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Mandibular overdentures supported by two Brånemark, IMZ or ITI implants: a 5-year prospective study

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Abstract

Objectives: The aim of this prospective comparative study was to evaluate the survival rate and the condition of the peri-implant tissues of the IMZ implant system (two-stage cylindertype), the Brånemark implant system (two-stage screwtype) and the ITI implant system (one-stage screwtype) supporting a mandibular overdenture during a 5-year follow-up period.

Material 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, 2, 3, 4 and 5 years of functional loading.

Results: The five-year survival rate is 98.3% for the IMZ group, 98.3% for the Brå group and 100% for the ITI group. Mean scores on indices for plaque, calculus, gingiva and bleeding were very low at all evaluation periods. Mean marginal bone loss over a period of 5 years, was 1.4 mm for the IMZ group, 0.7 mm for the Brå group and 0.9 mm for the ITI group.

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. After 5 years no clinically relevant and statistically significant radiographic changes had developed between the three implant systems.

Key words: edentulous; dental implants; 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 currently frequently applied treatment possibility is the use of endosseous implants to which an overdenture can be attached. One of the first studies concerning overdentures supported by endosseous implants was published by Van Steenberghe et al. (1987). Various studies have revealed an implant survival rate of approximately 96% (Batenburg et al. 1998). 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. Buser et al. (1999) reported a 10-year survival rate of 96.2% for implants mainly placed in the anterior region of the mandible. Mericske-Stern et al. (2001) reported a 91.4% 10-year survival rate, and this group comprised not only mandibular overdentures, but also fixed partial dentures and single crowns. Ferrigno et al. (2002) reported a 10-year survival rate of 95.9% of a group treated with overdentures or fixed full-arch bridges. Major prospective studies evaluating one implant system with a follow-up period of at least 5 years specifically about overdentures retained by endosseous implants are Mericske-Stern et al. (1994) with the ITI dental implant system, Jemt et al. (1996) with the Brånemark implants system, Naert et al. (1998) with the Brånemark implants system and Behneke et al. (2002) with the ITI dental implant system. Comparison of implant systems is optimal in a prospective study with predefined inclusion and exclusion criteria (Antczak-Bouckoms 1988, Barmes 1990). Only few studies have been published with two or more different

endosseous implant systems in one prospective study on mandibular overdentures with a follow-up of at least 5 years. Meijer et al. (2000) presented a survival rate of 93% for the IMZ implant system and 86% for the Brånemark implant system after 5 years. In another study by Meijer et al. (2001), the 6-year results were presented for the IMZ implant system and the Brånemark implant systems, being 97.5% and 97.1%, respectively. Five-year results of a prospective study comparing a one-stage implant system with a two-stage implant system has never been published. The aim of this prospective comparative study was to evaluate the survival rate and the condition of the peri-implant tissues of the IMZ implant system (two-stage cylindertype), the Brånemark implant system (two-stage screwtype) and the ITI implant system (one-stage screwtype) supporting a mandibular overdenture during a 5-year follow-up period.

Materials and Methods

Patient selection and treatment

For this study, patients with severely resorbed mandibles were selected. All patients had persistent problems with 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 class V–VI according to the Cawood & Howell (1988) classification. 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 done by means of 90 envelopes, which contained a note with the implant system. Thirty patients (IMZ group) were treated with the two-stage 4 mm diameter IMZ cylinder implant with TPS coating (Friatec, Mannheim, Germany), 30 patients (Brå group) with the two-stage 3.75 mm diameter Brånemark screw implant with a machined surface (Nobel Biocare, Gothenburg, Sweden) and 30 patients (ITI group) with the one-stage 4.1 mm diameter ITI solid screw implant with TPS coating (Straumann, Waldenburg, 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 by one experienced oral-maxillofacial surgeon and one experienced prosthodontist. Two weeks after the abutment connection (for the two-stage implant systems) or 2 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. Characteristics of the groups are listed in Table 1. Bone height was measured on a rotational panoramic radiograph with correction for distortion. Bone quality was determined according to Lekholm & Zarb (1985) on a lateral cephalometric radiograph.

Data collection of all patients was performed as follows: T_0 (baseline evaluation after placement of the overdenture), T_1 (evaluation 1 year after placement of the overdenture) and T_2, T_3, T_4 and T_5 (evaluation, respectively, 2, 3, 4 and 5 years after placement of the overdenture). One investigator performed the measurements in all patients to prevent inter-observer differences.

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; 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) index was used (score 0: normal peri-implant mucosa; score 1: mild inflammation, slight change in colour, slight edema; score 2: moderate inflammation, redness, edema and glazing; score 3: severe inflammation, marked redness and edema, 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; score 3: heavy or profuse bleeding). Probing depth was measured at four sites of each implant (mesially, labially, distally, lingually) by using a periodontal probe (Merit B, Hu Friedy, Chicago, 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 done 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

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

measuring the radiographs and measurements were not done per patient. In this way, there was no recollection by the observer what bone loss was in earlier years.

Data analysis

Probing depth was measured at four sites around each implant and bone height measurement was done 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. ANOVA was carried out. Differences were tested with the Student's *t*-test. Analysis was done with SPSS (Statistical Package Social Sciences, version 10.0, 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_3 two patients of the IMZ group and one patient of the Brå group did not attend the evaluation due to sickness and another patient had died in the ITI group. At T_4 three patients of the Brå group and two patients of the ITI group did not attend the evaluation due to sickness. At T_5 three patients of the Brå group and one patient of the ITI group did not attend the evaluation due to sickness. The assumption was made that not attending the evaluation was independent of the clinical or radiographic state. Of one patient of the Brå group intra-oral radiographs could not be made due to the position of the bar.

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 bone-healing period of 6 months, another implant was placed successfully in these patients. During the functional period none of the implants were lost. Survival rate after 5 years is 98.3% for the IMZ group, 98.3% for the Brå group and 100% for the ITI group.

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); at T_3 for the bleeding index (the Brå group and the ITI group had a lower score than the IMZ group) and at T_4 for the bleeding index (the ITI group had a lower score than the other groups). The mean probing depth (Table 2) was the highest for the IMZ group, followed by the Brå group and then by the ITI group with the lowest mean probing depth.

The mean marginal bone loss is listed in Table 3. The mean location of the bone level, measured from the top of the implant (= reference point), at the baseline (T_0) was 1.80 mm for the IMZ system, 1.86 mm for the Brå system and 3.34 mm for the ITI system. Significant differences between the groups were after 1 year (more bone loss in the IMZ group than in the Brå group and the ITI group) and after 4 years (less bone loss in the Brå group than in the IMZ group and the ITI group).

Discussion

The 5-year survival rate of implants in this prospective study is 98.3% for the IMZ group, 98.3% for the Brå group and 100% for the ITI group. These percentages are comparable to other prospective studies that have reported survival rates of implants supporting an overdenture ranging from 94.5% to 98.8% (Mericske-Stern et al. 1994, Jemt et al. 1996, Naert et al. 1998, Behneke et al. 2002). In a comparative study Meijer et al. (2000) reported a 5-year survival rate of 93% for the IMZ implant system and 86% for the Brånemark implant system. In another comparative study of Meijer et al. (2001), the 6-year results were presented of the IMZ implant system and the Brånemark implant system, being 97.5% and 97.1%, respectively.

Mean indices for plaque, calculus, gingiva and bleeding were very low at all evaluation periods for all three groups. Scores are comparable with studies of Meijer et al. (2000, 2001) in which the same criteria were used. The strict oral hygiene regime to which patients were subjected provided healthy peri-implant tissues. Mean probing depth was different between 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 are minor for all three implant systems: from 3.9 mm at the baseline to 4.2 mm at 5 years for IMZ implants, from 3.3 to 3.0 mm for Brånemark implants and from 2.6 to 2.4 mm for ITI implants. These changes are not significant. Since recession was not measured, it is not known whether the attachment levels are stable. The bone loss that happened suggests that the attachment level changes with the change in 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 marginal bone level, significant differences between the groups were noted after 1 year (more bone loss in the IMZ group than in the Brå group and the ITI group) and after 4 years (less bone loss in the Brå group than in the IMZ group and the ITI group). After 5 years there is not a significant difference in bone loss between the implant systems. In the present study, standardized intra-oral radiographs were used. So comparison is done with other studies that have made intra-oral radiographs to evaluate peri-implant bone levels. Intra-oral radiographs were used in the study of Jemt et al. (1996), who reported 0.5 mm bone loss during the entire 5 years follow-up. Naert et al. (1998) reported 0.6 mm during the first year and thereafter an annual bone loss of less than 0.1 mm. Bone loss reported in the present study is comparable to the results of the mentioned studies.

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. An annual bone loss of 0.2 mm after this period has been recognized as acceptable (Albrektsson et al. 1986). Annual bone loss was seen in all groups, but did not exceed 0.2 mm. Table 3 illustrates that the difference occurs in the first year (IMZ more bone loss than Brå and ITI), but after this period, the annual bone is more or less the same in the

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 millimeters at T_0 (evaluation after placement of the overdenture) and T_1, T_2, T_3, T_4 and T_5 (evaluation, respectively, 1, 2, 3, 4 and 5 years after placement of the overdenture) and the significance level of the differences between the IMZ group, the Brå group and the ITI group

	T0: evaluation after placement of overdenture			
	IMZ group ($n = 30$)	Brå group ($n = 30$)	ITI group ($n = 30$)	Significance
Mean plaque index (SD)	0.3 (0.5)	0.3 (0.8)	0.6 (0.7)	Not significant
Mean calculus index (SD)	0.4 (0.5)	0.4 (0.5)	0.5 (0.5)	Not significant
Mean gingival index (SD)	0.5 (0.9)	0.4 (0.6)	0.3 (0.5)	Not significant
Mean bleeding index (SD)	1.1 (0.6)	0.8 (0.5)	0.8 (0.7)	Not significant
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			
	IMZ group ($n = 30$)	Brå group ($n = 30$)	ITI group ($n = 29$)	Significance
Mean plaque index (SD)	0.4 (0.8)	0.6 (1.0)	0.1 (0.4)	Not significant
Mean calculus index (SD)	0.3 (0.5)	0.5 (0.5)	0.4 (0.5)	Not significant
Mean gingival index (SD)	0.5 (0.7)	0.2 (0.4)	0.7 (0.6)	Brå < IMZ,ITI ($p = 0.006$)
Mean bleeding index (SD)	1.0 (0.5)	0.8 (0.6)	0.7 (0.6)	Not significant
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_2: evaluation 2 years after placement of overdenture			
	IMZ group ($n = 30$)	Brå group ($n = 30$)	ITI group ($n = 29$)	Significance
Mean plaque index (SD)	0.5 (0.8)	0.8 (1.0)	0.4 (0.7)	Not significant
Mean calculus index (SD)	0.5 (0.6)	0.4 (0.5)	0.5 (0.5)	Not significant
Mean gingival index (SD)	0.7 (0.7)	0.5 (0.6)	0.3 (0.6)	Not significant
Mean bleeding index (SD)	1.1 (0.6)	1.0 (0.7)	0.9 (0.6)	Not significant
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_3: evaluation 3 years after placement of overdenture			
	IMZ group ($n = 28$)	Brå group ($n = 29$)	ITI group ($n = 28$)	Significance
Mean plaque index (SD)	0.5 (0.7)	0.6 (1.0)	0.6 (0.8)	Not significant
Mean calculus index (SD)	0.4 (0.5)	0.5 (0.5)	0.6 (0.5)	Not significant
Mean gingival index (SD)	0.9 (0.8)	0.6 (0.7)	0.5 (0.6)	Not significant
Mean bleeding index (SD)	1.2 (0.7)	0.8 (0.5)	0.8 (0.6)	Brå,ITI < IMZ ($p = 0.016$)
Mean probing depth in mm (SD)	3.8 (1.3)	3.0 (0.4)	2.3 (0.7)	ITI < Brå < IMZ ($p < 0.001$)
	T_4: evaluation 4 years after placement of overdenture			
	IMZ group ($n = 30$)	Brå group ($n = 27$)	ITI group ($n = 26$)	Significance
Mean plaque index (SD)	0.6 (0.7)	0.8 (1.0)	0.7 (0.8)	Not significant
Mean calculus index (SD)	0.5 (0.6)	0.6 (0.5)	0.7 (0.6)	Not significant
Mean gingival index (SD)	0.8 (0.7)	0.6 (0.6)	0.7 (0.7)	Not significant
Mean bleeding index (SD)	0.9 (0.4)	1.0 (0.4)	0.6 (0.6)	ITI < IMZ,Brå ($p = 0.036$)
Mean probing depth in mm (SD)	3.8 (1.4)	2.9 (0.6)	2.6 (0.6)	ITI,Brå < IMZ ($p < 0.001$)
	T_5: evaluation 5 years after placement of overdenture			
	IMZ group ($n = 30$)	Brå group ($n = 27$)	ITI group ($n = 27$)	Significance
Mean plaque index (SD)	0.5 (0.7)	0.8 (1.0)	0.4 (0.8)	Not significant
Mean calculus index (SD)	0.4 (0.5)	0.5 (0.5)	0.5 (0.5)	Not significant
Mean gingival index (SD)	0.7 (0.8)	0.5 (0.6)	0.6 (0.8)	Not significant
Mean bleeding index (SD)	0.9 (0.6)	0.7 (0.5)	0.7 (0.8)	Not significant
Mean probing depth in mm (SD)	4.2 (1.3)	3.0 (0.6)	2.4 (0.7)	ITI < Brå < IMZ ($p < 0.001$)

Table 3. Mean loss of marginal bone in millimeters (and standard deviation) after 1, 2, 3, 4 and 5 years 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
Mean loss of marginal bone between T_0 and T_1 in mm (SD)	0.8 (1.2) ($n = 30$)	0.2 (0.7) ($n = 29$)	0.3 (0.6) ($n = 29$)	Brå,ITI < IMZ ($p = 0.028$)
Mean loss of marginal bone between T_0 and T_2 in mm (SD)	0.9 (1.5) ($n = 30$)	0.6 (1.1) ($n = 29$)	0.5 (0.7) ($n = 29$)	Not significant
Mean loss of marginal bone between T_0 and T_3 in mm (SD)	0.8 (1.5) ($n = 28$)	0.4 (0.9) ($n = 28$)	0.5 (0.8) ($n = 29$)	Not significant
Mean loss of marginal bone between T_0 and T_4 in mm (SD)	1.3 (1.5) ($n = 30$)	0.4 (0.6) ($n = 26$)	(0.7) ($n = 26$)	Brå < IMZ,ITI ($p = 0.015$)
Mean loss of marginal bone between T_0 and T_5 in mm (SD)	1.4 (1.8) ($n = 30$)	0.7 (0.8) ($n = 26$)	0.9 (0.9) ($n = 27$)	Not significant

three groups. The bone loss for the IMZ system could be caused by a different implant surface around the neck of the IMZ implant. The large standard deviation for the parameter bone loss in the IMZ group indicates that some patients showed significant amounts of bone loss. These patients may be at risk for loss of implants.

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 5 years no clinically relevant and statistically significant radiographic changes had developed between the three implant systems.

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