Four-Millimeter Implants Supporting Fixed Partial Dental Prostheses in the Severely Resorbed Posterior Mandible: Two-Year Results

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ABSTRACT

Background: Reduced alveolar bone volume complicates implant dentistry.

Purpose: In this prospective multicenter study, a new, 4-mm long Straumann SLActive implant (Ø 4.1 mm) supporting a fixed dental prosthesis (FDP) in the severely resorbed posterior mandible was evaluated for two years.

Material and Methods: Thirty-two patients (11 men, 21 women; mean age 64.1 years) participated. Ten to 12 weeks after single-stage surgery, a screw-retained FDP was attached to three or four 4-mm implants.

Results and Discussion: One hundred implants were inserted. Three failed at surgery and four were lost before loading. Twenty-eight patients received FDPs (93 implants). Two patients were discontinued because of secondary exclusion criteria; therefore, 26 patients were followed up from baseline (BL). After 1 year, one patient insisted on removal of all implants and one patient died because of nonstudy-related complications. Twenty-four patients (87 implants) were eligible for examination 2 years post-loading. All implants were found to be stable [survival rate 95.7% (confidence interval, CI 88.8–98.3) after 1 year and 92.3% (CI 84.5–96.2) after 2 years]. The mean change from BL to 12 months was – 0.43 mm (CI 0.31–0.59; $p < .001$) and from 12 to 24 months – 0.11 mm (CI –0.01–0.23; $p = .056$). The survival rate is only slightly lower than in similar studies on 6 to 8.5 mm implants. This may be related to high initial stability and effective use of the residual bone volume with high primary bone-to-implant contact in dense bone structures. The surgical handling of the tested implant was found to be similar to that of implants of common length. However, the preparation procedure must be done with great care to avoid overdrilling. Careful planning and design of the prosthetic construction is mandatory to prevent unfavorable occlusion and avoid harmful shear forces.

Conclusion: This study showed that 4 mm implants can support an FDP in severely resorbed posterior mandibles for at least 2 years and with healthy peri-implant conditions.

KEY WORDS: bone loss, crown–implant ratio, jaw bone atrophy, short implants

INTRODUCTION

Over the past 30 years, oral implantology has seen continuous development of techniques and designs. Since its early stages, considerably more is known about what influences success rates and the procedures that dictate this to ensure predictable outcomes. The limiting factors for implant placement are insufficient bone volume and density, frequently found in long-term edentulous patients with severely resorbed jaws[1] or in

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patients requiring maxillofacial reconstructions after trauma or tumor resection.[2] Applying various bone augmentation techniques such as bone grafting, guided bone regeneration, and osteodistraction, it is now possible to rehabilitate many of these cases with implant therapy,[3,4] although reports on clinical outcome on, for example, vertical bone augmentation is limited.[5] Even if time frames for such treatments are very much reduced, this is dictated by the extent of augmentation, physiology, and cost. The larger or more complicated the reconstruction, the longer time this may take, which may be socially unacceptable and can be associated with increased morbidity because of long and painful healing times after augmentation. In addition, some of these techniques have been reported to be operator-sensitive.[3]

Modification of the design of the implant is another approach to overcome jaw bone atrophy. For example, zygomatic implants, placed transantrally from the posterior maxilla into the body of the zygomatic bone and combined with implants in the anterior maxilla, have a survival rate 94% to 100%.[6–8] In the atrophic lower jaw, besides augmentation techniques, transposition of the mental nerve is another treatment option; however, there may be serious risk for sensory disturbance.[9,10]

Early studies by Jaffin and Berman[11] indicated that bone quality was not the only success defining criteria since shorter implant lengths were claimed to be related to failure. Using a short implant, primary stability and healing may be challenged because of a reduced contact area for integration with the surrounding bone. Moreover, successful placement of short implants in dense bone qualities may be furthermore dependent on careful surgical technique so as not to overheat the bone site. Implant lengths commonly used are ≥10 mm; however, in recent years, 6 and 8 mm implants became available for reduced alveolar bone height (<10 mm). In a 7-year study composed of 126 patients, ten Bruggenkate and colleagues[12] inserted 253 short (4.1 mm diameter and 6 mm in length) titanium hollow screw, hollow cylinder, and titanium plasma-sprayed solid screw implants in sites with reduced alveolar height. Seven out of the 253 implants were lost, and the overall survival rate was 93.8%. In a long-term follow-up study on severely atrophic edentulous mandibles treated with 6 or 7 mm Brånemark implants, Friberg and colleagues reported cumulative survival rates of 95.5% after 5 years and 92.3% after 10 years of loading.[13] In another article by Friberg and colleagues, placement of 7 to 8.5 mm implants with 3.75 to 5 mm width in both the maxilla and the mandible was reported up to 5 years retrospectively. None of the 30 inserted implants were lost in the lower jaw and six out of the 66 implants were lost in the maxilla. The favorable outcome was ascribed partly to the use of an adapted preparation technique.[14] Recently, Renouard and Nisand[15] placed 6 to 8.5 mm implants in severely resorbed maxillas and reported a 94.6% survival rate after 2 years. In a case series, Misch and colleagues[16] placed 745 7- to 9-mm long implants in 273 patients. After 1 to 5 years, the authors reported a 98.9% survival rate.

The aim of this study is to report 2-year data on the treatment of severely resorbed posterior mandibles using a novel 4-mm short implant.

MATERIALS AND METHODS

This prospective 5-year multicenter study was approved by the regional ethics committees for research at Gothenburg University (Dnr 255–05) and Bergen University (Sak-nr 04/10280) and was performed in accordance with International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use and Good Clinical Practice guidelines and that of the Declaration of Helsinki for patients participating in clinical studies. The informed consent document was written in accordance with the Declaration of Helsinki 1964 and subsequent revisions and recommendations from the Norwegian and Swedish national ethics committees.

The study design is graphically shown in Figure 1.

Centers

The study was performed in five centers (center 1: Borås, three patients; center 2: Halmstad, five patients; center 3: Bergen, 13 patients; center 4: Jönköping/Nässjö, 10 patients; center 5: Gävle, one patient) and included a total of 32 patients.

Implants

Straumann prototype SLActive solid screw two-part SynOcta implants 4.1 mm diameter, thread width 0.8 mm and 4 mm long (Institut Straumann AG, Basel, Switzerland) were used according to the manufacturer's instructions.

Patients

Twenty-one women and 11 men with a mean age of 64 (range 44–86) years were recruited for treatment of

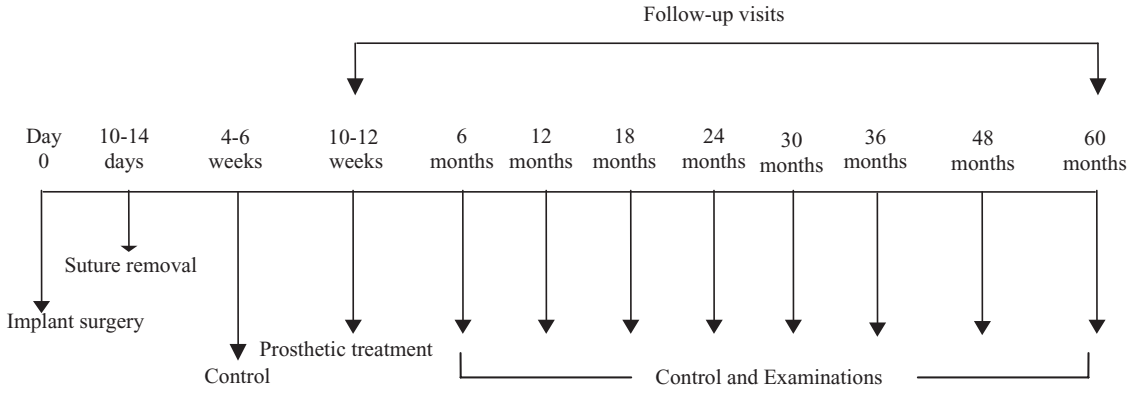

Figure 1 Study outline.

unilateral or bilateral tooth loss in the mandible. Each individual was thoroughly informed of the overall requirements/procedures of the study after explaining the purposes of the study, the nature of the planned treatment, and alternative procedures. In addition, potential risks, possible complications, and benefits of the proposed treatment were explained to the study subjects. All information was given both verbally and in writing. Thereafter, the participants signed an informed consent. The inclusion and exclusion criteria are outlined in Table 1.

Pretreatment Procedures

A clinical and radiological examination was carried out. Intraoral images were obtained. A thorough oral hygiene instruction was performed followed by a follow-up control appointment to ensure optimal presurgical conditions.

Treatment

Each patient received three to four 4-mm implants in the selected sites to support a three- to four-unit screw-retained fixed dental prosthesis (FDP). One implant had to be placed for each tooth unit of the bridge.

Surgical Procedure and Assessments. Implant placement was performed using single-stage surgery. Briefly, local anesthesia was achieved by inferior alveolar nerve block and administration of an appropriate dose of Xylocaine® Dental adrenalin 20 mg/mL + 12 μg/mL (Dentsply, Skarpnäck, Sweden). A midline incision was done at the alveolar crest from the distal surface of the most distally placed tooth and approximately 2 cm to the posterior. Full thickness mucoperiosteal flaps were raised and the path of the mental foramen identified. Careful ridge contouring to achieve a flat bone surface of sufficient width (≥6.1 mm) was done. Preparation of the implant sites was performed according to the Straumann information manual. All implants were inserted manually with a hand device. Immediately postoperatively, initial implant stability was assessed by direct hand pressure around implant and the insertion torque value was recorded. Cover screws were placed over the implants and the flaps were replaced and sutured.

The available bone height, crest width, and bone quality were measured during surgery (Figures 2–4). The bone quality was classified as type I-IV according to the Lekholm and Zarb criteria.[17]

Postoperative Care. Antibiotics were prescribed at the discretion of the surgeon. Analgesics were given as required for pain control. The patients were instructed to rinse with a 0.1% chlorhexidine solution twice a day for 1 or 2 weeks until suture removal. After suture removal, the patients were instructed in proper mechanical brushing of the implants using 1% chlorhexidine gel until placement of the FDP. The use of a removable temporary prosthesis in the mandible was not permitted, in order to prevent stress/load during healing. Dentures in the opposing dentition were allowed as long as there was no occlusion at the implant sites.

Prosthetic Treatment. After 70 to 84 days (10 to 12 weeks) post-surgery, the permanent screw-retained FDP was placed (baseline; BL). The restorations were constructed using Straumann prosthodontic components and used according to the manufacturer's instructions. At the time of loading, the restoration was placed in full functional occlusion. Care was taken to design the FDP

TABLE 1 Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
• Aged ≥18 years, committed to participate up to 5 years follow-up • Unilateral or bilateral edentulousness in the posterior mandible to allow placement of three to four implants distal to the canines: if only 4-mm implants could be placed in either side, then a sealed treatment envelope was opened to denote the study site; if longer implants could be placed and there was a difference in bone height, the side with lower bone height was designated as the study side; if longer implants could be placed and there was no difference in bone height, a sealed treatment envelope was opened to denote the study site • The implant site had to be edentulous for >3 months and fully healed, with evidence of bone resorption and atrophy • Adequate bone height (≥5 mm) for placement of 4.1 mm Ø and 4-mm long implants without concurrent bone augmentation; bone harvested from the drilling sites was allowed to cover minor dehiscence defects but not other augmentation procedures were allowed • Full or partial dentition opposing the implants	*Systemic* • Presence of blood, metabolic, endocrine, renal, or neoplastic disease • Human immunodeficiency virus infection • Conditions requiring prolonged use of steroids or prophylactic antibiotics • Smoking >10 cigarettes or cigar or chew tobacco equivalents per day • Alcoholism or drug abuse • Any conditions that may prevent study participation or interfere with analysis of results *Local* • Inflammation, including untreated periodontitis • Mucosal diseases • History of irradiation therapy • Osseous lesions or unhealed extraction sites • Guided bone regeneration (GBR) treatment at implant surgery • Previous reconstruction, bone grafting, or failed GBR at thesite of intended implant surgery • Severe bruxism/clenching • Persistent intraoral infection • Inadequate oral hygiene or unmotivated for home care *Secondary exclusion criteria at surgery* • Lack of primary stability of one or more implants • Insufficient bone or any abnormality that would contraindicate implant placement

with freedom in centric occlusion, avoiding steep cusp slopes and extreme working contacts.

Radiographs. Radiographs were obtained after surgery. The projection geometry in these was highly variable, which did not allow proper assessment at this time point, and was therefore not used for further calculations. Therefore, radiographs after loading were used as BL. Individual standardized periapical radiographs were thus taken postoperatively in situ and at the placement of the FPD. Further radiographs were taken at 6 months and 1 and 2 years after the completion of the prosthetic work. Further follow-up includes radiographs at 3 and 5 years.

Follow-Up Procedures and Assessments. The first check-up and suture removal was performed after 2 weeks and another post-surgery checkup at 4 to 6 weeks. After BL follow-up, appointments were done after 6 months, 1 year, 18 months, and 2 years and will be further done after 30 months and 3, 4, and 5 years (Figure 1). Each visit consisted of a general health and dental history evaluation as well as a patient satisfaction questionnaire. Peri-implant health and oral hygiene were assessed and revised with the patient. Radiographs were obtained as described earlier. The FDP was cleaned and maintained. The occlusion and bridge stability was followed up and the FDP was removed at the 1- and 2-year follow-up visits and was also planned after 3 and 5 years. All clinical parameters were recorded by the same examiner. All patient complaints or any complications resulting from a change in health status from BL or any implant-related complications such as pain, paresthesia, or infection was strictly monitored and recorded as an adverse event. Any condition was monitored until the condition had resolved, or up

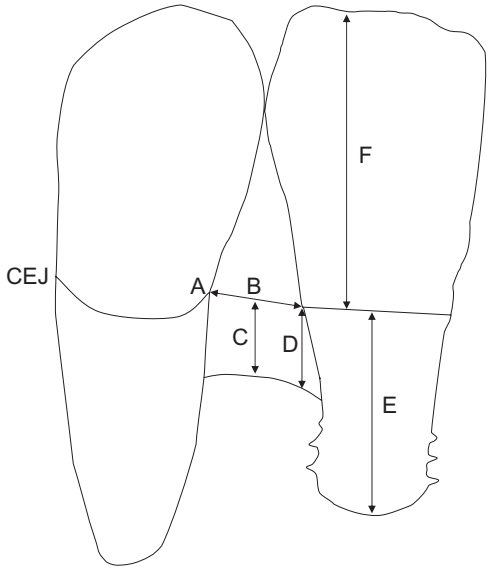

Figure 2 Mesial and distal measurements were made at each study implant. The following distances were assessed: the distance between the neck of the implant to the cement/enamel junction (CEJ) of the adjacent tooth (A); the midpoint of the line between the neck of the implant to tooth landmark (CEJ) was defined (B); the distance from the midpoint of the line defined under B to the highest point on the alveolar crest between implant and adjacent tooth (C); the distance between the neck of implant to bone level (D); length of implant (E); crown height (F).

to 3 months post-study termination. Implant mobility was assessed indirectly (by movement of the FDP, radiolucency, or infection around the implants) or directly (after removal of FDP). If more than one implant was mobile, this was regarded as a treatment failure as the units could not be supported; therefore the patient was withdrawn from the study. Plaque index (PI) and sulcus bleeding index (SBI) were obtained at all four aspects on each implant according to Mombelli and colleagues.[18]

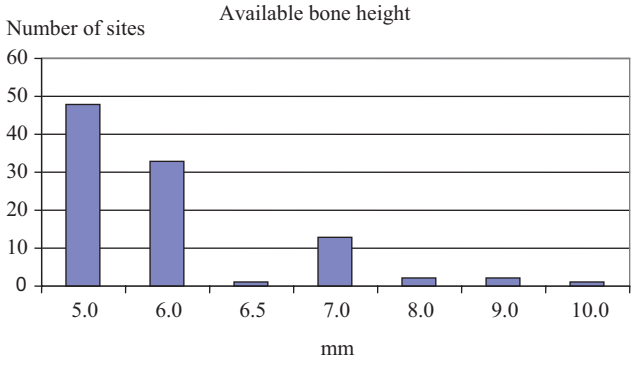

Figure 3 Frequency distribution of available bone height.

A well-experienced masked non-investigator analyzed the radiographs for any continuous peri-implant radiolucency or structural failure and performed linear measurements of bone crest changes as follows:

- *Standard intraoral radiographs:* the radiographs were placed on a view box fitted with a micromanipulator, and the analog signals from such *trans*illuminated radiographs were received by a commercially available charged coupled device (CCD) camera for black and white images (CI-20 PM, 734 x 580 pixels with a Canon 18–108 mm 1:1.6 zoom lens, Canon Still Video Products Group, Tokyo, Japan) adapted for image processing. The images were digitized using a frame grabber hardware card (MVP/AT, Matrox Electronic Systems, Dorval, Quebec, Canada) supported by a personal computer (Compaq USA 386/20, Hewlett Packard, Palo Alto, CA, USA). The images were calibrated against a millimeter-defined standard. Linear measurements between defined reference points were made using the software. The equipment was placed in a laboratory with optimal light control.
- *Digital intraoral radiographs:* the images were analyzed with the UTHSCSA Image Tool Version 3.0 (Dental Diagnostic Science, San Antonio, TX, USA) software program on a MAC Powerbook G4 Computer (Apple Computer Inc., Cupertino, CA, USA). The linear measurements were calibrated by assessing the distances between defined landmarks on the implants. Therefore, the distance between threads on the implants around which bone measurements would be made was assessed and calibrated against the known information on this distance (i.e., a distance of 0.8 mm between two threads). For calibration, the distance between five threads or more ($5 \times 0.8 = 4.0$ mm) was used when possible. Each image was calibrated this way to control for any distortion between clinical images. For mesial and distal measurements, the calibrated values were defined by measurements between the threads at both the mesial and the distal aspects of the implant. A depiction of assessed distances is shown in Figure 2.

Implant success criteria were assessed by the treating dentist at the 1- and 2-year follow-up visit and judged as 1 to 5 according to the following: 1 = no problems; 2 = presence of continuous peri-implant radiolucency based on radiographic findings; 3 = presence

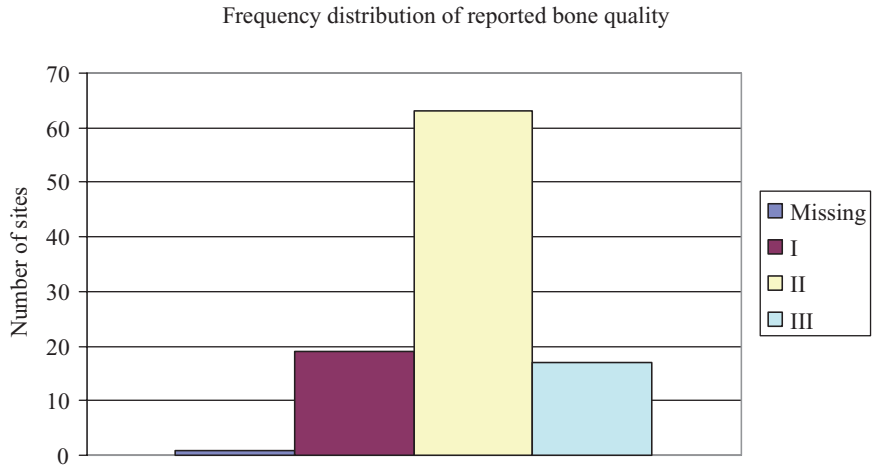

Figure 4 Frequency distribution of bone quality.

of recurrent peri implant infection; 4 = presence of continuous or recurrent pain; 5 = structural failure of implant/loss of implant.

Statistical Analyses. Sample size calculations were done with a one-sided paired *t*-test. A power analysis was carried out assuming no greater than 0.2 mm crestal bone loss between 1 and 2 years. This hypothesis was tested with a power of 80%, SD 0.3, at the $p = .05$ level.

The primary efficacy parameter was crestal bone level change from 1 year up to 2 years post-loading. The means in each center and for the total of all implants were calculated (assuming all implants as independent). A second analysis was performed by calculating a mixed model using the center as fixed effect and the patient as random effect. The degree of freedom in the denominator was calculated by the Kenward–Roger method. Calculated were 95% confidence intervals for the mean bone level change in each center and for the total of all studies.

Secondary and tertiary objectives were to estimate implant survival rates and treatment success outcomes and to obtain overall survival and safety data up to 5 years post-loading. Two different analytical approaches were used for study evaluation, one where all implants were taken into account and the other where only one implant was taken as representative of all. An analysis of variance (ANOVA)-type mixed model with random cluster-specific effect and fixed effects (time, center, and time x center), which can be applied to verified normal distributions, were used. In addition, the two-factorial nonparametric ANOVA (Friedman test) was applied. These analyses were done using SPSS statistical software (SPSS Inc., Chicago, IL, USA). To analyze SBI and the modified PI, general estimation equations were applied using certified commercial software (ML; Multiprocess Multilevel Modeling, EconWare, Los Angeles, CA, USA) implants. Pearson analysis was performed to evaluate the correlation between the change in crestal bone level between loading and 1 year and between 1 and 2 years.

RESULTS

In general, healing after surgery was uneventful. One patient reported paresthesia that was normalized within 4 weeks. In another patient, mucosal overgrowth was reported, resulting in surgical excision before prosthetic treatment. Implant bone site characteristics are shown in Figures 3–5.

The study included 32 patients, 24 with unilateral and eight with bilateral eligible sites, respectively. Twenty-eight patients received three implants each, and four patients received four implants each. Four patients

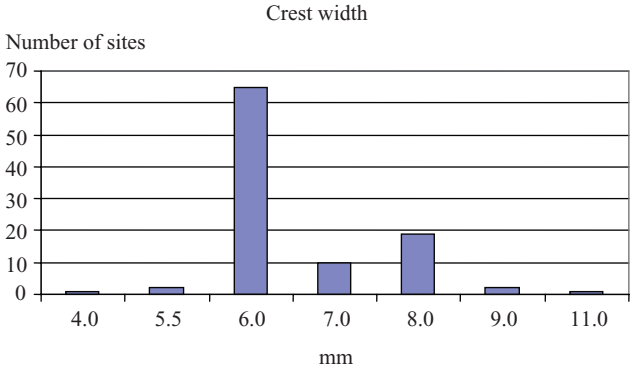

Figure 5 Frequency distribution of crest width.

TABLE 2 Implant Positions

Position	48	47	46	45	44	34	35	36	37	38	Total
Number of implants	1	7	14	14	7	13	18	17	8	1	100
%	1	7	14	14	7	13	18	17	8	1	100

were excluded before prosthetic treatment because of loss of implants, and two patients discontinued because of to secondary exclusion criteria (insufficient crest width at one implant); therefore, 26 patients received prosthetic constructions. The 12-month evaluation included 25 patients; one patient was excluded because of removal of all implants (on the patient's demand). The 24-month evaluation included 24 patients (one patient died because of general health problems not related to the implant treatment).

In total, 100 implants were placed. Three failed at surgery because of lack of primary stability and four implants were lost before loading. At the 24-month follow-up, 87 implants were still included in the study. The distribution of implant positions is shown in Table 2.

Twenty-four FDPs were evaluated after 2 years. Most bridges (76.7%) were three-unit, 16.7% were a four-unit, 3.3% were a two-unit, and the number of units was not reported in 3.3% of the cases. The restorations were porcelain fused to metal; mostly with a gold frame (66.7%), while some had a chrome–cobalt (20%) or titanium (13.3%) frame. No cantilever prostheses were fabricated. Full functional occlusion was found for all cases except one (not reported). In 50% of the cases, group function was established while canine guidance was done in 36.9% of the cases; data were missing from 6.7% of cases. Cuspless or prenormal occlusion was established in one case each (3.3%, respectively). The average (standard error) crown length as measured on the radiographs was 9.9 (0.2) mm (the distance from the top of the crown to the most coronal bone implant contact), giving a crown/implant ratio of 2.5.

Soft Tissue Assessments

Presurgically, oral hygiene was excellent or good in 40% and 60% of patients, respectively. Oral hygiene was excellent, good, or fair in 36.7%, 56.7%, and 6.7%, respectively, at day 10, and 63.3%, 33.3%, and 3.3%, respectively, at day 70. At the 2-year follow-up, oral hygiene had improved to excellent in 76.9% of the patients, good in 19.2%, and fair in 3.8%. The distribution of plaque and sulcus bleeding are presented in Table 3: at day 10, 72% to 81% of the sites showed no plaque. At the 2-year examination, the values improved to 85% to 99%. At this appointment, the mean (SE) PI was 0.12 (0.02). At day 10, no sulcus bleeding was recorded at 74% to 84% of the sites. This value improved, and after 2 years, 92% to 100% of the sites showed no bleeding. The average (SE) bleeding index was 0.06 (0.01) at the 2-year examination. At center 4, pocket probing depths were measured in a subset of 10 patients. Mean (SE) probing pocket depth at the 2-year examination was 2.1 (0.2) mm.

Patient Satisfaction

The questionnaire showed generally excellent or good satisfaction (96% to 100%). This value improved over time for all parameters (Table 4).

Intention to Treat (ITT) Analysis

Thirty-two subjects with 100 implants were in the ITT population (all patients who signed the informed consent), and the ITT 1 population (safety population), and 30 patients with 93 implants were in the ITT 2 population (efficacy population).

Radiographic Assessments and Statistical Outcome Analysis

The primary outcome was implant success at the 1- and 2-year follow-up visit (ITT2 population). The mean change in crestal bone level change from BL to 12 months was – 0.43 mm (CI 0.31–0.59; $p < .001$). From 12 to 24 months, a close to significant bone loss of 0.11 mm (CI –0.01–0.23; $p = .056$) occurred (Table 5). Figure 6 illustrates the radiographic appearance after surgery, after loading, and after 12 and 24 months.

Implant survival rate was the second outcome variable and was 95.7% (95% CI 88.8–98.3%) after 1 year and 92.3% (95% CI 84.5–96.2%) after 2 years. These figures were calculated on implant basis. All inserted 4-mm implants were included regardless of

TABLE 3 Frequency Distribution of Plaque and Sulcus Bleeding at Four Follow-Up Examinations

		Plaque Index			Sulcus Bleeding Index		
Visit	Site	No Plaque *n* (%)	Plaque on Running a Probe *n* (%)	Plaque Seen by Naked Eye *n* (%)	No Bleeding *n* (%)	Isolated Bleeding *n* (%)	Blood Forms Red Line on Margin *n* (%)
Study day 10	B	46 (80.7)	8 (14.0)	3 (5.3)	48 (84.2)	8 (14.0)	1 (1.8)
	D	43 (75.4)	8 (14.0)	6 (10.5)	44 (77.2)	11 (19.3)	2 (3.5)
	L	43 (75.4)	8 (14.0)	6 (10.5)	47 (82.5)	9 (15.8)	1 (1.8)
	M	41 (71.9)	10 (17.5)	6 (10.5)	42 (73.7)	14 (24.6)	1 (1.8)
6-month. follow-up	B	73 (92.4)	5 (6.3)	1 (1.3)	73 (96.1)	3 (3.9)	
	D	68 (86.1)	10 (12.7)	1 (1.3)	69 (90.8)	7 (9.2)	
	L	62 (78.5)	16 (20.3)	1 (1.3)	70 (92.1)	5 (6.6)	1 (1.3)
	M	70 (88.6)	8 (10.1)	1 (1.3)	74 (97.4)	2 (2.6)	
1-year follow-up	B	71 (95.9)	3 (4.1)		71 (95.9)	2 (2.7)	1 (1.4)
	D	66 (86.8)	10 (13.2)		69 (90.8)	3 (3.9)	4 (5.3)
	L	61 (82.4)	10 (13.5)	3 (4.1)	70 (94.6)	2 (2.7)	2 (2.7)
	M	68 (91.9)	6 (8.1)		70 (94.6)	3 (4.1)	1 (1.4)
2-year follow-up	B	78 (98.7)	1 (1.3)		76 (100)		
	D	67 (84.8)	12 (15.2)		70 (92.1)	5 (6.6)	1 (1.3)
	L	70 (88.6)	5 (6.3)	4 (5.1)	73 (96.1)	2 (2.6)	1 (1.3)
	M	67 (84.8)	12 (15.2)		70 (92.1)	6 (7.9)	

B = buccal; D = distal; L = lingual; M = mesial side.

discontinuation on patient level due to loss of one implant. Some of the patients lost one study implant that was then, in some cases, replaced with a regular implant or had a pontic in the FDP.

Missing data and data from dropouts were not substituted for the analysis of the change in bone level. One patient insisted on removal of all implants, and one patient died because of a nonstudy-related cause. Both patients were analyzed for the change in crestal bone level up to 1 year post-loading. While the reason for the drop out was not dependent on treatment success (bone level change), no systematic bias was expected by the exclusion of these two patients from the analysis of the crestal bone level changes from the 1- to 2-year follow-up visit. The discontinuations occurred before any 2-year follow-up radiographs were obtained, and therefore, no substitution of missing values was possible in these patients. In the Kaplan–Meier analysis of implant survival, dropouts were calculated as censored observations. On the implant level, if only one implant failed in one patient and the patient was discontinued after implant removal, the remaining implants were calculated as censored observations. Care should be taken with the interpretation of these results because these censored observations may not have the same risk of implant failure as other observed implants.

Multicenter Analyses. For the analysis of the change in crestal bone level, the center was considered as fixed effect, and a type 3 test was performed to test for the significance of the center as independent predictor. Because of the small sample size, no stratification according to the centers was performed for the analysis of the implant survival.

Mean change in crestal bone levels in the individual centers are shown in Table 6. Analyses in a mixed model change from BL to 1 year follow-up and from 1- to 2-year follow-up were carried out. A significant center effect ($p = .025$) was found for BL to year 1. No significant center effect ($p = .496$) was found for the crestal bone level change between years 1 and 2.

DISCUSSION

The implant survival rate of 100 4-mm implants was 95.7% at 12 months after surgery. Four implants were lost prior to loading. At 450 days after surgery, one patient experienced diffused pain and insisted on removal of her three implants, all of which were

TABLE 4 Patient Satisfaction

	Visit	Missing *n* (%)	Excellent *n* (%)	Good *n* (%)	Fair *n* (%)	Not Done *n* (%)
Comfort	Study day 70	—	20 (69.0)	8 (27.6)	—	1 (3.4)
	6-month follow-up	1 (3.7)	19 (70.4)	6 (22.2)	1 (3.7)	—
	1-year follow-up	—	18 (69.2)	7 (26.9)	1 (3.8)	—
	2-year follow-up	—	23 (88.5)	3 (11.5)	—	—
Appearance	Study day 70	—	17 (58.6)	11 (37.9)	—	1 (3.4)
	6-month follow-up	1 (3.7)	21 (77.8)	5 (18.5)	—	—
	1-year follow-up	—	17 (65.4)	9 (34.6)	—	—
	2-year follow-up	—	21 (80.8)	4 (15.4)	1 (3.8)	—
Ability to chew	Study day 70	—	15 (51.7)	3 (10.3)	—	11 (37.9)
	6-month follow-up	1 (3.7)	19 (70.4)	7 (25.9)	—	—
	1-year follow-up	—	22 (84.6)	4 (15.4)	—	—
	2-year follow-up	—	24 (92.3)	2 (7.7)	—	—
Ability to taste	Study day 70	—	16 (55.2)	2 (6.9)	—	11 (37.9)
	6-month follow-up	2 (7.4)	20 (74.1)	4 (14.8)	—	1 (3.7)
	1-year follow-up	—	21 (80.8)	5 (19.2)	—	—
	2-year follow-up	—	24 (92.3)	2 (7.7)	—	—
General satisfaction	Study day 70	—	20 (69.0)	6 (20.7)	—	3 (10.3)
	6-month follow-up	1 (3.7)	22 (81.5)	4 (14.8)	—	—
	1-year follow-up	—	20 (76.9)	5 (19.2)	1 (3.8)	—
	2-year follow-up	—	25 (96.2)	1 (3.8)	—	—

TABLE 5 Radiographic Change in Crestal Bone Levels to from Baseline to 1-Year Follow-Up and from 1- to 2-Year Follow-Up by Center (ITT2 Population)

Center	*n*	Mean	SD	Min	Median	Max
Change in crestal bone from baseline to 1-year follow-up						
1	6	1.21	0.66	0.29	1.53	1.88
2	14	0.51	0.36	–0.02	0.58	1.16
3	27	0.32	0.35	–0.68	0.31	1.08
4	31	0.40	0.49	–0.45	0.33	1.38
5	3	–0.15	0.04	–0.19	–0.14	–0.11
All	81	0.43	0.49	–0.68	0.34	1.88
Change in crestal bone level from 1- to 2-year follow-up						
1	6	0.09	0.29	–0.37	0.09	0.54
2	14	0.03	0.51	–0.93	–0.08	1.31
3	27	0.03	0.18	–0.26	0.00	0.41
4	27	0.25	0.53	–0.66	0.13	1.63
5	3	–0.01	0.23	–0.17	–0.12	0.26
All	77	0.11	0.41	–0.93	0.04	1.63

Mean values in millimeters.

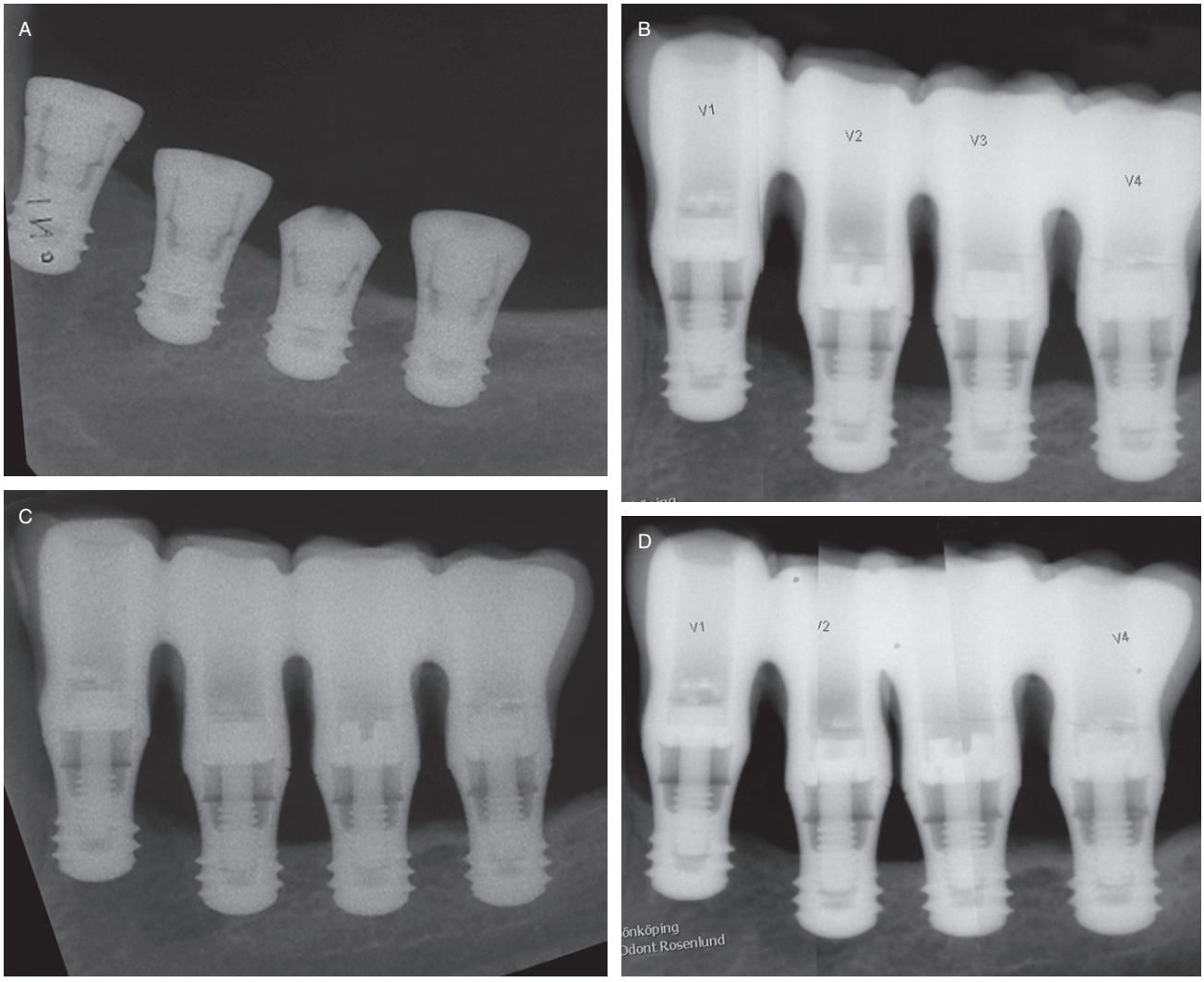

Figure 6 Radiographical appearance of 4-mm implants; patient 04-09, Study Center Jönköping: (A) immediately after placement of implants; (B) immediately after placement of fixed prosthesis; (C) 1 year postoperative; (D) 2 years postoperative; (B) and (D) are composites of digital radiographs.

classified as successful at the time of removal. Besides the earlier described event, no side effects were observed during the study, confirming the predictability and safety of short implants. One patient died after the 18-month examination for general health reasons. Notwithstanding the exclusion of these two patients, the implant survival rate was 92.3% at 24 months post-surgery, which is only slightly lower than in a similar retrospective study on 6- to 8.5-mm implants placed in the maxilla by Renouard and Nisand,[15] who reported 94.6% survival after 2 years of loading. As discussed by these authors, the reason for the good results with short implants may be related to high initial stability and effective use of the residual bone volume with high primary bone-to-implant contact in dense bone structures. Similar results were reported by Misch and colleagues, who placed 745 7- to 9-mm long implants in 273 patients. After 1 to 5 years, the authors reported a 98.9% survival rate.[16] Further, a systematic review by Renouard and Nisand[19] indicated that an increased failure rate with short implants was associated with operators' learning curves, routine surgical preparation (independent of the bone density), the use of machined-surfaced implants, and the placement in sites with poor bone density. It was indicated that an adapted surgical preparation and the use of textured-surfaced implants resulted in comparable survival rates between short implants and longer ones.

The mean change in crestal bone level was 0.43 mm in the first year and 0.11 mm in the second year). These

TABLE 6 Center Effects, Baseline to 1 Year and 1 Year to 2 Years

Center	Mean (mm)	95% CI		*p* Value for Mean = 0
		Lower	Upper	
Baseline to 1 year				
1	1.21	0.70	1.73	<.001
2	0.52	0.19	0.85	.003
3	0.32	0.08	0.56	.012
4	0.43	0.20	0.66	<.001
5	–0.14	–0.87	0.58	.682
1 year to 2 years				
1	0.09	–0.32	0.51	.650
2	0.03	–0.24	0.30	.810
3	0.03	–0.17	0.22	.757
4	0.25	0.05	0.45	.015
5	–0.01	–0.60	0.58	.972

figures are well in line with the earlier described study by Renouard and Nisand.[15] In addition, the bone loss at year one is similar to or even better than in investigations with longer implants. The additional loss of 0.11 mm in the second year is below the success criteria stated by Albrektsson and colleagues.[20] The greater marginal bone loss during the first year may be explained by the considerable trauma and inflammation to the tissue, even with careful surgery. Initial necrosis of the bone adjacent to the implant has been shown experimentally and further bone loss takes place around the loaded implant as an adaptive remodeling response to shear forces until a steady state is established.[21]

Because of highly variable projection geometry in the radiographs obtained after surgery, it was not possible to properly assess the marginal bone level at this time point. Consequently, no explicit judgment of the bone changes before loading could be done. However, as has been shown by other investigators, marginal bone remodeling may start already after surgery.[22]

The implant shape and design parameters that affect load transfer (stress/strain) to the surrounding bone include both implant diameter, length, and thread shape. Finite element models have found that the cortical bone (as in the posterior mandible) seems to be more affected by implant diameter and stress peaks rather than implant length, while the opposite was found for the trabecular bone.[23] The use of a short implant in the posterior mandible may therefore be supported because it is mainly dependent on the cortical part of the bone. In accordance with recent reports and systematic reviews,[24–26] the unfavorable ratio of implant length to height of the suprastructure in this study was not found to cause more bone loss than reported for longer implants. Higher peak strains (due to, e.g., increased crown–implant ratio) have been shown experimentally to promote periosteal/endosteal bone formation while at the same time, not affect bone remodeling within the skeletal envelope.[27] However, it should be noted that the protocol in this study prescribed that all occlusal units should be supported by one implant. In addition, bruxing patients were not included in the study. Moreover, the suprastructures were designed with freedom-in-centric and avoided steep cuspal inclinations and extreme lateral contacts. These measures of precaution were most likely beneficial to the study outcome.[28]

In general, oral hygiene was considered excellent among the patients (excellent in 77%, and good in 19% of the cases), showing median plaque and sulcus bleeding scores of 0. In a subset (Jönköping/Nässjö), the average probing pocket depths was 2.1 (SD: 0.8 mm) at year 2. Plaque accumulations around implants have experimentally been shown to induce inflammation and breakdown of marginal bone.[29] A high standard of plaque control has been shown to prevent plaque-induced peri-implant marginal bone loss.[30,31] This fact seems to be even more crucial for a long-term stable result using 4-mm implants.[32–34]

The authors' experience of the tested implant is that handling during surgery was similar to as implants of

more standard lengths. But as indicated by the two implants that did not reach primary stability during surgery, the preparation procedure must be done with great care to avoid overdrilling. In addition, threading the implant bed makes placement much easier.

Implant therapy has developed greatly over the years because of growing experience, technical development, and conjunctive procedures to enable treatment. This means that implant therapy has also become available for patients with reduced bone support due to, for example, cancer, periodontal disease, or previous implant failures. A 4-mm implant has potential for use in special clinical situations as shown in this study and also in combination with longer implants. Regarding cost–benefit, placing a short implant in the available bone reduces treatment time by avoiding alternative procedures such as bone grafting or GBR. Also, as shown in this study, the predictable outcome, even in demanding situations, is a great advantage compared with sometimes unpredictable augmentation procedures. Designing a short implant for the preexisting available bone appears to be a good alternative to time-consuming, often painful, and expensive conjunctive methods. From the specialist horizon, there are still indications where a short implant very well fills in a demanded need. However, before long-term studies are available, this implant should primarily be suited for well-experienced clinicians/specialists in order to not jeopardize treatment outcome in difficult cases.

CONCLUSION

This study shows that 4-mm long titanium implants with an SLActive surface can be safely and successfully used to support a FDP in severely resorbed posterior mandibles for at least 2 years with healthy periodontal conditions.

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