Tensile Strength of Human Pericardium Treated with Glutaraldehyde

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Purpose: We have reconstructed aortic valves using autologous pericardium treated with glutaraldehyde since April 2007. However, the strength of the human pericardium has not been confirmed. We compared tensile strength between glutaraldehyde-treated human pericardium and aortic valve leaflets with various degrees of calcification to determine their suitability for use in aortic valve reconstruction.

Methods: We measured the ultimate tensile strength and elasticity of samples of glutaraldehyde-treated pericardia (n = 8), non-calcified (n = 12), calcified (n = 9) and decalcified (n = 21) aortic leaflets collected from 23 patients who underwent aortic valve surgery. Aortic valves were decalcified using a cavitation ultrasonic surgical aspirator. The pericardium was immersed in 0.6% buffered glutaraldehyde for 10 minutes and then rinsed three times for 6 minutes each in normal saline.

Results: The ultimate tensile strength of the glutaraldehyde-treated human pericardium, non-calcified, calcified and decalcified leaflets was 10, 2.8, 1.0 and 0.8 MPa, respectively.

Conclusions: The ultimate tensile strength of glutaraldehyde-treated human pericardium was 4 times higher than non-calcified leaflets, indicating its suitability for application to aortic valve reconstruction. Calcified leaflets were slightly stronger than decalcified leaflets. Thus, calcification can be removed without altering the tensile strength of valve materials.

Keywords: aortic valve reconstruction, autologous pericardium, glutaraldehyde treatment, mechanical strength

Introduction

Aortic valve replacement (AVR) using prosthesis is the most popular surgical strategy for treating aortic valve diseases. However, replacement with a mechanical valve requires the oral administration of anticoagulants and often results in a patient-prosthesis mismatch when patients have a small aortic annulus and conditions such as aortic stenosis, the incidence of which has recently increased.¹,²)

Since April 2007, we have surgically reconstructed diseased aortic valves using autologous pericardium. An aortic valve cusp created from glutaraldehyde-treated autologous pericardium is directly sutured to the aortic annulus.³,⁴ The advantages are that a large aortic valve area can be achieved after surgery and post-operative anticoagulants are unnecessary.

Al Halees et al. have described the postoperative results of reconstructive aortic valve surgery using autologous human and bovine pericardium, but the tensile strength of the autologous pericardium remains unclear.⁵)
The present study compares the tensile strength of autologous pericardia treated with glutaraldehyde with that of aortic valve cusps using uni-axial tensile tests.

Materials and Methods

Sample collection

We collected samples of aortic valve leaflets and autologous pericardia from 23 patients with aortic valve diseases who underwent surgery between April 2006 and April 2007. We classified the aortic valve leaflets into three groups based on calcification as follows. The control group comprised non calcified leaflets resected from patients with aortic regurgitation (n = 12). The calcification (calc) group comprised calcified leaflets from patients with aortic valve stenosis (n = 9) and the decalcification (decalc) group comprised leaflets decalcified by cavitational ultrasonic surgical aspiration (n = 21).

Human autologous pericardia (HP) collected from eight patients were examined from 114 viewpoints. All patients provided written, informed consent to sample collection and all other procedures described herein.

Processing samples of human autologous pericardia

After a median sternotomy, pericardia (around 8 × 7 cm) were separated from surrounding tissues, resected and fixed onto plates. Superficial fat was surgically removed, and then the samples were immersed in 0.6% glutaraldehyde for 10 minutes and rinsed three times for 6 minutes each in normal saline.

Uni-axial tensile test

Ultimate tensile strength, which is the maximum stress that a material can withstand while being stretched, was examined using a uni-axial tensile tester as shown in Fig. 1 (AG-250kNI, Shimadzu, Japan). Control, calcified, and decalcified aortic cusps were resected in circumferential direction (Fig. 1B). As for pericardium treated with glutaraldehyde, specimens were resected along two orthogonal directions from each pericardia.

Specimens with a width of 3 mm were mounted into a specially-designed chuck holder which realized the tests in liquid environment. The length between tissue-chuck was pre-set 7mm. Specimens were stretched at the speed of 10mm/min. From stress-strain curves of each specimen groups, ultimate tensile strength and elastic modulus were obtained. Ultimate tensile strength were obtained by dividing stress, which broke tissue by a cross-section area of tissue (Pa = N/m²). Elastic modulus were obtained from the slope of stress-strain curves.

Results

Stress-strain curves of HP and comparison of control, calc, and decalc aortic valve leaflets were shown in Fig. 2 and Fig. 3, respectively.
The ultimate tensile strength were 10.03, 2.31, 1.09 and 0.84 MPa for the HP, control, calc and decalc groups, respectively (Fig. 4). The ultimate tensile strength of the glutaraldehyde-treated autologous pericardia was about 4 times higher than that of non-calcified aortic valve leaflets and about 10 times higher than that of calcified and decalcified aortic valve leaflets.

Ultimate tensile strength of decalcified aortic leaflets by cavitational ultrasonic surgical aspiration was slightly less than or comparable to that of calcified leaflets.

The elastic modulus, which is an indication of elasticity, were 50.8, 16.3, 6.8 and 4.3 MPa autologous pericardia treated with glutaraldehyde, non-calcified, calcified and decalcified aortic valve cusps, respectively (Fig. 5).

**Discussion**

The ultimate tensile strength of the glutaraldehyde-treated autologous pericardia was about 4 times higher than that of non-calcified aortic valve cusps and about 10 times higher than that of calcified or decalcified cusps.

Although calcification removal has been described as a strategy for treating aortic stenosis, it might result in later aortic regurgitation despite immediate post-procedural improvements in aortic stenosis. Aortic regurgitation can also be considered based on the fact that the ultimate tensile strength of aortic valve cusps is very low after decalcification.

Here, we decalcified cusps using cavitational ultrasonic surgical aspiration. We found that decalcification does not reduce tensile strength because the ultimate strength of the calcified and decalcified aortic valve cusps was similar. These findings suggest that calcification can be removed without reducing the tensile strength of the aortic annulus using a cavitational ultrasonic surgical aspirator, which can remove calcification extending to the aortic annulus. This method may maintain the strength of aortic annulus better than crush and resection method that is another method of decalcification of aortic annulus.
The development of prosthetic valves has recently advanced since they now have a wider valve area and can produce favorable hemodynamic effects. However, the frequency of patients with a small aortic annulus is increasing together with increasing incidence of aortic stenosis. Treating such patients requires techniques such as surgical enlargement of the aortic annulus and full root replacement to avoid patient-prosthesis mismatches. Moreover, the application of a prosthetic valve requires the oral administration of postoperative anticoagulants, and the risk of postoperative thromboembolism should also be considered.

The aortic valve that we developed has the advantage of a wider valve area because an aortic valve cusp is created from autologous pericardium treated with glutaraldehyde and directly sutured to the aortic annular ring. Another advantage of this technique is that postoperative anticoagulants are unnecessary.

Much about the autologous pericardium remains unknown. The present study confirmed that in the use of comparative uni-axial tensile tests, the autologous pericardium treated with glutaraldehyde has sufficient tensile strength for use in aortic valve reconstruction.

Nevertheless, strict follow-up of durability and calcification is required for patients who have received such grafts.

Conclusion

Glutaraldehyde treated autologous pericardium showed high tensile strength, and suitability for the material for aortic valve reconstruction. Cavitation ultrasonic surgical aspiration could remove calcification without severely reducing the strength of materials and was a useful device to remove aortic annular calcification.

Disclosure Statement

Nothing to disclosure.

References