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RAPID PROTOTYPING AND RAPID MACHINING OF MEDICAL IMPLANTS

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Medical implants, rapid prototyping (RP), machining

1. Introduction

In recent years several research institutions, medical companies and commercial organizations have integrated Computer Aided Design (CAD) and Rapid Prototyping (RP) to produce 3D physical medical models. These models are being used for several applications: visualization, diagnosis, surgery planning, design of implants, external prosthesis, surgical templates, production of artificial organs, communication (between the medical team and/or medical doctors and patients), and teaching, or didactic aids. Another application field is the production of medical surgical instrumentation tooling.

The use of RP in medicine is not satisfactory high since it is relatively young field with very wide potentials to be reached. The main limitations for wider application of this manufacturing procedure, so far, are: biological incompatibility of the existing materials used in RP processes; relatively high costs of model production; time and work intensive process to achieve an appropriate model quality (surface finish and anatomical accuracy).

Therefore, it seems that the most practical way of surgery is early implant machining (on milling machine) and fixing on the certain tolerances (using the user friendly interface and visualization techniques) based on the CT data (enhanced with additionally SSD technique for 3D object obtaining). This platform containing digital model data provides that implant materials produced in blocks can be machined or even tested on the model of the origin bone material before the surgery act starts in practice. This procedure doesn't suffer from sterilization problem as one can expect if the implant is made during the surgery (that means reshaping of the implants produced in the sheet (folia) forms.

Finally, the product created in this way i.e. modeled from one massive piece of biomaterial, will match exactly (3D shape) patient's anatomical region to be cured (changed or replaced). For each patient the customized 3D models of anatomical regions to be surgically treated and replaced after the tumor process has been removed, will be manufactured. This approach exhibits a huge benefit for surgery practice, because it ensures properly postoperative functioning of patient's anatomical/organic system, which by this means, becomes in fact almost the same to its original natural model.

2. Background

The possibility of exact preoperative, non-invasive visualization of the spatial relationships of anatomic and pathologic structures, including extremely fragile ones, size and extent of pathologic process, and of precisely predicting the course of surgical procedure, allows the surgeon to achieve considerable advantage in the preoperative examination of the patient and to reduce the risk of intraoperative complications, all this by use of virtual surgery (VS) or diagnosis *per viam* 3D models. It could be done by using patient's images created for diagnostic purposes. Storage of the patient's images and diagnoses in a multimedia form in computer systems allows them to be subsequently searched and some specific cases re-examined for analysis and physician education, even *via* Internet (e.g. *Eurorad Project*). By use of DICOM protocol, not only image recordings but all general data of the patient, that have previously been entered onto the diagnostic device console as well as all data on the device setting during patient's image production are transferred from the diagnostic device to computer systems [1].

Concerning the implants, medical models obtained by RP are normally used indirectly, as masters, to produce prosthesis in biocompatible conventional materials (e.g. titanium, cobalt-chrome alloys, medical-grade aluminum, medical-grade silicone etc.) mainly by casting and spray metal molding [2,3].

However, RP technology has the ability to fabricate models with complex geometric forms, and so is very suitable to reproduce the intricate forms of human body. By using of RP models, visualization of intricate and hidden details of traumas by surgeon is enhanced.

The majority of the references found in literature on this subject are concerned with the production of medical models via Stereolitography (SL). However, SL medical models, unfortunately, cannot be used inside the human body, as direct implants, due to the resin toxicity, which creates concerns about the long-term biocompatibility of SL models. Nevertheless, the range of applications of those models is very large [3].

Some recent researches aiming to improve the use of RP in the production of medical implants are directed toward producing implants of biocompatible materials directly in the RP process. Among this group of materials, high-purity calcium phosphate ceramics (hydroxyapatite, HA or HAp) alone, or in composites with biodegradable polymers (poly (L-lactide), PLLA) offer long-term biocompatibility and therefore have a large potential to be used in medical applications [3,4].

On the other hand, there is a group of porous polymeric materials (e.g. Porex) which can be used as implants while these materials are biocompatible [5]. Those materials can be produced either in thin films forms and be individually reshaped for certain application either in block forms for wider application. This technique allows the in-vitro planning and implant shaping while the first one means shaping on the human body models (produced by RP) or directly during the surgery on real object.

3. Basics of rapid prototyping of medical models

Rapid prototyping (RP) is one of the fastest developing manufacturing technologies in the world today. It is different to the conventional manufacturing procedures (i.e. milling, casting, injection molding etc.). RP is additive type manufacturing procedure, because parts are built on a layer-by-layer basis [2].

The prototypes can be made of plastic, paper, wax, ceramics and metals, and, in general, RP systems can be classified into three different categories based on the initial form of materials used: Liquid-based (e.g. SL); Solid-based (e.g. LOM) and Powder-based (e.g. SLS) [2].

A distinct advantage of creating a part layer-by-layer is that the geometric complexity of the part has significantly less impact on the manufacturing process than in the case of conventional manufacturing technologies. Other advantages are: no need of tools, short time to produce the parts, very little human intervention and set-up time, and lower manufacturing costs.

Some of the more popular RP processes are Stereolitography (SL), Fused Deposition Modeling (FDM), Selective Laser Sintering (SLS), Laminated Object Manufacturing (LOM), Three Dimensional Printing (3DP) and Solid Ground Curing (SGC).

Depending on the system, post-processing is usually necessary after the part is built (i.e. cleaning, removal of supports, sanding, painting, post-curing, infiltration, etc.).

The manufacturing of medical models using RP technology starts with the acquisition of three dimensional shape data of both internal and external human body structures, allowing the production of 3D physical object, via CAD/CAM system, in a RP apparatus. This is a so-called Reverse Engineering (RE) process. The common systems used in medical imaging to obtain anatomical information are: Computer Tomography (CT), Magnetic Resonance Imaging (MRI), Ultrasound System (US), Mammography, Radiography (Plain X-Ray) and Laser Digitizer. Most medical models are produced via CT for bone structures and MRI for soft tissue [6-7].

4. An approach to customized implants manufacturing

We have been continuously investigating technique of individually (customized) shaping of appropriate metal materials (mainly stainless steel) as well as porous polymeric material. This approach seems to become more comprehensive and it is going forward in slight different, more practical way [8,9]. Such procedure includes few phases: 1. CT–scanning, 2. Digitalization of the data and CAD model building, 3. RP for creation of the environment which surgeries will be faced in during the surgery, 4. CAM (machining planning and simulation on computer), and 5. Real implant machining on CNC milling machine using the G-code after the CAM results.

This procedure, where the implant is produced by milling, could be cheaper than the one where the implants are produced in RP process and even more if the RP model does not produce.

This procedure is revolutionized since it could be planed and starts at the moment when the preventive CT is performed. All the phases are based wholly on CT data and also the procedure of implant production is automatically linked with CT report. That means that the human errors and its leakage are reduced to minimum and the surgery results because of that become more successful. Basic idea of the investigations to be carried out is summarized by the scheme in Fig. 1.

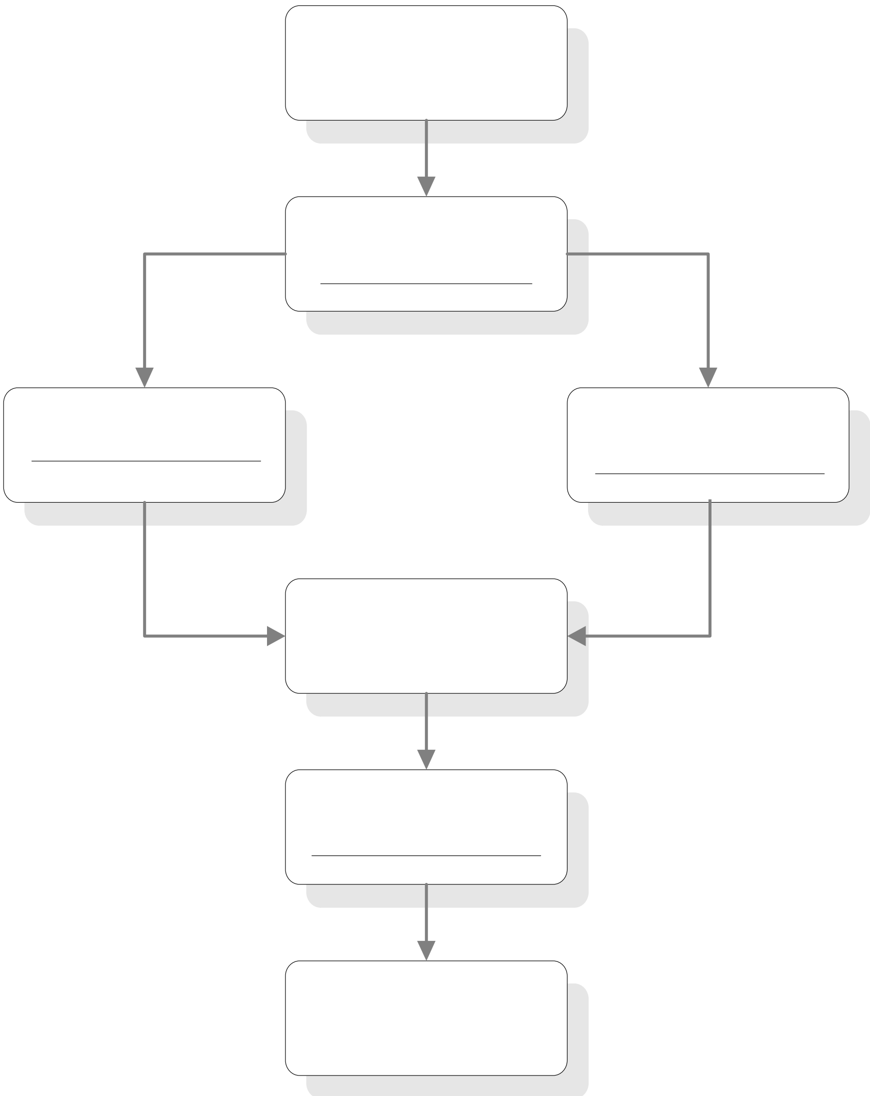

Figure 1. Our approach in obtaining customized implants

Machining of PE-UHMW and PE-HD with conventional manufacturing processes is possible and is not problematic but nevertheless it is specific technique and suffer from some restricted demands. Generally, there is no necessity for classic application of coolants because of relatively low specific cutting forces. Furthermore, cutting speeds can be increased in order to obtain better surface quality till the value when the temperature rapidly becomes higher and so far that can damage or even destroy the implants. Assuming that the implants have to be machined with very low roughness and neck free some test have to be performed in order to define acceptable overlapping of the milling tool paths. Because of porousity of the material blocks (e.g. Porex), machining has to prevent that residual particles with micro size left into porous structure. Nevetheless, residual particles could be reduced by posterior cleaning with air.

Geometrical complexity of geometry of implants is oneother constraining parameter concerned with material handling and fixing since the implants geometry could be very thin and so far the selection of the base plane for fixing and applied value of fixing forces is of big importance. Complex geometry of implants result with demands on construction of machine tool which has to allow 4D or even 5D machining. Nevertheless, application of tools with small diameter for obtaining very small radii of convergence on implants is possible only if the main spindle can rotate at very high values. Concerning depth of cutting, there is restriction when the production is close to final shape of implants.

Also, attention has to be paid on tool trajectory in the area where the radii of the curvature is small in the way that cutting feed has to be lowered. This restriction is powered when the tools with small diameter are used and when the surface feeding speed is high. This condition, with very high value of acceleration and deceleration of the spindle (frequently higher than 1 G – 9,81 m/s^2), could be problematic on the geometric accuracy of the implants. Appropriate tool geometry and cutting feed and depth of cutting has to be chosen in order to achieve good chip transportation.

The RP models obtained by 3D Printing process (*Z-Corp ZPrint 310 System*) will be used in planning of implants surgery i.e. to test whether the implants produced by machining of porous biomaterial blocks fit appropriately in complex neighboring anatomical structure modeled by RP technique. Secondly, we will compare shape characteristics of implants obtained by machining with those produced in RP process.

5. Case study – hip bone implant

The modeling of an upper part of the human hip bone was chosen as a case study to show the possibility of using technology of rapid prototyping and rapid machining in medical implant producing.

To visualize hip bone we have used Computerized Tomography System *Sytec 2000+* (GE). Based on CT scan pictures a file containing 3D shape data, so-called STL-file was created (Fig. 2). From created STL-file, a physical RP model of an upper part of hip bone was generically produced in 3D Printing technology on *Z-Corp ZPrint 310* rapid prototyping machine (Fig. 3).

To materialize a part of hip bone we have used cylindrical block (diameter 70 mm and 130 mm length). Milling was performed on *Mori Seiki Frontier M CNC machining centre* with three tool (smallest diameter was 2 mm). Some details during the milling of implant are shown in Figs. 4 and 5 and a final implant shape is displayed in Fig. 6.

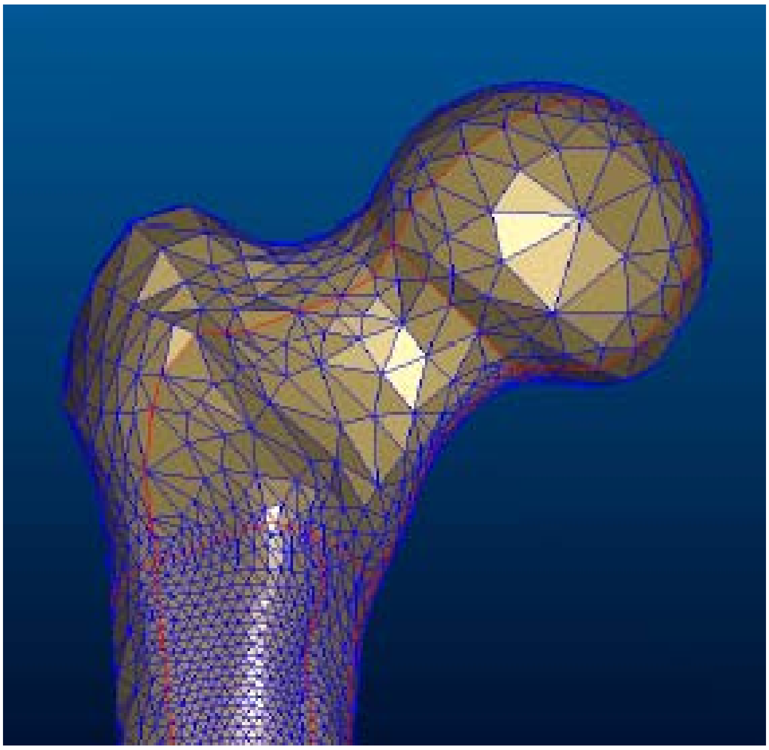

Figure 2. STL model of the hip bone

Figure 3. Hip bone shape obtained in 3D printing RP technique

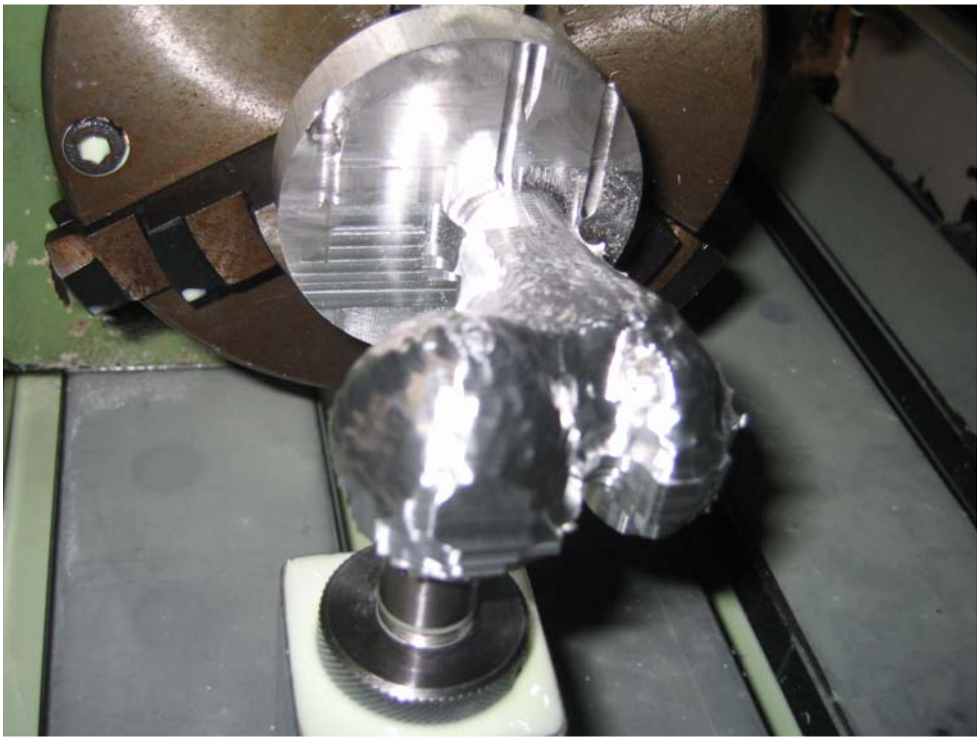

Figure 4. Hip bone after rough machining

Figure 5. Machining process of the hip bone

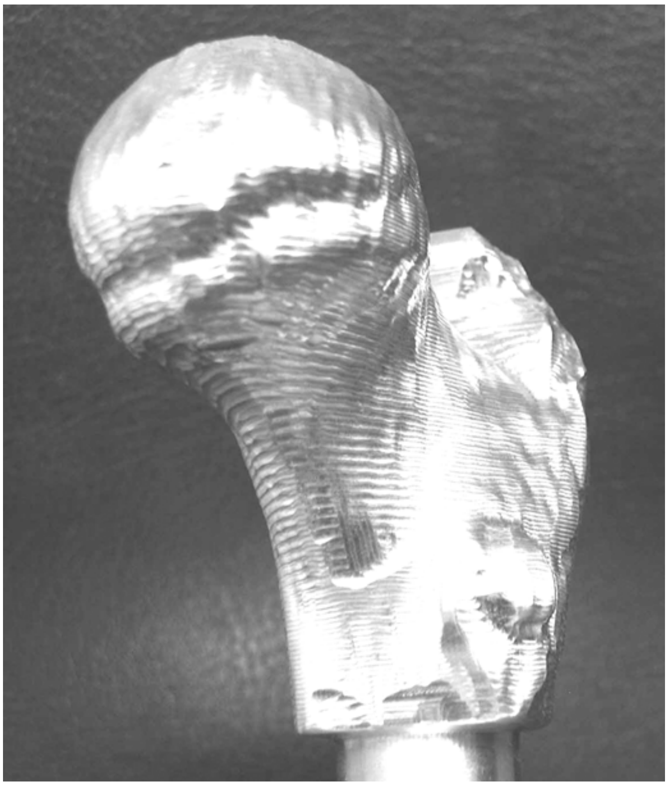

Figure 6. Final shape of the machined hip bone

While implant is machining, it is very important to minimize scallops and burrs on machined surface of the implants [10]. Therefore grove profiles and large tool path spacing are not convenient. However, if tool overlapping is increased machining time is dramatically increased. Currently, a lot of machining shops employ the traditional method of constant feed rate cutting for sculptured surface parts. This can result in significant tolerance deviations. By varying the feed rate based on the cutter chip load predicted by machining models, a more constant tool deflection can be attained, resulting in much better tolerances in the same machining time or similar tolerances in less time.

In order to minimise number of tool changes either automatic or interactive, cutting parameters are dynamically optimised and a single tool is selected for each machining feature. Feature tool selection depends on the geometry to be machined. It has been pointed out that number of tool changes is not crucial as the volume of material left behind for smaller tool. Issues coverings the effects of residual material left behind by oversized cutters are also not adequately addressed.

6. Conclusion

In accordance with solid model obtained after CT it is possible to manufacture hip bone implants from block material on milling machine. Approach in bone surgery treatment that was presented in this paper offers great potentials in time saving and eventually possible postoperative treatments. This procedure is revolutionized since it could be planed and starts at the moment when the preventive CT is performed. All the phases are based only on CT data and procedure of implant production is automatically linked with CT report. That means that the human errors and its leakage are reduced to minimum and the surgery results because of that become more successful. Machining time has to be improved and we pointed out a tool selection (number and paths) as very important and critical in that manner. Also, there is consideration regarding tool path overlapping to achieve better surface quality. In following work we will try to apply our theoretical considerations addressed on machining process. Also, our future work will be directed toward investigation of machining capabilities of special biocompatible polymeric materials.

7. References

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