

Finite Element Analysis of External Fixator for Treating Femur Fracture: Analysis on Stainless Steel and Titanium as Material of External Fixator

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Abstract An external fixator device is a medical implant used to keep fractured bones stabilized and in alignment. It consists of pins which are placed into the bone, extending outside the surface of the skin, and attached to a rigid external rod to keep it in place. The aim of this study is to investigate the most suitable material used for the external fixator. Firstly, the 3D model of two unilateral uniplanar external fixator with the properties of titanium and stainless steel were constructed at Solidworks software with all the other parameters set to constant. Meanwhile, CT images of the lower limb were used to reconstruct a 3D model of the femur fracture at Mimics Medical software. Positioning and meshing of both the external fixator and the femur done at 3-Matics Medical and export as Patran for simulation at Marc Mentat software. 375 N load was applied at the most proximal femur to simulate stance phase of a gait cycle. From the findings, external fixator by using stainless steel as material properties have lower maximum von Mises Stress (18.40 MPa) at the femur and (103.69 MPa) at the fixator compared to the titanium (32.38 MPa) at the femur and (182.93 MPa) at the fixator. The result shows a difference of 75% of maximum von Mises Stress at the femur and the external fixator. Configuration by using stainless steel displaced 1.15 mm at the femur and 1.01 mm at the fixator which almost double value of displacement for titanium material for both femur (2.35 mm) and external fixator (2.11 mm). In conclusion, stainless steel external fixators provide better stability when compared to titanium external fixators.

Keywords: Finite element analysis, stainless steel, titanium, Von Mises Stress, Displacement, Femur

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Introduction

Femur is the strongest bone in the body where it takes a lot of force to be broken or fracture. Most of the cases that lead to femur fracture are caused by accident such as for motor vehicle accident, fall from the high place, high speed trauma and also accident that cause by extreme sport activity (DeCamp *et al.*, 2016). From research, about 5880 people experienced femur fracture which contribute 1% to Malaysia population in 2018. Same study also stated that femur fracture will increase from 1.124 million in 2018 to 2.563 million at 2050 only in nine country of Asia including China, Hong Kong, Taiwan, India, Japan, Korea, Malaysia, Singapore and Thailand (Cheung *et al.*, 2018).

Femoral fracture are sometimes treated by using external fixators that help in stabilizing the fractured bone during the healing process (Praveen & Jaiganesh, 2015). The use of external implant for treating bone fracture is very common to achieve the aim which to stabilized and also heal the fracture. This devices is the most stable implant compared to internal due to the strength mechanical support and also can increase fracture bone healing (Giannoudis *et al.*, 2007). The most major advantages of this treatment is the ability of the implant to support the fracture without performing any dissection in fracture area and provided minimum tissue cell damage (Bliven *et al.*, 2019). Unilateral, bilateral, multilateral, and circular is example of external fixator that exist. Each of the type will have different stability and function based on the needed and type of bone fracture.

However, there is a lot of complication in using this method for treatment. For instance, applying external fixation can cause bacterial colonization and also can cause additional injury to other tissues and muscles if not done properly (Frydrysek *et al.*, 2013). These complications lead to physical failure such as pin loosening that might effect the time duration of healing and the optimal way to minimize complications is to pay careful attention to the principles of fixator selection and application (Egger, 1991). Material of the external fixator is also the main focus of researchers and surgeon in other to produce a good mechanical attributes of the design (Sham *et al.*, 2011). These characteristics can influence the fixator's mechanical properties in term of strenght and stability. The specifications of material selection could provide a good starting point for most designs of the external fixator.

Recently, the manufacturers proposed the use of a 'better' fixator material which is titanium. The titanium is a biocompatible material with relatively small modulus elasticity (closer to that of bone than that of stainless steel 316L) and well known for being MRI-safe (Li *et al.*, 2019). For instance, one experiment was conduct which this study involved the selection of materials and the design of a miniature external fixator that can be easily assembled, resulting in increased usability and affordability (Basat *et al.*, 2020). From the result, it shows that the titanium is the most ideal material which has high tensile strength, high fatigue strength, high corrosion resistance and good formability that can limit the movement during the healing process (Basat *et al.*, 2020).

Another analysis was done to compare the effects of different materials of fixators by using stainless steel, titanium and carbon-fibre composite. The analysis was conducted by using illizarov fixator on tibia bone with 1200 N load (considered as maximum load for external fixator and found that maximum stress by using stainless steel was lowest than titanium and carbon-fibre composite materials (Tomanec *et al.*, 2018). Meanwhile, same study also conduct to compared performance of unilateral uniplanar fixator between two different materials (specifically for the material of pin) and found that by using titanium alloy, the von Mises stress higher compared to Model 1 which referring to stainless steel (Sham *et al.*, 2011). This situation might risk the patients after several months the fractures will undergo cyclic loading which can lead to pin loosening of higher stress exist at that particular area (Donaldson *et al.*, 2012).

From previous study, it clear stated some expert recommended the titanium and some of it by using stainless steel. By considering these two situations, there is no argument found in the literature to justify the choices. To our best knowlegde, it is important to compare the stability of materials used for external fixator in term of stress distribution which to achieve a main function of the implant. However, this study was conduct to specifically analyse the best materials based on stress and displacement distribution at

both femur and external fixator. Finite element analysis method was used to simulate the external fixator construct.

Materials and methods

Bone reconstruction

The existing healthy bone structure produced by CT images is used in femur reconstruction. The data was acquired from a CT images of 27 years old man with 75 kg weight and 169 cm. The data was taken from Hospital Tengku Ampuan Afzan, Kuantan, Pahang, Malaysia. To get the exact model of the femur bone, a CT scan datasheet then transfer to the Mimics Software (Materialise, Leuven, Belgium). Threshold 701 HU to 3071 HU was used to highlight the cortical bone of the femur on the software (Mohd Amir Shahlan *et al.*, 2017). Once the 3D bone was completed, the next step was to develop a transverse fracture of femur. Development of the femur fracture done by using 3-Matics Software (Materialise, Leuven, Belgium). Specifically, the fracture that generates is the transverse middle zone. The transverse fracture generated less than 30 degrees and the gap of fracture was set to 4 mm (Roseiro *et al.*, 2014). In our previous studies, we have conducted a convergence analysis where h-refinement was used to choose the optimum mesh size of tibia and femur bone. We found that the optimum mesh size for the tibia and femur bone was 3 mm (M. H. Ramlee *et al.*, 2014a; Abd Aziz *et al.*, 2020). Therefore, we set 3 mm size for the tetrahedral elements in this model. Next, the file converted to STL format for next step pre-processing.

External fixator development

The most important part of this project is to develop external fixator devices. Since the external fixator consists of many components which are rod, clamp, and pin, the design was done separately. The uniplanar-unilateral external fixator was developed and designed by using a computer aided design (CAD) software, Solidworks. The modelling was started off by developing every single components such as pin, rod and clamp. The diameter and length of the rod are 11 mm and 170 mm, respectively (Ramlee *et al.*, 2014b). The length of the rod according to the suitable size of the fixator (Kluk *et al.*, 2017). The pin diameter is 5.0 mm was taken from Depuy Synthes company where the instrument and implant have been approved by the AO Foundation and supported by ASTM F 1541-02 where referring to Standard Specification and Test Methods for External Fixator Skeletal Fixation Devices. All external fixators model were mesh using 1.5 mm mesh size and then converted to STL file to implement with the femur bone (Ramlee *et al.*, 2014a). Finally, the 3D model of external fixator was converted into STL file for further pre-processing step.

Virtual Surgery

After 3D model of both fixator and femur were completed, the next step was to assemble both 3D model before proceed to simulation stage. 3-Matics Medical software was used in positioning and align the external fixator with the femur (Ramlee *et al.*, 2019). Both external fixation techniques were consisted of four pins, four clamps and one connecting rod. In this study, the configuration was fixed with 40 mm distance from femur to the fixator and 15 mm distance from second and third pin to the fracture gap (Roseiro *et al.*, 2014; Kluk *et al.*, 2017). Once the position was identify, the virtual surgery was conducted by a virtual surgery was conducted to fix the fixator onto the bone by applying 'create manifold assembly' tool in the 3-Matics software. To avoid concentrate stress during the simulation, it is important to do some modificaton at pin bone interafce to modify the non-uniform triangle mesh element by using adaptive remesh tools. The file then export as Patran file for next processing step.

Finite element analysis

All Patran file was important into simulation software (Marc. Mentat 2016.0.0, MSC.Software, Canada). In nature, cortical bone exists as anisotropic material however for this study the femur assumed as isotropic. The young's modulus for cortical bone was 16.2 GPa with 0.3 poisson's ratio and tensile strength 170 MPa (Nishijima *et al.*, 2016). Bone consists of 551 938 elements with 7365 nodes after

converted to solid at Marc Mentat simulation software. As for materials properties of the external fixator, a stainless steel used for the first design and name as Model 1 with 200 000 MPa young's modulus and 0.3 poisson's ratio (Elmedin *et al.*, 2015; Padovec *et al.*, 2017) and titanium for the second design named as Model 2 with 110 000 MPa young's modulus and 0.3 poisson's ratio (Radcliffe *et al.*, 2007).

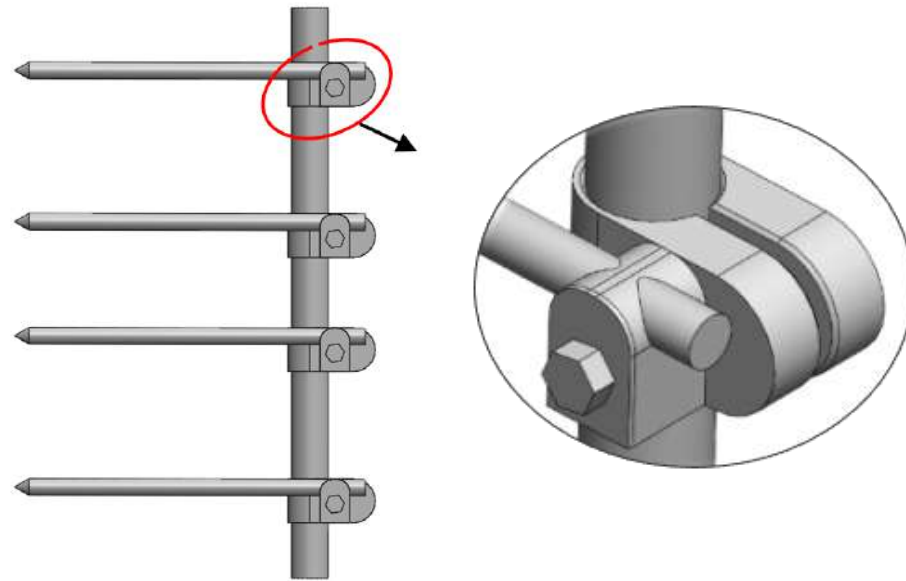


Figure 1. External fixator assembled at Solidworks

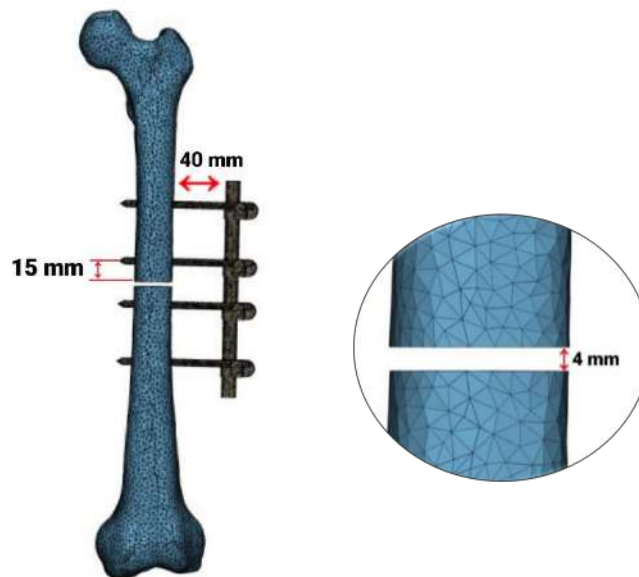


Figure 2. Configuration of the external fixator and the femur with 4 mm fracture gap

Table 1. Materials properties of the external fixator.

| External fixator | Young's Modulus (MPa) |
|---------------------------|-----------------------|
| Model 1 (Stainless Steel) | 200 000 |
| Model 2 (Titanium) | 110 000 |

This study focusing on the stance phase condition to evaluate the configuration of the external fixator. Referring to research done by Oken. O, state that each lower limb applied 50% of human body weight at the stand condition (Oken *et al.*, 2017). Since the body weight of the patient was 75 kg thus 375 N load was applied at the most proximal point of the femur (Radcliffe *et.al.*, 2007). Fixed load applied at x,y and z-direction as shown at figure 3 below.

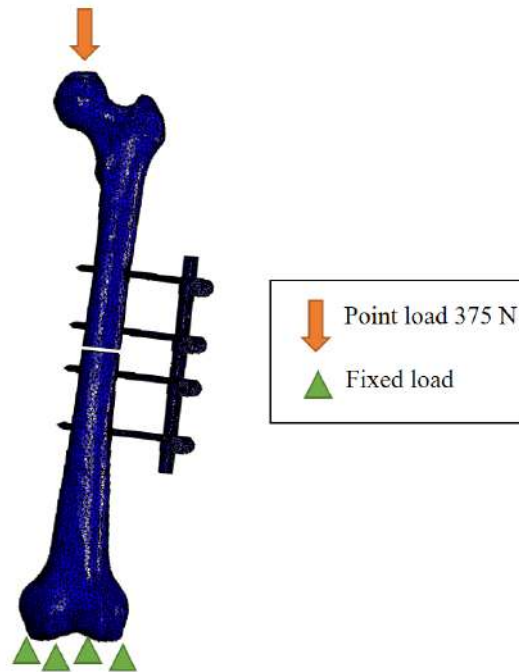


Figure 3. Loading condition of the femur

Results and discussion

Equivalent von Mises Stress

Fig. 4 shows the contour plot of equivalent von Mises stress of tibia bone for both fixation material during a stance phase of a gait cycle. Based on the contour result, the peak von Mises stress shows at pin-bone interface. Stress at the pin-bone interface and also the implant during the installation and time healing cannot be avoided since there is load and force act at the bone, in order to reduce the risk of complication, lower von Mises stress should be considered in choosing suitable materials. For Model 1 which referring to the stainless-steel materials highest von Mises stress was shown at third pin-bone interface with 18.40 MPa. As for Model 2 (titanium) highest von Mises stress shows at third pin-bone interface with 32.38 MPa. As comparing for both materials, external fixator by using stainless steel shows

lower von Mises stress. The value of using titanium is almost two times the value of external fixator with stainless steel as the material. However, all models still consider safe when it is applied to treat the fractures since all values do not exceed the ultimate strength of bone which is 170 MPa (Nishijima *et al.*, 2016; Ebrahimi *et al.*, 2012).

The distribution of von Mises stress on the external fixator also record different, with 103.69 MPa for stainless steel and 189.93 for titanium. The result clearly shows that the material fixator by using stainless steel claimed as the most suitable material compared titanium. Same as previous study, when two materials of fixator was simulate and found that the value of von Mises stress at fixator increase from 190 MPa (stainless steel) and 225 MPa (titanium). This difference value indicate that stainless steel promoted lower von Mises stress that can affect healing process of bone fracture (Sham *et al.*, 2011). However, both materials did not exceed the ultimate strength which is 600 MPa for stainless steel and 800-900 MPa for titanium (Nishijima *et al.*, 2016; Bitsakos *et al.*, 2005).

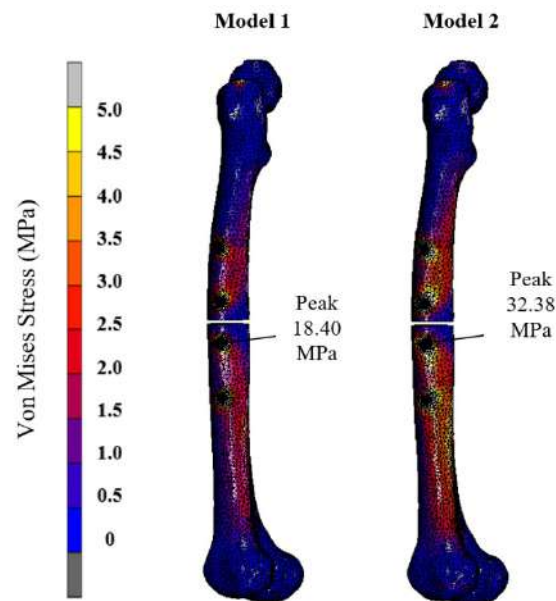


Figure 4. Peak von Mises stress of the femur (a) stainless steel (b) titanium.

Displacement

By comparing the displacement as shown at figure 6 and 7, as expected titanium shows the large value of displacement compared to stainless steel material which should be taken more seriously when this material was applied especially as pin materials. This is because of after several of time the application of external fixator will displaced to maintain the stability, if the high von Mises stress exist at both bone and fixator the system will undergo loosening. Thus, achieving lower maximum von Mises stress has to be the main concern when considering real life application on the external fixator (Sham *et al.*, 2011).

Model 1 which possesses low local von Mises stress for femur and fixator also shows the small value of maximum displacement with 1.15 mm at the femur and 1.01 mm for the fixator. The contour plot for the femur and external shows significant differences where the titanium material displaced for 2.35 mm at the femur and 2.11 mm at the external fixator. The highest value can lead to failure of the external fixator to achieve the aim due to the pin loosening that might be happened.

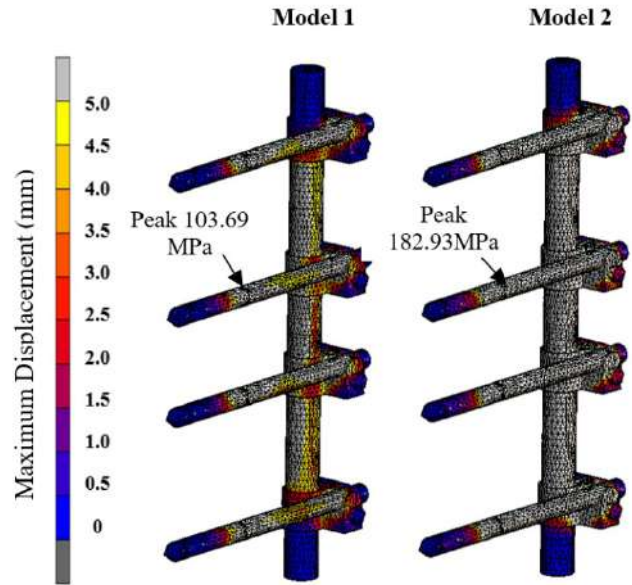


Figure 5. Peak von Mises stress of the external fixator (a) stainless steel (b) titanium.

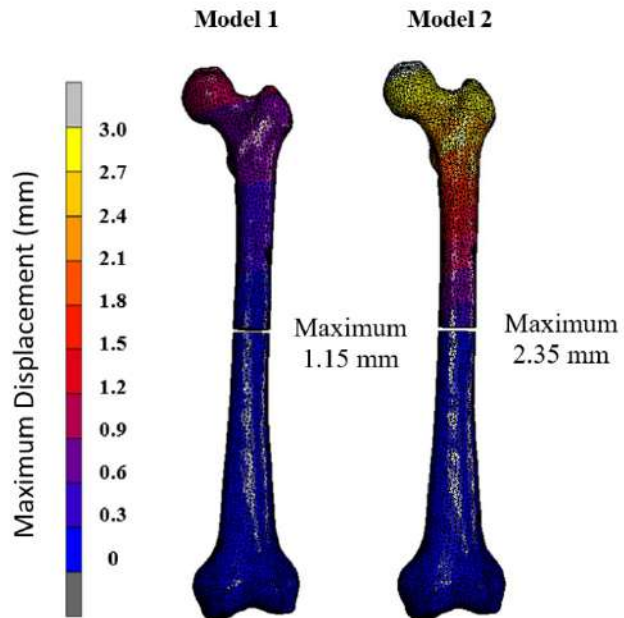


Figure 6. Maximum displacement of the femur (a) stainless steel (b) titanium.

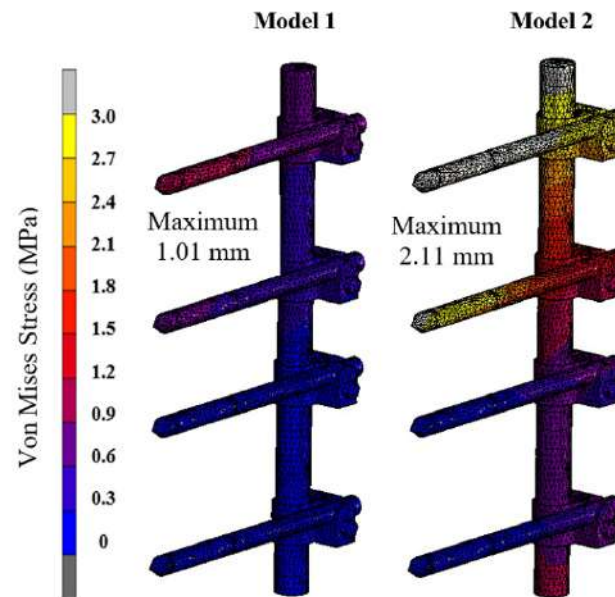


Figure 7. Maximum displacement of the external fixator (a) stainless steel (b) titanium.

Discussion

The main aim of this study is to perform biomechanical investigation on the external fixator with different type of materials (titanium and stainless steel) used in clinical application for treating femur fractures. A medical specialist (one of the co-author of this paper, Wui N.B.) have many experiences in treating patients associated with bone fractures where external fixator devices are taking place in his treatment. We found that this study is deeply important to be investigated where the findings can be useful and give new insight to medical surgeons to justify their choices of the external fixator materials in treating fracture bone.

Von Mises stress is usually used to investigate the yielding of material that combining stresses in x, y and z-direction. Based on some theory, material started to be yield when the von Mises stress has reached the yield strength (Palmer *et al.*, 2009). In this study, von Mises stress was used to predict the stability of the model of external. The type of material for the external fixator also plays an important role to produce the most stable system which can give a more positive outcome in treating femur fracture. The findings found that material properties by using stainless steel referring to 200 000 MPa young's modulus produce the lowest von Mises stress compare to the titanium. Model 2 which is simulated by using 110 000 MPa young's modulus and found the von Mises stress increase almost two times from stainless steel materials. The huge difference between both materials concludes that the use of titanium can affect the duration time of the healing process (Benli *et al.*, 2008; Sham *et al.*, 2011). Previous research stated that titanium the most higher specific strength compared to stainless steel and more suitable material to as external fixator material (Li *et al.*, 2019; Basat *et al.*, 2020). However, the main focus of the study is material for connecting rod and of course strength needed to support the system. Nevertheless, in this study, the external fixator considers as one whole body with the same young's modulus for each component where the main focus is von Mises stress at the pin bone interface. The higher the young's modulus of the pin the lower the von Mises stress (Pan *et al.*, 2017). So, the most suitable material for the external fixator that can faster the healing process was stainless steel based on the von Mises stress value with 18.40 MPa at the femur and 103.69 MPa at the external fixator.

Other than von Mises stress, displacement also the essential parameter to be evaluate to find the most stable configuration and material for the external fixator in the femur (Nishijima *et al.*, 2016). Displacement refers to the distance of bone and fixator displaced after a specific load was applied. This

particular displacement is needed to allow micromovement to control stability during the healing process (Sternick *et al.*, 2012). This small displaced can avoid pin and rod loosening during the healing process. To be noted, loosening of the external fixator and bone can give pain to the fracture (Donaldson *et al.*, 2012). The huge difference between two materials which is increasing almost 100% from stainless steel to considers very risky. The risk consists of pin loosening which leads to the infection at pin-bone interface and can cause secondary fracture (Donaldson *et al.*, 2012).

Despite the successful simulation of the external fixator, there is still a limitation that should be happened since assumption during the simulation cannot be avoided. First and foremost, the 3D model of the femur is only considered as cortical and it can cause some prediction and reading of the parameters different. Besides, the cortical bone is also assumed as linear, isotropic and homogeneous without considered muscles and ligaments. This may not truly reflect human femur, which is non-linear, anisotropic, and visco-elastic (Vitins *et al.*, 2003). Thus the result not 100% followed the real result when a particular load was applied. This assumption usually used by other researchers to simulate a complete femur structure (Mughal *et al.*, 2015; Cuppone *et al.*, 2004).

Secondly, another limitation in this study where material properties of the external fixator were assumed the same for all components (pins, clamp and rod) (Ramlee *et al.*, 2014c). A previous study shows accurate materials for the external fixator was stainless steel for the pin and titanium for the rod (Pan *et al.*, 2017). Since this study only highlights the von Mises stress at pin bone interface, the result is valid due to the pins still using the stainless steel.

Other than that, the limitation also regarding the load that is applied to the bone. In this study, only the static point load was examined which referring to the stance phase (Abd Aziz *et al.*, 2019). However, the proximal femur could potentially be subjected to cyclic axial forces during the phase in other to stabilize the position (Vitins *et al.*, 2003). Despite that limitations, this simulation only assumed the static load due to the fact that the medical surgeon not allowed the patient to have a lot of movement during the application (Chen *et al.*, 2015). Also, muscles force where negligible and were not accounted for (Abd Aziz *et al.*, 2019). When muscle force applied to the femur, the result must be more realistic since fracture healing involving more muscle attachment during recovery and remodeling process (Ebrahimi *et al.*, 2012).

For the future study, it suggests the researcher do some improvements to make this biomechanical analysis more realistic. Firstly, it suggests using a high resolution of CT bone image to compute an anisotropic material for bone. Second, simulate the external fixator by using different materials for each different component. Besides that, the biomechanical analysis also can be done by using a different type of fracture and different types of external fixators to give to specific optimum configuration for each model and type of fracture (Abd Aziz *et al.*, 2019). Next, research about the real loading condition for the femur should more specific (considered the cyclic load and muscles force) to avoid confusion and assumption during the experiment. Last but not least, a future study should emphasis on the real environmental testing such as *in vitro* analysis where cadaveric specimen or synthetic bone can be used to evaluate the performance of the external fixator using Universal Testing Machine (Instron).

Conclusions

Overall, this study is successfully done to biomechanically analyze external fixators to treat femur fractures. Based on the obtained results, Model 1 which referring to stainless steel material considered as the best materials used for the external fixator. To reduce complication during the application it is important to maintain lower stress and displacement. However, both materials still can be considered since it is not exceeded ultimate strength for both materials. On the other hand, if medical surgeons applied titanium (Model 2) as external fixator's material extra care should be considered in allowing patients to stand alone due to high stress and displacement at both bone and external fixator that can lead to pain and loosening of external fixator within the time healing.

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