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Research Paper

Biomechanical properties of a structurally optimized carbon-fibre/epoxy intramedullary nail for femoral shaft fracture fixation

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ABSTRACT

Intramedullary nails are the golden treatment option for diaphyseal fractures. However, their high stiffness can shield the surrounding bone from the natural physiologic load resulting in subsequent bone loss. Their stiff structure can also delay union by reducing compressive loads at the fracture site, thereby inhibiting secondary bone healing. Composite intramedullary nails have recently been introduced to address these drawbacks. The purpose of this study is to evaluate the mechanical properties of a previously developed composite IM nail made of carbon-fibre/epoxy whose structure was optimized based on fracture healing requirements using the selective stress shielding approach. Following manufacturing, the cross-section of the composite nail was examined under an optical microscope to find the porosity of the structure. Mechanical properties of the proposed composite intramedullary nail were determined using standard tension, compression, bending, and torsion tests. The failed specimens were then examined to obtain the modes of failure. The material showed high strength in tension (403.9 ± 7.8 MPa), compression (316.9 ± 10.9 MPa), bending (405.3 ± 8.1 MPa), and torsion (328.5 ± 7.3 MPa). Comparing the flexural modulus (41.1 ± 0.9 GPa) with the compressive modulus (10.0 ± 0.2 GPa) yielded that the material was significantly more flexible in compression than in bending. This customized flexibility along with the high torsional stiffness of the nail (70.7 ± 2.0 N m^2) has made it ideal as a fracture fixation device since this unique structure can stabilize the fracture while allowing for compression of fracture ends. Negligible moisture absorption ($\sim0.5\%$) and low porosity of the laminate structure ($<3\%$) are other advantages of the proposed structure. The findings suggested that the carbon-fibre/epoxy intramedullary nail is flexible axially while being relatively rigid in bending and torsion

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and is strong enough in all types of physiologic loading, making it a potential candidate for use as an alternative to the conventional titanium-alloy intramedullary nails.

1. Introduction

An efficient fixation device must stabilize the fracture by keeping detrimental fragments' motions to a minimum, while allowing for some levels of axial movements between fracture ends (Rockwood et al., 2010). To fulfil this requirement, the fixation device must bear torsional and bending loads (i.e. has high bending and torsional stiffnesses) while being axially flexible (i.e. has a moderately low axial stiffness). Designing such a structure is technically impractical using isotropic materials (e.g. metallic alloys) since axial, bending, and torsional stiffnesses of an isotropic material depend on the elastic modulus which is identical in all directions. On the other hand, fibre-reinforced composites can be customized to obtain desired stiffness and strength in different directions by changing the composition of fibres or the stacking sequence of plies.

The focus of the present study is on intramedullary (IM) nails that are the standard treatment of choice for diaphyseal fractures and are widely used to treat femoral shaft fractures. Conventional metallic IM nails made of titanium (Ti)-alloys or Stainless Steel can provide appropriate stability at the fracture site as a result of their high bending and torsional stiffnesses. However, an undesirable consequence of such sturdy implants is peri-implant osteopenia as their high axial rigidity causes the nail to bear the majority of the load once implanted, deviating the surrounding bone from the load to which it would be naturally subjected (Cheung et al., 2004). This removal of normal stress from the bone, which is known as “stress shielding” effect, causes the bone to adapt by reducing its density which can lead to re-fracture (Wolff, 1892). Moreover, decreased compressive loading at the fracture site due to the high axial stiffness of metallic implants can slow the healing process (Buckwalter and Grodzinsky, 1999; Rockwood et al., 2010). Composite IM nails have recently been introduced to address these drawbacks. They were shown to significantly increase the load levels on the surrounding bone while remaining stiff enough to stabilise the fracture and strong enough to withstand physiologic loading (Samiezadeh et al., 2014). In addition, a composite nail can be customized to be stiffer in bending and torsion than in compression. Such customization was performed on a carbon-fibre (CF)/epoxy in one of the authors' previous studies (Samiezadeh et al., 2015a) in which a composite tube with similar geometry to a conventional IM nail was optimized to yield maximum bending and torsional stiffness while having a low axial stiffness. Although several researchers have investigated the use of carbon-fibre-reinforced composites for bone fracture plate applications (Ali et al., 1990; Fujihara et al., 2003; Tayton et al., 1982), there are very few studies on the use of composite materials for IM nails (Morawska-Chochół et al., 2015; Moritz et al., 2014). In one recent study, Moritz et al. (2014) developed composite IM nails made of E-glass fibres and bisphenol A dimethacrylate (BisGMA) and triethylene glycol dimethacrylate (TEGDMA) resin. Braided glass fibre sleeves were added to the unidirectional (UD) structure to enhance its properties in bending and torsion. The composite IM nails were then used to fix fractured femurs of 14 rabbits. They harvested the femurs after 12 weeks of follow-up and compared the torsional strength of healed femurs with that of the contralateral intact femur of same rabbit which served as the control group. They found that the healed bone had 83% of the torsional strength of the contralateral femurs, and did not observe any implant debris or adverse tissue reaction following fixation. The findings of their study suggested the possibility of using fibre-reinforced composite IM nails to fix diaphyseal fractures. However, they only considered two types of structure for their IM nail and no optimization was performed on the nail structure to fulfil the requirements of a proper healing.

As part of an ongoing research programme for fabrication of composite IM nails, the authors performed a comprehensive study to obtain the optimal composite structure for an IM nail based on fracture healing requirements. The optimization was performed through altering the thickness and the stacking sequence of the laminate forming the IM nail wall to minimize axial stiffness, while maximizing torsional and bending stiffnesses (Samiezadeh et al., 2015a). Stiffnesses rather than moduli were optimized as the former defines the load sharing characteristics of an implant. Closed-form solutions for different stiffnesses of the composite beam were obtained using the combination of the classical laminate theory and beam theory. All configurations resulting in extension-twist and extension-bending couplings were excluded from the set. The best candidates were examined in a comprehensive validated finite element analysis to evaluate their performance in transverse and oblique femoral shaft fractures with all major muscle loading present (Samiezadeh et al., 2015a). However, the mechanical properties of the optimized composite IM nail are yet to be evaluated.

Therefore, the purpose of the current work was to determine the most influential mechanical properties of the CF/epoxy composite IM nail whose structure was previously customized to fulfil fracture healing requirements (Samiezadeh et al., 2015a). In particular, the composite nail was tested in tension, compression, 3-point bending, and torsion to simulate clinical-type loading the nail is subjected to when placed into the femoral canal. In addition, the moisture absorption behaviour of the composite nail was investigated to seek the possibility of using such structure in-vivo, and the surface hardness was obtained through the Rockwell Hardness B test. Finally, surface rough measurements were performed in the fibres direction and perpendicular to them and the surface roughness was compared to that of the Ti-alloy used to manufacture conventional IM nails.