

Ten-Year Retrospective Follow-Up Study of the TiOblast™ Dental Implant

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ABSTRACT

Purpose: Long-term results in the clinical outcome of different implant systems, including high patient numbers and a long follow-up time, are rare. This retrospective study evaluated the cumulative survival rate of a self-tapping, cylindrical implant system with a conical implant-abutment connection after 10 years of prosthetic loading.

Materials and Methods: A total of 516 TiOblast™ implants (Astra Tech AB, Mölndal, Sweden) were placed in 108 patients. The patients were treated in the Department of Oral and Maxillofacial Surgery, Johannes Gutenberg University, Mainz, Germany, between September 1994 and May 2005. The main indications for implantation were the treatment of edentulous mandibles (74%) and partial edentulism (15%). Twenty-three implants were placed postradiation, and a further 64 implants were irradiated after insertion. In 153 implants, a bony augmentation was conducted prior to implantation.

Results: The in situ rate was 89.7% after an average implantation time of 108 months. Eighty-three patients with 403 implants were available for investigation. Seventeen patients with 76 implants have died since 1994. Absence of osseointegration ($n = 22$), peri-implantitis ($n = 18$), fracture of the implants ($n = 9$), failing of primary stability ($n = 2$), and implants next to tumors ($n = 2$) were the reasons of explantation in 26 patients. Under analysis with different implant success-assessment criteria, the success rate showed results from 76 to 89%.

Conclusion: With respect to the critical patient selection including a high number of patients with minor and major augmentations, the 10-year clinical use of the studied implant system showed acceptable results.

KEY WORDS: Astra Tech, dental implant, long term, retrospective, success-assessment criteria, 10 years, TiOblast™

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INTRODUCTION

The replacement of missing teeth with endosseous implants has become an integral part of modern dental health care. At present, there are far more than 100 different implant systems existing.¹ For all implant systems, longtime studies with high patient numbers are rare. For the standard self-tapping, cylindrical implant used in this study, several 5-year studies,^{2–6} and two publications containing a 10-year follow-up^{7,8} are available yet. In the first longtime study, a limited indication for implantation (edentulous patients) was investigated with a low patient number ($n = 33$)⁷ and, in the second study, a lower number of patients ($n = 40$) was operated and surveyed by a single surgeon only.⁸ To summarize, there is a lack of longtime data (>5 years) with high patient numbers ($n > 50$).

The implant system (AIS/Astra Tech AB, Mölndal, Sweden, Figure 1) was first tested in 1992 in clinical trials.⁷ The implants are made from commercially pure

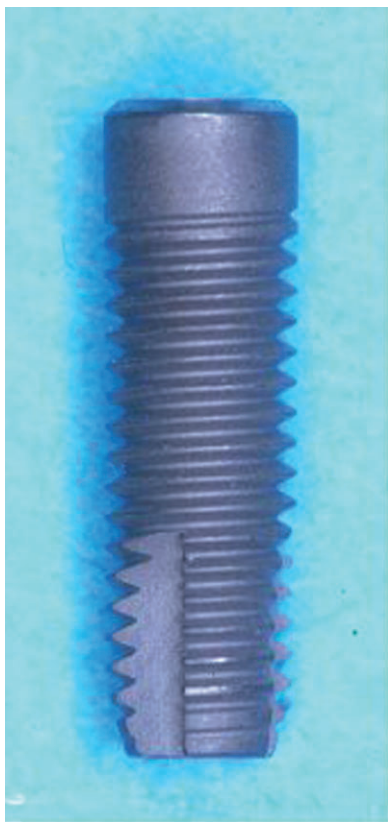


Figure 1 TiOblast implant (Astra Tech AB).

titanium, which is blasted with particles from titanium dioxide (TiO_2). They are screw shaped, surface enlarged, and equipped with a self-tapping anchorage. The connection between fixture and abutment is conical; the upper part of the abutment has a 20° angled cone. The surface is moderately rough and has an Sa value (average surface roughness parameter) of $1.10 \mu\text{m}$.^{9,10}

The aim of this study is an evaluation of the clinical longtime cumulative survival rate (CSR) and success rate of the TiOblast™ implant system.

MATERIALS AND METHODS

A direct continuation of the 5-year result of a study that has been conducted earlier³ was targeted. Between September 1994 and May 2005, 108 patients, 50 men and 58 women, received 516 implants. The patients were included in the study if they did receive a dental implant in the Department of Oral and Maxillofacial Surgery of the University of Mainz in the specified period. The mean age at implantation was 56.8 years (16–80 years). Two hundred eight implants were placed in the maxilla and 308 of the implants were used in the mandible. In the partially edentulous jaw, 135 implants were inserted.

Three hundred eighty implants were placed in edentulous jaws. One implant was used to substitute a single tooth loss at the front.

Five patients with a known tumor postradiation received 23 implants. Fifteen patients with 64 implants were irradiated after insertion. Three hundred sixty-three implants were inserted without osseous augmentation; in 115 implants, a graft from the iliac crest was taken, and in 38 implants, patients received a local bone graft. The implants differed in diameter (3.5/4.0 mm) and in effective length (8/9/11/13/15/17/19 mm).

A flowchart of patients, who were available for recall, or who were contacted via phone and completed the structured questionnaire, is shown in Figure 2.

Peri-implant late-time complications such as bleeding at the implant, recessive-atrophic changes, and hyperplasia of the mucosa were recorded. Mombelli's modified plaque index¹¹ and the peri-implant pocket depth in the mesial, distal, vestibular, and oral areas (millimeter) were measured. The Sulcus Bleeding Index¹² was determined as well as the extension of attached vestibular and lingual gingival. Furthermore, the clinical and mechanical degrees of loosening of the implant¹³ were defined by testing each individual implant after removing the screwed restorations. Radiography via orthopantomogram was performed at the time of examination. The up-to-date and the postoperative orthopantomogram were compared to evaluate the distance from the implant-abutment periphery to

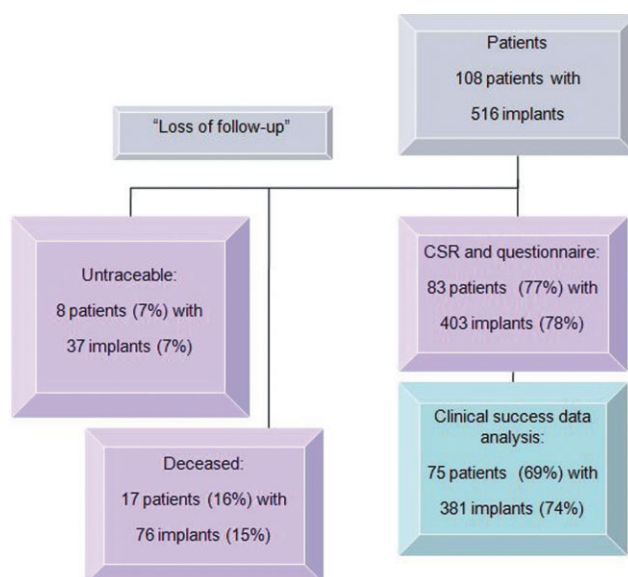


Figure 2 Flowchart of available patients with the respective number of implants. CSR = cumulative survival rate.

the apex of the implant. With limitations, this method has shown to be reliable for this purpose.^{14,15}

The results of the clinical examination were applied according to the definition of success of implantation according to Albrektsson et al.¹⁶ and Buser et al.¹⁷

The surgical procedure was performed in two stages. If indicated, the extractions were made at least 4 months before surgery. After a healing period of 3 to 6 months, the abutment was connected. Fixture and abutment installations were performed under local anesthesia. Nonresorbable sutures were used. The sutures were removed after 10 days.

For the statistical evaluation, implant-related data were calculated. A difference was considered to be significant when the *p* value was <.05. For the determination of the influence of different parameters, uni- and multivariate linear regression analyses were carried out. The Kaplan–Meier survival function was used for the description of survival rates.

RESULTS

Survival and Success Rate

Since 1994, 53 implants in 26 patients had to be removed. In consideration of all 516 inserted TiOblast implants, a CSR of 89.7% is calculated. The finding refers to an average length of stay of 91.2 months (7.6 years) and a maximal length of 138 months (11.5 years). The implant-oriented survival rate according to Kaplan–Meier showed a 10-year survival rate of 87.7% (Figure 3, Table 1). In the preprosthetic phase, 21 implants were lost. Nineteen were healing into the connective tissue only, and two were without primary stability. Reckoning the phase of secondary loss, 32 had to be explanted. Eighteen implants were lost because of a peri-implantitis. Nine implants broke. Three became loose and two were near of tumorous tissue. This sums up to a loss of 50 implants due to biologic and three implants due to technical complications (Figures 4 and 5). In regard to the assessment of success, the criteria based on Albrektsson et al.¹⁶ as well as the criteria based on Buser et al.¹⁷ were surveyed. The criteria of Albrektsson displayed a successful assessment in 76% of the implants, and the definition of Buser resulted in a success rate of 89%.

Clinical Follow-Up

The observed results in 75 patients with 381 implants were as follows. Regarding the peri-implant late-time

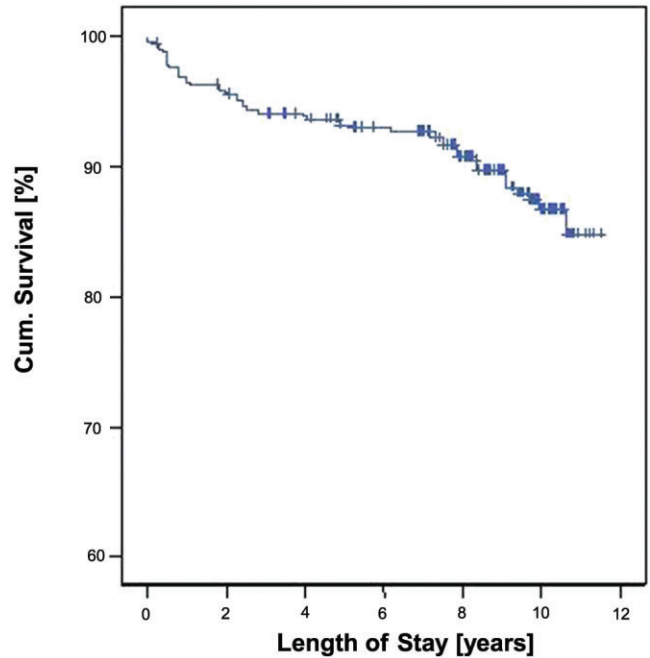


Figure 3 Cumulative survival rate according to Kaplan–Meier (*n* = 516).

complications, 63% of the examined implants were clinically inconspicuous. In 23% of the implants, threads are visible, which are attributed to the bone loss and are accompanied by an otherwise healthy, nonbleeding mucosa (“recessive-atrophical changes”). Ten percent showed an increased affection to bleed, and 4% of the implants demonstrated a hyperplasia of the oral mucosa. The plaque index according to Mombelli

TABLE 1 Implant Survival in Regard to the Length of Stay, Implants at Risk, and Lost Implants

Implant Survival (years)	Number of Survival at the Beginning	Implants at Risk	Lost Implants
0	516	515	17
1	496	492	5
2	482	479	8
3	468	448	1
4	426	411	3
5	393	382	1
6	370	364	1
7	356	333	7
8	302	258	3
9	210	165	6
10	113	66	1
11	17	9	0

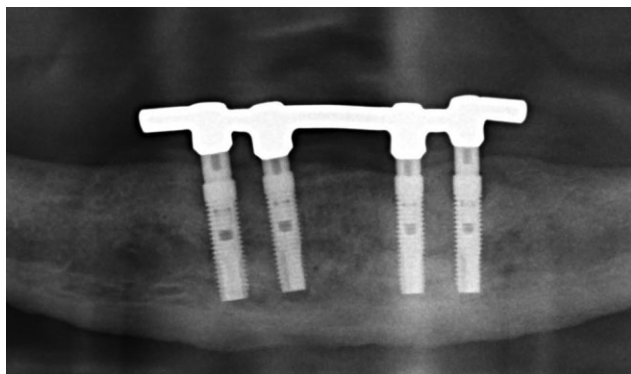


Figure 4 Panoramic X-ray: 10-year result of a patient wearing four TiOblast implants in the edentulous mandible.

indicated an average value of 1.2. Therefore, 66% of the patients exhibited a satisfactory degree of oral hygiene (grades 0 and 1). The frequency distributions of implants with no plaque at all (grade 0), strong plaque colonization (grade 2), and very strong plaque colonization were equivalent to each other. The average depth to probe was in the mesial (3.1 mm), distal (2.9 mm), vestibular (2.6 mm), and oral (3.0 mm) areas. The deepest measure was in 62% of the probed implants smaller than 4 mm. The tendency to bleed reached an average level of 0.7. A high tendency to bleed could only be observed in exceptional cases.

While measuring the attached gingiva, an average vestibular expansion of 2 mm could be found. The mean value of the oral expansion was 2.4 mm. Altogether, 48% of the vestibular and 39% of the oral readings showed an expansion of less than 1 mm.

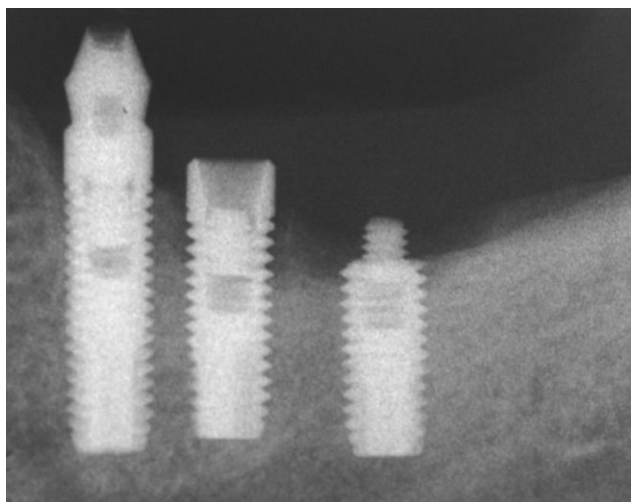


Figure 5 Three implant-related technical complications in one patient: fracture of implant, abutment, and screw.

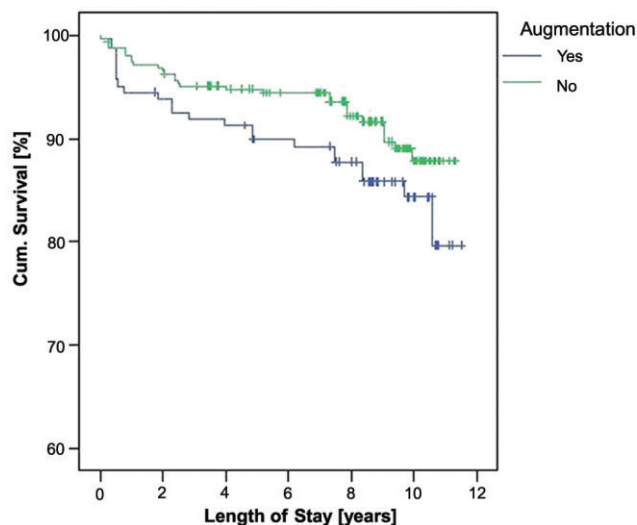


Figure 6 Survival rate of the implants in regard to a previous augmentation.

In 381 implants, the marginal bone level could be measured by using X-ray pictures. The mean marginal bone loss was 2.6 mm (min: -2; max: 10.77; SD: 2.3) after an average length of stay of 9.2 years. For the vertical cutback of bone, in 79% of the implants, an average value of up to 4 mm could be measured. Without augmentation, the mean marginal bone loss added up to 2.4 mm (min: -1.3; max: 10.77; SD: 2.15). With augmentation, the mean marginal bone loss was 2.7 mm (min: -2; max: 9.6; SD: 2.6). Between the different augmentation techniques, no statistical significant difference could be found.

Statistical Analysis

Augmentation, length of the implant, radiation, teeth status, and the age at the moment of the implantation had an influence on the length of stay of the implants ($p < .05$). Without augmentation, the survival rate was at 87.7% and therefore higher than with a conducted augmentation (Figure 6). The 10-year survival rate for implants with the length of 11 and 13 mm was 81.3%. This is significantly lower than the rate of 91.9% that was found for longer implants. For short implants (8 mm/9 mm), the analysis of the length of stay showed a dwelling rate of 88.2% after 10 years.

In the same manner, thinner implants demonstrated, in comparison to thicker implants, an insignificant disadvantage (Figure 7).

With a rate of 89.4% after a length of stay of 10 years, the total edentulous jaw showed a better outline of

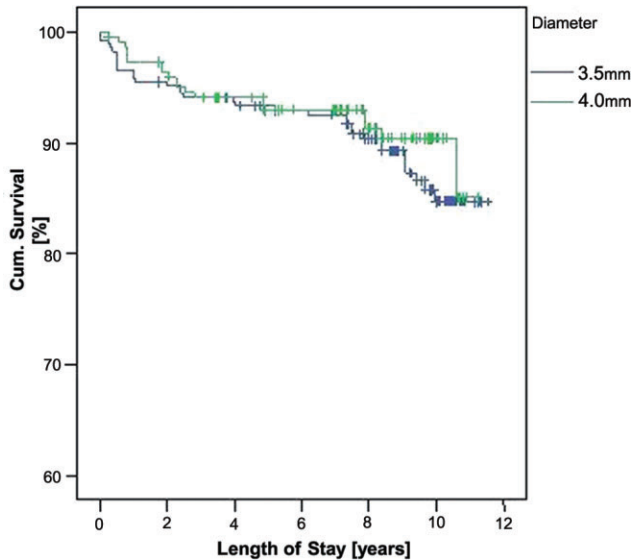


Figure 7 Survival rate of the implants according to Kaplan–Meier subject to the diameter of the implant ($n = 516$).

the implants (89.4%) than the partial edentulous jaw (81.6%) as shown in Figure 8.

Concerning the survival rate of the jaw, no significant difference between the length of stay in the mandible or maxilla could be detected ($p = .679$). A 10-year survival rate of 87% in male patients compared with 86% in female patients could be found. For nonsmokers, between the 5th and the 10th year, the study results advised a rate of loss of 6%. Smoking patients showed a rate of loss of 13% (Figure 9).

The multivariate Cox regression confirmed radiation ($p = .001$) and the patients' age at time of implan-

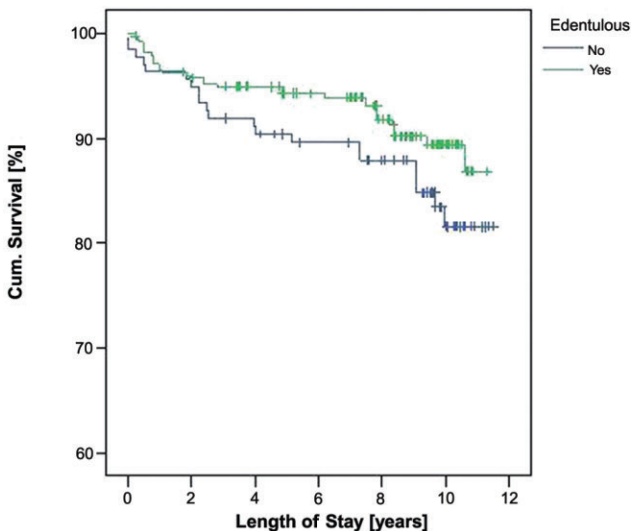


Figure 8 Survival rate according to Kaplan–Meier in regard to the edentulousness ($n = 516$).

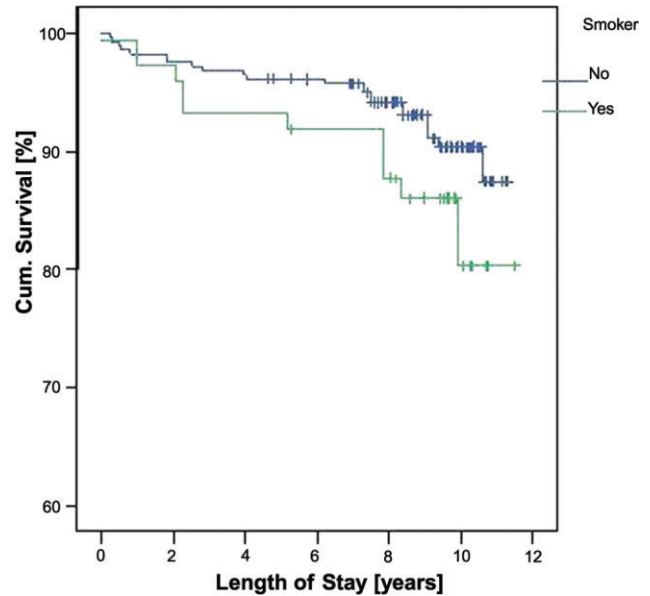


Figure 9 Survival rate according to Kaplan–Meier smoker versus nonsmoker ($n = 359$ implants in 76 patients).

tation ($p = .004$) to be influencing factors. Interestingly, in this study, the risk of losing an implant in patients without radiation in the area of the head and the neck was higher than in patients with radiation. In comparison of patients under 30 years, patients of the age between 30 and 60 years have a 71% higher risk for losing the implant. Compared with patients of the age of more than 60 years, the risk is 39% lower.

DISCUSSION

One important aspect in long-term data in dental implants is the possibility to compare data between different studies. Despite of all restrictions, the method of implant-related survival calculation is mostly available in other studies^{18,19} and therefore appropriate for comparison among different studies. In the present study, after a length of stay of 10 years, the CSR is 86.7%. This exceeds the average 10-year survival rate of 79.9% as calculated in a review.²⁰ Although, the very high implant survival of nearly 97% as in the study of Schulda and Steveling⁸ could not be shown. However, our study included a high percentage of implants in combination with augmentation procedures and therefore a critical patient selection.

The success rates according to Albrektsson et al.¹⁶ and to Buser et al.¹⁷ were 76 and 89%, respectively. By the way, it has to be kept in mind that the Buser criteria do not include any bone loss parameter, and early bone

loss is one of the most important ways to differentiate between a surviving and a successful dental implant. Therefore, the discrepancy underlines the important influence of different criteria of success, showing the importance of objective outcome criteria for clinical trails. One further main point of criticism to this study and its survival and success data is its retrospective character. But, in view of the long time, the "loss of follow-up" seems minor.

On the other hand, it should be noted, as an advantage of the present study, that there is a lack of implant-related longtime studies in general.

The chance of losing an implant seems to decrease in the course of time. In detail, in the first 2.8 years, the chance to lose an implant seems to be higher. After this time, a linear decrease of the risk could be shown.

The collective of patients with radiation in this study consisted of 19 persons with 87 implants with a 10-year survival rate of 97.7%. These findings are confirming the positive trend of the length of stay of dental implants in a radiated jaw that could also be shown in the 5-year study.³ Grötz et al.²¹ compared several implant systems and could only evaluate a rate of survival of 72% after 6 years of stay in an irradiated jaw. Yerit et al.²² found a lower implant survival in irradiated mandibles. The surprisingly high survival rate of implants in patients after head and neck irradiation in the present study should be subject to further investigation. Reasons for those data can be implant-specific factors or a bias because of the small group and/or the patient selection.

Interestingly, smaller and thinner implants did not show a significantly lower survival rate compared with normal dimension implants (84.7% [3.5 mm] and 90.4% [4 mm] survival rates), which is concordant to former studies.²⁰

Aghaloo and Moy²³ concluded that the survival of dental implants lessens if a bony augmentation was done. This could be seen in the study as well. One hundred sixty-four implants were inserted after augmentation. They showed an elevated risk of loss mostly because of peri-implantary incidents. A significant difference of the mean marginal bone loss between implants inserted with or without prior augmentation could not be seen.

In this long-term study, the risk of implant loss for nonsmokers and smokers is almost similar in the first 2 years, whereas a negative effect of nicotine on survival of

implants in smokers was seen in the later years. These findings cover up data from the literature. In the early phase, the chance of osseointegration for smokers is not less than for nonsmokers²⁴ in contrast to a higher loss rate for the 10-year analysis.²⁵ The meta-analysis of Hinode et al.²⁶ as well as Strietzel et al.²⁷ revealed the significant relationship between smoking and the risk of osseointegrated implant failure as well.

According to our study, the prognosis of seniors is not worse than the prognosis of a younger collective of patients. Nitschke and De Baat²⁸ as well as Bryant and Zarb²⁹ had the same findings in their studies. This indicates that the patients' age cannot be made responsible for failures in implantation. Especially for patients with an edentulous jaw, which can be found frequently in older patients, a better prognosis for implants could be indicated (10-year survival rate of 89.4%).

The testing of the plaque index showed a good oral hygiene for 2/3 of the implants (grades 0 and 1), which is the same range like in the 5-year study. This indicates that no change in oral hygiene attitudes of the patients is seen.

In 59% of the implants, a provocation of peri-implantary bleeding was possible. The bleeding was predominantly weak (83%, grade 1). Considering the iatrogenic-induced damage of the tissue,³⁰ it seems to be more reasonable to count only a reaction of grades 2 and 3 as a proof of a higher affection to bleed. Compared with the 5-year analysis, a gingival deficit of 22% in the vestibular area (67% before) and an oral deficit of 23% (80% before) could be measured. For 62% of the implants, a maximal depth less than 4 mm of the teeth pocket was registered. This value is significantly lower than the achievement of the 5-year analysis. Possibly, the limited comparability of different depths of probing in different sessions of examination without basing point is the reason for this discrepancy.³¹ In almost the same manner as the plaque index, the bleeding index and the loss of fixed gingival were increased. This could also be a real loss of the attachment. By all means, these values emphasize the need of an assiduous measurement.

As both the manual testing and the use of the Periostest device for signs of implant loosening did not show any notable result, it is advisable to question this method. In accordance to international findings, changes in the peri-implantary bone level are an essential parameter to describe the actual state of the implant and the success of implantation.³² In this study,

panoramic radiographs were consulted. The potential to evaluate changes and the possibility to achieve accurate and reproducible values on the basis of radiographs is a reliable method^{14,15} with some limitations. Based on the two-dimensional evaluability, only the mesial and distal areas of the implant can be interpreted. While looking at the peri-implantary loss of bone in 73 to 84% of the implants, a horizontal component can be counted.³³ This delimitates the quantification of the sole vertical intrusion. In the 5-year study, a bone loss of 1.5 mm was found, which preceded to 2.6 mm in the present study. These results indicate a physiological increment of the average bone degradation. A bone loss of less than 0.4 mm or even a new bone apposition after 10 years of clinical use that Schulda and Steveling⁸ found could not be seen in this study.

CONCLUSION

The comparison of the survival rate in this study with the results of aftercare examinations of other implant systems indicates that an acceptable 10-year survival rate for the studied system is documented. This applies to the partial as well as to the fully edentulous jaw and should be interpreted with respect to the critical patient selection in this study (high rate of major and minor augmentations). With the patient selection examined, the prognosis of success shows an acceptable long-term effect.

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