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Development of a multi-component fiber-reinforced composite implant for load-sharing conditions

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ABSTRACT

Fiber-reinforced composites (FRC) have the potential for use as load-bearing orthopaedic implants if the high strength and elastic modulus of FRC implant can be matched with local requirements. This study tested the *in vivo* performance of novel FRC implants made of unidirectional glass fibers (E-glass fibers in Bis-GMA and TEGDMA polymeric matrix). The implant surface was covered with bioactive glass granules. Control implants were made of surface-roughened titanium. Stress-shielding effects of the implants were predicted by finite element modelling (FEM). Surgical stabilization of bone metastasis in the subtrochanteric region of the femur was simulated in 12 rabbits. An oblong subtrochanteric defect of a standardized size (reducing the torsional strength of the bones approximately by 66%) was created and an intramedullary implant made of titanium or the FRC composite was inserted. The contralateral femur served as the intact control. At 12 weeks of healing, the femurs were harvested and analyzed by radiography, torsional testing, micro-CT imaging and hard tissue histology. The functional recovery was unremarkable in both groups, although the final analysis revealed two healed undisplaced peri-implant fractures in the group of FRC implants. FEM studies demonstrated differences in stress-shielding effects of the titanium and FRC implants, but the expected biological consequences did not become evident during the follow-up time of the animal study. Biomechanical testing of the retrieved femurs showed no significant differences between the groups. The torsional strength of the fixed bones had returned the level of contralateral intact femurs. Both implants showed ongrowth of intramedullary new bone. No adverse tissue reactions were observed. Based on these favorable results, a large-scale EU-project (NewBone, www.hb.se/ih/polymer/newbone) has been launched for development of orthopaedic FRC implants.

1. Introduction

Metallic implants used in reconstructive orthopaedic and trauma surgery have mechanical properties different from those of bone. The mismatch of the mechanical properties leads to physiological underloading of the bone, thus increasing the likelihood of adverse bone remodelling. In adults with hip and knee replacements, antiresorptive bisphosphonate may help to prevent periprosthetic bone loss caused by implant stress-shielding [1]. In contrast, the increasing use of large megaprosthesis has resulted in cases of serious periprosthetic bone loss (Fig. 1). This is an emerging problem of limb salvage surgery especially in young bone tumor patients with improved life expectance.

Fiber-reinforced composites (FRCs) are potentially useful alternatives for metallic implants as FRCs can be tailored to closely match the various moduli of bone. As another potential benefit, non-metallic implants may produce fewer artefacts with CT and MRI diagnostic imaging. This would be a major advantage particularly in patients with megaprosthesis for the follow-up of tumor control. Diagnostic imaging of FRC implants with suspected mechanical loosening or infection might be also more feasible compared with metallic implants.

Previously, carbon fiber-reinforced polymers have been promoted as promising orthopedic biomaterials [2]. However, most clinical applications such as hip arthroplasties have failed due to composite failures [3], poor implant design [4] or as a result of accumulation of wear debris due to increased implant-bone interface stresses [5]. Despite many theoretical advantages of less rigid

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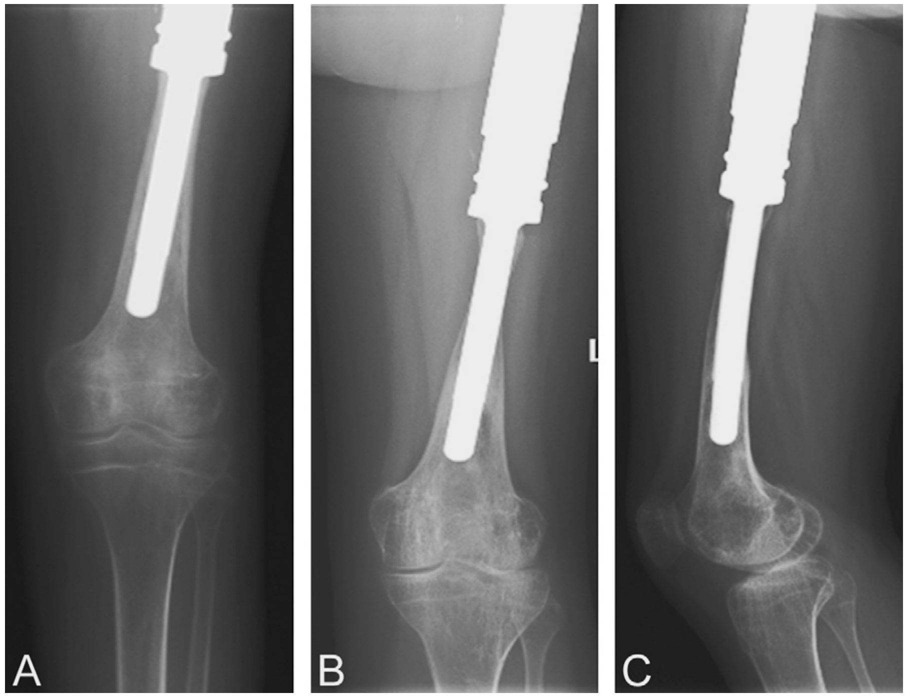

Fig. 1. X-rays of the distal femur of a 18-year-old woman, who underwent radical resection and megaprosthetic reconstruction of the left proximal femur due to Ewing's sarcoma at the age of 13. Two years after surgery, the distal femur showed early signs of cortical thinning around the distal prosthetic stem (A). Five years after surgery, there is a major progression of the periprosthetic cortical bone loss due to stress-shielding (B and C). The patient needs bone grafting procedure in order to restore the supporting bone structure and prevent periprosthetic bone fracture.

plate fixation of long bones [6], fracture fixation plates made of carbon fiber-reinforced polymers [7] never made clinical success. As a proof of concept recent studies have, however, suggested that low-modulus composite hip stems [8] and high stiffness carbon fiber-reinforced bone plates [9] indeed might represent a valuable option to metallic implants.

As the initial step of orthopaedic implant development, this study evaluated the use of novel FRC implants made of unidirectional glass fibers under load-sharing bone healing conditions. This high-strength and durable FRC [10] was originally developed for oral use in dental applications [11,12]. The *in vivo* tissue biocompatibility of the biomaterial was tested in calvarial defect models of the rabbit [13,14]. Using a rabbit model, the current study simulated surgical stabilization of bone metastasis in the subtrochanteric femur region by means of an intramedullary implant made of microroughened titanium or FRC with bioactive glass granules as osteoconductive surface component. Finite element modelling (FEM) was also applied to predict strains in the bones with defects stabilized with intramedullary implants.

2. Materials and methods

2.1. Study design

An explanatory block diagram (Fig. 2) describes the main components of the study. The first part of the study included the evaluation of the material properties of FRC implants and the structural properties of the intact cadaver bones for FEM as well as the torsional testing of bone specimens with subtrochanteric defects. The gathered information was applied in the FEM analyses and in

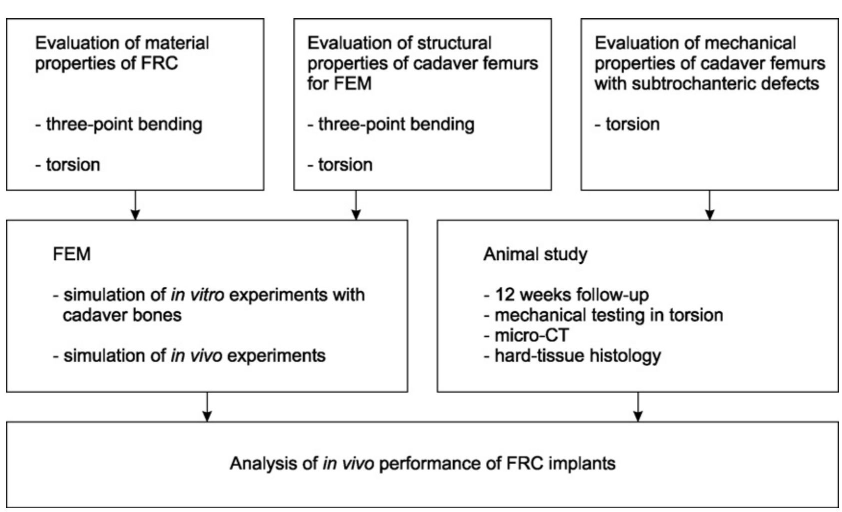

Fig. 2. The overall study design including different mechanical tests using cadaver bones, FEM analysis and animal experiment.