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A passive acoustic system for evaluating the *in vivo* performance of extracorporeal shockwave lithotripsy

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This invention relates to a sensor system for identifying the optimum positioning of extracorporeal shockwave lithotripsy equipment and for identifying the degree of fragmentation of the stone as treatment proceeds.

Introduction

Extracorporeal shockwave lithotripsy (ESWL) is a treatment used for patients suffering renal, ureteric, salivary duct and gall stone disease. An acoustic shockwave generated outside the body is used to fragment the stones to a small size, such that they can either pass normally through the body or can be more easily dissolved using drugs.

The end-point of the treatment is when the stones have been fragmented into small particles, normally less than 1 mm in dimension. Although the stones can be visualised at any time during the treatment on X-ray or ultrasound, it is difficult or impossible for the operator to judge the degree of fragmentation from viewing the image. As a result, it is normal practice to give a pre-set number of shocks, typically 3000 in one treatment. This is generally unsatisfactory because each acoustic shock causes some collateral damage to soft tissues. Ideally, one would give as few shocks as necessary. Related issues are that X ray analysis introduces additional radiation hazards, and the ultrasound analysis also requires additional active energy to be absorbed by the patient.

The intention of this invention is allow the operator to determine more accurately when the treatment should be ended using a passive sensing technique. It consists of a passive acoustic pressure sensor that can be placed against the patient during treatment (Figure 1). This sensor picks up the acoustic signals generated by, and scattered from, the stone as the shockwave lithotripsy is progressed, as well as signals resulting from an effect known as acoustic cavitation, that occurs close to the stone. By monitoring characteristics of these signals, it is possible to monitor whether the incident lithotripter shock is on-target, and the degree to which stone fragmentation has occurred. The great range of different (and sometimes overlapping) methods available for signal processing means that these characteristics and their interpretation might be described in many different ways. A specific example is given below whereby these characteristics are described in terms of the time evolution of spectral content of the signal. It is however recognised that there are a plethora of ways to describe the same basic idea (for example in terms of the wavelet decomposition of the signal).

A specific example Figure 2 illustrates a specific example of how the signals can be interpreted. The source of scatter in this illustrative case is a series of known stone samples (Figure 3) which are held within a sample holder and subjected to a lithotripter pulse projected down a shock tube in vitro (Figure 4). In this specific example the signal detected by the passive sensor is subjected to time-frequency analysis. The signal is first filtered into frequency bands (the precise number of bands, and their frequency limits, may vary from instrument to instrument). In this example the frequency bands are termed very low frequency (VLF, less than 30 kHz; shown in Figure 2a), low frequency (LF, from 30 to 300 kHz; shown in Figure 2b), and high frequency (HF, 300-900 kHz; shown in Figure 2c). Each of the six subplots within (a), (b) and (c) represent in time-frequency the scatter from different target materials, using equal volumes of each (33.5 ml), and consisting of (from the bottom upwards, with fragments sizes selected sieves) of:

- PLST: Plaster of Paris made using a ratio plaster:water of 2:1 and injected into the target holder in the liquid state by a syringe avoiding air entrainment.
- Big sand: 10-30 mm
- Medium sand: 4-10 mm (DG implies the degassed version)
- Fine sand: 1- 4 mm
- Water.

Using this example technique, it is clear from the VLF band (Figure 2a) that sometime after the main lithotripter pulse and its reverberation, there is a signal (in this Figure plotted at a time between 400-500 microseconds) which decreases in amplitude as the degree of fragmentation increases. The interpretation of the signal for the user may be achieved in a number of ways, including visual, audible representations of this signal. Not only does it give direct feedback to the practitioners, but also for the opportunity that they might learn and improve practice from monitoring such a signal.

An example scenario is as follows. At the start of the procedure, the focus of the lithotripter is aligned on the stone in the usual manner, using active ultrasonic imaging and x-rays. During treatment the passive sensing system would be monitored. At the beginning of the treatment the signal discussed above will be strong. If it remains strong, this could be in indication that the stone is not fragmenting. The more likely scenario is that the treatment begins to fragment the stone, in which case the signal becomes weaker. This would give an indication that sufficient treatment has been provided and the treatment could be stopped preventing any further collateral damage. A sudden decrease in the signal could be indicative that the lithotripter has lost its alignment with the stone. If the passive signal gradually weakens, this is a strong indication that the stone was fragmenting and that the treatment was successful.

Other characteristics of the passive signal can be used in a similar away. For example the HF component which occurs in Figure 2c between 300 and 500 microseconds is a result of cavitation. For cavitation to occur, liquid is required, and if the lithotripter focus contains only stone (as in the bottom plot of 2c) there will be negligible output from cavitation in this zone. As the degree of fragmentation increases, and more fluid enters the focal zone, cavitation occurs and the high frequency emissions begin to appear. These can be used to determine whether the lithotripter focus is on target, and the degree of fragmentation that has occurred, in a similar way as the low frequency signal is used.

The results of Figure 2 were taken using a specific example device (Figure 5) of the generic technology covered by this patent. It is an entirely passive sensor comprising a linear array of piezo-electric elements. Each of these elements receives an acoustic pressure wave (arising from the acoustic emissions generated by the interaction of the lithotripter pulse with a stone) and converts it into a measurable voltage. Many piezo-electric materials are available including piezo-polymers, piezo-ceramics and piezo-composites. This particular sensor employs a piezo-polymer because of the broadband frequency response of the material. To prevent internal reverberations within the sensor from influencing the measurement process, the sensor elements are backed by a sound absorbing material. Care must also be taken to ensure that any sensor is as insensitive as possible to electromagnetic interference (EMI). This has been accomplished by placing the entire sensor within an electrically conducting, grounded enclosure, and connecting this to both the ground electrode on the sensor active elements and the signal ground of the connector on the enclosure wall. However for safety reasons patients should not be able to become part of the electrical path of any sensor system, and consequently an insulating front face has been applied to the sensor. The facing material is dual purpose and also provides a wear face that can easily be cleaned with solvents such as Isopropyl Alcohol.

Claims

1. A lithotripter passive acoustic sensing system for locating and sensing the degree of fragmentation of a calculus in the body of a patient comprising a transducer system responsive to a wide range of frequencies, a signal processing system to filter and separate the transducer system output into defined frequency bands, means for measuring the energy in the output frequency bands in time, means for producing a representation of the energy in the output frequency bands in time.

2. A system according to claim 1 where the transducer system comprises a broadband acoustic pressure sensor.

3. A system according to claim 1 where the transducer system comprises an array of narrow band acoustic pressure sensors.

4. A system according to claim 1 where the frequency bands are very low frequency, less than 30 kHz; low frequency from 30 to 300 kHz; high frequency 300-900 kHz; and very high frequency (>900 kHz).

5. A system according to claim 1 where the transducer system output within each frequency band is measured using a time / frequency technique

6. A system according to claim 1 where the transducer system output within each frequency band is measured using a time / scale technique

7. According to claim 1, the measurements are used to determine the position of a calculus.

8. According to claim 1, the measurements are used to determine the degree of fragmentation of a calculus.

9. According to claim 1, the representation could be converted to an audible output.

10. According to claim 1, the representation could be converted to a visual output.

11. According to claim 1, the measurements could be used to control the lithotripter positioning.

12. According to claim 1, the measurements could be used to control the completion of treatment.

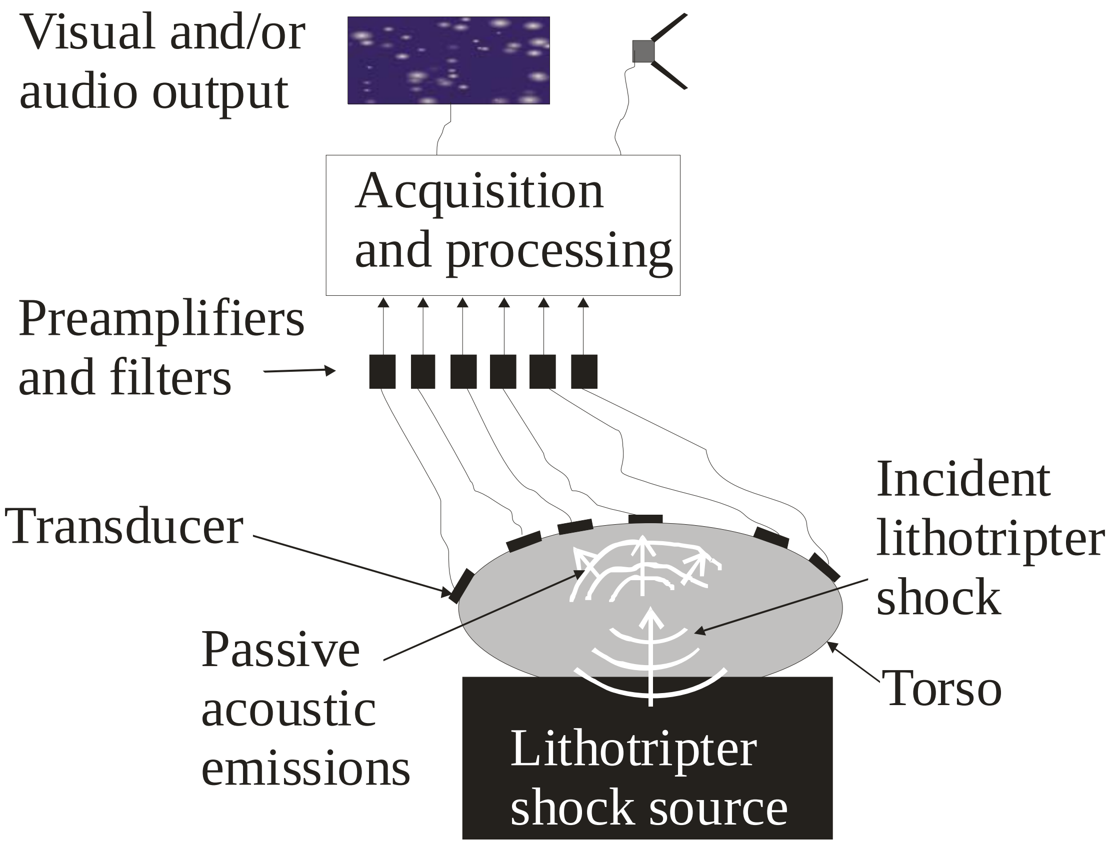

Figure 1. Schematic of apparatus

(a) (b) (c)

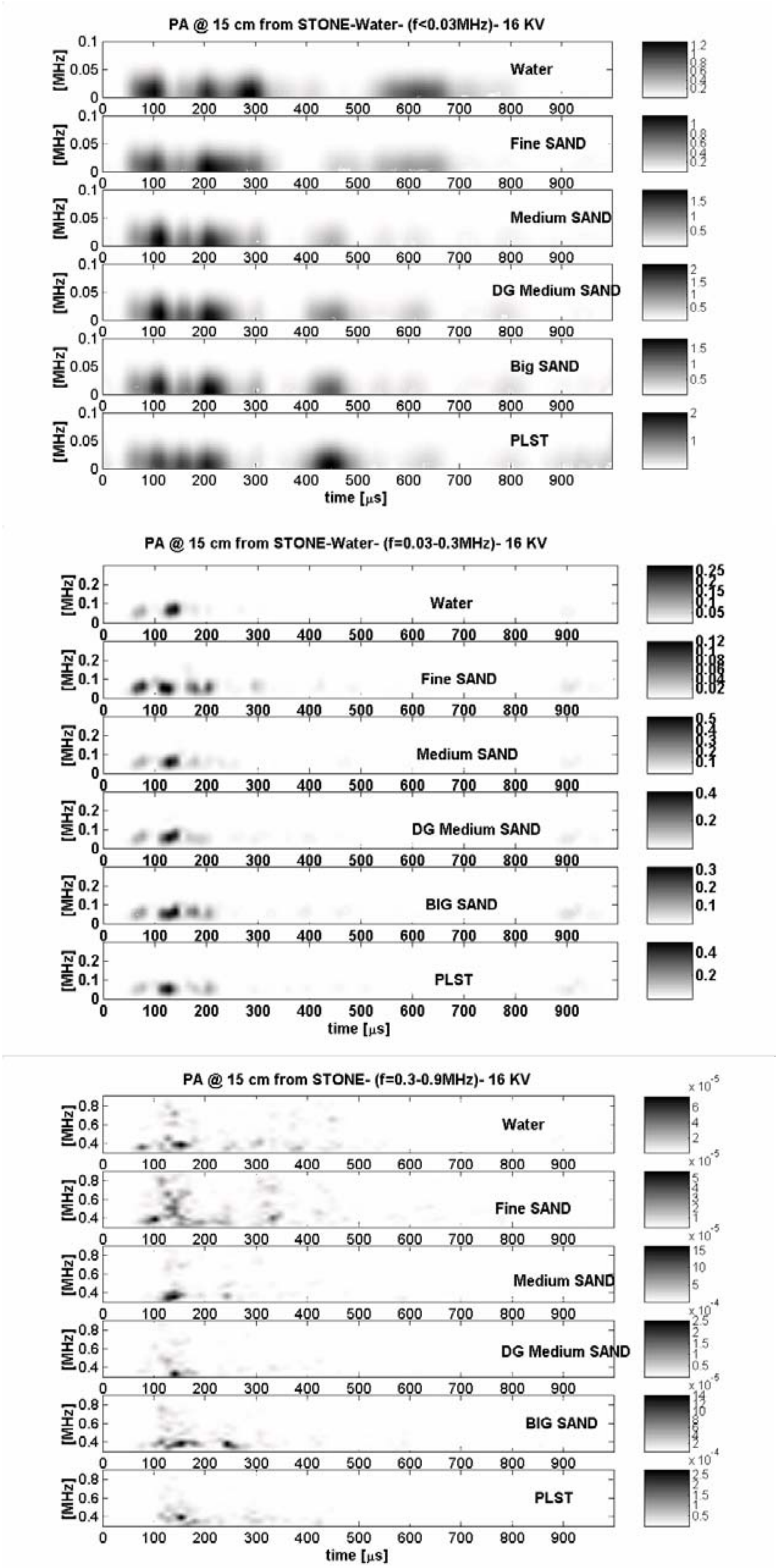

Figure 2. An example representation of the passive signals in time-frequency representation for (a) very low frequency (VLF, less than 30 kHz); (b) low frequency (LF, from 30 to 300 kHz); and (c) high frequency (HF, 300-900 kHz). The six subplots within (a), (b) and (c) represent the scatter from different target materials, using equal volumes of each (33.5 ml), and consisting of (from the bottom upwards, with fragments sizes selected sieves) of:

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- Water.

Figure 3. Four sources of stone sample used to obtain the data of figure 2.

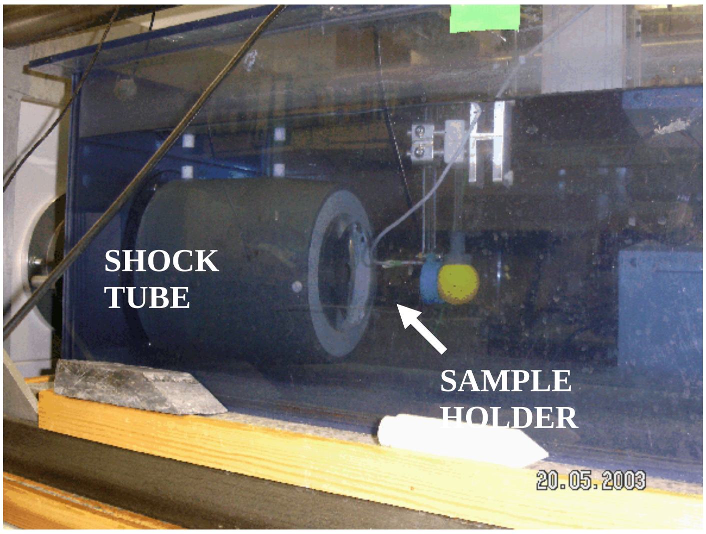

Figure 4. The apparatus for the in vitro tests used to obtain the data of figure 2.

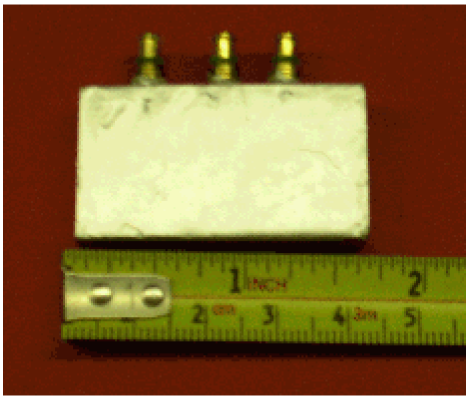

Figure 5. The specific example device used to measure the data of figure 2. A connector for each of the three frequency bands used in this instance is shown.

Abstract

A passive acoustic sensor is described which may be placed upon a patient during extracorporeal shockwave lithotripsy. It detects the acoustic emissions which results both directly and indirectly from the lithotripsy (including reverberation, reflection of the shock from the stone, and cavitation). Monitoring the temporal characteristics of these passive acoustic emissions with this system allows assessment of the degree of fragmentation which has occurred in the stone, whether the lithotripter focus is aligned with the stone, the degree of cavitation during etc.. This interpretation may be done with this passive sensor alone, or in conjunction with existing techniques (ultrasonic imaging, x-rays etc.).