Marginal Bone Level Changes and Prosthetic Maintenance of Mandibular Overdentures Supported by 2 Implants: A 5-Year Randomized Clinical Trial

Murat Cavit Cehreli, DDS, PhD;* Serdar Uysal, DDS, PhD;† Kivanc Akca, DDS, PhD‡

ABSTRACT

Background: Documentation of early loading of mandibular overdentures supported by different implant systems is scarce.

Purpose: This study aimed to compare the biologic and prosthetic outcome of mandibular overdentures supported by unsplinted early-loaded one- and two-stage oral implants after 5 years of function.

Materials and Methods: Twenty-eight consecutive patients were screened following an inclusion and exclusion criteria, and randomly allocated to treatment groups. Ball-retained mandibular overdentures were fabricated on two unsplinted Straumann® (Institut Straumann AG, Basel, Switzerland) and Brånemark® (Nobel Biocare AB, Göteborg, Sweden) dental implants and subjected to an early-loading protocol. During the 5-year period, prosthetic complications were recorded. At 5-years of function, plaque, peri-implant inflammation, bleeding, and calculus index scores were recorded, and standard periapical radiographs were obtained from each implant for measurement of marginal bone loss.

Results: All implants survived during the observation period. The peri-implant inflammation, bleeding, and calculus index scores around Straumann and Brånemark implants were similar ($p > .05$). The marginal bone loss around Brånemark implants (1.21 ± 0.1) was higher than Straumann implants (0.73 ± 0.06) at 5 years of function ($p = .002$). Kaplan–Meier tests revealed that 1- and 5-year survival of overdentures on Straumann and Brånemark implants were similar ($p = .85$). Wear of the ball abutment in the Brånemark group was higher than in the Straumann group ($p < .05$). Complications regarding the retainer and the need for occlusal adjustments were higher in the Straumann group ($p < .05$). Chi-square test revealed that the frequency of retightening of the retainer was higher in the Straumann group than in the Brånemark group ($p < .05$).

Conclusions: Mandibular overdentures supported by unsplinted early-loaded Straumann and Brånemark implants lead to similar peri-implant soft tissue and prosthetic outcomes, although higher marginal bone loss could be observed around Brånemark implants after 5 years.

KEY WORDS: dental implants, early loading, mandible, overdenture, randomized controlled clinical trial, unsplinted

INTRODUCTION

Clinical studies dedicated to explore the effectiveness of single implant systems have shown that marginal bone loss around Brånemark® (Nobel Biocare AB, Göteborg, Sweden) and Straumann® (Institut Straumann AG, Basel, Switzerland) implants supporting overdentures is slightly higher[1,2] or less[3,4] than 1 mm at first year of function, which tend to reach a plateau over time. Comparative clinical trials between Brånemark and Straumann implants have also been undertaken to explore the impact of implant design and one- versus two-stage surgical approaches. In a 5-year study, Meijer and colleagues[5] showed that marginal bone reactions as well as

*Associate professor, CosmORAL Oral and Dental Health Polyclinics, Section of Prosthodontics, Kavaklidere, Ankara, Turkey[1]; †instructor, Department of Oral Diagnosis and Radiology, Faculty of Dentistry, Hacettepe University, Sihhiye, Ankara, Turkey; ‡associate professor, Department of Prosthodontics, Faculty of Dentistry, Hacettepe University, Sıhhiye, Ankara, Turkey

Reprint requests: Dr. Murat Cehreli, Section of Prosthodontics, CosmORAL Oral and Dental Health Polyclinics, Cinnah Cad. 7/5 06680 Kavaklidere, Ankara, Turkey; e-mail:mcehreli@hotmail.com

[1]Formerly, Department of Prosthodontics, Faculty of Dentistry, Hacettepe University, 06100 Sıhhiye, Ankara, Turkey.

DOI 10.1111/j.1708-8208.2008.00143.x

time-dependent periodontal parameters of Brånemark, IMZ® (Friedrichsfeld AG, Mannheim, Germany), and Straumann implants retaining mandibular overdentures were similar. Immediate loading of splinted Brånemark and Straumann implants supporting bar-retained mandibular overdentures has also displayed comparable outcomes.[6]

Transition from the dentate state to complete edentulism, rehabilitated with or without implant-supported overdentures, is a path that is burdened with concern by the patient. Implant-retained overdentures may cause many prosthetic complications such as wear in retentive components, loosening of abutment or gold screws, activation or change of clip for bar attachments, exchange of rubber ring for ball attachments, and exchange of magnets particularly in the first year of function.[4,7–10] At present, a conclusion in strict scientific sense cannot be drawn both in the biologic and prosthetic aspects because of lack of clear evidence on the superiority of one implant and/or attachment design over another, and limited number of prospective comparative studies of at least 5 years. The purpose of this study was to compare possible effects of implant design on the biologic and prosthetic outcomes of early-loaded implants (Brånemark and Straumann) retaining mandibular overdentures. Owing to high survival rates and comparable time-dependent marginal bone loss around both implant systems, it was surmised that outcomes of the treatments would be comparable.

MATERIALS AND METHODS

Subjects

A total of 28 consecutive patients were included into the study (6 males, mean age: 63; 22 females, mean age: 64). The patients were selected and recruited based on the following inclusion criteria:

1. Mandibular edentulism
2. No history of previous implant surgery
3. Good oral hygiene
4. Absence of local inflammation and oral mucosal diseases
5. Residual bone volume in the intraforaminal area sufficient to receive two Ø 4 mm × 10/12 mm implants
6. Absence of systemic problems hindering surgery
7. Persistent problems with conventional complete dentures because of reduced stability and insufficient retention of the mandibular denture

The following criteria were used for excluding patients from this study:

1. A history of drug abuse and/or life-threatening diseases (ASA Classification)[11]
2. A history of radiotherapy in the head and neck region
3. Severe intermaxillary skeletal discrepancy
4. Excessive parafunctional activity leading to wear of prosthetic teeth or fracture of dentures
5. Heavy smoking (more than 20 cigarettes per day)

Study Design

This is a randomized, controlled, single-blind (prosthodontist) clinical trial in two groups:

Group 1: Two unsplinted Straumann implants retaining mandibular overdentures (retention mechanism: retentive anchor abutment with PVC ring covered gold matrix).

Group 2: Two unsplinted Brånemark implants retaining mandibular overdentures (retention mechanism: ball attachments with gold caps).

Allocation of patients to groups was provided by random assignment of the patients to one of the two prosthodontists, who used different implant systems in clinical practice. The randomization in allocation was provided by the method used by Meijer and colleagues.[5]

Study Procedures

Bone quantity and quality were assessed at surgery according to Lekholm and Zarb.[12] Most jaws had a resorption degree corresponding to score B and a bone quality score of 2. The implant sockets for placement of Straumann implants (sandblasted large grid acid etched [SLA] surface) were prepared by using Ø 2.2 and Ø 2.8 mm pilot and Ø 3.5 mm twist drills and the sockets of Brånemark implants (MK III TiUnite) were prepared by Ø 2 mm twist drill, Ø 2/2.7 mm pilot drill, and Ø 3 mm twist drill under copious saline irrigation. At insertion, the Straumann implants were placed at a depth where the SLA/machined surface junction was located at the level of the cortical bone. The upper outer edge of the neck of the Brånemark implants was located at the level of the cortical bone. These locations were used as a reference for radiographic comparison at

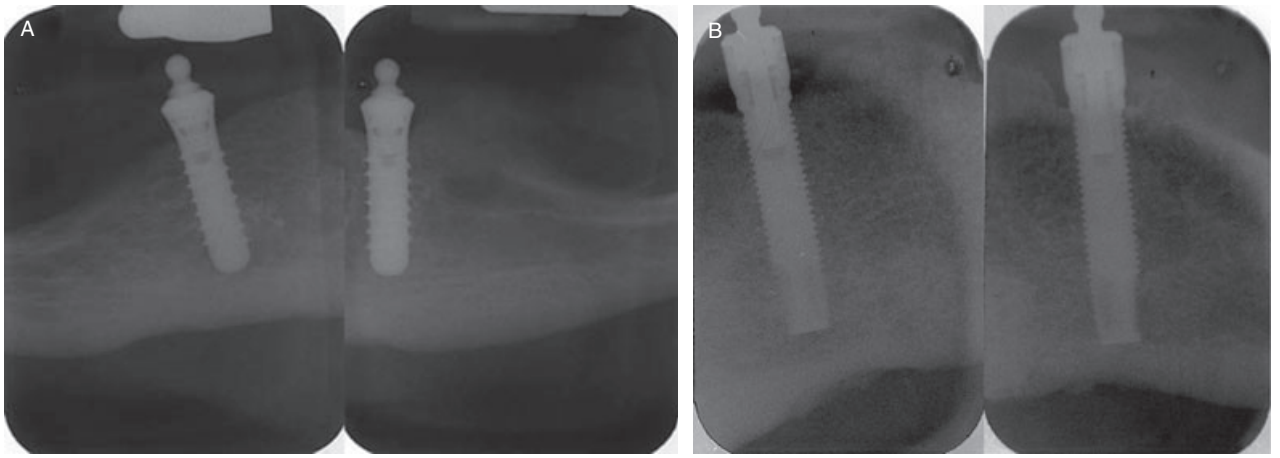

Figure 1 *A,* 5-year periapical view of a patient rehabilitated with Straumann implants. *B,* 5-year periapical view of a patient rehabilitated with Brånemark implants.

5-year recall. Standard postoperative treatment was composed of analgesics and chlorhexidin 0.2% mouth rinses and antibiotics and nonsteroidal analgesics postoperatively for 3 consecutive days. A soft diet was recommended to the patients for 1 week post surgery. During an osseous healing time of 4 to 6 weeks, the preexisting dentures were relined. At second-stage surgery, exposure of the implant and placement of healing abutment was undertaken for the Brånemark group. The prostheses of both groups were delivered to the patients at 6 to 8 weeks post surgery following final torque tightening of the ball abutments (20 Ncm) and retentive anchors (35 Ncm) and were therefore subjected to an early-loading protocol.[13]

Peri-implant Parameters

Baseline measurements were made 1 week after retentive anchors, and ball abutments were connected to the implants and repeated annually. Each implant was also evaluated at the 5-year recall appointment. The index according to Mombelli and colleagues[14] was used for detecting plaque around implants. The degree of peri-implant inflammation was evaluated by the modified Löe and Silness[15] index. In addition, the bleeding index according to Mombelli and colleagues[14] was used to detect bleeding. Calculus index of the oral hygiene index[16] was also recorded for the implants. The patients followed a maintenance program, which included annual removal of plaque or calculus from prosthetic retainers and the dentures.

Marginal Bone Level Changes

Panoramic radiographs were taken 1 week post surgery and annually as intraoral film holders are usually painful for the patients. The marginal bone level was examined at 5-year recall, and the initial bone level of actual implants placed according to the guidelines determined by the manufacturer was used as a baseline reference. Periapical radiographs were obtained by using a paralleling device (Dentsply RİNN, Rinn Cooperation, Elgin, IL, USA). Radiographs were digitized at 2,400 dpi by using a scanner (Epson Perfection 2,400 Photo, Seiko Epson Corp., Magano-Ken, Japan), and linear distance measurements were made,[17] referring the actual distance between consecutive two threads in an image analysis software (ImageJ 1.32j, NIH, USA) at ×400 magnification (Figure 1, A and B).

Prosthetic Maintenance

Prosthetic complications were recorded for each patient during the 5-year follow-up period[18] (Figure 2, A and B). This was carried out by referral of the patients with complaints and during annual examination of the dentures and implant components.

Statistical Analysis

As the frequency of some scores were very low for plaque index data, statistical comparisons could not be undertaken. The data of peri-implant inflammation, bleeding, and calculus index scores were compared by Fisher's Exact Test at 95% confidence level. Between-group comparisons on marginal bone loss values were undertaken by Mann-Whitney *U* test at 95% confidence level. For the comparison of prosthetic outcomes, the first incidence of the complication was taken into account, and the timing was referred to as failure period. The absence of the complication was referred to as "censored." The

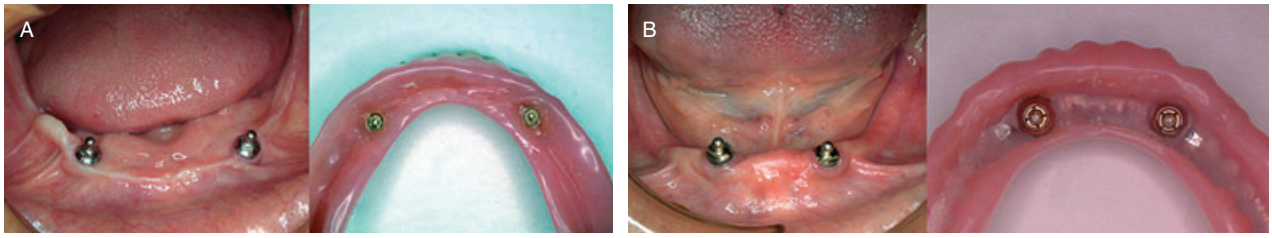

Figure 2 *A,* 5-year intraoral view of Straumann implants with retentive anchors and the tissue surface of the prosthesis with PVC ring-covered gold matrix. *B,* 5-year intraoral view of ball abutments on Brånemark implants and the tissue surface of the prosthesis with gold attachments.

survival of the prostheses was evaluated by Kaplan-Meier tests, and comparative evaluation between implant systems on survival probabilities (maximum time in function without experiencing any complications) of the prostheses was undertaken by long-rank tests at 95% confidence level. The statistical analysis for prosthetic complications was carried out for annual evaluations. In addition, the frequencies of the complications observed throughout the 5-year period in both groups were compared by chi-square tests at 95% confidence level.

RESULTS

Dropouts and Implant Failures

After 5 years, 6 patients had been excluded from the study because of loss of contact (2 Straumann, 4 Brånemark). Overall, a total of 23 patients (12 Straumann, 10 Brånemark) were subjected to 5-year evaluations in the present study. A total of 22 12 mm and 2 14 mm-long Ø 3.75 × 13 mm Straumann implants were placed. Eight Ø 3.75 (13 and 15 mm long) and 14 Ø 4.0 mm (predominantly 15-mm long) Brånemark implants were placed. During the 5-year period, none of the implants failed in both treatment groups.

Peri-implant Parameters

Five-year peri-implant data are presented in Table 1. The peri-implant inflammation, bleeding, and calculus index scores of Straumann and Brånemark implants were comparable ($p = .195$, $p = .571$, and $p = .078$, respectively).

Marginal Bone Level Changes

In none of the patients, excessive bone loss was observed. The maximum bone level changes observed for Brånemark and Straumann implants were 1.8 mm and 1.3 mm, respectively. Marginal bone loss for Brånemark implants (1.21 ± 0.1) was higher than that for Straumann implants (0.73 ± 0.06) at 5 years of function ($p = .002$) (Figure 3).

Prosthetic Maintenance

Kaplan-Meier analysis revealed that 1- and 5-year survival probabilities of the prostheses were 0.15 and 0.05, respectively. One- and five-year survival probabilities of overdentures on Straumann (mean ± SEM:1.33 ± 0.32 years) and Brånemark implants (mean ± SEM:1.5 ± 0.34 years) were similar (long rank test, $p = .85$). Wear of ball abutment was more observed in the Brånemark group. Broken/loose/lost retainers, occlusal adjustment, and retightening of the retainer were more experienced in the Straumann group (Tables 2 and 3 and Figure 4).

DISCUSSION

In the present study, the peri-implant soft tissue parameters between Straumann and Brånemark implants were comparable, although an equal distribution of scores was not observed between the two groups. It seemed that implant design did not have an effect on peri-implant parameters, an observation confirming previous findings.[5] Marginal bone level changes around

TABLE 1 Percentage of Peri-Implant Parameter Scores for the Two Implant Systems

	Brånemark				Straumann			
Score	0	1	2	3	0	1	2	3
Plaque index	70	10	10	10	91.7	8.3	—	—
Peri-implant inflammation	80	20	—	—	100	—	—	—
Bleeding index	80	20	—	—	91.7	8.3	—	—
Calculus index	70	30	—	—	100	—	—	—

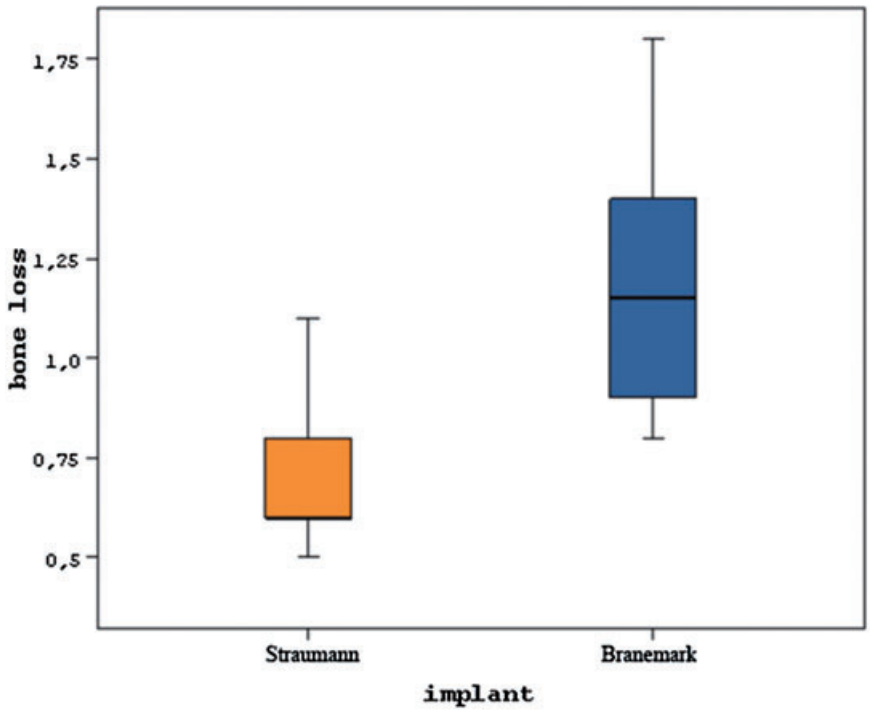

Figure 3 Box plot of marginal bone loss (mm) around Straumann and Brånemark implants at 5-year recall.

Brånemark implants were higher than around Straumann implants. As effects of surgically induced trauma, microbiota, and surface characteristics of implants may play a role on marginal bone reactions, it is difficult to identify the main reason for the differences between implant systems in the present study. Difference in the macrograp location in association with crestal bone level might have had an influence on early bone remodeling

TABLE 2 Comparative Evaluation of Prosthetic Complications

	Kaplan–Meier								
	One-Year			Five-Year			Survival Mean ± SEM		Long Rank Test (*p* Value)
	Overall	Str	Bra	Overall	Str	Bra	Str	Bra	
Loosening of ball abutment or retentive anchor	1			1					
Wear of the ball abutment or retentive anchor	1	1	1	0.86	1	0.70	5.0 ± 0	4.6 ± 0.2	.046*
Broken, loose, lost retainer	1	1	1	0.82	0.67	1	4.92 ± 0.08	5.0 ± 0	.049*
Retightening of retainer	0.77	0.92	0.6	0.23	0.33	0.1	3.08 ± 0.42	2.8 ± 0.49	.48
Fracture of the acrylic denture base	1	1	1	0.91	1	0.8	5.0 ± 0	4.6 ± 0.31	.112
Fracture of teeth	1			1					
Redesign or new denture	1	1	1	0.86	0.83	0.90	4.92 ± 0.08	4.8 ± 0.2	.699
Sore spots	0.14	0.08	0.2	0.14	0.08	0.2	1.33 ± 0.32	1.8 ± 0.51	.438
Relining of denture	1	1	1	0.91	0.83	1	5.0 ± 0	5.0 ± 0	.186
Occlusal adjustment	0.45	0.17	0.80	0.36	0.17	0.60	1.67 ± 0.45	4 ± 0.5	.019*
Rearrangement of teeth	1			1					
Excessive wear of teeth	1	1	1	0.55	0.58	0.5	4.92 ± 0.08	4.2 ± 0.33	.369

*Statistically significant.
SEM = standard error for mean; Str = Straumann implants group; Bra = Brånemark implants group.

TABLE 3 Chi-Square Analyses on the Comparative Evaluation of the Frequencies of Complications Observed in Both Implant Systems throughout the 5-Year Observation Period

Complication	Str	Bra	*p*
Loosening of abutment	0	0	—
Wear of the abutment	0	3	.091
Broken, loose, lost retainers	4	0	.124
Retightening of retainer	46	10	.000*
Fracture of resin denture base	0	3	.091
Fracture of teeth	0	0	—
Fracture of cast framework	0	0	—
Redesign or new denture	2	1	1
Sore spots	11	11	.632
Relining of denture	2	0	.50
Occlusal adjustment	10	5	.31
Rearrangement of teeth	0	0	—
Excessive wear of teeth	5	5	1

*Statistically significant.
Str = Straumann implants group; Bra = Brånemark implants group.

as suggested formerly in experimental studies.[19,20] It was not clear whether the differences in marginal bone level changes could be attributed to the two-stage approach followed for placement of Brånemark implants. The number of abutment dis/reconnection might have played a role[21] for Brånemark implants, but not for Straumann implants.

In the present study, panoramic radiographs were obtained from the patients during the 5-year follow-up period, as intraoral film holders are usually painful for the edentulous patient. Indeed, many studies have used panoramic radiographs to determine bone loss around implants.[6,22,23] Nevertheless, at the 5-year recall, standard periapical radiographs were obtained for a reliable comparison between implant systems.[3] Although the comparative evaluation of early-loaded Straumann and Brånemark implants supporting mandibular overdentures has not been reported to date, similar marginal bone level changes and periodontal parameters were observed for conventional loading of these implants.[5] Similar marginal bone level changes were also observed in panoramic radiographs for four rigidly splinted Straumann and Brånemark implants immediately loaded to retain mandibular overdentures.[6]

To date, comparative evaluation of prosthetic maintenance requirements was not reported for these implant systems. Wear of the ball abutment was only observed in three patients of the Brånemark group. This finding is in line with the observations of Naert and colleagues,[7] who detected high incidence of wear on ball abutments of the Brånemark system implants after 5 years. Unlike their findings, none of the ball abutments fractured in this study. Tightening of the ball abutment and problems in the ball-spring attachment in the Brånemark system have been reported as a frequent problem in the first year.[10] In the present study, however, such a finding was not evident in any of the Brånemark implants. Behr and colleagues[24] detected 3.4% fracture for the retentive anchors. In the present study, however, none of the retentive anchors fractured. The burden of maintenance for broken, loose, or lost retainers was paramount only in the Straumann group. Retightening of the gold matrix retainer was also a frequent problem for the Straumann group. Indeed, problems related to matrix maintenance has been observed for Straumann implants,[25,26] but it seems that the frequency in the present study was higher than in other studies during the 5-year period. This finding might be attributed to the retainer design of the Straumann system used.

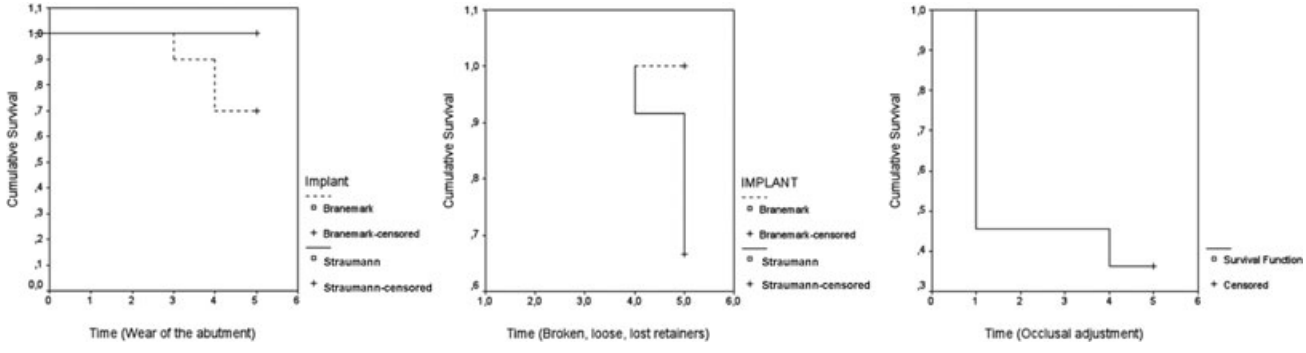

Figure 4 Kaplan–Meier analysis of complications showing differences between groups.

In conclusion, mandibular overdentures retained by unsplinted early-loaded Straumann and Brånemark implants had similar peri-implant parameters, and, despite the relatively higher marginal bone level changes around Brånemark® implants, all implants survived during the 5-year period. Prosthetic complications related to design of attachments may be observed in both implant systems, but the need for fabrication of new dentures seems very low.

ACKNOWLEDGMENT

This study was partly supported by the State Planning Organization, Prime Ministry, Republic of Turkey (Project no: 01 K 120 650).

REFERENCES

1. Adell R, Lekholm, U, Rockler B, Branemark P-I. A 15-year study of osseointegrated implants in the treatment of the edentulous jaw. Int J Oral Surg 1981; 10:387–416.
2. Ahlqvist J, Borg K, Gunne J, Nilson H, Olsson M, Astrand P. Osseointegrated implants in edentulous jaws: a 2-year longitudinal study. Int J Oral Maxillofac Implants 1990; 5:155–163.
3. Payne AGT, Tawse-Smith A, Duncan WD, Kumara R. Conventional and early loading of unsplinted ITI implants supporting mandibular overdentures. Clin Oral Implants Res 2002; 13:603–609.
4. Behneke A, Behneke N, d'Hoedt B. A 5-year longitudinal Study of the clinical effectiveness of ITI solid-screw implants in the treatment of mandibular edentulism. Int J Oral Maxillofac Implants 2002; 17:799–810.
5. Meijer HJA, Batenburg RHK, Raghoebar GM, Vissink A. Mandibular overdentures supported by two Brånemark, IMZ or ITI implants: a 5-year prospective study. J Clin Periodontol 2004; 31:522–526.
6. Chiapasco M, Gatti C. Implant-retained mandibular overdentures with immediate loading: a 3- to 8-year prospective study on 328 implants. Clin Implant Dent Relat Res 2003; 5:29–38.
7. Naert I, Gizani M, Vuylsteke M, van Steenberghe D. A 5-year prospective randomized clinical trial on the influence of splinted and unsplinted oral implants retaining a mandibular overdenture: prosthetic aspects and patient satisfaction. J Oral Rehabil 1999; 26:195–202.
8. Payne AG, Solomons YF. Mandibular implant-supported overdentures: a prospective evaluation of the burden of prosthodontic maintenance with 3 different attachment systems. Int J Prosthodont 2000; 13:246–253.
9. Payne AGT, Solomons YF. The prosthodontic maintenance requirements of mandibular mucosa- and implant-supported overdentures: a review of the literature. Int J Prosthodont 2000; 13:238–245.
10. MacEntee MI, Walton JN, Glick N. A clinical trial of patient satisfaction and prosthodontic needs with ball and bar attachments for implant-retained complete overdentures: three-year results. Int J Prosthodont 2005; 93:28–37.
11. Anesthesiologists ASO. New classification of physical status. Anesthesiology 1998; 234:111.
12. Lekholm U, Zarb GA. Patient selection and preparation. In: Branemark PI, Zarb GA, Albrektsson T, eds. Tissue integrated prostheses: osseointegration in clinical dentistry. Chicago, IL: Quintessence, 1985: 199–209.
13. Cochran DL, Morton D, Weber HP. Consensus statements and recommended clinical procedures regarding loading protocols for endosseous dental implants. Int J Oral Maxillofac Implants 2004; 19(Suppl):109–113.
14. Mombelli A, Van Oosten MAC, Schurch E, Lang N. The microbiota associated with successful or failing osseointegrated titanium implants. Oral Microbiol Immunol 1987; 2:145–151.
15. Löe H, Silness J. Periodontal disease in pregnancy. II: correlation between oral hygiene and periodontal condition. Acta Odontol Scand 1963; 21:533–551.
16. Greene JC, Vermillion JR. The oral hygiene index: a method for classifying oral hygiene status. J Am Dent Assoc 1960; 61:172–179.
17. Weber HP, Buser D, Fiorellini JP, Williams RC. Radiographic evaluation of crestal bone levels adjacent to nonsubmerged titanium implants. Clin Oral Implants Res 1992; 3:181–188.
18. Dudic A, Mericske-Stern R. Retention mechanisms and prosthetic complications of implant-supported mandibular overdentures: long-term results. Clin Implant Dent Relat Res 2002; 4:212–219.
19. Broggini N, McManus LM, Hermann JS, et al. Peri-implant inflammation defined by the implant-abutment interface. J Dent Res 2006; 85:473–478.
20. Hermann JS, Buser D, Schenk RK, Cochran DL. Crestal bone changes around titanium implants. A histometric evaluation of unloaded non-submerged and submerged implants in the canine mandible. J Periodontol 2000; 71:1412–1424.
21. Abrahamsson I, Berglundh T, Lindhe J. The mucosal barrier following abutment dis/reconnection. An experimental study in dogs. J Clin Periodontol 1997; 24:568–572.
22. Wismeijer D, van Waas MAJ, Mulder J, Vermeeren JIJF, Kalk W. Clinical and radiological results of patients treated with three treatment modalities for overdentures on implants of the ITI Dental Implant System. A randomized controlled clinical trial. Clin Oral Implants Res 1999; 10:297–306.
23. Batenburg RHK, Meijer HJA, Geraets WGM, van der Stelt PF. Radiographic assessment of changes in marginal bone around endosseous implants supporting mandibular overdentures. Dentomaxillofac Radiol 1998; 27:221–224.

24. Behr M, Lang R, Leibrock A, Rosentritt M, Handel G. Complication rate with prosthodontics reconstructions on ITI and IMZ dental implants. Clin Oral Implants Res 1998; 9:51–58.
25. Donatsky O, Hillerup S. Non-submerged osseointegrated dental implants with ball attachments supporting overdentures in patients with mandibular ridge atrophy. A short-term follow-up. Clin Oral Implants Res 1996; 7:170–174.
26. Watson GK, Payne AGT, Purton DG, Thomson WM. Mandibular overdentures: comparative evaluation of prosthodontics maintenance of three different implant systems during the first year. Int J Prosthodont 2002; 15:259–266.