

Short Dental Implants Retaining Two-Implant Mandibular Overdentures in Very Old, Dependent Patients: Radiologic and Clinical Observation Up to 5 Years

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Purpose: To describe the survival rate and peri-implant bone loss in very old patients dependent for their activities of daily living (ADL), treated with mandibular two-implant overdentures (IODs) in the context of a previously reported randomized controlled trial. **Materials and Methods:** A total of 19 patients received two interforaminal Straumann implants (Regular Neck, 4.1 mm diameter, 8 mm length) that were subsequently loaded with Locator attachments, transforming their preexisting inferior conventional denture into an IOD. The primary outcome measures were implant survival rate and radiographically assessed peri-implant bone loss. Secondary outcome measures included peri-implant probing depth and Plaque Index scores, as well as implant mobility. Nutritional state (body mass index and blood markers) and cognitive state (Mini-Mental State Examination) were also analyzed. **Results:** The patient cohort comprised eight men and 11 women with a mean age of 85.7 ± 6.6 years. The implant survival rate up to 5 years was 94.7%, with one early and one late implant failure. The mean loss of peri-implant bone height was 0.17 mm per year (95% confidence interval: 0.09 to 0.24; $P < .001$). Peri-implant probing depth and Plaque Index scores were low and stable during the first 2 years, and thereafter increased continuously. Correlation analysis suggests that a reduced cognitive function and nutritional state are not a particular risk factor for accelerated peri-implant bone loss. **Conclusion:** The high implant survival and acceptable peri-implant health suggest that neither age nor dependency for the ADLs is a contraindication for the placement of implants. Nevertheless, close monitoring of the patients concerning a potential further functional decline precluding denture management and performing oral hygiene measures is advised. *INT J ORAL MAXILLOFAC IMPLANTS* 2017;32:415–422. doi: 10.11607/jomi.5361

Keywords: dental care for aged, dental implants, geriatric dentistry, peri-implant bone loss, peri-implantitis

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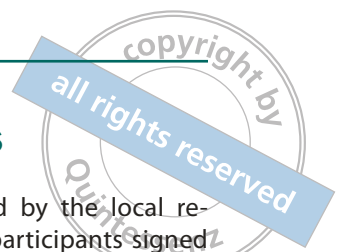
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The McGill Consensus Statement in 2002 and, more recently, the York Consensus Statement in 2009 have proposed two-implant-supported mandibular overdentures as the recommended first choice standard of care for the edentulous mandible,^{1,2} at least for elderly edentates. Several studies have already shown that these implant-supported overdentures (IODs) are an effective and satisfactory treatment for patients with an edentulous mandible, and offer numerous benefits.³

Patients treated with maxillary conventional dentures (CDs) and mandibular IODs have a significantly higher chewing efficiency, maximum occlusal force, and masseter muscle thickness when compared with patients treated with CDs.^{4,5} Apart from the effect of IODs on mastication, studies have also shown an improvement in oral health-related quality of life (OHRQoL).⁶ Using the Oral Health Impact



Profile (OHIP-Edent), the authors determined that treatment with an IOD provided a significant short-term improvement in OHRQoL compared with a CD. This effect was confirmed even in an observational study,⁷ and the subjective patient satisfaction was reported to be superior to CDs over an extended period of time.⁸

Many studies have determined high survival and success rates for both fixed and removable implant-supported prostheses.^{9–11} Dental implants have become an integral part of restorative dentistry. However, evidence in the aging population is still scarce.¹² Studies have shown that implants could be successfully placed and maintained in very old patients, even 80 years of age and older.¹³ However, most of these studies were performed in healthy and independently living patients, whereas the standard elderly population presents more often with functional impairment as well as multiple chronic diseases, which might affect implant osseointegration as well as peri-implant bone loss over time.

With the aging population, practitioners will be more frequently confronted with patients who are affected by various diseases and consequently multiple comorbidities, eventually becoming dependent for the activities of daily living (ADLs), including oral hygiene maintenance. These patients, therefore, require assistance from health-care personnel or caregivers. Furthermore, impaired vision, tactile perception, and dexterity might render the oral hygiene measures more difficult. The effect of the shifting of priorities in old age, when life is dominated by morbidity and disability, on oral hygiene should not be underestimated.¹⁴ It has still not been determined whether the placement and maintenance of implants in these very old patients with deteriorated health is a viable solution.

A first randomized controlled trial (RCT) was carried out on a cohort of elderly edentulous patients who were dependent on assistance for their ADLs. It aimed to evaluate patient satisfaction comparing a conventional reline of an existing mandibular CD with a transformation into a two-implant IOD. Secondary outcomes were implant survival and peri-implant bone loss, maximum voluntary occlusal force, masseter muscle thickness, chewing efficiency, salivary flow, nutritional status, and OHRQoL. The first results after a 1-year observation period have been reported previously, indicating a significantly increased subjective satisfaction in the study arm receiving IODs.¹⁵

The present paper aims at describing the survival rate and marginal bone loss around the implants placed within the context of the aforementioned RCT over the observation period of up to 5 years.

MATERIALS AND METHODS

The study protocol was approved by the local research ethics committee, and all participants signed a written, informed consent (PSY06-038). The RCT was registered under the number NCT01928004 at www.ClinicalTrials.gov.

Inclusion and Exclusion Criteria

This prospective study included the patients from the intervention group in the previously described RCT,¹⁵ as well as an additional three patients who were randomized in the control group, and thus, had received a reline of their mandibular CD, but wished to change the study arm for receiving implants after an observation period of 1 year.

The inclusion criteria for the initial study comprised being edentulous, aged 75 years or older, and wearing conventional CDs that did not need renewal. Furthermore, only patients who received help for their ADLs were included in the study. The exclusion criteria comprised of depression, dementia, poorly controlled diabetes, immunosuppression, or treatment with bisphosphonates. Depression was evaluated during screening with the Geriatric Depression Scale,¹⁶ and dementia was evaluated by means of the Mini-Mental State Examination (MMSE).¹⁷

Intervention and Protocol

Between September 2007 and March 2011, 19 subjects received two Straumann Standard Tissue Level Implants (sand-blasted, large-grit, acid-etched [SLA] surface, 8 mm length, Regular Neck [RN], 4.1 mm diameter; Institut Straumann) following the recommended surgical protocol. Implants were placed in both mandibular canine regions. After 6 to 8 weeks of healing, the implants were loaded with Locator attachments (Zest Anchors), hence transforming the preexisting mandibular CD into an IOD.

Patients were examined at set time periods: T0 (loading of implants), T1 (3 months), T2 (12 months), and subsequently on an annual basis until dropout or death. At T0, a panoramic radiograph (OPT) was taken. During the follow-up examinations, intraoral radiographs were taken unless due to alveolar ridge resorption, the floor of the mouth precluded the appropriate placement of the x-ray film. In these cases, an OPT radiograph was used as surrogate examination. In some patients and at some follow-up examinations, taking radiographs was not possible. This was due either to lack of consent, poor medical condition, or patients unwilling to move to the clinic for examination, and therefore, a lack of radiographic equipment. During the course of the study, the radiographic equipment was updated from analog to digital, and both types of radiographs were analyzed for this study.

Analog radiographs were digitized before being uploaded into Adobe Photoshop Elements 2.0 (Adobe Systems), while digital radiographs did not require conversion before analysis. Reference markings were made on all radiographs, using carefully chosen reproducible reference points on the implants. The measurements between reference points and marginal bone level were subsequently calculated using the software ImageJ (National Institutes of Health), to account for any distortion present. The reference height for the implant + attachment system was 12.58 mm + cuff height. This was calculated using the dimensions provided by the manufacturers (Straumann and Zest Anchors): 8 mm implant length + 2.8 mm Standard collar height + transmucosal cuff height of Locator attachment + 1.78 mm male seating area of the Locator attachment. All measurements of bone height were subsequently calculated using the set scale (Fig 1).

At baseline as well as at T1, T2, and T3, blood samples were taken to analyze blood markers.

Clinical Examination and Outcome Measures

The primary outcome measures of this study were implant survival rate and peri-implant bone loss. Implant survival was defined as the implant being physically present in the mouth during clinical inspection, whereas the peri-implant bone level was defined as the radiographically determined distance between the peri-implant bone level and the implant apex, calculated as described previously (Fig 1). In cases where the implant apex was not visible on the radiograph, other reproducible reference points were used, and the total bone height with respect to the apex was calculated accordingly.

Secondary outcome measures comprised the clinical peri-implant probing depth, as measured at four sites around the implant (mesially, labially, distally, and lingually) with a conventional manual periodontal probe (PCP-12; Hu-Friedy) as well as the peri-implant Plaque Index, scored according to Mombelli and co-workers (1987) as 0 (no detection of plaque), 1 (plaque detected by running a probe across the smooth marginal surface of the implant), 2 (plaque seen by the naked eye), or 3 (abundant amount of plaque).¹⁸ Lastly, implant mobility was manually tested and rated as absence or presence of mobility.

Blood sample markers comprised albumin, C-reactive protein (CRP), vitamin B12, folate, and hemoglobin levels (HB). The body mass index (BMI) was calculated from the patient's height and weight, as measured during examination (kg/m^2). If the physical condition of the patient did not allow these measurements to be taken, for example, in patients with reduced mobility, the measurements were provided by the medical team. An MMSE test was performed to evaluate the patient's cognitive performance.¹⁷ The test battery

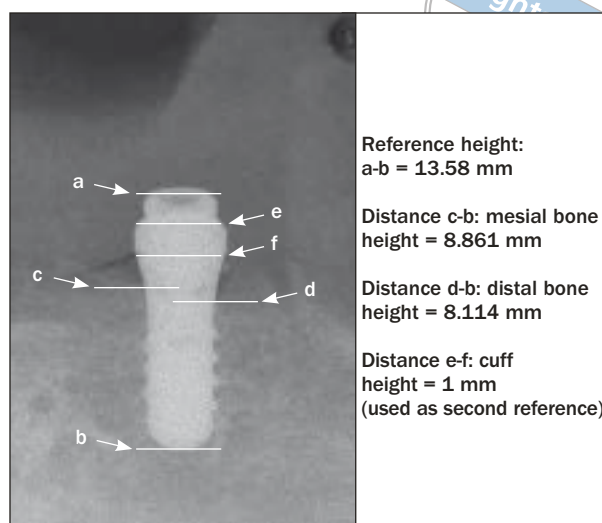


Fig 1 Example of radiograph with reference markings.

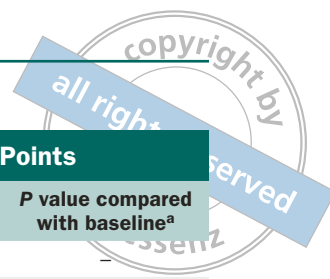
comprised further instruments, which are not reported in the present paper.

Statistical Analysis

Bone Level. From each available radiograph, the mesial and distal bone level of the implant was measured. The available time points varied between two and seven occasions, representing an observation period of up to 5 years. The within-patient correlations were taken into account by means of a mixed linear model, where the bone height was the dependent variable, the occasion was the primary fixed effect, and the site of measurement (side nested within implant, implant nested within patient) was a random effect on the intercept. A 95% confidence interval on the mean values was obtained for each occasion, with a *P* value for comparison with the baseline. This analysis was repeated using a linear trend over time, where the slope (in millimeters of bone height per year) was also treated as a random effect at the level of the measurement (side nested within implant, implant nested within patient). The software used was Stata version 13 (StataCorp). The level of significance was set at 5%.

Correlations Between Bone Loss and Other Variables

A slope for the progression of bone height loss for each individual was calculated, in linear regression analysis, adjusting for implant/site, and the corresponding standard error (SE). Then, a database of 16 observations was created with these slopes, and with baseline values for the other parameters. The statistical weights per patient were computed proportional to the inverse of the variance of the slope estimation ($1/\text{se}^2$), to account for uneven precision of the estimates.

**Table 1** Numbers of Patients and Mean Peri-implant Bone Height at Different Time Points

Time point	Patients (n)	Assessments (n)	Mean bone height ^a (mm)	95% confidence interval ^a	P value compared with baseline ^a
T0 (baseline)	15	57	8.37	8.08–8.67	–
T1 (3 months postinsertion)	16	59	8.13	7.84–8.43	.025
T2 (1 year postinsertion)	14	56	8.01	7.71–8.31	.001
T3 (2 years postinsertion)	11	42	8.02	7.70–8.33	.003
T4 (3 years postinsertion)	9	33	7.55	7.22–7.88	< .001
T5 (4 years postinsertion)	5	18	7.58	7.19–7.96	< .001
T6 (5 years postinsertion)	4	13	7.78	7.36–8.20	.002

^aEstimated by mixed linear regression with a random effect for measurement sites (sides nested within implants, implants nested within patients).

RESULTS

Participants

From the implant arm of the original RCT, 16 patients were included. Three additional patients from the reline arm of the study joined this analysis after having received implants after 1 year following the reline. For this study, T0 was considered the time point of implant loading. The patient cohort comprised eight men and 11 women with a mean age of 85.7 ± 6.6 years (range: 74 to 97 years) at baseline. Eight participants passed away during the course of the follow-up years, while six patients were unable to continue to participate in the study due to a severe deterioration of their general health. The latter did not express dissatisfaction with their implants at the time of last contact. At the time of analysis for this manuscript, five patients remained in the study.

Implant Survival

At the end of the reported follow-up, of the 38 implants initially placed in this study, only two implants failed. The first implant was lost due to early failure at T0 in a patient 97 years of age. This case was reported previously.¹⁹ The second failure was the loss of an implant 4 years after placement (T5) in a patient 95 years of age. These patients received replacement implants, which osseointegrated successfully in both cases and were included in the present analysis. The survival of the initially placed implants was therefore 94.7% (36 out of 38 initially placed implants). No worst-case scenario was calculated, as no dropout for an unknown reason had occurred.

Peri-implant Bone Health

Bone Level. Radiographs were available for analysis from 16 patients. A total of 280 measurements of bone height were taken (Table 1), calculated as described earlier. Of these, 250 were observed, and 30 were in-

terpolated given a valid measurement before and after the missing radiograph. In contrast, no extrapolation beyond dropout or death was performed. Patients who passed away during the study were not considered failures.

Most patients (13/16) had measurements performed on the mesial and distal side of both implants at each time point (ie, four measurements per time point). Two patients had valid measurements only for one implant. Four patients had all follow-up examinations of up to 5 years, of whom one had radiographs taken at the baseline that were not analyzable. One patient had follow-up measurements up to 4 years, four up to 3 years, and two had follow-up visits up to 2 years. Three patients were observed only for 1 year, and one patient dropped out after the T1 examination at 3 months postinsertion. The mean observation time before dropout was $1,088 \pm 630$ days (2.98 ± 1.7 years; range: 3.5 months to 5.2 years).

During the first 2 years after implant placement, a mean of 0.3 mm peri-implant bone loss was observed (Table 1). Until the 4-year follow-up, the total peri-implant bone loss had cumulated to a mean of 0.8 mm. Observations beyond this time point are only based on a rather small number of observations, so that a slightly increased bone level was found. In a linear trend model, allowing for separate slopes for each measurement site (side nested within implant, nested within patient), the mean loss of bone height was 0.17 mm per year (95% confidence interval: 0.09 to 0.24, $P < .001$).

The analysis was repeated by excluding interpolated results, and the reported findings were confirmed. In this analysis, the slope of individual loss in bone height was also 0.17 mm per year (95% confidence interval: 0.10 to 0.25, $P < .001$).

Peri-implant Probing Depth. At each time point, peri-implant probing depth was recorded for each implant. Most patients (14/16) had all necessary measurements

Table 2 Mean Peri-implant Probing Depth at Different Time Points

Time point	Patients with measurements (n)	Mean probing depth (mm)	Range (mm)
T0 (baseline)	15	1.87 ± 0.8	1–3
T1 (3 months postinsertion)	15	1.93 ± 0.8	1–3
T2 (1 year postinsertion)	16	1.75 ± 0.9	1–3
T3 (2 years postinsertion)	12	1.75 ± 0.8	1–3
T4 (3 years postinsertion)	9	2.22 ± 0.8	1–3
T5 (4 years postinsertion)	5	2.40 ± 0.9	1–3
T6 (5 years postinsertion)	4	3.00 ± 0.8	2–4

Table 3 Mean Peri-implant Plaque Index at Different Time Points

Time point	Patients with measurements (n)	Mean Plaque Index	Range
T0 (baseline)	15	0.60 ± 0.7	0–2
T1 (3 months postinsertion)	14	0.57 ± 0.6	0–2
T2 (1 year postinsertion)	14	0.55 ± 1.2	0–3
T3 (2 years postinsertion)	12	1.00 ± 1.2	0–3
T4 (3 years postinsertion)	9	1.85 ± 1.2	0–3
T5 (4 years postinsertion)	4	3.00 ± 0	3–3
T6 (5 years postinsertion)	3	1.50 ± 2.1	0–3

Table 4 Pearson Correlations (Weighted) Between Peri-implant Bone Change and Age, Cognitive Function, BMI, and Blood Markers

	Baseline bone level	Age	MMSE	BMI	Albumin	CRP	Folate	Vitamin B12	HB
Patients with measurements (n)	14	16	16	16	16	16	16	16	16
Slope : Pearson correlation	–0.655*	0.061	–0.563*	0.320	0.248	–0.272	0.013	0.561*	–0.517*
Significance (2-tailed)	.011	.823	.023	.227	.355	.308	.962	.024	.40

*Correlation is significant at the .05 level (2-tailed).

done during each examination. During the first 2 years of observation, the mean probing depth was stable at approximately 1.7 to 1.9 mm. At the third, fourth, and fifth year of observation, mean peri-implant probing depth increased constantly, reaching 2.22, 2.40, and 3.00 mm, respectively (Table 2).

Peri-implant Plaque Index. Peri-implant hygiene was assessed according to the Plaque Index proposed by Mombelli and coworkers at each set time point.¹⁸ Plaque Index (score 0 to 3) was recorded for each implant at four sites (mesial, vestibular, distal, and lingual). A majority of patients (10/16) had all the necessary measurements recorded at each time point. The mean Plaque Index was lowest during the first 2 years after implant placement (Table 3). It then increased to reach its peak (score 3) after 4 years of observation (Table 3).

Implant Mobility. Implants were tested for mobility at each set time point. To date, only one implant presented with mobility at the 3-year follow-up (T4), but was still in situ 2 years later. No other implants in the study lost stability.

Correlations Between Bone Level and Nutritional and Other Variables

The correlation between peri-implant bone level change and other variables was calculated for each patient. The variables tested were age, nutritional values (BMI and blood markers), and cognitive function (MMSE) (Table 4).

The progress of bone loss, expressed as a slope, was negatively correlated with the baseline bone level; this means that patients with the highest bone level at insertion, hence the deepest placed implants, lost the most peri-implant bone over time. Similarly, the slope was negatively correlated with the baseline MMSE, meaning patients with the best cognitive function lost the most peri-implant bone. The pattern was similar for the hemoglobin blood levels. In contrast, high levels of B12 at baseline were associated with less negative slopes of peri-implant bone loss.

In a separate multiple regression analysis, the only factor with a statistically significant association with the slope of peri-implant bone loss was the baseline bone level.

DISCUSSION

The challenge of studying a geriatric cohort of patients can clearly be seen in this study. Due to advanced age, more than 40% of the patients passed away during the follow-up. Severe health problems were a further major factor of passive patient dropout. Following the patients was also difficult, as some moved to long-term care facilities, and the organization of the follow-up visits was sometimes difficult. The logistics of such long-term observation at an advanced age must not be underestimated. The limited number of patients available for the 5-year follow-up visit compromises the power of the results.

Another limiting factor of this study is that it was unfortunately impossible to obtain radiographs at each set time period. Some patients were unable to have intraoral radiographs taken, as a high floor of the mouth following alveolar ridge atrophy precluded a correct placement of the film holder. When radiographs were nonetheless taken, this situation frequently caused the film holder to be highly inclined, and the resulting radiographs were consequently of poor quality and difficult to analyze. Over the many years of the study, some radiographs were misplaced and others were not correctly dated, and therefore, excluded from the analysis. Finally, some patients refused having radiographs taken, and others objected to leaving their home, rendering a radiographic examination impossible. Hence, in addition to the inherent problem mentioned earlier, only a limited number of measurements were available for analysis.

The results portrayed in this study show that the mean loss of bone height was 0.17 mm per year. An initial 1 mm of marginal bone loss during the first year after loading, followed by an annual loss of a maximum of 0.2 mm, is considered a successful treatment with implants.^{20–22} After 5 years, the total amount of peri-implant marginal bone loss should, therefore, not exceed 1.8 mm. In addition, the mean bone loss reported in this study is coherent with the results reported by other authors for younger cohorts.^{23–27} As could be expected, the mean peri-implant probing depth followed the same pattern as the mean bone loss. The mean peri-implant probing depth as well as mean Plaque Index scores varied with the observation time, being low and stable during the first 2 years after implant placement and later increasing every year. These results can be explained by the fact that maintaining oral hygiene in old patients becomes more and more difficult as age progresses and functional performance declines. Hence, treatment concepts for elderly patients should take a future functional decline into consideration, and IODs should be designed to avoid niches for food retention.

The influence of oral hygiene on the marginal peri-implant bone loss in old age is still unclear. Various nongeriatric cohort studies have shown that peri-implant hygiene impacts the development of peri-implant mucositis, and consequently, peri-implantitis, but these studies were not undertaken in a geriatric population.^{28–30} Aging increases the susceptibility to infections, due to a decline in the immune system, known as immunosenescence.³¹ The impact of these changes on peri-implant infection susceptibility in elderly patients has not yet been sufficiently studied.^{24,32} An increased amount of plaque around implants is indeed a common finding among elderly patients, but is surprisingly often accompanied by healthy peri-implant tissues and little or no loss of bone. At first sight, this clinical situation, often occurring over various years, would seem incompatible with a stable bone height. Olerud et al showed that nearly 40% of implant patients aged 65 years or older had high plaque scores, but this was clinically not correlated with bleeding scores indicating a peri-implant mucositis.³³ Given the absence of scientific evidence of the effect of biofilm on the peri-implant tissues, it seems nevertheless advisable to recommend a rigorous oral hygiene regimen to elderly patients, similar to younger implant patients.

Nutritional as well as mental state and other variables were comprehensively recorded during this study. Even if the number of patients and measurements was limited, and the peri-implant bone loss was very small in most patients, it was decided to analyze the correlation between peri-implant bone loss and the cognitive state as well as nutritional state to view the bone loss in a larger context. The only factor with a statistically significant association with the slope of peri-implant bone loss found in the multiple regression analysis was the baseline bone level. The results showed that the correlation was negative, meaning that the higher the baseline bone level, the more peri-implant bone was lost. The explanation for this result could be that some implants might have been initially placed slightly deeper inside the crest, and therefore, as remodeling of the bone occurred, the bone around the smooth implant collar was lost, thus accounting for a higher bone loss. Regarding the other tested factors, a statistically significant correlation was found only in the individual Pearson correlation test. Due to the small number of patients, the authors think that the correlations found are not clinically relevant. Hence, the results require careful interpretation, but they suggest that a reduced cognitive function and nutritional state are not a particular risk factor for an accelerated rate of peri-implant bone loss.

However, during the study, it was noted that some patients who became increasingly dependent were unable to handle the IOD, even if one would think that

a two-implant overdenture is technically easy to manage. The main reason was a decrease in hand force necessary to clip the overdenture into place. In these patients, the Locator attachments had to be replaced either by ball anchors with O-Ring attachments (Institut Straumann; Sid Dental, Angers), Titanmagnetics retention magnets (Steco-system-technik), or in one patient even by healing caps (Institut Straumann), in order to adapt the retention to the patient's ability to handle the prostheses. Hence, the authors would like to reinforce that implant therapy in elderly patients has to be considered not only from the implant survival and peri-implant bone level point of view, and that success criteria need to include denture management.³⁴ Patients receiving their implants at an advanced age, but also those who have received their implants earlier and have aged with them, need close monitoring concerning their denture management and oral hygiene performance. Access to dental care and backing off the technical sophistication of an IOD along with the patient's functional decline should therefore be continuously assured.

CONCLUSIONS

This study suggests that the placement of implants in very old dependent patients could be a viable solution for stabilizing inferior IODs, at least concerning implant survival and peri-implant health. However, other patient-centered outcome measures like patient satisfaction, chewing efficiency, cost effectiveness, and denture management might be relevant factors for clinical decision-making. Even with the high success rates portrayed in this study and the lack of scientific evidence concerning the impact of peri-implant hygiene in elderly patients, it seems important to closely monitor peri-implant health and denture handling in implant patients of an advanced age in order to adequately accompany them during their functional decline.

ACKNOWLEDGMENTS

The help of Dr Manfred Imsand in developing the study protocol and placing the implants is greatly acknowledged. This study was funded by the ITI foundation (grant no 458_2006). The authors declare no conflict of interest with respect to the authorship and/or publication of this article.

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