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Effect of stem sizing and position on short-term complications with canine press fit cementless total hip arthroplasty

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Abstract: OBJECTIVE: To determine the influence of stem sizing and positioning with early subsidence and stem complications with cementless (BFX) total hip arthroplasty (THA). STUDY DESIGN: Retrospective case series. ANIMALS: Fifty-five dogs; 58 THAs. METHODS: Eighty cobalt-chromium BFX THAs were reviewed, 58 met inclusion criteria. Implant size, positioning, and major complications within 12 months of surgery were recorded. Femoral canal flare (FCF), canal fill, stem angle, and subsidence at 3 months were measured from postoperative radiographs. Appropriateness of final stem size was assessed with digital templates. Odds ratios for associations were calculated. RESULTS: Mean ± SD coronal canal fill (Fillcor) was 75% ± 6, FCF was 2.0 ± 0.3, and subsidence was 1.7 mm ± 2.6. Stem angulation ranged from 7° varus to 6° valgus, and 7° cranial to 3° caudal. Appropriately sized stems (n = 45) had a mean Fillcor of 78%. Major stem complications occurred in 12% of THAs. Femora with subsidence > 3 mm were 45.3 times more likely to develop postoperative stem complications (P = .02). Stems with varus angulation 5° were 12.5 times more likely to sustain intraoperative fissures (P = .03). Stems considered undersized based on postoperative digital templating were 5.6 times more likely to develop stem complications (P = .04) and 5.7 times more likely to subside > 3 mm (P = .03). CONCLUSION: Varus stem angulation should be avoided to prevent fissures. Canal fill is a poor indicator of optimal stem size and the current recommendation of >85% is unnecessarily high. Postoperative templating may be useful for assessing appropriateness of stem size.

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Effect of Stem Sizing and Position on Short-term Complications with Canine Press Fit Cementless Total Hip Arthroplasty

Abstract:

Objective: To investigate the relationship between stem sizing and positioning with early subsidence and stem complications with cementless (BFX®) total hip arthroplasty (THA).

Study design: Retrospective case series

Animals: 55 dogs; 58 THAs

Methods: Eighty cobalt-chromium BFX® THAs were reviewed, 58 met inclusion criteria. Implant size, positioning, and major complications occurring up to 12 months post-operatively were recorded. Femoral canal flare (FCF), canal fill, stem angle and subsidence at 3 months were measured from post-operative radiographs. Appropriateness of final stem size was assessed with digital templates. Odds ratios for associations were calculated.

Results: Mean ± SD coronal canal fill ($Fill_{cor}$) was 75% ± 6, FCF was 2.0 ± 0.3 and subsidence was 1.7 mm ± 2.6. Stem angulation ranged from 7° varus to 6° valgus, and 7° cranial to 3° caudal. Appropriately sized stems (n=45) had a mean $Fill_{cor}$ of 78%. Major stem complication rate was 12%. Femora with subsidence > 3mm were 45.3 times more likely to have post-operative stem complication (p=0.02). Stems with varus angulation ≥ 5˚ were 12.5 times more likely to have intra-operative fissuring (p=0.03). Stems considered undersized by postoperative digital templating were 5.6 times more likely to have stem complications (p=0.04) and 5.7 times more likely to subside > 3mm (p=0.03).

Conclusions: Varus stem angulation should be avoided due to higher risk of fissuring. Canal fill is a poor indicator of optimal stem size and the current recommendation of > 85% is unnecessarily high. Post-operative templating may ~~provide a suitable alternative for~~be useful for assessing ~~ment of~~ appropriateness of stem size. ~~Templating may provide a suitable alternative for assessment of stem size.~~

Introduction:

Total hip arthroplasty (THA) is an established and reliable treatment method for dogs with coxofemoral osteoarthritis (OA). One of the most commonly used cementless THA systems, the BFX® (BioMedtrix, Boonton, NJ) THA, relies on generating a tight press fit mechanism to achieve sufficient friction at the bone-implant interface. Early and appropriate press-fit stability allows for ~~bone~~ osseointegration, which is subsequently responsible for long term implant stability.[1] It is thought that highly accurate stem sizing and positioning are critical for a successful outcome, and strict surgical technique-related guidelines have been developed to minimize the complication risk associated with THAs.[2] These guidelines advocate achieving a mean canal fill of >85% whilst placing the stem in axial alignment in both the sagittal and coronal planes.[2]

Due to the press-fit nature of the cementless THA, there is a risk for femoral fissure formation when using this system,[~~5~~ 3] with reported intra-operative BFX® fissure rates between 4 and 21%.[~~6-8~~4-6] Although, the majority of these fissures can be successfully treated by cerclage wiring,[~~9~~ 7] placement of wires necessitates increasing the size of the surgical approach, lengthens operative time and may slow bony in-growth.[~~5~~3, ~~10~~ 8] Femoral fissures that are not identified intra-operatively may manifest as a complete femoral fracture or create an unstable prosthesis with reduced bony in growth and increased risk of aseptic stem loosening, both of which require surgical revision.[~~5~~ 3]

Previous cadaveric studies in dogs have demonstrated that ~~maligning~~ malalignment of a cementless, press-fit femoral stem is biomechanically detrimental.[~~4~~ 9] Stems placed in varus orientation of ≥5˚ generated up to 50% more strain than those in neutral orientation, which may increase the risk of generating a femoral fissure.[~~4~~ 9] Despite the potential significance of poor stem alignment, the relationship between stem angulation and complications such as femoral fissure formation has not been thoroughly investigated in clinical studies.

Stem sizing with the BFX® THA is dictated by several factors, such as femoral morphology, the quality of trabecular bone and final stem orientation. Subsidence, which is migration of the stem distally within the medullary canal, may be more prevalent with undersized stems.[3-10] Mild subsidence of 1-3 mm is expected in the early post-operative period,[11, 12] however subsidence of > 3mm could reflect a lack of stability, which may predispose to major complications such as femoral fracture and coxofemoral luxation.[64, 13, 14] Numerous clinical studies have attempted to identify risk factors for subsidence[1, 35, 76, 810]; however, associations between early subsidence, stem sizing, and the development of complications remain unclear. Additionally, all previous clinical studies on BFX® THA utilize percent canal fill to reflect stem sizing, and this measurement may not accurately represent whether the stem is appropriately sized and therefore the role of stem sizing in development of subsidence or complications is unclear.

The purpose of this study was to investigate the relationship between precision of stem placement with subsidence at 3 months and major stem complications occurring up to a year post-operatively using the BFX® THA. As a secondary objective, we investigated the compared the appropriate stem size based on pre-operative digital templating against the actual stem size used. We hypothesized that under-sized stems and malaligned stems would be associated with the development of major stem complications and subsidence. We also hypothesized that pre-operative digital templating was an accurate method of predicting final stem size used.

Method and Materials:

Inclusion criteria:

Dogs that underwent THA using the BFX® cementless system with a cobalt-chromium stem between January 2007 and December 2014 were reviewed. Dogs without 3 month post-operative recheck radiographs, radiographic calibration markers or where no follow-up information > ~~1 year~~12 months post-operatively was available were excluded. Reason for procedure, age, breed and weight were obtained from the medical record. In dogs that underwent bilateral THAs, each hip was evaluated as a separate case and referred to as such during the analysis. Telephone follow-up > ~~1 year~~12 months following surgery was also performed for all dogs.

Surgical Procedure:

One of 2 experienced board-certified surgeons led each surgery, assisted by residents. Surgery was performed using the recognized standard technique, as previously described (BioMedtrix universal canine hip system. Surgical technique for BFX® cementless implants, BioMedtrix, Boonton, New Jersey. Released August 28, 2007). Final implant size was determined by a combination of pre-operative digital templating and intra-operative assessment.

Radiographic evaluation:

Radiographic evaluation was performed on immediate post-operative and 3-month post-operative radiographs, or earlier radiographs performed at the time of a major complication. Images were viewed on a dedicated PACS workstation using DICOM viewing software (Merge

Healthcare Inc., Chicago, IL) and exported to an orthopedic planning program (OrthoPlan, Sound™, Carlsbad, CA) for measuring purposes. Radiographic projections used included horizontal-beam craniocaudal (Fig 1a) and open-leg mediolateral views of the femur (Fig 1b). Radiographs were calibrated with either a 100 mm bar or 25 mm sphere and measurements were made by 1 person. The radiographic variables assessed included canal fill in the sagittal plane ($Fill_{sag}$) and coronal plane ($Fill_{cor}$); stem orientation; coronal ($Stem_{cor}$) and sagittal ($Stem_{sag}$) angulation; stem level ($Stem_{LEV}$); and femoral canal flare (FCF) (Fig 1,2).[1, 15] Stem subsidence ($Stem_{SUB}$) was calculated by comparing $Stem_{LEV}$ between immediate and 3 month post-operative radiographs. $Fill_{cor}$ and $Stem_{cor}$ measurements were performed in the craniocaudal view of post-operative and 3 month radiographs (Fig 1), while $Fill_{sag}$ and $Stem_{sag}$ were measured in the mediolateral view (Fig 2). For $Stem_{sag}$, the stem was designated cranial if it was tipped cranially with the distal tip deviated toward the caudal cortex.[15] For dogs with an open trochanteric physis at the time of surgery with subsidence quantified at > 3 mm, the radiographs were further assessed to determine if the apparent subsidence was due to continued proximal growth of the trochanter. This was achieved by assessing the stem position relative to other landmarks, such as the calcar region, trochanteric fossa, and (if present) proximally placed cerclage wire. Femoral canal flare (FCF) was measured on immediate and 3 month postoperative radiographs in the craniocaudal view.

The orthopedic planning program (OrthoPlan, Sound™, Carlsbad, CA) was used to template digital stems for the THA in the craniocaudal and mediolateral views on pre-operative and post-operative radiographs. Digital templating was performed by 1 board certified surgeon. ~~The~~ For postoperative radiographs, the digital templates of four sizes were overlaid on each radiographic view to determine if the implanted stem was appropriately sized, 1 or 2 sizes smaller than optimal or 1 size larger than optimal. Digital templating of the pre-operative radiographs was performed in a blinded manner, with the observer unaware of the actual stem size chosen. The optimal stem size based on pre-operative radiographs was then compared to the optimal stem size based on post-operative radiographs. Optimal stem size was defined as the maximal possible canal fill without encroachment of the implant into the surrounding cortex, when the shoulder of the stem was seated 1 third of the distance into the intertrochanteric fossa as per the surgical technique guidelines.[2]

Major Complications:

Major complications occurring within the first 12 months post-operatively were identified from the medical record, radiographic assessments and through a follow-up phone call > 12 months following the procedure. Definition of a major complication was based on previously proposed criteria.[16] Major complications were classified as either stem related or cup related. Major stem related complications were defined as complications resulting directly from problems with the stem that required surgical management, and included intra-operative femoral fissure formation, intra or post-operative femoral fracture. Post-operative coxofemoral luxation was categorized as a stem related complication when there was concurrent subsidence resulting in relative distal displacement of the stem and when no cup problems could be identified.

Statistical analysis:

All continuous variables were reported as mean ± (standard deviation). Linear correlation between $Stem_{SUB}$ and canal fill ($Fill_{cor}$), FCF and stem orientation on the post-operative radiographs was performed using Pearson Coefficient. Unconditional odds ratios were calculated for subsidence and canal fill and appropriateness of stem size, and complications and subsidence, canal fill, canal flare, stem angulation and appropriateness of stem size. Dogs that had > 3 mm of calculated subsidence that was attributed to on-going growth at the trochanteric physis were not considered to have truly experienced subsidence, and classified as having < 3 mm of subsidence~~not analyzed~~. Three separate categories were used when calculating odds ratios for stem related complications; total stem related complications, intra-operative stem related complications (femoral fissures or fractures) and post-operative stem related complications (femoral fracture and luxation). These were compared to $Fill_{cor}$~~$Fill_{CC}$~~ (< 85% vs ≥ 85%), $Stem_{SUB}$ (≤ 3 mm vs > 3 mm), FCF (< 1.8 vs ≥ 1.8), stem angulation in both views (< 5 ˚ vs ≥ 5˚ deviation from axial alignment) and appropriateness of stem size (stems correctly sized and oversized vs stems undersized). Wilcoxon signed rank test was used to compare the age and body weight between dogs with and without stem complications. Results were considered significant when P<0.05.

Results:

Eighty cobalt-chromium BFX® THAs were performed between January 2007 and December 2014; 55 dogs with 58 THAs met our inclusion criteria. The most common pure breeds represented included Golden Retriever (8), Rottweiler (6), and German shepherd (5). Mean (± SD) age of the dogs was 34.6 months (± 28.3 months) with a mean weight of 32.4 kg (± 7.8 kg). There were 29 neutered males, 16 spayed females, 7 intact males and 6 intact females. There was no significant difference in body weight or age between dogs that did and did not develop major stem related complication.

Complications:

Complications, including intra-operative fissures, occurred in 12/58 (21%) of THAs within the first 12 months post-operatively. Seven (12%) of these were stem related: 4 (7%) intra-operative fissures and 3 (5%) post-operative complications. Post-operative complications included 1 femoral fracture and 2 occurrences of subsidence with luxation. Other complications identified included luxation secondary to poor cup placement (n = 2), aseptic cup loosening (n = 2) and chronic lameness of unknown origin (n = 1).

Seventeen of the 22 THAs that did not meet our inclusion criteria were contacted for follow-up > ~~1 year~~12 months following surgery. Reasons for exclusion included lack of 3 month radiographic evaluation (n=14), lack of radiographic calibration markers (n=5) and occurrence of femoral fracture prior to the 3 month recheck resulting in an inability to make measurements (n=3). Eleven of 17 THAs had no associated complications. Intra-operative fissures ~~occurred~~ were identified in 6, with 3 of these progressing to femoral fracture < 2 weeks post-operatively despite cerclage placement intra-operatively. Long oblique mid-diaphsyeal fractures occurred distal to the most distal cerclage wire in ~~both~~ these cases. These were repaired with a combination of additional cerclage wires and one or more neutralization plates and went on to heal without complication.

Overall, of the seventy-five THAs with follow-up available for greater than ~~1 year~~12 months after surgery, total complications (including intra-operative fissures) occurred in~~-~~ 18/75 (24%). Major complications occurred in 11/75 (15%).

Radiographic findings:

Measurement values for canal fill, canal flare, stem angulation and stem ~~subsidence~~ level are shown in Table 1. Based on postoperative radiographic projections, no stem achieved a $Fill_{AV}$ of ≥85%. Based on 3 month recheck radiographs, 5 stems achieved a $Fill_{AV}$ of ≥85%. In the postoperative radiographs 1 stem had a $Fill_{cor}$ of ≥85%, and 5 stems had a $Fill_{sag}$ of ≥85%. On the 3 month radiographs, 3 stems had a $Fill_{cor}$ of ≥85% and 8 stems had a $Fill_{sag}$ of ≥85%.There was no association between the percent canal fill at either time point and magnitude of subsidence or risk of major complication~~ at either time point~~.

Femoral canal flare of < 1.8 was present in 12 femurs, and these were therefore classified as having a stovepipe femoral morphology. No association between FCF and stem complications or subsidence was identified. Femoral canal flare was also compared to patient age, ~~however~~and no association was identified.

Stem angulation in the postoperative radiographs ranged from 7˚ varus to 6˚ valgus in the craniocaudal view and 7˚ cranial to 3˚ caudal in the mediolateral view. Six stems had a varus angulation of ≥ 5˚, whilst 8 stems had a cranial angulation of ≥ 5˚. Stem angulation in the 3 month recheck radiographs ranged from 8˚ varus to 6˚ valgus in the craniocaudal view and 9˚

cranial to 3˚ caudal in the mediolateral view. Four stems had a varus angulation of ≥ 5˚, whilst 7 stems had a cranial angulation of ≥ 5˚. Femora with the stem placed in a varus angulation of ≥ 5˚ on the postoperative radiographs were 12.5 times more likely to have intra-operative fissuring (p=0.03), there was no association with major post-operative stem complications. Placing the stem in a cranial, caudal or valgus angulation of ≥ 5˚ was not associated with an increased risk of major stem related complication.

Mean ~~Stem~~ stem subsidence was 1.7 ± 2.6 mm ~~had a large range~~ (Range: -1.6 to 15.5 mm). ~~, which was partly due to a single stem undergoing a subsidence of 15.5 mm. This~~ One dog had subsidence of 15.5 mm; this dog had a $Fill_{AV}$ of 83 % and its stem was deemed appropriately sized following templating (Fig 4~~3~~). The cause for the excessive degree of subsidence in this dog was attributed to a failure to restrict the dog's exercise post-operatively. This dog had no clinical signs associated with this large degree of subsidence and was using the limb well at the 3 month recheck and ~~follow-up phone call to the owner~~ > 12 months post-operatively. Twelve stems (21 %) had a negative value for subsidence (range -0.1 to -1.6 mm). Twelve stems (21 %) experienced a subsidence of > 3mm; however, 2 of these stems were deemed not to have truly subsided due to on-going growth at the trochanteric physis. ~~.~~Three stems (5 %) with > 3 mm of subsidence at 3 months post-operatively developed post-operative stem related complications within 1 year following surgery. Femora with a stem subsidence of ≥ 3mm were ~~34~~ 45.3 times more likely to have a major post-operative stem complication (p=0.02). There was no association between the magnitude of subsidence and percent fill, canal flare or stem angle.

Orthopedic templating was performed on the immediate post-operative radiographs of all 58 stems. Forty five (78 %) of the 58 stems were deemed appropriately sized and these stems had a postoperative mean $Fill_{cor}$~~$Fill_{CC}$~~ of ~~78~~ 70.6 % ± 5.4 (range, ~~66~~59.6-~~88~~ 76.9 %) (Fig 4) and a 3 month mean Fill$_{cor}$ of 74.3 % ± 5.4 (range, 69.9-79.1 %). Four stems (7 %) were considered as being 1 size too large, with a postoperative mean Fill$_{cor}$ of 79.1 % (range, 75.4-85.0 %) and a 3 month mean Fill$_{cor}$ of 87.0 % (range, 83.7-92.2 %); 8 stems (14 %) were considered as being 1 size too small, with a postoperative mean Fill$_{cor}$ of 72.0 % ± 3.8 (range, 69.4-76.9 %) and a 3 month mean Fill$_{cor}$ of 75.7 % ± 3.5 (range, 69.9-76.1 %); 1 stem (2 %) was considered as being 2 sizes too small, with a postoperative Fill$_{cor}$ ~~Fill$_{CC}$~~ of ~~60~~ 59.6 % and a 3 month Fill$_{cor}$ of 62.9 %. Stems considered undersized based on templating were 5.6 times more likely to have a major stem complication (intra- and post-operative) ($p = 0.04$) than those that are appropriately or oversized and 5.7 times more likely to subside > 3 mm.

Optimal stem size based on templating pre-operative radiographs matched the optimal stem size based on post-operative radiographs in only 21 of 58 stems (37%). Preoperative templating under-estimated optimal stem size based on post-operative radiographs in 34 of 58 stems (58%), and over-estimated optimal stem size based on post-operative radiographs in 3 of 57 stems (5%). For all stems where pre-operative templating under-estimated the optimal size, the observed maximal coronal fit of the femur with the chosen stem size on the pre-operative radiographs limited selection of a larger size. Pre-operatively templated stem size matched the final stem size used in only 18 of 58 stems (31%); final stem size was larger than the pre-operatively templated stem size in 34 of 58 stems (59%), and smaller in 5 of 58 stems (9%).

Discussion:

We were able to demonstrate an association between varus stem angulation and the risk of intra-operative fissure formation. Malalignment of the stem in other orientations was not associated with stem complications or risk of subsidence. Our results also corroborate that undersized stems were at higher risk of subsiding, and stems subsiding > 3 mm within 3 months may be at risk of becoming clinically problematic, where there is an increased risk of post-operative stem complications such as femoral fracture and luxation. We found undersized stems, according to postoperative templating methods, were predisposed to subsidence. Despite ~~this~~ these associations, there were no clear predictors of subsidence based on % canal fill and angulation. The lack of association between canal fill and subsidence or stem complications suggests the % canal fill value carries little clinical relevance, and that assessing appropriateness of stem size by templating may provide a more valuable predictor for occurrence of stem subsidence and complications.

The association between a varus stem angulation of ≥ 5˚ and the risk of intra-operative femoral fissure identified in our study is likely due to encroachment of the broach on the medial cortex, and consequent increase in bone strain. The effect of stem positioning within the proximal femur has been evaluated for human and canine THAs.[49, 17, 18] Stems placed in a neutral position are associated with the most even distribution of strain ~~(Pernell et al.)~~.[9] Placing the stem in varus angulation results in medial positioning of the proximal stem and increased pressure on the craniomedial aspect of the proximal femur, the most common site for fissure formation.[19] No association was made between fissure formation and patient age, suggesting that positioning is the major cause of fissure formation. Our fissure rate of 7% is consistent with other BFX® THA studies, in which a femoral fissure rate of 4-21% has been documented.[6-8][4-6]

Our study found no association between % canal fill and subsidence or stem complications, which is consistent with previous *in vivo* studies.[4-6, 20]. In fact, all stems deemed appropriately sized based on digital templating, had a canal fill lower than the recommended 85%, and some femurs had canal fills as low as 66%. The lack of association between % canal fill and subsidence or complication, in addition to its discordance with assessment of appropriateness of stem size by templating, suggests that the canal fill measurement carries little clinical relevance. Canal fill is dependent on the difference between the area of the stem, which is of consistent geometry, and proximal femoral morphology, which is of varying geometry; thus, it was not surprising that stems deemed appropriately sized had widely varying canal fill measurements.

In contrast, femoral stems considered undersized based on templating were associated with an increased risk of stem-related complications and subsidence > 3mm. Templating requires a judgement by the surgeon that accounts for cortical contact and subjective assessment of whether a larger or smaller stem should have been placed. Although subjective measurements have inherent limitations, it may be a superior option for assessing stem size postoperatively with the BFX® system when compared to % canal fill.

Interestingly, we also demonstrated that pre-operative templating had a tendency to under-estimate the actual stem size used; the final stem size was larger than the pre-operatively templated stem size in 59% of stems. Upon review of the fit of the templates and subjective interpretation of projection, it appeared that foreshortening was common on the pre-operative craniocaudal projections, but less common in the post-operative radiographs. This discrepancy in positioning may be due to the altered ability to extend the affected hip. For instance, pre-operative radiographs were acquired under sedation, whereas the immediate post-operative radiographs were obtained under full anesthesia. It is likely that the hip region may also have had improved range of motion following THA, allowing for greater hip extension. Foreshortening appeared to affect the position of the template contours relative to the tapering proximal metaphysis, which may have caused the under-estimation in final stem size (Fig 65). Despite our radiographs being performed by experienced radiology technicians, and using the horizontal beam technique for the craniocaudal projection, it was apparent that positioning during pre-operative imaging may have been suboptimal. Our results highlight the importance, and difficulty, of careful radiographic quality control in dogs undergoing THA.

Femora with stovepipe morphology were not found to have -an increased major stem related complication rate in our study. This is in contrast to a previous study by Ganz et al., who found FCF to be associated with femoral fracture following THA.[6-4] It has been postulated that excessive subsidence places additional strain on the femur and increases the likelihood of a femoral fracture. Femora with a stovepipe morphology theoretically have an increased risk of subsidence, as was seen in an early clinical study of the porous-coated anatomic (PCA) THA in which they identified femora with a FCF of <1.8 to be 6 times more likely to subside than those with a normal appearance.[3-10] However, no association between stem morphology and subsidence has been identified in our study or a range of *in vivo* studies,[1, 6-84-6] suggesting that other clinical factors may play a more important role for minimizing stem related complications. The femurs in our study were specifically screened prior to surgery and deemed appropriate candidates for BFX® THA, which includes assessment of FCF; consequently, it may not have been possible to ascertain a true association between more prominent stove-pipe morphology and stem complications or subsidence with our case material.

A small degree of subsidence between surgery and the 3 month recheck was common in our study. Importantly, the magnitude of subsidence seemed relevant, where those dogs with a subsidence of > 3mm had a significantly higher risk of developing a post-operative stem related complication. Stem subsidence has previously been postulated to be associated with luxation in dogs due to loss of soft tissue tension following migration of the stem distally.[21] In addition, acute subsidence resulting in expansion of the femoral cortex has also been implicated as a cause for post-operative femoral fracture.[6]-[4] We identified undersized stems on templating as a risk factor for subsidence, corroborating that accurate stem sizing in relation to femur size is critical.

Our study focused on technique related risk factors for early stem complications; however there are many additional factors which can influence THA outcome. Increasing age and obesity have been associated with an increased risk of post-operative complication in humans[21-23] and increasing age has been associated with an increased risk of post-operative femoral fracture in dogs.[6]-[4] Changes in femur morphology towards a more stovepipe configuration may occur with increasing age,[3]-[10] as is seen in humans,[25] however no association between age and FCF was identified. In our study a FCF of < 1.8, increasing age or increasing weight were not associated with complications or subsidence. Due to the relatively small incidence of complications or major subsidence, the influence of age and weight may have been under appreciated.

Poor bone quality and thin femoral cortices have also been identified as a risk factor for THA complications in human patients.[26, 27] This has yet to be evaluated in canine subjects, although similar findings are likely as cortical bone thickness and the quality of cancellous bone are intrinsic to implant stability. Patient activity can also play a role in the occurrence of complications, with overloading of the femoral stem prior to osseointegration resulting in substantial subsidence, as was noted in 1 of our dogs. Therefore, despite optimal stem placement, complications and subsidence may still occur and it is important to account for many clinical factors during decision-making and estimating risk.

The largest limitation of our study is the statistical low power caused by the low number of complications and low number of inappropriately sized stems, which means we may have attributed more significance than was present in some instances and missed potential associations in others. Other limitations of this study include is its retrospective nature, which prevented the absolute standardization of perioperative protocols. Our follow-up time was limited to 12 months and therefore it is possible that we have missed late-onset complications such as aseptic loosening. An additional source of error that should be considered is that the digital stem templates are sized from the theoretical center of the lines (SolidWorks Corp., Dassault Systèmes, Concord, Massachusetts, USA). With the line being 0.25mm thick, ~~it could therefore generate~~ 0.125mm of error is present on each side of the image if the outside margin of the template line is used to represent the outer surface of the implant; this is likely to be the typical method of templating, which we also adopted during our study.~~.~~ Finally, the initial cobalt chromium BFX® stem used in this study has subsequently been superseded by a more tapered titanium stem, and templating guidelines with regard to fill are likely to be modified again with evolution of the implant design.

An additional significant limitation of our study was the method used to measure subsidence. Subsidence in this study was established by comparing stem level relative to the greater trochanter on post-operative and 3-month recheck radiographs. Ganz et al. ~~have~~

previously documented that marked femoral derangement following fracture can prevent measurement of subsidence.[6]–[4] Femoral fracture prior to the 3 month recheck occurred in 1 patient, where anatomic reconstruction of the femur without manipulation to the femoral stem allowed subsidence to be measured at the 3 month recheck. The second femoral fracture occurred at 10 months post-operatively and therefore the measurement of subsidence at 3 months was unaffected. In addition, a recent study by Korani et al. demonstrated that this measurement had a large degree of variability, which was attributed to differences in limb positioning between radiographs.[28] In the Korani study, stem subsidence occurring in the first three months, as measured from the greater trochanter to the shoulder of the stem, ranged from -73.79 to +2.20 mm with a mean ± SD of -0.8 mm ± 1.4. The positive value indicated that the stem appeared higher on the second radiographic evaluation, suggesting that the stem had migrated proximally. This is biologically unlikely to occur, and therefore this finding was considered to have occurred secondary to differences in radiographic positioning between the two time points; for this reason, the highest magnitude of proximal migration was used to estimate the variability associated with changes in positioning.[28] The highest observed -pProximal migration in our study (1.6 mm) was comparable to was documented in a small number of stems in our studywhat was observed in the Korani study (2.2 mm), thus similar errors associated with positioning were likely present in our study. Nevertheless, we feel our results may still be valid, as the magnitude of average positioning error is likely less than 3 mm, which was our cut-off value for statistical analysis.[28]

In conclusion, our study highlights that care should be taken to avoid placement of the stem in varus angulation due to the association with intra-operative femoral fissures. Associations between undersized stems, subsidence and stem-related complications were identified. In addition, nNo association was found between % canal fill and subsidence or early stem complications and we found ~~i~~% canal fill~~t~~ to be an inaccurate measure of assessing appropriateness of stem size. Assessing stem size by orthopedic templating provides an alternative, although subjective, measure of ~~appropriateness of~~optimal stem size.

Disclosure Statement:

One of the authors of this study teaches educational courses for Biomedtrix.~~The authors declare no conflict of interest related to this report.~~

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Tables:

Table 1: Measurement mean, SD and range values for average canal fill ($Fill_{Av}$), Canal fill in the coronal plane ($Fill_{cor}$), canal fill in the sagittal plane ($Fill_{sag}$), stem angulation in the coronal plane ($Stem_{cor}$), stem angulation in the sagittal plane ($Stem_{sag}$), stem level ($Stem_{lev}$) and femoral canal flare (FCF), on the immediate post-operative radiographs and 3 month post-operative radiographs.

	Postoperative		**3 months**	
Variable	**Mean ± SD**	**Range**	**Mean ± SD**	**Range**
$Fill_{AV}$	75.9 % ± 5.9	51.3 to 84.2	77.3 % ± 5.6	58.9 to 86.7
$Fill_{cor}$	74.9 % ± 7.5	43.0 to 87.6	74.9 % ± 7.5	55.0 to 89.7
$Fill_{sag}$	76.9 % ± 5.6	59.6 to 88.0	79.7 % ± 6.2	62.9 to 92.5
$Stem_{CC}$	1.5˚ varus ± 2.2	7˚ varus to 6 ˚ valgus	1.3˚ varus ± 2.1	8˚ varus to 6 ˚ valgus
$Stem_{ML}$	2.0˚ cranial ± 2.2	7˚ cranial to 3˚ caudal	2.1˚ cranial ± 2.2	9˚ cranial to 3˚ caudal
FCF	2.00 ± 0.27	1.44 to 2.60	1.98 ± 0.28	1.39 to 2.58
$Stem_{lev}$	5.7 mm ± 4.1	-3.9 to 15.0	7.4 mm ± 4.9	-2.8 to 26.1