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Improving Equine Intramedullary Nail Osteosynthesis via Fracture Adjacent Polymer Reinforcement

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Abstract:
Introduction: Osteosynthesis of the equine femur is still a challenge for veterinary medicine. Even though intramedullary fracture fixation is possible nowadays, the varying geometry of the medullary cavity along the bone axis is a critical factor. Limited contact area between implant and bone can cause insufficient primary stability. In this study, it was investigated whether the osteosynthesis stability can be improved with a form-adaptive reinforcement for the diaphyseal part of the proximal fragment.
Material and Methods: Eight equine femora were fitted with intramedullary nail osteosynthesis and analyzed by 4-point bending. Virtual position planning of the ex-vivo implantation using CT-data increased comparability. For five femora the proximal fragment was reinforced with a flexible polymer mixture. Longterm stability was tested via cyclic loading. Bending stiffness and its development due to cyclic loading was evaluated before and after reinforcement procedure. Finally, load-to-failure was tested in the same setup.
Results and Discussion: The application of the polymer reinforcement increased the maximum torque in the load-to-failure measurement by 26%. Bending stiffness was not affected in the measured loading range by the reinforcement. Cyclic loading increased bending stiffness for a conditioned state but showed to be reversible for the most part.
Conclusion: The fracture adjacent reinforcement showed to be beneficial to the osteosynthesis stability, but further investigation is necessary for surgical application.

Keywords: osteosynthesis, implant, equine, biomechanical testing, femur, internal fixation, intramedullary nail

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1 Introduction

In equine medicine, fracture treatment of the proximal long bones is still problematic. High loads, a lot of muscle attachment and limited immobilisation lead to a poor prognosis. Whereas fractures at the easily accessible areas in the distal limb can be managed well with plate and screw osteosynthesis [1]. Particularly in the femur and humerus, the large soft tissue coverage makes fracture treatment more difficult. In addition, external splinting of the fracture in this area is not yet possible. Therefore, primary stability is a critical criteria for internal fixation. Complete unloading of the fixed limb postoperatively is hard to achieve and often not tolerated by the animal. Moreover, during the recovery phase of anesthesia, the occurrence of stress peaks is possible [3]. In order to address this problem, an intramedullary nail was developed in cooperation with the fzmb GmbH and Königsee GmbH. Intramedullary nailing has been discussed and tested for equine fracture repair several times [2, 4, 6, 7]. But the main application were foals and young horses and the implant dimensions were adapted from human osteosynthesis. In the newly developed implant especially the diameter is more pronounced. This enables a higher stability for the osteosynthesis. However, especially in diaphyseal fractures, the proximal fragment is sometimes not perfectly supported by the implant alone. The medullary canal has a variable geometry in horses, which is why the implant does not sufficiently fill the cavity in the proximal diapyhsis. As a result, the osteosynthesis is unstable. Instability might lead to large interfragmentary motions under sustained loading, which impairs fracture healing [5]. In this study, it was investigated whether a fracture adjacent reinforcement of the implant influences the biomechanical stability of the osteosynthesis of an equine femur with an intramedullary nail.

2 Materials and Methods

Specimen information

Eight femora were collected from a local horse butchery (Josef Riedl, Straubing, GER). The bones had a length of (460 ± 21) mm (mean ± standard deviation). The bones were stripped of all soft tissue remains and stored at -28 °C. The frozen femora were also CT-scanned to exclude possible damage and to preplan the implant insertion (Radiology, MRI, TUM). Age, sex, race and size of the horses were unknown.

Specimen preparation

Before nail implantation, all thawed femora were first natively tested with 4-point bending. To avoid undesirable positioning of the implant and bone damage, reaming was preplanned. 3D models of the individual femora were extracted with automatic segmentation of CT scans via *Matlab* (The MathWorks Inc., USA) script. The drilling direction was manually defined using the software *Meshmixer* (Autodesk Inc., USA) in order to prevent penetrating through the cortical wall. Boolean operations were used to create drilling templates that fitted precisely on the individual proximal femur. These templates were additively manufactured (Ultimaker 2+, Ultimaker, NL) using standard thermoplastics. Drills with increasing diameter

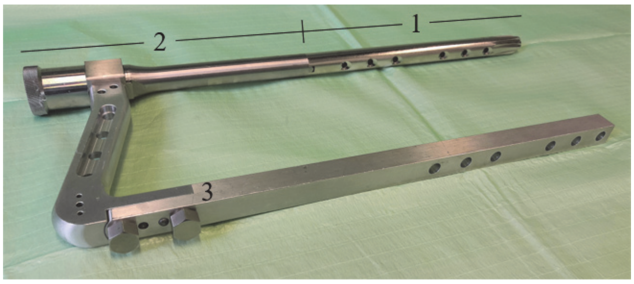

Fig. 1: Intramedullary nail combined with guiding frame for screw fixation. (1) intramedullary nail (length: 275 mm), (2) extension adapter, (3) guiding frame.

up to 25 mm were used to open the medullary cavity. The intramedullary nail (length: 275 mm, diameter: 22 mm, stainless steel, Königsee Implantate GmbH, GER) was connected to a guiding frame (Fig. 1) and inserted into the cavity. Six fixation screws (cortical screws w. conical head thread, diameter: 5.5 mm, stainless steel, Königsee Implantate GmbH, GER) were applied from lateral in accordance with the surgical procedure. A transverse fracture gap (size: 10 mm) was sawed at the middle of the femur. The implant was positioned for the fracture gap to be midway between the third and fourth fixation screw. For reinforcement, a polyurethane(PU)-filled

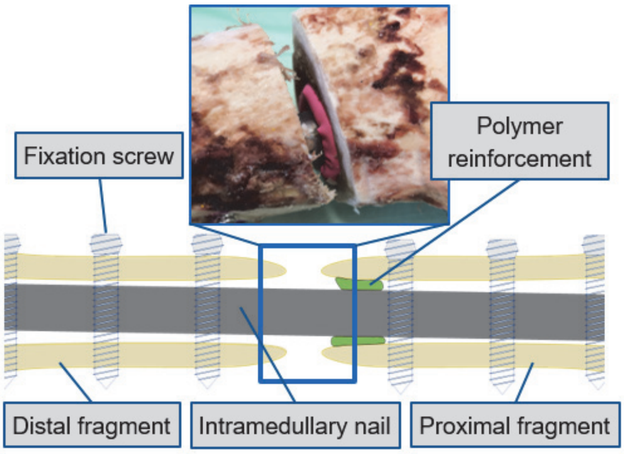

Fig. 2: Support of the proximal bone fragment by insertion of a polymeric reinforcement.

balloon was used to support the proximal fragment (Fig. 2). PU was used instead of standard bone cement due to better availability in the laboratory, since it has similar handling and curing properties as well as comparable mechanical characteristics. Two component PU mixture is introduced into a standard latex balloon during polymerization. Balloon material is chosen to enable precise application. Unwanted bone cement at the fracture surface must be avoided because it impairs the healing process [1]. The flexible balloon is inserted into the proximal fragment via the fracture gap. Positioning the balloon around the nail creates a circular support of the bone after curing. It adapts to the geometry and supports implant position and load transfer. This reinforcement procedure was randomly applied to five out of eight bones. The rest of the bones was provided as reference for comparison.

Testing

The osteosynthesis stability was analyzed with 4-point bending (Fig. 3). Cyclic loading was used to observe the longtime behaviour of the osteosynthesis and the reinforcement, while bending stiffness and load-to-failure were used for evaluation. The bending stiffness of each bone was evaluated five times for up to 1.5 kN. First, native bending prior to implantation

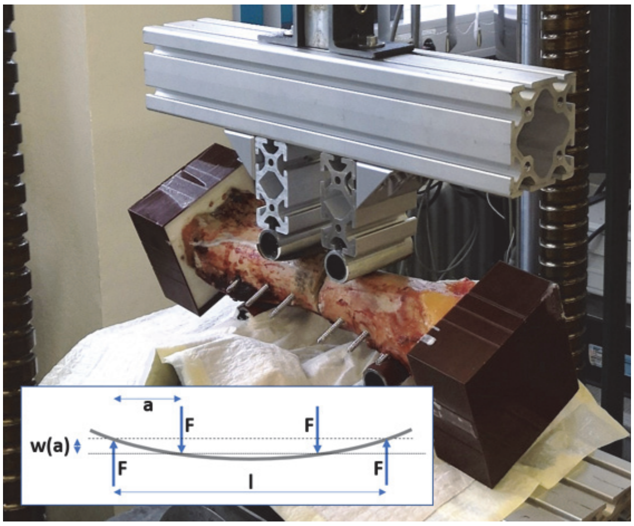

Fig. 3: Setup and schematic for 4-point bending with bone and intramedullary osteosynthesis

was performed (Evaluation point 1: EP1). Second and third evaluation (EP2 and EP3) were before and after the first set of cyclic loading (sinusoidal loading between 1.0 and 2.0 kN, 5 Hz, 100,000 cycles). Then, femora chosen for additional reinforcement were applied with the balloon and kept cool while curing over night. Reference bones were also kept cool over night for comparability. Fourth and fifth evaluation (EP4 and EP5) was performed before and after the second set of cyclic loading for all bones (same loading as before). Immediately after the last set of cyclic loading, a quasistatic 4-point bending load was applied until bone failure occurred (EP F). Bending stiffness *EI* was derived from Bernoulli's beam theory.

$$EI = \frac{F}{6w(a)} \cdot (3a^2 l - 4a^3) \qquad (1)$$

As visualized in the sketch of Figure 3, *F* corresponds to half of the machine force in symmetric 4-point bending, while *a* is the horizontal distance between upper and lower bearing

Tab. 1: Grouped bending stiffness and maximum torque (mean ± standard deviation in Nm^2/Nm) at the evaluation points (EP1: native, EP2 und EP3: before and after the first set of cyclic loading, EP4 and EP5: before and after the second set of cyclic loading, EP F: load-to-failure in Nm).

EP 1	EP 2	EP 3	EP 4	EP 5	EP F
			with polymer reinf.		
121 ± 19	89 ± 25	134 ± 43	94 ± 19	152 ± 27	354 ± 61
			without polymer reinf.		
123 ± 22	66 ± 9	100 ± 11	75 ± 19	108 ± 4	280 ± 44
total					
122 ± 20	81 ± 24	121 ± 38	—-	—-	—-

and *l* is the distance between both lower bearings. $w(a)$ represents the vertical displacement at the upper bearing. In order to test the same anatomical section for all bones, the bearing distances were defined in dependence on the bone size. Pretests have shown a ratio of 23:8:4 (total length of the bone : lower bearing distance : upper bearing distance) for the best possible horizontal bone alignment. This is important to avoid unsymmetrical loading due to discontinuities in the bone geometry. Similar problems were described by Radcliffe et al. [7].

3 Results

The use of additively manufactured drilling templates enabled complication-free implantation at the defined position. Segmentation and transformation into additive manufacturing enabled a clear fit of the templates. No penetration of the cortical bone during drilling was observed. The results of the five evaluation points for the bending stiffness can be found in Table 1. After cyclic loading, the bending stiffness increased in both groups, which is due to setting processes in the implant bone contact area. After balloon application for the reinforcement group and cooling over night for both groups, a stiffness decrease was measured. The stiffness did not reach the level as for EP2. Table 1 shows that the mean maximum torque in the load-to-failure measurement was distinctively higher for the reinforcement group.

4 Discussion

A critical bottleneck for the medullary canal is the fossa supracondylaris. During surgery, care must be taken not to penetrate the bone at this distal position during reaming. Decreasing this risk by reducing the nail diameter is insufficient because the mechanical strength is needed to support the animal weight . Additionally, this isthmus often matches the nail diameter which leads to an increased stability due to cortical bone contact all around the implant. Using the preplanned templates allowed a comparable, defined position for the implant in the femur. Bending stiffness was used as non-destructive test method for comparison of similar geometries. According to beam theory, if the same beam is bent with different support points, the same bending stiffness will result because the moduli of inertia and elasticity are constant along the length of the beam (see equation 1). This is not the case for the bone. Due to varying diameter across the length and the inhomogeneous material properties, the moduli of inertia and elasticity are not constant. Therefore, care was taken to bend the same geometry for comparability by determining the support point

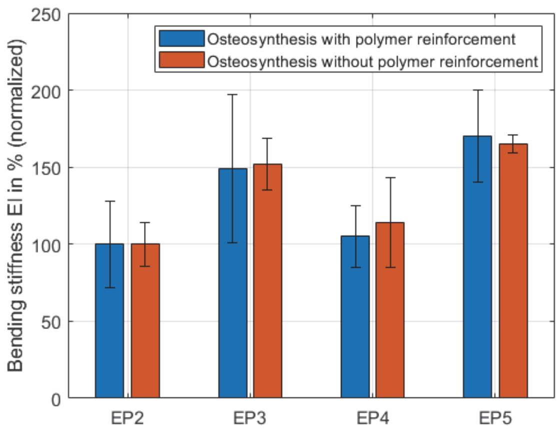

Fig. 4: Mean bending stiffness EI at different evaluation points (EP). EI values are normalized on the mean bending stiffness at the first measurement after implantation (EP2). The groups, which are compared, are equine femora with and without polymer reinforcement of the intramedullary osteosynthesis before EP4.(EP2 und EP3: before and after the first set of cyclic loading, EP4 and EP5: before and after the second set of cyclic loading)

positions as a function of the bone length. The lower support distance varied in a range of 18 mm. A lower bending stiffness was measured after implantation compared to intact bone. Combining the two groups, the bending stiffness is about 66% of intact bone in the first measurement. Radcliffe et al., who were also testing the structural stiffness of equine osteosynthesis with an intramedullary nail in the femur via 4-point bending, achieved only 32% of the intact bone measure [7], which might be due to a smaller nail diameter (12.5 mm). Figure 4 shows the development of the stiffness of the two groups over EP2 to EP5. After the last set of cyclic loading a distinctive increase of the bending stiffness is measured again. Figure 4 indicates the two groups behave very similar. It is striking that no stiffening can be recorded for the group with the reinforced osteosynthesis after the application of the balloon. Even in comparision with EP2 no distinctive stiffness increase can be observed for EP4. This suggests that after the cyclic loading, the stiffness is increased by fatigue processes. A conditioned state is reached at exactly this position. As soon as the specimen is moved afterwards, this state is left and the stiffness is reduced again, unaffected by the reinforcement. Even though the balloon application does not seem to have an effect on the bending stiffness in the lower loading regime, it did impact the failure load for the bone-implant constructs. The maximum torque was 26% higher for the reinforced osteosynthesis compared to the osteosynthesis without balloon application (EP F). The supportive ring around the implant prevents the proximal bone from reaching an extreme relative angle to the implant. Thus the force is more widely distributed over the bone and higher loading is possible. This is very important for the sufficiency of internal fixation as overloading is a critical problem for the equine fracture repair in the femur. Nevertheless, the unequal and limited group size must be mentioned as a limitation of this study. Before a transfer to surgery is possible, further investigations are necessary.

5 Conclusion

A flexible circular support for the intramedullary nail in the proximal fragment of the equine femur was analyzed in this study. The application resulted in a higher torque in the load-to-failure measurement for the osteosynthesis. For the stability in the lower loading range no distinctive effect was observed in this study. The application of CT-based, additively manufactured templates enabled sufficient positioning of the implant. This increased the comparability of the test specimen. Nevertheless, before the reinforcement with the described method should be considered in case of an open femur fracture, a cadaver study with bone cement and biocompatible balloon materials should be performed.

Author Statement

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