Biliary Lithotripsy II

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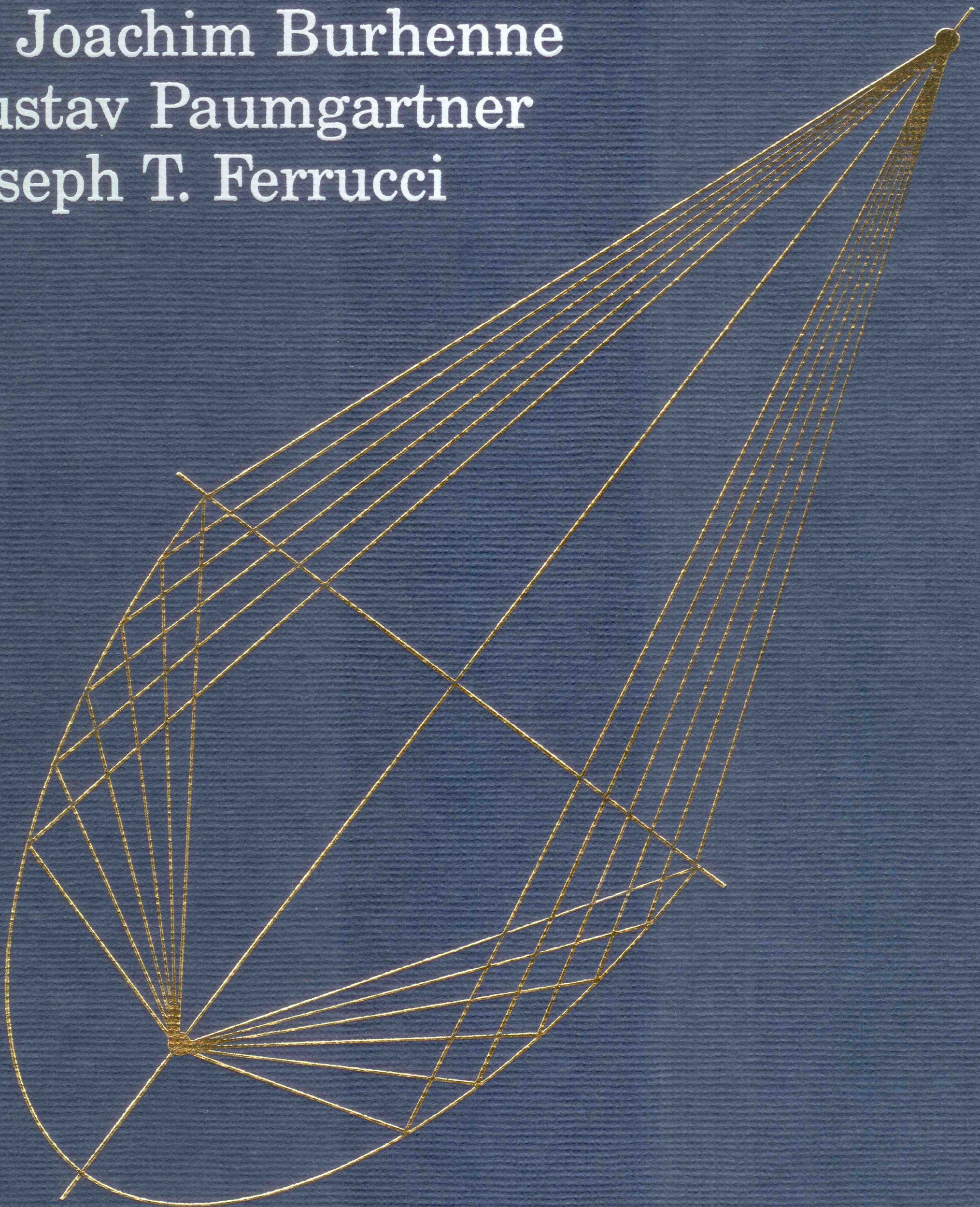

PIEZO-ELECTRIC LITHOTRIPSY WITH THE EDAP LT.01

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The EDAP LT.01 Extracorporeal Shock Wave Lithotripter is a compact system which uses 320 piezo-electric transducers activated by electronic generators to produce the shock wave. This is a monofocal system, i.e., the energy produced by the piezo-electric elements is not reflected before its convergence on the focal point and the renal stone (Fig 1). The piezoelectric elements are dispersed across the surface of a spherical cup which has a single focal point. All of the piezo-electric elements are caused to generate pulses simultaneously and in phase (coherent source). The energy waves produced are concentrated onto the focal point by the spherical shape of the cup. The spherical cup is part of a maneuverable treatment head that can be positioned so that the focal point of the spherical cup coincides with a target calculus. The converging pressure waves produced by the piezoelectric elements causes the destruction of the stone.

In addition to its unique method of generating shock waves, the EDAP LT.01 uses ultrasound imaging for stone localization instead of x-ray imaging. A 3.5 MHz sectorial ultrasound imaging probe is an integral part of the LT.01 treatment head. Its imaging field includes the focus of the treatment head. The operator is able to use the ultrasound image to locate the calculus and maneuver the treatment head so that its focus precisely coincides with the target stone. In addition, the destruction of the stone can be monitored continuously, in real time, on the screen of the ultrasound scanner.

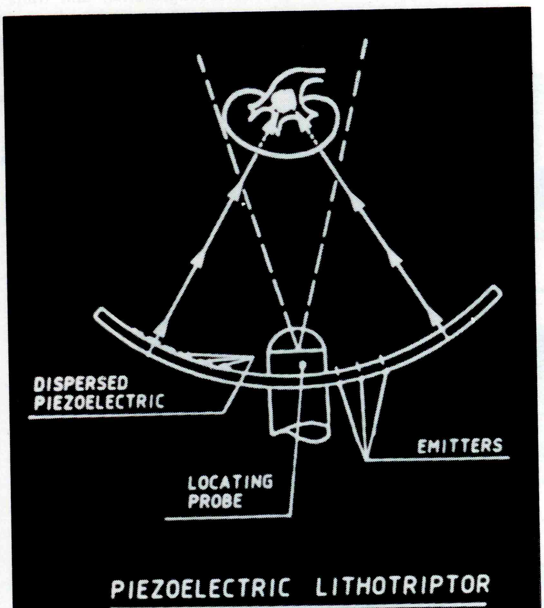

FIG 1.
Piezo-electric lithotripter principle.

The shock waves and imaging acoustic waves are transmitted through an adjustable-level water pocket covered by an elastic membrane above the spherical cup. The membrane is placed into contact with the patient and efficient coupling is assured by using conducting gel between the membrane and the patient's skin.

Generation of shock waves with the EDAP LT.01 can be adjusted precisely so that the treatment can be individualized for each patient. The shock wave generation system of the LT.01 allows the shock wave energy per pulse and the frequency of the pulses to be adjusted easily by the operator.

The EDAP LT.01 lithotripter consists of the following major components (Fig 2): treatment head and support, electronic generator, ultrasound scanner, control console, treatment table, power supply, and optional peripheral equipment. The treatment head (Fig 3) serves two purposes: it combines an ultrasound imaging probe for localization of the stone and a piezo-electric system for the destruction of the stone, both of which are housed in a fluid-filled container. The stone destruction system is based on the convergence on a single focal point of a series of ultra-short (less than 1 microsecond) shock wave pulses generated by 320 ceramic piezo-electric elements. Each piezo-electric element is excited by a separate emitter module in the electronic generator. A shock wave is produced when all 320 piezo-electric elements are pulsed in synchrony and the resulting individual pressure waves are focused exactly at the center of the sphere which constitutes the focal point.

The spherical segment of the cup with the piezo-electric elements is covered with insulating oil, and an elastomer membrane separates the oil from the water chamber. The water chamber is made of a light alloy cone placed over the spherical cup and closed at its upper part with a flexible latex membrane. The chamber has a variable height which is adjusted by adding or removing water. The latex membrane is placed into contact with the skin of the patient, eliminating any water immersion. An ultrasound conducting gel is placed on the membrane to ensure good contact between the membrane and the patient's skin. By inflating or deflating the water chamber, the distance between the focus and the surface of the membrane can be varied from 0 to about 14.6 cm.

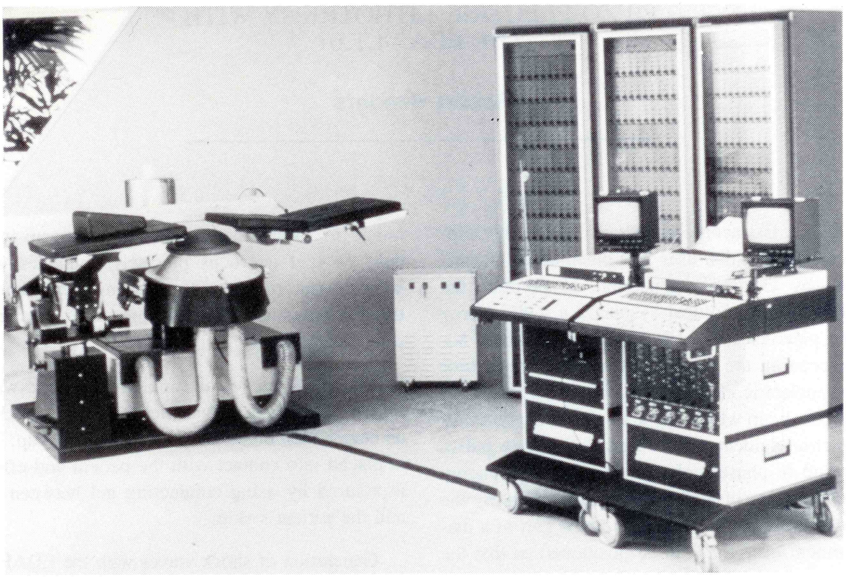

FIG 2.
The EDAP LT.01

The pulse produced by the piezo-electric elements is very brief (Fig 4). The rise time is 44 ns and the pulse width is 76 ns. This briefness reduces the risk of damage to biological tissues. The average maximum peak pressure is 1,031 atm, using a calibration for the hydrophone of 5.87 mV/atm. The pressure pulse falls as rapidly as it rises and does not possess any significant negative components. The size of the focal point is approximately 2.3 mm by 23 mm (Fig 5). The distribution of peak pressures, both positive and negative, are shown on Figure 6 for Z axis at 100% power.

A real time 3.5 MHz sectorial ultrasound probe is fitted through a cylindrical sleeve at the center of the treatment head. The probe is connected to the ultrasound scanner. It is a rotating transducer and provides longitudinal and transverse images and all oblique views. The ultrasound probe

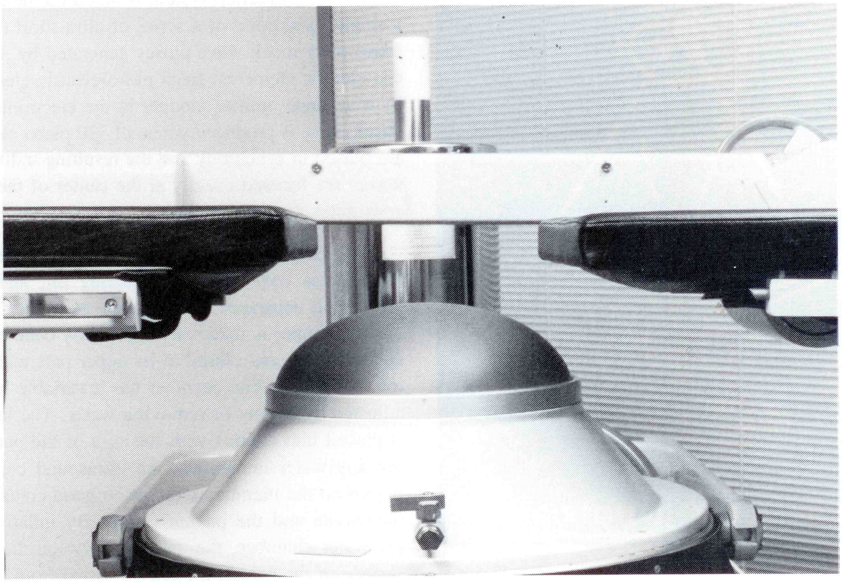

FIG 3.
The treatment head of the EDAP LT.01.

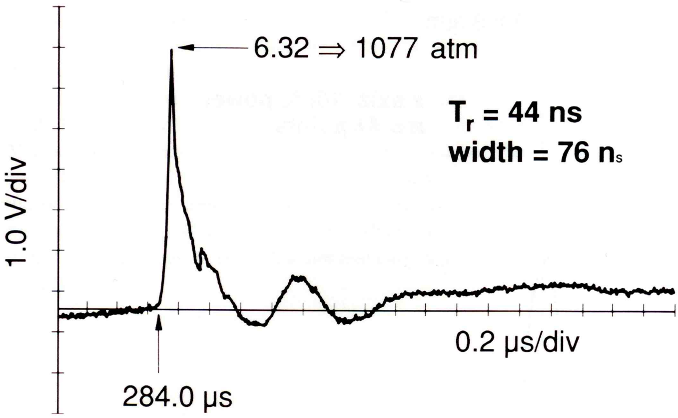

FIG 4.
Rise and time and pulse width.

provides an image of the area around the focal point of shock waves which is displayed on the ultrasound scanner and provides an electronic cursor which marks the position of the focal point on the scanner monitor so that the stone can be positioned precisely. Using the displayed image, the progress made in disintegration may be monitored in real time throughout the entire treatment.

The treatment head is mounted on a mobile support. It is controlled electronically from the control console and can be moved in five different directions: three linear ones (X, Y, and Z) and two rotating ones in perpendicular planes. The movable support is placed under the treatment table and can be locked in place. In use, the treatment head is positioned so that it is in direct contact with the patient, and the patient's stone is positioned in the treatment head focal area using the ultrasound scanner. A reservoir for water is also located on the movable treatment head support. The reservoir can be raised or lowered and is connected to the treatment head with a flexible tube. It supplies water to fill the treatment head. Since the treatment head can be oriented in all directions, the best firing axis can be selected. The energy delivered can be adjusted by means of a potentiometer on the control console. The rate of firing can be varied from 1.2 to 160 shots per second. In most applications, firing rates below 5 or 10 shots per second are used to reduce the pain level and avoid the use of anesthetics.

The electronic generator is the power unit for the piezoelectric elements on the treatment head. The generator contains 320 emitter modules mounted in 32 racks and distributed in 3 cabinets (2 cabinets have 11 emitter module racks and 1 cabinet has 10). The 320 emitter modules contain high-power semiconductors which excite the corresponding piezoelectric elements arranged in the spherical segment of the treatment head. The frequency of firing is controlled from the electronic generator central rack. Firing frequencies can be selected from a front panel control and can have the following values: 1.25, 2.5, 5, 10, 20, 40, 80, or 160 Hz.

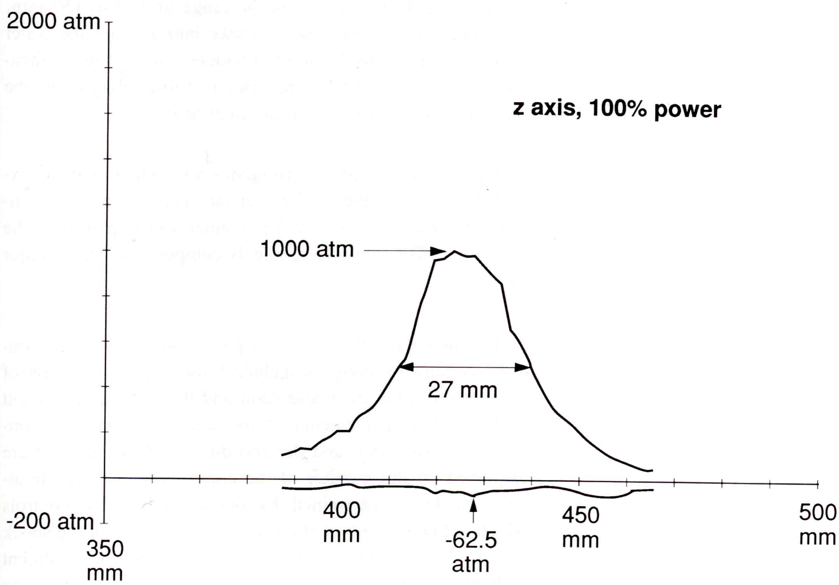

FIG 5.
Maximum peak pressure.