RESEARCH ARTICLE

Design and numerical investigation of an adaptive intramedullary nail with a novel interlocking mechanism

Mohammad Ali Bagheri and Gholamreza Rouhi*

Faculty of Biomedical Engineering, Amirkabir University of Technology, 424 Hafez Ave, Tehran 15875-4413, Iran

*Corresponding author. E-mail: grouhi@aut.ac.ir

Abstract

Malalignment is a common complication in the treatment of distal fractures of the tibia. Numerous efforts have been made to reduce the malalignment ratio. However, the reported cases with this disorder are still high. This study aimed at investigating an adaptive design of an intramedullary nail with a novel interlocking mechanism (AINIM), as an alternative for the customary nailing, in reducing malalignment ratio. A verified finite element model was employed to compare the performance of AINIM with the customary nail. The finite element model of the tibia follows the exact shape of the medullary canal, and nonhomogeneous material properties were assigned to the bone from bone ash density. It was assumed that the nails were implanted and interlocked in the tibia according to surgical protocols, and physiological-like loading was applied to finite element models. The results of this study showed that AINIM reduces the mean shear interfragmentary strains by about 30%, and the axial interfragmentary strain by 55%, also it increases the uniformity in the interfragmentary movements, compared to the customary nail. It was also found that AINIM caused a reduction of the stress on the nail by 60%, and an increase of 25% on the bone, compared to the customary nail. Moreover, average compressive principal strains in the tibia fixed by AINIM increased by 40% from 485 to 678 \( \mu \varepsilon \), compared to the tibia fixed by the customary nailing method. The results of this work also showed that AINIM causes an increase in the contact area with the intramedullary canal, particularly at the fracture site, and it also escalates the magnitude of contact pressure. Results of this work indicate that, from the biomechanical standpoint, the adaptive nail, i.e. AINIM, with an innovative interlocking mechanism, compared to the customary nailing, can lessen intra- and post-operative malalignment occurrence, and it also mitigates the side effects of stress shielding, and thus better conserves neighboring bone density in a long period.

Keywords: distal fracture of tibia; finite element method; adaptive nail; customary nail; innovative interlocking mechanism; malalignment

Nomenclature

\begin{tabular}{ll}
IM: & Intramedullary \\
FE: & Finite element \\
IFS: & Interfragmentary strain \\
AINIM: & Adaptive intramedullary nail with novel interlocking mechanism \\
CN: & Customary nail \\
AIN: & Adaptive intramedullary nail \\
NIM: & Novel interlocking mechanism \\
CAD: & Computer-aided design \\
\end{tabular}

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1. Introduction

Intramedullary (IM) nailing has now become a well-accepted approach for the fracture fixation of the tibia (Rosa et al., 2017). Evaluation of IM nailing has clarified its advantages, compared with minimally invasive plating, including elevation in stiffness of the bone-implant construct, lower risk of infection, and preservation of periosteal blood supplies, and osteoprogenitor cells (Costa et al., 2018; Morwood et al., 2019). However, some complications may appear when using IM nailing, such as malalignment, rotation of the distal end of the nail during the implantation process, hardware failure, and fracture propagation (Usoro et al., 2019; Cain et al., 2020), which require revision surgeries that raise the costs and cause uncomfortable condition for patients.

Malalignment is defined as the dislocation of the fractured segments of the bone, which can initially occur during osteosynthesis, where the nail is being placed inappropriately due to either reaming or passage of the nail (Brinkmann et al., 2019), or during its usage and weight-bearing condition of the bone-implant construct (De Giacomo & Tornetta III, 2016). As a result of excessive axial rotation and/or axial translation, between the bone distal and proximal segments, rotational and/or varus/valgus malalignments can occur, respectively (Brinkmann et al., 2019; Cain et al., 2020). Studies showed that distal tibia fractures are particularly more affected by malalignment risk during the surgery (Avilucea et al., 2016). The proximity of the fracture to plafond and initial nail target, as clinically reported variables, are associated with the likelihood of malalignment (Brinkmann et al., 2019). Moreover, loss of interference fit of the nail in the distal region, due to large diameter of the medullary canal at the distal tibia, and flexion and extension of the leg to enable proper instrumentation were reported to be the potential causes of malalignment, during IM nailing of distal tibia fractures (Avilucea et al., 2016). Even though guide frames are inseparable instruments for accurate insertion of the screws into the bone and nail, in the case of distal tibia fractures, they are not functional for the insertion of distal screws. During the surgery, dislocation of the distal part of the fractured tibia, i.e. distal foot and distal tibia, is almost inevitable; thus, surgeons solve this problem by manually repositioning the distal part, and inserting the distal screw accordingly, which raises the human errors, and consequently, the need arises for revision surgeries.

During surgery, the anatomical shape of the medullary canal, passage, and reaming may dislocate the nail and cause initial malalignment (Brinkmann et al., 2019). However, even an initially well-positioned nail may still be dislocated under post-operative loadings (Homeier, Howling, Zander, Kühne, & Graca, 2016). Initial mechanical stimuli at the fracture gap site regulate the bone healing process (Epari, Schell, Bail, & Duda, 2006). Less favorable mechanical condition compared with fractures at mid-shaft and proximal is reported from Finite Element (FE) analyses of the distal defect of the tibia managed by IM nail (Duda et al., 2001; Gómez-Benito et al., 2007), i.e. large amount of shear compared with axial interfragmentary strain (IFS) (Duda et al., 2001); largest unloading of the bone (Duda et al., 2003); and occurrence of the maximum nail stress compared with other fracture locations (Gómez-Benito et al., 2007). Shear IFSs delay healing process (Augat et al., 2003; Steiner, Claes, Ignatius, Simon, & Wehner, 2014; Ghiasi, Chen, Vaziri, Rodriguez, & Nazarian, 2017), and large axial to shear IFS ratio is identified as one of the causes of instability in the distal defect, and the main reason for the high rate of malalignment, reported in distal tibia fractures (Freedman & Johnson, 1995). Using angle stable interlocking screws (Wehner, Penzkofer, Augat, Claes, & Simon, 2011), reaming the bone before the insertion of the nail, and insertion of additional locking screws at the distal part of the tibia (Bono et al., 2003) were reported to be some of the improvements, which can mitigate the shear IFS (Kaspar et al., 2005; Epari, Kassi, Schell, & Duda, 2007), and so can reduce the risk of malalignment occurrence. On the other hand, unreamed nailing is known to be more appropriate due to better perseverance of blood supplies, compared with reamed nailing (Gómez-Benito et al., 2007). Nonetheless, screw failures are commonly reported in the unreamed IM nailing, due to high stresses in the screws (Hou, Wang, & Lin, 2002). Moreover, even though angle stable interlocking screw initially reduces the shear IFS, studies reported that high shear movement might occur in a long term, i.e. approximately up to 4 mm (Wehner et al., 2011). Insertion of locking screws is biomechanically desirable for improving mechanical stability, but exposure, drilling, and insertion of screws can cause serious vascular, neural, and tendinous disorders due to the proximity of screws to soft tissues (Bono et al., 2003). The risk of injury is particularly higher for the placement of screws at the distal tibia, on the sagittal plane, due to vulnerability of the artery and fibular nerve during the surgical procedure (Bono et al., 2003).

Herein, we designed and analyzed an adaptive IM nail with a novel interlocking mechanism (AINIM), which aimed at reducing the risk of malalignment occurrence during both osteosynthesis and post-operative loadings. Both biomechanical and clinical aspects of IM nailing were taken into account in the design of AINIM. The novel geometry of the adaptive IM nail (AIN) was based on the anatomical characteristics of the tibia, which were aimed to be used as guidelines for patient-specific design of IM nail. The adaptive nail was designed to facilitate the nail passage into the bone during the surgery, causing less injury to the intramedullary surface, and also to provide greater surface contact with the medullary canal, compared with the customary nail (CN). In AINIM, a novel interlocking mechanism (NIM) was introduced, which was proposed as a replacement for the conventional interlocking screws. NIM is a prototype that aimed at reducing the surgical complication of the nailing method, specifically for the distal tibia fractures, where preserving soft tissue and major blood supplies is crucial for a faster bone healing process, as well as in preventing malunion. The NIM was designed to offer biomechanical and clinical advantages, compared with interlocking screws, by increasing tibia-nail constraints particularly in the distal metaphysis, where poor connection between nail and tibia can be a concern. In this research, it was hypothesized that under post-operative loading, the application of AINIM compromises the distribution of load in the bone-implant construct, and can regulate IFS, in favor of a faster healing process. FE method is known as a well-established approach for the evaluation of customized products (Samsami, Saberi, Sadjighi, & Rouhi, 2015; Nourisa & Rouhi, 2016; Yao, Moon, & Bi, 2017), which was used here for the evaluation of the AINIM. In the first stage, the FE model, developed in this work, was verified, and then it was used to simulate and compare the behavior of AINIM with
Figure 1: The flowchart of work-flow employed in this study.

the CN to evaluate the performance of the newly suggested IM nail.

2. Materials and Methods

The work-flow chart used in this study is provided in Fig. 1.

2.1. Computer-aided design (CAD) of the tibia, AINIM, and CN

To design IM nails, a 3D model of an intact tibia was reconstructed in Mimics (V10.01), using computer tomography (CT) scan data of a healthy 43-year-old male (Fig. 2). Each image had a slice thickness of 0.4 mm and a pixel size of 0.441 mm on a $512 \times 512$-pixel frame. Bones were separated from the surrounding soft tissues through thresholding of the Hounsfield values (Fig. 2). After the segmentation, the tibia was separated from other neighboring bones, i.e. fibula, femur, and talus, by a region-growing algorithm provided in Mimics software, and the voxel-based 3D model of the bones was generated (Fig. 3a). The generated 3D geometry was created from triangular surface mesh, as a stereolithographic (STL) model (Fig. 3b). To preserve the surface geometry of the tibia, no smoothing filter was applied after the segmentation (Carfagni et al., 2019). The standard triangular mesh was converted to point cloud and then was exported from Mimics to SolidWorks software (Fig. 3c). Afterward, the point cloud was converted to the closed analytical surfaces, which makes analytical surfaces to one solid model (Fig. 3d).

To model the IM canal, materials were assigned to the tibia from bone ash density (Table 3). Yellow bone marrow, embedded in the IM canal, has the lowest density among various substances of the tibia (Chen et al., 2010). During image registration of the material assigned to the tibia, the substance with the lowest density was subtracted from the tibia on CT images, which can consequently result in an accurate geometry of the IM canal within the tibia (Fig. 4a). To minimize the simplifications made, the approximate mesh size of 1 mm was chosen, which is defined as a fine mesh for the material assignment from bone ash density (Chen et al., 2010). A 10-mm transverse osteotomy, which was graded as type C, according to Arbeitsgemeinschaft für Osteosynthesefragen (AO) classification, was mimicked, with a 45-mm distance from the distal articular surface of the tibia. It should be mentioned that fractures within 50 mm of plafond are reported to have a high risk of malalignment (Brinkmann et al., 2019).

The 3D model of CN was obtained from a 3D scanning of an unreamed Expert, with an outer diameter of 9.0 mm, an inner diameter of 4.8 mm, and a length of 330 mm, DePuy Synthes nail, with a distal bending of $3^\circ$, and a proximal bending of $10^\circ$ (Fig. 5), which was reconstructed in SolidWorks and scaled to the size of the tibia used in this study. CN was located in the tibia according to a surgical procedure provided by the AO...
2.2. Loads and boundary conditions

This study employed the physiological-like loading at 45% of the gait cycle, which is defined as the worst-case scenario mechanically, due to maximum muscles activity and high contact forces at the knee and ankle joints (Duda et al., 2001). Forces and attachment points, including joint contact forces, major active muscle, and ligaments’ forces (Fig. 7a) at the second pick ground reaction of the gait cycle (Table 1), were obtained from Duda et al. (2001) and scaled to the current model of the tibia. Knee contact forces were divided into a 60% and 40% portion, which were applied on the medial and lateral condyles, respectively (Duda et al., 2001). To restrict rigid body motion, three nodes were fixed on the distal end of the tibia. Moreover, a simplified load case, in which only the loads on the knee and ankle joints were included, was defined according to Duda et al. (2001).

2.3. Meshing, material properties, and contact modeling

After assembling the tibia-nail constructs in SolidWorks, models were imported to ABAQUS V6.12 and meshed by 10-node tetrahedral elements for the tibia and nails, and brick elements for the screws and NIMs (Fig. 8a, b, d, and e) (Table 2). To preserve the uniformity of mesh within the tibia, the solid model of the tibia was divided into smaller partitions, which provide more organized edges (Fig. 9a). Afterward, mesh seeds were assigned at the edges to regulate the size of the generated elements (Fig. 9a’). To achieve more accuracy in the results of FE analysis, the smaller size of mesh seeds was assigned to the contact surfaces of the models (Fig. 9b and b’).

The numerical convergence of each model was done before the main analysis. Mesh independency criterion was considered to be 0.4% or less difference in IFs, which was achieved for the element number of 239562.

The nails, screws, and NIMs were considered to be made by stainless steel, and were modeled as isotropic, linear elastic, and homogeneous materials with Young’s modulus and a Poisson’s ratio of 193 GPa and 0.3, respectively. To assign materials to the tibia, the CAD model of the tibia was meshed and imported to Mimics, and the FE mesh of the tibia was then registered on the CT images, using the same coordination as that of the 3D STL model of the tibia (Fig. 10). The average Hounsfield values for each element were calculated, and densities were assigned to each element, accordingly (Fig. 10). The bone density of the tibia was obtained using a linear relation with Hounsfield unit (HU) (Table 3) (Keller, 1994). The calibration coefficients, i.e. a and b, were calculated for the current CT data, and Young's modulus was then calculated from bone ash density through employing the equation provided by Keller (1994) (Table 3) (Fig. 8b’ and e’).
To investigate the performance of the nails immediately after the post-operative stage, and in the worst-case condition, a 42-C3 AO fracture (Fig. 7a) was simulated in each model of the tibia nail. In this study, the screw threads were not considered in the FE models, similar to some previous studies (Duda et al., 2001; MacLeod, Pankaj, & Simpson, 2012; Wang, Hao, & Wen, 2017), and the tangs of NIM assembly were simplified to bricks without changing their prescribed thickness, width, and the length. The screw-tibia was assumed to be bonded, in all degrees of freedom (MacLeod et al., 2012; Wang et al., 2017), while a nonlinear contact scenario with \( \mu = 0 \) and \( \mu = 0.4 \) was defined on the tibia-tang and tibia-tibia interfaces, respectively. There can be initial gaps at bone and nail surfaces (Fig. 7a) but may make contact during the loading and simulation (Duda et al., 2001; Gómez-Benito et al., 2007).

### 2.4. Output parameters

A total number of three models including the intact tibia, tibia-CN interlocked by angle stable screws, and tibia-AINIM were analyzed in this study. The intact tibia and tibia-CN constructs were subjected to a simplified loading pattern, i.e. loading on ankle and knee joints only, in addition to physiological-like loading, for the sake of validation of the FE models through comparing with in vivo (Lanyon, Hampson, Goodship, & Shah, 1975; Goodwin & Sharkey, 2002) and in vitro (Finlay, Bourne, & McLean, 1982; Schandelmaier, Krettek, & Tscherne, 1996) results. On the other hand, the loading condition for the tibia-AINIM was adopted from the physiological-like loading condition. Stress distribution on the tibia, nails, screws, and tangs; principal strains on the tibia; contact pressure at the tibia-nail interface, and axial and shear IFSs at the fracture site were derived from the FE models.

### 2.5. Statistical analysis

For each output parameter, FE data of the region of interest were collected and analyzed using Matlab (R20161). The assumption of normality and homogeneity of variance was tested using the Kolmogorov-Smirnov test. Testing among the data measured from tibia-CN and tibia-AINIM was performed using a Wilcoxon signed-rank test as analysis showed non-normally distributed data. For all tests, statistical significance was defined as \( P < 0.05 \).
3. Results

This section comprises the following parts: distribution of von Mises stress in the nail and tibia; principal strains distribution in the tibia; contact pressure in the tibia-nail construct; and axial and shear IFSs.

3.1. Distribution of von Mises stress in the nail and tibia

The von Mises stress distribution on the surface of the nails revealed that antero-lateral and postero-medial sides of the nails experienced a greater amount of stress (Fig. 11). The AINIM reduced the maximum von Mises stress by 9% at both antero-lateral, i.e. from 882 to 813 MPa, which was statistically significant ($P < 0.05$), and postero-medial sides of the nail, i.e. from 812 to 735 MPa, compared with the CN, which was statistically significant ($P < 0.05$) (Fig. 11). A similar location of the maximum von Mises stress, i.e. antero-lateral, was observed in both AINIM and CN (Fig. 11). Moreover, AINIM caused a reduction in the nail mid-shaft stress at the antero-lateral and postero-medial sides of the nail by 60.2% and 62.9%, respectively, compared with CN, and also reduced the mean value of von Mises stress by 5.7% on the circumference of the nail, at the fracture site (Fig. 11). Screws and NIMs at the proximity of the fracture site experienced maximum von Mises stress of 931 and 1250 MPa, respectively (Fig. 11). Besides, the average stress in the tangs showed around 20% increase ($P < 0.05$), compared with the customary screws.

It should be noted that, in both AINIM and CN models, the posterior surface of the medullary cavity experienced greater stresses (Fig. 12). The average von Mises stress on the posterior side, on the surface of the IM canal, was 25.3% greater in the tibia fixed by AINIM, compared with the tibia fixed by CN ($P < 0.001$). Moreover, AINIM caused an increase in the average value of von Mises stress of the tibia near the fracture site, from an average value of 2 MPa in the tibia fixed by CN to 10 MPa ($P < 0.001$). Furthermore, AINIM reduced the peak stresses by 44.5%, caused by the stress concentration, measured on the bone surface, at the distal tip of the tibia-nail interface, compared with CN.

3.2. Principal strain distribution in the tibia

Results of the FE analysis of this work showed that tibia implanted with the AINIM experiences the average principal strain of 678 με in compression at the postero-medial side, which was the side with greater compressive strains compared with the other sides, which is about 40% greater than the principal strains, at the same side, in the tibia fixed by CN ($P < 0.001$), i.e. 485 με (Fig. 13). Unlike compression, AINIM showed a reduction in the tensile principal strains in the tibia at the antero-lateral side, the side with greater tensile strains compared with other sides, by about 38%, compared with CN ($P < 0.001$) (Fig. 13).
Table 1: Components of muscles, ligaments, and joint contact forces exerted on the tibia, used in this study, under physiological-like loading (45% of the gait cycle) (Duda et al., 2001).

| Force exertion source | Force components (N) |
|-----------------------|----------------------|
| **Joint**             | **X** | **Y** | **Z** |
| Ankle                 | −120  | −154.4| 2070.4 |
| Knee                  | 232.3 | 214.9 | −1528.1 |

| **Muscles and ligaments** | **X** | **Y** | **Z** |
|---------------------------|-------|-------|-------|
| 1 Iliotibial tract I      | −8.5  | −8.8  | 61.3  |
| 2 Iliotibial tract II     | −97.4 | −64.4 | 291.5 |
| 3 Quadriceps femoris muscle | 13.6 | 32.8  | 303.5 |
| 4 Tibialis anterior muscle I | 17.2 | 38.7  | −327.7 |
| 5 Tibialis anterior muscle II | 25.9 | 53.6  | −191.8 |
| 6 Soleus muscle          | −63.1 | −47.1 | −679  |
| 7 Ant. tibiofibular ligament | −132.4| −111.2| −56.8 |
| 8 Ant. cruciate ligament | 87.5  | 101.5 | 41.1  |
| 9 Deltoid ligament       | 44.9  | 9.7   | 15.7  |

Figure 8: (a) Mesh configuration of the tibia-AINIM, and (d) the tibia-CN construct; (b) mesh density and contact zones near NIM, and (e) screw; (b’) nonhomogeneous material distribution of the tibia in tibia-AINIM and (e’) Tibia-CN models; (c) position of AIN; and (f) CN in the tibia.

Table 2: Number and type of elements used in the FE models of this study.

| Parts                              | Element type | Number of elements | Number of nodes | Approximate element size (mm) |
|------------------------------------|--------------|--------------------|----------------|-----------------------------|
| Tibia (Fixed with CN + screw)     | C3D10        | 324 203            | 485 055        | 0.5–2.5                     |
| Tibia (Fixed with AlN + NIMs)     | C3D10        | 524 617            | 688 253        | 0.5–2.5                     |
| AlN                                | C3D10        | 348 864            | 528 246        | 0.5–1.5                     |
| CN                                 | C3D10        | 206 414            | 317 747        | 0.5–1.0                     |
| Screw                              | C3D8R        | 8976               | 7293           | 0.5                         |
| NIMs                               | C3D8R        | 14 208             | 6893           | 0.5                         |

3.3. Contact pressure in the tibia-nail construct; axial and shear IFSs

Calculation of the contact pressure at 13 different positions, which were defined as contact regions of the IM canal and the nail, showed that the shaft region experienced greater contact pressures compared with the distal and proximal regions in both tibia-CN and tibia-AINIM. Regarding the distal part, i.e. regions 1–3, maximum contact pressure in AINIM decreased from 2.33 to 0.1 MPa, while it reduced from 2.3 MPa to 0 in CN (Fig. 14). Despite distal epiphysis, maximum contact pressure elevated to 5.39 MPa in the distal metaphysis, i.e. region 4, of AINIM, while remained 0 in CN in that region (Fig. 14). Regarding the diaphysis region, AINIM experienced greater mean contact pressure...
Figure 9: (a) The CAD model of the distal tibia and division of the model to smaller partitions; (a’) mesh seed configurations at the edges near the distal screw hole; (b) mesh distribution of distal tibia with special consideration of mesh seeds on edges; and (b’) elevation of mesh density at the contact surface.

Figure 10: (a) Solid model of the tibia and the geometry of IM canal; (b) meshing of the solid tibia, (bottom) sagittal, and (top) transverse cross-section view; (c) registration of mesh contour (in red color) on the CT scan images at the tibia shaft; and (d) density distribution on the shaft of the tibia.

Table 3: Material properties used in FE analysis of this study.

| Materials       | Young’s modulus (GPa) | Shear modulus (GPa) | Poisson’s ratio |
|-----------------|-----------------------|---------------------|---------------|
| Bone            | $E = 10 \ 500 \ \rho^{2.39} \ (MPa)$ | -                   | $\nu = 0.3$  |
| $\rho = aHU + b \ \left( g / cm^3 \right)$ | -                     |                     |
| Stainless Steel | $E = 193$             | -                   | $\nu = 0.3$  |

in all of the defined regions except region 7 ($P < 0.05$ except for region 10), which showed a pressure of 4.83 MPa for AINIM, and 5.07 MPa for CN, which was not statistically significant ($P > 0.05$). Moreover, greater differences were observed in regions near the fracture gap, i.e. regions 5 and 6, where contact pressures were 6.3, and 1.74 times greater in AINIM ($P < 0.05$), compared with those of the tibia-CN construct, respectively (Fig. 14). Moreover, the maximum contact pressure in CN decreased dramatically from 4.08 to 0.01 MPa between regions 11 and 13, while it remained steady, i.e. 1.94, 1.67, and 2.12 MPa, in those regions, respectively, in the AINIM ($P < 0.05$ for regions 11, 12, and 13) (Fig. 14).

Results of the FE analysis showed that average axial and shear IFSs, at the fracture gap, for the fractured tibia stabilized with AINIM was smaller than those treated with the CN (Fig. 13). The AINIM reduced the axial and shear IFSs by about 55%, i.e. from 25 to 17%, and 55%, i.e. from 9.8 to 4.4%, respectively, compared with those corresponding to the CN ($P < 0.001$ in both axial
Figure 11: von-Mises stress distribution in the nails and interlocking components near the fracture gap, under physiological-like loading: (a) von-Mises Stress on AIN; (b) von-Mises stress on CN; (a′) von-Mises stress on the distal tongs; and (b′) von-Mises stress on the distal screw close to the fracture gap; (Graph) stress along AINIM and CN, measured at antero-lateral and postero-medial aspects with the illustration of error limits. The error bars represent the range of data in each region.

and shear IFS groups). The axial-to-shear IFS ratio in the AINIM model was about 0.26, which was 33% lower than that of the CN model.

4. Discussion

IM nailing has been commonly used as a sufficient treatment of fractures at distal one-third of the tibia (Wysocki, Kapotas, & Virtus, 2009), but malalignment is reported as a relevant complication of this method of fixation. In this work, a NIM was designed as a potential solution for reducing the malalignment ratio. The design was numerically investigated, using a verified FE modeling approach, to find out if AINIM reduces the malalignment ratio, through comparison with a customary nailing system. The study was designed to simulate the worst-case scenario, both clinically and biomechanically, by choosing the distal one-third fracture of tibia, within 50 mm of plafond; a 10-mm fracture gap, which represents a comminuted fracture; and through applying physiological-like loads at 45% of a gait cycle.

4.1. Comparison with some former in vivo, in vitro, and FE studies

Stiffness of tibia-CN construct under simplified load, i.e. joint contact forces only, found from FE analyses of this study is in agreement with the results of both in vitro experimental findings (Schandelmaier et al., 1996), and a former FE study (Duda et al., 2001) (Fig. 16, top). FE results of this study also showed the maximum compressive and tensile principal strains of 283 and 223 με, respectively, on proximal intact tibia under simplified loading condition, which correspond well with those reported in an in vitro experimental study (Finlay et al., 1982), i.e. 220 με compression, and 125 με tensile, and is also in agreement with a former FE study (Duda et al., 2001), i.e. 240 με compression, and 250 με tension (Fig. 16, bottom).

For the physiological-like loading case on an intact tibia, FE analyses of this work resulted in peak strains of 1156 με in tension, and 1111 με in compression, on the distal third of the tibial diaphysis, which are in agreement with the results of an in vitro study (Goodwin & Sharkey, 2002), i.e. 719 ± 469 με in tension, and 1431 ± 310 με in compression, and a FE study (Ghiasi et al., 2017), i.e. 500 με in tension, and 1000 με in compression (Fig. 17, top). Moreover, a maximum compressive principal strain of 286 με was found in this study, on the antero-medial aspect of the tibia at mid-shaft, which corresponds well with the strains reported in an in vivo study (Lanyon et al., 1975), i.e. 230 με, and a former FE study (Duda et al., 2001), i.e. 180–300 με (Fig. 17, bottom).

The rest of this section consists of the following parts: load sharing and contact pressure in the tibia-nail construct; regulation of IFSs and malalignment prevention; novel interlocking mechanisms (NIMs); and limitations and future directions.

4.2. Load sharing and contact pressure in the tibia-nail construct

Stress distribution resulted from FE models showed that AINIM increased the loading of the interlocked bone specimens, compared with those of the CN construct (see Fig. 12), which makes sense since it was designed to be more adaptive to the medullary canal, compared with the customary nailing, and thus the contact area of the nail with the medullary canal was also increased. Escalation of the average von Mises stress in the bone fragments of AINIM (P < 0.001) and reduction of mean von Mises stress on the surface of the nail (P < 0.05) (see Figs 11 and 12) can be deemed as positive effects of adaptive design made in this study. A better load sharing between bone and the nail can reduce the side effect of stress shielding of neighboring bone, which can consequently cause a less reduction in bone mineral density in the long term (Allen Jr et al., 2008), especially in the cases in which a nail remains in the bone after completion of the healing.
Process. Moreover, less stress in the nail reduces the risk of its fatigue failure (see Fig. 11).

Similar to what was reported in former studies, for instance in Duda et al. (2001) and Gómez-Benito et al. (2007), the interlocked tibia experiences a combined bending–compression loading condition. Combination of AIN and NIMs increased the compressive maximum principal strains ($P < 0.001$) on the surface of the tibia (see Fig. 13), while decreased the principal tensile strains ($P < 0.001$) there, compared with those of the CN construct (see Fig. 13), which could be interpreted as a reduction in bending moment, and an elevation of compressive loading in the tibia. One may conclude that AINIM reduces the variation in the amount of IFSs measured around the fracture gap by controlling the excessive bending of the fragments, which results in an enhancement of mechanical stimuli at the fracture site in the early stage, and consequently in the healing process.

Measurement of the contact pressure at the interface of the tibia and IM nails showed that the AINIM experiences more contact regions near the fracture site, and at distal metaphysis, compared with the CN (see Fig. 14). Additional contact surfaces increased the structural stability of the tibia-AINIM construct, by decreasing the micromotion at the fracture gap, compared with the tibia-CN construct (see Fig. 15). Moreover, escalation in the maximum contact pressure ($P < 0.05$) at the mid-shaft and proximal parts of the tibia fixed with AINIM (see Fig. 15) implies that there is a better load sharing between the tibia and the AINIM, compared with the CN construct.

### 4.3. Regulation of IFSs and malalignment prevention

Results of IFSs under physiological-like loading showed that AIN with NIMs experiences an average shear IFS of 17%, whereas CN has an average shear IFS of 25% (see Fig. 15). By considering that shear IFS, and high axial-to-shear IFS ratio were introduced as one of the causes of delay in the bone healing process (Augat et al., 2003; Steiner et al., 2014), AINIM can more likely provide better structural stability, compared with CN, and thus can reduce the likelihood of malalignment. Although the exact amount of IFS that is ideal for bone healing, while using a relatively stable construct, such as an IM nail, has yet to be determined (Ghiasi et al., 2017), reduction of the axial IFS by 55%, i.e. from 9.8 to 4.4% ($P < 0.001$) (see Fig. 15) in AINIM, compared with CN, can be promising. Claes and Heigele (1999) reported that intramembranous ossification occurs for strains less than ±5%, while strains between ±(5 and 15)% result in endochondral ossification (Ghiasi et al., 2017). Regarding experimental and clin-
Figure 13: FE analysis results regarding principal strains in the tibia under physiological-like loading condition: (a) principal tensile strain distribution; and (c) principal compressive strain distribution in the fractured tibia implanted with AINIM and (b) CN, and (a’, b’, c’, and d’) transverse section view at the distal mid-shaft. (Graph) maximum principal strains on the surface of the fractured tibia at postero-medial for the measurement of tensile strains, and antero-lateral for the measurement of compressive strains. The error bars represent the range of data in each region.

Figure 14: Thirteen regions chosen in tibia-nail construct to measure maximum contact pressure at the bone-implant interfaces for the tibia-AINIM and tibia-CN construct (*P < 0.05). The error bars represent the standard deviation of the mean.

Clinical studies, excessive IFS is one of the reasons for the post-operative malalignment, as well as malunion or nonunion at the fracture site (Gueorguiev et al., 2011). The results of this study showed that maximum IFS, under physiological-like loadings, occurs on medial and lateral sides of the fracture gap, i.e. coronal plane, as tensile and compressive strains, respectively. Clinical studies also showed that valgus is the most common type of malalignment after IM nailing of distal tibia fractures (63–72% of malalignment) (Brinkmann et al., 2019), which corresponds well to our FE results at the fracture gap.
4.4. Novel interlocking mechanisms (NIMs)

Fractures of distal tibia usually come with the injury of soft tissues, and the nailing method avoids further damages on critically important soft tissues in that region (Kandemir, Herfat, Herzog, Viscogliosi, & Pekmezci, 2017). However, the insertion of orthopedic screws usually comes with the risk of serious damages to surrounding soft tissues (Bono et al., 2003). Moreover, the occurrence of the maximum von Mises stress in the screws (see Fig. 11) and consequently screw failure is commonly prevented by insertion of additional screws, which can cause further damage to soft tissue envelope, as well as increases the complexity of the surgery (Bono et al., 2003). The NIM designed and modeled in this study experiences 23% greater stress \((P < 0.05)\), compared with interlocking screws (see Fig. 11), which may not be a promising outcome. However, it should be noted that the configuration of NIMs was chosen to be similar to that of the CN, i.e. just four NIM units were employed in the nail, to make a valid comparison. Otherwise, alteration in the arrangement, and the number of NIMs can be done in order to reduce their stress level, without causing any further damages to soft tissues, or increasing the complexity of the osteosynthesis process. In case of the need for additional bone-implant constraints, for instance in osteoporotic bones, based on the surgeon’s discretion, cortical screws can also be inserted into the most distal and proximal ends of the AINIM. Moreover, loading condition, fracture scenario, neglecting the fibula, and considering a heavy patient were all worsening the loading condition for the screws and NIMs.

4.5. Limitations and future directions

The FE models of this study were based on the CT scan data of just one patient. The design of the AIN based on a fair number of tibia models from various individuals can make future steps of
this study to improve the patient-specific design of the AIN. Due to the scope of this work, only a rough quantitative, but mostly qualitative analysis of the results of the newly design IM nail was made on the bone healing process. No experiments were done in this work and validation of the results was made through comparison with some former studies related to this work (Lanyon et al., 1975; Finlay et al., 1982; Schandelmaier et al., 1996; Duda et al., 2001; Goodwin & Sharkey, 2002), which were marginally different from this work. Manufacturing of the AINIM, and then in vitro mechanical tests can make the next steps of this study, with the hope of shedding more light on the design made in this investigation. Furthermore, as it is well known, load-bearing is not recommended in the early stage of the healing process, but in this study, the loading condition and fracture scenario were chosen to mimic the most unfavorable condition.

5. Conclusions

In this study, AINIM was introduced as a solution for malalignment prevention, especially in the case of distal tibia fractures. The adaptive design of IM nail, which was made according to the anatomical shape of the medullary canal in this study (AINIM), exhibited a relatively better load-sharing property, compared with the customary nailing system, and consequently can lessen reduction in the bone apparent density during a long-term healing process (see Figs 12 and 13). Moreover, it was observed that the AINIM can reduce the malalignment ratio, and thus should be able to increase the rate of bone healing process by decreasing the shear and axial IFSs (see Fig. 15). Despite the elevation in the amount of stresses, compared with the angle stable screws (see Fig. 11), NIM shows an acceptable response to the most unfavorable biomechanical and clinical conditions (see Fig. 15). This study defined a nondestructive framework for biomechanical evaluation of IM nail designs before to manufacturing. Despite promising outcomes that resulted from in silico models of AINIM, both in vitro and in vivo investigations are needed to be made to approve and reinforce findings of this study, as well as to discover new aspects of it.

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Conflict of interest statement

None declared.

References

Allen, J. C., Jr, Lindsey, R. W., Hipp, J. A., Gugala, Z., Rianon, N., & LeBlanc, A. (2008). The effect of retained intramedullary nails on tibial bone mineral density. Clinical Biomechanics, 23(6), 839–843.

Augat, P., Burger, J., Schorlemmer, S., Henke, T., Peraus, M., & Claes, L. (2003). Shear movement at the fracture site delays healing in a diaphyseal fracture model. Journal of Orthopaedic Research, 21(6), 1011–1017.

Avilucea, F. R., Triantafillou, K., Whiting, P. S., Perez, E. A., & Mir, H. R. (2016). Suprapatellar intramedullary nail technique lowers rate of malalignment of distal tibia fractures. Journal of Orthopaedic Trauma, 30(10), 557–560.

Bono, C. M., Sirkin, M., Sabatino, C. T., Reilly, M. C., Tarkin, I., & Behrens, F. F. (2003). Neurovascular and tendinous damage with placement of anteroposterior distal locking bolts in the tibia. Journal of Orthopaedic Trauma, 17(10), 677–682.

Brinckmann, E., DiSilvio, F., Tripp, M., Bernstein, M., Summers, H., & Lack, W. D. (2019). Distal nail target and alignment of distal tibia fractures. Journal of Orthopaedic Trauma, 33(3), 137–142.

Byun, S.- E., & Jung, G.- H. (2020). Implications of three-dimensional modeling of tibia for intramedullary nail fixation: A virtual study on Asian cadaver tibia. Injury, 51(2), 505–509.

Cain, M. E., Hendrickx, L. A. M., Bleeker, N. J., Lambers, K. T. A., Doornberg, J. N., & Jaarsma, R. L. (2020). Prevalence of rotational malalignment after intramedullary nailing of tibial shaft fractures: Can we reliably use the contralateral uninjured side as the reference standard? Journal of Bone and Joint Surgery, 102(7), 582–591.

Carfagni, M., Facchini, F., Furferi, R., Ghionzoli, M., Governi, L., Messineo, A., Uccheddu, F., & Volpe, Y. (2019). Towards a CAD-based automatic procedure for patient-specific cutting guides to assist sternal osteotomies in pectus arcuatum surgical correction. Journal of Computational Design and Engineering, 6(1), 118–127.

Chen, G., Schmutz, B., Epari, D., Rathnayaka, K., Ibrahim, S., Schuetz, M. A., &佩ary, M. J. (2010). A new approach for assigning bone material properties from CT images into finite element models. Journal of Biomechanics, 43(5), 1011–1015.

Claes, L. E., & Heigele, C. A. (1999). Magnitudes of local stress and strain along bony surfaces predict the course and type of fracture healing. Journal of Biomechanics, 32(3), 255–266.

Costa, M. L., Achten, J., Hennings, S., Boota, N., Griffin, J., Petrou, S., Maredza, M., Dritsaki, M., Wood, T., Masters, J., Pallister, I., Lamb, S. E., & Parsons, N. R. (2018). Intramedullary nail fixation versus locking plate fixation for adults with a fracture of the distal tibia: The UK FixDT RCT. Health Technology Assessment, 22(25), 1–148.

De Giacomo, A. F., & Tornetta, P., III (2016). Alignment after intramedullary nailing of distal tibia fractures without fibula fixation. Journal of Orthopaedic Trauma, 30(10), 561–567.

Duda, G. N., Mandruzzato, F., Heller, M., Goldhahn, J., Moser, R., Hehl, M., Claes, L., & Haas, N. P. (2001). Mechanical boundary conditions of fracture healing: Borderline indications in the treatment of unreamed tibial nailing. Journal of Biomechanics, 34(5), 639–650.

Epari, D. R., Kassi, J. P., Schell, H., & Duda, G. N. (2007). Timely fracture-healing requires optimization of axial fixation stability. Journal of Bone and Joint Surgery, 89(7), 1575–1585.

Epari, D. R., Schell, H., Bail, H. J., & Duda, G. N. (2006). Instability prolongs the chondral phase during bone healing in sheep. Bone, 38(6), 864–870.

Finlay, J. B., Bourne, R. B., & McLean, J. (1982). A technique for the measurement of principal strains in the human tibia. Journal of Biomechanics, 15(10), 723–739.

Freedman, E. L., & Johnson, E. E. (1995). Radiographic analysis of tibial fracture malalignment following intramedullary nailing. Clinical Orthopaedics and Related Research, 315, 25–33.

Ghiasi, M. S., Chen, J., Vaziri, A., Rodriguez, E. K., & Nazarian, A. (2017). Bone fracture healing in mechanobiological modeling: A review of principles and methods. Bone Reports, 6, 87–100.
Gómez-Benito, M. J., Fornells, P., García-Aznar, J. M., Seral, B., Seral-Iñigo, F., & Doblaré, M. (2007). Computational comparison of reamed versus unreamed intramedullary tibial nails. *Journal of Orthopaedic Research*, 25(2), 191–200.

Goodwin, K. J., & Sharkey, N. A. (2002). Material properties of interstitial lamellae reflect local strain environments. *Journal of Orthopaedic Research*, 20(3), 600–606.

Gueorguiev, B., Ockert, B., Schwieger, K., Wählen, D., Lawson-Smith, M., Windolf, M., & Stoffel, K. (2011). Angular stability potentially permits fewer locking screws compared with conventional locking in intramedullary nailed distal tibia fractures: A biomechanical study. *Journal of Orthopaedic Trauma*, 25(6), 340–346.

Homeier, A., Howling, I., Zander, N., Kühne, L., & Graca, C. (2016). Method for tibial nail insertion. (Google Patents).

Hou, S.-M., Wang, J.-L., & Lin, J. (2002). Mechanical strength, fatigue life, and failure analysis of two prototypes and five conventional tibial locking screws. *Journal of Orthopaedic Trauma*, 16(10), 701–708.

Kandemir, U., Herfat, S., Herzog, M., Viscogiosi, P., & Pekmezci, M. (2017). Fatigue failure in extra-articular proximal tibia fractures: Locking Intramedullary nail versus double locking plates—A biomechanical study. *Journal of Orthopaedic Trauma*, 31(2), e49–e54.

Kaspar, K., Schell, H., Seebeck, P., Thompson, M. S., Schütz, 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. *Journal of Bone and Joint Surgery*, 87(9), 2028–2037.

Keller, T. S. (1994). Predicting the compressive mechanical behavior of bone. *Journal of Biomechanics*, 27(9), 1159–1168.

Lanyon, L. E., Hampson, W. G., Goodship, A. E., & Shah, J. S. (1975). Bone deformation recorded in vivo from strain gauges attached to the human tibial shaft. *Acta Orthopaedica Scandinavica*, 46(2), 256–268.

Lembcke, O., Rüter, A., & Beck, A. (2001). The nail-insertion point in unreamed tibial nailing and its influence on the axial malalignment in proximal tibial fractures. *Archives of Orthopaedic and Trauma Surgery*, 121(4), 197–200.

MacLeod, A. R., Pankaj, P., & Simpson, A. H. (2012). Does screw–bone interface modelling matter in finite element analyses? *Journal of Biomechanics*, 45(9), 1712–1716.

Morwood, M. P., Streufert, B. D., Bauer, A., Olinger, C., Tobey, D., Beebe, M., Avilucea, F., Buitrago, A. R., Collinge, C., Sanders, R., & Mir, H. (2019). Intramedullary nails yield superior results compared with plate fixation when using the Masquelet technique in the femur and tibia. *Journal of Orthopaedic Trauma*, 33(11), 547–552.

Nourisa, J., & Rouhi, G. (2016). Biomechanical evaluation of intramedullary nail and bone plate for the fixation of distal metaphyseal fractures. *Journal of the Mechanical Behavior of Biomedical Materials*, 56, 34–44.

Rosa, N., Marta, M., Vaz, M., Tavares, S. M. O., Simoes, R., Magalhães, F. D., & Marques, A. T. (2017). Recent developments on intramedullary nailing: A biomechanical perspective. *Annals of the New York Academy of Sciences*, 1408(1), 20–31.

Samsami, S., Saberi, S., Sadighi, S., & Rouhi, G. (2015). Comparison of three fixation methods for femoral neck fracture in young adults: Experimental and numerical investigations. *Journal of Medical and Biological Engineering*, 35(5), 566–579.

Schandelmaier, P., Krettek, C., & Tscherne, H. (1996). Biomechanical study of nine different tibia locking nails. *Journal of Orthopaedic Trauma*, 10(1), 37–44.

Steiner, M., Claes, L., Ignatius, A., Simon, U., & Wehner, T. (2014). Disadvantages of interfragmentary shear on fracture healing—Mechanical insights through numerical simulation. *Journal of Orthopaedic Research*, 32(7), 865–872.

Usoro, A. O., Bhushyam, A., Mohamadi, A., Dyer, G. S., Zirkle, L., & von Keudell, A. (2019). Clinical outcomes and complications of the Surgical Implant Generation Network (SIGN) intramedullary nail: A systematic review and meta-analysis. *Journal of Orthopaedic Trauma*, 33(1), 42–48.

Wang, H., Hao, Z., & Wen, S. (2017). Do biodegradable magnesium alloy intramedullary interlocking nails prematurely lose fixation stability in the treatment of tibial fracture? A numerical simulation. *Journal of the Mechanical Behavior of Biomedical Materials*, 65, 117–126.

Wehner, T., Penzkofer, R., Augat, P., Claes, L., & Simon, U. (2011). Improvement of the shear fixation stability of intramedullary nailing. *Clinical Biomechanics*, 26(2), 147–151.

Wysocki, R. W., Kapotas, J. S., & Virkus, W. W. (2009). Intramedullary nailing of proximal and distal one-third tibial shaft fractures with intraoperative two-pin external fixation. *Journal of Trauma and Acute Care Surgery*, 66(4), 1135–1139.

Yao, X., Moon, S. K., & Bi, G. (2017). Multidisciplinary design optimization to identify additive manufacturing resources in customized product development. *Journal of Computational Design and Engineering*, 4(2), 131–142.