Simplified Methods of Implant Treatment in the Edentulous Lower Jaw: A 3-Year Follow-Up Report of a Controlled Prospective Study of One-Stage versus Two-Stage Surgery and Early Loading

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ABSTRACT

Background: Interest in the use of one-stage surgery and immediate loading of oral implants has lately been increasing.

Purpose: The aim of this study was to compare the 3-year results of one-stage surgery versus two-stage surgery, early loading versus loading after a 3-month healing period, and the use of one-piece implants versus the use of two-piece implants.

Materials and Methods: The study included 108 patients with edentulous mandibles. Each patient was treated with four Brånemark System® implants (Nobel Biocare AB, Göteborg, Sweden) and with full fixed prostheses. Patients were consecutively treated and were distributed in four groups: group A (one-stage surgery), group B (control group with two-stage surgery), group C (one-piece implants), and group D (early loading). In groups A and B Brånemark Standard implants and standard abutments were used. In group C the conical one-piece Brånemark implant was used, and in group D the patients had Brånemark System Mk III implants together with multiunit abutments. All patients were observed for 3 years.

Results: Of the 432 inserted implants, 24 were lost. Survival rates in the three experimental groups ranged from 93.2 to 93.3% whereas the survival rate in group B (the control group with two-stage surgery) was 97.5%. The differences between the groups were not statistically significant. The changes in marginal bone level were measured from fixture insertion to the final follow-up at 3 years. The bone loss in group D (early loading) was significantly less than in group B (the control group) whereas there were no differences in marginal bone change between the other groups.

Conclusions: Early loading seemed to give good results in the anterior part of the mandible. The survival rate of the early-loaded implants did not significantly differ from that of implants inserted with the conventional two-stage procedure, but the mean marginal bone loss around the surviving implants was less with early loading.

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

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During the last two decades, implant treatment has become one of the first options for the prosthetic rehabilitation of edentulous and partially edentulous jaws. Its advantages have been presented in many studies.[1,2] The disadvantages can be summarized as long treatment periods and high costs in the short run. Methods for shorter and more effective treatment have been presented. The use of one-stage surgery and

TABLE 1 Age and Sex Distribution among Study Patients

		Age (yr)				
Group	Sex	41–50	51–60	61–70	> 70	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

early or immediate loading will improve patients' comfort and reduce treatment time. Costs will subsequently be lower, provided that results as good as two-stage procedures can be achieved. Some studies of early loading in the mandible have demonstrated such results.[3–10] Less acceptable results were reported by Glauser and colleagues.[11]

This article is part III of a report on a longitudinal study of full fixed prostheses in the edentulous lower jaw. The aim of the study (with three treatment groups using simplified methods and one control group) was to compare the 3-year results of one-stage surgery versus two-stage surgery, early loading versus loading after 3 months of healing, and the use of one-piece implants versus the use of two-piece implants.

MATERIALS AND METHODS

Patients and Overall Study Design

The study included 108 patients and 432 implants. The mean age of the patients was 64.9 years. The age and sex of the patients have been previously described in 1-year reports[12,13] and are shown in Table 1.

All patients who were referred to the specialist treating centers in Linköping and Norrköping between November 1996 and April 2001 for implant treatment in an edentulous lower jaw were consecutively considered for inclusion. Criteria for inclusion were as follows:

- Healing time after extraction, ≥ 6 months
- Age of 25 to 75 years
- Bone volume and quality judged to be sufficient without grafting or guided bone regeneration (GBR) procedures and permitting fixtures 10 mm in length
- Good general health
- Informed consent given

The following were exclusion criteria:

- Current known alcohol, drug, or medication abuse judged by the investigator to likely influence the follow-up program
- Uncontrolled diabetes or other significant disease judged by the investigator to likely influence the prognosis of the procedures
- Clinical or radiographic signs of pathology in the treatment area
- Heavy bruxism (as judged by the investigator)
- Heavy smoking (≥ 20 cigarettes per day)

The patients were divided into the following four groups: group A, treated with one-stage surgery; group B, the control group; group C, treated with one-piece implants; and Group D, treated with the early loading procedure. The treatment procedures and the implants used are shown in Table 2. All patients received Brånemark System® implants (Nobel Biocare AB, Göteborg, Sweden) with a turned surface texture.

The initial plan was to include 30 patients in each group and to treat the groups consecutively. However, recruitment of patients to group C was stopped after

TABLE 2 Treatment Procedures and Types of Implants in the Four Treatment Groups

Group	Surgical Technique	Implant	No. of Implants	Abutment	Time of Loading
A	1-stage	Brånemark Standard	4	Standard	12 weeks
B	2-stage	Brånemark Standard	4	Standard	12 weeks
C	1-stage	Brånemark conical 1-piece	4	(None)	12 weeks
D	1-stage	Brånemark Mk III	4	Multiunit	2–3 weeks

22 patients (mean age, 63 years) had been recruited, in order to get an earlier start on group D, in which early loading would be performed. Group D included 26 patients (mean age, 65 years). A total of 108 patients were thus included in the study.

Consecutive treatment of the different groups was used instead of individual randomization. Bone quality and quantity were assessed at surgery, according to the Lekholm and Zarb classification.[14]

Pre-treatment Examinations

Both an oral and maxillofacial surgeon and a prosthodontist examined all patients. The radiographic examination consisted of a panoramic view, a lateral view, and (if required) intraoral radiography. After the clinical and radiographic examinations, patients were informed of the treatment alternatives and the design of the study.

Treatment Procedures

Six oral and maxillofacial surgeons and four prosthodontists participated in the treatment of the patients.

Surgical Procedures. In all treatment groups surgical procedures were performed with the patients under local anesthesia combined with sedation and antibiotics, according to the standard protocol used in each clinic. All patients were provided with four vertically or nearly vertically placed implants. The implants most posterior on each side were inserted just anterior to the mental foramen, and the two medial implants were evenly distributed between these. Consequently the implants were placed in the regions of the first premolars and the lateral incisors. Most implants (238 of 432) were 15 mm in length (Table 3).

In group A (one-stage surgery) permanent standard abutments were connected at fixture insertion, after which the mucoperiosteal flaps were readapted. The lengths of the abutments were chosen with the intention of their reaching about 2 mm supragingivally after healing. Plastic healing caps were attached to the abutments and replaced with titanium healing caps 10 days postoperatively.[12] A total of 120 Brånemark Standard implants were inserted in this group.

In group B (the reference group) the 120 fixtures were positioned in the same way as in group A. Mucoperiosteal flaps were then sutured over the implants. Permanent standard abutments were connected 8 weeks after fixture installation; plastic healing caps were used.

In group C a one-piece type of fixture was used in connection with the one-stage surgical procedure. The implant had a smooth conical head, which was 3.5 mm high for mucosal penetration. The implants were inserted to a depth such that the border between the threaded part and the smooth neck was level with the mesiodistal crestal bone level. No abutments were used on these implants. Cover screws were inserted, and the flaps were thereafter adapted around the implants. Eighty-eight conical implants were inserted, mostly 18 to 20 mm in length (the greater length was due to the 3.5 mm mucosa-penetrating neck).

In group D 104 Brånemark System Mk III fixtures were used with multiunit abutments. The abutments used were standardized to 3 mm and were immediately connected at fixture insertion, after which the flaps were adapted around the abutments. Plastic healing caps were used. The final prosthetic procedure was commenced immediately after implant placement.

TABLE 3 Distribution of Implants by Implant Length

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

Postoperative Care. In all groups the sutures were removed after 7 to 10 days. During a 2-week healing period, no brushing of the operated sites was allowed. Maintenance of adequate oral hygiene was achieved with 0.1% chlorhexidine mouthwash used twice daily for 1 minute. A soft diet was recommended, and analgesics were used as required for pain control and antibiotic coverage, as described previously.[12] Patients in the one-stage groups were advised to brush with chlorhexidine gel on a soft toothbrush from 2 to 4 weeks after implant insertion.

Temporary dentures were used by patients in groups A, B, and C. However, the patients did not use the dentures during the first 10 days postoperatively. Then the dentures were relieved in the areas of the

implant sites and relined with Viscogel® (Dentsply DeTrey GmbH, Konstanz, Germany), which was changed regularly during the healing period.

Abutment Connections and Prosthetic Procedure. In group A the abutments were connected at fixture installation. In group B the abutments were connected about 8 weeks after fixture insertion. In group C the bridges were attached to the fixture level. In group D the abutments were connected at implant placement.

All patients were treated with full fixed prostheses.[12] In groups A, B, and C, the final impression and the construction of the fixed bridges were planned so that the bridges were connected to the abutments about 12 weeks after fixture installation.

A concept of early loading was followed for group D. Final impressions and bite registrations were performed after implant placement. Impressions were made with an open tray and a polyether impression material (Impregum™, 3M ESPE, Norristown, PA, USA). Registration of the intermaxillary jaw relation was taken with a silicone putty impression material (Provil®, Heraeus Kulzer, Dormagen, Germany) supported by conical impression copings attached to the abutments. The tooth setup was tried within a few days. If necessary, supplementary bite registration was undertaken with the setup.

The superstructure used for all patients was a titanium frame (Procera® All-in-One, Nobel Biocare) combined with acrylic teeth. The framework used with this technique is milled from a titanium block in a computer-steered three-dimensional milling machine with high precision. Each framework was measured at the dental laboratory against the working model, and discrepancies of no more than 30 μm were accepted. Due to the vertical placement of the four implants, the bridges were constructed with cantilevers having two teeth on each side.

The occlusion and lateral contacts were carefully adjusted for an even distribution of occlusal contacts over the bridge, with no hard contacts on the cantilevers. In lateral and sagittal occlusion, no contacts were planned for the cantilevers. The occlusion was supervised and adjusted (if necessary) during the first weeks after connection of the bridges. The patients in group D were advised to avoid hard food and to avoid hard biting on the leverages during the first 6 weeks. None of the patients received an occlusal rim.

Follow-Up

The clinical and radiographic examinations during the follow-up period were described in an earlier article.[13]

Ten patients were withdrawn from the study at different stages of the follow-up. Five died from unrelated causes, three were unwilling to cooperate, and one had severe illness. One patient lost all his implants and thus could not take part in the 2-year and 3-year examinations.

Statistical Considerations

The analysis addressed the following questions:

- Did implant survival and marginal bone level in group A differ from those in group B, indicating an influence of the one-stage (instead of the two-stage) surgical technique?
- Were implant survivals and marginal bone levels in group D inferior to those in group B, indicating a negative influence of the one-stage and early loading technique?
- Were there any differences in implant survival and marginal bone level between group D and group A or C, indicating any difference in the results of early loading versus delayed loading of implants treated with a one-stage technique?
- Were there any differences in survival rate and marginal bone loss between groups A and C, indicating an influence of a one-piece implant versus a two-piece implant?

To analyze the differences in implant survival rate between the treatment groups, we performed the Mann-Whitney test, using the relative frequency of implant loss in each patient as a unit. Comparison of differences of marginal bone change between the groups was made with independent sample *t*-tests after Levene's test had confirmed a gaussian population with equal variances. The level of significance was set at $p < .05$.

RESULTS

Clinical Experiences

Primary stability was assessed by the surgeon as good in 114 of the 120 implants in group A, in all 120 implants in group B, in 84 of the 88 implants in group C, and in 101 of the 104 implants in group D. Of these

13 implants with less acceptable stability, 3 were lost (1 in group A and 2 in group C).

For two implants in group D, primary stability was achieved by replacing both with Brånemark System Mk IV fixtures. None of the implants with reduced stability in group D were lost.

At 22 (5.1%) of the implants, limited marginal dehiscence was observed at surgery (6 implants in group A, 4 in group B, 8 in group C, and 4 in group D). None of these implants were lost.

The mean time required for the one-stage procedure was 82.5 minutes in group A and 68.2 minutes in group C. In group B the fixture insertion required 71.6 minutes, and the abutment connection required 33.1 minutes. This means that the mean total surgery time in group B was 104.7 minutes. In group D the mean operation time was 69.7 minutes.

The number of prosthetic-treatment occasions in group D was reduced to three. Impressions and bite registrations were taken directly in connection with implant insertions. After 4 days the tooth setup was tried-in, and the final bridge was connected 10 days later. The exceptions were three cases in which the delivery of the prostheses was delayed.

In all groups the fit of the framework was good owing to the customized procedure. Occlusal adjustments were finalized intraorally.

Implant Failures

A total of 24 implants were lost; 7 of these were lost before loading. In the control group (group B) three implants were lost in two patients. In group A the eight failures were distributed among five patients, and one patient lost three implants. In group C five patients lost altogether six implants. In group D (with early loading) one patient lost all of his four implants, one patient lost two implants, and one patient lost one implant. The fixture losses are detailed in Table 4.

The survival rate was highest in the control (two-stage surgery) group (97.5%) whereas the survival rates in the other groups ranged from 93.2 to 93.3%. The differences between the groups were not statistically significant.

TABLE 4 Implant Failures and Survival Rates

Patient Group and Observation Period	No. of Implants Placed	Failed Implants	Withdrawn Implants	SR within Period (%)	Cumulative SR (%)
Group A					
Insertion to loading	120	5	—	95.8	95.8
Loading to 1 yr	115	3	4	97.4	93.3
1–2 yr	108	—	—	100	93.3
2–3 yr	108	—	—	100	93.3
Group B					
Insertion to loading	120	3	—	97.5	97.5
Loading to 1 yr	117	—	—	100	97.5
1–2 yr	117	—	4	100	97.5
2–3 yr	113	—	4	100	97.5
Group C					
Insertion to loading	88	5	—	94.3	94.3
Loading to 1 yr	83	1	—	98.7	93.2
1–2 yr	82	—	4	100	93.2
2–3 yr	78	—	—	100	93.2
Group D					
Insertion to loading	104	—	—	96.2	96.2
Loading to 1 yr	104	2	—	98.1	96.2
1–2 yr	102	5	4	95.1	93.3
2–3 yr	93	—	—	100	93.3

SR = survival rate.

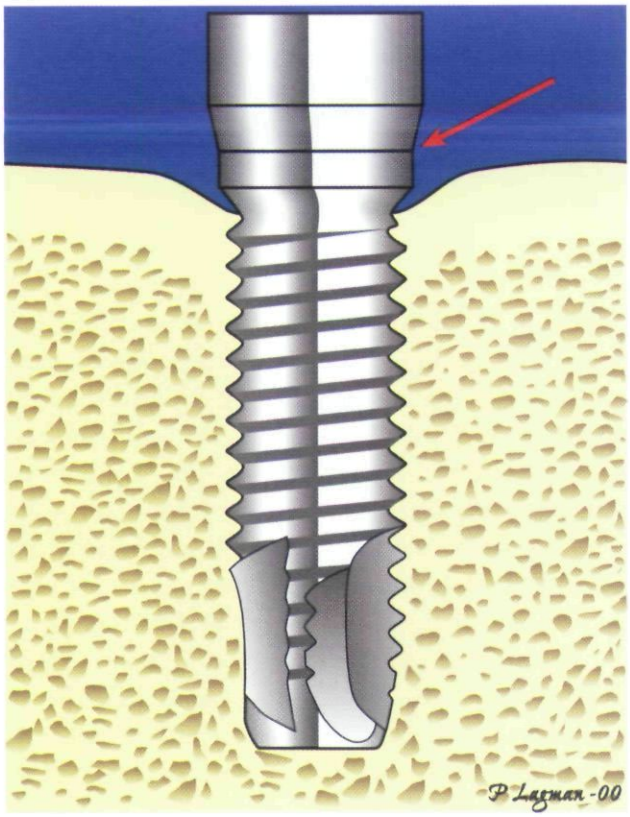

Figure 1 Diagram showing the reference point (*arrow*) between fixture and abutment, used for measuring marginal bone change.

Marginal Bone Level

Marginal bone level (Figure 1) was measured at all implants at baseline and at the 1- and 3-year examinations (except for one patient, for whom the radiographic examination inadvertently was not performed at the 3-year follow-up assessment). At fixture insertion the marginal bone level was measured at a reduced number of implants. Bone levels in the different groups throughout the study are presented in Table 5 and in Figures 2–5.

In groups A, B, and C, the change in marginal bone level (Table 6) was much greater between fixture insertion and baseline (1.2–1.3 mm) than between baseline and the 1-year examination (0.1–0.4 mm). Only in group B was the change between baseline and the 1-year examination significant. Between the 1-year and 3-year examinations, no significant change could be demonstrated in any group.

The changes in marginal bone level from fixture insertion to the final follow-up at 3 years are presented in Table 7. The bone loss in group D was significantly less than that in the control group (group B) whereas there were no differences in marginal bone change between the other groups.

To determine at which level steady state was reached, the number of implants with a bone loss of ≤ 4 mm and with >4 mm was calculated. Steady state according to this analysis could be demonstrated in 78.3% of implants in group A, 88.5% in group B, 71.8% in group C, and 79.0% in group D.

DISCUSSION

Study Aim and Grouping of Patients

The aim of this study was to investigate the outcome of using simplified methods in the treatment of patients with edentulous mandibles by means of fixed implant-supported prostheses on Brånemark implants. In four different groups of consecutively treated patients, different implants and techniques were compared. The main goal was to reduce treatment time and costs by using one-stage surgery, and, in addition, one

TABLE 5 Mean Marginal Bone Levels at Fixture Insertion and at the Three Examinations: Mean Distance from Reference Point

	Marginal Bone Level (mm)			
Group	At Fixture Insertion (Mean ± s_e)	At Baseline (Mean ± s_e)	At 1 Year (Mean ± s_e)	At 3 Years (Mean ± s_e)
A	0.16 ± 0.05 (n = 30)	1.48 ± 0.07 (n = 106)	1.56 ± 0.07 (n = 107)	1.66 ± 0.08 (n = 107)
B	0.23 ± 0.05 (n = 44)	1.61 ± 0.06 (n = 110)	1.96 ± 0.06 (n = 113)	1.89 ± 0.06 (n = 100)
C	3.39 ± 0.10 (n = 64)	4.62 ± 0.14 (n = 78)	4.79 ± 0.14 (n = 80)	5.01 ± 0.16 (n = 73)
D	0.55 ± 0.09 (n = 49)	0.92 ± 0.06 (n = 103)	1.69 ± 0.06 (n = 93)	1.79 ± 0.07 (n = 85)

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

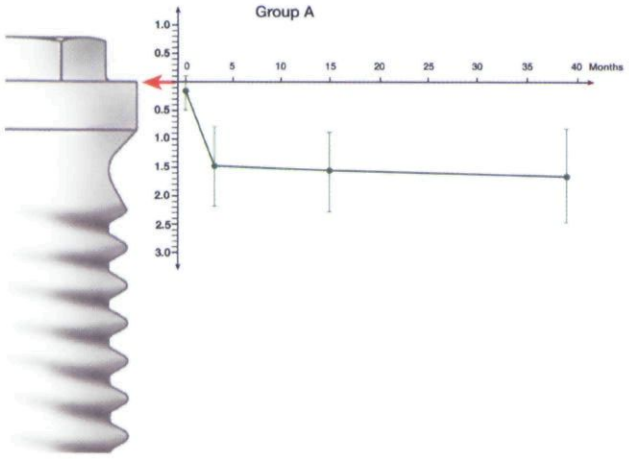

Figure 2 Diagram showing bone levels adjacent to the implants (mean and standard deviation, in millimeters) in group A patients at fixture insertion, at baseline, after 1 year, and after 3 years.

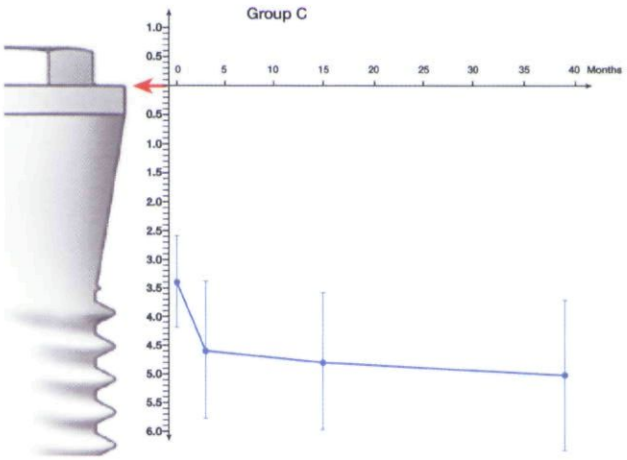

Figure 4 Diagram showing bone levels adjacent to the implants (mean and standard deviation, in millimeters) in group C patients at fixture insertion, at baseline, after 1 year, and after 3 years.

group with early loading was compared with a conventional two-stage procedure.

The total number of patients treated was 108. Of these, 10 patients were lost to follow-up: 5 patients were lost due to death, 1 patient was lost due to severe illness, 3 patients were uncooperative, and 1 patient lost all his implants.

The time required for the fixture and abutment procedures in the control group (group B) was 105 minutes whereas the one-stage procedures in the experimental groups required 83, 68, and 70 minutes. Thus there seems to be an advantage to one-stage procedures with regard to surgical procedure time.

The time required for the prosthetic procedure could not be measured. However, the number of treatment occasions before the final bridge was connected was reduced to three. That reduction could be achieved by using the customized framework procedure and a logistic procedure agreed to by the dental laboratory.

Early Loading

Early loading in edentulous mandibles before osseointegration has taken place is well documented[3–5,9,10,15] and seems justified in cases with good primary stability of the implants. Friberg and colleagues[16] showed that primary stability in dense mandibular bone can be very

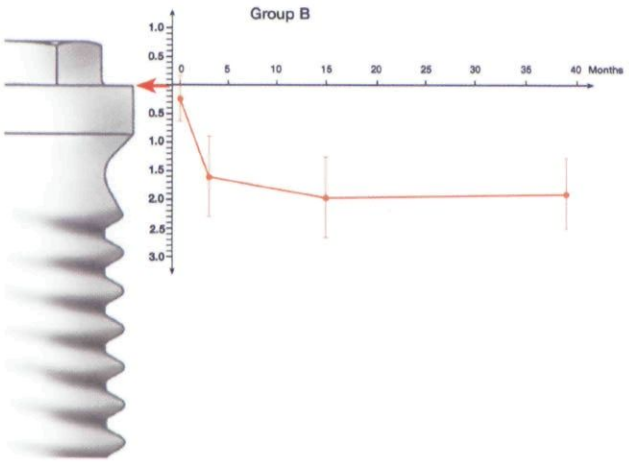

Figure 3 Diagram showing bone levels adjacent to the implants (mean and standard deviation, in millimeters) in group B patients at fixture insertion, at baseline, after 1 year, and after 3 years.

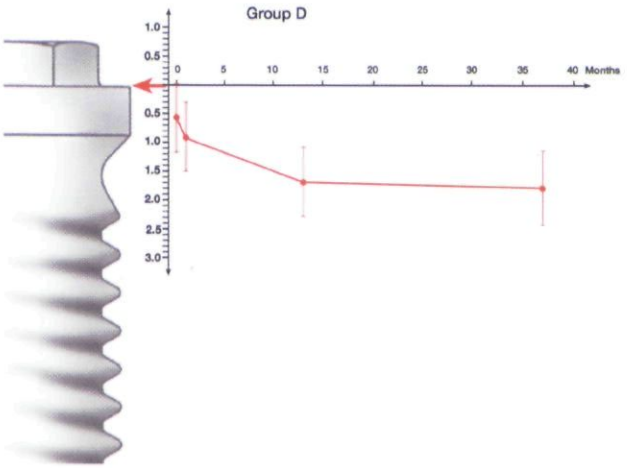

Figure 5 Diagram showing bone levels adjacent to the implants (mean and standard deviation, in millimeters) in group D patients at fixture insertion, at baseline, after 1 year, and after 3 years.

TABLE 6 Mean Marginal Bone Change between Fixture Insertion and Baseline, between Baseline and 1-Year Examination, and between 1-Year and 3-Year Examinations

	Marginal Bone Change (mm)		
Group	Fixture Insertion/Baseline (Mean ± s_e)	Baseline/1 Year (Mean ± s_e)	1 Year/3 Years (Mean ± s_e)
A	−1.22 ± 0.12 (n = 30)	−0.09 ± 0.05 (n = 106)	−0.09 ± 0.06 (n = 106)
B	−1.32 ± 0.10 (n = 43)	−0.35 ± 0.06 (n = 107)	0.08 ± 0.06 (n = 96)
C	−1.27 ± 0.12 (n = 64)	−0.13 ± 0.08 (n = 76)	−0.13 ± 0.13 (n = 71)
D	−0.52 ± 0.09 (n = 48)	−0.75 ± 0.07 (n = 92)	−0.08 ± 0.08 (n = 81)

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

good. During healing, stability deteriorates during the first weeks, but after 3 months it will be about the same as at installation. This seems to mean that the primary stability, together with splinting, is sufficient not to disturb the osseointegration procedure, as this study confirms. With the fast procedure the implants are splinted after 2 to 3 weeks, and micromotion of the implants is avoided. However, successful premature loading requires careful and strict selection of patients in order to achieve the best primary stability.[17]

Fixture Survival

In all four groups the number of implants was reduced from five to four, to reduce treatment costs. In the reference group B the survival rate was 97.5%, which is comparable with results from other studies using five or more implants.[18–21] In the experimental groups the survival rates ranged from 93.2 to 93.3%. The differences between the control group and the experimental groups were not significant ($p > .05$) and were probably due to a normal biologic variation. However, it is possible that there was a difference that could not be proved. The differences may indicate that the risk of implant failure is greater with early loading.[17] The differences may also be attributed to the fact that the technique with one-stage surgery and with early loading was at the beginning of the learning curve for all treating specialists. As reported in published articles, some studies of early loading in the edentulous mandible have found survival rates of 97 to 98% or more,[3–7] but several studies have yielded survival rates of 92 to 93%, such as were found in this study.[9,22–24]

One-Piece Implants

Most implants are designed as two-piece implants. The microgap between fixture and abutment has been speculated to adversely affect the marginal bone level,[25] and one-piece implants have been advocated.[26] A one-piece implant was therefore tried in this study. The results suggest that the microgap has no obvious effect on the clinical outcome.

Marginal Bone Changes

The mean marginal bone changes after 3 years were small and about the same in all groups except group D (see Table 7). In this early loading group marginal bone loss was significantly less than in the control group (group B). There was only a small change of the bone level between fixture insertion and baseline as this period includes only a few weeks. However, between baseline and the 1-year examination, the change was greater since this period spans part of the early remodeling. The change in bone level during these two periods was significant. A tendency toward less bone resorption in early loading has been found also in other studies.[9] A possible explanation for these differences between one-stage surgery and two-stage surgery could be that the trauma of the second operation is avoided

TABLE 7 Marginal Bone Change between Fixture Insertion and 1-Year Examination and between Fixture Insertion and 3-Year Examination

	Marginal Bone Change (mm)	
Group	Fixture Insertion/1 Year (Mean ± s_e)	Fixture Insertion/3 Years (Mean ± s_e)
A	−1.27 ± 0.14 (n = 30)	−1.33 ± 0.15 (n = 30)
B	−1.60 ± 0.09 (n = 42)	−1.68 ± 0.12 (n = 37)
C	−1.34 ± 0.12 (n = 62)	−1.42 ± 0.17 (n = 56)
D	−1.14 ± 0.12 (n = 42)	−1.24 ± 0.17 (n = 37)

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

by preservation of the biologic width by means of a more superficial placing of implants.

When one looks at the bone level at fixture insertion (see Table 5), it is obvious that the fixtures were placed more superficially in group D than in the control group. The background to this is that there is no need to avoid the load of a provisional prosthesis in this group. A less extensive countersinking may also contribute to less bone resorption.

Mean marginal changes include measured bone loss and bone gain. According to the success criteria proposed by Albrektsson and colleagues, annual bone loss after the first year of function should be no more than 0.2 mm for each individual implant.[27] According to Albrektsson and colleagues "steady state" in marginal bone resorption means that the changes for each individual implant should thus not exceed 0.4 mm between the 1-year and 3-year examinations.[27] Two other studies comparing different implant systems showed that steady state was not reached for all implants after 3 years and 5 years,[28,29] nor was steady state reached for all implants in this study. The frequency of steady state was lower in group C than in the other groups. The interpretation of this is uncertain. However, individual variations may occur, depending on medical prerequisites and loading circumstances. Individual recall routines are therefore advised. Further studies on the impact of the individual's medical status are important.

In summary the concept of early loading in the anterior part of the mandible seems to give good results. The implant survival rate did not significantly differ from that of the conventional two-stage procedure, and the mean marginal bone loss around the surviving implants was less with the early loading procedure than with the two-stage technique.

CONCLUSIONS

In this study of implant-supported prostheses in the edentulous mandible, the conventional two-stage procedure was compared with one-stage surgery and early or delayed loading. Survival rates of the implants showed a tendency toward better results with the two-stage technique, but the differences were not significant. The mean marginal bone loss from fixture insertion to the 3-year examination was significantly lower with early loading than with the conventional two-stage technique. The survival rates and marginal bone changes of the one-piece implants did not differ from those of the two-piece implants.

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