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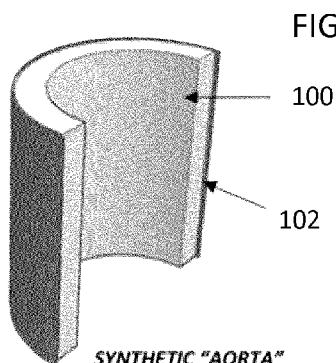
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(54) Title: ELASTOMERIC TUBES WITH SELF-REGULATED DISTENSION



(57) Abstract: A method of passive fluid actuation includes providing a jacketed elastomeric tube defining an internal channel, the jacketed elastomeric tube having a first end and a second end, a length extending from the first end to the second end, and a first diameter. The method then includes fixing the first end and the second end of the jacketed elastomeric tube, supplying a fluid to the internal channel of the jacketed elastomeric tube, and distending the jacketed elastomeric tube such that at least a portion of the jacketed elastomeric tube along the length expands from the first diameter to a second diameter. A jacketed elastomeric tube for use with the above described method includes an elastomeric tube defining internal channel and having an external surface and a fabric jacket wrapped around the external surface of the elastomeric tube.

ELASTOMERIC TUBES WITH SELF-REGULATED DISTENSION

RELATED APPLICATIONS

[0001] This application claims priority benefit of U.S. Provisional Application Serial Number 63/311,508, filed on February 18, 2022, the contents of which are hereby incorporated by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to elastomeric tubing. More particularly, it relates to jacketed elastomeric tubing with self-regulating distension in the radial direction.

BACKGROUND OF THE INVENTION

[0003] From small-scale robotics, to industry, to medical devices, development of system components which can accurately respond to and control a flowing fluid has become an incredibly important endeavor. Further, components which can passively respond to fluid behavior due to their inherent material properties are specifically valuable; design of an integrated system to actively monitor and respond to changing fluid flow can be very expensive from both a logistical and financial standpoint.

[0004] Use of bare elastomers to passively regulate flow in microfluidic channels has been previously reported in literature for many decades [1]. This is generally accomplished by designing a channel with elastomeric walls which contract as pressure increases, regulating the flow rate (or restricting it entirely if pressure is sufficiently high) although more complicated designs have been reported [2]. Applications range widely, from drug delivery to agriculture to lab-on-a-chip devices [3] [4] [5].

[0005] However, these devices are generally on the scale of tens of micrometers, where the prevailing fluid forces are viscous rather than volumetric. Larger-scale elastomeric channels with strictly regulated distension behavior must accommodate for different fluid flow properties as well as greatly increased volumetric forces - especially so in hydraulic instances, where the fluid is incompressible and its density may easily be hundreds of times greater than commonly used gases. One such instance is the ex vivo heart-perfusion device (EVHP), a medical device which keeps a donor heart alive ex vivo by connecting it to a tubing system and pumping a blood substitute through it [6]. The tubing immediately connected to the donor organ in this device is on the centimetre scale and should ideally be compliant enough to act as a shock absorber for the pulsatile fluid flow (which occurs at pressures in the tens of kPa) without being so compliant as to rupture during operation [7]. This replicates the function of human aortic, which displays this behavior in vivo and displays a distinct 'J-shaped' stress-strain curve when tested under uniaxial tension.

[0006] Zhalmuratova et al. suggested the use of fiber-elastomer composites as material for this compliant tubing [7]. Fiber-elastomer composites, which consist of stiff fibers embedded within a compliant elastomeric matrix, have garnered much attention in the scientific community for their properties which combine the most desirable aspects of both component materials. Specifically, the elastomeric matrix provides a robust and deformable base for the material which allows it to withstand many different stresses, while the stiffer fibers act as a reinforcement to prevent excessive deformation under large stress magnitudes. Under uniaxial tension, the same 'J-shaped' stress-strain curve seen in aorta and many other biological tissues is also observed. Preferential or prescribed orientation of the fibers leads to the creation of anisotropic materials, which display resistance to certain deformation modes [8] [9] [10].

[0007] The versatility of fiber-elastomer composites enables their use in soft robotic actuators [11] [12] [13], biomimetic or biomedical devices [14] [15] [16], flexible yet tear- or impact-resistant garments [17], devices found in harsh tribological settings such as tire treads [18] [19], and even heat-shielding layers for space vehicles [20]. In the context of tubing for an EVHP device, the soft elastomeric matrix of the composite dominates much of the material response when pressurized while an embedded fabric layer facilitates strain-stiffening if the tubing becomes overpressurized, preventing rupture. In this way the material could successfully act as a ‘neoaorta’, replicating both the structure, as shown in FIG. 1A, and the function of biological aorta (which itself is a fiber-reinforced material exhibiting J-shaped stress-strain behavior) in regulating somatic blood flow via the so-called Windkessel effect [21]. Furthermore, such tubing was theorized to have great utility as a general-purpose macroscale elastomeric flow regulator, or as a static actuator with self-regulating distension in the radial direction.

[0008] In development, the “embedded fibers” design later gave way to a simplified alternative in which the fabric layer was not embedded, and instead wrapped around the tubing as a ‘jacket’, as shown in FIG. 1A. This was hypothesized to retain most of the biomimetic behaviors sought after in the embedded model, while also allowing for greater movement of fibers and being easier to manufacture. While the term ‘fiber-elastomer composite’ generally refers to materials with embedded fibers, this alternative design is not without precedent. In fact, a spectrum of attachment methods for hollow or tubular complexes of fibrous and elastomeric materials has been reported in literature. These methods include cast elastomer-based structures with fully embedded fibrous layers [22] [23], fiber-based structures with elastomeric layers that are laminated or otherwise adhered together [24] [25] [26], braided fiber-based structures which are impregnated with elastomeric resin [27], and lastly ‘jacketed’ elastomeric structures with one or more external layers

of fibrous reinforcement that are not specifically adhered to the surface [28] [29] [30] [31] [32] [33] [34] [35] [36].

[0009] Perhaps the most well-known application of jacketed elastomeric tubing is the McKibben actuator, which sees use in various soft robotic applications. First developed in 1958 [37], this device consists of an elastomeric tube surrounded by a braided layer of fabric, which moves longitudinally when pressurized pneumatically or hydraulically due to the contraction of the surrounding fibers [28] [29]. In the 60+ years since, countless variations on this base design have been published; for example, Connolly et al. expanded upon this concept by attaching several such actuators in series with different patterns in the surrounding fibers to produce complex actuation modes [30], while Sridar et al. used extremely stiff surrounding fabric to produce an actuator that extended longitudinally and stiffened radially while pressurized [31]. Fairfield proposed the use of hydraulic McKibben actuators for use in an irrigation soft robot, although a physical prototype of this design was not built [38].

[0010] In the biomedical field, Belforte et al. created many McKibben actuator-inspired prototypes of similar fabric-reinforced soft actuators for various biomedical purposes, such as massage therapy for patients suffering from lymph edema [32]. Natividad et al. used an elastomeric ‘bladder’ surrounded by a heat-sealed fabric jacket and placed on the brachium as an assistive device for shoulder abduction for people with cerebral palsy [33]. Simpson et al. used a similar design with a sewn sleeve to act as an ‘exomuscle’ to help facilitate arm movement in stroke victims [34]. Finally, Zhu et al. developed flexible muscle ‘sheets’ which contained prescribed arrays of elastomeric tubing within a sewn fabric ‘shell’; these sheets were capable of several actuation modes depending on the tubing patterns, including gripping, bending, and twisting [35].

[0011] Despite these numerous applications, decidedly fewer attempts have been made to fully explain, model, and predict the distension behavior of jacketed elastomeric tubing at a base level. Doing so successfully requires taking into account a combination of several key material properties which must all be considered in modeling the material response:

- **Hyperelasticity:** Elastomers are a classic example of a hyperelastic material; that is, one whose deformation behavior is nonlinear and governed by a strain energy density function rather than a constant factor [39]. Many constitutive models exist to describe the behavior of different hyperelastic materials, and there is no universal agreement on which is most accurate. Furthermore, for any given hyperelastic material there may be great disagreement between sources on the material coefficients, even when the same constitutive model is used [40].
- **Strain-stiffening:** When subject to a uniaxial tensile test, elastomers display a distinct ‘J-shaped’ stress-strain curve at large strains (in the hundreds of percents). Addition of embedded fibers will greatly accelerate the onset of this effect [7]. It is hypothesized that even if the fibers form an encapsulating layer (such as a fabric jacket) rather than being embedded, the same strain-stiffening effect occurs.
- **Anisotropy:** Addition of a knit fabric, which has a repeating, directional structure (FIG. 1B) induces anisotropy in the structure. The tube will have directions of maximal stiffness (parallel to the directions of fiber elongation), which require complicated constitutive models to properly explain [41].
- **Hysteresis:** Elastomers, like all rubbers, are subject to material phenomena that increase their compliance after repeated loading-unloading cycles. The most significant of these is the Mullins effect [42], a complicated and multi-faceted phenomenon that results in gradual

and irreversible increases in compliance over many strain cycles. Fabrics, including knit fabrics, have been observed to display the same hysteresis behavior as well when under cyclic stress [43] [44].

[0012] Some works opt to forgo these steps entirely and focus solely on the behavior of their devices with respect to their applications (e.g. displacement or bending angle for a soft robotic actuator). Others provide some form of numerical modeling but use it primarily as a way to validate experimental results rather than make meaningful predictions about the deformation behavior. The parallel pipe-crawling soft robot designed by Zhang et al. is an excellent example of a work on jacketed elastomeric tubing in which the deformation behavior is deeply studied and preemptive numerical modeling is actually used to optimize the fabrication parameters of the prototype [36], although hysteresis behavior after repeated usage is not investigated. Additionally, in almost all studied literature the presented devices operate on a smaller scale than the tubing of the present invention.

[0013] Thus, there exists a need for highly tunable centimeter-scale jacketed elastomeric tubing and a method of predicting the distension behavior of such jacketed elastomeric tubing, the method taking in to account the combination of several key material properties including hyperelasticity, strain-stiffening, anisotropy, and hysteresis.

SUMMARY OF THE INVENTION

[0014] The present invention provides a method of passive fluid actuation that includes providing a jacketed elastomeric tube defining an internal channel, the jacketed elastomeric tube having a first end and a second end, a length extending from the first end to the second end, and a first diameter. The method then includes fixing the first end and the second end of the jacketed

elastomeric tube, supplying a fluid to the internal channel of the jacketed elastomeric tube, and distending the jacketed elastomeric tube such that at least a portion of the jacketed elastomeric tube along the length expands from the first diameter to a second diameter.

[0015] The present invention additionally provides a jacketed elastomeric tube for use with the above described method that includes an elastomeric tube defining internal channel and having an external surface and a fabric jacket wrapped around the external surface of the elastomeric tube.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] The subject matter that is regarded as the invention is particularly pointed out and distinctly claimed in the claims at the conclusion of the specification. The foregoing and other objects, features, and advantages of the invention are apparent from the following detailed description taken in conjunction with the accompanying drawings in which:

[0017] FIG. 1A is a schematic cross-sectional view of a natural aorta;

[0018] FIG. 1B is a schematic cross-sectional view of a jacketed elastomeric tube according to embodiments of the present invention;

[0019] FIG. 1C is a schematic drawing illustrating the knit directions of the fabric jacket layer according to embodiments of the present invention;

[0020] FIG. 1D is a graph showing trends in radial distension vs. pressure for jacketed tubes according to embodiments of the present invention and unjacketed tubes under hydrostatic pressure;

[0021] FIG. 2A schematic drawing of an inventive flow loop system according to embodiments of the present invention;

- [0022] FIG. 2B is a photograph of the compliant chamber of the flow loop of FIG. 2A with elastomeric tube inserted;
- [0023] FIG. 2C is an image of a distended elastomeric tube, with initial and final diameter measurements shown;
- [0024] FIG. 2D is a plot of radial tube distension (mm) vs. pressure (kPa);
- [0025] FIG. 2E is a plot of rate of distension (mm/kPa) vs. pressure (kPa);
- [0026] FIG. 2F are a series of experimental images for bare EcoFlex tubes at pressures of i) 6.52 kPa, ii) 10.25 kPa, and iii) 13.99 kPa, and for jacketed EcoFlex tubes at iv) 8.84 kPa, v) 18.99 kPa, and vi) 36.95 kPa;
- [0027] FIG. 3A is a labeled diagram of “dogbone” sample used for tensile testing elastomers’
- [0028] FIG. 3B is a labeled diagram of a strip sample used for testing fabric;
- [0029] FIG. 3C is a quasihysteresis plot of EcoFlex, with selected curve highlighted;
- [0030] FIG. 3D is a zoomed-in version of FIG. 3C
- [0031] FIG. 3E is a stress-strain plot of selected curve from quasi-hysteresis test overlaid with theoretical curve produced by fitted coefficients;
- [0032] FIG. 3F is a stress-strain curves of EcoFlex, fabric, and EcoFlex-fabric bilayer using fitted coefficients;
- [0033] FIG. 4A is an ABAQUS-modeled ‘slice’ of cylindrical tube wall, with coordinate system labeled;
- [0034] FIG. 4B is an assembly of the tube slice and analytical rigid roller;
- [0035] FIG. 4C shows a distended tube slice;
- [0036] FIG. 4D shows a full tubular representation of the distended slice in FIG. 4C;

[0037] FIG. 4E shows a plot of simulated radial tube distension (mm) vs. pressure (kPa), overlaid with experimental data;

[0038] FIG. 4F shows a plot of simulated rate of distension (mm/kPa) vs. pressure (kPa), overlaid with experimental data;

FIG. 4G show a series of finite element models of bare EcoFlex tubes at pressures of i) 6.52 kPa, ii) 10.25 kPa, and iii) 13.99 kPa, and jacketed EcoFlex tubes at pressures of iv) 8.84 kPa, v) 18.99 kPa, and vi) 36.95 kPa;

[0039] FIG. 5A is a photograph of a bare EcoFlex tube at high pressure displaying marked asymmetric distension;

[0040] FIG. 5B is a photograph of a jacketed EcoFlex tube at high pressure;

[0041] FIG. 6A shows an ABAQUS models of a fabric-jacketed tube (left) and a jacketed tube with kirigami patterns cut into the fabric (right) with the portions of the tube below the cuts defined as bare EcoFlex while the rest is defined to be the EcoFlex-fabric composite;

[0042] FIG. 6B shows the models of FIG. 6A with distended profiles of the tubes when clamped and subject to a 25 kPa hydrostatic pressure;

[0043] FIG. 7 is a graph showing experimental distension vs. pressure;

[0044] FIG. 8 is a graph showing experimental rate of distension vs. pressure;

[0045] FIG. 9 is a graph showing experimental volume vs. pressure;

[0046] FIG. 10 is a graph showing experimental rate of expansion vs. pressure;

[0047] FIG. 11 is a quasi-hysteresis plot for EcoFlex;

[0048] FIG. 12 is a closeup quasi-hysteresis plot of FIG. 11;

[0049] FIG. 13 is a quasi-hysteresis plot for Dragon Skin;

[0050] FIG. 14 is a closeup quasi-hysteresis plot of FIG. 13;

- [0051] FIG. 15 is a quasi-hysteresis plot for rayon-spandex fabric;
- [0052] FIG. 16 is a theoretical stress-strain data using fitted EcoFlex coefficients;
- [0053] FIG. 17 is a theoretical stress-strain data using fitted DragonSkin coefficients;
- [0054] FIG. 18 is a theoretical stress-strain data using fitted rayon-spandex fabric coefficients;
- [0055] FIG. 19 is a theoretical stress-strain curve for EcoFlex and fabric;
- [0056] FIG. 20 is a theoretical stress-strain curve for EcoFlex and fabric (closeup);
- [0057] FIG. 21 is a theoretical stress-strain curve for Dragon Skin and fabric;
- [0058] FIG. 22 is a theoretical stress-strain curve for DragonSkin and fabric (closeup);
- [0059] FIG. 23 is a simulated distension vs. pressure plot;
- [0060] FIG. 24 is a simulated volume vs. pressure plot;
- [0061] FIG. 25 is a simulated rate of distension vs. pressure plot;
- [0062] FIG. 26 is a simulated rate of expansion vs. pressure plot;
- [0063] FIG. 27 is a comparison of experimental and simulated distension values;
- [0064] FIG. 28 is a comparison of experimental and simulated rate of distension values;
- [0065] FIG. 29 is a comparison of experimental and simulated volume values;
- [0066] FIG. 30 is a comparison of experimental and simulated rate of expansion values;
- [0067] FIG. 31 is a EcoFlex tube distension parity plot;
- [0068] FIG. 32 is a DragonSkin tube distension parity plot;
- [0069] FIG. 33 is a EcoFlex tube volume parity plot;
- [0070] FIG. 34 is a DragonSkin tube volume parity plot;
- [0071] FIG. 35 is a EcoFlex + fabric tube distension parity plot;
- [0072] FIG. 36 is a DragonSkin + fabric tube distension parity plot;
- [0073] FIG. 37 is a EcoFlex + fabric tube volume parity plot;

[0074] FIG. 38 is a DragonSkin + fabric tube volume parity plot;

[0075] FIG. 39 is a graph showing a waveform of a rigid plastic tube under cyclic hydrodynamic pressure, which has a 'jagged' quality, with a large negative pressure at the cycle midpoint;

[0076] FIG. 40 is graph showing waveforms of elastomeric tubes (EF = Ecoflex 00-30, DS = Dragon Skin 10 SLOW, EFF = Ecoflex 00-30 + 95-5% rayon-Spandex blend knit fabric, DSF = Dragon Skin 10 SLOW + 95-5% rayon-Spandex blend knit fabric) under cyclic hydrodynamic pressure, which all are relatively 'smooth', reflecting the slow dissipation of residual pressure inside the tube over the course of the cycle;

[0077] FIG. 41 is a single hysteresis loop for a single tube length of a given material;

[0078] FIG. 42 are superimposed hysteresis loops for all tested tube lengths of Ecoflex 00-50 (ECO = Ecoflex 00-50) in which the position of the loops gradually shifts in the indicated direction as tube length increases; and

[0079] FIG. 43 are superimposed hysteresis loops for all tested tube lengths of all tested tube materials (EFO = Ecoflex 00-50 + pre-stressed 93-7% rayon-spandex fabric, ESW = Ecoflex 00-50 + 95-5% viscose-spandex fabric, ESTW = Ecoflex 00-50 + 65-30-5% rayon-nylon-spandex fabric), in which the position of the loops for all tube materials gradually shifts in the indicated direction as tube length increases.

DESCRIPTION OF THE INVENTION

[0080] The present invention has utility as a highly tunable centimeter-scale jacketed elastomeric tubing and a method of predicting the distension behavior of such jacketed elastomeric tubing, the method taking in to account the combination of several key material properties

including hyperelasticity, strain-stiffening, anisotropy, and hysteresis. The present invention having utility in a wide range of applications including in biomedical “exomuscles”, massage therapy implements, or soft robotic actuators for various industrial purposes.

[0081] According to embodiments, the present invention provides a highly tunable design for centimeter-scale elastomeric tubing 100 wrapped with a knit fabric jacket 102. According to embodiments, the elastomeric tubing 100 is formed of RTV silicone rubber and the knit fabric jacket 102 is formed of knitted rayon spandex fabric. It is appreciated that the tube scale can extend between 0.1 and 1000 centimeters. According to some inventive embodiments, a hydraulic or pneumatic flow loop for testing jacketed elastomeric tubing is provided which clamps the ends of such tubes and pumps fluids into the tubes to subject them to known hydrostatic pressures to measure trends in radial distension. The jacketed tubing is initially very compliant and deforms rapidly when first pressurized but displays marked self-regulation behavior at high pressures where their continued distension is tempered by the stiffening of fibers in the fabric jacket, a behavior that is not present in bare elastomeric tubes such as those shown in the graph of FIG. 1C. Further some inventive embodiments provide methods of 3D finite element simulations using material coefficients obtained from uniaxial, quasi-hysteresis tensile tests of the materials of interest to closely replicate experimental distension trends while also predicting a continuation of the observed trends at pressures beyond the experimental range. Such method of predicting the behavior of such jacketed elastomeric tubes provides a method of predicting deformation behavior of even more complex tube designs.

[0082] The present invention will now be described with reference to the following inventive embodiments. As is apparent by these descriptions, this invention can be embodied in different forms and should not be construed as limited to the embodiments set forth herein. Rather, these

embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. For example, features illustrated with respect to one embodiment can be incorporated into other embodiments, and features illustrated with respect to a particular embodiment may be deleted from the embodiment. In addition, numerous variations and additions to the embodiments suggested herein will be apparent to those skilled in the art in light of the instant disclosure, which do not depart from the instant invention. Hence, the following specification is intended to illustrate some particular embodiments of the invention, and not to exhaustively specify all permutations, combinations, and variations thereof.

[0083] It is to be understood that in instances where a range of values are provided that the range is intended to encompass not only the end point values of the range but also intermediate values of the range as explicitly being included within the range and varying by the last significant figure of the range. By way of example, a recited range of from 1 to 4 is intended to include 1-2, 1-3, 2-4, 3-4, and 1-4.

[0084] Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. The terminology used in the description of the invention herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention.

[0085] Unless indicated otherwise, explicitly or by context, the following terms are used herein as set forth below.

[0086] As used in the description of the invention and the appended claims, the singular forms “a,” “an” and “the” are intended to include the plural forms as well, unless the context clearly indicates otherwise.

[0087] Also as used herein, “and/or” refers to and encompasses any and all possible combinations of one or more of the associated listed items, as well as the lack of combinations when interpreted in the alternative (“or”).

[0088] According to some inventive embodiments, elastomeric tubes are provided. According to other inventive embodiments, such elastomeric tubes are cast in 3D printed molds using EcoFlex 00-50 (EF) and/or Dragon Skin 10 SLOW (DS), or another commercially available silicone rubber. According to other inventive embodiments, a fabric jacket is provided on an outer surface of the elastomeric tube. According to still other inventive embodiments, the fabric jackets are cut from a knit fabric blend, such as a 93-7% rayon-spandex. A fabric jacket is wrapped around an elastomeric tube. According to still other inventive embodiments, the fabric jackets wraps the tube such that the wale direction runs parallel to the longitudinal axis of the tube, as shown in FIG. 1B.

[0089] According to other inventive embodiments, bare (unjacketed) and jacketed EF and DS tubes (denoted EFF and DSF respectively) are subjected to hydrostatic pressure testing in an inventive custom-built hydraulic or pneumatic ‘flow loop’, as shown schematically in FIG. 2A. During testing a single tube is clamped in place in the compliant chamber, as shown in FIG. 2B, and is increasingly pressurized by running the centrifugal pump at incrementally faster speeds. A camera facing the compliant chamber captures images of the tubes at each pressure level, as shown in FIG. 2C, which are later analyzed to measure the extent of distension. Tests continue until significantly asymmetric distension of the tube is observed, such as in FIG. 2F:iii.

[0090] ‘Distension’, in this context, is defined as the difference between the initial and final diameters, as shown in FIG. 2C, where final diameter is taken as an average value over the middle 3 cm of the image of the tube. A plot of distension vs. pressure values for all tested tubes is shown in FIG. 2D and some corresponding real-life images are shown in FIG. 2F:i-vi.

[0091] The most notable trend is the difference in the shape of the curves forunjacketed and jacketed tubes. Unjacketed tubes display an exponential growth curve, rapidly approaching failure with increasing pressure. Conversely, jacketed tubes display a sigmoid (‘S-shaped’) curve in which the exponential growth begins but is eventually halted, entering a region of self-regulation in which the increasing tube distension slows and even appears to plateau.

[0092] FIG. 2E illustrates the self-regulating effect experienced by the jacketed tube at the highest pressures. The x-axis is pressure at each data point as shown in FIG. 2D, whereas y-axis is the unit ‘rate of distension’; that is, the mean increase in distension per kPa between each point and the one directly previous. While the rate of distension only increases across the pressure range for EF and DS tubes, it peaks and eventually decreases for the jacketed tubes.

[0093] The other main result is related to the symmetry of distension observed at high pressures in FIGS. 2F:i-vi. While the EF tube experiences a sudden onset of asymmetric distension near the end of its pressure range, as shown in FIG. 2F:iii, the EFF tube maintains a relatively symmetric distension profile even at pressure over twice the maximum experienced by the EF, as shown in FIG.2F:vi.

[0094] Additionally, 3-dimensional finite element simulations are provided using ABAQUS using material coefficients obtained from uniaxial tensile tests of the tubing materials; these simulations are successful in predicting distension trends of all tested tubes across the entire tested pressure range and beyond. ABAQUS requires that the coefficients of an appropriate constitutive model, selected from a list, are associated with the materials being simulated. Therefore, 1) the constitutive material model and material coefficients selected represents the behavior of both the elastomers and fabric used.

[0095] The Mooney-Rivlin model [45] is used for the elastomers based on its previously established accuracy in describing elastomeric deformation behavior [7]. For a uniaxial tensile test the Mooney-Rivlin equation takes the form of Equation 1.

Equation 1:

$$t_{1,elastomer} = 2C_{10}(\lambda_1^2 - \frac{1}{\lambda_1}) + 2C_{01}(\lambda_1 - \frac{1}{\lambda_1^2})$$

where $t_{1,elastomer}$ is the true stress in the direction of uniaxial elongation (Pa), λ_1 is the stretch ratio in the direction of elongation (mm/mm) and C_{10} and C_{01} (both Pa) are the coefficients of interest that must be fit to the uniaxial tensile test data.

[0096] For the fabric, the Holzapfel-Gasser-Ogden (HGO) model is used as it is supported by ABAQUS and was originally conceived to describe the hyperelastic anisotropic behavior of aortic tissue [41]. Ordinarily, the HGO model takes the form shown in Equation 2.

Equation 2:

$$t_{1,HGO} = 2C_{10}(\lambda_1^2 - \frac{1}{\lambda_1}) + 2k_1\lambda_1^2(\lambda_1^2 - 1)\exp(k_2(\lambda_1^2 - 1)^2)$$

where the first term represents the elastomer behavior and the second term represents the fiber behavior. The C_{01} term from the Mooney-Rivlin equation is dropped as it mainly affects the behavior of the elastomer at low strains, while the focus of the HGO equation is modeling the strain-stiffening behavior at higher strains. Although the equation is meant to describe aorta, which may be thought of as an embedded fiber-elastomer composite, the present invention establishes that the equation still holds for jacketed elastomer tubes where the fabric is not specifically adhered

to the elastomer in any way. Thus, Equation 2 is adapted for this scenario such that for the fabric alone, the uniaxial stress equation is based on Equation 3.

Equation 3:

$$t_{1,fabric} = 2k_1\lambda_1^2(\lambda_1^2 - 1) \exp(k_2(\lambda_1^2 - 1)^2)$$

where $t_{1,fabric}$ is the fabric's true stress in the direction of elongation (Pa), and k_1 (Pa) and k_2 (dimensionless) are the coefficients of interest.

[0097] For uniaxial tensile tests, 3D-printed molds are printed to cast elastomeric 'dogbones' for uniaxial tensile testing. The geometry of the dogbone is shown in FIG. 3A. The rayonspandex fabric was cut into rectangular strips, shown in FIG. 3B, and samples with the long edge running parallel to the wale and course directions are both cut in order to evaluate the material anisotropy.

[0098] However, since it is assumed the tubes will be subject to repeated load-unload cycles when in use, the hysteresis experienced by the material over time must be considered. Single uniaxial tensile tests to failure were not adequate to determine the material coefficients as they would underestimate the compliance. Instead, 'quasi-hysteresis' tests are conducted, where the samples are subject to multiple load-unload cycles at incrementally larger levels of strain and stress-strain data collected for each (unlike a conventional hysteresis test, stress-strain data was not collected when unloading). Ultimately, one of the curves on the quasi-hysteresis plot is deemed an appropriate approximation of the extent of hysteresis experienced by each material during testing, and the coefficients were selected that would reasonably fit the data to the selected equation. MATLAB's curve fitting toolbox is used to apply a leastsum-squares (LSR) regression that quantifies the accuracy of the selected coefficients with an R^2 value.

[0099] The extent of hysteresis for the elastomers and the fabric is assumed to be equal to that shown in the 200% strain hysteresis curve. This was initially based off a simple approximation; the tubes experienced the most deformation in the circumferential direction, and for all tubes the maximum pressure tested brought the tube to approximately 200% of its initial diameter. However, as explained herein, the 200% curves eventually were shown to be an excellent benchmark for fitting coefficients that produced accurate simulations.

[00100] For the fabric jackets, the circumferential direction of the tube runs parallel with the course direction of the knit; therefore, coefficients are fit to the 200% strain quasi-hysteresis curve of the fabric when uniaxially tested in the course direction. The material coefficients and associated R^2 values are tabulated in Table 1.

Table 1: Fitted coefficients for all tested materials.

Material	Material coefficients	R^2 value
EcoFlex 00-50 (EF)	$C_{10} = 18000 \text{ Pa}$ $C_{01} = 2700 \text{ Pa}$	$R^2 = 0.9923$
DragonSkin 10 (DS)	$C_{10} = 35000 \text{ Pa}$ $C_{01} = 3000 \text{ Pa}$	$R^2 = 0.9512$
Rayon-spandex fabric, course direction	$k_1 = 3336 \text{ Pa}$ k_2 $= 0.0399$	$R^2 = 0.9987$

[00101] A fabric jacketed tube is therefore be assumed to have a uniaxial tensile stress equation equivalent to Equation 2, using a combination of the coefficients in Table 1. The associated stress-strain curve is shown in FIG. 3F. As expected, the elastomer material response is dominant at the lower strains while the fabric quickly becomes responsible for most of the stiffness at higher strains.

[00102] According to other inventive embodiments, 3-dimensional finite element models are designed in ABAQUS to replicate the hydrostatic testing for all tested tubes. Since the base design of the tubes is axisymmetric, only a thin ‘slice’ of each tube, as shown in FIG. 4A, is modeled to save computational power. Different models are created to represent EF, DS, EFF, and DSF tubes, each using the relevant coefficients from Table 1 to define the material. Hydrostatic loads are applied to the inner surface of these modeled tube slices with analytical rigid rollers used to represent the clamps in the physical experiment, as in FIG. 4B. Over many steps in the simulation, the load is gradually increased to reflect each pressure level to which the physical tubes are subject during the experiment, plus one or more extra levels beyond the experimental maximum to monitor the continued evolution of the distension trends.

[00103] After each step in the simulation, the tube slice takes on a distended shape, as shown in FIG. 4C. Performing a 360-degree sweep of this shape allows for a better visualization of the distended profile of the entire tube, as shown in FIG. 3D. Analysis of the deformed models allows for calculation of maximum distension at each simulated pressure level and rate of distension per unit pressure increase using the same equations provided above, where maximum distension is defined as the average difference between final and initial diameter over the middle 3 cm of the tube. These results are plotted in FIGS. 4E-4F, with profiles of distended EF tubes at various pressures shown in FIGS. 4G:i-iii and distended EFF tubes at various pressures in FIGS. 4G:iv-vi.

[00104] Clear trends emerge from the ABAQUS simulation results. Theunjacketed tubes show exponential increases in distension and rate of distension as pressure increases, while the jacketed tubes have a sigmoid-shaped distension curve due to the strain-stiffening behavior of the fibers. Additionally, increasing the simulated pressure range allows for the full realization of the self-regulation behavior observed in the jacketed tubes; as seen in FIG. 4F, the rate of distension continues decreasing to nearly zero as hydrostatic pressure increases further.

[00105] FIGS. 4E-4F show that there is good agreement between physical experiment and numerical simulation for the distension trends of all tested tubes. The distension-pressure curves for the unjacketed elastomer tubes experience are exponential (continually increasing distension rates) whereas for the jacketed tubes they are sigmoidal (distension rates that peak and then fall).

[00106] Additionally, there is also excellent agreement in the numerical values of both distension and volume over the entire tested pressure range. This is quantifiable by using a least-squares reduction to determine R^2 values, as listed in Table 2.

Table 2: R^2 values of experimental tube distensions and volumes against simulated tube distensions and volumes.

Material	R ² (Distension)	R ² (Volume)
EF	0.9469	0.9332
DS	0.9856	0.9749
EFF	0.9862	0.9857
DSF	0.9702	0.9617

[00107] Predictably, the asymmetric distension observed in the elastomeric tubes at high pressures did not occur in the simulations. This discrepancy is reconciled by considering the real-life limitations of the tubular cast geometry and the flow loop setup. For example, due to printing errors or gradual warping of the 3D printed mold, there may be localized ‘thin’ regions on the tube where the wall thickness is slightly decreased. Alternatively, due to slight misalignment of the tube or clamps in the compliant chamber, there may be regions of the tube which are subject to more fluid pressure than others. In either case, there will be small areas of elevated stress on the tube wall which would result in localized regions of greater distension. Repeated over many pressure tests, this could accelerate the hysteresis behavior in these localized regions, creating regions of significantly lower compliance. This would catalyze a cascading effect that may be responsible for the ‘aneurysm’ shown in FIG. 5A.

[00108] Conversely, if such defects are present in a jacketed elastomeric tube, the strong strain stiffening behavior of the fabric acts as an inhibitor of the uneven distension that would occur in bare elastomeric tubes. FIG. 5B shows a clear difference in distension profiles between an unjacketed and jacketed elastomeric tube near the upper limits of their tested pressures. The observed self-regulation behavior in jacketed elastomeric tubes may play a pivotal role in several of its applications.

[00109] Ultimately, the present invention provides a proof of concept for a material phenomenon using a limited set of experiments. According to other inventive embodiments, tubing design is carefully altered to induce onset of self-regulation at a particular pressure or distension. Thus, inventive tunable tubing has utility for a myriad of purposes.

[00110] According to other inventive embodiments, the tubing is tuned by changing the circumference of the sewn fabric jacket. Increasing the circumference (introducing slack into the jacket) delays the onset of the self-regulation response, whereas decreasing the circumference introduces pre-stretch in the fabric (essentially changing its material coefficients) and hastens the onset of self-regulation. Similarly, by printing a new mold design, the base elastomeric tubing is customized by changing its radius, length, or wall thickness.

[00111] To produce tailored material responses with greater complexity, the use of metamaterial designs are provided. Kirigami, the Japanese art of cutting and folding paper to produce repeated patterns [46]. According to other inventive embodiments, such folds are induced in the fabric jacket to control the distension profile of the jacketed tube. Strategically cut regions in the fabric jacket create localized regions of increased compliance in the tube, which are then controlled carefully in accordance with the working conditions to produce highly specific material responses.

[00112] A simple simulation is designed to illustrate this concept. The left half of FIG. 6A depicts a jacketed EcoFlex tube, while the right half has a simple circumferential kirigami pattern cut into the fabric. The cuts are biased towards the center to encourage greater distension near the middle of the tube; the resulting distension profile in FIG. 6B shows that this goal is well-achieved. The altered distension profile is beneficial in some applications, given that the distended shape allows for quicker fluid flow during depressurization.

[00113] Accordingly, the present invention provides a design for jacketed elastomeric tubes that display self-regulation behavior at elevated hydrostatic pressures. According to other inventive embodiments, the jacketed tube are manufactured using 93-7% rayon-spandex blend knit fabric and cast elastomeric tubes made of both EcoFlex 00-50 and Dragon Skin 10 SLOW. According to other inventive embodiments, the jackets are created by sewing rectangular pieces of fabric along their long edges to form closed loops, then sliding them over the elastomeric tubes. Unlike, the distension-pressure curves of bare elastomeric tubes which are exponential (the tubes experienced rapid deformation with increasing pressure which quickly led to asymmetric distension), the jacketed tubes of the present invention have sigmoidal distension pressure curves and largely symmetric distension profiles. Further, the expansion of the knit fibers led to strain-stiffening, which is the basis of the self-regulation response.

[00114] Furthermore, the present invention provides a series of hydrostatic pressure tests and finite element models that validate, and expand on, the trends seen in the physical experiments. Material behavior in the simulation is defined using hyperelastic constitutive models, which required numerical coefficients; these coefficients were obtained by fitting them to uniaxial tensile test data of the materials of interest. In order to accurately represent the increase in compliance undergone by the elastomer after many load-unload cycles, a single uniaxial tensile test to failure could not be used. Instead, a quasi-hysteresis test is conducted (loading cycles measured only), and the coefficients are fit to a single curve on the overall plot that is deemed to best represent the extent of hysteresis experienced by the material. Simulations are successful in replicating the experimental results, both in terms of overall trends and numerical values.

[00115] Finally, the present invention additionally provides a highly tunable and customizable tube, making it potentially suitable for a wide variety of applications. Prospective applications for

the presented design span the biomedical, soft robotic, and industrial sectors. Small changes to the design such as altering tube wall thickness, fabric jacket circumference, or knit fabric orientation may be made to yield simple, uniform changes to the material behavior. More complex alterations, such as cutting kirigami designs in the jacket, are also contemplated to induce more complex material responses.

[00116] The invention is further illustrated by way of Example.

[00117] Materials of Interest

[00118] EcoFlex 00-50 and Dragon Skin 10 SLOW are platinum-catalyzed RTV silicone elastomers obtained from Smooth-On Inc. (US). In liquid resin form, EF and DS have 2 components that are mixed in a 1:1 ratio and degassed before being poured into molds to cure in their desired shape. Knitted fabric (93% rayon and 7% spandex) sourced from Telio (Canada) is obtained from Marshall Fabrics.

[00119] Hydrostatic Pressure Testing of Elastomeric Tubes

[00120] Sample Preparation

[00121] Elastomeric tubes are manufactured by pouring mixed and degassed liquid resin into a 3D printed cylindrical mold and allowed to cure for a minimum of 3 hours. The mold produces tubes with an outer diameter of 27.05 mm and had a center insert to produce an inner diameter of 19.05 mm.

[00122] For tests involving jacketed tubes, the fabric is cut into rectangular pieces and sewn to form ‘jackets’ 12 cm in length and 8 cm in circumference, with the wale direction parallel to the longitudinal direction of the tube. The fabric jackets are then pulled over the elastomeric tubes. An image of the compliant tube is shown in FIG. 1.

[00123] Flow Loop Setup

[00124] A custom-built closed flow loop system is used to test the tubes under hydrostatic pressure. A schematic of the flow loop is shown in FIG. 2A. Originally designed to simulate hydrodynamic conditions in the ascending aorta, the system is reconfigured for hydrostatic tests; namely, one of the two pumps is unused, and fluid does not flow continuously through the entire loop.

[00125] The compliance chamber houses a length of elastomeric tubing with the ends clamped in place as shown in FIG. 2B, and fluid flows into it via the centrifugal pump at the top of the flow loop. The check valve beneath the tube is closed to prevent fluid flow past the compliant chamber, achieving hydrostatic conditions.

[00126] Before testing begins, a degree of pre-stretch is applied by running the centrifugal pump at increasingly higher speeds until severe, asymmetric distension of the tube occurs (jacketed tubes are pre-stretched without the jacket on). Centrifugal pump speed is increased in 200 rpm increments and the corresponding pressure is measured by a tap just below the compliant chamber. As fluid flows into the tube, it distends and a camera facing the compliance chamber takes pictures of the distended tube's profile.

[00127] Image Analysis

[00128] FIG. 2C is an example of an image taken by the camera facing the compliant chamber. The images of the distended tubes are assessed to measure the amount of radial deformation experienced by the tube and the volume increase at each pressure level. A MATLAB program is written that binarizes the grayscale images and calculates the 'width' of the tube along its entire length, one row at a time from top to bottom.

[00129] The maximum distension is defined as the difference between the tube's maximum pressurized diameter and undeformed diameter. The 'maximum distension' is defined as the average distension measurement of the middle 3 cm of the image taken. To measure the distended volume of the tube, a row-by-row integration approximation method is used.

[00130] Uniaxial Tensile Testing of Materials

[00131] Stress-strain behavior of elastomer and fabric samples is measured using an Instron 5943 uniaxial tester. The main purpose of these tests is to obtain constitutive modelling coefficients for each material that may be used in the subsequent finite element simulations. This requires knowledge of the material hysteresis behavior, such that the increase in compliance with load history could be reflected in the selected coefficients; a single uniaxial tensile test to failure of each material would be insufficient as it would severely overestimate the stiffness of a sample that had been aged from previous loading-unloading cycles. For example, an aorta-substitute tube in an EVHP device undergoes cyclic deformations during operation; this results in the deviation of the tube material's stress-strain behavior from that measured from the virgin material.

[00132] Conventional cyclic hysteresis testing, in which the tester automatically performs a given number of load-unload cycles at a precisely controlled rate and continuously measures the output, is not possible with the instrument used (unloading rate is automated). Instead, a 'quasi-hysteresis' test is designed where the sample is stretched to a given maximum strain 3 times before the maximum strain increased by 50% (100% once max strain reached 400%), but the apparatus records the stress/strain data for each test during loading only. For every 50% of strain experienced by the sample in the previous loading cycle, 30 seconds of relaxation time is allowed between loading measurements.

[00133] The width, thickness, and gauge length of the elastomeric samples are measured using a caliper. The loading is performed at an extension rate of $0.1 \text{ } \varepsilon \cdot \text{s}^{-1}$ based on previous literature that conducted similar tests [47]. The stress-strain plots for the load ‘cycles’ is then superimposed to see the increase in compliance as the quasi-hysteresis test progresses, as shown in FIGS. 3C-3D. Further information on this process is provided below regarding Hydrostatic Pressure Testing.

[00134] Finite Element Modelling of Elastomeric Tube Distension

[00135] After obtaining the material coefficients, finite element modeling is performed in ABAQUS (Dassault Syst`emes SE). To minimize computation time, each tube is modeled as a longitudinal ‘slice’ encompassing a portion of the circumference equivalent to the thickness of a single element (approximately 0.5 mm). The tube slices are defined in a cylindrical coordinate system as shown FIG. 4A.

[00136] The tube slice’s material behavior is defined to be hyperelastic and governed by the coefficients obtained from the uniaxial tests performed. For the jacketed tubes, the material is assumed to be a homogeneous fiber-elastomer composite with fiber families running in the circumferential and longitudinal directions. Since most of the distension in the fabric jacket is circumferential, it is assumed that most of the material response is governed by the stiffness of the fabric in the course direction; therefore, the uniaxial coefficients of the fabric’s course direction are assumed to be representative of the fabric’s behavior in the simulation.

[00137] For boundary conditions, the ‘cut faces’ of the tube slices are restricted from moving in the circumferential direction; this essentially functions as a cyclic symmetry condition. The top and bottom faces of the tube slice are restricted from moving in the z-direction. Most notably, the outer face of the tube is constrained by analytical rigid parts at the top and bottom of the tube, which are loosely representative of the real-life clamps used to hold the tube in place in FIG. 2B.

Contact between the tube and the clamps is defined to be frictionless and the clamp's cross-sectional geometry is designed to maximize the stability of the simulation without greatly affecting the results. The finite element assembly is shown in FIG. 4B.

[00138] The pressure load is defined as hydrostatic, applied across the entire inner face of the tube, and its magnitude is increased with each sequential step of the analysis to reflect each of the experimental pressures. Each hydrostatic pressure applied is based off a measurement taken just below the height of the tube; for the simulations, these pressures are assumed to apply to the very bottom of the tube ($z = 0$) and decrease with increasing z due to gravity effects according to Equation 4.

Equation 4:

$$\Delta P = \rho \cdot g \cdot \Delta z$$

where $\rho = 999\text{g}/\text{m}^3$, $g = 9.81\text{m}/\text{s}^2$, and $\Delta z = 0.12\text{m}$ (the length of all tested compliant tubes). Equation 4 yields that the gravity effects are responsible for approximately 1.2 kPa of head loss up the length of the tube.

[00139] The distended finite element tube slice is pictured in FIG. 4C, the face of which could be swept to form a distended tube, as in FIG. 4D. After running the simulation, measurements of maximum tube distension and distended tube volume are calculated for each tested pressure. As with the experimental images, max tube distension is defined as the mean displacement of all nodes along the middle 3 cm of the tube's outer edge. Tube volume is calculated using a trapezoidal approximation method similar to the pixel-by-pixel approximation used for the experimental images.

[00140] Hydrostatic Pressure Testing

[00141] As noted above, a MATLAB program calculates the maximum distension of the tubes by averaging the distended tube's outer diameter D_f over the middle 3 cm of the image and subtracting the undistended outer diameter D_i . More specifically, the program splits the image into 'rows' of pixels and measures the width of the distended tube, in pixels, for each row. The measurements are later converted to SI units using a known calibration.

[00142] Similarly, the volume of the distended tubes is calculated by taking row-by-row measurements of the tube's width for the entire image except for the middle 3 cm. However, the images only measure the middle 8 cm of the 12 cm tubes. Since 1 cm on either end of the tube is clamped (and is ignored in the volume calculation), there is still an additional 1 cm of the distended tube wall which is not shown in the image. To account for this, an extrapolation method is used in which the tube diameter is assumed to return to the undistended diameter D_i linearly over the missing 1 cm (the pictures in FIG. 5 support this approximation). The formula to calculate the volume is then given in Equation 5.

Equation 5:

$$V_{exp} = \sum_{k=1}^{k_{max}} \frac{\pi}{4000} D_{f,k}^2 h_{pixel} - V_{walls}$$

[00143] $D_{f,k}$ is the distended outer diameter of the tube for row k in the image (mm), V_{exp} is the volume (mL), k_{max} is the height of the image plus the extrapolated regions in pixels (px), and h_{pixel} is the calibration length represented by one pixel in the image (mm/px). V_{walls} is the volume of the tube walls (mL), which are assumed to be incompressible and can have their volume calculated using Equation 6.

Equation 6:

$$V_{walls} = \frac{\pi h}{4000} (D_i - d_i)^2$$

where D_i is the undistended outer diameter, d_i is the undistended inner diameter, and h is the height of the undeformed tube (all mm). For all tested tubes, $d_i = 19.05$ mm and $h = 100$ mm. For unjacketed tubes $d_o = 27.05$ mm, while for jacketed tubes $d_o = 28.21$ mm due to the fabric in the jacket being 0.58 mm thick on average.

[00144] Plots of the experimental data for tube distension, rate of distension, tube volume, and rate of volumetric expansion are shown in FIGS. 7-10. Ultimately, the volume plots follow the same trends seen in the distension plots; unjacketed tubes undergo exponential volume increase and steadily increasing rate of volumetric expansion with increasing pressure, whereas jacketed tubes experience a plateau in volume increase due to the self-regulation behavior.

[00145] Constitutive Modeling of Elastomers and Fabrics

[00146] As mentioned above, elastomers (with or without fabric) are hyperelastic materials; this means their deformation behavior is governed by a strain energy density function instead of a single constant. The strain energy density W (J/mm³) is a non-linear function of the principal strain invariants, which themselves are functions of the stretch ratios λ ($= 1 + \varepsilon$) in the three principal directions.

[00147] Zhalmuratova *et al.* [7] performed a review of different constitutive hyperelastic material models to model the stress-strain behavior of fiber-elastomer composites. Of the models considered, the Mooney-Rivlin model was used for elastomer strain energy density and the Holzapfel-Gasser-Ogden (HGO) model was used for composite strain energy density. These are shown in Equations 7 and 8 [45] [41].

Equation 7:

$$W_{elastomer} = C_{10}(I_1 - 3) + C_{01}(I_2 - 3) + \frac{1}{D_1 - 1}(J - 1)^2$$

Equation 8:

$$W_{composite} = C_{10}(I_1 - 3) + \frac{k_1}{2k_2} \sum_{i=1,6} \left(\exp(k_2(I_i - 1)^2) - 1 \right)$$

[00148] In these equations the variables C_{10} , C_{01} , D_1 , k_1 , and k_2 are all material constants and so must be experimentally determined, whereas J is the volume variation factor which, assuming the bulk incompressibility condition, can be assumed to be ≈ 1 (this eliminates the third term in Equation 7). I_1 , I_2 , I_4 and I_6 are the first, second, fourth, and sixth strain invariants, shown in Equations 9-12 [48] [7].

Equation 9:

$$I_1 = \lambda_1^2 + \lambda_2^2 + \lambda_3^2$$

Equation 10:

$$I_2 = \lambda_1^2 \lambda_2^2 + \lambda_2^2 \lambda_3^2 + \lambda_3^2 \lambda_1^2$$

Equation 11:

$$I_4 = \lambda_1^2 \cos^2 \alpha + \lambda_2^2 \sin^2 \alpha$$

Equation 12:

$$I_6 = (\lambda_1^4 \cos^2 \alpha + \lambda_2^4 \sin^2 \alpha) \cos \theta$$

where α is defined as the angle between the fiber direction and stretching direction and θ is defined as the angle between the two fiber families (0 and 90 degrees respectively). This leads to Equations 13 and 14.

Equation 13:

$$I_1 = \lambda_1^2$$

Equation 14:

$$I_6 = 0$$

[00149] The strain energy density functions may be most easily converted to Cauchy stress equations under controlled conditions where the strain invariants are more easily determinable.

For example, in a uniaxial tensile test where the sample is extended along axis 1, $\lambda_1 = \lambda_2^{-1/2} = \lambda_3^{-1/2}$. For a Mooney-Rivlin solid, the uniaxial stress is then described by Equation 15 [48].

Equation 15:

$$t_{1,MR} = 2C_{10}(\lambda_1^2 - \lambda_1^{-1}) + 2C_{01}(\lambda_1 - \lambda_1^{-2})$$

[00150] Once the coefficients C_{10} , C_{01} have been fit to uniaxial test data, in theory they can be used to define the deformation behavior of the isotropic Mooney-Rivlin solid in any generalized stress state. This is the motivation behind the uniaxial testing conducted herein.

[00151] The Holzapfel model is a decoupled strain energy density model for fiber-elastomer composites [41], where terms for strain energy density of the bulk elastomer and fabric layer can be considered separately, shown in Equation 16.

Equation 16:

$$W_{composite} = W_{elastomer} + \left(W_{fibres} + W_{interaction} \right)$$

[00152] In the presented design in this work, the fabric is not embedded in the elastomer to prevent out-of-plane motion (as is the case with all true fiber-elastomer composites); therefore, it is assumed that $W_{interaction} \approx 0$. Meanwhile, it was also shown that $W_{elastomer}$ leads to the uniaxial stress formula in Equation 15 (the C_{01} term is omitted in the simulation due to a limited impact on the deformation behavior at higher strains). Therefore, combining Equation 8 with Equation 16 leads the following Equation 17 for the strain energy density of the fabric.

Equation 17:

$$W_{fabric} = W_{fibres} = \frac{k_1}{2k_2} \sum_{i=1,6} \left(\exp(k_2(I_i - 1)^2) - 1 \right)$$

which, combined with Equations 13 and 14, leads to Equation 18 for the uniaxial tensile stress of fabric.

Equation 18:

$$t_{1,fabric} = 2k_1\lambda_1(\lambda_1^2 - 1)\exp(k_2(\lambda_1^2 - 1)^2)$$

[00153] Hysteresis Testing

[00154] Complete quasi-hysteresis plots for all materials are shown in FIGS. 11-15. The legend associates the color of each plot curve with the maximum level of strain for that test. With the exception of some of the last entries in the legend, there will be two curves for each color: one with higher stress values and one with lower. These correspond to the first and third tensile tests to that level of strain, respectively.

[00155] Plots of the theoretical stress-strain curves using the fitted coefficients for all materials, overlaid with the selected quasi-hysteresis curves (3rd test to 200% strain), are shown in FIGS. 16-18.

[00156] Finally, plots of the theoretical stress-strain curves for the elastomer and fabric combined, using the fitted coefficients, are shown in FIGS. 19-22.

[00157] Maximum tube distension is calculated for the simulations using a similar process to how the experimental distension values are found. First, history outputs re specified in ABAQUS to measure the radial displacement and z-coordinates (position on the longitudinal axis) for all nodes along one outer edge of the tube slice. Next, a MATLAB program is written that averaged the radial displacement of the middle 3 cm of the tube, from which the maximum distension could be easily calculated.

[00158] Additionally, tube volume is calculated using a trapezoidal approximation method. The volume approximation was made by summing many thin volumes of revolution as shown in Equation 19.

Equation 19:

$$V_{sim} = \sum_{k=1}^{k_{max}} \left(\frac{\pi}{12000} (D_{f,k+1}^2 + D_{f,k+1}D_{f,k} + D_{f,k}^2) h_k \right) - V_{walls}$$

where V_{sim} is the volume (mL), D_k is the diameter of node k (in mm, noting there are $k_{max}+1$ nodes in the region of interest), and h_k is the thickness of the trapezoid, or the distance in the z-direction between nodes $n+1$ and n (mm). V_{walls} retains the same definition as in Equation 6.

[00159] Comparison of Experiment and Simulation Results

[00160] Comparison plots of tube distension, rate of tube distension per unit pressure increase, tube volume, and rate of volumetric expansion per unit pressure increase are shown in FIGS. 27-30. Superimposition of the experimental and simulated data allows for visual confirmation of the agreement between the two sets.

[00161] Alternatively, least-squares regression parity plots to quantitatively illustrate the similarity between the experimental and simulated data sets are below in FIGS. 31-38. All R^2 values are > 0.9 .

[00162] Behavior of Self-Regulating Reinforced Elastomeric Tubes Under Hydrodynamic Pressure

[00163] Experiments are conducted to further illustrate the ability of the tubes to facilitate the Windkessel effect safely and effectively under hydrodynamic flow.

[00164] 100 mm lengths of rigid, bare elastomeric, and fabric-jacketed elastomeric tubes are subjected to cyclic hydrodynamic pressure using the ‘flow loop’ mentioned above. This pressure is meant to be roughly representative of a human heartbeat; 40 mL of fluid is pumped through the tube length at a frequency of 1.07 Hz. Backpressure within the flow loop is controlled by strategically placed clamps that inhibited fluid flow, and it is modulated for each tube during tests to achieve fully monotonic increase and decrease in tube OD during each cycle.

[00165] Pressure and distension are measured over the course of several cycles of hydrodynamic flow before a single representative cycle could be isolated to form waveforms. The most significant

finding is the difference in pressure waveforms between the rigid tube and the elastomeric tubes. The rigid tube's pressure waveform, shown in FIG. 39 is very 'jagged' in character, with large variance including a negative 'valley' near the midpoint. Conversely, all compliant tubes, shown in FIG. 40, have much 'smoother' pressure waveforms where the mid-cycle local minimum is not negative, nor less than the pressure at the beginning and end of the cycle. This is highly indicative of the Windkessel effect; the relatively slow pressure decrease after the initial peak is due to gradual release of stored fluid in the compliant tube.

[00166] As in previous tests, the benefit of the jackets during this round of testing is its ability to act as a 'fail-safe' and broaden the working conditions of the tube. Backpressure needed to be controlled very precisely to obtain a usable distension waveform for the bare elastomeric tubes; too low and tube collapse would occur mid-cycle from a 'vacuum' inside the tube, too high and the tube would not fully return to its starting OD before the next cycle, leading to aneurysm. The jacketed tubes have a much larger range of backpressures under which an acceptable distension waveform could be obtained, and they are generally able to operate under higher pressures and at higher levels of distension.

[00167] Hysteresis Loops of Self-Regulating Reinforced Elastomeric Tubes Under Hydrodynamic Pressure

[00168] Various lengths (100-260 mm) of bare elastomeric and fabric-jacketed elastomeric tubes were subjected to cyclic hydrodynamic pressure using the 'flow loop' mentioned above. This pressure was meant to be roughly representative of a human heartbeat; 40 mL of fluid was pumped through the tube at a frequency of 1.07 Hz. Backpressure within the flow loop was controlled by strategically placed clamps that inhibited fluid flow and was increased for each tube until fully monotonic increase and decrease in tube OD was observed during each cycle. This is the desired

distension behavior for the EVHP application; if backpressure is too low the tube ‘collapses’ (OD drops below initial levels during the cycle), whereas if backpressure is too high the tube ‘cascades’ (OD does not return to its original value before the start of the next cycle, leading to eventual failure).

[00169] 9 lengths of tube for 4 tube compositions were tested. Pressure and distension were measured over the course of several cycles of hydrodynamic flow for each tube and were superimposed using a custom algorithm in MATLAB to form pressure-distension hysteresis loop (see Figure 1a), which could then be superimposed (see Figures 1b and 1c). The following trends were observed:

[00170] Mean distension (x-coordinate of the loop’s centre), distension range (horizontal width of the loop), and pressure range (vertical height of the loop) all decrease as tube length increases. Mean pressure (y-coordinate of the loop’s centre) stays roughly the same as tube length increases. This holds for all tested materials.

[00171] In jacketed tubes, the pressure range is much larger than that of the unjacketed tubes. This indicates there is a greater working pressure range for jacketed tubes at which the desired distension behavior can be observed.

[00172] In jacketed tubes, the mean distension is lower than that of the unjacketed tubes. This indicates that the desired distension behavior can be achieved with a lower ‘baseline’ level of distension, i.e. the material experiences less constant strain when in use.

[00173] It was also observed in previous tests that the jacketed tubes display the desired distension behavior over a much larger range of backpressures, although that was not evaluated in the set of experiments shown in Figs. 41-43.

[00174] Hysteresis loops for elastomeric tubes under cyclic hydrodynamic pressure. FIG. 41 is a single hysteresis loop for a single tube length of a given material. Fig. 42 are superimposed hysteresis loops for all tested tube lengths of Ecoflex 00-50 (ECO = Ecoflex 00-50), in which the position of the loops gradually shifts in the indicated direction as tube length increases. FIG. 43 are superimposed hysteresis loops for all tested tube lengths of all tested tube materials (EFO = Ecoflex 00-50 + pre-stressed 93-7% rayon-spandex fabric, ESW = Ecoflex 00-50 + 95-5% viscose-spandex fabric, ESTW = Ecoflex 00-50 + 65-30-5% rayon-nylon-spandex fabric), in which the position of the loops for all tube materials gradually shifts in the indicated direction as tube length increases. Thus, it is clear that the addition of a fabric jacket improves the theoretical versatility and durability of a given elastomeric tube.

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[00223] Patent documents and publications mentioned in the specification are indicative of the levels of those skilled in the art to which the invention pertains. These documents and publications are incorporated herein by reference to the same extent as if each individual document or publication was specifically and individually incorporated herein by reference.

[00224] The foregoing description is illustrative of particular embodiments of the invention but is not meant to be a limitation upon the practice thereof. The following claims, including all equivalents thereof, are intended to define the scope of the invention.

CLAIMS

1. A method of passive fluid actuation comprising:

providing a jacketed elastomeric tube defining an internal channel, the jacketed elastomeric tube having a first end and a second end, a length extending from the first end to the second end, and a first diameter;

fixing the first end and the second end of the jacketed elastomeric tube;

supplying a fluid to the internal channel of the jacketed elastomeric tube; and

distending the jacketed elastomeric tube such that at least a portion of the jacketed elastomeric tube along the length expands from the first diameter to a second diameter to achieve passive fluid actuation.

2. The method of claim 1 wherein the length of the jacketed elastomeric tube remains constant.

3. The method of claim 1 wherein the constant pressure is hydrostatic pressure.

4. The method of claim 1 wherein upon supplying the fluid to the internal channel at the constant pressure, the jacketed elastomeric tube initially distends rapidly.

5. The method of claim 1 further comprising stiffening the jacket such that the jacketed elastomeric tube self-regulates continued distension of the jacketed elastomeric tube.

6. The method of claim 5 wherein the self-regulation occurs when pressure within the channel is above 15 kPa.
7. The method of claim 1 wherein the jacketed elastomeric tube distends symmetrically.
8. The method of claim 1 further comprising forming the jacketed elastomeric tube.
9. The method of claim 8 wherein forming the jacketed elastomeric tube includes casting an elastomeric tube in a mold.
10. The method of claim 9 wherein the mold is a 3D printed mold.
11. The method of claim 8 wherein forming the jacketed elastomeric tube includes forming a fabric jacket.
12. The method of claim 11 wherein forming the fabric jacket includes cutting the fabric jackets from a fabric.
13. The method of claim 8 wherein forming the jacketed elastomeric tube includes wrapping a fabric jacket around an elastomeric tube.
14. The method of claim 1 wherein the method of passive fluid or gas actuation is used in a biomedical exomuscle, a massage therapy implement, or a soft robotic actuator.

15. The method of claim 1 wherein the fluid is supplied to the internal channel of the jacketed elastomeric tube at a constant pressure.

16. The method of claim 1 wherein the fluid pressure is cyclic or irregular hydrodynamic pressure.

17. The method of claim 16 wherein the jacketed elastomeric tube is used to regulate pressure levels within the tube during hydrodynamic flow.

18. The method of claim 16 wherein the jacketed elastomeric tube is used to regulate fluid flow output within the tube during hydrodynamic flow.

19. The method of claim 16 wherein the jacketed elastomeric tube is used to self-regulate rate of distension of the jacketed elastomeric tube when fluid flow occurs at a suddenly high volumetric flow rate.

20. The method of claim 16 wherein the jacketed elastomeric tube prevents the 'water hammer' effect in applications where fluid flow may be suddenly halted downstream of the elastomeric tube.

21. A jacketed elastomeric tube for use with the method of claim 1, the jacketed elastomeric tube comprising:

an elastomeric tube defining internal channel and having an external surface; and

a fabric jacket wrapped around the external surface of the elastomeric tube.

22. The jacketed elastomeric tube of claim 21 wherein the elastomeric tube is formed of a silicone rubber.

23. The jacketed elastomeric tube of claim 21 wherein the fabric jacket features a relief pattern therein.

24. The jacketed elastomeric tube of any one of claims 21 to 23 wherein the jacketed elastomeric tube has a size on a 0.1 to 1000 centimeters.

25. The jacketed elastomeric tube of any one of claims 21 to 23 wherein the jacketed elastomeric tube prevents water hammer effect.

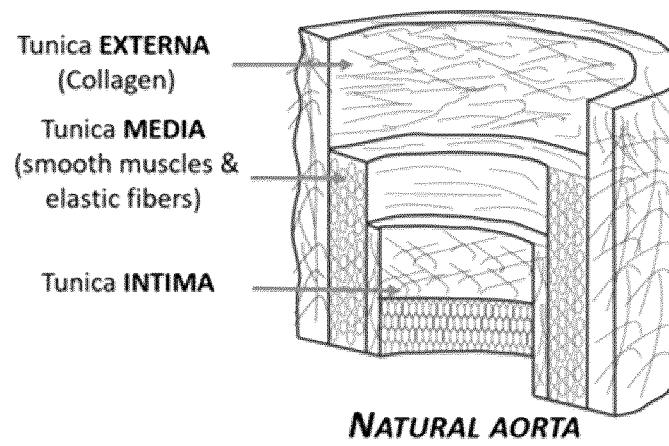


FIG. 1A

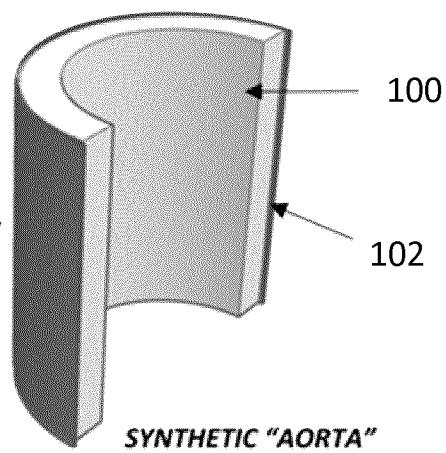


FIG. 1B

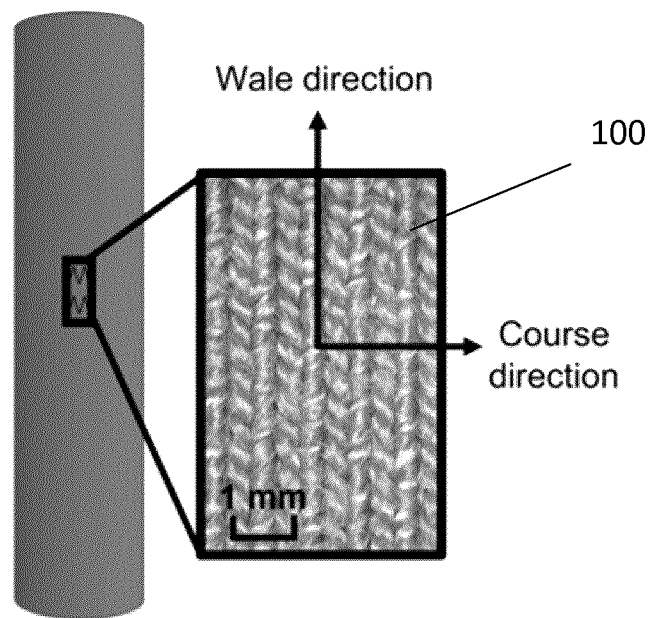


FIG. 1C

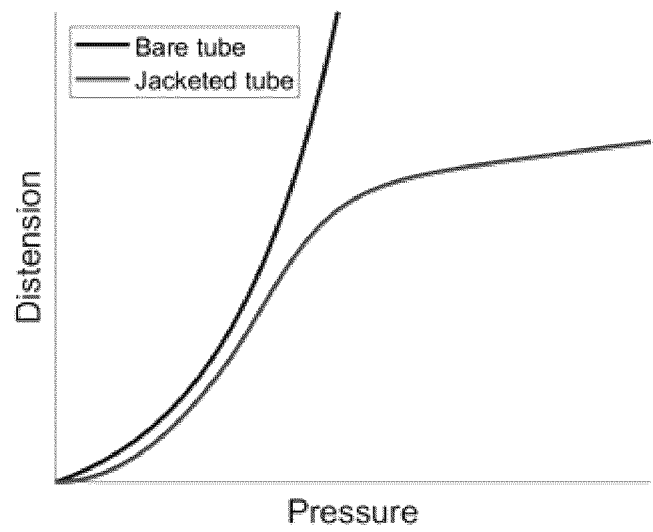


FIG. 1D

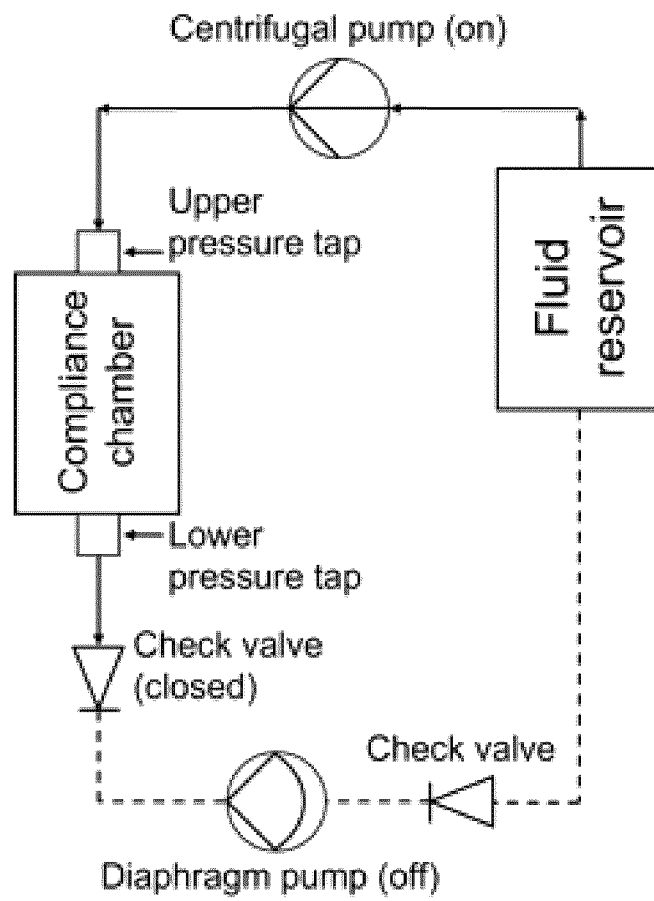


FIG. 2A

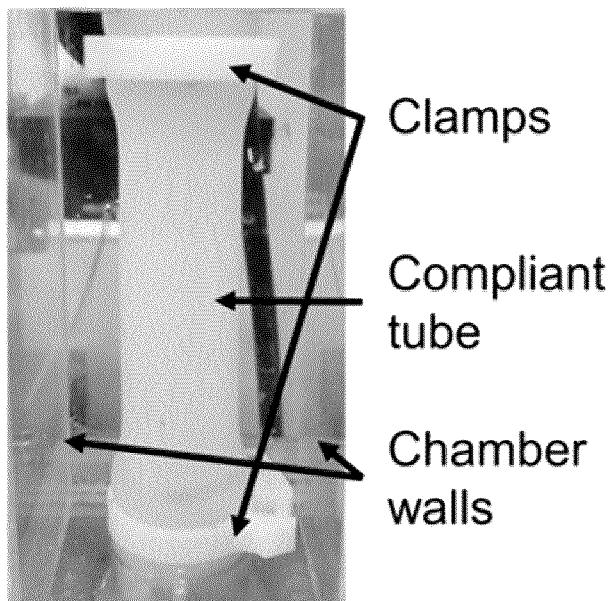


FIG. 2B

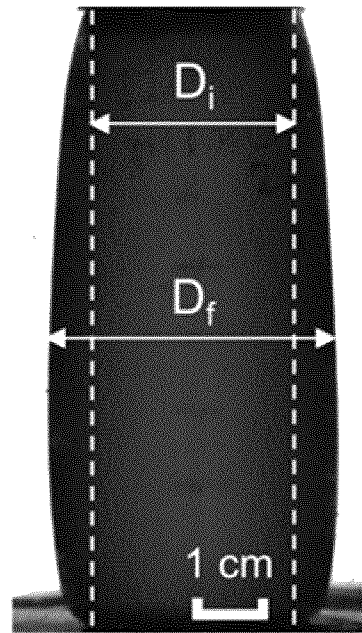


FIG. 2C

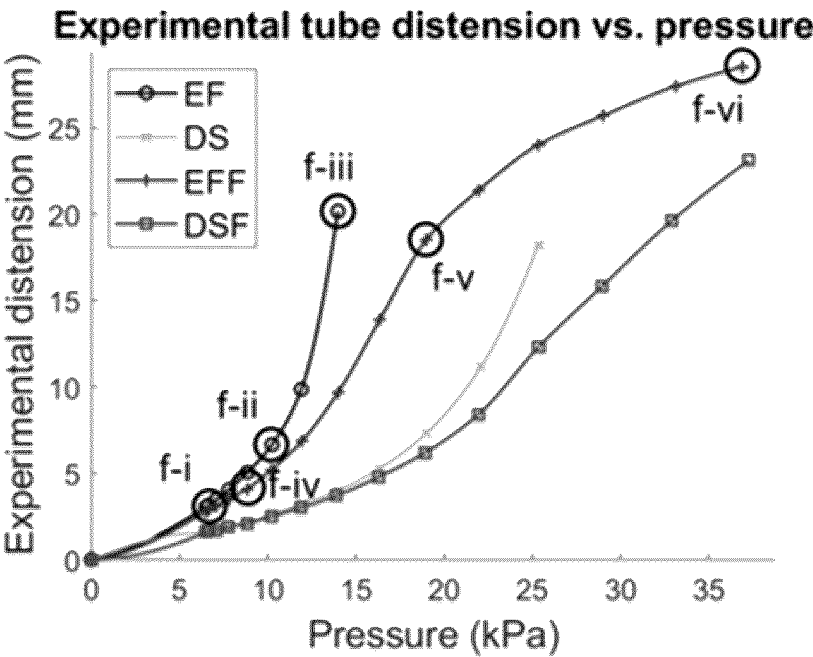


FIG. 2D

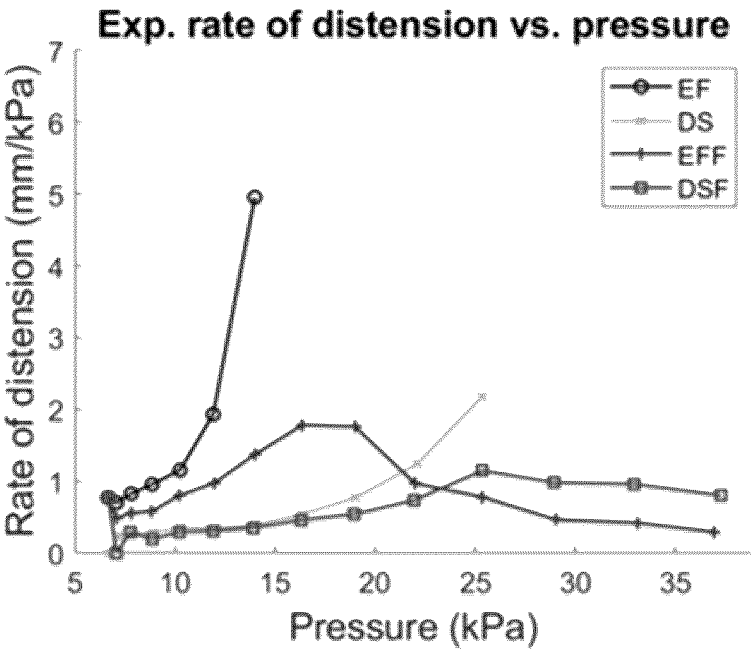


FIG. 2E

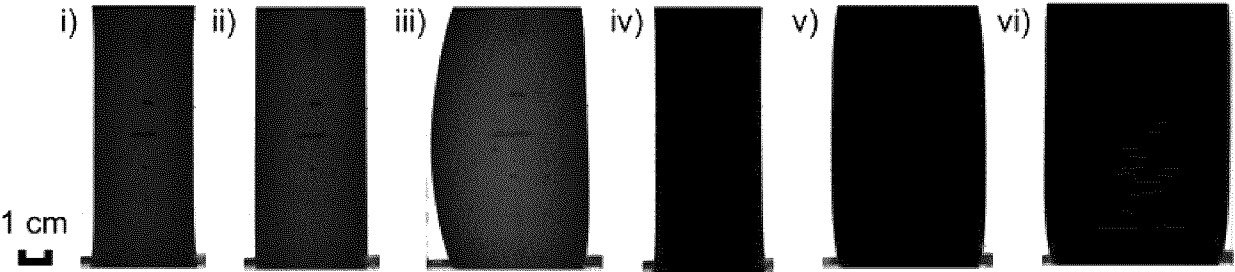


FIG. 2F

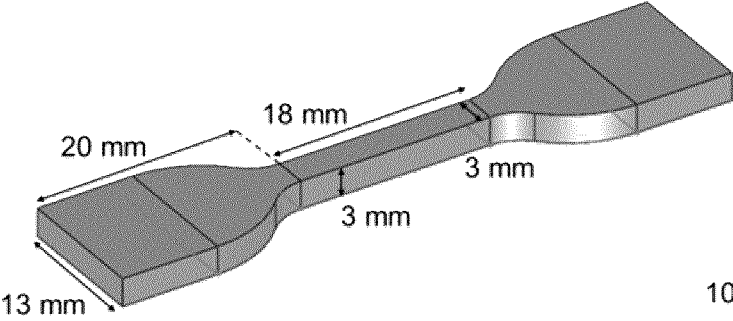


FIG. 3A

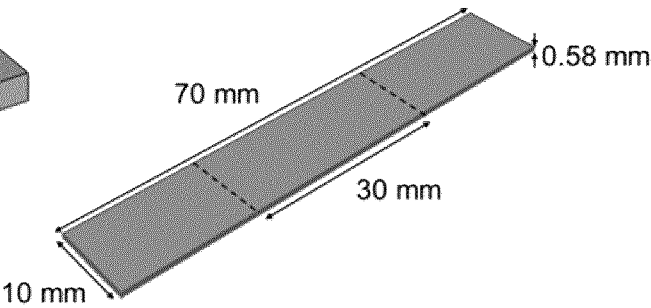


FIG. 3B

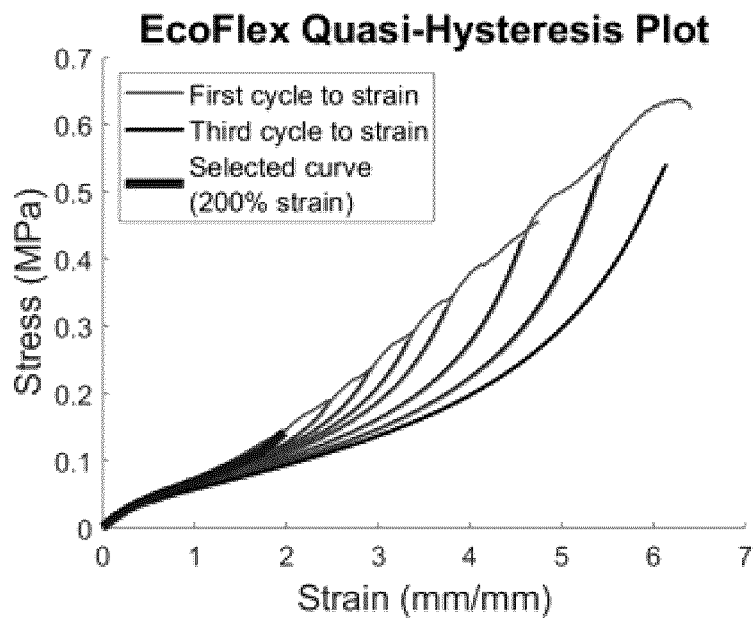


FIG. 3C

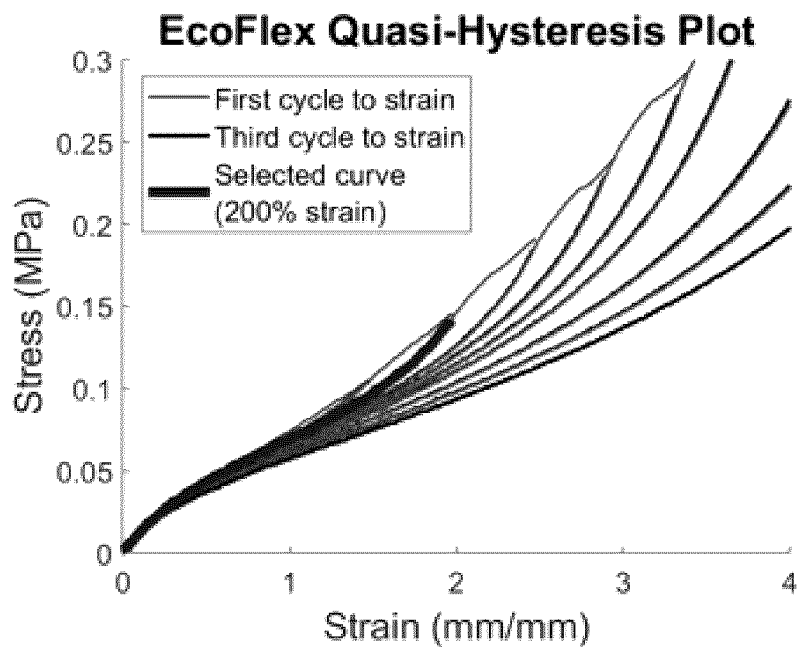


FIG. 3D

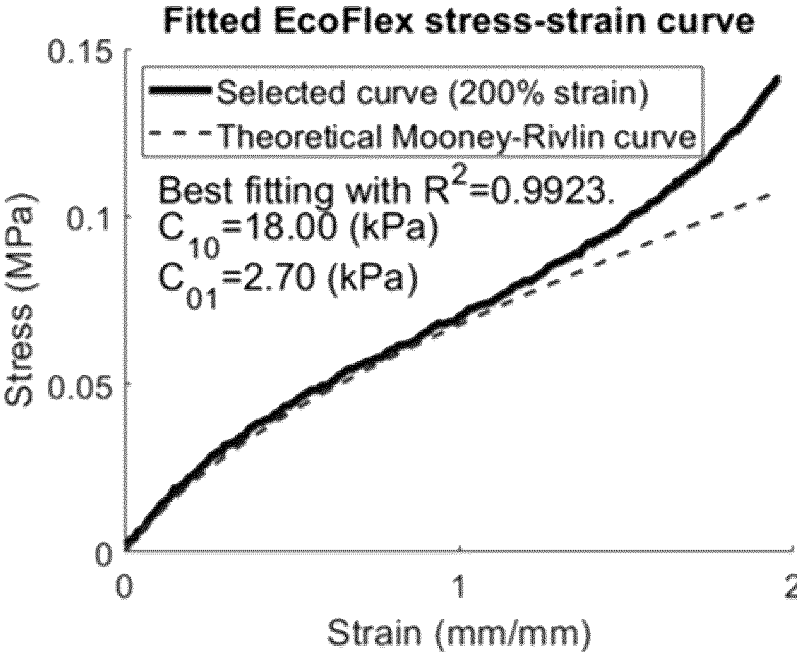


FIG. 3E

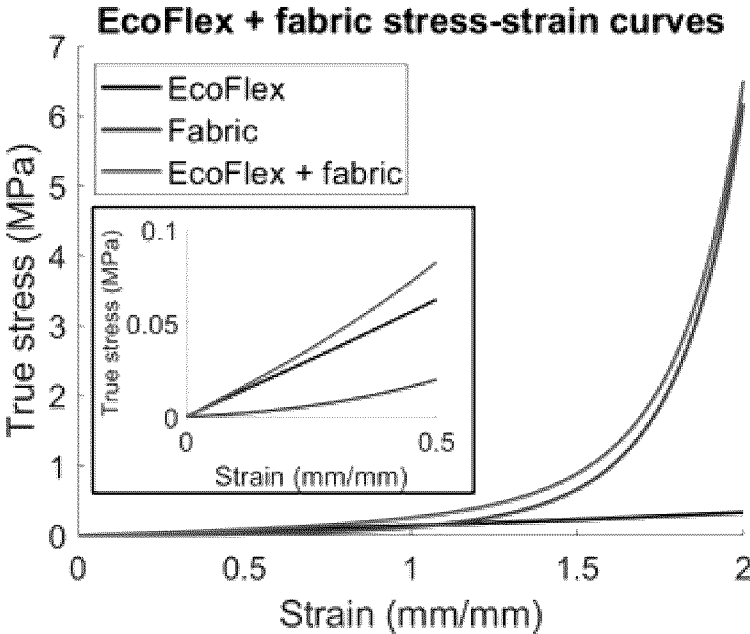


FIG. 3F

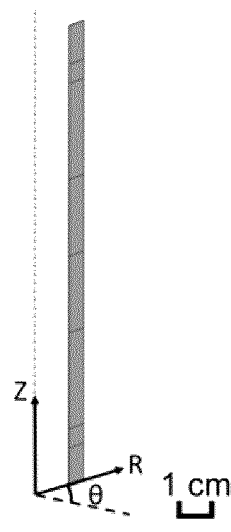


FIG. 4A

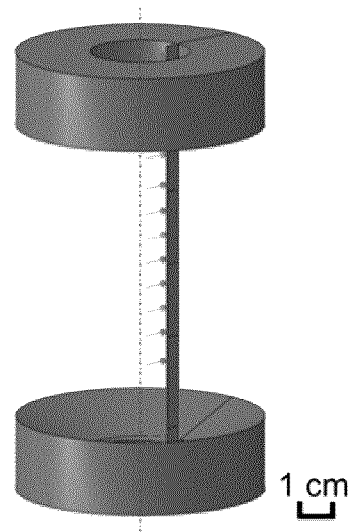


FIG. 4B

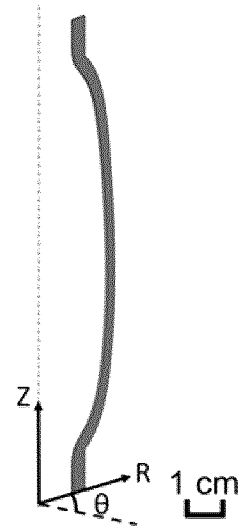
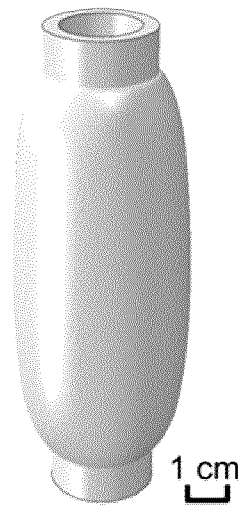


FIG. 4A



4C FIG. 4A4D

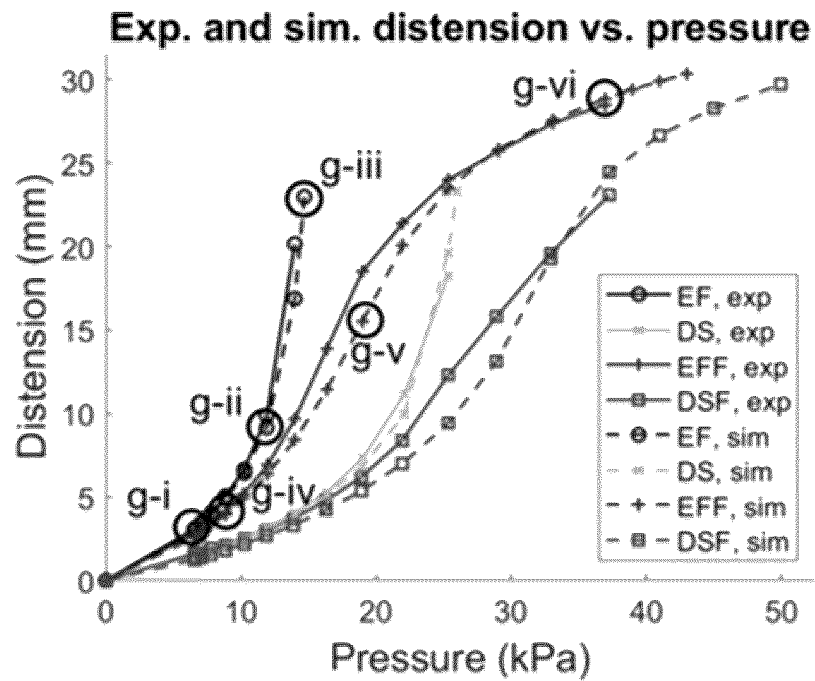


FIG. 4E

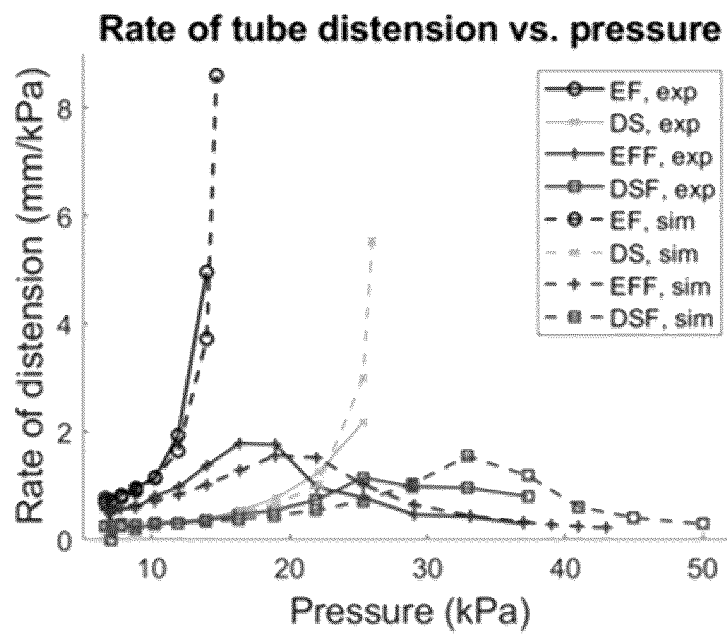


FIG. 4F

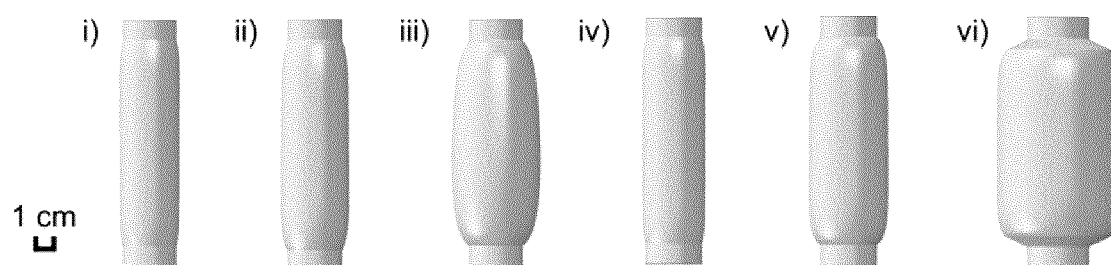


FIG. 4G

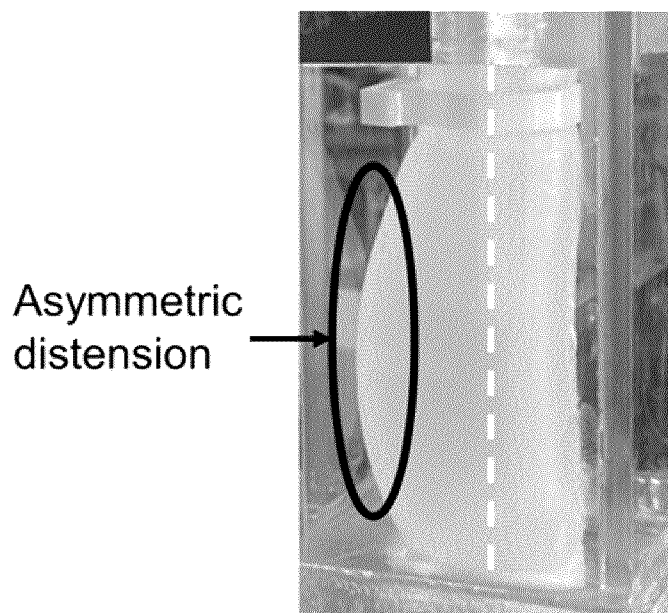


FIG. 5A

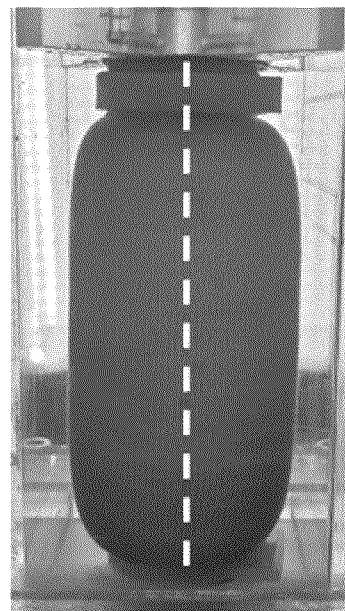


FIG. 5B

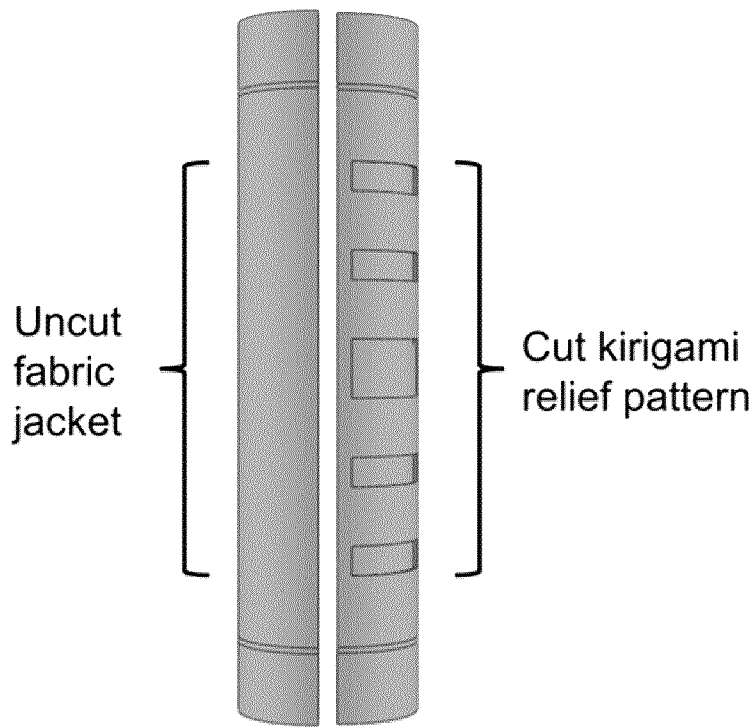


FIG. 6A

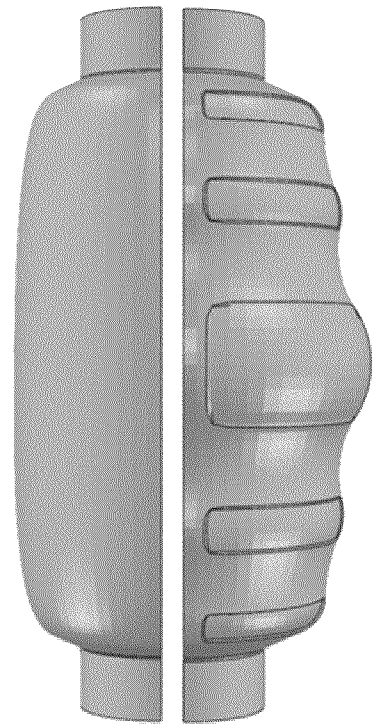


FIG. 6B

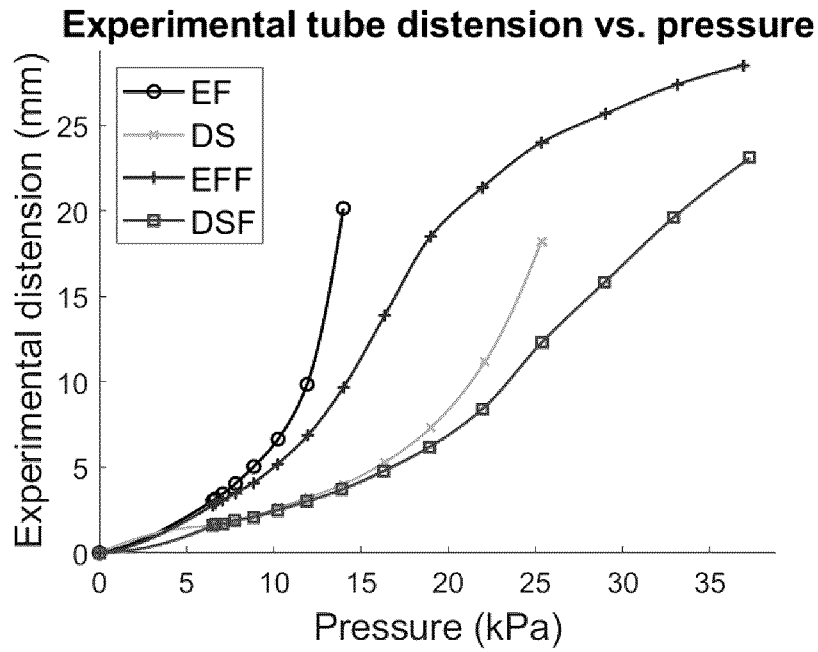


FIG. 7

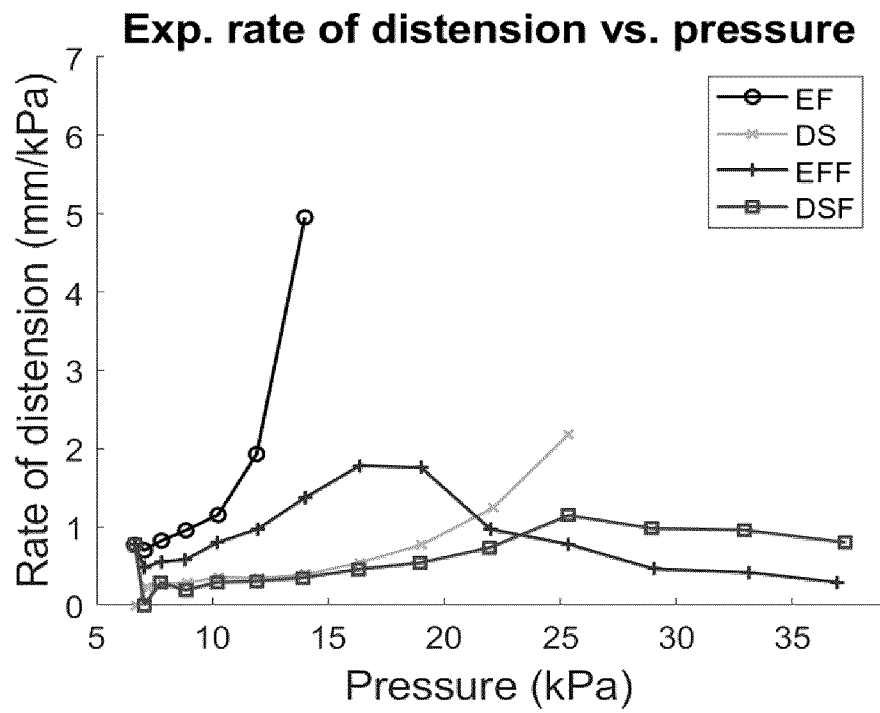


FIG. 8

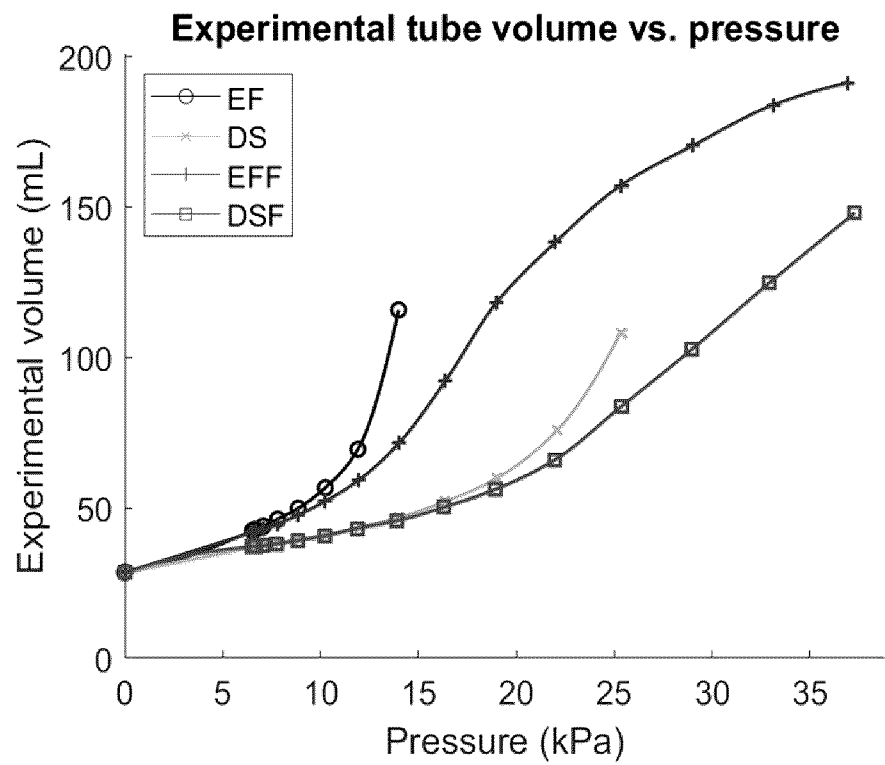


FIG. 9

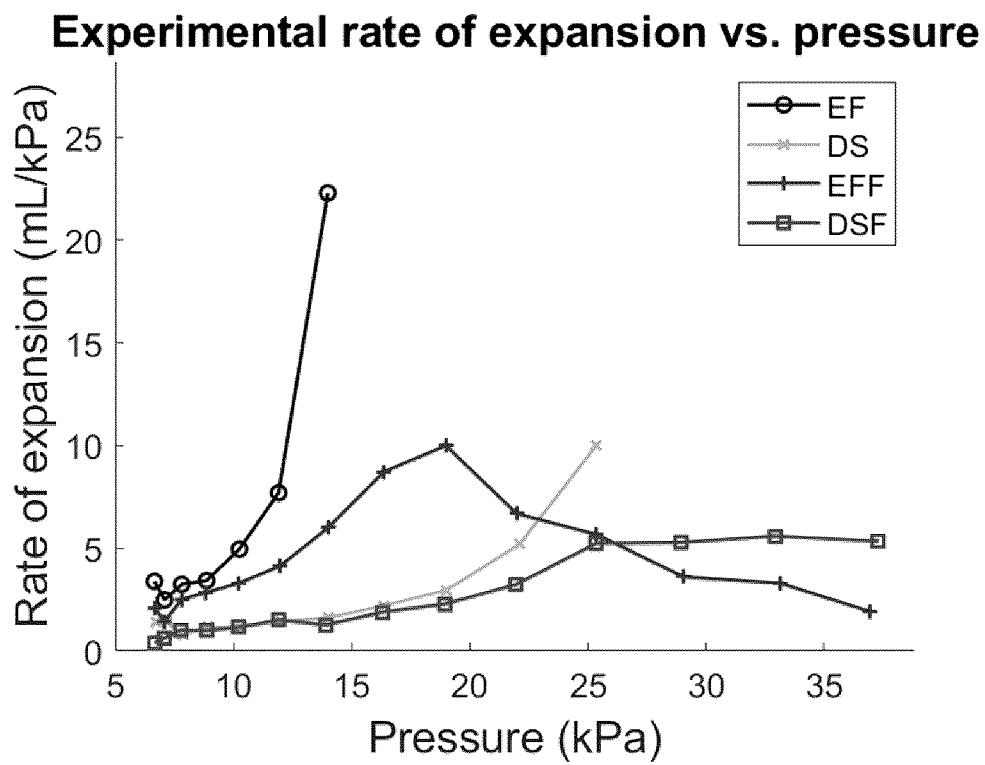


FIG. 10

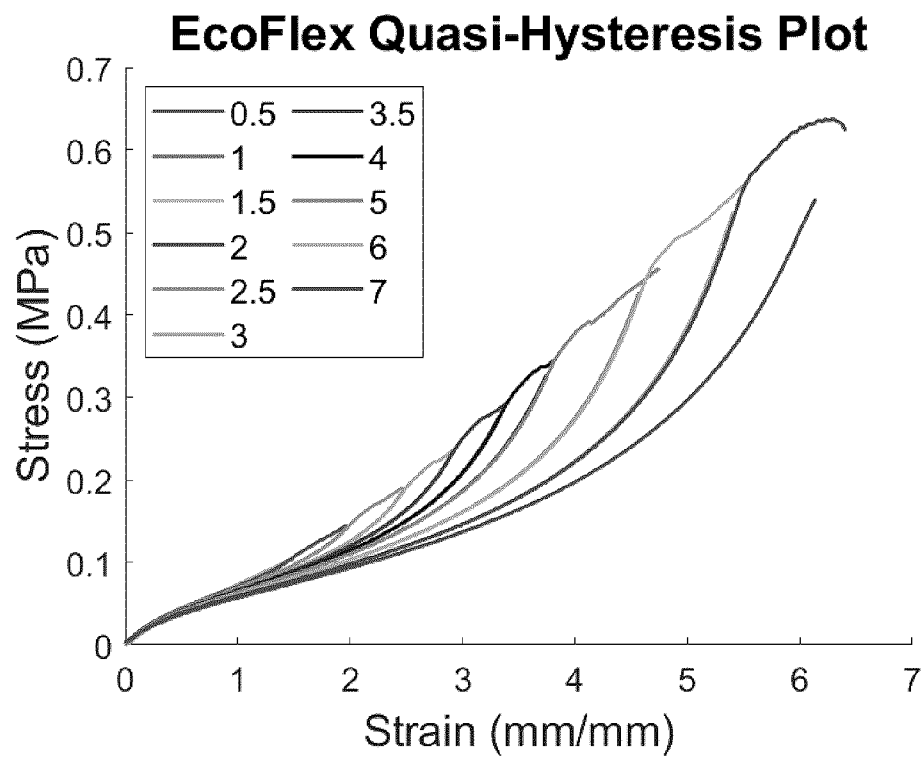


FIG. 11

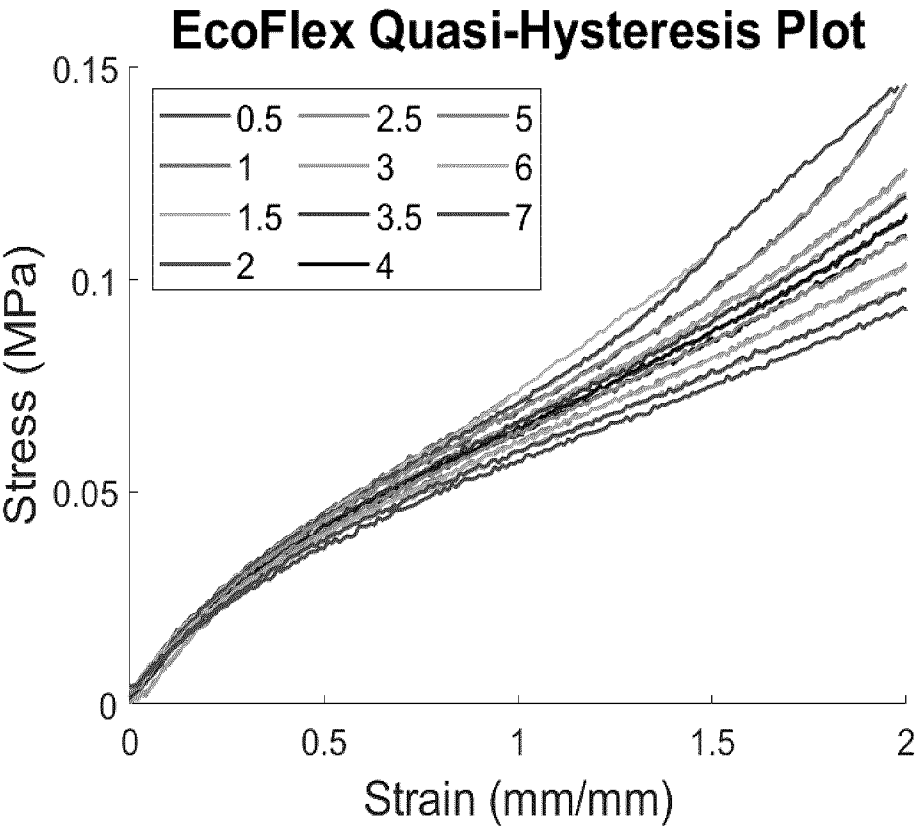


FIG. 12

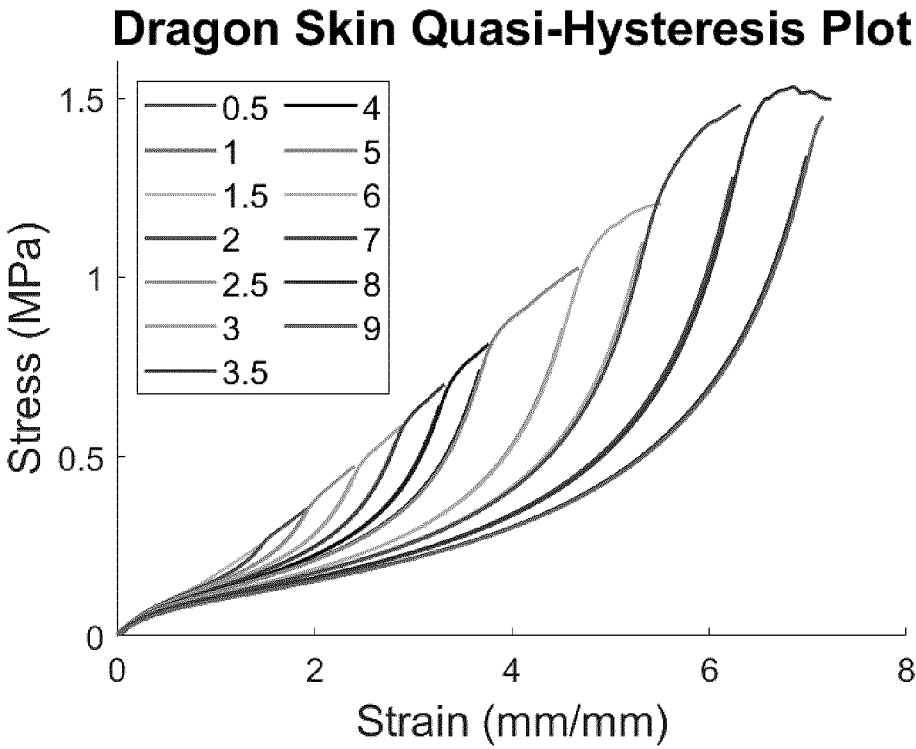


FIG. 13

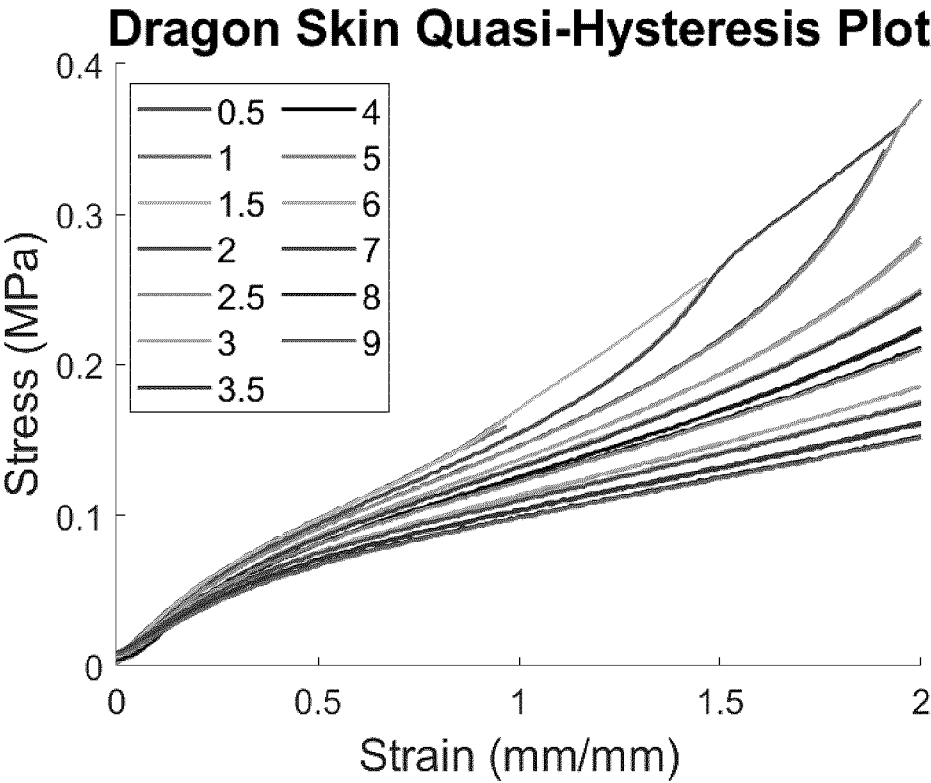
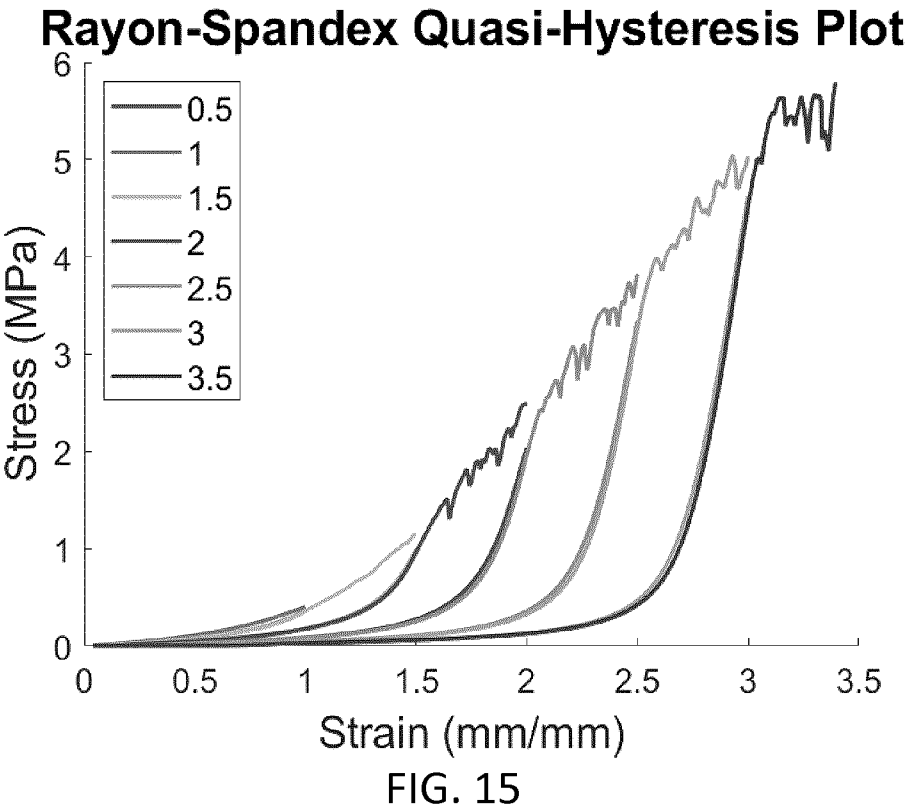


FIG. 14



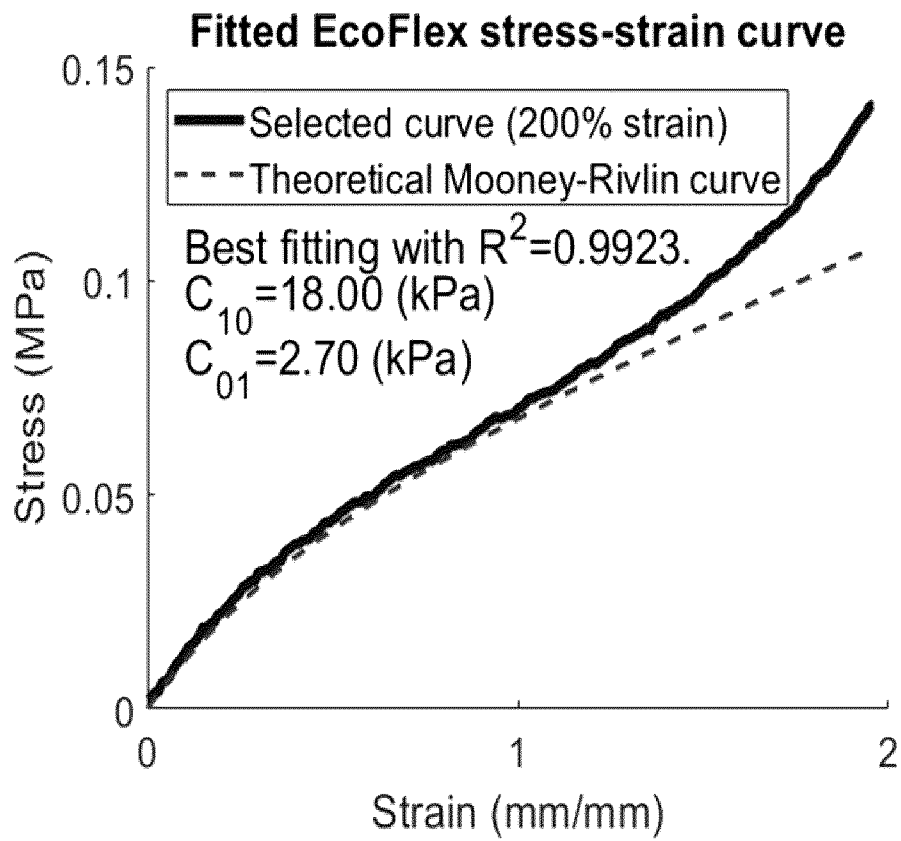


FIG. 16

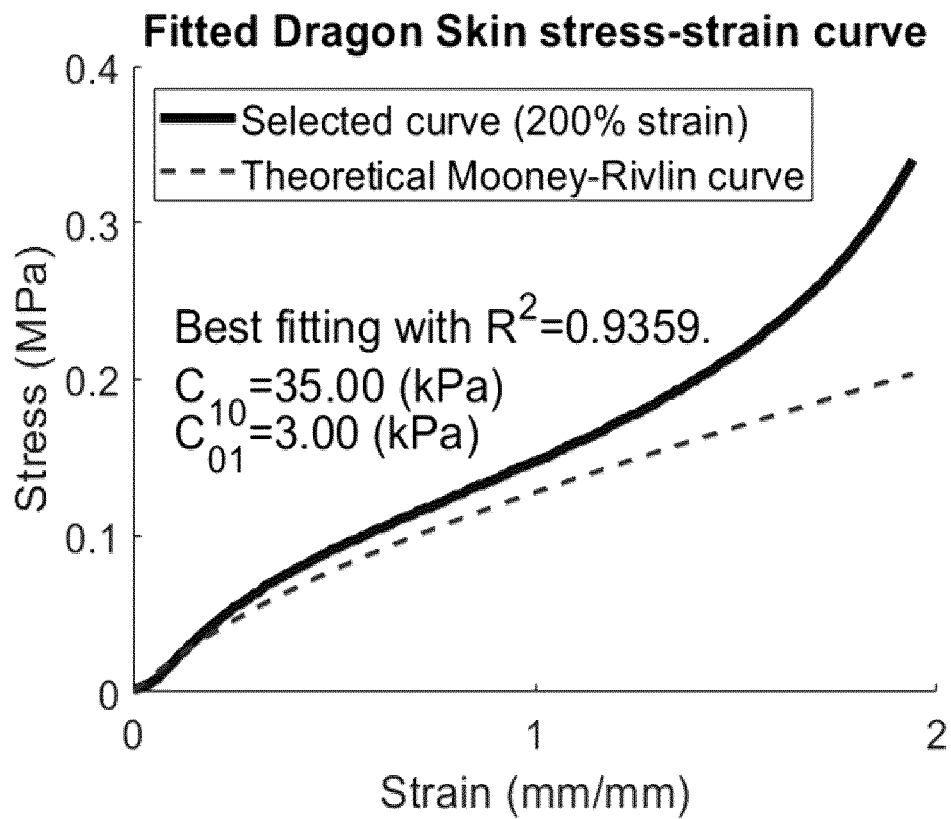


FIG. 17

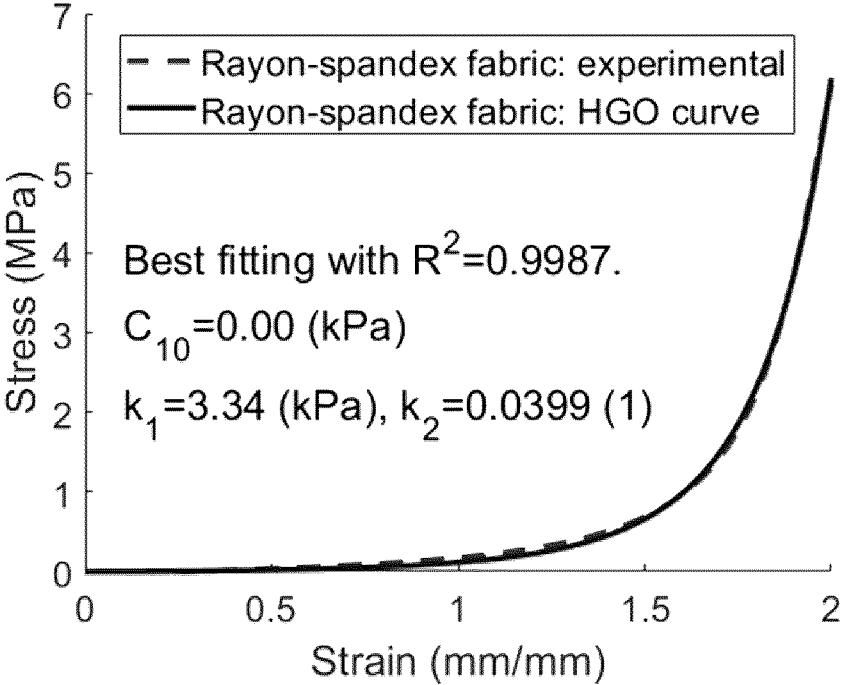


FIG. 18

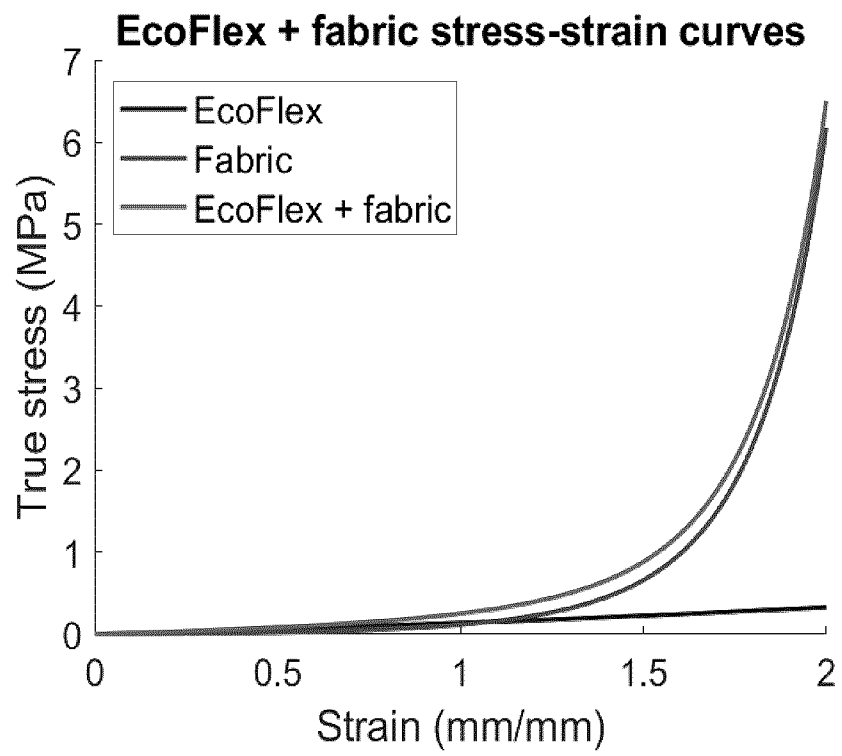


FIG. 19

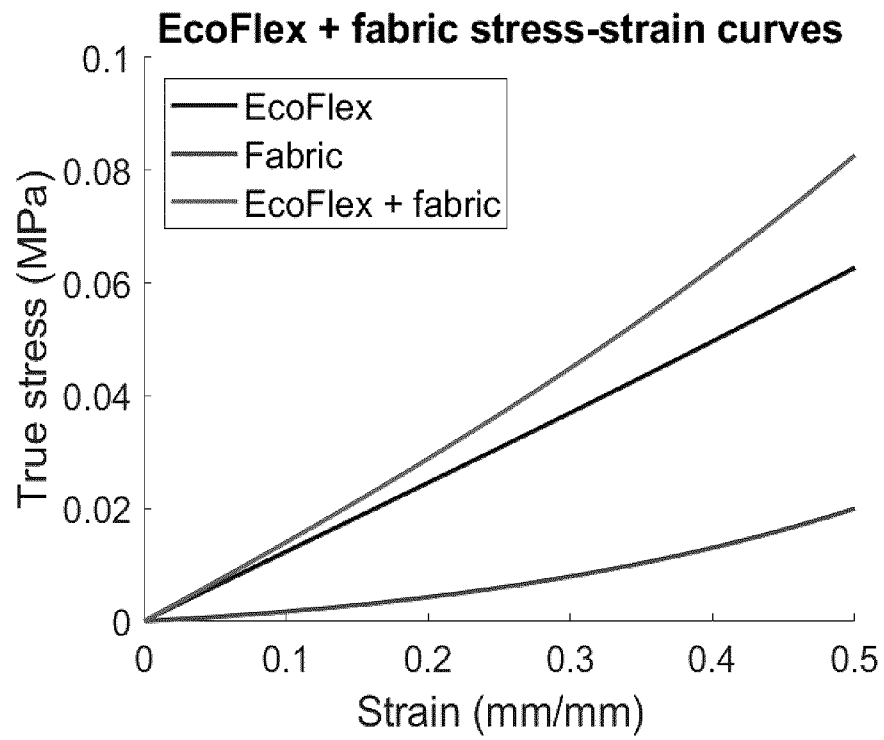


FIG. 20

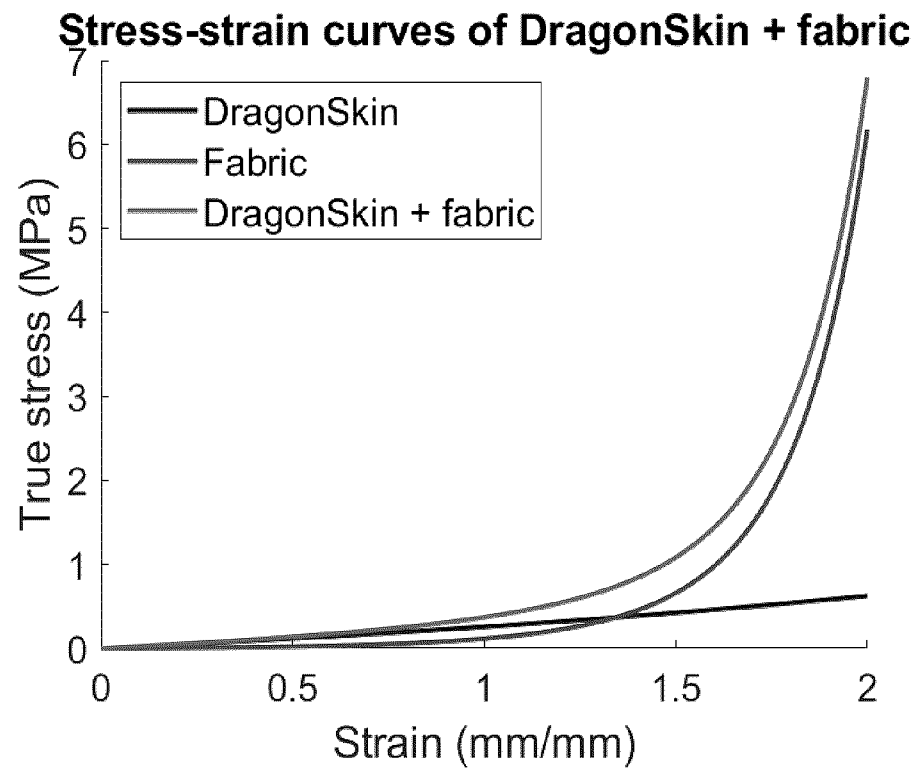


FIG. 21

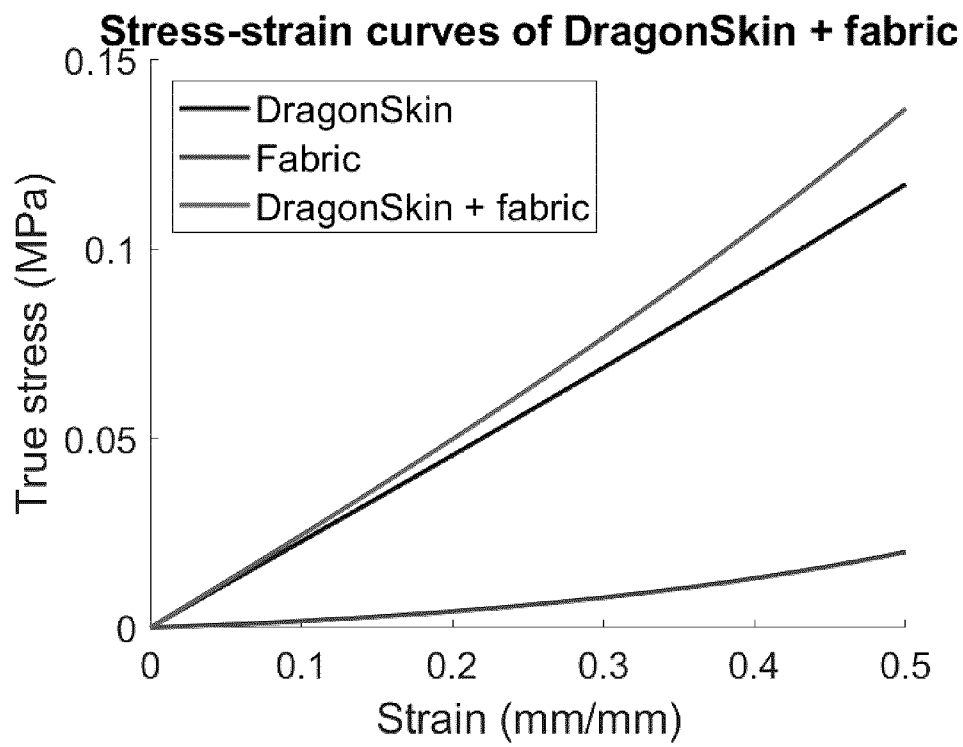


FIG. 22

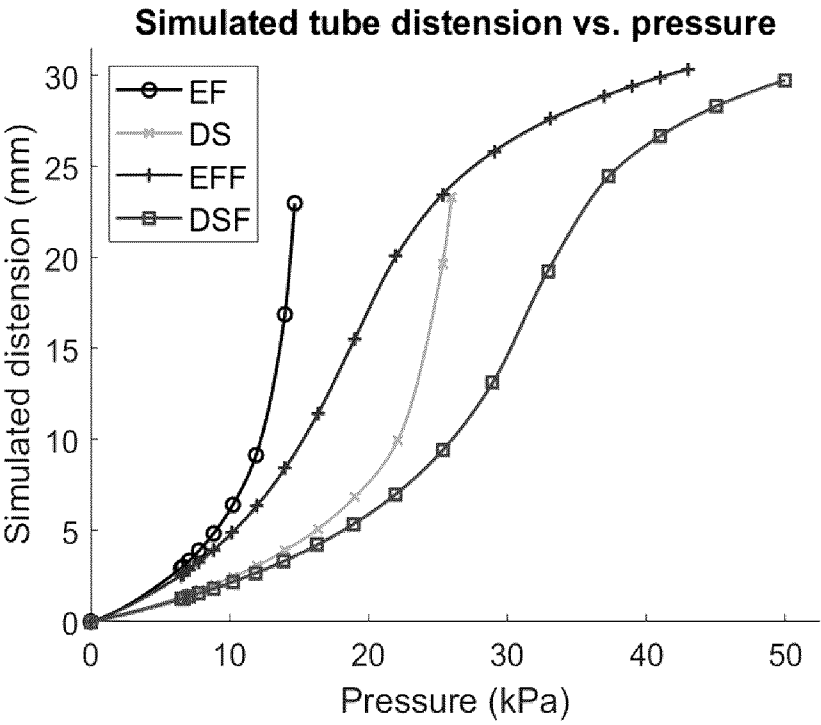


FIG. 23

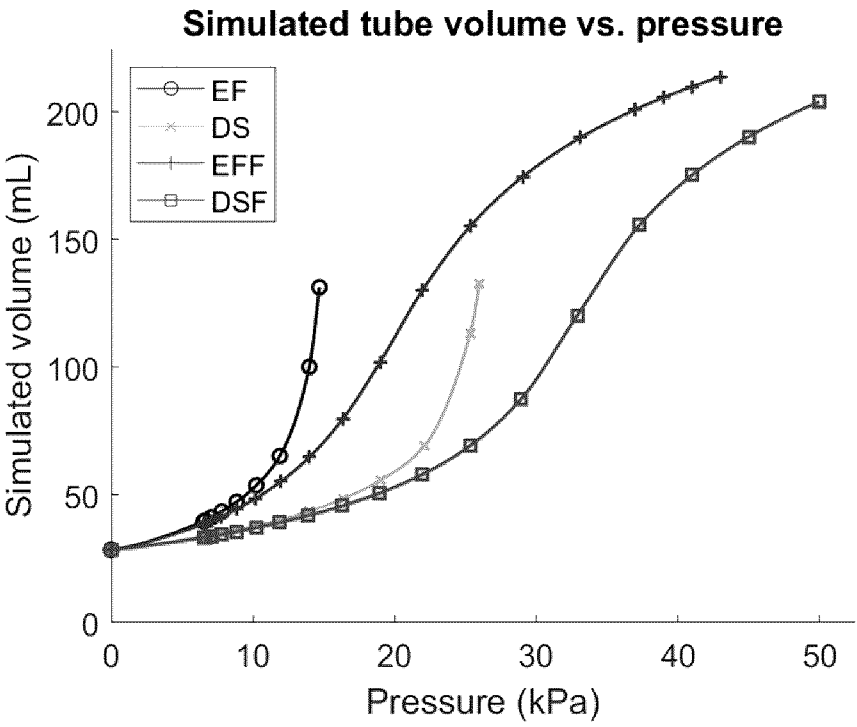


FIG. 24

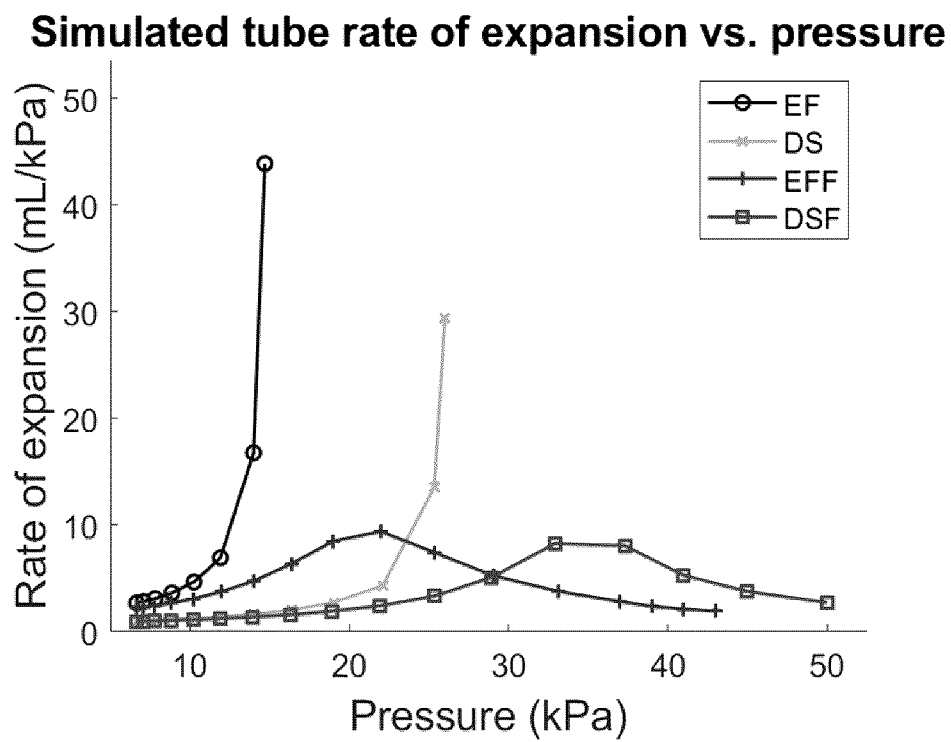


FIG. 25

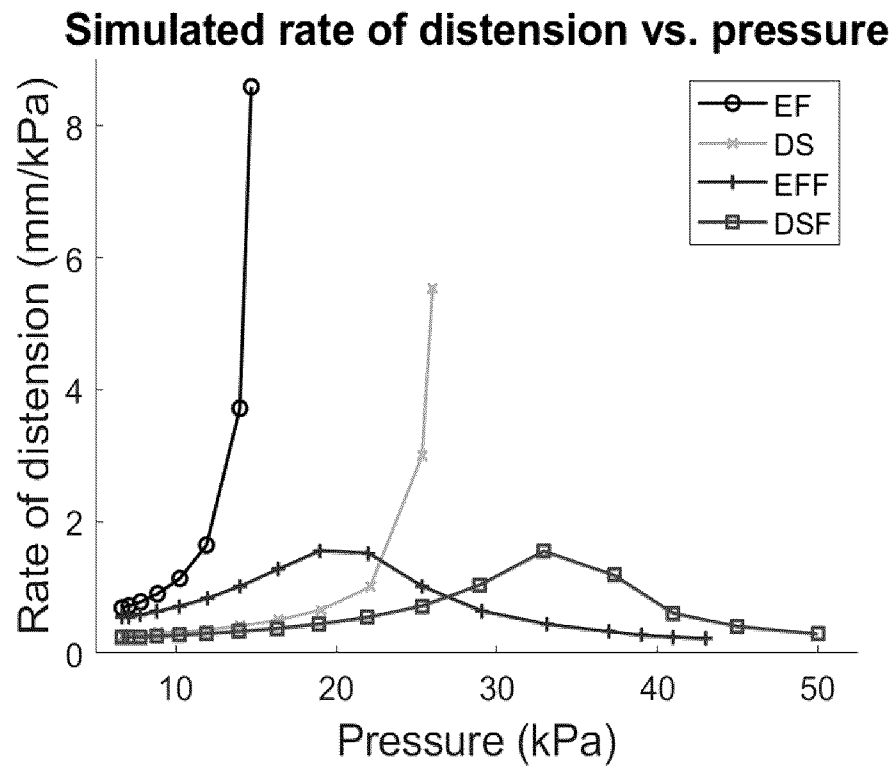


FIG. 26

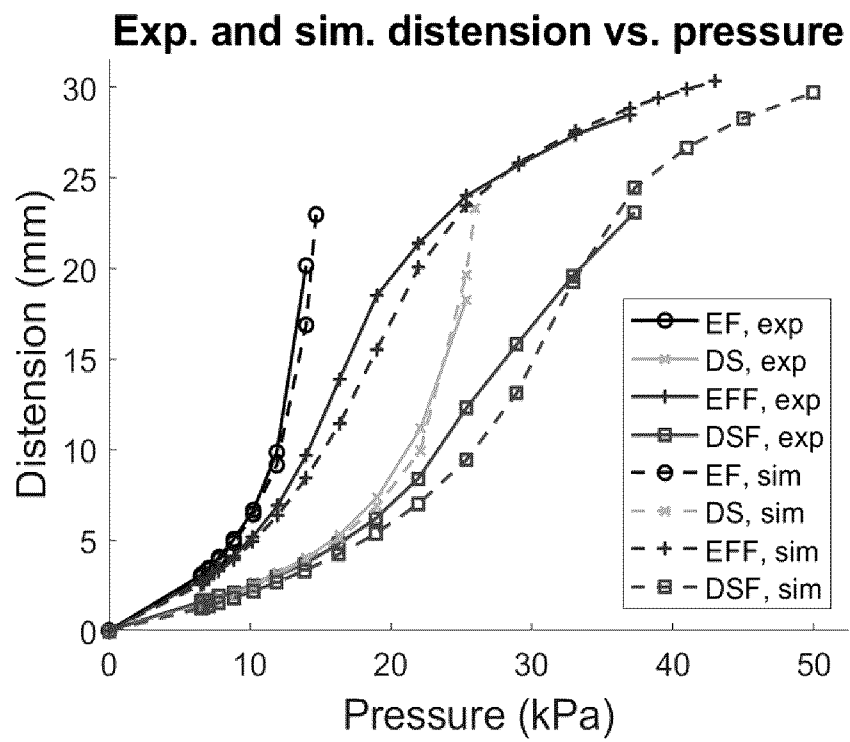


FIG. 27

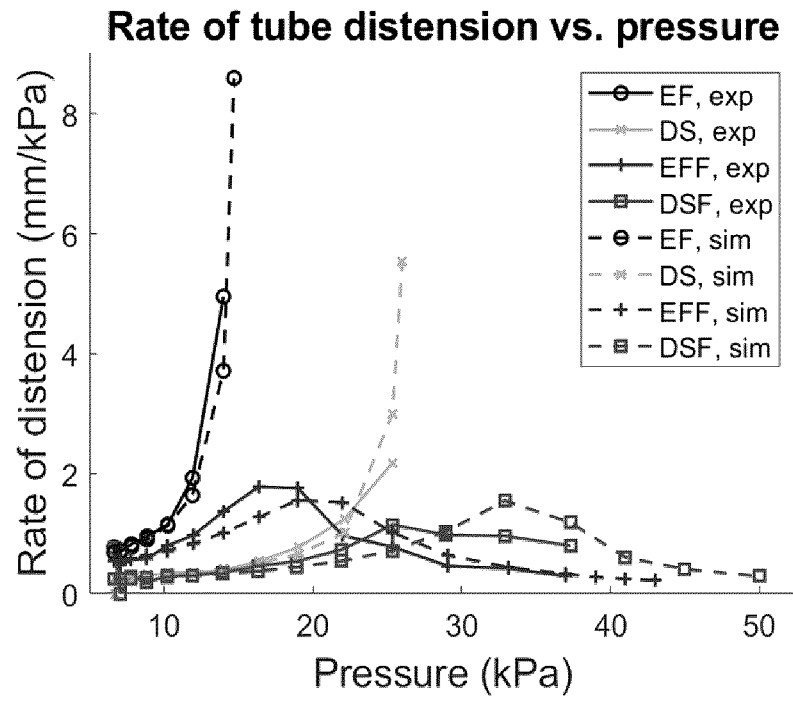


FIG. 28

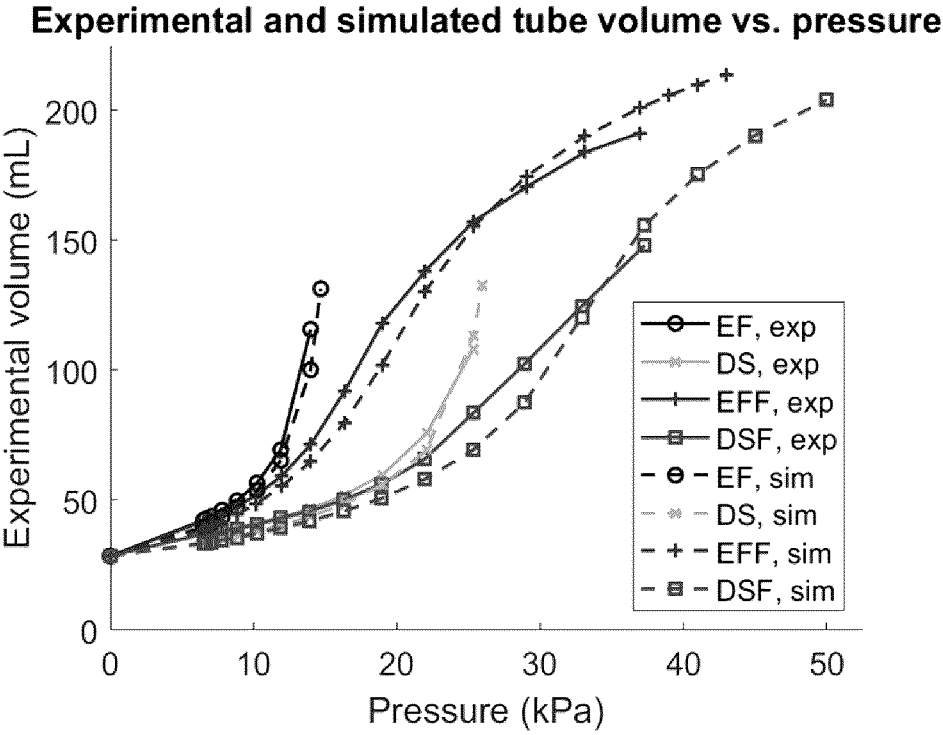


FIG. 29

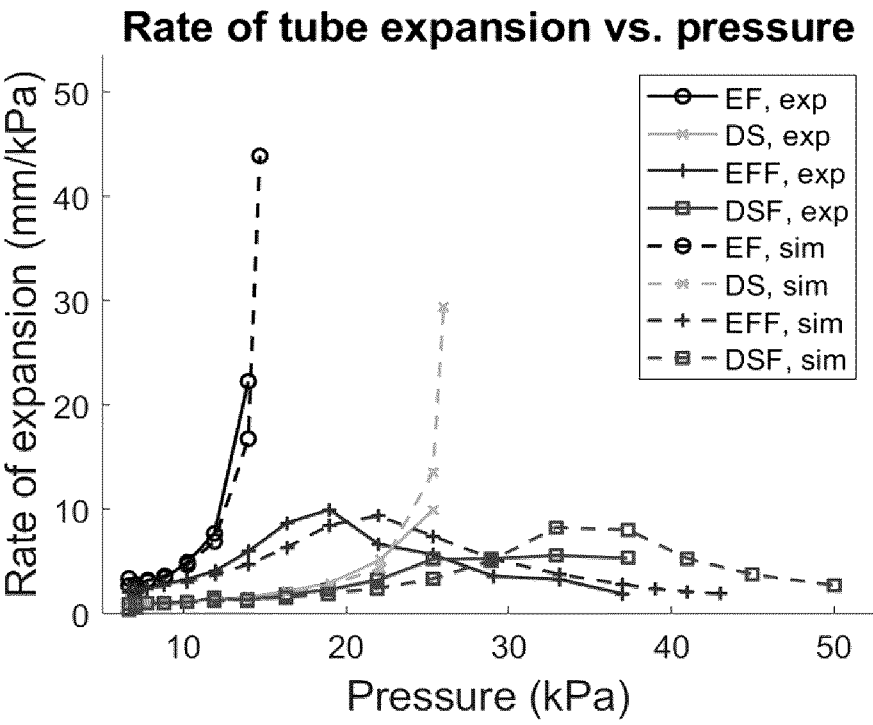


FIG. 30

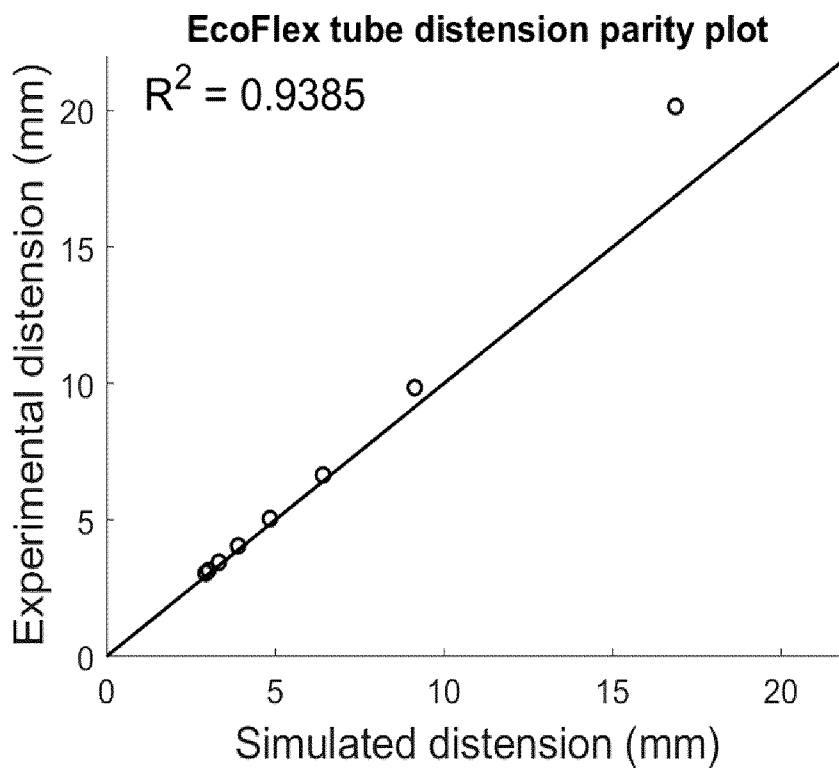


FIG. 31

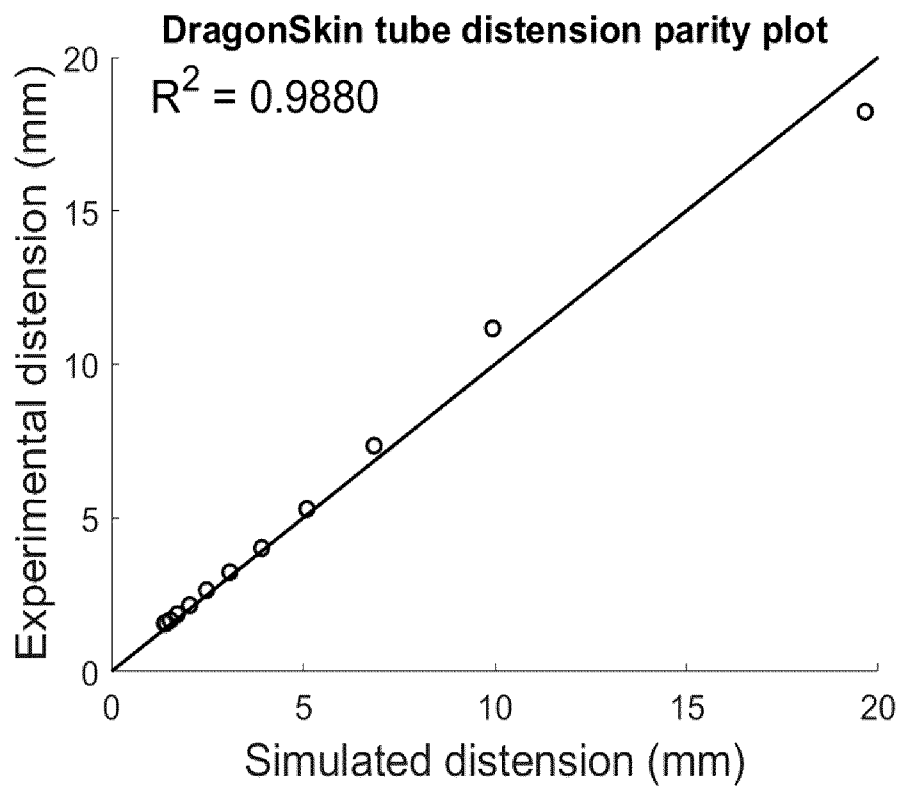


FIG. 32

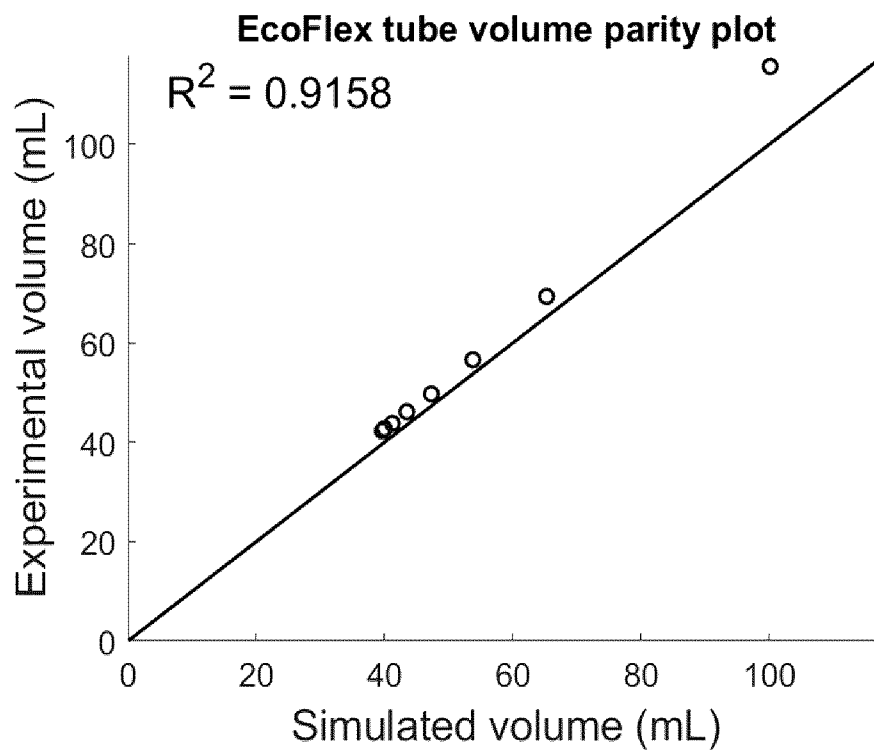


FIG. 33

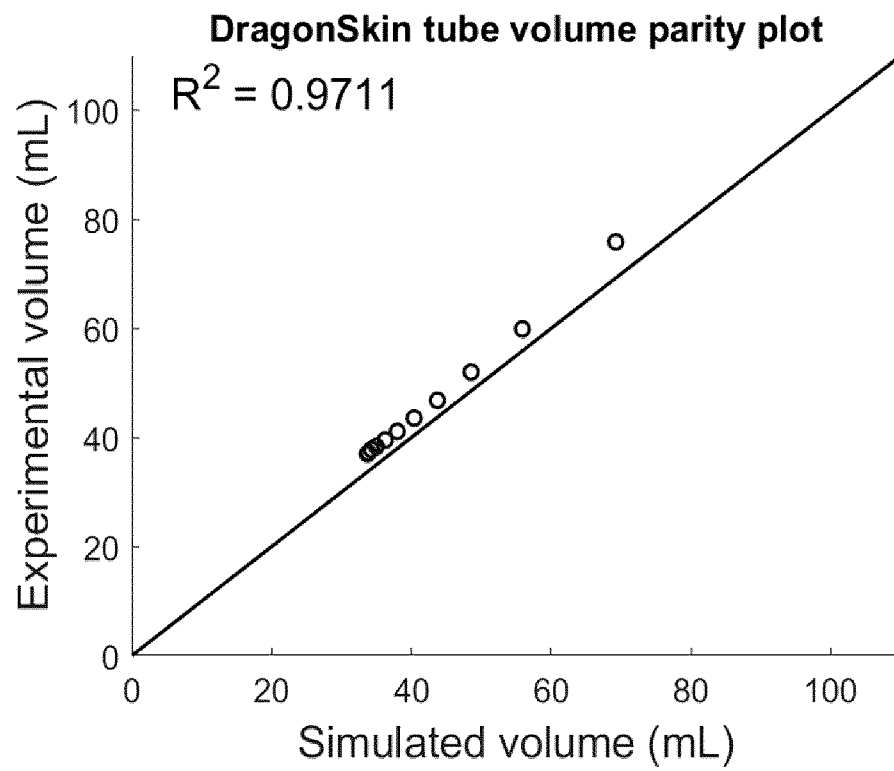


FIG. 34

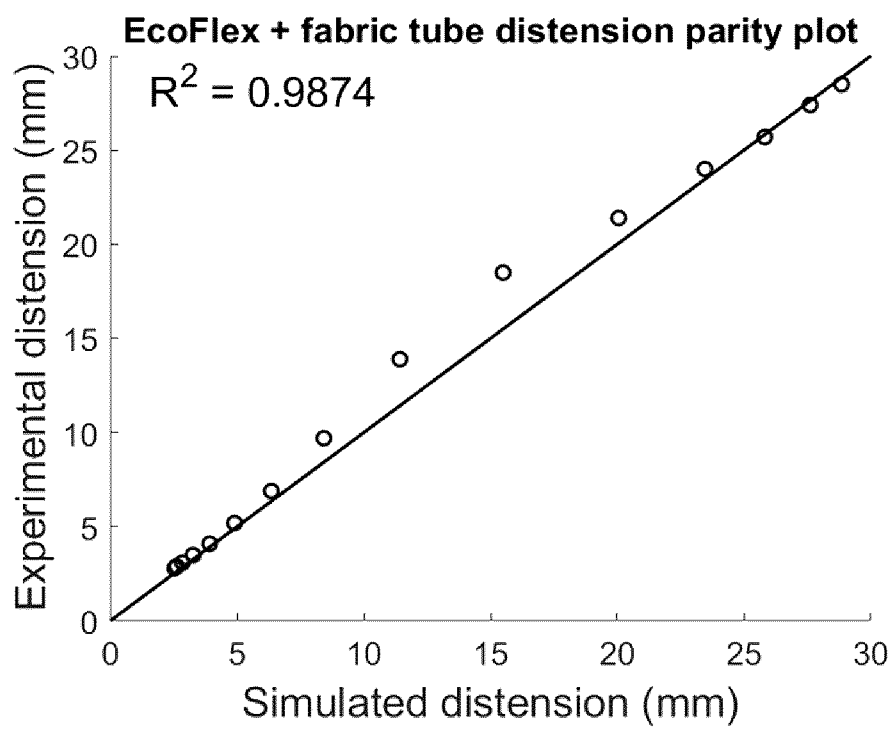


FIG. 35

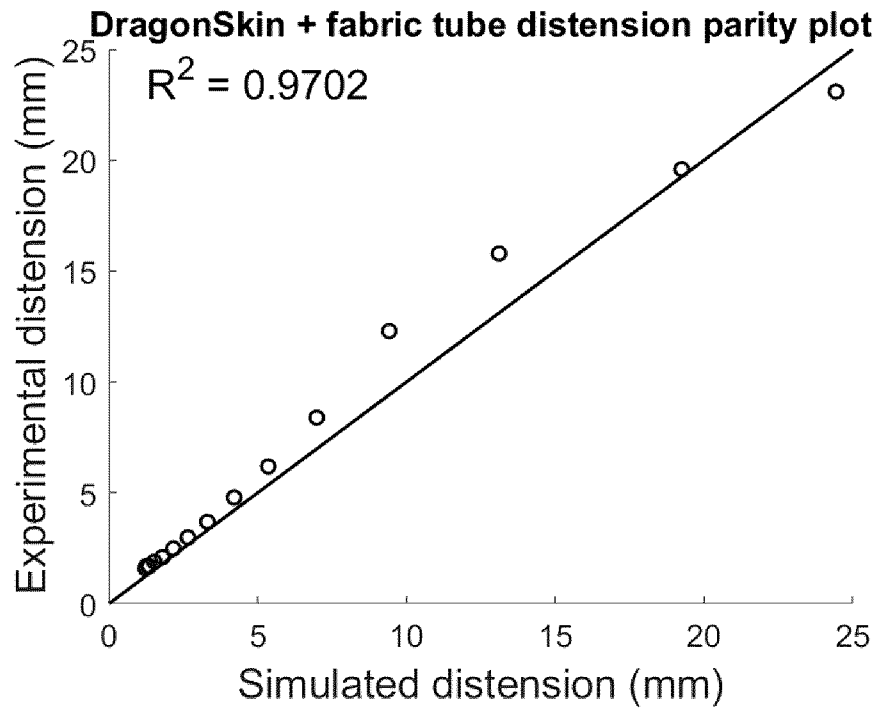


FIG. 36

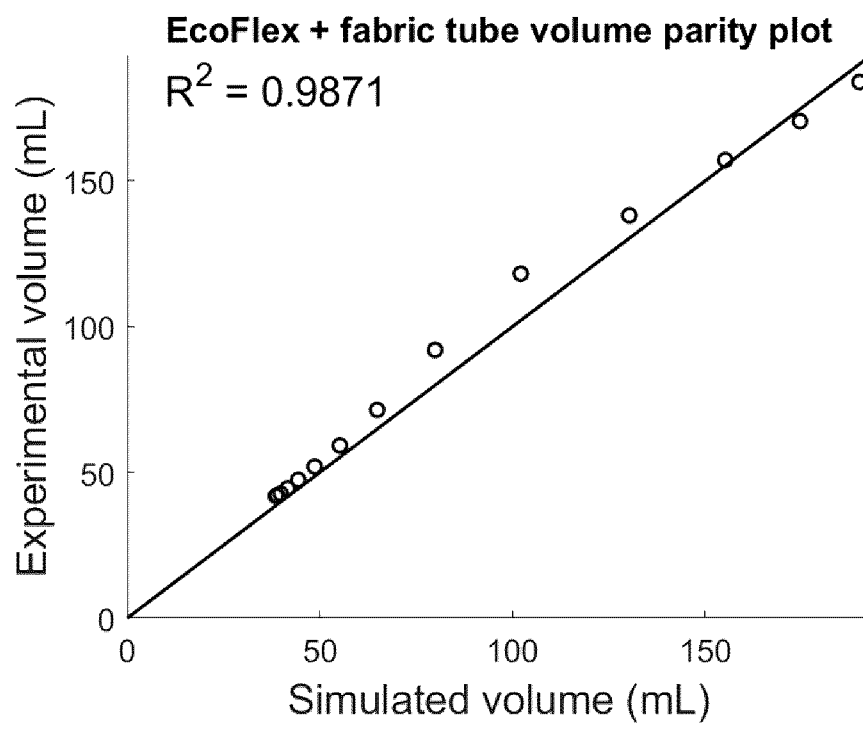


FIG. 37

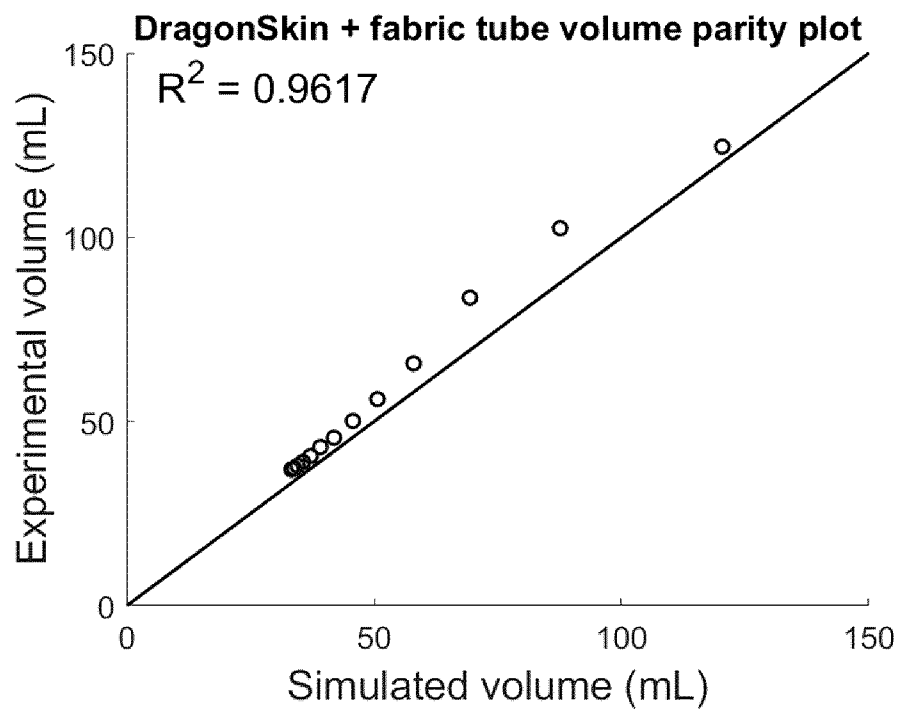


FIG. 38

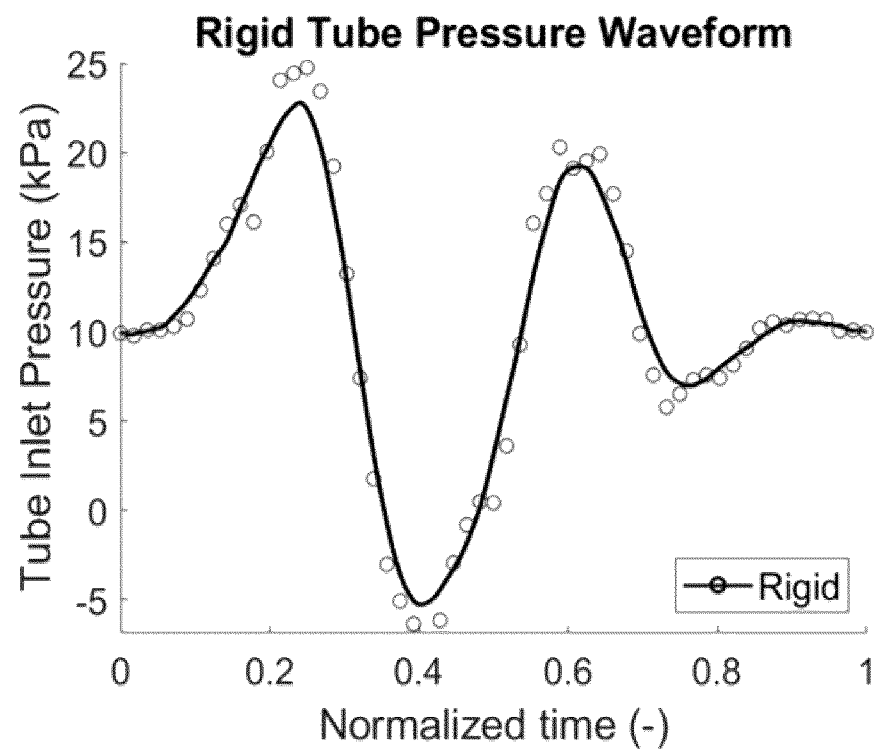


FIG. 39

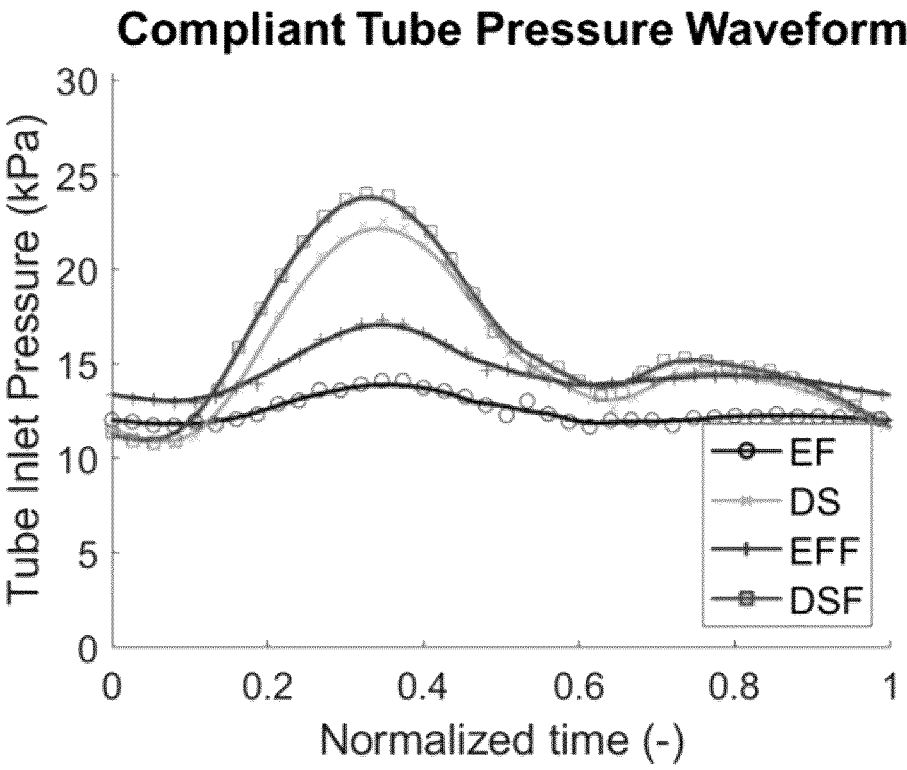


FIG. 40

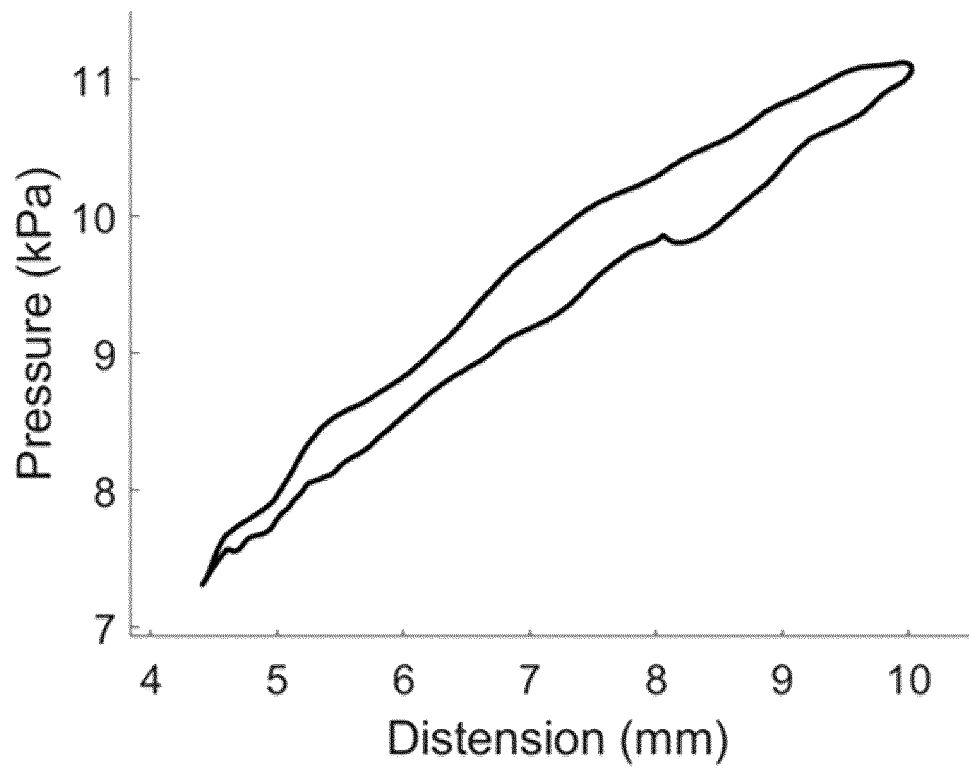


FIG. 41

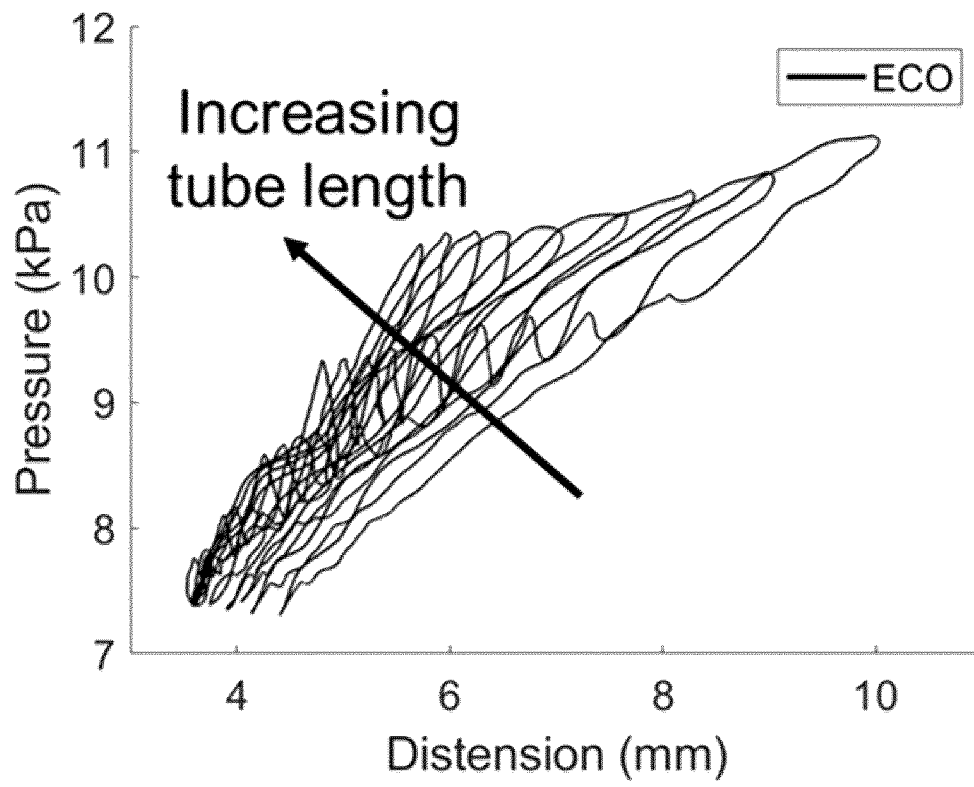


FIG. 42

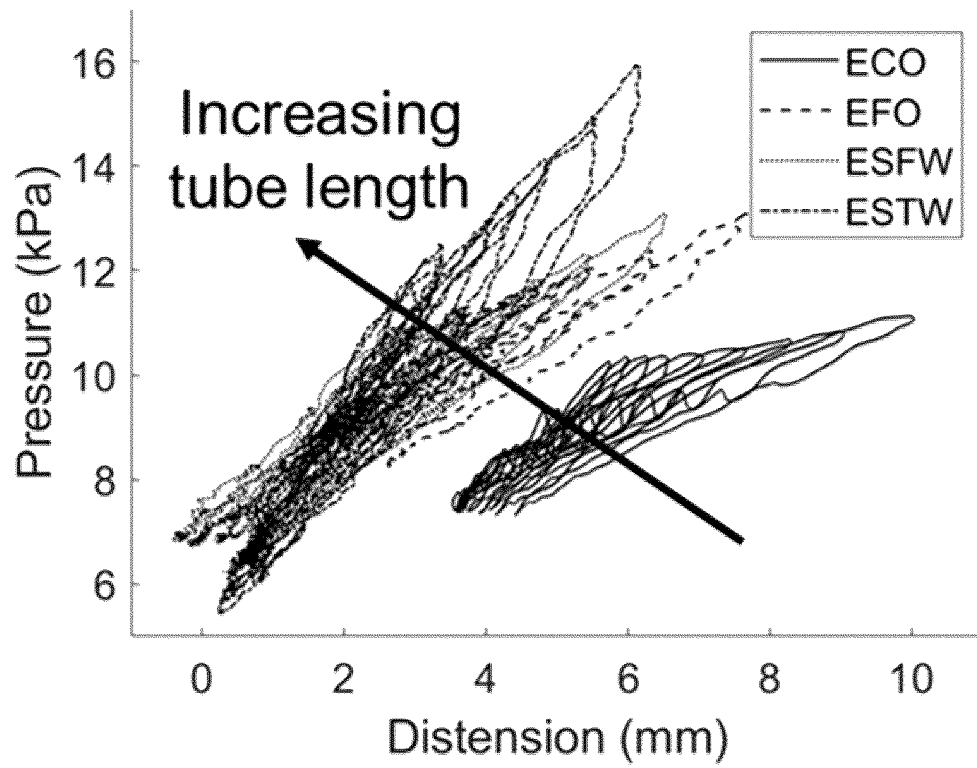


FIG. 43

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CA2023/050209

A. CLASSIFICATION OF SUBJECT MATTER

IPC: **G05D 7/01** (2006.01), **A61H 23/04** (2006.01), **A61M 60/117** (2021.01), **B25J 9/14** (2006.01),
B33Y 10/00 (2015.01), **B33Y 80/00** (2015.01) (more IPCs on the last page)

CPC: **G05D 7/01** (2020.01), **A61H 23/04** (2020.01), **A61M 60/117** (2021.01), **B25J 9/0006** (2020.01),
B25J 9/14 (2020.01), **B25J 9/142** (2020.01) (more CPCs on the last page)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC: **G05D 7/01** (2006.01), **A61H 23/04** (2006.01), **A61M 60/117** (2021.01), **B25J 9/14** (2006.01), **B33Y 10/00** (2015.01), **B33Y 80/00** (2015.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)

Databases: Questel Orbit, Google Patents, CPD (Canadian Patent Database)

Keywords: actuator, fluid, elastomeric, jacket, internal, channel, distending tube, hydrostatic pressure, diameter, self-regulate, symmetric

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US20210338922(A1) 4 Nov. 2021 (4-11-2021) by Lii et al. ** see abstract, entire application**	1-25
A	US11090458(B2) 17 Aug. 2021 (17-08-2021) by Cragg et al. ** see abstract, entire application**	1-25
A	EP3251716(B1) 6 Dec. 2017 (6-12-2017) by Fu et al. ** see abstract, entire document**	1-25

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* "A" "D" "E" "L" "O" "P"	Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance document cited by the applicant in the international application earlier application or patent but published on or after the international filing date document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the priority date claimed	"T" "X" "Y" "&"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art document member of the same patent family
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Date of the actual completion of the international search
24 May 2023 (24-05-2023)

Date of mailing of the international search report
25 May 2023 (25-05-2023)

Name and mailing address of the ISA/CA
Canadian Intellectual Property Office
Place du Portage I, C114 - 1st Floor, Box PCT
50 Victoria Street
Gatineau, Quebec K1A 0C9
Facsimile No.: 819-953-2476

Authorized officer

Karen Oprea (819) 639-8255

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2023/050209

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PCT/CA2023/050209

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