biocompatible material will be implanted, such as a physiological environment. For example, the temperature can be between about 30 °C and about 46 °C. In some cases, the implantable biocompatible material can be maintained at a temperature that is between about the temperature of an environment into which at least a portion of the implantable biocompatible material will be implanted and a temperature less than a temperature beyond which the implantable biocompatible material will experience damage from the temperature during the course of the stretching. Maintaining the temperature of the implantable biocompatible material at a temperature higher than that of an implantation environment, such as a temperature close to a temperature at which the implantable biocompatible material may become damaged by the temperature, can reduce the time needed to obtain a desired degree of pre-stretching, as well as reducing the tension to be applied to achieve the desired degree of pre-stretching.

[0010] The sheet can be maintained under tension until the sheet experiences a substantial decrease in an elongation rate of the sheet. The time the sheet is maintained under tension can be between about 11 days and about 45 days, or until the elongation rate is less than about 25% of an average initial elongation rate, where the average initial elongation rate is the average elongation rate of the first hour of applying tension to the sheet.

[0010a] An aspect of the disclosure provides a method of pre-stretching an implantable biocompatible material comprising applying a tensioning force of between 300 grams and 4000 grams to a sheet of implantable biocompatible material, while applying the tensioning force, maintaining the sheet of implantable biocompatible material at a temperature that is at least as high as a temperature of an environment into which at least a portion of the implantable biocompatible material will be implanted and maintaining the sheet of implantable biocompatible material under tension until the sheet experiences a decrease in an elongation rate of the sheet, wherein the tensioning force is applied for a period of at least 1 day.

[0010b] Another aspect of the disclosure provides a method of pre-stretching pericardial tissue comprising applying a tensioning force of between 400 grams and 1000 grams to a sheet of pericardial tissue, while applying the tensioning force, maintaining the sheet of pericardial tissue at a temperature of between 30 °C and 46 °C, and maintaining the sheet of pericardial tissue under tension until the elongation rate of the sheet is less than 10% of an average initial elongation

rate, where the average initial elongation rate is the elongation rate over the first hour in which tension is applied, wherein the tensioning force is applied for a period of at least 1 day.

[0010c] Another aspect of the disclosure provides a method of forming a prosthetic valve, comprising performing the method of pre-stretching an implantable biocompatible material of any of claims 1 to 12, wherein the tensioning force is between 400 grams and 1000 grams, wherein the implantable biocompatible material is a sheet of pericardial tissue, wherein the temperature is between 30 °C and 46 °C, and wherein the sheet of pericardial tissue is maintained under tension until the elongation rate of the sheet is less than 10% of an average initial elongation rate, where the average initial elongation rate is the elongation rate over the first hour in which tension is applied, and attaching at least a portion of the sheet of elongated pericardial tissue to a frame.

[0011] The foregoing and other objects, features, and advantages of the disclosure will become more apparent from the following detailed description, which proceeds with reference to the accompanying figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIG. 1 is a perspective view of a representative embodiment of a prosthetic heart valve.

[0013] FIG. 2 illustrates a schematic diagram of an implantable biocompatible material, including various manners of applying tensioning forces to the material.

[0014] FIG. 3 is a graph of measured thickness values (mm) for bovine pericardial tissue samples before (initial) and after (creep) applying tensioning forces to the tissue for a period of two weeks.

[0015] FIG. 4 is a plot of measured thickness values (mm) for individual bovine pericardial tissue samples before and after applying tensioning forces to the tissue for a period of two weeks.

What is claimed is:

1. A method of pre-stretching an implantable biocompatible material comprising:

applying a tensioning force of between 300 grams and 4000 grams to a sheet of implantable biocompatible material;

while applying the tensioning force, maintaining the sheet of implantable biocompatible material at a temperature that is at least as high as a temperature of an environment into which at least a portion of the implantable biocompatible material will be implanted; and

maintaining the sheet of implantable biocompatible material under tension until the sheet experiences a decrease in an elongation rate of the sheet, wherein the tensioning force is applied for a period of at least 1 day.

2. The method of claim 1, wherein the temperature is between 30 °C and 95 °C, preferably between 30 °C and 46 °C, more preferably between 36 °C and 39 °C.

3. The method of claim 1 or 2, wherein the tensioning force is between 300 grams and 1000 grams, preferably between 400 grams and 700 grams.

4. The method of any of claims 1 to 3, wherein the tensioning force is applied for a period of between 1 day and 45 days, preferably for a period of between 11 days and 45 days, more preferably for a period of between 10 days and 21 days.

5. The method of any of claims 1 to 4, wherein the implantable biocompatible material comprises pericardial tissue, preferably bovine pericardial tissue or porcine pericardial tissue.

6. The method of any of claims 1 to 5, wherein the sheet of implantable biocompatible material is maintained under tension until the elongation rate is less than 25%, preferably less than 10%, more preferably less than 5 %, of an average initial elongation rate.

7. The method of any of claims 1 to 6, wherein the tensioning force is applied along a single axis, preferably in opposing directions along a single axis, or along multiple axes.

8. The method of claim 7, wherein at least two of the multiple axes are perpendicular to one another.

9. The method of any of claims 1 to 8, further comprising incorporating the pre-stretched implantable biocompatible material into an implantable device, wherein the implantable device preferably comprises a prosthetic heart valve, wherein the stretched implantable biocompatible material more preferably forms at least one leaflet of the prosthetic heart valve.

10. The method of any of claims 1 to 9, wherein the implantable biocompatible material is unfixed when the tensioning force is applied and the implantable biocompatible material is fixed while under tension.

11. The method of any of claims 1 to 10, wherein the implantable biocompatible material is partially fixed when the tensioning force is applied and the implantable biocompatible material is fixed while under tension.

12. The method of any of claims 1 to 11, wherein the implantable biocompatible material is an at least partially fixed implantable biocompatible material maintained in a non-fixative solution for at least one hour prior to applying tension to the implantable biocompatible material.

13. A method of pre-stretching pericardial tissue comprising:

applying a tensioning force of between 400 grams and 1000 grams to a sheet of pericardial tissue;

while applying the tensioning force, maintaining the sheet of pericardial tissue at a temperature of between 30 °C and 46 °C; and

maintaining the sheet of pericardial tissue under tension until the elongation rate of the sheet is less than 10% of an average initial

elongation rate, where the average initial elongation rate is the elongation rate over the first hour in which tension is applied,

wherein the tensioning force is applied for a period of at least 1 day.

14. A method of forming a prosthetic valve, comprising:

performing the method of pre-stretching an implantable biocompatible material of any of claims 1 to 12, wherein the tensioning force is between 400 grams and 1000 grams, wherein the implantable biocompatible material is a sheet of pericardial tissue; wherein the temperature is between 30 °C and 46 °C; and wherein the sheet of pericardial tissue is maintained under tension until the elongation rate of the sheet is less than 10% of an average initial elongation rate, where the average initial elongation rate is the elongation rate over the first hour in which tension is applied; and

attaching at least a portion of the sheet of elongated pericardial tissue to a frame.