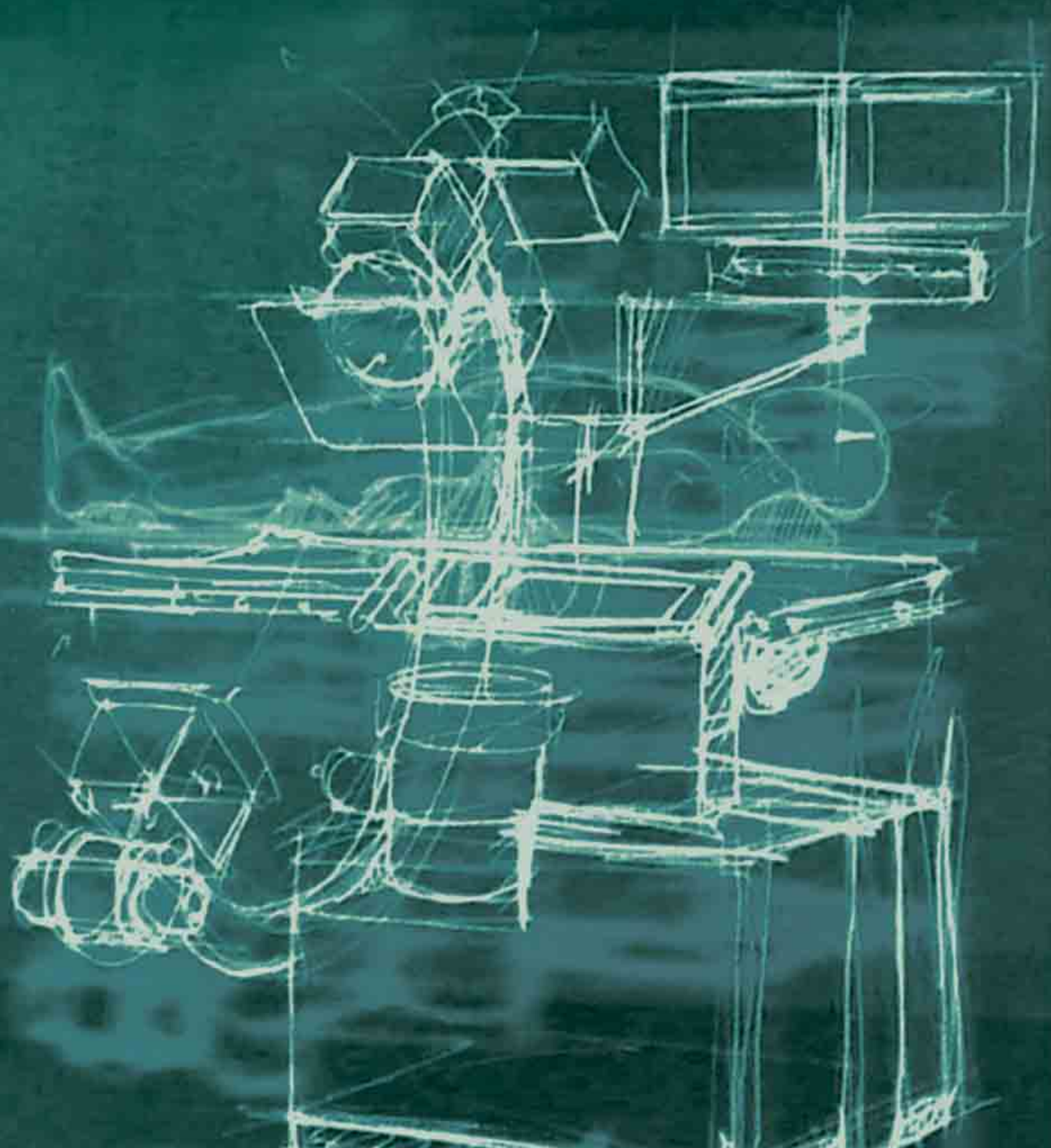
WHAT MAKES A GOOD LITHOTRIPTOR?



What makes a good lithotriptor?

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Historic and modern lithotriptors

20 years after introduction of shock wave lithotripsy into clinical practice, the pioneering HM3 spark gap lithotriptor of Dornier is still in use in some places. On the other hand advanced electro-magnetic lithotripsy systems are available. What progress has been made in the last 2 decades and does the patient benefit from it?

The most important component of a lithotriptor is the shock wave generating system, which may be considered the „motor" of a lithotriptor. It determines fragmentation efficiency, side effects, anaesthesia requirements and the possibility to implement different localization modalities. It also influences economical aspects such as running costs, patient throughput and the like.

Below we want to discuss general aspects of shock wave generation with special attention to the effect of big and small focal spot sizes. Based on the core technology, different lithotriptor concepts may be tailored to the specific needs of individual customers.

Advanced lithotripsy technology - What should we head for?

Like with medical drugs, physical therapeutic systems mostly combine the medical benefit with some sort of side effect. This principle of Paracelsus (16th century) holds true also for shock waves. They may not only fragmentize stones but also create superficial bleeding up to severe haemato-

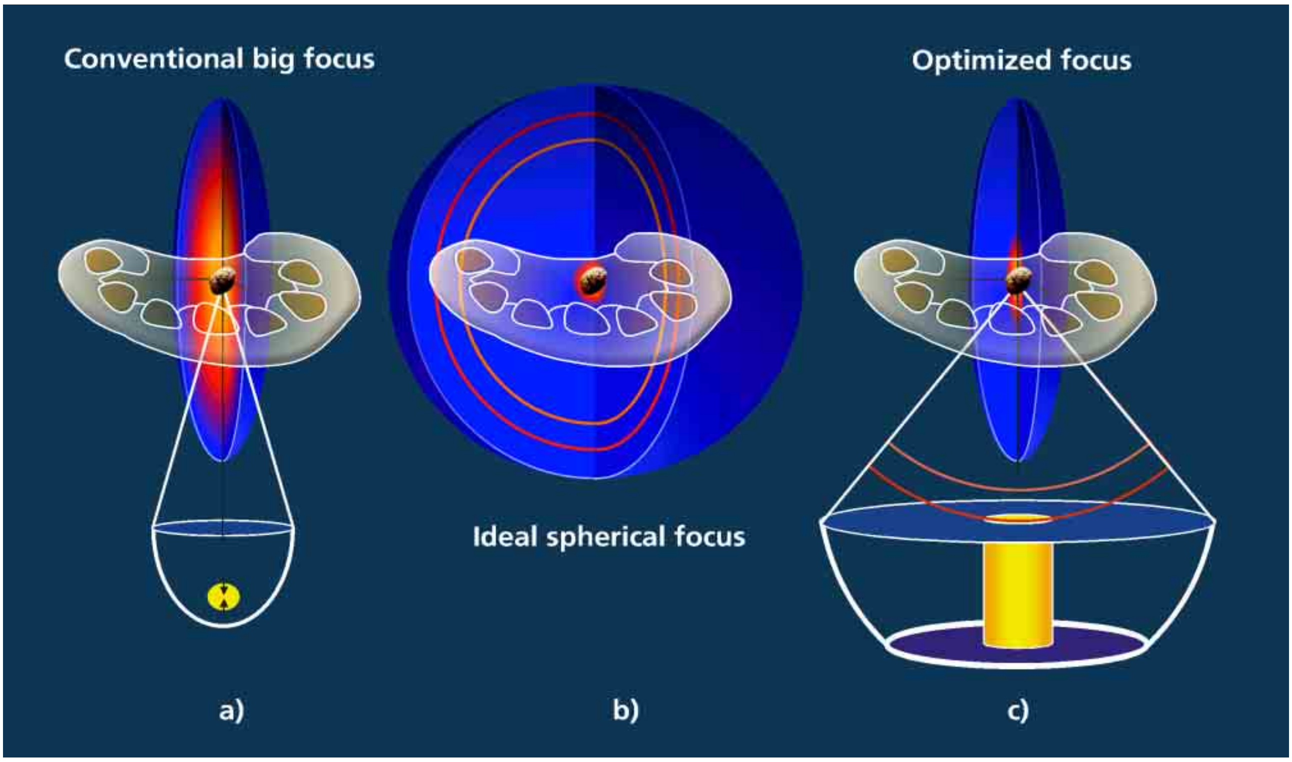

Fig. 1

mas. The ideal lithotriptor, thus, would expose shock wave energy only to the precise stone location and nowhere else. As shown in Fig 1b, the shock wave focus should have well defined spherical shape matched to the stone dimensions of approximately 10 mm in diameter. Ideally shock waves should not affect kidney parenchyma and other sensitive tissue surrounding the stone. Technically seen, spherical focal zones require spherical access from all sides outside the human body, which cannot be realised due to anatomic and other technical reasons. Realistically, a certain „shock wave transparent" tissue window of limited dimensions is used to transmit the acoustic energy over a relatively wide surface area into the body and concentrate the waves on the target or treatment area.

Due to utilizing only a segment of the ideal spherical access, the realistic focus dimensions of older devices are more like a cigar of 100 x 16 mm (Fig. 1a). Especially before and behind the stone, a significant amount of shock wave energy is disposed within the tissue. This part of the wave field does not contribute to the fragmentation process but may cause side effects as described above. The realistic goal is to optimize efficiency while, simultaneously, reduce side effects to a minimum. In other words:

- Adjust focal shock wave energy as high as necessary, not higher,
- Shrink the treatment zone with therapeutic energies to the region of interest and avoid shock wave exposure to any other area.
- Deliver shock wave energy as gentle as possible to the target area.

Advanced Shock Wave Technology with Optimized Focal Size

It is important to notice the difference between **focal area** and **treatment zone**. The focal zone is measured as the area where the pressure is equal or higher than half the peak pressure (-6dB) thus being a relative measure related

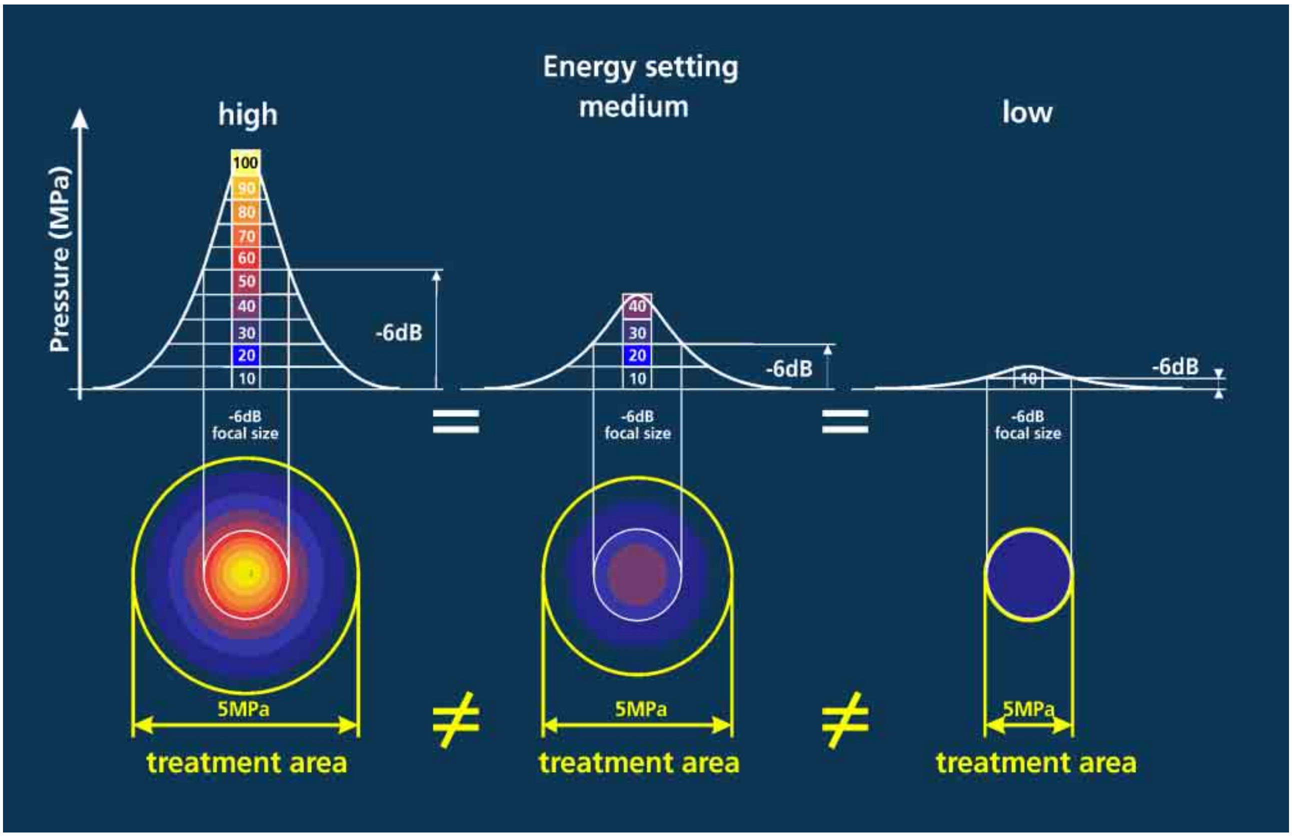

Fig. 2

to the variable peak pressure. It may not change with different power levels as shown in Fig. 2. Obviously, however, different power levels are associated with different amounts of shock wave energy which are considered more or less effective. If we assume a shock wave being effective when exceeding certain (absolute) pressure values (e.g. 5MPa), the according treatment zone may be significantly larger as shown in Fig. 2. It increases with peak pressure and energy content.

Some modern systems feature large aperture angles up to 80-90° matching excellently with the above-mentioned requirements. The focal zone could be reduced from 100 x 16 mm (HM3) to values around 30 x 5 mm with the option to increase peak pressure significantly when needed in case of impacted ureteral stones e.g. (Fig. 4c).

Less Anaesthesia required

Progress with respect to the old HM3 Lithotriptor is obvious due to reduced pain sensation and anaesthesia requirements while maintaining fragmentation efficiency. Analgosedation instead of general anaesthesia and dramatically less skin lesions are the results of modern large aperture systems. This is a big step ahead towards higher patient throughput and cost reduction.

Clinical Performance and Fragmentation Efficiency

Technical improvements do not necessarily result in improved clinical performance. A comparison of different technologies and devices under clinical conditions is extremely difficult due to varying parameters between different studies. Treatment strategy, patient selection, indication range, reimbursement system and other individual features may influence the outcome significantly. Only under long term observation certain trends may show up.

Fig. 3

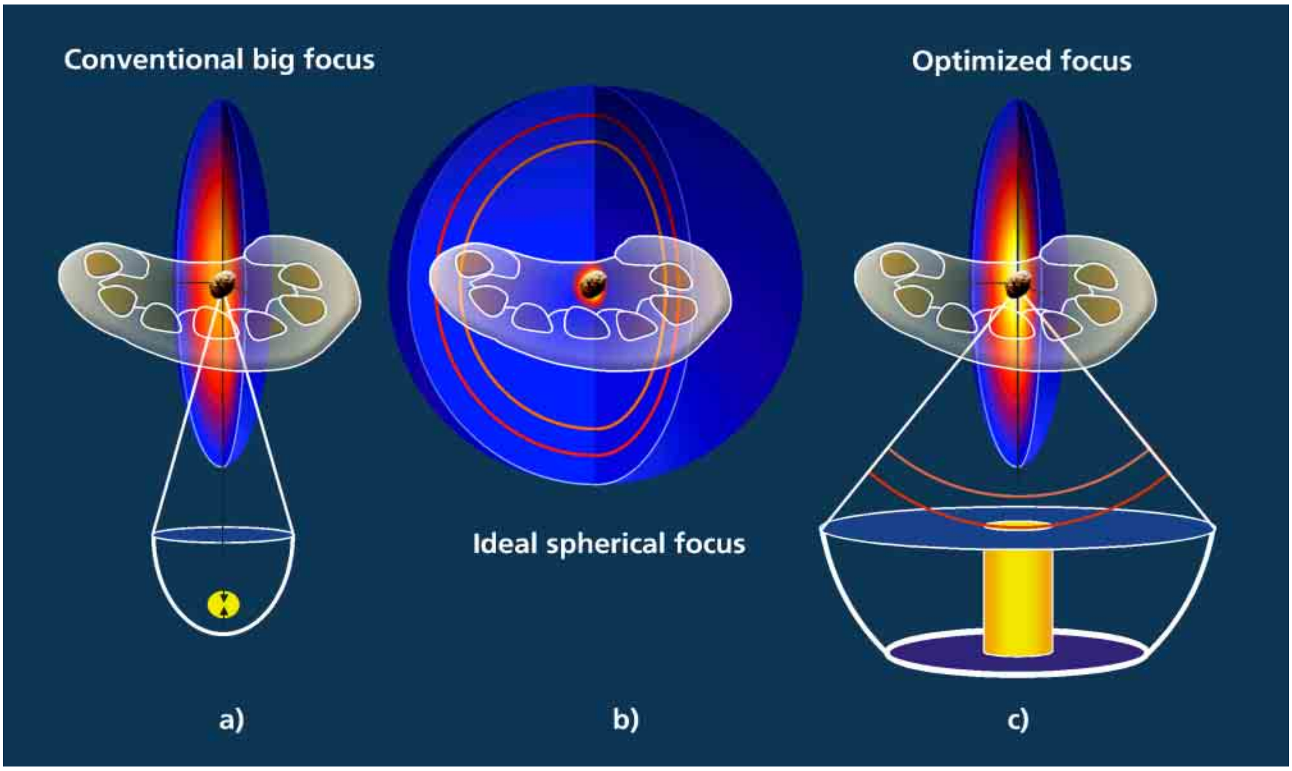

Fig. 4

In vivo Studies:

	Study	Lithotriptor	Stone location	Retreat. rate	Stone free after 3 month
First & second generation spark gap lithotriptors	Graff et al 1988	Dornier HM3	kidney + ureter	-	72,2% (19 month folow up)
	Lingeman et al 1989	Dornier HM3	kidney	7%	80,3%
	Cass 1995	Dornier HM3	kidney	4,4%	69,5%
			ureter	5,2%	81,5%
	Rassweiler 1988	Dornier HM3	kidney + ureter	14%	73%
		Dornier HM3 modified	kidney + ureter	13,6%	75%
	Tailly 1999	Dornier HM4	kidney + ureter	18,4%	85%
Newer electromagnetic lithotriptors		Donier Doli	kidney + ureter	17,7%	88,7%
	Coz et al 2000	Storz MODULITH SL 20	kidney + ureter	22,4%	87,3%
	Mobley et al 1993	Siemens Lithostar	kidney	16,5%	68,9%
			ureter	10,7%	83,5%
	Rassweiler et al 1988	Siemens Lithostar	kidney + ureter	11,4%	69%
	Wolf 1999	Storz MODULITH SLX	kidney	7,5%	91,4%
			ureter		87,1%

table 1

Below you find an overview of publications which either investigated the efficacy of HM3 and HM4 or of electromagnetic lithotripters.

In vitro study:

Teichman et al

There are only very few studies comparing fragmentation efficiency under controlled conditions. Up to our knowledge the only one on selected ensembles of human kidney stones was performed by Teichmann et al (Journal of Urology Vol.164, 1259-1264, October 2000).

The objective of the study was to find out whether or not lithotriptors of different brands and with different shock wave generation differ in the ability to fragment stones. Shock waves were applied in vitro. Human stones of different compositions were placed in a mesh and brought into the shock wave focus.

500, 2000 and the max. number of shock waves allowed by the FDA[1] were applied to the different stones.

The percentage of remaining fragments >2 mm was regarded to be the indicator for the efficacy of the specific lithotriptor. In ohter words: The less remaining fragments >2 mm, the better.

The results are listed below. Some systems are leaving almost no rest concrements > 2mm (Modulith SlX, HM3, Lithostar) others lack sufficient efficiency at hard stones e.g. cystine or CHPD-stones (STS-TD, Lithotron, Doli, Econolith).

Lower numbers indicate better disintegration

		Fragments > 2mm in % of stone mass											
	Stone Composition	**CHPD**			**COM**			**CYS**			**MAPH**		
	Number of Shock Waves	**500 SW**	**2000 SW**	**FDA limit[1]**	**500 SW**	**2000 SW**	**FDA limit[1]**	**500 SW**	**2000 SW**	**FDA limit[1]**	**500 SW**	**2000 SW**	**FDA limit[1]**
Dornier HM3		34±39	0±0	0±1	0±0	0±0	0±1	3±7	0±0	1±2	1±1	2±3	0±1
STORZ MEDICAL MODULITH SLX		2±3	0±0	0±0	0±0	0±0	0±0	0±0	0±0	0±0	0±0	0±0	0±0
Siemens Lithostar C		20±13	0±1	0±0	2±3	0±0	0±0	11±12	1±2	1±3	4±8	2±4	1±1
Medstone STS-T		46±18	10±18	10±15	5±3	0±1	0±0	72±35	0±0	10±21	4±7	0±0	0±0
Healthtronics (HMT/ Philips) Lithotron		35±29	11±18	3±2	5±4	0±0	0±1	67±31	25±28	14±18	40±41	10±15	3±4
Dornier DOLI		59±23	29±20	29±20	52±23	4±5	4±5	23±29	3±4	3±4	2±3	0±1	0±1
Medispec Econolith		57±27	18±33	18±33	10±13	9±14	9±14	22±17	9±18	9±18	7±10	0±0	0±0

table 2

CHPD = Calcium Hydrogene Phosphat Dihydrate
COM = Calcium Oxalate Monohydrate
CYS = Cystine
MAPH = Magnesium Ammonium Phosphate Hexahydrate

Both the in vivo and the in vitro studies indicate no significant difference between the „gold standard“ first generation lithotriptor and the best of the currently available electromagnetic lithtotripters.

Multifunctionality

A growing number of hospitals look for a versatile medical workstation rather than for a lithtotripter only. Apart from covering the entire spectrum of urinary calculi, advanced lithotripsy systems can also be employed for a variety of other endo-urological therapies. Dedicated accessories like uro-sink, leg supports, infusion stands should be available. Possible further shock wave indications are the treatment of gallstones or orthopeadic indications.

Fig. 5: Multifunctional Table

[1] The so called FDA limit indicates the maximum number of shock waves per treatment that were used for the FDA trial. The number depends on the lithotriptor and ranges from 2000 (Modulith SLX, Doli etc.) up to 4000 (Lithostar-C).

Treatment of Infants

Progress in lithotripsy also means to be prepared for the treatment of young children. There is a considerable stone incidence rate in infants. At least two crucial issues need to be considered:

Protection of lung tissue of the infants from exposure to high energy shock waves.

In electohydraulic lithotriptors the energy distribution of the shock wave with its huge focal point is not well suited for infant treatment. Also a primary divergent wave prior to the focussed shock wave is typical for spark gap systems. It covers big parts of the infants body. As a counter measure, the lung has to be acoustically shielded against shock waves. In early lithotriptors, infants were also exposed to a fairly high X-ray dose.

Last generation lithotriptors, especially those with electromagnetic shock wave generation are able to focus the shock wave energy more accurately and therefor minimise the risk of tissue damage in the lung. Furthermore most current lithotriptors do offer ultrasound localisation to avoid X-ray exposure.

Safe and quick placement of the infant should be possible

Fig. 6: Infant on Patient Foil

Basically shock wave lithotriptors were designed for adult patients and thus often do not match the anatomy of small children. Early day lithotriptors as well as many currently available systems need to be modified before the treatment of infants. In many patient stretchers there is a gap for the coupling of the shock wave source wich is way to big for infants. Only lithotriptors with a patient foil or with an over-table shock wave source are suited to comfortably treat small children.

The role of Imaging in ESWL

A further aspect when talking about quality in ESWL is certainly stone localization.

X-ray

Efficient stone disintegration can only be accomplished if accurate localization and stone targeting is given. In the early days of lithotripsy only fluoroscopy was available for stone localization. Within the water bath, quite a high X-ray dose was necessary to obtain an acceptable image quality.

New lithotripsy systems require a much lower dose rate. Special design modifications can reduce the X-ray dose even further. To keep the dose low, X-ray beams should pass little or no water. One method of eliminating the water path is the airbag technique. A central or axial airbag forces the water out of the X-ray path and minimizes the dose while enhancing the image quality.

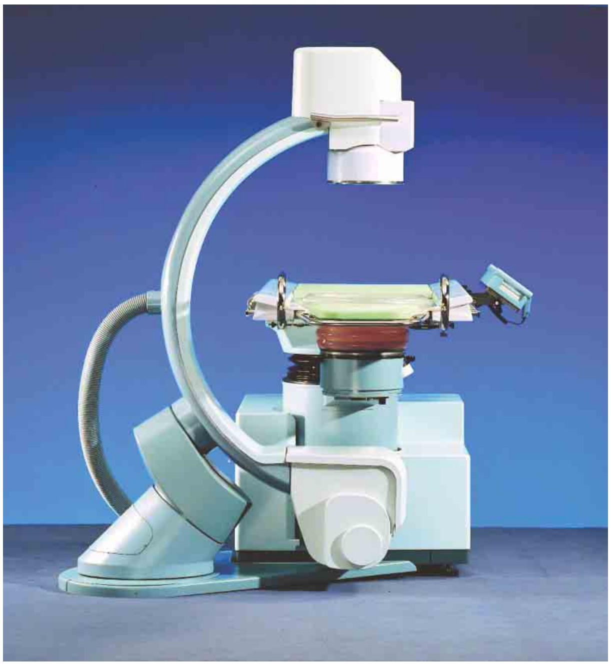

Fig. 7: Integrated Fluoroscopy System

The producers of top level lithotriptors offer a wide variety of imaging concepts.

Standard fluoroscopy systems as well as highest resolution systems with digital radiography and plenty of image processing features are available.

Meanwhile it is quite common to equip the lithotriptor with a DICOM 3 interface. DICOM is a standardized format for medical images + patient data. Images stored during lithotripsy or during auxiliary procedures can be sent to a central archiving station or printed out on a remote printer.

Ultrasound

Most of the kidney stones and some of the ureter stones can be localized by ultrasound. Although it requires more attention from the physician, it offers certain advantages over X-ray e.g. the absence of radiation or the ability of real time monitoring.

While early lithotriptors were equipped with X-ray only and some second generation systems with ultrasound only, state of the art lithotriptors usually offer both imaging solutions.

They cover the whole variety of stones while pure X-ray or pure ultrasound based lithotriptors always exclude a certain percentage of stones.

Inline or offline localisation.

In order to match the X-ray and ultrasound images with the shock wave field, there were always attempts to integrate the imaging modalities into the shock wave source.

However a certain engineering effort is necessary and not all methods of shock wave generation are equally suited for in-line X-ray or ultrasound.

Thus many currently available lithotriptors still use the off-line principle although in-line ultraound and X-ray is certainly preferable.

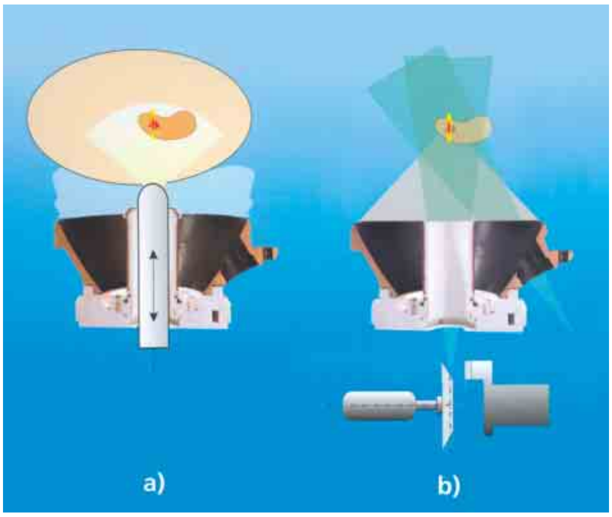

Fig. 8: a) Inline Ultrasound b) Inline X-ray

Conclusion

If stone desintegration would be considered to be the only indicator for quality in ESWL, the past two decades would have brought only little progress with respect to the HM3.

Both the in vivo and in vitro studies shown above indicate no significant difference between the former „gold standard" first generation spark gap lithotriptor and the best currently available electro-magnetic lithotriptors.

However, as seen in the last chapters there are a couple of other quite important factors that also contribute considerably to quality in ESWL.

Significant progress of modern devices can be stated, with respect to anaesthesia requirements, skin lesions, imaging, multifunctionality, patient comfort, radiation exposure etc. Likewise, very few hospitals would be able to afford the purchasing and running costs of the early lithotripters. State of the art electromagnetic lithotripters do offer a higher over all quality than first generation systems, for only a fraction of the costs.

While maintaining the fragmentation efficency at the level of the „gold standard" HM3, a new gold standard is created for the combined features of stone fragmentation and ergonomics.