Technical note

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

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Abstract:

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

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

Introduction:

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

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

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

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

Materials and Methods:

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

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

Loading and measurements: The specimens were then fixed proximally to a material testing machine (Zwick Testing Machines Ltd., Herefordshire, UK) and distally rested on a commercial vibrating platform (Juvent, FL, USA - 0.3g's of acceleration at 32-35 Hz with 0.05mm vertical displacement). It must be noted that (1) the vibrating platform first finds the resonant frequency of the system and then initiates the vibrations see the manufacturer website and previous studies describing and evaluating this system.[e.g.20-22]; (2) the natural frequency of a complete leg has been reported to be about 0.85Hz[23] while we are not confident if this has been picked up by the vibrating platform but we are confident that the vibrating frequency applied by the platform is well away from the natural frequency of the leg. A titanium "foot" was used to ensure direct contact between the surrogate tibia and the vibrating platform, while in the case of the cadaver leg the specimen was in contact with the vibrating platform through the foot.

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

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

Results:

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

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

In the cadaver leg, there was a statistically significant difference between the displacement applied via the vibrating platform (platform vibration) and the fracture movement induced at the fracture gap (fracture gap vibration) under each loading scenario. Average platform and fracture gap displacement (due to the vibration) across all loading scenarios were 0.027 ±0.002 mm and 0.013 ±0.003 mm respectively (significant difference - $p<0.05$ – Fig 4).

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

Discussion:

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

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

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

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

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

Acknowledgments

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Conflict of interest

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

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Figure captions:

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

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

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

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

Fig 1

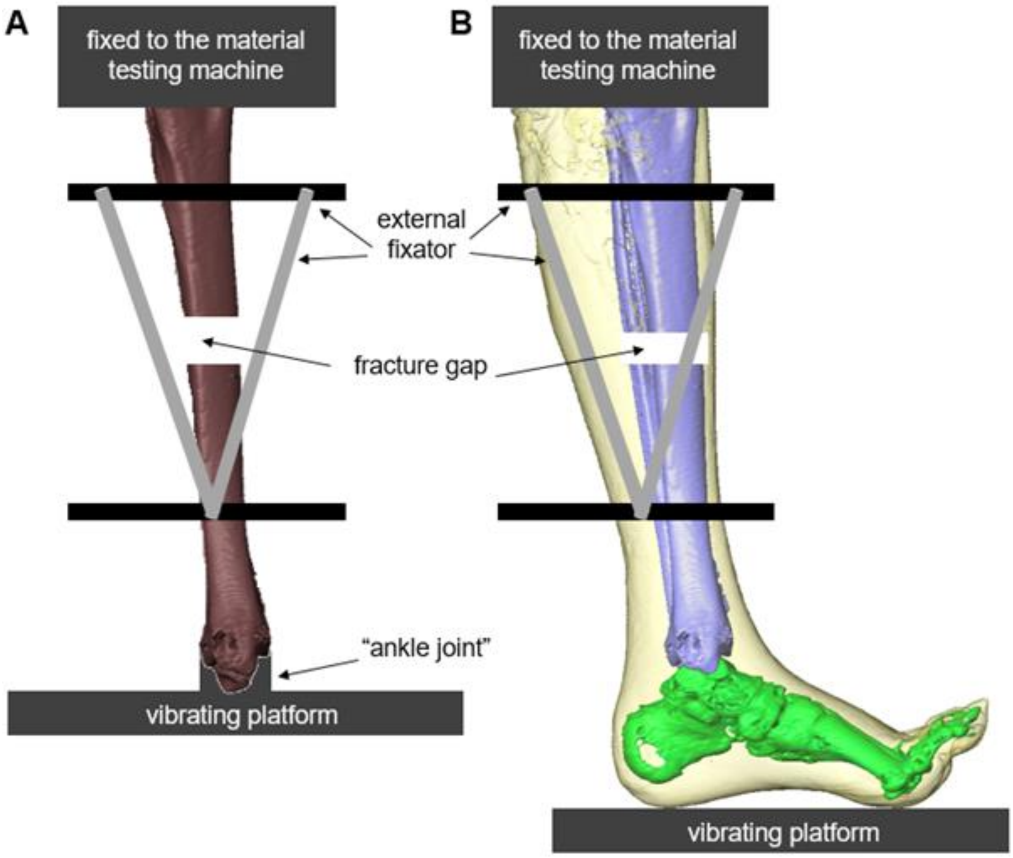


Fig 2

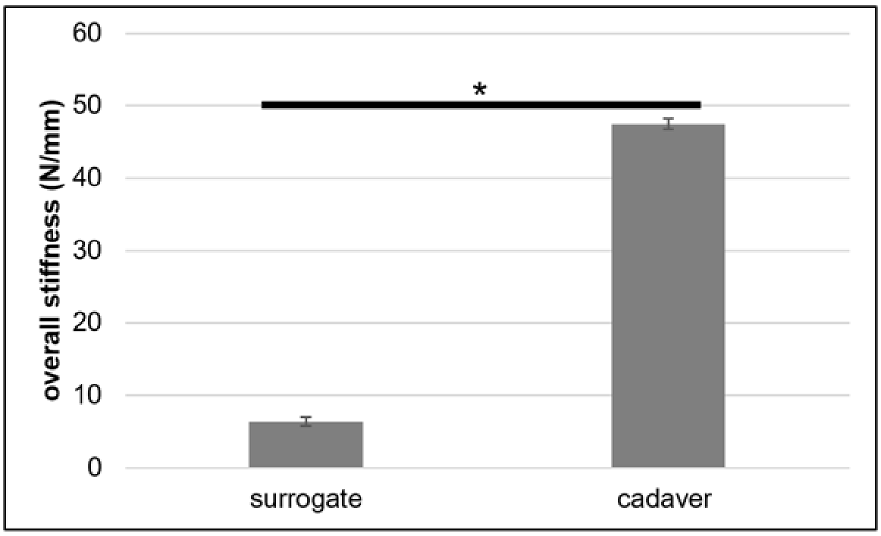


Fig 3

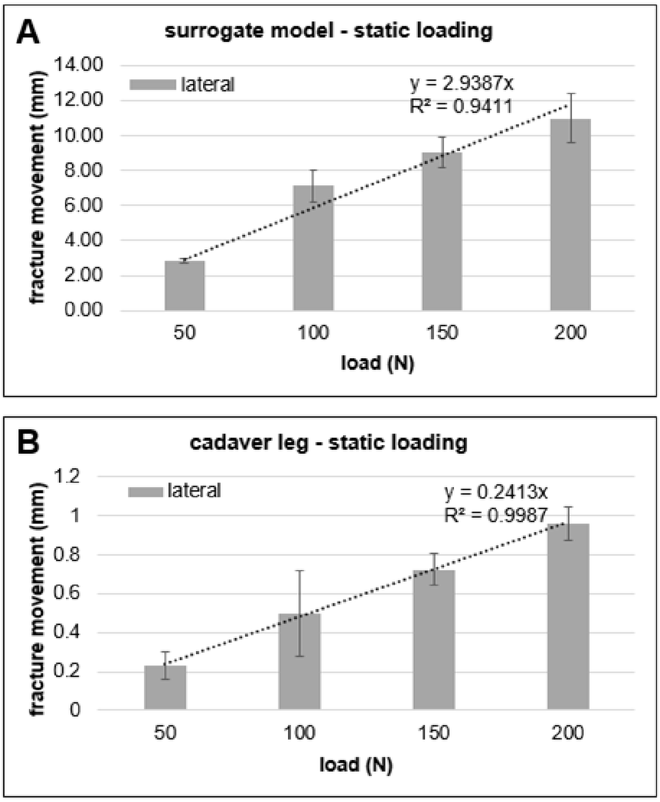
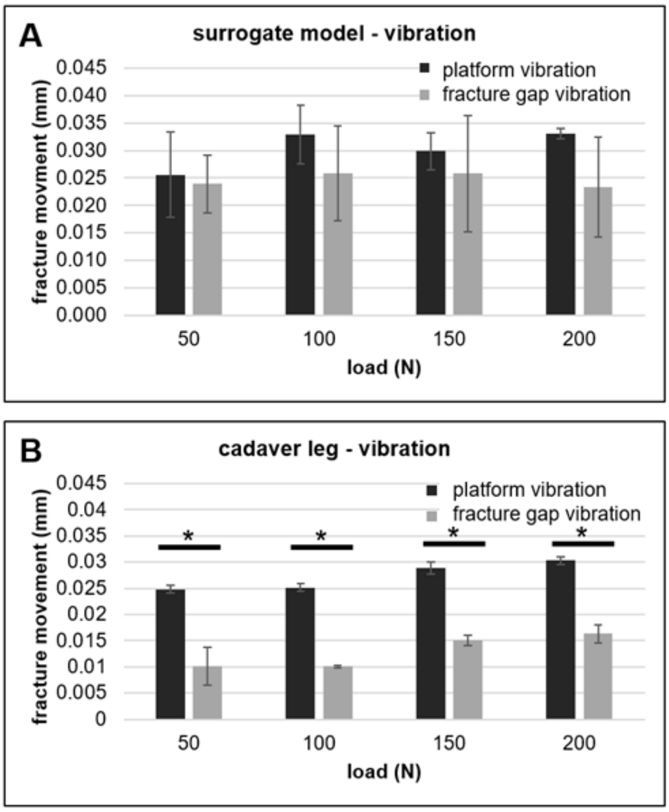

A
surrogate model - static loading
lateral
y = 2.9387x
R² = 0.9411
fracture movement (mm)
14.00
12.00
10.00
8.00
6.00
4.00
2.00
0.00
50
100
150
200
load (N)
B
cadaver leg - static loading
lateral
y = 0.2413x
R² = 0.9987
fracture movement (mm)
1.2
1
0.8
0.6
0.4
0.2
0
50
100
150
200
load (N)

Fig 4


A
surrogate model - vibration
platform vibration
fracture gap vibration
fracture movment (mm)
0.045
0.040
0.035
0.030
0.025
0.020
0.015
0.010
0.005
0.000
50
100
150
200
load (N)
B
cadaver leg - vibration
platform vibration
fracture gap vibration
fracture movement (mm)
0.045
0.04
0.035
0.03
0.025
0.02
0.015
0.01
0.005
0
*
*
*
*
50
100
150
200
load (N)