Early Loading of Implants with Fixed Dental Prostheses in Edentulous Mandibles: 7.2-Year Clinical Results from a Prospective Study

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ABSTRACT

Purpose: The purpose of this prospective follow-up study was to evaluate survival and success of early-loaded implants placed in the edentulous mandible and the survival of the fixed dental prostheses (FDPs) after in mean 7.2 years.

Materials and Methods: Thirty-seven patients (mean age 64.5 years, 18.9% male) received 185 implants in the intraforaminal area of the edentulous mandible (five implants per patient). Within 2 weeks, all implants were early loaded with fixed dental prostheses. The patients were recalled once a year for clinical and radiographic examinations. The 17 patients (79 implants) attending the recall in 2012 were additionally asked for their satisfaction of functional and aesthetic aspects.

Results: During a mean observation time of 7.2 years, 20 implants were lost in 11 patients, resulting in implant survival of 89.2%. Eight of all implants (4.3%) had too much marginal bone loss to satisfy the criteria of success. A total of 19 prosthetic complications and aftercare measurements had to be performed between in mean 4.5 to 7.2 years of observation. The survival of the original FDPs decreased to 83.8%. Of the 17 patients attending the recall in 2012, a total 59.5% had a satisfactory oral hygiene. According to the criteria of Albrektsson, the success rate for the remaining 79 implants was 89.9% after in mean 11.7 years. Patient satisfaction for assessment of functional and aesthetic aspects was in median 9 and 8 on the numeric rating scales.

Conclusion: Long-term observation of in mean 7.2 years showed satisfactory results for both implant and superstructure survival. Prosthetic complications were easy to repair in most cases, but patients' ability for oral hygiene was reduced after the longer observation period. Especially in elderly patients, their attitudes and manual skills should be considered when planning the design of a new superstructure.

KEY WORDS: early loading, edentulous mandible, fixed dental prosthesis, implant, survival

INTRODUCTION

Modern dentistry allows patients being edentulous in the mandible to be rehabilitated by a various number of surgical and prosthetic procedures. Minimal concepts on one or two implants[1–4] are established as well as extensive concepts on four or more implants, used both for removable or fixed superstructures.[5,6] Besides the prosthetic procedure, the loading protocol is of interest for both dentist and patient, because immediate or early load a few days after implant insertion reduces the amount of chairtime and therefore both physical and financial strains of the patient.[7–9]

Short-term results of early-loaded implants with fixed dental prostheses in the edentulous mandible have

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already been published by many authors,[10,11] and a few studies on long-term implant survival and success also exist.[12–15] Implant survival rates between 85 and 98% after up to 15 or 20 years are considered acceptable to satisfactory. However, the amount of aftercare and repair concerning the superstructure of those fixed treatment concepts on implants after a longer wearing period is rarely described in the literature yet. Furthermore, only a few information about the patients' satisfaction and ability to handle or clean both superstructure and implants after a long wearing period exist yet. This is especially important because patients with edentulous mandibles are generally older, might have a reduced general condition, and may increasingly have problems to clean fixed restorations.

The aim of this prospective study on 37 patients with 185 implants was to examine the survival and success rates of early-loaded implants placed in the interforaminal area of the edentulous mandible supporting fixed dental prostheses. The short-term results of in mean 4.5 years had resulted in implant survival of 89.7% and success of 84.9%. Denture-related complications consisted of one complete failure (the fixed dental prosthesis [FDP] had to be removed after all five implants had been replaced), 10 framework fractures, three extended superstructure modifications after implant loss, and 16 repairs of the facing of the FDP.[16]

Although one-stage early-loaded implants functioned well for most patients with edentulous mandibles, this procedure after in mean 4.5 years was associated with a large number of implant- and superstructure-related complications. Long-term results showing the development of both dentures and implants after more years in service therefore are of high interest.

Primary focus of this in mean 7.2-year long-term follow-up was set on prosthetic complications depending on the amount of aftercare or repair. The patients attending the recall in 2012 were also asked for their satisfaction and assessment of functional and aesthetic aspects and if they would have chosen the same procedure again. Furthermore, plaque accumulation and soft tissue reactions were measured by the oral indices of Gingiva Index (GI) and Plaque Index (PI) to evaluate the clinical parameters and the patients' oral hygiene performance. Implant survival as well as marginal bone-level changes and implant success, according to the Albrektsson criteria of success,[17] were also evaluated.

MATERIAL AND METHODS

Participants

In this prospective clinical trial participated by 37 patients (mean age 64.5 years at time of implant placement, 18.9% male) of the Dental School of the University of Heidelberg with edentulous mandibles who felt uncomfortable with their dentures and who fulfilled the inclusion criteria. The inclusion criteria consisted of being edentulous in the mandible, having adequate bone dimension of the intermentonian region, and giving informed consent for participation. Exclusion criteria were drug or alcohol abuse, uncontrolled diabetes, metabolic disorders, hemophilia, and pregnancy at the time of implant placement. The study was approved by the ethical committee of the University of Heidelberg (265/99). Patients received detailed information about the procedures used and were required to sign an informed consent form before participation. The results of this study within in mean 4.5 years of service were published by the authors in 2010.

Technical Procedure

Each recruited patient who fulfilled the inclusion criteria between 1999 and 2002 received five FRIALOC System implants (transgingival screw implants, FRIADENT GmbH, Mannheim, Germany), according to the manufacturers guidelines, whereas the choice of diameter and length of the inserted implants depended on bone dimensions. All surgery was performed by one experienced dental surgeon only.

Within 2 weeks after implant insertion all implants were loaded with an FDP (Figure 1). The FDPs had artificial teeth including the second bicuspid or the first molars (shortened dental arch), with a limit for the cantilever of no more than 1 cm distal to the most distal implant. Passive fit of the framework was secured for all suprastructures. In accordance to the maxillary dentition, the occlusal concepts of the canine guidance (upper jaw with fixed dentures or partial removable denture) or the bilateral balanced occlusion (upper jaw with complete denture) were realized.

In case of loss of more than two implants and subsequent reoperation, the respective patients were excluded from further participation. However, the data of these patients remained in the statistical analysis.

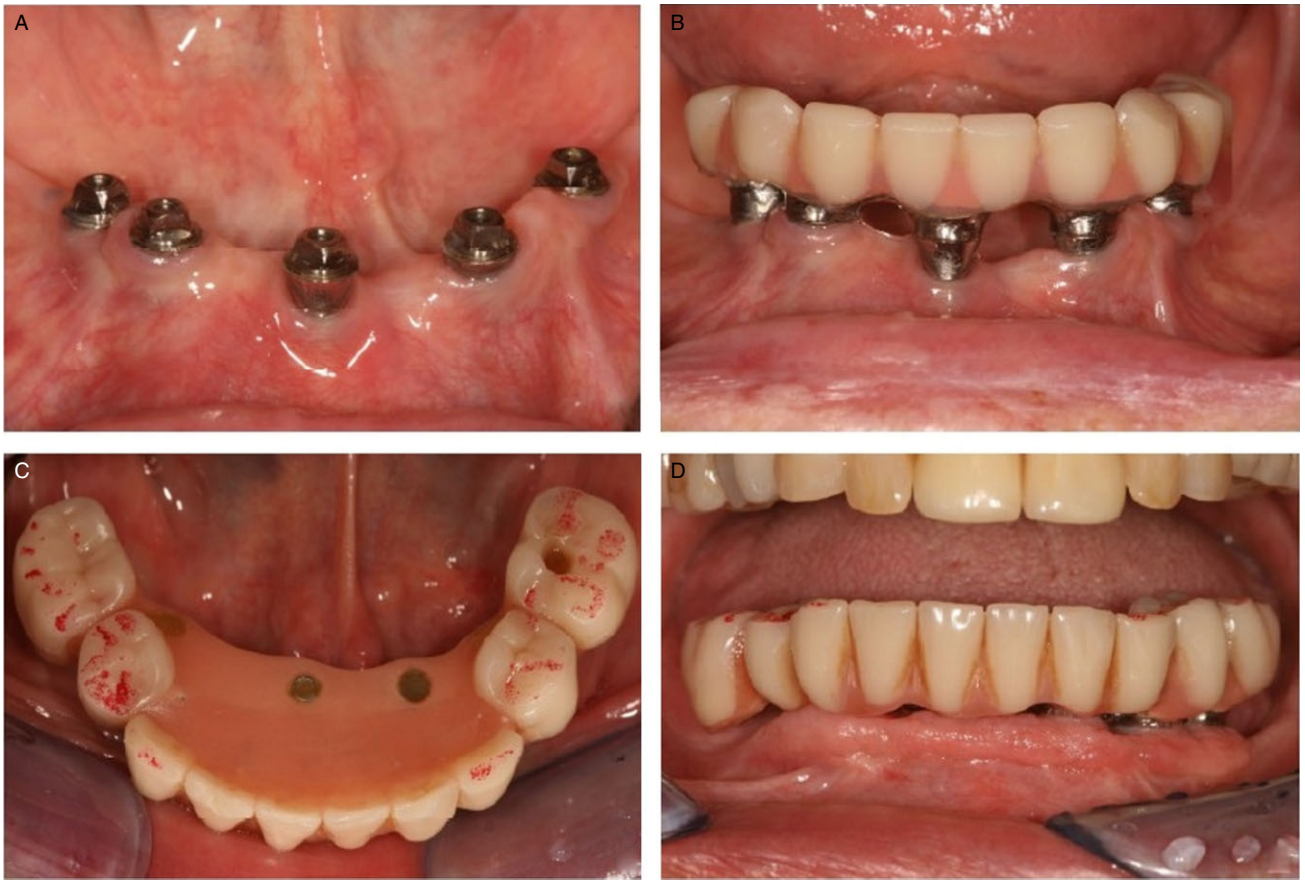

Figure 1 View on two complication-free FDPs after 12 (A + B) and 13 (C + D) years of function.

Follow-Up Examinations

At time of the first analysis published in 2010, a total of 25 patients with 126 implants were still under evaluation. Of these 25 patients, a total of 17 patients (45.9% of all patients) with 79 implants could be examined until 2012, whereas eight patients were lost to follow-up: four patients could not attend the examination because of serious illness and four patients denied consulting the clinic again for follow-up (Table 1).

The follow-up examinations included complete unscrewing and clinical inspection of the implants and the FDP. The torque used to screw the FDP into the implants was 25 Ncm. On a standardized documentation form, loss of implants and implant mobility were recorded, as also were fractures of the framework and the facing. The oral indices GI (scale 0–3) and PI (scale 0–3) were measured on the buccal, mesial, distal, and lingual faces of each implant, whereas the highest score per implant was counted. Patients, who attended the recall in 2012, were also asked to assess satisfaction concerning function and aesthetic of their FDP on a standardized questionnaire with a numeric rating scale (0–10; 0 = minimum, 10 = maximum). Furthermore, these patients were asked whether they would have chosen the same treatment again, knowing what this consists of.

After the first 5 years with yearly intervals, radiographic examinations (panoramic X-ray) were then performed at least at 2-year intervals. Of the patients attending the recall in 2012, the Albrektsson criteria of implant success were determined. Thereafter, an implant is defined to be successful, when the marginal bone loss is maximum 1 mm within the first year after insertion of the superstructure and not greater than 0.2 mm in each subsequent year of function. Using these criteria, crestal bone loss should not exceed 2.8 mm after 10 years in service and 3.4 mm after up to 13 years. For each patient of the study, the distance between the implant apex and the last visible bone implant contact was measured in millimeters at the distal and mesial aspect of each implant on the panoramic X-ray. This score was subtracted from the total implant length minus the polished

TABLE 1 Overview of Patients and Implants under Observation up to 14 years

Time Interval (Years)	Patients at Start of Interval	Number of Implants at Start of Interval	Implant Failures during Interval	Implant Dropouts during Interval (Death of Patient)	Unaccounted for Implants during Interval	Implants with Marginal Bone Loss* (Not Excluded) during Interval
0–1	37	185	18	5	12	2
1–2	31	150	1	0	9	
2–3	29	144	0	0	4	
3–4	28	140	0	5	5	
4–5	26	131	0	0	5	1
5–6	25	126	0	0	15	1
6–7	22	106	0	0	15	
7–8	19	91	0	0	5	
8–9	18	86	1	0	0	
9–10	18	85	0	0	0	2
10–11	18	85†	0	0	0	1
11–12	15	71†	0	0	0	1
12–13	9	43†	0	0	0	
13–14	2	10†	0	0	0	
Total			20	10	145	8

*Too much bone loss according to the criteria of Albrektsson.
†Different observation times result in different numbers of patients under recall at the respective times (implants inserted between 1999 and 2002).

implant shoulder (known length 4 mm). To correct dimensional distortion, the apparent dimension of each implant was measured mesial and distal on the radiograph and was compared with the known implant size. To avoid bias of overestimation, all radiographs were analyzed by one examiner, who was not involved in the study.

Statistical Procedures

All data were analyzed with SPSS 19.0 (SPSS Inc., Chicago, IL, USA). The probability of implant survival including all 37 patients with 185 implants was estimated by using a Kaplan–Meier survival curve. Complications and aftercare measurements of all 37 FDPs, as well as clinical parameters (GI and PI), radiographic examination of bone loss and patients' assessment of function and aesthetic of the 17 patients with 79 implants at the recall in 2012, were depicted graphically.

RESULTS

During the observation period of in mean 7.2 years, only one more implant of in total 185, which did not osseointegrate but had remained in situ because stability within the connective tissue was acceptable and inflammation was absent, was removed after 8.5 years in service because of increasing mobility and inflammation. Implant survival therefore decreased to 89.2% (a total of 20 implants failed) after in mean 7.2 years of observation (Figure 2). Furthermore, a total of eight implants had too much marginal bone loss compared with the

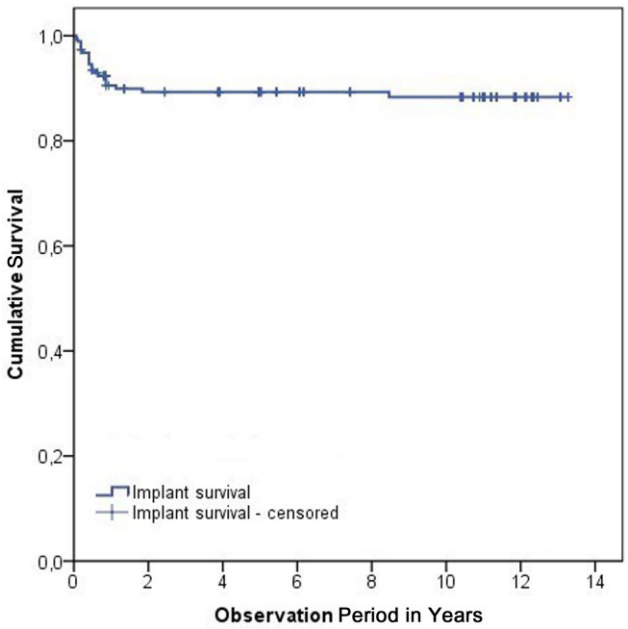

Figure 2 Kaplan–Meier survival curve of the implants.

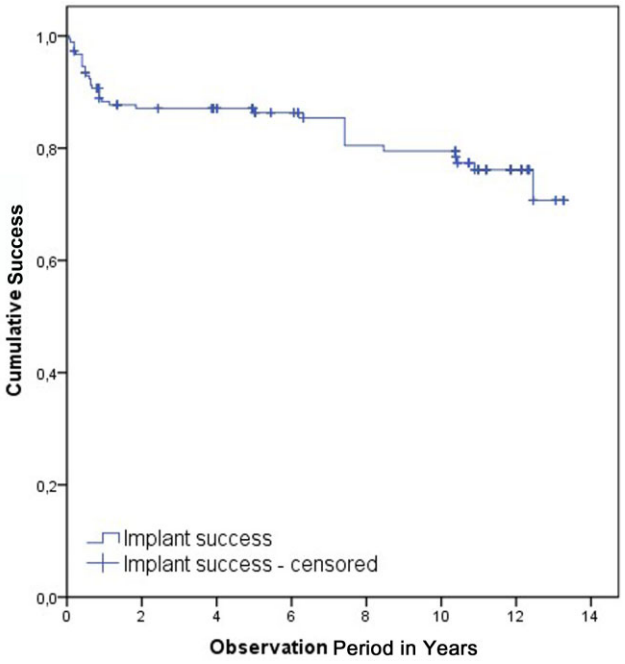

Figure 3 Kaplan–Meier success curve of the implants.

criteria of success (4.3% of all implants). Estimated cumulative success was 86.3% after 5 years and 79.5% after 10 years (Figure 3).

During the observation period of in mean 4.5 years to in mean 7.2 years, a total of 19 additional prosthetic complication and aftercare measures had to be performed, thereof one more fracture of the framework and twice the renewing of the complete superstructure on patients' wish (Table 2, Figure 4). The survival rate of the 37 original FDPs after in mean 7.2 years of service therefore decreased from 89.2% to 83.8%.

The results of the clinical examination of the 17 patients with 79 implants attending the recall in 2012 are listed in Table 3. Thereof, 47 of the implants had a satisfactory oral hygiene (score 0 and 1 on PI scale) and the incidence of bleeding in the soft tissue around the implant on at least one site was 59.5% (score 1–3 on GI scale).

TABLE 3 Plaque Index (PI) and Gingiva Index (GI) of the Implants at the Recall in 2012

Score on Scale	Number of Implants for PI	Number of Implants for GI
0	16	32
1	31	28
2	28	19
3	4	0
Total	79	79

The radiographic evaluation of the 79 implants according to the criteria of Albrektsson revealed a success rate of 89.9% after 10–13 years (mean 11.7 years, SD 0.9); the marginal bone loss of the eight implants was 3.2 to 4.5 mm (Figure 5).

The results of patient satisfaction for assessment of functional and aesthetic aspects ranged from 5 to 10 on the numeric rating scales and are pictured in Table 4. A total of 12 patients declared that they would have chosen the same procedure again. The other five patients would have preferred removable superstructures afterward because of problems with their oral hygiene (four patients) or problems with chewing because of the shortened dental arch (one patient).

DISCUSSION

In the literature, early loading of dental implants is known to be a desirable treatment option with survival

TABLE 2 Description of All Prosthetic Complications and Performed Aftercare during the Observation Period of in Mean 7.2 Years (Additional Complications Compared to in Mean 4.5 Years Are Highlighted in Bold)

Kind of Complication and Aftercare	Number until 2010 (Mean 4.5 years)	Number until 2012 (Mean 7.2 years)
Loss of superstructure after implant failure	1	1
Major rework of the framework after reimplantation	3	3
Fracture of the superstructure framework or saddle	10	**11**
Renewing of the superstructure on patients wish	0	**2**
Chipping or fracture of acrylic	16	**25**
Change of all acrylic teeth and facings	1	**5**
Changing of the fixing screws	0	**3**
Total number of complications	31	50

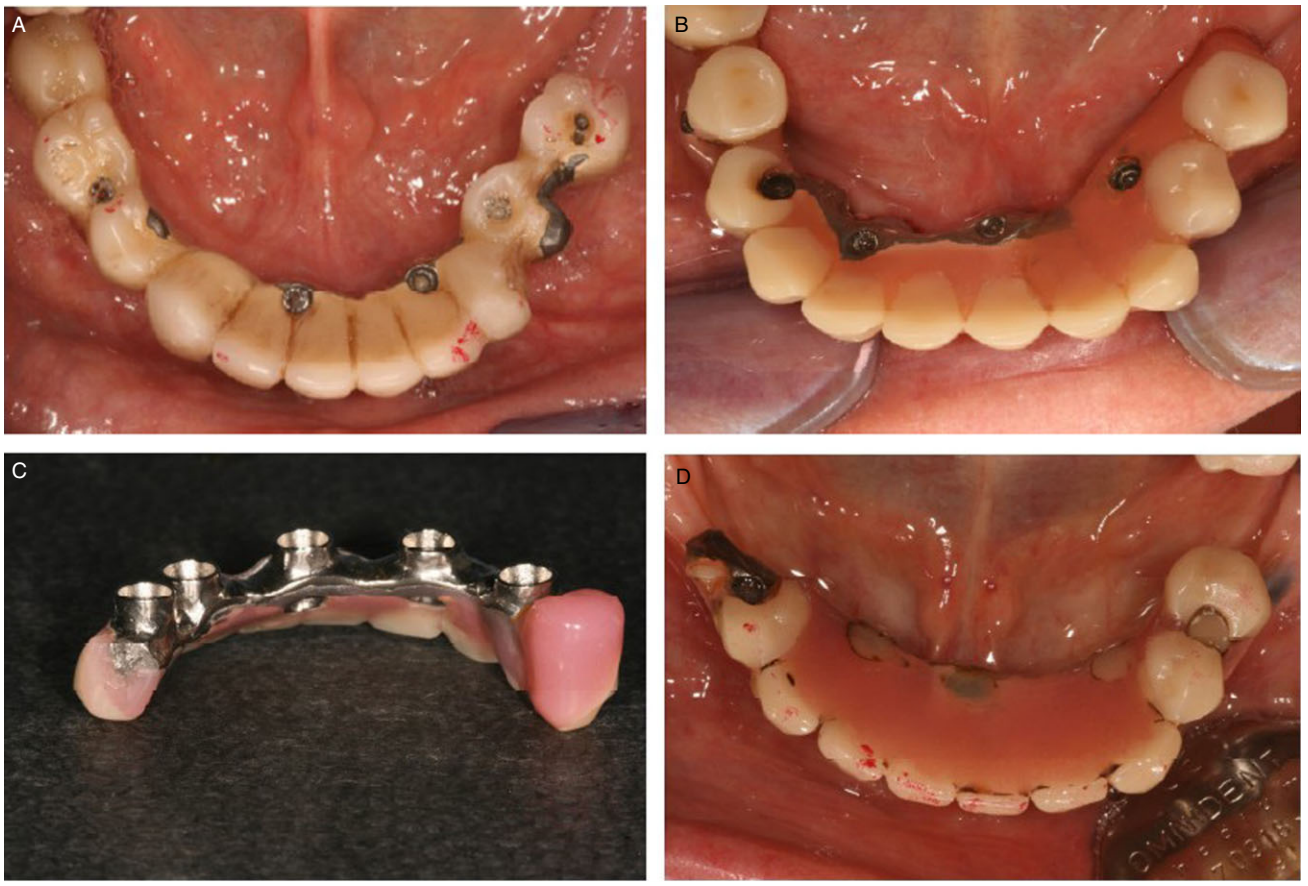

Figure 4 Complications occurred during the observation period of in mean 7.2 years. (A) Fracture of the acrylic. (B) Massive abrasion of the acrylic teeth after 12 years of function. (C) Framework fracture. (D) Fracture of the acrylic.

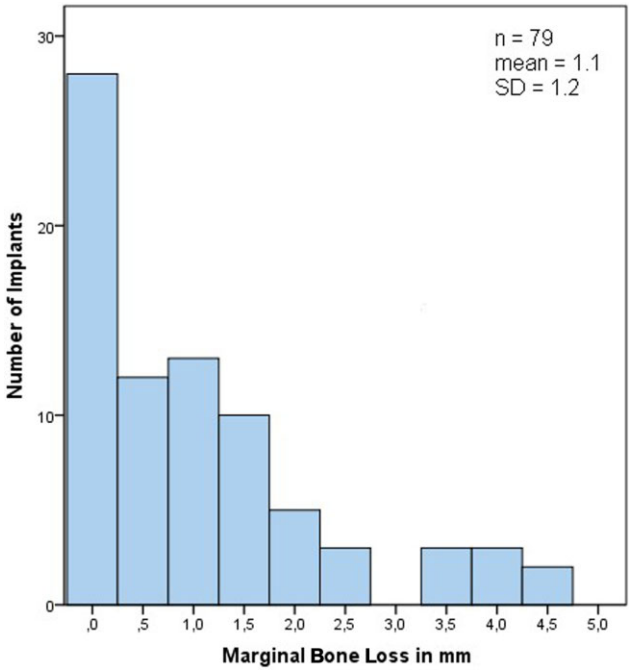

Figure 5 Marginal bone loss of the implants at the recall in 2012.

rates between 90 and 100% after 4 to 5 years.[18,19] The short-term results of this prospective study with implant survival of 89.7% are on the lower bound of this interval, what may be resulted from counting among the absolute complications implants without osseointegration that were clinical stable and free of inflammation and therefore not explanted. A total of 18 of these failures (94.7%) had occurred within the first 10 months after implant insertions; only one further implant had

TABLE 4 Patient Satisfaction Assessment of Functional and Aesthetic Aspects on Numeric Rating Scales (0–10; 0 = Minimum and 10 = Maximum) at the Recall in 2012

Parameter	Minimum	Maximum	Median	Standard Deviation
Aesthetic	5	10	8	1.579
Function	5	10	9	1.583

failed during the observation period of in mean 4.5 to 7.2 years.

Because most of the failures occurred during the implant healing period and the long-term results seem to be very stable, it may be concluded that once osseointegration was successful, the survival rates of early-loaded implants supporting FDPs are comparable with conventional loading protocols – a result that is in accordance to the literature.[20–22]

Furthermore, the implant success rates of the patients attending the recall in 2012 were satisfactory; only 10.1% of the 79 implants failed to meet the Albrektsson criteria of success. However, the number of unaccounted implants after the long observation period – only 42.7% of the implants could be examined until 2012 – is a considerable limitation for the generalizability of the results that should be interpreted with caution.

Besides implant survival and success, the prosthetic complications and necessary aftercare measurements are a major concern in daily practice. During the longer observation period in this study, the prosthetic complications (e.g., chipping of acrylic teeth and abrasions or changing of acrylic teeth) were mostly wear and resin related and therefore easily repairable without entailing high costs. Only one more fracture of a framework occurred. The results are comparable with those from the literature.[23,24] Eliasson in 2009 compared clinical outcome and patient satisfaction of early and delayed loading with FDPs in 109 patients with 490 implants. FDP cumulative survival rates after in mean 3.5 years in service were 92.5% for early loading and 98% for delayed loading. With early loading, significantly more prostheses needed adjustment.[25] In this prospective clinical trial, the superstructure survival rates were 89.2% after in mean 4.5 years and 83.8% after in mean 7.2 years. Both superstructures that were remade between 2010 and 2012 had not failed but were renewed on patient wish. Furthermore, both patients wished removable dentures in the future.

A within-subject comparison of fixed and removable implant supported prostheses that examined patient satisfaction and choice of prosthesis showed that significantly more patients (69.2%) after 2 months wearing of each superstructure chose the removable denture instead of the fixed one.[26] However, all of these dentures were fabricated in the maxilla, so the results are comparable with a limited extend only. Another randomized within-subject crossover study examining mandibular long-bar overdentures versus fixed dentures found no significant difference in patient satisfaction or denture choice.[27] Eight patients chose the fixed denture, and seven patients chose the removable denture. Both groups assessed chewing ability and stability to be better for the fixed denture, but the ease of cleaning of the removable denture for seven patients was the most important factor in their decision. There was also a tendency that older patients (50+) more often chose the removable denture.[28]

This tendency is underlined also by the results of our 2012 questionnaire, where the patients (mean age 74.4 years at time of the recall) attending the recall were asked whether they would have chosen the same procedure again, knowing what it in particular consists of. A total of 29.4% of these 17 patients would not choose FDPs again. Problems with oral hygiene were the most common reasons.

The results of the clinical examination confirm this patient assessment, as only 47 of the implants (59.5%) had a satisfactory oral hygiene, and the incidence of bleeding in the soft tissue around the implant on at least one site was 59.5%. Nevertheless, the scores concerning satisfaction with function and aesthetic were very high (median 9 and 8). One reason might be the discount the patients received for participating in this study.

All radiologic examinations in this study were performed by using panoramic X-ray studies. To limit magnification and distortion and to improve standardization intraoral radiographs with standardized beam direction, device today might be more precise. Panoramic radiographs are described to have poorer image resolution, unpredictable image distortion of bone adjacent to implants and reduced quality in anterior mandible resulting from overprojection of vertebra.[29] However, to correct dimensional distortion of the panoramic X-ray studies in this study, the apparent dimension of each implant was measured mesial and distal on the radiograph and was compared with the known implant size.

Strength of this study can be seen in the prospective study design. To achieve homogeneity of implant insertion, all surgery was performed by one experienced dental surgeon. Furthermore, only two dental technicians were involved in the fabrication of the FDPs, and all repairs and aftercare measurements were carried out in the same technical laboratory. However, the clinical working steps were performed by different dentists.

Nevertheless, important steps like fitting of the framework and monitoring of the vertical and horizontal relationship measurements were performed by one experienced dentist. Additionally, the follow-up examinations were done by dentists who were not involved in the study, and all patients attending the recall in 2012 were examined by one independent dentist only.

CONCLUSION

The long-term results (in mean 7.2 years) after early loading of implants with FDPs in the edentulous mandible are satisfactory concerning implant and superstructure survival. Prosthetic complications were resin related in most cases and therefore easily repairable. However, the clinical examination in 2012 showed higher rates of plaque and bleeding scores and the patients reported problems with dental hygiene. Individual patients' attitudes and manual skills should therefore be considered for the design of a superstructure, especially in elderly patients.

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