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Evaluation of peri-implant conditions of two immediate loaded unsplinted implants supporting mandibular overdenture and quality of life

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Abstract

This clinical prospective study evaluated the clinical and radiographic peri-implant conditions of two unsplinted implants immediate loaded with mandibular overdentures, as well, evaluated the oral health related quality of life (OHRQoL) in these patients.

Materials and Methods: Ten totally edentulous patients received 20 implants with ball attachment, being 6 immediate loaded (test group) and 4 conventional loaded (control group). For OHRQoL assessment, the OHIP-EDENT questionnaire was applied before the implants insertion, 3 and 6 months after. After 6 months of implant insertion, the following clinical parameters were evaluated: probing depth, width of the keratinized mucosa, modified bleeding index, modified plaque index. The marginal bone loss was obtained by analyses of periapical radiographs at the day of implant insertion, 3 and 6 months after.

Results: There was a significant improvement of quality of life at 3 months in immediate loaded group and at 6 months at the conventional loaded group comparing to initial time (P<0,001) with no significant difference between groups (P=0,488). There was no significant difference between groups for the clinical and radiographic parameters at 6 months.

Conclusion: There was no significant difference between groups in all quality of life, clinical and radiographic parameters, however the immediate load provided a better quality of life before the conventional load. Long term studies may be conducted due to follow peri-implant parameters and to obtain implant survival rate.

Keywords: Dental implant; Dental implant-abutment design; Prosthetic denture; Quality of life

1. Introduction

Currently mandibular overdenture over two implants is considered the first choice with minimum quality standard for edentulous patients and no longer the total conventional prosthesis, as stated in the 2002 McGill Consensus Statement [1]. In 2009, the York Consensus Declaration reaffirmed the Declaration of McGill and added that satisfaction and quality of life with implant-supported overdentures is significantly greater than for conventional total prostheses [2]. The discomfort generated by the conventional total prosthesis, such as lack of stability and retention, leading to a loss of masticatory efficiency, pain, problems in speech, communication difficulties, can cause psychosocial problems [3].

The assessment of the impact of dental treatment on quality of life and patient satisfaction can be measured through the application of questionnaires such as the Oral Health Impact Profile (OHIP), and may also help to detect long-term efficacy and prognosis [4]. The OHIP-EDENT questionnaire has been specially developed to evaluate the quality of life of total edentulous patients [5]. The OHIP-EDENT questionnaire consists of a list of self-administered test questions and

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the Brazilian version being composed of four domains and a total of 19 questions related to: chewing; discomfort and psychological inability; social incapacity and pain and mouth discomfort [6].

Systematic review studies have concluded that the type of connector does not significantly influence the success factors of overdenture treatment[7]. nor in patient satisfaction [8]. However, some factors should be taken into account when choosing the type of connector, such as durability, cost-benefit, simplicity and retention, besides age and motor coordination [9]. Given that elderly patients present a physiological loss of motor coordination, the use of isolated implants facilitates patient cleaning [10]. Regarding cost, the use of systems that require suprastructure or the association of different retention systems, make the treatment more expensive, whereas the use of isolated implants with simpler connectors, such as the "ball", make the treatment less expensive [11].

In order to reduce the time of discomfort of conventional total dentures, reduce surgical times, and promote the benefits of implant-supported prosthesis immediately after implant installation, immediate loading was introduced to mandibular overdentures [12,13]. Numerous studies have supported the feasibility of load on mandibular overdenture, especially when the implants are splinted by a bar [14-17]. More recently, immediate loading of mandibular overdenture using unsplinted implants has been introduced [18,19,20-24]. However, the literature has conflicting results in relation to the immediate load of unsplinted implants, mainly regarding the reliability of the reported data, insufficient follow-up, inadequate sample size and lack of well-defined success criteria [25].

Considering the aspects presented about overdentures and their socioeconomic context, as well as the need for randomized controlled trials, this study aimed to analyze the quality of life related to oral health provided by the use of two unsplinted with ball connection submitted to the immediate loading compared to the conventional treatment of mandibular overdenture rehabilitation, as well as to evaluate the clinical and radiographic conditions of the two implants used in the treatments.

2. Material and methods

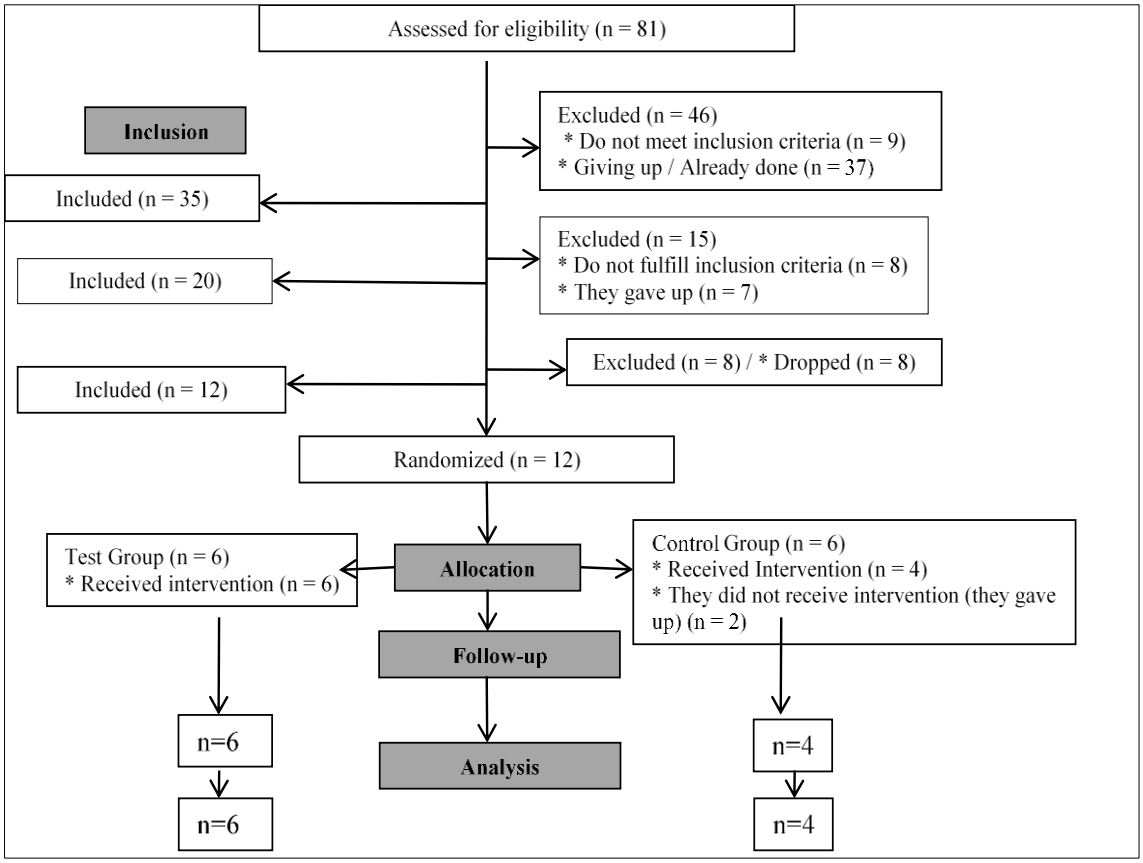

Figure 1 CONSORT 2010 Flow Diagram

This clinical prospective study was approved by the Research Ethics Committee of the State University of Western Paraná (UNIOESTE), Brazil (Protocol number: 1.696.947). The study protocol was explained to each subject, and signed informed consent was obtained from all patients. Twelve total edentulous patients were recruited from the UNIOESTE Dentistry Clinics in 2016, according to the CONSORT 2010 Flow Diagram (Figure 1).

Patient screening was performed by checking the medical records. After that, the subjects were physically evaluated, clinically, through complementary examinations through panoramic radiography and blood tests, and selected according to the inclusion and exclusion criteria.

2.1. Inclusion Criteria

Age between 40 and 80 years; gender: female and male; proper oral hygiene condition; total prosthesis antagonist; superior and inferior prostheses previously made, bone collar of minimum height of 10 mm, normal and controlled systemic health condition; implant installation torque of at least 30Ncm.

2.2. Exclusion Criteria

Any condition that was not fully edentulous, uncontrolled diabetes; use of bisphosphonates in the last 10 years; heavy smoker (more than 20 cigarettes per day); insufficient bone volume or grafted ridges; radiotherapy in oral cavity; chemotherapy; autoimmune and chronic inflammatory diseases; implant installation torque less than 30 Ncm.

The patients included were informed about the project, its risks and benefits and signed the Informed Consent Form.

For the randomness of the samples, 12 brown envelopes were arranjed, 6 written: "test" and 6 written: "control", which were drawn by a third person, after implant installation.

Two patients gave up from the treatment, receiving no intervention, and the remaining two envelopes were from the control group.

2.3. Surgical procedure

Before the implants installation a panoramic radiograph was requested for the surgical planning. All implants were installed by the same trained professional. All implants were 3.75 mm in diameter and the length ranged from 8 to 13 mm according to bone availability.

In order to standardize the position of the implants, a surgical guide was made by doubling the total inferior prosthesis in transparent acrylic resin, and the middle region between the lateral incisor and the canine was chosen on each side for reference point [20]., so all patients received 2 implants interforame.

2.4. Clinical procedures immediately after implant installation

In the test group, the o-rings were installed and the connectors were captured in the inferior prosthesis at the time of the implant placement. In the control group, the cover screws, wear and relapse screws were made with soft acrylic resin (Soft Comfort - Dencril®),at the time of the implant placement. The reopening in the control group was done 3 months after the surgery, with the installation of o'rings without the use of healing abutment to simulate the immediate loading group.

To avoid contact with the surgical wound, a protection was made with a rubber sheet fragment and added to each o-ring during the capture of the capsules with self-curing acrylic resin [23]. The o'rings were selected at the moment of its installation according to the height of the gingival tissue and inserted with a torque of 32 Ncm.

Patients from both groups were asked at the time of installation of the o'rings to remain without removing the prosthesis for 1 week and then removed after each meal for oral hygiene. For control of infection and inflammation it was prescribed: amoxicillin 500mg every 8 hours for 7 days, nimesulide 100mg every 12 hours for 5 days, paracetamol 750mg every 6 hours for 3 days and mouthwash with chlorhexidine 0.12% twice a day for 14 days, after implant surgery. Suture removal was done after 7 days. Patients received guidance on insertion and correct removal of the prosthesis. A pasty diet was requested in the first month.

2.5. Assessment of Oral Health Related Quality of Life (OHRQoL)

To evaluate the OHRQoL, the OHIP-EDENT questionnaire was used before implant installation, 3 and 6 months after the installation of the same. The total sum of scores (0 = never, 1 = sometimes, 2 = almost always) was obtained for statistical analysis. The higher the score, the worse the patient's quality of life and satisfaction [6].

2.5.1. Clinical Evaluation

After 6 months of implant installation, the participants were submitted to a clinical examination of peri-implant conditions by a single examiner. The evaluation of the Probing Depth (P.S); Width of the Keratinized Mucosa (L.M.Q.); Modified Sulcus Bleeding Index (mBI)[26].; Modified Plate Index (mPII)[26]. was performed using the millimeter implant probe (PCV12KIT6 Colorvue - HuFriedy). Six sites per implant were evaluated (mesiovestibular, buccal, distobuccal, mesiolingual, lingual and distolingual), and the mean values between the implant values (right and left) was assessed for statistical analysis of P.S. and L.M.Q. For mBI and mPII evaluation, only 1 representative value was used for each side, which was the highest value found.

2.5.2. Radiographic evaluation

At the time of implant placement, 3 and 6 months after implant placement, the participants were submitted to periapical radiographic evaluation (DabiAlante, 70KV), obtaining images using a digital sensor (New Ida-DabiAtlante®) and positioner of the sensor itself for parallelism technique. In each implant, measurements were made of the implant platform at the beginning of the external hexagon (Figure 2-A) to the distance of mesial (Figure 2-B) and distal (Figure 2-C) bone ridges. To obtain the real values, the images were edited and measured in the AutoCAD software (Autodesk®) and the measurements obtained in the program were related to the true implant length per rule of 3[27]. as follows:

Real distance AB (mesial*)* in millimeters = (measure AB in program x real AD measure known) / measure AD in the program

Real AC (distal) in millimeters = (measure AC in program x measure actual AD known) /measure AD in program.

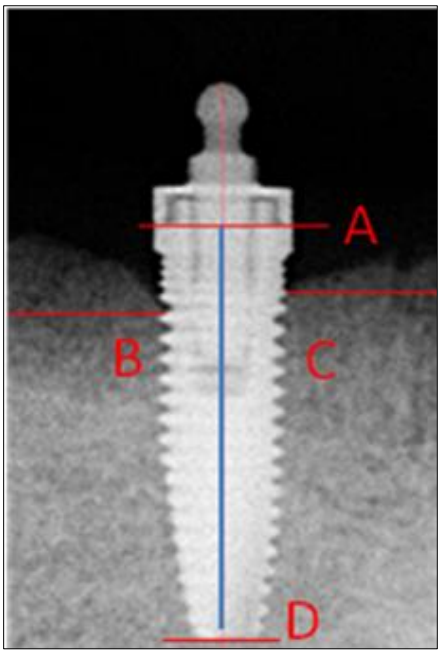

Figure 2 Periapical radiographic imaging in AutoCAD (Autodesk®) Software. Reference points on the radiograph: A. Implant platform at the beginning of the external hexagon. B. Mesial bone crest. C. Distal bone crest. D. Implant base

2.6. Statistical analysis

The analysis of the distribution of data in the two groups was evaluated using the Shapiro-Wilk test, testing the null hypothesis of normal data distribution. In addition to this analysis, we also evaluated the homogeneity of the variances between the groups using the F test.

For life quality and marginal bone loss between the times (T0, T3m and T6m), Variance Analysis for Repeated Measurements was performed, followed by the LSD-Fisher test, since they presented a normal distribution. The analyzes were done for each implant: right and left.The variables depth of probing and width of the keratinized mucosa were analyzed by Student's t-test for independent samples, since they presented normal distribution. The variables index of modified plaque and modified sulcus bleeding index were evaluated by the Mann-Whitney-U test, since they are scores.

Measurements of marginal bone loss were obtained by a single evaluator at two different times to verify the intra-examiner calibration, and the two measurements showed a high absolute agreement between them, with an Intra-Class Correlation value of 0.94 (IC95 % 0.92 - 0.96).

The univariate analyzes were performed in the Statistica 7.0 program (Statsoft, 2004), assuming a level of significance of 0.05. This study had a power of analysis of 0,29, being a pilot study of another one outlined in the following conditions: sample size of 34 patients, (28 plus 20% loss), power of 0.80, type I error equal to 0,05 and effect size equal to 0,25. (Sample calculation performed in the GPower 3.1.9 program using an F distribution, with a 3-step repeated measure design - Paul, 2010).

3. Results

3.1. Oral Health Related Quality of Life

The mean of the value obtained in the OHIP-EDENT questionnaire of the groups over the periods are presented in table 1. At 3 months after the intervention, the test group showed a significant improvement in relation to the initial time, and the control group presented a significant improvement in 6 months in relation to the initial time, but there was no statistical difference between the groups in any period evaluated.

Table 1 Mean of the OHRQoL values of the Control and Test groups throughout the periods after the intervention. P-values of the Analysis of Variance for Repeated Measures. F (2, 16) = 5.5171, P = 0.01505

	Control			Test			P-value periods	P-value groups	P-valoue interaction
	0 m	3 m	6 m	0 m	3 m	6 m			
OHRQoL	19.3aA	15.0aA	3.5aB	18.7aA	3.7aB	6.8aB	<0.001	0.488	0.015

* Lowercase letters represent the statistical comparisons between groups within each period, with different letters indicating significant statistical differences (P <0.05); ** Upper case letters represent statistical comparisons between periods within each group, with different letters indicating significant statistical differences (P <0.05).

3.2. Clinical Parameters

Table 2 Mean and standard deviations of variables collected at 6 months of intervention of Control and Test groups. P-values of the t-tests for independent samples and Mann-Whitney-U *

Variable	Side	Control	Test	P	Overall
					(Mean - Standard Deviation)
Probing Depth (Mean ± Standard Deviation)	Right	1.583+0.645	1.750+0.456	0.642	1.708+0.582
	Left	1.625+0.927	1.806+0.531	0.702	
Keratinized mucosal width (Mean ± standard deviation)	Right	1.625+0.160	1.611+0.272	0.930	1.600+0.256
	Left	1.750+0.215	1.472+0.306	0.157	
Plaque index (Median and interquartile range)	Right	1.0 [1.0 – 2.0].	1.0 [0.0 – 2.0].	0.580*	1.250+1.020
	Left	1.5 [1.0 – 2.5].	1.0 [0.0 – 2.0].	0.371*	
Bleeding index (Median and interquartile range)	Right	0.5 [0.0 – 1.5].	0.0 [0.0 – 1.0].	0.542*	0.350+0.587
	Left	0.0 [0.0 – 0.5].	0.0 [0.0 – 0.0].	0.878*	

Table 2 shows the mean and standard deviation of the variables of the clinical parameters at 6 months. There was no statistical difference between the groups for the probing depth, keratinized mucosa width, plaque index and modified sulcus bleeding index, regardless of the side evaluated (right implant and left implant).

3.3. Marginal Bone Loss

The mean of the value of the marginal bone loss variation at 3 and 6 months in relation to the initial time is presented in table 3. There was no statistical difference between the groups and between the evaluated periods. The mean total bone loss for both groups at 6 months was 1.081mm ±0.944.

Table 3 Mean and standard deviation of bone loss (variation between 3 and 6 months in relation to the initial month) of the Control and Test groups throughout the periods after the intervention. P-values of the Analysis of Variance for Repeated Measures

	Control		Test		F	P-value periods	P-value groups	P-valoue interac-tion
	3 m	6 m	3 m	6 m				
dAB	0.68±0.17^{aA}	1.61±0.31^{aA}	0.94±0.68^{aA}	1.16±1.13^{aA}	1.81	0.065	0.863	0.220
DAC	0.66±0.36^{aA}	0.80±1.34^{aA}	1.27±0.41^{aA}	0.95±1.23^{aA}	0.57	0.258	0.899	0.475
Mean	0.67±0.23^{aA}	1.44±0.06^{aA}	0.87±0.89^{aA}	1.05±1.16^{aA}	1.52	0.085	0.877	0.258
eAB	1.41±0.63^{aA}	1.38±0.44^{aA}	1.33±1.40^{aA}	1.15±1.10^{aA}	0.05	0.780	0.833	0.838
eAC	0.80±0.21^{aA}	1.01±0.52^{aA}	1.22±1.49^{aA}	0.82±1.29^{aA}	1.26	0.737	0.890	0.299
Mean	1.10±0.26^{aA}	1.19±0.42^{aA}	1.28±1.41^{aA}	0.99±1.17^{aA}	0.44	0.738	0.981	0.530
Over all	Mean Total Variation at 6 months (test and control group)					1.081±0.944		

* Lowercase letters represent the statistical comparisons between groups within each period, with different letters indicating significant statistical differences (P <0.05); ** Upper case letters represent statistical comparisons between periods within each group, with different letters indicating significant statistical differences (P <0.05); dAB - distance from the mesial bone crest of the right implant; dAC - distal bone crest distance from the right implant; eAB - distance from the mesial bone crest of the left implant and eAC - distance from the distal bone crest of the left implant.

All implants had an installation torque greater than 45Ncm. For the analysis of marginal bone loss, 1 patient in the control group had to be discarded because it was impossible to obtain satisfactory radiographic images, leaving only 3 patients in this group for this analysis.

4. Discussion

To evaluate implant overdentures, peri-implant tissue criteria, prosthetic maintenance, patient satisfaction and implant success rate may be used [28]. This study evaluated these criteria in the short term and it was not possible to obtain the success rate by time insufficient follow-up.

Studies evaluating overdentures on unsplinted implants varied in the number of implants, in the type of connector used and in the parameters evaluated [29]. Only a few studies, the majority of cases and short follow-up were associated with the immediate loading of two implants with ball connectors [20,22,23,25]. Still, most focused on the evaluation of marginal bone loss and the success rate of implants.

Studies have reported an improvement in satisfaction and quality of life in patients who have their conventional total dentures replaced by implant-supported overdentures[30-32]. and this satisfaction may continue for 5 or more years of follow-up [18,30]. This study, in agreement with the reported in the literature, observed a significant increase in patients' quality of life when they had their total dentures connected to the implants. At three months after the intervention, the test group presented a significant reduction of the total score of the questionnaire while the control group presented a great reduction at six months, due to the fact that, in the immediate loading group, the advantages of overdenture could be felt immediately after implant installation. However, the large confidence interval and the small sample number did not allow the observance of statistical relevance between the groups in any of the evaluated periods. The same result was obtained by Omura et al[33]., who observed the same pattern of improvement between the groups, but also did not observe statistical difference between the groups when using the OHIP EDENT J questionnaire, comparing immediate and conventional loading with the use of magnetic connectors. In our study, although not

significant, there was a small increase in the values in 6 months in the test group, due to two patients who lost o'rings retention, which had a negative influence on the quality of life and total sum. However, it is difficult to compare the results statistically by the difference in the scores of the questionnaires given by the cultural difference between the countries, the interpretation and validation of the questionnaires [3]. The Brazilian OHIP-EDENT[6]. consists of responses from 0 to 2, in the original in English[5]. the answers vary from 0 to 4. In addition, the diversity of the parameters of evaluation of satisfaction and quality of life, difference of questionnaires, load protocols and connectors system also makes it difficult to compare the results, as reported by a systematic review of Boven et al[31]., in which it was not possible to perform a meta-analysis due to the possibility of a combination of results. Even so, the literature shows no statistical difference in patient satisfaction when comparing several types of connectors. This can be explained by the significant improvement in retention with any connector when compared to conventional prostheses previously used by patients [8]. Studies comparing immediate and conventional loading on two implants with ball connectors supporting mandibular overdentures in relation to quality of life measured through of the OHIP-EDENT questionnaire could not be evaluated for comparison with this work.

Regarding the clinical parameters, this study did not show statistical differences between the immediate loading and the conventional loading groups at 6 months for probing depth, keratinized mucosal width, modified plaque index and modified sulcus bleeding index independent of the evaluated side (right and left), being in agreement with the results of Elsyad et al[25]. when it evaluated the clinical parameters of probing depth and plaque index.

In this study, although the patients had some level of plaque (1,250±1,020), all patients remained with healthy gingival tissue, with a low modified bleeding index (0.350±0.587) and normal probing depth (1,708mm±0.582). This plaque index can be explained by the small amount of keratinized gingiva presented by the patients (1,600mm±0,256), in agreement with the study by Chung et al[34]., which evaluated 339 implants for 3 years, and proved that the absence of adequate keratinized mucosa in implants, was associated with a higher plaque index and gingival inflammation, but failed to prove this correlation with alveolar bone loss. For a good maintenance of plaque index, studies[21]. showed the importance of periodic returns, reporting that there was an improvement in plaque index during the first year with regular follow-ups, and, after 1 year, with annual returns only, oral hygiene worsened, justly by the lack of this maintenance by the professional.

With regard to marginal bone loss, clinical studies [18,21]. showed a greater marginal bone loss in the first year (between 1 and 1.5 mm) with a tendency to stabilize over the next few years. In the present study there was no difference between groups for the marginal bone loss, and the mean marginal bone loss was 1.08±0.944 mm at 6 months, that was similar to mean bone loss (1.14±1.17 mm) obtained by the study Liao et al[22]. represented by a series of 10 cases of immediate loading. These results overcame the mean bone loss found in the studies by Marzola et al[23]. and Elsyad et al[25]. that were respectively 0.7mm ±0.5 and 0.91mm±0.63 for the 12-month time. The study of Elsyad et al[25]. showed that there is significantly greater bone loss between 1 and 3 years in the immediate loading group in unsplinted implants using ball connectors compared to the conventional loading group, indicating that long-term studies should be conducted to better assess bone loss in this situation. However, the radiographic method used for measurement may influence the results of marginal bone loss, therefore standardization of study design, methods of measurement and presentation of statistical power may benefit future clinical studies and systematic reviews [15]. In this study, periapical images through the use of a radiographic sensor, whose positioning was impaired by the reabsorption of the patients' mandibular ridges, making it difficult to standardize parallel to the implant. One patient had to be discarded for this analysis because of the impossibility of obtaining a satisfactory radiograph. The same difficulty in correctly positioning the radiographic film was reported by Tavakolizadeh et al[19]. In order to control this factor in an upcoming study, tomographic images can be used for the analysis of marginal bone loss, obtaining more faithful values and without discomfort for the patient, in addition to being able to measure all the peri-implant faces.

The prosthetic complications reported in overdentures on mandibular implants are: loss of retention, need for exchange of female rubbers, disengagement of the female in the prosthesis, loosening of the o'ring, prosthesis relining, connector fracture, fracture of the overdenture, fracture of the prosthesis antagonist, fracture of the acrylic resin base, and in general, occur in the first year [18,21,28]. In agreement with the literature, this work also presented prosthetic maintenance during the 6 months of follow-up: rubber exchanges, readaptation of females in the prosthesis, relining of the inferior prosthesis. But all of them easy to solve. There were no prosthetic fractures and no implant failed.

Long-term analyzes should be done to evaluate the success rate of the implants and behavior of the parameters evaluated and with larger sample size for greater analysis power.

5. Conclusion

The oral health related quality of life improved in all patients after the installation of overdenture, and this improvement was noticed at 3 months in the immediate loading group and at 6 months in the control group, but there was no statistical difference between the groups in any period analyzed.

There was no statistical difference between the groups for the clinical and radiographic parameters at 6 months.

Compliance with ethical standards

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Disclosure of conflict of interest

The authors declare that they do not have any commercial or associative interest that represents a conflict of interest in connection with the work submitted.

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