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## The effects of tibia profile, distraction angle, and knee load on wedge instability and hinge fracture: A finite element study

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### ABSTRACT

Several plate systems for high tibial osteotomy (HTO) have been developed to stabilize the opening wedge of an osteotomized tibia. Among them, the TomoFix system, having a quasi-straight and T-shaped design, has been widely adopted in the literature. However, this system is implemented by inserting a lag (i.e., cortical) screw through the proximal combi-hole, to deform the plate and pull the distal tibia toward the plate. This process potentially induces plate springback and creates an elastic preload on the osteotomized tibia, especially at the lateral hinge of the distracted wedge. Using the finite-element method, this study aims to investigate the contoured effect of lag-screw application on the biomechanical behavior of the tibia-plate construct. Two tibial profiles (normal and more concave), three distraction angles (6°, 9°, and 12°), and three knee loads (intraoperative: contouring plate; postoperative: weight and nonweight bearing) are systematically varied in this study. The wedge instability and fracture risk at the lateral hinge are chosen as the comparison indices. The results show the necessity of preoperative planning for a pre-contoured procedure, rather than elastic deformation using a lag screw. Within the intraoperative period, a more concave tibial profile and/or reduced distraction angle (i.e., 6° or 9°) necessitate a higher compressive load to elastically deform the plate, thereby deteriorating the lateral-hinge fracture risk. A pre-contoured plate is recommended in the case that the proximal tibia is highly concave and the distraction angle is insufficient to stretch the tibial profile.

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### 1. Introduction

High tibial osteotomy (HTO) is used to treat osteoarthritic knees with medial cartilage degeneration [1–6]. For a varus knee, a medial opening wedge is purposely created and distracted so as to shift the knee loads from the medial to lateral condyles. However, the lateral bone of the osteotomized tibia then becomes the only remaining zone that can serve as the load-transferring path during the various knee motions. This outcome inevitably renders the osteotomized tibia a highly unstable structure, with the lateral

zone of the distracted wedge being prone to stress fracturing. For HTO osteosynthesis, several plates have been developed to stabilize the distracted wedge, such as TomoFix, Puddu, Limmed, and Position plates [3–6]. Among them, the TomoFix plate is representative of the quasi-straight and T-shaped design, and is more commonly adopted in the literature. Above the wedge, the TomoFix plate has three screws inserted through locking holes and one screw through a combi-hole, in order to anchor the proximal tibia.

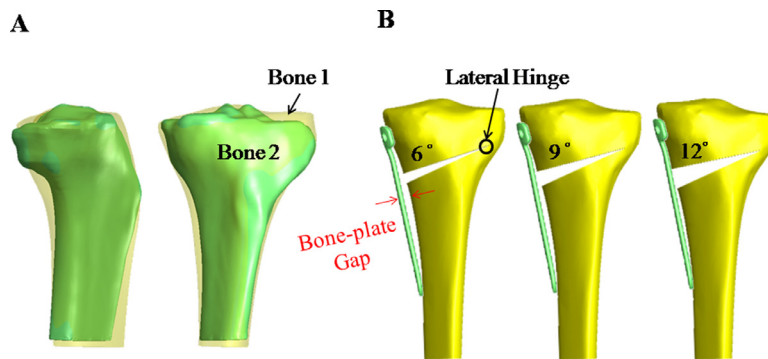
Without precontouring, an interfacial gap always exists between the tibial profile and quasi-straight plate. In the literature, the biomechanical effects of the bone-plate gap have been extensively investigated using numerical, experimental, and clinical methods [7–9]. As a lower-limb bone, the osteotomized and distracted tibia behaves as a highly stress-concentrated and unstable structure. However, it is still unknown whether or not the TomoFix should be contoured to fit the bone, to avoid inducing implant failure and bone fracture. The TomoFix plate surgical manual recommends attachment of the plate to the proximal tibia without precontouring [10]. In the surgical manual, however, it is recommended that

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**Fig. 1.** (A and B) Six constructs of two tibial profiles and three distraction angles: (A) Profile difference of two proximal tibiae: flatter (Bone 1) and more concave (Bone 2). (B) Tibia–plate gap of three distraction angles: 6°, 9°, and 12°. The initial plate is quasi-straight in shape.

the TomoFix plate be attached to the proximal tibia using the following three-stage procedure: (1) a lag screw pulls the distally osteotomized segment toward the plate; (2) the plate is forced into suspension, creating an elastic preload; and (3) pressure is imposed upon the lateral hinge [10]. In the authors' experience, however, three factors influence this process, which can be used to modify the aforementioned TomoFix plate application procedure.

The first is the geometric factor, as the surgical region of the osteotomized tibia is highly concave in profile (Fig. 1A). After wedge distraction, the tibial profile across the wedge is flatter, so as to fit the nearly straight profile of the TomoFix plate (Fig. 1B). However, the current authors hypothesize that an interfacial gap always exists between the initial plate and undistracted tibia, the characteristics of which depend on the tibial profile, distraction angle, and knee loads. The second consideration is the biomechanical factor, as the use of a lag screw to reduce the bone–plate gap potentially induces an elastic preload onto the osteotomized tibia. This alters and even deteriorates the stress distribution around the lateral hinge of the distracted wedge, leading to lateral cortex fractures. According to the classification and associated reports of both Takeuchi and Nakamura et al. [11,12], lateral cortical hinge fractures that reach the distal portion of the proximal tibiofibular joint, or that involve lateral plateau fractures, can result in marked instability at the osteotomy site. These complications are likely to contribute to delayed union, nonunion, or loss of angular correction of the osteotomy, along with implant failure [11,12]. In the case of an excessive gap, this study hypothesizes that the plate spring-back can potentially induce stress fracturing of the lateral cortex. The third consideration is the surgical factor. That is, the desired values of both the distraction angle and the tibial slope are most likely affected by the use of a quasi-straight plate, because of the unpredictable deformation.

This study aims to investigate the contouring effects of the TomoFix plate on the biomechanical behaviors of the osteotomized tibia–plate–screw construct. Using the finite-element method, the proximal tibial profile, distraction angle, and knee loads are varied in order to simulate different values of the tibia–plate gap. The changes in wedge height and stress distribution along the lateral hinge are chosen as the comparison indices between the variations. The outcome of this study can provide geometric, biomechanical, and surgical information concerning the appropriate contouring strategy for use of the quasi-straight TomoFix plate.

## 2. Methods

### 2.1. Tibia–plate–screw construct

The interfacial effects of the tibia–plate gap are evaluated by considering three factors: the tibial profile, distraction angle, and knee loads (Figs. 1 and 2). Two types of tibial profile are used

as representatives of the different concavities in the proximal region (Fig. 1A). The initial tibia–plate gap of the more concave tibia (i.e., Bone 2) is used as the control group for the standard tibia (i.e., Bone 1). Three-dimensional models of the standard tibia are developed from the CT-scanned images of two middle-aged male volunteers with no knee disease (age, weight, and height: 31 and 33 years, 68 and 73 kg, and 176 and 177 cm, respectively). The study design was approved by Medical Ethics Committee of the National Taiwan University of Science and Technology and written informed consent was obtained from the patients for participation in the study and publication of the accompanying images. The CT-scanned images are 1 mm slice separated and reconstructed as a tibial model with triangular surface meshes using the BioFit-Image Ed. 1.0 software (Buffett Co. Ltd, Taipei, Taiwan). The surface models of the proximal tibia are further transformed into solid models with smooth and seamless surfaces using the SolidWorks Ed. 2015 software (SolidWorks Corporation, Concord, MA, USA). The tibial model consists of a cortical shell and a cancellous core. A more concave profile of the proximal tibia is manually drawn from the standard tibia for substantially equivalent comparison.

Identical to the TomoFix specification, the plate and associated screws are developed using the SolidWorks Ed. 2015 software. The length, width, and thickness of the TomoFix plates are approximately 115, 35, and 3 mm, respectively. The entry site, inclination angle, and wedge depth of the medial wedge are cited from the TomoFix system surgical guide [10]. The wedge creation for two proximal tibiae is guided by a clinician, in order to simulate HTO surgery (Fig. 1B). The use of bone graft is excluded from this study, thus simulating the least-preferable scenario for the HTO plates. Six variations of two tibial profiles and three distraction angles (6°, 9°, and 12°) are considered. The wedge resection is directed from the osteotomized site (4.0 cm from the joint line) to the upper edge of the tibiofibular joint. For all six variations, the plate location and orientation are identical, so as to facilitate substantially equivalent comparison. The locking-screw threads are omitted for numerical simplification. The plate–screw and tibia–screw interfaces are assumed to be bonded in order to simulate firm fixation; thus, no interfacial loosening occurs.

### 2.2. Finite-element model

Two types of plate profile are examined in this study. For the first profile, a compressive load is gradually applied at the lag screw-hole, so that the loading value appropriate for plate deformation to fit the tibial profile can be estimated (Fig. 2A). This profile corresponds to the intraoperative scenario, allowing evaluation of the potential risk of the opening wedge due to compulsory contouring. During the intraoperative period, the contoured plate is subjected to the compressive load generated by the lag screw and the surgical load only, which is primarily attributed to the

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