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Ex vivo postimplantation biomechanical properties of a press-fit cementless femoral stem with transfixation pin for canine total hip replacement

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OBJECTIVE

To compare ex vivo postimplantation biomechanical characteristics of 3 implants for canine total hip replacement: a cementless press-fit femoral stem with a pin in the femoral neck (p-pfFS), a press-fit cementless femoral stem without this pin (pfFS), and a cemented femoral stem (cFS).

SAMPLE

18 cadaveric femurs from 9 dogs.

PROCEDURES

Femurs were assigned randomly to 3 groups, and biomechanical testing was performed by measuring vertical displacement during cyclic loading and resistance to failure with compression parallel to the longitudinal axis of the femur. Force-displacement curves were assessed for failure tests, and work necessary for failure was calculated.

RESULTS

No significant differences were observed in vertical displacement during cyclic loading ($P = .263$) or work necessary for failure ($P = .079$). Loads to failure for cFS and p-pfFS implants were significantly greater than that for the pfFS, but no significant difference in load to failure was observed between cFS and p-pfFS implants ($P = .48$).

CLINICAL RELEVANCE

Cementless femoral stems with a transfixation pin offer significantly greater immediate resistance to failure to compressive loads parallel to the longitudinal axis of the femur than standard cementless stems, and a level of stability comparable to that of cemented stems. p-pfFS implants may be valuable in total hip replacement, potentially reducing the risk of fracture during the early postoperative period prior to osteointegration.

Total hip replacement (THR) is the surgical treatment of choice for large adult dogs with hip osteoarthritis when medical treatment is no longer effective, with THR leading to recovery of hip joint function in 85% to 95% of cases.^{1,2} Implant stability is essential during the early postoperative period and depends on factors such as the shape and material of the implant, and properties of the surrounding bone.^{3,4} Historically, cemented prostheses for THR were the first prostheses released on the veterinary market. With these prostheses, the femoral stem is fixed in the bone by adhesion with polymethyl methacrylate cement (PMMA). After polymerization of the cement, the primary stability is excellent,⁵ and short-term clinical outcomes are generally good to excellent in 84% of cases, with middle- and long-term

complication rates ranging from 7% to 22%.⁶⁻⁸ Aseptic loosening is the main concern with cemented implants, although the exact etiology of this complication remains unclear.⁹ It is one of the main complications reported in surviving animals and postmortem studies, and there is a high rate of signs of radiographic changes at 8 weeks after surgery or necropsy, affecting 63.7% of dogs studied.^{7,10,11} Tyson et al¹² reported that revisions of THRs performed with cemented implants were mostly a result of aseptic loosening. Infection is now recognized as multifactorial¹³ and cannot be linked specifically to the use of PMMA. However, in a meta-analysis¹⁴ of studies involving human patients, the authors suggested that use of cement was associated with an increased risk of periprosthetic infection.

To avoid these limitations, cementless femoral stems have been developed. With these prostheses, primary stability is achieved by press-fit fixation and is based solely on the force of friction. The stem is usually made of titanium and is covered by a porous material composed of hydroxyapatite, cobalt-chromium, or titanium to promote osteointegration, which leads to long-term stability. A return to normal function has been reported in 80% to 88% of cases.^{15,16} Cementless femoral stems have several advantages compared with cemented stems, including shorter surgical time, lower risk of infection, and decreased risk of long-term implant loosening.¹⁵ However, during the osteointegration period, excessive loading may lead to excessive micromotion, which can disrupt the stroma and lead to delayed bone healing.¹⁷⁻¹⁹ Subsidence has been commonly reported as a short-term complication in clinical studies of cementless implants.¹⁵

To overcome complications associated with a lack of stability during the early postoperative period, manufacturers of cementless implants have designed new types of femoral stems with a lateral interlocking bolt to increase primary stability.^{20,21} In line with these results, a new implant was designed that combined a standard cementless femoral stem with a hole in the long axis of the neck of the stem, permitting the addition of a transfixing pin that passes through the prosthesis, beginning distal to the greater trochanter and extending to the lateral aspect of the femur. It was hypothesized that the addition of this transfixation pin would reinforce the cementless system, limiting torsion and compression during osteointegration.

The objective of our study was to compare *ex vivo* postimplantation biomechanical characteristics of 3 implants for canine THR: a cementless press-fit femoral stem with a pin in the femoral neck (p-pfFS), a press-fit cementless femoral stem without this pin (pfFS), and a cemented femoral stem (cFS). We hypothesized that p-pfFS implants would have a resistance to failure greater than that for pfFS implants but similar to that for cFS implants.

Materials and Methods

Femur preparation

Both femurs were harvested from 9 middle-aged adult dogs (mean \pm SD body weight, 23.45 \pm 5.22 kg) that had been euthanized for purposes unrelated to our study. Five dogs were males and 4 were females. The animal research ethics committee approved the study (No. 2160 Jacques Bonnod's ethical committee VetAgro-Sup 14/09/20). The muscles and tendons were detached from the bones, and the absence of bone disease was assessed by direct evaluation of the bones during dissection. Mediolateral and craniocaudal radiographs of the bones were obtained to confirm the absence of bone diseases, to measure the femoral length (corresponding to the distance between the trochanteric fossa proximally and the intercondyloid fossa distally), to measure the proximal femoral diameter (corresponding to the

diameter of the femur at the proximal third of the femoral length), and to validate that the standard stem size available for the study (7.5 mm) would fit. The bones were then wrapped in towels soaked with 0.9% sodium chloride solution, placed in congelation bags, and stored at -20°C until implantation. The femurs were assigned randomly to 3 femoral stem groups (6 femurs/group); care was taken so that both femurs of a single dog were not included in the same group.

Surgical implants

Three types of femoral stem implants obtained from a single manufacturer (PorteVet) were used in the study. The cFS implant was made with titanium ISO 5832-8, the distal part of the stem was flattened in a craniocaudal direction, and the distal extremity was teat-shaped; its widest diameter at the level of the proximal part of the stem was 7.5 mm (**Figure 1**). The pfFS implant was made with titanium ISO-5832-8 and had the same design as the cFS implant, except that the proximal part of the stem was coated with porous titanium for osteointegration (thickness, 0.25 mm). Therefore, the widest diameter was 8 mm. The p-pfFS implant had the same design as the pfFS, with the addition of a pin hole from the end of the femoral neck to the lateral area of porous coating, passing through the middle of the femoral neck. The pin hole had a diameter of 2.1 mm and allowed a 2-mm-diameter stainless steel 316L pin to pass through the prosthesis, ending at the level of the lateral aspect of the femur distal to the greater trochanter.

Surgical technique

The femurs were defrosted at room temperature for 12 hours prior to implantation. The implantation protocol was the same for all implants and met the manufacturer's recommendations. All femoral stems were implanted by a single board-certified surgeon (TC).

For the cFS implants, ostectomy of the femoral head and neck was performed with a 10-mm oscillating saw and lateralized guide. A 3-mm-diameter hole was drilled parallel to the anatomic axis of the femur in the intertrochanteric fossa, and the hole was enlarged with a bone rongeur. Initially, the femoral shaft was power reamed, increasing the femoral shaft diameter, then a rasp was used until the femoral stem would fit. A cement restrictor plug was placed in the bottom of the reamed shaft, and radiopaque bone cement (medium viscosity PMMA CMW3; DePuy) was placed in the femoral shaft with a 50-mL syringe. The femoral stem was then placed, and the specimen was observed visually to ensure that the anteversion angle did not change during polymerization.

For the pfFS implants, the same protocol was used until a size 7.5 reamer would fit. The implant was then inserted in the femoral shaft with a hammer for impaction. Particular attention was made to prevent iatrogenic fractures of the proximal part of the femur during implantation.

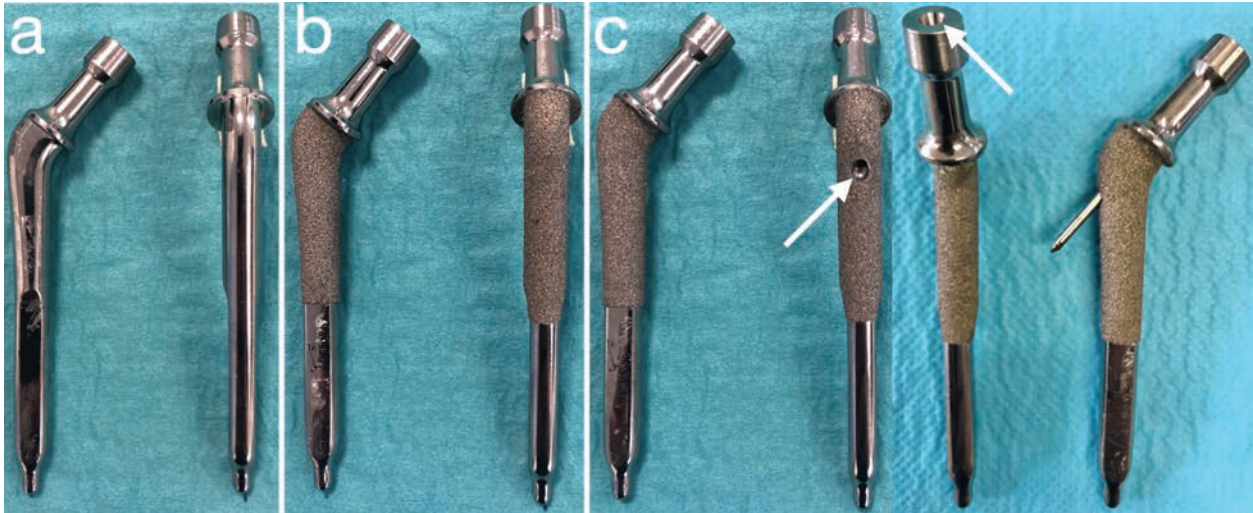


Figure 1—Photographs of 3 femoral implants used for canine total hip replacement. A—A cemented femoral stem. B—A press-fit cementless femoral stem. C—A cementless press-fit femoral stem with a hole through the femoral neck (arrows) allowing for placement of a transfixation pin.

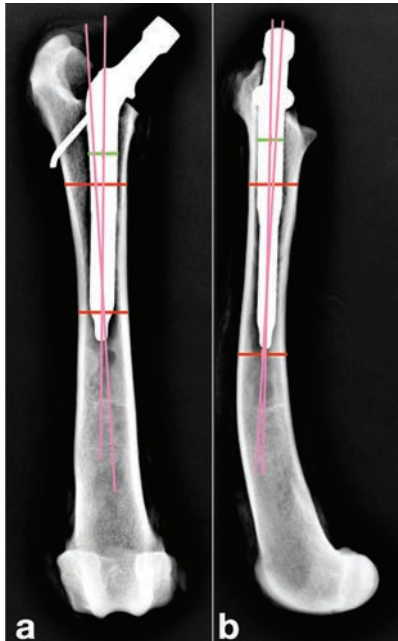


Figure 2—Craniocaudal (A) and mediolateral (B) radiographs of a cadaveric canine femur after implantation of a cementless press-fit femoral stem with a transfixation pin. The red lines represent the femoral shaft diameter; the green lines represent the diameter of the proximal portion of the femoral stem. The angle between the pink line passing through the middle of the red lines and the pink line between the middle of the green line and the middle of the distal red line represents the varus-valgus angle (A) or the craniocaudal angle (B).

For the p-pfFS implants, the same protocol as for the pfFS implants was used. After implantation of the stem, a pin was inserted in the femoral neck, exiting the lateral cortex of the femur just distal to the greater trochanter. The pin was then cut at both

extremities and was positioned appropriately in the femoral head.

The absence of fracture after implantation was assessed by careful observation of the external state of the bone. To confirm the absence of fracture after implantation, craniocaudal and mediolateral digital radiographs were obtained. To ensure accurate positioning of the femoral stem and repeatability of the biomechanical assays, the varus-valgus and craniolateral angles were calculated.^{22,23} On the craniocaudal and mediolateral radiographs, the angle between the long axis of the stem and the proximal anatomic axis of the femur was recorded to calculate the varus-valgus and craniocaudal angles, respectively (**Figure 2**). Femoral heads (diameter, 16 mm; angle, +0°) were then placed on each femoral stem with a head impactor.

Biomechanical assays

After implantation of the femoral stems, 2 dots (in the proximal third and mid-diaphysis of the femur) were drawn in perpendicular planes in the middle of the cranial and lateral aspects of the bone. The distal portions of the femurs were potted in 60- X 40-mm polyvinylchloride tubing with synthetic polyurethane polymeric resin (Resine Axson; ETS Vaillat SAS). Two orthogonal, vertical laser-optic measuring tools (Laser Level; Bosch Quigo) that joined the dots were used to ensure proper positioning of the femurs, with the proximal anatomic axes positioned vertical to the ground. After polymerization of the resin, the polyvinylchloride tubes were cut and removed.

A unidirectional servohydraulic press was used for biomechanical testing (AGS X-series; Shimadzu). The specimens were fixed distally to a specially designed base that could move in all directions in the horizontal plane and were fixed proximally to a manufactured cup for the femoral head that fit the diameter of the femoral head. The specimens were positioned so that the direction of the compression

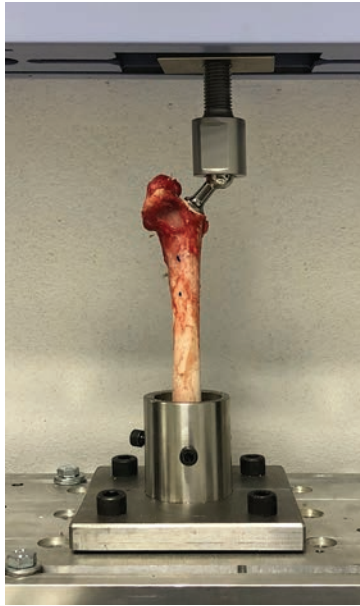


Figure 3—Photograph of a cadaveric canine femur after implantation of a femoral stem. The specimen has been positioned in a servohydraulic press for biomechanical testing. The base can move in all directions in the horizontal plane, permitting alignment with the manufactured cup that receives the femoral head.

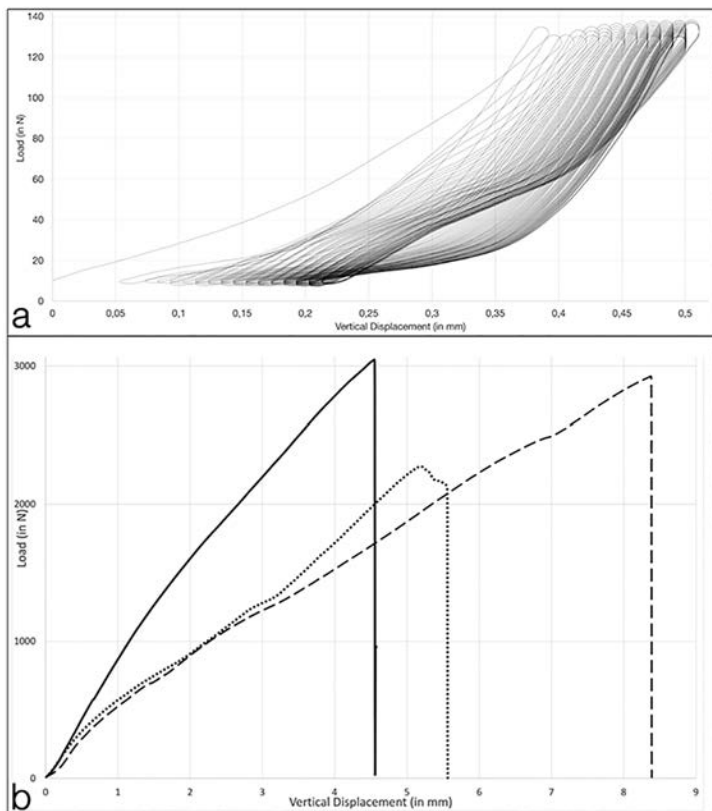


Figure 4—Examples of the load-displacement curves generated during cyclic testing of a cadaveric canine femur implanted with a cemented femoral stem (A) and during load-to-failure testing of cadaveric canine femurs implanted with a cemented femoral stem (solid line), a press-fit cementless femoral stem (dotted line), or a cementless press-fit femoral stem with a transfixation pin (dashed line; B).

force was parallel to the longitudinal axis of the femur (**Figure 3**).

The femurs were first subjected to cyclic testing. The system was initially preloaded to a compression of 10 N. Then, 90 cycles of axial compression were performed at 75% of the body weight of the dogs (mean \pm SD, 182 \pm 36.4 N), as suggested previously,^{24,25} at a vertical displacement of 0.2 mm/second. A cycle corresponded to loading from the preload value to the peak load and then back to the initial preload (**Figure 4**). The vertical displacement corresponded to the value at the end of the cycles, relative to the start. After the cyclic assays, the femurs were loaded to failure, with a uni-directional load applied at a rate of 0.2 mm/second. The load to failure was defined as a sudden drop in force on the force-displacement curve.

For both the cyclic and resistance-to-failure tests, data were recorded at 100 Hz with the manufacturer's software (Trapezium X; Shimadzu). After the failure tests, the type and location of fractures were recorded with digital photographs. A force-displacement curve was then plotted for each femur. The work necessary for failure was calculated as the area under the force-displacement curve (Excel OSX version 16.32; Microsoft Corp).

Data analysis

Descriptive statistics were calculated. The Shapiro-Wilk test indicated that data were not normally distributed. Therefore, the Kruskal-Wallis test followed by the Wilcoxon rank-sum tests was used to test for differences among groups. The Pearson correlation coefficient was calculated to test for possible correlations between craniocaudal angle and load to failure, and between varus-valgus angle and load to failure. Analyses were performed with standard software (R 3.5.2 GUI 1.70 El Capitan build; R Foundation for Statistical Computing); values of $P < .05$ were considered significant.

Results

Examination of the preimplantation digital radiographs revealed normal conformation of the femurs and closure of all growth plates. The mean \pm SD proximal femoral diameter was 19.4 \pm 1.4 mm, which was sufficient for implantation of the femoral stems. No fractures were created during implantation of the p-pfFS or pfFS implants, or during positioning of the transfixation pin. All pins were positioned in the target area, distal to the greater trochanter, without modifications of the stem's anteversion angle. On postimplantation radiographs, no fractures were identified in any of the femurs, and PMMA was distributed homogeneously around the stem in the femoral shaft in the cFS group. No femoral stem was positioned with valgus or caudal angulation.

Table 1—Mean \pm SD craniocaudal angulation, varus-valgus angulation, and results of cyclic and load-to-failure testing for cadaveric canine femurs ($n = 6/\text{group}$) implanted with a cemented femoral stem (cFS), a press-fit cementless femoral stem (pfFS), or a cementless press-fit femoral stem with a transfixation pin (p-pfFS).

Variable	cFS	pfFS	p-pfFS
Craniocaudal angulation ($^{\circ}$)	3.21 ± 2.04	2.99 ± 0.85	2.88 ± 1.444
Varus-valgus angulation ($^{\circ}$)	2.37 ± 0.69	2.18 ± 0.86	2.10 ± 0.87
Load to failure (N)	$3,542.52 \pm 1,426.45$ a ^a	$1,774.64 \pm 683.38$ ab	$2,856.62 \pm 675.88$ b
Work necessary for failure (J)	10.39 ± 6.26	4.89 ± 2.04	10.48 ± 3.39
Vertical displacement on cyclic testing (mm)	0.41 ± 0.24	0.42 ± 0.15	0.30 ± 0.16

^aValues with the same letter were significantly different ($P < .05$).

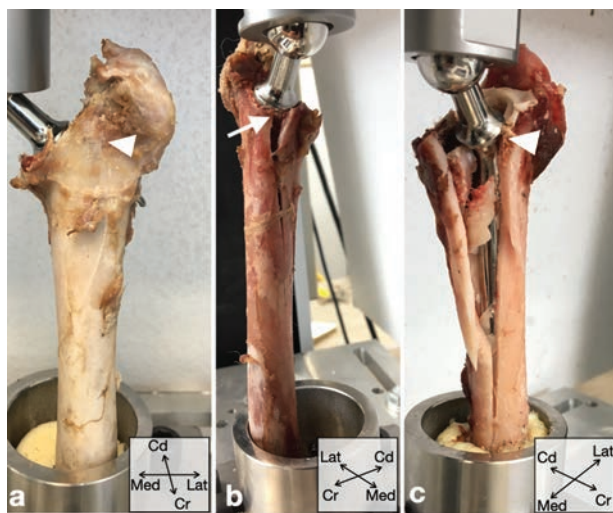


Figure 5—Photographs of cadaveric canine femurs implanted with a cementless press-fit femoral stem with a transfixation pin (A), a press-fit cementless femoral stem (B), or a cemented femoral stem (C) and loaded to failure. All 3 specimens fractured. The origin of the fracture is on the cranial aspect of the femur, with the fracture extending in a mediolateral direction (arrowhead; A and C) or on the medial aspect of the femur at the level of the stem collar (arrow; B). Cd = Caudal. Cr = Cranial. Lat = Lateral. Med = Medial.

No significant differences in varus-valgus ($P = .65$) or craniocaudal ($P = .81$) angles were observed among groups (**Table 1**). For all femurs considered together, no correlation between varus-valgus angle and load to failure ($P = .09$, $r = 0.40$) or between craniocaudal angle and load to failure ($P = .08$, $r = 0.41$) was observed. Similarly, when each group was considered separately, there was no correlation between varus-valgus angle and load to failure for the cFS ($P = .130$, $r = 0.71$) and p-pfFS ($P = .65$, $r = 0.25$) implants, and no correlation between craniocaudal angle and load to failure for the cFS ($P = .053$, $r = 0.80$), pfFS ($P = .56$, $r = 0.29$), and p-pfFS ($P = .55$; $r = 0.30$) implants. There was a significant correlation between varus-valgus angle and load to failure for the pfFS implants ($P = .03$, $r = 0.84$). No significant correlation between load to failure and proximal femoral diameter ($P = .73$, $r = 0.08$) was observed.

Vertical displacement in cyclic testing did not differ significantly ($P = .26$) among groups, nor did work necessary for failure ($P = .079$; **Table 1**). Load to

failure differed significantly among groups ($P = .03$), with loads to failure for the cFS ($P = .025$) and p-pfFS ($P = .041$) groups significantly greater than load to failure for the pfFS group. No significant difference in load to failure was observed between the cFS and p-pfFS groups ($P = .48$; **Supplemental Figure S1**).

In all 3 groups, fractures that occurred during load-to-failure testing were long oblique fractures. In the cFS and p-pfFS groups, the fractures were located on the cranial aspect of the femur and oriented in a mediolateral direction, whereas in the pfFS group, the fractures were located on the medial aspect of the femur, with the origin of the fractures at the press-fit femoral stem collar (**Figure 5**).

Discussion

The results of our study indicate that p-pfFS implants offer a significantly greater immediate load to failure than standard pfFS implants, without a significant difference between implant types with regard to vertical displacement during cyclic assays. We conclude that p-pfFS implants may be valuable in canine THR, potentially reducing the risk of fracture during the early postoperative period prior to osteointegration.

Similar to results of a previous study,⁶ the cFS implants in our study had a significantly greater load to failure than the pfFS implants. High resistance to failure resulting from immediate primary stability is well known for cemented THR systems,²⁶ and this is made possible by the cohesive action of the PMMA, which acts as grout. Bone cement penetrates the irregular microscopic grooves of the reamed bones, increasing resistance to shear forces at the interface. However, cement acts as a foreign body, potentially causing an inflammatory response and increasing the risk of aseptic loosening.²⁷

With pfFS implants, the initial fixation is obtained by press-fitting an oversized femoral stem in the femoral shaft to create primary stability through frictional forces.²⁸ Because the stiffness of the implant is greater than that of the bone, there is overloading of the implant and stress shielding of the bone.²⁸ The results of our study were in agreement with those reported previously.^{20,21} In the study by Buks et al,²⁰ the work necessary for failure, defined as failure energy in their report, was 4.198 ± 6.047 J (mean \pm SD) for a standard cementless femoral stem

and 9.579 ± 6.076 J for an interlocking cementless stem. The work necessary for failure in our study was less for the pFFS (4.89 ± 2.04 J) implants than for the cFS (10.39 ± 6.26 J) and p-pFFS (10.48 ± 3.38 J) implants, even though significant differences were not identified. These differences may be related to the lack of strong primary fixation with the p-pFFS implants. The addition of a transfixation pin in the neck of a pFFS in our study allowed for a significant increase in load to failure. Buks et al²⁰ compared subsidence of a standard pFFS and an interlocking femoral stem, and the peak load to failure was significantly greater for the interlocking femoral stem than for the standard pFFS (2.337 ± 782 N vs 1.405 ± 712 N, respectively). In that study,²⁰ resistance to subsidence was greater with a transfixing neutral rod and pFFS than with a standard pFFS. Their findings were in concordance with those of a clinical radiographic study by Mitchell et al,²⁹ in which radiographic subsidence was calculated for various pFFS implants with and without a lateral bolt. The lateral-bolt femoral stem was associated with less subsidence during the postoperative period than the standard stem. The rod strengthens the system by limiting compressive and torsional forces during axial loading, increasing the stability of the system significantly without the need for additional complex surgical procedures.²⁹ Similar to results of the studies by Ordway et al²¹ and Buks et al,²⁰ our results were encouraging, with the p-pFFS implant similar to the cFS implant in terms of immediate resistance to failure, with a similar magnitude of work necessary for failure. Subjectively, the pin could be placed easily and quickly in the lateral cortex of the femur without inducing fracture or altering the stem's anteversion angle, emphasizing the feasibility of the surgical technique. The procedure appeared to be less complicated than that for other hybrid implants, such as interlocking femoral stems. Importantly, however, there are no data on how well the pin stays in place in the long term or whether micromotion of the stem during gait could move or break the pin, and the potential for migration has yet to be determined. In this preliminary study, the pin was held by friction in the neck of the stem without other fixation; p-pFFS implants are currently being developed with a thread in the neck of the stem to allow the pin to be screwed into place, potentially preventing its potential migration. It is nevertheless essential to perform the drilling procedure with care to prevent damage to the sciatic nerve, which is close to the surgical site.³⁰

Proper positioning of the femoral stem is a critical aspect during THR as well as during biomechanical assays, and is strongly related to the surgeon's skills at the moment of positioning and impaction of the stem.²² In our study, all stems were implanted by a single experienced, board-certified surgeon (TC). All stems were well positioned with varus-valgus and craniocaudal angles in concordance with those reported in the literature,²² and no significant differences among groups. These parameters need to be assessed before biomechanical testing is performed. If only subjective eye evaluations are performed

after implantation, slight differences in angulation could affect the final results. It has been shown that varus angulation of the femoral stem $\geq 5^\circ$ leads to an increased risk of fracture intraoperatively. The medial position of the proximal part of the femoral stem overloads a common site of fractures: the craniomedial portion of the proximal femur.²² All the fractures in our study were long oblique fractures and were similar to fractures generally observed as a natural complication.³¹ However, the location of the fractures differed among groups. In the pFFS group, the fractures were on the medial aspect of the femur, with their origin on the craniomedial part of the proximal femur. This location represents the most common site of fracture, and it is generally a result of the varus angulation of the femoral stem.^{22,23} Although no femur had a varus-valgus angle $> 5^\circ$ in our study, there was a correlation for pFFS implants between varus-valgus angulation of the femoral stem and load to failure. We believe that pFFS implants could be more subject to the influence of angulation than cFS and p-pFFS implants, and the absence of a uniform force distribution might cause fractures in this area. During failure tests, the stem might tilt in relation to the femoral shaft, increasing its varus angulation and resulting in failure. Unfortunately, no digital images were available to measure vertical displacement during the load-to-failure tests. In the cFS and p-pFFS groups, the fractures were located on the cranial aspect of the femur. Because the position of the stems was similar in the pFFS and p-pFFS groups, we assume that the increase in resistance to failure for the p-pFFS group can be linked to the additional pin in the femoral stem.

The aim of cyclic testing in our study was not to imitate the immediate postoperative gait of a dog after surgery, but rather to prestress the femur before the load-to-failure test. Immediately postoperatively, dogs walk approximately 1,500 steps,³² whereas in our study, cyclic testing consisted of only 90 cycles. Considering the relatively low number of cycles, the load was set to be 75% of the dog's body weight, which corresponds to the reaction force of a dog at trot.^{24,33} Still, no significant difference in vertical displacement was observed among groups. Vertical displacement is expected during cyclic testing and can be understood as immediate postoperative subsidence. It is normal to expect subsidence of 1 to 2 mm with pFFS implants, and subsidence > 3 mm can lead to complications.²³ These results validate the reliability of the new implant and demonstrate that the new implant yields the same displacement as the other implants. Our results are concordant with those of Buks et al,²⁰ who found that the vertical displacement after cyclic loading was 0.79 ± 1.21 mm and 0.35 ± 0.41 mm, respectively, for the standard pFFS and the interlocking nail femoral stem.

Our study had several limitations. Use of a standard size for the femoral stem was a limitation. However, it appears that canal filling by femoral stems is a poor indicator of the correct stem size and has poor clinical relevance.²² The relatively low number of femurs studied influenced our statistical results

and may not characterize precisely the immediate postoperative period in living dogs. All dogs enrolled in the study were middle-aged adults with no macroscopic osseous disease or osteoporosis. However, because exact ages were not known, the population may not have been homogeneous. Notably, biomechanical testing is a simplification of what truly occurs in nature, and the femurs in this study were not subjected to physiologic forces encountered during normal canine gaits. Specifically, the actions of the gluteal and adductor muscles and the resulting rotational and shear forces were not taken into account during our biomechanical testing, and the axis of the femur during the compression tests did not correspond to the physiological axis of the femur during weight-bearing in life. Additional studies, especially under cyclic conditions and then in vivo, are mandatory to evaluate the results of implantation of a neutral femoral stem in the short, mid, and long term.

In our study, immediate postimplantation biomechanical behaviors were compared among 3 femoral stem implants: a cFS, a pfFS, and a p-pfFS. Our results show that the addition of a transfixation pin improves the immediate resistance to failure for a pfFS to a level similar to that for a cFS.

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Supplementary Materials

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