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Non-Invasive Method and Apparatus for Measuring Pressure Within a Pliable Vessel

Invention Abstract

The present invention relates in general to a non-invasive method and apparatus for measuring pressure within a pliable vessel such as a blood vessel.

In one embodiment (see FIGS. 1 and 2), a clamp structure consisting of a solid semicylindrical housing member 12 and a hollow semicylindrical member 13 are arranged for clamping a blood vessel 18 between the two clamping members. A pair of retaining rings 23 are slipped over the ends of the clamping structure for holding the clamping members 12 and 13 together. The solid semicylindrical clamping member 12 is counterbored at 14 to receive a pressure transducer 16 having a flat sensing diaphragm portion 17 for engaging the flattened portion of the blood vessel for measuring the pressure inside of the blood vessel without invading the blood vessel.

In a second embodiment (see FIG. 3), the clamp housing structure is of one piece construction having a solid semicylindrical portion integrally coupled to a hollow semicylindrical portion 26. There is a longitudinal slot 27 through the hollow semicylindrical wall through which to insert the blood vessel 18. In a third embodiment (see FIG. 4), an elastic band 29 clamps the blood vessel 18 to the diaphragm of the pressure sensor housed in the clamp structure 28.

The distinction between the present invention and the prior art is the provision of the clamp structure for clamping the blood vessel to the diaphragm of the pressure sensor. An advantage of the invention is the ability to provide long term continuous monitoring without ill effects to the blood vessels.

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**Fig. 6**

Graph showing the relationship between $A/A_0$ and $x/r_o$ for different values of $r/r_o$. The graph indicates that the original face is of poor quality.

**Fig. 7**

Three diagrams labeled (A), (B), and (C) showing different ratios of $r/r_o$ and $h/r_o$. Diagrams depict the geometry for $r/r_o = 1.4$, $h/r_o = 0$; $r/r_o = 1.2$, $h/r_o = 0.26$; and $r/r_o = 1.1$, $h/r_o = 0.41$.
Description

Non-Invasive Method and Apparatus for Measuring Pressure Within a Pliable Vessel

1 Origin of the Invention

The invention described herein was made in the performance of work under a NASA contract and is subject to the provisions of Section 305 of the National Aeronautics and Space Act of 1958, Public Law 85-568 (72 Stat. 435; 42 U.S.C. 2457).

Technical Field

The present invention relates in general to measuring pressure within pliable vessels and, more particularly, to an improved method and apparatus for providing non-invasive pressure measurements within blood vessels.

Background Art

To date, blood pressure and its measurements represent one of the most critical parameters in determining cardiovascular function and assessing its control. Many questions relating to such a function have required information concerning beat-by-beat measurements of pressure which have been accomplished in animals and/or man or through transducers designed to be introduced within a blood vessel with the aid of a needle or catheter. Pressure measurement in blood vessels with diameters smaller than 4 to 5 millimeters is especially challenging. To date, measurements in such blood vessels have only been attempted with a process requiring the insertion of a hypodermic needle. Invasive approaches like these, however, can result in excessive damage to the walls of the vessel and significant disturbances to blood flow resulting in turbulence and/or blood clotting.

Such approaches are not suitable for obtaining reliable pressure measurements in animals or man for prolonged periods, i.e., up to six months or longer.

Pressman and Newgard reveal apparatus for monitoring superficial arterial pressure in "A Transducer for the Continuous External Measurement of Arterial Blood Pressure," IEEE Trans-
actions on Biomedical Electronics, Vol. 10, pp. 73-81, 1963.

Their transducer is adapted to rest on the skin surface so that an arterial rider section of the transducer is above an artery to be monitored. Mounting problems make the transducer ill-suited for continuous monitoring. Readings are affected by the transducer position and the transducer is only intended for use with large superficial arteries.

In another non-invasive prior art method, the pressure within a fluid filled tube or balloon has been measured by pressing the pliable vessel against a flat perforated plate. A fluid is made to flow through the perforations in the plate against the pliable wall of the vessel. The back pressure on the flow of the fluid through the perforations is measured to obtain a measure of the pressure inside the pliable vessel. This latter approach has not been suggested for use in measuring the pressure within pliable blood vessels of animals or humans since such a system is not feasible for use with biological systems unless the blood vessel is exposed.

[Statement of Invention]
Disclosure of Invention

In the present invention, a method and apparatus is provided for non-invasive measurement of fluid pressure within a vessel having pliable side walls, for example, a blood vessel. The fluid filled vessel is pressed against a relatively flat surface so as to flatten the engaged portion of the vessel. A diaphragm type pressure sensor is disposed in the flat vessel engaging surface so that the pressure within the vessel is transmitted through the pliable wall thereof to the flexible diaphragm of the pressure sensor for sensing the pressure within the vessel. In a preferred embodiment for measurement of pressure within a blood vessel, a two member clamp is provided. One member of the clamp is a semicylindrical tubular structure which holds the pressure sensitive diaphragm. The two clamping members are held together via the intermediary of a clip.
Brief Description of the Drawings

FIGURE 1 is an exploded perspective view of a pressure measuring apparatus incorporating features of the present invention.
FIGURE 2 is a transverse sectional view of the structure of FIG. 1 taken along line 2-2 in the direction of the arrows.
FIGURE 3 is an inverted view similar to that of FIG. 2 depicting an alternative embodiment of the present invention, and
FIGURE 4 is a view similar to that of FIG. 3 depicting an alternative embodiment of the present invention.
FIGURE 5 is a schematic view of one-half the cross-sectional area of a flattened blood vessel.
FIGURE 6 is a graph showing the relationship among contact width, cross-sectional area, and h.
FIGURES 7(a)-(c) show some of the possible vessel shapes resulting from aplanation.

Detailed Description of the Invention

Referring now to FIGS. 1 and 2 there is shown a pressure measurement apparatus 11 of the present invention. The pressure measuring apparatus includes first and second semicylindrical clamping members 12 and 13. First clamping member 12 is of generally solid semicylindrical configuration having a generally radially directed counter sunk bore passing therethrough and intersecting with a generally rectangular planar or flat face 15. A pressure transducer 16, of generally cylindrical shape, is disposed within the counter sunk bore 14. The pressure sensor 16 has a pressure sensing flexible diaphragm portion 17 flush mounted with the flat or planar face 15 of the first clamping member 12. In a preferred embodiment for measuring the pressure within a relatively small blood vessel, the pressure transducer 16 is a model P4.5 made by Konigsberg Instruments, Inc. of Pasadena, California and having a maximum diameter of 4.5 millimeters, and an effective pressure sensing flexible diaphragm of 3.5 millimeters.

The second clamp member 13 is of semicylindrical tubular configuration disposed so that its axis of revolution is generally parallel to the axis of revolution of the semicylindrical first clamping member 12. A blood vessel 18, the fluid pressure in
which it is desired to be measured, is clamped between the first and second clamping members 12 and 13 with its longitudinal axis generally parallel to the longitudinal axis of the semi-cylindrical clamping members 12 and 13.

A pair of alignment pins 19 project normally from the flat face 15 of the first clamping member 12 at opposite diagonal corners thereof to be received within bores 21 in the second semicylindrical tubular clamping member 13. The semicylindrical tubular clamping member 13 is dimensioned relative to the diameter of the blood vessel 18 such that when the blood vessel is clamped between the first and second clamping members 12 and 13 in the measuring position, as shown in FIG. 2, the blood vessel is indented at the flattened portion thereof 22 by at least 10-20% of the normal diameter of the blood vessel 18.

A pair of split resilient clipping rings 23, are clipped coaxially over the assembled first and second clamping members 12 and 13 for clipping and retaining the clamping members in clamped relation.

From known engineering theory (LaPlace's Law) the pressure difference across the wall of a thin elastic chamber (inside vs outside pressure) \( \Delta p \) is related to the tension force developed within the wall \( T \) and the curvature of the wall \( r \) such that \( \Delta p = \frac{T}{r} \). Thus, if a part of the chamber wall is flat, i.e., if the curvature is made to become infinite \( (r \rightarrow \infty) \) the \( \Delta p \) or difference across the vessel wall becomes zero and the pressure on the outer surface of the tube 18 which is sustained by the flat surface of the pressure transducer 17 and its holder 15 is equal to the pressure inside the tube 18, hence, the inside pressure of the tube 18 is measured directly by the pressure transducer 16.

FIG. 5 schematically depicts one-half of the cross-sectional area of a blood vessel as it is flattened in accordance with the subject invention and the figure is presented to explain the geometry of the clamping structure. X and Y coordinates intersect at point 0 which is the center of the arc portion 39 having a radius \( r \). \( r \) is the inner radius of the clamping member, such as member 13 in FIG. 1. The Y axis bisects the vessel area into symmetrical right and
left halves (only the left half is illustrated). The uppermost vessel surface 40 is the surface contacted by the diaphragm of transducer 16, and h represents the vertical displacement of surface 40 from the X axis. h may be positive or negative or zero. t is the wall thickness of the vessel. The arcuate section of the blood vessel not directly in contact with the clamping apparatus has a radius r' with a center 41 at -x, -y. p is the line between center point 41 and O and θ is the angle subtended by p and the x axis. Accordingly, the outer circumference of the vessel wall 2 is expressed by the equation:

\[ l = 2\pi r \left( \frac{90-\theta}{180} \right) + 2\pi (h+y) \left( \frac{90+\theta}{180} \right) + 2x \]  

(1)

The length of r' is

\[ r' = h + y \]  

(2)

The length of p is

\[ p = \sqrt{x^2 + y^2} \]  

(3)

The holder radius (r) is the sum of Equations 2 and 3, hence:

\[ r = r' + p = h + y + \sqrt{x^2 + y^2} \]  

(4)

and x is expressed as:

\[ x + y \cot \theta \]  

(5)

Based on Equations 4 and 5:

\[ y = \frac{r - h}{1 + \sqrt{1 + \cot^2 \theta}} \]  

(6)
From Equations 5 and 6, we obtain:

\[ x = \frac{(r-h)\cot \theta}{1 + \sqrt{1 + \cot^2 \theta}} \quad (7) \]

By incorporating Equations 6 and 7 into Equation 1:

\[ \lambda = \pi r \left( \frac{90-\theta}{90} + \frac{\pi(90+\theta)}{90} \right) \left( h + \frac{r-h}{1 + \sqrt{1 + \cot^2 \theta}} \right) + \frac{2(r-h)\cot \theta}{1 + \sqrt{1 + \cot^2 \theta}} \quad (8) \]

The original outer circumference \((\lambda_0)\) of the vessel is:

\[ \lambda_0 = 2\pi r_0 \quad (9) \]

where \(r_0\) is the original outer radius of the vessel. Assuming that the circumference is the same before \((\lambda_0)\) and after \((\lambda)\) introduction to the holder, \(\lambda\) is equal to \(\lambda_0\); therefore:

\[ 2\pi r_0 = \pi r \left( \frac{90-\theta}{90} + \frac{\pi(90+\theta)}{90} \right) \left( h + \frac{r-h}{1 + \sqrt{1 + \cot^2 \theta}} \right) + \frac{2(r-h)\cot \theta}{1 + \sqrt{1 + \cot^2 \theta}} \quad (10) \]

From equation 10, \(\theta\) is determined for given pairs of \(r\) and \(h\); in turn \(x\) and \(y\) can also be determined using Equations 6 and 7.

If the original cross-sectional area of the blood vessel is \(A_0\), then a similar analysis will lead to this equation for the cross-sectional area \(A\) of the blood vessel while it is in the holder apparatus:

\[ A = \pi(r-t)^2 \left( \frac{90-\theta}{180} \right) + \pi(h+y-t)^2 \left( \frac{90+\theta}{180} \right) + xy + 2x(h-t) \quad (11) \]

The above analysis could be used to determine the relative ratio of the flattened wall to the original outer diameter of the vessel \((2X/2r_0)\) with respect to relative changes in vessel cross-sectional area while outside the holder \((A/A_0)\). These changes are plotted as \(h/r_0\) values for various \(r/r_0\) in FIG. 6. The ratio \(t/r_0\), relating vessel wall thickness \(t\) to its original radius \(r_0\), is assumed to be 0.13 based on experimental data involving the canine carotid artery (at
FIG. 6 shows that as \( x/r_0 \) is increased, \( A/A_0 \) is decreased. When the reduction in area is unimportant, a larger \( x/r_0 \) can be obtained with a larger \( r/r_0 \) vessel holder. When the \( A/A_0 \) must be held constant, however, the \( x/r_0 \) increases as the \( r/r_0 \) decreases, as shown by the broken lines in the figure.

FIGS. 7(a)-(c) depict the vessel cross-sectional areas resulting when \( r/r_0 = 1.4, 1.2, \) and 1.1, respectively (where \( A/A_0 = 0.85 \)). Note that the largest transducer contact area is produced in the case of \( r/r_0 = 1.1 \).

For measuring the pressure within blood vessels, any one of a number of commercially available diaphragm type pressure sensors which are capable of sensing pressures over the range of 0 to 300 millimeters Hg, or greater may be employed.

Referring now to FIG. 3, there is shown an alternative embodiment of the present invention. In the embodiment of FIG. 3, the clamp structure for clamping and deforming the blood vessel 18 is a one piece construction having a generally solid semicylindrical portion 25 and a generally semicylindrical tubular portion 26. A slot 27 extends longitudinally of the semicylindrical tubular member 26 so as to permit the blood vessel to be slipped through the slot into position within the clamp structure.

Referring now to FIG. 4, there is shown an alternative embodiment of the clamping structure wherein the blood vessel 18, the pressure of which is to be measured, is clamped to the base or transducer holder portion 28 of the clamp structure via the intermediary of an elastic strap 29 fixedly secured at one end to the holder portion 28 of the clamp. The strap 29 is adjustably affixed at its other end by means of a suitable adjustable fastener means such as eyelets 31 in the elastic strap 29, such eyelets fitting over a pin 32 affixed to the clamp holder portion 28.

Various vessel holders made in accordance with the invention were employed in bench tests and acute and chronic experiments in animals. In the bench tests, the clamping structures were used to measure flow in rubber tubes and carotid arteries and the effect of both steady and pulsatile flow were studied. In measurements of the living artery it was found that if the flattened area was 20% or greater of the circumference and if the transducer working surface and flattened
artery wall were significantly in contact, there was a linear relationship between transducer output and arterial pressure at rest and after provocation by drug infusion. If most of the transducer working surface was in contact with the vessel wall, the relationship between transducer output and internal pressure was still linear but the slope did not necessarily adhere to the original calibration curve of the pressure transducer. The clamp apparatus failed to significantly affect waveform, flow rate or level of arterial pressure with reductions in cross-sectional area up to 30%. In the longest experiment conducted (35 days) no significant or severe change in artery shape was observed either upstream or downstream of the clamp structure.

Prior art invasive blood pressure measurement methods required an incision in the blood vessel for the introduction of a transducer or to introduce an appropriate sensor by a needle or catheter, thereby altering the system monitored due to surgery or the presence of the sensor. The present invention remedies the shortcomings of the prior invasive methods by providing a non-invasive, non-destructive measurement system positioned as a cuff external to the pliable wall of the vessel and capable of measuring a range of vessels from 1 millimeter to 30 millimeters and producing reliable information for long monitoring periods. It is equally applicable to measure the small pressures in the veins as well as the larger pressures encountered in the arteries. It can be used on small blood vessels that would not accommodate other measuring devices. Accurate measurement chronic pressure measurement of small vessels as the carotid, coronary, and renal arteries is highly important in studying the cardiovascular system. The ability to make long term blood pressure measurements alone or in combination with flow measurements will allow for further study of disease processes and the nature of regulatory events at rest or during various physiologic stresses.
A non-invasive method and apparatus is disclosed for measuring pressure within a pliable vessel such as a blood vessel. The blood vessel is clamped by means of a clamping structure having a first portion housing a pressure sensor and a second portion extending over the remote side of the blood vessel for pressing the blood vessel into engagement with the pressure sensing device. The pressure sensing device includes a flat deflectable diaphragm portion arranged to engage a portion of the blood vessel flattened against the diaphragm by means of the clamp structure. In one embodiment, the clamp structure includes first and second semicylindrical members held together by retaining rings. In a second embodiment the clamp structure is of one piece construction having a solid semicylindrical portion and a hollow semicylindrical portion with a longitudinal slot in the hollow semicylindrical portion through which to slip the blood vessel. In a third embodiment, an elastic strap is employed for clamping the blood vessel against the pressure sensing device.