Simplified Methods of Implant Treatment in the Edentulous Lower Jaw. Part II: Early Loading

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ABSTRACT

Background: Most implant treatment is performed with a two-stage surgical procedure. A disadvantage of these implant treatments is that they are time-consuming.

Purpose: The aim of the present study was to evaluate the results of early loading in the edentulous mandible and to compare those results with treatment results of one-stage surgery followed by a healing period and with two-stage surgery.

Material and Methods: The material comprises four treatment groups with a total of 108 patients with edentulous lower jaws and 432 implants. All patients were treated with Brånemark implants (Nobel Biocare AB, Gothenburg, Sweden) with a turned surface and fixed prostheses in the lower jaw, supported by four implants. The patients in group A were treated with a one-stage procedure, a two-piece implant, and a 3-month healing period before loading. Group B (control group) had a two-stage procedure, a two-piece implant, and a 3-month healing period. Group C had a one-stage procedure, a one-piece implant, and a 3-month healing period. Group D was treated with a one-stage surgical procedure, a two-piece implant, and early loading (within 3 weeks). All patients were provided with a Procera® Implant Bridge (Nobel Biocare) with a framework made by computer-assisted milling of one piece of pure titanium. All patients have been followed up for 1 year.

Results: The survival rates were 93.2 to 93.3% in the experimental groups and 97.5% in the control group. The difference was not statistically significant. The measurements of the marginal bone level demonstrated a mean bone loss of 0.8 mm between fixture insertion and the 1-year examination in patients with early loading (group D) whereas the bone loss in patients who underwent a healing period before loading was 1.3 to 1.6 mm. The difference between the control group and the group with early loading was significant.

Conclusions: Survival rates for patients treated with a one-stage procedure were lower than survival rates for patients treated according to a ''classical concept,'' but the differences were not statistically significant. There was no difference between treatment results with one-piece and two-piece implants. The implant loss in patients with early loading was probably caused by overloading, and careful supervision of occlusal loading is recommended. Early loading gave significantly less marginal bone loss when compared with two-stage surgery.

KEY WORDS: endosseous implants, nonsubmerged implants, one-piece implants, prospective clinical study, submerged implants

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During the last three decades, implant-supported prostheses have become the first choice in the rehabilitation of the edentulous lower jaw. Many longitudinal studies have demonstrated excellent treatment results and high predictability.[1–3] Most studies have used a two-stage surgical procedure. However, several studies with the aim of simplifying the procedure have demonstrated that predictable treatment results can also be achieved with oral implantation with a one-stage surgical technique.[4–11]

A further step toward greater comfort for the patient and reduced treatment time and cost is to connect the final prosthesis as soon as possible after implant installation. Early loading thus means that non-osseointegrated implants are loaded with a prosthetic construction.

With such a procedure, implant stability and loading conditions are more critical. Some studies have demonstrated good results also for early-loaded implants.[12–16] These studies were performed in the mandibles, and the implants were loaded with fixed prostheses. Some studies also concern overdentures in the mandible, and many ongoing studies concern fixed full or partial prostheses in the maxilla.

An evaluation of simplified methods for the treatment of the edentulous mandible was published by the present authors in 2002[17] and was part of an investigation dealing with one-stage surgery and early loading. In the first part of this study, 82 patients were treated in three different groups. All patients were provided with four Brånemark implants (Nobel Biocare, Gothenburg, Sweden) and a Procera® Implant Bridge (Nobel Biocare) after 12 weeks. In the control group (group B), two-stage surgery and two-piece implants were used. In the two study groups (groups A and C), one-stage surgery was combined with two-piece and one-piece implants, respectively. In that part of the study, the patients used an adjusted and relined temporary denture during the 3-month healing period.

The results showed no statistically significant differences in implant survival between the three groups. However, a tendency to an increased risk of implant loss was found in the two study groups when compared with the control group. Whether this was due to unfavorable loading from the denture or to poorer oral hygiene caused by the denture is uncertain. The marginal bone changes were similar among the groups.

The aim of the second part of this study was to compare the results of the three groups of the first part of the study with those of a fourth group (group D) using two-piece implants, one-stage surgery, and early loading within 3 weeks with a Procera implant bridge with acrylic teeth.

MATERIAL AND METHODS

Inclusion Criteria and Grouping of Patients

The total number of patients (Table 1) was 108. Eighty-two of them were reported on in the material published earlier.[17] In this part of the study, another 26 patients were included. All patients referred to the treating specialist centers in Linköping and Norrköping and applying for implant treatment in the edentulous lower jaw between October 1999 and April 2001 were considered for inclusion in group D.

Inclusion criteria were as follows:

- Healing after extraction, > 6 months
- Age, 25 to 75 years
- Bone volume and quality judged to be sufficient without grafting GBR procedures and permitting fixtures of 10 mm in length
- Good general health
- Informed consent from the patient

Exclusion criteria were as follows:

- Current known alcohol, drug, or medication abuse judged by the investigator to influence the follow-up program

TABLE 1 Age and sex distribution among the patients

Group		41–50 Years	51–60 Years	61–70 Years	> 70 Years	Total
A	Male	0	4	6	7	17
	Female	0	2	4	7	13
B	Male	0	6	6	4	16
	Female	2	2	7	3	14
C	Male	0	3	4	2	9
	Female	1	4	7	1	13
D	Male	0	4	4	3	11
	Female	0	5	5	5	15
Total		3	30	43	32	108

- Uncontrolled diabetes or other significant disease judged by the investigator to influence the prognosis of the procedures
- Clinical or radiographic signs of pathology in the treatment area
- Heavy bruxism judged by the investigator
- Heavy smoking (> 20 cigarettes per day)

This part of the study (using group D) was planned as a study of early loading and was to be performed with one-stage surgery using four Brånemark Mk III implants and 3 mm multi-unit abutments in each patient. A Procera Implant Bridge with acrylic teeth was planned to be attached within 3 weeks after fixture installation. The four groups in the whole study were thus treated as follows:

- Group A
  - One-stage surgical technique
  - Four Brånemark Standard implants with a turned surface
  - Standard abutments
  - Loading after 12 weeks
- Group B (control group)
  - Two-stage surgical technique
  - Four Brånemark standard implants with a turned surface
  - Standard abutments
  - Abutment connection after 8 to 10 weeks and loading after 12 weeks
- Group C
  - 1-stage surgical technique
  - Four Brånemark Mk III implants (one-piece, conical type) with a turned surface
  - Loading after 12 weeks
- Group D
  - One-stage surgical technique
  - Four Brånemark Mk III implants with a turned surface
  - Multi-unit abutments
  - Early loading (2 to 3 weeks)

All patients in the four groups were treated consecutively between November 1996 and March and April 2001. Table 1 presents the age and sex distribution of the patients. Bone quality and quantity, presented in Table 2, were assessed at surgery according to the Lekholm and Zarb classification.[18]

Prior to treatment, all patients were examined both by an oral and maxillofacial surgeon and by a prosthodontist. The radiographic examination consisted of panoramic, lateral, and (if required) intraoral radiography.

After the clinical and radiographic examinations, the patients were informed about treatment alternatives and the design of the study.

Treatment Procedures

Surgical procedure. Surgery was performed under local anesthesia combined with sedation and antibiotics according to the standard protocol used in each clinic. The most posterior implants on each side were inserted just anterior to the mental foramen, and the two medial implants were evenly distributed between them, which means that the positions of the implants were in the regions of the first premolars and the lateral incisors.

In group D, multi-unit abutments were connected to the fixtures at the operation, and the mucoperiosteal flaps were adapted around them with tight sutures (Figure 1). The length of the abutments was standardized to 3 mm to reduce the lever arms above the crest. Eighty-one of 104 implants were 15 mm in length. The lengths of all fixtures in the four groups are presented in Table 3.

TABLE 2 Bone quantity (A–E) and quality (1–4) according to Lekholm and Zarb, 1985

	1				2				3				4			
Group A–D	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D
A	0	0	0	0	0	4	0	4	0	4	4	8	0	0	0	0
B	0	4	4	0	20	24	24	28	40	20	0	20	8	4	0	0
C	0	0	0	0	4	16	28	12	36	24	16	12	0	0	4	8
D	0	4	4	0	4	4	0	4	4	4	0	4	0	4	4	0
E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total	0	8	8	0	28	48	52	48	80	52	20	44	8	8	8	8

Data missing from one patient in group A and one patient in group C.

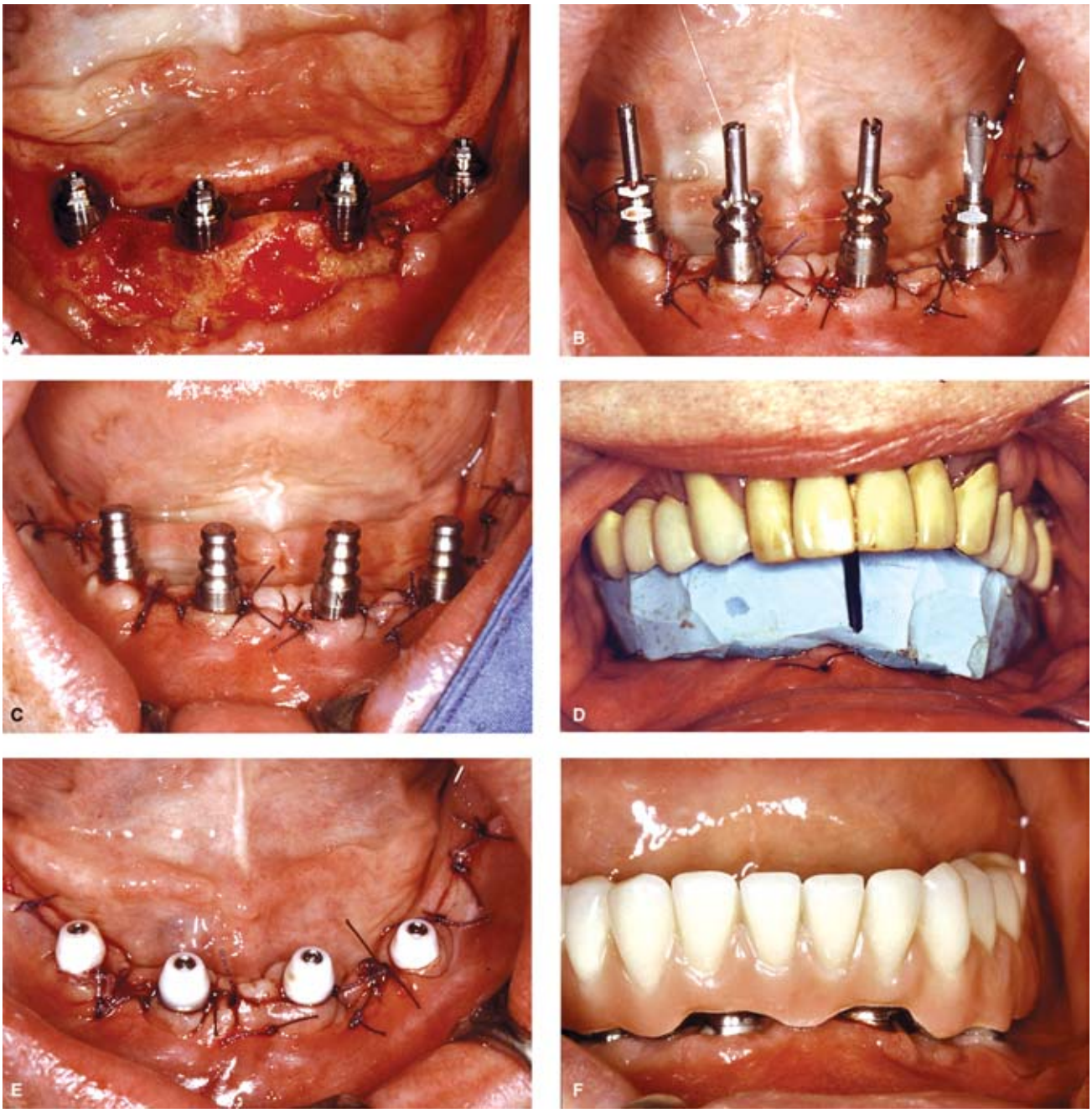

Figure 1 Patient number 256. *A*, The abutments were connected to the fixtures at the fixture insertion. *B*, Impression copings with guide pins were connected, and impressions were made. *C* and *D*, The impression copings were changed to tapered ones (C) and a jaw registration was performed (D). *E*, The sutures were left in place for 10 days. *F*, The implants were loaded with a fixed bridge about 3 weeks after implant insertion.

Prosthetic procedure. Final impression and bite registration were performed directly in connection with the operation. The impression was made with an open tray and a polyether impression material (Impregum™, 3M ESPE, Norristown, PA, USA). The registration of the intermaxillary jaw relation was made with a silicon putty impression material (Provil, Heraeus, Dormagen, Germany), supported by conical impression copings on top of the abutments (see Figure 1). A tooth setup was tried in within a few days. When necessary, a supplementary bite registration was made using the setup. A Procera Implant Bridge was then fabricated and attached within 3 weeks. During this period, the patients did not use their mandibular dentures. A

TABLE 3 Implant distribution by Length

Fixtures	Group A	Group B	Group C	Group D	Total
10 mm	3	0	0	4	7
13 mm	18	22	1	7	48
15 mm	63	85	9	81	238
18 mm	34	13	25	11	83
21 mm	2	0	53	1	56
Total	120	120	88	104	432

soft diet was recommended. After connection of the bridge, the occlusion and lateral contacts were carefully adjusted so that there was an even distribution of occlusal contacts over the bridge and no hard contacts on the cantilevers. In lateral and sagittal occlusion, no contacts were allowed on the cantilevers. The occlusion was supervised and adjusted (if necessary) during the first weeks after connection of the bridges. The patients were advised to follow a rather soft diet and to do no hard biting on the cantilevers during the first 6 weeks. None of the patients received an occlusal rim.

Postoperative care. The sutures were removed after 7 to 10 days. Oral hygiene was performed with 0.1% chlorhexidine mouthwash during the first 10 to 14 days. The patients were then instructed to use chlorhexidine gel 0.1% on a soft toothbrush and appropriate interdental brushes for another 2 to 4 weeks.

Follow-Up

A number of variables were recorded at the insertion of the implants, at the delivery of the prosthesis, and then at the annual follow-ups.

At implant insertion, information on the following was recorded:

- Bone quality and quantity (as described by the Lekholm and Zarb classification)[18]
- Implant positions and dimensions
- Primary stability of the implants
- Fenestration or marginal dehiscence (if any)
- Radiographic examination results
- Complications

At the baseline and annual examinations, information on the following was recorded:

- Bridge stability (clinical assessment)
- Implant stability (assessed with the superstructure removed)
- Plaque and bleeding on probing
- Hyperplasia of the periimplant mucosa
- Radiographic examination results
- Implant and superstructure complications

The radiographic examination at baseline (ie, visit number 0) and after 1 year included intraoral radiography with a modified Eggen-holder. Kodak Ultra-Speed™ intraoral dental film (Eastman Kodak Co., Rochester, NY, USA) was used.

Marginal bone changes and signs of loss of osseointegration in the interface zone were examined. To evaluate the marginal bone level, the distance to the nearest 0.1 mm was measured from a reference point at the implant to the most coronal point where the marginal bone met the implant (Figures 2–5). A Peak® scale loupe with a magnifying factor of 7× was used. The bone level was assessed at the mesial and distal surfaces of all implants.

The measurements were made by two of the investigators independently, and in cases with a difference of 0.5 mm or less between the measurements, the mean value was used. In cases of differences greater than 0.5 mm the radiographs were reexamined by both investigators, and a consensus was sought.

Statistical Considerations

The analysis addressed the following questions: (1) are implant survival and marginal bone height in group D inferior to implant survival and marginal bone height in group B, indicating a negative influence of the one-stage and early-loading technique and (2) is there any difference in implant survival and marginal bone height between group D and groups A and C, indicating a difference between early loading

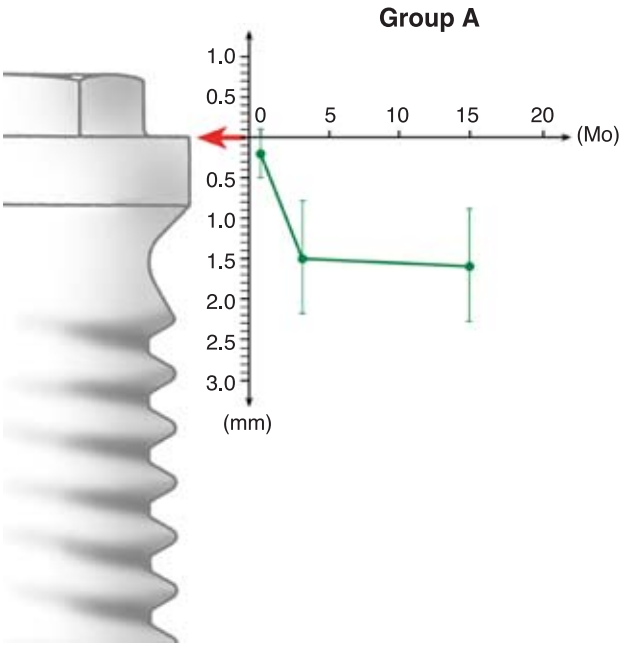

Figure 2 Group A bone level (mean and standard deviation) adjacent to the implants at fixture insertion, at baseline and after 1 year.

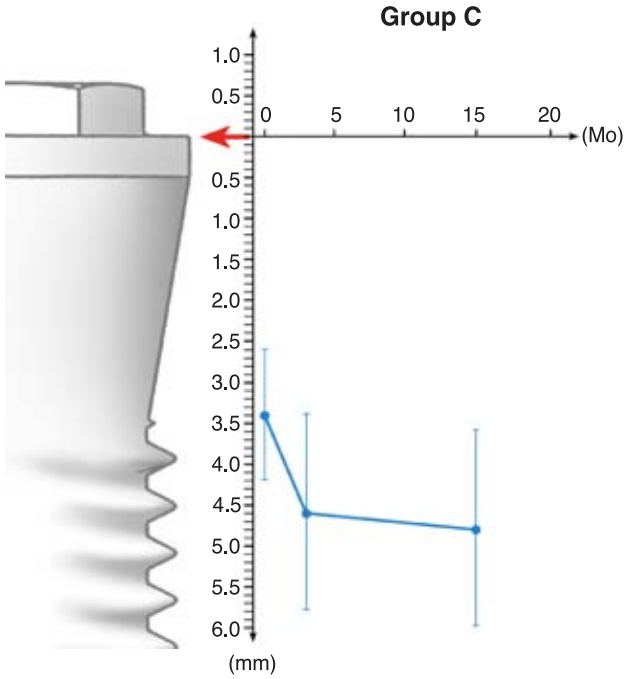

Figure 4 Group C bone level (mean and standard deviation) adjacent to the implants at fixture insertion, at baseline and after 1 year.

and delayed loading of implants inserted with a one-stage technique?

With the relative frequency of implant loss in each patient as the unit, the Kruskal-Wallis test was used to test differences in implant success rates between the treatment groups. To analyze differences between the groups with regard to marginal bone loss, the *t*-test was used; to test differences in standard

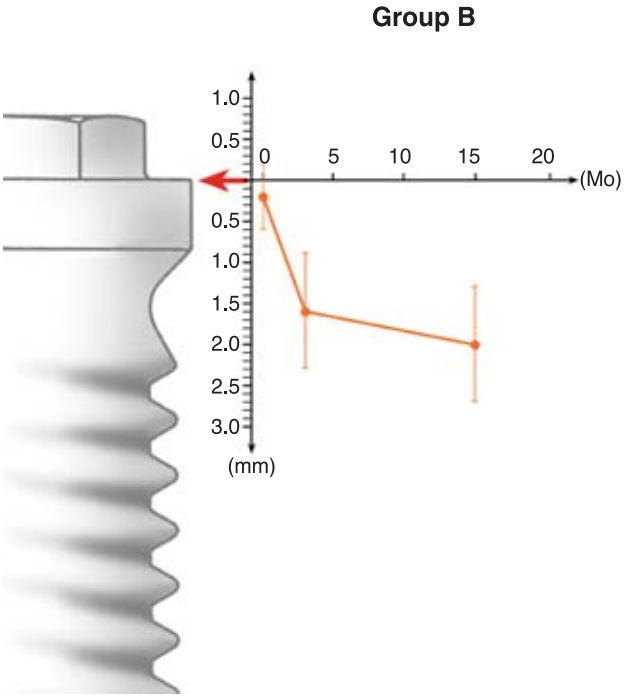

Figure 3 Group B bone level (mean and standard deviation) adjacent to the implants at fixture insertion, at baseline and after 1 year.

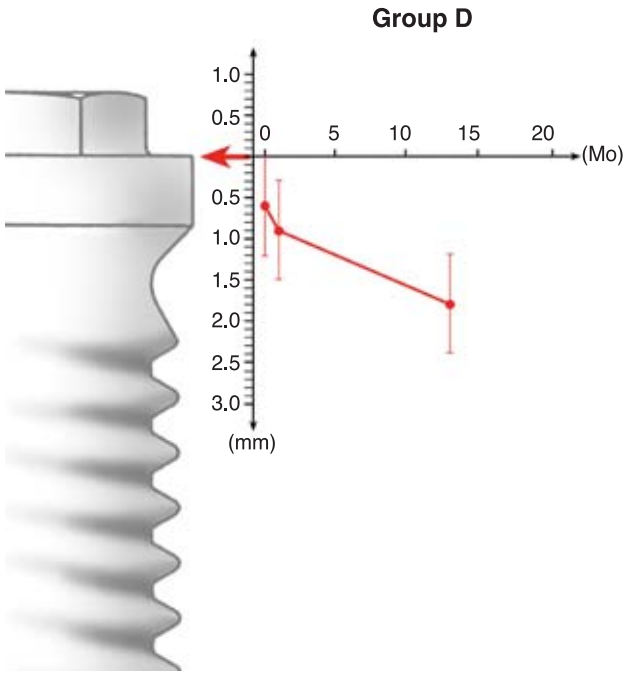

Figure 5 Group D bone level (mean and standard deviation) adjacent to the implants at fixture insertion, at baseline and after 1 year.

TABLE 4 Mean Duration of the Surgical Procedures, in Minutes

Patient Group	Fixture Insertion	Abutment Connection	1-Stage Procedure	Total Time
A	—	—	83 (50–150)	83
B	72 (30–125)	33 (20–60)	—	105
C	—	—	68 (30–100)	68
D	—	—	70 (30–99)	70

deviations, Levene's test was used. The level of significance was set at $p < .05$.

RESULTS

Surgical Experiences

The surgical procedure could be performed without difficulties. Primary stability was assessed as good in 101 of 104 implants. In two sites this was achieved by using Brånemark System® Mk IV implants. The bone coverage of the implants recorded at installation was good for 100 of 104 fixtures. The healing and adaptation of the mucosa were considered good in most of the cases. The mean time required for the operation was 69.7 minutes. The operation time recorded for each group is presented in Table 4.

Prosthetic Experiences

The impressions were made without difficulties while the anesthesia was still acceptable. No problems with the sutures or the mucosa were registered during that procedure. The bite registration was easily performed with the silicon putty material. At try-in of the tooth setup, a supplementary bite registration was made to ensure that the relation was correct. No try-in of the framework was done since it was measured at the laboratory in relation to the working model and because discrepancies of no more than 30 microns were accepted. In two cases the final prostheses did not fit in because one abutment had not been correctly adapted at the time for the impression. In two patients illness and private circumstances delayed the time for delivery. The mean time for delivery of the other bridges in group D was 24 days.

TABLE 5 Number of inserted and failed implants after 1 year

Patient group	Implants inserted	Implants failed	Survival rate (%)
A	120	8	93.3
B	120	3	97.5
C	88	6	93.2
D	104	7	93.3

TABLE 6 Marginal Bone Level at the Three Examinations Measured as the distance from the Reference Point (mm)

Group	Fixture insertion Mean + s_e	Baseline Mean + s_e	1-year examination Mean + s_e
A	0.16 + 0.05	1.48 + 0.07	1.56 + 0.07
	$n = 30$	$n = 106$	$n = 107$
B	0.23 + 0.05	1.61 + 0.06	1.96 + 0.06
	$n = 44$	$n = 110$	$n = 113$
C	3.39 + 0.10	4.62 + 0.14	4.79 + 0.14
	$n = 64$	$n = 78$	$n = 80$
D	0.55 + 0.09	0.92 + 0.06	1.69 + 0.06
	$n = 49$	$n = 103$	$n = 93$

n = number of observations; S_e = standard error of the mean.

Implant Failures

The survival rates of the implants are presented in Table 5. In groups A, B, and C, most of the failures were registered between insertion and loading. In

TABLE 7 Marginal Bone Change between Fixture Insertion and Baseline and between Baseline and 1-Year Examination

Group	Fixture Insertion to Baseline Mean ± S_e (mm)	Baseline to 1-Year Examination Mean ± S_e (mm)
A	–1.22 ± 0.12	–0.09 ± 0.05
	$n = 30$	$n = 106$
B	–1.32 ± 0.10	–0.35 ± 0.06
	$n = 43$	$n = 107$
C	–1.27 ± 0.13	–0.13 ± 0.08
	$n = 70$	$n = 76$
D	–0.52 ± 0.09	–0.75 ± 0.07
	$n = 48$	$n = 92$

n = number of observations; S_e = standard error of the mean.

TABLE 8 Marginal Bone Change between Fixture Insertion and the 1-Year Examination

Group	Fixture insertion/1-Year Mean + S_e (mm)
A	−1.27 + 0.14
	n = 30
B	−1.60 + 0.09
	n = 42
C	−1.34 + 0.12
	n = 62
D	−1.14 + 0.12
	n = 42

n = number of observations; S_e = standard error of the mean.

group D, seven implants were lost. One implant was lost after 16 months; no reoperation has been performed, and the bridge was adjusted and replaced. The other six implants were lost in two patients. One patient lost all four implants; the other patient lost the two posterior implants. Both patients later underwent successful reoperations.

For all one-stage groups the survival of the implants was lower than that of the implants in the two-stage control group. The differences were not statistically significant for any of the groups. The survival rate of the bridges was 93%.

Marginal Bone Level

Marginal bone level was measured at all implants at baseline and at the 1-year examination. It was also measured at a reduced number of implants at fixture insertion. The bone levels of the different groups are presented in Table 6 and in Figures 2–5.

Between baseline and the 1-year examination there were no significant changes in groups A and C (mean bone loss, 0.1 mm), but in group B the mean bone loss of 0.3 mm was statistically significant (Table 7). However, in group D the mean marginal bone loss of 0.74 mm from baseline to the 1-year examination includes the initial postsurgical remodeling and is consequently greater than the figures for the corresponding period in the other groups. The only comparable figures between the groups are consequently from fixture installation to the 1-year control. These figures are presented in Table 8. Resorption in group D was significantly lower than that in the control group.

DISCUSSION

The aim of this study was to investigate the possibility of using a one-stage surgical technique and early loading with Brånemark implants in the edentulous lower jaw and to compare the results with the earlier three groups in the study. In the whole study four different groups of consecutively treated patients with 432 different Brånemark implants and techniques were thus compared.

The patients were treated between November 1996 and April 2001. All patients with edentulous lower jaws who fulfilled the inclusion criteria were consecutively included in the study. The first 30 patients were referred to group A and were treated according to the one-stage surgical concept. The following 30 patients were referred to group B and were given the traditional two-stage treatment as a control group. In the third group (group C) the one-stage surgical treatment with a one-piece implant was used; the number of patients in this group was reduced to 22. The fourth group (group D) was treated with one-stage surgery and loading of the implants after 24 days [mean]. There were 26 patients in group D.

The number of patients who dropped out was very small. In group A all but one patient were followed up to the 1-year examination. The same low dropout rate occurred in group C whereas no patients in group B left the study.

In group D one patient lost all four implants. He was included in the failure analysis but will be withdrawn from future follow-ups.

The time required for the fixture and abutment procedures in group B was 105 minutes whereas the one-stage procedures used for groups A, C, and D required 83, 68, and 70 minutes, respectively. There thus seems to be an advantage of one-stage procedures with regard to surgical procedure time.

The time required for the whole prosthetic procedure was not measured. However, it was shorter in group D than in the other groups because the number of treatment occasions was reduced to three, namely, (1) impression and bite registration, (2) try-in of the tooth setup, and (3) delivery of the bridge.

Survival Rates

The survival rates of groups A (93.3%), C (93.2%), and D (93.3%) were lower than the rate normally achieved

with Brånemark implants[2,3] inserted with a two-stage technique. As most of the failures in groups A and C occurred before loading, this is probably an effect of the one-stage technique (combined with a healing period of 3 months), in which a complete denture was used over the implants.

The reduction from five or six implants to four implants did not seem to impair the results in the control group. This is also in accordance with an earlier publication by Brånemark and colleagues.[19] Kronström and colleagues[20] and Collaert and colleagues[21] used four implants and early loading. Their results are comparable with the results for group D in this study. Engstrand and colleagues[22] used three implants in the Brånemark Novum® concept (Nobel Biocare) and achieved a survival rate of 93.3%. They concluded that this rate was a little lower than that achieved with a traditional two-stage technique. De Bruyn and colleagues[23] used three Brånemark implants and lost 9.5%. Thus there seems to be a tendency toward better results with five implants than with three to four implants in early loading of full fixed mandibular prostheses. The difficulty of controlling the load distribution to the implants as well as the bacterial effect on the mucosa penetrating implants during healing under a denture was supposed to be the reason for the lower survival rates in groups A and C.

The lower survival rate in group D depended on fixture losses in three patients after loading, probably caused by overloading before osseointegration. One patient lost all four implants. He did not attend the regular controls until after 7 months. As the patient did not follow the treatment schedule and has lost all implants, he will be withdrawn from the study. The four implant losses are accounted for in the statistical evaluation, however. If they had not been accounted for, the success rate would have been 96.2%. The patient later underwent a successful reoperation. In one other patient, the two most posterior implants were found to be mobile at the 1-year control. He also underwent a successful reoperation and did not use his denture in the meantime. The third patient lost one posterior implant after 16 months. Illness has made it impossible to reoperate, but the adjusted bridge is still in function on three implants.

The implant losses were probably caused by overloading during healing as this is the main risk in early loading. All necessary precautions should therefore be taken to reduce this risk. Careful occlusal adjustments and loading information are thus recommended.

Marginal Bone Change

The marginal bone loss between fixture insertion and baseline was lower for group D according to the short period. Between baseline and the 1-year examination, the mean bone loss was consequently greater for group D and also a little greater for group B than for the two one-stage groups A and C. The greater resorption of 0.74 mm for group D includes the remodeling of marginal bone that the other groups underwent during the healing phase from fixture installation to baseline. The corresponding remodeling in group D occurred during the first period of loading. The comparison of group D with the other groups is therefore adequate only from fixture installation to the 1-year control. That resorption was significantly lower for group D than for group B. The period from fixture insertion to the 1-year follow-up was 15 months for group B and 13 months for group D. This difference may have theoretically affected the amount of bone loss. The loss is, however, smaller than what De Bruyn and colleagues[23] reported after 3 years (1.6 mm) with three implants but more than Kronström and colleagues,[20] who reported a mean loss of 0.24 mm during the first 12 months. However, in those studies the baseline radiography was done at bridge connection whereas in this study the resorption was measured from fixture installation. Individual variations were registered, however, which is in accordance with other studies. Carlsson and colleagues,[24] for example, reported small mean values after 10 years but with great individual variations. Mean values should therefore be carefully evaluated. Individual variations are often hidden behind them, and they do not guarantee a steady state for all implants.

During the evaluation of the radiographs, it was observed that the marginal bone had a more distinct border at the Brånemark Standard implants than at the conical implants. This was demonstrated by significantly greater standard deviations at the conical fixtures at baseline. The clinical effect, if any, of the small differences between all groups is uncertain.

Prosthetic Construction

Prosthetic construction followed the ordinary clinical procedure and included the computer-assisted manu-

facturing of the one-piece milled titanium framework. Before delivery to the dentist, the fit of the fabricated framework was measured in relation to the model, and the framework was accepted if the vertical discrepancy was less than 30 microns. As this procedure proved to be very reliable, no special try-in of the framework was necessary, making the procedure faster. As most of the patients used a full upper denture with acrylic teeth, the tooth setup was made with prefabricated acrylic teeth. During the first year, no complications in the form of bridge loosening or framework or acrylic fractures occurred.

The intention of using the simplified prosthetic construction (besides achieving a high quality) was to reduce time and material costs for the fabrication of the prosthesis.

CONCLUSIONS

In this study, a one-stage surgical procedure in the mandible with early loading after 3 weeks was compared with a one-stage technique with loading after 3 months and with a two-stage technique. The survival rates of patients in the one-stage groups were lower than those of patients in the two-stage control group, but the differences were not statistically significant.

Four implants were sufficient to support full fixed prostheses in the mandible even in early loading, but overloading was the probable reason for the loss of a few implants.

The changes in marginal bone level from fixture installation to the 1-year control were about the same in all groups with one-stage surgery. For group D with early loading, changes were significantly lower than for the two-stage control group.

ACKNOWLEDGMENTS

We are grateful to Mrs. Camilla Billström of Gothenburg, Sweden, who was statistical adviser and ran the database. We are also grateful to Östergötland County Public Dental Health Care and Nobel Biocare Norden AB, Gothenburg, Sweden, for financial support.

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