Analysis of the Mechanical Behavior of Porcine Graft Fixation in a Polyurethane Block Using a 3D-printed PLA Interference Screw*

Análise do comportamento mecânico da fixação do enxerto suíno em um bloco de poliuretano usando um parafuso de interferência PLA impresso em 3D

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Abstract

Objective The interest in using 3D printing in the healthcare field has grown over the years, given its advantages and potential in the rapid manufacturing of personalized devices and implants with complex geometries. Thus, the aim of the present study was to compare the mechanical fixation behavior of a 3D-printed interference screw, produced by fused deposition modeling of polylactic acid (PLA) filament, with that of a titanium interference screw.

Methods Eight deep flexor porcine tendons, approximately 8 mm wide and 9 cm long, were used as graft and fixed to a 40 pounds-per-cubic-foot (PCF) polyurethane block at each of its extremities. One group was fixed only with titanium interference screws (group 1) and the other only with 3D-printed PLA screws (BR 20 2021 018283-6 U2) (group 2). The tests were conducted using an EMIC DL 10000 electromechanical universal testing machine in axial traction mode.

Results Group 1 (titanium) obtained peak force of 200 ± 7 N, with mean graft deformation of 8 ± 2 mm, and group 2 (PLA) obtained peak force of 300 ± 30 N, and

Keywords
- bone screws
- lactic acid
- printing, three-dimensional

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mean graft deformation of 7 ± 3 mm. Both the titanium and PLA screws provided good graft fixation in the polyurethane block, with no slippage or apparent deformation. In all the samples, the test culminated in graft rupture, with around 20 mm of deformation in relation to the initial length.

Conclusion The 3D-printed PLA screw provided good fixation, similar to that of its titanium counterpart, producing satisfactory and promising results.

Resumo

Objetivo O interesse em utilizar a impressão 3D na área da saúde tem crescido ao longo dos anos, dadas as suas vantagens e o seu potencial na rápida fabricação de dispositivos e implantes personalizados com geometrias complexas. Assim, o objetivo do presente estudo foi comparar o comportamento de fixação mecânica de um parafuso de interferência impresso em 3D, produzido pela modelagem fundida de deposição do filamento de ácido polilático (PLA), com o de um parafuso de interferência de titânio.

Métodos Oito tendões suínos flexores profundos, de aproximadamente 8 mm de largura e 9 cm de comprimento, foram utilizados como enxerto e fixados em um bloco de poliuretano de 40 PCF em cada uma de suas extremidades. Um grupo foi fixado apenas com parafusos de interferência de titânio (grupo 1) e o outro apenas com parafusos PLA impressos em 3D (BR 20 2021 018283-6 U2) (grupo 2). Os testes foram realizados utilizando uma máquina de teste universal eletromecânica EMIC DL 10.000 no modo de tração axial.

Resultados O grupo 1 (titânio) obteve força máxima de 200 ± 7 N com deformação média do enxerto de 8 ± 2 mm, e a força máxima do grupo 2 (PLA) foi de 300 ± 30 N e deformação média do enxerto de 7 ± 3 mm. Ambos os parafusos de titânio e PLA forneceram boa fixação de enxerto no bloco de poliuretano, sem deslizamento ou deformação aparente. Em todas as amostras o teste culminou na ruptura do enxerto, com cerca de 20 mm de deformação em relação ao comprimento inicial.

Conclusão O parafuso PLA impresso em 3D proporcionou boa fixação, semelhante à de sua contraparte de titânio, produzindo resultados satisfatórios e promissores.

Palavras-chave
- parafusos ósseos
- ácido láctico
- impressão tridimensional

Introduction

Knee ligament reconstruction, especially of the anterior cruciate ligament (ACL), is among the most commonly performed orthopedic surgeries. Typically, these ligaments are not eligible for primary suture, requiring replacement of the injured ligament with a graft. As such, the type of graft and fixation methods have been extensively studied.[1]

There is a wide range of materials available to fix these grafts, with a significant difference in techniques and surgery costs. In surgery, interference screws are a widely used and accepted option,[2–4] but their cost remains a considerable obstacle. When public health policies are proposed, particularly in countries with few health resources, the cost of surgical materials is still a decisive factor in their selection.[5]

Rapid prototyping or 3D printing involves a set of technologies aimed at constructing physical prototypes from their virtual analogs. Interest in using 3D printing in the healthcare field has increased over the years, given its advantages and potential in the rapid production of personalized devices and implants with complex geometries. With an increase in 3D printing, operating costs decline, making this technology and its products more accessible.[6]

Polylactic acid (PLA) exhibits attractive properties for biomedical use due to its biocompatibility. It is biodegradable, since it can be disintegrated by biological agents, and bioabsorbable, because the product of its degradation participates in the metabolic process of the human body. Among the manufacturing techniques used for PLA parts aimed at biomedical applications, 3D printing is one of the most promising, primarily because of the possibility of producing personalized and individualized parts, in addition to detailed prototyping and lower costs, which would make them more accessible, such as 3D-printed PLA interference screws.[6,7]

Thus, the aim of the present study was to compare the mechanical fixation behavior of a 3D-printed interference screw, produced by fused deposition modeling of PLA filament, with that of a titanium interference screw.

Material and Methods

Manufacture of 3d-Printed Interference Screws

An interference screw was created, similar to a trapezoidal-threaded power screw, with an internal conical hexagonal cavity. After 3D modeling (.stl / Autodesk Fusion 360), a virtual 3D model was created, using the Ultimaker Cura software, responsible for printer slicer settings and parameter analysis, in which it is possible to obtain, beforehand, a sample of the printed part and map its entire development process.

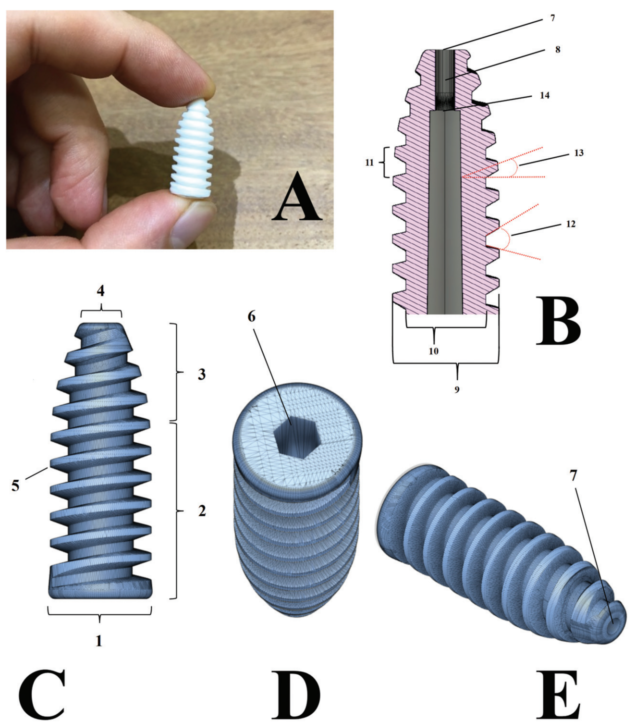

Fig. 1 A 3D-printed PLA interference screw, produced according to the BR 20 2021 018283-6 U2 utility model. **B** Section in the coronal plane with respect to the major axis of the interference screw in a profile view. **C** Profile view of the interference screw. **D** Oblique inferior view of interference screw. **E** Oblique superior view of interference screw. 1. Circular screw base; 2. Parallel zone, of the same diameter, corresponding to the proximal 2/3 of the screw length; 3. Conical zone, corresponding to the distal 1/3 of the screw length; 4. Screw apex; 5. Tangent, left-hand, trapezoidal-shaped external thread, similar to a power screw; 6. Hexagonal conical internal cavity, centered on the long axis, with a length corresponding to the proximal 80% of the total length of the screw, for fitting the wrench; 7. 1.5 mm diameter cylindrical internal cavity; 8. Cylindrical internal cavity, with a length corresponding to the distal 20% of the total length of the screw, centered on the long axis, which communicates with the hexagonal conical internal cavity (6), allowing the passage of a guide wire through the entire internal length of the screw; 9. Larger diameter of the screw thread, corresponds to the width of the screw in its proximal 2/3; 10. Minor thread diameter (10) is equivalent to 2/3 of the major thread diameter of screw (9); 11. Thread pitch, corresponding to 1/3 of the smaller diameter of the screw thread (10); 12. 30° thread angle; 13. 6.5° thread feed angle; 14. Most distal region of the hexagonal conical internal cavity.

The screw was 3D-printed (3DMax A1v2) using the fusion deposition method (FDM) of the PLA filament, a natural biodegradable thermoplastic polymer from renewable sources. The present solution complies with biomaterial guidelines, such as ABNT NBR 15998 and 15743-7. The printed screw (►**Fig. 1**), the object of study, was produced according to the BR 20 2021 018283-6 U2 utility model, measuring 30 mm long, 9 mm wide, with a thread pitch of 2 mm. The following parameters were used in printing:

- Table temperature: 60 °C.
- Nozzle temperature: 200 °C.
- Printing speed: 50 mm/s.
- Layer height: 0.16 mm.
- Infill: 100%.
- Fiber arrangement: Concentric.
- The PLA filament was used with the following characteristics: white, average diameter of 1.75 mm and 3.03 gram/meter.

Polyurethane Block

In order to prepare the test samples, a simulated surgery was carried out, in which a hole was opened in the polyurethane block, representing the "bone tunnel", allowing graft insertion, fixing with the interference screw, as would occur in practice.

According to the ABNT NBR 15678:2020, which regulates the standard material for the mechanical testing of implants and orthopedic instruments, rigid unicellular polyurethane foam with the following characteristics was applied:

- Dimensions: 100 mm x 100 mm x 30 mm.
- Color: brown.
- Density: 40 PCF – 0.96 g/cm3.
- Hole / tunnel: 9 mm in diameter on the central axis of the 100 mm x 100 mm surface, over the entire height of the block (30 mm).

Graft

Similar to that described in the biomechanical study of Moré et al.,[8] we used recently frozen Landrace pig legs in the experiments. The tendons were harvested in a slaughterhouse. Eight legs were stored at –20 °C and thawed 12 hours before the test. Each tibia was dissected, and the deep flexor tendon, approximately 8 mm wide and 9 cm long, was extracted for use as graft.

Sample Preparation

The samples were divided into two groups (►**Fig. 2**):

- (Group 1) control group: the graft was fixed at the extremities of the polyurethane blocks with 30 mm-long and 9 mm-wide metallic interference screws, made of ASTM F136 titanium alloy (Traumédica Ltda., Campinas, SP, Brazil).
- (Group 2) PLA group: the graft was fixed at the extremities of the polyurethane blocks with 30 mm-long and 9 mm-wide 3D-printed screws.

The average graft length was 9 cm, 3 cm inside each block and 3 cm "free" between the blocks. The fixation procedures were carried out by a trained orthopedic surgeon. All the polyurethane blocks contained a 9 mm-long tunnel, made by the surgeon into which an 8 mm graft was inserted. This procedure created a 1 mm space between the graft and the tunnel wall. The screw was implanted with the aid of a Kirschner wire to avoid divergence and false trajectory. At the end, the test specimens displayed the following configuration: screw – block – graft – block – screw (►**Fig. 3**).

Conducting the Tests

The tests were carried out on an EMIC DL 10000 electromechanical universal testing machine, using its axial traction in order to determine the efficiency of graft fixation with

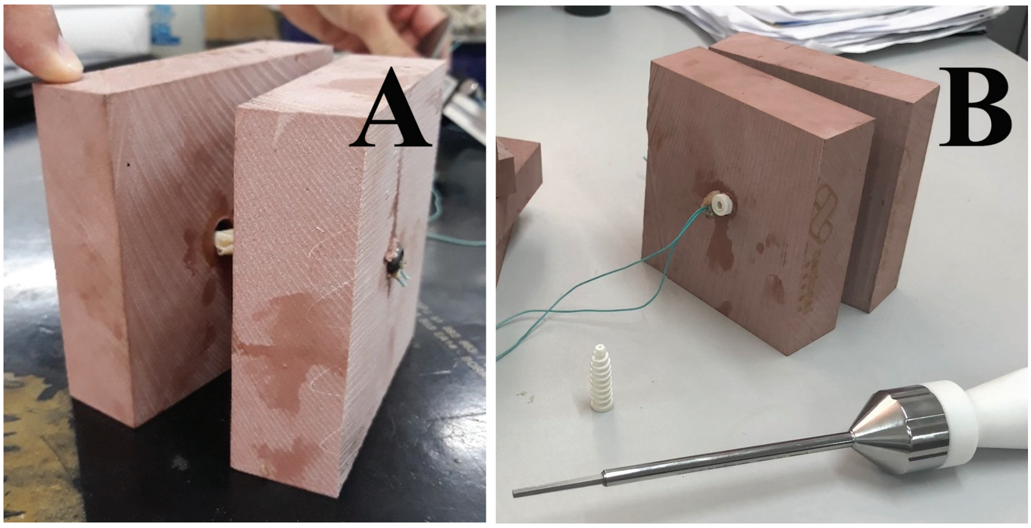

Fig. 2 The samples. A - (Group 1) control group: the graft was fixed at the extremities of the polyurethane blocks with 30 mm-long and 9 mm-wide metallic interference screws, made of ASTM F136 titanium alloy (Traumédica); B - (Group 2) PLA group: the graft was fixed at the extremities of the polyurethane blocks with 30 mm-long and 9 mm-wide 3D-printed screws.

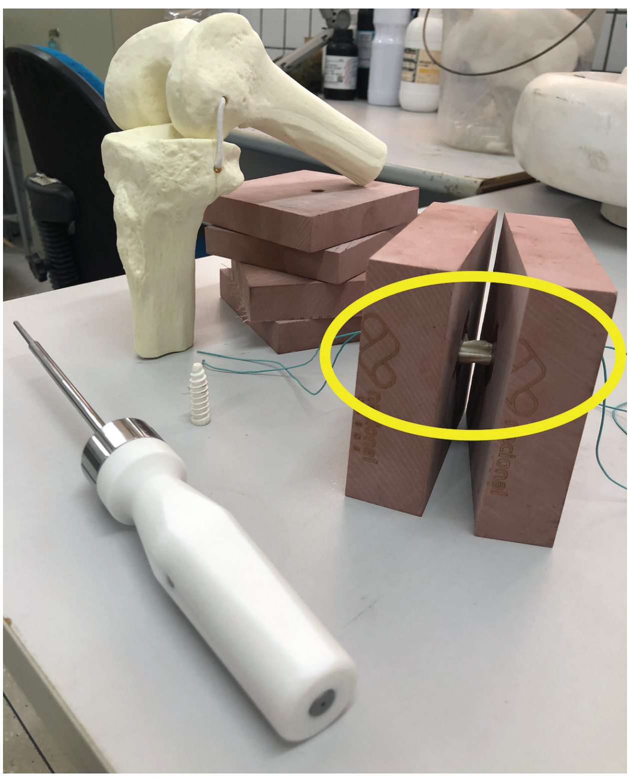

Fig. 3 Test specimens displayed the following configuration (yellow circle): screw – block – graft – block – screw.

Fig. 4 The sample (screw – block – graft – block – screw) on the testing machine (EMIC DL 10000 electromechanical universal testing machine).

interference screws, and a computer to register the data obtained.

In the tests, the experimental length of the sample was correlated by deformation (mm) in relation to time (seconds), stipulated as 10 mm^{-2}/s, with traction applied until graft rupture or slippage of the screw/graft assembly. The apparatus assembled in the testing machine is shown in ►**Fig. 4**.

Methodology and Data Analysis

The categorical and numerical variables were tabulated and analyzed using the R software Rr Mac OS X GUI 1.73 (7892 Catalina build). Analyses with a 95% confidence interval and p-value < 0.05 were considered statistically significant.

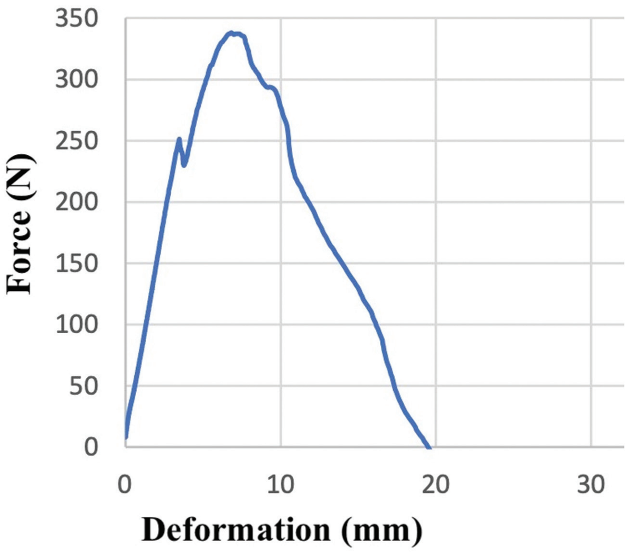

Fig. 5 Graph of the Force (N)/deformation (mm) ratio suffered by the sample number 1 fixed with the PLA screw.

Results

The data obtained from the tests were the time, deformation (mm), and force (N) to which the sample was submitted. With these data, graphs were made of the force (N)/deformation (mm) ratio suffered by the sample fixed with the titanium screw and with the PLA screw (►**Fig. 5**).

The samples in which the graft was fixed at their extremities with titanium interference screws obtained peak force of 200 ± 7 N, with average graft deformation of 8 ± 2 mm. With an increase in deformation, force declined until the graft ruptured, with around 20 ± 1 mm of deformation in relation to initial length. The titanium screw provided good graft fixation in the polyurethane block, with no slippage or apparent deformation. In all the samples, the test culminated in graft rupture.

The samples in which the graft was fixed at their extremities with PLA interference screws obtained peak force of 300 ± 30 N, in average deformation of 7 ± 3 mm. An increase in deformation caused a decline in force until the graft ruptured, with around 19 ± 2mm of deformation in relation to initial length. The PLA screw also exhibited good fixation in the polyurethane block, with no slippage or apparent deformation. In all the samples, the test culminated in graft rupture.

Discussion

The main finding of the present study was to demonstrate that the PLA screw fixation is similar to that of titanium, with similar maximum peak force and graft deformation, thereby exceeding graft strength.

During the tests, both control and PLA screws showed good block graft fixation, with no sign of slippage until the end of the tests, with graft strength being responsible for terminating the tests. However, the results obtained are not sufficient to recommend the use of the present PLA prototype for human ligament reconstruction.

Maximum tensile force of the native ACL is approximately $1,725 \pm 270$ N, lower than the peak that occurs during vigorous athletic activities.[9] Ideally, a graft used for ACL reconstruction surgery should, as much as possible, recreate the anatomical and biomechanical properties of the native ligament, which guarantees secure fixation and rapid biological integration, shortening recovery time and reducing donor site morbidity.[10] Several grafts are available for ACL reconstruction, including autografts (bone patellar tendon bone [BPTB], hamstring [HS] etc.), allografts, and synthetic grafts.[11] The HS graft shows failure with an average load of 2,422 N when compared to 1,785 N for the BPTB graft.[12] In other words, in the present study, we did not exceed the load needed for failure of a human graft.

Moré et al.[8] conducted a biomechanical study with a porcine model, using a deep Landrace pig flexor tendon model as graft. These grafts were then fixed to the tibia by 10 bioabsorbable interference screws (9×20 mm PLLA 70/30, Linvatec), and 10 metallic interference screws (9×20 mm Hexagon). The single-cycle load-to-failure test showed that the rupture load was not significantly different between the 2 types of screws (607.11 ± 97.49 N and 628.41 ± 234.93 N for bioabsorbable and metallic screws, respectively).[8]

Weiler et al.[13] compared flexor tendons as grafts and observed different behavior between metallic and bioabsorbable screws, with load to failure of 507 N for the bioabsorbable screw and 419 N for its metallic counterpart. The values reported by Weiler et al.[13] were closer to those of the present study.

Using 3D printing, Liu et al.[7] produced a well-defined, orthogonal porous PLA screw, subsequently coated with hydroxyapatite (HA) to improve its osteoconductivity, and, loaded with mesenchymal stem cells (MSCs). This screw was assessed by in vitro and in vivo tests, in rabbit ACL models. This model exhibited significant bone growth and bone-graft interface formation inside the bone tunnel, demonstrating that the manufacture of 3D-printed surgical implants may be feasible, effective, and economic.

After immersing a PLA component in a phosphate-buffered saline solution, Medeiros[14] assessed the changes in its mechanical properties, fatigue life and chemical alterations for biomedical applications produced by 3D printing. Medeiros[14] concluded that the printed PLA displayed relevant hydrolytic degradation properties as a biomaterial, exhibiting a decline in fatigue life and granular erosion due to degradation. This enables its application to release drugs and implants such as conductive cell membranes in tissue engineering, but further studies on enzymatic degradation and cell tests are needed for total confirmation regarding the efficacy of this biomaterial.

Feltz et al.[15] studied the mechanical properties of orthopedic 3D-printed, one third tubular plates, and cortical screws, concluding that 3D printers can print biocompatible materials to replicate low-cost surgical implant designs. However, current materials and structures do not resemble the properties of stainless-steel implants.

Carvalho et al.[16] studied the biocompatibility and biodegradation of PLA, implanting the material in the subcutaneous cell tissue on the lateral surface of horses necks, and concluded that PLA is biocompatible and biodegradable, with potential use in equine medicine.

Kamiya et al.[17] measured the financial-environmental performance of PLA parts using fusion deposition modeling. These authors concluded that 3D-printed PLA parts have a low environmental impact and good economic performance, demonstrating the biomedical and commercial usability of 3D-printed PLA parts.

Goes Filho[18] produced and biomechanically assessed orthopedic implants for fracture fixation in PLA (plates and screws), using 3D-printed fused polymer layer deposition for subsequent experimental application in rabbit femur. In a 4-point bending test, the 6-hole plate obtained values of 748 ± 62 N, while the 4-hole locking plate obtained 374 ± 29 N. The screw was submitted to the pullout capacity test in a polyurethane foam that simulates cortical bone, obtaining an average value of 33 ± 6 N. The anatomically optimized plate obtained 662 ± 220 N in the bend test and 193 ± 20 N after irradiated with 40 KGy. From the standpoint of mechanical resistance to the bend test, Goes Filho[18] showed the feasibility of producing orthopedic implants for fractures that received little mechanical load, although further in vivo studies are needed to confirm the efficacy of the production technique and the material used. These findings were similar to those reported by Lough et al.,[19] Tappa et al.,[20] and MacLeod et al.[21]

The expected dependence of graft fixation biomechanics on thread design generally differs between polymer and metallic screws. These differences typically involve distinct fixation performance, which was not observed in the tests. Thus, many other mechanical and tribological aspects clearly play important roles in the interfaces, ruling out simple explanations for different fixation behavior.

However, the main limitation of the present study was the graft selected for the tests. We used animal tissue as graft due to its easy acquisition, but a porcine graft is not as strong as its young human counterpart. As such, we could not test the strength of the screw-polyurethane-graft complex. Nevertheless, the methodology used is a useful model for future research. Despite these limitations, our results corroborate those reported by similar studies. In general, the findings obtained indicate that both types of interference screws exhibit similar biomechanical performance at low loads. However, more research is needed to determine the clinical relevance of these findings.

Conclusion

The 3D-printed PLA screw provided good fixation, similar to that of its titanium counterpart, producing satisfactory and promising results.

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Conflict of Interests

The authors have no conflict of interests to declare.

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