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THIS NASA INVENTION APPEARS TO HAVE
EXCELLENT COMMERCIAL POTENTIAL

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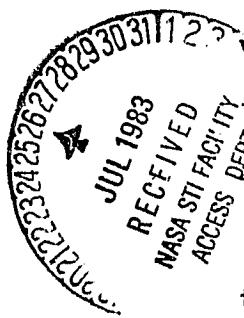
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Non-Invasive Method and Apparatus for
Measuring Pressure Within a Pliable Vessel

Invention Abstract

The present invention relates in general to a non-invasive method and appara-
tus 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 pro-
vision 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_1

Fig_2

Fig_3

Fig_4

465,370

Fig_5

Fig_6

$r/r_0 = 1.4$

1.3

1.2

1.1

1.0

x/r_0

A/A_0

0.85

0.90

$A/A_0 = 0.95$
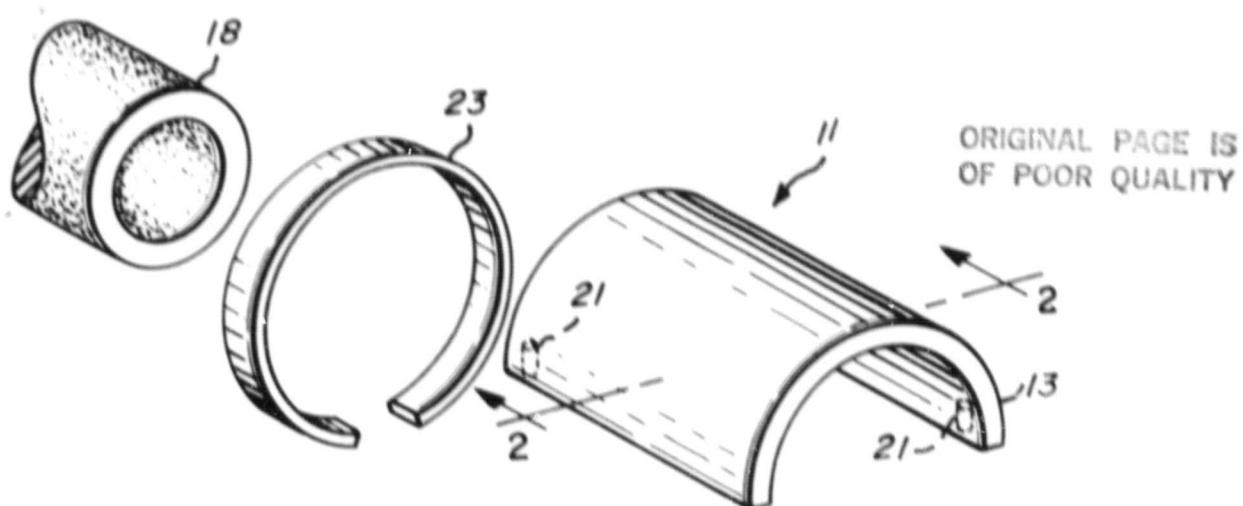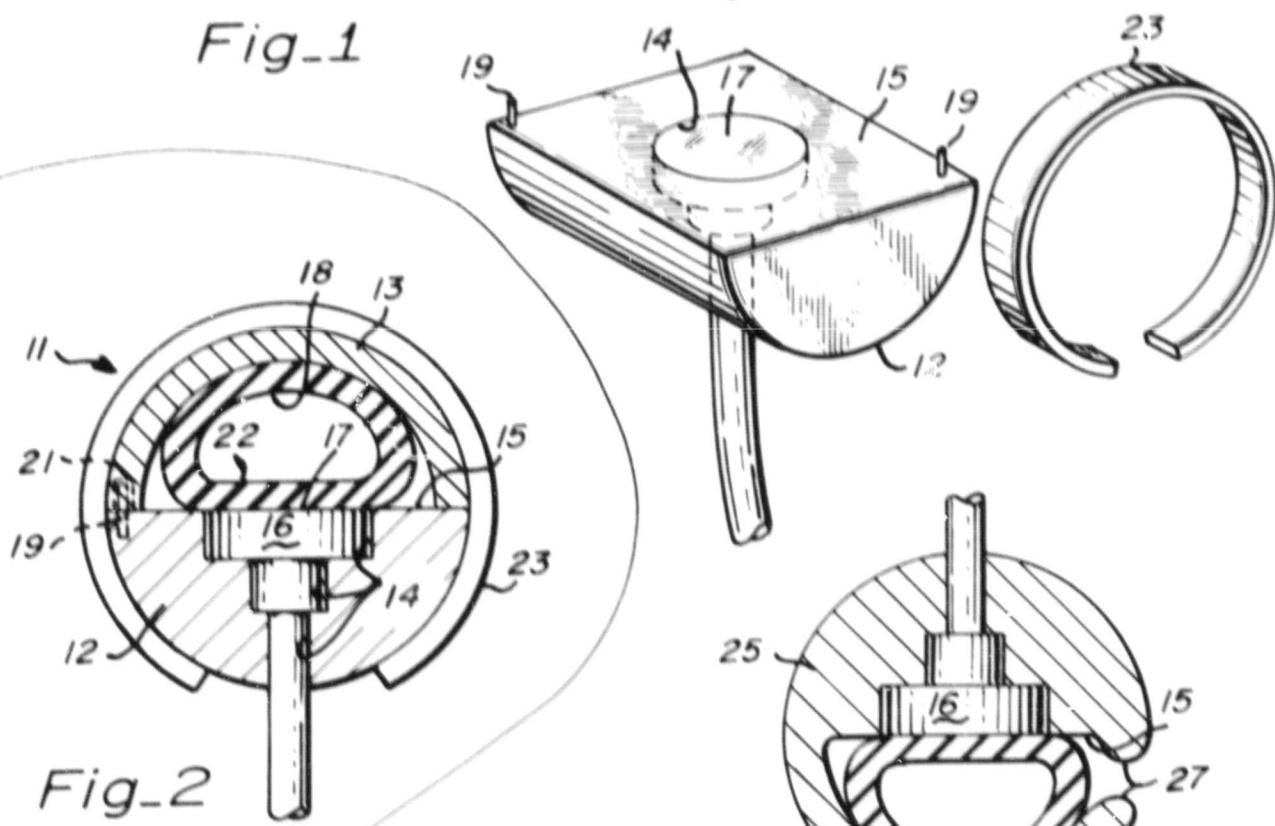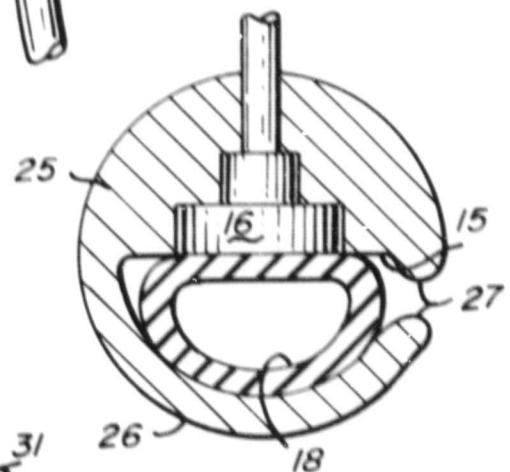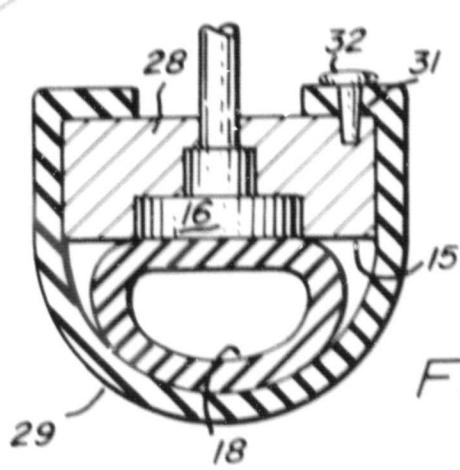
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1.5

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A/A_0 AND x/r_0

h/r_0

Fig_7

$x/r_0 = 0.7$

$x/r_0 = 0.76$

$x/r_0 = 0.87$

(A)

(B)

(C)
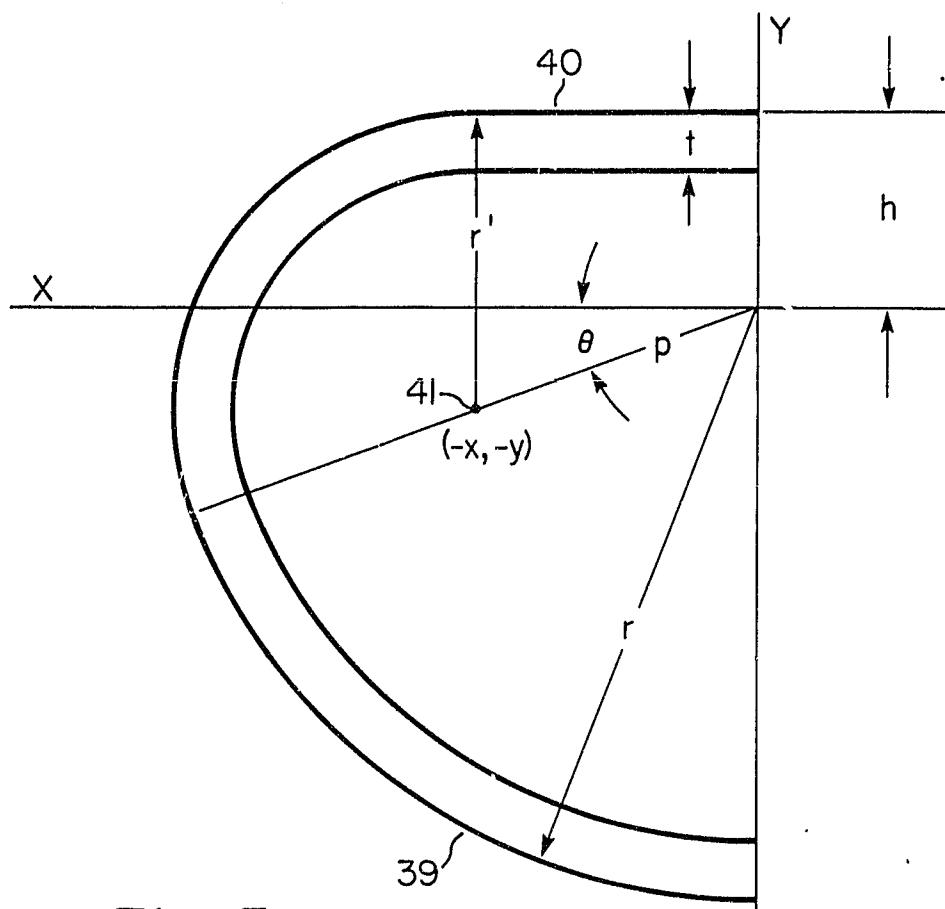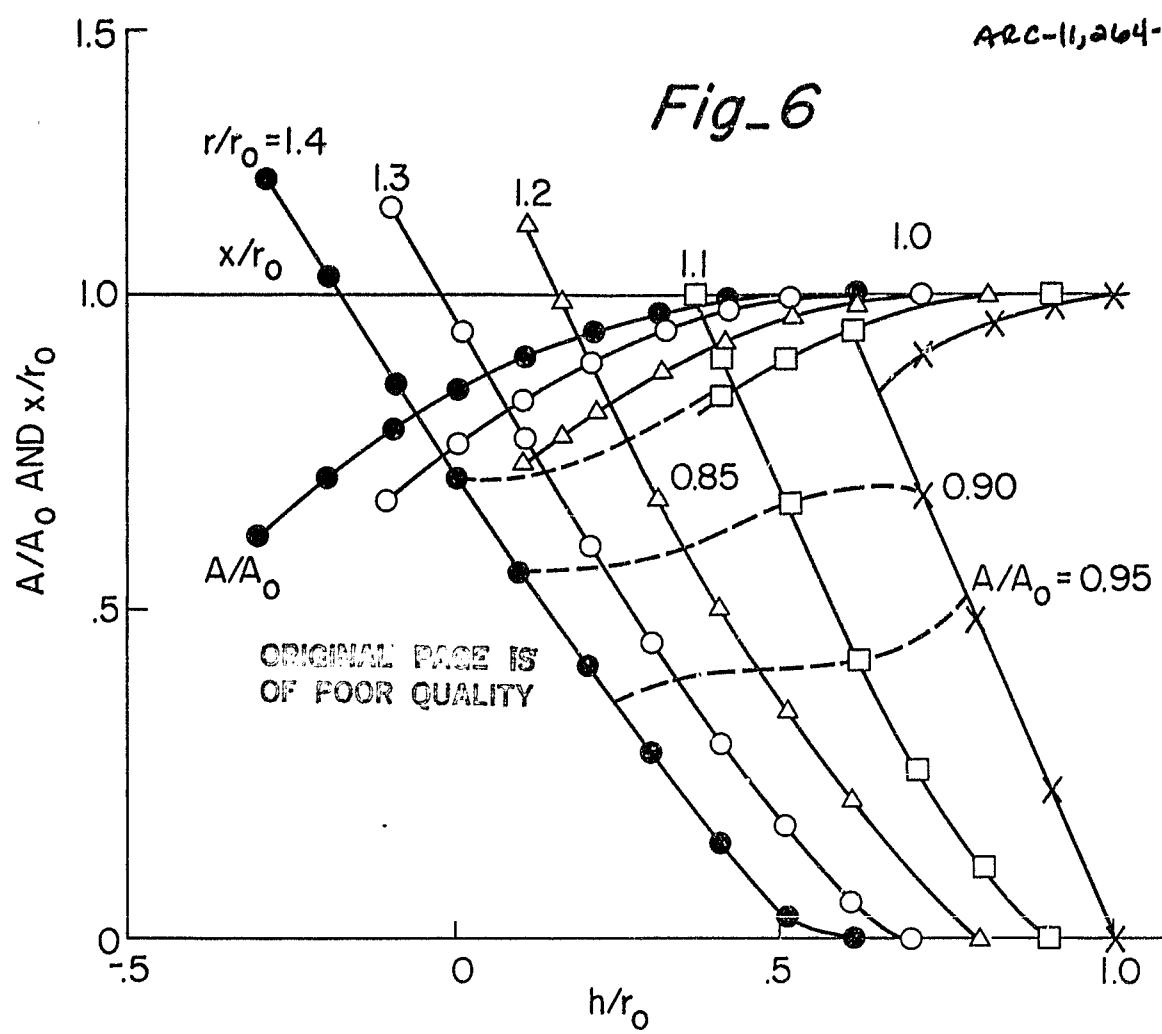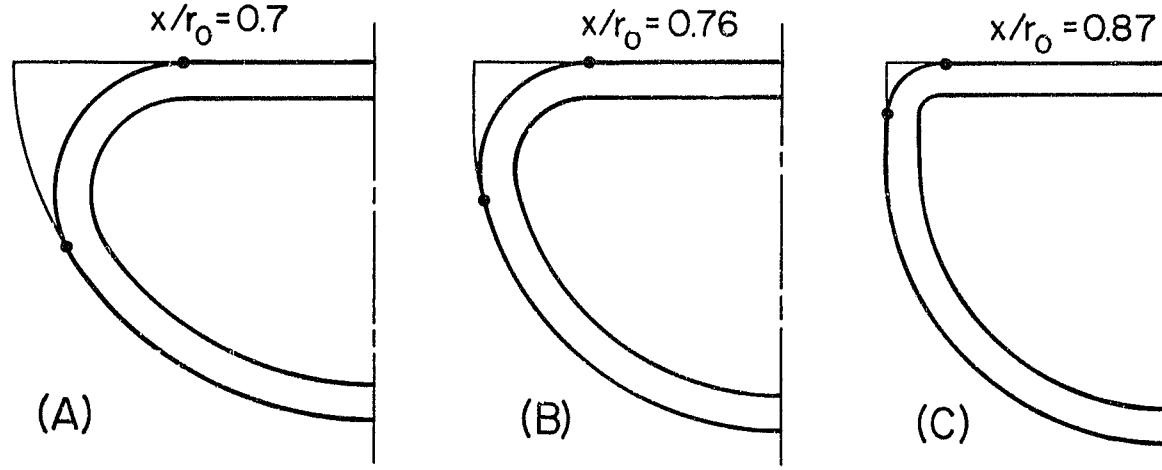
$\dfrac{r}{r_0} = 1.4$

$\dfrac{r}{r_0} = 1.2$

$\dfrac{r}{r_0} = 1.1$

$\dfrac{h}{r_0} = 0$

$\dfrac{h}{r_0} = 0.26$

$\dfrac{h}{r_0} = 0.41$

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
5   (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
10   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
15   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
20   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 distur-
bances to blood flow resulting in turbulance and/or blood clotting.
25   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
30   External Measurement of Arterial Blood Pressure," <u>IEEE Trans-</u>

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 illsuited for
5   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.
10   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
15   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
20   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
25   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
30   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 depiciting 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.

5   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

10   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.

15   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

20   difference across the wall of a thin elastic chamber (inside
vs outside pressure) (Δp) 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 ($r=\infty$) the Δp or

25   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

30   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

35   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

5 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 0 and Θ is the angle subtended by p and the x axis. Accordingly, the outer circumference of the vessel wall ℓ is expressed by the equation:

$$\ell = 2\pi r \frac{(90-\Theta)}{180} + 2\pi(h+y)\left(\frac{90+\Theta}{180}\right) + 2x \tag{1}$$

10 The length of r' is

$$r' = h + y \tag{2}$$

The length of p is

$$p = \sqrt{x^2 + y^2} \tag{3}$$

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

$$r = r' + p = h + y + \sqrt{x^2 + y^2} \tag{4}$$

and x is expressed as:

$$x + y \cot \Theta \tag{5}$$

Based on Equations 4 and 5:

$$y = \frac{r - h}{1 + \sqrt{1 + \cot^2 \Theta}} \tag{6}$$

From Equations 5 and 6, we obtain:

$$x = \frac{(r-h)\cot\Theta}{1 + \sqrt{1+\cot^2\Theta}} \tag{7}$$

By incorporating Equations 6 and 7 into Equation 1:

$$\ell = \pi r \frac{(90-\Theta)}{90} + \frac{\pi(90+\Theta)}{90}\left(h + \frac{r-h}{1+\sqrt{1+\cot^2\Theta}}\right) + \frac{2(r-h)\cot\Theta}{1+\sqrt{1+\cot^2\Theta}} \tag{8}$$

The original outer circumference (ℓ_0) of the vessel is:

$$\ell_0 = 2\pi r_0 \tag{9}$$

where r_0 is the original outer radius of the vessel. Assuming that the
5 circumference is the same before (ℓ_0) and after (ℓ) introduction to the
holder, ℓ is equal to ℓ_0; therefore:

$$2\pi r_0 = \pi r \frac{(90-\Theta)}{90} + \frac{\pi(90+\Theta)}{90}\left(h + \frac{r-h}{1+\sqrt{1+\cot^2\Theta}}\right) + \frac{2(r-h)\cot\Theta}{1+\sqrt{1+\cot^2\Theta}} \tag{10}$$

From equation 10, Θ 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,
10 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:

$$A = \pi(r-t)^2 \frac{(90-\Theta)}{180} + \pi(h+y-t)^2 \frac{(90+\Theta)}{180} + xy + 2x(h-t) \tag{11}$$

   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
15 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

100 mmHg arterial pressure). 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 16 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 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 corotid 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,

5   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

10 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

15 a transducer or to introduce an appropriate sensor by a needle
or catheter, thereby altering the system monitored due to
the 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

20 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.

25 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

30 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.

Abstract

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 semi-cylindrical 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.