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Research paper

Short-term fatigue testing can predict medium-term pericardium behaviour

R. Claramunt[a,*], *J.M. García Páez*[a], *L. Alvarez*[b], *J. Spottorno*[c], *A. Ros*[a], *M.C. Casado*[d]

[a] *Departamento de Mecánica Estructural y Construcciones Industriales, ETSI Industriales, Universidad Politécnica de Madrid, C/ José Gutiérrez Abascal, 2., 28006 Madrid, Spain*
[b] *Cirugía Experimental, Hospital Puerta de Hierro Majadahonda, Manuel de Falla, 1., 28222 Majadahonda, Spain*
[c] *Instituto de Magnetismo Aplicado (ADIF/UCM/CSIC), P.O. Box 155, 28230 Las Rozas, Spain*
[d] *Departamento de Didáctica, Universidad de Alcalá, Calle Madrid, 1, 19001 Guadalajara, Spain*

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ABSTRACT

The medium-term fatigue behaviour of calf pericardium (similar to the one used to manufacture cardiac bioprostheses valve leaflets) has been studied.

96 samples were tested under fatigue subjecting them to biaxial stress at 1 Hz frequency for 5000 cycles, in 4 series of 24 samples, at several supra-physiological mean pressures and pressure amplitudes. Short-term damage parameters such as the accumulated energy consumption in 10 cycles (E_{10}) and medium-term ones after 5000 cycles like total energy consumption (E_t) and maximum displacement of the membrane (D_t) have been evaluated.

E_{10} showed exponential growing tendency with pressure and linear tendency with pressure amplitude when only one parameter curve was plotted. Similar results were found when analysing E_t and D_t.

Linear correlation models were established between E_{10} and E_t and E_{10} and D_t. Similar results were achieved in the four series, with excellent determination coefficients.

The results confirm that the fatigue behaviour from the very first cycles of the test can predict the medium-term behaviour of the tissue by means of measurement of suitable damage markers.

The tendencies observed between the parameters seem to show that the results could have been the same ones if the test had been performed at physiological pressures and amplitudes.

This work opens the door to a non-destructive test of the tissue prior to employ it to manufacture valve leaflets.

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* *Corresponding address:* Laboratorio de Resistencia de Materiales, ETSI Industriales – UPM, C/ José Gutiérrez Abascal, 2., 28006 Madrid, Spain. Tel.: +34 91 336 3092; fax: +34 91 336 3092.
E-mail address: rclaramunt@etsii.upm.es (R. Claramunt).

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1. Introduction

The correct heart function becomes disabled when native heart valves experience severe opening or closing difficulties and valve replacement has to be then performed. Cardiac valve prostheses (Vongpatanasin et al., 1996) can be mechanical or biological.

Mechanical prostheses usually have more durability than bioprostheses but their high thrombosis risk makes it necessary to use anticoagulant drugs during the patient's lifetime and it increases both patient's mortality due to haemorrhage and sanitary and social costs (Vongpatanasin et al., 1996).

Modern biological prostheses are haemodynamically excellent (Jennings et al., 2002), and they do not need permanent anticoagulants; unfortunately, they have a high failure risk after ten years (Fann et al., 1996; Barratt-Boyes et al., 1998), due to structural damage (Tyers et al., 1995; Schoen et al., 1987; Kent et al., 1998; Butany and Leask, 2001), tearing or microcracks (Schoen et al., 1987; Haziza et al., 1996).

Spain is a European country with 45 million inhabitants, pioneer in cardiac transplants. In 2005 about 17 times more patients improved life quality by means of a cardiac biological prosthesis than by means of a cardiac transplant (Igual and Saura, 2007; Saura, 2007). Enlarging bioprostheses durability is therefore from the highest medical interest.

Valve leaflets are subjected to mechanical fatigue, with repetitive load and unload cycles. Since fatigue makes breakage of materials easier, failure takes place at lower stress than the one got from a static test (Broom, 1977). The continuum damage induced to the material is the responsible of failure, but in native valves the damage level of the tissue could be so low that it could properly heal itself.

Fatigue testing appears as a natural way to evaluate goodness of valve tissue behaviour, but valve leaflets have to support a very high number of cycles (about 10^9 for 30 years lifetime). Therefore, it is impossible to test them under fatigue at physiological stress and frequency: the lasting of the test would be about 30 years and consequently a simplified testing method is needed. Even more, if the tissue could be subjected to a non-destructive test prior to manufacture the valve, then the best zones of the biomaterial could be chosen to make the leaflets (Paez et al., 2009).

The first alternative to decrease testing time is to increase the frequency. Unfortunately, the biomaterials used to manufacture valve leaflets are highly viscoelastic and fatigue behaviour is severely altered at non-physiological frequencies (Zhang, 2005).

Another alternative to accelerate damage would be to increase the fatigue test parameters (mean stress and stress amplitude). The obtained data could be then extrapolated to the physiological parameters range if a defined relationship between damage markers and fatigue parameters could be properly established (Schott et al., 1996).

The fatigue testing method is also an important choice. Uniaxial tensile tests are the most widely extended ones (Broom, 1978; Gasser et al., 2008), but collagen-based biomaterials used for the manufacturing of valve leaflets (as pericardium) are highly anisotropic and so the initial orientation of the collagen fibres plays a critical role in the tissue fatigue response (Sellaro et al., 2007; Sacks et al., 1994). Such orientation is not known a priori, and the scatter of the results can be extremely high, depending on the load direction in respect to the fibres. The biaxial tensile test is closer to the real work of the valve leaflets (a thin sheet of tissue subjected to pressure perpendicular to its plane), and solves the problem of the load-fibres orientation (Paez et al., 2009).

The damage markers to be measured must also be carefully chosen. Since continuum damage modifies material characteristics, damage can be observed, for instance, in the form of changes in the tissue deformation experienced for a given stress. Damage can also be evaluated as the energetic loosening between the loading and unloading processes (consumed energy); this loss of energy is invested in generating damage (Paez et al., 2009).

The short-term fatigue behaviour of calf pericardium and the medium-term one have been evaluated in this work by means of two damage markers: the deformation of the tissue and the energy loss. Successful relationships between their values at 10 and 5000 cycles have been proved and thus the medium-term fatigue behaviour of pericardium can be inferred from a very short and non-destructive test.

The tests were carried on under biaxial tension at physiological frequency, but at non-physiological mean pressures and amplitudes in order to accelerate the assay. The tendencies found between the short- and medium-term damage parameters and the testing conditions (mean pressure and amplitude) were examined, and they encourage the possibility of finding in the future an extrapolation to the physiological range.

2. Material and methods

2.1. Material

Calf pericardium obtained from a local slaughterhouse was used for the test. The age of the sacrificed animals was between twelve and fifteen months. The tissue was transported in cold isotonic saline solution (0.9% sodium chloride) to the laboratory, where it was manually cleaned from greasy tissue.

All the pericardium specimens presented similar morphology and they covered the anterior part of the heart, between the right and left ventricles. Every membrane was approximately 15 cm high, in apical–caudal direction, by 10 cm wide.

The pericardial sacs were opened, leaving the diaphragmatic ligament in the centre and the breastbone–pericardial ligaments in its circumference (Fig. 1), in order to proceed to the orientation and cutting of samples (Purinya et al., 1994).

Three 20 mm diameter circular samples were cut from each membrane (Fig. 1).

The samples' thickness was measured by means of ten randomized point readings. A digital Mitutoyo Elecont micrometer, which had an accuracy of ± 3 μm at 20 °C, was used. The minimum thickness values were between 0.250 and 0.500 mm.

The tissue was treated with 0.625% glutaraldehyde, prepared from a commercial solution of 25% glutaraldehyde

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