Soft and hard tissue maintenance **following placement of immediate-loaded implants in the aesthetic zone: a prospective longitudinal clinical trial**

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Objective: *To evaluate by clinical and radiographic bi- and tridimensional means the soft and hard tissues alterations following immediate implant placement and loading in postextraction sockets in the anterior maxilla.* **Material and methods:** *Ten patients, treated with immediate-loaded implants in the maxillary central or lateral incisors, were evaluated in this study. Clinical parameters were evaluated in standardized pictures taken at baseline (immediately after), and 1, 3, and 6 months after provisional implant-supported single crown placement. Bi- and tridimensional radiographic parameters were evaluated from standardized digital periapical radiographies and from CBCT images. The volume of the buccal bone wall covering the central millimeter of the implant was also assessed in the CBCT images.* **Results:** *The variation for all clinical, bi- and tridimensional parameters assessed was non-statistically significant. There was 94% maintenance of bone volume.* **Conclusions:** *The parameters assessed showed good clinical, bi- and tridimensional radiographic stability of soft and hard tissues for implants immediately placed and loaded in aesthetic zones.* **Keywords:** *Clinical trial. Immediately loaded implant. Immediately placed implant.*

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» Patients displayed in this article previously approved the use of their facial and intraoral photographs.

INTRODUCTION

In the conventional (delayed loading) implant protocol, a certain period of undisturbed healing is suggested for uneventful implant osseointegration.[1,2,3] Although this approach has been proved to be a highly predictable and successful treatment modality, the extended treatment period may be perceived as a considerable inconvenience for patients expecting rapid rehabilitation, especially when the anterior region is considered.[4,5,6] Moreover, meta-analysis of treatment outcomes of single-tooth implants treated with immediate, early and conventional loading protocols demonstrated no discernible difference between the different loading protocols.[7] Thus, considerable effort has been directed towards immediate/early loading of dental implants, aiming at a reduction in time between tooth extraction and final prosthesis delivery.

In some cases, this protocol has been associated with immediate implant placement into fresh extraction sockets.[8-11] This procedure has been advocated as a means not only to reduce treatment time and cost, but also to preserve the alveolar structures that are resorbed following the extraction of the tooth.[12]

However, systematic literature reviews did not find clinical trials evaluating whether immediate implant placement and loading are capable to maintain the bone volume of the extraction socket and the peri-implant gingival architecture.[11] Sufficient alveolar bone volume and favorable architecture of the alveolar ridge are essential to obtain optimal functional and aesthetic prosthetic reconstructions. Therefore, knowledge about the healing process at extraction sites, including contour changes caused by bone resorption, is essential for treatment planning.

The objective of the present study is to evaluate — by clinical and radiographic bi- and tridimensional means — the alterations in soft and hard tissues following immediate implant placement and loading in the anterior maxilla.

MATERIAL AND METHODS

The present study have been approved by Universidade Federal de Uberlândia Ethics Committee for Human Research, Brazil (protocol #549.913).

Ten patients with one single anterior tooth in the maxilla (lateral or central incisor of both sides) referred for extraction were included. Extractions were accomplished with the aid of periotomes and forceps, without damaging the bone walls, in a flapless approach (Fig 1). All extraction sockets received immediate implants (Unitite®, SIN - Sistema de Implante, São Paulo, Brazil), with a double acid-etched surface coated with nanocrystalline hydroxyapatite (Unitite SINactive, SIN-Sistema de Implantes, São Paulo, Brazil). All implants were placed with the shoulder at least 1 mm and no more than 3 mm below the level of the marginal portion of the buccal bone plate. No bone grafting procedures were attempted to fill the gap between the implant and the buccal bone plate. The implants received individualized immediate prosthetic devices with light occlusal contact with the antagonist teeth at excursion movements of mandibular teeth (Fig 2). After 6 months, the provisional prosthetic devices were replaced for definitive ceramic crowns.

In this study model, images were acquired with the aid of a Newtom 3G device (QR Imaging, Verona, Italy) which generated images (DICOM-based data sets) with a resolution of 96 dpi, 14-bits gray scale and 0.25 mm voxel size. The CBCT unit was set up to operate at 120 kVp, 5 mA, with a 20-second exposure time.

All patients were scanned before and 6 months after surgery. The DICOM data

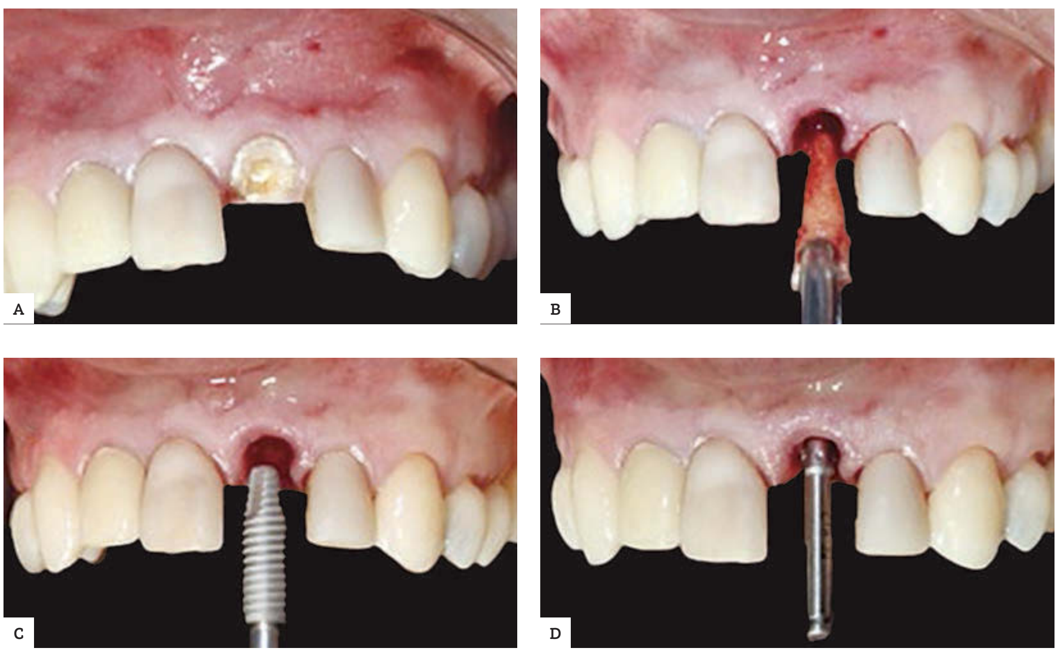

Figure 1. A) Hopeless root of a maxillary central incisor. **B**) Root extraction. **C**) Implant placement. **D**) Implant final position.

Figure 2. A) Provisional abutment. **B**) Provisional crown.

sets were saved on a hard disk and reconstructed using specific software (OnDemand 3D 1.0.7.0295, Cybermed, Seoul, South Korea) to reconstruct the image sections and export the bidimensional image sets for quantitative evaluation of bone size.

Based on the tooth selected for inclusion, and respecting a 2-mm margin both mesially and distally, 0.25-mm thick cross-sections (distance between sections = 1 mm), through the residual ridge and jaw bone, were generated perpendicular to the occlusal plane. The same number of sections was generated for each individual region for both observation periods. The exhibition contrast of the images was adjusted, and the center level (L) and band width (W) were set according to suggestions in the software (W = 3086 and L = 667).

For every CBCT section, one TIFF (tagged image file format) image was generated. The images had a resolution of 96 dpi, matching the scanner resolution and therefore avoiding distortion. They contained a ruler which allowed the setting of the linear scale of each image.

TIFF images were assessed with the aid of a specific image processing software (ImageJ, NIH, USA) by manually tracing the structures under study with the computer mouse (Fig 3). In order to attain a measuring standard in all images, the total maxilla visible in each image section was included (i.e. traced). The changes in bone area over time were also calculated and expressed as a percentage. Finally, to evaluate the reproducibility of measurements, 30% of samples were measured in duplicate with at least two weeks between measurements, and the differences were tested by means of Pearson's correlation analysis.

Radiographs were taken at baseline (prosthetic device installation), 1, 3 and 6 months after implant loading, with the paralleling technique using an intraoral radiographic unit (70 kV, 8 mA, and 0.2 s). A custom tooth-supported individualized positioning device ensured image standardization for radiographic follow-up (Fig 4). The digital sensor (Schick CDR Elite, Schick Technologies, USA) was used to obtain digital images. The images were stored in TIFF format in 8-bit depth (256 shades of gray) without compression. Images were imported to digital image software (Image J 1.32j, National Institutes of Health, USA) and displayed on a 17-inch S-VGA flat screen monitor (1280 x 960 pixel resolution). The following marginal bone level analysis were conducted: IT – fBIC = vertical distance from implant top to the first bone-implant contact; BC – fBIC = vertical distance from the bone crest to the first bone-implant contact; LBL (lateral bone loss) = horizontal distance from the implant top to the internal wall of crestal bone defect.

To objectively examine the aesthetic outcome of implants, intraoral photographs were taken. The images were imported to a digital image software (Image J 1.32j, National Institutes of Health, USA) and displayed on a 17-inch S-VGA flat screen monitor (1280 x 960 pixel resolution).

The following soft tissue level analysis were conducted: soft tissue level (C) = the distance between the incisal border of the provisional crown to the soft tissue margin at the facial site of the implant; height of keratinized mucosa (K) = the distance between the soft tissue margin and the mucogingival line at the facial aspect of the implant site; papilla level (P) = the distance between the incisal border of the provisional crown to the top of the papilla, mesial and distal to the implant-supported crown (Fig 5).

Data were subjected to normality test analysis (D'Agostino & Pearson omnibus normality test). Variables with normally distributed data were evaluated using repeated measures ANOVA followed by Tukey post-test for multiple comparisons. Statistical significance was set at 5% ($p < 0.05$).

RESULTS

The variation for all clinical (photographic), bi- and tridimensional parameters assessed was non-statistically significant (Figs 6, 7 and 8).

Mean 'P' was 5.55 ± 1 mm, considering all time periods, while 'C' and 'K' were 9.2 ± 1.2 mm and 5.3 ± 1.6 mm, respectively. Mean IT-fBIC was 1.3 ± 0.8 mm, considering all time periods, whilst BC-fBIC and LBL were 3.9 ± 1.1 mm and 0.3 ± 0.1 mm, respectively. There was a 94% maintenance of bone volume.

DISCUSSION

The present study was carried out to evaluate the alterations in soft and hard tissues following immediate implant placement and loading in the anterior maxilla. It has been demonstrated that implants immediately placed and loaded are capable to maintain good clinical, bi- and tridimensional stability of soft and hard tissues of extraction sockets.

Resulting from tooth extraction, a series of biological processes are likely to occur, such as: bone resorption, both vertically and horizontally, with a change in the height and thickness of the alveolar bone; gingival collapse; migratory movements of adjacent teeth and modification of bone quality with a collapse of compact bone and formation of alveolar bone marrow.[12-15] The process of alveolar remodeling is usually the cause of biological, aesthetic and functional damage, which sometimes hinders the possibility of implant treatment.

Some authors suggest that placement of non-loaded implants into post-extraction sockets could maintain the original shape of the alveolar ridge.[12] However, animal studies and clinical trials have shown that a process of bone resorption arises, mainly on the buccal surface of alveolar bone, regardless of the presence of the implant in the extraction socket.[16-19] In addition, experimental studies in humans have found a similar amount of horizontal bone resorption for extraction sockets that received immediate implant placement,[20,21] in comparison to the resorption observed when the socket is left to heal spontaneously after tooth extraction.[13] Nevertheless, the amount of resorption in

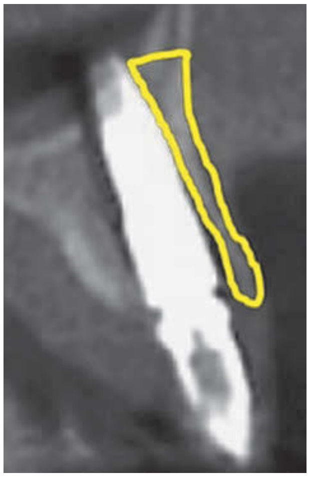

Figure 3. CBCT evaluation of buccal bone wall covering the central millimeter of the implant.

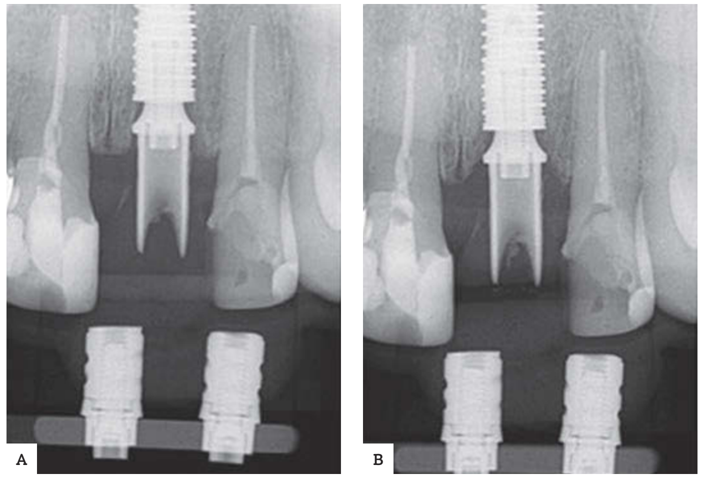

Figure 4. A) Radiograph taken at baseline. **B**) Radiograph taken at 6-month follow-up. Note the good standardization of geometric positioning.

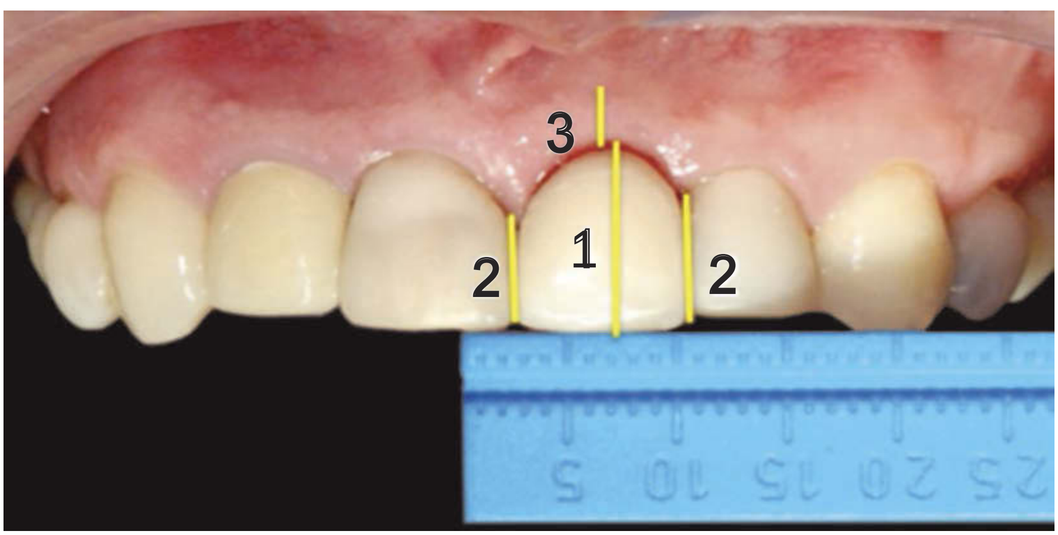

Figure 5. Assessment of aesthetic outcome of implants: **1**) Soft tissue level, **2**) Papilla level, **3**) Height of keratinized mucosa.

preclinical models of immediate implants is inconsistent and may be affected by implant location, implant diameter,[23] implant surface,[22,25] socket dimension, thickness of the buccal bone plate,[17,18] and the surgical approach.[19,24]

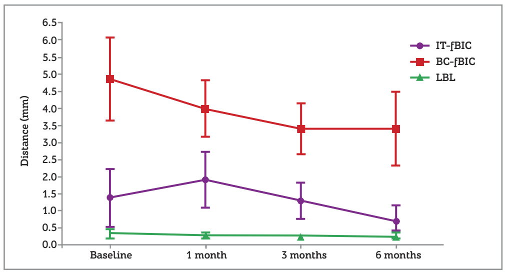

Figure 6. Radiographic measurements (mean and standard deviation) assessed in the patients. Although a tendency towards lower IT-ƒBIC and BC-ƒBIC through time can be seen in the graphic, changes were not statistically significant.

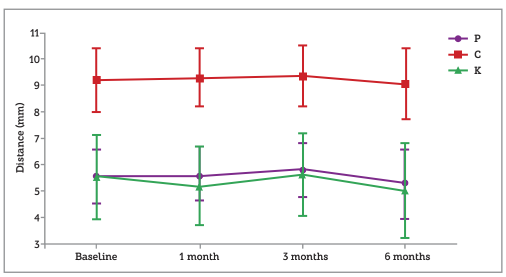

Figure 7. Clinical measurements (mean and standard deviation) assessed in the patients. All parameters were stable during the period of evaluation (P = papilla level, C = soft tissue level, K = height of keratinized mucosa).

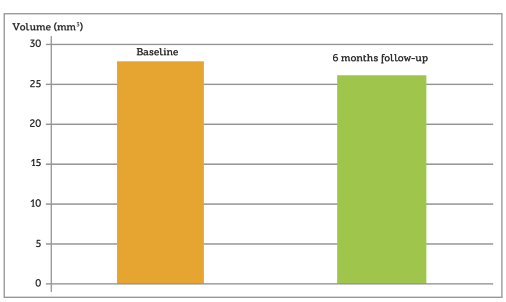

Figure 8. Comparison of buccal bone volume from baseline to 6-month follow-up. Bone volume changes were not statistically significant.

On the other hand, regardless of whether an implant is put in function following an undisturbed healing or immediately after placement, the long-term success of implant treatment is also greatly influenced by the biomechanical environment. The intimate bone-implant contact in the interface allows the direct transmission of the loads applied over the implant prosthetic device to the surrounding bone. Although precise determination of the loading level that separates mechanical loading into acceptable, osteogenic or failure-inducing levels is difficult and until now unresolved, some authors focused on the bone strain amplitudes as the mechanical stimulus determinant to bone adaptive process. It has been shown that above a certain strain threshold (100με), bone can be maintained and will respond with increasing formation activity with increasing strain, until it reaches a pathologic overload threshold (> 4000με), which may cause bone loss by microdamage accumulation.[26-31] Underloading and bone loss by disuse might be seen under the strain limit of 100με. Nevertheless, it is important to emphasize that despite the potential strain zones of bone underloading (< 100με, bone loss by disuse), normal load (100 – 1,500με, bone maintenance or homeostasis), mild overload (2.000 – 4.000 με, bone gain) and pathologic overload (> 4000 με, bone loss by microdamage accumulation) have been suggested in biomechanical studies, rather than only strain amplitude, also loading frequency and number of loading cycles are parameters capable to greatly influence cortical bone adaptive response.[31-35]

Evaluating the biomechanical environment of immediately placed and loaded implants by means of finite element method (FEM), Pessoa et al[36-39] found strain levels (>100 $\mu\varepsilon$) compatible with the maintenance of most part of the extraction socket, including the buccal alveolar plate. Similar results were yielded by Cehreli et al[40] in a cadaver model: the authors argued that the load was transferred to the labial marginal bone even without a direct contact with the implant due to the site-specific tridimensional shape of the bone defect. In addition, in real clinical practice, once an implant is immediately placed, the blood clot and thereafter the initial connective tissue in the bone defect could help to transfer functional load and stimulate the bone that is not contacting the implant.[41,42] One can speculate whether such stimulus could prevent disuse atrophy of marginal bone, as it was demonstrated by the results in the present study.

However, recently published animal studies have shown that the amount of bone resorption was similar in immediate implants with immediate loading and in immediate implants with delayed loading.[43,44] These results are in contrast with a recent meta-analysis that showed, corroborating the present study, favorable marginal bone changes after one year for bimodal approach.[45] Nevertheless, a larger sample should be considered for further studies due to the rather large standard deviation found.

CONCLUSIONS

Within the limitations of the present clinical study, it can be concluded that implants immediately placed and loaded in aesthetic zones showed good clinical, bi- and tridimensional radiographic stability of soft and hard tissues.

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