



Title	Role of the fibula in the stability of diaphyseal tibial fractures fixed by intramedullary nailing
Author(s)	Galbraith, John G.; Daly, Charles J.; Harty, James A.; Dailey, Hannah L.
Publication date	2016-08-17
Original citation	GALBRAITH, J. G., DALY, C. J., HARTY, J. A. and DAILEY, H. L. (2016) 'Role of the fibula in the stability of diaphyseal tibial fractures fixed by intramedullary nailing', <i>Clinical Biomechanics</i> , 38, pp. 42-49. doi: 10.1016/j.clinbiomech.2016.08.007
Type of publication	Article (peer-reviewed)
Link to publisher's version	http://dx.doi.org/10.1016/j.clinbiomech.2016.08.007 Access to the full text of the published version may require a subscription.
Rights	© 2016, Elsevier Ltd. This manuscript version is made available under the CC-BY-NC-ND 4.0 license. https://creativecommons.org/licenses/by-nc-nd/4.0/
Embargo information	Access to this article is restricted until 12 months after publication by request of the publisher.
Embargo lift date	2017-08-17
Item downloaded from	http://hdl.handle.net/10468/3119

Downloaded on 2017-09-05T00:03:59Z

Accepted Manuscript

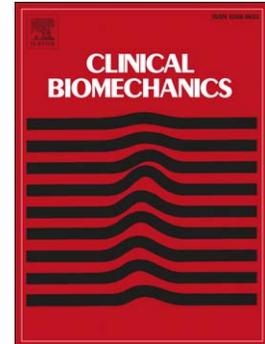
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PII: S0268-0033(16)30122-X
DOI: doi: [10.1016/j.clinbiomech.2016.08.007](https://doi.org/10.1016/j.clinbiomech.2016.08.007)
Reference: JCLB 4204

To appear in: *Clinical Biomechanics*

Received date: 15 October 2015
Accepted date: 16 August 2016



Please cite this article as: Galbraith, John G., Daly, Charles J., Harty, James A., Dailey, Hannah L., Role of the fibula in the stability of diaphyseal tibial fractures fixed by intramedullary nailing, *Clinical Biomechanics* (2016), doi: [10.1016/j.clinbiomech.2016.08.007](https://doi.org/10.1016/j.clinbiomech.2016.08.007)

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Role of the Fibula in the Stability of Diaphyseal Tibial Fractures Fixed by Intramedullary Nailing

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Abstract word count: 259 (250 max)

Main text word count (excl. references): 3974 at first submission, 4392 including changes recommended by reviewers (4000 max)

Number of Tables: 1

Number of Figures: 5

Keywords: fracture fixation, osteosynthesis, cadaver, biomechanics

Abstract

Background: For tibial fractures, the decision to fix a concomitant fibular fracture is undertaken on a case-by-case basis. To aid in this clinical decision-making process, we investigated whether loss of integrity of the fibula significantly destabilises midshaft tibial fractures, whether fixation of the fibula restores stability to the tibia, and whether removal of the fibula and interosseous membrane for expediency in biomechanical testing significantly influences tibial interfragmentary mechanics.

Methods: Tibia/fibula pairs were harvested from six cadaveric donors with the interosseous membrane intact. A tibial osteotomy fracture was fixed by reamed intramedullary (IM) nailing. Axial, torsion, bending, and shear tests were completed for four models of fibular involvement: intact fibula, osteotomy fracture, fibular plating, and resected fibula and interosseous membrane.

Findings: Overall construct stiffness decreased slightly with fibular osteotomy compared to intact bone, but this change was not statistically significant. Under low loads, the influence of the fibula on construct stability was only statistically significant in torsion (large effect size). Fibular plating stiffened the construct slightly, but this change was not statistically significant compared to the fibular osteotomy case. Complete resection of the fibula and interosseous membrane significantly decreased construct torsional stiffness only (large effect size).

Interpretation: These results suggest that fixation of the fibula may not contribute significantly to the stability of diaphyseal tibial fractures and should not be undertaken unless otherwise clinically indicated. For testing purposes, load-sharing through the interosseous membrane contributes significantly to overall construct mechanics, especially in torsion, and we recommend preservation of these structures when possible.

1. Introduction

Intramedullary (IM) nailing is often the treatment of choice in the management of tibial shaft fractures (Phieffer and Goulet, 2006). IM nailing works on the principle of relative stability, which allows the fracture to achieve union by secondary bone healing. The speed of this healing process is influenced by the magnitude and direction of the interfragmentary motion (IFM) allowed within the fracture site. Factors that are known to influence IFM include weight bearing, nail diameter, number and orientation of locking screws used, and specialised implant design features such as angular-stable locking, compression locking, and controlled axial micromotion (Brown, Bryan, & Stevens, 2007, Dailey et al., 2013, Kaspar et al., 2005). Less attention, however, has been given to the role of the fibula in tibial IFM after IM nailing.

Biomechanically, the fibula has been traditionally viewed as a static lateral strut for the talo-crural joint that provides the origin for several muscles of the foot. However, a number of studies on cadaveric lower limbs have estimated that the fibula bears between 6% and 30% of the axial load, depending on the orientation of the foot and ankle (Goh et al., 1992, Lambert, 1971, Takebe et al., 1984, Wang et al., 1996). *In vitro* studies have also demonstrated load transfer through the interosseous membrane, which connects the tibia and fibula (Skraba and Greenwald, 1984, Thomas et al., 1995, Vukicevic et al., 1980, Wang et al., 1996). In addition to its axial load-sharing role, the fibula has also been shown to contribute to the rotational stiffness of the lower leg (Thambyah and Pereira, 2006).

In recognition of the stabilising function of the fibula, some researchers have attempted to evaluate its role in tibial fractures fixed with IM nails in both a clinical and biomechanical context (Gerstenfeld et al., 2003, Kaderly, 1991, Marsell and Einhorn, 2011, Shapiro, 1988). The majority of the published work relates to distal metaphyseal tibial fractures, which are inherently less stable than midshaft fractures owing to the absence of endosteal fit of the nail within the widened metaphyseal canal and the lack of cortical contact with the nail (Morin et al., 2008). In a cadaveric study, Morin *et al.* (Morin et al., 2008) observed a slight increase in torsional stability by adding fibular fixation to tibial IM nailing in the treatment of combined distal-third tibiofibular fractures, which they concluded may not be clinically relevant. More recently, Attal *et al.* (Attal et al., 2014) used a cadaveric model to show that fibular plating does not enhance the

stability of distal tibial fractures when the distal locking screws are placed in multiple planes and that this approach renders fibular fixation unnecessary.

In contrast, there is some clinical evidence suggesting an influence of the fibula on patient outcomes. A recent retrospective study of 60 patients with distal tibiofibular fractures showed a tendency toward increased non-union risk with fibular fixation and tibial nailing, but this result was not statistically significant and an opposite trend was observed when the tibia was plated instead of nailed (Berlusconi et al., 2014). Hence, clinical decision-making in fibular fixation remains subjective and this was cited as a confounding factor in a recent clinical trial to investigate angular-stable locking of IM nails for distal tibial fractures (Hontzsch et al., 2014).

Considering mid-diaphyseal tibial fractures, there is a paucity of published work on the role of fibular fixation in tibial fracture stability post-IM nailing. This is surprising, given the high proportion of tibial fractures which occur in the mid-diaphyseal region with associated same-level fibular fractures (Court-Brown and McBirnie, 1995). Some authors advocate judicious caution in approaching fibular fixation, as the possible stabilising effect of a fixed fibula must be balanced against increased soft tissue morbidity (Varsalona and Liu, 2006). In addition, the role of the fibula in midshaft tibial fracture stability may be more subtle due to the natural enhanced stability of fractures at this level arising from the tight endosteal fit of the nail in the canal. Furthermore, for biomechanical studies of tibial fracture fixation, the current body of evidence is unclear on the necessity of preserving the fibula and interosseous membrane when the focus of the investigation is on mid-diaphyseal tibial fracture stability.

In this study, we used a cadaver osteotomy fracture model to investigate the role of the fibula in the stability of diaphyseal tibial fractures. We selected four models of fibular involvement—intact, unfixed osteotomised, plated, and resected. Tibial fractures were fixed by reamed IM nailing. For each fibular configuration, we measured axial and torsional interfragmentary motion at the tibial fracture site and calculated the total construct stiffness under axial, torsion, bending, and shear loading conditions for comparison to previous investigations. We hypothesised that load-sharing through the fibula would produce observable variations in the stability of the tibial fracture.

2. Methods

2.1 Cadaveric Samples

We used lower limbs from six formalin-fixed donors (two men and four women, aged 73 to 87 years). The tibia and fibula were harvested as an intact pair, preserving the proximal and distal ligamentous connections and interosseous membrane. All other soft tissue was stripped to the periosteum. Samples were held in saline throughout the testing to maintain hydration of the soft tissues.

2.2 Fixation Devices

Tibial fixation was done with Synthes Expert Tibial Nails and screws (Synthes GmbH, 2006). Fibular fixation was done with 6-hole one-third tubular plates and screws. IM nail diameter and length were chosen to suit the individual donor anatomy using pre-operative computed tomography scanning (LightSpeed VTC XTE, GE Healthcare, Wisconsin, USA). Two independent observers estimated appropriate nail size post-reaming using a previously-described ovalisation model of the medullary canal (Galbraith et al., 2012). Nail sizes were selected to produce the best fit with each donor as would be the case in clinical practice. The only difference between our approach and standard clinical practice is that nail size is usually chosen during reaming by the cortical chatter technique, whereas our nails were pre-ordered, so size was estimated from the CT scans and assumed to be ideal *a priori*. Nail sizes used were one 10-mm, four 11-mm, and one 12-mm nail.

2.3 Surgical Technique

Tibiae were reamed according to standard surgical technique, with last reamer used being 1 mm larger than the nail diameter chosen for that donor. A transverse midshaft diaphyseal osteotomy (AO 42-A3) was then performed at the approximate axial midpoint using a double-bladed oscillating saw. A spacer was used to maintain a consistent 3-mm gap throughout nail implantation and locking in all samples. Free-hand distal locking was carried out under image intensification with two mediolateral (ML) 5.0-mm screws. Proximal locking was carried out using the aiming instruments and two ML 5.0-mm screws. Samples were progressively modified after each round of mechanical testing as follows:

1. Fibula intact

2. Short oblique fibular osteotomy
3. Fibula fixed with 6-hole plate
4. Fibula and interosseous membrane resected

These configurations were selected to investigate whether loss of integrity of the fibula significantly destabilises the tibial fracture (Round 1 vs. 2), whether fixation of the fibula provides additional stabilisation for the tibial fracture (Round 2 vs. 3), and whether removal of the fibula and interosseous membrane significantly changes the observable interfragmentary motions and measured stiffnesses in the tibia (Round 4 vs. 1-3). The fibular osteotomy was slightly oblique to compensate for the small gap created by the saw blade and allow for direct apposition to be achieved in plating, as would be the case in a clinical setting.

2.4 Biomechanical Testing

The distal and proximal extremities of each sample were embedded in poly(methyl methacrylate) bone cement (PMMA; Technovit 3040, Heraeus Kulzer, Wertheim, Germany) using an established technique (Dailey et al., 2012, Dailey et al., 2013, Penzkofer et al., 2009). To prevent fusion of the nail and proximal bone fragment and preserve the ligamentous tibial/fibular connections, the nail entry portal and proximal/distal ends of the fibula were encapsulated in dental putty. The putty was extended to cover the entirety of the anterior and posterior ligaments and above the embedding depth of the bone cement. This procedure ensured that PMMA made contact with the tibia only during embedding. In some cases, excess putty above the bone cement was trimmed away after completion of the embedding procedure.

Following protocols developed by other investigators (Augat et al., 2008, Epari et al., 2007, Kaspar et al., 2005, Penzkofer et al., 2009, Schell et al., 2005) and applied by ourselves previously for characterisation of tibial IM nailing stability (Dailey et al., 2012, Dailey et al., 2013), we carried out testing in axial tension/compression, anteroposterior (AP) bending, and AP shear. The fixtures used are shown in Fig. 1. For axial and torsion testing, samples were mounted in a multi-axis materials testing machine (Zwick model Zwicki Z5.0TH, High Leominster, Herefordshire, UK) by means of a proximal cardanic hinge. The central mechanical axis of each tibia was aligned with the load-application axis to produce near-zero axial and torsion pre-load prior to commencement of each test cycle. Cyclic axial loading consisted of a peak compressive load of 75 kgf (735N) and peak tensile load of 37.5 kgf, with a ramp rate of 0.25 mm/s. An extensometer (Instron model 2620, High Wycombe, Bucks, UK) was used to measure axial

interfragmentary motion and was secured using elastic bands passed through small slits in the interosseous membrane at the surface of the tibia. This was done to maintain adequate compression of the extensometer blades on the bone fragments to prevent slippage without loading the fibula. The extensometer was removed for torsion testing to prevent damage to the instrument. Fully-reversed torsion loading was applied at 18 deg/min up to ± 5 N-m peak torque. Interfragmentary motion in torsion loading was inferred from crosshead position.

Bending and shear tests were carried out on a uniaxial materials testing machine (Instron model 3345, High Wycombe, Bucks, UK) with a custom-designed modular fixture having 10-mm support rollers based on recommendations in ASTM F1264 (ASTM International, 2007). For the four-point bending tests, rollers were placed with support spans of 62 mm to be consistent with the previously-published method for testing composite tibiae (Cristofolini and Viceconti, 2000). For the bending test, the crosshead load was ramped at 0.25 mm/s to produce a maximum bending moment of 20 N-m with tension on the anterior side of the tibia. Some previous investigators have clamped specimens at all four support points, which allows for bi-directional bending (Augat et al., 2008, Penzkofer et al., 2009). We followed the procedure used for testing composite bones, in which only one clamp and three rollers are used to minimise the geometric constraints and more-closely mimic physiological conditions. During shear loading, the support spans were maintained and the crosshead was ramped at 0.25 mm/s to 100 N peak shear load. No ML bending or shear tests were performed because the presence of the fibula prevents loading the tibia in these modes. For AP bending and shear testing, the osteotomy was centred at the load-application axis of the tester and one bone fragment was clamped to prevent rotation of the sample during the test. Due to variations in individual donor anatomy, particularly the relative positions of the tibia and fibula, clamping was achieved using a variety of clamp extension blocks to ensure load application through the tibia only, but always with consistent 62-mm support spans maintained via the modular configurability of the custom fixture.

2.5 Data Processing and Statistics

Data was processed using MATLAB (The MathWorks, Inc., Natick, Mass., USA) based on the extensometry data for the axial case and crosshead deflection data in the other loading modes. For the axial and torsion tests, a script was used to calculate the length of the free-movement plateau (mm or deg) and the overall construct stiffness (N/mm or N-m/deg), as shown in Fig. 2. Briefly, plateaus were detected by identifying the increase in slope that characterises

the pseudo-elastic force-displacement behaviour associated with load transmission through the bone-screw-nail pathway. For the bending and shear tests in which the loading was non-reversible, no plateau appears and only the stiffness was assessed. In all loading modes except for bending, stiffness was defined as load divided by displacement. For bending stiffness, a fixture geometry-independent flexural rigidity was calculated as described elsewhere (Dailey et al., 2013). In all tests, the data analysis excluded the first cycle of loading to eliminate run-in effects and then evaluated the average of the subsequent three complete loading cycles for that test.

All statistical analysis was carried out in IBM SPSS Statistics 19 (SPSS, Inc., Chicago, Ill., USA). Data normality was verified by Kolmogorov-Smirnov/Shapiro-Wilk testing and checking Q-Q plots. Statistically-significant differences between different fibular configurations were identified using the repeated-measures general linear model with LSD pairwise comparisons. Mauchly's test of sphericity was applied and where necessary, degrees of freedom were corrected using Greenhouse-Geisser estimates of sphericity (ϵ was always < 0.75 throughout this study). All significance levels were $P < 0.05$. For statistically-significant pairings, effect size was calculated using Cohen's d .

3. Results

All results presented are in the form of box-and-whiskers plots. The boxed regions represent the bounds of the upper and lower quartiles about the median and the whiskers represent the min and max values.

3.1 Representative Load-Displacement Data

Fig. 2 illustrates representative load-displacement raw data from one sample with an intact fibula in all loading modes—axial, torsion, bending, and shear. Similar hysteresis curves under bi-directional loading, including the plateau regions have been previously described (Attal et al., 2014, Dailey et al., 2012, Dailey et al., 2013). In axial and torsion data, the low-load plateaus arise due to dimensional clearance between the nail and screws, and in some cases, screw loosening if it occurs. A longer plateau length is indicative of a larger dimensional clearance or more screw loosening. The plateau force or torque magnitude represents the average value of the load required to induce interfragmentary movement over this range of motion (i.e. the screw-hole clearance). The plateau slope is provided for comparison to the overall construct

stiffness and this plateau stiffness arises from interference between the IM nail and tibial IM space and the contribution of the fibula and interosseous membrane. Overall axial stiffness was calculated using peak-to-peak distraction/compression loading and total axial deflection. Overall torsional stiffness was based on peak-to-peak loading and total angular deflection.

In the AP bending and shear data, maximum stiffness was calculated from the load-application segments of the curves as shown in Fig. 2C and D. No plateaus appear in the bending and shear data because load application was unilateral to preserve four-point bending conditions, protect the fibula, and avoid skewing the stiffness calculations by measuring deflection due to nail-canal clearance (Augat et al., 2008).

3.2 Effect of the Fibula

To investigate the role of the fibula in the stability of the tibial fracture, we compared the data from Rounds 1 through 4 in each of the loading modes.

3.2.1 Axial Loading

Fig. 3 shows construct axial stiffness, plateau slope, plateau force magnitude, and plateau length for the four rounds of testing. Overall there was no significant effect of fibular configuration on axial stiffness ($P = 0.910$) and the one significant pairwise comparison between Rounds 1 and 4 had a trivial effect size ($P = 0.031$, $d < 0.01$). All other pairwise comparisons were non-significant ($P \geq 0.143$). Overall, there was no significant effect of fibular configuration on plateau slope ($P = 0.060$) and the two significant pairwise comparisons both had trivial effect size: Rounds 2 and 3 ($P = 0.003$, $d < 0.01$) and Rounds 3 and 4 ($P = 0.002$, $d < 0.01$). All other pairwise comparisons were non-significant ($P \geq 0.067$). Overall, there was no significant effect of fibular configuration on plateau force ($P = 0.592$) and the one significant pairwise comparison between Rounds 3 and 4 had a trivial effect size ($P = 0.032$, $d < 0.01$). All other pairwise comparisons were non-significant ($P \geq 0.400$). Finally, overall there was no significant effect of fibular configuration on plateau length ($P = 0.075$) and there were no significant pairwise comparisons ($P \geq 0.062$). The observable trend toward lengthening in the plateau length data was non-significant and upon closer inspection, was caused by only two of the six samples.

3.2.2 Torsion Loading

Fig. 4 shows construct torsional stiffness, plateau slope, plateau torque magnitude, and plateau length for the four rounds of testing. Overall there was a significant effect of fibular configuration on torsional stiffness in Rounds 1 through 4 ($P = 0.003$), and there were three significant pairwise comparisons: Rounds 1 and 4 ($P = 0.017$, $d = 4.7$), Rounds 2 and 4 ($P = 0.013$, $d = 1.7$), and Rounds 3 and 4 ($P = 0.005$, $d = 2.5$). All other pairwise comparisons were non-significant ($P \geq 0.074$). Overall, there was a significant effect of fibular configuration on plateau slope ($P = 0.003$), and there were several significant pairwise comparisons: Rounds 1 and 2 ($P = 0.045$, $d = 7.6$) and Rounds 1 and 4 ($P = 0.029$, $d = 8.6$), and Rounds 3 and 4 ($P = 0.040$, $d = 5.1$). All other pairwise comparisons were non-significant ($P \geq 0.058$). Overall, there was no significant effect of fibular configuration on plateau torque ($P = 0.203$) and no significant pairwise comparisons ($P \geq 0.066$). Finally, overall there was no significant effect of fibular configuration on plateau length ($P = 0.239$) and no significant pairwise comparisons (all $P \geq 0.179$).

3.2.3 Bending and Shear Loading

Fig. 5 shows construct AP bending and shear stiffness in the four rounds of testing. ML bending and shear tests were not performed due to risk of damaging the fibula during clamping. Overall there was no significant effect of fibular configuration on AP bending stiffness ($P = 0.758$) and there were no significant pairwise comparisons ($P \geq 0.327$). Overall there was no significant effect of fibular configuration on AP shear stiffness ($P = 0.468$) and the single significant pairwise comparison had trivial effect size: Rounds 1 and 2 ($P = 0.042$, $d = 0.01$).

4. Discussion

4.1 Effect of Fibula on Tibial Fracture Stability

In this work, first we asked whether loss of integrity of the fibula significantly destabilises midshaft tibial fractures. Although the overall construct stiffness decreased slightly with fibular osteotomy compared to the intact bone (Round 2 vs. 1, see Table 1), this change was not statistically significant. The low-load plateau slope also decreased after fibular osteotomy and in torsion, this change was statistically-significant with a large effect size.

Next we considered whether fibular plating can restore the lost stability compared to an intact fibula. Overall construct stiffness was unchanged by fibular fixation (Round 3 vs. 2). The axial low-load plateau slope was significantly increased by plating and was equivalent to the intact fibula case. The torsion low-load plateau slope also increased, but the construct was not restored to pre-osteotomy equivalence, which agrees with other investigators' observations (Kumar et al., 2003). This suggests that fibular fixation has a subtle effect on the stability of a midshaft tibial fracture, which may be more significant in the very early stages of healing before a patient begins significant weightbearing. It also suggests that fibular plating is more effective in restoring axial stability than torsional stability, but this effect is only apparent under low-loading conditions.

Next, we resected the fibula and interosseous membrane to assess whether these structures have an observable effect on the mechanics of midshaft tibial fractures (Round 4 vs. 1-3). In terms of overall construct stiffness, there was no significant axial contribution from fibula in our data. For torsion, fibular resection significantly decreased overall stiffness compared to the other groups. Notably, the overall stiffness of the osteotomised and plated fibula cases were not significantly different from stiffness measured with the intact fibula. This suggests that the fibula and interosseous membrane do influence the mechanics at the fracture site, and that this effect may be attributable to load-sharing mediated by the interosseous membrane, which occurs regardless of the fracture state of the fibula.

Finally, we observed that the role of the fibula was most evident when looking at the low-load stability characteristics (plateau slope and plateau force/torque). In these measures, the resistance to movement tended to decrease after fibular osteotomy, increase when the fibula was plated, and decrease again when the fibula was resected. Clinically, the relevance of this finding is that the role of fibula may be more pronounced in the very early stages of healing, prior to commencement of significant weightbearing. This observation agrees with other investigators who found evidence of stability enhancements with plating distal fibular fractures, but only under low-torque loading conditions (Kumar et al., 2003). Considering then whether or not to surgically intervene for the sole reason of contributing stability to the tibial healing zone by fixing the fibula, we found a very small stability benefit with the plated fibula, especially in torsion, which is critical for successful speedy healing. The most dramatic changes in stability occurred with resection of the fibula and interosseous membrane, suggesting that whether or not

a fractured fibula is surgically fixed, the structure can still offer some supporting benefit to the tibia via the soft tissue.

4.2 Limitations

We have used a midshaft tibial osteotomy to represent tibial fractures, which may be significantly more complex or located away from the mid-diaphysis. Fibular fractures accompanying distal-third tibial fractures may also be more likely to be addressed by surgical intervention when surgeons exercise discretionary choice (Egol et al., 2006, Whorton and Henley, 1998). However, we selected the midshaft osteotomy model for this study because this model has been used by previous investigators in cadaveric tests (Augat et al., 2008, Penzkofer et al., 2009) and biomechanical stability of these fractures has not been as well-documented. We did not find compelling evidence to support the clinical choice to fix fibular fractures in order to support speedy diaphyseal tibial fracture healing. However, other investigators have demonstrated a more vital role of the fibula in far-distal fractures and care should be taken not to extend the conclusions presented herein beyond the midshaft geometry.

Our approach to testing involved embedding the proximal and distal ends of the tibia in bone cement, taking care to prevent fusion of the tibia and fibula and prevent infiltration of bone cement into the IM space, thereby allowing relative movement of the nail within the tibia, as evidenced by the presence of the low-load plateau in the axial and torsion data. Although this approach also retains some of the flexibility of the syndesmotic joints, it does not allow as much deformation of the ankle joint as would be present during normal weightbearing, in which an intact fibula can translate to deepen the ankle mortise (Goh et al., 1992). However, our results do suggest that load transfer through the fibula and interosseous membrane was occurring due to significant differences in observed plateau slope between different fibular configurations.

When comparing the results presented herein to numerical values reported by other investigators, it is important to note that we have taken care to size our IM nails according to donor tibial anatomy. Some investigators have used a consistent nail diameter (e.g. 9 or 10 mm) for all samples, regardless of anatomy (Morin et al., 2008, Strauss et al., 2007). Attal et al. (Attal et al., 2014) used a range of nail sizes (9-11mm) with consistent over-reaming, but it is unclear how those sizes were chosen. We maintain that by sizing nails according to clinical best practice, with nail diameter set by IM canal size, the investigator can be assured of good cortical contact

without excessive reaming and avoid artificially-reduced stiffness measurements that could be produced when using under-sized nails.

A notable limitation of this work is that preservation of the fibula and interosseous membrane introduces significant experimental complications for the bending and shear tests. With the fibula present, no ML bending or shear tests could be carried out. Furthermore, individual anatomical variations in the relative size and curvature of the bones and the necessity of applying bending and shear loads through the tibia made clamping and loading the samples challenging. The results of our bending and shear tests (Fig. 5) do not demonstrate an obvious trend associated with the various treatments of the fibula, and we attribute this to the difficulties inherent in reproducibly clamping and loading the tibia when the fibula is present. However, the axial and torsion tests we undertook were not obstructed by the presence of the fibula, except in the care taken to preserve the soft tissue connections when embedding the tibia in bone cement. Upon reflection, we suggest that the inherent challenges of the approach we and other investigators have used to testing bending and shear stiffness of bone-implant constructs provide significant motivation for the development of alternative test methods in which physiologically-relevant bending loads may be generated simultaneously with the axial and/or torsional loading as is the case in functional weightbearing.

5. Conclusions

These results suggest a subtle but observable influence of the fibula on the mechanics of midshaft tibial fractures fixed by intramedullary nailing. Compared with an intact fibula, constructs with an osteotomised fibula are slightly less stiff under axial and torsion loading. Plating the fibula increases the construct stiffness compared to the unfixed case, and this is more apparent under axial loading than in torsion. In terms of clinical guidance, these results suggest that midshaft tibial fracture patients who have concomitant fibular fractures may have slightly less-stable tibial interfragmentary zones than patients who have an intact fibula. When considering the broader question of whether or not to fix the fibula, care should be taken to consider the potential for soft tissue damage and the likelihood of successful fibular union without fixation support. However, our results suggest that for midshaft tibial fractures, fibular plating may not effectively restore the tibial stability produced with an intact fibula and should not be undertaken unless fibular fixation is otherwise indicated.

For future cadaver biomechanics studies, our results suggest that testing the tibia without the fibula and interosseous membrane reduces the apparent stiffness of the bone-implant construct. For this reason, we recommend harvesting the tibia and fibula with the interosseous membrane intact when possible. However, the decision to keep the fibula does prevent testing the bone-implant construct in ML bending and shear and adds complexity to all stages of the experiment, due to extra care required to preserve the fibula and ligamentous connections during surgery, mounting, and testing.

Acknowledgements

The authors would like to express our sincere gratitude towards those who donate their bodies to the Department of Anatomy in University College Cork for medical science and education; without their generosity this work could not have been achieved. We are also deeply grateful for the support received from Michael Cronin, without whom this work could not have been completed. Financial support for personnel and materials was provided by the Irish Health Research Board (HRA_POR/2011/44). The funding body did not influence the design of the study described herein, the collection, analysis, or interpretation of the data, or the preparation the manuscript.

References

- ASTM International, 2007. Standard Specification and Test Methods for Intramedullary Fixation Devices.
- Attal, R., Maestri, V., Doshi, H.K., Onder, U., Smekal, V., Blauth, M., Schmoelz, W., 2014. The influence of distal locking on the need for fibular plating in intramedullary nailing of distal metaphyseal tibiofibular fractures. *Bone Joint J.* 96B, 385-389.
- Augat, P., Penzkofer, R., Nolte, A., Maier, M., Panzer, S., Von Oldenburg, G., Poeschl, K., Simon, U., Bühren, V., 2008. Interfragmentary movement in diaphyseal tibia fractures fixed with locked intramedullary nails. *J. Orthop. Trauma.* 22, 30-36.
- Berlusconi, M., Busnelli, L., Chiodini, F., Portinaro, N., 2014. To fix or not to fix? The role of fibular fixation in distal shaft fractures of the leg. *Injury-International Journal of the Care of the Injured.* 45, 408-411.
- Brown, N.A., Bryan, N.A., Stevens, P.M., 2007. Torsional stability of intramedullary compression nails: Tibial osteotomy model. *Clin Biomech.* 22, 449-456.
- Court-Brown, C.M., McBirnie, J., 1995. The Epidemiology of Tibial Fractures. *J. Bone Joint Surg Br.* 77B, 417-421.
- Cristofolini, L., Viceconti, M., 2000. Mechanical validation of whole bone composite tibia models. *Journal of Biomechanics.* 33, 279-288.
- Dailey, H.L., Daly, C.J., Galbraith, J.G., Cronin, M., Harty, J.A., 2013. The Flexible Axial Stimulation (FAST) intramedullary nail provides interfragmentary micromotion and enhanced torsional stability. *Clin. Biomech.* 28, 579-585.
- Dailey, H.L., Daly, C.J., Galbraith, J.G., Cronin, M., Harty, J.A., 2012. A novel intramedullary nail for micromotion stimulation of tibial fractures. *Clin. Biomech.* 27, 182-188.
- Egol, K.A., Weisz, R., Hiebert, R., Tejwani, N.C., Koval, K.J., Sanders, R.W., 2006. Does fibular plating improve alignment after intramedullary nailing of distal metaphyseal tibia fractures? *J. Orthop. Trauma.* 20, 94-103.
- Epari, D.R., Kassi, J.P., Schell, H., Duda, G.N., 2007. Timely fracture-healing requires optimization of axial fixation stability. *J Bone Joint Surg Am.* 89A, 1575-1585.
- Galbraith, J.G., O'Leary, D.P., Dailey, H.L., Kennedy, T.E., Mitra, A., Harty, J.A., 2012. Preoperative estimation of tibial nail length-Because size does matter. *Injury-International Journal of the Care of the Injured.* 43, 1962-1968.

- Gerstenfeld, L.C., Cullinane, D.M., Barnes, G.L., Graves, D.T., Einhorn, T.A., 2003. Fracture healing as a post-natal developmental process: Molecular, spatial, and temporal aspects of its regulation. *J. Cell. Biochem.* 88, 873-884.
- Goh, J.C.H., Lee, E.H., Ang, E.J., Bayon, P., Pho, R.W.H., 1992. Biomechanical Study on the Load-Bearing Characteristics of the Fibula and the Effects of Fibular Resection. *Clin. Orthop.* , 223-228.
- Hontzsch, E., Schaser, K.D., Hofmann, G.O., Pohlemann, T., Hem, E.S., Rothenbach, E., Krettek, C., Attal, R., 2014. Evaluation of the Effectiveness of the Angular Stable Locking System in Patients with Distal Tibial Fractures Treated with Intramedullary Nailing. *J Bone Joint Surg Am.* 96, 1889-1897.
- Kaderly, R.E., 1991. Primary Bone Healing. *Seminars in Veterinary Medicine and Surgery-Small Animal.* 6, 21-25.
- Kaspar, K., Schell, H., Seebeck, P., Thompson, M.S., Schutz, M., Haas, N.P., Duda, G.N., 2005. Angle stable locking reduces interfragmentary movements and promotes healing after unreamed nailing - Study of a displaced osteotomy model in sheep tibiae. *J Bone Joint Surg Am.* 87A, 2028-2037.
- Kumar, A., Charlebois, S.J., Cain, E.L., Smith, R.A., Daniels, A.U., Crates, J.M., 2003. Effect of fibular plate fixation on rotational stability of simulated distal tibial fractures treated with intramedullary nailing. *Journal of Bone and Joint Surgery-American Volume.* 85A, 604-608.
- Lambert, K.L., 1971. Weight-Bearing Function of Fibula - Strain Gauge Study. *Journal of Bone and Joint Surgery-American Volume.* A 53, 507-&.
- Marsell, R., Einhorn, T.A., 2011. The biology of fracture healing. *Injury-International Journal of the Care of the Injured.* 42, 551-555.
- Morin, P.M., Reindl, R., Harvey, E.J., Beckman, L., Steffen, T., 2008. Fibular fixation as an adjuvant to tibial intramedullary nailing in the treatment of combined distal third tibia and fibula fractures: a biomechanical investigation. *Canadian Journal of Surgery.* 51, 45-50.
- Penzkofer, R., Maier, M., Nolte, A., von Oldenburg, G., Püschel, K., Bühren, V., Augat, P., 2009. Influence of intramedullary nail diameter and locking mode on the stability of tibial shaft fracture fixation. *Arch Orthop Trauma Surg.* 129, 525-531.
- Phieffer, L.S., Goulet, J.A., 2006. Delayed Unions of the Tibia. *J Bone Joint Surg Am.* 88, 205-216.
- Schell, H., Epari, D.R., Kassi, J.P., Bragulla, H., Bail, H.J., Duda, G.N., 2005. The course of bone healing is influenced by the initial shear fixation stability. *J Orthop Res.* 23, 1022-1028.

Shapiro, F., 1988. Cortical Bone Repair - the Relationship of the Lacunar-Canalicular System and Intercellular Gap-Junctions to the Repair Process. *Journal of Bone and Joint Surgery-American Volume*. 70A, 1067-1081.

Skraba, J.S., Greenwald, A.S., 1984. The Role of the Interosseous Membrane on Tibiofibular Weightbearing. *Foot Ankle*. 4, 301-304.

Strauss, E.J., Alfonso, D., Kummer, F.J., Egol, K.A., Tejwani, N.C., 2007. The effect of concurrent fibular fracture on the fixation of distal tibia fractures: A laboratory comparison of intramedullary nails with locked plates. *J. Orthop. Trauma*. 21, 172-177.

Synthes GmbH, 2006. Expert Tibial Nail--Technique Guide.

Takebe, K., Nakagawa, A., Minami, H., Kanazawa, H., Hirohata, K., 1984. Role of the Fibula in Weight-Bearing. *Clin. Orthop.* , 289-292.

Thambyah, A., Pereira, B.P., 2006. Mechanical contribution of the fibula to torsion stiffness in the lower extremity. *Clinical Anatomy*. 19, 615-620.

Thomas, K.A., Harris, M.B., Willis, M.C., Lu, Y., McEwen, G.D., 1995. The Effects of the Interosseous Membrane, and Partial Fibulectomy on Loading of the Tibia - a Biomechanical Study. *Orthopedics*. 18, 373-383.

Varsalona, R., Liu, G.T., 2006. *Strat Traum Limb Recon*. 1, 42-50.

Vukicevic, S., Sternpadovan, R., Vukicevic, D., Keros, P., 1980. Holographic Investigations of the Human Tibiofibular Interosseous Membrane. *Clin. Orthop.* , 210-214.

Wang, Q., Whittle, M., Cunningham, J., Kenwright, J., 1996. Fibula and its ligaments in load transmission and ankle joint stability. *Clin. Orthop.* , 261-270.

Whorton, A.M., Henley, M.B., 1998. The role of fixation of the fibula in open fractures of the tibial shaft with fractures of the ipsilateral fibula: Indications and outcomes. *Orthopedics*. 21, 1101-1105.

Figure Legends

Fig. 1 – A) The axial/torsion tester was fitted with a custom fixture for holding PMMA-mounted bones and an extensometer was used to measure interfragmentary displacement during axial loading. The uniaxial tester was fitted with a shear testing fixture (B) and four-point bending fixture (C). D) Tests were repeated with the fibula (from right to left) intact, osteotomised, plated, and resected.

Fig. 2 – Sample hysteresis loops from the same sample tested in axial, torsion, bending, and shear loading with an intact fibula (Round 1).

Fig. 3 – Effect of the fibula on tibial fracture axial stability with an intact fibula (Round 1), osteotomised fibula (Round 2), plated fibula (Round 3), and no fibula (Round 4-1). Box-and-whiskers plots show median, interquartile range, and min/max.

Fig. 4 – Effect of the fibula on tibial fracture torsional stability with an intact fibula (Round 1), osteotomised fibula (Round 2), plated fibula (Round 3), and no fibula (Round 4). Box-and-whiskers plots show median, interquartile range, and min/max.

Fig. 5 – AP bending stiffness (A) and shear stiffness (B) with an intact fibula (Round 1), osteotomised fibula (Round 2), plated fibula (Round 3), and no fibula (Round 4). Box-and-whiskers plots show median, interquartile range, and min/max.

Figure 1

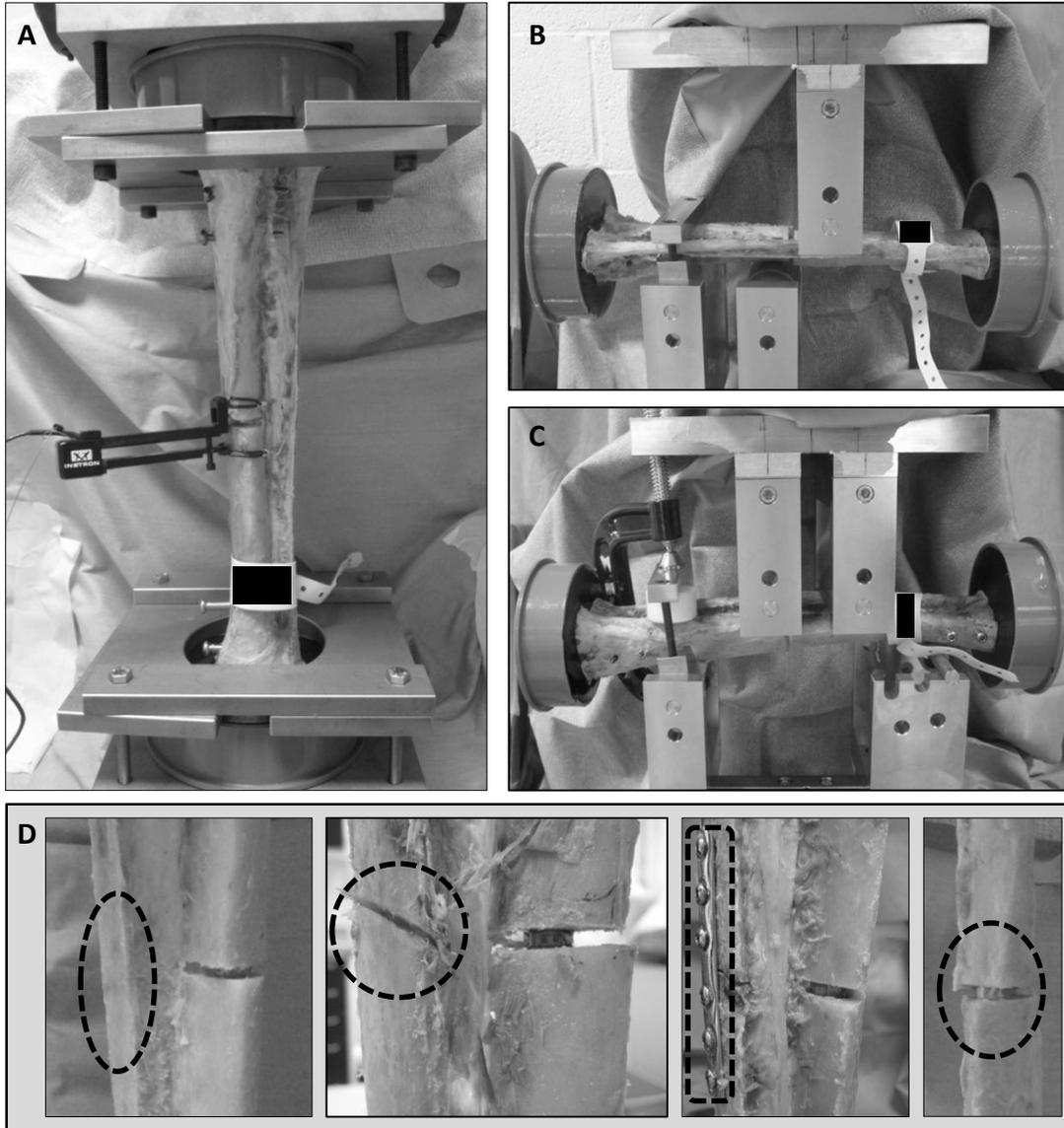


Figure 2

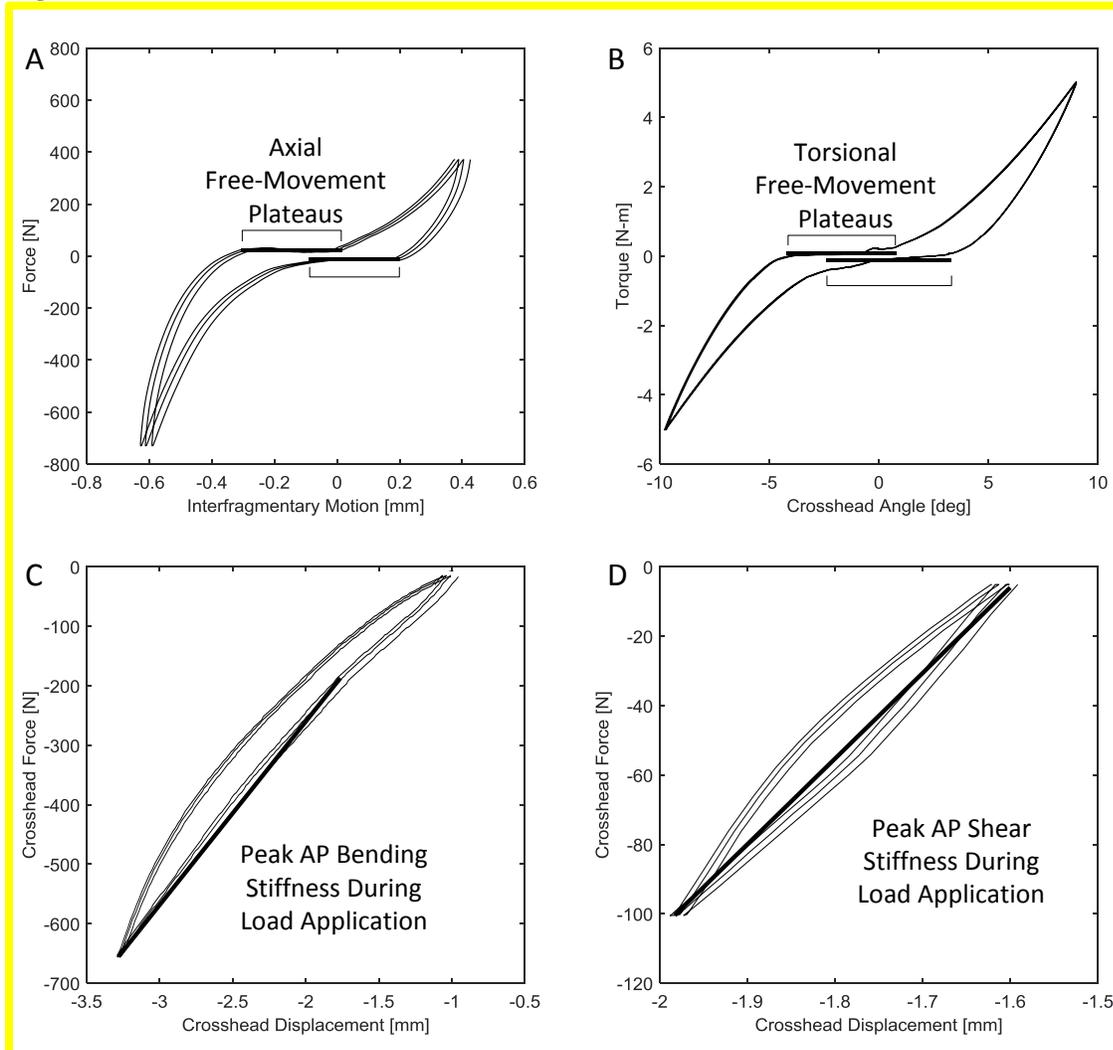


Figure 3

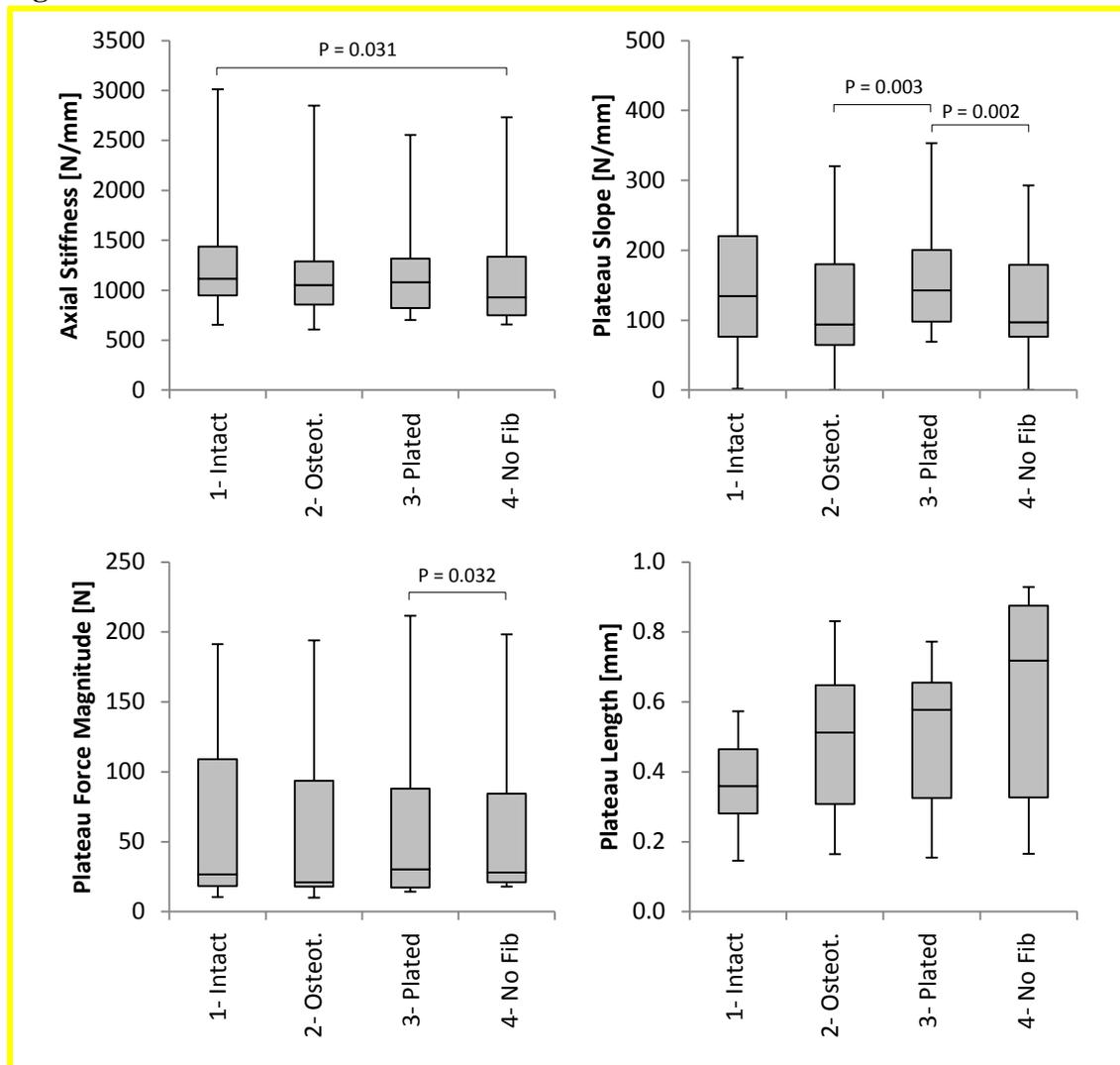


Figure 4

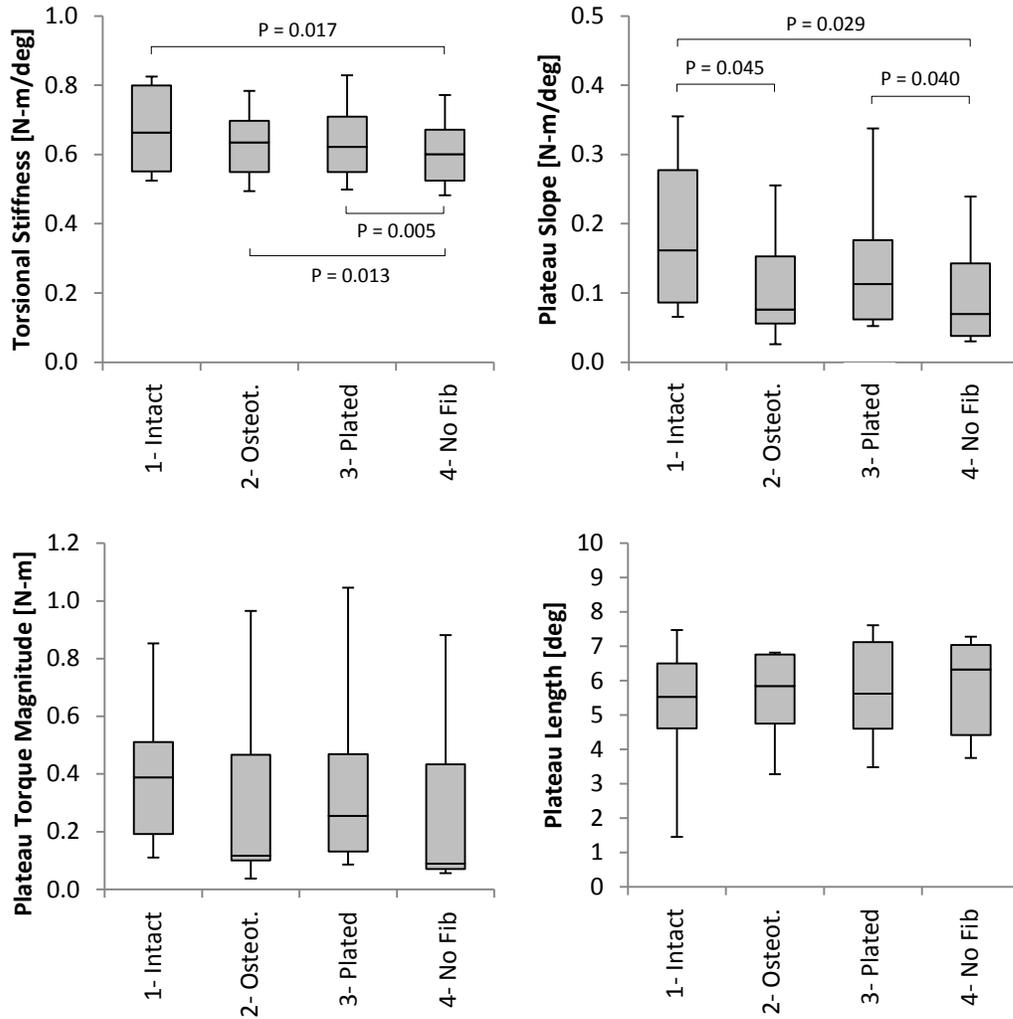


Figure 5

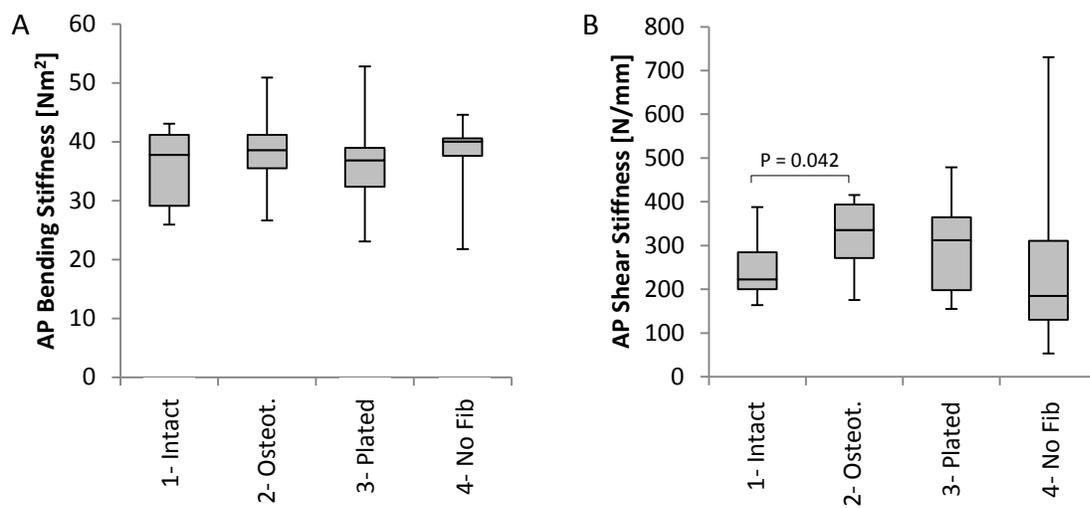


Table 1. Multi-axial total stiffness and plateau characteristics for each round of testing with medians and interquartile (IQ) ranges. Statistically-significant pairings and their *P*-values are annotated in accompanying Figures 3, 4, and 5, with effect sizes for those pairings indicated in the text.

	1. Intact Fibula		2. Fibular Osteotomy		3. Plated Fibula		4. Resected Fibula	
	Median	IQ Range	Median	IQ Range	Median	IQ Range	Median	IQ Range
Axial Loading								
Total Stiffness [N/mm]	1117	948-1436	1053	858-1289	1079	822-1318	930	751-1335
Plateau Slope [N/mm]	135	76-220	88	59-174	143	98-200	76	55-157
Plateau Force [N]	27	18-109	21	18-94	30	17-88	28	21-84
Plateau Length [mm]	0.36	0.28-0.47	0.51	0.31-0.65	0.58	0.33-0.66	0.72	0.33-0.88
Torsion Loading								
Total Stiffness [N-m/deg]	0.66	0.55-0.80	0.64	0.55-0.70	0.62	0.55-0.71	0.60	0.52-0.67
Plateau Slope [N-m/deg]	0.16	0.09-0.28	0.08	0.06-0.15	0.11	0.06-0.18	0.07	0.04-0.14
Plateau Torque [N-m]	0.39	0.19-0.51	0.12	0.10-0.47	0.25	0.13-0.47	0.09	0.07-0.43
Plateau Length [deg]	5.5	4.6-6.5	5.8	4.8-6.8	5.6	4.6-7.1	6.3	4.4-7.0
AP Loading								
Bending Stiffness [Nm ²]	38	29-41	39	35-41	37	32-39	40	38-41
Shear Stiffness [N/mm]	223	200-285	335	272-394	312	198-364	185	130-311

Highlights

- Cadaver model of fibular involvement in diaphyseal tibial fracture stability
- Influence of the fibula is only significant in torsional loading
- Fibular plating does not restore stability equivalent to intact bone
- Torsional stability contribution of the fibula is due to the interosseous membrane
- Retain the fibula and interosseous membrane when possible in biomechanical tests