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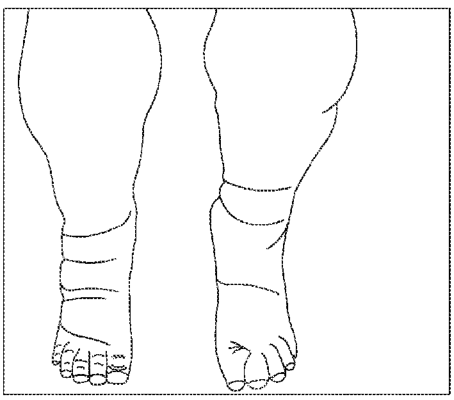
(54) **Title:** EXOSKELETAL FLUID CIRCULATION DEVICE

(57) **Abstract:** A fluid circulation device for treating edema of a patient's body limb includes a flexible sleeve having at least one wire and defining a passage for receiving at least a portion of a body limb. At least one motor adjusts tension on the at least one wire for controlling a degree of compression of the sleeve on the at least one portion of the limb.



PRIOR ART

FIG. 1A

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EXOSKELETAL FLUID CIRCULATION DEVICE

RELATED APPLICATION

[0001] This application claims priority from U.S. Provisional Application No. 63/587,568, filed October 3, 2023, the subject matter of which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present invention relates generally to a fluid circulation device and, in particular, is directed to an exoskeletal, motor-driven, adjustable compression sleeve for treating fluid circulation disorders, such as edema.

BACKGROUND

[0003] During chronic venous insufficiency (CVI), deoxygenated blood is not returned from the extremities to the heart due to valvular incompetence. This can lead to venous hypertension and pooling of the blood in lower extremities. Over time, venous hypertension can lead to a condition known as phlebolymphedema, which is a secondary type of lymphedema where the accumulation of fluid associated with CVI is not completely removed by the overburdened lymphatic system, leading to pain and extreme swelling of lower limbs (*see* Fig. 1A).

[0004] Edema results from the outflow of proteins through the permeabilized vascular lining along with attraction of water into the interstitial space, ultimately resulting in reduced mobility of the joints. Disturbances in the circulation of the vascular and lymphatic system leave patients vulnerable to recurrent infections, and/or skin complications, such as statis dermatitis or lipodermatosclerosis. Patients with lymphedemia therefore experience poor, health-related quality of life and/or compromised functional independence, thereby making them unable to be productive members of society, and at times losing their professions.

[0005] CVI and venous hypertension can be caused by many factors, such as thrombosis, surgery, obesity, edema-related side effects of certain medications and/or cardiac problems – all of which are further confounded in the aging population. As a result of these factors, CVI is prevalent in an estimated 5-7% of the population above 50 years of age, which is equivalent to 6M individuals. It is reported that 10% of CVI patients develop lymphedemia and, thus, in the U.S alone 600,000 patients can be estimated to be affected by the condition. When lymphedemia is not managed effectively, it may result in venous leg ulcers with an associated cost of ~$16k/year/patient. Hospitalizations of lymphedema alone have an economic burden of $1.4B. It is reported that 10% of lymphedema patients are in the lymphedemia category.

[0006] Complete decongestive therapy, or wearable intermittent pressure compression devices are two common methods that are employed to manage lymphedemia and are often implemented together in a patient's treatment plan. The current standard treatment protocol for lymphedema is complete decongestive therapy (CDT), which has an acute phase and maintenance phase. The acute treatment phase lasts for 2-4 weeks with a certified lymphedema therapist who performs manual drainage massages and guides patients through exercises that target stimulating lymph flow. Manual drainage massage therapy (MDT) is a crucial step of CDT as it most effectively promotes lymphatic flow to reduce swelling. The therapist also helps patients apply compression bandaging that acts as a support for the muscles to expand against during contractions, translating that force onto the lymphatic system. Bandaging may be applied anywhere from 2 to 8 weeks, depending on the degree of reduction of the swelling with respect to the baseline. To track progression, the therapist takes weekly measurements of the affected limbs.

[0007] As lymphedemia is a lifelong condition, the second phase consists of the same elements as the first phase, with the inclusion of compression garments for maintenance. Currently, many health insurance policies, including Medicare, cover the cost of the treatments associated with CDT. Compliance with the treatment regimen, however, is a cumbersome process to the patient and can be cost-prohibitive, especially if treatment sessions need repeating to combat the return of swelling.

[0008] MDT helps relieve the overburdened lymphatic network; however, it may not address the key contributor of the disease which is insufficient venous outflow. Many patients are treated with wearable pneumatic devices that apply compression in a peristalsis motion. These devices are sometimes used as part of the CDT process to replace the MDT step, with an intent to increase patient compliance by facilitating at-home drainage of the limb.

[0009] One example device is a pneumatic, intermittent pressure compression therapy (IPC) device that consists of a pump, garment, and tubings that are connecting the pump to the garment (Fig. 1B). I n use, the air pump sequentially inflates and deflates the chambers within the garment to promote flow in the venous and lymph networks. The inflatable garment typically includes fillable air compartments oriented perpendicular to the lymphatic system that has clinically shown to reduce chronic swelling. The major drawback of IPC systems is their bulkiness, which limits the portability of the system, in turn also limiting patient compliance and preventing use outside of the home setting. The use of IPC devices is recommended to complement the CDT process; however, their widespread use is limited by cost.

[0010] There is therefore a need for a more portable, easier to wear, and more affordable device to treat lymphedemia specifically that is suitable for use by the patient, in and outside home. Fulfilling this need would improve patient compliance, increase treatment effectiveness, and reduce healthcare delivery costs.

SUMMARY

[0011] The present invention relates generally to a fluid circulation device and, in particular, is directed to an exoskeletal, motor-driven, adjustable compression sleeve for treating fluid circulation disorders, such as edema. The exoskeletal fluid circulation device need not be tethered to an outside module, thereby providing a portable edema treatment device that can allow a patient to wear it and walk around, easily transport during travel or carry the device between work and home as needed. This provides an advantage over existing IPCs, which generate compression using pneumatic pumps that are tethered externally to the garment. To this end, the exoskeletal fluid circulation device utilizes a servo motor network integrated into a wearable metamaterial fabric, thereby eliminating the tubing tether and the main pump unit.

[0012] Mechanical metamaterials, such as shown in Figs. 2A-2C, are engineered structures of which mechanical properties primarily originate from a repeating pattern of unit-cells. Lattice-based metamaterials enable designers to create porous media with unconventional mechanical behaviors that fall outside of standard materials, such as lateral expansion under tension. A honeycomb structure is a well-known lattice-based metamaterial that was previously used in passive load-bearing and small-amplitude deformation applications such as impact-resistant packaging or vibration damping. Example metamaterial structures, including nodal honeycomb, are shown in Figs. 2A-2C and more fully described in

U.S. Patent Application Serial No. 18/613,999, filed March 22, 2024, the entirety of which is incorporated by reference herein.

[0013] The servo motor network is formed by lightweight motors powered by a cell-phone-sized, low voltage battery that further augments portability. The distributed and coordinated actuation of the servo motors can be controlled and optimized to enable execution of a peristalsis motion that will promote venous flow through the affected limb while minimizing backflow.

[0014] Moreover, a servo motor is much faster than pneumatic inflation/deflation and can deliver the drainage regimen within a shorter time frame per session than existing treatment regimens that can last 1 hour/session. In particular, compared to the pneumatic approach, servo motors offer fast response, more precise control, and greater efficiency of power consumption.

[0015] Operational principles, manufacturing, and components of the exoskeletal fluid circulation device cumulatively result in a more affordable system than existing technologies, thereby increasing the utilization of the device and increasing accessibility to patients from underprivileged communities who cannot afford adequate treatment.

[0016] In one example, a fluid circulation device for treating edema of a patient's body limb includes a flexible sleeve having at least one wire and defining a passage for receiving at least a portion of a body limb. At least one motor adjusts tension on the at least one wire for controlling a degree of compression of the sleeve on the at least one portion of the limb.

[0017] In another example, a fluid circulation device for treating edema includes a flexible sleeve defining a passage for receiving at least a portion of a patient's body limb. The flexible sleeve includes rigid connectors arranged in multiple rows about a circumference of the sleeve. Ligaments connect the rigid connectors to one another and extend transverse to a centerline of the sleeve. Wires are coupled to the rigid connectors in the same row. Motors are connected to each respective wire for independently varying tension on the respective wire for controlling a degree of compression of the sleeve on the at least one portion of the body limb.

[0018] In another example, a method for treating edema of a patient's body limb includes positioning a flexible sleeve that includes at least one wire over at least a portion of a body limb. At least one motor provided on the sleeve and connected to the at least one wire is actuated for adjusting tension on the at least one wire for controlling a degree of compression of the sleeve on the at least one portion of the limb.

[0019] In another aspect of the invention, the sleeve further includes a series of rigid connectors and flexible ligaments that cooperate to define an exoskeletal lattice connected to the at least one wire.

[0020] In another aspect of the invention, the sleeve extends along a centerline and the ligaments extend between the rigid connectors and transverse to the centerline.

[0021] In another aspect of the invention, the rigid connectors are arranged in a series of rows extending circumferentially about the centerline and columns extending parallel to the centerline.

[0022] In another aspect of the invention, the flexible ligaments interconnect the rigid connectors in different rows from one another.

[0023] In another aspect of the invention, the flexible ligaments are connected to corners of diagonally opposed rigid connectors and cross one another between different pairs of the rigid connectors.

[0024] In another aspect of the invention, the at least one wire comprises a plurality of wires, with each wire being connected to the rigid connectors arranged in the same rows about the circumference of the sleeve.

[0025] In another aspect of the invention, the at least one motor is connected to the wires for varying the tension in the wires about the circumference of the sleeve for controlling the degree of compression of the sleeve on the at least a portion of the limb.

[0026] In another aspect of the invention, the at least one motor comprises a plurality of motors each associated with one of the respective wires for independently varying the tension in each of the wires about the circumference of the sleeve for controlling the degree of compression of the sleeve on the at least portion of the limb.

[0027] In another aspect of the invention, a controller is connected to the at least one motor for controlling the at least one motor.

[0028] In another aspect of the invention, the controller controls the motors for generating a salvo of contractions in a pre-programmed fashion to drive accumulated fluid in the limb in a specific direction to reduce fluid volume in the limb.

[0029] In another aspect of the invention, the fluid circulation device is configured for placement on a patient's foot, leg, hand or arm.

[0030] In another aspect of the invention, at least one pressure sensor connected to the controller for monitoring the degree of compression of the sleeve on the at least one portion of the limb such that the controller is configured to control operation of the motors in response to signals received from the at least one pressure sensor.

[0031] In another aspect of the invention, the sleeve includes a plurality of wires and a plurality of motors associated therewith and the step of actuating the at least one motor comprises individually actuating the motors for independently varying the tension in each of the wires about the circumference of the sleeve for controlling the degree of compression of the sleeve on the at least portion of the limb.

[0032] In another aspect of the invention, the degree of compression of the sleeve on the at least one portion of the limb is monitored and the tension on at least one of the wires is adjusted in response thereto.

[0033] In another aspect of the invention, the degree of compression of the sleeve is monitored in a feedback loop between pressure sensors associated with each of the wires and a controller connected to the motors for controlling actuation thereof.

[0034] In another aspect of the invention, tension in the at least one wire is automatically adjusted in response input from a user.

[0035]

[0036] Other objects and advantages and a fuller understanding of the invention will be had from the following detailed description and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0037] Fig. 1A is a photograph illustrating swelling in a patient's legs due to lymphedemia.

[0038] Fig. 1B is a photograph illustrating a patient using an existing edema mitigation system.

[0039] Fig. 2A is a schematic illustrations of example tubular lattice metamaterial structures.

[0040] Fig. 2B is a schematic illustrations of another example tubular lattice metamaterial structure.

[0041] Fig. 2C is a schematic illustrations of another example tubular lattice metamaterial structure.

[0042] Fig. 3A is a schematic illustration of one example edema mitigation device in accordance with the present invention.

[0043] Fig. 3B is a schematic illustration of the nodal arrangement of a sleeve of the device of Fig. 3A.

[0044] Fig. 3C is a schematic illustration of a sleeve of the device rolled into a tube.

[0045] Fig. 4A is a photograph of the sleeve provided on a calf of a patient.

[0046] Fig. 4B is a schematic illustration of the device Fig. 3A during use on a calf of a patient.

[0047] Fig. 4C is a schematic illustration of an example display for the device.

[0048] Fig. 4D is a schematic illustration of an example user interface for the device.

[0049] Fig. 5 is a schematic illustration of multiples device from Fig. 3A during use on both a thigh and a calf of a patient.

DETAILED DESCRIPTION

[0050] The present invention relates generally to an exoskeletal fluid circulation device and system, and, in particular, to a motor-driven, adjustable compression sleeve for treating edema. The device can be constructed as a wearable, metamaterial fabric sleeve formed from a lattice-based material, such as classical or nodal honeycomb patterned mechanical metamaterial. The device can have large elongation along the limb axis under circumferential contraction applied by a servo motor network. This wearable compression sleeve results in better imitation of manual drainage massage therapy (MDT) than marketed intermittent pressure compression (IPC) therapy devices are capable of. To this end, the contraction-elongation mechanism of the honeycomb pattern of the present invention enables MDT that applies not only compression but simultaneously stretches the skin.

[0051] Moreover, by using a nodal honeycomb pattern in which a square-shaped node made of hard material is added at the vertices of the soft hexagonal array, these nodes not only house the actuation hardware, but allow for assembling the components easily as one cohesive structure.

[0052] One example implementation uses six circumferentially contractile actuation units stacked longitudinally along the leg with a servo motor dedicated to each contractile unit. Each contracting unit has a circumferentially extending polypropylene wire. When the motor is actuated, it spools the polypropylene wire beneath the servo motor housing unit to pull the neighboring nodes together. In response, the user feels a slight compression.

[0053] Main components of the device are electronic hardware that are commonly available off-the-shelf. The metamaterial structural components can be fabricated by 3D printing, specifically the softer ligaments can be printed by flexible TPU filament whereas hard components can be printed by using PLA filament. Consequently, the device of the present invention is lighter and more mobile/less cumbersome than existing devices. Furthermore, it is believed that the device of the present invention will cause a significantly greater venous outflow than that imparted by pneumatic intermittent pressure (PIP) therapy while being lighter and more portable.

[0054] Fig. 3A illustrates an example exoskeletal fluid circulation device 100 in accordance with an aspect of the invention. The device 100 includes an exoskeletal sleeve 101 extending along a centerline 102 and having a first end 104 and a second end 106 on opposite sides of the centerline.

[0055] In one instance, the sleeve 101 is formed by a series of connectors 112 interconnected by a series of ligaments 114. The connectors 112 can be formed from a rigid or hard material, such as a plastic or polymer, including polyurethane. Referring further to Fig. 3B, the connectors 112 are generally rectangular and arranged in an array defined by a series of rows R_1, R_2, R_3,. . . R_n and a series of columns C_1, C_2, C_3, . . . C_n. The rows R extend between the ends 104, 106 of the sleeve 101 and are generally parallel to one another. The columns C extend generally along or parallel to the centerline 102 and are generally parallel to one another.

[0056] Returning to Fig. 3A, as shown the sleeve 101 can include six rows R_1-R_6 and six columns C_1-C_6. It will be appreciated, however, that the sleeve 101 could have any number of rows R or columns C, including a single row (not shown). In any case, the ends

104, 106 of the sleeve 101 coincide with the first and last columns C (here C_1 and C_6, respectively) of the array.

[0057] The ligaments 114 can be formed from a flexible material, such as rubber. In one instance, ligaments 114 extend from each of the four corners of each connector 112 such that the connectors 112 in the same row R are indirectly connected to one another and the connectors in adjacent rows R are directly connected together. The connectors 112 in the same column C, however, are not directly connected to one another by the ligaments 114. Other configurations for the connections between the connectors 112 and ligaments 114 is appreciated.

[0058] As shown, the ligaments 114 extend at an angle or diagonally between adjacent connectors 112. More specifically, a pair of individual ligaments 114 can be arranged in an X-shape connected to four corners of four different connectors 112. Alternatively, a single, X-shaped ligament 114 can be formed and connected to four connectors 112 in the same manner. Regardless, the ligaments 114 and connectors 112 cooperate to form a flexible lattice in which the components are movable in multiple directions relative to one another, including into and out of plane from one another. More specifically, the connectors 112 act as nodes interconnected by the ligaments 114 in a honeycomb or nodal honeycomb lattice structure.

[0059] A wire 116 is associated with each row R of connectors 112 and is coupled to every connector in the same row. Each wire 116 extends transverse, *e.g.*, perpendicular, to the centerline 102. The wire 116 can be made from a polymer, such as nylon or polypropylene. The wire 116 in each row R has a first end 117 terminating at the connector 112 at the first end 104 of the sleeve 101 and a second end 119 fixed to the connector 112 at the second end 106 of the sleeve. The portion of the wire 116 between the ends 117, 119 is guided by the remaining connectors 112 in that row R in a manner that allows the wire to move relative to those remaining connectors in a prescribed manner. In one example, the wire 116 extends through and is slidable relative to an eyelit or similar opening/passage/receiving member (not shown) in each of those remaining connectors 112.

[0060] The sleeve 101 includes one or more actuators or motors 120, such as servo motors. Each motor 120 has a housing secured to one of the connectors 112 at the first end 104. Each motor 120 is also connected to the first end 117 of each wire 116 to form an "actuation unit" or "contractile unit" for controlling/varying tension on the wire. To this end, each motor 120 drives an associated spool 122 on which the first end 117 of the wire 116 is wound.

[0061] That said, each wire 116 has its first end 117 wound on the spool 122 provided on the connector 112 at the first end 104. The wire 116 then extends through a portion of each connector 112 in the same row R until being fixed to the last connector in the row, *i.e.*, the connector at the second end 106. Consequently, the wires 116 extend parallel to one another while the ligaments 114 extend transverse to the wires. It will be appreciated that each row R can have its own actuation unit. Alternatively, a single motor 120 can be attached to a single wire 116 coupled to every connector 112 in the sleeve 101 (not shown), whether this is a single row R or multiple rows.

[0062] The device 100 can further include a controller 140 for controlling operation of the motors 120. The controller 140 and motors 120 are powered by an on-board battery 142 connected to the controller by a converter 144. Alternatively, the converter 144 can be omitted (not shown).

[0063] Attachment members 130 are secured to the connectors 112 at each end 104, 106 of the sleeve 101. In one example, the attachment members 130 are Velcro® but other constructions are contemplated, such as hooks, clasps, fasteners, magnets, etc. In any case, the attachment members 130 cooperate with one another to enable the ends 104, 106 to be secured directly to one another. With this in mind, the ends 104, 106 can be positioned adjacent each other such that the sleeve 101 encircles the centerline 102 as shown in Fig. 3C.

[0064] Securing the attachment members 130 together forms the sleeve 101 into a tubular structure defining a passage 110 extending the entire length thereof of the sleeve. As will be discussed, this passage 110 is configured to receive at least a portion of body limb, *e.g.*, foot, lower leg, knee, thigh, hand, lower arm, elbow, upper arm, etc., of the patient to be treated. In this manner, the tubular sleeve 101 can form a multi-dimensional array or grid of connectors 112 approximating the shape and contour of a body part to be treated.

[0065] To this end, when the attachment members 130 secure the ends 104, 106 together, the rows R of connectors 112 are arranged along the centerline 102 and are thereby stacked in a longitudinal direction coinciding with a direction of extension of the body part to be treated. The columns C are arranged circumferentially about the centerline 102. With this in mind, each row R of connectors 112 encircles the centerline 102 and has a circumference dictated by the length of wire 116 connected to that particular row. In other words, the wires 116 extend between the interconnected ends 104, 106 of the sleeve 101 and thus, varying the length of any wire 116 necessarily varies the circumference of the sleeve at that particular wire.

[0066] The sleeve 101 is configured such that actuation of any motor(s) 120 varies the circumference of the wire 116 connected thereto by varying the tension on that particular wire. More specifically, increasing the tension on a wire 116 by actuating the motor 120 in one direction reels/winds the wire associated therewith onto its spool 122, thereby increasing the tension in the wire. The second end 119 of that tensioned wire 116 is fixed to the last connector 112 at the second end 106 while the ends 104, 106 are fixed to one another by the attachment members 130. That said, winding the wire 116 onto the spool 122 draws the remaining connectors 112 in that row radially towards one another as the wire shortens. Consequently, the circumference of the wire 116 – and therefore of the portion of the sleeve 101 associated therewith – decreases.

[0067] On the other hand, decreasing the tension on a wire 116 by actuating the motor 120 in the opposite direction unwinds the wire associated therewith from its spool 122, thereby decreasing the tension in the wire. As a result, the remaining connectors 112 in that row move radially away from one another as the wire 116 lengthens. Consequently, the circumference of the wire 116 – and therefore of the portion of the sleeve 101 associated therewith – increases.

[0068] Radial movement of the connectors 112 in either direction is facilitated by the sliding connection between the wire 116 and each of the connectors between the ends 104, 106. The nodal honeycomb configuration of the sleeve 101 also helps accommodate relative movement between the connectors 112, including movement of connectors within a single row R, movement of connectors between rows, and/or movement between connectors in different columns C.

[0069] When a separate motor 120 and associated spool 122 is provided for each wire 116 (individual "actuation units"), the sleeve 101 is provided with maximum flexibility/adaptability. In particular, when each row R of connectors 112 has an associated actuation unit the circumference of the sleeve 101 at that corresponding wire 116 can be independently controlled (increased or decreased). It will be appreciated that the flexibility of the ligaments 114 and the configuration of the connections between the ligaments and connectors 112 can help determine the degree to which the circumferences of the different wires 116 can vary relative to one another.

[0070] Referring to Figs. 4A and 4B, in use the patient P wraps the sleeve 101 in its planar/un-rolled form around the limb (a leg L as shown) to be treated and secures the attachment members 130 together. This forms the sleeve 101 into a tube and positions the leg L within the passage 110. The attachment members 130 allow the patient P to wrap the sleeve 101 around the leg L to a desired comfort level while accommodating the specific shape and contour of the leg.

[0071] In this specific example, the sleeve 101 is wrapped around the calf of the leg L. It will be appreciated that the connector 112/ligament 114 lattice of the sleeve 101 can be applied directly to the leg L (Fig. 4A). Alternatively, the lattice can be secured to a barrier layer or underlayment 136 (Fig. 4B) that provides additional stability to the sleeve 101 while preventing direct contact between the lattice and the patient P. In one example, the underlayment 136 is a flexible, polymer sheet, such as spandex.

[0072] In either case, the controller 140 can be a hand-held controller having an interface 142 by which the patient P can individually control the motors 120. Alternatively or additionally, the controller 140 can be provided with pre-set, programmed routines that actuate the motors 120 in a predetermined pattern. In either scenario, the motors 120 adjust the tension in one or more wires 116 by spooling or unspooling the wire(s) on its respective spool 122 in a controlled manner. This, as noted, varies the circumference(s) of the sleeve 101 where the wire(s) 116 are adjusted. As a result, the sleeve 101 applies and releases compressive forces F on the leg L in a desired manner, namely, in a manner tailored to help redistribute or remove accumulated fluid within the leg L to which the sleeve 101 is attached in order to treat edema.

[0073] To this end, the controller 140 (whether pre-programmed or in response to patient P input) can control the amplitude, frequency, and/or duty cycle for the contractions provided by each individual actuation unit 116, 120. The controller 140 can also control the number of actuations units 116, 120 contracting at the same time, the number of times any given pattern of actuation unit activations is performed, the activation time duration, etc.

[0074] Once the sleeve 101 is wrapped around the leg L, it will be appreciated that the leg L will provide resistance to contraction of the sleeve and ultimately prevent the sleeve from contracting beyond a certain degree. In one example, the motors 120 are programmed to generate a salvo of contractions of the sleeve 101 (thereby compressing the leg L) in a pre-programmed fashion to drive the accumulated fluid in the leg in a specific direction to reduce the fluid volume in the limb. More specifically, the sleeve 101 actuation is configured to provide the patient P with a wave of compression traveling proximally through the leg L. This not only applies compression but simultaneously stretches the skin.

[0075] Furthermore, as noted, the sleeve 101 can be adjusted or sized to accommodate other limbs or appendages. Consequently, the pre-programmed control sequence available to the patient P in the interface 142 can be selected to coincide with those sequences most appropriate for the limb/appendage being treated. A Doppler probe 150 can be used to track venous flow before and during use of the sleeve 101 on the patient P.

[0076] Referring to Fig. 4C, a display 146 on the controller 140 can provide the patient P instant feedback of the sleeve 101 being used as well as the interface 142 by which the patient can individually control the motors 120. In one instance shown in Fig. 4D, the sleeve 101 includes sixteen actuation units 116, 120. Consequently, the interface 142 includes the following:

[0077] Pressure graph (indicates at ①): during use, the pressure applied in mmHg by each actuation unit 116, 120 on the y axis is plotted against time.

[0078] Motor control (indicates at ②): for each actuation unit 116, 120, there is a "M[#] T", "M[#] L", and "Pressure: " reading. When "M[#] T" button is pressed, the associated actuation unit 116, 120 (labeled 1-16) will tighten. When "M[#] L" button is pressed, the associated actuation unit 116, 120 will loosen. The "Pressure:" indicates the current pressure applied at that actuation unit 116, 120 in mmHg.

[0079] "ALL STOP" Button (indicates at ③): When the all stop button is pressed, the controller 140 will stop rotation of the motors 120. If this button is pressed during a stimulation pattern, all motors 120 will stop after the wave of compression reaches the 14th segment.

[0080] "ALL LOOSEN" Button (indicates at ④): When pressed, all actuation units 116, 120 will loosen for the duration the button is pressed.

[0081] "ALL TIGHTEN" Button (indicates at ⑤): When pressed, all actuation units 116, 120 will tighten for the duration the button is pressed.

[0082] "AUTO TIGHTEN" Button (indicates at ⑥): When pressed, this causes all actuation units 116, 120 to tighten to an initial pressure and stop adjusting once that pressure is achieved.

[0083] Actuation Sequences (indicates at ⑦): The buttons labeled 1-8 are associated with 8 different pre-programmed stimulation patterns having different variations of actuation unit 116, 120 actuations. When pressed, actuation of that particular stimulation pattern will begin.

[0084] With this interface 142 in mind, one example use sequence includes initially pressing the "ALL LOOSEN" button such that the user can put the sleeve 101 on the leg L similar to putting on a sock. The sleeve 101 can fit between the knee and ankle with the motors 120 centered along the front of the leg and cables running towards the knee. The user then presses the "AUTO TIGHTEN" button, which causes the controller 140 to actuate the motors 120 to tighten the sleeve 101 to a specified pressure along the limb (corresponding with a degree of tension in each wire 116), relying on the continuous feedback loop between the controller 140 and pressure sensors 160. Once all motors 120 stop adjusting, the user presses the "STOP ALL" button to set the fitment. The user can then individually adjust the fit/compression of the sleeve 101 row-by-row as needed/desired.

[0085] In one example, the user can press the desired stimulation pattern from the 8 preset options at the bottom of the interface 142. The pattern will run repeatedly until the "STOP ALL" button is pressed. Stimulation will end after the current cycle completes to ensure all rows R return to the fitment set prior to stimulation. When the user wishes to end stimulation, the "STOP ALL" button is pressed. The "LOOSEN ALL" button is then pressed as needed until the sleeve 101 has a loose fit sufficient to be slid off the leg L. Individual actuation units 116, 120 can also be loosened as needed.

Example

[0086] This Example refers to Fig. 5 and describes a design pathway for an example exoskeletal fluid circulation device in accordance with the present invention. The design pathway had the following design requirements (DR) and benchmarks in mind:

DR1-Wearability and adjustability

[0087] The fluid circulation device was designed to include sleeves formed from two separate planar sheets, one of which would be wrapped around the calf, and the other around the thigh, akin to a blood-pressure cuff. The sleeves would be strapped around the limbs *via* adjustable Velcro bands. As a benchmark, the sleeve would be worn by the patient and without any assistance within a duration that is less than about 3-5 minutes.

DR2-Portability

[0088] The fluid circulation device could be packed in a shoebox-sized volume and would weigh less than 3 lbs. Design variables that would be controlled to attain the benchmark were the thickness of 3D printed parts, the type of fabric, and the selection of lighter weight servo motors with smaller footprints.

DR3-Enhanced Venous Outflow

[0089] Outflow attained through the fluid circulation device would be two-fold greater than existing edema treatment systems. Design variables that were surveyed to fulfill this requirement were frequency of contractions, peristalsis patterns, and the amplitude of contractions.

Concept

[0090] The exoskeletal fluid circulation device was configured based on our studies of actuatable metamaterials arranged in tubular configurations. The limbless soft robots mimic a worm or snake-like locomotion through coordinated sequential actuation of servo motors over segments to generate a wave propagation. Lattice-based mechanical metamaterials are engineered structures with unconventional mechanical properties that result from a repeating pattern of unit- cells. The honeycomb structure is a well-established, lattice-based metamaterial previously used in passive load-bearing and small-amplitude deformation applications such as impact- resistant packaging or vibration damping.

[0091] Regarding the construction of the exoskeletal fluid circulation device, we transformed the characteristics of the classical honeycomb pattern to obtain a wearable tubular structure that generates elongation along the limb axis when a circumferential contraction is applied by a servo motor. To transform the classic honeycomb pattern into a wearable exoskeletal sleeve, we used a nodal honeycomb construction in which square-shaped nodes made of hard material were added in the lattice to house the servo motors.

Fabrication of Wearable Metamaterial Exoskeleton Phase

[0092] An exoskeletal fluid circulation device in accordance with the present invention and under the framework of the aforementioned design pathway was composed of the following main components: 1) 3D-Printed servo motor housings, 2) flexible nodes to guide and shield actuation wires, 3) flexible metamaterial lattice units as connectors between nodes, 4) underlayment spandex fabric, 5) adjustable Velcro bands, and 6) battery and servo motor driver circuit. The system was driven by a custom-written software.

[0093] Manufactured components such as servo motors 120, shields, drivers, and batteries 142 were purchased off-the-shelf. In this instance, the driver was a PCS9685 Servo Driver connected to a 3.8B lipo battery 142. Soft and hard components of the structural framework, *e.g.*, the connectors 112, ligaments 114, and wire 116. were 3D printed. 3D-printing allowed prototyping for different design iterations and multiple sizing arrangements to ensure proper fit on users.

[0094] With the above components in mind, the wearable phases of sleeve included the metamaterial exoskeleton layer and a soft spandex underlayment layer adhered to each other using E-6000 glue. The metamaterial phase included lattice connectors and nodes 112 that guided the nylon actuation wire 116 to prevent contact between the wire and the user. Lattice connectors and nodes 112 were 3D-printed in one piece as a 1.5 mm thick layer using a soft TPU filament. Hard plastic motor housings were 3D-printed using PLA filament and connected to the metamaterial adhered Spandex fabric 136 by heat welding.

[0095] After all components were printed, soft ligaments 114 and hard plastic motor housing nodes 112 were assembled as described above. A polypropylene monofilament wire 216 ran circumferentially and connected rows of connectors 112 to the spool 122 on each motor 120. We aimed to increase the number of contractile units in the sleeve 101 from

6 units in the previous prototype to 10 units/segment (segments being the thigh and the calf as shown). The resolution of the sleeve 101 was increased by decreasing the size of the nodes 112 and ligaments 114 of the metamaterial. In doing so, the gap between contracting units decreased, while increasing overall contact with the user's limb. Increasing the resolution in this manner also provided a smoother peristaltic motion of the sleeve 101 and reduced fluid backflow.

Fitment of Exoskeleton

[0096] First the thigh piece, then the calf piece was worn. The circumference of the sleeve was about 10 mm longer than the circumference or the calf (or the thigh for the thigh-segment) so that the users could slide it through the feet, akin to wearing a sock. The spandex 136 and the deformable 'X' shaped connectors 112, 114 provided flexibility for the sleeve 101 to conform to the limb. The Velcro bands 130 were secured together to fix the sleeves 101 to the leg L.

Electronic actuation system

[0097] The amplitude, duration and frequency of contractions was controlled by a custom-written program (C++). All the servo motors 120 were wired to an Arduino Nano microcontroller 140 that runs the operational software. Using torque controlled servo motors 120 also enabled automated adjustment of baseline tightness in each actuation wire 116 so that the sleeve 101 conforms to the user's anatomy autonomously before initiating the compression treatment.

[0098] When the motors 120 were actuated, the wires 216 spooled at their respective motor housing units, which caused contraction of all connecting pieces. All wiring for the motors 120 ran on the exterior of the sleeve 101, which prevented any contact with the user's skin or clothing.

Advantage 1: Variability of Waveforms

[0099] The sleeve had 16 individually contacting segments/actuation units 116, 120 along the calf portion. Through software incorporated into the device 100, the stimulation sequence could be varied through changing the waveform. The waveform was a combination of the number of contracting segments/wires 116 present at once and the number of waves traveling along the device 100 at once. Through varying the waveform, the amount of fluid being pushed proximally through the leg L can be altered in order to provide the most effective treatment to the patient P.

[00100] Two waveform examples are provided below. Each '-' represents a contractile segment in a neutral state. Each '+' represents a contractile segment in a contracted state. 16 segments are shown side by side along the page and each frame shows the propagation of the waveform. The speed that the waveform travels at is also adjustable by increasing or decreasing the speed of the motors 120.

Device control set to 2 contracting segments with 1 wave:
Frame 1: + + - - - - - - - - - - - - - -
Frame 2: - + + - - - - - - - - - - - - -
Frame 3: - - + + - - - - - - - - - - - -
Frame 4: - - - + + - - - - - - - - - - -
Frame 5: - - - - + + - - - - - - - - - -
Frame 6: - - - - - + + - - - - - - - - -
Frame 8: - - - - - - + + - - - - - - - -
***
Frame 15: - - - - - - - - - - - - - - + +
Frame 16: + - - - - - - - - - - - - - - +

Device control set to 4 contracting segments with 2 waves:
Frame 1: + + + + - - - - + + + + - - - -
Frame 2: - + + + + - - - - + + + + - - -
Frame 3: - - + + + + - - - - + + + + - -
Frame 4: - - - + + + + - - - - + + + + -
Frame 5: - - - - + + + + - - - - + + + +
Frame 6: + - - - - + + + + - - - - + + +
Frame 7: + + - - - - + + + + - - - - + +
Frame 8: + + + - - - - + + + + - - - - +

Advantage 2: Limb Girth Measurement and Tracking

[00101] The exoskeletal fluid circulation device of the present invention can measure the girth of the limb and store these measurements such that patients and their healthcare providers can track the progression of swelling. The motor 120 associated with each contracting segment rotates and spools the wire 116 in order to generate circumferential pressure on the limb L. The amount the wires 116 spool to achieve a certain pressure can be measured by built in encoders as an example, and stored by the device, thus indicating the circumference of the limb. For this measurement, the pressure would be set at an amount such that the sleeve 101 fits the limb at a neutral state and measures the true, unaltered circumference of the limb. This is accomplished by each servo motor 120 recording/tracking the length of its associated wire 116 such as by using built-in encoders. The limb's dimensions can be continually monitored during the therapy and reported to inform the physician the responsiveness of limb volume to therapy, whole limb, as well as the segments of the limb itself that are not responsive to the therapy.

Advantage 3: Sensorization at Every Contracting Unit

[00102] At each contracting segment, there was a pressure sensor 160 integrated into the sleeve 101. This pressure sensor 160 measured the pressure between the sleeve 101 and the user's limb L. The measurement was continuously received by the controller 140, which responded to the pressure sensor 160 signals by tightening each segment/wire 116 to a consistent pressure along the limb L prior to the start of treatment. Since the polyurethane structure is flexible to allow users to wear the sleeve 101 like a sock, tightening each of the segments to a baseline pressure enables the sleeve 101 to conform to the user's specific anatomy autonomously. Users can change the value of this baseline pressure for comfort.

[00103] The pressure sensors 160 are also used to ensure that the motors 120 contract the sleeve 101 to a preset pressure during stimulation. The amount of compression provided could also be input by the user under the guidance of the healthcare provider. Having a pressure sensor 160 at each segment enables users to have complete control of their treatment and make changes for comfort.

Adjustment of the operational parameters of the device

Rationale and Benchmarks

[00104] The actuation variables that can be controlled for each circumferential contractile unit are amplitude of contraction, duration of contraction, and frequency of contractions. For patient comfort, it is desirable to experimentally determine the minimum amplitude of contraction to attain the maximum venous outflow. It is also desirable to minimize the duration of contraction and increase the frequency of contractions to reduce the time it takes to drive fluid away from affected limbs. As such, operational settings of the device are determined to maximize venous outflow.

Identification of contraction pattern to maximize venous outflow from the calf

[00105] Five participants are recruited from the campus through fliers. Both genders who are older than 18 yo are included in the study and exclusion criteria involves people who are under risk for blood clot formation to eliminate thromboembolism risk during the course of the study. Prior to application of the exoskeletal fluid circulation device, baseline venous flow is measured at the proximal downstream of segments (popliteal region for calf, and saphenous vein for thigh) using a 8 MHz flat doppler ultrasound probe 160 (Huntleigh Dopper or Bidop 3, Koven Technologies). The mean velocity, peak velocity, and blood flow volume is recorded as outcome measures. The probe 150 is positioned consistently by using a polystyrene block shaped to accommodate the probe and to fit on the limb contour.

[00106] Following the baseline measurements, vascular flow is repeated with the participant wearing the sleeve on their calf and/or thigh to determine the percentage increase with respect to the baseline. The ten contractile actuation units of the sleeve are independently controlled such that each unit holds the contraction for a defined period. In this context the frequency of contractions (1 Hz, 0.5 Hz, 0.1 Hz), the amplitude of contraction (5%, 10% 20% circumferential strain), and the duration of contraction (1s, 2s, 10s) is changed to maximize the venous blood outflow.

[00107] To this end, a feedback-based adjustment is implemented to track these parameters such that when any given actuation unit is contracted under a given combination of contraction parameters, venous outflow is measured at the proximal downstream using the doppler ultrasound probe 150. The optimal combination of contraction amplitude and duration is chosen accordingly for every contractile actuation unit. The next step involves the identification of the speed at which the peristaltic wave travels distally to proximally. The feedback on venous outflow is collected at the location of the popliteal vein.

Coordination of actuation between calf and thigh compartments

[00108] Inspired by MDT, it is important that fluid volume in the thigh compartment should be drained first to create space for the fluid that will then be pumped from the calf to the thigh. Therefore, the feedback controlled approach that is described for the calf region in the previous paragraph is also performed for the thigh region with the feedback collected from the femoral vein proximally.

Comparison of Venous flow obtained via optimal Exoskeletal Fluid Circulation Device actuation vs. Flexitouch

[00109] Flexitouch is the most widely used intermittent pneumatic pressure device in the market for treatment of lymphedema; thus it is selected as a reference point for assessing the sleeve 101. Ten participants of the profile that is described above are subjected to the sleeve 101 and Flexitouch (the order being randomized) in one session. Flow velocity and volume are measured at popliteal and saphenous locations using doppler ultrasound probe 150 over a duration of 15 minutes for each device. Users are provided with a survey to compare the ease of wearing, comfort of fitment, and comfort during operation on a Likert scale to compare the two devices.

Data Analysis

[00110] For normal data, standard methods such as one-way ANOVA with Tukey's post hoc comparisons is used to compare different stimulation conditions. Should the normality test fail, non-parametric tests such as Kruskal Wallis followed by Mann-Whitney are used for pairwise comparisons with Bonferroni corrections. Likert scale data is compared by Wilcoxon Signed Rank test. Comparisons between Flexitouch vs. the sleeve 101 involves a paired-test. The efficacy of the sleeve 101 is compared to the clinical standard with N=10, which is sufficient to resolve the target effect size of 50% increase in venous volume assuming that the coefficient of variation is within 25% of the mean. Significance is set at $p < 0.05$ for all tests.

[00111] What have been described above are examples of the present invention. It is, of course, not possible to describe every conceivable combination of components or methodologies for purposes of describing the present invention, but one of ordinary skill in the art will recognize that many further combinations and permutations of the present invention are possible. Accordingly, the present invention is intended to embrace all such alterations, modifications and variations that fall within the spirit and scope of the appended claims.

CLAIMS

What is claimed is:

1. A fluid circulation device for treating edema of a patient's body limb, comprising:

a flexible sleeve that includes at least one wire and that defines a passage for receiving at least a portion of a body limb; and

at least one motor for adjusting tension on the at least one wire for controlling a degree of compression of the sleeve on the at least one portion of the limb.

2. The fluid circulation device recited in claim 1, wherein the sleeve further comprises a series of rigid connectors and flexible ligaments that cooperate to define an exoskeletal lattice connected to the at least one wire.

3. The fluid circulation device recited in claim 2, wherein the sleeve extends along a centerline and the ligaments extend between the rigid connectors and transverse to the centerline.

4. The fluid circulation device recited in claim 2 or claim 3, wherein the rigid connectors are arranged in a series of rows extending circumferentially about the centerline and columns extending parallel to the centerline.

5. The fluid circulation device recited in any of claims 2 to 4, wherein the flexible ligaments interconnect the rigid connectors in different rows from one another.

6. The fluid circulation device recited in any of claims 2 to 5, wherein the flexible ligaments are connected to corners of diagonally opposed rigid connectors and cross one another between different pairs of the rigid connectors.

7. The fluid circulation device recited in any of claims 4 to 6, wherein the at least one wire comprises a plurality of wires, with each wire being connected to the rigid connectors arranged in the same rows about the circumference of the sleeve.

8. The fluid circulation device recited in claim 7, wherein the at least one motor is connected to the wires for varying the tension in the wires about the circumference of the sleeve for controlling the degree of compression of the sleeve on the at least portion of the limb.

9. The fluid circulation device recited in claim 7 or claim 8, wherein the at least one motor comprises a plurality of motors each associated with one of the respective wires for independently varying the tension in each of the wires about the circumference of the sleeve for controlling the degree of compression of the sleeve on the at least portion of the limb.

10. The fluid circulation device recited in any of claims 1 to 9, further comprising a controller connected to the at least one motor for controlling the at least one motor.

11. The fluid circulation device recited in claim 10, wherein the controller controls the motors for generating a salvo of contractions in a pre-programmed fashion to drive accumulated fluid in the limb in a specific direction to reduce fluid volume in the limb.

12. The fluid circulation device recited in any of claims 1 to 11, further comprising at least one pressure sensor connected to the controller for monitoring the degree of compression of the sleeve on the at least one portion of the limb such that the controller is configured to control operation of the at least one motor in response to signals received from the at least one pressure sensor.

13. The fluid circulation device recited in any of claims 1 to 12, wherein the fluid circulation device is configured for placement on a patient's foot, leg, hand or arm.

14. A fluid circulation device for treating edema of a patient's body limb, comprising:

a flexible sleeve defining a passage for receiving at least a portion of the body limb and comprising:

rigid connectors arranged in multiple rows about a circumference of the sleeve;

flexible ligaments connecting the rigid connectors to one another and extending transverse to a centerline of the sleeve;

wires coupled to the rigid connectors in the same row; and

motors connected to each respective wire for independently varying tension on the respective wire for controlling a degree of compression of the sleeve on the at least one portion of the body limb.

15. The fluid circulation device recited in claim 15, wherein the rigid connectors and flexible ligaments cooperate to define an exoskeletal lattice connected to the at least one wire.

16. The fluid circulation device recited in any of claims 14 or 15, wherein the flexible ligaments interconnect the rigid connectors in different rows from one another.

17. The fluid circulation device recited in any of claims 14 to 16, wherein the flexible ligaments are connected to corners of diagonally opposed rigid connectors and cross one another between different pairs of the rigid connectors.

18. The fluid circulation device recited in any of claims 14 to 17, further comprising a controller connected to the motors for controlling the motors.

19. The fluid circulation device recited in claim 18, wherein the controller controls the motors for generating a salvo of contractions in a pre-programmed fashion to drive accumulated fluid in the limb in a specific direction to reduce fluid volume in the limb.

20. The fluid circulation device recited in claim 18 or claim 19, further comprising at least one pressure sensor connected to the controller for monitoring the degree of compression of the sleeve on the at least one portion of the limb such that the controller is configured to control operation of the motors in response to signals received from the at least one pressure sensor.

21. The fluid circulation device recited in any of claims 14 to 20, wherein the fluid circulation device is configured for placement on a patient's foot, leg, hand or arm.

22. A method for treating edema of a patient's body limb, comprising:

positioning the flexible sleeve of the fluid circulation device of any of claims 1 to 21 over at least a portion of a body limb; and

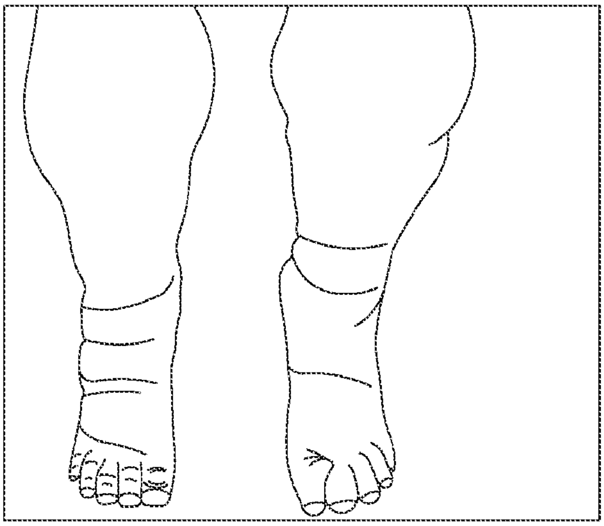
actuating at least one motor provided on the sleeve and connected to the at least one wire for adjusting tension on the at least one wire for controlling a degree of compression of the sleeve on the at least one portion of the limb.

23. The method recited in claim 22, wherein the sleeve includes a plurality of wires and a plurality of motors associated therewith and the step of actuating the at least one motor comprises individually actuating the motors for independently varying the tension in each of the wires about the circumference of the sleeve for controlling the degree of compression of the sleeve on the at least portion of the limb.

24. The method recited in claim 23, further comprising monitoring the degree of compression of the sleeve on the at least one portion of the limb and adjusting the tension on at least one of the wires in response thereto.

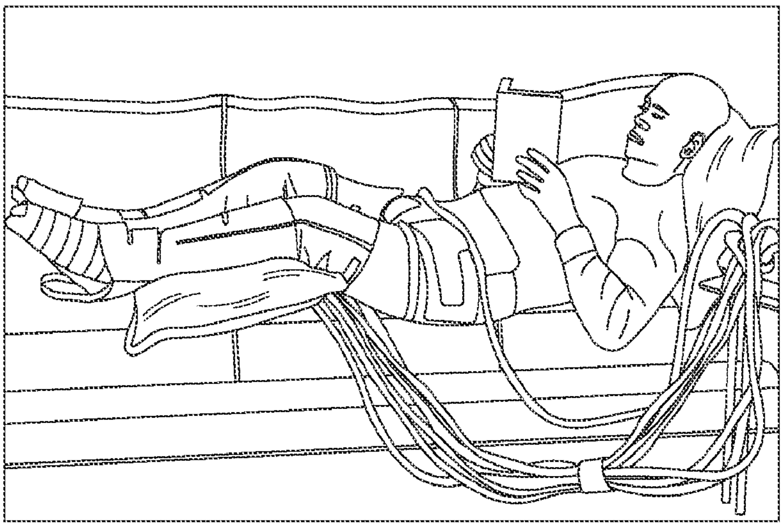
25. The method recited in claim 24, wherein the degree of compression of the sleeve is monitored in a feedback loop between pressure sensors associated with each of the wires and a controller connected to the motors for controlling actuation thereof.

26. The method recited in any of claims 22 to 25, further comprising automatically adjusting the tension in the at least one wire in response input from a user.



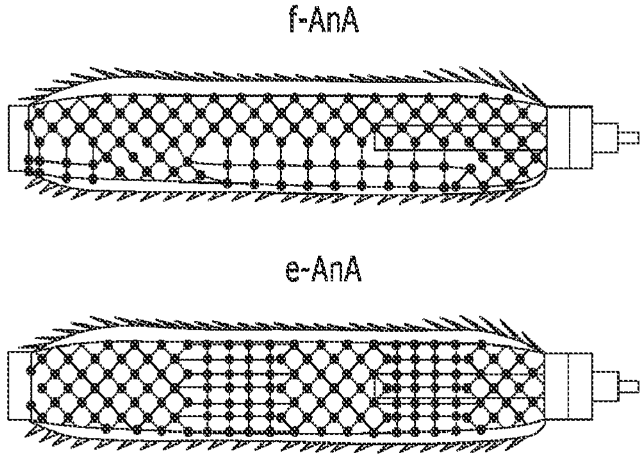
PRIOR ART

FIG. 1A



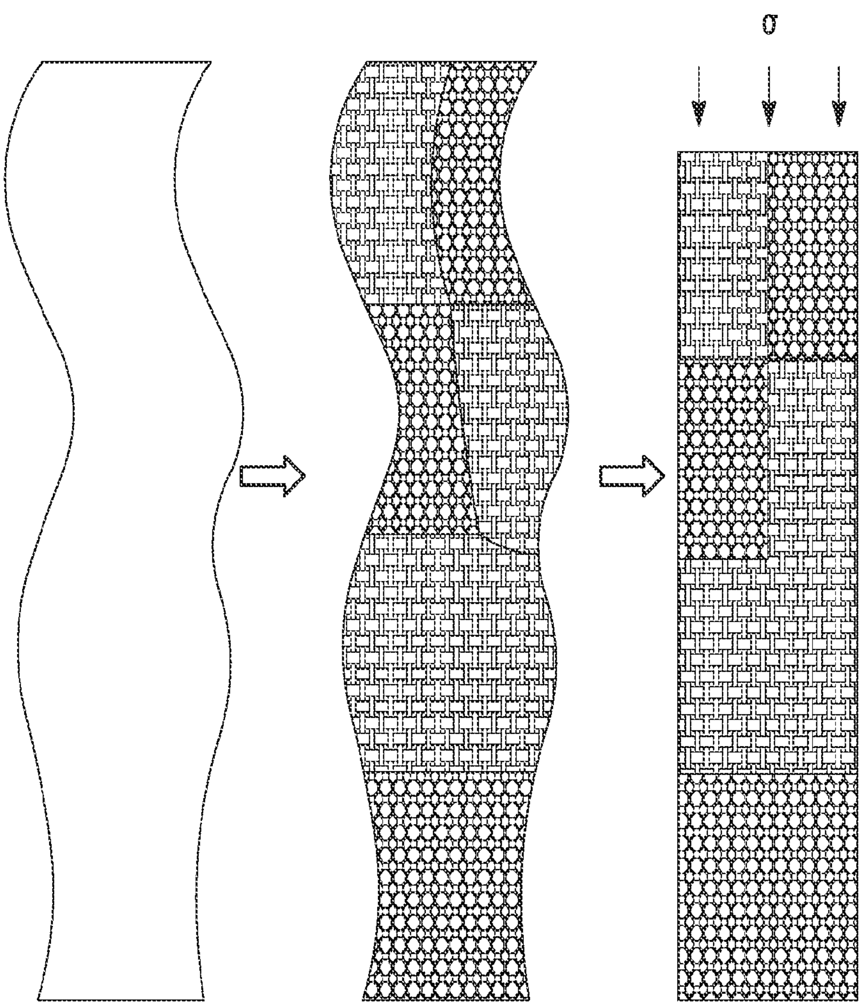
PRIOR ART

FIG. 1B



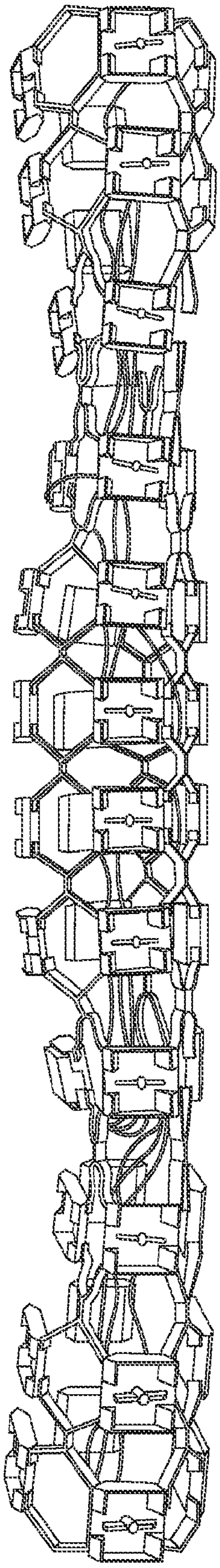
PRIOR ART

FIG. 2A



PRIOR ART

FIG. 2B



PRIOR ART

FIG. 2C

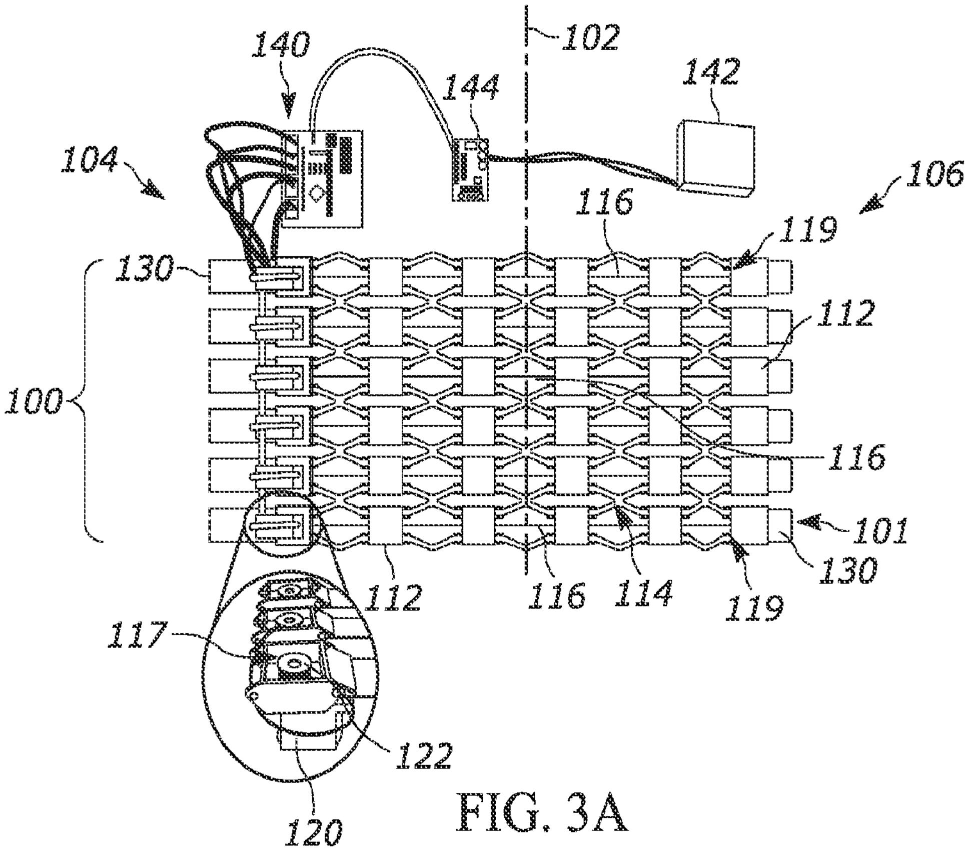

140
102
144
142
104
106
116
119
130
112
100
116
101
130
112
116
114
119
117
122
120

FIG. 3A

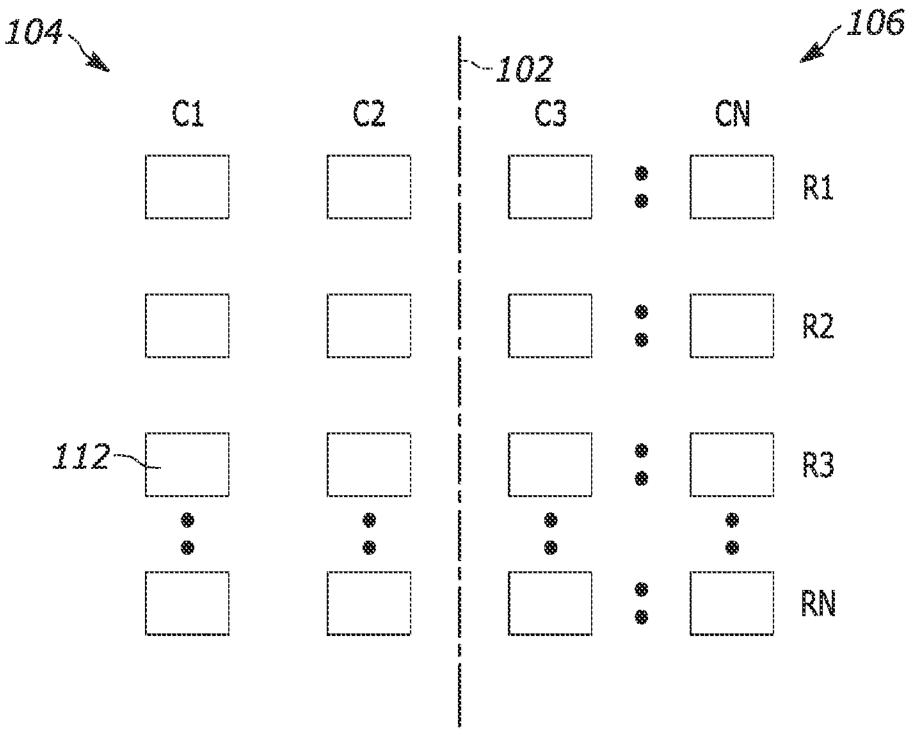

104
106
102
C1
C2
C3
CN
R1
R2
112
R3
RN

FIG. 3B

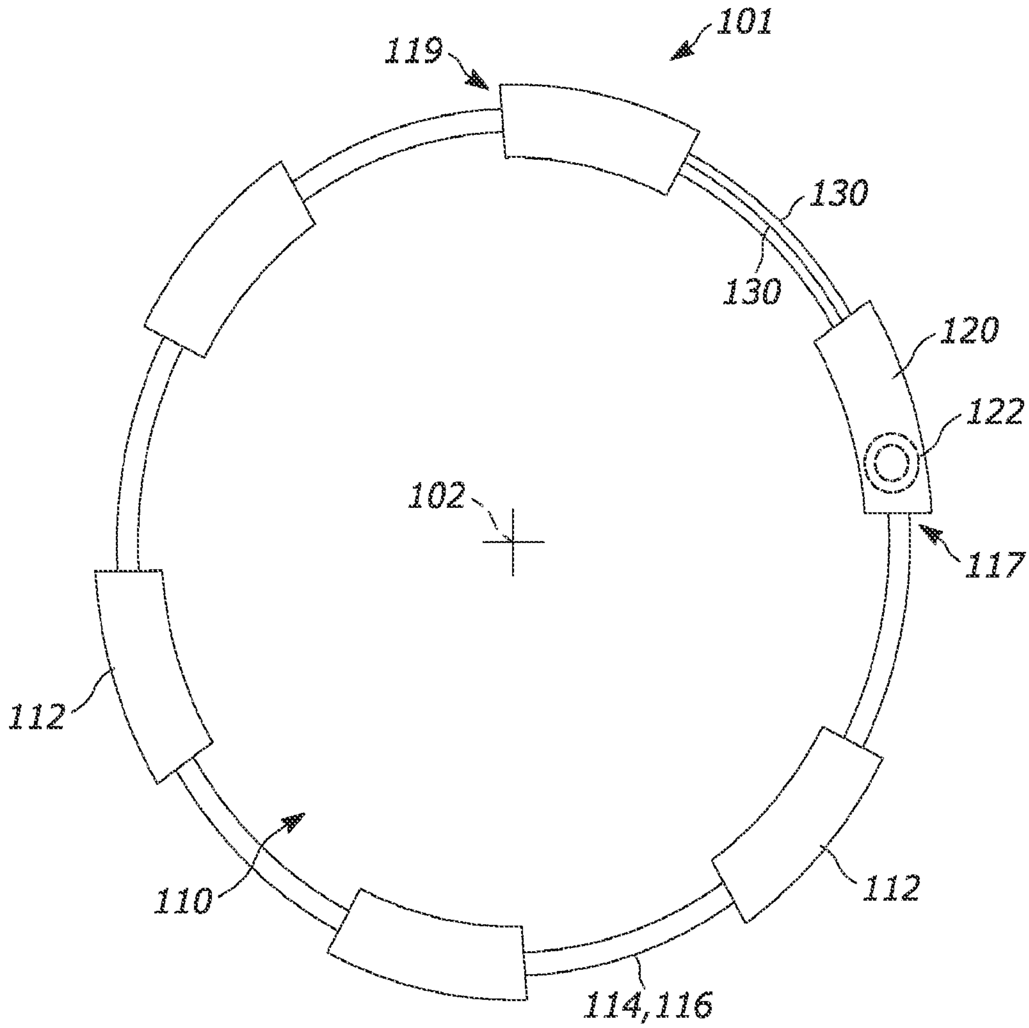


FIG. 3C

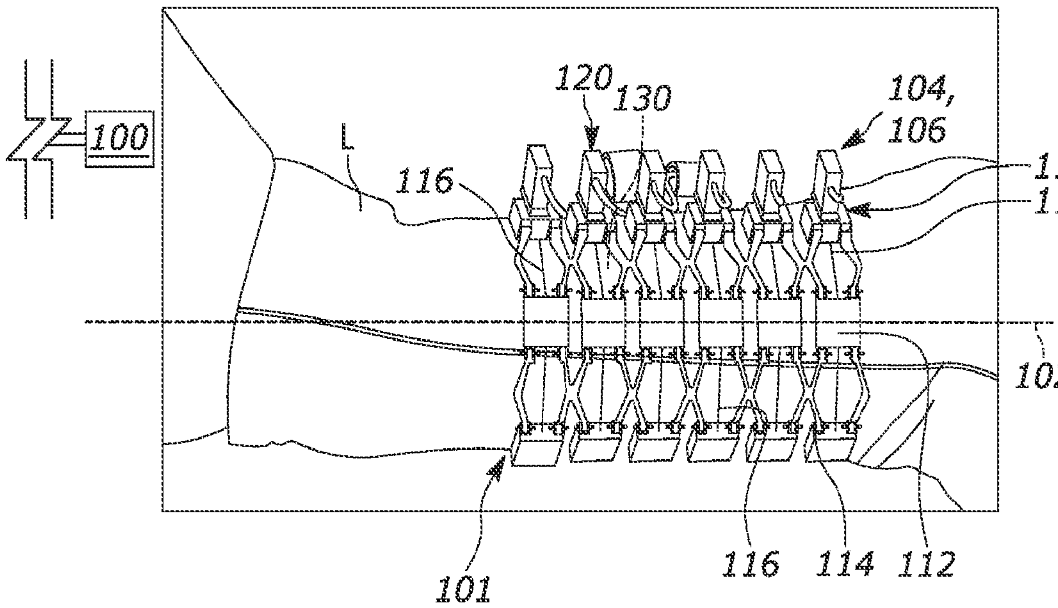

100
L
120
130
104,
106
110
116
116
102
101
116
114
112

FIG. 4A

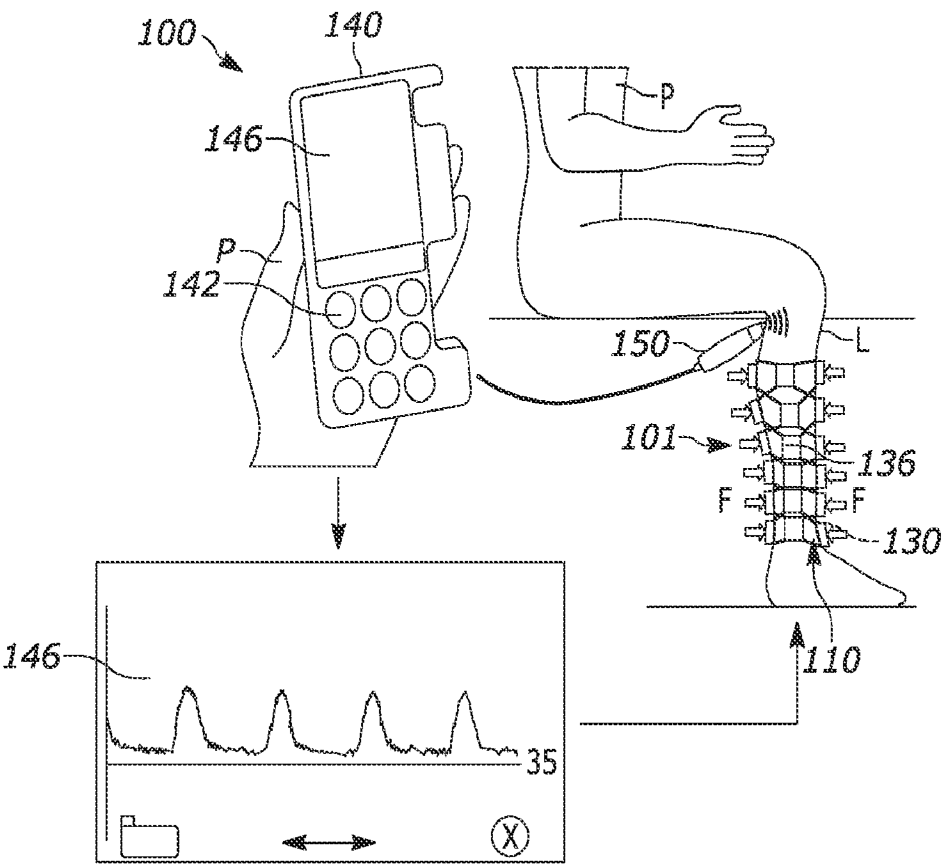

100
140
146
P
142
P
150
L
101
136
F
F
130
110
146
35

FIG. 4B

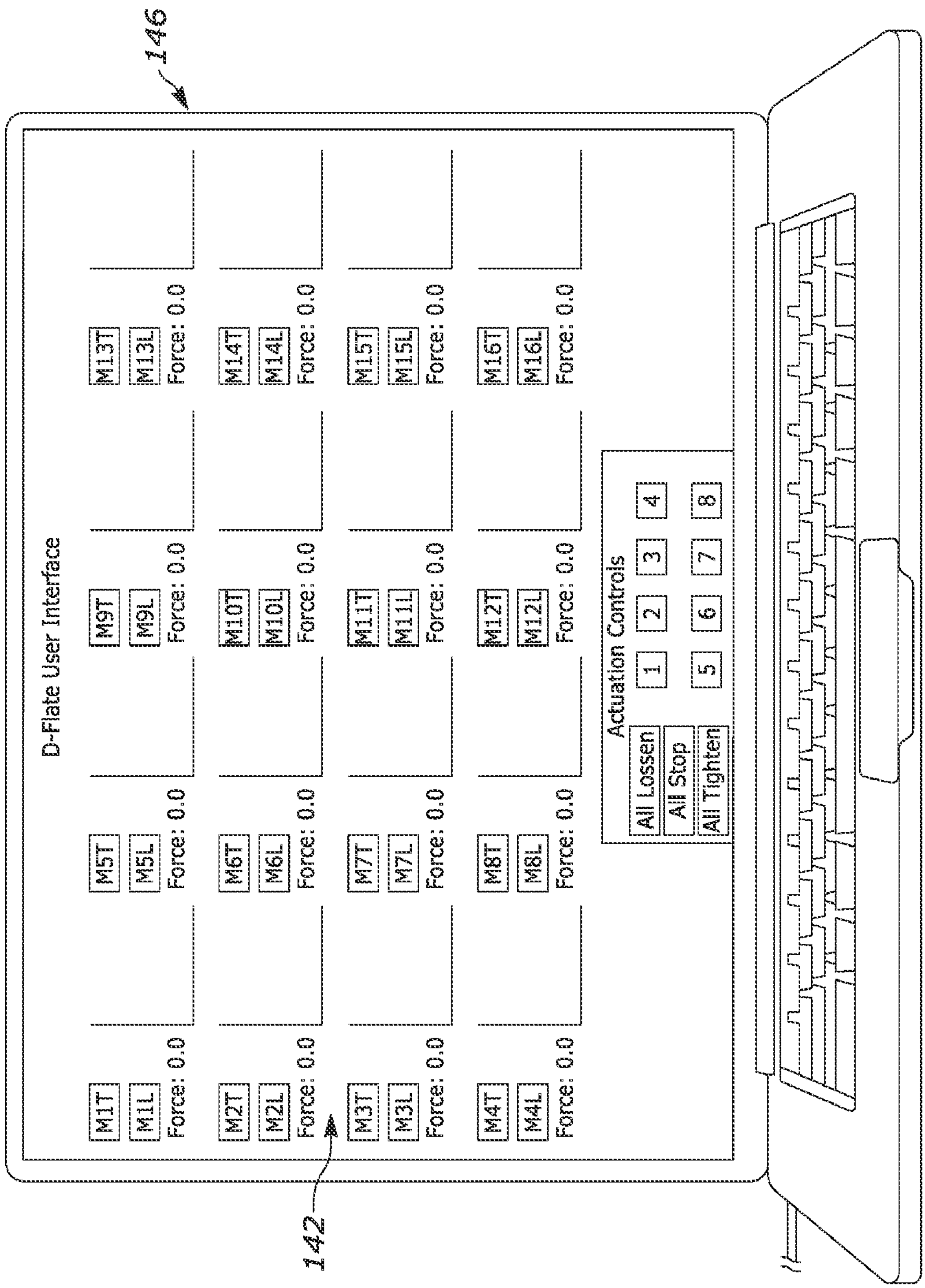

146
D-Flate User Interface
M1T
M1L
Force: 0.0
M2T
M2L
Force: 0.0
M3T
M3L
Force: 0.0
M4T
M4L
Force: 0.0
M5T
M5L
Force: 0.0
M6T
M6L
Force: 0.0
M7T
M7L
Force: 0.0
M8T
M8L
Force: 0.0
M9T
M9L
Force: 0.0
M10T
M10L
Force: 0.0
M11T
M11L
Force: 0.0
M12T
M12L
Force: 0.0
M13T
M13L
Force: 0.0
M14T
M14L
Force: 0.0
M15T
M15L
Force: 0.0
M16T
M16L
Force: 0.0
Actuation Controls
All Lossen
All Stop
All Tighten
1
2
3
4
5
6
7
8
142

FIG. 4C

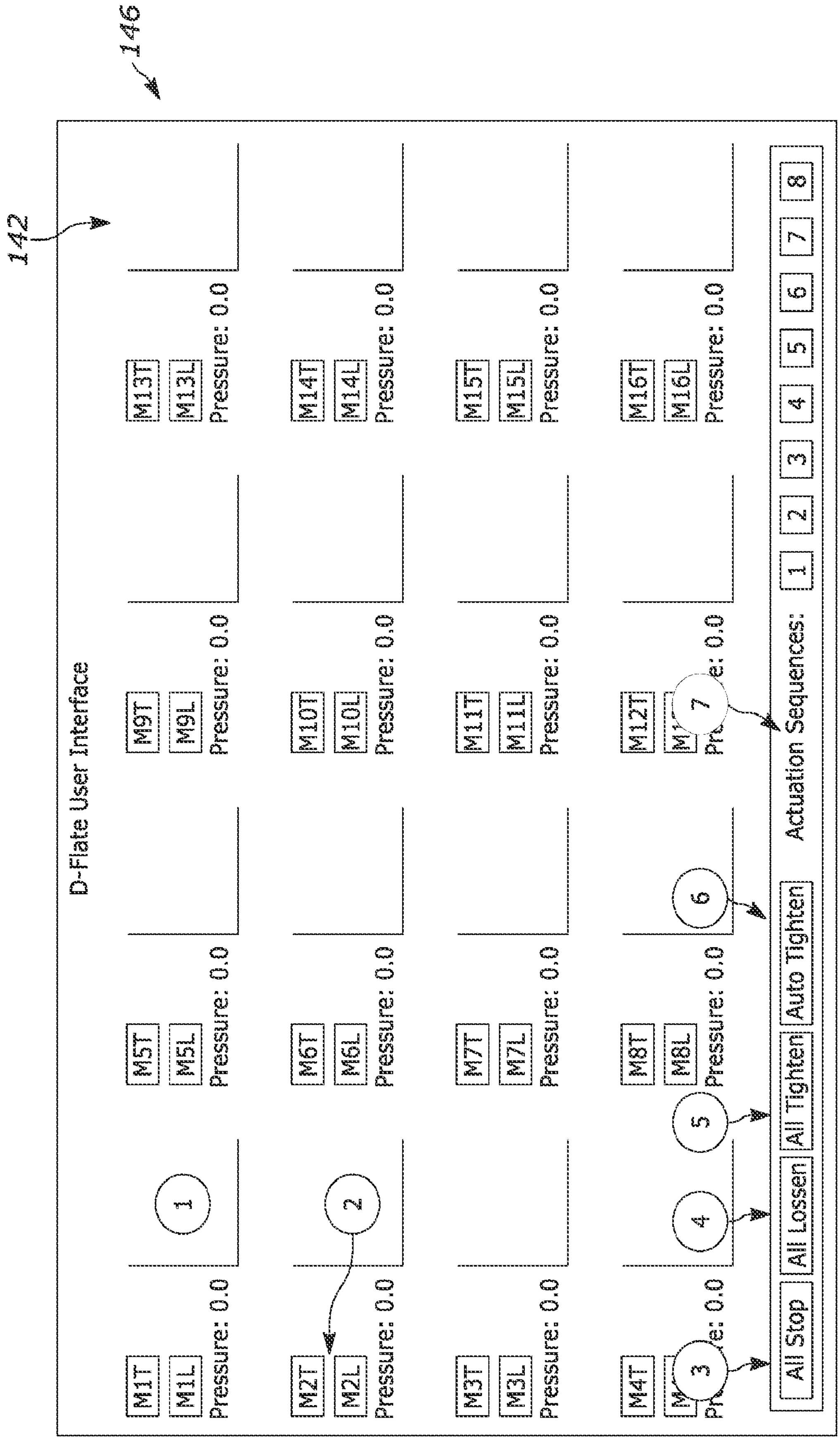

146
142
D-Flate User Interface
M1T
M1L
Pressure: 0.0
M2T
M2L
Pressure: 0.0
M3T
M3L
Pressure: 0.0
M4T
M5T
M5L
Pressure: 0.0
M6T
M6L
Pressure: 0.0
M7T
M7L
Pressure: 0.0
M8T
M8L
Pressure: 0.0
M9T
M9L
Pressure: 0.0
M10T
M10L
Pressure: 0.0
M11T
M11L
Pressure: 0.0
M12T
M13T
M13L
Pressure: 0.0
M14T
M14L
Pressure: 0.0
M15T
M15L
Pressure: 0.0
M16T
M16L
Pressure: 0.0
1
2
3
4
5
6
7
All Stop
All Lossen
All Tighten
Auto Tighten
Actuation Sequences:
1
2
3
4
5
6
7
8

FIG. 4D

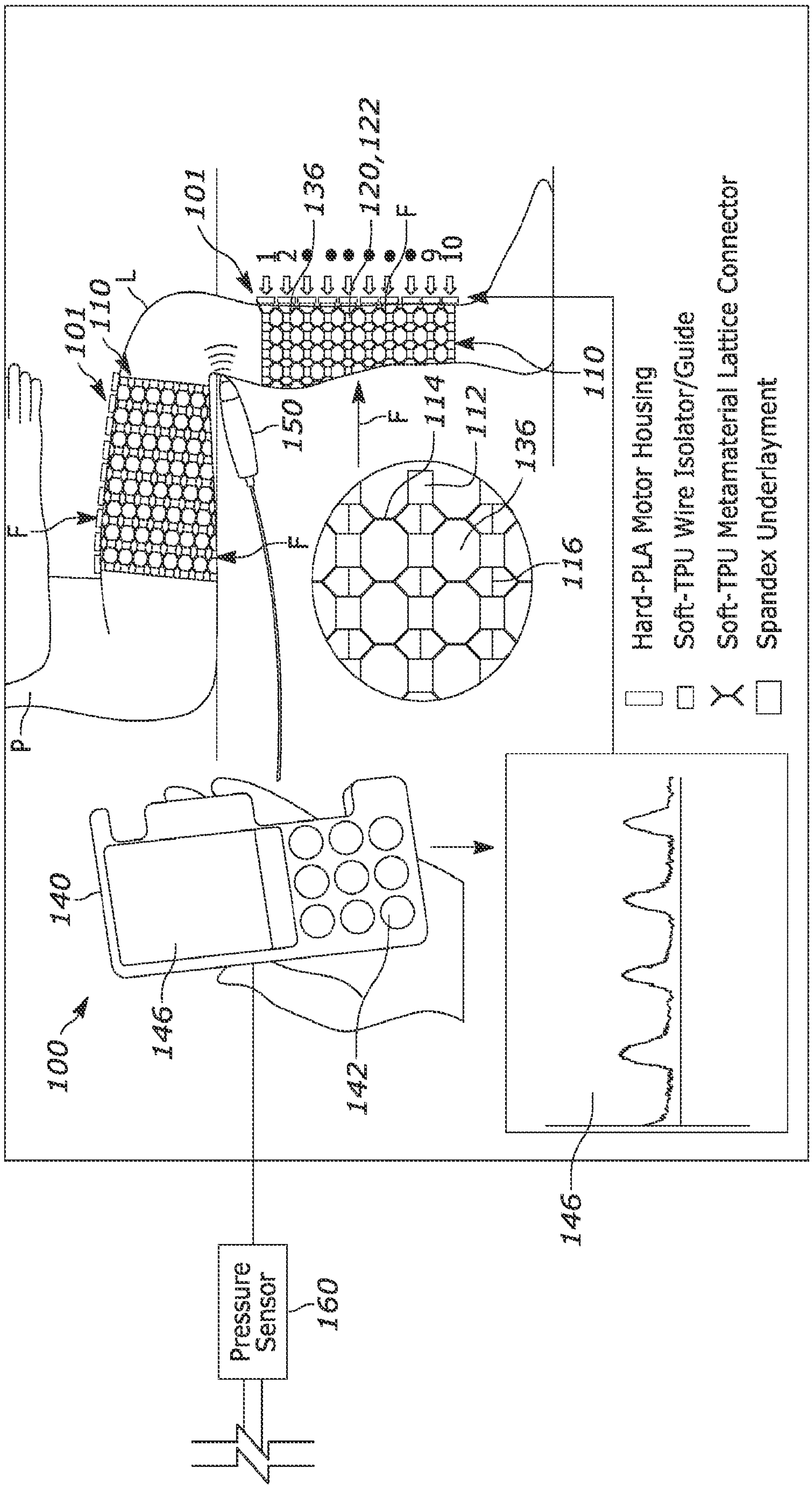

Hard-PLA Motor Housing
Soft-TPU Wire Isolator/Guide
Soft-TPU Metamaterial Lattice Connector
Spandex Underlayment
Pressure Sensor
100
101
110
112
114
116
120,122
136
140
142
146
150
160
F
L
P

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2024/049784

A. CLASSIFICATION OF SUBJECT MATTER

IPC: ***A61H 11/02*** (2024.01); ***A61F 5/02*** (2024.01); ***A61H 1/00*** (2024.01)
CPC: ***A61H 11/02; A61F 5/02; A61H 1/006; A61H 1/008***

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 2023/0117892 A1 (KOYA MEDICAL, INC.) 20 April 2023 (20.04.2023) entire document	1-3, 14, 15
X	US 2021/0121356 A1 (RECOVERY FORCE, LLC) 29 April 2021 (29.04.2021) entire document	1
A	US 2013/0345612 A1 (BIO CYBERNETICS INTERNATIONAL, INC.) 26 December 2013 (26.12.2013) entire document	1-4, 14-16
A	US 2017/0312161 A1 (JOHNSON et al.) 02 November 2017 (02.11.2017) entire document	1-4, 14-16
A	US 2017/0128306 A1 (TACTICLE SYSTEMS TECHNOLOGY, INC.) 11 May 2017 (11.05.2017) entire document	1-4, 14-16

☐ 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
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
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"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
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Date of the actual completion of the international search	Date of mailing of the international search report
06 December 2024 (06.12.2024)	**16 December 2024 (16.12.2024)**

Name and mailing address of the ISA/US	Authorized officer
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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.: **5-13, 17-26**
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).