

METHOD OF DETERMINING BLOOD PRESSURE AND AN APPARATUS FOR DETERMINING BLOOD PRESSURE

5 FIELD OF THE INVENTION

The invention relates to a method of determining blood pressure and an apparatus for determining blood pressure. The invention is particularly directed to determining blood pressure at the superficial temporal artery.

BACKGROUND TO THE INVENTION

10 The following discussion of the background to the invention is intended to facilitate an understanding of the present invention. However, it should be appreciated that the discussion is not an acknowledgment or admission that any of the material referred to was published, known or part of the common general knowledge in any jurisdiction as at the priority date of the application.

15 Blood pressure is commonly measured at arteries positioned in a patient's arm. Such measurements may be taken by invasive means or non-invasive means. Blood pressure measurements in the arteries of the brain are generally measured using invasive methods to determine the pressure at the Internal Carotid artery (CA), and Middle cerebral artery (MCA). This traditional invasive
20 measurement provides early predictors of stroke and the chance of stroke reoccurrence, however due to the invasive nature of such measurements they are not routine tests. There are risks that blood will form a clot around the tip of the catheter, blocking the artery and making it necessary to operate to reopen the vessel. There is a remote risk of the catheter puncturing the artery causing
25 internal bleeding. It is also possible that the catheter tip will separate material from the inner lining of the artery, causing a block downstream in the blood vessel.

Transcranial cardio Doppler TCCD is another method that provides assessment of blood flow velocities in the major cranial vessels using
30 ultrasound techniques. However, the measurements obtained are of the blood movement through the artery. The Doppler must be correctly positioned to ensure there is movement in the direction of the ultrasound beam. Ambiguity in

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the Doppler signal known as aliasing can occur. This requires adjustments in the pulse repetition by a skilled operator and the pulse repetition frequency may be further constrained by the range of sample volume. Similarly there is a large amount of adjustment as to the frequency used, such adjustment requires a great amount of skill and experience. The choice of frequency is a compromise between better sensitivity to flow (higher frequencies) and better penetration (lower frequencies). The capability of ultrasound to penetrate bone to permit sampling of flow dynamics in the large intracranial vessels is inversely proportional to skull thickness. Thickening of the bone in stroke-age patients, however, may obviate detection.

Accordingly, it is an object of the present invention to determine the blood pressure of a patient at arteries within brain while ameliorating the problems of current devices and techniques.

SUMMARY OF THE INVENTION

Throughout this document, unless otherwise indicated to the contrary, the terms "comprising", "consisting of", and the like, are to be construed as non-exhaustive, or in other words, as meaning "including, but not limited to".

An apparatus and method enables a reading of blood pressure of the brain at the superficial temporal artery to give an indication of blood related diseases.

The apparatus is non-invasive. Preferably a reading of blood pressure of the brain is measured as a continuous beat to beat rate on both the left superficial temporal artery and the right superficial temporal artery simultaneously during the same heart beat. Where the waveform measured from the left temporal artery differs from the wave form measured from the right temporal artery this may be an indication of an impending stroke or an indication that a stroke has recently happened. Further the indices of the wave forms may be used as a clinical indication of other blood related diseases

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

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Figure 1 is a front view of the apparatus.

Figure 2 is a side view demonstrating the connection of the sensor to the head band.

Figure 3 depicts the intended location of use of the apparatus.

5 Figure 4 depicts the internal location of the superficial temporal artery within the brain.

Figure 5 is a system diagram of the cranial artery network in relation to each other.

10 Figure 6, 7 and 8 are graphic results of measurement of both the left superficial temporal artery and the right superficial temporal artery in a subject.

PREFERRED EMBODIMENTS OF THE INVENTION

In accordance with a first embodiment of the invention referring to figure 1 there is an apparatus 10 for determining blood pressure. The apparatus 10 comprises a pair of pressure sensors 12. Bridging the two pressure sensors 12 is a head band 14. The head band 14 is curved so that the two pressure sensors 12 are tensioned towards each other so that when it is placed on a wearer the tension of the head band 14 can hold the pressure sensors 12 in place.

Components of the sensor 12 according to the preferred embodiment are similar to those discussed in patent application WO/2002/030277 which is incorporated herewith by reference. The sensor 12 according to the preferred embodiment includes a transducer, which produces a voltage output according to pressure changes acting on its diaphragm. A plunger 16 is affixed next to the diaphragm of the transducer. The plunger 16 and sensor 12 of the current system is build to a smaller scale than that disclosed in WO/2002/030277 to negotiate the constraints of the proximity of the superficial temporal artery to the pinna of the ear. It is important that the plunger 16 is able to be positioned such that appplanation pressure can be exerted on the superficial temporal artery to allow measurement of a waveform.

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The plunger 16 is a specially designed hemispherical component made of a rigid material. In the preferred embodiment the plunger 16 is made of a molded polymer plastic which is biocompatible. The hemispherical surface of the plunger 16 is adapted to push onto the superficial temporal artery of a subject and partially occludes the superficial temporal artery. The base of the plunger 16 housed within the sensor covers the surface of the diaphragm and is in direct contact with the diaphragm.

There is a layer of gel between the diaphragm and the plunger 16 to filter out interference and sharp changes due to unnatural movement. It also dampens the noise ratio. The plunger depth is specially designed such that on most normal heads, it could occlude not more than half the diameter of the superficial temporal artery 102 when the head band 14 is comfortably worn. This will enable full and faithful transmission of the arterial pulsation to be picked up, including the expansion of the arterial walls, the turbulence of the flow and the vibration transmitted along the artery wall from the heart.

As the plunger 16 and the diaphragm are the only moving units at each pulsation, the arterial pressure is accurately picked up as a waveform as each heart beat reaches the superficial temporal artery. For a change in pressure between 0 mmHg-300 mmHg, the displacement of the diaphragm against the pressure variation forms a linear relationship. The range of voltage change in the sensor for such an equation is between 0.5V to 4V, after amplification of the signal. The hemispherical plunger 16 allows for faithful transmission of a continuous beat to bead measurement of the wave form of each heart beat.

Referring to figure 2 each pressure sensor 12 is attached to one end of the head band 14 at the side opposite the plunger 16. The method of attachment takes the form of a ball joint 18. A bracket 20 is housed within the pressure sensor 12 at the side opposite the plunger 16. A ball joint 18 connected to a linking piece 22 is snapped into the bracket 20 allowing the pressure sensor to be moved to a wide range of locations independent of the location of the head band 14. This structure allows the plunger 16 to be accurately located over the superficial temporal artery of a wide range of wearers. Preferably, the ball joint

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comprises a spherical or hemispherical head that has a diameter large enough to allow the ball joint to have a large range of movement to negotiate the facial features or facial structures of a subject while not being larger than the width of the end of the head band 14.

- 5 Preferably, the linking piece 22 is cylindrical with fine threads 24 that can be screwed into an aperture 26 within one end of the head band 14. The aperture contains tracts to facilitate fine movement of the linking piece 22 into and out of the aperture 26.

Each pressure sensor 12 also is connected to a data and control cable 28. As
10 shown in Figure 1, it is preferred that the point of connection be such that the cable 28 is substantially parallel to the portion of the head band 14 that it also connects to that pressure sensor 12. The cable 28 is connected to a screen such that two separate waveforms can be displayed either side by side or overlapping one another. The waveform is measured in ADC units.

- 15 In this manner, the overall visual impact of the apparatus 10 is similar to that of a pair of conventional headphones. The pressure sensors 12 may have padding for the comfort of the wearer

The apparatus 10 will now be described with reference to its intended use.

- Referring to figure 3, a subject places the apparatus 10 over their head 100.
20 The tensioned curve of the head band 14 ensures that the pressure sensors 12 remain pressed against the side of the head. A medical personnel (not shown) thereafter adjusts the apparatus 10 by swivelling the ball joint 18 within its bracket 20 such that the two plungers 16 are positioned over the superficial temporal artery 102 of the subject 100. This positioning is important as the
25 superficial temporal artery 102 provides the following advantages for blood pressure reading:

- Its position against a bone assists the vertical applanation methodology employed by the pressure sensors 12 to determine blood pressure.

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- Commonly, there is very little fat in this region allowing full transmission of the pulse to be recorded as it would not allow for any significant soft tissue compensation.
- The artery is external of the skull bones at this point; and
- 5 • The artery is constant in position, as there is no recorded variation in the superficial temporal artery position in humans.

The internal location of the superficial temporal artery is depicted in figure 4 and the system of the cranial artery network in relation to each other is depicted in figure 5. It can be understood that a plaque in one of the arteries will affect
10 the blood flow of the interconnected arteries. The location of any obstruction or narrowing will change the blood flow differently depending on the obstructions location and it should be possible to derive a range of indices from a waveform to determine roughly where in the system a problem exists non-invasively.

Following appropriate positioning of the apparatus 10, each sensor 12a, 12b
15 sends its blood pressure measurement signals to a processing station 104 via their respective cables 28a, 28b.

On receipt of the various signals, the processing station 104 separates the measurement data according to the sensor 12 that produced the data.

In the final adjustment the output for both the left superficial temporal artery
20 102a and the right superficial temporal artery 102b in ADC units is zeroed or levelled. This is achieved by adjusting the fine tuning of the plunger against the superficial temporal artery 102 by turning the linking piece 22 into and out of the aperture 26 at the end of the head band 14. It is important that the applanation pressure on the artery is equalised between both the left superficial
25 temporal artery and the right superficial temporal artery to ensure that any variations between the waveforms measured on both sides is not due to a variation in the applanation pressure. Once the device is secured in position the measurement is quite constant and can be taken over a long time with the wearer being in almost any position.

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Figure 6, is a display from the processing station 104 showing a measurement of both the left superficial temporal artery and the right superficial temporal artery in a normal subject. While there are very minor variations between the measurements taken from either side the waveforms more or less mirror each other.

Figure 7 is a display from the processing station 104 showing a measurement of both the left superficial temporal artery and the right superficial temporal artery in a subject that has recently undergone a stroke. The waveforms vary greatly between the left and right side in this case.

Figure 8 is a display from the processing station 104 showing a measurement of both the left superficial temporal artery and the right superficial temporal artery in a subject who appeared to be normal and had no other indications of a possible impending stroke. There is, however, a variation in the timing of the dicrotic notch which is also higher on the left side than the right side. This subject may be at potential risk of stroke or other such blood related diseases in the brain.

The main aortic artery branches into the left and right common carotid artery A these arteries branch further into two internal carotid arteries C and two external carotid arteries B. The left common carotid artery A branches into the left internal carotid artery C and the left external carotid artery B. Similarly the right common carotid artery A branches into the right internal carotid artery C and the right external carotid artery B. Due to this branching any narrowing or blockages of the arteries will affect blood flow which will be reflected in the waveform measured at the superficial temporal artery. Medical procedures are often limited to arteries in one side of the brain. Similarly problems related to narrowing of the arteries, blockages or other complications may be in one branch eg: in the left internal carotid artery. Measuring and comparing both sides of the main cranial arteries can be used to assess the adequacy of cerebral circulation and blood pressure in the arteries from both sides of the brain.

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For example in neonates with extracorporeal membrane oxygenation there is sometimes a need for right common carotid reconstruction that would benefit from monitoring blood pressure in both right and left side arteries. Similarly in high risk stroke cases differences between the blood pressure in the right and the left side arteries using the apparatus 10 provides a non invasive method of detecting obstructive lesions of the arteries or aneurisms that generally only occur in arteries on one rather than both sides of the brain. Such monitoring can be beneficial in people who have never had a stroke or in monitoring post stroke patients. As the measurement is non-invasive which is less risky than invasive methods, the apparatus 10 can be used to monitor a much larger group.

Blood pressure monitoring with the apparatus 10 can be conducted over a long time frame while the person carries out their normal daily activities and recorded so that the data can be passed to a medical practitioner for further analysis.

It should be appreciated by the person skilled in the art that the above invention is not limited to the embodiment described. In particular, the following modifications and improvements may be made without departing from the scope of the present invention:

- The head band 14 may be padded to provide extra comfort to the wearer during use.
- The portion of the head band 14 to which the pressure sensors 12 are connected may be extendible from the remainder of the head band 12. In this manner, the apparatus 10 can be used by people having a wide variety of head sizes and shapes.
- As the use of the ball joint 16 allows free movement of the pressure sensor 12, it is important that the point of connection between the pressure sensor 12 and the data and control cable 22 be at a position such that the weight of the data and control cable 22 does not cause the pressure sensor 12 to move.

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- The pressure sensors may be positioned at the superficial temporal artery by a clip or some other attachment means that does not require the headband in which case the sensors may not be connected in any way and may be connected to two separate measuring devices.

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Claims:

1. A non-invasive apparatus for measuring blood pressure of the brain at a superficial temporal artery comprising: a pressure sensor and at least one adjustment means attached to the pressure sensor whereby the adjustment means allows the pressure sensor to be located over and provide an applanation pressure on the superficial temporal artery when in use.
2. The non-invasive apparatus of claim 1 further comprising a head band tensioned to allow the pressure sensors to be pressed against the side of a head on the superficial temporal artery when in use.
3. The non-invasive apparatus of claim 1 or claim 2 wherein the adjustment means comprises a ball joint attached to the pressure sensor via a bracket housed within the pressure sensor whereby the pressure sensor is capable of being moved to a wide range of locations.
4. The non-invasive apparatus of claim 3 wherein the adjustment means further comprises a linking piece connected to the ball joint capable of being screwed into an aperture formed within a head band to facilitate fine adjustment of the pressure sensor on the superficial temporal artery when in use.
5. The non-invasive apparatus of claim 2 further comprising a second pressure sensor and a second adjustment means attached to the second pressure sensor whereby the head band is curved to bridge the pressure sensor and the second pressure sensor so that the two pressure sensors are tensioned towards each other whereby the tension of the head band can hold the first and second pressure sensor on the superficial temporal arteries when in use.
6. The non-invasive apparatus of any one of the proceeding claims wherein the pressure sensor further comprises a plunger affixed adjacent a diaphragm of a transducer.
7. The non-invasive apparatus of claim 6 wherein the plunger is a rigid hemispherical component adapted to push into and provide an applanation pressure on the superficial temporal artery when in use.

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8. The non-invasive apparatus of claim 6 or claim 7 wherein there is a layer of gel between the plunger and the diaphragm.
9. The non-invasive apparatus of any one of the preceding claims wherein the pressure sensor is connected to a cable.
- 5 10. The non-invasive apparatus of claim 9 wherein the cable connects to a processing station where a waveform measured by the sensor when in use is capable of being displayed on the processing station.
11. A non-invasive method for measuring blood pressure of the brain at a superficial temporal artery comprising the steps of:
 - 10 a. Positioning a pressure sensor over the superficial temporal artery;
 - b. Adjusting the pressure sensor to exert an applanation pressure on the superficial temporal artery; and
 - c. Measuring a waveform as each heart beat reaches the superficial temporal artery.
- 15 12. The non-invasive method of claim 11 further comprising the step of tensioning a second pressure sensor over a superficial temporal artery on the head of a wearer such that a first sensor is positioned over a left superficial temporal artery and a second sensor is positioned over a right superficial temporal artery of the wearer.
- 20 13. The non-invasive method of claim 12 further comprising the step of equalising the applanation pressure between the left superficial temporal artery and the right superficial temporal artery.
14. The non-invasive method of claim 12 or claim 13 wherein the waveform measured from the left superficial temporal artery is compared with the
25 waveform measured from the right superficial temporal artery to assess cerebral blood circulation and pressure in the arteries on both sides of the brain.