FACULDADE ILAPEO

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Marginal bone loss of posterior rehabilitation with injection molded zirconia implant: partial results of 24-month follow-up

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Orientador: Prof. Dr. Rubens Moreno de Freitas

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Sumário

1. Artigo científico

Artigo de acordo com as normas da Faculdade ILAPEO.

MARGINAL BONE LOSS OF POSTERIOR REHABILITATION WITH INJECTION MOLDED ZIRCONIA IMPLANT: PARTIAL RESULTS OF 24-MONTH FOLLOW-UP

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ABSTRACT

The demand for metal-free and more esthetic implants lead to the development of zirconia implants. This study aimed to evaluate the peri-implant bone loss of a two-piece injected molded zirconia implant in a 24-month follow-up. Thirty-eight implants were placed in 30 patients. The loading protocol was selected according to each patient's needs and the manufacturer's instructions. All patients received temporary prostheses, and after three months, they received the definitive crowns cemented over the abutment. Patients were re-evaluated 6, 12 and 24 months after implant loading. Peri-implant bone level and bone changes were calculated for each patient visit and visit intervals. Additionally, implant cumulative survival and success rates were calculated. Quantitative variables were described by mean, standard deviation, median, minimum, and maximum. For qualitative variables, absolute and relative frequencies were provided. Data from the 24-month follow-up visits (T12) was available for 26 patients and 30 implants. A higher marginal bone level was observed in the implant placement visit compared to follow-up visits. At 24 months visit, a mean bone loss of 0.30±0.31mm (range -0.88 to 0,12) was observed, considering bone levels at the time of implant placement. In total, four implants were lost before the final prosthesis installation, within four months of follow-up, leading to a cumulative implant success rate of 97.3% (95% CI: 93.3 - 99.3%). Six patients experienced local edema, pain, and suppuration. Technical and mechanical complications were observed, such as abutment fracture, prosthesis fracture, loss of prosthesis cement retention, excessive bone resorption, and implant failure. This study's results confirm the peri-implant bone level maintenance in up to 24 months of follow-up.

Keywords: Zirconia implant; Bone loss; Survival Rate; Dental Implants.

INTRODUCTION

Dental implants have become the primary treatment for replacing compromised teeth, and titanium is the most used material. However, the demand for metal-free devices associated with sensitivity or allergy to titanium experienced by a small part of the population leads

manufacturers to search for alternatives[1]. In this way, ceramic implants have become an important alternative to titanium implants.

The first ceramic implant was developed in the 1960s with alumina material. Due to its poor biomechanical properties, many fracture cases occurred, and the implant was removed from the market[2]. After this episode, zirconia dental implants were developed. Zirconia has been used in the orthopedic field, and studies have already proven its osseointegration. Both zirconia dioxide and yttria-stabilized tetragonal zirconia polycrystal (Y-TZP) are widely used as ceramic implant raw materials[3].

The first zirconia implants were one-piece. This implant configuration has limitations, such as reduced prosthetic versatility due to a lack of abutment angulations that could compromise rehabilitation esthetics. Additionally, even with implant protection, loading forces are applied to the abutment, which can impair the healing process[4]. Due to the limitations of one-piece zirconia implants, two-piece zirconia implants were developed to improve the treatment.

To the authors' knowledge, few studies in the literature show the safety and performance of two-piece zirconia implants. Thus, this study aimed to evaluate the peri-implant bone loss of a two-piece injected molded zirconia implant in a 12-month follow-up.

MATERIAL AND METHODS

The study protocol was submitted and approved by the Ethical Committee of the Instituto de Neurologia de Curitiba (Curitiba, Brazil; opinion nº 4.329.885). The investigation was conducted according to the revised principles of the Helsinki Declaration and ISO 14155. Written informed consent was obtained from each enrolled patient. The study was registered in the Clinical Trials database under the number NCT04545840.

Study population

The sample size calculation was based on the primary endpoint, peri-implant bone level. Considering an alpha level of 5% and beta of 20% to detect a mean peri-implant bone level change of 0.91mm, with a standard deviation of 1.4mm, 36 months after implant loading[3]. Sample size calculation showed that a sample of 30 implants was needed. Estimating a rate of 1 implant per patient and a drop-out rate of 15%, a sample size of 36 patients resulting in an estimated number of 36 implants was considered sufficient to allow for a descriptive analysis of clinical outcome data up to 36 months after implant placement.

This observational study involved 30 patients (18 females and 12 males; mean age 46.1±9.5 years), in whom 38 implants were placed. The sample was prospectively selected and comprises patients 18 years of age or older, with single-tooth edentulous sites, with adjacent natural teeth, indicated for oral rehabilitation with dental implants and single-unit prostheses, assessed as qualified for placement of Zirconia Implants at Faculdade ILAPEO (Curitiba, Brazil).

Only contraindications to the device, according to the instructions for users, were applied as exclusion criteria. Patients who show signs of allergy or hypersensitivity to the chemical components of the implant material were not included. In addition, implant placement in the presence of an acute infectious or inflammatory process, inadequate bone volume or quality, serious medical problems such as bone metabolism disorders, blood coagulation disorders, inadequate healing, inadequate oral hygiene, incomplete jaw growth, uncooperative and unmotivated patient, drug or alcohol abuse, psychoses, prolonged functional disorders that resist any drug treatment, xerostomia, weakened immune system, diseases that require the regular use of steroids, uncontrolled endocrine diseases, and pregnancy were considered factors for patient exclusion.

Surgical procedures

Zi® implants (Neodent, Curitiba, Brazil) with a diameter of 4.3 mm were placed under local anesthesia (4% Articaine with 1:100,000 epinephrine) and with adequate bone bed preparation according to the manufacturer's recommendations. All patients received the same brand and implant model with variation only in the implant length according to the patient's need. The patients were also given post-operatory and oral hygiene orientations.

After implant placement, the suture was performed, and an X-ray was taken (baseline - TP). Patients were instructed to return between 7 and 14 days after surgery to remove the sutures.

The loading protocol (delayed or immediate) was selected according to each patient's needs and the manufacturer's instructions (IFU). At the surgeon's discretion, immediate loading was applied when primary stability reached at least 32 N.cm and the patient presented physiological occlusion.

All patients received a temporary prosthesis installed in the PEEK CR Abutment (Neodent®, Curitiba, Brazil). Three months after implant placement, all final crowns were cemented over the Zirconia Base (Neodent®, Curitiba, Brazil). After the prosthesis installation, a radiographic examination was performed to confirm the adaptation of the prosthetic work. Patients were re-evaluated 6, 12 and 24 months after implant loading.

Outcomes

Peri-implant bone level

Intraoral radiographs were taken at each patient’s visit using the Heliodent X-ray device (Sirona, Bensheim, Germany), with a CMOS sensor (Xios Supreme, Sirona). The periapical parallelism technique was used to obtain radiography with standardized distance. After image calibration using the implant diameter as a reference, linear mesial and distal peri-implant bone height measurements were performed using the Sidexis 4 Software (Sirona). A reference line was drawn on the implant platform in the calibrated image. The measurement was obtained

from the most apical point of the radiolucent image (at the bone/implant interface) to the implant platform reference line for implants with bone level below the implant platform line. In implants with bone level above the implant platform, the measurement was performed from the highest point of the alveolar crest to the implant platform line.

Implant and prosthetic survival and success

Survival was considered when the implant was present and functioning in the oral cavity at the time of the follow-up visit. A failure was defined as an implant that was mobile, outside the oral cavity, or planned for removal.

Success was evaluated according to Buser[5,6] considering the factors below:

1) Absence of persisting subjective discomfort such as pain, foreign body perception, and or dysesthesia.
2) Absence of recurrent peri-implant infection with suppuration (an infection was termed recurrent when observed at two or more follow-up visits after treatment with systemic antibiotics).
3) Absence of implant mobility on manual palpation.
4) Absence of any continuous peri-implant radiolucency.

Prosthetic survival and success were also evaluated. Prosthetic survival was assessed as the prosthesis remaining in situ at each follow-up, irrespective of its condition. On the other hand, success was defined as the prosthesis that remained unchanged and did not require any intervention during the entire observational period.

Clinician satisfaction

Clinician satisfaction was assessed using a questionnaire and a visual analog scale (VAS) in the form of a 10 cm horizontal line, where 0 (left end) indicates minimum satisfaction and 10 (right end) indicates maximum satisfaction. The clinicians were instructed to mark the best position to represent their general satisfaction with patient treatment. The score was measured in centimeters from the left end of the line to the marked point.

Additional data were also collected, such as demographics, bone augmentation procedures, bone site characteristics, and occurrence of complications.

Statistics

Quantitative variables were described by mean, standard deviation, median, minimum, and maximum. For qualitative variables, absolute and relative frequencies were provided.

The implant and prosthesis loss rates were calculated based on the relation between the total events and the final sample. The prosthesis sample was calculated based on the total number of survived implants. To verify implant survival over time, the cumulative survival rate was calculated according to the life table method, and the Kaplan–Meier survival curve was used to estimate the survival function.

To confirm the reliability of the bone level measurements, interrater analysis was applied between the two blinded researchers using the intraclass correlation coefficient (ICC).

All analyses were done in JASP® 0.16.3.

RESULTS

Forty-six subjects provided written consent to participate in the study and were screened. Of these, 32 met all inclusion criteria and were included in the study. Of the subjects included, one withdrew consent to participate prior to the installation of any study device, and one patient could not be contacted to schedule the implant placement visit (TP).

Thirty patients (18 females and 12 males) with a mean age of 46.1 ± 9.5 years were considered eligible according to the study criteria, with the majority (n=23; 76.7%) presenting only one edentulous region, 6 patients (20%) with two regions and 1 patient (4.3%) with three regions. Regarding patient characteristics, 27 (90%) were non-smokers, 2 past smokers (6.7%), and 1 current smoker (3.3%) with a frequency of less than ten cigarettes per day. Regarding systemic diseases, the majority (n=25; 83.3%) did not present hypertension, 4 (13.3%) had

controlled hypertension, and only 1 (3.4%) had uncontrolled hypertension. No patient had diabetes.

Thirty-eight 4.3-mm diameter Zi® implants (Neodent, Curitiba, Brazil) varying from 10 to 13 mm in length were placed; the majority were 11.5 mm (n=20; 52.6%), followed by 10 mm (n=14; 36.9%). Most were inserted in the molar region (n=23; 60.5%), type III bone (n=22; 57.9%), with satisfactory oral hygiene (n=20; 52.6%) and with final insertion torque between 35-60 N.cm (n=24; 63.1%). Regarding bone grafting, 3 sites received bone grafts (7.9%), and 1 (2.6%) was submitted to a procedure for bone augmentation. Two implants (2 patients) received a collagen membrane (5.3%). The descriptive analyses of the frequencies of the variables collected at the level of the implants are described in Table 1.

Table 1 – Descriptive analysis of variables frequency collected at implant level (n = 38)

Variable		**n**	**%**
Diameter	4.3 mm	38	100
Length	10 mm	14	36.9
	11.5 mm	1	2.6
	13 mm	20	52.6
Region	Molar	23	60.5
	Premolar	15	39.5
Bone quality	Type I	0	0
	Type II	25	65.7
	Type III	16	42.
	Type IV	0	0
Primary stability	< 35 N.cm	12	31.6
	35-60 N.cm	24	63.1
	> 60 N.cm	2	5.3
Bone graft	No	3	7.9
	Yes	35	92.1
Collagen membrane	Yes	2	5.3
Loading protocol	Immediate	31	81.6
	Delayed	7	18.4
Temporary prosthetic abutment	Peek CR Abutment	38	100
	Cover screw	7	18.4
	Healing abutment	7	18.4

n = sample size.

Complications were observed during the study. Six patients experienced local edema, pain, and suppuration. Technical and mechanical complications were observed, such as

abutment fracture, prosthesis fracture, loss of prosthesis cement retention, excessive bone resorption, and implant failure.

Four of the 38 implants placed were lost before the final prosthesis installation, within four months of follow-up. Implant loss events were probably related to bone overheating during site preparation. New implants replaced all lost implants, and none were lost again. Data from at least 12 months of follow-up have been collected for all remaining 34 implants and final prostheses (30 patients). One implant non-success (recurrent peri-implantitis infection with suppuration) has been reported within this period, resulting in implant survival and success rates of 89.47% (34/38) and 86.84%% (33/38) at T24.

Seven of the 34 temporary prostheses on surviving implants were lost and 11 interventions were reported. Thus, survival and success rates of 79.4% (27/34) and 67.6% (23/34) were observed for the temporary prosthesis. The final prosthesis survival rate was 97.06% (33/34), and success was 94.12% (32/34) at the mean follow-up period of final prostheses 9.1±1.3 months. The reasons for non-success were loss of cement retention, abutment fracture (need for new prosthesis), and lack of contact point.

Two calibrated evaluators measured bone level and showed high inter-examiner agreement rates according to the interclass correlation coefficient. Bone level data from 26 implants were available at 24-month visit. A higher marginal bone level was observed in the implant placement visit compared to follow-up visits (Table 2).

Table 2 – Descriptive analysis of bone level in each study visit

Study visit	n	Mean	S.D.	Median	Min	Max
TP	31	0.37	0.42	0.36	-0.22	1.20
T0	31	0.34	0.44	0.36	-0.22	1.20
TF	29	-0.06	0.45	-0.06	-1.00	1.18
T6	30	0.12	0.40	0.00	-0.60	0.99
T12	30	0.07	0.34	0.00	-0.50	0.92
T24	26	0.09	0.36	0.03	-0.82	0.82

S.D = standard deviation; Min = minimum; Max = maximum; TP = implant placement; T0 = temporary prosthesis installation; TF = final prosthesis installation; T6 = 6-month follow-up; T12 = 12-month follow-up; T24 = 24-months follow-up.

At 12 months visit, a mean bone loss of 0.30±0.31mm (range -0.88 to 0,12) was observed, considering bone levels observed at the time of implant placement (Table 3).

Table 3 - Descriptive analysis of bone loss in study visit intervals

Study visit interval	n	Mean	S.D.	Median	Min	Max
TP-T0	31	0.03	0.20	0.00	-0.76	0.68
TP-TF	30	0.40	0.27	-0.42	-1.08	0.08
TP-T6	30	0.26	0.21	-0.24	-0.73	0.01
TP-T12	30	0.30	0.23	-0.29	-0.73	0.02
TP-T24	26	0.30	0.31	-0.29	-0.88	0.12

S.D = standard deviation; Min = minimum; Max = maximum; TP = implant placement; T0 = temporary prosthesis installation; TF = final prosthesis installation; T6 = 6-month follow-up; T12 = 12-month follow-up; T24 = 24-month follow-up.

The surgeon's satisfaction showed satisfactory results, as shown in Table 4. At the implant placement visit, the parameters regarding implant final placement torque, suitability of the implant for the patient’s needs, and the general opinion regarding the surgery during the implant placement period were evaluated with a mean of 8.9, 8.3, and 9.3, respectively. Finally, the satisfaction of the impression procedure for the temporary rehabilitation was 8.7.

Table 4 – Clinician Satisfaction Assessment

Parameter	Visit	Mean	S.D.	Median	Min	Max
Implant final placement torque	TP	8.9	2.4	9.9	1.5	10.0
Suitability of the implant for the patient's needs	TP	8.3	2.6	9.3	0.0	10.0
General surgical outcomes	TP	9.3	2.0	9.9	4.8	10.0
Impression procedure (temporary rehabilitation)	T0	8.7	4.0	10.0	0.0	10.00

S.D = standard deviation; Min = minimum; Max = maximum; TP = implant placement; T0 = temporary prosthesis installation.

DISCUSSION

Ceramic implants have been widely used as an alternative to titanium implants due to aesthetic factors, ease of production, and the need for metal-free dental rehabilitation[7–9]Among ceramic materials, Zirconia Y-TZP (polycrystal tetragonal zirconia stabilized with yttria) stands out for its superiority in terms of flexural strength and fracture toughness. It also presents excellent biocompatibility with tissues and low susceptibility to plaque adhesion[10–12].

The 24-month follow-up results presented in this report showed an implant survival rate of 89.5% (34/38), with 86.84%% (33/38) implant success. All four implants were lost before final prosthesis installation visit, within 4 months of follow-up, resulting in an implant survival rate of 89.5% at TF. After image exams analyses, bone overheating during implant bed preparation was identified as the possible cause of these losses. Heat generated at the time of drilling, elevation of the periosteal flap, and excessive pressure at the crestal region during implant placement may contribute to implant bone loss during the healing period[13]. The implant survival and success rates of 2-piece zirconia implants observed in the present study are in line with rates reported in the literature, which vary from 87.3 to 95.8%[8,11].

Mean bone loss of 0.30±0.23mm was observed 24 months after implant placement. These are much lower than the expected bone loss values, even for titanium implants with

internal conical connections, and they suggest that peri-implant bone maintenance should be expected with Zi implant rehabilitation[14].

Thirty-four temporary prostheses over PEEK CR Abutments (Neodent, Curitiba, Brazil) were followed for a mean period of 3.8±0.7 months, with survival and success rates of 79.4% (27/34) and 67.6% (23/34), respectively. Provisional crowns are an essential step in single-unit implant-supported rehabilitation as they allow for soft-tissue healing before final rehabilitation, and provisional cementation has been recommended to enable retrievability[15]. However, the risk for leakage and retention loss may be higher than definitive cementation[16].

Concerning final rehabilitation over Zirconia abutments, the prosthesis survival rate was 97.06% (33/34) and success 94.12% (32/34) at T24 (mean follow-up period of final prostheses 9.1±1.3 months). Cionca et al. described the use of 32 zirconia abutments in 32 partially edentulous patients, with two abutments fracture and a prosthesis survival of 96%[8]. Chen et al. performed an extensive literature review of zirconia applications in medicine and dentistry. The included studies described survival rates of zirconia abutments ranging from 82.2% to 100%[17].

Complications were reported in 24 months of follow-up, and all were non-serious, and of mild or moderate severity. Most complications can be classified as probably unrelated to the study device but possibly to the procedure. The most frequent event was the loss of prosthesis cementation. Likewise, previous studies found as the most frequent technical complications concerning prostheses over digital-flow abutments are the decementation of the crown, screw loosening, and ceramic fracture[16].

The follow-up time is a limitation of this study. More follow-up time is necessary to ensure the long-term safety and performance of the two-piece injected zirconia implant. Additionally, only one implant diameter was used in this study, which limit the results. Finally, the implants were placed only in posterior regions lacking data in all mouth regions.

CONCLUSION

The mean bone loss of 0.30±0.31mm (range -0.88 to 0,12) was observed in the 24-month follow-up of the two-piece injected zirconia implant placed in the posterior region. Additionally, implant survival and success rates of 89.47% and 86.84%% were obtained. These results confirm the peri-implant bone level maintenance in up to 24 months of follow-up.

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