Properties of Biomaterials in Bone Augmentation

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In the present, the insertion of dental implants is not an exhaustive technique due to the leap of medicine in the last years. This is the reason why, if inserting a dental implant is needed, the main problem encountered is related to the existence of enough bone tissue to support the implant. In the absence of sufficient hard tissue it is needed bone augmentation . Whether it is bone from patients body or not, it is indicated the addition of a synthetic material to assist the osseointegration. Using SLS techniques, the augmentations were performed based on HA/PLLA, that helped to analyze the osseointegration materials, and search the perfect material capable of withstanding the conditions given by the body. The results showed the importance of this bone tissue in order to attend implant osseointegration. Also, porosity is a key factor in achieving the needed results.

Keywords: dental implants, bone tissue, osseointegration, SLS techniques

In the last period of time, dental implants became one of the most common dental surgeries, the teeth loss being a problem of a specific edentulous population, but not only. The success or failure of implants depends on many factors, for example the health of the patient, medication, and also the health and integrity of the periodontal tissues and bone tissue condition. To be capable to deal with the occlusal forces, the implant must have a stable base to be inserted in. This is the contribution of bone, so in the absence of enough tissue, the succes is questionable.

Bone loss is caused by many factors, a good example is osteoporosis, which is a progressive bone illness characterized by a reduction of bone density and mass that can lead to an increased risk of fracture [1]. Other cause of bone loss is age, elderly women being the most susceptible to have bone loss. Sometimes, bone loss can occur without a specific cause, or bone loss and thin bones runs in family.

Regardless of the cause, when tissue is needed, there must be found a way to put it there. One of the methods used is bone augmentation. This procedure is a safe and highly successful way to reconstruct the lost or reduced bone, which involves the "building up" or adding bone to the jaw, by using the patient's own tissue, from other location of the body, and/or by using tissue from a donor (the same species or another), or synthetic bone materials. In many cases, the new bone can be collected from inside the patient's mouth.

In order to maximize the results, besides bone and synthetic, is added a resorbable membrane. It is indicated in guided tissue regeneration, also providing lasting protection against external agents.

After the bone addition, it is required a period of time from 2-3 to 6 months for the bone to heal, before the implant insertion. This healing period is contained in a relatively long time, the decision when to insert the implant can be rushed or delayed. Therefore, it was attempted to find a way to have under control and analyse the osseointegration.

The main disadvantage of the common methods of analysing the bone osseointegration is their invasiveness that renders them unsuitable for clinical practice [2]. Another disadvantage is that they all require specific preparations, such as sectioning, staining or decalcification, accompanied by loss of important information during the experimental protocol [3].

A non-destructive and non-invasive method of investigation is the synchrotron radiation. It is an electromagnetic radiation, which is emitted when charged particles are accelerated radially. This method of analysis is a very efficient tool, used for a better understanding of the morphological features of the area of interest, being capable to achieve a high 3D resolution in a non-destructive way.

It is very similar to the conventional computer tomography (CT), usually employed in medical diagnosis and industrial applied research. The difference between CT and micro-CT is that the resolution of CT is about 0.5 mm, compared with the resolution of micro-CT which is 0.3 microns.

The use of X-ray delivered by Synchrotron Facilities has a couple of advantages, compared to the X-rays produced by the Laboratory Sources. It is taken into consideration the possibility of using the advantage of the high increased photon flux, that guarantees the existence of high spacial resolution. Also, the synchrotron technology produces tuneable radiation. This is the explication of how are performed the measurements at different energies. However, the monochromatic radiation is used to eliminatethe beam hardening effects [4].

In the following article an overview of research work performed is presented in order to find a fast way of making bioceramics (HA)/ biopolymers (PLLA) composite scaffolds with Selective Laser Sintering (SLS) technique, that should be used in bone augmentation.

SLS is an Additive Manufacturing Technology (AMT) which sinters powders in a selective way, from solid or

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Fig. 1. Aspect from the CT investigation.

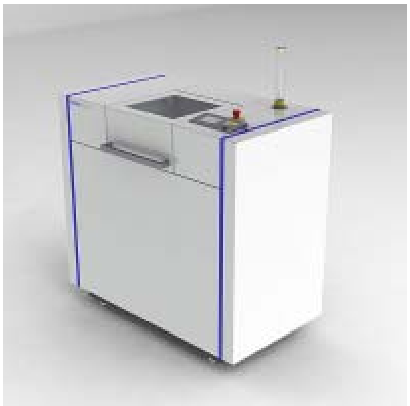

Fig. 2. The aspect of a commercial compact cabinet microCT scanner

surface models made by a CAD-3D file, with CO2 laser and in a layer-by-layer basis.

Hydroxyapatite is a bioceramic, used for a long period of time in medical field. Also, ceramics and composites are used for a couple of years to augment various parts of the human body, especially bone. Porous hydroxyapatite was analyzed for its use on repairing vast defects in bone. If it is implanted, HA is slowly absorbed by the organism and substituted by new bone, the main reason is because it makes direct chemical bond with hard tissues. The new lamellar cancellous bone are formed within 1 to 2 months.

Ceramics are used in detistry because of their high compressive strenght, relative inertness in body fluids, their very good aesthetics, but also as reinforcing components of composite implants. In the last thirty years, calcium phosphate based bioceramics were used in medicine, in general, but especially in dentistry: dental implants, alveolar ridge augmentation, maxillofacial surgery or orthopaedics.

During the last decade, the interest for biodegradable polymeric biomaterials (PLLA) increased dramatically because of their two advantages that non-biodegradable materials do not have: firstly, they give permanent chronic foreighn-body reactions, also, do not retain signs of residues in the implantation sites; secondly, it was discovered that they are capable of regenerating tissues, so on, the biodegradable biomaterials surgical implants may be used as temporary scaffolds for tissue regeneration [22, 23].

One of the future bone formation strategies is to create bio-scaffold, that enables bone regeneration once it is surgically settled in the defect existing in bone.

Whereas, HA was used in bone augmentation for more than 20 years, as a logical chosen material in this field, PLLA was picked up as a cement, because of its large degradation period of time and low melting temperature, compared with other derivates. In view of the fact that it acts as a cement during the sintering operation, it increases the mechanical properties of the implants.

Experimental part

Materials and methods

Biomaterials are a type of materials, natural or synthetic, needed in the replacement of parts of the body and are represented by metals, ceramics, polymers, composites.

To be used in the artificial tissue engineering, the biomaterials must have properties such as: bio-compatibility, biodegradability, sterilizability, stability over timescales, to permit the expansion of the new tissue, suitable manufacturing, physical and mechanical characteristics.

Analyzing anterior screening trials, it was chosen an ratio of 40% PLLA by weight.

This option was based on the fact that attaching lower than 30% weight of PLLA to HA will not be enough for the biodegradation or to increase the ductility properties, and higher than 50 % weight, the implant will become too plastic and so will not behave as bone tissue (Cruz, 2005).

The materials needed in such an experiment (in powder form) are:HA: Captal® 110 grade–sintering powder, with mean particle size (D50) of 111±5μm, melting point of 1250 (-0 +50) °C and 1.30 g/cm^3 of density (~Ł300 /Kg); PLLA: Purasorb L, with mean particle size (D50) of 163±5μm (after sieving), melting range of 182.4–192.3°C and 0.47 g/cm^3 of density (after sieving) (~Ł1700 /Kg).

However, most of the experiments were made on a SLS Sinterstation 2000 (3D Systems™, USA) machine, installed at CRDM (Centre for Rapid Design and Manufacture) [21].

It needed to be modified, especially the envelopes of the supply and the part platform, to permit the operations with non-standard materials and with low quantities of HA/PLLA (1Kg in the place of the standard 20Kg) because of the cost control of testing.

After identifying those factors that have high effects on the variables response was chosen to establish the most important factors of interest on the manufacture of HA/PLLA models by SLS. It was used a DoE (Design of Experiments) methodology.

The results of the tests were focused on three directions (density, surface quality and geometric accuracy of the produced parts).

The results of the screening review showed that the factors with the most influence on the physical properties of the SLS parts, were scan speed, laser power and scan space. In fact, these three factors all gathered, are the Andrew's Equation, corresponding to the energy density affixed to the powder basis, that will determine the scanning plan pending the SLS operation.

After the first phase of the experimental work, the next step was to measure the final resistance and the elastic modulus of compression, also, the bending strength of the parts produced, by means of a 2k full factorial design and analysis, with the intention of achieving more data about the most important factors chosen in the anterior phase.

In order to obtain a mathematical equation that expresses the effects of the AED in the last compressing endurance, folding and density of HA/PLLA samples, a 23 full factorial design was applied. It was conducted a design formed of sixteen (16=8+8) experiments in a randomised sequence.

Trying to analyze the degradation conduct of the HA/PLLA samples produced by SLS, (its PLLA component), were done in vitro tests. To look over the in vitro degradation behaviour of the HA/PLLA samples, was used saline phosphate buffer (SPB, *p*H=7.4).

It has been taken as an example of biological fluids (Taddei et al., 2002). The study was performed on their mass loss along the time (six months).

Results and discussions

The principal objective of this experiment was to prove the feasibility of producing HA/PLLA samples by selective laser sintering. The results showed the success in demonstrating this feasibility.

Actually, the must important results of the studies made, showed: the possibility of producing bioceramic peaces (HA based) by resources of AMT (Additive Manufacturing Technologies), especially the Selective Laser Sintering (SLS) trial, using a biocompatible/biodegradable polymer as cement. This is the reason why it is needed to be used a polymeric binder (40% wt.) to improve the congestion of the ceramic particles by the time of laser operation (sintering). If using a biocompatible binder (e.g. PLLA), the mixture HA/PLLA makes a part that can be used directly in the body without removal of the cement. This method is a direct phase in manufacturing laser sintered HA based ceramic peaces for medical needs. Although, this path permits the generation of direct peaces, without the need of postprocess phase, so reducing the cost and time of production. The mechanical properties of the parts produced represent an important limitation, allowing their application only in non-load bearing situations.

The internal porosity of the HA/PLLA parts produced (mean value >150μm) is appropriate to increase the gain of new tissues in the scaffold. Actually, this is the essential condition to afford extensive blood supply of the new bodies, offering a rich supply of cells, increasing factors and other needed elements to make bone grow. However, the small holes permit the access of bone marrow elements between the bone graft and so, the bone feeding. The density of the HA/PLLA sintered peaces (mean value = 0.883 g/cm^3) is within the density values for the cancellous bone (0.14 to 1.10 g/cm^3) as previously mentioned. The value of the density is extremely important, because it depends on the resistance and osteointegration of the implant.

The results of applying the full factorial design revealed that the mechanical properties of the HA/PLLA parts as SLS manufactured, are relatively low compared with another biomaterials.

These results came to confirm the low mechanical strength of the HA/PLLA parts, as SLS produced, and it constitutes a restriction for the applications in load-bearing cases.

Also, the mechanical properties of the HA/PLLA sintered peaces, by SLS require to increase after the optimisation of the parameters involved, especially the energy density applied and the grain dimension of the starting powder.

The Selective Laser Sintering (SLS) process belongs to Additive Manufacturing Technologies, which firstly use powder as the basic medium for fabrication. The samples are built step by step by sintering / interfusing thin layers of powder. Each layer fuses to the previous one producing a physical piece. Anyway, the Selective Laser Sintering process produces three-dimensional objects, step by step, from powdered materials, with the heat made by a CO_2 laser within the apparatus (Sinterstation System).

Firstly, 3D-CAD information must be output in the standard industry STL (Standard Triangulation Language) format. The process knows 4 phases: after the selective laser sintering process starts, a thin cover of the heat-fusible powder is deposited into the part build chamber. A first cross-section of the peace under fabrication is chosen to be "drawn" (or scanned) on the layer of powder by a heat-generating CO_2 laser. The interaction of the laser beam with the powder elevates the temperature to the point of melting, fusing the powder particles and forming a solid mass, i.e., sinters the powder particles (heats and bonds selected portions of each layer). The power of the laser beam is adjusted to melt the powder only in defined by the object design geometry areas. An extra layer of powder is stored, via a roller mechanism, on the top of the anterior scanned layer. The steps are repeated, with each layer fusing to the layer under it. Successive layers of powder are stored and the process repeates, until the part is completed. After the construction of the part, is taken from the build room and the loose powder is lost. Parts may require then some post-processing, such as sanding, depending on the indicated field. There is no need to produce support structures with the CAD design prior to or during fabricating and, therefore, no support removal is needed when the part is complete.

The software components of the Sinterstation System are: a Unix operating system and proprietary application software.

Conclusions

SLS technology could act as a valuable tool in bone tissue engineering, to replace and/or repair bone defects, due to damaged, traumatised or lost bone.

Also, the feasibility of making hydroxyapatite based bone shapes scaffolds, from SLS, was presented.

The porous calcium phosphate/poly-lactide implants, even if very biocompatible, probably do not have enough strenght to load bearing applications, for example, artificial hips, dental implants or bone screws. This is a restriction of the SLS technology, even if this process cannot make directly full-density implants, due to its efficiency of the porous parts.

This bioactive and resorbable composite (HA/PLLA) can be improved with the help of the frequently used internal fixation devices in orthopaedic surgery, the reason why, is that bone healing is a dynamic process and this material must be resorbable to maintain a progressive stress transfer to the bone tissue.

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