Biomechanical Simulation of Sugita Aneurysm Clip: Reverse Engineering Approach using Metal 3D-Printing

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Abstract. Aneurysm clips have helped hundred cases for brain abnormalities including the haemorrhagic strokes over the world, including Indonesia. As one of the contributors of a hundred trillion rupiahs for medical devices imports each year, the technology of aneurysm clips is expected to be self-manufactured. However, there is no study if the process can be done in the whole country of Indonesia. This study aims to conduct a preliminary study by using an approach of reverse engineering for the Sugita aneurysm clips as an effort to independently provide domestic medical devices. The methods consist of a 3D scanning process, a 3D printing process, biomechanical simulations, and tension measurements. The clip has been scanned and printed using SS316L and Ti6Al4V. Biomechanical simulations reach 0.054 GPa for the von Misses stress and deformation number of 4.0302E-6 mm. The tension measurement on the 3D-printed clip shows identical range numbers compared to the original clip. The experiment concludes that the acquired Sugita aneurysm clip can be reversed using a 3D metal printing and shows a significant similarity on geometrical analysis.

1. Introduction
The reason for an aneurysm clipping is to seclude the aneurysm from the normal flow without closing off any small puncturing arteries or veins close by [1]. Walter Dandy firstly found an aneurysm clipping technique in 1937 with a V-shaped malleable silver clip. This device’s development is followed by other inventions of Olivecrona clips, Mayfield clips, Drake clips, Heifetz clips, Lougheed clips, and Sundt clip in the end of 1967[2]. In the new modern era, the researchers adjusted the manufacturing of aneurysm clip as the requirement of magnetic-resonance (MR) compatible, such as constructed by Sugita, Yasargil and Spetzler [3–5]. Despite of MR-compatible, future evolution needs evaluations of many factors. Biocompatibility and bio-magnetic compatibility, metallurgical patterns, the clip closing pressure that cause catastrophic hemorrhage, non-corrosion material, clap surfaces technology, direction and design that tailor to patients angioarchitecture are challenging improvement [2,6]. Today, almost all countries around the world utilized the aneurysm clip. Several states, for example, Japan, with its trademark of Sugita and Germany with its brand of Yasargil and Perneczky, have manufactured, mass-produced, and distributed the aneurysm clip in many different shapes and their suitable applicators [3,4,7].
The body-part of an aneurysm clip consists of body-shape, leg, closing, and tip [8]. Since 1994 titanium alloy is the material most often employed for the aneurysm clip material [9]. The combination of low density, low Young’s modulus, good mechanical properties, good corrosion resistance, and high biocompatibility make titanium alloys one of the most used materials for biomedical implant materials. Titanium alloys have a much lower Young modulus (55-110 GPa) compared to Stainless Steel alloys 316L (210 GPa) and Co-Cr (240 GPa). However, this titanium alloy still has a much a higher Young modulus than the bone (10-30 GPa)[10–13]. Yasargil and Sugita, as the two most widely used aneurysm clips in the hospitals, manufactures Ti6Al4V for the aneurysm clip material.

In Indonesia, the utilization of an aneurysm clip in Indonesia has started in the last decades. As one of the contributors of a hundred trillion rupiah for medical devices imports each year, is also overburdening the state budget. A national online newspaper in 2020 reported that Indonesian national insurance, called as BPJS, bear debts to hospitals throughout Indonesia in the range of seven trillion rupiahs [14]. The high number of imports of medical devices which reached 92% of the availability of equipment throughout Indonesia contributes to one of the major causes of the debts and national issues. This paper aims to conduct a preliminary study of constructing a reverse engineering model of a high demand medical tool of aneurysm clip. Unlike general metal forming activities in the aneurysm clip’s manufacturing process, this paper tries to overcome it using 3D metal printing [15]. In the end, this research expects to be a solution for Indonesia to become independently providing healthcare access particularly in medical equipment and facilities.

2. Method
2.1. 3D Scanner and Refinement
A Sugita aneurysm clip was acquired from the Siloam Hospital Lippo Karawaci bought by a neurosurgeon, Prof. Dr. dr. Eka Julianta Wahjoepramono, Sp.B. The clip was scanned using the 3D scanner of ATOS 3D Scanner from GOM. The scanning process was tried several times until they achieve the best scanner result. The result from the 3D scanner was refined using the 3D CAD software of Autodesk Powershape 2021. The software of Solid Doctor was used to re-check the problem overlaps, gap, and the hole in the 3D model. The refinement process was conducted to meet the criteria of the additive manufacturing machine.

2.2. 3D Printing and Finishing
The 3D model of an aneurysm clip has been made and adjusted with the 3D printer feature. The model was printed using 3D printing metal of Renishaw AM-400. The Renishaw AM-400 is the latest development of Renishaw platform, a company that leads the sophistication of 3D metal printing over the world. The model was printed using two types medical-grade material of Ti6Al4V and SS316L. There were post-processing steps after the 3D printing of aneurysm clip, particularly surface treatment using polishing and heat treatment. Hot isostatic pressing is also utilized to eliminate residual porosities.

2.3. Biomechanical Simulation
The biomechanical simulation was run using the software of Autodesk Inventor 2021. Since 3D printing results using SS316L do not meet the closing requirement as the original clip, the simulation only conducted using Ti6Al4V. In the inventor 2021, there are many libraries of materials, including Ti6Al4V. In this simulation, it did not input the properties of Ti6Al4V manually, yet it was using the all set-up information of properties in the library. The decision of constrained area and load area were considered as the real case of clipping process. In the clipping process, the surface that in contact with the vessel is the blade’s surfaces that restrain the aneurysm’s bloodstream. However, the area that receives a force by the applicator or hand-force is the spring. For this reason, the blade surface is decided as the constrained area and the load area is the spring. Since there is no literature on the flow rate of brain vessels, the load was given based on general arterial vessel’s flow rate on the human body, particularly heart vessel flow rate, that is 15 mmHg or 1999.84 Pa[16]. The 3D model then
meshed into 9047 elements and run using a finite element method. This simulation provides several analyses of von misses’ stress, displacement, safety factor, reaction force and deformed.

![Meshed Elements](image1)

**Figure 1.** The Constrained Area and the Load Placement in the Biomechanical Simulation.

### 2.4. Tension Measurement

The method used to make this tension measurement device consists of several stages: those are preparing the measurement mechanical hardware system, building the circuit from the sensor and microcontroller, and integrating the hardware with the circuit that already installed the measurement code. The tension measurement device consists of two plates separated by a screw with a width of 2 mm. The width 2 mm size was chosen to approach the real diameter of the anterior cerebral artery which is 2.09 mm [17]. The strain gauge sensor installed at the top and the bottom of the plates. This tension measurements device is previously developed in the Delong research [18]. It refers by using a dynamometer gauge and a piece of paper. The tension measurements device works when the aneurism clip clamps the two separate plates. The force of the aneurysm clip changes the strain of the plate and the resistance sensor, the changed resistance of the sensor measured by the microcontroller then convert the changed resistance into the force. Figure 2 describes the scheme for the tension measurements device mechanism.

![Tension Measurement Mechanism](image2)

**Figure 2.** Tension Measurement Mechanism

### 3. Results and Discussion

#### 3.1. 3-D Aneurysm Clip Model

This project generates several types of aneurysm clip model regarding the need. Figure 3 shows the original clip that was acquired from the Siloam Hospital, the 3D model as a result from the 3D scanner, and the 3D model which would be used to meet the manufacturing needs. The 3D model from
the 3D scanner (Figure 3b) as the reverse engineering process was refined to approach the original clip model. In this step, the blading surface cannot be scanned. The surface was designed manually based on the literature that the depth of general clip aneurysm’s surface structure has a range in between 0.03-0.07mm [6]. In this project, the surface was constructed by having the depth and distances of 0.04 mm. The reverse engineering result was reformulated to form the 3D model of clip aneurysm to have distances in all shapes and lines of 0.37 mm. This number is adjusted to fit the maximum resolution of the Renishaw 3D printer. Since the design in the figure 3c has differences for some millimeters with the original clip, the biomechanical simulation is necessary to predict how well the 3D printer result of aneurysm clip works.

![Figure 3.](image)

Figure 3. (a) A Sugita Aneurysm clip. (b) The Reverse Engineering of Sugita Aneurysm Clip. (c) The 3D Ready to Print Model of Sugita Aneurysm Clip.

Reverse engineering techniques (RET) have been applied in many technology and research [19,20]. The actual purpose of reverse engineering practice in this study is not to duplicate the existing and commercial product, yet to analyse how the system works and have better insight for further improvement. The official page of Yasargil aneurysm clip information shows that to produce the aneurysm clip, the company need several metal-forming stages, such as stamping, hand-rolling, manual-polishing, and many more. By looking back at the first era of technique in clipping the brain, the surgeon used the paper clip to handle the operation. The spring in the latest development of aneurysm clips has similar approach with the spring on the pin-brooch [21]. The primary consideration of choosing the manufacturing company for reverse engineering technique of clip aneurysm in a country, for example, in Indonesia, is to understanding how the paper clip and pin-brooch are constructed. This research reveals that both simple technologies of paper clip and pin-brooch are not manufactured in Indonesia. It means producing the aneurysm clip cannot be done in the manufacturing companies as well as the provided metallurgical devices throughout the country.

3.2. 3-D Printing and Finishing Results

The model of aneurysm clips has been printed using two materials of Ti6Al4V and SS316L. Figure 4 shows the 3D printing results. The two materials show different configurations. The 3D printed products using SS316L cannot close as the original clip was designed, whereas the titanium alloy result can have better organization. For this reason, the further analysis will focus on titanium alloy both in the biomechanical simulation and the tension measurement. Figure 5 exhibits the length of the acquired original clip model is 18 mm, and the two 3D printed results have the same length of 18 mm. This measurement concludes that the 3D printing with its finishing results are proven to have identical geometry between the original clip and the 3D prints. However, since the clamp surface cannot be printed using the 3D printer, the prints cannot be clamping as the original clip. The clamp surface is essential in the factor of clamping forces [6].
3.3. Biomechanical Simulation Results

Figures 6, 7, 8, 9, and 10 display the biomechanical simulation in this study, respectively, the von Mises stress, the displacement, the safety factors, the reaction force, and the deformation. In the implant study, for example, in designing of implant device or the analysis of post-marketing implant application, researchers practiced the biomechanical simulation to find the von Mises stress of the device and the circumstances of related tissues surrounding the device [22,23]. The von Mises stress predicts the yielding of material under complex loading from the results of uniaxial tensile test. The von Mises stress simulation shows that the maximum stress that happened around the spring part with 0.054 GPa. It is smaller than the properties of Ti6Al4V, particularly the yield strength of 0.87 GPa and the tensile strength of 1.05 GPa. It means that the 3D printed result using titanium alloy can withstand the loading of blood flow rate that streams in the aneurysm area [24].

![Figure 6. Von Mises Stress of the Aneurysm Clip 3D Model](image)
In the displacement simulation, the result expects to have a significant number of moving steps. The 3D-printed result using Ti6Al4V can close and open precisely, similar to the acquired clip device. The figure 7 shows that the area with has no movement, particularly the spring area, is dark blue with zero millimeters of displacement. The dotted red line outside the clip model indicates the displacement from the original design to the given load result. The edge of the blade tip shows an opening width of 0.04 cm after the given load simulation. The safety factor is an important parameter to determine if a construction is safe. Safety factor is a comparison between the allowed stress of the material and the stress that occurs. A model’s structure can be declared safe if the safety number is above one [25]. Figure 8 shows that, after having the load by 1999.84 Pa as the vessel flow rate, the minimum and maximum safety factor has higher number than 1 in the unitless.

![Figure 7. Displacement of the Aneurysm Clip 3D Model](image1)

![Figure 8. The Safety Factors of the Aneurysm Clip 3D Model](image2)

Reaction forces are the forces that are taken up by the constraining regions. In a static stress analysis, the forces system and the reaction forces will be in static equilibrium. In the simulation, there
are two area constrained-fixed and load. Each constraint will get a reaction force based on the loading. Figure 9 shows the maximum total reaction force is in the spring area by the number of 0.104 N. Furthermore, the deformation is the amount of stretching that an object undergoes due to the loading. The deformation simulation results are used to determine where and how much a part can bend and determine how much force is required to make it bends a particular distance. Figure 10 shows that the total deformation on the 3D-printed clip is 4.0302E-6 mm, and it indicates the probability of the real model will be bending after applied a force is very small. The picture also shows that the clip’s shape after given a force remains at the original shape and has no significant difference.

**Figure 9.** The Reaction Force of the Aneurysm Clip 3D Model

**Figure 10.** The Deformation of the Aneurysm Clip 3D Model

3.4. Tension Measurement Result

In the tension measurement experiment, the device arrangement can measure the tension of the aneurysm clip accurately. This tension can be considered as the clamping force in both original clip and the 3D printed results. The measurement’s mechanism approaches the real condition of how the clip clamps the aneurysm, with the cerebral artery’s approached diameter in 2 mm. Also, the strain of the measurement plates has come from the real cerebral artery strain. Research by Iino in 2019 reveals that the carotid artery strain was 2.92% from the regular size [26]. Based on the Orto Medical Implant Catalogue, the aneurysm clip’s tension range is 0.69-1.96 N [27]. The measurement result of device shows that the clips have tension with the range 0.7-3 N.
4. Conclusions
The reverse engineering approach of the Sugita aneurysm clip has been successfully done using a metal 3D-printed with the utilized material of Ti6Al4V and SS316L. Biomechanical simulation of the built model of aneurysm clip using the library properties of T4Al6V reveals that the clip can open and close as the original clip. It acquires the von Misses stress of 0.054 GPa with total deformation of 4.0302E-6 mm.

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