Fabrication and Biomechanical Evaluation of Polyurethane Material for Synthetic Bone

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Abstract. Synthetic bone has become an important tool for education in the orthopaedics field and biomechanical research. The use of the conventional tool such as cadaver has become a challenge to the researcher and orthopaedic surgeon, as it was highly cost, ethical issues and storage. In addition, the available synthetic bones in the market were expensive and only in European size. This research was focusing on developing the synthetic bone using polyurethane material, evaluate the mechanical strength of the developed synthetic bone and characterize the morphological structure of the developed synthetic bone. The development of the synthetic bone was using Polyurethane (PU) as its material. Two type composition of PU was used for this research. The material mixed and poured into the mould that has been designed according to American Society Testing and Material (ASTM) standard which was ASTM-F1839. Then, composition 1 and composition 2 undergo mechanical testing and morphology analysis by using Instron and Scanning Electron Microscopy (SEM) respectively. The average Young’s Modulus of composition 1 and composition 2 were 208.6963 MPa and 384.6304 MPa respectively. In short, the developed synthetic bone has greater Young's modulus compared to the synthetic bone that available in the market and which are 132.3254 MPa (Sawbone) and 68.1483 MPa (Symbone). The morphological analysis has shown the fabricated synthetic bone has compact structure compare to the one in the market that mimic the cancellous bone. In conclusion, composition 2 of PU have the highest Young's modulus but from the morphological analysis it does not mimic the morphology of cancellous bone.

1. Introduction

Bones were very essential in daily life activities as it gives support to the locomotion such as walking, standing, running and many more [1]. Moreover, in the body there was a bone, which was tibia that plays an essential role in our life. The study was focus on optimizing the Young’s modulus of the synthetic bone to meet Young’s modulus of cancellous bone. Young’s modulus for cancellous bone was range between 350 MPa to 700 MPa. The value of cancellous bone of 350 MPa was for the bone that encounters metabolic bone disorder while 700 MPa was for the normal bone [2]. Nonetheless, the tibia was exposed to the fractures that might occur due to the impact while doing various type of activities. There are several types of fracture that might occur such as transverse, oblique, comminuted and compound fractures [3,4].

In the orthopaedic field, it was very essential for the surgeon to prescribe the best treatment to the patient. In addition, the orthopaedic surgeon also needs skills in order to perform the surgery to prevent any unwanted event. Hence, the use of the synthetic bone will provide the surgeon and medical students to familiarize with the surgical tools and simulate the surgery in the operation theatre [5,6]. For the biomechanics researcher, to simulate implant would need cadaver in order to have accurate data. This cadaver would cause several issues due to the limited storage and life span, cost and the most crucial is
ethical approval [7–9]. Even though several companies such as Synbone and Sawbone are providing synthetic bone, the size of the bone was in European size. Thus, the biomechanics researcher has limitation in their study where the bones that can be available were only in European size. In order to fabricate the synthetic tibia bone, PU was used as the material. PU was first discovered by Otto Bayer and his coworkers at the laboratories of I.G. Farben in Leverkusen, Germany on 1937. In recent year, PU was widely used in automotive, building and home construction, medical devices and implants [10,11]. As reported by Nuno V. Gama et al, the consumption of PU in 2017 was estimated at 60.5 billion USD in 2017. However, it was predicted to increase which is over 79 billion USD in 2021. Furthermore, PU was formed by the reaction of exothermic of isocyanates and polyol. Isocyanates acted as a hard segment which has NCO functional group while polyol acted as a soft segment that contains OH group [10]. N. Sidek et al mentioned that the ideal ratio of isocyanates and polyol was 1:1. In other words, the ratio of 1:1 will give the best result for the formation of Polyurethane. In this study, the ratio to produce Polyurethane is 1:1 [11]. To summarize, this study was intended on developing the synthetic bone by using polyurethane material, evaluate the mechanical strength of the developed synthetic bone and characterize the morphological structure.

2. Methodology
The experimental work of the study started by preparing the mould based on ASTM-F1839. Consequently, the preparation mixture of Polyurethane was made for composition 1 and composition 2. Then, composition 1, composition 2 and tibia synthetic bone from Sawbone and Synbone undergo mechanical testing and morphological analysis.

2.1. Preparation of Mould
The mould was designed to meet the requirement from ASTM-F1839 as shown in Fig. 1. The standard specification is for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopedic Devices and Instruments. Figure 1 illustrates the flow for preparation of mould. Firstly, the mould was sketched on 3D Computer Aided (CAD) software, Solidworks (Dassault System Solidworks Corp., USA). The dimension of the mould was based ASTM F1839 which were 50.8mm x 50.8mm x 25.4mm. After sketching, the file was saved in the STL file. In order to 3D print the mould, the STL file was converted into the x3g file by using Markerbot software. Next, the mould was 3D printed by using the Flashforge 3D printer. The time consumed for the mould to be completely printed was approximately 5 hours. Once the 3D printed mould was ready, the mixture of the Moldmaker Silicone and hardener was mix together to make the silicone rubber mould. After the mixture was ready, the mixture was poured into the 3D printed mould. The mixture was left to dry for 24 hours. After 24 hours, the silicone mould was pulled out from the 3D printed mould.

![Figure 1. Show the flow to produce mould based on ASTM F1939.](image)

2.2. Preparation of PU
There were two type composition of PU were used in this study. Basically, for composition 1 and composition 2 were the fabricated PU which given in two parts which were Part A (Polyol) and Part B (isocyanate). As stated in the introduction the ideal ratio for the polyurethane was 1:1. Nonetheless, the ideal ratio for composition 1 was 2:1 based on the manufacturer’s guideline. In contrast, composition 2
was using ratio 1:1 to get the optimum mechanical strength based on manufacturer's guideline. Hence, to prepare the specimen the mixture of Part A and Part B from both composition were mixed according manufacturer’s guideline as shown in Fig 2. The mixture then was poured into silicone rubber mould. Composition 1 take longer time to cure which is 2 to 3 days while for composition 2 take only 2 minutes to cure.

![Figure 2. Show the procedure to mix isocyanate (Part A) and polyol (Part B) for both composition.](image)

### 2.3. Mechanical Testing

The specimens will undergo mechanical testing by using a universal testing machine (8874 Model, Instron). Particularly, the specimen will undergo compression testing to evaluate its mechanical strength. The specimen was placed under the 25 kN load where the load was adjusted until the gap between the load and the specimen is approximately 0.5 cm in distance (Fig 2). During the compression test, the crosshead speed was set to $2.5 \pm 0.25$ mm/min based on ASTM-F1839. Furthermore, after the specimens have undergone the compression testing Bluehill software will provide data of the sample such as Young’s modulus, compression stress and strain and many more. Then, the data was plotted by using Microsoft Excel.

### 2.4. Morphological analysis

The specimen undergo the morphological analysis using Scanning Electron Microscopy (SEM). SEM was used to visualize the morphology of the cell structure of the PU and existing synthetic bone. Before entering the SEM, several steps need to be conducted for the best visualization. The specimens of the different composition and existing synthetic bone (Sawbone and Synbone) were cut by using the band saw into 1cm x 0.5cm x 1cm. Following that, the specimens were coated with gold by Leica EN ACE to prevent charging on the surface. For this study, the magnification to use to visualize the morphology of the specimens are 500X and 1000X.

### 3. Results and Discussion

This study focused on mechanical strength and microstructure of the specimen. The results are shown at the following part.

#### 3.1. Mechanical Testing using Instron

Fig. 3 depicts the Young’s modulus for Sample A, Sample B, Sawbone and Synbone after undergone compression testing by using Instron. This finding has significant impact as it show the Young’s modulus from the available product in the market. Comparatively, based on the results of Young’s modulus of the Synbone and Sawbone, it showed that Sawbone has higher Young’s modulus compared to Synbone. The value of Young’s modulus for Sawbone is 132.3254 MPa while Synbone is 68.1483 MPa. In contrast, the Young’s modulus for the sample A and Sample B are 208.6963 MPa and 384.6304 MPa respectively. This evident prove that Sample B has higher Young’s modulus compared to Sample A.

As states earlier, cancellous bone for tibia range from 350 MPa to 700MPa. Based on the experiment it proved that sample B has Young’s Modulus which in the range of tibia cancellous bone. Together, the present findings confirm that sample A, bone from Synbone and Sawbone does not meet the Young’s Modulus for tibia cancellous bone.
3.2. **Microstructure testing by using SEM**

Overall, the visualization of morphology of specimens done under Table Top SEM with 500X. Hence, this technique was used to facilitate the third objective of this study which to enable a comparative analysis in regards to microstructural properties of synthetic bone. The results of the experiment found that composition 1 possess some inhomogeneous microstructural properties as compared to commercial products, Sawbone and Synbone (Fig. 3). In addition, composition 2 does not possess microstructure of the bone (Fig. 4) as it does not any pore to mimic cancellous bone. Hence, composition 2 need alternation in regard of microstructure by using additives such as blowing agent and surfactant (Fig. 5). Nonetheless, the microstructure of the Synbone and Sawbone in Fig. 6 and Fig. 7 respectively illustrate slightly different in term of the pore size. Yet, the microstructure of the commercial synthetic bone does not mimic the microstructure of cancellous bone. In addition, Fig. 6 and Fig. 7 appeared with slight contamination as compared to composition 1 and composition 2.

![Figure 3](image1.png)

**Figure 3.** Depict the bar graph for average of Young’s Modulus for the specimen

![Figure 4](image2.png)

**Figure 4.** Depicts composition 1 of PU.

![Figure 5](image3.png)

**Figure 5.** Illustrate composition 2 of PU.

![Figure 6](image4.png)

**Figure 6.** Show sample for Sawbone.

![Figure 7](image5.png)

**Figure 7.** Depict sample for Synbone.
4. Conclusion
From this study, it proved that the average Young’s modulus for composition 2 was higher compared to composition 1 and commercial product from Sawbone and Synbone that was 384.6304 MPa. This value of Young’s modulus is in the range of cancellous bone. In addition, the commercial product does not meet the value of Young’s Modulus of the cancellous bone that ranges 350 MPa (metabolic bone disorder) to 700 MPa (healthy bone). However, composition 1 and composition 2 does not mimic the microstructure of cancellous bone if compared to commercial product and need the addition of additives to form the porous structure. Nevertheless, it can be showed that the synthetic bone can be used for the biomechanical studies as demonstrated in the previous studies [12-13].

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