COMPUTER AIDED DESIGN AND MANUFACTURING OF REVERSE SHOULDER PROSTHESIS: A 3D PRINTER STUDY

Didem Venüs YILDIZ[a,b], Mehmet Burçin PİŞKİN[b]*

[a], *9 Eylül University, İzmir Vocational School, TURKEY*
[b] *Yıldız Technical University, Chemistry Metallurgical Faculty, Department of Bioengineering, TURKEY*

**Corresponding Author: venus.yildiz@deu.edu.tr*

ABSTRACT
The shoulder joint is a more complex structure than the hip or knee joints. In addition to the overall complexity of the shoulder joint, two different factors influence the insufficient outcome of shoulder replacement: the shoulder prosthesis design is far from fully developed and it is difficult to place these shoulder prosthesis due to shoulder anatomy. There are various treatments for any shoulder failure such as total shoulder arthroplasty and reverse total shoulder arthroplasty. Due to its reverse design than normal shoulder anatomy, reverse total shoulder arthroplasty has different physiological and biomechanical properties. Post-operative achievement of this arthroplasty depends on improved design of reverse total shoulder prosthesis. In this study, data of human shoulder was collected by 3D Computer Tomography (CT) machine in dicom format. This data transferred into 3D medical image processing software to reconstruct patient's shoulder bones geometry. 3D design of prosthesis was imported into 3D printer system to manufacture the structure. In this study, application of 3D design and 3D printing technique were demonstrated for the orthopedic surgical procedures. This additive manufacturing technique opens new doors to patient specific implants and customized treatment with several advantages as less production time, prosthesis longevity, cost savings and pre-operative planning opportunity.

Keywords: Reverse Total Shoulder Prosthesis, Custom-Built Implants, 3D Printing Technique

1. INTRODUCTION
The shoulder joint is the most moveable joint in the human body [1] and a more complex structure than the hip or knee joint. [2] In addition to the overall complexity of the shoulder joint, two different factors influence the insufficient outcome of shoulder replacement: the shoulder prosthesis design is far from fully developed and it is difficult to place these shoulder prosthesis due to shoulder anatomy.

The human shoulder is made up of three bones such as the clavicle, the scapula and the humerus as well as related muscles, ligaments and tendons. [2, 3] Associated articulation of these bones gives to the human arm the greatest mobility in the human body with allowing a large range of combined motions. [1, 4]

Independent articulations occurs in the shoulder bones contributes the shoulder complexity. [2] The scapulothoracic articulation and the glenohumeral joint are the most important articulations which have the largest contribution of shoulder total motion. [3]

Until today, for treatment of shoulder defects, different shoulder arthroplasties have been performed. The first, second, third and fourth generation of shoulder prosthesis design and arthroplasty were defined as mono-block implants, humeral implants incorporated by modular humeral heads with coating for bone ingrowth, humeral implants with variable design parameters allowance as head diameter, retroversion, medial offset, posterior offset and reverse total shoulder prosthesis respectively. Today, the fourth generation of shoulder implants as reverse design of anatomical shoulder are currently using in shoulder arthroplasties. Three dimensional (3D) pre-operative planning of surgeons and 3D printing technology are the future trends of shoulder arthroplasty. 3D designed and 3D printed patient specific prosthesis enables the implant to fit the bone exactly by construction of geometries matching fully with the defect sides. 3D design and 3D printer technologies offer reconstruction of patient's own anatomic shoulder geometries, which are suitable for such arthroplasties. [5]

The reverse total shoulder prosthesis (RTSP), which is described as an alternative way for treatment of especially rotator cuff tear arthroplasty or irremediable massive rotator cuff tear, creates different joint biomechanics than the native shoulder by replacing the joint's ball and socket location oppositely than in total shoulder prosthesis. [1, 6, 7] Moreover, until today there are insufficient numbers of computational methods' investigations, used in biomechanical observations that have evaluated the shoulder function after a reverse total shoulder arthroplasty (RTSA). [1]

The disadvantages of reverse total shoulder prosthesis are scapular notching and impingement. [7] The incidence of scapular notching has high rates and varies between 44% and 96%. [7] Therefore, advanced technological 3D designs with computer and their computational analysis for reverse total shoulder prosthesis need to be studied to overcome these disadvantages. Currently, three dimensional modelling can improve the designing of joint replacements. [1] In addition, selection of appropriate manufacturing technique has great importance due to its direct effects on achievement of the shoulder arthroplasty. Recently, significant technological progresses were made in computer-aided design and manufacturing (CAD/CAM) and 3D printing especially for bone reconstruction in the orthopedic surgery. [8]

Additive manufacturing (AM) or rapid prototyping (RP) technology, which is a fabrication method using additive technique, have great potential to take place of the traditional manufacturing techniques. This technology makes possible to fabricate physical structures through data provided directly by a 3D geometric model CAD system. AM technologies has been classified in seven categories including stereo lithography, poly jet, binder jetting, material extrusion, sheet lamination, powder bed fusion, stereo lithography, and direct energy deposition by The 'American Society of Testing and Materials' (ASTM) International committee. The direct metal laser sintering (DMLS) is also known as selective laser melting (SLM) and is one of the 3D printing techniques, with making possible to print designs in metals. AM technologies use a design constructed in a 3D modeling software and digital light processing (DLP) technology to print the 3D object. [9]

This rapid prototyping offers to build body parts in complex geometries with different materials in less time and cost. [11] Three-dimensional printing is a rapidly growing technology [10] in orthopedic surgery and contributes the improvement of shoulder prosthesis quality. Furthermore, this technique make possible to clinicians can examine patient specific anatomy and can make pre-operative planning without direct inspect on patient. Recently, individualized treatment becomes popular and this technique only serves to this purpose. In addition, the use of 3D models of anatomical constructs is widely spread on educational area in medicine. This method is effective, time shortening and economic for this area.

This study presents 3D printing technology, which was used to manufacture a customized shoulder prosthesis. For this purpose, 3D design was carried out with 3D reconstruction of shoulder bone geometries by Mimics software. Furthermore, metal 3D printer as additive manufacturing technique performed fabrication process of the reverse total shoulder prosthesis. 3D printing method, compared to traditional ones, has shorter time to manufacture and is practical manufacturing technique with allowing direct prototyping.

2. MATERIAL AND METHOD

2.1. 3D Computer Design:

The bone geometries of patient's shoulder, 3D reconstructed by medical image processing software (Mimics Materialise ver. 19.0, Materialise, Leuven, Belgium). For this purpose, three steps were followed respectively as (i) data acquisition, (ii) image processing of computer tomography (CT) data and (iii) 3D CAD modeling of the shoulder. In data acquisition stage, shoulder of a 42-year-old male patient who needed reverse total shoulder arthroplasty, was scanned by CT machine (Philips, Brilliance, 64 slice CT scanner, Koninklijke Philips N.V, Netherlands) in 9 Eylül University Hospital.
Computer tomography data was provided in dicom format (Digital Imaging in Medicine and Communications) which is medical imaging's standard format (512 × 512 pixels, pixel size: 0.803 mm and slice thickness: 0,2 mm). This standard format was firstly announced in the year of 1985 in order to systematize data from various devices: X-ray, MRI, and CT. In our study, voxels of CT images were stored by this format with the information of material status, age, examination.

The CT images were introduced into Mimics software to reconstruct geometrical bony structure of the shoulder (Figure 1). CT scans processed by Mimics Software (Materialise, Leuven, Belgium) as masking, segmentation, 3D model formation and reconstruction of the patient's own shoulder model (Figure 2). Also 3-Matic medical design software, which converts Mimics processed image to entire triangular surface meshes, was employed for prosthesis part design. The stem of prosthesis was designed in proper shape and size according to the canal cavity of the patient's humerus. In addition, stem's outside was constrained as rough surface shape in order to enable proper adhesion to the bone. Moreover, screw cavities were created inside of the stem for proper fixation of the prosthesis to the bone. A guide was designed for screw's placement into the cavities.

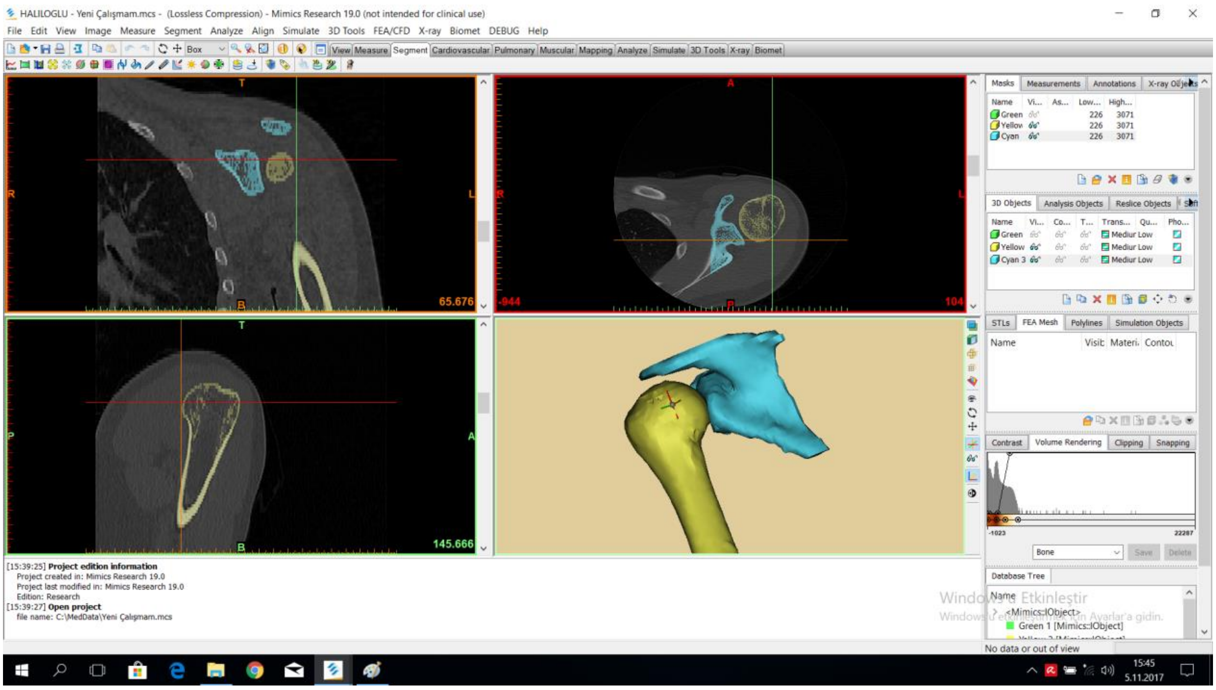


Figure 1. CT images of patient's humerus and scapula with applied anatomical coordinates using Mimics Software for image segmentation.

At surface of humerus head, a 360^0 canal was opened to fit polyethylene insert of the prosthesis. In this canal, also small processes were constrained in order to avoid of polyethylene part's movement. Polyethylene part's surface was constituted in large angle form in order to provide free rotation movement of the prosthesis sphere. In addition, a screw, which puts together scapula and sphere, was located to the posterior side of the prosthesis. Moreover, an additional polyethylene part, which allows creating convenient surface for attachment of scapula and sphere to each other, was fixed onto scapula by two screws (Figure 3).

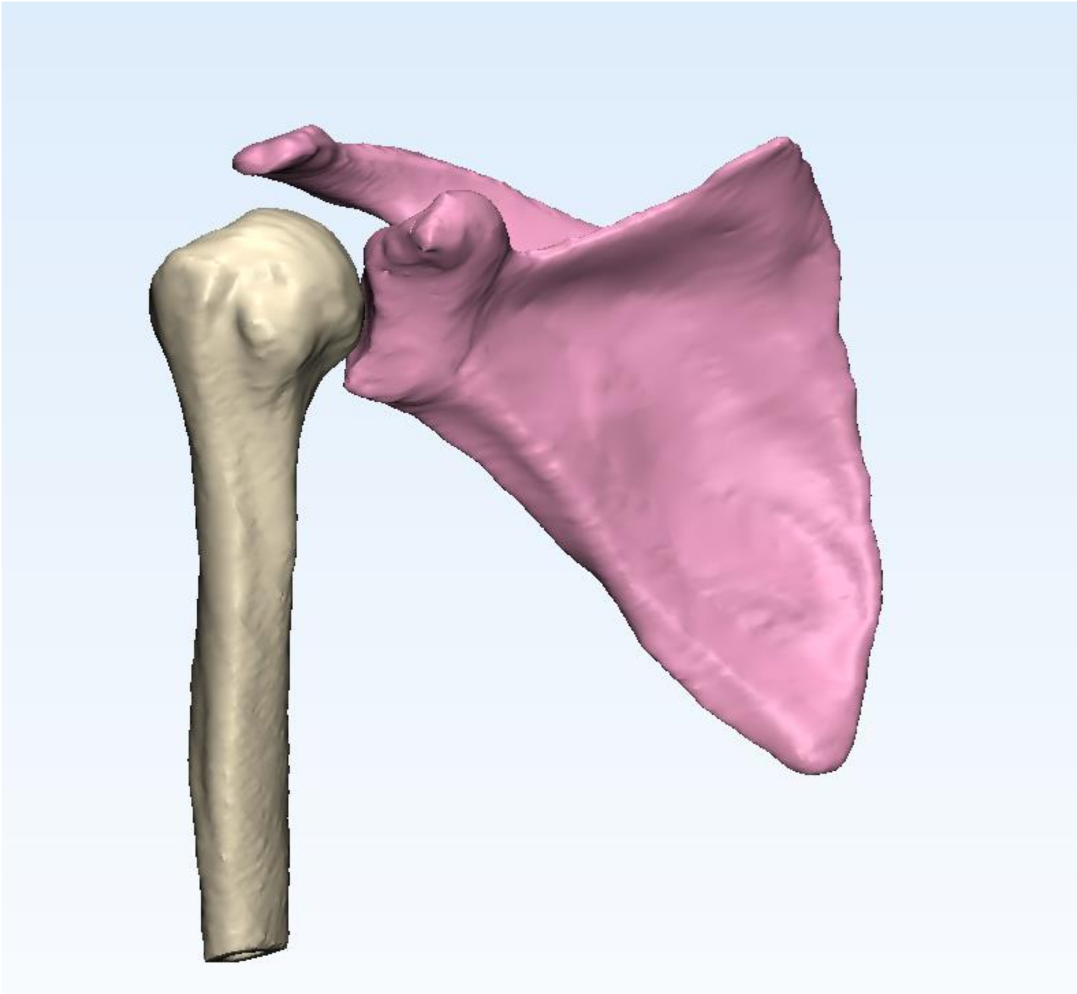
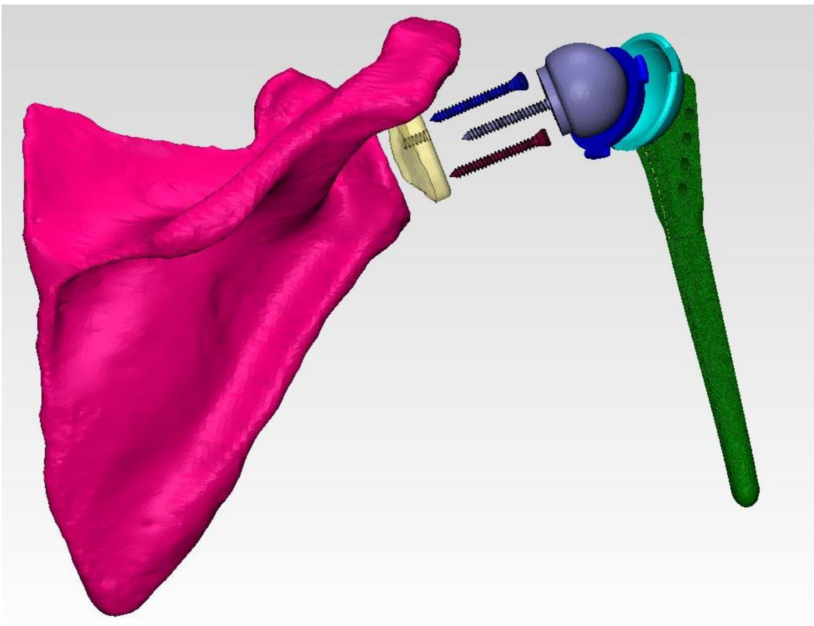
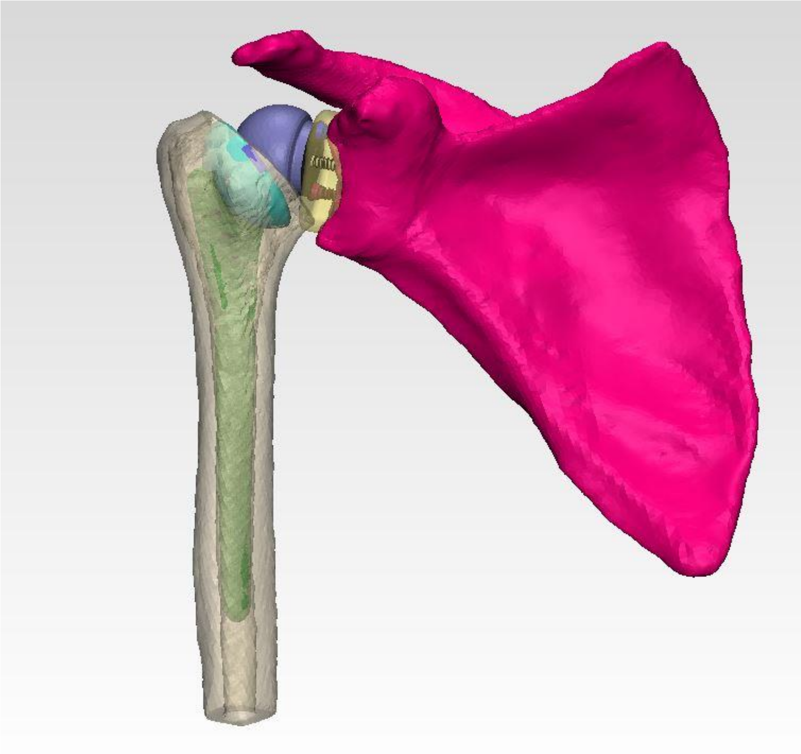


Figure 2. 3D Reconstructed Shoulder Model



A



B

Figure 3. 3D CAD Design of Prosthesis for surgical procedure **A.** Prosthesis Parts Open Demonstration **B.** Fixed Prosthesis inside the bone.

2.2. 3D Printer Manufacturing

The created 3D design of constrained shoulder prosthesis was imported as a structure completely with triangular surface meshes in .STL file into 3D metal printer system (Figure 4). The prosthesis was fabricated by DMLS technique using the Concept Laser 3D Printer (GE Additive, Lichtenfels, Deutschland) shown in Figure 5. In this technique, in a thermally controlled and vacuumed environment inside the machine chamber, metal powder in a powder bed melted layer by layer with an infrared laser. This melting resulted in bonding of the metal powder created a structure in the related layer. Once one layer was processed, new powder was spread onto bed as another layer and was melted by laser again. The process circulated until prosthesis creation was accomplished. The metal powder used in this study was Ti_6Al_4V alloy with material specifications as 110 GPa Young's Modulus and 0.3 Poison Ratio (Table 1). [12]

Multi material 3D printing is performed for prosthesis construction including polyethylene (PE) and metal parts with different 3D printers. Metal printing part was mentioned above. Polyethylene was Ultra High Molecule Weight PE with mechanical properties as 1.2 GPa Young's Modulus and 0.4 Poison Ratio (Table 1). [16] Polyethylene part was printed by Stratasys 3D printer (Stratasys, Los Angeles, CA, USA). This 3D printer work principle is layer by layer similar to one mentioned above. However, in this 3D printer there is glue instead of laser for bonding materials layer by layer. In addition, in this 3D printer, there is no need to vacuum environment in the process chamber.

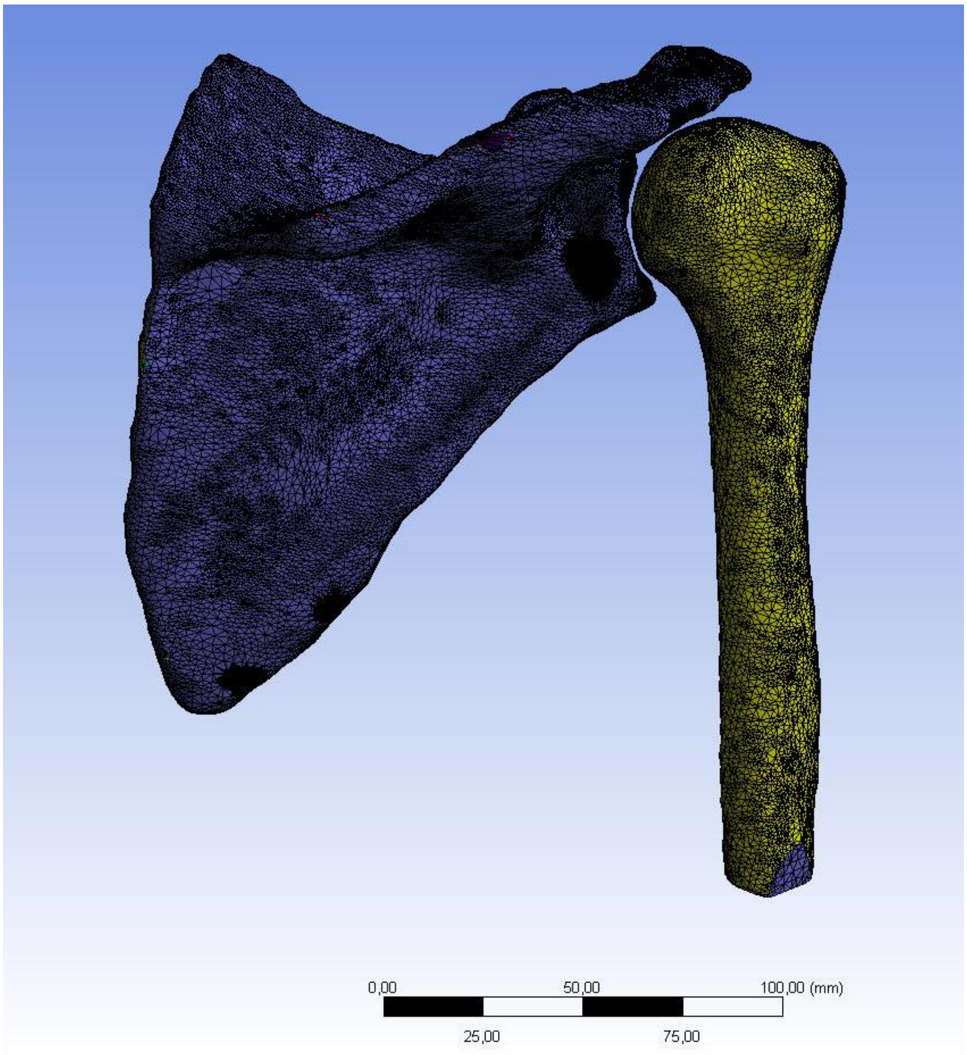


Figure 4. Triangular Surface Meshes Design of Shoulder Model

Çizelge 1. Description of the constitutive laws used in materials. [13, 14, 15]

Element	Type of the Law	Mathematical Expression	Constants	References
Bone	non-homogeneous, isotropic, linearly elastic	$E(\rho)=E_0\{\rho/\rho_0\}^2$ $\nu = \nu_0$	E_0= 17 GPa, ν_0=0.29 ρ_0=1.8 g/cm^3,ρ:bone density	[13,14,15]
Titanium Alloy	Homogeneous, linear elastic, isotropic	Hook's Law: **σ = Dε**	E_0=110 GPa ν_0=0.3	[13,14,15]
UHMWPE	Homogeneous, linear visco- elastic	$\varepsilon_{ch} = ln\sqrt{tr(B)/3}$	E_0=1.2 GPa, ν_0=0.4	[15,16]

Figure 5. Metal 3D Printer

3. RESULTS

In current study, a manufacturing method for custom made shoulder prosthesis with 3D modelling and printing was dev eloped by reconstructing the shoulder geometry from CT data. The prosthesis-bone geometric match has great importance for shoulder arthroplasty achievement, therefore custom-made prosthesis design and manufacturing rapidly increase and this method is the accurate method to produce patient specific prosthesis.

In current study, multi-material printing have been performed. Polyethylene and titanium alloy were 3D printed by different 3D printers. Titanium alloy was used as material of metallic part of the prosthesis due to its advanced biocompatibility and its high physical properties (mass, rigidity, elastic modulus, high toughness, corrosion resistance) make it possible easy manufacturing. There are various biocompatible materials used in orthopedic surgery as stainless steel, cobalt-chrome alloys etc. Although these mentioned materials have good physical properties, titanium alloys are the best choice due to its manufacturing ease and biocompatibility compared to others.

This study demonstrated that 3D reconstruction of body parts with complex geometry in different types of materials can be carry out with advantages including less time and cost compared with other manufacturing processes. Furthermore, 3D printing of prosthesis allows customized design and fabrication, which is suitable with individual patient's needs in terms of shape, size and mechanical properties. The prosthesis produced in this study is patient specific reverse shoulder prosthesis with improved quality. Improved designs of prosthesis have direct impact on prosthesis longevity and decrease requirement to revision arthroplasty.

In addition, patient specific 3D printed model of scapula produced from CT scans of patient was shown in Figure 6. This model can be useful tool in preoperative planning or in medicine education.

Although different studies reported application of this technology to pre-operative planning of surgeries, this data is insufficient. This study shows that 3D designation and 3D printed shoulder models could be valuable tool to assist surgeons overcoming challenges of operations due to shoulder complexity.

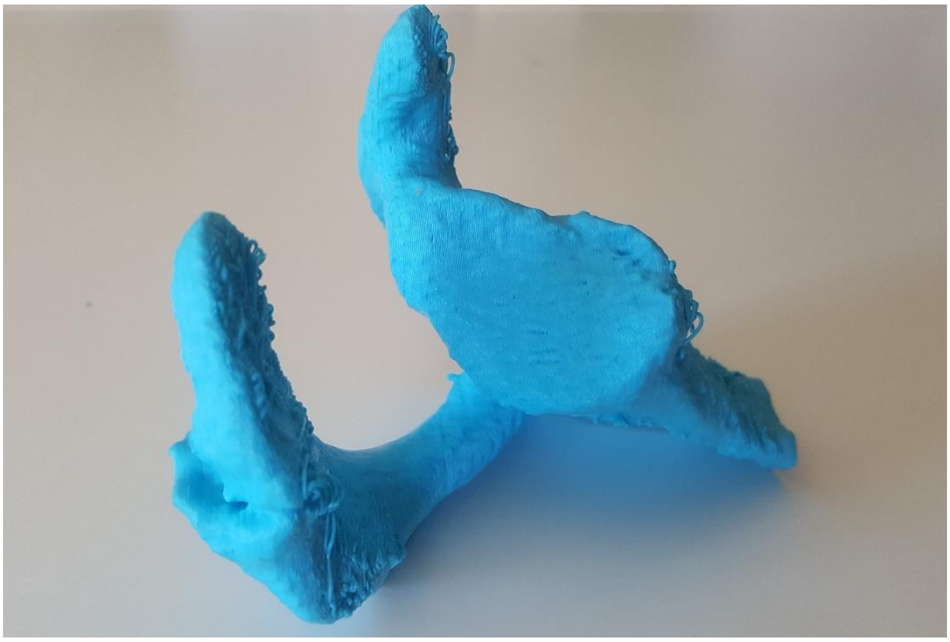


Figure 6. 3D Printed Scapula Model made by PLA (Polylactic acid) material.

4. CONCLUSION

Current study investigates the application of 3D modelling and printing method for the shoulder arthroplasty. 3D printing, which is one of the AM technologies, open new doors for individualized treatment in joint replacement surgery. The further advances in 3D design and printing could increase the number of customized prostheses and could serve as a useful clinical tool for both patient and surgeon benefits in the future.

Implant fit accuracy into the bone is one of the major factors effects on surgical achievement. 3D computer aided design and 3D printing techniques constrain prostheses, which exactly fit to the bone. Prosthesis fabricated with 3D printer technique has several advantages including improved design quality, less fabrication time, cost savings, and shorter operation time with allowing pre-operative planning to surgeon. Pre-operative planning allows medical staff to simulate the surgical operations before its performance. With this opportunity, surgical procedures can be optimized and can be carried out in less time. This will result in significant cost savings for health facilities and decreasing risks to the patient. Although CAD/CAM technology has these advantages, the limitations of this technology is that it requires highly trained personnel.

3D design and printing are not only used in prosthesis manufacturing in healthcare field but also they are used in medical educational purposes at increasing rates. The medical educational usage of these technologies has good consequences such as time effectiveness, economic and postoperative predictive rather than its alternatives. These advanced technologies serves the public health and large number of people, who need orthopedic surgical procedures, around the world.

In the light of this study, further work should be performed for improve surgical procedures, prosthesis quality and preoperative planning opportunity for surgeons.

ACKNOWLEDGE

This study was financially supported by Scientific Research Projects Grant Council in 9 Eylül University.

REFERENCES

1. Martins A, Quental C, Folgado J, Ambrósio J, Monteiro J, Sarmento M.. Computational reverse shoulder prosthesis model: Experimantal data and verification. Journal of Biomechanics. 48(2015)3242–3251.
2. Engin A.E., Tümer S.T.. Three-Dimensional Kinematic Modelling of the Human Shoulder Complex—Part I: Physical Model and Determination of Joint Sinus Cones. Journal of Biomechanical Engineering. May 1989, Vol. 111/107.
3. Maurel W., Thalmann D.. Human shoulder modeling including scapulo-thoracic constraint and joint sinus cones. Computers & Graphics 24 (2000) 203-218.
4. Halder A., Itoi E., An K. Anatomy And Biomechanıcs of The Shoulder. Orthopedic Clinics Of North Amerıca. Volume 31 Number 2 April 2000
5. Deore V., Griffiths E., Monga P. Shoulder arthroplasty- Past, present and future. Journal of Arthroscopy and Joint Surgery 5 (2018) 3-8.
6. Kim M., Lim K., Lee D., Kovacevic D., Cho N. How does scapula motion change after reverse total shoulder arthroplasty? - a preliminary report. BMC Musculoskeletal Disorders 2012, 13:210.
7. Smith T., Bäunker A., Krämer M., Hurschler C., Kaufmann M., Pastor M., Wellmann M.. Biomechanical evaluation of inferior scapula notching of reverse shoulder arthroplasty depending on implant configuration and scapula neck anatomy. International Journal of Shoulder Surgery 2015;9:103-109.
8. Qassemyar Q., Assouly N., Temam S., Kolb F.. Use of a three dimensional custom-made porous titanium prosthesis for mandibular body reconstruction. International Journal of Oral&Maxillofacial Surgery. 2017; 46: 1248-1251.
9. León M., Rubio J., Calatayud J., Özcan M.. Impression Technique For A Complete-Arch Prosthesis With Multiple Implants Using Additive Manufacturing Technologies. The Journal Of Prosthetıc Dentistry. Volume 117 Issue 6. June 2017.
10. Birbara S, Otton J, Pather N. 3D Modelling and Printing Technology to Produce Patient-Specific 3D Models. Heart, Lung and Circulation. (2019) 28, 302-313.
11. Jardini A, Larosa M, Filho R, Amelia C, Berbardes L, Lambert C, Calderoni D, Kharmandayan P. Cranial reconstruction: 3D biomodel and custom-built implant created using additive manufacturing. Journal of Cranio-Maxillo-Facial Surgery 42 (2014) 1877-1884.
12. Hua Z., Fan Y., Cao Q., Wu X. Biomechanical Study on the Novel Hemi-Pelvis Prosthesis. Journal of Bionic Engineering 10 (2013) 506 – 513.
13. Büchler P., Ramaniraka N.A., Rakotomanana L.R., Iannotti J.P., Farron A.. A finite element model of the shoulder: application to comparison of normal and osteoarthritic joints. Clinical Biomechanics. 17 (2002) 630-639.
14. Büchler P, Farron A. Benefits of an anatomical reconstruction of the humeral head during shoulder arthroplasty: a finite element analysis. Clinical Biomechanics 19 (2004) 16–23.
15. Sharma G, Debski R., McMahon P., Robertson D. Effect of glenoid prosthesis design on glenoid bone remodeling: Adaptive finite element based simulation. Journal of Biomechanics 43 (2010) 1653 – 1659.
16. Bergström JS, Rimnac CM, Kurtz SM. Molecular chain stretch is a multiaxial failure criterion for conventional and highly crosslinked UHMWPE. Journal of Orthopaedic Research. 2005 March 23 (2): 367-375.