Randomized Multicenter Comparison of 2 IMZ and 4 TPS Screw Implants Supporting Bar-Retained Overdentures in 425 Edentulous Mandibles

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Purpose: *Two treatment concepts for implant-supported bar retention of mandibular overdentures—2 intramobile cylinder (IMZ) implants and a Dolder bar and 4 titanium plasma-sprayed (TPS) screw implants and an angulated bar—were compared in a randomized controlled clinical trial with respect to postprosthetic efficacy and safety.* ***Materials and Methods:*** *Four hundred twenty-five patients with edentulous mandibles were enrolled; 212 were randomized to TPS implants (control group) and 213 to IMZ implants (test group). Endpoints were occurrences of postprosthetic integration deficiency (ID), functional deficiency (FD), and complications. The trial was sized to detect a 10% difference in 5-year ID-free postprosthetic system lifetime with a power of 80%.* ***Results:*** *With 340 protocol-completed cases, the trial achieved its predetermined power. The 2 systems did not show statistically significant differences in occurrences of postprosthetic ID and FD; 5-year occurrence-free postprosthetic system lifetime probabilities were estimated as 42.5% with IMZ and 42.8% with TPS, for ID; and as 82.6% with IMZ and 87.2% with TPS, for FD. However, at 3 to 6 months after surgery, mean Periotest values were significantly higher (P = .0001 without adjustment) with IMZ implants (5.6, SD 4.2) than with TPS implants (0.8, SD 4.3). TPS implants showed a higher incidence of inflammation and recession, while IMZ implants had a higher incidence of implant fracture after functional loading.* ***Discussion:*** *The system-wise approach overcomes potential bias with implant-wise analyses. A combination of radiographic and clinical criteria distinguishes between desirable integration and functional anchorage. The in situ survival rates at 5 years in this study (95% for IMZ, 92% for TPS) match rates reported in the literature.* ***Conclusion:*** *This study demonstrated equivalent efficacy of 2 IMZ cylinders and 4 TPS screws in implant-supported, bar-retained mandibular overdentures and indicated a higher rate of complications with the TPS screw implants.* INT J ORAL MAXILLOFAC IMPLANTS 2003;18:835–847

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Edentulous patients with a severely resorbed mandible often experience problems with conventional dentures, such as insufficient stability and retention during masticatory function. Various treatment concepts involving different numbers and types of implants as well as different superstructure designs have been proposed for the support of mandibular dentures. Clinical studies have shown high long-term effectiveness of fixed complete-arch prostheses supported by 5 or 6 endosseous implants in edentulous patients.[1–6] Since many patients suffer only from

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retention problems of the mandibular prosthesis and do not desire complete fixed prostheses, the implant-retained overdenture has become a treatment alternative that is reliable and offers phonetic, hygienic, esthetic, and economic advantages. Reported implant survival rates are comparable to results from studies with fixed implant-supported prostheses.[7–20] Different implant systems, numbers of implants, and attachment systems have been used, but very few studies have applied adequate experimental and statistical methodology for a valid comparison.

The aim of this study was to compare 2 treatment concepts for implant-supported, bar-retained mandibular overdentures: *(1)* 2 intramobile cylinder (IMZ) implants with a straight Dolder bar (Interpore, Irvine, CA), and *(2)* 4 titanium plasma-flame sprayed (TPS) screw implants with an angulated bar (Straumann, Freiburg, Germany). Though from a methodologic viewpoint it would have been more desirable to compare 2 and 4 supporting implants within the same implant system, either IMZ cylinders or TPS screws, concepts with well-standardized surgical and prosthetic procedures were chosen for ethical reasons. The 2 concepts were to be compared with respect to the duration of integration and function in terms of clinical and radiologic parameters after functional loading for at least 3 years of follow-up. The comparison of occurrences of complications was a collateral objective.

MATERIALS AND METHODS

Trial Population

The trial was carried out in 5 German clinics in Aachen, Berlin, Düsseldorf, Mainz, and Tübingen. The study population consisted of mandibular edentulous patients who had complaints about their conventional dentures. Patients who had sufficient mandibular bone height (at least 13 mm), in whom the last extraction at implantation sites had occurred at least 8 months earlier, and who gave informed consent were eligible. The following patients were excluded from the study: those who had previously received dental implants; those with limited ability to communicate (for speech or neurologic reasons) or to cooperate (ie, adhere to examination schedule or hygienic recommendations); those with any diseases or therapeutic treatment that could seriously affect the surgical procedure or outcome (systemic corticosteroidal, local radiologic, immunosuppressive, or anticoagulative therapy, as well as mental illness or epileptic diseases); and those in whom the width of the alveolar crest was less than 5 mm.

Treatment Protocols

Under the test regimen, 2 plasma-flame–coated IMZ implants with spacer sleeves with a diameter of 3.3 mm were placed in the canine region and connected by a straight oval Dolder bar, while the control regimen used 4 TPS screw implants (Ledermann) with a diameter of 3.5 mm connected with an angulated bar. Common surgical procedures for the placement of IMZ cylinders and TPS screw implants included: *(1)* presurgical clinical and radiographic examinations to determine anatomic conditions with respect to bone volume and denture-bearing mucosa, and *(2)* surgical procedures and prosthodontic treatment according to the instruction manuals for the IMZ and TPS implant systems, which require a 2-stage procedure and immediate loading, respectively. Surgery was discontinued if bone volume was insufficient, according to the judgment of the surgeon, or upon the occurrence of severe intrasurgical complications. Osteoplasty was allowed.

With the TPS screws, a superstructure consisting of prefabricated gold cylinders connected by a bar was put into place within 48 hours, and within 2 weeks after implantation the mandibular overdenture was fitted onto the bar with internal clips. With IMZ implants, a normal 2-stage technique was used, with a healing period of 3 to 4 months and maximum time until completion of the prosthetic restoration of 6 months. However, practice revealed a generally longer waiting time until completed prosthetic restoration, which led to allowance of another 2 months. Therefore, waiting times longer than 77 days and 8 months for TPS and IMZ implants, respectively, were considered as protocol violations that implied exclusion from the per-protocol population (PPP) analyses, though not from the intent-to-treat (ITT) analyses. The intramobile elements of IMZ implants were to be replaced every 12 months. Systemic administration of antibiotics, along with curettage, gingivectomy, vestibuloplasty, denture rebasing, and occlusal corrections, as local adjuvant therapeutic measures, were permitted.

Examination Protocols

Parameters and procedures were documented initially after pretreatment assessment, prior to randomization, and then after surgery (baseline), after completion of prosthetic treatment, and every 6 months during subsequent follow-up. Radiographs were planned to be taken immediately after implant placement and then once per year for follow-up. Intrasurgical recordings included width of the alveolar crest at 3 mm and at 6 mm (measured with a 3-dimensional osteometer), usable bone height, buccal

width of keratinized mucosa, thickness of bone wall buccally and lingually, uncovered implant neck buccally and lingually, and vestibular depth after wound covering. Follow-up examinations included the following clinical parameters measured at the buccal surfaces of the implants: Plaque Index,[21] Gingival Index,[22] probing depth, Periotest values (PTV),[23] and manually assessed mobility,[24] which was graded as either 0 = no mobility, 1 = slight (just perceptible) mobility, 2 = visible mobility, or 3 = mobile under pressure of lip and tongue and/or manually mobile in the axial direction. For changes in alveolar bone level, panoramic radiographs were analyzed with the immediate postoperative radiograph as the baseline reference.[25] Readings were adjusted according to known implant dimensions.

Table 1 Success Criteria for No Integration Deficiency (No ID) and for No Functional Deficiency (No FD) for Single Implants, Either IMZ or TPS

Criterion	No ID*	No FD†
In situ	Yes	Yes
Bone loss	Max 3 mm	≤ 1/2 implant length
Periotest value	≤ 10	Not applied
Manual mobility of implant‡	0	≤ 1

*Must be met by every implant of system to qualify for no system ID.
†Must be met by 2 IMZ implants and at least 3 TPS implants to qualify for no system FD.
‡Grade 0 = no mobility; Grade 1 = slight (just perceptable) mobility.

Trial Design and Statistical Analyses

Comparison of the 2 treatment protocols was designed as a prospective, multicenter, between-patients, randomized controlled trial; assignment by central telephone randomization was balanced within each center. Patients were enrolled after informed consent was obtained and prior to communication of the assigned protocol. Masking of assigned implant systems was not feasible. Criteria for patient dropout had been specified in a peer-reviewed trial protocol prior to admission of any patients: *(1)* discontinuation of surgery for any of the reasons mentioned above, *(2)* patient's wish to remove the implants or to withdraw from the trial for any reason, *(3)* exogenous injury implying implant loss, and *(4)* more than 1 failure to adhere to scheduled recall appointments within 3 months.

The primary efficacy endpoint had been defined a priori as the time after completion of the prosthetic restoration (functional loading) until the first occurrence of an integration deficiency (ID) (Table 1) at any implant of a system (system ID). Three secondary efficacy endpoints had also been specified in the trial protocol: *(1)* postprosthetic time until the first occurrence of a functional deficiency (FD) (Table 1) at 1 IMZ or 2 TPS implants of a system (system FD), *(2)* occurrence of an FD in an implant system within 3 years after functional loading, and *(3)* mean PTV among the implants of a system 3 to 6 months after surgery (system PTV). Hence, system ID was observed when at least 1 implant within a system did not meet every criterion of integration, and system FD was observed when at least 1 implant in an IMZ patient or at least 2 implants within a TPS patient failed to meet every criterion of function as defined in Table 1 for ID and FD, respectively. Safety endpoints were occurrences of predefined complications *(1)* during surgery and the first 2 weeks after placement, *(2)* during the healing period, and *(3)* after functional loading.

The trial had been sized to detect an absolute difference of 10% between postprosthetic 5-year ID-free system lifetime probabilities of IMZ and TPS systems in the patient population at a significance level of 5% with a power of at least 80%. This implied at least 340 evaluable patients for analysis. With an anticipated proportion of dropouts of 10% to 15%, the total recruitment goal had been set at 390 randomized patients.

Case record forms were mailed, queried regularly, and monitored on site in a later stage of the trial. After visual screening, collected raw data were entered concurrently into an electronic database, using independent, duplicate data entry into screen masks with automatic plausibility checks. Interim analyses were conducted at the data center, and results were communicated in a partially masked form; otherwise, no interim data were released to avoid unnecessary bias. After completion of data collection, radiographs were re-evaluated in panel sessions to achieve a common standard across the 5 centers. Prior to the final analysis, all ambiguous records were reviewed in panel sessions without disclosure of the assigned treatment.

Postprosthetic system ID-free survival (primary endpoint) curves were computed according to Kaplan and Meier[26]; by the trial protocol, the log-rank test for right-censored failure time data was used to assess the statistical significance of numeric differences between survival curves of IMZ and TPS implant systems. In terms of system failure hazard functions (λ), the null hypothesis of equal system ID-free survival is stated as $\lambda_{IMZ} = \lambda_{TPS}$. For the present randomization analysis, structural heterogeneities in the baseline parameters were not adjusted.

As supplemental descriptives only, system ID and system FD average failure proportions (number of respective failures over number exposed among postprosthetic systems), and average failure rates of system ID and of system FD after functional loading (number of respective failures over system versus years of postprosthetic follow-up) were calculated.

For safety or tolerability analysis, the 2 systems were compared in terms of postprosthetic time to first occurrence of a complication with a system (system-wise analysis), using the Kaplan-Meier estimation and the log-rank test. As a supplement, 1-, 3-, and 5-year event-free probabilities and their standard approximate point-wise 95% confidence intervals (CI) were collected for some specific complications, for other unspecific complications, and for all postprosthetic complications together. The full list of complications that was specified explicitly in the trial protocol mentioned earlier stages of a system within a patient as well; however, the recurrence frequency would be disregarded with only the system-wise survival-type analysis. Therefore, average frequencies of occurrence of complications were calculated, too, as total numbers of occurrences of some specific kind of complication over the total number of examinations of individual implants at which such a complication could have been observed. Since numbers of observations of complications are related to the total number of opportunities for observation (ie, examinations of individual implants), these ratios may be considered as rates and are reported per 100 implants and implant-examination visits (% pii). For example, observation of inflammation at 1 implant of a 4-implant system at one recall visit during a follow-up that included a total of 10 recall visits, and no implants lost, would yield an average frequency of 1/40 or 2.5% pii.

Data were processed with the Statistical Analysis System[27] (version 6.12; SAS Software, Cary, NC) with an AIX 4.3 operating system on RS/6000 hardware.

RESULTS

Comparability Analysis: Actual Trial Population and Randomization

Four hundred twenty-five admitted patients aged 30 to 82 years (mean 60.3 years) who met the inclusion criteria were enrolled in this study; 157 (30.9%) were men and 268 (63.1%) were women. Two hundred twelve (49.9%) patients were randomized to 4 (TPS) screw implants (control group) and 213 (50.1%) patients were randomized to 2 IMZ implants (test group).

Forty-eight patients did not enter the protocol because surgery was not done (n = 40) or was discontinued (n = 8); 3 patients received the wrong implant systems, ie, IMZ instead of TPS or vice versa, and 8 patients lost implants before functional loading (Fig 1, Table 2a). Thus, there were 369 patients eligible for an intent-to-treat strictu sensu (ITT-ss) analysis of the postprosthetic primary endpoint: 193 in the IMZ group and 176 in the TPS group.

Six patients were lost from the preprosthetic follow-up, and 3 patients were lost from the postprosthetic follow-up. The remaining 360 patients (186 in the IMZ and 174 in the TPS group) represent the sample for intent-to-treat "as available" (ITT-aa) analyses. The postprosthetic ITT-aa sample thus consisted of all admitted and randomized patients, irrespective of their consistency or compliance with the protocol schedule of recall visits.

An additional 20 patients were excluded because prostheses were placed too late, which left 340 patients (177 in the IMZ and 163 in the TPS group) eligible for primary and secondary endpoint analyses of per-protocol population (PPP). The postprosthetic PPP sample thus consisted of all admitted and randomized patients whose baseline characteristics were consistent with the inclusion and exclusion criteria of the protocol, and who complied with the treatment protocol, but irrespective of their adherence to the exact protocol schedule of follow-up examinations. The PPP comprised 129 men (37.9%) and 211 women (62.1%) (Table 2a). No patients withdrew consent after an assignment to treatment in this trial.

The descriptive comparisons of the 2 randomized treatment groups across all centers with respect to the PPP baseline values are summarized in Tables 2a and 2b for patient/data and implant/data comparisons, respectively.

Efficacy Analysis: Intent-to-Treat Strictu Sensu

For the ITT-ss analysis of the primary endpoint (postprosthetic ID-free survival), an appropriate binary endpoint is needed to make assumptions about missing assessments of those patients who were not available for examination. Occurrence of ID (failure) or no occurrence of ID (success) during follow-up of any length was chosen for simplicity. There are therefore 3 possible scenarios to include patients in an analysis who were not assessed according to the protocol: *(1)* by a "worst-case" assumption, ie, patients who were not assessed are considered as treatment failures for either regimen (IMZ or TPS); *(2)* by a "best-case" assumption, ie, patients who were not assessed are considered as

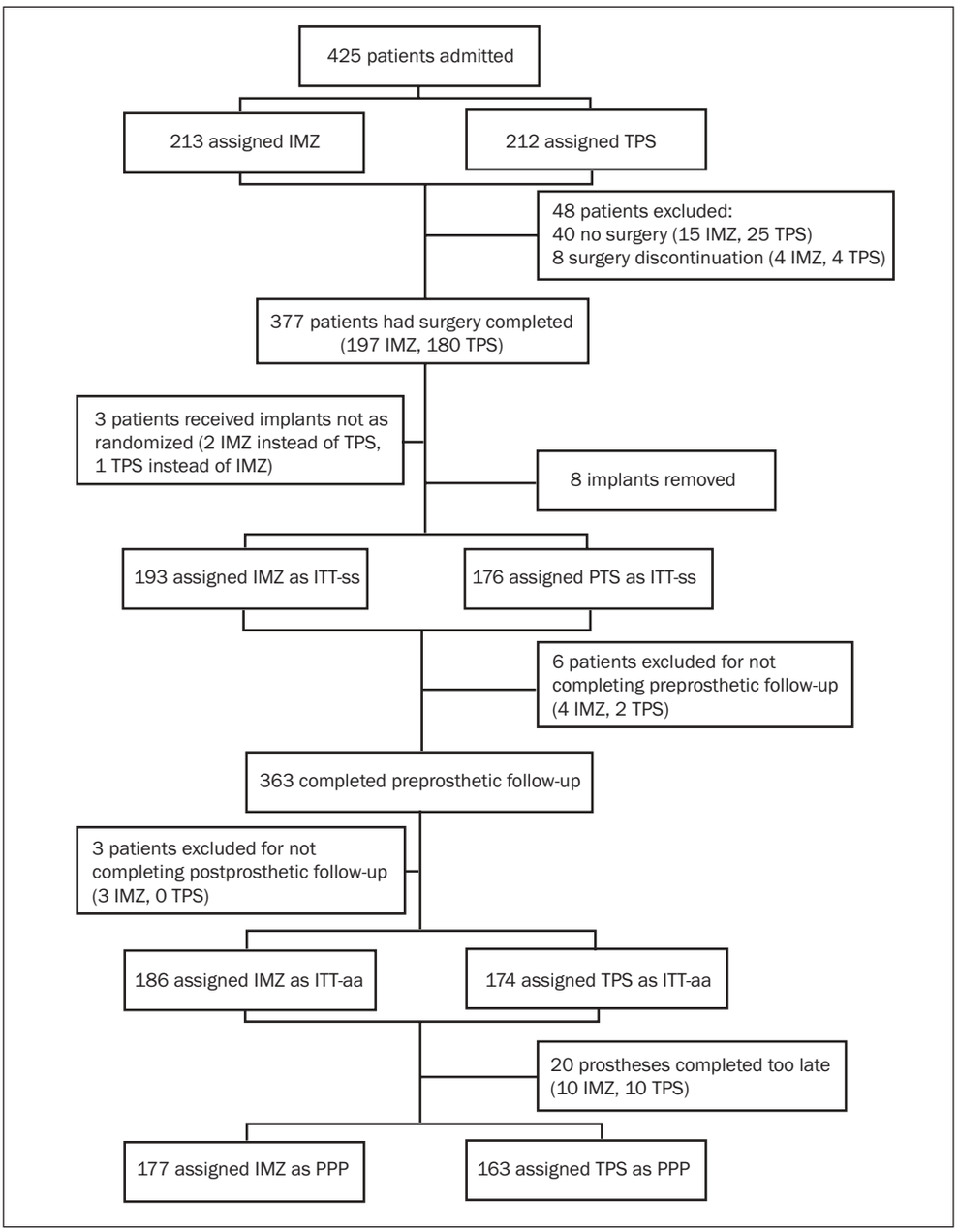

Fig 1 Trial flow diagram for efficacy analyses. IMZ = intramobile cylinder implants (2 per patient); TPS = titanium plasma flame-sprayed screw-shaped implants (4 per patient); ITT-ss = intention to treat strictu sensu; ITT-aa = intention to treat as available; PPP = per-protocol population.

treatment successes for either regimen; and *(3)* by a "mixed worst/best-case" assumption, ie, patients who were not assessed are considered as treatment failures if assigned to the test treatment (IMZ) and as treatment successes if assigned to the control treatment (TPS). Scenario 3 may also be called the "least favorable case" for the test treatment (IMZ). No statistically significant differences were found in proportions of ID-free patients with any of the 3 scenarios (Table 3).

Efficacy Analysis: Per-protocol Population

Here, preference is given to a description of results of PPP analyses. Because of the small discrepancy

Table 2a Sample Sizes and Demographic Data of ITT-As Available (ITT-aa) and PPP Patients

Data	Assigned treatment		Total	*z*	*P*
	IMZ	TPS			
Total no. of randomized patients					
No surgery done	15	25	425		
Surgery discontinued	1	7	40		
System as randomized	197	180	374	6.531	.011
Deviations from system					
TPS instead of IMS	—	1	1		
IMZ instead of TPS	2	—	2		
No. of preprosthetic patients					
ITT	197	180	377		
PPP	198	179	377		
Total no. of patients without postprosthetic follow-up	21	16	37	0.312	.577
No preprosthetic follow-up	4	2	6		
Preprosthetic implant removal	4	4	8		
Prosthesis done too late	10	10	20		
No postprosthetic follow-up	3	0	3		
No. of postprosthetic patients					
ITT-aa	186	174	360		
PPP	177	163	340		
No. of implants					
ITT-aa	376	690	1,066		
PPP	354	652	1,006		
Gender (M/F)					
ITT-aa	61/126	76/97	137/223	4.877	.027
PPP	58/119	71/92	129/211	4.196	.041
Age (y) (mean ± SD)					
ITT-aa	60.4 ± 8.8	60.3 ± 9.9	60.3 ± 9.3	0.036	.971
PPP	60.6 ± 8.9	60.2 ± 9.6	60.4 ± 9.2	0.345	.730

IMZ = intramobile cylinder implants (test); ITT = intent to treat; PPP = per-protocol population; TPS = titanium plasma-flame sprayed screw implants (control).
z values are approximate chi-square values, 1 degree of freedom for the common chi-square test of 2-by-2 contingency tables for perioperative and postprosthetic dropouts and for gender, and approximate standard-normal values of the Mann-Whitney *U* test, for age. *P* values are not adjusted for multiple testing.

between the ITT-aa cohort and the PPP cohort, the analogous analysis of every endpoint with the former yielded practically negligible differences in numeric results (Table 4).

Postprosthetic occurrence of system ID (primary endpoint) was reported for 116 patients in the IMZ group and 109 patients in the TPS group (Table 4). Differences in Kaplan-Meier ID-free survival estimates (Fig 2) were not statistically significant (log-rank test chi-square of 1 df was 0.39, $P = .53$); 1-year and 5-year ID-free survival estimates were 73.4% (95% CI 66.2% to 80.5%) and 42.5% (95% CI 34.2% to 50.7%), respectively, for IMZ, and 83.1% (95% CI 76.6% to 89.5%) and 42.8% (95% CI 34.0% to 51.6%), respectively, for TPS. The differences of –1.4% and +1.7% per year (of postprosthetic follow-up) between average proportions and average rates, respectively, of postprosthetic system ID occurrences with IMZ and TPS reflect the lack of relevant differences in system ID–free survival as well.

Postprosthetic occurrence of system FD (first secondary endpoint) was reported for 38 patients in the IMZ group and for 41 patients in the TPS group (Table 4). Differences in Kaplan-Meier FD-free survival estimates (Fig 3) were not statistically significant (log-rank test chi-square [1 df] = 2.10, $P = .15$); 1-year and 5-year FD-free survival estimates were 94.3% (95% CI 90.8% to 97.7%) and 82.6% (95% CI 76.8% to 88.4%), respectively, for IMZ, and 91.4% (95% CI 87.1% to 95.7%) and 87.2% (95% CI 82.0% to 92.5%), respectively, for TPS. The differences of +5.5% and +1.3% per year (of postprosthetic follow-up) between average proportions and average rates, respectively, of postprosthetic system FD occurrences with IMZ and TPS do not imply relevant differences in system-FD free survival.

Table 2b Comparison of Baseline Data (Median, Min, and Max) for Homogeneity Assessment of Randomized Groups in ITT-aa and PPP Patients

Data	Assigned treatment IMZ	TPS	Total
Width (mm) of alveolar crest at 3 mm			
ITT-aa	8 (4–13)	7 (3–16)	7 (3–16)
PPP	7 (2–15)	7 (3–16)	7 (2–16)
Width (mm) of alveolar crest at 6 mm			
ITT-aa	9.8 (5–15)	9 (5–21)	9.5 (5–21)
PPP	9 (5–17)	9 (5–21)	9 (5–21)
Usable bone height (mm)			
ITT-aa	18 (13–28)	19 (10–30)	19 (10–30)
PPP	19 (13–28)	19 (10–30)	19 (10–30)
Keratinized mucosa buccally (mm)			
ITT-aa	2 (0–9)	2 (0–10)	2 (0–10)
PPP	2 (0–9)	2 (0–10)	2 (0–10)
Implant length (mm)			
ITT-aa	15 (10–15)	14 (1–21)	14 (1–21)
PPP	15 (10–15)	14 (8–21)	14.5 (8–21)
Thickness of bone wall buccally (mm)			
ITT-aa	1 (0–5)	1 (0–6)	1 (0–6)
PPP	1 (0–5)	1 (0–6)	1 (0–6)
Thickness of bone wall lingually (mm)			
ITT-aa	2 (0–7)	2 (0–8)	2 (0–8)
PPP	2 (0–6)	2 (0.5–6)	2 (0–6)
Vestibulum depth after wound coverage (mm)			
ITT-aa	2 (0–15)	1.8 (0–15)	2 (0–15)
PPP	4 (0–15)	2 (0–15)	2 (0–15)
Uncovered implant neck buccally (mm)			
ITT-aa	0 (0–4)	0 (0–7)	0 (0–7)
PPP	0 (0–5)	0 (0–3)	0 (0–5)
Uncovered implant neck lingually (mm)			
ITT-aa	0 (0–2)	0 (0–3)	0 (0–3)
PPP	0 (0–2)	0 (0–3)	0 (0–3)
Primary stability (yes/no)			
ITT-aa	351/21	676/16	1,027/37
PPP	340/18	640/12	980/30
Osteoplasty (yes/no)			
ITT-aa	245/129	452/240	697/369
PPP	233/127	424/228	657/355

IMZ = intramobile cylinder implants (test); ITT = intent to treat; PPP = per-protocol population; TPS = titanium plasma-flame sprayed screw implants (control).

Table 3 ITT-Strictu Sensu Efficacy Analysis of the Primary Endpoint (First Occurrence of System ID) in 3 Scenarios with Inclusion of Patients Lost from Protocol After Placement of Implant

Data	Assigned treatment IMZ	TPS	Total	*z*	*P*
Randomized	213	212	425		
Surgery not completed	19	29	48		
Preprosthetic explantation	4	4	8		
Total lost from postprosthetic protocol	7	2	9		
No preprosthetic follow-up	4	2	6		
No postprosthetic follow-up	3	0	3		
Completed postprosthetic follow-up	176	164	340	1.845	.174
Occurrence of system ID					
No system ID in postprosthetic follow-up	61	61	122		
System ID in postprosthetic follow-up	125	113	238		
Total	186	174	360		
Lost from protocol	7	2	9	2.288	.130
Scenario 1					
Good outcome	61	61	122		
Bad outcome	132	115	247		
Total	193	176	369	0.388	.534
Scenario 2					
Good outcome	68	63	131		
Bad outcome	125	113	238		
Total	193	176	369	0.013	.910
Scenario 3					
Good outcome	61	63	124		
Bad outcome	132	113	245		
Total	193	176	369	0.724	.395

Good outcome with respect to primary endpoint = no ID at any implant (no system ID) during postprosthetic follow-up; bad outcome = occurrence of an ID at one or more implants of a system (system ID) during postprosthetic follow-up. Scenario 1 represents the worst-case assumption: all systems lost to follow-up are system ID. Scenario 2 represents the best-case assumption: all systems lost to follow-up are no system ID. Scenario 3 represents the mixed-case assumption: IMZ systems lost to follow-up are system ID, TPS systems lost to follow-up are no system ID.
z values are approximate chi-square values, 1 df, for the common chi-square test of 2-by-2 contingency tables with unadjusted observed *P* values ($P < .0475$ is significant according to trial protocol).

Postprosthetic occurrence of system FD within 3 years after functional loading (second secondary endpoint) was reported for 23 patients (14.4%, 95% CI 9.3% to 20.8%) in the IMZ group of 160 assessable patients and for 17 patients (11.5%, 95% CI 6.8% to 17.8%) in the TPS group of 148 assessable patients. Differences in proportions were not statistically significant (chi-square [1 df] = 0.57, $P = .45$).

Mean system PTV at 3 to 6 months after placement of implants (third secondary endpoint) was 5.58 (SD = 4.24) in 177 IMZ patients and 0.80 (SD = 4.33) in 163 TPS patients. Difference in location was statistically highly significant (Mann-Whitney *U* test value = –10.52; unadjusted $P = .0001$; $P = .0004$ after adjustment for multiple testing).

Table 4 Efficacy Analysis of PPP Patients

	Assigned treatment				
	IMZ	TPS	Total	*z*	*P*†
Primary endpoint analysis					
Postprosthetic follow-up until occurrences of first system ID					
No ID at any implant	61	54	115		
At least 1 implant with ID	116	109	225		
Total no. at risk	177	163	340		
Proportion of system ID (%)	65.5 (58.0–72.5)	66.9 (59.1–74.0)			
Mean ID-free time (y)	2.70	2.96			
Rate of system ID (%/y)	24.23 (19.8–28.6)	22.56 (18.3–26.8)			
5-y ID-free system survival (%)	42.5 (34.2–50.7)	42.8 (34.0–51.6)		0.39*	.53
Secondary endpoint analyses					
Postprosthetic follow-up until occurrence of first system FD					
No FD at any implant	139	137	276		
At least 1 implant with FD	38	26	64		
Total no. at risk	177	163	340		
Proportion of system FD (%)	21.5 (15.7–28.3)	16.0 (10.7–22.5)			
Mean FD-free time (y)	5.03	5.42			
Rate of system FD (%/y)	4.27 (2.91–5.62)	2.94 (1.81–4.08)			
5-y FD-free system survival (%)	82.6 (76.8–88.4)	87.2 (82.0–92.5)		2.10*	.15
Three-y postprosthetic follow-up until occurrence of first system FD					
No system FD w/FU > 3 y	137	131	268		
System FD within 3 y FU	23	17	40		
Subtotal	160	148	318	0.57**	.45
Proportion of system FD (%)	14.4 (9.3–20.8)	11.5 (6.8–17.8)			
No system FD w/FU ≤ 3 y	17	15	32		
Total	177	163	340		
PTV at 3 to 6 mo after surgery					
Mean	5.58	0.80	3.28	–10.52***	.0001
SD (system PTV)	4.24	4.33	4.90		
Median system PTV	5	–0.5	3		
Lower quartile system PTV	–2	–2	–0.5		
Upper quartile system PTV	7	2.5	6		
No. of complete systems	177	163	340		

FD = functional deficiency; FU = follow-up; ID = integration deficiency; IMZ = intramobile cylinder implants (test); PTV = Periotest value; TPS = titanium plasma-sprayed screw implants (control); SD = standard deviation.
*log-rank chi-square values, 1 df;**chi-square values for the common chi-square test of 2-by-2 contingency tables;
***approximate standard-normal values of the Mann-Whitney *U* test.
†Unadjusted observed *P* values ($P < .0475$ is significant for primary endpoint analysis, and $P < .0119$ is significant for secondary endpoint analysis, according to trial protocol).

Safety Analysis

Comparative System-wise Analysis of Complications. With regard to a statistical comparison of complication events with IMZ and TPS systems after functional loading, Kaplan-Meier estimates of postprosthetic 1-, 3-, and 5-year event-free system lifetime probabilities were not significantly larger with IMZ systems for all complications together (log-rank test; $P = .07$). However, this was significantly larger for IMZ systems for some specific complications, ie, inflammation, pain, and recession (log-rank test; $P < .0001$, $P < .0005$, $P < .0001$, respectively) and was significantly larger for TPS systems for other unspecific complications (log-rank test $P = .003$) (Table 5).

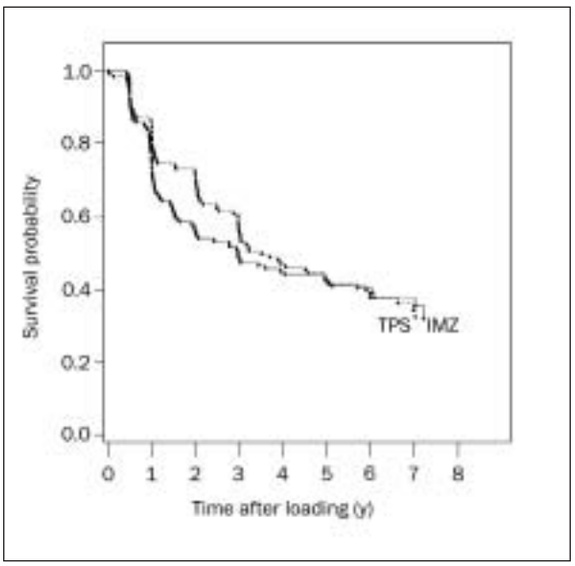

Fig 2 Kaplan-Meier event-free proportions of systems without integration deficiency (ID) after functional loading according to treatment for PPP analyses (log-rank test statistic = 0.39 with 1 df, $P = .53$).

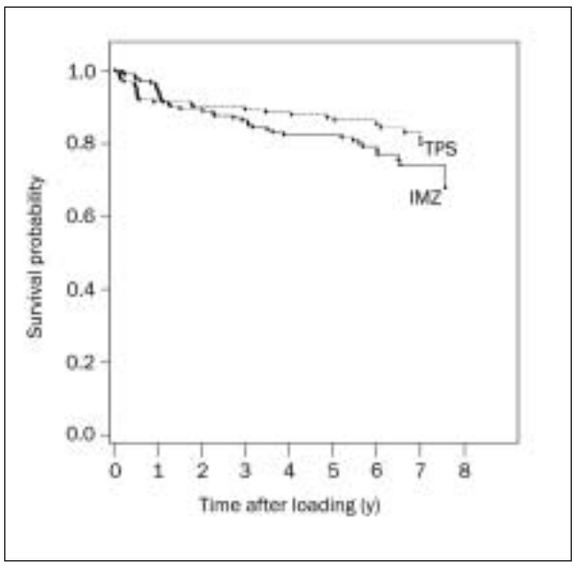

Fig 3 Kaplan-Meier event-free proportions of systems without functional deficiency (FD) after functional loading according to treatment for PPP analyses (log-rank test statistic = 2.10 with 1 df, $P = .15$).

Average Frequencies of Complications. Average frequencies of occurrence of complications are reported as percentage per implant and implant examination visit or "per 100 implant examinations" (% pii). "Examination of a (single) implant" will subsequently be the unit reference to adjust proportions of occurrences for the systematic difference in numbers of supporting implants (2 IMZ and 4 TPS) as well as for possibly different lengths of follow-up after functional loading. Recorded types of complications and detailed numeric results are given in Table 6.

Intraoperative Complications. Suture dehiscence and hematoma were the most frequent complications, with 10.7% pii and 10.7% pii, respectively, in the IMZ group, and 8.8% pii and 6.8% pii, respectively, in the TPS group.

Complications During the Healing Period. The most frequently observed complications were inflammation, pain, and flap dehiscence, which were numerically more frequent in the TPS group. Recession was observed more frequently in the IMZ group, with 2.0% pii (95% CI 0.5% to 3.4% pii); in the TPS group, the frequency of recession was 0.1% pii (95% CI 0% to 0.3% pii).

Postprosthetic Complications. Inflammation was still the most frequently reported complication. Other than in the healing period, recession was observed more frequently in the TPS group, with 2.7% pii (95% CI 2.3% to 3.1% pii). In the IMZ group, recession frequency was 0.6% pii (95% CI 0.3% to 0.8% pii). Six IMZ implants were reported fractured, while no fractures were reported with TPS implants.

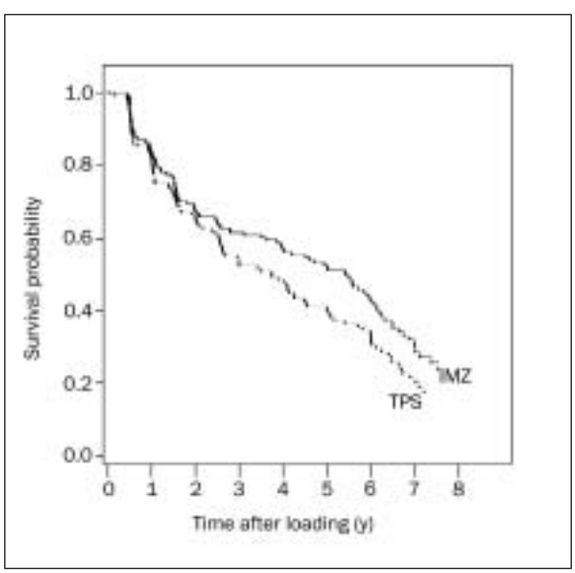

Fig 4 Kaplan-Meier event-free proportions of systems without any complication after functional loading according to treatment for PPP analyses (log-rank test statistic = 3.36 with 1 df, $P = .07$).

Table 5 Comparative Safety Analysis of PPP Patients

	Assigned treatment			
	IMZ (95% CI)	TPS (95% CI)	*z*	*P*
Inflammation				
1-y no event probability estimate	0.935 (0.900–0.973)	0.892 (0.843–0.940)		
3-y no event probability estimate	0.868 (0.816–0.919)	0.718 (0.646–0.790)		
5-y no event probability estimate	0.779 (0.714–0.844)	0.568 (0.487–0.650)		
Log-rank test comparison			16.39	.0001
Pain				
1-y no event probability estimate	0.971 (0.946–0.996)	0.955 (0.923–0.988)		
3-y no event probability estimate	0.952 (0.920–0.985)	0.893 (0.844–0.943)		
5-y no event probability estimate	0.938 (0.900–0.975)	0.824 (0.762–0.877)		
Log-rank test comparison			12.04	.0005
Recession				
1-y no event probability estimate	1.000 (1.000–1.000)	0.968 (0.940–0.996)		
3-y no event probability estimate	0.981 (0.960–1.000)	0.968 (0.940–0.996)		
5-y no event probability estimate	0.960 (0.929–0.991)	0.866 (0.810–0.921)		
Log-rank test comparison			24.96	.0001
Other complication				
1-y no event probability estimate	0.884 (0.836–0.932)	0.948 (0.914–0.983)		
3-y no event probability estimate	0.724 (0.656–0.792)	0.821 (0.760–0.883)		
5-y no event probability estimate	0.656 (0.582–0.730)	0.784 (0.717–0.851)		
Log-rank test comparison			8.78	.003
Any complication				
1-y no event probability estimate	0.832 (0.776–0.888)	0.804 (0.743–0.866)		
3-y no event probability estimate	0.618 (0.544–0.692)	0.527 (0.448–0.606)		
5-y no event probability estimate	0.524 (0.446–0.601)	0.408 (0.328–0.488)		
Log-rank test comparison			3.36	.07

z values are log-rank test statistic with 1 df.
"Any complication" includes aforementioned complications categories as well as rarely occurring position changes and implant fractures.

DISCUSSION

This multicenter trial, with an effective randomization of 425 enrolled patients, aimed to compare overdentures retained by 2 IMZ or 4 TPS implants over time with respect to no system ID and no system FD after functional loading and with respect to the occurrences of complications. Because of differences in the experimental design and in endpoints for comparison of outcomes, the results of most studies in edentulous patients are not fully comparable with each other, and only general tendencies can be derived.

Several studies of implant-retained overdentures in edentulous mandibles have reported satisfactory results with IMZ and TPS implants in the medium- and long-term perspective. The cumulative proportions of surviving (in terms of implant in situ) IMZ implants ranged between 93% and 100% after 5 years.[13,17,28–32] Comparable results have been described for TPS implants, with values between 87% and 97%[7,11,13,16,17] after 5 years and between 81% and 89%[12,16,17] after 10 years. In the present study, average follow-up was more than 5 years, and implant in situ survival proportions were 95.0% for IMZ and 91.9% for TPS implants; hence, both kinds of implants met the success criterion of 85% survival after 5 years set by Smith and Zarb,[33] although single implant loss was not considered as a separate endpoint for statistical comparison in the trial protocol.

The present study is one of the few with randomized treatment assignment. This kind of study design seems to be used more frequently to compare prosthesis suprastructures.[19,20] Wismeijer and coworkers[14] compared implant survival rates and peri-implant tissue reactions between 2 and 4 ITI implants with either bars or ball attachments during 19 months; no statistically significant differences were found.

Many different criteria for successful integration have been suggested in the recent literature.[33–36] In the present study, benefits and risks were considered

Table 6 Frequency Analysis of Safety Endpoints in PPP Patients (Mean and 95% CI)

	Assigned treatment	
	IMZ (95% CI)	TPS (95% CI)
During surgery and the first 2 weeks after placement		
Hematoma	10.7% (7.3%–14.1%)	6.8% (4.8%–8.7%)
Infection	1.7% (0.3%–3.1%)	4.1% (2.6%–5.7%)
Flap dehiscence	10.7% (7.3%–14.1%)	8.8% (5.9%–10.3%)
Disorder sensibility	1.1% (0.02%–2.2%)	2.2% (1.0%–3.3%)
Other complications	0.6% (0.3%–0.8%)	2.0% (0.9%–3.1%)
No. of implant examinations	354	652
During healing period		
Infection	4.5% (2.3%–6.7%)	11.3% (8.7%–13.9%)
Pain	3.4% (1.5%–5.3%)	8.2% (6.0%–10.4%)
Position change	0.1% (0.0%–0.5%)	0.1% (0.0%–0.3%)
Flap dehiscence	2.3% (0.7%–3.8%)	5.8% (4.0%–7.6%)
Recession	2.0% (0.5%–3.4%)	0.1% (0.0%–0.3%)
Other complications	0.4% (0.0%–0.8%)	2.1% (1.0%–3.3%)
No. of implant examinations	354	656
During functional loading		
Infection	3.3% (2.7%–3.9%)	7.4% (6.8%–8.1%)
Pain	0.3% (0.1%–0.5%)	0.3% (0.2%–0.5%)
Position change	0.01% (0.0%–0.05%)	0.04% (0.0%–0.1%)
Recession	0.6% (0.3%–0.8%)	2.7% (2.3%–3.1%)
Implant fracture	0.2% (0.03%–0.3%)	0.01% (0.0%–0.03%)
Other complications	5.6% (4.8%–6.3%)	2.8% (2.4%–3.2%)
No. of implant examinations	3,626	6,821

% = %pii = per 100 examinations of (single) implants.

separately as efficacy and safety or tolerability endpoints, which is in agreement with common guidelines on clinical trials.

A particular difficulty arises from the difference in both numbers and designs of the implants used in this study. To overcome this problem, a system-oriented approach was adopted. It considers the system of either 2 IMZ or 4 TPS screw implants as an entity.

For the primary efficacy endpoint, an integration deficiency of any implant within a system of either 2 IMZ or 4 TPS implants generated a case of system ID. In addition to the implant being in situ, this criterion considers also peri-implant bone loss and implant mobility (Table 1). Similar criteria have been used by Spiekermann and associates[13] and Behneke and colleagues.[17] Note that in the present study, as in Mau and coworkers,[37] these criteria had been defined a priori, ie, before enrollment of patients into the trial had started.

While rather stringent requirements must be met by each implant to maintain system integration in the primary endpoint, the secondary endpoints involve only aspects that are immediately relevant to adequate support of the overdenture, both in terms of integration specifics and number of implants affected. Mean implant PTV within a system was chosen as a surrogate marker to avoid taking radiographs more frequently; details about repeated measurements are postponed to a subsequent report.

Evaluation of the integration and functional deficiency endpoints in this study depended strongly upon panoramic radiographs. Their drawback is the potential inaccuracy of measurement (± 0.5 mm) because of limited quality, especially in the anterior mandible where the spinal column overlays. However, the panoramic radiograph does have some practical value as a result of good reproducibility, especially in the vertical dimension.

As to the safety analysis, no serious adverse events were observed in this study. The results show that patients in the TPS group had a higher risk of complication than patients in the IMZ group, independent of different stages (ie, during surgery, during the healing period, or after placement of the prosthesis). One should note that 4 implants were used in the TPS group but only 2 were used in the IMZ group, which implies an increased chance of

occurrence of complication for the TPS group in the system-wise complication analysis. It may also be noted that implants in the TPS group were immediately loaded after implant placement, while there was a healing phase of 3 to 4 months before loading of IMZ implants, during which time the implants were covered and thus not exposed to risks from within the oral cavity. Since the Kaplan-Meier curves of complication-free survival after functional loading diverge only after 1.5 years, this procedural difference seems to have had no bearing.

Implant-wise and system-wise analyses differ in their objectives. The latter addresses event-free time until a first occurrence and disregards any recidivism. The former disregards event-free times and gives weight according to the recurrence of complications within systems in a group. Because of a fixed examination schedule, which is common to all patients, no bias is introduced.

The comparison of failure time distributions with respect to first ID in either IMZ or TPS patients showed no hint of a statistically relevant difference under any statistical approach. A binomial, an exponential, and the protocol's time-ordered log-rank testing gave practically identical results. However, reinterpretation of this system-oriented result in terms of the hazards of a single implant within a system does imply that any single TPS implant in a system of 4 TPS screws has only half the hazard of ID of a single IMZ implant in a system of 2 IMZ cylinders. In this sense, any TPS screw within a 4-TPS-screw system is less prone to implant ID than any IMZ cylinder within a 2-IMZ-cylinder system.

There could be a potential for confounding in the nonavailability of follow-up data by the patients not assessed. This suggested an analysis with 3 scenarios for a binary endpoint in the ITT-strictu sensu sample. Neither scenario showed a significant difference; thus, absence of follow-up data should not compromise the statistical results obtained from the available data in this trial.

Lack of statistical significance in the sampled data does not automatically justify a claim of lack of relevant difference in the population. This study, however, succeeded incidentally, because of a recruitment overshoot of 35 patients (ie, 425 × 390), to provide 340 patients (almost equally spread between the 2 treatment groups) for the PPP analysis, which had been foreseen to detect an absolute difference of at least ± 10% in 5-year ID-free system survival at the conventional significance level of 5% with a power of 80%. Accordingly, this trial demonstrates equivalence in treatment efficacy with its primary endpoint.

SUMMARY

The study compared 2 treatment concepts, 2 IMZ cylinders and 4 TPS screws, to support bar-retained overdentures in the edentulous mandible. With respect to efficacy, equivalence in terms of 5-year ID-free system survival within a range of ± 10% could be established. FD-free survival was not a statistically significant endpoint either. TPS implant systems seemed to imply a higher risk of complications. By its design as a randomized controlled trial, its achieved sample size, and the robustness in its randomization analysis outcome, this trial provides valid experimental evidence of equivalent efficacy of the compared systems.

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