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Evaluating the Stability of the Fractured Bone Implanted with Titanium Elastic Nails in C and S Configurations

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Abstract: In this paper, numerical and experimental studies have been performed on titanium intramedullary nails. S-shaped and C-shaped elastic nails have been implanted in sheep bone to compare and evaluate the mechanical axial compressive and flexural strength during loading. The purpose of this analysis is to prevent the deformity of the fracture site (closure of the gap) that may cause leg length discrepancy. A simulation process was performed to investigate the nail's mechanical response inside the bone, and the effects of pre-bending of the nails and using end caps on the bone strength were investigated. An experiment was also performed on a fractured implanted sheep bone for validation. The results showed that S-shaped symmetrical nails caused more stability under compressive and flexural loading in the fractured bone than C-shaped symmetrical nails. Increasing the pre-bending diameter of the nail caused more contact between the medullary canal and the nails, thus increasing stability. Fixing the ends of the nails at the points of entry into the medullary canal was crucial to ensure strength and prevent bone instability. In this simulation, we fixed the end of the tibia in the boundary condition, and then the loading condition was applied.

Keywords: sheep bone fracture, titanium elastic nail, finite element analysis, experimental method, S-configuration, C-configuration.

評估植入和配置的鈦彈性釘的骨折骨的穩定性

摘要: 本文對鈦髓內釘和羊骨中植入形和形彈性釘進行了數值和實驗研究，以比較和評估加載過程中骨的機械軸向抗壓強度和彎曲強度。此分析的目的是防止可能導致腿長差異的骨折部位畸形（間隙閉合）。為了研究骨內釘的機械響應，進行了模擬過程並研究了釘的預彎曲和使用端帽對骨強度的影響。還對骨折的植入羊骨進行了實驗以進行驗證。結果表明，與形對稱釘相比，使用 S 形對稱釘在骨折骨中在壓縮和彎曲載荷下具有更高的穩定性。增加釘子的預彎直徑會增加髓管和釘子之間的接觸，從而增加穩定性。將釘的末端固定在進入髓管的位置對於確保強度和防止骨骼不穩定至關重要。在這個模擬中，我們將脛骨末端固定在邊界條件下，然後應用加載條件。

关键词： 羊骨骨折，鈦彈性釘，有限元分析，實驗方法，構型，構型。

1. Introduction

Intramedullary nails are orthopedic equipment used to treat fractures. They have been effective and prominent in the management of bone fractures. Flexible nails are sometimes placed in pairs in the medullary canal to treat the medial tibial shaft fractures. The use of intramedullary nails is a common practice in orthopedics. Animal bone fractures are the most common type of injury treated by orthopedic surgeons. Intramedullary nailing is a common treatment for unstable fractures [1]. Bone fractures cause severe

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injuries, most of which are caused by road accidents. A significant amount of impact energy is transmitted to the limb and damages soft tissue and bone.

Due to their biomechanical and biological foci, intramedullary (IM) nails are considered a standard method of treating fractured bones. The risk of infection following implantation in fractured bones is present after any procedure. However, the risk of repairing open fractures expands dramatically and is estimated to range from 4% to 7% [1]. Intramedullary nails have been used to repair diaphyseal fractures to align bone [1, 2]. A pair of straight nails that enter the medullary canal can only play an aligning role. To date, the mechanical strength of tibial diaphyseal fractures with different nail implants and different degrees of pre-bending has not been discussed in any article [2].

Pre-bending of flexible nails allows more contact points to be made between the bone canal and the nails. In the same vein, elastic nails prevent the bone from dropping back [3]. When the nails are in the medullary canal, the implant configuration of these two nails is another factor that may affect their healing properties. Several articles have previously recommended the use of a C-shaped nail configuration. Compared to the C-shaped configuration, the S configuration of the nails essentially provides a significant amount of flexural and compressive strength [3-5].

End caps are used to stabilize the implanted bone. They are used to fix the nail tip and protect the soft tissue from irritation by improving bone stability. [7] compared the effect of the end cap on the stability of nails with different degrees of pre-bending. [19] proved that using end caps cannot improve the stability of femur bone with nails pre-bent a 40 degree.

In the case of the double C-shaped nails, each nail has three stabilization zones: at the entry of the nail, at the turning point of the bent nail, which has a mutual contact surface with the fracture site and at the end of the nail. In the S configuration, there is a greater contact surface between the nail and the intramedullary canal of the bone, which provides the most reasonable elastic strength for the fractured bone. The structure of straight nails showed less strength than the unique C and S structures [5]. The tips of the nails that protrude from the bone after implantation may irritate the delicate muscle tissue around the bone, causing pain around it [4].

Various strategies have been proposed to reduce the effects of nail pain. Pain in the treatment of bone diaphysis fractures in children with elastic stable intramedullary nailing (ESIN) has been reported in numerous studies, especially in managing femoral fractures [3-7]. Most areas of pain include pain in the site where the nail enters the bone canal, which causes swelling due to stimulation by the tip of the nail. Other causes of pain in patients are the improper angle of entry of the nail into the canal and lack of stabilization of the nail at the end of the bone canal [10].

Examination of the femoral fractures revealed a high degree of known pain in the site where the nail enters the bone. This pain generally occurs when the end of the nail protrudes too much from the bone, or due to the lack of strength of the nail, the nail drops back, causing the nail to protrude from the bone canal, which stimulates the delicate tissue around the bone. In such cases, superficial skin infection and deep wound infection may also occur. Restricting the movement of the nail by holding its end to the bone increases bone stability and prevents the bone from dropping back [8-10].

Few investigations have been performed on clinical or analytical models based on the FE model used for the intramedullary nailing study of femoral shaft fractures. [11] studied the complications of pediatric femur fractures by comparing different types of femur fracture. [13] studied the role of compression screw in the dynamic hip–screw system using a finite element study. [15] analyzed the behavior of intramedullary ankle arthrodesis nail under pseudoelastic compressive load. [25] compared the fixation stability between the reconstruction plate and titanium elastic nail. [18] evaluated the effect of intramedullary nail material properties on stabilizing simulated femoral shaft fractures by using a finite element study. [19] studied the effect of pre-bending on the stability of intramedullary nailing.

More recently, [20] used a light-curable monomer for evaluating the stability of a fractured sheep bone. [24] studied the stability of stainless steel elastic nails in femoral shaft fractures. [25] performed a systematic review on distal locked and unlocked intramedullary nailing in Intertrochanteric fracture. [26] studies the behavior of rigid nails in the treatment of pediatric tibial Fractures. [22] investigated the effect of nail pre-bending degrees on the stability of fractured bone and under various loading conditions. They developed an FE model and simulated a diaphyseal fractured bone composed of two elastic C-shaped nails.

The major reason for this test is to establish a finite element (FE)-based system to demonstrate the successful performance of intramedullary (IM) nailing in compressive and flexural loading on a real sheep bone implemented in the Finite-Element simulator. The other reason for this paper is to utilize a new simulation process to evaluate and compare the mechanical stability in the C and S configurations of elastic implanted nails. The third purpose is to evaluate the simulation and experimental results on bone and then to confirm the simulation results.

2. Materials and Methods

2.1. Solid Model

In this article, two implantation methods have been used to treat fractured bones. One method uses two S-shaped titanium elastic nails with two degrees of pre-bending: a degree equal to the medullary canal's diameter and twice the medullary canal's diameter [11]. Another method is to use two C-shaped titanium nails. The three-dimensional model of the bone was created using CT images of a sheep tibia with a bodyweight of 52 kg and a height of 80 cm. A transverse incision was made in the middle of the bone. We used a 3D computer model to display the nails and the bone. Two nails were drawn in the shape of S and C in the software. The implants consisted of a curved nail the size of the canal diameter (PB1) and twice the diameter of the medullary canal (PB2).

The outer diameter of the nail was adjusted to 3.5 mm to stabilize the bone. Two elastic titanium nails were embedded in the C and S configurations in the fractured bone. Elastic C-shaped nails were also modeled as components in CAD software. They were then assembled symmetrically in the software assembly environment. Using the Boolean function in CAD software, a gap was created in the middle of the bone. Then, the models were exported to ABAQUS 6.12 to implement the boundary and loading conditions (Figure 1).

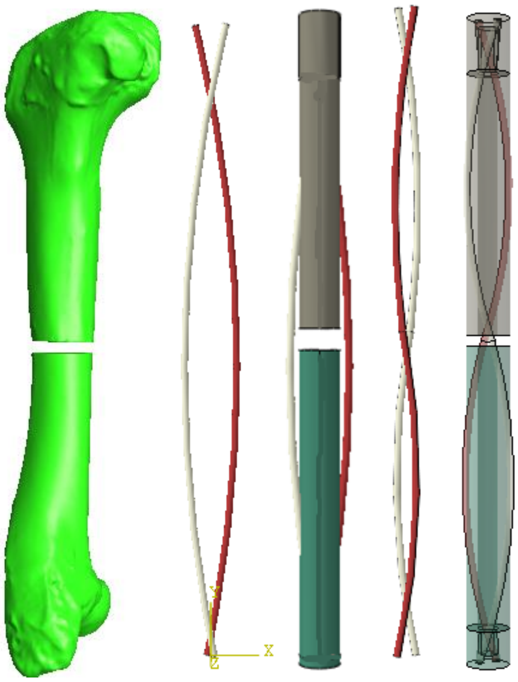


Fig. 1 Implanted bone model and nails

The nail pre-bending is a clinical technique for improving diaphyseal fractures stability by bending the nail equal to or twice the canal's diameter to increase the contact points between the nail and bone. Pre-bending prevents the nail from dropping back during loading. The arch's apex should be placed just at the fracture site, and this shape allows the nail to generate optimal resistance to bone misalignment (Figure 2) [23].

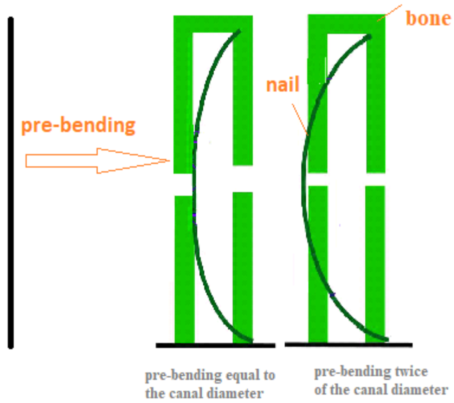


Fig. 2 Pre-bending of the flexible intramedullary nail before insertion

2.2. Finite Element Analysis

After modeling the nails and bones in CAD software, we imported them into FE software to define the properties, assemble them, and load them. In the simulation process, we calculated the strength of the nail and bone and the contact force between the nails and the bone implanted in the C and S symmetrical configurations. When the nails are bent twice the diameter of the bone canal, the volume interference between the nails and the bone is removed by FE software, producing a contact force between the nail and the bone canal. In this study, the nails and bone were considered homogeneous and isotropic materials.

The meshing was defined as quadratic tetrahedron elements, and the element's size in the nail and bone was 2 mm. The quadrilateral elements were selected for modeling because of their ability to accommodate a combination of bone anatomy shapes (Figure 3, a, b). There were a total of 105024 nodes and 57150 elements. We defined the contact behavior in this simulation as friction from one surface to another for both nail-to-nail and nail-to-bone contact. For nail-to-nail contact, we set the coefficient of friction at 0.2 and for the nail to bone at 0.3.

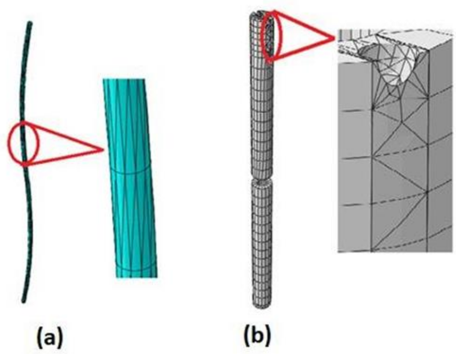


Fig. 3 Mesh type used for nail and bone in the FEA simulation

End caps prevent the nail ends from slipping and collapsing into the bone (Figure 4). They prevent irritation of the soft tissue around the bone by improving stability under loading conditions.

In this research, end caps were not created in a 3D model, and to stabilize the nails in the simulation during loading, we attached the end of the nails to the surrounding bone in boundary conditions in FE software.

Fig. 4 The use of end caps in a fractured bone [23]

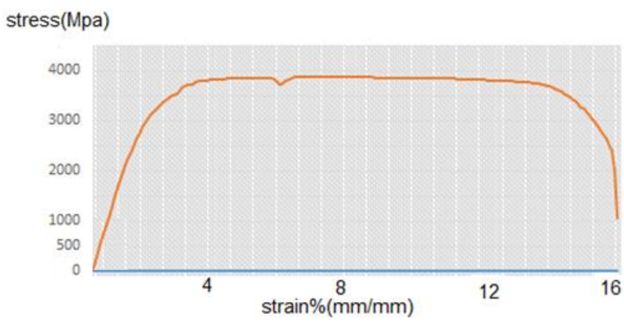
2.3. Material Properties

In this section, we describe the properties of bone materials and nails. The bone used in this study was considered to have a uniform distribution with a mass density of 1900(kg/m^3) and Young's modulus and Poisson ratios of 17 GP and 0.3, respectively (Table 1). The nails used in this study had elastic modulus and the Poisson ratio of 110 GPa and 0.3, respectively. In this study, an adult sheep with an approximate age of 10 years and a weight of 52 kg was used.

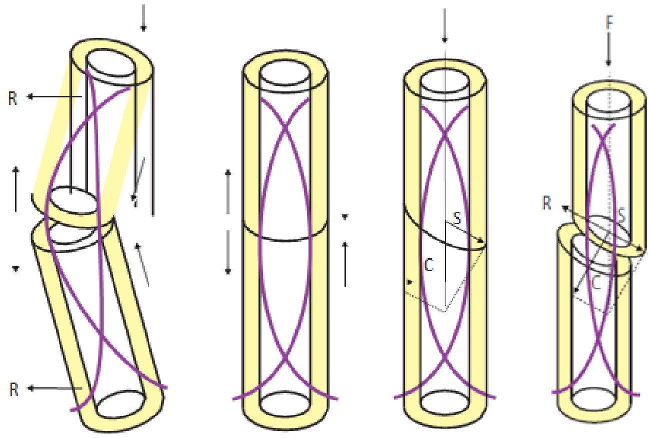
All the materials, consisting of bone and metal, were defined as homogeneous and isotropic. The bone was identified as a linear elastic material, and the modulus of tangential and yield strength was considered to be 1250 MPa and 3388 MPa, respectively (Figure 5-a). In this simulation, stiffness was derived from the formula “K=F/(X),” which shows the relationship between force and displacement. In this formula, “F” is the applied force on the implanted bone, and “X” is the gap deformation under loading, which was used as an index for stability in the elastic analysis.

Table 1 Material properties of the titanium used in this study

Material	Elastic Modulus (GPa)	Poisson Ratio	Yield Strength (Mpa)	Tangent Modulus (Mpa)
Titanium	110	0.3	3388	1250



a)



b) c)

Fig. 5 a) Relationship between the stress and strain of the titanium nail; b) Flexural stability; c) Axial stability (F = force acting on the bone, R = restoring force of the nail, S = shear force, C = compressive force)

The biomechanical rule of the flexible nail depends on the symmetrical bracing action of two elastic nails embedded into the metaphysis, every one of which bears against the inward bone at three points. This creates the accompanying properties of flexural strength, axial stability [23, 24]. All properties are necessary for accomplishing ideal outcomes. Protection from relocation at the fracture site is because of the flexible nails recoil. (Figure 5b, c).

2.4. Convergence Test

A mesh convergence study was carried out using the changing element density of the bone model and applying a simple compression test inside ABAQUS. The coarse mesh estimates less accurate displacements at the Diaphyseal fracture gap, but the normal, fine, and very fine meshes all predict similar results. The normal mesh is thus, as far as the displacements are concerned, converged. This table also shows that the results are similar to those of the very fine mesh, but it took substantially less Processor time for the simulation with the normal mesh than for analysis with the very fine mesh (Table 2).

Table 2 Results of mesh refinement study

Mesh	Number of Elements	Displacement of Diaphyseal fracture Gap (mm)	Stress (MPa)	Error % compared to the previous mesh refinement	Relative CPU time
Corse	3949	4.1E-4	143	4.8	0.73
Normal	57150	4.30E-4	255	9.6	0.9
Fine	42017	4.32E-4	310	3.2	3.1
Very fine	166130	4.36E-4	350	0.8	14.5

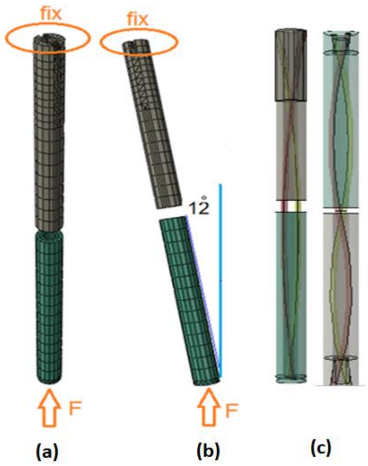


Fig. 6 a) Axial and b) flexural Loading and boundary conditions; c) S-configuration & C-configuration in this simulation

In this study, axial compressive loading was performed on sheep bone. In most fractures, the load on the bone was less than the force required for normal walking because fractured bones need protection and care immediately after surgery. In this simulation, due to the pre-bending of the nail before implantation, the implanted part of the nail was larger than the medullary canal; thus, there was volume interference between the nails and the bone. To generate contact force, we must ignore this difference during the simulation process. In the first stage of simulation in FE software, this volume interference was eliminated, and the nails were restricted in the medullary canal. We fully fixed the lower part of the bone in the simulation, and by attaching the ends of the nails to the surrounding bone, we completely restricted them in boundary conditions (Figure 6a, b).

After applying the boundary conditions on the bone and the nails, the axial pressure force and the bending force were applied in the loading conditions and the fractured bone gap changed with the application of force. It ought to be reminded that in this simulation, muscle force was omitted, and we considered the pre-bending diameter of the nails to be twice the diameter of the medullary canal.

2.5. Validation

Sheep bone was implanted with C-shaped and S-shaped symmetrical nails and compared with the FE model to validate the simulation method and demonstrate the actual behavior of the elastic nails implanted in the canal. Sheep bone length of 195 mm (with a fracture gap of 5 mm) and internal and external diameters of 12 and 20 mm, respectively, were considered. Two 3-mm thick titanium elastic nails with a pre-flexural radius equivalent to the canal's diameter were inserted into the fractured bone (Figures 7a,b). The nails were inserted into the bone canal from both sides of the bone. The two loading conditions mentioned earlier were applied sequentially using the material property testing system for this example. The load was applied at a 1 mm/min rate, and the experimental results of both nail arrangements were compared with the simulation results. The height of the simulated bone sample was considered the same as the real bone sample. The simulation and experimental results were close for C-shaped and S-shaped implant configurations in compressive and flexural loading.

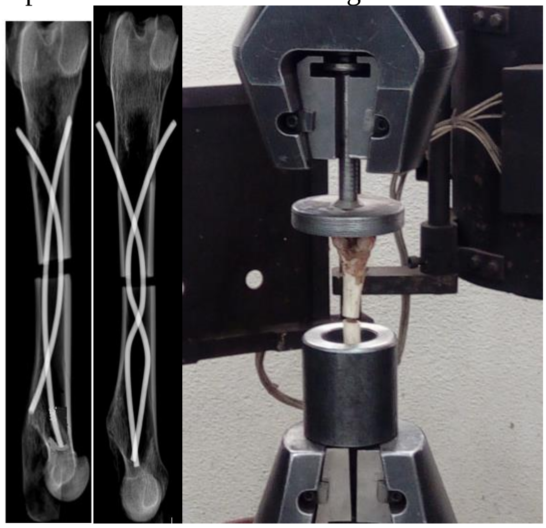


Fig. 7 An experimental test for validation and CT images of the implanted bone

3. Results

3.1. Validation

In this study, after implanting a fractured sheep bone with C-shaped and S-shaped pre-bent nails, we obtained stiffness for both structures in the simulation and laboratory and compared them through Table 3 in the compressive and flexural loading conditions. Between the C and S configurations, the highest stiffness was found in the S configuration. While the average stiffness of the sheep bone model and the FE model was the same in each loading condition, the greatest difference in stiffness between the bone and FE model was in axial compressive loading mode. Table 3 shows the stiffness in sheep bone and FE models in flexural loading mode. The results showed that our modeling method largely demonstrated the proper biomechanical response of ESIN in a medial bone fracture.

Table 3 Structural stiffness comparison in the experiment and FE (N/MM)

Compression stiffness			Bending stiffness	
C-Config		S-Config	C-Config	S-Config
Experiment	1410	1520	6	11.7
FE	1644	1740	6.8	10.2

3.2. Nail and Bone Deformation

In Table 4, the slipping distance in the S-configuration was less than the C- configuration in different degrees of the nail pre-bending during compression, which can be inferred that the stability of the S-shaped nail in axial loading condition is much greater than C-shaped. Therefore, the bone strength in the S-type nail implant is higher than in the C-type nail. After implantation, about 2 cm from the end of the nails protruded from the bone. Using an end cap, we can increase the strength of the bone in the S and C configurations in all pre-bending modes. Under compressive and flexural loading conditions, using end caps and pre-bending the nails before implantation increased bone strength. The use of symmetrical S-shaped nails that are twice the diameter of the bone canal and the end of which is fixed to the bone increased the compressive and flexural strength of the bone. In contrast, the use of symmetrical C-shaped nails with end caps and pre-bending equal to the canal increased the axial stability of the compressive load but reduced the flexural load strength.

The strength of nails pre-bent to the canal's diameter without end caps diminished during loading, disturbing the nail configuration inside the canal and causing slipping (Table 4). According to the simulation results, we concluded that in C-shaped nails, the maximum deformation of the nail was in the middle curvature and at the fracture site (closure of the gap). However, in the S configuration, the minimum deformation of the nail was at the fracture site (closure of the gap), which indicated that the stability of the S-shaped nail was more than the C-shaped nail during loading. It should also be noted that increasing the pre-bending radius of the nail in both implantation configurations and loading conditions decreases the gap deformation at the fracture site due to the stiffness increase (Figure 8, 9).

Table 4 Nail slipping distance (mm) in different configurations during compression

	Fixed-end (with the end cap)	Unfixed-end (without end cap)
PBE-C-shape	4.1	5.3
PBE-S-shape	3.2	4.1
PB2-C-shape	3.8	3.3
Pb2-S-shape	2.8	2.95

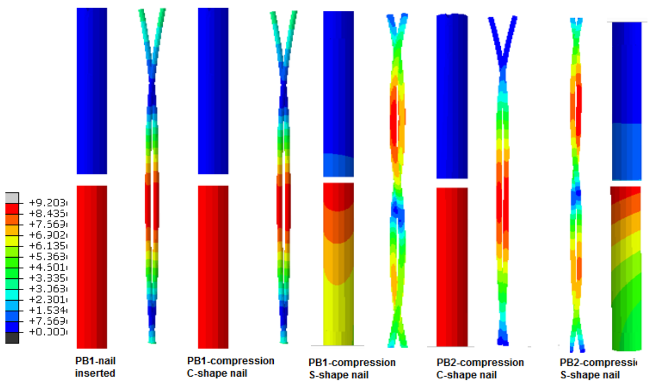


Fig. 8 Bone and nail deformation (mm) under compression in C and S configurations at different degrees of pre-bending

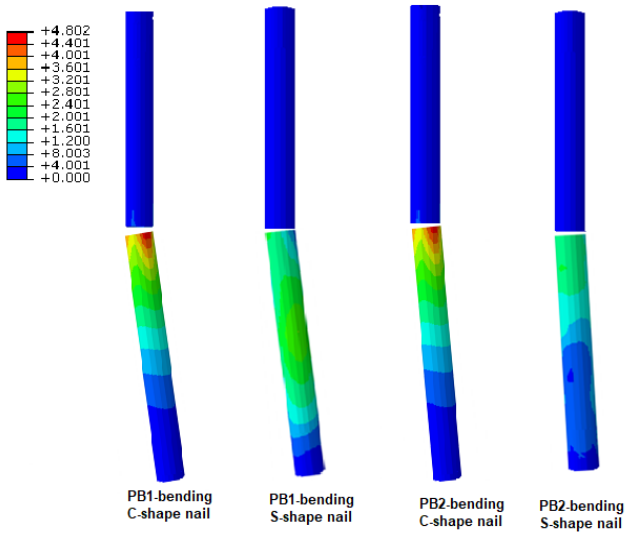


Fig. 9 Bone deformation (mm) under flexural loading in C and S configurations at different degrees of pre-bending

3.3. Equivalent Stress on the Nail

There were two locations with high identical stress regions on the nails: at the center shaft partition and the proximal shaft partition through the insertion opening of the cortical bones. Increasing pre-bending of the nail elevated the equivalent stress. We concluded that the increase in the equivalent stress of the nails was greater in the C configuration than in the S configuration under compression, especially in the nails with pre-bending degrees twice the canal's diameter (Figure 10).

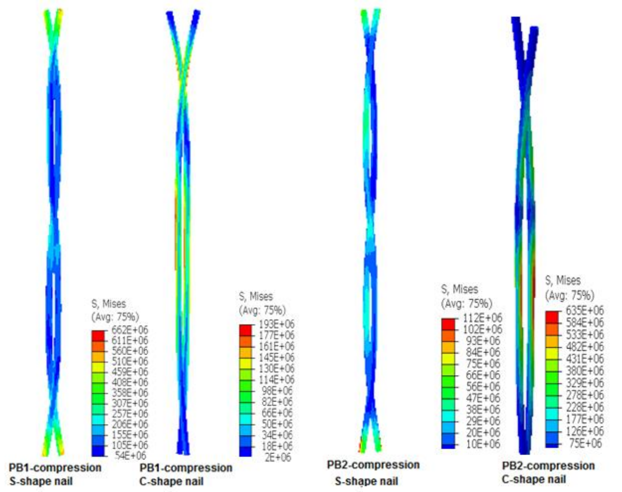


Fig. 10 The Von Mises stresses (MPa) of the nails under compression in C and S configurations at different pre-bending degrees

In two areas, high equivalent stress was noted on the nails: in the middle part of the bone, at the fracture site, and at the point where the nails entered the bone canal. Increasing nail pre-bending increased its equivalent stress. We concluded that the increase in nail equivalent stress in the S configuration was greater than in the C configuration under compressive loading, especially in nails whose pre-bending radius was twice the diameter of the bone canal.

3.4. Contact Force and Nail Deformation

In comparison, S-shaped nails had a higher contact surface with the bone than C-shaped nails. This increased the friction force and the contact force (Figure 11). We discussed the amount of contact force in different nailing configurations with different pre-bending modes (Table 5). The maximum contact force in the S implantation mode had a pre-bending radius twice that of the canal diameter, and with increasing the degree of the nail pre-bending in the S configuration, the contact force was greater than in the C configuration.

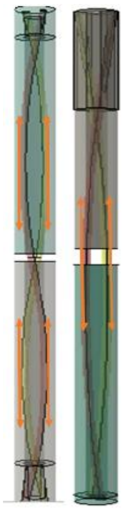


Fig. 11 Contact surfaces between the bone and the nails in C and S configurations

Table 5 Contact force (N) between the nails and cortical bone

	Initial insertion/Distal Proximal	Compression/Distal Proximal	Bending/Distal Proximal
PBE-C-shape	0.6/4.8	1.5/12.3	10/12.2
PBE-S-shape	5.3/6.1	2.3/15.6	16.1/16.7
PB2-C-shape	11.8/354	7.2/457	4.5/5.6
PB2-S-shape	14.3/1610	28.2/1840	8.9/7

4. Discussion

Realigning a fractured bone is the main motivation for using elastic nails. This method depends on improving the outer membrane of the bone, which is the physiological option of the compound [21]. This outer membrane of the bone is formed quickly and has strength from the beginning. This study examined and compared the strength of bone implanted by symmetrical C-shaped and S-shaped nails [3]. In the simulation, two types of nails with different degrees of pre-bending, embedded with and without endcaps, were used and analyzed under two loading conditions [15].

The results showed that pre-bending changes the shape of the nail during implantation and maintains bone strength under different loading conditions. In addition, we protected them from slipping by using end caps and increased the compressive and flexural strength of the nails that were already pre-bent to the canal's diameter. This is the first study to compare the stability of C and S implant configurations, and the bone was modeled as a tube to facilitate the simulation process. In C and S configurations, the titanium nails were implanted inside real sheep bone samples and tested for pressure and flexure, and the results were compared with simulation outcomes [19, 20].

The results of axial and flexural compressive loads in both FE and experimental models were compared, showing our simulation's reliability and validity. In the sheep bone model, nails were inserted into the bone canal through two holes made in the lower part of the bone, and their ends were fixed to the bone body. The nail diameter in the experiment (3 mm) was not exactly equal to the simulation model (3.5 mm). As a result, we used a nail with an outer diameter of 3 mm and compared it with the FE model for validation. The nail configurations with different degrees of pre-bending during placement in the bone canal determined the mechanical response of the fractured bone under different loading conditions and implant configurations.

Inertia and bone resistance to flexion increase by increasing the pre-bending degree of the nails in the S configuration, considering that the distance of the center of curvature to the tip of the nail increases. In both C and S nail configurations, increasing the pre-bending radius increases the contact area of the nail with the bone and, as a result, enhances the contact force and the bone strength in flexural and compressive loading conditions [12].

It is worth noting that in the C and S implant configurations using end caps and a pre-bending radius equal to the canal diameter, the axial compressive load strength in the S configuration increases more than in the C configuration because the C-shaped nails have less contact surface. This causes less friction between the bone and the nail, resulting in less contact force and bone strength during loading [16].

Using end caps prevents the nails from slipping under various loading conditions, especially under axial compressive loading. Increasing the pre-bending degree of the nail increases the contact force between the inside of the bone and the nail, and then the frictional force between the nails and the bone canal increases. The friction force between the nail and the bone prevents the nail from slipping and disrupts the implant configuration during loading, ultimately reducing the deformation of the fractured bone. Using a femur model (FE), Perez inferred comparable results: the maximum nail-slipping rate was 0.471 mm under a compressive load of 15 N.

[6] showed that using end caps could not increase the strength of the fractured bone with nails with a pre-bending of 40 degrees. The current study showed that using S-shaped nails increases the strength of fractured bones more than the C-shaped nails. In clinical practice, the axial stiffness of bones with multiple fractures is important because prevention of bone length

discrepancy after implantation and healing is considered a basic principle [5, 6]. In this regard, pre-bending of flexible nails before implantation is recommended to manage medial bone fractures. However, pre-bending of elastic nails to the diameter of the implanted part using end caps is recommended to repair cases of medial fractures [17].

[22] suggested that the stability of diaphysis-fractured bone can be enhanced by using C-shaped nails with different degrees of pre-bending, but they did not compare the results with other nail configurations.

In this simulation, we compared the stability of diaphysis-fractured bone implanted with C-shaped nails and S-shaped nails. The outcomes of this study suggested that utilizing S-shaped nails with different degrees of pre-bending compared with C-shaped nails caused more stability in accordance to less slippage of S-shaped nails (Table 4). Less slippage of S-shaped nails in the diaphysis, fractured bone caused more stiffness during loading.

In this research, the bone was modeled as a simple, uniform cylinder, and the nails were substantially placed symmetrically in the canal to control the initial contact and check the strength of the configuration. Clinically, after fixing the ends of the nails to the bone body, special caps are closed to the ends of the nails protruding from the bone.

The important point for the patient is that since the bone does not have the initial strength immediately after the operation, full-weight force should not be applied to the bone, and only part of the bodyweight should be imposed on the fractured bone. As a result, the loading conditions in this study significantly contribute to assessing the stability of fractured bones managed through surgery.

5. Conclusion

This preliminary report simulates the biomechanical behaviors of flexible intramedullary nails implanted in a bone with different configurations. Simulations were performed to realign a fractured sheep bone, and the following results were obtained in this simulation. First, the nail configuration type and fixing the nail's end to the bone using a cap are important in repairing fractured bones. Second, the results showed that the pre-bending of the nails with the end cap provides greater strength and less gap deformation in the S configuration than the C configuration under the same loading conditions.

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