RESEARCH ARTICLE

Is a Complete Anatomical Fit of the Tomofix Plate Biomechanically Favorable? A Parametric Study Using the Finite Element Method

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Abstract

Background: The opening wedge high tibial osteotomy (HTO) fixation using the Tomofix system is at the risk of mechanical failure due to unstable fixation, lateral hinge fracture, and hardware breakage. This study aimed to investigate the effect of the level of anatomical fit (LOF) of the plate on the failure mechanisms of fixation.

Methods: A finite element model of the HTO with a correction angle of 12 degrees was developed. The LOF of the TomoFix plate was changed parametrically by altering the curvature of the plate in the sagittal plane. The effect of the LOF on the fixation performance was studied in terms of the factor of safety (FOS) against failure mechanisms. The FOSs were found by 1) dividing the actual stiffness of the plate-bone construct by the minimum allowable one for unstable fixation, 2) dividing the compressive strength of the cortical bone by the actual maximum pressure at the lateral hinge for the lateral hinge fracture, and 3) the Soderberg criterion for fatigue fracture of the plate and screws.

Results: The increase of the LOF by applying a larger bent to the plate changed the fixation stiffness slightly. However, it reduced the lateral hinge pressure substantially (from 182 MPa to 71 MPa) and increased the maximum equivalent stresses in screws considerably (from 187 MPa to 258 MPa). Based on the FOS-LOF diagram, a gap smaller than 2.3 mm was safe, with the highest biomechanical performance associated with a 0.5 mm gap size.

Conclusion: Although a high LOF is necessary for the Tomofix plate fixation to avoid mechanical failure, a gap size of 0.5mm is favored biomechanically over complete anatomical fit.

Level of evidence: V

Keywords: Failure mechanisms, Fixation stiffness, Hardware breakage, Lateral hinge pressure, Plate contouring

Introduction

High tibial osteotomy (HTO) is a common surgical procedure for treating patients with unicompartmental knee osteoarthritis associated with the misalignments of the lower limb (i.e., genu varus and genu valgus) (1-3). By realignment of the mechanical axis of the knee joint, the HTO decreases the excessive knee adduction/adduction moment and redistributes the weight-bearing stresses from the degenerated compartment of the knee into a wider area of healthy cartilage (3,4). As a result, it prevents further degeneration, reduces pain, and enables biological healing of the damaged articular cartilage.

A variety of surgical techniques have been described in orthopedic literature for the HTO, including but not limited to closing wedge osteotomy, opening wedge osteotomy, dome osteotomy, progressive callus distraction, and chevron osteotomy (5). Among these techniques, the medial opening wedge osteotomy is the

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most common due to its relatively simple procedure that involves a single osteotomy and a few dissections (6). However, this operation faces the risks of lateral cortical hinge fracture and postoperative hardware failure (4, 7-9). In particular, a high rate (18%-39%) of lateral hinge fractures has been reported in the clinical literature, which might result in accelerated osteoarthritis, non-union, or a loss of correction (7, 9, 10-15).

The failure mechanisms of the opening wedge HTO are primarily associated with its fixation system. To successfully operate and avoid failure, the fixator device should satisfy several different biomechanical requirements. It should provide sufficient fixation stability to maintain the corrected alignment and enable callus formation (12). Additionally, it should preserve the lateral hinge from overloading, which leads to fracture (13-15). Finally, it should keep the components of the fixation construct (i.e., the plate and screws from excessive stress to avoid hardware breakage) (10, 11).

In response to the challenging requirements of HTO fixation, a large variety of fixation devices have been designed and used in clinical practice, including TomoFix (Synthes Medical, Oberdorf, Switzerland), Puddu (Arthrex Ltd., Naples, FL, USA), PEEKPower (Arthrex, Munich, Germany), iBalance (Arthrex, Munich, Germany), Activemotion (Newclip Technics, Haute-Goulaine, France), Contour Lock (Arthrex, Munich, Germany), and LCfit (Corentec, Cheonan-si, South Korea). The TomoFix Medial High Tibia Plate (Synthes Medical, Oberdorf, Switzerland) is one of the most established devices to fix medial opening wedge osteotomy (6). However, along with the supportive clinical literature, there are also reports of the HTO complications associated with the TomoFix plate fixation. As a case in point, Takeuchi *et al*. and Martin *et al*. reported lateral hinge fractures in 20%-25% of their HTO patients treated with TomoFix. Nha *et al*. also reported a limited number of TomoFix plate breakage cases (16-18).

Numerous researchers have studied the biomechanical characteristics of the TomoFix system fixation and compared them to those of the other HTO fixation systems (8, 19-30). They, however, have often neglected the critical role of the level of anatomical fit (LOF) of the plate (i.e., the degree of geometrical match between the plate and the underlying bone) on the biomechanical performance of the fixation. Similar to other locking plates, the distance between the TomoFix plate and the bone can affect the biomechanics of the fixation. Both clinical and biomechanical studies have reported that a large gap not only weakens the structural stiffness of the fixation but also imposes high stresses on the construct, leading to hardware failure, which includes screw and plate breakage or screws pull out (10,11,13-15). For the TomoFix plate, the anatomical design provides a generally good geometrical match with the underlying bone. However, there would always be a level of mismatch between the plate and the bone because the proximal tibia includes multiple structures with complicated patient-specific morphology in the tibial plateau, posterior intercondylar fossa, posterior cortex, and abrupt geometrical changes at the osteotomy site (31).

Despite the extensive literature on the biomechanics of the TomoFix system, the effect of the LOF of the plate on the biomechanical performance of the HTO fixation has not been studied before (8, 19-30). This study aimed to investigate the impact of the LOF of the TomoFix plate with the underlying bone on the structural stiffness of the HTO fixation and the stresses applied to the fixation construct. It was hypothesized that a high LOF increases the structural stiffness of the fixation and unloads the lateral hinge, helping to maintain the corrected alignment and minimize the risk of non-union of bone fragments. However, at the same time, it can enlarge mechanical stresses in the plate and screws excessively, raising the risk of hardware breakage. Therefore, there would be an optimal range for the LOF of the TomoFix plate, and thus, a complete anatomical fit might not always be favorable from a biomechanical point of view.

Materials and Methods

The effect of the LOF of the TomoFix plate on the biomechanics of the fixation of the medial opening wedge HTO was studied using a three-dimensional (3D) finite element (FE) model. The geometry of the tibia was acquired from the quantitative computed tomography of a fresh frozen human cadaver after the approval of the University Ethics Committee (Islamic Azad University, Tehran, Iran). The bone was scanned, along with a calibration phantom (QRM- BDC/3 H200, QRM Gmbh, Germany), using a CT 64-channel machine (Somatom Sensation 64, Siemens Healthcare, Erlangen, Germany) with a slice thickness of 0.28 mm. The Hounsfield unit (HU) number of each voxel was mapped onto the bone mineral density, according to the reference HUs of the calibrating phantom, to obtain the modulus of elasticity at each voxel. The details of the modeling procedure have been reported elsewhere (32).

The original tibia had a moderate varus orientation [Figure 1. a]. A medial opening wedge HTO was simulated. The osteotomy line was located 37.5 mm distal to the tibial plateau, and the correction angle was 12 degrees to align the weight-bearing axis on the anatomical axis [Figure 1. b]. The 3D models of the Tomofix plate, as well as the locking and cortical screws, were reconstructed using the dimensional details provided by the manufacturer. The plate length, width, and thickness were 115 mm, 16 mm, and 3 mm, respectively, and the diameters of locking and cortical screws were 5 mm and 4.5 mm, respectively. The simulated HTO was then fixed using the TomoFix plate [Figures 1. c]. Five locking screws were incorporated at the threaded holes and three locking screws at the Combi holes of the plate.

The biomechanics of the TomoFix plate fixation of HTO was studied using FE modeling in ABAQUS (version 6.14; Dassault Systèmes, France) through ABAQUS/Standard implicit FE solver. The bone, plate, and screws were meshed using quadratic tetrahedral elements of type C3D10 (10-node tetrahedral solid elements). The threads of the plate, as well as locking screw heads and shafts, were not modeled, considering the perfect lock assumption in-between. Furthermore, the threads of the screw shafts were neglected, considering the ideal engagement assumed in the screw-bone interface. The bone was considered isotropic and linearly elastic with a modulus, according to the HU number of each bone voxel (33). The means of the elastic modulus of the cancellous and cortical bones were 5,000 MPa and 17,000 MPa, respectively, both of which are in good agreement with the data reported in the literature (19,24,25). The plate and screws were considered to be made from Ti-6Al- 4V alloy and were modeled as homogeneous, isotropic, and linear elastic materials with an elastic modulus of 110,000 MPa (25,27). The engagement of the bone segments at the lateral hinge, as well as that of the bone and screw shafts, were modeled using surface-to-surface contact elements that allow for separation and slippage (19,27). For the first engagement, a hard contact condition, and for the latter, a Coulomb friction model (friction coefficient 0.4) was employed (27).

The model was subjected to a 175 N compressive force evenly distributed on the tibial plateau. As suggested in the literature, patients can start partial weight-bearing on the affected leg immediately after HTO with plate fixation, using walkers or crutches (34). The extent of the weight-bearing force has been suggested to be in the range of 150 to 200 N, depending on the amount of pain and wound healing (34). The 175 N force used in this study was in the middle of the suggested range. In addition, the distal part of the tibial bone was fixed in the model as the boundary condition to avoid rigid body motion. The model predictions were verified using a mesh convergence study. The final mesh contained over 820,000, 23,000, and 5,000 elements for bone, plate, and screws, respectively.

The impact of the LOF of the TomoFix plate on the biomechanical performance of the HTO fixation was studied by changing the curvature of the middle part of the plate while its distal portion was completely adapted to the underlying bone to accept non-locking screws [Figure 2]. The LOF was described quantitatively as the largest gap (i.e., perpendicular distance) between the plate and the bone in millimeters. As shown in [Figure 2], the LOF changed parametrically in six states, from a 5 mm gap (state a) to zero (state f).

For each state, the corresponding FE model was executed to investigate the biomechanical performance of the HTO fixation against failure in terms of the factor of safety (FOS). Four failure modes were considered: 1) unstable fixation, 2) lateral hinge fracture, 3) plate breakage, and 4) screw breakage. The stability of fixation was characterized as the stiffness of the bone-plate-screw construct in the axial direction, and the FOS against unstable fixation was found as the actual stiffness divided by the minimum allowable stiffness (Eq. (1)):

$$FOS_{stab} = \frac{K_{act}}{K_{allow}} \qquad (1)$$

where FOS_{stab} is the FOS against unstable fixation, and K_{act} and K_{allow} represent the actual and the minimum allowable stiffness of the bone-plate-screw construct in the axial direction, respectively.

The minimum allowable stiffness, K_{allow}, was estimated based on the interfragmentary strain theory (35). Considering the maximum width of the osteotomy gap (12 mm), the maximum displacement (d_{max}) should be less than 1.2 mm to keep the interfragmentary strain lower than 10% and allow for callus formation. Therefore, K_{allow} would be 145 N/mm for the 175 N axial force applied to the fixation construct of this study (Eq. (2)).

$$K_{allow} = \frac{F}{d_{max}} = \frac{175}{1.2} = 145\ N/mm \qquad (2)$$

The FOS against the lateral hinge bone fracture was

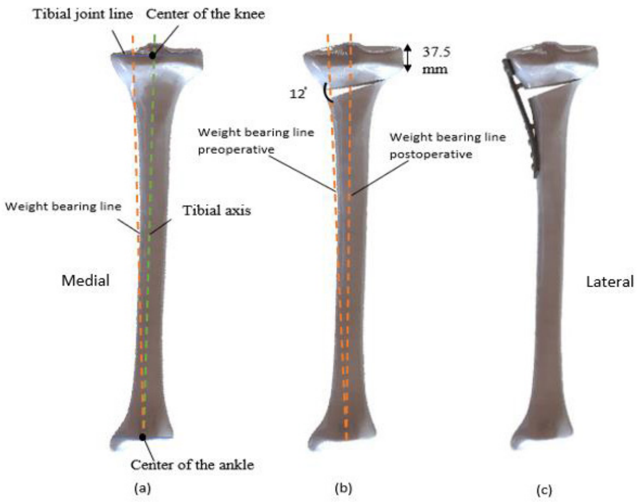

Figure 1. Simulation of open-wedge High Tibial Osteotomy: (a) Original tibia with varus orientation, (b) Simulation of the High Tibial Osteotomy operation, and (c) TomoFix plate fixation of High Tibial Osteotomy.

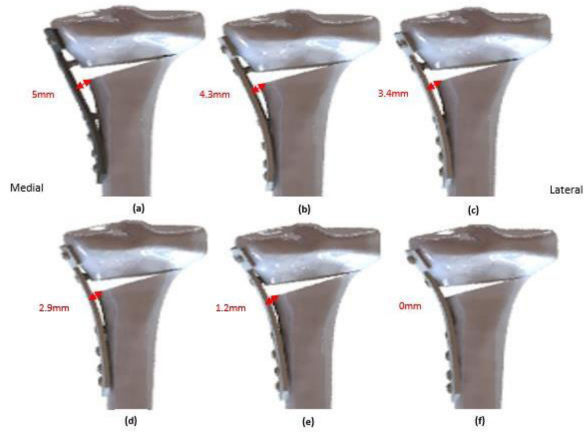

Figure 2. Six states of the anatomical fit examined in this study: (a) State 1: 5 mm gap, (b) State 2: 4.3 mm gap, (c) State 3: 3.4 mm gap, (d) State 4: 2.9 mm gap, (e) State 5: 1.2 mm gap, and (f) State 6: 0 mm gap.

determined as the compressive strength of the cortical bone at the lateral hinge divided by the actual maximum pressure predicted by the model (Eq. (3)).

$$FOS_{bone} = \frac{S_C^{bone}}{P_{max}} \quad (3)$$

where FOS_{bone} is the FOS against the lateral hinge bone fracture, P_{max} is the maximum pressure applied to the bone at the lateral hinge, S_C^{bone} and is the compressive strength of the cortical bone, assumed to be 205 MPa (36).

Finally, the FOSs against the fatigue fracture of the plate and screws were found using the Soderberg criterion. Since at each walking cycle, the load reaches its peak magnitude at heel strike and is zero during the sewing phase, the minimum stress equals zero, and the alternating, as well as midrange stresses, are equal to one-half the maximum stress (Eq. (4)).

$$\frac{\sigma_a}{S_e^{Ti}} + \frac{\sigma_m}{S_y^{Ti}} = \frac{\sigma_{max}}{2S_e^{Ti}} + \frac{\sigma_{max}}{2S_y^{Ti}} = \frac{1}{FOS_{fatigue}} \quad (4)$$

$$FOS_{fatigue} = 2\,\frac{S_e^{Ti}.S_y^{Ti}}{S_e^{Ti}+S_y^{Ti}}/\sigma_{max} \quad (5)$$

where, $FOS_{fatigue}$ is the FOS against the fatigue fracture of the plate or a screw, σ_a and σ_m are the alternating and midrange stresses, and σ_{max} is the maximum equivalent (von Mises) stresses observed in the plate or screws. Also, S_e^{Ti} and S_y^{Ti} are the endurance limit and the yield strength of the Ti-6Al-4V alloy, assumed to be 529 MPa and 786 MPa, respectively (37).

Results

The results of the FE model for different states of the LOF examined in this study are shown in [Figure 3]. For all states, the maximum equivalent stress in the bone occurred at the lateral hinge area. Additionally, among the screws, the locking screw just above the osteotomy site received the highest level of equivalent stress, with its maximum happening in the neck area. For the plate, the maximum equivalent stress occurred in the span between the holes proximal and distal to the osteotomy site. In the 5 mm gap state, the maximum equivalent stresses observed in the lateral hinge, the plate, and the screws were 182 MPa, 163 MPa, and 187 MPa, respectively. In the zero-gap state, these stresses changed to 71 MPa, 177 MPa, and 258 MPa, respectively.

The effects of the LOF of the Tomofix plate on the biomechanical characteristics of the HTO fixation are shown in [Figure 4]. The stiffness of the fixation increased very slightly with the increasing LOF; the change was only 5% when the gap reduced from 5 mm (state a) to zero (state f). However, for the contact pressure at the lateral hinge, a substantial decrease was observed when the LOF was improved; the 182 MPa stress observed for the 5 mm gap (state a) reduced by about 61% to 71 MPa for the zero gap (state f). Similarly, the LOF had a considerable effect on the equivalent stresses of the plate and screws. The maximum equivalent stress increased by about 8% for the plate and 37% for the screws when the gap decreased from 5 mm to zero.

The study results in terms of the FOS against the four modes of failure, including unstable fixation, lateral hinge fracture, plate breakage, and screw breakage, are shown in the FAS-LOF diagram of [Figure 5]. The minimum acceptable FOS has been considered 1.5. Based on this diagram, the HTO fixations with lower LOFs (gap larger than 2.3 mm) were unsafe due to the susceptibility to lateral hinge fracture. With the higher LOF (gap smaller than 2.3 mm), the risk of hardware

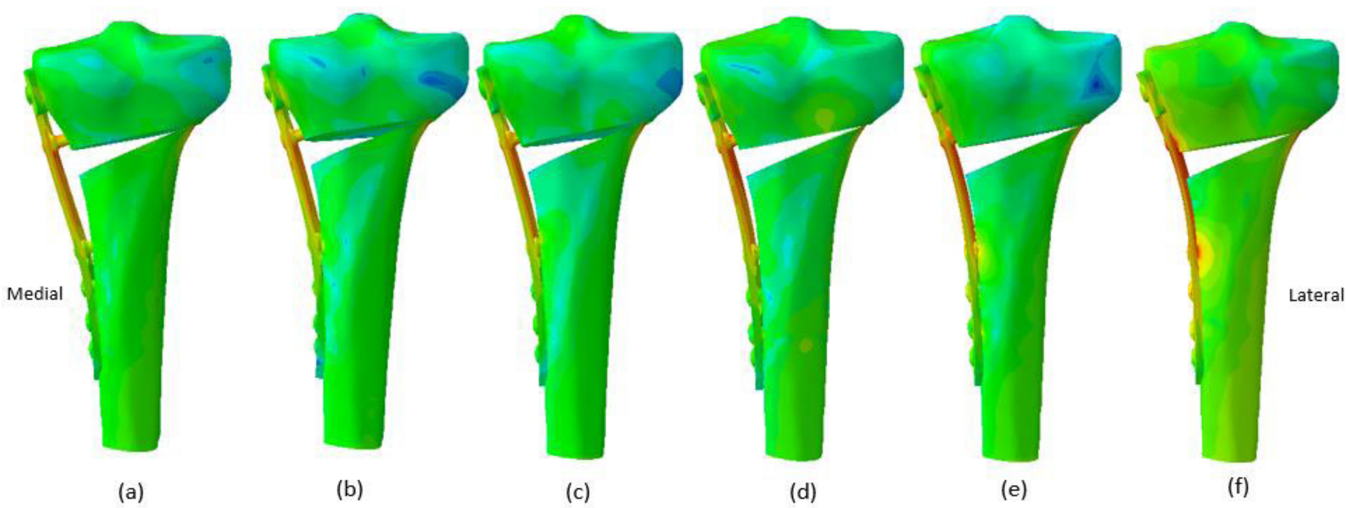

Figure 3. Results of the finite element model for the six states of the anatomical fit: (a) 5 mm gap, (b) 4.3 mm gap, (c) 3.4 mm gap, (d) 2.9 mm gap, (e) 1.2 mm gap, and (f) zero gap.

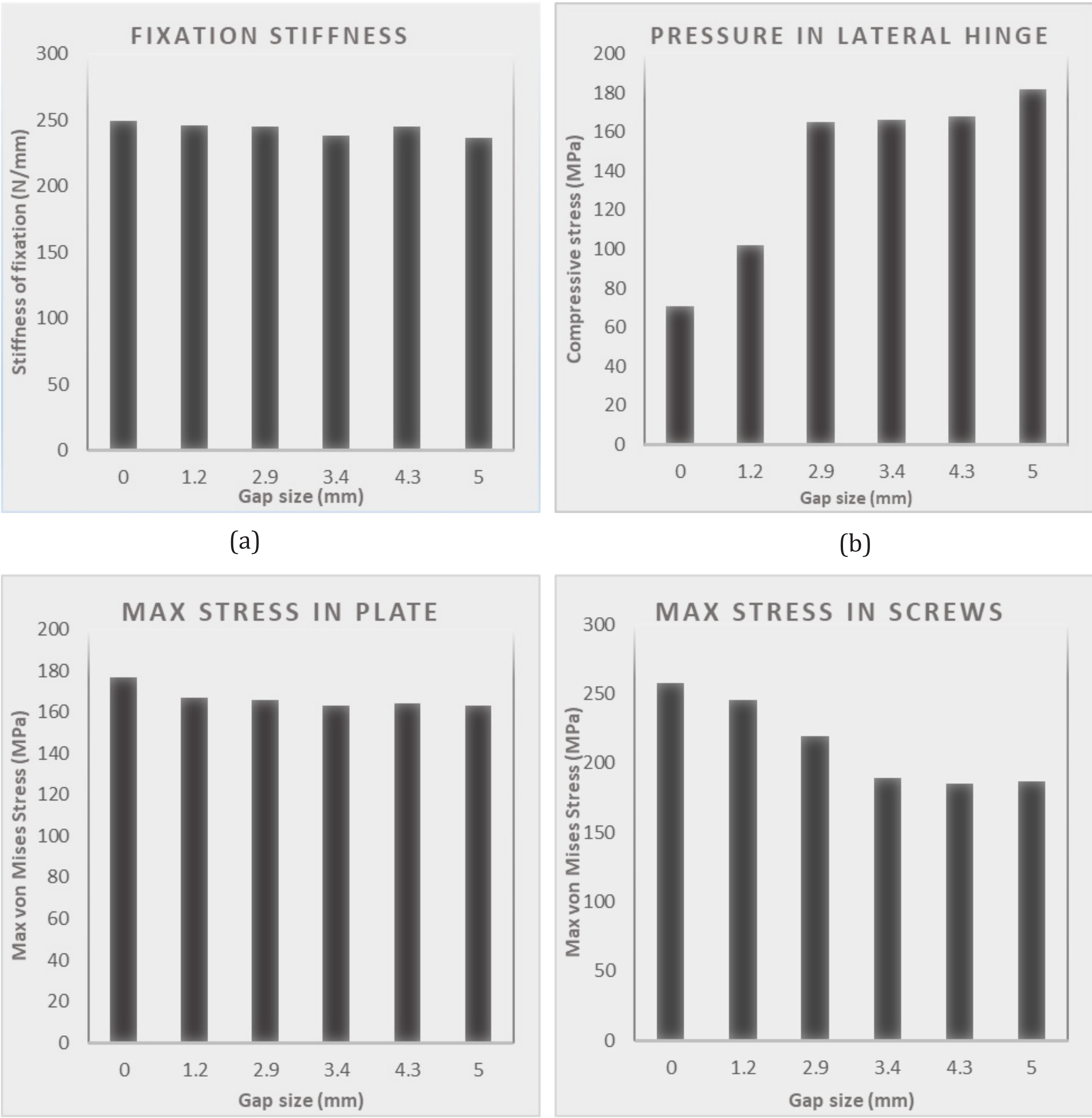

Figure 4. Effect of the level of anatomical fit of the TomoFix plate on (a) Stiffness of fixation, (b) Lateral hinge pressure, (c) Maximum equivalent stress in plate, and (d) Maximum equivalent stress in screws.

breakage, in particular the screw fracture, rose due to the higher stresses imposed on the plate and screws. However, the FOS remained consistently higher than the 1.5 threshold, and the system was safe. The best biomechanical performance of the fixation system was associated with a 0.5 mm gap, in which the minimum FOS against three modes of failure (lateral hinge fracture, as well as plate and screws breakage) was larger than 2.5, and the FOS against the other failure mode (unstable fixation) was maximum. At the higher LOFs, the risk of screw breakage continued to grow, resulting in a slight decrease in the overall FOS.

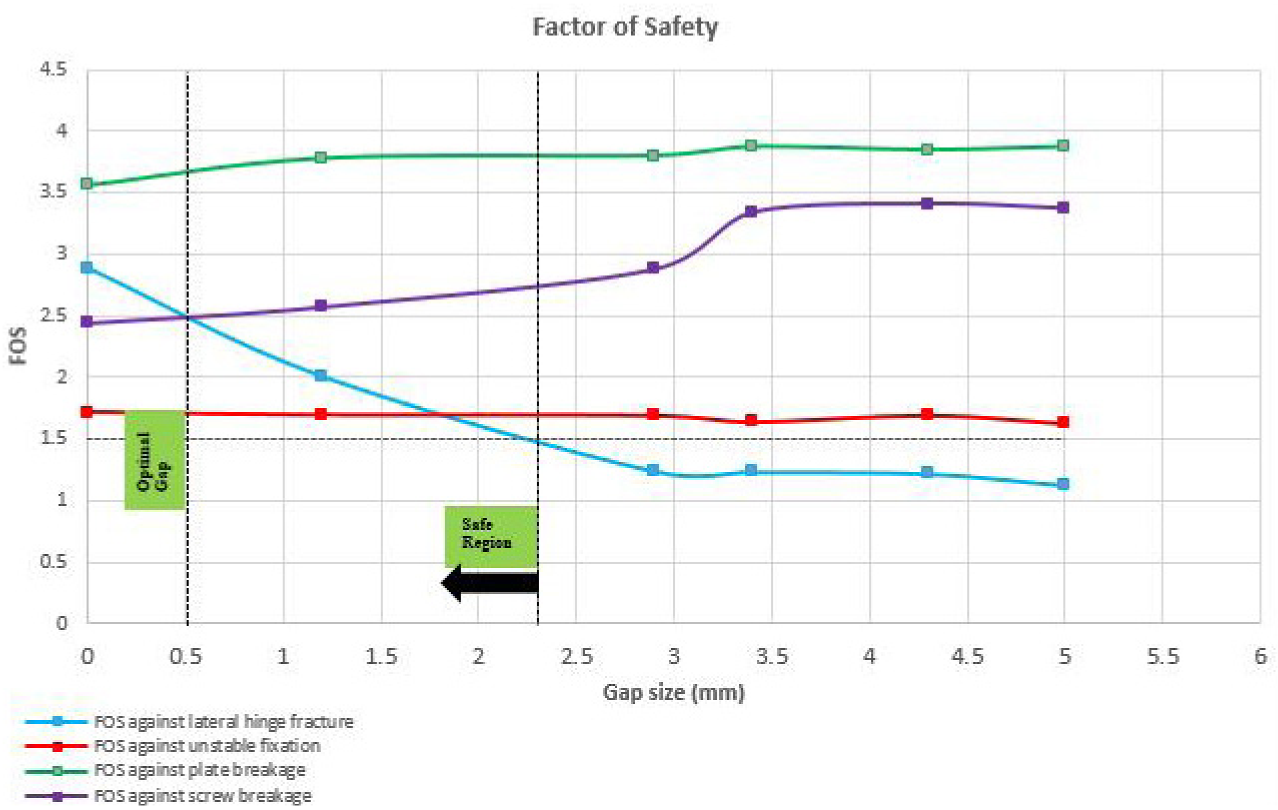

Figure 5. Factor of safety-level of anatomical fit diagram of High Tibial Osteotomy fixation using TomoFix plate. The safe region includes the range of the anatomical fit with a factor of safety higher than 1.5 against all four modes of failure. The optimal state (gap=0.5 mm) indicates the anatomical fit with the highest possible factor of safety for all four modes of failure.

Discussion

Clinically, an anatomically well-fitted plate can greatly facilitate the operation procedure, specifically the reduction process (i.e., the axial and rotational alignment of the fragments). It has also been reported to help reduce soft-tissue impingement/irritations and create a stable structure during the healing period (38, 13). However, the effects of the LOF of the plate on the detailed biomechanical performance of the fixation are not well understood. This is particularly true for the HTO fixation, where a complete anatomical fit is often difficult to achieve. It is due to the complicated patient-specific morphology of the proximal tibia and the abrupt geometrical changes at the osteotomy site, even with modern additive manufacturing techniques (34, 39-41). For the first time in the literature, this study investigated the effect of the LOF of the TomoFix plate on the biomechanical characteristics of the HTO fixation in detail.

The results of the present study, in general, support the hypothesis that a higher LOF of the plate increases the structural stiffness of the fixation. As [Figure 4. a] shows, with a higher LOF, the structural stiffness of the fixation construct increased. However, the rate of this increase was minimal (only 5%) when the gap size decreased from 5 mm to zero. Moreover, even for a large gap of 5 mm, the structural stiffness was higher than the 217 N/mm threshold, considered the minimum acceptable stiffness for maintaining the corrected alignment and callus formation. As the FOS-LOF diagram of illustrates, the FOS against unstable fixation experienced only a minimal change with increasing LOF [Figure 5].

More importantly, the findings support the hypothesis that a higher LOF of the plate unloads the lateral hinge. As [Figure 4. b] illustrates, the LOF had a considerable effect on the lateral hinge pressure of the HTO, and the contact pressure was relatively high for the 5 mm gap but decreased sharply at higher LOFs. This observation is crucial from a practical point of view because the lateral hinge pressure is in the same order as the mechanical strength of the cortical bone. With a large gap between the plate and the underlying bone, there would be a high risk of the lateral hinge fracture as a leading cause of open-wedge HTO failures (13-15). This fact is also illustrated in the FOS-LOF diagram of, which shows that the gap between the plate and the bone should be smaller than 2.3 mm to make the HTO fixation safe against later hinge fractures [Figure 5].

Concerning the fixation hardware, the results for the maximum equivalent stresses support the hypothesis that a higher LOF enlarges mechanical stresses in the plate and screws [Figure 4. c and 4.d]. However, despite the relatively high rate of increase found for these stresses (up to 37% for the screw just above the osteotomy site), the resulting stresses remained well beyond the mechanical strength of the Titanium alloy. This observation indicates that the risk of mechanical breakage of the fixation hardware is not high in general. As [Figure 5] illustrates, the FOS against plate breakage is always higher than 3.5. For the screw breakage, the FOS is somewhat smaller but still greater than 2.5, except for the complete anatomical fit.

Considering the FOS-LOF diagram, the findings suggest that the riskiest modes of failure of the TomoFix plate fixation of the HTO are as follows: 1) lateral hinge fracture, 2) unstable fixation, and 3) screw breakage [Figure 5]. As the results indicate, a higher LOF improves the performance of the fixation against the first two modes of failure, but it adversely affects the third mode. The safe region in the FOS-LOF diagram starts from a 2.3 mm gap, indicating that the gap between the plate and the underlying bone should always be less than 2.3 mm. This is in good agreement with the conclusion of the study by Miller and Goswami (2007) from the biomechanical and clinical literature, suggesting that the clearance between the plate and the bone should be kept minimal, less than 2 mm (12).

Moreover, the findings suggest that the optimal state of the LOF happens at a high anatomical fit of 0.5 mm gap, rather than the complete anatomical fit. This observation supports the proposed hypothesis that there is an optimal range for the LOF of the TomoFix plate and a complete anatomical fit might not always be favorable since it raises concerns over hardware breakage. However, it should be noted that the FOS against screw breakage was always higher than two due to fatigue. This result, supported by the relatively rare clinical reports of the TomoFix hardware breakage, suggests that a complete anatomical fit is acceptable from a biomechanical point of view (18).

The findings of this study are in general agreement with those of the previous biomechanical investigations. The 236 to 249 N/mm axial stiffness found in this study for the TomoFix plate fixation is close to the results reported by Izaham *et al*. and MacLeod *et al*. (20, 42). Furthermore, the obtained result for the maximum lateral hinge pressure (182 MPa) is in the range of the data reported previously (159 to 292 MPa) (22, 43). Finally, the maximum equivalent stresses found in this study for the plate and screws under partial weight-bearing (177 MPa and 258 MPa, respectively) are comparable with previous findings under larger loads (160 to 236 MPa and 200 to 530 MPa, respectively) (22, 25, 27).

Nevertheless, the present methodology has some limitations that should be addressed in future investigations. First, the FE model suffers from simplifications in representing the material properties of the bone, the geometry of the screw threads, the bone-screw contact interface, and the mechanical loading of the system, which might have affected the obtained results. In particular, the density of the cancellous bone can affect the findings. Moreover, this study only investigated the mismatch between the TomoFix plate and the underlying bone at the middle part of the plate in the sagittal plane. There is, thus, a need for a more comprehensive investigation of the effects of LOF in the transverse plane, and in particular, the proximal and distal ends of the plate. Furthermore, the results of this modeling study can be considered only an approximation of the reality in the absence of experimental validation. To validate the findings, detailed *in vitro* biomechanical experiments are needed on the TomoFix plate fixation with different LOFs. Finally, this study was limited to a specific HTO fixation system (the TomoFix plate) made from a simple engineering alloy. Therefore, more effective fixation devices can be designed and analyzed in future studies based on advanced materials and topology optimization techniques, which have provided encouraging results in other orthopedic implants (44, 45).

The level of the anatomical fit of the plate has adverse effects on the biomechanical performance parameters of the HTO fixation using the Tomofix plate. A higher level of fit reduces the lateral hinge pressure but increases the maximum equivalent stress experienced by the plate and screws. The gap between the plate and the underlying bone should be kept lower than 2.3 mm to avoid mechanical failure. However, the highest biomechanical performance is associated with a 0.5 mm gap size rather than a complete anatomical fit.

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