POLYURETHANE MATERIAL FOR SYNTHETIC TIBIA BONE APPLICATION

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CHAPTER 2

POLYURETHANE MATERIAL FOR SYNTHETIC TIBIA BONE APPLICATION

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2.1 INTRODUCTION

In human body, tibia is the second longest bone that essential for locomotion after femur bone. Based on the literature to the author's knowledge, tibia bone has high tendency to have injuries such as fractures (1,2). The fractures are varies depend on the cause of the injury which are from acute to chronic. In addition, the fractures could be an oblique, transverse or stable fracture (2,3). As the consequence of the fractures, many treatment that had been introduce and recommended by the orthopedics practitioner in order to treat injuries involving tibia bone (4). For instance, bone grafting, external fixator and bone implant (3,5,6). Before prescribing a treatment to the patient, the treatment should have justification on injuries and the possibilities after having surgery. Undoubtedly, due to the requirement of justification by the surgeons it is prove that bone analogue is essentials for orthopedics evaluation and assessment in biomechanics research.

In addition, lot of research had been conducted from past until recent specifically in orthopedics biomechanics research (5). Subsequently, due to the increase in human population globally had been result in high demand of bone analogue in biomechanics orthopedics field (6). In order to conduct the experiment, cadaver are required and it had been challenging. As a consequence of the problem , a synthetic bone has been introduced by engineers (7,8). Recent, the existence of synthetic bone is to overcome the problem of using cadaver (8,9). In fact, synthetic bone had been main tool and widely used in vitro biomechanical evaluation. This experiment is to measure the accuracy of the estimated bone stresses along the dimension of synthetic tibia bone as the highlight within this area (10).

Admittedly, research regarding orthopaedics biomechanic research is extensively evolved and grow up until today (11). Realizing its significance, a study was conductes to replace the use of fresh cadaver bone as specimen for in vitro experimentation with a synthetic bone (8,12). The utilization of fresh human cadaver bone had been challenging due to its limitations. Consequence to that, the rate of success decrease when conducting in vitro evaluation for joint biomechanics and implant testing. The availability of storage for the fresh human cadaver bone is low and limited (8,13). Plus, to prevent defect to the cadaver , a proper store are required for the preservation purpose (9,14). As a results, the specimen need to store in a proper storage. However it cost nearly up to $500 per specimen (13,15). From the previous report had mentioned that the cost for the whole cadaver ranges between $1000 to $1500 that is much higher (13). Nonetheless, this cost does not include the cost of the experiment and storage. Moreover, the tendency of being infected while using cadaver is high

(11). Thus, this condition are not favorable to the researcher as it will cause harm and may infected by the contagious disease.

Undoubtedly, the roles of tibia bone are importance to the human body. From the previous report stated that a lot of injuries related to tibia bone such as bone bruises, varus deformed tibia and tibial head depression fractures (16,17). Therefore, a validation must be properly justified in order to evaluate and analyse the joint biomechanics and implant testing before the medical devices can be used for real patients. A part from that, if the custom tibia bone is required, the in vitro assessment of tibia bone may be tougher. In other hand, there are a case where the bone are having osteogenesis imperfecta, where the long bones including tibiae is differing from the normal tibia bone as its shape is bowing and curvy(4). In consequence, a special tibia bone analogue is needed to evaluate its microstructural as well as its mechanical properties. Though, this requires a synthetic tibia bone with pathologies and it is very rare to find this kind of bone analogue.

2.1.1 TYPES OF SYNTHETIC BONE

Kinds of manufactured bone available in the market are changes relying upon its motivation of use. For example, a portion of the product are design for display and some of them are intended for testing reason. By and large, the model type is ordered as biomechanical and single fracture. Furthermore, the materials that been used to fabricate the synthetic bone also differ from others. It might have been made either for cortical or cancellous bone. Else, it is made of both cancellous and cortical bone. That is the reason, the materials utilized for the bone analogue is various relying upon its application. Every material that has been choose as the main component or minor component of the engineered bone must with a reason. Clearly, the materials must be able to characterize and mimic the structure and properties of the healthy human bone whether it be a cancellous or cortical bone. As shown in Figure 2.1, there are various type of synthetic bone that available in the market such as plastic cortical shell with cellular PU foam inside it. In addition, there are also synthetic bone made from PU foam cortical shell with cellular PU foam inside it. Another type of synthetic bone where the cortical are made with transparent plastic and the cancellous bone are made from cellular PU foam. There are also synthetic bone that develop by using only solid PU foam. The best material delineates the succesful rate of in vitro experimentation as the material is an essential component that will appropriately be advocated in directing an investigation [15]. A terrible material will therefore prompt erroneous outcomes acquired

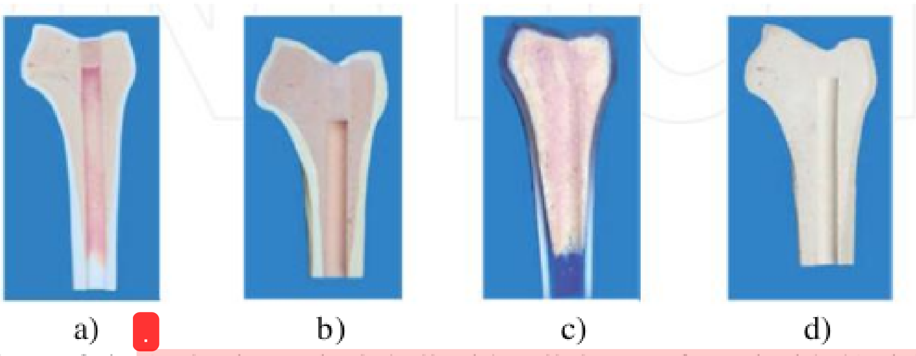

Figure 2.1: a) plastic cortical shell with cellular PU-foam inside b) rigid PU-foam cortical shell with cellular PU-foam inside c) transparent plastic cortical shell with cellular PU-foam inside and d) solid PU-foam throughout (18)

From previous report, it is discover that polymer foams as a testing substrate for the assessment of orthopaedic devices have prevalently used and popular over time (19). This may be due to the close resemblance of the polymer itself with cortical and cancellous bone. Subsequently, this clearly explains why polymer is favorable. Polymer have numerous categories to a numerous types of polymer such as polyethylene (PE), polystyrene (PS) and polypropylene (PP). However, among the types of polymers existed, PU had been acknowledging as a polymer that fits and compatible material for synthetic bone. The fabrication of commercial synthetic bone, Sawbones and Synbone has been prove as the material used is PU.

From the past decades, to develop synthetic bone there are many types of materials that be used. Moderately, some study utilized PU as the main material for the synthetic bone while others used PE. From the previous report stated that, the material can mimic the cancellous bone if only one material is used for the fabricated synthetic bone. In a contrary, the structure of cortical bone is not imitated by any materials. Alternatively, the composite bone analogue is use as a substrate in order to resemble both cancellous and cortical bone. Composite bone analogue also permit an investigation of biomechanical through geometric as well as structural properties (2). In significant to that, one material resembles a cortical bone structure, conversely another material mimics the structure of cancellous bone. This is show by the common materials used as a composite is short glass fibre-reinforced epoxy with PU or else, the PU is substituted with PE. Precisely, to mimic the cancellous bone PU and PE is use while glass fibre-reinforced epoxy resembles the cortical structure of the bone.

In summary, the purpose of the study and application of the synthetic bone determine the type of materials that is used to fabricate the bone analogue. In addition, studies have proved that out of all polymer, PU is the best material that enables to mimic the properties of human wet bone (9). Furthermore, Figure 2.2 show the composite tibia from Sawbones. The fourth generation of large tibia composite model are manufactured by using pressure-injected technique made up from short glass fibre reinforced epoxy (as cortical bone) with PU (as cancellous bone).

Figure 2.2 Depicts fourth generation of large tibia composite model from Sawbones(2)

2.1.2 CURRENT APPLICATION OF SYNTHETIC BONE

The utilization of the bone analogue have given significant to the field of orthopaedic biomechanics. It is very useful for surgeons as an orthopaedic devices in their training. Futhermore, it would help the medical students and orthopaedic surgeon to familiarize with the tools as it can reduced the failure while doing the surgery (20). Not only to emphasize the important of synthetic bone for surgeons, it is also beneficial for the houseman-ship officer as well as the students of medicine in their medical studies (21,22). This is also can be used to help the junior doctors to have simulation in operating theathre before come to real surgery (20). In medical field, the utilization of bone analogue allows them to be exposed of the structure of the human real bones in the process of learning of pathologies, fractures and bone grafting. Importantly, to use of cadaver for the medical students and orthopaedic practitioner to study orthopaedic is high in cost. Furthermore, the limitation of the human bone has limit the study in medical setting due to its variability, preservation, low availability and possibility of infection. This have made cadaver as the second choice in orthopaedic studies prior to synthetic bone (22). Nonetheless, the cadaver has cause problem as a tool for the experimental research. In contrast, researcher are use synthetic bone as an alternative for cadaver. Figure 2.3 depicts the application of synthetic bone in orthopaedic surgical simulation in order to investigate the effectiveness of low-cost orthopaedic drilling technique.

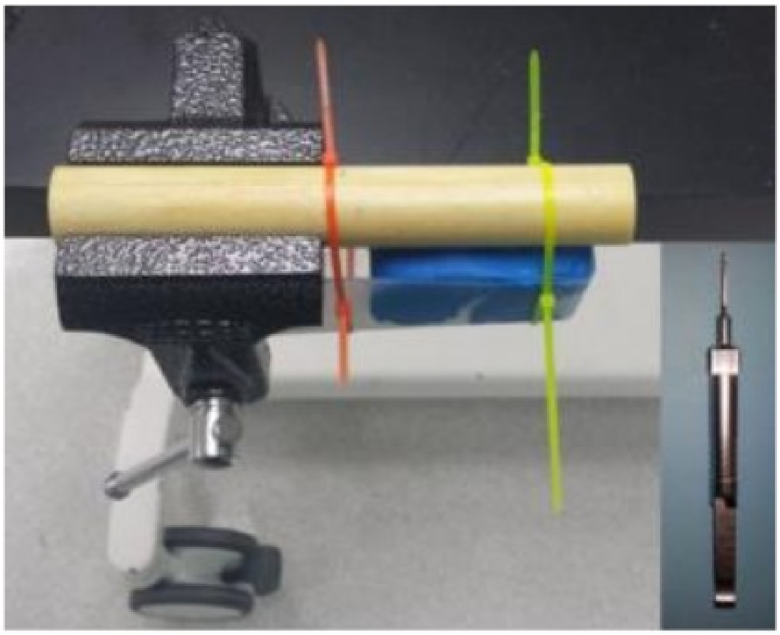

Figure 2.3 Portrays a synthetic bone model clamped by a clay mode to investigate the effectiveness of low-cost orthopaedic drilling technique during orthopaedic surgical simulation.(23).

Equally important in research into orthopedic biomechanics is the use of synthetic bone. Before applying to real patients, an experime nt must be conducted in the assessment of pathologies, including bone f ractures (4,13). .This is to provide a proper justification for the patient's abnormalities. Instead of fresh human corpse bone as previously described, synthetic bone is preferable in in vitro experimentation. (23). The orthopedic in vitro assessment allows the researcher to estimate any effects of adverse events that may occur before the patient receives the treatment. (21). For example, the surgeon must know the appropriate fixator to be used by the patient, whether an external or internal fixator, when evaluating oblique tibia bone (21). A study was conducted by the researcher to analyze its safety, comfort and efficacy in order to propose the best configuration of the fixator. Again, these require bone analog and in a way to explain why the field of research on orthopedic biomechanics continues to develop.

2.1.3 BIOMECHANICAL STUDY USING SYNTHETIC BONE

Synthetic bone is recognized as orthopedics surgical techniques since 1950 and recent (6,22). Establishing synthetic bone as an orthopedic tool has overcome the challenges of using cadaver specimen. Firstly, the cadaver is not use due to bone analog is more consistent (8,22). This consistency allows bone substrates to be mass-produced. The cost is therefore minimal rather than the bone of the cadaver itself. Certainly, the cost of synthetic bone composite of the fourth generation is only $ 170, implying indirectly a huge gap with the cost of the cadaver specimen (15,24). From the cost, it clearly describes the relatively cheap and widely available synthetic bone. Although the use of synthetic bone that lacks the' true feeling' of the real human bone, it is useful in providing understanding and familiarity with the orthopedic equipment and instrument (22). It also allows orthopedic training for surgeons and trainees, such as fracture fixation (21). Its bone analog advantages orthopedic trainees in the development of experience, however they are incomparable with the senior surgeons (22). In a much more in-depth explanation is to say they lack fidelity and quality in order to be of value to senior surgeons. For the meantime, Figure 2.4 shows the use of synthetic bone for four-point bending tests which are useful in biomechanical environments.

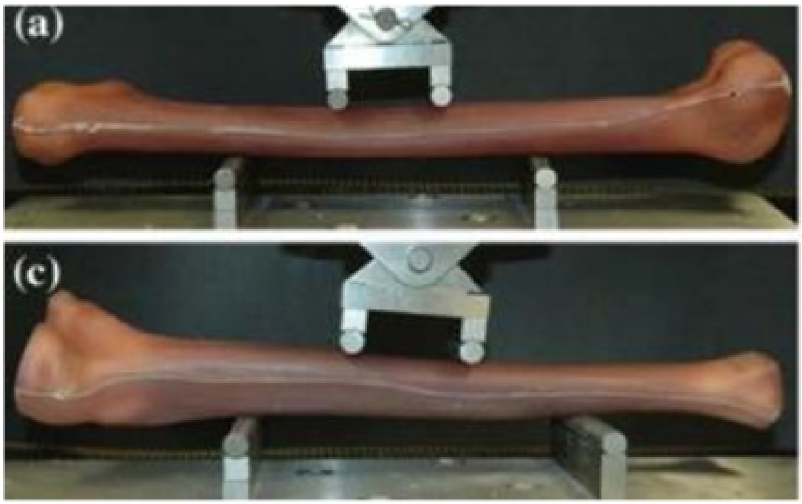

Figure 2.4 Specifies four-point bending test setup of the fourth generation of Sawbones ' large tibia composite model (2)

2.2 FABRICATION OF CUSTOMIZED SYNTHETIC BONE

2.2.1 Bone Segmentation

The CT scan data, particularly, covered the whole human anatomy. Hence, To specify the ROI in tibia only, segmentation was performed. This step was accomplished using Mimics 10.01 software. A predefined threshold (ranging from 226 to 3071) was set to bone as the hub in this study was subsequently loaded into this software by a project (CT lower limb). In addition, only the bone area of the CT Scan data should be highlighted and focused. Moreover, a region growing tool was applied to focus on shinbone that was the required region. Particularly, in order for more convincing of manipulation and operation while segmenting tibia bone from the other bone in the software, different color is recommended for the tresholds.
Next step was edit mask as the procedure is required to segment slice by slice by eliminating bones which are near the tibia bone such as calcaneus, femur, fibula and patella. As well as a sub software in Mimic which was Magix was used to applied the remesh technique for segmenting the tibia.

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In addition, the three-dimensional mask was calculated and displayed a sole tibia. Clearly, in order to get better appearance, the smoothing process must be conducted. From that point forward, the ROI was estimated to get the rough length of Malaysian male tibia by choosing measure 3D distance devices on the recorded toolbar in Mimics and essentially drag start to finish on the veil. At instant, the value of tibia's length was popped out. Notably, before fabrication was continued both procedures required Mimics. Generally, Mimics was used to segment the bone (Figure 2.5).

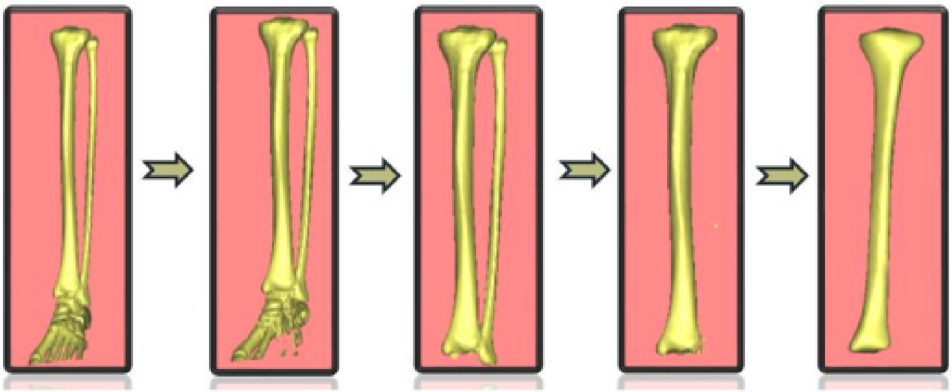

Figure 2.5: Illustrate Mimic software was utilize to do the process of segmentation.

2.2.3 Fabrication of Mold

In order to cast the first layer of the mould, ply woods, plasticine (approximately 15 boxes) As for the casting of first layer of mould, the equipment acquired were ply woods, plastiline (approximately 15 boxes)), glove, master bone, vesaline, Moldmaker RTV silicone rubber and its hardener were required. Significantly,the reference for this project and preparation of mould was using synthetic bone from the Sawbone. The master bone as shown in Figure 2.6 used was a display product instead of the Sawbones test product. The dimensions were approximately similar (374.86 mm and 355 mm respectively in terms of length) after a comparative measurement between the CT scan data and the master bone. Therefore, during the whole process of molding technique, there was no significant changes were required. The tibia bone analog was

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placed on a piece of flat wood in the process of developing the first layer of mould. Then, the the bone was by plastiline. Plasticine was used to assemble the ply woods and to build a container for moulding. Plus, the use of plastiline facilitated by adhering it around the tibia bone to create the bone pattern in a mould. Figure 2.6 revealed the initial process of adhering plastiline to assemble the plywood in a container.

It also grasped the bone in place to ensure even or regular plus a consistent bone moulding configuration (Figure 2.7). Whilst the silicon rubber was poures into the mold, it prevent the master bone from moving. Understandably, a custom-made ply wood was used as a container rather than a ready-made container as the container had to be dismantled as the dried mould and removed from the container. Additionally, to enclose the tibia bone, a rectangular box was constructed. Nonetheless, in order to prevent any leakage that could be happened while pouring the silicone rubber a precaution step was taken. A thick plasticine were applied to overlay the joints.

As precaution, assured that a thick plastiline were applied at the joints' area of ply woods box to avoid any leakages that might happened after the pouring of silicone rubber. The volume of the box would be measured approximately to confirm the size of the rectangular box. This was to ensure that the drying agent and silicon rubber mixture were properly filled into the rectangular box made of plywood. After that, the wholesurface of plasticine surrounded the master bone was applied vesaline (Figure 2.8). This was meant to ensure that the rubber of silicone would not adhere to these areas and for easier disassembling of ply wood container.

Figure 2.6: Dipected The plastiline adhering process to assemble the plywoods into a container .

Figure 2.7: Disclosed The master bone (Sawbones) used to create a mould.

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Figure 2.8: Depicted the placement of tibia and fibula adhered by plastiline.

2.2.4 Preparation of Polyurethane

PU and its hardener were used as resin. PU usually consisted of two parts, Part A and Part B. Basically, PU usually consisted of two parts, Part A and Part B. Part A defined the PU solution itself (see Figure 2.9) while Part B defined the hardening agent. Based on manufacturer recommendations stated that the ration between PU and its harderner is 2:1. PU was chosen because of its popularity and widely use as resin for bone substrate (19,25). The recyclable materials were used as a safety measure during resin preparation to prevent damage to the laboratory equipment. The properties of PU used in this research execute high strength. Hence the damage that occur because the PU cannot be wash by universal solvent soon after it dried. In order to determine the volume of chemical solution (PU) for tibia acquired through this moulding method, water was filled in through the holes of the second moulding layer. Beforehand, ruber band is use to tighten both layer of the mould. This was to ensure no leakage happened once the mold were filled with resin.

After the mould was filled with water, the water was poured out into a beaker. This method used to measure the exact volume of resin that required to fill the tibia mould. Then, the water was transferred to a bottle. The bottle use was cut into half to make it as container. As the water was in the bottle, the level of the water was mark to indicate the volume of required resin. As PU have two part which were Part A and Part B, two bottle were used. Two bottles were deployed for Part A and Part B. It was subsequently reported that the resin volume acquired was approximately 600 ml, referring to the volume of water poured out of the mould. According to the guidelines of the manufacturer, the ratio of Part A and Part B of the PU system was 2:1. Thus, the volume for part A and Part B were 400ml and 200ml respectively resulting in a total volume of 600ml.

Soon after both parts combined together, to make sure that the mixture was mixed well and blended it was continuously stirred about six to nine minutes. Plus, to prevent the presence of bubbles. The resin's inconsistency may affect the composition, structure and duration of the bone. In this regard, after being mixed together, Figure 2.10 reveals the composition between Part A and Part B. The mould was later filled with resin through the holes as soon as possible as its gel time took only 20 minutes. Generally, two to three days were usually sufficient to let the sample dry. Again, the first and second layer moulding process would be repeated for another four times as this project required a total of five tibia bone analogues. Notably, the hardest part of this experiment was to make five bone samples within seven days of the expiry date of the PU system being seven days after opening its container.

Figure 2.9: Portrayed PU (Part A) solution before mixing with the hardener (Part B)

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Figure 2.10 Disclosed PU (Part A) solution after mixing with the hardener (Part B)

2.2.5 Synthetic Bone

Figure 2.11 shows the structure of physical synthetic bone after fabrication. The synthetic bone is normally will be used for the orthopaedic training and also for the biomechanical study of implant (Figure 2.11).

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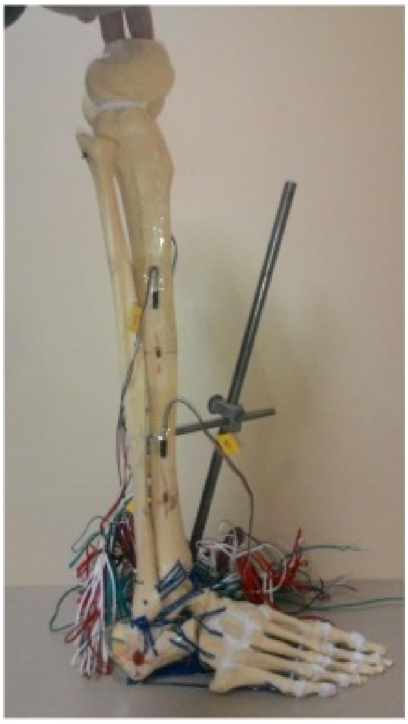

Figure 2.11 Tibia synthetic bone (left) and example of the application of synthetic bone for the external fixator analysis (right).

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