Stability and marginal bone level measurements of unsplinted implants used for mandibular overdentures: a 1-year randomized prospective clinical study comparing early and conventional loading protocols

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Abstract
Objectives: The aim of this study was to compare the performance of two non-splinted implants used as retention for a mandibular overdenture when applying conventional or early loading protocols.

Material and methods: Twenty edentulous patients were treated with two unsplinted and non-submerged implants (15 mm long, TiUnite RP, Bränemark System) in the anterior mandible. The patients were randomly allotted into two groups: (i) test group (Group A), in which the overdenture was connected 1 week after surgery, and (ii) control group (Group B), in which the overdenture was connected after 12 weeks of healing. Resonance frequency analyses (RFA) for implant stability measurements were performed at implant surgery and after 1, 3, 6, 9 and 12 months. Marginal bone levels were evaluated at implant surgery and after 6 and 12 months.

Results: No implant from either group was lost and all implants showed less than 1 mm of marginal bone resorption during the first year. The mean implant stability quotient (ISQ) values at implant surgery were 76.2 ± 2.8 for Group A and 75.6 ± 4.5 for Group B. The 12-month measurements showed 76.4 ± 2.5 ISQ and 76.4 ± 2.8 ISQ for Groups A and B, respectively. There were no statistically significant changes between or within the groups with time. There were no differences in marginal bone loss, which was on average 0.3 mm for both groups after 1 year.

Conclusion: Although a limited number of patients were followed for 1 year only, the results of the present study indicate that early loading of two unsplinted 15 mm long implants with an overdenture does not negatively affect implant stability or marginal bone conditions when compared with implants subjected to 12 weeks of healing before loading.

Clinical follow-up studies have reported good and predictable long-term treatment outcomes with implant-supported mandibular overdentures [van Steenberghe et al. 2001; Behneke et al. 2002; Zechner et al. 2004]. The use of two to four or more implants connected with a bar seems to dominate the literature, although the use of two unsplinted implants has been reported to be a feasible option [Naert et al. 2004]. Advantages with the latter technique are simplicity and less costs, as the full treatment can be made chair side without any laboratory procedures. This treatment modality has been proposed to be the minimal acceptable standard of care of the edentulous mandible [Thomason 2002].

The use of one-stage surgical procedures and immediate/early loading protocols is one way of further simplifying implant treatment. The outcomes of early loading protocols for splinted implants supporting...
mandibular overdentures have been reported in the literature [Chiapasco et al. 1997; Collaert & De Bruyn 1998]. Only a few studies have dealt with early loading of unsplinted implants supporting mandibular overdentures [Payne et al. 2001; Roynesdal et al. 2001], and no trials comparing different loading regimens are available. It is possible that non-splinted implants may be negatively affected by immediate/early loading because the load is not shared between implants, i.e. decreased stability and/or marginal bone resorption.

The aim of this prospective clinical study was to compare implant stability and marginal bone resorption when using conventional or early functional loading protocols in patients rehabilitated with implant-supported mandibular overdentures.

**Material and methods**

**Patients**

Twenty totally edentulous patients (10 males, 10 females, mean age 62 years) with a history of problems with their conventional mandibular and maxillary complete dentures presenting at the Clinical Overdenture Research Project (Faculty of Dentistry, University of Hacettepe, Ankara, Turkey) were considered for the clinical trial. Ethical approval was obtained from Hacettepe University Ethics Committee, and all participants gave informed consent.

**Inclusion criteria**

[a] Fifty to 75 years old.
[b] Bone volume for two 15 mm implants in the anterior mandible.

**Exclusion criteria**

[a] Systemic disease likely to compromise implant surgery.
[b] Previously bone grafting in the anterior part of the mandible.

Preoperative panoramic radiographs (Planmeca OY, Helsinki, Finland) and computerized tomography (Siemens AR-SP 40, Munich, Germany) were used for surgical evaluation of the selected sites for each patient.

**Surgical and prostodontic procedures**

Antimicrobial prophylaxis (2 g amoxicillin) was given orally 1 h before surgery. The patients were rinsed with chlorhexidine digluconate solution (0.2%) for 1 min 10 min before the operation. Local anaesthesia was induced by infiltration of Ultracaine® D-S (Hoechst Marion Roussel, Deutschland GmbH, Germany) buccally and lingually of the canine regions in the mandible. A mid-crestal incision was made in keratinized mucosa and a small flap was raised at each site to expose the bone. The sites were prepared according to the standard procedure for Brånemark System implants [Nobel Biocare AB]. Two 15 mm implants (TiUnite RP MKIII, Nobel Biocare AB) were placed in each patient. The patients were randomly allocated into two groups.

**Group A**

Ball attachments (3 mm, Nobel Biocare AB) were screwed to the implants before suturing. Mucoperiosteal flap closure was performed using interrupted or horizontal mattress sutures (4-0 Vicryl®, Ethicon, Johnson & Johnson, Brussels, Belgium). The patients were prescribed a soft diet 10 min before the operation. Local anaesthesia was induced by infiltration of Ultracaine® D-S (Hoechst Marion Roussel, Deutschland GmbH, Germany) buccally and lingually of the canine regions in the mandible. A mid-crestal incision was made in keratinized mucosa and a small flap was raised at each site to expose the bone. The sites were prepared according to the standard procedure for Brånemark System implants [Nobel Biocare AB]. Two 15 mm implants (TiUnite RP MKIII, Nobel Biocare AB) were placed in each patient. The patients were randomly allocated into two groups.

**Group B**

Healing abutments (5 mm) were attached to the implants. New maxillary and mandibular complete dentures were manufactured as described above and delivered 1 week after the implant surgery. However, care was taken to ensure that the mandibular denture did not contact the implants.

**Results**

The mean ISQ values at implant surgery were 76.2 ± 2.8 for Group A and 75.6 ± 0.05 after 3 months of healing the healing abutments were replaced with ball attachments (3 mm). A reline impression procedure was performed and the implant–tissue-supported mandibular overdenture was delivered the next day.

**Follow-up**

Clinical examinations and resonance frequency analysis (RFA) [Ostell, Integration Diagnostics AB, Gothenburg, Sweden] were performed at implant surgery and after 1, 3, 6, 9 and 12 months. On these occasions, the abutments were removed from the patient and RFA measurements were taken on implant level. The measurements were given in implant stability quotient (ISQ) units [Integration Diagnostics AB]. Standardized intraoral radiographs of the coronal parts of the implants were taken at each implant placement after 6 and 12 months. On these occasions an impression coping was attached to each implant to guide a plastic film holder. The radiographs were scanned to digital files and marginal bone changes were measured in a computer using an image analysis software (Adobe Photoshop, Adobe Systems Incorporated, San Jose, CA, USA) by one examiner using the implant–abutment junction as a reference [Payne et al. 1999]. The distance between two threads (0.6 mm) was used for calibration of measurements.

The success criteria were absence of mobility and less than 1 mm of marginal bone resorption between placement and 1 year. The survival criterion was a stable implant–tissue-supported mandibular overdenture with respective gold caps were delivered to the participants 1 week after the implant surgery.

**Statistics**

All data were analysed with SPSS version 10 statistical package (SPSS Inc., Chicago, IL, USA). Statistical tests were made on patient level, meaning that mean ISQ and marginal bone level values were calculated for each patient based on two implants. The Spearman correlation test was used to find possible relations between RFA and marginal bone resorption. A difference was considered if \( P < 0.05 \).
There was a tendency of higher ISQ values for Group A during follow-up, however with no statistically significant differences [Fig. 1]. There were no statistically significant changes within the groups with time. The 12-month measurements showed 76.4 ± 2.5 ISQ and 76.4 ± 2.8 ISQ for Groups A and B, respectively [Table 1].

In Group A, the marginal bone was located 0.7 ± 0.3 mm from the reference point immediately after implant placement, 0.8 ± 0.3 mm after 6 months and 1 ± 0.3 mm after 12 months. The corresponding figures for Group B were 0.6 ± 0.2 mm at baseline and 0.8 ± 0.2 and 0.9 ± 0.3 mm after 6 and 12 months, respectively [Table 2]. Thus the average marginal bone resorption was 0.3 mm for both groups during 1 year. There were no statistical significant differences between the two groups.

There was a statistically significant correlation between change of stability and marginal bone resorption from baseline to 6 months [Fig. 2] but not from 6 to 12 months [Fig. 3] based on measurements of all patients [n = 40].

All implants were stable and no single implant showed more than 1 mm of bone resorption after 1 year; thus, all 40 implants were judged as successful.

Discussion

The present study showed that one-stage surgery is feasible when using two unsplinted implants as support for an overdenture in the mandible as no implants were lost during the 1-year follow-up period. The implant stability and marginal bone-level measurements showed no differences between implants loaded 1 week or 3 months after surgery, indicating that early loading did not negatively influence the performance of the implants. When validating an implant treatment approach, the use of well-defined criteria for success is essential. The absence of implant mobility and set levels of acceptable marginal bone resorption have commonly been utilized [Roos et al. 1997]. In the present study, all implants were individually checked for stability using the RFA technique and marginal bone levels were measured. No implant failed and all 40 implants in this study showed less than 1 mm of resorption, meaning that the success rate after 1 year was 100% in spite of if conventional or early loading protocols were applied. The present 1-year results corroborate with the results reported in other studies on mandibular overdentures when using 3 months and 6 weeks of healing before loading [Jemt et al. 1996; Schmitt & Zarb 1998; Tawse-Smith et al. 2002; Payne et al. 2003; Naert et al. 2004]. This is most encouraging and indicates that early loading of two unsplinted implants is a safe procedure, which will further simplify an already effective and recognized treatment modality of the edentulous mandible [Thomason 2002].

All implants used in this study were placed in the anterior mandible, where bone density is high compared with other regions [Friberg et al. 1995]. High bone density results in high primary stability [Friberg et al. 1999a, 1999b; O’Sullivan et al. 2000], which is considered as one important determinant of success [Sennertby & Roos 1998]. RFA showed an average primary stability of about 75 ISQ units, which is in line with ISQ values reported for similar implant designs by other researchers [Payne et al. 2003]. The ISQ values decreased slightly during the initial quarter following surgery and increased from the third month to the 12th month measurements. This is in line with the findings reported by Friberg et al.
who made repeated measurements of one-stage implants in the mandible during 15 weeks of healing. They also found some marginal bone resorption during that period which could explain the decrease, as RFA measurements are affected by the effective implant length, i.e. the distance from the RFA transducer to the first bone contact (Meredith et al. 1996, 1997). In the present study there was a correlation between change of stability and marginal bone resorption [mm] from baseline to 6 months. A statistically significant correlation cannot be found.

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References


