Experimental and numerical investigation into the influence of loading conditions in biomechanical testing of locking plate fracture fixation devices

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Objectives
Secondary fracture healing is strongly influenced by the stiffness of the bone-fixator system. Biomechanical tests are extensively used to investigate stiffness and strength of fixation devices. The stiffness values reported in the literature for locked plating, however, vary by three orders of magnitude. The aim of this study was to examine the influence that the method of restraint and load application has on the stiffness produced, the strain distribution within the bone, and the stresses in the implant for locking plate constructs.

Methods
Synthetic composite bones were used to evaluate experimentally the influence of four different methods of loading and restraining specimens, all used in recent previous studies. Two plate types and three screw arrangements were also evaluated for each loading scenario. Computational models were also developed and validated using the experimental tests.

Results
The method of loading was found to affect the gap stiffness strongly (by up to six times) but also the magnitude of the plate stress and the location and magnitude of strains at the bone-screw interface.

Conclusions
This study demonstrates that the method of loading is responsible for much of the difference in reported stiffness values in the literature. It also shows that previous contradictory findings, such as the influence of working length and very large differences in failure loads, can be readily explained by the choice of loading condition.

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Keywords: Fracture healing, Strain, Boundary conditions

Article focus
- The influence that the method of restraining and load application has on the stiffness of the bone-plate system in vitro.
- The effect of loading conditions on the strain distribution within the bone and the stresses in the implant.

Key messages
- The method of loading is responsible for much of the difference in reported stiffness values in the literature.
- Previous contradictory findings, such as the influence of working length and very large differences in failure loads, can be readily explained by the choice of loading condition.

Strengths and limitations
- This is an experimental and validated finite element simulation study evaluating a range of widely used in vitro testing conditions.
- The study does not address the in vivo condition, but speculates as to the most appropriate in vitro loading condition.

Introduction
Secondary fracture healing is strongly influenced by the interfragmentary motion (IFM)
between fractured bone segments. A controlled amount of axial motion is known to be beneficial for the healing process, whereas shear or torsional motions have been shown to be disruptive. It is important to be able to determine accurately the amount of axial movement a fixator will produce at the fracture site, as too much or too little can cause nonunion.

Interfragmentary motion depends on the stiffness of the bone-fixator system; however, stiffness defined as the slope of the load-displacement curve has been evaluated by several different methods and reported in the fixation literature. First, most studies use the secant line to evaluate stiffness, which is obtained from the applied load divided by the displacement at a chosen location. Second, the point chosen to determine the displacement can influence its value considerably. In this study, the term ‘axial stiffness’ will imply that the displacement is being measured at the loading actuator, whereas stiffness evaluated from maximal fracture gap closure (or IFM) will be called ‘gap stiffness’. Stiffness is useful for comparisons between studies because comparing the IFM alone does not take into consideration the level of loading. The range of values of stiffness reported in the literature for locked plating (also known as locking compression plating) vary by three orders of magnitude. Several factors have been shown to influence the IFM produced by a locking plate: the geometry and material of the plate, the bone-plate off-set, and the position of screws within the plate. This wide variation, however, cannot be readily explained solely on the basis of studies’ differing materials, geometries and methods of stiffness evaluation.

One aspect of mechanical testing that has a strong influence on stiffness evaluation but has received relatively little attention is the way that bone samples are restrained and loaded during tests. Bone samples that are fully restrained (or potted) at the ends will provide displacements that are significantly different from tests in which bone ends are pinned (allowing rotation). The use of fully restrained boundary conditions in computer simulation has been criticized; nevertheless, many biomechanical studies of locking plates use clamped or potted loading conditions to make predictions of fracture gap motion, implant strength, and fatigue resistance. Predictions of stiffness in studies using a similar loading condition, for example where both ends of the specimen are pinned, are generally confined to differences within a single order of magnitude. The influence of in vitro testing conditions must be understood so that results can be interpreted in context.

In addition to the wide range of IFM predictions, previous studies have produced other conflicting results. In a study with titanium femoral locking plates loaded in axial compression, Hoffmeier et al found failure loads between 385 N and 391 N, whereas in another study by Liang et al, specimens withstood loads of between 4250 N and 4600 N. A previous study by Stoffel et al has shown working length (the distance between the two innermost screws) to have a dramatic influence on stiffness and fatigue resistance, but other studies report almost no influence. Peak strains within the bone were predicted to be located around screws farthest away from the fracture gap in some studies, but others have found them to be located at the screws nearest the fracture site.

The aim of this study is to inform on the importance of the loading conditions in experimental or numerical bone tests. Experimental and computational models of the bone-plate system are used to examine the influence that...
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The method of restraining and load application has on the IFM produced. This study also uses finite element (FE) analyses to examine the effect of loading conditions on the strain distribution within the bone and the stresses in the implant. While this study speculates which of the several experimental loading scenarios examined is closest to the in vivo condition, it does not attempt to recreate it.

Materials and Methods

In vitro studies. Composite tibias (fourth-generation large Sawbones tibia #3402, Sawbones Europe AB, Malmö, Sweden) were implanted with narrow (n = 2) and broad (n = 2) steel locking plates and screws (AxSOS Locking Plate System; Stryker, Kalamazoo, Michigan). We experimentally determined the second moments of area in the weak axis to be 50.6 mm⁴ and 96.9 mm⁴ for the narrow and broad plates, respectively.30,31 The plates were fitted by an orthopaedic surgeon (who was not an author on this paper) and offset 2 mm from the bone. A 10 mm osteotomy of the diaphysis was used.11,18,32 The specimens were 405 mm long, with an outer bone width at the fracture site of 28 mm. The locking screw dimensions were 5.0 mm external and 4.3 mm core diameter. The pilot hole was the same size as the internal diameter as recommended by the manufacturer. Threads had a depth of 0.7 mm and a spacing of 1.2 mm. Each implanted specimen was tested using four different loading conditions (Fig. 1).

Condition A: clamped proximally, clamped distally, where both ends of the bone are restrained against rotation. Previous studies that have used this condition for in vitro testing include Strauss et al16 and Yanez et al.25

Condition B: clamped proximally, pinned distally, where the proximal tibia is restrained against rotation and the ankle is free to rotate. Previous studies that have used this condition for in vitro testing include Bottlang et al,10 Chao et al,22 Liang et al,23 and Granata et al.21

Condition C: pinned proximally, pinned distally, where both ends of the bone are free to rotate. Previous studies that have used this condition for in vitro testing include Stoffel et al,7 Hoffmeier et al,8 and Zlowodzki et al.33

Condition D: hinged proximally, pinned distally; medial and lateral condylar restraint was provided, permitting rotation in the sagittal plane proximally while the ankle is free to rotate. A previous study that used this condition for in vitro testing was Assari et al.34

Universal joints were used to allow rotation, and positioned 20 mm from the articular surfaces of the tibias,
making the effective length of the specimens 445 mm for conditions C and D. For the clamped conditions, the bone was bolted directly into the test machine, resulting in an effective length of 405 mm. In all cases, the fittings were secured to the bone using M8 steel bolts and a 10 mm thick steel plate within the metaphysis. While many studies have used idealized bone models, such as cylinders,7,10,11,13,15,25 the reason for modelling the whole tibia was to situate the boundary conditions at the relevant anatomical locations. It was expected that the bone length and shape would alter the stiffness prediction and this was later confirmed.

For each loading condition, three tests were conducted corresponding to different screw configurations, which are summarized in Figure 2. Screw configuration ‘C1234’ indicates that screws were placed in holes one to four counting from the fracture site. In all cases, the screw configurations were symmetrical on either side of the fracture. The specimens were loaded at a rate of 5 N/s using an Instron 4505 testing frame (Instron, Norwood, Massachusetts). A black-on-white speckled paint pattern was applied to the surface of the bone. A camera (EOS 5D Mark II 21.1 megapixel digital single-lens reflex (SLR); Canon (UK) Ltd, Surrey, United Kingdom) was positioned at the height of the osteotomy site; the specimen was aligned such that the dominant plate deformation during testing was in the plane of view. Photos were taken at regular load intervals (25 N) during testing. Fracture gap motions were obtained using digital image correlation software GeoPIV in Matlab 7.6 (MathWorks, Cambridge, United Kingdom).35 The accuracy of this method was evaluated using a rigid body motion test; this demonstrated that we could achieve an accuracy of ±0.02 mm. The axial movement at the fracture gap (IFM) was evaluated at the cortex furthest away from the plate for each loading configuration and screw configuration (transverse motions also provided in Supplementary figure 1). The testing regime for each specimen is summarized in Figure 3. For each specimen (n = 2 for narrow plates and broad plates), there were four loading conditions and three screw arrangements tested (12 tests), resulting in a total of 48 tests. The IFM was recorded at 200 N, except for screw configuration C34, which was recorded at 100 N due to the large deformations.

The gap stiffness was evaluated for each loading condition and for each screw configuration using the applied load divided by the IFM. These values were compared with previous studies that predicted the stiffness of locking plates in vitro.7–16,18,22–26,28,34,36–40

Finite element simulation. A 3D finite element model was developed based on the experimental models (Fig. 4). The geometry of the tibia and plates were obtained using a desktop 3D laser scanner (NextEngine, Santa Monica, California). This surface was offset by 5 mm internally to produce the cortical shell. As the simulated fracture was in the tibial diaphysis, screw anchorage is provided by cortical bone.36 As such, only the cortical bone was included in the models (Fig. 4).29,41 The Sawbones cortex was given a Young’s modulus of 16.35 GPa, based on a mean of the tensile and compressive moduli.42 The steel was assigned a Young’s modulus of 180 GPa. All materials were assumed to be homogeneous, isotropic, and linear elastic, and were assigned a Poisson’s ratio of 0.3.36,43

The screw threads were modelled as rings rather than helical,6 and screw-bone interaction used a Coulomb friction coefficient of 0.3.44,45 It has been previously shown that, in locking plates, although the screw head is locked into the plate’s threaded chamber, the two cannot be assumed to be monolithic or completely bonded.30,46 To model the plate-screw interaction, the predicted displacement at the tip of the screw was evaluated for the FE model (Fig. 5a) and compared with experiments in which the screw was subjected to a force (Fig. 5b).30,31 It was found that the assumption of a fully bonded plate-screw interface resulted in the FE model being approximately eight times stiffer than the experiments. The interface was modelled using eight spring elements (four each, both top and bottom) around the screw head, connecting to the plate (Fig. 5a). A linear spring stiffness of 10 kN/mm per spring produced the closest match to the experimental results.

The models used over 1.3 million linear elements, and 81,000 quadratic tetrahedral elements with refinement around screw holes. In the region around screw holes, the mean element edge length was 0.3 mm to 0.4 mm. A mesh convergence study was performed and the results showed that doubling mesh density of the plate only increased the fracture gap motion by 0.3%. Similarly, when doubling the mesh resolution in the bone, the change in peak minimum (and maximum) compressive strain was 3.0% (2.1%), and the increase in fracture gap motion was 4.5%. The analyses were conducted using geometrical nonlinearity using Abaqus 6.10 (Simulia, Providence, Rhode Island).
The FE models were used to predict the IFM in an identical manner to experimental tests, incorporating the different plate geometries, boundary conditions, and screw configurations. Additionally, to examine the influence of loading conditions on the internal stress-strain environment, the load was increased to 500 N. This increased load was selected to represent partial weight-bearing in the early stages of healing where the fixator is transmitting most of the load.47

Results
To validate the FE models, the load-deformation response of loading condition C (Fig. 1c) was used; the comparison is shown in Figure 6. There was good agreement with the experimentally predicted stiffness results, with the maximum difference of 23.9% for all screw configurations and plate types (Table I).

The axial IFM predictions for each loading condition are shown in Figure 7. In each case, the influence of screw placement is shown by the size of the bar (the lower value is the motion with C1234; the higher is with C34). Taking a mean of all screw configurations and plate types, the finite element IFM predictions of conditions C (rotation allowed at both ends) and D (rotation allowed distally and hinged proximally) were within 9% and 22% of the experimental results, respectively. On the other hand, the FE predictions for conditions A (fully clamped) and B (clamped proximally and pinned distally) were approximately two to three times smaller than those of the experimental tests. Our experimental tests showed that the choice of loading condition alone could alter the gap stiffness prediction by nearly three times for the smallest working length, and six times for the largest working length. In FE simulations, the observed differences were much larger (as much as 24 times), as the clamp in FE models is ideally rigid. This is very difficult to achieve in in vitro experiments. Translational IFM predictions are provided in Supplementary figure 1.

The experimental gap stiffness predictions are shown against values from the literature in Figure 8. The last four

| Plate type and screw configuration | Gap stiffness (N / mm) | Load (N) | Error (%) |
|-----------------------------------|-----------------------|----------|-----------|
|                                  | Experimental T1 | Experimental T2 | Mean | Finite element | |
| Loading condition A              |                       |                       |      |               | |
| Narrow AxSOS                     |                       |                       |      |               | |
| C1234                             | 1008.7                | 908.0                | 958.3 | 3342.6        | 200 | 248.8 |
| C34                               | 950.3                 | 613.5                | 781.9 | 3076.4        | 200 | 293.4 |
| C1234                             | 680.5                 | 440.6                | 560.5 | 2785.6        | 100 | 396.9 |
| Broad AxSOS                       |                       |                       |      |               | |
| C1234                             | 1398.9                | 1297.0                | 1347.9 | 3495.5        | 200 | 159.3 |
| C34                               | 534.7                 | 1029.7                | 782.2 | 3174.5        | 200 | 305.8 |
| C34                               | 701.6                 | 989.5                | 701.6 | 2834.1        | 100 | 303.9 |
| Loading condition B               |                       |                       |      |               | |
| Narrow AxSOS                      |                       |                       |      |               | |
| C1234                             | 764.6                 | 985.6                | 875.1 | 3249.5        | 200 | 271.3 |
| C34                               | 596.6                 | 613.1                | 604.8 | 3014.5        | 200 | 398.4 |
| C1234                             | 425.1                 | 553.2                | 489.2 | 2564.6        | 100 | 424.3 |
| Broad AxSOS                       |                       |                       |      |               | |
| C1234                             | 1063.2                | 776.1                | 919.7 | 3334.1        | 200 | 262.5 |
| C34                               | 684.9                 | 769.5                | 727.2 | 2927.9        | 200 | 302.6 |
| C34                               | 462.3                 | 301.2                | 462.3 | 2407.7        | 100 | 420.8 |
| Loading condition C               |                       |                       |      |               | |
| Narrow AxSOS                      |                       |                       |      |               | |
| C1234                             | 299.0                 | 366.5                | 332.8 | 323.6         | 200 | -2.7 |
| C34                               | 269.7                 | 216.3                | 243.1 | 185.1         | 200 | -23.9 |
| C1234                             | 114.1                 | 105.0                | 109.6 | 112.9         | 100 | 3.0 |
| Broad AxSOS                       |                       |                       |      |               | |
| C1234                             | 628.5                 | 744.7                | 686.6 | 580.4         | 200 | -15.5 |
| C34                               | 374.0                 | 323.0                | 348.5 | 337.5         | 200 | -3.2 |
| C34                               | 210.1                 | 467.7*               | 210.1 | 209.0         | 100 | -0.6 |
| Loading condition D               |                       |                       |      |               | |
| Narrow AxSOS                      |                       |                       |      |               | |
| C1234                             | 556.8                 | 426.2                | 491.5 | 931.9         | 200 | 89.6 |
| C34                               | 388.3                 | 377.5                | 382.9 | 638.9         | 200 | 66.9 |
| C34                               | 273.6                 | 257.2                | 265.4 | 375.0         | 100 | 41.3 |
| Broad AxSOS                       |                       |                       |      |               | |
| C1234                             | 946.0                 | 742.3                | 844.1 | 1132.2        | 200 | 34.1 |
| C34                               | 708.4                 | 555.6                | 632.0 | 734.9         | 200 | 16.3 |
| C34                               | 397.4                 | 403.0                | 397.4 | 434.0         | 100 | 9.2 |

*This value was excluded from the mean stiffness and error calculation as bone-plate contact occurred during deformation
bars corresponding to the present study have the upper value of stiffness evaluated from screw configuration C1234 and the lower value derived from C34.

Minimum principal strain was examined for the various loading scenarios on the surface of the bone underneath the plate (Fig. 9). Minimum principal strain was chosen because compressive strains dominate within the bone under axial loading. Each loading condition produces a unique pattern of strain within the bone around the screw hole locations. The peak compressive strains were 0.36%, 0.31%, 0.28%, and 0.51% for loading conditions A, B, C, and D, respectively. For loading conditions A and B, the peak strains were located around the screw farthest from the fracture, whereas for loading conditions C and D, the peak strains were located around the screw closest to the fracture.

The von Mises stress was plotted for the screws and plate for each loading condition using screw configuration SC1234 at a load of 500 N (Fig. 10). The maximum stress within the narrow plate was 53 MPa, 58 MPa, 603 MPa, and 295 MPa for loading conditions A, B, C, and D, respectively. Loading condition C produced large regions of high stress as the plate is free to bend. Loading conditions A and B resulted in much smaller plate stresses as they are prevented from bending, thus carrying predominantly axial stress. Loading condition D resulted in biaxial bending and had smaller regions of high stress than condition C.

**Discussion**

Experimental and numerical models of fractured bone implanted with fixation devices were used to make predictions of IFM and stiffness, strength of implants, and strain within the bone. This study shows that the method of load application can have substantial influence on IFM and stiffness predictions in locking plate constructs. This study also demonstrates for the first time that the pattern of strains within the bone, as well as the stresses within the metalwork, is strongly influenced by the choice of loading condition.

All of the restraint conditions examined in the present study have been previously employed in the experimental testing literature. It is evident that studies using clamped approaches (conditions A and B) produced the highest stiffness and lowest plate stresses as they restrict plate bending. Studies using the pinned approach (condition C), on the other hand, allowed the plate to bend freely, producing the lowest stiffness and highest stresses. While the previous studies considered in Figure 8 are not directly comparable, the range of stiffness values quoted varies by three orders of magnitude; predictions of stiffness for studies using loading condition C are generally confined to within a single order of magnitude. Condition C also produced a nonlinear deformation response with increasing load. This was captured by the geometrically nonlinear FE analysis conducted. The IFM produced using condition B (Fig. 7b) was very similar to that of condition A (Fig. 7a). This shows that the clamped boundary condition dominated the behaviour. Bottlang et al. used a mean value of IFM (taking a mean of the motion at the near and far cortices) for their stiffness prediction; using the maximum value reduces their axial stiffness prediction by approximately 40%, but it still remains much larger than the majority of the studies (Fig. 8). In the present study, condition D produced stiffness values in
between the extremes represented by the other loading conditions (Fig. 8). However, this condition was used by Assari et al.34 and their stiffness values are at the upper end of the range found in the literature. Differences between the loading conditions become even more pronounced when considering the influence of different screw arrangements (Fig. 7). Condition C was sensitive to changes in working length (distance between innermost screws), while conditions A and B were relatively insensitive. This explains the comparatively small differences between working lengths observed by Chao et al22 (using condition A) and the much larger difference predicted by Stoffel et al7.

In a study of various unilateral fixators, Epari et al.49 found that fixators which had ‘moderate’ axial stiffness (2000 N/mm) and ‘high’ shear stiffness (500 N/mm) produced the best healing outcomes in terms of residual torsional stiffness. These values are at the upper end of the stiffness range presented in the literature and must be taken in the context of the loading condition used to evaluate them. In their study, both ends of the bones were potted in poly(methyl methacrylate) (PMMA), representing a clamped condition. The use of a clamped condition implies unrealistic rotational rigidity at the knee and ankle, and it restricts plate bending and therefore cannot be used for predictions of IFM.

Some studies have used a clamped condition comparing newer ‘flexible’ locking screw types with standard locking screws.10,13,15,24 In these studies, the plate bending will be restricted, thus exaggerating the differences in IFM found between the types of screw tested. Differences in loading conditions may also explain the large differences in failure loads found by various studies. Pinned studies such as Hoffmeier et al8 and Zlowodzki et al33 predict static failure loads between 385 N and 1126 N. In clamped studies, Liang et al23 found mean static failure loads of 4438 N.

As many of the previous studies considered had different lengths of test specimen, the influence that bone length had on the motion prediction was investigated. In this study, both ends of the bones were potted in poly(methyl methacrylate) (PMMA), representing a clamped condition. The use of a clamped condition implies unrealistic rotational rigidity at the knee and ankle, and it restricts plate bending and therefore cannot be used for predictions of IFM.

The recorded stiffness values of locking plate constructs found by previous studies (orange bars) and the stiffness values of each of the loading conditions used in this study (blue bars). IFM, interfragmentary motion.
mechanical response. However, this is not straightforward, and simplified loading conditions will continue to be used in experiments and provide biomechanical guidance on fracture fixation. In condition D, restraint was provided at both condyles to produce the hinge; this was to mimic the condylar joint reactions at the knee as opposed to a single knee joint reaction. As the thin dimension of the plate was in a different plane to the rotation allowed at the knee, condition D resulted in biaxial bending of the plate. The authors believe that the true physiological joint restraint is likely to be in between conditions C and D.

As shown, the peak strains within the bone around screw holes are the highest at the screw closest to the fracture gap for condition C (Fig. 9c). This is consistent with a recent study by Donaldson et al\textsuperscript{29} on unilateral fixators that predicted the highest degree of yielding and associated loosening at this location. Conversely, studies using clamped conditions\textsuperscript{10,27,28} predicted the highest strains at the screw farthest from the fracture (Figs 9a and 9b). While periprosthetic fractures are known to occur at this location, they have been attributed to osteoporotic bone and/or excessive plate rigidity.\textsuperscript{50} Additional simulations confirmed that both reducing the Young’s modulus of bone and increasing plate rigidity increased the level of strain within the bone at the plate ends, even when using loading condition C. Condition D produced large strains both near and far from the fracture site.

This study has a few limitations. It only considers axial loading, and boundary conditions may influence the response in a different way for bending and torsional loading conditions; these can arise due to a range of different physiological activities. We recommend that future studies should also investigate the influence of bending and torsional loading regimes. While the study highlights the influence of boundary conditions on the bone-plate system, it does not recreate the \textit{in vivo} environment, which can be a complex mix of some of these idealized conditions. Some previous studies have validated computational models of intact cadaveric bones under different loading regimes.\textsuperscript{51,52} The present study considered fixation constructs, which are influenced by changes in loading and restraint due to the lower construct stiffness.\textsuperscript{53} Therefore, it would be valuable to confirm the findings of this study using a cadaveric model, although it is unlikely that the use of cadaveric bone would change our conclusions relating to construct stiffness or plate stress.\textsuperscript{31} On the other hand, the variation in material properties would alter the strains in the bone around the screws. The study is limited to the period in which no healing has taken place. The role of boundary conditions is very likely to change once callus formation has been initiated. We did not include material nonlinearity in the FE models as the loading considered did not cause the metalwork to reach the yield stress, or cause the bone to reach the yield strain. In addition, we considered only short-term static loading; for long-term predictions, viscoelasticity or fatigue effects may play a role.

Many previous studies have used clamped loading conditions.\textsuperscript{9,10,12–14,16,21–25} This study showed that clamped
loading conditions were relatively insensitive to the positioning of screws. In our experimental tests, some motion was seen from the digital image correlation, which revealed that the clamp was not completely restraining movement. Consequently, the experimental stiffness for loading conditions A and B was much smaller than that of the FE modelling, which assumes perfect clamps. Studies that choose to use such loading conditions must be aware that the rigidity of the clamp or potting material may be more influential than any of the other variables being examined. Additionally, computational studies must be aware that modelling representations of clamped boundary conditions will generally be much more rigid than reality and therefore make validation challenging. The hinged condition fully restrains the bone in the direction perpendicular to the hinge and therefore may not be readily replicated in experiments. Thus, the authors believe that the most readily comparable results from different studies are from condition C, where the bone ends can rotate freely. Since both the knee and the ankle joints allow some rotation in all directions, condition C is also close to the in vivo scenario. To improve comparisons further, studies that use condition C should quote the distance between the centres of rotation at the joints and the position of the fracture relative to the joints in addition to other measurements regarding the test set-up. Condition C can also be used to create moments at the joints by using eccentric loading. To avoid the large variation in predictions between studies and conflicting results, we recommend that loading condition C, where both ends of the bone are free to rotate, is used as the standard for the in vitro evaluation of fractured bone specimens under axial loading.

Supplementary material

The transverse IFM results are available alongside this article at www.bjr.boneandjoint.org.uk

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