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Biomechanics of Two External Fixator Devices Used in Rat Femoral Fractures

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running title: external fixator biomechanics, and FEA

Author contributions: LOC, manuscript preparation, data collection, experimental design. JK experimental design, data collection. GB, experimental design, manuscript preparation. MC/CP/TB, experimental design and data analysis. RM, computational modelling and manuscript preparation. MM, experimental design, data analysis, manuscript preparation. all authors have read and approved the final submitted manuscript

Abstract

The use of external fixators allows for the direct investigation of newly formed intrafragmentary bone, and the radiographic evaluation of the fracture. We compared the in vitro stiffness' of two widely used external fixator devices used for in vivo analysis of fracture healing in rat femoral fractures with differing construction (Ti alloy ExFix1 and PEEK ExFix2) and correlated the results to a finite element (FE) model.

Rat femoral fracture fixation was modelled using two external fixators. For both constructs an osteotomy of 2.75mm was used, and offset maintained at 5mm. Tufnol, served as standardized substitutes for rat femora. Constructs were loaded under axial compression and torsion. Overall axial and torsional stiffness were compared between the in vitro models and FE results. FE models were also used to compare the fracture movement and overall pattern of von Mises stress across the external fixators.

In vitro axial stiffness of ExFix1 was 29.26N/mm± 3.83 compared to ExFix2 6.31N/mm± 0.67 ($p^*<0.05$). Torsional stiffness of ExFix1 was 47.5Nmm/º ± 2.71 compared to ExFix2 at 19.1Nmm/º ±1.18 ($p^*<0.05$). FE results predicted similar comparative ratios between the ExFix1 and 2 as the in vitro studies. FE results predicted considerably larger intrafragmentry motion in the ExFix2 comparing to ExFix1.

We demonstrated significant differences in the stiffness' of the two external fixators; thus highlighting the large variations in the biomechanics of available external fixators and suggests that care must be taken when interpreting fracture healing outcomes; moreover, we also illustrate the utility of FEA modelling in this context.

Keywords: fracture fixation, finite element analysis, biomechanics

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1. Introduction

Multiple physiological and mechanical factors govern the fracture healing process. Overall stiffness of the fracture fixation construct directly impacts the axial, torsional and shear intrafragmentary movement at the fracture site (1-3). These subsequently impact the healing process and as with physiological healing, rigid fixation will lead to intramembranous ossification, while those that are less rigid, allow for the creation of cartilaginous callus and endochonrdral ossification (4, 5).

Rodents have been widely used to investigate the fracture fixation. They are an invaluable animal model used to understand the fracture healing process and to develop new technologies and treatments to address complications such as non-union. A number of external fixators have been used to fix femoral fractures in rodents. These fixators, typically result in a combination of intramembranous and endochondral ossification with studies illustrating healing by various biological scenarios in different models (6, 7).

The literature comparing the biomechanical differences of existing external fixators in rodents is limited. Harrison et al. (8) reported no significant difference in axial stiffness between aluminium and titanium fixator bar materials. However pin material and thickness does have a large effect on torsional and axial stiffness. Mark et al. (9) reported a 50% decrease in axial stiffness and transverse stiffness of the fixator, when using a 1.0-mm compared to a 1.2-mm outer diameter pin. Willey et al (10) demonstrated significantly reduced stiffness at the fracture site of titanium alloy pins versus stainless steel in fixators of the same design, with similar effects of body material and offset on stiffness as previous studies. Glatt et al. (11) reported the development of a variable stiffness PEEK fixator where fracture rigidity can be altered during healing. This PEEK fixator is gaining favour for use in the investigation of rodent fracture healing as the four pin construct is lighter than traditional titanium and stainless steel fixators and has been shown to be well tolerated in vivo (12). In

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contrast, the majority of studies utilise a more traditional unilateral fixator design such as the Harrison et al. titanium alloy fixator. Recently reported variations of the Harrison fixator utilise 2 carbon fibre cross bars with four aluminium pins (13, 14); heavier than the Glatt fixator. No study to date has compared the effects of a variable stiffness fixator and a static fixator on the in vitro stabilisation of a rat femoral fracture model.

Studies investigating the effect of fixator construct on fracture stabilisation can be laborious, necessitating investigation of each design parameter-including crossbar number/size/ offset, pin size and each component material. Subsequently, the ability to utilise computational modelling to determine the mechanical characteristics of any fixator construct, is invaluable. So long as the models are validated using in vivo or in vitro experimental data finite element (FE) modelling provides a unique opportunity to model experimental scenarios computationally and accurately (15-17).

The aim of this study was to compare the biomechanics of two increasingly utilised rodent external fixators; a derivation of the Harrison et al titanium alloy fixator, and the Glatt/AO PEEK external fixator. We utilised a series of experimental in vitro testing and in silico computational models based on finite element method.

2. Materials and Methods

2.1 External fixator designs

The study compared two external fixator designs. The first (EXFix 1) has two graphite cross bars of 2x40mm, spaced 4mm apart, fixed between two titanium alloy (Ti6Al-4v) blocks. These blocks measured 8mm in height, 10mm in width and 7.2mm in depth. This design used 4 titanium alloy threaded pins of 0.8/1.0mm, fixed within the blocks with stainless steel grub screws. The second fixator (ExFix 2) was comprised of a single PEEK crossbar and again four stainless steel threaded pins. The crossbar measured 16.5mm long, 5mm wide and 2mm deep with four 1mm holes to locate the steel pins. A single 12.5mm long, 1mm wide rectangular opening runs parallel with the openings for the steel pins; again each pin

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measured 0.8/1.0mm. The offset as measured from the free length of the pins beneath the crossbar to the upper surface of the bone, was kept constant at 5mm throughout testing. ExFix 1 weighed 6.23g (range 6.22-6.31g), and ExFix 2 3.11g (range 3.08-3.65g).

A hollowed homogenous rod of laminated Tufnol (Tufnol Composites, Birmingham, UK), of similar elastic modulus to adolescent rat femora (inner diameter 1.5mm, outer diameter 4mm, length 35mm) served as standardised substitute for bone and fixed using ExFix1(n=5) and 2 (n=5). Fixation was carried out using custom drill guides of 0.8mm that allowed for the accurate predrilling of holes into the Tufnol, after which pins were manually screwed into position to breach both cortices by one thread. After the fixator was fixed to the Tufnol bone a fracture was created with a 2.75mm fracture gap maintained.

2.2 In vitro testing

The Tufnol specimens were tested non-destructively using a Zwick (Zwick-Roell, Germany) materials testing machine to determine axial and torsional stiffness. In compression, a maximum load of 40N was applied, with a preload of 0.5N at a rate of 0.5mm/min. Load was applied onto potted concave ends of the Tufnol via steel beads attached to the testing machine, and the loading-unloading process repeated three times for each sample.

In torsion both ends of the sample were fixed into titanium cylinders with grub screws to negate slipping during testing. One end of the Tufnol remained static, whilst a maximum vertical load of 40N was applied to the other end with a lever arm of 75mm, which led to a torsion of 3000 Nmm (26). Loading was repeated three times per specimen and torsional stiffness was calculated by dividing the applied torque by the degrees of rotation of the proximal end of the Tufnol.

2.3 Finite element analysis

Computer-aided design models of the bone and two external fixators were developed in CATIA V5 (Dassault Systèmes, Paris FR - Figure 1). Dimensions exactly reflected those of

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the real-life fixator models and all parts assigned isotropic material properties; The Tufnol bone model has an elastic modulus of 6.5GPa and Poisson's ratio 0.4 (18-20). Titanium alloy blocks in the ExFix1 have an elastic modulus of 96GPa and a Poisson's ratio of 0.36. The Graphite rods have an elastic modulus of 4.1GPa and a Poisson's ratio of 0.17. The PEEK crossbar of the ExFix2 has an elastic modulus of 3.6GPa and a Poisson's ratio of 0.38. Finally, stainless steel pins in both fixators were given the same mechanical properties: an elastic modulus of 193GPa and Poisson's ratio of 0.31. The effect of screw pull-out at the fixator-Tufnol interface was ameliorated by gluing these contacts during experimental testing; subsequently, the interface experienced minimal micro-motion upon loading in-vitro and allowed all pin-Tufnol interfaces to be modelled as "fully fixed".

Interfaces such as at the crossbar-pin interface had inherent micro-motion as they were either threaded into position or held with grub screws. Thus two simulations were created, one with all contacts "fully fixed" and a second with all grub screws and threaded contacts "relaxed" to account for this motion. The relaxed model used contact elements at the interfaces with a friction coefficient of 0.4 (15). The expectation being that the properties of each fixator would be between these two extreme models.

In order to replicate the boundary conditions of the test rigs, the constraints were applied within the concave housing of the Tufnol under axial loading conditions and along the outside face of the housing under torsional loading conditions. Additionally, the surface/node in which the load was applied was also constrained to translate in only the axis parallel to the line of loading.

Analyses were carried out in FE package ANSYS (Academic Research, Pennsylvania USA). Tetrahedral elements were used to mesh all components of the fixators and Tufnol. Convergence was tested on each fixator by increasing the number of elements from ca. 5,000 to 2,000,000 incrementally. The solution for ExFix1 converged to within 5% at approximately 135,000 elements when measuring axial stiffness and approximately 260,000

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158 elements when measuring torsional stiffness. For ExFix2, the solution converged for both
159 quantities of interest at approximately 322,000 elements. Results converged substantially
160 faster with the use of midside nodes, and as such they were used throughout.

161 In addition to axial and torsional stiffness, FEA was also used to evaluate fracture gap
162 displacement as measured by nodes either side of the osteotomy. Von Mises stresses were
163 calculated for each fixator and the points of maximal stress also determined. It must be
164 noted that since in this study no detail validation of the strain pattern was carried out the
165 stress results were analysed qualitatively.

166 **2.4 Statistical Analysis**

167 Statistical analysis was performed on the experimental data. The ANOVA assumption of
168 normality was tested using the Shapiro–Wilks normality test. If the assumption was met, an
169 ANOVA was performed, if not, a Mann Whitney *U* test was used. The data was analysed
170 using Prism 4.03 (GraphPad Software Inc., San Diego, USA) and a significance level when
171 comparing data was set at $p<0.05$.

172 **3. Results**

173 **3.1 Axial stiffness:**

174 ExFix1 was 29.26N/mm± 3.83 compared to ExFix2 6.31N/mm± 0.67 ($p^*<0.05$). The fully
175 restricted FEA model predicted axial values of 79.95N/mm and 31.57N/mm for ExFix1 and 2
176 respectively. The model under secondary contact conditions produced axial values of 46.12
177 N/mm and 7.52 N/mm respectively (Figure 2A).

178

179 **3.2 Torsional stiffness**:

180 ExFix 1 was 47.5Nmm/º ± 2.71 compared to ExFix 2 at 19.1Nmm/º ±1.18 ($p^*<0.05$). The
181 fully restricted FEA model predicted torsional stiffness of 98Nmm/º and 50Nmm/º for ExFix 1

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and 2 respectively. The model under secondary contact conditions produced torsional stiffness of 89.8Nmm/º and 27Nmm/º respectively (Figure 2B).

3.3 Comparative ratios:

The ratio of ExFix1: ExFix2, axial and torsional stiffness based on the in vitro experimental data was 4.6 and 2.5 respectively. The same ratio based on the FEA with fully fixed interface conditions were 2.5 (46% lower than the experimental data) and 2 (20% lower than the experimental data) for the axial and torsional stiffness respectively. The same ratio based on the FEA with relaxed interface were 5.1 (11% greater than experimental data) and 3.3 (32% greater than experimental data) for the axial and torsional stiffness respectively (Figure 3).

3.4 Fracture movement:

Total fracture movement as measured in the FE models, was greater for ExFix2 in all planes versus ExFix 1. Under 1mm of movement occurred with ExFix 1 at the maximal loading however, in the ExFix 2 the fragments come into contact leading to a fracture movement of about 2.7mm based on the relaxed interface model. Under axial loading ExFix 1 was found to have 0.54 and 0.91mm of movement with the fully fixed and relaxed models. Whereas ExFix 2 demonstrated 1.49 and 2.75mm of movement respectively. Under torsional conditions, ExFix1 showed 0.52 and 0.64mm of movement with the fully fixed and relaxed models. Versus ExFix2 with 2.20 and 2.74mm of movement respectively (Figure 4A and b).

3.5 Stress pattern:

The stress contour plots of the equivalent von Mises stresses for each fixator component are shown in Figure 5. In all components of the fixator ExFix1 experienced lower overall stress than ExFix2, in both axial and torsional loading. For all FE analysis maximum stress

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occurred at the pin-Tufnol interface. In axial loading of both fixators, stress peaks in the pin closest to the point of loading was seen, whilst in torsion, maximum stress occurred in the pins either side of the fracture gap.

4. Discussion

This study compared the mechanical characteristics of two commonly used external fixators in small animal fracture models. We used our in vitro findings to validate a series of finite element models based on axial and torsional stiffness data. Between the two fixators, we found significant differences in stiffness in both the axial and rotational planes, with ExFix1 markedly more rigid in both planes. Throughout the study we maintained a constant offset, pin material and pin diameter, thus allowing the fixator design and crossbar material (Ti alloy/carbon fibre vs. PEEK) to be the dominating factors on overall stiffness. Previous studies have determined that pin size and material are the greatest determinants of fixator stiffness and intrafragmentary fracture movement (10, 21, 22), our data also suggests the significant impact that the fixator material properties and bar configuration have on the overall stiffness.

In vitro axial stiffness of both ExFix constructs were significantly less than those found with locked nailing techniques (23). ExFix1 was a third as stiff, and ExFix2 just over half as stiff as reported nailing data (23). Conversely rotational stiffness was greater for the external fixators than locked intramedullary nails, and indeed was greater than physiological numbers from intact bone (torsional stiffness 23Nmm/º). This greater stiffness in rotation, if related in vivo, will lead to reduced intrafragmentary movement in shear and as such will impact bone formation.

Our data suggests the FE model could predict the relative differences between the two external fixators. However, the FE models consistently predicted larger stiffness' then those found in vitro, this difference was considerably larger in the "fixed" model that did not account for any micro-motion at the pin-tufnol or the pin-fixator interfaces. When relaxing the

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234 interfaces, the comparative ratios fell notably and were closer to the experimental in vitro
235 data (see Fig 2). Again highlighting the fundamental role of micromotion at the interfaces in
236 both the *in silico* and *in vitro* tests.

237 The difference in stiffness has a predictable effect on movement at the fracture gap, which
238 has important implications on fracture healing. Intrafragmentary motion of between 0.2-1mm
239 perpendicular to a diaphyseal fracture has been found to promote union, however, excessive
240 axial and shear motion will result in delayed healing (1-3). Under axial conditions ExFix2
241 experiences significant motion where bony fragments come into contact. ExFix1, however,
242 restricts vertical motion under axial loading to under 1mm, within the desired envelope.
243 Under torsion, this increases to a value equating to a rotation of up to 17 degrees. ExFix1
244 limits rotation to less than half this amount at the same levels of loading. Under axial loading,
245 translation and rotation at the fracture gap in ExFix1 is also negligible. Additionally, our
246 findings are particularly relevant when investigating biological and pharmacological
247 interventions where variability in stress across the gap will directly influence the efficacy of
248 these factors (24-26).

249 The specific pin where the maximum stress occurs changes between loading conditions. In
250 axial loading, maximum stress is located on the most proximal pin in both ExFix1 and ExFix2
251 whereas under torsion, maximum stress occurred in the pin nearest the proximal end of the
252 fracture. These changes are likely to be a function of the constraint of the tufnol bone
253 creating higher stresses in the pins adjacent to the fracture site.

254 While the FE model could not exactly represent the in vitro assembly boundary conditions,
255 the two conditions that were investigated can accurately predict upper and lower limits for in
256 vitro results. Ultimately, we demonstrated considerable differences in the overall stiffness
257 between the two fixators, which should be considered when comparing experimental *in vivo*
258 data on fracture healing. Given a consistent fracture gap fractures stabilised using Exfix 2
259 are more likely to heal though endochondral ossification or go onto a delayed or non union

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compared to ExFix1. The *in silico* model where the threads are not fully bonded, predicted the comparative stiffness between the two fixators, as evidenced by the similar ratios. This data suggests that a computational protocol that includes the micro-motion present at the pin-bone interface, results in a reproducible model of experimental conditions. Further in vivo and computational work is required to demonstrate the effect of gap distance and fixator stiffness on the rate, type and quality of ossification and healing.

Acknowledgments

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Figure Legends

Figure 1. Computer aided designs of both external fixator models, with arrows demonstrating load constraint conditions.

Figure 2A and B. Demonstrating the torsional and axial stiffness' of both external fixators in vitro and in silico.

Figure 3. Demonstrating the comparative stiffness ratios in torsion and compression for in vitro and in silico testing.

Figure 4A and B. Demonstrating total fracture movement as found in silico under compression (A) and torsion (B).

Figure 5. Equivalent von-Mises stress contour plots on the crossbars of both fixator models.

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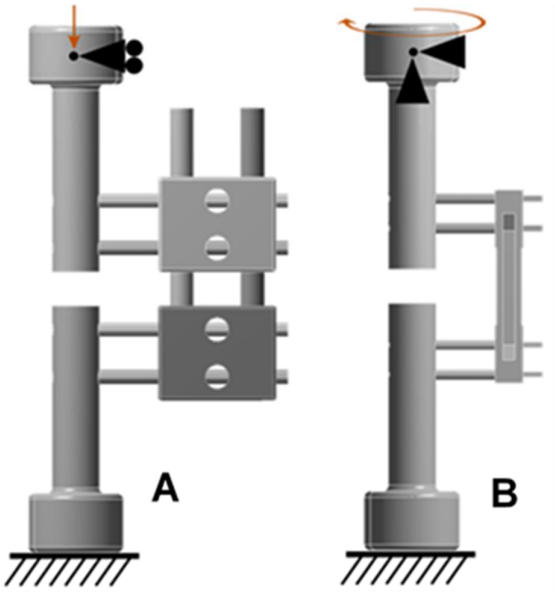

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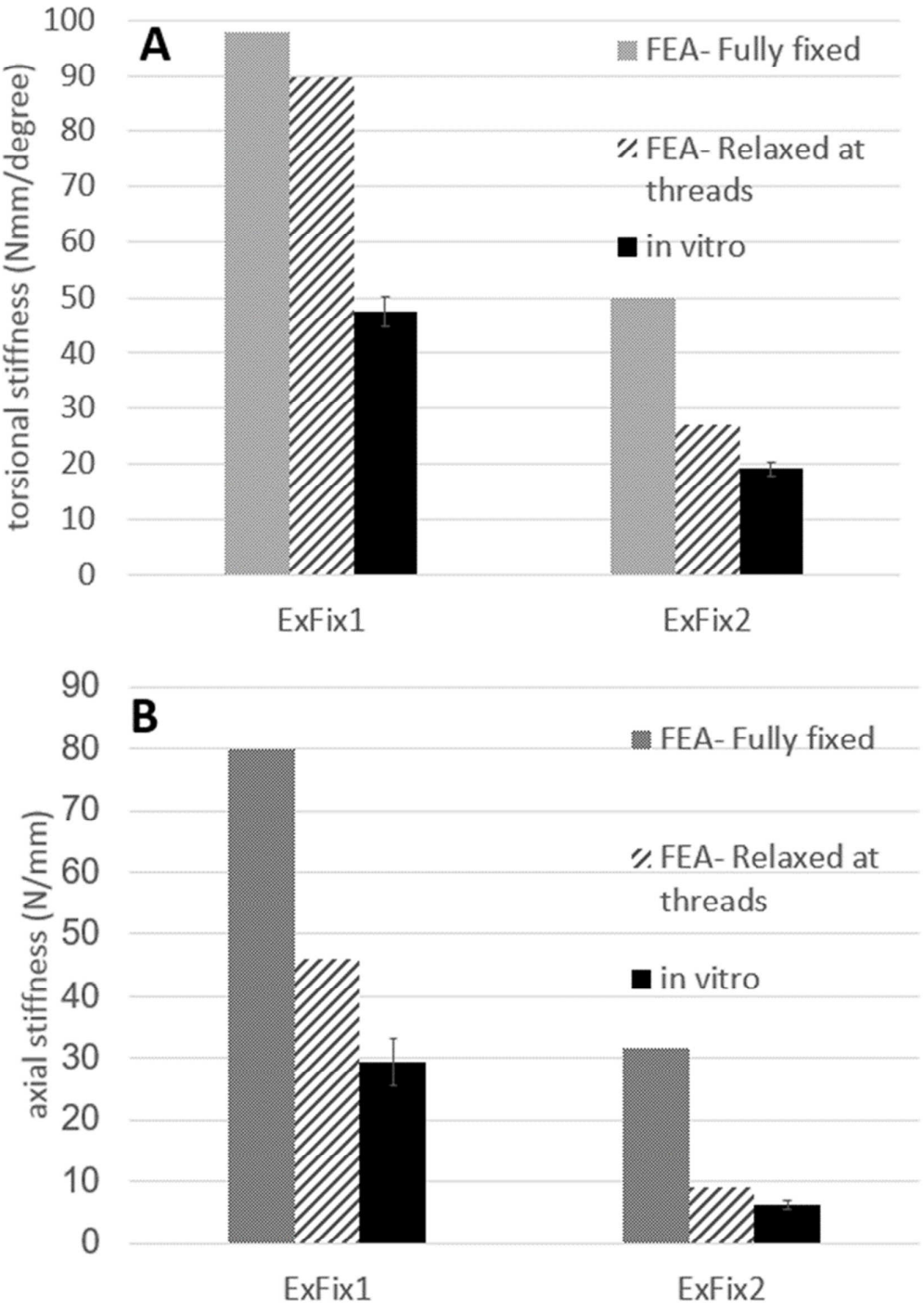
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FEA- Fully fixed
FEA- Relaxed at threads
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FEA- Relaxed at threads
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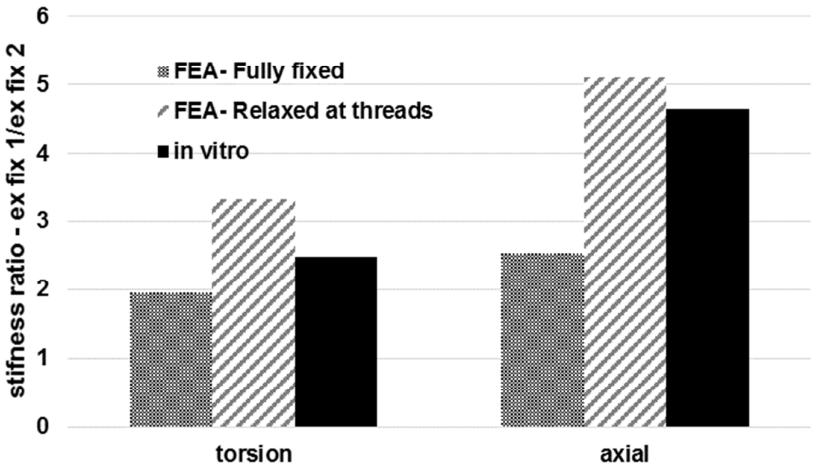

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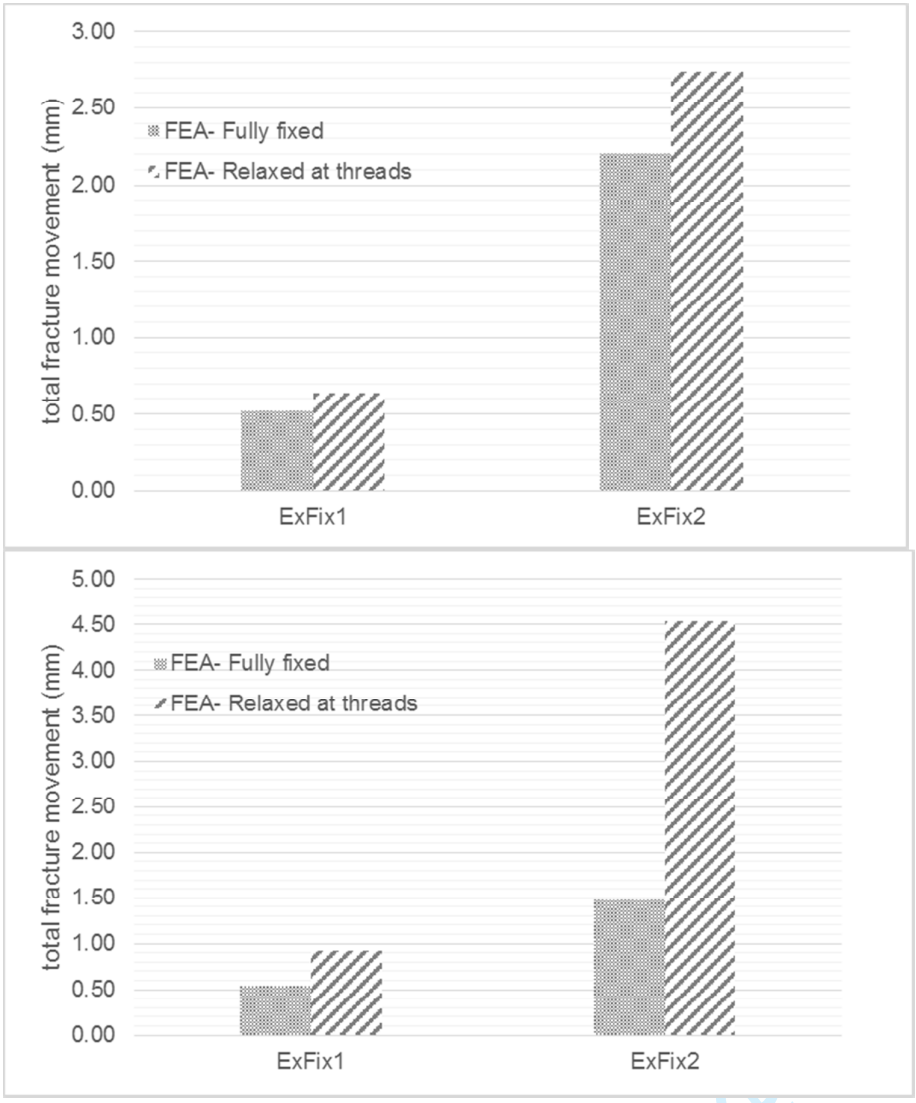
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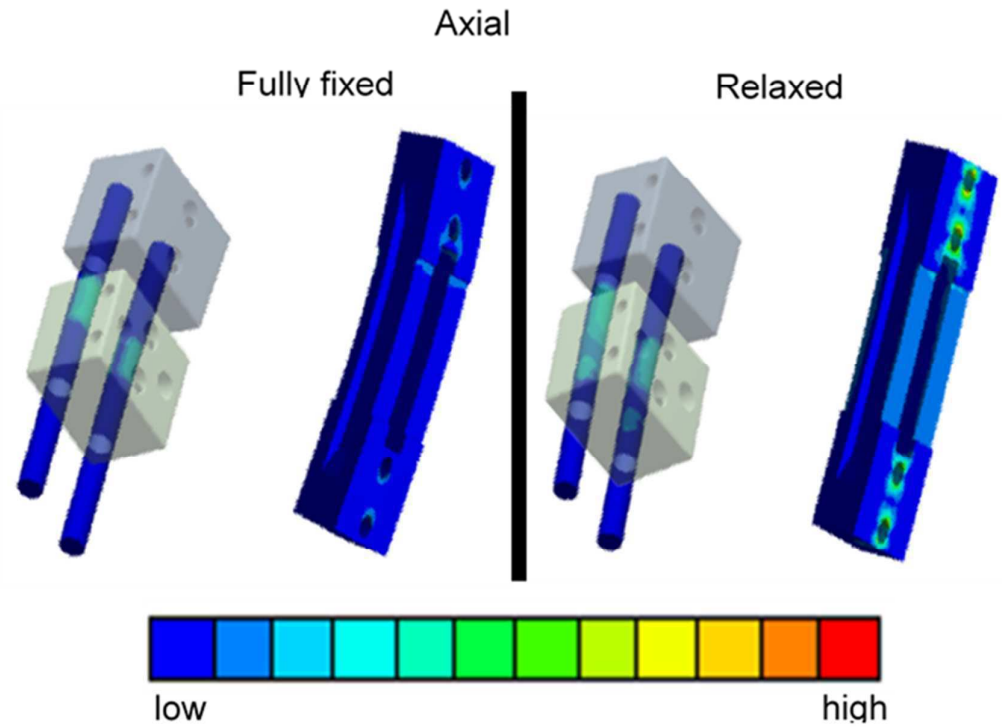

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