A method is presented for determining diastolic intracranial pressure (ICP) in a patient. A first change in the length of a path across the skull of the patient caused by a known change in ICP is measured and used to determine an elasticity constant for the patient. Next, a second change in the length of the path across the patient’s skull occurring between systolic and diastolic portions of the patient’s heartbeat is measured. The patient’s diastolic ICP is a function of the elasticity constant and the second change.

20 Claims, 3 Drawing Sheets
FIG. 2

PULSATILE VARIATIONS IN ICP

MEAN DIASTOLIC ICP

0 10 20 30 40 50

0 20 40 60 80 100
FIG. 4

FIG. 5
1. Field of the Invention

This invention relates to determination of intracranial pressure. More specifically, the invention is a non-invasive method for determining the diastolic intracranial pressure in a patient.

2. Description of the Related Art

Bone tissue is the most rigid of all animal tissues. The skull bone surrounds and protects one’s cranial complex which includes the brain and cerebrospinal fluid (CSF) surrounding the brain. The human brain and the spinal cord are immersed in CSF which is continuously generated and reabsorbed by the body. The CSF is contained in a membrane covering the inside of the skull and the spinal cord which terminates in a sack located at the sacrum. The brain and the membrane containing the CSF also contain blood vessels, which are in direct communication with the CSF and add to the total volume of the cerebrospinal system. The blood volume in these blood vessels varies rhythmically with the heartbeat thereby causing corresponding oscillations in the intracranial pressure (ICP). The collective compliance (i.e., the ability to increase in volume with increasing pressure) of the skull and CSF is too small to accommodate the pressure regulation needed for proper circulation of blood within the brain and spinal cord. Hence, pressure within the cranial complex is controlled by the compliance of the brain’s venous bed in association with the creation and removal of CSF by specialized structures within the brain.

Pressure is regulated by rate of production of CSF by the choroid plexus, and rate of removal of cerebrospinal fluid by the arachnoid villi. These rates therefore play a crucial role in blood flow regulation, while also relating to disease and pathologies which can occur. A complex interaction between the blood vessels and ICP accomplishes the needed regulation of blood flow in brain tissue.

Substantial effort has been devoted to understanding the dynamics of pulsatile effects on ICP. Towards this end, many investigators have developed an “equation of state” which describes pressure and volume relationships in the cranial complex. While the various relationships differ, it is generally accepted that increases in diastolic ICP (i.e., increases in ICP occurring during the diastolic rhythm of one’s heartbeat) generate intracranial hypertension that affects the viability and function of the human brain.

Given the above, monitoring of diastolic ICP is of significant diagnostic and post-operative importance for patients with cranial injuries, pathologies or other conditions that may affect the pressure of the subarachnoidal fluid around the brain, and for patients who have undergone brain surgery. In general, ICP has traditionally been measured and monitored by means of a pressure sensor inserted through the skull into the brain. Usually a hole is drilled in the skull and a catheter with a pressure sensor is inserted into the brain fluid. This known procedure, while simple and accurate is not suitable for long-term monitoring because an open wound must be maintained in the skull. Antibiotics are only partially effective in treating cranial infections so the pressure sensor can only be left in place for two weeks or less.

Long-term monitoring of ICP is currently achieved by implanting a pressure sensor and transmitter into the brain. The ICP is thereafter monitored by means of a receiver located outside the skull. However, this solution is not preferred because it includes the risks associated with implanting anything in the brain, and because of the problems associated with providing power to an implanted transmitter.

A variety of non-invasive systems and/or methods of measuring relative changes in ICP have been described in each of U.S. patent application Ser. Nos. 09/459,384, 09/493,044, 10/094,023, and 10/121,932. However, none of these provide for the measurement or determination of a diastolic ICP.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a method of determining diastolic ICP in a non-invasive fashion.

Another object of the present invention is to provide a method of determining diastolic ICP that minimizes the number of procedures used.

Other objects and advantages of the present invention will become more obvious hereinafter in the specification and drawings.

In accordance with the present invention, a method is presented for determining diastolic intracranial pressure (ICP) in a patient. A first change in the length of any path across the skull of the patient caused by a known change in ICP is measured. This first change relative to the known change in ICP is indicative of an elasticity constant for the patient. Next, a second change in the length of the path across the patient’s skull occurring between systolic and diastolic portions of the patient’s heartbeat is measured. The patient’s diastolic ICP is a function of the elasticity constant for the path and the second change in the length of the path across the patient’s skull.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic view of the skull and brain of a patient with the brain being coupled to the patient’s heart;

FIG. 2 is a graphical view of a model relating pulsatile variations in ICP to the mean diastolic ICP for a typical human CSF system;

FIG. 3 is a schematic view of a system that can be used to measure/monitor skull expansion in a patient for use by the method of the present invention;
pulsatile changes in ICP with a very slight increase in pressure. Surrounding brain variations in ICP and a mean diastolic ICP can be written venous structure that is coupled to the patient’s heart. Accordingly, pressure within skull is not sufficient to accommodate the pressure regulation needed for proper circulation of blood within brain 12 and the patient’s CSF system (not shown). Accordingly, pressure within skull 10 is controlled by compliance of the brain’s venous bed in association with the addition/removal of CSF 16.

As mentioned above, substantial effort has been devoted to understanding the dynamics of pulsatile effects of ICP. The present invention makes use of a hydrodynamic model that describes a numerical relationship between pulsatile variations in ICP (i.e., difference between systolic ICP and diastolic ICP) and a mean diastolic ICP. The hydrodynamic model is described in detail by Mauro Ursino in “A Mathematical Study of Human Intracranial Hydrodynamics Part I-The Cerebrospinal Fluid Pulse Pressure,” Annals of Biomedical Engineering, Volume 16, pages 379-401, 1988, which article is incorporated herein by reference as if set forth in its entirety. The graphical version of the hydrodynamic model relating the pulsatile variations in ICP to the mean diastolic ICP is shown for a general human population in FIG. 1. When a best-fit curve is applied to the values in FIG. 2, a power law relationship between pulsatile variations in ICP and a mean diastolic ICP can be written mathematically as

\[ ICP_{pulsatile} = A(KAx)^b \]  

where \( ICP_{pulsatile} \) is diastolic ICP for a patient at a measurement point in time, \( K \) is an elasticity constant to be determined for the patient by the present invention, \( Ax \) is the amount of linear skull expansion (i.e., path length change) occurring (at the “measurement point in time”) between the systolic and diastolic points in the heartbeat of the patient, and \( A \) and \( B \) are constants determined from a best fit to the general population data in FIG. 2. For example, for the curve illustrated, \( A \) is 5.6957 and \( B \) is 0.77312. However, it is to be understood that some variation in \( A \) and \( B \) will occur depending on the “best-fit curve” used. Accordingly, particular choices for \( A \) and \( B \) are not limitations of the present invention.

In addition to the above-mentioned work by Ursino, the present invention takes note of the fact that the skull responds to pulsatile changes in ICP with a very slight increase in volume referred to hereafter as pulsatile skull expansion, i.e., the amount of skull expansion between the systolic and diastolic portions of a heartbeat. The volume change resulting from pulsatile skull expansion can be viewed as a change in path length measured, for example, across the skull.
Control of force device 34 can be maintained by control system 32 which can be entirely automatic or can include means for accepting manual inputs. To monitor the amount of pressure applied to skull 10, pressure sensors 36 and 38 can be provided at each of pressure pads 26 and 28, respectively. The pressure readings can be used by control system 32 as a feedback control for force device 34. Pressure outputs can also be displayed on a display 40.

To monitor skull expansion using the pulse-echo approach, headband 22 is placed on skull 10 such that pads 26 and 28 are in contact with the patient's skin 11 adjacent to skull 10. With the pads 26 and 28 in contact with the patient's skin 11, the transmission location will level off to a constant once the effects of pulsatile blood perfusion have subsided. Accordingly, a peak-to-valley measurement of the wave-length change will contact skin 11. This ensures good coupling of acoustic signals transmitted into skull 10 from transducer 30 as well as good coupling of acoustic signal reflections from skull 10 to transducer 30.

In general, system 20 monitors skull expansion in accordance with the teachings of U.S. Pat. Nos. 5,214,955 and 5,671,873. That is, system 20 measures path length changes as a function of phase difference between the acoustic signal transmitted into skull 10 and the acoustic signal measured at a detection location at two different points in time. As mentioned above, the detection location can be: i) the same as the transmission location when a single transmission/reception transducer 30 is used, ii) adjacent the transmission location if a dedicated reception transducer is mounted adjacent transducer 30, iii) at another location that is spaced apart from the transmission location, e.g., at a location diametrically-opposed to the transmission location as would be the case if dedicated reception transducer 31 were used.

Prior to monitoring skull expansion using system 20, the patient (with headband 22 still in place) is "manipulated" to bring about known changes in ICP and AICP. For example, a representative output of system 20 is illustrated in FIG. 5. Where phase difference is measured in terms of an output voltage. That is, the present invention, the phase difference waveform depicted in FIG. 5 correlates well with the patient's pulse waveform. According to the present invention, the phase difference waveform depicted in FIG. 5 is indicative of skull expansion Aδx. The conversion of a peak-to-valley voltage to a pulsatile skull expansion Aδx is made possible by calibration of system 20 as would be understood by one of ordinary skill in the art. The advantages of the present invention are numerous. Determination of diastolic ICP is determined through the use of easily taken measurements. The process is non-invasive in nature and, therefore, can be used for both one-time and longer term monitoring scenarios. Thus, the present invention will find great utility in both critical and non-critical ICP-related pathologies as well as other medical applications requiring knowledge of diastolic ICP.

Although the invention has been described relative to a specific embodiment thereof, there are numerous variations and modifications that will be readily apparent to those skilled in the art in light of the above teachings. For example, rather than using the tilt bed approach to causing known changes in ICP, system 20 could be used to apply incremental increases in headband pressure to bring about changes in path length to permit calibration. It is therefore to be understood that, within the scope of the appended claims, the invention may be practiced other than as specifically described.
What is claimed as new and desired to be secured by Letters Patent of the United States is:

1. A method of determining diastolic intracranial pressure (ICP) in a patient, comprising the steps of:
   - measuring a first change in the length of a path across the skull of the patient caused by a known change in ICP in the patient, wherein said first change in the length of said path relative to said known change in ICP is indicative of an elasticity constant for the patient; and
   - measuring a second change in the length of said path occurring between systolic and diastolic portions of a heartbeat of the patient, wherein a diastolic ICP is a function of said elasticity constant and said second change in the length of said path.

2. A method according to claim 1 wherein each of said steps of measuring comprises the steps of:
   - coupling an acoustic signal to a first location on the patient’s skin adjacent the skull of the patient; and
   - detecting said acoustic signal at a second location on the patient’s skin adjacent the skull of the patient; and
   - measuring a phase difference between said acoustic signal so-coupled at said first location and said acoustic signal so-detected at said second location, wherein said phase difference is indicative of one of said first change and said second change.

3. A method according to claim 2 further comprising the step of applying pressure to the patient’s skin at each of said first location and said second location prior to said steps of coupling and detecting, wherein pulsatile blood perfusion at said first location and said second location is reduced.

4. A method according to claim 2 wherein said first location and said second location are approximately diametrically-opposed to one another on either side of the skull of the patient.

5. A method according to claim 2 wherein said first location and said second location are approximately the same location.

6. A method according to claim 1 wherein said known change in ICP is induced by the step of manipulating the patient in a mechanical fashion.

7. A method according to claim 1 wherein said known change in ICP is induced by the step of manipulating the patient in a chemical fashion.

8. A method of determining diastolic ICP in a patient, comprising the steps of:
   - measuring a first change Δl in the length of a path across the skull of the patient caused by a known change ΔICP in ICP in the patient, wherein ΔICP/Δl defines an elasticity constant K for the patient; and
   - measuring a second change Δx in the length of said path occurring between systolic and diastolic portions of a heartbeat of the patient, wherein a diastolic ICP is equal to A(KΔx)², wherein A and B are constants derived from a data relationship between pulsatile variations in ICP and a mean diastolic ICP, wherein said data relationship is defined for a general human population.

9. A method according to claim 8 wherein each of said steps of measuring comprises the steps of:
   - coupling an acoustic signal to a first location on the patient’s skin adjacent the skull of the patient; and
   - detecting said acoustic signal at a second location on the patient’s skin adjacent the skull of the patient; and
   - measuring a phase difference between said acoustic signal so-coupled at said first location and said acoustic signal so-detected at said second location, wherein said phase difference is indicative of one of said first change and said second change.

10. A method according to claim 9 further comprising the step of applying pressure to the patient’s skin at each of said first location and said second location prior to said steps of coupling and detecting, wherein pulsatile blood perfusion at said first location and said second location is reduced.

11. A method according to claim 9 wherein said first location and said second location are approximately diametrically-opposed to one another on either side of the skull of the patient.

12. A method according to claim 9 wherein said first location and said second location are approximately the same location.

13. A method according to claim 8 wherein said known change in ICP is induced by the step of manipulating the patient in a mechanical fashion.

14. A method according to claim 8 wherein said known change in ICP is induced by the step of manipulating the patient in a chemical fashion.

15. A method of determining diastolic ICP in a patient, comprising the steps of:
   - coupling an acoustic signal to a first location on the patient’s skin adjacent the skull of the patient; and
   - detecting said acoustic signal at a second location on the patient’s skin adjacent the skull of the patient; and
   - inducing a known change in ICP in the patient;
   - measuring a first phase difference between said acoustic signal so-coupled at said first location and said acoustic signal so-detected at said second location, said first phase difference being caused by said known change in ICP, wherein said first phase difference is indicative of a first change in the length of a path across the skull of the patient, and wherein said first change in the length of said path relative to said known change in ICP is indicative of an elasticity constant for the patient;
   - repeating said steps of coupling and detecting; and
   - measuring, during said step of repeating, a second phase difference between said acoustic signal so-coupled at said first location and said acoustic signal so-detected at said second location, said second phase difference occurring between systolic and diastolic portions of a heartbeat of the patient, wherein said second phase difference is indicative of a second change in the length of said path occurring between said systolic and diastolic portions, wherein a diastolic ICP is a function of said elasticity constant and said second change in the length of said path.

16. A method according to claim 15 further comprising the step of applying pressure to the patient’s skin at each of said first location and said second location prior to said steps of coupling and detecting, wherein pulsatile blood perfusion at said first location and said second location is reduced.

17. A method according to claim 15 wherein said first location and said second location are approximately diametrically-opposed to one another on either side of the skull of the patient.

18. A method according to claim 15 wherein said first location and said second location are approximately the same location.

19. A method according to claim 15 wherein said known change in ICP is induced by the step of manipulating the patient in a mechanical fashion.

20. A method according to claim 15 wherein said known change in ICP is induced by the step of manipulating the patient in a chemical fashion.