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Mandibular overdentures supported by two Brånemark, IMZ or ITI implants: a ten-year prospective randomized study

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Abstract

Objectives: The aim of this prospective comparative study was to evaluate the survival rate, condition of peri-implant tissues, patient satisfaction and surgical and prosthetic aftercare of the IMZ-implant system (two-stage cylinder type), the Brånemark-implant system (two-stage screw type) and the ITI-implant system (one-stage screw type) supporting a mandibular overdenture during a 10-year follow-up period.

Materials and Methods: Three groups of 30 edentulous patients were treated with two endosseous implants in the interforaminal region of the mandible. Clinical and radiographic parameters were evaluated immediately after completion of the prosthetic treatment and after 1, 5 and 10 years of functional loading. Prosthetic and surgical aftercare was scored during the evaluation period, as well as patient satisfaction.

Results: The 10-year survival rate was 93% for the IMZ group, 98% for the Brånemark group and 100% for the ITI group (IMZ < ITI, $p < 0.05$). Mean marginal bone loss was limited over a period of 10 years. No differences in satisfaction and aftercare were observed between the groups.

Conclusion: It is concluded that two implants placed in the interforaminal region, connected with a bar, supply a proper base for the support of a mandibular overdenture in the edentulous patient. After10 years, no relevant changes had developed between the three implant systems.

Key words: dental implants; edentulous; mandible; overdenture

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Edentulous patients often experience problems with their mandibular full dentures. Lack of stability and retention, together with a decreased chewing ability are the main complaints of these patients (Van Waas 1990). A current frequently applied treatment possibility is the use of endosseous implants to which an overdenture can be attached.

Conflict of interest and source of funding statement

The authors declare that there are no conflicts of interest in this study and no external funding was obtained.

One of the first studies concerning overdentures supported by endosseous implants was published by Van Steenberghe et al. (1987). This treatment is still of great value in the rehabilitation of edentulous patients (Meijer et al. 2003, Raghoebar et al. 2003, Visser et al. 2006). For general application in the edentulous mandible, a treatment concept utilizing two or four implants to support a mandibular overdenture has been proposed (Batenburg et al. 1998a). Comparative prospective studies (with two or four implants in the edentulous mandible) have been conducted by Batenburg et al. (1998b), Wismeijer et al. (1999), Mau et al. (2003), Visser et al. (2005) and Stoker et al. (2007). The survival rates, clinical aspects and patients' satisfaction in the two-implant overdenture groups and the four-implant overdenture groups were shown to be more or less equal in these studies. Also in the consensus statement of Feine et al. (2002), a two-implant overdenture has been proposed as a regular treatment for the edentulous mandible. At present, the results of prospective studies concerning overdentures retained by endosseous implants with a follow-up period of at least 10 years have become available. Deporter

et al. (2002) reported a 10-year survival rate of 92.7% for the Endopore dental implant system. Meijer et al. (2004b) reported on a clinical trial with a 93% 10-year survival rate for IMZ implants and an 86% 10-year survival rate for Brånemark implants. Naert et al. (2004b) reported a 10-year survival rate of 100% for Brånemark implants, but it must be mentioned that implants lost during the healing period were not included in this survival rate. Telleman et al. (2006) reported a 10-year survival rate of 96.6% for Hollow Screw ITI implants and 96.1% for Hollow Cylinder ITI implants in a retrospective study. Comparison of implant systems is optimal in prospective studies with predefined inclusion and exclusion criteria (Antczak-Bouckoms & Chalmers 1988, Barmes 1990). Patients' satisfaction and the need for aftercare including complications are other factors that can influence the choice of implants. Ten-year reports on patients' satisfaction are very scarce in the literature. Raghoebar et al. (2003) and Naert et al. (2004a) described patients' satisfaction during a 10-year period. It appeared that patients were very satisfied with a two-implant mandibular overdenture. Meijer et al. (2004b) and Visser et al. (2006) described aftercare and complications during a 10-year period. They mentioned that implant-retained mandibular overdentures needed continuous maintenance during the follow-up period.

The aim of this prospective comparative study was to evaluate the treatment outcome (condition of hard and soft peri-implant tissues, patients' satisfaction, surgical and prosthetic aftercare) of two IMZ implants (two-stage cylinder type), two Brånemark implants (two-stage screw type) and two ITI implants (one-stage screw type) supporting a mandibular overdenture during a 10-year follow-up period. The hypothesis is that there is no difference between the three groups.

The patients involved in this study are the same patients as reported on by Batenburg et al. (1998b) for the 1-year results and Meijer et al. (2004a) for the 5-year results.

Materials and Methods

Patient selection and treatment

For this study, patients with severely resorbed mandibles were selected. All patients had persistent problems with their conventional complete dentures due to reduced stability and insufficient retention of their mandibular denture. The patients were informed about the treatment options and possible risks. Informed consent was obtained from all participants. The study was approved by the hospital medical ethical committee. Inclusion criteria for the clinical trial were an edentulous period of at least 2 years and severe resorption of the mandible, being classes V–VI according to the Cawood classification (Cawood & Howell 1988). Patients with a history of radiotherapy in the head and neck region or a history of preprosthetic surgery or previous implant placement were excluded. Allocation to one of the treatment options was carried out by means of 90 envelopes, which contained a note with the implant system. Sample size was copied from the study of Meijer et al. (2003). Thirty patients (IMZ group) were treated with the two-stage 4-mm-diameter IMZ cylinder implant with a TPS coating (Dentsply Friadent, Mannheim, Germany), 30 patients (Brå group) with the two-stage 3.75-mm-diameter Brånemark screw implant with a machined surface (Nobel Biocare Holding AG, Zürich, Switzerland) and 30 patients (ITI group) with the one-stage 4.1-mm-diameter ITI solid screw implant with a TPS coating (Institut Straumann AG, Basel, Switzerland). All patients were treated under local anaesthesia with an implant in the right and left canine region of the mandible. Three months after implant placement, a standard prosthetic procedure was carried out. A new maxillary complete denture and an overdenture supported by a round bar and clip attachment were fabricated. All patients were treated in the same department (Department of Oral Surgery, University Medical Center Groningen, Groningen, the Netherlands) by one experienced oral-maxillofacial surgeon and one experienced prosthodontist. Two weeks after the abutment connection (for the two-stage implant systems) or two weeks after implant placement (for the one-stage implant system) an oral hygiene instruction was given. Two weeks thereafter, this was checked and, if necessary, an additional instruction was given. At each evaluation visit for the study, patients were also recalled by the oral hygienist for removal of plaque and calculus and additional instruction. If necessary, patients were recalled every 6 months. The characteristics of the groups are listed in Table 1. Bone height was measured on a rotational panoramic radiograph with correction for distortion (Batenburg et al. 1997). Bone quality was determined according to Lekholm & Zarb (1985) on a lateral cephalometric radiograph.

Clinical analysis

The clinical analysis included a number of parameters. Loss of implants was scored after removal of a loose implant any time after placement. For presence of plaque, the index according to Mombelli et al. (1987) was used (score 0: no detection of plaque, score 1: plaque can be detected by running a probe across the smooth marginal surface of the implant, score 2: plaque can be seen by the naked eye and score 3: abundance amount of plaque). The presence of calculus (score 1) or the absence of calculus (score 0) was scored. To qualify the degree of peri-implant inflammation, the modified Löe & Silness (1963) was used (score 0: normal peri-implant mucosa, score 1: mild inflammation, slight change in colour, slight oedema, score 2: moderate inflammation; redness, oedema and glazing and score 3: severe inflammation; marked redness and oedema, ulceration). For bleeding, the bleeding index according to Mombelli et al. (1987) was used (score 0: no bleeding when using a periodontal probe, score 1: isolated bleeding spots visible, score 2: a confluent red line of blood along the mucosal margin and score 3: heavy or profuse bleeding). Probing depth was measured at four sites of each implant (mesially, labially, distally and lingually) by using a perio-

Table 1. Characteristics of the groups at the baseline of the study

	IMZ group ($n = 30$)	Brå group ($n = 30$)	ITI group ($n = 30$)
Mean age in years (range)	54.0 (38–77)	56.6 (35–79)	52.8 (38–74)
Gender; number male/female	9/21	6/24	12/18
Mean edentulous period lower jaw in years (SD)	21.0 (9.0)	21.8 (10.5)	19.6 (9.7)
Mean mandibular bone height in mm (SD)	15.8 (2.3)	15.7 (2.7)	15.6 (2.5)
Mean bone quality (possible score 1–4)	3.0	2.7	2.6

dontal probe (Merit B, Hu Friedy, Chicago, IL, USA) after removal of the bar; the distance between the marginal border of the mucosa and the tip of the periodontal probe was scored as the probing depth.

Radiographic analysis

Standardized intra-oral radiographs of each implant were obtained using a beam direction device as described by Meijer et al. (1992). Analysis was performed with a digital sliding gauge (Helios digit E 2056, Schneider & Kern, Niedernhall, Germany). Two-point measurements were made along the implant axis from a fixed reference point to the level of bone (Meijer et al. 1993). Measurement was performed mesially and distally of each implant. Bias was prevented by the fact that there was no sequence in measuring the radiographs and measurements were not performed per patient. In this way, there was no recollection by the observer as to bone loss in earlier years.

Patients' satisfaction

The questionnaire focused on complaints and consisted of 54 items (Vervoorn et al. 1988). It was divided into six scales:

A. Nine items concerning functional problems of the lower denture.
B. Nine items concerning functional problems of the upper denture.
C. Eighteen items concerning functional problems complaints in general.
D. Three items concerning facial aesthetics.
E. Three items concerning accidental lip, cheek, and tongue biting (''neutral space'').
F. Twelve items concerning aesthetics of the denture.

The extent of each specific complaint could be expressed on a four-point rating scale (0 = no complaints, 1 = little, 2 = moderate and 3 = severe complaints).

Surgical and prosthetic care and aftercare

The method of analysing care and aftercare has been described in detail by Visser et al. (2006). From the first day that patients visited the clinic until 10 years after the first treatment session, all surgical or prosthetic therapeutic interventions were scored using a standardized score list. Prosthetic aftercare included routine recall visits every year. At a routine recall visit, implants, bars and the prostheses were checked. If needed, there were additional procedures for hygiene support and adjustment or repair of the mandibular overdenture or the maxillary denture. The average treatment time allocated to a particular variable was based on the average treatment time for that variable as indicated by three experienced prosthodontists and three experienced oral and maxillofacial surgeons. Surgical and prosthetic care and aftercare were scored for five well-defined periods.

1. *Pretreatment period*: time between first appointment and start of treatment.
2. *Surgical period*: time from start of the surgical treatment until 2 months after the prosthesis was placed.
3. *Prosthetic period*: time from start of prosthetic treatment until 2 months after the prosthesis was placed.
4. *Surgical aftercare*: time from 2 months after the prosthesis was placed until 10 years after treatment was started.
5. *Prosthetic aftercare*: time from 2 months after the prosthesis was placed until 10 years after treatment was started.

Data collection

Pre-treatment satisfaction of the patients with their dentures was scored according to the method described above. The subsequent data collection (clinical analysis, radiographic analysis and patient satisfaction) of all patients was performed as follows: T_0 (baseline evaluation, 6 weeks after placement of the overdenture) and 1 (T_1), 5 (T_5) and 10 (T_{10}) years after placement of the overdenture. Prosthetic and surgical aftercare was continuously scored during the 10-year follow-up. One investigator performed the measurements in all patients to prevent inter-observer differences.

Data analysis

Probing depth was measured at four sites around each implant and bone height measurement was performed mesially and distally on the radiograph. It was assumed that the deepest pocket and the largest bone loss would have the most influence on the survival and clinical status of the implant. Therefore, in case of the items probing depth and radiographic bone height, the worst score per implant was used as representative. One-way analysis of variance (ANOVA), with post hoc Bonferroni's testing, was carried out. Where appropriate, differences were tested with either the paired (within-group comparisons) or the unpaired (between group comparisons) Student's *t*-test, again with post hoc Bonferroni's testing. Analysis was performed with SPSS (Statistical Package Social Sciences, version 16.0, SPSS Incorporated, Chicago, IL, USA). In all tests a significance level of 0.05 was chosen.

Results

All patients completed T_0 (evaluation after placement of the overdenture). At T_1 one patient of the ITI group had died. At T_5 three patients of the Brå group and one patient of the ITI group did not attend the evaluation due to sickness. Another patient had died in the ITI group. At T_{10} three patients of the Brå group and one patient of the ITI group did not attend the evaluation due to sickness. In addition, one patient of the IMZ group had died between the 5- and 10-year follow-up meeting. The assumption was made that not attending the evaluation was independent of the clinical or the radiographic condition as well as that it was independent of the patients' satisfaction.

Clinical parameters

During the healing phase, one implant was lost in the IMZ group and one implant was lost in the Brå group. Both implants appeared to be mobile 3 months after placement at the second-stage operation procedure. After removal of the implants and a subsequent bone-healing period of 6 months, another implant was placed successfully in these patients. During the functional period, three implants in the IMZ group were lost. In one patient, the IMZ implant was lost after 7 years in function due to severe peri-implant bone loss. After a healing period for the bone a new implant was inserted. In another patient, both IMZ implants were lost after 9 years and 6 months due to severe peri-implant bone loss. This patient did not have new implant surgery during the follow-up

Table 2. Mean values and standard deviations of plaque index (possible score 0–3), calculus index (possible score 0–1), gingival index (possible score 0–3), bleeding index (possible score 0–3) and probing depth in mm at T_0 (evaluation after placement of the overdenture) and T_1, T_5 and T_{10} (evaluation, respectively, 1, 5 and 10 years after placement of the overdenture) and the significance level of the differences between the IMZ group, the Brå group and the ITI group

	IMZ group	Brå group	ITI group	Significance
T_0: evaluation after placement of overdenture	($n = 30$)	($n = 30$)	($n = 30$)	
Mean plaque index (SD)	0.3 (0.5)	0.3 (0.8)	0.6 (0.7)	NS
Mean calculus index (SD)	0.4 (0.5)	0.4 (0.5)	0.5 (0.5)	NS
Mean gingival index (SD)	0.5 (0.9)	0.4 (0.6)	0.3 (0.5)	NS
Mean bleeding index (SD)	1.1 (0.6)	0.8 (0.5)	0.8 (0.7)	NS
Mean probing depth in mm (SD)	3.9 (1.2)	3.3 (0.8)	2.6 (0.6)	ITI < Brå < IMZ ($p < 0.001$)
T_1: evaluation 1 year after placement of overdenture	($n = 30$)	($n = 30$)	($n = 29$)	
Mean plaque index (SD)	0.4 (0.8)	0.6 (1.0)	0.1 (0.4)	NS
Mean calculus index (SD)	0.3 (0.5)	0.5 (0.5)	0.4 (0.5)	NS
Mean gingival index (SD)	0.5 (0.7)	0.2 (0.4)	0.7 (0.6)	Brå < IMZ,ITI ($p < 0.01$)
Mean bleeding index (SD)	1.0 (0.5)	0.8 (0.6)	0.7 (0.6)	NS
Mean probing depth in mm (SD)	3.9 (1.3)	3.1 (0.6)	2.5 (0.5)	ITI < Brå < IMZ ($p < 0.001$)
T_5: evaluation 5 years after placement of overdenture	($n = 30$)	($n = 27$)	($n = 27$)	
Mean plaque index (SD)	0.5 (0.8)	0.8 (1.0)	0.4 (0.7)	NS
Mean calculus index (SD)	0.5 (0.6)	0.4 (0.5)	0.5 (0.5)	NS
Mean gingival index (sd)	0.7 (0.7)	0.5 (0.6)	0.3 (0.6)	NS
Mean bleeding index (SD)	1.1 (0.6)	1.0 (0.7)	0.9 (0.6)	NS
Mean probing depth in mm (SD)	4.1 (1.2)	2.9 (0.6)	2.3 (0.6)	ITI < Brå < IMZ ($p < 0.001$)
T_{10}: evaluation 10 years after placement of overdenture	($n = 27$)	($n = 27$)	($n = 27$)	
Mean plaque index (SD)	0.4 (0.7)	0.6 (0.9)	0.4 (0.7)	NS
Mean calculus index (SD)	0.3 (0.4)	0.3 (0.5)	0.3 (0.4)	NS
Mean gingival index (SD)	0.2 (0.4)	0.1 (0.2)	0.2 (0.5)	NS
Mean bleeding index (SD)	0.4 (0.6)	0.3 (0.5)	0.3 (0.6)	NS
Mean probing depth in mm (SD)	3.8 (1.0)	3.0 (0.5)	3.3 (1.0)	Brå < IMZ ($p < 0.001$)

NS, not significant; SD, standard deviation.

period as we respect a 6-month healing period of the implant sites before placing new implants. When considering these numbers, the 5-year survival of implants, including the ones lost during the osseointegration period, was 98% for the IMZ group and the Brå group and 100% for the ITI group. Ten-year survival rates were 93% for the IMZ group, 98% for the Brå group and 100% for the ITI group. The survival rate of the IMZ group was significantly lower than that of the ITI group ($p < 0.05$).

The mean scores on the indices for plaque, calculus, gingiva and bleeding were very low at all evaluation periods (Table 2). Significant differences between the groups were at T_1 for the gingival index (the Brå group had a lower score than the other groups). The mean probing depth (Table 2) was the highest for the IMZ group at T_0, T_1 and T_5, followed by the Brå group and the ITI group. At T_{10} probing depth was still significantly higher in the IMZ group than in the Brå group.

Radiographic parameters

At the 5-year evaluation, intra-oral radiographs could not be made of one patient of the Brå group due to a change in the position of the bar. Change to a more labial position of the bar was carried out because of persistent sore spots at the floor of the mouth in the vicinity of the bar-clip attachment. At the 10-year evaluation, this was also the case for another two patients of the Brå group and two patients of the ITI group. The mean loss of marginal bone between base line and the 1-year evaluation was 0.8 mm [standard deviation (SD) = 1.2] in the IMZ group, 0.2 mm (SD = 0.7) in the Brånemark group and 0.3 mm (SD = 0.6) in the ITI group. The mean loss of marginal bone between base line and the 5-year evaluation was 1.4 mm (SD = 1.8) in the IMZ group, 0.7 mm (SD = 0.8) in the Brånemark group and 0.9 mm (SD = 0.9) in the ITI group. The mean loss of marginal bone between base line and the 10-year evaluation was 1.4 mm (SD = 1.1) in the IMZ group, 0.7 mm (SD = 0.5) in the Brånemark group and 1.3 mm (SD = 1.1) in the ITI group. Significant differences between the groups were observed after 1 year (more bone loss in the IMZ group than in the Brå group and the ITI group) and after 10 years (more bone loss in the IMZ group and the ITI group than in the Brå group). A frequency distribution of bone loss per implant per group is listed in Table 3.

Table 3. Frequency distribution of marginal bone changes to the nearest millimetre per implant after 1, 5 and 10 years of the IMZ group, the Brå group and the ITI group

	$\geqslant +2$	1	0	−1	−2	−3	−4	−5	$\leqslant -6$
IMZ T_1 ($n = 60$)	0	2	30	19	5	3	0	1	0
IMZ T_5 ($n = 60$)	1	2	14	16	12	9	2	3	1
IMZ T_{10} ($n = 54$)	0	1	14	21	9	3	4	0	2
Brå T_1 ($n = 58$)	1	0	46	7	2	0	0	0	0
Brå T_5 ($n = 52$)	0	0	23	21	6	2	0	0	0
Brå T_{10} ($n = 48$)	0	1	20	21	6	0	0	0	0
ITI group T_1 ($n = 58$)	0	1	37	16	3	1	0	0	0
ITI group T_5 ($n = 54$)	0	2	16	21	11	4	0	0	0
ITI group T_{10} ($n = 50$)	0	2	11	18	7	11	1	0	0

Patient satisfaction

The mean scores of the six scales of the questionnaire focusing on the complaints of the patients are listed in Table 4. Before treatment, patients from all three groups were equally dissatisfied with regard to their lower dentures as well as the other scales assessed. The functional complaints related to the lower denture had significantly improved at the 1-year evaluation ($p < 0.05$) and remained at this level during the 5- and 10-year follow-up. Also, the other five scales showed significant improvements between the pre-treatment and the post-treatment assessments. In addition, the satisfaction of the patients was independent of the implant system used. At the 10-year evaluation, there were some significant differences when compared with the 1-year results, although the patients were still much more satisfied when compared with the pre-treatment assessments. Not surprisingly, as most patients have functioned 10 years with their mandibular overdenture and new conventional upper denture, there was an overall trend wherein the patients had become slightly more dissatisfied regarding their functional complaints about the lower denture and their facial aesthetics.

Surgical and prosthetic aftercare

The overall surgical and prosthetic aftercare during the 10-year follow-up is listed in Tables 5a and b and 6. Concerning the surgical care period, there significantly less time was needed in the ITI group. In the surgical aftercare period, there were significantly less minor consults and significantly less sessions for removal of implants in the ITI group. In addition, there was a significantly less need to remove hyperplasia in the IMZ group. However, when considering all surgical aftercare given, there were no significant differences in the overall treatment time between the three implant systems applied. There were no significant differences in the overall treatment time in the prosthetic care period and the prosthetic aftercare period between the three groups.

Discussion

Two implants placed in the interforaminal region, connected with a bar, supply a proper base for the support of a mandibular overdenture in the edentulous patient. The 10-year survival rate is 98% for the Brå group, 93% for the IMZ group and 100% for the ITI group. Although a significant difference was observed between the survival rate of the IMZ implants and ITI implants, it has to be taken into account that only four implants were lost in the IMZ group. These percentages are comparable to other prospective studies that have reported survival rates of implants supporting an overdenture. Deporter et al. (2002) reported a 10-year survival rate of 92.7% for the Endopore dental implant system. Meijer et al. (2004b) reported on a clinical trial with a 93% 10-year survival rate for IMZ implants and an 86% 10-year survival rate for Brånemark implants. Naert et al. (2004b) reported a 10-year survival rate of 100% for Brånemark implants. Telleman et al. (2006) reported a 10-

Table 4. Mean score of 6 scales concerning denture complaints before, and 1, 5 and 10 years after treatment (possible range 0–3), the significance level of the differences between the IMZ group, the Brå group and the ITI group and the mean score for all patients

	IMZ group	Brå group	ITI group	Significance
Pre-treatment	($n = 30$)	($n = 30$)	($n = 30$)	
A. Functional complaints about the lower denture	2.2 (0.5)	2.4 (0.6)	2.2 (0.7)	NS
B. Functional complaints about the upper denture	0.4 (0.5)	0.6 (0.5)	0.5 (0.4)	NS
C. Functional complaints in general	1.0 (0.4)	1.3 (0.7)	1.0 (0.5)	NS
D. Facial aesthetics	1.1 (0.9)	1.2 (1.0)	1.1 (0.9)	NS
E. ''Neutral space''	0.6 (0.7)	0.8 (0.8)	0.6 (0.7)	NS
F. Aesthetics	0.3 (0.3)	0.4 (0.4)	0.5 (0.4)	NS
T_1: evaluation 1 year after placement of overdenture	($n = 30$)	($n = 30$)	($n = 29$)	
A. Functional complaints about the lower denture	0.2 (0.1)	0.2 (0.2)	0.3 (0.4)	NS
B. Functional complaints about the upper denture	0.1 (0.1)	0.2 (0.2)	0.2 (0.3)	NS
C. Functional complaints in general	0.1 (0.1)	0.2 (0.2)	0.2 (0.2)	NS
D. Facial aesthetics	0.1 (0.3)	0.2 (0.5)	0.2 (0.4)	NS
E. ''Neutral space''	0.1 (0.3)	0.2 (0.4)	0.3 (0.4)	NS
F. Aesthetics	0.1 (0.1)	0.1 (0.2)	0.1 (0.2)	NS
T_5: evaluation 5 years after placement of overdenture	($n = 30$)	($n = 27$)	($n = 27$)	
A. Functional complaints about the lower denture	0.3 (0.3)	0.3 (0.3)	0.3 (0.3)	NS
B. Functional complaints about the upper denture	0.2 (0.2)	0.1 (0.3)	0.3 (0.4)	NS
C. Functional complaints in general	0.2 (0.2)	0.2 (0.2)	0.2 (0.4)	NS
D. Facial aesthetics	0.4 (0.5)	0.3 (0.5)	0.6 (0.8)	NS
E. ''Neutral space''	0.2 (0.3)	0.3 (0.5)	0.2 (0.4)	NS
F. Aesthetics	0.1 (0.2)	0.1 (0.2)	0.2 (0.2)	NS
T_{10}: evaluation 10 years after placement of overdenture	($n = 27$)	($n = 27$)	($n = 27$)	
A. Functional complaints about the lower denture	0.4 (0.5)	0.5 (0.5)	0.3 (0.4)	NS
B. Functional complaints about the upper denture	0.2 (0.3)	0.2 (0.3)	0.3 (0.4)	NS
C. Functional complaints in general	0.2 (0.3)	0.2 (0.3)	0.2 (0.2)	NS
D. Facial aesthetics	0.4 (0.7)	0.7 (0.8)	0.3 (0.5)	NS
E. ''Neutral space''	0.3 (0.5)	0.4 (0.5)	0.2 (0.4)	NS
F. Aesthetics	0.2 (0.3)	0.1 (0.2)	0.2 (0.2)	NS

Complaints concerning all six factors had significantly improved for all systems between T_0 and the other evaluation times ($p < 0.05$).

Significant difference between T_1 and T_{10} concerning functional problems in the lower denture and facial aesthetics in the Brå group (more complaints at 10 years, $p < 0.05$).

Trend between T_1 and T_{10} concerning functional problems in the lower denture and facial aesthetics in the IMZ group (more complaints at 10 years). NS, not significant; SD, standard deviation.

Table 5a. Surgical period: mean number (± SD) of interventions, overall treatment time per patient and significance level of the differences

Intervention (average treatment time)	IMZ group ($n = 30$)	Brå group ($n = 30$)	ITI group ($n = 30$)	Significance
Session for placing implants (45 min.)	1.00 ± 0.00	1.00 ± 0.00	1.00 ± 0.00	NS
Session for abutment operation (30 min.)	1.00 ± 0.00	1.00 ± 0.00	0.00 ± 0.00	ITI < IMZ, Brå
Session for postoperative care (10 min.)	4.47 ± 1.01	2.65 ± 0.84	2.89 ± 1.29	NS
Softliner application in mandibular denture (15 min.)	0.83 ± 0.59	0.68 ± 0.65	0.38 ± 0.49	NS
Overall treatment time needed per patient (min.)	132	112	80	ITI < IMZ

NS, not significant; SD, standard deviation.

Table 5b. Surgical aftercare period: mean number (± SD) of interventions, overall treatment time per patient and significance level of the differences

Intervention (average treatment time)	IMZ group ($n = 29$)	Brå group ($n = 30$)	ITI group ($n = 28$)	Significance
Consult				
Consult without treatment (15 min.)	0.17 ± 0.38	0.17 ± 0.46	0.33 ± 1.00	NS
Consult with minor treatment (20 min.)	0.10 ± 0.31	0.07 ± 0.25	0.00 ± 0.00	ITI < IMZ, Brå
Session for postoperative care (15 min.)	0.48 ± 2.41	0.17 ± 0.53	0.11 ± 0.32	NS
Bacterial biopsy (5 min.)	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	NS
Implant treatment				
Session for removal of implants (30 min.)	0.11 ± 0.42	0.03 ± 0.18	0.00 ± 0.00	ITI < IMZ
Session for adding implants (45 min.)	0.04 ± 0.19	0.03 ± 0.18	0.00 ± 0.00	NS
Session for placing abutments (30 min.)	0.04 ± 0.19	0.03 ± 0.18	0.00 ± 0.00	NS
Soft tissue treatment				
Palatal grafts (45 min.)	0.03 ± 0.19	0.10 ± 0.40	0.07 ± 0.27	NS
Gingivectomy (15 min.)	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	NS
Flap treatment (30 min.)	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	NS
Removal of hyperplasia (15 min.)	0.00 ± 0.00	0.07 ± 0.25	0.19 ± 0.40	IMZ < Brå < ITI
Local vestibuloplasty (30 min.)	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	NS
Overall treatment time per patient (min.)	19	15	13	NS

NS, not significant; SD, standard deviation.

Table 6. Prosthetic care and aftercare period: overall treatment per patient and significance level of the differences

	IMZ group	Brå group	ITI group	Significance
Prosthetic care	($n = 30$)	($n = 30$)	($n = 30$)	
Overall treatment time per patient (min.)	197	205	202	NS
Prosthetic aftercare	($n = 29$)	($n = 30$)	($n = 28$)	
Overall treatment time per patient (min.)	413	372	452	NS

NS, not significant.

year survival rate of 96.6% for Hollow Screw ITI implants and 96.1% for Hollow Cylinder ITI implants in a retrospective study.

The mean indices for plaque, calculus, gingiva and bleeding were very low at all evaluation periods for all three groups. The scores are comparable with the study of Meijer et al. (2004b) in which the same criteria were used. The strict oral hygiene regime to which patients were subjected to had probably resulted in healthy peri-implant tissues. The mean probing depth was different between the groups, but appeared to be stable over time. This difference in probing depth, already present at the first evaluation just after placement of the overdenture, is probably caused by the different operation procedure and/or the different implant design. Probing depth changes over time were minor and not significant for all three implant systems: from 3.9 mm at the baseline to 3.8 mm at 10 years for IMZ implants, from 3.3 to 3.0 mm for Brånemark implants and from 2.6 to 3.3 mm for ITI implants. Because recession was not measured, it is not known whether the attachment levels were stable. As some bone loss occurred during the 10-year evaluation period while the probing depths remained unchanged, this bone loss suggests that the attachment level probably follows the change in the level of bone around the implants. In this way, the peri-implant soft tissues remain healthy with a low gingival index and no deepening of the peri-implant sulcus.

With regard to the mean marginal bone level, some minor significant differences between the groups were noted after 1 year and after 10 years. The Brånemark system with a machined surface showed very little bone loss in the first year and the mean marginal bone level was stable between 5 and 10 years. The IMZ system with a roughened surface showed more loss in the first year, and the mean marginal bone level was also stable between 5 and 10 years. The ITI system with a roughened surface showed very little bone loss in the first years, but the mean marginal level appeared not to be stable between 5 and 10 years. In addition to this, the standard deviation for bone loss in the Brånemark group was small compared with the other groups. Although some differences are present between the systems, it is probably not clinically relevant at this level. The method used to analyse the peri-implant marginal bone level on the intra-oral radiographs has been described by Meijer et al. (1993). They found a minimum detectable dif-

ference of 0.3 mm, given the inter- and intra-observer errors in detecting and measuring marginal bone level. This minimum detectable difference could imply that relevant differences between the groups were not observed as the differences in the measured mean bone levels are either within or just above this level. However, if the measured differences between the groups would have been significant in all cases, this would not have clinical relevance as the observed bone loss is well within the limits as formulated by Albrektsson et al. (1986). The mean bone loss during the first year was within 1 mm and the subsequent annual bone was within 0.1 mm. The frequency distribution of marginal bone loss (Table 3) shows that in the IMZ group and in the ITI group more implants are ''at risk'' with 3 mm or more marginal bone loss (for all follow-up periods) than in the Brå group. In the present study, standardized intra-oral radiographs were used, and so comparison is performed with other 10-year studies that have prepared intra-oral radiographs to evaluate peri-implant bone levels. Intra-oral radiographs were used in the study of Naert et al. (2004b), who reported 1.2 mm bone loss for bar-connected Brånemark implants during the entire 10-year follow-up. Telleman et al. (2006) reported 2.2 mm bone loss for bar-connected ITI implants after 10 years. Bone loss reported in the present study is comparable to the results of the studies mentioned. Marginal bone loss was 0.8 mm for the IMZ group, 0.2 mm for the Brå group and 0.3 mm for the ITI group during the first year. This phenomenon of up to 1 mm bone loss has been described previously (Adell et al. 1981) and is related to maturation of bone after implant placement and adaptation of bone to withstand functional forces.

After the treatment, patients of all three groups were equally satisfied with their overdentures. At the 10-year evaluation, a tendency was observed wherein patients had become slightly dissatisfied when compared with the 1-year post-treatment data regarding the functional problems of the lower denture and the facial aesthetics. Apparently, adjustments are needed after 10 years and patients start to become less satisfied with the lower denture and the related facial aesthetics. A new prosthetic treatment would be a satisfying solution. This was also an observation made by Visser et al. (2006) when evaluating the patients' need for surgical and prosthetic care and aftercare related to an implant-retained lower denture. During their assessment of the 10-year follow-up data, they became aware of the phenomenon that the need for prosthetic aftercare was rather minor during the 10-year follow-up, but that it was not uncommon that during the 11th and 12th year there was a need to renew this overdenture.

Concerning the surgical care period, significantly less time was needed in the ITI group. This is not surprising because the ITI system is carried out in a one-stage technique and the other two systems in a two-stage procedure. This one-stage technique did not lead to significantly more implant loss or significant more marginal bone loss compared with a two-stage technique. Thus, there is apparently no rationale to insert dental implants into the edentulous mandible in two stages in healthy subjects. This statement was also made by Heijdenrijk et al. (2006). They found no clinical differences between systems inserted in a one-stage technique and a two-stage technique after a 5-year evaluation period. The need for surgical aftercare was shown to be minor in all three groups, being 19 min. in 10 years for the IMZ group, 15 min. for the Brå group and 13 min. in the ITI group (on average 1–2 min./year). It must be noted, however, that regular yearly check-ups for both peri-implant tissues and prosthetics were carried out by the prosthodontist and the dental hygienist. Prosthetic aftercare was much more time-consuming than the surgical aftercare, but still of a low magnitude (on average 20–25 min./year), and mainly comprised of routine check-ups and routine oral hygiene checks. The extensive method of analysis of aftercare can best be compared with the studies of Visser et al. (2006) and Stoker et al. (2007). In the study of Visser et al. (2006), a cost-analysis was performed after 10 years of a group of edentulous patients that started with a conventional denture as treatment and a group that started with a two-implant overdenture at the beginning of the study. The overdenture group consumed more or less the same amount of time as in this study. In the study of Stoker et al. (2007), aftercare was 353 min. in the two-implant overdenture group and 354 min. in the four-implant overdenture group. Keeping in mind that this aftercare was carried out in 8 years, the 405 and 477 min., respectively, from our 10-year study lies well within this range.

From this study, it is concluded that two implants (two-stage IMZ, two-stage Brånemark or one-stage ITI) placed in the interforaminal region, connected with a bar, supply a proper base for the support of a mandibular overdenture in the (Cawood V–VI) edentulous patient. After 10 years, no clinical and radiographic relevant changes had developed between the three implant systems and the patients were still very satisfied with their implant-retained mandibular overdenture. Moreover, the need for surgical and prosthetic aftercare was minor.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1. Supporting information in accordance with the CONSORT Statement 2001 checklist used in reporting randomized trials.

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Clinical Relevance

Scientific rationale for the study: Endosseous implants are frequently used to support a mandibular overdenture. It is beneficial for patients and clinicians to know whether this therapy represents a reliable procedure with favourable long-term outcomes.

Principal findings: Irrespective of the implant system used, patients with a two-implant overdenture are still very satisfied with this type of prosthetic rehabilitation 10 years after treatment.

Practical implications: People with complaints concerning lack of retention and stability of their mandibular conventional denture can be treated with a two-implant overdenture, because they will have a proven long-term satisfactory treatment with minor aftercare.