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Effect of composite bone plates on callus generation and healing of fractured tibia with different screw configurations

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ABSTRACT

In this paper, finite element analysis of a fractured tibia with a glass/polypropylene composite implant is introduced. A rejection coefficient algorithm (for callus development) that is sensitive to interfragmentary movement is programmed, calibrated (using experimental *in vivo* statistics), and successfully implemented on a 3D fractured tibia model. A biphasic mechano-regulation algorithm is implemented to verify healing status under five different screw configurations (C1–C5) using glass/polypropylene composite bone plates and the development of tissue phenotypes in calluses is estimated. A 300% increase in circumferential callus volume is obtained when using the composite bone plate. Furthermore, the C5 configuration of the composite bone plate results in a maximum interfragmentary movement of 4.33% on day one with faster and stronger healing through 95% of bone growth during the final day of healing.

1. Introduction

Radial fractures (diaphyseal fractures) in tibia bones are commonly occurring fractures that are treated with internal fixation prostheses such as intramedullary nails and bone plates, depending on the type of fracture [1,2]. Bone plates preserve bone marrow with only a quarter of soft tissue dissection surrounding the bone [3,4]. Bone plates provide an improved plate–bone interface with a superior biomechanical environment at the fracture site. Different prostheses exhibit dissimilar fixation constructs. These constructs are vital for callus generation and fracture bridging. Metallic implants have a significant mismatch with bone mechanical properties and create stress concentrations at the plate, which results in stress shielding. This phenomenon impedes load transmission at the fracture site, which can lead to non-union, delayed healing, re-fracture, and construct failure [2,5,6]. Flexible implants respond to biological friendly healing (secondary healing) and promote callus generation and soft tissue maturation [7,8]. Fiber-reinforced composite prostheses have recently attracted significant attention because they can provide solutions to aforementioned problems [9]. These composites have been successfully applied to the treatment of long bones fractures [2,10–13]. Furthermore, suitable mechanical properties of such composites can easily be achieved by changing their ply orientation and number of laminas [14]. Screw density and implant type have a significant influence on structural rigidity. Increasing the number of screws increases the structural rigidity. Based on material inflexibility, researchers have been able to predict the initial mechanical environment at a fracture site [15]. Additionally, several mechano-regulation algorithms have been utilized to predict fracture healing [16,17] and biphasic mechano-regulation algorithms have been utilized to precisely predict bone healing [18,19]. In this study, a flexible composite bone plate made of a glass/polypropylene composite was introduced to enhance the healing efficiency of a tibial fracture. A glass/polypropylene composite (Twintex $[0]_{2nT}$) with in-plane Young's modulus of 20 GPa and carbon/epoxy composites (WSN3k) with stacking sequences of $[0]_{2nT}$, $[\pm 15]_{nT}$, $[\pm 30]_{nT}$, and $[\pm 45]_{nT}$ (Young's moduli of 70 GPa, 60.9 GPa, 35.90 GPa and 17.90 GPa, respectively) were introduced for bone plate design [20]. The glass/polypropylene composite is a strong candidate with 20 GPa Young's modulus which closely matches the properties of the cortical bone and gave the best healing performance [1,19,21]. So, the glass/polypropylene composite was selected in comparison with stainless steel to investigate the influence on calluses generation and its healing. We have developed a relationship between the generated initial interfragmentary movement (IFM) and range of the rejection coefficient (RC) to accurately predict callus volume following calibration utilizing *in vivo* data. This derived relationship between IFM and RC values (5% of maximum principal strain (MPS) for 1.2-mm IFM and 8.5% of MPS for 0.18-mm IFM) was then applied to a real tibia bone model to predict callus shapes according to the mechanical properties of the bone plate, which constitutes the main novelty of this paper. By utilizing the

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estimated callus configurations, the biomechanical environment at the fracture site was examined under a series of screw configurations for fastening the composite bone plate. The effects of these configurations on overall fracture healing were investigated by utilizing a biphasic mechano-regulation algorithm over a rehabilitation period of 16 weeks. The algorithm was implemented and executed utilizing the Python programming language and ABAQUS 6.12 software package, respectively.

2. Materials and methods

2.1. Calibration of rejection coefficient algorithm

Calluses (composed of central and external calluses) are a basic fracture stabilization structure composed of soft tissues, which are hardened by an endochondral ossification procedure and eventually absorbed after the bone heals. A central callus fills the cavities in broken bones and an external callus covers the fractured area to facilitate receiving nutrients from the medullary canal and external soft tissues. The external callus affects much of the stiffness of the fracture site, and therefore, it should be closely estimated for the accurate simulation of the bone healing process. Two-dimensional (2D) finite element models of transverse and oblique fractures were constructed to calibrate the suggested rejection coefficient (RC) algorithm for estimating the callus shape in our previous study [18]. A pool of null elements was introduced around the fracture to predict the callus shape. The RC algorithm was programmed using 5% of the maximum compressive principal (MCP) strain to define the boundary of the external calluses. Elements below 5% of the MCP strains were deleted, and the remaining elements were used for the next iteration. In the 2nd and 3rd iterations, narrowing of the callus bridging occurred that lead the callus to attain a more refined rounded shape. The final shape of the callus was determined in the 4th iteration, similar to the idealized *in vivo* results [22] of complete bridging in 6th week. Researchers have attempted to predict callus profile utilizing various approaches, such as MPS [18,22]. Previous studies utilized exact values of MPS to define idealized callus profiles. However, the limitation of the RC algorithm is, if the RC value remains the same then the algorithm produces the same volume of callus regardless the load magnitude (generated IFM). A low value of RC algorithm produces a large callus and vice versa. So, the values of IFM in FEA were generated according to the two *in vivo* IFMs cases and then the percentage of MCP strain (like 4%, 5% or 7%) was optimized to cooperate the *in vivo* calluses histology. Moreover, to assume the calluses shape during the simulation with the RC algorithm the tissues domain was homogeneous (granulation tissues) and elements were solid elastic. To overcome this problem, we have derived a relationship between RC values and IFM based on experimental *in vivo* data. Two different types of bone plates (locking and active plates) and a sheep bone with a 3-mm fracture gap were modeled using SOLIDWORKS and ABAQUS 6.12 [7,23,24]. The locking plate provides rigid fixation of a fracture with virtually no movement, which facilitates primary healing, whereas the active plate contains lateral pockets beneath its screw holes to facilitate interfragmentary motion between broken bones to promote callus formation, as shown in Fig. 1. These lateral pockets are arranged in an alternating pattern from both sides of the plate, which results in a staggered combination of locking holes. These locking holes are fitted with silicon pads to provide shock absorption. The resulting motion at the near and far cortexes was measured and calibrated using the values of the RC algorithm. Detailed implementation and execution of the RC algorithm was described in our previous study [18].

2.2. Computational 3D modelling

The 3D ovine tibia osteotomy model with outer diameter of 23 mm, thickness of 2.6 mm and length of 180 mm was used for calibration of RC algorithm as it represents the most prevalent large animal model for estimation of fracture healing [23,24]. A gap of 3 mm was created to mimic the *in vivo* fracture. Both plates used for calibration were 127 mm long, 16 mm wide, 5.6 mm thick with 6 holes and were made of surgical grade (Ti6Al4V) titanium alloy. Plates were applied with six 5 mm bicortical locking screws. Fractured bones were embedded into null elements so the calluses may develop according to the mechanical environment delivered. A solid 3D tibia model of a healthy male, which consists of cortical and trabecular bones with the most commonly occurring 3-mm diaphyseal transverse fracture, was created. For internal fixation of the fracture, the commonly used low contact dynamic compression plate (LC-DCP, USA) for long bone fractures was applied using two different materials (stainless steel and a glass/polypropylene composite). In our previous study [20], a plain weave glass/polypropylene composite (Twintex $[0]_{2nT}$) was fabricated with several forming conditions to find the optimal mechanical properties of a bone plate. The specimens whose forming conditions were 6 min pre-heating, 3 MPa forming pressure, and 10 min forming time had the highest strength with in-plane Young's modulus of 20 GPa as listed in Table 1. Also we have added the geometrical configurations of bone plate used in FEA. The bone plate is 106 mm in length, 13.5 mm in width and 3.3 mm in thickness with screw diameter of 3.5 mm. Threads of screws and holes were neglected to reduce the complexity. Its construction is illustrated in Fig. 2a [25]. The material properties of a glass/polypropylene (Twintex; *JB* Martin, France) composite and stainless steel are used in our finite element analysis (FEA). The distance between the holes was uniform (13 mm) and screws (without threads to reduce FEA complexity) were inserted into the plate-bone assembly. To overcome the mismatch between the asymmetrical surface of the bone and bone plate, we assembled the plate with a 1-mm elevation from the bone's surface [25]. The 3D callus was modeled as a pool of granulation tissues in which the central callus filled the fracture gap and external calluses were estimated after the RC algorithm was calibrated. In order to maintain fixation stability, there should be at least three screws in a plate-bone assembly on each side of a fracture [26]. Once the calluses were produced, we simulated five different screw configurations with three screws on each side of the fracture to estimate the progression of the tissue differentiation procedure during fracture healing. The calluses, cortical and trabecular bones were modeled as poroelastic (solids and fluids) structures to mimic natural biological procedures. The properties of the bones were kept constant while the calluses were allowed to change under intramembranous (direct bone formation) and endochondral ossification (tissue maturation under different successions of healing 0.2–6000 MPa) procedures. The time-dependent properties of these tissues are listed in Table 1 [27]. The bone plates were either stainless steel or a glass/polypropylene composite, while the screws were stainless steel in all cases. The cortical bone was modeled as an anisotropic material (like fibrous composite). A ten-node tetrahedral element for bones and eight-node solid element (C3D8R) for screws, calluses, and bone plates was utilized. After obtaining the final shapes of the calluses, the elements were changed from elastic to poroelastic and the eight-node solid elements (C3D8R) were converted into eight-node poroelastic elements (C3D8RP). The outer boundary of the calluses was set to be impermeable to prevent exchange of fluid with external tissues, but fluid could move independently within the calluses. Tie conditions were applied between the bone-screw and plate-screw assemblies. Loading condition was assumed to be 10% of a 70-kg human during the first eight weeks and was shared across the tibial plateau with 60% and 40% loading over areas of 452 and 290 mm^2, respectively (see Fig. 2b). The opposite end of the tibia was fixed with six degrees of autonomy.

2.3. Simulative approach to bone fracture healing

Computer simulations of bone healing were based on an iterative procedure using a biphasic mechano-regulation algorithm, where at