

Biocomposite Interference Screw for Internal Fixation from 3D Printed Material: A Review

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Abstract: *The interference screw fixation technique has gained immense popularity as a method for reconstructing the Anterior Cruciate Ligament (ACL). Initially, metal materials were used for the interference screws, but this caused difficulty in enduring the screws during the healing process. Consequently, bioabsorbable interference screws were developed to overcome this problem, which were made from biocomposite materials that included bioceramics to accelerate bone healing. While biopolymers lacked bioactive properties, the addition of bioceramics addressed this issue. The use of 3D printing as an alternative method for producing interference screws is worth considering, but further research is needed to ensure that the products have mechanical properties that are balanced with the injection molding method.*

Keywords: Interference screw, Anterior Cruciate Ligament, 3D printing, Biopolymers, Bioceramics, Biocomposite, Bone, Materials

1. Introduction

In the field of orthopedic surgery, implants made of biomaterials such as metals, ceramics, polymers, and composites are used that are compatible with living body tissues. Among the different types of materials used, metal alloys have been widely used over the years to repair fractured bones or soft tissue breaks due to their desirable mechanical properties and biocompatibility [1]. However, the use of metal interference screws for ACL reconstruction had some drawbacks, such as the difficulty in removing them during the healing process. This led to the development of bioabsorbable interference screws, which are non-metallic and provide firm fixation until the graft fuses with the bone, and then undergo full resorption to be replaced by bone [2].

Bioabsorbable materials used for interference screws must meet specific requirements, such as being naturally absorbed in the body, having good mechanical properties, and degrading at an appropriate rate. If the material degrades too quickly, its mechanical strength will decrease, resulting in inadequate healing due to incomplete immobilization of the bone fragments [3]. Using biocomposite materials is a suitable choice for producing bioabsorbable interference screws. Biocomposites are biomaterials composed of multiple materials to obtain desired properties, which provides an advantage in engineering properties compared to single materials. Biopolymer matrices and bioceramic fillers are currently used as the main ingredients for bioabsorbable interference screws. Polylactic Acid (PLA) and its various enantiomers, Poly-L-lactic Acid and Poly-D-lactic Acid, as well as Polyglycolic Acid (PGA) are commonly used as biopolymers, while HA, BCP, TMC, and-TCP are utilized as osteoconductive and osteoinductive bioceramic fillers. PLA is the most frequently used material due to its longer absorption time compared to

PGA. The absorption process of bioabsorbable screws goes through hydration, depolymerization, loss of mass integrity, absorption, and elimination stages. The screw composition can affect the degree of degradation and absorption [4]. Currently, casting is the most commonly used method for producing implant products such as interference screws, but 3D printing methods are also being developed. Fused Deposition Modeling (FDM) is a 3D printing technique that uses filament as a material and can produce products with precise dimensions and perfect shapes. Customization of 3D printing devices has been successfully applied in the medical field and can save costs [5]. This paper aims to compare suitable materials as biocomposite-based bioabsorbable materials for interference screws produced using the 3D printing FDM method, with the goal of selecting a suitable material for producing interference screws via 3D printing.

2. Biocomposite Interference Screw

2.1 Interference Screw

The interference screw is a type of compression fixation device that relies on screw threads to engage and compress the graft during fixation. It is commonly used in cruciate ligament reconstruction with double loop hamstring tendon grafting. However, using interference screws in ACL reconstruction may result in potential problems such as screw mismatch, occlusion of the graft, and graft loosening. Metal interference screws have been found to cause a high incidence of tendon rupture due to graft lacerations between screws. Although using bioabsorbable interference screws can reduce the risk of graft laceration during screw insertion into bone, there is still a possibility of graft twisting or cracking. Many hospitals use various brands of bioabsorbable interference screws with different material contents, as shown in Table 1.

The price of bioabsorbable interference screws varies depending on their clinical history, with the cheapest one costing around 200 US dollars and the most expensive one reach-

ing up to 500 US dollars. Typically, bioabsorbable interference screws currently used are priced around 200-300 US dollars.

Table 1: Commercial Interference Screws [1].

Manufacturer	Product	Composition
Smith & Nephew	Calaxo	PGA-co-PDLLA/Calciumcarbonate (CC)
	Biorci-HA	PLLA/Hydroxyapatite
DePuyMitek, Inc.	Bio-IntrafixBiocryl	PLLA/ β -Tricalciumphosphate (β -TCP)
	Milagro	PLGA/ β -Tricalciumphosphate (β -TCP)
Stryker	Biosteon	PLLA/Hydroxyapatite
Arthrex, Inc.	BioComposite	PDLLA/Biphasic calciumphosphate (BCP)
ArthroCare Corporation	Bilok	PLLA/ β -Tricalciumphosphate (β -TCP)

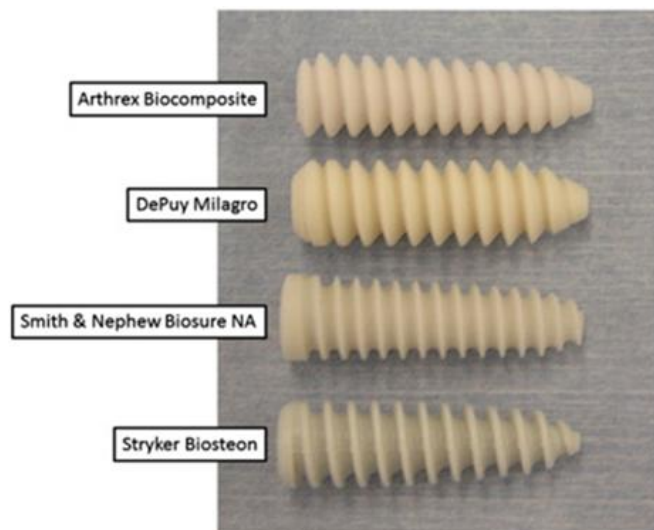


Figure 1: Commercial Interference Screws [2]

2.2 Materials

Biopolymer

In Organ Tissue Engineering, biodegradable synthetic polymers are preferred over other materials for scaffold development due to several advantages. These polymers offer the flexibility to adjust their mechanical properties and degradation kinetics according to the application. Additionally, they can be molded into different shapes with pore structures that are conducive to tissue growth. Synthetic polymers can also be designed with chemical groups that can promote tissue growth. However, meeting the demanding requirements for orthopedic injury/disease tissue engineering requires not only mechanical support during tissue growth and gradual degradation, but also biocompatibility and the ability to incorporate cells, growth factors, and create an osteoconductive and osteoinductive environment. Although many degradable polymers are available (as shown in Table 2), not all polymers meet all of these requirements. Therefore, a combination of materials is often necessary to meet these requirements.

Bioceramics

Bioceramics refer to ceramics that are specifically designed to treat and reconstruct damaged or abnormal parts of teeth or bones. In order to be suitable for medical use, bioceramics need to be biocompatible, non-toxic, highly resistant to wear, and have the same composition as the hard mineral tissue found in the body. Bioceramics used in implants can be cate-

gorized as non-absorbable (inert), bioactive or surface reactive (semi-inert), or biodegradable or resorbable (non-inert). Examples of inert bioceramics include alumina, zirconia, silicon nitride, and carbon. Semi-inert bioceramics include certain glass ceramics and hydroxyapatite, while calcium phosphate and calcium aluminate are resorbable ceramics that can be absorbed by the body. Although ceramics are excellent materials for implants, they have some drawbacks, including their stiffness, brittleness, susceptibility to fracture, and fatigue caused by their interaction with water. Therefore, it is necessary to combine ceramics with other materials to address these limitations.

Table 2: Chemical structure of biodegradable synthetic polymers [6]

Polymers	Chemical Structure
Poly(glycolic acid)	$\left[\text{O}-\text{CH}_2-\text{C}(=\text{O}) \right]_n$
Poly(lactic acid)	$\left[\text{O}-\underset{\text{CH}_3}{\text{CH}}-\text{C}(=\text{O}) \right]_n$
Poly(caprolactone)	$\left[\text{O}-(\text{CH}_2)_5-\text{C}(=\text{O}) \right]_n$
Poly(glycolic-co-lactic acid)	$\left[\text{O}-\text{CH}_2-\text{C}(=\text{O})-\text{O}-\underset{\text{CH}_3}{\text{CH}}-\text{C}(=\text{O}) \right]_n$
Poly(dioxanone)	$\left[\text{O}-(\text{CH}_2)_2-\text{O}-\text{CH}_2-\text{C}(=\text{O}) \right]_n$
Poly(3-hydroxybutyrate)	$\left[\text{O}-\underset{\text{CH}_3}{\text{CH}}-\text{CH}_2-\text{C}(=\text{O}) \right]_n$
Poly(3-hydroxyvalerate)	$\left[\text{O}-\underset{\text{C}_2\text{H}_5}{\text{CH}}-\text{CH}_2-\text{C}(=\text{O}) \right]_n$

Hydroxyapatite is a type of calcium phosphate compound with the chemical formula $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$, composed of phosphorus and calcium. It is a crystalline molecule that is extensively studied for medical applications, such as bone or tooth repair, filling, or replacement, due to its biocompatibility, osteoconductivity, and immunogenic properties. Hydroxyapatite is easily accepted by bone tissue, helps in the acceleration of bone tissue healing, and has a chemical composition

similar to bone, making it nontoxic and non-inflammatory. It constitutes 60-70% of the inorganic component of human bones and is a vital component of the mineral phase of bone tissue [7]. Table 3 shows mechanical properties of Hydroxyapatite.

Table 3: Mechanical Properties Hydroxyapatite

Properties	Rate
Molar Ratio Ca/P	1.67
Modulus young (GPa)	80 - 110
Modulus Elasticity (GPa)	114
Compressive strength (MPa)	400 - 900
Bending strength (MPa)	115 - 200
Density (g/cm ³)	3, 16
Hardness (HV)	600
Decomposition Temperature (°C)	>1000
Melting Point (°C)	1614
Thermal Conduction (W/cm. K)	0.013
Biocompatibility	High
Bioactive	High
Biodegradation	Low
Osteoconductivity	High

Biocomposite

Biocomposites are a combination of different materials used to achieve specific properties required for biomaterials. As these materials are composite, they provide the advantage of improved engineering properties. Biocomposites made of biopolymers such as PLA and PGA, along with bioceramics like hydroxyapatite and calcium carbonate, are commonly used as interference screw materials. The addition of bioceramics offers bioactive properties, which are not present in biopolymers and are known to enhance bone healing.

2.3 Fused Deposition Modelling (FDM) 3D Printing

The application of 3D printing technology has become widespread in various industries, such as engineering, automotive, education, design, dentistry, architecture, and pharmaceutical manufacturing. The technology has numerous advantages, including fast prototyping, flexibility in changing prototypes, cost-effectiveness, and high efficiency. There are various 3D printing methods, such as Stereolithography (SLA), Selective Laser Sintering (SLS), Fused Deposition Modeling (FDM), Laminated Object Manufacturing (LOM), Inkjet Printing techniques, and Two-Photon polymerization (2PP), with FDM and SLS being the most commonly used. FDM is an economical method that produces solid geometry layer by layer using filament as a material. This method is ideal for creating functional models, prototypes, or components in thermoplastic materials with high mechanical, thermal, and chemical resistance [8]. Customization of 3D printing devices in the medical field will be cost-effective and allow for custom product adjustments for various diseases, thereby saving time and costs. FDM method uses several parameters such as nozzle diameter, bed calibration, nozzle temperature, bed temperature, extrusion width, and raster angle to ensure high geometric accuracy of the printed objects [9]. Figure 2 shows 3D Print FDM (Fused Deposition Modelling).

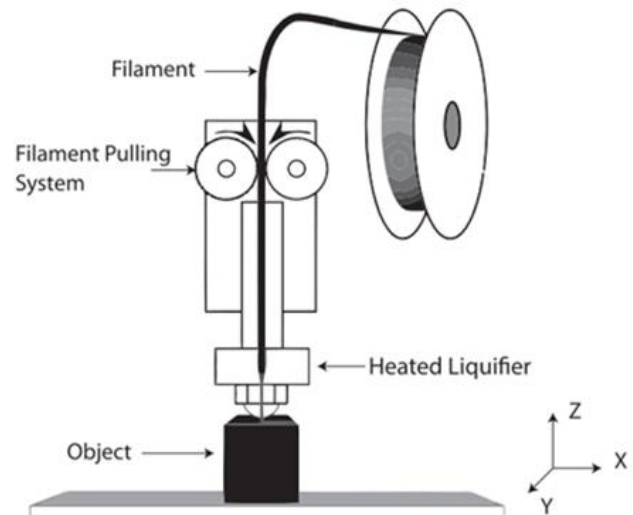


Figure 2: Fused Deposition Modelling [10].

2.4 Biocomposite Filament

Orozco-Díaz et al. [11] conducted research on the formation of biocomposites (PLA/HA) into filaments for the purpose of bone scaffold formation using 3D printing. The biocomposite was produced by mixing PLA and HA filaments, which were melted in a PTFE tube at 185°C using a dry oven. The resulting mixture was cooled at room temperature for 6 hours until it formed composite plates. The plates were cut into ± 5 mm pellets which were then used to create biocomposite filaments using the Filabot Original Filament Extruder. These biocomposite filaments were then used as raw material for the 3D printing process using the BFB-3000 3D printer to form biocomposite specimens.

Similarly, Mystridou et al. [12] used 3D printing to create a bioscaffold made from a PLA/PCL/HA/BaTiO₃ biocomposite. The Fused Deposition Modeling (FDM) method was used to produce the bioscaffolds, which were then characterized to obtain their morphology and mechanical properties. The study found that a mixture of PLA and HA/BT minerals was too brittle for 3D printing and required the addition of PCL to increase the elastic properties of the biocomposite. FTIR results showed no chemical interaction between PLA, PCL, and HA/BT, while XRD results showed no change in the crystallinity of each material even after exposure to heat from the filament extrusion and 3D printing processes.

A study by Akerlund [13] utilized a biocomposite made of PLA, PCL, and HA to create 3D printing filaments for specific patient implants. Various ratios of the biocomposite were tested, and it was found that filaments with a ratio of 90% PLA, 10% PCL, and 15 wt% HA had the best mechanical properties, were easy to extrude into filaments, and were easiest to shape using the 3D printing method. Pitjmit et al. [14] also developed 3D printing filaments using a desktop single-screw extruder machine with PLA, PCL, and HA biocomposite mixtures of varying ratios. Filaments with a lower percentage of HA appeared more transparent, and the composition of HA affected the mechanical properties. Filaments with 15 wt% HA had the highest compressive strength but the lowest tensile stress. Additionally, coating the specimens with silk fibroin improved their biological properties and increased bone cell proliferation. The study suggested that

these composite biomaterials have potential for making interlocking screws for diaphyseal fractures in dogs.

The use of 3D printing for manufacturing screws, pins, and bone plate fixation devices with drug-filled materials has been studied by Tappa and colleagues [15]. They made sets of specimens with different ratios of PLA infill with and without gentamicin (GS) and methotrexate (MTX) fillers in cylindrical and rectangular shapes. Pure PLA specimens had higher flexural strength when cast in the Y-axis at 100% infill compared to other infill axes and ratios, but no significant difference was observed. On the other hand, GS and MTX-filled specimens had significantly lower flexural and compressive strengths, respectively, compared to pure PLA specimens. However, GS-impregnated implants demonstrated bacterial inhibition, and MTX-impregnated implants had a cytotoxic effect in the osteosarcoma assay. This research showed the potential of 3D printing to develop custom implants with the required mechanical properties and drug-impregnation capabilities, although the addition of drugs significantly reduced the implants' strength.

Another study by Dhandapani and colleagues [16] demonstrated the use of additive manufacturing in developing porous orthopedic screws that can be gradually absorbed by the body. They 3D printed screws with different pore sizes and infill densities, and the results showed that screws with 45% infill had optimal pore sizes and porous interconnections without reducing mechanical strength. The porous screws also exhibited greater osteoblast-like cell adhesion, proliferation, and mineralized matrix synthesis over 21 days in an *in vitro* environment compared to non-porous screws. These porous screws also had significantly increased vascularity in implanted subcutaneous mice compared to control screws, indicating better osteointegration due to increased mineralization and vascularization.

2.5 Initial Study of 3D Printed Biocomposite Interference Screw

Recently, there is ongoing research focused on the development of materials for interference screw biocomposites. The objective is to create 3D printed interference screws that can serve as an alternative or cost-effective substitute for commercially available interference screws. The aim is to produce these 3D printed screws with mechanical properties that are on par with or even superior to those of the commercial screws.

The utilization of green mussel and crab shells following industrial and consumption activities offers numerous advantages, particularly in the field of biomaterials. The successful synthesis of hydroxyapatite from green mussel shells using the hydrothermal method has been achieved [17]. In this particular study, the green mussel shells were purified using the precipitated calcium carbonate (PCC) method, resulting in a crystalline phase primarily composed of vaterite. The duration of the hydrothermal process played a significant role in the quality of the hydroxyapatite synthesis derived from the PCC product rich in vaterite phase. Specifically, when the hydrothermal holding time was set to 18 hours, high-purity hydroxyapatite was obtained, as it did not contain any other apatite compounds such as dicalcium phosphate, dibasic

phosphate, tricalcium phosphate, or amorphous phases found in other calcium phosphates.

Another study by Ismail et al. [18] highlights the significant influence of calcination and precipitation processes on the chemical composition, crystal phase, crystal size, and crystal system of the obtained calcium carbonate (CaCO_3). By subjecting the aragonite and calcite crystalline phases present in green mussel and crab shell powders to calcination, they were successfully converted into $\text{Ca}(\text{OH})_2$ or portlandite. Furthermore, calcination played a role in removing organic compounds and reducing impurity content in the green mussel powder and crab shells. Comparative analysis of the chemical composition between powdered green mussel shells (PMS), commercial CaCO_3 , and powdered crab shells (PCS) revealed that PMS and commercial CaCO_3 consisted solely of Ca, C, and O, whereas PCS contained an additional impurity element, N. The study's findings indicate that PMS has potential as a biomaterial candidate due to its chemical composition closely resembling that of commercial CaCO_3 , with no impurities detected. Moreover, the prevalence of the vaterite crystal phase in PMS presents a distinct advantage for biomaterial applications, offering non-toxicity, excellent biocompatibility and affinity, affordability, and ease of large-scale production.

Bioceramic materials can be combined with biopolymers to create bioceramic and biopolymer-based biocomposites. These biocomposites have the potential to be utilized as materials for interference screws. They offer bioactive properties, enhance the biodegradability of biopolymers, and improve the mechanical properties of biopolymers. Study from Ismail et al. [19] aim to investigate the utilization of HA derived from green mussel shells in biocomposites. They are interested in exploring how the composition of biomaterials, including polycaprolactone (PCL), polylactic acid (PLA), and HA from green mussel shells, affects the mechanical properties and degradation rate. The experimental process involved immersing a PLA/PCL mixture (with ratios of 85:15 and 60:40) in a chloroform solution for 30 minutes, followed by stirring for an additional 30 minutes at 50°C and 300 rpm using a magnetic stirrer. Then, various percentages of HA (5%, 10%, 15%, and 20% of the total weight of the PLA/PCL mixture) were added and stirred for an hour at 65°C and 100 rpm to achieve a homogeneous HA and polymer mixture. The resulting biocomposite mixture was poured into a glass mold following ASTM D790 standards. Subsequently, the density, biodegradability, and three-point bending of the biocomposite specimens were tested to assess the impact of HA and polymer composition on mechanical properties and degradation rate. The study's findings indicate that increasing the HA and PLA composition enhances the mechanical properties of the biocomposites, but it also leads to an increase in the degradation rate of the biocomposites. In another study by Fitriyana et al. [20] also indicate as the concentration of hydroxyapatite (HA) increases, the mechanical properties of the biocomposite improve. However, it also states that with a higher HA content, the degradation rate of the biocomposite accelerates.

The successful production of 3D-printed biodegradable bone screws using polylactic acid (PLA) has been achieved [21]. These bone screws have a diameter of 7 mm and a length of

30 mm result from reverse engineering from commercial ones. The tests conducted indicate that commercially available biodegradable bone screws have a higher density compared to the PLA-based biodegradable bone screws. In terms of torsion efficiency, the commercial bone screws outperform the PLA-based ones. The degradation rate is highest in the case of the commercial bone screws due to the presence of hydroxyapatite (HA), which absorbs water more rapidly. Consequently, the weight loss is accelerated due to preferential degradation at the interface between the polymer and the ceramic. On the other hand, the PLA-based biodegradable bone screws exhibit a lower mass loss compared to the commercial ones. This is because the PLA-based screws absorb less water, leading to a slower degradation rate. Research from Jamari et al. [22] was succeeded develop interference screw biocomposite 3D printed from PLA/PCL/HA. The utilization of a 3D printer for the fabrication of biodegradable interference screws biocomposites yielded density values (ranging from 1.11 to 1.25 g/cm³) that fall within the range of cortical bone density, a range that could not be achieved through traditional screw casting methods. Compared to commercial interference screws, the biodegradable interference screws exhibited lower torsion strength (only fulfills 46%) and degradation rates. In vitro biodegradation tests on the commercial screws demonstrated accelerated degradation over a span of six days, which corresponded to a higher hydroxyapatite content. Moreover, the fracture surface analysis indicated that the commercial screw was more brittle than the screws produced in this study.

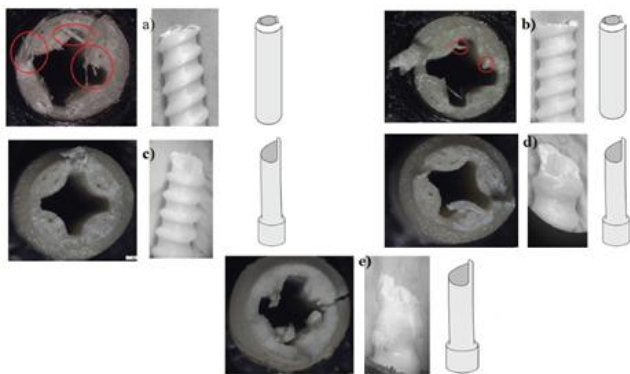


Figure 3: Interference screws 3D printed [22]

3. Conclusion

In modern times, the interference screws used in the medical field are typically composed of polymers such as PLA, PGA, PCL, and sometimes, a combination of these with inorganic filler phases such as Ca-P and hydroxyapatite. The addition of bone mineral phase to the screw can enhance its absorption rate, neutralize the bone site environment, and improve its mechanical properties. It has been proven that a mixture of these materials can be converted into 3D printing filament. 3D printing has been shown to be effective in creating products with desired shapes. While using 3D printing as an alternative to injection molding for making interference screws is promising, further research is required to produce products with balanced mechanical properties.

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