JOURNAL OF THE MECHANICAL BEHAVIOR OF BIOMEDICAL MATERIALS 43 (2015) 78–90

Available online at www.sciencedirect.com

ScienceDirect

www.elsevier.com/locate/jmbbm

Research Paper

Mechanical and structural characterization of tibial prosthetic interfaces before and after aging under simulated service conditions

A. Cavaco[a,b], A. Ramalho[c], S. Pais[b], L. Durães[a,*]

[a]CIEPQPF, Department of Chemical Engineering, University of Coimbra, Rua Sílvio Lima, 3030-790 Coimbra, Portugal
[b]ESSUAlg, School of Health, University of Algarve, Avª. Dr. Adelino da Palma Carlos, 8000-510 Faro, Portugal
[c]CEMUC, Department of Mechanical Engineering, University of Coimbra, Rua Luís Reis Santos, 3030-788 Coimbra, Portugal

ARTICLE INFO

Article history:
Received 19 September 2014
Accepted 5 December 2014
Available online 18 December 2014

Keywords:
Tibial prosthesis
Elastomeric interface materials
Aging in sweat
Dynamic-mechanical characterization

ABSTRACT

Prosthesis interface is one of the most important components to promote individual's health and comfort, as it establishes direct contact with the skin and transfers loads generated during gait. The aim of this study was to mechanically characterize, three commercial interfaces (block copolymer, silicone gel and silicone elestomer), under static and dynamic conditions, before and after undergoing a process of chemical aging in synthetic sweat for periods up to 90 days. Static mechanical compression tests were performed on the materials, as well as fatigue tests to assess their static and dynamic mechanical behaviors, respectively. For the second, a sinusoidal load was applied with an appropriate range of deformation for each material. Several analytical techniques were also used to characterize the materials, namely Fourier Transform Infrared Spectroscopy (FTIR), X-ray diffraction (XRD), and morphology characterization by Scanning Electron Microscopy (SEM). All the tested materials have strong viscoelastic behavior, showing a linear response for small deformations, followed by a nonlinear behavior for higher deformation. The block copolymer and the silicone gel are affected by aging in synthetic sweat in a similar way, with a significant increase of their rigidity after 30 days, followed by a progressive reduction. The silicone elastomer displays a continuous increase of rigidity along the 90 days of storage, being the most sensitive to aging affects. It also exhibits the lowest stiffness value, being suitable for uses that require maximum comfort. All materials demonstrate chemical and structural stability under service simulated conditions.

*Corresponding author. Tel.: +351 239798737; fax: +351 239798703.
E-mail address: luisa@eq.uc.pt (L. Durães).

http://dx.doi.org/10.1016/j.jmbbm.2014.12.005
1751-6161/

1. Introduction

Amputation causes profound changes in individual's health, affecting their perception of comfort (Carvalho, 2003; Martín and Pérez, 2009; Ramos et al., 2007), quality of life (De Godoy et al., 2004), activity level and society participation (Huang et al., 2001; Sinha et al., 2011). In this context, the correct selection and application of the prosthesis determines the success of the rehabilitation process (Klute et al., 2001; Linde et al., 2004). The prosthesis must fulfill certain conditions, such as comfort, donning, weightlessness, durability, good mechanical function, pleasing esthetics, easy maintenance and low cost (Huang et al., 2001).

The proper application of the prosthesis is directly dependent on the correct selection of materials, according to their structure, properties and behavior (Lunsford and Contoyannis, 2009). Of all prosthesis components, the interface is specially important, due to its function in establishing a direct connection between the stump (*i.e.* the individual) and the prosthesis, being responsible for the transmission of ground reaction forces, damping gait loads and tissue protection (Huang et al., 2001; Klute et al., 2001). Silicone-based materials and polymeric elastomers, for instance urethane elastomers, have been used in its confection. The inadequacy of the interface may result in discomfort and serious skin problems, such as ulcers, contact dermatitis, eczema, epidermoid cysts and fungal infections or bacterial infections (Levy, 1980; Mak et al., 2001; Meulenbelt et al., 2009).

In the absence of joints and tissues for cushioning the impact on the amputated limb, the stump becomes vulnerable to the transmission of loads (Berge et al., 2005; Klute et al., 2001). The repetitive impact load that exists between the heel and the ground when walking, coupled to the referred absence of anatomical structures, can lead to pain on the stump (Klute et al., 2001).

To better understand the mechanical behavior of interfaces, exposed to these load cycles, Sanders et al. (2000) investigated the compressive stiffness of eight types of materials: spenco, poron, silicone, soft pelite, medium pelite, firm plastozote, normal plastozote and nickelplas. Spenco, poron and silicone were recommended for situations where it is desirable to keep the interface thickness and volume, as these materials have high capacity to recoverable deformation. The nickleplast behaved with linearity but with greater stiffness, suggesting that it does not offer a significant effect of cushioning. In a later stage, more fifteen commercial interfaces were tested under compression, tension and shear forces by Sanders et al. (2004), including specimens made of silicone elastomer, silicone gel and polyurethane. The silicone gel was softer during the compression tests and more like the biological tissues of the stump, suggesting that it would be more appropriate to cushion and protect the bony prominences of the stump. The silicone elastomer has shown more compression rigidity, as well as the polyurethane sample, proving to be advantageous for stumps with excess soft tissue, as they do not add more strain to the already existing soft tissue. The results of the shear tests led to the conclusion that the silicone elastomers and polyurethane are the most suitable materials for stumps with high proportion of soft tissue, because they prevent the slide of the stump in the socket, while silicone gels are appropriate for stumps with abundant bony prominences, due to the already mentioned cushioning effect (Klute et al., 2010; Sanders et al., 2004).

Moreover, Selinger (2004) identified only three published studies comparing the properties of various materials used in interfaces. These studies report that the physical properties of the silicone gel and silicone elastomers are quite similar. They indicate that elastomers are often preferred due to their stiffness properties and compressive strength, while polyurethane shows higher coefficient of friction.

Dynamic mechanical tests were conducted on interface materials by Emrich and Slater (1998), who investigated samples of bock-lite, pedilin, silicone and polyurethane. The interfaces were tested under cyclic compressive load, cyclic abrasive cutting load and friction. Bock-lite and silicone needed the highest number of cycles to failure under mechanical compressive loads, in contrast to polyurethane and pedilin that needed a lower number of cycles. It was also possible to verify that the sample of bock-lite resisted 15 times more cycles than pedilin under abrasion shear forces.

The relationship between normal and shear components of the force applied by the socket in the stump is very complex. It changes along the residual limb surface and depends on the loads exerted during gait. It also depends on the design of prosthetic units outside the socket. Exact evaluation of pressures requires the ability to deal with the viscous-elastic properties of prosthetic interfaces, residual limb skin, and soft tissues compressed against the bones (Pitkin, 2010).

In summary, the soft interface plays a key role in gait performance and comfort because it acts as a coupling body between the limb and the hard socket, having the following goals, from the mechanical point of view: transmit the load; distribute the pressure by the limb surface, reducing interface stresses; smooth the peak of the transmitted forces; adapt the motion between the limb and the interface by deformation, preventing the relative motion in order to minimize the occurrence of pressure ulcers. The availability of rigidity and damping characteristics of the interfaces materials is thus crucial to allow the use of numerical models to estimate the values of the contact forces and the corresponding stress distribution on the contact limb-prosthesis. Only assessing the material properties will be possible to optimize the interface material selection and adapt its geometry to the needs of the amputee, essentially concerning his activity. For this purpose, a functionality classification method was developed by DMERC Medicare Advisory (1994). This scale has five levels, from K0 (highly dependent – patients do not have the ability or potential to ambulate or perform transfers safely with or without assistance; in this case the prosthesis does not enhance their quality of life or mobility) to K4 (highly independent – patients have skills or potential to ambulate with a prosthesis and exceeds daily living basic skills activities, namely those involving high levels of impact, stress or energy consumption during activity). This classification method is normally used by manufacturers to classify the suitability of prosthesis components according to patients functional level (Berke, 2007).