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Study of mechanical properties of fractured bone implant with interlocking intramedullary nail polyamide.

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Abstract: *Fractures in long bones of animals are easily found on day-to-day veterinary surgeons and several immobilization techniques are available to adequately treat them. The interlocking intramedullary nail made of steel or titanium has been used successfully in the treatment of fractures of long bones, both in animals and in humans, but some difficulties have been observed with respect to their use. With the advancement of technology and innovative manufacturing processes, it becomes feasible to use low cost materials for the immobilization and treatment of these kinds of fractures. This study aims to compare the mechanical properties of ex vivo bone of an animal with the fractured bone-implant system ex vivo using interlocking nail polyamide 12, through bending tests performed on a universal testing machine. The nails had cylindrical geometry, uniform, constant and all of them were manufactured by using additive manufacturing technology. They were split in two sets: one solid and the other hollow with an inner passing hole. By the results, it was possible to establish a comparison between bone and interlocking nail. Then, can be used as input data for a numerical analysis by the finite element method which will be useful to see the properties of the ex vivo bone-implant system, to develop new materials as well as to simulate different loading conditions for the treatment in question.*

Keywords: *Implants, Interlocking intramedullary nail, Polyamide*

1. INTRODUCTION AND LITERATURE REVIEW

The long bones have varied and complex shapes and routinely suffer from complex forces, which are responsible for stress and strain throughout the axial length (Carter and Spengler, 1977). The inter-relationship between stress and deformities presented in long bones generates exponential curve response, denoting the biomechanical behavior of the structure in question (Sumner-Smith, 2002).

The femur, like other long bones, suffers from the combined action of compression and flexural (bending) loadings. The result of this combined action is the formation of a compressive force eccentric with greater stress distributed on the opposite side of the application force. However, there is the torsional strength which provides the rotation of the axial bone (Sumner-Smith, 2002). The sum of these forces in the long bones provides greater longitudinal deformity than transversal. This deformation can explain the fact that the bones are tubular structures rather than solid cylindrical.

When a load is applied in a certain region of the bone exceeding its resistance, it leads to fractures. In fractured bone, the "force arm" generates higher concentration of vector at the point of fracture, reducing the inertial moment (Hulse, *et al.*, 1997).

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Fractures of long bones are one of the main goals of orthopedic treatment in veterinary medicine. Nevertheless, femur fractures account for approximately 20-25% of all fractures of the long bones of dogs and cats (Larin, *et al.*, 2001). In a retrospective study, Harasen (2003) cites that 45% (128/282) of all long bone fractures treated corresponded to the femur, while 26% were fractures of the tibia and fibula.

The choice of the implants and bone fixation should be based on the classification and location of the fracture, gait, temperament and age of the animal, the degree of commitment of the owner and economic factors (Dias, 2006).

Currently no overall treatment method is suitable to all types of fractures, thus no implant or stabilization method is perfect, all of them have positive and negative characteristics (Dias, 2006).

In fractures of long bones, various techniques and stabilization methods can be used, such as bone plates, intramedullary pins, external fixators, cerclages and locked intramedullary nail (Dueland, *et al.*, 1996, Mc Laughlin, 1999; Larin, *et al,* 2001).

In order to develop a stabilization method that combines the ease of application and the biomechanical advantages of intramedullary pins with stiffness and blockage of forces acting in the fracture focus offered by plates and screws, Modney (Dueland, *et al.,* 1999) developed, in the 50s, the technique of interlocking nail. The intramedullary locking nail is no more than an adaptation of rod of Küntscher, being basically an intramedullary pin with transverse holes, proximal and distal to the fracture focus, in standardized positions that allow the placement of screws and consequently blocking and nullifying forces of rotation and axial (Dueland, *et al.,* 1996; Schmaedecke, 2007).

The system used in veterinary orthopedic surgical procedures require an external guide which is coupled to the proximal end of the intramedullary nail, and thus assists the exact location of holes for inserting the shank of the screws, allowing its use even without the fluoroscope presence. After blocking the guide is removed (McLaughlin, 1999). Many papers in human medicine mention locking nails with great advantages in procedures for osteosynthesis of diaphyseal long bones when compared to other methods of stabilization maintaining the biological mechanism of fracture repair (Schmaedecke, 2007).

The interlocking nail in the way it is fixed to the bone by screws minimizes the forces acting on the fracture focus (Johnson and Hulse, 2002). Thus, locking nails are considered biomechanically higher than intramedullary pins, plates and the external skeletal fixator (Dueland, *et al.,* 1999; Schmaedecke, 2007).

By an allocation of forces at the neutral axis and also by the geometrical conformation, the rods provide greater rigidity against the bending force compared to the plate and also a lower rate of material fatigue (Larin, *et al.,* 2001; Galuppo, *et al.,* 2002). This fact occurs because the implants located within the medullary canal have higher flexural strength than those located elsewhere and is less susceptible to deformation (Schmaedecke, 2007).

Several studies demonstrate the use of the technique in animals. Dueland, et al., (1999) used interlocking nail in 134 dogs, 92 femoral fractures, 23 tibia and 19 humerus, reporting that 83% of the cases were treated without any complications and only one patient showed no bone healing. It's also cited for the stabilization of corrective surgeries comminuted fractures, pseudoarthrosis and bone exposure cases (Lopez, *et al.*, 2001). The literature also cites its use in poultry (Hollamby, *et al.*, 2004).

Errors lock rod by screws beyond the breaking or bending the rod and screw are possible complications arising from the use of intramedullary locking nail, which can cause delayed union or nonunion, and infection (Dueland, *et al.,* 1997; Larin, *et al.,* 2001; Schmaedecke, 2007). When using a rod smaller than the ideal, or even placing the locking screw is very close to the fracture focus there is a large chance of occurring fatigue of locking implants and the whole system becomes unstable (Dueland, *et al.,* 1999; Mc Laughlin, 1999).

Another drawback relates to the use of rigid metal rod can provide reactions to the body, interference with postoperative radiographic procedures and restrictions physiological bone development in immature animals, besides its high cost (Pietrzak, *et al.*, 1996). However, their permanence within the medullary canal can provide decrease of bone mineral density (osteopenia) caused by the continued presence of the metallic implant (Böstman, 1991).

Besides the type of material the rods are made, biomechanical tests determine basic information that may provide knowledge for understanding the influences on the process of bone repair. Reemns, *et al.*, (2006) evaluated the test cyclic torsion, femoral canines and interlocking nail 8mm in diameter, with one and two locking screws in the distal fragment. Authors concluded that there significant increase in resistance rod when the two locked distal screws. Despite the inherent complications and scarce biomechanical studies, locked intramedullary nail is the treatment of choice for the correction of open or closed diaphyseal fractures in long bones (Schmaedecke, 2007).

Currently research is focused on the development of rods composed of lighter materials, resistant, low-cost and biocompatible characteristics with bone tissue (Van der Elst, *et al.*, 1999). Polymeric materials have been continuously discovered, tested and incorporated into surgical procedures both in human and in veterinary medicine, especially for orthopedic implants and tissue reconstruction. Polypropylene rods have been used successfully in humeral fractures in young cattle (De Marval, 2006).

Rapid prototyping (RP), also known as additive manufacturing processes are relatively recent manufacturing methods in the field of computer-aided manufacturing (CAM - Computer Aided Manufacturing), which enables to produce models or prototypes with complex geometries using the aid of computer system CAD (Computer Aided Design) (Upgraft and Fletcher, 2003).

Currently there are several commercial rapid prototyping processes available in the market and may be cited the following as the most used (Gibson and Shi, 1997):

SL - Stereolithography;
SLS - Selective Laser Sintering;
LOM - Laminated Objet Manufaturing;
FDM - Fused Deposition Modeling;
MJT - Multi Jet Modeling;
3D Printing.

The rapid prototyping processes are broadly used in automotive, aerospace and consumer products industry. In the medical area, can be used directly or indirectly as: design and manufacture of biomodels; tools to aid in surgeries and implants, development of surgical training models and the design and manufacture of scaffolds for tissue engineering (Hieu, *et al.,* 2005).

The first prototype machine of Selective Laser Sintering (SLS) was created at the University of Austin, Texas - USA, in 1987. In the process of SLS, a layer of powder is deposited on the platform. The laser beam with the aid of an optical system that sweeps the surface sintering or melting the material, tracing the profile of the sliced section previously acquired through the STL file. After this process, a new layer of powder is deposited onto the previously sintered layer and the process repeats until achieving desired final piece (Juster, 1994; Upgraft and Fletcher, 2003).

There are different types of polyamides and their properties vary according to the number of carbons present in their structure and consequently the amount of carboxylic groups present in a given volume of material. There are some common characteristics of different types of polyamide, including high impact resistance and mechanical strength, moderate hardness and processability conditions styling such as thermoplastic resins. In general, the polyamides exhibit characteristics of hygroscopicity due mainly to the possibility of formation of hydrogen bonds between the amide groups and the water molecules present in the environment. Compared to other polymers, polyamides have high processing temperatures of the order of 250-300 ° C (Harada and Wiebeck, 2005).

Differently from common features presented earlier, polyamide 12 characterized by presenting a relatively low melting temperature (~ 180 ° C) giving moderate processing temperatures. Due to the number of carbons present in their chain, this polyamide has a very low moisture absorption and does not require drying before processing. These features presented confer favorable characteristics to this material its use in SLS, since its final mechanical properties and surface finish characteristics are quite close to the most usual polyamides.

In terms of their selection for material used as matrix composites manufactured by SLS, in addition to availability, the class of polyamides is more proximity to engineering applications, being at an intermediary level between polymers such as polypropylene and other specials, like the polysulfide phenylene or polyether ether ketone.

To this article, the objective is to verify the enforceability of polyamide locking nail in fractures of long bones, and also check if there will be differences in biomechanical for strength bending (flexion) when the shaft is massive or not massive. The use of the polyamide material for making the rods will purpose, test their resistance to subsequently be used in future studies of non-conventional locks, for being a material that allows drilling and inserting screws in accordance with the need to block the forces of fracture lines, differently from the pre-established locations of stainless steel rods blocked. The use of femurs of pigs will aim to acquire copies quickly and easily in standard sizes, minimizing possible complications of obtaining copies of the same material canines, for obvious reasons of comparison between animals of production and pets.

2. MATERIAL AND METHODS

The material specifically used in this work (DuraForm PA) has special features like high resistance when exposed to harsh environments, excellent surface finish indicated for the manufacture of complex parts, in addition to being a material approved for use in vivo and likely to undergo sterilization (3D Systems Corporation)

The mechanical bending test is characterized into a load at certain points of a geometrically patterned bar, and follow through precise measurements varies as the load versus deflection relationship. The load application happens through the displacement at a constant rate from a plate which is located in the cylinder (or cylinders, depending on the type of assay) responsible for applying the load to the system bi supported. Thus, the load apply from an initial value of zero and slowly increases until failure of the test body or in case of ductile materials until the end of the test that will occur before failure.

During the bending test, the specimen test are subjected to a mixed state of tension, in other words, tensile loads occurs in its lower fibers and compression in the upper fibers. The rupture of the material in this test will occurs by traction and therefore it will start in the lower fibers of the test body. A bending test can be of two types: three-point and four points. The first one is to use a bi supported bar with load applied in the center of the distance between supports, so that there are three load points as shown in Fig. 1. In Fig. 2 is also using a bi supported bar, but with load applied at two points equidistant from the support.

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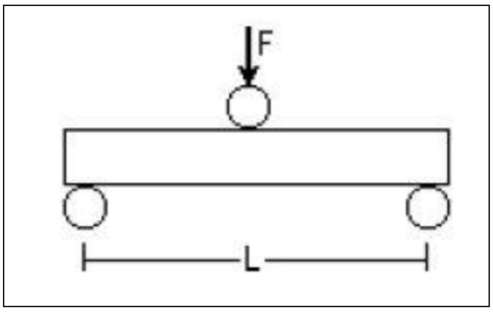

Figure 1. Schematic test at three points.

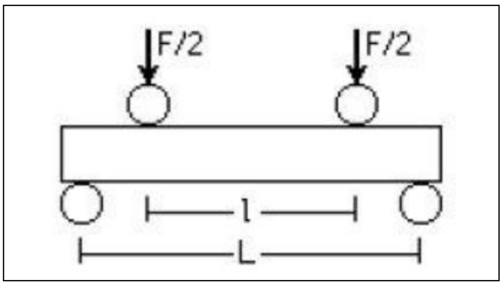

Figure 2. Schematic test at four points

The main results of the bending tests are the tensile strength and the flexural modulus. The values of these properties can vary with temperature, the rate of load application, the surface defects and especially with the geometry of the cross section of the specimens.

In this work, the bending tests were performed according to ASTM D790-00. It was used an universal testing machine model D10000 of Emic, operating with a load cell of 100 kN with speed of the platter 2.0 mm / min. Tests were performed under three-point loading, with the maximum loading occurred exactly half the distance between the two fixed supports ("span").

The distance between the two fixed supports ("span") was chosen so that the bones should not slide down and allow that the central region of the bone would be free for the test, as can be seen in Fig.3, by using the value of 100 mm for all tests.

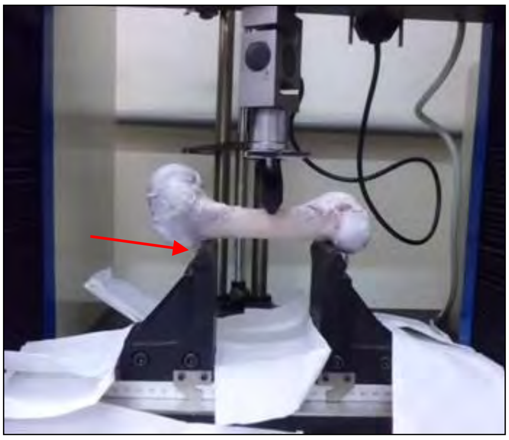

Figure 3. Photographic image of the bending test. Note the arrow to the bone (femur pig) supported with span of 100 mm

The flexural modulus may be determined according to the following Eq. (1) for massive bodies:

$$E_M = \frac{(4 * L^3 * m)}{3 * \pi * D^4} \tag{1}$$

In addition, according to the following Eq. (2) for hollow bodies:

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$$E_V = \frac{(4 * L^3 * m)}{3 * \pi * (D^4 - d^4)} \tag{2}$$

Where,
L is the distance between supports;
m is the slope of the line tangent to the initial straight curve load versus deflection;
d is the internal diameter of the test body, and
D is the diameter of the test body.

The stress rupture strength was calculated from the Eq. 3:

$$\sigma_{máx} = \frac{M_{f_{máx}}}{\omega_f} \tag{3}$$

Where,
$M_{f_{máx}}$, the maximum bending moment; and
ω_f, is flexural modulus.

The maximum bending moment occurs at mid-distance between the fixed supports of the machine ("span"), so Eq. (4) is:

$$M_{f_{máx}} = \frac{F * L}{4} \tag{4}$$

Where,
F, is the force applied to the test; and
L, is the distance between supports.

Equation (5) of flexural modulus is, for massive circular cross section with outer diameter D:

$$\omega_f = \pi * \frac{D^3}{32} \tag{5}$$

Equation (6) for circular hollow section with outer diameter D and inner diameter d:

$$\omega_f = \pi * \frac{(D^4 - d^4)}{32 * D} \tag{6}$$

Femurs from slaughtered pigs were used for weight and size be the most homogeneous possible. After cleaning the surrounding soft tissues, the middle region of the diaphysis of each femur was cut transversely using appropriate orthopedic saw, creating a transverse fracture line. Immediately thereafter, the medullary cavity is milled progressively with manual cutter starting with a diameter of 5 mm to 15 mm in both osteotomized bone fragments as Fig.4. Then, depending on the group (solid rod or hollow) the rod was inserted manually into the cavity milled to allow bone reduction After this step it was determined four points (two on each fragment) and equidistant from the line of fracture. These points were hammering with orthopedic drill (2.5 mm diameter) in the direction parallel to the fracture line, with the aid of orthopedic pneumatic drill. These holes were drilling total. Shortly after the system was locked, screwing orthopedic screws with 3.5 mm diameter lengths compatible.

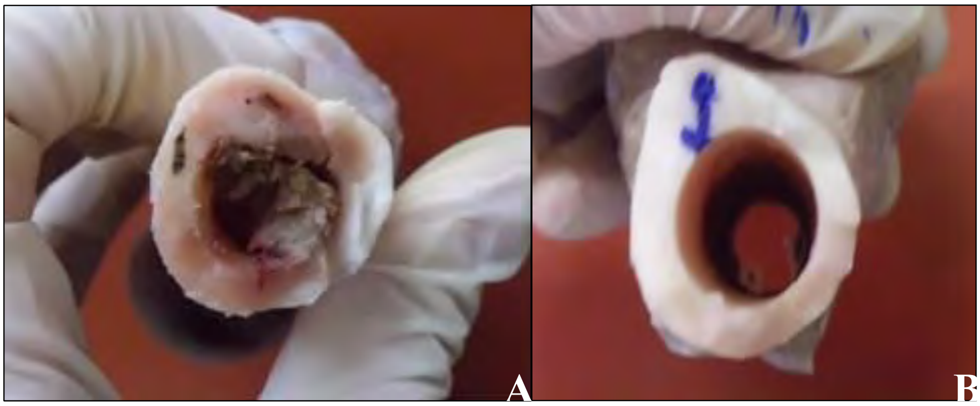

Figure 4. Photographic images of the medullary canal of the femur intact (A) and milled (B).

Due to this procedure before implantation of the stem into the bone, tests were performed on whole bones, with and without the milling procedure, to verify if there was some weakening of the bone after the milling operation.

Bending tests were made on rods polyamide, massive and hollow, in order to determine whether there was a significant alteration in mechanical properties, modulus of elasticity and tensile strength in bending, due to the changing geometry of the same as Fig. 5.

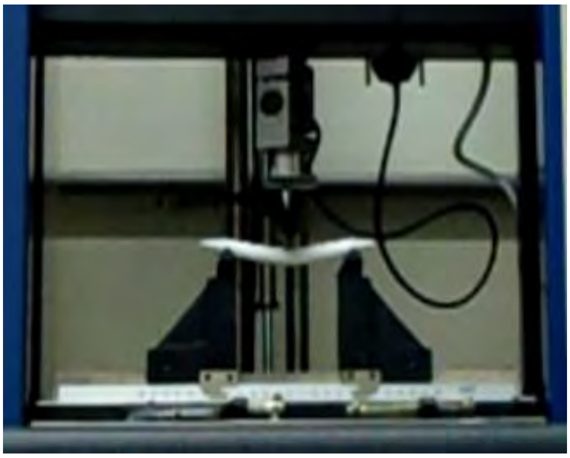

Figure 5. Photographic image of the rod being tested

Finally, tests were performed on the bone-implant system with massive rod and hollow rod, as Fig. 6, for comparison of mechanical properties with the real bone. This is necessary because it is desirable that the bone-implant system have values of modulus of elasticity and tensile strength equal to or above bone integrity.

Figure 6. Photographic image of the test bone - implant system

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After the tests, there were measured inside and outside diameters of the cross section of both, the broken bones and the stems, in order to enable the calculation of geometrical parameters of each sample, necessary for determining the mechanical properties.

3. RESULTS AND DISCUSSION

In bending tests, applied to rigid and semi-rigid materials, are often determined:

* The modulus of elasticity in bending, which value is employed as the most important criterion for assessing the stiffness of polymeric materials.

* Flexural strength that is equal to the maximum stress in the outer fibers of a test body of a polymer, at the time of breakage.

As previously mentioned, on bending test, while the bone is compressed on one side and pulled on the other and due to their anisotropy, when subjected to bending, failure often occurs in the face subjected to tension (), which can be seen in Fig.7. It was found that the crack nucleation occurs in the region tensioned, since the bone resists tensile strength less than the compressive.

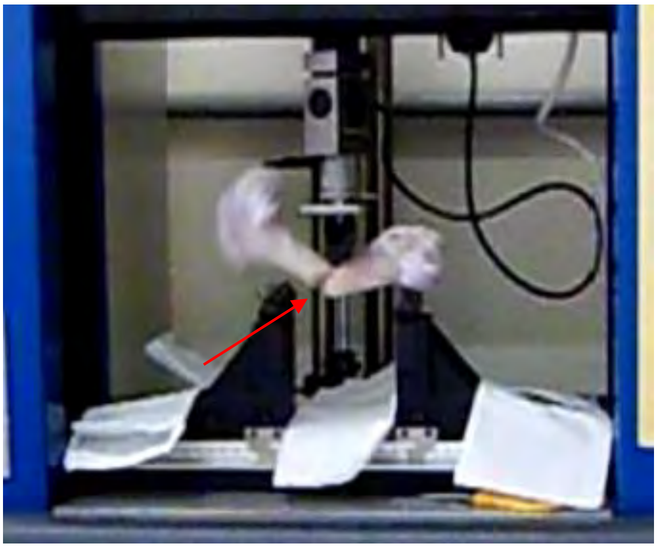

Figure 7. Photographic image of the bone being fractured. Note the arrow to the failure occurring by traction

3.1. BONES

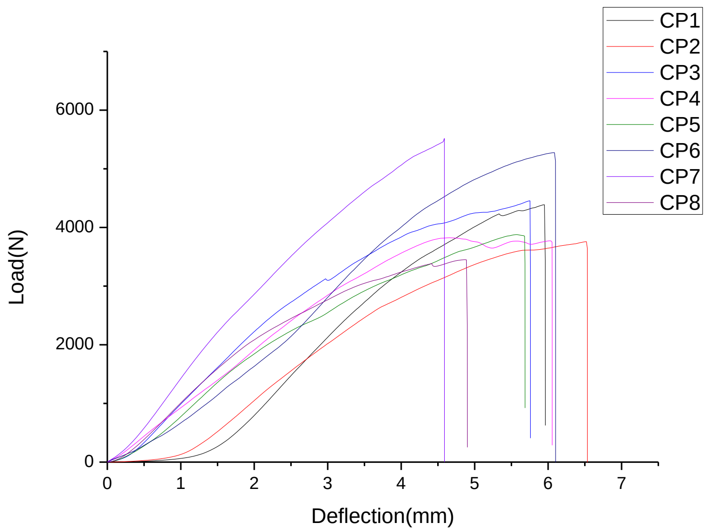

Figure 8. Curves of tests of common bones

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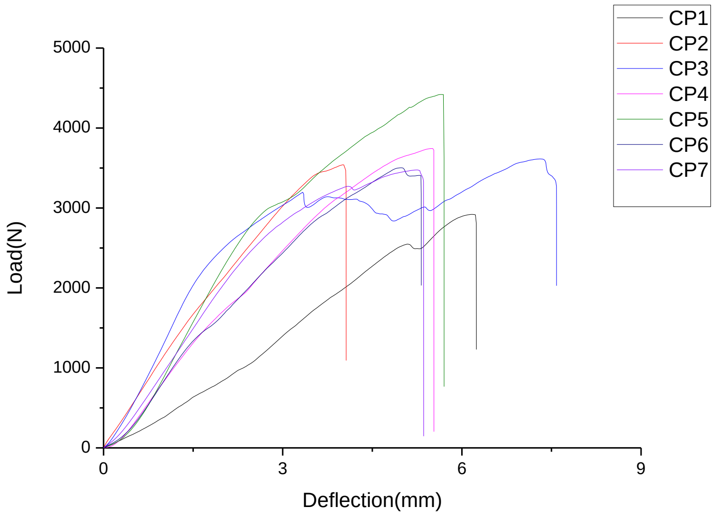

Figure 9. Curves of tests of milled bones

As seen in the results shown in Fig. 8 and Fig. 9 and in the Tab. 1 and Tab. 2, no significant influence by milling the bone on their mechanical properties evaluated in the bending test. Thus, for all subsequent analysis, in which a comparison is made of the properties of the bone, the rod of polyamide 12 and the rod-bone system, will be considered as the properties of the healthy bone.

Table 1. Modulus of elasticity of bone tested

Modulus of Elasticity (MPa) – MOE										
	CP1	CP2	CP3	CP4	CP5	CP6	CP7	CP8	Average	Standard Deviation
Healthy bone (1)	2014,59	1169,81	3022,71	2019,27	1607,50	3152,88	3131,29	2668,30	2348,29	753,55
Milled bone (2)	1004,07	1317,86	2366,47	2586,49	2204,48	1178,57	2074,16		1818,87	636,12

(1) obtained by applying the Eq. (1)
(2) obtained by applying the Eq. (2)

Table 2. Rupture tension of the bones tested

Ultimate strength (MPa) – MOR										
	CP1	CP2	CP3	CP4	CP5	CP6	CP7	CP8	Average	Standard Deviation
Healthy bone (1)	106,52	69,57	139,11	109,25	84,67	203,12	138,99	104,18	119,43	41,35
Milled bone (2)	85,78	66,40	89,97	130,11	107,94	61,01	100,88		91,72	23,96

(1) and (2) obtained by applying the Eq. (3)

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3.2. RODS

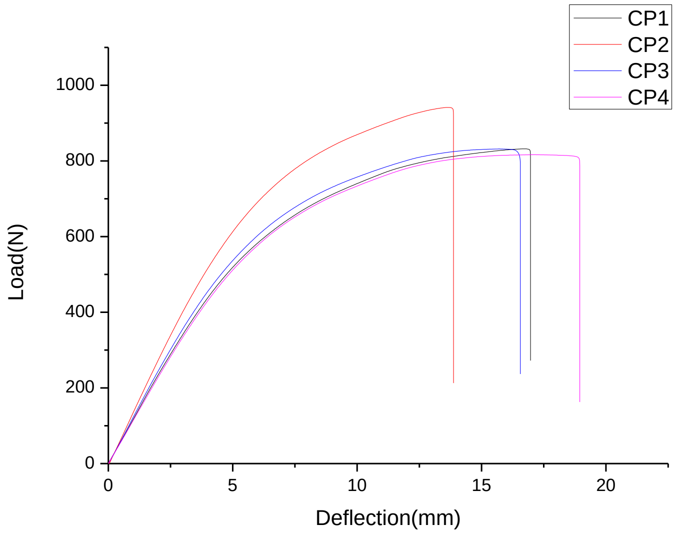

Figure 10. Curves of tests of the rods

Table 3. Modulus of elasticity of the stems tested

Modulus of Elasticity (MPa) – MOE				
	CP1	CP2	Average	Standard Deviation
Solid rod (1)	1260,78	1501,84	1381,31	170,46
Hollow rod (2)	1349,45	1267,32	1308,39	58,08

(1) obtained by applying the Eq. (1)
(2) obtained by applying the Eq. (2)

The results of elastic modulus in flexure of the rod material, polyamide 12 being processed by selective laser sintering, shown in Fig. 10 and in the Table 3 and Table 4 correspond exactly to the values given by the supplier of the material (3D system), evaluated according to ASTM D790.

Table 4. Rupture tension of the rods tested

Ultimate strength (MPa) - MOR				
	CP1	CP2	Average	Standard Deviation
Solid rod (1)	77,20	87,36	82,28	7,18
Hollow rod (2)	79,36	77,91	78,64	1,02

(1) and (2) obtained by applying the Eq. (3)

It is important to note that all experiments were left in water for 48 hours to ensure that the materials would be in a saturated humidity conditions given the characteristic of hygroscopicity of both materials, the bone and the rod of polyamide 12.

It can also be seen that there was no significant influence on the mechanical properties measurements of massive and hollow rods, which can be attributed to the fact that there are no significant differences in their geometrical dimensions, despite the difference of their cross section.

A positive aspect for the use of hollow rods, is the fact that although these do not appear more rigid than the massive, it shows a similar strength, with a smaller amount of material. This could be further explored in future developments of this study.

Comparing the mechanical properties in flexure measures of bone and the rods, made of polyamide 12 by selective laser sintering, it appears that the main mechanical property to be improved is the modulus of elasticity. This mechanical property can be significantly improved by the use of reinforcements such as glass fibers or carbon, using the same

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manufacturing process or studying the possibility of using other polyamides processed by other processes, such as injection molding.

3.3. BONE-IMPLANT SYSTEM

In addition, for the bone-implant system, it can be seen on Fig. 11 and Fig. 12 that there was no significant influence on the mechanical properties measurements of rods, massive or hollow, which can be attributed to the fact that there are no significant differences in their geometrical dimensions, despite the difference of their transverse section.

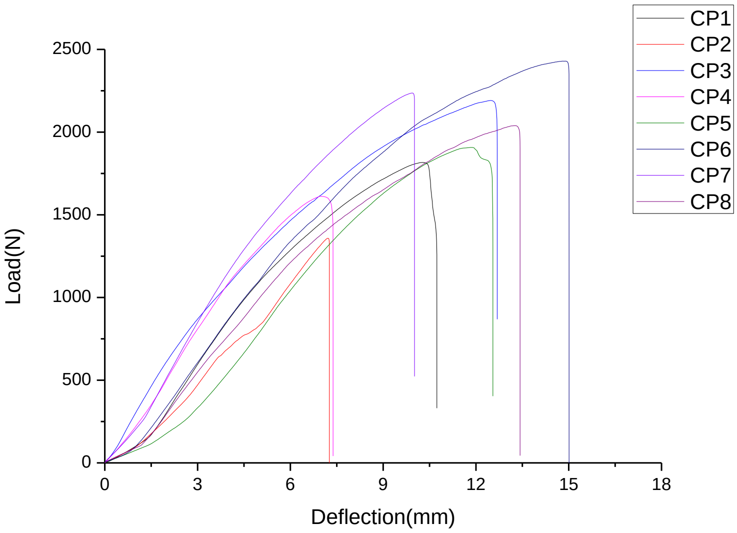

Figure 11. Curves of testing the bone-implant system with solid rod

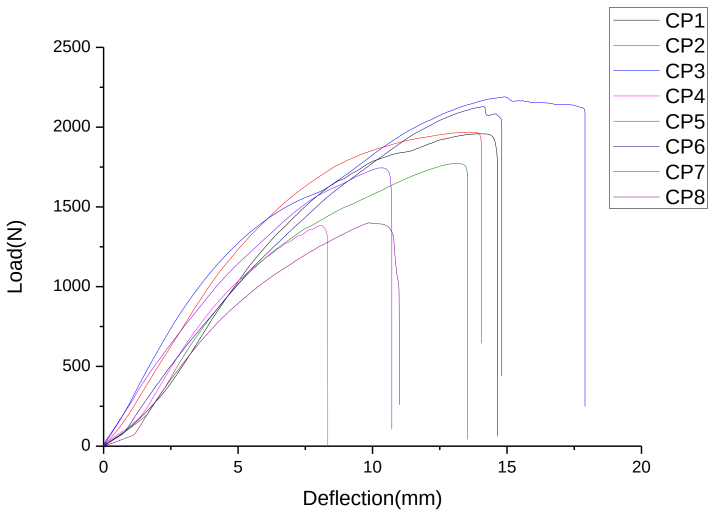

Figure 12. Curves of testing the bone-implant system with hollow rod

The bone-implant system does not reach the level of mechanical resistance of real bone, but may be observed a synergy using the rods and the locking system used, by means of screws, because the bone-implant system resisted to higher loading levels than the rods. This observation, together with the possibility of enhanced polyamide, indicates that the continuation of this study are promising to be used , in future, reinforced polyamide 12 rods obtained through the same manufacturing process and implemented in the same way.

It was not possible to calculate the value of the modulus of elasticity and neither the value of the rupture tension in bending for the bone-implant system. Its occur by the complex geometry of the structure, which can be seen in Fig. 13, it was difficult to determine and apply a mathematical model that adequately represents physical situation of loads, geometry, boundary conditions and material behavior.

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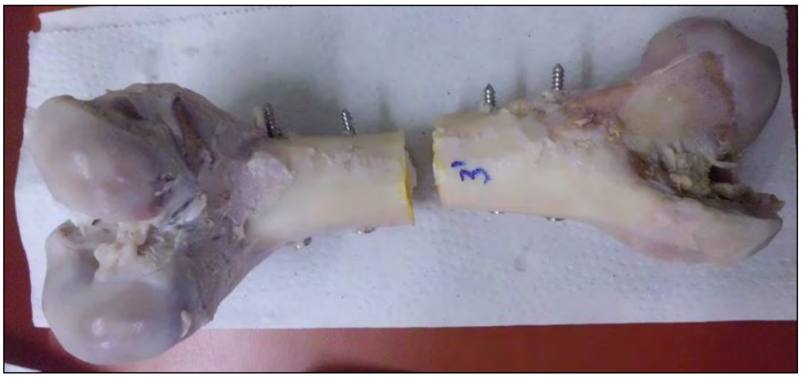

Figure 13. Photographic image of the fractured bone - implant system.

Therefore, approximate methods must be used for applying the principles of elasticity theory in an accessible and accurate. The method used for this have been based on the division of the system into simpler parts making the discretization of the problem. Due to their wide application in various types of problems from various sources, the Finite Element Method (FEM) is the most widely used today, and it will be used in the next steps of this research.

4. CONCLUSION

Polyamide rods have proved to be extremely feasible regarding the deployment after milling as well as during the lock bolt, providing easy drilling and screwing the screws, which makes promising its implantation in living animals after further study with the incorporation of materials that provide greater resistance to rod-bone system.

From the tests it is verified that the major mechanical property that the needs to be improved is the modulus of elasticity. This property can be improved by using reinforcements of fiberglass, carbon and also the use of other polyamide, processed differently.

The bone-implant system resisted to loadings levels higher than the rods and coupled with the possibility of reinforcing polyamide indicates that the study is promising.

As proposal for future work, the use of Finite Element analysis to determine the adequate mechanical properties of the bone-implant system and the loadings involved in the whole system.

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