Biomechanical evaluation of pin placement of external fixator in treating transverse tibia fracture: Analysis on first and second cortex of cortical bone

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INTRODUCTION

In the worldwide, it is reported that 85% of extreme limb injuries come from lower limb cases(Fernandez et al., 2017). Lower limb region includes femur, patella, tibia, fibula, talus, hind foot, mid-foot and forefoot bone (van Niekerk et al., 2017). Accordingly, the tibia fracture is the most common bone fracture; contributes to at least 8.1% until 37% of lower limb injuries per annum (van Niekerk et al., 2017). This high percentage of injuries related to the lower limb region is due to the fact that the tibia bone is exposed to external load surrounding (Meleppuram & Ibrahim, 2016). Besides, tibia injuries can be caused by an excessive internal force (compression, torsion, and shear) at the knee and ankle joint (Meleppuram & Ibrahim, 2016).

In general, the tibia fracture can be divided into two categories; open and close fracture. The former is a fracture condition where some parts of tibia broken bone are exposed to outside tissue. According to a study by Fernandez et. al (Fernandez et al., 2017), they found that the tibia fracture was occurred at least 10% in a year and 40% of them were open fracture. Many medical surgeons experienced a lot of difficulties in treating open tibia fracture due to complications such as high rate of infections, as well as mal-union, non-union and mis-allignment of bone (Meleppuram & Ibrahim, 2016). To avoid those complications during the treatment period, early fixation on the fracture is deeply necessary (Nambi et al., 2017. This is not only can prevent many complications to be occurred, but can also maximize the healing process of the broken bone of tibia (Nambi et al., 2017). One method to fix the open tibia fracture is by using an external fixator. The use of external fixator has been proven to be able to heal the broken bone within an appropriate time by aligning the tibia bone to its original position and minimizing the rate of infections (Elmedin et al., 2015).

The successful healing process of tibia fracture can be achieved in many ways. One of them is an optimum stability of the external fixator used in treating the fracture may increase the healing rate. As far as the authors are concerned, the external fixator is the most stable fixation compared with internal fixation such as screws, plates and...
wires (M. H. Ramlee et al., 2014a). The external fixator can prevent the movement of broken bone by fixating a number of pins at the desired position in tibia bone (Elmedin et al., 2015). The external fixator that is applied in this situation must indirectly preserve and protect damage of soft tissues while providing support to bone fracture from mobilization (Meng & Zhou, 2016). Moreover, this system is a great alternative treatment for an easy applications due to the assembling of components in this system can maintain the stiffness and stability of the fracture in bone (Roseiro et al., 2014).

There are several configurations of external fixation: uniplanar–unilateral, uniplanar–bilateral, biplanar, multiplanar and ring-type frame. The most common type of external fixator used by medical surgeons to treat a simple open tibia fracture is uniplanar-unilateral frame (Roseiro et al., 2014). However, pin of uniplanar-unilateral frame is often penetrated the bone. Some experts recommended to fix the pin until second cortex of bone while some of them recommended at first cortex (Prashanth et al., 2016). By considering these two situations, there is no argument found in the literature to justify the choices. From biomechanical point of view, stability of external fixator can alter the healing rate of broken bone. The external fixator that provides an optimum stability can minimize many complications as mentioned earlier (Prashanth et al., 2016). To our best knowledge, there is no study conducted yet to compare the above two choices. Therefore, this study was conducted with main aim to evaluate two different fixation techniques (pin passing through the second cortex versus pin locating at the first cortex) in order to treat transverse fracture via finite element method. The findings from this research would be valuable for medical surgeons to justify the choices in treating open tibia fracture, thus preventing more complications.

**MATERIALS AND METHOD**

**Three-dimensional modelling of tibia bone and fracture**

Three-dimensional (3D) model of tibia bone was reconstructed from Computed Tomography (CT) images data. The data was acquired from a 80kg healthy male of 22 years old at Hospital Tunku Ampuan Afzan, Kuantan Pahang, Malaysia. A modelling software, Mimics (Materialise, Belgium), was used to reconstruct the 3D model of tibia in which consisted of cortical and cancellous bone (Oken et al., 2017; Ramlee et al., 2015). To differentiate between cortical and cancellous bone in Mimics software, a threshold value was set at 700(Ramlee et al., 2014a). Then, the segmentation and masking process were conducted to remove data noise. Some modifications were made where the bone’s shape and size were in accordance with an anatomy book in mimicking the real geometrical conditions of tibia bone. The geometry of tibia bone was checked by a medical experts (Ramlee et al., 2014a). Once the 3D bone was completed, the next step was to develop a transverse fracture. This step was done by using Mimics software where a fracture gap of 4 mm was cut using cutting tools. The gap length was suggested from a study by Fagelberg et al. (Fagelberg et al., 2015) to simulate the tibia shaft transverse fracture. Finally the 3D model of tibia bone was triangular meshed with 3 mm size and was saved in STL format for next pre-processing step (Ramlee et al., 2014a).

**Three-dimensional modelling of external fixator**

The uniplanar-unilateral external fixator was developed and designed by using a computer aided design (CAD) software, Solidworks (Dassault, USA). The modelling was started off by developing every single components such as pin, rod and clamp. The dimensions of those components were based on the commercial product of Synthes where the diameters of pin and rod were 5.5 mm and 11 mm, respectively (Muhammad Hanif Ramlee et al., 2015). The length of rod was set at 170 mm (M. H. Ramlee, M. R. Kadir, M. R. Murali, & T. Kamarul, 2014b). Later, all components of pin, rod and clamp were assembled into one single rigid body via similar CAD software. Then, the external fixator constructed was remeshed with triangular mesh element of 1.5 mm in size. Finally, the 3D model of external fixator was converted into STL file for futher pre-processing step.

**Virtual surgery**

Once the 3D model of tibia bone and external fixator were completed, the next step was to assemble both models. This step was conducted in Mimics software where the position of bone-to-rod was set to 40 mm distance (Sternick et al., 2012). In this study, there were two different fixation techniques i.e. Fixation 1 that assembled the external fixator to be fixated through the second cortex of tibia bone and Fixation 2 that only considered pin penetration at first cortex, as shown in Fig. 1. Both external fixation techniques were consisted of four pins, four clamps and one connecting rod. Once the position of the external fixator was set, a virtual surgery was conducted to fix the fixator onto the bone by applying ‘create manifold assembly’ tool in the Mimics software. Due to manifold assembly, some modifications were performed to modify the non-uniform triangular mesh element at the pin-bone interface into uniform size of element. This was done in 3-Matic software.

**Finite element analysis**

All STL files of the tibia bone and external fixator were imported into a finite element software, Marc.Mentat (MSC.Software, USA). The files were then converted into 3D model of linear first-order tetrahedral elements (Abd Rahman et al., 2008). For material properties, the 3D tibia bone of cortical and cancellous were set at 16.2 GPa and 480 MPa modulus, respectively (Pitkin et al., 2007). Meanwhile their Poisson’s ratios were 0.3 and 0.26, respectively (M. H. Ramlee et al., 2014a). As for the external fixator, a stainless material was used to simulate it where the material properties was set at 200,000 MPa. All models were assigned with isotropic and homogeneous material properties. A convergence analysis was performed in our previous study (Ramlee et al., 2014a) using h-refinement method where the optimum mesh size for bone was 3 mm and the external fixator was 1.5 mm. A validation of the finite element model was conducted in the previous reported literature. The validation results showed that all four selected points at tibia bone were similar to that experimental findings (Ramlee et al., 2018). The previous findings showed that the trend and profile of the graph were the same for both the finite element results and experimental data.
Boundary conditions

In this study, we simulated a stance phase condition to evaluate the fixation techniques. According to a study, 50% of the body weight was applied to one part of lower limb of human (Oken et al., 2017). Since the body weight of patient was 80 kg, therefore a 400 N load was applied to the proximal tibia bone, where 60% of the load at the medial curvature and another 40% at the lateral curvature as shown in the Fig. 1 (Raja Izaham et al., 2012). The axial compression force was normally applied by many researchers to mimic the weight bearing condition.

RESULTS AND DISCUSSION

Equivalent Von Mises Stress

Fig. 2 shows the contour plot of equivalent von Mises stress of tibia bone for both fixation techniques during a stance phase of a gait cycle. From the results, in general, the high stress was found at the pin-bone interface for both fixations where the highest value was specifically located at the distal pin-bone. Undoubtedly, the high stress at this surrounding tissue was similar to previous study by others where this could not be avoided when using an external fixator (Brianza et al., 2011; Donaldson et al., 2012). As comparing both fixation techniques, the Fixation 2 experienced higher stress (21.41 MPa) than Fixation 1 (15.20 MPa) with 34% difference in value. Due to the high stress for Fixation 2, this was a main reason on why medical experts did not allow patients to experience full weight bearing during a period of treatment (Ansah & Sella, 2000; Dlimi et al., 2008). Nevertheless, this high value of stress at the critical local point of pin-bone interface was not exceed the ultimate strength of bone (193 MPa) (Pinner & Sangeorzan, 2001). From the Fig. 2, it could be observed that high stress was illustrated at approximately 10 cm above tibia malleolus for the Fixation 2 compared to the Fixation 1. This high stress at surrounding tissues might lead to secondary fracture if patients were allowed to experience full gait condition. Based on these findings, it was suggested that medical surgeons and patients should take extra care if Fixation 2 was applied to treat transverse tibia fracture, in order to avoid any complications during early medical interventions.

Fig. 3 shows the contour plot of equivalent von Mises stress of external fixator for both fixation techniques. Between both fixations, a small difference (4.5%) was found at the second pin of external fixator. The higher stress was experienced in the Fixation 2 (129.55 MPa) compared to the Fixation 1 (123.83 MPa). To be noted, the uniform distribution of stress was illustrated at the rod of external fixator for both techniques. There was no significant difference in Fixation 1 and Fixation in terms of stress value at this particular point of rod. From these findings, both fixation techniques were safe to be used in treating transverse tibia fracture in terms of biomechanical aspect due to the fact that the stresses did not exceed the ultimate strength of that particular material (800-900 MPa) (Gorsse & Miracle, 2003; M.H. Ramlee et al., 2018). As far as the authors were concerned, the use of external fixator was favourable option to allow weight bearing forces to be distributed from the upper to lower patient’s body through the pin and rod. Therefore, minimal force distribution would impose to the broken bone. From this study, we simulated the global stress value at the external fixator where we found that higher stress was located at pin-bone interface. For the future research, we were highly recommended that other researchers could focus on the local stress at the clamps. This was due to the fact that high stress at the clamps could allow pin and rod loosening during the weight bearing, thus affecting the stability of the external fixator. Other than that, stress shielding at the pin-bone interface could be evaluated further in the next study where this could predict the pin loosening.

Displacement

Global displacements of the two different techniques were illustrated in Figure 4. In general, the global displacement for Fixation 1 showed a significant difference at the proximal tibia bone as compared with Fixation 2. The proximal tibia bone of the Fixation 1 experienced at least 3.21 mm of displacement, while for the Fixation 2 was 1.42 mm. These values demonstrated at least 77.3% of difference. For the external fixator alone, the Fixation 1 and Fixation 2 showed at least 1.67 mm and 1.20 mm of displacement, respectively, where demonstrated at least 32.8% of difference. This small value of displacement at the external fixator concluded that both techniques were safe to be used, however medical surgeons should consider the movement of tibia bone to avoid complications. Based on the high displacement at the proximal tibia for Fixation 1, it should be avoided since the healing process of a broken bone would take place only if small displacement or micromovements was appeared. Nevertheless, future research should be conducted to prove this claim.

Fig. 2 Stress contour plot of tibia bone for a) Fixation 1 b) Fixation 2.

Fig. 3 Stress contour plot of external fixator fora) Fixation 1 b) Fixation 2.

Fig. 4 Displacement contour plot for a) Fixation 1 b) Fixation 2.
Fig. 5 shows the global mapping condition between deformed and original model for both Fixation 1 and 2. Fixation 1 has more obvious deformation than Fixation 2. Based on this findings, it was not suggested to use the first technique which was the Fixation 1 in treating transverse tibia fracture.

Fig. 5 Mapping of original and deformed configuration for a) Fixation 1 b) Fixation 2.

The use of external fixator in treating tibia fracture is considered as favourable option as compared to other medical devices. The ability of the external fixator in providing minimal invasive procedure giving adequate stability and promoting less infection proved that this medical device is opted for the best choice among others (Pinner & Sangeorzan, 2001; Seibert et al., 2003). Moreover, the high stability of the external fixator has been taken into consideration, giving that it could hasten soft tissue healing during the medical intervention period (Chandran et al., 2006; Seibert et al., 2003). However, before the successful outcome can be delivered, a proper step and procedure should be conducted properly by medical experts upon the surgery process. One of the step is by choosing the correct fixation techniques. As demonstrated in this study, there were two different techniques have been analysed to evaluate the best external fixator. Based on the results, it was suggested that the Fixation 2 as the good fixation technique where the pin was penetrated until the second cortex of bone. In terms of biomechanical aspect, the technique of Fixation 2 could provide adequate stability to the broken bone and avoid many complications such as mal-union and mis-alignment. On the other hand, if the Fixation 1 was used, above complications might appear in treating the patients. It should be noticed that inability to provide a stable construction might cause secondary fracture at the pin-bone interface (Inokuchi et al., 1996; Vasquez et al., 2003).

As far as the authors concerned, biomechanical studies related to the external fixator for lower limb of human were very limited. Therefore, this study was conducted to justify the medical surgeon’s choices in treating lower limb injuries. In addition, these findings were expected to help medical experts and engineers to choose suitable configurations and techniques for a specific pathological problem of transverse tibia bone. Other than these findings, the studies that have been conducted were only on the external fixator for the horse, ankle dislocations and pilon fractures of human (M.H. Ramlee, Kadir, & Harun, 2014; M. H. Ramlee, M. R. A. Kadir, M. R. Murali, & T. Kamarul, 2014; M.H. Ramlee et al., 2018). In accordance with previous studies, this work also reported similar high stress at the pin-bone interface where this situation could not be avoided since the material for external fixator wasss higher than of bone.

In this study, there were several assumptions and limitations to be considered since the assumptions could not be simply avoided when dealing with finite element simulation. Firstly, the material properties for all models of cortical and cancellous bone were assigned with linear, isotropic and homogeneous characteristics, thus all other factors that might alter the predicted results were excluded. Although these characteristics were unreal, nevertheless these assumptions were normally used by the others and became acceptable as demonstrated by many researchers (Benli et al., 2008; Brianza et al., 2011; Ezquerra et al., 2007; Izaham et al., 2012). In comparing isotropic and orthotropic characteristics, a study has been conducted by others in which there was only small difference (1.2%) in terms of maximum equivalent von Mises stress and the maximum nodal displacement (Peng et al., 2006). Thus it was recommended that the future research to consider the usage of greyscale value of CT images in mimicking real properties of the cortical and cancellous bone. Other than that, the use of inhomogeneous properties should be considered in later studies. Second limitation in this study was the limitation of region of interest (ROI) of the bone to tibia only due to computer resources. Nevertheless the future study should consider the whole lower limb in order to provide optimum results. Another limitation in this study was the stance phase loading. In this work, the stance phase of a gait cycle was only simulated in statics condition due to the fact that medical surgeons would not allow patients to experience full weight bearing after the surgery. The best practise in simulating the gait cycle was by applying all the phases. The next limitation was the axial load applied at the proximal tibia bone. The value of 50% of patient’s weight was taken from previous study in which the load from Achilles tendon force was only simulated during the stance phase condition (Simkin, 1982). Meanwhile, other forces from other muscles such as longus (peroneus, flexor digitorum, flexor halluces) and peroneus brevis were not considered in this study due to low magnitude of forces.

For the development of tibia bone, it was based on the CT images from a healthy person where the fracture was constructed later on. This process was another limitation of this work. It was strongly suggested that patient-specific condition should be used to model transverse tibia fracture in the future. Furthermore, the development of 3D tibia model was only simplified by applying Hounsfield unit (HU) at 700 to differentiate cortical and cancellous bone. To date, a technique called as micromechanics-based determination of voxel-specific Young’s modulus and Poisson’s ratio should be considered in 3D model tibia bone. For the results, von Mises stress was simulated for evaluating the failure criterion of bone (Fig. 2). There was no issue for stainless steel external fixator (Fig. 3) since the characteristics of that particular material were isotropic, linear and homogeneous. However, the bone itself was not steel due to the characteristics of bone failure could be known as water-induced ductile and followed by rupture of collagen crosslinks (Fritsch et al., 2009). Therefore, it was suggested that the failure characteristics to be analysed via Mohr-Coulomb failure criterion. Nevertheless, our results on von Mises stress were still acceptable after considering above limitations and assumptions as demonstrated by other scholars (Chen et al., 2012; Cheung et al., 2006; Haraguchi et al., 2009; Izaham et al., 2012; Kim et al., 2011).

Other limitation in this study was the design of external fixator. The development of external fixator was not considered the pin thread, rod thread and clamp thread. The external fixator was only developed by considering one single body which was another simplification due to computer resources. Future studies should develop a very detail of external fixator in giving off better findings.

CONCLUSION

This study has been successfully conducted where the main aim was to evaluate the fixation techniques of external fixator to treat transverse tibia fracture. Based on the obtained results, the Fixation 2 was considered as the best technique where the pin placement was located and penetrated until the second cortex of cortical bone to allow full weight bearing for patients. On the other hand, if medical surgeons applied the Fixation 1, extra care should be considered in allowing patients to stand alone due to high stress and displacement at both bone and external fixator. Therefore, to allow full weight bearing for patients, it was suggested that the Fixation 2 should be used.

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