Remote Monitoring of Internal Bleeding Based on Magnetic Induction and Cellular Phone Technology: *A Potential Application in Poor Regions in México*

Monitoreo Remoto de Hemorragias Internas Basado en Inducción Magnética y Tecnología de Telefonía Celular: Una Potencial Aplicación en Regiones Pobres de México

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Abstract. The goal of this study is to introduce the theoretical foundation of a new concept in medical technology that is centered on the cellular phone. The concept was conceived with the needs of medically underserved regions of Mexico in mind. The application introduced here deals with undetected intraperitoneal bleeding that is responsible for the death of one of four women who die at childbirths and that of 20% of accident trauma deaths; even brain trauma. The concept is made possible by the wide availability of cellular phone technology in Mexico, even in the poorest of regions, where other infrastructure is missing. The biophysical principles of the technology are based on the observation that electromagnetic properties of tissue change with disease and internal bleeding. We introduce a new paradigm of medical diagnostic in which inexpensive electromagnetic coils at the patient site are used to take bulk data from a magnetic field that is generated through the tissue or organ of interest. Instead of processing the data with a computer at the remote site the raw data is send via a cellular phone to a central facility that processes the raw data for the entire country or region. The diagnostic is returned in real time to the cellular phone at the patient site, thereby substantially reducing the cost of the devices and with good quality of the diagnostics. Components and functionality required to support the remote monitoring concept by magnetic fields and cell phone technology are presented. The study includes criteria for data processing at the remote site and gives a linear optimal solution to the problem. More advanced data processing methods and calibration of the system will be developed in future. While designed with the needs of Mexico in mind, this concept could become valuable worldwide.

Keywords: Phase Shift, Magnetic Induction, Spectroscopy, Cell Phone, Internal Bleeding.

Resumen. El objetivo de este estudio es introducir el fundamento teórico de un nuevo concepto en tecnología médica basado en telefonía celular. El concepto fue concebido teniendo en mente las necesidades médicas de las regiones marginadas de México y confronta el problema clínico que representan las hemorragias internas no detectadas a tiempo, tal problema es responsable de la muerte de una de cada cuatro mujeres que mueren durante el trabajo de parto así como del 20% de muertes por accidentes traumáticos; incluyendo trauma craneoencefálico. El concepto planteado es posible debido a la amplia disponibilidad de tecnología de telefonía celular en México, la cual incluye a las regiones más pobres en donde se carece de otro tipo de infraestructura básica. El principio biofísico de la tecnología está basado en la observación de los cambios en las propiedades electromagnéticas de tejido enfermo y hemorragias internas. Introducimos un nuevo paradigma de diagnóstico médico en el que bobinas electromagnéticas de bajo costo son empleadas en el sitio del paciente para adquirir datos volumétricos de un campo magnético que es generado a través del tejido u órgano de interés. En lugar de procesar los datos con una computadora en el sitio remoto, los datos crudos son enviados vía un teléfono celular a una estación central que procesa los datos crudos para toda una región o inclusive el país entero. El diagnóstico se envía en tiempo real al teléfono celular en el

lugar del paciente, reduciendo sustancialmente el costo de los dispositivos e incrementando la calidad de los diagnósticos. Se presentan los componentes y funcionalidad requerida para soportar el concepto de monitoreo a distancia mediante campos magnéticos y tecnología de telefonía celular. El estudio incluye criterios para el procesamiento de datos en el sitio remoto y proporciona una solución lineal óptima del problema. Métodos más avanzados de procesamiento de los datos, así como una calibración del sistema aún representan trabajos a futuro. Si bien el concepto aquí presentado fue diseñado con las necesidades de México en mente, este podría convertirse valioso en todo el mundo.
Palabras clave: Corrimiento de fase, Inducción Magnética, Espectroscopía, Teléfono Celular, Hemorragía Interna.

1 Introduction

This study was undertaken as a way to find a solution to the difficult situation of health care in poor parts of the world in general and poor parts of Mexico in particular. According to the World Health Organization (WHO): "…. the majority of the world's population is suffering from poverty and is denied adequate, safe and reliable access to solutions that health technologies can offer." [1]. Health technologies are the backbone of health services in rich and poor countries, alike [2]. However, "…access to health technologies is ……. one of the most distinct differences between rich and poor countries – far more so than access to technologies associated with basic medical education" [2]. Diagnostic imaging and medical devices and equipment are two trust topics of what the WHO considers essential health technologies [1]. "Diagnostic imaging is a prerequisite for the appropriate and successful treatment of at least a quarter of all patients worldwide." [3]. However, it is estimated that some two-thirds of the world's population have no access to medical imaging [1]. "There is a depressing lack of equipment, inadequate types of equipment, non-functioning equipment and incorrect handling of equipment" [1]. "Scaling up health services in a country implies that essential diagnostic imaging services are available nationwide. However, countries face major challenges in achieving this goal. This includes weak national systems, rudimentary procurement and supply procedures, great disparity between urban and rural areas, a lack of human resources, variable quality of laboratory performance and equipment that is either inappropriate or ill-maintained." [4]. Furthermore, even when medical imaging devices become available they are often of an inadequate type, non-functional, or handled incorrectly [1]. Around 95% of medical technology in developing countries is imported and over 50% of equipment is not being used, because of lack of maintenance or spare parts, because it is too sophisticated or in disrepair, or because of lack of trained personal [1]. On the other hand, basic medical imaging is taken for granted in industrialized countries, leading to insufficient aid and support being channeled to medical imaging in the developing world [3]. The goal of our research is to develop new medical technologies that will address and solve these issues.

Some of the major health issues related to lack of diagnostic devices are in connection with detection of internal bleeding. Internal bleeding is the cause of one of four maternal deaths during childbirth, worldwide. Death may occur within two hours after childbirth if the bleeding is not detected in time [5]. Obviously, early detection of internal bleeding could save the lives of one of four women who die at childbirth. Internal bleeding is also the cause of about 20% of the fatalities from trauma. Trauma from accidents is the third most common cause of death in all age groups and the leading cause of death in the first three decades of life [6]. Early intraperitoneal bleeding cannot be detected by vital signs (rate pulse or blood pressure) and it becomes evident only after a critical amount of blood has found its way into the abdominal cavity. Death from abdominal hemorrhage is a common cause of preventable death in trauma patients.

Medical imaging with magnetic resonance imaging, X-ray and sometimes ultrasound could detect the occurrence of internal bleeding. However, as indicated above, these technologies are prohibitedly expensive in poor areas of the world and not available to poor regions of the world. Furthermore, medical imaging detects the occurrence of internal bleeding by producing a complete image of the interior of the body. It occurred to us that detection of the occurrence of internal bleeding may not require a complete image of the body and the use of the prohibitedly expensive medical imaging systems. It would be sufficient if inexpensive means for detection of occurrence of internal bleeding would become affordable and available everywhere. If the detection of internal bleeding is made early enough the patient could be transferred for treatment at central hospitals, since often hours pass from incipience of undetected internal bleeding to death.

Our solution to this problem draws from the knowledge that accumulation of fluid and changes in the water content of the tissue can be detected with bioelectric measurements on [7], [8]. Electrical Impedance Tomography (EIT) was suggested as a possible method for detection and quantification of intraperitoneal fluid [9], [10]. EIT is used to reconstruct a map of the electrical impedance of tissue and in the case of accumulation of fluid, determine its location. Electromagnetic induction measurements with non-contact electrical coils are a valuable alternative to contact electrode measurement. [11], [12], [13]. Inductive measurement does not require galvanic coupling between the electrode and the skin or the tissue under measurement. Imaging with Magnetic Induction Tomography (MIT) are described in several publications [14], [15], [16] and [17].

While EIT and MIT medical imaging of edema is valuable, it is expensive and time consuming. As indicated earlier, in clinical practice, in order to deliver life saving treatment, it may be sufficient to know that internal bleeding or edema occurs in the bulk of certain organ or parts of the body, such as the brain, lung, muscle or the abdomen, and not the precise location of the damaged tissue in the organ.

Therefore, we have proposed that to detect internal bleeding it would be both sufficient and inexpensive to perform measurements of the changes in time in the bulk electromagnetic properties of the tissue or organ of interest [18] and [19]. To detect the bulk change in tissue properties we developed a system to measure the electromagnetic induction phase shift between two electromagnetic coils placed to develop an electromagnetic field through the part of the body of interest. These measurements are made in a wide range of frequencies. The phase shift changes at the different frequencies in time are analyzed and used to detect internal bleeding. This is a completely non-invasive technique, inexpensive and of general use. In our studies we have shown the use of time dependent measurement to detect the progress of the phase shift in time to determine the development of brain edema or in general internal bleedings [20] and [21].

In our first theoretical studies, we evaluated the feasibility of detecting accumulations of fluids or blood, edema or haematomas in various types of tissue such as brain, lung and muscle by measuring the changes in spectroscopic phase shift in the bulk of tissue [18] and [22]. We followed the theoretical work with a study with theoretical and in vitro experimental parts on detecting edema and hematoma in the bulk of brain tissue with phase shift spectroscopy [20]. Recently we reported our first in vivo study. We infused the abdomen of rats with four different volumes of physiological saline and measured the spectroscopic phase shift across the entire abdomen at frequencies higher than 1 MHz, as suggested by our theoretical studies. That study has confirmed that measuring the changes in spectroscopic phase shift in the bulk of the abdomen can detect increasing accumulation of fluid in the abdomen through non-contact measurements [21]. However, our work also shows that the detection of internal bleeding is a complex function of frequencies and the analysis of the raw data is not trivial and requires a computer. Considering that we want to reduce as much as possible the cost and complexity of the measuring device at the patient site we propose in this study a new idea that is relevant to the poor parts of the world in general and in particular of Mexico and is centered on the use of the cellular phone.

In México, poor regions located in states such as Chiapas, Guerrero, Michoacán and Oaxaca have some of the highest national economical isolation levels accordingly to the “Instituto Nacional de Geografía y Estadística” (INEGI) [23]. The “Consejo Nacional de Población” (CONAPO) in Mexico reported for those states the highest percentages of the national childbirths in 2008 (4.73%, 3.31%, 3.97 and 3.73% respectively). The “Secretaría de Salud” (SESA) reported that these areas had the minimal hospital infrastructure available in 2006 (0.4, 0.5, 0.4 and 0.5 beds/1000hab respectively) [24].

Paradoxically, despite the economical isolation levels discussed above, those states are not excluded from the cell phone GSM/3G technological roaming. The cell phone infrastructure is administrated by Radiomovil Dipsa S.A. de C.V. (TELCEL) which represents the biggest cellular phone company in México. Figure 1 shows the quality of the regional GSM roaming in México [25]. In addition; during the last decade the amount of Mexican cellular phone users shows an exponential increment. Figure 2 shows the increments of Mexican cell and home phone users from 1995 to 2006 [25]. This demonstrates that the cellular phone is ubiquitous around the world and in Mexico, even in areas in which the economics and the medical care are poor. The reasons are obvious; the cellular phone does not require a complex infrastructure.

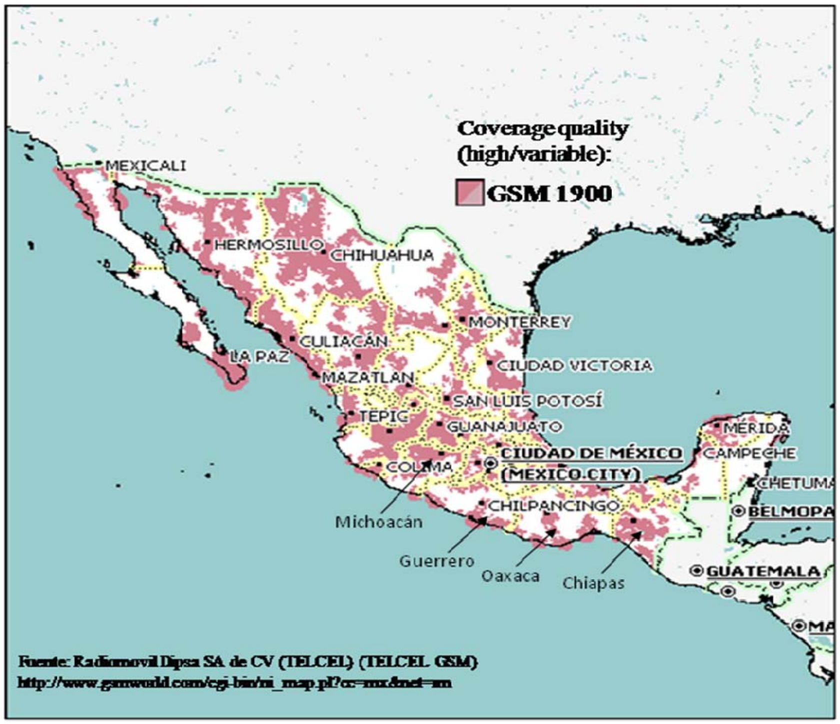

Fig. 1. Regional GSM technology roaming in México provided by Radiomovil Dipsa SA de CV. Coverage quality (high/variable): GSM 1900. (Taken and adapted for academic purpose from Radiomovil Dipsa website) [25]

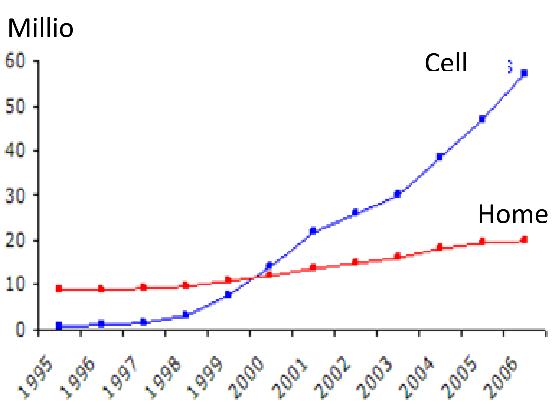

Fig. 2. Increments of the Mexican cell and home phone users from 1995 to 2006. (Taken and adapted for academic purpose from Radiomovil Dipsa website) [25]

As indicated earlier the cellular phone technology, which is ubiquitous around the world, because it does not require an expensive infrastructure could bring changes in medical care in Mexico as well as the rest of the world. In this study we introduce a new concept in remote medical monitoring that is based on the combined use of the cellular phone technology in medicine [26] and our inductive phase shift monitoring system [20] and [21]. Here we suggest that it would be possible to reduce the cost of a device for detecting internal bleeding by transferring the raw data from the measuring device through a cellular phone to a central processing facility. Specifically, we suggest that it would be sufficient to have at the patient site a simple two coil system for measuring the phase shift as a function of frequency between the two electromagnetic coils. The raw data acquisition system would connect through a cellular phone to a central processing facility equipped with powerful computers and data bases, for instance in Mexico City. This facility could process raw data from the entire country. Wireless would replace hard wired connections. The central facility would produce the diagnostic which could be returned in real time, through the cellular to the remote site, and the patient brought by car to a central hospital - if needed. A schematic of the concept is shown in Figure 3. In summary, the new system replaces the conventional stand-alone medical imaging device with a new medical volumetric monitoring system made of two independent components connected through cellular phone technology. The independent units are: a) a data acquisition device (DAD) at a remote patient site that is simple, with limited controls and no image display capability and b) an advanced signal processing facility with eventually image reconstruction and hardware control multiserver unit at a central site. The cellular phone technology transmits unprocessed raw data from the patient site DAD and receives and displays the processed signal or image from the central site. (This is different from conventional telemedicine where the image reconstruction and control is at the patient site and telecommunication is used to transmit processed images from the patient site).

Our group has already demonstrated the feasibility of this concept for medical imaging using a new frequency division multiplexing electrical impedance tomography system [26]. The DAD is connected to the cell phone, via a standard USB cable. The cell phone connects to the data processing computer via a modem by dialing directly to the data processing computer using a Telnet application. The cell phone is used for several tasks – as a display, as a communication link to the processing center, and as a graphical user interface that connects to the DAD and allows the user to initiate a test, or modify settings and other local control functions [26].

Different from our previous work [26] we suggest here that for internal bleeding detection, bulk electromagnetic properties measurements would suffice and the cell phone technology would be used as a system for remote monitoring of the volumetric tissue water properties by inductive phase shift measurements. The goal is to provide a continuous monitoring system to detect volumetric tissue edema or internal bleeding in remote clinics, poor hospitals as well as diagnostics of victims of motor-road/work accidents and natural disaster. Recently we have shown the feasibility of this new concept with the remote diagnostic of an experimental simulation of internal bleeding and hypoperfusion conditions in brain [27]. The experiments were performed in Mexico City. The raw spectroscopic data was send from Mexico City in real time through a cellular phone to a computer facility in Jerusalem which analyzed the data and then returned the correct diagnostics of the experimental simulation to the cellular phone in Mexico City [27]. We consider that this technology has the potential to benefit many poor people in undeserved regions in México and the world who do not have access to advance and expensive medical monitoring services and will save many lives in accidents.

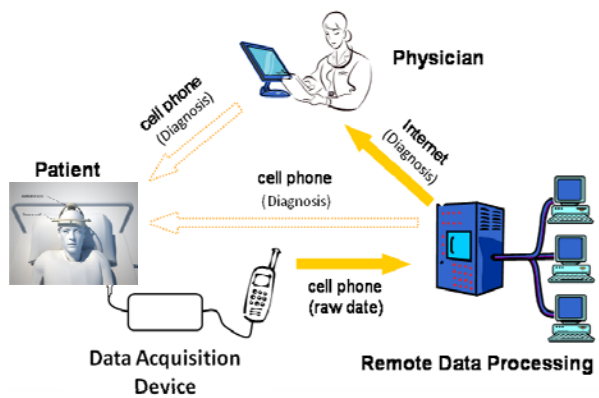

Fig. 3. Schematic representation of the general concept for volumetric internal bleeding monitoring by electromagnetic induction phase shift spectroscopy. The figure shows the general design of the Data Acquisition Device to estimate the magnetic induction phase shift from the difference in phase between a reference voltage (Vref) and a sensing voltage (Vind) in an excitation and a sensing antenna respectively. The system includes the cell phone for data transmission by telecommunication lines for remote monitoring as well as the Advance Signal Processing unit. (Taken and adapted for academic purpose from Granot y. et al.) [26]

2 Components and functionality

The DAD is the component at the remote patient site. The DAD measures continuously bulk electromagnetic data from the patient. The DAD is a set of two electromagnetic induction coils placed around the tissue of interest to produce an electromagnetic field throughout that volume of tissue. To keep the coils coaxially centered with respect to the studied tissue volume; ergonomical harnesses are designed accordingly to the specific anatomical tissue shape. Those harnesses minimize transversal and longitudinal movements of the coils in order to increase the rate signal to noise of the inductive phase shift measurements. Figure 4 shows a schematic representation of the anatomical harness designed for internal bleeding detection in brain, the system is designed for continuous monitoring of the ill patient in critical care units and emergency rooms. Details of the electronic design of the device are given in [20] and [21].

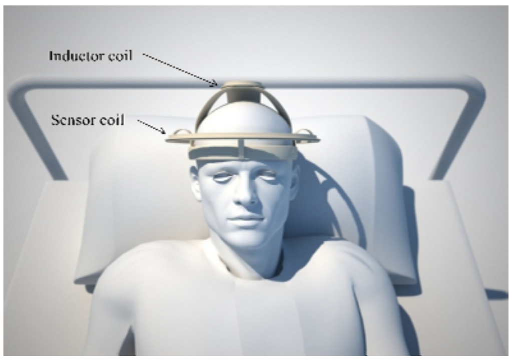

Fig. 4. Schematic representation of an anatomical harness designed for internal bleeding detection in brain

The second component is a long distance data transceiver. The transceiver can be an ordinary cellular phone served by a cellular phone network. The wide availability of cellular phones and cellular phone networks makes the proposed system possible. The data transceiver is also at the remote patient site. The primary function of the second component is to transfer the raw data from the patient site to a central processing unit and to receive and display the diagnostic from the central processing unit. The third component is a central facility for processing raw data. This facility can serve a large number of data acquisition devices around the world or state via cellular phones.

The DAD induction coils will be placed at a known position near the tissue of interest. As indicated above the device is simple and consists of two concentric coils that do not touch the body. A data acquisition unit measures the complex transfer function between the two coils when one is a transmitter and the other a receiver of electromagnetic signals. Changes in the transfer function between the coils in time are taken to imply changes in the bulk tissue composition, which is indicative of injury or internal bleeding. The main goal of the system is to detect the bulk changes in tissue composition in time [19], [20], [21], [28], [29], [30] and [31].

The inductive system proposal will generate magnetic fields at frequencies below 100MHz and its average power density calculated is less than 0.01mW/cm2. The maximum frequency used is below the ionizing energy frequencies (above 30GHz), and it doesn´t represent a risk of genetic mutations including for pregnant women. The risk of ablation is also excluded because the radiated power is less than needed to induce denaturation of proteins by hyperthermia so it is within allowable safety limits (the limit set by the International Commission for the Protection of Non-Ionizing Radiation, ICNIRP is 0.2 mW/cm2).

The intensity of the magnetic field generated by the prototype proposed in this study is estimated in the order of 50 mGauss (about a million times less intense than that generated by the systems of transcranial magnetic stimulation). Since the field strength generated by the proposed prototype is very low, there is no risk of inducing neuronal depolarization level that could induce epileptic-type crisis, interference with pacemaker or any communication devices.

At the central facility, data processing is applied to the measured changes for diagnostic. Given the variability between patients and the complexity of the frequency dependent data analysis [19], [28], [29], [30] and [31], the central facility needs to tailor the diagnostic algorithm to the patient. A specific algorithm may employ additional information to the measured complex transfer function between the two coils such as coils configuration, geometry, placement and other details that may turn out to be relevant. The additional information may also include results from calibration tests at the patient site. The diagnostic algorithm is supported by a data base that is maintained at the central processing facility [32]. It is anticipated that this will be a continuously growing data base which will store information on a growing population of patients with various pathological conditions, e.g. stroke, bleeding, edema and ischemia.

3 Data processing and analysis

Our earlier publications [19], [28], [29], [30] and [31] have shown through mathematical and experimental studies that bulk changes in tissue composition produce changes in the complex transfer function between the induction and the sensor coils. Particular important is our observation that these changes are a strong function of the frequency at which they are measured as well many individual parameters of the subject of observation, such as geometry and initial tissue composition. Those studies show that measurements made at only one frequency cannot be used reliably because for certain conditions there are frequencies at which the transfer function is not affected by changes in tissue composition. These frequencies are case dependent and cannot be know a-priori. Analyzing the data to evaluate the type of tissue injury occurrence becomes difficult because the pattern of changes as a function of measurement frequency, geometry and pathology is not evident.

We introduce here a new concept of, Minimum Square Error (MSE) optimization criterion to the problem of detection of the nature of changes in the tissue. We further suggest here to use its linear optimal solution. This solution is based on a-priory knowledge of statistical features of the phase shift and blood content. We suggest here to obtain these statistical parameters through a calibration process.

The calibration process must be tailored to each individual. The statistical parameters obtained from the calibration should be stored at the central utility and used during the diagnosis.

4 Data analysis algorithm

For data analysis we define a transfer function H between the induction coil and the sensor coil currents. The transfer function depends on a vector of electrical properties of the studied tissue $\bar{e}$, frequency f as well as on the geometrical properties and configuration of the analyzed system, e.g. coils position. Therefore, the transfer function can be written as:

$$H(\bar{e}, f) \tag{1}$$

The bulk changes in the blood content of the tissue relative to a baseline content, ΔC, produce changes in the transfer function H, ΔH. As shown in [31], the changes in the transfer function can be easily captured by changes of the phase shift between the induction and the sensor coils currents relative to a baseline phase, ΔP_I.

The problem of approximating the blood change content by changes in the transfer function or the phase shift is in general a non linear complex one. We can simplify the problem by linear weighting of the phase shift at different frequencies. The criteria for finding the optimal weight vector W of the problem in Minimum Square Error (MSE) sense is given by:

$$\begin{aligned} &\hat{W} = \arg\min_{W} E\left(W^T \Delta P_I - \Delta C\right)^2 \\ &s.t. \qquad \|W\| = 1 \end{aligned} \tag{2}$$

Where the norm $\|W\|$ is given by $(W^T W)^{1/2}$, ΔP_I and ΔC are the vector of size of number of frequencies N_F of blood content and phase shift difference from a basal phase reference respectively. The optimal linear solution to (2) is the Wiener filter [33] which is the MSE linear optimal linear solution of the problem for stationary statistics and with white additive noise:

$$\hat{W}_L = R^{-1}_{\Delta P_I,\Delta P_I} R^T_{\Delta P_I,\Delta C} \tag{3}$$

Where $R_{\Delta P_I,\Delta P_I}, R_{\Delta P_I,\Delta C}$ are the autocorrelation matrixes size $N_F \times N_F$ of ΔP_I and cross correlation vector size $N_F \times 1$ of ΔP_I and ΔC respectively.

It is difficult to derive these correlation matrixes analytically from the transfer function H. In particular, the cross correlation of the phase shift and concentration needs a-priory knowledge of the blood concentration. These matrixes must be obtained through a set of calibration experiments. e.g. calibration performed over many patients with many pathological diseases with MRI feedback for the real blood content. The calibration process must be tailored to each individual. The results of the calibration can be a data base at a central utility storing the correlation matrixes, which can be fetched according to individual parameters such as coils configuration or patient history. The risk to determine false-positive can be minimized considering healthy phase shift data as part of the calibration process and stored at the central utility data base. In addition; the derivation of the transfer function under normal condition accordingly to experimental data of healthy volunteers could reduce the error margin.

5 Conclusion

Inductive phase shift spectroscopy is a non-invasive and inexpensive technique that has the ability to detect tissue water properties and in general internal bleeding. The cell phone infrastructure available in undeserved regions in México provides the possibility to transfer raw inductive phase shift data to a remote central processing by GSM/3G technology. The introduction of a remote central unit for data processing and analysis enable the possibility for remote diagnosis.

The link of the inductive phase shift concept and the cell phone technology has the potential to benefit many in poor Mexican regions who do not have access to advance and expensive medical monitoring services and will save many lives in accidents or internal bleeding of women after giving birth. More advanced data processing methods and calibration of the system should be developed in future.

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