

Dimensional change assessment of Lyophilized Bovine Pericardium

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Introduction

Lyophilization is one of the best methods for obtaining dehydrated products of high quality with good stability of storage. Glutaraldehyde (GA) treated bovine pericardium (BP) is widely used in implants as heart valves prostheses, valved ducts and patches.

Lyophilization of these products have been shown to improve its characteristics [1], with improved biocompatibility and a less residual aldehydes. The lyophilization of GA treated BP in spite of these advantages, may impart a certain degree of dimensional changes altering the characteristics of the rehydrated product.

This study has for objective to evaluate the dimensional changes imparted by two lyophilization protocols, one using fast freezing and another using annealing.

Material and Methods

The membranes of BP treated chemically by GA and preserved in formaldehyde were washed in saline solution (NaCl 0.9%) and cut as circular test specimens and divided in two groups. Group 1: n=5, fast freezing stage immersing in liquid nitrogen and freeze-drying. Group 2: n=5, annealing and freeze-drying. The annealing consists of the thermal treatment done in steps during the stage of freezing of the lyophilization process. The material is frozen to -50°C for 15 hours, afterwards warmed to -20°C, being left for 5 hours before drying.

Dimensional evaluation of the test specimens was made using a program for image processing (ImageJ, NIH, USA). The images of all the test specimens were captured and the areas measured before they were submitted to lyophilization. This constituted the control group.

After lyophilization, the areas of the test specimens of both groups were compared with the controls and the differences being expressed in percentage (mean \pm standard deviation). This procedure was repeated again after rehydration of the specimens in saline solution.

Statistical analysis: Student's t test was used.

Differences were considered to be significant when $P < 0.05$.

Results

Both lyophilization protocols imparted shrinkage altering their surface areas: Group1 = $(-16 \pm 3) \%$; Group2 = $(-23 \pm 2) \%$, $P = 0.002$.

After the rehydration the specimens suffered dimensional changes that were short of returning to the initial size of the controls: Group1 = $(-12 \pm 5)\%$, Group2 = $(-4 \pm 3)\%$, $P = 0.015$.

Conclusion

The lyophilization process using annealing during the freezing stage provided a better dimensional stability after rehydration, maintaining closer resemblance to the original specimens.

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Keywords: Cardiovascular tissue, Material properties/ characterization, Surface analysis/modification.

References

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