Extracorporeal Pressure Pulse Therapy (PPT), often called “Shock Wave Therapy” (ESWT) originally is a by-product of lithotripter technology used in extracorporeal shockwave lithotripsy. During in-vivo evaluation of unwanted side effects of extracorporeal shockwave lithotripsy osteo-oblasm-stimulation and bone apposition was observed. Since then the PPT was augmented to a variety of other applications using the first generation focused or second generation non-focused devices. A review of the publications available on the PPT, shows that neither the physical principle of the shockwave-field nor the therapeutic effects in biological tissue are fully understood. Furthermore, clinical trial reports of shockwave therapies reveal contradictory results, especially with second-generation devices, predominantly connected to the lack of knowledge on the physical properties of the pressure pulse (PP) field. As a proper measurement standard for unfocused PP devices is not in place, measurements for the certification process are carried out according to the IEC standard 61846, which was originally developed for the characterisation of focused shockwave-lithotripters and is in many aspects not appropriate for the non-focused PP sources. A Chinese national standard YY 0950-2015 exists. In this paper, an unfocused second-generation PP source was measured based on this Chinese standard. Results show that the acoustic output measurements according to the standard are not suited for the characterization of the “fast” (duration < ca. 20µs) leading PP portion of high amplitude. Instead, the method described in the Chinese standard measures the inertial behaviour of the device, which is responsible for generating oscillating, significantly slower (e.g. millisecond range) wave packets. Until today, there are no clinical reports on the therapeutic significance of these inertial waves, which only are generated by ballistic PP sources.

Keywords: Shockwave, ESWT, ESWL, r-ESWT, ballistic pressure pulse (PP) sources

1. Introduction

Pressure pulses (PP) are acoustic signals of a short duration of some microseconds, mainly composed of a (leading) positive (compressional) pulse of some Megapascals amplitude and a trailing rarefaction part. When the rise time of the compressional pulse is less than a few nanoseconds, they
are called shockwaves. Some hundred up to 3000 PPs are applied per treatment with repetition rates of 1 to ca. 20 per second. Since the introduction of extracorporeal shockwave lithotripsy (ESWL) for the treatment of kidney stones in the 90th the PP technology (ESWT) was augmented to a variety of other therapeutic fields, e.g. in the treatment of musculoskeletal disorders [1]. During the in-vivo evaluation of potential unwanted side effects of ESWL in the 90th, shockwave induced osteoblast stimulation and bone apposition after an initial osteocyte-damage was observed [2], [3]. This marks the initiation of shockwave therapy for the treatment of pseudarthrosis [2]. Nowadays ESWT is a widely used method in orthopaedics for the treatment of epicondylitis, calcific tendinitis, achillodynia and calcaneal spur, and e.g. myofascial pain treated with trigger-point-therapy [4]. Clinical trials report good results in comparison to conventional therapies, without significant side effects [1], [3–6]. Therapeutic success with such a wide range of different indications suggest the assumption that there must be many different bio-effects related with PPT [2].

In contrast to conventional first-generation piezoelectric, electrohydraulic or electromagnetic ESWT sources, ballistic PP sources (also called second generation ESWT or radial (r-ESWT) sources) use the same principle as air guns. Pressurised air (typically 2 – 4 Bar) is used to accelerate a cylindrical steel projectile (typical weight 3 g) guided through a tube, of about 20 cm, onto the rear face of a cylindrical or (stepped) conical waveguide, called applicator, which is typically made of steel or other metal with a weight of 30 g. Typical diameter of an applicator at the patient side is 15 mm. Other applicators with different diameters (6 mm - 36 mm), different shapes (convex or concave end-surface) and different length are also available. After the impact of the projectile on the applicator a compression wave of few microseconds duration travels through the applicator material and is transferred at the adjacent side into the patient via a coupling gel [7], [8]. This “fast” pulse (Figure 4, right), accompanied by a trailing rarefaction pulse and, depending on the applicator geometry, some spurious oscillations, can be compared to the pulses released by first-generation (focused) PP sources. Additionally, the applicator performs a slower inertial motion caused by the total impulse transfer from the projectile to the mass of the applicator (Figure 4, left). This motion is only sparsely described in literature up to now [8] and can be widely influenced by the mechanical construction of the device.

2. Acoustic Metrology

The physical properties of the acoustic field of a Pressure Pulse Therapy (PPT) source, the principle of pulse generation and the parameters of the field are well defined in [9], [10]. In addition, the measurements of the field parameters of focused PP sources are described by the IEC standard 61846 and are mandatory for regulatory certifications. Although the physical parameters of the field are well known, the biological and the bio-molecular effects are not fully understood [1], [11]. It is assumed that the biological effects of ESWT are based on a bio-molecular mechanism and not on the plain physical-mechanical level [5].

Since the end of the last century a new type of source, the ballistic or radial extracorporeal shock-wave therapy sources (r-ESWT) is on the market and used for soft-tissue pain situations [3], [4]. In contrast to the conventional focused ESWT devices, the pulses in r-ESWT are guided by patient feedback to the intended treatment area, without ultrasound or X-ray control. While several reports and clinical studies find good results with r-ESWT, such as in the therapy of chronic plantar fasciitis [12], Tennis elbow [4], some others find no effect [13] or no advantages of r-ESWT compared to standard procedures [14]. The varying results could be an indication for the influence of clinical-study conditions and the settings of the hand-piece on the study outcome [15]. The acoustic output of these devices is mostly indicated by arbitrary units, which are different from manufacturer to manufacturer. While some manufacturers provide the acoustic output by the load of the hand-piece in bar, others provide step-values ranging from e.g. 1 to 20. Thus, the comparison of a therapy using devices from different manufacturers, and even different applicators or hand-pieces from the same manufacturer is not possible. Without knowledge on the physical level, predictions on biological effects are
difficult to make. Furthermore, the present lack of technical requirements on the measurement-conditions may result in a large variation in the range of measurement values declared by different manufacturers.

The IEC standard 61846 was published in 1998, defining the measurement parameters of focused PP fields. The standard was written for lithotripters, but it may also be used to describe other focused ESWT devices [9]. It is inappropriate for non-focused second generation ESWT devices, as many parameters do not apply or need to be re-defined for non-focusing fields. Therefore, a new international standard for unfocused PP devices is in the process of development (IEC 63045), but not yet in place.

Due to the lack of international standardization and technical requirements for the measurement of the second-generation PP devices the Chinese notified body published a national standard (YY 0950-2015) to close the requirement gap, defining some simplified measurement methods.

The aim of this paper is to evaluate the national standard with a second-generation PPT source.

2.1 The Chinese measurement standard

The Pharmaceutical Industry Standards YY 0950-2015 “Extracorporeal pressure wave therapy device by compressed air” is a Chinese Food and Drug Administration directive, specifying the storing, the packaging, the transport and biocompatibility etc. of these devices. In terms of the acoustic output of ballistic sources the standard requires several parameters:

- The acoustic output-energy $E_{Ac}$ of the shockwave source is measured by converting the potential energy $E_{pot}$ of mass-block (mass $m$) which is accelerated by the impulse of the applicator head, according to Figure 1. The applicator is attached to the mass-block and the flight height of the mass-block after the PP is applied should be recorded using a length-scale on a transparent tube, with the mass-block raising inside. The potential energy is calculated according to $E_{pot} = mgh$ (1)

- The energy density $ED$ is calculated by dividing the maximum energy from the potential-energy setup ($E_{pot}$) by the surface of the applicator $S$: $ED = E_{pot}/S$ (2)

- The depth of penetration is measured by a setup, where the ballistic source is loaded with a static load of 25 N and the acoustic pressure is measured using a non-specified piezoelectric or piezoresistive sensor under two hydrogel pads with two different thicknesses ($15\text{ mm}$ and $20\text{ mm}$, each with a Young’s modulus in the range of 0.2 MPa). In this paper, we do not assess this part of the standard.

2.2 Materials and methods

A test setup (Figure 2) was built according to the requirements of the Chinese standard. The energy values obtained by the setup are compared with the results of acoustic measurements using calibrated hydrophones. In addition to the requirements of the standard, a fixation of the ballistic source was added to ensure constant contact of the applicator to the mass-block and to ensure stable measurement conditions (see fixations in Figure 2).

A “DolorClast Power” handpiece (EMS Electro Medical Systems S.A., Nyon - Switzerland) is used as PP source. In order to guarantee reproducible readouts, the flight height of the mass-block is measured using the high-speed-camera of a smartphone with 240 fps (iPhone 7). The mass-block is a polished steel-cylinder with a weight of $95\text{ g}$ For comparison, the same source with equal settings is measured in water using a Polyvinylidenfluorid (PVDF) Hydrophone (HGL0200, ONDA Corp. Sunnyvale - USA). The Hydrophone has an active diameter of $200\text{ µm}$ and the calibration is given for the range $1\text{ MHz}$ to $20\text{ MHz}$. All hydrophone measurements are performed $1\text{ mm}$ above the applicator. A HAMEG 1508-2 oscilloscope (HAMEG Instruments GmbH - Germany) is used for signal acquisition, signal-processing is performed in Matlab (Math Works Inc.) and Excel. Hydrophone measurements are done in degassed and deionised water at $25^\circ\text{C}$ (IEC 61846, 63045).
Figure 1: The setup for the measurement of the potential energy of a mass-block for the conversation to the acoustic energy of a ballistic source. The PP applicator is coupled to the (grey) mass block from below. Picture has been taken from the Chinese standard YY 0950-2015.

Figure 2: The measurement setup which is used in the current investigation. The setup is built according to the description in the Chinese standard YY 0950-2015.

For each setting, 50 measurements of the flight height are made in order to evaluate the mean values and the pulse-to-pulse deviation. For the hydrophone measurements for each setting 2 measurements are averaged, and the energy values are calculated from the averaged pressure-time-curve values integrated over the surface of the applicator. The applicator of the PPT hand-piece has a circular symmetry, so that the hydrophone measurements are done for one single plane perpendicular to the applicator axis and interpolated for the whole geometry. The averaging over just 2 measurements is possible due to low standard deviation of the hydrophone measurements (< 10%).

3. Results

The investigation is divided in two parts. The first part investigates the traceability of the measurements done with the measurement setup described in YY 0950-2015 (Figure 1). In our second investigation the validity of the energy and energy density measurements are assessed by comparing energy values measured using the proposed setup (Figure 2) with acoustic measurements using a calibrated hydrophone.

3.1 Acoustic Energy Calculation

In the first investigation the influence of the fixation of the hand-piece on the flight-height of the mass-block is evaluated. Two cases were evaluated:

1. The hand-piece is just attached to the mass-block without any clamping (first case),
2. The hand-piece is clamped on both ends of the hand-piece (second case), at the upper (proximal) part and the lower distal part of the hand-piece (See Figure 2).

In the first case, the flight-height of the mass-block was found to be minimal, while the pulse-to-pulse deviation is maximal (Figure 3 left). A maximum deviation of up to 30 % from pulse to pulse was observed at identical settings. In contrast, in the second case, with both sides of the hand-piece being clamped, the flight-height is maximal, and the standard deviation is minimal (Figure 3 right). The average difference for the flight-height between the first and the second case is up to 60 % ± 20 %. This means, with the same hand-piece using identical loading different acoustic energy output values are measured depending on how the device is fixed in the measurement setup.

As there is no specification in standard on how to clamp the hand-piece in the setup, the measurement results can be “adjusted” by simply changing the clamping forces. Thus, a comparison of two measurements done by different personnel and / or at different facilities may differ vastly and is not reliable.
3.2 Energy calculation and acoustic measurement

The second task is to compare the energy values calculated with this setup with PP energies derived from acoustic measurements using calibrated hydrophones.

For this purpose, the hand-piece is fixated at both ends (case 2), as the lowest pulse-to-pulse deviation for the flight height was observed in this case. The flight-height for the mass-block is measured at 3 Bar loading. The measurement is repeated 20 times and gives a mean height of 300 mm.

According to (1) the potential energy of the mass-block is

$$E_{pot} = mgh = 0.095 \text{ kg} \cdot 9.81 \text{ m/s}^2 \cdot 0.3 \text{ m} = 0.28 \text{ J}.$$  

The energy density for the 15 mm diameter applicator according to (2) is

$$ED = \frac{E_{pot}}{A} = \frac{280 \text{ mJ}}{\pi \cdot 7.5^2 \text{ mm}^2} = 1.58 \text{ mJ/mm}^2.$$

Then, the same hand-piece using the same fixation and loading is used to measure the acoustic pressure signals with a calibrated PVDF Hydrophone at $z = 1$ mm distance from the applicator (Typical signals see Figure 4) in water. The hydrophone is laterally shifted in steps of $\Delta x = 1$ mm, thus 7 measurements are taken. The acoustic energy flux density is calculated from each of the pressure signals using the formula according to the IEC standard 61846 and applying an integration time $T = 7$ $\mu$s, which corresponds to the duration between the first onset of the positive pulse (Figure 4 Right) until the end of the first negative signal portion:

$$ED(x) \cdot T = \frac{p(x,t)^2(t) \cdot dx}{\pi^2 \cdot (x^2 + t^2)^3/2} = 0.5 \text{ mJ/mm}^2.$$

The acoustic PP energy then is calculated by integrating the ED(x) values over the surface of the applicator and gives

$$E = 2\pi \int_0^{7.5} ED(x) \cdot dx = 9 \text{ mJ}.$$  

For a mass of 95 g, the potential energy of 9 mJ would correspond to a flight height of 9.6 mm, which is much smaller than the observed 300 mm. According to the law of conservation of Energy no energy can be lost in an isolated system. The lower energy measured with the acoustic measurements can be explained by the specifications of the IEC standard 61846 on how to measure the PP and how to calculate the acoustic energy from the “fast” leading signal portion. The precise specification of the measurements and calculations are defined from the signals of the (focusing) first-generation PP (electrohydraulic, electromagnetic or piezoelectric) sources, which do not generate the inertial behaviour of the ballistic 2$^{nd}$ generation devices.

3.3 Discussion

The investigated setup using the mass-block measures the total energy of the signal, which does not correlate to the acoustic energy of the PP as calculated from the “fast” pulse portion according to existing standards. In contrast, the total energy as measured by the flight height includes the inertial
pulse part (See arrow in Figure 4 left). According to our results, this inertial part may change largely from pulse to pulse, from hand-piece to hand-piece and depending clamping conditions, while the “fast” pulse portions are almost identical (Figure 4 right). Calculation of the pulse energy from the complete signal, i.e. by choosing an integration time \( T = 400 \mu s \), which includes the complete measured pressure signals (Figure 4 left), results in a total energy of 0.2 J. Although this compares well with the mean value of 0.28 J calculated from the flight height of the mass block, the finding must be taken with care, as the hydrophone signal over such a long time may contain additional components from reflections between applicator and hydrophone, or other reflectors in the measurement setup including water surface etc.

The question arises, if the comparably small energy (9 mJ) from the “fast” pulse or the huge value (0.28 J) of the total energy play the major role for the therapeutic effects. To evaluate this question, the same hand-piece is measured with a calibrated hydrophone in water: a) with a direct coupling of the applicator to the measurement-medium (water) and an applicator – hydrophone distance of 1 mm, and b) with a 1 mm silicon rubber pad instead of the water between the probe and the applicator. The silicon rubber mimicks the patients skin and acts as an acoustic filter damping the inertial part of the pulse. As can be seen in Figure 4 (right) the “fast” signal looks comparable in both cases. Then the same 1 mm silicon rubber pad is placed between the clamped applicator and the mass-block in the measurement setup (Figure 2). The flight-height of the mass block as an average of 50 impulses is measured, with and without the silicon rubber between the applicator and the mass-block.

Result: the measured flight height without silicon rubber pad is well comparable to the flight height as in Figure 3 (Right). In contrast, with the 1 mm silicon rubber pad, we could only observe some minor non-measurable jumps of the mass block.

The inertial motion of the applicator obviously is converted into inertial oscillations in the range of several hundred microseconds to milliseconds after the “fast” PP. This inertial energy part will not penetrate the patient when the applicator isn’t pressed to the tissue with a large force, comparable to the fixation of the hand-piece in the test bench. Thus we assume that the energies measured by the flight height when directly coupling the applicator to the mass block without a pad are not reliably describing the (by todays knowledge) therapeutic effective “fast” part of the PP.

In a review of the available publications on ballistic PP sources, no study investigated or even mentioned the effect of the inertial oscillations on biological tissue. The inertial oscillations are usually not documented, if the measurements are done according to the IEC Standard 61846, as the standard specifies acquisition times are determined from the duration of the fast PP, which is just a few microseconds.

![Figure 4 (left): p(t) of fixated 15 mm applicator at 3 Bar loading, measured 1 mm above the applicator with a PVDF Hydrophone HGL0200 in degassed de-ionized water at 25°C. Red arrow: inertial pulse. (Figure 4 right): Red graph: “fast” PP portion with the same hand-piece at 4 Bar load with a 1mm silicon rubber pad between the hydrophone and the applicator. Black graph: without silicon rubber pad.](image-url)
4. Conclusions

The Chinese Standard needs further evaluation. As the results of this paper indicate, the flight height and thus the calculated energy and energy density values depend strongly on the energy transfer from the applicator to the hand-piece and the measurement setup. As demonstrated, they are heavily influenced by the clamping conditions, which do not reflect the clinical situation. Therefore, the proposed measurement setup in its current state, seems not suited for the generation of energy specifications, which are handed to physicians to predict the therapeutic effect and possible side effects of ballistic PP sources. It is also not advisable to use the energies for a comparison of hand-pieces or devices from different manufacturers. However, if the clamping conditions for the hand pieces are specified and controlled, the investigated setup proposed in the Chinese Standard still may be used for in house testing, e.g. for quality control measurements.

As demonstrated by the experiment with a thin silicone pad between the applicator and the mass block, the large inertial PP energy is immediately dispersed, whereas the initial “fast” PP is transferred into the adjacent layers, which e.g. represent the patient’s tissue. This supports the theory that these fast PP portions in the range of few microseconds are the main cause for the known therapeutic effects. The theory is further supported by the known clinical success of devices with electrohydraulic, electromagnetic and piezoelectric sources, which only produce these “fast” PP’s at comparable or even higher PP energies.

On the other hand, there is a need for further research on the therapeutic role and on side-effects of the inertial PP portions, which, according to present knowledge, are only generated by ballistic second-generation PP sources.

The fast PP’s can only be measured reliably by acoustic measurements using calibrated hydrophones. There are some promising methods described in the literature, e.g. the interferometric approach [17] and the dry test-bench ([16] and upcoming IEC 63045).

5. Literature


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