J Clin Periodontol 2006; 33: 233–238 doi: 10.1111/j.1600-051X.2006.00895.x

Journal of Clinical Periodontology

Clinical and radiological results of patients treated with two loading protocols for mandibular overdentures on Brånemark implants

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Turkyilmaz I. Clinical and radiological results of patients treated with two loading protocols for mandibular overdentures on Brånemark implants. J Clin Periodontol 2006; 33: 233–238. doi: 10.1111/j.1600-051X.2006.00895.x. Blackwell Munksgaard, 2006.

Abstract

Objective: The aim of this study was to evaluate clinical and radiological outcomes of the unsplinted implants supporting mandibular overdenture when applying conventional or early loading protocols.

Material and Methods: Twenty-six edentulous patients were treated with two unsplinted Brånemark System implants supporting mandibular overdenture. There was a test group, in which the overdenture was connected 1 week after surgery, and a control group, in which the overdenture was connected 3 months after surgery. Peri-implant paremeters were recorded 1, 6, and 12 months after surgery. Clinical stability measurements were performed at surgery, and after 3, 6, and 12 months. Marginal bone levels were evaluated at implant surgery, after 6, and after 12 months.

Results: No implant from either group was lost. Clinical peri-implant parameters, clinical stability measurements, and marginal bone resorptions showed no statistically significant differences between two groups during 12 months.

Conclusion: The results of this study suggest that one-week of early loading protocol of two Brånemark implants supporting mandibular overdenture does not compromise implant stability, marginal bone loss, and peri-implant soft-tissue health.

Key words: early loading; mandibular overdentures; marginal bone loss; peri-implant results; resonance frequency analysis

Accepted for publication 7 November 2005

Although dental rehabilitation with conventional removable prosthesis in patients with completely edentulous mandibles may represent a satisfactory solution to restore function and aesthetics for many patients, in others, removable complete dentures may result in functional and psychological problems. Lack of stability and retention, together with decreased chewing ability, are frequent complaints of these patients (Tallgren 1972, Vigild 1993, Zarb & Schmitt 1995, Jemt et al. 1996).

When a fixed prosthesis anchored to osseointegrated implants is not indicated for anatomic, functional, or particularly economic reasons, implant-supported overdentures may be considered as a possible alternative treatment. Numerous researches have concluded that this treatment can be very successful (Quirynen et al. 1991, Mericske-Stern et al. 1994, Collaert & De Bruyn 1998, Naert et al. 1998, Haisch 2000, Chiapasco et al. 2001, Heydecke 2002, Meijer et al. 2003, MacEntee et al. 2005). Jemt et al. (1996) were among the first to report on the possibility of using overdentures supported by two implants to improve mandibular denture retention. It is clear that the survival rate of endosseous titanium implants is high with this treatment modality (Collaert & De Bruyn 1998, Haisch 2000, Heydecke 2002, Meijer et al. 2003, MacEntee et al. 2005). Some studies regarding conventional loading protocol included 100% implant success (Quirynen et al. 1991, Mericske-Stern et al. 1994) while the others regarding the early/immediate loading protocol as having 98% implant success (Chiapasco et al. 2001, Tawse-Smith 2001). In addition, a recent consensus conference stated that implant-supported mandibular overdenture retained by two

unsplinted dental implants was the minimal acceptable standard care of the edentulous mandible (Thomason 2002).

Currently, the increasing acceptance of a one-stage implant treatment, either by continued use of non-submerged implants (Merickse-Stern 1990, Merickse-Stern 1998) or by the modified two-stage submerged treatment using a one-stage operative technique (Frieberg et al. 1999a, Tawse-Smith 2001), has enhanced the quality of the overdenture treatment for elderly edentulous patients. The placement of implants in a one-stage procedure has some advantages: only one surgical intervention is needed, treatment time is shorter, costs are lower, and the implants are accessible for clinical monitoring during the healing phase.

Three types of loading protocols have been stated in the consensus report (Aparicio et al. 2003) as follows:

- *Immediate loading:* The prosthesis is attached to the implants on the same day the implants are inserted.
- *Early loading:* The prosthesis is attached during a second procedure, earlier than the conventional healing period of 3–6 months; time of loading should be stated in days/weeks.
- *Delayed loading:* The prosthesis is attached during a second procedure after a conventional healing period of 3–6 months.

Animal (Kim et al. 2003) and human (Ivanoff et al. 2003) studies showed that rough-surfaced implants can become osseointegrated faster than machined-surfaced titanium implants. Ivanoff et al. (2003) who conducted one of the human studies on bone response to oxidized (TiUnite) and gave Brånemark System titanium micro-implants in the human jawbone, reported that bone–implant contact was higher for TiUnite surface. Consequently, improvements in the implant surfaces in the recent years have been one of the reasons for immediate/early loading protocols.

Early or immediate loading protocols for splinted implants supporting mandibular overdentures have been reported (Ledermann 1989, Krekeler 1991, Chiapasco et al. 2001). However, few reports have evaluated early or immediate loading of unsplinted implants that support mandibular overdenture (Payne et al. 2001, Roynesdal 2001, Tawse-Smith 2001).

It has been hypothesized that one-week of healing period may not have any detrimental effect on the implant osseointegration.

The aim of this clinical study was to assess the effect of early loading on osseointegration of unsplinted Brånemark System MK III TiUnite implants (Nobel Biocare AB, Göteborg, Sweden) using implant-supported mandibular overdentures, and to compare these results with those for conventional loading.

Material and Methods

The study population consisted of 26 edentulous patients (mean age 63 years) having problems with their conventional mandibular complete dentures. Ethical approval was obtained from Ethics Committee of Hacettepe University, Ankara, Turkey. Inclusion criteria were 50–76 years of age, sufficent bone volume in the anterior mandible to place two implants with a length of 15 mm, and complaints about their existing dentures. Patients excluded from the study: those who had systemic disease likely to compromise implant surgery, and those who previously had bone grafting and fresh extraction sockets in the anterior part of the mandible. Panoramic radiograph (Planmeca OY, SF 00810, Helsinki, Finland) and computerized tomography (Siemens AR-SP 40, Munich, Germany) were used for pre-operative surgical evaluation of the mandible for each patient.

Surgical and prosthodontic procedures

All patients signed informed-consent form before implant surgery. The surgical protocol for implant placement was the same for both groups. The same surgeon performed the surgical procedure for all patients. Antimicrobial prophylaxis was obtained with following regimen: (1) mouthrinse with a 0.12% chlorhexidine digluconate solution, 15 min. prior to surgery; and (2) oral antibiotics (2 g amoxicillin), 1 h before surgery.

Local anaesthesia (Ultracaine® D-S, Hoechst Marion Roussel, Deutschland GmbH) was administered before implant placement. The surgical procedure was initiated with an intra-oral crestal incision in the canine regions of the mandible. Mucoperiosteal flaps were elevated both buccally and lingually to expose the bone. When indicated, a flattening of the alveolar crest was performed with a bur under irrigation with a sterile saline to obtain a flat bony base. The surgical procedure for implant placement followed the standard procedures relative to the Brånemark System. Two 15 mm implants (TiUnite RP MKIII, Nobel Biocare AB) were placed in the canine regions of mandibles of each patient (Fig. 1).

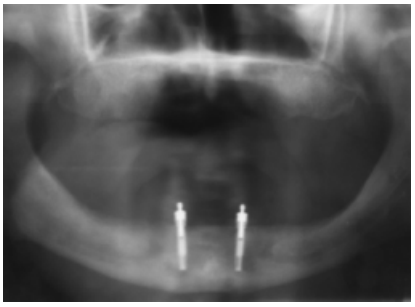

Fig. 1. Postoperative radiograph showing two 15 mm long implants in the anterior mandible.

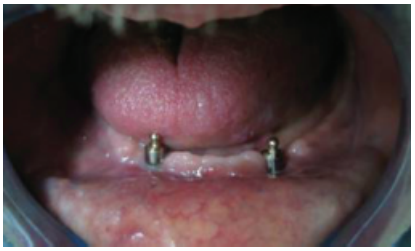

Fig. 2. Clinical view of ball attachments.

Two groups of patients were formed.

Group T (Test group): ball attachments (3 mm; Nobel Biocare AB) were attached to the implants immediately after the implant placement. After performing initial resonance frequency (RF) measurements at the implant level, mucoperiosteal flaps were sutured allowing ball attachments (Fig. 2). The patients were prescribed a soft diet for the first week. The following standardized steps were performed to fabricate new prostheses on the fifth day after the surgery: The anatomic impressions were made with a stock tray using alginate (Cavex, CA37, Haarlem, the Netherlands). The functional impressions were taken with a custom-made resin tray using Coltex Medium impression material (Coltex® Medium, Coltene/Whaledent AG, Altstatten, Switzerland). The ball attachment replicas were inserted into the impression and the master model was poured (Moldano

type III, Bayer, Leverrusen, Germany). Wax occlusal rims were created after the master models were obtained. Teeth try–in (Major Dent, Moncalieri, Italy), corrections, and fabrication of acrylic dentures (Meliodent, Heraeus Kulzer Ltd, Newbury, Berkshire, Germany) were performed on the sixth day after the surgery. The maxillary complete denture and implant-retained mandibular overdentures with respective gold caps were delivered to the patients 1 week after the implant surgery. All prostheses were made by the same dental technician for standardization.

Group C (Control group): healing abutments (5 mm; Nobel Biocare AB) were screwed to the implants after the placement of implants. New maxillary and mandibular complete dentures were delivered 1 week after the implant surgery. However, care was taken to ensure that the mandibular complete denture did not make contact with the healing abutments. The healing abutments were replaced with ball attachments (3 mm) at the 3-month follow-up recall. A reline impression was taken (Coltex® Medium, Coltene/Whaledent AG), and a mandibular complete denture was converted into an implant-supported mandibular overdenture.

Follow-up

Peri-implant evaluation

The following three peri-implant parameters were recorded at follow-up visits of 1, 6, and 12 months after the implant surgery for each implant.

- *Peri-implant plaque index (PI):* plaque adherent to all abutments, at sites at or below the crest of the peri-implant mucosa, was quantified using the plaque index of Silness & Löe (1964) as modified by Mombelli et al. (1987).
- *Peri-implant probing depth (PD):* using a standardized Michigan O-periodontal probe with Williams markings (Hu-Friedy, Chicago, IL, USA), the probing pocket depth was measured at four sites per implant (mid-mesial, mid-distal, mid-buccal, mid-lingual). Then, the average of the four values was determined for each implant. Special care was taken to ensure strict parallelism between the probe and the long axis of the healing abutment or ball attachment.
- *Peri-implant bleeding index (BI):* measured by applying the principles of previous overdenture studies and the sulcus bleeding index of Muhlemann & Son (1971) as modified by Mombelli et al. (1987).

Implant stability evaluation

Resonance frequency analysis (RFA) (Osstell, Integration Diagnostics AB, Göteborg, Sweden) was performed during implant surgery and after 3, 6, and 12 months, at these follow-up recalls, the ball attachments/healing abutments were removed from the patient and RFA measurements were taken on the implant level. The measurements were given in implant stability quotient, (ISQ) units (Integration Diagnostics AB) and ranged from 0 to 100.

Radiographic evaluation

The measurements of marginal bone loss. Standardized intra-oral radiographs of the coronal parts of the implants were taken with an extended cone, using a modified plastic-film holder with impression coping that screwed to the fixture at implant placement, after 6 and 12 months (Payne et al. 1999). 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 (Gröndahl et al. 1998). The distance between two threads of the implant, that is 0.6 mm, was used for calibration of measurements.

Statistical analysis

Descriptive analysis of the raw data was performed with commercial statistical software (SPSS 11.0 software for Windows, SPSS Inc., Chicago, IL, USA). The pertinent comparisons between the relevant variables in the two groups were performed.The 2-tailed *t*-test was used for comparison of treatment groups with respect to age. The Mann–Whitney *U*-test was used to compare the peri-implant (PI, PD, BI), marginal bone resorption, and implant stability values between two groups as the criteria for using parametric tests were not fulfilled. Spearman's test was used to determine the relationship between the crestal bone changes and the ISQ values. In connection with statistical evaluations, a ''*p*'' value of 0.05 was considered statistically relevant.

Results

Twenty-six patients (14 females, 12 males), whose ages were 50–76 years, participated in this clinical trial. The mean age of the patients in Group T was 62.3 and of those in Group C was 63.2. No significant difference was found between the two groups ($p > 0.05$). Postoperative recovery was eventful for all patients in both groups. No patients were dropped out of the study in the follow-up period.

Peri-implant paramaters

Table 1 gives an overview of all peri-implant parameters at months 1, 6, and 12 of this study. The mean PI values indicated no significant difference between two groups in 1 year ($p > 0.05$). The mean PI values decreased for both groups until month 6. Then, the mean PI value of Group T slightly decreased during the next 6 months while the corresponding value of Group C increased from months 6 to 12. The amount of changes in PI values between two groups indicated no statistical significance after 1 year ($p > 0.05$). The mean PD and BI values showed no significant difference between two

Table 1. Comparison of periimplant parameters

Parameters	Group	Month 1	Month 6	Month 12
PI	Group T	1.1 ± 0.9	0.85 ± 0.9	0.8 ± 1
	Group C	1.13 ± 0.9	0.46 ± 0.6	0.54 ± 0.7
PD	Group T	2.46 ± 0.5	1.63 ± 0.6	1.28 ± 0.6
	Group C	2.32 ± 0.6	1.39 ± 0.5	1.02 ± 0.6
BI	Group T	0.95 ± 0.9	0.65 ± 0.7	0.35 ± 0.5
	Group C	0.79 ± 0.6	0.59 ± 0.6	0.26 ± 0.5

Values shown in mean ± SD.
PD, probing depth ; PI, plaque index; BI, bleeding index.

groups during 1 year ($p > 0.05$). Both mean PD and BI values for each group had a tendency to decrease during the study, but the amount of decrease was not statistically significant between the two groups as $p > 0.05$.

Implant stability parameters

RFA measurements (Osstell, Integration Diagnostics AB) were performed at implant surgery and after 3, 6, and 12 months. The mean ISQ values were 74.9 and 75 for Groups T and C at surgery, respectively, and the corresponding values were 76.2 and 75.4 at 1-year recall, respectively, indicating no statistical significance ($p = 0.36$). Also, no significant differences were found between the two groups at other follow-up recalls during the study ($p > 0.05$) (Fig. 3).

Radiographic parameters

In Group T, the mean marginal bone resorptions were determined to be 0.15 ± 0.3 and 0.27 ± 0.3 mm, in months 6–0 and 12–0, respectively. The corresponding values for Group C were 0.19 ± 0.2 and 0.28 ± 0.3 mm, respectively (Table 2). The difference was not statistical significant between the two groups during the 12-month study period ($p > 0.05$).

The results of the present study showed that there were no statistically significant correlations between peri-implant parameters (PI, PD, BI) and marginal bone levels during 1 year ($p > 0.05$). Also, significant correlations between peri-implant parameters and ISQ values were not found, over time ($p > 0.05$).

No implant from either group was lost. The marginal bone resorptions of all implants were less than 1 mm after 12 months, yielding a success rate of 100%.

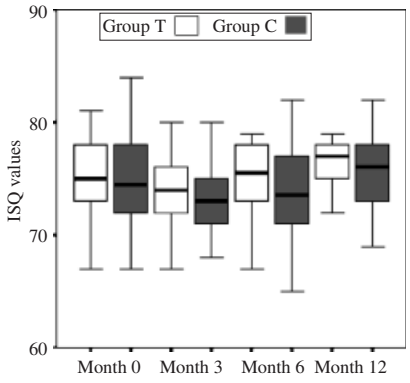

Fig. 3. Mean implant stability quotient values for both groups during 1 year.

Table 2. Mean values (mm ± SD) of marginal bone levels

Group	Month 0	Month 6	Month 12
Group T	0.7 ± 0.3	0.85 ± 0.3	0.97 ± 0.3
Group C	0.63 ± 0.2	0.82 ± 0.2	0.91 ± 0.3

Group T, test group; Group c, control group.

Discussion

Edentulism is a problem predominantly in elderly people, among whom limited physical and economic resources may prevent consideration of extensive treatment. If optimal treatment can be provided in a short period of time with single-stage surgery and early loading of the implants, it would be beneficial for these patients. Thirteen patients were treated with the early loading concept and compared with a control group of 13 patients, in whom the conventional loading protocol (after 3 months of healing) was applied in the present study. The implant success rate in both groups (100%) indicated that this was a promising treatment concept, and this implant success was consistent with other implant overdenture studies (Merickse-Stern 1990, Roynesdal et al. 2001, Karabuda et al. 2002, Payne et al. 2003, Naert et al. 2004).

Peri-implant soft tissue parameters (PI, PD, BI) did not present significant differences between test and control groups after 1 year, and were also consistent with those reported in the literature (Naert et al. 1994, Boerrigter et al. 1997, Tawse-Smith et al. 2002). The mean PI values decreased for both groups until month 6. Then, the mean PI value of Group T decreased slightly during the next 6 months while the corresponding value of Group C increased in months 6–12. This indicates that our patients' sensitivity to cleaning the ball attachments was good until months 6 since the mean PI values decreased, and then this sentivity reduced between months 6 and 12. The mean PI values of Group C were lower than those of Group T. It has been thought that this difference resulted from the period of use of ball attachments since they were screwed to implants at month 3 (Group C).

The mean PD values were limited as the excess amount of gingiva was removed by cervicular incision at surgery. This limited amount of cervical gingiva around the ball attachments/healing abutments allowed RF measurements to be made at the implant level easily. The mean PD values decreased particularly from month 1 to 6. This decrease might have resulted from the shrinkage of gingiva after surgery as a natural result of healing. The mean BI values decreased from months 1 to 12. This can be explained by the good oral hygiene of patients with time, and was consistent with other studies reported previously (Chiapasco et al. 2001, Meijer et al. 2004, Visser et al. 2004).

Although only a few patients were followed, no significant associations between the peri-implant mucosal aspects and the amount of bone resorption between months 1 and 12 were found, which have been reported earlier in other overdenture studies (Batenburg et al. 1998, Naert et al. 1998, 2004, Weber et al. 2000, Oetterli et al. 2001, Heydenrijk et al. 2003,).

All implants have been placed in the anterior region of mandible in this study. The bone density is relatively high in the anterior mandible (Friberg et al. 1995). This high bone density results in high primary stability, which is considered as one important determinant of success (Sennerby & Roos 1998, Friberg et al. 1999a, O'Sullivan et al. 2000). Payne et al. (2003) reported an average primary stability of about 75 ISQ units for Southern implants, whose designs are similar to Brånemark implants. The result of this present study is in agreement with their findings. The ISQ values decreased slightly during the 3 months following surgery and increased from months 3 to 12, which is consistent with the findings reported by Friberg et al. (1999b), who made repeated measurements of Brånemark implants using the one-stage surgical approach in the mandible. Friberg et al. (1999b) also reported some marginal bone resorption during the first months that could explain the decrease, as RFA measurements are affected by the distance from the RFA transducer to

the bone contact (Meredith et al. 1997). This decrease could be explained by the crestal bone loss. However, it seemed that bone formation did affect implant stability positively over time and therefore counteracted the effect of crestal bone loss.

The mean marginal bone resorption was 0.28 mm for all patients during the first year, which was lower than those reported by Heydenrijk et al. (2003) and Naert et al. (1998). Heydenrijk et al. (2003) reported a 0.6 mm marginal bone loss for both ITI and IMZ implants supporting mandibular overdentures while Naert et al. (1998) reported a 0.55 mm marginal bone resorption for unsplinted Brånemark implants supporting mandibular overdentures. This difference might have resulted from patient-related factors such as quality of mandibular bone and chewing force. The patients participated in this study were edentulous, hence all were wearing removable maxillary complete dentures, which resulted in limited forces on the mandibular implants. It is possible that the limited chewing force transmitted to the implants contributed to the good result. This phenomenon of up to 1 mm bone resorption has been described previously (Albrektsson et al. 1986), and is related to maturation of bone after implant placement and adaptation of bone to withstand functional forces. The mean marginal bone resorption of the present study has been recognized as being acceptable.

The results of this clinical trial suggest that one-week of early loading protocol of two 15 mm long unsplinted Brånemark TiUnite implants supporting mandibular overdenture does not compromise implant stability, marginal bone loss, and peri-implant soft tissue health.

Acknowledgements

This study was supported by Nobel Biocare AB, and Integration Diagnostics AB, Göteborg, Sweden.

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Clinical Relevance

Scientific rationale for study: The use of endosseous implants to which an overdenture can be attached has been a successful and predictable treatment alternative for edentulous patients. The rationale of this study was to investigate the effects of the early loading approach on the clinical performance of unsplinted two implants supporting mandibular overdenture.

Principal findings: The clinical, radiological, and stability outcomes of the early loaded implants supporting mandibular overdenture did not show significant differences compared with conventional loaded implants.

Practical implications: The results of this study indicated that one-week of early loading of two unsplinted 15 mm long Brånemark implants retaining mandibular overdenture may be a feasible treatment option for edentulous patients.