

TABLE 6-continued

Exp. No. Treatment	Storage		$\mu\text{g Ca/Mg}$	
	Rinse (14 Days)		Cusp	Wall
Control (No Treatment)	—	—	107.059 \pm 3.239	49.915 \pm 2.160

As shown in Table 6, in embodiments where the biomaterial is specifically aortic wall tissue, incorporation of Al^{+3} in the treatment solution, or storage solution, results in much greater inhibition of calcification than treatment with an alcohol solution.

Example 11

Specimens of the glutaraldehyde-pretreated porcine aortic wall tissue were subjected, for 24 hours, to aqueous (pH 7.4 buffered HEPES) treating solutions of 0.1M FeCl_3 ; 0.01M FeCl_3 ; 80% ethanol; 80% ethanol and 0.1M FeCl_3 ; and 80% ethanol and 0.01M FeCl_3 . Following treatment, the tissue was rinsed in three 100 ml portions of neutral buffer, specifically HEPES at pH 7.4. Specimens of glutaraldehyde-pretreated porcine aortic wall tissue, obtained from St. Jude Medical, Inc., were used as controls. The tissue samples, prepared as described above, were implanted in rat subdermal pouches and analyzed for calcium content after 21 days. The results are reported below in Table 7.

TABLE 7

TISSUE	PRETREATMENT	WASHING	Ca ($\mu\text{g/mg}$)
Porcine	Control	No	36.46 \pm 4.04
Aortic	0.1 M FeCl_3	Rinse	13.37 \pm 1.5
Wall	0.01 M FeCl_3	Rinse	13.52 \pm 2.93
	80% EtOH	Rinse	18.55 \pm 3.61
	80% EtOH +	Rinse	6.31 \pm 0.55
	0.1 M Fe		
	80% EtOH +	Rinse	7.01 \pm 1.03
	0.01 M Fe		

Table 7 demonstrates that incorporation of Fe^{+3} ions in the alcohol treatment and/or storage solutions will produce improved resistance to calcification for porcine aortic wall specimens.

Although the invention has been described in terms of specific embodiments and applications, persons skilled in the art can, in light of this teaching, generate additional embodiments without exceeding the scope or departing from the spirit of the claimed invention. Accordingly, it is to be understood that the drawing and description in this disclosure are proffered to facilitate comprehension of the invention, and should not be construed to limit the scope thereof.

What is claimed is:

1. A method of treating a biomaterial, the method comprising the steps of:

(1) forming a liquid treatment solution consisting essentially of greater than 50% by volume of a water-soluble C1-C3 aliphatic alcohol in an aqueous buffer of a pH between 6.0 and 8.0;

(2) exposing the biomaterial, wherein the biomaterial is a collagenous material derived from a mammalian species selected from the group consisting of bovine pericardium, porcine aortic heart valves, saphenous bypass grafts, aortic homografts, and dura mater, to the

liquid treatment solution for a period of time sufficient to render the biomaterial resistant to calcification; and
(3) rinsing the exposed biomaterial with a rinsing solution.

2. The method of claim 1 wherein the biomaterial rendered resistant to calcification is rendered resistant to in vivo pathologic calcification.

3. The method of claim 1 wherein said step of exposing comprises immersing the biomaterial in the liquid treatment solution.

4. The method of claim 3 wherein the alcohol is present in an amount of approximately between 60% and 80% by volume of the liquid treatment solution.

5. The method of claim 3 wherein the treatment solution further contains an anticalcification agent.

6. The method of claim 5 wherein the anticalcification agent is a multivalent metallic cation selected from the group consisting of a salt of Al^{+3} and Fe^{+3} which is soluble in the treatment solution.

7. The method of claim 6 wherein the anticalcification agent is AlCl_3 in a concentration range of from about 0.1M to 0.001M.

8. The method of claim 1 wherein the water-soluble aliphatic alcohol is selected from the group consisting of methanol, ethanol, propanol, and isopropanol.

9. The method of claim 8 wherein the water-soluble aliphatic alcohol is ethanol.

10. The method of claim 1 wherein the biomaterial has been cross-linked.

11. The method of claim 10 wherein the biomaterial has been crosslinked with glutaraldehyde.

12. The method of claim 1 wherein the time sufficient to render the biomaterial resistant to calcification is at least about 20 minutes.

13. The method of claim 12 wherein the time sufficient to render the biomaterial resistant to calcification is between about 24 to 96 hours.

14. The method of claim 1 wherein there is provided the further step of storing the treated biomaterial in a sterile, glutaraldehyde-free environment.

15. The method of claim 1 wherein there is provided the further step of storing the treated biomaterial in a storage solution of a lower aliphatic alcohol and glutaraldehyde.

16. The method of claim 15 wherein the storage solution is an aqueous solution containing approximately between 60% to 80% by volume of ethanol and approximately between 0.2% to 0.5% glutaraldehyde.

17. The method of claim 3 wherein the biomaterial is an aortic valve cusp and the alcohol is ethanol.

18. The method of claim 5 wherein the biomaterial is an aortic valve wall, and the anticalcification agent is an aluminum salt in ethanol.

19. The method of claim 1 wherein there is provided the further step of sterilizing the bioprosthetic tissue.

20. The method of claim 3 wherein the treatment solution is buffered to a pH in the range of between 7.0 and 7.6.

21. The method of claim 20 wherein the liquid treatment solution is buffered to a pH of 7.4.