Journal of the Mechanical Behavior of Biomedical Materials 82 (2018) 1–8

Contents lists available at ScienceDirect

Journal of the Mechanical Behavior of Biomedical Materials

journal homepage: www.elsevier.com/locate/jmbbm

Assessment of the viscoelastic mechanical properties of polycarbonate urethane for medical devices

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ARTICLE INFO

Keywords:
Polycarbonate urethane
Medical devices
Viscoelasticity
Bergström-Boyce
Implant material

ABSTRACT

The underlying research work introduces a study of the mechanical properties of polycarbonate urethane (PCU), used in the construction of various medical devices. This comprises the discussion of a suitable material model, the application of elemental experiments to identify the related parameters and the numerical simulation of the applied experiments in order to calibrate and validate the mathematical model. In particular, the model of choice for the simulation of PCU response is the non-linear viscoelastic Bergström-Boyce material model, applied in the finite-element (FE) package Abaqus®. For the parameter identification, uniaxial tension and unconfined compression tests under in-laboratory physiological conditions were carried out. The geometry of the samples together with the applied loadings were simulated in Abaqus®, to insure the suitability of the modelling approach. The obtained parameters show a very good agreement between the numerical and the experimental results.

1. Introduction

PCU belongs to the class of elastomers used for medical devices, which is characterised by its non-linear and strain-rate dependent mechanical behaviour. Due to its biocompatibility and mechanical properties, it has been incorporated in catheters, vascular grafts, artificial heart valves, and pacemaker leads (St. John, 2014; Khan et al., 2005a, 2005b). Moreover, due to its wear resistance compared to cross-linked ultra-high-molecular-weight polyethylene (UHMWPE), PCU is used for hard-on-soft bearings to mimic natural cartilage as the acetabulum in hip arthroplasty, the meniscus in knee arthroplasty (Kurtz, 2009; St. John and Gupta, 2012; Shemesh et al., 2014) or in artificial intervertebral discs (Benzel et al., 2011; van den Broek et al., 2012). In addition, PCU components are incorporated in numerous spinal posterior dynamic stabilisation devices (PDSD) to gain flexibility and viscous damping in the device, such as the Dynesys® (Zimmer Spine, Inc., USA), the Flex + 2® (Spine Vision, S.A., Belgium), the TDX® (Orthofix, Inc.) or the Transition® (Globus Medical, Inc.), to name a few.

Apart from clinical studies, the performance of spinal implants is usually measured by standardised tests, described by certification institutions, using in vitro tests or numerical simulations. Several numerical studies on implants with PCU components can be found in the literature. FE studies using the hyperelastic Mooney-Rivlin material model were performed by Gabarre et al. (2014) and Elsner et al. (2010) to simulate an artificial meniscus, composed of Bionate® 80A PCU. The most extensively investigated PDSDs using the FE method are the Dynesys (Lin et al., 2013; Tsai et al., 2016; Shin et al., 2007; Jahng et al., 2013; Kim et al., 2009; Kiapour et al., 2012; Shih et al., 2012; Zhang et al., 2009; Zhang and Teo, 2008; Liu et al., 2010; Park et al., 2015), and the Flex + (Zhang et al., 2009; Galbusera et al., 2011). However, a common drawback in many of the related published numerical studies is the implementation of pure elastic material models and ignoring the for PCU characteristic damping properties. Only few studies, such as Lawless et al. (2016) and Benzel et al. (2011), investigated the energy absorbing properties of spinal implants containing PCU dampers by determining the elastic and damping parameters.

With regard to experimental studies, it is worth mentioning that the manufacturing of standardised PCU specimens is challenging and expensive, as an injection mould has to be fabricated. Therefore, only few studies addressing the mechanical properties of PCU using standardised test methods can be found in the literature. For instance, Nic An Ghaill and Little (2008) performed volumetric compression tests, uniaxial tension tests and equi-biaxial tension tests on Bionate® 80A and Bionate® 75D specimens at 37.5 ° C to measure their bulk moduli, Young's moduli and Poission's ratio for the application of cushion form bearings. In this study, a strain-rate dependency has been observed and the identified Poission's ratios were around 0.49 for Bionate® 80A. A significant dependency of the material's properties on soaking time and temperature of Bionate® 80A was shown by Shemesh et al. (2014) and Geary et al. (2008), where it was found that the Bionate® materials reach water absorption equilibrium after two weeks to one month of soaking.

The aim of the underlying study is to assess the viscoelastic mechanical properties of Bionate® II PCU material using standardised tests

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https://doi.org/10.1016/j.jmbbm.2018.02.015
Received 31 December 2017; Accepted 12 February 2018
Available online 09 March 2018

and to calibrate viscoelastic material models for Bionate® II 80A and 90A. In particular, the experimental results were used for a parameter identification study of a non-linear viscoelastic framework model (see Section 3.2) with Yeoh hyperelasticity and Bergström-Boyce viscoelasticity, see Yeoh (1990), Bergström (1998), Bergström and Boyce (2000) and Dal and Kaliske (2009), among others. The assessed material parameters can be used to predict deformations, stresses and creep in implants under physiological load conditions using the FE method. To this end, uniaxial tension and unconfined compression tests were carried out on Bionate® II 80A and 90A PCU (DSM Biomedical, Berkeley, CA) under physiological conditions.

To give an overview, Section 2 is concerned with the experimental methods, followed by the theoretical background of the used model in Sections 3.1–3.2 and the methods of the parameter study in Section 3.3. The experimental results are presented in Section 4.1–4.2 and the calibrated material model in Section 5. Section 6 gives an overview of the study.

2. Experimental materials and methods

2.1. Experimental materials

In the underlying tests, specimens with two different geometries of Bionate® II 80A and 90A materials were prepared using injection moulding and water-jet cutting. For the compression tests, cylindrical specimens with a diameter of 29 mm and height of 12.5 mm were manufactured according to specimen type 7.1.2 of ASTM-D (6147)-97 (2014). For the tensile tests, dog-bone-shaped specimens (Fig. 1a) were produced according to specimen type 1BA of DIN EN ISO 527-2 (2012), with a testing length of 25 mm, a total length of 80 mm and a width and thickness of 5 mm, respectively.

2.2. Testing methods

A bioreactor (Fig. 1b), mounted on a uniaxial hydraulic testing machine (MTS, Canada) controlled the temperature and prevented drying of the soaked specimens by testing in heated vapour atmosphere. The water vapour was continuously supplied using a customary ultrasonic nebuliser, which was connected to the bioreactor. The bioreactor was sealed using a PE sleeve with an extraction system for the vapour. To regulate the temperature during testing, a temperature control unit was installed. This unit controls two heating cables, that are placed in the tube between the ultrasonic nebuliser and the bioreactor and around the specimen as illustrated in Fig. 1b. Moreover, the temperature was recorded using a third temperature sensor, placed next to the specimen. During testing, the reaction force and machine displacement were measured using a uniaxial load cell recording with 100 Hz (HBM GmbH, Germany) and an optical tracking system (Nexonar®, soft2tec GmbH, Germany), which was installed at the grips to track the global displacements with 10 Hz. In preliminary tests, the friction and bulging of the compression specimens were minimised, while preventing slipping of the specimen between the compression platens.

The test protocol (i.e. loading and boundary conditions) for the two tested materials was identical, and a displacement-controlled method with constant displacement rates was applied. Following the method for assessing the viscoelastic behaviour of elastomers given by Qi and Boyce (2005) and Bergström (1998), stepwise relaxation tests were performed with tensile and compression loading. Moreover, all specimens were constantly soaked at least 30 days in distilled water of 37 °C and preconditioned with 50 cycles and a strain of 30%. Further, the specimens were preconditioned and tested on different days to guarantee a fully relaxed initial condition. The compression tests were carried out on 3 specimens for each material with a displacement-rate of 0.5 mm/s up to 5% strain, 10% strain and 20% strain with holding periods of 60 min, 120 min and 180 min, respectively. For the uniaxial tensile tests, 3 specimens for each material were loaded with a displacement-rate of 0.5 mm/s until 60% of strain with holding periods of 60 min at 5%, 120 min at 30% and 180 min at 60% strain.

As the measurement volume of the bioreactor was closed to obtain physiological conditions regarding temperature and humidity, no direct sight on the specimen was possible, and thus, the local strain in the center of the dog-bone shaped specimen could not been assessed using

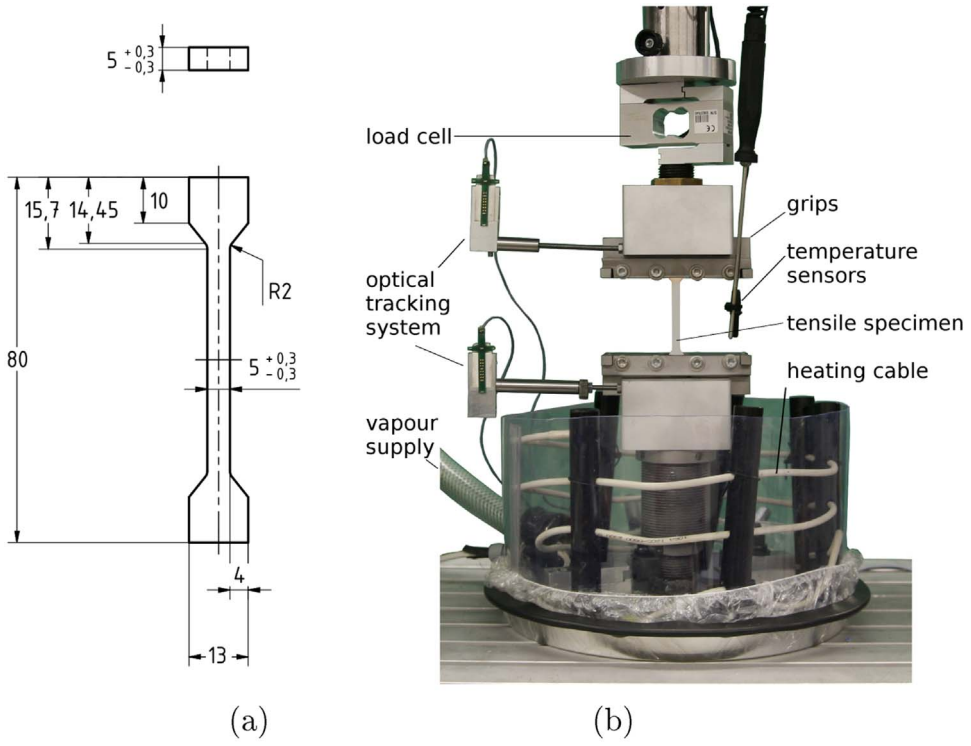

Fig. 1. (a) Geometry of the uniaxial tensile specimens in [mm], (b) Open test set-up to simulate body temperature and moist atmosphere.