

1 **Technical note**

2 **An experimental evaluation of fracture movement in two alternative**
3 **tibial fracture fixation models using a vibrating platform**

4 Mehran Moazen¹; Peter Calder²; Paul Koroma²; Jonathan Wright²; Stephen Taylor²;
5 Gordon Blunn^{2,3}

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7 ¹Department of Mechanical Engineering, University College London, Torrington Place,
8 London, WC1E 7JE, UK.

9 ²Institute of Orthopaedics and Musculo-Skeletal Science, Division of Surgery &
10 Interventional Science, University College London, Royal National Orthopaedic Hospital,
11 Stanmore HA7 4LP, UK.

12 ³School of Pharmacy and Biomedical Sciences, University of Portsmouth, Portsmouth, P01
13 2UP, UK.

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16 **Corresponding author:**

17 Mehran Moazen, BSc, PhD, CEng, MIMechE, FHEA
18 Lecturer in Biomedical Engineering

19

20 UCL Mechanical Engineering,
21 University College London,
22 Torrington Place,
23 London WC1E 7JE, UK

24

25 E: M.Moazen@ucl.ac.uk

26 T: +44 (0) 207 679 3862

27

28 **Abstract:**

29 Several studies have investigated the effect of low-magnitude-high-frequency vibration on the
30 outcome of fracture healing in animal models. The aim of this study was to quantify and
31 compare the micromovement at the fracture gap in a tibial fracture fixed with an external fixator
32 in both a surrogate model of a tibial fracture and a cadaver human leg under static loading,
33 both subjected to vibration. The constructs were loaded under static axial loads of 50, 100,
34 150 and 200 N and then subjected to vibration at each load using a commercial vibration
35 platform, using a DVRT sensor to quantify static and dynamic fracture movement. The overall
36 stiffness of the cadaver leg was significantly higher than the surrogate model under static
37 loading. This resulted in a significantly higher fracture movement in the surrogate model. Under
38 vibration the fracture movements induced at the fracture gap in the surrogate model and the
39 cadaver leg were 0.024 ± 0.009 mm and 0.016 ± 0.002 mm respectively, at 200N loading. Soft
40 tissues can alter the overall stiffness and fracture movement recorded in biomechanical
41 studies investigating the effect of various devices or therapies. While the relative comparison
42 between the devices or therapies may remain valid, absolute magnitude of recordings
43 measured externally must be interpreted with caution.

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45 **Keywords:** biomechanics, fracture fixation, stiffness, fracture movement, external fixator,
46 cadaver, tibiae, non-union

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56 **Introduction:**

57 Ilizarov Frame hexapods of various design are typically used in the management of long bone
58 fractures in the field of orthopaedic trauma. Non-union fractures remain a challenge however,
59 and account for around 10% of all fractures treated and about 2% of tibial diaphyseal
60 fractures.¹⁻³ There are several contributing factors to non-union including the patient, injury
61 and treatment protocols.^{2,3} The stability of initial fracture fixation and post-operative loading of
62 the fracture are among the key treatment related factors.⁴⁻¹³ Both contribute to the
63 mechanobiology of the healing fracture where it is well established that there are certain strain
64 thresholds that promote callus formation. For example, interfragmentary motion (IFM) in the
65 range of 0.2-1mm and 2-10% strain is suggested to improve fracture healing.^{4,5,11,12}

66 There are some studies suggesting that the application of low-intensity pulsed ultrasound
67 (LIPUS) and whole body vibration (WBV) may possibly improve fracture healing and
68 potentially address non-union.¹⁴⁻¹⁹ The exact mechanisms by which these methods improve
69 fracture healing at the molecular and cellular level are still unknown. However, it is generally
70 accepted that LIPUS generates nano-scale motions while WBV generates micro-scale motion
71 at the fracture site leading to different mechanisms of improved healing.

72 There has been no prior study to quantify the movement induced at the fracture gap as a result
73 of external vibration in a tibial fracture fixed with an external fixator. Surrogate bone models
74 and cadaveric tissue can be used to compare the fracture movement in an *in vitro* study. An
75 *in vitro* fixation of a surrogate bone in the absence of soft tissues should provide little
76 attenuation to vibration applied at the foot when observed at the fracture gap. Whilst, in a
77 cadaver model, the magnitude of the displacement induced by the vibrating platform at the
78 foot may be attenuated by the presence of the soft tissues. Incremental fracture displacements
79 of 1mm/day are usually induced clinically using an external frame, although the soft tissues
80 and bone remodelling stiffness determine the actual mode of distraction at the fracture gap. In
81 this study we were not able to replicate the bone remodelling response, but just the soft
82 tissues. However, the growing bone formed during distraction osteogenesis would have a low
83 modulus of elasticity compared to mature bone.

84 The aim of this study was to quantify and compare the micromovement at the fracture gap in
85 a tibial fracture fixed with an external fixator in both a surrogate model and cadaver leg under
86 both static loading and subject to vibration. Therefore, the study quantifies and compares the
87 overall stiffness and fracture movement in both models, and investigates if comparable trends
88 exist between the two models. Cadaver studies are more challenging to perform than the
89 surrogate models, but are more realistic.

90 **Materials and Methods:**

91 **Specimens:** A fourth generation tibia was purchased from Sawbones Worldwide (SKU:3402-
92 overall length: 405mm; tibia plateau diameter: 84mm; distal tibia diameter: 58mm; mid shaft
93 diameter: 10mm - WA, USA) and a left cadaver leg including all the soft tissue from the knee
94 below was obtained from Anatomy gifts registry (Sex: male; Age: 62; body weight: 56 kg - MD,
95 USA). The host institute had all the required approvals to perform this study. A transverse
96 osteotomy was performed in each model using an oscillating saw (D_EWALT - MD, USA). In
97 the surrogate model the sawbone tibia was cut. In the cadaver leg, the tibia and fibula were
98 divided using a minimally invasive technique that preserved the soft tissues. Both transections
99 were made in the mid-disphyseal region.

100 The tibiae in both cases were stabilized with an external fixator (Taylor Spatial Frame - Smith
101 & Nephew plc, TN, USA). This is shown schematically in Fig 1. A two-ring Taylor Spatial Frame
102 (TSF) construct was used with two proximal half pins and two distal half pins with a 90-degree
103 divergence between the pins on each ring. The external fixator was then extended to produce
104 a 50 mm fracture gap in the surrogate model, this was to ensure that the bony fragments did
105 not come into contact during the experimental loading. In the case of the cadaver specimen a
106 13 mm fracture gap was produced, and further extension to match the surrogate model was
107 not possible without overstretching the soft tissue (see Fig 1). This is a clinically typical fixation,
108 although such fractures might be fixed with additional pins/wires pending various patient and
109 injury related factors. Considering that in this biomechanical study the surrogate and cadaver
110 models were fixed in the same configuration, the relative differences in outcome should remain
111 valid.

112 **Loading and measurements:** The specimens were then fixed proximally to a material testing
113 machine (Zwick Testing Machines Ltd., Herefordshire, UK) and distally rested on a commercial
114 vibrating platform (Juvent, FL, USA - 0.3g's of acceleration at 32-35 Hz with 0.05mm vertical
115 displacement). It must be noted that (1) the vibrating platform first finds the resonant frequency
116 of the system and then initiates the vibrations see the manufacturer website and previous
117 studies describing and evaluating this system.^{e.g.20-22}; (2) the natural frequency of a complete
118 leg has been reported to be about 0.85Hz²³ while we are not confident if this has been picked
119 up by the vibrating platform but we are confident that the vibrating frequency applied by the
120 platform is well away from the natural frequency of the leg. A titanium "foot" was used to ensure
121 direct contact between the surrogate tibia and the vibrating platform, while in the case of the
122 cadaver leg the specimen was in contact with the vibrating platform through the foot.

123 The specimens were loaded five times under static axial loads of 50, 100, 150 and 200 N
124 equivalent to partial weight bearing.^{24,25} Note, normal limb loads are approximately of 3xBW,
125 but the use of far lower loads here is due to the fact that the subjects do not weight bear
126 significantly during distraction osteogenesis, and are in line with measurements of frame loads
127 carried out in author's lab.²⁶ At the end of each loading scenario (1) the overall stiffness of the
128 constructs were calculated based on the load-displacement data from the material testing
129 machine. (2) The displacement at the fracture gap under the static loads was recorded with a
130 caliper (with the resolution of 0.01 mm) on the lateral side. (3) The vibrating platform was
131 turned on to vibrate the tibial shaft along its long axis. The fracture gap vibration (differential
132 displacement across the medial fracture side) and the platform vibration were recorded using
133 displacement sensors (with the resolution of 0.001 mm - DVRT- LORD MicroStrain, VT, USA)
134 configured to LabVIEW (National Instruments, TX, USA).

135 Independent (two sample) t-test was used to compare the overall stiffness between the
136 surrogate and cadaver models at 200 N loading. A dependent (paired) t-test was used to
137 compare the difference between the displacement applied via the vibrating platform and the
138 fracture movement both in the surrogate model and the cadaveric specimen. Significance level
139 was set at $p < 0.05$.

140 **Results:**

141 Static loading: The overall stiffness of the surrogate model was 6.39 ± 0.57 N/mm, and of the
142 cadaver leg was 47.46 ± 0.74 N/mm, based on the load-displacement data at 200N ($p < 0.05$ -).
143 The fracture movement at the lateral side of the surrogate model and cadaver leg increased
144 linearly ($R^2 = 0.9$) from 2.82 ± 0.13 mm and 0.23 ± 0.07 mm under 50 N to 10.99 ± 1.40 mm and
145 0.96 ± 0.08 under 200 N respectively (Fig 3).

146 Dynamic loading: In the surrogate model, there was no significant difference between the
147 displacement applied via the vibrating platform (platform vibration) and the fracture movement
148 induced at the fracture gap (fracture gap vibration) under each loading scenario, figure 4. The
149 displacement applied via the vibrating platform was however always higher than the fracture
150 gap displacement. Average platform and fracture gap displacement (due to the vibration)
151 across all loading scenarios were 0.030 ± 0.006 mm and 0.025 ± 0.008 mm respectively
152 (significant difference - $p < 0.05$ – Fig 4).

153 In the cadaver leg, there was a statistically significant difference between the displacement
154 applied via the vibrating platform (platform vibration) and the fracture movement induced at
155 the fracture gap (fracture gap vibration) under each loading scenario. Average platform and

156 fracture gap displacement (due to the vibration) across all loading scenarios were 0.027
157 ± 0.002 mm and 0.013 ± 0.003 mm respectively (significant difference - $p < 0.05$ – Fig 4).

158 There was found to be a significant difference between the amount of displacement of the
159 vibrating platform between the surrogate model (0.030 ± 0.006 mm) and the cadaver leg
160 specimen (0.027 ± 0.002 mm) during vibration across all loading scenarios.

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162 **Discussion:**

163 A tibial fracture, fixed with an external fixator, was tested experimentally in a surrogate model
164 and a cadaveric leg. The constructs were statically loaded and then subjected to vibration with
165 a commercial vibration platform, at each load interval, to quantify fracture movement as a
166 result of static loading and then with vibration.

167 The results highlighted a significant difference (eight times) between the overall stiffness of
168 the surrogate model and the cadaveric leg (Fig 2). This is mainly due to the presence of soft
169 tissues and the fibula in the cadaver model. However, other factors could have been
170 contributing to the difference observed here. The frame constructs may not have been
171 identically positioned resulting in different biomechanical properties.

172 A linear pattern of increase in fracture movement was observed in both cases due to the linear
173 increase of loading from 50 to 200 N (Fig 3). However, there was about one order of magnitude
174 difference between the fracture movement data obtained from the surrogate model and the
175 cadaver leg. This was not surprising given the lower overall stiffness recorded for the surrogate
176 model. In the case of the cadaver leg at 200 N, corresponding to partial weight bearing,
177 fracture movement of 0.96 \pm 0.08 mm was measured. This is within the acceptable 0.2-1 mm
178 fracture movement that is suggested to promote callus formation and enhance the healing
179 process.^{4,5,7,11} In distraction osteogenesis, the TSF is typically extended by 1mm/day clinically.
180 From figure 3B this would correspond to 210N at the bone ends. This seems to agree well
181 with data from an instrumented fixator used in a clinical study^{26,27} thus indicating that the
182 stiffness of the cadaver tissues is likely to be similar to normal. Distal vibration of the tibia led
183 to vibration at the fracture gap in both the surrogate model and cadaver leg. In the cadaver
184 leg, a significant difference was observed between the displacement applied via the vibrating
185 platform (0.027 \pm 0.003 mm - averaged over all tests) and the fracture movement (0.013 \pm 0.003
186 mm- averaged over all tests – see Fig 4). The difference between the two displacements at
187 the fracture gaps is likely to have been altered by the soft tissues in the cadaver leg, and
188 highlights the contribution made by the soft tissues to both static and dynamic stiffness.

189 This study has several limitations but perhaps the key limitation is that only one surrogate
190 model and one cadaveric leg were used. While the study would have benefited from a larger
191 sample size, the authors think that the differences captured in this study will remain valid with
192 a larger sample size. Note, considering that only one surrogate and one cadaver leg were
193 used in this study (while several tests were carried out) statistical analysis data must be
194 considered with caution. Further in vivo studies are required to test the hypothesis that whole
195 body vibration can improve the fracture healing process in humans and to investigate the effect
196 of different frequencies, since only one frequency band was used here. Depending on the
197 frequency and magnitude of the load, other vibrational regimes may also be osteogenic. In
198 this paper we have chosen to investigate one level and suggest that this would be osteogenic.

199 In summary, this study has highlighted the effect of soft tissues in biomechanical studies. Soft
200 tissues can alter the overall stiffness and fracture movement recorded in biomechanical
201 studies investigating the effect of various devices or therapies. While the relative comparison
202 between the devices or therapies may remain valid, absolute magnitude of recordings in such
203 studies must be interpreted with caution.

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213 **Conflict of interest**

214 The authors confirm that there is no conflict of interest in this manuscript.

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323 **Figure captions:**

324 **Fig 1:** Schematic of the experimental set up in a lateral view: (A) the surrogate model, (B) the
325 cadaver leg.

326 **Fig 2:** Overall stiffness of the fracture fixation constructs. Note standard deviation is for 5
327 number of repeats of the axial compression test. * highlight significant difference.

328 **Fig 3:** Fracture movement induced via static loading in the surrogate model (A) and the
329 cadaver leg (B).

330 **Fig 4:** Fracture movement induced via the vibrating platform in the surrogate model (A) and
331 the cadaver leg (B). Note standard deviation is for five number of repeats of the axial
332 compression test. * highlight significant difference.

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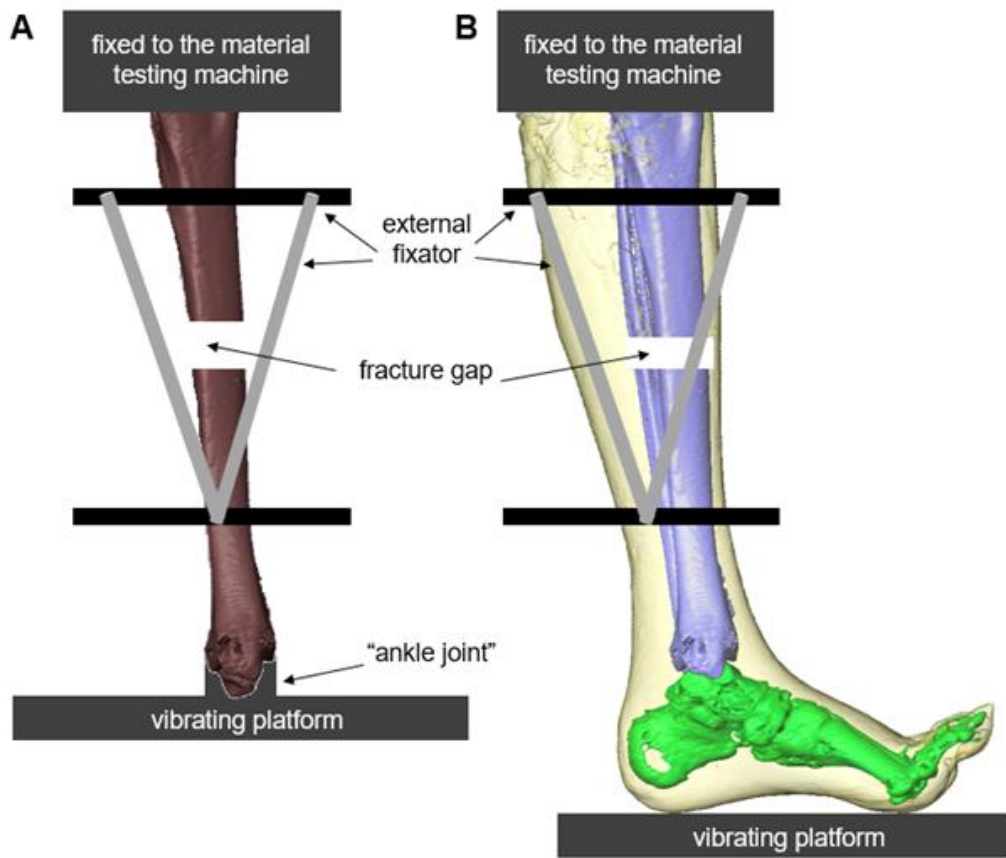
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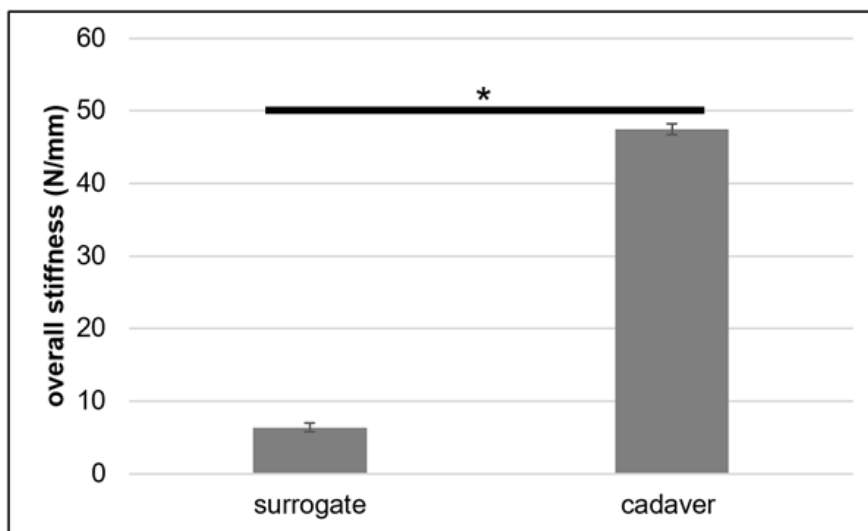
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348 Fig 1



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350 Fig 2

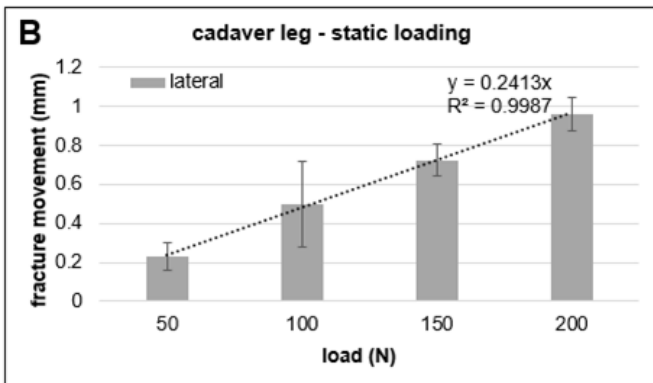
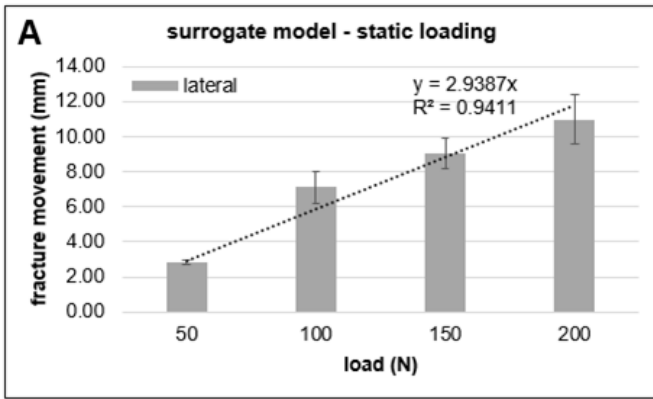


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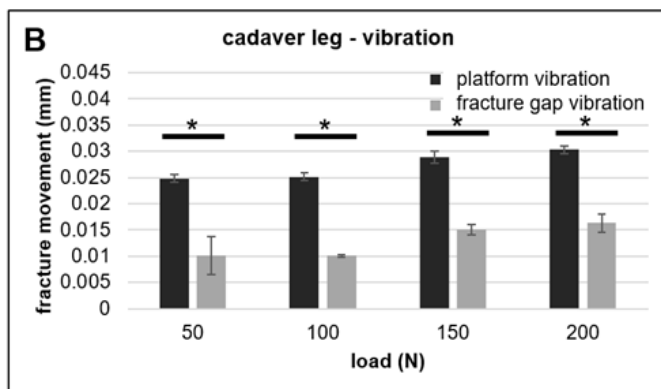
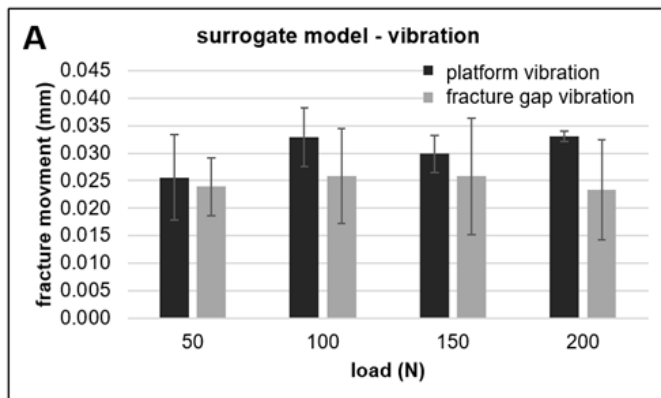
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354 Fig 3



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356 Fig 4



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