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ORIGINAL PAPER

Improved acoustic coupling for shock wave lithotripsy

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Abstract Previous in vitro studies of acoustic coupling in shock wave lithotripsy (SWL) have shown that air pockets trapped at the surface of the treatment head significantly reduce transmission of shock wave (SW) energy to the focal zone of the lithotripter, reducing the effectiveness of stone breakage. Since there are no reliable means to monitor the quality of coupling during SWL, we looked for a practical protocol to improve how coupling is achieved. In vitro studies were performed using a Dornier DoLi-50 lithotripter. LithoClear™ gel was used to couple the treatment head to the acoustic window of a clear acrylic test tank. Numerous methods of applying gel were tested including common sense variations of routine protocols typically used with patients. For each method the coverage of air pockets (% defects) was determined using digital imaging. Different coupling regimes were tested for effect on the breakage of gypsum model stones. The quality of acoustic coupling was affected by how the gel was handled—how it was dispensed and applied, and whether the gel was applied only to the treatment head or to both the lithotripter water cushion and the test tank (surrogate patient). Dispensing gel from a squeeze bottle for application by hand created significantly more defects than when a large volume (~250 ml) of gel from the stock jug was applied as a mound to just the treatment head (26.5 ± 2.7 vs. $1.2 \pm 0.5\%$ defects, $P < 0.001$). The efficiency of stone breakage was better when gel was applied from the stock jug compared to application by hand ($P < 0.006$). Poor coupling was substantially improved by using the inflation feature of the water cushion to collapse air pockets, but this strategy was not a substitute for establishing good coupling at the outset. The quality of coupling in shock wave lithotripsy can be improved by minimizing the handling of the coupling medium. Hand application of coupling gel is clearly not the best way to prepare for lithotripsy. Better results can be obtained by delivering lithotripsy gel as a bolus to the treatment head alone, and allowing it to spread upon contact between the treatment head and the skin. These in vitro tests also suggest that the inflation feature of the lithotripter may be useful in reducing defects in coupling.

Keywords Lithotripsy · Shock waves · Acoustic coupling · Kidney stones

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Introduction

Success rates with modern lithotripters are often reported to be below outcomes achieved with the Dornier HM3 [1–4]. Chan et al conducted a prospective study in which the 3-month stone-free rate for lower calyceal stones was found to be 80% with the HM3 compared to 56% with the Dornier MFL 5000 [1]. Graber et al. also using a prospective design, compared the HM3 with the Siemens Lithostar Plus. They found that at postoperative day 1, 91% of patients treated with the HM3 compared to 65% of patients treated with the Lithostar Plus were either stone free or retained fragments all less than 2 mm [2]. A follow-up study in which performance of the Storz SLX was compared to the same data sets, showed the SLX to be even less effective (48% stone-free or fragments <2 mm at 24 h) [4].

Since lithotripters differ in acoustic output, including the shock wave (SW) amplitudes they produce and the dimensions of the focal zone each machine generates, it is difficult to know what physical factors could be responsible for this apparent disparity in performance [5]. One possibility is that acoustic coupling is involved. Coupling in the water-tub-style HM3 is ideal for efficient transmission of SW-energy. With dry-head lithotripters on the other hand, the treatment head must be coupled to the patient using a medium such as gel or oil, and if air pockets get caught at this interface the transmission of SW energy is reduced [6–8].

In previous in vitro studies we observed that coupling between the treatment head of the lithotripter and the acoustic window of a test tank was highly variable [6]. In those experiments lithotripsy gel was applied to the treatment head and acoustic window (surrogate skin surface) by hand as is typically done in preparing a patient for treatment. The percent coverage of the interface by air pockets ranged from 1.5 to 19%, and increased defects in coupling resulted in a dramatic reduction in stone breakage. Indeed, defects of only 2% coverage by air pockets reduced stone breakage by 20–40%, and if coupling was established and then broken and re-established—modeling what occurs when a patient is repositioned during lithotripsy—this manipulation introduced defects of nearly 20% coverage and reduced stone breakage by more than 80%. Similar findings have recently been reported by others [9]. Together, these studies suggest that coupling in dry-head lithotripsy is problematic, and that inefficient and variable coupling can diminish the effectiveness of SW treatment.

The implications for poor acoustic coupling include ineffective stone breakage, reduced stone clearance, and the possibility of exposing the patient to more SW's than are needed. Clearly, a practical solution to this problem would be beneficial. The objective of the current study was to determine how the handling and application of lithotripsy gel affects the quality of coupling in a controlled in vitro setting. The findings suggest several methods to achieve improved acoustic coupling—simple steps that may help to improve the effectiveness of SWL.

Materials and methods

Studies were performed with an established in vitro test system for assessment of the quality of acoustic coupling in SWL [6]. In this system the treatment head of the lithotripter was brought into contact with the Mylar window (surrogate skin surface) of a clear acrylic test tank, and defects (air pockets) at the coupling interface were photographed under controlled lighting from a set vantage point at the back of the tank. The digital images were thresholded using Adobe™ Photoshop™ to highlight air pockets, and the surface area of the defects was determined using ImageJ (http://rsb.info.nih.gov/ij/).

Experiments were conducted using a Dornier DoLi-50 electromagnetic lithotripter. LithoClear™ gel (Sonotech Inc., Bellingham, WA, USA), bubble-free within 5 l wide-mouth pliable plastic jugs, was used as the coupling medium. For tests to determine how the handling of gel affected the quality of coupling, or to assess the effect of coupling on stone breakage, water pressure in the cushion of the treatment head was held at setting 1. Water in the test tank was at ambient temperature (20–22°C), while water in the cushion of the treatment head was about 37°C. The breakage of gypsum model stones was used to measure the effect of selected coupling regimens on lithotripter function [10]. For these tests model stones were placed in a 2 mm mesh basket with the position of the stone centered at the focal point of the lithotripter marked by crossed laser beams. Tap water in the tank was continuously degassed to about 20% saturation [11]. A dose of 500 SW was delivered at power level 6, 120 SW/min, and the effectiveness of stone breakage was determined by weighing the fragments retained by the mesh.

Numerous methods for handling the coupling gel were attempted using a systematic survey of three factors, including the source of the gel (stock jug vs. squeeze bottle), the surfaces to which the gel was applied (treatment head, acoustic window, or both the treatment head and window), and the method for application of gel to the surface(s) (Table 1). Four techniques for applying gel to the treatment head or test tank were tried and included smearing a liberal quantity (~100 ml) of the gel by hand, depositing the gel as a mound (~250 ml) from the squeeze bottle or directly from the stock container (5 l, wide mouth jug), covering the surface(s) by delivering gel from the source container (jug or squeeze bottle) moved in a uniform zigzag pattern, and delivering the gel in this way followed by smoothing out the furrows by hand. Handling of the squeeze bottle was standardized, in that it was filled prior to each series, was refilled when it was half-empty, and was stored upright between tests. For each coupling method, gel was applied to the shock head while in the disengaged vertical position (Fig. 2). In this position, the water cushion sits partially deflated and forms a slight concavity. After gel was applied, the shock head was raised to the treatment position (approximately 45°) at which point it automatically inflated to the pre-selected level (setting 1). It was during this inflation process that the water cushion came into contact with the acoustic window of the test tank. In all, 20 different methods were attempted, and each was repeated at least six times.

Coupling and stone breakage data are presented as the mean ± SD. Percent area of coupling defects for given

Table 1 Effect of application method on percentage of air pockets at lithotripter coupling interface

	Stock container			Squeeze bottle		
	Cushion only	Test tank only	Both surfaces	Cushion only	Test tank only	Both surfaces
Hand	11.1 ± 5.6	18.0 ± 7.4**	15.8 ± 4.3*	24.5 ± 9.5**	20.9 ± 7.2**	26.5 ± 2.7**
Mound	**1.2 ± 0.5**			6.7 ± 3.4		
Zigzag	10.8 ± 5.4	14.3 ± 3.3*	11.0 ± 2.3	23.8 ± 6.5**	25.0 ± 7.0**	23.4 ± 10.7**
Smoothed	8.8 ± 3.6	20.6 ± 8.7**	12.1 ± 6.3	19.3 ± 8.0**	23.4 ± 6.2**	24.3 ± 8.8**

Different from mound from stock container (bold), $^{**}P < 0.001$, $^{*}P < 0.01$ (Dunnet's method)

coupling regimens, and loss of stone mass during treatment with SW's were analyzed using ANOVA, with $P < 0.05$ considered statistically significant. For ad hoc tests, either Tukey–Kramer HSD or Dunnet's test was used.

Results

The quality of coupling was affected by how the gel was dispensed, how it was distributed and whether the gel was applied to just the treatment head, to just the test tank or to both surfaces. Table 1 shows values for percentage of the coupling interface occupied by air pockets with the various methods. In all cases, dispensing the gel from a squeeze bottle produced more air pockets than did taking gel from the stock container.

Two methods for applying the gel stood out. Application of gel by hand gave particularly poor coupling, while delivering gel as a mound at the center of the shock head, and then letting the force of contact between the water cushion and the test tank smooth out the gel, gave the best result. Applying gel by hand is probably the most common method used to prepare for lithotripsy. In a typical procedure the technician dispenses gel from a squeeze bottle then rubs it on the skin and onto the water cushion of the treatment head. Regardless of whether the gel was dispensed from a squeeze bottle or was taken directly from the stock container, applying gel by hand created more air pockets than when the gel was deposited as a mound and then smoothed out by contact between the head and test tank. This latter method was clearly the most effective, and the best coupling was attained when the gel was dispensed from the stock container. By this method, air pockets covered slightly more than 1% of the interface (1.2%), tenfold less than that created by hand application (11.1%), and more than 20-fold less than when the hand-applied gel came from a squeeze bottle (24.5%).

Representative images of the coupling interface highlighted to show air pockets are illustrated in Fig. 1. In this example, application of gel by hand to both the treatment head and "surrogate skin" created air pockets occupying nearly five times more area than the mound method (18.8 and 2.8%, respectively). Although the mound method used a large volume of gel (Fig. 2) it was clearly better than hand application.

We found that quality of acoustic coupling could be improved by increasing the inflation pressure of the water cushion to collapse air pockets or push them out of the field (Fig. 3). In these tests, two methods for handling the gel were used, including the method that gave the fewest air pockets (a mound of gel delivered from the stock jug) and the technique that induced the most air pockets (gel from a squeeze bottle smeared by hand to both the treatment head and surrogate skin). The cushion, pre-set to water pressure setting 3, was brought into contact with the Mylar membrane and the interface was photographed. Inflation pressure was then raised stepwise to level 8 and back down to level 3, and the interface was photographed again. When gel from a squeeze bottle was rubbed by hand over both surfaces the mean value for air pockets in the initial coupling was 17.8 ± 3.1% ($n = 7$, range 13.0–21.8%). Raising cushion pressure to level 8 and back to level 3 reduced air pockets to a mean of 4.0 ± 1.4% (range 2.6–6.2%, $P < 0.001$ versus before inflation of water cushion). Proportionally similar improvement was seen when gel was applied from the stock jug, though initial coverage by air pockets was only 0.5 ± 0.4% with this method. For both methods, air pockets were reduced by two-thirds or more—78 ± 6% reduction for hand-smeared, and 64 ± 18% for stock jug application, when followed by pressurization of the water cushion. Thus, this relatively simple manipulation was able to improve the acoustic interface for the case of very poor coupling, but it did not eliminate air pockets altogether.

The breakage of model stones was affected by the quality of coupling, and these tests showed that how the gel was dispensed made a difference. When the mound method for coupling was used, dispensing gel directly from the stock jug gave coupling that yielded better breakage than when the gel was dispensed from a squeeze bottle (88.0 ± 4.51 vs. 58.3 ± 15% breakage, $P < 0.0005$). Similarly, the mound method from the stock jug resulted in better stone breakage than when gel was applied by hand (67.7 ± 17.7%, $P < 0.006$). In a previous study we observed that when gel was applied by hand, the percent coverage by air

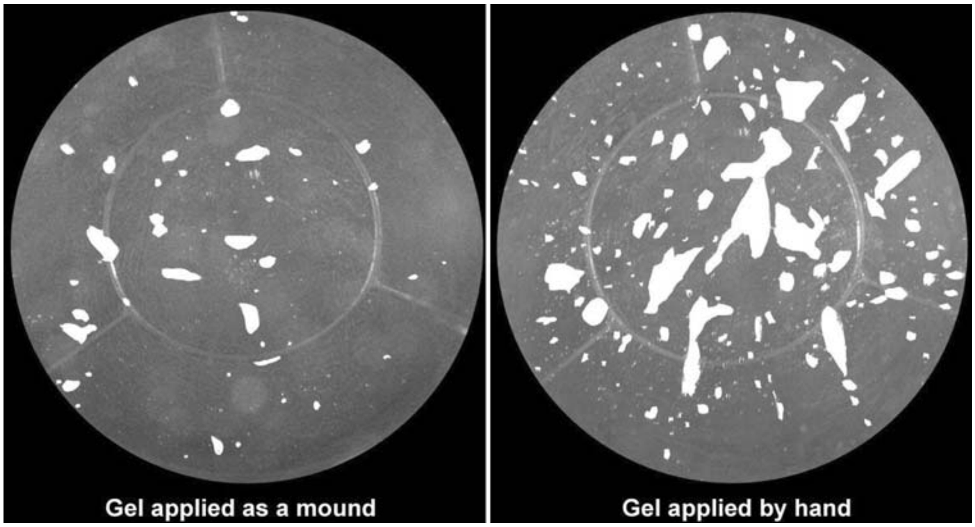

Fig. 1 Good versus poor coupling. The coupling interface was photographed from the back of the test tank, and the images were processed to highlight air pockets for determination of surface area. Image at left (good coupling) is of coupling achieved using the "mound" method, and the image at the right (poor coupling) shows coupling when gel was applied by hand to both the treatment head and the test tank. In these examples, coverage by air pockets was 2.8% for the "mound" method (*left*) and 18.8% by hand application (*right*). For reference, the diameter of the wire ring seen deep to the coupling interface is 70 mm

pockets varied more than tenfold (1.5–19.1%) and breakage efficiency ranged from about 80% to less than 10% [6]. To simulate the way variability in coupling may influence stone breakage, an additional experiment was done in which five consecutive couplings were carried out using hand application to the treatment head and test tank, mimicking what is typically done in the clinical setting. With each coupling, five stones were treated, each with 500 SW's (PL-6, 120 SW/min). The results are shown in Fig. 4. The consecutive couplings gave significantly different stone breakage results ($P < 0.0001$ by ANOVA). Moreover, the proportion of air pocket defects within each coupling (shown as percentages in Fig. 4) correlated with the stone breakage ($P < 0.0007$ for linear regression, not shown). Thus, consecutive couplings, even using the same coupling protocol, can vary in air pocket inclusion in the coupling interface, thereby leading to significant variation in the effectiveness of the SW treatment. It is probably also true that the position of the air pockets within the shock path has an effect; note that couplings 'A' and 'B' of Fig. 4 had significantly different stone breakage, even though the percent coverage by air pockets was similar, suggesting that the location of air pocket defects in coupling 'B' were such that stone breakage was better.

In experiments such as this test of variability in coupling, it was observed that the pattern of air pockets prior to SW delivery sometimes did not match the pattern of defects at the completion of SW administration. A test was performed to determine if this apparent change in coupling was repeatable, and if so, to measure the degree of change that occurred. Coupling was established using the mound and hand application methods with the shock head at water pressure setting 1. The interface was imaged, 1500 SW's were fired (PL-6, 120 SW/min) and the interface was imaged again. Except when gel was dispensed from the stock jug as a mound, coupling improved substantially over the course of firing 1500 SW's. For example, mean percent coverage by air pockets when gel from a squeeze bottle was used for the mound method improved from 10.1 to 6.7% (34% improvement), while application of gel by hand to the shock head or both surfaces showed similar improvement (23 and 34%, respectively). Thus, when initial coupling was poor the quality of coupling actually improved during SW delivery, presumably by SW's causing air pockets to collapse or by forcing them to the perimeter of the field.

Discussion

The findings of this in vitro study suggest that the technique used to apply lithotripsy gel to the treatment head and patient can have a significant effect on the quality of coupling. The data show that excessive handling of the gel leads to poor coupling. Application of gel by hand, which is likely the most common method followed in clinical practice, creates air pockets at the coupling interface. Likewise, dispensing gel from a squeeze bottle—also a common practice—gives a poor result. Further, the application of gel to both the treatment head and the surrogate skin produced more air pockets than when gel was applied to just one surface. The most effective method was to dispense the gel directly from the 5-l stock jug as a mound at the center of

Fig. 2 Method used to dispense lithotripsy gel for best coupling. Gel was delivered directly from the stock jug as a mound (~250 ml) to the center of the water cushion (in vertical standby position). The treatment head was moved to ready position. As the cushion automatically inflated, gel was smoothed against the "surrogate skin" and very few air pockets were caught at the interface

the treatment cushion. When the treatment head was engaged with the test tank (the "patient") the gel spread out from the point of contact, and few air pockets were caught in the process. This method used more than twice as much gel (~250 ml) as when gel was rubbed or smeared by hand, but the result was significantly better than all other methods that were attempted.

We also found that the quality of coupling could be improved by using the inflation feature of the treatment head. This result is encouraging, but using the water cushion to collapse air pockets or force them to the periphery of the coupling area did not eliminate defects altogether. Clearly it is best to achieve good coupling at the outset of treatment. Although this technique substantially improved coupling with our in vitro system, it is hard to know whether this would have a similar effect with a patient. The Mylar window of the test tank had limited resilience and may have offered more resistance to pressure, permitting a more uniform displacement of excess gel than would have occurred against the skin of a patient.

Coupling was best when we used a large volume of bubble-free gel taken directly from the stock container. Such a procedure seems relatively simple, but may have its drawbacks. For example, we observed that as the jug became depleted bubbles could be introduced into the gel. Also, at centers where there is heightened concern for cross contamination between surfaces that have come into contact with a patient, it may not be acceptable to repeatedly draw gel from a large volume stock container in this way. As such, it would be helpful if lithotripsy gel were available in volumes for single use, packaged to permit application without inadvertent creation of air pockets.

In previous in vitro studies we have found that the quality of coupling suffers significantly if the interface is broken and then re-established [6]. Indeed, pristine coupling in which less than 1% of the coupling area is occupied by air pockets can degrade to defects of 20% or more with decoupling and re-coupling. This suggests that good coupling is easily disrupted. In the treatment of patients, whereas it is possible to start with very good acoustic coupling, this may be difficult to maintain as patient movement or adjustments to keep the lithotripter on target are both likely to introduce air pockets into the coupling interface. Unfortunately, one has no way of judging the quality of coupling during lithotripsy. The coupling interface is simply not visible. This is true of all dry head lithotripters, even those in which the shock head is integrated into the treatment table (e.g. Storz, Medstone). It would be a very positive step to have a way to assess the quality of coupling during treatment. Some lithotripters are equipped with in-line diagnostic ultrasound. It seems feasible that imaging of this sort could be used to check for defects in coupling, both at the start of treatment and periodically throughout the case.

Conclusions

Acoustic coupling is a key factor affecting the efficacy of shock wave lithotripsy. When air pockets get caught at the interface between the treatment head and the patient the transmission of SW energy to the target is decreased and the efficiency of stone breakage is reduced. Lithotripsy gels give effective coupling when handled and applied properly. Our in vitro tests show that excessive handling of gel leads to poor coupling. Methods commonly used to dispense and

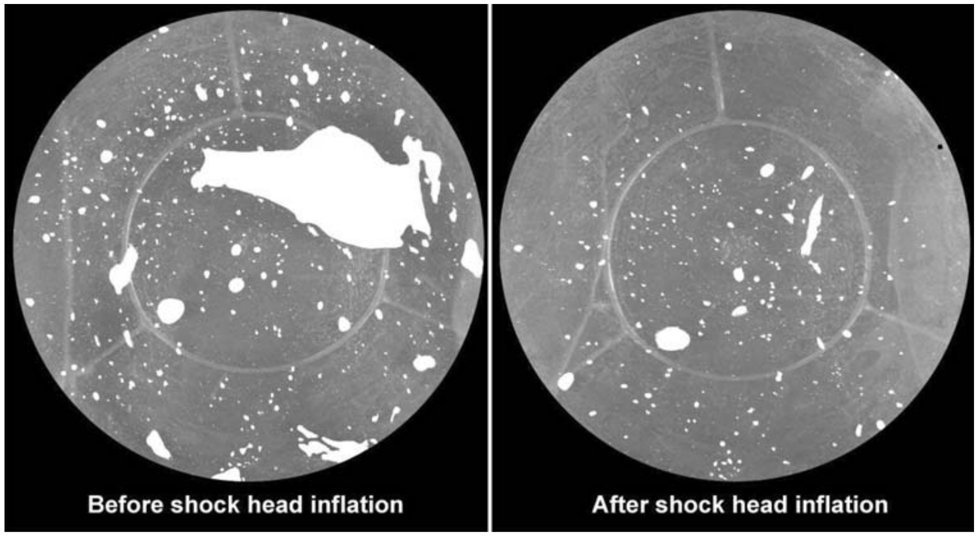

Fig. 3 Use of inflation feature of lithotripter shock head to improve quality of coupling. Image at left is coupling typical of when gel from a squeeze bottle was applied by hand to both the shock head and the acoustic window of the test tank. Image at right, the water cushion was inflated to setting 8, and then returned to setting 3. This manipulation reduced air pockets at the coupling interface from 17.8% (*left*) to 4.1% (*right*). Overall, this method was very effective and in no instance did use of the inflation feature result in degradation of the quality of coupling

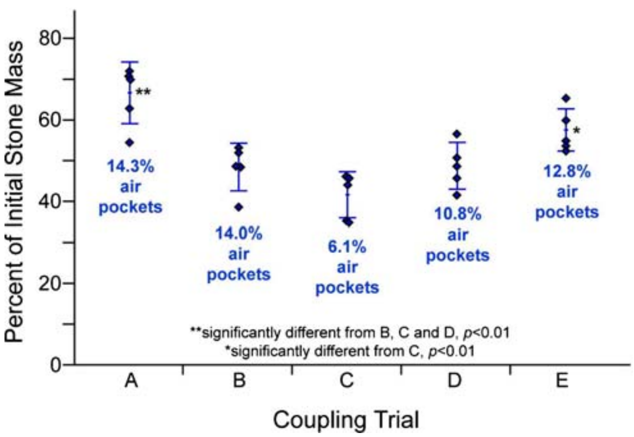

Fig. 4 Simulation of effect of variability in coupling of treatment head to surrogate 'patient' in shock wave lithotripsy. Each trial (A–E) indicates a different coupling, each produced by hand application of gel to both treatment head and test tank. Each diamond represents one artificial stone, each of which received 500 SW's. Lower numbers indicate superior stone breakage. *Bars* show standard errors above and below means. Significant difference for groups was calculated using Tukey–Kramer HSD test. Overall analysis of variance, $P < 0.0001$

distribute gel, such as delivering the gel from a squeeze bottle and smearing the gel by hand, give poor results. It is better to deliver a large volume of gel to the treatment head alone and use the inflation feature of the head to smooth out the gel at the coupling interface.

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