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Use of Prototyping Technology as an Aid for Oral Rehabilitation

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Authors' contributions

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ABSTRACT

The purpose of this manuscript is report the novel prototyping device for intra-oral rehabilitation in patients with atrophic and extended areas of bone loss. Virtual maxilla models were produced using 3D reconstruction of CT scan, using InVersalius Software. On virtual models was designed the customized device, with determinate characteristics such as porosity, pore range, wall thickness and extension and also number and position of hexagonal attachment. Maxilla models and customized devices were printed using additive manufacturing technology to analyze the compatibility of virtual characteristics. Mechanical flexural test and cytotoxicity tests were produced to valid the chosen material alloy. The results demonstrate viability of the novel device. Ti-6Al-4V alloy presents compatible flexural strength with the maxilla bone, and do not show any characteristic of cytotoxicity. The proposed design shows a saddle juxtaposed on the mandibular crest, allowing a homogenous tension distribution; a variable numbers and positions of screws with hexagonal attachment. Due the flexible screw design it brings an improvement to an easy prosthesis fixation, and since the hexagonal attachment is compatible with commercial parts it enables a cost reduction and increase the viability. The novel device has suitable characteristics to become a feasible option for patients with atrophic oral regions.

Keywords: Dental implants; prototype device; atrophic mandible.

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1. INTRODUCTION

The increase in life expectancy and the search for more comfort and health, lead to several studies for devices development that could provide a prolongation in the quality of life [1]. In dental area, this development generated a search by professionals and patients for more advanced techniques aiming a less invasive oral rehabilitation treatment, with aspect and functions closer to natural [2].

Implants are devices used to replace lost teeth, usually with cylinder or dental root shapes, usually made of a titanium-based metal alloy. The adhesion of the implants occurs through a mechanism called osseointegration, which is the union or adhesion between the bone structure and the surface of the implants. This process occurs between four to six months, however modifications in the surface demonstrate to reduce this time. In general terms, the dental implant is a device that is placed in the maxillary bones of the patient and that after the osseointegration will allow prosthesis to be built supported on it. The success of titanium implants is mainly due to their biological and chemical stability. Commercially pure titanium (cpTi) and alloys such as Ti-6AL-4V are the most widely used metallic materials since they are biocompatible and have excellent mechanical properties [3]. In addition, other advantages of this metal can be highlighted as its specific weight, its good mechanical resistance and the absence of allergic and immunogenic reactions. The biocompatibility of titanium implants is attributed to the oxide layer, which is formed spontaneously upon the contact of titanium with oxygen [4]. This reaction prevents the formation of fibrous tissue around the implant, thus enabling the formation of bone tissue. The surface of the titanium is ideal for the retention of fibrin on its surface. Once this layer of fibrin is fixed, the osteogenic cells migrate towards it and begin the process of bone neoformation. Initially the osteogenic cells are fixed on the surface secreting proteins and proteoglycans, later a calcium phosphate precipitation occurs, followed by the formation of collagen fibers and mineralization of this matrix [5].

In the attempt to increase the success rate of osseointegration, several treatments were performed on the surface of the titanium, which could have a smooth surface, sandblasted by acid treatment, have a coating of hydroxyapatite, or spray plasma [6]. Most dental implants offer some form of surface treatment, giving roughness to the surface of the titanium. Commercially, titanium implants are covered with hydroxyapatite by means of processes generally called "thermal spraying", with more plasma atomization being used. Thus, with the use of a coating on the surface of the titanium, by components that imitate the organic and inorganic portion of the bone tissue, thus occurring a physiological transition between the surface of the titanium and the bone tissue. In this way, the titanium coating functions as a scaffold to promote the fixation of bone cells.

Implants with higher surface area, bioactive surface, and new designs are results of technology improvement [7]. However, even with advances in the development of techniques and materials, oral rehabilitation is still a great challenge, especially when there is little vertical bone height, resulting in the need for bone grafting and subsequent implant placement.

Recent technologies such as additive manufacturing allow objects to be produced with complex architecture and with high precision [8,9,10]. One of the additive manufacturing methods is the direct sintering of the metal by laser, thus obtaining the object through the sintering of mixtures of 100% metal powders [11,12]. Some equipment may use biocompatible materials, as in the case using Ti-6Al-4V alloy with the EOS equipment. This biomedical alloy is widely used in the medical and dental area due to its biocompatibility, corrosion resistance and mechanical properties [13].

Our purpose was the development of a new device, for oral rehabilitation using additive manufacturing technology, which will allow a treatment option in cases of oral rehabilitation with minimal vertical bone quantity.

2. MATERIALS AND METHODS

The device project had different stages process: 1) initially, it was carried an study for the design creation: diameter of the pores, thickness of the device and an ideal area for the dental prosthesis attachment; 2) investigation of Ti6Al4V biocompatibility; 3) Flexural test to provide data of mechanical property; 4) 3D maxilla's and device virtual models; 5) 3D maxilla's and device polymer models; 6) Investigation of the rehabilitation with prosthesis simulations.

Stage 1- in this process an investigation on the literature was carried out to allow ideal

characteristics of this new device, e.g. pores dimensions, biomaterial choice and a study of the area for dental prosthesis attachment.

Stage 2- indirect cytotoxicity assay was performed, using the ISO 10993 protocols [14]. Firstly, it was printed samples for this in vitro assay, using EOSINT equipment. The equipment had the adjustment of the standards according to the literature: 170 W laser power, scanning speed 1250 mm / s, layer thickness 30 microns, line spacing 100 microns and scanning angle 45 degrees [15]. The software used in the process was the EOS RP-Tool, which is provided by the equipment manufacturer. Using this software it was possible to convert the STL or CLI extension CAD model in the SLI format, specific to the equipment. Samples were produced in Ti6Al4V, with 1.3x2.0x25 mm dimensions.

The fluid extracts were obtained by mixing the test material (Ti6Al4V) at a final concentration of 0.2 g / ml. The assay was performed using a 96-well plate seeded with 10000 cells per well and extract dilutions of 100 to 6.25%. Meanwhile, suspensions of CHO-k1 cells (Chinese ATCC ovary hamster cells) and incubated in RPMI 1640 (Gibco 23400) cell culture medium with antibiotic and antimycotic (100 µg / ml penicillin, 100 µg / ml streptomycin and amphotericin 0.025 Âµg / ml). Also 2 mM glutamine and 10% calf serum were added at 37Â°C in a 5% CO2 humidified atmosphere until reaching confluency. For the experiments, the cells were detached using 0.05% trypsin and 0.02 EDTA in phosphate buffered saline at pH 7.4. Cell viability was measured by addition of MTS / PMS solution (tetrazolium compound and phenazine methosulfate) (20:1) and incubated for 2 hours at 37ºC in a humidified 5% CO2 incubator. The wells were analyzed in a spectrophotometer at 490 nm using 0.2 g / mL commercial titanium as negative control and a 0.5% phenol positive control.

Stage 3- the new device has pore size and interconnectivity dimensions determined using literature data. However, to investigate the thickness influence on the bending property it was performed flexural tests. Samples were produced using EOSINT equipment, in final dimensions 1.3x2.0x25 mm and 2.4x2.0x25 mm.

The bending test had the following parameters: Distance between the supports of 20 mm, speed of 3 mm / min and 3-point bending. All parameters of the test and the preparation of the samples followed the standard F382-99-astm (Specification, 2013) and it was used the MTS-DEMA-FEM-Unicamp equipment.

Stage 4- CT scans on DICOM format was documented. This data was worked by the InVersalius Software and it was possible to create 3D maxilla's models: Overlapping images to construct from the two-dimensional images a three-dimensional model identical to the anatomical structure; in addition, through the segmentation tool it was possible to expose only the part of interest, in this case the bone tissue the others tissues such as skin, muscles, arteries, nerves and connective tissue were removed.

With this 3D maxilla's models the new device for personalized dental reconstruction was developed.

Stage 5- 3D maxilla and the new device models were printed using stereolithographiy 3D printer (Biofabris- INCT).

Stage 6- Cast arcades models were adapted on a vertex articulator to reproduce the static and dynamic mandible positions simulations. With the 3D new device model, printed by SLA, it was possible to fabricate a temporary prosthesis in acrylic resin (Dencor®) to simulate the final result of the rehabilitation.

The 3D maxilla's models with the temporary prosthesis were scanned overlaying on the 3D virtual models. It was also investigated the ideal area for the prosthesis placement.

Revised standards for quality improvement reporting excellence (SQUIRE 2.0) was used as guideline for the manuscript preparation. All the results are expressed as mean ± SE. Comparisons between groups were made using ANOVA, followed by Tukey's correction factor for multiple comparisons as a post-hoc test.

3. RESULTS

The new device prototype specifications were determined on literature base data: Pores size and interconnectivity are important factors for bone ingrowth, the range 100-400 µm is considered as optimal pore size [16]. Tissue differentiation and bone ingrowth are characteristics results of an optimal implant surface, therefore it was determined Ti-6Al-4V alloy as the biomaterial choice. Since, this alloy

presents excellent mechanical and corrosion resistance, absence of problems related to allergies and biocompatibility therefore it is highly used in dentistry and medicine [3,17].

For the biocompatibility and mechanical tests, samples were produced using EOSINT equipment. Fig. 1 shows the morphology of the surface, likewise the pores diameter and interconnectivity.

The use of pure titanium and Ti-6Al-4V alloy are still the most used for biomedical applications compared to other alloys [3]. Fig. 2 presents a graph of MTS data with data obtained by ISO 10993-5 protocol: The cell viability% of the extract biomaterial had value similar with the negative control.

One characteristic of this biomaterial is the biocompatibility property. Another important characteristic of the Ti-Al-V alloy choice as the alloy for implant devices is the chemical composition. This alloy allows its elements to be altered in order to modify the properties, the amount of aluminum tends to stabilize the α phase, the vanadium ß phase, reducing the transformation temperature from α to ß. The α phase promotes good wettability and excellent resistance characteristics, besides presenting more resistance to oxidation. The beta phase has low stiffness and excellent malleability [3]. Flexural tests were performed to quantify the influence of pores size and thickness on the structure: two groups were investigated thickness of 1.3 and 2.4 mm, according to Fig. 3.

The device was constructed using a maxilla's human CT scan model; tissues were segmented to allow the expose of the bone tissue Fig. 4. The parameters of the device construction were discussed before on stage 1. Model and the new device were printed using stereolithography 3D equipment (Fig. 5).

Verification of the device position was made using cast arcades models with SLA printed device. The structure was scanned to compare with the virtual model (Fig. 6).

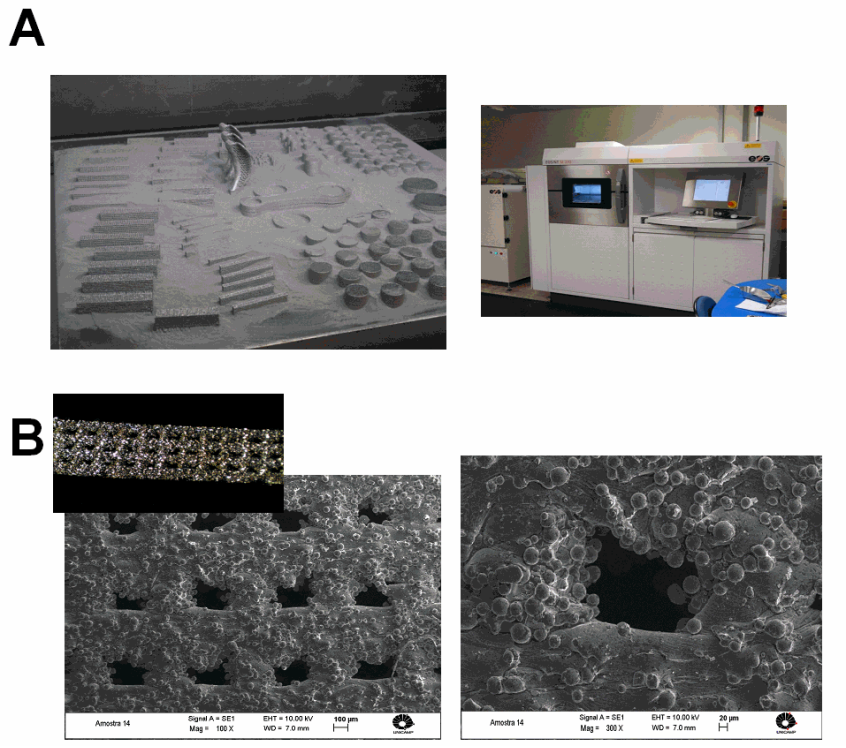

Fig. 1. Equipment used for samples production and your morphology: A) Different samples produced during one cycle of the EOSIN equipment, image on the right; B) Morphology of the prototype sample by optical and scanning electron microscopes: magnitudes 40x, 100x and 300x (scale bar 100 and 20µm, respectively)

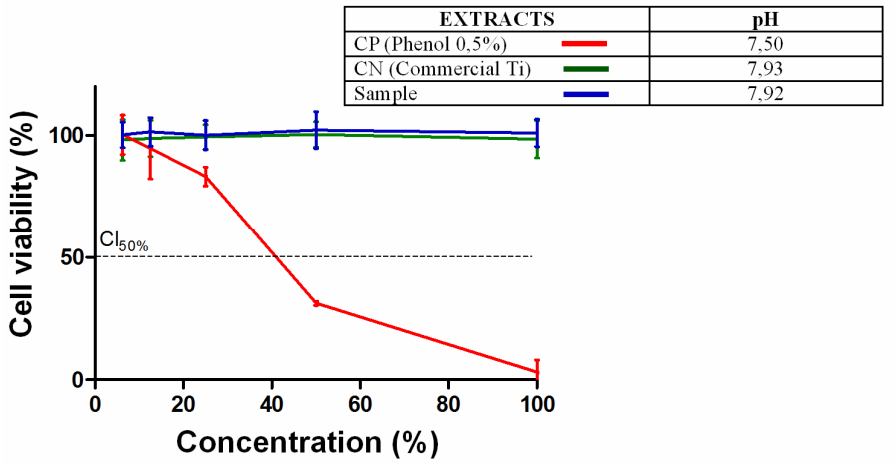

Fig. 2. *In vitro* cell viability assay: Positive control was phenol 0.5% (red line), Negative was commercial Ti (green line) and prototype sample (blue line); pHs of extracts were 7.5, 7.93 and 7.92, respectively; cell viability of prototype samples was similar with the negative control and approximately of 100%, indicating the non-toxicity of the alloy

A

Samples	Thickness (mm)	UTS (MPa)	Max load (N)	Fracture load (N)
A	2.4 (0.014)	428.8 (60.7)	165.2 (5.6)	163.7 (3.9)
B	1.3 (0.05)	383.2 (36.6)	46.3 (1.3)	45.9 (1.1)

B

Fig. 3. Mechanical flexural test: A) Data of 2.4 and 1.3 (mm) thickness samples, fracture load 163 and 45 (N), respectively; Instron equipment used to perform the tests (FEM-UNICAMP)

4. DISCUSSION

Customized prosthesis are very used nowadays, they provide a greater comfort and performance. In dentistry field, computer technology and medical imaging together with rapid manufacturing have elevated expectations, e.g. customized drill guide assists the professional during jawbone drilling, that allows a precise and correct drill, on the position and angulation defined [18]. A wide range of solutions is provided using additive manufacturing technology, in this report it is demonstrate an oral rehabilitation solution for patients that presents low vertical bone especially in posterior mandible area.

Normally, the rehabilitation of those cases is often limited to the use of dentures or removed partial prosthesis. However, the use of dental implant is possible with a previous surgery to dislocate the mandibular nerve, which enhances potential permanent sequelae, such as paresthesia, hypoesthesia and anaesthesia of the nerve [19]. The dislocation causes an increase of vertical bone that may be used to attach dental implants, however is considered a high-risk surgery since this technique presents disadvantages such as does not recover alveolar ridge anatomy, causes a temporarily mandibular weakness and it is not indicated to patients with bruxism or poor occlusal relations [19–21].

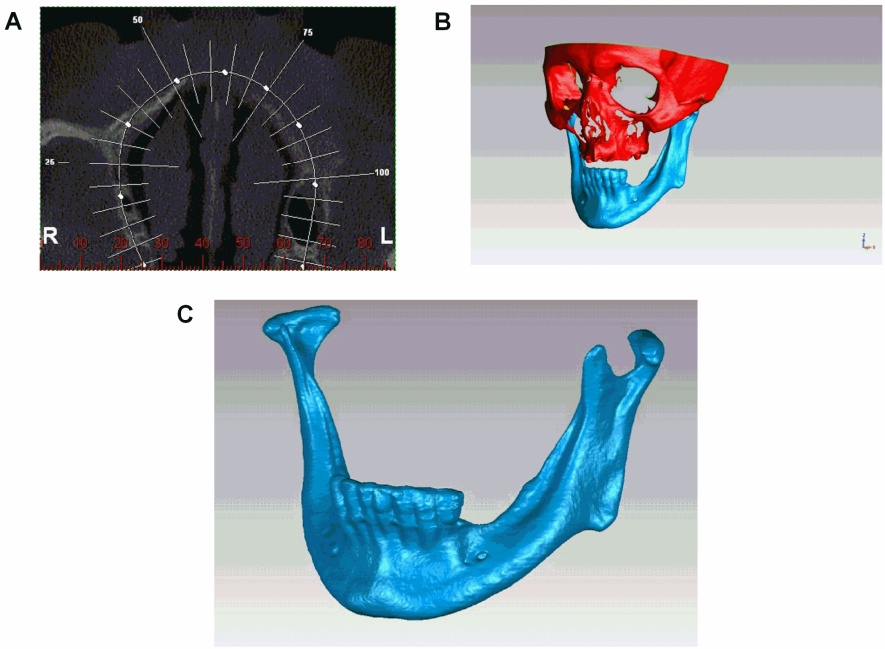

Fig. 4. Virtual treatment of cranium CT scan: A) profile of CT slides for better definition of the structure; B) Image of bone structure using InVersalius software, in blue mandibular structure; C) in detail the structure (model) used to create the novel device

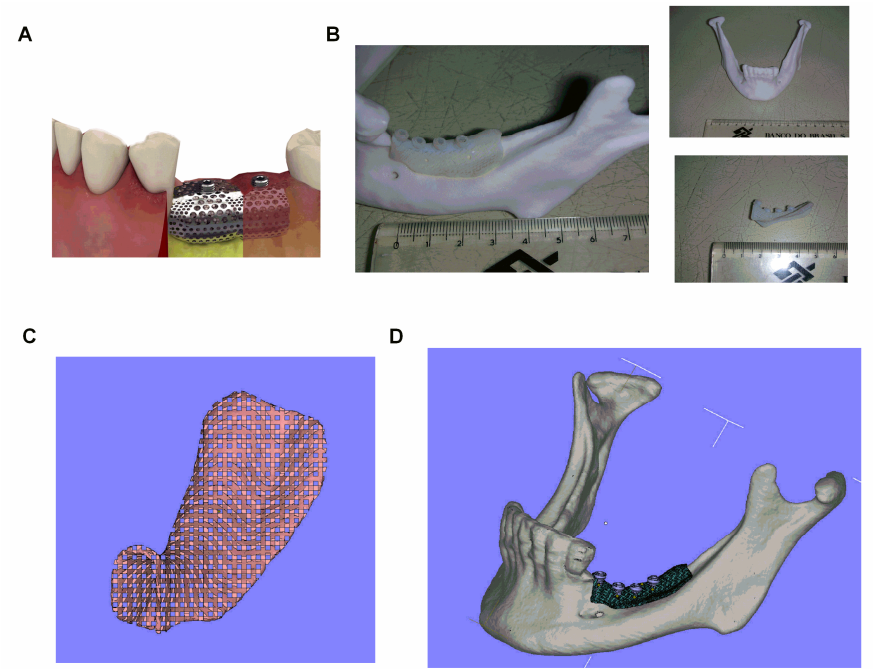

Fig. 5. Virtual design and models printed using stereolithography 3D equipment: A) Simulation of the novel device, details on the juxtaposition to the mandibular crest and hexagonal attachment located above gingivae; B)Mandibular stereolithography model with device model attached, in details separated models; C) Virtual mesh with design and porosity controlled and D) Device structure modelling in virtual mandible

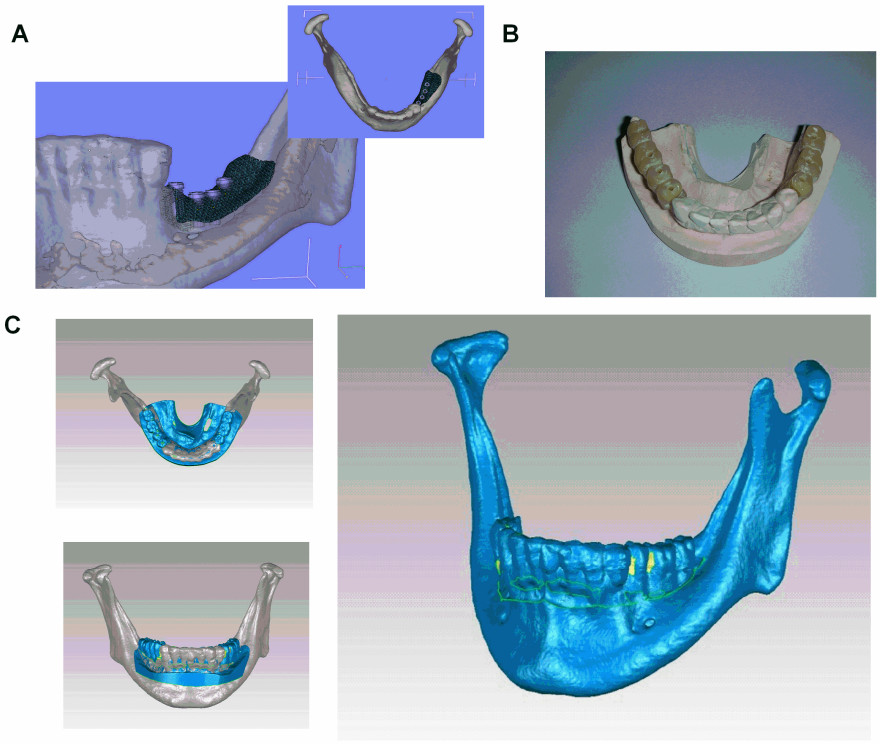

Fig. 6. Virtual and real models with device prosthesis adaptation: A)virtual models of mandible and device structure; B) cast model with prosthesis resin restorations; C) Scan of the cast/prosthesis and overlap on mandible/device structure, details contain in blue the scan structure that demonstrates the ideal position of rehabilitation prosthesis compatible with hexagonal design of the device

A new device patented in 2011, introduce an alternative treatment [22]. The design of the device follows the out part of the bone; therefore it presents a saddle shape and on the top in the marginal crest it has a hexagonal format as the prosthesis implant. Prosthesis will be hold by screws and is compatible with the commercials parts, allowing a wide range of components to fulfill the needs in the prosthetic part.

The developed device demonstrates to be faithful to the virtual model, adapting perfectly to the maxilla's models, indicating a possible juxtaposition of the device to the bone that will allow a correct fixation on the cortical bone. Also, the prosthetic components will have a good occlusal position.

The material choice demonstrates the potential of bioactivity, biocompatibility and biomimic mechanical resistance. The relationship between extract concentration and amount of viable cells resulted in a dose-response curve and IC 50% which is a parameter used to evaluate cytotoxicity, which is the concentration of the extract that kills 50% of the cells exposed in the test (CI - Inhibitory Concentration). Indeed it is possible to affirm the biocompatibility of the biomaterial used. The modulus of flexural strength of the biomaterial shows superiority to use in the mandibular region and the material of choice (Ti-6Al-4V) shows no evidence of toxicity. According to the literature the properties of cortical and trabecular bone tissue are in the range of 100-230 and 2-12 MPa for compressive strength, 7-30 and 0.5-0.005 GPa for the Young's modulus respectively and 120 -210 MPa for flexural strength in the cortical bone [23,24,25]. The samples of group A showed a flexural strength of 428.8 ± 60.7 MPa, whereas the samples of group B showed more promising results, in the range of 328.2 ± 36.6 MPa.

5. CONCLUSION

The findings of the current research were the development of a customized device for maxillary or mandibular regions with vertical atrophic

height, allowing a new treatment option. The 3D model created with data by the InVersalius Software, exposed only the part of interest, in this case the bone tissue the other tissues such as skin, muscles, arteries, nerves and connective tissue were removed. With this 3D "bony" model a device for personalized dental reconstruction was developed. The device showed to be faithful to the model, adapting perfectly to the prototype of the jaw, allowing later to become juxtaposed to the bone and allowing the fixation of the prosthetic part. The results of the flexural and in vitro tests presented are viable for the dental application. The modulus of flexural strength of the biomaterial shows superiority to the mandibular region of a healthy human and the material of choice (titanium Ti-6Al-4V) shows no evidence of toxicity. Thus, the developed device has adequate characteristics to become a feasible option that will be used on patients with posterior atrophic oral regions. However, further research on multiple levels is needed to explore this novel approach.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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