Title: Medical Rapid Prototyping Technologies: State of the Art and Current Limitations for Application in Oral and Maxillofacial Surgery.

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Abstract

Purpose

We describe state of the art software and hardware requirements for the manufacture of high quality medical models manufactured using medical rapid prototyping. The source of the medical model artefacts and there physical appearance are illustrated along with remedies for their removal.

Materials and Methods

Medical models were built using predominantly stereolithography and fused deposition modelling at both institutions over a period of 6 years. A combined total of 350 models have been produced for a range of maxillofacial, neurosurgical and orthopaedic applications. Stereolithography, fused deposition modelling computerised numerical milling and other technologies are described.

Results

A range of unwanted artefacts that create distortions on medical models have been identified. These include, data import, CT gantry distortion, metal, motion, surface roughness due to support structure removal or surface modelling and image data thresholding. The source of the artefact has been related to the patient, imaging modality performance or the modelling technology. Discussion as to the significance of the artefacts on clinical use is provided.

Conclusions

It is recommended that models of human anatomy generated by medical rapid prototyping are subject to rigorous quality assurance at all stages of the manufacturing process. Clinicians should be aware of potential areas for inaccuracies within models and review the source images in cases where model integrity is in doubt.

Introduction

Medical rapid prototyping (MRP) is defined as the manufacture of dimensionally accurate physical models of human anatomy derived from medical image data using a variety rapid prototyping (RP) technologies. It has been applied to a range of medical specialities including oral and maxillofacial surgery (1-7), dental implantology (8), neurosurgery (9-10) and orthopaedics (11-12). The source of image data for 3D modelling is principally computed tomography (CT), although magnetic resonance imaging and ultrasound have also been utilised. Medical models have been successfully built of hard tissue (bone) and soft tissues (blood vessels and nasal passages) (13-14). MRP was described originally by Mankowich et al in 1990 (15). The development of the technique has been facilitated by improvements in medical imaging technology, computer hardware, 3D image processing software and the technology transfer of engineering methods into the field of surgical medicine.

The clinical application of medical models has been analysed in a European multi-centre study (16). Results were collated from a questionnaire sent out to partners of the Phidias Network on each institution's use of MRP stereolithography models. The 172 responses indicated the following the following range applications:

- To aid production of a surgical implant;
- To improve surgical planning;
- To act as an orienting aid during surgery;
- To enhance diagnostic quality;
- Useful in preoperative simulation;
- To achieve patient's agreement prior to surgery;
- To prepare a template for resection.

Further, it was noted that the diagnosis in which an SL model was employed were as follows, neoplasms (19.2%), congenital disease (20%), trauma (15%), dentofacial anomalies (28.9%) and others (16.9%). MRP is also being developed for use in dental implants. Greater accuracy was achieved with the use of rapid prototyped surgical guides for creating osteotomies in the jaw (17) and a CAD/CAM approach to the fabrication of partial dental frameworks has been developed (18).

The creation of medical models requires a number of steps: the acquisition of high quality volumetric (3D) image data of the anatomy to be modelled; 3D image processing to extract the region of interest from surrounding tissues; mathematical surface modelling of the anatomical surfaces; formatting of data for rapid prototyping (this includes the creation of model support structures which support the model during building and

are subsequently manually removed); model building; quality assurance of model quality and dimensional accuracy. These steps require significant expertise and knowledge in medical imaging, 3D medical image processing, computer assisted design and manufacturing software and engineering processes. The production of reliable, high quality models requires a team of specialists that may include medical imaging specialists, engineers and surgeons.

The purpose of this report is, firstly, to describe the range of rapid prototyping technologies (including software and hardware) available for MRP, secondly, to compare their relative strengths and weaknesses, and thirdly, to illustrate the range of pitfalls that we have experienced in the production of human anatomical models. The authors have a combined experience of 17 years working in the field of MRP and have direct experience of the technologies described later. The report begins with a description of 3D image acquisition and processing and computer modelling methods required, common medical rapid prototyping techniques, followed by the a discussion model artefacts and manufacturing pitfalls. At present there is no suitable text describing MRP or its clinical applications, however, there are two useful review papers (19-20).

3D Image Acquisition and Processing for MRP

The volumetric or 3D image data required for MRP models has certain particular requirements. Specialised CT scanning protocols are required to generate a volume of data which is isotropic in nature. This means that the three physical dimensions of the voxels (image volume elements) are equal or nearly equal. This has become achievable with the introduction of multi-slice CT scanners where in-plane pixel size is of the order of 0.5 mm and slice thickness as low as 1.0 mm (21). Data interpolation is often required to convert the image data volume into an isotropic data set for mathematical modelling. Further image processing steps will be required to identify and separate out the anatomy (segmentation) for modelling from surrounding structures. Segmentation may be carried out by image thresholding, manual editing, or auto-contouring to extract volumes of interest. Final delineation of the anatomy of interest may require 2D or 3D image editing to remove any unwanted details. A number of software packages are available for data conditioning and image processing for MRP and include Analyze (Lenexa, KS, www.AnalyzeDirect.com), Mimics by Materialise (Leuven, Belgium, www.materialise.com), and Anatomics (Brisbane, Australia). There is still a need for seamless and inexpensive software which provides a comprehensive range of data interpretation, image processing and model building techniques to interface with RP technology.

The first models created were of bone which was easily segmented in CT image data. Bone has a CT number range from approximately 200 to 2000. This range is unique to bone within the human body as it did not numerically overlap with any other tissues. In many circumstances a simple threshold value was obtained and applied to the data volume. All soft tissues outside the threshold range were deleted leaving only bone structures. Thresholding required the user to determine the CT number value that represented the edge of bone where it interfaced with soft tissue. Note that the choice of threshold may cause loss of information in areas where only thin bone is present.

In many circumstances the volume of the body scanned is much larger than that actually required for model making. To reduce the model size, and therefore the cost, 3D image editing procedures may be employed. The most useful tool was a mouse-driven 3D volume editor that enabled the operator to delete or cut out sections of the data volume. The editing function deleted sections to the full depth of the data volume along the line of sight of the operator. Image editing reduced the overall model size which would also reduced RP build time. Clearer and less complex models may be generated making structures of interest more clearly visible. Other image processing functions such as smoothing, volume data mirroring, image addition and subtraction should be available for the production of models.

Rapid Prototyping Technology

Rapid prototyping is a generic name given to a range of related technologies that may be used to fabricate physical objects directly from computer aided design (CAD) data sources. RP enables design and manufacturing of models to be performed much more quickly than conventional manual methods of prototyping. In all aspects of manufacture the speed of moving from concept to product is an important part of making a product commercially competitive. RP technologies enable an engineer to produce a working prototype of a CAD design for visualisation and testing purposes. There are a number of texts describing the development of rapid prototyping technology and its applications (22-23). Though many RP processes exist and have been applied to medical modelling the two RP processes most extensively employed are stereolithography and fused deposition modelling.

1 Stereolithography (SL)

An SL RP system consists of a bath of photosensitive resin, a model-building platform and an ultraviolet (UV) laser for curing the resin. Figure 1 shows the principle of operation of stereolithography

apparatus. A mirror is used to guide the laser focus onto the surface of the resin where the resin becomes cured when exposed to UV radiation. The mirror is computer controlled with its movement being guided to cure the resin on a slice-by-slice basis. A model is initially designed with CAD software and a suitable file format (commonly STL) and transferred to the SL machine for building. The CAD data file is converted into individual slices of known dimensions. This slice data are then fed to the RP machine, which guides the exposure path of the UV laser onto the resin surface. The layers are cured sequentially and bond together to form a solid object beginning from the bottom of the model and building upwards. As the resin is exposed to the UV light a thin well-defined layer thickness becomes hardened. After a layer of resin is exposed, the resin platform is lowered within the bath by a small known distance. A new layer of resin is wiped across the surface of the previous layer using a wiper blade and this second layer is subsequently exposed and cured. The process of curing and lowering the platform into the resin bath is repeated until the full model is complete. The self-adhesive property of the material causes the layers to bond to one another and eventually form a complete, robust, three-dimensional object. The model is then removed from the bath and cured for a further period of time in a UV cabinet. The build part may contain layers, which significantly overhang layers below. If this is the case then a network of support structures, made of the same material, are added beneath these over-hanging layers at the design stage to add support during the curing process. These support structures, analogous to a scaffold, are removed by hand after the model is fully cured. This is a labour intensive and time-consuming process. Generally, SL is considered to provide the greatest accuracy and best surface finish of any rapid prototyping technology. The model material is robust, slightly brittle and relatively light, although it is hydroscopic and may physically warp over time (a few months) if exposed to high humidity.

The following data provide some technical specifications of a typical SL machine (3D systems SLA 3500, 3D Systems, Valencia, CA, www.3dsystems.com):

- Laser beam diameter = 0.2 – 0.3 mm;
- Laser scanning speed = 2.54. meters/second;
- Build platform = 250 x 250 x 250 mm;
- Layer build thickness = 0.05 – 0.2 mm;
- Minimum vertical platform movement = 0.0017 mm.

The above specification indicates the precision of model building that is achievable with SL. The laser focus defines the in-plane resolution whilst the platform vertical increment defines the slice thickness at which

the model is built. It should be noted that the imaging modality acquisition parameters are the limiting factors in model accuracy.

2 Fused Deposition Modelling (FDM)

FDM employs a similar principle to SL in that it builds models on a layer-by-layer basis. The main difference is that the layers are deposited as a thermoplastic that is extruded from a fine nozzle. A commonly used material is acrylonitrile butadiene styrene (ABS). The physical properties of ABS are, it is rigid, has dimensional stability, has thermoplastic properties and is inexpensive. Figure 2 shows a schematic of a typical FDM system. The model is constructed by extruding the heated thermoplastic material onto a foam surface in a path guided by the model data. Once a layer has been deposited the nozzle is raised between 0.178 to 0.356 mm and the next layer is deposited on top of the previous layer. This process is repeated until the model is complete. As with SL, support structures are required for FDM models as it takes time for the thermoplastic to harden and the layers to bond together. The supports are added to the model at the design stage and built using a different thermoplastic material, extruded through a second nozzle. The support material is a different colour to the build material and does not adhere to it. This enables easy identification and subsequent removal of the supports by hand after the model is completed. A more recent development is the availability of a soluble support material, which enables support structures to be dissolved from the model in an agitated water bath.

Technical specification of the FDM machine (Stratasys FDM 3000, Eden Prairie, MN, www.stratasys.com) used for models in the our projects are as follows:

- Build envelope 254 x 254 x 254 mm;
- Achievable accuracy of ± 0.127 mm;
- Road widths (extruded thermoplastic width) between 0.250 to 0.965 mm;
- Layer thickness (extruded thermoplastic height) from 0.178 to 0.356 mm.

A further technical development in the FDM process is the multi-headed jet. This enables models to be built more rapidly and therefore at less expense. Also, a 3D printer offers a model size of up to 203 x 254 x 203 mm with print resolution similar to other RP systems. Our limited experience of models from these systems indicates and that they may require coating to add strength and careful manual handling. With continuous development of materials for RP it is expected that cheaper and robust modelling methods will emerge.

3 Computer Controlled Milling

Although generally not considered one of the many rapid prototyping technologies, Computerised Numerically Controlled (CNC) milling can successfully build some medical models (22). This technology was applied in the construction of custom titanium implants for cranioplasty. CNC milling uses a cutting tool, which traverses a block of material removing it on a layer-by-layer basis. Figure 3 shows a model of skull defect (only half the skull has been created). The complexity of models that can be achieved using CNC milling is limited as it only cuts on one side of the model data. If the model required has any internal features or complex surfaces facing a number of directions, then CNC milling would not be suitable.

4 Other Rapid Prototyping Technologies

Selective laser sintering (SLS) cures a thermoplastic powder, which is fused by exposure to an infrared laser in a manner similar to SL. SLS models do not require support structures and are therefore relatively easily cleaned, thus saving labour costs. An example of the use of SLS in medical modelling is described by Berry et al (25). Laminated object manufacturing (LOM) builds models from layers of paper cut using a laser, which are bonded together by heating. Inexpensive sheet materials make LOM very cost effective for large volume models. However, the solid nature of the waste material mean it is not suited to models with intern voids or cavities often encountered in human anatomy.

Discussion of MRP Technologies

The main factors in choosing which rapid prototyping technology are most appropriate for our clinical applications were as follows:

- Dimensional accuracy of the models;
- Overall cost of the model;
- Availability of technology;
- Model build material.

SL models are typically colourless to amber in colour, transparent and of sufficient accuracy to be suitable for MRP work. FDM models are typically made of white acrylonitrile-butadiene-styrene (ABS) and attractive both in terms of appearance and material. It has been pointed out that medical models may be dimensionally accurate to 0.62 mm +/- 0.35 mm (26). It should be noted that the limiting factor in model accuracy is the imaging technique rather than the RP technology employed. In general CT and MR typically

acquire images slices, which have slice thickness of the order of 1.0 to 3.0 mm, which is much greater than the limiting build resolution of any of the RP technologies.

The potential benefits of exploiting rapid prototyping techniques in surgical planning have been widely acknowledged and described. The process of producing accurate physical models directly from three-dimensional scan data of an individual patient has proved particularly popular in head and neck reconstruction. In addition most of the work done to date has concentrated on the use of three-dimensional computed tomography (CT) data as this produces excellent images of bone. However the process is still not conducted in the large volumes associated with industrial rapid prototyping and as such practitioners applying these techniques to medicine often confront problems that are not encountered in industry. The small turnover associated with medical modelling also means that many manufacturers and vendors cannot justify investment in specific software, processes and materials for this sector. These characteristics combine to make medical modelling a challenging field of work with many potential pitfalls.

The authors many years practical experience in medical modelling has resulted in a knowledge base that has identified the problems that may be encountered, many of which are simple or procedural in nature. This paper aims to highlight some of these common problems, the effect they have on the resultant models and suggest methods that can be employed to avoid or minimise their occurrence or impact on the usefulness of the models produced.

Medical Rapid Prototyped Model Artefacts

Associated with all medical imaging equipment are unusual or unexpected image appearances referred to as artefacts. Some imaging modalities are prone to geometric distortion like MR (27) and this should be accounted for in soft tissue models manufactured from this source. CT does not suffer from the same distortion as MR and models produced from this source have been proven to be dimensionally accurate (28). In some circumstances artefacts are easily recognisable and taken into account by the viewer whilst in other circumstances they can be problematic and difficult to explain. Artefacts present in the image data may subsequently be transferred to a medical model. In addition, due to the image processing steps and surface modelling required in the production of medical models there is scope for the appearance of a wide range of artefacts. This section describes and illustrates some of the problems and pitfalls encountered in the production of medical models.

1. CT Data Import Errors

CT data consists of a series of pixel images of slices through the human body. When importing data the key characteristics that determine size and scale of the data are the pixel size and the slice thickness. The pixel size is calculated by dividing the field of view by the number of pixels. The field of view is a variable set by the radiographer at the time of scanning. The number of pixels in the x and y-axis is typically 512 by 512 or 1024 by 1024. If there is a numerical error in any of these parameters whilst data is being translated from one data format to another the model may be inadvertently scaled to an incorrect size. The slice thickness and any inter slice gap must be known, (although the inter-slice gap is not applicable in CT where images are reconstructed contiguously or overlapping. Numerical error in the slice thickness dimension will lead to inadvertent incorrect scaling in the third dimension. This distance is typically in the order of 1.5 mm but may be as small as 0.5 mm or as high as 5 mm. Smaller scan distances result in higher quality of the three-dimensional reconstruction. The use of the internationally recognised DICOM (Digital Image Communications in Medicine, www.acrnema.org) standard for the format of medical images has largely eliminated these errors (29).

2. CT Gantry Tilt Distortion

A CT scanner typically operates with the x-ray tube and detector gantry perpendicular to the long axis of the patient (Z direction). The scan therefore produces the axial images that form the basis of three-dimensional CT scans. However, in some cases the gantry may be inclined at an angle of up to 30^{o}. When a set of 2D slices is combined into an image volume for three-dimensional modelling the gantry angle must be taken into account. Figure 4 (a) shows the spatial relationship of 2D CT slices taken without with a gantry tilt. With no gantry tilt the slices are correctly aligned and produce an undistorted 3D volume. Slices acquired with a gantry tilt of 15^{o} and converted into a data volume without the gantry tilt being taken into account may have a shear distortion arising from the misalignment of slices. At large angles this is immediately visually apparent and can therefore be detected. However at small angles it may not be so obvious. Building a model with a small, uncorrected gantry tilt angle could be easily done and result in significant geometrical inaccuracies in the resulting model. The use of the image transfer standard, DICOM, automatically provides the scan parameters including gantry tilt angle. However, DICOM does not provide the direction of the angle and can therefore not be relied on to automatically correct gantry tilt. It is therefore advisable to avoid gantry tilt when acquiring a three-dimensional CT image data set otherwise sophisticated mathematical algorithms are required to

successfully correct the data. Figure 4 (b) shows how a distorted 3D CT volume may be corrected using affine transformation to produce a data set with no distortion.

2. Model Stair-Step Artefact

There are two elements that contribute to the stepped effect seen in medical models. One contribution is from the discrete layer thickness at which the model is built. This is a characteristic of the particular RP process and material being used. Typically these range from 0.1mm to 0.3 mm. This affect can be minimised by selecting processes and parameters that minimise the build layer thickness. However thinner layers result in longer build-times and increased costs and an economic compromise is typically found for each RP process. As the layer thickness is typically an order of magnitude smaller than the scan distance of the CT images it does not have an overriding effect on the quality of the model.

The second effect is arises from the slice thickness of the acquired CT or MR images and any potential gap between them. The stair-step artefact is a common feature on conventional and single slice helical CT scans where the slice thickness is near to an order of magnitude greater than the in-plane pixel size (30). The artefact is manifest as a series of concentric axial rings around the model. The depth and size of these rings depends on the CT imaging protocol, but may be very slight where there is a thin slice used (e.g. 3 mm acquisition with 1 mm reconstruction interval). In thick slice acquisitions (e.g. > 3mm with similar reconstruction interval to the slice thickness) the stair-step artefact will cause significant distortion to the model. Figure 5 shows a stereolithography model of a full skull. The CT scan was performed on a conventional CT scanner with 5 mm slice thickness and no interpolation of the image data to create thin slices. Note there was significant stair-step artefact around the top of the skull and on the lower edge of the mandible. The stair-step artefact was most prominent on surfaces that were inclined to the data acquisition plane as is the case for 3D surface rendered images. This model was used for surgical planning and reconstruction but was limited in the use for obtaining physical measurements.

These effects can be countered to some degree by using interpolation between the original image data. The following images illustrate the difference between using no interpolation and using a cubic (natural curve) interpolation. Due the natural nature of the cubic curve the resulting interpolated data results in a good, smooth and natural appearing surface.

3. Irregular Surface due to Support Structures

Both SL and FDM required support structures during the build process. These were subsequently cleaned from the model manually although generally left a rough surface. This did not affect the overall accuracy of the model but contributed to a degradation of its aesthetic appearance. Figure 6 shows an SL where surface roughness was attributed to the support structures. Models were easily cleaned using a light abrasive techniques although this was felt unnecessary as the indentations were of sub-millimetre depth. It is unlikely that these structures would have a detrimental effect in surgical planning or implant design.

4. Irregular Surface due to Mathematical Modelling

The mathematical modelling of a surface will introduce its own surface effects. The smoothness (governed by the size of the triangle mesh) of the model surface becomes poorer as the surface mesh becomes larger. A larger mesh resulted in a lower number of triangles, reduced computer file size and quicker rendering. A smaller mesh resulted in much better surface representation, much greater computer file size and slower rendering. Figure 7 shows irregular surface structures due to the mathematical modelling process (31). Figure 7 (a) shows a model where the mesh structure is not readily apparent and (b) where the model contours are more clearly observed. In both cases the surface produced was acceptable for its own clinical application. One could imagine that the mesh resolution used in model (b) would be unacceptable for smaller models where a fine detail would be masked.

These effects can be avoided by eliminating the creation of a three dimensional surface mash and creating the RP build data directly from the CT image data. This essentially creates the two-and-a-half dimensional layer data for the RP machine from the CT images. Interpolation is used to create accurate intermediate layers between the CT images. This route not only eliminates surface modelling effects but also results in much smaller computer files and faster preparation.

5. Metal Artefact

Metal artefact was present within CT scans of the maxilla and mandible due to the presence of metal within fillings of the teeth or the presence of dental implants. This was manifest as high signal intensities (in the form of scattered rays) around the upper and lower mandible. Figure 8 (a) shows an FDM model with significant metal artefact around the teeth. These ray appearances extended from a couple of millimetres to over one centimetre in length. In some circumstances the artefact may be reduced by software during CT image

reconstruction (31). This artefact was plainly visible and added many superfluous structures to the medical models. Although, no significant geometric distortion was observed on models, large spikes were visible emanating from a round the teeth which distorted the bone in the local area. The artefact may be removed by detailed slice-by-slice editing of the original CT images, to produce a cleaner model (Figure 8 (b)). This process is very time consuming and if not performed with great care can result in anatomy of interest being removed and the subsequent model becoming unusable.

6. Movement Artefact

CT scanning was prone to movement artefact if a patient was restless. This artefact was readily apparent in a model if the degree of movement was significantly large i.e. greater than 1 mm. Figure 9 shows a mandible with a distinct artefact present. The patient moved slightly during the acquisition of a couple of images that left a bulge of 4 mm height extending right around the mandible. In addition, present in this model were concentric axial rings of about 3 mm thickness. These corresponded to the common stair-step observed in single slice helical CT scanning. Obviously the degree of the movement during the scan determines the size of the movement artefact in the model. In the example shown the artefact was felt not to be significant clinically as it did not interfere directly with the placement of a distraction device.

In another example where a model was being used for facial reconstruction the patient moved whilst the scanner was acquiring data at the region where the surgery was to be performed. The movement artefact resulted in distortion of the model that the surgeon lost confidence in its physical integrity. During the scan, around the supra-orbital ridge, we believe the child rotated its head to look at a parent, which resulted in rotation of this part of the data, which was subsequently transferred to the model. In this case the patient, a 7-year-old child had to be rescanned under full general anaesthetic. It was interesting to note that the degree of the artefact was not noted until a physical model was produced. This indicates the need for good quality assurance of the original data set to ensure a useful model was produced.

7. Image Threshold Artefact

One of the simplest and commonest methods of tissue segmentation applied to the skull is CT number thresholding. A CT number range was identified by either ROI pixel measurements or pixel intensity profiles, which was representative of bone. If the bone was particularly thin or the threshold inappropriately measured a continuous surface was unachievable. This left the model with a hole where the surface was not closed. In

some cases large areas of bone were removed completely, especially at the back of the orbit and around the cheekbones. Figure 10 illustrates bone deletion by data thresholding in the back of the orbit in this magnified surface shaded image. Anatomical detail is lost as the chosen threshold removed thin bone at the back of the orbit, as indicated by the black arrow. Adjusting the threshold to include bone in this case would have resulted in the inclusion of soft tissue that would have made the image more difficult to interpret. It is useful to specify clearly what is required of a model so that an appropriate threshold can be chosen to preserve tissue of interest

Conclusion

Medical rapid prototyping models of human anatomy may be constructed from a number of image data sources and using a range of RP technologies. They are prone to artefacts both from the imaging source, the method of manufacture and from the model cleaning process. It is important to ensure that high quality source data is available to assure model quality. Clinicians requesting medical models should be aware of their physical accuracy and integrity which is generally dependent on the original imaging parameters and image processing rather than the method of manufacture an determine that this is sufficient for its purpose. We have demonstrated a range of model artefact sources ranging from reading computer files to the removal of support structures and suggested ways to avoid or cure them. It is important that the source images are reviewed thoroughly, that robust image transfer and image processing procedures are in place and that the model build material is fit for the purpose for which it was intended. A multi-disciplinary team approach to the manufacture of medical models with rigorous quality assurance is highly recommended.