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A passive acoustic monitor of treatment effectiveness during extracorporeal lithotripsy

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Abstract. Although extracorporeal shockwave lithotripsy (ESWL) has now been in the clinic for at least three decades, there has been little advance in efforts (i) to estimate the efficacy of the treatment whilst it is in progress, or (ii) to determine the end-point of a treatment session in terms of the degree of stone fragmentation achieved. Previous *in vitro* experimentation and clinical trials have shown that a passive acoustic monitor has the potential to provide evidence of the effectiveness and end-point of lithotripsy. The system exploits secondary emissions generated during shock-tissue interaction, whose features depend on the quality of tissue at the beam focus. This prototype was developed into the first commercially available clinical ESWL treatment monitor (Precision Acoustic Ltd, Dorchester, UK), and a unit has been acquired and tested in the clinical routine by urologists at Guy's and St Thomas NHS Trust in March 2009. This paper critically assesses the performance of the new system for the first 25 treatments monitored. The ESWL monitor correctly predicted the treatment outcome of 15 of the 18 treatments that were followed-up clinically. In addition, it was noted that the measure of treatment effectiveness provided by the monitor after 500 shocks was predictive of the final treatment outcome ($p < 0.001$). This suggests that the system could be used in pre-assessment; indicating if the stone is susceptible to ESWL or if the patient should be sent for surgery.

1. Introduction

Extracorporeal shockwave lithotripsy (ESWL) has been used since the 1980s for the non-invasive treatment of urinary stones [1, 2]. A patient's stone is fragmented by means of thousands of ultrasound shock waves, administered with at a rate of about 1-2 per second [1, 2]. Even after three generations of commercial lithotripters there has been little advance in providing the operator feedback on the procedure success [1, 2].

In the early nineties Coleman et al. identified a characteristic double-burst acoustic emission structure (Figure 1) arising form the focus of lithotripters, driven by the shock-tissue interaction [3-4]. A research team formed by members of both Guy's and St Thomas NHS Foundation Trust (GSTT) and the University of Southampton has since focused on analyzing the characteristics of these double-burst

emissions by means of both computational fluid dynamics models (CFD) [5, 7-8] and in vitro experiments [4,5, 10-15]. These studies proved that the emissions, which are formed by a mixture of components [13, 16-18], showed features dependent on stone targeting and fragmentation [9-14]. In particular, one feature, the time between the two bursts of emission, known as the collapse time (t_c), was shown to be sensitive to targeting, whilst the ratio of the amplitude of the two bursts, m_2/m_1, could be used to classify different stages of stone fragmentation [13-15]. This knowledge was exploited to design a first passive prototype acoustic system (PAS) for monitoring lithotripsy procedures in collaboration with Precision Acoustics Ltd. (PA, Dorchester, UK) [5, 10-12]. The prototype design was completed and tested during a two stage clinical trial on 79 patients from January 2006 and June 2007 [5, 13-15]. After some re-design of its components to facilitate further use in the clinical environment, a first commercial prototype [19-21], was made available to the Urology Department of GSTT, for clinical evaluation in March 2009. A comprehensive report on the development of the PAS system into a commercial treatment monitor for ESWL can be found at http://www.isvr.soton.ac.uk/fdag/Litho_07/litho_07(main).htm.
This paper reports on the first attempts to use the first commercial clinical prototype routinely in the clinic.

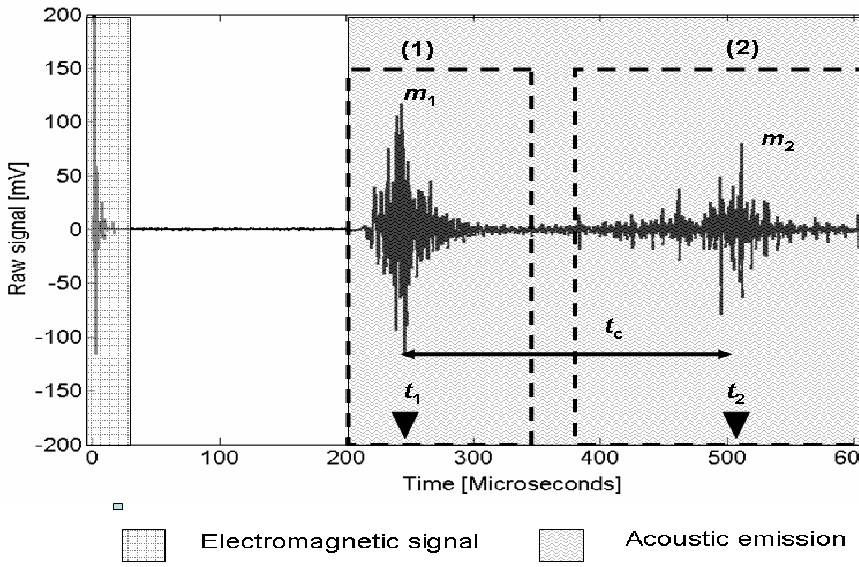

Figure 1. Typical signal acquired for a single ESWL treatment shock. An electromagnetic triggering signal, is followed after about 200 μs by an acoustic emission, which lasts about 500 μs. The main features of this double burst emission are labelled: m_1: maximum amplitude of the first burst, m_2: maximum amplitude of the second burst, t_1: central time of the first burst, t_2: central time of the second burst; t_c: interval between the two bursts, named collapse time. The method of calculating the values of these parameters is detailed in references [13, 14].

2. Material and methods

The commercial clinical prototype monitor, based on the PAS system described in details in references [13-14], was used by the Stone unit at GSTT to monitor 25 treatments between March and June 2009. After obtaining the approval of GSTT Ethical Committee, 25 patients with a BMI of 27±4 were recruited and administered a dose of ~3000 shocks using a Storz Modulith SLX-MX lithotripter (Storz Medical, Tägerwilen, Switzerland) at a power settings of 5±1 and a rate of 120 shocks per minute. The monitored treatments were, for most patients, their first or second session (20/25). Unlike clinical trials of the previous monitor prototypes [5, 13-15], this study included both kidney (17) and ureteric

stones (8). The ESWL treatment monitor (Figure 2) consists of four main components, which have previously been described in detail [13-14]:

- (Figure 2a) A passive acoustic probe, which includes a broadband acoustic sensor and a commercial 8dB preamplifier (PAL)
- (Figure 2b) A data conditioning module, which includes high pass noise filtering at 300 kHz, a DC coupler and a rechargeable batteries unit
- (Figure 2c) A commercially available digital scope for data acquisition and digitalization (TiePie Handyscope 3, TiePie engineering, WL Sneek, Netherlands)
- (Figure 2d) A laptop-based MATLAB™ user interface for system control and on-line monitoring (figure 2d shows a screen-shot, with explanatory labels on each area of the screen).

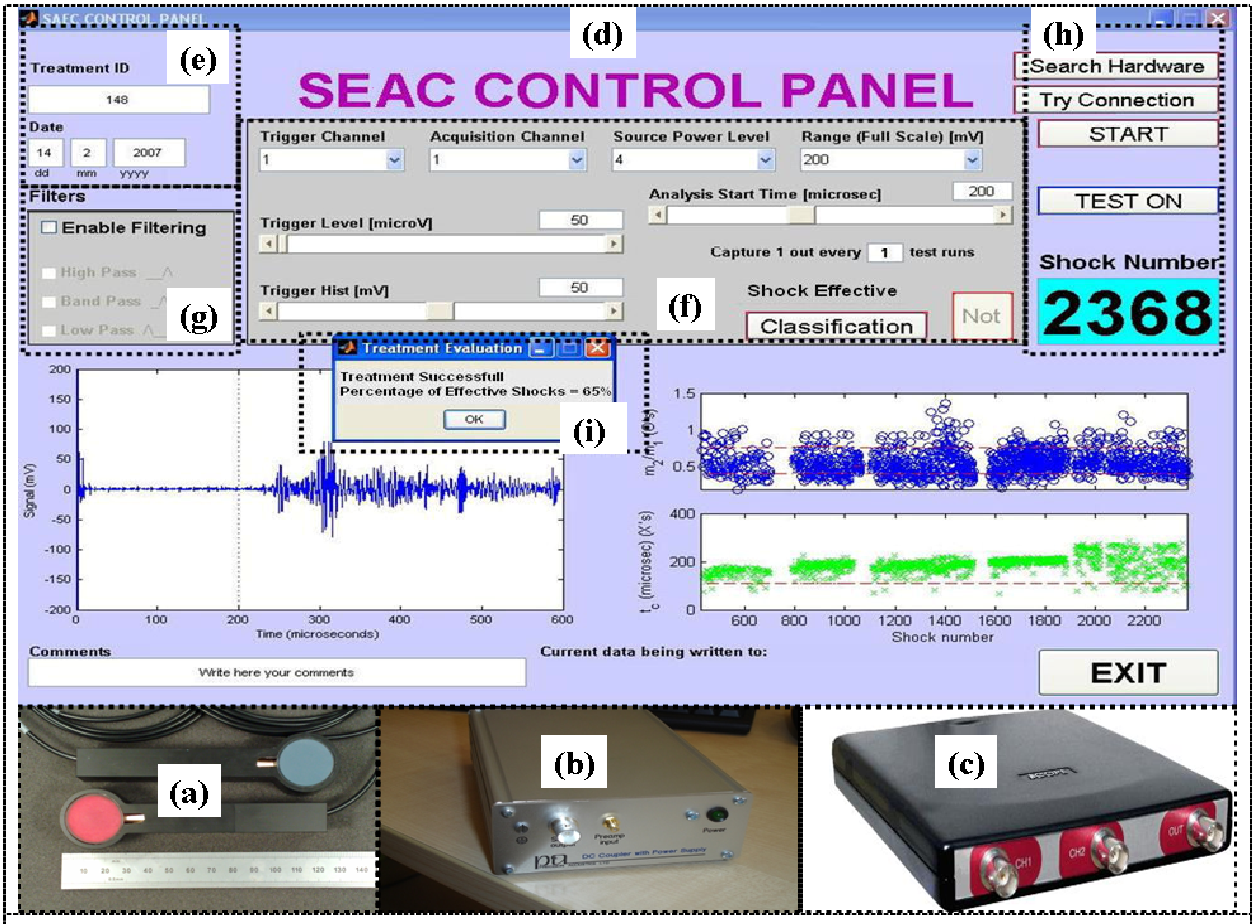

Figure 2. ESWL treatment monitor components: (a) The acoustic probes, (b) The data conditioning module, (c) the TiePie digital scope, (d) the MATLAB™ software interface (screen shot shown here). The interface (d) displays, for every shock, the shock number (panel h), the acoustic emission (left chart), the value of its main features: the ratio of the two peak amplitudes m_2/m_1 (top right chart) and the collapse time t_c (bottom right chart), and the estimated effectiveness of that particular shock (panel f). It also includes some control panels: (e) treatment details, (f) controls of the digital acquisition, (g) bank of optional digital filters and (h) a section to test the software-hardware synchronisation. Clicking with the PC mouse on the classification button in (f) reveals screen (i), which displays an estimate of the cumulative percentage of effective shocks, which is the treatment score (*TS*) used to classify a treatment. A treatment with a final *TS* of 50% or higher is considered successful. This may be done at any time during the treatment, and is always done at the end of treatment.

The passive probe (Fig 2a) is placed on the patient's flank at the beginning of the procedure. It monitors the emission generated after each shock. The data is acquired and processed on-line in real time to provide an estimate of the effectiveness of each shock and a cumulative percentage of effective shocks (Figure 2i) is used as the acoustic treatment score (*TS*) by which the treatment outcome is classified. That is to say, if at the end of the session (~3000 shocks) at least half of the monitored shocks were considered to be effective (TS_0=*TS*(3000)≥50%) the treatment is acoustically classified as having been '*successful*' [12-14, 18-20]. Treatments with TS_0≤30% are considered '*unsuccessful*' and those with 30<TS_0≤49% are classified as 'borderline' [12].
In this trial *TS* was estimated after each block of 500 shocks, and the correlation between the score after an initial test dose of 500 shocks, *TS*(500), and the final score TS_0 was examined. The outcome of each monitored treatment was established at the patient's follow-up appointment 1-3 weeks after the procedure. A team of 3 clinicians (blinded to the classification results from the acoustic monitor) were asked to agree and assign to each treatment an X-Ray based clinical treatment score (CTS_2, [12-14, 18-20]). CTS_2, based on the comparison of the pre–treatment stone X-Ray against the follow-up X-Ray, could range from 0 (no change in the stone) to 5 (stone disappeared). Treatments with a CTS_2≥3 (the stone was halved in size or smaller) were considered as successful. The quality of the raw acoustic data collected (which are automatically stored by the system) was also examined.

3. Results

Five treatments were excluded on the basis that the raw acoustic data showed one of the following issues: flat noisy signals (1/5) denoting coupling problems, clipped signals (2/5) and signals (2/5) associated with the saturation of the preamplifier. The system was used by a variety of users: urology consultants, research urology fellows, radiologists and clinical nurses. All these issues could be linked to the difficulty nurses had in using the system. Of the 20 cases with adequate signal, 18 could be assessed clinically.
The monitor results (Table 1) provide agreement with the clinical classification in 14/18 cases and, in particular it correctly classified 11/12 unsuccessful treatments (specificity = 92%) and 3/6 successful treatments (sensitivity = 50%). Two 'successful' treatments were misclassified and one 'successful' and one 'unsuccessful' treatment were classified as 'borderline'. The high specificity confirmed the ability of the system to identify stone not suitable for ESWL.
The two subsets of cumulative scores *TS*(500) and TS_0=*TS*(3000) (Figure 3) are highly correlated (R^2=0.83) and do not differ statistically (p<0.001), showing that the evaluation of the results from the monitor after a test dose of only 500 shocks, is a good predictor of treatment outcome.

4. Discussion and future work

This first clinical experience showed the ability of the commercial prototype ESWL treatment monitor to predict treatment outcome early-on during the procedure, and confirmed its particular suitability to identify unsuccessful treatments, which most likely can be associated with hard stones that are refractory to ESWL [20-21].
On the other hand, some clinical users found the system difficult to use and felt that they would have preferred a different method of visual feedback. These suggestions were exploited to redesign the visual appearance of the system. Figure 4 and Figure 5 illustrate the new design. Figure 4, in particular shows the simplified monitoring screen that will give a simpler feedback on targeting and percentage of effective shocks.

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Table 1. Classification of the acoustic treatment cumulative score at the end of the treatment TS_0=TS(3000) versus the treatment clinical follow-up score CTS_2. *TP*, true positive (treatment classified correctly as *successful*) *FP*, false positive (treatment classified incorrectly as *successful*), *FN*, false negative (treatment classified incorrectly as *unsuccessful*), *TN*, true negative (treatment classified correctly as *unsuccessful*).

		Treatments (as assessed at follow-up by the clinical score CTS_2)	
		Successful	*Unsuccessful*
Classification of the monitor based on the acoustic treatment score TS_0=TS(3000)	*Successful*	*TP* = 3	*FP* = 1
	Unsuccessful	*FN* = 3	*TN* = 11
	Sensitivity = 50%	Specificity= 92%	

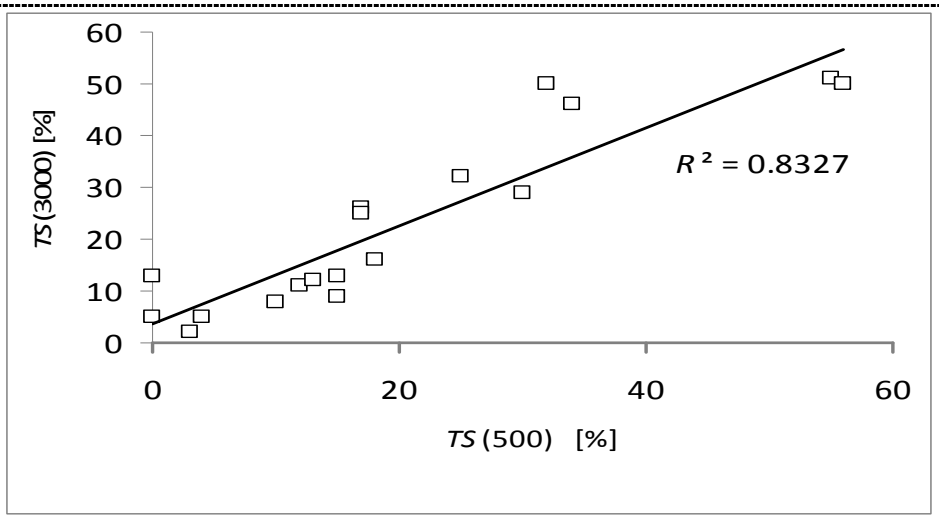

Figure 3. Correlation between the cumulative treatment score after a test dose of 500 shocks TS(500) and that at the end of the treatment TS_0=TS(3000).

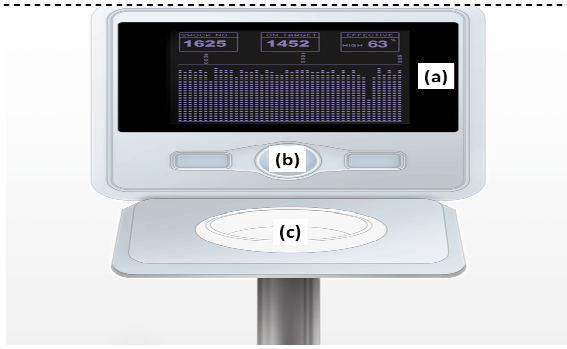

Figure 4. Visual design of the new monitoring system. (a) Monitoring screen. (b) Navigation controls. (c) Probe testing station. Picture courtesy of Chris Page, Brunel University.

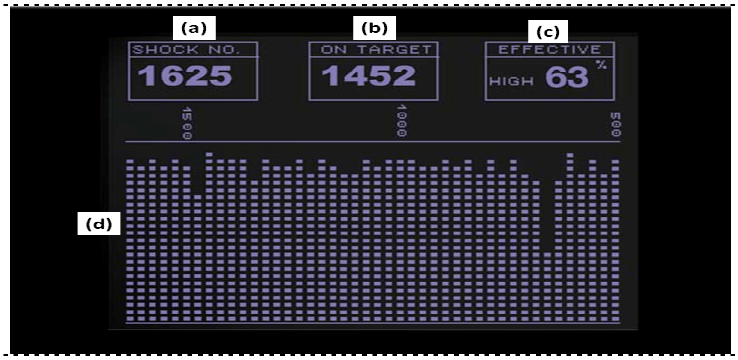

Figure 5. New monitoring screen. (a) Shock number. (b) Shocks on target. (c) Cumulative percentage of effective shocks *TS*. (d) Feedback on targeting. A shock with good targeting (t_c> 100 μs) is shown as a white dot. Shocks are grouped in columns of 25. Picture courtesy of Chris Page, Brunel University.

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