Effect of bending direction on the mechanical behaviour of interlocking nail systems

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Summary
Objectives: To compare the mechanical properties of various interlocking nail constructs in medio-lateral (ML) and cranio-caudal (CC) bending.

Methods: Synthetic bone models simulating a severely comminuted tibial fracture were treated with either screwed or bolted, 6 or 8 mm standard interlocking nails (ILN), or an angle-stable ILN (AS-ILN), after which they were then sequentially tested in ML and CC bending. Construct compliance, maximum angular deformation (MaxDef) and slack were statistically compared (p<0.05).

Results: The compliance of all constructs was significantly greater in CC than in ML bending. However, due to the presence of a greater slack in the ML plane, standard ILN constructs sustained significantly more deformation in that plane. Maximum deformation of the novel AS-ILN constructs was the smallest of all constructs and consistently occurred without slack regardless of bending direction.

Clinical significance: This study suggested that standard ILN construct overall deformation and acute instability (slack) may be more critical in ML than in CC bending. Conversely, the small MaxDef and the absence of slack in both bending planes seen in novel angle-stable AS-ILN may provide optimal construct stability and in turn may be more conducive to bone healing.

Introduction

Acute perioperative instability, referred to as ‘slack’, of fractures repaired using current standard veterinary interlocking nails (ILN), has been recently documented in clinical reports (1, 2). Similarly, recent in vitro studies using a tibial bone model have demonstrated that slack in both torsion and medio-lateral (ML) bending was a consistent feature of constructs stabilised with currently available ILN (3–5). Construct slack has been associated with delayed bone healing and functional recovery in sheep (6), and likely contributes to the 14% rate of delayed or non-unions reported clinically in dogs (7–9). As a result of perioperative instability, approximately 12% of diaphyseal fractures treated with standard ILN require additional fixation (1, 2). In addition, construct slack has been attributed to the lack of rigid interaction between the locking device and the nail hole in standard ILN (3, 5, 10). This design limitation was the impetus for the development of an angle-stable nail (AS-ILN) in our laboratory. This new system features a conical locking bolt firmly linked to a matching tapered nail hole (3). The resulting rigid locking of the bolt and nail has already been shown to improve fixation stability in vitro by fully eliminating construct slack in both torsion and ML bending (3, 5).

Assuming that ILN construct mechanical behaviour would be more critical in ML than in cranio-caudal (CC) bending, recent mechanical evaluations of veterinary ILN have focused on bending in the ML plane (5). This conjecture was based upon intrinsic structural properties of the nails as well as common surgical practices. Indeed, although the orientation of the plane of an ILN locking device may be adjusted to conform to various fracture configurations, in the vast majority of the clinical cases, this plane will be parallel to the frontal plane (with this in mind, the orientation of the locking devices will be assumed to coincide with the ML plane throughout this study). Accordingly, the area moment of inertia (AMI) at the level of the nail holes is greater in the CC than in the ML plane (3, 11). Consequently, the ability of a nail to resist bending is higher in the CC that in the ML plane. This assumption, however, does not take into account the contribution of the locking devices to overall construct stability in either plane of deformation. Moreover, because contraction of the extensor and flexor muscle groups during gait occurs in the sagittal plane, constructs are likely subjected to large CC bending moments. Indeed, previous in vivo studies have demonstrated that tibial strains are greater in the CC than in the ML plane in both dogs (12) and sheep (13). Because the bending stiffness of the canine tibia in vitro is similar in the CC and ML planes (14), these studies suggest that bending moments acting in the CC plane are greater than those acting in the ML plane. However, to the authors’ knowledge, the effect of bending moments in the CC plane on
overall mechanical behaviour of tibial construct stability in dogs has yet to be investigated.

Therefore, the purpose of this study was twofold: 1) to compare the ML and CC bending behaviour of synthetic tibial constructs stabilised with currently available 6 and 8 mm veterinary ILN locked with screws (sc) or bolts (bo) (ILN6sc, ILN6bo, ILN8sc, and ILN8bo, respectively) or an AS-ILN; and 2) to compare the CC bending behaviour of standard ILN constructs to that of novel AS-ILN constructs.

We hypothesised that the bending direction would have a significant effect on the construct bending compliance, maximum angular deformation and slack for all groups. We further hypothesised that AS-ILN deformation would occur without slack regardless of the orientation of the bending plane.

**Material and methods**

**Study design**

Five groups (ILN6sc, ILN6bo, ILN8sc, ILN8bo and AS-ILN) of four specimens each were tested in four-point bending in the ML and CC planes. The sizes of the groups were determined by means of a power analysis (power>0.8) based on means and standard deviations obtained during a previous study (5).

**Specimen preparation**

Custom-made, synthetic, canine tibial bone models, similar to those used in previous studies (3–5), featured a 12 cm central gap, simulating a severely comminuted diaphyseal fracture extending to the sub-metaphyseal regions. This fracture configuration was chosen to insulate that no interactions between the ILN and the endocortices of the bone model would occur, since such interactions could in turn mask intrinsic differences between groups. Standard ILN consisted of the following:

- 185 mm x 8 mm³ nails locked with 3.5 mm bicortical screws or bolts.

The previously described hourglass-shaped AS-ILN (3) was 185 mm long, with a diameter gradually increasing from 6 mm at the centre to 8 mm at the extremities (Fig. 1).

The AS-ILN was locked by use of dedicated locking devices (SCPs). The SCPs featured a 4 mm (core diameter) self-taping extremity engaging the cis-cortex, a central Morse taper section matching the tapered nail hole and a 3.2 mm smooth terminal peg engaging the trans-cortex (Fig. 1). This reengineered locking system creates an angle-stable design which rigidly secures the SCP to the nail. Implants were applied following a procedure previously established (3). A custom-designed drilling fixture insured consistent positioning of the locking devices. All ILN were locked with two proximal and two distal devices (screws, bolts or SCPs) oriented in the ML direction. Furthermore, standard nails were maintained along the central axis of the bone model via custom-made polyurethane foam plugs.

**Mechanical testing**

Specimens were mounted via a custom-designed frame on a servo-hydraulic testing machine fitted with a 2,225 N load cell, and then tested non-destructively in four-point bending. Testing procedures were identical to those previously described (5). Briefly, bending moments (± 3.5 Nm) were applied in a haversine waveform centred on the neutral position for 10 cycles under load control. Each specimen was sequentially tested in ML and CC bending, alternating the order of the two testing conditions with each specimen change. The load and actuator displacement were recorded at a sampling rate of 250 Hz. Bending moments were computed from data generated by the load cell and the

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*Bone model: Olympian Tool, St. Johns, MN, USA
ILN model 11–08–185–02–02–3.5: Innovative Animal Products, Rochester, MN, USA
Intron Model 1331: Intron Corp., Canton, MA, USA
Load cell 1010AF-500: Interface Manufacturing Inc., Scottsdale, AZ, USA
configuration of the frame (5). Each loading cup was instrumented with a rotary encoder\(^\text{b}\) centred along the rotational axis of each cup to enable measurement of the specimen angular deformation during testing. Note: Although a standard test for intramedullary devices is available (ASTM F1264 – 03\(^\text{c}\)), the authors elected not to follow this procedure because it does not provide for evaluation of the bone-implant construct. Instead, nails and locking devices were tested separately in conventional four-point-bending. Furthermore, even if the ASTM F1264–03 described a testing procedure for entire constructs, the assessment of slack would not have been possible since the protocol does not allow reversal of the bending direction during the loading cycle. Following such a standard four-point bending protocol was a major limitation of previous studies, which failed to document construct slack (10, 15). It is the authors’ opinion that the testing protocol used in the current as well as in previous similar studies better models the in vivo conditions, where bending direction changes during the gait cycle (or other activities) (4, 5).

**Data analysis**

Data from the 10\(^{\text{th}}\) cycle were used to determine construct compliance, maximum angular deformation and slack. Since tests were conducted under load-control, construct compliance (rather than stiffness) was determined. Construct compliance is the inverse of stiffness, and is defined as the slope of the deformation versus load curve. Construct compliance was determined using linear regression with an \(r^2\) value greater than 0.98 between 1.5 and 3.5 Nm and between –1.5 and –3.5 Nm, during positive and negative loading, respectively (Fig. 3). The central portion of the curve, where slack, if present, gives a sigmoid shape to the curve, was not included in the compliance computation. The overall construct compliance (used for statistical analyses) was calculated as the mean compliance during positive and negative loading. Construct slack, if present, corresponded to the central region of the compliance curve where there was no quantifiable resistance to bending (4, 5). Slack was calculated as the angular difference between the Y-axis intercepts of the positive and negative compliance slopes. Angular deformation was computed as the sum of the absolute angles obtained from both rotary encoders. Maximum construct deformation was then computed as the difference between angular deformation at maximum positive and negative bending moments.

Construct compliance, MaxDef and slack were compared between groups using a two-factor ANOVA. The two factors were bending plane and type of implant. Student Newman-Keuls post-hoc tests were used whenever significance was present. Statistical significance was set at \(p<0.05\).

### Results

For an overview, see Table 1.

#### Compliance

**ML versus CC bending**

All constructs were significantly less compliant in ML than in CC bending (Fig. 3). The compliance was approximately 50% (screwed constructs) and approximately 30% (bolted and AS-ILN constructs) smaller in ML than in CC bending (\(p<0.05\)).

**CC bending**

In CC bending, the ILN6sc construct compliance was the greatest amongst all groups (\(p<0.05\)) while AS-ILN and ILN8bo constructs had the lowest compliance of all groups (\(p<0.05\)).

#### Maximum angular deformation

**ML versus CC bending**

Maximum angular deformation was significantly greater in ML than in CC bending for all standard ILN constructs. Compared to ML bending, construct MaxDef in CC bending was reduced by 22% in the ILN6sc, 17% in the ILN6bo, 31% in the ILN8sc and 22% in the ILN8bo (\(p<0.05\)). Conversely, the AS-ILN showed a 25% smaller MaxDef in ML than in CC bending (\(p<0.05\)).

**CC bending**

In CC bending, construct MaxDef decreased progressively from the ILN6sc, ILN8sc, ILN6bo and ILN8bo (\(p<0.05\)). The AS-ILN
constructs permitted the least amount of MaxDef of all constructs (p<0.05).

Slack

While slack was present in both bending planes in all standard nail groups, AS-ILN construct deformation occurred without slack. Construct slack was significantly greater in ML than in CC bending in all standard ILN.

Discussion

The bending compliance of an ILN is a structural property used to predict the deformation sustained by the ILN under a given loading condition. The higher the compliance, the less resistant the ILN is to deformation under a given bending moment. The bending compliance of an ILN is inversely proportional to its area moment of inertia (C = L²/3EI with C: compliance; L: working length; E: modulus of elasticity; I: area moment of inertia) (11). Accordingly, ILN with holes oriented in the ML direction are theoretically more compliant in ML than in CC bending because the nail AMI at the level of the holes is approximately three-times lower in ML than in CC bending (3). While this theory may be true when considering the nail alone, the compliance of the whole construct may not follow the same trend due to the presence of the locking devices linking the nail and bone. Indeed, despite the greater theoretical bending resistance intrinsic to all tested nails in the CC plane, construct compliance was invariably higher in this plane than in the ML plane.

The above finding can be tentatively explained by a greater deformation of the locking devices in CC than in ML bending. Because of the tapered profile of the extremities of our bone model (simulating the tibial metaphyses), the exposed length (i.e. working length) of the most proximal and most distal locking devices was greater than that of the two innermost ones. Since the compliance of an implant is

Table 1 Mean (± SD) compliance, maximum deformation and slack of each type of construct in medio-lateral and cranio-caudal bending. Comparing constructs (within each column), values with identical letters were not significantly different from each other. For each type of construct (within each row), all means, i.e. compliance, maximum deformation (MaxDef) and slack were significantly different between the medio-lateral and cranio-caudal bending planes, with the exception of the slack for the AS-ILN. Since no slack was recorded in either bending plane in the AS-ILN group, statistical analysis was not applicable (NA).

<table>
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<tr>
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<th>Medio-lateral bending</th>
<th>Cranio-caudal bending</th>
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<tr>
<td></td>
<td>Compliance (°/Nm x 10⁻²)</td>
<td>Maximum angular deformation (°)</td>
</tr>
<tr>
<td>6 mm interlocking nail and 2.7 mm screws</td>
<td>0.97 ± 0.03&lt;sup&gt;a&lt;/sup&gt;</td>
<td>22.87 ± 2.12&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>6 mm interlocking nail and 2.7 mm bolts</td>
<td>0.85 ± 0.03&lt;sup&gt;a&lt;/sup&gt;</td>
<td>12.98 ± 1.13&lt;sup&gt;b&lt;/sup&gt;</td>
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<tr>
<td>8 mm interlocking nail and 3.5 mm screws</td>
<td>0.50 ± 0.01&lt;sup&gt;α,b,c&lt;/sup&gt;</td>
<td>18.09 ± 0.33&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>8 mm interlocking nail and 3.5 mm bolts</td>
<td>0.53 ± 0.03&lt;sup&gt;α,b,d&lt;/sup&gt;</td>
<td>9.28 ± 0.22&lt;sup&gt;d&lt;/sup&gt;</td>
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<tr>
<td>Angle stable nail</td>
<td>0.57 ± 0.01&lt;sup&gt;α,b,d&lt;/sup&gt;</td>
<td>3.92 ± 0.04&lt;sup&gt;b&lt;/sup&gt;</td>
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Key: NA: not applicable (no slack was recorded in either bending plane in the AS-ILN group).
proportional to its working length elevated to the 3\textsuperscript{rd} power (16), the proximal and distal locking devices will be more compliant and will potentially sustain more deformation than the innermost locking devices.

In CC bending, the long axis of each locking device is perpendicular to the plane of construct deformation. Consequently, the nail swivels around the less compliant, innermost locking devices, thus allowing independent deformation of each locking device (Fig. 4A). Construct compliance is therefore mainly limited by the more compliant outermost locking devices. In contrast, in ML bending, since the long axis of each locking device is parallel to the plane of construct deformation, both locking devices, in each bone segment, tend to deform in the same manner (Fig. 4B). In addition, while the outermost locking devices remain relatively more compliant, the less compliant, adjacent innermost locking devices tend to further limit construct compliance. The differential deformation of the locking devices in different planes could explain the greater construct compliance in CC than in ML bending.

The maximum angular deformation experienced by a construct is the result of both compliance and slack, when present. As expected, despite a greater compliance in the CC plane, the maximum angular deformation of all standard ILN constructs was greater in ML bending, mainly because of a significantly greater slack in ML than in CC bending. In standard ILN, for a given tolerance between the nail hole and the corresponding screw or bolt, construct slack in the ML plane is primarily affected by the nail diameter (Fig. 5A), while in the CC plane, it is mostly affected by the distance between the nail holes (Fig. 5B). Based on trigonometric calculations, for a given mismatch between the diameter of the nail hole and the locking device, the amount of slack will be greater in ML bending than in CC bending as long as the nail diameter is smaller than the distance between the holes. In the novel AS-ILN, the tapered SCPs and nail holes act as a rigid unit that precludes any motion between the nail and the reengineered locking device. Therefore, in the absence of slack, construct deformation was solely influenced by the compliance of the construct, and therefore was smaller in the ML plane.

From a clinical standpoint, construct deformation contributes to the level of strain sustained at the fracture site. A relatively compliant construct, allowing subtle and continuous deformation at the fracture site, can be conducive to bone healing (17, 18). Conversely, the presence of acute construct slack, contributing to up to 50% of the total deformation in standard ILN constructs, is likely responsible for abrupt and high tissue shear strains that can potentially delay bone healing (19).

We previously reported the mechanical behaviour of the standard and novel nails under ML bending in a comminuted mid-diaphyseal fracture model (5). The current study is the first to document the bending properties of these implants in CC bending. This study suggested that overall construct deformation and acute instability (slack) might be more critical in ML than in CC bending. Because the re-designed angle-stable locking mechanism of the AS-ILN eliminates slack in both bending directions, the AS-ILN constructs experienced the lowest maximum deformation of all nail constructs in both bending planes. This in turn improves construct stability and could result in faster bone healing. This assumption is currently being investigated in an in vivo study in our laboratory.

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