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Optimal design of a functionally graded biodegradable composite bone plate by using the Taguchi method and finite element analysis

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ABSTRACT

The current study aimed to investigate the influence of design factors of a functionally graded biodegradable composite bone plate on the healing of a tibia fracture. A finite element model of a human fractured tibia was constructed in ABAQUS 6.10, and the bone fragments were assembled with a bone plate and screws. Four design parameters of a composite bone plate were studied to investigate their influence on bone fracture healing. The Taguchi method with the design of experiments (DOE) was used for optimal design of the bone plate. Three levels of each design parameter were determined, and a standard orthogonal array L_9 (3^4) was constructed to perform the simulations according to the table array. To optimize the design parameters of the bone plate and maximize the healing performance, signal-to-noise ratio was used, as a larger signal-to-noise ratio was better. The optimum levels of design parameters of the bone plate were selected, and the optimal design of a bone plate was suggested to maximize the healing performance. The optimal condition of design parameters was successfully determined by using the Taguchi method, and it was shown to maximize the healing of bone fractures.

1. Introduction

Internal fixations by using the minimally invasive percutaneous plate osteosynthesis (MIPPO) technique has many advantages including excessive blood loss prevention, less pain, rapid recovery, short operation time, among others [1–3]. Fractured bones are commonly assembled with bone plates and screws. Conventionally, metallic materials such as stainless steel, titanium alloy, and cobalt chromium are used for bone plates and screws. These metallic bone plates have much higher elastic moduli than that of fractured bones, which cause a stress shielding effect and can lead to bone necrosis, nonunion, and a delay in bone union followed by stress shielding [4–7]. Stress shielding also disturbs the formation of the calluses and does not provide a complete bridge to fractured bones, leading to deterioration of the healing process. Additionally, when subjected to body fluids, metallic plates may cause problems such as corrosion, implant loosening, poor fatigue life, harmful metallic ions, and incompatibility with magnetic resonance imaging and computed tomography [8–10]. Moreover, a second surgery is required to remove the metallic bone plates after union of the fractured bones, leading to many problems such as blood loss, pain, additional operation costs, refractures, among others.

A completely biodegradable and bioactive bone plate can be used instead of a metallic bone plate. This type of bone plate provides not only the solution for the aforementioned fundamental problems but also has additional benefits such as gradual stress transfer at the fracture site, no second surgery needed, bioactive ions to enhance bone healing, and ultimately provides excellent bone union [11,12]. Stress shielding is sensitive to the Young's modulus of a bone plate [13] and an appropriate Young's modulus (20 GPa) was determined in our previous studies [11,14,15]. A composite bone plate made of functionally graded material (FGM) was introduced to achieve a different bending stiffness while keeping the same Young's modulus which can give different healing of bone fractures [16].

The healing of bone fractures can be estimated by using various mechano-regulation theories that are associated with local biomechanical environments [17–19]. All the theories reported similar results but a simple and efficient mechano-regulation theory with a deviatoric strain has been proven the best for the estimation of bone healing [20,21].

Healing of bone fractures is influenced by the initial loading condition, and the loading condition is dependent on gait pattern. The loading is associated with the mechanical environment at the fracture site, and these mechanical forces are used to predict bone healing by using mechano-regulation theories [17]. Therefore, according to our previous studies [14,22], the best loading condition used in our study gave the highest healing of bone fractures.

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The design of a bone plate also affects the healing of bone fractures. The design parameters including the average Young's modulus, spatial distribution of FGM layers, degradation rate of material, and the thickness of the bone plate are the major influential parameters that should be optimally selected.

The current study describes the methodology used for the optimal design of a bone plate. The Taguchi method [23] was used to design the experiments to determine the influence of the design factors of a bone plate on the healing of bone fractures. Three levels of each design parameter were selected in our study. A mechano-regulation theory with a deviatoric strain and finite element analyses were used to estimate the healing of bone fractures. Signal-to-noise (SN) ratio was chosen to maximize the bone healing, as a larger SN ratio is better. The optimal design of the bone plate was selected by choosing optimal levels of each design parameter that maximized the healing performance.

2. Material and methods

2.1. Finite element model

Ganesh et al. [24] measured the dimensions of a tibia bone by using a digitizer. A diaphyseal section of the tibia of a healthy male patient who was 30-years-old and weighed 70 kg was studied. The dimensions and geometry of the bone were simplified to a smooth circular shape [24,25], which was also used in our current study. A 3-D finite element model of the tibia bone was constructed in ABAQUS 6.10. The simplified tibia consisted of a 5-mm thick orthotropic cortical bone with an outer diameter of 25 mm that surrounded an isotropic trabecular bone with an outer diameter of 15 mm. A smooth transverse fracture with a 3-mm gap was created in the middle of the bone. The central and external calluses were also modeled to fill the fracture gap and bridge the fractured bone segments, respectively. Six holes were created in the bone to assemble the bone fragments, bone plate, and screws, as shown in Fig. 1a. A commercially available compression bone plate with 7 holes (Model 3-642, TREU-Instrumente, Germany) and 6 bicortical screws were modeled to fix the bone plate (Fig. 1a), while 1 hole remained empty. The bone plate was divided into 6 sections along its thickness, and different material properties were assigned to make it a FGM bone plate. Additionally, the thickness of the bone plate varied (2 mm, 3.5 mm, and 4.5 mm). An 8-node solid element (C3D8R) was used, and the mesh size of the calluses was 1 mm for accurate convergence. The number of elements of the bones, calluses, bone plate, and screws varied (28728, 7090, 3924–7512, and 1728, respectively). The screws were tied to the bones, and a friction coefficient of 0.4 was imposed at the plate-bone and plate-screws interface [24].

2.2. Material properties

Cortical bone is anisotropic and trabecular bone is isotropic in nature; therefore, orthotropic and isotropic material properties were used, respectively [26,27]. Bone plates were designed by using completely biodegradable materials (phosphate glass fiber [PGF]/polylactic acid [PLA] composite) [28]. The material properties of the PGF, PLA, bones, and screws are provided in Table 1. The initial material properties of composite bone plates were calculated by using the rule of mixtures and the Halpin–Tsai model [29], as in our previous study [16]. All the material properties were calculated by the assumption of unidirectional long fibers aligned in the longitudinal direction (0° orientation) of the bone plate. The material properties varied in each layer of the FGM bone plate (see Fig. 1b); however, the average Young's moduli of bone plates were designed to be 10 GPa, 20 GPa, and 30 GPa by adjusting the combination of the 6 layers (see Fig. 1c). One homogenous and 2 FGM bone plates (symmetric 1 and symmetric 2) were modeled, as shown in Fig. 1b. The Young's moduli of the outermost, intermediate, and innermost layers of the 10 GPa (average modulus) bone plate were 15 GPa, 10 GPa, and 5 GPa, respectively, and the Young's moduli of the outermost, intermediate, and innermost layers of the 20 GPa (average modulus) bone plate were 30 GPa, 20 GPa, and 10 GPa, respectively. Similarly, the Young's moduli of the outermost, intermediate, and innermost layers of the 30 GPa (average modulus) bone plate were 40 GPa, 30 GPa, and 20 GPa, respectively (see Fig. 1d). Additionally, various degradation rates of material of each bone plate were considered, as shown in Fig. 1e. The rate of degradation in each layer was assumed the same owing to the bulk erosion. In biodegradable polymer materials such as PLA, water reaches the core of the material before it reacts and degradation starts homogeneously when τ_H (rate of hydrolysis) is much higher than τ_D (rate of diffusion). The water diffusion is very fast compared to water-mediated hydrolysis therefore, water can be uniformly distributed within the polymer from the beginning of erosion process, and hydrolysis promotes homogeneous bulk erosion [30,31].

2.3. Loading and boundary conditions

Load at the fractured part of a tibia bone creates the mechanical environment at the fracture site, and the healing process is greatly influenced by mechanical forces [22]. Therefore, the best loading conditions were determined in our previous study [22,14] and used in the current study. Surgeons suggest that patients walk with a pair of crutches immediately after surgery. The injured leg alternatively swings in this gait pattern, and only muscular forces are applied to the fracture, which were measured as 10% of the body weight (BW) [32-34]. This was used for the loading condition for 7 weeks after surgery. From 8–11 weeks after surgery, 200% of the BW was used when a patients walk with a stick or during abnormal walk. This load gradually increased from 200–300% of the BW 12–16 weeks after surgery (see Fig. 2). The pressure (MPa) was calculated as BW (Newton) divided by the cross-sectional area (mm^2) of the cortical bone; the pressure was 0.22 MPa, 4.4 MPa, and 6.6 MPa for 10% BW, 200% BW, and 300% BW, respectively. This pressure was applied at one end of the cortical bone, and the other end of the bone was fixed in all directions (see Fig. 1a). The load was updated in every iteration and executed by using the user's subroutine programmed by Python 3.1.

2.4. Mechano-regulation algorithm for estimation of bone healing

The mechano-regulation theory with deviatoric strain has been proven the best for estimation of bone healing [20, 21, 34]. To estimate the effect of various design parameters of bone plates on bone fracture healing, mechano-regulation theory with deviatoric strain was used. Sixteen iterative calculations were carried out with the user's subroutine programmed by Python 3.1 and ABAQUS 6.10 (Fig. 2). One iteration represents 1 week of healing. The loading condition and material properties of the calluses were updated during iterative calculations. The deviatoric strains in the calluses determined the Young's modulus in each element of the calluses and the tissue phenotypes accordingly. The deviatoric strain (ε_{ds}) is given in the following equation

$$\varepsilon_{ds} = \frac{2}{3}\sqrt{(\varepsilon_1 - \varepsilon_2)^2 + (\varepsilon_2 - \varepsilon_3)^2 + (\varepsilon_3 - \varepsilon_1)^2} \qquad (1)$$

where ε_1, ε_2, ε_3 are the principal strains of the calluses.