

A finite element study of a fractured tibia treated with a unilateral external fixator: The effects of the number of pins and cortical thickness

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ABSTRACT

Introduction: In the early stage of fracture fixation, the aim of a unilateral external fixator (UEF) to stimulate healing and maintain stability may be suppressed by using inadequate number of pins. Cortical thinning due to age or osteoporosis endangers a successful fracture fixation.

Materials and methods: This study evaluates the initial strength and stability of the fracture fixation and tissue differentiation under the influences of variable cortical thickness (5 mm to 1 mm) and variable number of pins (1 to 4 in each bone fragment). A finite element program was utilised to develop 20 three-dimensional models of simplified diaphyseal tibia with fracture callus fixed with UEF. A mechano-regulation code based on the deviatoric strain theory was written and applied to simulate tissue differentiation. The values of von Mises stress, interfragmentary strain (IFS), and fibrocartilage index (FCI) were evaluated.

Results: Cortical thinning from 5 mm to 1 mm increased IFS and FCI by an average of 30.3% and 18.7%, respectively, and resulted in higher stresses in the UEF and bone. Using 1 pin in each bone fragment produced excessive IFS in the models with 1 mm, 2 mm and 3 mm cortical thickness. Inserting the second pin into the bone fragment could considerably reduce the IFS and fibrocartilaginous tissue formation in the fracture site and improve load transmission to the fixator. Whereas inserting the fourth pin could minimally affect the mechano-biological environment of healing.

Conclusions: This study suggests that initial instability due to cortical thinning can be efficiently alleviated by adding the number of pins up to 3 in a UEF; additionally, it may improve the knowledge about applying UEFs adequately stable, whilst promoting inclination toward endochondral ossification, simultaneously.

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Introduction

External fixators are widely used as a provisional treatment for patients with severe open fractures and in the environment of damage control orthopaedics [1,2]. They can provide initial stability with less dissection through the fractured area, enabling soft tissue recovery prior to definitive treatment [3,4]. Definitive treatment of closed tibial fractures using external fixation can be considered a method of fracture repair when there is a need to manage severe soft tissue injuries, compartment syndrome, and patients with multiple injuries [5]. In orthopaedics, the main goal

for fracture fixation is to rapidly regain the bone's functional ability using a successful fixation method with minor complications. A successful fixation is defined as not being too rigid to initiate primary bone healing or too flexible, leading to delayed healing or nonunion [6,7]. In the mechano-biological environment of fracture healing, both bone properties and fixator's characteristics affect the initial mechanical stability and, therefore, the quality of the healing outcome [8,9]. Recent studies showed that insufficient mechanical stability of the external fixation leads to secondary displacement, delayed healing, nonunion, and most commonly, pin tract infection [10–14]. Also, it was reported that the decline in bone cortical thickness during senile osteoporosis due to ageing is considered a challenge in preserving the capacity for successful healing and initial mechanical stability [15,16].

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Since the number of pins in a UEF is one of the critical parameters affecting the stability of the construct [1], a number of studies evaluated the effects of variable number of pins on the structural stability and the course of healing [6,17–19]. Wu et al. [6] investigated the influence of the rigidity of external fixation on osteotomy healing by comparing four-pin and six-pin unilateral external fixators. The study reported that less rigidly four-pin configuration provided weaker osseous tissue but more periosteal callus, allowing for a stronger structure [6]. Briggs and Chao [17] obtained that the incremental increase of the external fixator stiffness resulted by adding pins decreased remarkably when the number of pins in the fixator exceeded eight. On the other hand, adding the number of pins creates portals for infection and causes damage to the bone and soft tissue [1].

In addition to the inadequate number of pins, cortical thinning can also increase the risk of implant failure [20]. Donaldson et al. [19] revealed that cortical thinning due to age or osteoporosis increases the incidence of pin loosening, which can be alleviated by adding the number of pins from 2 to 3 in either bone fragment. Furthermore, the decline in the cortical bone's cross-section area produces excessive stress, leading to mechanical instability [21].

To the best of our knowledge, no study has been conducted yet to investigate the influences of the cortical thickness (T) and the number of pins (P) in a UEF on the mechano-biological environment of the fracture healing using a mechano-regulation algorithm. In this study, the finite element (FE) analysis, in conjunction with a mechano-regulation algorithm, simulated tissue differentiation in the initial stage of a tibial fracture healing in which deviatoric strain acts as a single stimulator. This study aims to answer two questions: How does adding pins of a UEF affect the mechano-biology of healing? How does an aged osteoporotic fractured bone react to the variable number of pins in a UEF? As the external fixation method has experienced a resurgence [22], the information provided in this effort may have important implications in minimising the complications of externally fixated fracture healing.

Materials and methods

In order to evaluate initial healing performance along with initial fracture stability and strength, three-dimensional (3D) FE models were developed using a FE program, Abaqus 6.14–2. In this comparative study, the tibial diaphyseal fractures were fixed with the UEFs, in which P and T were determined variable parameters. A Python user's subroutine was created based on the mechano-regulation theory proposed by Isaksson et al. [23], utilised in conjunction with FE modelling to simulate tissue differentiation during the initial healing process.

A human diaphyseal tibia was modelled as a cylinder with a 25 mm outer diameter, 300 mm length [24], and variable cortical thickness of 1, 2, 3, 4 and 5 mm, since the loss of cortical thickness is one of the contributing factors in bone osteoporosis (Fig. 1). The 5 mm thickness was assumed to belong to a young and healthy tibial cortex, but an old osteoporotic tibia was deemed to have 1 mm cortical thickness. A transverse bone fracture was modelled as a 3 mm gap at the midheight of the tibia [25]. The fracture gap was filled with a 3 mm thick disk simulating internal callus in which the outer diameter and the intercortical thickness dimensions are similar to those of the bone shaft. The external callus model was considered to have an oval shape with a callus index of 1.4 [25] and 41 mm extension along the periosteum [26]. The two bone fragments were fixed with a UEF, comprising a single longitudinal stainless steel rod of 11 mm and 300 mm dimensions [27] that was connected to the bone via 5 mm and 175 mm stainless steel pins [28] (Fig. 1). The pins were inserted into the

bone fragments with a distance of 26 mm between them, whilst the number of pins can vary from 1 to 4 in each bone fragment (Fig. 1). The adjacent pin to the fracture site was positioned at a 35.5 mm distance from the centre of the fracture gap. A single rod positioned 80 mm from the bone axis sustained the pins and bone fragments. The setup we used can be found in the previous studies [28,29]. Tie constraint was imposed on pin-bone interfaces; the same was imposed on pin-rod interfaces to simulate corresponding clamps. All the bone-fixator components were assigned linear elastic, isotropic and homogeneous materials presented in Table 1. A constant pressure equal to 25% body weight of a 75 kg adult was applied on the proximal end of the cortical bone to simulate initial partial weight-bearing, whilst the distal end of the bone was fully constrained [30].

A mesh convergence study was carried out to find an optimal mesh size for the bone and the fixator elements. A coarse element size was initially selected to mesh all parts. In each step, the element size was shrunk by half, and Abaqus calculated the specific outputs of this study. This process continued until the error in the results of the two subsequent steps became less than 2% [31]. The resulting global sizes were chosen 1 mm for callus elements and 2 mm for the rest, all with C3D4 elements. The number of elements generated for bone, calluses and rod is variable within 110,242–125,212, 76,187–77,979 and 20,739–21,391, respectively, due to the variable parameters P and T, whilst 3411 elements were created for each pin.

In order to prove the reliability of the calculated mechanical stimuli, the FE modelling was validated against an experimental study proposed by Ang et al. [32]. The suggested bone and UEF construct were accurately modelled; however, the synthetic tibia was simplified to a cylinder with an averaged outer diameter, whilst the length and inner diameter of the bone was modelled identically. By simulating axial loading and boundary conditions, the maximum stiffness induced in the bone was calculated as 519 N/mm, which in comparison with the stiffness achieved in that paper (528 N/mm), made a 1.7% error. Since the error was under 5%, our FE analysis could be considered biomechanically validated.

In this study, a mechano-regulation theory, which considers deviatoric strain as a single contributor to tissue formation, was implemented on the FE models to simulate the initial stages of bone fracture healing [23]. In the post haematoma phase, the early callus is assumed to be totally composed of granulation tissue, a conducive environment to forming new connective tissues [33]. After the modelling process, finite element analysis was carried out in the Abaqus program in two specific jobs; in the first, loading condition was applied, whilst no tissue differentiation had happened, and the callus contained 1 MPa granulation tissue. In order to assess the initial strength and stability of the bone-fixator construct, the maximum von Mises stress (Max.VMS) in the bone and the fixator components and the maximum interfragmentary strain (IFS) in the fracture site were calculated, respectively. As load is applied on the proximal cortex of the bone, two fragments get closer, and interfragmentary movement (IFM) is induced in the fracture site whereby, using Eq. (1), IFS can be calculated.

$$IFS\% = \frac{IFM}{gap\ size} \times 100 \quad (1)$$

Afterwards, in the second job, the principal strains (ε_1 , ε_2 and ε_3) were found for each element of the calluses. The Python code, which was created to simulate tissue differentiation in the fracture calluses, calculated the deviatoric strain using Eq. (2).

$$\varepsilon_d = \frac{2}{3} \sqrt{(\varepsilon_1 - \varepsilon_3)^2 + (\varepsilon_1 - \varepsilon_2)^2 + (\varepsilon_2 - \varepsilon_3)^2} \quad (2)$$

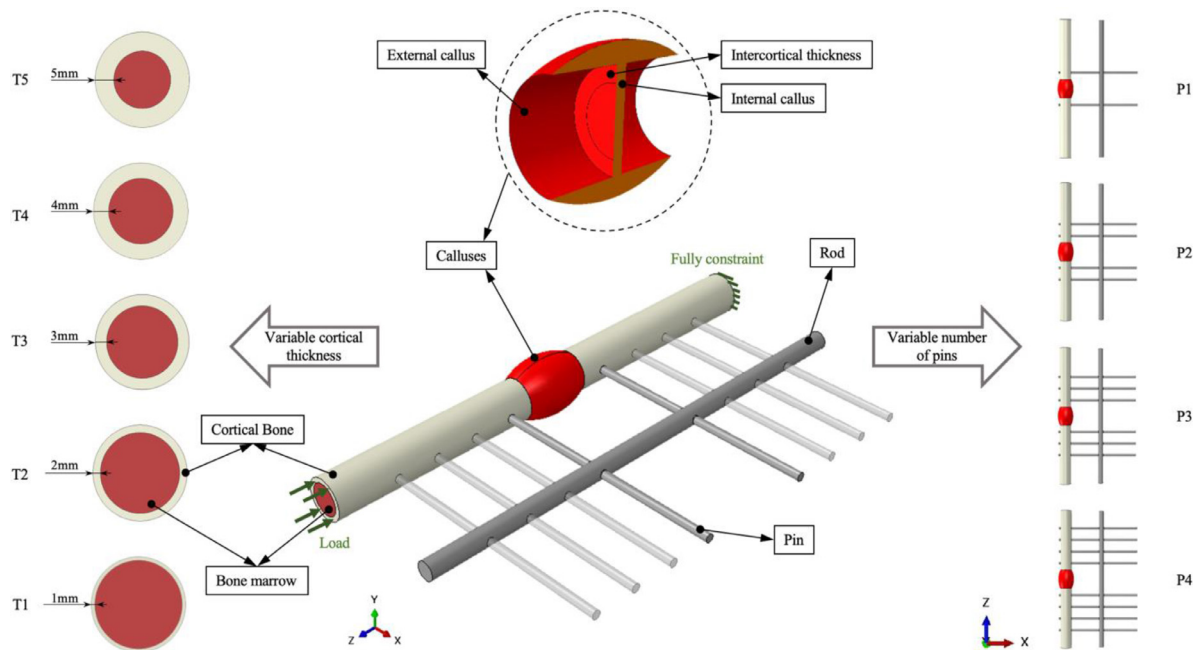


Fig. 1. Schematic view of the external fixation and fractured tibia bone system with the variable number of pins and cortical thickness.

Table 1
Material properties of the bone and the UEF.

Material	Young's modulus (MPa)	Poisson's ratio (MPa)	References
Cortical bone	20,000	0.3	[1]
Bone marrow	2	0.167	[1]
Granulation tissue	1	0.167	[2]
Stainless steel	200,000	0.3	[3]

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Table 2
Tissue phenotype and Young's modulus according to the deviatoric strain theory.

Deviatoric strain (%)	Young's modulus (Mpa)	Tissue type
$5 \leq \epsilon_d$	$1 < E < 5$	Fibrous tissue
$2.5 \leq \epsilon_d < 5$	$5 < E < 500$	Cartilage
$0.05 \leq \epsilon_d < 2.5$	$500 < E < 1000$	Immature bone
$0.041 \leq \epsilon_d < 0.05$	$1000 < E < 2000$	Intermediate bone
$0.005 \leq \epsilon_d < 0.041$	$2000 < E < 6000$	Mature bone

Finally, the Python code found the young's modulus and corresponding tissue phenotype of each element according to the algorithm's threshold shown in Table 2 [23,34]. The number of the predicted fibrous tissue and cartilage elements was calculated for each model to find out the fibrocartilage index (FCI), which explains the tendency of the fracture site to initiate healing through fibrocartilaginous callus formation (Eq. (3)). These two specified stages of FE simulation were conducted for 20 design cases distinguished by the variable parameters P and T.

$$FCI\% = \frac{\text{number of fibrous and immature and mature cartilaginous elements}}{\text{total elements of the calluses}} \times 100 \quad (3)$$

Results

von Mises stress (VMS)

A consistent rising trend of Max.VMS was observed in all components resulting from cortical thinning, but increasing the number of pins resulted in some variations in the stress amounts (Fig. 2a-c). Owing to cortical thinning from 5 mm to 1 mm, the Max.VMS produced in the bone increased by 334.7% for P1 models, whereas for the models secured with greater number of pins ($P > 1$) increased with an average of 77.2% (Fig. 2a). Changing the number of pins from 1 to 2 in each bone fragment of different thicknesses significantly increased Max.VMS value in bone by an average of 968.8%, whereas changing the number of pins from 2 to 4 reduced that value by 31.9% (Fig. 2a). Fig. 3a and b show the VMS distribution in UEF's frame with the variable number of pins and the tibia bone with the thickest and thinnest cortex. For the bone, the Max.VMS (27.5 MPa) was observed in P2T1 at the pin-bone interface (Fig. 3b). For the fixator's frame, the highest VMS was found in the pin for all the models; thus, the pin was defined as a critical component determining the initial strength in the UEF (Fig. 2b and c). For all models with variable number of pins, cortical thinning (from 5 mm to 1 mm) increased the stress value by an average of 24.3% in the pin. In

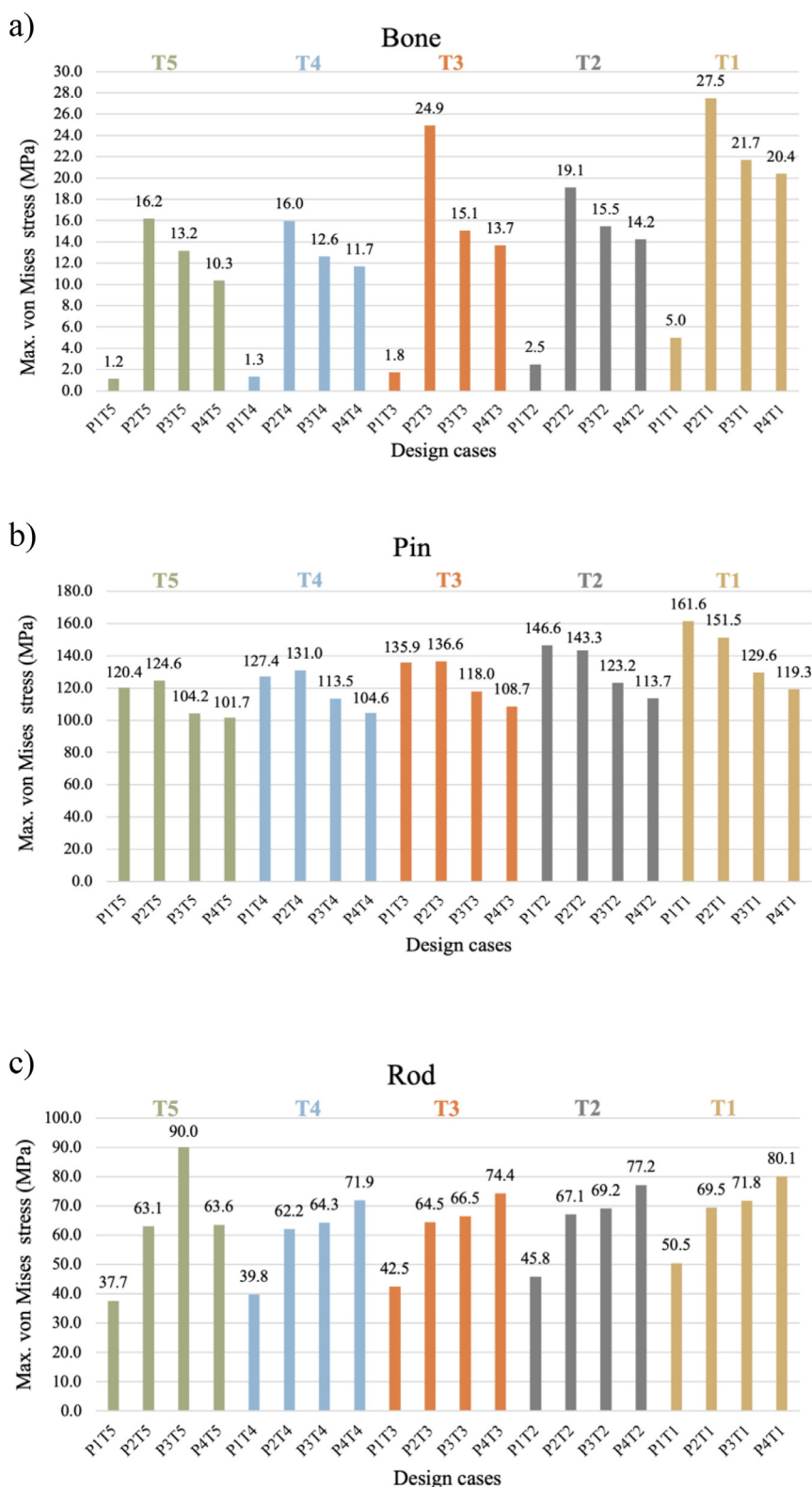


Fig. 2. Max. von Mises stress values in the a) Bone, b) Pin and d) Rod.

comparison, an average of 20.4% reduction was observed for the Max.VMS in pin when the number of pins rose from 1 to 4 in the models of different cortical thicknesses (Fig. 2b). In the fixator’s frame, the Max.VMS was found in P1T1 model with 161.6 MPa (Fig. 3b).

Interfragmentary strain (IFS)

As shown in Fig. 4, the IFS percentage decreased by increasing pins, but a loss of cortical thickness resulted in a rising trend in IFS values. There was a considerably higher reduction in IFS

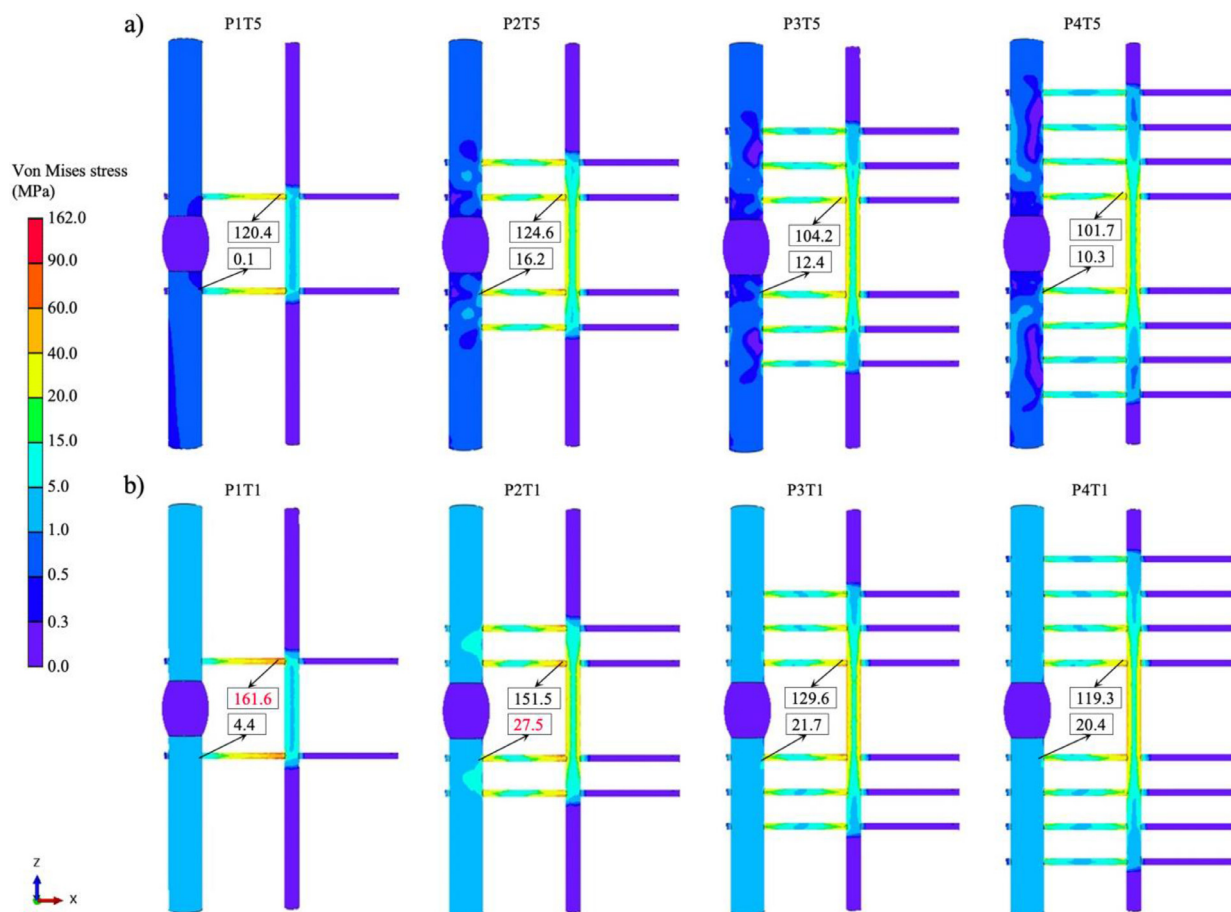


Fig. 3. Comparing von Mises stress contours in the UEF and the tibia bone a) with 5 mm cortex (thickest) and b) with 1 mm cortex (thinnest).

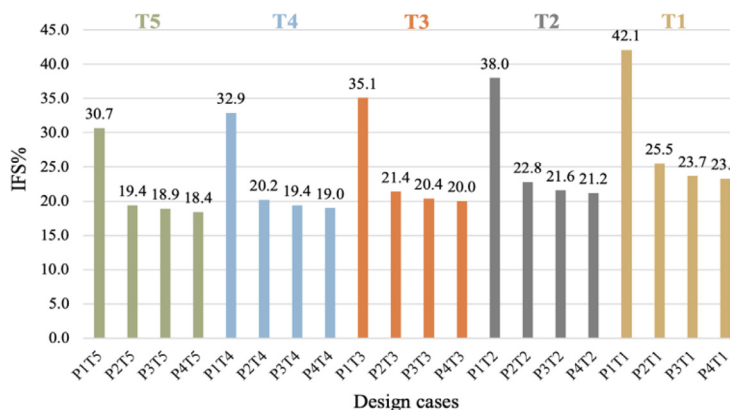


Fig. 4. The effects of the number of pins (P) and cortical thickness (T) on IFS.

percentage with an average of 38.7% when the number of pins in each fragment of different thicknesses rose from 1 to 2 as compared to the situation when the number of pins rose from 2 to 3 (4.8%) and from 3 to 4 (2.0%). When 5 mm thickness was reduced to 1 mm, IFS increased by an average of 30.3% in the models with different pin numbers. The maximum IFS was found at P1T1 (42.1%); in contrast, the least was found at the P4T5 model (18.4%). Models P1T1, P1T2 and P1T3 produced IFS values of more than 33%, whilst others produced IFS values in the range of 18–33%.

Fibrocartilage index (FCI)

Fig. 5 illustrates that as cortical thickness decreased from 5 mm to 1 mm, FCI value increased by an average of 18.7% in the models with different pin numbers; on the other hand, the higher number of pins resulted in lower FCI values. A significantly higher reduction of 19.7% (by average) was observed when the number of pins changed from 1 to 2 in each fragment of different thicknesses, whilst there was a minimal reduction of 5.3% and 3.0% (by average) when the number of pins changed from 2 to 3 and 3 to 4, respec-

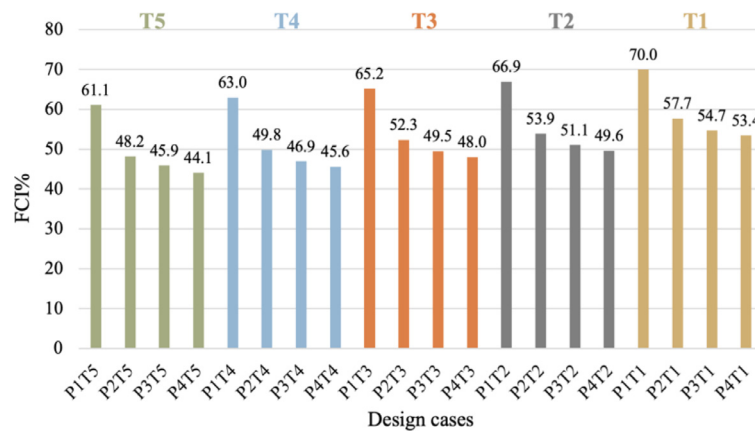


Fig. 5. The effects of the number of pins (P) and cortical thickness (T) on FCI.

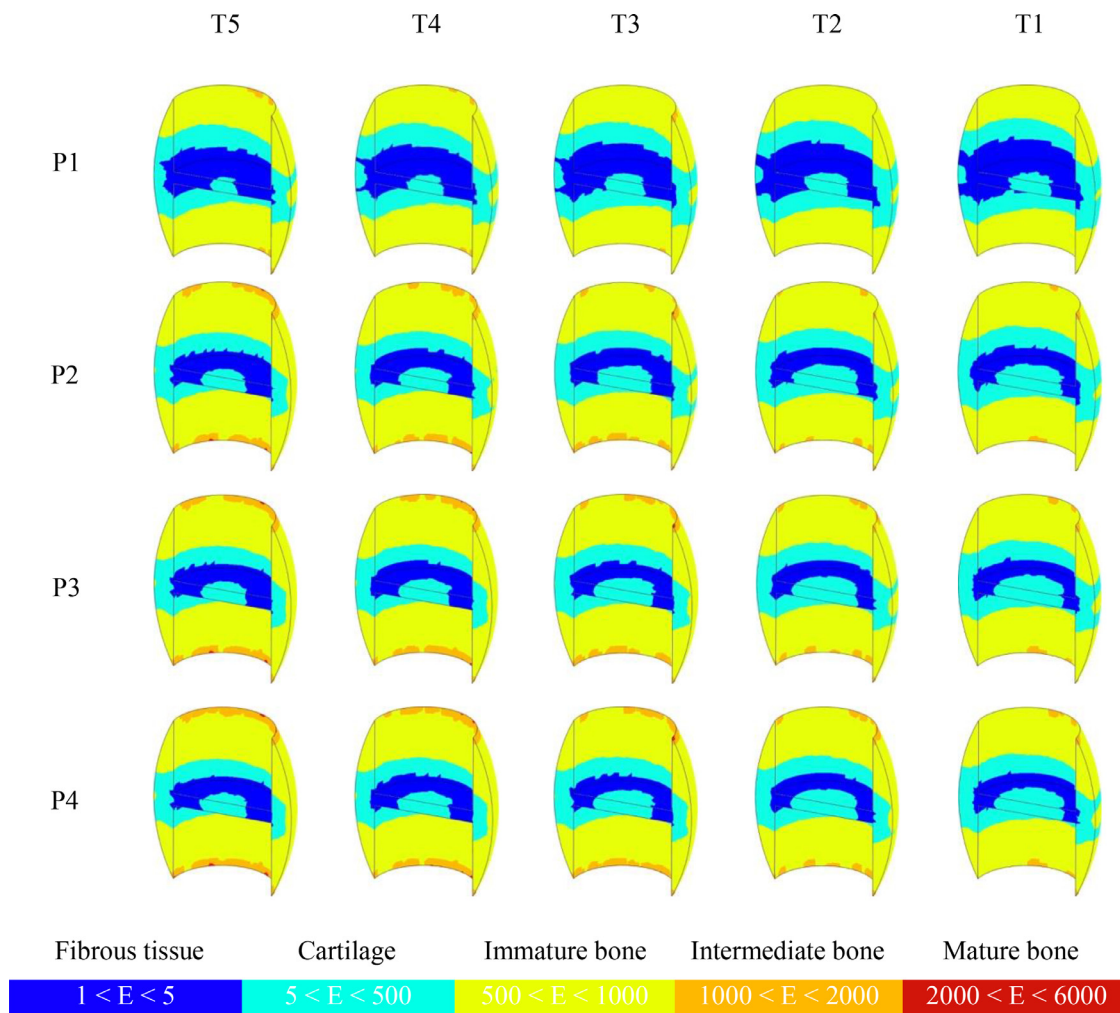


Fig. 6. The patterns of predicted tissue differentiation in the fracture calluses during initial healing stage.

tively. The highest formation of fibrocartilage was in model P1T1 with an index of 70.0%, whilst the lowest was observed in model P4T5 with that of 44.1%.

The models of predicted tissue phenotypes in the fracture callus under the different number of pins and cortical thicknesses during the early-stage healing is shown in Fig. 6. As expected, there was intramembranous bone formation in the external callus at some distance from the fracture site, cartilaginous tissue formation in the external callus adjacent to the fracture site, and the centre

of the internal callus, and fibrous tissue formation mainly in the internal callus in the fracture gap. Intermediate and mature bone formed in the callus tips where experienced the least IFS induced in the fracture site, except for model P1T1, which had no mature bone formation. In contrast, the highest amount of mature bone formation (0.2%) was predicted in model P4T5. Models P1 experienced considerably higher fibrous tissue formation than models with a greater number of pins. Cartilage production increased both in the internal and external calluses by cortical thinning.

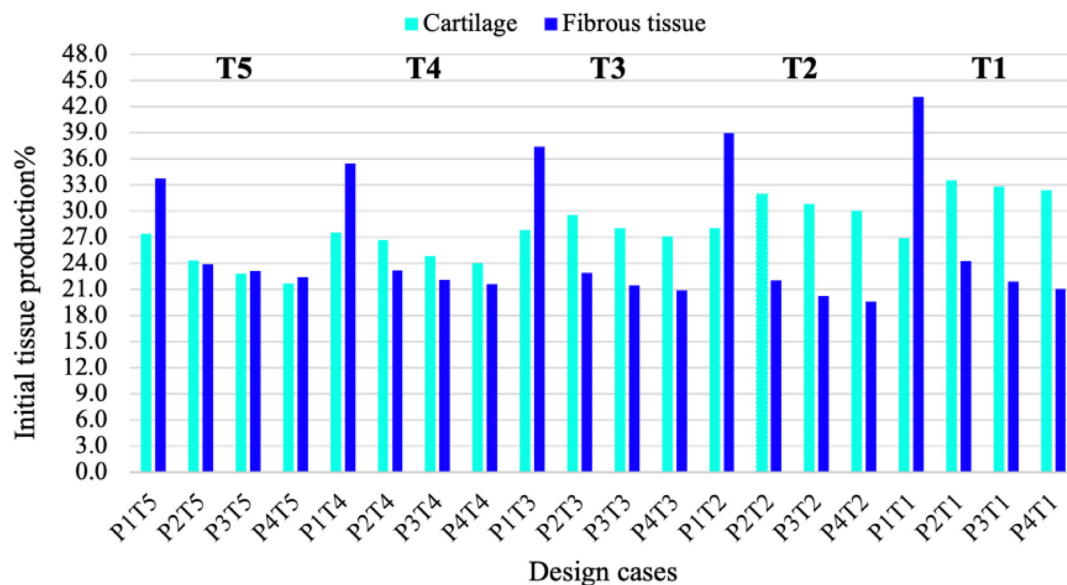


Fig. 7. Initial fibrous tissue and cartilage production under the effects of P and T.

Fig. 7 compares fibrous tissue production versus cartilage production in the initial healing stage and shows that increasing the pin number in T5 and T4 models produced less cartilage while in T2 and T1 models stimulated more cartilage formation.

Discussion

The results showed that increasing the number of pins provided a stronger and more stable construct but lower levels of FCI (Figs. 2, 4 and 5). Reducing the cortical thickness deteriorated the initial strength and stability condition; nonetheless, it produced higher mechanical stimulus and therefore increased the FCI value during the early-stage healing (Figs. 2, 4 and 5). The induced changes in VMS distribution and IFS and FCI values by adding pins were substantial when 1 pin rose to 2 pins in each bone fragment (Figs. 2, 4 and 5).

From the strength of material point of view, Fig. 2 demonstrates that the external fixation designs did not fail since the Max.VMS in the UEF and the bone did not reach near the yield strength of the materials, which is 690 MPa for pin [35] and 111 MPa for bone [36]. Additionally, Max.VMS values for the UEF occurred in the pins (Fig. 2b and c); therefore, pins are the weakest part of the fixator and are more susceptible to failure. This result agrees with [29], in which pins were identified as the main determinant of the initial strength of the external fixator. Also, the high-stress zone in the pin was located near the pin-rod interface (Fig. 3a and b). This result corroborates the findings of previous literature in the initial-stage healing with soft callus when the UEF is most responsible for load bearing [37,38].

Bone loss due to ageing or osteoporosis decreases the cortical thickness in the tibial diaphysis, reducing the cortical area where the load is applied and leading to more VMS magnitude in all bone-fixator parts. Increasing the number of pins proved to be effective in reducing the Max.VMS, particularly when the bone has a lower cortical thickness (Fig. 2). The same situation was reported by Donaldson et al. [19], whereby adding the number of pins from 2 to 3 in each bone fragment could reduce stress in the bone hence, reducing the risk of pin loosening in an aged osteoporotic tibia. Nevertheless, changing the number of pins from 1 to 2 showed different behaviour compared to adding pins from 2 to 4 (Fig. 2). In the models with 1 pin insertion, significantly

lower stress values in the bone and rod showed that pins carried a greater portion of the load, particularly in models T1 and T2 (Fig. 2). In the initial stages of healing, the soft callus has a lower potential to stabilise the fracture site. As a result, the majority of the applied load should be carried by the fixator. Models P1 showed less suitable early-stage load transmission to the fixator; adding the second pin could effectively transmit higher load from the fracture callus to the fixator and the bone cortex (Fig. 2). When the number of pins rose from 2 to 4, the Max.VMS decreased in the bone and pin but increased in the rod (Fig. 2). Consistent with other literature, these findings demonstrate that a greater number of pins promote load transmission to the fixator and improve load distribution in the pins [1,39].

Cortical thinning due to bone loss in osteoporosis was proved to induce higher levels of IFS between the bone fragments and lower mechanical stability in the initial stage after fracture (Fig. 4). Based on the allowable IFS threshold of 10% to 33%, proposed by Claes [40], models P1T1, P1T2 and P1T3 resulted in excessive IFS that likely lead to delayed healing or nonunion (Fig. 4). Furthermore, a substantial drop in IFS value by changing 1 pin to 2 pins in each fragment indicated that stabilising the fracture site with 1 pin insertion is not sufficient (Fig. 4). Based on a study presenting principles for tibial fracture fixation utilising UEF, a minimum number of 2 pins in each bone fragment was suggested [41]. The results showed that adding the fourth pin could minimally influence the IFS value even in models with lower cortical thickness (Fig. 4), which is consistent with a study reported that increasing pins from 2 to 4 in a UEF with a single connecting rod does not significantly increase the structural stiffness [42]. This study demonstrates that adding more pins can promote initial stability, particularly in tibia bones with a thinner cortex.

Cortical thinning induced higher strain in the fracture site, which according to the mechano-regulation theory presented in Table 2, increased the differentiation of fibrocartilaginous tissue in the early-stage healing (Fig. 5). Higher amounts of FCI indicate the increased inclination to initiate ossification through cartilaginous callus formation. Models P1T1, P1T2 and P1T3 showed maximum FCI values, but they were failed to maintain initial stability (Figs. 4 and 5). It was reported that excessive fibrocartilage makes the fracture site less stable and may prolong or hinder the secondary heal-

ing process [12,43]. As a consequence, increased FCI due to cortical thinning does not indicate improved initial healing performance since increased IFS and stress values are other consequences of cortical thinning.

This study could successfully model early-stage tissue differentiation in fracture healing based on the mechano-regulation theory developed by Isaksson et al. [23]. The tissue differentiation patterns presented in Fig. 6 are consistent with the mechanobiological models of tissue differentiation in the initial stage of healing proposed by Lacroix and Prendergast [25]. Calcification of external callus in the early stage is critical since it can preserve the fracture site from excessive micromovement and enable the ossification process in the subsequent healing stages. The results from Figs. 6 and 7 show that using 1 pin in each fragment produces greater fibrous tissue in the calluses, making the external callus less stable. In models with 4 pins in each fragment, early bony bridging was observed even for 2 mm cortical thickness because small IFS promotes bone healing via stimulating osteoblast activities resulting in early bone formation [7] (Fig. 6). Fig. 7 shows that increasing the pin numbers from 1 to 4 in the bones with 1 mm and 2 mm cortical thickness could sufficiently encourage cartilage formation and callus consolidation in the initial stage of healing. However, the stimulation resulting from inserting the fourth pin was relatively minimal in all models (Fig. 7).

In this effort, several simplifications were considered in FE modelling and analysis. First, isotropic, linear elastic and homogeneous materials were assigned to the bone. Generating models with more complex material behaviours may alter the calculated results; nonetheless, several studies conducted analysis and developed FE modelling considering the same material behaviours [44–46]. Second, the tibial cortex with different thicknesses was assigned identical Young's modulus and yield strength, whilst osteoporosis deteriorates both the bone's geometry and material properties. Third, several factors contribute to the healing process, such as chemical, biological and genetic stimulators and the necessity of a sufficient blood supply to enable bone formation, but they were excluded from the analysis. Additionally, the bone reaction to the biomechanical stimulators during the initial healing process was deemed to be consistent, whilst young and old bones may respond differently to the biomechanical condition induced in the fracture site. This paper investigated the effects of the number of pins and cortical thinning only in the initial phase of healing which was proved to be critical in clinical fracture treatment [47]. However, the success of the fixation is also affected by the subsequent phases of healing. Another potential limitation lies in the fact that although pin loosening is one of the main complications in applying external fixators, particularly for old and osteoporotic bones [19], it was not evaluated in this effort.

Conclusions

The findings from this study revealed that using 1 pin in each bone fragment results in initial instability but the highest amount of FCI in bones with thinner cortex; and also results in poor load transmission to the fixator device. Significant changes of IFS, FCI and stress values by adding the second pin in each fragment imply excessive mechanical stimulus in models with 1 pin insertion even for thicker cortex ($T > 3$ mm). Higher FCI in the models with the thinner cortex ($T \leq 3$ mm) does not imply improved healing condition since it induces excessive IFS and high-stress zones. It is suggested that adding the number of pins (up to 3) in either bone fragment can sufficiently reduce the initial instability caused by cortical thinning in osteoporotic or aged tibia bone whilst promoting healing via endochondral pathway of ossification.

Funding

Not applicable.

Declarations of Competing Interest

None.

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