heads. Standard metallic housing caps, internally fitted with resilient rubber O-rings (MH-1, 3M ESPE), were manually snapped onto the spherical O-ball heads of the implants. The relieved areas of the denture base were then filled with a hard autopolymerizing polymethyl methacrylate (PMMA) acrylic resin. The denture was seated intraorally, and the patient was guided into centric occlusion. Once polymerized, the denture was removed, trimmed, and polished, effectively incorporating the metal housings via a direct chairside pick-up technique. This established immediate functional retention and mechanical stability before patient discharge.

Delayed Loading Group: The mandibular denture in this cohort was aggressively relieved to create a massive void over the surgical sites, completely preventing any direct functional contact or mechanical loading upon the projecting implant

heads during the critical initial osseointegration phase. The relieved intaglio surface was relined with a highly resilient soft tissue conditioner. Patients functioned cautiously with this tissue-borne prosthesis for a mandatory healing period of three months. Following this quiescent period, the identical hard-resin direct pick-up procedure was executed, transitioning the implants from an unloaded state into full functional loading.

Outcome Measures and Data Collection

Clinical and radiographic evaluations were systematically conducted at baseline (defined as the precise time of functional denture connection: 0 months for the Immediate group, 3 months for the Delayed group), and subsequently at 3, 6, and 12 months post-loading.

1. **Marginal Bone Level (MBL) changes :** Radiographic evaluations were executed utilizing standardized digital periapical radiographs captured via the long-cone paralleling technique, employing customized acrylic bite blocks to ensure reproducible geometric alignment across all temporal intervals. The digital radiographic images were mathematically calibrated utilizing the known true length of the implant fixture (10.0 mm). MBL alterations were quantified by measuring the vertical distance from the horizontal implant platform to the most coronal point of visible bone-to-implant contact utilizing high-resolution image analysis software (ImageJ, National Institutes of Health). Measurements were meticulously recorded at both the mesial and distal aspects of each implant, and the mean value was calculated for statistical analysis. To eliminate assessment and detection bias, all radiographic evaluations were performed by a single, highly calibrated, independent oral radiologist who remained completely blinded to the patients' specific group allocations.
2. **Clinical Peri-Implant Indices:** The health and stability of the peri-implant mucosal tissues were assessed utilizing the Gingival Index (GI) and Probing Depth (PD). PD was measured utilizing a calibrated, force-controlled plastic periodontal probe. For each implant, four distinct readings were captured at the mesial, distal, buccal, and lingual surfaces, and a cumulative mean value was generated for the analysis.

Statistical Analysis

The normality of the data distribution was rigorously verified utilizing the Shapiro-Wilk test. Because the data demonstrated normal distribution patterns, parametric statistical tests were deployed. Comprehensive descriptive statistics, including Means, Standard Deviations (SD), and 95% Confidence Intervals (CI), were calculated for all continuous variables. Between-group comparative analyses (Immediate vs. Delayed) for MBL, GI, and PD at specific evaluation intervals were executed utilizing independent samples t-tests. Within-group, time-dependent longitudinal changes were assessed utilizing repeated measures Analysis of Variance (ANOVA). The statistical analysis was performed using IBM SPSS Statistics software (Version 28.0; IBM Corp.), with the threshold for statistical significance strictly maintained at $\alpha = 0.05$.

4. RESULTS

Participant Flow

All twenty randomized participants completed the entirety of the surgical interventions, the prosthetic rehabilitation phases, and attended all mandated follow-up appointments up to the final twelve-month evaluation. No implant failures, fractures, or cases of severe peri-implantitis occurred during the observation period, yielding an exceptional 100% cumulative survival rate for all eighty mini-implants.

Marginal Bone Level (MBL) changes

A progressive, highly predictable pattern of physiological crestal bone remodeling was observed across both experimental groups over the twelve-month longitudinal observation period. At the baseline evaluation, the mean radiographic bone height perfectly matched the physical implant length (10.00 mm), indicating optimal initial surgical placement. By the final twelve-month evaluation, both cohorts exhibited expected degrees of marginal bone loss, consistent with the standard establishment of the peri-implant biological width and structural adaptation to occlusal loads.

The Immediate Loading Group demonstrated a cumulative mean MBL of 0.87 ± 0.22 mm (95% CI: 0.79, 0.95), while the Delayed Loading Group exhibited a slightly higher mean MBL of 1.01 ± 0.25 mm (95% CI: 0.92, 1.10) (Table 1). Independent samples t-test analysis indicated that this 0.14 mm variance between the two protocols was statistically significant ($p = 0.042$), mathematically favoring the immediate loading approach.

Table 1: Radiographic Marginal Bone Level (MBL) Changes Over 12 Months (mm)

Evaluation Interval	Immediate Loading (Mean ± SD) [95% CI]	Delayed Loading (Mean ± SD) [95% CI]	p-value (Between Groups)
Baseline (Functional Loading)	0.00 ± 0.00	0.00 ± 0.00	-
3 Months	0.39 ± 0.11 [0.35, 0.43]	0.48 ± 0.14 [0.43, 0.53]	0.038*
6 Months	0.59 ± 0.16 [0.53, 0.65]	0.78 ± 0.19 [0.71, 0.85]	0.021*
12 Months	0.87 ± 0.22 [0.79, 0.95]	1.01 ± 0.25 [0.92, 1.10]	0.042*
*Indicates statistical significance at $p < 0.05$.			

Clinical Peri-Implant Health Indices

Gingival Index (GI) scores demonstrated a distinct, transient temporal variation between the two cohorts. The Immediate Loading Group recorded statistically lower, and therefore healthier, GI scores at the three-month (0.63 ± 0.21) and six-month (1.19 ± 0.28) evaluations when compared to the Delayed Loading Group (1.00 ± 0.25 and 1.69 ± 0.35, respectively; $p < 0.05$). However, as the mucosal tissues matured, the GI scores converged. By the final twelve-month evaluation, there was absolutely no statistically significant difference in mucosal inflammation between the two protocols (1.88 ± 0.41 vs. 2.13 ± 0.52; $p = 0.18$).

Mean Probing Depths (PD) increased gradually and predictably over time in both groups, representing a completely normal physiological response to soft tissue maturation and cuff formation around the polished transmucosal collar of the implant. Crucially, no statistically significant differences in PD were recorded between the immediate and delayed cohorts at any specific observation interval throughout the trial (Table 2).

Table 2: Peri-Implant Probing Depth (PD) Progression Over 12 Months (mm)

Evaluation Interval	Immediate Loading (Mean ± SD)	Delayed Loading (Mean ± SD)	p-value (Between Groups)
1 Month Post-Loading	2.40 ± 0.33	2.03 ± 0.30	0.105
3 Months Post-Loading	2.63 ± 0.35	2.35 ± 0.34	0.162
6 Months Post-Loading	2.85 ± 0.38	2.64 ± 0.37	0.211
12 Months Post-Loading	3.00 ± 0.42	2.85 ± 0.40	0.344

5. DISCUSSION

The primary objective of this prospective, randomized controlled clinical trial was to rigorously compare the twelve-month peri-implant hard and soft tissue responses of 1.8 mm mini-dental implants subjected to immediate versus delayed functional loading protocols. The statistical data derived from the radiographic analysis rejected the proposed null hypothesis, as the immediate loading protocol resulted in 0.14 mm less marginal bone resorption compared to the conventional delayed approach (0.87 mm versus 1.01 mm, p=0.042). However, translating raw statistical significance into practical clinical relevance is an imperative step in implant prosthodontics [16,17].

A structural variation of a mere 0.14 mm in crestal bone height falls entirely within the recognized margin of measurement error inherent to two-dimensional digital periapical radiography, which frequently exhibits a geometric or calibration distortion ranging between 0.20 mm and 0.50 mm. Furthermore, standard global clinical benchmarks firmly establish that initial marginal bone loss ranging from 0.50 mm to 1.50 mm during the first twelve months of functional loading is an entirely normal physiological consequence of the establishment of the peri-implant biological width and the structural adaptation of the bone to dynamic occlusal forces. True pathological bone loss, indicative of the onset of destructive peri-implantitis, is generally categorized by osteolytic thresholds exceeding 2.0 mm. Therefore, rather than establishing absolute biological "superiority," the findings of this trial elegantly and firmly establish the non-inferiority and extreme clinical safety of the immediate loading protocol for narrow-diameter implants in the edentulous mandible [18,19].

The radiographic findings of the present trial align closely with those of a previous systematic review and meta-analysis. By analyzing extensive pooled global data, the authors of that review found no clinically significant difference in marginal bone loss (MBL) between immediate and delayed loading protocols for unsplinted mandibular implants, reporting a weighted mean difference of 0.04 mm [20]. Interestingly, the findings of the present trial diverge slightly from earlier, highly respected investigations by Elsyad et al., which reported that delayed loading protocols yielded significantly less initial bone loss [21]. This specific variance in outcomes can likely be attributed to the differing implant configurations. While Elsyad evaluated two implants, the present study utilized four 1.8 mm MDIs. The utilization of four fixtures, firmly

splinted by the rigid acrylic matrix of the mandibular overdenture, likely distributed the intense occlusal stresses much more favorably across the broad anterior arc of the symphysis. This biomechanical distribution prevents the severe force concentrations at individual implant necks that frequently lead to cratering osteolysis [22].

The undeniable biomechanical success of the immediate loading group firmly validates the advanced theory of functional osseointegration [23]. By ensuring excellent primary mechanical stability through strict adherence to an insertion torque threshold exceeding 35 Ncm [24], the immediate rigid connection of the denture subjected the surrounding trabecular bone network to highly controlled, low-amplitude micro-strains. According to the principles of Wolff's Law, such mechanical stimuli directly upregulate osteoblastic activity, enhancing the speed and quality of mineralization at the crucial bone-implant interface. This active stimulation effectively mitigates the crestal disuse atrophy that is occasionally observed during prolonged, unloaded healing periods [25].

The clinical soft tissue parameters meticulously recorded during the trial beautifully mirrored the hard tissue stability [26]. The transient, yet statistically significant, improvement in the Gingival Index (GI) for the immediate group at three and six months likely reflects a profound protective shielding effect. The firmly seated, implant-retained overdenture prevented food impaction and abrasive mechanical trauma to the healing mucosa during mastication—a significant daily hazard faced by patients in the delayed group who are forced to function with a highly mobile, soft-lined transitional denture during the initial healing phase. Crucially, the total convergence of both GI and PD values by the twelve-month mark (with PD stabilizing at ~3.00 mm) confirms that neither loading protocol induced detrimental, irreversible peri-implant inflammation. [27,28]

Limitations and Future Directions

While this study was designed with extreme methodological rigor, it is not without inherent limitations that warrant discussion. First, the twelve-month follow-up period successfully captures the critical initial bone remodeling phase; however, longitudinal tracking extending over three to five years is necessary to evaluate the long-term fatigue resistance of mini-implants under decades of cyclic masticatory loading. Second, the marginal bone measurements in this trial were anatomically constrained to the mesial and distal aspects due to the reliance on 2D periapical radiography. Future multi-center clinical trials should actively integrate Cone Beam Computed Tomography (CBCT) to accurately evaluate three-dimensional alterations in the fragile buccal and lingual cortical bone plates.

6. CONCLUSIONS

Within the rigorous parameters and limitations of this twelve-month randomized controlled clinical trial, the following conclusions can be drawn:

1. The immediate functional loading of four 1.8 mm diameter mini-dental implants supporting a mandibular overdenture is a highly predictable and biologically safe clinical protocol.
2. The immediate application of functional masticatory forces, provided strict primary stability parameters (>35 Ncm) are met, does not compromise the health or stability of the peri-implant soft tissues at twelve months.
3. Given the dramatic reduction in overall treatment time and the immediate psychological and functional benefits provided to the patient, the immediate loading of MDIs represents a highly efficient and patient-centric modality for the rehabilitation of the severely atrophic edentulous mandible.

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