0022-5347/00/1644-1259/0
THE JOURNAL OF UROLOGY®

Vol. 164, 1259–1264, October 2000
Printed in U.S.A.

IN VITRO COMPARISON OF SHOCK WAVE LITHOTRIPSY MACHINES

JOEL M. H. TEICHMAN,* ANDREW J. PORTIS, PATRICIA P. CECCONI, WILLIAM L. BUB, ROBERT C. ENDICOTT, BELA DENES, MARGARET S. PEARLE† AND RALPH V. CLAYMAN‡

From the Division of Urology, University of Texas Health Science Center, San Antonio and Department of Urology, University of Texas Southwestern Medical Center, Dallas, Texas, and Division of Urology and Department of Radiology, Washington University School of Medicine and DePaul Health Center, St. Louis, Missouri

ABSTRACT

Purpose: We tested the hypothesis that shock wave lithotripsy machines vary in the ability to fragment stones to small size.

Materials and Methods: Calcium oxalate monohydrate, calcium hydrogen phosphate dihydrate, cystine and magnesium ammonium phosphate hexahydrate calculi were fragmented in vitro with the 22 kV. Dornier HM3,§ 20 kV. Storz Modulith SLX,‖, 15.6 kV. Siemens Lithostar C,¶ 24 kV. Medstone STS-T,** 26 kV. HealthTronics LithoTron 160,†† 20 kV. Dornier Doli§ and 22.5 kV. Medispec Econolith‡‡ lithotriptors. Stones were given 500 or 2,000 shocks, or the Food and Drug Administration limit. Post-lithotripsy fragment size was characterized using sequential sieves and compared.

Results: Stone mass was statistically similar in the cohorts ($p > 0.94$). Fragment size decreased as the number of shocks increased when the machine and stone composition were constant. Magnesium ammonium phosphate hexahydrate calculi were completely fragmented by all devices. At Food and Drug Administration treatment limits the mean incidence per device of calcium hydrogen phosphate dihydrate, calcium oxalate monohydrate, cystine and magnesium ammonium phosphate hexahydrate stones rendered into fragments greater than 2 mm. was 0% for the HM3, Modulith SLX and Lithostar C, 10% for the STS-T, 3% for the LithoTron 160, 29% for the Doli and 18% for the Econolith ($p = 0.04$); 0% for the HM3, Modulith SLX, Lithostar C, STS-T and LithoTron 160, 4% for the Doli and 9% for the Econolith ($p = 0.15$); 1% for the HM3, 0% for the Modulith SLX, 1% for the Lithostar C, 10% for the STS-T, 14% for the LithoTron 160, 3% for the Doli and 9% for the Econolith ($p = 0.44$); and 1% for the HM3, 0% for the Modulith SLX, 1% for the Lithostar C, 10% for the STS-T, 14% for the LithoTron 160, 3% for the Doli and 9% for the Econolith ($p = 0.44$), respectively.

Conclusions: Shock wave lithotriptors vary in fragmentation ability. The HM3, Modulith SLX and Lithostar C machines yield smaller fragments than other machines.

KEY WORDS: urinary calculi, urinary tract, lithotripsy, outcome assessment (health care)

Shock wave lithotripsy has revolutionized the treatment of urinary calculi.[1] Despite the worldwide success and acceptance of this modality new studies have directly compared the results of various machines[2–8] and few objective independent comparisons of shock wave lithotripsy parameters have been done.[9] We compared 7 shock wave lithotripsy machines currently in use in a controlled in vitro setting using human urinary calculi to test the hypothesis that fragmentation varies among shock wave lithotripsy machines.

METHODS

Human urinary calculi were obtained from a stone composition laboratory. Stones were included for study only when they were 97% or greater pure for calcium hydrogen phosphate dihydrate, calcium oxalate monohydrate, cystine and 92% or greater pure for magnesium ammonium phosphate hexahydrate. The dry mass of each calculus was determined and all were 1 to 3 cm. Stones of each composition were randomly distributed among the various lithotriptors, so that there were 5 with each composition per shock group per machine.

In vitro shock wave lithotripsy was performed using the 22 kV. Dornier HM3, 20 kV. Dornier Doli, 20 kV. Storz Modulith SLX, 15.6 kV. Siemens Lithostar, 24 kV. Medstone ST-S and 26 kV. HealthTronics LithoTron 160 lithotriptors (table 1). Each calculus was placed in sterile degassed water within a finger cot for a minimum of 48 hours. The same brand of finger cot was used throughout the study. Finger cots were not lubricated and did not contain talc. For the Dornier HM3 the calculus in its finger cot was suspended in the tank filled with degassed water. For the other lithotriptors the manufacturers supplied containers with flat polypropylene windows through which the shock heads transmitted energy.[10] Mineral oil was placed between the interface of the shock wave lithotripsy table and container bottom. The water filled finger cots were stabilized with a plastic cylinder and positioned at the focal point F2. The containers were filled with degassed water, so that in all machines tested stones were dependent in water filled finger cots and finger cots were surrounded by degassed water. Stones were targeted and focused using the imaging system of each lithotriptor. Imag-

Accepted for publication May 26, 2000.
Supported by grants from Dornier, HealthTronics, Storz, Medispec and Medstone.
* Financial interest and/or other relationship with Alza Pharmaceuticals.
† Financial interest and/or other relationship with Microvasive and U. S. Surgical.
‡ Financial interest and/or other relationship with Applied Medical, Cook Urological, Greenwald, Microvasive, Orthopedic Systems, Inc. and Storz Endoscopy.
§ Dornier Medical Systems, Inc., Marietta, Georgia.
‖ Storz Medical, Kreuzlingen, Switzerland.
¶ Siemens Medical Systems, Inc., Iselin, New Jersey.
** Medstone International, Inc., Aliso Viejo, California.
†† HealthTronics, Inc., Atlanta, Georgia.
‡‡ Medispec, Montgomery Village, Maryland.

TABLE 1. *Shock wave lithotripsy machines and parameters**

Model	Energy Source	No. Shocks FDA Limit	Rate (No. shocks/min.)	Power (kV.)	F2 Peak Power* (bar)	Focal Zone Width × Length* (mm.)
Dornier HM3	Electrohydraulic	2,400	90	22	311	15 × 90
Storz Modulith SLX	Electromagnetic	2,000	100	20	1,056	6 × 28
Siemens Lithostar C	Electromagnetic	4,000	100	15.6 (level 4)	487	5 × 68
Medstone STS-T	Electrohydraulic	2,400	90	24	350	15 × 35
HealthTronics LithoTron 160	Electrohydraulic	3,000	120	26	530	8 × 31
Dornier Doli	Electromagnetic	2,000	100	20	715	3 × 58
Medispec Econolith	Electrohydraulic	2,000	80	22.5	850	13 × 58

* Data were provided by manufacturer and not independently confirmed.

ing was done every 500 shocks. For the electrohydraulic machines a new spark plug was used for each calculus. Table 1 lists the parameters of kV., shock rate and Food and Drug Administration (FDA) shock limits. Each machine was used to deliver 500 or 2,000 shocks or the FDA shock limit. Company representatives of the LithoTron 160, STS-T, Modulith SLX, Econolith and Doli machines were present to assist in optimal use of their machines.

After lithotripsy was complete the finger cot was opened over a funnel, and fragments and fluid were collected. Gentle water irrigation and scraping with a spatula were done to ensure that all visible fragments were collected into a test tube. The test tube was then centrifuged at 2,500 rpm for 15 minutes and the supernatant was discarded. Fragments were placed overnight in a −80C freezer. Specimens were removed from the freezer and desiccated by vacuum lyophilization to sublimate water off of the calculi.

Fragments were passed through sequential geological brass sieves with 4, 2, 1.4, 1, 0.71, 0.425, 0.25, 0.125 and 0.063 mm. openings, respectively. The mass of fragments per size was measured and the mass of stone fragments recovered was divided by the original stone mass to determine the recovery rate. Values were compared for each lithotriptor and stone composition. Fragment size was then compared. For the mean percent of stone mass in each category of greater than 4, 2 to 4, 1.4 to 2, 1 to 1.4, 0.71 to 1, 0.425 to 0.71, 0.25 to 0.425, 0.125 to 0.25, 0.063 to 0.125 and less than 0.063 mm. a value of 4, 3, 1.7, 1.2, 0.855, 0.563, 0.337, 0.19, 0.09 and 0.063 mm. was assigned, respectively. A worksheet was constructed assuming 100 fragments per stone in proportion to the percent mass of stones per group with an aforementioned value assigned per stone. For example, if 37% of the mass of fragments of a stone were between 2 and 4 mm., we considered that 37 of 100 fragments were 3 mm. In addition, we converted the mass of fragments greater than 2 mm. to a percent mass of the total recovered mass and compared the rate of fragments greater than 2 mm.

We performed statistical comparisons for initial stone mass, stone recovery rate, fragment size and the mass of fragments greater than 2 mm. for the various lithotriptors according to the same stone composition and number of shocks, and for the various numbers of shocks per lithotriptor and stone composition. Since the Doli, Modulith SLX and Econolith devices had an FDA limit of 2,000 shocks, the 2,000 shock cohorts were used for comparisons among machines at 2,000 shocks and for the FDA treatment limit. Group comparisons were done with analysis of variance. When analysis of variance was statistically significant, pairwise comparisons were made with Fisher's protected least significant difference. We performed simple regression analysis to correlate peak power at the F2 focal point versus mean fragment size at 500 shocks and focal zone volume versus mean fragment size at 500 shocks with statistical significance considered at $p < 0.05$ or $r^2 > 90\%$. All post-lithotripsy procedures, including stone processing, lyophilization, sorting and statistical analysis, were done by investigators blinded to cohort identity. The rank order of lithotriptors for fragmentation was done before the investigators were unblinded.

RESULTS

Pre-lithotripsy stone masses were not statistically different (table 2). The stone mass recovery rate was 91% to 100% in all cohorts. For each comparison of number of shocks per stone composition and machine, or of machines per stone composition or number of shocks the differences in the mass recovery rates were not statistically different ($p = 0.94$ to 1.00, median $p = 1.00$). Mean fragment size and the mass of fragments greater than 2 mm. decreased as shock number increased and were generally smallest for the HM3, Modulith SLX and Lithostar C lithotriptors (tables 3 and 4). The Modulith SLX generally produced small fragments at an earlier shock count than the other shock wave lithotripsy machines, while the Doli and Econolith models generally produced the

TABLE 2. *Pre-lithotripsy stone mass*

Composition	No. Shocks	Mean Mg. Stone Mass ± SD						
		HM3	Modulith SLX	Lithostar C	STS-T	LithoTron 160	Doli	Econolith
Calcium hydrogen phosphate dihydrate	500	472 ± 211	451 ± 209	483 ± 193	456 ± 239	468 ± 342	468 ± 228	495 ± 208
	2,000	462 ± 289	488 ± 283	455 ± 176	486 ± 277	440 ± 231	481 ± 228	503 ± 280
	FDA limit	487 ± 234	488 ± 283	492 ± 187	490 ± 189	502 ± 230	481 ± 228	503 ± 280
p Value		0.99	0.97	0.95	0.97	0.94	0.97	1.00
Calcium oxalate monohydrate	500	404 ± 131	404 ± 120	402 ± 201	402 ± 120	399 ± 82	405 ± 266	420 ± 186
	2,000	402 ± 130	408 ± 180	408 ± 180	395 ± 117	393 ± 106	401 ± 139	423 ± 188
	FDA limit	399 ± 121	408 ± 180	407 ± 255	404 ± 130	411 ± 131	401 ± 139	423 ± 188
p Value		1.00	1.00	1.00	0.99	0.97	1.00	1.00
Cystine	500	412 ± 265	411 ± 264	404 ± 127	422 ± 216	408 ± 196	411 ± 329	421 ± 176
	2,000	408 ± 216	402 ± 173	413 ± 249	412 ± 214	405 ± 220	408 ± 160	402 ± 231
	FDA limit	421 ± 259	402 ± 173	417 ± 312	419 ± 260	409 ± 222	411 ± 180	411 ± 151
p Value		1.00	1.00	1.00	1.00	1.00	1.00	0.99
Magnesium ammonium phosphate hexahydrate ($p = 1.00$)	500	1,002 ± 295	1,027 ± 521	1,013 ± 438	1,017 ± 400	1,028 ± 500	1,011 ± 414	1,007 ± 469
	2,000	1,018 ± 562	1,001 ± 499	1,021 ± 364	1,034 ± 277	1,013 ± 440	1,021 ± 384	1,012 ± 522
	FDA limit	1,010 ± 442	1,001 ± 499	1,021 ± 381	1,010 ± 253	1,034 ± 195	1,001 ± 326	1,003 ± 572

For all lithotriptor comparisons $p = 1.00$.

TABLE 3. *Fragment size*

Composition	No. Shocks	Mean Mm. Fragment Size ± SD						
		HM3	Modulith SLX	Lithostar C	STS-T	LithoTron 160	Doli	Econolith
Calcium hydrogen phosphate dihydrate (p <0.001)	500	1.9 ± 1.4	1.0 ± 0.6	1.5 ± 0.9	2.0 ± 1.2	2.0 ± 1.3	2.3 ± 1.1	2.4 ± 1.2
	2,000	0.5 ± 0.4	0.5 ± 0.3	0.9 ± 0.5	1.0 ± 0.8	1.2 ± 0.8	1.6 ± 1.0	1.6 ± 1.2
	FDA limit	0.5 ± 0.4	0.5 ± 0.3	0.8 ± 0.5	1.1 ± 0.8	0.9 ± 0.6	1.6 ± 1.0	1.6 ± 1.2
Calcium oxalate monohydrate	500	0.6 ± 0.4	0.8 ± 0.4	1.1 ± 0.5	1.1 ± 0.7	1.3 ± 0.8	2.2 ± 1.0	1.2 ± 0.8
	2,000	0.5 ± 0.3	0.6 ± 0.4	0.7 ± 0.4	0.7 ± 0.4	0.8 ± 0.4	1.1 ± 0.6	1.2 ± 0.7
	FDA limit	0.5 ± 0.3	0.6 ± 0.4	0.6 ± 0.3	0.6 ± 0.3	0.9 ± 0.5	1.1 ± 0.6	1.2 ± 0.7
p Value		0.02	0.01	<0.0001	<0.0001	<0.0001	<0.0001	0.78
Cystine	500	0.7 ± 0.5	0.5 ± 0.3	1.2 ± 0.8	3.0 ± 1.4	2.9 ± 1.4	1.6 ± 1.2	1.5 ± 1.0
	2,000	0.4 ± 0.3	0.6 ± 0.3	0.7 ± 0.4	0.6 ± 0.5	1.4 ± 1.4	0.8 ± 0.6	1.0 ± 0.8
	FDA limit	0.4 ± 0.4	0.6 ± 0.3	0.8 ± 0.5	0.9 ± 0.9	1.1 ± 1.1	0.8 ± 0.6	1.0 ± 0.8
p Value		<0.0001	0.71	<0.0001	<0.0001	<0.0001	<0.0001	
Magnesium ammonium phosphate hexahydrate	500	0.6 ± 0.5	0.6 ± 0.4	0.9 ± 0.6	0.8 ± 0.6	2.0 ± 1.6	0.9 ± 0.6	1.1 ± 0.8
	2,000	0.5 ± 0.6	0.4 ± 0.2	0.7 ± 0.5	0.5 ± 0.3	0.9 ± 0.9	0.5 ± 0.3	0.6 ± 0.3
	FDA limit	0.3 ± 0.3	0.4 ± 0.2	0.5 ± 0.4	0.5 ± 0.3	0.6 ± 0.5	0.5 ± 0.3	0.6 ± 0.3
p Value		<0.0001	0.01	0.005	0.01	<0.0001	<0.0001	<0.0001

For all lithotriptor comparisons p <0.001.

Pairwise differences were statistically significant for calcium hydrogen phosphate dihydrate 500 shocks for Modulith SLX and Lithostar C versus all other machines, and for HM3, LithoTron 160 and STS-T versus Doli and Econolith; calcium hydrogen phosphate dihydrate 2,000 shocks for HM3 and Modulith SLX versus all other machines, and for Lithostar C and STS-T versus LithoTron 160, Doli, and Econolith; calcium hydrogen phosphate dihydrate FDA limit for HM3 and Modulith SLX, and Lithostar C and LithoTron 160 versus all other machines, and STS-T versus Doli and Econolith; calcium oxalate dihydrate 500 shocks for HM3, Modulith SLX, STS-T and Lithostar C, and LithoTron 160 and Econolith versus all other machines; calcium oxalate monohydrate 2,000 shocks for HM3 versus all other machines except Modulith SLX, Modulith SLX versus LithoTron 160, Doli and Econolith, and LithoTron 160, STS-T and Lithostar C versus Doli and Econolith; calcium oxalate monohydrate FDA limit for HM3 versus LithoTron 160, Doli and Econolith, LithoTron 160 versus STS-T, Doli and Econolith, STS-T versus Doli and Econolith, and Modulith SLX versus Doli and Econolith; cystine 500 shocks for HM3, Modulith SLX and Lithostar C versus all other machines, and Doli and Econolith versus LithoTron 160 and STS-T; cystine 2,000 shocks for HM3 versus all other machines, Modulith SLX versus LithoTron 160, Doli and Econolith, LithoTron 160 versus all other machines; STS-T versus Doli, Econolith and LithoTron 160, and Lithostar C versus LithoTron 160 and Econolith; cystine FDA limit for HM3 and Modulith SLX versus all other machines, LithoTron 160 versus all other machines except Econolith; STS-T versus all other machines except Lithostar C and Doli; Lithostar C versus Econolith and Doli versus Econolith; magnesium ammonium phosphate hexahydrate 500 shocks for HM3 and Modulith SLX versus all other machines, STS-T, Lithostar C and Doli versus all other machines, and LithoTron 160 versus Econolith; magnesium ammonium phosphate hexahydrate 2,000 shocks for HM3 versus LithoTron 160 and Lithostar C, LithoTron 160 versus STS-T, Modulith SLX, Lithostar C, Doli and Econolith, STS-T versus Lithostar C, Modulith SLX versus Lithostar C and Econolith, and Lithostar C versus Doli; magnesium ammonium phosphate hexahydrate FDA limit for HM3 versus all other machines; LithoTron 160 versus Modulith SLX and Modulith SLX versus Econolith; calcium hydrogen phosphate dihydrate HM3, Modulith SLX, Lithostar C, STS-T, Doli and Econolith for 500 versus 2,000 shocks and FDA limit; calcium hydrogen phosphate dihydrate LithoTron 160 for 500 versus 2,000 shocks FDA limit, and 2,000 shocks versus FDA limit; calcium oxalate monohydrate HM3, Modulith SLX, Lithostar C, STS-T, LithoTron 160, Doli and Econolith for 500 versus 2,000 shocks and FDA limit; cystine HM3, Lithostar C, LithoTron 160, Doli and Econolith for 500 versus 2,000 shocks and FDA limit; cystine STS-T for 500 versus 2,000 shocks and FDA limit, and 2,000 shocks versus FDA limit; magnesium ammonium phosphate hexahydrate HM3, Lithostar C and LithoTron 160 for 500 versus 2,000 shocks and FDA limit, and 2,000 shocks versus FDA limit; and magnesium ammonium phosphate hexahydrate Modulith SLX, STS-T, Doli and Econolith for 500 versus 2,000 shocks and FDA limit.

TABLE 4. *Fragments less than 2 mm.*

Composition	No. Shocks	Mean % Stone ± SD							
		HM3	Modulith SLX	Lithostar C	STS-T	LithoTron 160	Doli	Econolith	p Value
Calcium hydrogen phosphate dihydrate	500	34 ± 39	2 ± 3	20 ± 13	46 ± 18	35 ± 29	59 ± 23	57 ± 27	0.01
	2,000	0 ± 0	0 ± 0	0 ± 1	10 ± 18	11 ± 18	29 ± 20	18 ± 33	0.07
	FDA limit	0 ± 1	0 ± 0	0 ± 0	10 ± 15	3 ± 2	29 ± 20	18 ± 33	0.04
p Value		0.006	0.84	0.09	0.004	0.01	0.005	0.0004	
Calcium oxalate monohydrate	500	0 ± 0	0 ± 0	2 ± 3	5 ± 3	5 ± 4	52 ± 23	10 ± 13	<0.0001
	2,000	0 ± 0	0 ± 0	0 ± 0	0 ± 1	0 ± 0	4 ± 5	9 ± 14	0.13
	FDA limit	0 ± 1	0 ± 0	0 ± 0	0 ± 0	0 ± 1	4 ± 5	9 ± 14	0.15
p Value		0.96	1.00	0.74	0.29	0.38	<0.0001	0.77	
Cystine	500	3 ± 7	0 ± 0	11 ± 12	72 ± 35	67 ± 31	23 ± 29	22 ± 17	<0.0001
	2,000	0 ± 0	0 ± 0	1 ± 2	0 ± 0	25 ± 28	3 ± 4	9 ± 18	0.03
	FDA limit	1 ± 2	0 ± 0	1 ± 3	10 ± 21	14 ± 18	3 ± 4	9 ± 18	0.44
p Value		0.49	1.00	0.05	0.0007	0.01	0.18	0.30	
Magnesium ammonium phosphate hexahydrate	500	1 ± 1	0 ± 0	4 ± 8	4 ± 7	40 ± 41	2 ± 3	7 ± 10	0.006
	2,000	2 ± 3	0 ± 0	2 ± 4	0 ± 0	10 ± 15	0 ± 1	0 ± 0	0.14
	FDA limit	0 ± 1	0 ± 0	1 ± 1	0 ± 0	3 ± 4	0 ± 1	0 ± 0	0.05
p Value		0.87	1.00	0.66	0.57	<0.0001	0.77	0.19	

Pairwise differences were statistically significant for calcium hydrogen phosphate monohydrate 500 shocks for Modulith SLX versus all other machines; calcium hydrogen phosphate dihydrate FDA limit for HM3, LithoTron 160, Modulith SLX and Lithostar C versus Doli; calcium oxalate monohydrate 500 shocks for HM3, LithoTron 160, STS-T, Modulith SLX and Lithostar C versus Doli and Econolith; cystine 500 shocks for HM3 and Modulith SLX versus LithoTron 160, STS-T, Doli and Econolith; cystine 2,000 shocks for HM3, STS-T, Modulith SLX and Lithostar C versus LithoTron 160; magnesium ammonium phosphate hexahydrate 500 shocks for HM3, Modulith SLX, Doli and STS-T versus LithoTron 160; magnesium ammonium phosphate hexahydrate FDA limit for LithoTron 160 versus Modulith SLX and Econolith; calcium hydrogen phosphate dihydrate HM3, STS-T, Doli and Econolith for 500 versus 2,000 shocks and FDA limit; calcium hydrogen phosphate dihydrate LithoTron 160 for 500 versus 2000 versus limit; calcium oxalate monohydrate Doli for 500 versus 2,000 shocks and FDA limit; cystine Lithostar C, LithoTron 160, Doli and Econolith for 500 versus 2,000 shocks and FDA limit; cystine STS-T for 500 versus 2,000 shocks and FDA limit, and 2,000 shocks versus FDA limit; and magnesium ammonium phosphate hexahydrate LithoTron 160 for 500 versus 2,000 shocks and FDA limit, and 2,000 shocks versus FDA limit.

largest fragments. We noted no correlation of mean fragment size at 500 shocks with peak power at focal point F2 for calcium hydrogen phosphate dihydrate (r^2 = 8%), calcium oxalate monohydrate (r^2 = 3%), cystine (r^2 = 0.2%) or magnesium ammonium phosphate hexahydrate (r^2 = 0.6%) stone composition. There was also no correlation of mean fragment size at 500 shocks with focal zone volume for calcium hydrogen phosphate dihydrate (r^2 = 18%), calcium oxalate monohydrate (r^2 = 11%), cystine (r^2 = 3%) or magnesium ammonium phosphate hexahydrate (r^2 = 11%) composition.

DISCUSSION

The objective of shock wave lithotripsy is to produce small passable fragments. The data show that shock wave lithotripsy devices vary in the ability to reduce stones to small passable fragments. This observation is important because the few clinical studies that compared lithotriptors used various definitions of success and followup, incorporated various stone sizes and locations, and had variable practice patterns.[2-8,11] Others define success as residual fragments less than 4 or 2 mm., or stone-free status.[12-14] Patients are most likely to pass fragments rapidly and with less likelihood of repeat intervention as fragment size decreases.[15] It is important that shock wave lithotripsy reduce residual fragments to small passable fragments to minimize the risk of future symptomatic stone episodes.[14]

The data also show that lithotriptors produce progressively smaller fragments as the shock count increases. In our study calcium oxalate monohydrate and magnesium ammonium phosphate hexahydrate calculi were more common than the relatively rare calcium hydrogen phosphate dihydrate (brushite) or cystine stones.[16] Calcium oxalate monohydrate and magnesium ammonium phosphate hexahydrate calculi fragment adequately with most devices well before the FDA treatment limit, while complete treatment is necessary for complete fragmentation of calcium hydrogen phosphate dihydrate and cystine stones. Different stone compositions respond unequally to shock wave lithotripsy.[17] Particularly, cystine and calcium hydrogen phosphate dihydrate or brushite resist shock wave fragmentation.[17-19] Since these durile compositions are less common in the pure form than the more fragile mixed calcium oxalate or hydroxyapatite calculi, our data may over state clinical differences in the lithotriptors. Patients with more fragile calculi may be over treated due to the general practice of applying the complete shock count to ensure adequate fragmentation. Recent advances in computerized tomography make it possible to identify many stones before therapy based on Hounsfield density, raising the possibility that fragile stones may be identified before shock wave lithotripsy and over treatment may be avoided.[20] The potential for over treatment appeared most relevant for the Modulith SLX, which achieved adequate fragmentation at and marginally increased fragmentation after 500 shocks. Based on our data urologists who use this device may wish to limit the shock counts to attain adequate fragmentation without excess risk of renal injury.

Interpreting peak pressures at focal point F2 is difficult in these lithotriptors. To our knowledge the various machines were not previously evaluated objectively by independent observers. Published peak pressures are the result of in-house testing by shock wave lithotripsy device manufacturers and there is no industry acknowledged, standard method of evaluation. Nevertheless, if we cautiously accept manufacturer specifications (table 1), our data indicate no obvious correlation of manufacturer specifications for peak power at focal point F2 with fragmentation outcome. Similarly we observed no correlation of focal zone volume and fragmentation outcome, although this finding was not surprising since all stones were positioned at focal point F2. We infer that there are no intuitive means of rating a lithotriptor based on manufacturer specifications because these values do not correlate with fragmentation. Accordingly it would be valuable to enter various lithotriptors into prospective randomized clinical trials to determine relative efficacy. To date only Chan et al have reported a randomized prospective trial, although randomization was not strictly applied.[2] We propose that lithotriptors should be evaluated in randomized prospective clinical trials in which 2 or more are directly compared. Alternatively since few institutions have more than 1 shock wave lithotripsy device, we propose multi-institutional prospective studies in which groups at all sites agree to complete similar data sheets. Less ideally lithotriptors may be tested in vitro, as in our series. Moreover, more study is necessary to understand the physical parameters that enhance shock wave lithotripsy.

We believe that our in vitro study correlates with clinical shock wave lithotripsy. Clinically no shock wave lithotripsy results with subsequent generations of lithotriptors have any clear fragmentation advantage over those of the Dornier HM3 (table 5).[1,3,12,21-30] The 70% to 77% stone-free rate in large numbers of patients achieved with the HM3 for stones generally larger than those treated with other shock wave lithotripsy devices compares favorably to that of other lithotriptors.[1,3] The best stone-free rates were attained using the Modulith SL20 but there were high re-treatment and post-shock wave lithotripsy auxiliary procedure rates.[21,22] A measure of shock wave lithotripsy performance is the efficiency quotient, calculated using the formula, 100% (% stone-free)/ 100% initial treatment + % re-treatment + % auxiliary procedures. Efficiency quotients for the HM3 and Modulith SLX are 82% and 67%, respectively.[22,31]

In our methodology there was no attenuation of shock waves and each stone was in the focal point for 100% of the shock waves with no respiratory motion, which would not occur with shock wave lithotripsy in vivo.[32] Thus, our in vitro results represent a best case scenario for each machine. Lithotriptors with a small focal zone, such as the Modulith SLX, would be expected to perform well in this in vitro setting since targeting was optimal and fixed. However, clinical results may be less successful because stones move in and out of the small focal zone with respiration. We infer that the large focal zone of the HM3 may increase the clinical likelihood that shock waves would impact the stone, although the fragmentation characteristics of these 2 machines are equivalent in vitro.[33] Hence, the clinical superiority of the HM3 is understandable and compatible with our results in

TABLE 5. *Clinical results of machines in renal calculi*

Model	References	No. Pts.	% Stone-Free Overall	% Re-Treatment Overall	% Post-Lithotripsy Procedures	Efficiency Quotient
Dornier HM3	Drach et al[1]	1,840	77	7	8	0.67
	Cass[3]	2,402	70	6	3	0.64
Modulith SL20	Liston et al[21]	500	78	32	4	0.57
	Köhrmann et al[22]	549	91	23	12	0.67
Lithostar C	Elabbady et al[23]	319	63	10	3	0.56
	El-Damanhoury et al[24]	3,278	64	10	2	0.57
	Mobley et al[12]	19,962	76	14	5	0.64
Medstone 1050 ST	Lipson et al[25]	50	46	8	8	0.40
Medstone STS	Thomas and Cass[26]	81	68	11	3	0.60
	Cass[3]	2,934	72	5	2	0.67
LithoTron 160	Fuselier et al[27]	150	71	4	Not available	Not available
Econolith	Simon[28]	500	75	18	17	0.56
Doli	Fuselier et al[29]	50	68	22	Not available	Not available
	Lippert and Koser[30]	103	57	43	14	0.36

vitro. Nevertheless, it may be argued that the fragmentation differences of lithotriptors in this study were small enough not to affect the clinical outcome. However, we believe that there are clinical advantages for lithotriptors that produce smaller fragments and fewer less than 2 mm.[14,15]

Several methodological considerations validate our study results. Initial stone mass was statistically identical in all cohort (median $p = 1.0$ for the initial stone mass comparisons but the largest statistical difference in these comparisons was $p = 0.94$). In addition, all stones were human urinary calculi of a known pure composition. Furthermore, all post-lithotripsy stone processing and analysis were done in blinded fashion to minimize bias.

Our study has some potential limitations. Testing in vitro requires using an apparatus to mimic the clinical scenario. All lithotriptors evaluated had a container with a flat polypropylene bottom except the HM3, which introduces a potential confounding variable. However, the flat polypropylene surface transmits shock wave energy comparably to water.[10] Also, each device had a specific testing rig, introducing potential variability. This rig was re-coupled for each treatment in the 3 dry electrohydraulic lithotriptors. In this group the testing rig was fixed to the table with the Medstone and Medispec but to the shock head of the LithoTron 160, making coupling and stone positioning more challenging. Of the electromagnetic machines the testing rig was fixed to the table with the Lithostar C, and directly to the shock head of the Doli and Modulith SLX. Coupling each device to the shock head remains a critical variable.

Our study also only addressed fragmentation characteristics. No inferences were drawn regarding lithotriptor imaging resolution characteristics, targeting accuracy or multipurpose capabilities. Moreover, our analysis implied equal outcomes in calcium oxalate monohydrate stones for the Doli and Econolith models at the FDA limit of shocks ($p = 0.15$, table 4). Post hoc analysis revealed a statistical power of 0.54, indicating only 54% ability to detect a difference when it was present. If we had evaluated more stones per cohort, the trend of more calcium oxalate monohydrate fragments greater than 2 mm. for the Doli and Econolith versus the other models may have reached statistical significance.

CONCLUSIONS

To our knowledge our study represents the first time that shock wave lithotripsy device manufacturers participated in broad interdevice evaluation using an externally designed, objective protocol involving completely characterized human urinary calculi of known composition for testing each lithotriptor. Until randomized prospective clinical trials or meaningful device specifications are available, testing in vitro may be the best basis of shock wave lithotripsy comparison. Lithotriptors vary in the ability to fragment urinary calculi. Overall the Dornier HM3, Modulith SLX and Lithostar C achieved the best fragmentation characteristics. Available clinical data corroborate these in vitro findings, validating our in vitro model.

David S. Fletcher, Louis C. Herring and Co., Orlando, Florida supplied the stones, and Drs. Steven Mattingly and Robert Klebe provided technical assistance.

REFERENCES

1. Drach, G. W., Dretler, S., Fair, W. et al: Report on the United States Cooperative Study of extracorporeal shock wave lithotripsy. J Urol, **135:** 1127, 1986
2. Chan, S. L., Stothers, L., Rowley, A. et al: A prospective trial comparing the efficacy and complications of the modified Dornier HM3 and MFL 5000 lithotriptors for solitary renal calculi. J Urol, **153:** 1794, 1995
3. Cass, A. S.: Comparison of first generation (Dornier HM3) and second generation (Medstone STS) lithotriptors: treatment results with 13,864 renal and ureteral calculi. J Urol, **153:** 588, 1996
4. Bierkens, A. F., Hendrikx, A. J. M., DeKort, V. J. W. et al: Efficacy of second generation lithotriptors: a multicenter comparative study of 2206 extracorporeal shock wave lithotripsy treatments with the Siemens Lithostar, Dornier HM4, Wolf Piezolith 2300, Direx Tripter X-1 and Breakstone lithotriptors. J Urol, **148:** 1052, 1992
5. Tailly, G.: Experience with the Dornier HM4 and the MPL 9000 lithotriptors in urinary stone treatment. J Urol, **144:** 622, 1990
6. Tan, E. C., Tung, K. H. and Foo, K. T.: Comparative studies of extracorporeal shock wave lithotripsy by Dornier HM3, EDAP LT 01 and Sonolith 2000 devices. J Urol, **146:** 294, 1991
7. Sofras, F., Karayannis, A., Kastriotis, J. et al: Extracorporeal shockwave lithotripsy or extracorporeal piezoelectric lithotripsy? Comparison of costs and results. Br J Urol, **68:** 15, 1991
8. Siebold, J., Rassweiler, J., Schmiedt, A. et al: Advanced technology in extracorporeal shock wave lithotripsy: the Dornier MPL 9000 versus the Dornier HM3. J Endourol, **2:** 173, 1988
9. Coleman, A. J. and Saunders, J. E.: Comparison of extracorporeal shock wave lithotriptors. (Based on measurements in the acoustic field.) In: Lithotripsy II: Textbook of Second Generation Extracorporeal Lithotripsy. Edited by M. J. Coptcoat, R. A. Miller and J. E. A. Wickham. London: BDI Publishing, chapt. 8, pp. 121–131, 1987
10. Cleveland, R. O., McAteer, J. A., Andreoli, S. P. et al: The effect of polypropylene vials on lithotriptor shock waves. Ultrasound Med Biol, **23:** 939, 1997
11. Rassweiler, J., Gumpinger, R., Mayer, R. et al: Extracorporeal piezoelectric lithotripsy using the Wolf-lithotriptor versus low energy lithotripsy with the modified Dornier HM-3: a cooperative study. World J Urol, **5:** 218, 1987
12. Mobley, T. B., Myers, D. A., Grine, W. B. et al: Low energy lithotripsy with the Lithostar: treatment results with 19,962 renal and ureteral calculi. J Urol, **149:** 1419, 1993
13. Ehreth, J. T., Drach, G. W., Arnett, M. L. et al: Extracorporeal shock wave lithotripsy: multicenter study of kidney and upper ureter versus middle and lower ureter treatments. J Urol, **152:** 1379, 1994
14. Streem, S. B., Yost, A. and Mascha, E.: Clinical implications of clinically insignificant stone fragments after extracorporeal shock wave lithotripsy. J Urol, **155:** 1186, 1996
15. Miller, O. F. and Kane, C. J.: Time to stone passage for observed ureteral calculi: a guide for patient education. J Urol, **162:** 688, 1999
16. Sperrin, M. W. and Rogers, K.: The architecture and composition of uroliths. Brit J Urol, **82:** 781, 1998
17. Bhatta, K. M., Prien, E. L., Jr. and Dretler, S. P.: Cystine calculi—rough and smooth: a new clinical distinction. J Urol, **142:** 937, 1989
18. Wang, Y. H., Grenabo, L., Hedelin, H. et al: Analysis of stone fragility in vitro and in vivo with piezoelectric shock waves using the EDAP LT-01. J Urol, **149:** 699, 1993
19. Grenabo, L., Hedelin, H., Mohsenvand, C. et al: Stone fragmentation pattern of piezoelectric shockwave lithotripsy in vitro. J Endourol, **12:** 247, 1998
20. Mostafavi, M. R., Ernst, R. D. and Saltzman, B.: Accurate determination of chemical composition of urinary calculi by spiral computerized tomography. J Urol, **159:** 673, 1998
21. Liston, T. G., Montgomery, B. S. I., Bultitude, M. I. et al: Extracorporeal shock wave lithotripsy with the Storz Modulith SL20: the first 500 patients. Brit J Urol, **69:** 465, 1992
22. Kohrmann, K. U., Rassweiler, J. J., Manning, M. et al: The clinical introduction of a third generation lithotriptor: Modulith SL20. J Urol, **153:** 1379, 1995
23. Elabbady, A., Mathes, G., Morehouse, D. D. et al: Safety and effectiveness of Lithostar shock tube C in the treatment of urinary calculi. J Endourol, **9:** 225, 1995
24. El-Damanhoury, H., Schärfe, T., Rüth, J. et al: Extracorporeal shock wave lithotripsy of urinary calculi: experience in treatment of 3,278 patients using the Siemens Lithostar and Lithostar Plus. J Urol, **145:** 484, 1991
25. Lipson, S. B., Ross, L. S. and Sonda, L. P.: Initial clinical trials with a tubless lithotriptor. J Urol, **143:** 10, 1990
26. Thomas, R. and Cass, A. S.: Extracorporeal shock wave lithotripsy in morbidly obese patients. J Urol, **150:** 30, 1993
27. Fuselier, H. A., Mardis, H. A., Giesy, J. D. et al: A new modular

electrohydraulic lithotripter: outcomes and observations. J Urol, suppl., 157: 86, abstract 333, 1997
28. Simon, D.: Experience with 500 extracorporeal shockwave lithotripsy patients using a low-cost unit: the "Econolith." J Endourol, 9: 215, 1995
29. Fuselier, H. A., Prats, L. and Fontenot, C.: Comparison of mobile lithotripters at one institution: Dornier MFL 5000, Dornier Doli and Healthtronics Lithotron. J Endourol, suppl., 12: S170, 1998
30. Lippert, C.-M. and Koser, M. F.: A modified shock wave source—the Dornier flat EMSE: First clinical experience with anaesthesia-free in-situ-ESWL of ureteral calculi. J Endourol, suppl., 12: S173, 1998
31. Anderson, K. R., Keetch, D. W., Albala, D. M. et al: Optimal therapy for the distal ureteral stone: extracorporeal shock wave lithotripsy versus ureteroscopy. J Urol, 152: 62, 1994
32. Honey, R. J. D'A., Healy, M., Yeung, M. et al: The use of an abdominal compression belt to reduce stone movement during extracorporeal shock wave lithotripsy. J Urol, part 2, 148: 1034, 1992
33. Rassweiler, J., Westhauser, A., Bub, P. et al: Second-generation lithotripters: a comparative study. J Endourol, 2: 193, 1988