Introduction

Looking back at 28 years of pressure pulse therapy experience, my first experience in 1984 was the development of the transducers and locating systems for piezoelectric lithotripsy (Wolf Piezolith). During this time, we already recognized the importance of cavitation for tissue damage. As these side effects are undesired in lithotripsy, the early development goals were the reduction of negative pressures and the development of very short pulse sources.

After the successful launch of the lithotripter, we started developing piezoelectric sources with a high cavitation potential (HEPUS – High Energy Pulsed Ultrasound) in order to research the effects of these signals on tumour tissue. Animal experiments were done in cooperation with the German Cancer Research Center in Heidelberg at that time. The project was later discarded because at that time it was not clear if as a side effect cavitation would also release functional tumour cells from tumours, thus producing the danger of remote metastases.

After Ph.D. thesis, from 1988 on I was working as a research and development engineer at Dornier MedTech on the development of lithotripters, pain therapy (ESWT from 1993) and Biotripsy (Use of cavitation for the transfection of cells, ca. 2000). In 2002, after a change to the University of Applied Sciences in Hamburg, research on pressure pulse was focused on measurement techniques (Optical hydrophones, artificial stones for quality control purpose). At present we are working on the characterization of ballistic pressure pulse sources used in extracorporeal pain therapy (ESWT).

Involvement in the development of international Standards started ca. 1994 when the relevant measurement standard for pressure pulse lithotripters (IEC 61846) and a safety standard (IEC 601-2-36) were developed. Until today I am responsible for the maintenance team mt24 – safety of lithotripters and member of IEC TC87-ultrasonics (e.g. Working Group 7 – Surgical Devices).

During the employment at the University, scientific collaborations since 2002 include the PTB and ESWL / E SWT companies Siemens and EMS. I am member of the German Society of Shock Wave lithotripsy, and the DGBMT.

Current approach

In our lab, we study the potential of optical hydrophones (FASO, FOPH, LSHD) for the measurement of high energy pressure pulses. Measurement of the parameters as defined in IEC 61846 are a continuing task, as well as the collection of data for advancing the knowledge on different types of pressure pulse sources. Our further goals are the development of the use of optical hydrophones for the measurement and characterization of HITU sources. Measurements are made in (degassed) water, and we are also experimenting with other coupling materials for quality control and constancy measurements of ESWT devices. Additionally, the properties and (linear and non-linear) fields of pressure pulse sources are modelled using FEM and Field-II approach.

Important criteria for selection of potential exposure/dose definitions

Long year experience in the description of focused and unfocused lithotripsy and ESWT sources show, that it is necessary to define a set of stable parameters, which can be measured with a high
reproducibility. It is strongly recommended to define a broad range of parameters which are required from the manufacturers, because parameters which are not well understood today might turn out to be of much importance for the description of biological / medical effects. During the development of deeper understanding of the lithotripsy parameters and their importance for stone comminution as well as for their effect on tissues, the importance of different parameters (peak pressure, peak rarefaction pressure, Pulse Intensity Integral (Energy Flux Density), Energies in the focal area etc.) were discussed and are still under discussion after 30 Years.

Some of the parameters which were mentioned as the most important ones in the past, e.g. peak positive pressure, pulse rise time, focus diameter (-6dB) today are known as very apt to large errors and little correlation to the efficacy of stone comminution and side effects. In contrast, other parameters like the 5 MPa focus size and energies inside this (and other) areas seem to play an important role.

**Concrete suggestion**

Besides the definition of descriptive field parameters, which are needed for the evaluation of their importance on biological / medical effects, there should also be a set of reliable measurement methods for quick check of the constancy of devices. For these methods, it is important that also non-trained (medical) personal should be able to perform some quick and reliable tests.

The set of measurement methods should comprise means of defining and checking targeting accuracy and mechanisms for the identification of changes of source field parameters (e.g. deviation of focus position and increasing side lobes / hot spots etc.

**Literature recommendation(s)**


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