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Comparative study of manufacturing condyle implant using rapid prototyping and CNC machining

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Abstract. Injuries to the cranio-maxillofacial area caused by road traffic accidents (RTAs), fall from heights, birth defects, metabolic disorders and tumors affect a rising number of patients in the United Arab Emirates (UAE), and require maxillofacial surgery. Mandibular reconstruction poses a specific challenge in both functionality and aesthetics, and involves replacement of the damaged bone by a custom made implant. Due to material, design cycle time and manufacturing process time, such implants are in many instances not affordable to patients. In this paper, the feasibility of designing and manufacturing low-cost, custom made condyle implant is assessed using two different approaches, consisting of rapid prototyping and three-axis computer numerically controlled (CNC) machining. Two candidate rapid prototyping techniques are considered, namely fused deposition modeling (FDM) and three-dimensional printing followed by sand casting The feasibility of the proposed manufacturing processes is evaluated based on manufacturing time, cost, quality, and reliability.

Key words: CAD, CAM, CNC, Rapid prototyping, Mandible, Condyle, Image processing.

1. Introduction

Biomedical engineering has undergone considerable intellectual and commercial growth in the 21st century, with the discipline now integrating engineering with medicine. Biomedical devices, in particular medical implants, have been employed to restore or replace living tissues and their functions, such as Cranioplasty implant, Mandibular implant, dental root implant and implant for knee replacement. In relation to the human head, injuries to the craniomaxillofacial area affect a significant number of trauma patients with the number of maxillofacial surgeries continually rising. Considering the population of the United Arab Emirates (UAE), the main cause of oral and facial trauma is road traffic related accidents. Statistics show that road traffic accidents in the UAE are 3.33 fatalities per hundred million, which is considerably higher than 0.72 and 1.51 in U.K and USA, respectively [1]. 70.5% road accident patients in UAE have a mandibular fracture or damage to the mandible [2]. Another unique type of facial trauma is falling from height. Although the figures from patient trauma resulting from falls have reduced considerably in the UAE since 2008, when construction Industry was at its peak, there are still an alarming number of patients seeking treatment for this type of injury [3]. Other craniomaxillofacial issues include birth deformities and tumors are other factors for which the patient may undergo maxillofacial surgery. Mandible reconstruction due to trauma, metabolic disorder or tumor poses a specific challenge in both functionality and aesthetics. Replacement of damaged bone or bone with a tumor is required during mandible reconstruction. In such cases, the bone is replaced by a custom made implant. In this case study, condyle which is part of the mandible is considered as a region of interest for manufacturing the implant for the reason that condylar and subcondylar fractures constitute 26-40 % of all mandible fractures [4].

Over the last decade, rapid prototyping (RP) techniques have been exploited in the field of medicine from medical modelling to the manufacturing of the implantable prototypes. Medical modelling involves fabricating custom implants and prostheses for surgical planning and 3D visualization prior to surgery. The scope of direct manufacture of biologically active implants by RP techniques incorporating medical modelling is being currently being addressed by the research community and could offer considerable potential to yield positive progress in the future.

Computerized Numerical Control (CNC) technology has been widely used for manufacturing implant directly from the Computer Aided Design (CAD) drawing on biocompatible materials such as titanium and Poly methyl methacrylate. With 7 axis CNC milling machines on the market, with high machining accuracy, complicated profiles can now be machined faster.

Parallel development in RP and CNC techniques will help guarantee cutting edge development in both areas of engineering and medicine for the coming years, which will further permit innovation in developing quality implants at low cost. Both technologies are used for manufacturing implants, but which technology can manufacture direct implants at low cost, higher quality and shorter lead time is yet be answered clearly.

The case study undertaken is a first step towards researching in implant manufacturing by studying the feasibility of manufacturing the implant using three different manufacturing processes FDM-CASTING, 3D-CASTING and Direct CNC using a CNC machine.

2. Methodology

The methodology used in this case study is given in the figure 1.

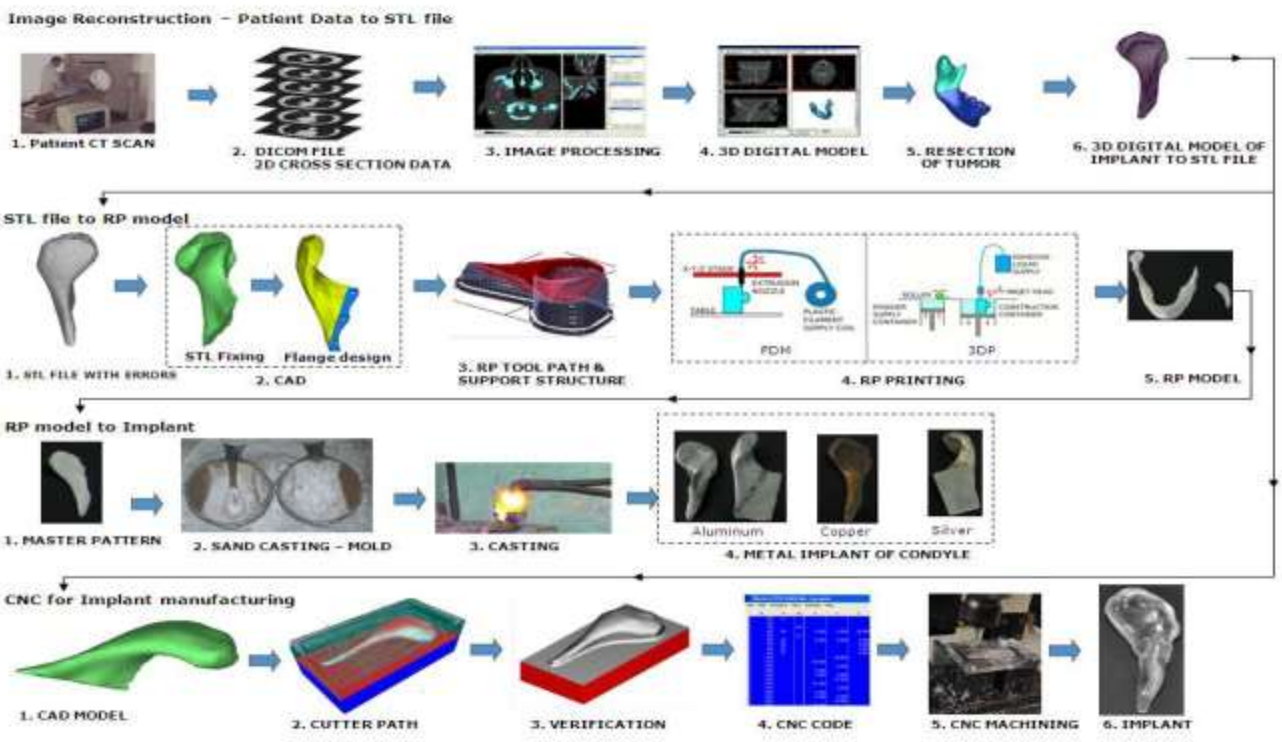


Figure 1. Methodology for manufacturing the condyle implant

The first step in manufacturing the implant starts with Image reconstruction, which is a common procedure for manufacturing the implant using FDM-CASTING, 3DP-CASTING and Direct CNC machining. Stereolithography (STL) file of the Condyle implant generated by the image processing software is printed on a Rapid prototyping machine. This 3D printed Condyle model is used as a master pattern for casting the Condyle implant. The STL file of the Condyle implant is also used for generating the CNC code using CAM software and then the Condyle implant is machined on CNC machine. Procedure for Image processing, Rapid prototyping, Casting and CNC are discussed below

2.1. Image reconstruction

Materialise Mimics software a 3D image processing and editing software was used for image processing. DICOM (Digital communication) file which is a format of CT scan data is imported into the software. The software converts the 2D images into high resolution 3D rendering image. Mimics Base, Simulation and STL module of the Mimics software was used in this case study to generate the STL file.

2.1.1 3D imaging methodologies using MIMICS base module

An overview of conversion of CT data to 3D digital model is given in figure 2.

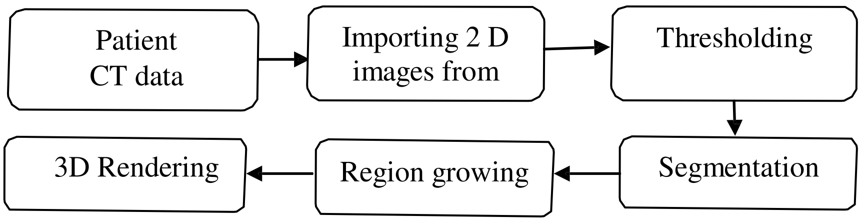


Figure 2. Image processing workflow

2.1.1.1 Importing 2D images from DICOM files

Patient CT scan data in the form of DICOM file were imported and the orientation of the image is selected. The orientation of the image for this case study was selected as Anterior at the front and Posterior at the back.

2.1.1.2 Segmentation and Thresholding

When the CT scan data of the patient is imported it contains details of both hard and soft tissues. Image segmentation is the process of partitioning an image into multiple labelled regions locating objects and boundaries in images [5]. Segmentation mask was used to highlight regions of interest which is mandible. Since mandible is a hard tissue the region was selected by defining a range of grey values between 226 to 3071 which corresponds to bone. The boundaries of the range are the lower and upper threshold values.

2.1.1.3 Region growing and 3D rendering

Region of growing tool was used for joining the region of interest of different slice of CT data and to split the segmentation into separate objects. The 2D images below all the slices get connected to provide 3D image. “Calculate 3D” command was used to generate the 3D digital model with optimal quality. The 3D model obtained contains the entire patient facial bone data. Mandible the region of interest for this study was separated from the facial bone data using “EDIT Mask” command and parts other then the mandible was erased. 3D digital model of the mandible was saved for further work.

2.1.2 Generating 3D model of the condyle

The 3D model of the mandible obtained is opened in the simulation module of MIMICS to remove the defective condyle and to create a condyle digital model which will replace the defective model. The Created 3D condyle model is used in further steps to create the implants. Figure 3 shows how the simulation module is used to create the condyle. The Mimics Simulation module with its Cut, Mirror and repositioning operations allows to define the required shape of a condyle implant by mirroring one side of the patient's condyle. The 3D digital model of the condyle that was mirrored is a representation of implant that will be manufactured by FDM-CASTING, 3DP-CASTING and Direct CNC process.

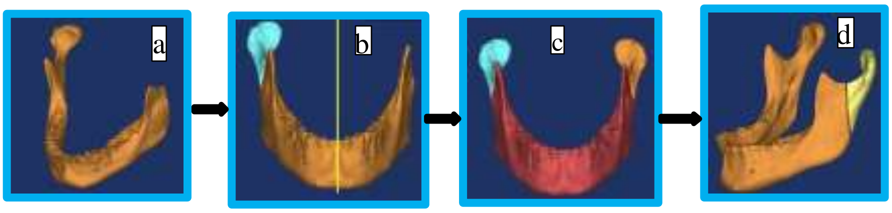
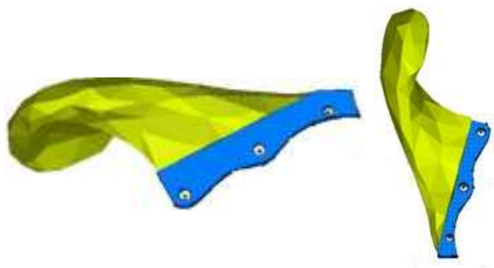


Figure 3. Simulation process to obtain 3D digital model of the Condyle
a. Defective condyle removed using cut and spit operation
b. Mirror plane defined for mirroring the condyle
c. Mirror operation performed on the condyle
d. Mandible with mirrored condyle.

2.1.3 Design of flange

3- Matic software was used to design an attachment to the 3D digital condyle so that when the implant is manufactured it can be fixed to the mandible. There are three holes provided on the flange for attaching the flange to the mandible using screws which is shown in figure 4.



a. Front view b. Back view

Figure 4. Condyle with flange

2.2 Rapid Prototyping (RP)

RP system quickly produces models and prototype parts from 3D computer-aided design (CAD) model data. Parts built on the RP in the health field are called biomodel [6].
The 3D digital model of the Condyle and the mandible with resection Condyle were printed using Stratasys Dimension 1200es series (FDM technology) and Z Corp 510 3DP machine (3DP technology) as shown in figure 5. Also rectangular blocks were printed on the printer for measuring the accuracy of the machine.

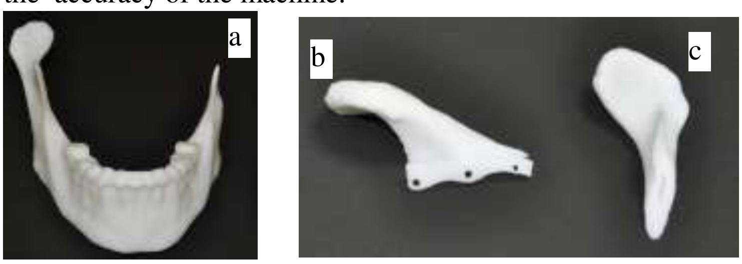


Figure 5. Rapid prototype of biomodel using FDM technology
a. Mandible with resection Condyle
b. Condyle with flange
c. Condyle without flange

2.3 Casting Implant

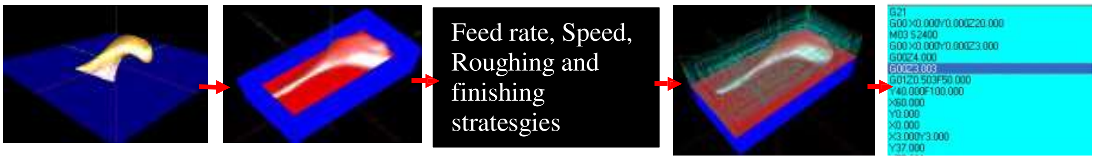
The Condyle model which was printed on rapid prototyping machine was used as a pattern for casting. Using the common process cycle for sand casting like mold-making, pouring, cooling, removal and trimming the condyle implant was cast on Silver, Copper and Aluminium which is shown in figure 6.

a. Aluminium Casting b. Silver Casting

Figure 6. Condyle Implant

2.4 CNC machining

3DGeoCAM module of Boxford software was used to generate the CNC code directly from the STL File of the condyle. The procedure for generating the NC code is shown in figure 7.



Importing the STL file | Defining the Stock Size and Datum | Defining the M/c. parameters | Generating tool path | Selecting Fanuc Post processor to generate CNC code

Figure 7. Generating CNC code from STL file on 3DGeoCAM software

CNC program generated on the 3DGeoCAM was opened in CNC machine software The simulation on the CNC software was carried out to check the program and to make sure that there is no tool collision. The workpiece was set on the CNC machine and tool offset were taken for machining the condyle implant using a 6mm ball nose cutter.The machined implant is shown in the figure 8.

a. Machining Implant b. Bottom part of implant c. Top part of impant

Figure 8. Machining on 3 axis CNC milling machine

3. Result

Different process of condyle implant manufacturing was compared by estimating the time, cost and accuracy of manufacturing the implant. For the time and cost calculation following factors were considered:-

1. Time and cost for 3D reconstruction and CAD process is not considered for the reason that is a common process.
2. Cost of RP machine and CNC machine are not considered as the cost calculation is only for the manufacturing process.
3. Time taken for preprocessing, Actual build or machining time and Post- processing time are considered.

4. Tool wear and tool replacement time is not considered.
5. Ideal time of the part before it is carried out to the next stage of process is not considered.

3.1. Time Analysis
Time and material required data for building the part using FDM and 3DP are taken from the software of the RP machine and are shown in the Table 1 and Table 2 respectively.

Table 1. Material and built time details of condyle implant on FDM machine

Layer resolution	0.0130 in	0.0130 in	0.010	0.010
Orientation of the model	Top to bottom	Bottom to top	Top to bottom	Bottom to top
Model material	0.198 in^3	0.198 in^3	0.20 in^3	0.20 in^3
Support material	0.179 in^3	0.179 in^3	0.20 in^3	0.20 in^3
Time to buiid	0.25	0.22	0.30	0.34
Support fill	Basic	Basic	Basic	Basic

Table 2. Material and built time details of condyle Implant on 3DP machine

Layer resolution	0.004 in	0.004 in
Orientation of the model	Top to bottom	Bottom to top
Model material	0.198 in^3	0.198 in^3
Resin	1 ml	1 ml
Time to build	0.25	0.22
Support fill	Basic	Basic

3.1.1. Time required to manufacture the Implant
Pre-procesing time, actual build time and post processing time was considered for estimating the time. This is given in the Table 3 for FDM- Casting and 3DP-Casting process.

Table 3. Time analysis for manufacturing the implant using RP process

Process	FDM	3DP
Pre-processing time		
Creation of tool path and Support structure	2 min	2 min
Setting up the machine (adding the build plate, purging the nozzle)	10 min	12 min
Printing time		
Build time	34 min	30 min
Post processing time		
Removal of support structure in BST FDM system. Applying Cynoacrylate in 3DP system	20min	10min
Casting		
Preparation of sand mold and pouring the molten metal	5 hrs	5 hrs
Total time to build the implant	**6 hrs 6 min**	**5 hrs 54 min**

3.1.2. Time required to manufacture the implant using Direct CNC process
Time data for machining the parts were taken from the 3DGeoCAM software. Acrylic block of 100 X 100 X 50 was used for machining the Implant.Time taken to manufacture the implant through Direct CNC process is given in Table 4.

Table 4. Time analysis for Direct CNC manufacturing process.

CAM software	
Generation of tool path and CNC code.	25 min
Pre processing	
Setting up the tool	10 min
Machining the stock	30 min
Machining time	
Build time	1 hr 58 min
Post processing time	
Removal of additional material from the stock manually	35 min
Grinding and polishing	26 min
Total time to build the implant	**4 hrs 2min**

3.2. Accuracy analysis

The accuracy of the implant manufactured by different process was compared with the measurement made on the 3D digital model. MIMICS software, Measurement module was used for dimensioning the implant part as shown in figure 9. More number of dimension measurements on the part of the condyle which gets attached to the mandible (4,5,6,7,8) were taken as this is the region of interest for fixing the implant. Height of the implant is also very important for proper matching of the condyle with the upper jaw.

Measurement on the FDM, 3DP, Cast and CNC manufactured implant were done using a micrometer and the results are shown in Table 5.

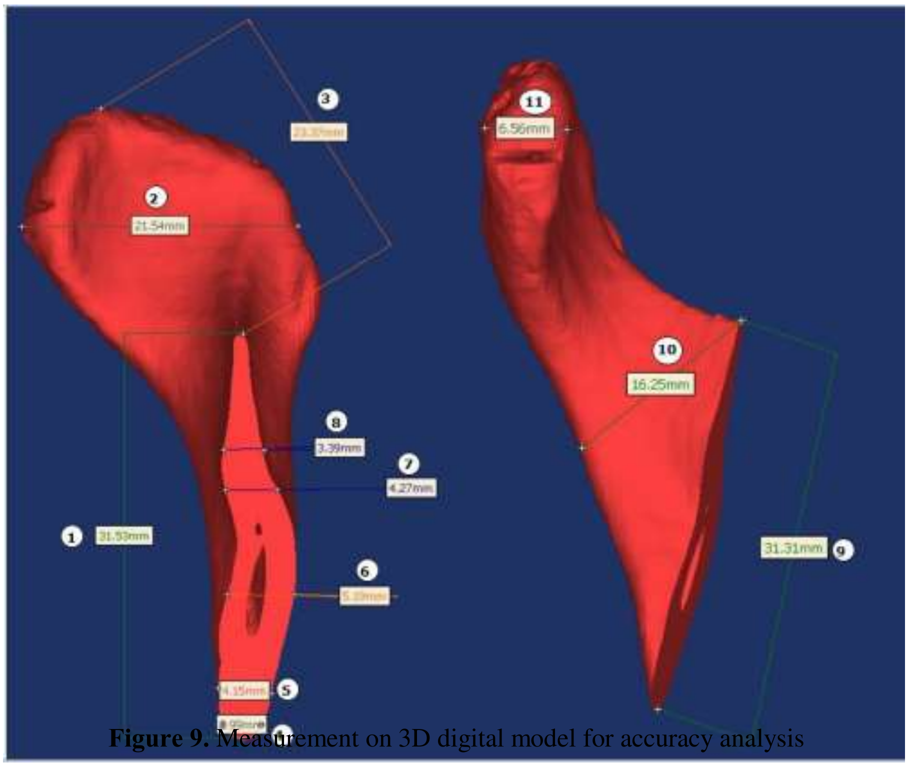


Figure 9. Measurement on 3D digital model for accuracy analysis

Table 5. Accuracy measurement of the implant manufactured using different processes.

Location	**Measured value of prototype (mm)**					**Error analysis %**			
	3D Digital Model	FDM	3DP	CNC	Casting	FDM	3DP	CNC	Casting
1	31.53	30.69	31.58	30.53	30.53	2.66	-0.16	3.17	3.17
2	21.54	20.26	20.32	21	18.87	5.94	5.66	2.51	12.40
3	23.37	25.56	25.96	22.1	23	-9.37	-11.08	5.43	1.58
4	2.99	3.2	3.26	2.89	2.91	-7.02	-9.03	3.34	2.68
5	4.15	4.24	4.45	4.02	4.03	-2.17	-7.23	3.13	2.89
6	5.19	5.1	5.43	5.04	5.1	1.73	-4.62	2.89	1.73
7	4.27	4.03	4.57	3.93	3.99	5.62	-7.03	7.96	6.56
8	3.39	3.4	3.47	3.27	2.84	-0.29	-2.36	3.54	16.22
9	31.31	29.82	30.61	30.2	30.12	4.76	2.24	3.55	3.80
10	16.25	15.64	16.82	17	15.44	3.75	-3.51	-4.62	4.98
11	6.56	6.32	7.11	6.02	6.09	3.66	-8.38	8.23	7.16
12	50.75	50.59	50.95	50.2	50.3	0.32	-0.39	1.08	0.89

3.3 Material cost

Cost for different process of manufacturing is given in Table 6.

Table 6. Material Cost

Process	Material	Material consumed	Cost (INR)	Total Cost (INR)
FDM	Model and support material	0.4 cubic inches	295.2	1795.20
Z Corp	Z150	1.514 cubic inches	185.6	1685.6
CNC	PMMA	100 X 100 X 50	1016	1016
	Acrylic	100 X100 X50	500	500

4. Discussion

4.1. Time analysis

Manufacturing time taken to build the implant using CNC is shorter by 2 hrs 4min (33.87% and 1hr 52 min (31.63 %)when compared to FDM and 3DP process.

The part built on the RP machine is faster, but the time for manufacturing the implant by casting is higher.

4.2. Cost analysis

Manufacturing process cost of building the model on both the RP process is 23% of cost of CNC material. The major cost of building the implant is the material cost. Cost of building the implant depends mainly on its material. The cost of building the Condyle implant is lower using CNC as compared to FDM-Casting and 3DP casting as the RP process accounts for the cost of the material used for making the model and the cost of material for casting.

4.3. Accuracy analysis

The % error for FDM printed implant is lower when compared to other technology. It is noticed that the part printed on the 3DP are oversized and the accuracy of 3DP compared to FDM is 0.07 mm considering the overall length. The CNC and Casting are undersized compared to the 3D digital model. Error in the accuracy of CNC with respect to 3D digital model is 1.08% as compared to 0.89% for RP and casting process. The accuracy of the FDM process is higher than all the other process. The repeatability of the FDM was checked and It was noticed that the FDM is more accurate when printing along X axis. Z axis has more error compared to X and Y.

Normally the accuracy of the CNC machine is higher that the RP. RP accuracy is 0.005 to 0.030 inches, whereas CNC is 0.0005 to 0.005 inches. But the implant built using CNC had a lower accuracy which could be due to the following reasons.

- Use of CNC training machine
- Use of not a professional CAM software
- 3mm diameter tool was selected for the finishing process. It would have been better to use a 1.5mm diameter tool for finishing. This was not used because the cutting length was shorter than the depth of cut.
- Finish the part using grinding machine.

It is also noticed that the part produced on the 3DP is bigger than the actual size due spreading of the binder during printing.

5. Conclusion

Considering the results it is noticed that CNC process can produce a condyle implant at low cost and shorter manufacturing time. It is seen from this project that CNC trainer machine and CAD/CAM education software can be used to produce an implant further reducing the cost of the implant. For implants of Condyle, error up to 1mm can be accepted therefore the implant produced using RP and CNC process are acceptable. 3DP produced biomodel at shorter time than the FDM at low cost, so 3DP can be used instead of FDM for manufacturing Condyle implant through casting. From the results the manufacturing process can be arranged in ascending order of preference based on time, cost and accuracy analysis as Direct CNC process, 3DP-Casting process, FDM-Casting process. It should be noted that this ranking is based for manufacturing the condyle using the facilities available in the educational institute. If a different anatomical part needs to be manufactured, it would be cheaper using some other manufacturing process and machine.

Choosing the best technology for the manufacturing of implant depends mainly on understanding how to balance time, quality or cost of the manufacturing process for which thorough knowledge of both RP and CNC is required.

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