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Research Article

Finite Element Analysis of Patient-Specific Bone Plate with Ti6Al4V Material Selection

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Abstract

A patient-specific implant is a designed implant that considers the needs of a specialized patient's condition. In several surgical cases, the implant design needs to be adjusted based on the patient's bone surface to suit the bone morphometry. This study aims to conduct the finite element analysis (FEA) to investigate the stress distribution alongside the plate performance and estimate the installation's clinical failures before the manufacturing process. A bone plate has been designed following an adult pelvic bone shape for the pelvic fracture's clinical case management. The FEA calculation achieved the highest number of von Misses stress (VM) on the pelvic bone plate by 3.616 MPa. The obtained VM number on the simulation is smaller than the yield strength of Ti6Al4V. It concludes that the customized iliac plate's design using Ti6Al4V can have excellent mechanical strength and withstand the loading. An additional similar simulation using another software strengthens the results.

Keywords: *finite element analysis; bone plate; implant; titanium alloy*

Analisis Elemen Hingga pada Plat Tulang Pasien Khusus dengan Pemilihan Bahan Ti6Al4V

Abstrak

Implan khusus pasien adalah implan yang dirancang dengan mempertimbangkan kebutuhan khusus pasien. Dalam beberapa kasus pembedahan, desain implan perlu disesuaikan dengan permukaan tulang pasein agar menyesuaikan morfometri tulang. Penelitian ini bertujuan melakukan analisis elemen hingga (FEA) untuk mengetahui distribusi tegangan pada sepanjang badan pelat dan memperkirakan kegagalan klinis instalasi sebelum proses pembuatan. Pelat tulang dirancang mengikuti bentuk tulang panggul orang dewasa untuk manajemen klinis, khususnya fraktur panggul. Perhitungan FEA mencapai jumlah tegangan von Misses (VM) tertinggi pada pelat tulang panggul sebesar 3,616 MPa. Angka VM yang diperoleh pada simulasi ini lebih kecil dari kekuatan luluh Ti6Al4V. Penelitian ini menyimpulkan bahwa *desain pelat yang disesuaikan dengan kondisi pasien dan pemilihan bahan Ti6Al4V memiliki kekuatan mekanik yang sangat baik dan dapat menahan pembebanan. Sebuah tambahan simulasi yang serupa dengan menggunakan perangkat lunak lain memperkuat hasil penelitian ini.*

Kata Kunci: *analisis elemen hingga; pelat tulang; implant; paduan titanium*

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I. INTRODUCTION

One of the cutting-edge technologies in these recent years as problem-solving in engineering, physical, and mathematical modeling is the finite element analysis (FEA) method. FEA is a numerical analysis for understanding the prediction of mechanical performance in specific fields [1]. This projection is trustworthy to reduce development time and cost, so the value of the efficiency and the effectivity will accomplish the purpose of many constructions [2].

FEA has a huge impact in the manufacturing process, whereby one of the most applications that face the effect is the manufacturing of medical devices, particularly implant equipment [3]. The assembling of implant components is predominantly made of metal alloys and composites [4,5]. The material used for implant assemblies must meet the biocompatibility criteria, wear resistance, and high resistance of the corrosion process, and osteointegration [4]. Most orthopedic implant manufacturers use Co-CR alloys, stainless steel (SS316L), Ti, and Ti alloys; because these three materials are proven to have biocompatible properties [4]. Based on several implant's latest review papers, Ti and its alloys have the best wear and corrosion arrangement [4]. Despite the development of titanium alloys for metal implant material being popular research, the Ti alloys raw material is costly and difficult to cast [6]. The utilization of this raw material must be as economical as possible to lessen research and fabrication expenses; therefore, FEA can be an alternative to estimate the optimum result of the fabrication plan [7].

Nowadays, the implant component's design considers the most people's anatomical background to ensure the approximation of human organ size will fine-tune the part's dimension. The existing commercial implants are manufactured by well-known companies, such as Scorpio, NexGen, and Native-Knee, are adjusted for the entire human race [8]. However, several reports of bone anthropometry study, regarding the investigation of whether the existing implant components in several countries are appropriately fit its population, were found to have a slight incompatibility in differences of several millimeters and suggested to be adjusted to better fits patients [8–11]. Also, major surgery cases need an exclusive implant design based on the loss of organ part of the patient [12–14]. The development of implant configuration, either for the existing commercial product or the patient-specific implant, must be performed many times to certify the implant surgeries will be undergone well and has a high percentage of satisfaction in post-market evaluation [14]. The FEA study can be conducted to forecast stress, heat, mass, fatigue, and probability of failure both in manufacturing and in installation [15]. It is believed to appraise whether an implant model's manufacturing process will accommodate the patients need.

Experimentation of FEA in implant designing demands a recommendation related to the calculation before implant machining. FEA experimentations principally were finding the von Mises stress as a parameter to determine if the used material will be yield or fracture [1,2]. To date, several FEA investigations have been done, both the existing implant with a slight difference and the new design or based on the patient condition [14–20]. This research theme will update the recent phenomenon, particularly when a new technique has been built based on a specific case [21]. In Indonesia, research of FEA for implant planning is scarce to be conducted. The latest FEA research in Indonesia mainly focuses on the existing devices, such as total knee replacement and total hip replacement [22,23]. There is no research on Indonesian human bone anthropometry as well as the correlation between the shape of Indonesian human bone and the implant installation of the existing devices. Therefore, no implant devices are manufactured based on the anatomical background of Indonesian human bone. Yet, to support Indonesia to be an independent country in providing health access, the ability to create medical devices, including patient-specific implants, is urgently needed.

Hence, this study aims to build a new implant device design, particularly a fixation plate. This plate is constructed following the iliac bone surface of a patient's imaging data. This study expects to answer whether the fixation plate can be manufactured using biocompatible material of Ti6Al4V by investigating it using the FEA method. The result includes the economic aspect of material utilization. The practical validation was also conducted to confirm this recommendation study.

II. METHOD

CT-Data Preparation

The primary data was obtained from free source imaging data of Osirix named AMNESIX. The Osirix-Viewer provides many digital imaging and communication in medicine (DICOM) image sample sets for research and teaching in their online library. The study's utilized data is recorded by a modality of computed tomography abdomen (CTA) in the post-stent placement of 64 detectors [24]. The patient of this sample data has an iliac aneurysm. The data was loaded in the Radiant software, which has free-access for the first 90 days.

Medical Image Processing

Volume Rendering

Volume rendering is a process to compose the sequence of two-dimensional (2D) slice data in medical imaging to have three-dimensional (3D) volume data [24]. In this study, volume rendering is employed using Radiant software by utilizing a tool of 3D. This tool will automatically render the slices of CT data to build 3D volume data.

Segmentation and 3D Modelling

The volume data consist of the whole lower body image. However, in this study, we limit the organ for the iliac area. Segmentation will cut the region of interest in the iliac area to be separated by outer parts. The segmentation step is also executed using Radiant software by utilizing sculpt tool [25,26]. The segmented iliac bone in the display view of Radiant software is converted into the 3D model. Generally, a 3D model has a format of stereolitography (STL). The STL format is a ready-to-print format of a 3D object. The conversion process is done using the conversion tool in Radiant software. The selection of STL format adjusts to the compatibility for image restoration software.

Image Restoration

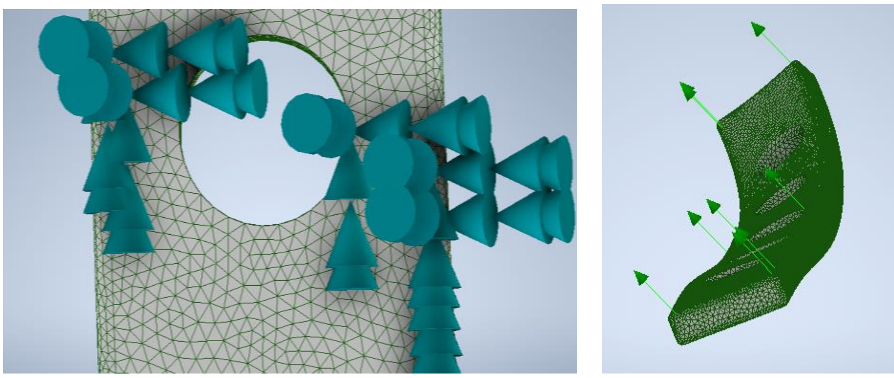
The 3D STL data from the 3D modeling step is broken. The object's surface is not entirely closed, and several parts of the region are missing. Besides, the 3D modeling's result provides several noises around the object's interest. Unneeded parts, such as femur heads and blood vessels, must be removed as well. The image restoration phase will fix the solid part of the iliac bone [24]. This process aims to achieve a better surface and an identical shape to the bone for constructing the specific plate. Image restoration is done using Autodesk Powershape software tools: cut, mirroring, fillet, meshing, and surface inspection.

Implant Designing

A wireframe tool is drawn 8 cm horizontally along the right ilium to make the patient-specific plate. Since the wire adjusts the ilium surface, the wire was automatically lengthening around 2 mm. After that, the wire was drawn for the width of 1 cm and the height of 0.5 cm. The edge of wire in the height, width, and length was curved with a radius of 2 mm for having smooth edges. The plate dimension was considered based on the commercial plate for iliac bone, i.e., Johnson and Johnson pelvic implant instrument. However, the commercial plate is manufactured in the straight line and does not follow the specific-patient's surface. 3D model for implant designing is done using Autodesk Powershape [26].

FEA Simulation

The fixation plate's design was saved into initial graphic exchange specification (IGES) to be run at the FEA software of INVENTOR. This FEA simulation study was started by dividing the plate structure into smaller elements and produced 162143 elements. Once dividing process, the plate was given a load of 307 N. This load number is based on load transfer data that passes through the pelvis in an adult [27]. The direction of the load is on the side that not in contact with the surface bone. Meanwhile, the side attached with the bone that will be placed for screws is constrained. Figure 1a shows the given load, and figure 1b shows the side of the plate that is constrained. The Ti6Al4V properties provided in table 1 are the parameter inputs in the simulation. FEA simulation will estimate the von Mises stress regarding to the material property set, particularly the density, tensile strength, yield strength, elastic modulus, shear modulus, and poisson's ratio.



(a) (b)

Figure 1. The Constrained Position (a) and The Load Placement in The FEA Simulation

Table 1. Mechanical Properties of Ti6Al4V[22]

Parameter	Value
Density (kg/m^3)	4428.78
Tensile Strength (GPa)	1.05
Yield Strength (GPa)	0.87
Elastic Modulus (GPa)	104.8
Shear Modulus (GPa)	41.02
Poisson's Ratio	0.31

Validation Study

In this validation study, the FEA simulation will be run in another FEA software, particularly ABAQUS. The simulation steps are similar to the simulation using INVENTOR. The plate was divided into more minor elements, setting the same numbers of constrained and load sides, and input the mechanical properties of Ti4L6V.

III. RESULTS AND DISCUSSION

Data Acquiring and Image Processing Results

Figure 2 shows the acquired data. Radiant software presents information when took the data. The data has 1624 slices of two-dimensional images, recorded and saved into DICOM data in lossy compression mode. In the top right of Figure 2, the Radiant software shows that the data was taken from the diaphragm to the ankles. In the bottom left of Figure 2, the software declares the thickness of the slice, which means that the gap between the two slides is 2.0 mm. The consideration of whether the data can be proposed for designing a patient-specific field has been examined from medical image processing steps. Figure 3a, Figure 3b, and Figure 4a display the image processing results, respectively volume rendering, segmentation, and 3D modeling. Radiant Dicom Viewer can effectively model the medical imaging data, proven in many similar studies [28,29]. The result of image restoration is revealed in Figure 4b. The image restoration process was repeated many times to construct the surface bone. Based on the image restoration final result in the iliac bone area, it turns out that both the ilium right and left surface structure can be reconditioned as the original bone. The plate's design is considered based on one side of the ilium, particularly the suitable ilium surface by this appearance.

Conversion of CT data into volumetric models and then segmentation and cleanup to produce a model of the iliac bone requires a significant amount of data processing, artifact, noise removal, and what to segment and remove the volume. Three preliminary studies using Radiant have demonstrated that these steps can produce high percentages above 80 % in similarity dimensions among CT data, the volumetric model, and the 3D prints [24-26]. Therefore, the resulting model in this study presumes to have a high accuracy representation of the bone.

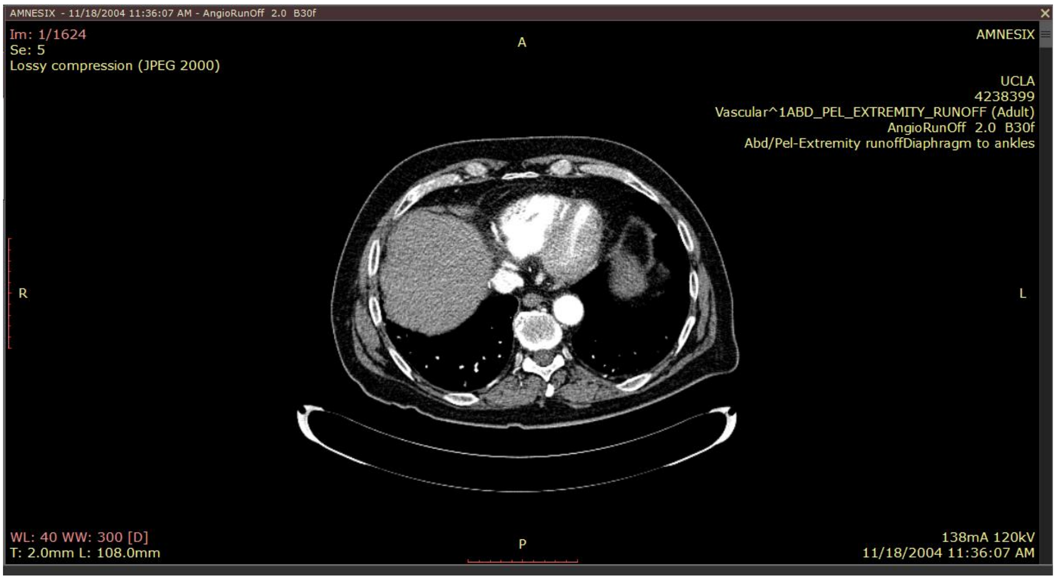
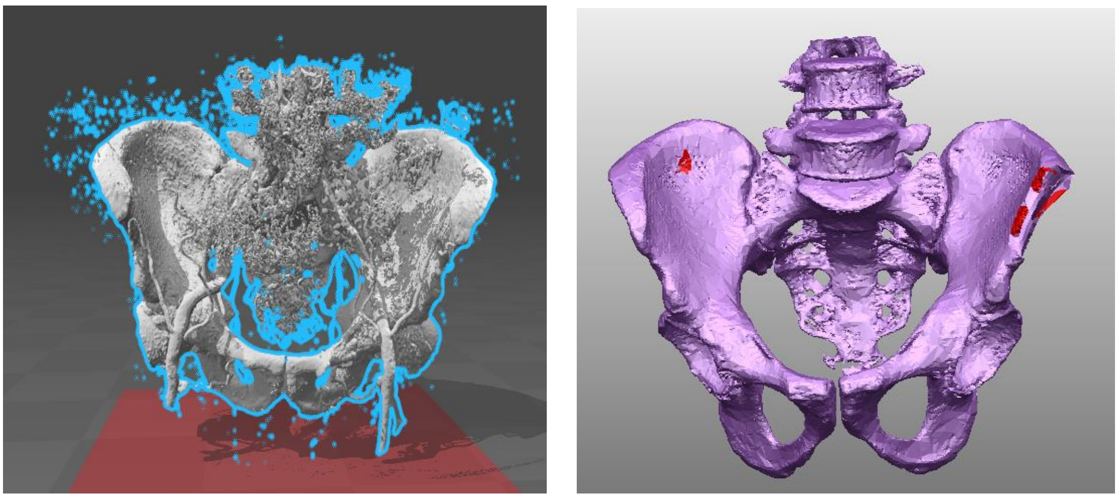


Figure 2. The Acquired Data Loaded in Radiant

(a) (b)

Figure 3. Volume Rendering Result (a) and Segmentation Result (b) Loaded in The Radiant Viewer

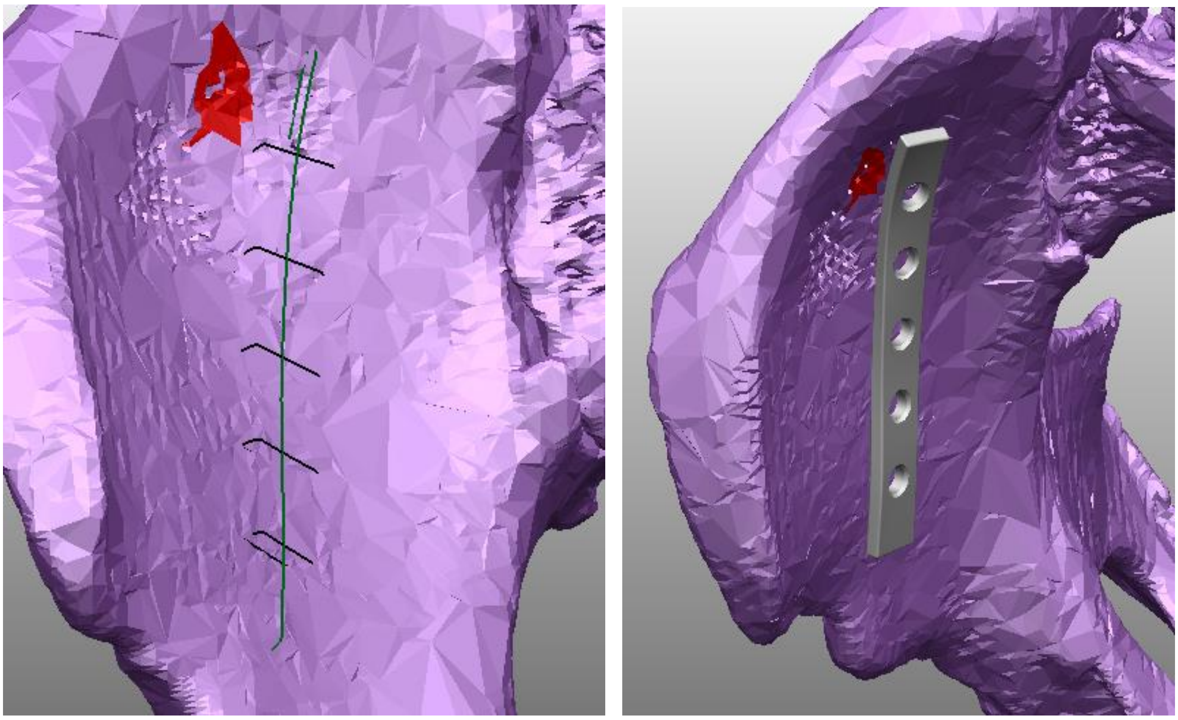


(a) (b)

Figure 4. (a) 3D Modelling Loaded in 3D Builder (b) Image Restoration of Iliac Bone

Implant Designing Result

Figure 5 exhibits the implant design process results. Figure 5a shows the drawn wire that following the structure of iliac bone surface. In the figure 5b, the solid plate was constructed based on the wire that is already drawn completely for the length, height, and width. The Autodesk Powershape is very powerful to build a field that needs a specific surface or irregular surface [30]. However, although many projects have proved prior manufacturing process, in this study, Autodesk Powershape has disadvantages that the constructed plat was read as a surface plan. When the object is directly exported to the ready to print of stereolitography (STL) format, the plate was read only as surface field. To be able to run the FEA simulation, the plate must be converted using Solid8 toolbox and save it to the needed format. The tool of Solid8 will lead to another direction in which it can be changed to the suitable format is for the next step, for example, the format of IGES for ABAQUS software and the format of X_T for INVENTOR and COMSOL.

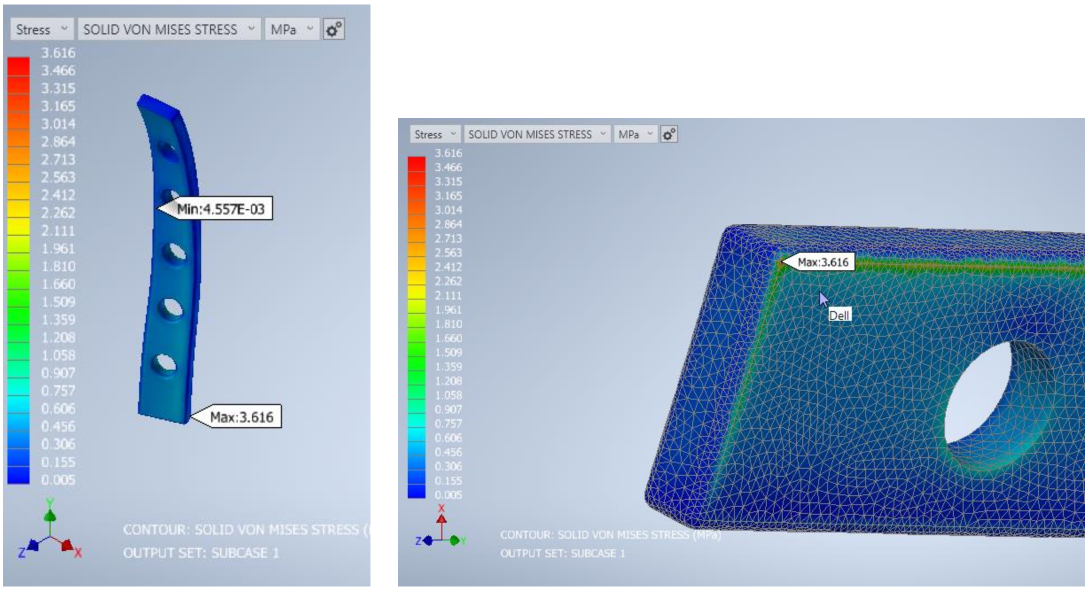


(a) (b)

Figure 5. Patient-Specific Implant Design

FEA Simulation

The FEA simulation in the specific-patient plate for the iliac bone has been undergone. The result of the FEA simulation is given in figure 6. Figure 6 provides the distribution of von mises stresses on many different sides. The highest number of von Mises stresses in the plate is 3.616 MPa, which is very significantly lower than the yield stress value of Ti6Al4V, which is 870 MPa. By this fact, the material is proven to have good mechanical strength that can be competent to withhold the loading. It is in accordance with other research in FEA simulations that generally find the relation between the von Mises stress of the simulation and the yield strength properties of the material [23]. If VM <yield strength, then the material has good mechanical strength to withstand loading, whereas if VM> yield strength, the material has a shortage to withstand loading.



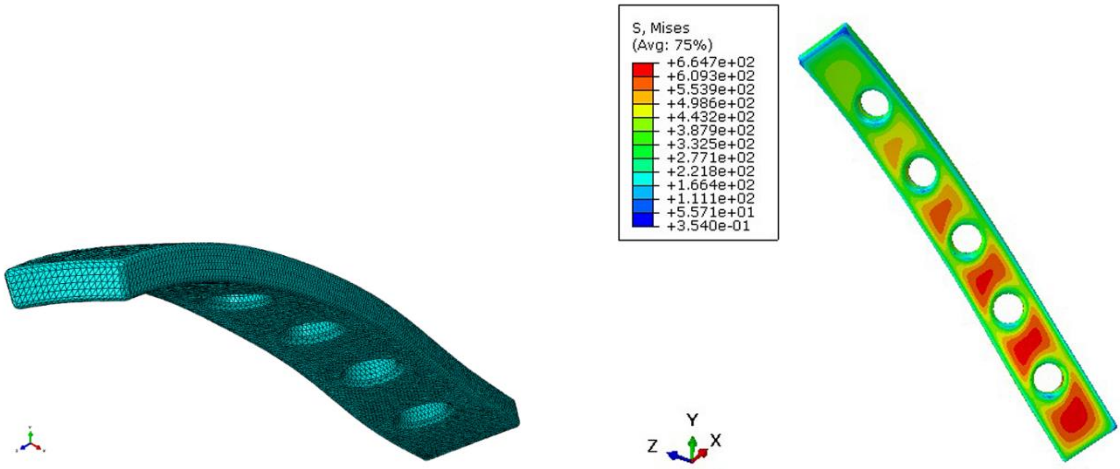
(a) (b)

Figure 6. FEA Simulation Using INVENTOR

Validation Study

FEA simulations have succeeded in many fields using standard software, such as COMSOL, ANSYS, ABAQUS, MATLAB, INVENTOR, and many more [7,14-16,18-23]. However, there is no prior investigation on which results of the simulation are close to the actual properties. This part only supports the previous simulation using INVENTOR, whereby to measure the von Mises stress using ABAQUS. It expects to have a similar result of a lower number than the Ti6Al4V yield's strength. The FEA simulation in this study was started by dividing the plate structure into more minor elements using the form C3D10 elements and produced 744290 elements. The dividing process from the whole plate become the 744290 parts of the meshing plate took more than 4 hours in running time. The meshing plate is shown in Figure 7a. In this study, the more a solid part is meshed in large numbers, the longer the running time will take on the FEA simulation. Despite taking a long time to computerize, the large number in discretization will have a good impact on the whole part analysis. Figure 7b shows that the highest von Mises' number in this simulation is 664 MPa, which is still lower than the yield strength analysis.

To conclude, by having two FEA simulations using different software on this study, despite of showing a huge different number in range, these prove that the design of the patient-specific implant for iliac bone can be built efficiently and should have further analysis. To understand which software that can produce the right number, in the further research, the experiment might separately compare several FEA software with the specific number of forces, the same load placement, and the same constrained value in the 3D model. The comparison cannot refer to the referencing properties of the utilized material's yield strength. The properties on the reference [22] indicate the maximum limit of the simulation should reach. Therefore the computational study will always expect below that limit number. To prove the von Misses stress examination, the simulation results from different software should be compared with a real test in the same number of loads, such as a hardness test using Micro Vicker and a tensile test using Tinius Olsen.



(a) (b)

Figure 7. (a) Meshing Plate on The Purposed Implant (b) FEA Simulation Using ABAQUS

IV. CONCLUSION

Finite element analysis to obtain the value of von Mises stress on the specific design of patient-specific bone plat for iliac implant has been done. The simulation shows that the material of Ti6Al4V can be applied and manufactured for that purpose. From the mechanical properties, it has a good strong position to hold the load.

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