Rehabilitation of Edentulous Mandibles by Means of Turned Brånemark System® Implants after One-Stage Surgery: A 1-Year Retrospective Study of 152 Patients

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ABSTRACT

Background: Rehabilitation of the edentulous mandible with oral implants is today predominantly executed with one-stage surgery and early or immediate loading. It is generally claimed that the outcome is similar to that of the classic two-stage technique.

Purpose: The aim of the present investigation was to retrospectively evaluate the 1-year results of one-stage surgery and early loading performed in edentulous mandibles in a large group of patients. The outcome was compared with that of a study, from the same clinic (control), that used the two-stage surgical technique in edentulous mandibles and whose data were well controlled.

Materials and Methods: The study included 152 individuals with 750 turned Brånemark System® implants of various designs placed in edentulous mandibles by means of one-stage surgery. The prosthetic procedure was commenced at a mean of 13 days after the surgical intervention. Intraoral apical radiography was performed at the time of prosthesis placement and at the 1-year annual checkup. Comparison of failure rates between the test and the control groups was made by means of the chi-square test.

Results: A total of 18 implants in 12 patients in the study group were found to be mobile up to and including the first annual checkup, equivalent to a 1-year implant cumulative survival rate (CSR) of 97.5%. The corresponding CSR for the control group was 99.7%. Differences between the two groups in regard to implant survival reached significant levels when analyzed with the chi-square test ($p < .05$). No such significant difference was seen on the patient level ($p > .05$). Because of implant failures one prosthesis in the study group was remade. The mean marginal bone resorption during the first year of function was 0.4 mm in both groups.

Conclusions: The present investigation showed a high but (compared with the classic two-stage technique) somewhat lower CSR after 1 year for the one-stage technique. More prosthetic adjustments due to implant failures were observed in the study group, and the results emphasize the need for large study samples in order to statistically verify small differences between various treatment techniques.

KEY WORDS: early loading, edentulous mandibles, implant failure, one-stage surgery, oral implants

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Rehabilitation of the edentulous mandible by means of placing five to six Brånemark System® implants (Nobel Biocare AB, Göteborg, Sweden) in the anterior region with the traditional two-stage surgical technique has yielded implant survival rates of 98.9 to 99.7% after 5 to 20 years of follow-up.[1–3] Over the years various attempts have been made to shorten and facilitate the procedure by using one-stage surgery with delayed early or direct immediate loading. The terminology for the timing of implant loading has been confusing,

which is why a consensus statement was presented during the Sociedad Espanola de Implantes World Congress in Barcelona in 2002.[4]

A pioneering study on immediate loading with Brånemark System implants was made by Schnitman and colleagues,[5] who placed two additional implants in the posterior mandible, to be loaded immediately in a tripodal arrangement together with one of the anterior implants. Remaining anterior implants were kept submerged. Thus, an interim fixed prosthesis could be connected on the same day. Of the immediately loaded implants, 85% survived for 10 years.[6] A similar approach, with an excessive amount of inserted implants, was executed by Tarnow and colleagues[7]; 67 of 69 (97.1%) immediately loaded implants survived during the study period of 1 to 5 years. Wolfinger and colleagues[8] used the same concept and found an implant survival rate of 80% for the development group after 5 years. When they "simplified" the procedure (ie, inserted fewer implants and maintained the initial implant splinting over a healing period of 3 months), the implant survival rate was 97%.

Efforts have been made to further reduce the number of implants in edentulous mandibles. In two recent studies, each with 14 patients, treatment was executed with four immediately loaded turned Brånemark System implants and interim fixed prostheses.[9,10] Implant survival rates were as high as 98.2 to 100% after 1 year.

A novel technique of immediate loading in mandibles, the Brånemark Novum® system (Nobel Biocare AB), was introduced in 1999. The purpose was to insert three implants only, without the need for submerged rescue implants, and to finalize a permanent fixed prosthesis on the day of implant surgery.[11–13] The authors have shown implant survival rates of 91 to 98% after 1 year of function. Hatano[14] described a way of simplifying this treatment by using three Brånemark System implants and placing a permanent fixed prosthesis on the same day. The 1-year implant survival rate was 97.7%.

Several reports on one-stage surgery and early or delayed loading in edentulous mandibles are available. Ericsson and colleagues[15] used a split-mouth technique with both submerged (two-stage surgery) and nonsubmerged (one-stage surgery) implants with delayed loading. Two of the 33 nonsubmerged implants failed during the initial healing period of 3 months. No further losses were reported when the same study material was evaluated at 5 years.[16] In a later publication, Ericsson and colleagues[17] presented the 5-year outcome of early loading with fixed permanent constructions delivered within 20 days. None of the 88 implants failed during the study period.

Uncontrolled load in the early postoperative period is regarded as a risk factor. Ericsson and colleagues advocated a denture-free period of 10 days after surgery.[17] However, the immediate use of relined dentures together with one-stage surgery has been reported.[18,19] In the study done by Henry and Rosenberg,[18] all implants survived the 2-year follow-up whereas Becker and colleagues[19] reported an implant survival rate of 96.7% in mandibles after 1 year. A more evenly distributed load, as exerted by a denture, may be advantageous to patients with a history of clenching since grinding on single nonsubmerged implants in the healing phase could be detrimental. Nevertheless, splinting of implants on the day of surgery, as advocated in immediate loading, must be regarded as a safer procedure.

Collaert and De Bruyn[20] compared Brånemark System implant integration and short-term survival when one- and two-stage surgical techniques are used for completely edentulous mandibles. The early survival rate of 97.6% for one-stage implantation (33 patients) and the rather low survival rate of 92.9% for two-stage implantation (17 patients) revealed no significant difference between the two treatment modalities. The lack of difference is most likely a result of the small study samples used.

The aim of the current study was to retrospectively evaluate the 1-year treatment outcome in all edentulous mandibles treated with a one-stage surgical technique and turned-surface implants and fixed prostheses with mainly early loading in a larger group of patients. Furthermore the result was compared with that of a study having well-controlled data retrieved from the same clinic when the two-stage surgical technique was used in edentulous mandibles.

MATERIALS AND METHODS

Patients and Implants

The present study included 152 individuals with edentulous mandibles (90 females and 62 males) with a mean age of 66 years (range, 37–95 years) at the time

of implant surgery (Table 1). Treatment was executed at one clinic (The Brånemark Clinic, Göteborg, Sweden) between November 1996 and November 2002. Three patients received prosthetic rehabilitation by the referring dentists.

Information on the patients' medical histories and general health problems is presented in Table 2. Data on smoking habits were available for 121 patients, indicating 47 (39%) smokers and 74 nonsmokers.

A total of 750 implants were inserted in the mandible (Table 3); 104 were of the standard design, 25 were conical self-tapping implants, 180 were Brånemark System Mk II implants (Nobel Biocare AB), and 441 were Brånemark System Mk III implants (Nobel Biocare AB). The use of various implant designs reflects the development of new components in the Brånemark System. In the early study period the standard and Mk II implants were the implants of choice whereas the Mk III implant dominated from 1999. The use of 25 conical self-tapping implants is explained by the design of an early contemporary study performed at The Brånemark Clinic.[21] All implants had turned surfaces and a diameter of 3.75 mm. The majority of patients (140 patients) received 5 implants. Four implants were inserted in 11 patients, and one patient received six implants.

The type of dentition (either natural or artificial) in opposite jaws was registered; the data are presented in Table 4.

Treatment Protocol

Preoperative examinations followed a standard and well-established protocol regarding clinical and radiographic assessments.[22,23] Preoperative bone quantity and quality were judged from radiographs and from tactile perception during drilling; assessment was based on the classification proposed by Lekholm and Zarb.[22] The distributions are shown in Table 5.

TABLE 1 Distribution of Treated Patients with Regard to Gender and Mean Age at the Time of Implant Treatment

Group	Mean Age (yr)*	Females	Males	Total
Test	66.0 (10.4)	90	62	152
Control†	67.3 (11.0)	34	34	68

*Numbers in parentheses indicate standard deviations.
†Data from Örtorp A and Jemt T.[30]

TABLE 2 Distribution of Patients with General Health Disorders

Diagnosed Disorder	Test Group (n = 152)	Control Group* (n = 68)
Cancer	3	1
Cardiac and vascular diseases	53	19
Deep depression	1	3
Diabetes	5	8
Down syndrome	1	0
Hepatitis C	2	0
Rheumatoid arthritis	4	5
Tuberculosis	1	0
Anticoagulation medication with warfarin	6	0
Smoking	39%	36%

*Data from Örtorp A and Jemt T.[30]

Patients were informed of the possibility of including both implant placement and abutment connection in one session. However, the final decision for one- or two-stage surgery was made during the surgical procedure and was based on an insertion torque[24] of > 30 Ncm and/or an implant stability quotient[25] of > 60. In 21 patients extractions of residual lower teeth were performed during the implant placement session.

One hour prior to surgery patients received a single dose of amoxicillin (3 g) or (in case of penicillin allergy) a single dose of clindamycin (600 mg). Implant placement followed the guidelines described by Adell and colleagues[26] and by Widmark and colleagues.[27] Pretapping was performed prior to the insertion of standard and conical implants. Conical implants were originally introduced in 1983 as self-tapping implants for the softer bone of maxillas, which is why they required pre-tapping before being inserted in the present study. The Mk II and Mk III implants served as self-tapping implants in the dense bone texture of the mandibles. Abutments were connected at the same time.

The prosthetic procedure was commenced at a mean of 13 days after the surgical procedure, showing a clear trend toward shorter intervals (7 days) during the last 2 to 3 years of the study period. Conventional removable prostheses, when used, were adjusted and relined with a soft tissue conditioner 7 to 14 days after implant placement and were thereafter used during

TABLE 3 Life Table Analysis Showing the Cumulative Survival Rate for Implants and Prostheses

	Study Group (One-Stage Surgery)							
	Implants				Patients			
	Number of Implants				Number of Patients			
Time Period	Followed	Failure*	Withdrawn	CSR (%)	Followed	Failure†	Withdrawn	CSR (%)
Implant placement	750	5	—	99.3	152	—	—	100
Prosthesis placement	745	13	48	97.5	152	1	10	99.3
1 year	684	—	—	—	141	—	—	—
			Control Group‡					
Implant placement	338	1	—	99.7	68	—	—	100
Prosthesis placement	337	—	10	99.7	68	—	2	100
1 year	327	—	—	—	66	—	—	—

CSR = cumulative survival rate.
*Study group – Control Group: $p < 0.05\%$.
†Study group – Control Group: $p > 0.05\%$.
‡Data from Örtorp A and Jemt T.[30]

the prosthetic treatment. Most patients (*n*, 147) received fixed prostheses with machined titanium frameworks[28] and resin veneers whereas the remaining five prostheses were made with frameworks of cast gold alloy and resin teeth.[29]

There was a mean interval of 42 days (standard deviation [SD], 28.5 days; range, 10–133 days) between implant placement and delivery of prostheses. The reasons for the extended prosthetic treatment periods were that (1) some early patients had participated in the aforementioned study on implant stability,[21] (2) there were initial logistic problems with manufactured titanium frameworks, and (3) some patients were afflicted with rather severe general health problems.

TABLE 4 Distribution of Natural and Artificial Dentitions of Opposite Upper Jaw

Dentition	Test Group	Control Group*
Full natural dentition (including 2nd premolar)	35	16
Natural teeth and removable partial dentition	3	4
Natural teeth and implants	3	2
Fixed implant-supported prosthesis	30	12
Removable implant-supported prosthesis	1	2
Complete removable denture	78	32
No data	2	0

*Data from Örtorp A and Jemt T.[30]

TABLE 5 Distribution of Jaws with Regard to Bone Quality and Bone Quantity, for Placed Implants and Failed Implants*

Bone Quantity	Bone Quality 1	2	3	4	Total
		Test Group			
A	0	7 (5)	0	0	7 (5)
B	1	80 (4)	23 (2)	3	107 (6)
C	1 (1)	17 (1)	9 (5)	2	29 (7)
D	2	3	2	0	7
E	0	1	0	0	1
Total	4 (1)	108 (10)	34 (7)	5	151 (18)†
		Control Group‡			
A	0	3	3	0	6
B	1	28	11	3	43
C	2	2	6 (1)	2	12 (1)
D	1	0	2	1	4
E	2	1	0	0	3
Total	6	34	22	6	68

*Figures in parentheses indicate the number of failed implants.
†Data missing for one patient.
‡Data from Örtorp A and Jemt T.[30]

Intraoral apical radiography was performed at the time of prosthesis placement. The patients were then scheduled for the first annual checkup, but they were encouraged to contact the clinic whenever they had a problem with their prostheses. Intraoral apical radiography was again performed at the first annual examination. Mean levels of marginal bone (mesial, distal) in relation to the fixture/abutment junction were assessed from radiographs made at prosthesis placement and at the 1-year checkup. When the marginal bone levels for the conical implants were calculated, a value of 3.5 mm, corresponding to the height of the tapered collar, was subtracted from the registered bone level values. All complications that occurred during the study period were documented.

Reference Groups for Two-Stage Surgical Treatment

One specific study[30] with well-controlled data has been used as a control. This control study comprised results from the most recently published study of a group of patients treated with the two-stage surgical protocol for edentulous mandibles during 1996 and 1997 at the same clinic. It was assumed that this control study matches the present study well with regard to patient age, smoking habits, and general health disorders. More females were represented in the present study, but since no study has shown a gender-based difference in success, this was considered acceptable. Furthermore both studies were carried out at the same clinic, mainly by the same surgeons and prosthodontists and with the same surgical setup, and the treatment periods do partly coincide. With regard to the various implant designs, they were similar except for the Mk III implant, which had not been launched when the control group was treated in 1996 and 1997. However, the Mk III implant has shown the same success rate as the others have shown.[27] All control patients received fixed prostheses designed with titanium or cast gold alloy frameworks with resin teeth. Seven patients were excluded from the control study[30] (they were treated with one-stage surgery). The retrieved available data are presented in Tables 1 to 6.

Statistical Analyses

In the present study descriptive statistics and conventional life table analysis showing implant CSRs were used. Comparisons between the test and control groups in regard to failure rates were made by means of the chi-square test. Statistical significance was set to 5%.

TABLE 6 Mean Bone Level* and Mean Bone Resorption during the First Year in Function

	Bone Level (mm)†		Bone Loss (mm)†
Group	At Prosthesis Placement	At 1 Year	At 1 Year
Test	1.2 (0.46)	1.6 (0.67)	0.4 (0.54)
Control‡	1.2 (0.40)	1.6 (0.48)	0.4 (0.36)

*In relation to fixture/abutment junction.
†Numbers in parentheses indicate standard deviations of the mean.
‡Data from Örtorp A and Jemt T.[30]

RESULTS

Altogether 142 (93%) patients were followed up for 1 year. Eight patients, provided with 38 implants, died before the first annual checkup. Another two patients, provided with 10 implants, did not show up for the first annual checkup (see Table 3). Radiographs were available for all 142 patients that were followed up for the entire period.

A total of 18 implants in 12 patients were found to be mobile up to and including the first annual checkup (see Table 3), equivalent to a 1-year implant CSR of 97.5%. Table 3 shows the corresponding figures for the two-stage control study.[30] Differences between one- and two-stage surgeries in regard to implant survival reached significant levels when tested with the chi-square test ($p < .05$). However, no such significant difference was seen at the patient level ($p > .05$).

Eight implants were recorded as failures in 7 patients (one patient lost two implants) during the prosthetic procedure or within the first 5 months. At the 1-year visit another 10 implants were removed in five patients, of which two patients lost 5 and 2 implants, respectively.

The majority of implants were placed in jaws of bone quality 2 or 3, and shape groups B and C predominated. Most failing implants were also seen in bone of quality 2 or 3, and the losses were more equally distributed among shape groups A, B, and C (see Table 5).

With regard to failures by implant design, the distribution was as follows: 1 conical self-tapping implant (4.0%), 6 Mk II implants (3.3%), and 11 Mk

III implants (2.5%). None of the original standard Brånemark System implants failed during the study period.

No clear patterns could be found between failures and general health disorders although 5 patients with implant losses were diagnosed with cardiac and vascular diseases, 2 patients had rheumatoid arthritis (one of these patients was also diabetic), 2 patients had cancer, and 1 patient was diagnosed with Down syndrome. However, one cancer patient, who had a history of irradiation of the head and neck region (64.6 Gy), exhibited an irregular radiographic bone pattern at the 1-year follow-up and had two implant failures. The other two patients with multiple losses (five and two implants, respectively) were healthy individuals who were taking no medication. On the other hand they were heavy smokers and showed signs of severe clenching. Both patients were successfully operated upon again with traditional two-stage surgery. It should be noted that three patients accounted for 50% of the failures, corresponding to nine implants. The patient with five implant losses and another two patients who each had one implant loss had their residual lower teeth extracted during the implant placement session.

The types of dentition of the opposite jaws were equally distributed among the patients with failing implants (4 patients with natural dentition, 5 patients with removable prostheses, and 3 patients with implant-supported fixed constructions).

Thirteen implants in eight patients were lost after the prostheses had been connected to the implants. Seven of these prostheses had to be adjusted by shortening the posterior extension, and one construction had to be remade after additional implant surgery. Apart from prosthesis adjustments, impaired sensation of the lower alveolar nerve was reported in one patient, acrylic tooth fractures were reported in two patients, and one prosthesis was reported to be mobile (the bridge locking screws were retightened in this patient).

Radiographs were obtained from 151 patients after prosthesis placement and from 142 patients at the 1-year checkup. Table 6 shows data on bone levels for the test and control groups.

DISCUSSION

This study's resulting 1-year CSR (97.5%) for implants with one-stage surgery and early loading compares well with the outcomes of traditional two-stage surgical procedures with Brånemark System implants.[1–3,31] However, even though this result compares well with the average implant survival rate of 94.5% that was found in an extensive meta-analysis of implant survival in edentulous mandibles,[32] the failure rate was significantly higher ($p < .05$) than that of the control study[30] used as a reference. This observation can be related to the fact that The Brånemark Clinic, with extensive experience of this treatment situation with more than 3,000 patients during more than 15 years,[33] has established a predictable treatment protocol with lower failure rates for two-stage procedures than expected for the average clinic.[32] Thus the present relatively large sample of one-stage protocols with good clinical results can be compared to relatively large samples of two-stage protocols with extensive experience and a low failure rate. The present significant difference is then an important finding, revealing the need for large study samples to verify relatively small differences between different treatment techniques. However, when the corresponding test was performed on the patient level, no significant difference was found.

An implant failure in the anterior mandible is a rare finding, and multiple losses are extremely rare in two-stage surgery. In the present study one patient lost five implants and two patients lost two implants each, which reduced the number of patients afflicted with failures to an insignificant level and also indicated a cluster pattern among patients that has previously been observed for treatment of the edentulous upper jaw.[34,35] However, all three patients with a cluster pattern in this study can be accounted for by specific risks (cancer in one patient; bruxism in the second patient; and complete failure, with smoking habits and tooth extraction in connection to implant placement, in the third).

Certainly it must entail a higher biologic risk to early-load only mechanically anchored non-osseointegrated implants than to wait for osseointegration before loading. This study's implant losses could be partly a result of clenching on non-osseointegrated implants. Although resonance frequency measurements[36] of implants placed between the mental foramina show the same stability values at placement as they show after 3 months of healing,[21,37] one-stage nonsplinted implants must be more vulnerable during the first postoperative weeks. Thus patients with a habit of

clenching must be handled somewhat gently, either with a two-stage surgical technique or with immediate loading (ie, with implant splinting on the day of surgery).

Seven failures were recorded in patients in whom implants were immediately inserted after extraction. Malo and colleagues[38] reported on immediate loading in the esthetic zone and found that all their failures were registered in fresh extraction sites. One of the conclusions of that study was that extra care should be taken when dealing with potentially inflamed and infectious implant sites. However, in a more recent report of a prospective multicenter study on early loading mainly in the esthetic zone of maxillas and mandibles, the authors reported no failures in extraction sites.[39] Despite these controversial outcomes extraction with immediate implant placement must be regarded a risk factor, especially when combined with one-stage surgery.

One patient with a history of cancer and irradiation of the head and neck region lost two implants. Increased implant failure rates in the head and neck region of irradiated cancer patients have been reported in a series of publications.[40,41] Whether radiotherapy was the cause of the current losses is not possible to determine although parts of the mandible (lower and posterior) were targeted. Pre- and postoperative treatment with hyperbaric oxygen in relation to implant placement has been shown to significantly improve implant survival.[40,42] However, the patient in our study did not receive any adjunctive hyperbaric oxygen therapy.

In two-stage surgical procedures successful osseointegration is established prior to the prosthetic procedure. The very few implants that then may be loose at second-stage surgery can be removed, and the prosthetic treatment can be evaluated in relation to this complication prior to completion. This is in contrast to one-stage procedures with early/immediate loading, in which the prosthesis is initially supported by mechanically anchored nonintegrated implants. After the prostheses were completed in this study, the majority (72%) of the failing implants were found to be loose. The clinical implication of this is that there is a risk that about 5% (8 of 152) of the prostheses will have to be redesigned or even remade in the one-stage protocol, as compared to an extremely rare clinical situation for the two-stage surgery protocol in the mandible.[30,33] Thus the obvious clinical and economic advantages of a one-stage surgical protocol have to be balanced against the uncertainty of whether osseointegration will take place, and modified prosthetic protocols may have to be introduced for the one-stage protocol. Either a temporary prosthesis may be used, which will increase the treatment cost per se, or a permanent prosthesis may be placed from the start, with a higher risk for prosthesis adjustment or remaking. The trend in implant treatment today is to disregard the slightly increased failure rate (statistically proven in the present study) and the increased prosthetic treatment cost that early/immediate loading may render. On the other hand, from the patient's perspective there is much to gain from having one operation instead of two, namely, a shorter treatment period and the avoidance of an intermediate removable prosthesis between the two surgical stages. However, patients must be given information concerning those rare events of partial or complete failure that require a second (two-stage) surgical intervention and new implant prostheses.

The mean marginal bone level at the first annual checkup revealed a bone resorption of 0.4 mm during the first year, which compares well with the outcome of the reference group treated with the two-stage surgical technique.[30] This observation is also in accordance with a study by Petersson and colleagues,[43] who evaluated marginal bone resorption after using three different treatment concepts for Brånemark implants in anterior mandibles. At 18 months and after 5 years, the marginal bone was located approximately 1 mm apical to the fixture/abutment level in all three groups, and the investigators concluded that in a long-term perspective there was no difference in marginal bone resorption between one- and two-stage surgical procedures and a one-stage surgical procedure with early functional loading of Brånemark implants.

The implants used in the present study all had turned surfaces. Since the introduction of the oxidized TiUnite™ surface (Nobel Biocare AB), a series of experimental and clinical studies have been performed. The immediate loading concept that uses turned Brånemark System implants was presented by Glauser and colleagues[44]; the treatment concept was later repeated with Brånemark System TiUnite implants.[45] When matching the study samples, the authors found the oxidized implant CSR to be significantly higher. Thus it may be of interest to follow up the present report with data on TiUnite implants used with the same treatment modality. Such a study is in progress.

CONCLUSIONS

The present investigation of 152 edentulous mandibles and 750 Brånemark System implants placed by using a one-stage surgical procedure with mainly early loading and fixed prostheses demonstrated an implant cumulative survival rate of 97.5% at 1 year. Despite the high success, it was possible to show a significantly higher implant failure rate than that found with the classic two-stage surgical technique ($p < .05$). This difference may be explained by the large number of patients treated. However, when the corresponding test was performed at the patient level, no significant difference was found.

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