Immediate Loading of Two Dental Implants, in Edentulous Mandibles, with Locator® Attachments or Dolder® Bars: First Results from a Prospective Randomized Clinical Study

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[Correction made on November 19, 2013 after first online publication: "Attachments" added to title]

ABSTRACT

Objective: The study aims to evaluate survival and the incidence of complications for pairs of implants placed in the frontal area of edentulous mandibles and immediately loaded with either bar or Locator® (Zest Anchors LLC, Escondido, CA, USA) attachments.

Material and Methods: Forty-six patients (mean age 69.4 years; 73.9% male) with edentulous mandibles each received two immediately loaded implants in the interforaminal area of the symphysis. Immediately after implant placement, Dolder® bar (Sub-Tec Wirobond; BEGO Implant Systems GmbH & Co. KG, Bremen, Germany) or Locator® attachments, allocated randomly, were attached, and both clips and a framework were incorporated into the denture by the dental technician. The implants were loaded within 72 hours.

Results: During a mean observation period of 6 months (maximum 24 months, SD 0.43) eight implants in five patients were lost. Survival was 93.5% for the Locator® group and 89.1% for the bar group. Estimated cumulative survival after 1 year of function was 93.4% for the Locator® group and 87.1% for the bar group.

During the observation period, 12 prosthetic complications required aftercare. No superstructure was lost or had to be remade for prosthetic reasons, but five dentures had to be removed or reworked after implant failure. Survival of the original dentures was, therefore, 95.7% for the Locator® group and 93.5% for the bar group.

Conclusion: Within the limitations of this study, immediate loading of two implants in the edentulous mandible with either Locator® or bar attachments did hardly differ. Ease of repair and cleaning, in particular, might be arguments for choosing the single attachment system.

KEY WORDS: bars, edentulous mandible, immediate loading, implant, Locator®, overdentures, survival

INTRODUCTION

Demographic changes in Germany show an increasing number of elderly patients, often in poor general condition and with low income and poor stamina. Edentulism is prevalent in this population group and often poses a major problem: despite wearing a complete denture, those patients have diminished oral functional capacity. Their oral health-related quality of life is often low.[1] This is especially true in cases of progressed atrophy of bone, described as groups V-VI by Terry and Zarb.[2]

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Thus, the edentulous mandible is a common indication for implant insertion in dentistry. Depending on patients' wish, age, general constitution, and financial situation, treatment options vary from simple concepts on one or two implants supporting ball attachments, Locator® (Zest Anchors LLC, Escondido, CA, USA), or bars, to technically advanced concepts on four to eight implants supporting bars, fixed dental prostheses, or single crowns.[3–8]

According to the McGill consensus statement, the two-implant-supported mandibular overdenture is regarded as the "standard of care for the edentulous patient".[9] For conventional loading after a period of healing, different types of attachment on these two interforaminal implants have already been examined in prospective and retrospective clinical studies.[10–12] Primary splinting of the implants by use of bar systems or unsplinted designs, for example, ball attachments or Locator®, both result in high implant survival. A systematic review on whether or not to splint dental implants in the edentulous mandible concluded that survival and peri-implant outcome were no different for conventionally loaded implants with splinted or unsplinted overdenture designs. In the studies included in the review, however, the unsplinted attachment systems resulted in a greater incidence of prosthetic complications and aftercare measures.[13]

Immediate loading of dental implants is known to be a time and money-saving treatment option.[14–17] Second surgery for implant exposure is avoided and, because the impression is taken on the day of surgery, prosthetic treatment time is also reduced. Clinical studies of two immediately or early loaded implants in the interforaminal area supporting bars or ball attachments have revealed that implant survival is good.[18–23] However, only a few results are yet available on immediate[24] or early[25] loading of dental implants with unsplinted Locator® attachments.

The purpose of this prospective randomized clinical trial was to evaluate survival and incidence of complications for pairs of immediately loaded implants placed in the symphyseal area of the edentulous mandible and supporting primary splinted bars or unsplinted Locator® attachments. The null hypothesis was that survival of immediately loaded implants supporting Locator® attachments or bars is no different.

MATERIALS AND METHODS

Participants

Seventy-eight patients (mean age 73.4 years; 78.2% male) of the Dental School of the University of Heidelberg and other members of the community with edentulous mandibles, who felt uncomfortable with their dentures, were examined for participation in the study between 2010 and 2012 (Figure 1). The inclusion criteria were: edentulous mandible, adequate vertical and horizontal bone dimensions of the intermentonian region (vertically and horizontally at least 1 mm of bone around the implant), adequate bone quality for immediate loading, implant insertion torque of minimum 35 Ncm, and informed consent to participation. Exclusion criteria were: drug or alcohol abuse, inadequate vertical or horizontal bone dimensions or quality, insertion torque of less than 35 Ncm, pregnancy at the time of implant placement, and intravenous bisphosphonates in the last 10 years. The exclusion criteria did not include type of maxillary dentition (complete dentures or fixed or removable partial dentures). The study was approved by the ethics committee of the Medical Faculty of the University of Heidelberg (S-208/2010). Patients received detailed information about the procedures, risks, and alternatives, and were required to sign an informed consent form before participation.

Prosthetic Procedure Before Surgery

To achieve homogeneity, all patients recruited for the study initially received new complete dentures for the mandible. All clinical working steps were performed by two specialized dentists and all dentures were fabricated by the same two dental technicians in the same dental laboratory. Centric relation and bilateral balanced occlusion were achieved for all patients. The dentures were worn for 3 months to enable the patients to adapt.

Surgical Procedure

Panoramic X-rays (Orthophos Plus; Sirona GmbH, Bensheim, Germany) of the initial situation and with the drilling template inserted were acquired for all patients in order to plan the implant position in advance (Figure 2). To obtain a drilling template, the fabricated complete dentures were duplicated by the dental technician in transparent resin.

Surgery started with triangular incisions, with a trajectory over the alveolar crest, and incisions in the region

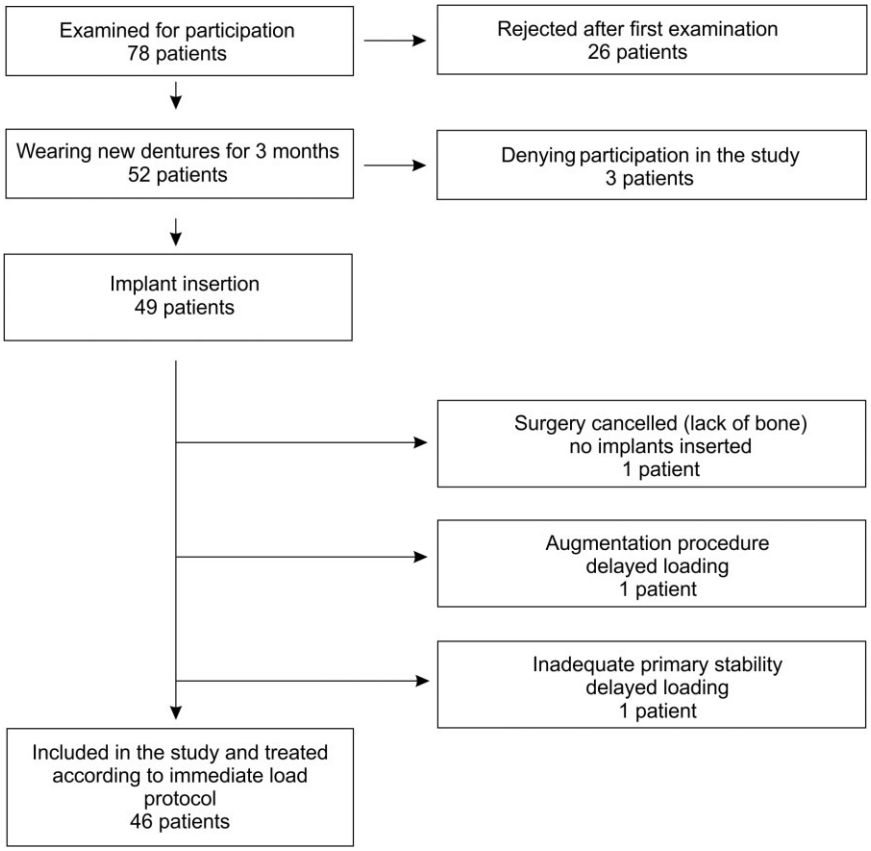

Figure 1 Study participant flow diagram.

of the second incisor on both sides. Raising of the mucoperiostal layers was followed by creation of notches in the region of the canines by use of tapered drills. The sequence required for preparation of the bone bed was completed by use of appropriate drills.

Each patient received two BEGO-System implants (BEGO Semados®; BEGO Implant Systems GmbH & Co.KG, Bremen, Germany). The length of all implants was 10 mm; choice of diameter depended on bone dimensions (3.75 mm or 4.1 mm; Table 1). The torque of each implant was monitored manually, the requirement was 35 Ncm. If one of the implants failed to achieve 35 Ncm, the treatment was changed to conventional loading and the patient was not included in the study. The flaps were sutured with Seralon 5/0 thread (Serag-Wiessner GmbH & Co.KG, Naila, Germany) for open healing of the implants. Radiographic monitoring of the implant position (panoramic X-ray) was performed directly after implant insertion. All surgery was performed by two calibrated dentists, who were instructed and trained in a standardized procedure by the implant manufacturer.

Prosthetic Procedure after Surgery

Special sealed and sequentially numbered envelopes containing the randomized allocation were prepared at

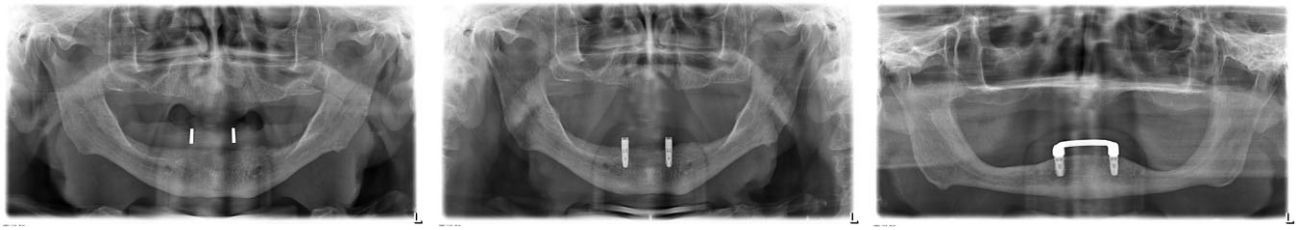

Figure 2 Panoramic X-rays with the drilling template, and after insertion of the Locator® or bar attachments.

TABLE 1 Baseline Characteristics of the 92 Immediately Loaded Implants Inserted in 46 Patients

Implant Diameter in mm	Locator® Group n	Bar Group n	Total Number of Implants
3.75	10	12	22
4.1	36	34	70

the beginning of the study by an external source. After the implants had been inserted with an insertion torque of at least 35 Ncm, the patients were allocated to one treatment group according to the content of the next in the sequence envelope. The prosthetic treatment started immediately after allocation. Thus, each patient participating in the study received either two Locator® attachments or an egg-shaped Dolder® bar (Sub-Tec Wirobond; BEGO Implant Systems GmbH & Co. KG).

Again, to achieve homogeneity within the two groups and to avoid chairside technical mistakes, all technical procedures, including fixing of clips in the dentures, were performed by the same dental technicians in the same dental laboratory.

Immediately after implant insertion, the Locator® attachments with the impression caps or the implant impression copings for the Dolder bar were inserted (Figure 3). The dentures were ground in the region of the implants, and the open-impression technique with polyether material (Impregum; 3M ESPE, Seefeld, Germany) was used for both groups. The polyether was left to set in maximum intercuspidation to secure the correct relationship with the maxillary dentition. After removal of the denture, healing caps were inserted in the bar group. In the Locator® group, the attachments tightened with a torque of 15 Ncm remained in situ and were not removed again.

The patients were reminded to abstain from use of any prosthesis in the mandible until insertion of the adapted denture. They were, furthermore, instructed to consume soft food and to rinse the mouth with a mild antibacterial rinsing solution without alcohol or chlorexidin (Meridol, GABA GmbH, Lörrach, Germany) at least three times a day and after food intake.

Within 72 hours, the dental technician fabricated the egg-shaped Dolder bar, and installed the Locator® matrixes or bar clips in the dentures. A metal framework was fabricated in all cases to improve the fracture resistance of the complete dentures (Figure 4).

On the day of prosthesis insertion, the adapted dentures of the Locator® group were directly clipped on to the Locator® attachments; blue inserts were used in all cases. In the Dolder bar group, first, the bars were tightened on to the implants, by use of a torque of 15 Ncm;

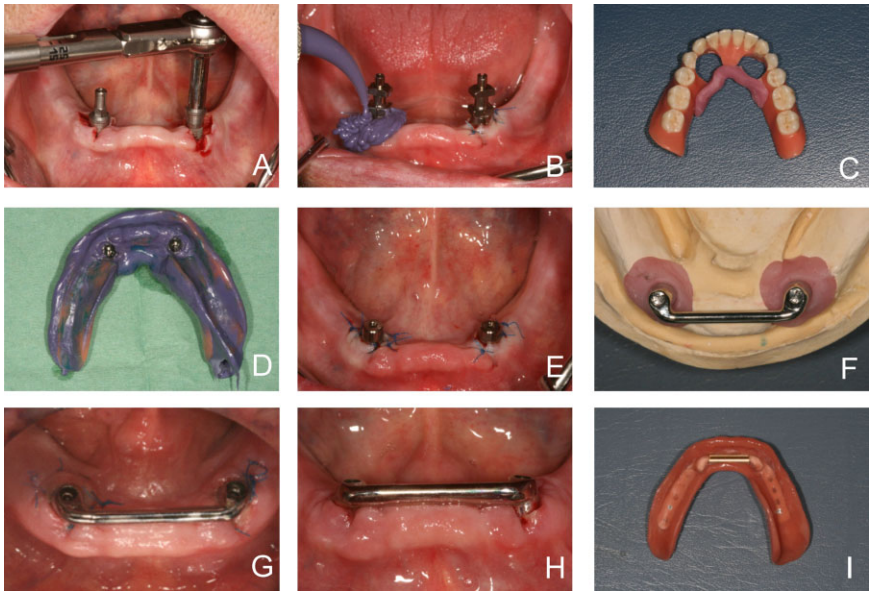

Figure 3 Clinical example of the prosthetic procedure in the bar group: implant insertion (A), the impression posts with polyether (B), complete denture ground in region of the implants (C), impression with denture (basal [D]), implants with healing caps (E), bar on the cast (F), bar placed on the implants (frontal [G] and occlusal [H]), denture with matrix and framework (basal [I]).

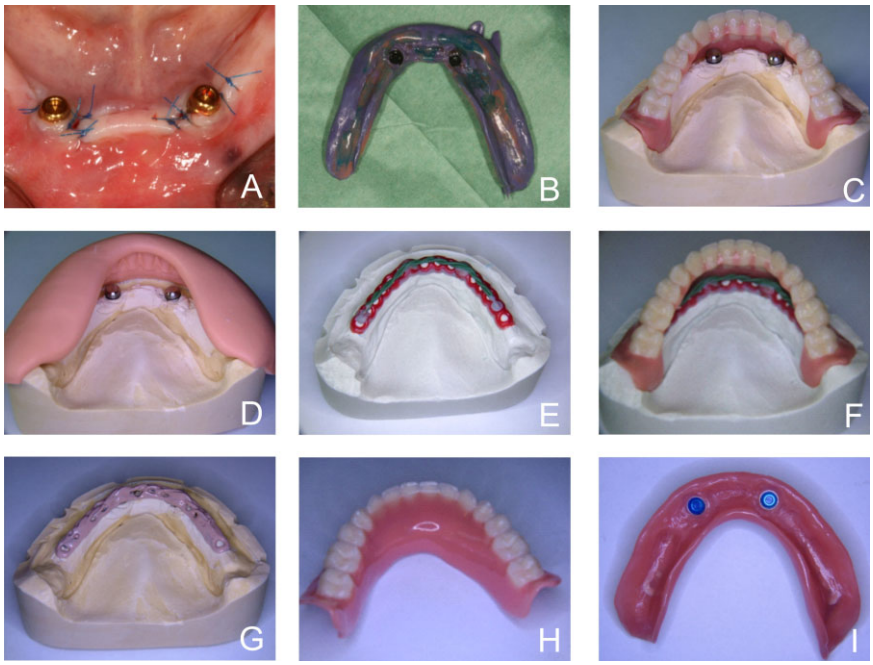

Figure 4 Clinical example of the prosthetic procedure in the Locator® group: Implants with Locator® attachments (A), polyether-impression with denture (basal [B]), grounded denture on the cast (C), silicon matrix (D), waxing of the framework (E), try on of the grounded denture on the framework (F), opaquer on metal framework (G), complete denture with framework and clips (occlusal [H] and basal [I]).

the dentures were then inserted. On the same day, an X-ray was taken to monitor the fit of the bars. The patients were instructed to consult the clinic in the event of any problems (possible pressure points) and to rinse the mouth with mild rinsing solution (Meridol, GABA GmbH) at least three times a day and after food intake. One week after surgery, the sutures were removed and the patients were advised to start brushing the Locator® attachments or the bar twice daily. The patients were instructed to consume soft food and not to wear the dentures at night for a further 6 weeks.

Follow-Up Examinations

Follow-up examinations were performed after 3, 6, 12, and 24 months. To identify real failure time, the patients were also asked to visit the clinic immediately after noticing any changes to the gingiva, the denture, or the implants. Radiographic examinations (panoramic X-ray) were performed after 6, 12, and 24 months.

The follow-up examinations included clinical inspection of the implants and the denture. Implant survival was defined on the basis of clinical stability and immobility, whether or not it was fully functional, whether light percussion resulted in no pain from the implant, healthy peri-implant soft tissue, and no radiolucency or other radiographic pathology conditions. Loss of implants and implant mobility were recorded on standardized documentation forms, as also were complications with the dentures.

The modified oral indices mGI (modified gingiva index, scale 0–3) and mPI (modified plaque index, scale 0–3)[26] were measured on the buccal, mesial, distal, and lingual sites of each implant; the highest score per implant was recorded. The patients were also asked whether they would recommend the treatment knowing what it entailed.

Loss of one or both implants was associated with end of study for the patient. When one implant was lost during the healing period, the attachment of the remaining implant was removed, a healing cap was placed, and the implant underwent the closed healing procedure. In all cases of implant loss within the healing period, the patients could receive up to two implants again after 3 months. The delayed loading protocol was performed then.

Statistical Procedures

All data were analyzed by use of SPSS 19.0 (SPSS Inc., Chicago, IL, USA). Power analysis revealed that to detect a difference in survival of 10% at a level of alpha = 0.05

and beta = 0.80, a total of 150 patients would be needed. This estimate was approximated in 2009, because, as far as the authors were aware at the time of study planning, prospective studies focusing on immediate loading of implants with Locator® attachments had not yet been reported. Preliminary analysis of the data was, therefore, planned after recruitment of one third of the total study population.

The probability of implant survival for all 46 patients with 92 immediately loaded implants was estimated by use of Kaplan–Meier survival curves plotted for both groups. Survival differences between the groups were estimated by use of the log-rank test. Because each patient had received two implants, and complications may not have been independent of the factor "patient," a nontime-dependent general estimation equation (binary logistic, with loss of implant, yes or no, as target variable) model was produced with age, gender, smoking (yes or no), diabetes (yes or no), implant diameter (3.75 or 4.1), and type of attachment (Locator® or Dolder bar) as independent factors/covariates. The probability level for statistical significance was set at alpha ≤0.05.

Prosthetic complications and aftercare measurements for all 46 dentures, and clinical data (mGI and mPI), were depicted graphically. Differences between mGI and mPI in both groups were compared by use of a *t*-test with a significance level of $p < .05$.

RESULTS

Of the 78 patients examined for the study, a total of 32 patients could not be included in the immediate loading study protocol: 26 patients were rejected in the initial clinical or radiographic examination as they did not have enough bone vertically or horizontally. Three patients refused implantation after receiving new complete dentures: two patients were satisfied with the fit of the new dentures and one patient cancelled further treatment because of bereavement in the family (Figure 1). Surgery was cancelled for one patient because of lack of bone (no implants could be inserted). All these patients received no implants within this study.

One other patient was excluded from the study because, during surgery, additional augmentation procedures became necessary, resulting in delayed loading. For another patient, because the insertion torque for one implant was less than 35 Ncm, loading was, again, delayed. Both patients were excluded from the study as it was not possible to adhere to the predetermined study protocol before their assignment to a study group. Therefore, they were not considered for further statistical assessment. The four implants with delayed loading osseointegrated and received the attachments the patients chose (once locator and once bar) after 3 months.

Forty-six patients (mean age 69.4 years; 73.9% male) with 92 implants were treated according to the immediate-loading study protocol. The main characteristics of the 46 patients who received two immediately loaded implants each are listed in Table 2. During a mean observation period of 6 months (min. 3 months, max. 24 months, SD 0.43), no complications were encountered for 84 implants in 41 patients. Eight implants in five patients were lost – five implants in three patients with bars and three implants in two patients with Locator® attachments. Survival was 93.5% for the Locator® group and 89.1% for the Dolder bar group (log-rank $p = 0.464$). All implants lost were removed within the first 3 months of observation. Estimated cumulative survival after 1 year of function was 93.4% for the Locator® group and 87.1% for the Dolder bar group (Figure 5). The factors age, gender, smoking, diabetes, implant diameter, or type of attachment had no statistically significant effect on the incidence of implant failure after immediate loading (Table 3).

During the mean observation period of 6 months, a total of 12 prosthetic complications occurred with the mandibular dentures and aftercare measures had to be performed: thereof one bar fractured and three changes were made to both bar and Locator® clips (Table 4). No superstructure was lost or had to be remade for prosthetic reasons. However, a total of five dentures had to be removed or adapted after implant failure. Nevertheless, all repairs were performed by the dental technician within 24 hours, so the immediate-loading protocol was not interrupted. Survival of the original dentures was, therefore, 95.7% for the Locator® group and 93.5% for the Dolder bar group.

The mPI and mGI results for the bar group were significantly higher than for the Locator® group (Table 5, $p < .001$ and $p < .001$). Twenty-three patients in the Locator® group and 22 in the bar group would recommend the treatment. One patient in the bar group was satisfied with the result but would not recommend the treatment of immediate loading because of the pain he had in the operated area.

TABLE 2 Baseline Characteristics of the 46 Patients Treated with Two Immediately Loaded Implants Each

Characteristic	Level	Total Number of Patients	Locator® Group	Bar Group
Age	Fewer than 60	9	3	6
	60–69	11	10	1
	70+	26	10	16
Gender	Female	12	9	3
	Male	34	14	20
Smoking (number of cigarettes)	No	38	18	20
	<10/day	2	1	1
	>10<20/day	3	1	2
	>20/day	3	3	0
Diabetes	No	34	18	16
	Type I	0	0	0
	Type II	12	5	7
Age of previous denture	<10 years	33	14	19
	≥10 years	13	9	4
Maxilla	Complete denture	42	22	20
	Removable partial denture	3	0	3
	Fixed dental prosthesis	1	1	0

DISCUSSION

Immediate loading of mandibular overdentures is clinically well documented but not scientifically validated.[27] Several studies have been conducted on immediately loaded bar-splinted implants, although, for most of these, three to five implants per patient were inserted. Survival in those studies varied between 80 and 100% after 1 to 8 years.[28,29] Stoker and Wismeijer treated 124 patients, each with two immediately loaded implants supporting an egg-shaped Dolder bar, and implant survival was 98.8% after 12 to 40 months of observation.[21] Stricker and colleagues reported 100% implant survival after 2 years for 10 patients with bar connectors on two implants.[18] Attard and colleagues treated patients with both immediately loaded and conventionally loaded implants supporting resilient bar mechanisms; implant success was 95% for both groups.[19]

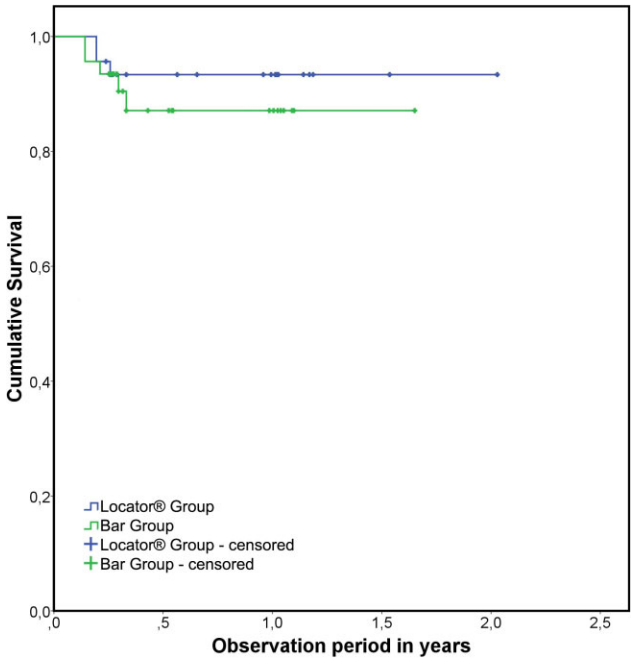

Figure 5 Kaplan–Meier curves for survival of implants in the Locator® and Dolder bar groups.

With survival of 89.3% after a mean observation time of 6 months, the results for the bar in this study are comparable with literature results for three to five implants but at the lower end of the scale for two-implant-supported dentures. One reason might be the inclusion of smokers ($n = 9$) and diabetics ($n = 12$) in this study, although no significant effect on implant survival could be found for this sample size, leaving the suggestion unanswered.

As far as the authors are aware, only one prospective study has been conducted on immediate loading of implants with Locator® attachments. Thacker treated 14 patients with 28 implants supporting Locator®

TABLE 3 General Estimation Equation Model for the Dependent Variable "Loss of Implant" for the Attachment Groups "Locator®" or "Bar"

Factor	Exp (B)	Significance	95% Wald Confidence Interval	
			Minimum	Maximum
Age	0.110	0.059	−0.004	0.223
Gender				
Men	−0.051	0.973	−2.955	2.853
Women	1	—	—	—
Smoker				
No	1.501	0.226	−0.928	3.930
Yes	1	—	—	—
Diabetes				
No	−0.738	0.555	−3.192	1.715
Yes	1	—	—	—
Implant diameter				
3.75	0.814	0.691	−3.207	4.835
4.1	1	—	—	—
Type of attachment				
Locator®	1.139	0.345	−1.224	3.501
Bar	1	—	—	—

attachments, 10 with delayed loading and the remainder with immediate loading. Survival after 6 months was 100% for the delayed group and 87.5% for the immediate loading group.[24] The results of our study with 93.5% implant survival after in mean 6 months are slightly higher but comparable with the results of Thacker. Good clinical results have been reported for case series with conventional loading on Locator® attachments,[30] but no reliable survival data are available for immediately loaded Locator® attachments.

With survival of 93.5%, however, the results in this study are lower to those from conventional loading of implants by use of Locator® attachments[31] and to those from immediate implant loading by use of other attachments.[32] One reason might be the differences in sample size (only 10 patients in the study of El-Sheikh and colleagues) and the study protocol (ball attachments in the study of Büttel and colleagues). It can be assumed that the two unsplinted attachment designs of balls and Locator® are, because of the different retention

TABLE 4 Description of all Prosthetic Complications, and Aftercare Performed, for the 46 Patients with Immediate Loading during the Mean Observation Period of 6 Months for the Locator® and Dolder Bar Groups

Kind of Complication and Aftercare	Locator® Group	Bar Group
Fracture of Locator® or bar	0	1
Refixing of the retention clips	1	1
Change or activation of the clips	3	3
Relining of mandibular denture	1	2
Total number of mandibular prosthetic complications and aftercare	5	7
Relining of maxillary denture	5	5

TABLE 5 Modified Plaque Index (mPI) and Modified Gingiva Index (mGI) for All Immediately Loaded Implants in the Locator® and Dolder Bar Groups

Score on Scale	Number of Implants for mPI		Number of Implants for mGI	
	Locator® Group	Bar Group	Locator® Group	Bar Group
0	30	18	45	26
1	12	8	1	12
2	4	12	0	8
3	0	8	0	0
Score	20	56	1	28

mechanisms, comparable with a limited extent only. The differences in survival rates for such relative small samples could also be due to normal biological variability.

Prosthetic complications after the first few months of observation were rare in this study. In addition to dentures that had to be adapted after implant failure, one fracture of a bar occurred, refixing of the clips had to be performed twice, and the clips had to be changed or activated six times after up to 24 months of service. Taking into consideration that changing the clips because of poor retention can be regarded as a very small complication, taking only a few minutes of chair time, the results of our study are comparable with literature results.[28]

No fractures of the prostheses occurred during our study. Including a metal framework in the denture when incorporating retention attachments in edentulous mandibles might be a means of avoiding complications in such simple implant-supported treatment.

Ten maxillary dentures had to be relined during the observation period, because the patients reported lowering of prosthesis retention after fixation of the dentures to the implant in the mandible. Forty-five patients were, nevertheless, satisfied with their intraoral situation after implant insertion and would recommend the treatment.

In this study, mPI and mGI differed significantly between the groups; both scores were significantly higher in the bar group. The highest scores per implant in the bar group were for the lingual and approximal mesial sites of the implants, where the bar is connected to the implant cylinders. The ease of cleaning unsplinted attachments might be an advantage of this system, especially for elderly patients.

This study has some limitations. The number of patients included enables interpretation of the results with a statistical power of beta = 0.60. The length of the observation time (min. 3 months) is not consistent for all study participants as some have been observed for up to 2 years. This aspect should be taken into account when interpreting the results. A strength of the study is, nevertheless, its prospective, randomized design. All surgery, follow-up examinations, and technical working steps were, furthermore, each performed by two persons only. This led to high homogeneity in all parts of the study.

CONCLUSION

Within the limitations of this study, the outcome of immediate loading of two implants in the edentulous mandible, supporting either Dolder bars or Locator® attachments, did hardly differ regarding their short-term survival and patient satisfaction. Ease of repair and cleaning, in particular, might be arguments for choosing the single attachment system. Further randomized, prospective clinical trials achieving the sample size necessary for a higher level of beta are, however, needed to confirm this initial trend.

CONFLICT OF INTEREST AND FUNDING STATEMENT

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