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# Modification of the Edge Wave in Shock Wave Lithotripsy

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**Abstract.** To reduce the bubble cavitation and the consequent vascular injury of shock wave lithotripsy (SWL), a new method was devised to modify the diffraction wave generated at the aperture of a Dornier HM-3 lithotripter. Subsequently, the duration of the tensile wave was shortened significantly ( $3.2 \pm 0.54 \mu\text{s}$  vs.  $5.83 \pm 0.56 \mu\text{s}$ ). However, the amplitude and duration of the compressive wave of LSW between these two groups as well as the -6 dB beam width and the amplitude of the tensile wave are almost unchanged. The suppression on bubble cavitation was confirmed using the passive cavitation technique. At the lithotripter focus, while 30 shocks can cause rupture of blood vessel phantom using the HM-3 lithotripter at 20 kV; no rupture could be found after 300 shocks with the edge extender. On the other hand, after 200 shocks the HM-3 lithotripter at 20 kV can achieve a stone fragmentation of  $50.4 \pm 2.0\%$  on plaster-of-Paris stone phantom, which is comparable to that of using the edge extender ( $46.8 \pm 4.1\%$ ,  $p=0.005$ ). Altogether, the modification on the diffraction wave at the lithotripter aperture can significantly reduce the bubble cavitation activities. As a result, potential for vessel rupture in shock wave lithotripsy is expected.

**Keywords:** diffraction wave, shock wave lithotripsy, bubble cavitation

**PACS:** 43.20.Ei, 43.28.Mw, 43.35.Ei, 43.80.Gx

## INTRODUCTION

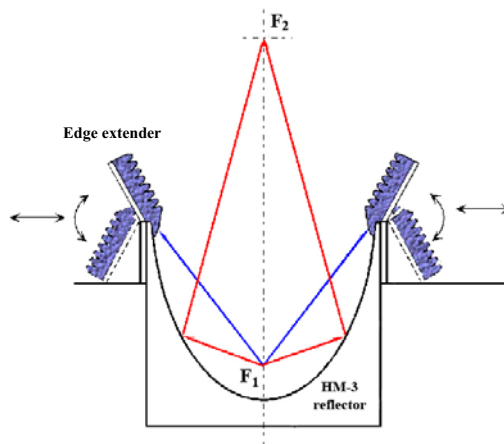
Kidney stones have plagued mankind for centuries and are one of the most common and painful disorders of the urinary tract. Since its introduction in the early 1980s, shock wave lithotripsy (SWL) has revolutionized the treatment for upper urinary stone disease. With this technique, 80% of patients can be rendered stone-free 3 months after treatment without open surgery or endourologic procedures. Despite its great success and the development of several generations of clinical lithotripters in the past three decades, no fundamental improvement in SWL technology has been accomplished to achieve better treatment efficiency with reduced tissue injury [1]. There are substantial evidences from both clinical and basic studies that SWL produces acute renal injury, such as hematuria, kidney enlargement, renal and perirenal hemorrhage and hematomas [2]. Although most patients recover well following lithotripsy, there are subgroups of patients who are at much higher risk for chronic SWL injury. These include patients with solitary kidneys, pre-existing hypertension, and, in particular, pediatric and elderly patients [2]. Therefore, the reduction of SWL-induced renal injury is of importance for both clinician and stone patients.

Two mechanisms have been implicated for SWL-induced tissue injury: bubble cavitation activities of gas nuclei (i.e., expansion, invagination and microjet) and shear stress due to a shock front propagating through a heterogeneous medium. Rupture of capillary and small blood vessels, which are the primary characteristics of vascular injury in SWL [2]. To reduce SWL-induced vascular injury, several approaches have been applied, such as the use of pressure release reflector [4], overpressure (a few bars) to the focal region [5], the reflector insert using in-situ pulse superposition [6-7] and the acoustic diode [8]. Although promising results were obtained in vitro, the limitations of these methods include no stone fragmentation, inconvenience in the install or removal, or complexity in the design. Therefore, there is no effective strategy applied in the commercial lithotripters. Altogether, a simple, reliable and universal protection device for SWL treatment is in a great need.

## METHODS

### Lithotripter and Edge Extender

The experiment was carried out in a Dornier HM-3 lithotripter with an 80 nF capacitor and a truncated brass ellipsoidal reflector (Fig. 1). A prototype edge extender was fabricated and fitted on the HM-3 lithotripter, which consists of eight segments. Each segment essentially comprises of a piece of wavy foam, which absorbs the diffraction wave generated at the aperture, attached to a supporting plate and connected with an adaptor ring via hinge. Therefore, if the edge blocker is not in use, each segment can be rotated outwards with no influence on the lithotripter field.



**FIGURE 1.** The schematic diagram of the edge extender in relation to the original HM-3 reflector.

### Pressure Field Mapping

The waveforms of SW were measured using a light spot hydrophone (LSHD), which was attached to a three-dimensional position system (Velmex, Bloomfield, NY) with a minimum step size of 5  $\mu\text{m}$  and a maximum scanning range of 250 mm and titled at 14°. A mechanical pointer was used to align the laser spot with the focal point of the lithotripter, F2. A LabView (National Instruments, Austin, TX) program

controlled the automatic field mapping in a step size of 1 mm. At each location, at least six pressure waveforms were recorded by a digital oscilloscope (LeCroy 9304, Chestnut Ridge, NY) operated at 100 MHz sampling rate and the data were subsequently transferred to a PC for off-line analysis.

### **Passive cavitation Detection**

A 1 MHz focused transducer (V392-SU, Olympus-IMS, Waltham, MA) with a focal length of 100 mm and a -6 dB beam diameter of 4 mm was used to measure the acoustic emission (AE) associated with bubble oscillations in water [3, 6]. The focused transducer, attached to a three-axis translational stage, was first aligned perpendicularly to the lithotripter axis and confocally with F2, and then scanned along the lithotripter axis in a 5-mm step both prefocally and postfocally, and transverse to it at the focal plane in a step size of 2.5 mm. Ten AE signals were recorded at each position.

### **Stone Comminution**

Stone comminution ability of lithotripter was evaluated using our established system simulating stone comminution in the renal pelvis [6-7]. Spherical stone phantoms ( $D = 10$  mm) was made of either BegoStone (BEGO USA, Smithfield, RI) or plaster-of-Paris with a powder to water ratio of 1.5:1 by weight. Before placing it into a plastic cylindrical (70×25 mm, L×D) holder, each stone phantom was immersed in degassed water for 1 hour. Furthermore, the holder was connected to the hydraulic gantry of the HM-3 lithotripter so that the stone phantom could be aligned to F2 under the guidance of the bi-planar fluoroscopic imaging. A total of 500 and 200 shocks were delivered to the BegoStone and plaster-of-Paris stone phantoms, respectively, at a rate of 1 Hz at the output voltage of 20 kV. Afterwards, all fragments were spread out into a layer on paper and let dry at room temperature for 24 hours. The dry fragments were then filtered through a series of ASTM standard sieves with 4, 2.8, and 2 mm grids, which were placed vertically in a rack in descending order of grid size. Stone comminution efficiency was determined by the percentage of fragments less than 2 mm. Six samples were used under each lithotripter configuration.

### **Vessel Phantom Rupture**

The propensity of vascular injury produced by the LSWs was evaluated using a vessel phantom made of a single cellulose hollow fiber (i.d.=200 $\mu$ m, 132290, Spectrum, Gardena, CA) [3]. Degassed water, seeded with 0.1~0.2% contrast agent Optison (Amershan Health, Princeton, NJ) by volume, was circulated by a peristaltic pump. The vessel phantom was immersed in the testing chamber with fresh castor oil to minimize cavitation activity outside it. Rupture of the vessel phantom can be easily identified since the circulating fluid will leak out and form a droplet in the castor oil at the rupture site. At this moment, the experiment was stopped to record the number of shocks delivered. If there was no rupture after 300 shocks, the experiment would also be terminated. A total of six samples were used for statistical analysis.

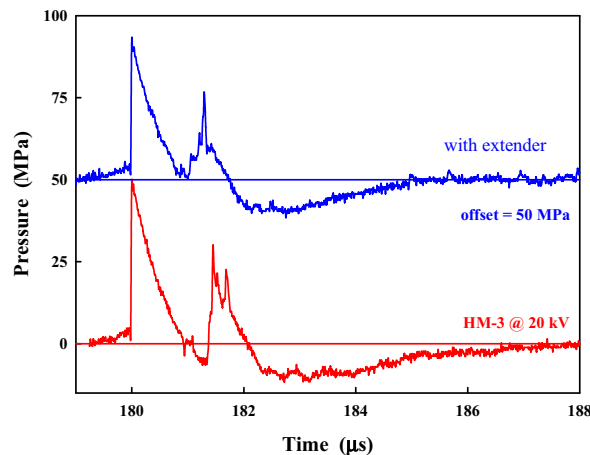
## Statistical Analysis

To determine the statistical difference between the test groups, a student's t-test was used in SigmaPlot 8 (Systat Software, San Jose, CA). The level of statistical significance was fixed at  $p < 0.05$ .

## RESULTS

### Pressure Waveforms and Distribution

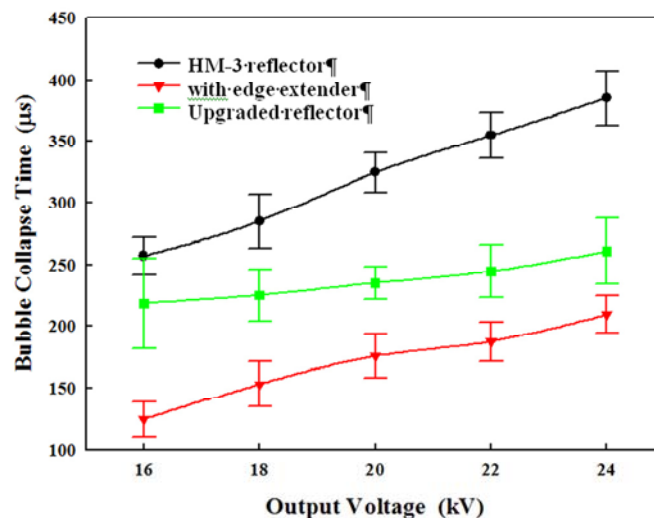
Representative waveforms at the lithotripter focus are shown in Fig. 2. Using the edge extender the compressive wave is almost unchanged,  $44.6 \pm 4.0$  MPa in amplitude and  $1.83 \pm 0.11$   $\mu\text{s}$  in duration, in comparison to those of original HM-3 reflector,  $45.2 \pm 3.8$  MPa and  $1.98 \pm 0.24$   $\mu\text{s}$ , without statistical difference ( $p=0.15$  and  $0.47$ , respectively). The significant difference lies in the tensile part of the pressure waveform. Using the original HM-3 reflector, the tensile pressure is about  $-10.6 \pm 0.7$  MPa in amplitude and  $5.83 \pm 0.56$   $\mu\text{s}$  in duration. However, when the edge extender is fitted at the lithotripter aperture, the negative peak pressure is almost same,  $-11.1 \pm 0.9$  MPa ( $p=0.24$ ), but the duration of the tensile wave reduces to  $3.2 \pm 0.54$   $\mu\text{s}$  ( $p<0.001$ ). As a result, the tensile energy for bubble cavitation is reduced significantly with the edge extender. In addition, if all segments of the edge extender were rotated outwards, the measured pressure waveform was identical to that of the original HM-3 reflector. Therefore, the tensile energy and the associated bubble cavitation can be easily restored. It was found that pressure distribution patterns and  $-6$  dB beam widths produced by the HM-3 reflector were almost identical ( $12.7 \times 8.7$  and  $11.3 \times 10.2$  mm, respectively) no matter whether the edge extender was used, which ensures the sufficiently strong LSWs exposure to kidney calculus or its fragments for successful comminution. In comparison, when using the reflector insert, the  $-6$  dB beam width was smaller [9].



**FIGURE 2.** Representative pressure waveforms produced at the focal point of the lithotripter using the original Dornier HM-3 reflector and the edge extender fitted with the aperture at output voltage of 20 kV.

## Acoustic Emission

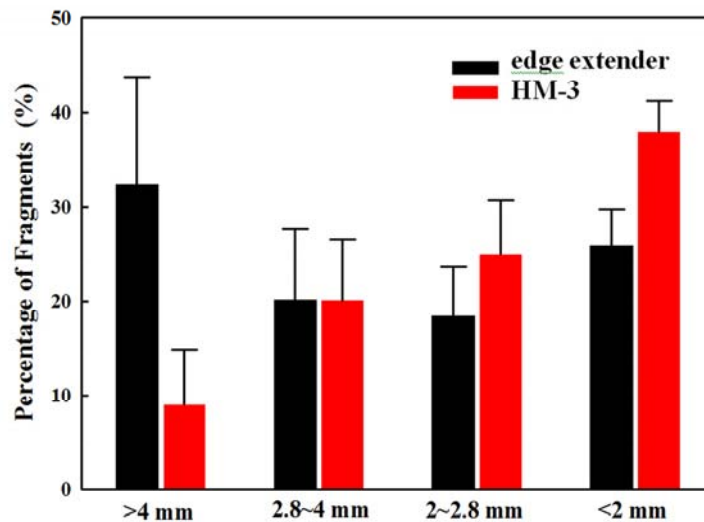
Using passive cavitation detection (PCD) system AE signals associated with the dynamics of bubble cluster generated by the LSWs at the focal region were recorded. The collapse time of the bubble cluster is found to be proportional to the maximum bubble expansion size. By using an edge extender the bubble collapse time ( $175.8 \pm 17.9 \mu\text{s}$ , mean  $\pm$  std) is only 58% of that of the original HM-3 reflector at the output voltage of 20 kV ( $324.4 \pm 16.5 \mu\text{s}$ ) (Fig. 3). In comparison, by using the *in-situ* pulse superposition technique [6-7], the bubble collapse time is  $235.0 \pm 13.1 \mu\text{s}$ . Therefore, modifying the diffraction wave at the reflector aperture seems more effective to suppress bubble cavitation. It is interesting to notice that the dose dependences of the bubble collapse time with and without using the edge blocker are similar. However, the *in-situ* pulse superposition methods seem more dominant at higher output voltage, which is expected in the theoretical estimation since the larger amplitude of the second compressive wave coming from the uncovered bottom of the original HM-3 reflector provides more suppression effect on the bubble expansion induced by the leading LSW [3]. Significant differences ( $p < 0.05$ ) were found between the original and the upgraded reflector except at 16 kV. Furthermore, the bubble cavitation suppression effect using the edge blocker is consistent throughout the whole focal volume of the lithotripter ( $\Delta z = -20 \sim 6.5 \text{ mm}$ ,  $\Delta x = 0 \sim 13 \text{ mm}$ ), whose characteristics are similar to those of the upgraded reflector [6], because the modification is applied on the whole lithotripter field, not at a certain position. Therefore, protecting a rather large portion of renal tissue during SWL is expected.



**FIGURE 3.** Collapse time of the bubble cluster generated in water at the focal point of the Dornier HM-3 lithotripter with the original reflector, the upgraded reflector and the edge extender at the output voltage from 16 to 24 kV.

## Stone Comminution

BegoStone, which has both similar physical and acoustical properties as the calcium oxalate monohydrate (COM) calculus, is harder than plaster-of-P phantom. After 500 shocks the remaining fragments treated by the HM-3 lithotripter with and without using the edge blocker at 20 kV were compared. It is found that using the edge extender there are more larger size of fragments ( $> 4$  mm, Fig. 4) and, therefore, the stone comminution efficiency (the percentage of fragments  $< 2$  mm,  $25.8 \pm 3.9\%$ ) is less than that of the original HM-3 reflector ( $37.9 \pm 3.3\%$ ). However, when using the plaster-of-Paris stone phantom, there is no statistical difference ( $p < 0.05$ ) between the stone comminution efficiencies after 200 shocks produced by the original HM-3 lithotripter at 20 kV ( $50.4 \pm 2.0\%$ ) and by using the edge extender ( $46.8 \pm 4.1\%$ ).



**FIGURE 4.** The size distribution of BegoStone fragments after exposure of 500 shocks.

## Vessel Rupture

The impact of the edge extender on the vascular injury in SWL was investigated on a vessel phantom made of a regenerated cellulose hollow fiber (inner diameter = 200  $\mu\text{m}$ ). Using the original HM-3 reflector at 20 kV, the number of shocks required to cause a rupture of the vessel phantom at the lithotripter focus is  $32.3 \pm 8.7$ . In comparison, using the edge extender fitted at the aperture, no rupture could be produced in the tested vessel phantom after 300 shocks. This protective effect of the edge extender is similar to that by using the upgraded reflector via the *in-situ* pulse superposition technique [7], and is also believed to be consistent throughout a large volume around the lithotripter focus because of the significant decrease of bubble collapse time measured by PCD.



## DISCUSSION

To investigate the effect of diffraction wave in the acoustic field on SWL, a novel method was proposed to modify the generated diffraction wave at the reflector aperture in order to suppress the bubble cavitation at the focal region. This strategy is based on the theoretical simulation of acoustic wave propagation and evolution in the lithotripter field [9] and the observation of intraluminal bubble dynamics [3]. In this study, it is shown that such a strategy can significantly reduce the potential for vessel phantom rupture.

Stone fragmentation is the fundamental issue in SWL treatment. From previous physical studies it is found that the disintegration of renal calculi in a lithotripter field is the consequence of dynamic fracture of the stone material caused by stress waves and bubble cavitation, who they act synergistically, rather than independently, to ensure successful calculi fragmentation [10]. Stress wave-induced fracture is dominant in the initial disintegration of kidney stones, while cavitation is necessary to produce fine passable fragments, which are most critical for the success of clinical SWL. In order to obtain the successful comminution of renal calculi, it is necessary to restore the bubble cavitation in the latter stage. Eight segments of the edge extender could be rotated individually to adjust the suppression effect on bubble cavitation dynamically. Therefore, restoring bubble cavitation would achieve successful stone fragmentation without increasing the propensity of vascular injury because of the vasonconstriction effect.

Although the *in-situ* pulse superposition method works satisfactory both *in vitro* and *in vivo* [6-7] and is applicable for all types of lithotripters, the design depends on both the geometries of lithotripter and pressure waveform profile of SW [9]. Although the theoretical models have been improved in simulating the SW evolution, extensive experiments are still necessary for parameter optimization. In contrast, the working principle of the edge extender is rather simple so that the device design does not need critical requirements and can be easily fabricated and then fitted to all commercial lithotripters with a low cost. The implementation of the edge extender is also easy since there is no requirement of remodeling current lithotripter system.

The diffraction wave is produced at the aperture of the ellipsoidal reflector and gradually catches up with the focused shock front as the SW propagates towards the lithotripter focus. Around the focal point, the leading focused shock front is followed immediately by the convex edge waves propagating laterally and crossing each other on the lithotripter axis. The presented edge extender was used to modify the diffraction wave. However, it cannot completely remove the diffraction wave from the SW. At the outer rim of the edge extender diffraction wave will be generated as well but at a delayed time than that from the lithotripter aperture.

In summary, using the edge extender presented in this study the contribution of the diffraction wave to the tensile component of the SW at the focal region will be reduced and lead to a consistent suppression on bubble cavitation, which was confirmed by the measured bubble activities using PCD. Although the characteristics of the SWs are similar to those of the original HM-3 lithotripter (compressive wave, the peak negative pressures and focal width), the duration of the tensile wave was shortened significantly. Subsequently, propensity of vessel phantom injury was

improved more than 10-folds. Altogether, it has been shown that modifying the diffraction wave at the aperture can improve the safety of lithotripter.

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