

# A 5-year Prospective Multicenter Study on 1-Stage Smooth-Surface Brånemark System Implants with Early Loading in Edentulous Mandibles

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**Purpose:** The purpose of the current prospective multicenter study was to evaluate the 5-year implant success and peri-implant conditions of smooth-surface Brånemark System implants when using a novel technique including a 1-stage surgical procedure with early loading in edentulous mandibles.

**Materials and Methods:** The study protocol included 1-stage surgery as well as placement of the definitive prosthesis within 6 weeks after implant insertion (ie, early loading). Clinical evaluation, as well as evaluation of function and esthetics, was performed at each follow-up visit. Radiographs were obtained at connection of the prostheses and at the 1-, 3-, and 5-year check-ups. **Results:** A total of 40 patients with a mean age of 56 years (range, 30 to 70) were included in the study. In all, 170 implants were placed in between the mental foramina, of which 120 implants in 30 patients were associated with overdenture treatment and 50 implants in 10 patients with fixed complete dentures. Twelve implants failed in 6 patients. The cumulative implant survival rate was 92.9% after both 1 and 5 years of follow-up. Another 3 implants were recorded as mobile but still in function when individually checked at the 5-year visit, which resulted in a cumulative success rate of 91.0%. Mean bone remodeling over the study period was less than 0.1 mm/y after the first year of loading, resulting in a mean marginal bone level of 0.66 mm (SD 0.73, n = 138) apical to the implant collar reference point after 5 years. **Conclusions:** One-stage, early loaded smooth-surface Brånemark System implants functioned well for the majority of patients with edentulous mandibles. Stable peri-implant conditions were observed. Bone remodeling resulted in a mean bone level above the first implant thread after 5 years. The somewhat lower success rate of 91.0% compared to a 2-stage procedure may be related to generous inclusion criteria and to a learning curve involving a novel treatment procedure. INT J ORAL MAXILLOFAC IMPLANTS 2008;23:481-486

**Key words:** early loading, edentulous mandible, endosseous smooth-surface implants, osseointegration

The terminology for the timing of implant loading was established by Aparicio et al<sup>1</sup> during a con-

sensus meeting in Spain in 2002. The initiative was justified by the existing confusion in nomenclature of the immediate, early, and delayed loading concepts. The terminology for early loading in mandibles was thus defined as: "The prosthesis is attached at a second procedure, earlier than the conventional healing period of 3 months...." The shortening of implant procedures and 1-stage surgery with early or immediate loading in the rehabilitation of edentulous mandibles has become a more frequently used treatment modality.<sup>2-11</sup> Implant survival rates at 1 to 5 years of follow-up range between 90% and 100%. Most reports claim survival rates similar to those obtained with the classical 2-stage surgical technique. However, a novel technique requires time for learning, and accurate evaluation of the outcome is of utmost importance in trying to identify and weigh the pros and cons of the procedure.

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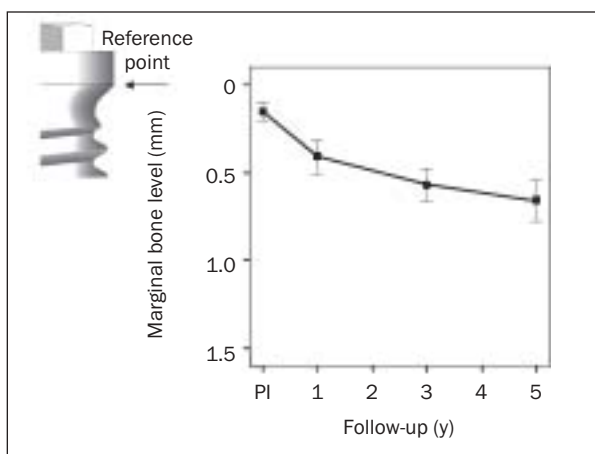
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**Table 1** Distribution of No. of Implants with Regard to Bone Quality and Quantity

Bone quantity	Bone quality				Total
	1	2	3	4	
A	0	0	4	0	4
B	1	46 (4)	26 (2)	0	73 (6)
C	0	30	27 (1)	7 (4)	64 (5)
D	8 (1)	17	0	0	25 (1)
E	4	0	0	0	4
Total	13 (1)	93 (4)	57 (3)	7 (4)	170 (12)

The number of failed implants appears in parenthesis.  
 A = Most of the alveolar ridge is present; B = Moderate residual ridge resorption has occurred; C = Advanced residual ridge resorption has occurred and only basal bone remains; D = Some resorption of the basal bone has started; E = Extreme resorption of the basal bone has taken place.



**Fig 1** Change in marginal bone level from placement of definitive prosthesis (PI) up to 5 years. An illustration of the implant collar with radiographic reference point (arrow) is shown. Dots and error bars show mean values ± standard error.

The aim of the current investigation was to evaluate the 5-year implant success and peri-implant conditions of smooth-surface Brånemark System implants when using a novel technique, including the use of a 1-stage surgical procedure with early loading in edentulous mandibles.

### MATERIALS AND METHODS

The study sample comprised 40 patients with edentulous mandibles. The criteria for participation included mandibular edentulism of at least 3 to 4 months. Patients from 18 to 70 years old were eligible for inclusion. Exclusion criteria included drug or alcohol abuse and psychiatric or administrative problems, which were anticipated to lead to disruption of the planned

follow-up period of 5 years. Patients with a history of radiotherapy in the head and neck region, bone grafting, or oral implantology were also excluded. The protocol included 1-stage surgery and early loading. Placement of the definitive prosthesis within 6 weeks after implant insertion was intended. All patients completed an informed consent form, and the study was approved by the local research ethics committees at each of the participating centers.

Jawbone quality and quantity were registered according to the proposed criteria by Lekholm and Zarb,<sup>12</sup> and the distribution is shown in Table 1. Clinical evaluation forms on soft tissue bleeding and plaque accumulation were completed at 1, 3, and 5 years of follow-up. The clinicians' assessments of esthetic and functional results were registered as excellent, good, acceptable, or unacceptable, and the patients' assessments as either fully satisfied or not fully satisfied. The occurrence of plaque was assessed both buccally and lingually according to a modified version of Silness and Löe's scale<sup>13</sup>: 0 = no plaque in the implant area, 1 = visible plaque. The status of the peri-implant mucosa around the abutments was registered as 0 = normal peri-implant mucosa, 1 = bleeding on superficial probing, 2 = discoloration and spontaneous bleeding.<sup>14</sup> Surgical and prosthetic complications were registered throughout the 5-year study period.

Long-cone intraoral radiographs were obtained at connection of the prostheses and at 1, 3, and 5 years of follow-up. Measurements of the mesial and distal marginal bone levels were executed to the nearest 0.1 mm by a single independent radiologist. The lower corner of the implant collar was used as the reference point (Fig 1). The marginal bone loss was determined during the first year and after 5 years of function.

At the 5-year visit, complete dentures/overdentures were removed, and the stability of each implant was checked individually.

**Table 2 5-year Cumulative Success Rate (CSR)**

Period	Placed/followed implants	Failed	Withdrawn	CSR (%)
Implant insertion to definitive prosthesis	170	1	0	99.4
Prosthesis to 4 wk	169	9	0	94.1
4 wk to 6 mo	160	0	4	94.1
6 mo to 1 y	156	2	0	92.9
1 to 2 y	154	0	0	92.9
2 to 3 y	154	0	0	92.9
3 to 4 y	154	0	8	92.9
4 to 5 y	146	3*	6	91.0
5 y	137			

\*Mobile but still in function.

**Table 3 Esthetic Evaluation**

	Follow-up					
	1-year		3-year		5-year	
	n	(%)	n	(%)	n	(%)
Clinician's assessment						
Excellent	12	33	12	33	6	18
Good	24	67	24	67	27	82
Acceptable	0		0		0	
Unacceptable	0		0		0	
Patient's assessment						
Fully satisfied	33	100	34	100	30	100
Not fully satisfied	0		0		0	

**Table 4 Functional Evaluation**

	Follow-up					
	1-year		3-year		5-year	
	n	(%)	n	(%)	n	(%)
Clinician's assessment						
Excellent	11	31	13	36	10	30
Good	24	67	23	67	23	70
Acceptable	1	3	0		0	
Unacceptable	0		0		0	
Patient's assessment						
Fully satisfied	31	94	33	100	30	100
Not fully satisfied	2	6	0		0	

## Statistical Analysis

Descriptive statistics have been used in the present study. Cumulative survival/success rates were calculated by an actuarial life table method.<sup>15</sup>

## RESULTS

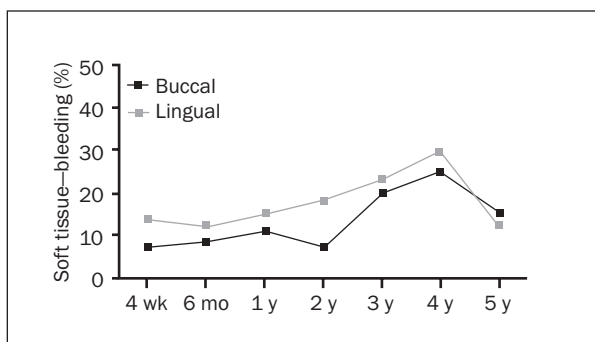
Thirty-four of the patients were followed for 5 years. Three patients required additional treatment because of loss of 2 or more implants and were thereafter withdrawn. Two other patients did not attend the follow-up visits, and 1 patient is deceased. The patients were predominantly female (28/40), and the mean age at implant insertion was 56 years (range, 30 to 70). Placement of implants was executed from April 1997 through June 2000 and involved 5 clinics in 4 countries. A total of 170 smooth-surface Brånemark System implants (Nobel Biocare, Göteborg, Sweden) were placed between the mental foramina according to a 1-stage surgical protocol and loaded within 6 weeks (mean, 30 days; range, 6 to 42 days). The most common implant lengths were 13 mm (n = 78) and 15 mm (n = 45). The other implants were 10 mm (n = 22), 11.5 mm (n = 9), or 18 mm (n = 16). Further data on patient and implant characteristics were presented by Raghoobar et al.<sup>11</sup>

Thirty patients received overdentures, and 10 patients were equipped with fixed complete dentures. Overdentures were supported by 4 implants and a prosthetic bar, whereas fixed complete dentures were supported by 5 implants.

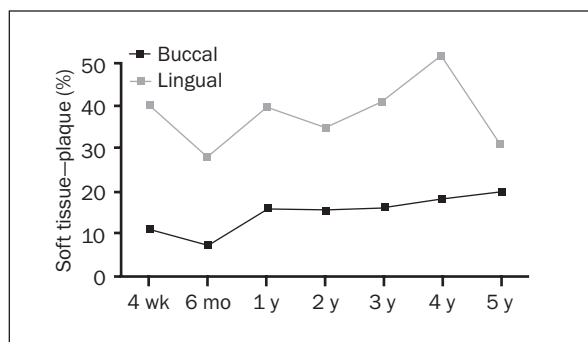
Of the 170 inserted implants, 12 failed in 6 patients. Implant losses were equally distributed among bone quality classes 2, 3, and 4 (Table 1). Thus, four implants failed in the 7 sites (57%) classed as type 4 bone. The cumulative implant survival rate was 92.9% after both 1 and 5 years of follow-up. Another three implants were recorded as mobile albeit still in function, when individually checked at the 5-year visit, which resulted in a cumulative success rate of 91.0% (Table 2). In 3 patients, a new prosthesis was required because of 2 or more implant failures; thus, the cumulative success rate for prostheses was 92.5%.

The clinician assessment of esthetics at the 5-year follow-up visit was excellent (18%) or good (82%). Regarding function, the judgments were excellent (30%) or good (70%). All patients were fully satisfied with the esthetics and function after 5 years (Tables 3 and 4).

Figs 2 and 3 illustrate the occurrence of bleeding and plaque, respectively, during the study period. A normal peri-implant mucosa (ie, score 0 on all sur-



**Fig 2** Percentage of implants with a plaque score of 1 on any of the distal and mesial surfaces during the 5-year follow-up (no patients had bleeding index score 2).



**Fig 3** Percentage of implants with a plaque score of 1 during the 5-year follow-up.

**Table 5 Frequency of Reported Complications**

Complication	Number of patients
Pain during surgery	1
Pain during prosthesis insertion	3
Pain during follow-up	3
Fistulae	1
Bar superstructure fracture	3
Clip fracture /clip out of overdenture	3/11
Abutment screw loosening	2
Occlusal surface fracture	2

In 4 patients, 2 or more complications related to the prosthetic restoration were reported.

**Table 6 Marginal Bone Levels Around Implants at Follow-up Examinations**

	Marginal bone level per position*					
	1-year		3-year		5-year	
Mean (mm)	0.41		0.57		0.66	
SD (mm)	0.59		0.57		0.73	
No. of implants	154		149		138	
	n	%	n	%	n	%
0	77	50	52	35	47	34
0.1 - 1.0	61	40	70	47	63	46
1.1 - 2.0	12	8	24	16	21	15
>2.0 mm	4	2	3	2	7	5

\*Average of mesial and distal values.

All mean values are apical to the reference point, ie, the lower corner of the implant collar.

faces around the abutments) was seen in 82% after 1 year, 76% after 3 years, and 80% after 5 years. The corresponding figures for all surfaces free of plaque were 56%, 54%, and 62%, respectively. Reported complications other than implant failures were few and are listed in Table 5.

The mean marginal bone resorption was 0.26 mm (SD 0.57, n = 151) during the first year of loading and 0.51 mm (SD 0.72, n = 135) from prosthesis insertion up to 5 years (Fig 1). The mean marginal bone level was after 5 years 0.66 mm (SD 0.73, n = 138) apical to the reference point, ie, the lower corner of the implant collar (Table 6).

## DISCUSSION

Pioneering work using Brånemark System implants with 1-stage surgery and early loading was executed by Ericsson et al and described in a series of reports.<sup>7,16,17</sup> The present investigation was an early attempt to evaluate the technique in an international

multicenter study approach. The outcome at 5 years with implant survival and success rates of 92.9% and 91.0%, respectively, leaves a great deal to be desired in edentulous mandibles. Thus, the loss of 12 to 15 implants of 170 in such jaw situations yielded a rather high failure rate and should perhaps be related to a learning curve involving a new treatment procedure. In a clinical comparative study of 750 1-stage and 338 2-stage smooth-surface Brånemark System implants,<sup>8</sup> the implant survival rates at the 1-year follow-up were noticeably better. The authors assumed that the 2 patient groups matched each other well with regard to patient age, smoking habits, and general health disorders. Furthermore, treatment of both patient groups was executed under more or less identical conditions. Nonetheless, the result was significantly better for the 2-stage technique (99.7% versus 97.5%). Whether this documented difference was coincidental or the result of 2 various treatment modalities per se is not possible to say. Perhaps the lower survival rate of 1-stage surgery mainly relates to the use of the smooth

implant surface. The introduction of an oxidized, moderately rough implant surface (TiUnite; Nobel Biocare, Göteborg, Sweden) was correlated with a stronger early bone response and a bony contact that developed markedly faster<sup>18–21</sup> than for the smooth surface. A clinical follow-up study on 450 1-stage TiUnite implants with early loading in edentulous mandibles revealed no implant losses at the 1-year check-up.<sup>22</sup> It has been suggested that the oxidized, moderately rough implant surface is more forgiving in less favorable clinical situations.

Mobile implants were more frequent in relation to the overdenture treatment, a finding that may be coincidental and is otherwise difficult to explain. Most losses (ie, 8 of 12 supporting overdentures and 2 of 3 supporting fixed complete dentures) were registered during the first month of function, when the prosthetic restorations may have had little impact on the outcome. However, more probable causes for implant losses could be the uncritical inclusion of patients with a clenching habit or those with jaw-bone classified as quality 4, who accounted for the loss of at least 6 implants.<sup>12</sup> These patient categories may probably benefit from using the immediate loading concept (ie, splinting of implants within the same day) or, more preferably, from the use of a conventional 2-stage surgical technique. Two patients (with 4 failures) were smokers.

Regarding peri-implant conditions, scores on bleeding and probing were all in accordance with other reports, ie, mainly healthy conditions were observed.<sup>7,23</sup>

The mean marginal bone level at the first annual follow-up revealed that bone resorption was 0.26 mm during the first year and 0.51 mm at the 5-year follow-up examination. Frequency distributions at 5 years revealed a bone level lower than 2 mm in 5% of the implants. Bone remodeling resulted in a mean bone level above first implant thread after 5 years. All figures at 5 years compare well with other reports on 2-stage surgery in edentulous mandibles.<sup>24,25</sup> In a study by Petersson et al,<sup>26</sup> the marginal bone resorption was evaluated after using 3 different treatment concepts for Brånemark System implants in anterior mandibles. After 5 years, the marginal bone was located approximately 1 mm apical to the implant-abutment level in all 3 groups. The authors could not find any difference in long-term marginal bone resorption when comparing 1- and 2-stage surgical procedures and a 1-stage surgical procedure with early functional loading.

All patients were fully satisfied esthetically and functionally with their restorations at 5 years, which is in alignment with most studies on various jaw situations.<sup>27,28</sup>

## CONCLUSIONS

It can be concluded that smooth-surface implants used in a 1-stage surgical procedure with early loading in edentulous mandibles functioned well during this 5-year prospective multicenter study period for the majority of patients. Stable peri-implant conditions were observed. Bone remodeling resulted in a mean bone level above first implant thread after 5 years. An implant success rate of 91.0% is somewhat lower than may be expected, however, especially as the teams at each center were well-experienced in implant treatment, and is perhaps a result of broad inclusion criteria and the learning curve for a treatment procedure that was novel at first. With more experience with the procedure and the use of the oxidized implants with an appropriate surface texture (eg, TiUnite), greater success would be expected.

## ACKNOWLEDGMENTS

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