Four-Millimeter-Long Posterior-Mandible Implants: 5-Year Outcomes of a Prospective Multicenter Study

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ABSTRACT

Background: There is lack of evidence on long-term success of short dental implants in reduced alveolar bone.

Purpose: In this prospective 5-year study, survival and marginal bone loss of 4-mm implants, which supported fixed dental prostheses (FDPs) in severely resorbed posterior mandibles, were evaluated.

Material and Methods: In 28 patients, evaluation of 86 osseointegrated 4-mm-long implants, which supported a 3- or a 4-unit FDP by crown splinting without the use of pontics or cantilevers, was performed over a 5-year period.

Results: Three subjects dropped out for non-study reasons: one subject had her three implants removed after 1 year and two subjects died (six implants). Five implants in three subjects were lost between 3 and 5 years. Twenty-four subjects and 71 implants were active at the 5-year follow-up (92.2% survival). After 1 year, significant \( p < .001 \) mean (standard error of the mean [SEM]) 0.44-mm (0.05) marginal bone loss occurred. At 2, 3, and 5 years, mean (SEM) bone loss of 0.57 mm (0.06), 0.55 mm (0.07), and 0.53 mm (0.08) occurred, respectively (no significant change after 1 year). At 5 years, average plaque levels were 13.3%; 69% of the implants were plaque free. On average, mucosal bleeding occurred at 8.1% of the implants. During 5 years, two subjects experienced uncomplicated bridge loosening. No other complications occurred during the study.

Conclusion: Four-millimeter implants can support FDPs in severely resorbed posterior mandibles for 5 years with healthy peri-implant conditions.

KEY WORDS: bone atrophy, bone loss, bone resorption, clinical trial, crown-implant ratio, short implants

INTRODUCTION

Often, dental implant rehabilitation is a safe, well-documented treatment. In situations regarding limited bone, new techniques emerged to enable implant placement – but not always without risk for failure or biological complications. In addition, such procedures are technically demanding, require longer treatment times, and incur higher morbidity and costs for patients. Implant device designs, which facilitate fitting that is aligned with anatomical and morphologic circumstances in the jaws, have enabled avoidance of augmentation procedures and long treatment times.

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In the last decade, use of short implants has become a growing interest among clinicians. Encouraging survival rates have been reported over time. Recent systematic reviews indicated that short implants have the same survival rates and degree of marginal bone loss as longer implants. Several studies and reviews include implant lengths of up to 10 mm in the short category. But a more strict definition of short implants indicates a length of ≤8 mm. Some investigations evaluated short implants that were incorporated in superstructures with longer implants, thus making it difficult to analyze short-implant efficacy per se. Wide heterogeneity also occurs regarding type and length of superstructures reported in various studies.

A recent analysis comprising 12 retrospective studies, 16 prospective studies, 5 randomized controlled trials, and 1 study with retrospective and prospective elements reported high survival rates for short implants in posterior partial edentulism. Here, most short implant failures occurred before loading. Other recent reviews revealed that most failures with short implants occur before loading.

Up to now, few prospective studies have been available. Randomized trials that compared short implant placement in native bone with placement of longer implants in augmented bone were reported. To the authors’ knowledge, only one study reports data collected over a period longer than 1 year. Altogether, no definite consensus can be announced regarding the safety of using short implants in general or regarding indications for which they should be recommended.

Recently, we reported 2-year data from a prospective multicenter study on 4-mm long Straumann SLActive implants that support fixed dental prostheses (FDPs) in subjects with severely resorbed posterior mandibles. The present article reports 5-year outcomes of this investigation. The primary objective was to evaluate changes in peri-implant crestal bone levels up to 5 years post-loading. The secondary objective was to assess implant survival and safety.

**MATERIAL AND METHODS**

Regional ethics committees for research at Göteborg University (doc. no. 255-05) and Bergen University (Sak no. 04/10280) approved this prospective 5-year multicenter study that was implemented as per the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use standards, Good Clinical Practice guidelines, and the Declaration of Helsinki for subjects participating in clinical studies. The informed consent document was written as per the Declaration of Helsinki 1964 and subsequent revisions and recommendations as per the Norwegian and Swedish national ethics committees.

**Centers**

The study was performed in five centers (Borås; Halmstad, Bergen, Jönköping, and Gävle) and included a total of 32 subjects (for power estimation, see the “Statistical Analysis” section below). The study started in 2004. All centers had completed treatments in 2006 and their final examinations in 2011.

**Implants**

These implants were used as per manufacturer instructions: 4.1 mm–diameter Straumann Regular Neck, solid screw, SLActive soft tissue-level implants with 0.8-mm thread pitch and 4-mm length (titanium grade-4 prototype, product number: 80246S; Institut Straumann AG, Basel, Switzerland).

**Subjects**

In this open, single-group, prospective, nonrandomized study, the subjects were consecutively recruited as per inclusion criteria among patients referred to participating centers. Twenty-one women and 11 men (mean age 64; range 44–86) were enrolled for treatment of uni- or bilateral tooth loss in the posterior mandible. Each patient was informed of overall study requirements and procedures – after receiving an explanation of the study’s purposes, the nature of the planned treatment, and alternative procedures. In addition, potential risks, possible complications, and proposed treatment benefits were explained to the patients. All information was given verbally and in writing. Thereafter, they signed informed consent forms. Table 1 describes inclusion and exclusion criteria.

**Treatment and Follow-Up**

The pretreatment, surgical, prosthetic, and follow-up procedures are described in detail in a previous paper. Briefly, 32 subjects received three implants or four implants in the severely resorbed posterior mandible in a one-stage procedure. For bilateral eligible sites in the mandible (eight subjects), one side was assigned as the
study side via randomization (by breaking a sealed envelope that disclosed allocation; Institut Straumann AG prepared the envelope). The other side was provided with the same type, diameter, and implant length as on the study side; 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 ($\geq 3.5$ mm) for placement of 4.1-mm diameter and 4-mm long implants without concurrent bone augmentation; bone harvested from the drilling sites was allowed to cover minor dehiscence defects, but no other augmentation procedures were allowed.
- Full or partial dentition opposing the implants

After 10–12 weeks (postsurgery), a permanent 3- or 4-unit screw-retained FDP – without pontics or cantilevers – was connected to the implants. At the time of loading, the restoration was placed in full functional occlusion. Care was taken to design the FDP with freedom in centric occlusion, avoiding steep cusp slopes and extreme working contacts. Clinical follow-ups were done every 6 months during the first 30 months and thereafter annually up to 5 years (Table 2 and Figure 1). Individual standardized peri-apical radiographs were obtained at the FDP placement and start of loading (baseline). Further radiographs were taken 6 months and then 1, 2, 3, and 5 years after completion of the prosthetic work.

### Assessments

An earlier article reported recordings that were made during surgery, that is, implant positions, bone quality, bone volume, and crestal width. Each follow-up visit consisted of a general health and dental history evaluation. The same examiner recorded all clinical parameters. The subjects’ treatment experiences were evaluated using a questionnaire on comfort, appearance, ability to chew and taste, and general satisfaction.

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**TABLE 1 Study Inclusion and Exclusion Criteria**

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tbody>
<tr>
<td>• Aged $\geq$ 18 years, committed to participate up to 5 years follow-up</td>
<td>Systemic</td>
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<tr>
<td>• Uni- 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.</td>
<td>• Presence of blood, metabolic, endocrine, renal, or neoplastic disease</td>
</tr>
<tr>
<td>• Adequate bone height ($\geq 3.5$ mm) for placement of 4.1-mm diameter and 4-mm long implants without concurrent bone augmentation; bone harvested from the drilling sites was allowed to cover minor dehiscence defects, but no other augmentation procedures were allowed.</td>
<td>• HIV infection</td>
</tr>
<tr>
<td>• Full or partial dentition opposing the implants</td>
<td>• Conditions requiring prolonged use of steroids or prophylactic antibiotics</td>
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<td></td>
<td>• Smoking $&gt;10$ cigarettes or cigar or chew tobacco equivalents per day</td>
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<td>• Alcoholism or drug abuse</td>
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<td></td>
<td>• Any conditions that may prevent study participation or interfere with analysis of results</td>
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<tr>
<td></td>
<td>Local</td>
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<td></td>
<td>• Inflammation, including untreated periodontitis</td>
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<td>• Mucosal diseases</td>
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<td>• History of irradiation therapy</td>
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<td></td>
<td>• Osseous lesions or unhealed extraction sites</td>
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<td></td>
<td>• GBR treatment at implant surgery</td>
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<td></td>
<td>• Previous reconstruction, bone grafting, or failed GBR at the site of intended implant surgery</td>
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<td></td>
<td>• Severe bruxism/clenching</td>
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<td></td>
<td>• Persistent intraoral infection</td>
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<td></td>
<td>• Inadequate oral hygiene or unmotivated for home care</td>
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<td></td>
<td>Secondary exclusion criteria at surgery</td>
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<tr>
<td></td>
<td>• Lack of primary stability of one or more implants</td>
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<td></td>
<td>• Insufficient bone or any abnormality that would contraindicate implant placement</td>
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</table>

GBR = Guided Bone Regeneration.
Plaque index (PI) and sulcus bleeding index data were obtained at all four aspects on each implant as per Mombelli and colleagues.\(^\text{20}\) The FDP was cleaned and maintained. The occlusion and bridge stability was followed up, and the FDP was removed at the 1-, 2-, 3-, and 5-year follow-up visits. All patient complaints or any complications that resulted from a change in health from baseline or any implant-related complications were strictly monitored and recorded as an adverse event. All observed conditions were monitored until the conditions were resolved – or up to 3-months, post-study termination. Implant mobility was assessed (1) indirectly – by FDP movement, radiolucency, or infection around implants or (2) directly – after FDP removal.

If more than one implant was mobile, this was regarded as a treatment failure, because the units could not be supported; consequently, the patient was withdrawn from the study. Radiographs were obtained as described above. A very experienced, non-investigator (1) blindly analyzed radiographs for any continuous peri-implant radiolucency or structural failure and (2) performed linear marginal bone loss of each implant; the distance from the neck of implant to the bone level was measured at the mesial and distal sides (for further details, see Slotte and colleagues\(^\text{19}\)).

**Statistical Analyses**

The null hypothesis was accepted if crestal bone changes occurred less than 0.2 mm annually after the first year (from 1 year until 5-year follow-up). The primary efficacy parameter was crestal bone level change from baseline up to 5 years post-loading. A one-sided analysis with a mean difference from baseline of 0.1 mm with a standard deviation of 0.3 mm, with \(\alpha = 0.05\) and \(\beta = 0.80\), yielded a minimum sample size of 58 implants. Mean values, standard error of the mean (SEM) or median values, and minimum and maximum values were reported. Student’s t-test was used to analyze crestal bone changes between start of loading up to 5 years. The Kaplan–Meier analysis was carried out for implant survival. Missing data and data from withdrawals were not substituted for the analysis of marginal bone loss. Because reason for withdrawal does not depend on treatment success (bone level change), no systematic bias should be expected from the exclusion of these subjects from marginal bone-loss analysis at the 5-year follow-up visit.
RESULTS

The outcomes of the initial treatment up to 2 years were presented in the earlier report. During preparation of the present paper, an error was detected in the earlier paper regarding the number of patients/implants included in the follow-up. So 28 subjects with 86 implants received prosthetic superstructures and were included in the 5-year follow-up analysis presented here (study group).

After 1 year, all implants were still in function. For mental health reasons, one patient insisted on removal of all implants (which was done after 12 months). The implants were classified as successful at removal.

Two patients died of natural causes during the study period (22 and 55 months, respectively); the implants in these two subjects were all successful at the last visit.

Of the 86 implants loaded from baseline, 9 implants were censored in the analyses for the above-described reasons. After 37.5 months, the first of the remaining implants was lost because of overload. This subject lost two more implants for the same reason – after 48 months – and the remaining implant was censored. One implant was lost after 40.7 months, and after 59.4 months, one implant was lost in another subject; superstructures were still in function in both subjects.

Hence, 24 subjects were followed up as per protocol for 5 years after loading. Five lost implants and one censored implant in three patients were judged as failures, thus yielding a 5-year implant survival rate of 71 out of 77 (92.2%) (Figure 2).

Seven subjects received superstructures at non-study sides and were followed up separately in the same manner as the test sides (non-study group).

In one subject, who displayed preloading implant failure, a longer implant replaced the lost one. In eight subjects, who displayed bilateral edentulism, implants were placed on both sides. In another two subjects, two-unit superstructures were fabricated.

In total, 11 subjects with 18 short (4 mm) implants were in the non-study group. After 5 years, all implants and superstructures were still in function in the non-study group.

Based on all sites, marginal bone loss was calculated, that is, mesial and distal (see Table 3 and Figure 3). Between baseline and 1 year, significant ($p < .001$), mean (SEM), $0.44 \text{ mm (0.05)}$ marginal bone loss occurred. At 2, 3, and 5 years, these mean (SEM) bone loss values were recorded: $0.57 \text{ mm (0.06)}$, $0.55 \text{ mm (0.07)}$, and $0.53 \text{ mm (0.08)}$, respectively, with no significant change after year one.

In general, patients maintained high oral hygiene standards. Freedom of sulcus bleeding was found in 81.7% of the implant surfaces. At the 5-year follow-up, oral hygiene was considered excellent in 66.7%, good
in 25%, and fair in 8.3% of the subjects. The overall mean PI of the implants was 13.3%. Forty-nine implants (69%) had no plaque, 11 implants had plaque on 1 surface, and 9 implants had plaque on 2 surfaces, while 2 implants had plaque on all 4 surfaces. Sulcus bleeding was evaluated for 272 surfaces, 22 (8.1%) of which showed bleeding. Bleeding was observed at 1 surface for 4 implants and at 2 surfaces for 9 implants; 58 implants (81.7%) showed no bleeding surfaces. In a subset (Jönköping study center), peri-implant pocket probing was done at four sites per implant. At 5 years, the remaining 19 study implants (76 sites) were evaluated. Thirteen sites had a 1-mm pocket. At 29 sites each, 2–mm or 3-mm pockets were found. Four sites displayed a 4-mm pocket, while one implant site with a 6-mm pocket was observed. No peri-implant lesion with marginal bone loss was recorded.

At the 5-year follow-up, all subjects rated comfort and appearance as “excellent,” except for two subjects who rated the appearance as “good.” All subjects reported general satisfaction and excellent chewing and tasting capabilities.

**DISCUSSION**

Seventy-one out of 77 implants were in function at 5-year follow-up (92.2%), a survival rate in line with previous studies on ≤6-mm implants and slightly lower than reported in studies with >6 mm-implants in posterior areas or various indications.

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**Figure 2** Mean marginal bone level changes. Marginal bone level changes in millimeters (mm) around implants up to 5 years.

<table>
<thead>
<tr>
<th>Year</th>
<th>Mean</th>
<th>Standard error of the mean</th>
<th>Median</th>
<th>Minimum</th>
<th>Maximum</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.44*</td>
<td>0.05</td>
<td>0.36</td>
<td>−0.95</td>
<td>2.38</td>
<td>168</td>
</tr>
<tr>
<td>2</td>
<td>0.57</td>
<td>0.06</td>
<td>0.51</td>
<td>−1.09</td>
<td>2.87</td>
<td>158</td>
</tr>
<tr>
<td>3</td>
<td>0.55</td>
<td>0.07</td>
<td>0.49</td>
<td>−1.01</td>
<td>4.47</td>
<td>144</td>
</tr>
<tr>
<td>5</td>
<td>0.53</td>
<td>0.08</td>
<td>0.57</td>
<td>−1.76</td>
<td>2.53</td>
<td>111</td>
</tr>
</tbody>
</table>

*p < .001; significant change from start of loading to 1 year.

n = number of radiographically assessed proximal implant sides.
Mean marginal bone loss from baseline to 5 years post-loading was 0.53 mm, with no significant further bone loss after 1 year (see Table 3). This favorable result might be because of surgical and prosthetic handling and biological and biomechanical factors. The authors’ experience of the 4-mm implant is that handling during surgery was similar to implants of more common lengths. But the short length mandates careful bone site preparation to optimize primary stability and to avoid heat-induced bone tissue damage. The nearly doubled implant-healing time in this study (10–12 weeks) most likely ensured osseointegration and implant stability, compared with recommended procedures for longer implants that use the same macro design and surface topography. In addition, splinting implants – as done in this study – enabled increased load sharing between implants – irrespective of loading direction. Note, however, that careful prosthetic procedure planning and design are mandatory to prevent unfavorable occlusion and avoid shear forces. The crown-implant length ratio of the FDPs in this study was high (3.2). Bone loss, however, was not larger than reported for longer implants. But this study’s protocol prescribed all occlusal units to be supported by one implant, and the superstructures were designed with freedom in centric and avoided steep cuspal inclinations and extreme lateral contacts. In addition, bruxing subjects were not included in the study, but it appeared that one subject developed excessive parafunctional forces and subsequently lost three out of four implants. This finding highlights the importance of patient selection.

In a severely resorbed posterior mandible, most of the alveolar ridge is lost. Implants must thus be placed in the basal bone, which may be more resistant to marginal bone loss. Studies on ridge resorption support this indirectly, but substantial individual variations are found so further research is necessary to evaluate this hypothesis.

Using an implant with a roughened surface would increase Sdr (the ratio of the developed surface area) by about 50% (compared with a machine-milled surface) and thereby enhance bone-implant contact. Others reported that roughened surfaces increase primary implant stability and promote faster recruitment of mesenchymal stem cells to the surgical area and higher gene expression.

The implant shape and design parameters that affect load transfer (stress/strain) to the surrounding bone include implant diameter, length, and thread shape. To assess influences of implant length and diameter under various conditions, many biomechanical simulation models examined stress distribution patterns in the bone around implants of various lengths. Finite element analyses (FEAs) revealed that implant diameter and stress peaks seem to affect cortical bone (as in the posterior mandible) more than implant length, while the opposite was revealed for trabecular bone. Himmlova and colleagues found that an increase in the implant diameter decreased the maximum von Mises-equivalent stress around the implant neck more than an increase in the implant length because of more favorable distribution of the simulated masticatory forces applied in that study. Pierrisnard and colleagues studied effect of implant length on bicortical anchorage and stress transfer with various implant lengths and suggested that although maximum implant stress increases with implant length and bicortical anchorage, maximum bone stress remains virtually constant. So the aforementioned simulation models seem to support use of
short, posterior-mandible implants because of dependence on the bone’s cortical part.

However, results from recent FEAs designed to represent the posterior left side of the mandible revealed short implants to be capable of dissipating bone stress, although this was achieved almost at the threshold level between elastic and plastic deformation and here, off-axis loading should be minimized for short implants to prevent high strain and stress forces in the surrounding bone. These findings emphasize that superstructures carried by short implants need careful monitoring, because overload may result in stress beyond the physiological threshold of the bone.

The indication investigated here is limited to the mandible. Other studies also used short implants in the maxilla. Esposito and colleagues compared 5-mm implants placed in resorbed native bone in the posterior maxilla with implants placed in sites in which sinus lifting was performed. Similar survival rates were reported after 3 years.

Besides the advantage of avoiding bone augmentation procedures, need for short implants might be overestimated. Few studies assessed prevalence of tooth gaps that represent possible implant sites on a population level. In particular, we found no studies on available bone height in potential implant sites in posterior tooth gaps. But many reports of bone augmentation in the posterior areas (especially in the maxilla) indicate that bone volume in these areas limits use of implants with common lengths.

Plaque and sulcus bleeding scores were generally very low throughout the study. A high standard of plaque control is reported to prevent plaque-induced, peri-implant marginal bone loss. This fact seems to be even more crucial for long-term, stable results using 4-mm implants.

At the 5-year follow-up, all subjects highly rated comfort, appearance, and ability to chew and taste. Previous to treatment, most of the included subjects had been denied implant therapy because of minimal amounts of available bone. Their awareness of this fact most likely influenced their judgments. However, from a scientific perspective, the nonstandardized way of assessing the patient outcome in this study makes comparison with other interventions difficult. Moreover, no preoperative, oral health, quality-of-life assessments were done in this study. Nevertheless, Esposito and colleagues reported that patients seem to prefer less invasive surgical interventions; this study is one example.

Implant therapy has developed extensively over the years because of increasing experience, technical development, and concomitant procedures to enable treatment. So implant therapy has also become available for patients with severely reduced bone support, who suffer, for example, from cancer, periodontal disease, or previous implant failures. As shown in this study, a 4-mm implant has potential for use in special clinical situations and 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 Guided Bone Regeneration (GBR). And as this study demonstrated, 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 an alternative to time-consuming, often painful, expensive concomitant methods.

CONCLUSION

Although based on a limited number of individuals and implants, this prospective study shows that provided that careful selection, treatment, and follow-up are carried out, 4-mm-long titanium implants, with the SLActive surface, can be safely and successfully used to support an FDP in severely resorbed posterior mandibles for at least 5 years, with healthy peri-implant conditions.

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