AN ULTRASOUND-BASED PASSIVE MONITORING SYSTEM FOR ESWL

F Fedele Guy's and St Thomas' NHS Foundation Trust, London, UK
AJ Coleman Guy's and St Thomas' NHS Foundation Trust, London, UK
TG Leighton Institute of Sound and Vibration Research, Southampton, UK
PR White Institute of Sound and Vibration Research, Southampton, UK
VF Humphrey Institute of Sound and Vibration Research, Southampton, UK
S Ryves Guy's and St Thomas' NHS Foundation Trust, London, UK
AM Hurrell Precision Acoustics Ltd, Dorchester, UK
DC Finfer Institute of Sound and Vibration Research, Southampton, UK

1 INTRODUCTION

Extracorporeal Shock Wave Lithotripsy (ESWL) is currently used in the non-invasive treatment of kidney stones. Kidney stones represent a concretion of salts that, for metabolic reasons, have crystallized out of solution. Untreated, they can lead to severe pain, infection or loss of renal function.

In ESWL thousands of externally generated shock waves are focused onto the stone so that it fragments into particles that can pass down the urinary tract[1]. The stone may be localised using X-Ray and/or Ultrasound (US) imaging.

Despite the wide-spread use of ESWL the treatment may induce some collateral damage[2,3,4] (haemorrhages, thrombi, arrhythmias, hypertension, reduction of renal functionality). Most significantly the re-treatment rate is still around 50%, suggesting that stones either reform or are not fully fragmented[5].

The main limitation of the current technology is the stone imaging system. In many cases, fragments remain grouped together following shock exposure. Neither X-Ray nor US imaging let the operator distinguish this situation from an intact stone. A very significant limitation of the current technology is the absence of any on-line objective and quantitative measure of the degree of fragmentation.

Previous studies by the authors have shown that acoustic emissions are generated during the process and that these may be detected and characterised *in vitro*[6,7]. On the basis of this, a passive sensor was designed to be employed in clinical practice[8,9]. This paper describes the design and the preliminary testing of a clinical monitoring system that exploits the developed sensor. The plan for a set of clinical trials is also outlined.

2 THE ULTRASOUND MONITORING SYSTEM

Figure 1-(a) illustrates the system in operation, during the clinical trials, in the lithotripsy theatre at Guy's and St. Thomas' Hospital NHS Trust. The secondary acoustic emissions are acquired by a passive PVdF US sensor (Figure 1-(b)) placed on the patient's torso. This sensor was developed by the authors during previous *in vitro* experiments[9]. Subsequently the signal is filtered through a high-pass filter with cut-off frequency at 300 kHz in order to reduce the background noise (which is mainly due to reverberations of the lithotripter shocks) and pre-amplified. Figure 1-(c) shows a typical captured emission with details of the electromagnetic discharge from the lithotripter source Figure 1-(d) and the actual acoustic signal (Figure 1-(e)). Finally the signal is analysed on-line using custom software on a laptop. The next subsection describes the processing in more detail.

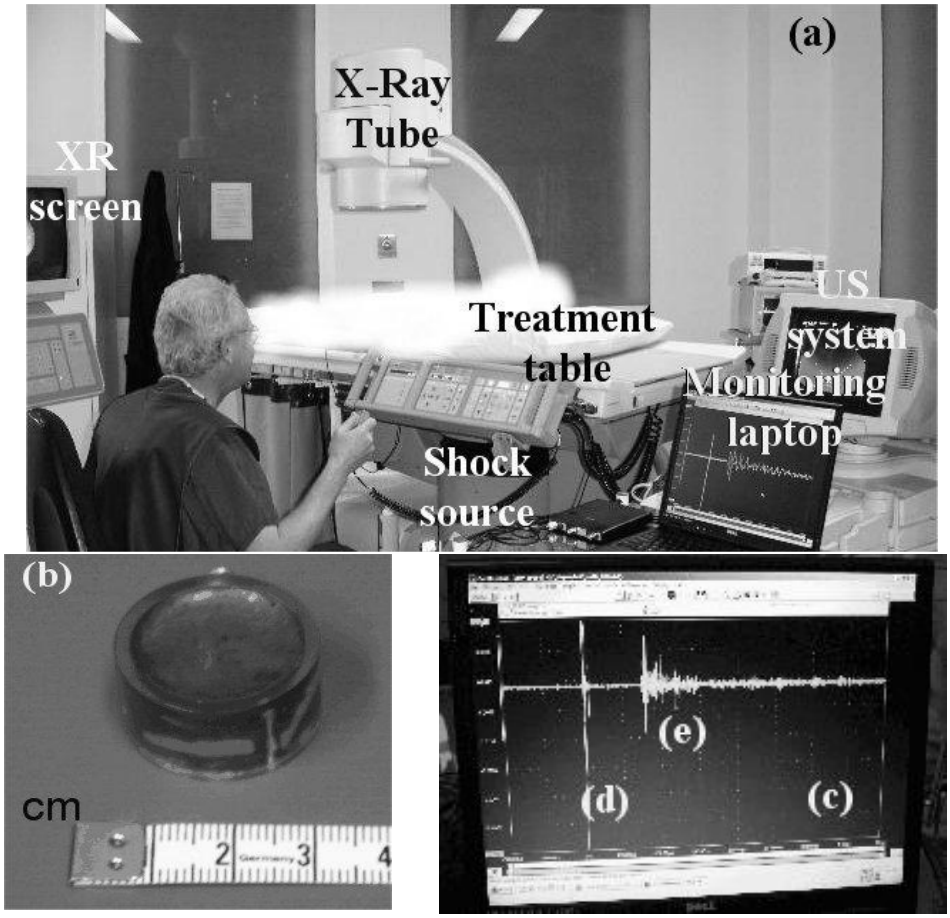

Figure 1: Ultrasound Monitoring system in operation in the lithotripsy theatre at Guy's and St. Thomas' Hospital NHS Trust, during the clinical trials (a), with details of the passive ultrasound sensor used to record the secondary acoustic emissions (b), and a typical captured signal (c). In the recorded signal an initial spike (d), which is due to the electrical discharge of the electromagnetic source, and the acoustic signal (e) are distinguishable.

2.1 On-line analysis of the secondary acoustic emissions

The secondary acoustic emissions are broadband signals generated by different acoustic sources: the direct stress wave, the shock-wave reflections and secondary shocks generated by cavitation[3, 10]. A typical emission presents a double burst structure that may be characterised in terms of few parameters[7,8,9]: the maximum amplitude of the first and second burst (m_1 and m_2 respectively), which represent the strongest acoustic interaction occurring during each burst; the duration of the first and second burst (d_1 and d_2), the kurtosis of the first and second burst (k_{u1} and k_{u2}), which measure the *flatness* of the bursts, and the collapse time t_c, which is a measure of the average collapse time for each bubble-collapse happening in the cavitation cloud. *In vitro* experiments[8,9] proved that of these parameters the maximum amplitude of the first burst m_1 and the collapse time t_c could be used to monitor different stages of stone fragmentation. Preliminary in vivo experiments showed that it was possible to extract these two features during clinical treatments. The aim of the current project is to correlate changes in these features with treatment outcomes. A special software interface has now been developed that allows the continuous monitoring of m_1 and t_c during the treatment (Figure 3).

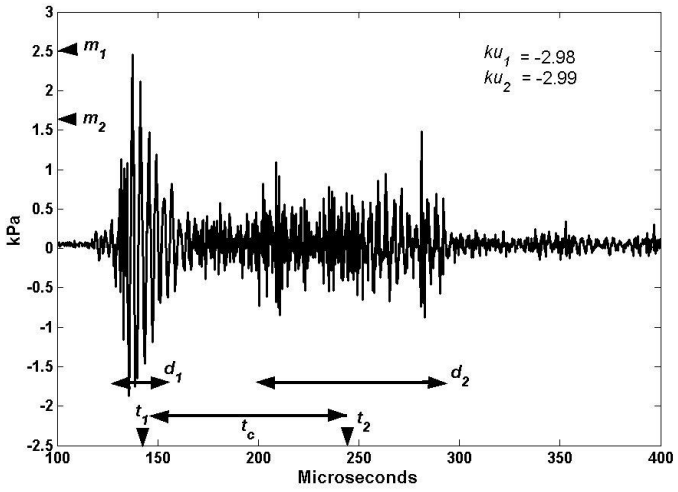

Figure 2: A typical secondary emission acquired in the clinic using the developed US sensor [8,9] and the features extracted from it: the maximum amplitude of the first burst (m_1); the duration of the first burst (d_1); the central time of the first burst (t_1); the collapse time (t_c); the maximum amplitude of the second burst (m_2); the duration of the second burst (d_2); the central time of the second burst (t_2). The plot also gives the values for the kurtosis of the two bursts (ku_1 and ku_2 respectively); these are a measure of the burst *flatness*.

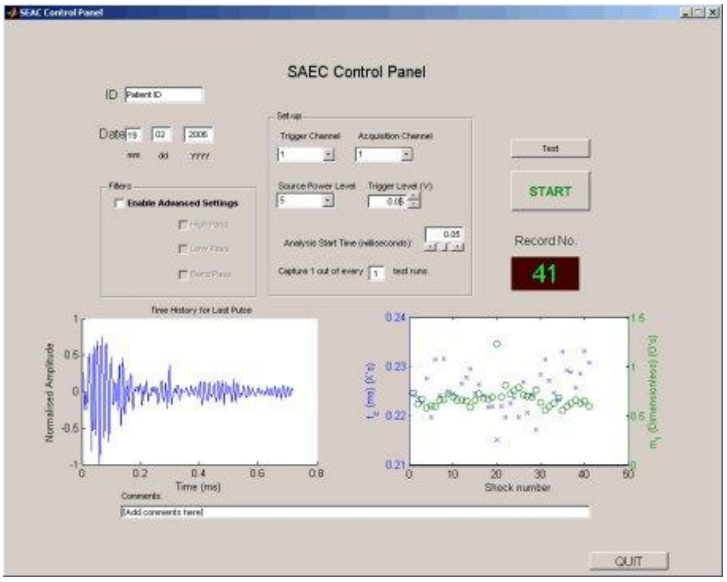

Figure 3: Software interface

3 THE CLINICAL TRIAL

A clinical trial has been organised in two stages. Stage 1, currently ongoing, is a training stage in which the results of the processing are being compared with the clinicians' diagnosis. Specifically, trends in m_1 and t_1 are compared with two independent experts' opinions: the radiographer's

diagnosis during the treatment and the urologist follow-up diagnosis 10-15 days after the treatment. Each of the experts sets a treatment score ranging from 0 (stone not broken) to 5 (stone broken) and gives to this score a confidence level that may be *low*, *medium* or *high*. The aim is to have 50 patients for Stage 1. Once a set of decisions rules have been established from Stage 1, Stage 2 will follow in which the classifications of the monitoring system and the expert's opinions will be given independently and compared. Stage 2 should include 50 patients. The study was approved by Guy's and St Thomas's NHS Foundation Trust research ethics committee, and informed consent was obtained from each patient.

4 CONCLUDING REMARKS

This paper describes on-going trials to train and validate an US monitoring system for lithotripsy. Previous experiments *in vitro* suggest that the development of a classification system is possible, but as the clinical trials are only just beginning it is not possible to draw any positive conclusions at this stage.

5 ACKNOWLEDGEMENTS

This research was financed by the Engineering and Physical Sciences Research Council, UK follow-up GR/N19243/01. The authors thanks Mrs Terri Gill and Mr David Bell at PAL, Mr. Richard Tiptaft, Mr. Jonathan Glass and the Lithotripsy unit, the Mechanical Workshop and Electro Biomedical Engineering Section at Guy's and St. Thomas' Hospital, London, for their collaboration.

6 REFERENCES

1. B.K. Auge and G.M. Preminger., 'Update on shock wave lithotripsy technology'. Current Opinion in Urology, 12(4) 287-290. (2002).
2. M. Delius, M. Jordan, H.G. Liebich and W. Brendel., 'Biological effects of shock waves: effect of shock waves on the liver and gallbladder wall of dogs-administration rate dependence', Ultrasound in Medicine and Biology, 16(5) 459-466. (1990).
3. A.J. Coleman, M. Whitlock, T.G. Leighton and J.E. Saunders.,' The spatial distribution of cavitation induced acoustic emission, sonoluminescence and cell lysis in the field of a shock wave lithotripter',. Physiology in Medicine and Biology, 38(11) 1545-1560. (1993).
4. K. Madbouly, K.Z. Sheir, E. Elsobky, I. Eraky and M. Kenawy., 'Risk factors for the formation of a steinstrasse after extracorporeal shock wave lithotripsy: a statistical model'. Journal of Urology 167(3) 1239-1242. (2002).
5. D.A. Tolley and P Downey., 'Current advances in shock wave lithotripsy'. Current Opinion in Urology, 9(4) 319-323. (1999).
6. A.J. Coleman, M.J. Choi, J.E. Saunders and T.G.Leighton., 'Acoustic emission and sonoluminescence due to cavitation at the beam focus of an electrohydraulic shock wave lithotripter'. Ultrasound in Medicine and Biology, 18(3) 267-281. (1992).
7. F. Fedele, A.J. Coleman and T.G. Leighton. 'Use of cylindrical PVdF hydrophone in a study of cavitation adjacent to stone phantoms during extracorporeal shockwave lithotripsy'. 66. Proc. of the IPEM Annual Scientific Meeting. Bath (September 2003).
8. F. Fedele, A.J. Coleman, T.G. Leighton, P.R. White and A.M. Hurrell AM., 'A new sensor for detecting and characterising acoustics cavitation *in vivo* during ESWL'. CD Proc. of the Spring Conference of the Institute of Acoustics. Southampton (March 2004).
9. F.Fedele, A.J. Coleman, T.G. Leighton, P.R. White and A.M. Hurrell., 'Development of a new diagnostic sensor for Extra-corporeal Shockwave Lithotripsy'. Proc. of the Advanced Metrology for Ultrasound in Medicine, 1 134-139. Teddington (April 2004).
10. S. Zhu, F.H. Cocks, G.M. Preminger and P. Zhong., 'The role of stress waves and cavitation in stone comminution in shock wave lithotripsy'. Ultrasound in Medicine and Biology, 28(5) 661-671. (2002).