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● *Original Contribution*

SHIFTING THE SPLIT REFLECTORS TO ENHANCE STONE FRAGMENTATION OF SHOCK WAVE LITHOTRIPSY

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Abstract—Shock wave lithotripsy (SWL) has been used widely in urology for about three decades to treat kidney calculi. Technical development to improve performance (*i.e.,* stone fragmentation efficiency) is continuous. Low-pressure wide-focus lithotripters have already achieved promising results. In this study, the lithotripter field and profile of lithotripter shock waves were changed simultaneously using a cost-effective and convenient design. An intact parabolic reflector was split into four pieces, and each part was moved individually. By shifting the split reflectors, the focused acoustic beams were separated. As a result, the beam width in the focal region could be increased. Both numerical models of wave propagation using a k-wave approach and hydrophone measurements showed similar pressure waveforms at the focus and the distributions along and transverse to the lithotripter axis. The increase of the shifting distance from 0 mm to 7 mm resulted in the increase of −6 dB beam width from 7.1 mm to 13.9 mm and location of tensile peak on axis moving from $z = -14$ mm to 1 mm. The Lithotripters at 10 kV (intact reflector) and at 12 kV with the split reflectors shifted by 5 mm were compared with each other because of their similar peak positive pressures at the focus (8.07 MPa ± 0.05 MPa vs. 7.90 MPa ± 0.11 MPa, respectively). However, there were significant differences in their positive beam width (8.7 mm vs. 10.2 mm), peak negative pressure (−6.34 MPa ± 0.04 MPa vs. −7.13 MPa ± 0.13 MPa), the maximum tensile stress (7.55 MPa vs. 8.95 MPa) and shear stress (6.1 MPa vs. 7.76 MPa) in a 10-mm diameter spherical stone and bubble collapse time (127.6 μs ± 5.4 μs vs. 212.7 μs ± 8.2 μs). As a result, stone fragmentation efficiency was enhanced about 1.8-fold (57.9% ± 4.6% vs. 32.2% ± 5.6%, $p < 0.05$) when shifting the split reflectors. These results suggest that this new reflector design could change the characteristics of the lithotripter field and increase stone fragmentation efficiency. (E-mail: yfzhou@ntu.edu.sg) © 2016 World Federation for Ultrasound in Medicine and Biology. All rights reserved.

Key Words: **Shock wave lithotripsy, Split reflector, Focus shifting, Beam width, Bubble collapse time, Stone fragmentation efficiency, Cavitation damage.**

INTRODUCTION

The prevalence of kidney stones in the United States was 8.8% (95% confidence interval, 8.1–9.5) from 2007–2010 (Scales et al. 2012). Among men, the prevalence of stones increased from 6.3% to 10.6%, while among women it increased from 4.1% to 7.1%. The likelihood of developing a second stone within 5 y of the first stone event is estimated as high as 50%. The total annual medical expenditures for urolithiasis in the United States were estimated at $2.1 billion in 2000 (Lotan and Pearle 2007). Changes in dietary practices may be a key factor (Adair and Popkin 2005). Global climate change is an environmental factor that affects stone disease rates (Brikowski et al. 2008). Since its introduction in the early 1980s, shock wave lithotripsy (SWL) has revolutionized the treatment of urolithiasis. The American Urologic Association and European Urologic Association guidelines committees for the management of renal and ureteral calculi consider SWL and endourological procedures as the first choice of treatment for most urinary stones (Neisius et al. 2015; Preminger et al. 2007).

Lithotripter devices have been developed into the third generation, with significant improvements to the multi-functionality, better imaging quality, and less need for anesthesia. The electromagnetic source of lithotripsy shock wave (LSW) generation has obtained more popularity and acceptance than electrohydraulic and piezoelectric ones because of high output pressure, stable outcome, long lifespan, and low consumable cost. Based on empirical experience that dramatic reduction in focal zone (by 50% or more) may significantly improve the

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effectiveness of stone fragmentation in SWL, the third generation lithotripters are characterized by high peak pressure and small −6 dB beam width for tight focusing LSWs with the increased aperture size and focusing angle of the shock wave source. However, the latest electromagnetic lithotripters have less stone fragmentation efficiency but a higher propensity for renal injuries and stone recurrence (Gerber et al. 2005; Lingeman et al. 2003). Thus, practicing urologists still regard the original HM-3 lithotripter (the first clinical model; Dornier MedTech America Inc., Kennesaw, GA, USA) as the gold standard of SWL (Kerbl et al. 2002; Lingeman 1997). The performance discrepancy may be due to the different −6 dB focal zones and peak pressures (Gerber et al. 2005; Lingeman et al. 2009). The HM-3 has wide −6 dB beam width of 10–12 mm with a low peak pressure of about 40 MPa, while the most modern electromagnetic lithotripters have a narrow −6 dB beam width of 4–7 mm with a high peak pressure of up to 100 MPa.

By applying the same axial pressure but with different Gaussian distributions, the simulation shows that the maximum principal stresses inside a 6.5-mm stone increase significantly with the −6 dB beam width. The increase of the −6 dB beam width from 4 mm to 11 mm leads to the enhancement of peak stresses (tensile, compression and shear stress) inside the stone by at least a factor of 2 (Cleveland and Sapozhnikov 2005). Because stress is one of the main mechanisms of stone fragmentation, the wide −6 dB beam width correlates with better stone fragmentation, especially at the beginning of SWL (Zhu et al. 2002). The fracture thresholds for kidney calculi (2–10 MPa) are much lower than the peak pressure produced by most lithotripters (Rassweiler et al. 2011). Therefore, in the past a few years there has been a renewed interest in lithotripters with wide-focus and low-pressure. Such an electromagnetic model (XX-ES; Xi Xin Medical Instruments Co. Ltd., Suzhou, China) with a peak positive pressure of 10–25 MPa and a −6 dB beam width of 18 mm has already achieved promising clinical results (Eisenmenger et al. 2002). A stone-free rate of 86% was found after a follow-up of 3 mo in a total of 297 patients after an average of 1532 shock pulses. Fewer LSWs were required to completely break stones in a swine model using XX-ES (average, 634) with a peak pressure of 17 MPa than using the HM-3 (average, 831) with a peak pressure of 37 MPa and −6 dB beam width of 8 mm (Evan et al. 2008). Modifying the acoustic lens of the Modularis lithotripter could produce a 47% broader focal zone and an idealized pressure waveform for significant reduction of the secondary compressive wave (Mancini et al. 2013). As a result, stone fragmentation is improved *in vivo* by 20% with minimal difference in tissue injury. The peak pressure of the HM-3 lithotripter at 20 kV increased from 33 MPa to 87 MPa, but with a −6 dB beam width decreased from 18 mm to 4 mm using a reflector insert, and the *in vitro* stone fragmentation in a 15-mm finger cot and a 30-mm membrane holder decreased from 56% to 45% and from 26% to 14%, respectively (Qin et al. 2010). Furthermore, a 10-cycle ultrasonic burst at a pulse repetition frequency (PRF) of 200 Hz and driving frequency of 170 kHz with a focal pressure of 6.5 MPa and a −6 dB beam width of 7.6 mm (burst wave lithotripsy) could fragmentize uric acid, cysteine human stones (8.2 ± 3.0 mm in size) and cylindrical Bego stones (powder to water ratio of 5:1, 6 mm in diameter and 10–12 mm in length) in 36 s, 14.7 min and 9.7 min (on average), respectively (Maxwell et al. 2015). For some artificial stones, the pressure threshold could be as low as 2.8 MPa. A shocked waveform is not required for stone comminution since such bursts produce the necessary tension in the stone to generate and propagate fractures.

In this study, a novel way to produce wide beam width by shifting the focus of lithotripter reflector was proposed and tested. A conventional parabolic reflector was split into four parts, and the geometric focus could be shifted by moving the split reflector individually. As a result, the beam width was increased. The evolution of LSW toward the focal region was simulated, and pressure waveforms along and transverse to the lithotripter axis were measured. The bubble collapse time at the focus associated with cavitation activities was determined by passive cavitation detection (PCD). Fragmentation efficiency of stone phantoms and the pitting or denting deformation on aluminum foil placed at the focus were also evaluated. It was found that by shifting the split reflector wide beam width, low pressure could be achieved, and the peak tensile pressure moved toward the focus. The stone fragmentation efficiency increased from 32.2% ± 5.6% to 57.9% ± 4.6%. Altogether, shifting the split reflectors could change the acoustic field of lithotripter and improve the stone fragmentation of SWL.

MATERIALS AND METHODS

Design of shifted reflector

An electromagnetic lithotripter (ANK Medical Equipment, Shenzhen, China) with a cylindrical core and a parabolic reflector was used in this study. The surface of the parabolic reflector can be described in a polar coordinate system with the origin at the reflector focus as eqn (1):

$$R = \frac{R_0 + \sqrt{R_0^2 + f^2}}{1 + \sin\theta} \tag{1}$$

where R is the distance between focus and surface of the reflector; R_0 = 91.1 mm, which is the radius of