

APPLICATION OF BIOMODELS FOR SURGICAL PLANNING BY USING RAPID PROTOTYPING: A REVIEW & CASE STUDIES

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ABSTRACT— *The application of rapid prototyping (RP) to surgical planning came as a natural extension of the development of the technology. Current high technology scanners analyzing biological samples present their data in a layered format providing a straightforward interface to the RP technologies. The highest spatial resolutions are available from CT and MRI scan data, but other modalities also provide valuable diagnostic information. Presenting the results in a physical 3D model, either scaled 1:1 or magnified, provides the medical user with invaluable insights beyond 2D data. Depth is a critical parameter in planning procedures. These techniques allow one to reproduce human anatomical objects as 3D physical models, which give the surgeon a practical impression of complex structures before a surgical intervention. This paper will focus on surgical planning and the development of prostheses in advance of invasive procedures.*

Biomodelling is an perceptive, user-friendly technology that facilitated diagnosis and operative planning. Biomodels allowed surgeons to rehearse procedures readily and improved communication between colleagues and patients. The paradigm shift from the visual to the visual-tactile representation of anatomical objects introduces a new kind of interface. The RP models are very well suited for use in the opinion and the precise preoperative simulations. The case studies included cover applications like the fabrication of custom implants & models for pre-operating surgical planning.

Keywords—Rapid Prototyping; Rapid Manufacturing; Biomodelling; Medical applications.

INTRODUCTION

Prior studies have recommended that biomodels increase patient education. The usefulness of biomodels for pre-operative planning and intra-operative surgery compared to regular imaging modalities such as x-ray, CT and MRI has not been quantified. The aim of this study was to quantify surgeon's perceptions on the usefulness of biomodels compared to standard visualization modalities for pre-operative planning and intra-operative anatomical reference. Additive fabrication (AF) is a relatively new concept that emerged during the last decade in order to describe a set of new or under development manufacturing methods, processes and technologies that function through material addition, in contrast to the established traditional cutting, forming or casting methods. Rapid Prototyping (RP) technologies are the most widely applied and known fabrication methods that are based on additive fabrication principles. Some of the major RP technologies used worldwide are Stereo lithography (SLS), Selective Laser Sintering (SLS), Fused Deposition Modelling (FDM), 3D printing (3DP), Laminated Object Manufacturing (LOM). Main applications of RP include the fabrication of various kinds of models and prototypes for concept evaluation and presentation as well as functional testing of new products, early in the product development process [1]. The continuous improvement of RP systems accuracy and materials, expand gradually their applications to other areas like medical applications. What makes RP particularly appealing for the above applications is the fact that compared to alternative manufacturing technologies, like for instance CNC machining, RP systems can fabricate parts of almost any geometrical complexity in relatively lower time and with reduced cost and without significant requirements in technical expertise. This kind of geometric flexibility, which is mostly a consequence of their additive nature, is the main reason that RP technologies are increasingly used. The medical branch in particular has attracted the attention of many researchers and scientists since the first introduction of RP technologies. The reported medical applications of RP technologies can be classified to the following categories:

- Biomodelling, which involves the fabrication of physical models of parts of the human anatomy and biological structures in general, for surgery planning or testing.
- Design and fabrication of customized implants for prosthetic operations, rehabilitation and plastic surgery
- Fabrication of porous implants and tissue engineering

Despite of their great flexibility and potential, RP technologies have not yet been widely adopted in the medical and health-care sector.

This can be attributed to the high cost and time required for the fabrication of corresponding models which at present can only be justified in relatively complex medical cases [2]. Besides time and cost, there is the issue of accuracy of RP systems, which is not sufficient for some applications due to poor or inaccurate medical imaging data. Nevertheless, RP technologies and AF in general have great potential in the area of medical and health-care applications due to their divergent features.

II. LITERATURE REVIEW

Muller et al. [3] investigated the usefulness of RP models of the skull in craniofacial and neurosurgical practice. RP biomodels of 52 patients, whose treatment required corrective/reconstructive cranioplasty or involved complex surgical operations, were fabricated. They report that SLS models help in better understanding of the anatomy, increase intra-operative accuracy, support accurate fabrication of implants, facilitate pre-surgical simulation and improve education of trainees. Kermer et al. [4] propose in their study an enhancement of the RP biomodelling approach by investigating the possibility of selectively colored RP biomodels. Their findings indicated that selectively colored models facilitate the management of ablative surgery and reconstructive procedures as well. The value of SLS surgical biomodels has also been shown in the case of reconstructing of complex orbital fractures in a study by Fan et al. [5].

Biomodelling of soft-tissue parts of the human body using RP, are rather rare in practice. This can be mainly attributed to the difficulty of separating the area of interest from the surrounding soft tissues, due to the relatively small differences of grayscale in medical scanned images. D'Urso et al. [6] have studied the possibility of biomodelling of cerebral aneurysms based on data obtained through CT angiography (CTA) and MR angiography (MRA). Their results indicate that the SLS models are sufficiently accurate and can be quite useful for surgical planning in complex cases or when the standard imaging is felt to be equivocal. In a similar study Wurm et al. [7] investigated the usefulness of cerebrovascular biomodels for aneurysm surgery with similar results. The feasibility of RP biomodelling for the replication of soft-tissue parts is shown in the study of Binder et al. [8]. They applied SLS for the construction of replicates of the mitral valve with good results.

Although the results of the previous mentioned studies show the usefulness of biomodels for operation planning and rehearsal, the high fabrication cost and time involved is in most cases a major drawback. In particular, SLS and SLS models are very expensive and the associated cost can be justified only in rather complex cases. In order decrease the fabrication cost and time the utilization of 3D-printing is proposed, which is much less expensive and time-consuming [9].

But, biomodels are not only used in the pre-surgical phase but also they can be used in actual surgery, The images obtained by biomodels, can be utilized to guide the operation, assuring the accuracy and the quality of results. D'Urso et al. [10,11] investigated the possibility of using accurate SLS biomodels of the patient in planning and rehearsing stereotactic surgery. The method of stereotaxy is a minimally-invasive form of surgical intervention which uses 3D coordinates in order to locate specific targets and perform on them an operation like removal, implantation or injection. The location of the target is based on MRI/CT data and is determined with respect to a reference frame that is attached to the patient's body. In order to simplify the method and enhance its accuracy, D'Urso et al. [10,11] employed SLS biomodels in a neurosurgical operation. They report that biomodel-guided stereotaxy offers significant advantages in terms of speed, simplicity, accuracy, and versatility but with the extra cost and time required for biomodel fabrication. Ngan et al. [12] also proposed the use of RP models, fabricated with SLS and 3DP, for preoperative and intraoperative planning of pulmonary atresia surgical treatment. They report that the surgeons found biomodels very useful in visualizing the vascular anatomy, but construction of virtual models was relatively labor intensive and required expert knowledge of the pulmonary vasculature.

Another application of SLS models is presented by Starly et al. [13], in which the SLS model is used as a medium for the transfer of the anticipated skull geometry in a surgical guidance system of over-laying images. In this approach the 3D virtual model of the patient's skull is constructed first through CT data interpolation. The virtual model is then split in two symmetrical parts, the undamaged half and the defective half that contains the suffering. Next, the defective part is discarded and replaced by the mirror image of the other half and a new virtual model of the skull with the required symmetry is constructed and fabricated with SLS. The SLS model is then scanned with CT and the obtained stack of images is transferred to the surgery guidance system, thus providing an image reference that accurately guides the surgeon during operation.

SLS has also been used for the fabrication of surgical guides for the placement of dental implants, a restoration process that requires detailed planning and high accuracy. Sarment et al. [14] investigated the accuracy of dental implant placement with the aid of SLS surgical guides, which according to their findings improved the implant placement. In a similar study Di Giacomo et al. [15] came to the same conclusion, but denoted that the technique requires improvement

to provide better stability of the guide during the surgery, in cases of unilateral bone- supported and non-tooth-supported guides.

Testing of new treating methods and technologies is another field that RP has been applied successfully. Johnson and Young [16] have investigated the feasibility of using RP biomodels as expendable test parts, in an experimental study of the response of the human head to impact, during a car accident. In a similar manner, SLS models of cancellous bones, like those caused by osteoporosis, were fabricated and mechanically tested, in order to investigate the relationship between their geometry and their mechanical strength, implicitly assessing fracture risk [17]. Also, RP models of pelvic bones have been used to prove experimentally the higher efficiency of computer assisted screw insertion procedures over conventional ones in spinal surgery [18]. The study of exposure of the human respiratory system to dangerous or pathogenic aerosols is another area where RP models have been used successfully. Clinkbeard et al. [19] applied SLS for the fabrication of human tracheobronchial airway models and carried out an experimental investigation of the location and the amount of deposition of dangerous aerosols under different conditions. They propose the utilization of such models as the standard for relevant studies.

III. RP MANUFACTURING APPROACH BASED ON MEDICAL DATA

One of the major medical applications of RP is the fabrication of models of parts of human anatomy of a patient based on data obtained through the various well established techniques of CT or MRI. The fabrication process of these physical models, which are now a day's often called biomodels, involves three phases:

- The first step is to obtain the data of the patient's area of interest with the use of the previously mentioned techniques (CT, MRI, etc.), which provide an indirect representation of the patient's anatomy through a series of 2D DICOM images.
- The images are next manipulated employing special code/software, which facilitate the separation and highlighting of the tissues (soft or hard) that represent the area of the biomodel, and allow the conversion of the 2D image information to a 3D representation by converting into the standard STL representation is utilized for the latter.
- Finally the biomodel is fabricated using an RP system.

The accuracy of RP biomodels depends on various factors associated with all phases of the process. Choi et al. [20] analyzed the possible sources of error in SLS biomodelling and identified the main sources of error in the second phase, namely, the translation of 2D data to a 3D virtual model. This has led to the development of special software tools like Invesalious open source software which enhances the accuracy of the 2D-3D data transformation process. Regarding the manufacturing accuracy of RP technologies, Santler et al. [21] concluded that it is sufficient for clinical purposes.

IV RAPID PROTOTYPING BIOMODELS FOR SURGICAL PLANNING

Among the first (and major) applications of AF/RP in medicine and health-care is the production of (physical) biomodels that can be used as an aiding tool for surgical planning and rehearsal. Since every patient is unique, the surgeon must fully understand the anatomy of the patient before operation. Obtaining a full understanding of the patient's anatomy only by the study of a mass of CT/MRI images in these cases requires great experience from the surgeon, especially in complex surgical operations [22]. In such cases RP biomodels greatly facilitate diagnosis and treatment planning, and decrease the risk of misinterpretation of the medical problem. Having a physical biomodel in hand also facilitates surgery planning and makes possible the rehearsal and simulation of the operation through marking, cutting and reassembling of the biomodel. Furthermore, the pre-surgical study of a biomodel allows not only the detailed evaluation of the operation, without the time pressure present during actual operation, but also possible problem prediction. This way, actual operation time, and consequently operation cost and infection/anaesthesia risk are decreased. Biomodels are also very useful as a communication tool between medical personnel. They are also very useful for the presentation of operation details to people with no medical expertise (e.g. the patient or its relatives), thus increasing consent and trust.

In most cases, RP is applied for the fabrication of customized bone models. The most widely reported application of RP biomodelling for surgical planning is in the field of maxillo-craniofacial surgery, which involves the surgical treatment of congenital or acquired deformations both for functional and aesthetic purposes. The geometry of the skull is quite complex and cannot be easily reproduced in a physical model using cutting manufacturing methods like CNC milling. RP therefore presents a reasonable alternative. Among RP technologies, SLS is the most commonly used in craniofacial biomodelling.

CASE-1- This case is an example of a SLS skull model, fabricated is presented in Fig.1. This SLS model is an accurate replicate of the damaged skull of a young girl, which was injured in a car accident and it has been used for pre-operative planning of the surgery as well as an aid for the design of the prosthetic implant that would restore the anatomy of the damaged area.



Fig. 1 Skull biomodel of an injured girl for surgical planning fabricated with SLS.

CASE-2- This particular case is of a 23 year old man with a rare complex congenital cranio-facial cleft involving the maxilla (upper jaw), nose (including the bony nasal cavity) and nasal septum, upper lip and both orbits (eye sockets).

The abnormal anatomy is difficult to understand by a physical examination as there is gross absence, displacement or hyperplasia (stunted growth) of a variety of tissues in a 3dimensional field, especially the central third of the face (nose and nasal cavity). The anomalies of the skeleton are important to understand pre-operatively as pre-surgical planning will be of paramount importance in this case. The smallest surprise faced suddenly at the time of operation could be the difference between success and failure; between correction of this ghastly disfigurement and its continuance. The model has resolved a lot of our queries and allowed us to thoroughly understand the highly abnormal anatomy in this case. It has allowed us to plan our surgery completely step-by step, especially the bone cuts (osteotomies) which will be needed, and we can now operate on this patient with greater confidence than before.

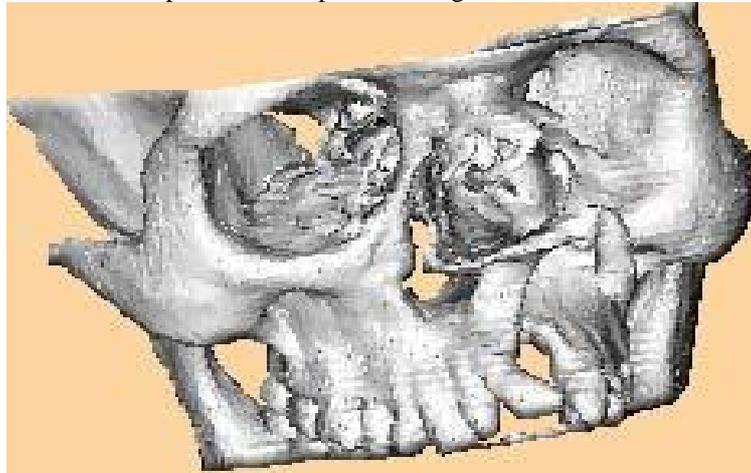


Fig. 2 Complex congenital cranio-facial cleft involving the maxilla, nose and nasal septum, upper lip and both orbits.

*CASE-3-*Fractures of the upper end of the shoulder bone, humerus, especially if it is broken into 3 or 4 pieces as per Need's classification are very challenging to treat. This is a case of a 70 year old lady whose humerus was fractured into 4 pieces. The surgical approach, the steps of reduction, placement of implants and the necessity for the bone graft can all now be pre-planned using the model.

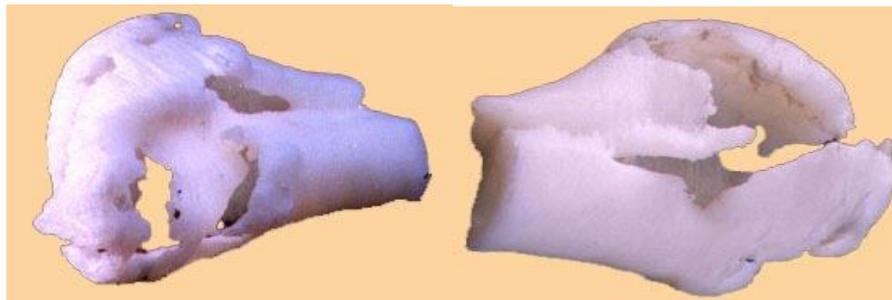


Fig. 3 Fractures of the upper end of the shoulder bone, humerus, broken into 3 or 4 pieces.

CASE-4- Heel (calcaneus) bone fractures are caused because of fall from a height which crushes this important load bearing bone of the foot. Since the shape of the calcaneus is complex and also difficult to see, even during surgery, fractures of this bone are usually not treated surgically. In this case of a 30 year old man, where the calcaneus was fractured with a small piece being internally twisted, the model proved to be an excellent tool for visualization of the post traumatic anatomy and helped in planning the surgical steps for reconstruction.



Fig. 4 Heel bone fractures are caused because of fall from a height which crushes this important load bearing bone of the foot.

CASE-5-A 24 year old man was suffering from this deformity of the foot because of polio. Foot is a complex organ consisting of various bones connected by multiple joints that are controlled by various groups of muscles. In conditions like polio myelitis & arthritis, these joints are affected and this alters the shape of the foot which in-turn affects the walking cycle. Since multiple joints are affected, careful planning of the surgery is required to achieve the desired results. X-ray and CT scans do provide necessary information but the model gives one an opportunity to simulate the surgical steps before it is actually performed.



Fig.5 Deformity of the A foot because of polio.

*CASE-6-*This is a case of a 11 year old boy with bilateral congenital dislocation of the hip. He was operated on the right side using open reduction with femoral shortening, various osteotomy and salvers procedure was done for the containment of the hip joint. This was performed just before the medical model facility was available. Model offered a real-life 3-dimensional picture of the dislocated joint with proper status of the opposing surface and irregularities of the femoral head, acetabular index and congruency. It was possible to reconstitute the post surgical picture pre-operatively and visually correlate the effectiveness of the surgery on one side. This also established the planning of the surgery of the second side.



Fig.6 Bilateral congenital dislocation of the hip.

CASE-7- This is a case of a 24 year old man who had met with a vehicular accident and fractured his hip. The hip is a ball (femoral head) and socket (acetabulum) type joint and in this case, the acetabulum was fractured into 4 pieces. The reduction of this fracture was difficult because it was located on the posterior side and also one of the smallest fractured piece had been grossly dislocated and hence was obstructing the normal process. The 3D CT scan did show this small piece but it could not delineate the origin of this piece. The model enabled to locate the origin of this piece. A few pre-operative trials were done on the model to arrive at its proper orientation. This reduced the surgery time and possibly avoided additional surgeries as well.



Fig.7 Fractured hip ball (femoral head) and socket.

V. PATIENT-SPECIFIC IMPLANTS

Another area that the application of RP systems seems to have great potential is the construction of customized implants for reconstructive and plastic surgery. In this area the connection of medical imaging techniques and RP can lead to significant time savings in operation time and much higher accuracy and quality in surgical operation. He et. al. [23] presented a design method for exact-fit customized implants that employs virtual and RP models of injured or healthy bones in order to reduce the associated time and cost. This methodology is employed in a case study investigated by Truscott et al. [24] that focused on the use of SLS models in the design process of customized titanium elbow implants. According to their findings the complementary use of virtual and physical models greatly improves the accuracy and reduces the cost of the implant design process.

Winder et al. [25] present 10 clinical cases, in which the required titanium implants for the reconstruction of skull defects were created using RP models as masters for casting. The geometry of the data was obtained by comparing the defected side of the head to the contra lateral, so as to retain symmetry in the final result. Applying a similar method D'Urso et al. [26] used SLS models of both the actual defected side and the customized implant (the latter to be used for casting acrylic implants) in cranioplasty operations. They report reduced operating time and excellent results at a 'reasonable' cost.

SLS models have been used for the fabrication of mandible titanium trays, which are implanted in the patient as a replacement of the actual bone that was lost or removed because to a tumor [27]. The implant SLS model served as the casting pattern for the construction of a silicon mould and the subsequent casting of an identical wax model, which was finally used as an expendable pattern for the production of the titanium part by investment casting.



Fig.8 Titanium implant for the replacement of a damaged hemi-knee joint.

Who carried out this work, report that using CT data and SLS provides very accurate implants that have significant functional and aesthetically pleasing results. Singare et al. [28] employed directly SLS Quick cast models as expendable patterns for investment casting of titanium implants. SLS models have also been used directly as expendable patterns for casting of a titanium implant for the replacement of a damaged hemi-knee joint.(Fig 8.) [29].

Direct production of 'soft' biocompatible implants employing available RP technologies requires the development of new specialized materials. In order to address this need Bens et al. [30] developed a flexible (meth) acrylate- based resin for SLS that could be useful in various bio-medical applications.

VI. MERITS OF BIOMODELLING

1. 3D Visualization

An anatomically trained mind is excellent at correctly imagining the shape of normal structures. Biomodels provide anatomical data in the third-dimension, in a more accessible form that can be thoroughly examined and more concretely visualized.

2. A Tactile Interface

Biomodel gives a much deeper and more intuitive understanding of the patient's condition than viewing a computer screen, hard X-rays. Surgical instruments identical to those used in the actual procedure can be employed on the biomodels to determine the most conservative strategy to reduce potential surgical complications and costs.

3. Measurement Precision

Where precise measurements are required, these can often be performed better on the Biomodel than on raw scan data. The spatial resolution of the Biomodel fabrication process is higher than that of the best clinical CT or MRI scanners. Cubic interpolation is used to reduce noise and stair-stepping from scan data. Complex and sensitive surgeries require extensive planning. In a surgery as delicate and involved as a cranial osteotomy, for example, the displacement of bone segments can be more accurately evaluated using a Biomodel.

4. Personalized Medicine

The use of Biomodels has enhanced the design and fabrication of prosthetic implants, improving and simplifying the process. Patient-specific models used as molds or templates allow for the production of personalized-fit implants.

VII. DISCUSSION AND CONCLUDING REMARKS

In conclusion, the literature review carried out in this work showed that although RP technologies exhibit a great potential in the field of medical applications, they have not been widely adopted yet in standard medical practice, because of the high cost and fabrication time involved. In this paper applications of AF/RP technologies in medicine and current research issues in the field of Rapid Medical Prototyping are presented. The review of the international specialized literature showed that custom biomodels fabricated with RP technologies are quite useful for planning and rehearsal of complex surgical operations. According to the results of most studies RP biomodels aid the surgeons in diagnosis, planning, problem prediction and communication, thus reducing operation time infection risk and improving the results of the operation.

RP although faster and more flexible than other manufacturing methods is neither fast enough nor cost effective to cater for emergency cases. Depending on the size and complexity of the biomodel, RP fabrication times vary between a few hours to two days, which maybe unacceptably long for emergency cases. Time and cost requirements, therefore, restrict the utilization of RP to rather complex cases where considerable cost savings and quality benefits are expected. Also by using RP cost and time expenses are justifiable for custom implant fabrication applications, e.g. for orthopedic surgery, simply because in such cases the utilization of conventional manufacturing methods, implies significantly higher fabrication time and cost. Furthermore, the customization of the implant assures accurate fitting, reduces operating time and enhances quality.

Another advantage of these RP technologies is that they are office friendly and can process biocompatible materials with some minor modifications. Further reduction in the fabrication time involved, can be achieved through higher automation of the medical imaging data manipulation process that is required for the construction of the virtual model. The virtual model construction phase is reported as the main source of observed inaccuracies, mainly due to the low level of detail and information that can be obtained through conventional medical imaging (diagnostic) systems.

SLS technology has the greatest potential among commercial RP technologies or direct fabrication of implants. This is mainly due to the fact that SLS can fabricate implants from a variety of materials including metals, ceramics and thermoplastics with sufficient accuracy. In this context the main research issue is to develop and test materials that are biocompatible so that can be used safely for direct fabrication of implants. The End results in functional as in aesthetic aspects were satisfactory in most cases & biomodels offer the great advantages of three-dimensional visualization, a tactile interface, high measurement accuracy and precision and a platform for personalized medicine.

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