Evaluation of the effect of monocortical and bicortical screw numbers on the properties of a locking plate/intramedullary rod configuration: an *in vitro* study on a canine femoral fracture gap model

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Conflicts of Interest: None

Structured Summary

Objectives: To evaluate the effect of varying the number and configuration of locking bicortical and locking monocortical screws on a plate-rod construct using a mid-diaphyseal femoral ostectomy model subject to cyclic loading followed by load to failure.

Study design: *Ex-vivo* cadaveric study

Methods: 30 femurs obtained from dogs euthanized for reasons unrelated to the study were subject to DEXA scanning prior to division into six groups (A-F) each comprising five bones. An intramedullary (IM) pin comprising 40% of the mid femoral diaphyseal width was placed in each bone following which a 3.5mm locking plate was applied with six differing locking screw configurations. Groups A-C had one bicortical screw in the most proximal and distal plate holes and one to three monocortical locking screws in the proximal and distal fragments. Groups D to F had no bicortical screws placed and two to four monocortical locking screws in proximal and distal fragments. Each construct was potted in dental plaster and axially loaded on a custom jig at 4Hz from a preload of 10 Newtons(N) to 72N, increasing to 144N and 216N, each of 6000 cycles with a further 45,000 cycles at 216N to simulate a three to six week postoperative convalescence period. Constructs were then loaded to failure.

Results: No construct suffered screw loosening or a significant change in construct stiffness during cyclic loading. There was no significant difference in load to failure of any construct ($p=0.34$) however, less variation was seen with monocortical constructs. All constructs failed at greater than 2.5 times physiological load, and failure was by bending of the IM pin and plate and medial cortical fracture rather than screw loosening or pull out.

Clinical Significance: Locking monocortical plate-rod constructs applied to the canine femur may confer no difference biomechanically to those employing locking bicortical screws.

Keywords:

Plate-rod, comminuted fracture, monocortical locking screws, bicortical locking screws

Introduction

Comminuted fractures of the femur occur frequently in dogs (1). Strategies for stabilisation of these fractures have recently focused away from primary reconstruction of bone fragments in favour of bridging osteosynthesis with spatial realignment of the bony column and maximal preservation of soft tissue attachment and vascular supply (2,3). This approach has been demonstrated to offer significantly reduced surgical and healing times when compared to anatomic reconstruction (4).

Plate-rod constructs have been demonstrated to be a highly adaptable means by which to perform bridging osteosynthesis in dogs and cats (5). They are significantly stiffer than a bone plate alone and inclusion of an intramedullary (IM) pin has been shown to increase the fatigue life of a bone plate as much as 10-fold (6). In the latter study, one bicortical screw and three monocortical screws were employed proximal and distal to the osteotomy and subsequently this number/configuration of screws has been cited as a minimum guideline in the application of this technique to clinical cases (5). However, a recent *ex-vivo* study varying the number of monocortical screws in a non-locking plate-rod fracture model revealed a linear increase in stiffness with increasing monocortical screw number, with load to failure being similar between groups even when only a single bicortical and monocortical screw were placed either side of the femoral ostectomy (7).

Over a century ago, the concept of the locking plate was developed by Hansman (8). Since this inception, a plethora of fixed and variable angle locking plates systems have developed in both human and veterinary orthopaedics (9–15). In addition to a construct only permitting placement of locking screws, locking compression plates (LCP) have been developed where a 'combination hole' may accept either a standard cortical screw that can be placed in load or locking screws (16). As a locking construct does not rely on frictional force developed between the plate and bone for stability (17), precise anatomic contouring of the LCP is not a prerequisite and as such, this system lends itself to use with minimally invasive percutaneous osteosynthesis (MIPO) and biological osteosynthesis (16).

Whist the working length of a locking plate in both axial (18), and torsional cyclic loading (19,20), as well as the inference of pin diameter (21) have been investigated, the minimum number and optimum configuration of screws required to stabilise a long bone fracture with a locking plate-rod construct in the dog has not been studied. Similarly, direct comparisons between the cyclic loading and failure properties of non-locking and locking plate rod construct configurations subjected to identical *in vitro* testing have so far not been elucidated. Such information would be useful to allow direct comparison of constructs to infer whether any benefit of locking fixation exists.

The aim of this study was to evaluate the effect of varying the number and configuration of locking bicortical and locking monocortical screws in a plate-rod construct in a mid-diaphyseal femoral ostectomy model subject to cyclic loading with subsequent load to failure. Our null hypotheses were that there would be no difference in construct behaviour between locking screw configurations and that the incidence of screw loosening, when compared to our previous study employing an identical testing protocol with non-locking implants, (7) would be significantly reduced.

Materials and Methods

Thirty femora were obtained from skeletally mature greyhounds euthanized for reasons unrelated to the study and following consent by owners for the use of material in this study. Femora were harvested and all soft tissues removed. Each bone was inspected for evidence of pre-existing trauma or disease and catalogued with an individual identity number following which, bone mineral density (BMD) was measured using Dual X-ray Absorptiometry (DXA) scanning (Lunar Prodigy DXA, GE Healthcare, USA). Femora were all scanned in a craniocaudal orientation and total BMD was recorded. Following scanning, bones were individually wrapped in saline (0.9% NaCl) soaked gauze swabs, sealed in drip seal plastic bag and stored at -20ºC prior to mechanical testing. Limbs were allowed to thaw at ambient temperature for 24 hours prior to mechanical testing.

For each bone in turn, an IM pin with diameter measuring 40% of the mid-diaphyseal femur width was placed normograde via the intertrochanteric fossa. Following placement of the IM pin, the position on the lateral aspect of the femoral diaphysis corresponding to the midpoint of the length of the bone was scored on the bone with a sagittal saw (Colibri, DePuy SynthesVet, U.K.). A 12-hole 3.5mm locking limited contact compression plate (Veterinary Instrumentation, U.K.) was contoured and applied to the lateral aspect of the femur. Care was taken to ensure that the centre of the plate (between holes 6 & 7) overlaid the score line on the lateral cortical surface of the bone defining its mid-diaphyseal length. Prior to application of the plate on the bone, an incomplete 20mm osteotomy centred on the previously measured score line and through the lateral third of the femoral diaphysis was performed with the oscillating saw.

Femora were then divided into six construct groups (A-F), each comprising five bones. Each construct group were allotted a different configuration of all locking screws to be applied through the plate as illustrated in Figure 1. Screw holes were numbered 1 to 12 from proximal to distal as orientated on the bone. Group A, B and C had bicortical screws placed in holes 1 and 12 and monocortical screws placed in holes 2 and 11. Group B had monocortical screws placed in holes 3 and 10. Group C had additional monocortical screws placed in holes 3,4, 9 and 10. Group D, E and F had only monocortical screws, with group D having screws at holes 1, 2, 11 and 12, group E having screws at holes 1,2,3,10,11 and 12, group F having screws at holes 1,2,3,4,9,10,11 and 12. Plates were manually compressed to the bone and screw holes were drilled through a 3.5mm locking drill guide with 2.8mm drill bit. Screws were power driven into position and hand tightened into the plate hole. Following placement of the implants, the mid-femoral ostectomy was circumferentially completed and the osteotomised bone segment removed from around the IM pin. All implants were placed by a board certified surgeon (XXX).

For each bone in turn, a 2.5mm drill was used to drill a hole in the medial portion of the femoral condyle and another caudally in the intercondylar notch. Two 32mm long wood screws (B&Q, U.K.) were placed in each hole protruding from the bone approximately 50% of their length. Each bone was then positioned perpendicular to the table in a craniocaudal and mediolateral orientation in a bespoke custom square aluminium mould, and stabilised proximally in a 10 inch extension clamp (hometrainingtools.com). Dental plaster (Denstone KD Plaster) was mixed and the aluminium mould filled with the plaster to a level proximal to the femoral condyle and level immediately distal to the distal extent of the plate. The dental plaster was allowed to cure for 12 hours during which time the entire construct was wrapped in saline soaked gauze swabs and refrigerated at $5^{o}C$. Each construct in turn was then loaded into a custom built jig used for a previous study (7). The jig was loaded into a mechanical testing machine (Instron 8872, Servohydraulic Fatigue Testing System) with a 5kN load cell (Figure 2).

The loading protocol employed was based on a previous non-locking plate-rod protocol (7). The constructs were loaded axially at 40N/sec from a preload of 10 Newtons (N) to 72N. The constructs were then cyclically loaded at 4Hz starting at the preload of 72N for 6000 cycles and then increasing to 144N and then 216N with 6000 cycles at each stage. With each increasing load stage the constructs were loaded from a standardised preload of 10N. The sequential increase in loads from 72N to 216N were to mimic the increasing load placed on the construct post operatively (20%, 40% and 60% of mean body weight). After the 6000 cycles at 216N, a further 45000 cycles were performed at 216N. Thus, each construct was cycled a total of 63000 times. This previously described protocol (7,22) was designed to mimic the cyclic loading applied to constructs *in vivo* during a three to six week period of postoperative convalescence. Stiffness and axial displacement were measured between each stage of increasing load and after the final cycle of 216N, the construct stiffness being calculated using the initial load control protocol. Data was collected from the materials testing machine using a software programme (WaveMatrix Dynmaic and Fatigue Materials Testing Software: Instron, High Wycombe, UK). Each construct was radiographed orthogonally both after the final cycle of loading and then following load to failure.

Constructs were loaded to failure from a 10N preload, using a displacement control protocol with a rate of 5mm/min. Axial construct displacement was recorded using the materials testing machine software. Failure was defined as a reduction of at least 30% from the peak load recorded. The mode of failure was recorded and objectified with orthogonal radiographs.

Statistical analysis

Data was entered into a statistical software programme (PASW Statistics 21.0 IBM Corp, Somers, New York USA) and a one-way ANOVA was used to assess differences in BMD between constructs with Bonferroni correction used as appropriate. Student t-tests were used to compare the difference in mean stiffness between bicortical and without bicortical screws after 6000 and 63000 cycles. Simple linear regression models were performed to assess the effects of factors on construct stiffness after 63000 cycles. These factors were construct group, number of monocortical screws, presence of bicortical screws, BMD and mode of construct failure. The significance level was defined as a value of $p < 0.05$.

Results

All femora, when inspected prior to testing, had no gross evidence of pre-existing trauma or disease and thus all were included in the study. The mean BMD for the femora was 0.837g/cm^2 (SD+/-0.076). There was no statistical difference in total BMD between the implant groups ($p = 0.341$) and no statistical difference between left and right femurs. ($p = 0.958$) (Table 1).

Cyclic Loading

The stiffness following cyclic loading was not statistically different between construct groups A-F ($p = 0.08$) (Table 1). When comparing mean stiffness of constructs with bicortical screws (A-C) after 6000 (635.9N/m (SD 248.8)) and 63000 cycles (769.1N/m (SD 327.4)) (Table 2), no significant difference was found ($p=0.09$). However, mean stiffness of constructs with only monocortical screws (D-F) was significantly greater at 63000 cycles (757.4N/m (SD 400)) than at 6000 cycles (559.3 N/m (SD 204.5)) ($p=0.01$) (Table 2).

When comparing mean stiffness in constructs after 6000 and 63000 cycles, between groups with bicortical screws and those without bicortical screws, no statistical differences were found ($p=0.46$ and 0.71 respectively).

No construct failed and no evidence of fracture or implant loosening was observed in any specimen either grossly or on orthogonal radiographs following cyclic loading. Regression analysis found that construct group, number of monocortical screws, presences of bicortical screws, BMD or mode of failure did not affect construct stiffness after 63000 cycles (Table 3).

Load to failure

The mean load at failure (Figure 3) was not significantly different between implant groups (p=0.34) (Table 1). Analysis of radiographs following failure of constructs revealed 80% (24/30) of constructs failed due to IM and plate bending (Figure 4). Two constructs in Group A failed by fracture through the bicortical screw hole in the trans cortex of the proximal fragment (Figure 4). Two constructs in Group C and one construct in Group D failed by implant bending and subsequent fracture of the proximal fragment from contact of the IM pin on the trans cortex closest to the ostectomy site. One construct in Group F failed by fracture of the femoral neck. No constructs failed by screw pull out from the bone and no evidence of screw loosening was evident in any construct.

Discussion

The results of our study revealed no difference between monocortical locking and monocortical/bicortical locking plate-rod constructs for an extended period of incremental cyclic loading followed by ultimate load to failure. Our results bear similarities to those found by Delisser et al (2013)(7), where non-locking plate-rod constructs with varying monocortical screw numbers were compared. That study found no difference in the ultimate load to failure between constructs. Considering the methodology between studies is similar, it is a significant finding that use of locking screws resulted in uniformity in stiffness of the constructs even when only a total of four monocortical screws were employed. Previous studies have revealed that increasing the working length of the plate reduces construct stiffness (21,23), however this was not a finding in our study. Although we used a locking construct, we chose to contour the plate to the bone in an effort for uniformity of plate application technique between this and our former study (24). As such, due to direct contact of the plate on the bone the functional plate working length was limited to that overlying the ostectomy site which was the same size in all constructs. A recent femoral ostectomy model using a combination of locking and non-locking screws found similar results with comparable stiffness between groups (18).

In our study, there was a statistically significant increase in stiffness observed through cyclic loading in the monocortical constructs and a trend towards an increase in stiffness in bicortical constructs. Constructs were inspected following cyclic loading prior to loading to failure and no gross evidence of change to the implants or bone was observed thus this increase in stiffness must be attributable to changes within the implants as a function of the cyclic loading experienced. A potential mechanism by which to explain this phenomenon would be differences in the magnitude of cold working / stress hardening of the plate between monocortical and bicortical constructs. Locking plate-rod constructs have been shown clinically to afford sufficient rigidity to stabilise comminuted femoral fractures (25). The locking addition enables the system to be placed rapidly in a biological manner through bridging osteosynthesis with minimal disruption to the soft tissue envelope. Practically, the presence of an IM pin can make placement of bicortical screws difficult and a disadvantage of a fixed-angle locking construct is that the screws cannot be angled to avoid the IM pin. Interestingly, the addition of bicortical locking screws in our study did not result in superior stability of constructs. Furthermore, our results reveal less variation in the load to failure data for monocortical screw constructs compared to those with bicortical screws, (Figure 2). Thus, monocortical screw constructs had less variability in their load to failure data and thus, in this respect, were a more predictable fixation.

The results of our study are in contrast to some of the findings of previous studies evaluating non-locking plate-rod constructs in *ex-vivo* femoral fracture models (6,7). Non locking plate rod constructs confer stiffness as a function of friction between the plate and bone (26), something that will increase with increased numbers of screws pressing more of the plate to the bone. Conversely, as locking constructs do not require plate-bone friction for stability, so the influence of increasing screw number is negated above a minimum conferring excessive strain to either the locking mechanism causing screw breakage or the screw-bone interface predisposing to bone resorption or screw pull out. A minimum acceptable number of locking screws has so far, not been evaluated clinically for canine femoral plate constructs. However, a recent clinical study did not reveal significant differences in fracture healing between fractures stabilised with only two bi-cortical locking screws verses more per main fracture fragment (27)

Constructs were loaded to failure and we defined the ‘failure point’ for our constructs as a 30% reduction in load. Whist constructs were subjected to axial compression, the majority failed by cantilever bending of the medial plate and IM pin with evidence of concurrent medial cortical fracturing of the distal end of the proximal femoral segment. The mechanism of this failure appeared to be medial plastic deformation of the plate at the level of the ostectomy with subsequent medio-distal pivoting of the proximal bone segment, IM pin contact with the endosteum of the distal end of the proximal bone segment, medial bending of the pin and cortical fracture medially. Therefore, constructs had already failed through implant bending prior to fracture of the proximal femoral segment. This is the same mechanism of failure as observed in three of the non-locking plate-rod constructs in our previous study (24), and bears similarities to that of another *ex vivo* locking plate femoral ostectomy study evaluating the effect of plate working length on plate stiffness (22). In this latter study, bending of the plate occurred at the level of the osteotomy with mediodistal pivot of the proximal femoral segment similarly. Medial cortical fracture was not observed in this study presumably due to the absence of an IM pin. One of our constructs failed through fracture of the femoral neck. This is likely due to eccentric loading of the femoral head in the jig rather then a finding attributable to the construct.

No screw loosening or pull out was observed in our constructs. This is in direct contrast to our preceding study, where 70% of non-locking screw constructs failed by screw pull out (7) but in concordance with the findings of two recent studies evaluating cyclic loading and load to failure of locking-plate rod constructs (21,28). Comparison of the mean stiffness data between our current and previous study (7) for constructs with the same configuration of monocortical and bicortical screws revealed similar stiffness after 6000 cycles but an increase in stiffness in locking constructs at 63000 cycles. The reason for this increase in stiffness is not clear but could similarly relate to differences in relative cold working / stress hardening within the locking verses non-locking constructs. In the present study, loads required to achieve construct failure, regardless of the screw configuration were all in excess of 500N. This force significantly exceeds the 200N that was applied for cyclic loading and thus all constructs, based on our model, performed competently to a factor at least 2.5 times that that would be required clinically in the postoperative period.

Study limitations

Our study was cadaveric and the methodology employed was deliberately comparable to our previously non locking plate rod study (7). Whist we used bones of a single breed in both studies, there was otherwise no standardisation of size and shape of the bones although BMD revealed no significant difference between groups.

The use of locking plates negates the need to contour plates to the bone, however, we chose to accurately contour plates in this study. Our rationale for plate contouring was to minimise the differences in methodology between locking and non-locking studies to facilitate direct comparisons. Secondly, it has been shown that locking plates should be within two millimetres of the bone to minimise the shear force on the screw between the locking thread of the plate and bone (29). The topography of the lateral cortex of the canine femur is mildly concave in most breeds of dog and without a degree of contouring, the central section of the plate would have been be proud from the bone by greater than three millimetres increasing the risk of construct failure by this mechanism. Thus, should minimal or no contouring of a plate in clinical practice be employed as part of a MIPO strategy of fracture stabilisation, our results may not be directly applicable to such a construct due to the increased offset of the plate from the bone and the propensity for failure by screw breakage. We chose to tighten screws manually rather than using a torque limiter to ensure uniformity of screw tightening technique between studies as in our preceding study screws were manually tightened (24). It is possible that this could have resulted in either over or under-tightening of screws. However, screw loosening did not occur in any construct and on removal of constructs from bones following testing, cold-welding of screws was not evident.

Our loading protocol employed a jig to simulate the acetabulum but clear differences in loading between this and *in vivo* exist, namely a different articular contour, static rather than dynamic loading as would be experienced during stance phase and no extraneous influence of soft tissues and their moments over the forces experienced by the construct. Our small sample sizes was limited by a finite number of bones being available for the study and this may have accounted for the lack of significant findings between groups. In addition, there was a large standard deviation from the mean for our samples, which could again account for the lack of significant findings between groups. It is possible and that this could be secondary to the different shaped femoral head within the jig with any misalignment making the samples more prone to bending, rather then experiencing true compressive loads.

Two recent studies have revealed a variable effect of locking screw configuration on torsional stiffness of locking plate and screw constructs of both the canine tibia and bone substitute (19,30). In contrast, a cadaveric femoral ostectomy model, comparing a monocortical locking and mono and bicortical non locking plate rod constructs revealed bending, torsional and axial displacement to show very similar statistical trends between groups (3). As our study employed a similar axial cyclic testing methodology as this latter study we would expect differences in bending and torsional displacement to follow those of axial displacement although these parameters were not measured in our study.

In summary, when axially loaded there were no difference in both the cyclic fatigue or ultimate load to failure data for differing monocortical and bicortical locking screw configurations in this locking plate-rod model. Our model suggests it may not be imperative to place bicortical screws in a locking plate rod femoral construct and that both fewer and solely monocortical screws may confer comparable construct stiffness.

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