*Ilser Turkyilmaz*
*Lars Sennerby*
*Celal Tumer*
*Muhittin Yenigul*
*Mehmet Avci*

# 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

**Authors' affiliations:**
*Ilser Turkyilmaz, Muhittin Yenigul, Mehmet Avci*, Department of Prosthodontics, Faculty of Dentistry, Hacettepe University, Ankara, Turkey
*Celal Tumer*, Department of Oral & Maxillofacial Surgery, Faculty of Dentistry, Hacettepe University, Ankara, Turkey
*Ilser Turkyilmaz, Lars Sennerby*, Department of Biomaterials, Institute of Surgical Sciences, Sahlgrenska Academy, Gothenburg University, Gothenburg, Sweden

**Correspondence to:**
*Dr Ilser Turkyilmaz*
Department of Biomaterials
Institute of Surgical Sciences
Sahlgrenska Academy
Gothenburg University
PO Box 412
SE 405 30 Gothenburg
Sweden
Tel.: +46 31 773 29 50
Fax: +46 31 773 29 41
e-mail: ilser@hacettepe.edu.tr

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**Key words:** early loading, mandibular overdentures, marginal bone resorption, resonance frequency analysis

**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, Brånemark 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; Røynesdal 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 radiograph (Planmeca OY, Helsinki, Finland) and computerized tomograpy (Siemens AR-SP 40, Munich, Germany) were used for surgical evaluation of the selected sites for each patient.

### Surgical and prosthodontic procedures

Antimicrobial prophylaxis (2 g amoxicillin) was given orally 1 h before each 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 for the first week and a strict regimen of removal of their old dentures during night.

Five days after surgery, the sutures were removed and preliminary impressions were taken with a stok tray using alginate (Caex, CA37, Haarlem, the Netherlands). Secondary impressions were taken with a custom-made tray using Coltex Medium impression materials (Coltene/Whaledent AG Feldweisenstrasse 20, Altstatten, Switzerland). The ball abutment replicas were placed into the impression material after the impression was removed. Wax occlusal rims were created on the master models for try-in the same day. Teeth try-in (Major Dent, Moncalieri, Italy) and corrections and manufacturing of the acrylic dentures (Meliodent, Heraeus Kulzer Ltd, Newbury, Berkshire, Germany) were performed on the sixth day after surgery. The maxillary complete denture and implant–tissue-supported mandibular overdentures with respective gold caps were delivered to the participants 1 week after the implant surgery.

#### 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.

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) (Osstell, 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 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 showing more than 1 mm of bone resorption after 1 year. Implants removed for any reason were regarded as failures.

### 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 $P<0.05$.

## Results

The mean ISQ values at implant surgery were 76.2 ± 2.8 for Group A and 75.6 ±

4.5 for Group B (NS) (Table 1). There was a tendency of higher ISQ values for Group A during follow-up, however with no 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 (NS) (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 ($n = 20$).

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.

***Table 1.*** **Results from RFA measurements**

| | Mean ISQ + SD | | | | | |
|---|---|---|---|---|---|---|
| | Surgery | Month 1 | Month 3 | Month 6 | Month 9 | Month 12 |
| Group A | 76.2 ± 2.8 | 75.6 ± 2.2 | 75 ± 2.6 | 75.2 ± 3.4 | 76 ± 2.8 | 76.4 ± 2.5 |
| Group B | 75.6 ± 4.5 | 73.2 ± 3.4 | 73 ± 3.6 | 74.1 ± 3.6 | 74.7 ± 3.1 | 76.4 ± 2.8 |

RFA, resonance frequency analyses; ISQ, implant stability quotient.

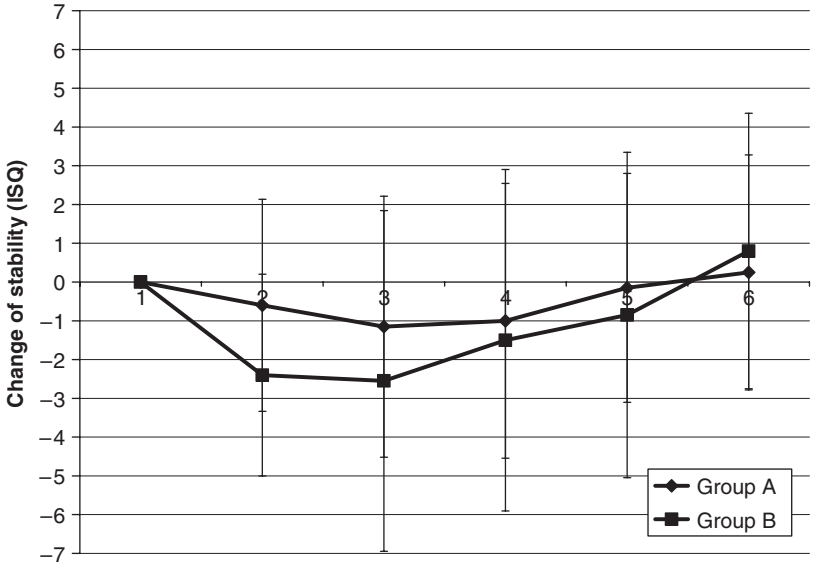


*Fig. 1.* Change of implant stability with time in Groups A and B. A tendency of steeper decrease is seen for Group B implants; however, this is not statistically significant.

***Table 2.*** **Results from radiographic measurements**

| | Mean mm + SD | | | | | |
|---|---|---|---|---|---|---|
| | Surgery | Month 6 | Month 12 | Change 0–6 months | Change 0–12 months | Change 6–12 months |
| Group A | 0.7 ± 0.3 | 0.9 ± 0.3 | 1 ± 0.3 | 0.2 ± 0.2 | 0.3 ± 0.2 | 0.1 ± 0.1 |
| Group B | 0.6 ± 0.2 | 0.8 ± 0.2 | 0.9 ± 0.2 | 0.2 ± 0.2 | 0.3 ± 0.1 | 0.1 ± 0.1 |

## 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 (Sennerby & 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.

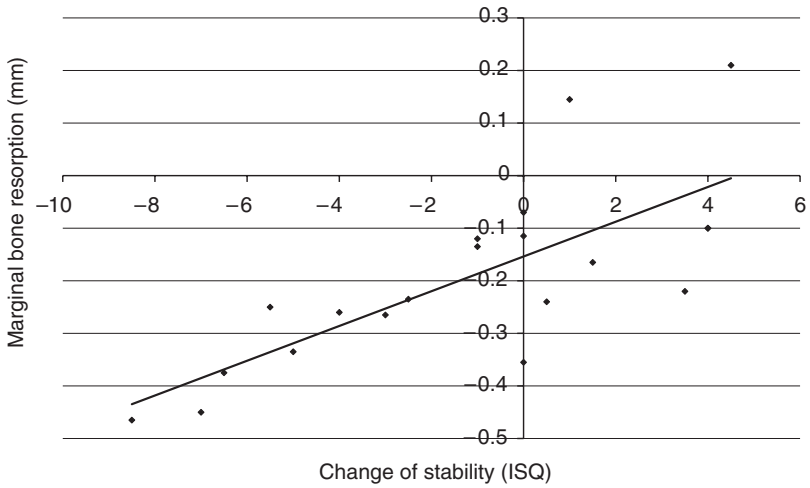


*Fig. 2*. Correlation plot between change of stability (implant stability quotient (ISQ)) and marginal bone resorption (mm) from baseline to 6 months. There is a statistically significant correlation ($P<0.001$).

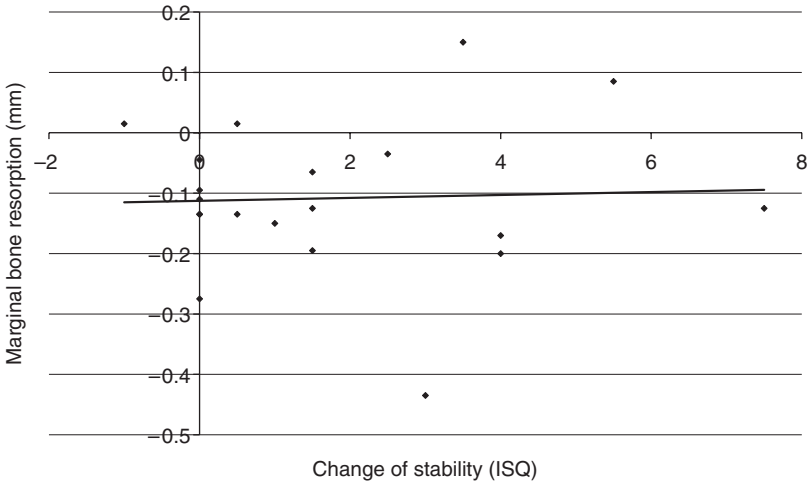


*Fig. 3*. Correlation plot between change of stability (implant stability quotient (ISQ)) and marginal bone resorption (mm) from 6 to 12 months. A statistically significant correlation cannot be found.

(1999a, 1999b) 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 from baseline to 6 months but not from 6 to 12 months. This decrease could be explained in terms of increased effective implant length and indicates that bone formation had no impact on implant stability during the first 6 months, as this would have counteracted the effect of resorption. However, after 6 months it seems that bone formation did affect implant stability positively and thus counteracted the effect of bone resorption. In a study by Glauser et al. (2004), the authors observed a marked decrease of implant stability during the first months in spite of minimal marginal bone resorption. The greater fluctuations of implant stability compared with the present study can be explained by the greater loads applied by Glauser et al. as the implants were used to support crowns and bridges in all jaw regions. Apart from effective implant length, the RFA technique meaures stability as a function of interface stiffness. It is likely that loading affects healing and remodelling around implants, which in turn influences the mechanical properties of the supporting bone. However, the correlation between histomorphometric parameters such as bone-to-implant contacts/bone volume and RFA is presently unclear and more studies are needed (Nkenke et al. 2003). In the study referred to above, Glauser et al. (2004) demonstrated that implants failing during the 1-year study period showed a pattern of continuous loss of stability until clinical failure. The available data indicate that RFA may serve as a sensitive tool to monitor the performance of clinical implants.

The implants used in this study had oxidized surfaces. It is known from clinical and experimental studies that such implants integrate more rapidly and with higher degrees of bone–implant contacts than machined implants (Ivanoff et al. 2003; Zechner et al. 2003). Although implants with machined surface are known to be highly successful in the anterior mandible using a two-stage procedure, early loading may challenge the integration process. A recent study on 152 patients and 750 implants showed lower survival rates for early loaded than for two-stage machined implants when using the implant as unit for statistical analysis (Friberg et al. 2005). Oxidized implants have been shown to be more resistant to immediate loading than machined ones, at least in soft maxillary bone (Glauser et al. 2001), and it is possible that the use of oxidized implants in the present study contributed to the good outcome.

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.

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要旨

**目的**：本研究の目的は、通法または早期荷重のプロトコールに基づいて、下顎オーバーデンチャーの維持として用いた２本の単独植立（非連結）のインプラントの性能を比較することであった。

**材料と方法**：無歯顎患者２０名の下顎前歯部を、連結しない、非埋入式のインプラント２本（１５ｍｍ長、**TiUnite RP**、**Branemark** システム）で治療した。患者は２群に無作為に振り分けた；1）試験群（Ａ群）ではオーバーデンチャーを手術後１週間後に連結した、２）対照群（Ｂ群）ではオーバーデンチャーを治癒１２週間後に連結した。インプラント手術時と術後１、３、６、９及び１２ヶ月後に共振周波数分析（ＲＦＡ）によってインプラントの安定性を測定した。辺縁骨レベルは、インプラント手術時と６及び１２ヵ月後に評価した。

**結果**：２群とも失われたインプラントはなく、全てのインプラントは最初の１年の辺縁骨吸収は１ｍｍ未満であった。インプラント手術時の平均ＩＳＱ値は、Ａ群が７６．２±２．８、Ｂ群が７５．６±４．５であった。１２ヶ月後の測定値は、Ａ群、Ｂ群で各々７６．４±２．５ＩＳＱと７６．４±２．８ＩＳＱであった。経時的に２群間に統計学的な有意差は認められなかった。辺縁骨吸収にも差異はなく、２群とも１年後の平均は０．３ｍｍであった。

**結論**：少数の患者を１年間観察したのみであるが、本研究の結果は単独植立の１５ｍｍ長インプラントにオーバーデンチャーを連結する方式での早期荷重は、荷重前に１２週間の治癒期間を設けたインプラントに比べ、インプラントの安定性や辺縁骨の条件に悪影響を及ぼさないことを示唆している。

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