

## Mechanical Evaluation for the 1<sup>st</sup> Generation of Korat Static External Fixtation Device

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**Abstract.** The aim of present study was to evaluate the mechanical performance of the first generation of Korat Static External Fixation device (KSEF-1) for the tibial fracture stabilization. The evaluation was performed virtually based on 3D Finite Element (FE) technique. The domain of FE model included tibial fracture which was stabilized by the KSEF-1 device. In this study, the investigation covered four major loading conditions consisting of axial loading, anterior-posterior bending, medial-lateral bending and torsion. From the results, it has revealed that the maximum von Mises stress value displays in the region of pin insertion which adjacent the holder part with magnitude of 174.6 MPa (torsional load case). However, it was below the yield stress of materials. In addition, the KSEF-1 device has the construction stiffness of 93.4 N/mm, 638.3 N/mm, 331.7 N/mm and 7.7 Nm/deg for axial, anterior-posterior bending, medial-lateral bending and torsional load cases, respectively. In conclusion, the KSEF-1 device was safe enough for further clinical study.

**Keywords:** External fixator, Tibia fracture, Mechanical evaluation, Finite Element Analysis

### 1. Introduction

Fracture of tibia can be caused by high energy trauma such as traffic accident and falling from height. Just after trauma, patient finds difficulty himself/herself in walking, because of the instability of bone fracture. In general practice, surgeon needs to reduce the fracture into the normal anatomical alignment and use the fixation device to stabilize the fracture. The preliminary functions of the fixation device are to realign the fragment according to normal position as well as to provide early stability for fracture gap to allow the bone regeneration. Accepted internal fixation devices that have been used and shown the good clinical result are intramedullary nail and dynamic compression plate. However, an alternative treatment that has been also purposed is to stabilize externally as called external fixation device.

The principle of external fixation device is to use pins for connecting between bone and stabilized structure which are normally straight rod. After the fixation is placed, the weight is then transferred from tibia to the supported structure in the early stage of bone healing. As a result, the bone gap is constrained the degree of movement. The movements of fracture gap have a significant effect on bone healing process, high stiffness and low stiffness external fixation device subsequently present the delay callus forming. Therefore, only the proper gap movement is good for bone regeneration.

External fixation device in hospitals around Thailand is usually provided by commercial medical device company. Current demand of devices is high since the number of long bone traumatic patient increases in rural area, especially injury from transportation. In addition, the cost for external fixation device is considered to be high comparing to the income per capita of population in rural area. Therefore, it is better to utilize the local available materials in order to develop the self-made external fixation device.

This attempt has been implemented by Maharat Nakhon Ratchasima Hospital, Nakhon Ratchasima, Thailand which the Orthopedic Department has purposed the 1st generation of Korat static external fixation (KSEF-1) for tibial fracture as shown in Fig 1. The underlying concept of this design is based on simplicity with possible practice. The design has pins that transfer loads from bone to supported structure and also another way around. Since the pins must direct contact to bone, it is necessary to make these pins from stainless steel medical grade such SS316LVM. For other components, it is no direct contact to tissue. Therefore, it can be made of non-medical stainless steel grade. In this case, the SS304 grade is utilized.

## 2. Materials and methods

In this study, the KSEF-1 device was created using computer-aided design (CAD) software (SolidWorks 2010). The device composes of pins, slot, holder, locked pin, 8-mm x 8-mm square cross section rod, bolt, and nut as represented in Fig 1. To simplify, the acrylic rods 30-mm in diameter were used as the tibia bone models. The external fixator was virtually mounted on the rods, also 20-mm fracture gap according to Yang et al [2].

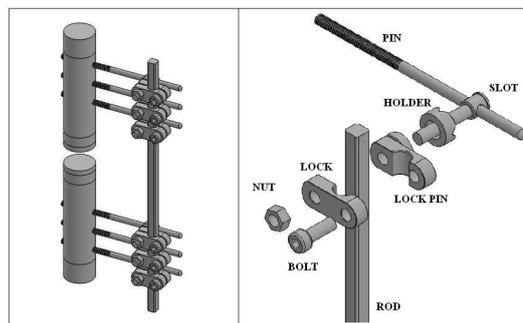
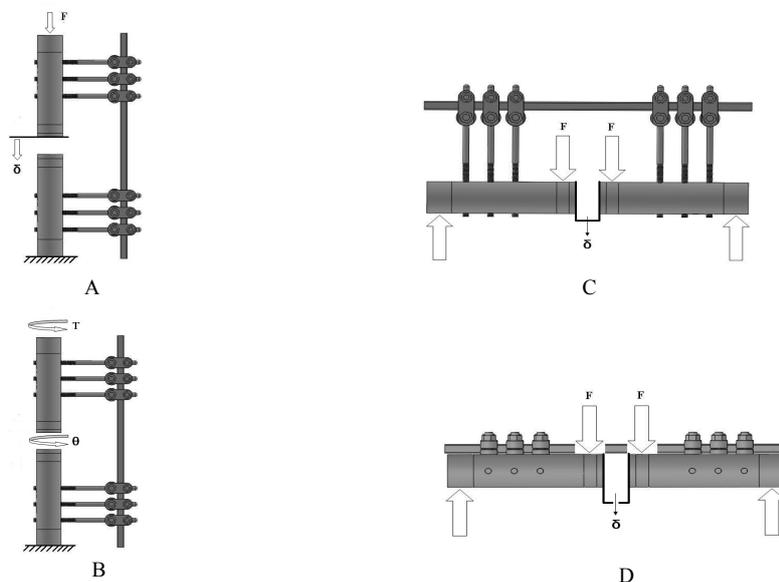


Fig 1. The first generation of Korat static external fixation device

Finite element (FE) analysis was performed based on commercial FE software package (ANSYS Workbench). In the analysis, ten-node tetrahedral element (Tet-10) was used to generate FE model. For contact condition, all contact areas were assumed frictionless mode. The contacts between two adjacent objects had no relative movement, excepting for contact between pin and acrylic rod which allow relative displacement [3]. The material properties in the FE analysis were as follows (Elastic modulus/Poisson's ratio): Stainless Steel 304: 190-GPa/0.29, Stainless Steel S316LVM: 200-GPa/0.33 and Acrylic: 2.4-GPa/0.35. Construction stiffness was investigated under four loading conditions that consist of axial loading, anterior-posterior bending, medial-lateral bending and torsion as shown in Fig 2, respectively. Construction stiffness was calculated from relation between load and deformation. The low construction stiffness shows the elastic external fixation device whereas the high construction stiffness shows the rigid external fixation device.



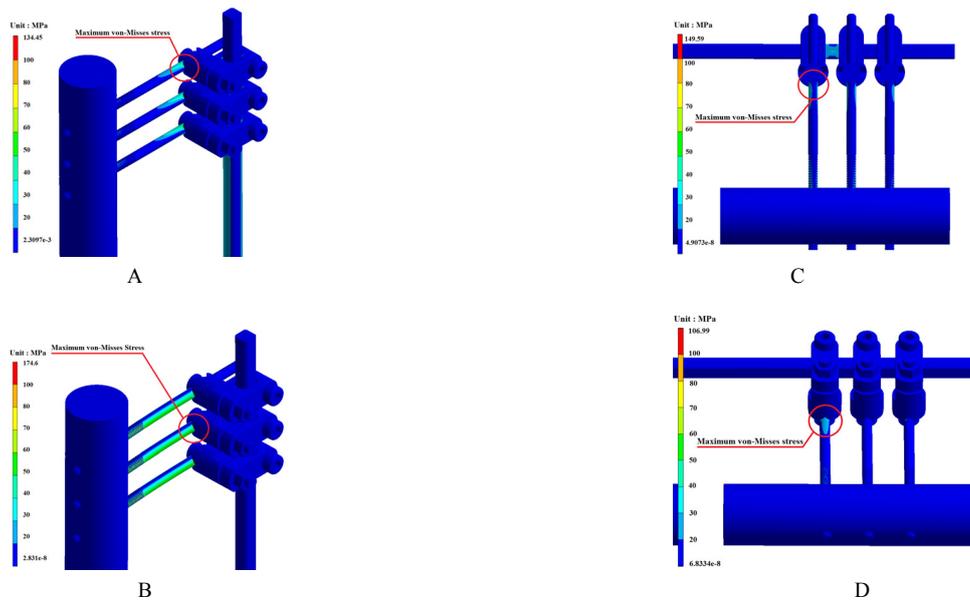


Fig 2. Boundary Conditions and result of stress distribution, (A) axial loading, (B) torsional loading, (C) anterior-posterior bending and (D) medial-lateral bending.

### 3. RESULTS

The stress distributions under four loading conditions were presented in Fig 2. The magnitude of maximum stress values in the case of axial loading, antero-posterior bending, Medio-lateral bending, and torsion were 134.4 MPa, 149.6 MPa, 107.0 MPa, and 174.6 MPa, respectively. It also reveals that the high stress concentration occurred on the region of pin insertion component that close to the holder part. In each load case, the results of deflection at the fracture gap were used to calculate the construction stiffness. According to the analysis, the KSEF-1 device have the stiffness of 93.4 N/mm for the axial loading, 638.3 N/mm for anterior-posterior bending, 331.7 N/mm for medial-lateral bending, and 7.7 N.m/deg for torsion as shown in Tab 1.

### 4. DISSCUSSION

Regarding to the results, the high stress concentration occurred on the region of contact zone between the pin insertions and the holder component. This is due to the small contact area of holder and pin. However, it was below yield stress of materials in all conditions. Normally, the yield strength of stainless steel SS304 and SS316LVM were around 215 MPa, 899 MPa, respectively. Therefore, in term of mechanical failure, the KSEF-1 device is considered to be safe for clinical implementation. For construction stiffness, the result from present study was then compared to the other two designs. The first design was a standard external fixation device which was evaluated by Yang et al [2]. The second design was a Dynafix system which was designed and evaluated by Koo et al [4]. The results from the previous and present investigation are given in the Tab. 1.

Tab.1 construction stiffness

External Fixation System	Axial Stiffness (N/mm)	Anterior-posterior Stiffness (N/mm)	Medial-lateral Stiffness (N/mm)	Torsion Stiffness (Nm/degree)
Present Study	93.4	638.3	331.7	7.7
Yang et al [2]	126.0	578.6	66.5	N/A
Koo et al [4]	246.6	50.2	376.2	2.3

The result shows that, axial construction stiffness of the KSEF-1 device is lower than standard external fixation investigated by Yang et al [2] approximately 25.9%. However, the construction stiffness under anterior-posterior bending and medial-lateral bending is higher than standard external fixation approximately

10.3% and 398.8% respectively. In addition, axial construction stiffness and Medio-lateral bending stiffness of the KSEF-1 devices were lower than Dynafix approximately 62.1% and 11.8% respectively. However, construction stiffness under Antero-posterior bending and Torsion load of is higher than Dynafix about 1171.6% and 233.9% respectively.

According to the comparison, the mechanical performance of the KSEF-1 device was comparable with standard external fixation device under anterior-posterior bending. Considering the activities of Asian people such as kneeling, changing the posture from sitting to standing, tibia is normally subjected to bending along anterior-posterior direction. Therefore, in aspect of construction stiffness under anterior-posterior bending is considered to be sufficient. Additionally, the construction stiffness under axial loading is still lower than the Standard external fixation device and Dynafix system. This is important, because axial construction stiffness is directly subjected to body weight. As a result, the KSEF-1 device needs some improvements to meet the standard device. The simplest way is to enlarge the size of rod. This would subsequently increase the rigidity of overall structure as well as construction stiffness. However, the consequent issue of the increasing weight must be consideration. Alternatively, the lightweight material such as carbon fiber may be consideration for next generation of developed external fixation device. Additonaly, The present study also investigated the improvement of current KSEF-1 design. This was performed by increasing rod sizes as shown in Tab 2. It can be seen that increasing rod size to 12.5x12.5 mm leading better performances by the weight of device increase only 33.38%.

Tab.2 construction stiffness: increase rod size

Rod size (mm)	Axial Stiffness (N/mm)	Anterior-posterior Stiffness (N/mm)	Medial-lateral Stiffness (N/mm)	Torsion Stiffness (N.m/degree)	Weight (gram)
8 x 8	93.4	638.3	331.7	7.7	617.8
12.5 x 12.5	166.5	781.3	335.6	8.1	824.0

## 5. CONCLUSION

External fixation device is a support device which aimed to stabilize the fracture gap by bearing load from bone to the external device. The reasons to design the KSEF-1 device are the high cost of commercial device and the increasing number of traumatic patient. From the FE analysis, it can be seen that KSEF-1 is good enough for clinical study. However, the desired improvement to meet the standard should be enlarging rod size.

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