A Retrospective Analysis of Early and Delayed Loading of Full-Arch Mandibular Prostheses Using Three Different Implant Systems: Clinical Results with Up to 5 Years of Loading

Alf Eliasson, DDS, MSc;^{*†} Fredrik Blomqvist, DDS, MSc;^{*} Ann Wennerberg, DDS, PhD/Med Dr;^{‡§} Anders Johansson, DDS, PhD/Odont Dr[¶]

ABSTRACT

Background: Early loading of implant-supported prostheses in the edentulous mandible is widely accepted, but do the clinical results replicate those of delayed loading?

Purpose: The aim of this study was to evaluate clinical outcome and patient satisfaction with early or delayed loading in patients treated with fixed prostheses, using three different implant systems.

Materials and Methods: One hundred and nine consecutively treated patients received 490 implants supporting fixed prostheses; 82 patients with Brånemark System[®] implants (Nobel Biocare AB, Göteborg, Sweden), 16 with Astra Tech[®] implants (Astra Tech AB Dental Implant system, Mölndal, Sweden), and 11 with ITI[®] MonoType[®] implants (ITI Dental Implant System[®], Institute Straumann AG, Waldenburg, Switzerland). Prostheses were placed within 2 to 3 weeks in 55 patients; 54 patients underwent a two-stage procedure. Data were collected from patient records and radiographs; 83 patients attended a clinical examination and received a questionnaire.

Results: All patients had fixed prostheses at follow-up with a mean observation time of 3.5 years. Cumulative survival rates (CSRs) were 92.5% of prostheses and 94.4% of implants for early loading, and 98.0 and 97.9% for delayed loading. The mean radiographic bone loss after the first year was small, and at 5 years less than 0.2 mm for both groups. With early loading, significantly more prostheses (p < .05) needed adjustment or replacement.

Conclusion: Statistically significantly more prostheses needed adjustment or replacement in the early group. The present study suggested lower CSRs for prostheses and implants in the early loading group after 5 years; the difference was not statistically significant. Larger study samples are needed to verify statistically small differences between treatment techniques.

KEY WORDS: clinical retrospective study, complications, delayed loading, dental implants, early loading, fixed prostheses

Reprint requests: Dr. Alf Eliasson, Department of Prosthetic Dentistry, Postgraduate Dental Education Center, Box 1126, S – 701 11 Örebro, Sweden; e-mail: alf.eliasson@orebroll.se Titanium implants supporting prosthetic rehabilitations of edentulous jaws have been one of the most significant breakthroughs in dentistry over the past 30 years. With survival rates for individual implants of 98 to 100% after 5 years, and up to 99% over 10 to 20 years in the edentulous mandible, the treatment appears to be highly predictable in large patient groups.¹⁻⁷ Over the

^{*}Consultant, Department of Prosthetic Dentistry, Postgraduate Dental Education Center, Örebro, Sweden; †PhD student, Department of Prosthetic Dentistry/Dental Material Science, Sahlgrenska Akademin Göteborg University, Göteborg, Sweden; †professor, Department of Prosthetic Dentistry, Faculty of Odontology, Malmö University, Malmö, Sweden; ^{\$}Department of Biomaterials/Handicap Research, Sahlgrenska Akademin Göteborg University, Göteborg, Sweden; ^{\$}professor, Department of Oral Sciences – Prosthodontics, Faculty of Dentistry, University of Bergen, Bergen, Norway

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past 20 years, the original Brånemark protocol has been reevaluated and significantly modified, by development of implant design, implant surfaces, surgical technique, and biomechanical features of the prosthesis.⁸ With the development of a new implant system, Schroeder et al. 1981 showed that non-submerged dental implants with a one-stage technique osseointegrated as predictably as implants installed using the traditional submerged procedure; subsequently confirmed in numerous animal and clinical studies.9-17 As a result of these findings and patients' demands for a shorter treatment period, different techniques have been tested to provide patients with a fixed interim or permanent prosthesis within the first weeks after implant placement.18-24 The use of immediate and early loading protocols has obvious advantages for the patient; for instance, treatment time and the number of surgical interventions are reduced. Many researchers, including Brånemark and colleagues, have demonstrated comparable results for integration of implants placed under immediate and early functional load.25-30

Despite an increasing number of publications on immediate and early loading reporting high survival rates, controversy still exists over the reliability of the reported data, often because of methodological errors and small study populations.^{31–34} Although most results for early and immediate loading protocols in the interforamina area are convincing, the implant survival figures presented are somewhat lower than the results from earlier studies using delayed loading, and the reason for this has not been elucidated.^{30,35}

Few publications report prosthetic complications and maintenance procedures during the first years in function and modification of the prosthesis to accommodate the soft tissue.36 The aim of this study was to evaluate retrospectively early loading and delayed loading treatments in consecutively treated patients with screw-retained fixed prostheses in the edentulous mandible. A further aim was to evaluate the results by biological and prosthodontic variables such as implant and bone loss, framework and acrylic teeth fractures, loosening screw joints, and patient satisfaction. The study reflects the clinical situation where many prosthodontists and oral surgeons are involved in the treatment, have different expertise and experiences, and more than one implant system is used. The hypothesis was that there is no difference between treatment outcomes for the two methods.

MATERIALS AND METHODS

The early loading protocol of fixed implant-supported prostheses (ISPs) was adopted at the Department of Prosthetic Dentistry, Postgraduate Dental Education Centre, Örebro, Sweden, in March 1999. This retrospective study includes all consecutive patients treated with complete arch ISP during the period March 1999 to December 2004. Ten prosthodontists performed the prosthetic treatment; five oral and maxillofacial surgeons and five periodontists performed the implant insertions. The evaluation commenced with implant placement, and the end of the study period was chosen to make it possible to have at least a 1-year follow-up of the prosthesis.

One hundred and nine patients with edentulous mandibles were treated with fixed prostheses, 55 with early loading and 54 with delayed loading; 83 of these patients (39 men and 44 women) participated in a clinical follow-up.

Patients having received irradiation to the head and neck, with diabetes, signs of bruxism, or heavy smokers (>20 cigarettes/day) were normally allocated to the delayed loading group; however, there was one patient with diabetes in the early loading group and patients smoking <20 cigarettes/day were included in both groups. For the majority of patients, the choice of treatment method (early or delayed loading concept) was made by the prosthodontist, and oral and maxillofacial surgeon/periodontist. Hence, there was no random allocation to the two treatment groups.

Patients were provided with four to six implants each according to the one-stage surgical procedure (n = 55) and early loading (loading within the first 3 weeks), or with a standard two-stage surgical procedure and delayed loading after 3 months of submerged healing (n = 54). At the time of prosthesis placement, 47 of the patients wore a complete maxillary denture (Figure 1).

The regional ethics review board in Örebro County in Sweden approved the study design, and all participants signed an informed consent form.

Early Loading Group

Fifty-five patients with a mean age of 70 years (range 51 to 90 years, SD 11.20) at follow-up were treated with a one-stage surgical procedure and early loading proto-col.³⁷ Experienced surgeons treated all but one patient.



Figure 1 Status of the maxilla at the time of prosthesis placement in the mandible for early and delayed loading groups.

They were provided with four to six fixtures each (mean 4.5) (Table 1). Implant placement followed the guidelines described by Buser and colleagues.³⁸ Impression copings, abutments, or healing abutments were connected at the same occasion and tightened according to the manufacturer's instruction without counter torque. The mucoperiosteal flaps were closely adapted to the impression copings or abutments. Antibiotics and

Treatment, Ma	Treatment, Manufacturing Company, and Loading Protocol													
			Early L	oading		Delayed Loading								
		Men		Men Women		Men		Women		То	tal			
Implant	Туре	Р	I	Р	I	Р	I	Р	I	Р	I.			
Nobel Biocare	Conical machined	13	63	15	67	1	4	0	0	29	134			
	MK III turned	1	4	1	4	13	58	12	53	27	119			
	MK III TiUnite	3	15	7	30	9	40	7	32	26	117			
Astra Tech	TiOblast	3	14	1	5	7	32	5	23	16	74			
Straumann	ITI MonoType SLA	3	12	8	34	0	0	0	0	11	46			
Total		23	108	32	140	30	134	24	108	109	490			

TABLE 1 Distribution of Patients with Regard to Sex. Implants According to Implant System, Surface

I = implants; P = patients.

TABLE 2 Number and Lengths of Loaded Implants According to Loading Protocol											
Manufacturer	Туре	Length	Early Loading	Delayed Loading	Total						
Nobel Biocare	Brånemark conical machined	10	11 (1)		11						
		11.5	0		0						
		13	31	4	35						
		15	49 (5)		49						
		18	38		38						
		21	9		9						
	Brånemark turned	10		5 (1)	5						
		11.5		1 (1)	1						
		13	4	14	18						
		15		68 (1)	68						
		18	4	23	27						
	Brånemark TiUnite	7 and 8.5		5	5						
		10	2	5 (1)	7						
		13	11 (3)	14 (1)	25						
		15	32 (2)	42	74						
		18		6	6						
Astra Tech	TiOblast	11	1	4	5						
		13	1	9	10						
		15	14 (1)	29	43						
		17	3	13	16						
Straumann ITI	Monotype SLA	10	14		14						
		12	27		27						
		15	5		5						
Total			248 (12)	242 (5)	490						

Implant losses are given in parentheses.

All Nobel Biocare implants were regular platform, Astra Tech implants were 4.0 diameter implants, and the ITI Monotype implants were 4.1 diameter regular neck implants.

nonsteroidal analgesics were prescribed for a 7-day period, as was a daily rinse with a 0.2% clorhexidine (Corsodyl[®], GlaxoSmithKline, Brentford, England) mouthwash. In most cases, sutures were removed at delivery of the prosthesis, usually 10 to 14 days after fixture placement. In the one-stage group, three different implant systems were used: Brånemark System® implants (Mk III and fixture conical, Nobel Biocare AB, Göteborg, Sweden), Astra Tech® implants (Astra Tech AB Dental Implant system, Mölndal, Sweden), and ITI® MonoType® SLA implants (ITI Dental Implant System®, Institute Straumann AG, Waldenburg, Switzerland) (see Table 1). The Brånemark system implants were of two different kinds: the conical fixture with a turned surface and a 3.5 mm conical neck (fixture conical, Nobel Biocare AB) and the Mk III fixture with or without a multiunit abutment. They also had received two different surface treatments: the traditional turned

surface and the oxidized (TiUnite[™], Nobel Biocare AB) surface. The ITI implants were sandblasted and acidetched with the 2.8-mm-long regular neck. The lengths of the implants used are presented in Table 2.

Delayed Loading Group

Fifty-four patients with a mean age of 69 years (range 47 to 89 years, SD 8.7) received four to six implants each (mean 4.5) in accordance with the standard two-stage surgery described by Adell and colleagues³⁹ (see Table 1). Experienced surgeons performed most of the implant placements, but inexperienced surgeons treated 13 patients. Sutures were removed 10 to 14 days after implant placement. The antibiotic regime described earlier was used. The prescribed 3 months of submerged healing was allowed before second-stage surgery was undertaken and abutments or healing abutments were mounted as described earlier.

In the delayed loading group, patients were treated with two different implant systems: Brånemark system implants (n = 42 patients, 187 implants) and Astra Tech implants (n = 12 patients, 55 implants). The Brånemark system implants were Mk III implants either with the turned surface or the TiUnite surface, and the Astra Tech implants had the TiOblastTM surface, as used in the early loading group. The lengths of the implants used are presented in Table 2.

Prosthetic Procedures

Seventy-one percent of the patients in the early loading group received impression copings mounted on the implants at the surgical department, and were then admitted to the Department of Prosthodontics directly after suturing of the adapted mucoperiosteal flaps. Impressions were made using a polyether impression material (Impregum[™], ESPE, Seefeld, Germany), and an occlusion record was made with silicon putty (Provil®, Heraeus Kulzer GmbH & Co. KG, Hanau, Germany) or wax (Tenaxvax, SS White Group, Gloucester, England) on healing abutments. The tooth arrangement was tried within the next few days, and in seven cases a try in of the metal framework was performed separately before the prosthesis was delivered. In 44 patients, the prostheses were delivered within 2 weeks. Thirty-four of the prostheses in the early loading group were fabricated with metal frameworks in computer numeric controlled (CNC) milled titanium (Procera® Implant Bridge, Nobel Biocare AB), and 21 were cast in a high noble alloy (C3 gold, KAR Sjödings®, Stockholm, Sweden). Acrylic teeth (SR Vivodent®, Ivoclar Vivadent AG, Schaan, Liechtenstein) were used for all prostheses.

Occlusal adjustments were performed to ensure an even distribution of occlusal forces and no contacts on the cantilevers during excursive movements. A soft diet was recommended during the first 4 to 6 weeks after prosthesis placement.

Patients treated according to delayed loading had their temporary removable prostheses adjusted with soft relining material (CoeSoft[™], GC America, Inc., Alsip, IL, USA or Viscogel[®], Dentsply, DeTrey GmbH, Konstanz, Germany) 7 to 10 days after implant placement and again every sixth week until delivery of the final prosthesis. For patients not receiving definitive abutments at second-stage surgery, healing abutments were replaced with definitive abutments 1 to 3 weeks after secondstage surgery. Abutments were tightened in accordance with the manufacturer's instructions. Impression copings were adapted, and an impression was made with Impregum. Fabrication of the prosthesis included the same procedures as for the early loading group, except an extra visit was used to check the fit of the framework before delivery of the prosthesis. Thirty-nine of the prostheses were delivered within 28 weeks of implant placement. Forty-seven of the frameworks in the delayed loading group were cast in high noble alloy, and five were CNC-milled frameworks; all were fabricated with acrylic resin teeth as for the early loading group. Two prostheses were fabricated in metal ceramic using a high noble alloy and porcelain fused to metal.

Follow-Up and Registered Variables

Radiographs were taken 3 months after implant placement in the early loading group and after prosthesis placement in the delayed loading group (baseline), and at the 1- and 5-year checkups. For all patients treated, information on the number of follow-up visits and adjustments/repairs of prosthesis was collected from their dental records. All patients were enrolled in the clinic's routine follow-up system with yearly checkups of the prosthesis and peri-implant tissues. The majority of the patients also visited a dental hygienist at least once a year and completed a self-administered questionnaire 6 weeks before the clinical follow-up examination. The questionnaire covered issues concerning general health such as type and number of drugs used daily; general health; smoking habits; temporomandibular disorder (TMD) symptoms; discomfort associated with the manufacturing; and use of the ISP in addition to general satisfaction with speech, hygiene, and aesthetics.

The clinical examination included registration of variables such as wear of the acrylic teeth, distance between soft tissue and prosthesis, peri-implant tissue assessment with respect to keratinized or non-keratinized attachment, pus, bleeding on probing of the peri-implant sulcus, and presence of calculus. A silicon impression (Provil) was made under the prosthesis in order to establish the distance between the soft tissue and the prosthesis. The thickness of the impression was measured in six regions (regions 45, 43, 41, 31, 33, and 35) using a caliper with a 0.1 mm scale. Additional radiographs were taken for patients presenting signs of peri-implantitis and those patients having at least 3 years of follow-up, but not having reached the 5-year follow-up examination.

At the last recall, the prostheses were not removed to check individual stability of the implants, which is a drawback, and excludes the use of success criteria in the evaluation. However, 33 of the prostheses were removed at one point or another for other reasons such as repairs and tightening of loose screws (23 in the early loading group and 10 in the delayed loading group). Prosthetic complications such as loosening or fracture of retention and abutment screws, acrylic fractures, fractures of acrylic resin teeth, loosening of screw access-hole fillings, and fractures of frameworks were noted. The number and type of implants used were registered, and the length of the cantilever from the most distal implant to the distal end of the prosthesis was measured to the nearest millimeter. Occlusal tooth wear was registered as minor (<0.5 mm), moderate (0.5 to 1.0 mm), or pronounced (>1.0 mm). The opposing dentition and occlusal relation in the horizontal, vertical, and transversal planes were registered (see Figure 1). Detailed information about treatment outcome, number of planned and unplanned appointments, number of days requested to complete the rehabilitation, and all complications during the follow-up period was retrieved from the patients' records. Bone level at the implants was estimated from conventional analogue intraoral radiographs, except a few cases using digital images because of a change from analogue to digital radiographs at the Radiographic Department late in 2005. The distance from the implant-abutment/prosthesis junction to the most apical marginal bone level in contact with the implant surface was measured by one of the senior consultants at the Prosthetic Department, using the reference point described by Åstrand and colleagues.⁴⁰ A peak scale loupe with a magnifying factor of ×7 and a scale graded in 0.1 mm steps was used, and the measurements were made at the mesial and distal surface of the implant. The mean of the mesial and distal measures was used in the statistical analyses. The fit of the framework was evaluated both clinically (n = 83 patients)and from the radiographs (n = 109 patients). A misfit was registered when a gap was visible at the junction between implant and abutment and/or framework clinically or in the radiographs.

Statistical Analysis

All data were analyzed in Statistical Package for Social Science (SPSS) version 15 (SPSS, Inc., Chicago, IL, USA). Independent *t*-test was used to compare bone loss

between countersunk/noncountersunk implants, and to compare the effect of loading protocol on bone loss for those implants used according to both loading protocols. Conventional descriptive statistics were used to characterize bone-level changes. The Mann-Whitney *U* test was used to analyze differences in the number of scheduled and nonscheduled visits after prosthesis placement, and to analyze the self-administered questionnaire. The chi-square test was used to analyze differences in prostheses remade/repaired in the laboratory according to loading protocol, and a Kruskal-Wallis test was used to analyze complications with respect to the opposing dentition.

RESULTS

Patients Lost to Follow-Up

Of the original 109 patients, 83 were examined clinically after 1 to 6 years in whom a total of 378 implants had been placed. Twenty-six patients (12 in the early loading group and 14 in the delayed loading group) with a total of 112 implants were lost to follow-up; 18 had died, two had moved out of the county, and another six patients did not want to continue in the study because of poor health or lack of interest (Table 3).

Implant Losses

The pattern of implant losses differed between the groups. In the early loading group, 12 (4.8%) implants were lost; two patients lost one implant each, and two patients lost all implants (four and five implants, respectively) during the first year, and one patient lost one implant after 5 years. One of the patients who lost all implants was diabetic; the reason for implant loss could not be established. For the patient losing one implant after 5 years, radiographs taken at the 1-year follow-up indicated that this implant probably had lost its osseointegration already then, but the prosthesis was not removed in order to check the individual implants. One experienced surgeon treated all the patients with implant losses. The implants lost during the first year were six Brånemark system implants with a turned surface, and one patient lost all five TiUnite implants inserted. The implant lost after 5 years was an Astra Tech implant with a TiOblast surface. Both patients who lost all implants were successfully reoperated with two-stage surgery and delayed loading using the same type of implant.

Placed/Examined		Lost to Fo	ollow-Up	Fail	ed	CSR (%)			
Prostheses	Implants	Prostheses	Implants	Prostheses	Implants	Prostheses	Implants		
	248								
55	248								
49	228	2	9	4	11	92.5	95.4		
47	219	2	9			92.5	95.4		
41	187	2	8			92.5	95.4		
33	151	4	16			92.5	95.4		
23	103	2	10		1	92.5	94.4		
23	103	12	52	4	12	92.5	94.4		
	243				5		97.9		
54	242					100	97.9		
50	230	3	12	1		98.0	97.9		
41	181	3	15			98.0	97.9		
35	157	3	12			98.0	97.9		
29	129	3	12			98.0	97.9		
24	106	2	9			98.0	97.9		
24	106	14	60	1	5	98.0	97.9		
	Placed/Ex Prostheses 49 47 41 33 23 23 23 54 50 41 35 29 24 24 24	Placed/Examined Prostheses Implants 248 248 55 248 49 228 47 219 41 187 33 151 23 103 23 103 55 248 47 219 41 187 33 151 23 103 23 103 54 242 50 230 41 181 35 157 29 129 24 106 24 106	Placed/Examined Lost to Formation Prostheses Implants Prostheses 248 248 1000000000000000000000000000000000000	Placed/ExminedLost to Follow-UpProsthesesImplantsProsthesesImplants248295524894922829472192941187283315141623103210231031252542425031255157312351573122912931224310629241106292411061460	Placed/ExaminedLost to Follow-UpFaileProsthesesImplantsProsthesesImplantsProstheses2482945524829449228294472192944118728 23103210	$ \begin{array}{ c c c } \hline Placed/Examined & Lost to Follow-Up & Failed \\ \hline Prostheses & Implants & Prostheses & Implants & Implants \\ \hline Prostheses & 248 & & & & & & & & & & & & & & & & & & &$	$ \begin{array}{ c c c c c } Placed/Examined & Lost to Follow-Up & Failed & CSR (\end{tabular}{lllllllllllllllllllllllllllllllllll$		

TABLE 3 Distribution of Prostheses and Implants Followed-Up and Lost to Follow-Up in the Early Loading Group and Delayed Loading Group During the Inclusion Period

Reason for patients lost to follow-up: During year 1, two patients did not want to participate in follow-up examinations; three patients died. During year 2, two patients did not want further checkups at the specialist clinic, and three patients died. During year 3, one patient moved out of the county, and four patients died. During year 4, one patient moved out of the county, and six patients died. During year 5, two patients were too ill to participate, and two patients died.

In the delayed loading group, five (2.1%) implants were lost; two patients lost two implants and one patient lost one implant prior to loading, and no implants were lost after loading. One of the patients who lost two implants had oral parafunction; the reason for implant losses could not be established. The inexperienced surgeons treated all three patients who lost implants. The lost implants were Brånemark system implants; two with TiUnite surface and three with a turned surface. Four of the lost implants were replaced by new implants prior to prosthesis placement.

Bone Loss

Bone loss was calculated using the baseline and 1- and 5-year radiographs. For 10 patients, radiographs were not taken at baseline or at the 1-year follow-up. Bone loss was generally small during the first year of healing with a mean of 0.49 mm (SD 0.80) in the early loading group, and 0.25 (SD 0.85) in the delayed loading group. Most implants (52.5% in the early and 60.4% in the delayed loading group) presented no bone loss after the

first year. The change in registered bone level during follow-up was small (Table 4). A few implants displayed bone loss exceeding 0.6 mm from the 1- to the 5-year follow-up; 14 (13.2%) in the early loading group and 10 (9.0%) in the delayed group. Only 4.3% of the implants demonstrated bone loss exceeding 1.2 mm after the first year (Table 5). For those patients with radiographs available at the 1- and 5-year follow-up visits, the bone loss after the first year was small in both groups, with a mean of 0.18 mm in the early and 0.15 mm in the delayed loading group at the 5-year follow-up (Table 6).

The bone loss pattern differed between the different implants and placement techniques used. In the early loading group, most implants were one-piece implants with a turned neck (conical fixture, Brånemark system, and ITI MonoType). Of these, 36.5% were countersunk at implant insertion. At the 1-year follow-up, the bone level was often registered at the first thread of the Brånemark system conical fixtures and at the rough surface of the ITI implants. Countersunk implants incurred significantly greater bone loss than noncountersunk

TABLE 4 Mean Marginal Bone Level (mm) in Relation to the Implant Reference Point (IRP) at Baseline and After 1 and 5 Years of Follow-Up According to Loading Protocol

	Mean Bone Level (SD) in Relation to IRP									
		Baseline		1 Year	5 Years					
Treatment Group	n	n Mean (SD)		Mean (SD)	n	Mean (SD)				
Early loading										
NB conical	25	3.79 (0.93)	21	4.20 (0.79)	14	4.13 (0.90)				
NB turned	2	0.50 (0.00)	2	0.81 (0.26)	1	0.75 (0.00)				
NB TiUnite	10	0.93 (0.77)	9	1.54 (0.80)						
ASTRA Tech	4	0.33 (0.54)	3	0.63 (0.87)	1	0.18 (0.00)				
Straumann ITI	11	1.62 (0.69)	11	2.33 (0.53)	7	2.68 (0.82)				
Total early loading	52	2.43 (1.66)	46	2.84 (1.50)	23	3.36 (1.41)				
Delayed loading										
NB turned	22	1.38 (0.68)	19	1.48 (0.76)	15	1.62 (0.92)				
NB TiUnite	15	1.15 (0.61)	13	1.68 (1.58)	2	1.84 (0.28)				
Astra Tech	12	1.00 (0.43)	11	1.04 (0.32)	7	0.90 (0.23)				
Total delayed loading	49	1.22 (0.62)	43	1.43 (1.02)	24	1.43 (0.81)				
Total All	101	1.84 (1.40)	89	2.16 (1.47)	47	2.37 (1.50)				

n = number of X-rayed patients; NB = Nobel Biocare.

implants (see Table 6) (p < .001). The bone loss registered during the first and succeeding years up to the 5-year radiographs was small for all implant systems irrespective of types of implants and surfaces (see Table 6). No significant differences were seen in bone loss between the same type of implant for different loading regimes (p > .05), and so the bone loss for dif-

ferent implant systems is presented without distinguishing by loading protocol (see Table 6).

Soft Tissue Complications

Soft tissue was registered as healthy at most implants irrespective of attached or nonattached peri-implant mucosa. Neither were there any statistically significant

TABLE 5 Frequency Distribution of Marginal Bone Loss at the 1-Year (437 Implants) and 5-Year (210 Implants)														
	Baseline to 1 \					1 to 5 ነ	1 to 5 Years							
	Early Loading n = 220		Delayed <i>n</i> = 217		Early I n :	Loading = 99	Delayed <i>n</i> = 111							
Bone Loss (mm)	n	%	n	%	n	%	n	%						
0	80	36.4	116	53.4	52	52.5	67	60.4						
>0-0.6	72	32.7	65	29.9	34	34.3	34	30.6						
>0.6-1.2	40	18.2	28	12.9	8	8.1	6	5.4						
>1.2-1.8	14	6.4	3	1.4	4	4.1	2	1.8						
>1.8-2.4	8	3.6	1	0.5	1	1.0	1	0.9						
>2.4-3.0	4	1.8	1	0.5			1	0.9						
>3.0	2	0.9	3	1.4										

Radiographic examination according to loading protocol.

n = number of X-rayed implants.

Different Implants and Surfaces											
	Ba	seline to 1	Year		1 to 5 Years						
Implant System	n	Mean	(SD)	n	Mean	(SD)					
Nobel conical machined											
Noncountersunk	83	-0.32	(0.79)	54	-0.14	(0.45)					
Countersunk	24	-0.85	(1.18)	10	-0.03	(0.07)					
Total conical machined	111	-0.42	(0.90)	64	-0.13	(0.42)					
Nobel MK III machined	106	-0.21	(0.53)	75	-0.18	(0.61)					
Nobel MK III TiUnite	105	-0.54	(1.10)	9	-0.24	(0.24)					
Astra Tech TiOblast	70	-0.04	(0.40)	36	-0.05	(0.25)					
Strauman ITI Monotype SLA											
Noncountersunk	12	-0.25	(0.40)	4	-0.25	(0.38)					
Countersunk	34	-0.91	(0.84)	22	-0.50	(0.56)					
Total ITI Monotype SLA	46	-0.72	(0.80)	26	-0.46	(0.54)					
Total	437	-0.37	(0.83)	210	-0.17	(0.52)					

TABLE 6 Mean Bone Loss (in mm) During Follow-Un

Number of implants analyzed at the 1- and 5-year follow-up visits (n). Brånemark system conical fixture and ITI Monotype implants were only used in the early loading group. All other implants were used in both groups.

differences between type of implant and loading group. No correlation was seen between attached or nonattached peri-implant mucosa and bone loss. Soft tissue complications were rare, and peri-implantitis was only registered in three patients, two in the early loading group and one in the delayed loading group. These three patients had Brånemark system implants, two patients with TiUnite surfaces and one with the turned surface.

Soft tissue shrinkage after prosthesis placement was measured by silicon impression and a caliper. The distance between the ISP and the alveolar crest was less in the posterior region than anteriorly (Table 7). The mean distances were 1.1 mm (posterior) and 1.6 mm (anterior) in the early loading group, and 0.9 and 1.5 mm in the delayed loading group. Generally, greater distances between the alveolar crest and the ISP were registered in

the early loading group. This was despite prosthesis adjustment/refashioning after the first delivery in four patients in the early loading group because of unacceptable soft tissue adaptation, or remaking because of misfit of the framework before the registrations in two patients.

Prosthetic Complications

All patients participating in the clinical follow-up examination wore a fixed prosthesis at the follow-up registration, but the original prosthesis was exchanged in some patients, and the survival rate for the prostheses was 92.5% in the early loading group and 98.0% in the delayed loading group.

Framework fracture occurred in one patient in the delayed loading group. The framework that fractured

at the Sites 45, 43, 41, 31, 33, and 35 According to Loading Protocol												
Distance Between Soft Tissue and Base of the Prosthesis in Different Regions (mm)												
	Region 45		Region 43		Region 41		Region 31		Region 33		Region 35	
	Mean	(SD)										
Early loading	1.17	(0.75)	1.35	(0.80)	1.51	(0.82)	1.74	(0.92)	1.58	(0.91)	0.96	(0.64)
Delayed loading	0.94	(0.71)	1.45	(0.89)	1.57	(0.76)	1.45	(0.79)	1.51	(0.76)	0.88	(0.66)
Total	1.06	(0.74)	1.40	(0.84)	1.54	(0.79)	1.60	(0.87)	1.55	(0.84)	0.92	(0.65)

TABLE 7 Distance Between Soft Tissue and the Base of the Implant-Supported Prostheses Measured (in mm)

	Early Loading (<i>n</i> = 55)			De	Delayed Loading (n = 54)			Total (<i>n</i> = 109)		
Type of Problem	Р	I/A	0	Р	I/A	0	Р	I/A	0	
No complication	32			42			74			
Implant loss before loading				3	5	3	3	5	3	
Implant loss after loading	5	12	5				5	12	5	
New implant insertion	2	9	3	2	4	2	4	13	5	
New prosthesis	4		4	1		1	5		5	
Framework fracture				1		1	1		1	
Relining	4		4				4		4	
New acrylic teeth	3		3	0	0	0	3		3	
Acrylic fracture	4		5	0	0	0	4		5	
Loss of acrylic resin teeth	5		9	4		5	9		14	
Abutment screw fracture				1	1	1	1	1	1	
Loose abutment screw	1	3	1	1	2	1	2	5	2	
Retaining screw fracture	1	12	4				1	12	4	
Loss of access hole filling	7	12	10	5	5	5	12	17	15	
Peri-implantitis	2	3	4	1	1	1	3	4	5	
Loose retaining screw	2		3	1		1	3		4	
Prosthesis removed for adjustments and/or repair	23		38	10		18	33		56	

TABLE 8 Distribution of Reported Number of Problems Related to the Prosthesis in the Two Groups During the Follow-Up Period on Patient and Occasion Level

A = abutments; I = implants; O = occasions; P = patients.

was the only one fabricated in cast titanium and it was replaced by a new prosthesis within the first year. Because of implant losses (n = 2) and misfit (n = 2) of the prosthesis (as a result of improper mounting of impression copings and/or insufficient impressions), four prostheses had to be remade in the early loading group (all titanium frameworks). Relining of the prostheses was also more common in the early loading group (n = 4) because of unacceptable distance between prosthesis and peri-implant tissue (Table 8).

Ninety-six of the prostheses were fabricated with two-unit bilateral cantilevers. The mean number of acrylic teeth was 11.5 in both groups (range 10 to 13). Most of the patients examined (n = 79) displayed an angle class I jaw relation; only a few patients (n = 4)presented slight class II or class III relations. However, cross-bite was more often found among the early loading group (nine patients compared to three patients), and patients with one-piece implants more often displayed screw access holes on the buccal side. Complete removable dentures in the maxilla were used by 42% of the patients, while fixed ISPs in the opposing jaw were more common in the delayed loading group, 35 versus 18% in the early group (see Figure 1).

The amount of tooth wear on the ISP was comparable in the two groups and in most cases was related to the time in service; no difference was seen between the sexes. However, in two patients in the early loading group (titanium frameworks), the tooth wear was so extensive that the acrylic teeth needed to be replaced within the first 5 years.

The most common complication was fracture of the acrylic/acrylic resin teeth, and it was seen more often in the early loading group; seven patients with 14 occasions in the early loading group and four patients with five occasions in the delayed loading group. No significant differences were noticed between the various framework materials (p > .05). When analyzed further, patients with ISPs in the maxilla had significantly more problems (p < .05) with loose and/or fractured acrylic resin teeth than patients with natural dentition or removable prostheses in the opposing jaw.

The need for emergency visits, additional to scheduled appointments after completed treatment during the first year, was more common in the early loading group (3.4 planned and 1.3 unplanned visits) than the delayed loading group (2.2 and 0.7, respectively).

The mean number of days from implant insertion to prosthesis placement was 2.07 weeks (range 7 to 49 days, SD 8.4) for the early loading group, and 24.1 weeks (range 9 to 42 weeks, SD 8.0) for the delayed loading group. The reason for a delayed prosthesis placement in the early loading group (after 49 days) was because of initial problems with wound healing, which postponed the impression procedure, and later illness, which postponed the placement of prosthesis. Implant losses and additional implant placement in one patient in the delayed loading group delayed prosthesis placement until 42 weeks after surgery. The number of scheduled appointments during manufacture of the prosthesis was lower for the early loading group.

Loosening and fracture of retaining and abutment screws were seen in five patients; one patient had recurrent problems with a total of 12 fractured retaining screws during the 5-year follow-up. The patient with recurrent retaining screw fractures had fixtures placed in a reduced arch form because of a short interforaminal distance and signs of bruxism.

Questionnaire

The questionnaire comprised 16 questions, and all of the patients participating in the clinical examination responded. The results indicated that significantly more patients treated according to the early loading protocol were satisfied with the treatment than in the delayed loading group (81 vs 71%; p < .05). The reasons given for this by the patients in the early loading group were: (1) not having to wear a temporary prosthesis; (2) not having to undergo a second surgery; and (3) less time associated with the treatment. Most patients in both groups considered the treatment cost appropriate and were generally satisfied with the aesthetic result. There were no differences in self-reported general health, TMD symptoms, number of drugs used, chewing ability, hygiene, or speech problems. Most of the patients who reported speech problems had received a new complete prosthesis in the maxilla at the time of delivery of the ISP, and there were no differences between treatment groups or implant system used.

DISCUSSION

From the originally treated 109 patients, only 83 patients were available for clinical follow-up, corresponding to a

participation rate of 76%. Seventy-four percent of the 26 patients not attending the follow-up had either died (63%) or moved from the county (11%). Thus, it was generally "natural" reasons for not attending, which suggests that the results were not biased by the dropout rate.

The lack of randomization in the two different treatment groups, and the different numbers of implants used in each implant system in the present study are two drawbacks to the study, which may limit the interpretation of the results.

Patients with a calculated higher risk of implant failures were mostly treated according to the delayed loading protocol. However, one patient with diabetes was treated according to the early loading protocol and lost all five implants installed; the reason for implant loss was not established. The 83 patients answering the questionnaire reported no differences in general health or number of drugs taken daily between groups with early or delayed loading.

Patients in the early loading group had been edentulous in the mandible a shorter time prior to implant placement, with less than 5% being edentulous for more than 5 years compared to 23% in the delayed loading group.

Well-trained surgeons, who had placed more than 500 implants each before the study, performed most of the implant placement in both groups. However, in 13 patients in the delayed loading group, more inexperienced surgeons performed the implant insertion. All three patients experiencing implant losses in the delayed group occurred within these 13 patients. Whether this was a result of lack of surgical skill or experience could not be ascertained. However, this may partly be why five or six fixtures instead of four were placed in some patients to support an ISP. The standard procedure for treating routine cases with mandibular implant-retained fixed prosthesis at the clinic is to place four implants in the interforaminal area.³ Placement of more than four implants may be because of a higher risk of complications, such as patients having undergone radiation therapy and/or mandibular reconstruction, bruxism, or patients with general health problems. In the present study, some surgeons used five implants in most of the early loading patients. It can be speculated that this reflects the uncertainty in using fewer implants than the original protocol postulates. When a new method is tried, it may be safer to use more implants than perhaps are needed.

Prostheses in the early loading group did not differ from prostheses in the delayed loading group with regard to number of teeth, length of cantilever, and number of supporting implants. However, there was a difference in the choice of framework in that most frameworks in the early loading group were CNCmilled titanium whereas cast gold frameworks predominated in the delayed loading group. More biological and time-consuming technical complications occurred in the early loading group, as also reported by Friberg and colleagues.³⁰ The two prostheses remade because of misfit in the early loading group had impression copings placed by the surgeon who performed the implant placement. The misfit was probably a result of incorrect placement of the impression copings and could have been avoided by taking radiographs of the copings before the impression was made.

Divided by group, the survival rates for prostheses and implants were 92.5 and 94.4% with early loading, and 98.0 and 97.9% with delayed loading. These results agree with other studies conducted in a similar manner.^{19,35,41,42}

The use of three different implant systems has probably not influenced bone loss results because most implants in both groups were Brånemark system implants, and prospective studies comparing Brånemark system implants with ITI implants and Astra Tech implants have shown no significant differences in bone losses in the different implant systems.^{40,43} In addition, the bone losses reported for turned and moderately rough surfaces in different studies are of the same magnitude.44,45 However, because the two other implant systems were only used to a minor degree, the difference in bone loss between the implant systems should be interpreted carefully. Nevertheless, it could be stated that the mean marginal bone loss at the 1- and 5-year radiographic examination in the present study was low for both types of rehabilitation, for all implant systems used, and compares favorably with other studies.^{3,35,46–48} Countersinking of implants combined with the use of implants with a turned conical neck had a significant influence on the bone loss during the first year; in the present study, it was the main reason for greater mean bone loss during the first year in the early loading group. Because of the complex effect on marginal bone loss of surgically induced trauma, stress distribution, microbiota, and host response, the exact role played by separate implant design and surface characteristics is difficult to discern.^{43,49}

Opinions diverge whether submerging of implants reduces initial bone resorption after implant installation. However, most reports of the different loading protocols report comparable bone loss after abutment connection.^{35,36,50,51} Immediate loading protocols may act as an osteogenic stimulus because of the immediate transmission of functional forces. Current bone biology suggests that bone formation is enhanced and bone density is increased by mechanical stimulation within certain limits.^{52,53} Another explanation could be that the trauma of the second operation is avoided, thus preserving biological width by more superficial placement of implants.^{10,27,50}

Concerning soft tissue condition, differences between the two groups were observed regarding implant/abutments penetrating keratinized or nonkeratinized peri-implant mucosa. This was probably because subjects with more remaining crestal bone were selected as more suitable for early loading. Differences in soft tissue appearance could not be substantiated. In general, the peri-implant mucosal status was good and soft tissue pathology was seen in only a few cases. This observation is supported by Esposito and colleagues⁵⁴ who stated that implants penetrating unattached peri-implant mucosa were not associated with periimplantitis and accompanied bone loss, but did increase the risk of entrapment of food debris and foreign particles with obvious consequences.

The technique with early loading has certain advantages, which were reflected in the questionnaire, with a significant difference in satisfaction between the two techniques in favor of early loading. More patients were pleased with the shorter treatment time and just one surgical intervention and experienced less discomfort during the manufacturing process than patients treated according to the original protocol. This is supported by another study comparing the number of clinic visits for early loading and conventional loading.⁵⁵ In the present study, try in of the framework was omitted in the early loading group, resulting in fewer visits during fabrication of the prostheses. On the other hand, the early loading group had more planned visits after prosthesis placement with a mean of 3.4 compared to 2.2 for the delayed loading group. However, in the present study, the total cost for the prostheses was higher in the early loading group with six prostheses being remade as a

result of implant losses (n = 4) and unacceptable fit (n = 2), and another four prostheses having the base of the prosthesis adjusted in the dental laboratory as a result of soft tissue shrinkage.

Because of lack of randomization in the present study, the two patient populations were probably different because of subjective allocation. This is to say that patients allocated to the early loading group may have been healthier and subject to fewer conditions which may prejudice osseointegration, such as having undergone radiation therapy, bruxism, and diabetes. A proper randomization and only experienced surgeons performing implant placement might have allowed a stronger difference between the groups to be observed.

CONCLUSIONS

Within the limitations of this study, the following conclusions can be made:

- 1. Acceptable clinical results can be achieved with early loading of ISP in the mandible with implant survival rates of 94.4%, when risk patients are excluded.
- The frequency of biological and mechanical complications was higher in the early loading group than in the delayed loading group, resulting in a higher mean prosthetic cost for prostheses fabricated according to early loading.
- 3. Patients treated according to the early loading concept were more satisfied than those treated according to the original protocol.
- 4. No differences were seen between the different implant systems.

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