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Influence of the intramedullary nail locking method on the stiffness of the bone-implant system

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Purpose: Bone fractures are one of the most commonly seen problems in veterinary traumatology. The authors of this study strive to find a new intramedullary nail, which is intended for treating femoral bone fractures for canine patients. The purpose of this study was to analyze biomechanical parameters of the intramedullary nails, which use a new bolt system concept. *Methods*: Dissected femoral bones of a large breed dog were cut in order to simulate interfragmentary gap, and then the bones were stabilized using intramedullary nail with locking bolts. Bone-nail systems were subjected to cyclic loading using force which corresponds to the load on the femoral bone in the first few days after surgery. Micro-CT scans were taken of the bone samples around implant in order to determine deformation and structural parameters of bone tissue. *Results*: The calculation of the bone-nail system stiffness was done through analysis of the force-displacement curves recorded during experimental studies. Using monocortical locking bolts resulted in smaller stiffness of the bone-nail system than using bicortical locking bolts. *Conclusions*: The results obtained in this study can indicate that the intramedullary nail could work well when used for treatment of bone fractures in dogs. The authors focused on using monocortical bolts which provides good stability and adequate biomechanical environment. Described fixation method is easily adjustable to a particular patient individual parameters.

Key words: *intramedullary nail, femur, dog bone, Micro-CT*

1. Introduction

Many surgical techniques are used in veterinary surgery to stabilize bone fragments. In approximately 90% of cases, long bone fractures qualify for surgical treatment by performing an osteosynthesis procedure. Leading osteosynthesis methods include intramedullary osteosynthesis and plate osteosynthesis [2], [4], [7], [10], [13], [16]. In recent years, especially in treatment of humans, one of the main criteria for selecting an appropriate technique for the treatment of bone fragments is the degree of invasiveness of the procedure. Low tissue traumatization during the procedure and good stabilization allow for a rapid healing process and rehabilitation of the injured limb [20]. A technique that meets these conditions is osteosynthesis with a locking intramedullary nail.

Intramedullary nail is placed in the bone and it creates a biomechanical system that stabilizes bone fragments and takes over the load transfer function. Biomechanical conditions require the system to be dynamic in order to heal faster, so analysis of parameters such as interfragmentary movement (IFM) can assist the healing process [8] by selecting the appropriate implant for given fracture. The placement of a large implant, usually made of metal, in the marrow cavity also carries adverse consequences, such as increased risk of infection and immune response, damage to a significant portion of cancellous bone that will need time to regenerate, and, most importantly, damage to the blood vessel system that supplies nutri-

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ents to the bone. Additionally, excessive stiffness of implants can significantly prolong the bone healing process [5]. Implants made of composite biomaterials are increasingly used to minimize the risk of infection and to better match the stiffness of the bone-implant system [22]. Despite these inconveniences, intramedullary nails are readily used because of the simplicity of the design of the stabilizing system and, above all, because of the usually minimally invasive method of implantation [19]. Because of the above mentioned features, the intramedullary stabilization is becoming more and more popular method for treating limb fractures in dogs [9], [14], [21], [24], where inaccessibility of stabilizer components to the animal is particularly important.

The interlocking nails used in veterinary surgery to date have typically been a scaled-down form of those used to treat humans, but new solutions designed to treat bone fractures in dogs are also created [7], [23]. Small number of such studies prompted the authors to search for design solutions for the intramedullary nail that would solve the problems discussed earlier. However, one of the problems is to define the mechanical and physical properties of the dog's bone tissue, which due to the large number of species, breeds and geometries are little described. Knowledge of these properties allows us to obtain information about the stiffness of the structure and predict the healing process of this bone. The main goal of the work was to perform a biomechanical analysis of a locking nail intended for specific patients such as dogs. The intramedullary nail examined by us differs from others by the fact that the bolts are immobilized with respect to the nail, and the contact surface with the bone tissue is smooth and cylindrical, allowing rotation and displacement of the bolt in the area of contact with the bone (Fig. 1A). The discussed intramedullary nail is the result of cooperation between researchers from the Faculty of Mechanical Engineering of the Wrocław University of Science and Technology and the Wrocław University of Environmental and Life Sciences. The experimental study presented in this publication was designed: first – to determine the mechanical properties of the bone-intramedullary nail system for treatment of fractures in large-breed dogs using a novel concept of monocortical or bicortical locking, and secondly – to determine the deformation of holes in the bone as a result of cooperation with the intramedullary nail in the monocortical and bicortical bolts configuration.

The mechanical properties characterizing a bone-implant system determine the biological response related to the functional adaptation of bone tissue in the whole bone, especially in the tissue layers around the implant. Stiffness of the system, conditioned by different configuration of the stabilizer, influences interfragmentary movements, stimulating regenerate formation and tissue healing processes [2], [15]. This has a decisive influence on the density and quality of the bone tissue around the implant. Results of this study allowed for a comprehensive assessment of the stability of the analyzed systems, which directly supports the selection of locking options that favorably affect the fracture healing process.

2. Materials and methods

Physical model of the bone-implant system – sample preparation

Determination of the mechanical properties of the bone-intramedullary nail system was carried out on femurs of large breed dogs ($N = 20$). From each animal, both femurs were collected for further measurements. Each bone was stabilized with an intramedullary nail, 185 mm long and 8 mm in diameter. The nail has a narrowing in the central part with a diameter of 6 mm (Fig. 1A). The chosen nail construction allows static stabilization of bone fragments. The characteristic feature of the implant is that the bolts in the part cooperating with the bone tissue are smooth and they are connected with the nail via a thread connection. In its central part, the bolts have an external thread M4, which allows them to be screwed into a threaded through hole in the intramedullary nail. There are three such holes in the upper and lower part of the nail.

The intramedullary nail and bolts are made of 316L steel. This is an austenitic steel with good corrosion resistance, even in the environment of the body. For this reason 316L is often used for implants that are removed from the body once they have fulfilled their stabilizing role.

The nail was placed in the bone in such a way that at the central part of the shaft the nail is in the long axis of the bone, at the distal epiphysis it rests in the cancellous tissue, and at the proximal epiphysis it protrudes between the greater trochanter and the bone head, according to the implantation technique (Fig. 1B).

In this paper, a case of a transverse fracture located in the central part of the shaft of a dog femur was analyzed. The fracture was stabilized intramedullary with a nail. An inter-fracture gap was added, which was 4 mm in size and allowed for uncompressed movement of the fragments during measure-

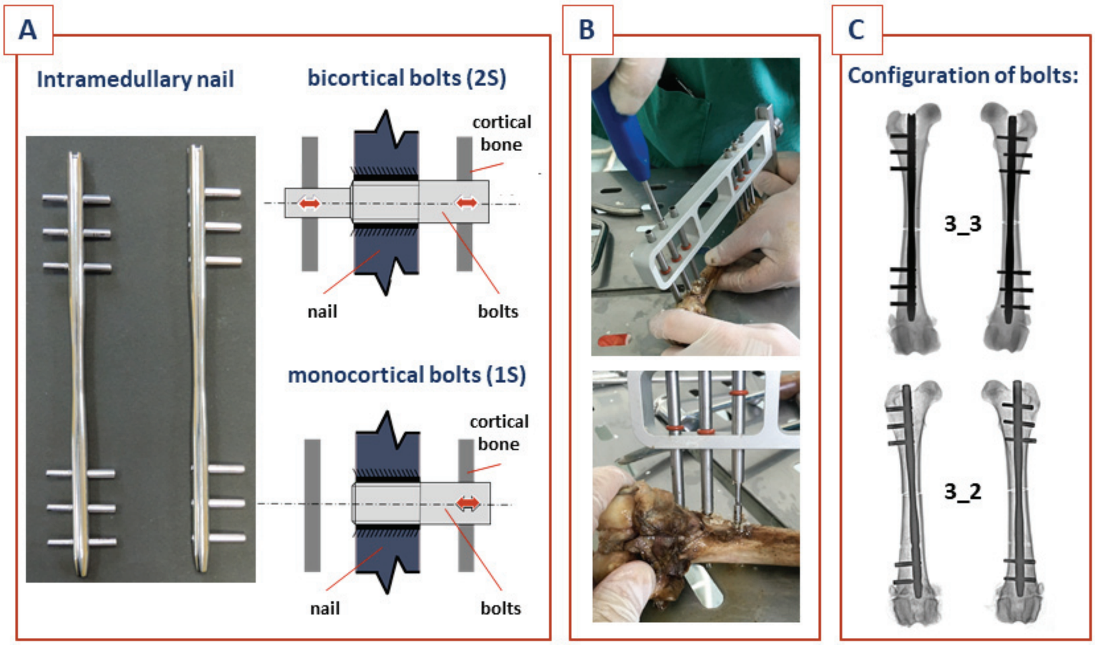

Fig. 1. Physical models of the bone-implant system: a) intramedullary nail for the treatment of long bone fractures in large breed dogs, with two types of locking bolt, bicortical (2S) and monocortical (1S), b) insertion of the bolt into the guideway and installation of the locking bolt, c) X-ray images of the bone-implant system in configurations 3_3 and 3_2, taken to verify the correct preparation of the specimens for testing

ments. Until the time of measurement, each preparation was stored at –20 °C. Surgical implantation procedures were performed in the Department of Surgery of Wrocław University of Life Sciences.

Locking systems with two types of bolts were studied: bicortical, which are embedded in both sides of the femur cortex and monocortical, embedded only on one side of the femur cortex. In addition, two selected configurations of locking bolt placement were tested for both types of locking bolts. After implantation, X-ray stabilization control was performed for each implanted bone (Fig. 1C).

Intramedullary nails were fixed in the bone with monocortical (1S) and bicortical (2S) bolts in the following configurations: with three bolts in the proximal and distal parts, with three bolts in the proximal part and two in the distal part (Fig. 1C). Both configurations (mono- and bicortical) were implanted in bones from the same dog. By studying different configurations, the authors demonstrated the versatility of the design and its adaptability to a variety of patients. In the conducted study, 20 bone-nail systems were analyzed.

Determination of mechanical properties of bone–implant system

The prepared physical models of the bone-implant system were subjected to uniaxial compression test under cyclic loading conditions using a MiniBionix 858 mechanical testing machine (Fig. 2A). The femoral epiphyses were rigidly fixed in special mounts allowing for precise axial positioning of the bone during the tests. The value of force F varied from 20 to 100 N with a frequency of 0.5 Hz in phase 1, from 20 to 150 N in phase 2, from 20 to 200 N in phase 3, and from 20 to 250 N in phase 4 (Fig. 2B). The load ranges were chosen to represent the values of forces acting on the dog's femur in subsequent stages of rehabilitation after nail implantation [2]. Mechanical parameters, such as dissipation energy and axial stiffness, were determined.

Analysis of cancellous bone deformation around the implant

Diameters of the holes after removal of the bolts were calculated and compared to the reference values. Measurements of the geometrical parameters of cancellous bone around the implanted system were carried out with the use of CTAn software based on reconstructions obtained by NRecon software with the use of the Bruker 1172 SkyScan (Kontich, Belgium) computer microtomography. Each sample was registered with a resolution of 12.5 µm, with the lamp parameters: 89 kV/112 mA, Al+Cu filter. (0.5 mm), with a unit rotation angle of 0.4 degrees.

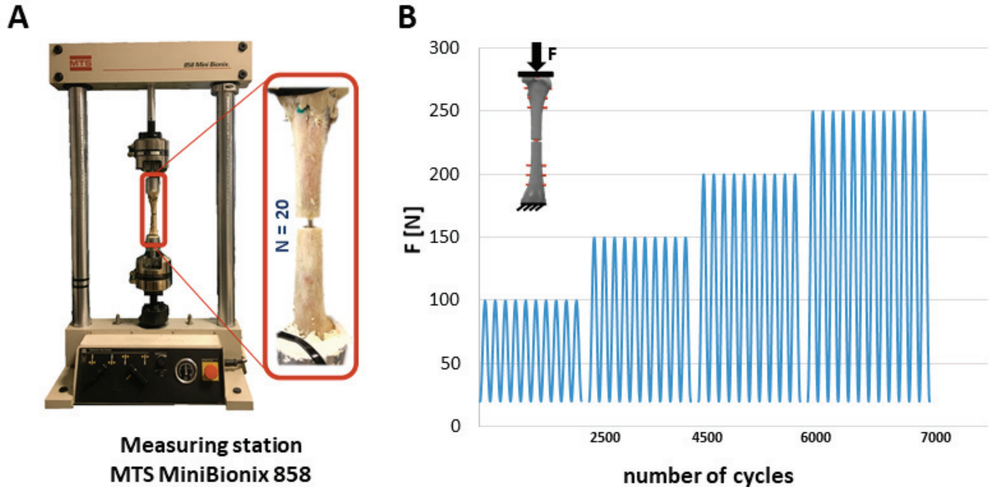

Fig. 2. Test stand (A) and loading characteristics of specimens in cyclic compression test (B)

The research was carried out on four proximal epiphyses reconstructions where two were samples with monocortical bolts and two, in which bicortical bolts were used. Based on the obtained reconstructions the samples of bone tissue from the area around the bolt were then prepared (Fig. 3) and used for determination of structural parameters in the CTAn software. In order to determine the impact of implantation on the structure of bone tissue around the intramedullary nail, samples were prepared in two different diameters: ϕd_1 had a value 4 mm larger than the diameter of the bolt, while ϕd_2 had a value 8 mm larger (Fig. 3C). On the other hand, lengths of the samples were related to the bone region, and so the longest samples were obtained for the bolt no. 1. while the shortest – for the bolt no. 3. For each sample, the changes in the diameters of the bolt holes along the bolt axis were determined (Fig. 4).

Statistical analysis

Statistical analysis was performed using software package Prism 9.3.1, GraphPad Software (San Diego, CA, USA). The statistical significance in the values of the mechanical parameters of the physical models locked with monocortical and bicortical bolts in both 3_3 and 3_2 configurations was checked using the Welsh test ($p < 0.05$). On the other hand, the statistical significance in the values of mechanical parameters

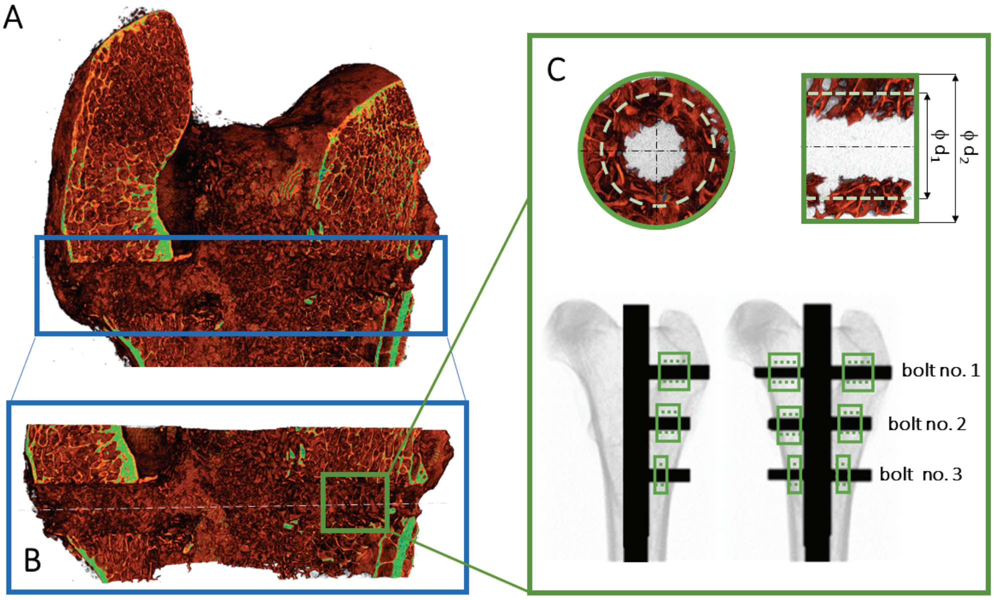

Fig. 3. Virtual model of the proximal femoral epiphysis (A) from which samples of cancellous bone tissue (B) in direct contact with the bolt (C) were extracted

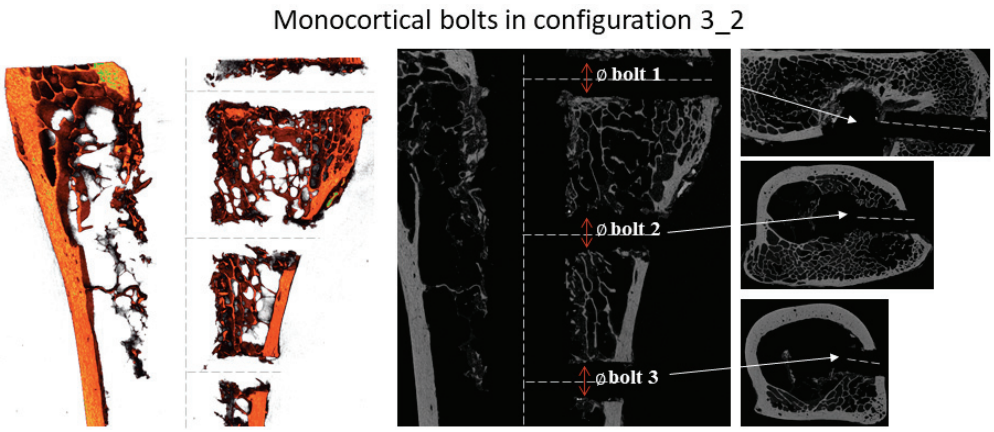

Fig. 4. Schematic of the proximal canine bone epiphysis after removal of intramedullary nails in configuration 3_3

occurring between the 3_3 and 3_2 configurations locked with bolts of the same type was analyzed by Student's *t* test, at the significance level of ($p < 0.05$).

3. Results

Determination of mechanical properties of bone-implant system

Based on results from the cyclic compression test, force-displacement characteristics were determined for each force range values. The results were analyzed for two monocortical and two bicortical configurations. The value of the axial stiffness coefficient was determined for all tested systems. The axial stiffness was determined as the ratio of the force value to the value of the bone fragment displacement in the axial direction, as described in Fig. 5. Axial stiffness values determined for the tested models are shown in Figs. 5–7.

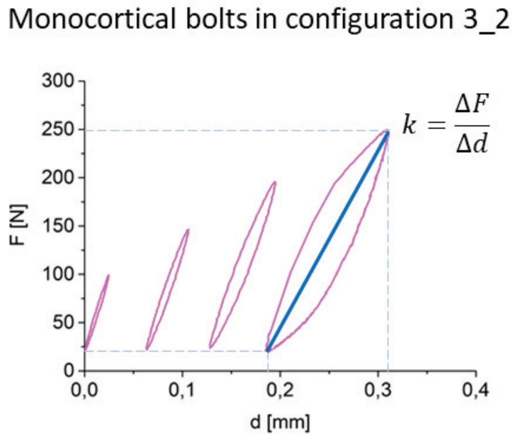

Fig. 5. Stiffness coefficient determination based on force-displacement characteristics

Analyzing the force-displacement curves, we noticed that the system returns to its initial state after loading and unloading cycle. However, the path of the curves during loading is different from the curves during unloading. It follows that the examined physical models have the characteristic of a viscoelastic system.

The force-displacement characteristics were also used to determine the dissipation energy of the studied systems. The dissipation energy was calculated as the area limited by force-displacement curves recorded during loading and unloading the physical model. When the sample is loaded, part of the mechanical energy is dissipated causing energy losses in the region of implant-bone tissue interaction, due to porous structure of cancellous bone tissue filled with bone marrow. This results in the system becoming uncalibrated. The value of the dissipation energy directly affects the wear of the system components [3], [27].

For the configurations with three fixation bolts in both epiphyses (3_3) and with three in the proximal part and two in the distal part of the bone (3_2), tests were carried out using a larger number of specimens (five specimens per configuration for both the systems with mono and bicortical bolts). The results of these tests are presented in Figs. 6–9).

Analysis of cancellous bone deformation around the implant

The bone structures recorded with micro-CT were analyzed from the point of view of loss of implant stability. Different geometry and dimensions of the canine femur cause the locking bolts of the intramedullary nail to contact the bone tissue at different femur lengths. Locking bolts closer to the bone shaft have smaller contact surface with compact bone due to smaller thickness of bone.

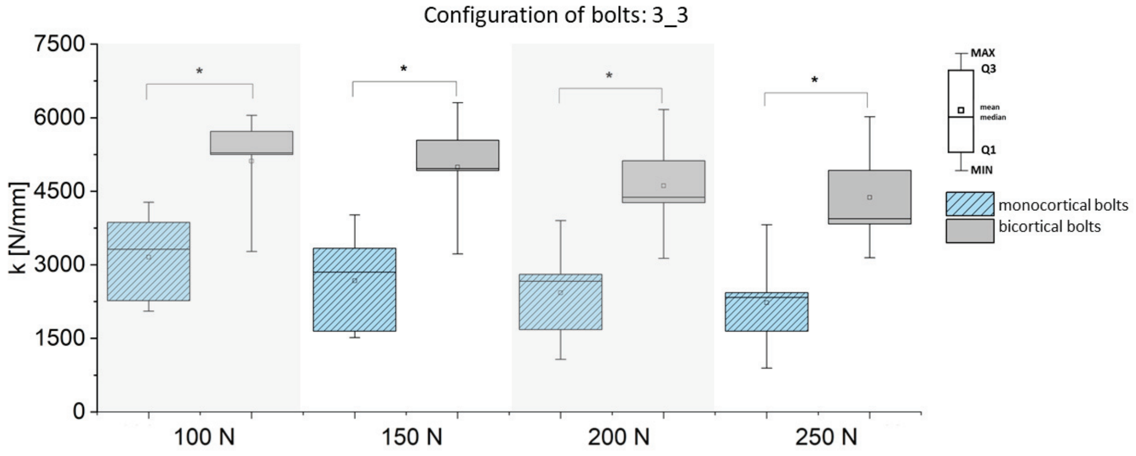

Fig. 6. Comparison of axial stiffness values in the 3_3 configuration in the analyzed bone-implant systems; $*p < 0.1$, $**p < 0.05$, $***p < 0.01$

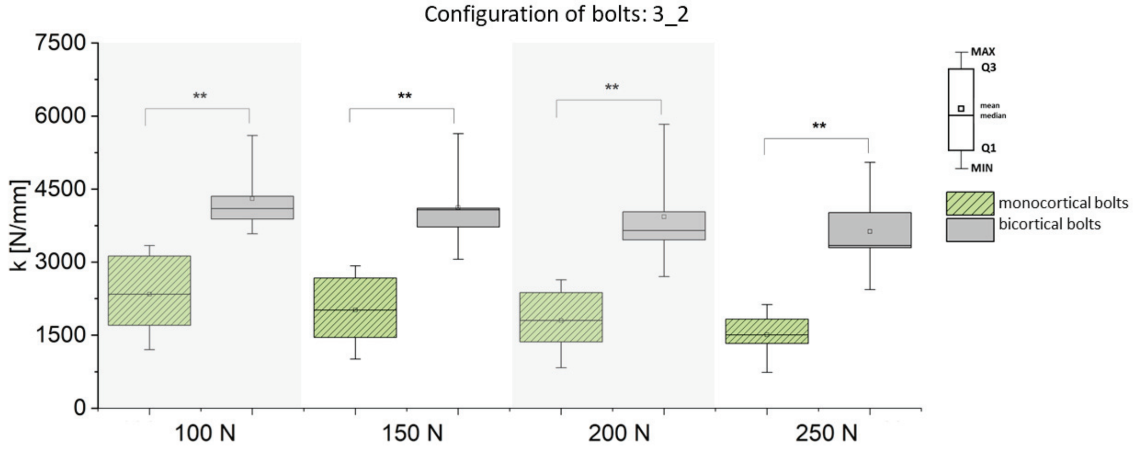

Fig. 7. Comparison of axial stiffness values in the 3_2 configuration in the analyzed bone-implant systems; $*p < 0.1$, $**p < 0.05$, $***p < 0.01$

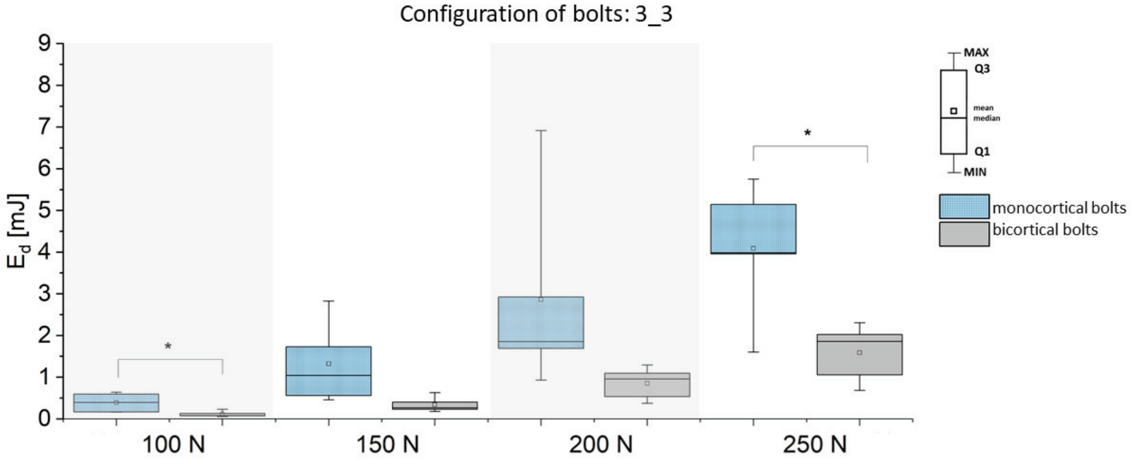

Fig. 8. Comparison of dissipation energy values in the 3_3 configuration in the analyzed bone-implant systems; $*p < 0.1$, $**p < 0.05$, $***p < 0.01$

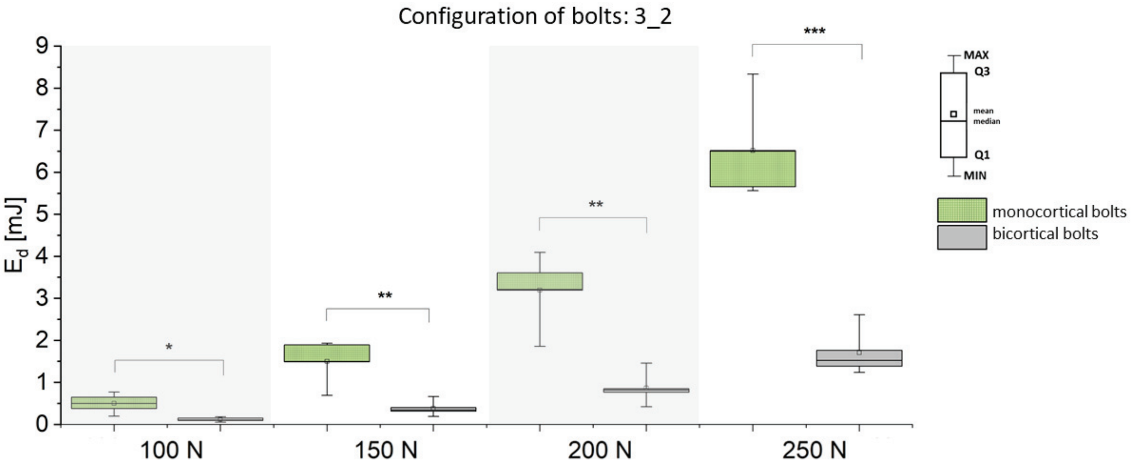

Fig. 9. Comparison of dissipation energy values in the 3_2 configuration in the analyzed bone-implant systems; * $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$

Analysis of hole diameters within bolt no. 1 (Fig. 10) showed the highest values occurred in configuration 3_3 with monocortical bolts. Additionally, in configuration 2_2 with bicortical bolts, at the bolt diameter of ϕ 3 mm, the hole diameter values were higher than in the other analyzed configurations (Fig. 11). For bolts no. 2 in all configurations, no significant changes in hole diameter values were observed. The values of hole diameters after removal of bolt no. 3 were higher in bicortical bolt holes than in monocortical bolt holes.

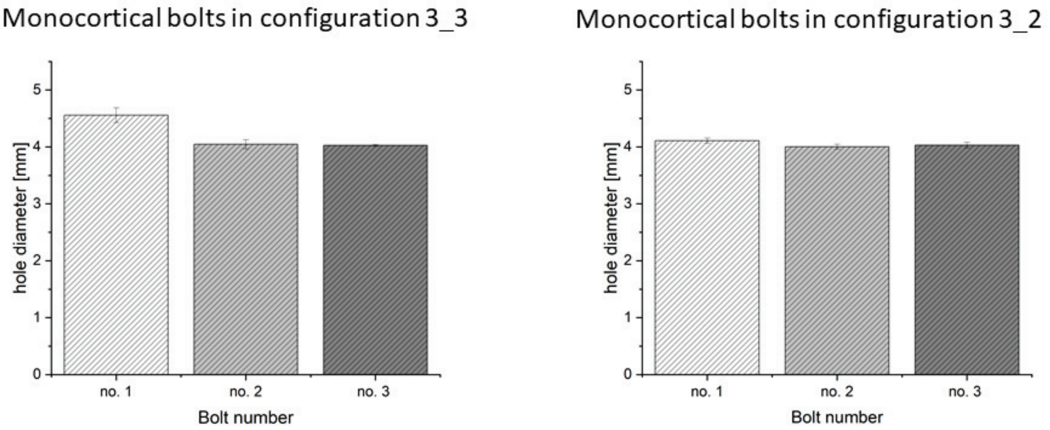

Fig. 10. Comparison of mean hole diameters determined after removal of monocortical bolts in the proximal bone epiphysis

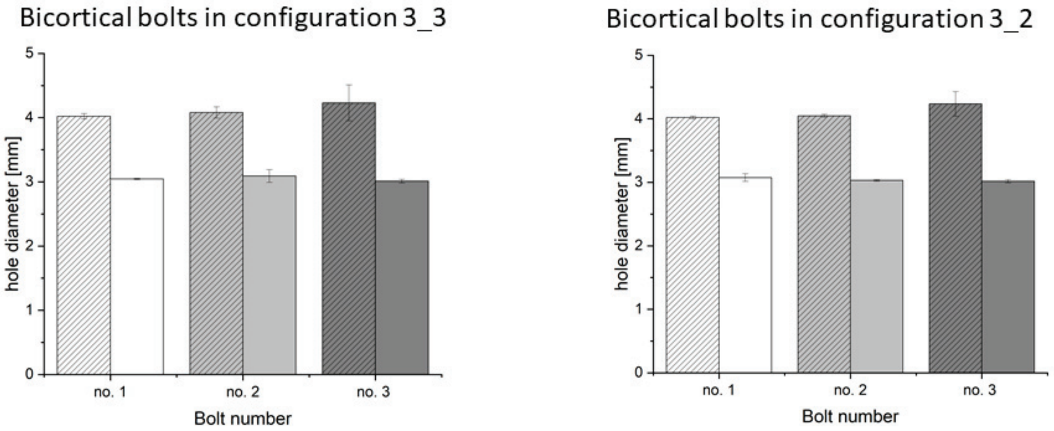

Fig. 11. Comparison of mean hole diameters determined after removal of bicortical bolts in the proximal bone epiphysis

In the 1S:3_3 configurations, differences of more than 10% in the value of the hole diameters measured after loading the specimens, compared to the nominal hole diameter, were observed near the bolt no. 1 (Table 1). In the other analyzed holes after monocortical bolts, the differences did not exceed 3%. However, in the holes created after bicortical bolts no. 3 on the side of the bolt with a larger diameter, the differences with respect to the nominal hole value were almost 6%. In the distal epiphysis of the bone, no extensive permanent damage to the bone trabeculae was observed within the bolt and nail holes.

Table 1. Variation of hole diameter values around the bolts

	Configuration of bolts	change in the value of the hole diameter [%]		
		bolt 2S $\phi = 4$ mm	bolt 2S $\phi = 3$ mm	bolt 1S $\phi = 4$ mm
bolt 1	3_3	0.5	1.5	14.0
	3_2	0.5	2.5	2.7
bolt 2	3_3	2.0	3.0	1.1
	3_2	1.2	0.8	0.1
bolt 3	3_3	5.8	0.4	0.7
	3_2	5.9	0.6	0.8

Analysis of structural parameters of bone tissue around the implant

Analysis of structural parameters of the bone tissue in which the implant is placed helps to assess the quality of the bone tissue, especially around the implant, and can help to estimate the stability of the bone tissue-implant connection. During intramedullary nail and bolts implantation, the drilling process damages the bone tissue that is in direct contact with the drill and small particles of the damaged bone tissue appear in the space between bone trabeculae [12]. In addition, after implantation, when the limb stabilized with the intramedullary nail is loaded, compression of the bone trabeculae and the displacement of the damaged bone particles deeper into the structure may occur. The micro-CT image (Fig. 12) shows a sample hole with fragments of the broken tissue from the process of drilling and inserting a bolt. When introducing the implant into the bone, changes are visible in the bone tissue itself, especially in the area of direct contact between the tissue and the bolt.

The quantitative analysis of bone tissue carried out for 2 regions (for diameters of 4 and 8 mm) for each bolt showed changes in the structure of the tissue both in terms of its geometry (BV/TV, Tb.N parameter) but also in its structure type (SMI parameter) and integrity of the whole structure (Conn.Dn). The highest values of the BV/TV parameter (30%) were obtained for the bone tissue around bolt no. 1, while for bolts no. 2 and no. 3 they were 15% and 20% lower, respectively (Fig. 13). The exceptions were the samples located at bolt no. 3 for the nail locking system with monocortical bolts in configuration 3_3, for which the values were around 37%.

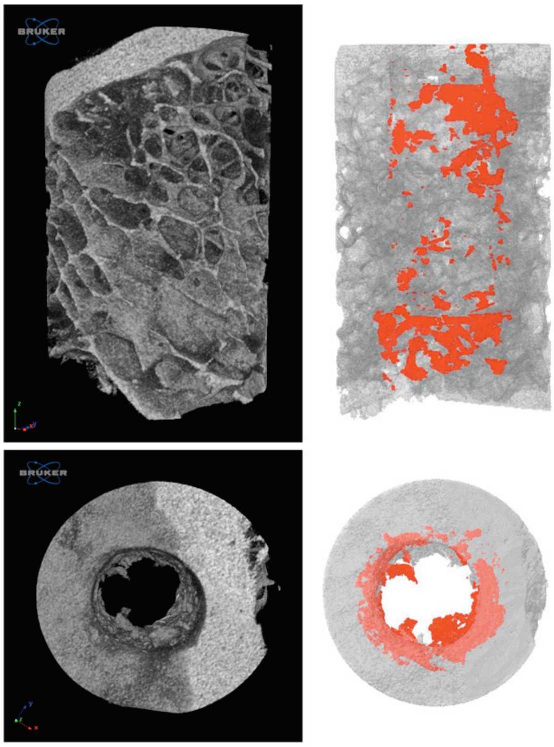

Fig. 12. The micro-CT image of bone particles present in the space between bone trabeculae

The analysis of the SMI parameter showed that in systems locked with bicortical bolts, the values differed significantly from each other depending on the examined epiphysis. In the configuration 3_2, for the samples taken from both the medial and lateral region, the values of the SMI parameter ranged between 2.13–3.3. The exception to this range were samples with a diameter of ϕd_2, which were characterized by an increase in the SMI value by 8%. This suggests a change in the nature of the trabecular structure from mixed to rod-like structure in this bone region. In the epiphysis locked with bicortical bolts in the 3_3 configuration, the values were lower than in the epiphysis in the 3_2 configuration, and ranged from 1.25 to 1.85. Comparison of the SMI values for the different diameters indicates that higher values were for the specimens with diameter ϕd_1 and they were by 21% higher on average. A similar dependence of higher SMI values (2.7) in configuration 3_2, compared to configuration 3_3, was observed for monocortical bolts.

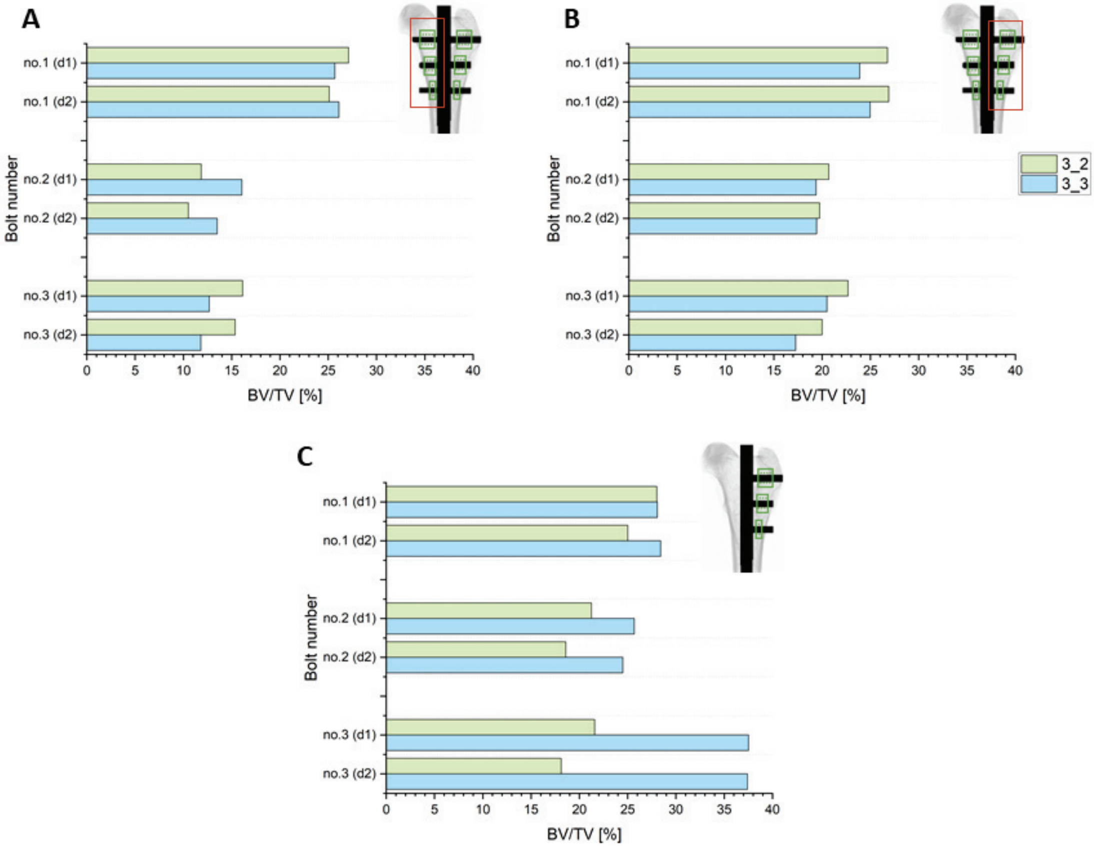

Fig. 13. BV/TV parameter values for analyzed samples of cancellous bone tissue around bolts

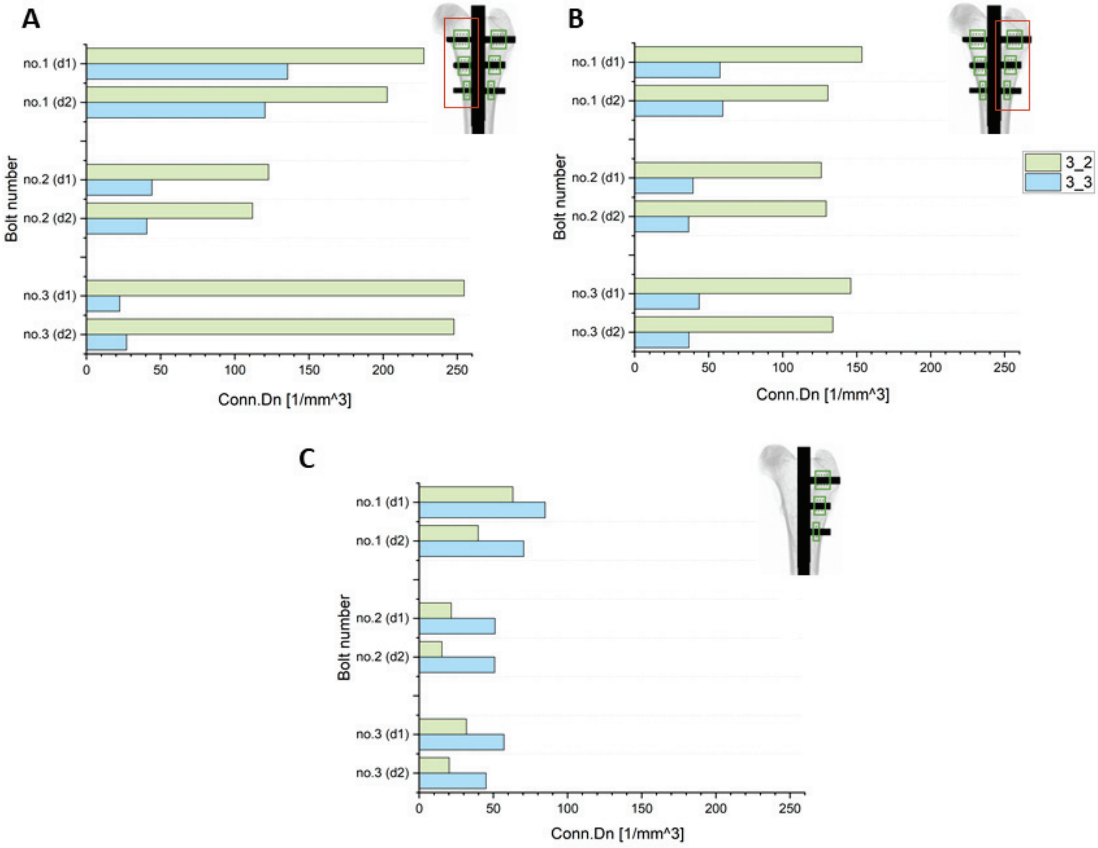

Fig. 14. Conn.Dn parameter values for analyzed samples of cancellous bone tissue around bolts

The more bone tissue around the bolt, the greater stability of the connection between the implant and the bone, therefore the Tb.N is a very important parameter describing the bone geometry. The highest values of the Tb.N parameter were observed for bolt no. 1, where the most bone tissue is located. Additionally, due to implantation, in the area of the direct connection of the bolt with the bone (diameter ϕd_1), there are the most bone trabeculae and this parameter (regardless of the configuration) takes the highest values in the range of 1.1–2.8 mm^{-1}.These damage to the trabeculae are shown in Fig. 12.

Comparing the values of the structural parameters of bone tissue around the bolts for different tested configurations, differences were also noticed in the values of the connectivity density (Conn.Dn) parameter. This parameter determines the consistency and integrity of the structure of bone tissue [18]. Analyzing the obtained values of the Conn.Dn parameter (Fig. 14), the highest values were observed for the bicortical configuration 3_2, and they were in the range of 112–255 mm^{-3}. For the remaining configurations, the Conn.Dn parameter took the lower values in the range of 22–135 mm^{-3}. Additionally, when comparing the Conn.Dn values for individual bone levels (bolts no. 1–3), the highest values were obtained for bolt no. 1, and the lowest for bolt no. 2.

4. Discussion

This paper presents the results of experimental study of the biomechanical system formed by fragments of a fractured bone and an intramedullary nail. Particular attention was paid to determine the effect of using monocortical and bicortical smooth bolts on the biomechanical properties. In the intramedullary stabilization system presented in this paper, the smooth cylindrical surface of the bolts directly interacts with the bone tissue, creating a connection in which the bolts can move freely in the hole made in the bone. This is the main feature that distinguishes the proposed solution from classical systems using threaded bolts immobilized with respect to bone [10], [25], [26].

Stiffness is a parameter that directly affects faster bone union and successful healing, and its value should be close to the stiffness of uninjured bone. If a stiffness of a system is too low, it may cause excessive movement of fragments, which could prevent bone union. On the other hand, too high stiffness of the system might decrease the regenerative potential of the tissues [2], [28].

Values of mechanical parameters of the system depend on tested configuration, number of bolts and their type (monocortical or bicortical). The change in stiffness values with increasing number of loading cycles is smaller for configuration 3_2 than for 3_3, suggesting slower structural changes in bone tissue. This provides stable loading conditions for the fragments during bone healing, which is associated with a faster adaptation process of the bone tissue to the prevailing conditions [2]. An additional advantage of the 3_2 configuration is that one less lock is inserted, thus, reducing the invasiveness of the procedure.

The use of monocortical bolts may reduce postoperative trauma while it can stabilize the system as well as bicortical bolts. The intramedullary stabilization system analyzed by the authors, which use optional monocortical bolts, also provides good adaptation to handle higher loads resulting from the dog's unpredictable behavior in the initial postoperative period. Less rigid stabilization allows for controlled dynamization of callus, so the use of monocortical bolts proposed by the authors' may prove valuable. Our observations correlate with the results of research by other authors. Claes [5] showed that the value of interfragmentary movement is extremely important to the rate of tissue regeneration. Moreover, Claes in another work [6] confirmed that poorly chosen biomechanical conditions can cause longer fracture healing time and, in extreme cases, can lead to disruption of the fracture healing process. Similar findings are presented by Miriamini et al. [17]. They draw attention to the direct relationship between IFM and the course of bone fracture healing. Aliert et al. [1] showed that stabilization dynamics can beneficially promote bone healing. Rigid fixation, on the other hand, causes direct ossification, which can cause lower quality of the reconstructed bone and fractures may occur again.

The determined dissipation energy increased with the force value in both configurations with three bolts in both epiphyses, however, this increase was observed more in the systems with monocortical bolts. During cyclic loading of the physical model, the value of dissipation energy increased 11 and 14 times in systems locked with bicortical bolts and 13 and 16 times in systems locked with monocortical bolts. The dissipated energy indicates the wear of system components, especially bone tissue around the bolts, and affects the stiffness value of the model.

The higher dissipation energy value observed with the increase in the load range and the number of load cycles suggests the appearance of some changes in the structure of the bone fragments – intramedullary nail. Taking the large variation in the mechanical parameters of the nail and bone tissue into account, it can be assumed that the changes occur mainly in the bone. We mean changes in the geometry of the holes in the bone, i.e., in the place where the bolts directly cooperate with the bone tissue.

To clarify this issue, research was carried out on the geometry of the holes in the bones in which the bolts were embedded. Changes in the structure of the trabecular tissue and the volume around the holes were also analyzed.

Analysis of bone tissue scans with the use of computer microtomography, in the proximal epiphyses of bone, around the bolt and nail holes, enabled us to observe differences in the nominal diameters of the holes in relation to their actual dimensions. The obtained results indicate that the greatest changes observed in the values of the examined diameters did not exceed 6%. Loosening of locking bolts is one of the main complications associated with long-term use of internal stabilizers.

In the literature, studies describing the relationship between the values of structural parameters and the quality of the bone-implant connection can be found, therefore the bone structures were analyzed using μCT. Structural parameters such as bone volume BV/TV, trabecular thickness Tb.Th, trabecular number Tb.N are positively correlated with the stability of the connection, which means that a higher value positively affects the quality of the connection. On the other hand, the value of the structure model index (SMI) parameter is negatively correlated [11]. The results of the structural parameters of cancellous bone tissue show a great variability depending on the studied sample, so it is important to approach treatment of a bone fracture of a specific patient individually.

5. Conclusions

The results of the performed experimental study of an intramedullary stabilization system, designed to treat limb fractures in dogs, may indicate that the discussed intramedullary nail can be very useful in the treatment of various types of fractures in dogs. Special cylindrical bolts with two degrees of freedom (translation along and rotation around the bolt axis) ensure safe operation of the stabilizing system and favorable biomechanical conditions for the bone tissue.

The use of monocortical locking reduces tissue interference during implantation, while the nail design provides stability to the bone-implant system. Intramedullary nail with monocortical bolts fulfills the stabilizing function and provides appropriate biomechanical conditions while limiting the area of surgical interference. The design of the nail allows the implant to be adapted to a patient, taking into account many individual factors (type of fracture, weight of the animal and its mobility). This allows the mechanical parameters of the stabilizing system, such as stiffness, to be adjusted to achieve the most favorable biomechanical conditions for treating canine limb fractures.

In addition, the analysis of bone deformation carried out on the basis of the structural parameters of the bone tissue in which the implant is placed, makes it possible to determine the quality of bone tissue, which enables the researchers to assess the stability of the connection between this tissue and the implant.

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