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The Use of Rapid Prototyping in Clinical Applications

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1. Introduction

This chapter will present a brief overview of the possible applications of rapid prototyping in the medical context. Different options of clinical inputs will be discussed as well as five detailed case studies which will demonstrate the flexibility and clinical usefulness of this technique.

Rapid prototyping broadly indicates the fabrication of a three-dimensional (3D) model from a computer-aided design (CAD), traditionally built layer by layer according to the 3D input (Laoui & Shaik, 2003). Rapid prototyping has also been indicated as solid free-form, computer-automated or layer manufacturing (Rengier et al., 2008). The development of this technique in the clinical world has been rendered possible by the concomitant advances in all its three fundamental steps:

1. Medical imaging (data acquisition),
2. Image processing (image segmentation and reconstruction by means of appropriate software) and
3. Rapid prototyping itself (3D printing).

These steps are visually summarised in Figure 1.

In clinical terms, the possibility of observing, manipulating or manufacturing an anatomical model can serve a range of significant functions (Kim et al., 2008). For instance, it can address visualisation issues that virtual examination cannot always resolve. Also, it can be adopted as a simulation tool or a teaching device. Moreover, it allows medical practitioners and researchers to fully make use of the "patient-specific" concept, in terms of prosthesis design and implant fitting but also in terms of *ad hoc* simulations. Finally, it can facilitate the communication between the clinician and the patient.

The functions of rapid prototyping in the current clinical world are several (Adler & Vickman, 1999):

- Pre-surgical planning: A 3D model not only can be useful in surgical practice (i.e. a better fitting, purposefully designed implant), but it can also help a surgical team in visually analysing the location, size and shape of the problem. In the event of a long operation, the model can also be used to plan and customise the surgery. This can be especially valuable when the surgery is performed on anatomical abnormalities.
- Mechanical replicas: A 3D model can be tailored to specific material properties, including non-homogenous variations within a region. Specifically, mechanically

correct bone replicas are useful in evaluating the behaviour of the bone under different testing conditions.

- Teaching aids: Offering both visualisation of anatomical details and the possibility of practicing directly on a specimen without involving a patient, 3D models can be a valuable tool for training nurses and doctors.
- Customised implants: Instead of using a standard implant and adapting it to the implantation site during the surgical procedure, rapid prototyping enables the fabrication of patient-specific implants, ensuring better fitting and reduced operation time.
- Microelectromechanical systems (MEMS): These are micro-sized objects that are fabricated by the same technique as integrated circuits. MEMS can have different applications, including diagnostics (used in catheters, ultrasound intravascular diagnostics, angioplasty, ECG), pumping systems, drug delivery systems, monitoring, artificial organs, minimally invasive surgery.
- Forensics: Reconstruction of crime scene and wound are also benefiting from rapid prototyping. In particular, in the case of a surviving victim where a wound is of difficult access, e.g. the skull, a model can be used for detailed analysis.

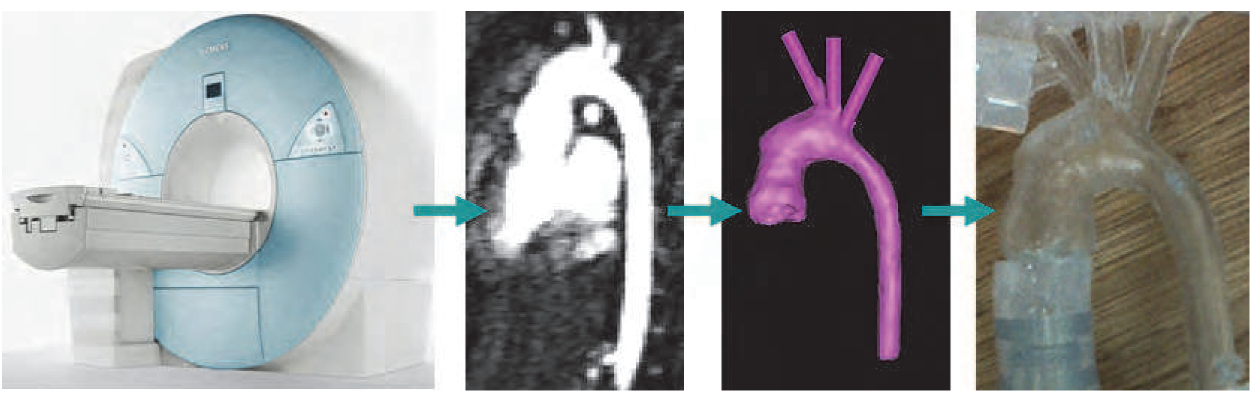

Fig. 1. Stages of rapid prototyping in a clinical setting. From left to right: data acquisition (in this case with magnetic resonance (MR) imaging), image processing, 3D volume reconstruction with appropriate software (in this case, Mimics®, Materialise, Leuven, Belgium) and final 3D model printed in a transparent resin. The above example (aortic arch of a paediatric patient) is discussed further in paragraph 4.2.

Despite its clinical use to the present day is still somewhat limited, considering the potential and flexibility of this technique, it is likely that applications of rapid prototyping such as individual patient care and academic research will be increasingly utilised (Rengier et al., 2010).

2. Anatomical data and image acquisition

The clinical input for rapid prototyping is represented by all the information contained in imaging data. Most commonly, MR and computerized tomography (CT) imaging are used for this purpose. Other sources include laser surface digitizing, ultrasound and mammography. The output of the imaging acquisition process and input of the rapid prototyping following appropriate processing is a DICOM image (Digital Imaging and Communications in Medicine), which is the outcome of virtually all medical professions utilising images, including endoscopy, mammography, ophthalmology, orthopaedics, pathology and even veterinary imaging (Lim & Zein, 2006).

2.1 Magnetic resonance imaging

MR imaging is an imaging technique based on detecting different tissue characteristics by varying the number and sequence of pulsed radio frequency fields, taking advantage of the magnetic relaxation properties of different tissues (Liu et al., 2006). MR imaging has the crucial advantage of not emitting X-ray radiations. Instead, the MR scanner provides a strong magnetic field, which causes protons to align parallel or anti-parallel to it. MR measures the density of a specific nucleus, normally hydrogen, which is magnetic and largely present in the human body, approximately 63% (Hornak, 1996), except for bone structures. The speed at which protons lose their magnetic energy varies in different tissues allowing detailed representation of the region of interest. This measurement system is volumetric, producing isometric 3D images (i.e. the same resolution in all directions).

2.2 Computerized tomography

Hard tissues and bony structures, which are assessed less well by MR imaging, can be captured by means of CT. This is a radiographic technique that uses a narrow fan X-ray beam to scan a slice of tissue from multiple directions. The absorption of different tissues is calculated and displayed according to gray-scale values. The resolution of CT data can be increased by decreasing the slice thickness, producing more slices along the same scanned region. However, the resulting longer scanning time has to be weighed by the clinician against the consequence of increased radiation dose (Liu et al., 2006). The technology known as spiral CT allows for shorter scanning time and small slice intervals with respect to previous scanners. In this case the patient is translated continuously through the gantry while the X-ray tube and detector system are continuously rotating, the focus of the X-ray tube essentially describing a spiral.

2.3 Other methods

Laser surface digitizing is a technique that permits acquisition only of external data, while MR and CT comprise both internal and external data, thus reducing scanning time and file size (Liu et al., 2006). This technology is based on a laser probe emitting a diode-based laser beam which forms profiles on the surface of the anatomy being imaged. Each profile is collected as a polyline entity and the combination of profiles yields a 3D volume. Apart from the speed of acquisition, this method has the advantage of not emitting any radiation. An early proposed application of laser surface digitizing regarded the case study of an ear prosthesis model (Ching et al., 1998).

3D ultrasound has also been used as input for rapid prototyping applications, as in the case of foetal modelling (Werner et al., 2010)

3. Model fabrication

The methods used for manufacturing a physical model by rapid prototyping can be generally divided into two major categories: “additive” and “subtractive”. Additive manufacturing indicates the fabrication of a part by adding materials to a substrate. On the other hand, a subtractive process involves machining using high-speed spindles and fairly machinable aluminium alloys in order to provide fast turnarounds for tooling and functional parts (Destefani, 2005). The choice between additive and subtractive rapid prototyping requires the evaluation of parameters such as speed of manufacturing, desired accuracy and budget (Mishek, 2009). In the clinical context, since subtractive techniques have the limitation of reduced ability in printing complex geometries and of requiring hard materials, additive techniques are more commonly employed.

- *Stereolithography*: A stereolithographic system includes a bath of photosensitive resin, a model-building platform and an ultraviolet laser for curing the resin (Winder & Bibb, 2005). The input image is divided into slices and such data is fed to the stereolithography machine. Layers are cured in sequence, the laser guided onto the surface of the resin by means of a PC-controlled mirror. The support platform is lowered following the completion of each layer. Further curing occurs in an apposite cabinet once the model is removed from the resin bath. Support structures are added to the model in order to aid layers adhesion and then removed once the model is printed. It is regarded that stereolithography provides the most accurate 3D models with best surface finishing.
- *Fused deposition modelling*: Similarly to stereolithography, this is a layer-by-layer process, the main difference between the two being that the layers are deposited as a thermoplastic that is extruded from a fine moving tip (Laoui & Shaik, 2003). As for stereolithography, support structures are necessary and are extruded with a second nozzle. The supporting elements are often printed in a different colour or using soluble material (Winder & Bibb, 2005).
- *Selective laser siltering*: In this case an infrared laser is used to cure a thermoplastic powder. This technique does not require supporting structures, facilitating the cleaning process of the models (Berry et al., 1997).
- *Laminated object manufacturing*: Models produced with this technique are formed by layers of paper, cut using a laser and bonded by a heating process. By nature this is an inexpensive printing method, thus advantageous for large volumes. In clinical terms, however, hollow structures cannot be properly modelled by this technique, so its clinical application is limited. It has been used to produce bioceramic bone implants and prostheses for craniofacial defects (Laoui & Shaik, 2003).

Alongside these additive-printing methods, a subtractive rapid prototyping technology can be employed for clinical applications:

- *Computerised numerically controlled milling*: In this case the printing process consists in removing a layer at a time from a block of material. Albeit the complexity of the surfaces and the detail of internal finishing are limited, this subtractive technology has been applied to medical modelling. One example is the construction of custom titanium implants for cranioplasty (Joffe et al., 1999).

4. Clinical case studies

The following case studies present a range of different, specific applications of rapid prototyping in the clinical context.

4.1 Cardiac I: Refining the process of patient selection

In the past two decades, great advances in transcatheter treatment of several cardiovascular disorders have been reported. In September 2000, Bonhoeffer et al. reported the first successful case of a minimally-invasive procedure known as percutaneous pulmonary valve implantation, or PPVI (Bonhoeffer et al., 2000). PPVI combines the replacement of a functional valve with relief of stenosis of the right ventricular outflow tract (RVOT) in patients with repaired congenital heart disease who require pulmonary valve replacement (Hijazi et al., 2006; Lurz et al., 2008). This technique potentially offers a major alternative to surgical valve replacement, but the success of PPVI is greatly dependent on patient selection based on assessment of implantation site morphology and dimensions (Schievano et al., 2007).

Rapid prototyping can be a valuable instrument in assessing patient-specific characteristics determining PPVI suitability, as demonstrated by a recent study (Schievano et al., 2007). A population of twelve patients was retrospectively investigated, including a range of different anatomical configurations. All patients had been referred for possible PPVI treatment. All patients also underwent MR examinations and the MR angiogram data was used as input for rapid prototyping development. Image processing was carried out using Mimics® software (Materialise, Leuven, Belgium). Imaging data was viewed in 2D (sagittal, coronal and transverse planes) and in 3D following segmentation. Segmentation masks were appropriately modified in order to highlight the area of interest, i.e. the RVOT. Following operations of thresholding and region-growing, a 3D volume was obtained by means of pattern recognition and interpolation algorithms. Such volume corresponds to the blood volume of the RVOT and, if further modifications are necessary, it is possible to operate on a pixel-by-pixel basis on the corresponding segmentation mask and render an “updated” 3D volume. The outer surface of the resulting volume essentially corresponds to the inner surface of the RVOT walls. The final step of RVOT model creation is hence to create an additional layer of fixed thickness (in this case 2 mm) around the blood volume and delete the latter. The final volume is saved as a standard stereolithography solid-to-layer format (STL file) and is ready to be exported into a rapid prototyping machine. The 3D printer employed in this study was a drop-on-demand machine using thermoplastic resin (Stratasys Genisys, Eden Prairie, MN, USA). The printer operates by means of a nozzle driven by an x-y stage to create outlines of each layer, whose thickness was 0.33 mm. The software controlling the machine is able to determine optimal orientation for printing the object and the supports necessary during the printing phase. Total time for printing one model was 3-4 hours. The thin-layer finishing of the printer ensures fine definition of the physical model. All twelve anatomical models are shown in Figure 2.

For all patients, clinical decision regarding PPVI suitability was agreed by cardiologists, image experts and cardiac surgeons. The result was that four patients were judged as unsuitable for PPVI, while for the remaining eight cases, where PPVI was attempted, the procedure was successful only in four patients.

The utility of the 3D models was then evaluated retrospectively. 3D MR images alone or 3D physical models alone were given randomly to two cardiologists who were unaware of the clinical outcomes and who blindly re-evaluated each case solely on the base of the data provided. For the four cases previously clinically rejected for PPVI, both cardiologists confirmed that PPVI should have not been performed. Regarding the remaining eight patients, the two observers correctly determined PPVI suitability in four and two cases respectively based on MR images alone. However, when assessing the 3D models, PPVI assessment was correct in five cases each (Table 1).

In the present application, some advantages of rapid prototyping were clearly shown, such as facilitating clinical assessment, enabling measurements and providing a quick and instinctive appreciation of different morphologies. One limitation of the aforementioned

RVOT models is represented by the rigidity of the surface and its lack of transparency. A compliant surface could mimic more closely, and to varying degrees of accuracy, the mechanical properties of blood vessels. In the case of a valved stent-graft positioned in the RVOT, such as PPVI procedure, this additional element would allow the model's wall to deform and accommodate the device, thus simulating the *in vivo* case more correctly. In addition, wall transparency could facilitate assessment of the position of the device and also render the model suitable for visualisation experiments. Both these points will be further discussed in the following paragraphs.

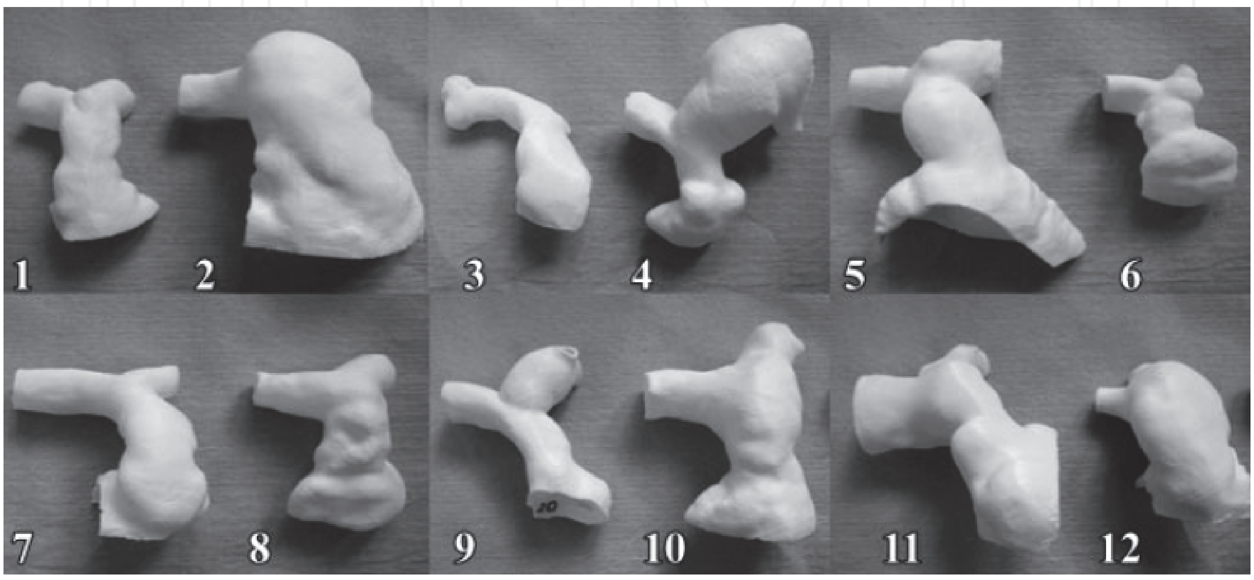

Fig. 2. Rapid prototyping 3D models of right-ventricular outflow tract, printed by means of stereolithography, for assessment of percutaneous pulmonary valve implantation in twelve patients. Note, these are 12 patients with the same congenital heart disease (tetralogy of Fallot), who have undergone the same surgical repair as neonates (complete repair), but present with a wide variety of anatomies 10-15 years later. This demonstrates the patient-specific nature and importance of understanding these individual anatomies. Image from Schievano et al., 2007.

	Diagnosis with MRI				**Diagnosis with rapid prototyping**			
	Observer 1		*Observer 2*		*Observer 1*		*Observer 2*	
	Correct	*Incorrect*	*Correct*	*Incorrect*	*Correct*	*Incorrect*	*Correct*	*Incorrect*
PPVI	4	4	2	6	5	3	5	3
no PPVI	4	0	4	0	4	0	4	0
Correct diagnosis	14/24				18/24			

Table 1. Two operators evaluating patient suitability for percutaneous pulmonary valve implantation (PPVI): in comparison to assessment based on MR images alone, assessment based on rapid prototyping 3D models alone increased the number of cases evaluated correctly.

4.2 Cardiac II: Planning first-in-man device implantation

Following directly from paragraph 4.1, the wide range of RVOT anatomies impinges on the suitability of PPVI in up to 85% of patients (Shievano et al., 2007). For this reason a second-generation device for PPVI was conceived in order to suit a larger proportion of patients. While the first-generation device (Melody™, Medtronic Inc., Minneapolis, MN, USA) is a cylindrical platinum-iridium stent, the new device is an hourglass-shaped nitinol covered stent (Schievano et al., 2010). At the time of first-in-man implantation, following bench and animal testing, rapid prototyping proved to be a precious tool for refining the procedure.
The patient-specific anatomy of RVOT, pulmonary trunk and proximal pulmonary arteries was reconstructed from 4D CT data. The model was printed in transparent rigid resin and the interventional cardiologists involved in this case of a novel PPVI device implantation could study access route and placement on the 3D phantom. As a result, the implanters could identify an optimal approach: guide wire in the left pulmonary artery, device deployment with the distal portion just within the left pulmonary artery, pullback of the device from the delivery system until correct positioning in the pulmonary trunk is achieved. This approach, together with the alternative and unsuccessful approach via the right pulmonary artery, is shown in Figure 3.
In this case, rapid prototyping enabled the interventional cardiologists with a visualisation tool that they cannot normally rely on, as opposed to a surgeon who has direct visual access to the area of interest. Testing correct positioning of the guide wire and practicing the implantation were important steps in ensuring procedural success.

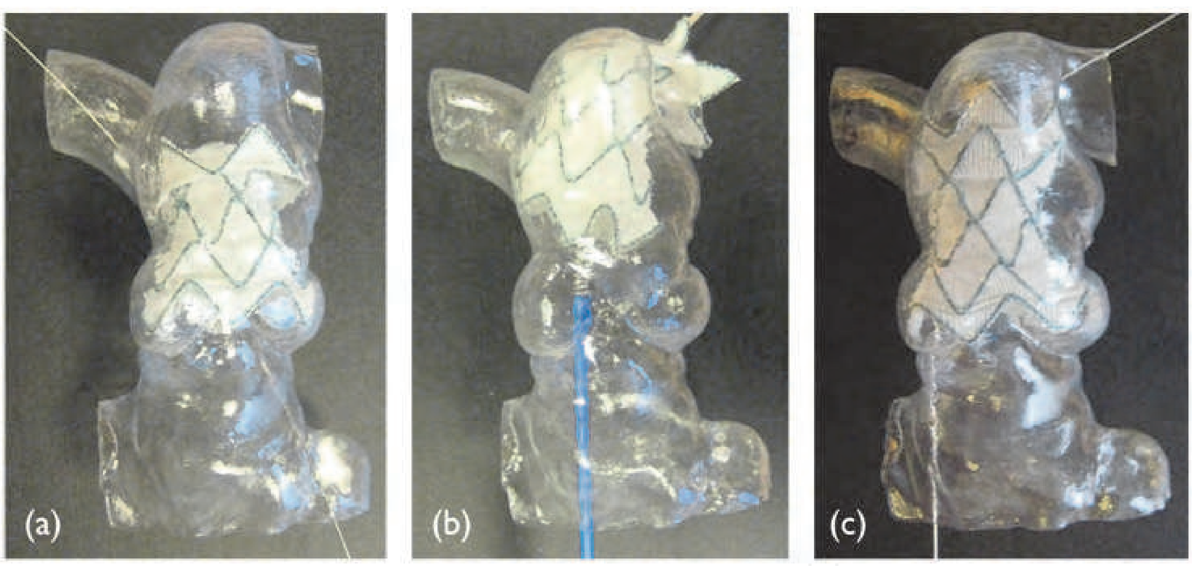

Fig. 3. Implantation of a new PPVI device into the same, patient-specific rapid prototyping model (a) via the right pulmonary artery (RPA) and (b & c) the left pulmonary artery (LPA). It was impossible to place the device accurately via the RPA, but implantation into the LPA (b) with pullback into the pulmonary trunk (c) was successful. This trial implantation directed the implantation used in the actual first-in-man procedure, which was performed via the LPA.

4.3 Cardiac III: Bench-top experiments to integrate clinical knowledge

The first stage of Fontan palliation for neonates with hypoplastic left heart syndrome (HLHS), namely the Norwood procedure, aims to increase the flow of oxygenated blood to the systemic circulation while, simultaneously, provide a source of pulmonary blood flow in these single-ventricle patients (Norwood, 1991). This operation involves enlargement of the hypoplastic aorta by means of a patch, reconstruction of aortic coarctation and increase of pulmonary flow, the latter by means of an arterio-pulmonary (Norwood, 1991) or ventriculo-pulmonary (Sano et al., 2003) shunt or stenting of the ductus arteriosus (Galantowicz & Cheatham, 2005). It is thus evident that Norwood patients present a very specific and complex arrangement of their circulatory system.

A computational model of the Norwood circulation has been already introduced (Migliavacca et al., 2001). On the experimental side, mock circulatory systems are acknowledged as a tool for addressing fluid mechanics questions in a systematic and rigorous way, allowing to isolate a variable of interest in a reproducible environment. Recent work from our group has shown the development of an *in vitro* setup suitable for studying features of the circulation following the Norwood procedure and focusing initially on the presence of aortic coarctation (Biglino et al., 2011). The setup is broadly based on the "multiscale" concept, as it includes an anatomically accurate 3D element (the region of interest, in this case the aortic arch) attached to a lumped parameter network (Quarteroni & Veneziani, 2003). Rapid prototyping technology was thus employed to manufacture the 3D elements for this first – to our knowledge – Norwood mock circulatory system.

Initially, four distinct aortic arch geometries were selected: (a) "control" morphology, with straight unreconstructed arch, (b) enlarged arch, (c) aortic coarctation (coarctation index[1] = 0.5) and (d) severe aortic coarctation (coarctation index = 0.3). Retrospective MR angiographic data were used as input for the rapid prototyping process. Images were analysed in Mimics® (Materialise, Leuven, Belgium) as described in paragraph 4.1. Once a first volume rendering was available, each 3D model was modified considering the purpose of the study. In fact, since the aim was to comment on the effect of aortic coarctation *in vitro*, the brachiocephalic vessels were modified so that the variations in their dimensions from one case to the other would not influence flow distribution, thus rendering more difficult to discern the effect of varying arch geometry alone and nullifying one of the main benefits of bench experiments, i.e. the ability of varying one variable at a time. Instead, CAD cylindrical elements of equal, physiologically reasonable diameter and length were placed in the position of the brachiocephalic vessels. Also, another element was added on all models on one of the brachiocephalic branches (corresponding to the innominate artery) providing an attachment for an arterio-pulmonary (or modified Blalock-Taussig) shunt-equivalent conduit. Furthermore, conical elements were merged at all endings (shunt, upper body vessels, and descending aorta) in order to facilitate the insertion of the model into the mock circuit. Finally, in order to take pressure measurements at different locations, three small cylinders the size of a 4F catheter were placed at different locations on the models (arch, just after the coarctation – if present – and descending aorta) in order to create three ports for pressure catheters insertion. All these volumes were merged in a unique volume, extruded with a thickness of 1.5 mm and exported as a STL file for printing.

Each model was printed twice, employing a rigid transparent resin and a compliant opaque composite, each offering different advantages. On the one hand, rigid models are suitable for visualisation experiments (such as particle image velocimetry) and, albeit non-

[1] The coarctation index (CI) defines the severity of a coarctation as the ratio of the narrowest diameter at the isthmus (D_1) and the distal diameter in the descending thoracic aorta (D_2), $CI = D_1/D_2$ (Lemler et al., 2000).

physiological, they allow observing flow distribution without the additional variable of compliant walls. On the other hand, flexible models are more physiological and can replicate the arterial Windkessel.
Both versions of the models were printed with a PolyJet machine (Object Geometries Inc, Billerica, MA, USA). The transparent resin is a commercially available material (Watershed® XC11122). Until recently, printing a compliant phantom proved to be more difficult, involving processes such as dripping or dipping and using rigid stereolithographic models as scaffolds (Armillotta et al., 2007). PolyJet technology, however, allows printing flexible models and the material of choice appears to be TangoPlus FullCure 930® or 980®, the only difference between the two being that the first one is opaque while the latter has a black finishing. Preliminary work from our group reveals that this material can implement physiological compliance, depending on the wall thickness and the part of the vasculature being modelled (Biglino et al., 2011). Both rigid and compliant models could be printed within 24 hours[2]. The four printed geometries are shown in Figure 4.
This study showed the usefulness of PolyJet technology in producing accurate patient-specific vascular models that can be inserted into mock circulatory systems.

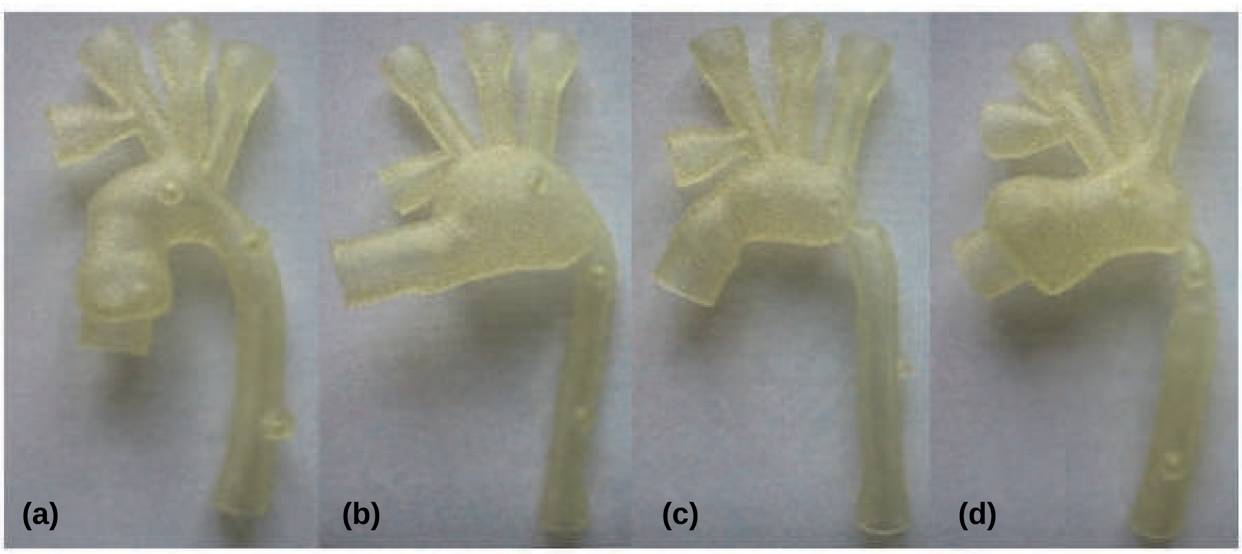

Fig. 4. Four neonate aortic arches, modified for *in vitro* experiments, printed in TangoPlus FullCure 930® material. Four patient-specific morphologies were selected: (a) control, (b) enlarged aortic arch, (c) aortic coarctation and (d) severe aortic coarctation.

4.4 Dental: The use of stereolithography in maxillofacial surgery

“Can rapid prototyping ever become a routine feature in general dental practice?” asked Harris & Rimell less than ten years ago (Harris & Rimell, 2002). Certainly, since they highlighted the potential of this technique in their study, experience has shown that rapid prototyping can play a role in this field. The importance of modelling in this context is further confirmed by publications of the late 1980s and early 1990s already exploring the potential of stereolithographic technology for maxillofacial surgery (Arvier et al., 1994; Bill et al., 1995; Karcher et al., 1992; Lambrecht et al., 1989).

[2] All models described in this paragraph were printed by Rapidform, Royal College of Art, London, UK.

Robiony et al. recently showed an integrated process involving maxillofacial surgeons, radiologists and engineers for dental virtual surgical planning (Robiony et al., 2008). In this case, the input data for the printing process is represented by CT images. Once the images are imported in the dedicated software (Mimics®), the anatomical region of interest is contoured by segmentation algorithms and the 3D structure is described by a triangle mesh which is exported as STL file for rapid prototyping. The printing process is a standard stereolithographic technique using liquid resin and polymerisation by a UV laser beam. While acknowledging the importance of the physical 3D model *per se*, this study also stressed the importance of being able to simulate a surgical procedure on the digital model. Manipulation of the STL file, rather than other formats such as IGES, appeared to be the best solution. Surgeons and engineers were thus able to import the skull model in the digital environment and replicate a surgical procedure. This study reports that 11 patients have been treated using this method: 3 cases of mandibular reconstruction, 5 cases of elongation of the vertical ramus and 3 cases of sagittal elongation of the mandible.
More specifically, one of the reported cases (surgical planning of emimandibular resection in oral cancer) shows how the rapid prototyping model can highlight cancerous tissues, enable the surgeon to make hypotheses of intervention for tumour resection and plan accurate postoperative reconstruction (Figure 5).

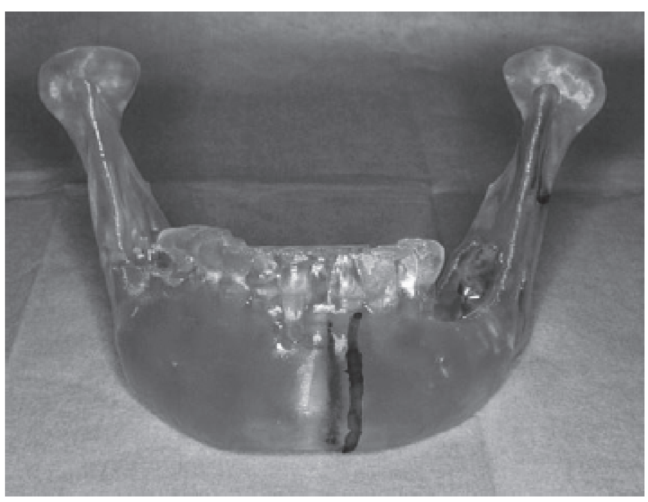

Fig. 5. Stereolithographic model of the mandible printed with rigid resin. Image from Robiony et al., 2008.

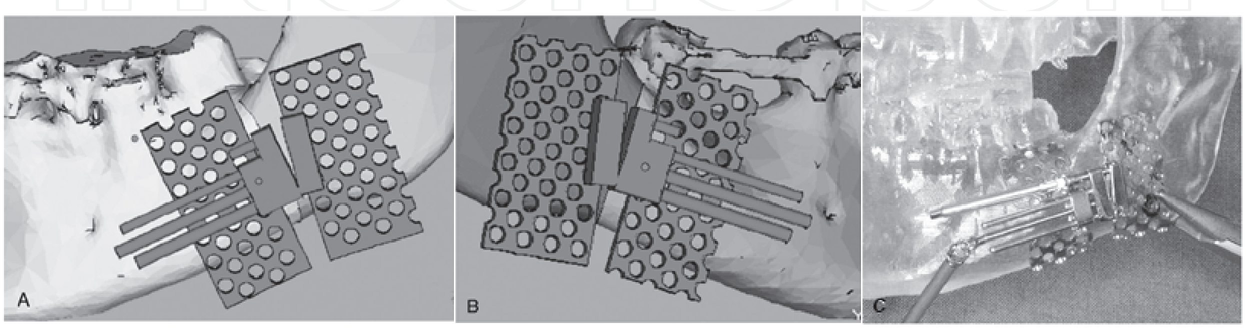

Fig. 6. Virtual simulation of mandibular elongation (A and B) and transfer of the surgical solution to the stereolithographic model (C). Image modified from Robiony et al., 2008.

Another case reported in the same study (gradual elongation of the mandible by means of osteogenesis distraction) shows how correct mandibular elongation is planned virtually, by simulating its most desirable final position. In fact, the mandible is virtually cut performing bilateral sagittal osteotomy and moved in different ways (Figure 6A and 6B), the result being evaluated on the basis of aesthetics and functionality. Then, the surgical solution is first applied to the rapid prototyping patient-specific model (Figure 6C) and finally to the patient.

The advantages of employing rapid prototyping technology in maxillofacial surgery have been recognised as: providing an understandable clinical picture; allowing evaluation of different surgical options; shaping of implants (e.g. titanium plates) directly on the 3D model; more accurate evaluation of shape and dimensions of a bone graft avoiding unnecessary removal of bone; and consequently: reduced length of operation and improved exchange of ideas between experts of different backgrounds (D'Urso et al., 1999; Robiony et al., 2008).

4.5 Orthopedic: Fabrication of patient-specific prostheses

Orthopedics is probably one of the fields in which rapid prototyping technology has been employed more extensively. Different applications include for example: construction of an anatomical model in a case presenting a complex shoulder injury (Potamianos et al., 1998); generating patient-specific templates for total knee arthroplasty (Hafez et al., 2006); assessment, classification and surgical planning of acetabular fractures (Hurson et al., 2007); production of porous titanium scaffolds for orthopaedic implant design (Ryan et al., 2008); fabrication of a surgical guide for cup insertion in total hip arthroplasty (Hananouchi et al., 2009); understanding fracture configuration and management of complex fractures (Bagaria et al., 2011).

One recent application concerns tailored ankle-foot orthoses (Mavroidis et al., 2011; Schrank & Stanhope, 2011). The ‚Americans with Disabilities' report stated that in 2005 approximately 27 million people above the age of 15 had an ambulatory disability (Brault, 2008). Patients exhibiting weakness in the region of the ankle joint musculature as a consequence of motor neuron disorders or lower limb injuries are often treated with ankle-foot orthoses, which support gait function (Pomeranz et al., 2006). The aforementioned studies used rapid prototyping technology aiming on the one hand to achieve better fitting patient-specific orthoses and on the other hand to facilitate the fabrication process of these devices, which currently is rather cumbersome.

Mavroidis et al. performed image acquisition of the ankle-foot complex using laser scanning (3D FaceCam 500 scanner, Technest Inc, Bethesda, MD, USA). Image reconstruction was carried out by means of commercially available software Rapidform® (Seoul, South Korea) which allowed operations such as removal of unwanted parts and remeshing. The model was extruded with a wall thickness of 3 mm and exported as an STL file for the rapid prototyping process. The physical models were printed using stereolithography (Viper Si2 machine, 3D Systems, Rock Hill, SC, US) curing liquid resin. An example is shown in Figure 7. Two ankle-foot orthoses were realised using two different materials (Accura 40 resin and Somos® 9120 Epoxy photopolymer). Gait analysis was then conducted using a motion capture system and comparing four different scenarios: an healthy subject (a) walking without ankle-foot orthosis, (b) walking with a prefabricated ankle-foot orthosis, (c) walking with custom-made orthosis made in Accura 40 resin and (d) walking with custom-made orthosis made in Somos® 9120 Epoxy. Gait analysis aimed to assess spatio-temporal parameters, kinematics (joint angles) and kinetics (joint moments and powers) of hip, knee and ankle.

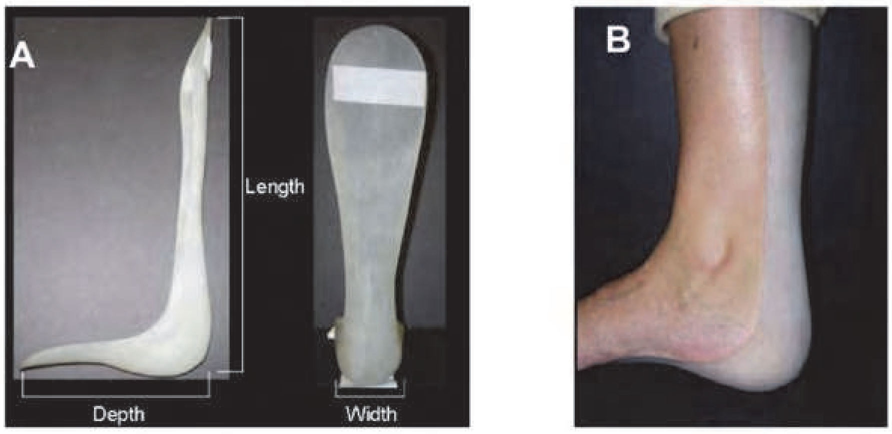

Fig. 7. Flexible ankle-foot orthosis fabricated by rapid prototyping (A) and fitting of the flexible orthosis on the leg of the tested subject (B). Image from Mavroidis et al., 2011.

On the other hand, Schrank & Stanhope, after digital acquisition of the subject's shape and size characteristics, performed a virtual orthopaedic alignment process producing the custom-fit parameters for a fully parameterized CAD model. Without analysing in detail such parameterization procedure, aimed to the refinement of model fabrication, it is noted that in this case the authors opted for selective laser sintering printing technique (Vanguard HS SLS machine, 3D Systems, Rock Hill, SC, USA). Patient-specific orthoses were realised using data from two nondisabled subjects and assessed for dimensional accuracy and stiffness.

Both these studies show that rapid prototyping can be very valuable for the fabrication of ankle-foot orthoses. Results showed that the rapid prototyping prosthesis matched standards of prefabricated designs while increasing freedom with geometric features (Mavroidis et al., 2011) and that the accuracy of the orthoses fabricated by selective laser sintering was also within tolerance values from the literature (Schrank & Stanhope, 2011). Moreover, both stressed the substantial reduction in prosthesis production time.

4.6 Ethical predicament: Post mortem examinations

Training of surgeons and pathologists has traditionally relied on dissections, but in 2007 the Royal Colleges and the Department of Health reported that a very substantial drop in the number of donor bodies was endangering medical training in the United Kingdom (www.bio-medicine.org, 2007). In order not to loose the important information provided by post mortem examinations, increasing interest has been focused on developing or exploring non-invasive techniques to perform these assessments. In particular, MR has been indicated as a viable alternative to invasive autopsies (Thayyil et al., 2009). At the same time, in the unfortunate case of neonatal or foetal autopsies, this sort of non-invasive examination is also more acceptable for parents, as it avoids dissection of the body (Brookes et al., 1996; Cohen et al., 2007; Griffiths et al., 2005).

A recent study from our group (Schievano et al., 2010) has highlighted the potential of rapid prototyping technology for foetal and infant anatomical reconstructions from post mortem MR images. A range of 11 cases was studied, with images using a 1.5 T MR scanner (Avanto,

Siemens, Erlangen, Germany) or, for the case of one foetus under 20 weeks, a 9.4 T scanner (VNMRS, Varian, Palo Alto, CA, USA). The cases were selected purposefully to showcase a range of structural abnormalities or injuries, thus demonstrating the applicability of the technique to different organs. The images were analysed using suitable software (Mimics®, Materialise, Leuven, Belgium) following the methodology described in paragraph 4.1 for a different application. Different volumes, including entire organs, were rendered in 3D. In this case, two different machines were employed for printing the 3D models: a Z Corp printer (Z Corporation, Burlington, MA, USA) employing inkjet print heads depositing a binder into plaster powder was used for manufacturing opaque and coloured parts, while an iPro SLA machine (3D Systems Corporation, Rock Hill, SC, USA) employing an ultraviolet laser curing liquid resin was used for manufacturing transparent parts.
Visual examination of the 3D models allowed recognition of all structural anatomies, relationship between organs and relevant pathologies. The authors of this study stressed several advantageous applications of this technology, including:

- Improved understanding of complex congenital anatomies: the size of small foetuses renders studying congenital abnormalities intrinsically difficult. Rapid prototyping allows for a permanent physical record to be analysed at a later stage (e.g. for teaching purposes) but also allows for magnification/scaling of small features, as shown in Figure 8. In the presented example rapid prototyping facilitated the analysis of the specimen, since conventional autopsy was difficult due to autolysis and small dimensions.

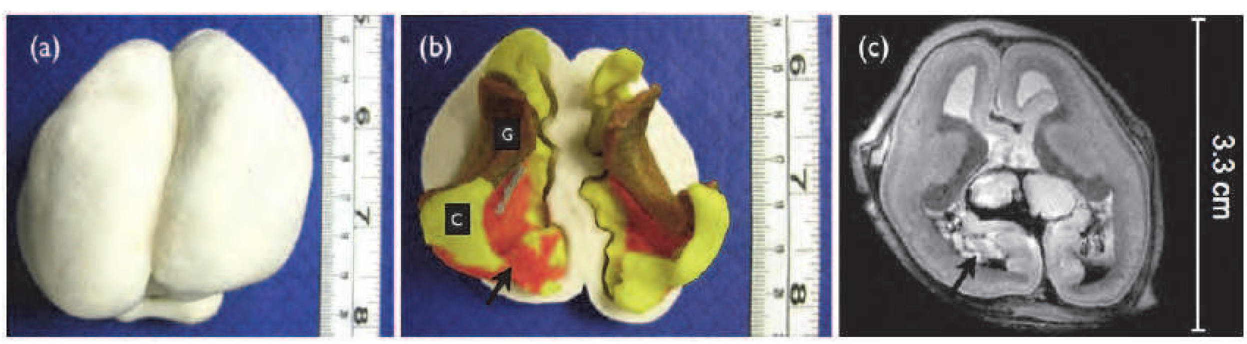

Fig. 8. Rapid prototyping of the brain of a 16 week foetus. (a) The outer surface, showing the absence of sulci and gyri. (b) Internal section in the axial plane, showing the germinal matrix (G) and cerebrospinal fluid in the lateral ventricles (C) while the arrow indicates bleeding in the choroid plexus and ventricular cavity. (c) The 9.4 T MR image in the same axial plane. Note that the rapid prototyping model is scaled to twice the original size. Image from Schievano et al., 2010.

- Medical training: rapid prototyping models facilitate storage and categorization of samples, which can be a precious tool for anatomy and pathology teaching.
- Parental counselling: in the event of identification of abnormalities and terminated pregnancy, traditional post mortem photographic images can be highly disturbing when shown to parents. A rapid prototyping model can instead facilitate communication with the parents, being less graphic and allowing the observer to be more detached from the object.
- Medico-legal demonstrations: court cases relating to injuries and deaths suffered by infants may require the use of post mortem images which, as in the case of parental

counselling, may be regarded as inappropriate, as either gruesome or revealing features not strictly related to the case. Evidence of this nature is however crucial and rapid prototyping can provide a scientific way to show pathological findings to a jury. An example of this application is shown in Figure 9 and it is particularly interesting as it involves the use of MR images for identification of bleeding regions while CT data (SOMATOM Definition, Siemens, Forchheim, Germany) was used to reconstruct the fractured skull.

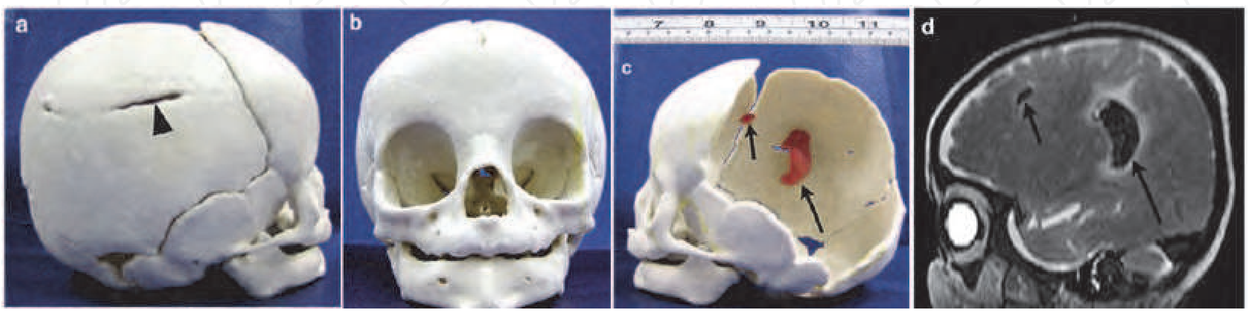

Fig. 9. The case of a fractured skull (a-c), showing parenchymal bleed in the brain of an infant. Post mortem MR images (d) indicated the position of the bleed. The model was built combining and registering CT images, providing the skull structure, and MR images, providing the bleed volume and position. Image modified from Schievano et al., 2010.

- In utero foetal diagnosis and management: it has been shown that 3D volume reconstruction of foetal organs can be achieved using rapid multi-slice snapshot MR sequences (Hayat et al., 2008). In utero foetal MR imaging can thus be used as input for rapid prototyping, which would be particularly useful for detecting the exact position of the internal organs in complex conditions such as foetal diaphragmatic hernia and conjoined twins (Christensen et al., 2004), identifying facial dysmorphism in some genetic conditions and diagnosis cases of skeletal dysplasia.
- Replacement for plastination: the use of human body parts for the process of plastination can "trivialis[e] the very important act of body donation" (http://news.bbc.co.uk, 2002), while rapid prototyping can preserve organs' appearance and size without the use of human tissues.

It is true that the abovementioned applications require the presence of specialised staff, either for image acquisition or image processing, and the need for proper printing equipment. On the other hand, Schievano et al. have reported in their comprehensive study that image processing required between 1 and 20 hours, rapid prototyping required between 1 and 12 hours and the cost of the models varied between £10 and £240 depending on the size, highlighting the effectiveness of the method (Schievano et al., 2010).

5. Conclusion

In broad terms, rapid prototyping is today extensively used in a variety of industries and fields, from more obvious applications (such as product design) to less intuitive ones (such as archaeology). It has been noted that "rapid prototyping is so pervasive that it would be unlikely any individual could go about his daily routine without using a product that has in some way benefited from rapid prototyping" (Grimm, 2004). Clinically, this technique represents a flexible tool, from diagnostics to prostheses design, as briefly outlined in this chapter. It is envisaged that, because of its relatively inexpensive nature and the wider range of available materials for printing, including compliant materials, rapid prototyping will be increasingly used in clinical practice.

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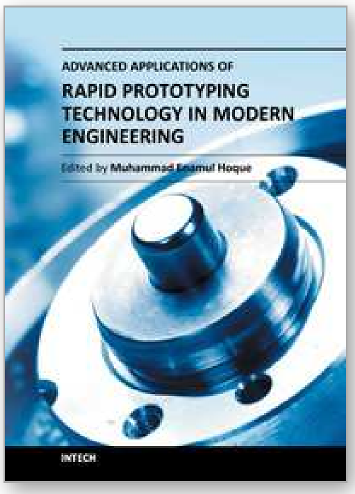

Advanced Applications of Rapid Prototyping Technology in Modern Engineering

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Rapid prototyping (RP) technology has been widely known and appreciated due to its flexible and customized manufacturing capabilities. The widely studied RP techniques include stereolithography apparatus (SLA), selective laser sintering (SLS), three-dimensional printing (3DP), fused deposition modeling (FDM), 3D plotting, solid ground curing (SGC), multiphase jet solidification (MJS), laminated object manufacturing (LOM). Different techniques are associated with different materials and/or processing principles and thus are devoted to specific applications. RP technology has no longer been only for prototype building rather has been extended for real industrial manufacturing solutions. Today, the RP technology has contributed to almost all engineering areas that include mechanical, materials, industrial, aerospace, electrical and most recently biomedical engineering. This book aims to present the advanced development of RP technologies in various engineering areas as the solutions to the real world engineering problems.

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