Original Article

Optimization of the Manufacturing Process and Mechanical Evaluation of a Functionally Graded Biodegradable Composite Screw for Orthopedic Applications

Abstract

Background: Metal screws are commonly used for fracture fixations. However, the high modulus of elasticity relative to bones and releasing metallic ions by the metal screw needed a second surgery to remove the implant after the healing period. Furthermore, the removal of metal screws following the healing of the bone is a serious problem that can lead to refracture due to the presence of holes in the screw. Bioresorbable screws can overcome most of the problems associated with metallic screws which motivated research on manufacturing nonmetallic screws. **Methods:** In this study, three-layer poly L-lactic acid/bioactive glass composite screws were manufactured according to functionally graded material theory, by the forging process. All of the physical and chemical parameters in the manufacturing stages from making composite layers to the forging process were optimized to obtain suitable mechanical properties and durability off the screw in load-bearing positions. **Results:** The tri-layer composite screw with unidirectional, ±20° angled, and random fibers orientation from core to shell shows a flexural load of 661.5 ± 20.3 (N) with a decrease about 31% after 4-week degradation. Furthermore, its pull-out force was 1.8 ± 0.1 (N) which is considerably more than the degradable polymeric screws. Moreover, the integrity of the composite screws was maintained during the degradation process. **Conclusions:** By optimizing the manufacturing process and composition of the composite and crystallinity, mechanical properties (flexural, torsion, and pull-out) were improved and making it a perfect candidate for load-bearing applications in orthopedic implants. Improving the fiber/matrix interface through the use of a coupling agent was also considered to preserve the initial mechanical properties. The manufactured screw is sufficiently robust enough to replace metals for orthopedic load-bearing applications.

Keywords: *Composite screw, degradation, flexural strength, forging, mechanical property*

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Introduction

Internal fixation devices such as screws, pins, and plates are extensively used in orthopedic practice.[1] Orthopedic screws are glides into the bones and attach fragment particles and are placed in cortical and cancellous screws categories. The pitch and thread depth of cortical screws is smaller than the cancellous screws, but the core diameter is larger, which made it stronger than cancellous screws.[2] Metal bone screw fastener is generally made of titanium and their alloys, surgical stainless steels (commonly austenitic SAE 316), and cobalt-chromium alloys.[3] Despite establishing adequate screw stability, metal screws have many complications such as osteoporosis and implant loosening (due to Wolff's Law), releasing harmful ions, allergic or foreign body reaction, corrosion, and magnetic resonance imaging (MRI) interference.[4-8]

Resorbable polymeric biomaterials such as polylactic acid (PLA), polyglycolic acid, and polycaprolactone were used in implant products to eliminate second surgery for removing the implants; however, they are not suitable for using in load-bearing applications due to their low mechanical properties.[9] Magnesium base alloy screws were also developed to overcome the lack of mechanical properties for load-bearing applications. However, the ion release and their degradation products are still challenges for clinical applications.[10] Polymer matrix composite structures are

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designable by changing parameters such as fiber volume fraction (VF), shape, an arrangement of fiber reinforcement, chemical components, and composite layers thickness to achieve a wide range of mechanical properties.[11] The use of suitable composite and appropriate geometry for screws is among the essential factors to provide sufficient strength with a successful healing process.[12]

Poly L-lactic acid (PLLA) is the slowest degrading material used currently in implants.[13] Animal studies indicate that the degradation of PLLA is complete by 5 years,[14] but human evidence from PLLA interference screws shows that the screw degraded after 30 months of implantation.[15] The development of composite materials with suitable mechanical and biological properties could be performed by adding reinforcements to the biodegradable polymers to meet or advance the mechanical properties of cortical bone.[16] These properties should decrease in healing time, due to the degradation process and new bone tissue should be completely replaced without any harmful effect.

In the last decade, partially resorbable composites were developed using a bioabsorbable polymer for matrix and a biocompatible reinforcement. A variety of techniques have been introduced by researchers to optimize the direction and wrapping pattern of the texture. Researchers exhibited that using a coupling agent, we can perceive better bonding between matrix and reinforcement, controlled penetration of water to the interface, and as a result, decreasing degradation rate and strength loss in the composite. Furthermore, fiber action increased the mechanical properties of the composite compared to untreated fibers.[17,18] PLLA/bioactive glass (BG) fibers composite bone plate is a proper candidate for orthopedic load-bearing applications because of its mechanical properties, biocompatibility, osteoconductivity, and controlled degradation rate.[19] Functionally graded materials (FGM) are designed with a variation in composition and structure gradually over volume (or continuously across the thickness), resulting in corresponding changes in the mechanical properties, gradually from the outer to the inner layers.[20,21]

In our previous work, tri-layered PLLA/BG composite screws were modeled and analyzed using Abaqus software. The volume percentage of the inner/middle/outer layers of the screw were selected (60/20/20), (55/20/25), (60/10/30), and (65/10/25). The VF of fibers in all layers was equal to 40%. The fibers in the inner layer were placed unidirectional (UD) along the longitudinal axis of the screw, in the middle layer with an angle of ±20° to the longitudinal axis, and were randomly in the outer layer. The highest mechanical properties were obtained for the screw with the layer arrangement of (65/10/25).[22]

In the present study, the optimized bioresorbable composite screw was manufactured using PLLA (as matrix) and BG (as reinforcement) and also the manufacturing parameters were optimized. The screw was evaluated from mechanical properties and degradation rate.

Materials and Methods

Materials

PLLA (Resomer® L210-S) was purchased from Boehringer Ingelheim (Germany). Chloroform solvent, phosphate-buffered saline (PBS), and ɣ-aminopropyltriethoxysilane (APS) as a coupling agent and modifier of glass fiber were purchased from Sigma-Aldrich Chemical Company (St. Louis, MO, USA). A silicate BG 13–93 (composition 6.0 Na_2O, 7.9 K_2O, 7.7 MgO, 22.1 CaO, 1.7 P_2O 5, 54.6 SiO_2 (mol.%) was supplied by MO-SCI Corporation (USA).

Fabrication of composite layers

Silane coupling agent (APS) was hydrolyzed and can form a rigid linkage between matrix and reinforcement that remarkably lower the degradation rate. For this purpose, we use the APS solution by adding 1 wt% of the APS to a solution of 95 wt% ethanol and 5 wt% of deionized water. The solution was stirred for 5 min to obtain a uniform solution. BG fibers were soaked in this solution for 2 h and dried at ambient temperature. A homogeneous polymer solution was prepared by dissolving PLA polymer in chloroform (10 w/v), and stirring BG fibers were divided into equal tows with a weight of about 100 mg to prepare UD and angled plies about 100 mg. The polymer solution was poured into the Teflon mold and fiber tow was added at the desired angle by hand laying up. After the fixation of fibers at the matrix, again polymer solution was pouring into the mold. For the preparation of random layers, bioglass fibers were cut to the fibers with an aspect ratio of 100, then mixed with the polymer solution and poured into the mold. The VF of BG fibers was about 40% in all layers.

Composite screw manufacturing

PLLA/BG composite screws were prepared by forging composite bars. After exiting the resulting stack of plies from the Teflon mold, placed into a stainless-steel mold with a dimension of 100 mm (length) × 80 mm (width) × 30 mm (thickness) made by a three-axis Computer Numerical Control (CNC) milling machine. The steel mold has been put in a hot-pressing machine at 130°C and a pressure of 150 MPa for 1 h and slowly cool down to ambient temperature for 48 h. It causes proper crystallinity and establishes an appropriate connection between the matrix and reinforcement.

Figure 1 shows geometric sizes and manufactured of the stainless-steel mold by CNC milling and spark process.

First, the mold was heated at 110°C for 10 min, and then, the layers were arranged in the mold in which, random layers are the outer layers and form screw threads. UD layers were

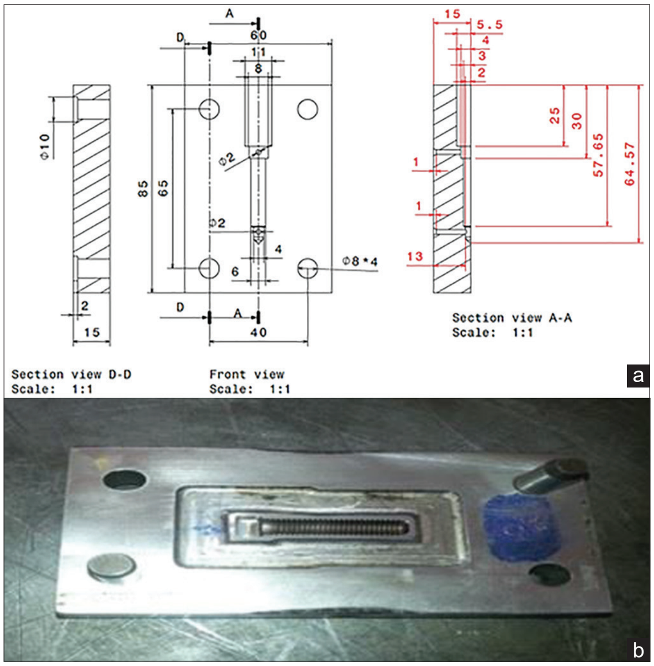

Figure 1: (a) Schematic drawing of the steel mold, (b) Manufactured stainless-steel mold

placed in the inner layers and angled layers were placed in the middle layers. Layer arrangement (UD/±20/Rn) was squeezed between two steel plates by hydraulic presses after that stacks were placed under the press in the mold.

Optimizing of forging process

In the forging process, temperature, time, and pressure have a key role in the physical and chemical structures of the product. In this study, 150 and 170 MPa pressure was applied in 15–35 min at 130°C–170°C to obtain the best forging parameters for the screw manufacturing process.

Mechanical study of screw

Flexural test

The bending strength of screws was measured by a three-point bending method test using a Hounsfield Testing Machine (model H25KS) at room temperature (25°C) according to ASTM D7264 shown in Figure 2a. For the flexural test, the support roller span was 20 mm and the loading applicator and support radius were 2.5 mm with a crosshead speed of 5 mm/min. Bending strength (σb) and bending modulus (*E*b) are obtained from Eq. 1 to 2, respectively.[23] The experiments were done in triplicate (n = 3).

$$E_B = \frac{P}{\delta}\frac{l^3}{12\pi r^4} \tag{1}$$

$$\sigma_b = \frac{pl}{\pi r^3} \tag{2}$$

where δ is the displacement of the sample, l is the tested span, r is sample radius, and P is exerted force.

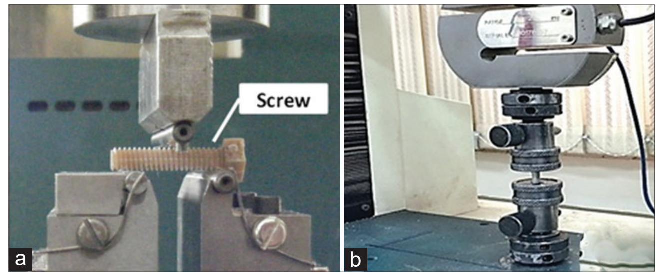

Figure 2: (a) Flexural test and (b) Pull-out test of tri-layer PLLA/BG screw. PLLA - Poly L-lactic acid, BG - Bioactive glass

Pull-out test

The pull-out test also utilized the universal test Hounsfield according to the ASTM F2502-05 standard. A crosshead speed of 5 mm/min and 25 KN load cell was used. All the measurements were performed in triplicate which is shown in Figure 2b.

Torsion test

The torsion test was performed according to the ASTM F2502–05 standard. The test was performed at room temperature (25°C) with a torque speed of 1 revolution/min and considering a 30 KN load cell.

Degradational studies of screw

The *in vitro* degradation studies were performed for 4 weeks according to ASTM F1634–95 standard. Degradation experiments for composite screws were conducted by immersing the screw in a PBS solution (pH 7.4) at 36.5°C. Weight changes were monitored by removing the corresponding samples from the solution after a predestined period, washing three times with distilled water, and drying at 37°C for 1 h. Weight loss (WL) percentage was computed according to Eq. 3

$$WL(\%) = \frac{\left(W_i - W_f\right)}{W_i} \times 100$$

Where Wi is the initial dry weight and W_f is the dry weight at each interval time.

Moreover, composite screws after 4 weeks of immersion in the PBS solution were dried out and then subjected to a three-point bending test. The strength loss was evaluated after 4 weeks of degradation.

Results

Optimization of the manufacturing process

The selected temperature, pressure, and time of the forging process and consequently, their effect on the composite screw product are presented in Table 1. The melting of the PLLA starts at about 165°C (at ambient pressure) and 180°C is the peak of the melting point. Furthermore, the polymer crystallization point is about 120°C. By applying the temperature and pressure at 175°C and 150 MPa, respectively, for 35 min, the composite films burned. Decreasing the temperature to 130°C led to the separation between the layers. At the temperature of 150°C, a pressure of 170 MPa, and a time of 25 min, the screws were manufactured successfully. These parameters were selected as an optimized condition. In the final step of the forged manufacturing process, the mold was cooled at ambient temperature for a better connection between polymer and glass and also more crystallization of the polymer matrix.

Mechanical characterization of composite screws

The maximum flexural load and stiffness of optimized models through FE analysis were evaluated. According to the results of the initial flexural test in this study, composite screw with layer percentage (65/10/25) and VF of 40% has the most flexural stiffness about 1000 (N/mm). Figure 3 shows the load-deflection results of PLLA/BG screws with the percentage of plies (65/10/25) in flexural and pull-out tests, respectively. Furthermore, flexural stiffness, maximum flexural load, tensile strength, and maximum torque of the designed composite screw are presented in Table 2.

Degradation study

Weight loss

WL of all composite screws increased progressively with time during the soaking period. Figure 4 shows the degradation rate of composite screws in 4 weeks. In the 1st week, WL was about 10%. After that, it showed a slower trend and reached to about 28% after 28 days. The PBS penetrates to the structure of the screw, and the internal loss is due to the surface degradation of the polymer amorphous regions and also ion release of the surface's bioceramics.

Strength loss

In this study, the flexural force at break and before degradation process was 661.5 ± 20.3 (N) while it was about 445 ± 10.7 (N) after 4-week degradation. Therefore, a 33% decrease in flexural strength was observed after 4-week soaking in PBS. In degradable polymer matrix composites, the molecular weight and crystallinity of the polymer affect the rate of decomposition. In the degradation process, water molecules penetrate into the polymer matrix and cause the polymer chains to break into shorter pieces. This situation leads to a decrease in the strength of the composite as well as a decrease in weight due to the exit of shortened chains from the polymer body. In addition, water penetration at the matrix/fiber interface (due to polymer degradation and fiber surface dissolution) leads to separation at the interface and loss of strength. Figure 5 shows the reduction in strength of composite screws after 4 weeks of immersion in PBS solution.

Discussion

In this research, a tri-layered partially resorbable composite screw from BG/PLLA was made. The screw plies have a UD, ±20° angle, and random fiber arrangement characterized by a gradual variation of the mechanical properties over the thickness of the materials. The fiber/matrix interface was improved using a coupling agent that preserves optimal initial mechanical properties. The manufacturing process parameters were also optimized. Degradation studies such as strength loss and WL showed an acceptable rate in comparison with those of cortical bone that keeps their integrity throughout the study (4 weeks). Furthermore, by optimizing the FGM structure that causes a reduction in layer separation, a better transformation of the load from the outer layer to the inner and a more forceful screw was obtained. Results showed outstanding mechanical properties and degradation

Table 1: Optimization of manufacturing parameters

Composite screw situation	Pressure (MPa)	Time (min)	Temperature (°C)
Burned base matrix polymer	150	35	175
Screw with mock and separation between the layers	150	15	130
Optimized temperature, pressure, and time	170	25	150

Table 2: Mechanical properties of the composite screw

Model	Flexural stiffness (N/mm)	Maximum flexural load (N)	Pull out strength (KN)	Maximum torque (m.Nm)
65/10/25	999.3±52.1	661.5±20.3	1.8±0.1	1617.8±85.7

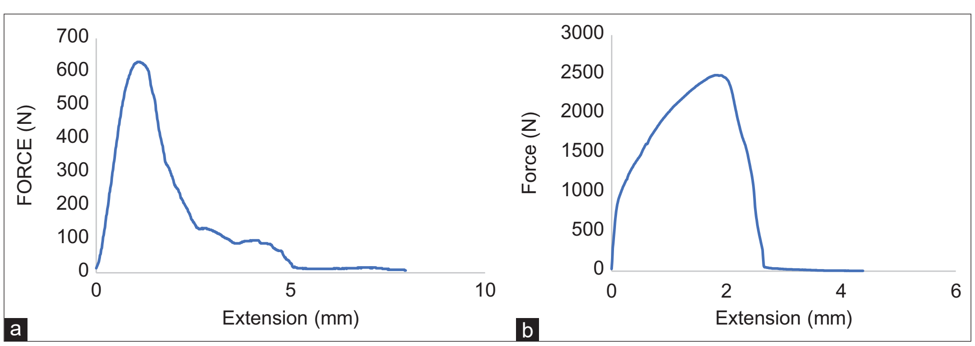

Figure 3: Force-extension curve for the biodegradable screw. (a) Flexural test, (b) Pull-out test

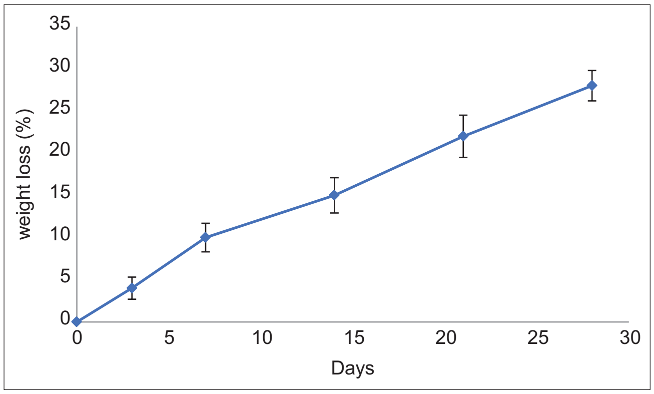

Figure 4: Degradation rate of the tri-layered PLLA-BG composite screw in 4 weeks. PLLA - Poly L-lactic acid, BG - Bioactive glass

rates, suggesting successful use of PLLA/BG composite screws for load-bearing applications in orthopedic implants.

As the mechanical properties of implants closer to the bone, it can reduce the concentration of stress and the failure load on the bone.[24,25] The screw's mechanical properties depend on the geometric specifications, materials, and manufacturing process of the screws.[26] Metallic screws are stronger than bioresorbable screws, but bioresorbable screws showed enough strength against physiological bone for bone fracture fixation.[24,27-29]

The flexural and tensile properties of fiber-reinforced composites depended on VF, fiber properties, and orientation. In contrast, the shear properties are more related to the matrix. By optimizing the manufacturing process, proper attachment between the fibers and matrix and also between the layers occurred. Moreover, the crystallinity of the polymer matrix was increased. All of these phenomena improved the initial mechanical properties also control the degradation rate and reduced the loss of mechanical properties in PBS.[30,31]

According to the results, the initial flexural for three layer (65/10/25) screw with 40% VF has the most flexural stiffness about 1000 (N/mm) which was slightly more than cortical bone. Macro-mechanical finite element analysis has been showed that the screw with a ply percentage of 65/10/25 has appropriate flexural modulus and flexural strength of 22.7 GPa and 347 MPa, respectively.[22] The flexural modulus and flexural strength of the composite screw results were close to the cortical bone which was 90–180 MPa and 6–20 GPa, respectively. Compare to Felfel *et al*.[32] that proposed a composite screw made from PLA/phosphate glass with a UD/random arrangement with a 30% fiber VF, the maximum flexural strength, and the pull-out strength of the screws manufactured in the present study were increased by about 30% and 50%, respectively. López *et al*. reported a 120 N strength in the pull-out test for the PLDA screw. They revealed that composition, screw size, and crystallinity

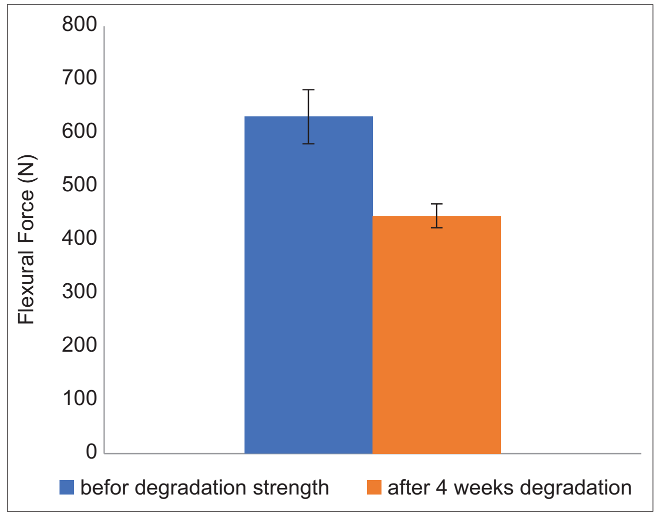

Figure 5: Strength of tri-layered PLLA-BG in the flexural test before and after 4-week degradation. PLLA - Poly L-lactic acid, BG - Bioactive glass

of the polymer matrix are important parameters in the initial pull-out strength and also in long-term strength related to the degradation process.[33] Many studies try to design and fabricate degradable composite screws from hydroxyapatite/PLLA, self-reinforced-PLLA, etc., however, the lack of initial mechanical properties and its reduction in hydrolytic degradation environment is still a challenge, especially for load-bearing applications such as tendon and ligaments as well as long bone fracture fixations.[34,35] In the present study, the use of fiber reinforcement, an increase in the VF of reinforcement, layers with proper arrays, and optimization of thickness percentage assigned to each layer had an important role in achieving suitable mechanical properties. Other factors are the use of a coupling agent that improved the bonding of fiber to the matrix, and thus, load transfer from matrix to reinforcement is fully accomplished. Optimization of the forging process, in addition to proper bonding of layers to each other and bonding of fibers to the matrix, increases the loading capacity of composite screws by making them crystalize in the polymeric matrix. As a result, an appropriate screw for orthopedic applications in load-bearing sites was obtained.

Conclusions

Based on the types and positions of the fracture, screws are used to attach plates to bone fragments or to repair the fracture directly without plates. Metallic screws were used for internal fixation but in some cases, it is necessary to remove the screws after bone healing, which causes the patient more injury. However, successful removals of the screw may produce stress shielding that could contribute to re-fracture. To eliminate the need for procedures and other drawbacks of removal, the screw is made from bioresorbable materials. Implants with mechanical properties adjacent to the bone can also prevent stress shielding of the bone. In the present work, a composite screw was achieved based on PLLA and BG fibers. To eliminate the need for second surgery, PLLA/BG bioresorbable composite screws could probably offer alternative solutions to eradicate the need for a second surgery. New modeling of the fiber reinforcement significantly improved the initial flexural strength of the composite screws above those of PLA alone and UD screws. Initial mechanical properties (flexural strength and tensile strength) were increased by changing plies percentages. Flexural modulus and flexural strength exhibited acceptable results in comparison with those of cortical bone. These findings indicate excellent mechanical properties that suggest promising use of such composite screws for high load-bearing applications in orthopedic implants.

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None.

Conflicts of interest

There are no conflicts of interest.

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