DEVELOPMENT OF A NEW DIAGNOSTIC DEVICE FOR EXTRACORPOREAL SHOCK-WAVE LITHOTRIPSY

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Abstract: Extracorporeal Shock-Wave Lithotripsy (ESWL) is the leading technique for the non-invasive treatment of urinary stones. Thousands of ultrasound shocks are focused on the stones in order to break them into fragments small enough to be passed naturally by the body. The procedure is well established, though the re-treatment rate is around 50%. One of the limits of the procedure is that there is no capability for on-line monitoring of the degree of fragmentation of the stone. The output of the treatments could probably be improved if this facility was made available. The underlying physical mechanisms responsible for the break-up of the stone are still subject to investigation. However both direct stress damage and indirect cavitation erosion seem to be necessary to obtain eliminable fragments. In previous studies, Coleman et al. monitored cavitation in-vivo through the associated acoustic emissions. The objective of this research was to design a new diagnostic device for lithotripsy, exploiting the information carried by these acoustic emissions. After preliminary laboratory experiments some clinical prototypes were developed in collaboration with Precision Acoustic Ltd., UK. The prototypes are currently been tested in the clinic. The project was sponsored by the Engineering and Physical Sciences Research Council, UK.

Introduction

Extracorporeal Shock-Wave Lithotripsy (ESWL) was introduced in the 1981 [1] to treat kidney stones and it is today the leading technique for the non-invasive treatment of kidney, ureteric and biliary stones.

Lying on a table, the patient is coupled to an ultrasound shock source through a water cushion (Figure 1). Thousands of ultrasound shocks, with peak-positive pressure up to 100 MPa, are focused on the stone in order to break it into fragments small enough to be passed naturally by the body. The stone is localised using X-Ray and Ultrasound (US) systems. Though the procedure is well established, the re-treatment rate is still around 50% [2].

Both X-Ray and US systems are affected by alignment errors [3] and X-Ray, which gives a clearer image, can not be used continuously to contain the patient's dose.

Several projects have been working on the development of auxiliary targeting techniques that may identify if the stone has actually been hit by the beam [4, 5].

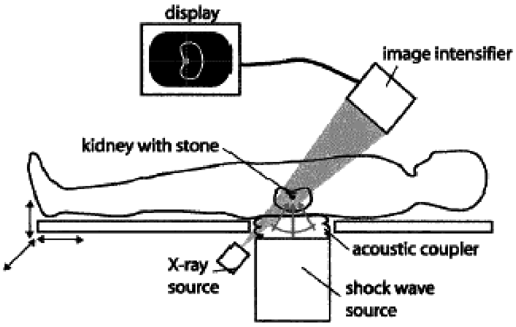

Figure 1: Schematic of Lithotripsy

One significant limitation of the present lithotripters is that there is no capability for on-line monitoring of the degree of fragmentation of the stone. Usually the urologist tries to assess this by observing if any changes appear in the density or size of the stone in the X-Ray image. The underlying physical mechanisms responsible of the fragmentation of the stone are still subject to investigation. Several studies indicate that both direct stress damage and indirect cavitation erosion seem to be necessary to obtain eliminable fragments [6].

In previous studies the authors [7] monitored cavitation *in-vivo* through the associated acoustic emissions. The objective of this research was to design a new diagnostic device for lithotripsy exploiting the information carried by these acoustic emissions

The first phase of the study used an experimental cavitation sensor (developed by the National Physical Laboratory, NPL, UK [8]) to record passive emissions from cavitation generated in vitro by an experimental lithotripter [9]. This paper reports on the analysis of these emissions and shows that they possess characteristics, which depend on the degree of fragmentation of the stone. Exploiting these preliminary results, some clinical prototypes (an example of which is displayed in Figure 2) were developed in collaboration with Precision Acoustics Ltd. (PAL), UK. The prototypes have been patented [10] and they are currently being tested in the clinical environment.

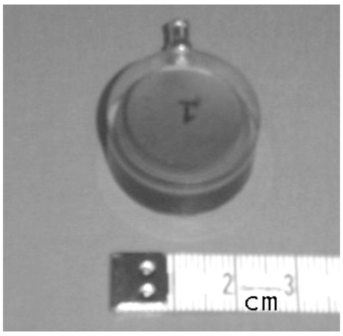

Figure 2: Clinical Prototype developed with PAL.

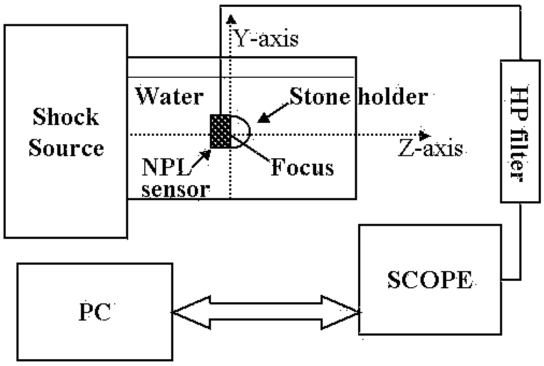

Figure 3: Experimental set-up

Materials and Methods

Experimental Set-up: Figure 3 shows a diagram of the experimental set-up. Stone samples were placed at the focus of a bench top electromagnetic (EM) lithotripter [11] in spherical plastic holders (table-tennis balls) of 2 cm diameter. Tests ensured that the holder walls did not significantly alter the lithotripter pressure field. A novel cylindrical broadband cavitation sensor [8], made by the NPL, was then coupled to the stone holder. The balls were each filled with different grades of sand, minimising the presence of entrained air bubbles: coarse sand (CS; grain diameter 10-30 mm); medium sand (MS; grain diameter 4-10 mm) or fine sand (FS; grain diameter 1-4mm). These graded sand targets were used to simulate a stone at different, well-characterised stages of fragmentation as it is encountered during the course of an ESWL treatment. One ball was filled with tap water (TW) to act as a control. The discharge potential of the EM source was set and maintained at 16 kV, which gave lithotripter shocks of 16 MPa peak-positive pressure and 3 MPa peak-negative pressure. The lithotripter pulses were measured using a Marconi Y-34-3598 PVDF bilaminar membrane hydrophone (Ser. no. IP116, Sensitivity 53 mV/MPa). The detected signals were filtered using an analog high pass filter with a cut-off frequency of 0.2 MHz, to suppress most of the background noise due to the EM source itself. The filtered signals were acquired using a LeCroy 9354L digital scope with a sampling frequency of 100 Msamples/s and the digital data were transferred to a PC with a LabVIEW interface to be stored as text files. The stored data could then be processed using the MATLAB ™. Figure 4 (upper box) displays a 16 kV lithotripter pulse, measured as described above. The lower box displays a typical output from the NPL cavitation sensor (currently uncalibrated). Two main bursts in the lower plot may be identified in the acoustic emission above the noise level. Previous work [12] indicates that these components are related respectively to the first and second collapse of microscopic bubbles that are present in a cloud around the beam axis and in proximity of the stone [13] during the shock-bubble interaction. The interval between these two bursts is taken to represent the mean interval (t_c) between the first and second rebound of each individual cavitation bubble during ESWL.

Analysis in the Time domain: An adaptative threshold algorithm that automatically detects the two bursts in an emission signal has been developed. It calculates their main parameters: duration, maximum amplitude and kurtosis.

In order to estimate t_c, the algorithm calculates the central times of the two bursts and estimates t_c as the difference between these two times. This distinguishes the method of this paper from all previous studies, which estimated t_c as the interval between the two maxima of the two bursts.

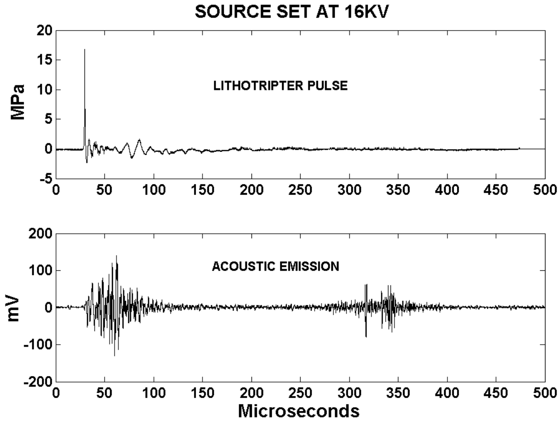

Figure 4: Experimental lithotripter pulse at 16KV (top). Detected secondary acoustic emission (bottom)

Analysis in the Frequency domain: An algorithm analyses a set of traces recorded under the same conditions in order to extract the key frequency characteristics of the first and the second burst. Given the set of data, each burst is windowed and coherently averaged with the corresponding ones in the other recordings. Subsequently the Power Spectral Densities of the two averages obtained (one for the first burst and one for the second) and the central frequency of each is estimated.

Design of the prototype: The prototype (Figure 2) is a passive hydrophone made of a spherical plastic PVdF element of 2 cm diameter encapsulated in an external insulating shield. The size of the element has been designed to ensure that a path difference no greater than 0.1 mm occurs for emissions coming from the kidney at 3 MHz. The sensor is applied to the patient satisfying the restrictions of a class BF medical device according to the IEC60601-1. All the equipment has successfully passed electrical safety tests before its use in the clinic.

Results

The results show a significant dependency of some of the emission parameters on the size of the stone fragments.

Time domain: The collapse time t_c (Figure 5A) decreases significantly with the size of the fragments implying that smaller bubbles are present [14]. The first burst contains both energy scattered from the incident lithotripter pulse; plus any cavitation emission: the amplitude (Figure 5 B) of the first burst clearly decreases with the size of the fragments, while its duration increases (Figure 5 C). This may indicate less coherent scattering from the stone.

Frequency domain: The central frequency (Figure 6) of the first burst is, for each sample, lower than that for the second burst and close to the main frequency of the lithotripter pulse (0.2 MHz). This result is in agreement with the hypothesis that there is considerable scattering component of the first burst. Comparison of a set of measurements related to the same burst shows no significant difference between the frequencies of the different samples.

Test of the prototype: The clinical prototype was tested in the experimental lithotripter and its data showed a good correlation (correlation coefficient of 0.7) with those of the NPL. The prototype was then tested on 15 consenting patients undergoing lithotripsy at Guy's and St. Thomas' Hospital, after the design of the experiments was approved by the Ethical Committee of the hospital. The clinical lithotripter, held at Guy's Hospital, London, is a Storz Modulith SLX-MX. The results of the clinical study have yet to be fully evaluated.

Discussion

This study has examined a range of parameters that describe the acoustic emission detected during *in vitro* ESWL. The parameters provide some discrimination between the three grades of the target material. The amplitude of the first burst of emission, for example, provides the greatest discrimination between coarse, medium and fine sand, with the amplitude decreasing as the sand becomes finer. This suggests that the first burst signal arises largely from scatter of the shockwave by the target; as the target becomes a finer grade, this scatter becomes more incoherent and the amplitude lower. The results also show that the time duration of the detected signal from the second burst increases as the target grade becomes finer. The second burst is associated almost entirely with cavitation, and occurs long after the shockwave has passed the target. The results suggest that cavitation occurs over an increasing volume of the target as the target includes finer particles, possibly as a result of an increase in cavitation nuclei on the increased area of material. The control sample of tap water generates results consistent with the presence of cavitation over a relatively large volume, as is found in the finest sand grade. As expected, it generates no scatter, although, in this case, due to the absence of scatterers rather than absorption by the fine sand target. Finally, it is clear that greater discrimination of the condition of the target may be obtained by combining these measures of the quality of the acoustic emission. This awaits further study. Initial steps towards a clinical implementation of a system for detecting the condition of the target material have been made. A prototype device has been tested in the clinic, and has been shown to be capable of detecting the first and second bursts of acoustic emission from the target. Preliminary analysis of the signal demonstrates similar features to those observed in vitro. Further work is needed to establish the parameters that correlate with the condition of the target material.

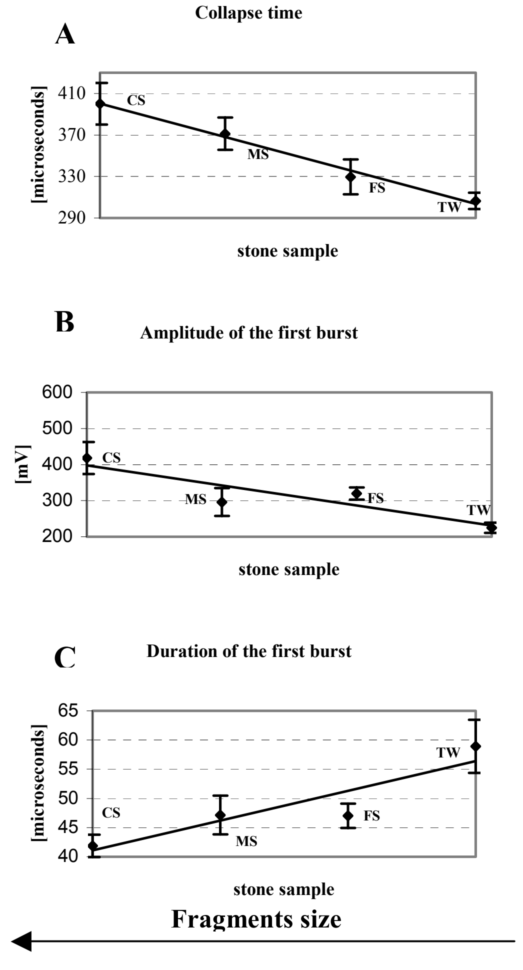

Figure 5: A, collapse time t_c B, Maximum amplitude of the first burst, C, Duration of the first burst. The lines between each point indicate best linear fitting.

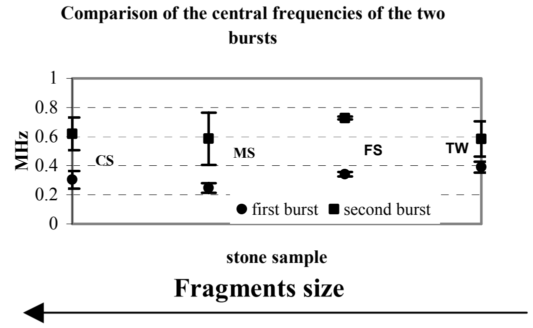

Figure 6: Central frequencies of the two bursts

Acknowledgments

This research was financed by the Engineering and Physical Sciences Research Council, UK GR/N19243. The authors thanks Mrs Terri Gill at PAL, Dr. Bajram Zeqiri and Ms. Catherine Bickley at NPL, Mr. Jonathan Glass, Mr. Richard Tiptaff, , Mr Simon Ryves and all the Lithotripsy unit, the Mechanical Workshop and Electro Biomedical Engineering Section at Guy's and St. Thomas'Hospital, London, for their collaboration.

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