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Technical note

A preliminary biomechanical study of a novel carbon–fibre hip implant versus standard metallic hip implants

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ABSTRACT

Total hip arthroplasty is a widespread surgical approach for treating severe osteoarthritis of the human hip. Aseptic loosening of standard metallic hip implants due to stress shielding and bone loss has motivated the development of new materials for hip prostheses.

Numerically, a three-dimensional finite element (FE) model that mimicked hip implants was used to compare a new hip stem to two commercially available implants. The hip implants simulated were a novel CF/PA12 carbon–fibre polyamide-based composite hip stem, the Exeter hip stem (Stryker, Mahwah, NJ, USA), and the Omnifit Eon (Stryker, Mahwah, NJ, USA). A virtual axial load of 3 kN was applied to the FE model. Strain and stress distributions were computed. Experimentally, the three hip stems had their distal portions rigidly mounted and had strain gauges placed along the surface at 3 medial and 3 lateral locations. Axial loads of 3 kN were applied. Measurements of axial stiffness and strain were taken and compared to FE analysis.

The overall linear correlation between FE model versus experimental strains showed reasonable results for the lines-of-best-fit for the Composite (Pearson $R^2 = 0.69$, slope = 0.82), Exeter (Pearson $R^2 = 0.78$, slope = 0.59), and Omnifit (Pearson $R^2 = 0.66$, slope = 0.45), with some divergence for the most distal strain locations. From FE analysis, the von Mises stress range for the Composite stem was much lower than that in the Omnifit and Exeter implants by 200% and 45%, respectively. The preliminary experiments showed that the Composite stem stiffness (1982 N/mm) was lower than the metallic hip stem stiffnesses (Exeter, 2460 N/mm; Omnifit, 2543 N/mm). This is the first assessment of stress, strain, and stiffness of the CF/PA12 carbon–fibre hip stem compared to standard commercially-available devices.

1. Introduction

Degeneration of articular cartilage (i.e. osteoarthritis) of the human hip joint may be caused by a complex interplay between mechanical injuries and chemical processes [1]. This can lead to severe pain, loss of function, instability, and deformity brought on by high or uneven stress distributions across the hip [2–4]. The most common surgical treatment for this condition is the implantation of a total hip replacement (THR). It consists of a cobalt–chrome (or ceramic) femoral head inserted over the neck of a cobalt–chrome (or titanium) alloy stem, which then articulates against an acetabular cup made from ultra-high-molecular-weight polyethylene, ceramic, or cobalt–chrome alloy [5]. About 1 million people worldwide receive THR's each year, with high clinical success rates of 93% at 10 years and 85% at 15 years following surgery [6].

The most susceptible regions to failure in standard THR's are those where two contacting surfaces have dissimilar mechanical properties, such as implant–cement, bone–cement, and implant–bone interfaces [7]. At implant–bone interfaces, the phenomenon of bone stress shielding can be problematic. It occurs because of the large difference in mechanical stiffness between the metallic stem and the often osteoporotic and osteopenic host femur. Bone stress shielding is a persistent challenge because of the large disparity in mechanical stiffness between the metallic stem and the often osteoporotic and osteopenic host bone. Stress shielding and osteoporosis can lead to bone resorption which can potentially contribute to the implant loosening caused by micromotion and particle debris from osteolysis. This has motivated the development of hip stems from other materials which are more closely stiffness-matched with the host femur. One suggestion has

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been the use of low-modulus titanium-based alloys [8–10], which have elastic moduli ranging from 60 to 80 GPa. When compared with conventional biomedical titanium (Ti–6Al–4 V) stems the low-modulus alloys are able to reduce stress shielding, but their moduli are still four to five times higher than that of the host bone. Moreover, their high cost, inferior wear properties, and susceptibility to corrosion effects have prevented their common use [11,12].

Carbon–fibre composite stems have also shown promise because they are able to reduce stress gradients at the bone–stem interface [13–15]. Recent investigations on a carbon fibre-based polymer known as CF/PA12 (carbon fibres/polyamide 12) has demonstrated that it is biocompatible [16] and its cross-weave surface texture permits good bony ongrowth [17]. Computer modeling has indicated that CF/PA12 can reduce stress shielding compared to stainless steel stems [18,19]. Moreover, mechanical tests have shown that CF/PA12 stems have a similar flexural modulus as human cortical bone [20]. However, no prior studies have experimentally determined the surface strains and stresses of hip prostheses manufactured from CF/PA12 and compared them directly to standard metallic hip stems under the same conditions.

The purpose of this preliminary study, therefore, was to compare the mechanical behaviour of the novel composite material hip stem with two standard commercially-available metal hip implants, namely, the Exeter and the Omnifit manufactured by Stryker (Mahwah, NJ, USA). A finite element (FE) model was developed to determine hip stem strain and stress values under static axial loads. The FE model was validated using mechanical tests. It was hypothesized that the composite hip stem would carry less axial load compared to the two Stryker implants, thereby potentially reducing stress shielding and minimizing implant loosening, than the standard metallic hip stems.

2. Methods

2.1. Hip implants

2.1.1. Composite hip stem

The composite hip stem is composed of a 3 mm thick substructure composite (CF/PA12, carbon fibre polyamide 12). It has a carbon fibre weight of 68%, as determined from thermal gravimetric analysis, and a 100 μ thick bioactive hydroxyapatite coating in the proximal section to promote bone osseointegration and enhance the fixation strength [18,20]. The substructure of the stem is composed of 6 concentric layers of composite oriented at ±45° to reproduce the stiffness of cortical bone, which typically has an elastic modulus E of 12–20 GPa. The hollow stem follows the natural curve of femoral bone and has an oval cross-section, a shaft angle of 135°, a wall thickness of 3 mm, an overall length of 230 mm, a maximum diameter of 30.3 mm at the proximal base of the neck, a 37.5 mm offset, and a minimum diameter of 15.8 mm at the distal tip.

2.1.2. Exeter hip stem

The Exeter hip stem (size 2, offset 37.5) (Stryker, Mahwah, NJ, USA) is comprised of a single piece of CoCrMo alloy material. The stem was characterized by a double-taper geometry and the absence of a collar with a polished surface, which allows gradual subsidence of the stem into the cement mantle [21]. Dimensions include total length (150 mm) and the distal tip diameter (4 mm).

2.1.3. Omnifit hip stem

The Omnifit Eon hip stem (Size 7, offset 41 mm) (Stryker, Mahwah, NJ, USA) is comprised of a single piece of titanium alloy material [21]. The implant has a collar at the neck base to assist seating in the intramedullary canal. The outer surface is multi-sided to enhance bony ongrowth around the implant and increase rotational stability. Dimensions included total length (165 mm) and distal tip diameter (10.4 mm).

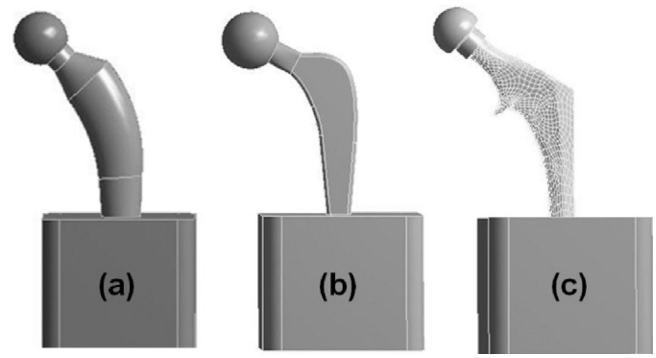

Fig. 1. CAD models for hip implant using the (a) Composite, (b) Exeter, and (c) Omnifit devices. The vertical force indenter is not shown.

2.2. Finite element (FE) models

2.2.1. General approach

CAD models of the three hip stems (Fig. 1) were developed and strain and stress maps generated. The FE models were created so that each stem model was of identical working length while subjected to an applied load. Hip stems were subjected to a static axial force of 3 kN at 0° of adduction. This load level represented one-legged stance activity during normal walking and is approximately 3–4 times body weight for a 75 kg person [22].

Hip stems may be clinically exposed to axial forces over a range of adduction angles during activities of daily living, such as walking, sitting/rising from a chair, stair climbing, one-legged stance, two-legged stance, etc. Choosing one of these angles might have limited the generalizability of the results. However, the intention of this study was to assess the hip stems in a generic orientation. Thus, a mechanically neutral alignment was chosen in which the axial force was parallel to the mechanical long axis of the stems themselves. Numerical simulations for the three devices were then validated experimentally at 3 kN of axial load as described below (Fig. 2) (see Section 2.3).

2.2.2. CAD model of hip implants

SolidWorks 2008 (SolidWorks Corp., Dassault Systèmes Concord, MA, USA) CAD software was employed to create a solid model of the composite and Exeter hip stems, while a NextEngine 3D scanner (NextEngine, Inc., Santa Monica, CA, USA) was used to generate the complex geometry of the Omnifit stem. The NextEngine Scanner has the capacity to measure 50,000 points every second with multi-laser precision. This permits the user to rapidly generate digital models in colour and with great detail. The models were generated based on the geometries of specimens used in the experimental phase of the study. This involved scanning and modeling individual components and assembly for export in Parasolid, IGES or STL format.

2.2.3. Assembly of the CAD models

All hip stems were positioned in a fixed distal base replicating the experimental set-up. A stainless steel acetabular cup indenter was added to simulate vertical loading on the cobalt–chrome femoral heads. This was done within Solidworks 2008 to ensure that the CAD model accurately replicated the experiments. The geometry was exported as a parasolid file into ANSYS Design Modeler, where Body Operations were performed to guarantee no overlap of components within the assembly. This geometry was