# The Longitudinal Clinical Effectiveness of ITI Solid-Screw Implants in Partially Edentulous Patients: A 5-Year Follow-up Report

Alexandra Behneke, Priv-Doz Dr med dent<sup>1</sup>/Nikolaus Behneke, Prof Dr med dent<sup>2</sup>/ Bernd d'Hoedt, Prof Dr med dent<sup>3</sup>

A total of 114 ITI solid-screw implants was consecutively placed in 55 partially edentulous patients and restored with 68 fixed prostheses. The patients were followed for at least 5 years in a prospective study that focused on implant success and longitudinal reactions of the periimplant hard and soft tissues. During the study period, 5 implants failed and 15 implants were lost to follow-up, resulting in a cumulative survival rate of 95.3% after 5 years of loading. The success analysis included additional strictly defined events ("first occurrence of marginal bone loss  $\geq$  4 mm," "first occurrence of pocket depth  $\geq$  4 mm," and "first occurrence of crevicular fluid volume  $\geq$  2.5 mm") and resulted in a cumulative 5-year success rate of 89.0%. Median loss of marginal bone, as observed on radiographs, was 0.7 mm between implant placement and prosthetic treatment and 0.5 mm between prosthesis placement and the 5-year evaluation. Compared to the previous year's value, the annual increase in marginal bone loss did not reach a level of statistical significance between 1 and 5 years of function, so that a steady state prevailed. The incidence of lingual-palatal surfaces affected with remarkable plaque deposits increased from 13% after prosthesis placement to 23% after 5 years. Sulcus Bleeding Index, probing depth, attachment level, and crevicular fluid volume were used to describe the health of the peri-implant soft tissues. The research parameters remained almost unchanged and indicated a soft tissue response within physiologic levels. Most mechanical complications were experienced during the first year of loading and were related to loosening of occlusal screws, which occurred in 8 (12%) of 68 restorations. (INT J ORAL MAXILLOFAC IMPLANTS 2000;15: 633-645)

**Key words:** bone resorption, dental implants, endosseous dental implantation, oral mucosa, partially edentulous jaw

Clinical studies indicate a high long-term probability of successful soft tissue integration and minimal bone resorption with submerged as well as nonsubmerged osseointegrated implants in completely edentulous arches.<sup>1–9</sup> Based on these encouraging data, dental implants have become an increasingly common treatment method in partially edentulous patients as an alternative to conventional fixed or removable dentures. The main distinctive features of partial edentulism compared to complete edentulism are the presence of natural teeth, which might serve as bacterial reservoirs for colonization of the periimplant sulcus,<sup>10-15</sup> as well as an altered load distribution resulting from the lack of cross-arch stabilization, unfavorable relationships between bone volume and masticatory forces, higher bending moments, and dynamic contacts. In spite of these reservations, clinical reports have indicated satisfactory prognosis with partial<sup>16-21</sup> and single<sup>22-27</sup> implant-supported prostheses in the short- and medium-term perspective. In most of the literature references, the outcome has been based on experience with the Brånemark technique. The cumulative implant survival rates in partially edentulous arches followed for 5 years of functional loading have been documented in several

<sup>&</sup>lt;sup>1</sup>Associate Professor, Department of Oral Surgery, University of Mainz, Mainz, Germany.

<sup>&</sup>lt;sup>2</sup>Professor, Department of Prosthodontics, University of Mainz, Mainz, Germany.

<sup>&</sup>lt;sup>3</sup>Professor, Department of Oral Surgery, University of Mainz, Mainz, Germany.

**Reprint requests:** Alexandra Behneke, Department of Oral Surgery, University of Mainz, Augustusplatz 2, 55131 Mainz, Germany. Fax: +49-6131-173434.

COPYRIGHT © 2000 BY QUINTESSENCE PUBLISHING CO, INC. PRINTING OF THIS DOCUMENT IS RESTRICTED TO PERSONAL USE ONLY. NO PART OF THIS ARTICLE MAY BE REPRODUCED OR TRANSMITTED IN ANY FORM WITH-OUT WRITTEN PERMISSION FROM THE PUBLISHER.

prospective studies and ranged between 88% and 97.3%.<sup>19,20,24,26,27</sup> However, statistical evidence concerning the effectiveness of nonsubmerged implants in partially edentulous patients is more limited. The general advantages of intentional nonsubmerged implants include the need for only 1 surgical procedure, with primary formation of the soft tissues directly after implant placement and without shrinkage after abutment connection, maintenance of keratinized mucosa, and avoidance of subgingival microgaps, considered to be conducive to healthy peri-implant conditions.

The aim of the current report was to present the treatment outcome of ITI 2-part , nonsubmerged solid-screw implants used to rehabilitate partially edentulous arches with a follow-up period of at least 5 years. Thus, uniformly combined patient pools were available for the different examinations. The longitudinal results of monitoring the peri-implant tissue reactions are presented, along with mechanical complications encountered with the implant components and suprastructures.

### MATERIALS AND METHODS

### **Patients and Implants**

Previous results on some of the same patient material were presented in the context of a heterogenous indication report with a follow-up period of at least 3 years.<sup>28</sup> Over the inclusion period between December 1, 1989, and December 31, 1992, 55 partially edentulous patients (28 females, 27 males) were consecutively treated and documented biannually in this prospective study. With the exception of dropouts, all patients have been followed for 5 years. Treatment of the patients was conducted according to a standardized surgical and prosthodontic protocol. Patients were informed of the terms for participation in the study, and the data were used according to the declaration of Helsinki<sup>29</sup> and guidelines set forth by the University of Mainz for biomedical research in human subjects. The mean age of the patients at the time of implant placement was 44.2 years, with a range from 17 to 81 years.

A total of 114 ITI solid-screw implants (Institut Straumann AG, Waldenburg, Switzerland) was placed, 19 in the maxilla and 95 in the mandible. Considering the first premolars as the division between anterior and posterior areas, the posterior mandible (90 implants) was the preferred site. The remaining group comprised 14 implants in the posterior maxilla, 5 implants in the anterior mandible, and 5 implants in the anterior maxilla. The majority of implants were 12 mm in length (80, or 70%), followed by 10 mm (21, or 19%) and 8 mm (13, or 11%). Implants with a standard diameter of 4.1 mm were used most frequently (101), and the remaining 13 implants had a diameter of 3.3 mm. The mean observational time was 5.4 years, with a maximum of 8.3 years. Sixty-eight restorations (55 screw-retained restorations and 13 cemented restorations) were involved, of which 56 were monitored over 5 years after prosthesis placement. Eighty-five implants were loaded with 40 implant-supported fixed partial prostheses (27 connected single crowns, 9 cantilever partial prostheses, and 4 conventional fixed partial prostheses). Ten implants served as abutments for 9 combined implant/tooth-supported restorations, and 19 implants were used for single tooth replacements.

#### **Data Collection and Study Parameters**

The follow-up documentation was executed using a strict recall system, as described earlier.<sup>28</sup> Upon completion of prosthetic treatment, the clinical parameters mentioned below were documented at biannual follow-up visits. The evaluated parameters were performed after removal of the prostheses and were assessed at all times by a single investigator.

- Plaque Index, according to Mombelli et al,<sup>30</sup> measured on the buccal and lingual-palatal surfaces
- Sulcus Bleeding Index according to Mombelli et al,<sup>30</sup> measured on the buccal and lingual-palatal surfaces
- Probing depth, measured to the nearest 0.5 mm with a Plast-o-Probe (Maillefer, Stuttgart, Germany) at the buccal, lingual-palatal, 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 volume, collected with indicator strips (Merck, Darmstadt, Germany) inserted at the buccal and lingual-palatal in 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, veneer fractures, mucosal inflammation, and peri-implantitis, were reported at each followup visit and at any time of occurrence.

#### **Radiographic Evaluation**

Periapical radiographs (Rinn System, Rinn Corporation, Elgin, IL) and standardized panoramic radiographs (Orthophos CD, Siemens) were taken

 Table 1
 Intra-observer Variability in Periapical and Panoramic Radiography (Differences Between 2 Repeated Measurements in mm)

	Periapical radiography (n = 40)			Panoramic radiography (n = 38)			
Measurement	Median	Mean (SD)	Р	Median	Mean (SD)	Р	
Vertical distance from first thread to first visible bone-implant contact	0.01	0.01 (0.09)	.16	0.01	0.02 (0.15)	.13	
Vertical distance from first thread to alveolar crest	0.0	0.003 (0.08)	.54	0.02	0.05 (0.17)	.08	
Implant length	0.01	0.01 (0.14)	.68	0.01	0.01 (0.12)	.49	

immediately postoperatively, after prosthesis placement, and annually thereafter. A panoramic technique was applied when anatomic conditions did not permit use of the periapical method. Distortion of panoramic radiographs was taken into account, using known implant dimensions as a measurement guide. The radiographs were analyzed for changes in alveolar bone levels with reference to the immediate postoperative radiograph as the baseline. The distance betweeen the first implant thread and the first visible bone contact was defined as marginal bone loss and measured to the closest 0.1 mm at the mesial and distal aspect of each implant. In addition to determination of marginal bone loss, bone resorption was morphologically differentiated into horizontal and vertical components.<sup>31–33</sup> 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 80 randomly selected radiographs (40 panoramic, 40 periapical), distances were remeasured after a 4-week interval. The differences were considered negligible (Table 1).

#### **Statistical Analyses**

Cumulative survival and success rates were calculated for individual implants by means of life table methods. To be regarded as successful, an implant had to be immobile and in a prosthetically convenient position. In addition, marginal bone loss of less than 4 mm, probing depth of less than 4 mm, and crevicular fluid volume of less than 2.5 mm were used as strict success criteria for the assessment of hard and soft tissue response. The graphical presentation of research parameters for the descriptive statistics was done by notched box and whisker plots. The mean values, medians, and number of implants are indicated in the graph footnotes. When the study parameters were tested for significant differences at various times of investigation, the Wilcoxon signed rank test, as paired statistical analysis, was used. The relationship between marginal bone loss and dental arch parameter was examined by means of a Mann-Whitney U test; P values of less than .05 were considered statistically significant.

# RESULTS

### **Cumulative Survival and Success Rates**

All 114 implants placed were stable during the healing phase and could be used to support fixed prostheses. During function, after loading times of 35 to 60 months, 4 implants (2 in the maxilla, 2 in the mandible) were lost in 3 patients because of progressive bone loss. Another single implant in the mandible was removed 54 months after prosthesis placement at the patient's request, in spite of the fact that the implant was stable and appeared to be well osseointegrated. This patient experienced episodes of severe myofascial pain and insisted on the implant's removal. Of the 4 patients with implant failures, in 3 situations the fixed partial prostheses were supported by the remaining implants. The patient with facial pain was later treated with a conventional removable partial denture. The majority of patients complied with the prescribed recall system. Eight patients, representing 15 implants, dropped out of the study. For 3 patients, the cause of dropping out was unknown, 2 patients could not continue to attend further follow-up appointments because of a change in residence, and 3 patients were on recall elsewhere. Consequently, 94 implants remained in the study for the final examination after 5 years of loading.

The cumulative implant survival rate was 95.3% at the end of the 5-year period (Table 2). This cumulative survival rate resulted from the aforementioned 5 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  $\geq$  4 mm," "first occurrence of pocket depth  $\geq$  4 mm," and "first occurrence of crevicular fluid volume  $\geq 2.5$  mm." A total of 12 events had occurred at the time of statistical survey. Five of these events were failures, and 7 events involved implants that exceeded the defined thresholds for radiographic or clinical criteria. During the first year after prosthesis

Table 2 Life Table	e Analysis o	of Cumu	lative Surv	ival Rate	e	
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	114	0	0	0	0	100
Loading to 1 year	114	0	0	0	0	100
1 to 2 years	114	0	4	0	0	100
2 to 3 years	110	2	6	1.8	1.8	98.2
3 to 4 years	102	0	1	0	1.8	98.2
4 to 5 years	101	3	4	3.0	4.7	95.3
5 years	94					95.3

Table 3 Life Table	Analysis o	of Cumu	lative Succ	ess Rate	e	
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	114	0	0	0	0	100
Loading to 1 year	114	2	0	1.7	1.7	98.3
1 to 2 years	112	3	4	2.7	4.3	95.7
2 to 3 years	105	1	6	1.0	5.2	94.8
3 to 4 years	98	3	1	3.1	8.1	91.9
4 to 5 years	94	3	4	3.2	11.0	89.0
5 years	87					89.0

placement, 98.3% of the implants remained free of radiographically determined bone loss  $\geq$  4 mm, probing depth  $\geq$  4 mm, and crevicular fluid volume  $\geq$  2.5 mm. Corresponding values for the 3- and 5-year intervals were 94.8% and 89.0%, respectively.

#### **Clinical Observations**

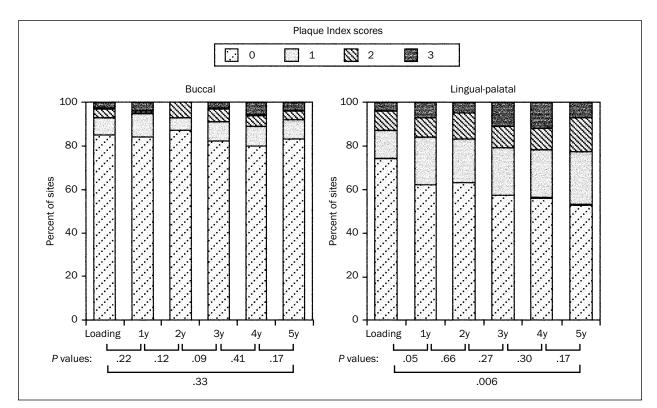
Figure 1 shows the frequency distribution of Plaque Index scores assessed at the buccal and lingualpalatal surfaces of the implants. At the buccal aspects, plaque scores were consistently low and remained nearly unchanged during the 5-year period of service. Over the entire observation period, more than 90% of the implants showed Plaque Index scores of 0 or 1, indicating excellent or good oral hygiene practices. At the lingual-palatal surfaces, oral hygiene procedures were less effective, and mean Plaque Index scores were higher. The portion of lingual-palatal surfaces with remarkable plaque deposits (score of 2 or 3) rose from 13% after prosthesis placement to 23% after 5 years. A comparison of baseline examination and re-examination after 5 years revealed significant differences in Plaque Index scores at lingual-palatal surfaces.

The bleeding tendency of the peri-implant sulcus is illustrated in Fig 2. The results at the buccal surfaces were not much different from those assessed at the lingual-palatal surfaces. Except for the examinations carried out at the buccal surfaces 3 and 4 years after prosthesis placement, more than 90% of the sites showed no or very little bleeding on probing during the evaluation period. Only 1% to 4% of the sites had a Sulcus Bleeding Index score of 3.

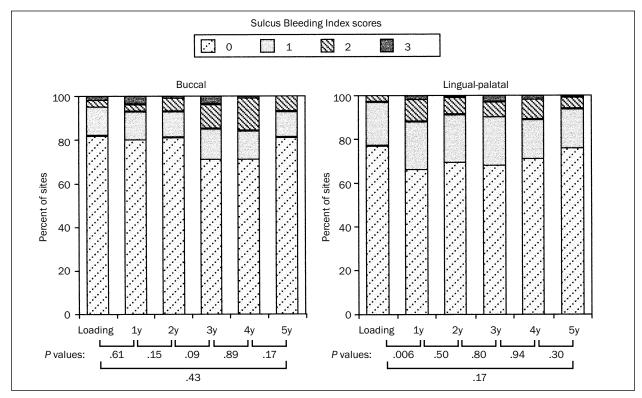
The longitudinal alterations in probing depth and attachment level are shown in Fig 3. Only minimal changes in the 2 parameters were noted; the median probing depth ranged from 1.5 mm to 2.0 mm and the median attachment level ranged from 1.4 mm to 1.7 mm. The greatest increase in probing depth and loss of attachment took place between the 1-year and 2-year examinations, but at the final examination, these parameters were not significantly different from those at the baseline.

A significant increase was observed in crevicular fluid volume (Fig 4), from a median of 0.2 mm after prosthesis placement to 0.7 mm at the 1-year examination (P = .0002). In the 1- to 5-year observation period crevicular fluid volume did not change significantly, and the median value showed only a slight variation (between 0.7 and 1.2 mm).

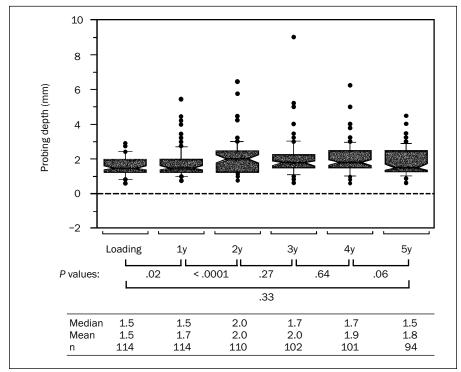
Results of the assessment of implant mobility with the Periotest device showed a decreasing Periotest value, from a median of -2 at baseline (after completion of the prosthetic treatment) to a median of -4 after 1 year (P < .0001). During the following 12 months, another slight decrease occurred, and a median of -5 was seen at the 2-year examination. In the 2- to 5-year period, no further alteration in the Periotest value was noted, and the interquartile range remained almost unchanged (Fig 5).



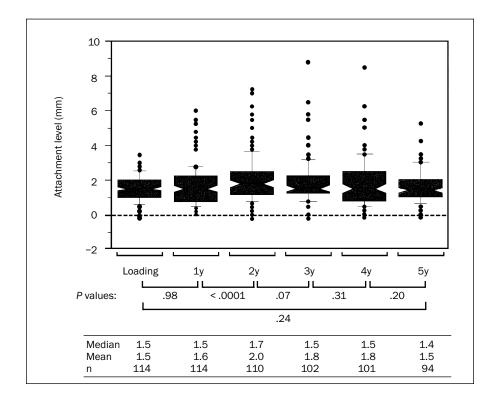
**Fig 1** Plaque Index scores for (*left*) buccal and (*right*) lingual-palatal implant surfaces at the baseline examination (prosthesis placement) and at the annual re-examinations. The figure indicates low and unaltered plaque scores at buccal surfaces but a tendency toward increased plaque scores at lingual-palatal surfaces.



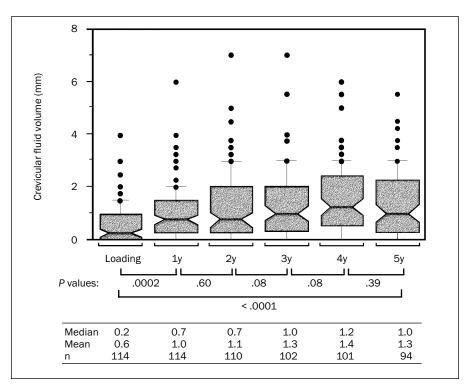
**Fig 2** Sulcus Bleeding Index scores for (*left*) buccal and (*right*) lingual-palatal implant surfaces at the baseline examination (prosthesis placement) and at the annual re-examinations. Buccal and lingual-palatal surfaces showed a similar pattern; the percentage of sites that showed no bleeding ranged from 66% to 82%.



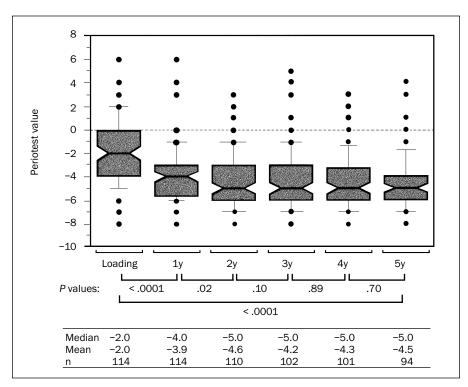
**Fig 3** Box plots showing alterations in (*top*) probing depth and (*bottom*) attachment level. No significant differences existed between baseline and the final examination.



Copyright O 2000 by Quintessence Publishing Co, Inc. Printing of this document is restricted to personal use only. No part of this article may be reproduced or transmitted in any form without written permission from the publisher.



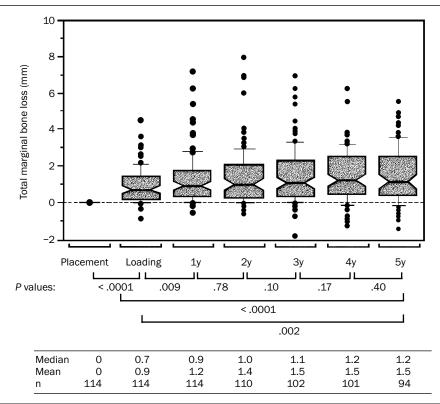
**Fig 4** Box plot illustrating alterations in crevicular fluid volume. There was a significant difference in this parameter between the time of prosthesis placement and the 1-year examination. During the following 4 years, no remarkable changes were noted.

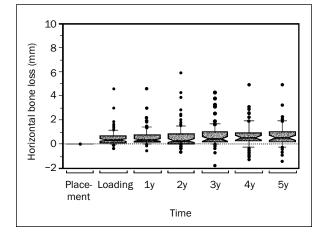


**Fig 5** Box plot showing Periotest values. The median Periotest value was between -2 and -5, with the highest score (ie, lowest stability) obtained directly after prosthesis placement.

Copyright © 2000 by Quintessence Publishing Co, Inc. Printing of this document is restricted to personal use only. No part of this article may be reproduced or transmitted in any form without written permission from the publisher.

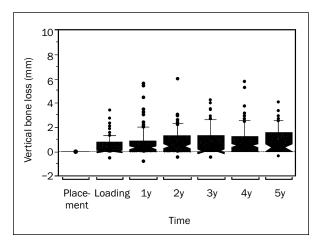
**Fig 6** Box plots illustrating alterations in marginal bone loss (total, horizontal, and vertical components) for the different time intervals. Loss of marginal bone was 0.7 mm (median) between implant placement and prosthetic treatment and 0.5 mm (median) between prosthesis placement and the 5-year evaluation. Subsequently, the 1-year examination of radiographic data revealed a constant course, without significant differences.





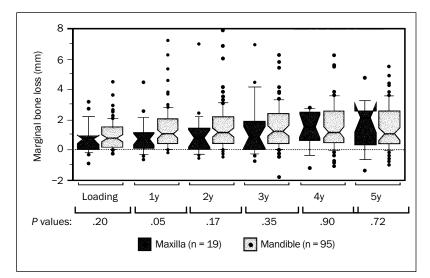
#### **Radiographic Evaluation**

The progression of marginal bone loss (total, horizontal, and vertical components) is expressed in Fig 6. The diagrams depict the changes with respect to the postoperative radiograph. Between implant placement and prosthetic treatment, median marginal bone loss of 0.7 mm (P < .0001) was observed. Up to 1 year after prosthesis placement, marginal bone loss tended to increase (median 0.9 mm, P =



.009), while in the subsequent research period, differences were either no longer present or minimal. At the final examination, after 5 years of functional loading, marginal bone loss of 1.2 mm (median value) was measured, corresponding to an average marginal bone loss per year of 0.1 mm. Furthermore, it was noted that 90% of all implants demonstrated a marginal bone loss  $\leq$  3 mm during the entire trial period. For several implants (4% to

COPYRIGHT © 2000 BY QUINTESSENCE PUBLISHING CO, INC. PRINTING OF THIS DOCUMENT IS RESTRICTED TO PERSONAL USE ONLY. NO PART OF THIS ARTICLE MAY BE REPRODUCED OR TRANSMITTED IN ANY FORM WITH-OUT WRITTEN PERMISSION FROM THE PUBLISHER.



**Fig 7** Longitudinal evaluation of marginal bone loss in mandibular and maxillary sites. Mandibular sites showed ongoing bone loss up to the end of the first year after prosthesis placement, while subsequent radiographic monitoring revealed no further loss. Maxillary implants showed a more stable result up to 3 years after prosthesis placement, while in the last 2 years of observation, the median rose from 0.8 mm to 2.0 mm.

12%), a gain in bone height was observed. For the horizontal component (measured remote to the implant as the distance between the first thread and the osseous crest), morphologic differentiated evaluation revealed bone loss of 0.4 mm (median) during the healing period and 0.2 mm from prosthesis placement to the 5-year follow-up. Vertical bone resorption was 0 mm (median) during the healing period and 0.3 mm after 5 years.

Regarding location of the implants in the maxilla or mandible, slight distinctions in the dynamic reaction of marginal bone loss were observed, but the differences did not reach statistical significance (Fig 7). For implants in mandibular sites, the median values for marginal bone loss were 0.8 mm, 0.3 mm, and 0 mm for the periods implant placement to prosthesis placement, prosthesis placement to 1year examination, and 1-year to 5-year examination, respectively. For the maxillary sites, the median values were 0.7 mm, 0 mm, and 1.3 mm for the same periods. Based on these data, the average annual bone loss in the functional phase (ie, after the healing period) was 0.06 mm in the mandible and 0.3 mm in the maxilla.

Complications and maintenance requirements during the study period are presented in Table 4 and classified as structural complications or biologic alterations affecting the hard and soft tissues. For 2% to 9% of the patients, peri-implant inflammation was observed; these alterations did not seem to

COPYRIGHT © 2000 BY QUINTESSENCE PUBLISHING CO, INC. PRINTING OF THIS DOCUMENT IS RESTRICTED TO PERSONAL USE ONLY. NO PART OF THIS ARTICLE MAY BE REPRODUCED OR TRANSMITTED IN ANY FORM WITH-OUT WRITTEN PERMISSION FROM THE PUBLISHER. increase with time. Separate infections of the mucosal soft tissue were associated with the presence of plaque and/or an immunocompromised situation and were remedied by local disinfection and additional oral hygiene instruction. Peri-implantitis defects were treated with autogenous bone grafts as described elsewhere.34 Prosthesis mobility related to loose screws was documented 12 times; the majority of these screw complications occurred in the first year. The most common reason for laboratory repair was fracture of the veneers, a condition that again was observed most often in the first year following prosthesis placement. No implant or abutment fractures were noted. In summary, it could be noted that the majority of complications were recorded during the first year of function; thereafter, the incidence of complications was rare. Seventy-two percent of the restorations were complication-free between the time of prosthesis placement and the first annual examination; for the subsequent years, the corresponding values were 93% to 96%.

#### DISCUSSION

The present data demonstrate a positive outcome for the use of ITI solid-screw implants to rehabilitate partially edentulous patients during a 5-year period of functional loading. The use of ITI implants in partially edentulous arches has not been

Complication	Prosthesis placement	1 year	2 years	3 years	4 years	5 years
Structural complications						
Screw loosening	_	8	1	1	1	1
Screw fracture	_	_	_	_	_	_
Abutment loosening	_	_	_	_	_	1
Veneer fracture	—	5	—	—	1	1
Implant fracture	—	—	—	—	—	—
Total	—	13 (19%)	1 (1%)	1 (2%)	2 (3%)	3 (5%)
Biologic alterations						
Mucositis	_	1	1	1	_	_
Peri-implantitis	3	5	2	1	2	1
Total	3 (4%)	6 (9%)	3 (5%)	2 (3%)	2 (3%)	1 (2%)
Restorations without complications	65 (96%)	49 (72%)	62 (94%)	59 (95%)	57 (94%)	52 (93%)
Restorations at risk	68	68	66	62	61	56

Table 4	Structural and Biologic Complications During the 5-Year Follow-up
Period	

sufficiently documented in the implant scientific literature. Several of the survival studies have shortcomings, since they are based on limited material, report only average failure rates unrelated to time, or are cross-sectional analyses of research parameters.<sup>35–38</sup> Furthermore, the majority of studies used mainly hollow cylinders and hollow screws. Compared to hollow-body implants, solid screws offer advantages with regard to fracture resistance and accessibility for peri-implantitis therapy. Treatment of hollow-body implants affected with progressive bone loss is unpredictable when the first row of perforations is reached and the infection has reached the inner part of the implant. Because of differences in study designs and types of implants, it would be problematic to extrapolate results of the abovementioned studies to the current findings.

Clinical trials, estimating or calculating implant survival as a function of time, were reported by Buser et al,<sup>16</sup> Ellegaard et al,<sup>39</sup> Kemppainen et al,<sup>25</sup> and Levine et al.<sup>40</sup> The most detailed study appears to be the prospective 3-year follow-up trial carried out by Buser et al,<sup>16</sup> which included 54 hollow screws and hollow cylinders. The cumulative survival rate calculated by a modified life table approach was 96.2% after the third year and corresponds well to the 3year results (98.2%) of the current study. Results from a multicenter retrospective study of singletooth hollow and solid-body ITI implants showed an overall survival rate of 95.5% after 2 years of loading.<sup>40</sup> In the 1-year study of Kemppainen et al,<sup>25</sup> no implant failures occurred. Using the Kaplan-Meier method, Ellegaard et al<sup>39</sup> estimated a survival rate of 95% after 5 years for 93 ITI hollow screws. The

estimated success rate under application of the criteria "first occurrence of radiographic bone loss  $\geq 3.5$ mm" was 79.2%. When the cumulative survival and success rates of the present study are compared with the estimated data of Ellegaard et al, the findings are in agreement for the event "implant failure." However, when peri-implant bone loss is included in the definition of success, the current success rate is approximately 10% higher than that described by Ellegaard and coworkers. The currently observed higher success rate could be related to differences in the definition of success criteria, implant design, patient selection, or statistical methods. The cumulative 5-year survival rate (95.3%) of this current report on nonsubmerged ITI screw implants is comparable to,<sup>18,19,24,26</sup> or higher than,<sup>20,27</sup> the 5-year data presented for the Brånemark System (range from 88% to 100%).

The oral hygiene and soft tissue conditions around the implants were found to be satisfactory, and the almost constant course of research parameter evaluation indicated that the soft tissue response maintained a level of comparative health and stability over the 5-year period of service. The magnitude of changes in bleeding on probing, probing depth, and attachment level was small and did not reach statistical significance when baseline and final measurements were compared. The findings of low percentage of sites with bleeding on probing and no signs of progression are in agreement with the data of Buser et al<sup>16</sup> for ITI implants and Henry et al<sup>24</sup> for Brånemark System implants. On the other hand, most studies have found a tendency toward increasing Sulcus Bleeding Indices.<sup>17,19,26,27</sup> These results

may be attributed to trauma of the vulnerable periimplant tissues (lack of fibrous attachment), leading to a bleeding tendency as a result of injury, rather than as a result of inflammation. Although significant differences in crevicular fluid volume were shown between the baseline measurements after prosthesis placement and those after 5 years, the majority of implant sites produced physiologic amounts of this exudate. Crevicular fluid volume, noninvasively harvested on paper strips in this study, has proven to be a suitable parameter for monitoring peri-implant soft tissue conditions. The linear coherences between marginal bone loss and crevicular fluid volume were described in a previous article.28 In addition, crevicular fluid volume has been shown to render predictive information for pathologic processes of peri-implant bony support.41 Concerning these relations, comparable or similar findings obtained in the present patient group for longitudinal changes in peri-implant osseous support and crevicular fluid volume, as well as results of the paired statistical tests, were not surprising.

The decrease in Periotest values over time is in agreement with other reports on ITI implants in partially edentulous patients<sup>16,42</sup> and may be interpreted as a function-related increase in bone contact<sup>43</sup> or mineralization<sup>44</sup> at the implant interface. The tendency toward decreasing Periotest values over time, as well as the the majority of negative values (between –1 and –8), resembled the results observed in various screw-type implant systems.<sup>7,17,45–47</sup>

In most clinical trials studying peri-implant bone level changes, no baseline radiographs were taken immediately postsurgically; instead, the first radiographic assessment was taken at second-stage surgery or at prosthesis placement, ie, 13 or more months after surgical placement of the implants. Therefore, sparse information about the amount of bone loss in the pre-loading period can be found in the literature. In the present study, baseline 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 partially edentulous patients is relatively small, and the evaluation time has been limited to a maximum of 3 years. Two investigations, both referring to hollow screws and hollow cylinders of the ITI system, reported bone level changes during the healing period and early phase of functional loading. Hämmerle et al<sup>48</sup> evaluated 28 ITI implants and found that mean marginal bone loss varied with modifications in the sink depth, from 0.2 mm to 0.6 mm between baseline and 4 months, and from 0.3 mm to 0.4 mm between 4 and 12 months. Brägger et al<sup>49</sup> found a change in bone level of 0.8 mm (median) for 57 implants up to 1 year after implant placement. For the period between prosthesis placement and the 1-year examination, Kemppainen et al<sup>25</sup> observed an average bone loss of 0.1 mm for 56 ITI implants (hollow screws and hollow cylinders). This trend of an annual rate of bone loss of 0.1 mm was confirmed by Weber et al<sup>50</sup> and Buser et al<sup>16</sup> for the 1- to 2-year period and the 1- to 3-year period, respectively. With a median marginal bone loss of 0.7 mm during the healing period and 0.1 mm bone resorption per year after prosthetic treatment, the present results were satisfactory and corroborated the aforementioned short-term observations. Furthermore, the amount of marginal bone loss seems to be comparable to 19,20,23,24,27 or less than 17,26,51 the outcome derived from longitudinal studies of the Brånemark System in partially edentulous patients.

The fact that no statistically significant differences were found when marginal bone loss for mandibular implants was compared with that for maxillary implants is in general agreement with the published literature. For 55 partially edentulous patients with ITI hollow screws and hollow cylinders, Weber et al<sup>50</sup> reported greater mean bone loss for maxillary implants at the 1-year examination. Though this finding could not be confirmed in the second year of observation, the initial arch-related differences have weakened. Van Steenberghe,<sup>52</sup> Quirynen et al,<sup>17</sup> and Brägger et al<sup>49</sup> also failed to identify the dental arch as a predictor for periimplant bone loss in partially edentulous patients. Adell et al<sup>53</sup> described the relationship between the dental arch and marginal bone loss for fixed prostheses in edentulous arches supported by Brånemark System implants. They found more bone loss in maxillae than in mandibles during the healing period, while the opposite was observed for the first year after abutment connection. The authors stated that the rich vascular supply and cancellous character of the maxillary bone would possibly result in a shortened remodeling time, while the compact mandibular bone demanded an extended period of time for structural changes associated with implant placement. This trend was not seen in the present study. During the healing period, maxillary and mandibular bone responded similarly to the implants' presence in the oral cavity. In the longer term, mandibular sites showed ongoing bone loss up to the end of the first year after prosthesis placement. Subsequent radiographic monitoring of implants in the mandible revealed no further increase, and the median stabilized at a level of 1.2 mm. No remarkable bone level changes were noted for maxillary implants up to 3 years after prosthesis

COPYRIGHT © 2000 BY QUINTESSENCE PUBLISHING CO, INC. PRINTING OF THIS DOCUMENT IS RESTRICTED TO PERSONAL USE ONLY. NO PART OF THIS ARTICLE MAY BE REPRODUCED OR TRANSMITTED IN ANY FORM WITH-OUT WRITTEN PERMISSION FROM THE PUBLISHER.

placement, while in the last 2 years of observation, stable conditions were no longer present and the median tended to rise from 0.8 mm to 2.0 mm. The observed differences between maxillae and mandibles should be interpreted with caution because of the limitations resulting from unequal numbers of implants in the 2 groups.

## SUMMARY

With a high cumulative survival rate of 95.3% and almost stable conditions of peri-implant hard and soft tissues, ITI solid-screw implants may be considered as a reliable treatment alternative for the rehabilitation of partially edentulous patients in a medium-term perspective. Loss of marginal bone occurred at a low level (a median of 0.7 mm during the healing period, and 0.5 mm for the period between prosthesis placement and the 5-year followup), and after 1 year of loading, a steady state was recorded. The soft tissue response demonstrated a level of comparative health and stability over the 5year period of service. The rare occurrence of mechanical alterations of implant and suprastructure components seemed to indicate that the ITI system provides a safe prosthodontic treatment concept.

### REFERENCES

- Brånemark P-I, Svensson B, van Steenberghe D. Ten-year survival rates of fixed prostheses on four or six implants ad modum Brånemark in full edentulism. Clin Oral Implants Res 1995;6:227–231.
- Jemt T, Lekholm U. Implant treatment in edentulous maxillae: A 5-year follow-up report on patients with different degrees of jaw resorption. Int J Oral Maxillofac Implants 1995;10:303–311.
- Spiekermann H, Jansen VK, Richter EJ. A 10-year followup study of IMZ and TPS implants in the edentulous mandible using bar-retained overdentures. Int J Oral Maxillofac Implants 1995;10:231–243.
- Jemt T, Chai J, Harnett J, Heath MR, Hutton JE, Johns RB, et al. A 5-year prospective multicenter follow-up report on overdentures supported by osseointegrated implants. Int J Oral Maxillofac Implants 1996;11:291–298.
- Ledermann PD. Über 20jährige Erfahrung mit der sofortigen funktionellen Belastung von Implantatstegen in der regio interforaminalis. Z Zahnärztl Implantol 1996;12: 123–136.
- Lindquist LW, Carlsson GE, Jemt T. A prospective 15-year follow-up study of mandibular fixed prostheses supported by osseointegrated implants. Clinical results and marginal bone loss. Clin Oral Implants Res 1996;7:329–336.
- Behneke N, Behneke A, Fuhr K, d'Hoedt B. Langzeitergebnisse mit IMZ- und TPS-Implantaten im zahnlosen Unterkiefer. Verlaufsstudie anhand eines konsekutiv aufgenommenen Patientenkollektivs mit maximal 15-jähriger Beobachtungszeit. Dtsch Zahnärztl Z 1997;52:283–290.

- Friberg B, Nilson H, Olsson M, Palmquist C. Mk II: The self-tapping Brånemark implant: 5-year results of a prospective 3-center study. Clin Oral Implants Res 1997;8:279–285.
- 9. Naert IE, Hooghe M, Quirynen M, van Steenberghe D. The reliability of implant-retained hinging overdentures for the fully edentulous mandible. An up to 9-year longitudinal study. Clin Oral Invest 1997;1:119–124.
- Lekholm U, Ericsson I, Adell R, Slots J. The condition of the soft tissues at tooth and fixture abutment supporting fixed bridges—A microbial and histological study. J Clin Periodontol 1986;13:558–562.
- Quirynen M, Listgarten MA. The distribution of bacterial morphotypes around natural teeth and titanium implants ad modum Brånemark. Clin Oral Implants Res 1990;1:8–12.
- Sanz M, Newman MG, Nachnani S, Holt R, Stewart R, Flemmig T. Characterization of the subgingival microbial flora around endosteal sapphire dental implants in partially edentulous patients. Int J Oral Maxillofac Implants 1990;5: 247–253.
- Dharmar S, Yoshida K, Adachi Y, Kishi M, Okuda K, Sekine H. Subgingival microbial flora associated with Brånemark implants. Int J Oral Maxillofac Implants 1994;9:314–318.
- Mombelli A, Marxer M, Gaberthüel T, Grunder U, Lang NP. The microbiota of osseointegrated implants in patients with history of periodontal disease. J Clin Periodontol 1995; 22:124–130.
- Papaioannou W, Quirynen M, van Steenberghe D. The influence of periodontitis on the subgingival flora around implants in partially edentulous patients. Clin Oral Implants Res 1996;7:405–409.
- Buser D, Weber H-P, Brägger U, Balsiger C. Tissue integration of one-stage ITI implants: 3-year results of a longitudinal study with hollow-cylinder and hollow-screw implants. Int J Oral Maxillofac Implants 1991;6:405–412.
- Quirynen M, Naert I, van Steenberghe D, Dekeyser C, Callens A. Periodontal aspects of osseointegrated fixtures supporting a partial bridge. An up to 6-years retrospective study. J Clin Periodontol 1992;19:118–126.
- Jemt T, Lekholm U. Oral implant treatment in posterior partially edentulous jaws: A 5-year follow-up report. Int J Oral Maxillofac Implants 1993;8:635–640.
- Lekholm U, van Steenberghe D, Herrmann I, Bolender C, Folmer T, Gunne J, et al. Osseointegrated implants in the treatment of partially edentulous jaws: A prospective 5-year multicenter study. Int J Oral Maxillofac Implants 1994;9: 627–635.
- Olsson M, Gunne J, Åstrand P, Borg K. Bridges supported by free-standing implants versus bridges supported by tooth and implant. A five-year prospective study. Clin Oral Implants Res 1995;6:114–121.
- Parein AM, Eckert SE, Wollan PC, Keller EE. Implant reconstruction in the posterior mandible: A long-term retrospective study. J Prosthet Dent 1997;78:34–42.
- Jemt T, Lekholm U, Gröndahl K. Single implant restorations ad modum Brånemark. A three-year follow-up study of the development group. Int J Periodontics Restorative Dent 1990;5:341–349.
- Thilander B, Ödman J, Gröndahl K, Friberg B. Osseointegrated implants in adolescents. An alternative in replacing missing teeth? Eur J Orthod 1994;16:84–95.
- Henry PJ, Laney WR, Jemt T, Harris D, Krogh PHJ, Polizzi G, et al. Osseointegrated implants for single-tooth replacement: A prospective 5-year multicenter study. Int J Oral Maxillofac Implants 1996;11:450–455.

- Kemppainen P, Eskola S, Ylipaavalniemi P. A comparative prospective clinical study of two single-tooth implants: A preliminary report of 102 implants. J Prosthet Dent 1997; 77:382–387.
- Andersson B, Ödman P, Lindvall A-M, Brånemark P-I. Cemented single crowns on osseointegrated implants after 5 years: Results from a prospective study on CeraOne. Int J Prosthodont 1998;11:212–218.
- Scheller H, Pi Urgell JP, Kultje C, Klineberg I, Goldberg PV, Stevenson-Moore P, et al. A 5-year multicenter study on implant-supported single crown restorations. Int J Oral Maxillofac Implants 1998;13:212–218.
- Behneke A, Behneke N, d'Hoedt B, Wagner W. Hard and soft tissue reactions to ITI screw implants: 3-year longitudinal results of a prospective study. Int J Oral Maxillofac Implants 1997;12:749–757.
- Deklaration von Helsinki, beschlossen auf der 18. Generalversammlung in Helsinki, Juni 1964, revidiert von der 29. Generalversammlung in Tokio, Oktober 1975, von der 35. Generalversammlung in Venedig, Oktober 1983, und der 41. Generalversammlung in Hongkong, September 1989. Dt Ärztbl 1991;87:4691–4692.
- Mombelli A, Van Osten MAC, Schürch E, Lang NP. The microbiota associated with successful or failing osseointegrated titanium implants. Oral Microbiol Immunol 1987;2: 145–151.
- Quirynen M, van Steenberghe D, Jacobs R, Schotte A, Darius P. The reliability of pocket probing around screw-type implants. Clin Oral Implants Res 1991;2:186–192.
- Richter E-J, Jansen V, Spiekermann H, Jovanovic SA. Langzeitergebnisse von IMZ- und TPS-Implantaten im interforaminalen Bereich des zahnlosen Unterkiefers. Dtsch Zahnärztl Z 1992;47:449–454.
- Gómez-Román G, Axmann D, d'Hoedt B, Schulte W. Eine Methode zur quantitativen Erfassung und statistischen Auswertung des periimplantären Knochenabbaus. Stomatologie 1995;92:463–471.
- Behneke A, Behneke N, d'Hoedt B. Treatment of periimplantitis defects with autogenous bone grafts: Six-month to 3-year results of a prospective study in 17 patients. Int J Oral Maxillofac Implants 2000;15:125–138.
- Buser DA, Schroeder A, Sutter F, Lang NP. The new concept of ITI hollow-cylinder and hollow-screw implants: Part
   Clinical aspects, indications and early clinical results. Int J Oral Maxillofac Implants 1988;3:173–181.
- Frisch E, Pehrsson K. Einzelzahnversorgungen mit dem ITI-Bonefit-Implantatsystem. Erfahrungen nach fünf Jahren. Zahnärztl Welt 1993;11:797–802.
- 37. Levine RA, Clem DS III, Wilson TG, Higginbottom F, Saunders SL. A multicenter retrospective analysis of the ITI implant system used for single-tooth replacements: Preliminary results at 6 or more months of loading. Int J Oral Maxillofac Implants 1997;12:237–242.
- Moberg L-E, Köndell P-Å, Kullmann L, Heimdahl A, Gynther GW. Evaluation of single-tooth restorations on ITI dental implants. A prospective study of 29 patients. Clin Oral Implants Res 1999;10:45–53.

- Ellegaard B, Baelum V, Karring T. Implant therapy in periodontally compromised patients. Clin Oral Implants Res 1997;8:180–188.
- Levine RA, Clem DS III, Wilson TG, Higginbottom F, Solnit G. Multicenter retrospective analysis of the ITI implant system used for single-tooth replacement: Results of loading for 2 or more years. Int J Oral Maxillofac Implants 1999;14: 516–520.
- Behneke A, Behneke N. Korrelation und Prädiktion klinischer und radiologischer Parameter enossaler Implantate. Ergebnisse anhand einer Longitudinalstudie über 7 Jahre. Z Zahnärztl Implantol 1999;15:209–223.
- Kröll K. Nachuntersuchung von ITI-Implantaten in einer zahnärztlichen Praxis. Z Zahnärztl Implantol 1998;14: 112–116.
- Johansson C, Albrektsson T. Integration of screw implants in the rabbit: A 1-year follow-up of removal torque of titanium implants. Int J Oral Maxillofac Implants 1987;2:69–75.
- Isidor F. Mobility assessment with the Periotest system in relation to histologic findings of oral implants. Int J Oral Maxillofac Implants 1998;13:377–383.
- Hartmann H-J, Nistor C. Frialit-2 Implantate: Knochenapposition mit Periotestmessungen. Zahnärztl Welt 1993;6: 404–407.
- 46. Einsele FT, Merkel U, Romanos G, Strub JR, Weingart D. Implantatretinierte Hybridprothesen auf Brånemark sowie Bonefit (ITI)-Implantaten mit Kugelattachments im Unterkiefer: Eine Longitudinalstudie über vier Jahre. Implantologie 1994;1:23–37.
- Van Steenberghe D, Tricio J, Naert I, Nys M. Damping characteristics of bone-to-implant interfaces. A clinical study with the Periotest device. Clin Oral Implants Res 1995;6: 31–39.
- Hämmerle CHF, Brägger U, Bürgin W, Lang NP. The effect of subcrestal placement of the polished surface of ITI implants on marginal soft and hard tissues. Clin Oral Implants Res 1996;7:111–119.
- Brägger U, Häfeli U, Huber B, Hämmerle CHF, Lang NP. Evaluation of postsurgical crestal bone levels adjacent to non-submerged dental implants. Clin Oral Implants Res 1998;9:218–224.
- Weber HP, Buser D, Fiorellini JP, Williams RC. Radiographic evaluation of crestal bone levels adjacent to nonsubmerged titanium implants. Clin Oral Implants Res 1992; 3:181–188.
- Esposito M, Ekestubbe A, Gröndahl K. Radiological evaluation of marginal bone loss at tooth surfaces facing single Brånemark implants. Clin Oral Implants Res 1993;4: 151–157.
- 52. Van Steenberghe D. A retrospective multicenter evaluation of the survival rate of osseointegrated fixtures supporting fixed partial prostheses in the treatment of partial edentulism. J Prosthet Dent 1989;61:217–223.
- Adell R, Lekholm U, Rockler B, Brånemark P-I. A 15-year study of osseointegrated implants in the treatment of the edentulous jaw. Int J Oral Surg 1981;10:387–416.