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Received: 8 January 2021 | Revised: 6 October 2021 | Accepted: 13 October 2021

DOI: 10.1111/clr.13872

ORIGINAL ARTICLE

CLINICAL ORAL IMPLANTS RESEARCH WILEY

Influence of the loading protocol and platform switching in two-implant bar-retained overdentures: 3-year results from a randomized controlled equivalence clinical trial

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Funding information
The materials were provided by Schilli Implantology Circle (Basel, CH), C+M (Biel, CH). Open Access funding enabled and organized by projekt DEAL.

Abstract

Objectives: To test the null hypothesis that vertical peri-implant bone level alterations (ΔIBL) are equivalent in immediately (IL) and 3-month post-placement (DL) loaded implants in mandibular implant overdentures (IODs) on two implants.

Materials and Methods: Thirty-two patients receiving two interforaminal implants, one with a platform-switched and one with a platform-matching abutment were randomly assigned to the IL or DL group (allocation ratio 1:1). All implants were primarily splinted with chairside-customized bars, converting the existing removable complete dentures to IODs. Standardized radiographs were recorded. The influence of the loading protocol (IL vs. DL), implant platform (platform switched vs. platform matching), implant site (43 vs. 33), participant age (≤65 vs. >65 years), and definition of baseline (implant placement vs. implant loading) were analyzed, applying linear regression analyses ($\alpha = 0.05$). The equivalence range was [−0.4; 0.4].

Results: Three participants of the IL group were lost during follow-up. The overall mean ΔIBL was −0.96 ± 0.89 mm. The ΔIBL was equivalent in terms of the implant platform and implant site but not in terms of participant age (in favor of more elderly participants) and the loading protocol. A significantly smaller ΔIBL was observed in the IL when the baseline was considered to be implant placement ($p = .017$), but not when it was considered to be implant loading ($p = .084$).

Conclusion: Immediate loading of primary-splinted implants in two-implant bar-retained overdentures, seems beneficial relative to loading 3 months post-placement, with respect to ΔIBL. The ΔIBL were equivalent in terms of platform switching.

KEYWORDS
bone-level, dental implants, immediate loading, platform-switching, randomized controlled trial

Kokoschka and Schumacher made equal contribution as second author.

1 | INTRODUCTION

Dental implant treatment has become a predictable treatment option for replacing missing teeth in various clinical situations (Ducommun et al., 2019). Today, high implant survival and success rates are reported, even after long-term observation periods (Bakker et al., 2019; Chappuis et al., 2018). Due to this high predictability, the focus in implant dentistry has now shifted from implant survival as a single success criterion to clinical and esthetic peri-implant parameters, as well as decreasing the invasiveness and morbidity of implant treatment from both the clinician's and the patient's points of view (Papaspyridakos et al., 2012). Currently, two major strategies for decreasing morbidity are pursued: The first one is to decrease the invasiveness of the treatment itself by using less invasive treatment options; for example, shorter (Papaspyridakos et al., 2018), reduced diameter (Enkling et al., 2020), or even fewer implants (Passia et al., 2017). The second strategy is to reduce the period of edentulism by applying immediate or early loading protocols (Schimmel et al., 2014).

Immediate and early loading protocols are widely applied for both fixed and removable prosthodontics (Gallucci et al., 2018; Leão et al., 2018). Shortening the duration of edentulism by applying an immediate implant loading protocol seems to be particularly advantageous in completely edentulous patients (Kutkut et al., 2019). The consequences of complete edentulism are reduced oral health-related quality of life (Alves et al., 2018), impaired eating and speaking abilities (Furuta et al., 2018; Musacchio et al., 2007), and increased psychological strain (Polzer et al., 2010). Stabilizing a mandibular complete denture without implants is very challenging, especially when the edentulous mandible is severely resorbed (Thomason et al., 2012). Thus, two implants retaining an overdenture (OD) has been promoted to be the first choice of treatment for the edentulous mandible (Feine et al., 2002). In these situations, applying an immediate loading protocol shortens the period of wearing an unstable complete denture, reducing the aforementioned consequences of complete edentulism (Kutkut et al., 2019; Singh et al., 2019). However, there are also studies refuting these beneficial effects of immediate compared with other implant loading protocols in edentulous subjects (Abou-Ayash, von Maltzahn, et al., 2020; Schwindling et al., 2018).

When mandibular ODs were retained by a single, immediately loaded implant, significantly lower implant survival rates relative to single implants with a delayed loading protocol were reported (Kern et al., 2021). However, implant survival rates in two-implant retained, immediately loaded mandibular ODs are reported to be similar to those of early- or delayed-loaded implants (Salman et al., 2019). Evidence regarding two primarily splinted, immediately loaded implants retaining mandibular ODs is scarce, as studies focusing on various loading protocols in mandibular implant overdentures (IODs) evaluated either unsplinted or more than two implants (Schimmel et al., 2014). To the best of the authors' knowledge, no data on the influence of the loading protocol on bone level alterations (ΔIBL) around implants in two-implant bar-retained mandibular ODs from a randomized controlled clinical study, with follow-up periods longer than 1 year, are currently available. Therefore, the aim of this split-mouth randomized controlled clinical trial was to test the equivalence in terms of vertical bone level alterations (ΔIBL) in two-implant bar-retained mandibular overdentures, applying different implant loading protocols. The null hypothesis (H0) was that ΔIBL in immediately and delayed-loaded implants would be equivalent after 3 years. Furthermore, the influence of the implant platform (platform switched vs. platform matching), implant position (43 vs. 33), participant age (≤65 vs. >65 years), and the definition of baseline (implant placement vs. implant loading) were analyzed.

2 | MATERIALS AND METHODS

This study was conducted in compliance with the ethical standards as described by the current version of the Declaration of Helsinki, the ICH-GCP, or ISO EN 14155, and fulfilling all the national legal and regulatory requirements (General Assembly of the World Medical Association, 2014). The study protocol was approved by the Cantonal Ethics Committee of Bern (KEK 157/08). Written informed consent was signed by all study participants.

2.1 | Participant eligibility criteria

At the School of Dental Medicine University of Bern, subjects wearing complete dentures in the upper and lower jaw were recruited for possible participation. The eligibility criteria were as follows:

Inclusion criteria

- Good general health (ASA classification 1 or 2)
- The minimum period of edentulism should be 6 months or more
- A minimum interforaminal bone width of 7 mm, at the desired implant position (determined by bone mapping)
- A minimum interforaminal bone height of 11 mm (determined in the panoramic x-ray)
- Wearing of sufficient complete dentures for at least 2 months, but with expressed patient request for stabilization of the mandibular denture

Exclusion criteria prior to surgical treatment

- Presence of any systemic medical conditions that contraindicating implant placement/therapy
- Osteoporosis
- Use of any medication that may influence bone metabolism
- Dental anxiety
- Drug abuse

Exclusion criteria during surgery

- Insufficient bone height after osteotomy
- Implant insertion torque <35 Ncm

All eligible subjects were grouped in pairs, with the same gender and a maximum age difference of 5 years. Subjects fulfilling the eligibility criteria, but who could not be paired, were excluded. Within each pair, patients were randomly allocated to either the immediate (IL) or the delayed loading (DL) group (allocation ratio 1:1). The implant abutments were randomized to be either platform-switched or platform-matching (allocation ratio 1:1), resulting in one platform-switched and one platform-matching abutment in each patient. For randomization, a computer-generated list, administered by an independent clinician not involved in the clinical treatment, was used. The result of randomization was not announced until after implant surgery to avoid possible surgeon influence.

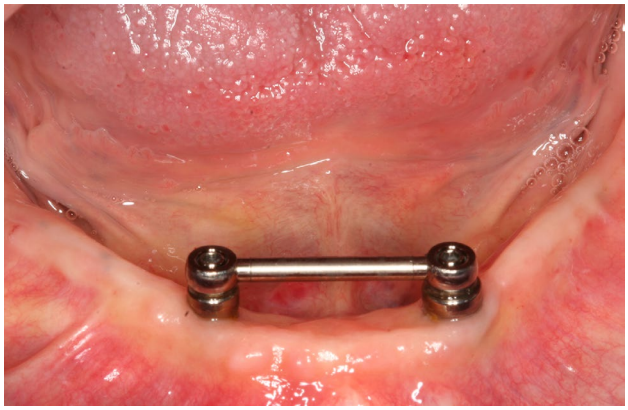


FIGURE 1 Clinical example of the round bar on two implants after 3 years

2.2 | Implant surgery and bar connection

The existing mandibular dentures served as surgical guides for implant placement at the lower canine sites. After premedication with amoxicillin (Clamoxyl®), starting 1 h preoperatively (3 × 750 mg), and local anesthesia (Ubestesin forte, Epinephrine 1:100,000, 3 M-Espe), a mucoperiosteal flap with a median releasing incision, was prepared. The crest width was measured and, if necessary, shortened, resulting in a width of at least 7 mm at the designated implant positions. The osteotomy was performed as advised by the manufacturer (SIC invent) without pretaping. Subsequently, the implants (SICace®) were inserted and torque-controlled. The implants were placed at the level of the buccal bone using a torque-controlled handpiece. All implants were made from titanium grade 4, had a micro-rough surface (ZrO_2 blasted, acid etched), a length of 9.5 mm, and a diameter of 4 mm. The implant–abutment connection was a parallel-walled, hexagonal internal connection.

After implant placement, a chairside-customized round bar (SFI-Bar; Cendres + Métaux) was mounted onto the implants: the male part indicated for a two-implant solution consists of seven prefabricated parts: two implant-adapter abutments (available in heights of 2–5 mm), two large ball joints attached to the implant-adapter abutments with two occlusal screws, and one bar tube connecting the two ball joints to a round bar (Figure 1). The length of the bar and the matching matrices were adapted chairside using a cutting disc. Due to the surgically performed bone leveling, the two implants could be placed in similar vertical positions in all patients. Thus, all implant-adapter abutments had a height of 3 mm, resulting in a supramucosal abutment height of approximately 1 mm. The abutments were mounted and torqued to 20 Ncm with a hand ratchet. The abutment diameter at the implant shoulder was either 3.3 mm (circular platform switch of 0.35 mm) or 4 mm (platform matching). Subsequently, after the round bar was installed on the implant abutments, the matrices were directly polymerized into the existing dentures, which were modified prior to the procedure by grinding in the interforaminal region. The prosthodontic workflow is detailed in another publication (Abou-Ayash, Schimmel, et al., 2020).

For each implant, stock x-ray film holders were customized using a putty silicone material and a screwdriver blade, enabling direct attachment to the occlusal screw of the bar (Figures 2 and 3). After taking post-surgical x-rays of each implant, the bar was either left in place (IL group) or removed (DL group); for the latter, healing abutments (height of 5 mm) were mounted in its place. Subsequently, the dentures in the DL group were relined and the integrated female parts protected using a soft temporary relining material. The relining material around the implants was reduced to avoid direct contact between the dentures and the healing abutments as much as possible. However, a certain amount of load on the implants most likely could not be avoided (Tawse-Smith et al., 2002).

A mouth rinse (0.2% chlorhexidine gluconate mouthwash; Meridol perio, GABA) was provided to the patients with instruction to use it twice daily until suture removal. Afterward, the patients were advised to clean their gums with a soft toothbrush. In the IL group, the participants were instructed how to clean below the bar using interdental brushes.

In the DL group, 3 months after implant insertion, the bars were mounted, the soft-relining material removed, and the dentures adapted.

2.3 | Evaluation of vertical bone level changes (ΔIBLs) and clinical parameters

At the following time points, X-rays of each implant were recorded with the customized x-ray holders in a paralleling technique: implant placement, implant loading, 3, 6, 12, 24, and 36 months after implant loading. Two clinicians were calibrated to evaluate the digital X-rays at 20-fold magnification using the DBS-Win 4.5 software (Dürr Dental AG). The calibration between the two clinicians was done by identifying the position of the first bone-to-implant contact (BIC) in 20 randomly selected X-rays, together with the senior author. Each clinician evaluated the X-rays twice. Before each measurement, the distance from the implant shoulder to the apex was defined to be 9.5 mm, to define the correct dimension for the measurements. The distance from the first bone-to-implant contact to the implant shoulder (IBL) was measured mesially and

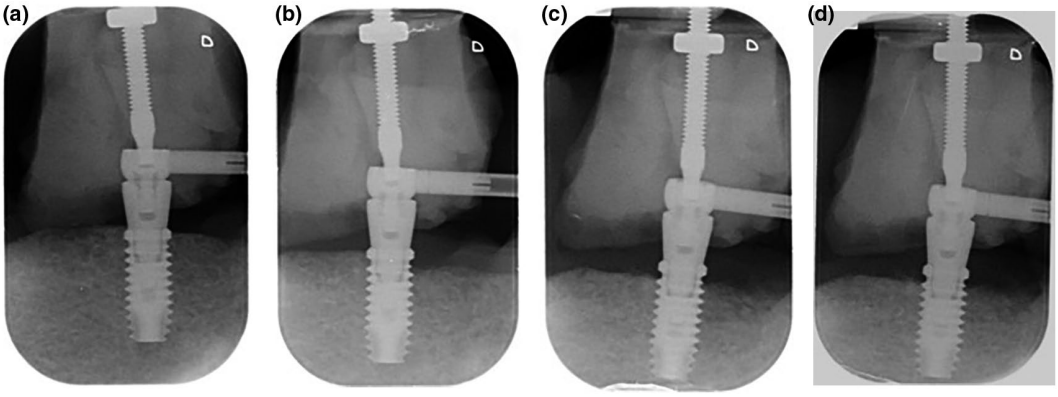
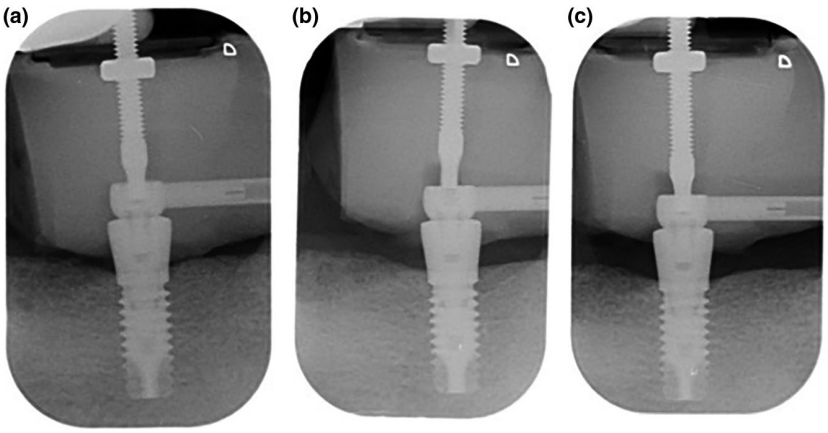


FIGURE 2 X-rays of a platform-switched implant in position 43; from left to right (a) at implant placement, (b) implant loading, (c) 1 year, (d) and 3 years after loading. Peri-implant bone level alterations (ΔIBL) are obvious from placement to loading (mesial aspect) and from loading to the 1-year follow-up. Afterward, the peri-implant bone level seems stable

FIGURE 3 X-rays of a non-platform-switched implant in position 43; from left to right (a) at implant placement/implant loading, (b) 1-year, (c) and 3-years after loading, demonstrating stable peri-implant bone levels



distally along the vertical implant axis, at two measurement sessions, resulting in four values per implant. The average IBL of these four values was then calculated. When the average IBL of the two evaluators differed by more than 0.1 mm, the position of the first bone-to-implant contact was evaluated together by the two clinicians, followed by a second independent evaluation. Afterward, ΔIBL was calculated, subtracting the IBL at each follow-up appointment from the IBL at implant placement, considering implant placement as the baseline for subsequent analyses (Misch et al., 2008). Additionally, ΔIBL in the delayed loading group was calculated by subtracting the follow-up IBL from the IBL at implant loading, considering the prosthetic loading as the baseline (Albrektsson & Zarb, 1993).

At the same clinical appointments, the following peri-implant parameters were evaluated: probing depths (PDs), bleeding on probing (BOP), and the presence of plaque at 4 sides of each implant (yes/no). Furthermore, any technical complications and/or need for denture relining were noted. Implants were considered surviving when they were in place at all follow-up appointments, regardless of their condition. Implant success was assessed with the criteria defined by the International Congress of Oral Implantologists (ICOI), considering the presence of pain, exudate, mobility, probing depth, and marginal bone level changes (Misch et al., 2008).

2.4 | Statistical analyses

The sample size calculation for the primary outcome (ΔIBL), assuming a standard deviation of 0.5 mm in immediately and in delayed-loaded implants retaining mandibular overdentures (Schincaglia et al., 2016), and an equivalence range of [−0.4; +0.4] (Astrand et al., 1999; Wellek, 2002) resulted in 28 implants (14 participants) per study group (calculation by BiAS for Windows 11.10, two-sided two-sample equivalence of mean, level of significance 0.05, power 0.8, sampling ratio 1). For descriptive analyses, means and standard deviations (SD) (clinical parameters) were calculated. For equivalence testing, two-sided 95% confidence intervals were calculated, and the upper and lower limit of the 95% confidence intervals were compared with the equivalence range [−0.4; 0.4]. If the 95% confidence interval was within the equivalence range, i.e., if both the lower and the upper limit of the 95% CI were within the equivalence range, then the ΔIBL of corresponding groups were considered equivalent.

Multivariate linear regression with random effect patient as intercept and fixed effects loading, platform-switching, implant site, and age, adjusted for baseline IBL were used to investigate the presence of any statistically significant differences in ΔIBL. The Bland–Altman analysis was used to analyze the interrater reliability in terms of ΔIBL. All analyses were done using statistics software (Stata/IC 16.1), with alpha set to 0.05.

3 | RESULTS

3.1 | Description of participants

After evaluating the eligibility criteria, 32 participants [N = 32: ♀ = 16, ♂ = 16] were recruited and grouped in pairs of two, matching gender and age (±5 years). Within each pair, one participant was randomized to the IL group and one to the DL group. Of the course of the follow-up, three patients of the IL group dropped out due to unrelated mortality, resulting in a final number of 16 participants in the DL group [♀ = 8, ♂ = 8; mean age 65.9 ± 9.3 years] and 13 participants in the IL group [♀ = 6, ♂ = 7; mean age 66.1 ± 10.2 years], who attended all follow-up appointments. Of the included participants, 12 were 65 years or younger and 17 were older than 65 years. Figure 4 provides an overview of the course of the study and the number of participants at the respective points in time.

3.2 | Bone level alterations

The overall mean ΔIBL was −0.96 ± 0.89 mm. In the IL group, the mean ΔIBL after 3 years was −0.53 ± 0.5 mm. In the DL group, the mean ΔIBL was −1.28 ± 0.99 mm when the baseline was considered to be implant placement, and −0.92 ± 0.79 mm when the baseline was considered to be implant loading. Figure 5 shows the evolution of ΔIBL for both baseline definitions. When implant placement was considered as the baseline, the ΔIBL were significantly smaller in the IL compared to the DL group (mean difference [95% CI]: −0.79 mm [−1.44; −0.14]; p = .017), but not when implant loading was considered to be the baseline (mean difference [95% CI]: −0.58 [−1.24; 0.08]; p = .084). However, the ΔIBL was not equivalent, comparing the IL and DL groups independent of the loading protocol. No statistically significant differences of ΔIBL could be identified in terms of the implant platform, implant position, or participant age, independent of the baseline definition (Tables 1 and 2). Although no statistically significant different ΔIBL between participants ≤65 years and >65 years could be demonstrated, the ΔIBL was not equivalent in the two groups, as the upper limit of the 95% CI was outside the equivalence range of [−0.4; 0.4 mm; Tables 1 and 2]. The ΔIBL in participants ≤65 years was −0.83 ± 1.01 mm (baseline: implant loading) or −1.05 ± 1.27 mm (baseline: implant placement), whereas it was −0.70 ± 0.38 mm or −0.90 ± 0.38 mm in participants >65 years. For the analyses of the radiographs, the mean interobserver variability was 0.008 mm (limits of agreement: −0.12; 0.13 mm), resulting from n = 248 comparisons. The mean intraobserver variability was 0.002 mm (limits of agreement: −0.24; 0.24 mm).

3.3 | Clinical parameters

During the 3-year follow-up period, no implant was lost, resulting in an implant survival rate of 100%. The overall implant success rate was 95.2% based on the criteria described in the PISA consensus conference (Misch et al., 2008): a ΔIBL greater than 2 mm was recorded in four implants (considering implant placement as the baseline). All implants exceeding a ΔIBL of 2 mm were in the DL group. In both the IL and DL groups, one IOD fractured in the matrix region after 3 and 12 months, respectively. In twelve participants of each group, the dentures had to be relined. Denture stomatitis grade 1 (Newton, 1962) was found in one participant of the DL group. No further technical or biological complications were observed. Table 3 gives an overview of PDs, BOP positive sites, and the presence of plaque at the 3-year follow-up separated for the two study groups.

4 | DISCUSSION

The current randomized controlled clinical study aimed to compare ΔIBL in immediately (IL) with delayed loaded (DL) implants, in two-implant bar-retained overdentures. The null hypothesis of observing equivalent ΔIBLs was rejected since the ΔIBL was not equivalent.

Pairwise randomization based on age and gender is one of the major strengths of the current study, resulting in highly comparable study groups (Imbens & Rubin, 2015). Furthermore, the split-mouth design with respect to abutment diameter facilitates direct comparison of ΔIBL within each subject, minimizing the risk for interindividual contributing factors (e.g., denture hygiene routines). Another strength is the application of standardized x-ray holders, resulting in reproducible longitudinal radiographs. All radiographs were acquired using the latest radiographic technology to meet the ethical guidelines of frequent radiographs, especially regarding the high number of radiographs during the first year of the study.

Although the follow-up period of 3 years seems rather short, the current study may be the first randomized controlled clinical study comparing immediate and delayed loading in two-implant bar-retained overdentures. Existing controlled studies were either non-randomized (Stephan et al., 2007) or reported on shorter follow-up periods (Reis et al., 2019). Despite the short follow-up, the study was limited due to patient death and, therefore, dropout (n = 3). Nevertheless, according to the sample size calculation, a sufficient number of participants was initially included. For a correct interpretation of the results, it should also be kept in mind that a sub-randomization with respect to the abutment platform was performed.

In the current study, ΔIBLs in immediately and delayed-loaded implants were not equivalent, neither when the baseline was defined to be implant placement nor when defined to be implant loading. It should be considered that the follow-up appointments were scheduled in relation to implant loading. Consequently, the implants in the immediate loading group had been in place 3 months less than those of the conventional loading group, at all follow-up appointments. Nevertheless, in both baseline scenarios, the mean ΔIBL was lower in the IL group. This finding follows the results of a previous study on various loading protocols in bar-retained overdentures, which demonstrated increased bone level alterations in delayed (1.1 mm ± 0.5 mm) relative to immediately loaded implants

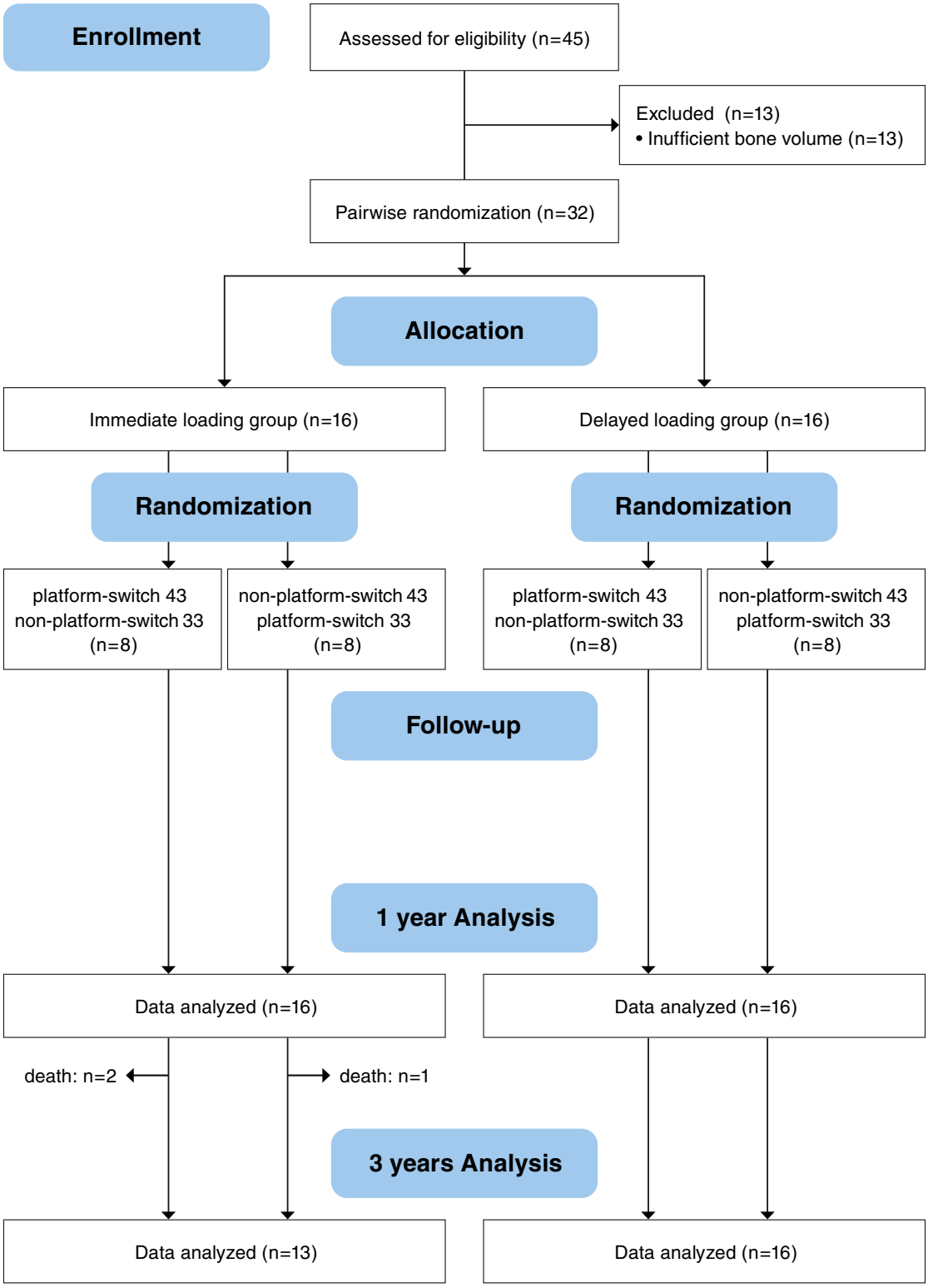


FIGURE 4 Study flow chart summarizing the randomization and follow-up procedures

(0.4 ± 0.4 mm) after 1 year (Attard et al., 2005). However, that study included a relevant risk of bias since different implants were used in the immediate and delayed loading groups (Attard et al., 2005). Conversely, a systematic review on loading protocols in implant overdentures demonstrated no differences in ΔIBL, applying either an immediate or a delayed loading protocol (Sanda et al., 2019). In that review, only one included study reported data on bar-retained overdentures on three implants (Stephan et al., 2007). This specific study also demonstrated a significantly lower ΔIBL in the immediate loading group after 1 year.

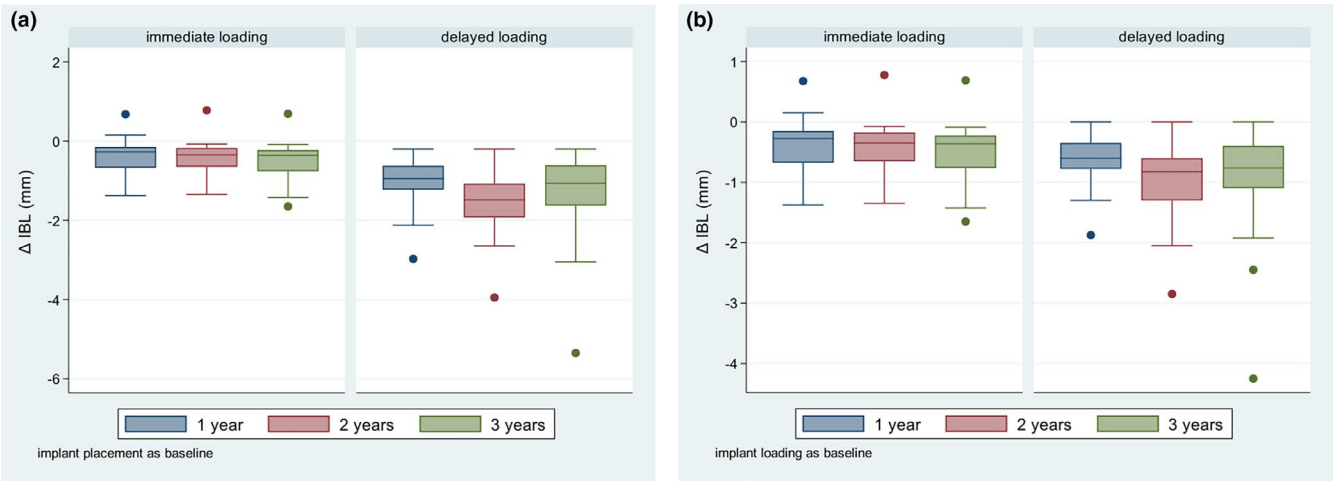


FIGURE 5 Peri-implant bone level alterations (ΔIBL) at 1, 2, and 3 years, in the immediate and delayed loading groups, (a) considering implant placement, and (b) implant loading as the baseline

Although ΔIBLs for the IL and DL groups were unequal, independent of the loading protocol, a statistically significant difference of ΔIBL could only be demonstrated when the baseline was considered to be implant placement. Initially, this may seem counterintuitive, as a non-equal outcome implies a qualitative difference. However, to demonstrate equivalence, upper and lower equivalence bounds based on the smallest effect size of interest are specified, when observations do not otherwise indicate a statistically significant difference. The mean difference between IL and DL, as well as the lower limit of the 95% CI, was outside of the defined equivalence bounds [−0.4; +0.4] in both baseline scenarios. It has been shown that a non-significant difference does not necessarily indicate equivalence, which is a common misinterpretation in the scientific literature (Lakens, 2017). Nevertheless, a significant difference in ΔIBL between IL and DL could be demonstrated, when the baseline was considered implant placement. The distinct considerations of baseline, being either implant placement or implant loading, result from the use of multiple conventions in the scientific literature (Albrektsson & Zarb, 1993; Misch et al., 2008). As implant placement was accompanied by implant loading in the IL group but not in the DL group, two separate analyses considering both baseline definitions have been performed. Since both definitions are used for analyses in current studies (Ko et al., 2019; Krennmair et al., 2019), it seems to be particularly important to pay attention to which of the two is used in order to correctly interpret the results.

The finding of non-equivalent ΔIBL in participants ≤65 years relative to participants >65 years is consistent with previous studies, which have reported smaller ΔIBL in older subjects with mandibular IODs (Enkling et al., 2020; Krennmair et al., 2016). One reason may be the reduced chewing forces applied by elderly subjects, which generate weaker loading forces on the implants (Enkling et al., 2019). Another reason could be the reduced acute inflammatory response of the older patient, which could possibly also lead to a reduction in peri-implantitis (Meyer et al., 2017). However, patients may suffer from increased chronic inflammation due to immunosenescence (Bektas et al., 2018). Equivalent ΔIBL were observed in platform-switched and non-platform switched implants, as well as in the two implant sites. Generally, factors described as influencing the effect of platform switching on ΔIBL include the type of prosthetic restoration (Chrcanovic et al., 2015) and the amount of the circular platform switch (Atieh et al., 2010). In our study, the platform switch was smaller than the assumed limit of 0.4 mm described in the literature (Atieh et al., 2010), which may explain why platform switching did not influence ΔIBL. Four implants were found to have a ΔIBL between 2 and 4 mm, which still places them in the "satisfactory survival" category. Interestingly, these implants with satisfactory survival belonged to the DL group.

The clinical peri-implant parameters were very similar in both test groups. The PDs, presence of plaque, and BOP-positive implant sites are described in the literature to a similar extent (Baskaradoss et al., 2021). Interestingly, there were only two prosthesis fractures (one per group), although the space requirements for converting a complete denture to an IOD are relatively high for a bar compared with single anchors (Albrecht et al., 2015). The presence of denture stomatitis in only one patient is interesting since a higher incidence has been reported in the literature, particularly in overdentures. Although denture stomatitis seems to be less frequent in the mandible than in the maxilla (Stalder et al., 2021), especially bar-retained overdenture wearers are reported to be vulnerable to mucosal hyperplasia (Naert et al., 1999).

5 | CONCLUSION

Within the limitations of the study design, especially in terms of the small sample size and short follow-up time of 3 years, immediate loading in mandibular two-implant bar-retained overdentures could be beneficial in terms of ΔIBL. The baseline definition (implant placement vs. implant loading) directly influences ΔIBL and

TABLE 1 Differences in peri-implant bone level alteration (ΔIBL), considering implant placement as the baseline

Influencing factor	Group (1) vs. (2)	Coeff [95%-CI] (mm)	*p*-value
Loading	(1) Delayed vs. (2)immediate	−0.79 [−1.44; −0.14]	.017
Platformswitch	(1) Yes vs. (2) no	0.08 [−0.11; 0.23]	.495
Implant site	(1) 43 vs. (2) 33	0.02 [−0.16; 0.20]	.970
Age	(1) >65 vs (2) ≤65 Jahre	0.36 [−0.40; 1.12]	.350

Note: Estimated difference (Coeff) in peri-implant bone level alteration (ΔIBL), between corresponding groups, considering implant placement as the baseline. Negative values indicating higher ΔIBL in group (1). Differences and *p*-values resulting from univariate linear regression analyses.

Italics indicate statistically significant *p*-values.

TABLE 2 Differences in peri-implant bone level alteration (ΔIBL), considering implant loading as the baseline

Influencing factor	Group (1) vs. (2)	Coeff [95%-CI] (mm)	*p*-value
Loading	(1) Delayed vs. (2) immediate	−0.58 [−1.24; 0.08]	.084
Platformswitch	(1) Yes vs. (2) no	0.06 [−0.12; 0.24]	.514
Implant site	(1) 43 vs. (2) 33	0.04 [−0.14; 0.22]	.753
Age	(1) >65 vs. (2) ≤65 Jahre	0.29 [−0.40; 0.97]	.428

Note: Estimated difference (Coeff) in peri-implant bone level alteration (ΔIBL), between corresponding groups, considering implant loading as the baseline. Negative values indicating higher ΔIBL in group (1). Differences and *p*-values resulting from univariate linear regression analyses.

TABLE 3 Clinical peri-implant parameters

	Immediate loading		Delayed loading	
	Mean	SD	Mean	SD
Presence of plaque [%]	55.1	25.2	42.1	29.2
BOP positive sites [%]	15.9	22.5	13.9	14
Probing depths [mm]	2.1	0.4	2.3	0.5

Note: Means and standard deviations (SDs) of clinical parameters at the 3-year follow-up appointment.

Abbreviation: BOP, bleeding in probing.

should, consequently, be considered for the correct interpretation. Advanced age does not lead to higher peri-implant ΔIBL and may even be beneficial for peri-implant bone stability. The clinical soft tissue parameters are not influenced by the loading protocol.

ACKNOWLEDGMENTS

Sample size calculation and statistical analysis were performed with the support of Dr. rer. nat. Niki Zumbrunnen (Institute of Mathematical Statistics and Actuarial Science (IMSV), University of Bern, Switzerland) and Mrs. Hiltrud Niggemann (p-Wert, Jena Germany). Additionally, the authors would like to thank Dr. med. Dr. med. dent. Dominic Albrecht for his excellent support in organizing the study appointment and for the data acquisition.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interest.

AUTHOR CONTRIBUTIONS

Norbert Enkling: Conceptualization (lead); Data curation (supporting); Formal analysis (equal); Funding acquisition (lead); Methodology (lead); Project administration (equal); Writing-original draft (equal); Writing-review & editing (equal). **Franziska Kokoschka:** Data curation (equal); Writing-original draft (supporting); Writing-review & editing (equal). **Daniel Schumacher:** Data curation (equal); Writing-original draft (supporting); Writing-review & editing (equal). **Dominik Kraus:** Data curation (equal); Writing-original draft (equal); Writing-review & editing (equal). **Martin Schimmel:** Formal analysis (equal); Project administration (equal); Writing-original draft (equal); Writing-review & editing (equal). **Samir Abou-Ayash:** Formal analysis (equal); Project administration (equal); Supervision (equal); Writing-original draft (lead); Writing-review & editing (lead).

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

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How to cite this article: Enkling, N., Kokoschka, F., Schumacher, D., Kraus, D., Schimmel, M., & Abou-Ayash, S. (2022). Influence of the loading protocol and platform switching in two-implant bar-retained overdentures: 3-year results from a randomized controlled equivalence clinical trial. *Clinical Oral Implants Research*, 33, 120–129. https://doi.org/10.1111/clr.13872