The major problem with heart valve bioprostheses made from chemically treated porcine aortic valves is their limited longevity caused by gradual deterioration, which has a causal link with valve tissue mechanical properties. To our best knowledge, there are no published studies on the mechanical properties of modern, commercially available bioprostheses comparing them to native human valves. The objective of this study is to determine the mechanical properties of St Jude Epic bioprostheses and to compare them with native human and porcine aortic valves. Leaflets from eight porcine aortic valve leaflets and six Epic bioprostheses were analyzed using uni-axial tensile tests in radial and circumferential directions. Mechanical properties of human valves have been previously published by our group. Results are presented as mean values ± S.D. Results: Circumferential direction. Modulus of elasticity of Epic bioprostheses in circumferential direction at the level of stress 1.0 MPa is 101.99 ± 58.24 MPa, 42.3 ± 4.96 MPa for native porcine and 15.34 ± 3.84 MPa for human aortic valves. Ultimate stress is highest for Epic bioprostheses 5.77 ± 1.94 MPa, human valves have ultimate stress of 1.74 ± 0.29 MPa and porcine 1.58 ± 0.26 MPa. Ultimate strain in circumferential direction is highest for human valves 18.35 ± 7.61% followed by 7.26 ± 0.69% for porcine valves and 5.95 ± 1.54% for Epic bioprostheses. Radial direction. Modulus of elasticity in radial direction is 9.18 ± 1.81 MPa for Epic bioprostheses, 5.33 ± 0.61 MPa for native porcine, and 1.98 ± 0.15 MPa for human aortic valve leaflets. In the radial direction ultimate stress is highest for Epic bioprostheses 0.7 ± 0.21 MPa followed by native porcine valves 0.55 ± 0.11 MPa and 0.32 ± 0.04 MPa for human valves. For human valves ultimate strain is 23.92 ± 4.87%, for native porcine valves 8.57 ± 0.8% and 7.92 ± 1.74% for Epic bioprostheses. Conclusions: Epic bioprostheses have non-linear stress–strain behavior similar to native valve tissue, but they are significantly stiffer and hence less elastic compared to native porcine and human aortic valves. These differences in mechanical properties may cause variations in stress distribution within leaflets of the bioprosthetic valves and accelerate their deterioration.

© 2009 Published by European Association for Cardio-Thoracic Surgery. All rights reserved.

Keywords: Aortic valve; Mechanical properties; Bioprosthesis
animals’ death and from six St Jude Epic bioprostheses which all were within 1–2 weeks due to their expiry date. We determined their mechanical properties using uni-axial tensile tests with a universal testing machine Zwick/Roell BDO-FBO.5TS (Zwick GmbH & Co, Ulm, Germany) equipped with test Xpert software. The tested valve leaflet material was cut into 3.5 mm wide and 20 mm long specimens in circumferential and radial directions (Fig. 1). The thickness of all leaflets was measured using a cathetometer MK-6 (LOMO, Saint Petersburg, Russia) with a precision of ±0.01 mm. Uni-axial tensile tests were performed to examine the deformability and strength of the tissues. The mechanical properties of pathologically unchanged native human aortic valves and the methods used have been published previously [7].

Experimental data were analyzed using SPSS for Windows 16.0 (SPSS Inc, Chicago, USA). Statistical significance among the mechanical properties of the three tested materials was evaluated using single-parameter ANOVA and the appropriate post-hoc tests. Statistical significance of differences between values was defined as having P<0.05. All measurement values are shown as mean values ± S.D.

3. Results

3.1. Circumferential direction

The modulus of elasticity values in the circumferential direction at the level of stress 1.0 MPa are significantly different amongst all three tested specimens, the biggest being for the Epic bioprostheses with 101.99 ± 58.24 MPa, followed by native porcine 42.3 ± 4.96 MPa and human valve leaflets 15.34 ± 5.3 MPa (Fig. 2a). Epic bioprostheses have also the highest ultimate stress value 5.77 ± 1.94 MPa, which is significantly higher than that of native human 1.74 ± 0.37 MPa and porcine aortic valves 1.58 ± 0.26 MPa (Fig. 2b). Ultimate strain in the circumferential direction is highest for the native human valves 18.35 ± 7.61%, followed by 7.26 ± 0.69% for native porcine valve leaflets and 5.95 ± 1.54% for Epic bioprostheses, respectively (Fig. 2c).

Also in radial direction at the level of stress 0.1 MPa modulus of elasticity is significantly different among all tested samples (Fig. 2d), the biggest for St Jude Epic bioprostheses 9.18 ± 1.81 MPa, with 5.33 ± 0.61 MPa for por-
porcine aortic valve leaflets used in Epic bioprostheses 0.92 ± 0.17 mm thickness, and significantly thicker than the other two samples. There is no statistically significant difference between sample thickness of native human valve leaflet samples 0.57 ± 0.16 mm and the thickness of chemically treated porcine aortic valve leaflets used in Epic bioprostheses 0.59 ± 0.15 mm. The native porcine valve tissue is of 0.92 ± 0.17 mm thickness, and significantly thicker than the other two samples.

4. Discussion

Experimental results show that the mechanical properties of aortic valve leaflets are different in circumferential and radial directions which is in accordance with previously published data about the anisotropy of this material [8, 9]. This feature is determined by the structural composition of heart valve leaflets, more precisely – the orientation of connective tissue fibers in the leaflets. Several authors have demonstrated by histological and ultrasturctural studies that elastin fibers are oriented more or less equally both in radial and circumferential directions but collagen fibers are mostly aligned in the circumferential direction [7, 10]. Our study has shown that the ultimate stress is 2.9 – 8.3 times higher in the circumferential direction compared to radial direction, as it is dependent on the concentration of collagen fibers. Modulus of elasticity in circumferential direction is even 7.6 – 11.1 times higher than in radial direction, a similar tendency has been observed also by Sauren and Missirilis with colleagues [9, 11] for porcine valve tissue – they reported the modulus of elasticity being respectively 21 and 3 times higher in circumferential direction. The apparent discrepancy between the results could be explained by different stress levels at which the elasticity modulus was calculated.

Although all three tested tissue types have a similar nonlinear stress–strain response (Figs. 3 and 4), Epic bioprostheses show a prominent shift to the stress axis and significantly higher ultimate stress values. As shown previously [4, 12], mechanical properties of the tissue are determined by fixing the tissue in a loaded or unloaded state. Fixation in a loaded state causes a shift to the left of the stress–strain curve closer to the stress axis but fixation in an unloaded state to the right.

Tissue thickness also has been shown to be dependent on loading during fixation; Rousseau in 1983 [4] showed that after fixation in a loaded state the thickness is reduced by ~40%, in our study the difference between thickness of Epic bioprostheses leaflets and native porcine leaflets is ~36%.

Thubrikar and colleagues [13] have come to a conclusion that valve leaflets to function properly require mechanical strength during diastole to prevent excess bulging and prolapse of valve leaflets as well as elasticity during the first part of systole – it is required so that the valve can open as fast and efficient as possible, and is dependent on the flexion rigidity of the valve leaflets. Flexion rigidity on the other hand is directly proportional to modulus of elasticity and tissue thickness [14]. In a recent study, Mirnajafi and colleagues have shown that the region most exposed to flexion deformity is around commissures – the leaflets during opening undergo a rotation of ~65° at this region [15]. It is supported by observations that bioprostheses are very often damaged exactly in this region [16]. Flexion fatigue is thought to be one of the main causes of leaflet rupture [17, 18]. Arcidiacono and colleagues [19] with means of computer modeling have shown that even the slightest differences in rigidity of valve leaflets have an impact on the dynamics of valve opening and closure, stressing the importance of leaflet mechanical properties homogeneity within one valve. All these previous studies point out that increased leaflet rigidity characterized by
higher modulus of elasticity values may have significant impact on bioprosthesis longevity and hemodynamic properties.

There is also a significant difference in ultimate strain amongst the tested materials, especially between native human valves and Epic bioprostheses in both directions. Several authors have pointed out that deformability in the radial direction is very important for proper leaflet coaptation and prolapse prevention [20]. In our study, the ultimate strain of Epic bioprostheses and native porcine valves does not differ very much and both are significantly smaller than for native human valves, which causes concerns about the suitability of this material for creation of an ‘ideal prosthesis’.

Data on the failure of bioprostheses to copy the mechanical properties of the native human heart valves are in accordance with the large number of publications about non-calcifying valve leaflet degeneration [17, 21]. Although it is most likely that these processes – gradual structural deterioration and calcification work hand in hand. It is supported by many studies which demonstrate that calcification often begins in the regions of increased stress and deformation [16, 22, 23]. Further on calcification causes a loss of elasticity and an increase in flexion stress which accelerates further tissue degeneration. Although, when talking about the current generation of bioprostheses calcification is not the most actual problem – there is an increasing tendency to highlight damage caused solely by mechanical factors [17].

This study has certain limitations – we, limited by the expensiveness of bioprostheses, analyzed the mechanical properties of only one xenoaortic bioprosthetic heart valve model. At the moment we have no data on other xenoaortic or pericardial bioprostheses to compare. Still, taking into account that the main steps in chemical and physical treatment of biological tissues prior to use in bioprostheses are similar, we believe that the observed mechanical properties and drawn conclusions to some extent can be extrapolated to most of the traditional bioprostheses made from porcine aortic valves on the market. It should be kept in mind that this study shows neither superiority nor weakness of the analyzed bioprosthesis type compared to other bioprostheses. Only a study comparing mechanical properties of different bioprostheses before implantation and after in vivo or in vitro aging could give an answer on the superiority of a certain biological material or its treatment for use in bioprostheses.

5. Conclusions

Epic bioprostheses have a non-linear and anisotropic response to stress in uniaxial tensile tests similar to native human and porcine aortic valve leaflets. They have the highest ultimate stress values but together with the gained mechanical strength they have lost tissue elasticity and are significantly more rigid compared to native valve tissue.

The before-mentioned differences in mechanical properties between bioprostheses and native valves may cause variations in stress distribution within leaflets of the prosthetic valve and accelerate its deterioration.

References

eComment: CorBeat trileaflet mechanical full-flow heart valve prosthesis versus native human aortic valves – evaluation of functional performance

Authors: Leo A. Bockeria, Bakoulev Center for Cardiovascular Surgery, 121552 Moscow, Russia; Aleksandr Fadeev, Olga Bockeria, Osman Makhachev
doi:10.1510/icvts.2008.196220A

We read with great interest the findings of Martins Kalejs and colleagues [1] evaluating new bioprostheses by following the mechanics of the native human aortic valve. There are two good things about bioprostheses. First, they follow the natural structure of native human and reproduce the mode of its functioning. Second, they have a favorable effect on both the physiological blood flow constancy and the shortening of the patient’s hemodynamics recovery. Attempts to develop a new bioprosthesis with regard to mechanics of human aortic valve leaflets are worthwhile. But there is still room for improvement in mechanical valves possessing one common disadvantage: they are stenotic due to unnatural design [2]. The imperfection of the design, particularly noticeable when using small size prostheses, has a number of impacts on the patient’s hemodynamics. The valve occluder (disc, leaflets) located directly in the blood flow may cause its obstruction and separation, high pressure gradients, etc. Finally, the conventional mechanical valves do not keep the physiological blood flow constancy.

The need for a new valve led the Bakoulev Center to the development of the CorBeat trileaflet mechanical valve prosthesis which is close by its design and mode of functioning to the native human. The all-carbon CorBeat has been specially designed for aortic valve replacement in children and adults with small aortic valves. CorBeat has a three hinge mechanism located on the top of housing. The major design achievement is a free of occluder full-flow orifice area of the prosthesis when leaflets open. In vitro values of effective orifice area of CorBeat were as much as 0.95–0.97 of its geometric values.

The first implantations of the CorBeat trileaflet prosthesis were performed in the Bakoulev Center of Moscow on November 2007 [3], and June–July 2008.

References