Timing of Loading—Immediate, Early, or Delayed—in the Outcome of Implants in the Edentulous Mandible: A Prospective Clinical Trial

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Purpose: *To report on the implant outcome of delayed, early, and immediate loading of implants in the edentulous mandible in a prospective controlled study.* ***Materials and Methods:*** *On a consecutive basis, the first 10 patients received an overdenture retained by 2 ball attachments 4 months after implant insertion (delayed), and the next 10 patients received an overdenture 1 week after implant surgery (early). The next 10 patients were treated with a fixed prosthesis on 3 implants (Brånemark Novum) either the day of or the day after surgery (immediate). All patients were followed for 1 year; half were followed for 2 years. Measures of assessment for this prospective clinical trial included monitoring of loading at prosthesis level (bite fork) as well as at the abutment level (strain gauges), 3-dimensional imaging of marginal bone remodeling, and implant stability.* ***Results and Discussion:*** *One patient in each OD group lost both implants. The losses occurred 6 months after loading in the delayed group and 1 month after loading in the early group. In the immediate group, 1 patient lost both distal implants 5 months after loading. In 2 other patients, 1 distal implant failed after 1 year of loading. Maximal bite forces increased over time for all groups. Marginal bone loss was the highest for the immediate group, while no differences in implants stability were observed between the 3 groups after 1 year of loading.* ***Conclusions:*** *According to this prospective controlled clinical trial, the results achieved with implants loaded early were comparable to those achieved with implants loaded after a delay. Distal implants are at higher risk for failure in the immediate loaded protocol.* (Clinical Trial) INT J ORAL MAXILLOFAC IMPLANTS 2007;22:580–594

Key words: *early loading, immediate loading, occlusal bite forces, 3D imaging of bone remodeling*

In 1977, Brånemark introduced the principles of osseointegration.[1] Primary stability and lack of micromotion were considered 2 of the main factors necessary for achieving predictably high 10-year success rates for osseointegrated oral implants of 92% in the maxilla and 98% in the mandible.[2] To minimize the risk of implant failure, a 2-stage surgical technique was used, and oral implants were kept load-protected during a healing period of 3 to 4 months for the mandible and 6 to 8 months for the maxilla.[1] During healing, patients were rehabilitated by means of removable dentures. However, it was found that transitional prostheses are rather uncomfortable and inconvenient for the patients, because of lack of stability and retention. Researchers realized that it would be beneficial if a 1-stage surgical protocol could be used and if the healing period could be shortened, so that patients can return to their economic and social lives earlier, without jeopardizing implant success. A longitudinal clinical trial suggested that implants could be loaded immediately or early in the mandibles of selected patients.[3] Today, immediate and early loaded implants are already frequently used in mandibles with sufficient jaw geometry and good bone quality.[4–8] Still, prospective con-

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trolled studies that examine the implant outcome in immediately or early loaded implants compared to delayed loaded ones are scarce; more research is necessary to better understand the rationale behind early and immediate loading. The final conclusion of the most recent Cochrane review concurred that the predictability of successful immediate loading in selected patients is unknown.[9]

Apart from implant-related factors (material, design, topography, and surface chemistry), surgical technique, and patient variables (bone quantity and quality, health condition, smoking habit, bruxism), mechanical loading of the peri-implant bone is considered an important biomechanical factor in implant outcome. During healing, excessive micromotion between the implant and the peri-implant bone can be a compromising factor, but the exact tolerance to micromotion is not known. It is believed that predictable results with early or immediately loaded implants might be possible if sufficient primary stability could be achieved and patients with severe bruxism habits could be excluded. After initial healing, mechanical overload is considered 1 of the main reasons for late implant failure, because of component fractures or bone remodeling leading to excessive marginal bone loss.[10]

In the present prospective clinical trial, load measurements are included in the follow-up of the implants in a delayed, early, and immediate loading protocol. It was the aim of the study to investigate the implant outcome based on 3 different loading time points in the edentulous mandible. The null hypothesis to be tested was that there is no difference in implant outcome related to the time of loading.

MATERIALS AND METHODS

Patient Selection

Delayed and Early Loading Group. Patients who had been edentulous in the mandible for at least 3 months were consecutively examined. Sufficient jawbone volume in the symphyseal area and discomfort with their conventional denture were the first inclusion criteria. Jawbone dimensions sufficient for placement of 2 commercially pure titanium implants at least 13 mm long and 3.75 to 4 mm wide were required; patients were examined radiographically to determine whether they met this requirement. In addition, patients had to meet the inclusion criteria required for conventional implant treatment, and they had to be available for follow-up for at least 1 year. Exclusion criteria were grafted or irradiated jaws and any systemic diseases likely to compromise implant surgery. Ten patients were selected for each group. The delayed loading group of 10 patients was treated first, followed by the early loaded group, to maximally reduce the intake period.

Immediate Loading Group. In keeping with the Brånemark Novum protocol (Nobel Biocare, Göteborg, Sweden),[4] recent extractions and peroperative extractions in the symphyseal area of the mandible were allowed. Otherwise, jawbone curvature and dimensions sufficient for the placement of 3 wide-platform implants in a tripodal position were required to accommodate the prefabricated guide and mandibular standard baseplate. Transparent templates were used on panoramic, occlusal, and tomographic radiographs to check jawbone volume in the 3 dimensions. Due to the fact that the Brånemark Novum protocol is only for patients with enough bone volume and a specific skeletal maxillomandibular relationship, it was not possible to allocate the patients to the 3 groups according to a randomized scheme.

Surgical and Prosthetic Procedures

Delayed Loading Group. Implant surgery was performed following the Brånemark System guidelines at the Department of Periodontology of the Catholic University Leuven Hospital by a single surgeon. The traditional 2-stage procedure was followed, where the second surgery was performed after 3 to 4 months of subgingival healing. Abutments (5.5 mm) with ball attachments (2.25 mm diameter; Nobel Biocare) were connected. After 1 week of tissue healing, sutures were removed, and overdenture fabrication was begun. The overdenture was inserted an average of 3 weeks after second-stage surgery.

Early Loading Group. For these patients a conventional mandibular denture was made preoperatively. Patients were treated with the same type of implants used in the delayed loading group, but a 1-stage surgery was performed. Abutments with ball attachments were immediately connected. After 1 week of soft tissue healing, sutures were removed. The preoperatively made denture was adjusted and partially relined, and the appropriate matrices for ball attachments (2.25 mm diameter; Nobel Biocare) were inserted. A soft diet was recommended during the first 8 weeks after prosthesis insertion.

Immediate Loading Group. The Brånemark Novum procedure features a 1-day approach using precision fitting ready-made components for surgical and prosthetic templates to be able to deliver the hybrid prosthesis in one day.[4] All surgery was performed by a single surgeon. This technique requires adequate preprosthetic preparation and intensive laboratory work the day of surgery to allow insertion of the fixed prosthesis the same day or the day after. These patients were instructed to keep on a soft diet for 8 weeks as well.

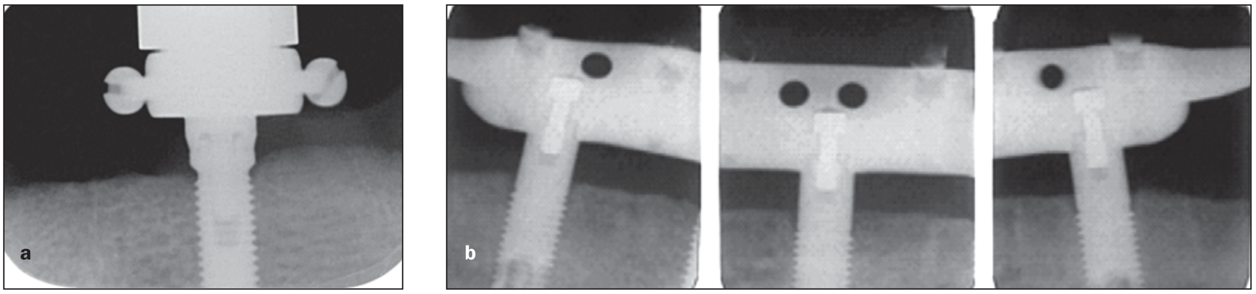


Fig 1 *(a)* Intraoral periapical radiograph of an overdenture implant with a ball attachment in the delayed/early loading group. *(b)* Intraoral periapical radiographs of a Brånemark Novum implant of the immediate loading group. Radiographs were obtained with appropriate aiming devices for standardized images for marginal bone level follow-up in the transversal plane.

Follow-up

One week after prosthesis placement, and thus implant loading, was considered the baseline.

Delayed Loading Group. Patients were seen 1 week (baseline), 1 month, and 3 months after prosthesis placement to closely follow the bone remodeling. They were then seen 1 year after loading. Half of the patients were also examined 2 years after loading.

Early and Immediate Loading Group. The patients of the test groups were seen 1 week (baseline), 1 month, 6 months, and 1 year after prosthesis placement. Half were seen at 2 years after loading as well. For the immediate loading group, bite-force measurements could only be performed using the bite fork (prosthesis level). The Brånemark Novum system did not allow the connection of strain gauges because the implant and abutment were 1 piece. Furthermore, the protocol did not allow removal of the baseplate during the first year. Thus, individual implant stability measurements could only be performed at the 1-year recall. However, if the baseplate had to be removed because of complications, stability measurements were performed.

Radiographic Examination

Intraoral paralleling images were used to assess the mesiodistal marginal bone level, while spiral tomographic images were obtained to assess the buccolingual marginal bone level. Digital intraoral periapical radiographs of each implant were obtained using Digora storage phosphor plates (Digora; Soredex Medical Systems, Helsinki, Finland; Fig 1). Extraoral digital tomographic images were obtained with the Cranex Tome multimodal x-ray unit (Soredex, Helsinki, Finland) and printed on Agfa Drystar TM 1 B transparent films (Agfa-Gevaert, Mortsel, Belgium; Fig 2). The Dental Tomo program for the mandible was selected, with a layer thickness of 2 mm. For both techniques, appropriate aiming devices were used to allow standardized follow-up of the marginal bone. For extraoral imaging, patients were oriented, and an individual occlusal guide was connected to the Cranex Tome. For the intraoral imaging technique, the standardized aiming device of Meijer et al[11] was used for the delayed and early loading groups. For the immediate loading group, a custom-made acrylic splint that could be screw-tightened on the Brånemark Novum baseplate was fabricated. This splint allowed standardized positioning of regular aiming devices used for dentate patients (XCP; Rinn, Elgin, IL; Fig 3). All images were evaluated using a Mitutoyo digimatic sliding caliper (Mitutoyo, Kanagawa, Japan) with an accuracy of 0.01 mm.

Delayed and Early Loading Group. The implant-abutment junction was used as a reference point for measurement.

Immediate Loading Group. The distance between the lower side of the base plate and the most superior point of the marginal bone level judged to be in contact with the implant surface was measured.

Bite Force Measurement

A miniature bite fork[12] (Fig 4) was used to quantify the bite forces exerted at the level of the occlusal plane. The methodology for the 3-dimensional force measurements on oral implants described by Duyck et al[13] was applied for the qualification and quantification of the resulting forces at the level of the abutments.

Delayed and Early Loading Group. The bite fork was placed at 7 defined locations along the occlusal surface of the overdenture (Fig 4b). Simultaneously, 3 strain gauges on each abutment registered the type (axial force or bending moment) and amplitude of the forces at the abutment level (Fig 5). Measurements were also performed during parafunctional activities (grinding and clenching in maximal occlusion). The mean of 10 consecutive registrations representing 0.2 second of registration time was calculated.

Immediate Loading Group. The bite fork was placed at 5 different locations on the fixed prosthesis (Fig 4c).

Early and Immediate Loading Group. The patients were asked to mimic chewing as indicated in the soft-diet instructions at the 1-week and 1-month sessions. They were only asked to bite maximally at the 6- and 12-month sessions.

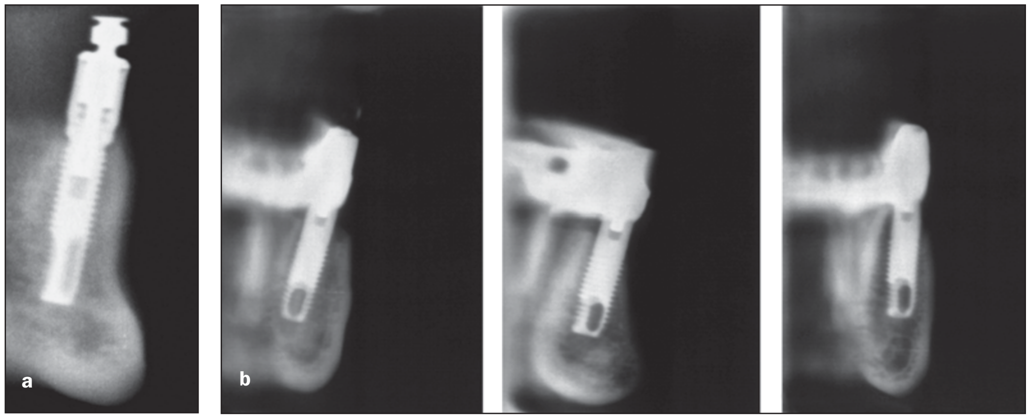


Fig 2 *(a)* Extraoral tomographic radiograph of an overdenture implant with a ball attachment in the delayed and early loading group. *(b)* Extraoral tomographic radiographs of a Brånemark Novum implant of the immediate loading group. Radiographs were obtained with an individual guide for standardized images for marginal bone level follow-up in the sagittal plane.

Fig 3 *(a)* Aiming device developed by Meijer et al.[11] This device can be screw-retained on the abutment to allow standardized parallel periapical radiography. *(b and c)* Custom-made aiming device. This device can be screw-retained on the Brånemark Novum baseplate to allow standardized parallel periapical radiography.

Fig 4 *(a)* Miniature bite fork for occlusal bite-force measurements. *(b)* Overdenture with the 7 predetermined positions indicated for occlusal force measurements: 1, the right second molar; 2, the right second premolar; 3, the right canine; 4, the midincisal point between 2 implants; 5, the left canine; 6, the left second premolar; and 7, the left second molar. *(c)* Brånemark Novum suprastructure with the 5 predetermined positions indicated for occlusal force measurements: 1, at the right distal extension; 2, at the right canine, above the right distal implant; 3, midincisally, above the central implant; 4, at the left canine; and 5, at the left distal extension.

Stability Measurements

The stability of each implant was recorded using the Periotest system (Periotest; Siemens, Bensheim, Germany).

Delayed and Early Loading Group. For the unsplinted implants of the overdenture groups, stability measurements were performed at implant placement and during each follow-up session.

Immediate Loading Group. Individual implant stability measurements were performed at 1 and 2 years postloading, when the baseplate was removed.

Statistical Analysis

Descriptive statistics were expressed with means and standard errors of the mean. Analysis of variance and the Fisher exact tests were used to compare patient

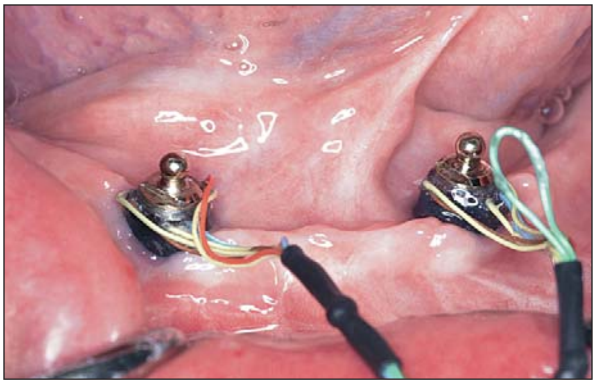


Fig 5 Replacement of the original 5.5-mm abutments by strain-gauged 5.5-mm abutments for force measurements at the abutment level.

Table 1 Patient/Implant Variables for the Delayed, Early, and Immediate Loading Groups

	Delayed	Early	Immediate
Patient no.	1–10	11–20	21–30
Mean age and age range (y)	64 (33–72)	69 (57–86)	58 (44–68)
Male/female (n)	5/5	3/7	6/4
Compromised health condition (n)	2	2	3
Smoking habit (n)	5	0	2
Status of maxilla*	8 CD, 2 ND	10 CD	1 ISF, 6 CD, 3 ND
No. of implants	20	20	30
No. of implants of each length			
11.6 mm			10
13 mm	6	8	
15 mm	14	11	
Bone quality†			
I			1
I	4	6	2
III	4	3	6
IV	2	1	1
Recent extractions			
Within 3 mo	4	4	2
Within 2 mo			1
Peroperative			7
Mean healing time before loading	16.2 weeks	1.3 weeks	0.6 days
Patients evaluated			
1 y follow-up	1–10	11–20	21–30
2 y follow-up	1–5	11–15	21–25

*FD = complete denture, ND = natural dentition, ISF = implant-supported fixed complete prosthesis.
†Index of Lekholm and Zarb.[14]

variables between the 3 groups. A mixed linear model with repeated measurements for each patient was used (SAS, Cary, NC). To adjust for multiple testing, the Tukey procedure was used. The level of significance was set at 5%.

RESULTS

Patient Selection

For each group, 10 patients were selected on a consecutive basis. Descriptive statistics are summarized in Table 1.

Surgical and Prosthetic Procedures

Delayed Loading Group. Two patients with bone quality type 4 according to the Lekholm and Zarb index[14] were treated. No surgical complications occurred. The soft tissue healing following abutment connection (2-stage) was uneventful in all patients. All overdentures were inserted within 3 weeks after abutment insertion.

Early Loading Group. One patient with bone quality class 4[14] was treated. No surgical complications occurred. The soft tissue healing following implant insertion and abutment connection (1-stage) provoked in 3 patients mucosal swelling that prevented prosthesis insertion 1 week after surgery. After 2 weeks, overdenture matrix connection and overdenture insertion were possible.

Immediate Loading Group. In 1 patient, teeth were extracted only 2 months before surgery, and in 7 patients, extractions were performed peroperatively. In 4 patients, a buccal or lingual dehiscence or fenestration was noted on 1 of the 3 implants. In 1 patient, a distal implant was placed in the remainder of an extraction socket, and the void between the cavity wall and the implant was filled with bone chips. One patient with bone quality class 4[14] was treated as well. In 7 patients, the fixed prosthesis was inserted the day of surgery; in 3 patients it was inserted 2 days after surgery. One patient experienced temporary hypoesthesia at 1 side of the mandible. In 2 patients, the baseplate was loose after a few weeks and had to be tightened.

According to ANOVA and the Fisher exact test, the patients of the 3 groups did not differ significantly with respect to age, gender, health condition, maxilla status, or bone quality. The early loading group did not include any smokers, while the delayed and immediate loading groups included 5 and 2 smokers, respectively. Implant length of the immediate loading group differed from the 2 overdenture groups, and the number of patients with recent or peroperative extractions was significantly higher in the immediate loading group. However, after removal of the sharp edges of the mandibular crestal bone and creation of a flat plateau of the mandibular crest, these extraction sockets were almost totally removed, so no implants were inserted in a wide open extraction socket.

Implant/Prosthesis Failure

Delayed Loading Group. Six months after loading, both implants in 1 patient showed excessive marginal bone loss; they were clinically mobile and had to be removed (Table 2). This patient was a heavy bruxer (wear of denture teeth), with a compromised health condition (Parkinson disease) and a heavy smoking habit. A lack of motivation for oral hygiene was noted as well.

Early Loading Group. One month after loading, 2 implants in 1 patient failed. This patient had been classified earlier with type 4 bone.[14]

Immediate Loading Group. Five months after loading, patient 21 presented with a loose baseplate. Both distal implants were clinically mobile and had to be removed. This was the only patient with the type 1 bone in the study.[14] This patient had a fixed implant-supported complete denture in the maxilla. The mandibular prosthesis could not be maintained on the remaining medial implant alone. Later this patient was retreated with 4 additional implants, which were restored with a fixed complete denture after a healing period of 4 months.

Table 2 Failed Implants/Prostheses for the Delayed, Early, and Immediate Loading Groups

Loading group/ patient no.	Time point after loading (mo)	Failed implants	Failed prostheses
Delayed			
Patient 7	6	2	1
Early			
Patient 16	1	2	1
Immediate			
Patient 21	5	2 (distal)	1
Patient 25	12 and 21*	2 (distal)	0
Patient 26	12	1 (distal)	0

*Six months after reinsertion of the failed distal implant, both distal implants (original and reinserted) failed in this patient.

At the 1-year follow-up session, suprastructures and baseplates of the Brånemark Novum system were removed for individual implant stability measurements. In 2 patients, 1 distal implant, although asymptomatic, showed high positive Periotest values (PTVs), +5.5 and +11, and were clinically mobile. In both cases, it was decided to remove the mobile implant and to reinsert an implant 3 months after healing, following the retrieval protocol. During these 3 months, the prosthesis was maintained on the 2 remaining implants, with relief of the occlusal contacts at the failed implant side. In 1 of these 2 patients, both distal implants failed 6 months after reinsertion. This patient was later retreated with the traditional delayed 2-implant mandibular overdenture, and the medial Brånemark Novum implant was removed. At the 6-month follow-up, 1 patient, who was a heavy bruxer, showed a lack of oral hygiene, severe gingivitis, pus from pockets up to 10 mm, and radiologic bony craters around the distal implants. Exploratory surgery was performed to remove granulation tissue. Despite excessive bone loss, the individual implants were stable. The patient was reinstructed in oral hygiene. At the 2-year follow-up session, only 3 of the first 5 selected patients were still included for the immediate loading group.

Radiographic Examination

The number of patients and implants examined per follow-up session is shown in Table 3.

Delayed Loading Group. During the first year of loading, more than half of the marginal bone loss was

Table 3 No. of Patients and Implants Included per Follow-up Session

	1 week		1 mo		3/6 mo*		12 mo		24 mo	
	No. of patients	No. of implants	No. of patients	No. of implants	No. of patients	No. of implants	No. of patients	No. of implants	No. of patients	No. of implants
Delayed	10	20	10	20	10	20	9	18	5	10
Early	10	20	9	18	9	18	9	18	5	10
Immediate	10	30	10	30	9	27	9	27	3	9

*Patients in the delayed group were observed 3 months postsurgery; patients in the early and immediate groups were observed 6 months postsurgery.

concentrated during the first 3 months after prosthesis insertion. Average marginal bone loss in the transverse plane was 0.29 mm (SEM 0.1) after 3 months of loading, 0.47 mm (SEM 0.2) after 1 year, and 0.49 mm (SEM 0.2) after 2 years. In the sagittal plane, average marginal bone loss was 0.28 mm (SEM 0.1) after 3 months of loading, 0.43 mm (SEM 0.1) after 1 year, and 0.51 mm (SEM 0.2) after 2 years (Fig 6).

Early Loading Group. During the first year of loading, more than half of the marginal bone loss concentrated during the first 6 months after prosthesis insertion. Average marginal bone loss in the transverse plane was 0.83 mm (SEM 0.1) after 6 months of loading, 1.07 mm (SEM 0.2) after 1 year, and 1.26 mm (SEM 0.1) after 2 years. In the sagittal plane, average marginal bone loss was 0.97 mm (SEM 0.04) after 6 months of loading, 1.28 mm (SEM 0.2) after 1 year, and 1.19 mm (SEM 0.2) after 2 years (Fig 6).

Immediate Loading Group. During the first year of loading, more than half of the marginal bone loss was concentrated during the first 6 months after prosthesis insertion. Average marginal bone loss in the transverse plane was 1.18 mm (SEM 0.1) after 6 months of loading, 1.53 mm (SEM 0.1) after 1 year, and 1.67 mm (SEM 0.1) after 2 years. In the sagittal plane, average marginal bone loss was 0.74 mm (SEM 0.05) after 6 months of loading, 1.07 mm (SEM 0.1) after 1 year, and 1.35 mm (SEM 0.1) after 2 years (Fig 6).

All groups showed significant bone loss ($P < .05$) over time compared to zero in both the transverse and sagittal planes. One and 2 years after loading there was significantly more marginal bone loss in the early and immediate loading groups compared to the delayed loading group ($P < .05$). Six months after loading, marginal bone loss was already significantly larger in the immediate loading group compared to the early loading group in the transverse plane ($P < .05$).

Bite-Force Measurement

Delayed Loading Group. The mean maximum bite forces measured with the bite fork at the 7 different locations are shown in Fig 7. There was a significant increase in maximum occlusal bite forces with time for the most distal positions (1 and 7; $P = .015$) and for positions 3 and 5 above the implants ($P = .026$). Figure 8 represents the average axial forces (compression and tensile) and bending moments resulting from maximal biting on the 7 bite-fork positions, measured by strain gauges on the abutments. The mean peak axial forces and bending moments, measured by strain gauges at the abutment level, during clenching and grinding in maximal occlusion are shown in Fig 9.

Early Loading Group. The mean maximum bite forces measured with the bite fork at the 7 different locations are shown in Fig 7. During the 1-week and 1-month sessions, patients were asked not to bite maximally but to mimic the occlusal forces as described in their soft-diet instructions to prevent interface damage. Logically, the increase in occlusal bite force was significant between 1 week/1 month after loading and 1 and 2 years after loading ($P < .05$ for all bite-fork positions). Figure 8 represents the average axial forces (compression and tensile) and bending moments resulting from maximal biting on the 7 bite-fork positions (with the exception of the 1-week and 1-month follow-up sessions), measured by strain gauges on the abutments. The mean peak axial force and bending moment, measured by strain gauges at the abutment level, during clenching and grinding in maximal occlusion are shown in Fig 9.

Immediate Loading Group. Figure 7 shows mean maximum occlusal bite-force measurements with the bite fork placed at the 5 predetermined locations on the fixed prosthesis. During the 1-week and 1-month sessions, patients were asked not to bite

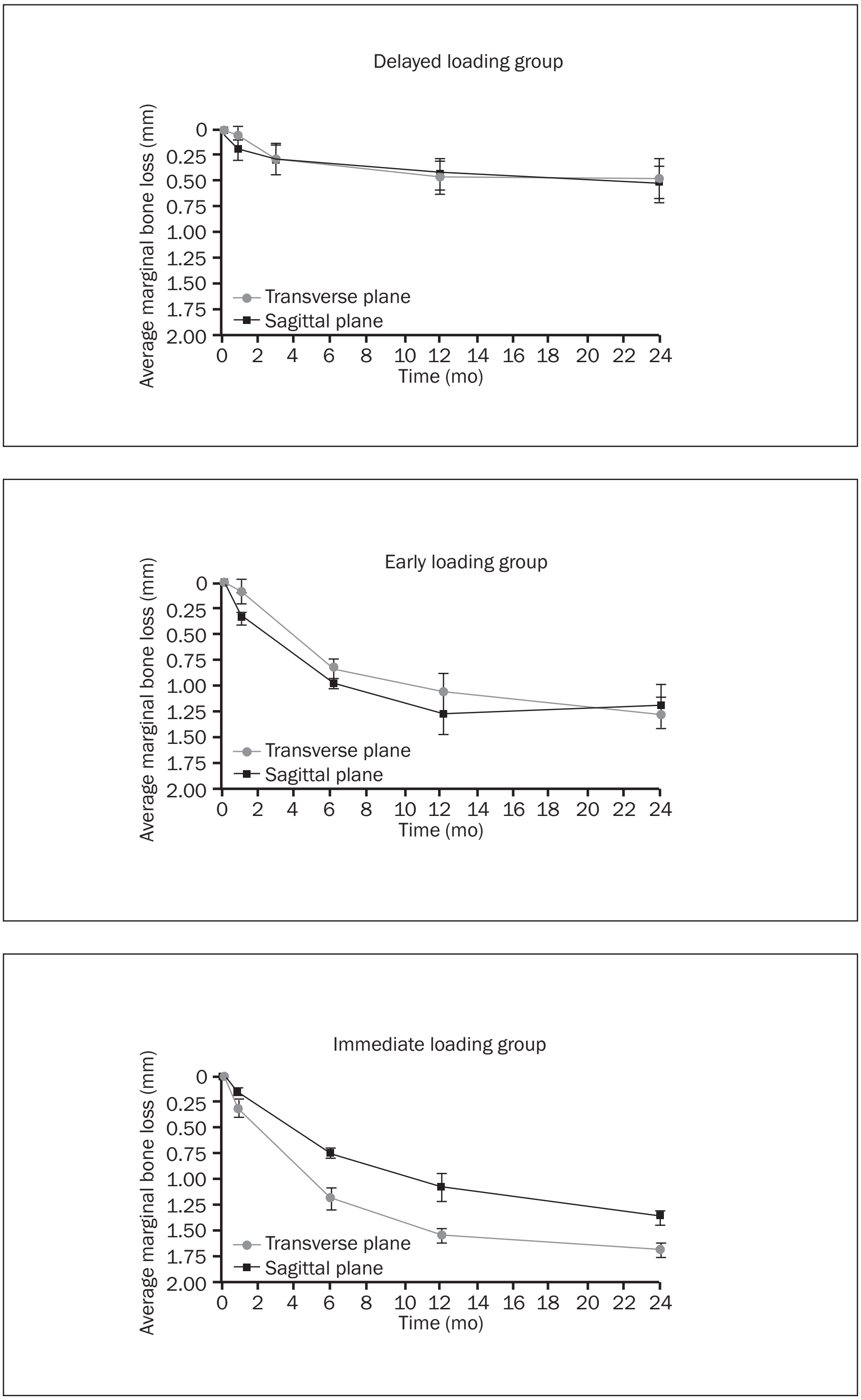


Fig 6 Mean marginal bone loss in the transverse and sagittal planes, expressed in mm (SEM) with radiographs of 1 week after loading (prosthesis placement) as baseline for the delayed, early, and immediate loading groups. For the 2-year results, only 5 patients per group were included.

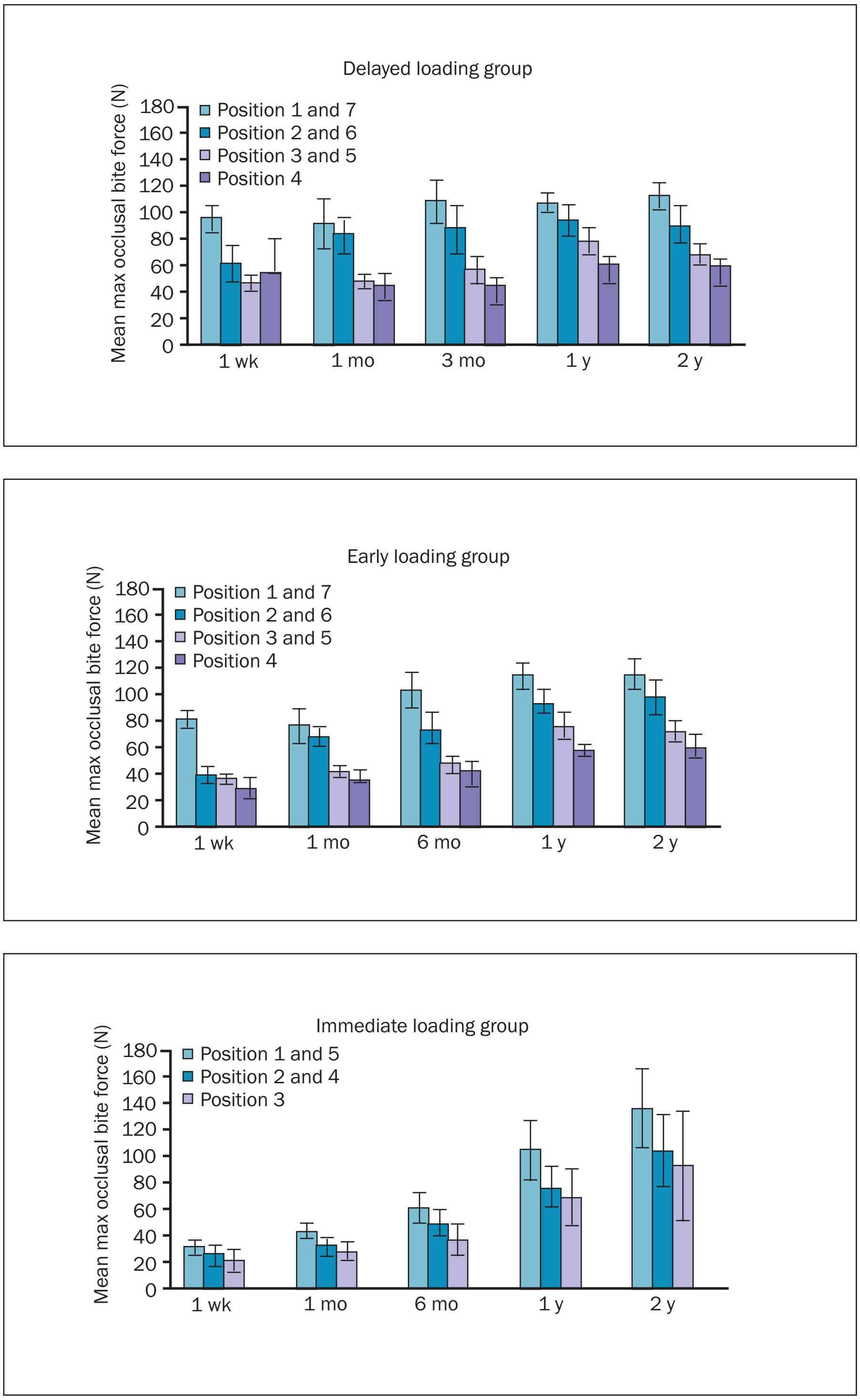
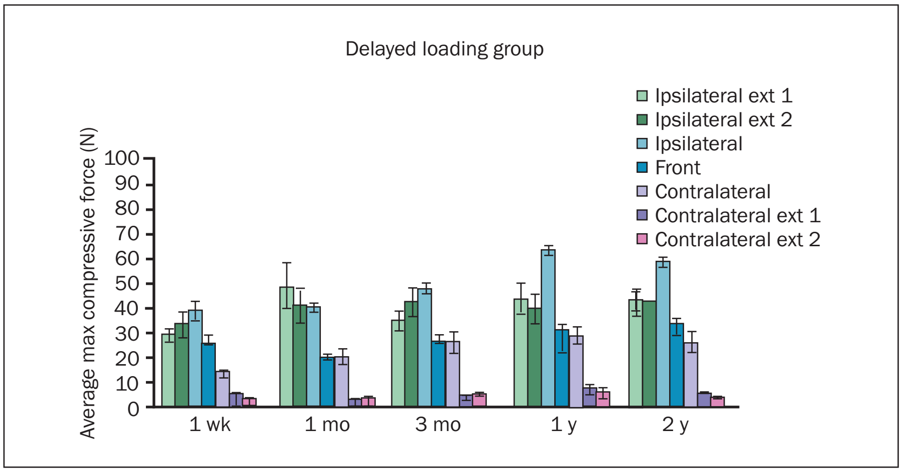


Fig 7 Mean maximum occlusal forces measured with the bite fork at the 7 predetermined positions for the delayed and early loading groups and at the 5 predetermined positions for the immediate loading group. For the 2-year results, only 5 patients per group were included. For the 1-week and 1-month follow-up, patients of the early loading group were asked to mimic their soft-diet instructions and thus not to bite maximally.



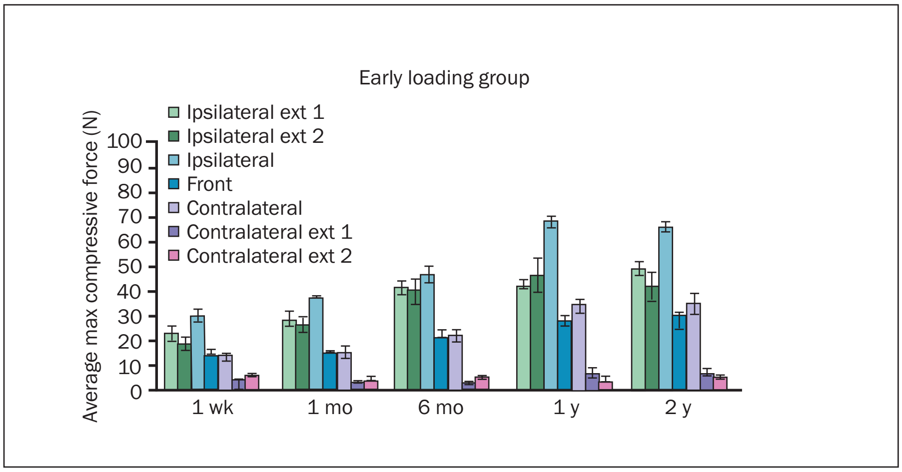


Fig 8 Mean maximal axial forces (N) and bending moments (Ncm) were measured at abutment level during maximal biting on the bite fork at the 7 predetermined positions for the delayed and early loading groups. For the 2-year results, only 5 patients per group were included. For the 1-week and 1-month follow-ups, patients of the early loading group were asked to mimic their soft-diet instructions and thus not to bite maximally.

maximally but to mimic occlusal forces (ie, to bite as described in their soft-diet instructions). As expected, the increase in occlusal bite force was significant between 1 week and 1 month after loading and 1 and 2 years after loading for all different bite-fork positions ($P < .05$).

Patients of the delayed loading group were asked to bite maximally on the bite fork at the 1-week and 1-month follow-up sessions, while the early and immediate loading groups were not yet allowed to bite maximally. They were asked to mimic occlusal forces as in their soft-diet instructions to measure whether tactile sensitivity in implant patients allowed differentiation between different magnitudes of occlusal forces. Table 4 summarizes the significant differences in occlusal bite forces between the 3 groups. As could be expected from the 1-week and 1-month data, bite forces were significantly higher in the delayed group. At the 1-month session, "maximum soft" occlusal forces were also significantly higher in the early loading group than in the immediate loading group. These differences were only significant for the distal bite-fork positions. In the frontal regions, at the implant and the midincisal locations, no significant differences between maximal bite forces for the delayed loading group and "maximum soft" bite forces for the early and immediate loading groups could be registered at the 1-week or 1-month sessions. At subsequent sessions, all patients were allowed to bite maximally on the bite fork. No significant differences were measured between the 3 groups at subsequent sessions.

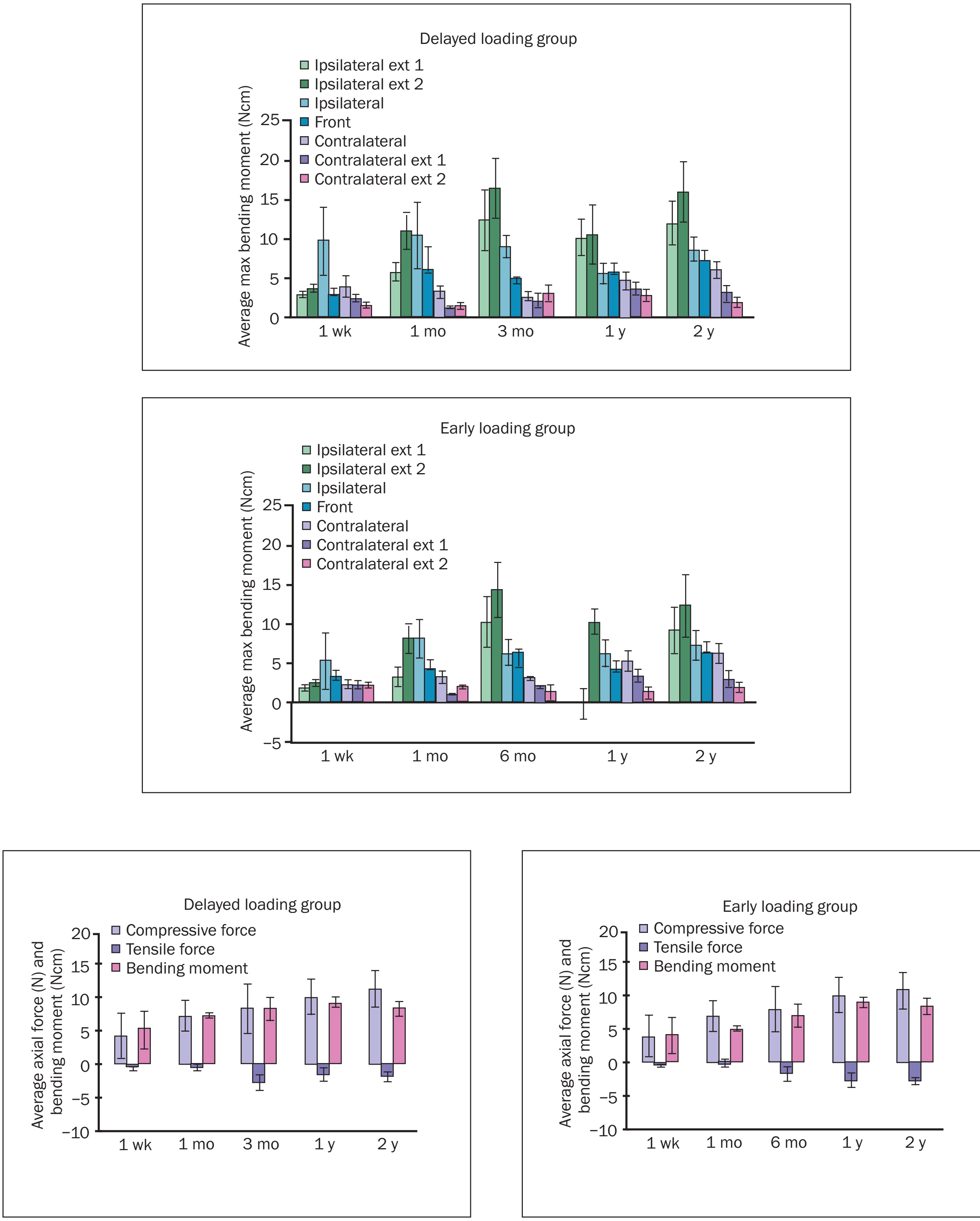


Fig 9 Axial forces (compressive/tensile forces) (N) and bending moments (Ncm) measured at abutment level during grinding for the delayed and early loading groups. For the 2-year results, only 5 patients per group were included.

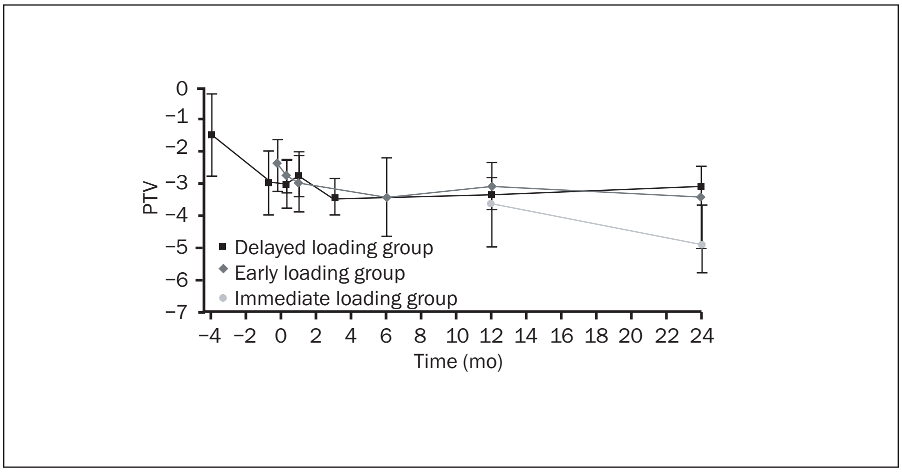


Fig 10 Average Periotest values (PTVs) for the delayed, early, and immediate loading groups.

Table 4 *P* Values for Differences in Occlusal Bite Forces Between the 3 Groups for Maximal Biting on the Bite Fork

	Early group	Immediate group
Delayed group	.036 (1 wk)* .044 (1 mo)*	.013 (1 wk)† .024 (1 mo)†
Early group		.024 (1 mo)†

*With bite fork in positions 1 and 7.
†With bite fork in position 2 and 6 versus 1 and 5.
Only statistically significant differences are shown.

Stability Measurement

Delayed Loading Group. Average Periotest values decreased from −1.5 (SEM 1.3) at implant insertion to −3.05 (SEM 0.8) 1 week after prosthesis insertion and −3.45 (SEM 0.6) 3 months after prosthesis insertion (Fig 10). From then on, implant fixation stabilized. The increase in stability over time was not statistically significant.

Early Loading Group. Average Periotest values decreased from −2.45 (SEM 0.7) at implant insertion to −2.8 (SEM 0.8) 1 week after prosthesis insertion and −3.45 (SEM 0.5) 6 months after prosthesis insertion. From then on, implant fixation stabilized. The increase in stability over time was not statistically significant.

Immediate Loading Group. Periotest values of the 2 failed implants, 5 months after loading, were +8 and +20. The 2 other failed distal implants in 2 patients had positive Periotest values (+5.5 and + 11) and were visually mobile after baseplate removal at the 1-year follow-up session. Average Periotest value after 1 year of loading (the latter implants included) was −3.67 (SEM 1.3). For medial and distal implants separately, average Periotest values were −4.33 (SEM 0.8) and −3.34 (SEM 1.1), respectively. Two years after loading, average Periotest value was −4.89 (SEM 0.9). Considering medial and distal implants separately, average Periotest values were −4.83 (SEM 1.0) and −4.92 (SEM 0.7), respectively, but no statistically significant differences were found.

There were no statistically significant differences in individual implant stability between the different groups.

DISCUSSION

Patient Selection

For each group, 10 patients were selected following the predetermined inclusion/exclusion criteria. Patients were not randomly allocated to a group but treated consecutively because the immediate loading group differed in selection criteria from the others. The dimensions required for the mandible and the requirements for the maxillomandibular relationship were stricter for the immediate loading group. Moreover, the Brånemark Novum protocol allowed peroperative extractions in the symphyseal area because the alveolar crest was removed to create a wide platform for the first drill guide, thereby eliminating most of the extraction sockets.

Patients with known possible risk factors such as smoking habit, compromised health conditions, and bruxism were not excluded to allow the study sample to represent a moderate patient population.

Surgical and Prosthetic Procedures

Compared to the traditional delayed loading approach as described by Brånemark et al,[1] early and especially immediate loading protocols significantly reduce treatment time for the patient. One surgical session can be avoided using the 1-stage approach, and the definitive prosthesis is inserted a few weeks after or even the same day as implant insertion, allowing the patients to return to their usual routines of life and work much sooner. For the early loading group, the overdenture was ready preoperatively, and the retaining matrices were added to the prosthesis within 1 week after surgery. Immediate loading via prefabricated components, as in Novum, allows fabrication and insertion of the definitive prosthesis the day of surgery, which also results in a significant cost reduction.

Early Loading Group. Insufficient soft tissue healing did not allow placement of the overdenture within 1 week after implant placement in 3 patients.

Immediate Loading Group. In 4 patients, a lingual or buccal fenestration or dehiscence occurred at surgery. For some patients this was inevitable, because once the first implant of the Brånemark Novum system is inserted, the other 2 implants must be positioned and inclined accordingly (ie, adjustments are no longer possible). Three patients only received the suprastructure after 2 days, because surgery was performed late in the afternoon, or because more than 1 try-in had to be performed.

Based on the surgeon's experience, all implants were judged to have sufficient primary stability to allow early or immediate loading.

Implant/Prosthesis Failure

Delayed Loading Group. In 1 patient late failure of both implants and thus also of the prosthesis occurred 6 months after loading.

Early Loading Group. Only 1 month after prosthesis insertion in 1 patient both implants and the prosthesis failed.

Immediate Loading Group. Five months after loading, 2 distal implants and the suprastructure failed in 1 patient. In 2 patients, 1 distal implant was considered a failure because of positive Periotest values. Their prostheses survived on the 2 other implants. In 1 of these patients, 6 months after reinsertion of the 1 distal implant, both distal implants were mobile, leading to failure of the prosthesis.

As described in literature,[15] factors that could have influenced the failures in this study include low bone quality, compromised health conditions, smoking, insufficient oral hygiene, bruxism, and pathological loading. Failures occurred in all 3 groups. Implant and prosthesis success did not differ significantly for the 2 overdenture groups, which indicates that early loading does not negatively affect osseointegration in 2-implant mandibular overdenture treatment, even with nonsplinted titanium implants. In the 2-year follow-up study of Payne et al,[6] overdentures were connected to ball attachments 2 weeks after implant insertion. During those 2 weeks of soft tissue healing, patients were allowed to wear their removable denture adjusted with a soft liner. Strict inclusion and exclusion criteria were utilized. Patients with type 4 bone quality, previously grafted or irradiated jaws, a history of bruxism, any evidence of current or previous smoking, and any systemic diseases likely to compromise implant surgery were excluded. No implants of the delayed and early loading group failed in that study. Instead of turned commercially pure titanium screw-shaped implants, Straumann sand-blasted, large-grit, acid-etched (SLA) implants (Institut Straumann, Basel, Switzerland) were used. Stricker et al[16] used the same implant type as Payne et al[6] and loaded the implants 1 day after implant surgery with a bar-connected overdenture. They also reported no failures and supported the use of a rough implant surface in early or immediate loading. Chiapasco et al[5] and Romeo et al[7] found no statistically significant differences in prosthesis or implant failure between an immediate loading group and a delayed loading group 1 year after loading of 4 splinted implants with an overdenture in the edentulous mandible. They used turned Brånemark and Straumann SLA implants, respectively. Earlier results from a prospective multicenter study on immediate rehabilitation of edentulous mandibles according to the Brånemark Novum protocol showed cumulative survival rates of 91% for implants and 94% for prostheses after 12 months.[17] In a 1-year follow-up report of 50 consecutive patients treated according to the Novum protocol, cumulative survival rates of 92.7% for implants and 95% for prostheses were shown at 1 year.[18] Engstrand et al[19] reported on the results of 95 patients treated according to the Brånemark Novum concept in a prospective follow-up study with a mean follow-up of 2.5 years. They reported a cumulative implant survival rate of 99%. Kaplan-Meier survival estimates showed an implant survival rate of 95% at 1 year and of 93.3% at 5 years (9 patients only). They concluded that the Novum approach could have results comparable to those achieved with the traditional 2-staged delayed loading protocol with respect to prosthesis survival, but that at the individual implant level the survival rate could be expected to be lower. The suprastructure and baseplate were never removed in these studies,[17–19] unless there were complications, so individual implant stability was not a criterion for implant survival. In the present study, in 3 of 10 patients, 1 or 2 implants were mobile. In a fourth patient, bone loss was excessive, jeopardizing the prognosis of the 3 implants. If one considers success, 4 of 10 patients could not have been successfully rehabilitated 2 years after implant insertion.

Radiographic Examination

In a methodologic study, the described radiographic methods for 3-dimensional imaging of the marginal bone level around oral implants were tested for reliability and accuracy.[20] It was shown that both the intraoral paralleling technique and extraoral conventional tomography technique were reliable for 3-dimensional peri-implant marginal bone follow-up.

For all 3 groups, it can be shown that more than half the marginal bone loss took place during the first months after loading and that marginal bone loss stabilized after that point. For the delayed loading group, of the 0.47 mm of the bone loss found in the transverse plane after 1 year, 0.29 occurred during the first 3 months. Of the 0.43 mm of bone loss in the sagittal plane after 1 year, 0.28 occurred during the first 3 months. This marginal bone remodeling can be explained by the influence of abutment connection surgery and of mechanical loading of the peri-implant bone. It appeared that twice as much marginal bone loss occurred in the early loading group compared to the delayed loading group. Six months after loading, mean marginal bone loss was 0.83 mm in the transverse plane and 0.97 mm in the sagittal plane. At the 1-year follow-up session, bone loss in this group was only 0.21 mm greater in the transverse plane and 0.31 mm greater in the sagittal plane than after 6 months of loading. For the immediate loading group, mean marginal bone loss was 1.18 mm in the transversal and 0.74 mm in the sagittal plane after 6 months of loading. At the 1-year follow-up session, it was 1.53 mm and 1.07 mm, respectively. The patient with the excessive marginal bone loss was included. For the early and immediate loading protocols, marginal bone modeling due to bone healing and marginal bone remodeling due to mechanical loading are combined during the first months after loading. Stricker et al[16] reported average marginal bone resorption around immediately loaded SLA implants (bar-connected OD in the mandible) of 0.71 mm after 12 months. Others[5–8] also report no statistically significant differences in marginal bone loss between implants loaded at different time points after 1 year of function.

For the Brånemark Novum protocol, van Steenberghe et al[18] reported an average marginal bone loss of 1.08 mm, while Engstrand et al[19] (transverse plane only) reported an average marginal bone loss of 0.73 mm.

Bite-Force Measurement

There was a tendency for increasing bite forces during the first year of function for both overdenture groups, although this only reached significance for the bending moments during grinding and clenching. Hinging of the overdenture should prevent high bending moments on the implants; the counterparts of the ball attachments in the prostheses can rotate around the ball attachments in any direction. However, this effect appears to diminish after 1 year in function, probably because of resorption of the jawbone in the posterior regions, which increases the lever action on the implants. Maximum biting on the bite fork showed the highest average occlusal forces with the bite fork positioned at the most posterior locations (1 and 7), with accompanying maximum bending moments measured by the strain gauges at the ipsilateral implant. If 1 side is preferred for chewing, implants will not be loaded equally. All but 3 patients in this study claimed to have no preferred chewing side. A correlated effect of potential unilateral overloading could not be evidenced in this study. The impact of the occlusal loading forces seemed to be highly dependent on the position of load application. There was a tendency to induce the highest compressive forces when the bite fork was positioned directly above the implant (ipsilateral). The larger the distance between the location of the bite fork and the implant, the less axial forces were transferred to the latter, but the higher the registered bending moments were. The immediate loading group also showed increasing maximum occlusal bite forces during the first year of loading. Bite forces were also maximal with the bite fork located at the distal extensions of the Novum prosthesis. This is more posterior than the distal implant location, which probably created an increased bending moment at the distal ipsilateral implant. Considering mean marginal bone loss separately for the medial and the 2 distal implants—0.59 mm and 1.32 mm, respectively—1 year after loading, and the fact that all failures in the Brånemark Novum patients were distal implants, it can be concluded that immediately loaded distal implants are at higher risk for mechanical overload and failure. In the early and immediate loading situations, patients were instructed to use a soft diet during the first months. At the 1-week and 1-month sessions, they were asked to mimic occlusal forces as for soft-diet chewing. However, occlusal forces measured using the bite fork were not significantly lower for the early loading group than for the delayed loading group, in which the patients were allowed to bite maximally. The experiments were performed in a hospital environment, so patients who experience no pain or discomfort and are in their normal social environment might forget these diet instructions. Together with bruxism, occlusal loading is a patient-dependent factor that cannot be controlled by instructions only. Therefore, studies are underway to warn the patients, by means of "smart" prostheses, when excessive load is exerted on their implants (http://imload.mech.kuleuven.ac.be), especially in the case of immediate loading.

Stability Measurement

The recorded clinical implant stability value (PTV) demonstrated negative mean values, indicating good bone anchorage (osseointegration) of the implants. PTVs decreased progressively with time during the first 6 months for the delayed and early loading groups. From then on PTVs stabilized, which is in agreement with the finding that marginal bone loss and thus bone (re)modeling were stable after that time point. For the immediately loaded implants, the average PTV was negative in spite of the inclusion of 2 asymptomatic mobile implants, which indicates that on implant stability was very high on average. No differences in average individual implant stability between the 3 groups were found.

CONCLUSIONS

Based on this prospective clinical trial, it seems that differences in implant outcome do not depend on the time of loading—delayed, early, immediate—in the edentulous mandible. However, occlusal loading and more particularly the magnitudes of bending moments do seem to play an important role. In this limited clinical study of 30 patients, it was not possible to demonstrate the impact of other confounding patient dependent factors such as bone quality, bone healing capacity, smoking habit, condition of the opposing jaw, bruxism, and the combination of all these factors. Further research is needed to provide better answers regarding the "how and why" of successful implant-supported restorations.

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