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On the mechanical behaviour of PEEK and HA cranial implants under impact loading

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ABSTRACT

The human head can be subjected to numerous impact loadings such as those produced by a fall or during sport activities. These accidents can result in skull fracture and in some complex cases, part of the skull may need to be replaced by a biomedical implant. Even when the skull is not damaged, such accidents can result in brain swelling treated by decompressive craniectomy. Usually, after recovery, the part of the skull that has been removed is replaced by a prosthesis. In such situations, a computational tool able to analyse the choice of prosthesis material depending on the patient's specific activity has the potential to be extremely useful for clinicians. The work proposed here focusses on the development and use of a numerical model for the analysis of cranial implants under impact conditions. In particular, two main biomaterials commonly employed for this kind of prosthesis are polyether-ether-ketone (PEEK) and macroporous hydroxyapatite (HA). In order to study the suitability of these implants, a finite element head model comprising scalp, skull, cerebral falx, cerebrospinal fluid and brain tissues, with a cranial implant replacing part of the skull has been developed from magnetic resonance imaging data. The human tissues and these two biocompatible materials have been independently studied and their constitutive models are provided here. A computational model of the human head under impact loading is then implemented and validated, and a numerical comparison of the mechanical impact response of PEEK and HA implants is presented. This comparison was carried out in terms of the effectiveness of both implants in ensuring structural integrity and preventing traumatic brain injury. The results obtained in this work highlight the need to take into account environmental mechanical considerations to select the optimal implant depending on the specific patient: whereas HA implants present attractive biointegration properties, PEEK implant can potentially be a much more appropriate choice in a demanding mechanical life style. Finally, a novel methodology is proposed to assess the need for further clinical evaluation in case of impact with both implants over a large range of impact conditions.

1. Introduction

The human head is often subjected to impact loading during automobile accidents, falls or sport-related events. These impact conditions can lead to mechanically-induced head injury, which constitutes one of the major causes of accidental death (Sahoo et al., 2016). Head injuries are generally grouped into three categories: scalp damage, skull fracture, brain injury, or a combination of these (Khalil and Hubbard, 1977). Skull fracture occurs when the tolerance limit of the skull is exceeded due to mechanical loading. These fractures result in permanent damage and account for 32% of all head injuries sustained by pedestrians, motorcyclists, vehicle occupants and sportsmen (Fredriksson et al., 2001). In some cases, where there is contamination from a laceration, the fractured zone of the skull can be removed and later replaced by a biomedical implant whose main functions are cosmetic and to act as a structural component protecting the brain against external loads. However, the replacement of part of the skull does not necessarily result from skull fracture. In this regard, cranial implants are also widely used after decompressive craniectomy. This has become a relatively common intervention when managing traumatic brain injury (TBI), subarachnoid hemorrhage, severe intracranial infection and stroke (Honeybul and Ho, 2016). In these terms,

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the main aim of neurosurgeons dealing with the reconstruction of large and complex-formed bone defects is a predictable and stable functional and aesthetic result (Eolchiyan, 2014). Often, when decompressive surgery is needed, the use of an autologous bone for large cranial reconstructions is not possible due to size, unacceptable appearance, or infection, fragmentation and bone resorption after grafting (Rosenthal et al., 2014). Neurosurgeons have to choose a material to be used; polyether-ether-ketone (PEEK) and macroporous hydroxyapatite (HA) are the most common biomaterials selected due to their biocompatibility and mechanical properties.

PEEK is a semi-crystalline thermoplastic polymer considered as an engineering material for use in high-quality applications due to its excellent mechanical and thermal properties as well as good chemical resistance (Garcia-Gonzalez et al., 2015a, 2015b). Large cranial defects are often dealt with through cranioplasties involving PEEK implants designed from preoperative high-resolution computed tomography (CT) scans. The direct contact between the implant and bone tissue is ensured by the customisation of the implant from the CT images thus achieving a precise definition of its contour and curvature (El Halabi et al., 2011). The suitability of using PEEK for implants is known and its biocompatibility has been studied and demonstrated (Horak et al., 2010; Jockisch et al., 1992; Rivard et al., 2002).

Macroporous HA is a bioceramic material which constitutes 60% of bone, and has similar mechanical characteristics. This material exhibits a number of properties which make it suitable to be used in skull defect reconstructions: biocompatible, sterilisable, adequate weight, compatible with diagnostic imaging and easy to design and manufacture (Stefini et al., 2013). The presence of calcium and phosphate ions (similarly to natural bone) participates to the formation of new bone tissues on the surface of the implant (Chistolini et al., 1999). Furthermore, HA mimics the macroporous structure of the living bone. This structure allows new bone to grow by filling not only the voids on the surface of the cranioplasty, but also the pores within the internal structure (Frassanito et al., 2013). As such, once the prosthesis has been placed in the skull and bone has grown within, the implant can be treated as a composite material where HA acts as the matrix and bone as the reinforcement. Moreover, HA shows excellent biocompatibility due to the absence of host immune reactions (Boyde et al., 1999; Marcacci et al., 1999; Olmi et al., 1984). However, despite these advantages, HA implants are rigid and offer a considerably lower resilience than human bone. This fact implies a minor mechanical resistance and minor energy absorption capability with respect to human bone (Frassanito et al., 2013).

When dealing with large cranial defects, an important aspect to take into account is the load-bearing capacity of the structural prostheses, since the patients need to go back to active life, with their heads potentially subjected to future impact loadings. While the use of biocompatible materials such as PEEK and HA in cranial implants is widely accepted, there is a lack of knowledge in terms of their mechanical response under potential future impact loads arising from the patient life style. The main aim of the research presented in the current paper is to develop a computational tool able to simulate the mechanical behaviour of implants under impact loading which can help clinicians to determine the optimal patient-specific implant material. As a second contribution, a numerical tool is proposed to evaluate the risk of implant failure when a patient has been involved in a given accidental impact. To this end, a finite element head model (FEHM) has been developed from magnetic resonance imaging (MRI) data comprising scalp, skull, cerebral falx, cerebrospinal fluid (CSF), brain tissues and an implant replacing part of the skull. The constitutive models of the human tissues included in the FEHM are individually chosen from the literature. For the PEEK, a constitutive model previously developed and validated for this specific material by the authors is used (Garcia-Gonzalez et al., 2017). An experimental programme aimed at characterising experimentally macroporous HA has been carried out with specimens manufactured from a real cranial implant. As a second step, its mechanical properties after bone regrowth have been numerically estimated. The FEHM is then used to study the mechanical response under a wide range of impact conditions. Numerical simulations were conducted in order to compare the mechanical response of PEEK and HA cranial implants. This analysis was carried out by focussing on the implant effectiveness in avoiding failure and TBI, while covering an impact velocity range from 1 m/s to 7 m/s for several impact locations on the skull along three different paths: from the parietal zone to vertex; from the parietal zone to occipital; and from the parietal zone to frontal. Ultimately, selection criteria for implant materials and a roadmap for further clinical assessments of bone and/or implant failure in case of post-operative impact are proposed.

2. Materials and methods

This section introduces the methodology followed in the development of the numerical head model for impact loading. Special attention is first paid to the mechanical characterisation of each human tissue and the correct identification of the boundary conditions during the impact process. The FEHM is then presented.

2.1. Mechanical behaviour of human head tissues and biomaterials

In this section, the constitutive modelling of each tissue and biomaterial is discussed in detail.

2.1.1. Scalp

Ottenio et al. (2015) tested skin specimens from a human back and identified an anisotropic rate-dependent behaviour of the skin. These properties are known to vary with its localisation in the human body as has been observed in experimental studies (Annaidha et al., 2012; Dunn and Silver, 1983; Khatam et al., 2014; Jacquemoud et al., 2007; Vogel, 1972; Zahouani et al., 2009).

More particularly, Gambarotta et al. (2005) carried out an experimental and numerical study of the mechanical behaviour of human scalp. The authors finally proposed a rate-independent, isotropic and hyperelastic constitutive model based on the phenomenological scheme developed by Tong and Fung (1976). However, because of the computational cost of numerical simulations which involve a full head model, most previous FEHM traditionally define scalp as an isotropic and homogeneous material through linear elastic constitutive laws (Horgan and Gilchrist, 2003; Liu et al., 2007; Sahoo et al., 2014; Willinger et al., 2000; Zhang et al., 2001). In this work, the scalp mechanical behaviour has thus been assumed to be rate-independent, isotropic, homogeneous and linear elastic, see Table 1. Note that, when a cranial implant is needed, the mechanical properties of this tissue can vary both in time and space in the zone affected by the surgery. While fully integrated HA could potentially be considered to be surrounded by the same surrounding tissue mechanical properties as in a normal situation (with full skull), such argumentation is not straightforwardly justifiable in the case of PEEK. However, as the immediate surrounding tissue (damaged or not) is in any case much softer than either the implants or the bone, it most likely does not influence significantly the

Table 1
Material properties for scalp.

Scalp			
Density (kg/m^3)	Poisson's ratio	Young's modulus (MPa)	Reference
1100	0.42	16.7	(Horgan and Gilchrist, 2003; Liu et al., 2007; Sahoo et al., 2014 Zhang et al., 2001)