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Design, Manufacturing and Characterization of Biodegradable Bone Screw from PLA Prepared by Fused Deposition Modelling (FDM) 3D Printing Technique

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ABSTRACT

Biopolymers are utilized extensively in the medical field. The production of biodegradable bone screws for bone implants utilizing biopolymer materials is one of the advances developments. Polylactic acid (PLA) is a biopolymer frequently employed in medicinal applications. Using 3D printing, this research was done to create a biodegradable bone screw derived from PLA. The 3D printing process was chosen to reduce the cost and duration of bone repair. A nozzle temperature of 210oC and a bed temperature of 60oC are utilized in the production of biodegradable PLA screws. The torque test, fracture analysis, density test, and biodegradation test were utilized to characterize biodegradable bone screws. The results of this study will be compared with commercial biodegradable bone screws (BIOSURE HA). The findings of torsion tests indicate that commercially biodegradable bone screws have superior clamping quality than PLA-based biodegradable bone screws. The degradation rate of commercial biodegradable bone screws is greater than that of PLA-based biodegradable bone screws. In addition, commercial bone screws are denser than PLA-based biodegradable bone screws.

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1. Introduction

Over eight million people are diagnosed with osteoporosis each year, which results in a fracture every three seconds [1]. Several medical diseases, including cancers and osteogenesis imperfecta may also accompany the fracture.

By decreasing the fracture space and applying compression to the fractured bones, rigid internal fixation devices, primarily orthopedic screws, accelerate the healing and mobility of wounded tissues. Complete immobilization, preservation of bone segments, and bone ingrowth with the re-establishment of local blood arteries are crucial for the optimal healing of bone fractures. However, gold-standard orthopedic screws made of titanium or stainless steel are overly rigid, causing the surrounding tissues to deteriorate. The increased elastic modulus of metallic screws in comparison to natural bone results in a "stress shielding" effect, which causes localized osteopenia. In addition, strong adhesion between the screw thread and adjacent bone tissue complicates revision surgery for screw removal. Because of this, scientists have come up with biodegradable polymer screws that can hold bones together without the need for more surgery [1,2].

Additive manufacturing (AM), often known as 3D printing is a method that accumulates materials layer by layer. It has substantial advantages over conventional manufacturing processes, including a high degree of design freedom, low cost, and great efficiency. The rapid development and major influence of AM technology on the manufacturing industry have opened up new possibilities for engineering applications in a variety of industries. AM technologies have been utilized extensively in the biomedical sector during the past three decades, with advantages such as the ability to create implants that are specific to each individual patient. This technology's ability to generate patient-specific devices and therapies is one of its greatest features. Since some mechanisms are entirely material-dependent, additive manufacturing (AM) technology can be called a material-based manufacturing technique [3,4].

Rapid innovations in 3D printing and biomaterials have shown significant promise in bone implant applications. Since its initial announcement in 1970, biodegradable polymers have demonstrated their effectiveness as good bone implant materials. They offer the necessary mechanical support at the site of implantation and resorb over time, transferring the burden to newly created tissue and eliminating the need for hardware removal revision surgery. Biopolymers can be easily shaped into any complicated geometry and exist in numerous forms. Numerous osseous fixation devices, such as screws, pins, plates, and rods, are currently manufactured commercially with biopolymers and are employed in a variety of dental and orthopedic applications. The customizability, speed, and precision of additive manufacturing and 3D printing technologies are improved. Due to these benefits and the capacity of 3D printers to employ biopolymers as their raw material, the usage of this technology in the medical and pharmaceutical areas has exploded. In the last ten years, this rapid prototyping method has made it possible to make implants, biomedical equipment, and prostheses that are very well suited to the needs of each patient [3,4].

Polylactic acid (PLA) is the most commonly used bioplastic, with biodegradable and biocompatible properties [5]. PLA is essential to the execution of numerous tissue engineering and regenerative medicine therapy techniques. PLA has remarkable bio resorption properties, allowing it to interact with host cells and tissues. This characteristic is especially important for bone grafting [6]. Polylactic acid (PLA) polymer gained attention as a good support structure that allows natural tissue to rebuild itself and has a gradual degradation profile in the implanted area [6]. Biocompatibility has made it the polymer of choice for Bone Tissue Engineering (BTE) applications [6,7]. With the advancement of technology, the creation of biomedical products using 3D printers is now relatively straightforward. PLA-printed scaffolds have gained prominence in biomedical applications and are used often in BTE

[6-10]. PLA printing is often performed by direct or indirect 3D printing or FDM [6-10]. By modifying the 3D printer's parameters, it is possible to alter the pore diameter of PLA scaffolds. The behavior of the melt flow (MFB) in the filaments has a considerable impact on the quality of 3D-printed scaffolds. Pressure gradient, velocity, temperature gradient, melting temperature, and shape change studies have a significant impact on the MFB. Melt flow behavior (MFB) is a crucial feature for polycaprolactone (PCL) filament-based 3D-printed products. This is because MFB can impact the precision and adhesion of the printed product's interlayer. Better flow decreases the probability of print nozzle clogging. However, the excessive flow has a negative effect on the end product's quality [11,12].

Gremare *et al.,* [13] evaluated the effect of scaffold pore sizes on BTE, particularly between 150 and 250 mm.

Furthermore, Zhang *et al.,* [14] contrasted conventional methods with 3D printer technology and studied the impact of both production methods and pore diameters for scaffolds ranging from 273 to 473 mm. Liu *et al.,* [15] investigated the PLA screw-like scaffold using a 3D print method with a heated metal nozzle 0.4 mm in diameter at 205 °C and deposited it onto a receiving station to form the desired scaffolds. Overall, the results of these studies demonstrate that fabricating surgical implants at the clinic with a desktop 3D printer (D3DPs) can be feasible, effective and economical.

Fabrication and characterization of screws for anterior cruciate ligament (ACL) reconstruction utilizing 3D printing technology with PLA filaments are relatively uncommon. The objective of this study is to demonstrate the possibility of utilizing 3D printing technology to create biodegradable bone screws from polylactic acid (PLA). The PLA filament will be 3D-printed in the same shape as already available biodegradable bone screws (BIOSURE HA) from Smith & Nephew Healthcare Ltd. Using a torsion test, fracture analysis, density test, and biodegradation test, biodegradable bone screws produced from polylactic acid (PLA) will be evaluated. The physical and mechanical properties of commercial biodegradable bone screws (BIOSURE HA) will be compared with the outcomes of this investigation.

2. Materials and Methods

In this study, Polylactic acid (PLA) filament measuring 1.75 mm is shown in Figure 1. Polylactic acid (PLA) is a type of thermoplastic polymer that is biocompatible, environmentally friendly, biodegradable, can be recycled, and can be composited. PLA biocompatibility is very suitable for use as a material in the biomedical field.

Fig. 1. Filament of *Polylactid-acid* (PLA)

This study uses the reverse engineering method on a commercial bone screw which has a diameter of 7 mm and a length of 30 mm. The design of the biodegradable bone screw is shown in Figure 2.

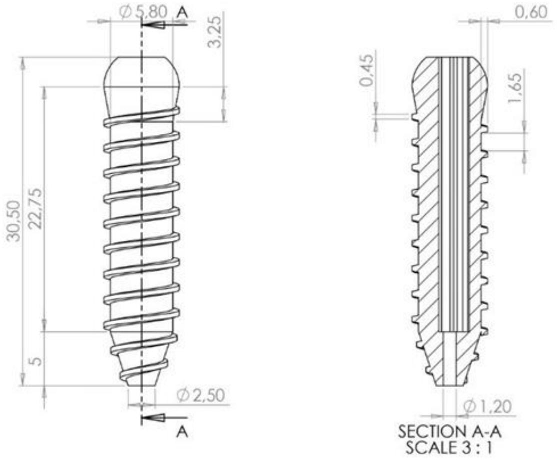


Fig. 2. The design of biodegradable bone screw

The 3D printing process on the biodegradable bone screw uses the Ender 3 pro machine. The 3D printing process is carried out by setting the nozzle temperature, bed temperature and speed of 210°C, 60°C and 60 mm/s. The 3D print process to produce biodegradable bone screws is carried out in a vertical position as shown in Figure 3.

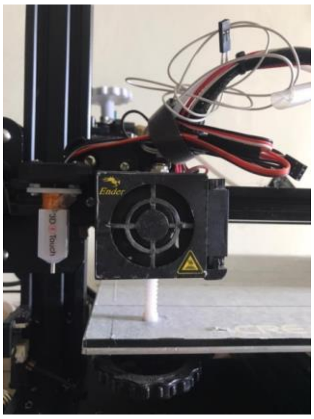


Fig. 3. 3D printing process of biodegradable bone screw

The resulting biodegradable bone screw (Figure 4) was then tested to evaluate its mechanical properties. Tests carried out in this study include a torsion test, density test, biodegradable test and fracture analysis. Torque testing using ASTM F543 guidelines. From the torque test, the Threshold Torque (TT) and Peak Failure Torque (PFT) values will be obtained which will be used to determine the peak clamping torque (PCT) on the biodegradable bone screw. Density testing is carried out using a densitymeter following the ASTM 792-08 standard. The biodegradable test was carried out by soaking the biodegradable bone screw in NaCl solution (8.75-gram NaCl + 250 ml aquadest) 3 times with observation times of 2 days, 4 days, and 6 days. In this study, fracture analysis was carried out by looking at the fracture model on the biodegradable bone screw after the torsion test was performed. Commercial biodegradable bone screws will also be tested using the method used in this study.

Fig. 4. Biodegradable bone screw with PLA material

3. Result and Discussions

A comparison of the results of density testing on PLA and commercial biodegradable bone screws is shown in Figure 5. The densities of PLA and commercial biodegradable bone screws are 1.00 g/cm^3 and 1.31 g/cm^3. The commercial biodegradable bone screw has a higher density value than the density produced on 3D printed biodegradable bone screw made of PLA. This can happen because the material used in the manufacture of biodegradable bone screws is a composite made of PLLA and hydroxyapatite as a matrix and reinforcement. This results in a denser commercial biodegradable bone screw with a mixture of hydroxyapatite (ceramic) as reinforcement. The presence of reinforcement improves the mechanical properties of the composite [16-18]. The greater the hydroxyapatite content, the higher the density of the composite [19]. The density of the biodegradable bone screw made from PLA produced using the 3D print method is greater than the cancellous bone density range in humans (0.05–0.3 g/cm^3) [20]. However, the density of PLA biodegradable bone screws is close to that of human cortical bone. According to Kroemer *et al.,* and Fitriyana *et al.,* human cortical bone has a density of 1.1 g/cm^3–1.3 g/cm^3 [19,21].

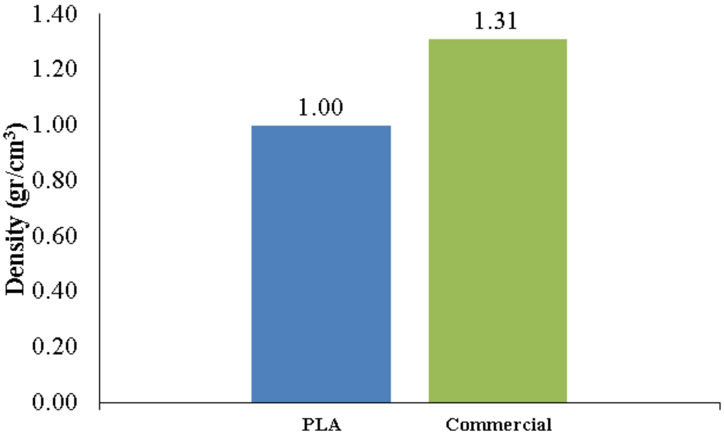


Fig. 5. Density of PLA and commercial biodegradable bone screws

Figure 6 shows the torsion testing process on a biodegradable bone screw inserted into a synthetic bone block using a torque wrench. Torque testing aims to obtain the value of Threshold Torque (TT) and Peak Failure Torque (PFT).

Fig. 6. Torque Testing on biodegradable bone screw

Torsion testing is carried out according to ASTM F543 regarding standard specifications and test methods for medical bone screws. The results of the torsion test which include TT, PFT, and Peak Clamping Torque (PCT) are shown in Figure 7.

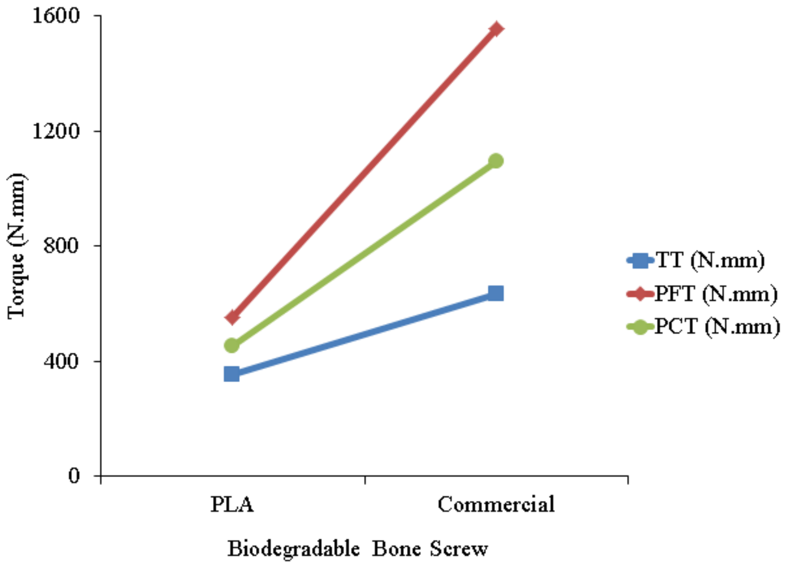


Fig. 7. Torque comparison on made from PLA biodegradable and commercial bone screw

Threshold Torque (TT) is the torque value (N.mm) required to insert a biodegradable bone screw until it starts to tighten on the bone, usually in Call it the insertion torque. Threshold Torque (TT) on biodegradable bone screws made from PLA and commercial are 354 N.mm and 635 N.mm, respectively. The higher the Threshold Torque (TT) value indicates that the greater the torque required to insert the bone screw into the bone [22].

Peak Failure Torque (PFT) is the torque value when the bone screw begins to fail (torsional breaking). Peak Failure Torque (PFT) on biodegradable bone screws made of PLA and commercial biodegradable bone screws were 554 N.mm and 1556 N.mm, respectively. The greater the Peak Failure Torque (PFT), the greater the torque that the biodegradable bone screw can withstand before failure/fracture [22]. The results of the PFT test on commercial biodegradable bone screws showed a greater value than the research conducted by Moldovan *et al.,* which was 840 N.mm [22]. Meanwhile, the Peak Failure Torque (PFT) of the biodegradable bone screw made of PLA produced in this study is greater than the research produced by Dhampani *et al.,* with a PFT value of 530 N.mm [1]. Peak Clamping Torque (PCT) is a torque value on a biodegradable bone screw indicating the ability to withstand clamping loads when the screw is attached to the bone. Calculation of Peak Clamping Torque (PCT) in this study using equation [22]

$$\mathrm{PCT} = \frac{\mathrm{TT+PFT}}{2} \tag{1}$$

Description:
PCT = Peak Clamping Torque (N.mm)
TT = Threshold Torque (N.mm)
PFT = Peak Failure Torque (N.mm)

The calculation results of Peak Clamping Torque (PCT) on biodegradable bone screws made of PLA, and commercial ones are 454 N.mm and 1095 N.mm, respectively. The results of this study show that the PCT of commercial biodegradable bone screws is greater than that of biodegradable bone screws made of PLA. This is because the PFT and TT values in commercial biodegradable bone screws are higher than those made from PLA. The content of hydroxyapatite in commercial biodegradable bone screws causes a significant increase in mechanical properties. Hydroxyapatite (HA) is a ceramic substance that is the mineral phase of bone. Calcium and phosphate are present in a ratio of 1.67 in HA. In orthopedics, HA has been widely utilized as a biomaterial to assist tissue regeneration [19] [23-26]. The addition of HA powder in the matrix reduces the movements of matrix phases in the surrounding area of each particle, contributing to the overall increase in modulus. Hydroxyapatite addition can be attributable to the fact that the well-dispersed particles lengthen the crack propagation path, absorb more energy, and improve the plastic deformation. As a result, the surface fracture energy and composite strength improved [19].

Clamping Torque Limit (CTL) is a standard used to determine the quality of clamping screws on bone. Figure 8 shows the efficient clamping visualization diagram. If the PCT value is 1 TT, then the screw does not have clamping because it is still in the Threshold Torque (TT) zone. The PCT value which is in the range of 1 TT 1.5 TT shows the clamping starts but the screw is not very tight and can spread over time. If the PCT value is at 1.5 TT 2.25 TT, then the screw is quite tight and can't spread over time. The clamping strength in this range is in the good clamping zone which allows the screw to produce good fixing and positioning on the internal fixation device. If the PCT value is at 2.25 TT 2.5 TT, then the screw will fail during the clamping process. This causes the internal fixation device to not be installed.

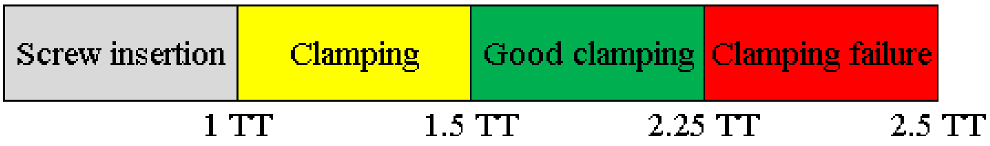
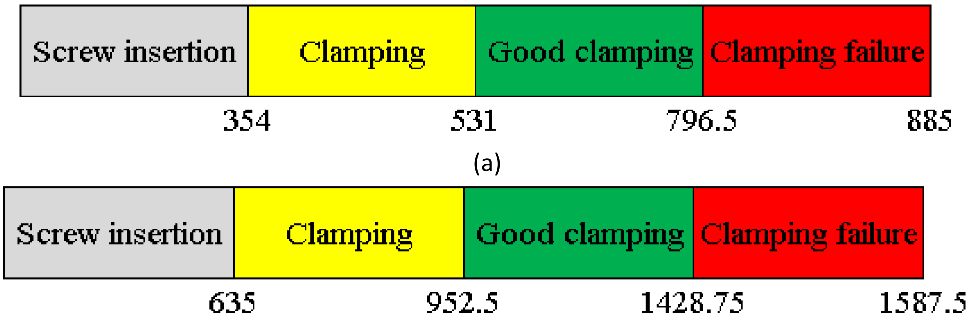


Fig. 8. Diagram of efficient clamping visualization

The Threshold Torque (TT) produced in this study were 354 N.mm and 635 N.mm, respectively, for biodegradable bone screws made of PLA and commercial. The TT value is used to determine the Clamping Torque Limit (CTL) with efficient clamping visualization as shown in Figure 9. PLA has a Peak

Clamping Torque (PCT) value of 454 N.mm. This value is lower than the range in the good clamping zone (531-796.5 N.mm). The results of this study indicate that the biodegradable bone screw made of PLA has a clamping strength that is in the clamping zone. This shows that the biodegradable bone screw made from PLA is not too tight and can spread over time. A significant difference was found in the commercial biodegradable bone screw which has a Peak Clamping Torque (PCT) value of 1095 N.mm which is in the good clamping zone (952.5 – 1428.75 N.mm). This shows that commercial biodegradable bone screw is quite tight and can't spread over time. The difference in the value of the Clamping Torque Limit (CTL) indicates that the greater the value of the Clamping Torque Limit (CTL), the greater the torque that the bone screw can withstand so that the quality of the clamping force possessed by the bone screw will be better [22].



(a)

(b)

Fig. 9. Comparison of Efficient clamping visualization on biodegradable bone screws made from PLA (a) and the commercial (b)

The results of the biodegradable test on PLA and commercial biodegradable bone screws are shown in Figure 10. The weight reduction or degradation in PLA and commercial biodegradable bone screws is directly proportional to the immersion time. The immersion for 6 days resulted in a greater reduction in specimen weight than the immersion for 4 and 2 days. Commercial biodegradable bone screws experienced a faster mass reduction because commercial bone screw is a bio composite made from PLLA and hydroxyapatite (HA). The content of hydroxyapatite in polymer composites results in faster degradation [19].

The results of this study are in accordance with research conducted by Azevedo *et al., t*he study combined biopolymer with hydroxyapatite, where bio composites containing more hydroxyapatite were degraded more rapidly [27]. The results of the tests that have been carried out are also in accordance with the results of research by Moura *et al.,* which mixed PLA/PCL and added HA. The results of this study indicate that the higher HA content has the property of absorbing water faster and has a higher weight loss due to the preferential occurrence at the polymer/ceramic interface [28].

Biodegradable bone screw made from PLA has lower mass loss than commercial biodegradable bone screw. This is because the biodegradable bone screw made of PLA absorbs lower water content, resulting in a slower rate of degradation [29]. The degrading behavior of biodegradable orthopedic implants is crucial. The preferred mode of degradation is the slow, steady decline of mechanical properties that permits the mechanical stress to be gradually absorbed by newly formed bones, so providing the essential impetus for the regeneration of bone with load-bearing capability. In contrast, rapid loss of mechanical characteristics and implant failure (premature breakdown/deformation) should be avoided to prevent bone fixation failure [30]. The mechanical strength of biodegradable bone screws decreased after implantation due to their rapid rate of degradation [31]. When fragments of bone are not entirely immobilized, a more rapid drop in mechanical strength after implantation leads to insufficient healing [30-32].

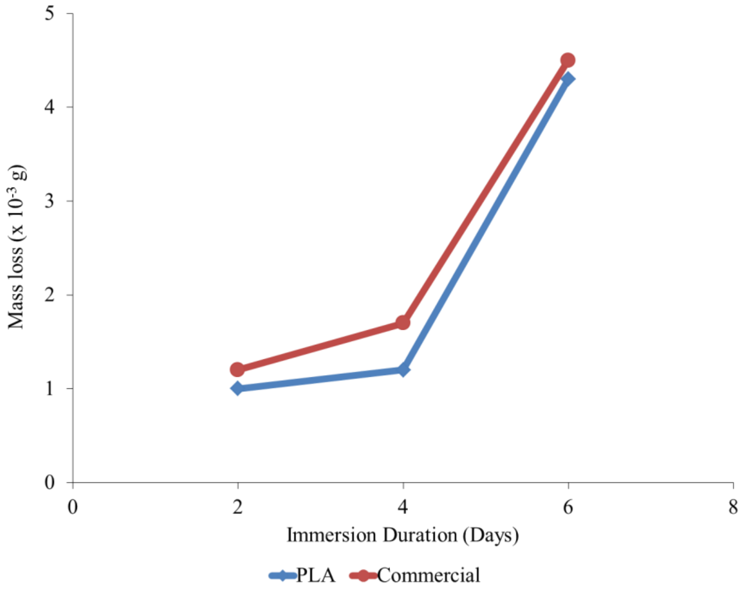


Fig. 10. Mass Loss on PLA and commercial biodegradable bone screws

4. Conclusions

The manufacture of biodegradable bone screws made from polylactid-acid (PLA) using 3D printing technology has been successfully carried out. The resulting biodegradable bone screw has a diameter of 7 mm and a length of 30 mm. The test results show that commercial biodegradable bone screw has a higher density of 1.31 gr/cm3 compared to biodegradable bone screw made of PLA. The commercial biodegradable bone screw has better clamping quality because it has a PCT value that is in the good clamping zone with a range of 1.5 TT to 2.25 TT. Meanwhile, biodegradable bone screw made from PLA has a PCT value lower than 1.5 TT 2.25 TT. From the evaluation of torsion efficiency, commercial biodegradable bone screws have better torsional efficiency because they are in a good clamping zone. While the biodegradable bone screw made of PLA is in the clamping zone. Commercial biodegradable bone screws have the highest degradation rate due to the presence of hydroxyapatite (HA) which has the property of absorbing water faster. This results in faster weight loss due to preferentiality at the polymer/ceramic interface. Meanwhile, biodegradable bone screw made from PLA has lower mass loss than a commercial biodegradable bone screw. This is because the biodegradable bone screw made of PLA absorbs lower water content, resulting in a slower rate of degradation.

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