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Bone attachment to glass-fibre-reinforced composite implant with porous surface

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Abstract

A method has recently been developed for producing fibre-reinforced composites (FRC) with porous surfaces, intended for use as load-bearing orthopaedic implants. This study focuses on evaluation of the bone-bonding behaviour of FRC implants. Three types of cylindrical implants, i.e. FRC implants with a porous surface, solid polymethyl methacrylate (PMMA) implants and titanium (Ti) implants, were inserted in a transverse direction into the intercondular trabeculous bone area of distal femurs and proximal tibias of New Zealand White rabbits. Animals were sacrificed at 3, 6 and 12 weeks post operation, and push-out tests ($n = 5$–6 per implant type per time point) were then carried out. At 12 weeks the shear force at the porous FRC–bone interface was significantly higher (283.3 ± 55.3 N) than the shear force at interfaces of solid PMMA/bone (14.4 ± 11.0 N; $p < 0.001$) and Ti/bone (130.6 ± 22.2 N; $p = 0.001$). Histological observation revealed new bone growth into the porous surface structure of FRC implants. Solid PMMA and Ti implants were encapsulated mostly with fibrous connective tissue. Finite element analysis (FEA) revealed that porous FRC implants had mechanical properties which could be tailored to smooth the shear stress distribution at the bone–implant interface and reduce the stress-shielding effect.
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1. Introduction

Non-resorbable fibre-reinforced composites (FRC) are potential materials for use in load-bearing orthopaedic implants, because they have a lower stiffness than conventional metallic implants and this can reduce the "stress-shielding" effect [1,2]. FRCs based on biocompatible polymer matrices, such as polyetheretherketone (PEEK) and polyetherimide (PEI), reinforced with glass and/or carbon fibres, have recently been extensively studied [3–8]. However, in the case of carbon-fibre-reinforced composites, most clinical applications such as hip prostheses have failed due to composite failures [9], unsuccessful implant design, deficient primary stability [10], or wear debris as a result of increased implant–bone interface stresses [11].

In this study, poly(methyl methacrylate) (PMMA) was chosen for matrix polymer due to its relatively good biocompatibility, after being polymerized ex vivo [12], and due to its good adherence to silanated glass fibres [13]. PMMA has been successfully and widely used in orthopaedic surgery despite fibrous encapsulation [14].

To achieve a long-term success of the implant, rigid fixation between implant and bone is required. One method to promote mechanical interlocking between implant and bone is to make the surface of the implant porous [15–17]. The push-out test has been demonstrated to provide a relatively simple method to evaluate the shear strength

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at the bone–implant interface [18–20]. The objective of in vivo study was to measure the attachment between the bone and three different implant materials, i.e. glass-fibre-reinforced PMMA composite with a porous surface (FRC), titanium (Ti) and PMMA with a solid surface, by implementing a push-out test.

Finite element analysis (FEA) is a valuable tool for the development of human joint implants and prediction of potential failure mechanisms [21–23]. In this study, shear stress and strain energy density (SED, material's ability to absorb energy up to the point of fracture) distributions were used to clarify the effect of porosity and elastic modulus of the material. Strain energy density was chosen since it has been used in predictions of bone remodelling before, and both stress and strain are considered to be important for bone growth [24].

Our hypotheses were: (1) the porous surface structure of the FRC implant would remarkably enhance the fixation between bone and implant; (2) an implant with a porous surface layer made of material with elastic properties closer to the structure of the surrounding bone would have smoother stress distribution than if it were made of significantly stiffer material like Ti; (3) in terms of volume and amount (average strain energy density level) the implant with a porous interface would load the surrounding bone more than the implant with a solid surface would.

2. Materials and methods

2.1. Preparation of the implants

Three types of rod-shaped implant materials were prepared, implanted in rabbits and examined with push-out tests. PMMA-based E-glass-fibre-reinforced composite (FRC) implants (including 10wt.% of chopped, randomly orientated fibres) with porous surfaces and PMMA implants with solid surfaces were prepared as described in our previous article [15]. The porous surface layer of the FRC was created by a tetrahydrofuran solvent treatment method [15]. Commercially pure (c.p.) Ti (grade 2) implants were used as controls. All materials were in the form of rods measuring 10 or 15 mm in length depending on the site of implantation (femur of tibia), and approximately 5.3 mm in diameter (Fig. 1). All implants were stored for 24 h at 37 °C in distilled water to wash out the residual solvent and MMA monomers.

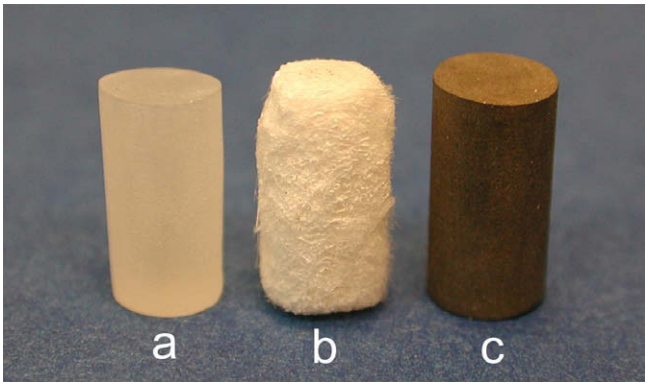

Fig. 1. Photograph of the implants ($Ø = 5.3$ mm, $l = 10$ or 15 mm): (a) PMMA, (b) FRC with porous surface, and (c) Ti.

Surface roughness of the implants ($n = 3$/implant type) was measured with a surface roughness tester (Surftest 301, Mitutoyo Corporation, Japan). The surface textures of the implants were examined with a scanning electron microscope (SEM, JSM-5500, JEOL, Tokyo, Japan) (Fig. 2). The specimens were coated with a gold layer using a sputter coater (BAL-TEC SCD 050 Sputter Coater, Balzers, Liechtenstein).

2.2. Surgical procedure

The animal experiments were approved by the Lab-Animal Care & Use Committee, the Central Animal Laboratory, the University of Turku and the State Provincial Office of Western Finland (permission no. 1345/03). Eighteen adult female New Zealand White rabbits weighing 3.0–3.5 kg were used in this study. The follow-up times in this study were 3 and 6 weeks for FRC and PMMA implants, and 12 weeks for all implant types including the control Ti implant. The implants were sterilized in autoclave for 20 min before the surgical operation at a temperature of 120 °C and a pressure of 0.1 MPa.

General anesthesia by midazolam (Dormicum® Roche Oy, Espoo, Finland) 1.5 mg kg^{-1} i.m. and medetomidine (Domitor® Orion-Yhtymä Oyj, Espoo, Finland) 0.25 mg kg^{-1} i.m. and ketamine (Ketalar® Pfizer Oy, Espoo, Finland) 15 mg kg^{-1} i.m. was used, the operational area was shaved and surgery was performed in sterile operating conditions. The cortical surface of the distal part of the left femur and the proximal part of the left tibia were exposed through the anteromedial approach. Holes (5.3 mm) were drilled using a dental burr, with sterile physiological saline irrigation transversally through the intercondylar area of the bone. One randomly selected implant ($n = 5$–6 implants/type/follow-up time) was inserted into each femur (length of implant: 15 mm) and tibia (length of implant: 10 mm). Incisions were closed with interrupted absorbable polyglycolic acid sutures (Dexon®, Tyco Healthcare UK Ltd., Gosport, UK) and uninterrupted polyamid sutures (Ethilon®, Johnson & Johnson Intl., Brussels, Belgium).

The rabbits were placed in cages, given post-operative doses of buprenorphine (Temgesic® Schering-Plough Europe, Brussels, Belgium) 0.015 mg kg^{-1} s.c. for three days and allowed unrestricted movement at all times. The rabbits were sacrificed with an overdose of pentobarbital (Nembutal®, Orion Oyj, Espoo, Finland).

2.3. Push-out test

Fresh bones were separated from surrounding tissue and cut into two blocks (Fig. 3). One block ($l = 5.2$ mm) was used in a push-out test, which was performed on a univer-

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