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

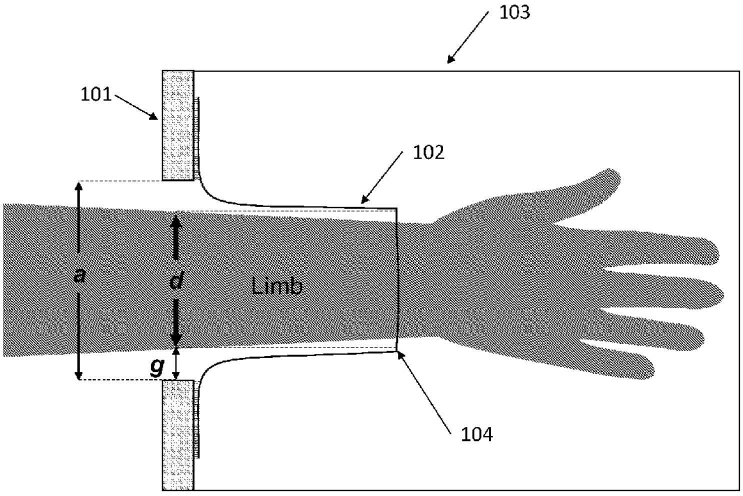

FIG. 3

(57) **Abstract:** 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.

[Continued on next page]

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Self-Sealing Pressurized Limb Enclosure

[01] Technical Field

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

[03] Background Art

[04] 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 US 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.

[05] Summary of Invention

[06] 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.

[07] 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.

[08] 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.

[09] 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 not generate any circumferential pressure on the limb that exceeds the enclosure pressure.

[10] 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.

[11] **Brief Description of Drawings**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[36] **Description of Embodiments and Industrial Applicability**

[37] Definitions

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

[39] Seal Location is the location of the seal junction relative to definable location, such as the plane defined by the rigid aperture.

[40] Radial Pressure is the pressure normal to the limb surface acting towards the center of the limb.

[41] 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.

[42] 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 H_2O.

[43] 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 that the pressure tolerance are not present.

[44] 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.

[45] 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.

[46] 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.

[47] Properties and Features of Example Embodiments

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

[49] 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.

[50] 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.

[51] 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.

[52] 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.

[53] 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.

[54] 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.

[55] 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.

[56] 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.

[57] System Components

[58] 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.

[59] 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.

[60] 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.

[61] 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.

[62] 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.

[63] System Operation

[64] 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.

[65] 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.

[66] 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.

[67] 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.

[68] 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.

[69] 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.

[70] 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.

[71] 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.

[72] 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.

[73] 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.

[74] 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.

[75] 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.

[76] 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.

[77] 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.

[78] **Additional Embodiments**

[79] Axial Rigidity-Based Seal System

[80] 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.

[81] 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.

[82] 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.

[83] 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.

[84] 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 then 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.

[85] FIG. 17shows 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.

[86] Variable-Sized Apertures

[87] 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.

[88] Variable Iris with Flexible Sleeve

[89] 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.

[90] 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.

[91] **Demonstration of Applications**

[92] 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 0.5mm thick, in the example 0.42 mm thick), thick silicone (between 0.5mm and 3mm thick, in the example 1.05mm 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.

[93] 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.

[94] 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.

[95] 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 cmH2O 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.

[96] 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.

Claims

We claim:

1. A sealing apparatus for use with a pressurizable enclosure accommodating a limb and subjecting the limb to varying pressures, wherein the pressurizable enclosure has an opening sized to allow ingress of a limb into the enclosure, comprising a sleeve of flexible material, configured to sealingly engage the pressure management system at the opening, wherein the sleeve has a length sufficient to engage the opening and to extend a distance along a limb within the enclosure, and can allow the distal end of the limb to extend into the enclosure without exerting pressure above a predetermined threshold on the limb when the enclosure is not pressurized relative to ambient, wherein the sleeve is flexible enough to sealingly engage the surface of the limb when the enclosure is pressurized above ambient.

2. A sealing apparatus as in claim 1, wherein the material has a non-positive angular progression at pressures relative to ambient of 30cm H_2O or more.

3. A sealing apparatus as in claim 1, wherein the flexible material 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 1, further comprising a plurality of contact sensors disposed relative to the sleeve and the pressure management system 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 1, 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 1, 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 enclosure.

7. A sealing apparatus as in claim 1, 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. A sealing apparatus as in claim 7, wherein the sleeve's thickness, material composition, density, or a combination thereof, changes from a region near the engagement with the opening to a region distal from the engagement with the opening.

10. A sealing apparatus as in claim 1, 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 1, wherein the flexible material comprises thin silicone, thick silicone, or a combination thereof.

14. A pressurizable enclosure accommodating a limb and subjecting the limb to varying pressures, having an opening sized to allow ingress of a limb into the enclosure, wherein the size of the opening can be adjusted to accommodate different sized limbs and changes in the limb due to pressure, and to surround the limb with a gap between the limb and the opening small enough that the system can maintain a predetermined pressure within the enclosure.

15. A pressure management system as in claim 14, comprising an iris aperture providing an adjustable opening by adjustment of the iris.

16. A pressurizable enclosure as in claim 14, comprising a plurality of overlapping leaves, flexibly mounted with the pressurizable enclosure such that the leaves accommodate ingress of a limb into the volume, and overlap to provide a reduced opening that approximates the size of a limb placed within the overlapping leaves.

17. A pressurizable enclosure as in any of claims 14-16, further comprising a sealing apparatus as in claim 1.

18. A pressurizable enclosure as in claim 14, further comprising a sealing apparatus as in any of claims 1-13.

19. A pressure management system comprising a sealing apparatus as in any of claims 1-13.

20. A medical instrument configured to measure a limb in conditions of pressure above ambient, comprising a pressure management system as in claim 19.

21. A method of making a measurement of a limb at a pressure above ambient, comprising providing a pressure management system as in claim 19, inserting the limb into the pressure management system, pressurizing the pressurizable enclosure, and making the measurement.

22. A sealing apparatus as in claim 1, wherein the sleeve is configured such that the limb extends past the distal end of the sleeve into the enclosure.

23. 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.

24. The limb seal apparatus of claim 23 where the seal changes its physical configuration to obtain a non-positive angular progression configuration at pressures less than 30 cm H20.

25. The limb seal apparatus of claim 23 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 23 wherein the flexible tube is attached to the enclosure and is subject to increasing axial tension due to increasing pressure.

27. The limb seal apparatus of claim 23 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 23 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 23, 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. The limb seal apparatus of claim 23, 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.

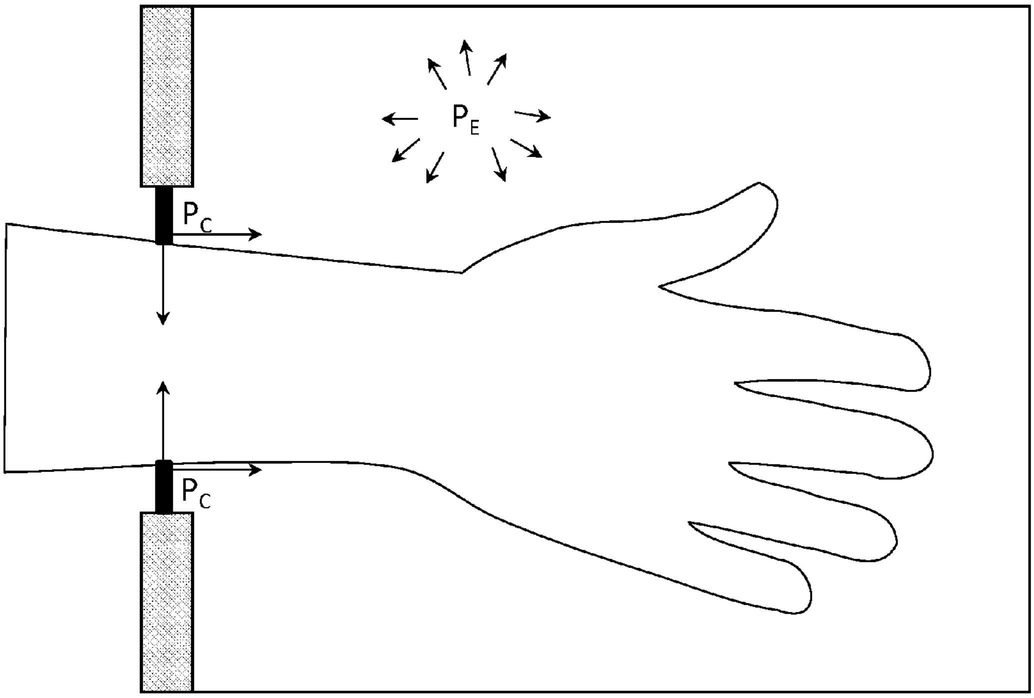
31. The limb seal apparatus of claim 30, wherein the force due to friction between the seal and the limb when the enclosure is pressurized plus the sleeve's resistance to axial deformation is less than the force on the seal due to pressure on the gap at pressures below a second predetermined threshold.

32. A limb seal apparatus for use with a pressurizable enclosure comprising:

(a) a circulate ring of fibers that allows entrance of the limb into the enclosure through the circulate ring of fibers,

(b) the circular ring of fibers comprising multiple overlapping fibers that together provide air resistance,

(c) wherein the fibers having longitudinal stiffness so as to oppose pressure forces from within the enclosure, and radial flexibility to allow entrance of the limb into the enclosure and radial flexibility to allow the fibers to form a seal about the arm when the pressure in the enclosure is above ambient.



$P_C > P_E$

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

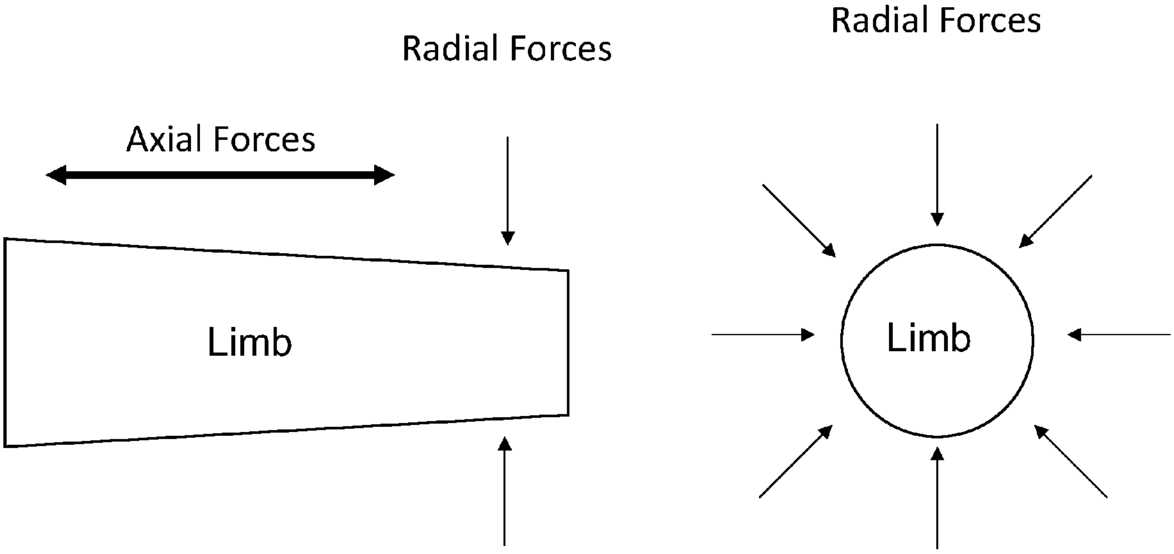


FIG. 2

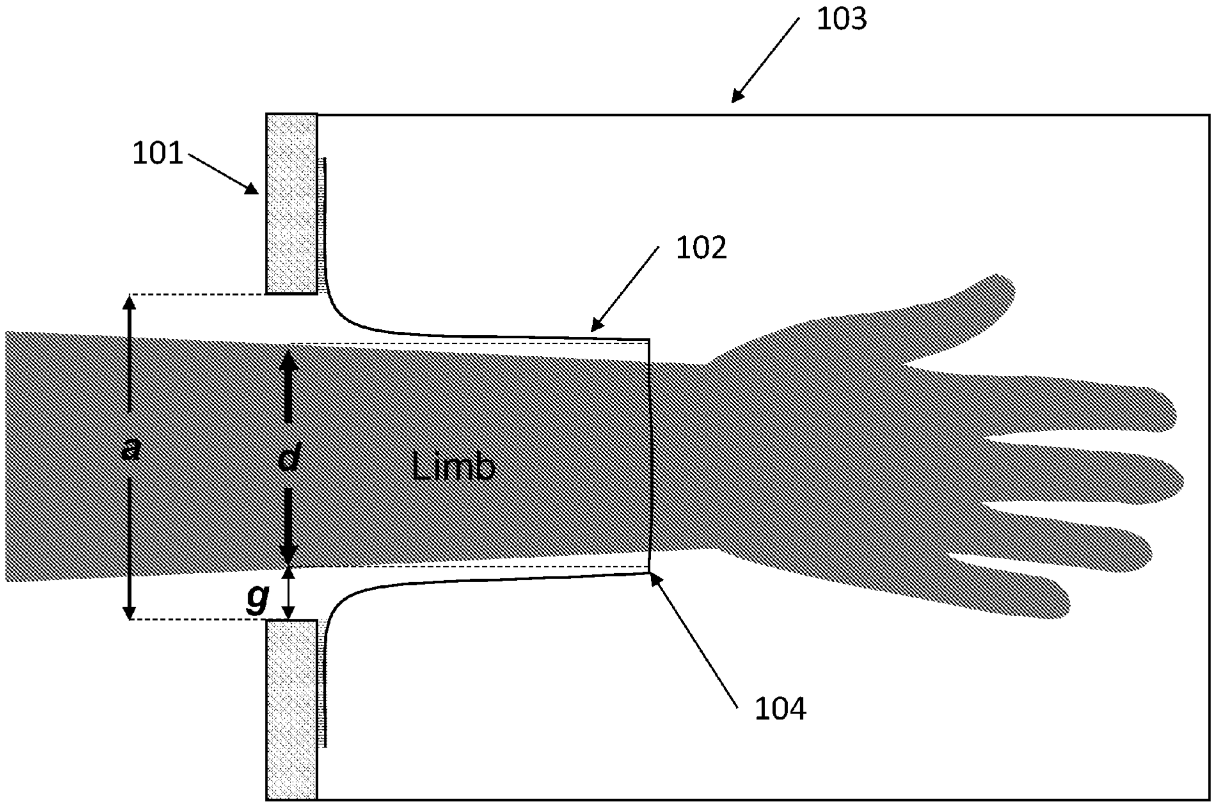


FIG. 3

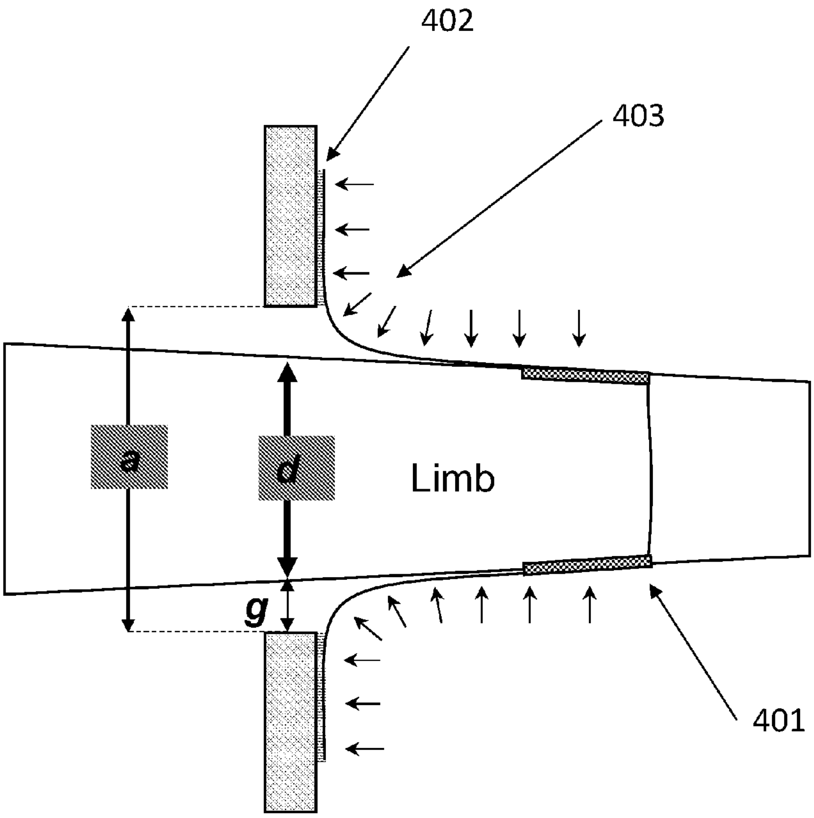
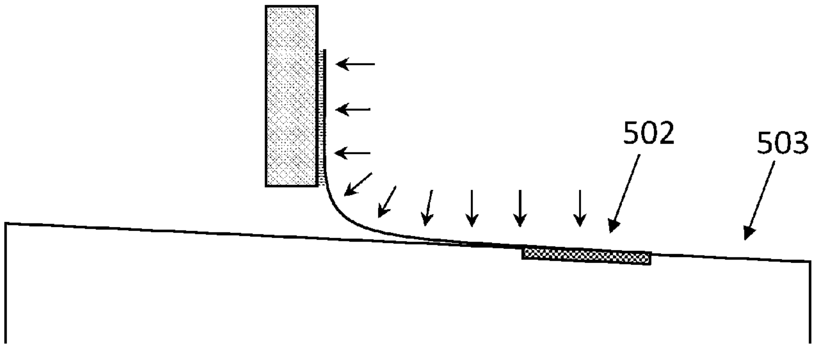
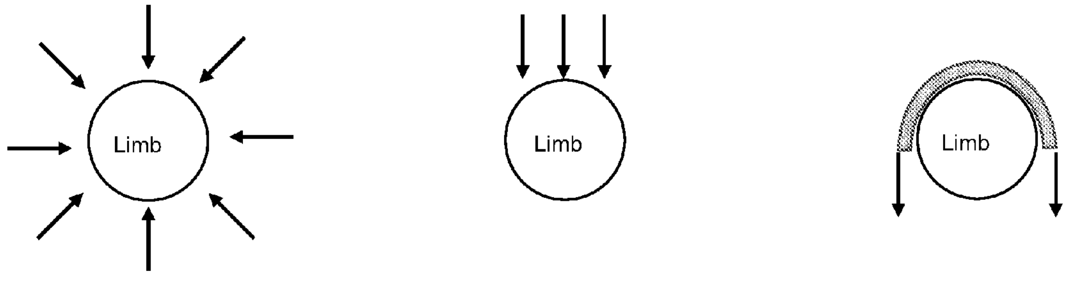


FIG. 4



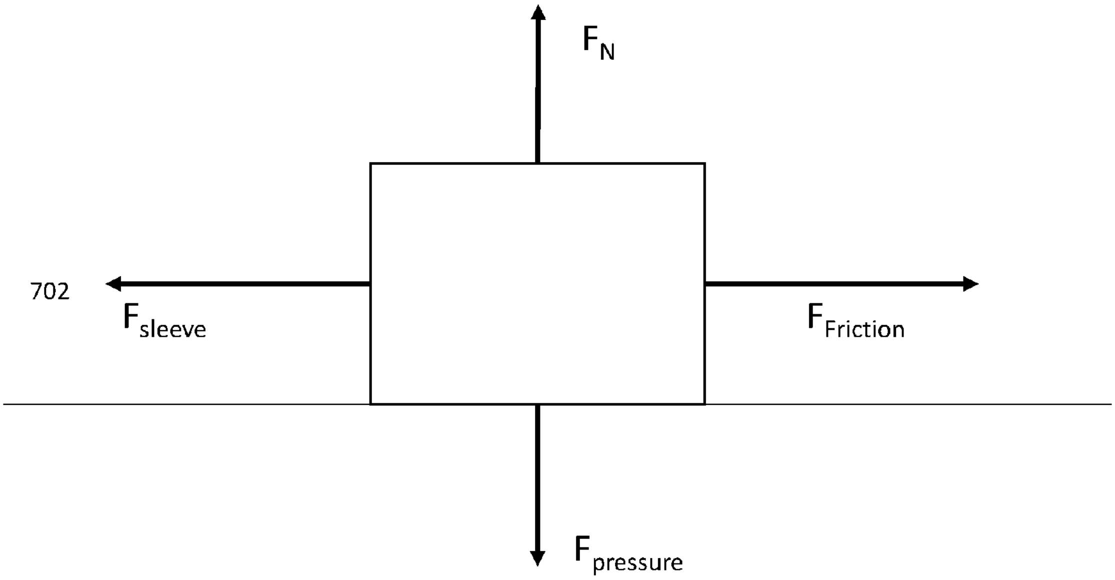
Contact Forces



Pressure Weight ≅ 0 Hoop = 0

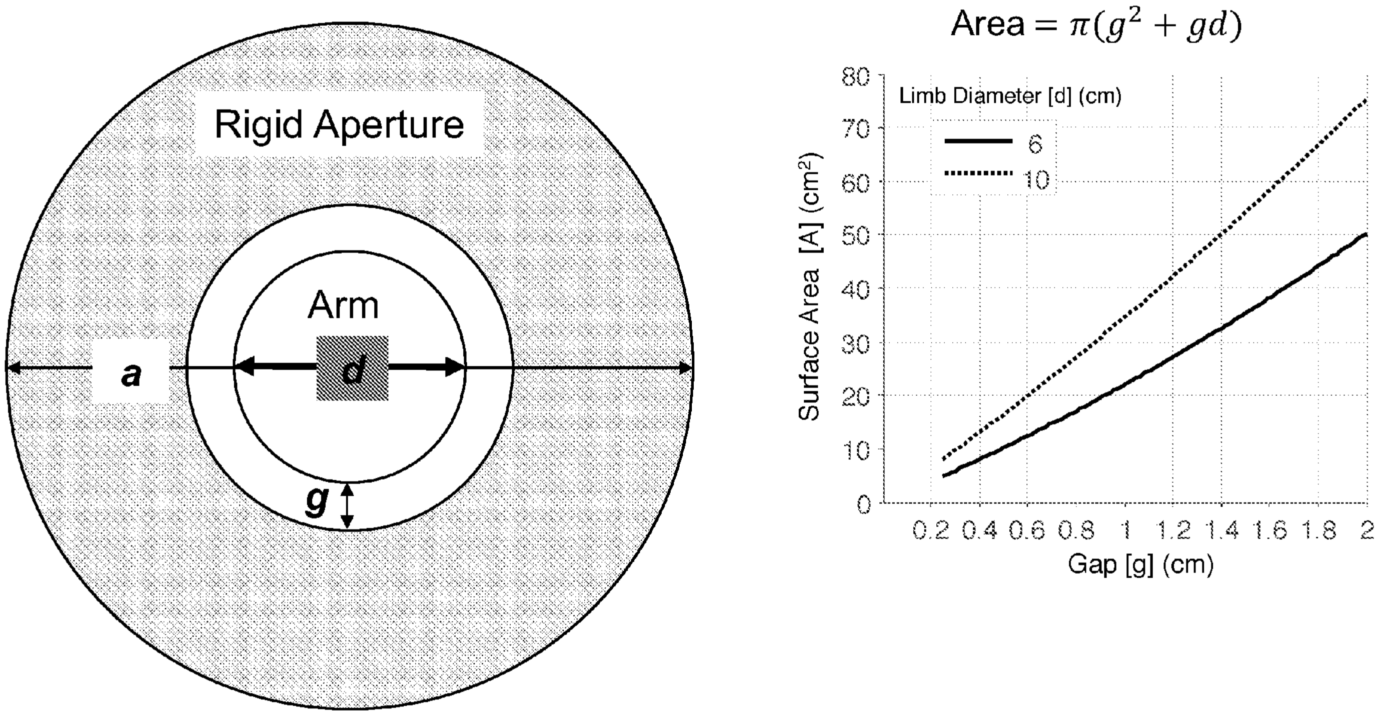
FIG. 5

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

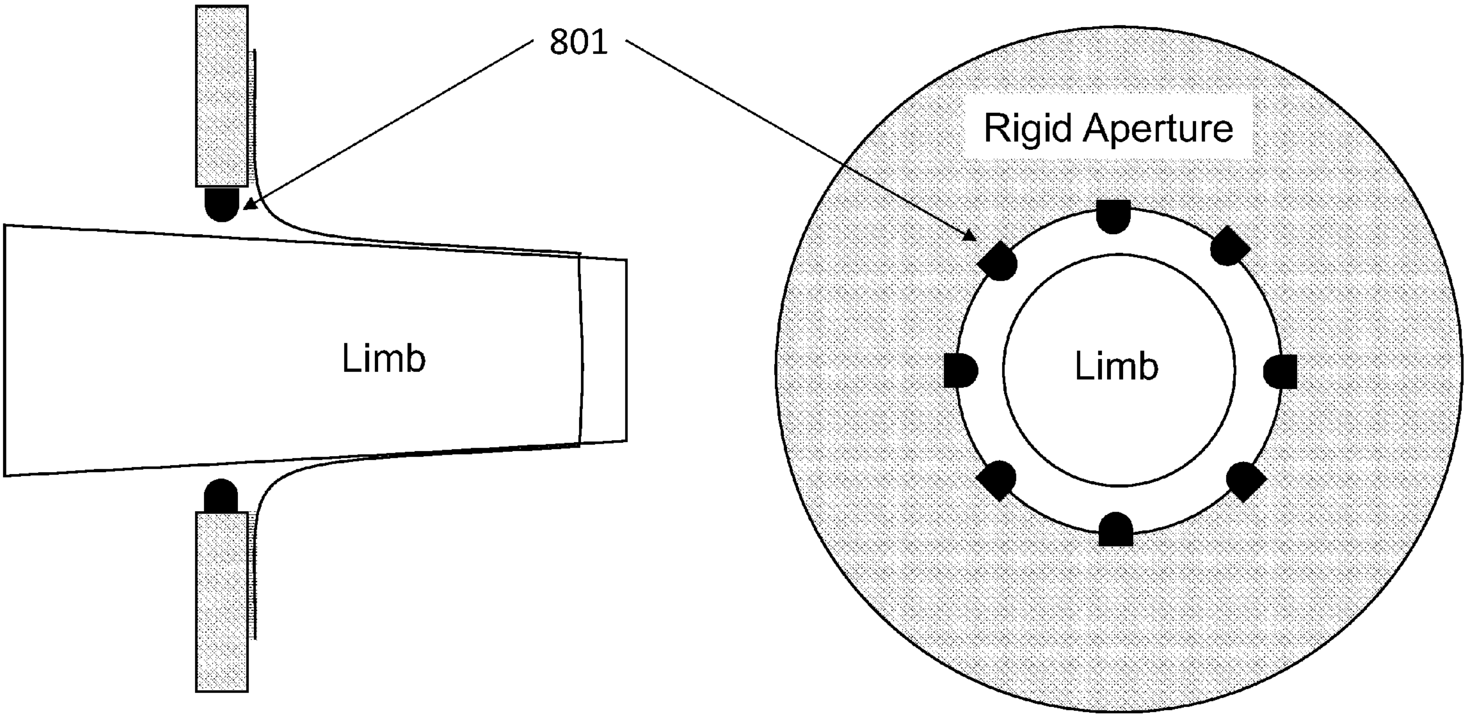


FIG. 8

Pressure Sensors

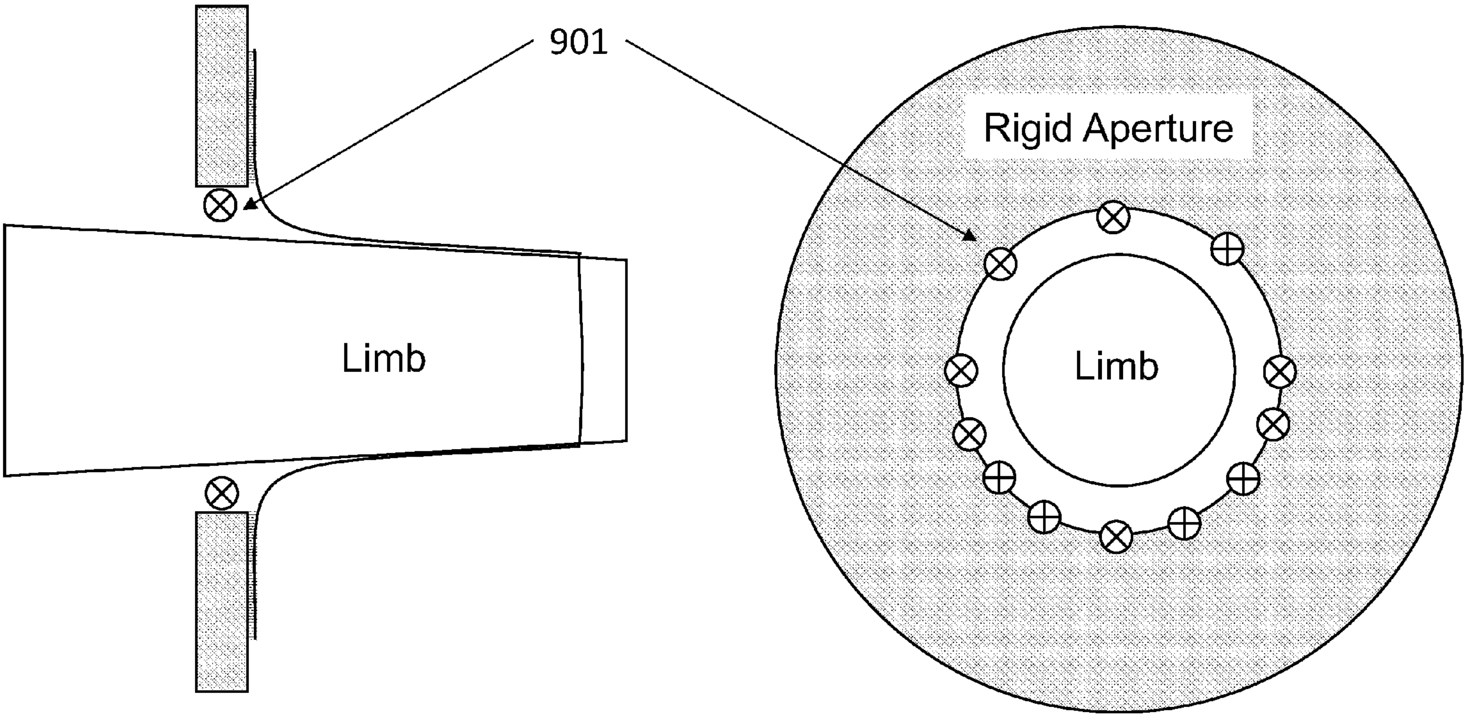


FIG. 9

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

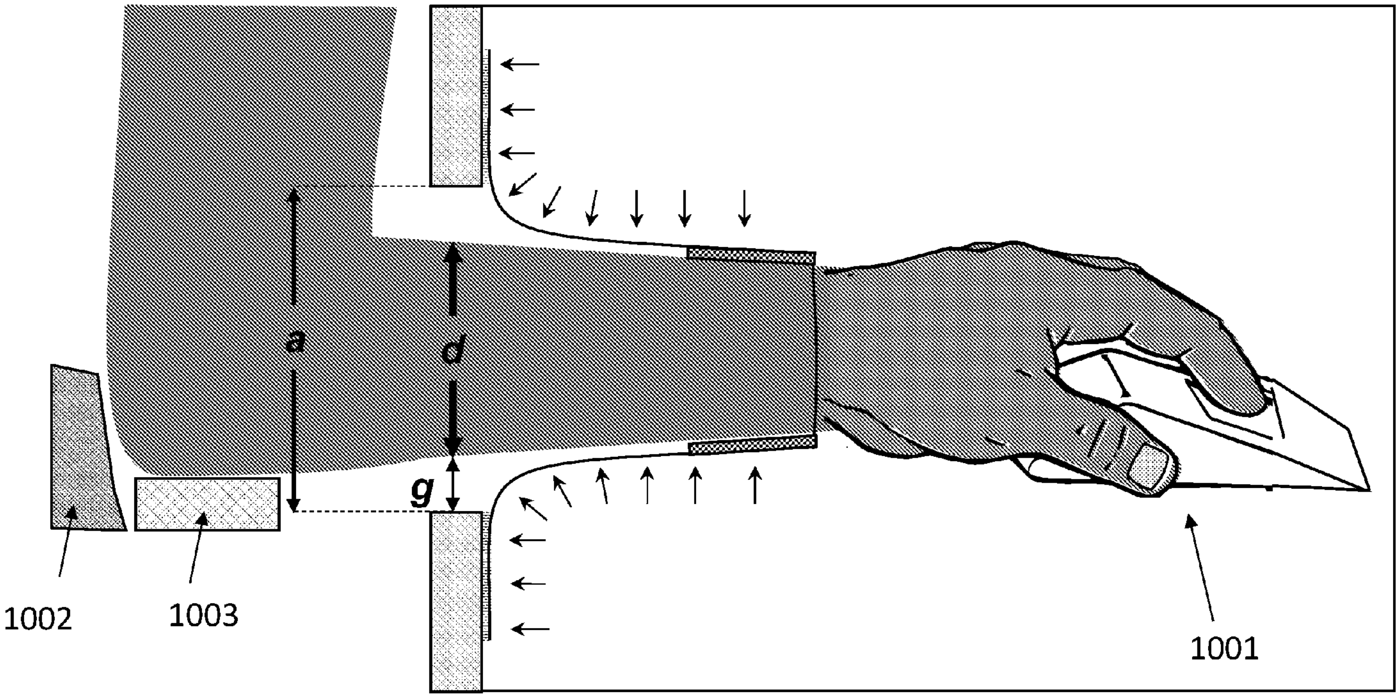


FIG. 10

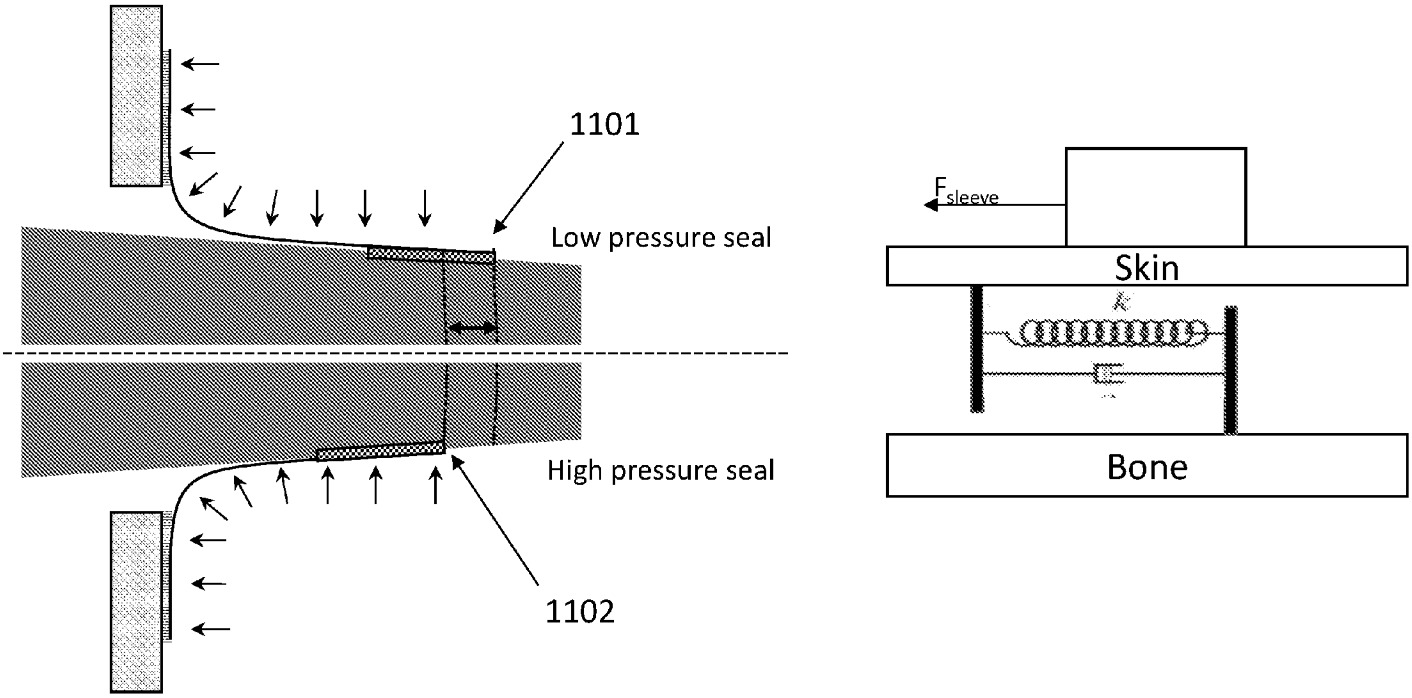

1101
Low pressure seal
High pressure seal
1102
F_sleeve
Skin
k
Bone

FIG. 11

The Importance of Fold Radius

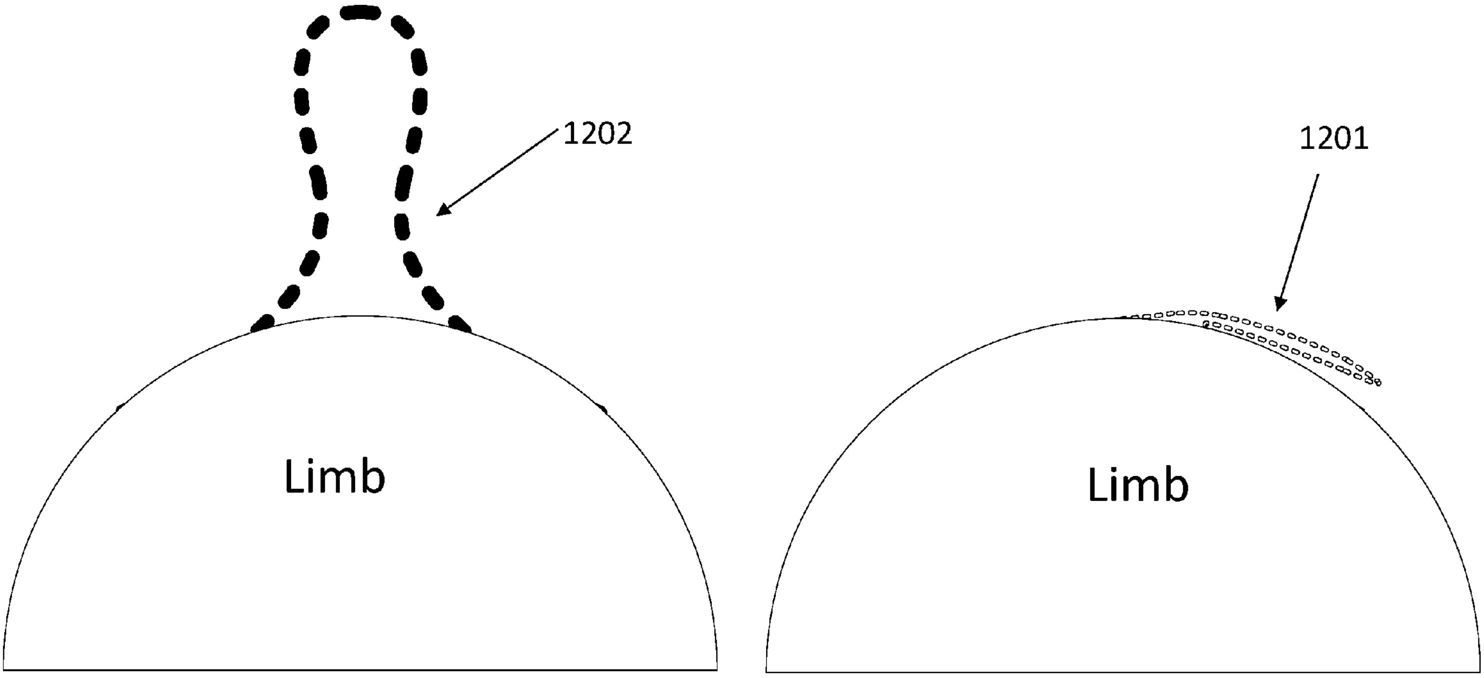


FIG. 12

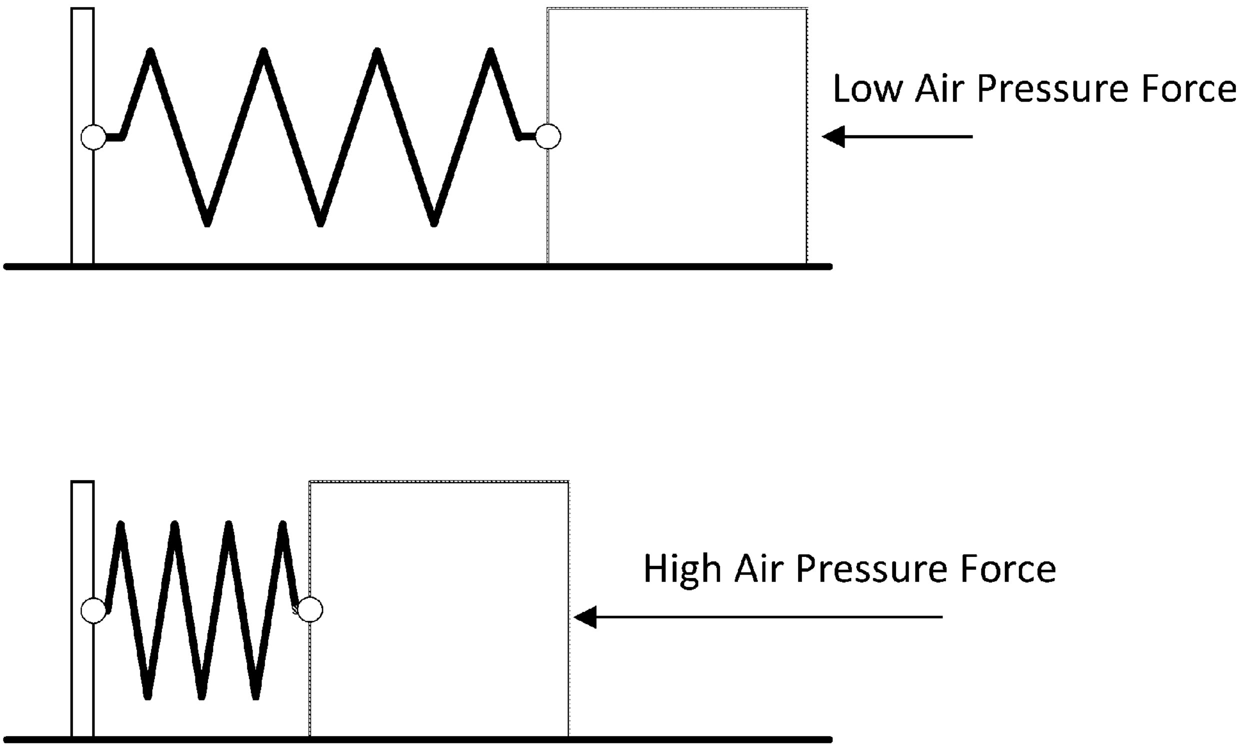


FIG. 13

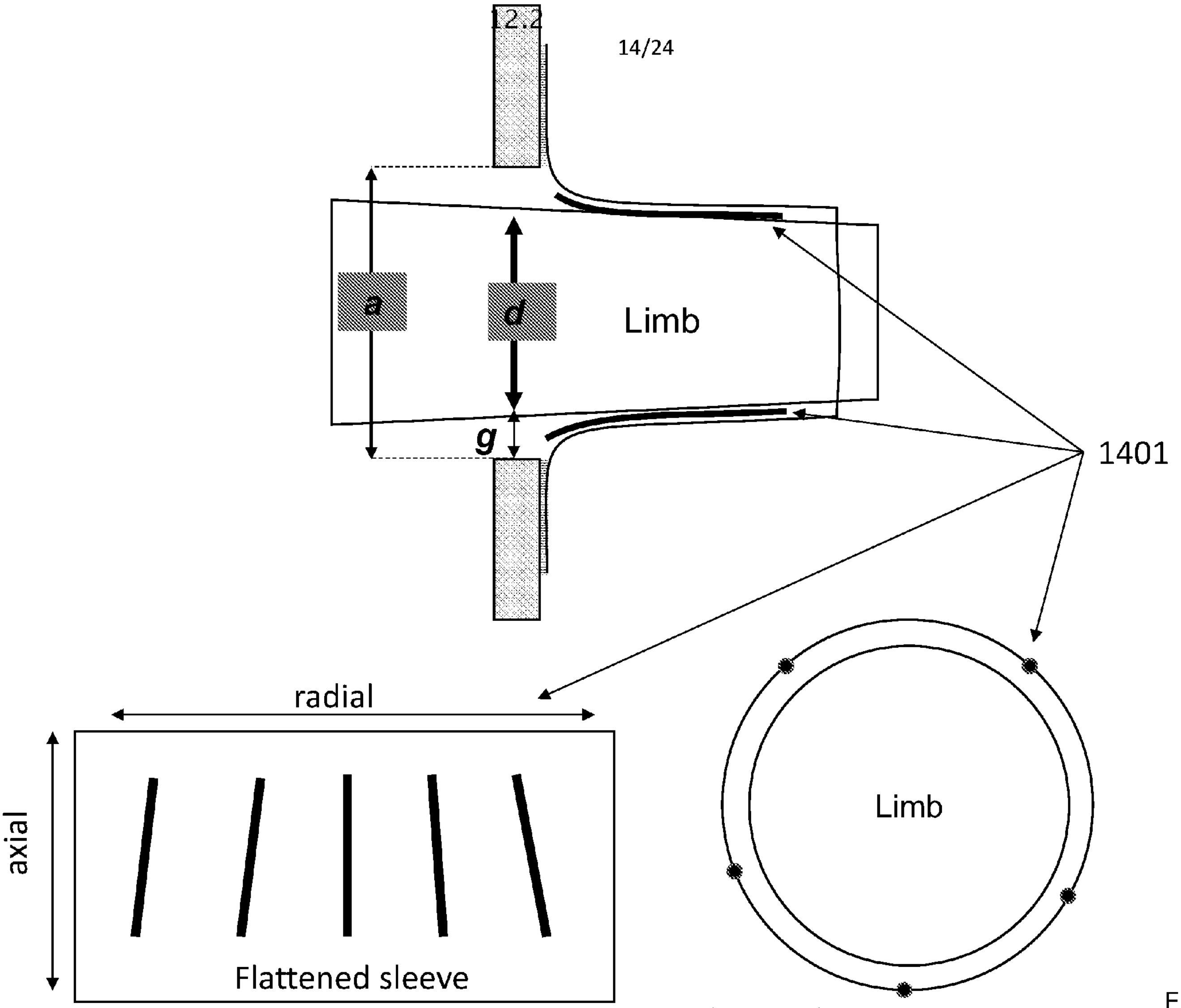


FIG. 14

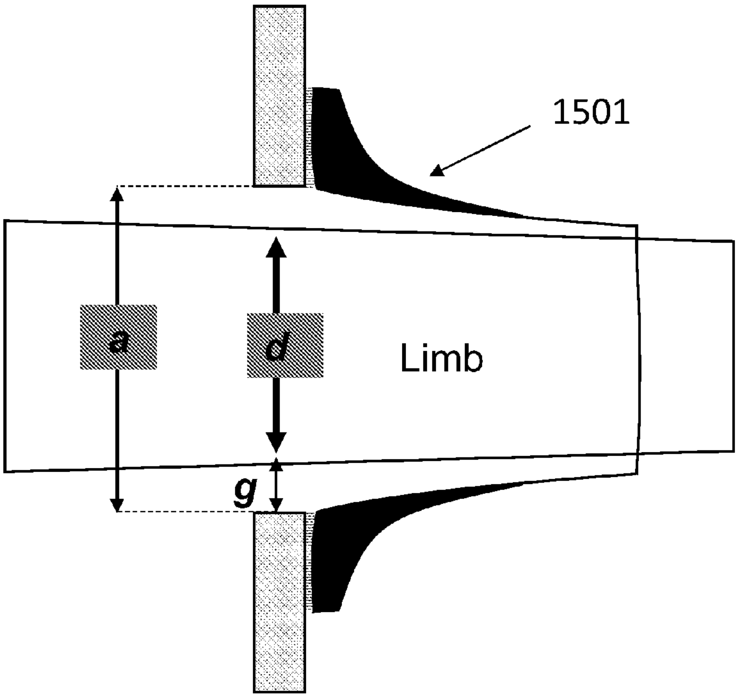


FIG. 15

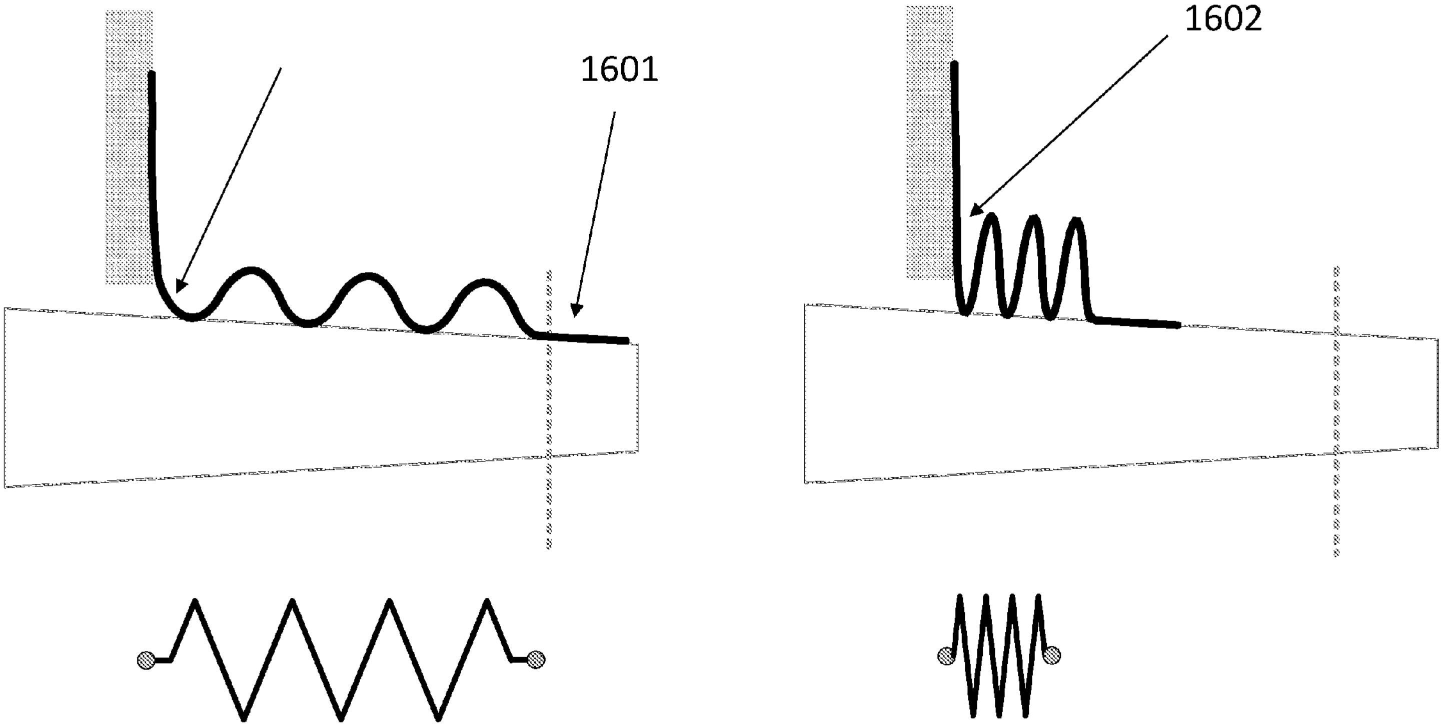
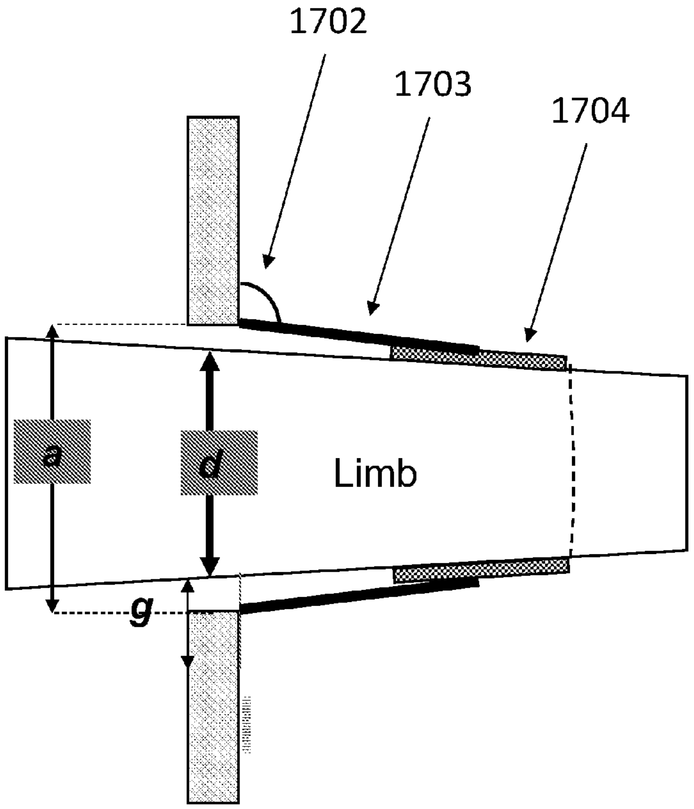


FIG. 16



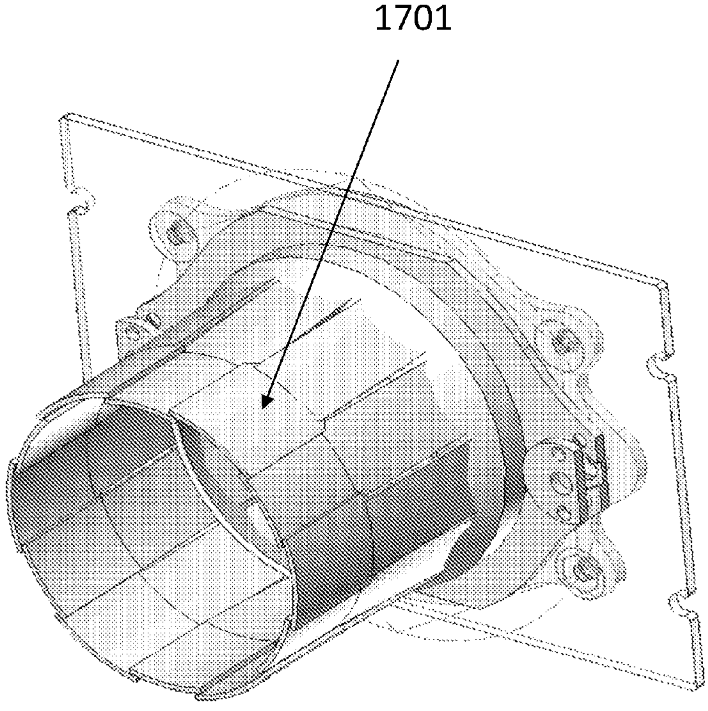
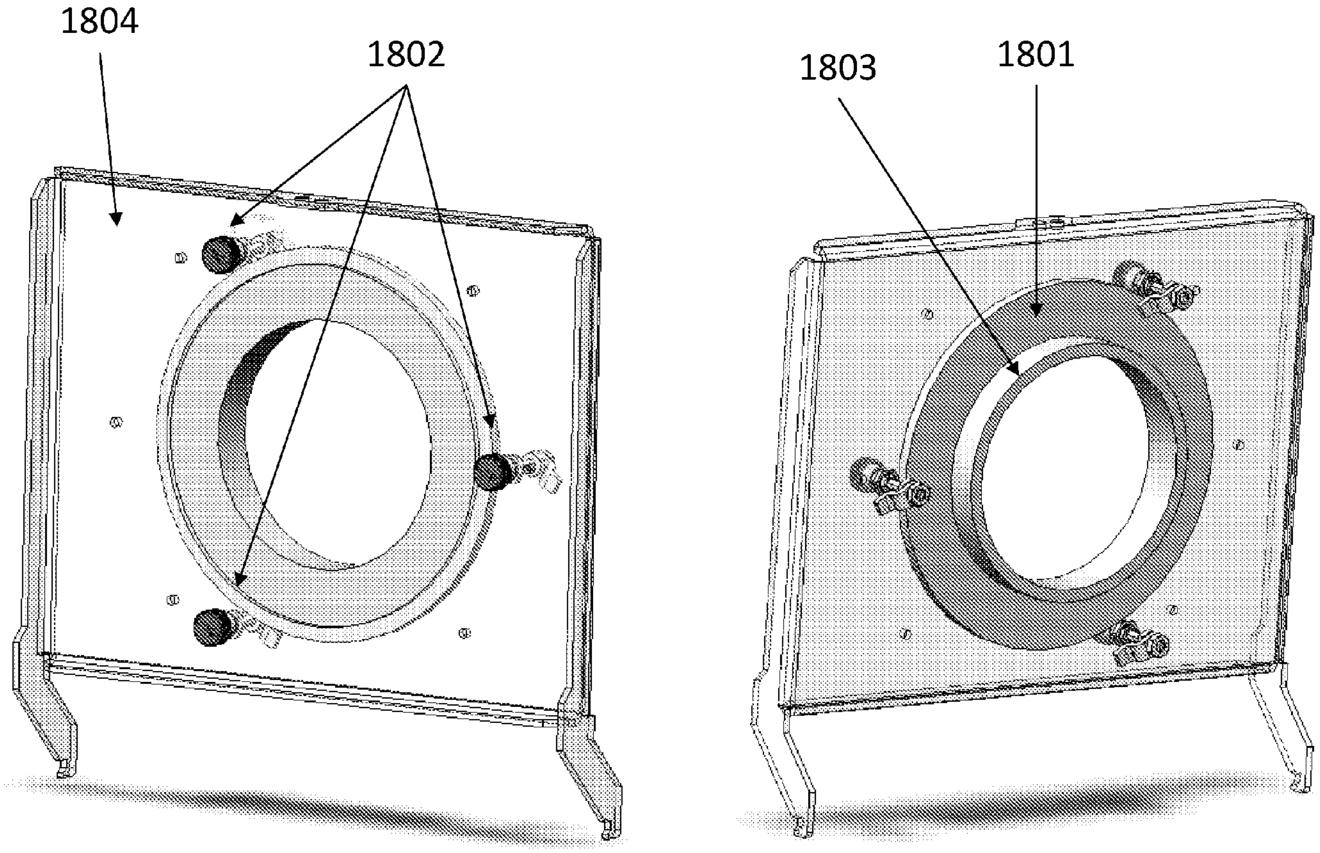


FIG. 17



Front View

Back View

FIG. 18

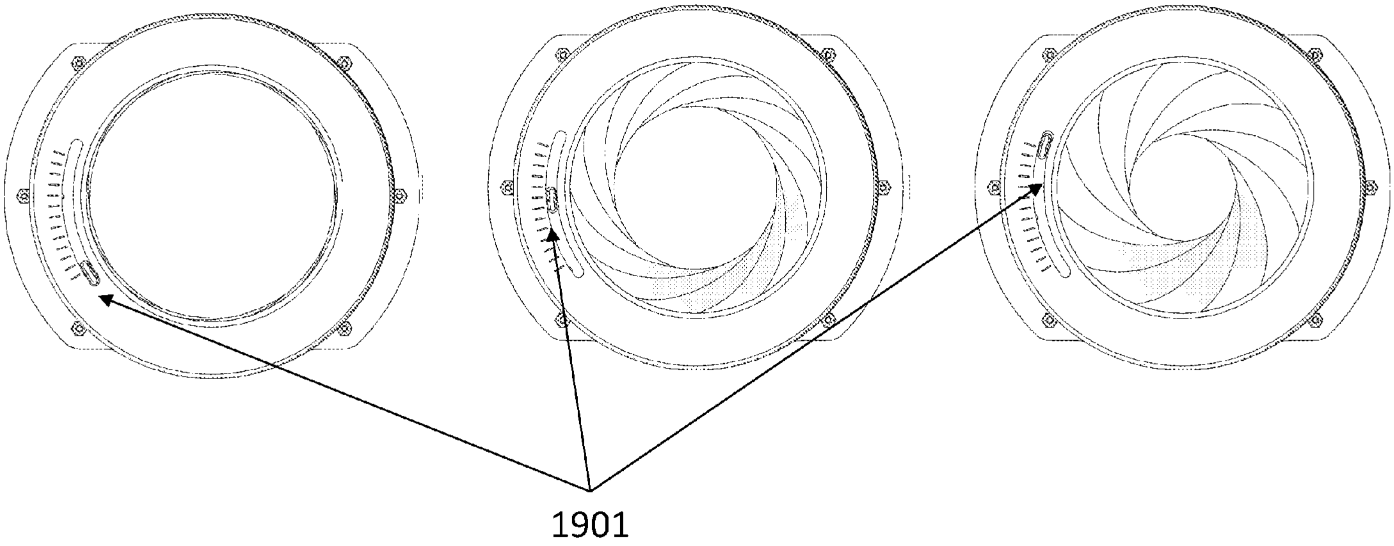


FIG. 19

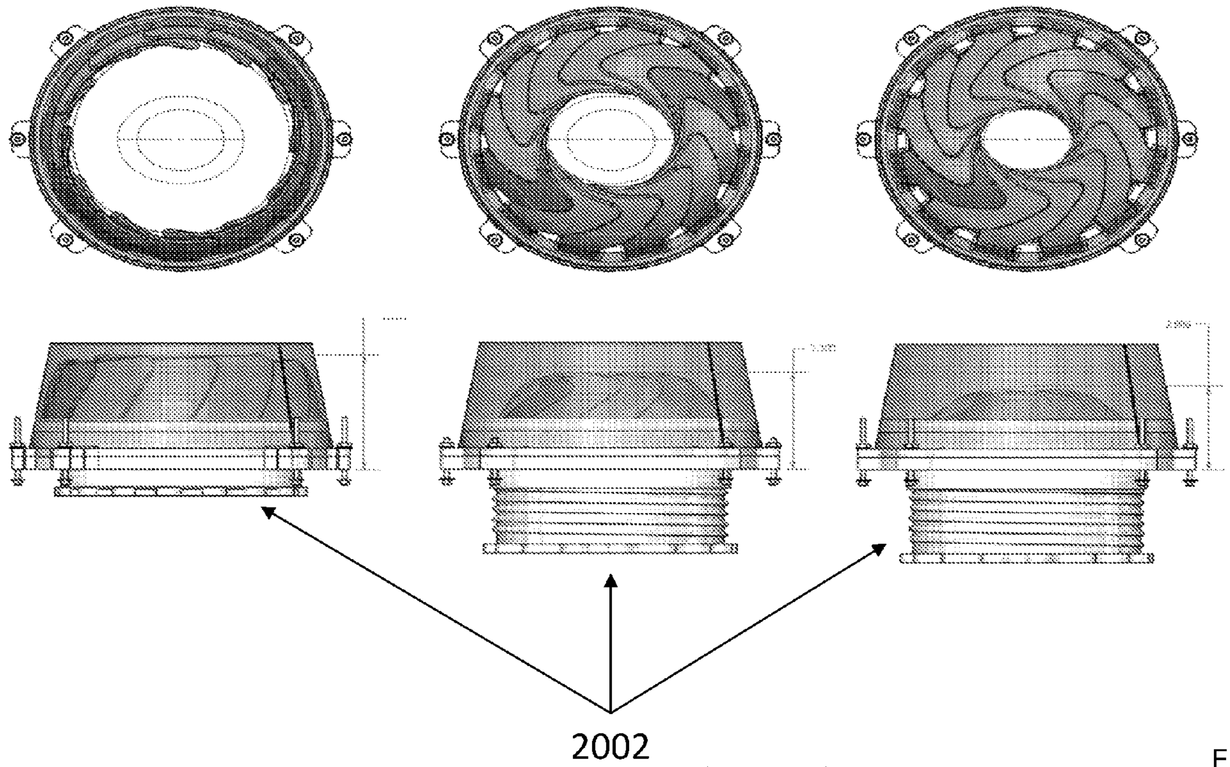


FIG. 20

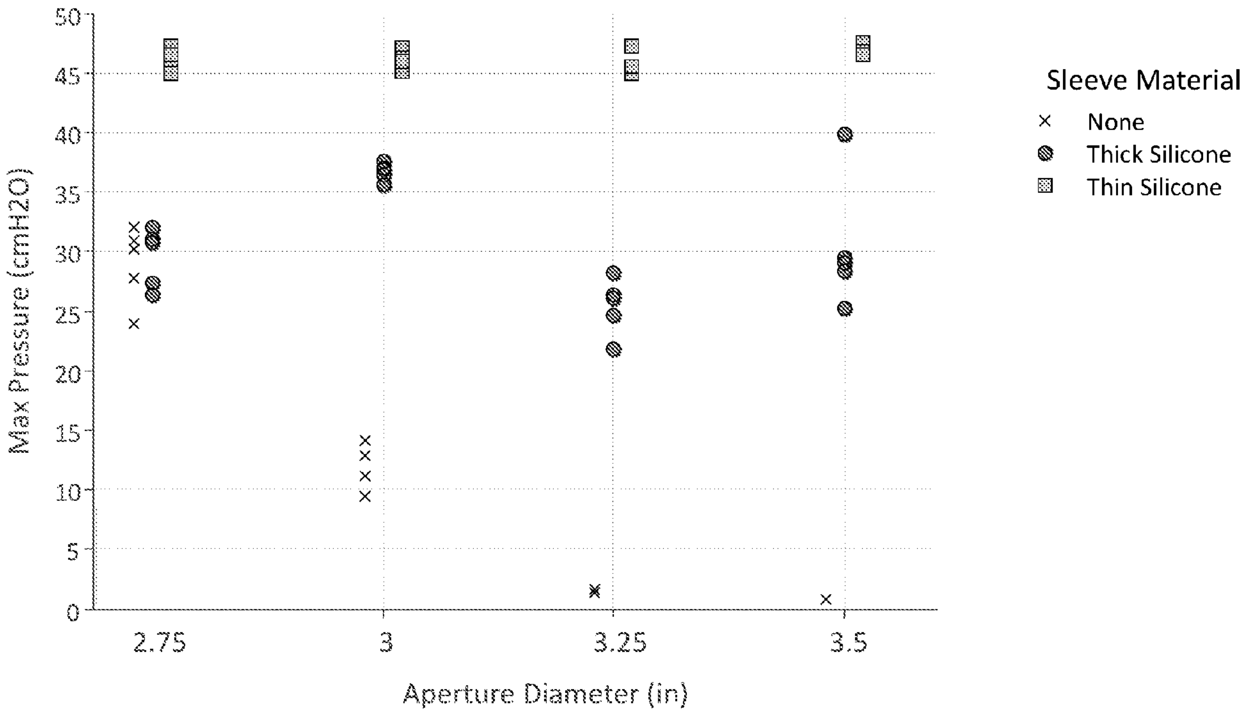

Max Pressure (cmH2O)
0
5
10
15
20
25
30
35
40
45
50
Aperture Diameter (in)
2.75
3
3.25
3.5
Sleeve Material
× None
Thick Silicone
Thin Silicone

FIG. 21

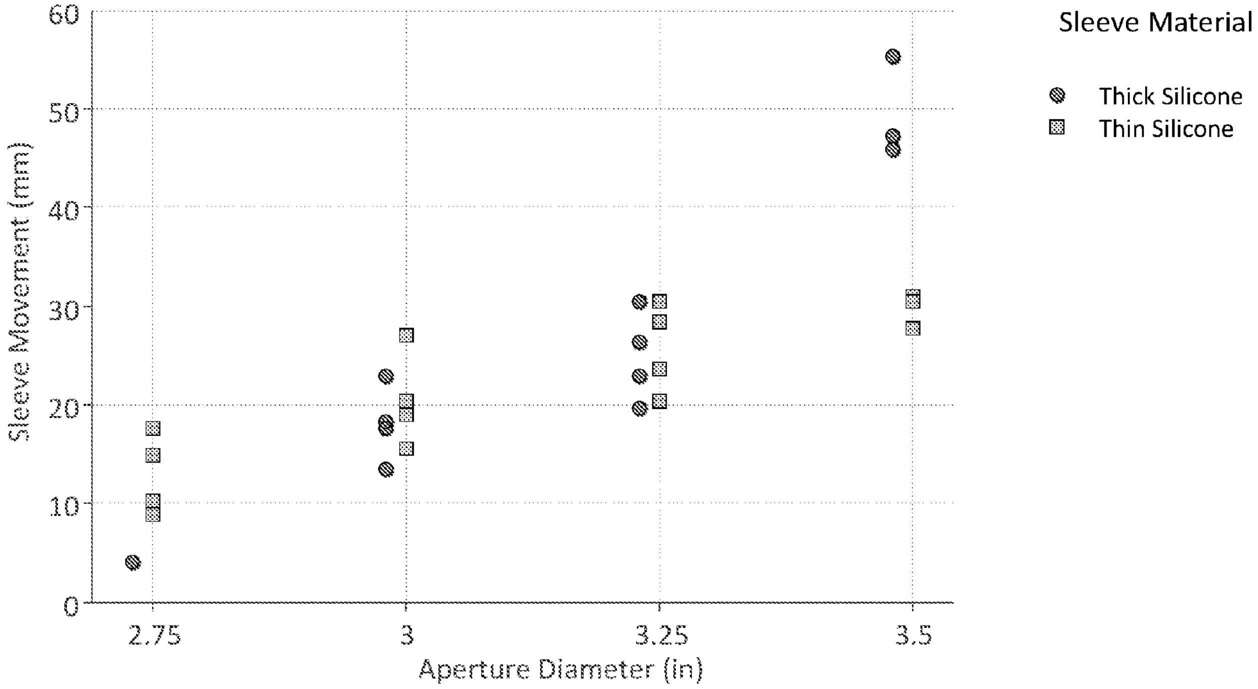

60
50
40
30
20
10
0
Sleeve Movement (mm)
2.75
3
3.25
3.5
Aperture Diameter (in)
Sleeve Material
Thick Silicone
Thin Silicone

FIG. 22

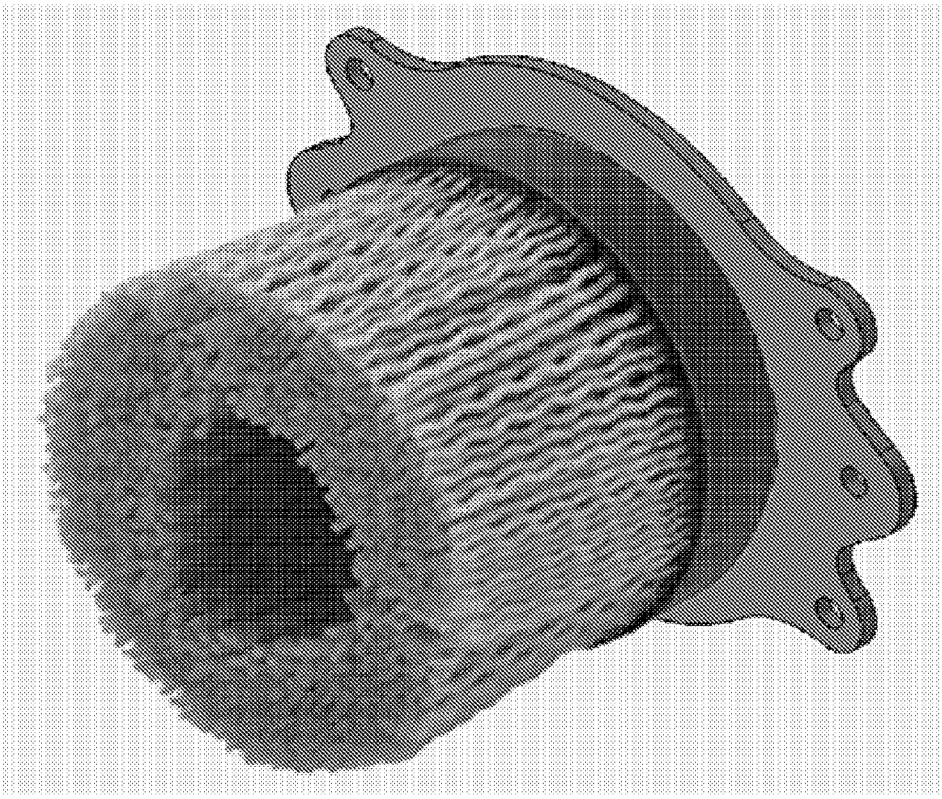


FIG. 23

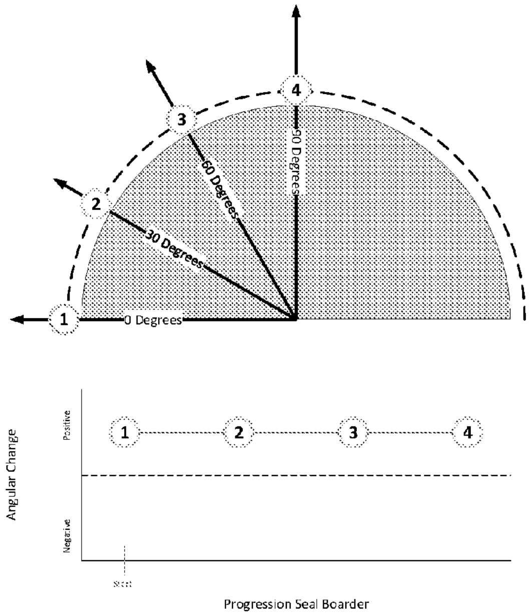


FIG. 24A

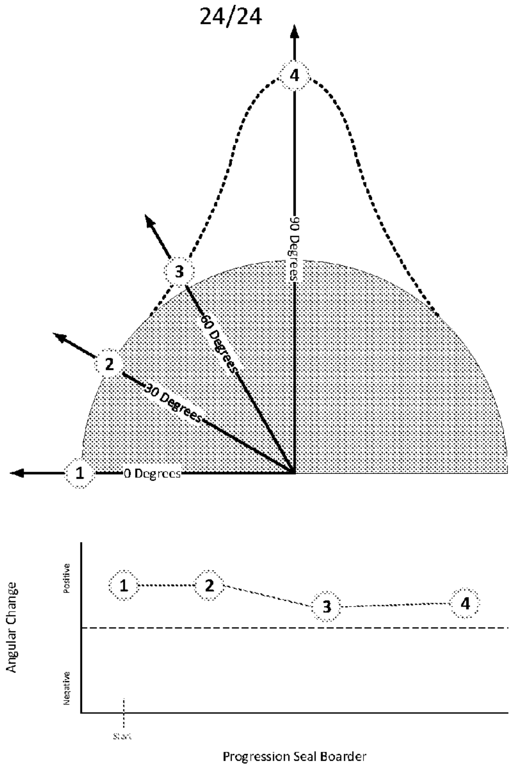


FIG. 24B

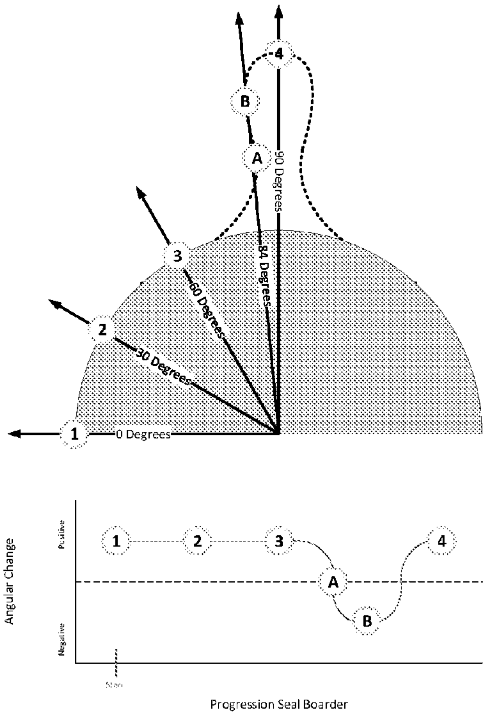


FIG. 24C

FIG. 24

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US17/62356

A. CLASSIFICATION OF SUBJECT MATTER
IPC - A61H 9/00; A61G 10/00 (2017.01)
CPC - A61H 1/008, 9/00, 9/005; A61G 10/00, 10/02, 10/023

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)
See Search History document

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/0024322 A1 (Caspers, C.) 5 February 2004; Figure 1; claim 33; paragraphs [0017]-[0018], [0024]	1-2, 14, 19/1-2, 20/19/1-2, 21/19/1-2, 23-26, 28-29
Y		3-13, 15-16, 19/3-13, 32
A		27, 30-31
Y	US 2013/0184624 A1 (Otivio AS) 18 July 2013; paragraph [0088]	3, 13, 19/3, 19/13, 20/19/3, 20/19/13, 21/19/3, 21/19/13
Y	US 2007/0249977 A1 (Bonnefin, W. et. al.) 25 October 2007; Figure 4; claim 19	4, 19/4, 20/19/4, 21/19/4
Y	US 2009/0126727 A1 (Loori, P. et. al.) 21 May 2009; paragraphs [0033], [0050]	5, 19/5, 20/19/5, 21/19/5
A		27, 30-31
Y	US 4003371 A (Fischer, B.) 18 January 1977; Figures 4-5; column 2, lines 44-51	6-9, 19/6-9, 20/19/6-9, 21/19/6-9
A		27, 30-31

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" 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)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" 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
"X" 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
"Y" 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

Date of the actual completion of the international search 11 January 2017 (11.01.2017)	Date of mailing of the international search report 30 JAN 2018
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US17/62356

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5688225 A (Walker, J.) 18 November 1997; Figure 1; column 7, lines 1-7	10-12, 19/10-12, 20/19//10-12, 21/19/10-12, 22
Y	US 2663467 A (Douglass, W. et. al.) 19 July 1947; Figures 4-6; column 1, lines 28-33	15
Y	US 3712298 A (Snowdon, C. et. al.) 23 January 1973; Figures 2-4	16
Y	US 2004/0111047 A1 (Reid, T.) 10 June 2004; paragraphs [0057]; claim 1	32

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US17/62356

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 17-18
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.