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# 3-Year Prospective Multicenter Study on One-Stage Implant Surgery and Early Loading in the Edentulous Mandible

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## ABSTRACT

*Background:* The long-term success rates achieved in dental implantology suggest that flexibility might well exist within the various implant systems to a degree that an altered protocol (ie, one-stage surgery and immediate or early loading) can be performed under controlled conditions. However, before variations of the protocol can be considered for general use, they must be subjected to critical analysis, particularly with respect to the predictability of osseointegration, alteration of soft tissue barrier, and relative change in bone height around the implants.

*Purpose:* The aim of this prospective multicenter study was to evaluate implant survival and periimplant conditions around endosseous implants placed in a one-stage surgical procedure and early loading.

*Materials and Methods:* A total of 170 implants were placed in 40 patients with mandibular edentulism and were functionally loaded within 6 weeks with overdentures ( $n = 30$ ) or fixed prostheses ( $n = 10$ ). All patients and prosthetic constructions were evaluated according to a standardized protocol during 3 years of follow-up. Cumulative implant survival rates were calculated, and implant loss in relation to implant size and bone quality and quantity were evaluated. Furthermore, the protocol included assessment of clinical (plaque and bleeding scores, prosthesis stability) and radiographic parameters.

*Results:* Over a period of 3 years, the implant survival rate was 93% for both implants and prostheses (fixed or removable). No implants were lost after the first year of loading. The periimplant tissues were in a healthy condition. Mean marginal bone resorption from the time of loading to the 3-year follow-up was 0.41 mm (SD 0.52).

*Conclusions:* From this study it may be concluded that early loading results in good implant survival and proper periimplant health in edentulous mandibles.

**KEY WORDS:** early loading, edentulous mandible, endosseous implants, osseointegration

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Problems associated with lack of stability and retention of a lower denture can often be solved with the use of endosseous implants to which an overden-

ture or bridge construction can be attached. Until recently one of the most emphasized requirements for predictability of implant integration according to Brånemark and colleagues was a stress-free healing period of 3 to 6 months.<sup>1-7</sup>

However, this multistep process of endosseous implant therapy is time consuming and may limit patient acceptance of the treatment. One-stage surgery has already solved part of this problem and has developed to a proven clinical alternative.<sup>8-10</sup> The next steps in increasing patient acceptance are thought to be early (prosthetic construction provided within 6 weeks after implant placement) and/or immediate (prosthetic construction provided on the day of implant placement) loading. Whether immediate or early loading is possible

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to perform depends greatly on bone and soft tissue qualities. Several reports have been presented in recent decades suggesting the potential applicability of both immediate and early loading.<sup>11-21</sup> However, additional research is needed before these techniques can be applied in daily practice. The long-term success rates achieved in dental implantology suggest that flexibility might exist within the implant systems to a degree that an altered protocol can be considered under controlled conditions when performed by experienced clinicians. Nevertheless, before variations of protocol can be considered for general use, they must be subjected to critical analysis, particularly with respect to the predictability of osseointegration, alteration of soft tissue barrier, and relative change in bone height around the implants.

The aim of this prospective multicenter clinical trial was to evaluate the implant survival and periimplant conditions around endosseous implants that were inserted in a one-stage surgery procedure and were loaded early. This report is an interim presentation of a subsample of 40 patients, with an observation time of 3 years after prosthesis placement.

## MATERIALS AND METHODS

The study was designed as a multicenter trial and involved five centers in four countries, all with experience using the Brånemark technique. A surgical and prosthodontic protocol was strictly followed, and Brånemark System<sup>®</sup> components (Nobel Biocare AB, Gothenburg, Sweden) were used. All teams were encouraged to include every patient consulting them for reduced stability and insufficient retention of their lower denture. The criteria for participation included mandibular edentulism of at least 3 to 4 months. Age limits were from 18 to 70 years. Exclusion criteria included drug or alcohol abuse and psychiatric or administrative problems, which were anticipated to lead to a disruption of the planned follow-up period of 5 years. Also patients with a history of radiotherapy in the head and neck region, of bone grafting, or of oral implantology were excluded. Furthermore, the protocol included early loading, that is, the intention was placement of the final prosthesis within 6 weeks after implant insertion. All patients completed an informed consent form in accordance with the Declaration of Helsinki on biomedical research in human subjects, and the study had the approval of the local ethics committees at each of the participating centers.

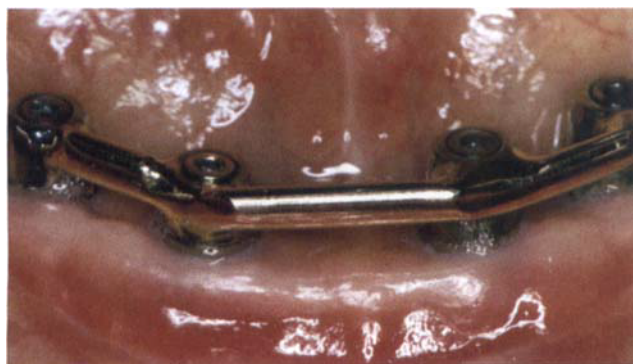
## Patients

A total of 83 patients were included in the study, of which 40 patients received their final prostheses within 6 weeks (mean, 30 d) after implant placement. The total material ( $n = 83$ ) will be presented in the 5-year follow-up report. Of the 40 patients, 28 were female and 12 were male. The mean age was 56 years (range, 30–70 yr). Ten patients (25%) were smokers at inclusion.

Implant insertion was carried out according to a one-stage procedure (Figure 1). The implant sites between the mental foramina were identified, and surgical placement was carried out with respect to anatomic structures.<sup>2</sup> The bone quality and quantity were noted and recorded.<sup>22</sup> In total, 170 machined Brånemark System implants were inserted (84 Brånemark System Standard, 3.75 mm diameter; 86 Brånemark System Mk II, 3.75 mm diameter). Thirty patients received an overdenture (4 implants, bar attachment; Figure 2) and 10 patients a fixed bridge (5 implants). The patients with fixed bridges have 38 standard abutments, 11 Estheti-Cone abutments, and 1 angulated abutment; the patients with overdentures all have standard abutments. The patients were permitted to wear a temporary denture if wanted. All but three patients have attended the 1- and 3-year follow-up visits. The three patients who did not complete the follow-up had undergone new treatment because of loss of two or more implants.



**Figure 1** Clinical view of insertion of five implants according to the one-stage procedure.



**Figure 2** Clinical appearance of the prosthetic bar on four implants for overdenture support.

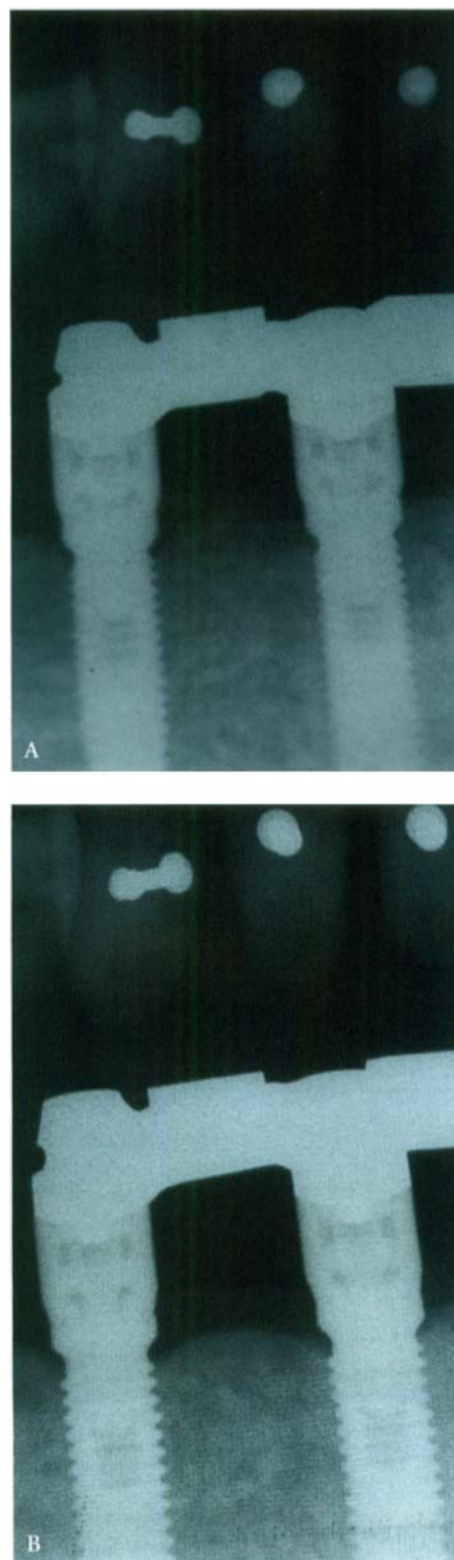
### Clinical and Radiographic Registrations

The following parameters were evaluated by one investigator at each center at 4 weeks, 6 months, and 1, 2, and 3 years after prosthesis insertion, respectively.

- **Plaque index.** The occurrence of plaque was assessed both buccally and lingually according to a modified version of Silness and Løe's scale<sup>23</sup>: 0 = no plaque in the implant area, 1 = visible plaque.
- **Bleeding index.** The status of the periimplant mucosa around the abutments was registered as 0 = normal periimplant mucosa, 1 = bleeding on superficial probing, 2 = discoloration and spontaneous bleeding.<sup>24</sup>
- **Esthetic and functional evaluation.** The dentist's assessment of the esthetic and functional results was registered as (1) excellent, (2) good, (3) acceptable, or (4) unacceptable. The patient's assessment was registered as either (1) fully satisfied or (2) not fully satisfied.
- **Mobility.** The mobility of the implants was recorded at the prosthesis-delivery appointment. The prosthetic constructions were not routinely removed at postloading follow-up visits, only in cases when the prosthesis itself or the bar constructions were mobile or when the patient experienced discomfort on function or percussion, or if radiographic loss of integration was suspected.

To accurately assess individual implant stability, one should remove the prosthesis and test the single implant. This means that in the results after 1 and 3 years of follow-up, the survival, not success, rates were presented. However, at the 5-year follow-up visit, the bridge/overdenture will be removed for an individual implant stability test.

Regardless of etiology, all surgical and prosthodontic complications were carefully reported. Long-cone intraoral radiographs were taken immediately after



**Figure 3** A, Intraoral radiograph 1 year after placement of prosthesis; B, intraoral radiograph 3 years after placement of prosthesis.

placement of the prosthesis and at the 1- and 3-year follow-up visits (Figure 3). All radiographic evaluations for measurement of marginal bone levels were made by one independent radiologist. Patients are scheduled for further follow-up visits that will include annual examinations up to 5 years post loading.

### Statistical Analysis

Descriptive statistics and conventional life table analysis with regard to cumulative success and survival rates (CSRs) have been used in the present study. The Mann-Whitney *U* test was used for comparison of marginal bone losses between the different types of prosthetic solutions. Tests for trend in contingency table (Mantel-Haenszel chi-square)<sup>25</sup> were used to analyze differences in bleeding and plaque. The statistical tests were based on the patient as unit (not on the implant), that is, a mean of all loaded implants was calculated per patient in the analysis of marginal bone levels. For comparisons in dichotomous variables, the percentage of surfaces with bleeding and plaque was calculated for each patient. Significance tests were two tailed and were conducted at the 5% significance level.

### RESULTS

Of the total number of implants placed and loaded within 6 weeks ( $n = 170$ ), 12 (7%) in 6 patients failed and were removed, giving a CSR of 93% for implants. Three patients had new treatment because of implant losses, giving a CSR of 93% for the prostheses also. Ten implants failed within the first 4 weeks of loading. The life table analysis showed no differences in CSR between

**TABLE 1 3-Year Cumulative Survival Rates (CSRs) of Early Loaded Implants\* Supporting Overdentures**

Time Period	Placed/ Followed			CSR%
	Implants	Failed	Withdrawn	
Implant insertion				
Final prosthesis	120	1	0	99
Prosthesis-4 wk	119	7	0	93
4 wk-6 mo	112	0	1	93
6 mo-1 yr	111	1	0	93
1 yr-2 yr	110	0	0	93
2 yr-3 yr	110	0	0	93
3 yr	110			

\*In 30 patients.

**TABLE 2 3-Year Cumulative Survival Rates (CSRs) of Early Loaded Implants\* Supporting Fixed Bridges**

Time Period	Placed/ Followed			CSR%
	Implants	Failed	Withdrawn	
Implant insertion				
Final prosthesis	50	0	0	100
Prosthesis-4 wk	50	2	0	96
4 wk-6 mo	48	0	3	96
6 mo-1 yr	45	1	0	94
1 yr-2 yr	44	0	0	94
2 yr-3 yr	44	0	0	94
3 yr	44			

\*In 10 patients.

implants supporting overdentures and those supporting fixed bridges, 93% and 94%, respectively (Tables 1 and 2). Most of the failures were long implants, 15 to 18 mm (Tables 3 and 4). All except one of the failed implants were placed in the bone quantity category B or C. Four of the 7 implants placed in bone quality 4 were lost (Table 5). The loss of implants did not correlate with the use of a temporary denture (16 patients had a temporary denture).

The periodontal parameters showed healthy tissues around the implants. A normal periimplant mucosa (ie, score 0 on all surfaces around the abutments) was seen in 82% of the patients after 1 year and in 76% after 3 years (Figure 4). The corresponding figures for surfaces free of plaque were 56% after 1 year and 54% after 3 years, respectively (see Figure 4). Plaque was more common lingually than buccally, 40% versus 15% ( $p = .039$ ) at the 3-year follow-up. This tendency was seen at all visits.

Radiographic observations at the 1-year follow-up visit were obtained on 151 implants in 37 patients. The corresponding figures at the 3-year follow-up were 146 implants in 36 patients. The mean marginal bone loss after the first year of loading was 0.26 mm (SD 0.57) and after 3 years 0.41 mm (SD 0.52; Table 6). There was no statistical difference between implants supporting fixed bridges or overdentures ( $p > .30$ ).

Except for the implant losses, prosthetic complications were mainly just reported (Table 7). The esthetic and functional evaluations showed that the dentists assessed the outcome as excellent or good in 100% and



**TABLE 3** Details of Implant Failure\*

Sex of Patient	Implant Position <sup>†</sup>	Timing of Loss	Implant Length (mm)	Prosthesis	Bone Quality/Quantity
Male	<b>44, 43, 33, 34</b>	Prior to loading	15	OD	2/B
Female	<b>44, 43, 41, 32, 34</b>	4 wk	18 and 15	FB	3/B
Male	<b>44, 41, 32, 34</b>	4 wk	18	OD	2/B
Male	<b>44, 42, 32, 34</b>	4 wk	15	OD	4/C
Female	<b>43, 42, 32, 33</b>	1 yr	10	OD	1/D
Female	<b>44, 43, 41, 32, 34</b>	1 yr	13	FB	3/C

FB = fixed bridge; OD = overdenture.

\**n* = 12.

<sup>†</sup>Those implants shown in boldface failed.

97%, respectively, after 1 year of follow-up and in 100% for both categories after 3 years. All patients were fully satisfied with the esthetics and function after 3 years (*n* = 32, 1 missing).

## DISCUSSION

In this report the implants were inserted according to a one-stage procedure and loaded within 6 weeks with a prosthetic construction. The results showed similar good survival rates for both implants supporting a fixed cross-arch bridge and implants supporting an overdenture. Furthermore, the conditions around the implants indicated proper periimplant health after 3 years of follow-up. In the literature, overall implant survival rates between 86 and 100% have been reported for endosseous implant systems in the edentulous mandible.<sup>21,26–30</sup> Latter early loading studies reported an implant survival of more than 97% in edentulous mandibles. For example, in a study by Ericsson and colleagues,<sup>27</sup> a survival rate of 100% after 5 years was demonstrated when using machined Brånemark System implants in a one-stage procedure combined with early loading. The somewhat lower survival rate found in the present investigation may be coincidental; it may be

owing to the multicenter study character with several performing dentists involved or it may be because of the selection of patients, which included those with characteristics such as bruxism and bone quality type 4.

The prosthetic procedure is normally commenced 3 to 6 months after implant placement when using standard protocols. The recommendation of 3 to 6 months was derived empirically and yet was verified as being sufficient to allow most implants to remain osseointegrated.<sup>1,2,4–7</sup> Although not proven to date, there are indications that an implant with sufficient primary stability on insertion may be able to withstand the immediate load of a prosthesis.<sup>11–20</sup> Primary stability is a function of local bone quality and quantity, the performed surgical technique, and the implant design.<sup>31</sup> Over the years the primary stability has been determined subjectively by the performing surgeon, using the hand-felt perception during insertion and checking for signs of clinical implant mobility. A quantitative method for evaluating the primary stability of an implant at the time of placement is highly beneficial as such information can be used to predict the optimal healing period for each indi-

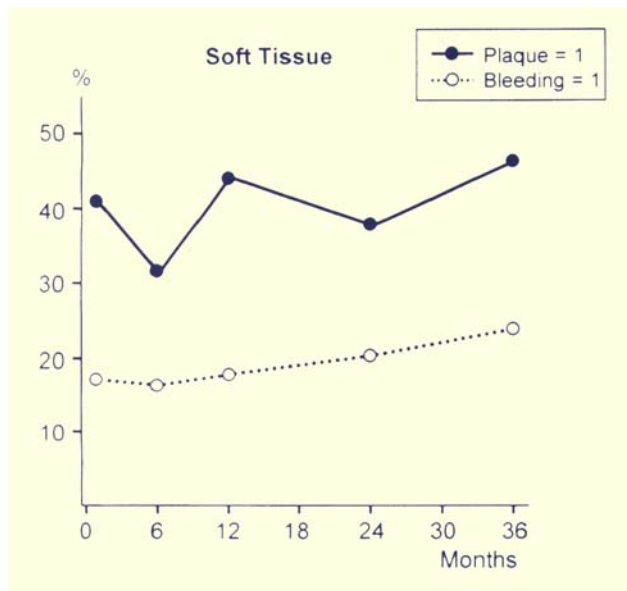
**TABLE 4** Distribution of Implants According to Length

Implant Length (mm)	Total (%)	Overdenture (%)	Fixed Bridge (%)
10	22 (13)	16 (13)	6 (12)
11.5	9 (5)	7 (6)	2 (4)
13	78 (46)	51 (43)	27 (54)
15	45 (27)	34 (28)	11 (22)
18	16 (9)	12 (10)	4 (8)

**TABLE 5** Distribution of Number of Implants According 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
C	0	30	27 (1)	7 (4)	64
D	8 (1)	17	0	0	25
E	4	0	0	0	4
Total	13	93	57	7	170

Number of failed implants appears in parentheses.



**Figure 4** Percentage of score 1 regarding soft tissue bleeding on any of the analyzed surfaces and percentage of score 1 regarding plaque occurrence on any of the analyzed surfaces (no patients had bleeding index score 2).

vidual implant. The use of noninvasive techniques to determine the implant stability, such as the Periotest® system (Siemens AG, Bensheim, Germany) or resonance frequency analysis (RFA) (Integration Diagnostics, Gothenburg, Sweden) has therefore been suggested. RFA quantifies the lateral movements of an implant under controlled force<sup>32</sup> by using a device that measures the resonance frequency of a small transducer attached to the implant. The resonance frequency values are related to the height of the implant that is not surrounded by bone and to the implant/tissue stiffness. In a clinical study, Friberg and colleagues<sup>33</sup> placed implants in the anterior mandible with a one-stage surgery technique. Resonance frequency measurements were executed after placement and at 2, 6, and 15 weeks postoperatively. The authors demonstrated that implants placed in bone of high density were as stable in the immediate postoperative period as they would be after a

3- to 4-month healing period. Thus, it was proposed that implants showing high primary stability in dense bone may be suitable for an immediate or early loading concept because the additional bone-implant contact, created as a result of bone remodeling and osteogenesis, would not markedly increase the secondary stability.

In the present study, a few patients with soft bone were included. Half of the implants being inserted in bone quality 4 failed, indicating that maybe a more cautious procedure should have been considered for these patients. However, roughened (microtextured) surfaces have been shown to better maintain primary implant stability<sup>34,35</sup> and to shorten the time needed to accomplish secondary stability, compared with a machined surface.<sup>36-39</sup> This could enhance the treatment outcome when applying an early or immediate-loading protocol, especially in soft bone regions.

The current study demonstrated proper periimplant conditions, which were in accordance with other studies.<sup>26-28,30</sup> With regard to the marginal bone loss, the values of 0.26 mm (SD 0.57) and 0.41 (SD 0.52) from prosthesis installation to the 1- and 3-year follow-ups, respectively, are similar to those reported by Ericsson and colleagues.<sup>27</sup>

Predictable osseointegration of oral implants is important. One key factor when dealing with immediate or early loading is the primary implant stability. To maintain osseointegration, the secondary stability must be kept at a high level. Thus, apart from the surgical approach, healing time intervals and implant surface characteristics, as well as a prosthetic design with proper distribution of forces among the supporting implants, are mandatory.<sup>40</sup>

From this study it is concluded that early loading may result in good implant survival in edentulous mandibles both for support of a fixed cross-arch suprastructure as well as for an overdenture. However, evidence-based treatment procedures demand scientific documentation before use. Therefore, before early or

**TABLE 6** Marginal Bone Resorption around Implants per Position\* Evaluated from Prosthesis Insertion (PI)

Time Period	Total		Overdentures		Fixed Bridges	
	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n
PI-1 yr	0.26 (0.57)	151	0.22 (0.55)	107	0.36 (0.60)	44
PI-3 yr	0.41 (0.52)	146	0.39 (0.48)	107	0.47 (0.62)	39

(Distal + mesial) ÷ 2.

**TABLE 7** Frequency of Reported Complications

Complication	No. of Patients
Pain during surgery	1
Pain during prosthesis insertion	3
Pain during follow-up	2
Fistulae	1
Framework fracture	1
Bar fracture	2
Clip fracture	2
Clip out of overdenture	10
Abutment screw loosening	2

immediate-loading protocols can be routinely recommended, additional controlled studies must be executed that validate implant treatment outcomes in bone of various densities and in restorative situations.

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