Rapid Prototype Technique in Medical Field
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ABSTRACT:
Rapid Prototype is an innovative technology that has evolved within the design and manufacturing industries. In medical industries the use of RP technology coupled with the other techniques has led to improvement in services offered to patients by improvement in such areas as 3D visualization of a specific anatomy, surgical planning, implant design, prosthesis production, and polymeric drug delivery devices. In this article we review the current technologies available in RPT and its application in different fields of medicine and future trends in this area.

KEY WORDS: Rapid prototyping (RP), computer aided design (CAD), medical modeling process, applications

INTRODUCTION:
Rapid prototyping is the automatic construction of physical objects using solid freeform fabrication. The first technique for rapid prototyping became available in the late 1980s and was used to produce models and prototype parts. Rapid prototyping takes virtual designs from Computer Aided Design (CAD) or animation modeling software, transforms them into thin, virtual, horizontal cross-sections and then creates each cross-section in physical space, one after the next until the model is finished. However, each rapid prototyping platform uses the same principles of slicing, layering and bonding to build parts. Several research institutions and commercial organizations have integrated Computer-aided Design (CAD) and Rapid Prototyping (RP) systems with medical imaging systems to fabricate medical devices or generate 3D hard copy of these objects for use in surgical rehearsal, custom implant design and casting. In manufacturing, models are planned and conceived entirely on the computer screen, then converted to physical reality. In bio-medical applications, the objects normally already exist physically. Prior to building, this highly complex data needs extensive pre-processing to provide a format that a CAD program can utilize, before transferring to an RP system.

2. RP TECHNIQUES:
There are currently a number of RP technologies on the market, based on special sintering, layering or deposition methods as described below.

2.1. Stereo lithography (SLA):
Patented in 1986, this is the leading technology, with over 500 SLA machines installed worldwide, developed by 3-D Systems Inc, of Valencia, CA. Stereo lithography creates 3-D models out of acrylate photopolymer or epoxy resin, by tracing a low-powered ultraviolet laser across a vat filled with resin. The material is cured by the laser to create a solid thin slice. The solid layer is then lowered just below the surface and the next slice formed on top of it, until the object is completed. It is regarded as a benchmark by which other technologies are judged. A recent development by Zeneca is a translucent resin which changes to red when acted upon by higher laser energy. This can be used to display local regions of interest, and an obvious application would be for the surgeon to draw round a tumor on the medical image slices and have it to build into the model.

2.2. Selective laser sintering (SLS):
This technology was developed by Carl Deckard for his master’s thesis at the University of Texas, patented in 1989 and commercialized by DTM Co, of Austin, TX. SLS creates 3-D models out of a heat-fusible powder, such as polycarbonate or glass-filled composite nylon, by tracing a modulated laser beam across a bin covered with the powder. Heating the particles causes them to fuse or sinter together to create a solid thin slice. The solid layer is then covered by more powder and the next slice formed on top of it, until the object is completed. The same process can be performed with...
a combination of low-carbon steel and thermoplastic binder powder, resulting in a 'green state' part. The binder is then burned off in a furnace and the steel particles are allowed to sinter together.

2.3. Solid Ground Curing (SGC):
Developed by Cubital, solid ground curing (SGC) is somewhat similar to stereolithography (SLA) in that both use ultraviolet light to selectively harden photosensitive polymers. Unlike SLA, SGC cures an entire layer at a time. It is also known as the Solider process. First, photosensitive resin is sprayed on the build platform. Next, the machine develops a photomask (like a stencil) of the layer to be built. This photomask is printed on a glass plate above the build platform using an electrostatic process similar to that found in photocopiers. The mask is then exposed to UV light, which only passes through the transparent portions of the mask to selectively harden the shape of the current layer. After the layer is cured, the machine vacuums up the excess liquid resin and sprays wax in its place to support the model during the build. The top surface is milled flat, and then the process repeats to build the next layer. When the part is complete, it must be de-waxed by immersing it in a solvent bath. SGC machines are distributed in the U.S. by Cubital America Inc. of Troy, MI. The machines are quite big and can produce large models.

2.4. Fused deposition modeling (FDM):
This technology was developed by Stratasys Inc, of Eden Prairie, MN. FDM creates 3-D models out of heated thermoplastic material, extruded through a nozzle positioned over a computer-controlled x-y table. The table is moved to accept the material until a single thin slice is formed. The next slice is built on top of it until the object is completed. FDM utilizes a variety of build materials, such as polycarbonate, polypropylene and various polyesters which are more robust than the SLA models. A similar approach is used by Sanders Prototype Inc, of Wilton, NH, to produce 3-D models by extruding thermoplastic material through ink-jet printer nozzles. FDM models can also be made in wax, enabling custom-made implants to be investment cast for individual patients.

2.5. Laminated object manufacturing (LOM):
In this technique, developed by Helisys of Torrance, CA, layers of adhesive-coated sheet material are bonded together to form a prototype. The original material consists of paper laminated with heat-activated glue and rolled up on spools. A feeder/collector mechanism advances the sheet over the build platform, where a base has been constructed from paper and double-sided foam tape. Next, a heated roller applies pressure to bond the paper to the base. A focused laser cuts the outline of the first layer into the paper and then cross-hatches the excess area (the negative space in the prototype). Cross-hatching breaks up the extra material, making it easier to remove during post-processing. During the build, the excess material provides excellent support for overhangs and thin-walled sections. After the first layer is cut, the platform lowers out of the way and fresh material is advanced. The platform rises slightly below the previous height, the roller bonds the second layer to the first, and the laser cuts the second layer. This process is repeated as needed to build the part, which will have a wood-like texture. Although these models are robust, it is difficult to remove unwanted regions of paper from areas of complex geometry.

2.6. 3-D printing:
This technology was developed at MIT and is being commercialized by a number of companies. 3-D printing creates models by spraying liquid through ink-jet printer nozzles on to a layer of metallic or ceramic precursor powder, thus creating a solid thin slice. The printing process is repeated for each subsequent slice until the object is completed as a 'green-state' part. The part is then fired in a furnace to sinter the powder. The resulting skeleton object is subsequently infiltrated with metal, resulting in a full-density part. This process is very fast and produces parts with a slightly grainy surface. Machines with 4 color printing capability are available.

2.7. Multiphase jet solidification (MJS):
This technology was developed by the network of Fraunhofer Institutes in Germany. MJS creates 3-D metal or ceramic models out of various low-viscosity materials in powder or pellet form, by extruding the build material through a jet in liquid form. Each layer that is deposited solidifies on to the previous one, until the entire object is created. This technology is still in the development phase.

3. FABRICATION OF MEDICAL MODELS:
The medical modeling process is broadly split into three areas, 1) Data acquisition, 2) Image processing, and 3) Model production.

3.1. Data Acquisition:
In medical imaging, the two most common systems used in acquiring detailed anatomical information are Computed Tomography (CT), and Magnetic Resonance Imaging (MRI). CT and MRI represent the finest resolution capability available in diagnostic systems achieving volumetric resolutions. During the scanning process, the patient is stepped through the measurement plane 2-3mm at a time. The information from each plane can be put together to provide a volumetric image of the structure as well as the size and location of anatomical structures. The scanned model becomes a virtual volume that resides in a computer, representing the real volumes of the patient’s bone(s). The virtual volume is displayed on-screen by reformattting the data to create orthographic projections, or by creating a pseudo 3D representation using surface-rendering algorithms.

3.2. Data reconstruction/Processing:
When a series of CT images is reassembled to illustrate a 3D presentation of an anatomic structure, the medical practitioner or prosthetic designer can use this information directly and the overall shape of body structures is more clearly
understood or visualized. This process requires a good visualization software packages. These software packages take anatomical data from CT and MRI scans and create computer models of anatomical structures. A user can modify the image by defining various tissue densities for display. This allows separation of data of interest from the general information available from the scanner. By combining the data generated with a traditional CAD system, design of new parts can be undertaken by comparison with the reconstructed 3-D anatomical shape. When segmentation and visualization is completed the data can be translated into instructions for manufacture of parts often by RP.

3.3. Evaluation of Design:
This step depends on a case-to-case basis. Sometimes the created model is directly used as an input for RP machine (biomodels). This is necessary for evaluation of design, quality of the made model, checking possible errors or other important steps which depends on the concrete case.

3.4. RP Medical Model Validation:
When the RP medical model is manufactured it should be validated by surgeons. If there are no errors the model is ready for application. The Materialize package has two modules: MIMICS and CTM suites.

A) Mimics: Mimic is a software suite that performs the segmentation of the anatomy through sophisticated three-dimensional selection and editing tools. The program also generates high-resolution 3D renderings in different colors directly from the slice information as shown in fig-1. After visualization, the data can be interfaced to CTM.

B) CTM: CTM is a software suite that interpolates the medical slice in very thin layers, and interfaces directly with most RP systems. Because of this direct interface and the use of higher-order interpolation mathematical algorithms such as Bilinear and C-Spline functions, it produces very accurate models in a very short time. A resolution enhancement technique is necessary when creating the RP models so as to minimize the effect of stair-stepping, and to retain the natural curvature of the surface.

6. APPLICATIONS:
6.1. Design and development of medical devices and instrumentation:
This is the field where applications of RP show the best results. It specially applies to hearing aids but also to other surgical aid tools.

6.2. Great improvements to the fields of prosthetics and implantation:
RP techniques are very useful in making prostheses and implants for years. The ability to quickly fit prosthesis to a patient's unique proportions is a great advantage. The techniques are also used for making hip sockets, knee joints and spinal implants for quite some time. Both the release of and the improvement of the properties of used materials have had a significant influence on the quality of prostheses and implants made by RP. One interesting example is maxillofacial prostheses of an ear which is obtained by creating a wax cast by laser sintering of a plaster cast of existing ear. Due to RP technologies it is very easy to manufacture custom implants. The made model could be used as a negative or a master model of the custom implant. Many researchers explored new applications of RP in this field.

Fig- 1: Flowchart diagram on the conversion of scanned data to physical 3D model

6.3. Planning and explaining complex surgical operations:
This is very important role of RP technologies in medicine which enable presurgery planning. The use of 3D medical models helps the surgeon to plan and perform complex surgical procedures and simulations and gives him an opportunity to study the bony structures of the patient before the surgery, to increase surgical precision, to reduce time of procedures and risk during surgery as well as costs (thus making surgery more efficient). The possibility to mark different structures in different colors (due to segmentation technique) in a 3D physical model can be very useful for surgery planning and better understanding of the problem as well as for teaching purpose. This is especially important in cancer surgery where tumor tissue can be clearly distinguished from healthy tissue by different color.

Surgical planning is most often done with stereolithography (SLA) where the made model has high accuracy, transparency but limited number of colors and 3DP (for more colored models, presentation of FEA results).

6.4. Teaching purposes:
RP models can be used as teaching aids for students in the classroom as well as for researchers. These models can be made in many colors and provide a better illustration of
anatomy, allow viewing of internal structures and much better understanding of some problems or procedures which should be taken in concrete case\textsuperscript{13}. They are also used as teaching simulators.

6.5. Design and manufacturing biocompatible and bioactive implants and tissue Engineering:
RP technologies gave significant contribution in the field of tissue engineering through the use of biomaterials including the direct manufacture of bioactive implants. Tissue engineering is a combination of living cells and a support structure called scaffolds. RP systems like fused deposition modeling (FDM), 3D printing (3-DP) and selective laser sintering (SLS) have been proved to be convenient for making porous structures for use in tissue engineering. In this field it is essential to be able to fabricate three-dimensional scaffolds of various geometric shapes, in order to repair defects caused by accidents, surgery, or birth. FDM, SLS and 3DP can be used to fabricate a functional scaffold directly but RP systems can also be used for manufacturing a sacrificial mould to fabricate tissue-engineering scaffolds\textsuperscript{14,15}.

7. RECENT AND FUTURE TRENDS:
Recently this technique was used for the separation of Siamese twins who was borned by the attaching of the skull portion as shown below.

![RP modeling for surgical planning to separate Siamese twins.](source)

It is a very significant discovery in medicine and the first step on the way to making other complex human organs. Further development in RP in tissue engineering requires the design of new materials, optimal scaffold design and the input of such kind of knowledge of cell physiology that would make it possible in the future to print whole replacement organs or whole bodies by machines. There are also many new trends of applying RP in orthopedics, oral and maxillofacial surgery and other fields of medicine.

8. CONCLUSION:
RP technology can make significant impact in the field of biomedical engineering and surgery. Physical models enable correct identification of bone abnormality, intuitive understanding of the anatomical issues for a surgeon, implant designers and patients as well. A precise RP model facilitates the pre-operative planning of am optimal surgical approach and enables selection of correct or appropriate implants. In the UK, RPT has been used to help plan treatment in more than 20 patients; however, the cost of the modeling process is currently a significant limitation to its use.

Surgical procedures continue to be more effective day by day with reduced risk and expense to both the patient and the hospital. This could help minimize the problem of long waiting list and congestion in ‘big’ hospitals by reducing referral cases.

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