Clinical Performance of Wide-Body Implants with a Sandblasted and Acid-Etched (SLA) Surface: Results of a 3-Year Follow-up Study in a Referral Clinic

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Purpose: *The aim of this study was to evaluate the 3-year success rates of wide-body implants with a regular- or wide-neck configuration and a sandblasted, large grit, acid-etched (SLA) surface.* ***Materials and Methods:*** *A total of 151 implants were consecutively placed in posterior sites of 116 partially edentulous patients in a referral clinic at the School of Dental Medicine, University of Bern. All implants were restored with cemented crowns or fixed partial dentures after a healing period of 6 to 8 weeks (for implants placed without simultaneous bone augmentation) or 10 to 14 weeks (for implants with simultaneous bone augmentation). All patients were recalled 36 months following implant placement for a clinical and radiographic examination.* ***Results:*** *One implant failed to integrate during healing, and 11 implants were lost to follow-up and considered dropouts. The remaining 139 implants showed favorable clinical and radiographic findings and were considered successfully integrated at the 3-year examination. This resulted in a 3-year success rate of 99.3%. Radiographic evaluation of 134 implants indicated stability of the crestal bone levels: During the study period, the crestal bone level changed less than 0.5 mm for 129 implants.* ***Conclusion:*** *Successful tissue integration was achieved with wide-body implants with a regular or a wide-neck configuration and an SLA surface with high predictability. This successful tissue integration was well maintained for up to 3 years of follow-up.* (Case Series) (More than 50 references) Int J Oral Maxillofac Implants 2007;22:631–638

Key words: *clinical trials, dental implants, wide-body implants, wide-neck implants*

In the last 2 decades, the utilization of endosseous implants for the rehabilitation of completely or partially edentulous patients has become the standard of care in dentistry. This significant progress in implant dentistry is based on the concept of osseointegration first described by the 2 research groups of Brånemark[1,2] and Schroeder.[3,4] In the past 25 years, numerous prospective long-term studies have documented a high efficacy and predictability of osseointegrated implants. Various implant systems are now available on the market, and good long-term documentation is available for several (eg, the Brånemark System, the Straumann Dental Implant System, the Osseotite Implant System, and the Astra Tech Implants Dental System). For these systems, prospective long-term studies have exhibited survival and success rates exceeding 90% at 5 and 10 years of follow-up.[5–18]

In the late 1980s and early 1990s, a series of studies was initiated to evaluate the possibility of using alternative titanium implant surfaces to achieve improved bone-implant contact (BIC), thereby allowing shorter healing periods before loading. A histometric study by Buser et al[19] evaluated 5 different titanium surfaces in long bones of miniature pigs and demonstrated greater bone apposition to a sandblasted, large-grit, acid-etched (SLA) surface than to a titanium plasma-sprayed (TPS) surface and other fine-textured or electropolished surfaces. A biomechanical study by Wilke et al[20] tested removal torque values (RTVs) of unloaded titanium implants with various surface characteristics in the tibia of sheep. The study demonstrated that the RTVs for the SLA surface clearly

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exceeded the mean RTVs of polished or fine-textured implant surfaces during the course of the study period. The advantages of the SLA surface compared with the TPS surface during the initial healing period were then confirmed in a histometric study in the canine mandible[21] and in a biomechanical study measuring the RTVs of 8-mm implants in the maxillae of miniature pigs.[22] In the latter study, implants with an SLA surface demonstrated a mean RTV approximating 140 Ncm at 4 weeks of healing. The osteophilic properties of the SLA surface were also confirmed in a series of in vitro studies examining various titanium surfaces in tissue cultures with osteoblastlike cells.[23–26] Based on these promising results, a prospective clinical study was initiated examining dental implants with an SLA surface placed in posterior sites without bone deficiencies. The study was performed under well-controlled conditions using strict inclusion criteria. All surgical procedures performed by the same highly experienced implant surgeon (DB). The concept of early loading was tested using a healing period of 6 weeks prior to loading (rather than the traditional 3 to 6 months[27,28]). The results were analyzed and published both as part of a multicenter study[29] and later individually in reports of up to 5 years of follow-up.[30,31] At 5 years, the success rate was 99% using strict success criteria.

The goal of the present study was to evaluate the clinical performance of wide-body implants with an SLA surface routinely used in a referral clinic at the School of Dental Medicine, University of Bern. All treated patients were referred by their private dentist to the Department of Oral Surgery and Stomatology for implant surgery. Standard inclusion criteria were applied. The surgical procedures were performed by postgraduate students and experienced senior surgeons, and the prosthetic treatment and follow-up were performed in a private office. The tested hypothesis was that SLA wide-body implants would achieve success rates similar to those reported in the previous prospective study performed under strict, well-defined conditions.[30,31]

MATERIALS AND METHODS

Patient Selection

Between February 1998 and May 2001, 116 partially edentulous patients were consecutively treated with Straumann wide-body implants (Institut Straumann, Basel, Switzerland) with a regular-neck or wide-neck configuration and an SLA surface. All patients were referred by their private dentist to the Department of Oral Surgery and Stomatology at the University of Bern for implant therapy. The group comprised 56 men and 60 women with a mean age of 55.7 years (range from 23 to 88 years). Patient selection excluded candidates with severe systemic health problems but included those with bone defects requiring local bone augmentation and smokers (5 light smokers [1 to 10 cigarettes per day] and 11 heavy smokers [11 cigarettes per day or more]). In these 116 patients, a total of 151 implants were placed. Of those, 75 implants (46 patients) were placed in distal extension situations, 56 implants (51 patients) in single-tooth gaps, and 20 implants (19 patients) in extended edentulous gaps.

Clinical Procedures

The surgical procedures were carried out under local anesthesia (Ultracain DS forte; Aventis Pharma, Zürich, Switzerland). A low-trauma surgical technique was employed. All patients received premedication with atropine (0.5 mg intramuscularly) and perioperative antibiotic prophylaxis beginning 2 hours prior to surgery (Aziclav, 2 × 1 g per day for 6 days, Spirig Pharma, Egerkingen, Switzerland). A total of 151 implants with an SLA surface were placed in various sites (Tables 1 and 2) by 7 different surgeons using a standardized surgical procedure. One hundred twenty implants (79.5%) were placed by 2 experienced senior surgeons, while 31 implants (20.5%) were placed by postgraduate students in oral surgery. The postgraduate students always had the assistance of an experienced instructor during surgery as a means of quality assurance. Details on presurgical evaluation, surgical techniques, and postoperative treatment have been previously published.[28,32,33] More than half of the implants (86 implants in 69 patients) were placed without an augmentation procedure. Sixty-five implants (47 patients) needed the following bone augmentation procedures: simultaneous bone augmentation using guided bone regeneration (29 implants, 21 patients), simultaneous internal sinus grafting (osteotome technique; 5 implants, 5 patients), simultaneous external sinus grafting (window technique; 10 implants, 6 patients), and external sinus grafting and/or lateral ridge augmentation using a staged approach (21 implants, 15 patients).

After a healing period of 6 to 8 weeks (for implants inserted without augmentation) or 10 to 14 weeks (after local bone augmentation), prosthetic rehabilitation was initiated by the referring dentists in their private offices. Ninety-five implants were restored with a single crown, 29 were restored with splinted single crowns, and 20 served as abutments for implant-supported fixed partial dentures. For 4 patients with a total of 6 implants, the prosthetic restoration could not be evaluated. One implant failed during the healing period.

Table 1 Distribution of Dental Implants (n = 151)									
Maxilla	**2(17)**	**3(16)**	**4(15)**	**5(14)**	**11(24)**	**13(25)**	**14(26)**	**15(27)**	**Total**
Implants	0	6	10	4	4	12	8	0	44
Mandible	**31(47)**	**30(46)**	**29(45)**	**28(44)**	**21(34)**	**20(35)**	**19(36)**	**18(37)**	**Total**
Implants	11	33	5	1	4	9	34	10	107

Tooth numbering is shown according to the Universal system, with numbers according to the System Federation Dentaire International (FDI) classification system in parentheses.

Follow-up Protocol

All patients were recalled 36 months after implant placement for clinical and radiographic examination. The following parameters were assessed, as described for previously published long-term studies with Straumann implants[34]:

- Modified Plaque Index (mPI) at 4 aspects around the implants.[35] For each implant, an mPI score was determined based on the average of the 4 obtained values. If there was no plaque, a score of 0 was given; a score of 1 indicated that plaque was only recognized by running a probe across the smooth marginal surface of the implant; 2, that plaque could be seen by the naked eye; and 3, that there was an abundance of soft matter.
- Modified Sulcus Bleeding Index (mSBI) at 4 aspects around the implants.[35] For each implant, an mSBI score was calculated based on the average of the 4 obtained values. If there was no bleeding when a periodontal probe was passed along the gingival margin adjacent to the implant, a score of 0 was given. A score of 1 indicated that bleeding was visible in isolated spots; 2, that blood formed a confluent red line on the margin; and 3, that there was heavy or profuse bleeding.
- Probing depth (PD, in mm) at 4 aspects around the implants. For each implant, 1 PD value was calculated based on the average of the 4 obtained values.
- The distance in millimeters between the implant shoulder and the mucosal margin (DIM) at 4 aspects around the implants.[28] A submucosal implant shoulder was recorded with a negative DIM value.
- Clinical attachment level (AL, in mm) at 4 aspects around the implants (AL = PD + DIM).
- Mobility. This was tested manually and evaluated with the Periotest (Siemens, Bensheim, Germany) procedure. The tip of the handpiece was applied perpendicularly to the facial surface of the crown, which remained in place, if possible, at a distance of 3 mm from the implant shoulder, with the patient seated in a vertical position. Crowns were not removed during testing of splinted implants and implants supporting fixed partial prostheses. Measurements were repeated until the same score was obtained 3 times.
- The distance between the implant shoulder and the first visible BIC (DIB) was measured (in mm) at the mesial and distal aspect of each implant using periapical radiographs with the long-cone technique, as described in previous publications.[28,36] All radiographs were examined by the same experienced examiner (HH). For each implant, 1 DIB value was calculated based on the average of the mesial and distal values. The 36-month DIB values were compared with the values at implant insertion to evaluate the crestal bone changes around the implants over the 36-month period (ΔDIB).

Table 2 Distribution of the 151 Implants According to Implant Type and Jaw				
			Total	
Implant type/length	**Maxilla**	**Mandible**	**n**	**%**
Wide neck (6.5 mm)				
6 mm	–	–	–	
8 mm	1	6	7	4.63
10 mm	6	29	35	23.18
12 mm	1	15	16	10.60
Regular neck (4.8 mm)				
6 mm	1	8	9	5.96
8 mm	7	20	27	17.88
10 mm	23	26	49	32.45
12 mm	5	3	8	5.30
Total	44	107	151	

Based on clinical and radiographic findings, each implant was classified as either successful or unsuccessful using the same success criteria as in previous prospective studies.[28] Success was defined as follows:

1. Absence of persistent subjective complaints, such as pain, foreign body sensation and/or dysesthesia
2. Absence of peri-implant infection with suppuration
3. Absence of mobility
4. Absence of continuous radiolucency around the implant

Statistical Analysis

First, all data were analyzed with descriptive methods using box plots and quantile quartile (QQ) plots (SPSS 11.0; SPSS Schweiz, Zürich, Switzerland). As they were normally distributed, parametric tests were performed. To take possible dependencies into account when multiple implants were inserted in the same patient, 1 mean value comprising all implants in the patient in question for the radiographic parameters (DIB) was calculated for further statistical analysis. The *t* test was applied to analyze a possible statistical difference between the DIB values at 36 months and those at implant insertion (0 mo). Analysis of variance (ANOVA) was employed to search for statistically significant factors influencing bone remodeling over time. The dependent variable was crestal bone changes around the implants over the 36-month period (ΔDIB), and the independent variables were implant location (maxilla/mandible), implant length/type, smoking habits (smoker/nonsmoker), augmentation procedure (no augmentation/any type of augmentation), and experience of the surgeon (experienced senior surgeons/postgraduate students). When using multiple comparisons, the *P* values were corrected using the Bonferroni adjustment procedure. The significance level chosen for all statistical tests was $P < .01$.

RESULTS

Healing Period

Following surgery, the patients reported no or only moderate discomfort at the surgical sites. During healing, 1 implant in the left maxilla developed instability due to a peri-implant infection with suppuration; it was subsequently removed. Another implant was placed in the same region; tissue integration of that implant was free of complications. Clinically, the remaining 150 implants showed no signs of peri-implant infection or detectable mobility throughout the healing period. After 6 to 8 weeks (for implants inserted without augmentation) or 10 to 14 weeks (following local bone augmentation procedures), a clinical and radiographic examination was scheduled at the Department of Oral Surgery and Stomatology. As all implants demonstrated favorable clinical results, prosthetic rehabilitation was initiated at the referring private dentists' offices.

36-month Follow-up

All 115 referred patients were recalled 3 years after implant placement for clinical and radiographic examination. Six patients (11 implants) did not attend the 36-month follow-up visit: 4 patients were referred from another region in Switzerland and did not want to come to Bern for the follow-up examination, and 2 patients had moved to unknown locations. These 6 patients were considered dropouts and removed from further study analysis. This corresponds to a dropout rate of 5.2%. The clinical and radiographic findings in 109 patients with a total of 139 dental implants are thus reported.

Gingival Parameters and Implant Mobility. The mean mPI for these 139 implants at the 36-month examination was 0.26 (95% CI: 0.20 to 0.32). The peri-implant soft tissues revealed little tendency to bleed following probing and were clinically healthy. The mean mSBI was 0.6 (95% CI: 0.52 to 0.69). The mean PD was 3.87 mm (95% CI: 3.69 to 4.05 mm). The mean DIM score at the 36-month examination was –1.13 mm (95% CI: –1.33 to –0.94 mm), indicating a subgingival implant shoulder. The addition of PD and DIM resulted in the AL. The mean AL at the 36-month examination was 2.79 mm (95% CI: 2.66 to 2.91 mm). The Periotest scores for the 139 osseointegrated implants ranged from –8 to +3, with a mean value of –3.24 (95% CI: –3.61 to –2.87).

Radiographic Findings. There were no signs of continuous peri-implant radiolucencies throughout the 3-year observation period of (Figs 1a and 1b). For 5 implants in 5 patients, a correct radiographic DIB analysis was not possible because of overlapping neighboring teeth; thus, only 134 implants were radiographically analyzed. The frequency analysis for 98 implants exhibited a DIB between –0.5 mm and +0.5 mm, which corresponds with a bone loss or bone gain of less than 0.2 mm per year (Fig 2). One implant demonstrated a bone gain of more than 0.5 mm, whereas 35 implants showed a bone loss of more than 0.5 mm. At the 3-year examination, the mean DIB, after adjusting for possible dependencies of multiple implants in the same patient, was 2.85 mm (standard error of the mean [SEM] ± 0.064 mm) for the 104 included patients. A mean value of 2.52 mm was found at implant insertion (SEM ± 0.056 mm). The increase of the mean DIB of 0.33 mm between implant placement and the 3-year examination was statistically significant ($P < .001$), although clinically there was no implant with progressive bone loss over the 3-year period. ANOVA to detect important factors influencing crestal bone changes around the implants over the 36-month period revealed no statistically significant results for implant location (maxilla/mandible), implant length/type, smokers/nonsmokers, experience of the surgeon, or use of augmentative procedures.

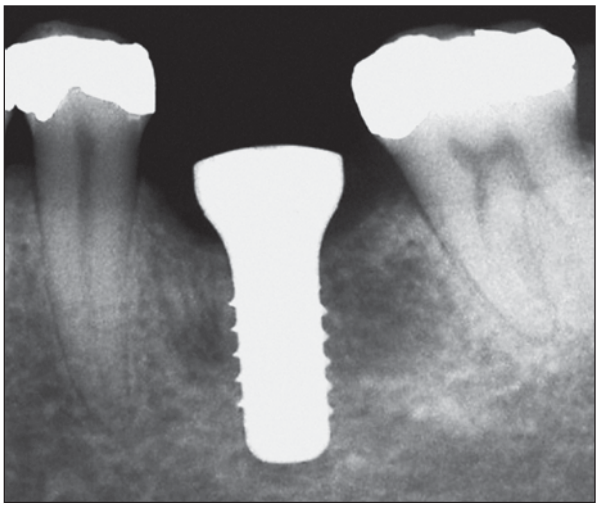


Fig 1a Postoperative radiograph of a wide-neck implant (10 mm length) in the first molar position in the left mandible of the same female patient.

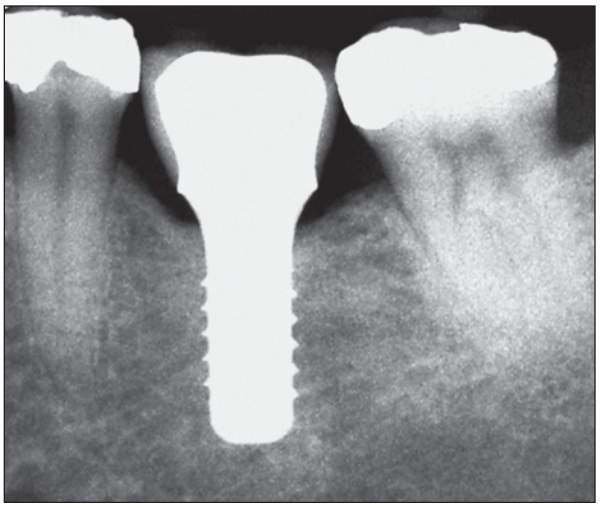
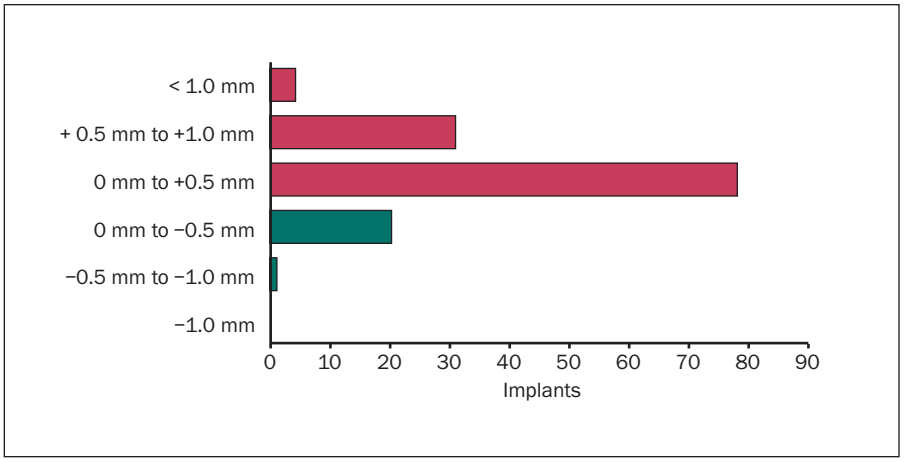


Fig 1b The 36-month periapical radiograph demonstrates normal bone structures around the implant without signs of periimplant radiolucencies.

Fig 2 Gain and loss of bone around 134 implants using the ΔDIB values.



Survival and Success Rates

At the end of the 3-year observation period, only 1 implant had been lost; that loss, which occurred during the healing period, was considered an early failure. Six patients (11 implants) did not attend the 3-year examination and dropped out of the study. Summarizing the clinical and radiographic results, 139 implants were considered successfully integrated at the 3-year examination using well-defined success criteria, resulting in a 3-year survival and success rate of 99.3%.

DISCUSSION

In recent years, numerous efforts have been made to simplify clinical procedures and thus make implant therapy more attractive for potential patients. One of these efforts has been a general reduction in the length of the healing period through the use of new titanium surfaces. Albrektsson et al[37] recognized early on that the implant surface has an important influence on osseointegration. In the late 1980s, several research groups started to examine new titanium surfaces and focused on subtractive techniques for altering the surface such as sandblasting and/or acid etching.[19–22,38–41] These experimental studies demonstrated better bone integration with the new titanium surfaces compared with machined titanium surfaces. The success rates up to 5 years in clinical studies examining titanium implants with a sandblasted and acid-etched surface in various indications for early loading at 6 weeks are reported to be around 99%.[29–31,42,43] Cochran et al[29] reported the results of an international multicenter study examining titanium implants with the SLA surface in various clinical situations for early loading at 6 weeks with up to 2 years of follow-up. Of 383 placed implants, 3 failed

during the healing period, resulting in an early failure rate of 0.8%. During follow-up, no additional implants failed or demonstrated signs of infection or implant mobility. Similar data were reported in a recent prospective 5-year follow-up study.[31] From a total of 104 implants initially inserted in posterior sites of 51 partially edentulous patients in this study, 1 implant failed to integrate during healing, and 3 implants were lost to follow-up and considered dropouts. The remaining 100 implants were considered successfully integrated, resulting in a 5-year success rate of 99%.

In a recent retrospective study, the indications for implant therapy in a referral clinic were analyzed between 2000 and 2002.[44] During these 3 years, a total of 737 patients received 1176 screw-type implants with the SLA surface. The most frequently inserted implant type was the standard screw (4.1 mm diameter), accounting for 53.8% (633 implants) of all implants placed in this study. The second and third most frequent implant types were wide-body implants (4.8 mm diameter) with a regular-neck (4.8 mm) or a wide-neck (6.5 mm) configuration, accounting for 34.9% of all inserted implants. These wide-body implants were mainly used in posterior sites to replace premolars and molars. Implants with a reduced diameter (3.3 mm) were only placed in 7.6% of all cases. This analysis demonstrates the importance of implants with a wide diameter in daily clinical practice and the need to know more about the long-term results of these implant types.

In the present study, the examined gingival parameters around wide-body implants demonstrated good overall gingival health at the 3-year follow-up, as documented by low mPI and mSBI scores. The peri-implant soft tissues seemed stable over time. The mean values obtained are comparable with previously published 3-year prospective studies with osseointegrated implants.[45–48] In addition, all inserted implants revealed ankylotic stability in the jawbone throughout the observation period, and mobility was never detected.

In the present study, no signs of continuous peri-implant radiolucency were observed, which confirmed ankylotic stability of all 139 implants. However, for the long-term follow-up of implants, the observation of bone crest levels is considered more important.[49] For Straumann implants, calculation of the distance from the implant shoulder to the first bone-implant contact, called DIB, has been used in previous studies.[28,36] This method is appropriate to follow changes of peri-implant bone levels over time by examining the DIB between 2 timepoints. In the present study, the mean DIB from 0 to 36 months was 0.33 mm, indicating good overall stability of the bone crest levels, although the *t* test was statistically significant for the DIB values at the 2 timepoints analyzed. This is further supported by the finding that the mean DIB value after implant surgery was 2.52 mm. This means that the SLA surface was positioned slightly below the crest at implant surgery, since the height of the machined implant neck measures 2.8 mm. At the 3-year examination, the mean DIB value was 2.85 mm, indicating that the bone had leveled off almost exactly at the border between the SLA surface and the machined neck.

The value of the mean DIB, however, is limited, since implants exhibiting bone loss are compensated by implants with bone gain. This can be documented with a frequency analysis, as in the present study. This analysis demonstrated for 129 implants a DIB between –0.5 mm and +0.5 mm. One implant had a bone gain of more than 0.5 mm, whereas 4 implants yielded a bone loss of more than 1.0 mm. A similar pattern of the frequency distribution has been reported for 3- and 5-year data on implants with the SLA surface[30,31] and recently for 5-year data on 61 implants in augmented bone.[50] In the present study, bone gain or bone loss was not influenced by the position of the implant in the maxilla or mandible, implant length or type, smoking status of the patient, type of augmentative procedure, or the experience of the surgeon.

A retrospective clinical study of wide-diameter implants used in posterior edentulous areas in the maxilla and mandible reported a survival rate of 89.8% (8 losses of 78 inserted implants) after a mean time of 33 months in situ.[51] In a retrospective analysis on the influence of variations of different implant diameters on the clinical outcome 3 to 5 years after implant insertion, Ivanoff et al found that 5-mm-diameter implants exhibited the highest failure rate (18%), whereas 3.75-mm-diameter and 4 mm-diameter implants performed significantly better, with 5% and 3% failure rates, respectively.[52] This increased failure for wide-diameter implants was explained by the fact that these implants were often used as so-called rescue implants when the standard ones were not considered suitable or did not reach primary stability. Better results are reported in the literature when wide-diameter implants are used as first-choice implants.[53–55] These findings are supported by a recent study demonstrating the results of resonance frequency measurements of implants at the time of insertion.[56] Implants showed statistically higher values (ISQ = implant stability quotient) for wide-platform implants in comparison with regular/narrow-platform implants. The wide-body implants used in the present study had a success rate of 99.3% at the 3-year examination. This success rate compares well to other trials with implants with a standard diameter and the SLA

surface in selected patient populations.[29–31,42,43] In contrast to the other trials, the patients in the present study were all referred for implant therapy by their private dentists. Implant surgery was performed under standard clinical conditions by experienced senior surgeons or by postgraduate students at the Department of Oral Surgery and Stomatology. The prosthetic treatment with fixed restorations was then done by the referring dentists in their private offices.

CONCLUSION

The results of this study demonstrated that wide-body implants with a regular- or wide-neck configuration and an SLA surface achieve successful tissue integration with high predictability in patients referred for implant therapy. Of 151 initially inserted dental implants, 1 implant failed to integrate during healing, and 11 implants were lost to follow-up and considered dropouts. The remaining 139 implants showed favorable clinical and radiographic results and were considered successfully integrated at the 3-year examination. This resulted in a 3-year success rate of 99.3%.

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