Comparison of immediate and conventional loading protocols with respect to marginal bone loss around implants supporting mandibular overdentures: A systematic review and meta-analysis☆

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ABSTRACT

Purpose: To compare marginal bone level changes (MBLCs) of immediately- and conventionally-loaded implants supporting a mandibular implant overdenture (IOD).
Materials and methods: Both electronic (MEDLINE, PubMed, and The Cochrane Library) and manual searches were conducted for all relevant studies published from 1 January 2000 to 1 November, 2017. Randomized controlled trials (RCTs) and prospective studies with a minimum follow-up of 12 months were selected. Studies which utilized implants narrower than 3 mm were excluded from analysis.
Results: Four studies met the criteria, with two evaluating horizontal bone loss. There were 70 patients in the test group (immediate loading) and 60 in the control group (conventional loading). Follow-up lasted 6–36 months, with MBLCs being interpreted from standardized periapical x-rays, panoramics or cone beam computed tomography. Each patient was given 2–3 implants.

After 6 and 12 months, the differences in MBLCs were 0.04 mm (95% CI: −0.21, 0.29) and 0. 00 mm (95% CI: −0.35, 0.36) respectively. Subgroup analysis of RCTs with 2 implants revealed group differences in MBLCs as 0.13 mm (95% CI: −0.22, 0.48) and that in horizontal bone loss as 0.04 mm (95% CI: −0.02, 0.10). No statistically significant differences were identified (p > 0.05).
Conclusion: The MBLCs of immediately-loaded implants for mandibular IODs seems comparable to those of conventional loading.

1. Introduction

In order to overcome instability of conventional complete mandibular dentures, implant overdentures (IODs) are prescribed for patients with edentulous mandibles on many occasions [1–4]. Many studies have proven the efficiency of IODs regarding a whole series of clinical parameters such as denture stability, chewing efficiency, patients' satisfaction, and oral health-related quality of life [5–7].

Initially, dental implants were to be free from loading forces for 3–6-months after implant placement in order to successfully achieve osseointegration [8]. Nowadays, immediate loading (IL) protocols, which allow the patient's occlusal forces to be loaded on implants within 1 week after surgery, have been widely applied to implant supported fixed prosthesis. This is because these protocols allow immediate restoration of oral function and esthetics and shorter total treatment timeframe without substantial deterioration of osseointegration [9–11].

Additionally, IL protocols have been applied to mandibular IODs since the late 1990s, and some retrospective studies have been published which show satisfactory survival rates [12,13]. Prospective studies evaluating MBLCs have also been published without control groups [14,15], and one systematic review comparing MBLCs of each loading protocol revealed no detrimental effects of immediate loading [16]. However, no randomized controlled trials (RCTs) were available at that time, and meta-analyses were not carried out in the review. Consequently, since some RCTs regarding this topic have already been published, we conducted a systematic review and meta-analysis of the data presented.

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Therefore, the clinical question for this systematic review was "Are the MBLCs of immediately-loaded implants supporting IODs higher than those of conventionally-loaded implants?"

2. Materials and methods

The protocol for systematic review was developed according to the Cochrane Handbook for Systematic Review of Interventions version 5.1.0 [17]. The results have been reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guideline [18].

2.1. Eligibility criteria

This systematic review and meta-analysis only included RCTs and non-RCTs. Case–control, cross-sectional and cohort studies, case series and reports, and analytical and narrative reviews were not included. Participants included in this review were adult males and females over 20 years of age who had mandibular IODs supported by two or more dental implants. Studies were included regardless of implant characteristics such as manufacturer, implant length, surface features, abutment connection design, and implant configuration. However, one-piece implants narrower than 3 mm, the so-called "mini-implants", were excluded from the analysis because their indications for use set out by their manufacturers differed from those of the standard implants, and hence were recognized as a different treatment modality [19]. No restriction was placed on the types of attachments and the fabricated denture.

2.2. Search methods and study selection

Online electronic databases, including the MEDLINE database and the Cochrane Central Register of Controlled Trials, were searched by a reviewer (MS) without any language filters for articles published between 2000 and 1 November, 2017. The search terms included "implant overdenture", "immediate loading", "Denture, Overlay" [MeSH] and "Immediate Dental Implant Loading" [MeSH]. For example, the search strategy in MEDLINE was "implant overdenture" [All Fields] OR "implant overdentures" [All Fields] OR IOD [All Fields] OR IODs [All Fields] OR "Denture, Overlay" [MeSH] AND ("immediate loading" [All Fields] OR "Immediate Dental Implant Loading" [MeSH]). In addition, reference lists of relevant articles were manually searched to identify eligible studies. The two authors (MS and KF) independently screened the titles and abstracts of the retrieved articles to identify studies that fulfilled the predetermined eligibility criteria. They also reviewed the full texts of the shortlisted articles to arrive at the final selection of studies for inclusion in this meta-analysis. Multiple publications from the same study were considered as a single study. In addition, previous review articles on the subject were searched, as well as the reference lists of the articles already identified for further potentially relevant publications. Although there was no language restriction, the minimum requirement was access to an English version of title and abstract.

2.3. Data synthesis and assessment of risk of bias

Data regarding study design, setting, follow-up period and frequency, number of participants, eligibility criteria, timeframe of treatment, method of MBL measurements, sex distribution, prosthetic situation in upper jaw, and mean and standard deviation (SD) of MBL were retrieved from the selected articles and checked by the other reviewer (KF) for completeness. In cases of studies with incomplete data, we contacted to the corresponding author for the additional information. Data syntheses were performed by one reviewer (MS) using Review Manager
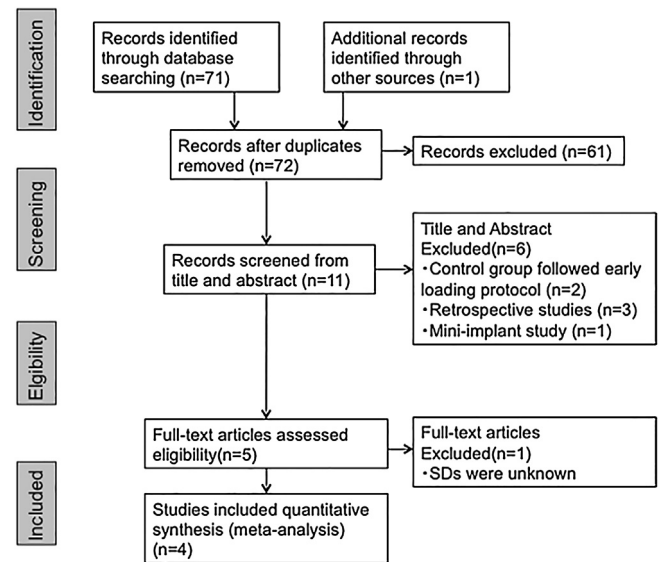

Fig. 1. Flowchart of the study process.

5 (http://community.cochrane.org/tools/review-production-tools/revman-5). Two reviewers (MS and KF) independently assessed the risk of bias of the included studies using the Cochrane risk of bias tool. In cases of heterogeneity in data among the included studies, mean differences and 95% confidence intervals (CIs) for pooled data were calculated using the random effects model and presented using forest plots. Three additional meta-analyses were conducted including only RCTs, only 2-IOD, and studies that evaluated horizontal bone loss. A P-value < 0.05 was considered statistically significant.

3. Results

3.1. Screening and selection

Fig. 1 shows the flow diagram of study screening and selection. An electronic search yielded 71 relevant articles, and manual search identified one more study. Eleven articles were screened based on the title and abstract. Through full-text review, six studies were excluded because their study designs did not meet the eligibility criteria. Specifically, two studies compared immediate-loading protocol and early-loading protocol, three studies employed retrospective design and one study dealt with implants narrower than 3 mm. Finally, two RCT from Egypt [20,21], one from the United States (USA) [22] and one non-RCT from France [23] were included in the qualitative and meta-analysis. Since one study provided mesial and distal MBLCs and their SDs separately, we requested the authors of the Egypt study to provide the mean values and SDs of MBL of averaged data of mesial and distal.

3.2. Characteristics of the included studies

Table 1 lists the included studies and their characteristics. Each of the four studies recruited participants from a university hospital. While participants in the French study were sex-matched, the US and Egyptian studies had a higher proportion of male compared to female subjects. Although the mean ages of participants at enrolment in the French and US studies were comparable (63.5 and 66.4 years old on average), one Egyptian study had slightly younger subjects (59.6 years old on average) and the other Egyptian study did not disclose participants' ages. The follow-up period of one Egyptian study (36 months) was longer compared to those

Table 1
Characteristics of included studies.

Study	No. of participants (male/female)	No. of patients in IL	No. of patients in CL	Time of IL	Time of CL	Implant system	Attachment	Radiographic method	Radiographic Time points	6M	1Y	2Y	3Y	Time point of baseline	No. of implant in each patient	Maxilla	Mandible	Age of participants	Torque for IL	Study design	Statistical analysis	Survival rates (implant level)	Dropouts (IL/CL)
Stephan et al. [23]	26(13/13)	17	9	2 day	3M	MK3 Nobel Biocare	Bar	Panoramic	12, 24M		○IL<CL	○IL=CL	○IL=CL	Abutment connection	3	Edentulous	Edentulous	63.5	>30Ncm	nonRCT	Patient level	IL:100%, CL:100%	0
Elsyad et al. [20]	36(22/14)	15	15	0 day	3M	Implant direct screw plant	Ball	CBCT	1Y, 3Y	-	○IL>CL	-	○IL>CL	4 months after implant placement	2	Edentulous	Edentulous	NA	NA	RCT	Patient level	IL:93% (2 implants lost), CL:100%	6(3/3):17%
Elsyad et al. [21]	36(20/16)	18	18	0 day	3M	Tiologic implant	Locator	Standardized periapical radiograph	6M, 12M	○IL>CL	○IL>CL	-	-	Delivery of IOD	2	Edentulous	Edentulous	59.6	>35Ncm	RCT	Patient level	IL:94% (2 implants lost) CL:100%	3(2/1):8%
Schincaglia et al. [22]	32(20/12)	15	15	0 day	3M	Astra Dentsply	Locator	Standardized periapical radiograph	6M, 12M	○IL=CL	○IL<CL	-	-	After the implant placement	2	Edentulous with exception of 2 in DL group (natural dentition and implant-supported fixed prostheses), 3 in the IL group (IODs).	Edentulous	66.4	>20Ncm	RCT (ITT analysis)	Patient level	IL:93% (2 implants lost) CL:100%	2(2/0):6%

of the other Egyptian study (12 months), the French study (24 months) and the US study (12 months); therefore, meta-analysis was conducted at the two common time points (6 and 12 months). Regarding the number of implants placed in each patient, though French study placed three implants (one in the center and the other two bilaterally, 12–15 mm distal to the center one), the other studies placed two implants bilaterally in canine or lateral incisor regions.

The brands of implants chosen in each study were Implant Direct (LLC, Spectra System Screw Plant, Calabasas, CA, USA) in one Egyptian study, Tiologic Implants in the other Egyptian study, MKIII (Nobel Biocare) in the French study and OsseoSpeed implants (Astra Tech/Dentsply) in the American study. All the implant systems are currently used products. The sites of implant placement were canine/lateral incisor region in the US study, center and 12–15 mm distal bilaterally in French study and canine region in two Egyptian studies. There were no differences between test group and control group in each study. Required insertion torque for immediate loading was 30 Ncm in the French study, 35 Ncm in one Egyptian study and 20 Ncm in the US study. The other Egyptian study did not address torque. In the French study, implants were loaded 2 days after placement in IL group, while in the other three studies implants were loaded at the same day of surgery. In the CL group, implants were loaded 3 months after placement. Regarding the dental condition of the opposing jaw, a majority of the patients wore a maxillary complete denture. However, in the US study, three subjects in the IL group and two in CL group did not use maxillary complete dentures. In terms of attachment system for the IODs, bar attachments were used in the French study, ball attachment in one of the Egyptian studies, and locator attachment in the other two studies. MBLCs were measured on panoramic X-rays in the French study and cone-beam computed tomography (CBCT) in one of the Egyptian studies, while the other two studies utilized standardized periapical radiographs. In the study in which panoramic radiographs were used, bone levels were determined by applying a distortion coefficient (true bone height which is equal to the true implant length, multiplied by the bone height measured on the radiograph, which was then divided by the implant length measured on the radiograph). The baseline of bone level measurement was set as the time of abutment connection in the French study, just after implant placement in the US study, at the time of delivery of IOD in one Egyptian study and 4 months after surgery in the other Egyptian study. Statistical analyses were conducted at patient-level in all studies.

3.3. Marginal bone level changes (MBLCs)

In the French study, although the CL group had higher MBLCs at 12 months follow-up, IL and CL were comparable at 24 months follow-up. In the two Egyptian studies, IL exhibited higher MBLCs through the whole observation period. In the US study, MBLCs were comparable at 6 months, but CL exhibited higher MBLCs at 12 months follow-up.

3.4. Survival rates

The French study reported 100% survival rates in both IL and CL groups. The other three studies lost 2 implants in their IL groups; thus, survival rates were 92–93%. Survival rates of the CL groups in all studies were 100%.

3.5. Risk of bias

Table 2 summarises the risk of bias in each study. On the whole, the bias risks of these studies appear relatively low. The Egyp-

Table 2
Risk of bias in included studies assessed by reviewers [23,20–22].

	Stephan 2007	Elsyad 2012	Elsyad 2014	Schincaglia 2016
Random sequence generation	-	+	+	+
Allocation concealment	-	+	+	+
Blinding of participants and personnel	-	+	?	+
Blinding of outcome assessment	?	?	?	?
Incomplete outcome data	+	?	?	+
Selective reporting	+	+	+	+
Other bias	?	?	?	?

−:high risk, +:low risk, ?:unknown.

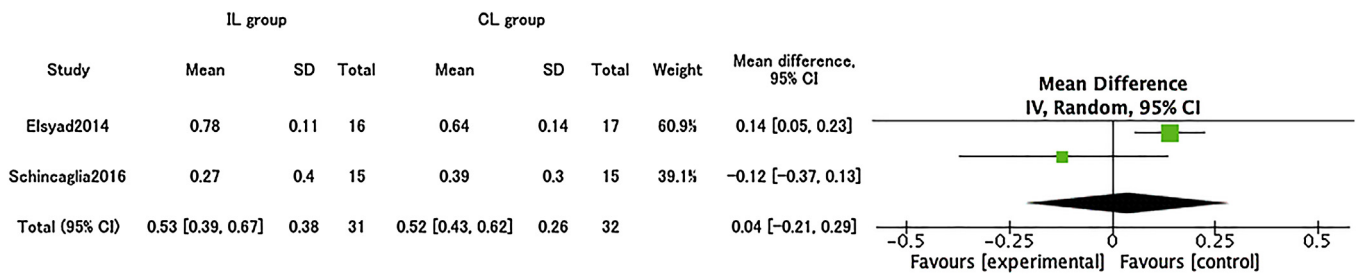|	IL group			CL group					
Study	Mean	SD	Total	Mean	SD	Total	Weight	Mean difference, 95% CI	Mean Difference IV, Random, 95% CI
Elsyad2014	0.78	0.11	16	0.64	0.14	17	60.9%	0.14 [0.05, 0.23]	
Schincaglia2016	0.27	0.4	15	0.39	0.3	15	39.1%	−0.12 [−0.37, 0.13]	
Total (95% CI)	0.53 [0.39, 0.67]	0.38	31	0.52 [0.43, 0.62]	0.26	32		0.04 [−0.21, 0.29]	

Fig. 2. Forest plots for comparison of marginal bone level changes (MBLCs) between the IL and CL groups included in this systematic review at 6 months follow-up. The MD with 95% CI in each study and the overall effect are presented. Positive MD indicates more bone loss in the IL group in comparison with the CL group. IL, immediate loading; CL, conventional loading; MD, mean difference; CI, confidence interval.
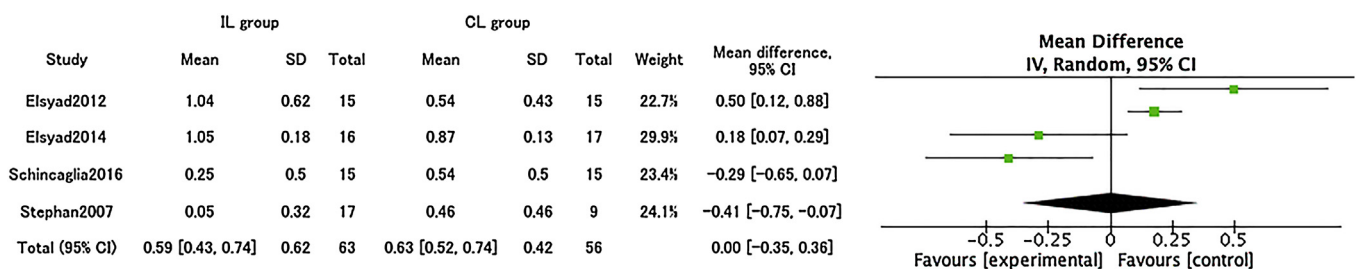
	IL group			CL group					
Study	Mean	SD	Total	Mean	SD	Total	Weight	Mean difference, 95% CI	Mean Difference IV, Random, 95% CI
Elsyad2012	1.04	0.62	15	0.54	0.43	15	22.7%	0.50 [0.12, 0.88]	
Elsyad2014	1.05	0.18	16	0.87	0.13	17	29.9%	0.18 [0.07, 0.29]	
Schincaglia2016	0.25	0.5	15	0.54	0.5	15	23.4%	−0.29 [−0.65, 0.07]	
Stephan2007	0.05	0.32	17	0.46	0.46	9	24.1%	−0.41 [−0.75, −0.07]	
Total (95% CI)	0.59 [0.43, 0.74]	0.62	63	0.63 [0.52, 0.74]	0.42	56		0.00 [−0.35, 0.36]	

Fig. 3. Forest plots for comparison of marginal bone level changes (MBLCs) between the IL and CL groups included in this systematic review at 12 months follow-up. The MD with 95% CI in each study and the overall effect are presented. Positive MD indicates more bone loss in the IL group in comparison with the CL group. IL, immediate loading; CL, conventional loading; MD, mean difference; CI, confidence interval.

tian studies and US study reported adequate random sampling and allocation concealment. The French study did not employ random allocation or propensity analysis and, consequently, presented a high risk of sampling bias. As all studies were registered in clinical trial registries, and all outcome measures were described in the study protocols, the risk of selective reporting bias appeared to be low. The follow-up rates of these studies were relatively high (100% [23], 83% [20], 92% [21] and 94% [22], respectively). The US study employed intention-to-treat analysis, which lowered the risk of overestimating treatment effect.

3.6. Meta-analyses

Forest plots of conducted meta-analyses are illustrated in Figs. 2–4. Meta-analyses were performed for comparison of MBLCs at patient level between IL and CL groups at 6 months and 12 months follow-up. A total of 63 participants at 6 months and 119 participants at 12 months were pooled for data synthesis. Three studies had measured the mesial and distal MBLCs and estimated the mean and standard deviation (SD) of each subject, while the other study which used CBCT had measured MBLCs at four points
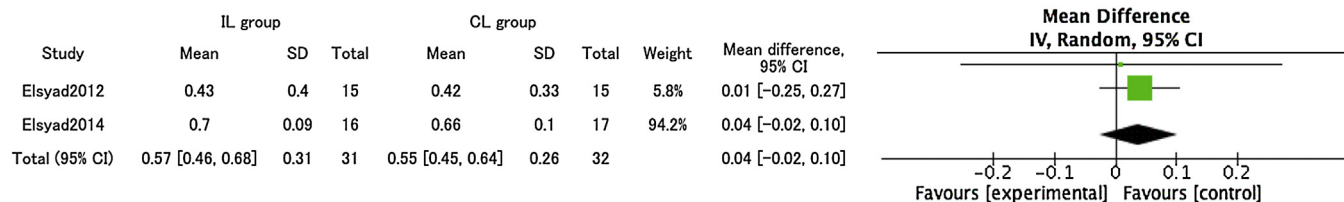
Fig. 4. Forest plots for comparison of horizontal marginal bone loss between the IL and CL groups included in this systematic review at 12 months follow-up. The MD with 95% CI in each study and the overall effect are presented. Positive MD indicates more bone loss in the IL group in comparison with the CL group. IL, immediate loading; CL, conventional loading; MD, mean difference; CI, confidence interval.

around the implants (mesial, distal, lingual and labial). Therefore, we picked up only the mesial and distal measurements and worked out their averages for use in the meta-analysis.

At 6 months follow-up, the mean MBLCs were 0.53 mm (95% CI: 0.39, 0.67) in IL group and 0.52 mm (95% CI: 0.43, 0.62) in CL group. The IL group showed slightly more bone loss than the CL group without any statistically significant differences (mean difference: 0.04, 95% CI: −0.21, 0.29, p = 0.76) (Fig. 2). At 12 months post-treatment, MBLCs in the IL and CL groups were 0.59 [0.43, 0.74] and 0.63 [0.52, 0.74] respectively. From the results of meta-analysis, they are almost equivalent (mean difference: 0.00, 95% CI: −0.35, 0.36, p = 1.00) (Fig. 3). Subgroup meta-analysis involving only the three RCTs, which included the studies with 2 implants, revealed similar results at 12 months post-treatment (mean difference: 0.13, 95% CI: −0.22, 0.48, p = 0.46). Subgroup analysis regarding horizontal bone loss in two studies at 12 months also revealed the same trend (IL: 0.57 mm [0.46, 0.68], CL: 0.55 mm [0.45, 0.64], mean difference: 0.04, 95% CI: −0.02, 0.10, p = 0.23) (Fig. 4). The prospect of publication bias was not assessed on a funnel plot, due to the small number of studies included in the study.

4. Discussion

In order to answer the clinical question, this systematic review identified 3 RCTs and one non-RCT that compared MBLCs around the implants supporting a IOD between 2 loading protocols. Meta-analysis of these studies did not reveal statistically significant differences between them.

Not only were the differences not statistically significant, but the range of 95% CI in each comparison demonstrated unsubstantial difference from a clinical perspective. As proposed by Albrektsson et al. and other literature, it is widely accepted that peri-implant marginal bone loss less than 1.5 mm is one of the requirements for implant success [24–26]. From this criteria, mean values of MBLCs in both IL and CL were consistently less than 1.5 mm in all included studies at each time point. This suggests that loading protocol should be regarded as clinically acceptable. Besides, no significant difference was found in the MBLCs between the 2 groups. Even the largest difference, which was found by the subgroup analysis, was found to be 0.13 (95% CI: −0.22, 0.48), which does not seem to be clinically significant. In terms of horizontal bone loss, two studies evaluated this clinical parameter and the mean difference found was 0.04 (95% CI: −0.02, 0.10). While clinical importance of horizontal bone loss evaluation is still open to discussion, horizontal bone loss smaller than 0.1 mm is apparently negligible from the clinical point of view.

Several systematic reviews on this topic including data of fixed reconstruction have been published. In terms of single implant crowns, Benić et al. revealed in their systematic review published in 2014 that the standardized mean difference of MBLCs were −0.05 mm (95% CI: −0.41, 0.31) at 1 year follow-up and −0.06 mm (95% CI: −0.45, 0.34) at 2 years follow-up (the negative sign indicates that IL group showed lower bone loss) [27]. Esposito et al. reported no significant differences in MBLCs (MD of 0.10 mm more

bone loss in CL group, 95% CI: 0.01, 0.20) at 1 year follow-up in a Cochrane systematic review [28]. Other reviews also arrived at the same results [29,30].

This systematic review had several limitations. Firstly, although eligibility criteria excluded retrospective studies and case series, study designs are not absolutely identical. (3 RCTs and 1 non-RCT). Secondly, the type of radiographs used for measuring MBLCs varied from study to study. Two studies employed standardized periapical radiographs, while the other two studies used CBCT and panoramic X-rays. While periapical radiographs and CBCTs are acceptable in measuring peri-implant bone levels [34,35], panoramic X-rays inevitably distort the images especially in the anterior region. Furthermore a cervical spine is superimposed in the areas at which the implant-supporting overdentures are typically placed [36]. Besides, it is difficult to distinguish between, or correctly measure magnitudes of MBLCs less than 1 mm on panoramic X-rays. On the other hand, standardized periapical radiographs are not always applicable to implants placed in edentulous mandibles due to the anatomical difficulties to situate the customised film holder correctly [23], and higher doses of radiation exposure by CBCT might not always be justified from an ethical perspective [37,38]. Thirdly, the time of indicating the baseline is different in each study, varying from the time of abutment connection, just after the implant placement, at the delivery of IOD to 4 months after surgery. This baseline should be standardized in order to implement optimal meta-analyses. Furthermore, though two studies followed-up for more than 12 months (24 and 36 months each), meta-analyses could only be carried out at 6 and 12 months. It has been well documented that MBLCs around implants would occur during the first year of function; however, future studies with a longer follow-up periods should be undertaken. Fourthly, since the number of researches met our inclusion criteria is limited, the sample size is relatively small. More RCTs are anticipated to complement the number of subjects for the future meta-analyses. Lastly, as Müller and Schimmel stated in their systematic review, early and conventional loading protocols are associated with fewer implant failures than immediate loading during the first year [26]. While we could not conduct systematic analyses of the failure rates due to the fact that we chose studies in the interest of MBLCs, assessment of survival rates was beyond our focus for this systematic review.

5. Conclusions

From the results of this systematic review and meta-analysis, there were no statistically significant differences in MBLCs around implants supporting a mandibular IOD irrespective of loading protocol. There was heterogeneity regarding evaluation and interpretation of bone level changes and assessment time frame. Thus these parameters should be standardized in future studies.

Conflict of interest

None.

Acknowledgments

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