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Biomechanical comparison of two locking plate constructs under cyclic torsional loading in a fracture gap model

Two screws versus three screws per fragment

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Keywords

Cyclic testing, locking plate, screw, torsion

Summary

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

Methods: Ten-hole 3.5 mm stainless steel locking compression plates (LCP) were fixed 1 mm away from bone surrogates with a fracture gap of 47 mm using two bicortical locking screws (10 constructs) or three bicortical locking screws (10 constructs) per fragment, placed at the extremities of each LCP. Constructs were tested in cyclic torsion (range: 0 to +0.218 rad) until failure.

Results: The 3-screws constructs (29.65 ± 1.89 N.m/rad) were stiffer than the 2-screws

constructs (23.73 ± 0.87 N.m/rad), and therefore, were subjected to a greater torque during cycling (6.05 ± 1.33 N.m and 4.88 ± 1.14 N.m respectively). The 3-screws constructs sustained a significantly greater number of cycles ($20,700 \pm 5,735$ cycles) than the 2-screws constructs ($15,600 \pm 5,272$ cycles). In most constructs, failure was due to screw damage at the junction of the shaft and head. The remaining constructs failed because of screw head unlocking, sometimes due to incomplete seating of the screw head prior to testing.

Clinical significance: Omitting the third innermost locking screw during bridging osteosynthesis led to a reduction in fatigue life of 25% and construct stiffness by 20%. Fracture of the screws is believed to occur sequentially, starting with the innermost screw that initially shields the other screws.

Introduction

Bridging plate osteosynthesis has gained popularity over the last ten years and is now a well-accepted technique for treating comminuted shaft fractures in small animals (1, 2). Bridging plate osteosynthesis is of particular interest when used in conjunction with an 'open-but-do-not-touch' or a minimally invasive approach, which preserves the soft tissue environment of the fracture site. Under these conditions, the plate is fixed to the main bone fragments with the screws placed at the plate extremities (1–3). Locking plates are particularly suitable for bridging osteosynthesis because they provide angular stability, require minimal contouring, and do not displace the fracture fragments during screw tightening (1, 2). The stability of locking compression plates is provided by a threaded or conical interface between the screw head and the plate hole.

In human orthopaedics, several authors have proposed guidelines for the recommended number of screws based on clinical observations and *in vitro* studies (3–7). The *in vitro* studies involved measurement of the stiffness of different constructs with varying numbers of screws (6, 7). In these studies, the screws were not concentrated at the plate extremities and the plates were applied in contact with the bone. Also, monocortical titanium screws were used in one study (7). The current recommendation for stabilization of comminuted fractures in non-osteoporotic human patients is to use at least three to four monocortical screws or two bi-

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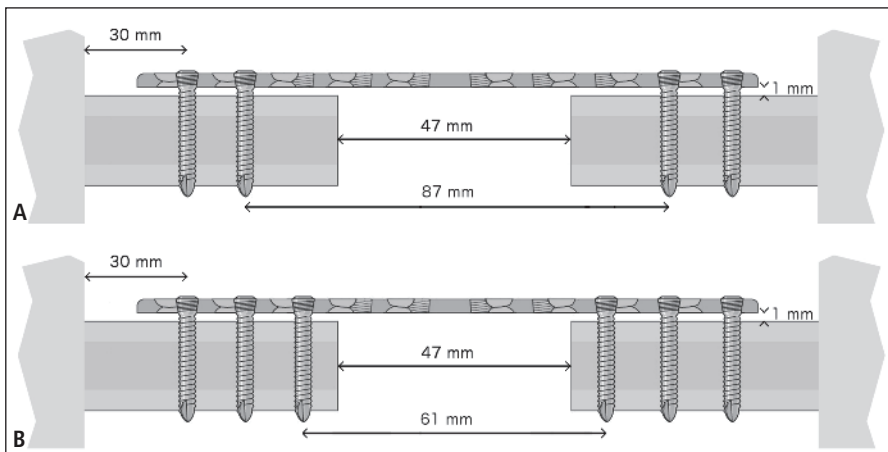


Figure 1 Illustration of the two constructs: A 10-hole 3.5 mm stainless steel locking compression plate (LCP) with 3.5 mm self-tapping locking screws was positioned on the bone fragments embedded in polyurethane blocks. Depending on the group, either two (A) or three (B) bicortical locking screws per fragment were placed in the outermost plate holes.

cortical screws per fragment (3, 7). Additionally, a plate-screw density of 0.4 to 0.5 is recommended for minimally invasive application of locking plates (3, 8).

The number of screws is critical because placing more screws than required results in damage to the bone and soft tissue and increases the cost of surgery (9, 10). On the

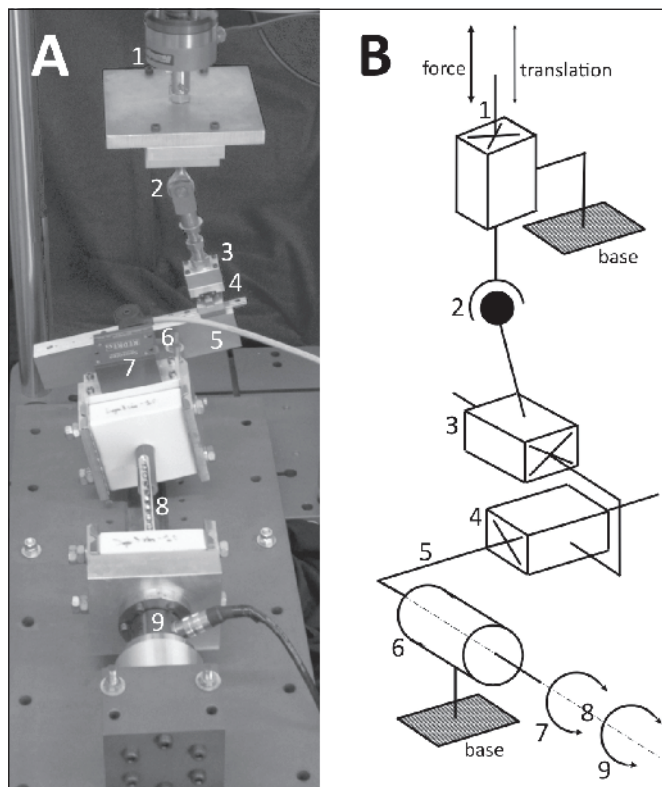


Figure 2 A) Test setup and B) kinematic representation. The torsion motion was obtained by trans-forming the translation of the electrodynamic actuator (1) into rotation using a series of kinematic links: ball joint (2), two orthogonal slide links (3 and 4), a cross-beam (5), and a sliding pivot (6). This set-up allowed a play-free kinematic to be obtained within the fixture and torsion without artefact within the construct (8). The angle of torsion was computed with a digital servo-inclinometer (7) placed on the proximal cup. The torque was measured with a non-rotating torque metre (9) attached to the distal cup.

other hand, reducing the number of screws would probably increase implant stress and, consequently, lead to failed osteosynthesis. Locking plates have been used clinically in dogs and cats, but no guidelines are currently available in veterinary surgery regarding the optimal number of screws per fragment (11–13).

The purpose of our study was to compare the mechanical behaviour of locking plate constructs with two or three bicortical locking screws per fragment during fatigue testing in torsion until failure. We hypothesized that a construct with three screws per fragment would have a higher stiffness and would survive longer than a construct with two screws per fragment.

Materials and methods

Preparation of the construct

Hollow fibre-filled epoxy cylinders^a, 83 mm long, with 3 mm wall thickness and 20 mm outer diameter were used as a bone model. Paired cylinders were embedded collinearly in polyurethane casting resin^b with a gap of 47 mm between the two cylinders. Two crossed Kirschner wires, 1.6 mm in diameter, were placed across the end of each cylinder before potting. Ten-hole 3.5 mm stainless steel locking compression plates^c (LCP) with 3.5 mm self-tapping locking screws^c were used for this study.

Two groups of plate-bone model constructs were assembled. The plates were applied to each bone substitute fragment with three bicortical screws (10 constructs) or two bicortical screws (10 constructs). In both groups, the screws were placed in the outermost plate holes (► Figure 1). The distance between the outermost screws and the casting resin was set at 30 mm for all constructs. A metal spacer with a thickness of 1 mm was used to make the plate separate from the bone. The plate and the spacer were applied to the cylinders using bone holding forceps. For drilling, a locking drill guide was used. The screws were tightened to 1.5 N.m using

a SawBones, Vashon Island, Washington, USA

b RenCast: Huntsman Corporation, Salt Lake City, Utah, USA

c LCP[®]: Depuy France SAS, Saint Priest, France

the torque-limiting screwdriver^c supplied by the manufacturer (precision: 1.49 ± 0.05 N.m). Correct insertion of the screws was checked visually. A screw was considered as being incompletely seated when at least one thread of the screw head was visible above the surface of the plate. In these constructs, additional attempts were made with the torque-limiting screwdriver to seat these screws before testing. After these attempts, the position of the screw was left unchanged, whatever the result of this re-tightening. A new set of implants was used for each construct, and no implant was reused for mechanical testing.

Mechanical testing

Cyclic torsional testing was performed with an electric linear fatigue testing machine^d. A custom-designed loading fixture was used to mount the embedded constructs in the testing machine (► Figure 2). The resin was firmly attached to the testing machine loading fixture aligning the axis of torsion with the axis of the bone surrogate. The torsional motion was obtained by transforming the translation of the electrodynamic actuator into rotation using a series of kinematic links involving a ball joint, two orthogonal slide links, and a sliding pivot (► Figure 2). This set-up made it possible to obtain a play-free kinematic in the fixture and torsion without artefact in the construct.

Cyclic torsion tests were performed in displacement control of the actuator with a sinusoidal waveform inducing an angle of 0 to +0.218 rad at a rate of 2 Hz until catastrophic failure. After three quasi-static load-unload tests to condition the construct, a quasi-static load-unload test was performed with an angle of 0 to +0.218 rad at a speed of 0.00024 rad per second at the beginning of the test and was repeated every 1,000 cycles.

Data acquisition

The angle of torsion was computed with a digital servo-inclinometer^e placed on the

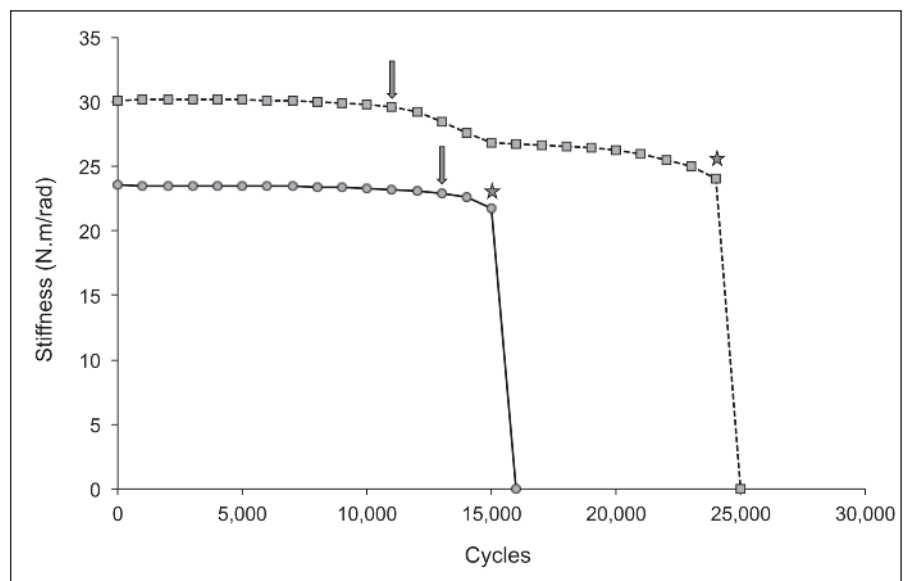


Figure 3 Evolution of stiffness over time for the 2-screws constructs (solid line with round plots) and 3-screws constructs (dashed line with square plots). The arrows indicate failure initiation and the stars show complete failure.

proximal cup. The torque was measured with a non-rotating torque meter^f attached to the distal cup (torque sensor range: 0–10 N.m). For each quasi-static load-unload test, torque and displacement data were recorded throughout the test with a dynamic data acquisition software^g. Torque

versus angular displacement curves were generated from each set of quasi-static test data using a commercially available spreadsheet software^h. For each quasi-static load, stiffness was determined from the slope of the linear portion of the torque-angular rotation loading curve and was expressed as Newton metres per radian. Failure initiation was considered as the first significant

f DF30: Scaime, Annemasse, France

g DCS 100-A: Kyowa Electronic Instruments, Tokyo, Japan

h Excel: Microsoft Corporation, Dublin, Ireland

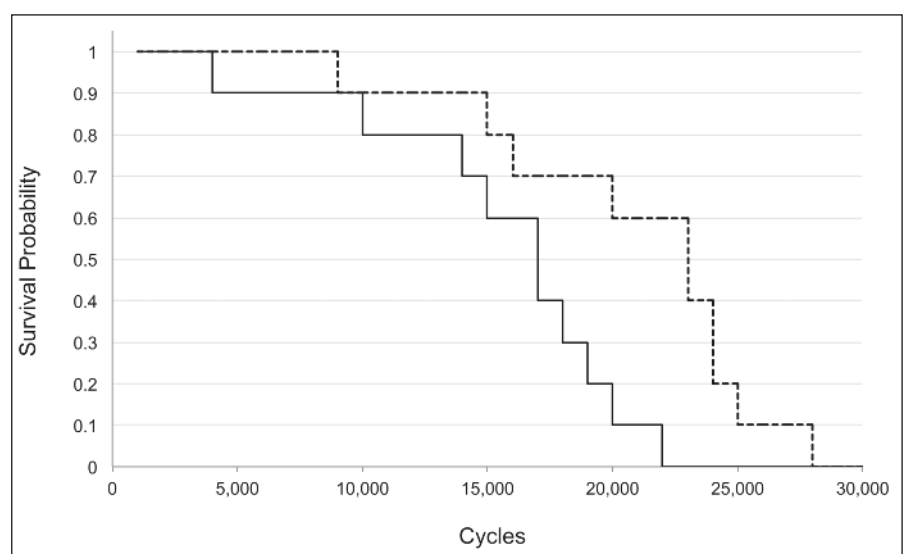


Figure 4 Kaplan-Meier survival curves for the two constructs. The mean survival time is significantly higher for the 3-screws constructs (dotted line) than for the 2-screws constructs (solid line).

d ElectroPuls E1000: Instron, High Wycomb, UK

e SX41142: Meggitt (Sensorex) SAS, Archamps, France

drop in stiffness as determined visually and mathematically on the curve. The difference D between two consecutive slopes of the curve stiffness-cycle was calculated using the formula:

$$D = \frac{(S_{n+1} - S_n)}{(C_{n+1} - C_n)} - \frac{(S_{n+2} - S_{n+1})}{(C_{n+2} - C_{n+1})}$$

where S_n is the stiffness for the cycle n (C_n) and S_{n+1} the stiffness for the cycle $n+1$ (C_{n+1}).

This difference was plotted against the number of cycles. The cycle corresponding to the failure of the constructs was indicated by an abrupt change in the curve.

Failure was similarly defined based on the observation of a catastrophic drop in stiffness.

Statistical analysis

Statistical analysis was performed using Mann-Whitney tests for comparison of stiffness at each quasi-static test, cycles to failure initiation, and catastrophic failure. A Kaplan-Meier with a Mantel test was used for the survival analysis. The significance level was set at $p < 0.05$. Results are expressed as mean \pm standard deviation.

Results

Torque was significantly higher for the 3-screws constructs (6.05 ± 1.33 N.m) than for the 2-screws constructs (4.88 ± 1.14 N.m) ($p < 0.05$).

Table 1 Mode of failure of the constructs.

	2-screws construct	3-screws construct
Number of failed constructs by fracture of the screws only	9	6
Number of failed constructs with screw head unlocking	1	4

The evolution of stiffness over time differed between the two constructs (► Figure 3). The 2-screws constructs exhibited monophasic evolution and stiffness remained stable (23.73 ± 0.87 N.m/rad) until failure initiation, which was shortly followed by complete failure. Six out of ten of the 3-screws constructs showed a biphasic evolution of stiffness (► Figure 3). From the beginning of the experiment to failure initiation, the stiffness of these constructs remained stable (29.65 ± 1.89 N.m/rad) and was significantly higher than that of 2-screws constructs ($p < 0.05$). After failure initiation, a lower stiffness was noticed until complete failure. This second stiffness (25.57 ± 1.89 N.m/rad) was significantly lower than the initial stiffness of the 3-screws constructs ($p < 0.05$) and significantly higher than the initial stiffness of the 2-screws constructs ($p < 0.05$).

Failure initiation did not differ significantly between the 2-screws constructs ($13,600 \pm 4,812$ cycles) and the 3-screws constructs ($11,600 \pm 3,204$ cycles) whereas

cycle to failure was significantly lower for the 2-screws constructs ($15,600 \pm 5,272$ cycles) than for the 3-screws constructs ($20,700 \pm 5,735$ cycles) ($p < 0.05$). Application of the Mantel log-rank test to the Kaplan-Meier survival analysis revealed a significant difference between the two groups, the mean survival time being 25% lower for the 2-screws constructs than for the 3-screws constructs ($p < 0.05$). The Kaplan-Meier survival curves are presented in ► Figure 4.

The constructs failed either by screw breakage or by a combination of screw head unlocking and screw breakage. These two modes of failure are reported in ► Table 1. Screw breakage occurred on the free portion of the shaft between the plate and the bone surrogate (► Figure 5). A fissure was visible on some of the 3-screws constructs, beneath the head of the innermost screw after failure initiation (► Figure 6). Nine screws were not completely seated in their plate hole during preparation of the constructs (► Figure 7). Four of these nine screws unlocked after cyclic testing. Three additional screws, which had been correctly placed during preparation of the constructs, also unlocked (► Figure 8).

Discussion

The results of our study showed that the stiffness of the 2-screws constructs was 20% lower than that of the 3-screws constructs, and confirmed our hypothesis that a construct with three screws per fragment would survive longer than a construct with

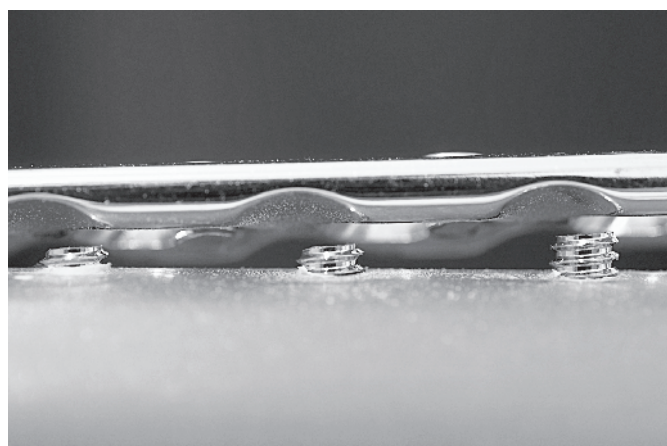


Figure 5 Fracture of the screws after cycling. Breakage of the screws occurred on the free portion of the shaft between the plate and the bone surrogate.

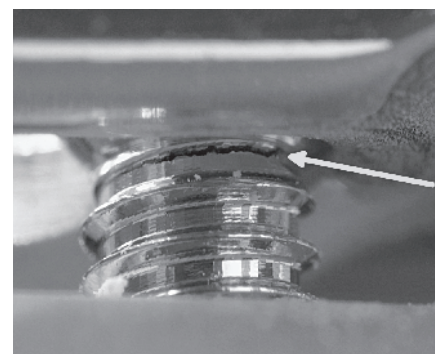


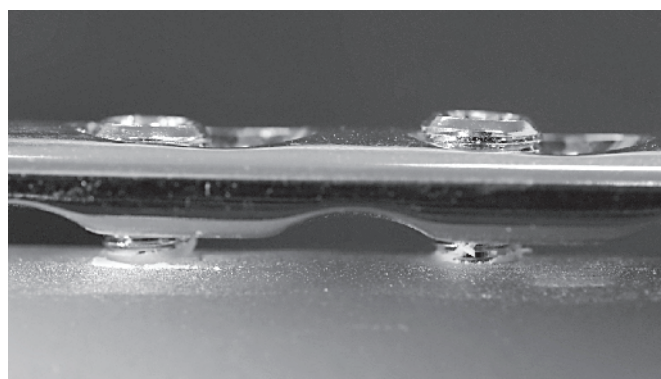
Figure 6 Fissure of a screw after failure initiation. The fissure (arrow) is visible below the screw head.

two screws per fragment. The construct with three screws subjected to the higher torque still had the longer fatigue life. In our model, omission of the third innermost locking screw on each fragment decreased the fatigue life by 25% even when the applied torque level was reduced.

As the bone-plate distance is commonly less than or equal to 2 mm when an LCP is used, a gap of 1 mm between the plate and the synthetic bone was chosen as an average (11). In clinical situations, it is likely that some screws would not have any offset and thus have a considerable increase in fatigue life, while other screws might have a 2 mm offset that would greatly decrease their fatigue life. The influence of screw offset on construct failure suggests that the locking plate should be contoured to minimize the free screw length between plate and bone, especially if only two screws are being used (14). As in many other studies, we used a validated synthetic bone with mechanical properties similar to those of native canine bone (7, 15-17). No failure of the synthetic bone was observed during the tests. It therefore had little influence on the data, though part of the stiffness measured was due to deformation of the synthetic bone material. Cyclic loading in torsion was used because torsion is a significant force applied on a long bone during walking and is considered as a potential mode of failure in plates and screws (18). The magnitude of angular deformation was lower than the torsion angle at yield previously described in static tests to keep the angular displacement within the elastic deformation phase of the constructs (15). It corresponded to a torque usually used in torsion tests for constructs designed for the treatment of fractures in dogs (19). None of the plates showed any gross shape change at the end of testing.

Our constructs failed after 15,000 cycles which is lower than that reported in a recent study on cadaveric canine tibiae loaded at 4.0 N.m (20). In that study, the mean number of cycles to failure under torsional testing was between 163,572 and 195,382 cycles (20). This discrepancy in results could be attributed to the mechanical setup which differed from that of the present study: shorter plates, shorter working length, and plates fixed in contact with the

Figure 7 Inadequately-seated screw head before testing. The left screw is correctly positioned. The right screw is inadequately seated with two threads visible above the plate surface.



bone but with no free portion of the screw shaft between the plate and the bone. Moreover, as most SN curves are logarithmic, the 10 times fewer cycles to failure in our study could be explained by the higher torques applied. This amount of rotation produced dynamic loading to failure within a reasonable number of load cycles, as has already been reported in previous studies (22-26). Given that the mechanical setup in our study was based on displacement control, the two constructs were subjected to different loads. Even so, our testing methodology did allow some comparison of the two fixation techniques in terms of failure life.

Construct failure under cyclic loading has been described as being the result of defect accumulation, crack initiation and crack propagation with an increasing

number of load cycles (27). As previously reported, the locking screws failed in our study by screw breakage between the plate and the bone, suggesting the presence of high stress on the free part of the screws between the bone and the plate and on the screw head coupling (23, 28).

Calculation of stiffness at each quasi-static test showed an evolution of stiffness over time and enabled the mechanisms of failure for both constructs to be evaluated. Omission of the third innermost screw probably resulted in an increased stress on the two remaining screws and decreased the fatigue life. A finite element analysis of bridging plate constructs showed that the screws closest to the fracture gap had the highest stresses (7). We hypothesized that the biphasic aspect of the stiffness over time curve for the 3-screws group could be

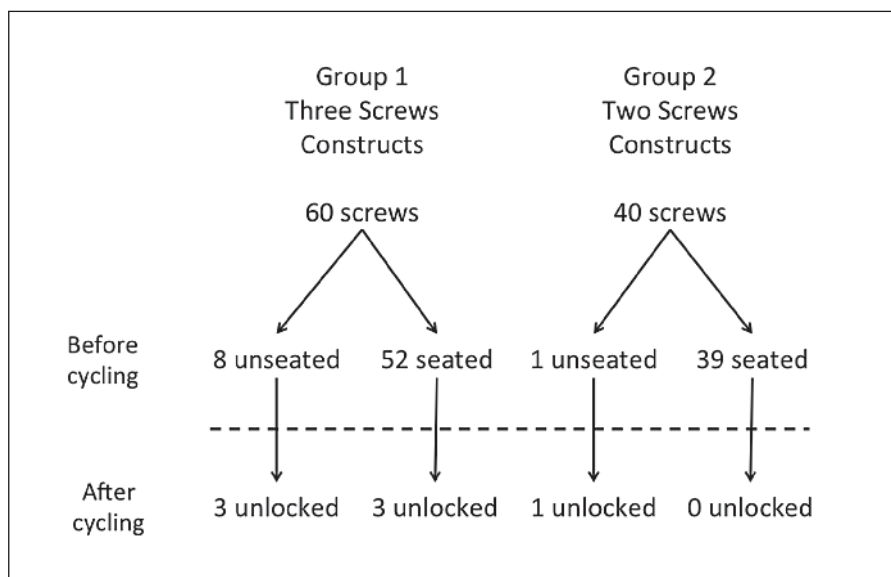


Figure 8 Status of the screws for the two groups of constructs before and after cyclic testing.

explained by failure of the innermost screw, which was visible as a fissure in some of the 3-screws constructs. In other words, the innermost screw on each fragment shielded the two outermost screws. Breakage of an innermost screw resulted in a mixed construct with two screws on one side and three on the other. The stiffness of this mixed construct was intermediate between that of the 2- and 3-screws constructs.

To our knowledge, the fatigue life of locking constructs with different numbers of screws has been assessed in only one other study to date (29). This other study compared the stiffness in bending, torsional, and axial loading of two constructs with either two or three bicortical screws per fragment. They did not find any difference between the two groups either before or after 1000 cycles of torsion. This lack of difference could be attributed to the low number of cycles or to the direct apposition of the plate on the bone, which would have prevented the occurrence of a high stress in the free unsupported portion of the screws. Additionally, the 2-screws constructs in this other study were obtained by omitting the middle screw on each fragment, thereby maintaining a similar working length in the two constructs (29). In our experiment, omitting the innermost screws increased the working length of the 2-screws constructs. From a mechanical point of view, varying the working length modifies the distribution of stress within the screws and affects survival of the constructs (7, 30). From a biological point of view, increasing or decreasing the working length changes the construct elasticity and stiffness that lead to strain changes in the fracture gap, which are important factors likely to influence the type and duration of fracture healing (31, 32).

Screw head unlocking was observed in five out of 20 constructs in our study. This phenomenon has been reported previously, both in clinical and experimental situations. In human orthopaedics, screw unlocking has been noted in 4.5% to 16% of cases (33, 34). Screw head unlocking under cyclic loading in experimental settings has been described in 12%, 25%, or 100% of cases (14, 35, 36). In the current study, despite the fact that all screws were inserted using the 1.5 N.m torque limiter, nine per-

cent of them were not completely seated in their plate hole before testing. Although additional attempts were made to seat these screws prior to testing, further tightening of all these screws was prevented by the torque limiter. Four (44.4%) of the inadequately seated screws unlocked during testing in the current study. Based on this finding, we suggest that if a screw does not completely seat, it should be tightened with a torque greater than 1.5 N.m, since the risk of screw loosening outweighs the concerns associated with cold welding (36). Furthermore, it is possible that the application of a higher tightening torque would have reduced the incidence of loosening of the three of the appropriately seated screws which unlocked after cycling.

There are several limitations to our study. The mechanical tests were conducted on bone substitute. Although these bone substitutes have been shown to perform similarly to native canine bones, they may have reduced the likelihood of screw pull-out or bone fracture (17). Indeed, when cyclic torsion was performed on constructs where the LCP were fixed in contact with cadaveric canine bone, bone fracture occurred through the screw hole adjacent to the gap (20). Even though screw breakage has been previously reported after cyclic torsion, it is not possible to predict what mode of failure would occur in clinical situations (23, 28). The aim of this study was to compare two plate-bone constructs that are commonly used to stabilize fractures in the dog. Mechanical tests were performed under angular displacement control because this produced stable control loops and was easier than load control. This mechanical setup resulted in a greater peak torque being applied to the 3-screws constructs. Even so, this group still resisted more cycles than the 2-screws constructs. Standard specification and test methods for testing bone plates only describe a standard single cycle test method in bending (37). Due to the lack of a standard specification for cyclic torsional testing, our protocol was based on previously reported studies, where testing was performed in torsion, under displacement control (36, 38–41). However, no comparison with our study was possible due to differences between the mechanical tests: locked or non-locked

constructs and bicortical or unicortical screws. A mechanical set-up with load control would have induced either a higher rotation for the 2-screws constructs or a lower rotation for the 3-screws constructs and would probably have increased the difference between the two constructs. On this basis, when possible, it would be safer to use 3-screws constructs rather than 2-screws constructs. Moreover, our model of repetitive loading did not take into account the bending and axial loading forces that are exerted postoperatively on a bone plate construct used in comminuted fractures. Stresses from bending and axial loading add to torsion stresses and would speed up cyclic failure, and indeed the plate might fail before the screws. The repetitive loading protocol was not based on the force which can be achieved with axial loading by the patient (42, 43). As with any biomechanical testing of bone plate constructs on synthetic bones, the conditions of patient loading on the bone were not exactly reproduced. A greater torque was applied than the expected torque during walking, making clinical transposition of our results difficult.

Finally, *in vivo* factors such as screw loosening due to bone resorption, or protection of the plate by callus development, were not created in this model and these factors are likely to vary in the clinical patient. Also, in clinical situations, the free screw length is likely to be more variable than in our model. Mechanical studies of cyclic axial loading and bending along with *in vivo* studies would be necessary for a complete assessment.

Conclusions

Our results indicate that the number of bicortical locking screws used in our model to secure a bridging locking plate significantly affected construct survival under cyclical torsion. The failure life of a construct with two screws per fragment was reduced by 25% compared to a construct with three screws per fragment; this suggests that a better safety margin is obtained by placing, when possible, three screws rather than two screws in a locked plate that is not closely contoured to the bone. However, this experimental study did not

provide sufficiently robust data with which to make clinical management suggestions such as when to use a two or a three locking-screws construct in a comminuted diaphyseal fracture in the dog. Clinical studies reporting fracture fixation using either a 2-screws or a 3-screws construct will provide complementary data that should help the veterinary surgeon to make the most appropriate choice.

Acknowledgements

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Conflict of interest

Depuy France SAS supplied the plate and screws used in this study. Depuy France SAS played no role in the study design or in the collection, analysis, and interpretation of data, or in the decision to submit the manuscript for publication. None of the authors have any financial or personal relationships that could inappropriately influence or bias the content of the paper.

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