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# Medical Applications of Rapid Prototyping - A New Horizon

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## 1. Introduction

Rapid Prototyping is a promising powerful technology that has the potential to revolutionise certain spheres in the ever changing and challenging field of medical science. The process involves building of prototypes or working models in relatively short time to help create and test various design features, ideas, concepts, functionality and in certain instances outcome and performance. The technology is also known by several other names like digital fabrication, 3D printing, solid imaging, solid free form fabrication, layer based manufacturing, laser prototyping, free form fabrication, and additive manufacturing. The history of use of this technique can be traced back to sixties and its foundation credited to engineering Prof *Herbert Voelcker* who devised basic tools of mathematics that described the three dimensional aspects of the objects and resulted in the mathematical and algorithmic theories for solid modelling and fabrication. However the true impetus came in 1987 through the work of Carl Deckard, a university of Texas researcher who developed layered manufacturing and printed 3 D model by utilizing laser light for fusing the metal powder in solid prototypes, single layer at a time. The first patent of an apparatus for production of 3D objects by stereolithography was awarded to *Charles Hull* whom many believe to be father of Rapid prototyping industry.

Since its first use in industrial design process, Rapid prototyping has covered vast territories right form aviation sector to the more artful sculpture designing. The use of Rapid prototyping for medical applications although still in early days has made impressive strides. Its use in orthopaedic surgery, maxillo-facial and dental reconstruction, preparation of scaffold for tissue engineering and as educational tool in fields as diverse as obstetrics and gynecology and forensic medicine to plastic surgery has now gained wide acceptance and is likely to have far reaching impact on how complicated cases are treated and various conditions taught in medical schools.

## 2. Steps in production of rapid prototyping models

The various steps in production of an RP model include-

1. Imaging using CT scan or MRI scan
2. Acquisition of DIACOM files.
3. Conversion of DIACOM into. STL files.
4. Evaluation of the design
5. Surgical planning and superimposition if desired
6. Additive Manufacturing and creation of model
7. Validation of the model.

In short, the procedure involves getting a CT scan or MRI scan of the patient. It is preferable that the CT scan is of high slice calibre and that slice thickness is of 1- 2mm. Most of the MRI and CT software give output in form of digital imaging and communication in medicine format popularly known as DIACOM image format.

Fig. 1. CT Scan Machine

**Acquisition of DIACOM files and conversion to .STL file format:** After the data is exported in DIACOM file format, it needs to be converted into a file format which can be processed for computing and manufacturing process. In most cases the desired file format for Rapid manufacturing is .STL or sterolithographic file format. The conversion requires specialised softwares like MIMICS, 3D Doctors, AMIRA. These softwares process the data by segmentation using threshold technique which takes into the account the tissue density. This ensures that at the end of the segmentation process, there are pixels with value equal to or higher than the threshold value. A good model production requires a good segmentation with good resolution and small pixels.
Softwares available for conversion:
MIMICS by Materialise (http://www.materialise.com/mt.asp?mp=mm_main)
Analyse by the Clinique Mayo
Amira http://amira.zib.de/
3D Doctor (http://www.ablesw.com/3d-doctor/)
BioBuild by Anatomics (http://www.qmi.asn.au/anatomics/)
SliceOmatic by TomoVision (http://www.tomovision.com/tomo_prod_sliceo.htm)

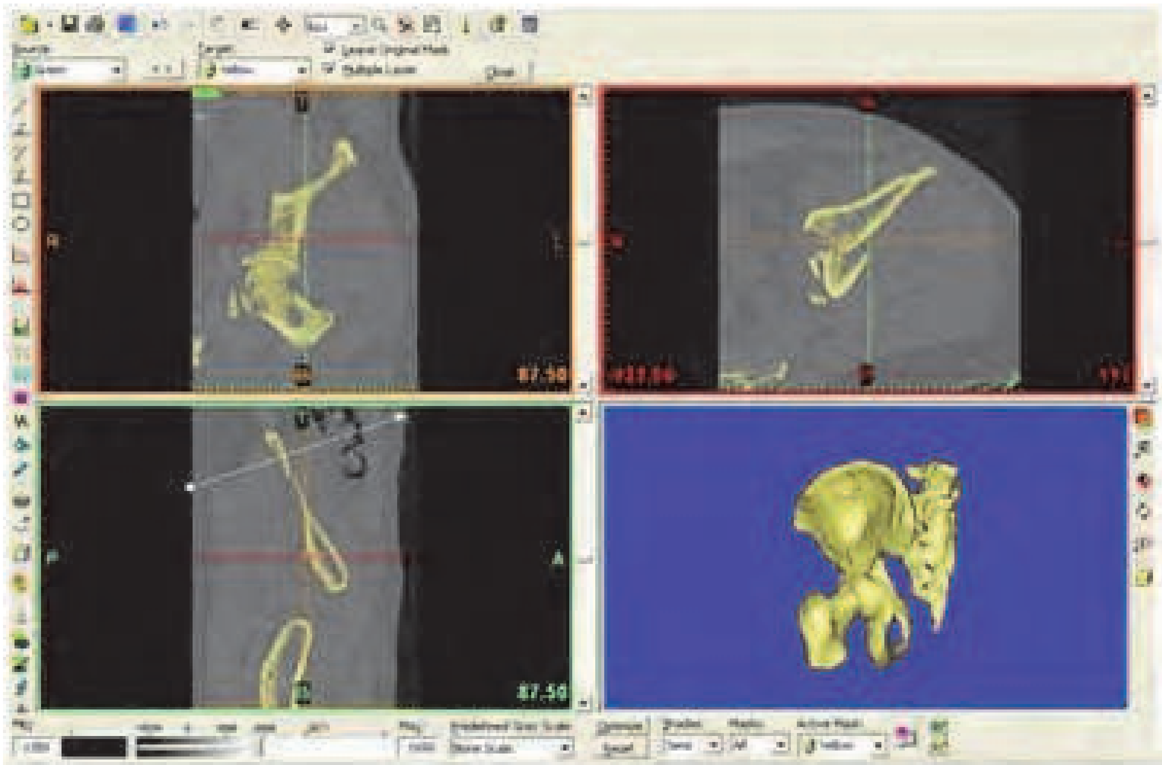

Fig. 2. Segmentation using the software

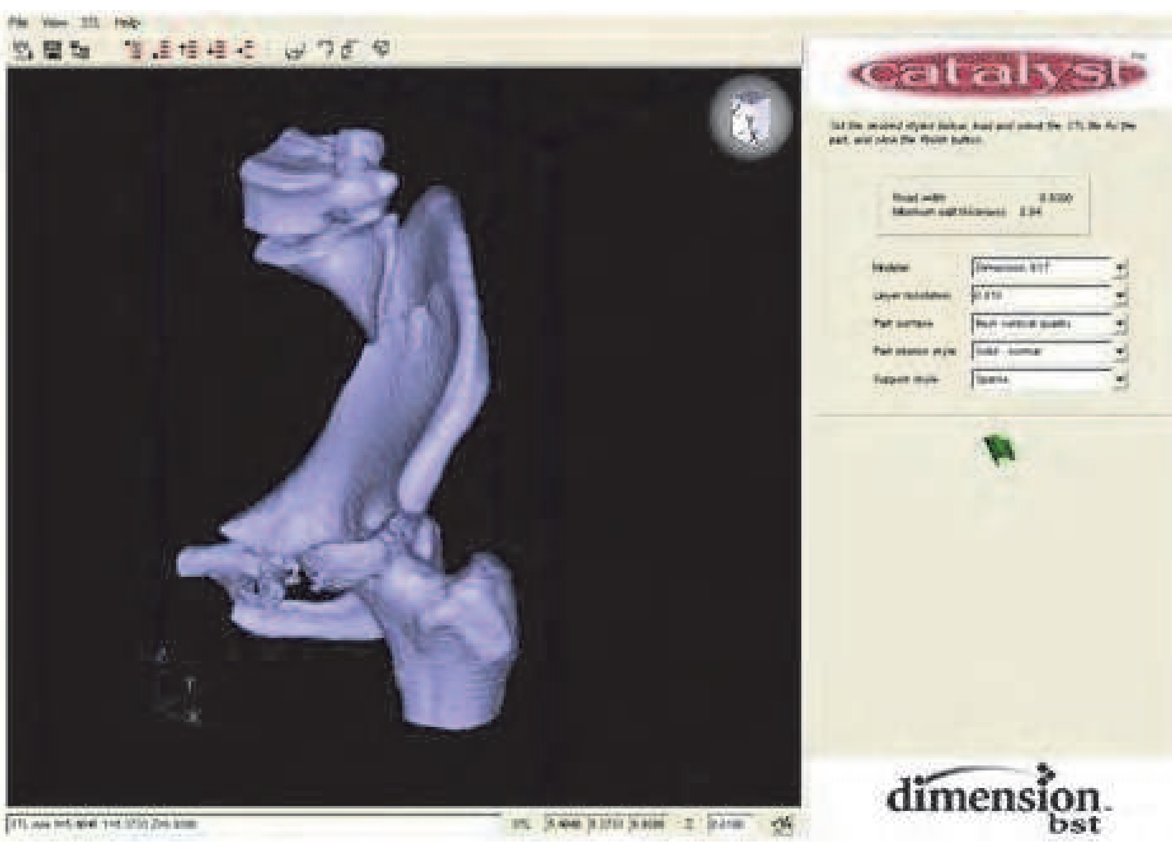


Fig. 3. Designing using CAD software

**Evaluation of design and surgical planning:** This step requires combined effort of surgeon, bio engineer and in some cases radiologist. It is important that unnecessary data is discarded and the data that is useful is retained. This decreases the time required for creating the model and also the material required and hence cost of production.
Sometimes this data can be sent directly to machine for the production of model especially when the purpose of model is to teach students. The real use however is in surgical planning in which it is critical that the surgeon and designer brain storm to create the final prototype. There may be a need to incorporate other objects such as fixation devices, prosthesis and implants. The step may involve a surgical simulation carried out by the surgeon and creation of templates or jigs. This may require in addition to the existing converting softwares, computer aided designing softwares like Pro- Engineer, Auto CAD or Turbo CAD.
**Additive manufacturing and production of the model:** There are various technologies available to create the RP model including stereolithography, selective laser sentring, laminated object manufacturing (LOM), fused deposition modelling (FDM), Solid Ground Curing (SGC) and Ink Jet printing techniques. The choice of the technology depends on the need for accuracy, finish, surface appearance, number of desired colours, strength and property of the materials. It also takes a bit of innovation and planning to orient the part during production so as to ensure that minimum machine running time is taken. The model can also be made on different scale to original size like 1: 0.5, this ensures a faster turnaround time for production and sometimes especially for teaching purpose this may be convenient and sufficient.

Fig. 4. Various types of Rapid Prototyping Machine

**Validation of the model:** Once the model is ready, it needs to evaluated and validated y the team and in particular surgeon so as to ensure that it is correct and serves the purpose.

## 3. Rapid prototyping applications

1. Orthopaedic and Spinal Surgery
2. Maxillofacial and Dental Surgeries
3. Oncology and Reconstruction surgeries
4. Customised joint replacement Prosthesis
5. Patient Specific Instrumentation
6. Patient Specific Orthoses
7. Implant design Testing and Validation
8. Teaching Tool – Orthopaedics, Congenital Defects, Obstetrics, Dental, Maxillofacial.

Table 1. Key Medical speciality areas in which Rapid Prototyping is currently used:

## 4. Surgical simulation and virtual planning

The importance of preoperative templating is well known to surgeons. Especially in difficult cases it gives the surgeon an opportunity to plan complex surgery accurately before actual performance. Advanced technologies like digital templating, computer aided surgical simulation; patient matched instrumentation and use of customized patient specific jigs are increasingly gaining ground. Once the entire process of model generated is accomplished, the surgeon can study the fracture configuration or the deformity that he wants to manage Different surgical options and modalities can be thought of and even be simulated upon the model. In the next stage, the surgeon can contour the desired implant according to bony anatomy. Often as in the complex cases involving acetabulum, calcaneum and other peri-articular area contouring the implant in three planes is usually necessary. The fixation hardware can thus be pre-planned, pre-contoured and prepositioned. Once the implant is contoured, computer generated inter-positioning templates or jigs can be used for easy, accurate, preplanning of the screw trajectories and osteotomies. Finally the surgeon can also accurately measure the screw sizes that he desires to use in the surgery thus saving valuable intraoperative time. The model could also be referred to intra operatively should a help is required in understanding the orientation during the surgery.

1. Better understanding of the fracture configuration or disease pathology.
2. Helped to achieve near anatomical reduction
3. Reduced the surgical time
4. Decreased intra-operative blood loss
5. Decreased the requirement of anaesthetic dosage

Table 2. Advantages of Rapid Prototyping

### 4.1 Illustrative cases

**Case 1** – Acetabular Fracture

Mr Y, a 29-year-old male, with a history of fall from a 20-ft height presented in the casualty department with multiple fractures. There was no history of head injury and his spine

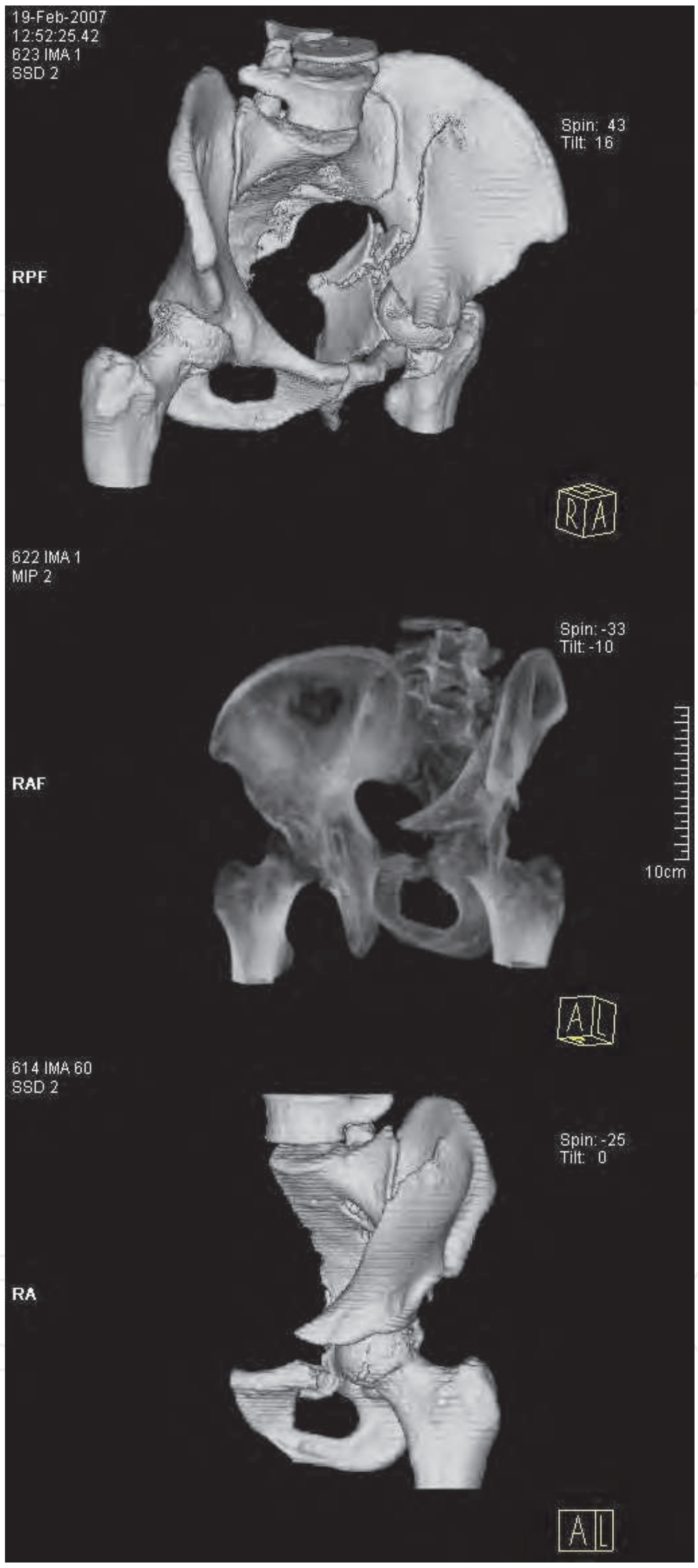


Fig. 5. A: Preoperative Xrays – Judet's obturator view.
Fig. 5. B, C: CT scan showing a vertical displaced a fracture involving iliac blade starting 3 cm below the iliac crest and extending forward reaching up to the acetabular roof and triradiate cartilage, involving both anterior and posterior column. There is also a mild protrusion of the femoral head and the fracture line extension was present till the superior pubic rami.

screening was normal. Other fractures included grade IIIb open fractures of the lower third of the right humerus, left volar Barton fracture, and a bicolumnar fracture of the acetabulum on the left side. His vitals were stable and after appropriate stabilization, a CT scan of the pelvis was taken.
The CT scan showed a vertical displaced fracture involving the iliac blade starting 3 cm below the iliac crest and extending forward, reaching up to the acetabular roof and triradiate cartilage, involving both anterior and posterior columns. There was a mild protrusion of the femoral head and the fracture line extension was present till the superior pubic rami [Figure 5A, B, C].
The preoperative planning before surgery of the acetabulum comprised sequential steps: 3-D reconstruction and segmentation of CT scan data], surgical simulation, template design, sizing and alignment of the implant and production of the templates using the RP technology [Figure 6]. CT scanning of all sections was done with 1-mm-thick slices.

Fig. 6. Rapid-prototyping (RP) Model of fractured acetabulum using a RP machine.

For the preoperative planning process, template was used to contour a 4.5-mm-thick reconstruction plate. The screw sizes were determined preoperatively and the position of the plate and holes was also decided and marked with indelible ink on the 3D model. An ilioinguinal approach was used for anteriorly exposing the fracture site. The total surgical time required was 3 h 10 min. Of this, the instrumentation took only 20 min. The blood loss during the procedure was 600 ml and the patient was transfused one unit of whole blood. Next morning, a haemoglobin check was done which was in the normal range and no postoperative transfusion was given. Post operative period was uneventful and normal postoperative rehabilitation protocol was followed.

The postoperative evaluation was carried out using radiographs and CT scans. Computer-assisted analyses were carried out for judging the accuracy of the reduction and sizing of the implants [Figures 7, 8].

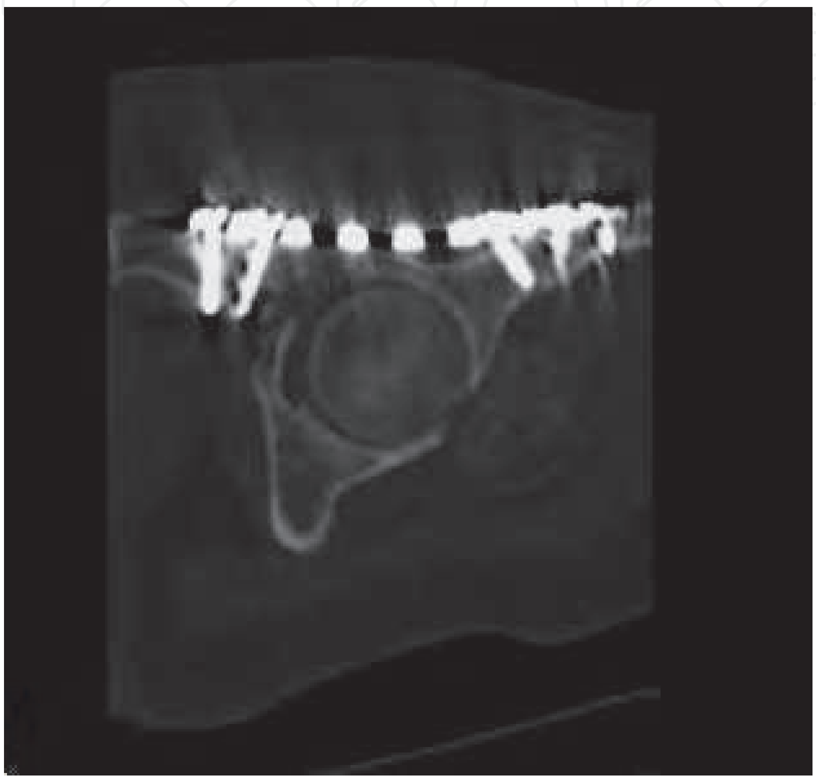

Fig. 7. Postoperative Judets view (obturator view) of Acetabulum.

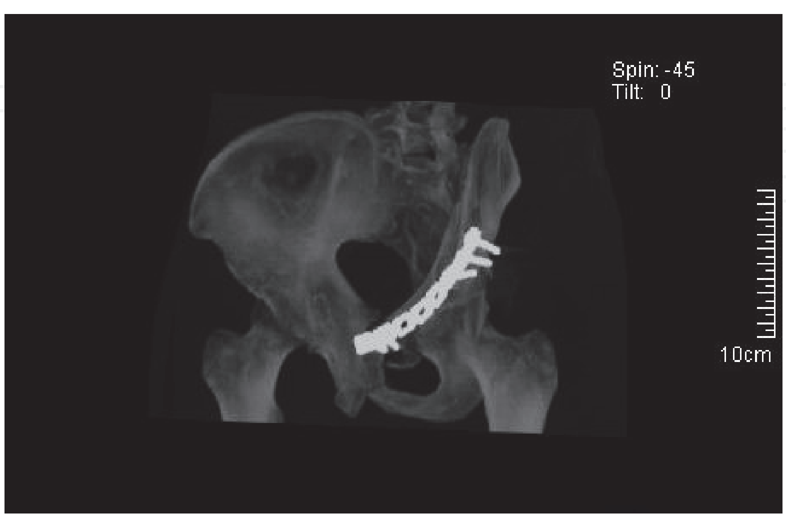


Fig. 8. Axial sections CT images along the plate showing the well contoured plate and fracture reduction.

**Case 2**: Calcaneal Fracture

A 16-year-old male was admitted with a history of fall from a 12-ft height 2 days after injury. He had sustained a type IIB Sanders' classification closed calcaneal fracture. Spine screening and other examinations were normal. After the swelling decreased as proven by the appearance of wrinkles on day 8, surgery was planned. A CT scan was done [FIG 9} and a 3D model of the calcaneum was made using the RP technique. The 3D model showed the fracture lines clearly and helped plan the surgery [Figures 10].

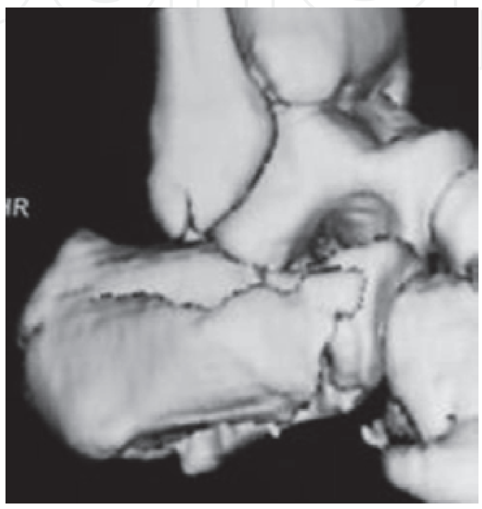


Fig. 9. Fracture Calcaneum CT scan image reconstruction.

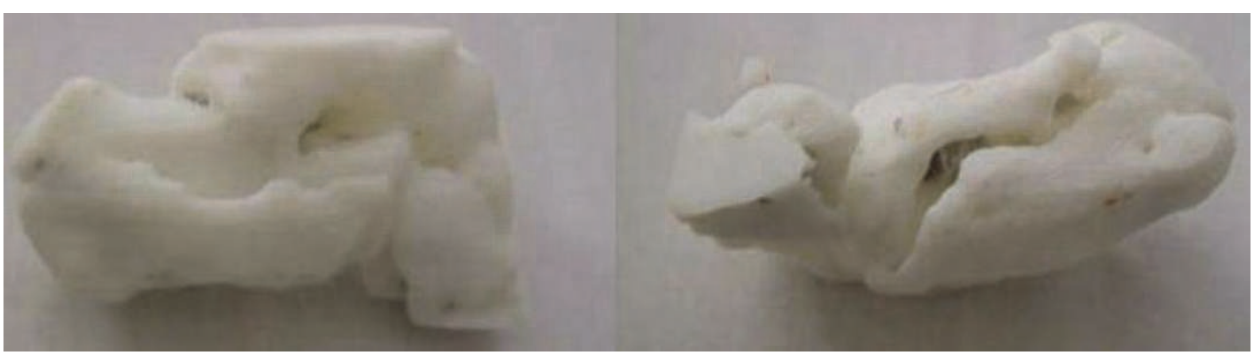

Fig. 10. Fracture Calcaneum Rapid prototype Model.

An open reduction and internal fixation was done using a lateral approach. The subtalar joint was anatomically reduced and a stable fixation was done. Postoperative radiographs [Figure 11] revealed an acceptable fracture reduction and the patient was mobilized at 6 weeks. At 2-year follow-up he is ambulating well without any pain and disability.

Fig. 11. ORIF done for fracture calcaneum showing good reduction.

**Case 3**: Hoffa’s Fracture

An 18-year-old male was brought to the emergency department with a head injury, and an injury to right knee and ankle. After stabilization, radiographs that were taken revealed a right Hoffa’s fracture involving the posteromedial femoral condyle and an open ankle dislocation. His right knee CT scan was done and the data was used to make a 3D model depicting the fracture pattern. The model was used to study the fracture pattern, for the possible reduction manoeuvre, and to decide the screw trajectory and length.

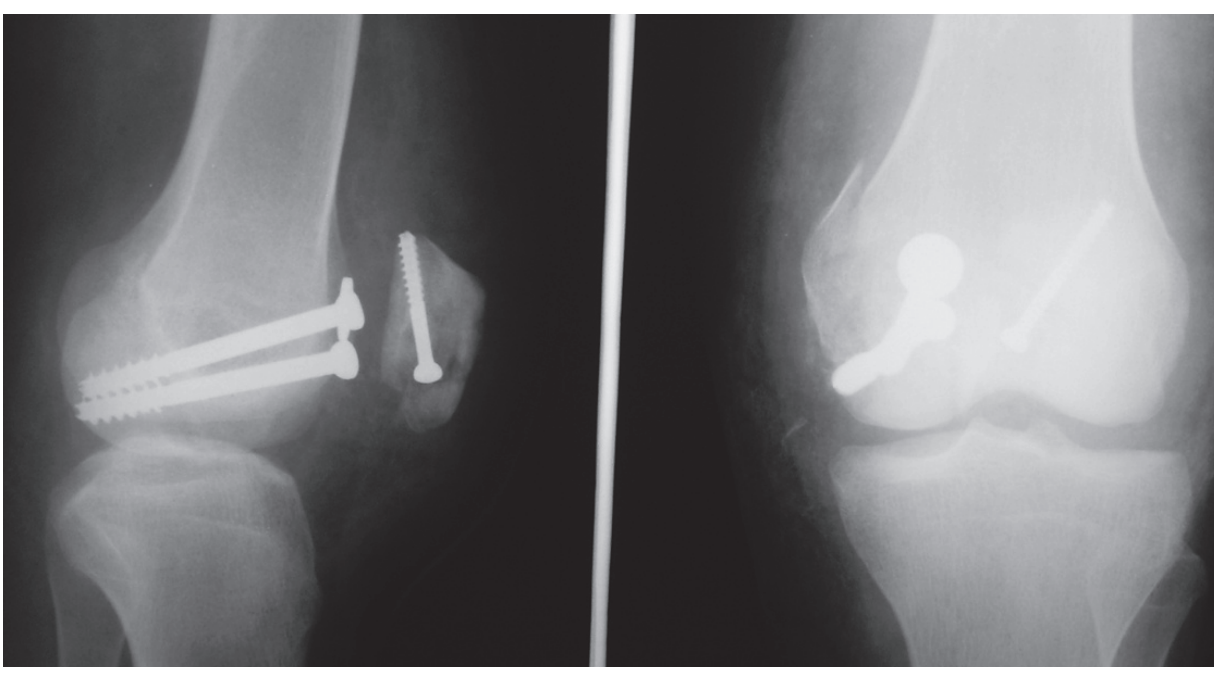

Fig. 12. Hoffas fracture fixation done with aid of surgical simulation on RP model showing anatomic reduction.

A median parapatellar approach was used to expose the fracture pattern and then fixation was done along the planned trajectory using two 6.5 CC screws [Figure 12]. Non weight bearing knee mobilization was started at 6 weeks. At 3-month follow-up, the patient is ambulating with a walker.

**Case 4:** Complex Spinal Deformity

A 3 year old child with scoliosis and D6 hemi vertebrae who was posted for a corrective surgery a 3 D Model was created (Fig 13, 14,15) using Rapid Prototyping technique. The model helped understand the complex anatomy and planning hemi-vertebrae resection anteriorly. The surgeon felt it immensely useful in providing preoperative rehearsal with a 360 degree visualisation of pedicles and planning entry point, screw trajectories and screw length.

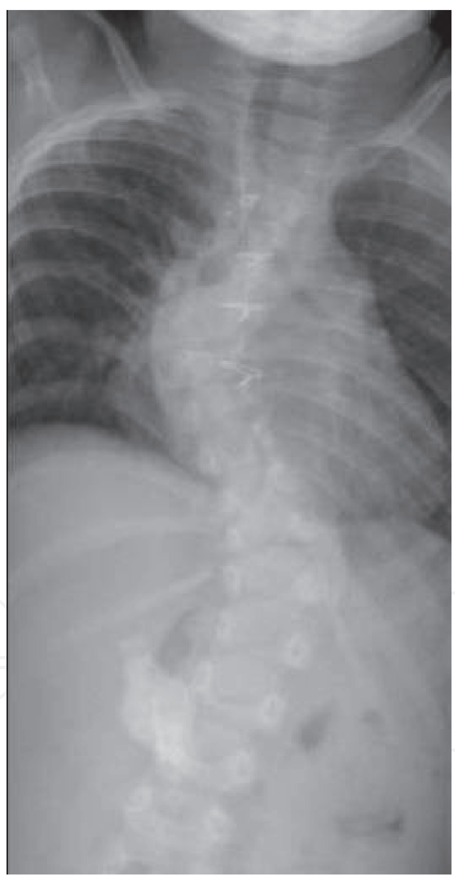

Fig. 13. Xray picture of congenital Scoliosis

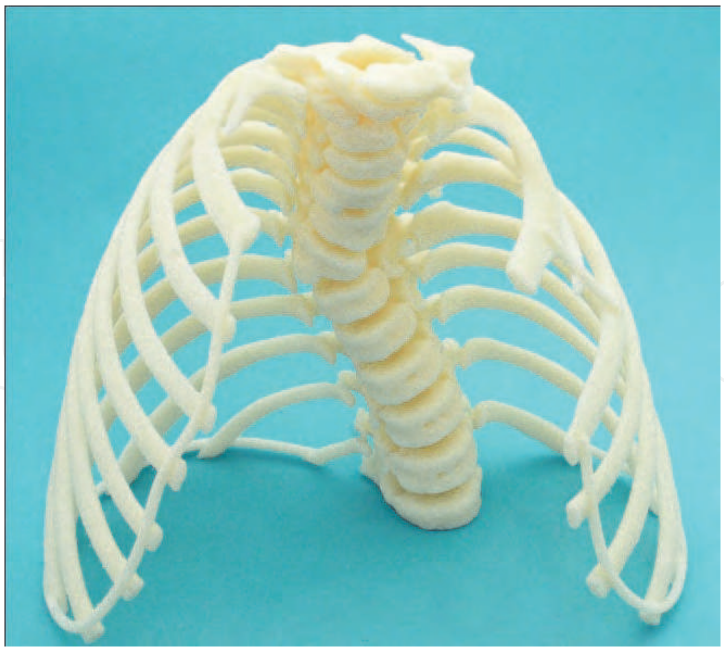

Fig. 14. RP model of congenital scoliosis.

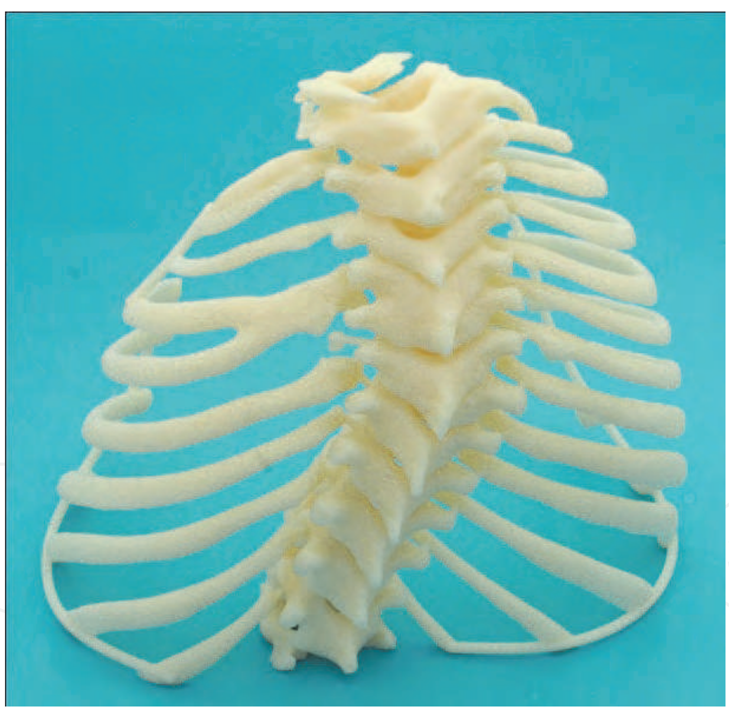

Fig. 15. RP model of Congenital scoliosis as seen from back.

**Case 5:** Acetabular defect reconstruction before THR

Complex adult reconstruction like those requiring total hip replacement in case of defects on the acetabular side require extensive planning and also various customised inventory. 3d modelling helps to plan and also design additional implants. The case described here had acetabular defect secondary to hip infection (FIG 16, 17). A 3D model using RP was made and an acetabular cage/ antiprotrusion ring designed for the same (FIG 18). The surgery in this case went smoothly and surgeon felt that the time required and inventory on table was also reduced.

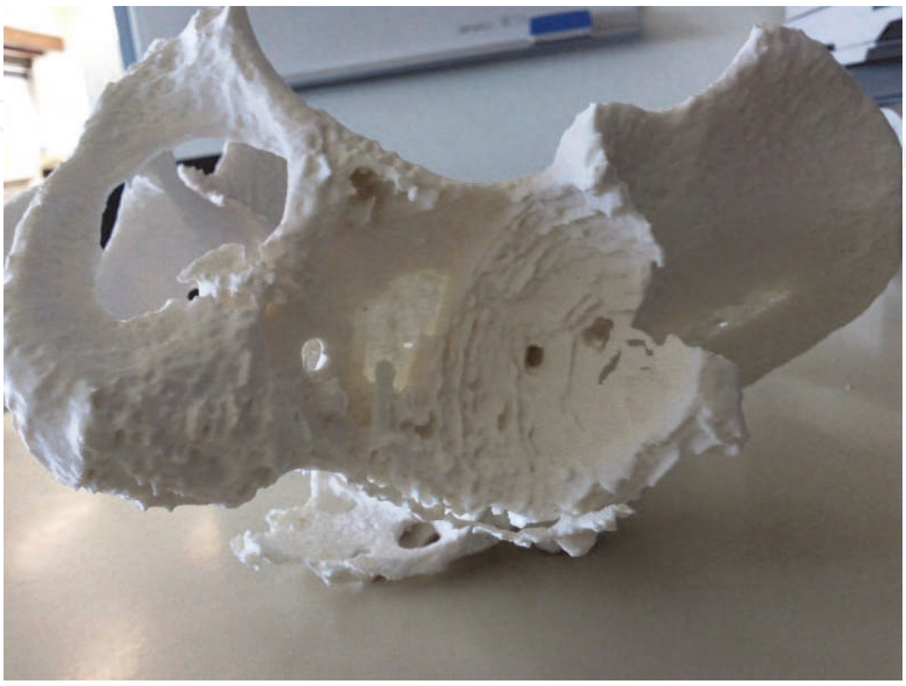

Fig. 16. RP model showing acetabular defect in patient scheduled to undergo total hip replacement.

Fig. 17. RP model of acetabulum as seen from front.

Fig. 18. Designing and planning the use of anti protrusion ring on the acetabular side before Total hip Replacement.

## 5. Patient specific implants/instruments

### 5.1 Designing patient specific knee and hip instrumentation and implants

Knee replacement surgery has gained wide spread popularity for managing arthritic cases. It repairs damage and relieves pain in patients with severe osteoarthritis or knee injury. The process involves removing diseased cartilage and bone from the surfaces of the knee joint--the thigh bone, shin bone, and kneecap--and replacing them with an artificial joint made from a combination of metal and plastic. A partial knee replacement can also be performed on one part of the joint. Typically, a surgeon chooses an artificial joint from several options of different sizes. However, the sizes available are limited and usually do not take into the account racial, gender or morphological factors in account. Although the limited sizes available have been used successfully for several years in past, there is growing number of surgeons who believe that the outcome may be better if the implants and instruments are designed based on patients anatomy and demand vis a vis the functional outcome. Recent years have shown some acceptability for gender specific implants and high flexion knee (catering to the functional need of deep flexion).

### 5.2 Patient specific instrumentation

Conventional knee replacement is carried out using jigs that take standard bone cuts depending on the planned size of implants. Patient specific instrument use preoperative planning to design jigs to ensure accurate bone cuts. Most of these systems use planning based on mechanical axis and for the purpose a long film X-rays, MRI or CT is used. CAD software then helps to simulate the surgical procedure and appropriate amount of bone resections and the degree of rotation in which the prosthesis should be implanted is determined. The calculations and drawings are then sent to surgeon for final approval. (Figure 19, 20) After the planning is done, the jigs are prepared customised to the patient anatomy and incorporating the planned resections and appropriate rotations. An appropriate size is also mentioned and provided the surgeon. The surgeon however has flexibility to intraoperatively switch to conventional procedure or to use different size.

Fig. 19. Patient specific Instrumentation used to make distal femoral cut.

Fig. 20. Patient specific jig being used for tibial cut during total knee replacement.

Benefits:

- Eliminate as many as 22 steps in the surgical procedure with patient match alignment that potentially can achieve a better outcome for the patient. Since the instruments are specifically designed according to patient dimension, the implant is likely to fit better, at the same time the system is versatile enough to allow the surgeon to take intra-operative decisions as deemed necessary.

- Reduce set-up, surgery and clean up time with shorter surgeries and less instrumentation.
- Patient specific alignment may lead to better patient outcomes and lowered risk of complications such as DVT due to lack of violation of the IM canal. There are potential risks with any surgery.
- Eliminating as many as 22 steps shortens surgery time, meaning the patient needs less time under anaesthesia.

### 5.3 Patient specific implant

In order to design patient specific implant – a MRI or CT scan of the patient is taken and DIACOM images acquired. After converting these into STL files, the planning stage starts. The team usually comprises of surgeon and bio engineer who identify the area where the cartilage is worn off. An exact negative topography is then generated and a customized knee implant is created which would replace only the areas of the cartilage defect, this could be unicompartmental or bicompartmental or in the case of hip or any other joint only the damaged area (fig 21, 22). The model and its negative are then used to create patient specific instrumentation and jigs that would resect only the desired part as described above.

Fig. 21. RP model designed as patient specific hip resurfacing Implant.

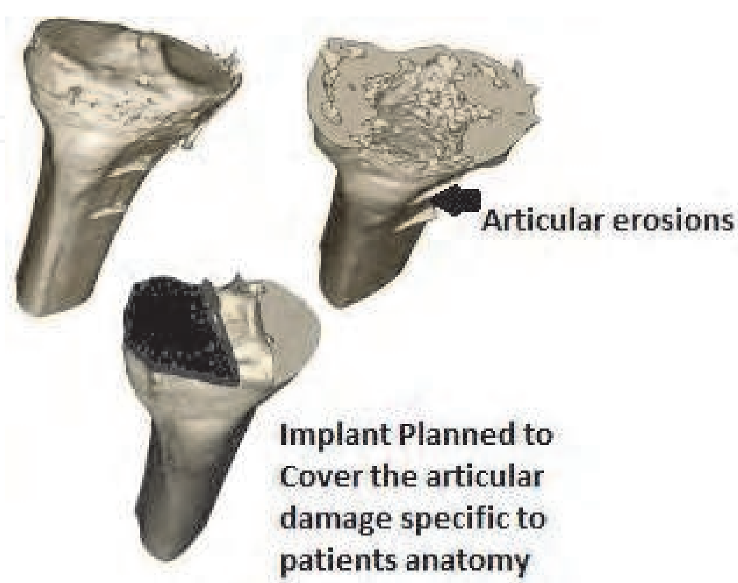


Fig. 22. Planning using CAD software to design patient specific knee Implants.

**5.4 Illustrative case report: Designing Temporo-Mandibular Joint (TMJ)**

There is significant variation in the structure and shape of the human skull and hence it is difficult to replace a jaw joint successfully without customising it according to the patient's anatomy. In contrast, prostheses for knees and hips are designed for large number of population who fall within the normal range and vary little, except for the size of the patient.

Case: A 12-year-old female presented to plastic and orthopaedic surgeon for management of a unilateral left Temporo-mandibular joint ankylosis. The ankylosis had probably been caused by trauma suffered 7 years back. The patient was significantly disabled secondary to difficulty with speech, mastication, and oral hygiene. There was a bony hard swelling around the left TMJ. Her inter-incisal opening distance was 3 mm. 3D-CT scan suggested feature of bony ankylosis of left TMJ with minimal changes in right TMJ. There was no facial deformity. Occlusion was of class I. It was decided to replace the left TMJ with customized TMJ prosthesis. [Fig 23].

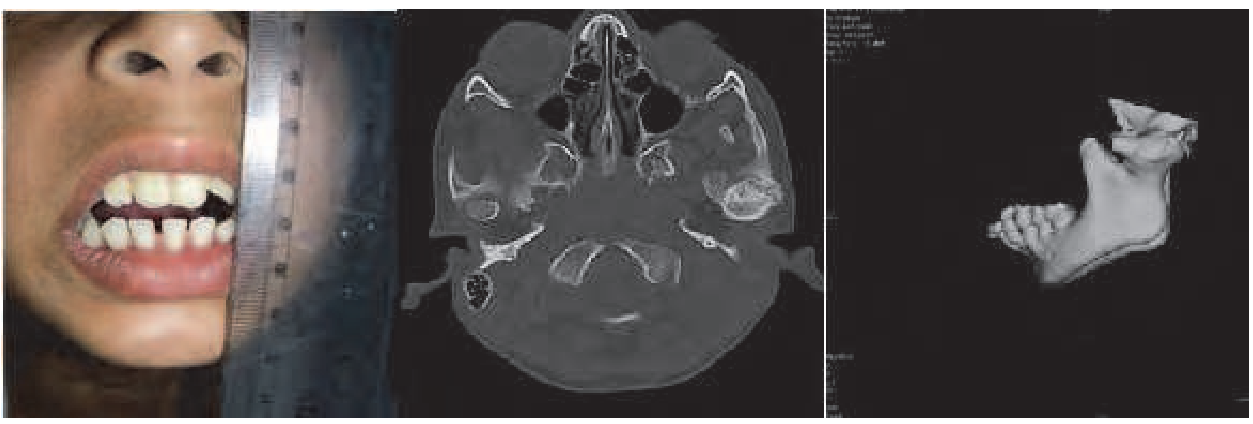

Fig. 23. Preoperative clinical, Ct images of a case of Temporomandibular (TMJ) joint ankylosis.

For the purpose, a preoperative computed tomography (CT) scan of the jaws and jaw joints was obtained using a specific protocol. Using the CT data in form of DIACOM images, a 3-D ABS plastic model of the joint and associated structures was made using stereo lithographic technology and CAD (Fig 24). The mandible was spatially repositioned on the model to correct the functional and aesthetic misalignment problems. From these models the

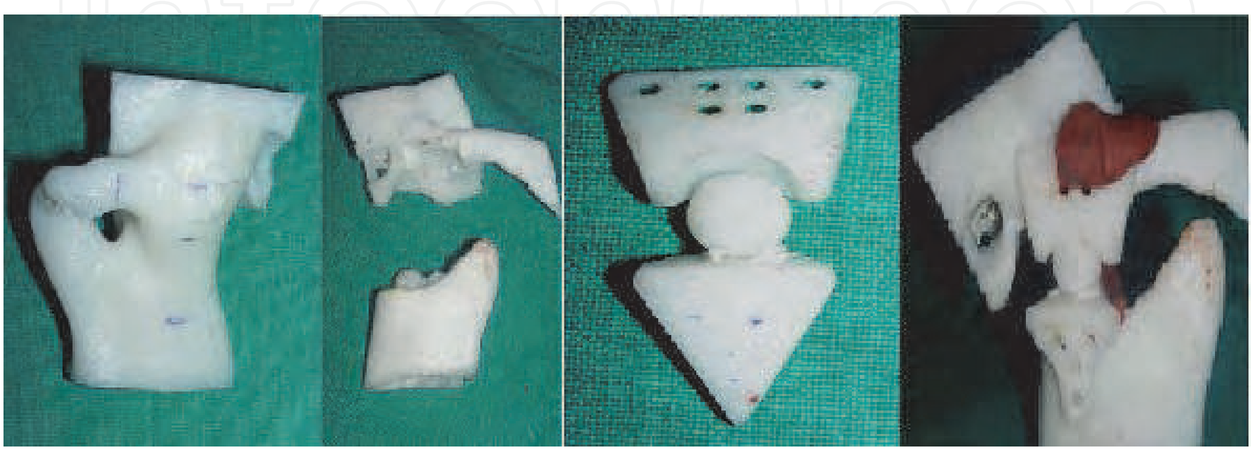

Fig. 24. Creation of RP model of TMJ joint and surgical planning.

distance of gap arthroplasty was planned. Cad was then used to design the prosthesis conforming to the patient anatomy and as per the surgical planning (Fig 25, 26). The procedure was successfully completed and patient had an excellent mouth opening exceeding 5 cm post operatively and the results were same at the end of 3 years with good patient satisfaction.

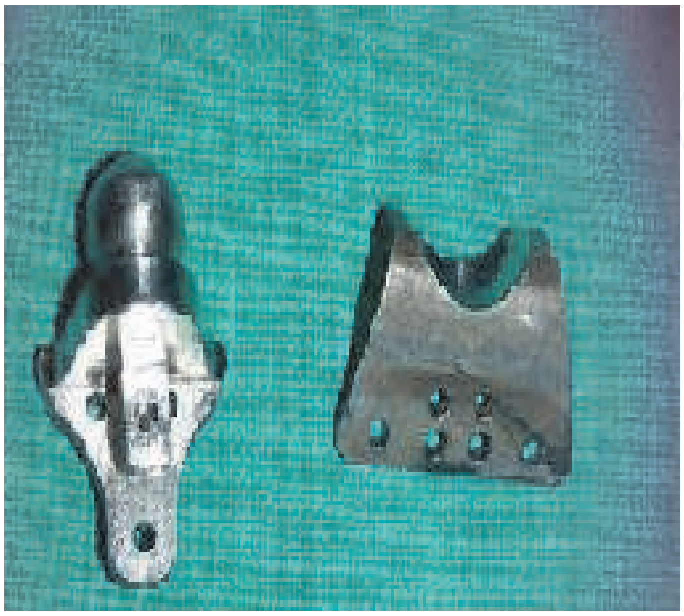

Fig. 25. Customised temporomandibular joint prepared based on RP model generated from patients CT data.

Fig. 26. Ball and socket mechanism employed in developing TMJ.

### 5.5 Didactic models for teaching purposes

As a vehicle for visualisation rapid prototyping models may also serve as important learning tools to young surgeons for practicing complex surgery which have a steep learning curve. The models of various conditions and fracture patterns may also provide

students an opportunity to understand the pathology and classifications better. This would be in some way similar to the use of cadaveric dissection and bone models to teach normal anatomy. These models can be made in different colours to better illustrate various anatomical structures (Fig 27).
Werner et al in 2008 published an interesting article in Ultrasound in Obstetrics and Gynaecology on the use of rapid prototyping didactic models in study of foetal malformation. In their study of eight cases, MRI scan of foetus was done at 36 weeks. The protocol consisted of: T2-weighted sequence in the three planes of the foetal body (HASTE; repetition time, shortest; echo time, 140 ms; field of view, 300–200 mm; 256 × 256 matrix; slice thickness, 4 mm; acquisition time, 17 s; 40 slices). The entire examination time did not exceed 30 min. After procuring DIACOM images, segmentation software (ScanIP version 2.0, Simpleware Ltd., Exeter, UK) was used to select the contours, allied to design and engineering software (Dassault Systèmes, SolidWorks Corp., and Autodesk Maya) used to create virtual model. Physical materialization was completed using thermoplastic acrylonitrile butadiene styrene. Santos J et al later enhanced and widened the horizon of this application in the field of obstetric by employing Ultrasound images to develop the rapid prototyping images. This is considered a significant step further in our understanding of feto maternal physiology and foetal anatomy and also picking up foetal anomalies at an early stage. Similar studies have also been reported from various fields but especially from orthopaedics, pulmonology and radiology department from across the world.

Fig. 27. Didactic model for teaching students anatomy and mechanics of the ankle joint. Differently coloured bone help easy identification and better understanding of the concepts

#### 5.6 Provide templates for designing bioactive and biocompatible material for tissue engineering

There are limitations of existing clinical treatment in managing end stage organ damage. Patient specific biological substitutes may provide a viable alternative in managing these cases. The primary regenerative approach has been transplantation the toti-potent cells with regenerative capacity on to a scaffold. The scaffold attempts to mimic the function of the natural extracellular matrix, providing a temporary template for the growth of target tissues. In order to serve the purpose the scaffold must have suitable architecture and optimal strength. Rapid prototyping promises to overcome the limitations of conventional scaffolds which are mainly inability to replicate the microscopic pores and structures so commonly found in the body. It can help replicates the porous and hierarchical structures of natural tissues at an unprecedented level thus ensuring that complicated organs like liver, kidney and heart are one day made to order in a lab.

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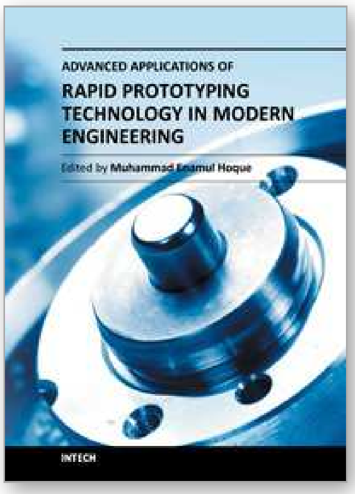


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Rapid prototyping (RP) technology has been widely known and appreciated due to its flexible and customized manufacturing capabilities. The widely studied RP techniques include stereolithography apparatus (SLA), selective laser sintering (SLS), three-dimensional 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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