Acousto-Optics and Applications

# Unfocused/Weakly Focused Pressure Pulse Sources for Pain Therapy: Measurements in Water and in a Dry Test Bench

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Unfocused/weakly focused pressure pulses (UPP) are generated by an "air-gun" like mechanism, with a projectile accelerated by pressurized air and impinging on a metal applicator. They were introduced in 1998 for the treatment of orthopedic soft tissue pain. The patient side of the applicator (a circular piston of 6–30 mm diameter) releases single pressure pulses of 2–10 MPa and 4–5 $\mu$s duration. Up today, there is no standard for the measurement of UPP sources (UPPS), so data are often reported on the basis of the *focused* lithotripter standard IEC61846. The purpose of this research is to establish methods to reliably measure UPPS acoustic parameters and establish a parameter set based on definitions from focused lithotripsy sources as applicable. Therefore, acoustic characteristics and wave fields of the pressure pulses of UPPS from different manufacturers were measured in a water bath and in a dry test bench. It was demonstrated by comparison with optical hydrophones that piezoelectric hydrophones are appropriate for the measurements of UPP. For on-axis measurements at a fixed distance, measurements in the dry test bench can replace water-bath measurements. Additionally, the dry test bench allows for reliable results at pulse rates > 1 Hz.

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## 1. Introduction

Extracorporeal pressure pulse therapy (frequently called "ESWT" — extracorporeal shock wave therapy) was originally established in 1993 for the treatment of calcified shoulders and tendonitis in elbows and heel spur with focused lithotripter sources [1]. Due to the instantaneous and continuing success of the method, it was soon extended to the treatment of orthopedic pain situations in various body parts.

The unfocused/weakly focused pressure pulse (UPP) sources (UPPS) were introduced in 1998 [2]. Compared to focused ESWT devices, the aperture of a UPPS is significantly smaller. Therefore non-focused pressure pulses are generated, which propagate into the tissue in a wide angle. Their maximum amplitude occurs at the source and decreases according to a $1/z$ law at longer distances $z$. The term "pressure pulse" describes the fact that these pulses have rise times in the range of $\mu$s — as opposed to shock waves with a rise time of ns. Frequent applications (reported success rates [3] in brackets) are e.g. shoulder pain (78–91%), tennis elbow (68–91%), runner's knee (74–88%), heel spur pain (34–88%), archillodynia (74–88%).

### 1.1. Technology

Usually, the UPPS is built as a pistol like handle (see Fig. 1), which is guided manually by the medical practitioner during therapy. Most UPPS generate the pulses by a projectile (typical mass 30 g, diameter 5 mm) which is accelerated by pressurized air (typically 2–5 bar) in a guiding barrel of 200 mm length. At the end of the barrel, the projectile hits the rear surface of the circular "applicator". The applicator, which is usually made of steel or other metals (aluminum) has a mass of > 10 times the projectile mass and a cylindrical or conical shape with a flat or slightly curved surface of 6–30 mm diameter at the patient side. The applicator surface is coupled to the skin of the patient by ultrasound gel, usually with mild coupling force applied by the practitioner guiding the handle. Treatment depths range from few mm to 20 mm in the tissue, depending on the treatment site (shoulder, elbow, leg, foot).

A typical treatment session comprises some hundred to 3000 pulses, released at a repeat rate of 1–20 per second. Each hit of the projectile at the applicator generates a single short pulse of 4–5 $\mu$s duration with 2–10 MPa amplitude [4], followed by an equally short rarefaction phase with comparable negative pressure amplitudes (Fig. 2). Depending on geometrical shape and material of the applicator, after the primary bipolar pulse, more spurious pulses (reverberations) with decaying amplitudes may occur, caused by internal reflections of the initial pulse inside the applicator. The biomedical significance of these reverberations is unknown.

The measurement of single pressure pulses poses high demands to the sensor technology [5]. Optical hydrophones [6, 7] have become a quasi-standard for lithotripter and focused pressure pulse (FPP) source measurement. For smaller amplitude pulses, the typical noise level of optical sensors may degrade the accuracy of the measurement or require time-consuming averaging of several consecutive pulses. As the peak pressure

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amplitudes of UPPS are significantly less than of FPP sources, rugged piezoelectric hydrophones may be used with the advantage of better signal-to-noise ratio. Due to a lack of an approved measurement standard, UPPS data are often reported based on the IEC61846 standard [5] for focused lithotripters. This leads to misinterpretation of the data and influences the level of understanding of the observed biomedical effects.

The present paper intends: 1. to demonstrate that piezoelectric hydrophones can be used for the measurements of UPPS with the same results as optical hydrophones and to present the measurements of axial and lateral parameters of an UPPS; 2. To show that measurements on-axis at a fixed distance (5 mm) can be made with a dry test bench with the same results as in a water bath and are usable at higher pulse repeat rates.

## 2. Materials and methods

For the comparison of the pressure–time signals in water, two types of optical hydrophones were used: A custom built fiberoptic hydrophone FASO (125 $\mu$m fibre diameter, 1000 Hz–40 MHz frequency range, > 1 MPa noise level [7]), and a light spot hydrophone LSHD (Univ. Erlangen, 100 Hz–20 MHz, 9.6 mV/MPa). For other measurements in water and in the dry test bench described below, robust piezoelectric hydrophones with 0.25–20 MHz (–3 dB) frequency range (Onda HGL-0200: 200 $\mu$m active diameter, –265.5 dB (re. 1 V/$\mu$Pa,) $\pm$1.5 dB and HGL-0400: 400 $\mu$m diameter, –256 dB $\pm$1.5 dB, both with preamplifier AH-2010 (+20 dB)) were used.

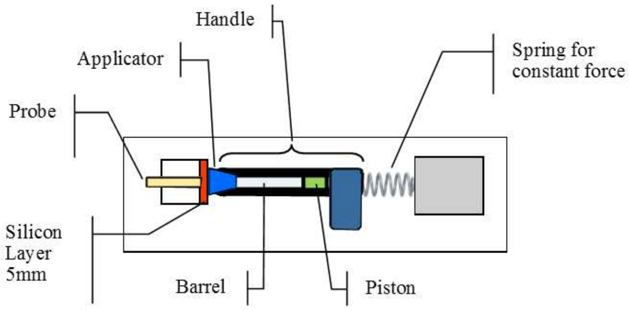


Fig. 1. Sketch of the dry test bench with treatment handle.

The time domain pulse parameters [6]: Peak positive and rarefaction pressure ($P+$, $P-$), rise time (10% to 90% of $P+$) $t_{\mathrm{R}}$, positive pulse width (50% to 50% of $P+$) $t_{\mathrm{W}}$, and the pressure-pulse integral $PII+ = 1/\rho c \int_{\text{Positive pulse duration}} p^2(t)\,\mathrm{d}t$ were evaluated using the definitions of the lithotripsy measurement standard IEC 61846 [5]. "+" denotes that only the positive pulse portion is taken, $\rho c$ is the characteristic impedance of the medium. The pulse energy was calculated by spatial integration of the lateral $PII+$ values in a circular area parallel to the applicator surface at a given distance. Measurements of four handles with 6 applicators of air pressure-driven ballistic UPPS were made in water and in a dry test bench (Fig. 1). This test bench uses a coupling pad of 5 mm thickness between applicator and hydrophone [4]. The pad is made of silicon (Sanitär-Silikon, Bauhaus, Germany, 20 mm diameter, 1134 m/s), which mimics the patient tissue. The same piezoelectric hydrophones (HGL-0200) as in water can be coupled to the rear side of the silicon pad, either taking advantage of the sticky nature of the silicon surface or by applying ultrasound coupling gel. The Applicators reported here (#2: steel, #5: aluminium) had 15 mm diameter at the patient side. The PPS driving pressure was set between 1.5–4 bar, given by an arbitrary scale (1–25). Measurements with single pulses (in water) and at 1, 2, 5, 10, and 12 Hz repeat rates (dry test bench) were made.

## 3. Results and discussion

Figure 2 shows the comparison of the pressure–time signals measured by the optical and the piezoelectric hydrophones. In order to compensate the dynamic properties of the optical hydrophones, deconvolution using the hydrophone's impulse response [6] was applied. After this processing, the parameters $P+$, $P-$, $PII+$, $t_{\mathrm{R}}$ and $t_{\mathrm{W}}$ [5, 6] of the first significant pulse parts show a good match.

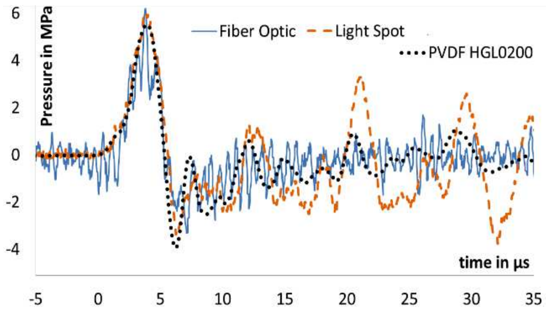


Fig. 2. On-axis pressure measurements of a PPS, measured at 5 mm distance with two optical and a piezoelectric hydrophone HGL200 (Applicator #2).

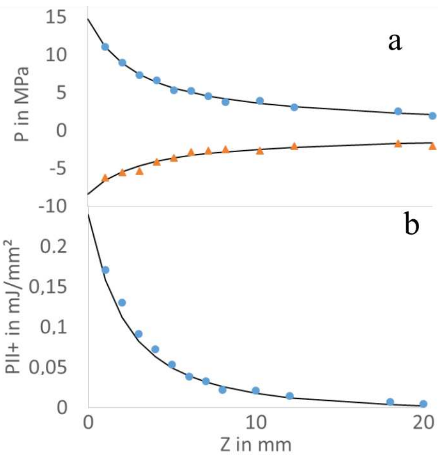


Fig. 3. Spatial distributions of $P+$, $P-$ and pulse intensity $PII+$ along the PPS axis, measured in degassed water (applicator #5, HGL400 hydrophone).

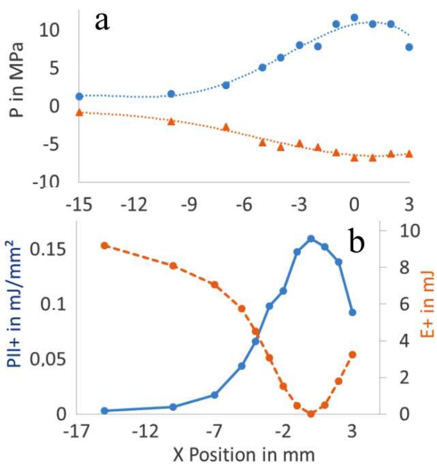


Fig. 4. Lateral distribution of pressure, energy flux density $PII+$ and pulse energy E+ at maximum driver setting (Applicator #5, HGL400 hydrophone at 1 mm).

Measurements at repeat rates higher than 2 Hz are often not possible in water due to the development of cavitation at higher driving settings. In the dry test bench, cavitation does not occur. Thus the characterization of the pulse-to-pulse variations and the long-term stability of the PPS as well as the measurement of pulse timing parameters $t_R$ and $t_W$ at a fixed distance from the applicator can be made in the dry test bench with the same accuracy as in water [4, 8]. As cavitation is avoided, the parameters can also be measured at higher pulse repeat rates (Fig. 5). It was observed that the $P+/P-/PII+$ values decrease at higher repeat rates in some devices.

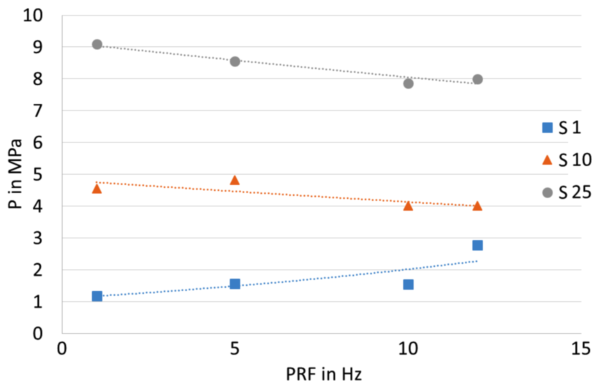


Fig. 5. Applicator #5 (aluminium, 15 mm), measurement in the dry test bench: pressure dependence on pulse repeat rate (HGL400).

## 4. Conclusions

Pressure pulse field parameters (axial and lateral distributions of $P+$, $P-$ and $PII+$, and the pulse energy E+ derived from the measurements [5]) can be measured in a water bath in single pulse mode, using a PVDF hydrophone. Some definitions as of the IEC standard for FPP sources [5]: rise time $t_R$ and Pulse width $t_W$, peak positive and negative pressures $P+$ and $P-$, and the Pulse Intensity Integral $PII+$ also apply for UPPS. Otherwise, field distribution parameters related to a focus do not apply for UPPS. Instead, they should be replaced by lateral field width values at a fixed distance (5 mm) from the applicator and by values measured on-axis at different distances (see Fig. 3, at least at 1, 5, 10, 20 mm).

Pressure-time parameters ($P+$, $P-$, $t_R$, $t_W$, $PII+$) at a fixed distance on-axis can be measured fast and reliable in the dry test bench, using the same piezoelectric hydrophones as in water. It could be demonstrated that $p(t)$, $P+$, $P-$ and $PII+$ values are the same as in water [4]. A major advantage of the dry test bench is that these parameters can also be measured reliably at high pulse repeat rates, as cavitation does not occur. The methods and results described in this paper will be used to propose a measurement standard for the characterization of UPPS, which facilitates the description of treatment parameters and of treatment results of different devices and helps to understand the biomedical effects of UPP.

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