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Study of Potential PCL for Bone Screw with Enhancement Mechanical Strength through Annealing Process

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ABSTRACT

This study was carried out to assess the potential mechanical properties of PCL (Polycaprolactone) applied as bone screws. PCL is a biocompatible and biodegradable, this material could be absorbed by the human body when used as a bone screw. However, PCL does not have high enough mechanical strength and stiffness, a micro injection molding process will be used to make PCL bone screws. To improve the mechanical strength and stiffness of the molded PCL screw, annealing was applied after the screws were molded. The experimental results showed that the strength at yield of the molded specimen was 15.855 MPa and the young modulus was 1.98 GPa while those of the after annealing specimen were 17.366 MPa and 3.47 GPa, respectively. Indicates that micromolding of a PCL can be improved by proper annealing process.

Keywords: Bone Screw, PCL (polycaprolactone), Micromolding Machine, Annealing, Tensile Test.

1. Introduction

Bone screws play an important role in the bone healing process in patients who require such treatment, but the materials used as bone screws are generally metals, such as stainless steel Titanium alloy which cannot be decomposed in the human body by themselves. The metallic screw implants have to be removed when the bone healed, the removal of metallic bone screws is not required if the screws are made of biodegradable and biocompatible materials [1][2]. The process can leave traumatic pain to patients. The use of biodegradable and biocompatible plastic materials continues to be developed to overcome this issue. In addition, polymer materials have various types, and the price is relatively affordable compared to metal materials. Besides, the FDA has allowed polymer materials to be used for medical implants [3]. Among the biodegradable polymers the most popular in healthcare applications are Poly (lactic-co-glycolic acid) (PLGA), Polycaprolactone (PCL), Polyhydroxyalkanoates (PHAs), polyanhydrides [4].

PCL is a hydrophobic semi-crystalline biodegradable, biocompatible, and non-toxicity polymer, having a glass transition temperature (T_g) of -60℃ and a low melting point around

59-64℃, these properties make PCL easier to fabricate with molding technologies for different applications, allowing its possible application in medical equipment [5][6]. PCL has strong solubility and blending characteristics with other biomaterials [7-9]. The low melting point of PCL allows blending with other materials to increase the mechanical strength of PCL instead of pure PCL [10][11]. PCL is a highly processable material. It can be easily formed into different shapes and forms using techniques such as 3D printing, injection molding, extrusion, and solvent casting. This versatility enables the creation of medical devices with complex designs and functionality [12].

This study aims to assess the potential of PCL material as a bone screw material. For easier to evaluate the PCL in bone screw applications, this study will use 3D printing process to quickly printing the mold inserts made of PLA(Polycaprolactone) for molding of the PCL bone screw. The use of PLA material as insert is suitable because both PLA and PCL are biodegradable and biocompatible [13-17]. The inserts will be assembled in the male and female mold bases made of steel. A micromolding machine developed by our lab, Molding Technology SyNergy Lab, will be used to mold the PCL bone screws in this study. Annealing of the molded PCL bone screws will be carried out to furtherly improve the mechanical properties of the PCL bone screws.

2. Materials and Method

2.1 Designing of Bone Screw

Fig 2.1. shows the screw designed with ASME standard (The American Society of Mechanical Engineers) M3 size using a hexagonal head. The geometry data are listed in Table 2.1.

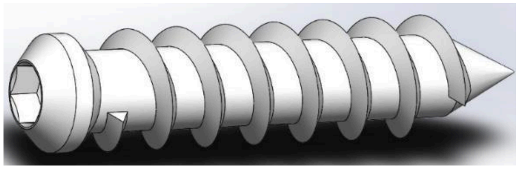

Fig 2.1. Bone screw design for this study

Table 2.1. American standard for M3 Screw.

Features	Size	Tolerance
Thread Diameter	3 mm	-0/+0.05 mm
Thread Pitch	0.5 mm	-0/+0.025 mm
Thread Angle	60°	-
Bolt Head Diameter (Hex)	5.5 mm	-0/+0.25 mm
Bolt Head Height (Hex)	2.5 mm	-0/+0.15 mm
Wrench Diameter (Hex)	4 mm	-
Bolt Foot Height	0.25 mm	-0/+0.15 mm
Bolt Length	Diverse	-

2.2 Preparation of PCL material

The PCL (Capa 6800) material is used for this study. The PCL pellet is placed in a storage room at room temperature in a dry state. In order to measure the mechanical properties through elongation test, both bone screws and ASTM D638 tensile test specimen was made using the same micromolding machine in this study, the dimensions of the tensile test specimen are 63 mm in length, 18 mm in width, and 5 mm in thickness. Fig 2.2 shows a molded screw and a tensile test specimen on the glass tray for further annealing process.

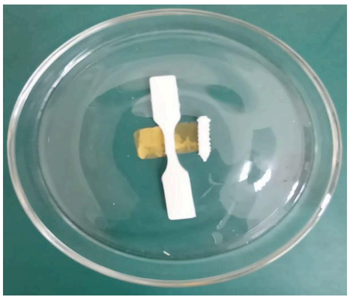

Fig 2.2 PCL tensile test specimen and bone screw.

2.3 Setting of Micromolding Machine

Micromolding machine used is a self-developed Electrical type molding machine. The clamping system uses a manual drive lever as a lock when operating. There are five temperature control zones in this micromolding machine that could be control, and the temperature setting for this study is listed in Table 2.2.

Table 2.2 Setting parameter of micro injection molding machine.

Feeding	Melting	Metering	Transfer part	Injection
50℃	120℃	120℃	80℃	70℃

3. Results and Discussion

3.1 Annealing Treatment

Annealing was conducted to improve the mechanical quality of the PCL material. In this study, used ASTM D638 standard bone tensile test specimens with the PCL material. Total of six shape specimens and also six screw bones were selected from the injection molding process, both the specimens and bone screws were placed in the same glass tray for further annealing process. Table 3.1 shows a summary of the results of experiments that have been carried out starting from the name of the specimen, temperature, time, stress at yield, strain at yield to the value of the young modulus. PCL0 is the first tensile test value taken without going through the annealing process, it shows stress at yield of (15,855 MPa) and the strain at yield (8%) resulting in a young modulus (1.98 GPa). The second experiment PCL1, annealing was carried out at a temperature of 35℃ within 15 minutes showing an increase in the value of stress at yield of (17. 366 MPa) and strain at yield at (5%) and a young modulus value (3.47 GPa). in the third experiment PCL2 with annealing temperature of 40℃ in 15 minutes shows the stress at yield (15. 957 MPa), strain at yield value (8%) and young modulus (1.10 GPa). In the fourth experiment PCL3 annealing was carried out at a temperature of 45℃ in 15 minutes resulting in a stress at yield (16.833 MPa) strain at yield value (12%) and young modulus (1.40 GPa). In the fifth experiment PCL4 in annealing at a temperature of 50℃ for 15 minutes and shows stress at yield (10.161 MPa), strain at yield (17%) and yong modulus (0.60 GPa), the lowest stress at yield value at PCL4, due to failure at the time of the tensile test. In the sixth trial, PCL5 was in annealing at a temperature of 55℃ for 15 minutes, shows stress at yield (15.539 MPa), a strain at yield (40%) and young modulus (0.39 GPa).

Here is the formula for young modulus:

E = σ / ε

E is the Young's modulus (GPa)

σ (sigma) is the stress (MPa

ε (epsilon) is the strain (%)

The data of experimental result for the annealing processes were listed in Table 3.1. The parts pictures after annealing were show in Fig 3.1.

Table 3.1 Sheet data of experimental results

Specimen	Temp (℃)	Time (min)	Stress at yield (MPa)	Strain at yield (%)	Young Modulus (GPa)
PCL0	-	-	15.855	8	1.98
PCL1	35℃	15	17.366	5	3.47
PCL2	40℃	15	15.957	8	1.10
PCL3	45℃	15	16.833	12	1.40
PCL4	50℃	15	10.161	17	0.60
PCL5	55℃	15	15.539	40	0.39

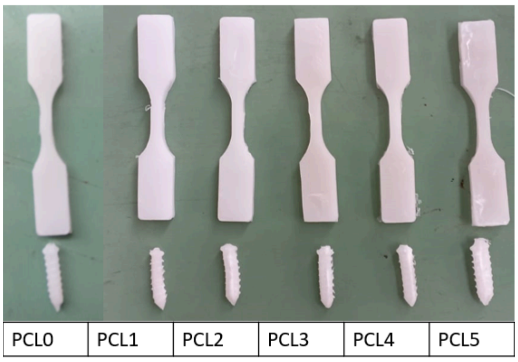

Fig 3.1 pictures of tensile test specimen and screw bone after annealing

3.2 Tensile Test

The tensile test was carried out when the parts are cooled to room temperature after annealing treatment, and the following figures showed the tensile test results of the specimens went through different annealing treatments.

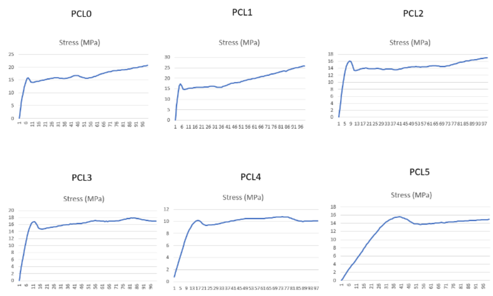

Fig 3.2. tensile test results of specimens with different annealing treatments

From Fig. 3.2, we can see that from PCL0 (without annealing) to PCL3, the yield stress increases as the temperature used is elevated. PCL4 decreased because it had a failure during the tensile test process. PCL5 showed a relatively small number as the testing temperature increased to 55 °C, which is close to the melting point of PCL. It then showed a much lower yield stress compared to the other samples tested at lower temperatures. This indicates that the material becomes softer and weaker due to increasing the temperature. Similarly, the yield strain increases as the temperature increases until approaching the melting temperature of the PCL material. Based on the data experiment in Table 3.1, Young's modulus generally seems to decrease with increasing temperature. PCL1 has the highest young modulus (3.47 GPa), while PCL4 and PCL5 have the lowest (0.60 GPa and 0.39 GPa), respectively, although they have the lowest strain value (5%). This indicates that the materials become less stiff (more flexible) at higher temperatures.

4. Conclusion

Biocompatible and also biodegradable polymers advance material may become an alternative as a substitute material for Titanium, or metal material. PCL is a polymer with low rigidity, which is one of the causes of deficiency when directly applied to bone screws. In this study, annealing was applied to improve the mechanical strength of PCL material. PCL1 has the highest stress at yield (17.366 MPa) and Young Modulus (3.47 GPa) compared to another specimen result. This study was conducted as a reference to support the utilisation of biodegradable materials in various fields, especially medicine.

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