

# Development of Synthetic Lumbar Vertebrae using Custom-made Mould for Orthopaedics Training: Micro-Structural Analysis

Nurul Najihah Ahmad Zamri<sup>a</sup>, Siti Adawiyah Zulkefli<sup>a</sup>, Nik Nur Ain Azrin Abdullah<sup>a</sup>, Nur Syafiqah Faidzul Hassan<sup>a</sup>, Ahmad Kafrawi Nasution<sup>b</sup>, Muhammad Hanif Ramlee<sup>a,c,\*</sup>

<sup>a</sup>Bone Biomechanics Laboratory (BBL), Department of Biomedical Engineering and Health Sciences, Faculty of Electrical Engineering, Universiti Teknologi Malaysia, 81310 UTM Johor Bahru, Johor, Malaysia; <sup>b</sup>Department of Mechanical Engineering, Faculty of Engineering, Muhammadiyah University of Riau, Pekanbaru, 28291 Riau, Indonesia; <sup>c</sup>Bioinspired Device and Tissue Engineering (BIOINSPIRA) Research Group, Universiti Teknologi Malaysia, 81310 UTM Johor Bahru, Johor, Malaysia

**Abstract** Human vertebrae composed of cortical and cancellous bone are crucial to provide the structural support of human framework and protect the organs underneath. Vertebrae from the Lumbar 3 (L3) was selected for fabrication because it is the most commonly used for surgical training. The use of human vertebrae in the orthopaedic studies is necessary to investigate various complications such as vertebral compression fracture and to propose the most suitable medical intervention for the treatment. However, investigations of cortical and cancellous material properties and composition have been limited. Therefore, the main objective of this study was to design a custom-made mould for synthetic lumbar vertebrae using moulding techniques that could exhibit the same anatomical structure as real vertebrae. Then, this study was carried out to establish a process of cortical and cancellous synthetic bone development. Lastly, this study was done to compare the morphological properties of synthetic bone produced with human bone. Utilizing Polyurethane (PU) as the main material was used for the fabrication, where it could inhibit the morphological properties that could mimic the human bone. The methods to fabricate the vertebrae also varied from static mould and rotational mould. The fabricated lumbar produced was tested for the morphological properties, targeting the pore diameter, was performed using Scanning Electron Microscopy (SEM). From this study, it was identified that the analysis of pore diameter from specimen of Ratio 3 from rotational mould depicts the smallest pore diameter and standard deviation,  $1.5 \pm 0.3$  mm. While this specimen has the smallest value, the results were still higher when compared to the pore diameter of human trabecular bone (which ranges from 0.3 mm to 0.6 mm). In conclusion, the use of silicone custom-made moulds could provide synthetic vertebrae with an anatomical structure mimicking real human vertebrae.

**Keywords:** Mould, Lumbar, Cortical, Cancellous, Pore, Polyurethane.

**\*For correspondence:**  
muhammad.hanif.ramlee@  
biomedical.utm.my

**Received:** 29 August 2023

**Accepted:** 14 April 2024

©Copyright Zamri. This article is distributed under the terms of the [Creative Commons Attribution License](#), which permits unrestricted use and redistribution provided that the original author and source are credited.

## Introduction

Bone is a rigid body tissue that makes up the framework which provides structural support of the organs, muscles and body tissues (Barba *et al.*, 2019). The structure and mechanical properties of the bone such that the porosity and fibrous direction of the tissue that are controlled by the biological process often led to their required functionality. Meanwhile, the spinal column, also known as the vertebral column, is a skeletal framework that houses the spinal cord, runs along the length of the back, connecting the head to the pelvis (Frost *et al.*, 2019). The lumbar spine, specifically designed to be highly resilient and distributed not only from the previous spinal section, but also from the majority of the body's weight maintains its mobility under these strenuous conditions (Frost *et al.*, 2019).

The vertebra consists of trabecular bone, which forms a spongy inner structure, surrounded by a thin outer layer of compact (cortical) bone. The trabecular bone is the primary component of the vertebral body and plays a crucial role in providing strength and carrying the majority of the load (Muhayudin *et al.*, 2020). However, some complications can occur to the lumbar spine such as the vertebral compression fracture. Several interventions can be proposed by utilizing the synthetic vertebrae which includes assessing the patients' anatomy. The common intervention by the orthopaedics includes the pedicle screw fixation, vertebroplasty and balloon tamp dilation. The application of synthetic vertebrae which mimics the composition of real human bone could broaden the scope of training scenarios for spine surgeries. This application aimed to enhance the range of training opportunities and provide a comprehensive understanding of this important surgical procedure (Hollensteiner, 2018). Moreover, synthetic bones are produced to mimic the properties of bone that could help in further research and training in the orthopaedics field. Many procedures have been widely introduced to create synthetic bones that resemble real bones, including both the compact and spongy parts, along with their mechanical properties, for clinical use. When it comes to synthetic bone materials, there are various options available, including polymer form, polyvinyl chloride (PVC) foam, and polyurethane (PU) foam, which can be either open or closed cell structures. PU foams are preferred over other materials due to their similarities to human bone in terms of mechanical properties, such as compression modulus and yield stress (Muhayudin *et al.*, 2020).

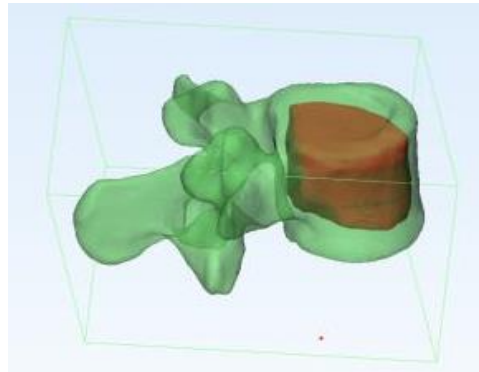
Next, the development of additive manufacturing in the middle of the 1980s paved the way for the fast and accurate manufacture of complex, customized medical models, implants, and prostheses (Modi & Sanadhya, 2018). From the simulation of synthetic bone model by 3D printing from Park *et al.* (2018), this technique can reproduce the bone model and diversify the training by providing better simulation seen in the operating room (OR). However, to enhance the availability and low-cost production of the synthetic bone, the development of mould for the casting of synthetic bone was introduced. The casting of mould in additive manufacturing (AM) involves rapid tooling and has great potential to lower the production cost. Unlike high-end AM methods that create the final product directly which need to be done by layering, casting mould does not require this direct approach. Instead, this method will create the tools such as mould or patterns that will be used to create the final product. The method will vary in two different approaches, static and rotational mould approach in order to distinguish which method could visualize the most accurate bone composition and structure. To add, current synthetic bones in the market are highly expensive and have common standards size, thus, by developing a custom-made mould, the models of synthetic bone can be easily reproduced with the precise measurement and under several volumes.

Primarily to that, this study was focused to produce synthetic lumbar vertebrae using polyurethane (PU) as the base of the fabricated materials. In accordance with guidance from previous studies, additives such as silicone surfactant and distilled water was also added to the PU solution under specific quantities. The fabrication process was done by applying moulding techniques with static and rotational mould approaches, in which utilized different compositions of PU solution and additives for the samples and subsequently conducted the morphological testing.

## Materials and Methods

### Fabrication of Synthetic Lumbar Vertebrae

The fabrication of the synthetic lumbar spine was done to produce a master bone that mimics the real anatomy of the bone to be used in the moulding technique. The information of the bone was extracted from a CT scan data. In this study, the region of interest (ROI) was at the lumbar spine or more specifically the Lumbar 3 (L3). To begin with, the targeted bone was segmented using Mimics Software (Mimics Research 21.0 Software) with a predefined Hounsfield Unit (HU) threshold within the range of 226 to 3071 to precisely outline the bone structure. Then, the 3D-model undergo further processing using 3-Matics Software (3-Matic Research 13.0 Software) for smoothing purposes. The use of 3-Matics software is due to the fact that it's acceptable accuracy and have been used by many researchers from previously published literature (Muhayudin *et al.*, 2021; Shim *et al.*, 2018; Abd Aziz *et al.*, 2024; Ramlee *et al.*, 2020; Zulkefli *et al.*, 2019; Zainal Abidin *et al.*, 2019). Alternatively, local smoothing and remesh tools were used in this process. Furthermore, the cortical and cancellous part of the L3 was also segmented and showed as in Figure 1 by transparency features. Lastly, the 3D-models for both the cortical and cancellous part of the L3 bone produced was converted to STL file and exported to Ultimaker Cura 5.2.1 Software to link with the 3D printer to print out the bone (referred as the master bone) for further procedures.

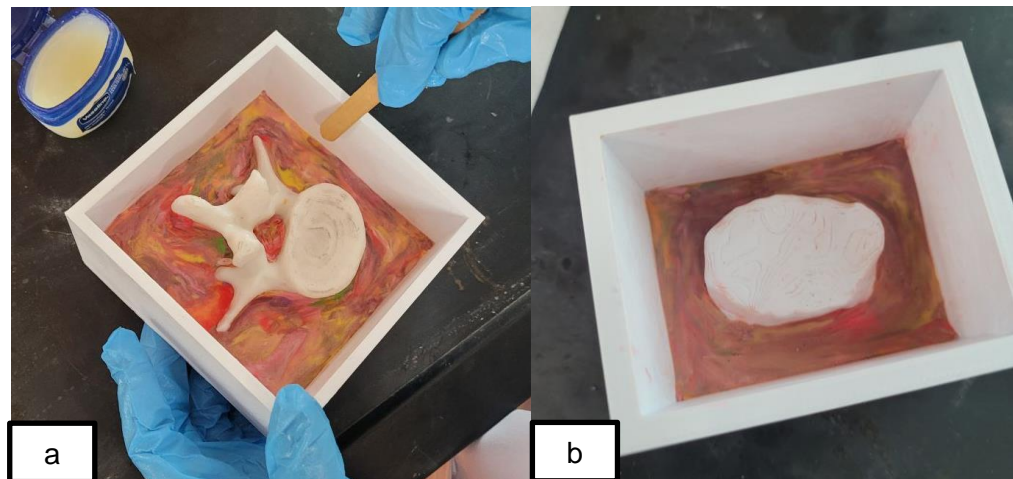


**Figure 1.** L3 in 3-Matic software showing the cortical (green) and cancellous part (orange) of the lumbar

### Preparation of Silicone Mould

The mould was designed with a two-part mould method. A sample of master bone which includes the cortical and cancellous part of the lumbar spine fabricated was prepared. For the first and second layer of silicone mould, the equipment needed are the same which are 3D-printed box, master bone, funnel, silicone free clay, vaseline, Silicone Mould Maker solution and its hardener.

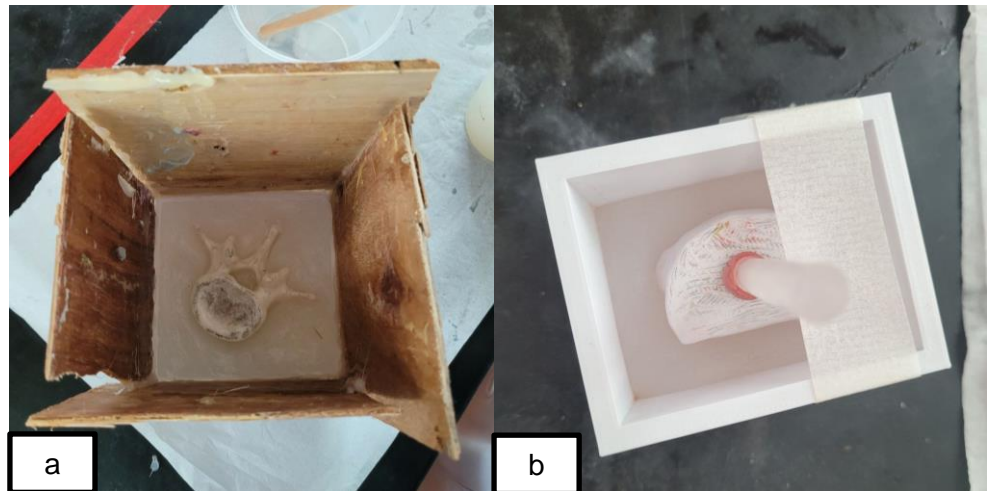
Firstly, the 3D printed mould box was filled in half by using the sulphur-free clay. It is important to use sulphur-free clay or oil-based clay as most silicones will be inhibited by anything containing sulphur. The master bone was traced into the clay without leaving any gaps to avoid seeping of the material on the bone. In this research, the master bone that meant for the fabrication is the lumbar (L3) spine as in Figure 2. Next, any hard-to-reach areas inside the mould box was applied with vaseline using a brush. This to ensure a smooth takeout of the cast during demoulding process. Next, the volume of silicone to be poured was identified by filling the mould box with water. The water was then removed from the mould box into a measuring cylinder and measured the volume. Then, the volume of Silicone Mouldmaker was measured accordingly and mixed with its hardener. The mixture was stirred to blend all together in 1:1 ratio as per the manufacturing guidelines. The mixture was then poured inside the mould box until the area of lumbar was fully covered. Afterwards, the mixture was allowed to dry for about 24 hours to complete the first half of the mould. The steps were repeated for the mould of the cancellous part of the lumbar spine.



**Figure 2.** Preparation of the first layer of silicone mould process for (a) cortical and (b) cancellous part of the lumbar

Subsequently, the moulding process proceeded with the second layer of the mould. The method for the second layer was similar to the first layer except that the number of holes was created by putting the cylinder stick on top of the lumbar spine. To start, after 24 hours of drying the first layer of mould, the clay and the silicone was taken out. Then, the mould surface was cleaned up with water to remove any

unnecessary clay residue prior to receiving the second layer silicone. The first layer of silicone mould was then put back inside the mould box. After that, vaseline was brushed against the edge and surface of hard silicone. Next, four holes were created by inserting cylinder sticks on top of the master bone to be used for the pouring of polyurethane and allowing the air bubbles to be released during chemical reaction later. Larger holes would ease the filling process while preventing air bubbles. Next, the Silicone Mouldmaker was mixed with its hardener and poured into the mould box as the second layer. The mould was allowed to fully cure and removed from the mould box. Until then, the mould box was now ready to be used to fabricate the polyurethane bone. The process of creating the silicone mould from the first to second layer was repeated for the cancellous part of the lumbar as shown in Figure 3.

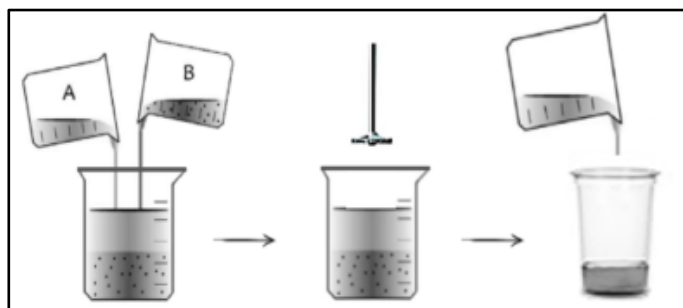


**Figure 3.** Preparation of the second layer of silicone mould process for (a) cortical and (b) cancellous part of the lumbar

### Preparation of Polyurethane

Polyurethane (PU) was used as the material for the fabrication of synthetic lumbar spine. Commonly, PU consists of two parts which are Polyol and Isocyanate that need to be mixed together as per the guidelines by the manufacturer.

Polyurethane has been chosen for the material for the synthetic lumbar spine as the PU foam have similar mechanical characteristics to those of human bone and can closely mimic the cortical and cancellous bone which directs to the research objectives (Muhayudin *et al.*, 2021). The preparation of the PU mixture for cortical part of the bone consists of two parts, which are Part A as the polyol and Part B as isocyanate which act as the hardening agent. The solution of Part A and Part B will need to be thoroughly premixed by shaking the container before use. These two parts of PU were poured in two different cups under a ratio of 1:1 by volume of the Part A and Part B solution as per manufacturing guidelines. The volume used was measured with a weighing scale beforehand. Then, Part A was poured in a bigger, clean container along with Part B. This mixture of Part A and Part B was then used for the fabrication of lumbar spine (L3). Figure 4 illustrated the steps of mixing the solution.



**Figure 4.** Illustration of preparing the mixture of Part A and Part B of Polyurethane before pouring into the silicone mould (Anna, 2019)

For the cancellous part of the bone, the main part for the mixture in this study consisted of polyol, isocyanate, distilled water and silicone surfactant. The existence of distilled water was used as a chemical blowing agent (Han, 2009). Meanwhile, the surfactants are essential ingredients that function in controlling the cell size of PUF (Polyurethane Foam). In this study, a common surfactant which is silicone surfactant was used which is a copolymer consisting of a polysiloxane backbone and a polyether side chain. They help stabilize the gas bubbles that are formed during the processes of nucleation and coalescence. These chemicals were weighted by the weighing scale beforehand.

To begin with, polyol and isocyanate was poured in two different containers and labelled to avoid mispouring. In this study, the volume of distilled water and silicone surfactant used for the ratio calculation were only a few drops, given the small size of the target bones compared to larger bones such as the femur or tibia. Thus, a dropper was used for this procedure. Then, distilled water and silicone surfactant was dropped inside the polyol container and mixed for 30 seconds. Isocyanate was then poured into the polyol container and mixed for 30 seconds as well. After 30 seconds had passed, the mixture was then poured inside the hole created at the mould immediately to create a rise-free foams and allowed to cure. It is advisable to note that pouring of the mixture should be as fast as possible and avoid a prolonged mix as the polyurethane will be cured before even pouring the mixture inside the mould. The chemical composition used of all samples in different ratios were tabulated in Table 1.

**Table 1.** Formulation of PU foams for static mould and rotational mould (Farhana *et al.*, 2014)

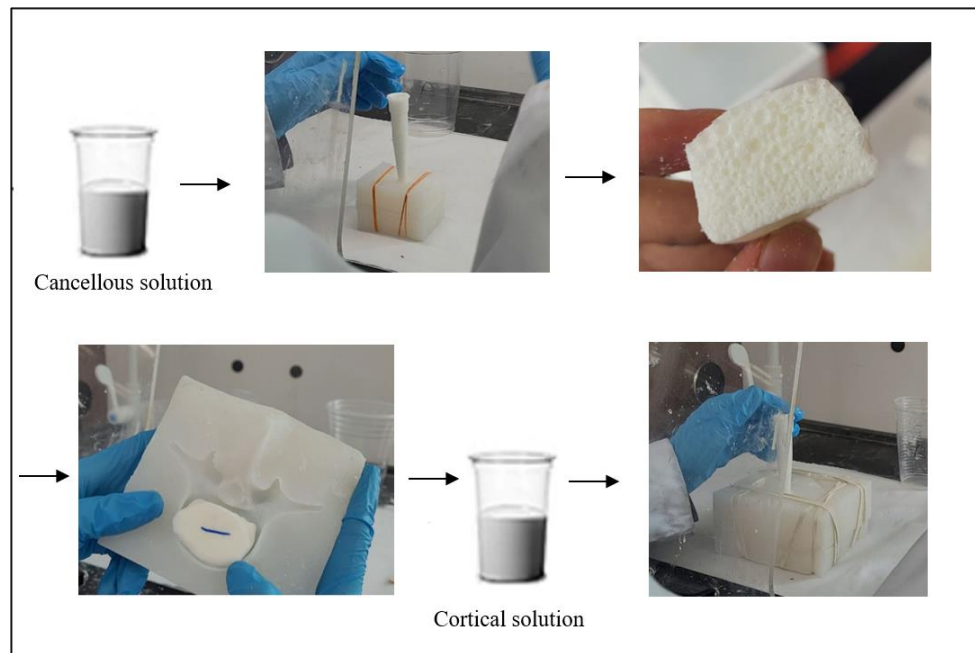
Sample	NCO:OH Ratio	Water [pbw]	Silicone Surfactant [pbw]
Ratio 1	1:1	1	2
Ratio 2	1:1	2	2
Ratio 3	1:1	1	3

### Casting of the Polyurethane-based Lumbar 3 (L3) Spine

From the moulds created in the previous step, it was then further used to fabricate the bone by pouring the PU inside the mould under two different approaches separately: static and rotational mould process.

Static approach is the basic approach for the casting of bone. It begins with the formation of the cancellous layer of the bone and proceeds with pouring the outer layer (cortical) solution to the mixture. Firstly, the silicone mould for cancellous was tightened up with rubber bands to both sides of the mould to give pressure all around and prevent the PU solutions from leaking. Then, the PU foams solution was poured inside the mould and allowed the material to spread inside the mould. Finally, after a few minutes or after the solution has set, rubber bands will be removed and the cancellous part was demoulded.

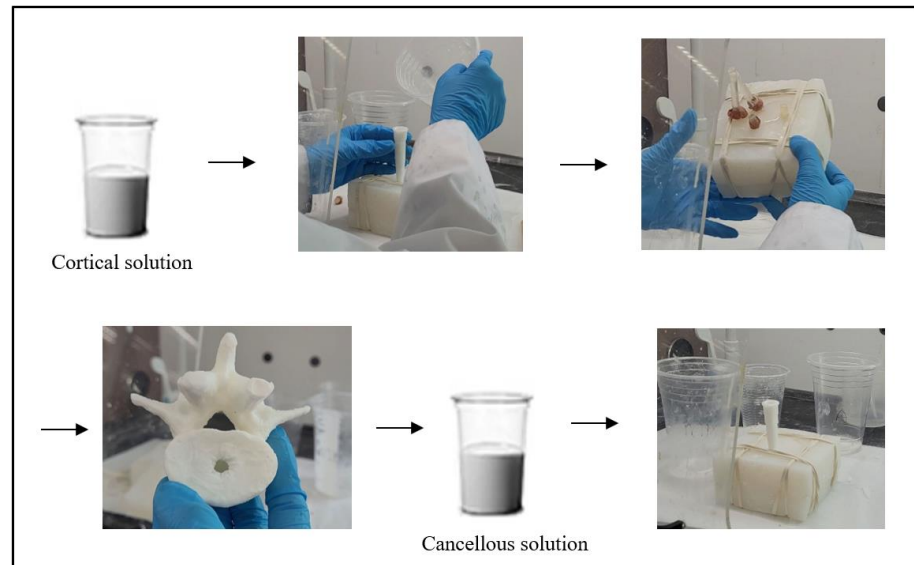
Further, the process proceeds with the creation of the outer part of the lumbar spine. The previous cured cancellous part was put inside the mould of the cortical part accordingly. Then, the PU solution for cortical was poured inside the mould through a funnel. Since this method is using a static approach, no shaking or rotational of the mould is required and thus the PU will only rely on the gravitational force to spread thoroughly inside the mould. Finally, after 24 hours or after the solution was set, rubber bands were removed and the synthetic bone was demoulded. This technique was repeated three times to produce three different samples with distinct ratios as in Table 1. Lastly, the lumbar vertebrae produced was used for further evaluation. Figure 5 illustrated the steps of fabricating L3 using static mould.



**Figure 5.** Illustration on the process of fabricating L3 using static mould

Next, the process proceeds with fabricating the lumbar using the rotational approach. Prior to the pouring of PU solutions, the silicone for rotational approach was also sealed with rubber bands to prevent leaking. For this approach, it begins with the formation of the outer layer of the bone (cortical) and proceeds with pouring the cancellous solution to the mixture. First, a specific quantity of cortical polyurethane (PU) mixture was poured into the silicone mould of the cortical lumbar vertebrae. The mixture was allowed to sit for about 15 seconds beforehand allowing the air bubbles to be removed and closing the holes with the clay for the rotational process. Then, the mould was rotated continuously at a constant speed for about 4 minutes, allowing the PU mixture to accumulate and take the shape of the negative mould, resulting in a hollow vertebra structure (Marianne *et al.*, 2018).

After the cortical mixture has fully cured, the cortical part was demoulded. A hole was made to the cured cortical part for the pouring of the cancellous mixture. Subsequently, a separate cancellous mixture was poured into the hollow vertebra using a funnel, creating a cancellous padding within the structure. Then, the mixture was allowed to cure before the demoulding process. This technique was repeated three times to produce three different samples with distinct ratios as in Table 1. After the solution has set, rubber bands will be removed and proceed to demould the bone. This fabricated lumbar spine produced was used for further evaluation. Figure 6 illustrated the steps of fabricating L3 using rotational mould.



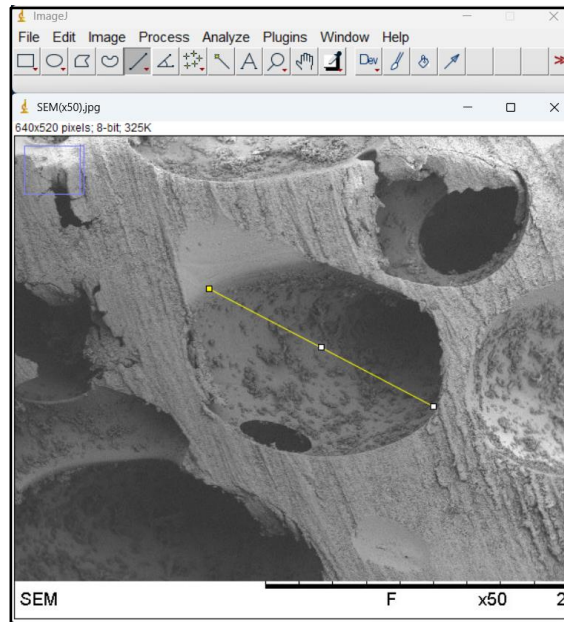
**Figure 6.** Illustration on the process of fabricating L3 using rotational mould

### Morphology Testing under Scanning Electron Microscopy (SEM)

To begin the test, the fabricated lumbar spine underwent several steps to obtain a high-resolution image by following the SEM guidelines. Firstly, the fabricated bone specimens were prepared by cutting into a cubic form of about 1 cm x 1 cm x 0.5 cm dimension using a bandsaw as prescribed by ASTM-F1839. For this test, six specimens from each of different techniques and ratios were prepared for the testing. To submit the samples for coating, each of the specimens was adhered to coins with carbon tape and labelled to avoid confusion. Then, the samples were sent for sputter coating with metal coatings such as gold (Au). This process of coating is crucial as it can reduce the charge effects, thus contributing to a high spatial resolution.

After the coating process of all six samples, the samples were then further sent for the testing using a Tabletop SEM machine (Model TM3000). Three samples were placed on the stage and analysed at the same time to reduce time for conducting the analysis. The samples were placed on stage and adhered with a double tape to prevent the samples from moving. Then, the samples were transferred into a chamber within the SEM. The machine was evacuated first to enable the operation. After that, each sample was magnified using a 15kV electron gun in analytical mode at 25X and 50X. The images were obtained on tiny rectangular sections to provide detailed insights into the foam's structure and characteristics. The photos of the sample's morphology were snapped in a high resolution and were used to distinguish the morphology between the ratio and technique of the sample. The procedure was then repeated for other remaining samples. Lastly, the data from the SEM machine were exported using a CD and proceeded with the analysis using ImageJ software. The ImageJ software was utilized to measure the pore diameter of the bone specimen.

To begin the analysis, the SEM images were dragged and dropped into the ImageJ software. The contrast and brightness were adjusted to obtain a clearer image for the analysis. Then, using the free-hand selection tools, the diameter of the pore was calculated by dragging a line approximately perpendicular across the pore using the cursor as per Figure 7. The scale of the value was set to a unit length of mm. Then, the diameter was measured by choosing the measure option and the results were acquired. The measurements were repeated for three times to ensure an average diameter size was obtained for each pore. Moreover, five holes from each batch were measured and calculated to get the mean value and the standard deviation of the overall pore diameter of the samples. The results were then recorded to compare the pore diameter between the techniques and ratios of the samples.

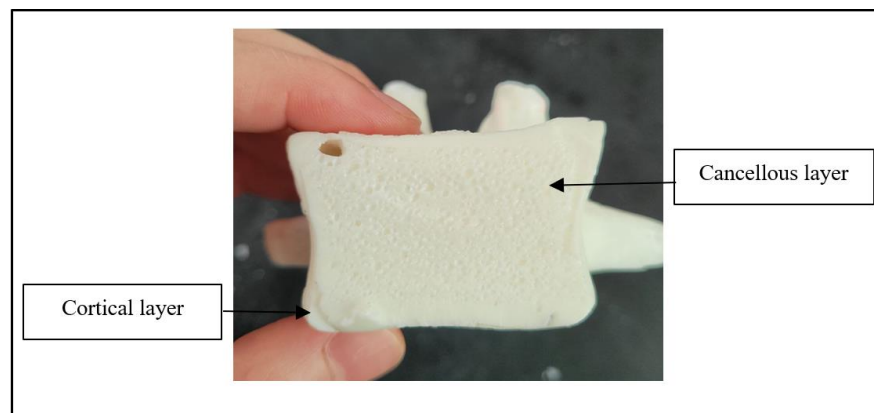


**Figure 7.** Measurement of the pore diameter in ImageJ software

## Results and Discussion

### Fabrication of Synthetic Lumbar Vertebrae

The mould was able to provide ways to produce a large number of synthetic bone calcaneus models without altering the bone's original structure. The casting of bone from the rotational method and static method were both able to produce the similar bone composition of cortical and cancellous bone as it provides uniformity in the distribution of gas reaction of the PU material inside the silicone mould. However, the rotational mould method was more favourable as it can produce the synthetic bone by only utilizing one mould which is from the cortical mould. Meanwhile, the static mould requires two moulds which are mould for cancellous and cortical mould. Other than that, time allocated for the segmentation in Mimics and 3-Matic for rotational mould was also shorter in time, since the segmentation can be done only by targeting the outer structure of the lumbar. Thus, the bone fabricated by the rotational mould techniques can reduce the costs financially and more efficiently, making it more suitable for the industry. Furthermore, the synthetic bone produced from the silicone mould is anticipated to be almost identical to the human bone in terms of the anatomical structure and the morphology. Figure 8 showed the cross-sectional area of the fabricated L3 that showing the cortical and cancellous region.

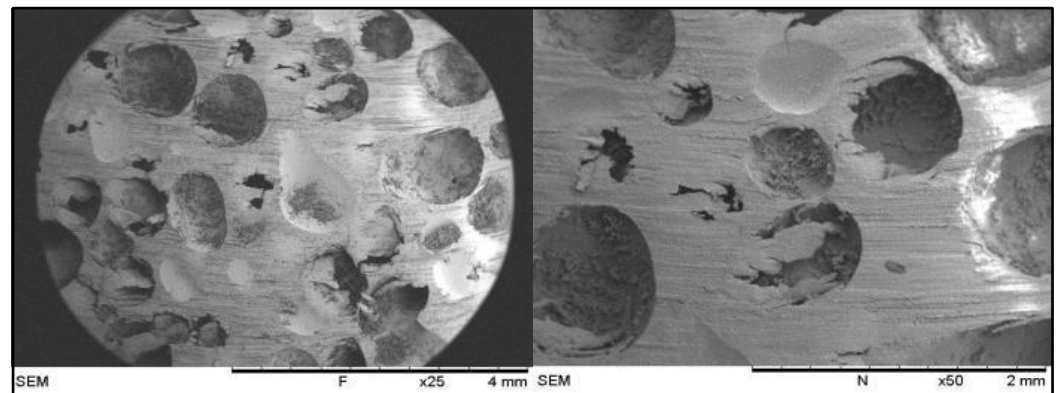


**Figure 8.** Cross section of fabricated lumbar vertebrae showing the cortical and cancellous layer

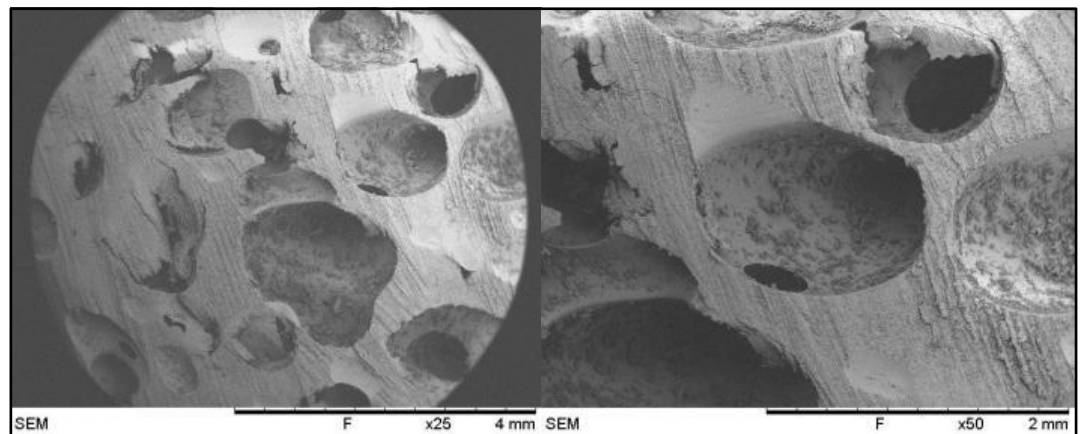


### Morphological Testing utilizing Scanning Electron Microscopy (SEM)

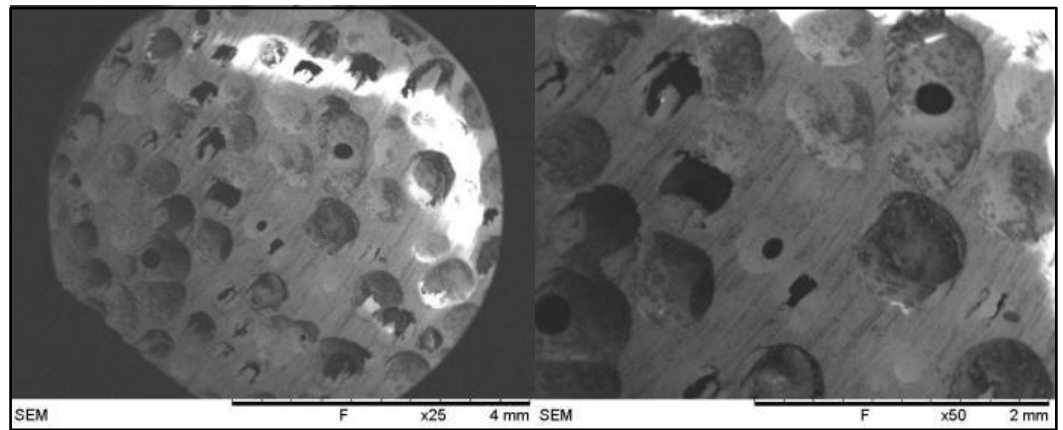
Images of the closed cell PU foam were captured using SEM microstructure analysis to examine the morphology of the expandable PU foam for two techniques at three distinct ratios. Each sample were undergoing sputter coating with gold beforehand to prevent charging of the samples during the testing. Next, the samples were magnified in 25X and 50X to have the overall view of the sample's morphology. Figure 9 to 11, and Figure 12 to 14 displays the morphology of the specimens for bone with static and rotational mould, respectively. However, there were still some spots of charging that occur within the specimen as in Figure 11 which appear as bright regions compared to the surrounding areas. This was caused by the accumulation of electrons which further resulted in sample damage. Then, the SEM images were exported to ImageJ software for the analysis of the pore diameter. Table 2 and Figure 15 showed the average pore diameter for each sample. From here, it was demonstrated that variety of pore diameter for the bone with static and rotational mould. For the static mould condition, the highest average pore diameter was ratio 2 ( $2.3 \pm 0.5\text{mm}$ ). Meanwhile for the rotational mould condition, the highest average pore diameter was ratio 1 ( $2.3 \pm 0.9\text{mm}$ )



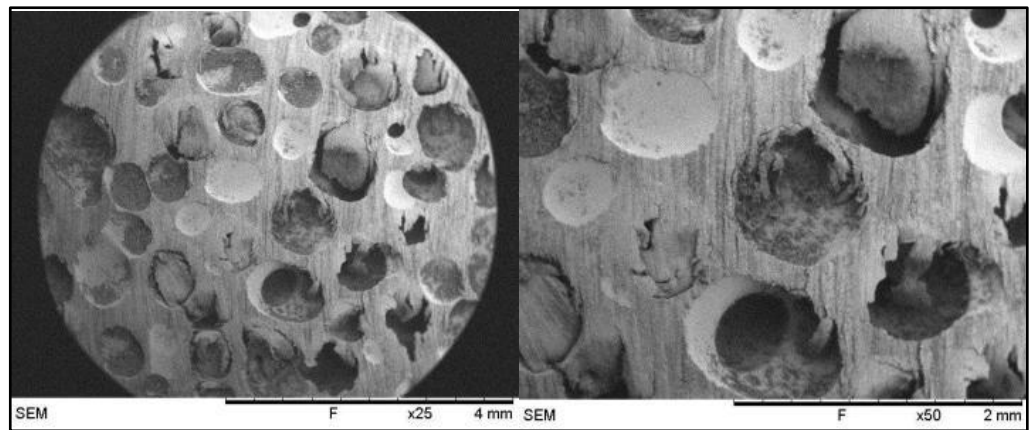
**Figure 9.** Displays the morphology of Ratio 1 (Static Mould) under 25X and 50X magnification



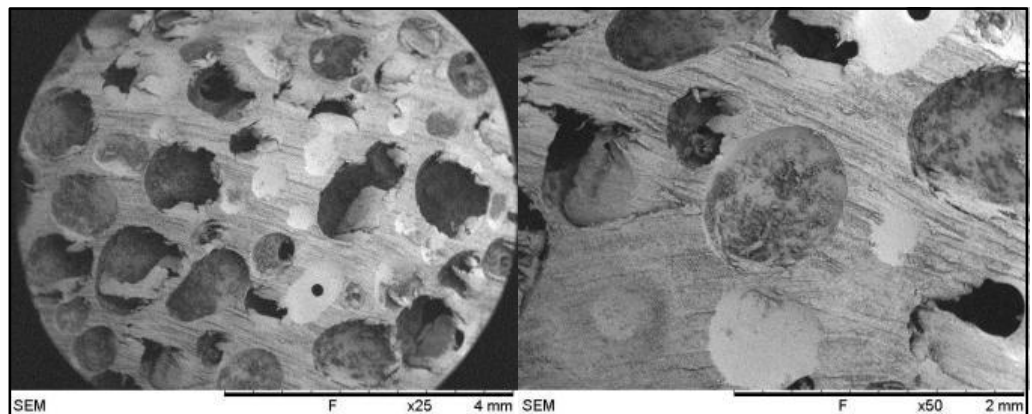
**Figure 10.** Displays the morphology of Ratio 2 (Static Mould) under 25X and 50X magnification



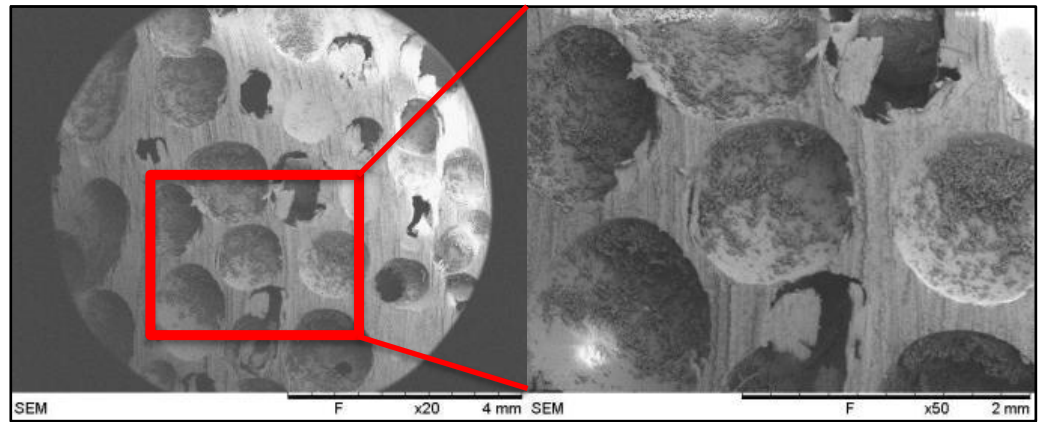
**Figure 11.** Displays the morphology of Ratio 3 (Static Mould) under 25X and 50X magnification



**Figure 12.** Displays the morphology of Ratio 1 (Rotational Mould) under 25X and 50X magnification



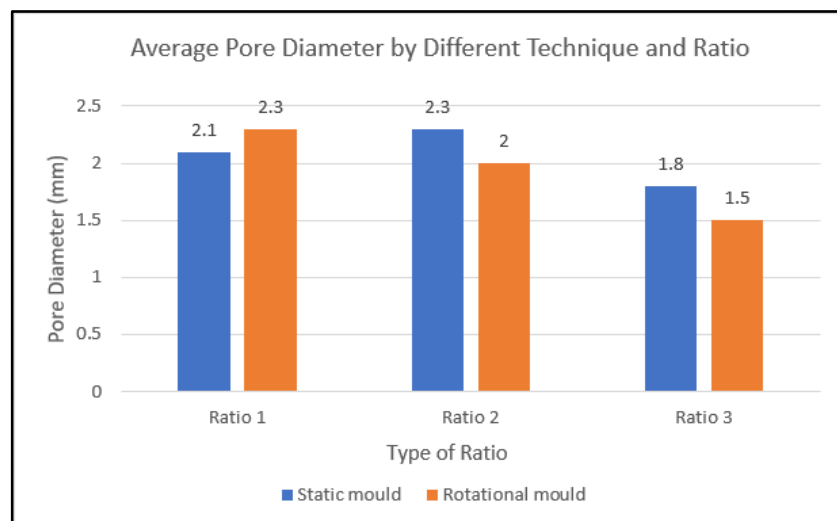
**Figure 13.** Displays the morphology of Ratio 2 (Rotational Mould) under 25X and 50X magnification



**Figure 14.** Displays the morphology of Ratio 3 (Rotational Mould) under 20X and 50X magnification

**Table 2.** Average pore diameter for each sample

Sample	Average Pore Diameter (mm)	
	Static Mould	Rotational Mould
Ratio 1	2.1 ± 0.4	2.3 ± 0.9
Ratio 2	2.3 ± 0.5	2.0 ± 0.7
Ratio 3	1.8 ± 0.4	1.5 ± 0.3



**Figure 15.** Average Pore Diameter by Different Technique and Ratio

Cancellous bone exhibits a high level of porosity, similar to a sponge or foam, leading to the use of polyurethane foam to mimic its structure (Muhayudin *et al.*, 2020). As per mentioned in the ratio of the composition in Table 1, the content of silicone surfactant for Ratio 1 and Ratio 3 was increased. Meanwhile, in Ratio 2, the PU mixture contained equivalent amounts of distilled water and silicone surfactant. Table 2 illustrates the impact of various ratio compositions on the sample morphology of PU, specifically concerning on the pore diameter produced.

Overall, the pore size distribution of the different composition was measured, considering the relationship with porosity (Barba *et al.*, 2019). As can be seen in Figure 15, the pore diameter of samples from Ratio 1 and Ratio 3 in static mould had demonstrated a decrease in pore diameter, with reductions of 2.1 mm to 1.8 mm. Similarly, rotational mould techniques had also shown a decrement of the pore diameter from Ratio 1 and Ratio 3 with 2.3 mm and 1.5 mm respectively. These results aligned and supported by a

previous study, in which increasing the concentration of silicone surfactant can lower the surface tension of the foaming system, leading to the reduction in pore diameter (Shim *et al.*, 2018). Then, in static mould techniques, Ratio 2 exhibits the largest average pore diameter among the other ratios, measuring 2.3 mm. This increase in diameter corresponds with the increase of blowing agents, specifically distilled water that has been added to the mixture, leading to an enlargement of pore size (Shim *et al.*, 2018). Moreover, the samples in the specimen from Ratio 1 in rotational mould and Ratio 2 in static mould acquired the highest pore diameter size which is 2.3 mm with distinct in the standard deviation of 0.9 mm and 0.5 mm respectively. The sequence continues with Ratio 1 in static mould acquired  $2.1 \pm 0.4$  mm while Ratio 2 from rotational mould possesses a smaller pore diameter, with  $2.0 \pm 0.7$  mm. Then, it can be seen that Ratio 3 from both techniques displays the smallest pore diameter for its categories which is from  $1.8 \pm 0.4$  mm and  $1.5 \pm 0.3$  mm, respectively.

Other than that, from Table 2, the standard deviation from Ratio 3 was observed to have the smallest value in both techniques which is 0.4 mm and 0.3 mm, respectively. Standard deviation quantified the amount of dispersion in a set of data points (Hopkins, 2017). In other words, a small standard deviation suggests that the data points are clustered around the mean, whereas a large standard deviation indicates that the data points are more widely dispersed from the mean. Consequently, this suggest that the pore distribution achieved with Ratio 3 was more even, regardless of the fabrication techniques employed for the cancellous part. This proves that surfactants play a vital role in controlling the size of polyurethane foam (PUF). It serves to stabilize the gas bubbles that form during the nucleation process and prevent coalescence. The presence of silicone surfactants was effective in inhibiting the coalescence of foam cells due to their ability to lower surface tension (Han *et al.*, 2009).

In comparison of the fabricated lumbar vertebrae with the human vertebrae, Ratio 1 (rotational mould) and Ratio 2 (static mould) possesses the closest pore diameter to human trabecular bone. However, the pore diameter of fabricated bone was still considerably lower than human trabecular bone, which ranges from 3 mm to 6 mm in diameter. Since the ratio used in this study was limited, there is an opportunity for additional investigations to be conducted with a broader range of ratios. This can be achieved by not only varying the additives but also diversifying the composition of polyol and isocyanate in the solution. By conducting these further investigations, researchers can explore a wider spectrum of possibilities to identify the optimal combination that would best achieve the desired pore diameter in the synthetic lumbar vertebrae. This will enable the identification of the optimal combination that yields the desired pore diameter, facilitating a deeper understanding of the factors influencing the final product's morphology in terms of its pore size. To conclude, the size of the pore does not only depend on the additives but can also be controlled by varying the amount of polyol and isocyanate in the solution.

## Conclusions

In conclusion, application of the custom-made mould in fabricating a synthetic lumbar vertebra allowed orthopaedics to study the anatomical and properties of the patient's lumbar before surgical intervention. The use of polyurethane (PU) material as the material for the synthetic bone is the most favourable material as the reaction of the polyurethane will produce the foam that could illustrate and distinguish the cortical and cancellous part of human bone composition. However, the composition may have drawbacks considering high-volume bone areas such as tibia and fibula and can be improved from time to time by diversified the range of the composition. Apart from that, studies have demonstrated that PU is a versatile material with adjustable morphological properties. By varying the ratio for additives like silicone surfactant and water, it is possible to enhance pore properties for the synthetic bone production. This ability to fine-tune the composition of PU enables the creation of synthetic bone with controlled pore structure, and other desired properties for various applications in the field of bone tissue engineering and orthopaedics.

Comparing the result of the pore diameter, composition Ratio 1 (rotational mould) and Ratio 2 (static mould) was the most preferred due to being the closest to the pore diameter of real human bone. All in all, the value of the recommendation was not fixed since the bone properties of humans varied from human to human due to their age, sex and physical activity levels. Thus, the recommended value of the bone properties should be subjected to our own target of patients' anatomical assessments.

## Conflicts of Interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

## Acknowledgment

We would like to thank Department of Biomedical Engineering and Health Sciences, Faculty of Electrical Engineering, Universiti Teknologi Malaysia for providing us with good facilities to conduct this study. This study was financially supported by Universitas Sriwijaya Indonesia (UNSRI) under International Grant (Grant no.: R.J130000.7323.1U051) and Universiti Teknologi Malaysia (UTM) under Matching Grant (Grant no.: R.J130000.7623.4B908).

## References

- [1] Abd Aziz, A. U., Ammarullah, M. I., Bing Wui, N., Hong-Seng, G., Abdul Kadir, M. R., Ramlee, M. H. (2024). Unilateral external fixator and its biomechanical effects in treating different types of femoral fracture: A finite element study with experimental validated model. *Heliyon*, 10, e26660.
- [2] Barba, D., Alabort, E., & Reed, R. C. (2019). Synthetic bone: Design by additive manufacturing. *Acta biomaterialia*, 97, 637-656.
- [3] Farhana, S. M. A., Mohd Haziq, D., Nurfatmah Pz, N., & Majid, R. A. (2014). Effects of silicone surfactant on the water absorption and surface morphology of rigid palm oil-based polyurethane foam. *Applied Mechanics and Materials*, 554, 185-188.
- [4] Frost, B. A., Camarero-Espinosa, S., & Foster, E. J. (2019). Materials for the spine: anatomy, problems, and solutions. *Materials*, 12(2), 253.
- [5] Han, M. S., Choi, S. J., Kim, J. M., Kim, Y. H., Kim, W. N., Lee, H. S., & Sung, J. Y. (2009). Effects of silicone surfactant on the cell size and thermal conductivity of rigid polyurethane foams by environmentally friendly blowing agents. *Macromolecular Research*, 17, 44-50.
- [6] Hollensteiner, M., Botzenmayer, M., Fürst, D., Winkler, M., Augat, P., Sandriesser, S., ... & Schrepf, A. (2018). Characterization of polyurethane-based synthetic vertebrae for spinal cement augmentation training. *Journal of Materials Science: Materials in Medicine*, 29, 1-11.
- [7] Hopkins, W. G. (2017). Spreadsheets for analysis of validity and reliability. *Sportscience*, 21.
- [8] Modi, Y. K., & Sanadhya, S. (2018). Design and additive manufacturing of patient-specific cranial and pelvic bone implants from computed tomography data. *Journal of the Brazilian Society of Mechanical Sciences and Engineering*, 40(10), 1-11.
- [9] Muhayudin, N. A., Basaruddin, K. S., McEvoy, F., & Tansey, A. (2020). Evaluating compressive properties and morphology of expandable polyurethane foam for use in a synthetic paediatric spine. *Journal of Materials Research and Technology*, 9(2), 2590-2597.
- [10] Shim, V., Boheme, J., Josten, C., & Anderson, I. (2018). Use of polyurethane foam in orthopaedic biomechanical experimentation and simulation. *Polyurethane*, 171-200.
- [11] Ramlee, M. H., Gan, H. S., Daud, S. A., Abdul Wahab, A., Abdul Kadir, M. R. (2020). Stress distributions and micromovement of fragment bone of pilon fracture treated with external fixator: A finite element analysis. *The Journal of Foot and Ankle Surgery*, 59(4), 664-472.
- [12] Zulkefli, S. A., Shaikhani, M. H., Nasution, A. K., Abdul Wahab, A., Abdul Kadir, M. R., Ramlee, M. H. (2019). Fabrication and biomechanical evaluation of polyurethane material for synthetic bone. *Journal of Physics: Conference Series*, 1372(1), 012013.
- [13] Zulkefli, S.A., Shaikhani, M. H., Nasution, A. K., Hong-Seng, G., Ramlee, M. H. (2019). Polyurethane material for synthetic tibia bone application. *Materials: Technology and Application*, 20-36.
- [14] Zainal Abidin, N. A., Abdul Kadir, M. R., Ramlee, M. H. (2019). Three dimensional finite element modelling and analysis of human knee joint- model verification. *Journal of Physics: Conference Series*, 1372(1), 012068.