ADITIVE FABRICATION OF MEDICAL MODELS USING THREE-DIMENSIONAL PRINTING

ABSTRACT

Additive Fabrication Technology (AFT) has much to offer to the medical device industry, namely due to two principle advantages offered in comparison with other manufacturing technologies, i.e., the ability to manufacture highly complex parts to very high standards in highly flexible production volumes and the ability to produce devices that suit anatomical or physiological requirements of specific individuals, resulting in lower fabrication costs for these medical devices. This article presents some case studies on the application of one of the fastest and most affordable AFTs presented in the market today, i.e., Three-Dimensional Printing (3DP), to produce customized anatomical devices from anatomical data captured from an individual, by Computed Tomography (CT) or Magnetic Resonance Imaging (MRI), creating a unique design used for medical applications, such as visualization, diagnosis, operation planning, design of implants, external prostheses, surgical templates, production of artificial organs, communication (between the medical team and/or medical doctors and patients), teaching or didactic aids, or the production of medical surgical instrumentation tooling.

Keywords: Medical Devices, Rapid Manufacturing, Three-Dimensional Printing, Reverse Engineering.

RESUMO

As Tecnologias de Fabrico Aditivo (TFA) têm, em relação às tecnologias convencionais, vantagens adicionais para serem usadas no fabrico de dispositivos médicos, quer pelo facto de poderem gerar formas geométricas de elevada complexidade, quer ainda por poderem gerar essas formas directamente a partir de informação médica individualizada, o que permite a obtenção desses modelos médicos em condições economicamente vantajosas. Neste artigo são apresentados os resultados de um trabalho de investigação abrangendo vários casos de estudo de modelos médicos obtidos pela tecnologia de Impressão Tridimensional (3DP), uma das tecnologias aditivas emergentes e com maior expansão comercial na actualidade. Estes
modelos foram produzidos a partir de dados anatômicos personalizados obtidos de pacientes através de Tomografia Computorizada (TAC) e Ressonância Magnética (RM), tendo sido feita uma análise técnico-económica dos modelos produzidos. As possíveis aplicações destes modelos pelos profissionais de medicina incluem modelos para visualização, para diagnóstico, para pré-cirurgia, para projecto e fabrico de implantes externos e internos, para fins educacionais e didácticos, para efeitos de comunicação, ou para o fabrico de instrumentação médica.

Palavras-Chave: Modelos Médicos, Tecnologias de Fabrico Aditivo, Impressão Tridimensional, Engenharia Inversa.

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1. INTRODUCTION

Additive Fabrication Technology (AFT) or Rapid Manufacturing (RM), originally known as Rapid Prototyping (RP), is one of the fastest developing manufacturing technologies in the world today. It is different from the conventional fabrication processes (i.e. subtractive type as milling or compressive type like casting and moulding). On contrary, RM processes are of additive type, because parts are built in a layer-by-layer basis.

Basically, most RM processes can be described as a layer-by-layer building technology with the exception of the holographic techniques. Solid or surface models created by a 3D CAD system are converted to a Standard Triangulation Language file (*STL) which is a list of triangular facets representing the surfaces of an object to be built, together with a unit normal vector associated with the outer surface of each triangle. Facets are created by a process called "tessellation", generating triangles that approximate to the object surface described in the CAD solid model. This facet file is then sliced into thin slices and a slicing file is created. This information is passed to an RM system to build the model. Then, a solid of some predefined shape is created, by successively adding raw material in 2 D layers.

The prototypes can be made from plastic, paper, ceramics, metals, and composites of them, and, in general, RM systems can be classified into three different categories based on the initial form of materials used (i.e., liquid-based, solid-based and powder-based).

A distinct advantage of creating a part layer-by-layer is that the geometric complexity of the part has significantly less impact on the fabrication process than in the case of traditional manufacturing processes. Other advantages are: no need of tools, short time to produce the parts, very little human intervention and set-up time, and lower fabrication costs (Cooper, 2001).

2. RAPID MANUFACTURING TECHNOLOGIES

The first commercial RM machine available was the Stereolithography Apparatus (SLA), introduced by 3D Systems Inc. (USA), which first appeared commercially in 1987. Nowadays some of the more popular processes are:

- Stereolithography (SL);
- Fused Deposition Modelling (FDM);
- Selective Laser Sintering (SLS);
- Laminated Object Manufacturing (LOM);
- Three-Dimensional Printing (3DP).

After the part is built, and depending on the system, post-processing will normally be necessary (i.e., cleaning, removal of supports, sanding, painting, sintering post-curing, infiltration, etc).

According to the Wohlers Report 2007, the five major RM technologies commercialised in the world today are SL, FDM, SLS, LOM and 3DP, being the SL, FDM and SLS as the most used in the USA, Japan and Europe.

Annual unit sales of RM machines have grown by more than 26 times – 157 units to 4,165 from 1993 to 2006.

In the last few years 3DP technology had an increase on sales of ≈ 34% (including systems from the major USA companies 3D Systems, Stratasys and Z Corp., and other minor companies). This technology represents nowadays ≈ 30% of all RM systems installed worldwide. In fact, and according to the report, 3D printers sold over the past four years (2003–2006) represent 68 percent of the total number of additive systems installed during this period. The main reason for this success is due to the fact that 3D printers are low-cost variations of additive systems that are office friendly, easier to use, and less expensive to operate (Wohlers, 2007).

3. THREE DIMENSIONAL PRINTING

The Three Dimensional Printing (3DP) process is a Rapid Manufacturing technology, invented and patented at Massachusetts Institute of Technology (MIT) for the rapid and flexible production of prototype parts and tooling directly from 3D CAD models.

The 3DP technology was subsequently licensed and further developed by Z Corporation (ZCorp) Company (Massachusetts, USA) which commercialised its first 3D non-colour printer (Z402) in 1997. Presently ZCorp commercialises three 3DP machines (i.e., ZPrinter 310 Plus, a non-colour printer machine, and ZPrinter 450 and Spectrum Z 510, colour printing machines).

Nowadays other companies in the market offer as well this technology, such as Dimension (Dimension website, 2007), a USA company, and Objet Geometries, from Israel (Objet website, 2007), although operating with polymers.
The study presented in this article was performed using a ZCorp apparatus. This process belongs to the solid-based Rapid Manufacturing systems which primarily use powder as the basic medium for prototyping (other RM technologies included in this group are, for example, Selective Laser Sintering/SLS and Direct Metal Laser Sintering/ DMLS).

3.1. THE ZCORP PROCESS

The basic principle of this Rapid Manufacturing technology is the building of parts in layers, i.e., on a layer-by-layer basis. First, a thin layer of powder is spread over the surface of the powder bed. From a computer 3D model of the part, a slicing algorithm computes information for the layer. Using technology similar to ink-jet printing, a binder material is ejected onto the powder where the object is to be formed. A piston then lowers so that the next layer of powder can be spread and selectively bonded. This layer-by-layer process repeats until the part is complete. Following the heat treatment, unbounded powder is removed, leaving the fabricated part.

3.2. PRINCIPLE OF ZCORP

3DP creates parts by a layered printing process and adhesive binder bonding, based on sliced cross-sectional data. A layer is created by adding another layer of powder. The powder layer is selectively joined, i.e., where the part is to be formed, by ink-jet printing of binder material. The process is repeated layer by layer until the part is completed.

When the ink droplet impinges on the powder layer, it forms a spherical aggregate of binder and power particles. Capillary forces will cause adjacent aggregates, including that of the previous layer, to merge.

This will form the solid network which will result in the solid model. The binding energy for forming the solid comes from the liquid adhesive droplets. This energy is composed of two components: one its surface energy and the other its kinetic energy. As this binding energy is low, it is about 104 times more efficient than sinter binding in converting powder to a solid object, as in the SLS process (Chua et al., 2003).

Parameters which influence the performance and functions of the process are the properties of the powder, the binder material, and the accuracy of the XY table and Z-axis control.
Figure 1 (ZCorp website, 2007) describes schematically the 3DP process (left hand side) and presents a view of a 3DP apparatus (right hand side):

Materials used include elastomers and composite plaster based materials (for prototypes and functional parts). The binder is, usually, a glue aqueous solution.

3.3 PROPERTIES OF PARTS PRODUCED BY 3DP (ZCORP)

Like the other powder based RM processes, packing densities are from 50 percent to 62 percent, meaning that subsequent post-processing work is necessary to transform the "green-bodies", as GDP produced, into full density parts.

This post-processing treatment includes heat treatment (sintering), or infiltration with a polymer (cyanoacrylate resin) or water, in order to obtain parts with better mechanical properties depending on the final application of parts.

3.4 ADVANTAGES AND DISADVANTAGES OF 3DP (ZCORP)

Like other RM processes, 3DP presents both strong and weak points.
Advantages:

i) High speed: Fastest 3D printer to date. Each layer is printed in seconds (typically 2-4 layers of 0.089-0.102mm per minute, depending on the model), reducing the prototyping time;

ii) Versatile: Parts are currently used for the automotive, packaging, education, footwear, medical, and aerospace and telecommunications industries. Parts are used in every step of the design process for communication, design review and limited functional testing. Parts can be infiltrated if necessary, offering the opportunity to produce parts with a variety of material properties to serve a range of modelling requirements;

iii) Simple to operate: The office compatible ZCorp system is straightforward to operate and does not require a designated technician to build a part. The system is based on the standard, off the shelf components developed for the in-jet printer industry (e.g., the machines use HP standard ink cartridges, which are voided and subsequently filed with the binder), resulting in a reliable and dependable 3D printer;

iv) No wastage of materials: Powder that is not printed during the cycle can be reused;

v) Colour: Enables complex colour schemes in the parts from a full 24-bit palette of colours;

vi) Resolution: The Spectrum Z510 system offers a resolution of 600x540 dpi, while the other two models offer a resolution of 300x450 dpi.

Disadvantages:

i) Limited functional parts: Relative to other RM processes (SLS, for example), parts built are much weaker, thereby limiting the functional testing capabilities;

ii) Limited materials: The materials available are only starch, high-performance plaster-based composites, elastomeric, investment casting and direct casting materials, with the added option to infiltrate paraffin wax, plastics or cyanoacrylate. Before infiltration parts are fragile and must be handled with care;

iii) Poor surface finish: Parts built by 3D printing have a relatively poorer surface finish and post-processing (as in the majority of the other RM processes) is frequently required (by means of a airbrush into a vacuum cleaner box integrated in the printer). The post processing time will depend on the complexity of the part, the skill of the user, and the
infiltrated used. Nonetheless, it is still minimal compared to some other RM processes.

4. RM OF MEDICAL MODELS: FROM SCAN DATA TO 3D PHYSICAL DATA

In the last few years several research institutions, medical industries and commercial organisations have integrated Medical Imaging (CT, MRI), Computer Aided Design (CAD) and Rapid Manufacture (RM) techniques to fabricate customised 3D physical medical models. These models are being used for several applications, such as visualisation, diagnosis, operation planning, design of implants, external prostheses, 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. As for implantation, medical models obtained by RM are normally used indirectly, as masters, to produce prostheses in biocompatible conventional materials (e.g. titanium, cobalt-chrome alloys, medical-grade alumina, medical-grade silicone elastomer, apatite, etc.), namely by casting and spray metal moulding.

RM has the ability to fabricate models with complex geometric forms and, thus, is very suitable to reproduce the intricate forms of the human body.

The use of RM in medical applications is a relatively young field and the main limitations of this manufacturing route, thus far, are:

- Non-biocompatibility of the existing materials used in the RM machines;
- Continuing high costs of model production;
- Time needed for model production;
- Model quality (surface finish, anatomical accuracy).

With the aid of a RM model, visualization of intricate and hidden details of traumas by surgeons is enhanced.

The selection of materials for medical models manufacture depends on the use of the model. This aspect can be summarized as shown in Table 1.
### Table 1: Selection of materials for medical models manufacture

<table>
<thead>
<tr>
<th>Use</th>
<th>Requirements</th>
</tr>
</thead>
</table>
| Visualization                | Medium mechanical properties.  
|                              | Transparency, low cost.  
|                              | Opacity in some applications (foot).                                         |
| Surgery Planning             | Good mechanical properties (robust).                                       |
|                              | Easy to use with surgical instruments, (cutting, drilling, tapping).         |
|                              | Transparency.                                                               |
|                              | Sterilizable (take to operation room).                                      |
| Implant Manufacturing        | High accuracy and dimensional stability.                                    |
|                              | Investment casting capability (metal implants)                               |
|                              | Use as patterns for moulds.                                                 |
|                              | Efficient thermal degradation.                                              |
| Direct Implants              | Excellent long-term mechanical properties.                                  |
|                              | Chemically stable no degradation.                                           |
|                              | Fully compatible with human tissue (no release of toxic or irritating       |
|                              | compounds).                                                                 |
|                              | Many years before adopted (toxicity)                                        |

The next steps to improve the use of RM in the production of medical models include (Bibb, 2007):
- Producing customised implants;
- Producing implants to be used directly, in biocompatible materials (e.g. hydroxyapatite based);
- Assuring long-term compatibility of the implants.

### 5. CASE STUDIES

In this section some relevant case studies of medical models manufactured using this research are presented.

These models were produced using the 3DP process (ZCorp technology), at Protosys - a Portuguese service bureau that provides CAD/CAM/RP solutions for several applications (Protosys, 2007).

#### 5.1 MODELS FOR TEACHING PURPOSES

Usually, is not easy to obtain medical models for anatomical studding (whether real organs or replicas).

The possibility of print, directly in colour, allows for a better way of identify the different parts of an organ. In addition, the low cost of the materials and the speed of construction allows students to print the models at school and take the models with them to continue their studies at home, or elsewhere.
In Figure 2, some examples of organs produced using a ZCorp colour printer (Z 510) are presented:

![Figure 2: Coloured heart (left hand side), open heart (middle) and kidney section (right hand side)](image)

5.2 MODELS FOR SURGERY PLANNING

The use of customised medical models to assist surgeons in preparing for especially complex operations (surgery planning), results in better surgical preparation, reduced surgery time (up to 50% operation reduction time) and reduced cost for the patient.

Figure 3 shows some examples of 3DP models, manufactured to allow analysing pathologies prior to surgery:

![Figure 3: Damaged skull (left hand side), mandible (middle), and foot (right hand side)](image)

Other models were produced for implantation and medical instruments applications.

The net costs involved in producing a model include the costs of powder, binder, print heads and infiltrate (if necessary).

In Table 2 a summary of the technical data for the production of the above mentioned medical models is presented.
Table 2: Technical construction data

<table>
<thead>
<tr>
<th>Model</th>
<th>Material</th>
<th>3DP Apparatus</th>
<th>Volume (cm³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skull</td>
<td>Plaster Composite</td>
<td>Zprinter 310</td>
<td>217.23</td>
</tr>
<tr>
<td>Mandible</td>
<td>Plaster Composite</td>
<td>Zprinter 310</td>
<td>22.82</td>
</tr>
<tr>
<td>Foot</td>
<td>Plaster Composite</td>
<td>Zprinter 510</td>
<td>203.84</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Model</th>
<th>Time of Construction (h)</th>
<th>Infiltrate</th>
<th>Net price of Model (materials only)/price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skull</td>
<td>3.62</td>
<td>Water resin</td>
<td>43.20/63.06</td>
</tr>
<tr>
<td>Mandible</td>
<td>0.88</td>
<td>Water resin</td>
<td>6.24/8.1</td>
</tr>
<tr>
<td>Foot</td>
<td>2.33</td>
<td>Water resin</td>
<td>45.56/65.48</td>
</tr>
</tbody>
</table>

Both the high speed of construction and the low cost of the manufacture are evident.

6. CONCLUSIONS AND FUTURE TRENDS

3D Printing is a very powerful route to rapidly produce accurate medical models from anatomical data captured from patients for several applications (e.g., teaching and communication aids, surgical planning, design of medical instruments, surgical guiding for dentistry).

The next frontier will be the fabrication of medical customised models for implantation in the human body, using biocompatible/bioresorbable materials (e.g., bioceramics, as hydroxyapatite), directly from a 3DP apparatus.

R&D in this emergent field is being carried out as this article is been written.

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