Comments from Ed made July 31:
Urinary Extracorporeal Shock Wave Lithotripsy (UESWL)
Certificate of Need (CON) Workgroup
Summary Report from June 27 and July 31, 2013 Meetings

Workgroup Charge: The UESWL workgroup will determine if the service (UESWL) should be deregulated, or if continuing to regulate, review the volume criteria for expansion.

First meeting: June 27, 2013
Second meeting: July 31, 2013

Present: See attached lists of attendees for both meetings.

Summary: At the June 27 meeting, Ed Goldman outlined the history of UEWSL in Michigan under CON and the charge for the workgroup. The charge is to determine if the service (UESWL) should be deregulated, or if continuing to regulate, review the volume criteria for expansion.

The group agreed that the plan is to finish workgroup meetings and submit a report to the Commission at their September meeting.

Following introductions and background, each participant gave their opinion. Discussion followed.

Participants acknowledged the CON Commission should always be on the lookout for areas no longer in need of regulation, but in this case, participants believe the Commission needs to be concerned about possible over use and increased costs through purchase of un-needed machines.

The discussion continued at the July 31 meeting. Topics included emergency regulation, expansion requirements, temporary CON for machine repair and need for continued regulation.

Workgroup consensus was that UESWL ought to continue to be regulated for the following reasons:

1. Access is appropriate, and there is existing capacity in the system to allow for both scheduled and unscheduled treatments.

2. Costs are lower in Michigan than States where there is no regulation.

3. Limiting the number of machines in the State contributes to quality since this keeps the number of treatments high so radiologic technologists are able to keep their skills at a high level.

4. De-regulation could result in additional machines which would not add necessary access but could diminish quality and may even result in un-necessary treatment for small stones in order to recover the cost of the machines.

Thus, while participants understood and acknowledged the need for on-going review and the need to only regulate high cost issues, they believed that UESWL was not yet ready for de-regulation.

Discussion then turned to any possible changes to the existing regulations. There was a question about the number of procedures necessary for expansion with additional discussion regarding a lower expansion threshold for rural/micropolitan statistical area counties. There was no consensus or data/documentation to support any suggested changes at this time, but if data is presented to the Commission in the future, expansion for access purposes may be a possibility. All participants agreed there was existing capacity in the existing system, and new machines are not currently a high priority.

There was discussion about the need for machines to fill in while maintenance was being performed, and the possibility that the standards may need an emergency or maintenance standard. It was clarified that emergency CONs were covered in statute and administrative rules and are not a topic for this workgroup.

The work group raised the question of a need for requirements for temporary replacement when a machine is being serviced. The workgroup agreed that this is an issue for all equipment and concluded that this could be a topic for future discussion by the Commission since this would involve a possible broader change to all applicable CON review standards.

Participants submitted data supporting their claims concerning cost, access and quality. Participants supplied information prior to the July 31st meeting. Participant information is attached to and made a part of this report.

Following receipt of materials, a draft report along with the participants submissions were posted on line for review, and the July 31st meeting was scheduled.

At the July 31st meeting, the participants reviewed this report, made changes and agreed that it reflected the opinions and conclusions of the workgroup. Thus, the workgroup submits this report to the Commission for its review.

Respectfully Submitted,
Edward Goldman,
Head of the UESWL workgroup.

SIGN IN LOG

Meeting Date: Thursday, June 27, 2013
Meeting Purpose: UESWL Workgroup Meeting

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Voluntary Sign In.
MCL 15.263 "Sec. 3(4) A person shall not be required as a condition of attendance at a meeting of a public body to register or otherwise provide his or her name or other information or otherwise to fulfill a condition precedent to attendance."

SIGN IN LOG

Meeting Date: Thursday, June 27, 2013
Meeting Purpose: UESWL Workgroup Meeting

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Voluntary Sign In.
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SIGN IN LOG

Meeting Date: Wednesday, July 31, 2013
Meeting Purpose: UESWL Workgroup Meeting

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SIGN IN LOG

Meeting Date: Wednesday, July 31, 2013
Meeting Purpose: UESWL Workgroup Meeting

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Voluntary Sign In.
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URINARY EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (UESWL) SERVICES

WORKGROUP CHARGE

Approved by the Certificate of Need (CON) Commission on January 29, 2013

The UESWL workgroup will determine if the service (UESWL) should be deregulated, or if continuing to regulate, review the volume criteria for expansion.

To: The Michigan Department of Community Health ("**Department**")
From: American Kidney Stone Management, Ltd. ("**AKSM"**)
Re: Materials Regarding the Department's recommendation to deregulate Urinary Extracorporeal Shock Wave Lithotripsy ("**UESWL**") Services
Date: July 24, 2013

AKSM respectfully provides the following Workgroup materials with respect to the Department's recommendation to deregulate UESWL.

AKSM agrees with the Workgroup's recommendation to continue regulation based on data derived from its experience as a national provider and manager of UESWL services and its management of Greater Michigan Lithotripsy, LLC ("**GML**"), which oversees three mobile UESWL Routes in Michigan.

AKSM also recommends: (i) modification of the UESWL services expansion requirements to provide greater elasticity to accommodate the needs of patients, physicians and facilities; and (ii) refinement of the emergency CON requirements to avoid cancellation and rescheduling of patient treatments in the event a UESWL unit requires non-routine maintenance or repairs.

I. AKSM AGREES WITH THE WORKGROUP RECOMMENDATION TO MAINTAIN UESWL REGULATION AND CERTIFICATE OF NEED ("CON") REQUIREMENTS.

A. QUALITY AND SAFETY

1. Radiation Technologists

a. UESWL is a surgical procedure performed by physicians with specialized technical assistance from Radiation Technologists ("**Technologists**"). For safe, efficient and effective UESWL treatment, Technologists must be able to:

- properly and quickly visualize and position the urinary calculus ("**Stone**").
  - "… accurate stone localization and targeting, especially using a lithotripter with a narrow focal zone of 6.5mm, are necessary for success". Variation in Clinical Outcome Following Shock Wave Lithotripsy *The Journal of Urology 163,* 721-725 (2000) – ***See Exhibit 1.***

- apply gel to effectively couple the patient to the water filled bellows in the UESWL equipment to enable the shock waves to be transmitted into the body. The coupling zone is not generally visible to the Technologist. Air pockets in the coupling area

block the shock wave delivery which reduces the effectiveness of Stone disintegration.

- "Air bubbles in coupling media used during SWL procedures create acoustic interfaces that impeded the efficiency of shock wave transmission, and it has been demonstrated that manually displacing macroscopic air bubbles can improve shock wave efficacy." Impact of Learning Curve on Efficacy of Shock Wave Lithotripsy *Radiologic Technology* 80, 20-24 (2008) – ***See Exhibit 2***.
- See also Monitoring the Coupling of the Lithotripter Therapy Head with Skin during Routine Shock Wave Lithotripsy with a Surveillance Camera and Coupling graphic. *The Journal of Urology 187,* 157-163 (2012) – ***See Exhibits 3 and 4***.

- properly pause the UESWL equipment between priming shocks and treatment to reduce tissue damage.
  - "Our findings also suggest that the interval between the initial shocks and the clinical dose of SWs [shock waves], in our one-step ramping protocol, is important for protecting the kidney against injury." Effect of Initial Shock Wave Voltage on Shock Wave Lithotripsy-Induced Lesion Size During Step-Wise Voltage Ramping *BJU International* 103, 104-107 (2008) - ***See Exhibit 5***.
  - See Pause for the Cause graphic BJU *Int.* 103(1), 104-7 (2009) – ***See Exhibit 6***.

b. The learning curve for UESWL Technologists is steep and to become proficient in the necessary skills and techniques, a Technologist must practice frequently.

- Studies show that the more experience the Technologist has, the more effective the UESWL treatment.
  - "Efficacy with SWL, as measured by stone-free rates, improved with increasing experience of the radiographer. Ongoing supervision and mentorship might be helpful in the first year of service". ". . . efficacy progressively increases from the first year of CRLT experience with SWL procedures to the third year of experience." Impact of Learning Curve on Efficacy of Shock Wave Lithotripsy *Radiologic Technology* 80, 20-24 (2008) – ***See Exhibit 2***.
  - ". . . efficacy progressively increases from the first year of CRLT experience with SWL procedures to the third year of experience." Impact of Learning Curve on Efficacy of Shock Wave Lithotripsy – ***See Exhibit 2***.
  - See also Litho Tech Learning curve graphic (2008)*Radiologic Technology* 80, 20-24 – ***See Exhibit 7.***

2. <u>Regulation Enhances Patient Care and Safety.</u>

a. Due to CON regulation of UESWL in Michigan, lithotripsy providers in this state have both the opportunity and the legal obligation to perform a greater number of

treatments than in non-regulated states. As a result, our Technologists are able to focus exclusively on UESWL and to provide assistance on a great number of treatments. This practice allows our Technologists to develop and retain the critical skills described in Item 1.

For example, GML Technologists:

- are dedicated exclusively to UESWL;
- have an average of 4+ years UESWL experience;
- provide, on average, treatment assistance on 680 UESWL patients per year; and
- receive annual and periodic training by AKSM, a national leader in UESWL services.

3. <u>Deregulation Will Jeopardize Patient Care and Safety.</u>

a. Without CON regulation, higher volume facilities can reasonably be expected to purchase their own UESWL machines.

b. Because even the highest volume facilities will not have sufficient Stone volume to ensure full time Technologist utilization, facilities will assign Technologists who are part-time or tasked with other duties to perform UESWL.

c. Technologists who are not dedicated to UESWL and/or not performing high volumes of UESWL treatments cannot develop and maintain the critical skills described above. The lack of skilled Technologists will reduce the effectiveness of UESWL treatment and jeopardize patient safety without a reduction in cost (See B. below) or an increase in access (See C. below).

d. Facilities that remain on existing mobile routes will be served by less proficient technologists, because treatment volumes will necessarily decrease due to proliferation.

B. <u>COST</u>

1. <u>Proliferation will not reduce costs.</u>

a. GML's average UESWL contract charge in Michigan is on par with AKSM's national average UESWL contract charge. ***See Exhibit 8***.

b. GML's average UESWL contract charge in Michigan is already lower than the average UESWL contract charge of AKSM owned or managed UESWL providers in deregulated neighboring states. ***See Exhibit 8***.

2. Proliferation may increase costs.

a. The proliferation of UESWL services can be expected to cause costs to increase as facilities and vendors entering the market will not have the efficiency and expertise that the current CON providers have.

b. Facilities purchasing UESWL equipment will:

- incur costly upfront UESWL equipment costs between $500,000 and $1 million, as well as incurring costly, but necessary, annual service and maintenance costs to treat Stones that are already being treated with the existing UESWL equipment. This will result in an unnecessary capital expenditure and diversion of funds from other needed healthcare services; and

- not effectively utilize the UESWL equipment or UESWL personnel resulting in increased cost.

C. ACCESS

1. Deregulation will not improve access.

a. Currently all patients requiring UESWL are able to receive treatment.

b. The three GML mobile machines managed by AKSM have, on average, slots available daily to provide UESWL services.

2. Deregulation may reduce access.

a. Proliferation can be expected to result in a loss of utilization (treatment volumes) of current UESWL providers and, therefore, a reduction in the number of UESWL Technologists and machines.

b. It is likely machines will be purchased by facilities in urban areas.

c. The potential reduction of availability of the current UESWL providers coupled with the likelihood that Facilities that purchase UESWL machines will be in urban areas may result in a loss of access to UESWL in smaller and rural locations.

II. AKSM RECOMMENDS MODIFICATION OF THE EXPANSION REQUIREMENTS TO PROVIDE ELASTICITY TO ACCOMMODATE PATIENT NEEDS.

A reduction in the number of procedures per UESWL unit required for a services provider to add an additional unit, would provide elasticity to ensure urgent cases can be accommodated in a timely fashion without jeopardizing the benefits regulation has brought to the State.

Therefore, AKSM recommends a minor edit to Section 8 of the CON Review Standards for UESWL Services, entitled "Requirements for approval to expand an existing UESWL service", by making the change marked below to the first sentence of Sub-section 8 (1):

> "All of the applicant's existing UESWL units, both fixed and mobile, at the same geographic location as the proposed additional UESWL unit, have performed an average of a least ~~1,800~~ 1,200 procedures per UESWL unit during the most recent 12-month period for which the Department has verifiable data."

III. AKSM RECOMMENDS REFINING THE EMERGENCY CON REQUIREMENT FOR REPLACEMENT OF UESWL EQUIPMENT.

A provider whose equipment requires non-routine repairs can face days or weeks without the equipment while the original equipment is being fixed and the replacement equipment awaits an emergency CON. This results in the UESWL services provider being forced to cancel and reschedule patient treatments. To alleviate delays in patient treatment caused by non-routine equipment repairs, AKSM recommends adding a new section to the CON Review Standards for UESWL Services.

The new section would provide that the Department will issue an emergency CON for replacement UESWL equipment within one business day of request if:

- the CON holder stipulates the following:

  1. the emergency CON is for an UESWL unit that is a temporary replacement for a unit being serviced;

  2. the original unit and the replacement unit will not be utilized at the same time; and

  3. the replacement unit will not be used for more than thirty (30) days.

Exhibit 1

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VARIATION IN CLINICAL OUTCOME FOLLOWING SHOCK WAVE LITHOTRIPSY

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ABSTRACT

Purpose: We measure and compare operator specific success rates of extracorporeal shock wave lithotripsy (ESWL*) performed by 12 urologists in 1 unit to determine interoperator variation.

Materials and Methods: From January 1, 1994 to September 1, 1997 a total of 5,769 renal and ureteral stones received 9,607 ESWL treatments by 15 urologists with a Dornier MFL 5000* lithotriptor. The 3-month followup data are available for 4,409 stones. Outcome measures consisted of patient demographics, stone characteristics, technical details of lithotripsy, and stone-free and success rates by treating urologists.

Results: Treatment results were analyzed for 12 urologists (surgeons A to L) who treated more than 100 stones each, totaling 4,244 with followup information available. Mean stone-free and success rates were 50.6% and 72.3%, respectively. Surgeon A had significantly higher stone-free and success rates of 56.2% and 76.7%, respectively ($p < 0.05$), with treatment results from 877 stones, which was a significantly higher number than others ($p < 0.05$). Significant differences existed in mean number of shocks delivered among urologists ($p = 0.0001$), with surgeons A and J delivering the highest mean numbers (2,317 and 2,801, respectively). There was no difference in treatment duration ($p = 0.75$) but variation existed among urologists in terms of mean maximum treatment voltage ($p = 0.0001$). Mean fluoroscopy time at 4.1 minutes was higher for surgeon A than others ($p < 0.05$). Mean complication rate following ESWL was 4.9% with no difference among urologists ($p = 0.175$). Re-treatment was required in 21.7% of cases and surgeon A had the lowest rate (15.9%, $p < 0.05$).

Conclusions: We demonstrated clinically and statistically significant intra-institutional differences in success rates following ESWL. The best results were obtained by the urologist who treated the greatest number of patients, used a high number of shocks and had the longest fluoroscopy time. Accurate targeting is crucial when using a lithotriptor, such as the Dornier MFL 5000, with a narrow focal zone of 6.5 mm. in diameter. Other centers should be encouraged to develop similar programs of outcome analysis in an attempt to improve performance.

KEY WORDS: lithotripsy, treatment outcome, benchmarking, comparative study, kidney calculi

With its low morbidity[1] and acceptable success rate extracorporeal shock wave lithotripsy (ESWL) has become the preferred treatment for stone disease by patients and urologists.[1–3] Benchmarking comparisons of treatment results by center and specific device have been reported[4–7] but to our knowledge those by individual operator at 1 center are lacking. Outcomes research in cardiac surgery reported mortality rates following coronary artery bypass by individual surgeon and respective surgical volume.[8] Local recurrence and disease specific survival for colorectal cancer surgery were improved with colorectal surgical subspecialty training and higher surgical volume.[9] Houghton cited positive and negative studies of the relationship between volume and outcome, and emphasized that it varies for different conditions and operative procedures.[10] Outcome analysis has been a controversial but apparently effective tool of quality assessment and improvement but there are few reports for urological procedures.

Benchmarking is a formalized approach to comparative care process analysis.[11] A fundamental assumption of outcome analysis is that patient outcomes vary according to the quality of care.[12] With fiscal accountability it is important to evaluate the cost and effectiveness, and monitor the quality of medical care.[13] By measuring variation in outcome rates among surgeons and/or institutions with adjustment for possible differences in patient characteristics it is possible to identify areas for quality improvement strategies.[13]

An analysis of interoperator variation in success following ESWL has not been reported to our knowledge. We report our experience with 5,769 renal and ureteral stones treated during a 4-year period, with 3-month followup in 58.5%. We measure and compare the operator specific success rates of ESWL performed by 12 urologists at 1 unit to determine interoperator variation.

MATERIALS AND METHODS

From January 1, 1994 to September 1, 1997, a total of 5,769 renal and ureteral stones were treated and studied prospectively at the E. C. Bovey Lithotripsy Unit at the University of Toronto. Lithotripsy was performed by 15 urologists who were assigned day long sessions. Staffing of the unit was done on a daily rotational basis. All procedures were performed on an outpatient basis. Data on patient age and gender, and size and location of stone(s) were collected for each urologist and stored in a lithotripsy stone tracking database.

All treatments were performed with a Dornier MFL 5000 lithotriptor. The treatment protocol has been previously described.[14, 15] Double pigtail ureteral stents were inserted in patients with high grade obstruction, a solitary kidney and stones larger than 15 mm. in diameter. Stones larger than 25 mm. were considered too large for ESWL. Although more

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* Dornier Medical Systems, Inc., Marietta, Georgia.

than 1 stone may have been treated during 1 session, each was tracked independently and the results were reported separately. Patients received intravenous analgesic sedation administered by an anesthesiologist. Treatment was terminated when complete fragmentation of the stone(s) was identified on fluoroscopy and confirmed by a magnified fluoroscopic spot film, or a maximum number of shocks for the kidney or ureter had been delivered. Our guidelines for treatment specify a maximum of 3,000 and 4,000 shocks per session for renal and ureteral stones, respectively. The number of stones treated, number of re-treatments, number of shocks, maximum energy used (kV.), fluoroscopy time (minutes) and treatment duration (minutes from first to last shock) were recorded.

Patient followup at our clinic was scheduled 2 weeks and 3 months after the last ESWL. Patients living more than a 1-hour drive from the unit were followed by the referring urologists, who were sent a detailed outcomes questionnaire. Treatment results were evaluated with plain abdominal x-ray and/or renal tomogram for renal calculi and abdominal x-ray or excretory urogram for ureteral stones. Films were reviewed by a urologist who may or may not have been the treating urologist, and a nurse clinician and a radiologist for the first half of the study period. Only patients with symptomatic fragments or fragments greater than 5 mm. were re-treated. Residual stone sizes were recorded by actual stone dimension so that treatment results could be determined with various definitions for success. Treatment was considered a success if the patient was stone-free or had asymptomatic fragments less than 4 mm. at 3-month followup. All post-ESWL complications were recorded, including hospitalization, pain requiring a visit to the emergency room, fever (temperature greater than 38C), documented perirenal hematoma and the need for a ureteral stent or percutaneous nephrostomy. Data were collected prospectively and statistical software was used for analysis. Chi-square and logistic regression analyses were used to test significant individual variation in the overall success and stone-free rates, and with respect to stone location, stone size and by year of treatment.

RESULTS

During the study period 5,769 stones were treated and 9,607 ESWL treatments were performed. Male-to-female ratio was 1.9:1. Average age was 50.3 years (range less than 1 to 91) for men and 47.9 (range less than 1 to 94) for women. One ESWL session was performed for 65.3% of stones, 2 for 19.4%, 3 for 7.7%, 4 for 3.7% and greater than 4 for 3.9%. The 3-month followup data were available for 4,244 stones. Of the stones 70.7% were renal and 29.3% were ureteral, and 54.9% were less than 10 mm., 42.6% were 10 to 20 mm. and 2.5% were greater than 20 mm. Of the 15 urologists who treated more than 100 patients each 12 performed 78.5% of the procedures. Treatment results are shown in table 1. Stone distribution by size and location for each urologist is shown in table 2.

Mean number of shocks per treatment was 2,125 overall, and 1,975 for renal and 2,291 for ureteral stones. There was a significant difference in the number of shocks by stone location ($p < 0.0001$). Surgeon A delivered more shocks than surgeons B to F, H and M ($p < 0.05$). Mean fluoroscopy time was 2.9 minutes overall, and the same for renal and ureteral stones. There was a significant difference ($p < 0.05$) in mean fluoroscopy times among surgeons, with surgeon A having a significantly higher time than all others ($p < 0.05$). Mean treatment duration was 51.2 minutes overall, and 50.9 and 49.5 for renal and ureteral stones, respectively (not significantly different, $p > 0.05$). There was no significant difference in mean treatment duration among urologists ($p > 0.05$). Mean maximum voltage was 24.3 kV. overall, and 24.0 and 24.8 for renal and ureteral stones, respectively. There was a significant difference in the mean maximum energy use for the 2 types of stones ($p < 0.05$). For renal stones the highest mean voltage (24.3 kV.) was used by surgeon B and the lowest (23.4) was used by surgeon J. For ureteral stones the highest energy (25.1 kV.) was used by surgeons E and M, and the lowest (24.3) was used by surgeons D and G. There was a significant difference in mean maximum voltage ($p < 0.05$).

The stone-free rate at 3-month followup was 50.6% overall (range 41.1% to 56.2%), with significant differences among urologists ($p = 0.006$). Surgeon A had the highest overall stone-free rate (56.2%), which was significantly higher than that of surgeons B to E and H to L ($p < 0.05$). Stone-free rates were not statistically different for surgeons F and G (53.8% and 50.5%) compared to surgeon A ($p > 0.05$).

Overall success rate was 71.9% and 73.2% for renal and ureteral stones, respectively (table 3). There was a difference among urologists for renal and ureteral stone-free status ($p = 0.0001$). The stone-free rate for renal stones was the highest (51.4%) for surgeon A, and the rates for ureteral stones were highest for surgeons K and A (74.2% and 66.9%, respectively). The stone-free rate by stone location was higher for surgeon A than for surgeons B to E, H, J and L ($p < 0.05$). The success rate, defined as asymptomatic fragments less than 4 mm., was also significantly different by urologist and stone location ($p = 0.0403$). Surgeon A had the highest success

TABLE 1. *Treatment results and technical data following lithotripsy*

	Surgeon												Overall
	A	B	C	D	E	F	G	H	I	J	K	L	
No. pts. treated	1,450	1,059	762	722	646	550	354	590	372	252	194	248	7,547
Mean shocks (renal stones)	2,059	1,754	1,945	927	1,832	1,769	1,989	1,947	2,180	2,484	2,229	1,810	1,975
Mean shocks (ureteral stones)	2,665	2,165	2,390	2,405	1,999	2,084	2,341	1,832	2,214	3,248	1,941	1,538	2,291
Mean shocks (overall)	2,317	1,949	2,074	2,169	1,913	2,005	2,261	1,892	2,285	2,802	2,170	1,722	2,126
Mean mins. fluoroscopy	4.1	2.5	2.8	2.7	2.2	2.9	2.1	3.1	2.7	2.9	2.3	2.9	2.9
Mean mins. duration	55.2	51.3	44.7	52.2	48.2	48.8	44.7	55.8	50.5	49.1	50.3	59.3	51.2
Mean max. voltage (kV)	24.2	24.7	24.1	24.0	24.5	24.3	23.9	24.3	24.6	24.0	24.3	24.3	24.3
% Followup	61.6	53.2	60	62.5	58.4	61.5	51.4	64.7	59.4	48.0	63.9	61.3	58.5
% Complications	4.3	3.4	5.0	5.5	4.5	4.7	7.1	7.1	6.8	2.5	4.9	2.6	4.9
% Re-treatment	15.9	26.2	23	23.7	24.3	20.6	21.9	22.9	23.6	18	21.9	23.5	21.7
% Stone-free:	56.2	50.4	48.6	47.9	48	53.8	50.5	49	49.3	46.3	47.2	41.1	50.6
1994	46.7	43.4	39.7	38.1	41	56.2	—	47.5	51.7	—	45.5	41.2	44.7
1995	56.9	55.5	61.4	46.5	56.7	51.3	59.3	48.8	56.1	—	46.7	41.2	53.2
1996	60.8	50	49.6	51.5	45.2	61.3	48.9	51.9	41.8	54.5	48.4	25.	52.5
1997	61.4	52.3	40.6	61.3	46.9	45.5	49.2	—	45.2	41.6	46.7	62.5	51.7
Less than 10 mm.	67.8	59	54.4	59.1	56.6	58.6	53.9	51.6	56.9	49.1	62.7	45.1	59
10–20 Mm.	43.8	39.1	44.4	34.5	34.5	50	46.7	47.3	38.4	43.3	32.8	39.5	42
Greater than 20 mm.	37	22.2	0	30	54.5	12.5	40	18.2	40	50	33.3	20	29
% Success*	76.7	71.8	70.5	70.1	69.8	72.2	68.1	69.9	75.6	76.9	73.2	67.8	72.3

* Stone-free and/or residual sand particles less than 2 mm. and/or asymptomatic particles less than 4 mm.

TABLE 2. *Stone distribution by size and location for each urologist*

Surgeon	% Renal Stones			% Ureteral Stones		
	Less than 10 Mm.	10–20 Mm.	Greater Than 20 Mm.	Less than 10 Mm.	10–20 Mm.	Greater Than 20 Mm.
A	32.5	33.6	2.9	20.0	10.8	0.2
B	34.6	28.4	1.4	23.8	11.5	0.2
C	35.0	35.9	2.0	17.7	9.0	0.4
D	38.8	35.0	1.6	16.0	8.0	0.7
E	42.2	28.9	2.4	16.4	9.5	0.5
F	38.8	29.6	2.4	16.3	13.0	0
G	37.4	28.6	2.7	18.7	12.6	0
H	39.8	28.0	2.6	18.6	10.7	0.3
I	39.4	28.5	2.3	19.5	10.4	0
J	30.6	36.4	2.5	16.5	13.2	0.8
K	35.8	37.4	1.6	12.2	12.2	0.8
L	32.2	40.1	3.3	14.5	9.9	0

For stones less than 10 versus 10 to 20 versus greater than 20 mm. $p = 0.001$, for renal versus ureteral stones $p = 0.001$ and among urologists $p = 0.068$.

TABLE 3. *Stone-free and success rates by stone location and size*

Size (mm.)	% Stone-Free	% Success
Renal:		
Less than 10	53.7	80
10–20	38.4	64.4
Greater than 20	28.1	43.8
Ureteral:		
Less than 10	67.8	79.6
10–20	51.1	63.6
Greater than 20	38.5	50

For stone-free versus success rates, renal versus ureteral stones and less than 10 versus 10 to 20 versus greater than 20 mm. $p = 0.001$.

rates for renal and ureteral stones (75.7% and 79%, respectively).

Stone-free rates for stones less than 10 mm., 10 to 20 mm. and greater than 20 mm. were 59%, 42% and 29%, respectively, and the success rates were 80%, 64% and 43.6%, respectively. There were significant differences by stone size in stone-free ($p = 0.0001$) and success ($p = 0.001$) rates among urologists. Stones less than 10 mm. were the most common and stone-free rates varied ($p < 0.05$), with surgeon A having the highest (67.8%). For stones 10 to 20 mm. surgeon F had the highest stone-free rate (50%), and for stones greater than 20 mm. surgeon E the highest (54.5%), although the smaller number of larger stones was such that these figures did not reach statistical significance. However, the overall stone-free rate by stone size was significantly higher for surgeon A than for surgeons B to E, H, I and L ($p < 0.05$). Similarly, the success rate by stone size was higher for surgeon A than for surgeons B to H ($p < 0.05$).

As 3-month followup represents the final result regardless of the number of treatments, the re-treatment rate is noteworthy. Of the 4,244 treated stones 78.3% required 1 and 21.7% required 2 or more treatments. The re-treatment rate was 21.7% overall, 21.5% for renal and 22.4% for ureteral stones, and 14.7% for those less than 10 mm., 29.8% for those 10 to 20 mm. and 50% for those greater than 20 mm. There was a significant difference ($p < 0.05$) among urologists for number of stone treatments required. Surgeons A and J had re-treatment rates significantly lower (15.9% and 18%) than others ($p < 0.05$). Surgeon B had the highest re-treatment rate (26.2%).

Mean stone-free rate for each year recorded from January 1 to December 31 was 44.7%, 53.2%, 52.5% and 51.7% for years 1994 to 1997, respectively. There was a significant difference among urologists for the stone-free rate by year ($p = 0.0012$) and a significant difference in mean stone-free rate by year ($p = 0.0108$). Surgeon A had improving stone-free rates of 44.7%, 56.9%, 60.8% and 61.4% during the 4-year period.

The overall complication rate following ESWL was 4.9%. There were no significant differences ($p > 0.05$) in the complication rate among urologists but rates were significantly different for renal and ureteral stones (5.5% and 3.4%, respectively, $p = 0.003$). There was no difference in the complication rate by stone size (4.9% overall, 4.6% for those less than 10 mm., 5.1% for those 10 to 20 mm. and 7.3% for those greater than 20 mm., $p = 0.385$). The overall percentage of stone treatments with followup was 58.5% and was significantly different among urologists ($p < 0.05$). Surgeon H had the highest followup rate (64.7%) and surgeon J had the lowest (48%).

Surgeon A results were analyzed to discover treatment variables that may predict success. Multivariate analysis suggested that the only characteristics predicting success were the number of shocks delivered and fluoroscopy time. The number of shocks for patients who became stone-free was 2,060, whereas those with failure to become stone-free received a significantly higher number (2,238, $p < 0.05$). Fluoroscopy time was not statistically different for surgeon A patients who became stone-free at 4.11 minutes and for those with failure to be stone-free at 4.15 minutes. There was no difference in lithotripsy complications in regard to the number of shocks or fluoroscopy time ($p > 0.05$).

DISCUSSION

We demonstrated a small but consistent variation in success rates following ESWL and an overall stone-free rate of 50.6% for all urologists. Bierkens et al reported similar stone-free rates (45%) in a multicenter comparative study of second generation lithotriptors.[4] Psihramis et al previously reported a stone-free rate of 55.7% overall at 3-month followup for all calculi, and 52% and 76%, respectively, for renal and ureteral stones.[14] One surgeon had a significantly higher stone-free rate of 56.2% compared to others, and rates were significantly different when stone location and size were considered ($p = 0.0001$). There was also a difference in the mean stone-free rate by year ($p = 0.0108$), suggesting that there is a measurable learning curve to ESWL.

The overall success rate 3 months following lithotripsy was 72.3%. Again, there were small but significant differences in the success rate by urologist for stone size and location ($p < 0.05$). As expected, stone location affected complication rates (mean 4.9). There was no difference based on the size of the stone but stents were inserted before ESWL on all larger stones (greater than 1.5 cm. in diameter).

There was a difference among the urologists for the number of shocks delivered ($p < 0.05$). Overall, renal stones received less shocks than ureteral stones ($p < 0.0001$). Mean fluoroscopy time was 2.9 minutes, with no difference for the 2 types of stones but significant differences among urologists ($p < 0.05$). Fluoroscopy time is defined as time spent by the operator visualizing and adjusting the position of the stone. Mean treatment duration was 51.2 minutes, with no difference for renal and ureteral calculi or among urologists ($p > 0.05$). Mean maximum voltage was 24.3 kV., with higher

voltages used for ureteral stones ($p < 0.05$), which may suggest that as fragmentation is less obvious in the ureter there is a tendency to increase the energy. The difference in mean maximum voltage among urologists ($p < 0.05$) did not translate into a difference in success as the difference in peak pressures obtained by increasing above 23 kV. is negligible using the MFL 5000 lithotriptor.

Surgeon L treated the second fewest number of stones (248), delivered the lowest number of shocks per stone (1,722), and had the lowest stone-free (41.1%) and success (67.8%) rates. Surgeon A treated the highest number of stones (1,450) with followup results for 60.6%, delivered more shocks than 7 others surgeons and had a stone-free rate of 56.2%, which was higher than 9 other surgeons ($p < 0.05$). Surgeon A had improving stone-free rates of 44.7%, 56.9%, 60.8% and 61.4% during the 4-year period. It is noteworthy that a clinical fellow performed the majority of the treatments during the first year (1994), which may account for the marked difference in this year. Mean fluoroscopy time was greater (4.1 minutes) for surgeon A than all others ($p < 0.05$), with no increase in treatment duration. This finding suggests that accurate stone localization and targeting, especially using a lithotriptor with a narrow focal zone of 6.5 mm., are necessary for success.

In the surgical literature few studies are devoted to outcomes analysis, particularly intra-institutional variation. In 1996 Clark reported a weak statistical correlation of volume to mortality after coronary artery bypass graft, although the results were not clinically relevant and surgeon specific data were lacking.[8] Surgical practice patterns also vary as evidenced by the geographic variation found in the rate of surgical procedures.[16–20] Furthermore, differences in outcome for surgical procedures exist between hospitals and individual surgeons.[10] Comparisons of ESWL treatment results by center and specific device have been reported, whereas to our knowledge there is only 1 report comparing treatment results by operator within 1 center. In 1995 Ilker et al reported that the results obtained by an experienced technician were just as reliable as those obtained by an experienced urologist using the Dornier MFL 5000.[21] It has been suggested that outcomes analysis at the local level may be useful in improving physician practice patterns.[22]

Analysis of this type requires research by unbiased investigators, and we attempted to reduce reporting bias on stone-free and success rates by having all radiographic films reviewed by a urologist who may or may not have been the treating urologist, a nurse clinician working at the lithotripsy center for the entire study duration and a radiologist. However, for logistical reasons from August 1995 to September 1997 the reported results were based on interpretation by the urologist and nurse clinician. Interobserver and intraobserver variability in x-ray review following ESWL has been reported.[23] Differences occurred 52% of the time among radiologists reporting on plain abdominal films and 24% by the same radiologist rereading the films. This difference among radiologists was decreased to 28% when plain abdominal films and tomograms were read together. Thus, our reporting of stone-free rates may be overestimated.[23]

Because our center is 1 of only 2 lithotripsy sites in the province of Ontario, covering a population of 12 million, patients who live more than 1 hour from the center are instructed to have followup performed by the referring urologist. This protocol would account for the high proportion of unknown treatment results (41.5%), which we attribute to lack of followup data submission by referring urologists. One could also argue that treating urologists, who know that a poor result was achieved with lithotripsy by seeing no fragmentation of the stone on initial treatment, may opt to refer the patient back to the referring urologist for other therapies. However, the percentage of patients followed did not correlate with success. The results of treatment were attributed to the first treating urologist. In some instances further ESWL treatments may not have been performed by the initial treating urologist but all attempts have been made to have patients re-treated by that urologist. In addition, stone composition was not recorded in our database, although Smith et al reported decreasing success rates following ESWL with increasing stone size and noted that treatment outcome was not influenced by stone composition.[1]

Clinical outcomes are strongly influenced by differences among patients as well as the standards of medical care.[13] In 1992 Manheim et al reported highly significant regional differences in Medicare hospital mortality which may have been related to important underlying differences in the quality of medical practice.[24] In an effort to provide quality health care the principles and techniques of modern industrial quality science should be applied.[25] Furthermore, discussion of identified outcomes, variations and best practice characteristics with the physicians involved is a powerful educational tool.[11] By measuring outcomes of individual urologists, variation may be observed that may lead to quality improvement strategies.

CONCLUSIONS

This prospective study demonstrates clinically and statistically significant intra-institutional variation in stone-free and success rates following ESWL. The best results appear to have been obtained by the urologist who treated the greatest number of patients, used a high number of shocks and had the longest fluoroscopy time. Accurate stone localization and targeting are crucial for success when using a lithotriptor with a small focal zone, such as the Dornier MFL 5000. Other centers should be encouraged to develop similar programs of outcome analysis to provide continuous feedback of information to surgeons in an attempt to improve performance.

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PEER REVIEW

Impact of Learning Curve on Efficacy of Shock Wave Lithotripsy

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Introduction *The purpose of this study was to evaluate the impact of a radiographer's learning curve on extracorporeal shock wave lithotripsy (SWL) efficacy.*

Methods *Five registered technologists who were certified to assist in SWL procedures but had no prior lithotripter experience were evaluated during a 4-year period. Stone-free (no residual fragments on plain radiographic imaging), re-treatment and post-SWL procedure rates were evaluated for the first 3 years of radiographer employment.*

Results *The overall stone-free rate increased from 55% (efficiency quotient [EQ] 45) in the first year to 68% (EQ 50) in the third year. The treatment success rate for the lower ca* Exhibit 1 *the first year to 62% (EQ 44) in the third year. There was no difference in re-treatment or post-*

Conclusion *Efficacy with SWL, as measured by stone-free rates, improved with increasing experience of the radiographer. Ongoing supervision and mentorship might be helpful in the first year of service.*

Urinary stone disease is a common problem in America and costs more than $2 billion each year.[1] The most common treatment of stone disease is extracorporeal shock wave lithotripsy (SWL).[2] The administration of SWL relies on a partnership between the treating urologist and a registered technologist (R.T.) who has been certified in renal lithotripsy procedures. For the purposes of this article, this R.T. will be referred to as the certified renal lithotripsy technologist (CRLT).

The learning curve associated with new technologies recently has come under scrutiny.[3-5] When SWL first became widely available in the United States, certified SWL training centers were set up by the American Urological Association (AUA) to ensure that urologists practicing SWL had received appropriate training.[6] In 1990 the AUA began certifying R.T.s for renal lithotripsy procedures to improve the standard of stone treatment care. To qualify as a CRLT, R.T.s must pass written exams and observe at least 50 SWL procedures.[7] Once certified by the AUA, CRLTs may assist with SWL procedures. Experienced CRLTs have proven to be as effective as experienced urologists in treating stones.[8]

This study evaluates the impact of the CRLT's learning curve on stone treatment efficacy. The hypothesis to be tested is that SWL treatment success (ie, a stone-free result) depends on the experience of the CRLT.

Methods

A retrospective chart review was conducted. Five CRLTs with no prior lithotripter experience were trained in SWL and their success tracked over the course of 3 years. Each of these 5 CRLTs had prior experience in diagnostic radiology as radiographers and currently were employed full time as CRLTs. All lithotripter units and treatment sites were staffed on a rotating basis by the same 5 CRLTs. Patient positioning and radiographic targeting of the stone were performed in collaboration with the treating urologist. The urologist decided when to end the treatments based on radiographic evidence of adequate fragmentation.

The choice of anesthesia and treatment rate (gated vs ungated) was at the discretion of the urologist and the anesthesiologist. Biplanar digital imaging was used for stone localization with the Medstone STS lithotripter, a second-generation electrohydraulic lithotripter. The Medstone STS Lithotripter (Medstone International

Inc, Aliso Viejo, California) uses a centered, spark-gap ellipsoid design. It has a voltage range of 18 to 24 volts, a focus range of 1.4 to 3 cm and a throw (F1-F2) of 17 cm.

Outcome reporting was conducted by a standardized mailing to the treating urologists as part of an ongoing quality assurance program. They documented treatment parameters, reported follow-up that included plain abdominal radiography to calculate stone-free rate (no residual fragments), recorded the need for auxiliary procedures or re-treatment and noted any complications. Re-treatment rates are defined as the need for a second SWL session; secondary procedures included ureteral stenting or endoscopic procedures for retained fragments.

Stone-free (no residual fragments on plain radiographic imaging at 1-month follow-up), re-treatment and post-SWL procedure rates were evaluated for the first 3 years of each CRLT's employment. Overall treatment success was stratified by stone size, and special attention was paid to the success rate of lower pole caliceal stones. An efficiency quotient (EQ) was calculated using the following formula:

$$\frac{\text{stone free \% x 1000}}{\text{100 + (re-treatment rate \% + auxiliary procedure \%)}}$$

The EQ, as reported, is not amenable to statistical comparison.[9] Statistical analysis was performed using the Fisher exact test to compare stone-free, re-treatment, auxiliary procedure and complication rates by year of training.

Results

The 5 CRLTs assisted in 779 SWL procedures during their first year of employment. The 5 CRLTs assisted in 1354 and 785 procedures in their second and third years, respectively. All treatments used the Medstone STS lithotripter machine.

For all procedures performed, average patient age was 48.4 years, and 58% were men. The distribution of stone sizes and locations treated are presented in Figures 1 and 2, respectively. There was no significant difference in average number of procedures performed per year per CRLT. There also was no significant difference in treatment parameters such as average number of shocks or patient body-mass index.

The overall stone-free rate increased significantly from 55% (EQ 45) in the first year to 68% (EQ 50, $P = .02$) in the third year (see Figure 3). It is important to note that, as a calculated value, statistical comparison of the EQ is not recommended in the urologic literature.[9] For stones 1 to 10 mm in size, stone-free rates increased from 60% (EQ 50) in the first year to 72% (EQ 55, $P = .008$) in the third year. Stone-free rates also increased for stones 11 to 20 mm in size (55% to 63%, EQ 41 to 45, $P = .04$) and stones greater than 30 mm (25% to 41%, EQ 19 to 24, $P = .02$); there was no significant change in the stone-free rate for stones 21 to 30 mm in size (55% to 52%, EQ 40 to 35, $P = .21$) (see Figures 4 and 5). Stone-free rates also increased between the first and third years for stones treated in the lower calyx (50% to 62%, EQ 41 to 44) (see Figure 6). There was no significant difference in re-treatment ($P = .68$) or secondary procedure rates ($P = .45$).

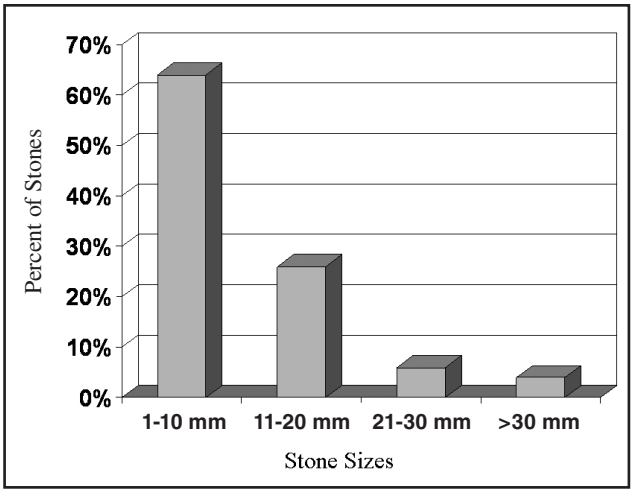

Figure 1. *Distribution of stones by size.*

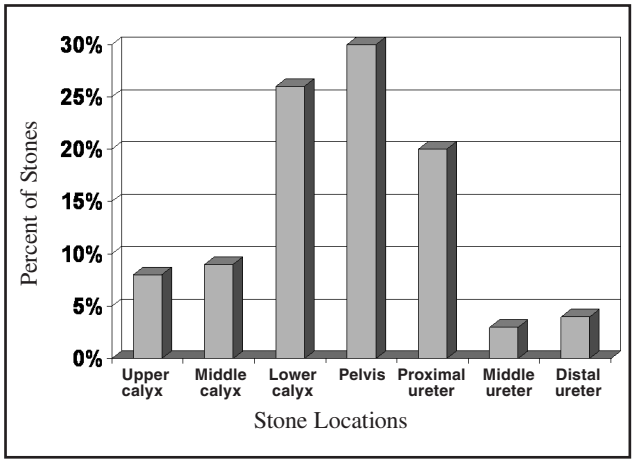

Figure 2. *Distribution of stones by location.*

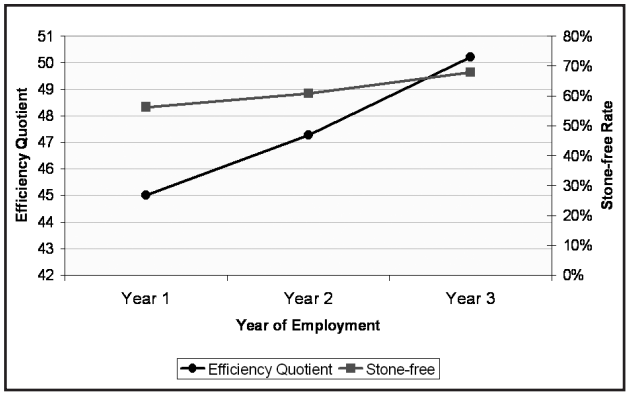

Figure 3. *Overall efficacy by year of employment.*

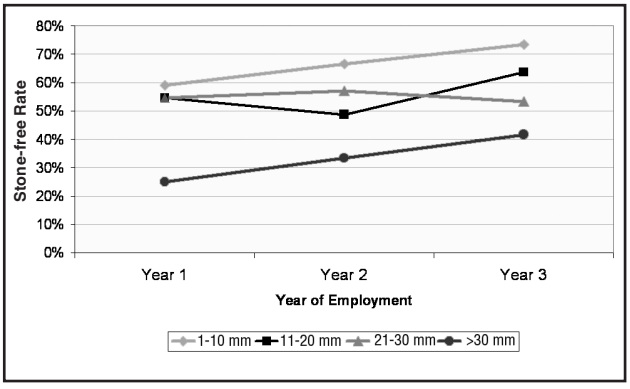

Figure 4. *Stone-free rates by size of stone and year of employment.*

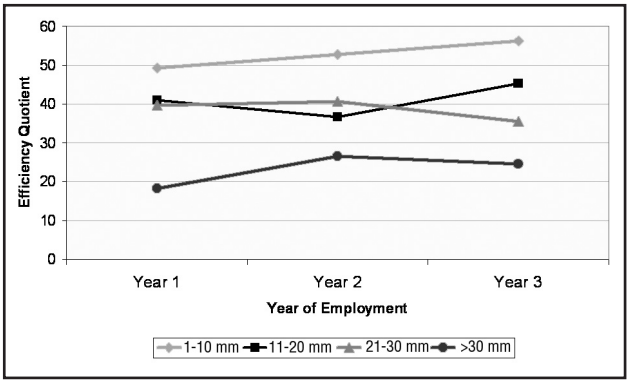

Figure 5. *Efficiency quotient by size of stone and year of employment.*

Discussion

Traditionally, the success of SWL procedures was thought to depend upon patient characteristics and stone location, size and composition. More recently it has been demonstrated that skin-to-stone distance (a surrogate marker of patient obesity) can help predict the likelihood of success with SWL.[10] An average skin-to-stone distance of more than 10 cm predicts failure (see Figure 7). Similarly, it has been reported that stone density as measured by CT Hounsfield units can help predict success of stone fragmentation procedures (see Figure 8).[11] Hounsfield units greater than 1000 HU predict a lower rate of stone fragmentation. Last, researchers have demonstrated that the lower pole renal anatomy can help predict the likelihood of stone clearance (see Figure 9). SWL success is not favorable for patients who have stones with a lower pole angle of less than 70°, an infundibular length of more than 3 cm or an infundibular width of 5 mm or less.[12]

New treatment strategies are helping to improve the success of SWL. Recent studies demonstrated that treating stones at a low energy setting and "ramping up" and treating at a slow gated rate can improve the efficiency of stone fragmentation, decrease renal trauma and improve stone-free results.[13-15] Air bubbles in coupling media used during SWL procedures create acoustic interfaces that impede the efficiency of shock wave transmission, and it has been demonstrated that manually displacing macroscopic air bubbles can improve shock wave efficacy.[16]

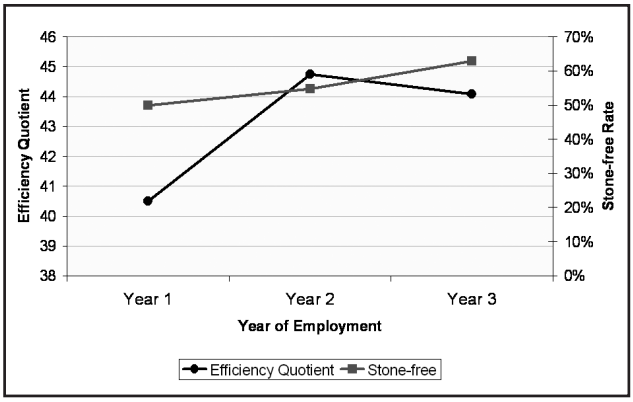

Figure 6. *Lower calyx efficacy by year of employment.*

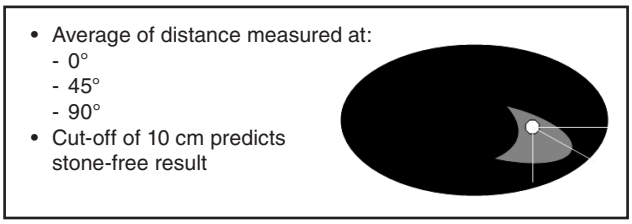

Figure 7. *Calculating the average skin-to-stone distance.*

To date, the only study evaluating the impact of operator experience suggests that the best results were obtained by the urologist who treated the greatest number of patients, used a high number of shocks and had the longest fluoroscopy time.[17] To our knowledge our study is the first to evaluate the impact of CRLT experience on SWL procedure success.

This study suggests that treatment efficacy progressively increases from the first year of CRLT experience with SWL procedures to the third year of experience. There was a marked improvement in stone-free rates for lower pole calculi. Because lower calyceal stone-free rates usually are about 20% lower than stone-free rates for other renal locations, any method to improve success specifically in this area deserves additional attention.

It is important to note that the most significant and linear improvement in stone-free rates occurred for smaller stones (1 to 10 mm). It is possible that success rates for smaller calculi could depend more heavily on patient positioning and stone localization during treatment and, consequently, would be more dependent on the skill and experience of the treating urologist and CRLT. In contrast, the impact of experience appeared to be more variable for lower pole calculi, with fluctuations in EQ noted from year 2 to year 3. This could be because treatment success for lower pole calculi depends on variables, such as lower pole anatomy, that are independent of the skill and experience of the treating urologist and CRLT.

This study was conducted in a retrospective manner; however, the large sample size helps to diminish the potential for study bias. A strength of this study is that 1 lithotripter machine was used for all treatments included in the evaluation.

It seems logical that more experience with SWL procedures would result in a greater success rate; however, the difference in the treatment success rates in this study from year 1 to year 3 is notable. Thus, closer supervision and mentorship by the attending urologist or an experienced CRLT during the new CRLT's first year of work could help ensure the highest level of

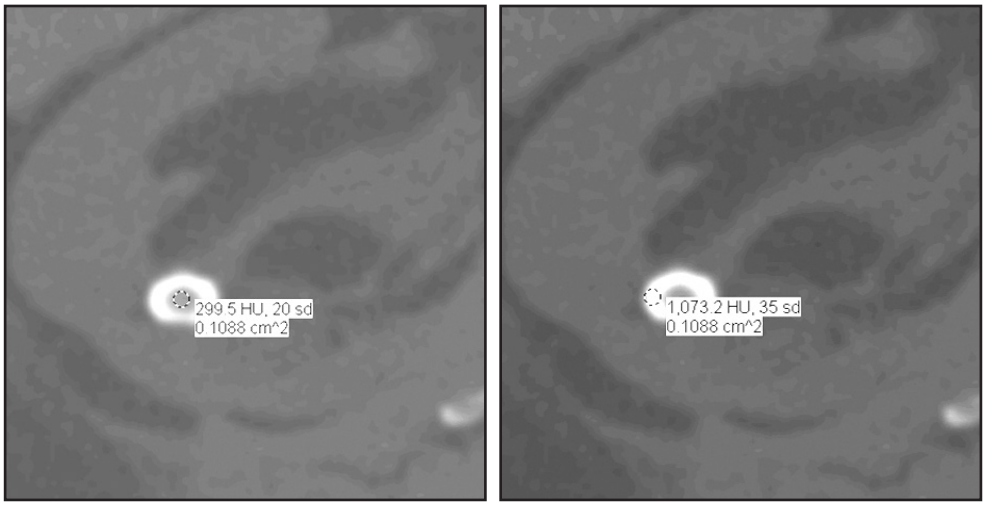

Figure 8. *Hounsfield units in bone windows demonstrate a hard shell (1073 HU) with a soft core (300 HU).*

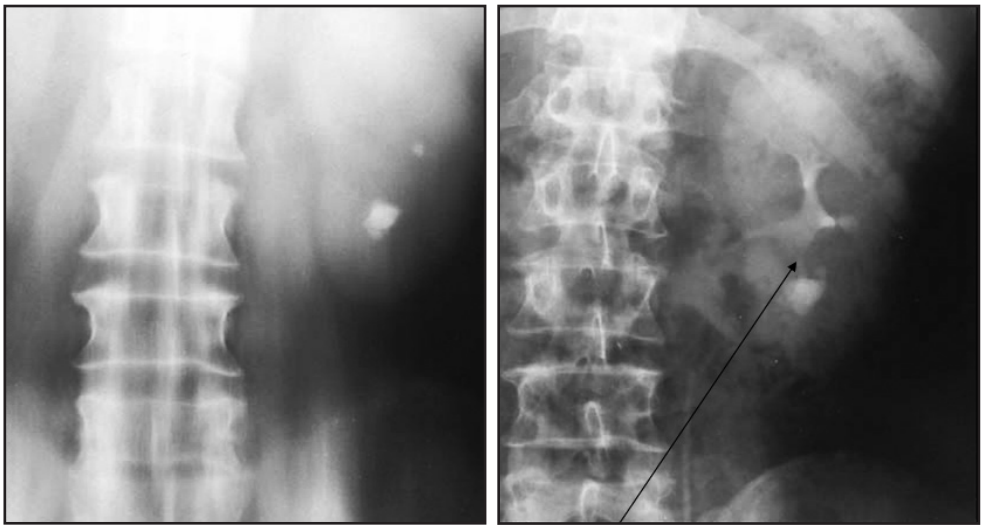

Figure 9. *Unfavorable lower pole anatomy with a long, narrow infundibulum (arrow) at an acute dependent angle.*

stone treatment success possible. Specifically, focusing on the areas of patient positioning, coupling and stone localization would be the most helpful.

Conclusion

Efficacy with SWL improves with increasing experience of the CRLT. Overall, there was an increased stone-free rate as the CRLT gained more experience. This was also true for stones located in the lower calyx. Although CRLTs are a proven benefit in the treatment of stone disease, ongoing supervision and mentorship in the first year of service may be helpful.

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Monitoring the Coupling of the Lithotripter Therapy Head With Skin During Routine Shock Wave Lithotripsy With a Surveillance Camera

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Purpose: With lithotripters today the shock waves are typically transmitted into the body via water filled bellows using coupling gel to make contact with the skin. Usually the coupling zone is not visible to the operator. We investigated coupling quality during routine clinical shock wave lithotripsy and the associated effect on shock wave disintegration efficiency.

Materials and Methods: During 30 routine shock wave lithotripsy treatments the coupling zone was continuously monitored by a video camera integrated into a DoLi SII lithotripter (Dornier MedTech, Wessling, Germany). However, it was not shown to the blinded operator to resemble the standard clinical situation. We used 3 coupling gels, including LithoClear®, Sonogel® and a custom-made gel of low viscosity. The ratio of air in the relevant coupling area was measured. Lithotripter disintegration efficiency was evaluated by in vitro model stone tests at an air ratio of 0%, 5%, 10% and 20%.

Results: Only in 10 of 30 treatments was good coupling achieved with an air ratio of less than 5%. In 8 treatments the ratio was greater than 20%. The best coupling conditions were achieved with low viscosity gel. The mean ± SD number of shock waves needed for complete fragmentation in the model stone tests was 100 ± 4 for bubble-free coupling, and 126 ± 3 for 5%, 151 ± 8 for 10% and 287 ± 5 for 20% air bubbles.

Conclusions: At 20 of 30 shock wave lithotripsy sessions there was imperfect coupling, accompanied by significant loss of disintegration capability. A surveillance camera is useful to monitor and improve coupling.

Key Words: urinary calculi, lithotripsy, high-energy shock waves, equipment and supplies

Abbreviations and Acronyms

A_{air} = coupling area air ratio

A_{SWL} = coupling area

D = skin-to-stone distance

SW = shock wave

SWL = SW lithotripsy

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With the HM3 (Dornier MedTech), the first commercially available lithotripter, the patient was immersed in a tub.[1–3] SWs were generated in the water in which the patient was immersed to provide perfect acoustic coupling.

Later generation lithotripters used coupling bellows. Ultrasound gel, oil or petroleum jelly typically serve as the coupling medium.[4–7] The function of the coupling medium is basically to remove any air gap between the coupling bellows and the skin since air produces strong SW reflections. Various in vitro studies have been done on the effect of air pockets in the coupling surface on disintegration capability.[7–12] Pishchalnikov et al found that only 2% coverage by air pockets decreased stone breakage by 20% to 40%.[8]

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Figure 1. When removing air bubbles by wiping cushion, cushion inflation pressure must be maintained so that bellows remains in contact with patient skin.

Although bubble-free coupling is essential, the coupling surface cannot be visually monitored with most lithotripters. Some devices are equipped with an inline ultrasound system that may be used for this purpose.[12–15]

Guidelines to optimize coupling were deduced from previous studies.[12,14,16] Briefly, 1) the patient skin should be shaved. 2) The ultrasound gel supplied by the manufacturer should be bubble free. 3) A large opening instead of a small diameter nozzle should be used when dispensing gel from a bottle or container. 4) A reasonably large amount of gel should be applied to the center of the coupling bellows as a mound. Spreading the gel uniformly over the bellows and patient skin is not recommended. 5) Contact between the cushion and the patient should be achieved by inflating the bellows or slowly lowering the patient on the bellows. Typically the gel spreads radially without air entrapment. 6) After good coupling is attained the contact between cushion and patient must not be lost during treatment or coupling must be restored. 7) Coupling can be improved by manually wiping the cushion with the hand (fig. 1). Wiping is recommended after decoupling or frequent patient repositioning steps.

We investigated coupling quality during routine clinical SWL. We determined the problems that may occur and factors with the greatest impact. For this purpose a lithotripter was equipped with a camera to allow monitoring of the coupling area throughout treatment. Our second goal was to evaluate the effect of observed air inclusions on disintegration efficiency by model stone tests. We also determined whether such a coupling monitor could improve SWL.

MATERIALS AND METHODS

Enrolled in the study were patients with urinary stones who underwent SWL between February 2010 and January 2011. Four urologists performed therapy. All patients were treated while supine and most received intravenous analgesia with remifentanil. The cushion was attached from the dorsolateral side when the stone was targeted by x-ray, and from the dorsal side when it was targeted by isocentric ultrasound. The way that the operator applied the gel to the cushion was noted by an observer. Three ultrasound gels were used, including Sonogel (250 ml bottle), LithoClear HV (5 l container) and a polyacrylic acid type, custom-made gel from the hospital pharmacy (500 ml bottle). The viscosity of all 3 gels was measured at 20C and 37C at a laboratory specializing in rheology.

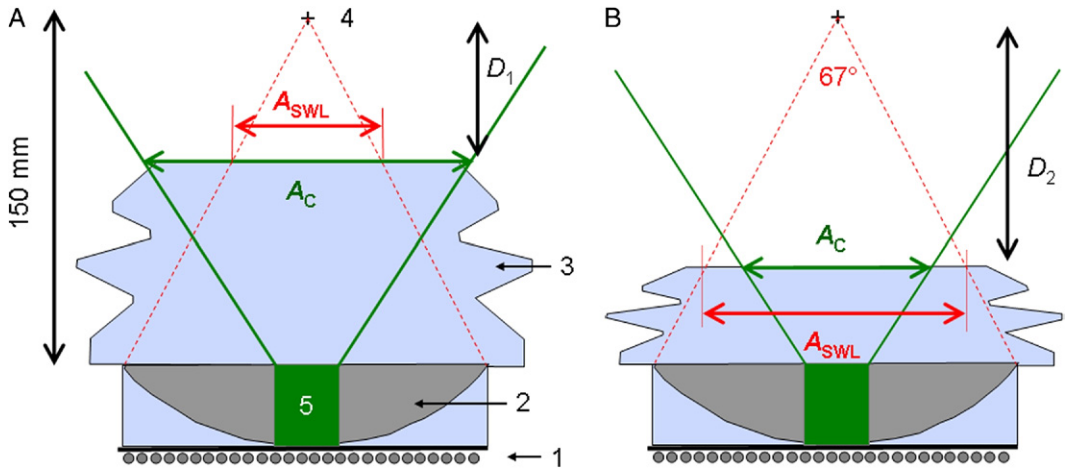

Figure 2. SW source. Electromagnetic SW emitter (*1*) generates plane acoustic waves focused by acoustic lens (*2*) with focus (*4*). Aperture angle is 67 degrees. Water filled cushion (*3*) serves as acoustic path between SW lens and skin. Red double-headed arrow indicates relevant area for SW transmission at skin level. Surveillance camera is in watertight housing at lens center (*5*) to monitor coupling area, of which part is visible (A_C). *A*, cushion inflated short D (D_1). *B*, cushion deflated long D (D_2).

A small video camera was installed in the water cushion of a DoLi SII lithotripter (fig. 2). Since the cushion is transparent, the coupling interface between cushion and patient skin could be imaged. The coupling area was not displayed to the operator during treatment but the observer viewed the monitor and manually corrected coupling as needed (fig. 1). Thus, coupling could be examined under standard clinical conditions while optimized treatment was provided to the patients. Data were obtained under a waiver from the institutional ethical review board.

Coupling Quality Quantitative Evaluation

The coupling area was analyzed off line using a Matlab custom designed program (MathWorks®). We measured D using markers at the cushion top (figs. 2 and 3, *A*). On the image the spacing of the pattern in pixels depends on the distance between camera and cushion and, thus, on D. For calibration, pattern spacing was measured with a disk mounted on the lithotripter at a known distance to the lithotripter focus, ie D.

A_{SWL}, which is the relevant area for SW transmission (fig. 2), was determined by D and the SW aperture angle. For that calculation the SW path was approximated as a cone with the SW lens as the base and the SWL focus as the top.

The boundary lines of bubbles in the gel were drawn manually using the computer mouse (fig. 3). Using circles as markers with known distances on the cushion the depicted bubbles were transformed into an orthogonal, scaled coordinate system allowing the correction of image distortion due to the uneven cushion surface and camera optics. Thus, bubble size could be calculated. Total bubble area was then divided by A_{SWL}, resulting in the ratio A_{air}.

Model Stone Tests

The effect of air bubbles in the gel on disintegration capability was estimated using standard model stone tests.[17] Gypsum stones (Dornier MedTech) were disintegrated in a 2 mm mesh, which allowed the debris to fall out (fig. 4). The test result represented the number of shocks needed until all stone fragments had passed through the mesh.

Air bubbles 10 mm in diameter that had been cut out from packaging foil were pasted to the cushion. They were uniformly distributed in each square, in every second or in every fourth square of the cushion marking pattern. A prepared cushion was coupled to the test tank using otherwise bubble-free LithoClear gel, resulting in a coupling with an A_{air} of 20%, 10% and 5%, respectively. The tests were done at 2 Ds (51 and 90 mm) from the SW focus at a

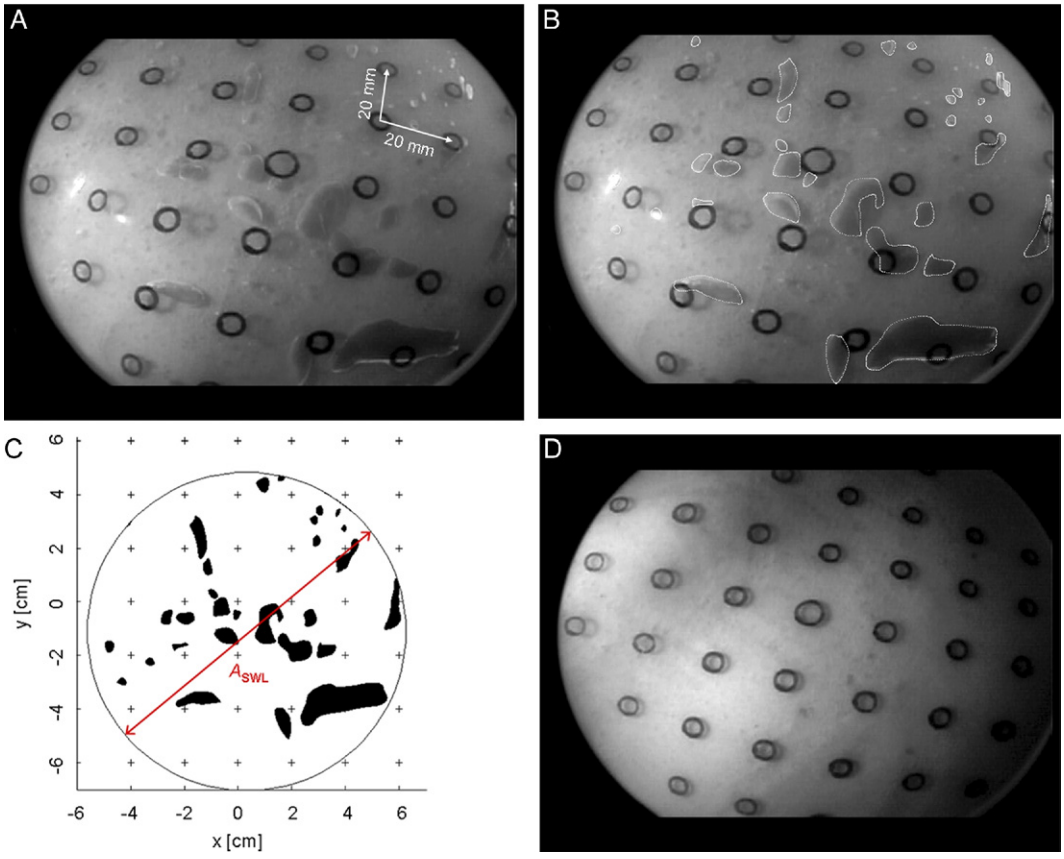

Figure 3. *A*, video image shows coupling area with numerous air bubbles trapped in ultrasound gel. For quantitative evaluation cushion top was provided with squared pattern of circular markings. *B*, bubble boundaries were manually drawn for offline evaluation. *C*, bubbles and circle centers in scaled orthogonal coordinate system after transformation. Bubble area (black areas) was related to area relevant to SW transmission (circle with diameter A_{SWL}). In this example total bubble area was 9.6 cm^2 at 81 mm D and 11% A_{air}. *D*, coupling surface after manual bubble removal.

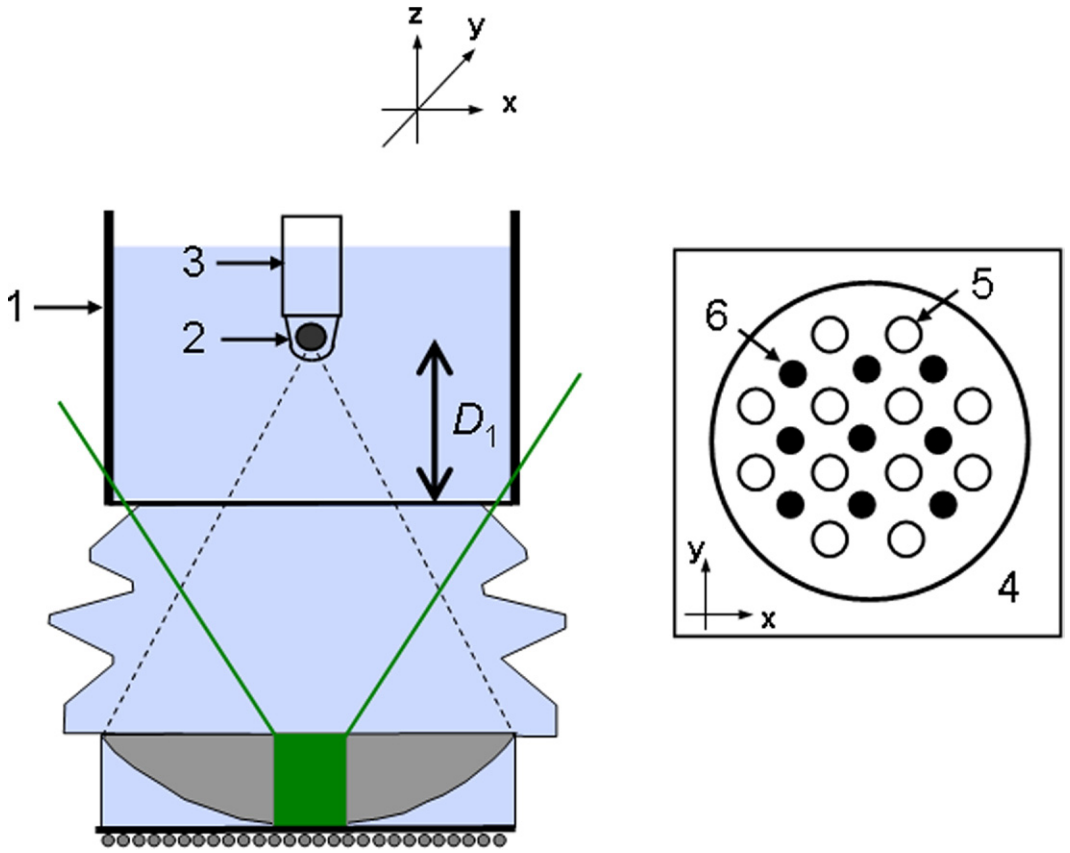

Figure 4. Experimental setup for model stone test. Test basin (*1*) with degassed water was mounted to SW source. Model stone (*2*) was positioned at SW focus by holder (*3*). Test was done under different coupling conditions, ie different number of artificial air bubbles. Coupling area (*4*) is shown with markings (*5*) and artificial air bubbles (*6*).

typical energy setting (level 7). At each test condition 3 model stones were fragmented.

RESULTS

Patients and Gel Application

Included in study were a total of 30 SWL treatments in 21 male and 5 female patients. The stone was located in the kidney at 26 treatments and in the ureter at 4. The stone was imaged by x-ray in 20 cases and by isocentric ultrasound in 10. Mean ± SD patient body mass index was 27.2 ± 4.5 kg/m^2.

At 20C and 37C the viscosity of the custom-made gel (43 and 43 Pa-seconds) was significantly lower than that of Sonogel (145 and 150 Pa-seconds) or LithoClear (124 and 119 Pa-seconds, respectively). The custom-made gel flowed easily catching bubbles when the gel bottle was turned upside down. When applying Sonogel or LithoClear, the corresponding containers had to be squeezed more and the gel remaining in the bottle showed some bubbles, which did not disappear. Stickiness was advantageous since after application Sonogel or LithoClear adhered to the cushion surface even when it was rotated at an angle while the custom-made gel flowed down toward the floor.

The gel was applied to the cushion as a mound or spread by hand in 15 cases each. The amount of gel varied between 75 and 250 ml. If the cushion lost contact after coupling, the operators did not restore the coupling or wipe the cushion.

Coupling Quality Quantitative Evaluation

Figure 3 shows an example of the imaged coupling zone and the calculation of A_{air}. Table 1 lists the results of the 30 treatments by gel type.

Table 1. *Coupling quality of all 30 treatments by 3 coupling gels, respectively*

	No. Treatments		
% A_{air}	LithoClear	Sonogel	Custom
Less than 5	3	—	7
5–10	1	5	1
10–20	3	2	—
Greater than 20	3	3	2
Totals	10	10	10

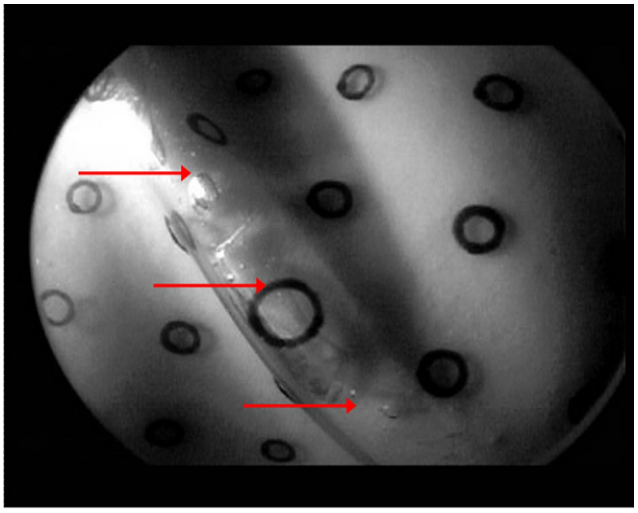

Figure 5. Coupling cushion with air filled fold (arrows). When cushion does not lie flat to skin, coupling is strongly disturbed.

In 8 cases A_{air} was greater than 20%, including 5 in which the cushion only partially contacted the patient. In these cases the gel was applied as a mound and did not spread sufficiently after contact. In another 2 cases the coupling was disturbed by an air-filled fold (fig. 5).

Most air bubbles entered the gel at the moment when the cushion touched the skin, immediately at the first coupling or after an intermediate decoupling. Decoupling events occurred at 11 treatments when the patient had to be repositioned, the cushion was retracted to obtain a better x-ray image under difficult to scan conditions or the patient moved. Otherwise the air bubble distribution remained stable throughout treatment. Only bubbles smaller than 2 mm oscillated at the SW release frequency. These small bubbles often moved toward the SW center and coalesced but without significantly increasing in size. Adjusting patient position by moving the stretcher did not result in new bubbles.

A_{air} was less than 5% in 3 and 0 of 10 treatments using the high viscous LithoClear and Sonogel gels, respectively (table 1). There were fewer bubbles when the gel was applied as a mound instead of spreading it by hand on the cushion. All 3 good results (A_{air} less than 5%) were achieved with gel applied as a mound. However, this method did not automatically lead to satisfactory results due to later decoupling or to the gel not spreading appropriately.

Results were better with the custom-made gel of low viscosity in that A_{air} was less than 5% in 7 of 10 treatments. It made no significant difference whether the gel was applied as a mound or spread by hand. Also, coupling recovered quite well after contact was lost while numerous bubbles appeared in LithoClear or Sonogel after a decoupling event.

Mean D ±SD between cushion surface and SW focus was 85 ± 24 mm (range 28 to 138). In 10 of 30 treatments D was greater than 100 mm, ie the cushion was rather deflated. In this group 5 cases showed strongly disturbed coupling with A_{air} greater than 20%. In the other 20 treatments with D less than 100 mm this poor coupling condition was observed in only 3 cases.

If the monitor showed air inclusions in the coupling zone, the observer removed the bubbles by wiping (fig. 1). Perfect coupling could be achieved in all cases. Improvement was readily visible on the monitor (fig. 3, *D*).

Model Stone Tests

Table 2 shows the results. Compared with the bubble-free coupling situation the number of shocks needed for complete stone fragmentation was already about a factor of 1.2 greater when A_{air} was 5%. Under poorer coupling conditions, ie an A_{air} of 20%, the number of shocks was about 3 times greater.

DISCUSSION

To our knowledge we report the first clinical study of the quality of acoustic coupling during SWL. Previous reports relied on in vitro studies or examinations with probationers.[4–12,16]

Visualizing the coupling area using a camera showed that coupling was disturbed during most treatments (table 1). In all cases with A_{air} greater than 5%, ie in 20 of 30, transmitted SW energy would have been significantly decreased if coupling had not been manually improved. Particularly when A_{air} was greater than 20%, treatment most likely would have failed. The in vitro model stone tests using the same lithotripter as for patient treatment confirmed the results of previous studies showing that the disintegration efficiency of a lithotripter is sensitive to air inclusions in the gel (table 2).[7–12]

The study provides evidence of the previous assumption that acoustic coupling is a relevant problem in clinical SWL.[7,13,18] Insufficient cou-

Table 2. *SWs needed for fragmentation during model stone tests with different coupling conditions and at 2 Ds between SW focus and coupling surface*

	Mean ± SD No. Shocks	
Coupling Condition	51 mm D	90 mm D
Bubble free	103 ± 2	100 ± 4
% A_{air}:		
5	122 ± 5	126 ± 3
10	177 ± 6	151 ± 8
20	387 ± 32	287 ± 5

pling appears to be an important factor of the less satisfactory treatment outcomes of modern lithotripters compared with those of the HM3. Using the latter device perfect coupling is guaranteed using the bathtub.

When the cushion was deflated, ie when there was a substantial skin-to-stone distance, coupling was more often disturbed. Studies using modern lithotripters showed that a great skin-to-stone distance correlates with a poor treatment outcome[19,20] while no such relationship was identified for the HM3.[18] Insufficient coupling could explain these differing results.[13]

We could not correlate perfect or poor coupling conditions with the corresponding treatment results of the study patients. Due to incomplete followup protocols, the lack of an appropriately documented control group and our low patient number the clinical effect was not verified. Thus, this is the objective of a subsequent study.

To avoid SWL failure due to poor acoustic coupling we must address coupling problems. Our series revealed that a camera is ideal for this purpose since it allows the operator to monitor coupling and improve it as needed. Thus, the camera feature that we used should become standard with future lithotripters. Inline ultrasound can be used in a similar way.[12] However, a camera is better suited since it presents the whole coupling area at a glance. With inline ultrasound the transducer must be rotated for a complete scan. Therefore, evaluating the magnitude of air inclusions and removing the disturbance by manual wiping becomes more difficult.

When the coupling area cannot be visualized by a camera or inline ultrasound, it is essential to follow the guidelines for good coupling.[12,14,16] In addition to the previous recommendations, our study showed that the gel may sometimes not fully spread as intended when applied as a mound. Thus, particularly when the cushion is deflated, it is recommended to improve gel spreading by wiping (fig. 1). At the same time any possible folds may be removed. Without camera feedback wiping may not always result in perfect coupling but it should at least avoid poor conditions under which A_{air} is greater than 20%. This is also recommended when coupling is temporarily interrupted. Such decoupling events, which were observed quite frequently, could negate all previous efforts to apply gel properly.

A low viscosity gel appears to be an effective way to improve coupling in clinical practice.[7,11] In an in vitro study Bergsdorf et al observed that fewer air inclusions result from using low viscosity gel than middle and high viscosity gels.[11] Nonetheless, the magnitude of the effect in the clinical situation was surprising (table 1). The low viscosity gel was much less susceptible to bubble uptake. However, it is questionable whether low viscosity gel would be widely accepted since it tends to flow downward toward the floor, requiring additional cleaning after treatment.

CONCLUSIONS

This clinical study shows the practical relevance of coupling for SWL. During most treatments the applied SW energy was decreased due to disturbed coupling. Video monitoring of the coupling area is ideal to achieve perfect coupling.

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Coupling

- Air pockets in the coupling medium
  - 2% surface area = 40% decrease in fragmentation
    - J Urol. 2006 Dec;176(6 Pt 1):2706-10

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Effect of initial shock wave voltage on shock wave lithotripsy-induced lesion size during step-wise voltage ramping

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OBJECTIVE

To determine if the starting voltage in a step-wise ramping protocol for extracorporeal shock wave lithotripsy (SWL) alters the size of the renal lesion caused by the SWs.

MATERIALS AND METHODS

To address this question, one kidney from 19 juvenile pigs (aged 7–8 weeks) was treated in an unmodified Dornier HM-3 lithotripter (Dornier Medical Systems, Kennesaw, GA, USA) with either 2000 SWs at 24 kV (standard clinical treatment, 120 SWs/min), 100 SWs at 18 kV followed by 2000 SWs at 24 kV or 100 SWs at 24 kV followed by 2000 SWs at 24 kV. The latter protocols included a 3–4 min interval, between the 100 SWs and the 2000 SWs, used to check the targeting of the focal zone. The kidneys were removed at the end of the experiment so that lesion size could be determined by sectioning the entire kidney and quantifying the amount of haemorrhage in each slice. The average parenchymal lesion for each pig was then determined and a group mean was calculated.

RESULTS

Kidneys that received the standard clinical treatment had a mean (SEM) lesion size of 3.93 (1.29)% functional renal volume (FRV). The mean lesion size for the 18 kV ramping group was 0.09 (0.01)% FRV, while lesion size for the 24 kV ramping group was 0.51 (0.14)% FRV. The lesion size for both of these groups was significantly smaller than the lesion size in the standard clinical treatment group.

CONCLUSIONS

The data suggest that initial voltage in a voltage-ramping protocol does not correlate with renal damage. While voltage ramping does reduce injury when compared with SWL with no voltage ramping, starting at low or high voltage produces lesions of the same approximate size. Our findings also suggest that the interval between the initial shocks and the clinical dose of SWs, in our one-step ramping protocol, is important for protecting the kidney against injury.

KEYWORDS

tissue injury, animal models, renal protection

INTRODUCTION

While extracorporeal shock wave lithotripsy (SWL) is considered a highly effective treatment for upper urinary tract stones, concerns about the safety and efficacy of SWL have dampened enthusiasm for the treatment [1–3]. These concerns have been heightened by the fact that second generation and more recent lithotripters appear less effective at breaking stones [4–7] and cause more tissue injury [8,9] than the original unmodified Dornier HM-3 lithotripter.

Our research has focused on the development of new treatment strategies to improve the safety and efficacy of SWL. One of these strategies involves 'step-wise voltage ramping' where treatment commences at a low SW voltage and then is subsequently increased with time. Originally, voltage ramping appears to have been introduced in the clinic as a means to reduce patient discomfort during SWL by allowing patients to acclimate to the SWL treatment without anaesthesia. Subsequent *in vitro* [10,11] and *in vivo* [12] studies applying this approach suggested that voltage ramping also improves stone fragmentation. More recently, a clinical comparison of voltage ramping against standard SWL treatment showed improved stone comminution with voltage ramping while using only a modest (11–13 kV) step-wise increase in SW voltage [13].

While voltage ramping appears promising for enhanced stone breakage, it is equally important to understand the consequences of step-wise voltage ramping on SWL-induced kidney injury. Willis *et al.* [14] provided the first data showing an effect of single-step voltage ramping on tissue injury. In that study porcine kidneys were treated with a limited number of low-energy (12 kV) SWs followed by a larger number of high-energy (24 kV) SWs, the latter being consistent with a standard dose of SWs used in the clinic. This strategy substantially reduced the acute haemorrhagic lesion normally observed in porcine kidneys after conventional SWL.

However, questions remain as to why a step-wise change in treatment voltage would 'protect' kidneys from injury. One such question concerns the starting SW voltage. Some groups begin their voltage-ramping protocol at 11 kV [13] while others report

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using 17 kV [15] or 18 kV [11,12], but no one has yet examined the relationship between starting voltage and renal injury. Because we have previously shown a positive correlation between the voltage and lesion size [16], we hypothesized that as the starting voltage increases, the subsequent lesion sizes will increase. Accordingly, the present study was undertaken to determine if the starting voltage in a step-wise ramping protocol alters the size of the renal lesion caused by the SWs.

MATERIALS AND METHODS

The present study was carried out with an unmodified Dornier HM-3 lithotripter (Dornier Medical Systems, Kennesaw, GA, USA) located at Methodist Hospital, Indianapolis, IN, USA. This lithotripter has an 80 nF capacitor and a focal zone (F2) of about 1.5 cm diameter × 2.5 cm length. Refurbished spark plugs (Healthtronics, Kennesaw, GA, USA) were used for all experiments and were discarded after 1000 shots.

The experimental protocol used in this study was carried out in accordance with the National Institutes of Health Guide for the Care and Use of Laboratory Animals and was approved by the Institutional Animal Care and Use Committee of the Indiana University School of Medicine. Nineteen female farm pigs, aged 7–8 weeks (Hardin Farms, Danville, IN, USA), were assigned to receive either 2000 SWs at 24 kV (a standard clinical treatment protocol, $n = 7$), 100 SWs at 18 kV followed by 2000 SWs at 24 kV ($n = 7$) or 100 SWs at 24 kV followed by 2000 SWs at 24 kV ($n = 5$). Both ramping protocols included a 3–4-min pause in SW delivery between the first 100 SWs and the remaining 2000 SWs to check targeting of F2. All SWs were delivered at a rate of 120 SWs/min. This protocol builds on a previously published study using 100 SWs at 12 kV followed by 2000 SWs at 24 kV [14]. That study was carried out with the same lithotripter, pigs of the same size and the same protocol as the present experiment.

At the beginning of the experiment the pigs were rendered unconscious with an i.m. injection of ketamine (15–20 mg/kg) and xylazine (2 mg/kg). They were then intubated and anaesthetized with isoflurane (1–3%) throughout the experiment. Sterile saline was infused through an ear vein at a rate of 1–3% of body weight per hour to maintain adequate hydration and urine flow. Surgical procedures for the placement of femoral artery and bilateral ureteric catheters have been described previously [17].

After a post-surgery acclimation period (2–2.5 h), the pigs were disconnected from the anaesthesia machine and transferred (unconscious) to the lithotripsy suite (a trip of ≈5 min) where administration of isoflurane anaesthesia was resumed. The pigs were then placed supine in the gantry of the HM-3 lithotripter. The pigs were positioned in the water bath (39 °C) so that one kidney could be exposed to the SWs. Positioning of each pig was accomplished by injecting a small amount of contrast medium (Renografin 60%, Bracco Diagnostics, Princeton, NJ, USA) through the ureteric catheter into the urinary collection system of the kidney to be treated. Using the positioning fluoroscopes of the lithotripter, F2 was located on a lower pole calyx of that kidney. The pigs were then treated with one of the three protocols listed above.

After SWL, each pig was returned to the surgical suite (once again disconnected from the anaesthesia machine for ≈5 min). At 4 h after the completion of the lithotripsy treatment, the kidneys were perfusion-fixed with 2.5% glutaraldehyde in 0.1 M sodium cacodylate buffer (pH = 7.4) as previously described [18]. After perfusion, the kidneys were removed and submerged in fresh fixative for subsequent determination of lesion size.

Kidneys used for quantification of lesion size were processed according to our previously published protocol [19]. Briefly, each kidney was cast, embedded in paraffin and serial sections were cut on a sliding microtome. A digital image of each section was captured and a computer-assisted segmentation technique was used to quantify the haemorrhagic lesion as a volume percentage of the total functional volume (FRV) of each treated kidney. The mean (SEM) was calculated for lesion size in each of the treated pigs.

The Kruskal–Wallis test, a nonparametric ANOVA for non-normally distributed data, was used for statistical analysis. Significant overall differences in the group medians were followed by *post hoc* comparisons adjusted by the Bonferroni method (comparing the standard clinical treatment protocol group, and the 18 kV and 24 kV voltage-ramping groups). The criterion for statistical significance was set at $P < 0.05$.

RESULTS

Figure 1 shows a digitized and pseudo-coloured cross-section of a kidney from each of the three treatment groups. Pigs from the standard clinical treatment group had a mean (SEM, range) lesion size of 3.93 (1.29, 1.15–9.37)% FRV. These kidneys had many areas of intraparenchymal bleeding. These sites were localized at the focus of the SW and involved both the cortex and medulla. In some cases, the haemorrhage extended all the way from the papilla tip to the capsule resulting in a subcapsular haematoma (Fig. 1). Kidneys from pigs in the 18 kV and 24 kV ramping groups lacked surface haematomas and contained very few areas of intraparenchymal haemorrhage. These damage sites were small, and were found almost exclusively in the medulla. The mean (SEM, range) lesion size for the 18 kV ramping group was 0.09 (0.01, 0.0–0.1)% FRV while the lesion size for the 24 kV ramping group was 0.51 (0.14, 0.15–0.87)% FRV. The mean lesion size for both of these groups was significantly smaller than the lesion size of pigs in the standard clinical treatment group ($P = 0.003$ for 18 kV, $P = 0.014$ for 24 kV).

DISCUSSION

These findings suggest that the beginning voltage is not the key determinant responsible for reduced lesion size in our ramping protocol. Starting voltages of 12 kV [14], 18 kV or 24 kV all produced the same degree of protection when compared with conventional nonramped SWL.

Studies over the last 20 years in our laboratory have shown that the application of 2000 SWs (24 kV, with a Dornier HM-3) to a juvenile pig kidney consistently produces a morphological lesion that averages 4–6% of the FRV [14,16,20]. Recently, Willis *et al.* [14] reported that one can 'protect' a kidney, i.e. reduce tissue injury, by treating that kidney with a series of low voltage shocks before delivering a clinical dose of SWs. While the cause of the protection is unknown, several factors could potentially trigger the response; e.g. the number of SWs given at the beginning of treatment, the starting voltage of the SWs, and the time interval between the SW applications.

The SW number was tested when Willis *et al.* [14] reduced the initial treatments of low voltage (12 kV) SWs from 2000 to 500 in one

series of experiments, and then to 100 in another series. Similar protective responses occurred in each instance, indicating that if a threshold exists for the number of SWs needed to trigger the protection, it must be ≤100. Certainly, further study will be needed to determine if <100 SWs will still invoke tissue protection.

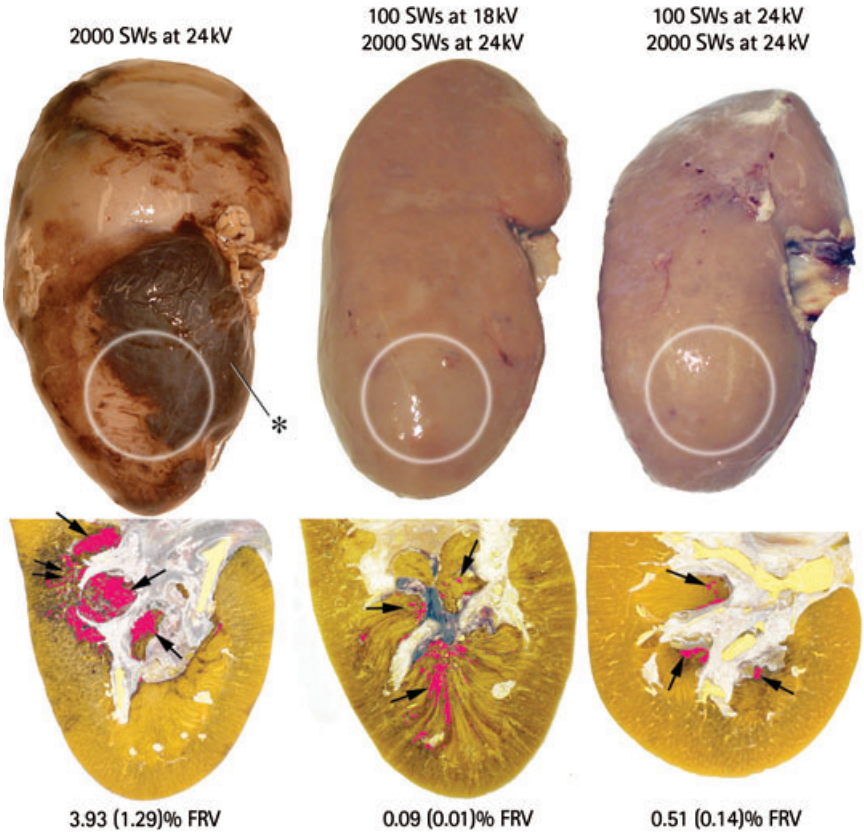
The second potential factor, starting voltage, was examined in the present study. Previous experience has shown us that tissue injury increases as treatment voltage increases [16]. In fact, we have shown that lesion size can increased 20-fold with only a doubling of SW voltage (12–24 kV) [16], and this led us to hypothesize that as the initial ramping voltage was increased the size of the renal lesion would also increase. However, the data showed that protection was comparable whether the treatment started at 12 kV [14], 18 kV or 24 kV. This suggests that, as a starting voltage of 24 kV was as effective as 12 kV at preventing renal injury, voltage ramping per se is not solely responsible for limiting lesion size. What mechanisms initiate the protective effect and how these mechanisms work to reduce lesion size are unknown. Recent work by Handa *et al.* [21] suggests that an increase in renal vascular resistive index, presumably from constriction of renal blood vessels during SWL, is involved in mediating the protective response, but these findings tell us nothing about what initiates the response.

The present findings support the rationale for using a voltage-ramping protocol in clinical SWL, as step-wise voltage ramping (from low to high voltage) improves stone fragmentation [10–13], and also limits renal injury. The present results indicate that a range of starting voltages (12–24 kV) can work to initiate the protective effect in the treated kidney. And, at least as conducted in the present experiment, voltage ramping causes less injury to the kidney than conventional nonramping protocols. Accordingly, clinical voltage-ramping protocols could be designed where the treatment regimens are optimized for stone fragmentation with the expectation that the ramping protocol will also initiate the protective response and limit injury. Clinical studies are needed to confirm this expectation.

The most intriguing and new implication arising from the present findings concerns, oddly enough, the 3–4-min interval of inactivity between the two applications of SWs. If starting voltage is not the factor that initiates the protective response, as appears to be the case in the present study, then the 3–4-min interval between the initial and clinical doses of SWs emerges as the principle factor that could be responsible for the protection. Otherwise, the 100 SWs at 24 kV ramping protocol, which includes the 3–4-min interval, should have produced a lesion at least as large as that without voltage ramping [14,16,20]. Although the present studies have not tested that the interval between SWs initiates the protection response, our data clearly suggest such a possibility. This, in turn, raises concerns for ramping protocols currently in use that do not include a resting interval between SWs applied at different energies. If a resting interval is critical for reducing SWL-related tissue damage, ramping protocols lacking this interval may predispose patients to unnecessary injury. Clearly, further study is needed to determine exactly if and how a period of inactivity between groups of SWs protects renal tissue from SWL-induced injury, but prudence suggests that brief resting intervals be added to clinical ramping protocols.

In conclusion, the present findings suggest that the initial voltage of a one-step voltage-ramping protocol for SWL does not correlate with renal damage. That is, voltage ramping

FIG. 1. Gross appearance of kidneys treated with 2000 SWs at 24 kV (standard treatment), 100 SWs at 18 kV followed by 2000 SWs at 24 kV, or 100 SWs at 24 kV followed by 2000 SWs at 24 kV with an unmodified Dornier HM-3 lithotripter. The white circles show the approximate location of the SW focus (F2) on the lower pole of each kidney. Note that no sites of haemorrhage are evident on the kidneys using the one-step ramping protocol of 18 kV or 24 kV, while a large subcapsular haematoma (asterisk) is located on the kidney after standard treatment. Beneath the gross view of each kidney is a lower pole section showing the typical lesion found using each protocol and the average lesion size calculated in each group (expressed as the mean (SEM) of the percentage of the FRV). The lesion has been segmented and pseudo-coloured (red), so that the size of the SWL-induced injury can be appreciated. Single arrows point to papillae showing evidence of haemorrhagic injury. Double arrows indicate an area where the injury extended up into the cortex, a common finding in the kidneys from pigs after the standard treatment.



reduced the amount of renal injury when compared with nonramped SWL regardless of whether low or high voltage SWs were applied to start the ramping protocol. Our findings also suggest that the time interval between the first and second sets of SWs, as used in our experiments, may initiate the response that limits the renal injury caused by SWL.

ACKNOWLEDGEMENT

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CONFLICT OF INTEREST

None declared. Source of funding: NIH grant.

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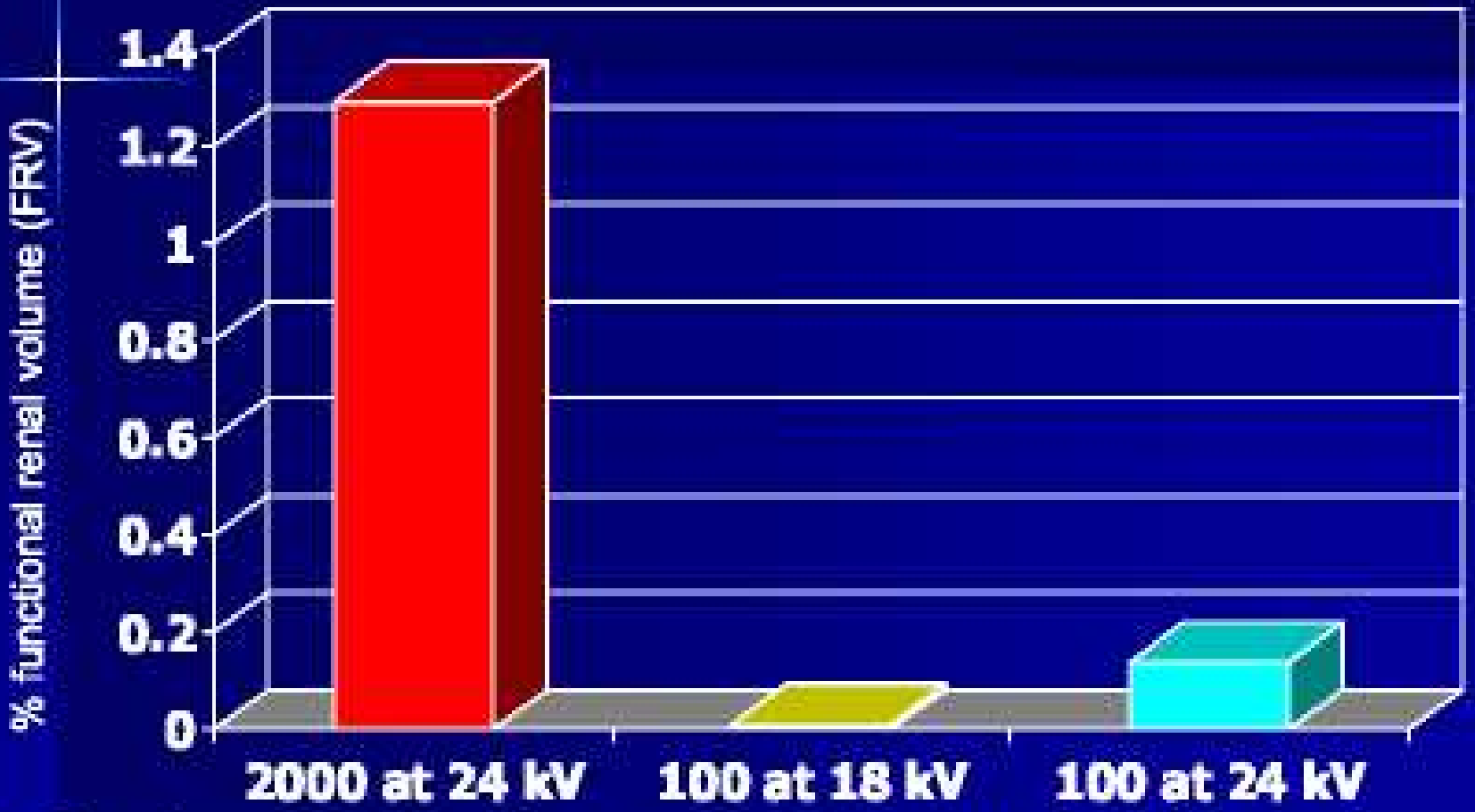
e-mail: connors@anatomy.iupui.edu

Abbreviations: **SW(L)**, shock wave (lithotripsy); **FRV**, functional renal volume; **F2**, focal zone.

Pause for the Cause

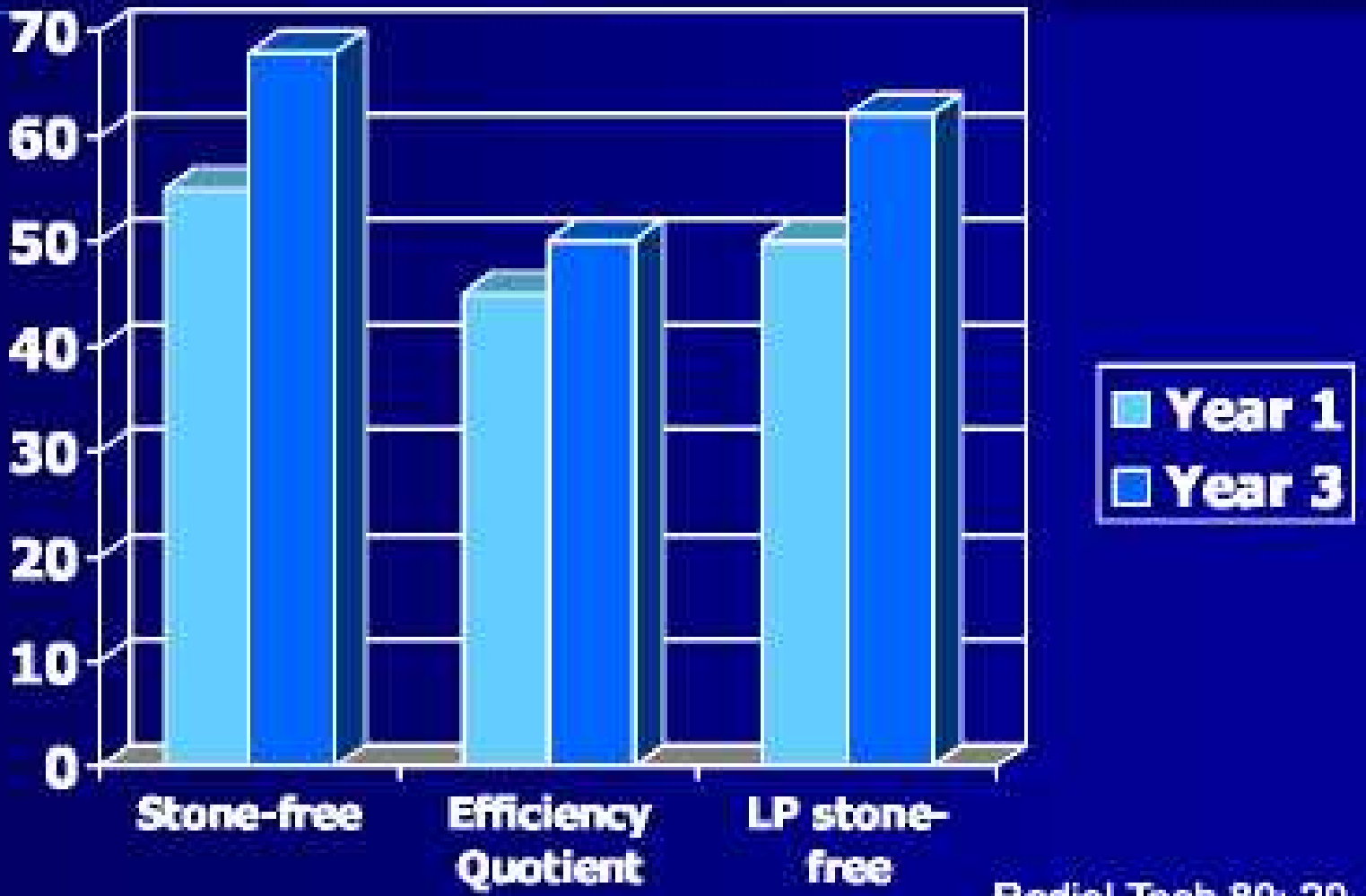


- 3 minute pause between priming shocks and treatment is the key

BJU Int. 2009 Jan;103(1):104-7.

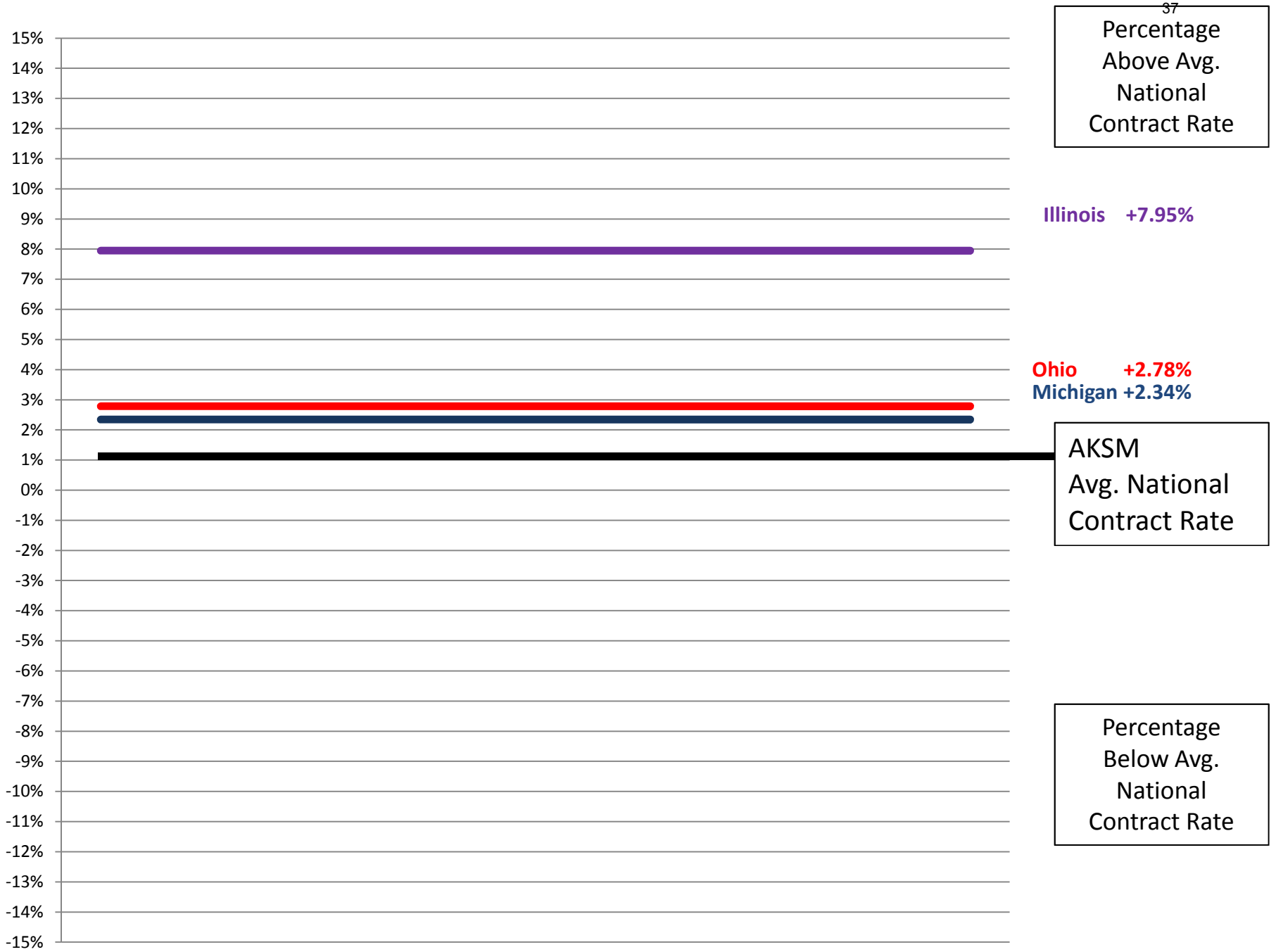
Exhibit 7

Litho Tech Learning curve



Radiol Tech 80: 20, 2008

Exhibit 8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Michigan +2.34%
AKSM Avg. National Contract Rate
Percentage Below Avg. National Contract Rate

UMS
UNITED MEDICAL SYSTEMS

July 17, 2013

Mr. Edward B. Goldman,
Chairman
CON Work Group, Lithotripsy

Re: CON Regulation for UESWL Services

Dear Mr. Goldman,

Thank you for the opportunity to participate in the Lithotripsy CON Workgroup last month. I thought the meeting was well attended and brought all of the key issues to the forefront for a very substantive discussion. As requested at the meeting, I am writing to follow up with documentation on some of the issues discussed.

As discussed last month, Michigan can be proud of having one of the most successfully implemented CON regulations, of any state. Quality, access and cost, are benefitting all the constituents who have an interest in providing this important service to the citizens of Michigan. Changing the regulation status of Lithotripsy can only have a negative impact on the three main objectives of the law.

Attached is a summary of the notable points discussed at last month's meeting, including references to attached documentation. We believe the continued regulation of lithotripsy under the CON standards is appropriate. We believe that health facilities, patients, and payers are all best served by the continued regulation of lithotripsy under the Certificate of Need program. I appreciate your time in chairing the workgroup and bringing these points to the CON Commission for their consideration. Please feel free to contact me directly with any questions at 1-800-516-9425.

Respectfully,

Jorgen Madsen
CEO

1500 West Park Drive, Suite 390
Westborough, MA 01581
Phone: 508-870-6565
Fax: 508-870-0682
www.ums-usa.com

Certificate Of Need

Mission: Access, Cost & Quality

Access:

Under the current lithotripsy CON structure, UMS and GLL have 7 mobile Units providing service at more than 65 sites of service. In 2012, the Units provided 1271 days of service, averaging 15 days of service per month per unit. Based upon an average of 21 business days per month, this leaves 6 days of service available on each Unit for a total of more than 500 days per year still unused. In addition, the average number of cases performed per day was 7 during 2012. Each Unit is capable of doing up to 14 or more cases per day. Any facility not currently receiving lithotripsy services can apply for a CON and generally be approved based upon current capacity levels. There should be no waiting lists at any facility. Any facility, whether large or small, urban or rural, can have lithotripsy service access if needed.

Cost:

Lithotripsy units cost anywhere from $600K to $800K depending on manufacturer and configuration. By mobilizing these units and spreading that cost over multiple facilities, the cost impact to the healthcare system is dramatically reduced. Nationally, the charge by a mobile lithotripsy provider to the facility receiving service is between $2,200 and $2,400 per procedure (see attached SEC 10K filing from HealthTronics). However, in Michigan the average rate is between $1,400 and $1,500 per procedure.

Quality:

Currently, our average technologist does more than 100 lithotripsy procedures per month, or more than 1,200 per year. The techs become highly skilled in the procedures because of this high level of volume. Quality comes from repetition (see attached American Urological Association White Paper). The average tenure of technologists in the GLL Michigan fleet is 9 years (see attached technologist experience data).

Deregulation consequences:

If deregulation were to occur there would be a massive proliferation of lithotripsy equipment within the State of Michigan. Each hospital or physician's practice of reasonable size would engage in a "technology arms race" to promote that they have the "next best widget" in lithotripsy. The need to recover the cost of this influx in technology will no doubt drive the pricing of services higher and could lead to unnecessary procedures being performed. In addition to the potential for higher costs, the quality of service would suffer as the technologists, who operate the Units on a day-to-day basis, would perform less procedures and the level of overall skill would degrade.

Access, quality and cost would potentially be negatively affected in particular for small and rural facilities after deregulation. Under the current system, facilities do not pay a different price due to their size and all receive the same high quality of service. If the higher volume accounts were cherry picked, either with own units or other possible scenarios, then the cost of servicing smaller and lower volume accounts would go up and unfairly disadvantage those smaller rural facilities.

Lithotripsy is not regulated under any law other than the CON. With deregulation there would be no limit to what setting could be used to facilitate the procedure. Lithotripsy is a relatively safe procedure, but only if provided in the right setting with proper medical back up capacity (see attached AUA White Paper). We do not believe that, for example, a physician's office would be the most appropriate setting for the procedure. However we have seen plenty of examples in non CON states, where the financial incentive drove a movement to perform the procedure in a less optimal setting.

An example of another urology procedure/device where the lack of CON regulation has resulted in undesirable consequences can be found in the so called DaVinci robotic procedure. Here is an example of how the "Medical Arms Race" has had a negative effect on all three of the major tenets of CON: cost quality and access. Due to competitive pressure from large urban medical facilities, many smaller hospitals have bought this technology, to ensure their competitiveness, even though it is not financially feasible as a standalone decision. Many times this can be driven by a need to attract physicians to these rural facilities. However, unless a physician performs a large number of these robotic procedures, his/her skill set is never going to be proficient. As a result, quality suffers, costs rise, and access to quality care is not benefitting. There are many law suits in progress around the country regarding the use of this technology and we encourage the commission to further investigate what the negative consequences to unfettered access can result in. (See attached CNBC article on the Da Vinci robot.)

Statements that are predictive in nature, that depend upon or refer to future events or conditions, or that include words such as "will", "would", "should", "plans", "likely", "expects", "anticipates", "intends", "believes", "estimates", "thinks", "may", and similar expressions, are forward-looking statements. The following important factors, in addition to those discussed under "Risk Factors" under Part I, Item 1, could affect the future results of the health care industry in general, and us in particular, and could cause those results to differ materially from those expressed in such forward-looking statements.

- uncertainties in our establishing or maintaining relationships with physicians and hospitals;
- the impact of current and future laws and governmental regulations;
- uncertainties inherent in third party payors' attempts to limit health care coverages and levels of reimbursement;
- the effects of competition and technological changes;
- the availability (or lack thereof) of acquisition or combination opportunities;
- the integration of acquired business; and
- general economic, market or business conditions.

General

We provide healthcare services and medical devices, primarily to the urology marketplace.

Lithotripsy services. We provide lithotripsy services, which is a medical procedure where a device called a lithotripter transmits high energy shockwaves through the body to break up kidney stones. Our lithotripsy services are provided principally through limited partnerships and other entities that we manage, which use lithotripters. In 2009, physicians who are affiliated with us used our lithotripters to perform approximately 50,000 procedures in the U.S. We do not render any medical services. Rather, the physicians do.

We have two types of contracts, retail and wholesale, that we enter into in providing our lithotripsy services. Retail contracts are contracts where we contract with the hospital and private insurance payors. Wholesale contracts are contracts where we contract only with the hospital. The two approaches functionally differ in that, under a retail contract, we generally bill for the entire non-physician fee for all patients other than governmental pay patients, for which the hospital bills the non-physician fee. Under a wholesale contract, the hospital generally bills for the entire non-physician fee for all patients. In both cases, the billing party contractually bears the costs associated with the billing service, including pre-certification, as well as non-collection. The non-billing party is generally entitled to its fees regardless of whether the billing party actually collects the non-physician fee. Accordingly, under the wholesale contracts where we are the non-billing party, the hospital generally receives a greater proportion of the total non-physician fee to compensate for its billing costs and collection risk. Conversely, under the retail contracts where we generally provide the billing services and bear the collection risk, we receive a greater portion of the total non-physician fee.

Although the non-physician fee under both retail and wholesale contracts varies widely based on geographical markets and the identity of the third party payor, we estimate that nationally, on average, our share of the non-physician fee was roughly $2,100, respectively, for both 2009 and 2008. At this time, we do not anticipate a material shift between our retail and wholesale arrangements, or a material change in our share of the non-physician fee.

WHITE PAPER

Current Perspective on Adverse Effects in Shock Wave Lithotripsy

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INTRODUCTION

In May 2006, a peer-reviewed paper published in *The Journal of Urology* reported the findings of a long-term follow-up study at the Mayo Clinic in which it was concluded that patients treated by shock wave lithotripsy (SWL) had an increased incidence of diabetes mellitus and were more likely to develop new-onset hypertension.[1] This report drew immediate attention in the popular press and sparked editorial comment in the urology literature.[2,3] Although research dating back to the 1980s had established a link between SWL and hypertension in some patient groups, the Mayo Clinic report was the first to suggest diabetes mellitus as a potential long-term consequence of lithotripsy. At the present time, it is widely accepted among clinicians that SWL is a safe procedure, and that the complication rate and severity of adverse effects are minimal and tolerable considering the benefits of this entirely noninvasive therapy. However, it has long been recognized by researchers that shock waves (SWs) can cause injury to the kidney and that acute tissue damage due to SW treatment can be significant.[4-7] Now, with the possibility of chronic, life-altering adverse effects linked to lithotripsy, it is clear that the potential for long-term effects in SWL needs to be addressed.

As patient safety is a fundamental concern of the American Urological Association (AUA), a Task Force (Appendix 1) was established to provide expert opinion on the issue of adverse effects in SWL. The following report offers perspective on the current status of SWL with the goal of addressing three main questions 1) Is shock wave lithotripsy safe? , 2) Are the chronic adverse effects linked to SWL significant? , 3) Do the advantages of SWL outweigh the potential risks? This report focuses on clinical evidence. However, information from animal studies is reviewed to illustrate the tissue effects of shock wave energy.

CURRENT STATUS OF SHOCK WAVE LITHOTRIPSY

Shock wave lithotripsy was introduced as a clinical treatment for renal calculi by Chaussy and colleagues in Munich in 1980 utilizing a prototype device, the Dornier HM1 (for Human Machine).[8] The first widely distributed clinical lithotriptor, the Dornier HM3, was introduced to the United States in February 1984. This was followed by rapid acceptance of this noninvasive technology as a treatment alternative for renal and ureteral stones in the United States.

At the time of its introduction into clinical use, SWL was applied to a broad spectrum of upper urinary tract stone problems. With growing experience, urologists realized that there was a limit to the ability of the kidney and ureter to discharge stone fragments and, thus, the concept of stone burden (stone size and number) became important in selecting appropriate patients for lithotripsy. Currently, SWL is indicated for most uncomplicated upper urinary tract calculi; that is, an aggregate stone burden of <2 cm in kidneys with normal renal anatomy. Shock wave lithotripsy is also considered an appropriate alternative for the management of ureteral stones anywhere in the ureter with a few caveats (pregnancy, mid and lower ureteral stones in women of child bearing age).[9-11]

A number of factors can affect outcomes in SWL. For example, some mineral types (i.e., homogeneous cystine, brushite, some calcium oxalate monohydrate stones) are particularly resistant to fragmentation by SWs.[12] Renal anatomy can be problematic and in particular, stone location in the lower pole, the presence of renal anomalies (horseshoe kidney, calyceal diverticula, renal ectopy) and significant hydronephrosis all reduce SWL stone-free rates.[9] The effectiveness of lithotripsy is affected by body mass index, and studies indicate reduced outcomes when skin-to-stone distance is greater than about 10 cm.[14] In addition, outcomes for a given lithotriptor may be affected by factors such as the experience of the operator and the treatment protocol, but there is also evidence to suggest that some lithotriptors are less effective than others.[13, 15-19]

In summary, the advantages of SWL include its noninvasive nature, the fact that it is technically easy to treat most upper urinary tract calculi and that, at least acutely, it is a well tolerated, low morbidity treatment for the vast majority of patients. On the other hand the disadvantages of SWL are that retreatments may be necessary, and there appears to be a volume of fragments (when stone burden exceeds ~2 cm) that becomes problematic for the ureter to discharge.

LITHOTRIPSY ADVERSE EFFECTS

SHOCK WAVE LITHOTRIPSY TRAUMA TO THE KIDNEY: ACUTE EFFECTS AND MECHANISMS OF SHOCK WAVE INJURY

Animal studies have clearly established that SWs cause damage to the kidney vasculature.[4-6, 20] Morphological analysis of pig kidneys treated with a clinical dose of SWs has shown that veins are particularly susceptible to injury and that vascular damage occurs to a broad range of vessels, from vasa recta and cortical capillaries to intralobular and arcuate arteries and veins.[4, 6, 21, 22] Most animal research in SWL injury has been conducted using the Dornier HM3 electrohydraulic lithotriptor, but all lithotriptors studied have produced vascular damage.[23]

Shock wave lithotripsy can cause parenchymal bleeding and mild to severe subcapsular hematomas. Radiologic detection of hematomas in patients after SWL was perhaps the first indication of the adverse effects of SWs.[24] Although some hematomas persist, it is reported that most resolve without lasting adverse effect.[25] Large hematomas, while uncommon, are a potentially significant clinical event that may lead to blood transfusion and acute renal failure, fortunately rare events.[26-31] Hematoma rates may depend in part on the type of lithotriptor as values of less than 1% and up to 13% have been reported for different machines.[6, 32, 33] Understandably, detection of hematomas is higher when computed tomography or magnetic resonance imaging is used.[34, 35] Clearly, not all patients are equally at risk of developing hematomas. Increasing age has been identified as a risk factor for hematoma development. Excluding individuals with clotting abnormalities, it has been reported that the incidence of hematomas increases about two-fold per decade.[36]

Most of what is known about shock wave injury to the kidney comes from work with experimental animals where invasive methods can be used to assess for damage at the tissue level. The standard for assessment of SWL trauma to the kidney is quantification of hemorrhage in the parenchyma. Such bleeding within tissue cannot be observed by routine x-ray or CT and is not linked to the occurrence of hematomas. Thus, the absence of a hematoma by x-ray or CT does not rule out the occurrence of potentially significant trauma to the SWL-treated kidney.

Tissue damage in SWL is dose-dependent. Studies in experimental animals have demonstrated that lesion size (i.e., the volume of hemorrhagic tissue) increases with the SW number and with the power setting of the lithotriptor.[37-39]

The precise physical mechanisms responsible for tissue damage in SWL have yet to be determined. A variety of studies suggest that cavitation (bubble formation and collapse) is involved, but other mechanisms may be at play as well.[23, 40, 41] Evidence that cavitation is involved includes the observation of increased hemorrhage when micro-bubbles or gas-laden micro-beads are injected into the circulation during SWL.[42, 43] It has also been shown that strategies to suppress cavitation, such as using

tandem delayed SWs or a phase-reversed waveform to interrupt bubble growth, significantly reduce tissue damage.[44, 45] It is important to note that cavitation does not occur readily in circulating blood, and it can take hundreds of SWs to generate bubble activity within tissue in the living kidney.[43, 46] This suggests that cavitation may be highly dependent on the micro-environment of the vasculature. It is hypothesized that cavitation within blood vessels is dependent on the presence of minute particles that act as nuclei for cavitation bubble formation. It has yet to be determined what constitutes a natural cavitation nucleus in the circulation, but the fact that cavitation does not initiate readily suggests that the blood vascular system is relatively free of such particles.[43] Shock wave induced shear has the potential to damage tissue, and such a mechanism may contribute to injury, particularly at fast SW rates. In vitro experiments have shown that when isolated cells are held under static pressure greater than the threshold for cavitation, SWs cause more cell lysis than in untreated controls.[47] This suggests that cell injury occurs in the absence of cavitation. In an in vivo study, pigs were treated with SWs from a lithotriptor (Dornier HM3) fitted with a reflector insert that suppressed cavitation without significantly reducing SW amplitude. This dramatically reduced vascular injury compared to animals treated with the standard reflector, but these animals still showed a modest degree of bleeding involving vessels of the renal papillae.[45] A subsequent numerical modeling study suggests that stress can accumulate within kidney tissue if the SW rate is faster than the displacement relaxation time of the tissue.[48, 49] The model predicts that the magnitude of shear deformation of the renal parenchyma varies for different regions of the kidney, and the portion of the renal medulla (inner medulla) closest to the tip of the papilla, the area of the kidney that is most susceptible to SW injury, will undergo the greatest strain. This lends support to the idea that vessel rupture could be induced by shear and that subsequent bleeding could create an environment for cavitation, in turn creating further SW damage.

In summary, lithotriptor SWs can cause acute tissue injury, primarily damage to blood vessels. This hemorrhagic injury is dose-dependent and can be severe. Hematomas can occur as a consequence of SWL but do not serve as a reliable marker of SW injury. Cavitation is a likely mechanism for SW injury, but shear may be involved as well.

CHRONIC INJURY: THE POTENTIAL FOR LONG-TERM ADVERSE EFFECTS IN SWL

A critical issue, central to the theme of this report, is the question of whether SWL injury can lead to long-term adverse effects. The limited research that has been conducted in this area indicates that long-term effects do, indeed, occur as a result of SWL. Renal scar formation may develop after

SWL. This was demonstrated in patients using Single Photon Emission Computed Tomography (SPECT) to measure exclusion of Technicium-99 label from areas of poor vascular perfusion. [50] Patients scanned before and 30 days following SWL showed a loss of marker uptake, and scars that developed measured larger (mean 19x15 mm) than the focal zone of the lithotriptor that was used.

Studies with experimental animals also show that acute SW damage leads to scarring. Chronic damage of this sort was first reported in a laboratory study in which dogs treated with SWL showed fibrosis after one month, and the severity of scarring was dependent on the dose of SWs.[20] A study in rabbits, likewise, showed a dose-dependent increase in scar formation one month after treatment and a significant increase (nearly 10-fold higher) in scar volume with treatment at 2,000 SWs compared to 1,000 SWs. [51] The inner medulla of the kidney may be particularly susceptible to SW damage, and a study in juvenile pigs has shown that treatment with 2,000 SWs can lead to complete atrophy of the renal papilla at three months post-SWL.[9]

Although these manifestations of chronic injury have been identified, it seems likely that the full spectrum of long-term injury—the form and severity of chronic adverse effects—has yet to be determined. It is intuitive that chronic effects derive from acute tissue damage, but very little is known about the progression of tissue changes that link the two. There is also limited information about treatment dose and the development of chronic effects and whether specific risk factors exist that predispose an individual to long-term effects.

New-onset hypertension is a potential consequence of SWL, and evidence suggests that blood pressure changes following lithotripsy may be dose dependent.[6, 23] This topic has stimulated considerable debate, as not all findings agree, but the implications posed by reports showing a link between SWL and hypertension are cause for concern.[1, 52-59] A credible prospective study by Janetschek et al. showed an increase in intrarenal resistive index in patients 60 years of age and older.[52] This finding implies that SW treatment for stone disease can have serious, long-lasting effects, and that age could be a risk factor.[55] One can only speculate about what cellular level mechanisms might be at play; however, the observation that SWL can stimulate mesangial cell proliferation in pigs up to one month after treatment suggests a potential causative factor.[60]

A POTENTIAL LINK HAS BEEN IDENTIFIED BETWEEN SWL AND THE DEVELOPMENT OF DIABETES MELLITUS

The Mayo Clinic retrospective case-control study by Krambeck et al. evaluated the long-term effects of SWL on 630 patients with renal and proximal ureteral stones treated with SWL using the HM3 lithotriptor in 1985.[1] A survey was sent to those patients still living in 2004 (489 patients). Patients

were asked to report on new conditions that developed since their original SWL. Survey response rate was 58.9% (n=288). Responders were matched 1:1 with regards to age, gender, and year of presentation to a group of urolithiasis patients treated conservatively (i.e., no surgical intervention) who were continuing active follow-up.

The study found an increased risk of developing hypertension at long-term follow-up after SWL compared to the control group (Odds Ratio [OR] 1.47, 95% Confidence Interval [CI] 1.03 to 2.1, p=0.034). The development of hypertension was also associated with bilateral SWL treatments (p=0.033). An additional and potentially concerning finding was that patients treated with SWL were more likely to develop diabetes mellitus compared to controls at long-term follow-up (OR 3.23, 95% CI 1.73 to 6.02, p<0.001). This risk persisted in multivariate analysis controlling for presence of obesity in 2004 (OR 3.28, 95% CI 1.49 to 7.24, p=0.003) and change in body mass index over 19 years (OR 3.75, 95% CI 1.56 to 9.02, p=0.003). The development of diabetes mellitus in the SWL group was also associated with the number of shocks administered (p=0.005) and the total intensity of the treatment (p=0.007). A follow-up article from the same group noted stone recurrence in 154 (53.5%) of the 288 SWL patients treated in 1985 at 19 years follow-up.[61] Pre-existing diabetes mellitus was not associated with recurrent stone events (p=1.000); however, recurrent stone events were associated with the development of diabetes mellitus (p=0.020).

The authors noted limitations to the study and did not make causal claims; however, they offered possible explanation for their findings. Reference is made to prior reports of acute symptomatic pancreatitis after SWL, providing evidence that the pancreas can be affected by SWs.[62] In addition, there is reference to a study demonstrating elevated serum amylase, lipase and urinary amylase up to one week after SWL of proximal ureteral and renal stones, while these enzymes were not increased when lower ureteral stones were treated.[63]

The Mayo Clinic report stimulated commentary that has urged caution in interpreting the results, citing several methodologic biases in the study design.[2, 3] First, the control patients in the study represent a different patient population. Average stone size of the control group was 0.45 cm (0.1 to 2.0) compared to 1.08 (0.2 to 3.0) in the SWL group; thus, the control group is considered to have less severe stone disease than the SWL group. Differences in stone size were not controlled for in multivariate analysis. Second, family history, a known risk factor for the development of diabetes mellitus, was not reported for either cohort. Also, outcome data for patients treated with SWL were obtained through self-report while data for controls were collected through chart review, which has the potential to introduce collection bias. Although there was a good response rate to the questionnaire, it is possible that patients who experienced adverse events may have been more likely to respond than those who had not. In addition, it has been demonstrated that stone formers are already at increased risk of

developing diabetes mellitus and hypertension.[64, 65] Finally, the data from this manuscript reflects early SWL experience using a first-generation lithotriptor with a relatively wide focal zone and modest pressure amplitudes. It is uncertain as to whether these findings can be generalized to current practice using lithotriptors that have narrower focal zones. Without prospective randomized trials, studies on SWL are limited to retrospective reviews. However, when forced to work within the confines of a retrospective review, matched case-control comparisons can provide statistically sound data. In the Mayo Clinic study, the control group, although comprised of stone formers, had a different severity of disease compared to the SWL group. However, due to the accessibility and liberal use of SWL, it would be a difficult task to identify patients with symptomatic stones that have not undergone surgical interventions such as percutaneous nephrolithotomy or SWL. Ureterorenoscopy for symptomatic renal calculi may be used as a control group in the future, but not until ureterorenoscopy for renal calculi is widely available and used for 20 years can the same matched comparison be accomplished.

Two recent retrospective studies conducted after publication of the Mayo Clinic report have found no association between SWL and the development of diabetes mellitus. [66, 67] However, limitations in the experimental design of these studies leaves the question of potential for development of diabetes mellitus following SWL unanswered. [68] That is, in the study by Makhlouf and colleagues the duration of the follow-up period was only 6 years—likely too short a period to be relevant to the development of chronic disease. In the report by Sato and co-authors, follow-up was long-term (10-22 years, average 17 years) but the treatment dose was much lower (~900 SW) than is typically utilized around the world. As it is well established that tissue injury in SWL is dose-dependent the report of Sato and colleagues is unfortunately not particularly reassuring.

Until further studies of comparable design become available, the Mayo Clinic paper should be viewed as a warning of possible long-term adverse consequences of SWL, prompting further clinical and basic science translational research.

In summary, there is some evidence to suggest that long-term adverse effects of several types can develop as a consequence of SWL. Animal studies in particular suggest that the acute hemorrhagic lesion progresses to scar formation, resulting in loss of functional renal volume. Renal subcapsular hematomas can be long lasting but the medical consequences of this are unknown. A prospective study indicates that elderly patients are at increased risk of developing new-onset hypertension following SWL. In addition, a 19-year follow-up study has found an association between SWL and the onset of diabetes mellitus and hypertension.

TREATMENT STRATEGIES WITH THE POTENTIAL TO IMPROVE SWL

Recent studies show that changes in procedure and technique can improve SWL outcomes. Such advances include reduced tissue injury when the protocol includes a brief pause following the initiation of treatment, and both improved stone breakage and a reduction in injury when SWL is carried out at slow SW-rate.

PRETREATMENT PROTOCOLS HAVE THE POTENTIAL TO PROTECT AGAINST SWL INJURY

Studies in the pig model have demonstrated that treatment with a priming dose of low amplitude SWs reduces renal injury in SWL.69 Delivery of a dose of 2000 SWs with the Dornier HM3 lithotriptor using settings typical of clinical treatment (24 kV, 120 SW per minute) created a lesion measuring approximately 6% of functional renal volume (FRV). However, initiating treatment with as few as 100 low power SWs (12 kV) before completion of the dose with the higher amplitude pulses resulted in a significant reduction in the size of the lesion to 0.3% FRV. Recent research suggests that the power level of the priming dose is not the factor responsible for this protective effect, as the lesion volume was similar when the priming dose was delivered at 12, 18 or 24 kV.70 Instead, it was observed that inclusion of a three to four minute pause following the priming dose was protective, while increasing the power setting without this delay did not result in reduced injury. That is, injury was reduced only when the priming dose was followed by a brief delay. These findings are potentially important as they suggest a simple treatment strategy to reduce adverse effects in SWL.71 Such treatment protocols need to be confirmed in a clinical setting.

SLOWING THE SW FIRING RATE REDUCES RENAL INJURY AND IMPROVES STONE BREAKAGE OUTCOMES

Recent studies in pigs shows that slowing the firing rate of the lithotriptor to 60 SW per minute or slower reduces lesion size in the kidney to less that 0.1% FRV compared to ~6% FRV at 120 SW per minute.[72, 73] That is, slowing the SW rate results in protection against renal trauma similar to that observed using the low SW power pretreatment or pause-protection protocols.[69, 70] Such results from animal studies are encouraging, but similar studies have yet to be conducted with patients.

Stone breakage is affected by SW rate, and a number of clinical studies report that slowing the firing rate of the lithotriptor to 60 SW per minute gives better outcomes than treatment at the typical rate of 120 SW per minute.[74-79] This effect is seen with both electrohydraulic and electromagnetic lithotriptors. The advantage of slowing the SW rate is that fewer SWs are needed for treatment, but a potential disadvantage is a modest increase in overall treatment time.

CONCLUSIONS

We return to the main questions posed at the outset of this report.

IS SWL SAFE?

Since its introduction into the US in 1984, SWL has been performed with great success on millions of patients, but not unlike a surgical procedure, SWL carries the risk of unintended consequences. Shock waves have the potential to cause tissue damage and acute injury may lead to long-term adverse effects. There is likely a treatment threshold for initiation of SWL injury, but the upper limit for SW dose that can be delivered without causing vascular trauma is not known. It is highly likely that the vast majority of patients who are treated with a typical dose of SWs using currently accepted treatment settings experience some degree of acute renal trauma. It is not known if such injury sustained from a single treatment session alone leads to lasting damage. Animal experimentation demonstrates the severity of acute SWL injury. Whether or not acute SW damage progresses to long-term effects likely depends on SW dose (i.e., not only SW number but power, SW rate, and treatment sequence), as well as pathophysiologic risk factors that predispose the patient and/or kidney to a heightened response or particular pattern of response. The risk factors for acute SWL injury may not be the same as those for chronic effects. Thus, the safety of SWL depends on multiple factors that include the dose, treatment settings and acoustic characteristics of the lithotriptor used, frequency of retreatment, and a background of physiologic factors that may predispose the patient to increased risk of acute injury or progression to long-term damage. Recent studies with experimental animals demonstrating that renal injury is significantly reduced at slow SW rate or when a protective "pretreatment" protocol is used are very encouraging, and suggest that under proper conditions lithotripsy can be both safe and effective.

ARE THE CHRONIC ADVERSE EFFECTS LINKED TO SWL SIGNIFICANT?

Research to date suggests that SWL may lead to potentially significant chronic adverse effects including new-onset hypertension and diabetes mellitus. The long-term consequences of acute SW injury deserve further investigation.

DO THE ADVANTAGES OF SWL OUTWEIGH THE POTENTIAL RISKS?

Shock wave lithotripsy is often the best treatment option, in some settings may be the only treatment available and in most cases presents distinct advantages that outweigh the foreseeable risks. Like any of the stone technologies there are risks in using SWs, but it is also true that new treatment strategies are being developed that reduce adverse effects and improve stone breakage outcomes. Steps that

significantly reduce acute injury may have the potential to eliminate long-term adverse effects altogether. Still, limited understanding of the factors that lead to lasting injury after SWL calls for continued research on the mechanisms and consequences of SW injury.

CONFLICT OF INTEREST DISCLOSURES

All panel members completed Conflict of Interest disclosures. Those marked with (C) indicate that compensation was received; relationships designated by (U) indicate no compensation was received.

Consultant or Advisor: Dean G. Assimos, Altus (C); Robert I. Kahn, American Medical Systems (C); James E. Lingeman, Boston Scientific Corporation (C), Lumenis (U); **Board Member, Officer, Trustee**: Dean G. Assimos, Med Review in Urology, (C), Urology Times (C); Robert I. Kahn, California Urological Services (SF Lithotripsy, Ca. Prostate) (C); **Meeting Participant or Lecturer**: Robert I. Kahn, Astellas (C); James E. Lingeman, Boston Scientific (C), Lumenis (C); **Scientific Study or Trial**: James E. Lingeman, Boston Scientific (U), Olympus (U); Pei Zhong, Siemens Medical Solutions (C); **Investment Interest:** James E. Lingeman, Beck Analytical Laboratories (U), Midstate Mobile Lithotripsy, LP (U) **Other:** James E. Lingeman, Beck Analytical Laboratories (U), Midstate Mobile Lithotripsy, LP (U).

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Michigan Lithotripsy Technologist Experience
United Medical Systems/Great Lakes Lithotripsy

	Start Date with UMS/GLL	UMS Years of Service	Prior Service	Years of Service
Litho Tech #1	1/27/1999	14.4	0.0	14.4
Litho Tech #2	6/18/2003	10.0	0.0	10.0
Litho Tech #3	2/1/2005	8.4	10.0	18.4
Litho Tech #4	12/16/2005	7.5	5.0	12.5
Litho Tech #5	4/1/2006	7.3	6.0	13.3
Litho Tech #6	1/8/2007	6.5	0.0	6.5
Litho Tech #7	6/24/2013	0.0	7.5	7.5
	Average	7.7	4.1	11.8

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Robotic Surgery: Growing Sales, but Growing Concerns

BUSINESS FRAUD, COMPANY MISTAKES, BUSINESS NEWS, CNBC, INVESTIGATIONS INC, HEALTH CARE EQUIPMENT, INVESTIGATIONS INC., INTUITIVE SURGICAL INC, FDA, BUSINESS NEWS

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When Intuitive Surgical went public 13 years ago at $9, it dazzled Wall Street with its sizzling story of something that would revolutionize medicine: a surgical robot called the da Vinci.

Born in Silicon Valley, the da Vinci was steeped in technology so advanced that it "overcomes many of the shortcomings" of traditional open surgery, notably less blood loss and a faster recovery, Intuitive boasted in its IPO filing.

Since then, da Vinci hospital robot placements and procedures have skyrocketed. Last year alone, installations rose by 21 percent to 2,585 units worldwide at a cost of more than $1.5 million each. And robotic surgical procedures leaped by 25 percent to 450,000.

While one of the downsides of robotic surgery is a lack of tactile feel, surgeons who sit at a console a few feet from the patients raved about its 3-D vision. "The vision compensated for everything," world-renowned prostate specialist Dr. Ash Tewari of New York Presbyterian Hospital said in a recent interview. He performs as many as four of the two-to-three hour procedures a day, four times a week. "If you look at it from a surgical standpoint, every surgeon's dream is to get to see exactly what he or she is doing and get to do it in a field (of vision) which is not pooled with a lot of blood."

Such testimonials have helped propel Intuitive into what Northland Capital analyst Suraj Kalia calls "the 'Apple' of the medtech sector."

Intuitive, which builds and sells the machines, also collects more than $100,000 in service maintenance agreements for each machine and sells the disposable instruments used by the machines for surgical procedures.

With revenue last year topping $2 billion, its stock has climbed well above $500, propelling its current market valuation to more than $20 billion.

In recent years, as the da Vinci's popularity has grown, so have questions and concerns about its safety, training and the aggressiveness of its marketing.

Intuitive executives declined to be interviewed for this story, and a spokeswoman said the company would not comment on issues of safety, training and marketing because they are "within the context of active litigation."

However, at a recent investment conference, Intuitive dismissed safety concerns, telling analysts that given the number of procedures it does, it believes its safety record is "exemplary."

And in a statement to CNBC, Intuitive said: "In any definitive treatment for complex disease, such as surgery of the cancerous prostate, heart, or other major organs there are risks of complications. Robotic surgery has proven benefits in reducing the risk and complications associated with open surgical procedures thereby extending the benefits of minimally invasive surgery to a broader population of patients. Overall, adverse event rates are very low. Da Vinci surgery has been shown to be safer than the open surgery alternatives in numerous independent large scale, peer reviewed studies."

Many surgeons, including critics, agree that in the right hands the da Vinci is generally safe.

However, a CNBC Investigations Inc. review, which included numerous interviews with surgeons,

lawyers, ex-employees and patients and an extensive review of internal documents, multiple studies, lawsuits and depositions of current employees, shows:

- A sharp rise in lawsuits and complaints about injuries, complications and even deaths following da Vinci procedures. At least 10 have been filed over the past two years, most of them in 2012; many more complaints, plaintiffs attorneys says, are headed toward mediation.
- Surgeons can use the robot to operate on patients after several steps, including at least an hour of online training, four hours watching two full-length procedures online, seven hours operating on a pig and as few as two surgeries, overseen by a more seasoned robotic surgeon. The number of supervised cases can vary by hospital.
- A high-pressure sales culture driven by quarterly "quotas" on surgical procedures has led sales people to lean on surgeons to do more robotic surgeries, according to interviews with former salespeople and internal emails.

On its website, Intuitive promotes the da Vinci as superior to open surgery, with such benefits as less blood loss, faster recovery and less pain.

In some procedures, such as hysterectomies, robotic surgery is being promoted and used as an alternative to laparoscopic surgery, another so-called "minimally invasive" surgical technique. A recent study published in the Journal of the American Medical Association concluded that "To date, robotically assisted hysterectomy has not been show to be more effective than laparoscopy."

And in prostatectomies, while robotic surgery is likely to result in less blood loss and faster recovery than traditional open surgery, the most feared side-effects of all—incontinence and sexual impotence —"are high after both," according to a study released last year by the Journal of Clinical Oncology.

Just last week, in what amounted to a stinging rebuke of robotic surgery, the president of the American Congress of Gynecologists and Obstetricians said: "Many women today are hearing about the claimed advantages of robotic surgery for hysterectomy, thanks to widespread marketing and advertising. Robotic surgery is not the only or the best minimally invasive approach for hysterectomy. Nor is it the most cost-efficient. It is important to separate the marketing hype from the reality when considering the best surgical approach for hysterectomies."

(*Read More:* Gynecologists Urge Caution on Robotic Hysterectomies)

The Food and Drug Administration recently asked surgeons to take part in a voluntary survey asking about complications involving the da Vinci. The FDA told CNBC the surveys are a routine part of its surveillance to help evaluate the device and its performance and to help understand the risk/benefit profile for devices like this.

Injury Complaints

"The robot has a place in surgery," said Dr. Francois Blaudeau, a practicing Alabama gynecologist who also is lead plaintiffs attorney focused on da Vinci-related injuries. Blaudeau, who has been trained on the da Vinci, also cautions that "it is a sophisticated piece of equipment that has its own set of issues." One, he said, is that it can inadvertently cause serious injury.

According to lawsuits, complaints, interviews with alleged victims, plaintiff attorneys and an FDA's database, many of the reported injuries during robotic surgery appear to be burns and other heat-related damage to intestines, ureter, bowels and other organs. Blaudeau and several surgeons interviewed for this story said the injuries can occur beyond the surgeon's range of vision and without the surgeon's knowledge and may only show days after the surgery. This, plaintiff lawyers say, has meant that many of the injuries and complications in the complaints have not been reported to the Food & Drug Administration as a da Vinci issue, resulting in an under-reporting of "adverse events" related to the machine.

Instead patients, unaware of a possible link between robotic surgery and their injuries, have in the past filed malpractice suits against doctors and hospitals, Blauedeau said. Intuitive declined to comment on the specific number of lawsuits and complaints. "Patients and attorneys have a right to make legal claims," a spokeswoman said. "We take any claim seriously, evaluate it on its own merits and trust in

the legal system to resolve these matters."

(**Read More:** What Happens When a Surgical Robot Malfunctions?)

The best official source for medical device "adverse events" is the FDA's Manufacturer and User Facility Device Experience (MAUDE) database. Submissions are voluntary, based only on reported cases and have not necessarily been investigated by the FDA. In fact, the agency cautions that it "is not intended to be used to evaluate" rates of adverse events. And doing so, Intuitive said, would be "factually and contextually inaccurate."

Since 2000, the database shows reports of at least 85 deaths and 245 da Vinci-related injuries. (A complete spreadhseet of 4,600 adverse events, including machine malfunction, filed with the FDA is included in this Intuitive report by Citron Research, which does investment research.)

During the same period, roughly 1.5 million robotic procedures have been performed, suggesting reported problems are statistically insignificant.

But critics like Dr. Marty Makary of Johns Hopkins University Hospital believe the number of injuries and complications are under-reported. A study he co-authored, which is under review by the Journal for Healthcare Quality, cross-referenced the FDA's database with press reports and lawsuits and found eight cases that were either incorrectly or never filed with the FDA.

While that may be a "fraction of procedures that are done," said Makary, the industry has done "a poor job of monitoring the safety profile of certain new technologies, and this is a classic example."

Makary, a pancreatic specialist known for doing complicated procedures—and trained on the robot—prefers straight non-robotic laparoscopy because of its lack "of what we call haptic (tactile) feedback. Because we're working around blood vessels, an inadvertent injury could result in a catastrophic bleed in seconds."

Yet, he added, "we have not even been keeping a national registry of robotic surgery-related complications. And from the ones that we have, we know from our research there is a massive under-reporting."

Blaudeau said after last fall's launch of his website badrobotsurgery.com—and in the wake of several lawsuits he filed—he has received "hundreds" of what he says are "confirmed" complaints involving "ureteral" and other injuries" during da Vinci gynecologic procedures.

And in the three months since advertising robotic injuries for Blaudeau's law firm on television in local markets, "We've probably had over 10,000 calls regarding vascular injuries, bowel, bladder, re-surgical procedures, punctures and tears," said Loni Liss, president of the Legal Communications Group, which conducts advertising campaigns seeking plaintiffs for personal injury lawsuits. "That's a very large response."

Among those who responded was Sonya Melton of Birmingham. Following six weeks in the hospital after what was supposed to be same-day robotic surgery, she said, she was home recovering and watching TV when "I see one of these commercials for attorneys. And they're talking about anyone had any problems with a robotic surgery. I'm like, 'hmmm.' … I start to do a little bit more research. And I was like, 'Well, is that the name of the robot that they used on me? Yeah, it is.'"

In an interview, she said she had become so sick almost immediately after her surgery to remove uterine fibroids that she thought she was going to die. Her condition, she said, puzzled doctors so much that within days they sliced open her stomach open to find out why she was in excruciating pain and had developed a full-fledged pneumonia. What they found, she said, was a perforation in her small intestine.

Shawn Todd, who lives outside of Mobile, Ala., also contacted Blaudeau's firm. She still breaks down and sobs when she tells how doctors, unable to get anesthesia to work, apologized for what they were about to do as they held her down and stuck needles into her kidneys, which had shut down. Turns out, she said they told her, her ureters, which carry urine from the kidneys to the bladder, had somehow been burned.

Intuitive declined to discuss both cases, which are in mediation.

Blaudeau and other surgeons we spoke with say they believe one reason for the injuries is the da Vinci's use of "monopolar" energy for cauterizing and cutting, which can create excessive heat. If there is a failure in insulation on the instruments, they said, it can cause what is known as a "stray current" or arching—when sparks from an instrument leap elsewhere.

Stray currents can occur in regular laparoscopy as well. However, a 2011 study published in the American Journal of Obstetrics & Gynecology said, "robotic instruments have a significantly higher incidence and prevalence of [insulation failure] compared with laparoscopic instruments."

Intuitive said instruments using monopolar energy have been employed in "open and laparoscopic surgery for decades," and the company is "confident that the da Vinci surgical system deploys monopolar energy in a safe and effective way when used as indicated."

The company said it offers instruments that use various types of energy, and "surgeons determine which energy instruments to use."

Training on a Pig

Surgeons, plaintiffs lawyers and at least one lawsuit cite training as a concern. Typically it involves seven hours of training over a weekend, usually operating on a pig.

Then, based on the hospital's criteria, the surgeon is required to conduct two to five surgeries supervised or "proctored" by an experienced robotic surgeon before doing their first unsupervised operation. The more practice, in general, the better, but that also adds to the cost of training.

"Many surgeons are trained the same way, with no differences made as to their prior knowledge or prior ability prior to entering the robotic training," Bladeau said. "It's not reasonable to believe that every surgeon across the country can be adequately trained with one pig lab and two proctored cases."

It was a lack of training, according to one lawsuit filed in Washington state, that ultimately led to the death of Fred Taylor in 2012, roughly four years after undergoing what was supposed to be a routine prostate surgery.

His was the third robotic case for Dr. Scott Bildsten—his first without a supervisor. Instead of taking a few hours, the lawsuit alleges, the surgery lasted around 13 hours and 26 minutes. Two hours later, Taylor was "intubated in an ambulance" after suffering from a torn rectum, losing 15 cups of blood and undergoing "a consequent hypovolemic shock," a lawsuit filed by Taylor's widow claims.

"The weeks and months to come showed the results of the surgery were devastating," it states. Taylor never fully recovered. The lawsuit alleges he died of complications from the surgery.

Meanwhile, Bildsten, according to his deposition in connection with the lawsuit, "gave up robotics forever" one year after he operated on Taylor, saying:

I was under the initial impression you would get a level of comfort within a certain number of cases. And as .... it went along, it seemed it was going to be much longer than that. ... And after speaking with some other urologists in a similar situation, who attempted to use the ....da Vinci robot prostatectomy, a lot of others have decided not to proceed as well. They found the learning curve so steep and lengthy that the level of comfort just took too long and decided to quit. I was one of those.

Neither Bildsten nor his lawyer returned calls seeking comment. Intuitive, in keeping with its policy, declined comment on the lawsuit.

The Marketing Drive

Underlying all of this, according to former salespeople and internal emails, is a company culture steeped in aggressive marketing techniques, that includes high-pressure sales efforts by Intuitive to hospitals and doctors.

"Our extensive field checks highlighted a story where aggressive marketing drives the message and

true clinical utility seems secondary in nature," wrote Kalia, the Northland Capital analyst.

Intuitive declined comment on Kalia's report.

His comments are supported by our interviews with former Intuitive salespeople and internal documents, including those filed with the Taylor lawsuit. One common theme is an effort to prod surgeons to "convert" previously scheduled non-robotic surgeries to robotic surgeries to meet quarterly sales quotas.

In one email, Intuitive's clinical sales director bemoaned how the "Mountain West team is forecasting about 285 procedures each week. We need to be at 345 procedures/week to close on our goal."

With two days left in one quarter, another sales leader wrote: "Let's bring it home! Be sure to scrub all schedules, identify cases on Thursday and Friday that can be moved up. ... Turn over every stone possible. I know there are 2 out there."

In another email that day, another sales leader wrote: "Guys, it's time to call in favors for these last 2 cases. ... We need to start calling our surgical champions who know our business first thing tomorrow."

Other emails show sales reps trying to persuade hospitals to lower the amount of supervised surgeries required before surgeons can operate solo.

Marketing the robots to the hospitals, the former salespeople said, was just as aggressive. "We would go to hospitals in a local geography and get docs to pledge they would take business away to other hospitals if their hospital didn't get the robot," said one former regional sales director, repeating something several sales reps said.

With Intuitive, the marketing is to doctors, hospitals and something quite unusual for a surgical device: marketing directly to the consumer.

Hospitals proudly display banners and advertise the arrival of the da Vinci. Northwest Medical Center in Margate, Fla, even put up the da Vinci outdoor billboard with slogans like "The Power Performer" and "da Vinci, same name, same genius."

Some hospitals that have the robot, however, have kept it low key. Massachusetts General, for example, has one robot, has never actively promoted it and has capped the doctors who can use it. "We have had a very conservative, cautious and skeptical approach to the use of it," said anesthesiologist Dr. Peter Dunn, who also oversees the hospital's new surgical technology as head of its perioperative operations.

Dunn said that after five years, Mass General, which prides itself on being on the cutting edge of new medical technologies, has determined the robot has not proven to be the best solution for all patients.

And while the hospital continues to consider new uses for the robot, Dunn said, "more important than the device, is the quality of the surgeon."

URL: http://www.cnbc.com/100564517

Lithotripsy Literature Search from HFHS

A literature search identified several complications that can arise with lithotripsy procedures:

Complications

- Perforation of the upper ureter
    - Case study: ureteral perforation can cause a series of problems including the retroperitoneal urinoma, urosepsis, abscess formation, infection, and subsequent renal function impairment. (1)
- Large subcapsular hepatic hematoma
    - Case study: severe hemaorrhagic shock required a partial coiling embolisation of the right hepatic artery. (2)
    - Large hematomas, while uncommon, are a potentially significant clinical event that may lead to blood transfusion and acute renal failure (3).
- Acute pancreatitis, perirenal hematoma, urosepsis, venous thrombosis, biliary obstruction, bowel perforation, lung injury, rupture of an aortic aneurysm and intracranial hemorrhage
    - Case study: Acute necrotizing pancreatitis (4)
- Intrarenal hematomas, interstitial edema, and temporary tubular dysfunction
    - Case study: reversible acute tubular necrosis in a nonobstructed system (22)

Although these complications occur in a small percentage of cases, they can still be life threatening. It is important that lithotripsy is provided in the appropriate setting in order for patients to be monitored in an environment where services are available to address any complications that may arise.

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Prepared by: Megan Passman, Student, Planning June 2013

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