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Mechanical evaluation of brazilian locking bone plates for veterinary use

Avaliação mecânica de placas ósseas bloqueadas brasileiras para uso veterinário

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Highlights

Stainless steel plates are stiff then titanium plates.
Stainless steel plates support highest load of bending forces then titanium plates.

Abstract

Several surgical implants have been developed to stabilize fractures in humans and animals. Osteosynthesis with Locking Compression Plate (LCP) is a widely used fixation method for the treatment of fractures, angular deviations, arthrodesis, among other surgical techniques. This implant, combined with bone screws, stands out as one of the most used by veterinary orthopedists in Brazil and worldwide. Thus, the present study aims to compare the static and dynamic compressive strength of F138 stainless steel and F67 titanium LCPs from different manufacturers. Four models of Brazilian-made veterinary LCPs were mechanically tested, divided into four groups (G) with fourteen items each, where G1 and G2 consisted of F138 stainless steel LCPs and G3 and G4 of F67 titanium LCPs. Tests were conducted according to the method described in ABNT NBR 15676-2 for static testing and ABNT NBR 15676-3 for dynamic testing. Statistical analysis detected differences in the static compression test. G2 showed better stiffness and strength than G1, whose stiffness and strength were, in turn, greater than G3 and G4. By contrast, no differences were observed between G3 and G4. Differences were detected for dynamic compression testing, obtaining the same results as static testing, that is, G2 exhibited higher maximum moment and cyclic strength than G1, which showed a higher maximum moment and cyclic strength than G3 and G4. Similarly, there was no difference between G3 and G4. Thus, it was concluded that F138 stainless steel compression plates displayed greater static and cyclic strength when compared to F67 titanium plates. Additionally, there were significant differences in the static and cyclic strength tests of the G1 and G2 compression plates, which have similar raw material composition (F138 stainless steel),

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albeit with statistically different results.
Key words: Orthopedics. Osteosynthesis. Implants. Biomechanics.

Resumo

Vários implantes cirúrgicos têm sido desenvolvidos para estabilizar fraturas em seres humanos e animais. A osteossíntese com Placa Bloqueada de Compressão (PBC) é um método de fixação amplamente utilizado para o tratamento de fraturas, desvios angulares, artrodeses entre outras técnicas cirúrgicas. Este implante destaca-se em conjunto com os parafusos ósseos, como um dos mais utilizados na rotina dos ortopedistas veterinários do Brasil e do mundo. Desta forma, o presente estudo tem por objetivo comparar a resistência à compressão estática e dinâmica de PBC de aço inox F138 e titânio F67, de fabricantes diferentes. Foram testados quatro modelos de PBC veterinárias de fabricação brasileira para os ensaios mecânicos, divididos em quatro grupos (G) com quatorze itens cada, sendo o G1 e G2 compostos de PBC de aço inox F138 e o G3 e G4 compostos de PBC de titânio F67. Os testes foram realizados segundo o método descrito nas normas da ABNT NBR 15676-2 para o ensaio estático e ABNT NBR 15676-3 para o ensaio dinâmico. Pela análise estatística, foram detectadas diferenças no ensaio de compressão estática. O G2 demonstrou rigidez e resistência superiores ao G1, que por sua vez, demonstrou rigidez e resistência superiores ao G3 e G4. Em contrapartida, não foram observadas diferenças entre o G3 e G4. Em relação ao ensaio de compressão dinâmica, foram detectadas diferenças seguindo os mesmos resultados do ensaio estático, ou seja, o G2 demonstrou um momento máximo e resistência cíclica superiores ao G1, o qual apresentou momento máximo e resistência cíclica superiores ao G3 e G4. Da mesma forma, não houve diferença entre o G3 e G4. Assim, concluiu-se que as placas bloqueadas de compressão de aço inox F138, apresentaram maior resistência estática e cíclica ao comparado às placas de titânio F67. Além disso, pode-se destacar as diferenças significativas obtidas nos ensaios de resistência estática e cíclica das placas bloqueadas de compressão do G1 e G2, que possuem matéria prima de composição semelhante (aço inox F138), mas que divergiram estatisticamente nos resultados.
Palavras-chave: Ortopedia. Osteossíntese. Implantes. Biomecânica.

Introduction

Veterinary orthopedics aims to provide functional therapy to restore the locomotor function of patients through less invasive surgical approaches with lower morbidity. Orthopedic conditions in small animals are among the most common in the veterinary medical routine in Brazilian veterinary hospitals, resulting in a demand for veterinary orthopedic implants (Cruz-Pinto et al., 2015).

Fractures represent a significant portion of cases in veterinary orthopedics and pose challenges due to the high anatomical bone diversity of the species treated, along with difficulties in maintaining postoperative rest, bandaging, and immobilization, among other particularities that can compromise the outcome of the surgical procedure (Piermattei et al., 2015; Tobias & Johnston, 2017).

Fracture treatment can be surgical or non-surgical (Piermattei et al., 2015). Surgical approaches include methods such as external fixators, intramedullary pins, locked intramedullary nails, cerclage wires, compression plates, and locking plates. Surgical intervention should be performed with an in-depth analysis of the patient's conditions and fracture characteristics, such as location (Fossum et al., 2019).

Mechanical tests allow the assessment of bone fixation efficiency and the ability to resist forces acting at the injury site. To that end, specific equipment and computer systems with data decoding programs are used. Although these tests assess forces individually, they act jointly on the skeleton (Mesquita et al., 2017).

Mechanical analysis methods are used to assess orthopedic implants, with the most common tests being failure and fatigue strength tests. The former applies direct and progressive force until the implant fails (breakage, loosening, destruction of the test specimen). The latter applies cyclic loads with increasing and decreasing force, mimicking the natural functioning of the locomotor system and representing the most common types of in vivo loading (Hammel et al., 2006; Kanchanomai et al., 2008).

Bending properties are critical characteristics of bone plates for orthopedic applications, since these plates are the primary means of bone fragment stabilization. Additionally, the bending stiffness of the bone plate can directly affect bone healing time and capacity (Agência Brasileira de Normas Técnicas [ABNT], 2017a). Reference parameter values (bending stiffness, structural bending stiffness, and bending strength) provide information to the user about bone plate strength and stiffness (ABNT, 2017b).

The dynamic testing method aims at assessing the properties of the material used in the manufacture of the medical device. The fatigue properties of bone plates are important factors in the surgical treatment of skeletal fractures. The bone plate may be submitted to significant numbers of repeated stress cycles during the osteointegration process (ABNT, 2017c).

Among the mechanical properties assessed during static and dynamic bending tests are: a) bending stiffness, expressed in newtons per millimeter (N/mm^2), which is the determining variable of the maximum slope of the linear elastic portion of the load-displacement curve for the tested implant; b) maximum bending load values, expressed in N/mm^2, which represent the load applied at the moment of implant failure or fracture; c) 0.2% yield strength, expressed in N/mm^2, which indicates the force applied at the transition from elastic (temporary) to plastic (permanent) deformation; d) bending strength, expressed in N/m^2, which identifies the bending moment applied to the bone plate to produce a specific amount of permanent deformation; and e) structural bending stiffness, expressed in N, which indicates the stiffness of the bone plate, regardless of the test configuration (NBR 15676).

The field of biomechanics is extensive and involves numerous analytical variables, with important aspects to consider, such as material composition and properties, geometry, and acting force (Dalmolin et al., 2013). Thus, the increasing research on innovation in orthopedic implants has promoted the development and improvement of techniques and materials, ensuring working conditions for veterinary orthopedic surgeons and better patient recovery (Cordey, 2000).

Knowledge of the different aspects of available locking plates in the Brazilian veterinary market can provide specialists with analytical comparisons in selecting the most suitable plate for the patient (Hak et al., 2018).

This study is justified by the lack of research on the mechanical assessment of compression locking plates for use in veterinary orthopedics. Thus, with the aim of evaluating the aspects of static and dynamic bending strength by comparing bending stiffness, maximum bending load, yield strength, bending strength, structural bending stiffness, and maximum moment of four Brazilian-made LCP models on the veterinary market, mechanical assessment tests were conducted based on ABNT NBR 15676-2 and ABNT NBR 15676-3 for static and dynamic testing, respectively.

Materials and Methods

The mechanical tests were divided into static and dynamic bending, which were subdivided into four points. In total, 56 blocked compression plates were used, from four different models and both from the 2.0 mm system, containing 10 holes along the plate's length. For evaluation, the plates were arranged into four groups, named G1, G2, G3, and G4, with 14 plates in each group according to the manufacturing model.

G1 consisted of F138 stainless steel plates measuring 79 mm long, 5.5 mm wide, and 2.3 mm thick, with one locked hole and nine combined holes (locked and dynamic compression), G2 of 92 mm long, 7.4 mm wide, and 2.8 mm thick F138 stainless steel plates, with 10 combined holes, G3 of 76 mm long, 5.4 mm wide, and 2.0 mm thick F67 titanium plates, with eight locked holes and two combined holes, and G4 of 83 mm long, 5.9 wide, and 2.0 mm thick F67 titanium plates, with eight locked holes and two combined holes (Figure 1).

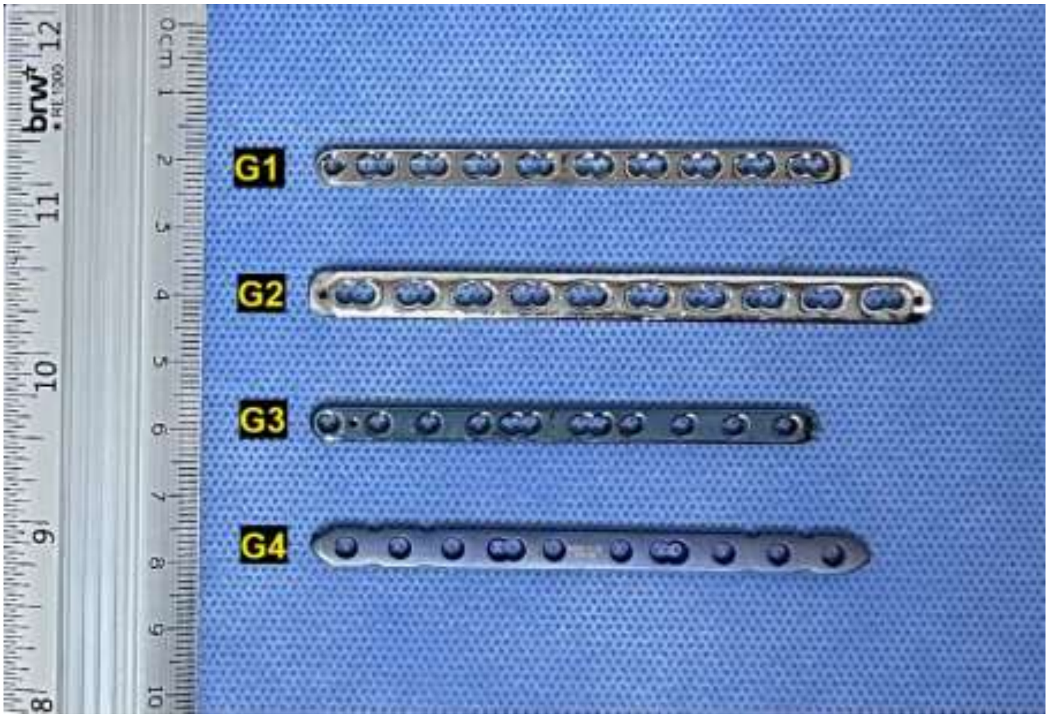

Figure 1. Locking compression plates in F138 stainless steel (G1 and G2) and F67 titanium (G3 and G4), respectively.

During the initial evaluation, the plates were inspected for material composition (metal alloy), and the nominal dimensions were measured (Table 1), according to bone plate dimension designation (Figure 2).

Table 1
Metal alloy composition of the implants and their nominal dimensions

Description	G1	G2	G3	G4
Metal Alloy	F138 Stainless steel	F138 Stainless steel	F67 Titanium	F67 Titanium
Length (mm)	79	92	76	83
Width (mm)	5.5	7.4	5.4	5.9
Thickness (mm)	2.3	2.8	2.0	2.0

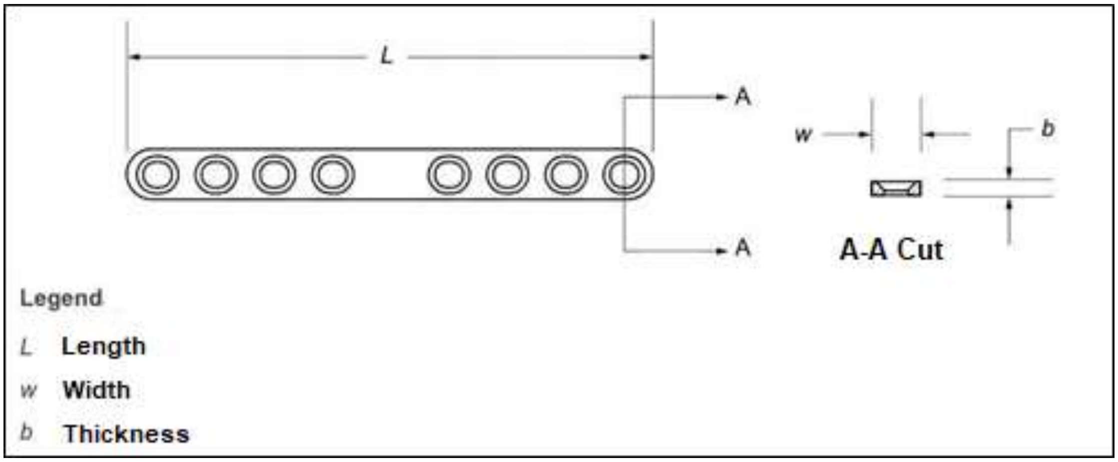

Figure 2. Designation of bone plate dimensions used in this study.

The tests were conducted at the Implants Testing Laboratory (LIM) of SENAI - Rio Claro - SP, and the mechanical tests were performed on an Instron® E3000 electrodynamic testing machine, equipped with a 5000N load cell.

Static bending test

The tests were based on ABNT NBR 15676-2, entitled "Orthopedic implants - Metallic bone plates," which describes four-point static bending tests. The tests were conducted at five mm/min on an Instron® E3000 electrodynamic testing machine equipped with a 5000N load cell.

The test device consisted of two actuator or loading rollers attached to the movable crosshead of the testing machine, positioned so that two holes of the plate were located between the rollers. Two support rollers were attached to the base of the machine and positioned symmetrically at a distance of two holes from the plate in relation to the actuator rollers (Figure 3).

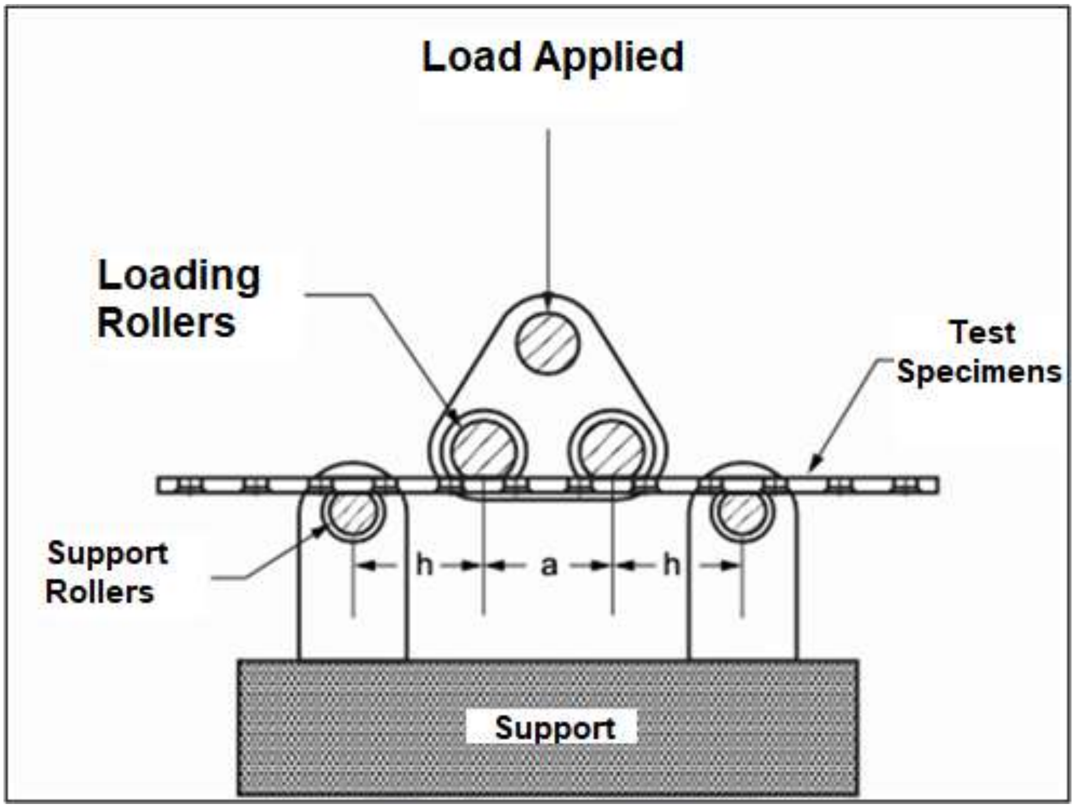

Figure 3. Schematic drawing of the front view of the bending device of the plate to be tested, where "h" represents the loading span and "a" the central span.

Dynamic bending test

The tests were based on ABNT NBR 15676-3, entitled "Orthopedic implants - Metallic bone plates," which also describes 4-point dynamic bending tests.

Each test item was submitted to cyclic sinusoidal bending loading with a loading ratio of R = 0.1, at a frequency of five Hertz (Hz), on an Instron® E3000 electrodynamic testing machine equipped with a 5000N load cell. The applied load "F" (reference value obtained in the static test representing force at 0.2% yield strength) acted perpendicular to the plate. The assembly configurations used the same dimensions as the static test.

The tests were suspended after 1,000,000 cycles if the assemblies did not fail. They were conducted in a dry environment at an ambient temperature of 22°C.

All tests were performed by a company certified by ANVISA for testing in line with ABNT 15676-1; 15676-2, and 15676-3, entitled "Orthopedic implants - Metallic bone plates," using certified equipment, with valid calibration certificates, and operated by qualified personnel.

The tests were conducted according to the standard determined by ANVISA for the regulation of orthopedic implants for human use, in order to obtain reliable results for discussion and analysis with as little bias as possible, which could occur due to the use of autologous tissues varying between individuals, as well as the handling and application of implants to test specimens.

In addition, triplicates were performed with an initial loading level of 75% of the average yield strength obtained in the static bending test. The loading level was increased by 10% in cases where the samples reached 1 x 10^6 cycles, and decreased by 10% in cases where plastic deformation or cracking occurred.

Finally, data on loading level (%), maximum moment (N.m), and maximum load (N) were obtained. The maximum moment (N.m) x cycles (N) curve was plotted for each of the tested groups.

Statistical analysis

The values of both static and dynamic tests were submitted to Tukey's multiple comparison t-test. Differences were considered statistically significant at p<0.0001.

Results and Discussion

With respect to the four-point static bending test, data were obtained for maximum bending load in N, 0.2% yield strength in N, bending strength in N/m, bending stiffness in N/mm, and structural bending stiffness in N/m². The force (N) versus deformation (mm) curve was plotted for each tested group.

The graphs are presented below for G1 (Figure 4), G2 (Figure 5), G3 (Figure 6), and G4 (Figure 7). Additionally, the mean and standard deviation of each group were calculated (Table 2).

The test table shows that G2 was significantly better than the other groups for the variables assessed, while G1 showed superior results when compared to G4 and G3, which exhibited no significant differences. Furthermore, the maximum bending load (N) demonstrated the highest statistical discrepancy, indicating greater resistance capacity of G2 to higher loads when compared to the other groups. Structural bending stiffness (N.m²) showed the lowest statistical difference, due to its direct relationship to the bone plate geometry and manufacturing material (Mariani, 2010).

The F138 stainless steel bone plates were significantly better than the F67 titanium plates in bending stiffness. This index is a major topic of analysis, given its high capacity to provide reliable stiffness values, since the test assesses the plate's stability when submitted to bending force, encompassing other test configuration influences (Mariani, 2010). Consistent with the bending stiffness results obtained, a study by Mugnai et al. (2018) compared human bone plates for distal radius fractures, finding that stainless steel-based plates had higher bending stiffness indices when compared to titanium-based plates.

With respect to the other parameters analyzed, no similar studies were found in the literature for valid analysis. However, it is understood that material characteristics, primarily the metal alloy and plate thickness, may be related to the results obtained.

In relation to the dynamic bending test, the graphs are presented below for G1 (Figure 8), G2 (Figure 9), G3 (Figure 10), and G4 (Figure 11). Additionally, the mean and standard deviation of each group were calculated (Table 3).

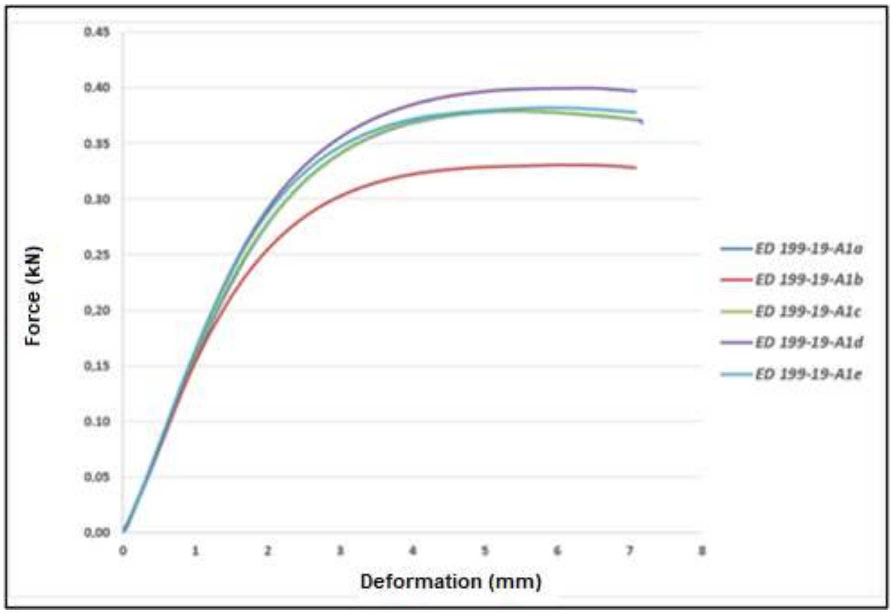

Figure 4. Graphical representation of the force-deformation curves obtained in the static axial compression test for the LCPs of G1, with the maximum bending load in N being obtained (a); 0.2% yield strength in N (b); bending strength in N/m (c); bending stiffness in N/mm (d), and structural bending stiffness in N/m² (e). The curves represent the progressive action of the force applied to the loading rollers and the consequent elastic and plastic deformation caused to the tested plates.

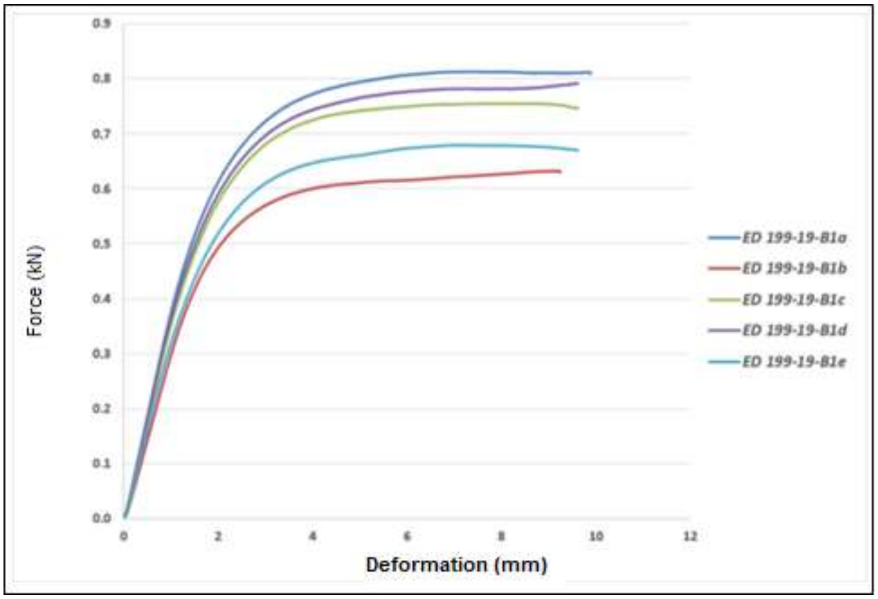

Figure 5. Force-deformation curves obtained in the static axial compression test for the LCPs of G2, with the maximum bending load in N being obtained (a); 0.2% yield strength in N (b); bending strength in N/m (c); bending stiffness in N/mm (d), and structural bending stiffness in N/m² (e). The curves represent the progressive action of the force applied to the loading rollers and the consequent elastic and plastic deformation caused to the tested plates.

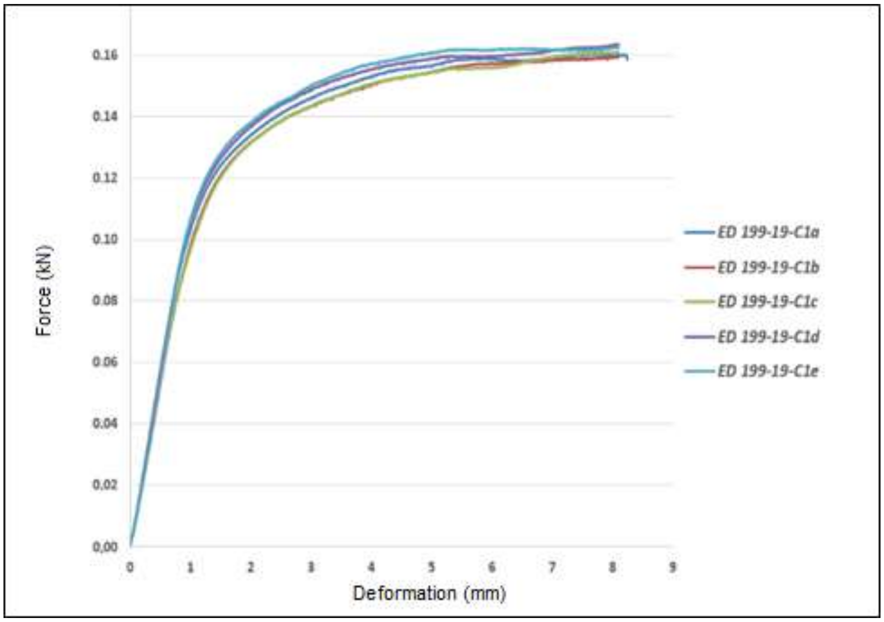

Figure 6. Force-deformation curves obtained in the static axial compression test for the LCPs of G3, with the maximum bending load in N being obtained (a); 0.2% yield strength in N (b); bending strength in N/m (c); bending stiffness in N/mm (d), and structural bending stiffness in N/m² (e). The curves represent the progressive action of the force applied to the loading rollers and the consequent elastic and plastic deformation caused to the tested plates.

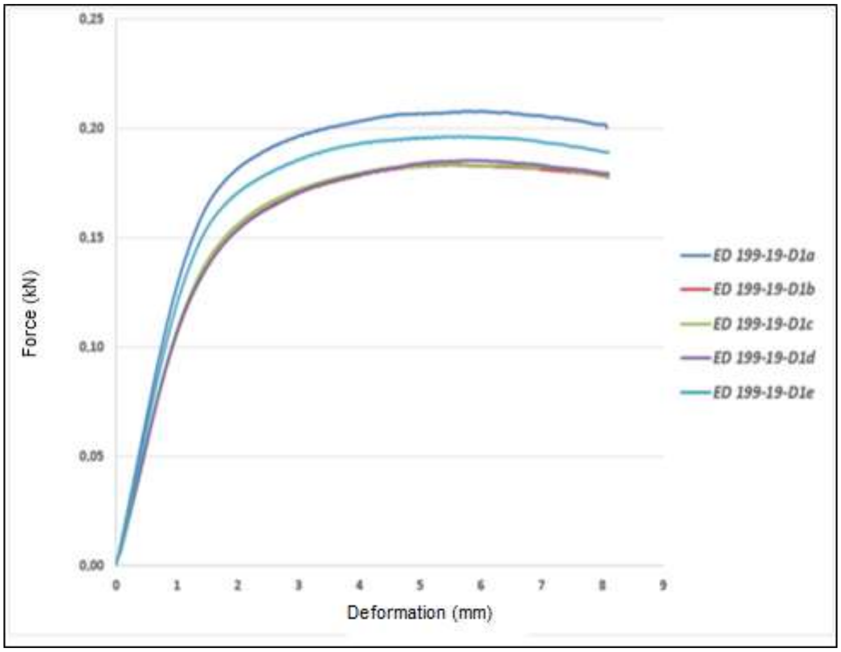

Figure 7. Force-deformation curves obtained in the static axial compression test for the LCPs of G4, with the maximum bending load in N being obtained (a); 0.2% yield strength in N (b); bending strength in N/m (c); bending stiffness in N/mm (d), and structural bending stiffness in N/m² (e). The curves represent the progressive action of the force applied to the loading rollers and the consequent elastic and plastic deformation caused to the tested plates.

Table 2
Mean and standard deviation (SD) of the variables obtained for the plates in the four-point static bending test. Different letters after each parameter indicate statistical difference

Variable	G1	G2	G3	G4
Bending Stiffness (N/mm)	164.2a±6.76	362.6b±33.72	112.7c±5.11	122.2c±11.46
Maximum Bending Load (N)	374.4a±25.74	734.2b±76.61	161.6c±1.82	191.2c±10.76
0.2% Yield strength (N)	198.2a±15.59	378.4b±31.85	94c±6.82	106c±4.85
Bending Strength (N.m)	1.57a±0.14	3.25b±0.28	0.63c±0.05	0.85c±0.04
Structural Bending Stiffness (N.m²)	0.28a±0.01	0.77b±0.07	0.14c±0.01	0.21d±0.02

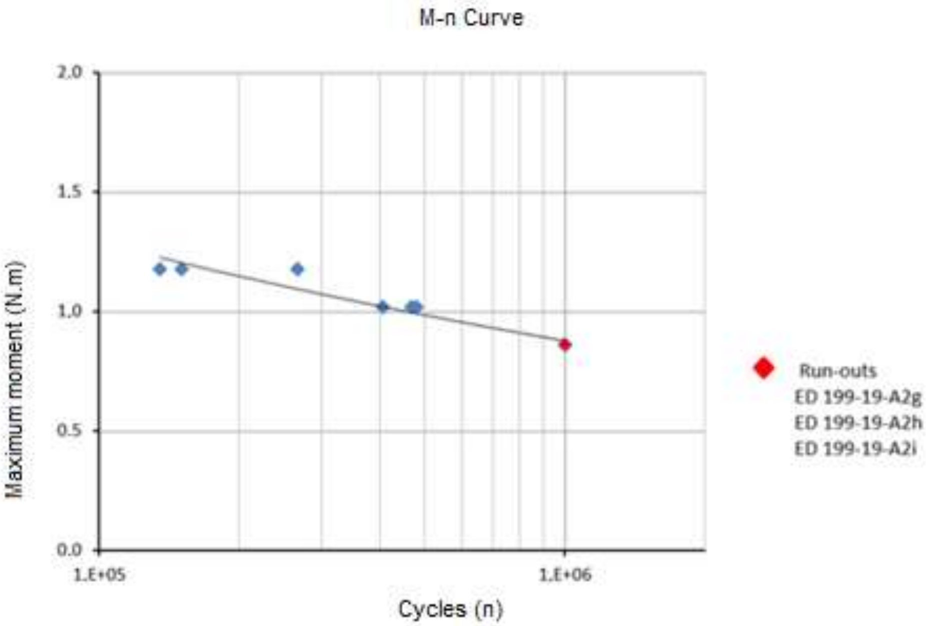

Figure 8. Graphical representation of the maximum moments (M) of load supported by the plates and the number of cycles (n) of resistive loads in the axial fatigue compression test for G1. The points shown in the figures represent the plate's resistance before mechanical failure, according to the number of cycles. The points described as run-outs represent plates that resisted more than one million cycles. 1,E + 05 = 100,000 cycles. 1,E + 06 = 1,000,000 cycles. The number of run-outs may vary according to the dynamic strength potential of each material assessed in the test.

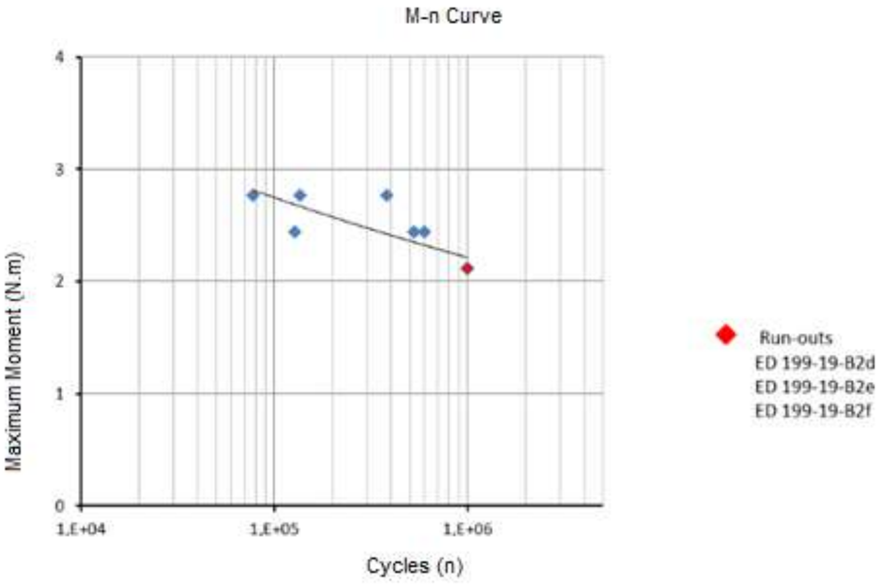

Figure 9. Graphical representation of the maximum moments (M) of load supported by the plates and the number of cycles (n) of resistive loads in the axial fatigue compression test for G2. The points shown in the figures represent the plate's resistance before mechanical failure, according to the number of cycles. Points described as run-outs represent plates that resisted more than one million cycles. 1,E + 04 = 10,000 cycles. 1,E + 05 = 100,000 cycles. 1,E + 06 = 1,000,000 cycles. The number of run-outs may vary according to the dynamic strength potential of each material assessed in the test.

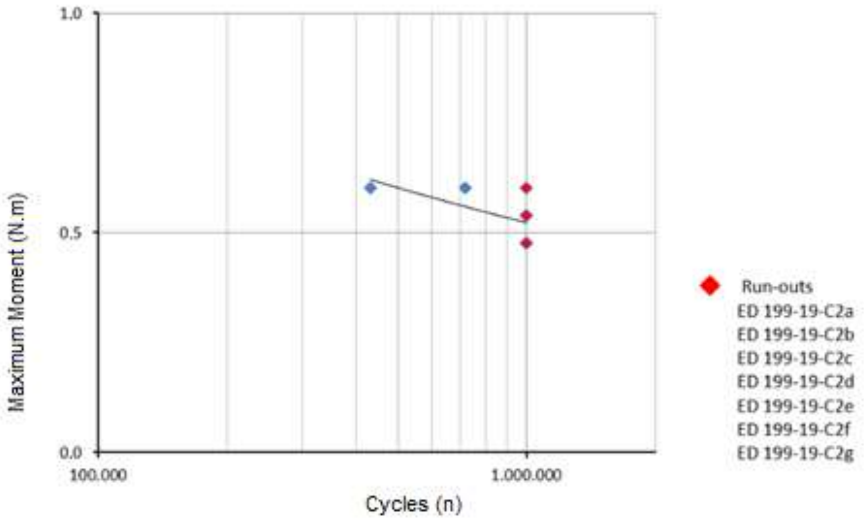

Figure 10. Graphical representation of the maximum moments (M) of load supported by the plates and the number of cycles (n) of resistive loads in the axial fatigue compression test for G3. The points shown in the figures represent the plate's resistance before mechanical failure, according to the number of cycles. Points described as run-outs represent plates that resisted more than one million cycles. The number of run-outs may vary according to the dynamic strength potential of each material evaluated in the test.

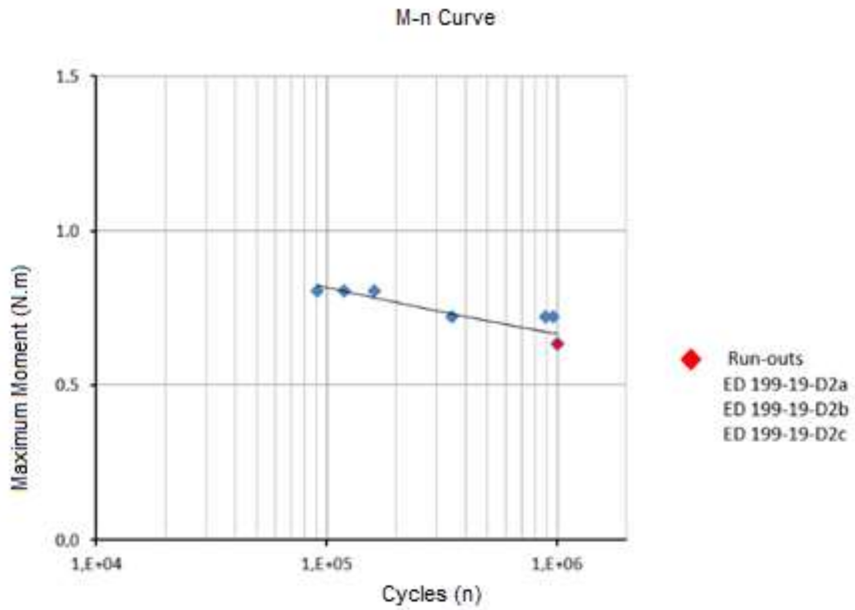

Figure 11. Graphical representation of the maximum moments (M) of load supported by the plates and the number of cycles (n) of resistive loads in the axial fatigue compression test for G4. The points shown in the figures represent the plate's resistance before mechanical failure, according to the number of cycles. Points described as run-outs represent plates that resisted more than one million cycles. 1,E + 04 = 10,000 cycles. 1,E + 05 = 100,000 cycles. 1,E + 06 = 1,000,000 cycles. The number of run-outs may vary according to the dynamic strength potential of each material evaluated in the test.

Table 3
Mean and standard deviation (SD) of the variables obtained for the plates in the four-point dynamic bending test. Different letters after each parameter indicate statistical difference

Variable	G1	G2	G3	G4
Maximum Moment (N.m)	1.02a±0.14	2.44b±0.28	0.54c±0.05	0.72c±0.07
Loading Level (%)	65a±8.66	75ab±8.66	85b±8.66	85b±8.66
Maximum Load (N)	61.1a±8.14	283.5b±32.74	89.9c±8.14	90.1c±9.18

During maximum moment analysis, significant intergroup differences were observed. G2 demonstrated superior stiffness and strength when compared to G1, which, in turn, showed superior stiffness and strength to G3 and G4, which did not differ.

The test loading level, expressed as a percentage, is predefined by ABNT NBR 15676-3 to start at 75% of the maximum bending load (obtained during the static bending test) and adjusted after the test in three samples, increased by more than

10% if there was no implant failure, crack, or breakage after 1,000,000 cycles, and decreased by 10% if failure, crack, or breakage occurred after 1,000,000 cycles. During analysis of this variable, differences in plate loading levels were observed. However, these differences are not significant in practice, given this is only a calibration and machine adjustment measure to obtain maximum moment values.

The maximum load expressed in N during the dynamic test is predetermined by multiplying the maximum bending load obtained during the static bending test by the loading level. Significant intergroup differences were found in the maximum bending load test, given that the variables are directly proportional.

Moreover, the results obtained corroborate those of Barber et al. (2021) in indicating that stainless steel possesses biomechanical attributes greater than or equal to titanium alloy implants. However, Marshall et al. (2015) found no differences in biomechanical analysis during failure and stiffness between titanium and stainless steel plates in fixed-angle compression models.

Similar results, with stainless steel superior to titanium, were also reported by Souer et al. (2010), corroborating the present study. The authors compared the fixation of extraarticular fractures in the radius, using titanium volar plates (2.4 mm) and stainless steel volar plates (3.5 mm), finding better movement efficiency in the group stabilized with the latter.

It is important to note that one limitation of this study was analyzing the stiffness and strength properties of locking compression plates in isolated conditions, typical of ex vivo mechanical implant tests without test specimens. Additionally, it is important to underscore that the protocol used may not accurately reflect the clinical conditions of implant use, since only two tests were conducted and did not include tests for resistance to axial compression, torsion, pull-out, and combined tests. Finally, the results should be interpreted with caution given that there is no concrete guideline for mechanical tests in Brazilian veterinary medicine.

Conclusions

This study assessed the static and cyclic strength variables of Brazilian-made locking compression plates for veterinary use, based on standards determined for the manufacture of human use implants. Based on the results obtained, it was concluded that the G2 plates composed of F138 stainless steel demonstrated the highest stiffness, strength, and maximum moment values when compared to the G1 (F138 stainless steel), G4 (F67 titanium), and G3 (F 67 titanium) plates, respectively.

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