Feasibility of extended use of an electromagnetic lithotripter beyond the manufacturer's recommended maintenance schedule

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Objectives: *The study evaluates the effect of chronic usage, beyond the recommended maintenance schedule, on the efficacy of electromagnetic lithotripter. To our knowledge, there is no publication investigating the effect of chronic usage on the electromagnetic lithotripter, despite the maintenance schedule established by the manufacturers. Our goal is to verify if the acoustic parameters of the shock wave changed with usage, and if this change could be associated with change in clinical efficacy.*
Methods: *This study lasted 18 months. Every 6 months the lithotripter's efficacy was evaluated in two ways: objectively and clinically. Objective efficacy was measured using a piezoelectric hydrophone and artificial stones to capture the acoustic parameters and the crater of fragmentation, respectively. Clinical efficacy data was collected by studying the rate of successful extracorporeal shock wave lithotripsy treatment in patients with urolithiasis. The changes in clinical efficacy, acoustic parameters, and craters of fragmentation were compared and analyzed with appropriate statistical methods.*
Results: *Five hundred twenty five patients participated in the study. The clinical efficacy remained stable throughout the three observation periods (55.7%, 66.2% and 55.5%; p = 0.11). The focal head of the lithotripter was used three times the recommended schedule. There was no obvious change in the acoustic parameters of the shock waves, and the focal zone remained stable.*
Conclusions: *The clinical efficacy of the electromagnetic lithotripter appears to be stable despite usage beyond the recommended maintenance schedule. More studies are needed to validate the safety of this practice.*

Key Words: quality control, shock wave lithotripsy, treatment outcome, urolithiasis

Introduction

It is estimated that the lifetime possibility a white male develops urolithiasis by the age of 70 is 1 in 8.[1]

Extracorporeal shock wave lithotripsy (SWL) was pioneered as treatment modality for urolithiasis. To better study factors influencing efficacy of SWL, Finlayson proposed two methods to approach these problems, mainly the use of an artificial stone model and the measurement of acoustic parameters of the shock wave, such as proposed the American Institute of Ultrasound in Medicine and the National Electrical Manufacturers Association (AIUM/NEMA), Table 1.[2] There has been much progress in the design of the

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TABLE 1. **AIUM/NEMA safety standards**

Aim accuracy
Focal positive and negative peak pressures
Pulse rise time, fall time, duration and width in the focus
Pressure distribution around the focus
Depth of the focus along z axis
Half-peak amplitude beam width in the focal plane along x- and y-axes
Focal area
Focal pulse intensities
Pulse acoustic energy
Pressure temporal peak distribution along two axes
Focal peak pressure repeatability
Impulse

extracorporeal shock wave lithotripter, such as in the imaging apparatus and coupling mechanism. The most important development is the creation of new shock wave energy sources. There are currently three commercially available sources: electrohydraulic, piezoelectric, and electromagnetic.[3] At our institution, we have an electromagnetic lithotripter (Siemens Multiline).

Although there is controversy regarding which acoustic parameters contribute to shock wave fragmentation ability,[4,5] the manufacturers propose a specific maintenance schedule for the lithotripter without readily accessible scientific data. In fact, it has been shown that the electrodes of Dornier MFL-5000 electrohydraulic lithotripter can be used beyond recommended lifespan.[6] For the Siemens Multiline, the model at our institution, the manufacturer suggests changing the focal head after 1 million shocks and changing the generator after 2 million shocks. Due to cost saving measures, these components, especially the focal head, are sometimes used beyond the recommended usage, and the effect of such practice remains unknown.

The current study aims to address this issue, to evaluate whether there is a decrease in clinical efficacy with prolonged usage of electromagnetic lithotripter, beyond the recommended maintenance schedule. The specific objectives are: (1) to evaluate the change, with chronic usage, of the acoustic parameters of shock waves emitted by one Siemens Multiline electromagnetic lithotripter; (2) to evaluate the possible change in clinical efficacy in SWL treatment of urolithiasis, with the extended usage of this electromagnetic lithotripter and (3) to verify if there is a relationship between the changes in acoustic parameters and the clinical efficacy in the treatment of urinary stone disease.

Methods

Study design

At our institution, we currently employ a Siemens Multiline electromagnetic lithotripter, serial number 6018. It was put into service in 1995. It has been maintained according to manufacturer's recommendation. This was a prospective observational study that did not involve randomization or sham treatment. The beginning of the experiment coincided with the installation of a new focal head. The observation intervals consisted of three 6-month periods since the installation of a new focal head.

Patient inclusion and exclusion criteria

The intended population included all patients referred to Sherbrooke University Hospital Centre (SUHC) for SWL as treatment for urolithiasis. Patients were seen pre-operatively with a basic questionnaire and physical exam, and their radiological documentation was also examined. The complete list of inclusion and exclusion criteria is listed in Table 2. This study was approved by the Ethics Committee of the SUHC (Institutional IRB # 01-84).

TABLE 2. **Inclusion and exclusion criteria**

Inclusion criteria
Patients referred to Sherbrooke University Hospital Centre for SWL for urolithiasis
Stone(s) demonstrable on radiological studies
Stones less than 20 mm
Exclusion criteria
Pregnancy
Coagulopathy
Infection
Functional or anatomic abnormality of the kidneys, such as renal failure, medullary sponge kidney, horseshoe kidney, malrotated kidney, and infundibular stenosis
Extreme body habitus: body mass index less than 20 or more than 28
Premature termination of treatment due to pain

mm: millimeter

Outcome measures

The acoustic parameters established by AIUM/NEMA were measured with piezoelectric hydrophone (PCB Piezotronics®, New York, USA). More specifically, these are focal positive and negative peak pressures, pulse rise and fall times, pulse width, dimensions of the focal zone (where peak positive pressure is at least half the magnitude compare to focal point), and focal peak pressure repeatability. We have omitted factors that are not commonly studied, such as pressure distribution around the focus and half-peak amplitude beam width in the focal plane along x- and y- axes. Factors, such as intensity and energy, which are derived from other parameters, are not studied as proposed by the AIUM/NEMA Safety Standards. The model and serial numbers of the hydrophone are W105C33/038AA010AC and 5862, respectively. In order to house the hydrophone, a water basin was manufactured by the Mechanical Engineering Department of University of Sherbrooke. This basin can form a watertight seal against the coupling balloon, and a module that allows for mobilization of the hydrophone or the artificial stone is attached to the cover of the basin. Degassed distilled water is used to minimize dispersion and attenuation of shock wave.[7] The hydrophone is then attached to the oscilloscope (LeCroy® 9310 M 300 MHz dual oscilloscope, New York, USA). The measurements were performed under two lithotripter power settings: mid (5/9) and max (9/9), and at 1 mm increments in the three dimensions of the focal zone. Due to engineering limitations of the mobilization module, we can only perform measurement along half of the y and z axes. The lengths obtained in the y and z axes are started from focal point and then multiplied by 2.

In order to provide an objective standardized way of comparing fragmentation efficacy, we have placed artificial stones and exposed them to a fixed number of shocks, resulting in a cone shaped crater of fragmentation. By comparing the dimensions and volumes of the craters of fragmentations, one can assess objectively the machine's ability to break stones. To estimate the volume, the craters were filled with icing sugar and then weighed with an electronic balance sensitive to 0.1 mg. Artificial stones (High Medical Technology, Lengwil, Switzerland) are made of plaster of Paris and used for lithotripter quality control and development.

Patients who had expressed written informed consent were followed until they reached the clinical endpoint, either success or failure. We decided that for stones smaller than 5.0 mm before treatment, there must be complete disappearance of the stone. For stones larger than 5.1 mm, we can accept asymptomatic fragments as success, provided they correspond to criteria of clinically insignificant residual fragment, as proposed by Rassweiler et al.[8] The follow-up is done through review of medical files or telephone interviews. Those who refused to participate were treated with SWL with no discrimination.

Sample size and statistical analysis

The sample size required was determined a priori. A survey of the urologists at our institution revealed that if the efficacy rate dropped by 10%, the components should be changed. A retrospective institutional review revealed a global success rate of approximately 80%. The sample size was determined according to the following equation:[9] $N=\{Z_\alpha\sqrt{2P(1-P)}+Z_\beta\sqrt{(P_1(1-P_1)+P_2(1-P_2)}\}^2/(P_1-P_2)^2$ where $P=(P_1+P_2)/2$, and P_1= 80%, P_2=70%, α=0.05 and β=0.70. Z_α and Z_β represent statistical coefficients. P_1 and P_2 signify initial success and lowest acceptable success rates respectively. A 156 patients would be needed per observation period. The recruitment would be attainable, as there are 400 SWL treatments per year in SUHC. Chi-square test was used to compare patient demographics and clinical outcome.

Results

The end of the study used the focal head of the lithotripter three times beyond the recommended maintenance schedule, at approximately 3 million shocks. During this period, there was no additional repair or dysfunction of the lithotripter.

There were 525 patients who participated in the study. Demographics data is similar during the three observation periods in terms of gender, age, stone burden and stone location, as shown in Table 3. Symptomatic cure rates (based on absence of symptoms) are similar between the three groups (65.6%, 72.0% and 61.2%, chi square, p = 0.14). Clinical efficacy (absence of symptoms and radiology) of the three periods are 55.7%, 66.2% and 55.5% respectively (chi square, p = 0.11). Missing patients were excluded from analysis. The symptomatic cure and clinical efficacy rates increased in the second observation period and then decreased in the final observation period.

The acoustic parameters of the shock wave fluctuated mildly through the observation periods without obvious trends. The maximum positive and negative pressures at the focus are summarized in Table 4, and the rise time, fall time and pulse width are summarized in Table 5. There is no discernible pattern of change in the acoustic parameters. Interestingly, the maximal positive pressure at mid power setting (P 5/9) and maximum power

TABLE 3. **Demographic data**

	Period of observation		
	A (0-6 months)	**B (6-12 months)**	**C (12-18 months)**
Women	65 (32.0%)	62 (34.3%)	45 (30.6%)
Men	138 (68.0%)	119 (65.7%)	102 (69.4%)
Age	51.5 ± 14.3	52.9 ± 13.0	49.2 ± 13.4
Single stone	169 (83.3%)	160 (88.4%)	117 (79.6%)
Multiple stones	34 (16.8%)	21 (11.6)	33 (20.4%)
Renal stone	81 (39.9%)	76 (42.0%)	68 (46.3%)
Ureteral stone	122 (60.1%)	105 (58.0%)	79 (53.7%)
Stone burden (mm)	7.2 ± 2.8	7.4 ± 2.7	8.0 ± 3.4

mm: millimeter

TABLE 4. **The maximum positive and negative pressures at the focus (atm)**

Period	**Power Setting**	**P+ve (atm)**	**P-ve (atm)**
0 month	Power 5/9	399.3 ± 9.7	-193.1 ± 11.1
6 month	Power 5/9	444.3 ± 10.3	-184.0 ± 13.6
12 month	Power 5/9	512.9 ± 14.9	-237.4 ± 12.6
18 month	Power 5/9	452.2 ± 8.1	-198.7 ± 15.6
0 month	Power 9/9	550.1 ± 6.7	-228.2 ± 14.4
6 month	Power 9/9	648.8 ± 16.9	-265.6 ± 14.5
12 month	Power 9/9	787.8 ± 9.7	-257.5 ± 12.5
18 month	Power 9/9	483.9 ± 58.4	-213.6 ± 30.3

atm: atmosphere

TABLE 5. **The rise time, fall time and pulse width at the focus**

Period	**Power setting**	**Rise time (μsec)**	**Fall time (μsec)**	**Pulse width (μsec)**
0 month	Power 5/9	1.01 ± 0.04	1.02 ± 0.04	1.09 ± 0.03
6 month	Power 5/9	1.12 ± 0.04	1.04 ± 0.04	1.16 ± 0.04
12 month	Power 5/9	1.14 ± 0.05	0.94 ± 0.03	0.98 ± 0.03
18 month	Power 5/9	1.28 ± 0.04	0.94 ± 0.04	1.21 ± 0.03
0 month	Power 9/9	1.01 ± 0.04	1.05 ± 0.03	1.00 ± 0.03
6 month	Power 9/9	1.09 ± 0.04	1.00 ± 0.04	1.07 ± 0.08
12 month	Power 9/9	1.20 ± 0.02	0.84 ± 0.03	0.83 ± 0.05
18 month	Power 9/9	1.57 ± 0.17	0.90 ± 0.02	1.43 ± 0.19

μsec: microsecond

TABLE 6. **The measurement of the focal zone and crater of fragmentation**

	Dimensions of the focal zone			Volume of crater of fragmentation
	X (mm)	Y (mm)	Z (mm)	(mg)
0 month	6	10	100	939 ± 52
6 month	5	8	110	975 ± 80
12 month	6	10	80	1123 ± 39
18 month	5	8	130	1030 ± 49

mm: millimeter
mg: milligram

setting (P 9/9) changed in the same direction, albeit in different proportions. They both increased from baseline until month 12, and then dropped by month 18.

The measurements of the focal zones and craters of fragmentation are listed in Table 6. The volume of crater of fragmentation is inferred from the icing sugar powder that fills the shock-wave-induced crater in the artificial stones; hence it is expressed in milligrams. The dimensions of the focal zone remain stable over time. In other words, it increased from baseline until month 12, and then declined by month 18.

Discussion

The use of hydrophones in lithotripter research has limitations. There are considerable uncertainties, up to 36%, and therefore it limits the device's ability to determine the accurate values of the acoustic parameter.[10] However, these uncertainties do not limit the precision of the hydrophone, as long as the same pressure probe is used for the different measurements.[11,12] In this study, the trend of the change in acoustic parameter is more important than the absolute values themselves. Hence, robust hydrophones, such as the piezoelectric devices, are useful in that regard and suit the purpose of the study.

In our study, there is lack of evident change in the acoustic parameters. A few explanations can be proposed. Firstly, there could be no change related to chronic usage, and therefore no pattern of change was detected. Secondly, it could be that the acoustic parameters measured are the wrong parameters; however, this is unlikely, since these are the standard parameters proposed by AIUM/NEMA. They are the physical features used to characterize a wave, such as an ultrasonic wave in the case of lithotripter. If one or more of the characteristics of the wave was to change, it should be reflected in one of these parameters. Thirdly, the hydrophone could be defective or not tough enough to withstand repeated pressure measurements. However, this is unlikely, since piezoelectric hydrophones are known for their robustness, and a calibration of the hydrophone at the end of the study confirmed its stability. In addition, the changes in maximum positive pressures at the focus appeared to be in the same direction as the volume of crater of fragmentation. It also corresponds to the trend in changes of clinical efficacy. Hence it is unlikely that the listed reasons could explain the observed changes.

If the changes in the acoustic parameters were real, then one would wonder about the absence of evident pattern. Here we will suggest some possible explanations for the changes in maximum positive pressures. They changed in the same direction as volumes of crater of fragmentation and clinical efficacy, and hence are most interesting. There could be a break-in period for the lithotripter, like for certain heavy machinery. Hence as the machine gets more usage, it works better, until it reaches a decay point. It is possible that the decrease in positive and negative pressures at the end of the study represents the decay in the lithotripter performance, as the volume of the crater of fragmentation and the clinical results also changed similarly. However, the study did not continue further due to ethical considerations, and it is difficult to draw additional conclusions. Secondly, there could be some instability with the hydrophone. This explanation is less likely, since piezoelectric hydrophones are more stable and the changes in maximum positive pressures at the focus in the study occurred in the same direction as the volumes of crater of fragmentation and clinical efficacy. Thirdly, the focal head could manifest certain instability, leading to random acoustic parameter changes. However, the focal zone remained stable in the experiment, making random changes less likely.

The sampling method in this study was non probabilistic: all patients were invited to participate. This sampling method was used because there was

minimal cost in including all the patients and the benefit of increased power was believed to be relevant. Although there were more patients per period than the predetermined necessary sample size, we had anticipated certain problems. Since the SUHC is a referral centre, many patients are followed by their own doctors in the communities. Hence we anticipated a significant number of patients lost to follow-up. Also, the success rate is not uniformly defined in the literature, and a lower than expected success rate might increase the necessary sample size quite dramatically. We have therefore decided to include all consenting patients in the study.

A significant number of patients were lost to follow-up. Most patients do not return to their doctor's office for follow-up because they are no longer symptomatic. In addition, the number of patients lost to follow up appears to be evenly distributed over the three periods, so there is no reason to suspect that it would influence the outcome. Therefore they were excluded from analysis, instead of counted as failure. This represents the difficulty in conducting a large scale clinical research from a hospital that covers a wide referral region. Most patients, for geographical convenience, were referred back to their doctor for the follow-up. However, not all doctors require post-treatment radiographic studies. As a result, twice as many patients show missing information regarding clinical efficacy, as compared with symptomatic cure. Despite the large number lost to follow-up, there are still enough subjects to achieve adequate power, except in the third period. However, the percentage during the third period is comparable to that of the first, with an acceptable number of patients. Therefore the loss to follow up most likely has limited effect.

Conclusion

This study shows that judicious prolongation of maintenance period of the focal head beyond recommended schedule has no major impact on clinical efficacy of electromagnetic lithotripter. This could lead to potential savings. However, there needs to be a quality control mechanism to ensure patient care is not jeopardized. More studies are needed to validate the safety of this practice. □

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