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Femoral Orthopedic Implants in Dogs with Titanium - Mechanical Evaluation

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ABSTRACT

***Background*:** Orthopedic implants are commonly used for different types of surgical procedures to gain optimal function and to provide stability to both bones and tendon structures. When inserting these implants, the characteristics of the material are important for surgical success, and the ideal implant must be biocompatible and nonallergenic. However, when molding an implant to the bone structure, its resistance can change significantly. Implants can be temporary or permanent in the body, and metal possesses properties that make it acceptable for bone repair. In biomedical implants, 2 types are most common, commercially pure (CP)-Ti and Ti-6A1-4V. They both provide stable fixation and low risk of loosening. Implants made with the same material and composition can perform differently if the material has been altered by processing techniques for different scenarios. Stress, strain and elastic modulus are the primary metrics used in the description of implant materials. They can be calculated based on mechanical tests of specimens with defined geometry, most commonly tensile, bending and torsional tests. In order to better evaluate those changes, we compared the mechanical characteristics of titanium bone plates, before and after they were molded to the bone, to verify and quantify the loss of stiffness and resistance after molding the plate.

***Materials, Methods & Results*:** The study was prospective. Orthopedic implant made of commercially pure titanium (CP-Ti) were divided into 2 groups, one group without plate molding and the other with plate molding to a dog femora bone. Thirty-six plates of different sizes (5.0, 6.5, 8.0, 9.0, 10.0- and 11.0-mm diameter) were divided into 6 groups containing 6 plates of each size and submitted to the 4-point flexion test of resistance, using a piece of dog femur (weights of 5, 10, 15, 20 and 25 kg) as the bone in which the molding was performed. The evaluations were tabulated and analyzed using the program GraphPad Prism version 5.0. Corrections of the normal distribution curve were made using the Bartlett test. After the corrections, one-way analysis of variance (ANOVA) was performed with $P < 0.05$. Assessments were made within the group and between groups. Subsequently, the Newman-Keuls test was performed, adopting $P < 0.05$. For analyses in 2 groups, Student's t-test was performed as a post-test, also with $P < 0.05$. When the plates were compared between equal sizes of groups 1 and 2, the non-molded plate group (G1) obtained the best results in the flexural stiffness and structural flexion tests. However, in the flexural resistance test, most plates obtained similar results and the plates with diameters of 8 mm, 9 mm and 10 mm of the molded plate group (G2) obtained the best results.

***Discussion*:** Our results show that the implants had adequate mechanical characteristics, but the unmolded plates had greater flexural and structural stiffness than the molded plates. This difference was significant, thus demonstrating a large loss of stiffness in relation to the original conformation. However, when we tested the flexural resistance, no significant differences were observed, and although without significant statistical changes, there was an increase in the resistance of the plate with the new conformation obtained by molding. In the results of the mechanical tests, we observed that after the molding, the implants gained greater resistance, although the difference was not statistically significant. This suggests that the architecture of the implants should have slight curvature in the medial direction of the bone, since this would lead to a better adaptation to the anatomy of the bone, and possibly greater resistance, as indicated by the new configuration after molding.

Keywords: bone implants, titanium, orthopedic implants, femur, dogs.

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INTRODUCTION

Orthopedic implants are commonly used for different types of surgical procedures to gain optimal function and to provide stability to both born and tendon structures [3,7]. When inserting these implants, the characteristics of the material are important for surgical success, and the ideal implant must be biocompatible, nontoxic, noncarcinogenic, nonpyrogenic and nonallergenic [1,6]. However, when molding an implant to the bone structure, its resistance can change significantly. Titanium (Ti) and its alloys are often used as biomaterials in orthopedics due to its superior properties of mechanical strength, toughness, corrosion resistance and biocompatibility [1,2,4]. Implants can be temporary or permanent in the body, and metal possesses properties that make it acceptable for bone repair. In biomedical implants, 2 types are most common, commercially pure (CP)-Ti and Ti-6A1-4V. They both provide stable fixation and low risk of loosening [6].

Implants made with the same material and composition can perform differently if the material has been altered by processing techniques for different scenarios [8]. Stress, strain and elastic modulus are the primary metrics used in the description of implant materials. They can be calculated based on mechanical tests of specimens with defined geometry, most commonly tensile, bending and torsional tests [8]. The structural properties of implants have more clinical relevance because it is possible to compare actual implants or simulations of fracture repair scenarios. Under normal conditions, the bone carries the body load by itself, but when and implant is inserted into the bone, the load will be shared by the bone and the implant.

MATERIALS AND METHODS

Orthopedic plates

The orthopedic plates were made of commercially pure titanium (CP-Ti)[1]. The implants were divided into 2 groups (one group without plate molding and the other with plate molding to dog femur bone. There were 36 plates between the groups, with different diameters (5.0, 6.5, 8.0, 9.0, 10.0 and 11.0 mm), containing 6 plates of each size. They were tested for resistance with the 4-point flexion test according to ASTM F 382-17. The dog femurs had different weights (5, 10, 15, 20 and 25 kg) [Figure 1]. The orthopedic plates were used according to the weight and load indicated by the manufacturer and were shaped to the bone material according to the weight.

Figure 1. Titanium orthopedic plates (8.0 mm), the first (from top to bottom) in group 1 without molding, and the second in group 2 with molding to the dog femur bone.

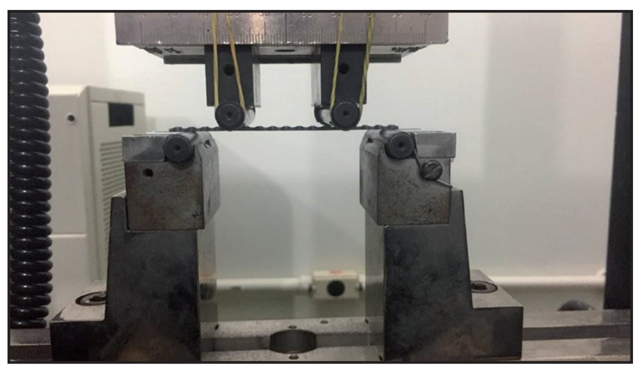

Figure 2. The flexion testing machine.

Static flexion test

The static flexion test was performed at 4 points. To determine the loads in the static tests, we tested 72 assemblies until the material fall, roll or break. An EMIC model 5582 universal testing machine was used, with a maximum load capacity of 10,000 N, speed of 1 mm / min, together with the EMESC TESC software. All tests were performed at room temperature (average of 21ºC). The tests were completed at the moment when touching between the specimens, failure or rupture of the plate, or slipping on the support table occurred. The flexion testing machine has 2 actuator rollers or loads attached to the movable beam on the machine and positioned so that holes in the plate are located between the rollers. Two other support rollers were attached to the machine base and positioned symmetrically at 2 holes in the plate in relation to the actuator rollers. The distance between the actuator rollers or central gap was 40 mm and the distance between the support rollers was 80 mm for the plate sizes of 5.0 and 6.5 mm in each group, and the plate sizes were 8.0, 9.0, 10.0 and 11.0 - 65 mm. The actuator rollers had a central span of 50 mm and the support rollers had a span of 90 mm. The diameter of all rollers was 10 mm (Figure 2). The positioning of the plate in relation to the support rollers was carried out in such a way that the holes in the plate between the rollers and the actuator were in contact with the surface of the plate that was in contact with the bone. The plate was centered on the support rollers using a predefined mark to ensure repeatability of the positioning of the plates during the experiment. After positioning the plate in the device, the forces were applied with increasing magnitude. The results were recorded in the form of a diagram of force versus displacement of the load application point. The test was interrupted after the peak of the graph, where a decrease in magnitude was possible to observe.

Statistical analysis

The evaluations were tabulated and analyzed using the program GraphPad Prism version 5.0. Corrections of the normal distribution curve were made using the Bartlett test. After the corrections, one-way analysis of variance (ANOVA) was performed with $P < 0.05$. Assessments were made within the group and between groups. Subsequently, the Newman-Keuls test was performed, adopting $P < 0.05$. For analysis in 2 groups, Student's *t*-test was performed as a post-test, also with $P < 0.05$.

RESULTS

When the plates were compared between the groups in the 3 tests, the 5 mm and 11 mm plates showed lower and higher flexural rigidity (Figure 3), structural rigidity (Figure 4) and flexural resistance (Figure 5), respectively.

When the plates were compared between equal sizes of groups 1 and 2, the non-molded plates (G1) obtained the best results in the flexural stiffness and structural flexion tests. However, in the flexural resistance test, most plates obtained similar results (Figures 6,7 & 11) and the 8 mm (Figure 8), 9 mm (Figure 9) and 10 mm (Figure10) molded plates (G2) obtained the best results.

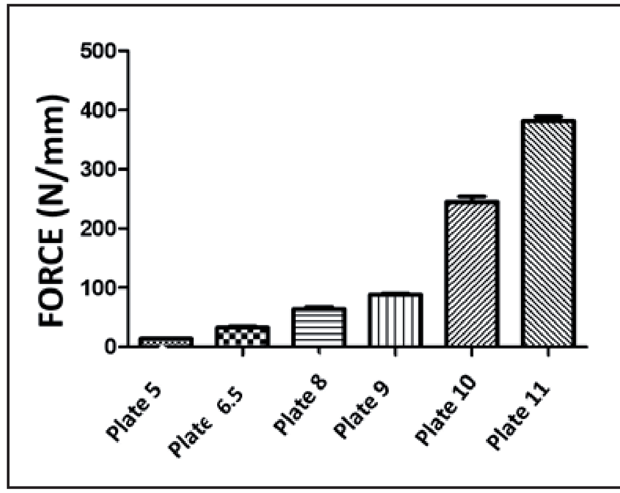

Figure 3. Comparison of all plates according to flexural stiffness. In group 1 of unmolded plates, the 5 mm plate presented the lowest resistance and the 11 mm plate presented the highest resistance. In group 2, when comparing different plate sizes, 5 mm and 11 mm plates also had the lowest and highest resistance, respectively.

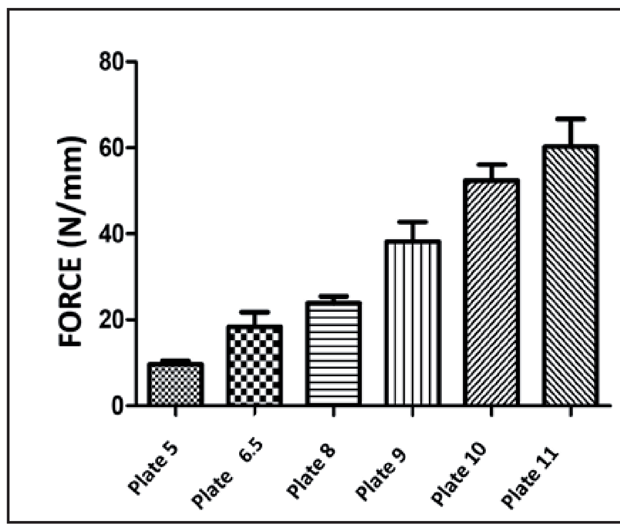

Figure 4. Comparison of all plates in each group. The 5 mm and 11 mm plates had the lowest and highest resistance, respectively.

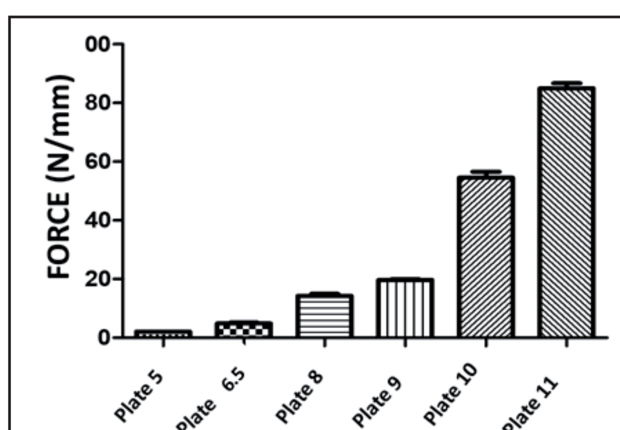

Figure 5. Comparison between groups. In both groups, the 5 mm and 11 mm plates had the lowest and highest resistance.

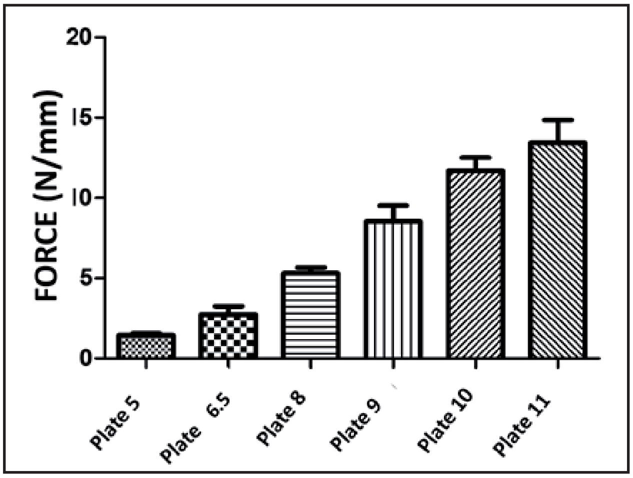

Figure 6. Comparison between groups G1 and G2, where the 5 mm plates differed significantly ($P < 0.0005$) for flexural and structural stiffness. However, there was no statistically significant difference for flexural resistance, since the unmolded plates presented better results than the molded plates.

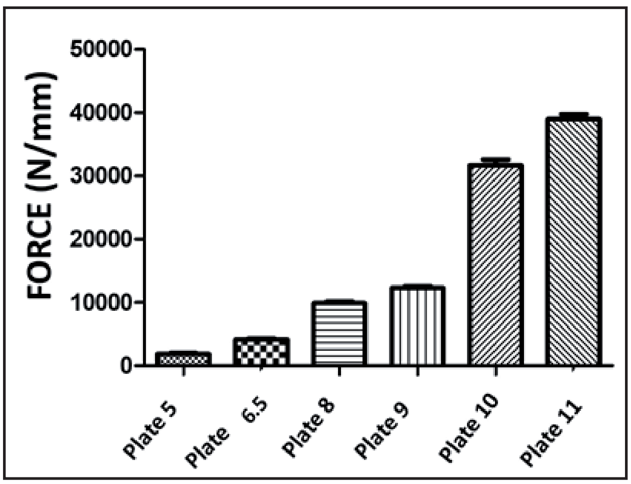

Figure 7. Comparison between groups G1 and G2, where the 6.5 mm plates differed significantly for flexural stiffness ($P < 0.0038$) and structural stiffness ($P < 0.0031$). However, there was no statistically significant difference for flexural resistance. These results indicate that the non-molded plates had the best results, except for the flexural resistance test, in which close results were obtained.

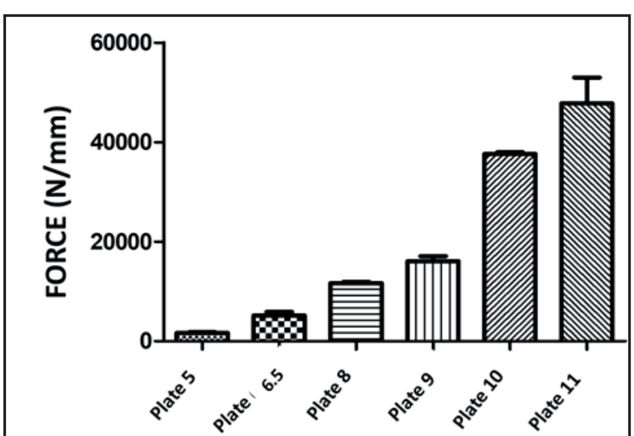

Figure 8. Comparison between groups G1 and G2, where the 8 mm plates differed significantly for flexural stiffness ($P < 0.0001$), structural stiffness ($P < 0.0001$) and flexural resistance ($P < 0.001$). These results show that the non-molded plates presented better results than the molded plates, except for the flexural resistance test, in which group G2 obtained better results.

DISCUSSION

The tests followed the standard of the International Association of Test Materials (ASTM), so they were in accordance with acceptable standards [9]. Mechanical tests are typically applied to implant materials, especially in the pre-clinical phase, so we selected the resistance and stiffness tests for this purpose [11].

Confirming our hypothesis, the unmolded plates had greater flexural and structural stiffness than the molded plates. This difference was significant, thus demonstrating a large loss of stiffness in relation to the original conformation. Stiffness is the slope of the load versus deformation curve and is reported in (N / mm) [9], so the statistical difference after molding can be explained by the change in the architecture of the plate, which produces deformation in its original structure, reducing its stiffness.

However, when we tested the flexural resistance, no significant differences were observed, and although without significant statistical changes, there was an increase in the resistance of the plate with the new conformation obtained by molding [5]. Another important observation, in contrast to the literature, we noticed that this plate had higher resistance and a lower stiffness than the compression plate and the polyaxial locking plate [5,7].

We believe that the molding of implants to the bone so they can have an adequate contact surface can change the resistance characteristics of these implants, since this changes their architecture, so their application may meet the needs of fracture correction. In the results of the mechanical tests, we observed that after the molding, the implants gained greater resistance, although the difference was not statistically significant. This demonstrated that the molding did not lead to loss of initial resistance with tests performed in the *ex-vivo* femur model. This result leads us to suggest that the architecture of the implants should have slight curvature in the medial direction of the bone, since this would lead to a better adaptation to the anatomy of the bone, and possibly greater resistance, as indicated by the new configuration after molding.

Since the stiffness is a measure of how much force a sample can withstand before deforming permanently, assessed through the relationship between applied stress and elastic deformation, and the tests we performed showed that molding leads to a statistically significant loss of the implant, we suggest that a new configuration of the implant, in addition to causing a gain in resistance of the implant, would avoid the significant loss of stiffness due to changed architecture [11].

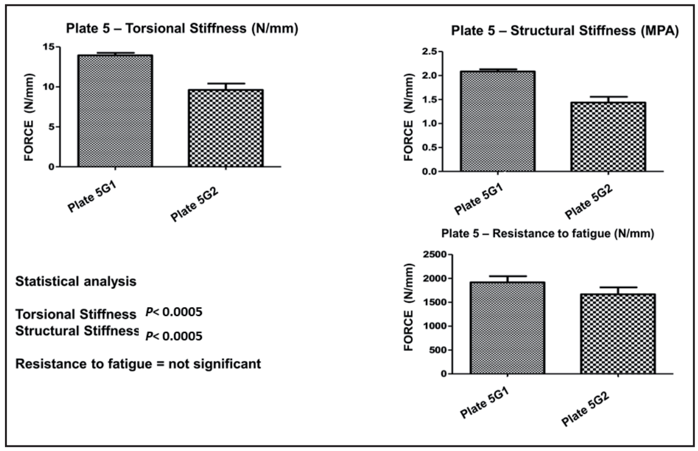

Figure 9. Comparison between groups G1 and G2, where the 9 mm plates differed significantly for flexural stiffness ($P < 0.0001$), structural stiffness ($P < 0.0001$) and flexural resistance ($P < 0.005$). These results show that the non-molded plates presented better results than the molded plates, except for the flexural resistance test, in which group G2 obtained better results.

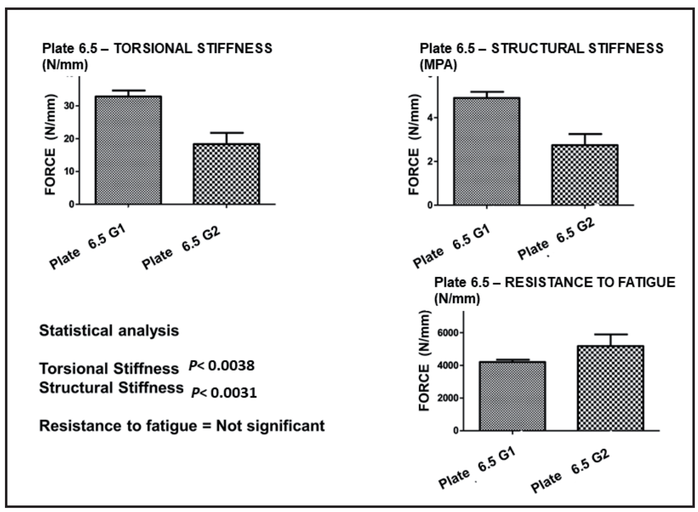

Figure 10. Comparison between groups G1 and G2, where the 10 mm plates differed significantly for flexural stiffness $P < 0.0001$), structural stiffness ($P < 0.0001$) and flexural resistance ($P < 0.0001$). These results show that the non-molded plates presented better results than the molded plates, except for the flexural resistance test, in which group G2 obtained better results.

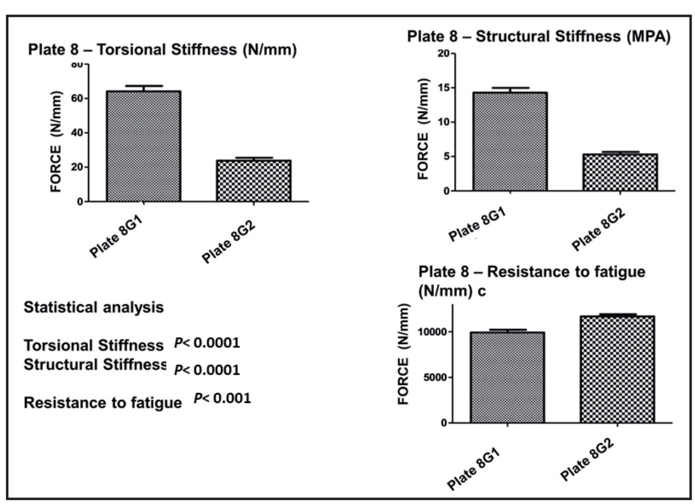

Figure 11. Comparison between groups G1 and G2, where the 11 mm plates differed significantly for flexural stiffness ($P < 0.0001$) and structural stiffness ($P < 0.0001$). However, there was no statistical difference for structural strength. These results show that the non-molded plates presented better results than the molded plates, except for the flexural resistance test, in which the two groups presented similar results.

CONCLUSION

The tested implants had adequate mechanical characteristics, but they lost rigidity due to molding to the bone despite gaining resistance.

MANUFACTURER

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***Declaration of interest*.** The authors report no conflicts of interest. The authors alone are responsible for the content and writing of paper.

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