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Biomechanical Comparison of Two Locking Plate Constructs Under Cyclic Loading in Four-Point Bending in a Fracture Gap Model: Two Screws versus Three Screws Per Fragment

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Abstract

Objectives The number of locking screws required per fragment during bridging osteosynthesis has not been fully determined in the dog. The purpose of this study was to assess the survival of two constructs, with either two or three screws per fragment, under cyclic bending.

Materials and Methods A 10-hole, 3.5-mm stainless steel locking compression plate was fixed 1 mm away from a bone surrogate in which the fracture gap was 47 mm. Two groups of 10 constructs, prepared with either two or three bicortical locking screws placed at the extremities of each fragment, were tested in a load-controlled 4-point bending test (range 0.7 to + 7 Nm) until failure.

Results The 3-screw constructs were stiffer than the 2-screw constructs (19.73 ± 0.68 N/mm vs. 15.52 ± 0.51 N/mm respectively) and the interfragmentary relative displacements were higher for the 2-screw constructs ($11.17 \pm 0.88\%$) than for the 3-screw constructs ($8.00 \pm 0.45\%$). The difference between the number of cycles to failure for the 3-screw constructs ($162,448 \pm 30,073$ cycles) and the 2-screw constructs ($143,786 \pm 10,103$ cycles) was not significant. Failure in all constructs was due to plate fracture at the level of the compression holes.

Clinical Significance Omission of the third innermost locking screw during bridging osteosynthesis subjected to bending forces led to a 20% reduction in construct stiffness and increased relative displacement (+39.6%) but did not change fatigue life.

Keywords

- ▶ cyclic loading
- ▶ locking plate
- ▶ bending
- ▶ fatigue life

Introduction

In the dog and cat, 38.6 to 45% of long bones fractures are femoral fractures and 16.5 to 26% are tibial fractures.^{1,3} Forty percent of femoral diaphyseal fractures and 64% of tibial diaphyseal fractures are comminuted.^{1,2}

Bridging plate osteosynthesis is a well-accepted technique for treating comminuted fractures of long bones in small animals.^{4,5} Locking plates and more particularly locking

compression plates (LCP) are suitable for treating comminuted diaphyseal fractures.^{4,6} Bridging plate osteosynthesis most often involves a minimally invasive approach, in which the plate is fixed to the main fragments of the comminuted fracture by placing screws at the plate extremities.^{4,5,7}

Guidelines indicating the recommended number of screws and the plate-screw density have been proposed when locking plates are used in minimally invasive osteosynthesis in human

medicine.⁷⁻⁹ The current recommendation for comminuted fracture in non-osteoporotic human patients is to use at least three to four monocortical screws or two bicortical screws per fragment.^{6,7} Although locking plates have been used in dogs and cats, no guidelines regarding the optimal number of screws per fragment are currently available in veterinary medicine.¹⁰⁻¹³

To our knowledge, only one study compared the use of two or three bicortical locking screws per fragment during mechanical fatigue tests, conducted under torsion to failure.¹⁴ No results are available for fatigue tests under bending or compression.

The purpose of our study was to compare the mechanical behaviour of two versus three bicortical locking screws per fragment during fatigue testing under four-point bending until failure. We hypothesized that the stiffness of a construct with three screws per fragment would be greater than that of a construct with two screws per fragment but that both constructs would survive for the same time, contrary to the observations reported for torsion tests.

Materials and Methods

Preparation of the Construct

A fourth-generation bone model consisting of short-fibre filled epoxy hollow cylinders, with a wall thickness of 3 mm and an outer diameter of 20 mm (SKU 3403-42, SawBones, Vashon Island, Washington, United States) was used to simulate the bone segments. Cylinders were cut into pieces 83 mm in length. Two segments were then aligned using a custom jig and leaving a gap of 47 mm between the two cylinders. The length of the cylinders was then extended by inserting a bronze rod 135 mm long 13.8 mm in diameter into the ends of the cylinders. The connection between each epoxy cylinder and bronze rod was rigid and was secured with a lock pin. Each bronze rod had a slot at the outer extremity, was inserted to a depth of 40 mm and was identical for all constructs. A bone plate was then centred on the gap and aligned over the bone segments. Ten-hole, 3.5-mm stainless steel LCP with 3.5-mm self-tapping locking screws were used for this study (LCP; DepuySynthes, France SAS, Saint Priest, France).

Plates, with either two or three bicortical screws, were applied to each bone substitute fragment. The constructs were divided into two groups, each with 10 specimens. In both groups, the screws were placed in the outermost plate holes (►Fig. 1). The plates were separated from the bone using a metal 1 mm thick spacer. A locking drill guide inserted in a custom jig was used for drilling. The screws were tightened to 1.5 Nm using the torque-limiting screwdriver supplied by the manufacturer (DepuySynthes). A new set of implants was used for each construct, and no implant was reused for mechanical testing.

Mechanical Testing

The construct was loaded in a four-point-bending set-up to generate a constant bending moment over the entire plate. Four-point bending tests were performed with an electric linear fatigue testing machine (ElectroPuls E1000; Instron, High Wycomb, United Kingdom) under a load control. A custom-designed loading fixture was used to mount the specimens in the testing machine (►Fig. 2). The set-up was constructed with one stationary anvil and one moving anvil. Each anvil used a spherical joint with an inner diameter that was slightly larger than the cylinder that crossed it. For the stationary anvil, the diameters of the spherical joint and the bronze rod were 14 mm and 13.8 mm, respectively. For the moving anvils, the inner diameter of the spherical joints was 20 mm and the cylinders of the bone substitute were slightly sanded over a length of 30 mm to obtain a diameter of 19.7 mm which allowed free movement of the bone substitute inside the spherical joints. Grease was applied to all the spherical joints. This set-up allowed free sliding of the cylinders throughout the study. Lock pins and washers were placed inside each stationary spherical joint to prevent any outward translation of the bone plate constructs. Moreover, another spherical joint was placed in line with the upper fixture to produce a slight tilt if necessary. This ensured that the two upper spherical joints of the moving anvil were always in simultaneous contact with the specimen. A greased partial thread screw was introduced into the slot of one of the rods affixed to the base of the testing machine to prevent axial rotation of the constructs during the fatigue tests. The centres of the inner and outer spherical joint supports were separated

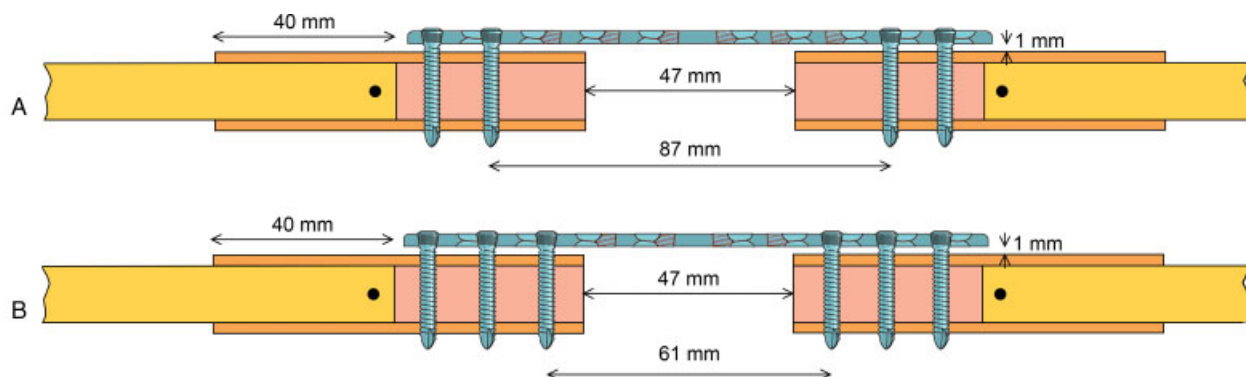


Fig. 1 Illustration of the two constructs. A 10 hole 3.5 mm stainless steel locking compression plate (LCP) with 3.5 mm self tapping locking screws was positioned on the bone substitutes. A bronze rod was inserted into the bone substitutes and was secured with a lock pin. Depending on the group, either two (A) or three (B) bicortical locking screws per fragment were placed in the outermost plate holes.



Fig. 2 Photograph of the mechanical setup. (A) Spherical joints; (B) bone substitute; (C) bronze rod; (D) partial thread screw avoiding axial rotation of the bone plate constructs during the tests; (E) strain gauge.

by 177.6 mm and 307.6 mm, respectively. The device was set up with the plates on the tension side to induce bending in a gap-closing mode.

Strain at the upper surface of the plate was measured using a monoaxial pre-wired strain gauge (KFG-1N-120-C1-11L1M2R; Kyowa Electronic Instruments, Tokyo, Japan). The strain gauges were glued on one side of the plate between the centre holes with the axis of the gauge aligned with the long axis of the plate. The strain gauges were connected to a digital acquisition system (PCD 300; Kyowa Electronic Instruments, Tokyo, Japan) and the channel was sampled at 10 Hz using a dedicated software (DSC 100-A; Kyowa Electronic Instruments, Tokyo, Japan). The actuator's linear variable displacement transducer was used to record the displacement of the moving anvil, while four-point bending was applied. A digital micrometre (LS-7000 series; Keyence SAS, Courbevoie, France) was used to measure the maximum displacement of the plate centre (►Fig. 3).

During unipolar sinusoidal cyclic waveform loading, a load of 215.4 N was applied at 2 Hz until catastrophic failure using a static preload of 21.54 N corresponding to a bending moment of 0.7 to 7 Nm.

After two quasi-static load–unload tests to condition the construct, a quasi-static load–unload test was performed with a maximum load of 215.4 N at a speed of 2.5 N per second at the beginning of the test and was repeated every 10,000 cycles. Bending stiffness was measured on the load-displacement

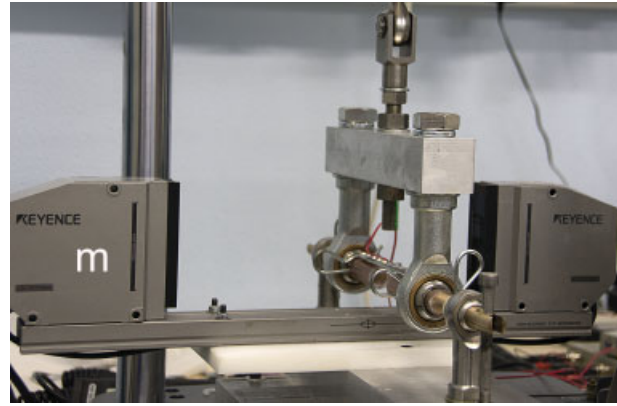


Fig. 3 Photograph of the mechanical setup. m: digital micrometre used to measure the displacement of the plate centre.

curves during the third cycle and every 10,000 cycles during quasi-static load–unload tests. Bending angles and interfracture relative displacements were calculated using the geometric relationships shown in ►Figs. 4 and 5.

On completion of cyclic 4-point bending, the screws were removed with a previously calibrated torque screwdriver and the peak removal torque was recorded. The percentage reduction in the removal torque from the baseline torque was calculated and compared as a function of screw position.

Data Acquisition

Throughout each quasi-static load–unload test, the displacement of the plate centre, the plate strain data and the displacement of the moving anvil were recorded.

Load versus moving anvil and plate displacement curves were generated using a commercially available spreadsheet software (Excel; Microsoft Corporation, Dublin, Ireland). For each quasi-static load, bending stiffness was determined from the slope of the linear portion of the load-moving anvil displacement curve between 20 and 80% of the peak applied load and expressed as Newtons/millimetre. The displacement of moving anvil was used to calculate the bending angle as shown in ►Fig. 4. Construct failure was defined as a catastrophic fracture of either the plate or bone substitute.

Statistical Analysis

Comparisons of stiffness during each quasi-static test, the number of cycles before catastrophic failure, displacement of the moving anvil, displacement of the plate and plate strains were analysed. For each variable, the normal distribution was analysed with a Shapiro–Wilk test. Most variables followed a normal distribution. A statistical analysis was then performed using analysis of variance for repeated measures followed by post hoc tests. Normality was not demonstrated for the strain data, and Mann–Whitney U tests were performed. The differences between torque insertion and torque removal were compared with a standard gaussian distribution using a z-test. The differences in stiffness between two consecutive tests were calculated for the last 15 quasi-static tests, and were compared with a standard normal distribution using a z-test.

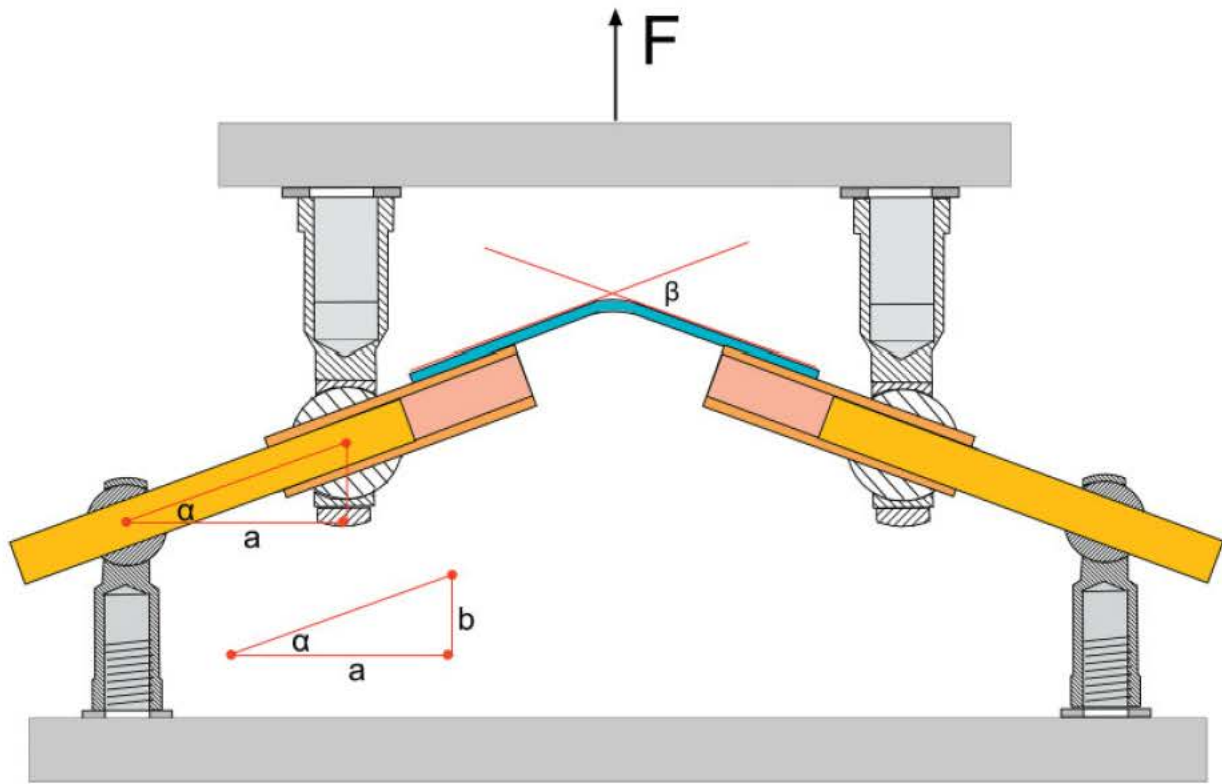


Fig. 4 Drawing of the four point bending device showing calculation of bending moment and bending angle. The bending moment $M = F/2 \cdot a$; the bending angle $\beta = 2\alpha$ with $\tan \alpha = b/a$, $b =$ actuator displacement and $a =$ span between inner and outer spherical joints (65 mm).

A Kaplan–Meier with Cox–Mantel test was applied to the survival analysis. The significance level was set at $p < 0.05$. Results are expressed as mean \pm standard deviation.

Results

The maximum displacement of the plate was significantly lower for the 3-screw constructs (10.95 ± 0.46 mm) than for the 2-screw constructs (14.07 ± 0.81 mm) ($p < 0.05$). The bending angle was also significantly lower for the 3-screw constructs ($10.25 \pm 0.56^\circ$) than for the 2-screw constructs ($14.06 \pm 1.04^\circ$) ($p < 0.05$). Bending stiffness was significantly higher for the 3-screw constructs (19.73 ± 0.68 N/mm) than for the 2-screw constructs (15.52 ± 0.51 N/mm) ($p < 0.05$). Plate strain did not differ significantly between the 2-screw constructs (2792.9 ± 386.9 $\mu\text{m/m}$) and the 3-screw constructs (3031.05 ± 331.7 $\mu\text{m/m}$), nor did the cycle to failure differ significantly between the 2-screw constructs ($143,786 \pm 10,103$ cycles) and the 3-screw constructs ($162,448 \pm 30,073$ cycles). The Kaplan–Meier survival curves are shown in **Fig. 6**. The interfragmentary relative displacement was significantly higher for the 2-screw constructs than for the 3-screw constructs at the level of the adjacent cortex (0.76 ± 0.11 vs. $0.40 \pm 0.04\%$ respectively) and opposite cortex (11.17 ± 0.88 vs $8.00 \pm 0.45\%$ respectively) ($p < 0.05$).

No significant difference between measurements was observed except for the last stiffness value obtained for the 3-screw construct (18.63 ± 0.79 Nm) which was significantly lower than the penultimate value (19.50 ± 0.49

N/mm) ($p < 0.05$). For the two-screw construct, the last stiffness value (14.82 ± 0.73 Nm) was also lower than the penultimate value (15.34 ± 0.61 N/mm), but this difference was not significant ($p = 0.1$) (**Fig. 7**).

All the constructs failed by plate breakage at a compression hole. The peak removal torque was lower than the peak insertion torque in 56 out of 60 screws (93.3%) in the 3-screw constructs and in 38 out of 40 screws (95%) in the 2-screw constructs. The mean initial peak removal torque was 1.19 ± 0.27 Nm for the 2-screw constructs and 1.09 ± 0.28 Nm for the 3-screw constructs. For each group, torque removal was significantly lower than torque insertion ($p < 0.05$). This represents a reduction of $27.27 \pm 18.77\%$ from the initial applied torque (1.5 Nm) for the 3-screw constructs and of $20.87 \pm 18.13\%$ for the 2-screw constructs, although this difference was not significant. The postcyclic removal torques of the screws, regardless of their position, were not significantly different.

Discussion

The results of our 4-point bending fatigue tests confirmed our hypotheses that (1) the bending stiffness of the 2-screw constructs was 21.3% lower than that of the 3-screw constructs and (2) a construct with three screws per fragment would survive for the same time as a construct with two screws per fragment.

A 1 mm gap between the plate and the synthetic bone was chosen as this had been previously used in a similar fatigue test under torsion.¹⁴ This screw offset did not affect construct

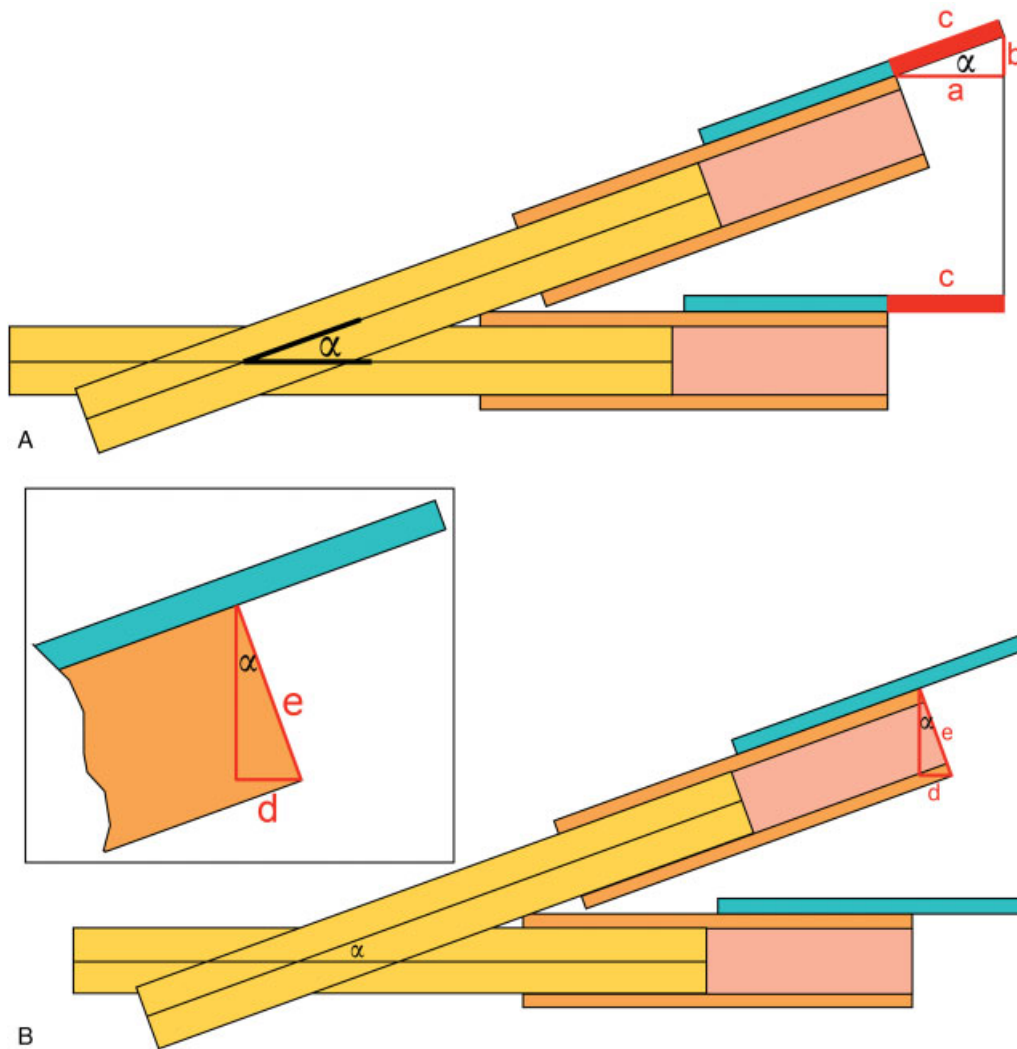


Fig. 5 Drawing showing half of the construct for calculation of the interfragmentary relative displacement. (A) Interfragmentary relative displacement (D_b) on the cortex beneath the plate. $D_b = ((\text{initial gap} - \text{final gap beneath the plate}) / \text{initial gap}) \times 100$. Initial gap = 47 mm; Final gap beneath the plate = $2a$; $a = c \times \cos \alpha$. $\alpha = 1/2$ bending angle (see **Fig. 4**); $b =$ actuator displacement, $c = 1/2$ initial gap ($47/2 = 23.5$ mm). (B) Interfragmentary relative displacement (D_o) on the cortex opposite to the plate. $D_o = ((\text{initial gap} - \text{final gap opposite to the plate}) / \text{initial gap}) \times 100$. Initial gap = 47 mm; Final gap opposite to the plate = Final gap beneath the plate ($2a$) $- 2d$; $d = e \times \sin \alpha$; $e = 20$ mm.

failure that occurred by plate fracture. As in many other studies, we used a validated synthetic bone with mechanical properties similar to those of native canine bone.^{6,14-17} No failure of the synthetic bone was observed during the tests. Cycling loading was applied during bending because of the significant strain and strong influence of the bending moment on long bones.¹⁸ Torsion and bending forces represent almost 95% of the load during walking.¹⁸

The magnitude of the maximum load applied during cyclic and quasi-static tests was 61% of the yield load that had previously been determined in preliminary tests to keep the displacement within the elastic deformation phase of the constructs. This value was less than the maximum load recommended in the standard specification and test method for testing bone plating.¹⁹ The amplitude of the corresponding bending moment (7 Nm) was within the same range as previously used in bending tests.²⁰⁻²³

Mechanical tests were performed under load control. The same bending moment was applied to all screw constructs

and corresponded to the standard specification and test methods for testing bone plates during bending.¹⁹

In the current study, the time to failure did not differ significantly between the 2-screw constructs (120,000–150,000 cycles) and the 3-screw constructs (120,000–220,000 cycles). Links were apparent between these data and the lack of significance of the plate strains between the two groups of screws constructs. In this 4-point bending fatigue test, the bending moment between the inner loaders was constant along the entire length of the plate and consequently the same for both the two-screw and three-screw constructs. This explains why the strains and fatigue lives were similar for both groups of constructs.

Failure of the construct in both groups was due to plate fracture that occurred at the level of a compression hole. Construct failure under cyclic loading has been described as the result of defect accumulation, crack initiation, and crack propagation as the number of load cycles increases.²⁴ When the LCP was used in bending tests, fatigue crack was

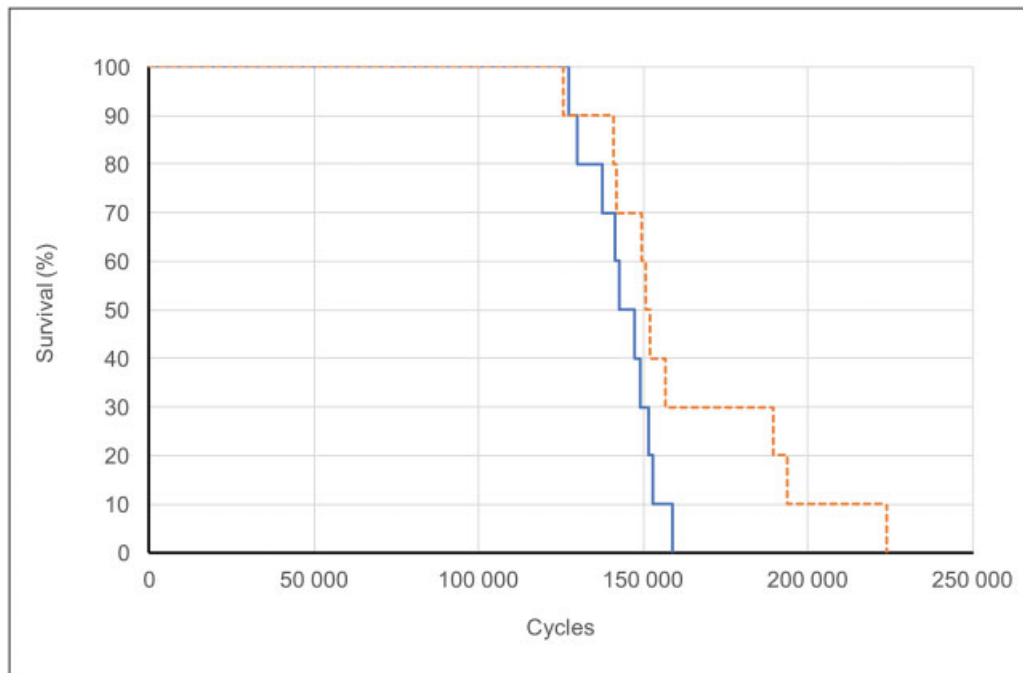


Fig. 6 Kaplan-Meier survival curves for the two constructs. The mean survival times for the 3 screw constructs (dotted line) and the 2 screw constructs (solid line) are not significantly different.

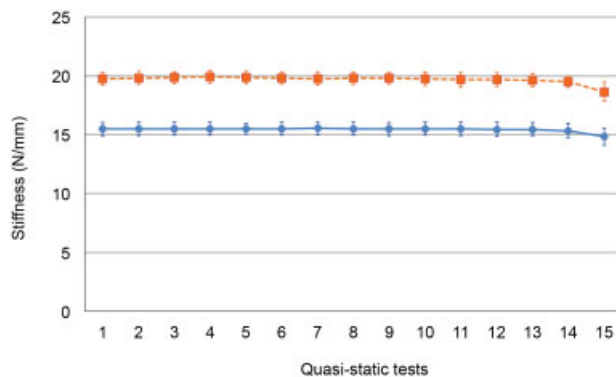


Fig. 7 Evolution of stiffness over time for the last 15 quasi static tests for the 2 screw constructs (solid line with round plots) and 3 screw constructs (dotted line with square plots).

described as starting from the surface of the compression hole.²⁴ Given that the bending moment along the whole plate-bone construct was constant, the observed fractures were situated at any of the holes between the inner screws. The propagation of fatigue crack from the initiation site to the entire thickness of the LCP was estimated to occur at the rate of 1,000 cycles per mm of plate thickness.²⁴ Given that the LCP used in the current study had a thickness of 3.3 mm, the fatigue crack was estimated to occur after approximately 3,300 cycles. The stiffness of the constructs decreases regularly during crack propagation.²⁴ In the current study, bending stiffness was calculated from the quasi-static load curves obtained every 10,000 cycles. In spite of this great span, a significant decrease in stiffness was observed during the last quasi-static load test for the 3-screw constructs and a trend to decrease was also noted for the 2-screw constructs.

These decreases in stiffness could be a sign of crack propagation. Decreasing the span to 1,000 cycles would have provided more accurate information but would have considerably increased the duration of the tests. The span between each quasi-static load test was chosen to produce dynamic loading to failure within a reasonable time, as already reported in previous studies.^{14,25-29}

To our knowledge, the fatigue life of locking constructs with different numbers of screws has never before been assessed in bending tests. The fatigue life of these constructs had only been determined in a single study involving torsion tests. In this study, the fatigue life of a construct with two screws per fragment was reduced by 25% compared with a construct with three screws per fragment.¹⁴ Failure of the constructs was due to screw fracture. Another study compared the mechanical properties of two constructs with either two or three bicortical screws per fragment during bending, torsional and axial loading.³⁰ No difference was found between the two groups either before or after 1,000 cycles of torsion. However, the bending tests were static tests, thus preventing any comparison with the current study.

In our experiment, unlike the study involving torsion tests, failure of all the constructs occurred through plate fracture. For these constructs under cyclic four-point bending, the critical point was apparently the fatigue life of the plate. The fatigue life for the two different screws constructs was similar, whereas the elasticity and stiffness of these constructs were altered by removing the innermost screws to increase the working length. Indeed, bending stiffness was 21.3% lower in the 2-screw constructs than in the 3-screw constructs and the interfragmentary relative displacement within the opposite cortex was 39.6% higher for the 2-screw

constructs. These changes within the fracture gap are important factors likely to influence the type and duration of fracture healing.^{31,32}

In the current study, even though all the screws were inserted using the 1.5 Nm torque limiter and were visually checked, torque removal was 20 to 27% lower than torque insertion in 95% of the constructs. Screw unlocking has been reported both in clinical and experimental situations. In human medicine, it was noted in 4.5 to 16% of cases.^{33,34} Screw head unlocking under cyclic loading in experimental settings on bone substitute has been described in 3 and 25% of cases.^{14,35} In the current study, the torque reduction, as compared with torque insertion, was not visually remarkable and, therefore, the moment of its occurrence could not be determined. A torque removal of 1.0 Nm had no apparent effect on construct stiffness, except possibly during the last quasi-static load test. The effect of such a magnitude of peak torque removal on fracture stability is unknown.

There are many limitations to our study. The major limitation is that the biomechanical results cannot be directly extrapolated to the clinical setting due to the greater complexity of the *in vivo* situation. The tests were only performed in one plane. No information is available on the fatigue behaviour of bone-plate constructs subjected to cyclic loading in a perpendicular plane. Even though slight loosening of the screws applied bicortically had no effect on construct stiffness, it is possible that in the case of monocortical screws, the significance of screw unlocking would have been greater and construct stability potentially decreased. The four-point bending test used in the current study is a standard biomechanical set-up that rarely occurs alone under clinical conditions.¹⁹ *In vivo* loading comprises a combination of compression, bending and torsion. Our model of repetitive loading did not take into account the torsion and axial loading forces that are also exerted postoperatively on a bone plate construct used to repair comminuted fractures. Even though the magnitude of these forces is unknown, the combination of bending and torsional forces has been shown to represent ~95% of the physiological loads.¹⁸ Stresses from torsion and axial loading would add to the bending stresses and speed up cyclic failure of the plate or the screws might fail before the plates. Finally, *in vivo* factors such as screw loosening due to bone resorption or protection of the plate by callus development were not represented in this model and are likely to vary in the live patient.

The mechanical tests were conducted on bone substitute. Although bone substitutes have been shown to perform similarly to native canine bone, the latter remain the ideal testing material.¹⁵ The choice of bone substitute instead of cadaveric bone was made to limit the specimen variability of cadaveric bone and to standardize construct preparation and testing, and maximize repeatability.¹⁵

The current study of cyclic 4-point bending loading did not reveal any difference in failure life between the 2-screw constructs and the 3-screw constructs, whereas in cyclic torsion loading, the fatigue life of a construct with two screws per fragment was reduced by 25% compared with a construct with three screws per fragment. As torsion induces bone deformation of 62% and bending 33%, torsion data are probably

more relevant to consider when decision making.¹⁸ On this basis, the choice of either using two screws or three screws per fragment in clinical practice would need to take into account the intrinsic stability of the fracture. This intrinsic stability of the fracture is one of many factors that play a role in the stability of bone-plate constructs such as length of the plate, thickness of the plate, number of screws, position of the screws and use of locked or non-locked screws. When intrinsic stability is present, as with an incomplete fracture or non-displaced fracture of the radius or tibia, without fracture of the ulna or fibula respectively, the plate does not support all the mechanical forces applied to the bone segment during locomotion. The stresses on the implants are reduced and this protects the implant from fatigue and early failure, which implies that a 2-screw construct might therefore be sufficient to allow bone healing. On the other hand, for comminuted long bone fractures which are preferentially subjected to torsion loads, it would be better to choose 3-screw constructs when using bridge plating. However, a complete assessment would require mechanical studies of cyclic axial loading along with *in vivo* studies.

Conclusions

Our results indicate that the number of bicortical locking screws used in our model of cyclic 4-point bending loading to secure a bridging locking plate does not significantly affect construct survival. The fatigue life of a construct with two screws per fragment was similar to that of a construct with three screws per fragment. However, the lower bending stiffness of 2-screw constructs was associated with a higher interfragmentary relative displacement in the opposite cortex. These results must be interpreted in conjunction with those obtained under cyclic torsion so that suitable clinical management suggestions can be made, such as when to use two versus three locking screw constructs to treat a comminuted diaphyseal fracture in the dog. It is also very important to consider that pure four-point bending loading rarely occurs *in vivo* and, consequently, that the results of this experimental study are not totally relevant to clinical situations. Clinical studies of fracture fixation with either a 2-screw or a 3-screw construct in different cases of fracture stability will provide complementary data that should help the veterinary surgeon to make the most appropriate choice.

Author Contribution

Sophie Palierne and André Autefage contributed to conception of study, study design, acquisition of data and data analysis and interpretation. Baptiste Froidefond contributed to study design, acquisition of data and data analysis and interpretation. Pascal Swider contributed to conception of study, study design, and data analysis and interpretation. All authors drafted, revised and approved the submitted manuscript.

Conflict of Interest

None.

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