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Optimization of Connecting Rod Design Parameters for External Fixation System: A Biomechanical Study

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ABSTRACT

The role of connecting rod in healing process of a fractured bone has always been of significant importance for surgeons. Adding a connecting rod to the fixator would be a secure option for increasing stability without increasing infection rate. The roles of 4 design parameters of the connecting rod (ie, connecting rod diameter, elevation, material, and configuration) were assessed by using finite element models to calculate axial stiffness and interfragmentary strain at the fracture gap. Taguchi method was used to achieve an optimal design set for maximizing stability with regard to connecting rod variables. Also, analysis of variance (ANOVA) approach was employed to determine contribution percentage of each design parameter on outputs. For optimizing connecting rod design parameters, an optimal set of variables consisting of 11 mm, 40 mm, 200 GPa, and Type 3 external fixator were determined by Taguchi for connecting rod diameter, elevation, modulus of elasticity, and configuration, respectively. However, as Type 3 external fixator stability is a little more than Type 2, it would be better if Type 3 external fixator in Taguchi suggestion be replaced by Type 2 external fixator to be as minimally invasive as possible. Furthermore, ANOVA results revealed that the connecting rod configuration is the most important parameter with 95% and 96% effectiveness on the interfragmentary strain and axial stiffness.

Nowadays external fixators are widely used by lower extremity surgeons for severe open fractures treatment or burns as well as infected fractures. External fixators have several advantages over other fixation devices, including configuration adjustability, simple application and minimal blood loss, a few to name (1,2). Nevertheless, once an external fixator is used for definitive treatment, some complications arise; loss of stability and the possibility of pin-site infection due to the direct connection between bone and the environment are 2 main disadvantages. Regarding fixator types, apart from hybrid external fixators, they can be categorized into 3 main groups: unilateral uniplanar (Type 1), unilateral biplanar (Type 2), and biplanar bilateral (Type 3).

External fixator stiffness is the primary value to determine the mechanical stability (3). By increasing stiffness in external fixators, it has been shown that the rate and the healing quality can be improved (4). Many biomechanical studies of the external fixators focused on analyzing the stiffness of different types of fixators and their configurations (5-7). Although the significance of stiffness has always been discussed, it should be noted that by calculating the stiffness, no direct information about the displacement of a fracture gap is provided. For this reason, in this study, the interfragmentary strain (IFS) is calculated to provide an accurate estimation of the movement at the fracture site.

The IFS is frequently employed as a reliable indicator of healing efficiency (8-10), and it was first introduced by Perren (11). To calculate the IFS, the interfragmentary movement (IFM) should be divided by the initial fracture gap length (12). Extent and orientation of the IFS are vitally important since they leave impacts on bone healing quality (13). It is suggested that for a normal healing process and for enhancing secondary healing, the IFS should be between 7% and 33% (14). The IFS less than 7% is associated with the primary pathway of healing. On the other hand, the IFS higher than 33% is a reliable indicator of fixation system instability.

Connecting rod has always been of significant importance for surgeons. For example, to increase the fixator stability and stiffness, manipulating connecting rod would always be the most popular choice. By changing connecting rod variables, the risk of infection is reduced as there is no direct contact between the connecting rod and bone. However, most foot and ankle surgeons cannot determine the significance of connecting rod variables in comparison with each other. For this

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Research Ethics: This study does not contain human and animal experimentation.

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reason, they cannot determine whether decreasing the distance of rod to bone or adding another rod, would be more influential on bone-implant stiffness. In current work, we focused on all important design parameters of a connecting rod; connecting rod diameter, elevation, material and configuration (number of connecting rods and their positions) to determine their effectiveness on the axial stiffness (AS) and IFS.

Design of experiments (DOE) methods were also used by Kim et al (15) and Sheng et al (16) to conduct optimization in the field of orthopedic biomechanics for internal fixation systems with the plate.

With this background, we aim to study the microenvironment in callus for different combinations of connecting rod design parameters using finite element models. In this study, the first goal was to develop optimum values using the Taguchi method to improve stability. It is necessary to note that the external fixation method is assumed to be a primary treatment for initial stabilization in this study. For this reason, optimum values for improving stability are investigated. Second, the effects of connecting rod on the AS and IFS were investigated. Nine design cases based on Taguchi orthogonal array were modeled. For all cases, the AS and IFS were calculated. Then analysis of variance (ANOVA) method was implemented to calculate the contribution percentages of connecting rod design parameters on the AS and IFS.

Materials and Methods

Design Parameters

In this numerical study, the most important connecting rod design parameters (ie, connecting rod diameter, elevation, material, and configuration) have been selected. Connecting rod diameter has a wide range from 5 to 11 mm. However, for long bone fractures, connecting rods with diameters 8 mm, 9 mm, 11 mm are mostly used (17,18), so these 3 diameters constituted 3 levels of Table 1. Concerning connecting rod elevation, in Type 1 external fixator, it can differ from 40 to 120 mm, but the advised distance which can be applied for all 3 types is between 40 and 50 mm (19); 40 mm, 45 mm, 50 mm were selected as our 3 levels. For connecting rod material, the most common materials were selected; aluminum alloy (6063-T5), titanium, and stainless steel have been selected with Young's modulus of 69 GPa, 110 GPa, and 193 GPa, respectively (20,21). Also, to evaluate and compare the number of connecting rods and their positions, configuration was defined as a design parameter. Many studies have focused on the configuration and its effect on mechanical or mechanobiological performance (22-24), but no study has investigated the impacts of it on the AS and IFS alongside other design parameters like connecting rod diameter, elevation or material. Although there are several configurations for tibia fractures, 3 main types of external fixators (shown in Fig. 1) have been selected in this study.

Taguchi and Analysis of Variance Method

Once the number of design parameters increases, a larger number of experiments needed to be done. By using a fractional factorial approach, Taguchi minimized the number of experiments. Taguchi approach was first used in design of experiments, but it is employed in this study to reduce the number of simulations.

Taguchi developed the concept of signal to noise (S/N) ratio to analyze the performance of a system. To represent a response or quality characteristic of a system, the S/N ratio is used in the Taguchi approach. Taguchi used signal factors and noise factors for output characteristics to indicate the desirable signal values and undesirable noise values. High values of S/N ratios mean that the signals are higher than the impacts of the noise factors. Due to this reason, the highest possible S/N ratio is always favorable, and it is the goal of any experiment.

Required number of simulations in our case is 81 (which is calculated by powering the number of levels to the number of factors), while based on the Taguchi method, a special set of arrays called orthogonal array reduces this number to only 9. Table 2 shows design cases based on orthogonal array. The software used in this study for employing the Taguchi method was Minitab 18.

Furthermore, ANOVA was utilized to estimate the contribution percentage of each design parameter on outputs. Although ANOVA is typically employed for evaluating data obtained from an experiment, it is also used as an approach in numerical studies (25,26).

Finite Element Model

To generate the long bone geometry, the shape of an intact tibia was simplified as a shaft, and finite element models were created based on simplified bone in ABAQUS 2017 (27,28). The simplified bone length is 300 mm, and a transverse fracture gap size of 3 mm was created in the middle of it. Cortical bone and bone marrow with a diameter of 25 mm and 15 mm were created at the intramedullary canal. Furthermore, callus geometry and dimensions were taken from other studies (Fig. 2) (29,30). In all design cases, pin length (150 mm), pin diameter (5 mm), pin material (193 GPa), the distance of the first pin to the fracture site (25 mm) and the distance of two adjacent pins (30 mm), connecting rod length (350 mm) remained unchanged. For simplification, instead of modeling clamps, tie constraints were applied between connecting rod and pins in all cases (7,31). Tie constraints were also applied between bone and pins in all 9 design cases.

Material Properties and Meshing

The material properties of the cortical bone, bone marrow, and initial callus are shown in Table 3.

All parts of the tibia-fixator construct were modeled as a 10-node solid element (C3D10). A convergence study in ABAQUS 2017 determined the most appropriate mesh size. To do so, by increasing the mesh density, the difference between axial stiffness was compared between 2 mesh sizes. Once this difference was less than 2%, and the results converge satisfactorily, the favorable mesh size was obtained. The mesh size of the callus, pin and connecting rod was 1 mm, and this figure for bone was 2 mm to ensure convergence. The number of elements of callus, bone and pin were 77931, 137042, and 32421, respectively. In terms of the number of connecting rod elements, it should be noted that since the connecting rod diameter differs from 8, 9 to 11, its elements are 53942, 56672, and 73858, respectively.

Loading and Boundary Conditions

The mechanical environment at the fractured part of tibia bone is of great importance, which influences healing pathway (32,33). Many studies have suggested the optimal mechanical environment (loading conditions) at different stages of the bone healing process (34-40). For current work, the AS and IFS are assumed to be analyzed at the early stage of healing, and according to the AO instructions, 25% of the body weight is applied on the fracture site (40). By assuming a body weight of 75 kg, this pressure is 0.381 MPa. This compressive pressure was applied at one end of the tibia bone, and a fully constraint boundary condition was set to the other end of the bone (Fig. 3).

Results

This section encompasses results obtained for validation of finite element models, the AS and the IFS. In addition, the Taguchi and ANOVA results are presented in this section.

Validation of Finite Element Models

Validation of finite element models was conducted by comparing the value of axial stiffness of a new bone-fixator (Type 1) construct (524 N/mm) with a similar construct used in an in-vitro experiment (528 N/mm) (41).

The AS and IFS

The AS and IFS are simple and crucial mechanical factors that could describe the rigidity of a fixation device. It is believed that the primary

Table 1
Connecting rod design parameters with their 3 levels

Design Parameters	Connecting Rod Diameter (mm)	Connecting Rod Elevation (mm)	Connecting Rod Material (GPa)	Connecting Rod Configuration
Level 1	8	40	Aluminum alloy	Type 1
Level 2	9	45	Titanium	Type 2
Level 3	11	50	Stainless steel	Type 3

value to evaluate mechanical stability of the external fixator is fixator stiffness (3), and scientists are seeking for new methods to increase stiffness. However, too rigid fixator is not favorable since it makes the bone healing process step foot in the primary healing pathway. As a matter of fact, micro-movement in callus can trigger secondary healing and enhance the healing quality.

Additionally, several research projects have focused on the IFS to provide a theoretical basis to evaluate fracture healing patterns (11,42,43). However, in this study, it was utilized to give insights into the fixator performance at the early stage of healing. To calculate the IFS, the greatest value of interfragmentary movement at 4 points of internal callus (medial, lateral, anterior, and posterior) was divided by the fracture gap (3 mm).

Table 4 shows the values of the AS and IFS. Design case 4 had the highest AS (145 mm/N), while the lowest AS with 96 mm/N was seen in design case 1. Likewise, in terms of the IFS, design cases 1 and 4 had the highest and the lowest values with 31% and 3%, respectively. Furthermore, the correlation between normalized values of the AS and IFS is presented in Fig. 4.

Taguchi and ANOVA Results

To achieve an optimum design case for improving stability, levels that had the highest mean values of S/N ratios were selected as the optimal levels (44). Taguchi suggestions for optimum designs consisted of 11 mm, 40 mm, 200 GPa, and Type 3 external fixator for connecting rod diameter, elevation, modulus of elasticity and configuration, respectively. Then, a simulation with optimum levels of each design parameter was carried out and the AS increased by 5% after optimization compared to the maximum AS seen in 9 design cases.

Figs. 5 and 6 show the contribution percentages of design parameters. As it can be seen, the configuration by far had the most contribution percentage on both the AS and IFS with 96% and 95%, respectively. Other design parameters are by far lower than configuration. Connecting rod material and diameter account for only small minorities with 2% and 1% in the AS and 2.7% and 1.9% in the IFS.

Discussion

Current work can provide a biomechanical insight into the influence of connecting rod on the construct AS and the IFS of a fractured bone. The impacts of each design parameter (ie, connecting rod diameter, elevation, material, and configuration) were analyzed numerically using the finite element models. Also, the Taguchi method was used to suggest an optimum design set for improving stiffness. It is vitally important to note that the maximum AS achieved by Taguchi optimal design case is not always a desirable case for surgeons, as it is highly likely to hinder the healing process to step foot in the secondary pathway of healing. However, in some circumstances, maximum stability is needed. The rationale for employing the IFS alongside the AS is estimating the possible path of healing more accurately as the IFS depicts the movements in callus.

Concerning the AS, it is worth mentioning that fixator stiffness plays the most important part in the healing process. By investigating different combinations of rod design parameters, stiffness is the most significant parameter which is changing, and consequently, the healing patterns will change. Those cases (Type 1 external fixators), which had more flexibility, experienced lower AS levels than more rigid cases (Types 2 and 3 external fixators). Although the AS of Type 2 fixators were considerably more than Type 1 cases, this trend was not significant between Type 2 and Type 3. This is due to the arrangements of connecting rods in Type 1 and Type 3, which resulted in bending in bone-implant construct, while Type 2 external fixators do not experience any bending. For this reason, once the stiffness is the primary concern for surgeons, it would be reasonable to assemble a Type 2 fixator

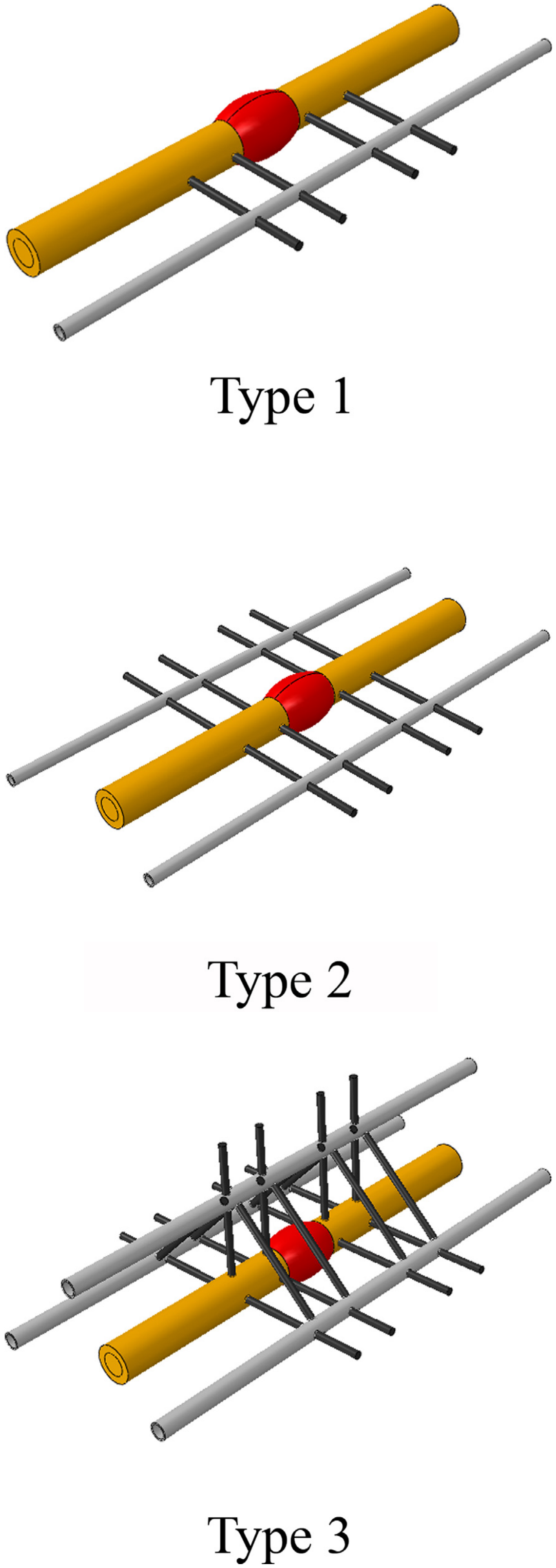

Fig. 1. Three main types of external fixators used in long bone fractures.

Table 2.
Design cases based on Taguchi orthogonal array

Design CaseNumber	Connecting Rod Diameter (mm)	Connecting Rod Elevation (mm)	Connecting Rod Material (GPa)	Connecting Rod Configuration
1	8	40	69	Type 1
2	8	45	110	Type 2
3	8	50	193	Type 3
4	9	40	110	Type 3
5	9	45	193	Type 1
6	9	50	69	Type 2
7	11	40	193	Type 2
8	11	45	69	Type 3
9	11	50	110	Type 1

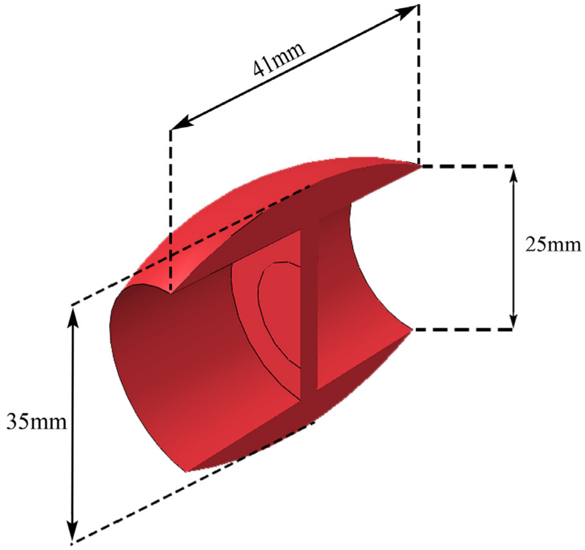

Fig. 2. Cross-sectional view of callus.

Table 3.
Material properties of bone, marrow and initial callus

Material	Young's Modulus (GPa)	Poisson's Ratio
Cortical bone (48)	20	0.3
Marrow (12)	0.002	0.167
Initial callus (granulation tissue)	0.001	0.167

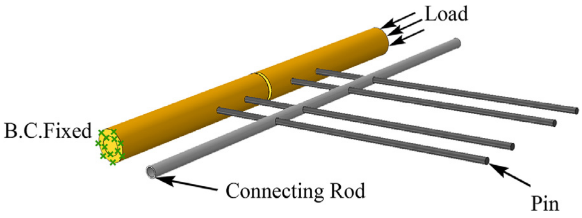

Fig. 3. Finite element model of loading and boundary conditions (without callus).

Table 4.
The axial stiffness and interfragmentary strain of all design cases.

Design Case	The Axial Stiffness(N/mm)	The Interfragmentary Strain(%)
1	96	31
2	139	5
3	138	5
4	145	3
5	106	22
6	134	7
7	143	4
8	141	5
9	103	23

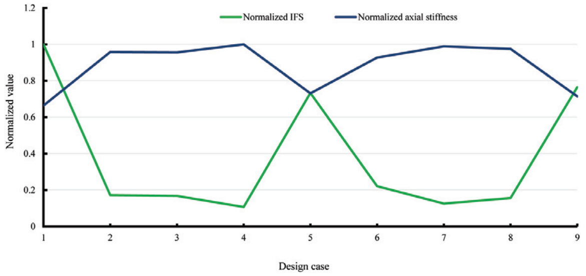

Fig. 4. The correlation between normalized values of the axial stiffness and interfragmentary strain.

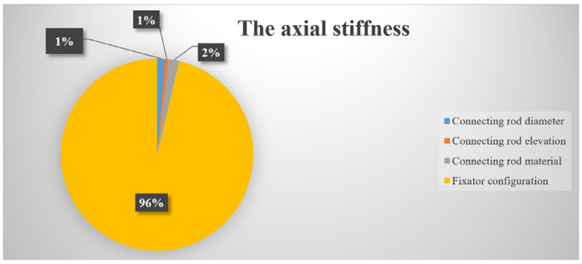

Fig. 5. The contribution percentages of design parameters on the axial stiffness.

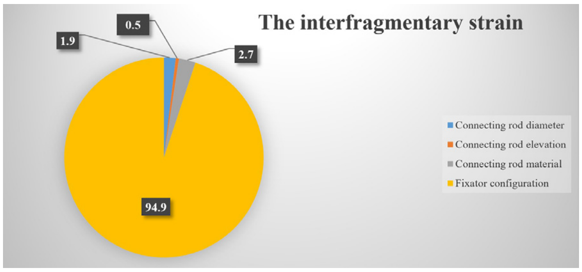

Fig. 6. The contribution percentages of design parameters on the interfragmentary strain.

rather than Type 3 with regard to the slight difference in the AS values between these 3 Types.

The IFS is an important indicator of bone-implant construct rigidity by showing micro-movement occurring in callus. For the best secondary healing quality, it is suggested that the IFS should be around 7%-33% (9). The IFS less than 7% means that almost no micro-movement happens in callus, and the IFS more than 33% means that too much micro-movement happens in callus. With regard to the former (IFS < 7%), the bone healing process is highly likely to step foot in the primary pathway of healing, or otherwise, the quality of bone healing might not be favorable. Also, it is important to note that in some occasions, like type 3 open fractures, there should not be any micro-movements at the fracture site at the early stage of healing, so in such circumstances, the IFS should be as minimum as possible (less than 7%). That is why Taguchi optimal design case for improving stability was suggested in this study.

Regarding the latter one (IFS > 33%), the fixator would not be stable, which can cause nonunion or mal-union. Among all 9 cases, design case 5 with 22% IFS, in a normal condition, seems to be the best choice for maximizing healing quality. This is in line with the results of Ganadhiepan et al (45), as a moderate IFS would be the best choice for surgeons, which can be achieved by limiting interfragmentary movement.

Furthermore, the relationship between the AS and IFS clearly shows a negative correlation, as it should be. By increasing the AS, it is expected that the interfragmentary movements in callus will be reduced, resulting in decreasing the IFS. This trend is plainly visible in all 9 design cases.

There are some limitations in this work. First, the whole study was investigated during the early stage of healing process when an external fixator is used as a primary method for stabilization. It is clear that the entire process is a cascade of events. However, the early stage of healing is the most important one (46). Second, simplifications in finite element models, such as neglecting the threads of Schanz screws (pins) or clamps, can lead to some errors in analyzing mechanical behaviors. Third, loosening of Schanz screws in external fixators, as a decisive factor in determining the failure or success of an implant (47), was not investigated.

In conclusion, this study provided a valuable insight into the importance of connecting rod design parameters (ie, connecting rod diameter, elevation, material and configuration) in the healing pathway of a fractured bone. A summary of findings of this study are as follows:

Given the ANOVA results, rod configuration played the key role in the AS and IFS. Hence, if possible, surgeons should play with the number and arrangement of connecting rods to change the bone-implant strength or stability.

Based on the Taguchi table results for the AS and IFS, Type 3 external fixator cannot improve stability considerably compared with Type 2 external fixator, so Type 2 external fixator would be a wiser choice rather than Type 3, as it is less invasive.

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