Short vs standard implants associated with sinus floor elevation: a randomized controlled trial

Implantes curtos versus *implantes convencionais associados à elevação do seixo maxilar: um ensaio clínico randomizado*

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Abstract

Objective: the present equivalence two-arm parallel randomized controlled trial aimed to compare survival and marginal bone loss (MBL) of short implants (≤6 mm) and standard implants (≥8.5 mm) associated with sinus floor elevation (SFE). Methods: adult patients with partial edentulism with occlusal stability in the sinus area and intermediate bone height were selected in this double-blind trial (patient and outcome assessment). Patients were randomly allocated into two groups: standard length implants with SFE (control) or short implants (test). Clinical and radiographic assessments were made at the time of implant placement, 6 months, and annually thereafter up to 2 years after loading. The inter-examiner agreement was analyzed using intraclass correlation coefficient (ICC). One-way ANOVA, Kaplan-Meier, and Log-rank tests were used to compare implant survival (primary outcome) and MBL (secondary outcome) (P<0.05). Results: eight short implants and six standard implants were placed (mean age of patients was 47 ±12.5 years). The implant survival rates were 87.5% for short (one 5 mm implant failed at 7 months) and 100% for standard implants with no statistically significant difference between groups (P=0.4). The mean MBL after 1 year was 0.30 ±0.62 mm for short and 0.21 ±0.36 mm for standard implants (P=0.123). The inter-examiner agreement was set in 0.831. Conclusion: survival of short implants and standard implants associated with SFE was similar after two years of clinical service. Trial registration: Registered on 27-03-2018 at ClinicalTrials.gov (NCT03479333). Funding: This study was partially funded by Capes Finance Code 001 and #88881.187933/2018-01. TPC is partially funded by National Council for Scientific and Technological Development (CNPq - Brazil). The funders had no role in the study design, data collection and analysis, decision to publish or preparation of the manuscript.

Keywords: bone resorption; dental implants; sinus floor augmentation; survival.

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Introduction

The use of dental implants in prosthetic rehabilitations has increased in the last decades. However, when the edentulous site is in the posterior maxilla there are some challenges to be dealt with as insufficient bone height and volume, poor bone quality, limited visibility, and sinus pneumatization[1]. The lateral window approach for sinus floor elevation (SFE) has been used for the last 40 years[2]. Even with high implant success rates, the technique presents important disadvantages such as high cost, sensitive surgical procedure, and high complication rates[3]. Short implants have emerged as an alternative that could minimize these issues.

For some time, there was no consensus about the threshold for an implant to be considered short, which explains the different lengths that can be found in the available clinical trials. The International Team for Implantology (ITI) Group recently published a consensus report establishing that implants with a length of ≤ 6 mm are considered short implants[4]. Easier and quicker procedure, with lower costs and fewer complications are the advantages of short implants when compared to sinus lift procedures associated with standard implants placement[5,6]. Recent systematic reviews also indicate reduced marginal bone loss (MBL) and fewer biological complications for short implants[7-9]. However, the reduced implant length and the consequent reduced crown-to-implant ratio are the major factures for failure in short implants, although the literature has shown that crown-to-implant ratio higher than 3 is the threshold to avoid an increased MBL, whilst values lower than that do not appear to influence MBL and complication rates[7,10,11].

Considering the high costs and complication rates as well as a the low number of studies to allow strong evidence about the best option to rehabilitate the sinus area with implants, the present study aimed to compare short implants (≤ 6 mm) to standard implants (≥ 8.5 mm) associated with SFE. The primary outcome assessed was implant survival and MBL secondary outcome. The hypothesis tested was that short and standard implants would present similar survival rates and marginal bone loss after at least 1 year of follow-up.

Materials and methods

This study was an equivalence two-arm parallel randomized controlled trial (RCT) following SPIRIT recommendations and reported according to the CONSORT guidelines[12]. The Institutional ethical board of the Federal University of Pelotas, Brazil approved this study (#62477016.0.0000.5318), which was conducted in accordance with the Declarations of Helsinki and registered on 27-03-2018 at ClinicalTrials.gov (NCT03479333). All participants received information about the purpose of the study and signed informed consent.

Patients older than 18 years old were selected and received the treatment at the dental clinic of the University. Inclusion criteria involved good oral and systemic health, bone height of 6-7 mm and 6 mm of thickness, and bilateral posterior occlusal contact. Bone dimensions were confirmed by cone beam computed tomography (CBCT) scans. Exclusion criteria were as follows: radiotherapy in the head and neck area; immunocompromised status; coagulation disorders; use of bisphosphonates; uncontrolled diabetes mellitus; drug abuse; pregnancy or lactation; psychological disorders; untreated periodontitis; poor oral hygiene; recent tooth extraction at the site (less than three months); sinus pathologies; no teeth or prosthesis in the opposite arch for occlusal contact. All patients were non-smokers with no parafunctional habits and with natural teeth as the antagonist arch. All data collection was made at the Federal University of Pelotas, Brazil.

The sample size calculation was based in published studies[13,14] considering a power of 80%, alfa = 5%, 90% of success from the groups, established in the literature when considering implant treatment with standard length, and a 25% difference between the groups, with 25 implants per group.

Due to the lack of similarity in the surgical procedures for the groups, blinding of the operator

was not possible and only the outcome assessment was made by two blind distinct researchers. The patients were blind to the outcome (all patients were unaware of the objective of the study although they knew that sinus floor elevation could happen at the time of the surgery). A person not directly involved in the study performed the randomization process in blocks of 8, 8, and 9 using Excel (Microsoft Corp, Washington, USA). Individual brown sealed envelopes were used to conceal the randomization sequence according to the treatment groups, which were coded as C (Control group) or S (Short implants group). The envelopes were sequentially numbered and opened at the surgery time. Patients were randomly assigned to one of the treatment groups: standard length implants (≥8.5 mm) associated with SFE or short implants (≤6 mm).

Clinical procedures

All patients were evaluated clinical and radiographically prior to the surgery. Since the randomization envelope would only be revealed at the surgery time, each case had the implant length planned based on the CBCT scans by the operator (BMV) for both group options beforehand.

Patients rinsed 0.2% chlorhexidine solution before surgery and the implants were placed under local anesthesia (4% articaine with 1:100,000 epinephrine) and prophylactic antibiotic therapy with 875 mg amoxicillin plus 125 mg clavulanic acid or 300 mg clindamycin in case of penicillin allergy, starting 1 hour before the surgery. A midcrestal incision was made and then a full-thickness flap was raised. At this moment, a person not involved in the procedure opened a sequentially numbered brown envelope containing the treatment group name (short or standard implant) according to the randomization previously made, to determine the group allocation.

In the control group, one vertical releasing incision was included in the flap design as the lateral window approach was used for the SFE. After careful elevation of the Schneiderian membrane, the sinus cavity was partially filled with deproteinized bovine bone substitute (Bio-Oss, Geistlich Pharma, Switzerland). The implant of standard length (Unitite Prime, S.I.N., Brazil) was then placed subcrestally according to the manufacturer's instructions and closed with a cover screw. The cavity was then filled with bone substitute and the flap was closed with vicryl 4-0 (Ethicon, Johnson & Johnson, Sint-Stevens-Woluwe, Belgium). No barrier was needed as none of the cases had a sinus membrane perforation. In the test group, the sites received a short implant (Unitite Compact, S.I.N., Brazil) placed at the crestal level with no need for a larger flap or bone graft. Both test and control groups received implants with Morse taper implant-abutment connection.

Baseline periapical radiographs were made with the paralleling technique. Patients received postoperative instructions of soft diet, oral hygiene including the use of mouth rinse containing 0.2% chlorhexidine for 21 days, 750 mg acetaminophen every 6 hours in case of pain and 600 mg ibuprofen every 8 hours for 5 days. Sutures were removed 1 week later.

Six months after the implant placement, its stability was checked based on radiographs and probing depth. Primary stability was considered in case of a minimum torque of 32 N.cm. The cover screw was then replaced by the healing abutment. After 2 weeks the definitive abutment was installed, impressions were taken and a provisional resin acrylic restoration was placed and kept in situ until the operators achieved a satisfactory soft tissue profile. Next, a metal-free single crown was cemented with a self-adhesive cement (RelyX U200, 3MESPE, Minnesota, EUA) in all cases. Occlusion was checked and the patients were recalled after 3 and 6 months and annually.

Outcomes and statistical analyses

The primary outcome was the implant survival, defined as implant mobility, removal of stable implants indicated due to a progressive marginal bone loss or infection, or any mechanical complication rendering the impracticable use of the implant. MBL was evaluated as a secondary

outcome on periapical radiographs taken at the time of implant placement, 6 months, and annually thereafter. The distance between the coronal margin of the implant collar and the most coronal point of the bone-to-implant contact was measured on each image by an external clinical examiner, using ImageJ software (National Institutes of Health, Bethesda, MD, USA). The known implant length was used to calibrate the software. The trial outcomes were kept the same from the day the trial commenced until the end of the trial.

Statistical analyses were made using R 3.6.1 and the packages 'irr', 'survival', and 'ANOVA. TFNs'[15-18]. The inter-examiner agreement was analyzed within the intraclass correlation coefficient (ICC). The unit of analysis was the implant, and bone level changes in the groups were compared statistically through one-way ANOVA (P<.05). Descriptive statistics as means and standard deviations (SD) were obtained from the patient's characteristics and implant measurements. Kaplan-Meier curves were used to show the longevity of the treatments and Log Rank test for differences between the groups (P<.05).

Results

After screening for eligibility (80 patients), 11 patients (8 female and 3 male) with a mean age of 47 (12.5) years old at baseline were included since April 2018 and followed up for 23.9 (5.7) months. There were no patients aged 60 or higher. Fourteen implants were placed, 8 short implants and 6 standard implants associated with SFE. Due to the lack of resources resulting from the COVID-19 pandemic, the study was cancelled and the initial results are being described.

The only implant failure occurred in the short implant group with 7 months of follow-up – time of reopening – and the patient was referred to another clinician to continue the treatment. The loss of integration of the failed implant was confirmed in the follow-up appointment when confirming the final torque to proceed with the prosthetic procedures.

For the statistical analyses, data from the 11 patients were included for the first MBL measurement (baseline to six months follow-up). The analysis from baseline to 1 year used data from 10 patients because of the failure, with an analysis of MBL of 7 short and 6 standard implants.

There was no statistically significant difference in MBL changes between the groups in the periods investigated (Table 1). After a follow-up period of 23.9 ±5.7 months, the MBL was 0.30 ±0.62 mm for the short implant group and 0.21 ±0.36 mm for the standard implants associated with SFE (P=0.123). The ICC of 0.831 indicates good reliability in the present results.

Table 1 – Marginal bone level changes (mm) between groups

	Group		
	Short	Standard	
Follow-up period	Mean (SD)	Mean (SD)	P-value*
0 to 6 months	0.02 (0.47)	0.06 (0.36)	0.8635
0 to 12 months	0.30 (0.62)	0.21 (0.36)	0.123

*Hypothesis of no difference in MBL between the test and the control groups (one-way ANOVA).

Source: research data.

The implant survival rate was 100% for standard implants and 87.5% for short implants, the survival analysis also showed no difference between the groups (P=0.4) (Figure 1).

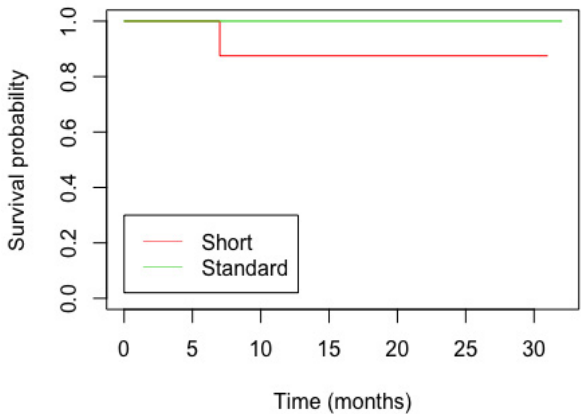

Figure 1 – Kaplan-Meier survival curves for the investigated treatments (P=0.4)

Source: research data.

Discussion

The present study reports the preliminary results of a RCT comparing short implants with standard implants associated with SFE. Despite 1 implant failure at the intervention group, our findings showed no differences in survival and MBL. To deal with insufficient bone height in consequence of tooth loss and sinus pneumatization, sinus lift with the lateral window approach has been used in the last decades[2]. Short implants have emerged as the current main alternative treatment for these clinical situations.

Marginal bone loss is considered one of the frequently assessed outcomes in implant dentistry. All implants were placed by the same experienced operator, which may partially respond to why there were few complications. Our study found no difference between the treatment alternatives (P=0.123), in agreement with part of the literature. Despite the acceptable MBL for both groups when considering the accepted values for standard implants[19], it is important to consider that even when the short implants present similar MBL compared to standard-length ones, a bone loss of 2-3 mm in a 6 mm implant has a different impact from an 11 mm implant[20]. From the systematic reviews of RCTs published on this topic, 1 found no difference between these groups[21] while other 2 advocated reduced MBL values for short implants[7,22]. This difference in the effect direction among reviews could be explained by the number of primary studies included. The reviews[7,22] that found a reduced MBL for short implants included more studies compared to the review[21] that found no difference between treatments.

Our findings for implant survival are in agreement with the ones from systematic reviews[7,21-23] and randomized controlled trials[5,24,25]. However, it is important to highlight that the reduced implant length is still the major factor for failure[7]. Lower bone quality from the area is related to a higher failure rate[26], mostly happening in an early phase of the osseointegrations process[27]. Despite the attempt to ensure greater contact between implant and bone by using implant with a surface treatment, we believe the poor bone quality was the reason for the failure that we had in the short implant group.

The 2-year follow-up period and the number of patients below the sample size previously calculated are the limitations from the present study. Even though 80 patients were screened for eligibility, inclusion criteria as nonsmokers or non-bruxers and the natural teeth in the opposing arch made the initially calculated sample size also difficult to achieve. Despite that, the similar performance of both groups for the primary (implant survival) and secondary outcome (marginal bone loss) suggests that clinical decision making has also to be based on other relevant aspects to the patient and/or to the dentist.

Conclusion

Despite the low number of patients included in the present study, it can be concluded that short implants and standard implants seem to perform similarly for implant survival and MBL. Costs, surgeon's preferred techniques, and other issues should be taken into account when selecting short or standard implants. Further studies with longer follow-up and considering patient-related outcomes should also be conducted.

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Resumo

Objetivo: o presente ensaio clínico randomizado de dois braços de equivalência comparou a taxa de sobrevivência e a perda óssea marginal de implantes curtos (≤ 6 mm) e implantes convencionais (≥ 8.5 mm) associados à elevação do seio maxilar. Métodos: edêntulos parciais adultos, com estabilidade oclusal e altura óssea

intermediária na região do seio maxilar, foram selecionados neste estudo duplo-cego e alocados randomicamente em dois grupos: implante de comprimento convencional associado à elevação do seio maxilar (controle) ou implante curto (teste). Avaliações clínicas e radiográficas foram realizadas logo após a instalação do implante, seis meses e anualmente por até dois anos. A concordância interexaminador foi avaliada através do coeficiente de correlação intraclasse. Os testes ANOVA de uma via, Kaplan-Meier e Log-rank foram utilizados para comparar a sobrevivência do implante e a perda óssea marginal (P<0.05). Resultados: oito implantes curtos e seis implantes de comprimento convencional foram instalados em onze pacientes (média de idade dos pacientes: 47 ± 12.5 anos). As taxas de sobrevivência dos implantes foram de 87,5% para implantes curtos (um implante de 5 mm falhou aos sete meses), e 100% para implantes convencionais, sem diferença estatisticamente significativa entre os grupos (P=0.4). A perda óssea marginal média após um ano foi de 0.30 ±0.62 mm para implantes curtos e 0.21 ±0.36 mm para implantes convencionais (P=0.123). A concordância interexaminador foi de 0.831. Conclusão: a taxa de sobrevivência de implantes curtos e convencionais associados ao seio maxilar foi semelhante após dois anos de acompanhamento.
Registro do estudo: Registrado em 27-03-2018 no ClinicalTrials.gov (NCT03479333).

Palavras-chave: reabsorção óssea; implantes dentários; levantamento do assoalho do seio maxilar; sobrevivência.

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