Effects of bone-plate materials on the healing process of fractured tibia bone under time-varying conditions: a finite element analysis

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Abstract

Stress shielding is known to cause bone refracture or cause low healing rate in fractured bones. The numerical study of bone healing process of a transverse fractured tibia was conducted in this research to reduce the stress shielding. The stress and strain on the callus were evaluated when bone plates of different metallic and non-metallic biomaterials were used. Time varying material properties of the callus were applied, and loading conditions were coupled with material properties of the callus. The strain distribution on the callus, and the maximum stress on the callus and bone plate were analysed. The analysis results shows that Polyether ether ketone/Nano-Hydroxyapatite/Short Carbon Fibre (PEEK/nano-HA/SCF) is most suitable for bone plating application for tibia. PEEK/nano-HA/SCF is chosen as it provides the optimum strain in the callus to promote bone healing. It has the closest stiffness to the cortical bone and hence stress shielding is minimized extensively. It has a uniform strain distribution at the fractured site for early bone healing process.

1. Introduction

Bone is a natural tissue composed of inorganic phase crystals of calcium which consists of 30wt% of matrix, 60wt% of mineral and 10wt% of water [1, 2]. There are two types of bone tissues; cortical bone for which elastic modulus ranges from 17 GPa to 20 GPa, and cancellous bone for which elastic modulus ranges from 50 MPa to 100 MPa [2, 3]. Bone tissues are prone to fractures due to trauma, pathology, and resorption [4, 5]. One of the most fractured long bones in the body is located at the lower limbs, which is known as the Tibia, where it sustains most of the bodyweight. Thus, it is prone to fractures when excessive force is applied and is known to be one of the most fractured long bones in the human body where it contributes to a maximum of 37% of lower limb failure per year [6].

There are several treatments to heal fractured bones; external fixators, intramedullary nailing, internal fixation etc [7]. Internal fixation treatment has been practiced for more than a century by using plate and screw. Bone plate with fastening screws for anchorage has been used to prevent any motion of the fractured bone where segments of the fractured bone is held in position without allowing any tensile stress at the fractured area, but at the same time, allowing critical amount of compressive stress at the fracture segments to maximize healing of fractured bone [8]. This treatment has been used for simple fractured tibia and other long fractured bones [9, 10]. Bone plates used here are mostly made with metals such as stainless steel, titanium and its alloys [11, 12] and they are removed when the fractured bone is completely healed. Bones are made of biocompatible materials with sufficient mechanical properties to support the fractured bone [9, 13–15]. Nevertheless, its healing process is highly influenced by the initial loading conditions which lead to an improved treatment for bone fractures. To stimulates the healing of tissues. A gradual increase of load at the fractured site is advisable as the bone fracture...
healing progresses and the healing rate is in fact, partially dependent on the applied loading conditions to a bone region [16, 17].

Interestingly, at a reduced applied load, the bone tissue is known to lose its density and in the long run, this leads to bone osteoporosis [18]. Therefore, upon the removal of bone plate, there are instances where bone refracture occurs due to bone osteoporosis where the bone itself does not have sufficient strength to bear the loads. A study had demonstrated that the mismatch of the mechanical properties of bone plate and the fractured bone leads to bone brittleness during the healing process. This occurs when the bone plate has higher stiffness than the bone, where mechanical forces and stresses are retained and not being transferred to the fractured bone at healing. This is termed as stress shielding [18–21]. To aid the healing process, physicians engage the use of bone plates and screws. Figure 1 shows the transformation of force and moment to a fractured bone ranging from a low stiffness bone plate to a high stiffness bone plate.

In the healing process, the fractured site will be filled with callus and eventually transforms into bone over time. The different types of callus present in bone healing are central callus, peripheral callus and adjacent callus [22]. Soft callus normally forms at the fractured site at week 4 and to 8 weeks after surgery [23]. At 8 weeks after surgery, stabilization at the fractured gap are the main prioritization for further bone healing [24, 25]. According to Perren et al [22], the optimum gap strain range for callus to heal is between 0.02 to 0.10 whereas Christel et al [25] mentioned that week 4 is the most crucial time for callus to heal as it is in the soft callus form. An optimal environment is crucial to aid healing during the 4th week to 8th week post-surgery as soft callus transforms into hard callus.

In previous studies, stress distribution on the specific areas during the healing of fractured bones like femurs, tibia and jaws under certain conditions have been investigated via finite element modelling [26–28]. As such, this modelling was used to investigate the stress analysis in stress shielding. Several approaches were explored in the investigation of stress shielding reduction in a fractured bone during the healing process. Among them are bone plate designs, types of fixation treatment, the number of screws used, configuration of the location of screws, materials of the bone plate [26, 29–31]. Of note, research had shown that for long bone fractures, stiffness-graded bone plates provides lower stress shielding compared to metal plates, as it provides higher compressive stresses in the fractured site and therefore, promotes better healing rate [32, 33]. In the previous studies, Elango et al [34] and Zhou et al [30] created a fractured bone model and studied the stress shielding effect based on stress of the bone plates through finite element analysis. Fractured gaps are created at the bone model. Zhou et al [30] had also studied the displacement at the gap of the fractured site to determine stress shielding using stainless steel, titanium, PEEK and Carbon/PEEK composite plates. Both authors demonstrated that lower stiffness bone plates like PEEK and Carbon/PEEK have reduced stress shielding at the fractured site. On the other hand, MoraRamirez et al [35], Barua et al [36], Kanu et al [37], and Fouda et al [38] had studied the stress exerted on the callus using different bone plate materials. MoraRamirez et al [35] and Kanu et al [37] had created a tibia bone

Figure 1. Illustration of the effect of force on the callus if high stiffness plate and low stiffness plate used.
model and a femur bone model whereas Barua et al.\textsuperscript{[36]} and Fouda et al.\textsuperscript{[38]} had used a cylindrical rod as the bone model. The calluses were evaluated in three different healing stages (1\%, 50\%, and 75\% healed callus) with respective to loading conditions. Bone plate materials such as stainless steel, titanium alloy, functionally graded Hydroxyapatite bone plate, and cobalt alloys and the corresponding stresses on the callus were evaluated. The studies had concluded that composite bone plates increase the stress in the callus and this, in fact, aids the healing process. Interestingly, Kabiri et al.\textsuperscript{[39]} had created a glass fiber/polypropylene composite bone plate. Stress and strain pattern of the composite fixation plate were evaluated and assessed via the finite element analysis. The assessment had shown that lower modulus glass fiber/polypropylene composite bone plate can indeed reduce stress shielding in the bone.

The aim of this research is to comprehensively understand and study the effects of thirteen different biocompatible bone plates on callus healing. Stress shielding will be evaluated based on the stress and strain on the callus in multiple timeframes i.e., 4 weeks, 8 weeks, 12 weeks, and 16 weeks. In addition, the correlation of bone plate stiffness and its effect on callus healing will be studied too. Lastly, based on our assessment and analysis, the most suitable material for the bone plate will be recommended to promote callus healing.

2. Materials and method

The research method in evaluating the suitability of the bone plates for fractured tibia is shown in figure 2. The development of a 3-Dimensional (3D) bone model involves the conversion of Computed Tomography (CT) images into a 3D bone model using various techniques including segmentation, surface editing, meshing. After validating the bone model using mesh density, a fracture gap was created with the presence of callus and a bone plate was attached to the fractured bone. Then, the appropriate loading condition was applied. After simulation, the stress and strain of the callus and the stress of bone plates were studied. CT scan image of a 60 kg, 59-year-old woman was acquired from Visible Human Project. It was in Digital Imaging and Communications in Medicine (DICOM) format with 1 mm thickness per slice at resolution of 512 $\times$ 512 pixels. Image processing software ITK Snap was used to build the 3D tibia model as shown in figure 3.

To extract the bone from other tissues, the threshold of the model was set to 226 to 1956HU. The left-tibia model was reconstructed using region growing and segmentation. Segmentation growing feature was used to fill up the holes of the tibia bone. Point cloud file was then imported into Geomagic Design X as shown in figure 4. After that, mesh build wizard feature was used to create the geometrical surface of cortical and cancellous bone as shown in figure 5. The length of tibia was 334 mm. After creating the 3D model in Geomagic Design X, the model is then exported into Hypermesh to create a 3D solid model. Three dimensional 10-node tetrahedral elements with 2 mm size (SOLID 187) were used to create the solid model, which consists of cortical bone and
cancellous bone. After meshing, the model is then exported into Ansys Workbench for validation to ensure the accuracy of the bone model before proceeding to the creation of the fractured tibia model [29, 40].

### 2.1. Validation of meshed model

Before creating the fractured bone model, an unfractured tibia bone model was done and validated to ensure the accuracy of the bone model. The mesh model of healthy tibia was validated through four-point bending using ANSYS Workbench. The loading conditions and support are shown in figure 6 [41].
Four-point bending on anteroposterior plane and lateromedial plane and the stiffness were observed accordingly. The deflection of the bone model was measured from mid-diaphyseal (figures 7 and 8).

The stiffness obtained from the numerical simulation were compared with the literature reported by Cristofolini [42] as shown in table 1. The current numerical simulation results are well within the values reported.

2.2. Creation of the fractured tibia model

After the bone model was successfully validated, the fractured tibia model was created. A gap of 1 mm was created to build a fracture at the middle shaft of the bone. The gap was then filled with callus. The complete 3D bone model in IGS format was then exported to Hypermesh. A generic bone plate model of 4.5 mm plate with dimensions of 141 mm in length, 13.5 mm in width and 4.3 mm in thickness and with 8-holes was used. The
bone plate was attached to the medial side of the bone model through translation and rotation feature. After assembly, meshing was done for parts. Three dimensional 10-node tetrahedral elements (SOLID 187) with 2 mm size were used in the meshing of the cortical bone, cancellous bone, callus, and bone plates. As for contacts, three dimensional 8-node surface-to-surface contact element (CONTA 174) was used as a contact element between bone plates and bone model as shown in figure 9. Furthermore, to obtain more accurate results, the element size of the callus was reduced to 1 mm. The total number of elements in the bone model is as follows: 52977 elements in cancellous bone, 104037 elements in cortical bone, and 773 elements in callus. After meshing, the bone model was exported into Ansys Workbench for loading and analysis.

2.3. Material properties of the bone, plates, and callus
The material properties were input based on the characteristic of bone, and respective implants used. For instance, anisotropic material properties were applied for cortical bone whereas isotropic material properties was applied for cancellous bone [43, 44]. Anisotropic material model used for cortical bone represents \( E_x \) is in lateral-medial direction, \( E_y \) is in the anterior-posterior direction, and \( E_z \) is longitudinal z direction of the bone. Figure 10 shows the anterior-posterior and lateral-medial direction on the tibia bone. Three types of tissues viz central callus, peripheral callus and adjacent callus were generated to study the healing process [22]. The properties of callus were defined as shown in table 2 [23].

Ten different biocompatible materials with different mechanical properties were investigated and they include titanium, stainless steel (SS), Plain weave glass/polypropylene composite (Twintex), Polyether ether ketone reinforced with short carbon fiber and Nano-silicon dioxide (PEEK/SCF/nano-SiO\(_2\)), PEEK reinforced with Carbon nano fibre (PEEK/CNF(15wt%)) composite, PEEK reinforced with Multi-walled carbon nanotubes (PEEK/MWCNT(10wt%)) composite, neat PEEK reinforced with Nano-hydroxyapatite/short carbon fibre (PEEK/n-HA/SCF), Polyphenylene sulfide reinforced with Aluminium Oxide (PPS/Al\(_2\)O\(_3\)) composite. The mechanical properties of these materials were tabulated in table 2.

2.4. Contact and loading conditions
Tibia bone was analyzed under axial compression loading. The distal end of the tibia was fixed in all directions. As for load, patient’s body weight of 60 kg was considered. For force distribution, 60% of load was applied on medial side and 40% of the load was applied on the lateral side of the tibia as shown in figure 11 [49, 50].

The contact condition of the model was bonded. Loading condition was gradually increased from 4th week to 12th week. At 4th week, 10% of body weight was used to simulate the partial weight bearing. This was to simulate that the patient is not walking using the fractured leg.
Table 2. Material properties of bone plates and bone.

| Material               | Composition of materials | Elastic modulus (MPa) | Shear modulus (MPa) | Poisson ratio |
|------------------------|--------------------------|-----------------------|---------------------|---------------|
| Cortical Bone [44]     | —                        | $E_x = 8500$          | $G_{xy} = 3500$     | $\nu_{xy} = 0.141$ |
|                        | —                        | $E_y = 700$           | $G_{xz} = 5060$     | $\nu_{xz} = 0.065$ |
|                        | —                        | $E_z = 18400$         | $G_{zx} = 3500$     | $\nu_{zx} = 0.099$ |
| Callus (4th week) [23] | —                        | 0.19                  | —                   | 0.3           |
| Callus (8th week) [23] | —                        | 28                    | —                   | 0.3           |
| Callus (12th week) [23]| —                        | 30.6                  | —                   | 0.3           |
| Callus (16th week) [23]| —                        | 75                    | —                   | 0.3           |
| Trabecular Bone [44]   | —                        | $E = 1.061$           | $G = 440$           | 0.225         |
| Stainless Steel [43]   | —                        | $E = 19300$           | $G = 74230$         | 0.3           |
| Titanium [43]          | —                        | $E = 55000$           | —                   | 0.3           |
| Twintex [0] T [44]     | Glass fibre (50%), Polypropylene fibre (50%) | $E_x = 5300$ | $G_{xy} = 1660$ | $\nu_{xy} = 0.098$ |
|                        |                          | $E_y = 20000$         | $G_{xz} = 1660$     | $\nu_{xz} = 0.098$ |
|                        |                          | $E_z = 20000$         | $G_{zx} = 1790$     | $\nu_{zx} = 0.120$ |
| PEEK (85%) [45]        | CNF (15%)                | $E = 7000$            | —                   | $\nu = 0.40$ |
| PEEK (90%) [46]        | MWCNT (10%)              | $E = 4900$            | —                   | $\nu = 0.40$ |
| PEEK (55%) [47]        | Nano-HA (20%), SCF (25%)| $E = 16500$           | —                   | $\nu = 0.40$ |
| PEEK (78%) [48]        | SCF (20%), Nano-SiO$_2$ (2%) | $E = 13000$    | —                   | $\nu = 0.40$ |
| PPS (95%)              | Al$_2$O$_3$ (5%)         | $E = 2570$            | —                   | $\nu = 0.35$ |
| PPS (90%)              | Al$_2$O$_3$ (10%)        | $E = 2665$            | —                   | $\nu = 0.35$ |
| PPS (85%)              | Al$_2$O$_3$ (15%)        | $E = 2873$            | —                   | $\nu = 0.35$ |

10% bodyweight was considered because of presence of muscle forces. 85% of bodyweight was simulated 8th week, in which patient start to walk but not with full pattern gait. 95% of bodyweight was applied at 12th week, and 100% of body weight was applied at 16th week [51].

Due to the nature of the bone plate assembly and the loading condition, the bending deflection was observed. Hence, gap strain differed along the path distance of the callus. Path distance of callus is shown in figure 12. The gap strains are calculated and analyzed.

2.5. Numerical analysis

The deformation on the fracture site was measured for 4th week, 8th week after surgery, 12th week after surgery, and 16th week after surgery. The gap strain was analysed based on the path created on the callus. Gap strains were calculated as in (1), where $t_{gap}$ is the gap thickness and $t$ is the original thickness. As the deformation on the callus increases, the gap strain also increases. The callus area, and stress distributions were also observed and evaluated. The strain and stress of the callus will be studied when the bone plate is made of different materials. The results are categorized in week 4, week 8, week 12 and week 16. Stress and strain of calluses from ten different...
bone plates were extracted and analysed in each specific week. The results are tabulated and plotted.

\[
\frac{t_{\text{gap}} - t}{t_{\text{gap}}}
\]

(1)

3. Results

3.1. Strain on the callus

3.1.1. 4 weeks after surgery

The callus plays an important role in bone remodelling. At 4 weeks post-surgery, soft callus is formed at the fracture site. As healing continues, the callus will be strengthened, and more stress will be transferred to the callus when patient is able to walk. The purpose of providing the optimum environment for callus healing is to increase the healing rate and promote union healing, in which union healing will be preventing refractures in the future after bone plate removal. In figure 13, the shaded region represents the most appropriate strain, which is 2%–10% for the healing of the callus. From the numerical simulations, gap strains on the path distance which are in the shaded region at the callus were calculated and listed in table 3.

Based on the results, PPS composite and PEEK composite tend to increase the gap strain in the callus. The strain along the path on the callus by using bone plate made of PPS polymer composites are the highest among all and exceeding the optimum gap strain (0.02–0.10) starting from 4.7 mm of the path distance. On the other hand, the strain along the path on the callus by using bone plate made of stainless steel and titanium bone plate is the lowest, which most of the values are lower than optimum strain region (0.02–0.10). For bone plate made of PEEK/nano-HA/SCF and PEEK/SCF/nano-SiO\(_2\), majority of the strain values along the path distance on the callus lies within the shaded region. Furthermore, PEEK/nano-HA/SCF provides optimum strain starting from 0.7 mm of the path distance to 19 mm, which optimum strain region covers that majority of the area in the callus. PEEK/SCF/nano-SiO\(_2\) comes in second, in which the optimum gap strain starts from 1.9 mm in the path and covers the area until the end of the path. Whereas for Twintex [0]_{10}, the coverage of gap strain lies in the
shaded region and is lesser than PEEK/nano-HA/SCF and PEEK SCF/nano-SiO2, where the gap strain has exceeded the 2%–10% region starting from distance of 16.5 mm to 19 mm. The trend of the strain values along the distance of the path on the callus shows that the strain is the lowest at the initial position of the path distance which is located at medial side, and strain increases gradually when the distance moves to point 2 on the path which the location is further from the bone plate location.

3.1.2. 8 weeks after surgery

At 8 weeks post-surgery, the stiffness of callus increased from 0.19 MPa to 28.6 MPa [23]. Similarly, it was observed that the loading condition has increased from 10% to 85% of the patient’s bodyweight. Overall, the strains along the path on the calluses significantly decreased compared to week 4 when bone plate of different materials are used as shown on figure 14. Figure 14 shows the strain distributions on week 8. It is observed that the overall strains along the path distance are in the range of the shaded region (0.02–0.1). The major contribution to the decrease is due to the transformation from soft callus to hard callus in week 4 [25].

When bone plates made from PEEK/MWCNT, PEEK/CF, PEEK/SCF/nano-SiO2 and PPS materials which demonstrates lower degree of stiffness are used, tensile strain on the callus is present at the near side region of the bone plate. In contrast, the maximum strain values in the callus using PEEK/MWCNT, PEEK/CF composite and PPS composite are higher among all. In contrast, using PEEK/nano-HA/SCF and PEEK/SCF/nano-SiO2 with higher stiffness than other PEEK composites does not exhibit tensile strain along the callus. Additionally, Twintex and other bone plates with higher stiffness has lower coverage on the optimum strain region on the callus as compared to PEEK/nano-HA/SCF and PEEK/SCF/nano-SiO2. As shown in table 4, the path distance of optimum strain for PEEK/nano-HA/SCF and PEEK/SCF/nano-SiO2 is in the range of 4.7 mm to 19 mm, which is a significant increase as compared to other bone plates.

| Bone plate material | 2%–10% gap strain region (mm) |
|---------------------|-------------------------------|
| Stainless steel     | —                             |
| Titanium            | 17–19                         |
| Twintex [0]18       | 0–16.5                        |
| PPS/Al2O3 (5%)      | 0–4.7                         |
| PPS/Al2O3 (10%)     | 0–4.7                         |
| PPS/Al2O3 (15%)     | 0–5.13                        |
| PEEK/nano-HA/SCF    | 0.7–19                        |
| PEEK/SCF/nano-SiO2  | 1.9–19                        |
| PEEK/CF             | 0–12.6                        |
| PEEK/MWCNT (10%)    | 0–8.6                         |

Figure 13. Strain distributions on 4th week after surgery.
3.1.3. 12 weeks after surgery

At 12 weeks post-surgery, the stiffness of callus has slightly increased, from 28 MPa to 30.6 MPa. During the 8th week to 12th week period, the healing of the bone is more focused on the peripheral tissue and adjacent tissue \[23\]. Therefore, there are no significant decrease in strain in the central callus. As a comparison of gap strains for week 8 and week 12, they display similar characteristics in behaviour. The stiffness of callus and bodyweight load has increased from week 8. When using PPS composites, PEEK/MWCNT, PEEK/CF, and PEEK/SCF/nano-SiO\(_2\), tensile strain is still existing during loading as shown in figure 15. Figure 15 shows the strain distributions on week 12. Besides, the lower stiffness bone plate generated the highest strain on the callus whereas stainless steel generated the lowest strain value on the callus. The overall decrease in strain on all the callus shows that the patients can retain more stresses in the fractured bone. Hence, the overall maximum strain values along the path on the callus using bone plates made of different materials lies in the optimum gap strain values of 2% to 10% as shown in table 5, where the far side region from the bone plate on the callus has the highest strain. This is a sign of continuous healing.

3.1.4. 16 weeks after surgery

At 16 weeks post-surgery, the patient can walk with 100% bodyweight, and this bodyweight is applied onto the tibia. Figure 16 demonstrates that at week 16 post surgery, all the callus using different bone plates exhibit a significant lower strain compared to week 12, indicating the significance of callus healing. However, the tensile strain still exists in the callus when bone plates made from PPS and lower stiffness PEEK/MWCNT, PEEK/CF composites are being used. On the other hand, bone plates which display a higher degree of stiffness shows lower strain values on the callus as compared to lower stiffness bone plate. Additionally, there is no presence of tensile strain at the callus using high stiffness bone plate. At this point, it can be concluded that week 4 is the most crucial period for bone healing. In contrast, stabilization is more important starting from week 8 \[25\]. Beyond this
period, the factor of callus development is more on biological related mechanisms, which is out of scope of this article.

From the results obtained from week 4 to week 16, it is demonstrated that the strain on the callus decreases overtime which is mainly because of healing throughout this period which is also demonstrated \[43\].

### 3.2. Stress distributions on the callus

Stress distributions on the callus is critical parameter in healing of callus. Because insufficient stress on the callus due to stress shielding or excessive stress on the callus will slow down the healing rate as reported \[52\]. When bone receives stress from daily activities or external forces, it results in producing strain on the callus. The interaction of stress and strain provides insight into the mechanical behaviour of the callus in bone healing \[53\]. Hence, the stress is the key factor for establishing optimum strain for callus healing. To further demonstrate the effects of bone plate stiffness on the callus, the maximum von-Mises stress and stress distributions on the callus from week 4 to week 16 are tabulated and plotted as shown in table 6 and figure 17. Figure 18 shows the maximum stress generated in the bone plate which will be discussed further. Based on figure 17, the stress on the calluses in week 4 is the lowest. This is mainly due to the presence of soft callus which is occupying the fractured site in week 4 post surgery \[10\].

Since patients are not allowed to walk with a fractured leg during this period, the stress is relatively low. Among the bone plates, it is observed that PPS polymer composites made bone plates generate the highest amount of stress on the callus whereas a stainless steel made bone plate exerts the least stress among all. The maximum and minimum stress locations across all the calluses using different bone plates are identical (figures 19–22).
Based on the diagrams, the maximum stress location of the calluses is located at the lateral side region of the bone, which is at the far side region of the bone plate. In contrast, the lowest stress location at the callus is located at the medial side, which is at the near side region of the bone plate. At 8 weeks post-surgery, mechanical properties of the callus increase significantly; allowing the patient to walk, partially. The increase in the stress on the callus can be observed and likewise, its ability to sustain load increases. The increase in loading conditions and improvement of mechanical property of the callus contributes to the significant increase in the maximum stress on the callus when different bone plates are used. The stress distributions of the calluses on week 8 is identical to week 4 where the stress of the callus at medial side region of the bone is the highest while the stress of the callus at the near side region of the bone plate location is lower. It is observed that stainless steel made bone plates generated the lowest maximum stress while PPS composites made bone plates generated highest amount of maximum stress on the callus.

At 12 weeks post-surgery, there is a slight increase of the maximum von-Mises stress in the callus as compared to week 8. Likewise, the mechanical property of the callus has also shown improvement, and this indicates that the callus can sustain more load. During 8th week to 12th week post-surgery, the healing of the bone focuses more on the peripheral tissue and adjacent tissue [23]. Therefore, there are no significant decrease in the strain on the central callus. The trend of stress distribution across the callus using different bone plates are being compared. As discussed earlier, when load is applied, for all bone plates, it is observed that stress in the callus at the lateral side is the highest while stress is at its lowest at the medial side. When PPS polymer composite made bone plate is used, the stress generated across the callus are the highest as compared to the other bone plates, whereas stainless steel made bone plates generated the lowest amount of stress. At 16 weeks post-surgery,
the mechanical properties of the callus would have significantly improved from 30.6 MPa to 75.0 MPa [23]. Similarly, this implies that the callus is now able to sustain more load and hence the patient able to apply a 100% bodyweight percentage on the tibia bone. Since the callus can sustain more load, it is expected that more stress is generated on the callus. When bone plates made of materials like PEEK and PPS composite which exhibits a lower degree of stiffness, the stress on the callus at the medial side of the bone appears to be higher and stress appears to be lower at the center region of the callus. In contrast, when bone plates with a higher degree of stiffness is used, the stress distributions on the callus are more widespread and stress at the center region of the callus is lower.
callus is higher; and stress is lowest at the region of the callus at the medial side. Interestingly, the maximum stress location on the callus is identical for all the different bone plates, and this region is located at the lateral side of the bone.

Figure 20. Stress distributions of the bone plates at week 8 after surgery.

Figure 21. Stress distributions of the bone plates at week 12 after surgery.

Figure 22. Stress distributions of the bone plates at week 16 after surgery.
4. Discussions

The ideal internal fixation treatment creates a stable and a gradual body weight transfer to the fracture gap to assist bone healing [24]. When a bone plate is being incorporated during internal fixation, a non-uniform deformation will occur along the bone radial section when loading is applied [10]. The loading conditions applied on the bone will then affect the outcome of the rate of remodeling of the fractured bone [16, 17]. The main purpose of the entire healing process is to unify the gap of the fractured bone by filling it with mature bones. There are many parameters such as fracture angle, fracture gap, design, and properties of implants, loading conditions should be considered to improve the healing process [10, 24]. One of the major roles to ensure bone healing is structural stabilization of the fractured bone. Alierta et al [54] has presented a study on the outcome of the mechanical properties of the callus under different conditions of mechanical stability. The stabilization of the fractured bone can be described in stress and strain magnitude from the result of displacement along the axial movement during weight bearing. The primary mode of loading in tibia is bending. The amount of strain is depending on the bending rigidity of the bone model [55]. The study of strain and stress on the callus will provide a better understanding of mechanically controlled tissue differentiation process and how it affects the healing process [36]. Additionally, to relate the current work to stress shielding, Wolff's law's theory is used in discussion [52]. According to Wolff et al [52], bone remodeling is subjected to loading and stress. Bone subjected to stress will regenerate whereas bone which are not subjected to stress will undergo atrophy. A bone plate with a higher degree of stiffness will cause unphysiological distribution of force transmission, whereby most of the loads will be transmitted by the bone plate, while limited load will be transmitted by the fractured bone. When no load is borne by the bone tissue, it will lead to osteoporosis and the possibilities of refracture after bone plate removal [21].

Throughout the healing process, the first four weeks is the most crucial period, as this period determines the final healing condition of the callus [43]. However in week 8, Kim et al [10] mentioned that the stabilization of the bone plate comes to play an important role for bone remodeling. At week 12, there is no significant change in stress patterns at week 8 and week 12, as healing of the bone focuses more on peripheral tissue and adjacent tissue [23]. According to Gardner et al [23], the strain below 2% in week 16 will help to unite the fracture, since a low strain environment is more conducive to the maturation of hard tissues. In this case, bone plates of higher stiffness are more suitable as it provides lower strain at week 16. To improve healing of the callus, interfragmentary motion is also crucial. According to the results obtained in this study, the region of calluses at the lateral side which is located at the opposite side of the bone plate location tend to generate more stress. This is due to the bending of the bone plate when force is applied. As the stiffness of the bone plate decreases, the bending increases and this leads to a higher degree of maximum stress in the callus. This implies that the degree of bending of the bone plate itself correlates with the stiffness of the bone plate. On the other hand, the interfragmentary motion of the cortical bone near to the bone plate are lower compared to the cortical region at the lateral side of the bone. According to Zhou et al [30], stress shielding happens when more stress is transferred to the bone plate instead of the callus. The decrease of stress in the callus happens when more stress is transferred to the bone plate. This phenomenon is also clearly observed in the current study.

This study aims to demonstrate the properties of bone plates of different materials and how they affect the bone healing process. As such, the stress and strain values exerted on the callus when these bone plates are incorporated during internal fixation, are taken into consideration as these factors plays a crucial role in the process. In this study, it is observed that PPS composites, PEEK/MWCNT, and PEEK/CF composite bone plates with stiffness ranging from 2.4 GPa to 7.0 GPa leads to an increase in the strain values on the callus, at which the strain values exceed the optimum strain region of 0.02 to 0.1. The high strain values on the callus when using the said materials bone plates indicates that the polymer composite bone plates are unable to resist the bending force when loading on the fractured bone is applied. This is due to the lower degree of bending stiffness of the bone plate in a higher loading condition. By comparing the maximum stress generated on the calluses using different bone plates, PEEK/MWCNT, PEEK/CF, and PPS composite bone plates generates 250% more stress on the callus as compared to stainless steel bone plate. It was observed that the stress and strain generated on the callus is excessive in week 4 compared to other bone plates. As this period is the most crucial period for bone healing, the optimal stress and strain values on the callus is of priority [10]. Therefore, it is of utmost importance to identify the most suitable material for this process. In addition, interfragmentary motion which includes both interfragmentary compression and interfragmentary tension play a role during the healing process. Therefore, in the situation when there is a decrease in the stiffness of the bone plate which lower its bending stiffness, an excessive interfragmentary motion is formed at the fractured site and this leads to a slower bone healing process [57].

To further elaborate on this, both interfragmentary motion affects the bone healing process differently. The presence of interfragmentary tension, in fact, distracts callus formation and thus, leads to lower bone formation and slows down the bone healing process. This phenomenon is observed in the callus when lower stiffness bone
plates are used [58]. On the other hand, intriguingly, interfragmentary compression provides the best stimulation for callus healing [7, 58]. Interfragmentary compression occurs when higher stiffness bone plates such as stainless steel, titanium, PEEK/nano-HA/SCF, and Twintex are being used as demonstrated in this study. The optimal strain of 0.02 to 0.1 is known to promote optimum healing of the callus [58]. However, in this study, when bone plates of higher degree of stiffness like Stainless steel (191 GPa), Titanium (55 GPa) are being used, the strain of the callus is lower than 0.02, which is unfortunately not out of the optimal strain range. As such, the optimal bone healing process is affected since the interfragmentary motion is insufficient to promote healing. In contrast, the strain on the callus using bone plate made of PEEK/nano-HA/SCF, and PEEK/SCF/nano-SiO₂ falls in the optimum range, which will be further discussed below. In general, a healthy tibia bone carries the external load exerted on it by itself during normal activities. However, a bone plate is introduced to heal the fractured site, and in this scenario, the load exerted is shared amongst the bone plate and the bone. When a stiffer bone plate is attached, the stress and strain on the callus is lower, and this is not the optimum environment for bone healing. In contrast, when a bone plate with lower stiffness is introduced, the stress and strain on the callus is higher, and this helps exerts a relatively higher amount of stress and strain on the callus which promotes bone healing [59]. In figure 16, the stress transmitted in the Stainless steel and Titanium bone plate itself during loading is significantly higher than other bone plates. Hence, the bone is subjected to lower stress and stress shielding occurs. As a comparison to other lower stiffness bone plates such as PEEK/nano-HA/SCF and PEEK/SCF/nano-SiO₂, and they provide optimum strain values which is within the 0.02 to 0.1 region for optimum healing. The strain region is the optimum condition to promote more callus formation and union healing [22]. Since the strain exerted lies in the optimum region, this shows that using PEEK/nano-HA/SCF and PEEK/SCF/nano-SiO₂ bone plates will lessen the stress shielding of the fractured bone.

Furthermore, PEEK/nano-HA/SCF and PEEK/SCF/nano-SiO₂ are the best candidates among the materials used for bone plating application. As in between the two materials, PEEK/nano-HA/SCF would be preferable as it provides more coverage on optimum strain region to promote healing. The reason is due to the lower mechanical properties of PEEK/SCF/nano-SiO₂ (13 GPa) as compared to PEEK/nano-HA/SCF (16 GPa). Furthermore, Kohn et al. [60] mentioned that implants which has a modulus similar to cortical bone will result in a more uniform stress distribution and stress transfer across the implant and the bone. It is demonstrated that PEEK/nano-HA/SCF provided the best environment in terms of strain and stress to promote bone healing, where this stiffness is indeed closer to the cortical bone (18.4 GPa) as compared to other bone plate materials in this study. As compared to higher stiffness bone plate, the stress in callus using PEEK/nano-HA/SCF is higher as compared to the stress in the callus using stainless steel bone plate, which proves that the stress transfer to the callus is higher when lower stiffness bone plate is used. The higher stress transfer to the callus can reduce the stress shielding and promote more healing in the callus. The second candidate would be PEEK/SCF/nano-SiO₂ as it also provides optimum strain in the callus along the path, however at week 12 the tensile strain exists in the callus area near to the bone plate location due to excessive bending of bone plate during loading, therefore the said region will have lower healing process as it is not in the optimum strain region.

In summary, a higher stiffness bone plate such as those made from Stainless steel (190 GPa), Titanium (55 GPa) has a significantly higher degree of stiffness than the cortical bone (18.4 GPa) has low strain on the callus, where this leads to most of the stresses being transmitted to the bone plate but not to the callus as seen in figures 16 and 17. In contrast, bone plates made from PPS and PEEK composites has a lower degree of stiffness causes excessive strain to the callus, where too much stress is transmitted to the callus due to excessive bending of the bone plate. Of all the materials being investigated in this study, it is found that bone plates made from PEEK/nano-HA/SCF is the most suitable material to be used for a bone plate to promote bone healing as it provides optimum strain throughout the healing period. Meanwhile, bone plates made of PEEK/SCF/nano-SiO₂ comes in second, as mentioned above. Hence, it is concluded that PEEK/SCF/nano-SiO₂ bone plate provides the best environment for fractured bone healing and helps to reduce the stress shielding effect to prevent further complications of bone refracture after bone plate removal.

As a comparison of this study with previous work done by other researcher, Kim et al. [43] has done a thorough research on choosing the suitable bone plate for fractured bone healing. As a comparison, there is a slight difference on the maximum strain value on the entire period. This is due to the difference in bone model, bone plate model, and loading conditions. The author has used 3-D cylindrical rod as the bone model, whereas in this research CT scanned bone model is used. On the other hand, the difference of bone plate design has contributed to the factor of result difference. The strain values found in the current study are lower than the previous works. Previous works have used assumptions of applied load force on the tibia from week 8 to 12 while in the current study, 85% of body weight was used on week 8, and 95% of weight bearing force was used on week 12. On the other hand, Zhou et al. [30] has determined the suitable bone plate material to reduce the stress shielding as compared to stainless steel bone plate. PEEK/CF is chosen in that study and the material is chosen based on the displacement at the bone fractured site during loading. In this study, the weight bearing force used was similar to Joslin et al. [51] where data has been obtained from patients recovering from fractured tibia.
Although there are differences in values, the behaviour in callus healing is identical to the results in this study which shows the decreasing trend in strain over the period of healing.

5. Conclusion

This study has investigated the effect of stiffness of bone plates on the healing of the callus. The investigation was performed on the tibia bone model through finite element analysis. Gap strains and stresses on the callus were evaluated from week 4 to week 16 and the bone plates. The results showed that PEEK/nano-HA/SCF provides the best condition for early callus generation especially at week 4 which is crucial for initial bone healing. The strains on the callus using the specific bone plate are in optimum gap strain region (2%–10%). Interfragmentary tension which slows down healing of the fractured bone are present on the callus when lower stiffness bone plate such as PPS and PEEK composite bone plate are used. It is due to excessive bending stiffness of the bone plate. It is understood from stress distributions analysis that, composite bone plates are shown to have relieved stress shielding effects by transferring more stress onto the callus. This would prevent osteoporosis, and chances of refracture. If a lower stiffness bone plate is being used, it will lead to excessive stress on the callus whereas higher stiffness bone plate will lead to insufficient stress on the callus. PEEK/nano-HA/SCF has modulus of closer to cortical bone, which provides a better environment with proper stress and strain. The presented results delivered useful information on selection of materials for bone plate for improved fracture healing and avoidance of refracture.

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Data availability statement

The data generated and/or analysed during the current study are not publicly available for legal/ethical reasons but are available from the corresponding author on reasonable request.

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