

# Immediate and Early Function of Brånemark System® Implants Placed in the Esthetic Zone: A 1-Year Prospective Clinical Multicenter Study

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## ABSTRACT

*Background:* Immediate/early implant function means great benefits for patients and therapists because treatment time and cost can be substantially reduced. This concept has become an accepted alternative for complete arch fixed restorations in the mandible, and clinical documentation is emerging for other indications.

*Purpose:* The purpose of this prospective clinical multicenter study was to evaluate the outcome of implants placed in incisor, canine, and premolar regions in maxillas or mandibles. Implants were loaded with provisional crowns and bridges on the same day or within a few days and were followed up for 1 year during function.

*Materials and Methods:* Four centers treated 76 patients each in need of an implant-retained prosthesis in the anterior and premolar regions in the maxilla or mandible. A total of 116 titanium implants with machined surfaces (Brånemark System®, Nobel Biocare AB, Gothenburg, Sweden) were placed: 74 in maxillas and 42 in mandibles. Eighty-seven prostheses were made, of which 63 were single crowns and 24 were bridges (supported by 53 splinted implants). Twenty-two implants in 14 patients were placed in fresh extraction sites. The goal with the preparation and insertion technique was to achieve good primary implant stability and a minimum implant insertion torque of 30 Ncm before the implant was completely seated. The occlusion was adjusted to eliminate direct contact with the provisional prostheses. After 6 months, the patients received their permanent prostheses. Sixty-seven patients were followed for 1 year.

*Results:* Five implants were lost in five patients, three in the maxilla and two in the mandible. Four of the lost implants were single-tooth replacements and one was splinted. The cumulative survival rate (CSR) was 95.7% for all implants after 1 year and 93.7% and 98.1% for single-tooth and splinted implants, respectively. There were no implant losses in the extraction sites.

*Conclusions:* The CSR of 96% at 1 year indicates that immediate function of Brånemark System implants placed in incisor to premolar regions in both jaws is a viable concept. More failures occurred with single-tooth replacements (6.3%) than with splinted implants (1.9%).

**KEY WORDS:** immediate loading, Brånemark System® implants, esthetic zone, early loading, single tooth, short-span bridges

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The use of osseointegrated dental implants has made it possible to rehabilitate edentulous jaws to near-normal levels of esthetics and function. The predictability of

dental implants ad modum Brånemark has been shown to be high when following a two-stage surgical procedure with a submerged healing period of 3 months in the mandible and of 6 months in the maxilla.<sup>1-3</sup>

During recent years it has been demonstrated that it is possible to achieve comparable results also with a one-stage surgical procedure when the implant is allowed to heal while the mucosa is penetrated with an abutment.<sup>4-7</sup> Providing the patient with an immediate solution may further shorten the treatment time and increase patient comfort. The viability of this modality has been demonstrated in several clinical studies.<sup>8-16</sup>

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These studies demonstrate high success rates for immediate implant function of complete arch prostheses in mandibles. However, there is little information available for single-tooth replacements and short-span bridges in different oral regions as well as for complete arch prostheses in maxillas. The survival rates reported for single-tooth replacements in the esthetic zone vary between 86 and 100%. The reason for this variation may be the different inclusion criteria and the use of different protocols and implant types.

The need for immediate implant function is probably most obvious in anterior regions to restore the esthetic appearance after tooth loss. Maló and colleagues<sup>12</sup> reported on a concept of immediate implant function in the esthetic zone in a retrospective clinical study from one clinic, giving a 95.7% survival rate. However, to the knowledge of the present authors, no prospective multicenter study on immediate implant function in anterior regions has been published.

The present prospective multicenter study is based on the clinical protocol described by Maló and coworkers.<sup>12</sup>

## **MATERIALS AND METHODS**

Four centers participated in the study. Seventy-six consecutive patients, 41 males and 35 females (mean age 41 yr, range 18–81 yr) were included in the study. The first patient was treated in April 1999 and the last patient in August 2000. The study protocol was approved by ethics committees. Twenty-five patients had been edentulous for less than 1 year, 18 for between 1 and 5 years, and another 18 patients for more than 5 years; immediate extractions were made in 14 patients (data from 1 patient are missing). Twenty-four patients smoked 10 cigarettes or more per day. Two patients had ongoing serious illness, such as asthma and hypertension, and 8 patients had been prescribed ongoing medications, including oral insulin as well as cardiac and respiratory medications. The oral hygiene was good for 24 of the patients and acceptable for the remaining 52.

A total of 116 machined titanium implants of various designs and diameters (Brånemark System®, Nobel Biocare AB, Gothenburg, Sweden) were placed: 74 in maxillas and 42 in mandibles. Eighty-seven prostheses were made, of which 63 were single crowns and 24 were bridges (supported by 53 splinted implants). Twenty-two implants in 14 patients were placed in fresh extraction sites.

## **Inclusion Criteria**

The following specific inclusion criteria were used: (1) the need of partial or single implant retained prosthetic solution in the anterior maxilla or mandible; (2) a sufficient amount of bone for placing implants with a length of at least 10 mm; (3) a crest that would admit a prosthetically correct sagittal implant placement; (4) implant site(s) free from infection and/or extraction remnants; and (5) high primary implant stability (preferably a minimum of 30 Ncm insertion torque before the final seating of the implant).

## **Exclusion Criteria**

If any of the following criteria were applicable, the patient was not included in the investigation: (1) patient circumstances were such that the treatment could affect the patient's health or the patient's cooperation; (2) any disorders in the planned implant area such as previous tumors, chronic bone disease, or previous irradiation; (3) hindrance of the patient to give his/her informed consent of participating; (4) alcohol or other drug abuse; (5) subjects with severe bruxism; and (6) infection or endodontic or periodontal problems in teeth adjacent to the implant site.

## **Surgical Protocol**

The patients received antibiotics 1 hour prior to surgery. The surgical treatment was performed following the principles for Brånemark System® procedures,<sup>17</sup> but minimal or no countersinking was performed. Altogether eight surgeons placed the implants and strived to achieve high implant stability and a minimum implant insertion torque of 30 Ncm at placement. The insertion torque was registered by the drilling unit, and the stability of the implant was evaluated by clinical judgment. Whenever possible a bicortical anchorage was attempted. In cases of extraction sites, the sockets were well cleaned before drilling. The implant types and dimensions and the bone quality and quantity (according to Lekholm and Zarb's classification<sup>18</sup>) were recorded at the time of implant placement for each individual site.

## **Prosthetic Protocol**

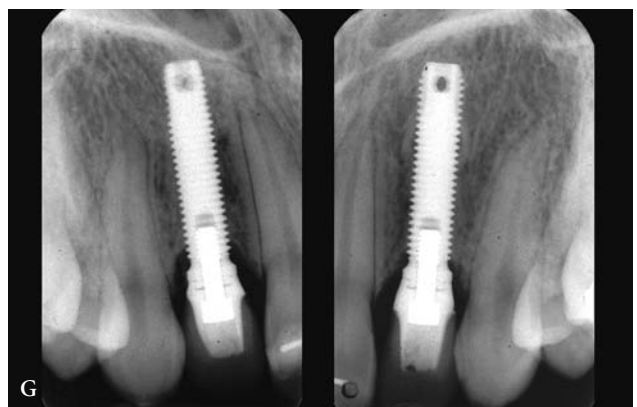
The intended final abutment was inserted at the time of surgery. Sixty-eight patients received a temporary crown or bridge on the day of surgery, and five patients received one or the other on the following day. All

patients received the prosthesis within a week after implant placement.

The occlusion was adjusted to eliminate direct contact to the prosthesis, and the patients were instructed to avoid biting or chewing directly on the implant-supported crown/bridge. At the 1- to 2-week follow-up, the occlusion was rechecked. After 5 months an impression was taken, and after 6 months the patients received

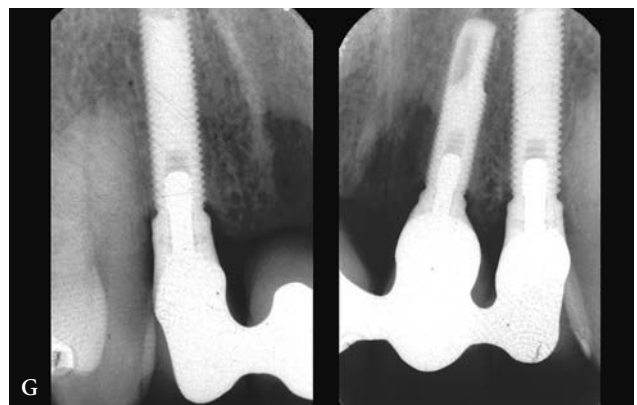
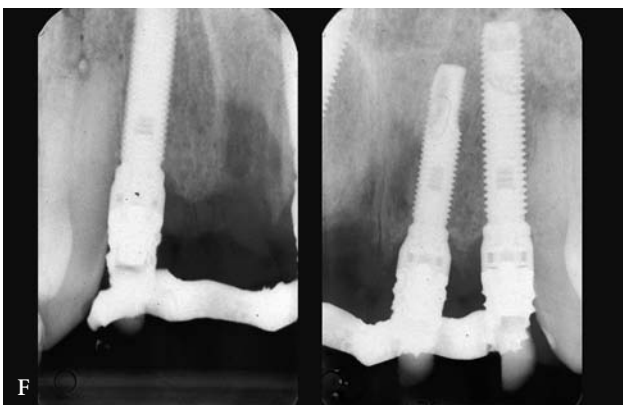
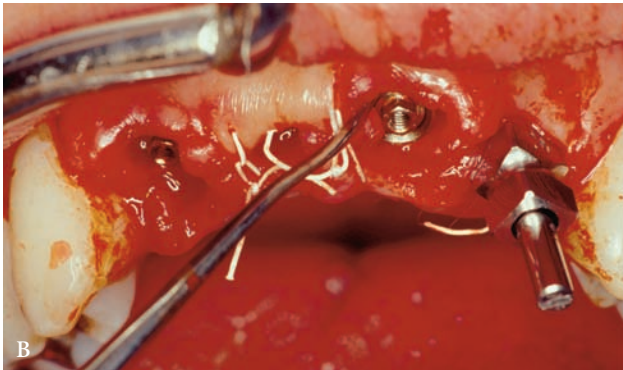
their permanent prosthetic reconstruction. Twenty-two abutments in 13 patients were changed before the final prosthesis was fabricated to adjust the abutment height to the soft tissue margin.

Figure 1A–G shows a case involving single-tooth replacements, and Figure 2A–G shows a case involving a splinted bridge, including the treatment procedure from surgery to final restorations and radiographic follow-up.



**Figure 1** Patient with immediately loaded single implants replacing both maxillary laterals. A, Extraction of primary laterals; B, impression copings in place following implant placement; C, temporary crowns in place; D, soft tissue conditions 6 months after surgery; E, Procera® AllCeram crowns (Nobel Biocare AB) in place 6 months after surgery; F, radiographs taken at baseline; G, radiographs taken after 1 year.

**Figure 2** Patient with an immediately loaded implant bridge in the anterior maxilla. *A*, Edentulous area before treatment; *B*, implants in place are being prepared for impression; *C*, temporary prosthesis in place; *D*, soft tissue conditions 6 months after surgery; *E*, final bridge in place; *F*, radiographs taken at baseline; *G*, radiographs taken after 1 year.



#### Follow-up Procedure and Postoperative Care

Follow-up visits were performed at 1 to 2 weeks, 6 months, and 1 year after implant insertion. At the first follow-up visit, the sutures were removed. The individual implant stability was checked at the 6-month and 1-year follow-ups. Esthetic and func-

tional evaluations were made by both the dentist and the patient at the 6-month and 1-year follow-ups. The dentist's assessments were measured in four values ("excellent," "good," "acceptable," and "unacceptable"), and the patient chose either "satisfied" or "not satisfied."

**Survival and Failure Criteria**

Implants were classified as survivals when clinically stable and fulfilling purported function without any discomfort to the patient, with no signs of infection or ongoing pathologic processes, and no shown radiolucency present around the implants. All other implants were classified as failures.

**Radiographic Examination**

Intraoral radiographs from the time of implant placement and at the 6-month (upon delivery of the final prosthesis) and 1-year follow-up visits were taken for evaluation. The radiographs were taken perpendicularly with a long-cone parallel technique, showing the whole implant and at least 2 mm on each side of it. An independent radiologist examined all radiographs. The implant-abutment platform was used as the reference for the bone level registrations.

**Patient Withdrawals**

Five patients were withdrawn from the study: one died, four exhibited poor compliance, and another four lost their single-tooth implants.

**RESULTS**

All 116 implants were considered stable at the time of insertion. Pretapping with a screw tap was applied in 21 of the sites (18%); the insertion torque ranged from 30 to 50 Ncm in all but two sites, where it was 20 Ncm. In 96 of the sites (83%), bicortical anchorage was achieved. Three unexpected events were reported at implant placement: two buccal fenestrations and one case of extremely thin bone crest. One patient was reported to have a clenching tendency.

Five implants were lost in five patients, three in the maxilla and two in the mandible. All failed implants were placed in quality 2 or 3 bone (Table 1). Specifications of implant lengths and diameters are shown in Table 2. Four of the lost implants were single-tooth replacements (unsplinted), and the remaining lost implant was splinted into a bridge. The cumulative survival rate (CSR) was 95.7% for all implants after 1 year and 93.7% and 98.1% for unsplinted (single) and splinted implants, respectively (Table 3). The majority of the failures occurred in incisor regions (Table 4). None of the failed implants were placed in fresh extraction sites (22 sites), and no failure was found among the smokers (32% of the patients). Except for

**TABLE 1 Implants in Relation to Bone Quality and Quantity**

Bone Quantity	Bone Quality				Total
	1	2	3	4	
A	0	22 (1)	33 (1)	0	55
B	4	23 (2)	19	6	52
C	0	4	5 (1)	0	9
D	0	0	0	0	0
E	0	0	0	0	0
Total	4	49	57	6	116

Numbers in parentheses indicate failed implants.

the nine withdrawn patients, all patients attended the 1-year follow-up visit.

**Marginal Bone Levels**

The mean marginal bone loss during 1 year follow-up after implant placement was 1.20 mm (SD 0.94 mm, *n* = 85; Table 5 and Figure 3).

**Subjective Treatment Evaluation**

The esthetic and functional outcomes of the treatment, based both on dentists' and patients' assessments, are detailed in Tables 6 and 7. The scores show a high degree of subjective satisfaction.

**Adverse Events**

No serious or severe adverse events were reported. Fistulas were reported in two patients (four events) at the 6- and 12-month follow-up visits. Loss of suture resulting in gingival retraction was reported for one patient at the 1- to 2-week follow-up. Paresthesia on one adjacent tooth was reported in one patient at the 1- to 2-week follow-up. In this patient the implant was removed 7 months later because of loss of osseointegration.

**Specification of Nonintegrated Implants**

All five lost implants were immediately loaded at the day of insertion. Further details for the lost implants are given in Table 8.

Two clinics had two failures each, and one clinic had one failure. The five situations with failures were as follows:

1. A male patient receiving implant treatment because of trauma on tooth 22. The region had been edentulous for about 8 weeks at the time of implant insertion. At the impression appointment 6

**TABLE 2 Implant Length, Diameter, and Type with Regard to Jaw Distribution**

Type	Length (mm)	Implants in Maxillas		Implants in Mandibles	
		Placed	Failed	Placed	Failed
Mk II and Mk III (3.3)	13	3	1	4	1
	15	14	0	6	0
Total: 27 (23%)		17	1	10	1
Standard implant (3.75)	13	1	0	2	1
	15	10	0	4	0
	18	12	0	1	0
	20	1	0	3	0
Total: 34 (29%)		24	0	10	1
Mk II (3.75)	11.5	0	0	1	0
	13	5	0	0	0
	15	8	0	3	0
	18	1	1	2	0
Total: 20 (17%)		14	1	6	0
Mk III (3.75)	15	6	0	0	0
	18	3	0	5	0
Total: 14 (12%)		9	0	5	0
Standard and Mk II (4.0)	13	0	0	1	0
	15	5	0	3	0
	18	1	0	2	0
Total: 12 (10%)		6	0	6	0
Mk IV (4.0)	10	0	0	1	0
	13	1	0	0	0
	15	2	0	4	0
Total: 8 (7%)		3	0	5	0
Standard (5)	10	1	1	0	0
Total: 1 (0.8 %)		1	1	0	0
Grand total (%)		(63.8)	(2.6)	(36.2)	(1.7)

months after implant insertion, the implant was found mobile and was removed.

2. A male patient with tooth 12 lost more than 5 years previously owing to a caries lesion and periapical inflammation. Paresthesia was noted on an adjacent tooth 1 week after insertion, and the implant was lost at the impression appointment 5 months later.
3. A male patient with tooth 44 extracted because of root fracture less than 1 year before implant insertion. The implant was removed 1 month after insertion because of persistent pain.
4. A male patient with tooth 21 lost as a result of trauma some years earlier. At the impression appointment 3 months after implant insertion, the implant was found to be mobile and was removed.
5. A female patient with teeth 31 and 41 lost because of adult periodontitis some years earlier. The

implant at position 31 was removed 9 months after insertion. No adverse events were reported at previous follow-up visits. The implants were splinted at the time of loading.

All patients with lost implants were successfully re-treated with new implants placed in one- or two-stage techniques.

## DISCUSSION

The result from this prospective multicenter study (CSR 96%) confirms the results of a previous retrospective single-center study,<sup>12</sup> in which a similar clinical protocol was used.

The survival rate for the splinted restorations (98.1%) is comparable to results with two-stage procedures,<sup>19</sup> whereas the survival rate for the single-tooth

**TABLE 3 Life Table Analyses**

	Time Period		
	Placement–6 mo	6 mo–1 yr	1 yr
<b>All implants</b>			
Fixtures	116	111	103
Failed	4	1	
Withdrawn	1	7	
Missing	0	0	
CSR (%)	96.6	95.7	
<b>Single implants</b>			
Fixtures	63	58	51
Failed	4	0	
Withdrawn	1	7	
Missing	0	0	
CSR (%)	93.7	93.7	
<b>Splinted implants</b>			
Fixtures	53	53	52
Failed	0	1	
Withdrawn	0	0	
Missing	0	0	
CSR (%)	100.0	98.1	

replacements (93.7%) is somewhat lower. This difference may be owing to the more advantageous load distribution at a bridge configuration compared with that of a single tooth.<sup>20</sup> Splinting of implants often reduces the bending moment transferred to the implants from lateral forces.

The bone resorption (1.2 mm the first year) is in accordance with what is normally found for two-stage protocols<sup>21,22</sup> but slightly higher than that in a previous study by Maló and colleagues<sup>12</sup> (0.8 mm after the first year). In the present study, however, the implants were placed slightly deeper, with a mean value of 0.3 mm above the crest; in the previous study, the implants were placed 0.8 mm above the crest as a mean. Relative to the implant platform, however, the bone levels were quite similar in the two studies, about 1.5 mm below the implant-abutment interface.

None of the failed implants were placed in fresh extraction sites (22 sites), which indicates that well-cleaned fresh extraction sockets are not a contraindication for immediate loading, provided that the implants

**TABLE 4 Implant Positions**

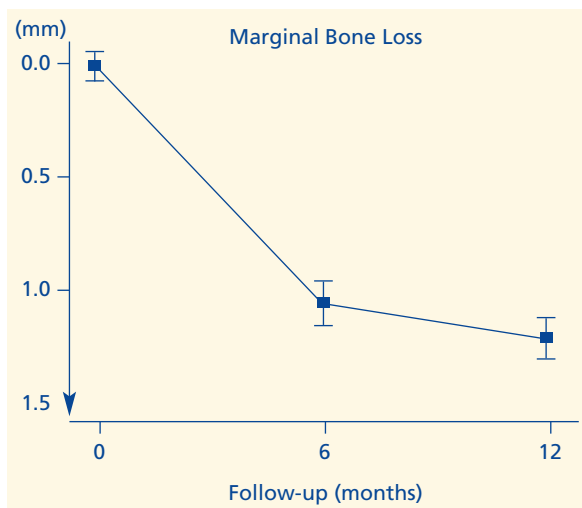
Location/Outcome	Tooth Position										Total
	15	14	13	12	11	21	22	23	24	25	
<b>Maxilla</b>											
Placed	0	3	2	14	17	16	12	3	6	1	74
Failed	0	0	0	0	1	1	1	0	0	0	3
<b>Mandible</b>											
Placed	1	3	3	9	4	5	8	2	6	1	42
Failed	0	1	0	0	0	1	0	0	0	0	2

**TABLE 5 Marginal Bone Loss from Baseline to 1 Year**

Bone Loss (mm)*	Distal (n = 84)		Mesial (n = 85)		Average† (n = 85)	
	n	%	n	%	n	%
0.0	24	29	16	19	14	16
0.1–0.5	6	7	4	5	9	11
0.6–1.0	9	11	20	23	10	12
1.1–2.0	33	39	30	35	40	47
> 2.0	12	14	15	18	12	14

\*Mean (SD) in mm: distal 1.11 (1.05); mesial 1.28 (0.98); average 1.20 (0.94).

†(mesial + distal) ÷ 2.



**Figure 3** Marginal bone loss ([distal + mesial] ÷ 2) during 1 year. The dots represent mean ± SE.

have sufficient initial stability. One-third of the patients were smokers (over 10 cigarettes per day), but they experienced no implant losses. This indicates that the potential reduction of vasculization that smoking may induce was not important for implant survival with the present protocol. Probably the initial implant stability was more important.

All failures but one occurred before the final prostheses were placed. The early failures were single-implant cases, whereas the late failure was a splinted situation. It could be speculated that the reason for failures was that the implants never became integrated, a fact that was earlier registered in the single-implant situations. However, more important from a practical clinical point of view is the fact that the

majority of the failures occurred before the final prostheses were manufactured.

It is important to note that all cases with implant failures were re-treated in a straightforward manner. This means that the majority of patients benefited from one surgery only, and only the patients with failed implants needed a second surgery. This is in contrast to the two-stage surgical protocol, in which all patients are subjected to a second surgery.

The high implant survival rate in this study, as well as that of the pilot study, and the favorable esthetic and functional evaluations from both patients and clinicians indicate that the immediate function protocol may be considered as a standard procedure.

TABLE 6 Esthetic Evaluation				
Assessment	6 Mo		1 Yr	
	n	%	n	%
Dentists'				
Excellent	21	30	18	27
Good	46	66	41	61
Acceptable	1	1	6	9
Unacceptable	2	3	2	3
Total	70*	—	67	—
Patients'				
Satisfied	70	100	65	100
Not satisfied	0	0	0	0
Total	70*	—	65†	—

\*Dentist and patient evaluations from one patient are missing from the 6-month follow-up.

†Patient evaluations from two patients are missing from the 1-year follow-up.

TABLE 7 Functional Evaluation				
Assessment	6 Mo		1 Yr	
	n	%	n	%
Dentists'				
Excellent	28	40	25	37
Good	42	60	37	55
Acceptable	0	0	5	8
Unacceptable	0	0	0	0
Total	70*	—	67	—
Patients'				
Satisfied	70	100	65	100
Not satisfied	0	0	0	0
Total	70*	—	65†	—

\*Dentist and patient evaluations from one patient are missing from the 6-month follow-up.

†Patient evaluations from two patients are missing from the 1-year follow-up.



**TABLE 8 Characteristics of Lost Implants**

Position of Implants	Type and Diameter/Length (mm)	Time to Failure (mo)	Bone Quality	Bone Quantity	Smoking	Extraction Site
22	Standard 5/10	6	3	C	No	No
12	Mk II 3.75/18	5	2	B	No	No
44	Standard 3.75/13	1	2	B	No	No
21	Mk II 3.3/13	3	2	A	No	No
31	Mk II 3.3/133	9	3	A	No	No

Recent clinical results have demonstrated that implant-surface modification by anodic oxidation (TiUnite™, Nobel Biocare AB) helps to maintain the initial mechanical implant stability during bone healing and improve implant survival at immediate loading.<sup>23,24</sup> Although high implant survival rates have been achieved with machined-surface implants, it is possible that immediate/early loading would be even more reliable with TiUnite implants. However, this needs to be confirmed in controlled clinical trials.

## CONCLUSIONS

The outcome of the present prospective 1-year study indicates that immediate function of Brånemark System implants in the esthetic zone is a viable clinical concept. A higher failure rate was seen for single-tooth replacements than for splinted implants.

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