



(19) **United States**

(12) **Patent Application Publication**
Robinson et al.

(10) **Pub. No.: US 2019/0290131 A1**

(43) **Pub. Date: Sep. 26, 2019**

(54) **SELF-SEALING PRESSURIZED LIMB ENCLOSURE**

Publication Classification

(71) Applicant: **Medici Technologies LLC**,
Albuquerque, NM (US)

(51) **Int. Cl.**
A61B 5/00 (2006.01)
A61B 5/03 (2006.01)

(72) Inventors: **Mark Ries Robinson**, Albuquerque,
NM (US); **Elena A Allen**, Albuquerque,
NM (US); **Fahimeh Salehpour**,
Albuquerque, NM (US)

(52) **U.S. Cl.**
CPC *A61B 5/0053* (2013.01); *A61B 2562/0247*
(2013.01); *A61B 5/683* (2013.01); *A61B 5/03*
(2013.01)

(21) Appl. No.: **16/074,773**

(57) **ABSTRACT**

(22) PCT Filed: **Nov. 17, 2017**

Method and system are provided for creating a self-sealing pressurized limb enclosure for the assessment of pressure effects on the limb. Embodiments can be self-sealing in that the seal is created by the positive pressure in the enclosure relative to the external environment and does not necessitate contact pressure at the seal location that exceeds the pressure in the enclosure. The seal accounts for anatomical size differences as well as deformations in the size and shape of the limb due to pressure. Furthermore, the seal maintains function in the presence of skin and tissue movement. In operation, the system can be used by an individual without external assistance.

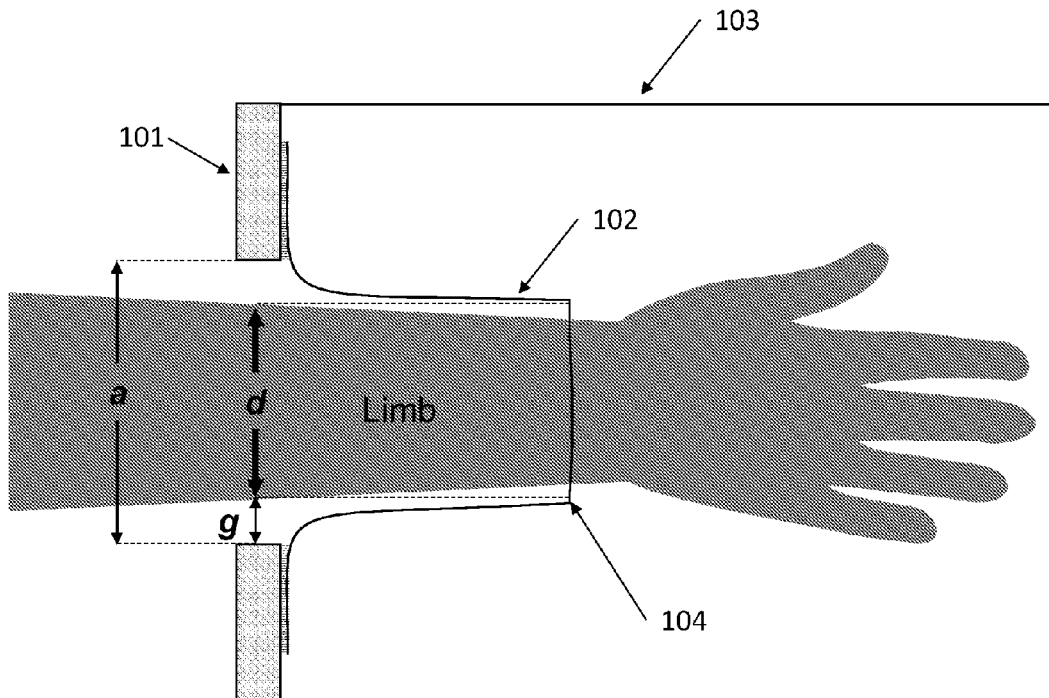
(86) PCT No.: **PCT/US2017/062356**

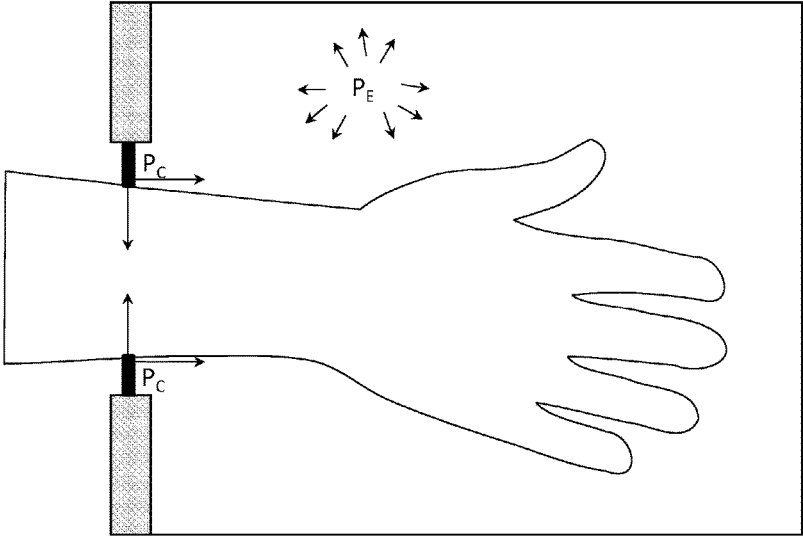
§ 371 (c)(1),

(2) Date: **Aug. 2, 2018**

Related U.S. Application Data

(60) Provisional application No. 62/423,768, filed on Nov. 17, 2016.





$$P_C > P_E$$

In a typical approach to creating a seal, air flow out of the enclosure is created by using a contact pressure (P_C) at the point of seal that exceeds the enclosure pressure (P_E).

FIG. 1

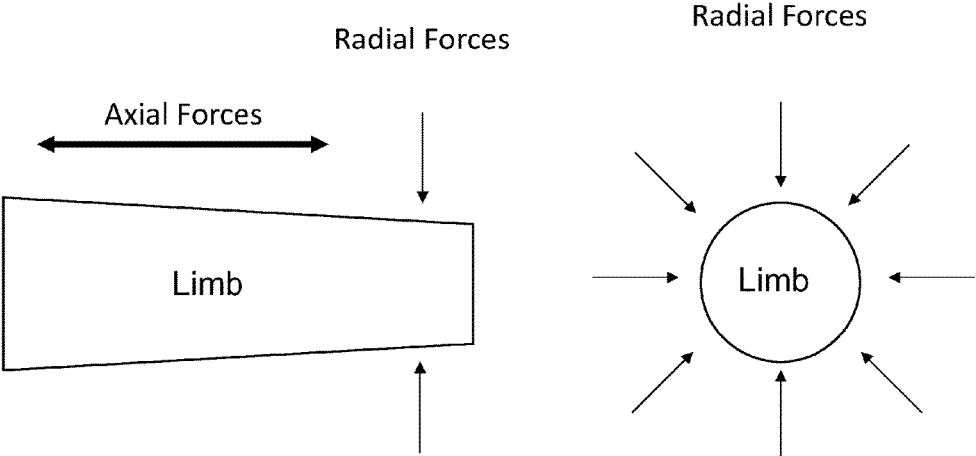


FIG. 2

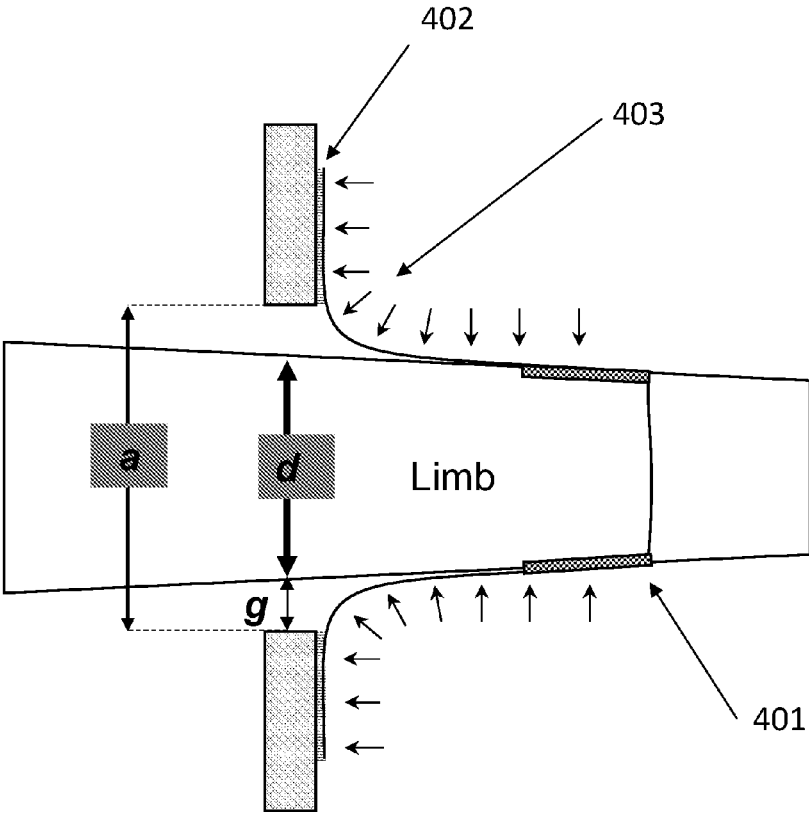
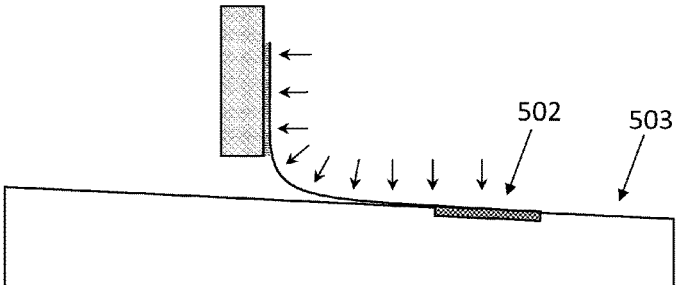
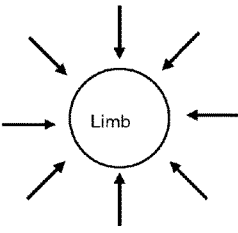


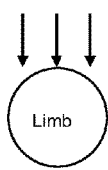
FIG. 4



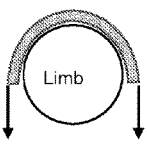
Contact Forces



Pressure



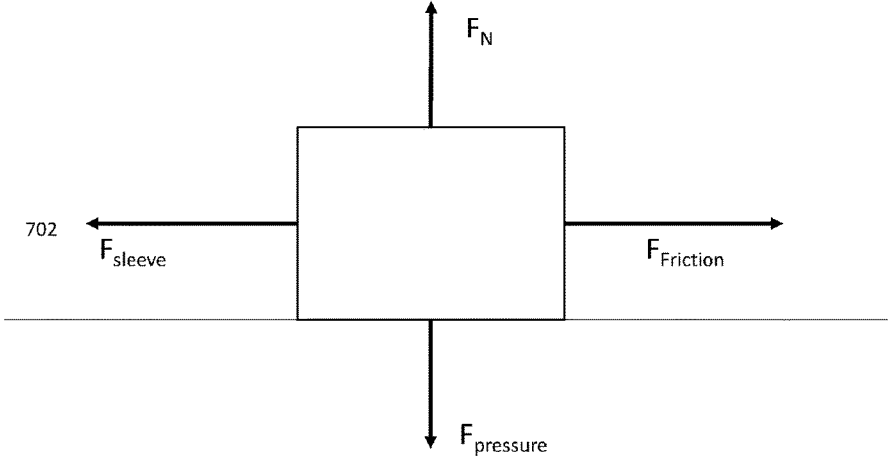
Weight $\cong 0$



Hoop = 0

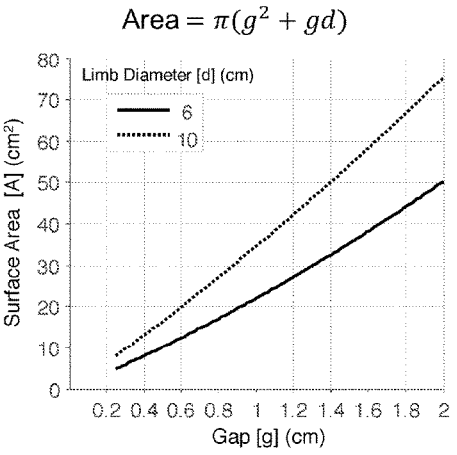
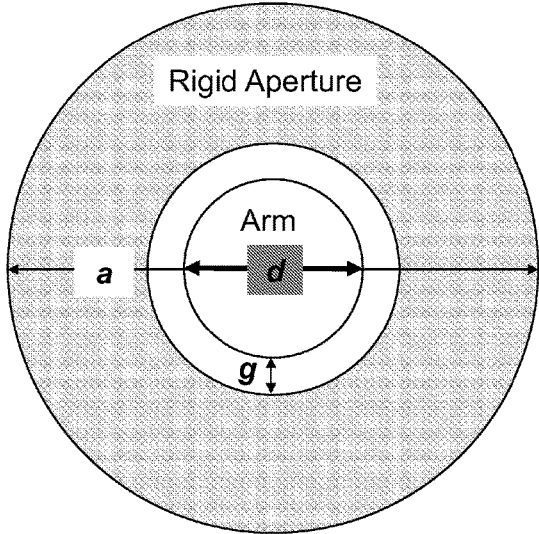
FIG. 5

Force Diagram



$$Friction\ Force = Pressure \times Contact\ Area \times \mu_{static}$$

FIG. 6



$$g = (a - d)/2$$
$$Area\ of\ non-rigid\ aperture = \frac{\pi}{4}(a^2 - d^2) = \pi(g^2 + gd)$$

FIG. 7

Contact Sensors

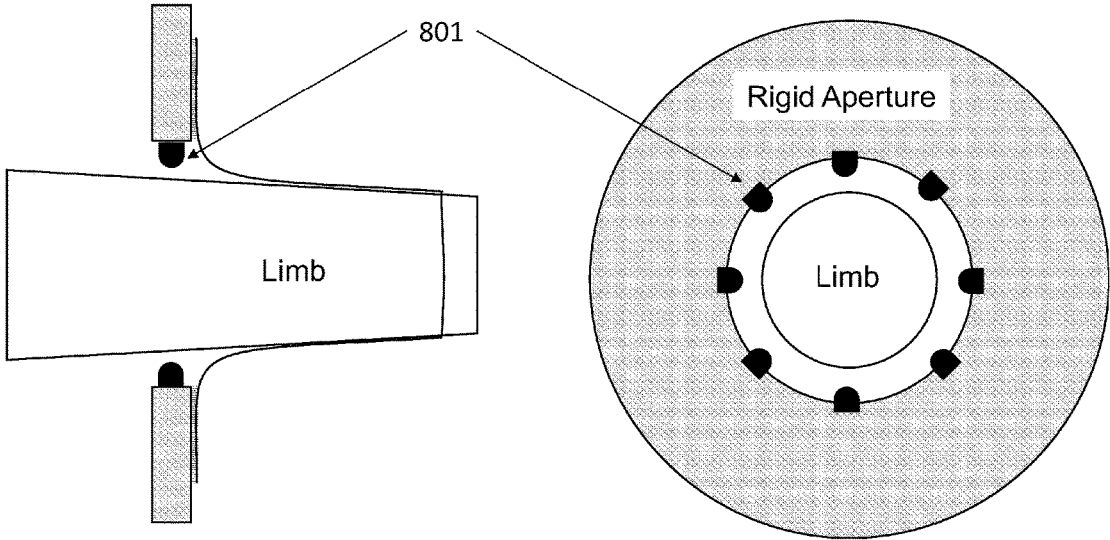


FIG. 8

Pressure Sensors

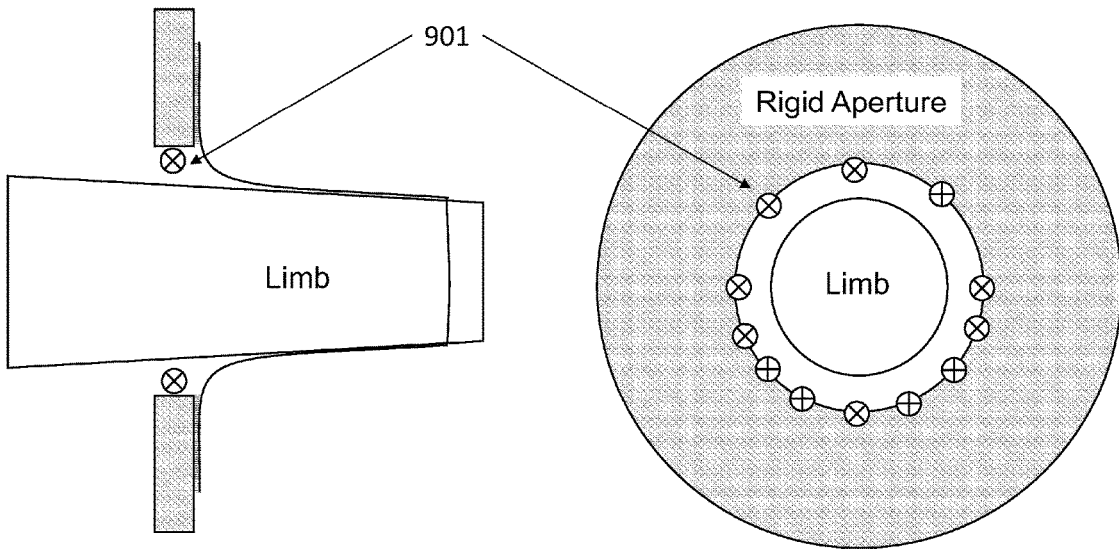


FIG. 9

$$\text{Pressure Force on Limb} = \pi \left(\frac{a}{2}\right)^2 \times \text{Pressure}$$

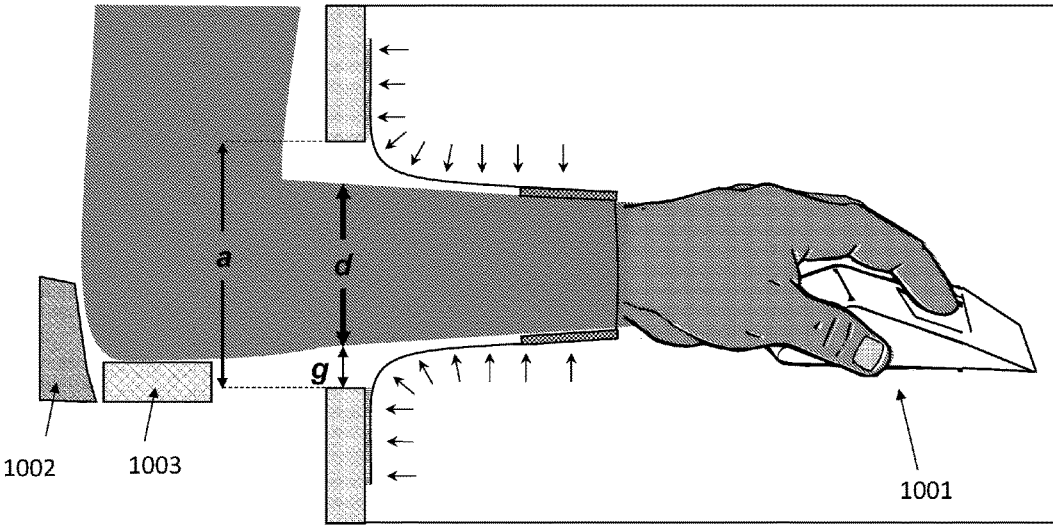


FIG. 10

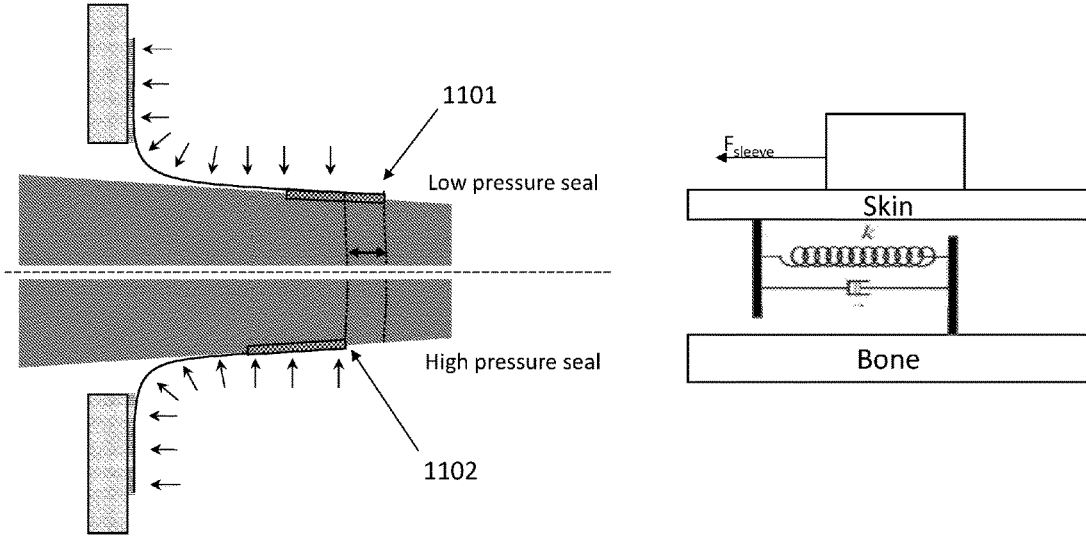


FIG. 11

The Importance of Fold Radius

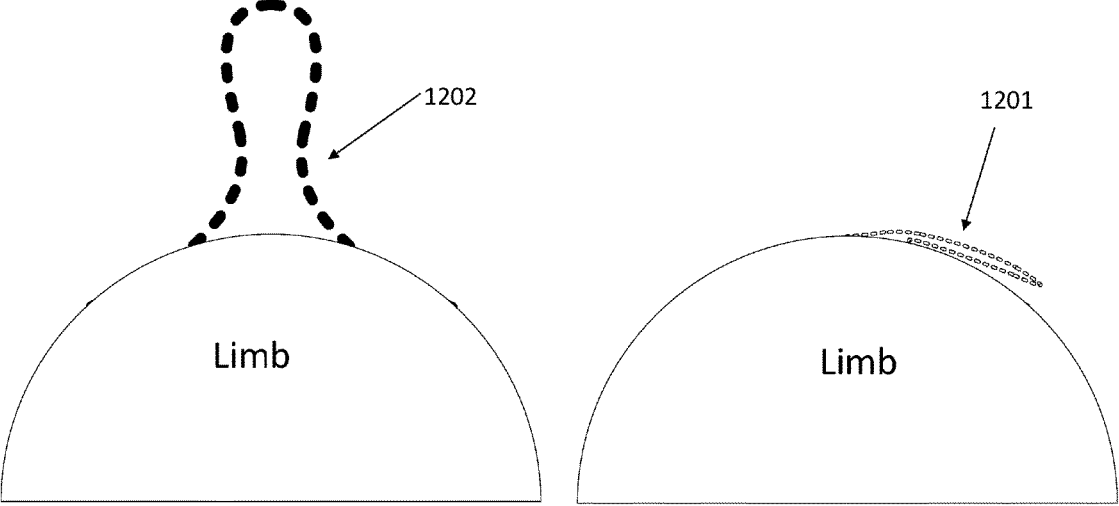


FIG. 12

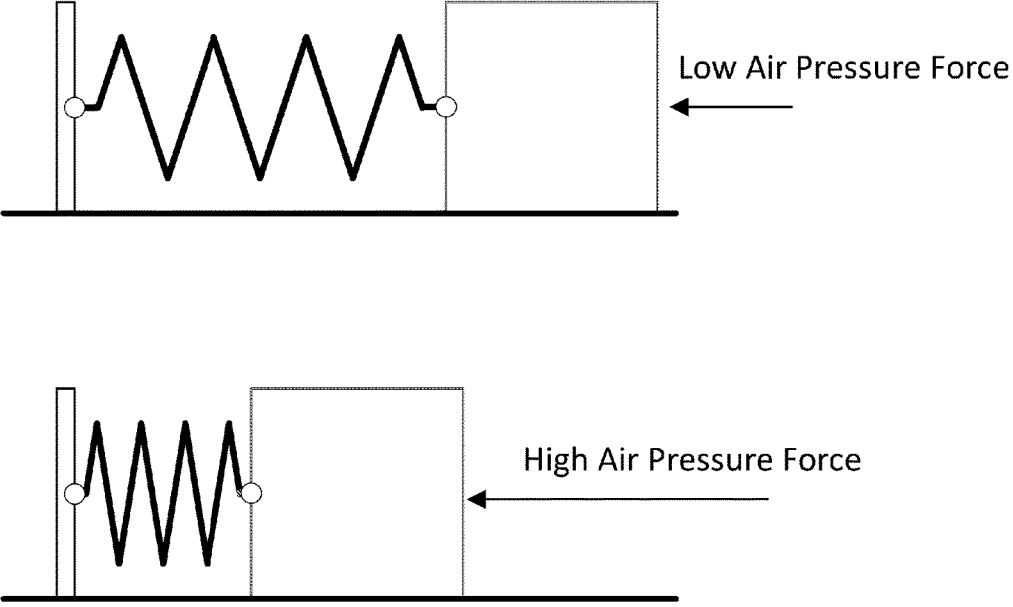


FIG. 13

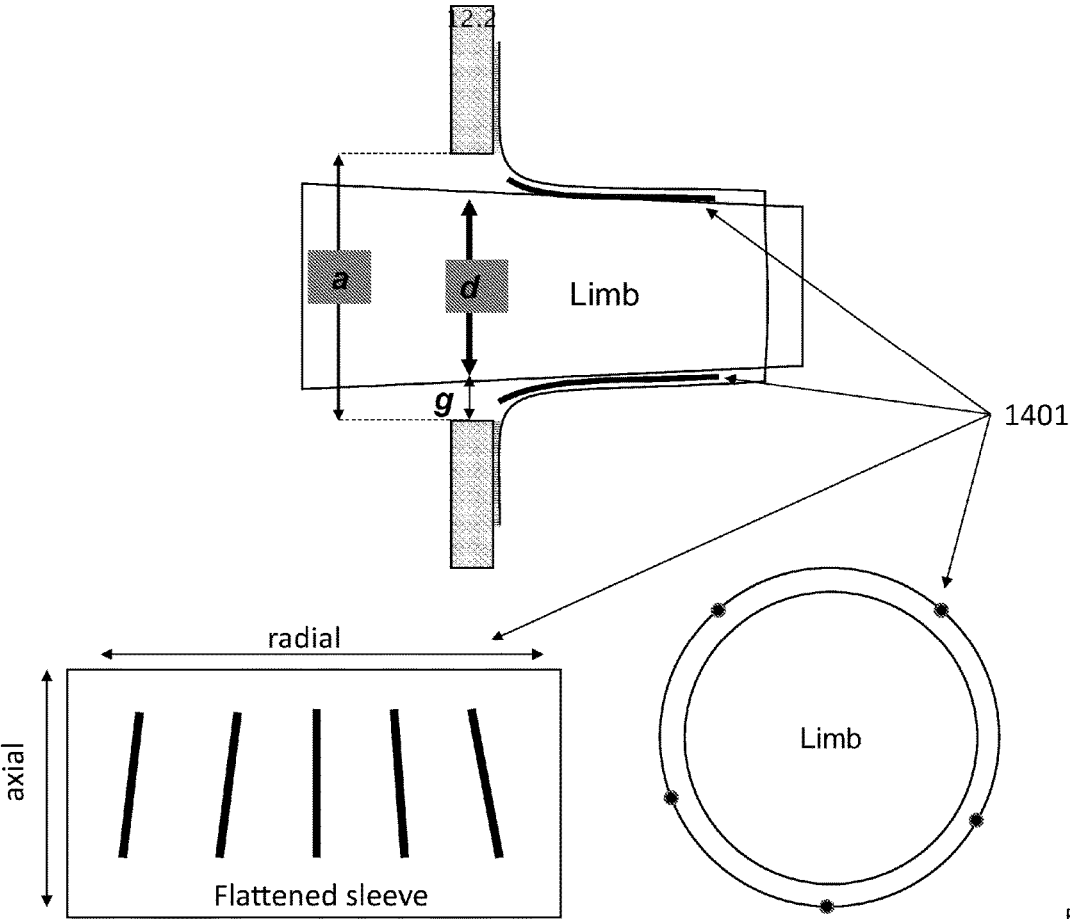


FIG. 14

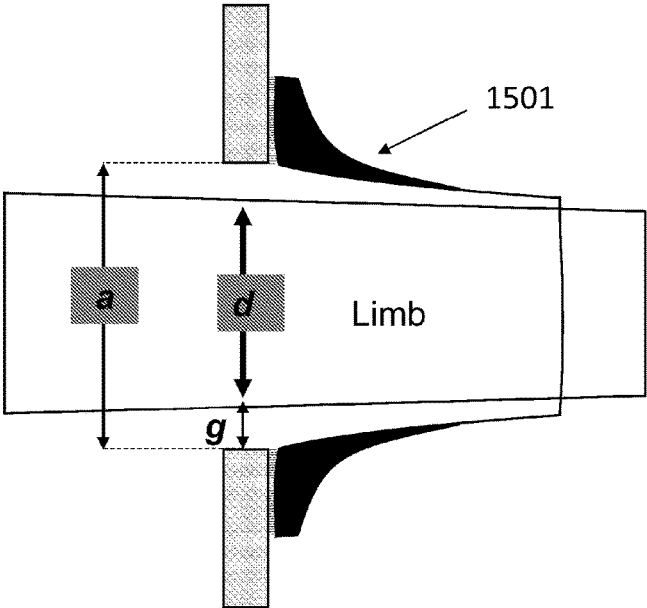


FIG. 15

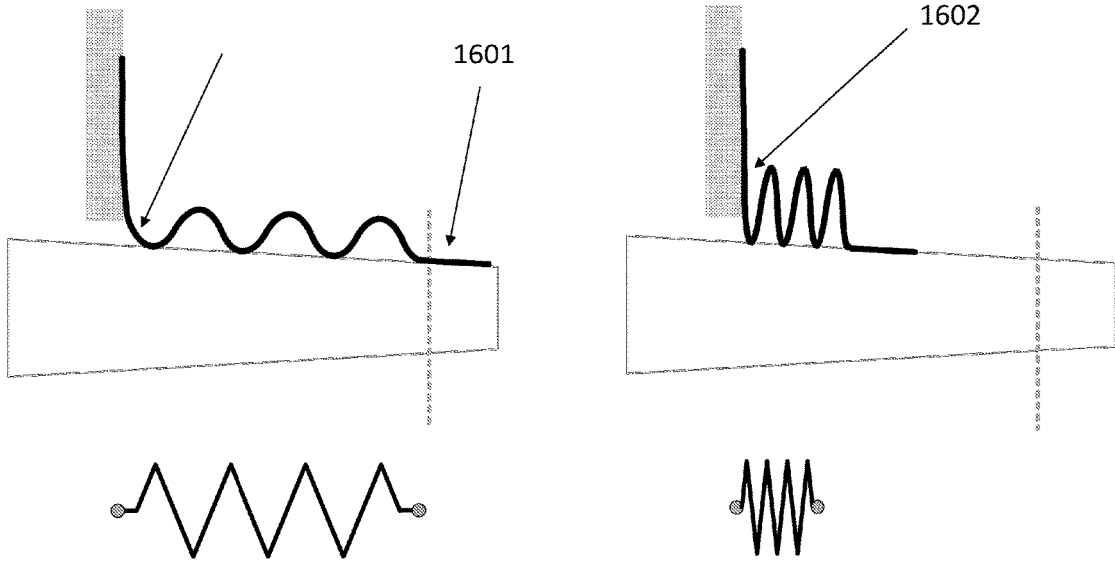


FIG. 16

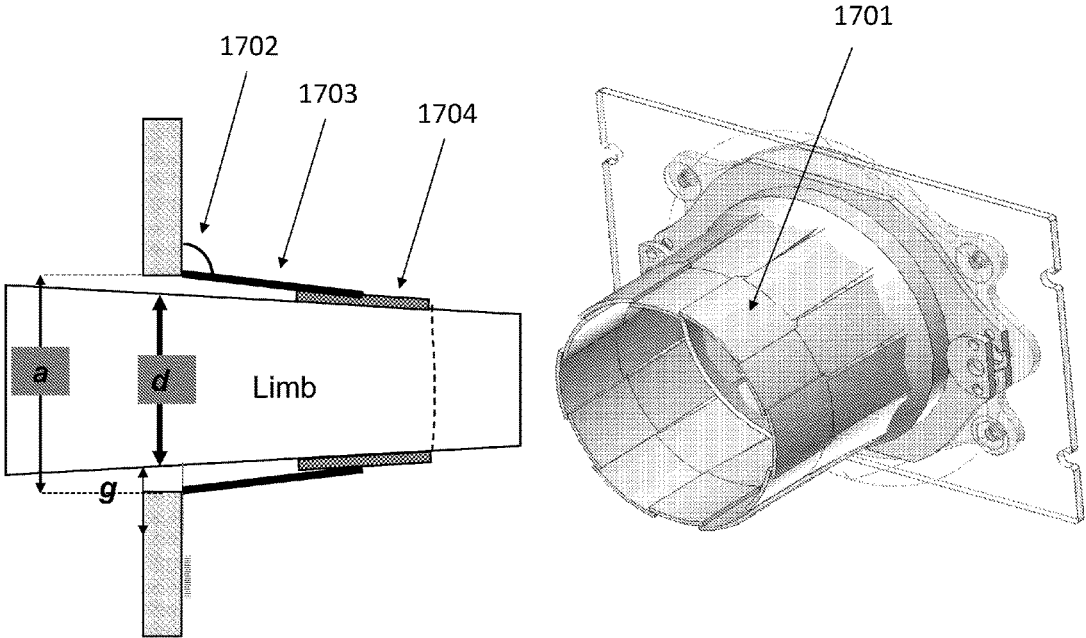


FIG. 17

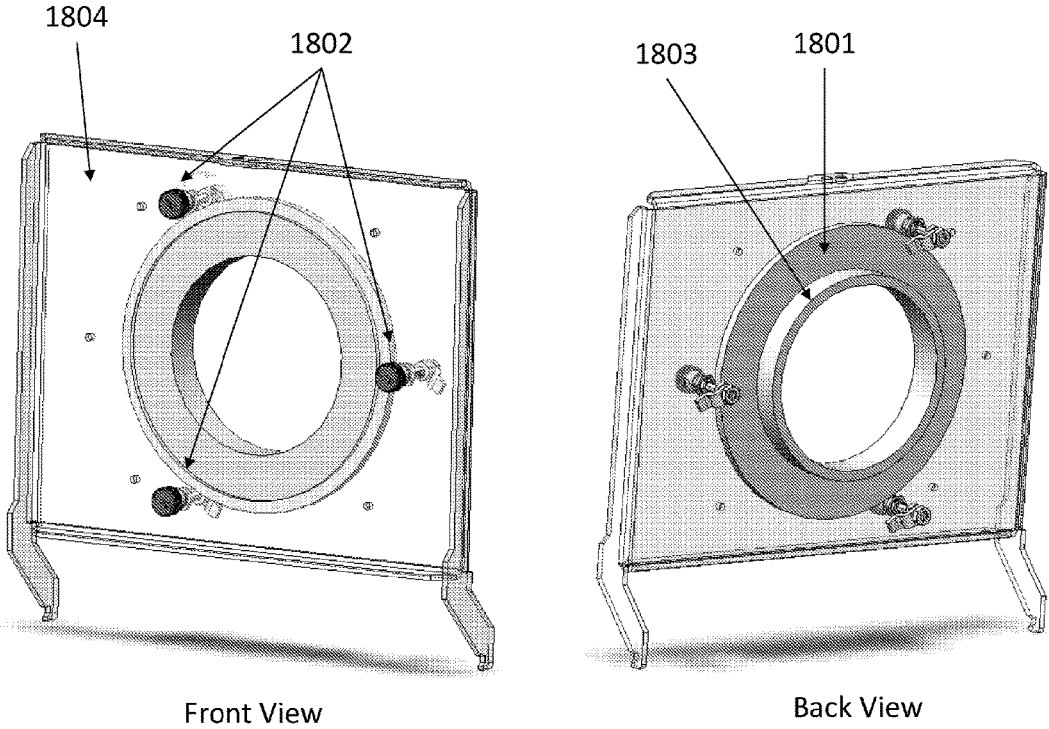


FIG. 18

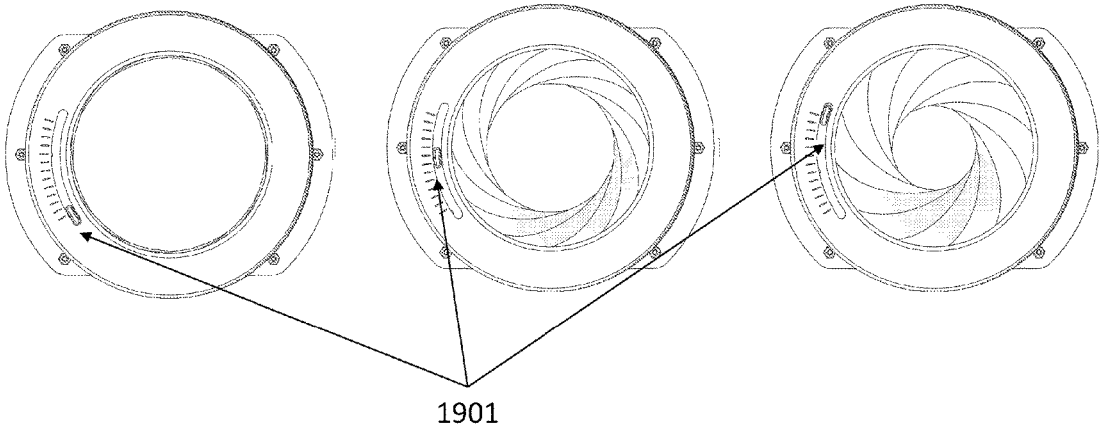


FIG. 19

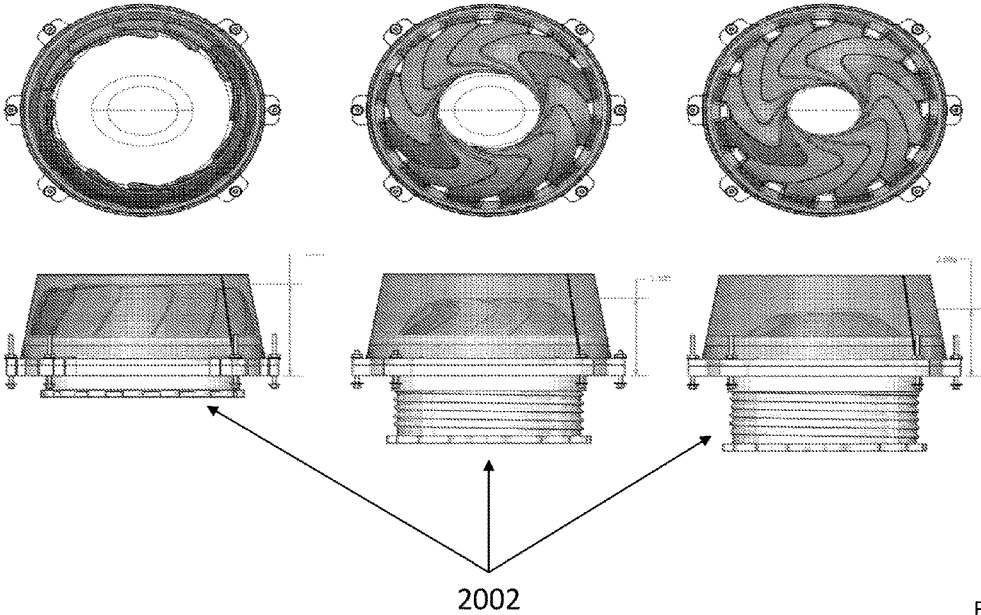


FIG. 20

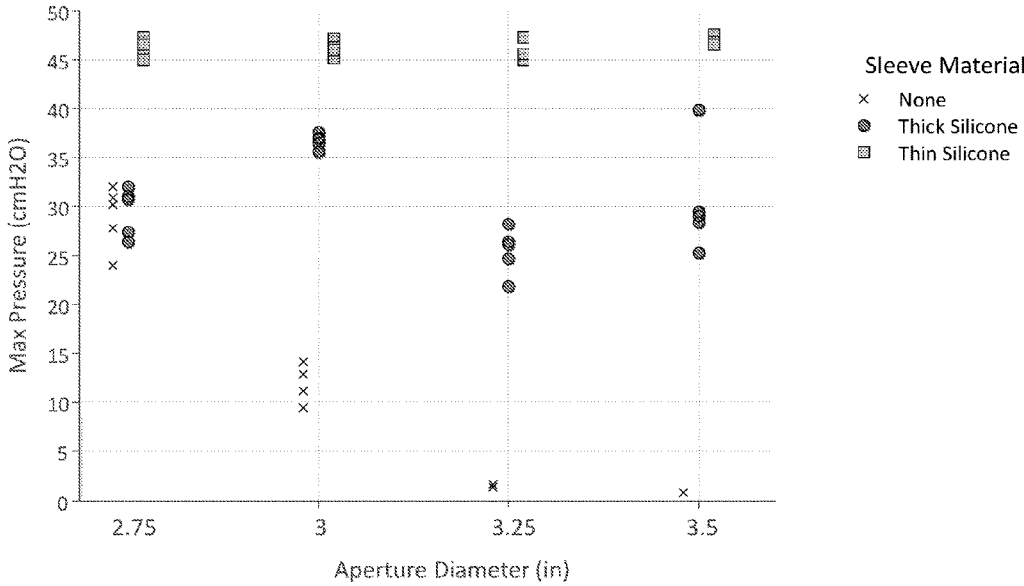


FIG. 21

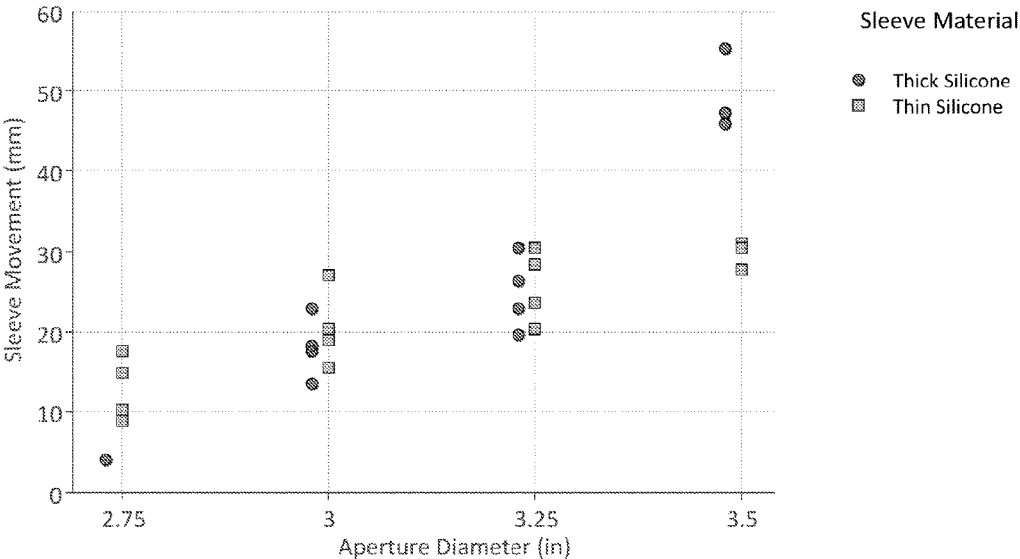


FIG. 22

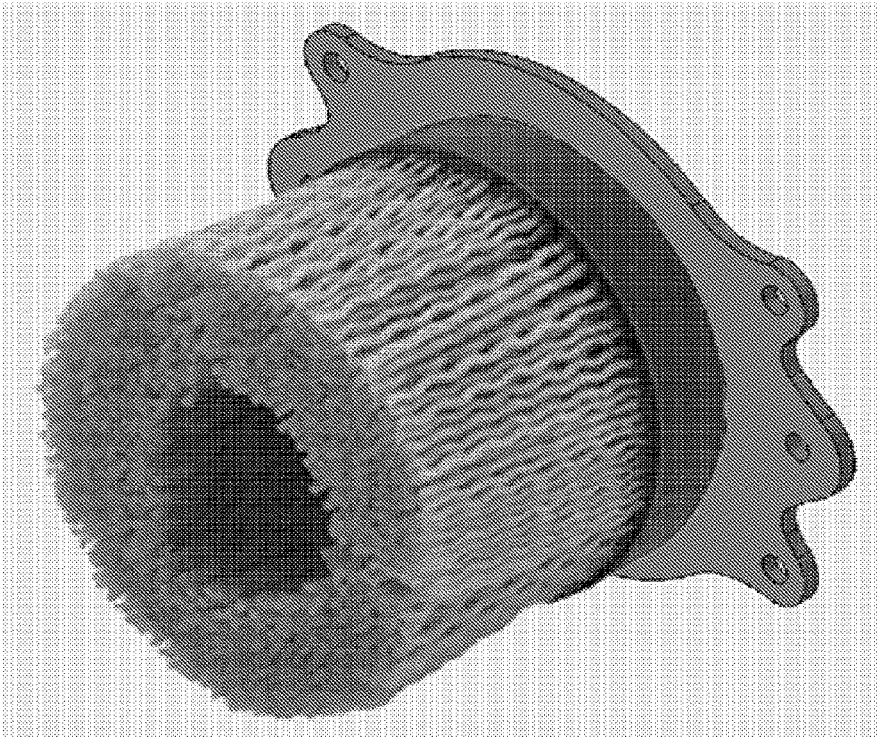


FIG. 23

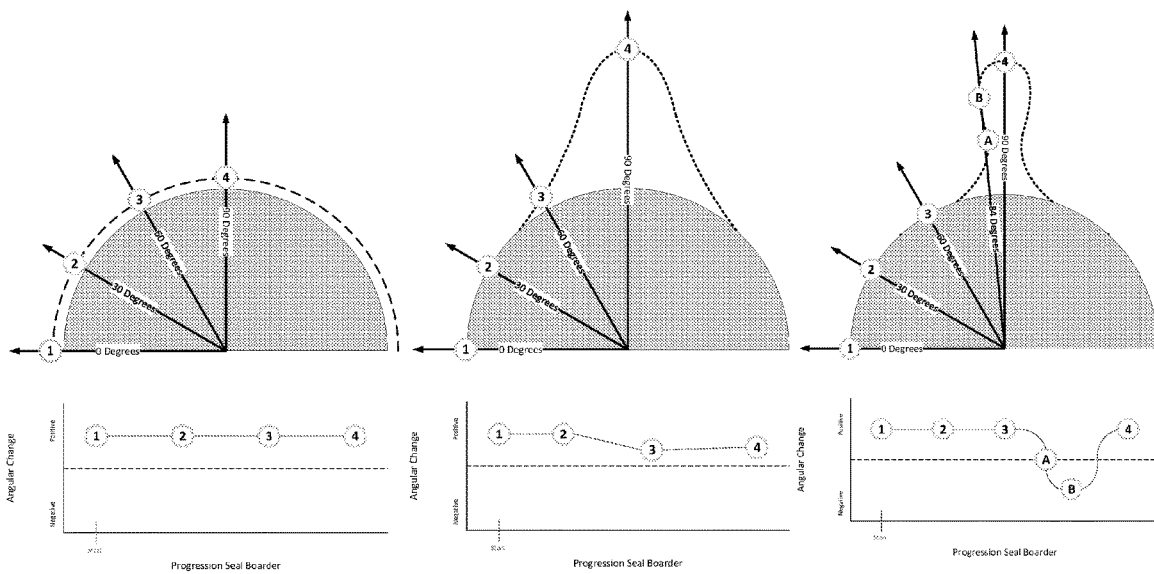


FIG. 24A

FIG. 24B

FIG. 24C

FIG. 24

SELF-SEALING PRESSURIZED LIMB ENCLOSURE

TECHNICAL FIELD

[0001] The present invention relates to the field of methods and apparatuses for managing the pressure around a limb.

BACKGROUND ART

[0002] In some medical applications it is desirable to study the effects of pressure on a limb. One example is the optical determination of central venous pressure from the dorsal hand veins as described in U.S. provisional patent application 62/423,768, incorporated herein by reference. In such applications, it can be important that the method used to generate pressure around the limb does not create additional contact pressures on the limb that exceed the pressure of interest. The creation of a pressurized enclosure around a limb in a manner that does not utilize contact pressures exceeding the enclosure pressure is a challenging problem. The difficulty is exacerbated by the physical complexity and anatomical variability inherent to human limbs, as well as by the desire that the sealing mechanism be easily used by a single operator.

SUMMARY OF INVENTION

[0003] Embodiments of the present invention enable the creation of a self-sealing pressurized limb enclosure for assessment of pressure effects on the limb by successfully addressing many nuances associated with human physiology and anatomy. Embodiments address criteria associated with the intended use by providing a system where the contact pressure at the seal location does not exceed the enclosure pressure or create significant local pressure gradients along the limb. Due to the physiological properties of the limb, the seal mechanism should function in the presence of skin and tissue deformations as well as movement of the tissue relative to the enclosure boundary.

[0004] Embodiments also provide other advantages associated with usability and comfort. Embodiments function in a manner that allows an individual to operate the system without additional assistance. Embodiments facilitate user comfort by not requiring the user to resist the forces acting on their limb due to the positive enclosure pressure.

[0005] An example seal mechanism comprises a rigid outer aperture and an inner flexible seal. The rigid outer aperture couples with the rigid enclosure and allows entrance of the hand into the enclosure. The aperture size can be adjusted to accommodate various sizes and shapes of the limbs under examination. The inner flexible seal compresses radially on to the limb due to the positive pressure in the enclosure, and is therefore self-sealing. The flexible seal accommodates deformation of the soft tissues and subtle movements of the limb within the aperture. The system maintains seal integrity in the presence of skin movement relative to the underlying bone structure.

[0006] Embodiments provide physical and geometrical properties of the inner seal that are important to creating an effective air seal. The seal is sufficiently compressible in the radial dimension to uniformly and consistently restrict airflow. At the same time, the seal resists forces in the axial dimension; in some embodiments this is achieved via friction with the limb, axial rigidity, or other means of stiffness

or resistance to deflection in the axial dimension. The circumference of the inner seal is equally important: the inner seal must also allow entrance of the terminal aspect of the limb (i.e., the hand or foot), which may have a larger diameter than more proximal aspects of the limb, and in general is constructed such that it does not generate any circumferential pressure on the limb that exceeds the enclosure pressure.

[0007] The distance or gap between the rigid outer aperture and the surface of the limb is an important parameter. A large gap increases the axial forces acting on the seal and the limb; excessive force will result in user discomfort and potentially eject the inner seal and limb from the enclosure. A smaller gap reduces the axial force such that an air seal can be maintained. Embodiments offset these axial forces via limb support mechanisms so that the user does not have to activate muscles or otherwise resist limb movement. Embodiments' use of an elbow stop or alignment of the limb such that movement is opposed by gravity, are examples of solutions to mitigate the axial force.

BRIEF DESCRIPTION OF DRAWINGS

[0008] FIG. 1 is an illustration of a typical seal mechanism with the seal pressure exceeding enclosure pressure.

[0009] FIG. 2 illustrates directions of forces acting on the limb.

[0010] FIG. 3 is an example of the seal system under no positive pressure.

[0011] FIG. 4 is an example of the seal system under positive pressure.

[0012] FIG. 5 shows the forces present at the distal sleeve.

[0013] FIG. 6 is a force diagram depicting the conditions at the point of contact.

[0014] FIG. 7 illustrates the relationship between gap size and non-rigid aperture surface area.

[0015] FIG. 8 is an illustration of seal system using contact sensors.

[0016] FIG. 9 is an illustration of seal system using pressure sensors.

[0017] FIG. 10 is an illustration showing the forces acting on the limb.

[0018] FIG. 11 is an illustration depicting the change in seal location due to increasing pressure.

[0019] FIG. 12 is an illustration of fold radius differences.

[0020] FIG. 13 is an illustration showing a fundamental concept of a compression seal.

[0021] FIG. 14 is an example of an axial-rigidity based seal.

[0022] FIG. 15 is a second example of an axial-rigidity based seal.

[0023] FIG. 16 is a third example of an axial-rigidity based seal.

[0024] FIG. 17 is a fourth example of an axial-rigidity based seal.

[0025] FIG. 18 is an illustration of multiple fixed apertures.

[0026] FIG. 19 is an illustration of a variable aperture using an iris diaphragm.

[0027] FIG. 20 is an illustration of a variable aperture using overlaying leaves.

[0028] FIG. 21 shows the influence of aperture size and seal material on seal effectiveness.

[0029] FIG. 22 shows the influence of aperture size and seal material on seal movement.

[0030] FIG. 23 is an illustration of a variable aperture using overlaying bristles.

[0031] FIG. 24 is an illustration of angular relationships concerning material folding in some embodiments.

DESCRIPTION OF EMBODIMENTS AND INDUSTRIAL APPLICABILITY

[0032] Definitions

[0033] Seal Junction describes the area over which there is contact between the flexible sleeve and the tissue of the limb.

[0034] Seal Location is the location of the seal junction relative to definable location, such as the plane defined by the rigid aperture. Radial Pressure is the pressure normal to the limb surface acting towards the center of the limb.

[0035] Axial Force is the pressure acting along the axis of the limb. A positive axial force acts to push the limb out of the enclosure.

[0036] Pressure Tolerance defines the permissible limit of variation in pressure relative to a set or desired value. The pressure tolerance for typical applications is roughly 1 cm H₂O.

[0037] Pressure Consistency defines a static condition where the pressure across a surface is consistent to within the pressure tolerance, i.e., local pressure gradients larger than the pressure tolerance are not present.

[0038] Non-positive angular progression configuration: as used in this document defines a configuration where progression around the circumference of the seal material results in a condition where the angular relationship between sequential point on the circumference does not result in an increase of the angle define by an line from the center of the object and the intersection with the material forming the seal. As illustrated in FIG. 24A, a circle maintains a positive and constant angle of progression. As illustrated in FIG. 24B, as the seal material begins to fold on itself, the angle of progression can decrease and become less positive as the material begins to form a fold. As illustrated in FIG. 24C, further formation of the seal creates a situation where the angle of progression become zero or can be negative as the material begins to fold back on itself. From another perspective, in a non-positive angular progression configuration a line drawn from the center of the object outward encounters the surface of the seal material more than once.

[0039] Tube: as used in this document simply defines a cylindrical object for transporting with a proximal and distal opening. The object can vary in circumference along the length of the tube.

[0040] Sealing engagement, or sealingly engaged, or seal, refers to an engagement between two entities, such as between a sleeve and a limb, that provides adequate resistance to airflow. Sealing engagement does not require absolute airtightness or zero air flow through the engagement, but only sufficient restriction to air flow that the engagement facilitates the desired pressure differential across the engagement.

[0041] Properties and Features of Example Embodiments

[0042] For the intended use of studying the effects of pressure variations on a limb, the following system capabilities are provided by various example embodiments:

[0043] The pressure at the seal junction should not exceed the pressure of the enclosure by more than the pressure tolerance. FIG. 1 shows a typical approach for creating an air seal. The pressure at the seal location exceeds the pressure

in the enclosure thus creating an effective resistance to air flow out of the enclosure. The use of such a standard seal design creates a local area of increased pressure that acts as a tourniquet and influences measurable pressure effects in the distal limb. Such localized pressure does not satisfy requirements for applications that can be accommodated by embodiments of the present invention.

[0044] The seal junction creates pressure consistency around the circumference of the limb. Spatial variances in the seal quality can create failure points that allow air to escape via high velocity flow. Air leakage creates localized pressure gradients and areas of skin deformation, permitting further air leakage. A seal with pressure inconsistency around the limb is unstable and unreliable, and unsuitable for the intended uses.

[0045] The seal system can compensate for large anatomical variations in the size and shapes of limbs. This includes both variances between individuals in a population, as well as the variance in the geometry of the limb within an individual. The typical limb increases in diameter as one moves proximally toward the point of attachment, though the diameter of the terminal limb element (i.e., hand or foot) can often exceed the limb diameter at more proximal locations. The seal mechanism can accommodate varying limb diameter and maintain functionality if the seal location moves along the limb.

[0046] The system can allow for some variance in the placement of the limb within the seal mechanism. It is anticipated that individuals will move their limbs slightly within the seal mechanism during any measurement protocol. Embodiments of the present invention will tolerate or adapt to these expected small variances in limb position.

[0047] Because the limb is a non-rigid object that deforms under forces, the seal can accommodate for changes in the size and shape of the limb. Limbs are complex, non-uniform objects composed of multiple tissue layers including bone, muscle, fat, vasculature and skin. The different tissue layers vary in their physical properties and some are easily deformable. Specifically, the skin has a moderate degree of elasticity and can be compressed or stretched relative to the bones of the limb. In addition, the volume of vascular tissues is highly affected by surrounding pressures. Embodiments can accommodate for changes in the size and shape of the limb which that occur in response to variations in the enclosure pressure.

[0048] Positive enclosure pressure relative to external environment will act to push the limb out of the enclosure, potentially creating an uncomfortable experience for the user. FIG. 2 shows key forces acting on the limb. Radial forces are defined as those forces acting into the limb in a manner normal to the surface of the limb, while axial forces act along the longitudinal axis of the limb. Embodiments provide that the axial force experienced by the user is minimized or mitigated to the extent possible. The axial force out of the enclosure is defined by the cross-sectional area of the rigid aperture, which includes the limb and the gap around the limb. Embodiments can manage the total axial force so that the force pushing the limb out of the enclosure is tolerable and does not require the user to actively resist this force. Some embodiments include limb support mechanisms or other considerations that act to oppose the axial force out of the enclosure and increase subject comfort.

[0049] To facilitate overall usability, embodiments can be operable by a single individual without assistance from another party. Specifically, the user is able to insert a limb into the device such that effective seal is formed without the assistance of a second individual. In some embodiments, the user can simply place their limb through the aperture. Many other user-friendly scenarios exist, but the general goal is to minimize the number of actions that must be performed by the user.

[0050] Embodiments of the present invention provide the advantages described above, and are effectively self-sealing because the pressure used to create the seal is generated by the pressure difference between the positive pressure in the closure relative to the external environment.

[0051] System Components

[0052] Embodiments of the present invention involve the integration of three components working in concert. Components include (1) an outer rigid aperture with variable opening that allows entrance of the limb into the enclosure; (2) an inner radially flexible material that is compressed radially to create an effective air seal; (3) a design element that enables the seal to oppose the axial forces of positive pressure. The properties of each component and their integrative function are described below.

[0053] The outer aperture is sufficiently rigid such that it is not deformed by the enclosure pressure. A variable opening size is provided in some embodiments to accommodate limbs of different sizes. The variable aperture can take many forms. For example, the system can use a continuously variable aperture, such as an iris diaphragm. Such an aperture can be opened to easily allow the limb entrance into the enclosure, and then can be closed to reduce the gap between the aperture and the limb. Alternatively, the system can employ a set of interchangeable fixed apertures that are sized to be as small as possible while avoiding contact with the limb and allowing entrance of the limb into the enclosure.

[0054] An inner flexible material forms the air seal around the limb. The seal is created using the radial forces generated by the pressure in the enclosure, and in this way, is self-sealing. The radial force places the material used to create the seal under compression. Compression is a term associated with the general forces on an object and used with an awareness that any bend of a material creates both tension and compression. As used to describe the formation of the seal at around the limb, the seal material is compressed around the arm to create a seal. The material properties of the seal are an important element of the invention, and the seal must have sufficient radial flexibility such that it can be compressed to create pressure consistency.

[0055] The examples depicted herein generally show the limb extending past the end of a sleeve, for example having a tube encircle an arm while the hand extends past the end of the tube. The invention also contemplates sleeves with closed ends, for example a portion encircling an arm with a glove-like or mitten-like portion that also covers the hand. In example embodiments, an optical measurement is made of a limb while at least a portion of the limb is surrounded by a sleeve. The portion being measured can be outside of the sleeve, or can be covered by, or even completely enclosed in, the sleeve, provided that the portion being measured is accessibly to the measurement system. As an example, an optically transparent glove end to an opaque tube can be suitable in some example embodiments. As used herein, the

term sleeve contemplates both structures with ends through which a portion of the limb protrudes, and structures that similarly surround a limb while also enclosing the end of the limb while still providing access as required for the measurement, e.g., an optically transparent portion.

[0056] The system also includes design elements that confer axial resistance or rigidity, enabling the seal to oppose the axial force of positive enclosure pressure. Opposing forces can be generated by the material, geometrical, or structural properties of the seal. Examples of opposing forces include, but are not limited to, friction generated between the seal and the limb, stiffness associated with tension of the seal, stiffness associated with compression of the seal, and any combination of the above.

[0057] System Operation

[0058] The constraint that the pressure on the limb not exceed the pressure in the enclosure is satisfied by using a flexible seal whose primary mechanism for creating pressure on the arm is the result of the pressure difference between the interior of the enclosure and the outside of the enclosure. FIG. 3 shows an example embodiment of this element. In this example, the flexible seal material is a sleeve that is attached to the inner surface of the enclosure, and axial resistance is provided by friction between the sleeve and the limb. The aperture is circular in shape and the limb is modeled as a truncated cone. Additionally, the limb is assumed to be centered in the aperture for ease of description. The figure shows several elements that define an effective seal system for the limb. An external rigid aperture, **101**, defines the entrance into the enclosure, **103**. A flexible sleeve, **102**, is attached to the enclosure in an airtight manner. The diameter of the aperture is denoted as diameter a . The unilateral gap between the limb and the rigid aperture is defined as distance g . The limb diameter varies in the axial direction, as is typical in most individuals. The distal diameter of the sleeve, **104**, is larger than the largest diameter of the limb at the seal junction, defined as diameter d . As pictured in FIG. 3, there is no positive pressure in the enclosure and the sleeve is not compressed against the limb.

[0059] As the pressure in the enclosure is increased the seal system must respond in a manner that allows a positive enclosure pressure to be created. FIG. 4 shows the seal system under conditions where the enclosure pressure is greater than the atmospheric pressure, and a seal around the limb has been created. Under pressure, the flexible sleeve is under compression in the radial direction and under tension in the axial direction. The sleeve contacts the limb over an area of skin, **401**, and is attached to the enclosure along area **402**. The pressure difference exerts force on the sleeve creating axial tension in sleeve, **403**. At the seal junction, **401**, the sleeve is forced into contact with the limb via radial forces and has compressed, collapsed or folded under the pressure gradient to create an effective seal around the limb. The radial pressure collapsing the flexible sleeve places the sleeve under compressive forces. The resulting air seal is a consequence of the pressure difference between the inside of the enclosure and the outside of the enclosure.

[0060] The requirement that the pressure at the seal junction not exceed the pressure in the enclosure by a pressure tolerance necessitates examination of the distal aspect of the sleeve. FIG. 5 is an illustration of the forces present at the distal junction of the sleeve with the limb. The distal sleeve at the seal junction is subject to three possible forces that must be managed appropriately. The major active force is

radial compression of the sleeve against the arm caused by the enclosure pressure. A second possible force is the physical weight of the sleeve pushing on the arm. The third possible force is a circumferential force or hoop force. To minimize the difference between the pressure on the arm under the sleeve, **502**, and the pressure on the arm in the enclosure, **503**, to within the pressure tolerance, the material selected for the sleeve can be of minimal weight. As it relates to minimization of circumferential force, the distal diameter of the sleeve is large enough that the distal aspect of the sleeve is not under tension and therefore does not generate circumferential forces. Sleeve design based upon defined geometric considerations and the selection of lightweight material create a system that satisfies pressure criteria.

[0061] To create a functional seal, the forces acting on the sleeve function must sum to create a static condition. Otherwise, the seal would fail. FIG. 6 is a force diagram depicting the forces present at the area of contact between the sleeve and the arm. As illustrated, the sleeve is subject to an axial force pushing out of the enclosure, **702**. Under static conditions, an equal and opposite force is generated due to the friction between the limb and the sleeve. The frictional force is the product of the pressure in the enclosure, the area of contact with the limb, and the static coefficient of friction. The flexible sleeve must therefore have sufficient length and the material must have a static coefficient of friction such that the static force of friction sufficiently opposes the sleeve force.

[0062] A concurrent consideration is associated with minimizing the sleeve force. The force on the sleeve is a function of the gap, g , between the aperture and the limb, as shown in FIG. 7. The force on the sleeve is the product of the gap area and the pressure in the enclosure, and the sleeve force is minimized by minimizing the gap size. Preferably, the rigid aperture is as close to the skin as possible, while ensuring that direct contact is avoided and that there is sufficient space for small movements of the limb.

[0063] Under preferable conditions, the limb does not contact the rigid aperture since such contact can create pressures that exceed the pressure tolerance. Contact sensors can be used to ensure that no contact with the rigid aperture. FIG. 8 is an illustration of how such contact sensors, **801**, can be used to determine the presence of contact between the limb and the hard aperture.

[0064] Pressure sensors can also provide valuable information to determine whether the contact pressure is negligible. For example, when testing individuals with less elastic skin, the gravitational pull on the tissue creates a significant sag in the skin, resulting in contact with the rigid aperture. The contact pressure due to sagging skin is often small and beneath the pressure tolerance. Thus, the use of pressure sensors in the aperture can distinguish between cases when contact pressure is negligible and when it can interfere with the measurement and must be addressed, e.g., by increasing the gap size. FIG. 9 shows an array of pressure sensors, **901**, concentrated on the bottom of the rigid aperture that enable such a determination.

[0065] Understanding of the system also requires evaluation of the forces acting to push the limb out of the enclosure. FIG. 10 shows that the axial force acting to push the limb out of the enclosure is dependent on the cross-sectional of the aperture, defined by diameter a , and the pressure in the enclosure. Opposing forces on the limb can include static friction between the limb and supporting

elements. For example, a forearm enclosure can use a palm rest, **1001**. Static friction between the hand and the palm can offset the axial force due to pressure. An elbow rest, **1003**, can also be used as supporting element that creates static friction with the limb. If the axial pressure force exceeds the cumulative frictional forces, an elbow stop, **1002**, can be added to the system. An elbow stop will oppose the movement of the forearm out of the enclosure and increase subject comfort because the subject will not feel the need to actively resist the axial forces exerted on the limb. Also, the limb and enclosure can be oriented such that the axial pressure is directly opposed by gravity.

[0066] The use of a flexible sleeve creates a system that allows the seal to move in the axial direction as the pressures on the skin create stretch of the skin. As the pressure in the enclosure increases, the sleeve force will increase and stretch the skin in the axial direction. FIG. 11 illustrates that the seal junction can move from location **1101** at low pressures to location **1102** at higher pressures due to skin deformation while the bones and other more rigid structure remains nominally stable in position. Skin stretch is often modeled as a spring damper system as illustrated. The flexible sleeve seal system maintains operational integrity as the seal location moves due to both tissue movement and skin stretch.

[0067] When using a flexible sleeve as the mechanism to create a seal, the formation of an effective seal around the limb is dependent upon material selection with attention given to the fold radius. The fold radius is the radius or curvature defined by the material under defined pressures. For visualization purposes, consider a very thin pliable piece of plastic folding back on itself. The material effectively folds back, and the resulting fold radius is remarkably small. In contrast, a piece of carpet when folded back on itself has a significant fold radius. The fold radius is defined by the physical and geometric properties of the material.

[0068] FIG. 12 is an illustration communicating the importance of fold radius. As shown, there are two flexible sleeves surrounding the upper half of a limb. Both are subjected to the same pressure, but the responses of the sleeves are dramatically different. The material on the right, **1201**, has effectively folded upon itself utilizing a very small fold radius to effectively create an air seal. In contrast, the sleeve used on the left, **1202**, has a much larger fold radius and may fail to create an effective air seal. If the bend radius of the sleeve is large at pressures used in the enclosure, then seal quality will be compromised and the uniformity of the seal across circumference of the limb will be poor. In general, if the material used for the seal cannot effectively fold onto itself with a small fold radius, the overall seal quality is compromised resulting in an unstable and unreliable seal. In contrast, if the material has a suitably small fold radius and can effectively fold back on itself, a stable and reliable seal will be created.

[0069] A primary material property affecting fold radius is the elastic modulus; the geometrical properties of the material, primarily thickness, are also important. A flexible sleeve can be selected such that the thickness and elastic modulus properties enable a small fold radius and create an air seal at the enclosure pressures. Materials that can satisfy these criteria include, but are not limited to, elastic materials such as latex or silicone, moderately inelastic material such as high-density polyethylene or low-density polyethylene, and fabric material such as nylon, Kevlar, and terylene. The

above list is not considered an exhaustive list of materials that may satisfy the flexible sleeve criteria but rather a list of example materials.

[0070] The fact that the terminal limb diameter is often larger than the more proximal limb diameter in most individuals makes it desirable, but not necessary, to use a sleeve element with elastic properties. In this case, the sleeve stretches over the larger diameter appendage and forms a distal circumference more consistent with the size of the limb. Elastic material properties are also desirable because they allow a sleeve to return its original size and position when the deforming forces are removed. Inelastic or viscoelastic materials may not return to their original size and shape without the application of other forces, or may return slowly, limiting the temporal response of the system.

[0071] The example embodiments satisfy all the criteria described. The use of radial compressive forces to create a seal around the limb meets the requirement that the seal pressure does not exceed the enclosure pressure. The concurrent use of the flexible sleeve with sufficient friction with the limb and a minimal gap between the limb and the rigid aperture creates an overall seal system that is effective and easy to use. In use, the user simply places their limb into the enclosure through the flexible seal. As the pressure increases in the enclosure, the flexible sleeve creates a self-sealing closure around the limb, and the axial pressure force on the seal and the limb is opposed by friction and other design elements.

[0072] Additional Embodiments

[0073] Axial Rigidity-Based Seal System

[0074] The embodiments described above used the example of a seal system where the opposing force to the axial pressure was provided by friction between the seal and the limb. The present invention also provides a seal system based upon axial rigidity of the seal. These example embodiments are not based upon a consideration that the forces due to static friction oppose the air pressure; rather, the seal provides axial compressive strength that opposes the air pressure. FIG. 13 shows important elements of the concept. As the pressure in the enclosure increases, the air pressure force is opposed by the structural elements of the seal mechanism. The structural elements can be solid, can deform under pressure, or can act like a spring. As shown in FIG. 13, small pressure forces result in a smaller degree of compression whereas increased pressure forces can create further compression. The stiffness or rigidity of the seal elements resist this compression. As illustrated in the figure, there is not a requirement of static coefficient of friction to oppose the axial pressure force and at the extreme, in theory, the system can operate effectively with a frictionless surface.

[0075] The concepts demonstrated in FIG. 13 can be used to implement a variety of seal mechanisms. FIG. 14 is an example of a seal mechanism based on resistance to axial compression. The seal mechanism has an axial rigidity that is used to oppose the force of air pressure. The sleeve is composed of a flexible sleeve with embedded battens, 1401. Battens are used in sails to add additional rigidity to the sail in a desired direction. For the seal system, the battens are composed of a lightweight material that confer axial rigidity. As the pressure in the enclosure increases, the axial pressure force will largely place the sleeve element into compression, rather than tension. The compressive strength of the battens resists deformation due to the axial pressure force while maintaining the radial flexibility of the sleeve such that the

distal aspects of the sleeve can conform to the limb and create an effective seal. The system does not have requirements regarding the static coefficient of friction between the sleeve and the limb, though in practice, some static frictional force will be present and will additively combine with the axial sleeve rigidity to oppose the axial pressure force.

[0076] The resulting seal system satisfies the design requirements but accomplishes these goals without creating significant axial stress at the skin surface. Depending upon application nuances, the reduction of skin stress might be a desirable attribute. The reduction of skin stress can be important in older individuals that have more fragile skin. Additionally, the degree of skin stress can be influenced by material selection and specifically by use of materials that have a minimal coefficient of friction of the material including the distal sleeve location.

[0077] A second embodiment of an axial rigidity-based seal system is shown in FIG. 15. As shown, the thickness of the seal element, 1501, varies along the axial dimension, with greatest stiffness and rigidity at the point of attachment to the enclosure. The distal seal is designed to retain sufficient radial flexibility to create an effect seal, and the axial rigidity conferred by the increasing thickness opposes the axial pressure force on the seal. In addition to or in alternative to changing material thickness in the axial dimension, the material of the seal element can also be varied along this axis to increase stiffness. Axially varying the material properties can be achieved by “doping” the seal element with stiffness enhancing agents, or inter-weaving fibers or filaments with axial rigidity.

[0078] A third embodiment of an axial rigidity-based seal system is shown in FIG. 16. The distal seal, 1601, is composed of a radially flexible material to enable adequate seal formation between the sleeve and arm. In the axial direction, the seal designed somewhat like an accordion with material characteristics that oppose the axial force of air pressure out of the enclosure. Elements of the system may be placed in compression or tension when acted upon by the axial pressure force. Due to the accordion nature of the structure, each curve represents a situation of compression on the inner radius and tension along the outer radius. The mechanical rigidity of the bellows acts to offset the axial pressure from the enclosure. It is important to note that the bellow mechanism obtains additional rigidity at the point the bellows contact each other. Specifically, at the point the bellows are collapsed on each other, they generate a static coefficient of friction between adjacent bellows, which results in additional structural rigidity. At location 1602, the physical height of the bellows increases under compression and can obtain a height such that it becomes exceedingly difficult for the seal mechanism to be forced through the gap. Thus, this seal design may be less influenced by the gap size than prior systems. As noted above, as the system compresses on itself, the bellows structure becomes increasingly rigid. As this occurs the effective gap size becomes extremely small since as a rigid structure files the gap area. Such a system may have benefits in terms of reducing the necessity for variable apertures.

[0079] FIG. 17 shows a fourth example of an axial rigidity-based seal system. This system does not utilize a continuous flexible sleeve, but instead a plurality of overlapping lightweight leaves. The leaves, 1701, are rigid in the axial direction and are designed to overlap to create an effective air seal. The leaves are able to bend and flex at the point of

attachment, **1702**, thus enabling a radially flexible seal at the distal seal element. In implementation, the large surface area of the leaf, **1703**, can create a location of high pressure as the leaf flexes from the solid aperture location. This pressure point issue can be mitigated by using a sheath that displaces the force over a wider area, **1704**, to meet the requirements of pressure tolerance. A similar embodiment shown in FIG. **21** uses overlapping filaments or bristles rather than leaves to create the leaves. Bristles offer axial rigidity with radial flexibility, and with sufficient overlapping can create an effective seal over the surface of the limb.

[0080] Variable-Sized Apertures

[0081] A variable aperture system can be implemented by using a set of fixed apertures that vary in size. FIG. **18** shows an example of such a system. A rigid disk, **1801**, forming the aperture is attached to the front panel of the enclosure, **1804**. The disk can be easily attached and removed using quick-release elements, **1802**, that allow optimization of the aperture size. A flexible sleeve to form the seal is attached to the lip of the disk at **1803**, not shown.

[0082] Variable Iris with Flexible Sleeve

[0083] A continuously variable aperture system is illustrated in FIG. **19**. The system uses an iris diaphragm to allow convenient adjusting of the aperture size. The user can open the aperture wide using adjustment lever **1901** to allow entrance of the limb into the enclosure, then reduce the aperture to minimize the gaps size around the more proximal limb. The individual leaves of the iris can be coated with a rubberized paint to ensure that the surface created by the leaves resists air flow.

[0084] FIG. **20** shows a second example of a continuously variable aperture system. The system design and operation have a similar configuration as in a common vegetable steamer, where overlapping leaves can create a variable aperture. A rigid cylinder, **2002**, is threaded into the front plate of the enclosure. The limb passes through the cylinder and into the enclosure. Turning the cylinder forces the leaves open, creating an easy-to-use adjustable aperture. Similar to the iris diaphragm, the individual leaves iris can be coated with a rubberized paint to ensure that the surface created by the leaves resists air flow. Alternatively, the sealing element, for example, a flexible sleeve, can be fitted over the outer surface of the leaves to prevent air flow.

[0085] Demonstration of Applications

[0086] We include experimental data to demonstrate the principles outlined above. Data were collected from a single subject using an enclosure around the forearm. Aperture sizes were varied using a set of rigid disks, as described and shown in FIG. **18**. A flexible sleeve was used to create a seal. The material used for the sleeve was varied to demonstrate the importance of physical and geometrical properties. Utilized sleeve materials included thin silicone (less than 0.5 mm thick, in the example 0.42 mm thick), thick silicone (between 0.5 mm and 3 mm thick, in the example 1.05 mm thick), and no sleeve at all. The thin and thick silicone sleeves had similar static coefficients of friction on the skin. The subject's forearm position was adjusted such the gap size between the arm and the rigid aperture was effectively zero for the smallest aperture diameter of 2.75 in. The gap size then increased linearly with aperture diameter. Each experiment was repeated four times to assess variability.

[0087] FIG. **21** shows the maximal pressure attainable in the enclosure using different sleeve materials and different apertures. Due to residual air leaks in the enclosure, the

maximal possible pressure attainable when no air is flowing around the arm was 47.5 cm H₂O. The thin silicone sleeve achieved near maximal pressure regardless of the aperture size due to (1) a small fold radius that allows an effective seal to be created and (2) a suitable static coefficient of friction. In contrast, the thick silicone sleeve created a less effective and highly variable seal due to the larger fold radius, which allowed air leaks.

[0088] FIG. **21** also demonstrates the advantage of a flexible seal due to deformation of the arm. When the enclosure pressure was equal to atmospheric pressure, there was effectively no gap between the arm and the rigid aperture. However, as positive enclosure pressure was generated, the skin and other tissues deformed, allowing for significant air leaks that precluded formation of an effective seal.

[0089] FIG. **22** shows the influence of gap size on the forces acting on the sleeve. In each experiment, the enclosure pressure was increased to a set value of 35 cm H₂O and the axial movement of the sleeve relative to its starting position was recorded. Static conditions are achieved when the friction with the arm and tensile forces in the sleeve oppose the axial pressure force. In agreement with the equations in FIG. **7**, the force acting on the sleeve increases with the aperture diameter and hence gap size. Although not observed in these experiments, if the sleeve length is too short, the coefficient of friction too low, or the enclosure pressure too high, the sleeve can be forced out of the enclosure to constitute total seal failure.

[0090] The present invention has been described in connection with various example embodiments. It will be understood that the above description is merely illustrative of the applications of the principles of the present invention, the scope of which is to be determined by the claims viewed in light of the specification. Other variants and modifications of the invention will be apparent to those skilled in the art.

1. (canceled)

2. A sealing apparatus as in claim **27**, wherein the sleeve comprises a material that has a non-positive angular progression at pressures relative to ambient of 30 cm H₂O or more.

3. A sealing apparatus as in claim **27**, wherein the sleeve comprises a flexible material that comprises one or more of latex or silicone, high-density polyethylene, low-density polyethylene, nylon fabric, Kevlar fabric, and terylene fabric.

4. A sealing apparatus as in claim **27**, further comprising a plurality of contact sensors disposed relative to the sleeve and the pressurizable enclosure such that they sense contact between the limb and a rigid portion of the sealing apparatus or the pressurizable enclosure.

5. A sealing apparatus as in claim **27**, further comprising a plurality of pressure sensors disposed relative to the sleeve and the pressurizable enclosure such that they sense pressure exerted on the limb by a rigid portion of the sealing apparatus or the pressurizable enclosure.

6. A sealing apparatus as in claim **27**, wherein the sleeve further comprises a plurality of battens, each batten being stiff in the axial direction, mounted with the sleeve such that the battens resist deformation of the sleeve out of the pressurizable enclosure.

7. A sealing apparatus as in claim 27, wherein the sleeve has an axial rigidity that is greater near the engagement with the opening than distal from the engagement with the opening.

8. A sealing apparatus as in claim 7, wherein the sleeve has an axial rigidity that smoothly decreases from the engagement with the opening to a region distal from the engagement with the opening.

9. (canceled)

10. A sealing apparatus as in claim 27, wherein the sleeve is configured with accordion folds and has resistance to folding such that pressure above ambient in the volume compresses the accordion folds.

11. A sealing apparatus as in claim 10, wherein the sleeve material has a low coefficient of friction with the surface of the limb.

12. A sealing apparatus as in claim 10, wherein the sleeve accordion folds compress at a lower pressure than the sleeve compresses to sealingly engage the limb.

13. A sealing apparatus as in claim 27, wherein the sleeve comprises a flexible material that comprises thin silicone, thick silicone, or a combination thereof.

14. (canceled)

15. (canceled)

16. (canceled)

17. (canceled)

18. (canceled)

19. (canceled)

20. (canceled)

21. (canceled)

22. A limb seal apparatus as in claim 27, wherein the sleeve is configured such that the limb extends past the distal end of the sleeve into the enclosure.

23. (canceled)

24. The limb seal apparatus of claim 27 where the seal changes its physical configuration to obtain a non-positive angular progression configuration at pressures less than 30 cm H₂O.

25. The limb seal apparatus of claim 27 where the sleeve does not exert pressure above a predetermined threshold when the enclosure is pressurized above ambient.

26. The limb seal apparatus of claim 27 wherein the flexible sleeve is attached to the enclosure and is subject to increasing axial tension due to increasing pressure.

27. A limb seal apparatus for use with a pressurizable enclosure, comprising a flexible sleeve that allows a limb to pass through the sleeve where the sleeve changes its physical configuration to create an air flow restriction responsive to a pressure gradient between the inside and outside of the enclosure, wherein the air flow restriction is sufficient to result in transmural pressure of zero in the veins of a limb in the enclosure.

28. The sealing apparatus of claim 27 wherein the sleeve has a proximal attachment to an aperture allowing access to the interior of the enclosure, and a distal aperture that circumferentially encloses the limb, wherein the sleeve's change in physical configuration are characterized by pressure increases in the enclosure causing the portions of the distal sleeve to compress against the limb while elements of the sleeve in proximity of the aperture experience axial tension.

29. The limb seal apparatus of claim 27, wherein the sleeve comprises an air resistant material with asymmetric material properties, in a configuration such that the material's resistance to compression is greater aligned with the axis of the limb than orthogonal to the axis of the limb.

30. A limb seal apparatus for use with a pressurizable enclosure, comprising a flexible sleeve that allows a limb to pass through the sleeve where the sleeve changes its physical configuration to create an air flow restriction responsive to a pressure gradient between the inside and outside of the enclosure, wherein sleeve mounts with the enclosure with a gap between an opening in the enclosure and the limb, and wherein the force due to friction between the seal and the limb when the enclosure is pressurized plus the sleeve's resistance to axial deformation is at least equal to the force on the seal due to pressure on the gap at pressures above a first predetermined threshold.

31. The limb seal apparatus of claim 30, wherein the force due to friction between the seal and the limb when the enclosure is pressurized plus the sleeve's resistance to axial deformation is less than the force on the seal due to pressure on the gap at pressures below a second predetermined threshold.

32. (canceled)

* * * * *