Pertanika J. Sci. & Technol. 33 (1): 313 - 332 (2025)

SCIENCE & TECHNOLOGY

Journal homepage: http://www.pertanika.upm.edu.my/

Reverse Engineering of Aneurysm Clip Using Metal Forming

Menik Dwi Kurniatie[1]*, Talitha Asmaria[2], Fendy Rokhmanto[3], Joko Triwardono[3], Galih Senopati[3,4], Dita Ayu Mayasari[1] and Wulan Tsabita Anandisa[5]

[1]*Department of Biomedical Engineering, Faculty of Engineering, Dian Nuswantoro University, Nakula 1 Street No.5-11, Semarang, Indonesia*
[2]*Centre of Biomedical Research, Research Organization for Health, National Research and Innovation Agency (BRIN), Cibinong Science Centre, Bogor, 16911, Indonesia*
[3]*Research Centre for Metallurgy, Research Organization for Nanotechnology and Materials, National Research and Innovation Agency (BRIN), South Tangerang, 15314, Indonesia*
[4]*School of Engineering, Swinburne University of Technology, Victoria, VIC 3122, Australia*
[5]*Department of Biomedical Engineering, International University of Liaison Indonesia, South Tangerang, 15310, Indonesia*

ABSTRACT

Aneurysm clip is widely used as the primary treatment of complex brain aneurysm, primarily in a haemorrhage stroke due to cerebral blood vessel blockages or ruptures, leading to severe neurological deficits. In some developing countries, such as Indonesia, open surgical clipping is sometimes unaffordable and causes a financial burden to the state. This study aims to reproduce the commercial aneurysm clip using metal forming to be more independent in providing medical equipment throughout the country. The metal forming employed rolling and bending techniques, utilizing a base and a jig system to press the Ti6Al4V wire into the desired shape of an R-shaped contour. Our investigation confirmed their structural integrity, fine-grain structure, and mechanical properties. The density of the aneurysm clip shows 4.3 g/cm3 after the forming process. The chemical composition of the aneurysm clip tested with a scanning electron microscope equipped with an energy-dispersive X-ray spectrometer revealed the presence of Ti, Al, and V elements. The fabricated clip exhibited a closing force of 1.689 N. It is about double the closing force exerted by the commercial aneurysm clip, 0.791 N.

Keywords: Fenestrated clips, metal machining, neural implant, remanufacturing, stroke haemorrhage

ARTICLE INFO

Article history:
Received: 6 June 2024
Accepted: 18 September 2024
Published: 27 January 2025

DOI: https://doi.org/10.47836/pjst.33.1.14

*E-mail address*es:
mayasari.dita@dsn.dinus.ac.id (Dita Ayu Mayasari)
nikdwika@dsn.dinus.ac.id (Menik Dwi Kurniatie)
tali001@brin.go.id (Talitha Asmaria)
lanabit26@gmail.com (Wulan Tsabita Anandisa)
fend001@brin.go.id (Fendy Rokhmanto)
joko028@brin.go.id (Joko Triwardono)
gsenopati@swin.edu.au; gali005@brin.go.id (Galih Senopati)
*Corresponding author

ISSN: 0128-7680
e-ISSN: 2231-8526

INTRODUCTION

An aneurysm clip is a metal surgery clip with a function to block the aneurysm, particularly in the brain (Louw et al., 2001). The history of the aneurysm clip began in 1937 when Walter Dandy introduced the V-shaped malleable silver clip during brain surgery. In this modern era, the commercial brands of Yasargil, Sugita, and Spetzler dominate the production of aneurysm clips worldwide. Aneurysm clip is commonly utilized as a procedure in the treatment of several brain diseases, including cerebrovascular accident (CVA), called a stroke, and particularly with a type of haemorrhagic stroke. The haemorrhagic stroke is due to bleeding into the brain by the rupture of blood vessels, which is associated with severe morbidity and high mortality (Montaño et al., 2021). In a specific case of spontaneous subarachnoid haemorrhage, it is due to the rupture of a brain aneurysm. Neurosurgeons, primarily conducting craniectomy, attach a clip to the neck of the aneurysm so that it can ultimately reduce pressure on the aneurysm wall and prevent the risk of aneurysm rupture (Oppong et al., 2020). Aneurysm clipping is one of the most promising treatments available, besides a coiling treatment, for brain aneurysms and eventually solves the problems in stroke patients (Jumah, Quinoa et al., 2020).

The manufacture of the aneurysm clip has been developed and equipped with its applier or installation tools by many inventors (Jumah, Quinoa et al., 2020). In 1911, the Cushing silver clip, well known as the Olivecrona clip, was manufactured by winding the silver wire in a tight could around an oval or diamond-shaped rod, followed by cutting each clip with a wire cutter, then forming the shape of a U-wire. This model was then modified by McKenzie, Duane, and Drew (Duane, 1950). The Mayfield aneurysm clip, which had been improved to overcome surgical problems using previous clips, was designed with a togetherness between the clip and the forceps to meet most anatomical situations and using the material of stainless steel 301 (van der Meulen et al., 2009; Mayfield & Kees, 1971). The Drake fenestrated clip, first introduced in 1969, has the proximal portion of the legs. The Drake clip design was expected to manage the basilar bifurcation aneurysm. The first production of Drake's idea was still controlled by Mayfield and the engineer of Kees (Del Maestro, 2000). The Lougheed-Kerr clip has a unique configuration that gains its spring action from an attached ring, and it can be moved to change the force of the spring. Another advantage is that the Lougheed-Kerr clip can also be swivelled in any direction in the clip holder; this configuration was also found in the Scoville-Lewis aneurysm clip and the McFadden aneurysm clips (Fox, 1976). The Heifetz clips, commercialized by Weck Corporation, were introduced in 1968 as a pivot-type, a stainless-steel aneurysm clip that could self-close. This clip has biconvex blades to prevent tissue laceration, minimize slippage, and maximize clipping force (Jumah, Ginalis et al., 2020). The Sundt encircling graft clip is a metallic spring with the primary function of pressuring a Teflon of Dacron synthetic graft, available in several lengths and diameters and designed to repair significant defects in vessels (Park & Meyer, 2010). The Yasargil clip was first introduced in 1968 and has been implanted in more than 1.5 million global in clipping procedures, made from a high-grade cobalt-chromium alloy and titanium alloy and manufactured by Aesculap, Germany (Dujovny et al., 2010; Jumah, Quinoa, et al., 2020). It is an alpha-type clip with solid, narrow blades and high closing pressure. The Sugita clip, introduced in the late 1970s and manufactured by Mizuho, Japan, had an external bridging between the blade and body that could reduce misalignment or uncrossing of the clip arm (Jumah, Quinoa et al., 2020; Sugita et al., 1982; 1984). The Spetzler clip, introduced in the late 1970s, was made of pure titanium and has interlocking sinusoidal grooves. It could enhance the contact area with the aneurysm neck and reduce the slippage (Jumah, Quinoa, et al., 2020; Shellock & Shellock, 1998). The discovery of titanium clip presented no magnetic attraction, less heating, and the artefacts involved a small signal void. Overall, the information about how others could manufacture them was still limited by all the inventors of the mentioned aneurysm clips. There are a lot of patents available under the theme of aneurysm clips as well as their surgical instruments. Most of them revealed the configuration designs of each component using aneurysm clips and delivered medicinal reasons and urgencies behind every development of aneurysm clips and their applicability. However, only a few patents declared the production phases of the aneurysm clip (Kim & Lee, 2020; Pleil et al., 2023).

The epidemiology of haemorrhagic stroke revealed that the incidence is extremely high in low and middle-income countries and Asians. The fatality rate is approaching 30% to 48% in low-to middle-income countries (Unnithan et al., 2023). Indonesia, also classified as a lower-middle income country that has a Gross National Income (GNI) of about $4050 per capita based on World Population Review, contributes a prevalence of around 10.9% or about seven hundred thousand stroke patients annually, spending the National Health Insurance Fund approximately 15.37 trillion Rupiahs or almost one billion US dollars annually (https://worldpopulationreview.com/Country-Rankings/Gni-per-Capita-by-Country). To tackle the high dependency on imported medical devices, some middle-income countries, including Indonesia, attempt to provide and produce their medical equipment needs. However, the production stages of aneurysm clips remain unfamiliar as one of the high demands for imported medical devices, particularly for implant urgencies and stroke prevention. Moreover, the available information, both in patents regarding the manufacturing process of the aneurysm clip and the commercial video of shortened methods in aneurysm clip manufacturing and evaluation process by Yasargil's official channel, presents the whole manufacturing process requires much-sophisticated equipment, high-skilled labour both in production and quality and control stages. The original idea of this research comes from a well-reputable Indonesian neurosurgeon who conducted over two hundred craniectomies for attaching aneurysm clips. His idea led to a research collaboration among metallurgists, biomedical engineers, medical experts, and an industrial representative. This study aims to employ a metal-forming method to reproduce the commercial aneurysm clip in Siloam Hospital Karawaci, Tangerang, Indonesia. Previously, three-dimensional (3D) printing had been used to reverse engineer the aneurysm clip (Asmaria et al., 2021; Walker et al., 2019). However, the reverse engineering method using additive manufacturing needs to improve the critical ability of the closing force as well as the ability to equalize the dimensions. In the attempt to remanufacture a specimen or other reverse engineering approaches, an investigation needs to be done to measure how far the attempt is successful and how to improve the attempt to reach the desired aim (Fegade et al., 2015; Poswal et al., 2022; Singhal et al., 2018).

The objective of this research is to investigate the replication process of the commercial aneurysm clip, with no prior detailed information or any catalogue from the brand, that is used broadly by neurosurgeons in Indonesia. This reverse engineering process is expected to provide medical equipment throughout the country. The investigation of the reverse-engineered aneurysm clip includes several factors, such as the physical appearance, the closing force, and the material used.

MATERIAL AND METHODS

The main methods of the remanufacturing process consist of 3D model scanning and construction, the remanufacturing process, material analysis, and characterization to investigate the remanufacturing results.

3D Model Scanning and Construction

Initially, the available clip, a fenestrated Sugita aneurysm clip, was scanned using a Cairnhill 3D scanner. The 3D model of the fenestrated aneurysm clip results from the scan was then processed using Uni Graphics parametric design software, the object surface was fixed, and the file was saved as a step file (.stp). In refabricating the existing 3D model, 3D scanning followed by creating the copy model or its modification is the most effective way rather than drawing from a sketch (Szwedziak et al., 2022). Figure 1 describes the scanning aneurysm 3D model and the detailed drawing dimensions, viewed from above and from the side. Figure 1A is the 3D model of the Sugita aneurysm clip after 3D scanning. Figures 1B and 1C are the line data to build detailed drawing dimensions from the scanned aneurysm clip and seen from an above view and a side view, respectively. Figure 1D describes the properties of a commercial fenestrated Sugita aneurysm clip. The chosen commercial fenestrated Sugita aneurysm clip in this study has a total length of 16.50 mm and a total width of 10 mm. This product has been fabricated with a cobalt alloy with a density of 7.96 g/cm^3. It has a measured closing force of 0.792N.

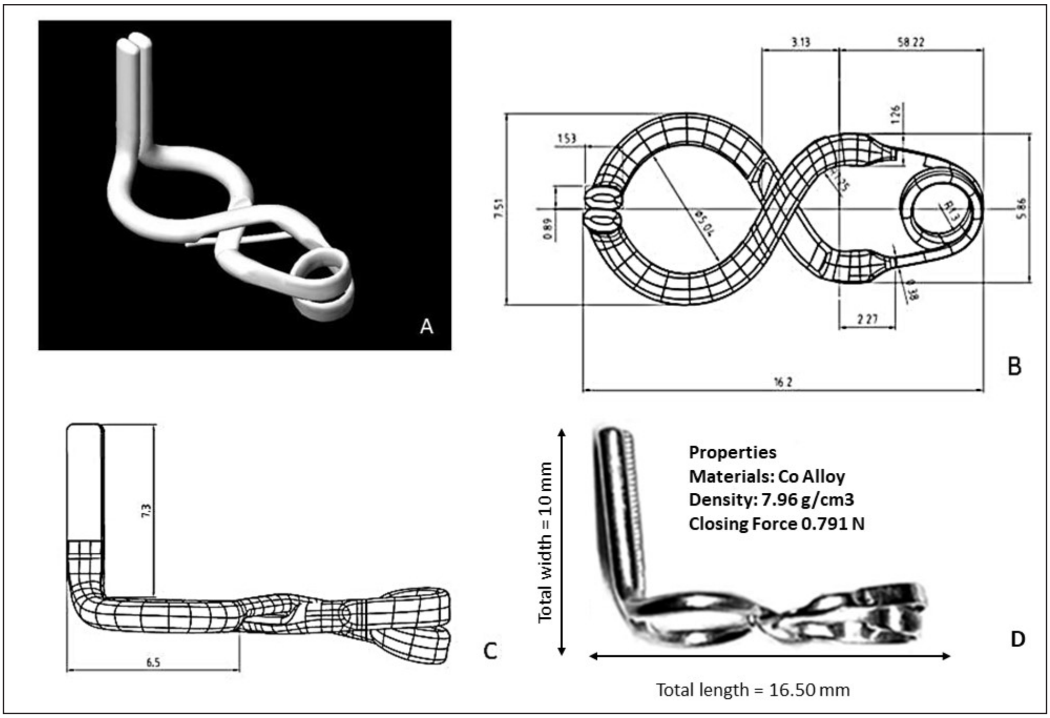


Figure 1. A fenestrated aneurysm clip model. (A) 3D scanning from the aneurysm clip; (B) A detailed drawing dimensions of the scanned aneurysm clip from an above view; (C) An aneurysm clip dimension viewed from the side; (D) Properties of commercial fenestrated Sugita aneurysm clip

Remanufacturing Process

The raw material in producing the aneurysm clip consists of Ti6Al4V wire with a 1.20±0.02 mm diameter. Since we did not receive any information or catalogue info on this product, we decided in this study to use the Ti6Al4V material because today, it is commonly used as implant material. Besides that, Ti6Al4V has some advantages, such as high strength properties, low density, and non-toxic to the human body. Firstly, the wire is subjected to compression using a mould combining SKD-11 hardened steel and carbon steel S45C materials to create an R-shaped form. This combination base and jig are custom-made to accommodate the need for an R-shape to the wire. In this stage, we pressed the wire into the R-shape. Subsequently, the R-shaped wire is rolled into a coil configuration with a pressing angle of 22 ° and a free angle of 34 °. The initiation of these angles is based on the scanning and 3D model reconstruction of the aneurysm clip. Finally, the aneurysm clip is bent to obtain a 90 ° blade angle. The process was then followed by bending the blade part of the clip to create an L-shaped blade. Figure 2 illustrates a detailed metal forming from design, the wire moulding, pressing the wire to R-shaped, and rolling the wire.

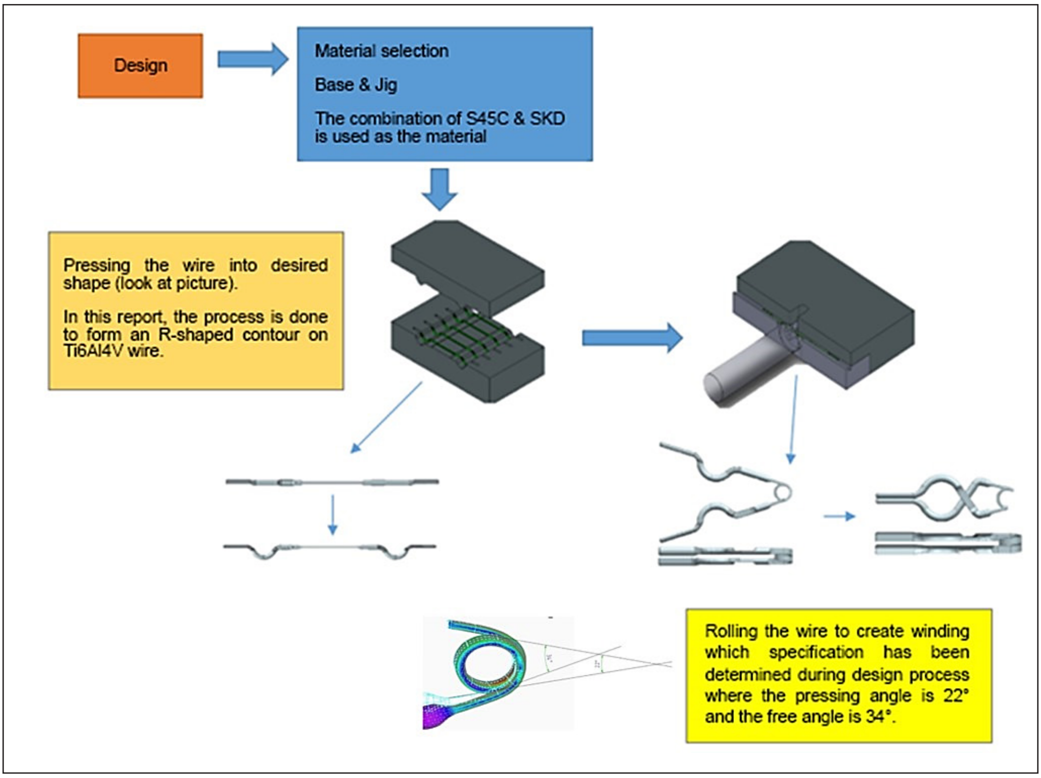


Figure 2. Metal forming diagram to reproduce the Ti6Al4V aneurysm clip. From the design of the aneurysm clip, we chose a material and formed the wire with customized moulding. The wire is pressed to form an R-shaped contour. The pressed wire is then rolled with determined angles of 22° and 34° before being bent 90° into an L-shaped

Closing Force Measurement

This study utilized a measurement setup comprising a force sensor and a microcontroller to quantify the closing force exerted by the aneurysm clip. Figure 3 describes the scheme for the closing force measurement. The two blades on the aneurysm clip are attached to the load cell and the linear actuator, respectively, and those are pulled towards each other, with a minimum distance set to 2mm. The blade distance was set to 2 mm, corresponding to the size of the arteries being considered (Asmaria et al., 2021). The force will be measured as the blades are pulled. The purpose of this self-manufacture measurement system is to provide an aneurysm clip tensile force measuring device consisting of a load cell equipped with a strain gauge pressure sensor connected to an amplifier, an amplifier connected to a microcontroller, an LCD connected to a microcontroller, a keypad connected to a microcontroller; a linear actuator connected to the motor; the motor connected to a 9V battery as a power supply for the motor; the motor connected to a microcontroller; which is characterized by a hook mounted on the end of the load cell which is equipped with a strain gauge pressure sensor; a hook mounted on the end of the linear actuator; and a keypad which functions to adjust the movement distance of the linear actuator.

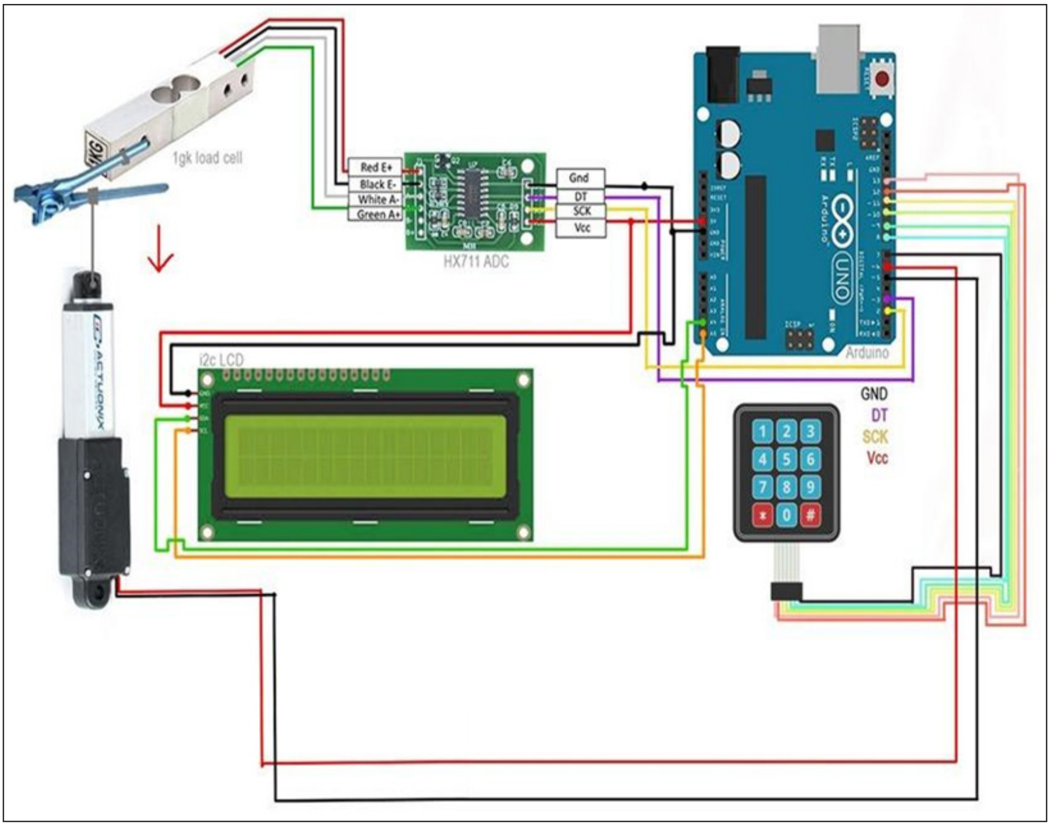


Figure 3. Closing force measuring device for aneurysm clips. The blades on the aneurysm clip are attached to the load cell and the linear actuator. The measured distance when the blades are pulled converts to a closing force through other equipment assistance, such as strain gauge pressure sensor and microcontroller

The Material Analysis and Characterization

This evaluation consists of physical analysis, a density test of aneurysm clips, a metallography test, a scanning electron microscope with energy dispersive spectroscopy (SEM-EDS), and a Vickers hardness test to acquire information regarding the reverse-engineered aneurysm clip's material characteristics.

The physical analysis refers to the gross analysis of the physical measurements and appearance between the scanned Sugita aneurysm clip and the reverse-engineered one.

The density of the aneurysm clip was determined using the Archimedes method following the ASTM B962-17 standard. A Radwag analytical balance, equipped with a density kit, was employed for the measurements.

Metallographic preparation was conducted to examine its microstructure. The clip sample was cut, mounted, ground with SiC paper ranging from grit 120 to 1500, and polished using colloidal silica. The polished samples were then etched with a mixture of Nitric Acid, Fluoric Acid, and water at a ratio of 6:2:92% vol to observe the microstructure and chemical composition of the clip using the SEM-EDX Jeol. As part of microstructure analysis, average grain size will be measured using the image resulting from metallurgy test microscopy. ImageJ software was used to calculate the grain size of the aneurysm clip. The line intercept method will be used to calculate the grain size. A line will be superimposed on the image, and the number of grains intercepting the line will be counted. The formula can be described as Equation 1. It must be noted that the line length must be adjusted to scale or magnification.

$$\text{Average grain size} = \text{Line length}/\text{Number of grain} \qquad [1]$$

A Mitutoyo Micro hardness tester assessed the aneurysm clip's hardness with utmost precision. A 0.3 N load was applied with a 12-second dwell time, ensuring accurate measurement. The hardness was measured at five different points, and the average value was subsequently determined, providing a reliable indication of the clip's hardness.

RESULTS AND DISCUSSION

The primary outcome of this study is the reverse-engineered prototype of an aneurysm clip. To analyse whether this attempt is a success, this study conducts several evaluations: the physical analysis of the aneurysm clip prototype, the closing force measurement, and the material analysis and characterization.

Physical Analysis

Figure 4 indicates nine parameters to compare: the total length, the blade length, the inner diameter of the fenestration side, the blade tip, the wire diameter, the wire width of the spring, the inner and outer diameter of the spring, and the arm length, which then all summarized in Table 1.

A reverse-engineered aneurysm clip is more prominent in size than a commercial aneurysm clip. The wire used for the reverse-engineered aneurysm clip has a diameter of 1.20±0.02 mm, which is only 0.04mm bigger than the commercial aneurysm clip. However, the wire thickness along the commercial aneurysm clip is more dynamic than the re-verse-engineered one. For instance, as shown in Figure 4(A), the wire tends to be flatter at the blade and spring area before reverting to a rod-like shape in its transitional or fulcrum area. The commercial one is different from the reverse-engineered aneurysm clip, which generally has uniform wire thickness throughout the body of the clip. The reason can be the lack of fine machining in the reverse-engineered aneurysm clip. The uniformity in wire thickness in the reverse-engineered aneurysm clip causes the overall dimension to be bigger and bulkier compared to the commercial aneurysm clip. The bulkiness, especially in the spring portion of the clip, may affect force exertion upon closure.

Based on the website of the commercial Yasargil aneurysm clip official, the total length, the blade length, and the arm length of aneurysm clips have been varied (Figure 4 no 1, no 2, and no 9) and been adjusted to the application on the size of patient's aneurysm. The metal forming in this reverse-engineering experiment produced the inner diameter of fenestration, blade tip, and the wire width of the spring inner and outer diameter of the spring (Figures 4 no 3, no 4, no 6, no 7, and no 8), which more significant in size than the commercial Sugita. These larger areas affect the performance of the reversed engineering aneurysm clip, making the blade more brittle when opening and closing.

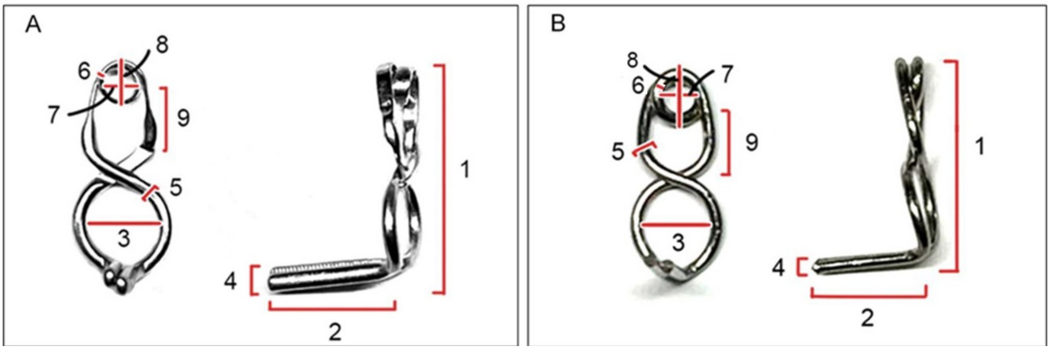


Figure 4. (A) The commercial Sugita aneurysm clip; (B) the reverse-engineered aneurysm clip

Table 1
Physical measurement between the Sugita aneurysm clip and the reverse engineering prototype of the aneurysm clip

No.	Parameters	Commercial Sugita (mm)	Reverse Engineering (mm)
1	Total Length	16.50	19.28
2	Blade Length	10.00	10.41
3	Inner Diameter of Fenestration	5.00	6.02
4	Blade Tip	1.45	1.27
5	Wire Diameter	1.16	1.20
6	Wire width of spring	0.37	1.00
7	Inner Diameter of Spring	2.26	2.81
8	Outer Diameter of Spring	3.01	5.09
9	Arm Length	7	8

Closing Force Results

The reverse-engineered Ti6Al4V aneurysm clip prototype developed in this study showed a closing force of 1.689 N, above double the closing force exerted by a commercial aneurysm clip, which is 0.791 N. The findings of another study suggest that the closing force magnitude is directly proportional to the distance by which the blade of the aneurysm clip opens, indicating that greater blade opening distances result in higher closing forces (Horiuchi et al., 2013; Tsutsumi et al., 2017).

The Material Analysis and Characterization

Since the reverse-engineered aneurysm clip has a higher closing force than the commercial Sugita aneurysm clip, the material analysis and characterization results are crucial to answering the microstructural and chemical reasons behind the issue.

Based on the measurements conducted using the Archimedes method, the density of the reverse-engineered aneurysm clip was determined to be 4.3 g/cm^3 after the forming process. However, the raw Ti6Al4V wire for the reverse-engineered aneurysm clip comes with a specification sheet from PT. Agru Solusi Industri, as the manufacturing company, and the sheet shows that the density of the Ti6Al4V wire is 4.42 g/cm^3. The Archimedes method used in this study also found that the density of the sample of the commercially available wire Ti6Al4V alloy is 4.4 g/cm^3. It can be observed that the density of the reverse-engineered aneurysm clip in this study closely approximates that of the wire (Tevet et al., 2022). Overall, the density test results show that the commercial aneurysm clip has a 7.9581 g/cm^3 density, whereas the reverse-engineered aneurysm clip has a 4.3424 g/cm^3 density. The density test result may be attributed to the overall bulkiness of the reverse-engineered aneurysm clip compared to the commercial one. Since there is no information regarding material density for commercial aneurysm clips, the commercial aneurysm clip would be tested using SEM-EDS. Figure 5 shows the SEM-EDS test on the commercial aneurysm clip that the material alloy of CoCr Mo, which, in the 1990s, most Sugita aneurysm clips were made from (Brothers et al., 1990). The commercial aneurysm clip's density test results of 7.9581 gr/cm^3 were close to the literature that the density of CoCr Mo by 8.3 g/cm^3.

This theoretical value sits closely with the value obtained from measurement for reverse-engineered aneurysm clip. Commercial aneurysm clip has nearly twice the density of the remanufacturing prototype, which may indicate that there is a difference in material specifications between the reverse-engineered clip and commercial aneurysm clip or that the two aneurysm clips are made from entirely different materials. Based on the literature, titanium alloys are magnetic resonance (MR) safe implantable medical devices since the susceptibility of Ti is about 1/10 that of the Co-Cr-Ni alloy, which was previously claimed to be the preferred MR-safe material (Tang et al., 2020). For this reason, there is no need to change the titanium alloy materials in the next reverse engineering aneurysm clips.

The microstructure of the Ti6AlV used in the reverse-engineered aneurysm clip will be thoroughly analysed using a metallography test. The chemical composition and hardness of the Ti6AlV will be determined through SEM EDX and Vickers hardness test results, which will be compared to the literature for validation. Figure 6 provides a detailed view of the microstructure of the Ti6Al4V aneurysm clip, demonstrating the thoroughness of our analysis.

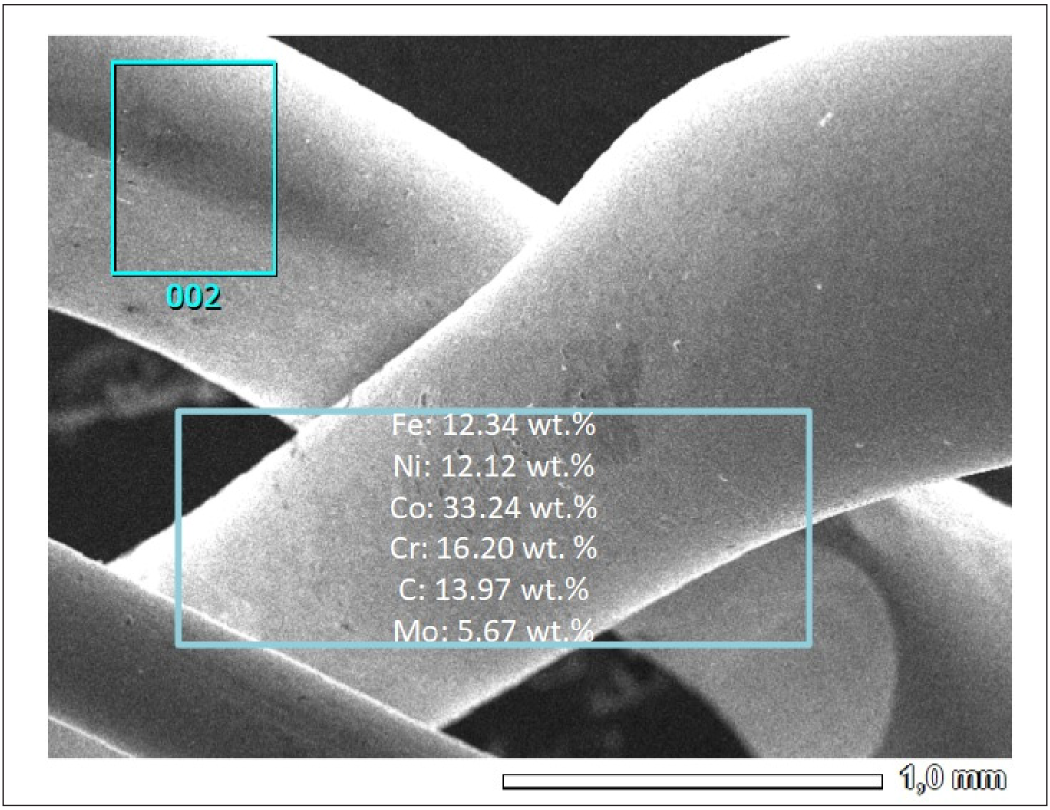


Figure 5. SEM image and EDS of the commercial aneurysm clip

It can be observed that the Ti6Al4V aneurysm clip consists of α and β Ti phases with fine grain size. The fine grain structure observed in clip aneurysm manufacturing can be attributed to the utilization of rolling and bending processes. Gurau et al. (2020) also stated that subjecting titanium alloys to severe plastic deformation through cold rolling can form refined grains. This process has an impact on the biocompatibility of the implant material. Kim et al. (2007) reported that a reduction in grain size is associated with increased surface energy, significantly enhancing cell proliferation. Cell proliferation is a basis for evaluating the in vitro biocompatibility of materials used for the metal implant.

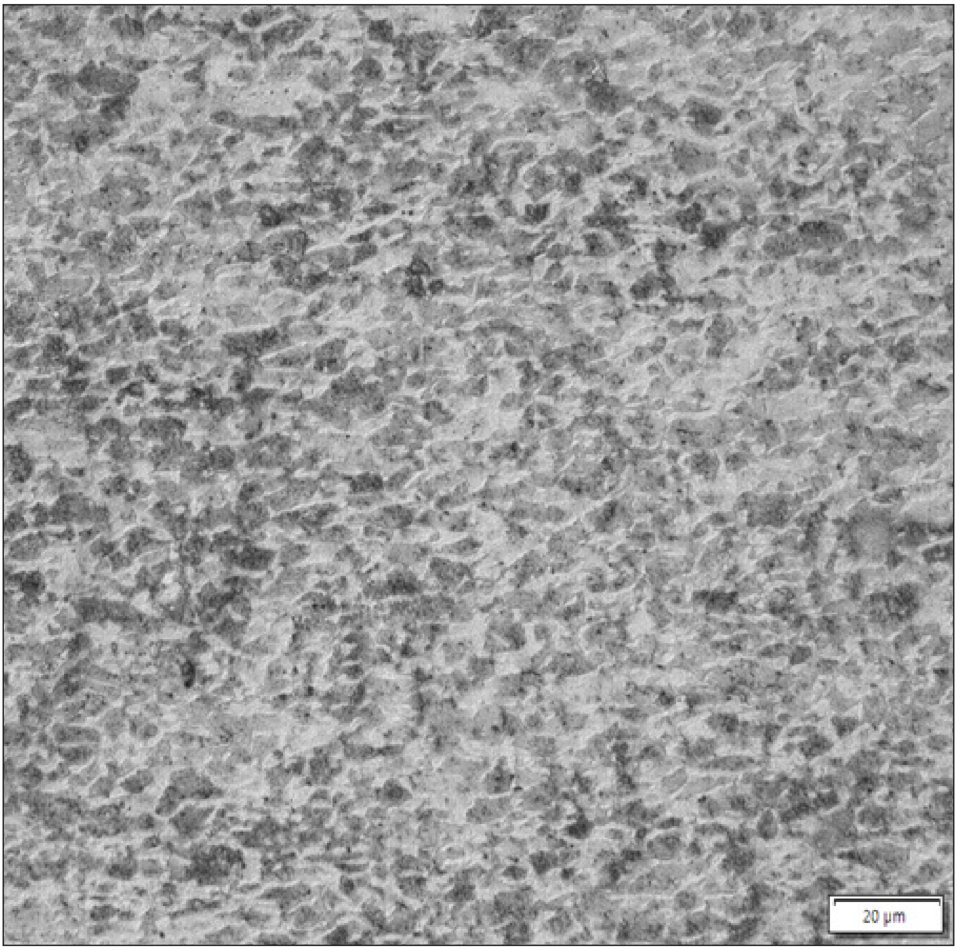


Figure 6. Microstructure of Ti6Al4V Aneurysm Clip

Figure 7 demonstrates grain size calculation using profile plotting. Average grain size will be measured using the image acquired through the metallography test. Nine different line segments will be superimposed on the enhanced image, which is the profile plot of the number 1 coloured in yellow in Figure 7. Due to the irregularities in shape, counting the number of grains using eyesight is difficult. Profile plotting is utilized to help with this problem. The α-primary phase tends to be darker in colour, and the β-phase boundary tends to be lighter. Using the intercept line method (Equation 1), the average grain size is calculated and showed the result of 10.48μm. It is known that with the decrease in grain size, tensile strength will increase at the expense of decreasing elongation (Chong & Tsuji, 2016).

The grain size becomes smaller than 1μm, and early necking happens shortly after yielding, which indicates the early plastic instability due to the limited work-hardening ability of the ultra-fine grain (UFG) equiaxed microstructure (Peng et al., 2014). It means that the material used in the reverse-engineered aneurysm clip has good workability, especially in the range of 10 to 25µm (https://www.copper.org/applications/industrial/DesignGuide/props/grain_size.html). This workability is based on the industrial recommendation by the Cooper Development Association, which mentioned that metal with typical operations and a grain size of 10 to 25µm, such as stampings, the parts will exhibit high strength (https://www.copper.org/applications/industrial/DesignGuide/props/grain_size.html). Bazner and Copponnex also wrote that a rule of thumb for good mechanical strength is when the thinnest object dimension is at least ten times larger than the grain size, a condition fulfilled by the reverse-engineered aneurysm clip (Baltzer & Copponnex, 2014).

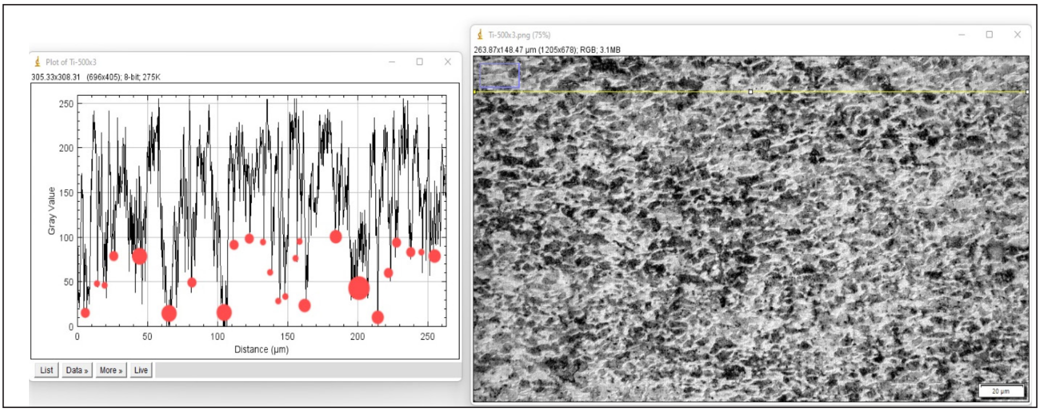
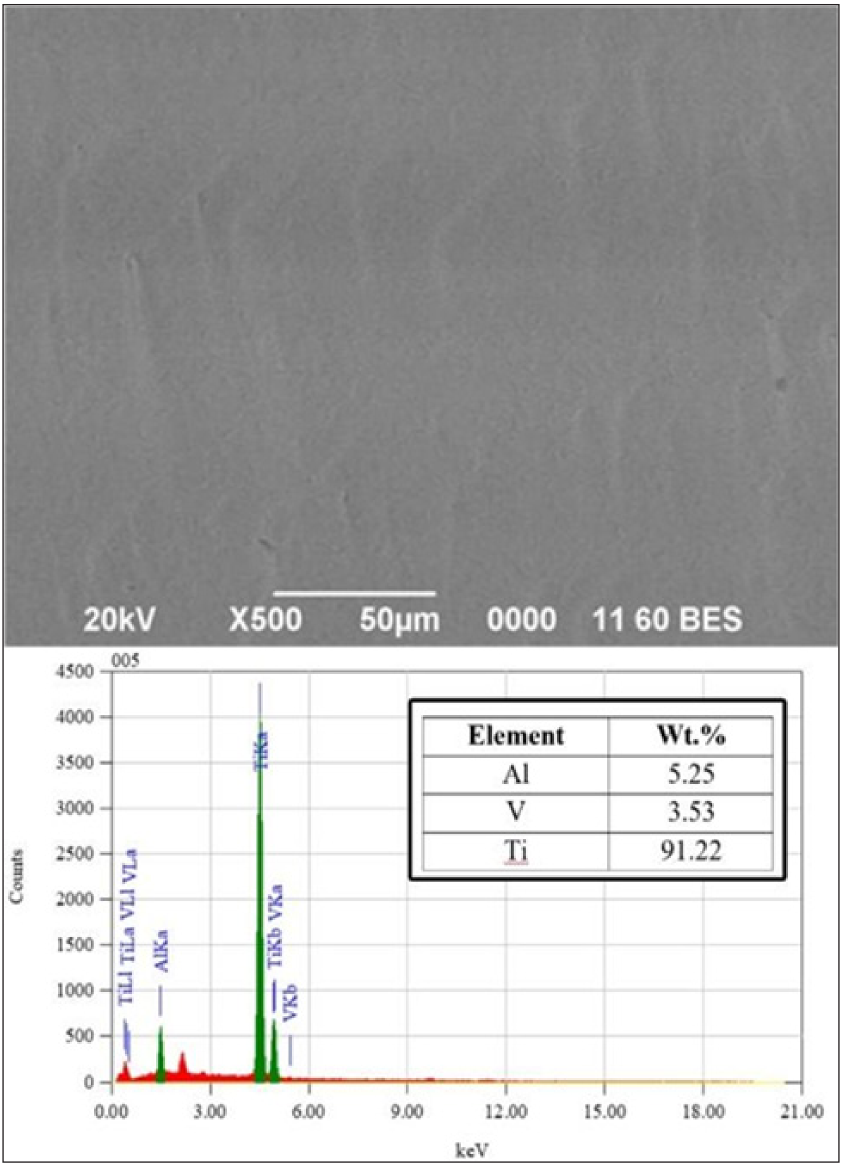


Figure 7. Profile plot of line number for grain size measurement. Line number 1 is coloured in yellow

Figure 8 shows the SEM micrograph and EDS Spectra of the alloying element of Ti6Al4V Aneurysm Clip. The SEM micrograph shows a similar structure to the optical microscope (OM) result. The EDS result shows that Ti6Al4V consists of Ti (91.22±0.28 wt.%), Al (5.25±0.21 wt.%), and V (3.53±0.36 wt.%). Lastly, the Vickers hardness value of the re-verse-engineered aneurysm clip was taken at different points along the clip with each of the five indentations. The test was done with a load of 0.3 N or 0.031-kilogram force. The aneurysm clip has a Vickers hardness mean of 330.64 HV ± 6.56. The value is close to the theoretical value of Ti6Al4V hardness, 300 ± 2 HV (Ma et al., 2017).

As the manufacturing process tends to be a trade secret, no in-detail aneurysm clip manufacturing process is published online. However, one renowned medical supply company, B. Braun, which produces aneurysm clips under the name Yasargil, does publish a corporate video about making their aneurysm clip. Yasargil commercial aneurysm clip uses a machining similar process to the reverse-engineered aneurysm clip in this study that involves pressing the wire into an R contour using the metal jig and rolling the wire to create the spring part on the aneurysm clip (https://www.youtube.com/watch?v=jlGleP8d7W8).

One note-worthy process featured in the video but not on the reverse-engineered aneurysm clip in this study is the manual polishing of the Yasargil clips. Manual clip polishing is a process for smoothing implant material surfaces apart from chemical polishing, electropolishing, and laser polishing.



Element	Wt.%
Al	5.25
V	3.53
Ti	91.22

Figure 8. SEM image and EDS result of the Ti6Al4V aneurysm clip

Moreover, on a patent by Florida Hospital Supply Inc., the manufacturing process of aneurysm clip is described as having a cylindrical metal wire made out of titanium or titanium alloy prepared, cold drawing the wire, cutting the wire, winding the wire around a mandrel to form the spring part, bending the arms next to the spring part into designated deflection angle, shaping the blades or clamping jaws and its connecting elements or fulcrum, coining the blades or clamping jaws at 9000–10,000° F and bending the blades or clamping jaws into parallel position (World Patent No. EP0724406A4, 1993) (Schmidt & Maughan, 1993). While the patent describes many processes that were also done in the re-verse-engineered aneurysm clip in this study, there are particular metal treatment processes, such as cold drawing and coining, which were not done in this remanufacturing of aneurysm clip prototype. Cold drawing of the starting wire was done to reduce the diameter of the wire and increase strength, while coining was needed to form raised sections, serrations, and other fine details. These key processes can be added to achieve closer results to commercial aneurysm clips.

Overall, to the best of our knowledge, the attempts of remanufacturing or mastering the technology behind aneurysm clip production still need to be understood. Previous research studies have used metal additive manufacturing to reproduce aneurysm clips (Asmaria et al., 2021; Walker et al., 2019). The first study could produce the aneurysm clip similarly and precisely in size compared to the commercial one; however, it lacked the closing force (Asmaria et al., 2021). The idea from the second study was remarkable for producing the patient-specific geometry of an aneurysm clip; however, the results from additive manufacturing are far different from their intended models of aneurysm clip, and there was no measurement of closing force (Walker et al., 2019). Compared to this study, our cold forming method could be better in aneurysm clip geometry and the measured closing force. Furthermore, reviewing the existing brain aneurysm models defines five main groups: sidewall, bifurcation stump, terminal, natural and artificial bifurcation, and complex aneurysm models (Marbacher et al., 2020).

The brain aneurysm also could appear in different locations of brain vessels of various sizes and has plenty of branches. Based on their geometries, the aneurysm could be categorized as fusiform and saccular (Pineda-Castillo et al., 2021). Current commercial metal clips, produced by several medical companies, have designed more than 300 configurations and sizes to accommodate uncertain forms, sizes, and locations of brain aneurysms (https://www.aesculapusa.com/en/healthcare-professionals/or-solutions/aneurysm-clips-for-neurosurgery.html). Significantly, the effort of remanufacturing aneurysm clip will not only help to reproduce the technology to be more independent in providing their medical equipment for Indonesia or other countries but also will be a fundamental knowledge of how to produce the aneurysm clip with a slight modification, particularly on the blade side in a purpose to overcome the occurrence of the patient-specific aneurysm geometries.

CONCLUSION AND OUTLOOK

In this study, the remanufacturing process was executed to reconfigure the aneurysm clip material, which underwent comprehensive characterization. Subsequent analysis involved a comparative assessment between the reconstituted aneurysm clip and their commercially available counterparts.

There is an apparent difference in the morphology of the two samples. The commercial aneurysm clip has a more dynamic wire shape where the spring and the blade part tend to be flatter and thinner than the transitional or fulcrum area, which tends to be more rod-like. The commercial one differs from the reverse-engineered aneurysm clip, where the wire shape is generally uniform with a rod-like shape. The reason can be the lack of fine machining on the reverse-engineered aneurysm clip. The dimension measurements of the reverse-engineered clip are considerably bigger than the existing commercial clip. For its application, the reverse-engineered clip could work, open, close, and clip as intended. However, performance deficiencies exist, such as the prototype being too brittle.

There is a significant divergence between the reverse-engineered aneurysm clip and the commercial aneurysm clip for the value of closing force, 1.689N and 0.791N, respectively. The possible main reason for the difference in the closing force is that the physical appearance of the reverse-engineered aneurysm clip is far from the detailed configuration of the commercial aneurysm clip, meaning both have different manufacturing processes.

In material analysis, the density of the remanufacturing prototype of an aneurysm clip conforms to the density of medical grade Ti6Al4V, which is 4.3424 g/cm^3. However, the commercial aneurysm clip's experimental density is 7.9581 g/cm^3. This value is far higher than the density of Ti6Al4V, which indicates that the commercial aneurysm clip may be manufactured using different materials. The SEM-EDS examination of the commercial aneurysm clip reveals the presence of CoCr Mo.

Furthermore, the material analysis is also concerned with the sample's micro-structural and chemical composition aspects. The reverse-engineered aneurysm clip shows an equiaxed microstructure, apparent from the metallurgy test results and SEM images. The microstructure result indicates a superior microhardness and ductility in the reverse-engineered aneurysm clip. The grain size calculation using the intercept line method shows the result of 10.48 μm, indicating good metal workability. Therefore, it is possible to emulate the dynamic shape of the commercial aneurysm clip on the reverse-engineered aneurysm clip through further machining. As for chemical composition, the result shows the typical value of Ti6Al4V. Vickers hardness test shows a close number to the theoretical Vickers hardness of Ti6Al4V.

Manufacturing analysis compares the reverse-engineered aneurysm clip and commercial aneurysm clips. Both share a similar machining process, which involves pressing the wire into an R contour using a metal jig and rolling the wire to create the spring part on the aneurysm clip. However, commercial aneurysm clips undergo more fine machining and manual polishing, which results in their dynamic wire shape and fine detailing compared to the bulkiness and lack of fine detailing of reverse-engineered aneurysm clips.

Despite the suspicion of material difference, changing the material of the next self-fabrication of aneurysm clip may not be required as Ti6Al4V is commonly used to fabricate aneurysm clips. The grain size of the reverse-engineered aneurysm clip shows that further working and detailing of the wire is possible. Therefore, the best recommendation that can be proposed is to do a more meticulous shaping of the raw wire to emulate the dynamic shape of commercial aneurysm clips.

These findings contribute to advancements in clip design and installation techniques. Cold metal forming and coining of the raw wire should be incorporated in the future.

ACKNOWLEDGMENT

This research was funded by the Research Center for Health, National Research and Innovation Agency, Indonesia (BRIN) in 2023 and 2024, grant number 23/III.9/HK/2023. The publication fee and the ICAEMC conference expenses were funded by the Department of Biomedical Engineering, Dian Nuswantoro University, Indonesia. Prof. Dr Eka Julianta Wahjoepramono, Sp.BS., PhD, from the Faculty of Medicine, Pelita Harapan University came up with the idea of reverse engineering for aneurysm clips. Y. M. Zuchruf first developed the closing force measuring device. We also thank Dr Albertus Deny for his advice regarding the writing process.

REFERENCES

Asmaria, T., Zuchruf, Y. M., Triwardono, J., Rokhmanto, F., Erryani, A., Lestari, F. P., Dwijaya, M. S., Kartika, I., Wahjoepramono, E. J., & Pramono, A. W. (2021). Biomechanical simulation of Sugita Aneurysm Clip: Reverse engineering approach using metal 3D-printing. *Journal of Physics: Conference Series*, *1805*(1), Article 012044. https://doi.org/10.1088/1742-6596/1805/1/012044

Baltzer, N., & Copponnex, T. (2014). Properties and processing of precious metal alloys for biomedical applications. In *Precious Metals for Biomedical Applications* (pp. 3–36). Elsevier. https://doi.org/10.1533/9780857099051.1.3

Brothers, M. F., Fox, A. J., Lee, D. H., Pelz, D. M., & Deveikis, J. P. (1990). MR imaging after surgery for vertebrobasilar aneurysm. *American Journal of Neuroradiology*, *11*(1), 149–161.

Chong, Y., & Tsuji, N. (2016). Mechanical properties of fine-grained and ultrafine-grained Ti-6Al-4V with equiaxed and bimodal microstructures. *Materials Science Forum*, *879*, 344–349. https://doi.org/10.4028/www.scientific.net/MSF.879.344

Del Maestro, R. F. (2000). Origin of the Drake fenestrated aneurysm clip. *Journal of Neurosurgery*, *92*(6), 1056–1064. https://doi.org/10.3171/jns.2000.92.6.1056

Duane, W. (1950). A Modification of the McKenzie Silver Clip. *Journal of Neurosurgery*, *7*(1), 92–93. https://doi.org/10.3171/jns.1950.7.1.0092

Dujovny, M., Agner, C., Ibe, O., & Perlin, A. (2010). Self-closing aneurysm clip: A historical review. *Neurological Research*, *32*(10), 1011–1020. https://doi.org/10.1179/016164110X12807570509817

Fegade, V., Shrivatsava, R. L., & Kale, A. V. (2015). Design for remanufacturing: Methods and their approaches. *Materials Today: Proceedings*, *2*(4–5), 1849–1858. https://doi.org/10.1016/j.matpr.2015.07.130

Fox, J. L. (1976). Vascular clips for the microsurgical treatment of stroke. *Stroke*, *7*(5), 489–500. https://doi.org/10.1161/01.STR.7.5.489

Gurau, C., Gurau, G., Mitran, V., Dan, A., & Cimpean, A. (2020). The influence of severe plastic deformation on microstructure and *in vitro* biocompatibility of the new Ti-Nb-Zr-Ta-Fe-O alloy composition. *Materials*, *13*(21), Article 4853. https://doi.org/10.3390/ma13214853

Horiuchi, T., Rahmah, N. N., Yanagawa, T., & Hongo, K. (2013). Revisit of aneurysm clip closing forces: Comparison of titanium versus cobalt alloy clip. *Neurosurgical Review*, *36*(1), 133–138. https://doi.org/10.1007/s10143-012-0398-x

Jumah, F., Ginalis, E. E., Yan, R. E., Atanassova, T., Narayan, V., Gupta, G., & Nanda, A. (2020). Tribute to Milton D. Heifetz (1921-2015): The man behind the Heifetz Aneurysm Clip. *Neurosurgery*, *87*(5), E584–E589. https://doi.org/10.1093/neuros/nyaa035

Jumah, F., Quinoa, T., Akel, O., Shah, S., Narayan, V., Adeeb, N., Gupta, G., & Nanda, A. (2020). The origins of Eponymous Aneurysm Clips: A review. *World Neurosurgery*, *134*, 518–531. https://doi.org/10.1016/j.wneu.2019.09.061

Kim, H. J., & Lee, Y. W. (2020). *Closed end - type cerebral aneurysm clip and manufacturing method therefor* (Patent US 20200197012A1).

Kim, T. N., Balakrishnan, A., Lee, B. C., Kim, W. S., Smetana, K., Park, J. K., & Panigrahi, B. B. (2007). *In vitro* biocompatibility of equal channel angular processed (ECAP) titanium. *Biomedical Materials*, *2*(3), S117–S120. https://doi.org/10.1088/1748-6041/2/3/S06

Louw, D. F., Asfora, W. T., & Sutherland, G. R. (2001). A brief history of aneurysm clips. *Neurosurgical Focus*, *11*(2), 1–4. https://doi.org/10.3171/foc.2001.11.2.5

Ma, X., Li, F., Cao, J., Li, J., Chen, H., & Zhao, C. (2017). Vickers microhardness and microstructure relationship of Ti-6Al-4V alloy under cyclic forward-reverse torsion and monotonic torsion loading. *Materials & Design*, *114*, 271–281. https://doi.org/10.1016/j.matdes.2016.11.028

Marbacher, S., Strange, F., Frösén, J., & Fandino, J. (2020). Preclinical extracranial aneurysm models for the study and treatment of brain aneurysms: A systematic review. *Journal of Cerebral Blood Flow & Metabolism*, *40*(5), 922–938. https://doi.org/10.1177/0271678X20908363

Mayfield, F. H., & Kees, G. (1971). A brief history of the development of the Mayfield clip. Technical note. *Journal of Neurosurgery*, *35*(1), 97–100. https://doi.org/10.3171/jns.1971.35.1.0097

Montaño, A., Hanley, D. F., & Hemphill, J. C. (2021). *Hemorrhagic stroke* (pp. 229–248). https://doi.org/10.1016/B978-0-444-64034-5.00019-5

Oppong, M. D., Golubovic, J., Hauck, E. F., Wrede, K. H., Sure, U., & Jabbarli, R. (2020). Decompressive craniectomy in aneurysmal subarachnoid hemorrhage: Who and when? – A systematic review and meta-analysis. *Clinical Neurology and Neurosurgery*, *199*, Article 106252. https://doi.org/10.1016/j.clineuro.2020.106252

Park, P. J., & Meyer, F. B. (2010). The Sundt clip graft. *Operative Neurosurgery*, *66*(6), ons300–ons305. https://doi.org/10.1227/01.NEU.0000369923.05148.67

Peng, X., Guo, H., Shi, Z., Qin, C., & Zhao, Z. (2014). Microstructure characterization and mechanical properties of TC4-DT titanium alloy after thermomechanical treatment. *Transactions of Nonferrous Metals Society of China*, *24*(3), 682–689. https://doi.org/10.1016/S1003-6326(14)63111-3

Pineda-Castillo, S. A., Luo, J., Lee, H., Bohnstedt, B. N., Liu, Y., & Lee, C. H. (2021). Effects of carbon nanotube infiltration on a shape memory polymer-based device for Brain Aneurysm Therapeutics: Design and characterization of a Joule-Heating Triggering Mechanism. *Advanced Engineering Materials*, *23*(6), Article 2100322. https://doi.org/10.1002/adem.202100322

Pleil, T., Scholten, T., Willman, M., Happle, A., & Beger, J. (2023). *Medical clip and method for producing a medical clip* (Patent US20230200824A1).

Poswal, P., Chauhan, A., Aarya, D. D., Boadh, R., Rajoria, Y. K., & Gaiola, S. U. (2022). Optimal strategy for remanufacturing system of sustainable products with trade credit under uncertain scenario. *Materials Today: Proceedings*, *69*, 165–173. https://doi.org/10.1016/j.matpr.2022.08.303

Schmidt, F. J., & Maughan, P. K. (1993). *Process for Manufacturing an Aneurismal Clip* (Patent EP0724406A4).

Shellock, F. G., & Shellock, V. J. (1998). Spetzler titanium aneurysm clips: Compatibility at MR imaging. *Radiology*, *206*(3), 838–841. https://doi.org/10.1148/radiology.206.3.9494511

Singhal, D., Tripathy, S., & Kumar Jena, S. (2018). DEMATEL approach for analyzing the critical factors in remanufacturing process. *Materials Today: Proceedings*, *5*(9), 18568–18573. https://doi.org/10.1016/j.matpr.2018.06.200

Sugita, K., Kobayashi, S., Inoue, T., & Takemae, T. (1984). Characteristics and use of ultra-long aneurysm clips. *Journal of Neurosurgery*, *60*(1), 145–150. https://doi.org/10.3171/jns.1984.60.1.0145

Sugita, K., Kobayashi, S., Kyoshima, K., & Nakagawa, F. (1982). Fenestrated clips for unusual aneurysms of the carotid artery. *Journal of Neurosurgery*, *57*(2), 240–246. https://doi.org/10.3171/jns.1982.57.2.0240

Szwedziak, K., Łusiak, T., Bąbel, R., Winiarski, P., Podsędek, S., Doležal, P., & Niedbała, G. (2022). Wind tunnel experiments on an aircraft model fabricated using a 3D printing technique. *Journal of Manufacturing and Materials Processing*, *6*(1), Article 12. https://doi.org/10.3390/jmmp6010012

Tang, M., Kawahira, S., Nomura, N., & Yamamoto, T. (2020). Torque property of titanium alloy cerebral aneurysm clips in a magnetic resonance scanner. *Journal of Materials Science: Materials in Medicine*, *31*(1), Article 6. https://doi.org/10.1007/s10856-019-6329-4

Tevet, O., Svetlizky, D., Harel, D., Barkay, Z., Geva, D., & Eliaz, N. (2022). Measurement of the anisotropic dynamic elastic constants of additive manufactured and wrought Ti6Al4V alloys. *Materials*, *15*(2), Article 638. https://doi.org/10.3390/ma15020638

Tsutsumi, K., Horiuchi, T., & Hongo, K. (2017). Mechanical evaluation of cerebral aneurysm clip scissoring phenomenon: Comparison of titanium alloy and cobalt alloy. *Journal of Materials Science: Materials in Medicine*, *28*(10), Article 159. https://doi.org/10.1007/s10856-017-5975-7

Unnithan, A. K. A., Das, J. M., & Mehta, P. (2023). *Hemorrhagic Stroke*. StatPearls Publishing.

van der Meulen, J., van der Hulst, R., van Adrichem, L., Arnaud, E., Chin-Shong, D., Duncan, C., Habets, E., Hinojosa, J., Mathijssen, I., May, P., Morritt, D., Nishikawa, H., Noons, P., Richardson, D., Wall, S., van der Vlugt, J., & Renier, D. (2009). The increase of metopic synostosis: A pan-European observation. *Journal of Craniofacial Surgery*, *20*(2), 283–286. https://doi.org/10.1097/SCS.0b013e31818436be

Walker, B. J., Cox, B. L., Cikla, U., de Bellefon, G. M., Rankouhi, B., Steiner, L. J., Mahadumrongkul, P., Petry, G., Thevamaran, M., Swader, R., Kuo, J. S., Suresh, K., Thoma, D., & Eliceiri, K. W. (2019). An investigation into the challenges of using metal additive manufacturing for the production of patient-specific Aneurysm Clips. *Journal of Medical Devices*, *13*(3), Article 031009. https://doi.org/10.1115/1.4043651