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Research Paper

Mechanical properties of human bone–implant interface tissue in aseptically loose hip implants

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ABSTRACT

The main cause of failure in total hip replacement is aseptic loosening which is associated with the formation of a periprosthetic fibrous (interface) tissue. Despite important applications for finite element modeling of loose implants, the mechanical properties of the bone–implant interface tissue have never been measured in humans. In this study, we performed unconfined compression tests to characterize the mechanical properties of the interface tissue and to determine the parameters of various hyperelastic material models which were fitted to the measurements. Human interface tissues were retrieved during 21 elective revision surgeries from aseptically loosened cemented ($N=10$) and uncemented hip implants ($N=11$). Specimens were tested at a fixed deformation rate of 0.1 mm/min up to a maximum force of 10 N. Elastic moduli for low and high strain regions of the stress–strain curves were determined. Interface tissue from aseptically loose cemented prostheses shows higher elastic moduli (mean = 1.85 MPa, 95% C.I. = 1.76–1.95 MPa) in the high strain region as compared to that of the interface tissue from the cementless group (mean = 1.65 MPa, 95% C.I. = 1.43–1.88 MPa). The 5-terms Mooney–Rivlin model ($W = C_1[I_1-3] + C_2[I_2-3] + C_3[I_1-3][I_2-3] + C_4[I_1-3]^2 + C_5[I_2-3]^2$) described the stress–strain behavior the best. Large variations in the mechanical behavior were observed both between specimens from the same patient as between those of different patients. The material model parameters were therefore estimated for the mean data as well as for the curves with the highest and lowest strain at the maximum load. The model parameters found for the mean data were $C_1 = -0.0074$ MPa, $C_2 = 0.0019$ MPa, $C_3 = 0$ MPa, $C_4 = -0.0032$ MPa and $C_5 = 0$ MPa in the cemented group and $C_1 = -0.0137$ MPa, $C_2 = 0.0069$ MPa, $C_3 = 0.0026$ MPa, $C_4 = -0.0094$ MPa and $C_5 = 0$ MPa in the cementless group. The results of this study can be used in finite element computer.

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1. Introduction

The main cause of failure in total hip replacements is aseptic loosening (Garellick et al., 2011) which is associated with the formation of a fibrous interface membrane (Edwards et al., 2008; Jones et al., 1999; Neale et al., 2000; Quinn et al., 1992; Wang et al., 2005). This interface membrane has inferior mechanical properties as compared to bone, resulting in subsequent mechanical instability of the implant within the bone. As a result, large displacements of the prosthesis relative to the host bone could occur that may result in walking difficulties as well as severe pain and higher risk of pathological fractures. Currently, patients with loose prostheses undergo open revision surgery, which is a highly demanding procedure. In patients with poor general health, the complication rate of this surgical procedure is high, with up to 60% complications and up to 20% mortality (Strehle et al., 2000). Therefore, it is important to develop a less demanding surgical procedure to refixate the loosened implant with subsequent restoration of function.

Recently, a minimally invasive refixation procedure has been developed (De Poorter et al., 2008). During this refixation procedure, the interface tissue is (partially) removed and bone cement is injected into the osteolytic areas. Andreykiv et al. (2012) analyzed whether this cement injection into the osteolytic areas contributed to the overall implant stability, by using a detailed finite element model. Regarding the mechanical properties of the interface tissue, Andreykiv et al. referred to the study of Hori and Lewis (1982). This is the only study that reports such properties, however, interface tissue from dogs was used. Furthermore, most studies on interface tissue focus on the histo-morphological properties (Boss et al., 1994; Bravo et al., 2011; Goldring et al., 1986, 1983; Shoji et al., 1983). No information regarding the mechanical properties of human interface tissue is currently available. In order to develop a patient-specific refixation procedure and to determine where to inject bone cement to obtain an optimal refixation, patient-specific finite element models of implanted joints are needed (Poelert et al., 2013) and this requires the evaluation of the human interface tissue.

In this study, we perform unconfined compression tests (Hori and Lewis, 1982; Miller, 2005; Miller and Chinzei, 1997; Miller-Young et al., 2002; Umale et al., 2013; Wu et al., 2007) on human interface tissues retrieved during revision surgeries from loose cemented and uncemented hip implants. Linear elastic models are not adequate for describing the mechanical behavior of such soft materials. Therefore, the obtained force–displacement data is analyzed within the context of hyperelastic material models. Six different types of hyperelastic material models are fitted to the obtained experimental data to determine the parameters of the considered hyperelastic material models. The goodness of fit as well as the parameters of the material models are reported and discussed.

2. Materials and methods

2.1. Specimens

We obtained interface tissue from 21 patients with aseptically loose hip prostheses who had elective revision surgery. The demographic characteristics are listed in Table 1. Exclusion criterion was presence of a prosthetic infection as reason for revision. Stratification of the interface tissue was based on whether the prosthesis was cemented or cementless. A certificate of no objection for this study was obtained from the local Medical Ethics Committee. Immediately after intraoperative harvesting, the interface tissue was kept in saline solution at room temperature and was transported to the lab. When the interface tissue was not immediately tested ($N=5$) and had to be stored overnight, it was kept at 5–7 °C. A core punch (diameter 6.2 mm) was used to cut at least three specimens from the interface tissue of each patient.

2.2. Unconfined compression test

After harvesting, the specimens were mechanically tested within 48 h in unconfined uni-axial compression tests using a static mechanical testing machine (LR5K, Lloyd Instruments ltd, UK). A punch and anvil were constructed from stainless steel. The punch was attached to a 100 N load cell and the anvil was bolted to the table of the testing machine. Prior to testing, the punch was humidified with phosphate-buffered saline (PBS) solution to minimize friction between tissue and the punch (Rashid et al., 2012). The specimens were not preconditioned, placed at an anvil (Fig. 1), and tested at a fixed deformation rate of 0.1 mm/min up to a maximum force of 10 N, with a data sampling rate of 8 kHz. The thickness of the specimen was considered to be equal to the difference between the anvil surface and the position of the punch at the load of 0.1 N. Each specimen was only tested once and was subsequently discarded. During the tests, the specimens were submerged in a standard saline solution bath at room temperature.

2.3. Material models and uni-axial compression tests

Soft tissues are often modeled as incompressible hyperelastic materials (Martins et al., 2006), because linear elastic material models cannot sufficiently describe their mechanical behavior. Based on the results of the Hori and Lewis (1982) study in the animal model, we expected a non-linear behavior in human interface tissue as well. The Ogden and Mooney–Rivlin material models are sophisticated hyperelastic material

Table 1 – Demographic characteristics of the patients.

Parameter	Total 21 patients
Age (years)	75.3 (61–88; sd 7.7)
Gender	
Men	9
Women	12
Implant fixation	
Cement	10
Cementless	11
Time since implantation	
0–2 Years	2 (9.5%)
2–5 Years	1 (4.8%)
>5 Years	17 (81%)
Unknown	1 (4.8%)