Clinical Oral Investigations (2023) 27:5935–5946
https://doi.org/10.1007/s00784-023-05205-w

RESEARCH

Immediate versus conventional loading of mandibular implant-retained overdentures: a 3-year follow-up of a randomized controlled trial

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Received: 1 October 2022 / Accepted: 11 August 2023 / Published online: 23 August 2023

Abstract

Objectives There is a scarcity of randomized clinical trials (RCT) that report medium- and long-term results and a lack of consensus in the literature on the predictability of immediately loaded unsplinted narrow diameter implants supporting mandibular overdentures. This RCT compared the performance of conventional (CL) and immediate loading (IL) of mandibular overdentures retained by two narrow-diameter implants for 3 years.

Materials and methods Patients from an RCT treated with CL or IL were invited to attend to 2- and 3-year follow-ups. Clinical, radiographic, functional, and oral health-related quality of life parameters were evaluated. Prosthetic maintenance events, biological complications, and success and survival rates were also recorded. The data were tested by multilevel mixed-effects linear regression analysis and chi-squared tests.

Results The 1-year survival rates of 90% in the CL group and 85% in the IL group were maintained as no implants were lost between 1 and 3 years. The marginal bone loss (MBL) in the IL group was significantly lower after year 3 (-0.04; $p < 0.01$). Significant changes were found only for the intra-group comparisons in the third year of function: (i) CL and IL presented similar progression of implant stability, MBL, and posterior bone area resorption; (ii) while CL started deteriorating of masticatory function, IL still exhibited functional evolution and (iii) oral comfort domain in the CL and pain domain in the IL were improved.

Conclusion Although IL experienced the lowest MBL after 3 years, the outcomes showed that both loading protocols result in predictable medium-term rehabilitation when monitored annually.

Clinical relevance It can be expected that in the third year of function, patients with immediate loading may present more complaints related to general performance even with acceptable masticatory function and self-reported improvements in oral comfort.

Keywords Implant-retained mandibular overdentures · Conventional loading · Immediate loading · Masticatory function · Oral health-related quality of life

Introduction

The robust evidence in literature currently leads many clinicians to recommend treatment of completely edentulous individuals with implant mandibular overdentures (IMO) retained by 2 implants using a conventional loading (CL), regardless of implant diameter [1], due to the cost–benefit effective nature of this treatment and the rapid increase in patient satisfaction [2]. However, patients who have undergone CL treatment have reported discomfort and trauma while using conventional complete dentures during the 3-month waiting period before occlusal loading [3]. The

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instability and lack of retention of the provisional dentures have resulted in inadequate function, adding to the patient's overall discomfort [3]. In addition, patients sometimes also experience social pressure during the waiting period [4]. In this sense, studies have demonstrated that immediate loading (IL) is able to improve oral health-related quality of life (OHRQoL) faster than CL [4, 5] and that satisfaction with IMO generally increases progressively from the first months to the second year, along with comfort, aesthetics, and the ability to masticate and speak [6].

Despite the encouraging results for the implementation of IL in clinical practice during rehabilitation with IMO, conclusions from recent systematic reviews conducted in the last 5 years are still contradictory or demonstrate the equivalence between CL and IL, indicating (I) a preference for the adoption of early or late loading protocols after analyzing the influence of biomechanical factors and the predictive clinical outcomes for the success of the IL protocol [7]; (II) that meta-analyses showed no statistically significant difference between both loading protocols in relation to implant failure or marginal bone loss for implants in IMO retained by non-splinted systems [8]; (III) that randomized clinical studies show that the healing period after implantation is a risky period and requires care and monitoring when adopting IL, since few studies have monitored the implant stability coefficient (ISQ) and periotest value [9]; (IV) that prospective clinical studies show similar success and survival rates and marginal bone loss for both loading protocols, but lower probing depth and plaque index in CL, along with favorable ISQ values (3 months) [10]; (V) similar peri-implant health and marginal bone loss in non-splinted retention systems, implant survival rates of 100% and 94.7% for Locator attachments with IL and CL, respectively [11] and inconclusive results for some peri-implant outcomes and prosthetic complications, and (VI) that despite the greater probing depth observed when adopting IL, no type of attachment, implant number, or loading protocol presented a clear advantage [12].

All recent systematic reviews that analyze IL in IMO treatment persistently indicate that the conclusions of the meta-analysis are constrained by the divergent design of the included clinical studies, which vary widely in terms of sample size, studied outcomes, and follow-up times. In addition, few studies have evaluated patient-centered outcomes to evaluate IMO treatment on OHRQoL and satisfaction, and they employ several instruments resulting in difficulty comparing studies [13]. Moreover, the conclusions of the meta-analyses are further limited by the relative scarcity of treatment results from medium- and long-term clinical trials [14].

Considering the scarcity of randomized clinical trials that report medium- and long-term results and the lack of a consensus in the literature on the predictability of the IL protocol during the rehabilitation of patients with IMO, the primary aim of the present study was to evaluate the differences in peri-implant health, marginal bone level (MBL), and implant survival rates, between CL and IL of IMO retained by two unsplinted narrow diameter implants at a follow-up period of 3 years. The secondary objectives were to compare posterior bone resorption of the mandible, functional, and patient-centered outcomes and prosthetic maintenance events between the two groups.

Materials and methods

Sample population and study design

The present longitudinal study is a 3-year follow-up of IMO wearers that participated in 3-month randomized controlled trial (RCT) that compared the performance of IL and CL protocols during rehabilitation with two unsplinted narrow diameter implants (Facility-Equator system) used as IMO retainers. A detailed description of this study's methodology, study design, patient's allocation, and inclusion and exclusion criteria, can be found in this previous study [15]. A new sample size calculation was performed to verify that this 3-year follow-up study has sufficient power for the new analyses presented here. The sample size calculation (G*Power) was based on the probing depth results from the previous 1-year follow-up study [16], as a significant difference in probing depth was found in this period between groups ($p \leq 0.01$), with mean values and standard deviations of CL group (2.17 ± 0.45) and IL group (1.50 ± 0.38). When using a power of 80%, the results of this calculation indicated that $n = 8$ in each group would be needed in this study, thus $n = 16$ overall. Additional post hoc sample size calculations based on the results by Katkut et al. (2019) [17] indicate that sample sizes of 10 and 16 are sufficient to compare ISQ and marginal bone loss outcomes between groups treated with IL and CL respectively. The 3-year follow-up was performed at the Service of Maintenance of Complete Dentures, Post-Graduation Clinic of Complete Dentures, from September 2017 to October 2019. The study protocol was approved by the Institutional Ethics Committee (protocol 3.725.829) and reported following the Consolidated Standards of Reporting Trials (CONSORT) guidelines for RCT [18]. Each patient who agreed to participate in the study signed a written informed consent form. IMO users were monitored annually over a 3-year period. All subjects were initially rehabilitated with maxillary conventional complete dentures and implant-retained mandibular overdentures (IMO) and all participants received maintenance appointments as necessary. When necessary, all the prosthetic interventions required were performed and when prostheses were inadequate, they were replaced by an experienced prosthodontist (AJS). In the original RCT [15], a total of 20 patients were selected and 10 patients were randomly allocated to each group through randomization. In relation, the surgical interventions and prosthetic treatment, two dental implants (NDIs—ø2.9 × 10 mm, Facility NeoPoros, Neodent Osseointegrated Implants, Curitiba, Brazil) were inserted in the inter foramen region, approximately 5 mm anterior to the mental foramina and a minimum inter-implant distance of 20 mm using a traditional single-stage surgical protocol. The implant surgery drill sequence followed the protocol recommended by the implant manufacturer and was executed by an experienced surgeon (OLCJ). The bone strength during the preparation of the bone site and the implant placement, based on subjective perception of the surgeon, was recorded based on the bone quality described by Lekholm & Zarb (1985) [19]. The insertion torque was recorded and values greater than 30 Ncm were considered adequate for IL. If IL was adopted, the IMO was loaded after surgery by connecting the O-ring cylinder for the Facility Equator attachment intraorally, using self-curing acrylic resin (VIPI Flash®, VIPI industry, São Paulo, Brazil) to fit the system to the internal surface of the prosthesis. In the CL group, the intaglio of the mandibular prosthesis was adjusted and rebased with an intermediate liner (Trusoft, Bossworth Company, USA) until the end of the 3-month bone healing period. The flowchart of the study is shown in Fig. 1.

Clinical outcomes

The peri-implant health was assessed through clinical examination of the 4 implant faces to monitor the visible plaque index (VPI), peri-implant inflammation (PI), calculus presence (CP), probing depth (PD), and bleeding on probing (BOP). The implant stability analysis was performed by measuring the ISQ by connecting an A3 type smartpeg directly to the Equator attachment. The measurements were performed in triplicate on all 4 implant faces using an Ostell device (Integration Diagnostics AB, Göteborg, Sweden). All clinical evaluation has made by a calibrated operator (APP).

Radiographic evaluation: marginal bone loss and posterior bone resorption

The MBL and the posterior area index (PAI) were analyzed using standardized digital panoramic radiographs and all analyses were performed by a single, calibrated examiner (APP). Radiographs calibration involved calculating the Intraclass Correlation Coefficient (ICC) based on two separate analyses at a one-week interval and the outcome was considered acceptable for a correlation index ≥ 0.80. MBL measurements were made at the mesial and distal side of each implant using the linear measurements tools available in the DBSwin 4.5 software (DürrDental,Bietigheim-Bissingen,Germany). The external edge of the implant head was used as a reference point during the evaluation, and the implant length was used as reference to correct distortions [20, 21]. The PAI was determined following the methodology proposed by Elsyad et al. [22]. The delimitation of reference and experimental areas traced in digital panoramic radiographs was performed using the Photoshop software, and measurements were subsequently performed in the ImageJ software. The PAI was calculated by dividing the experimental area by the reference area, and the average of the PAIs on both sides was reported as the final PAI value.

Functional and patient-centered outcomes

The masticatory performance (MP) test was used to analyze the masticatory function. In this test, patients were instructed to masticate a 3.7 g portion of Optocal test food for 40 chewing cycles, counted by a calibrated operator (APP). The triturated test material was subsequently expelled on filter paper, rinsed with water, and dried at room temperature for 7 days. The material then passed through a sieve stack composed of sieves with decreasing opening sizes (5.6–0.5 mm) mounted on a sieve shaker for 20 min. The material retained in each sieve was weighed and inserted into the Rosin–Rammler equation to calculate the theoretical opening through which 50% of the particles pass (MPX50) and the particle size homogeneity (MPB). The masticatory efficiency (ME) was calculated as the percentage of material weight retained in the 5.6 and 2.8 mm sieves [23]. This methodology is commonly employed in literature by our group [24–26] and others [27–29]. The impact of IMO use on OHRQoL was evaluated through the Dental Impact on Daily Living (DIDL) questionnaire [30]. This questionnaire comprises 36 questions divided into 5 domains that map patient satisfaction regarding the appearance, pain, oral comfort, general performance, and chewing. The final scores for each domain represent the average score of the questions in each domain, and are classified as dissatisfied (< 0), relatively satisfied (0–0.69), or satisfied (0.7–1.0) [31].

Complications and prosthetic maintenance events

Complications of the prostheses related to displacement of Facility-Equator attachment, fracturing of the mandibular prosthesis, construction of new overdentures, replacement of the Facility- Equator attachment (transmucosal length changes), matrix recapture or replacement, artificial teeth fractures, tissue reopening for the abutment replacement, surgery for vestibular deepening and removal of the peri-implant keratinized mucosa, and rebasing of the prosthesis were registered. Events related to prosthesis maintenance such as pink nylon O-ring exchanges and prosthesis

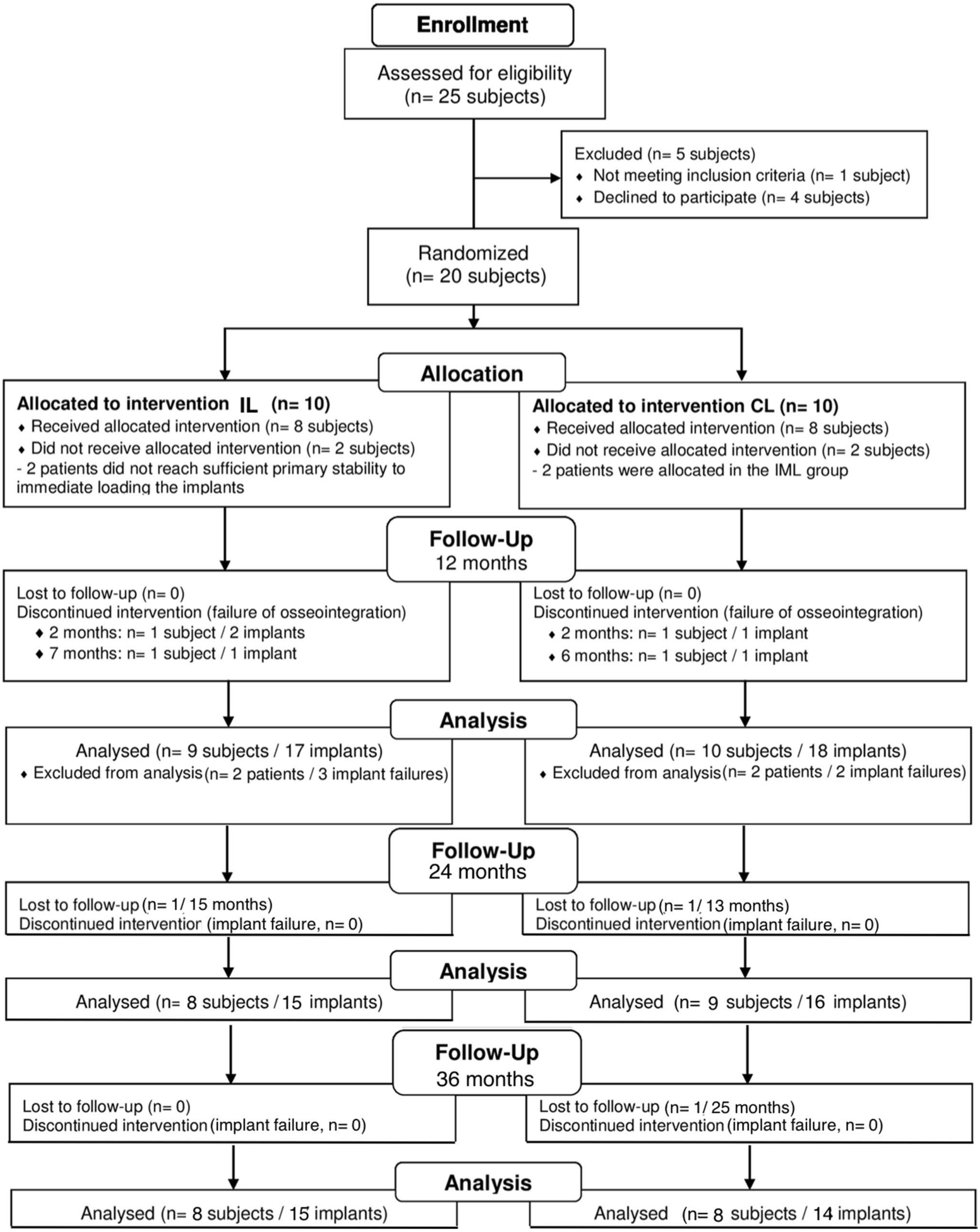

Fig. 1 CONSORT flow diagram

adjustments were also recorded. The following information was also reported: type of complication, number of patients, and number of events.

Biological complications and survival rates

Biological complications such as mucositis or peri-implantitis were diagnosed as reported in the recent World Workshop on the classification of periodontal and peri-implant diseases [32]. The success of the implants was evaluated according to the clinical criteria proposed by Albrektsson [33]: the absence of clinical implant mobility, the absence of peri-implant continuous radiolucency, and the absence of infections, persistent pain and discomfort, and marginal bone loss < 1.5 mm. Implant failure is defined by its absence from the mouth or determined when a condition manifests that requires its removal, such as radiolucency around the implant, mobility, suppuration, pain, or pathological processes such as osteonecrosis, overloading or advanced peri-implantititis. When implants are still in function in the follow-up, they are categorized into the survival category; survival rates were calculated at 2 and 3 years.

Statistical analysis

The VPI, PI, and BOP indices were grouped as follows; numeric scores of 0 and 1 correspond to the absence (numeric score 0) of the respective symptoms and numeric scores 2 and 3 correspond to their presence (numeric score 1) and in the final model was considered the scores means of the 4 faces. The average of the 4 faces analyzed was used for the ISQ and PD values. The survival rate of the groups was calculated using the Kaplan–Meier survival analysis. Initially, the data was tested for normality using the Shapiro–Wilk test. Considering that the data have a hierarchical structure (levels), as the time periods (3) are nested in the subjects, mixed effects multilevel linear regression models were used to test the changing trends of the outcome variables over time and to fit a growth model to repeated measures (longitudinal) data. Each outcome had the dependent variable of reference (time: 1 year and loading type: CL) and the time periods were grouped as the predictor variable (2 and 3 years). Time points were established as the fixed effect to test for linear trends and the age of individuals was selected as the random effect. Due to the normality of the data, the chi-squared test was used to verify differences in maintenance and complication events (categorical outcomes) between the time points. Values of $p \leq 0.05$ were considered significant. All statistical analyses were performed using Stata 14.0 software (StataCorp LP, Texas, USA).

Results

Three losses were registered during initial 1-year follow-up, 2 in the CL group (1 male and 1 female) and 1 male in the IL group. Thus, the remaining sample of the CL group comprises 6 female and 2 males with an average age of 68.9 years and a mean time since mandibular edentulism of 25 years. The IL group comprised 5 females and 3 males with an average age of 70 years and a mean time since mandibular edentulism of 27.4 years. Five implants were lost (3 IL and 2 CL) during the first year resulting in the survival rate of 90% in the CL group and 85% in the IL group (Fig. 2). After replacement with new cone morse implants (ø = 3.5 × 9 mm, Titamax Cone Morse Implant—Neodent Implants Osseointegrated, Curitiba, Brazil), no implants were lost between 1 and 3 years. These cone morse narrow diameter implants were not included in the subsequent analysis. In the CL group, 1 patient had mucositis in the right implant, this condition was absent after 3 years of treatment. The complete raw data are listed in Table S1.

Table 1 describes the inter-group analysis and shows differences between the IL and CL groups in the second year, with significantly lower PD ($p < 0.01$), VPI ($p = 0.03$), and MPB ($p < 0.01$). At year 3, only the MBL differed between the groups ($p < 0.01$), as the IL group presented less bone loss in the peri-implant region (Δ = -0.04). Table 2 lists the prosthesis-related complications and maintenance events (Table 2); no differences were observed between both groups after 2 and 3 years.

The changes over time for the CL group (Table 3) indicate that the average ISQ in the 3rd year increased significantly compared to the 1st year (+5.47%, $p < 0.01$). The VPI

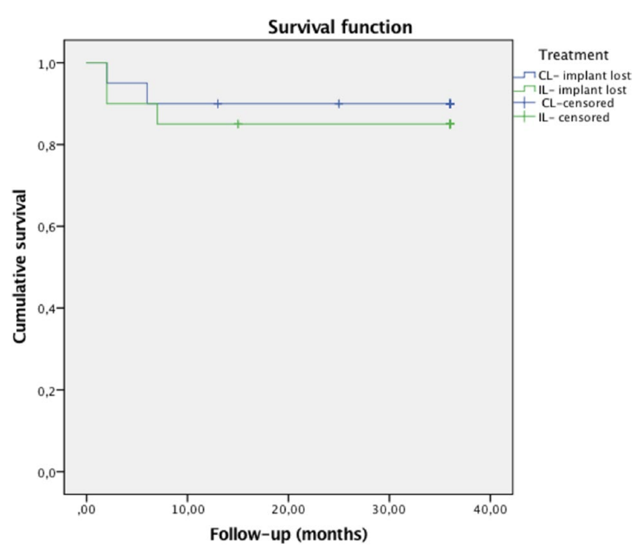

Fig. 2 Kaplan–Meier survival curve

Table 1 Multilevel mixed-effects linear regression of clinical, radiographic, and masticatory outcomes between groups

		1 year	2 years		3 years	
	Conventional loading	Immediate loading	Conventional loading	Immediate loading	Conventional loading	Immediate loading
Clinical outcomes		coef. (95% CI)	Ref	coef. (95% CI)	Ref	coef. (95% CI)
PD	1.00	-0.21 (-0.82;0.39)	1.00	**0.87 (0.28;1.46)***	1.00	0.44 (-0.06;0.95)
ISQ	1.00	**-0.23 (-0.37;-0.08)***	1.00	-0.00 (-0.01;0.01)	1.00	-0.89 (-4.76;2.98)
BOP	1.00	-0.27 (-0.70;0.16)	1.00	**	1.00	**
VPI	1.00	0.31 (-0.06;0.68)	1.00	**1.05 (0.05;2.05)***	1.00	1.9 (-0.14;3.94)
PI	1.00	**	1.00	**	1.00	**
Radiographic outcomes						
MBL	1.00	-0.13 (-0.68;0.40)	1.00	-0.23 (-1.07;0.60)	1.00	**-0.28 (-0.42;-0.15)***
PAI	1.00	-0.16 (-0.87;0.55)	1.00	-0.41 (-1.14;0.32)	1.00	-0.21 (-1.10;0.67)
Masticatory performance						
MPX50	1.00	-0.09 (-0.74;0.54)	1.00	0.09 (-0.21;0.40)	1.00	-0.11 (-1.09;0.86)
MPB	1.00	-2.47 (-6.78;1.84)	1.00	**-0.19 (-0.29;-0.08)***	1.00	0.33 (-0.25;0.92)
ME5.6	1.00	-0.13 (-0.77;0.50)	1.00	0.10 (-0.03;0.23)	1.00	-0.71 (-1.70;0.28)
ME2.8	1.00	-0.38 (-1.27;0.50)	1.00	-0.46 (-0.94;0.01)	1.00	-0.08 (-0.86;0.69)

* variables with statistically significant difference. ** collinearity; constant variables

Table 2 Type, number of patients (NP), and number of events (NE) of prosthetic intercurrences during the 3-year follow-up (chi-squared test)

Interventions	Conventional loading						Immediate loading					
	Second year			Third year			Second year			Third year		
Type of intercurrences	NP	NE	%	NP	NE	%	NP	NE	%	NP	NE	%
Complications												
Equator attachment dislodgement	1	1	1.90	0	0	0	0	0	0.00	0	0	0
Matrix dislodgement (female)	0	0	0	0	0	0	0	0	0.00	0	0	0
Prosthesis fracture	0	0	0	0	0	0	1	1	2.08	0	0	0
New overdentures	3	3	5.80	1	1	6.60	2	2	4.17	2	2	5.56
Equator attachment replacement	2	3	5.80	1	1	6.60	2	4	8.33	2	3	8.33
Matrix recapture (female)	5	10	19.60	2	2	13.30	5	9	18.75	3	7	19.44
Artificial tooth fracture	1	1	1.90	0	0	0	1	1	2.08	0	0	0
Matrix replacement (female)	1	2	3.90	0	0	0	1	1	2.08	0	0	0
Reopening for attachment replacement	0	0	0	0	0	0	1	1	2.08	0	0	0
Vestibular deepening surgery	1	1	1.90	0	0	0	0	0	0.00	0	0	0
Removal of keratinized mucosa	1	1	1.90	1	1	6.60	0	0	0.00	0	0	0
Prosthesis rebasing	2	2	3.90	0	0	0	4	5	10.42	1	1	2.78
Total	12	24	47	6	6	40	17	24	50.00	8	13	36.11
Maintenance events												
Prothesis adjustment	4	10	19.60	1	1	6.60	4	12	25.00	1	1	2.78
Nylon O-ring replacement	6	17	33.30	3	8	53.30	6	12	25.00	6	22	61.11
Total	10	27	52.94	4	9	60	10	24	50.00	7	23	63.89

doubled between the 2nd and the 3rd year ($p < 0.01$), while the MBL increased slightly (+4.17%, $p < 0.01$). The bone area of the posterior region increased by 5.83% between the 1st and the 2nd year ($p < 0.01$), followed by a minor but significant reduction of 0.79% in the third year ($p < 0.01$). In the CL group, 2 out of 8 individuals (25%) experienced loss of posterior bone area at the end of the 3rd year. Significant reductions in average triturated particle size (MPX50 -11.25%, $p = 0.04$), between the 1st and the 2nd year, followed by an increase in the 3rd year (MPX50 + 5.19%, $p < 0.01$).

Table 3 Multilevel mixed-effects linear regression of clinical, radiographic, and mastication outcomes intra-group

	Conventional loading				Immediate loading			
	1 year	2 years	3 years	2–3 years	1 year	2 years	3 years	2–3 years
Clinical outcomes	Ref	coef. (95% CI)	coef. (95% CI)	coef. (95% CI)	Ref	coef. (95% CI)	coef. (95% CI)	coef. (95% CI)
PD	1.00	0.07 (-0.13;0.28)	-0.11 (-0.53;0.30)	-0.16 (-1.20;0.86)	1.00	0.07 (-0.34;0.50)	**0.49 (0.08;0.90)***	0.40 (-0.04;0.85)
ISQ	1.00	0.18 (-0.23;0.61)	**0.51 (0.16;0.86)***	0.30 (0–0.10;0.70)	1.00	-0.00 (-0.02;0.00)	**0.64 (0.01;1.27)***	-6.89 (-36.38;22.58)
BOP	1.00	**	**	**	1.00	-0.33 (-1.00;0.32)	0.19 (-0.21;0.61)	-0.09 (-0.40;0.22)
VPI	1.00	-0.06 (-0.71;0.58)	-0.17 (-0.63;0.29)	**0.49 (0.21;0.76)***	1.00	-0.12 (-1.01;0.77)	-0.45 (-1.89;0.98)	-0.21 (-1.01;0.58)
PI	1.00	**	**	**	1.00	**	**	**
Radiographic outcomes								
MBL	1.00	1.00 (-0.08;2.10)	-0.20 (-1.78;1.37)	**1.34 (1.07;1.62)***	1.00	-0.46 (-1.10;0.18)	**0.55 (0.23;0.87)***	0.06 (-0.17;0.31)
PAI	1.00	**1.16 (0.69;1.63)***	0.00 (-0.40;0.42)	**0.82 (0.61;1.02)***	1.00	**0.94 (0.28;1.60)***	-0.02 (-0.69;0.64)	**0.96 (0.73;1.19)***
Masticatory performance								
MPX50	1.00	**0.52 (0.01;1.02)***	0.29 (-0.08;0.67)	**0.66 (0.40;0.91)***	1.00	**0.69 (0.04;1.34)***	-0.76 (-1.58;0.05)	**0.73 (0.01;1.44)***
MPB	1.00	**0.61 (0.12;1.09)***	**1.36 (1.00;1.72)***	**0.61 (0.33;0.89)***	1.00	0.13 (-0.02;0.30)	-0.05 (-0.41;0.30)	-0.27 (-1.74;1.19)
ME5.6	1.00	0.40 (-0.03;0.83)	**0.42 (0.05;0.79)***	**0.73 (0.44;1.03)***	1.00	0.58 (-0.12;1.29)	-0.81 (-2.33;0.70)	**1.22 (0.00;2.43)***
ME2.8	1.00	0.06 (-0.50;0.63)	**0.76 (0.12;1.40)***	0.39 (-0.33;1.12)	1.00	**0.55 (0.17;0.93)***	-0.60 (-1.22;0.01)	0.82 (-0.16;1.81)

*variables with statistically significant difference. ** collinearity; constant variables

The homogeneity of the triturated food particles (MPB) differed significantly at all evaluation periods (1–2 years, $p<0.01$; 1–3 years, $p<0.01$; 2–3 years, $p<0.01$), and a 9.56% increase in heterogeneity was observed between years 2 and 3. The % retention in the 5.6 mm sieve (ME5.6) increased significantly ($p<0.01$) between years 2 and 3 resulting in an overall increase between year 1 and 3 of 3.35% ($p=0.02$), reflecting a minor decrease in capacity to triturate coarse particles. Conversely, the ME2.8 values showed a minor but significant increase ($p=0.02$) of 5.10% between 1 and 3 years.

The changes over time for IL group (Table 3) indicate that changes in clinical outcomes over the entire follow-up period, with an increase of 12.20% increase in ISQ ($p=0.04$) between the 1st and the 3rd year, alongside a 13.16% increase in the probing depth ($p<0.01$). In addition, the MBL increased significantly (MBL + 16.66%; $p<0.01$) between the 1st and and the 3rd year, and a progressive reduction in the posterior bone area (PAI) between the 1st and 2nd year (PAI -5.26%, $p<0.01$) and between years 2 and 3 (PAI -0.93%, $p<0.01$). In the IL group, 5 out of 9 individuals (56%) experienced loss in the posterior bone area at year 3. The average triturated particle size reduced by 6.44% between years 1 and 2 ($p=0.03$), and subsequently increased by 7.18% between years 2 and 3 ($p=0.04$). The percentage of particles retained in the 5.6 mm sieve reduced by 43.75% between years 2 and 3 ($p=0.04$), whereas the percentage retained in the 2.8 mm sieve reduced by 0.32% between years 1 and 2 ($p<0.01$).

The only OHRQoL difference between groups occurred in the first year for the pain domain (coefficient: 0.50; 95% confidence interval (CI: 0.12 –0 0.87; $p<0.01$). Figure 3 presents the results of the multilevel mixed-effects linear regression and illustrates that the scores of the DIDL domains within each group varied over time. In the CL group, the score in the oral comfort domain slightly increased between years 1 and 3 (coefficient: 1.21; CI: 0.26–2.17; $p<0.01$). In the IL group, the pain domain scores reduced by 1.12% between years 1 and 2 (coefficient: 1.83; CI: 0.39–3.27; $p<0.01$), followed by a slight increase of 2.24% between years 1 and 3 (coefficient: -2.00; CI: − 3.78 to − 0.21; $p=0.02$). The oral comfort domain scores increase of 22.97% between years 1 and 2 (coefficient: 2.10; CI: 0.65–3.56; $p<0.01$), while general performance scores increased by 1.05% (coefficient: 1.45; CI: 0.91–1.99; $p<0.01$) and reduced by 10.52% between years

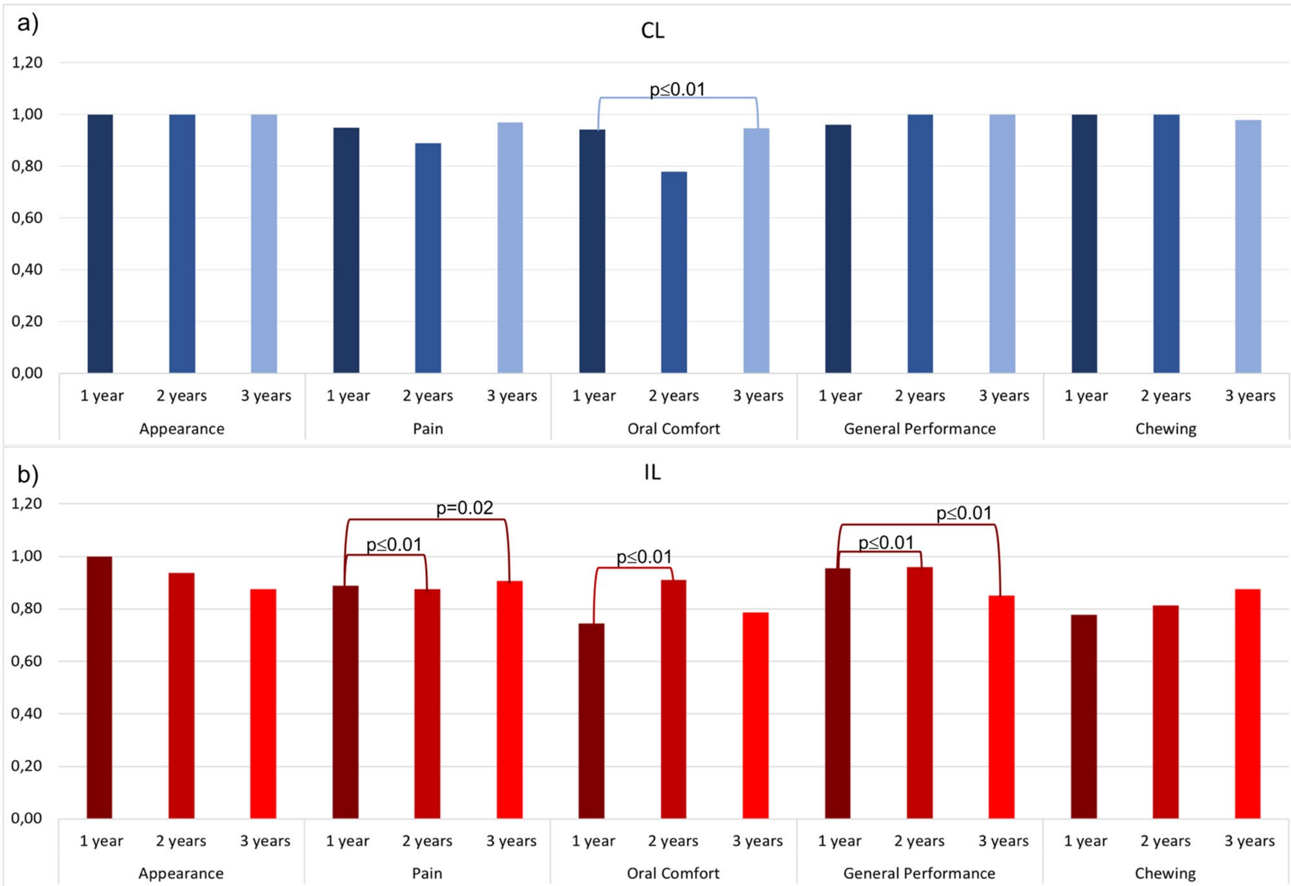

Fig. 3 DIDL outcomes: intra-group multilevel mixed-effects linear regression. **a** Conventional loading (CL); **b** Immediate loading (IL)

1 and 3 (coefficient: -0.23; CI: −0.36 to −0.10; $p < 0.01$). All individuals had a final satisfaction score greater than 0.7, showing everyone was satisfied with their rehabilitation regardless of the loading protocol adopted.

Discussion

Our robust statistical analysis indicates that there were no differences in clinical, radiographic, functional, or OHRQoL-related parameters between the conventional and immediate loading groups, expect for the MBL in the third year. Medium-term changes in outcomes were observed: the ISQ, MBL, and PAI varied over time in both groups, showing that there is still remodeling of peri-implant tissues and the posterior region of the mandible until 3 years after IMO loading, regardless of adopted loading protocol. Although peri-implant bone loss increased in both groups over the years, the IL group showed comparatively less bone loss. The 2- and 3-year implant survival rates of 100% for both groups are in accordance with the literature [34, 35]. The failure rates in the first year in both groups, especially in the IL group (15%, $n = 3$), can be partially attributed to the inability of the atrophic bone to respond adequately to the mechanical load in the short-term. Bone atrophy is associated with immobilization of the mandibular bone (long-term edentulism), which can in turn directly affect the vascular support of the implant recipient region. These characteristics may thus delay the formation of a connective tissue rich in vascular units and fibroblasts and may have contributed to this failure rate in the first year.

In addition, the IL group still experienced improvements in masticatory function and in the pain domain until the end of the 3rd year. These patients were monitored to investigate whether differences in objective and subjective outcomes related to masticatory function, quality of life, and cost-effectiveness of prosthetic maintenance would be equivalent over time. Our results could show that even for the IL patients who start the masticatory function during the osseointegration process and experience greater discomfort during the transition to IMO, only the results of the outcomes monitored in the first year are decisive for adhesion to the treatment. In addition, our results show that periodic prosthetic maintenance is equally effective for patients in both groups in the medium-term, even though the IL group has more interventions in the first year. It is also interesting to note that patients who received IL report a significant reduction in pain in the third year, indicating medium-term improvements in oral comfort. Even so, the IL group also reports a significant reduction in general performance of the IMO in the third year. Thus, this RCT provides valuable clinical information that emphasizes the importance of annual maintenance of the attachment system to guarantee comfort and effectiveness of the retention system. These are the main factors responsible for the retention and stability of the prostheses, absence of trauma, maintenance of peri-implant health, and control of posterior bone resorption.

The ISQ values in both groups increased in the 3rd years, reflecting in greater contact between bone tissue and the implant surface. The statistical analysis indicates no difference in final ISQ values between both groups, corroborating the results from Emami et al. [6]. The type of loading appears to influence the implant stability coefficient only in the initial period when early loading may induce greater initial circumferential bone remodeling. Evidence for this phenomenon was provided by Katkut et al., [17], Elsyad et al. [36], and Miyamoto et al. [37] as the authors found variations in the ISQ shortly after loading the IMO. The increase in average ISQ values in both groups in the present study indicates that the type of loading protocol no longer influences the ISQ at longer time periods. In the presence of osseointegrated implants, the masticatory forces and stresses arising from the IMO function are transmitted directly to the peri-implant bone, inducing changes in the ISQ for both groups. This would indicate that rehabilitation with IMO combined with mechanical stimulation of the prosthesis induces a positive bone response ensuring stability.

However, over the years, there is an increase in bone loss in the peri-implant region in both groups. The MBL in the CL group between 2 and 3 years was -0.01 mm, while the IL group lost -0.03 mm between 1 and 3 years. Vercruyssen and Quirynen [38] have shown that annual bone height loss is on average 0.01 mm, starting in the first year, thus showing that our results are in accordance with the expected values. Thus, our results show that both loading protocols present medium-term results consistent with the literature, and that peri-implant bone remodeling continues until 3 years of IMO function. Although the overall changes in MBL were higher in the IL group between 1 and 3 years, this group experienced less mean of bone loss in the 3rd year than the CL group. The yearly MBL values of the CL group show no significant changes between all periods; however, there is a trend towards greater peri-implant bone loss and with little variation and higher values than the IL group in all periods. This result corroborates the findings by Salman et al. [35] who found lower averages for the IL group during 5 years of IMO follow-up. The long-term MBL indicate less bone loss for the IL group. Thus, the lower height bone loss in the IL group may be a long-term consequence of early loading, which may have elicited a response from the peri-implant tissue to the forces transmitted to the bone tissue through the implants [39, 40].

The mandibular PAI reduced in both groups between 2 and 3 years, indicating that neither group was able to revert the bone remodeling of the posterior residual ridge. However, this reduction in the posterior area of the mandible was progressive in the IL group, whereas the CL group experienced an initial gain followed by reduction. No significant PAI difference was found between the groups; however, the IL group contained a greater number of patients experiencing bone loss. In addition, the IL group needed more changes in retentive capsules in the 3rd year (22 cases in IL versus 8 in CL), although this difference was not significant. We suggest that the greater loss of retention in the IL group in the 3rd year may be associated with the continuous remodeling of the residual ridge, as the IMO continue to be mucosally supported. Furthermore, the study by Tallarico et al. [41] also found that IMO with Locator/Equator attachments had a greater number of prosthetic complications and attributed this finding to the stress redistribution to the posterior region by this system, which places greater stress on the prosthesis. This may reflect the longer IMO function of this group due to early loading. Overall, the prosthetic maintenance data agree with those of Salmam et al. [35] who also found no long-term differences between these groups.

The groups showed no significant differences in masticatory outcomes, indicating that both loading protocols functionally equivalent in the long term, corroborating the 1-year results from Komagamine et al. [42]. However, the masticatory function of each group evolved differently. The IL group experienced improvements in triturated particle size between the 2nd and 3rd year and in the% of retention in the 5.6-mm sieve, while the triturated particle size, homogeneity, and capacity to triturate coarse particles in the CL group deteriorated. This indicates that the masticatory function of the IL group continued to improve in the long term. The literature points to initial functional improvements in the first months after loading when adopting IL [15, 42], but there is still a shortage of results constraining the long-term behavior. Our results that indicate long-term improvements in masticatory function in individuals with early loading corroborate those of a 5-year follow-up study of immediately loaded IMO [43]. The significant improvement between 2 and 5 years after loading may be a consequence of the adoption of immediate loading of IMO with 2 implants, which reproduces a prolonged improvement [43].

Finally, no OHRQoL differences were found between groups at any of the follow-up periods. However, the intragroup analyses in our study indicate improvements in pain scores and worsening of overall performance over the years in the IL group, while the CL group reported a small increase in oral comfort in the 3rd year. The improvement in the pain domain for the IL group may be related to the greater pain felt in the first months of function after loading with immediate loading, which serves as a reference point for IL patients. In addition, the self-reported worsening of the general performance domain in this group may be related to the continuous remodeling of the residual bone crest, which may influence worse retention, as suggested by the greater number of nylon O-ring replacements in the IL group. As seen, the worsening in retention and the greater number of maintenances were not able to influence the perception of pain when using IMO during the 3rd year, being able to influence only in the general performance item. These results can be explained by previous studies that investigated the influence of loading protocol on quality of life data are short-term, and indicate improvements in quality of life and satisfaction of patients when IL is adopted [5, 44]. Medium- and long-term studies show that improvements initially seen for the IL continue to be seen after 2 years [45, 46] and after 5 years [47]. Conversely, our results show that a medium-term deterioration in the general performance domain may also occur.

In terms of clinical implications, our study has shown that the immediate loading protocol can have a positive medium-term effect on for the peri-implant tissues. Despite a self-reported worsening of general performance, continued improvements in masticatory function are observed in the 3rd year. The failure rates reported in this study may be in part attributed to intrinsic variation expected in RCT studies with relatively small sample sizes (original $n=20$ in both treatment groups). Future meta-analysis that combines multiple RCT to achieve high sample size is needed to accurately and precisely determine the long-term failure rate expected for each treatment option. At present, the only masticatory test that provides direct information on crushing capability continues to be the one used in this study, which is why this well-established methodology was selected in the present study. Additional limitations of this study include to the absence of bite force measurements that are strongly associated with mastication, and the scarcity of long-term follow-up studies that can provide a basis for comparison of our results. For a better understanding of the long-term behavior of the two loading protocols, more studies with larger sample sizes and longer follow-up times using complementary measurement protocols are needed.

Conclusion

Although IL patients experienced the lowest MBL after 3 years, all the outcomes evaluated in this RCT showed that both loading protocols result in predictable medium-term rehabilitation when monitored annually. It can be expected that in the third year of function, IL patients may present more complaints related to general performance even with acceptable masticatory function and self-reported improvements in oral comfort.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00784-023-05205-w.

Acknowledgements This study was financed in part by the Coordination for the Improvement of Higher Education Personnel—Brazil (CAPES)—Finance code 001.

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Data availability All data generated or analyzed during this study are included in this published article (and its supplementary information files).

Declarations

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The investigation was approved by Research Ethics Committee of the School of Dentistry- UFPel (Report 3.725.829).

Competing interests The authors declare no competing interests.

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