

000-186,000 Av. MW), 99+% saponification, in deionized, sterile water. As with Example 1, the mixture was placed in a loosely capped container, heated, sealed removed from the autoclave, placed under a sterile ventilation hood, stirred to ensure a homogenous solution, poured into sterile syringes, and injected into the molds according to the process of Example 1. In this example, however, the tube was then subjected to ten (10) cycles of freezing and thawing. The freeze/thaw cycles were similar to that of Example 1, except that the sample was allowed to cool for about 24 hours for each freeze/thaw cycle. The tube was then thawed by removing the tube from the freezer and setting it upright under ambient conditions. The tube was allowed to thaw for about 12 hours before being returned to the freezer for another cycle. The resulting PVA biomaterial was stiff and strong with a burst pressure of approximately 1078 mm Hg.

EXAMPLE 3

[0048] 15% by weight poly(vinyl alcohol) solution was prepared by mixing poly(vinyl alcohol) polymer (89,000-98,000 Av. MW), 99+% saponification, in deionized, sterile water in a manner substantially identical with Example 1 except for the following differences. As with Example 1, the mixture was placed in a loosely capped container, heated, sealed removed from the autoclave, placed under a sterile ventilation hood, stirred to ensure a homogenous solution, poured into sterile syringes, and injected into the molds according to the process of Example 1. In this example, however, the tube was then subjected to five (5) cycles of freezing and thawing. The freeze/thaw cycles were similar to that of Example 1, in that each sample was allowed to cool for about 12 hours for each freeze/thaw cycle. The resulting PVA biomaterial was soft with a burst pressure of approximately 98 mm Hg.

EXAMPLE 4

[0049] A 25-30% by weight poly (vinyl alcohol) solution was prepared by mixing poly (vinyl alcohol) polymer (124,000-186,000 Av. MW) in sterile water or saline (0.9% Na Cl) in a manner substantially identical with Example 1 except for the following differences. The mixture is heated at 95-100° C. under atmospheric pressure to bring the mixture to a uniform fluid. This fluid is then poured into molds and frozen to -20° C. for four hours. Next, the material is thawed to 20° C. This freeze-thaw cycle is repeated until six cycles have been achieved. The material is, at least partially, removed from the mold, immersed, at least in part, and the freeze-thaw cycle is repeated until four additional cycles have been achieved. As an alternative to at least partially removing the material from the mold, the mold may be partially filled with fluid mixture, thereby allowing for expansion. The resultant PVA hydrogel construct is then ready for packaging and sterilization. This process yields a material having a modulus of elasticity (tensile or compression) which is greater than 1.0 nmPa. The % by weight and the MW of the PVA can be altered to provide materials with a different modulus of elasticity depending upon the particular medical application.

[0050] As demonstrated by the above-referenced examples, because the PVA hydrogel can be manufactured to be mechanically strong, or to possess various levels of strength among other physical properties depending upon the weight percentage of the PVA starting material with respect to other constituents in solution, freeze time, the number of freeze/thaw cycles, and the freeze temperature.

As discussed above, the end product hydrogel also has a high water content which provides desirable properties in numerous applications and which prevents the denaturing of additives.

[0051] The hydrogel tissue replacement construct is especially useful in surgical and other medical applications as an artificial material for replacing and reconstructing soft tissues in humans and other mammals. Soft tissue body parts which can be replaced or reconstructed by the hydrogel include, but are not limited to, vascular grafts, heart valves, esophageal tissue, skin, corneal tissue, ureteral stents, nerve bridge, wound covering cartilage, meniscus, and tendon. The hydrogel may be formed as an implantable articulating surface for a load bearing joint, whereby the articulating surface may be fixed to bone with screws, sutures, or biogluue such as a collagengluue. Furthermore, the hydrogel may also serve as a cartilage replacement for anatomical structures including, but not limited to an ear or nose.

[0052] The inventive hydrogel may also serve as a tissue expander. Additionally, the inventive hydrogel may be suitable for an implantable drug delivery device. In that application, the rate of drug delivery to tissue will depend upon hydrogel pore size and degree of intermolecular meshing resulting from the freeze/thaw cycles. The rate of drug delivery increases with the number of pores and decreases with an increasing degree of intermolecular meshing from an increased number of freeze/thaw cycles.

[0053] The hydrogel is especially suitable for vascular grafts and heart valve replacements, because the hydrogel is thromboresistant, and because of the particular mechanical and physiological requirements of vascular grafts when implanted into the body. The hydrogel may also be used for contact lenses, as a covering for wounds such as burns and abrasions, and in other applications wherein a mechanically strong material is preferred.

[0054] Throughout this application, various publications are referenced. The disclosures of these publications in their entireties are hereby incorporated by reference into this application in order to more fully describe the state of the art to which this invention pertains.

[0055] The foregoing description has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise examples or embodiments disclosed. Obvious modifications or variations are possible in light of the above teachings. The embodiment or embodiments discussed were chosen and described to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such modifications and variations are within the scope of the invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly and legally entitled.

That which is claimed:

1. A method of producing a solid polyvinyl alcohol medical construct, comprising:

providing an aqueous liquid mixture of water or saline and poly(vinyl) alcohol (PVA) polymer, the PVA polymer having an average molecular weight (MW) of between 124,000 to 186,000;