Medical Engineering & Physics 35 (2013) 422–432

Contents lists available at SciVerse ScienceDirect

Medical Engineering & Physics

journal homepage: www.elsevier.com/locate/medengphy

Finite element analysis on the biomechanical stability of open porous titanium scaffolds for large segmental bone defects under physiological load conditions

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ARTICLE INFO

Article history:
Received 4 October 2011
Received in revised form 25 April 2012
Accepted 15 June 2012

Keywords:
Finite element analysis
Segmental bone defect
Osteosynthesis system
Bone scaffolds
Titanium
Physiological loading
Muscle forces

ABSTRACT

Repairing large segmental defects in long bones caused by fracture, tumour or infection is still a challenging problem in orthopaedic surgery. Artificial materials, i.e. titanium and its alloys performed well in clinical applications, are plenary available, and can be manufactured in a wide range of scaffold designs. Although the mechanical properties are determined, studies about the biomechanical behaviour under physiological loading conditions are rare. The goal of our numerical study was to determine the suitability of open-porous titanium scaffolds to act as bone scaffolds. Hence, the mechanical stability of fourteen different scaffold designs was characterized under both axial compression and biomechanical loading within a large segmental distal femoral defect of 30 mm. This defect was stabilized with an osteosynthesis plate and physiological hip reaction forces as well as additional muscle forces were implemented to the femoral bone. Material properties of titanium scaffolds were evaluated from experimental testing. Scaffold porosity was varied between 64 and 80%. Furthermore, the amount of material was reduced up to 50%. Uniaxial compression testing revealed a structural modulus for the scaffolds between 3.5 GPa and 19.1 GPa depending on porosity and material consumption. The biomechanical testing showed defect gap alterations between 0.03 mm and 0.22 mm for the applied scaffolds and 0.09 mm for the intact bone. Our results revealed that minimizing the amount of material of the inner core has a smaller influence than increasing the porosity when the scaffolds are loaded under biomechanical loading. Furthermore, an advanced scaffold design was found acting similar as the intact bone.

1. Introduction

Healing of large segmental bone defects in long bones still represents a challenge in orthopaedic surgery. Autologous material offers good bone healing but is still associated with a number of limitations, e.g. limited availability and donor site morbidity [1–4].

Besides biological materials (autologous, allogen and xenogen) some synthetic materials like calcium phosphate (CaP)-based materials are successfully used in clinical applications for bone defects [5–9]. Nevertheless, their application is not recommended for load-bearing areas [5,8,10].

Therefore, bone substitutes made of titanium exhibit better mechanical resistance against mechanical loading and are used in a wide range of clinical applications. Because of long lead times for the fabrication of necessary tools, traditional fabrication methods like forging and casting are often expensive and time consuming. In contrast to that using additive manufacturing (AM) processes like selective electron beam melting (SEBM) and selective laser sintering (SLS), implants can be fabricated in a wide range of designs and modifications directly from CAD data. This offers the possibility to create completely formed implants as well as open-porous scaffolds with regularly arranged structures [11–14]. Scaffolds made of titanium, being intended to improve bone ingrowth throughout the whole scaffold, should fulfil the requirements of an open-porous structure with interconnecting pores. Scaffolds with an open cellular structure could show their suitability in both *in vitro* and *in vivo* studies [15,16]. AM fabrication processes allow a high degree of control over both internal architecture like pore size, structural design and degree of interconnectivity and external shape. Subsequently, the mechanical properties of open-porous scaffolds can be influenced directly by the arrangement of their geometry [17,18] and can be adapted to the mechanical properties of bone [19].

However, characterizing the mechanical properties of different scaffold designs and parameter variations requires a lot of experimental as well as *in vivo* testing for complex loading conditions and can be very time consuming. Finite element analysis (FEA) offers the possibility to investigate the mechanical properties like structural modulus, compressive strength and stress distribution within complex structures to optimize the requirements for the field of clinical application without the use of scaffold fabrication or destructive experimental testing.

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http://dx.doi.org/10.1016/j.medengphy.2012.06.006

There are mainly two different numerical approaches to analyse and optimize bone scaffolds.

The first method is an engineering approach. Varying designs and geometrical parameters are generated prior to testing. In order to describe the mechanical properties of the numerical scaffolds, uniaxial loading with or without comparison to experimental testing is performed [20–22]. This method is comparable to classical material testing and is suitable for one or more previously generated fixed geometries, as long as the material input parameters are well known in order to receive reliable numerical results.

The second method is an analytical approach. The geometrical shape and the structural design are automatically adapted to fit a target criterion with the aid of optimization algorithms. Target criterion can be either the optimization of the material distribution and scaffold design under different loading conditions, in order to minimize the amount of material and to improve the mechanical properties [23–25] or to fit the requirements of the surrounding tissue properties [26,27].

Besides the determination of the scaffold stability, the scaffold–tissue interaction could also be considered, e.g. effect of stress on the bone cells. In this case, the influence of shear stresses caused by elastic deformation and fluid dynamics within the pores due to the fluid flow rate through the scaffold can be determined [28,29].

Despite the optimization under different loading conditions or the alignment to specific material properties, studies about the biomechanical behaviour of bone scaffolds under physiological loading conditions are rare. Depending on the field of application, scaffolds for bone regeneration behave in a different way compared to uniaxial loading conditions. Therefore, biomechanical characterization of the mechanical behaviour of scaffolds cannot be performed only by uniaxial compression testing without concerning the physiological loading conditions.

Furthermore, there are still controversial findings about the correlation of the material properties of open-porous structures and the geometrical parameters. Scaffold porosity, i.e. relative density, is often used as a key factor for the characterization of the mechanical properties. On the one hand, the mechanical properties showed a good correlation with the porosity of the scaffolds [13,14], based on the findings of Gibson and Ashby for cellular structures [30]. On the other hand, there are findings of the mechanical properties, that correlate less with the porosity than with the strut cross-sectional area [18] or changes significantly with the load direction [31]. In order to aspire to desired scaffold geometry, the parameters influencing the properties have to be identified.

Therefore, the biomechanical response of fourteen scaffold designs generated with varying pore sizes and materials consumption were analysed numerically under both uniaxial and physiological load conditions within an entire femoral bone model with a segmental defect and physiological hip reaction and muscle load. For the numerical analysis mechanical properties of the scaffolds were determined by extracting parameters for both elastic and plastic regions from experimental tensile testing of a Ti6Al4V non-porous test sample. Structural modulus, biomechanical stability and correlation of the mechanical properties with the structural design of the scaffolds were analysed to characterize the behaviour of the scaffolds.

2. Materials and methods

2.1. Material properties for the bone scaffolds

Numerically generated scaffolds are meant to be made of titanium in order to provide sufficient mechanical stability. Material properties were modelled as homogeneous and isotropic with a non-linear elastic–plastic material behaviour. Isotropic hardening was implemented for the plasticity of the material. Poisson's ratio was assumed to be 0.33 [22,32,33].

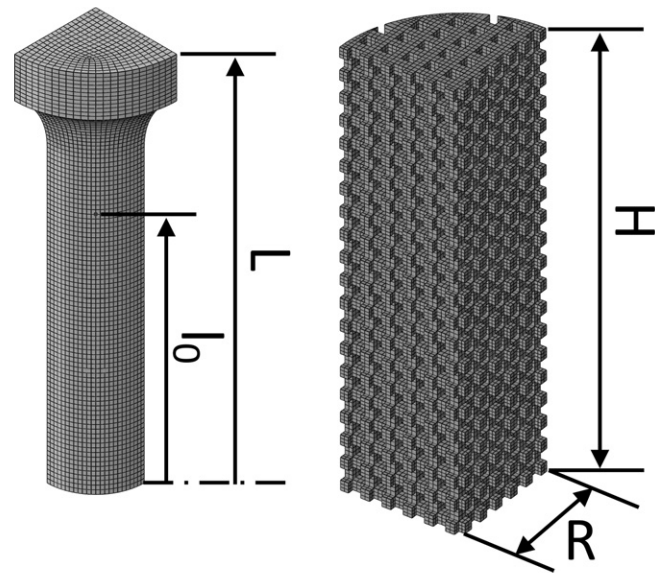

Fig. 1. FE models for the material property calculations. Non-porous numerical model, analogue to the tensile sample, according to DIN standard (DIN50125–B6 × 30, left). In order to reduce the computational time, only one-eighth were modelled, leveraging the symmetry of the part. L represents the free length of the sample between the clamps, i.e. 48 mm. L_0 is the length of the attachment points of the extensometer, i.e. 30 mm. Determined material properties were transferred on the open-porous numerical model, analogue to the compression sample (right). Again, due to the symmetry only a quarter was modelled. Height H and radius R of the sample are 27.9 and 7.8 mm, respectively. Overall porosity of the open-porous numerical model was 63.6% with a regular pore size of 700 μm.

Elastic–plastic material parameters for the numerical analysis have been determined from experimental testing of additive manufactured titanium samples. Test samples have been fabricated from titanium powder via SEBM process [34] as non-porous tensile ($n = 3$) samples as prescribed in DIN standard (DIN50125 – B6 × 30) and custom-made open-porous compression test samples ($n = 3$). The latter ones exhibited a cylindrical shape (15.5 mm diameter, 27.9 mm length, pore size of approximately 700 μm) with an overall porosity of 63.7 ± 0.4%, calculated by the weight and the volume of the scaffold. Testing was conducted by the manufacturer (Department of Material Science, University of Nuremberg-Erlangen) with a constant strain rate of 0.5% min^{-1} for the non-porous samples and a traverse velocity of 1.6 mm min^{-1} for the open-porous samples. Load–displacement relation was recorded for all testing procedures.

In order to implement the full non-linear material behaviour on the numerical scaffolds, two FE models were generated, according to the experimental test samples, i.e. featuring a non-porous and a small-size open-porous cylindrical shape (Fig. 1). These models were solely used for the determination of the material properties. The non-porous tensile FE model was used to evaluate the non-linear material properties by parameter modification for the plastic region. Subsequently, these material properties were implemented onto the small-size open-porous FE model in order to determine the deviation for an open-porous structure with idealized geometry (porosity = 63.6%) compared to the experimental compression testing [22].

Displacements were applied on the outer boundaries of the numerical models as performed on the experimental setup. Subsequently, engineering stress–strain relation for both numerical models was compared to the experimental test results.