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Survival and Complications of Single Dental Implants in the Edentulous Mandible Following Immediate or Delayed Loading: A Randomized Controlled Clinical Trial

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Abstract

It was the aim of this 24-mo randomized controlled clinical trial to investigate whether the survival of a single median implant placed in the edentulous mandible to retain a complete denture is not compromised by immediate loading. Secondary outcomes were differences in prosthetic complications between the loading principles. Each of the 158 patients who received an implant was randomly assigned to the immediate loading group (n = 81) or the delayed loading group (n = 77). Recall visits were performed 1 mo after implant placement (for only the delayed loading group) and 1, 4, 12, and 24 mo after implant loading. Nine implants failed in the immediate loading group, all within the first 3 mo of implant loading, and 1 implant failed in the delayed loading group prior to loading. Noninferiority of implant survival of the immediate loading group, as compared with the delayed loading group, could not be shown (P = 0.81). Consistent with this result, a secondary analysis with Fisher exact test revealed that the observed difference in implant survival between the treatment groups was indeed statistically significant (P = 0.019). The most frequent prosthetic complications and maintenance interventions in the mandible were retention adjustments, denture fractures, pressure sores, and matrix exchanges. There was only 1 statistically significant difference between the groups regarding the parameter "fracture of the denture base in the ball attachment area" (P = 0.007). The results indicate that immediate loading of a single implant in the edentulous mandible reveals inferior survival than that of delayed loading and therefore should be considered only in exceptional cases (German Clinical Trials Register: DRKS00003730).

Keywords: single mandibular implant, complete denture, prosthodontics, overdenture, dental implant, edentulism

Introduction

A single implant to retain a complete denture in the mandible was firstly introduced by Cordioli et al. in the 1990s (Cordioli 1993; Cordioli et al. 1997). In this first clinical trial, 21 patients received 1 mandibular midline implant that was used to retain an existing mandibular denture with an O-ring attachment. A submerged healing protocol was chosen, and implants were loaded 4 mo after implant placement. After 5 y of observation, all implants survived, and remarkable improvements of all parameters of oral comfort and prostheses function were observed. Since then, different clinical investigations with varying study designs have been conducted, mostly with a small number of participants over a short- to midterm observation period (Kern 2012; Passia and Kern 2014).

While 1 investigation followed a submerged healing protocol with late loading after 3 mo of healing (Krennmair and Ulm 2001), others chose a nonsubmerged healing protocol and loaded the implants from 7 d to 3 mo after implant placement (Gonda et al. 2010; Alsabeeha et al. 2011; Cheng et al. 2012; Grover et al. 2014; Bryant et al. 2015; Passia et al. 2015). The implant survival rates were overall high between 91.7% and 100%. Kronström et al. (2014) loaded the implants immediately at the day of implant placement. In this investigation, an

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implant survival rate of only 82% was obtained, with all implant failures occurring within the first 12 mo of observation (Kronström et al. 2010). Liddelow and Henry (2010) placed 7 implants with machined surfaces and 25 implants with oxidized surfaces and loaded them immediately at the day of implant placement. In the machined surface group, the failure rate was 37.5%, but all implants with oxidized surfaces survived during an observation period of 36 mo.

According to a consensus statement from 2009, the literature supports immediate loading of microroughened implants with fixed prostheses and overdentures in the edentulous mandible, with the understanding that this treatment is complex and can be considered for clinicians with the appropriated education, experience, and skill (Weber et al. 2009). Edentulous patients, who are often dissatisfied with their complete mandibular dentures (Fiske et al. 1998), might especially benefit from a direct loading protocol, which would finally lead to a shorter overall treatment time. They could benefit earlier from the advantages provided by the implant treatment (Cune et al. 2010; Oh et al. 2016).

In 2014, a consensus statement on loading protocols concluded that, due to a lack of research, immediate loading of a single implant in the edentulous mandible may not be indicated for the support/retention of overdentures (Gallucci et al. 2014). The influence of the loading protocol on the survival rate of a single mandibular implant in the edentulous mandible has never been investigated in a randomized clinical trial.

Therefore, the present multicenter randomized controlled clinical trial aimed to test the hypothesis that the prosthetic rehabilitation of the edentulous mandible with a single median implant and immediate loading will offer a noninferior implant survival rate as the rehabilitation with 1 implant and a second-stage surgery. The secondary aims were to assess differences in prosthetic complications and maintenance interventions between the study groups. Further secondary outcomes, not addressed in the article, were patients' denture satisfaction, chewing efficacy, oral health–related quality of life, and bone loss around the implant as well as in the posterior region of the mandible.

Materials and Methods

The Institutional Review Boards of all participating centers approved the study protocol of the present clinical trial. The study was registered at the German Clinical Trials Register (Deutsches Register Klinischer Studien, DRKS00003730). The clinical trial followed the CONSORT (Consolidated Standards of Reporting Trials) statement guidelines. Written informed consent was obtained from all participants prior to screening for possible inclusion. Experienced clinicians from 9 German university hospitals following previously defined standard operating procedures performed patients' treatments as well as all follow-up investigations. To avoid bias, each study center assigned 1 or 2 surgeons to carry out the treatment procedures and 1 or 2 investigators to perform the follow-up investigations.

The detailed study flow chart is shown in Figure 1. At baseline all patients answered a questionnaire where they reported on their smoking habits and were asked whether they were diabetic or not.

Implant placement was performed with local anesthesia. A crestal incision of 15 to 20 mm was chosen to elevate a full-thickness flap. If necessary, bone reduction was performed to allow placement of an implant with a diameter of 3.8 mm without bone augmentation. Finally, 163 patients received an implant with an air-abraded and acid-etched surface (3.8 × 11 mm, Promote Plus; Camlog Biotechnologies) in the midline of the edentulous mandible. A final insertion torque of at least 30 N cm and an implant stability quotient ≥60 were necessary before randomization. Patients whose implants did not fulfill these conditions were excluded from the study and treated according to a conventional delayed loading protocol. Finally, 158 patients were randomly assigned to the immediate loading group ($n = 81$) or the delayed loading group ($n = 77$) by opening a sealed envelope with the allocation. The trial statistician, using block randomization with a variable block size and an allocation ratio of 1:1, performed randomization centrally, which was stratified according to the patient's residual bone height (class II or III according to McGarry et al. 1999) as well as the study center. Due to the obvious differences between the treatment groups, neither the patient nor the surgeon could be blinded.

The existing mandibular dentures were connected to the implant with a ball attachment (Dalbo-Plus Elliptic; Cendres Métaux) at the day of implant surgery (immediate loading group) or 3 mo later at the day of second-stage surgery (delayed loading group). The matrices were integrated into the existing denture base intraorally with a self-curing bis-acrylate resin (LuxaPick-up; DMG). The multistage screening process with a detailed sample size calculation, the surgical approach, the randomization, and the prosthodontic procedure have been described in detail elsewhere (Passia et al. 2014; Mundt et al. 2017; Passia, Abou-Ayash, et al. 2017). Follow-up investigations were performed 1 mo after implant placement (for only the delayed loading group) and 1, 4, 12, and 24 mo after implant loading.

Peri-implant conditions (i.e., peri-implant probing depths and bleeding on probing; Cordaro et al. 2013) were recorded at 4 sides for each implant. The following parameters regarding prosthetic complications and maintenance interventions were recorded for the maxillary and mandible dentures: fracture of the denture base; in the mandible, the area of the fracture was recorded additionally (area of the ball attachment, fracture between the canines, or fracture between the canine and the distal margin of the denture base), number of relinings, pressure-sore at the denture base or the margin. For the mandible, the following parameters were additionally recorded: exchange of the ball attachment, exchange of the matrix, activation/adjustment of the matrix, and other complications.

Sample Size and Statistical Analysis

The primary endpoint of the study was the survival rate of the single median implant after 2 y. This is a binomial random variable, and the survival probability was assumed to be 97%

in both treatment groups. An inferiority of 7% of the survival rate in the direct loading group versus the conventional loading group was considered clinically tolerable due to the supposed advantages of an immediate loading, such as avoiding a second-stage surgery. Under these assumptions, a 1-sided test of binomial parameters at a 2.5% significance level has a power of 80% to reveal the noninferiority of the immediately loaded implant if the sample size is 148 (74 per group). Based on a loss-to-follow-up rate of approximately 20%, a total of 180 patients (90 per group) was considered necessary.

The statistical analysis was performed with the per-protocol set for the implant survival rates and the safety analysis set for prosthetic complications. Implant survival rates were estimated and provided with exact 1-sided 95% confidence intervals (95% CIs). In addition to the noninferiority analysis, a comparison of the 2 treatment groups with regard to implant survival was carried out with Fisher exact test. For the analysis of the prosthetic complications, Fisher exact test was used as well. SPSS Statistics 22 (IBM) and R 3.2.3 (R Foundation for Statistical Computing) was used for analysis.

Results

Between December 2012 and February 2014, 224 patients were screened for possible inclusion according to defined inclusion and exclusion criteria (Table 1). Fifty-five patients did not meet the criteria and were excluded. Another 6 patients were excluded before implant placement.

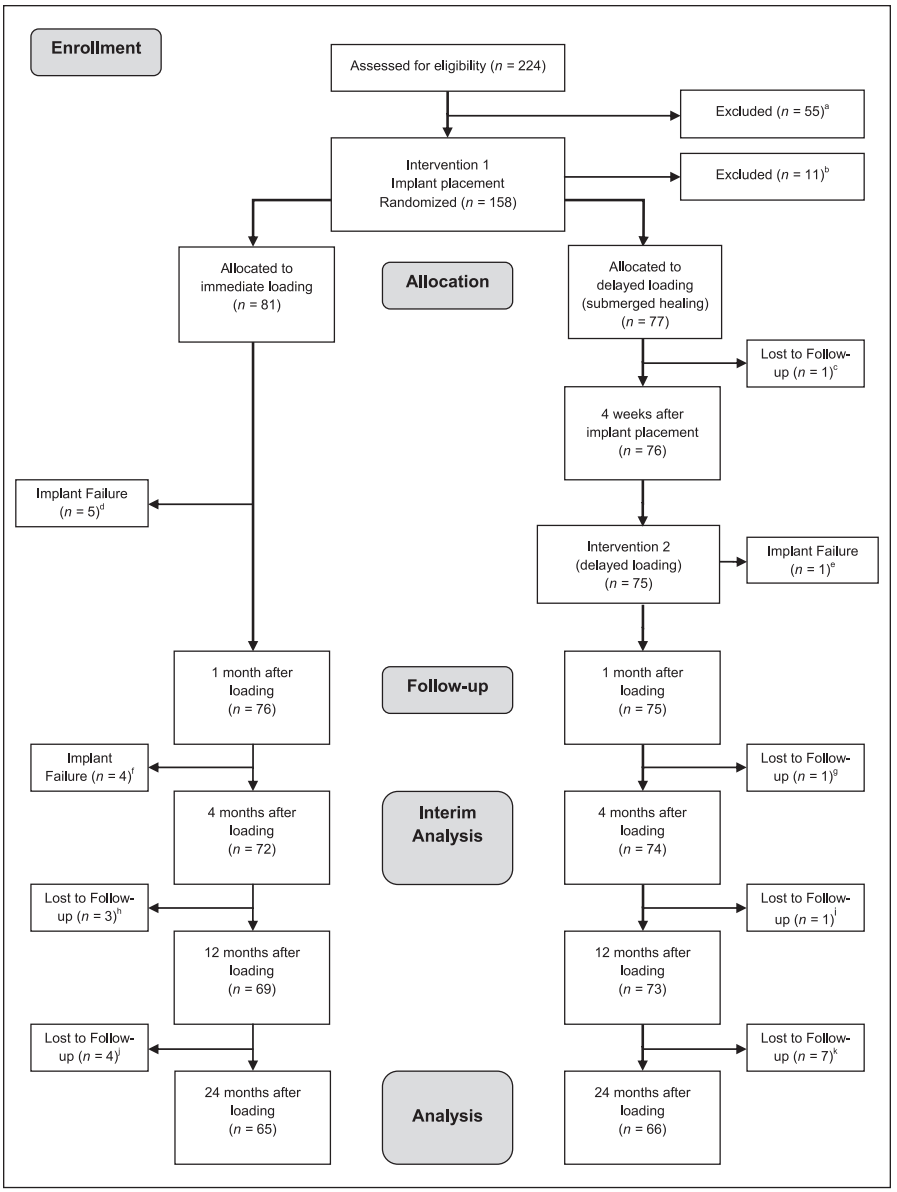

Figure 1. Study flowchart.
[a]Excluded prior to intervention 1 (*n* = 55)
• Ineligible by exclusion/inclusion criteria (*n* = 37)
• Lost to follow-up (*n* = 3)
• Noncompliance (*n* = 5)
• Medical contraindication (*n* = 2)
• Withdrawal of consent (*n* = 8)
[b]Excluded prior to implant placement (*n* = 6)
• Bone augmentation required (*n* = 5)
• Local anaestesia ineffectual (*n* = 1)
• Excluded after implant placement (*n* = 4)
• AE/SAE: Bone augmentation required (*n* = 1)
• Insufficient primary implant stability (*n* = 3)
• Excluded during randomization (*n* = 1)
• Excluded due to therapy error (*n* = 1)
[c]Lost to follow-up (*n* = 1)
• AE/SAE (except death or medical contraindication) (*n* = 1)
[d]Implant failure (*n* = 5)
[e]Implant failure (*n* = 1)
[f]Implant failure (*n* = 4)
[g]Lost to follow-up (*n* = 1)
• Lost to follow-up (*n* = 1)
[h]Lost to follow-up (*n* = 3)
• Lost to follow-up (*n* = 1)
• Death of patient (*n* = 2)
[i]Lost to follow-up (*n* = 1)
• Lost to follow-up (*n* = 1)
[j]Lost to follow-up (*n* = 4)
• AE/SAE (except death or medical contraindication) (*n* = 1)
• Lost to follow-up (*n* = 1)
• Death of patient (*n* = 2)
[k]Lost to follow-up (*n* = 7)
• AE/SAE (except death or medical contraindication) (*n* = 1)
• Lost to follow-up (*n* = 4)
• Death of patient (*n* = 2)

Table 1. Inclusion and Exclusion Criteria.

Inclusion Criteria	Exclusion Criteria
Provided written informed consent to participate in the clinical trial	Edentulous patients with contraindication for implant placement in the mandible caused by systematic diseases or local bone deficits
Edentulous male and female patients between 60 and 89 y with technically acceptable upper and lower complete dentures who were unsatisfied with the retention of their mandibular denture	Patients who were satisfied with the retention of their mandibular denture and/or were unsatisfied with the retention and/or stability of their denture in the maxilla
Existing dentures had been worn for at least 3 mo to allow adaptation.	Denture height between denture base and the denture tooth in the implant area was at least 6 mm
Residual bone height was 11 to 20 mm (class II and III according to McGarry et al. 1999) at the least vertical height of the mandible, and vertical bone height in the midline of the mandible was at least 13 mm	Subjects with Symptom Checklist–90 German version index T-scores ≥70 or with 2 symptom scale scores ≥70
Sufficient horizontal bone quantity in the anterior mandible to place an implant without lateral augmentation procedures	Signs for incompliance
Dentures with bilaterally balanced occlusion	Participation in a former clinical trial had not been finished for >2 wk

Table 2. Demographic Data between Immediate and Delayed Loading Groups.

	All Screened Patients[a]	Immediate Loading	Delayed Loading
n	224	74	67
Age, y			
Mean	69.8	70.5	68.8
Minimum	60.0	60.0	60.0
Maximum	89.0	84.0	85.0
Sex, *n* (%)			
Female	107 (47.8)	31 (41.9)	32 (47.8)
Male	117(52.2)	43 (58.1)	35 (52.2)
Diabetes, *n* (%)			
Type 1	4 (1.8)	3 (4.1)	1 (1.5)
Type 2	40 (17.9)	15 (20.3)	15 (22.4)
No diabetes	180 (80.4)	56 (75.7)	51 (76.1)

[a]All patients who were screened for possible inclusion in the study.

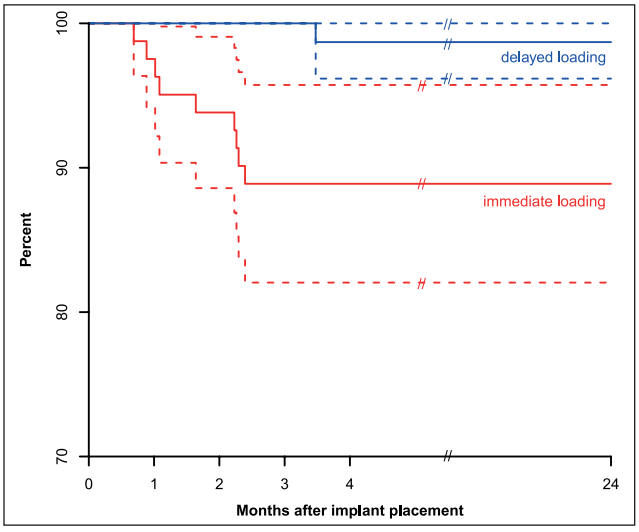

Figure 2. Implant survival rates. Dashed lines indicate 95% confidence intervals.

After 24 mo of observation, 65 patients from the immediate loading group and 66 patients from the delayed loading group attended the recall visit. The majority of the others had lost the implant, had died, or were lost to follow-up (Fig. 1). The demographic data of all patients who successfully underwent the 24-mo follow-up or lost an implant during the follow-up period are shown in Table 2.

Nine implants (12.2%, 1-sided 95% CI: 0.0% to 20.2%) failed in the immediate loading group and were removed. Of these, 5 implants failed during the first month of loading, while the other 4 failed within the next 2 mo. In the delayed loading group, 1 implant (1.5%, 1-sided 95% CI: 0.0% to 5.4%) had to be removed during second-stage surgery due to a lack of osseointegration (Fig. 2). No further implants failed within the 24-mo observation period with loading. Noninferiority of implant survival of the immediate loading group, as compared with the delayed loading group, could not be shown ($P = 0.81$). Consistent with this result, a secondary analysis with Fisher exact test revealed that the observed difference in implant survival between the treatment groups was indeed statistically significant ($P = 0.019$). Among the participants with implant loss in the immediate loading group, 2 were smokers (as were 14 others with no failure). Five patients with implant loss were assigned to McGarry type 2 and 4 patients to McGarry type 3. The patient from the delayed loading group whose implant failed was a smoker (as were 14 others with no failure) with diagnosed diabetes (as were 15 others with no failure); this patient was assigned to McGarry type 3.

Mean probing depths after 24 mo ranged from 2.37 mm to 2.74 mm for the immediate loading group and from 2.20 mm to 2.47 mm for the delayed loading group, with no statistically

Table 3. Prosthetic Complications and Maintenance Interventions between Immediate and Delayed Loading Groups.

Complications and Interventions[a]	All Screened Patients (N = 224)[b]	Immediate Loading (n = 81)	Delayed Loading (n = 77)
Maxilla			
Fracture of denture base, P = 0.24			
0	222 (99.1)	81 (100)	75 (97.4)
1	1 (0.4)	0 (0.0)	1 (1.3)
2	0 (0.0)	0 (0.0)	0 (0.0)
3	1 (0.4)	0 (0.0)	1 (1.3)
Relining, P = 0.89			
0	209 (93.3)	74 (91.4)	69 (89.6)
1	14 (6.3)	7 (8.6)	7 (9.1)
2	1 (0.4)	0 (0.0)	1 (1.3)
Pressure sore: basis, P = 0.5			
0	222 (99.1)	79 (97.5)	77 (100)
1	2 (0.9)	2 (2.5)	0 (0.0)
Pressure sore: margin			
0	224 (100)	81 (100)	77 (100)
Mandible			
Fracture, area of ball attachment, P = 0.007			
0	197 (87.9)	64 (79.0)	67 (87.0)
1	23 (10.3)	17 (21.0)	6 (7.8)
2	4 (1.8)	0 (0.0)	4 (5.2)
Fracture, area between the canines, not affecting the ball attachment, P = 0.42			
0	213 (95.1)	77 (95.1)	70 (90.9)
1	7 (3.1)	2 (2.5)	5 (6.5)
2	3 (1.3)	1 (1.2)	2 (2.6)
3	1 (0.4)	1 (1.2)	0 (0.0)
Fracture between the canine and the distal margin of the denture base, P = 0.49			
0	223 (99.6)	81 (100)	76 (98.7)
1	0 (0.0)	0 (0.0)	0 (0.0)
2	1 (0.4)	0 (0.0)	1 (1.3)
Relining, P = 0.62			
0	191 (85.3)	61 (75.3)	64 (83.1)
1	21 (9.4)	12 (14.8)	9 (11.7)
2	9 (4.0)	6 (7.4)	3 (3.9)
3	3 (1.3)	2 (2.5)	1 (1.3)
Pressure sore: basis, P = 0.19			
0	193 (86.2)	67 (82.7)	60 (77.9)
1	25 (11.2)	10 (12.3)	15 (19.5)
2	3 (1.3)	1 (1.2)	2 (2.6)
3	3 (1.3)	3 (3.7)	0 (0.0)
Pressure sore: margin, P = 0.61			
0	185 (82.6)	60 (74.1)	59 (76.6)
1	28 (12.5)	13 (16.0)	15 (19.5)
2	8 (3.6)	6 (7.4)	2 (2.6)
3	1 (0.4)	1 (1.2)	0 (0.0)
4	2 (0.9)	1 (1.2)	1 (1.3)
Exchange of ball attachment, P > 0.999			
0	219 (97.8)	78 (96.3)	75 (97.4)
1	5 (2.2)	3 (3.7)	2 (2.6)
Exchange matrix, P = 0.47			
0	161 (71.9)	45 (55.6)	50 (64.9)
1	38 (17.0)	21 (25.9)	17 (22.1)
2	23 (10.3)	13 (16.0)	10 (13.0)
3	2 (0.9)	2 (2.5)	0 (0.0)
Retention adjusted, P = 0.21			
0	133 (59.4)	32 (39.5)	35 (45.5)
1	48 (21.4)	22 (27.2)	26 (33.8)
2	23 (10.3)	17 (21.0)	6 (7.8)
3	12 (5.8)	7 (8.6)	6 (7.8)
4	6 (2.7)	3 (3.7)	3 (3.9)
5	1 (0.4)	0 (0.0)	1 (1.3)

Statistical analysis regarding differences between the treatment groups: Fisher exact test. Values are presented as n (%).
[a]This column contains information on how often prosthetic complications and maintenance interventions occurred during the follow-up period per patient.
[b]All patients who were screened for possible inclusion in the study.

significant difference between them ($P > 0.09$). Bleeding on probing occurred at 11 (16.9%, 95% CI: 8.8% to 28.3%) of the implants of the immediate loading group and 14 (21.1%, 95% CI: 12.1% to 33.0%) of the delayed loading group also, with no statistical significant differences between groups ($P = 0.657$). Regarding prosthetic complications and maintenance interventions, only the parameter "fracture of the denture base in the area of the ball attachment" revealed a statistical significant difference between the treatment groups ($P = 0.007$; Table 3). The most common complications and maintenance interventions in both groups were "adjustment of the retention," "relining of the mandibular denture," and "pressure sore" in the mandible. The most reported "other complication" was a reintegration of a detached matrix, either due to a former malpositioning or an accidental detachment during function. This complication occurred 10 times within the immediate loading group and 8 times within the delayed loading group. A hyperplastic gingiva in the area of the ball attachment was reported for 5 patients of the immediate loading group. This complication did not occur in the delayed loading group.

An interim analysis of secondary outcomes was performed after all patients had completed the 4-mo follow-up examination (after loading). These results have been presented elsewhere (Mundt et al. 2017; Passia, Att, et al. 2017).

Discussion

The initially estimated number of participants of 180 (90 per group) was not achieved during the designated recruitment time, which was initially 12 mo and then extended for another 3 mo (Passia, Abou-Ayash, et al. 2017). However, the current number of participants still had a power >77%. The smaller number of participants did not negatively influence the final statistical analysis.

The hypothesis has to be rejected—that the prosthetic rehabilitation of the edentulous mandible with a single median implant and immediate loading will offer a comparable survival rate as the rehabilitation with 1 implant and second-stage surgery. There was a statistically significant difference between the treatment groups regarding implant survival.

In general, the immediate loading of implants supporting overdentures is challenging and considered a valid treatment option for clinicians with the appropriate skills (Weber et al. 2009). According to several systematic literature reviews, the immediate loading of 2 or 4 implants in the edentulous mandible with overdentures is well documented and reveals high implant survival rates of between 94% and 100% (Alsabeeha et al. 2010; Schimmel et al. 2014; Zygogiannis et al. 2016). In a pilot study on 3 immediately loaded implants to retain a complete mandibular overdenture, the implant survival rate was 100% after an observation period of 2 y (Stephan et al. 2007). An investigation by Kronström et al. (2010) on the immediate loading of mandibular overdentures supported by 1 or 2 implants revealed implant survival rates between 81.6% and 82.4%. The survival rates of both groups were not statistically significant. In a clinical trial by Liddelow and Henry (2010), the survival rate of immediately loaded implants with air-abraded and acid-etched surfaces supporting a mandibular overdenture was 100% after 36 mo of observation. In the present study, the implant survival rate after 2 y was 87.8% for the immediate loading group. This is slightly higher than the implant survival rate reported by Kronström et al. but considerably lower than the survival rate reported by Liddelow and Henry for 1 implant and the reported average implant survival rate for 2 or 4 implants supporting a mandibular overdenture. In the present study, the retention elements were connected to the denture base intraorally. Kronström et al. took an impression and sent the denture to the laboratory. That might have led to inaccuracies, resulting in increased implant loading and a slightly higher implant failure rate.

In the present study, surgical and prosthetic procedures were carried out at 9 different university hospitals. Although all participating dentists were experienced clinicians following previously defined standard operation procedures, one might be less experienced with the implant or the attachment system, as well as the concept of a single implant in the edentulous mandible in general. It is known from the literature that learning curves have to be expected (Preiskel and Tsolka 1995; Lambert et al. 1997). This fact might have led to higher failure rates in the present study when compared with the results obtained by Liddelow and Henry (2010). Additionally, the intraoral integration of the attachment system into the denture base is a technique sensitive procedure. This is supported by the fact that detached matrices had to be reintegrated into the denture bases 18 times in total. Even minimal malpositioning of the matrix on top of the ball attachment may result in an implant overload and increase the risk of failure.

Another aspect that should be considered is the influence of the overdenture's movement and its biomechanical behavior. Liu et al. (2013) investigated the influence of the implant number on the biomechanical behavior of mandibular overdentures using a 3-dimensional finite element analysis. They found that the single-implant overdenture rotated over the implant from side to side under vertical load on the lower incisors, but they found no obvious increase of strain in peri-implant bone. In another laboratory investigation, Oda et al. (2017) revealed significantly smaller vertical displacement of a single implant–retained overdenture versus a 2-implant overdenture upon anterior loading. However, the authors also mention that, under clinical conditions, the single implant–retained overdenture may allow complex denture movements, as a single implant cannot limit the direction of movement. Although patients with severely resorbed mandibles were excluded in the present study, complex denture movements were still possible, as a single implant can act as a rotational axis. This might result in strong extra-axial implant loading during function, which might negatively influence the implant stability of the immediately loaded implants, resulting in more implant failures.

In the conventional loading group, 1 implant failed, resulting in a survival rate of 98.5%. This result falls well within published results on implant survival from other investigations on the single mandibular implant in the edentulous mandible (Passia and Kern 2014).

Regarding prosthetic complications, the most common maintenance intervention was an adjustment of the retention element in both treatment groups. This is in line with other investigations on the single midline implant in the edentulous mandible (Cordioli et al. 1997; Alsabeeha et al. 2011; Passia et al. 2015) and seems to be the most common maintenance intervention for implant-retained overdentures (Andreiotelli et al. 2010). A fracture of the denture base in the area of the ball attachment occurred significantly more often in the immediate loading group than in the delayed loading group. A fracture of the denture base in the area of the attachment was the most frequent complication in the investigation by Liddelow and Henry (2010) with a direct implant loading protocol. When implants are directly loaded at the day of implant placement, the soft tissue in the implant area might be slightly swollen. Also, due to necessary bone reduction in the anterior region, a surplus of soft tissue in the implant area might occur and has to be well adapted during suturing. After second-stage surgery, the surgical area is smaller than after an implant placement, and the soft tissue adaptation is easier. In the present investigation, the ball attachments were integrated into the already-existing denture bases. The recesses, which have to be prepared to pick up the matrix, will therefore be slightly bigger in the immediate loading group than the delayed loading group. In most cases, a metal framework did not support the denture bases. After the matrix was integrated into previously prepared recesses, the acrylic resin in the area of the ball attachment was rather thin, especially in the labiolingual dimension, and thus prone to fracture. All patients who experienced a second fracture of the denture base were offered a metal framework to support the implant area.

The revision of the dentures in both groups at the day of implant loading also explains the relining in approximately 10% of the dentures in both groups during the follow-up period. The tissues adapt to the new situation after bone reduction and implant placement, resulting in a slight misfit and need for relining.

The surplus of soft tissue in the implant area after bone reduction might also lead to a hyperplastic gingiva in the area of the ball attachment, which was observed in 5 cases of the immediately loaded group. Liddelow and Henry (2007) also reported a gingiva hypertrophy in some cases after immediate loading. They eliminated the problem by using a viscoelastic relining material in the implant area during the first weeks of implant loading. Payne et al. (2001) reported similar problems in a 2-implant overdenture study. They definitely relined all denture bases 2 wk after implant placement according to their study protocol. In the present study, all patients achieved healthy soft tissue conditions after a soft tissue conditioning of the hypertrophic gingiva in the implant area.

An interim analysis was performed after all patients had completed the 4-mo follow-up examination (after loading). This analysis considered only the secondary outcomes of this clinical trial (Mundt et al. 2017; Passia, Att, et al. 2017). This analysis had no influence on the primary endpoints for this study or the further conduct of the study, since all implants had been placed at this point and no further interventions were performed.

Conclusion

Over an observation period of 2 y, single midline implants in the edentulous mandible that were immediately loaded revealed a statistically significant lower survival rate than those loaded 3 mo after implant placement and second-stage surgery. The results of the present study indicate that immediate loading of a single implant in the edentulous mandible should be considered only in exceptional cases.

Author Contributions

M. Kern, contributed to conception, design, data analysis, and interpretation, drafted and critically revised the manuscript; W. Att, S. Kappel, T. Mundt, D. Reissmann, M. Rädel, contributed to data acquisition, critically revised the manuscript; E. Fritzer, contributed to conception, design, data analysis, and interpretation, critically revised the manuscript; R.G. Luthardt, M. Stiesch, S. Wolfart, contributed to conception, design, and data acquisition, critically revised the manuscript; N. Passia, contributed to acquisition, analysis, and interpretation, drafted the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work.

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