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# Mechanical resistance comparison between interlocking micro-nail and tension band for fractures subject to muscular flexion forces

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**ABSTRACT**: The ulna, humerus, femur, tibia, and calcaneus fractures repair, which are under constant tension due to exerted forces by the muscle groups adhered thereto, play a key role in the clinical-surgical routine, both in veterinary and human medicine. Therefore, the need for repairing orthopedic procedures is clear. Among the treatment options, the interlocking nail confers rigid stabilization on diaphyseal fractures. It has mechanical advantages over other stabilization techniques, such as plates, compression cortical screws (lag effect), or tension band technique. It was proposed in this study to mechanically compare two fixation methods (interlocking micro-nail or tension band) for fractures under muscular tension. The flexion force was assessed in a universal test machine (EMIC, DL 10000N model), comparing the interlocking micro-nail (IMN) to the tension band (TB) fixation system. The IMN and TB test specimens systems (n=6) went into total failure when the mean maximum force reached 511.20N and 279.90N, and the mean relative stiffness reached 31.33N/mm and 20.97 N/mm, respectively. A significant difference between IMN and TB for the variables maximum strength and relative stiffness were reported ($P < 0.01$). We concluded that, through mechanical flexion tests, the IMN system has superior resistance compared to the TB system. Thus, the IMN system may be a better option for fixing fractures under muscular tension forces.
**Key words**: biomaterial, internal bone fixation, bone healing, orthopedics, small animal surgery.

## Ensaio mecânico comparativo entre micro-haste bloqueada e banda de tensão submetidas a força muscular de flexão

**RESUMO**: As fraturas de ulna, úmero, fêmur, tíbia e calcâneo, que estão constantemente sob tensão devido às forças exercidas pelos grupos musculares nelas aderidas, têm papel de destaque na rotina clínico-cirúrgica, tanto na medicina veterinária quanto na medicina humana, visto a frequência em que ocorrem, sendo nítida a necessidade de procedimentos ortopédicos reparadores. Dentre as técnicas de tratamento, o método da haste bloqueada confere estabilização rígida em fraturas diafisárias e possui vantagens mecânicas em relação às demais técnicas de estabilização como placas, parafusos de compressão (lag) e banda de tensão. Comparou-se a resistência mecânica quanto à força de flexão do sistema de fixação composto pela micro-haste bloqueada (MHB - 6 corpos de prova) com o sistema banda de tensão (BT - 6 corpos de prova), realizados em máquina universal de ensaios EMIC, modelo DL 10000N. Os corpos de provas dos sistemas MHB e BT entraram em falência total quando a força máxima média atingiu 511.20N e 279.90N e rigidez relativa média de 31.33N/mm e 20.97 N/mm, respectivamente. Verificou-se diferença entre MHB e BT para as variáveis força máxima e rigidez relativa, sendo que as médias diferiram ao nível de 1% ($P < 0,01$). Conclui-se, portanto, que o sistema MHB apresentou resistência superior ao do sistema BT, quando submetido aos ensaios mecânicos de flexão, podendo, nesse caso, ser uma melhor opção para tratar fraturas sob forças musculares de tensão.
**Palavras-chave**: biomaterial, fixação óssea interna, cicatrização óssea, ortopedia, cirurgia de pequenos animais.

## INTRODUCTION

The ulna, humerus, femur, tibia, and calcaneus proximal extremities are constantly under tension due to the forces exerted by the attached muscle groups. When there is an imbalance in the mechanical forces present in the bone (mainly observed in car accidents), it can result in fractures. For primary bone healing, these fractures require a rigid stabilization system (OROSZ, 2002; WITTE & SCOTT, 2011; ALMEIDA et al., 2012). After anatomical reduction, they can be stabilized using

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a tension band, compression cortical screws (lag effect), or plate and screws fixation (DENNY, 1990; HORSTMAN et al., 2004; ALVES et al., 2010). Currently, more mechanically resistant fracture fixation techniques, such as interlocking nail and plates, are being studied and used in veterinary orthopedics (SCHMAEDECKE, 2005; FREITAS et al., 2013; DÉJARDIN et al., 2012; BARNHART & MARITATO, 2019; DÉJARDIN et al., 2020).

The tension band technique can be made using one or two Kirschner wires and a cerclage in a figure-eight pattern to promote fracture reduction and control the rotational forces of the bone fragments (DENNY, 1990; MURTHY et al., 2010; SCHLIEMANN et al., 2014). This fixation method opposes the contraction force of the muscle groups and maintains the dynamic compression between the bone fragments until fracture healing.

The interlocking nail method was initially applied in human medicine in the early 1950s and was later introduced into Veterinary Medicine in the early 1990s (SCHMAEDECKE, 2005; FREITAS et al., 2013; MCCLURE et al., 1998; DUELAND & JOHNSON, 1999; MOSE et al., 2002; DUHAUTOIS, 2003; SPADETO JUNIOR, 2011). It is indicated for simple or comminuted fractures of the bone diaphysis, pseudoarthrosis, and even corrective osteotomies. The mechanical advantages and the rigid stabilization are achieved because the nail is applied along the mechanical central axis of the bone. The nail, made of stainless steel or titanium, is placed in a normograde or retrograde fashion, previously chosen based on the bone's diameter, length, and anatomy (FREITAS et al., 2013; DUELAND & JOHNSON, 1999). After the nail insertion, a drill-guide jig with specific perforations is coupled to the extender already connected to the nail for the exact localization of the screw holes insertion points (MCLAUGHLIN, 1999). This fixation method can reduce complications, decrease patient hospitalization time, and thus reduce postoperative complications (SCHMAEDECKE, 2005; SPADETO JÚNIOR, 2011; LARIN et al., 2001; RAGHUNATH et al., 2012). It was proposed in this study to develop and evaluate an internal stabilization system of proximal fractures (bone fragment under tension), using an interlocking micro-nail (IMN) with four screws and to test, *in vitro*, the mechanical resistance of this system compared to the tension band system (TB).

## MATERIALS AND METHODS

Twelve test specimens made of polyamide (Dimetal Technyl™, Ribeirão Preto-SP, Brazil) were prepared, 6 for the interlocking micro-nail system (IMN) and 6 for the tension band system (TB). They had a cylindrical shape, 15mm diameter and a total length of 120 mm.

For the IMN test specimens, a hole (4mm diameter x 50mm deep) was centrally made in one end using a 4 mm drill bit (Cãomédica™, Campinas-SP, Brazil). On this same side, the cylindrical segment was sectioned 20mm away from the end resulting in two segments (100mm and 20mm).

The IMN system was made using a 316L stainless-steel cylinder, 4mm diameter x 50mm length (Cãomédica™, Campinas-SP, Brazil), with a beveled distal end and a 90º proximal end. Four equidistant transverse holes were created in the longitudinal axis, 10mm from each other and 2.2mm in diameter. A centrally and longitudinally threaded hole was created (2.4mm diameter and 10mm deep) at the proximal tip to match with those of the connecting screw. On this same side, a notch was made (1.7mm wide and 1.7mm deep) to connect the drill-guide jig (Figure 1C).

For the test specimens preparation, the IMN was connected to the guide (Cãomédica™, Campinas-SP, Brazil) using a connecting screw, inserted into the central hole of the smaller cylindrical segment, and then into the longer cylindrical segment. Four transverse holes (1.5mm) were made using the drill guide coupled to the IMN. The first one was made in the longer cylindrical segment (distal end), which corresponds to the fourth IMN hole, and then, the other three holes were created according to locations 3, 2, and 1. The surgical screws, 2mm diameter and 15mm length (Cãomédica™, Campinas-SP, Brazil), were secured to the IMN and to the longer and smaller cylindrical segments using a hexagonal screwdriver (Cãomédica™, Campinas-SP, Brazil), resulting in the final test specimen (Figures 1C and 1E).

The initial polyamide cylindrical segment (120mm) used in the test specimens composition of the TB system (Figure 1B) had one of its ends drilled with two holes located laterally and parallelly to its longitudinal axis (50mm deep), 4mm apart from the edge, using a 1.1mm diameter drill for the insertion of two Kirschner wires (Cãomédica™, Campinas-SP, Brazil). A third hole (1.1mm diameter) was created laterally and transversely to its longitudinal axis, 50mm apart from the edge, at the same level as the two previously created holes to pass the cerclage wire (Figure 1D). On the same side of these three holes, 20mm away from the edge, the cylindrical segment was sectioned, resulting in two other pieces (100mm and 20mm) (Figure 1B-c and 1B-d). The

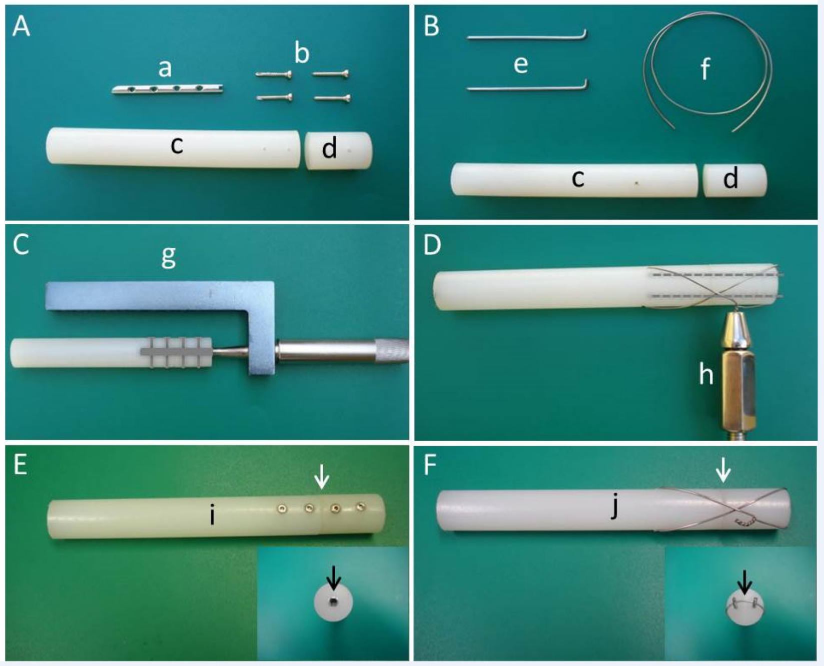


Figure 1 - IMN and TB systems test specimens assembling. A and B: IMN consisting of four equidistant transverse holes, 10mm from each other, the tip with a beveled distal end and the proximal end cut at a 90° angle (a); self-tapping cortical stainless-steel surgical screws (b); longer (c) and shorter (d) polyamide segments; Kirschner wires (e); cerclage wire (f). C: IMN connected to the template (g), introduced into the shorter and longer segments and blocked by screws. D: Two Kirschner wires were introduced into the shorter and longer segments and maintained by a cerclage wire in figure-eight pattern. D-h: orthopedic wire twister. (E-i) IMN test specimen final configuration and (F-j) TB test specimen final configuration. White arrow: longer and smaller segments connection point. (E inset): Front view of the IMN system shows the centered nail position (black arrow), and (F inset) shows two Kirschner wires with angled ends (90º) attached to the orthopedic cerclage wire (black arrow).

(IMN) Interlocking micro-nail; (TB) Tension Band.

segments were then stabilized using two Kirschner wires (1.5mm diameter x 55mm length) introduced into the longitudinal holes previously created. The ends of the Kirschner wires were bent dorsally at 90º using an orthopedic wire twister (Brasmed™, Campinas-SP, Brazil) (Figure 1D-h). For rigid TB stability, a cerclage wire (0.8mm diameter), previously passed through the transverse hole, was anchored, twisted, and tensioned in a figure-eight pattern resulting in the final TB test specimen configuration (Figure 1F).

Before mechanical tests, the test specimens of the IMN and TB systems were radiographed (Siemens Heliphor 4B, 42KV, and 6.4mA models) to evaluate the internal arrangement and integrity of the implants. The analyses were performed in a universal test machine, using a 200kgf load cell, at the Bioengineering Laboratory, Faculty of Medicine at the Universidade de São Paulo (USP), Ribeirão Preto - SP, Brazil.

The longer segment of each test specimen was coupled to a vise attached to the base of the testing machine. A vertical force, with a constant speed of 5mm/min, was applied on a point 6mm away from the free end of the shorter cylindrical segment (Figure 2A), and a curve (force x deformation) was recorded referring to the maximum strength and the relative stiffness. For the IMN system, the screws were kept parallel to the testing machine, and for the TB system, the figure-eight cerclage was positioned dorsally. Both IMN and TB systems test specimens allowed the flexion tests since they remained attached to the vise during the time that the piston remained activated until the system bent and failed (Figure 2B).

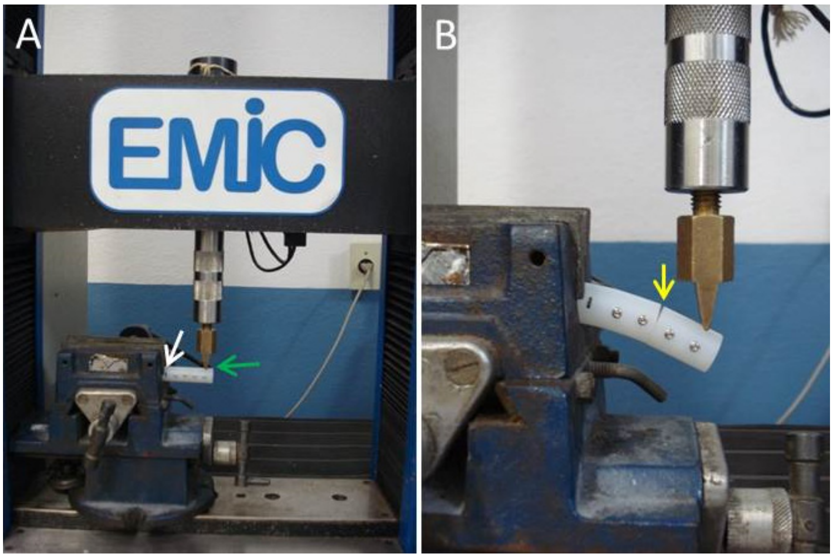


Figure 2 - (A) IMN test specimen coupled to a vise (white arrow) and the contact point of the drive piston on its end (green arrow). (B) Gap formation between the longer and shorter segments (yellow arrow).

(IMN) Interlocking micro-nail.

*Statistical Analyses*

Initially, all parameters were tested for normality and variance equality. For the parametric data, a Student's t-test was used to compare the IMN and TB systems. All data were analyzed using Statistical Analysis System-SAS™ (Version 9.2) software at $P < 0.01$ significance.

## RESULTS

All the IMN and TB systems test specimens tested did not return to their initial configuration. As expected, the deformation was observed at the gap between the longer and shorter cylindrical segments (Figures 3A and B). After the mechanical flexion tests, all the IMN and TB system test specimens were disassembled, and their components were macroscopically analyzed (Figures 3C and 4D).

The polyamide cylindrical segments of all IMN and TB system test specimens returned to their previous forms after disassembling and did not show macroscopic changes (Figure 3C-c, d and 3D-c, d). The four self-tapping surgical screws from the IMN system did not suffer angular deformation (Figure 3C-b). However, all the screw threads that have meet the IMN were damaged.

All IMN has shown angular deviation and rupture (at the upper/dorsal portion) in the third hole region, which was under tension during the mechanical test (Figure 3C-a). The cerclage wire used in one of the TB test specimens has ruptured (Figure 4B-2). All the others remained in their original positions (Figure 4B).

Immediately after the IMN and TB systems tests, all test specimens were radiologically assessed to confirm their components' positions. The IMN components remained connected to the polyamide cylindrical segments with the four surgical screws in position. On TB systems, Kirschner wires remained in position, but angular deformation was observed. Wedge-shaped radiolucent areas were also observed on the side under tension between the polyamide segments in all systems (Figures 4A and 4B).

The flexion test results for the IMN and TB systems are shown in table 1. The IMN system had a coefficient of variation of 8.85 for maximum strength and 15.20 for relative stiffness. The TB system had a coefficient of variation of 7.76 for maximum strength and 9.84 for relative stiffness. These results showed that the samples of both systems are quite homogeneous.

When IMN and TB systems were compared, significant differences ($P < 0.01$) were observed for the maximum strength and relative stiffness variables.

## DISCUSSION

The polyamide cylinder, composed of the longer and shorter segment in the pre-established

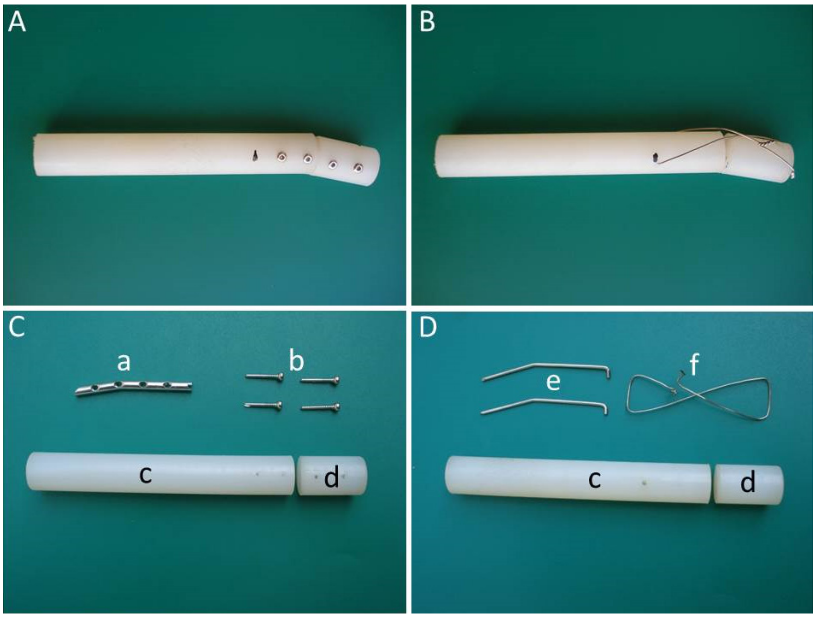


Figure 3 - IMN and TB systems test specimens after mechanical testing. The angular deformation between the segments of the IMN (A) and TB (B). (C and D) IMN and TB systems disassembled: deformed IMN (C-a); self-tapping cortical screws (C-b); longer (C-c, D-c) and shorter (C-d, D-d) segments; deformed Kirschner wires (D-e) and orthopedic cerclage wires (D-f).

(IMN) Interlocking micro-nail; (TB) Tension Band.

dimensions, was chosen because it has physical properties that allowed its preparation so that the IMN could be implanted and properly blocked with four self-tapping surgical screws (Figures 1A, 1C, and 1E). It was also possible to stabilize the segments (longer and shorter) with the TB system, in which two Kirschner wires were inserted longitudinally and maintained with a figure-eight cerclage wire (Figures 1B, 1D, and 1F). Moreover, the physical characteristics of the polyamide cylinder also allowed both IMN and TB systems test specimens, once fixed to the vise, to remain positioned throughout the analysis period until the total failure of the fixing system (Figure 2).

Since there is a biological variability inherent to each individual, several types and patterns of fractures can occur depending on factors such as the direction and intensity of the force affecting the bone, bone composition, resistance, and others. Therefore, simulating and repeating the same fracture pattern for each sample in a bone model is challenging. Hence, the polyamide cylinder was the ideal choice for this experiment, allowing the standardization of the size, diameter, and material used to simulate identical transverse fractures that were assessed by the same strength tests, corroborating the reliability of the results.

The TB system used in this study was produced following the technique described by DEYOUNG & PROBST (1998). The adequate stabilization of this method depends on the Kirschner wires' and cerclage diameters, as well as the surgeon's experience. When properly applied, the TB method becomes safe to stabilize fractures under tension, such as the femur's greater trochanter, the greater tuberosity of the humerus, calcaneus, and olecranon, in small animals. The polyamide cylinders used to simulate the fractured bone were 15 mm in diameter. This size is consistent with the bones of medium-sized and large dogs (SISSON, 1986). Furthermore, the Kirschner wires and the cerclage used in this study had 1.5 mm and 0.8 mm diameters, respectively. These dimensions are in accordance with the recommended specifications for TB application in small animals (DEYOUNG & PROBST, 1998).

The interlocking nail method is indicated to stabilize diaphyseal fractures of the femur, humerus, and also some specific tibial fractures (FREITAS et

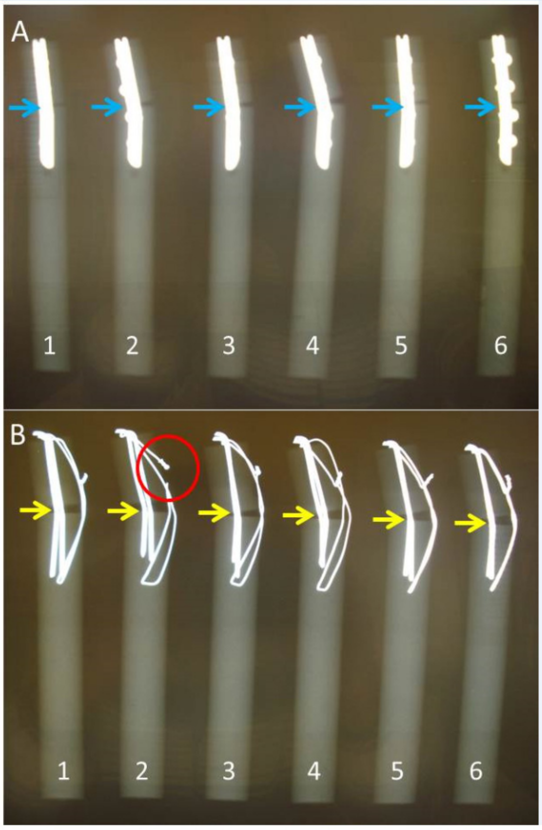


Figure 4 - Radiographic images of the IMN and TB test specimens after mechanical flexion test. (A) Angular deformation is observed in all IMN test specimens at the third hole of the nail (blue arrows). (B) A triangular-shaped opening between the longer and shorter segments is observed (yellow arrows). Red circle: The cerclage wire rupture is highlighted on the second test specimen of the TB system.

(IMN) Interlocking micro-nail; (TB) Tension Band.

al., 2013; SPADETO JÚNIOR, 2011). Although, not indicated for epiphyseal or metaphyseal fractures treatment (such as calcaneus or olecranon), it was observed in this study that the IMN system applied to the polyamide cylindrical segments, using four self-tapping cortical screws for blocking (two proximal and two distal to the fracture), was efficient, and when compared to the TB system, it had a superior mechanical strength (Table 1).

The IMN and TB test specimens standardization was fundamental to the study. This process allowed a reduced number of samples, leading to more homogeneous outcomes, which considerably increased the reliability of the research (BERQUÓ et al., 1981). By choosing the same material (polyamide) for both systems, we also reduced the heterogeneity found in biological tissues such as cadavers' preserved bones (SHIMANO & VOLPON, 2007; DE MARVAL et al., 2011). A model using a cadaveric specimen would have reproduced the physiologic variables, such as the viscoelastic and anisotropic properties that we see in an actual bone, at the same time, it would have increased the heterogeneity of this study.

Clinically, radiography has been used in preoperative evaluations and planning, during the surgical procedure, for accurate implant insertion, and in the immediate postoperative period to confirm implant position. In addition, it is possible to assess bone healing when implant removal is indicated (POZZI et al., 2012).

DE MARVEL et al. (2011), when analyzing fractured bovine humerus stabilized by interlocking nail, employed a U-shaped wooden device positioned at the base of the universal test machine to support the bone epiphysis. Then, using a piston vertically pointed

Table 1 - The mechanical flexion assays result of the TS and IMN systems.

| Samples (TS) | Maximum strength (N) of TB system | Relative stiffness (N/mm) of TS system | Maximum strength (N) of IMN system | Relative stiffness (N/mm) of IMN system |
|---|---|---|---|---|
| TS1 | 276.20 | 24.44 | 569.11 | 34.24 |
| TS2 | 278.77 | 18.83 | 478.30 | 36.76 |
| TS3 | 284.26 | 22.23 | 545.08 | 23.52 |
| TS4 | 256.22 | 20.68 | 511.52 | 29.49 |
| TS5 | 319.06 | 20.27 | 443.44 | 29.72 |
| TS6 | 264.77 | 19.38 | 519.62 | 34.24 |
| Mean | 279.88 | 20.97 | 511.18 | 31.33 |
| Standard deviation | 21.71 | 2.06 | 45.27 | 4.76 |
| Coefficient of Variation | 7.76 | 9.84 | 8.85 | 15.20 |

(TS) test specimen.

to the humeral diaphysis, tested the mechanical stability of this system until failure. In our study, the IMN and TB systems were designed to stabilize fractures constantly under tension, and therefore, to simulate *in vivo* situations, the distal edge of the test specimen, which corresponds to the longer cylindrical segment, was fixed to the vise positioned at the base of the universal test machine. The other tip (free edge), which corresponds to the shorter cylindrical segment, was subjected to mechanical force through a drive piston until the total system failure (Figures 2A and 2B). In human and veterinary medicine, the complications associated with interlocking nails are uncommon; however, infections, non-union, and screws or nail bending have been reported (DURALL et al., 2003).

In this study, after the IMN test specimens mechanical analyses, there were no failures of the self-tapping cortical screws used to fix the nail to the longer and shorter segments (Figure 3C-b); however, we observed threads wear in the region that transposed the nail holes. Therefore, whether this damage occurred during the IMN system assembly or disassembly is unknown. Moreover, there was a partial failure in all IMNs, in the region under tension (the upper/dorsal portion of the third hole) located near the interface between the longer and shorter cylindrical segments (Figure 3C-a). This same failure was also reported by DE MARVAL et al. (2011) in their mechanical flexion analyses using bovine humerus. Although, this study does not reproduce an *in vivo* biological environment under the influence of muscles, tendons, and a physiologic tension (cyclical tension), the *in vitro* analyses are an essential initial part of the further clinical application of any new device.

A significant statistical difference was observed between the IMN and TB systems regarding the means of maximum strength and relative stiffness (Table 2), which are, according to SHIMANO & VOLPON (2007) and DE MARVEL et al. (2011), highly reliable variables for this kind of analyses.

Table 2 - The mechanical compression assays results (± Standard deviation) of the IMN and TB systems.

| Samples (TS) | Maximum Strength (N) | Relative Stiffness (N/mm) |
|---|---|---|
| Interlocking micro-nail (IMN) | 511.18±45.27 | 31.33±4.76 |
| Tension Band (TB) | 279.88±21.71 | 20.97±2.06 |

(TS) Test Specimen.

## CONCLUSION

The IMN system, when submitted to the mechanical flexion tests until total failure, had superior resistance than the TB system; therefore, the first may be a better option for the stabilization and treatment of fractures under-tension.

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## DECLARATION OF CONFLICT OF INTEREST

The authors report no financial or other conflict related to this study.

## AUTHORS' CONTRIBUTIONS

All authors contributed equally for the conception and writing of the manuscript. All authors critically revised the manuscript and approved of the final version.

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