High Precision in Lithotripsy

The Siemens LITHOSKOP lithotripsy system features a wide shockwave focus for efficiency in stone disintegration. Transferring this efficiency into routine clinical success requires precise positioning of the shockwave to the stone location. Meeting this technical prerequisite was the most demanding challenge in the system's development. In view of the favorable results, it was unquestionably a worthwhile effort.

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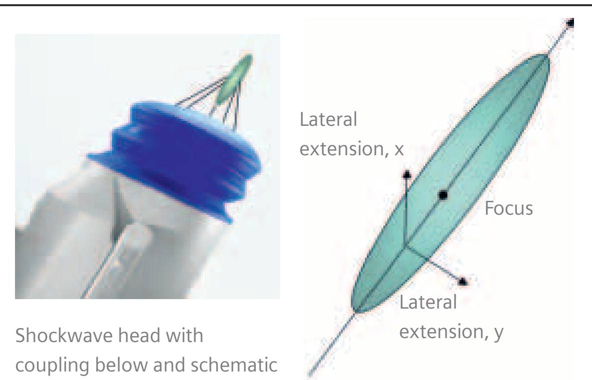
Lithotripsy with extracorporeally generated focused ultrasound shockwaves (ESWL) is the gold standard for the therapy of urinary tract stones and it has demonstrated overwhelming success. Initially it would seem that only minimal accuracy is necessary for this procedure, because the dimensions of the stones associated with it are quite large. The lateral widths and the axial length of the shockwave foci utilized are in the order of centimeters, and even a system with an unstable and moving focus exhibits an accepted disintegration efficiency. It follows, one could assume, that there is relatively little precision required in lithotripter system engineering and therapy focus positioning, because adequate performance already exists. But this is only upon first inspection. Further analysis suggests otherwise.



Shockwave head with coupling below and schematic view of the focus

SHOCKWAVE head with focus cigar.

The Focus Cigar

Cylindrically symmetric treatment systems are used by all manufacturers. In these systems, the 3-dimensional distribution of the pressure in the focal zone shows its typical cigar-like shape, with the smaller extension in the two lateral directions (x and y), and the longer one in the axial direction (z), which is the beam propagation direction (see diagram). Basic considerations [1] for system parameters used in lithotripsy yield to a factor of roughly 10 times larger axial than lateral extensions. Consequently, for an ultrasound focus with a lateral width (-6 dB) of 1 cm, an axial width of 10 cm can be expected.

THE NEW SIEMENS LITHOSKOP lithotripsy system.

A wide focus is prerequisite for good disintegration efficiency and low side effects [2]. The focus position is defined as the location of the maximum peak positive pressure [3].

Axial Extension and Efficiency

If we are directing this long focus to a stone which is larger than the lateral focus width, then the axial position of the stone inside the cigar should be of no importance, especially as we know that the energy of the shockwave is the physical parameter describing the shockwave disintegration efficiency [4], and the energy along the pulse propagation path is the same everywhere. Looking closer, we see that the energy quoted in this paper is the energy above the disintegration threshold of the stone material, and this energy above threshold is strongly dependent upon the axial distance to the focus. Current published measurements show that there is an axial peak in disintegration efficiency, and that the efficiency drops approximately 15% per cm at both axial sides of this peak [5]. This is in accordance with in-house measurements. These results emphasize that, even for a long focus cigar, the

THE SHOCKWAVE HEAD of the LITHOSKOP lithotripsy system.

relative position of the shockwave focus to the stone must be determined with high accuracy.

Lateral Extension and Efficiency

The smaller lateral extensions of the focus cigar result in increased requirements for the lateral focus measurement and focus positioning. For the Siemens LITHOSKOP®* the lateral focus widths (-6 dB) are 8 to 12 mm, depending on energy levels. And not only for large, cherry-sized stones, but stones down to 4-mm diameter [6], and for the "BOOSTER" strategy [2], even down to 3-mm diameter have to be treated. These are the worst case scenarios in the opinion of the developer, but they must be considered. Calculations with a 4-mm stone show a decrease of 20% of the efficiency for a lateral positioning error of 2-mm, consistent with a measured decrease of 35% for a 10-mm stone and a 5-mm positioning error of the focus. Please note: we are referring to millimeters here and not to centimeters as with the axial case. But the decrease in efficiency is only one consideration. There will also be an increase in side effects if the stone is not hit. A clear directive in the IEC standard [3], requires the lateral separation between the focus and the target location to be determined to a precision of ± 2-mm. And, in a concensus, ESWL is the primary choice for the treatment particularly of small urinary stones [7]. In a lithotripter system, the target location is represented by a cross hair on the diagnostic image for localization.

* This product is not commercially available in the United States.

Technical Challenges

Up to this point we have only discussed the properties of the ultrasound field. In its technical application, we need this field aimed at a stone, and the stone's location measured by diagnostic ultrasound and X-ray imaging to an accuracy that meets the requirements previously mentioned.

In the new Siemens lithotripter LITHOSKOP with its in-line ultrasound system, the ultrasound transducer is closely situated in the center of the shockwave generating head. The maximum lateral deviation of the ultrasound center beam with respect to the displayed center beam is less than 0.5°. This holds for both the imaging plane and the elevation direction. This results in a measurement precision of lateral less than 2-mm also for a maximal stone distance of 16-cm.

To achieve the measurement accuracy with the X-ray system is more demanding. The X-ray C-arm and the shockwave head mount are mechanically separated components, yet it is necessary to assure precision even when a large patient is loading the shockwave head with a mechanical force of 300 N. The solution to this involves an elaborate trade-off between the requirements of stable mechanical construction and having unobstructed access to the patient during therapy.

References

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