A 5-year Longitudinal Study of the Clinical Effectiveness of ITI Solid-Screw Implants in the Treatment of Mandibular Edentulism

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Purpose: *The aim of this longitudinal study was to gain 5-year clinical documentation of the 1-stage surgical technique in connection with ITI solid-screw implants used in the edentulous mandible.* ***Materials and Methods:*** *One hundred patients with totally edentulous mandibles were treated with bar-retained overdentures supported by a total of 340 consecutively placed ITI solid-screw implants. The patients were followed at annual intervals for at least 5 years to evaluate implant success, longitudinal reactions of the peri-implant hard and soft tissues, and incidences of biologic and mechanical complications.* ***Results:*** *During the trial period, a total of 4 implants failed, all prior to loading, and 51 implants were lost to follow-up, resulting in a cumulative survival rate of 98.8% after 5 years of functional service. The success analysis included additional strictly defined events (either "first occurrence of marginal bone loss ≥ 4 mm" or "first occurrence of pocket depth ≥ 4 mm" and "first occurrence of crevicular fluid flow rate ≥ 2.5 mm") and resulted in a cumulative 5-year success rate of 95.7%. The median marginal bone loss experienced between implant placement and prosthetic treatment was 0.5 mm, followed by an annual bone level change of 0.1 mm for the functional period of 5 years. The increasing incidence of remarkable plaque deposits from 19% to 50% represented the difficulties of the patients in maintaining a high level of oral hygiene, particularly for the lingual surfaces. Sulcus Bleeding Index, probing depth, attachment level, and crevicular fluid flow rate were used to describe the health of the peri-implant soft tissues and remained almost within acceptable standards.* ***Discussion:*** *Survival and success rates of implants, amount of marginal bone loss, and periodontal indices of peri-implant soft tissues were consistent with those reported in the literature regarding implants with the submerged healing concept.* ***Conclusion:*** *With a cumulative survival rate of 98.8%, a cumulative success rate of 95.7%, and a median marginal bone loss of 0.5 mm during the healing period, followed by an annual rate of 0.1 mm after loading, non-submerged ITI solid-screw implants confirm the good clinical outcome of implant-supported treatment concepts for the rehabilitation of totally edentulous patients in a medium-term perspective.* (INT J ORAL MAXILLOFAC IMPLANTS 2002;17:799–810)

Key words: *clinical parameters, edentulism, endosseous dental implants, longitudinal study, marginal bone loss, non-submerged implants*

Rehabilitation of the edentulous mandible with dental implants has been shown to be a highly predictable clinical procedure. Fixed implant-supported prostheses,[1–6] as well as the concept of removable implant-supported overdentures,[7–22] provide a comparable level of long-term success. Submergence is not required as a condition for osseointegration, and many implant systems are now incorporating the 1-stage surgical technique. The ITI Implant System (Institut Straumann, Waldenburg, Switzerland) was intentionally designed for the nonsubmerged healing concept, and clinical reports of implants placed in the edentulous mandible have indicated satisfactory prognosis.[9,23–30] However, prospective studies with periods of functional loading of at least 5 years are limited in number. Furthermore, the majority of studies

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concerning ITI implants refer to hollow cylinders and hollow screws. Because of the higher potential risk of hollow-body implants for fatigue fractures and their inaccessibility for peri-implant infection therapy when bone loss has reached the first row of perforations, the solid screw has been increasingly recommended as the design of choice. Therefore, well-designed studies dealing with ITI solid-screw implants are needed to document the effectiveness of this type of implant.

The purpose of this report was to present the treatment outcome of ITI solid-screw implants when used to support mandibular removable prostheses. The longitudinal results of monitoring the peri-implant tissue reactions, as well as mechanical complications with implant components and suprastructures, are presented over a follow-up period of at least 5 years.

MATERIALS AND METHODS

Patients and Implants

Previous results for parts of the same patient material have been presented in the frame of a heterogeneous indication report with a follow-up period of at least 3 years.[31] The present material comprised patients with edentulous mandibles having implant-supported overdentures. Patients were informed of the terms for participating in this clinical trial, and the data were used according to the Declaration of Helsinki[32] and the guidelines set forth by the University of Mainz for biomedical research in human subjects. One hundred subjects (57 women, 43 men) aged 42 to 86 years (mean age 62.2 years) formed the study group. The implant placement procedures were carried out during the period from November 1, 1988, to December 31, 1992, according to a standardized protocol and the recommendations of the manufacturer. A total of 337 ITI solid-screw plasma-sprayed implants were placed; an additional 3 implants were placed because of implant loss during the healing period. All implants were placed in the anterior mandible between the mental foramina. A surgical template aided optimal positioning of the implants in relation to definitive prosthesis planning.

Data Collection and Study Parameters

The follow-up documentation was executed using a strict recall system, as described earlier.[31,33] Upon completion of the prosthetic treatment, the clinical parameters mentioned below were documented at biannual follow-up visits. The evaluated parameters were carried out after removal of the prostheses and were assessed at all times by the same investigator.

- Plaque Index according to Mombelli and coworkers,[34] determined on the buccal and lingual surfaces
- Sulcus Bleeding Index according to Mombelli and coworkers,[34] determined on the buccal and lingual surfaces
- Probing depth, measured to the nearest 0.5 mm with a Plast-o-Probe (Maillefer, Stuttgart, Germany) at the buccal, lingual, mesial, and distal surfaces of the implants
- Distance between implant shoulder and mucosal margin, measured to the nearest 0.5 mm with the same probe at the same 4 locations
- Attachment level, calculated by adding probing depth and distance for each site
- Crevicular fluid flow rate, collected with indicator strips (Merck, Darmstadt, Germany) inserted at the buccal and lingual sites of the peri-implant sulcus for 30 seconds
- Periotest value, measured buccally at a distance of 3 mm from the implant shoulder (Siemens, Bensheim, Germany)

Complications, including screw or abutment loosening, bar or denture fractures, mucosal enlargement, mucosal inflammation, and peri-implantitis, were reported at each follow-up visit and at any time of occurrence.

Radiographic Evaluation

Standardized panoramic radiographs (Orthophos CD; Siemens, Bensheim, Germany) were taken immediately postoperatively, after prosthesis placement, and annually thereafter. Distortion of panoramic radiographs was taken into account, using known implant dimensions as the measurement guide. The radiographs were analyzed for changes in alveolar bone levels with reference to the immediate postoperative radiograph as baseline. The distance between the first implant thread and the first visible bone contact was defined as marginal bone loss and measured at the mesial and distal aspect of each implant. In addition to determination of the marginal bone loss, bone resorption was morphologically differentiated into horizontal and vertical components.[35–37] The radiographs were analyzed on a view box with a digital sliding gauge (Mauser, Niedernhall, Germany), and all measurements were made by one of the authors. In 40 randomly selected radiographs, the bone height measurements were assessed twice with an interval of 4 weeks. The mean intra-examiner variability of the different radiographically determined distances was 0.01 to 0.02 mm (Table 1).

Statistical Analyses

Concerning the implant outcome, a distinction was made between survival and success rates. Cumulative survival and success rates were calculated for individual implants by means of life table methods. To be considered as surviving, an implant had to be in function in a prosthetically convenient position, without peri-implant radiolucency or persistent pain, and clinically stable when tested individually. Two further criteria were used as additional strict success criteria for the assessment of hard and soft tissue response: either *(1)* marginal bone loss of less than 4 mm, or *(2)* probing depth of less than 4 mm and crevicular fluid flow rate of less than 2.5 mm. The graphic presentation of research parameters for the descriptive statistics was done by notched box-and-whisker plots, and the mean values, medians, and number of implants were indicated in the graph footnotes. When study parameters were tested with regard to significant differences at various times of investigation, the Wilcoxon signed rank test, as paired statistical analysis, was used. *P* values of less than .05 were accepted as statistically significant.

RESULTS

In 29 patients, 2 implants were used to anchor hinging overdentures, 4 patients had 3 implants placed, 66 patients received 4 implants each, and 1 patient was supplied with 5 implants. The majority of implants were 12 mm in length (n = 314, 92.4%); this was followed by 10 mm (n = 15, 4.4%); 16 mm (n = 8, 2.3%); and 8 mm (n = 3, 0.9%). Implants with a standard diameter of 4.1 mm were used most frequently (n = 305); the remaining 35 had a diameter of 3.3 mm. The prosthetic treatment stage started after 3 to 4 months of healing. Ninety-nine restorations were involved, of which 82 were monitored for more than 5 years after prosthesis placement. The mean observational time was 5.8 years, with a maximum of 8.7 years. In all patients, nonresilient Dolder bars were used as the retentive system. Twenty-eight patients received straight bar restorations fixed to 2 implants as an anchorage system, which allowed rotational movements of the prosthesis; 46 patients were provided with rigid junctions on angulated bars, whereby the bars were fixed on 3, 4, or 5 implants (representing 6%, 39%, and 1%, respectively). A group of 25 patients was treated with overdentures with high rigidity stabilized by distal-extension bars on 4 implants. One patient never received an overdenture because he refused any further cooperation after loss of 1 of 2 earlier placed implants.

Table 1 Intraobserver Variability in Panoramic Radiography (Differences Between 2 Repeated Measurements)

	Measurement difference (mm) (n = 40)		
Measurement	Median	Mean (SD)	*P* value
Vertical distance from first thread to first visible bone-implant contact	0.0	0.02 (0.15)	.9
Vertical distance from first thread to alveolar crest	0.0	0.01 (0.15)	.8
Implant length	0.01	0.01 (0.13)	.4

Implant Failures and Patient Dropout

Of the 340 implants placed, 4 demonstrated mobility during the healing period and were removed. After connection of the prostheses, no further failures occurred. The 4 patients with implant losses were treated as follows. In 2 patients, 1 of the original 4 implants failed, so the remaining 3 implants were engaged as prosthesis support. In another patient, 3 supplementary implants were placed after loss of 1 of 2 earlier placed implants. The fourth patient affected by an implant failure did not want further rehabilitation.

The majority of patients complied with the prescribed recall system. Six patients, representing 15 implants, dropped out of the study. For 2 patients, the cause of dropping out was unknown; 3 patients could not continue to attend further follow-up appointments because of severe illness; and 1 patient was on recall elsewhere. Eleven patients died within the study period, and thus 36 implants were lost to follow-up. Consequently, 285 implants remained in the study for the final examination after 5 years of loading.

Cumulative Survival and Success Rates

Table 2 illustrates that at the end of the 5-year period, a cumulative implant survival rate of 98.8% was recorded. This result was derived from the aforementioned 4 implant failures, while none of the remaining implants showed mobility, peri-implant radiolucency, or caused persistent pain. For a more accurate view with regard to the peri-implant conditions, Table 3 shows the result of the success analyses, which included the events "first occurrence of marginal bone loss ≥ 4 mm" or the combination of "first occurrence of pocket depth ≥ 4 mm" and "first occurrence of crevicular fluid flow rate ≥ 2.5 mm." A total of 14 events had occurred at the time of the statistical survey. Four of these

Table 2 Life Table Analysis of Cumulative Survival Rate

Time period	At risk at start of interval	Failures during interval	Withdrawn during interval	Interval failure rate (%)	Cumulative failure rate (%)	Cumulative survival rate (%)
Placement to loading	340	4	1	1.2	1.2	98.8
Loading to 1 y	335	0	6	0.0	1.2	98.8
1 to 2 y	329	0	2	0.0	1.2	98.8
2 to 3 y	327	0	4	0.0	1.2	98.8
3 to 4 y	323	0	16	0.0	1.2	98.8
4 to 5 y	307	0	22	0.0	1.2	98.8
5y	285	—	—	—	—	98.8

Table 3 Life Table Analysis of Cumulative Success Rate

Time period	At risk at start of interval	Failures during interval	Withdrawn during interval	Interval failure rate (%)	Cumulative failure rate (%)	Cumulative success rate (%)
Placement to loading	340	5	1	1.5	1.5	98.5
Loading to 1 y	334	0	6	1.5	1.5	98.5
1 to 2 y	328	0	2	1.5	1.5	98.5
2 to 3 y	326	2	4	0.6	2.1	97.9
3 to 4 y	320	3	14	0.9	3.0	97.0
4 to 5 y	303	4	22	1.3	4.3	95.7
5y	277	—	—	—	—	95.7

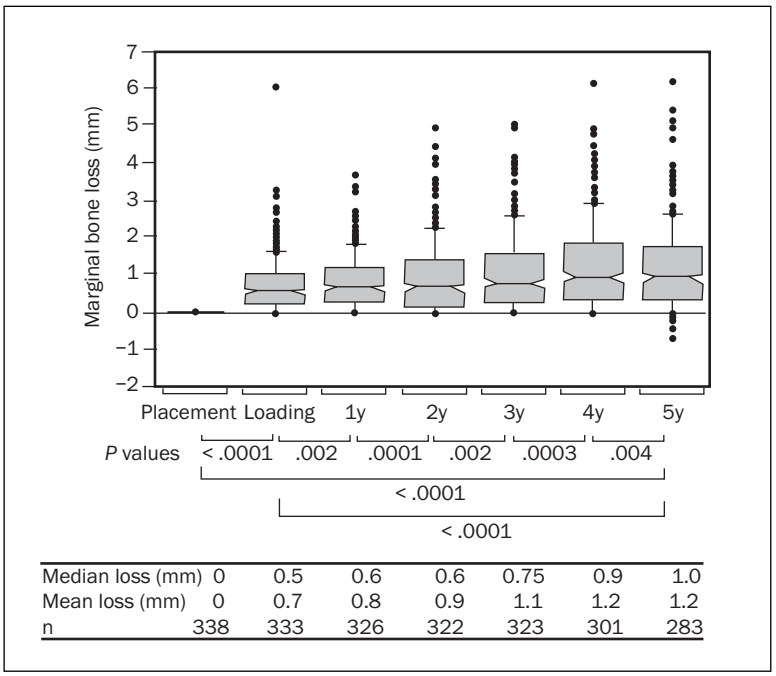
events were implant failures, and 10 events involved implants that exceeded the defined thresholds for radiographic and clinical criteria, respectively. During the first year after prosthesis placement, 98.5% of the implants remained free from radiographically determined bone loss ≥ 4 mm or probing depth ≥ 4 mm and crevicular fluid flow rate ≥ 2.5 mm. Corresponding values for the 3- and 5-year intervals were 97.0% and 95.7%, respectively.

Radiographic Evaluation

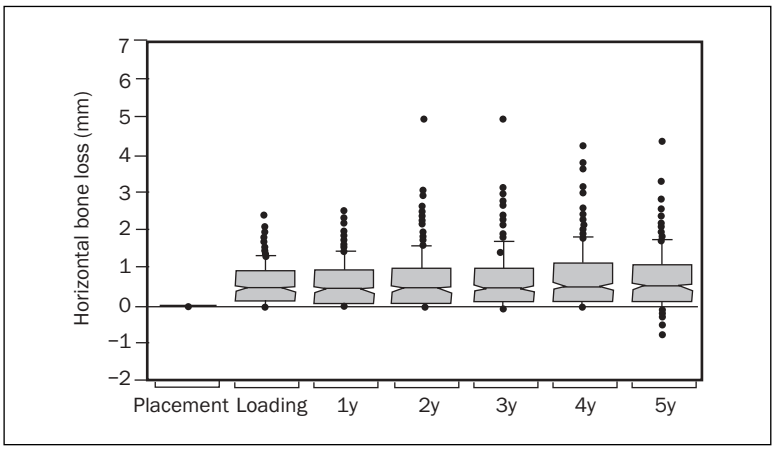
The longitudinal changes in marginal bone loss (total, horizontal, and vertical components) with respect to the baseline radiograph (ie, postoperative) are depicted in Figs 1a to 1c. Between implant placement and prosthesis placement, median marginal bone loss of 0.5 mm ($P < .0001$) was observed. After loading of the implants, the bone loss tended to rise slightly, to a median of 0.6 mm during the first year, and it reached 0.8 mm and 1.0 mm after 3 and 5 years, respectively. Furthermore, it was noted that 98.5% to 91.4% of all implants demonstrated a marginal bone loss ≤ 3 mm over the functional period of 5 years. A few (2.4%) sites exhibited a gain in bone height, ranging from 0.1 to 0.8 mm. During the entire research period, the annual increase in bone resorption was significantly different from the previous year's value. The morphologic differentiated evaluation of the horizontal component of bone loss (measured remote to the implant as the distance between first thread and osseous crest) was a median of 0.45 mm during the healing period and 0.05 mm from prosthesis placement to the 5-year follow-up. Vertical bone resorption was a median of 0 mm during the entire period up to 5 years.

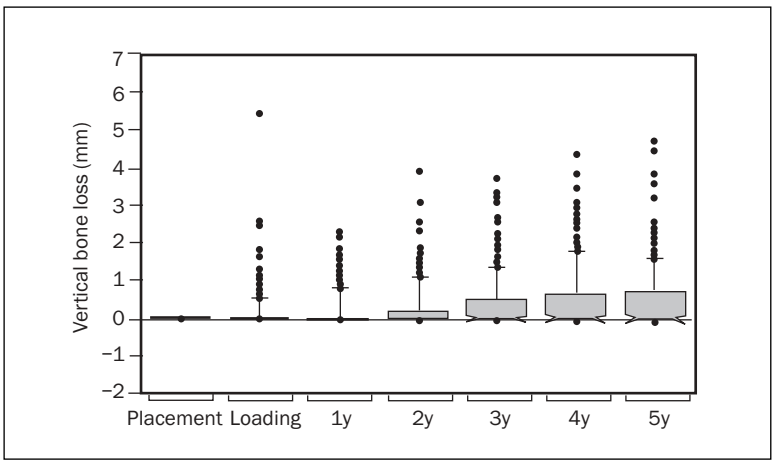
Clinical Observations

Figure 2 shows the efficacy of oral hygiene practices by means of the Plaque Index scores assessed at the buccal and lingual surfaces of the implants. At the buccal aspects, plaque levels were consistently low and showed only a slight tendency to deterioration. Over the 5-year period of service, 95% to 83% of the implants showed Plaque Index scores of 0 or 1, indicating excellent or good plaque control habits. At the lingual surfaces, oral hygiene procedures were less effective, and plaque control measures showed an increasing tendency from baseline to 5 years. The portion of surfaces with remarkable plaque deposits (score of 2 or 3) rose from 19% after prosthesis placement to 50% after 5 years. When scores of the baseline examination and reexamination were compared after 5 years, the Plaque



Median loss (mm)	0	0.5	0.6	0.6	0.75	0.9	1.0
Mean loss (mm)	0	0.7	0.8	0.9	1.1	1.2	1.2
n	338	333	326	322	323	301	283





Figs 1a to 1c Box plot showing longitudinal evaluation of marginal bone loss (total, horizontal, and vertical components). Loss of marginal bone was 0.5 mm (median) between implant placement and prosthetic treatment and 0.5 mm (median) between loading and the 5-year examination. During the entire research period, the annual increase in bone resorption was significantly different from the previous year's value.

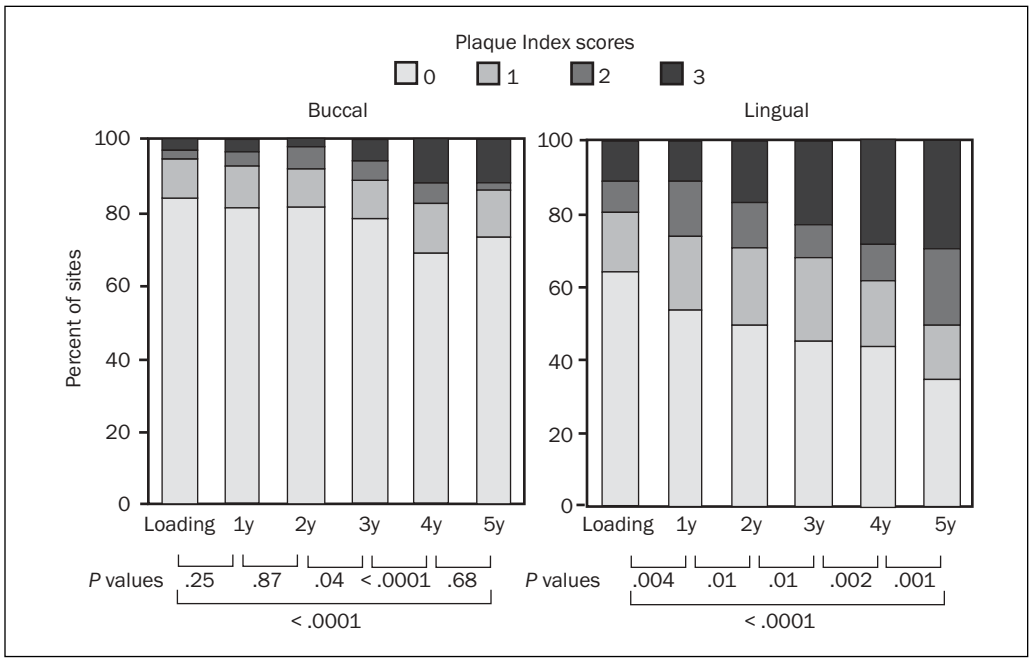
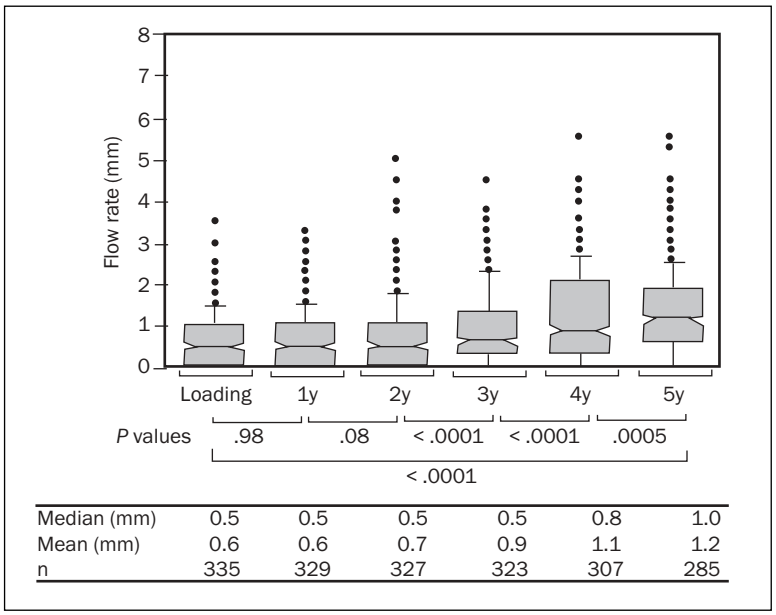


Fig 2 Plaque Index scores (0 to 3) for buccal and lingual implant surfaces at the baseline examination (prosthesis placement) and at the annual re-examinations. A significant increase was seen over time, and the percentage of sites with remarkable plaque deposits (scores of 2 or 3) rose from 5% to 17% for buccal surfaces and from 19% to 50% for lingual surfaces.



	Loading	1y	2y	3y	4y	5y
Median (mm)	0.5	0.5	0.5	0.5	0.8	1.0
Mean (mm)	0.6	0.6	0.7	0.9	1.1	1.2
n	335	329	327	323	307	285

Fig 3 Box plot illustrating alterations in the crevicular fluid flow rate. This parameter showed a stable result up to 2 years after prosthesis placement, while in the following 3 years of observation, the median rose from 0.5 mm to 1.0 mm.

Index scores varied significantly over time for both surfaces.

For the crevicular fluid flow rate (Fig 3), no changes were registered between baseline and the 2-year examination. Median and interquartile range remained stable, at levels of 0.5 and 1.0 mm, respectively. In the following 2- to 5-year period, an increase with significant differences (range P = .0005 to < .0001) occurred, and the median rose to 1.0 mm at the time of final examination. The percent of sites with elevated crevicular fluid flow rates that exceeded the threshold of 2.5 mm (representing a manifestation of marginal inflammation) increased from 0.6% to 9.7% over time.

Table 4 Changes in Clinical Parameters

Time	Probing depth (mm)	*P*	Attachment level (mm)	*P*	Periotest value	*P*	Bleeding Index (%)*	*P*
Loading								
Mean	1.7		2.1		–3.9		99	
Median	1.5		2.0		–4.0		1	
1 year		.06		.73		< .0001		.002
Mean	1.7		2.1		–4.8		97	
Median	1.5		2.0		–5.0		3	
2 years		.0007		.002		.07		< .0001
Mean	1.8		2.2		–5.1		92	
Median	1.8		2.1		–5.0		8	
3 years		< .0001		< .0001		.95		.005
Mean	2.0		2.5		–5.1		92	
Median	2.0		2.4		–5.0		8	
4 years		< .0001		< .0001		.95		.17
Mean	2.2		2.6		–5.0		90	
Median	2.0		2.5		–5.0		10	
5 years		.05		.13		.32		.50
Mean	2.1		2.6		–5.2		93	
Median	2.0		2.5		–5.0		7	

*Scores shown as % of sites scoring 0 or 1 and percent of sites scoring 2 or 3.

Changes in other clinical parameters are presented in Table 4. The longitudinal alterations in probing depth and attachment level presented a median increase from 1.5 to 2.0 mm and from 2.0 to 2.5 mm, respectively. The percentage of sites with probing depths exceeding the threshold of 4 mm showed a range between 0% and 2.2%. Except for the 1- and 5-year intervals, the annual changes in probing depth and attachment level were significantly different from the previous year's value. Results of the assessment of implant mobility with the Periotest device showed a decreasing Periotest value, from a median of –4 at the baseline measurement (after completion of prosthetic treatment) to a median of –5 after 1 year ($P < .0001$). Concerning the mean, a slight decrease occurred during the following 4 years, while the median remained stable; the Wilcoxon test found no differences for the .05 level. The bleeding tendency of the peri-implant sulcus was generally low. The percentage of sites with no or only punctate bleeding on probing varied between 99% and 90% during the evaluation period. Zero percent to 4% of the sites revealed a Sulcus Bleeding Index score of 3, representing a bleeding with flow or spontaneous bleeding. Up to the third year after prosthesis placement, the Bleeding Index tended to increase, while in the subsequent research period the annual variations were no longer significantly different.

Complications

Complications and maintenance requirements during the study period are presented in Table 5 and were classified as structural complications or biologic alterations affecting the hard and soft tissues. Mechanical complications included screw loosening, abutment loosening, and bar and prosthesis fractures. No implant or abutment fractures were noted. With an incidence ranging from 0% to 4.1%, screw and abutment loosening were found to be a minor problem. Fractures of distal extensions of the bars ranged between 5.2% and 12.6%. Comparable results with a 1.0% to 15.8% range were observed for overdenture fractures. For 1.0% to 6.3% of the patients, inflammatory changes leading to either mucositis or peri-implantitis were observed; these alterations did not seem to increase with time. Infections confined to superficial soft tissues usually occurred because of poor oral hygiene and/or an immunocompromised situation, and were remedied by local disinfection treatment and additional oral hygiene instruction. The peri-implantitis defects were treated with autogenous bone grafts, as described elsewhere.[34] Mucosal enlargement in the dead space underneath the bars was, with an incidence range of 9.3% to 17.1%, the most common soft tissue alteration. As in the majority of cases, these proliferative changes were not associated with inflammatory tissue response or discomfort, and

Table 5 Structural and Biologic Complications During the 5-year Follow-up Period

Complication	Prosthesis placement	1 year	2 years	3 years	4 years	5 years
Structural complications						
Screw loosening	—	4 (4.1%)	2 (2.1%)	—	1 (1.1%)	2 (2.4%)
Screw fracture	—	—	—	—	—	—
Abutment loosening	—	1 (1.0%)	1 (1.0%)	—	1 (1.1%)	—
Abutment fracture	—	—	—	—	—	—
Implant fracture	—	—	—	—	—	—
Bar fracture	—	5 (5.2%)	5 (5.2%)	12 (12.6%)	7 (7.8%)	7 (8.5%)
Overdenture fracture	—	1 (1.0%)	3 (3.1%)	15 (15.8%)	7 (7.8%)	6 (7.3%)
Biologic Alterations						
Mucositis	3 (3%)	4 (4.1%)	4 (4.2%)	6 (6.3%)	4 (4.4%)	5 (6.1%)
Peri-implantitis	—	—	1 (1.0%)	2 (2.1%)	—	2 (2.4%)
Mucosal enlargement	—	9 (9.3%)	15 (15.6%)	13 (13.7%)	11 (12.2%)	14 (17.1%)
Restorations at risk	99	97	96	95	90	82

usually no treatment was needed. However, optimal plaque control, the use of interproximal brushes, and peri-implant tissue massage were recommended. Mucosal enlargements, evoking localized inflammations or soft tissue irritations, were treated by surgical excision and relining of the overdenture base, respectively.

DISCUSSION

In accordance with previous published results on partially edentulous patients,[33] the present report demonstrates a positive 5-year outcome for the use of ITI solid-screw implants in the treatment of mandibular edentulism with bar-retained overdentures. The overall cumulative implant survival rate was 98.8% after 5 years, with all implant losses occurring before loading. This result seems to be in line with other ITI overdenture studies reported in the literature. For comparison, some short- and medium-term clinical trials, estimating or calculating implant survival as a function of time, are available. Mericske-Stern and associates[9] reported an overall cumulative 5-year survival rate of 97.4% for 78 ITI implants of the first generation (Type F, hollow baskets). Data of longitudinal studies described by Donatsky and Hillerup[23] (156 hollow-screws), Batenburg and colleagues[25] (60 hollow screws), and Wismeijer and coworkers[27] (283 hollow cylinders) suggested favorable survival rates of 97.9% to 100%, but referred to limited observation periods of 1 to 1.5 years. Hellem and associates[30] found a survival rate of 95.7% for 216 ITI hollow-screw implants after a follow-up period of at least 5 years. The 5-year survival rate of 98.8% for the implants in the present patient pool represents an approximately 1% to 3% better result than in the above-mentioned studies. This may be attributed to the specific features of implants with the hollow-body design, which result in an increased tendency to fatigue fracture and peri-implantitis. There is limited literature analyzing the outcome of ITI solid screws in edentulous mandibles. One prospective[29] and 2 retrospective[24,26] studies showed nearly identical results of 96% to 97% related to an estimated 5-year survival probability of solid screws. The number of implants followed over 5 years in these studies varied between 10 and 120.

The act of comparison with respect to success rates is more difficult because of the wide variety of study protocols. A series of publications related to implant outcome agreed that the individual implant can be designated successful if there is absence of pain, inflammation, mobility, and peri-implant radiolucency.[3,4,13,17,18,38] Other reports recommend an extended success analysis with predefined thresholds for bone level changes and clinical parameters. These differing success criteria compromise comparisons with other studies. The cumulative success rate observed in the present study shows that 95.7% of the implants remained free from radiographically determined bone loss ≥ 4 mm or probing depth ≥ 4 mm and crevicular fluid flow rate ≥ 2.5 mm over 5 years of functional loading. Only a minor portion of the implants demonstrated remarkable bone loss or soft tissue alterations. Hellem and coworkers[30] reported a 5-year success rate of 91.3% under application of the criteria "marginal bone loss less than 2.5 mm between prosthesis insertion and 5-year follow-up." Brocard

and colleagues[28] applied the success criteria suggested by Albrektsson and colleagues[39] for the assessment of the clinical effectiveness of the 3 ITI implant designs (75% hollow screws or hollow cylinders, 25% solid screws) in edentulous patients. Success data gave a remaining number of implants of 84 out of 208 implants originally placed and a success probability of 88.2% after 5 years.

Radiographic evaluation of marginal bone level changes by means of panoramic radiographs may be criticized because of lack of precision. In the present study, a high percentage of patients (52%) suffered advanced resorption of the residual ridge, and so were acknowledged as difficult candidates for periapical radiographs of desirable quality. Intraoral radiographs can be very difficult to obtain because of the superficial insertion of the floor of the mouth, and several authors have reported that one fourth to one third of the periapical radiographs were unreadable.[39–41] The underestimation of bone loss in panoramic radiographs compared to the true value of an open bone measurement ranged from approximately 10% to 32%.[42–44] Although panoramic radiography presents a higher underestimation than the periapical technique (9% to 20%), it seems to be an acceptable method for large study populations and long-term trials with annual radiograph intervals.

In the present study, the baseline for radiographic assessment was considered to be immediately after implant placement, a fact that results in restricted comparability to other clinical trials. The number of studies dealing with bone level changes around ITI implants in totally edentulous patients is relatively small. Two investigations, 1 referring to hollow cylinders and 1 to solid screws, reported bone level changes around ITI implants during the healing period. Gómez-Roman and coworkers[26] evaluated 150 ITI screw-type implants by means of panoramic and intraoral radiographs and found a median change in bone level of 0.8 mm between implant placement and prosthesis placement. For 283 hollow cylinders followed for up to 19 months after implant placement, Wismeijer and associates[27] found that the mean marginal bone loss, as assessed by orthopantomography, varied with the treatment modality from 1.0 mm to 2.3 mm. For the period between prosthesis placement and 1-year examination, Batenburg and colleagues[25] observed an average bone loss of 0.2 mm for 60 ITI hollow screws. In the present study, the marginal bone level rose slightly but continuously over the 5 years, and significant differences occurred between each of the yearly follow-up examinations. Therefore, the steady state of marginal bone level observed in a longitudinal 5-year study of ITI solid-screw implants in partially edentulous patients[33] was not achieved with the present population. With a mean marginal bone loss of 0.7 mm during the healing period, and further resorption of 0.1 mm during the first year followed by an annual rate of 0.1 mm bone loss for the 1- to 5-year interval, the present results were satisfactory and corroborated the aforementioned short-term observations. The outcome also corresponds well with the findings by Hellem and associates,[30] who reported a mean bone loss of 1.2 mm among 216 ITI hollow screws for the period between implant placement and the 5-year follow-up examination. This result is based on the assumption that the implants were placed with a fixed sink depth (postsurgical radiographs not available).

When the efficacy of oral hygiene practices over time was considered, the Plaque Index showed a significant increase in the period between prosthesis placement and the 5-year examination, and the portion of sites with remarkable plaque deposits (scores of 2 or 3) rose from 5% to 17% for buccal surfaces and from 19% to 50% for lingual surfaces. In spite of a well-organized maintenance program and repeated instructions in adequate cleaning practices, the elderly patients in the present study had difficulties in maintaining a high level of oral hygiene, particularly for the lingual surfaces. These observations confirm the results of Gómez-Roman and coworkers[26] and Naert and colleagues,[18] who also found an increase in Plaque Index over 5 years for patients with edentulous mandibles. A number of studies[8–10,15,20,27,30] reported on the incidence rate of the presence of plaque on implants as anchors for bar reconstructions; the range for medium-term trials was 18% to 71%. The hypothesis that unsplinted implants retaining a mandibular overdenture may harbor less plaque because of easier accessibility for cleaning devices could not be confirmed in randomized studies.[18,20,27] In spite of the increasing plaque incidence, in the present study the frequencies of bleeding surfaces were low and the longitudinal deepening of the peri-implant sulcus, as well as the apical shift of the attachment level, was of a small magnitude. In an ongoing further statistical analysis, the relationship between various factors, particularly oral hygiene, and bone resorption was analyzed by means of univariate (analysis of variance) and multivariate (multiple regression model with forward selection) methods. If the patient pool were divided into 2 groups—one with no or slight plaque registration during the whole observation period and the other with frequent registration of remarkable plaque deposits—poor oral hygiene did negatively influence marginal

bone loss (P = .0022 to < .0001). Furthermore, calculations of relative risk were used to assess the etiologic factors resulting in implant loss and/or pathologic reactions of the peri-implant hard and soft tissues. The risk of implant failure for patients with poor oral hygiene was 5 times greater than for those with good hygiene.

For crevicular fluid flow rate, significant differences were shown between the baseline measurements after prosthesis placement and those after 5 years, and the percentage of implant sites producing more than 2.5 mm of this exudate (threshold for an apparent inflammation) increased from 0.6% to 9.7%. The linear associations between marginal bone loss and crevicular fluid flow rate[31] and the predictive characteristics of the crevicular fluid flow rate for pathologic processes of peri-implant bony support[45] have been described in previous articles. In spite of the fact that bleeding scores, crevicular fluid flow rate, probing depth, and attachment level increased significantly in the present pool of patients, for the majority of implants, values within physiologic levels, representing healthy peri-implant conditions, were seen throughout the 5-year observation period.

The low incidence (0% to 4.1%) of occlusal screw loosening and abutment loosening confirmed the advantages of the cone-fit design of the ITI system in preventing the abutment-implant joint from high bending movements.[46] The literature reviews of Goodacre and coworkers[47] and Payne and Solomons[48] found that screw loosening with splinted implants retaining mandibular overdentures ranged from 2% to 18%.

One of the most common mechanical complications in the present material was fractures of the bars. This problem can be ascribed to the specific bar design, which had distal cantilever extensions that improved retention capacity and reduced resorption of the posterior ridge[49] but at the same time enhanced the risk of fatigue fracture by evoking higher bending moments. Den Dunnen and colleagues[50] reported that 50% of patients who had received a triple bar with cantilever extensions supported by 4 IMZ implants (Interpore International, Irvine, CA) were afflicted by fractures of the extensions during a 2-year follow-up. The relatively high incidence range (1.0% to 15.8%) for denture fractures in the present patient population may be attributed to the fact that the overdenture base was not reinforced by a metal framework.

Mucosal enlargement has been reported as a common soft tissue alteration with implant overdenture treatment and has ranged from 4% to 35%.[47,51] Inadequate oral hygiene, peripheral seal with negative pressure gradient, and absence of keratinized mucosa have been discussed as etiologic factors. In the present study, mucosal enlargements occurred underneath the bars with a frequency of 9.3% to 17.1%, which usually required no therapeutic treatment.

SUMMARY

With a cumulative survival rate of 98.8%, a cumulative success rate of 95.7%, and a median marginal bone loss of 0.5 mm during the healing period followed by an annual rate of 0.1 mm after loading, non-submerged ITI solid-screw implants demonstrated a good clinical outcome of implant-supported treatment concepts for the rehabilitation of totally edentulous patients in this patient population in a medium-term perspective.

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