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Dimensional accuracy of select laser sintering and three-dimensional printing biomodels after autoclaving: a preliminary descriptive study

Precisão dimensional da sinterização seletiva a laser e da impressão tridimensional de biomodelos após esterilização em autoclave: um estudo preliminar descritivo

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Abstract

Objective: This is a preliminary descriptive study to evaluate the dimensional accuracy of two biomodels after autoclaving. **Materials and methods**: Data were obtained using computed tomography (CT) scans of a dry skull, and were used as the basis for the construction of two prototypes using two rapid prototyping techniques: three-dimensional printing (3DP™) with plaster powder; and selective laser sintering (SLS) with polyamide powder. Using 19 cranial landmarks, 10 linear measurements of each prototype were repeated twenty times each using a digital caliper. After that, the SLS and 3DP™ biomodels were autoclaved under the same conditions and technical parameters. Each linear measurement was repeated 20 times after autoclaving, but only for the SLS model because the 3DP™ model deformed during autoclaving. **Results and conclusion**: The biomodel manufactured with polyamide powder using the SLS technique (SLS model) did not undergo any significant dimensional changes during autoclaving, which suggests that this technique may have potential clinical and surgical applicability.

Keywords: Bioprosthesis. Measure. Sterilization.

Resumo

***Objetivo**: Este é um estudo preliminar descritivo para avaliar a precisão dimensional de dois biomodelos após a autoclavagem. **Materiais e métodos**: Os dados foram obtidos por meio de tomografia computadorizada (TC) de um crânio seco, sendo usados como base para a construção de dois protótipos, utilizando duas técnicas de prototipagem rápida: impressão tridimensional (3DP®) com pó de gesso e sinterização seletiva a laser (SLS) de pó de poliamida. Utilizando 19 caracteres cranianos, dez medidas lineares de cada protótipo foram repetidas 20 vezes cada uma, utilizando-se um paquímetro digital. Depois disso, os biomodelos de SLS e 3DP® foram autoclavados sob as mesmas condições e parâmetros técnicos. Cada medição linear foi repetida 20 vezes após a autoclavagem, mas apenas para o modelo SLS, pois o modelo 3DP® foi deformado durante a autoclavagem. **Resultados e conclusão**: Os biomodelos fabricados com pó de poliamida utilizando a técnica SLS (modelo SLS) não sofreram alteração dimensional significativa durante a autoclavagem, o que sugere que essa técnica pode ter aplicabilidade clínica e cirúrgica em potencial.*

***Palavras-chave**: Bioprótese. Medida. Esterilização.*

Introduction

Computer-aided design (CAD) is a technique to produce virtual parts using a computer. The combination of CAD and computer-aided manufacturing (CAM) can be used to manufacture prototypes using rapid prototyping technologies (RP). RP biomodels are biomedical prototypes manufactured from images acquired using computed tomography (CT), magnetic resonance imaging (MRI) or ultrasonography (US) (1-4).

Biomodels can be used for the measurement of anatomic structures and the simulation of osteotomies and resections, which can aid surgical planning. Their use reduces operating time; final results are potentially better, and total treatment cost is lower (1-11).

Selective laser sintering (SLS) builds physical models from powders processed in an inert and thermally controlled environment inside a chamber. A CO_2 laser is used to reach fusion (sintering) temperature. After one layer is sintered, a new powder layer is deposited and sintered, and the procedure is repeated as many times as necessary to complete the construction of the part. Parts manufactured using this technique require surface finishing, but the greatest advantage of SLS is that a large variety of materials, such as metals, can be used (12-15).

SLS produces functional, sterilizable prototypes with high thermal and mechanical resistance. (12, 16, 17).

Autoclaving uses saturated steam under pressure. Sterilization is achieved due to the combined action of temperature, pressure and humidity. (18).

Prototyping by means of 3DP™ three-dimensional printing builds biomodels by adding layers, and has a lower production cost. However, models have excessive roughness and low mechanical resistance (19-22).

PA 2200 (Munich, Germany) is a fine polyamide powder, and its typical application is in the manufacture of fully functional prototypes that easily support high mechanical and thermal loads. Polyamide has a density of 1.4 g/cm^3, fusion point at 255 °C, softening point at 235 °C, and good chemical resistance to acids; it does not resist weak and strong phenolic or alkaline solvents (23-25).

Materials and methods

This study was approved by the Ethics Committee of Pontifícia Universidade Católica do Rio Grande do Sul (PUCRS), Porto Alegre, Brazil, under n. CEP 0089/04.

Data were obtained using computed tomography (CT) scans of a dry skull, and were used as the basis for the construction of two prototypes using two rapid prototyping techniques: three-dimensional printing and selective laser sintering.

The unit used to manufacture the SLS biomodel was Sinteristation 2000™ (DTM, USA). Fine polyamide powder, PA 2200™, EOS™ (Munich, Germany), was

used to manufacture the model. Manufacturing time was 15 hours.

The ZPrinter 310 System™ (Burlington, USA) was used to print the 3DP™ model. The materials used for the manufacture were *ZP*™ 102 plaster powder and a water-based binder. Z Bond 100 (Laguna Niguel, CA), a cyanoacrylate-based infiltration agent, was applied to the model surfaces after manufacture.

Measurements of the SLS and 3DP™ biomodels before sterilization and of the SLS biomodel after sterilization were made with a 300-mm Starrett™ (Itu, SP, Brazil) digital caliper model 727-12/300 with an accuracy to 0.01 mm according to calibration certificate n. 17913/2007 issued by Metroquality™, a laboratory accredited by Rede Metrológica do Rio Grande do Sul (RMRS) under no. 5301.

Each measurement was repeated 20 times by the same examiner, and a paired Student *t* test was used to check examiner's calibration. The order of measurements was random to ensure that it would not affect results.

Figures 1, 2 and 3 show the linear measures used in this study.

External horizontal measures

Maximal cranial length (MCL): anteroposterior length of external bone plate of the cranium; distance between (EF) and (EO); palate length (PL): distance between (ANS) and (PNS); oval foramen (OF): distance between right and left (OF); bizygomatic breadth (BZB): distance between right and left (Zy); maxillary breadth (MXB): distance between right and left (T).

Internal horizontal measures

Foramen magnum length (FML): anteroposterior length of foramen magnum; distance between (Ba) and (Op); frontozygomatic (FZ): distance between right and left (FZ); piriform aperture width (PAW): distance between right and left (AP); foramen magnum width (FMW): greatest diameter of the foramen magnum (LFM) measured from right to left side.

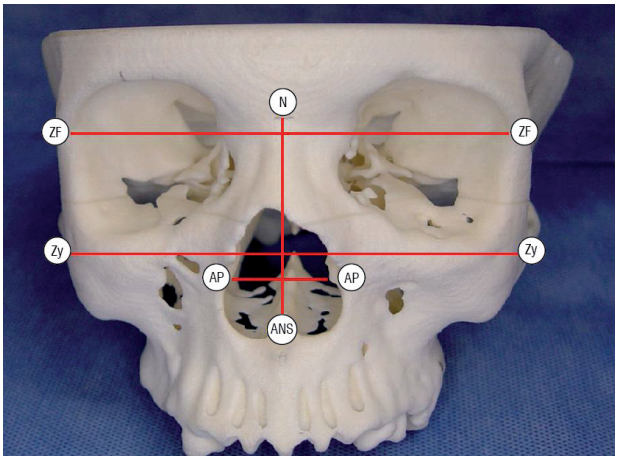

Figure 1 - Landmarks and lines used for horizontal linear measurements and one vertical linear measurement of the skull prototype; frontal view

Note for Figure 1, 2, 3: Cranial landmarks = AP – aperture piriformis: point at the lateral margin of the aperture piriformis (bilateral); ANS – anterior nasal spine: tip of the bony anterior nasal spine; Ba – basion: the median point of the anterior margin of the foramen magnum; EF – external frontal: the anterior-most point of the frontal in the median plane; EO – external occipital: the median point of the anterior margin of the occipital; LFM – lateral foramen magnum: point at the lateral-most margin of the foramen magnum (bilateral); N – nasion: point at the intersection of the frontal and nasal bones; OF – oval foramen: point at the medial margin of the oval foramen (bilateral); Op – opisthion: the median point of the posterior margin of the foramen Magnum; PNS – posterior nasal spine: the median point on the dorsal limit of palate; T – tuberosity: point at the lateral margin of the maxillary tuberosity (bilateral); ZF – zygomaticofrontal: point at the medial margin of the zygomaticofrontal (bilateral); Zy – zygion: point at the lateral-most border of the centre of the zygomatic arch (bilateral).

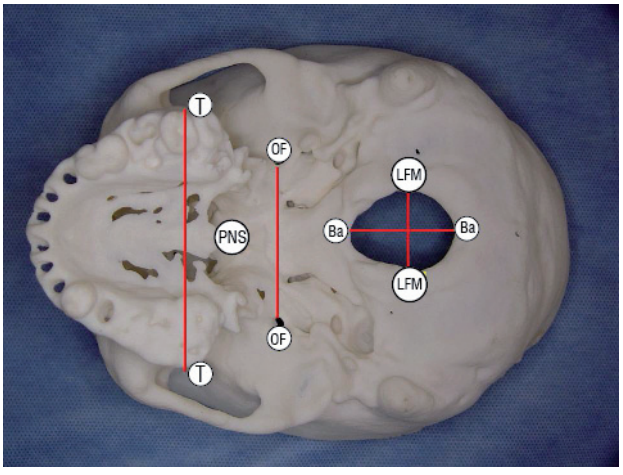

Figure 2 - Landmarks and lines used for horizontal linear measurements of the skull; basal view

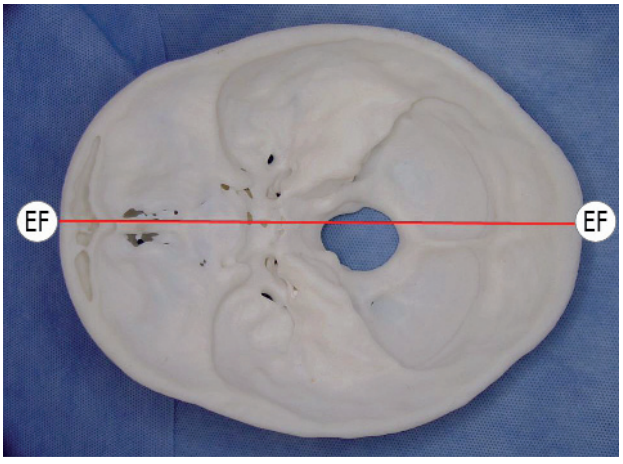

Figure 3 - Landmarks and lines used for horizontal linear measurements of the skull, top view

Vertical

N-ANS: distance between (N) and (ANS)

The autoclave unit used for SLS and 3DP™ biomodels was a Cristofoli™ Vitale 21™ unit that belonged to the Center of Dental Sterilization of Center of Dental Sterilization of Policlínica Militar of Porto Alegre, Brazil.

Results

Means and standard deviations of each measurement were calculated for both biomodels before autoclaving. After sterilization, only the SLS biomodel was evaluated because the 3DP™ model deformed. The SPSS™ 11.5 software and Microsoft Windows™ were used for data processing and analysis. A paired Student *t* test was used for the comparison of measurements obtained before and after sterilization of the SLS biomodel, at $p \leq 0.01$.

After autoclaving sterilization process, external horizontal linear measures presented a dimensional change of up to 190 hundredths of millimeters maximal cranial length (MCL): before sterilization 187.14 mm; after sterilization, 187.33mm. Internal horizontal linear measures showed a dimensional change of up to 5 hundredths of millimeter presented foramen magnum width (FMW): before sterilization, 26.20 mm; after sterilization 26.25 mm. The external vertical linear measure showed a dimensional change of up to 190 hundredths of millimeter (N-ANS): before sterilization 49.73 mm; after sterilization: 49.92 mm. The standard deviation was never bigger than 320 hundredths of millimeters and the Student *t* test did not show any statistically significant differences before and after autoclaving ($p \leq 0.01$). These results are listed on the Tables 1 and 2.

Discussion

The material used in biomodel prototyping should have excellent dimensional stability after autoclaving to ensure that a sterilized biomodel

Table 1 - Mean and standard deviation of external horizontal and vertical linear measures of the SLS biomodel before and after autoclaving

External horizontal linear measures	SLS biomodel before sterilization		SLS biomodel after sterilization		P
	Mean (mm)	SD	Mean (mm)	SD	
MCL	187.14	0.26	187.33	0.20	0.024
BZB	110.63	0.25	110.69	0.16	0.251
PL	45.39	0.21	45.34	0.30	0.398
OF	50.35	0.13	50.42	0.12	0.097
MXB	73.61	0.26	73.55	0.31	0.256
External vertical linear measure	**SLS biomodel before sterilization**		**SLS biomodel after sterilization**		**P**
N-ANS	49.73	0.32	49.92	0.26	0.023

Note: BZB = bizygomatic breadth; MCL = maximal cranial length; MXB = maxillary breadth; N-ANS = nasion anterior nasal spine; OF = oval foramen; P = Student *t* test; mm = millimeters; PL = palate length; SD = standard deviation; SLS = selective laser sintering.

Table 2 - Mean and standard deviations of internal horizontal linear measures of the SLS biomodel before and after autoclaving

Internal linear measure	SLS biomodel before autoclaving		SLS biomodel after autoclaving		P
	Mean (mm)	SD	Mean (mm)	SD	
LFM	33.80	0.11	33.83	0.10	0.289
FMW	26.20	0.12	26.25	0.07	0.084
FZ	96.59	0.25	96.58	0.19	0.851
PAW	25.54	0.17	25.58	0.12	0.403

Note: LFM = foramen magnum length; FMW = foramen magnum width; FZ = frontozygomatic; P = Student t test; mm = millimeters; PAW = piriform aperture width; SLS = selective laser sintering; SD = standard deviation.

can be used in surgeries safely. Autoclaving produces sterilization by the interaction of temperature, pressure and humidity and the consequent coagulation and denaturation of cell proteins and genetic structures of microorganisms. Autoclaving uses distilled water, a biocompatible substance, as the vehicle for sterilization; therefore, no residual effect may be assigned to this process. When correctly indicated, the use of a biomodel reduces operating time, time in the operating room, and, consequently, use of intraoperative drugs. Benefits may also be expected for postoperative recovery, with reductions in infection rates, use of antibiotics and surgical complications. The use of sterile biomodels in surgeries generates great benefits for the patient. (1, 4-6, 13, 17, 22).

According to James et al. (2), 34% of surgical costs are a result of operating time. Therefore, a cost-benefit analysis suggests that, when biomodels are correctly indicated, this analysis will be positive and justify the financial investment in biomodel prototyping for diagnosis and surgeries. Therefore, our purpose is to find a low-cost material with excellent dimensional stability after autoclaving that will bring efficiency and efficacy to surgical procedures that use sterile biomodels.

Reconstructive surgeries, such as tumor resection followed by tissue implants, facial deformities and orthognathic procedures, and correction of ankylosis of the temporomandibular joint, gain substantial benefits from the use of a sterile biomodel in the operating room. In such conditions, biomodel prototyping brings benefits to patients, simplifies treatments, and results in better prognoses (7, 9, 10, 17). At the same time, this technique does not bring substantial advantages and do not reduce costs in cases of bone trauma, orthognathic surgeries without segmentation, and small implants (10, 11, 14).

Prototyping systems may be classified according to the form of the material used. This study focused on powder materials because it evaluated the SLS technique, which uses polyamide powder, and 3DP™, which uses plaster powder (13).

The low mechanical resistance and the great absorption of steam after autoclaving make it impossible to use biomodels manufactured using the 3DP™ technique and plaster.

The plaster prototype absorbed steam when autoclaved, which resulted in new crystallization and crystal dissolution. When dried, the new crystals became larger and formed a more porous structure with lower mechanical resistance. Moreover, its mechanical resistance is inversely proportional to the amount of water absorbed. After autoclaving, great dimensional changes and several pores were seen. This indicated that water had been absorbed. Plaster loses mechanical resistance in the presence of water, heat and high pressures, which makes it impossible to sterilize this type of material using an autoclave (1, 14, 19-21).

Sintering occurs by heating the powder and bonding it by fusion. This type of manufacturing process produces biomodels with good thermoplastic resistance (8, 12-14, 16, 24). Polyamide has good mechanical and thermal resistance, and is also resistant to atmospheric and industrial corrosion, UV beams, wear and impacts. It has good elasticity and low friction and water absorption coefficients (24).

The dimensional stability of a polyamide biomodel sterilized by autoclaving was the fundamental condition for this study to achieve its objective. Results showed that polyamide is a thermally resistant material that can be autoclaved. The use of steam as the sterilizing agent did not result in new pores on the biomodel, and there was no loss of mechanical resistance or damage to its three-dimensional structure. The Student t test revealed that there were no significant differences between the ten linear measures obtained before and after autoclaving, calculated using a total of 400 measurements. At a level of significance of 1% ($p \leq 0.01$), all measures had a normal distribution, and no statistically significant variations were found, which suggests that this material has an excellent potential to be used in surgeries.

Therefore, the autoclaving did not cause significant dimensional changes in the SLS model, which indicates its clinical and surgical applicability.

The 3DP™ biomodel could not be measured after autoclaving because of dimensional changes seen in the biomodel after autoclaving. Therefore, this type of prototype is not indicated for surgeries if the same sterilization method is used.

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