PAPER • OPEN ACCESS

Metrological characterization of a therapeutic device for pressure wave therapy

View the article online for updates and enhancements.

IOP ebooks™

Bringing you innovative digital publishing with leading voices to create your essential collection of books in STEM research.

Start exploring the collection - download the first chapter of every title for free.

Metrological characterization of a therapeutic device for pressure wave therapy

G Cosoli[1], L Scalise[1]
[1]Department of Industrial Engineering and Mathematical Sciences, Università Politecnica delle Marche, via Brecce Bianche, 60033 Ancona, Italy


E-mail: l.scalise@univpm.it

Abstract. This study aims to characterize an electromedical device used for pressure wave therapy delivered by shock waves. The test protocol analyses different pressures and evaluates both the tip displacement, by means of a laser Doppler vibrometer, and the transmitted force, by means of a piezoelectric load cell; a silicone rubber was used as a tissue phantom. Finally, the provided energy density in terms of J/m^2 was computed. Results show variability in the tip displacement values (up to 15%), particularly at the lower working pressure values. It is also possible to note that the higher is the value of the pressure created by means of the solenoid valve, the higher is the force transmitted to the tissues (i.e. hundreds of N). Also the force data are affected by a certain degree of variability (up to 18%). Such study allows to better understand the effective force delivered to the tissues and to optimise the energy density provided to the different patient's districts, specifically at high pressures (i.e. ≥ 3 bar; 300 kPa) and on soft tissues (e.g. skin and connective tissue) where the energy densities can reach the limits indicated in DIGEST and ISTMT guidelines (i.e. 300 J/m^2). Consequently, it is important that the operators of such machines carefully evaluate the machine operating settings in order to maximise the benefits.

1. Introduction
An acoustic wave is a longitudinal wave propagating through adiabatic compression and decompression. In medicine, there are three types of acoustic waves: shockwaves, pressure waves and ultrasound. While ultrasound are mainly used in diagnosis, the others have therapeutic aims (1–3); shockwaves are acoustic waves characterised by high pressure amplitudes rapidly propagating in a medium, with an initial rise in amplitude, as shown in 'figure 1' (1,5).
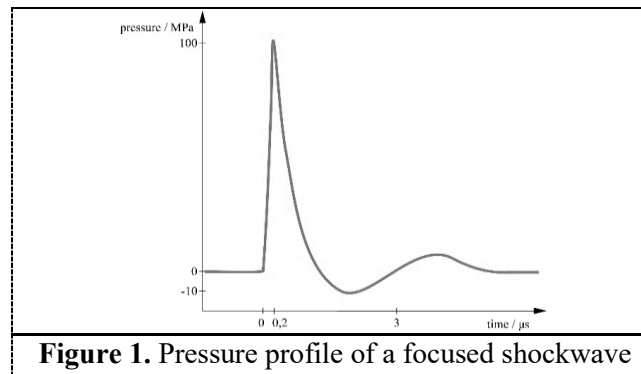
Figure 1. Pressure profile of a focused shockwave

The attenuation of the shockwave depends on the medium where it is travelling; in particular, it depends on the acoustic impedance, given by 'equation 1':

$$Z_0 = \rho * c \tag{1}$$

where ρ [kg/m^3] is the density and c [m/s] is the speed of sound in the medium (6,7).

In 'table 1' there are reported the values of density, speed and characteristic impedance of water and main tissues (i.e. blood, bone, connective tissue, fat and muscle) (1,6,8).

Table 1. Density (ρ), speed (c) and acoustic impedance (Z_0) of water and main biological tissues (i.e. blood, bone, connective tissue, fat and muscle)

| Means	ρ [kg/m^3]	c [m/s]	Z_0 [kg/(s*m^2)*10^6]
Water	1000	1480	1.48
Blood	1055	1575	1.66
Bone	1380-1810	4080	1.55-1.66
Connective tissue	1027	1545	1.59
Fat	950	1450	1.38
Muscle	1070	1584	1.70

Pressure waves differ from shockwaves on the generation method, since pressure waves are generated by an accelerated bullet colliding with a solid body. The projectile is pushed by means of compressed air, then it is abruptly slowed down by the impact with a solid body, whose motion is transferred to the tissues in correspondence of the contact area (1).

With respect to shockwaves, pressure waves have lower energy flux density, longer rise time and compression pulse duration, as shown in 'table 2' (1).

Table 2. Characteristics and differences of shock and pressure waves

	Shockwaves	Pressure waves
Focus	Yes	No
Propagation	Non-linear	Linear
Steepening	Yes	No
Rise time	0.01 µs	50 µs
Compression pulse duration	≈0.3 µs	200-2000 µs
Positive peak pressure	0-100 MPa	0-10 MPa
Energy flux density	0-3 mJ/mm^2	0-0.3 mJ/mm^2

A typical pressure wave is reported in 'figure 2' (5).

Figure 2. Pressure profile of a radial pressure wave
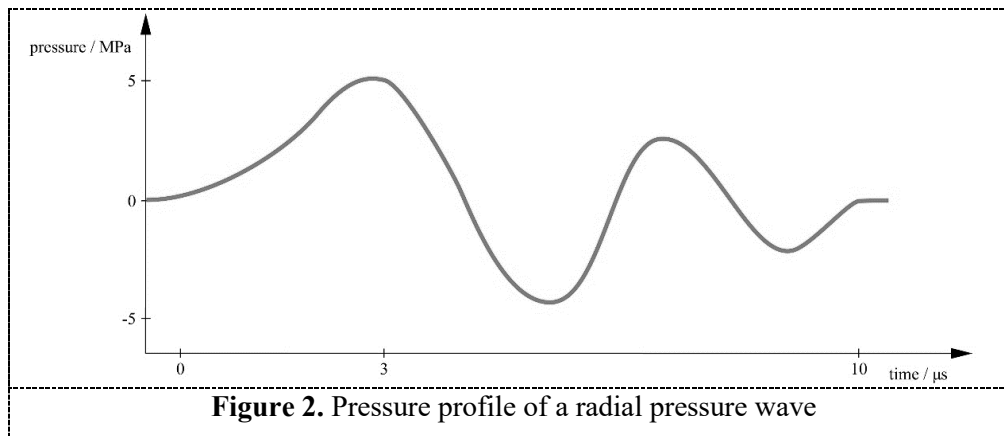
While shockwaves can reach deep tissues, pressure waves act on the tissue layers near the surface. Pressure waves stimulate the metabolism and enhance blood flow, so promoting the tissue regeneration. Pressure wave therapy is able to eliminate pathological alterations of tendons, ligaments, muscles and bones without surgery nor side effects.

In order to choose the most suitable therapy for a patient, the healthcare provider has to take into consideration some parameters:

- Energy flow density, which can be obtained by means of 'equation 2' (9):

$$energy\ density = \frac{1}{A^2 \rho_0 c_0} \int F^2 dt$$

(2)

where A is the transmitter area, while $\rho_0 c_0$ is the acoustic impedance of the means. There are guidelines about typical values of this parameter (4,5);

- Number of delivered pulses;
- Frequency of delivered pulses;
- Shape of the transmitter: diameter, focused/unfocused.

A typical geometry of a therapeutic device applicator supplying pressure waves is reported in 'figure 3'.

Figure 3. Typical handpiece of a pressure wave device
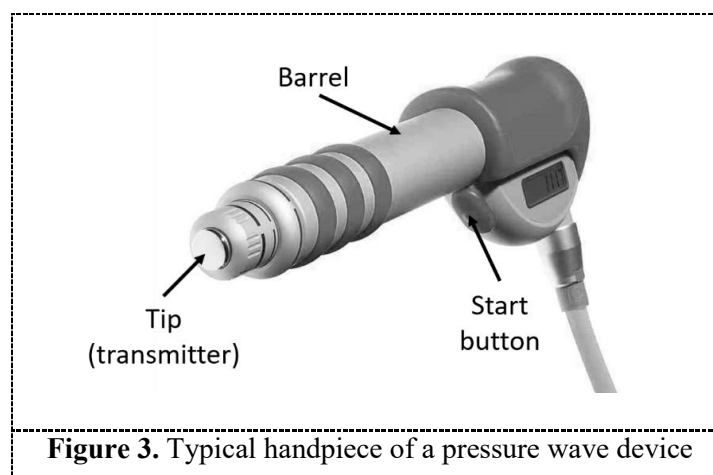
Even if shockwave and pressure wave therapies are commonly used, to the best of the authors' knowledge in the literature there are no studies dealing with the precision and the metrological characteristics of such devices.

The present study just wants to explore quantitatively the performance of a device used for pressure wave treatment, focusing on the variability of the pulses delivered to the tissue in terms of amplitude, as well as the average waveform produced by the bullet hitting the impact body.

2. Materials and methods

The therapeutic device was characterised in terms of different physical quantities:
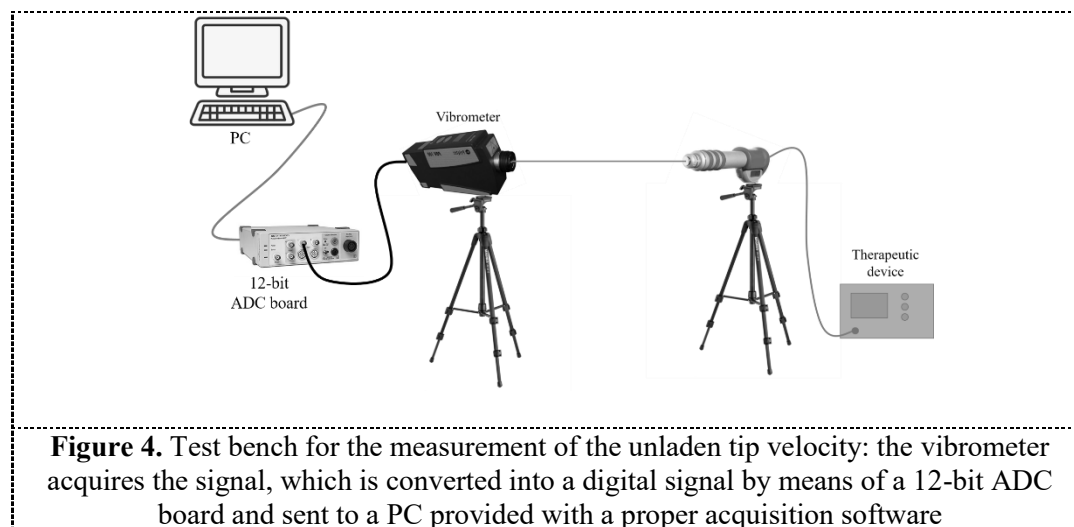- Displacement of the unladen transmitter (tip in the air), measured by means of a laser Doppler vibrometer;
- Strength transmitted to the treated tissues, measured by means of a piezoelectric load cell;
- Energy flow density provided to the tissue, derived from the strength measurement results;

Each of these quantities will be described more in detail in the following paragraphs.

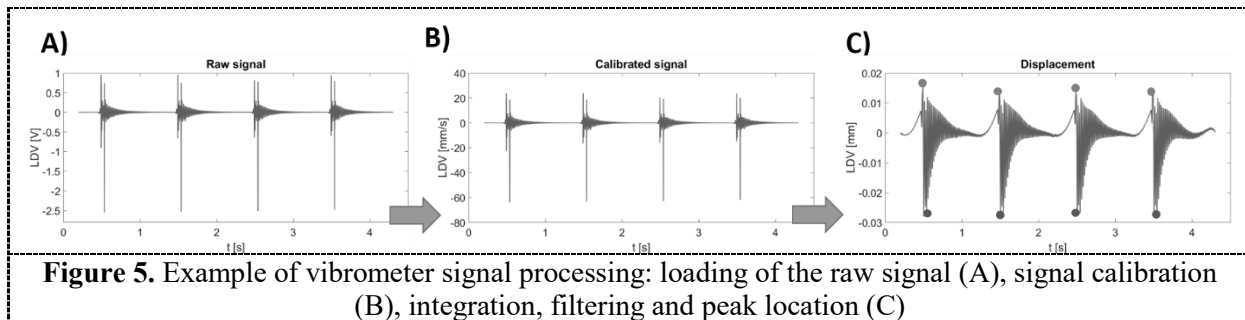*2.1 Measurement of the displacement of the unladen tip, with no target in contact*

In order to measure the velocity signal of the unladen transmitter, the authors used a single point vibrometer (PDV100, Polytec, sensitivity: 0.04 V/(mm/s), full scale: 100 mm/s *(10)*).

The therapeutic device was fixed by on a tripod at a distance of 1 m from the vibrometer head; the beam was directed perpendicularly at the centre of the tip, where a retro-reflective tape was attached (in order to improve the signal SNR).

Figure 4. Test bench for the measurement of the unladen tip velocity: the vibrometer acquires the signal, which is converted into a digital signal by means of a 12-bit ADC board and sent to a PC provided with a proper acquisition software
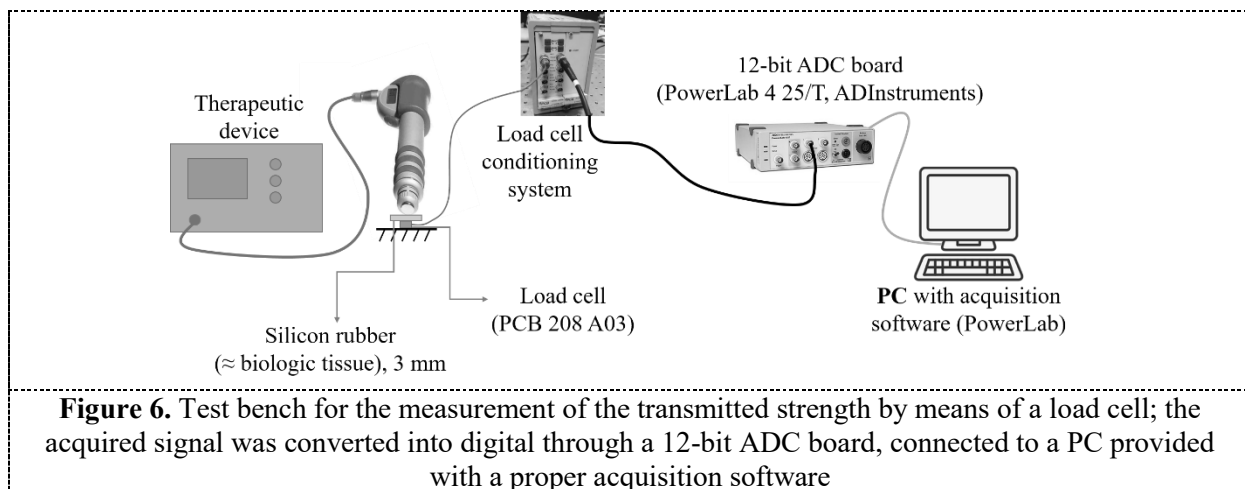
The considered signal consisted in a 350-pulse train at 1 Hz, generated at different pressure values (i.e. 1.5, 2, 3, 4 and 5 bar); each test was repeated for 3 times, for a total of 1050 pulses for each test configuration.

Vibrometer signal was acquired thanks to a 12-bit ADC board (PowerLab 4/25T, ADInstruments (11)), connected to a PC with a proper acquisition software (LabChart 7, ADInstruments (12)); it was sampled at 20 kHz. In a post-processing phase, the raw signal was calibrated, integrated (in order to obtain the displacement information) and high-pass filtered (cutoff frequency: 2 Hz). Then, the pulse peaks were located and a histogram of the total 1050 pulses set for each pressure value was obtained, as well as the waveform averaged on the 1050 pulses. An example of the signal processing can be observed in 'figure 5'.
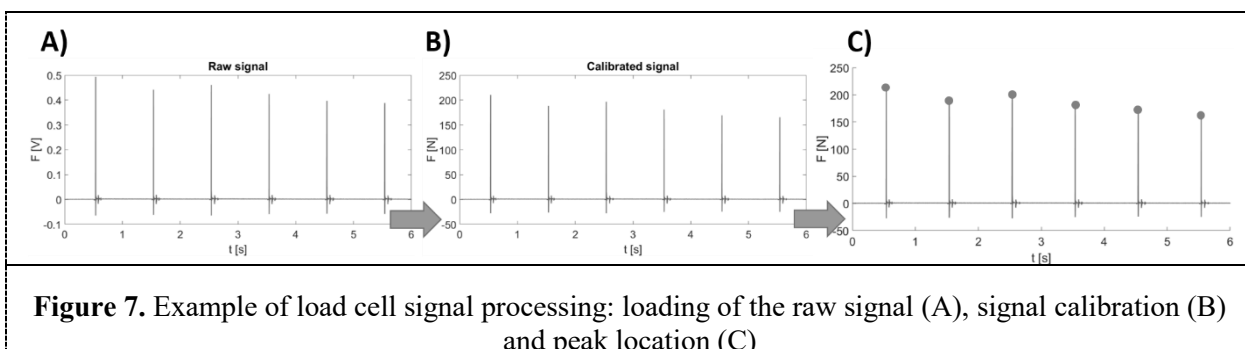
Figure 5. Example of vibrometer signal processing: loading of the raw signal (A), signal calibration (B), integration, filtering and peak location (C)

2.2 Test on a tissue phantom (i.e. silicone rubber): measurement of the transmitted strength and assessment of the energy density provided to the tissues

The strength transmitted during the therapeutic pulses was measured by means of a load cell (PCB 208 A03, sensitivity of the calibrated sensor: 426.07 N/V, full scale: 2225 N *(13)*), fastened to the test table by means of a specific magnet; a 3-mm silicone rubber was inserted between the transmitter and the cell, in order to simulate a biological tissue (consequently measuring the force in correspondence of a 3-mm depth); for the minimum and the maximum pressure values (i.e. 1.5 bar and 5 bar, respectively), also a 6-mm silicone rubber was used for the test. The handler was maintained in a vertical position by means of an appropriate metallic support. The sensor was connected to a 12-bit ADC board (PowerLab 4/25T, ADInstruments *(11)*), which was in turn attached to a PC equipped with a proper acquisition software (LabChart 7, ADInstruments *(12)*).

Figure 6. Test bench for the measurement of the transmitted strength by means of a load cell; the acquired signal was converted into digital through a 12-bit ADC board, connected to a PC provided with a proper acquisition software

The strength signal was sampled at 10 kHz; the same configurations described in the previous paragraph were used and the processing was the same (an example is reported in 'figure 7').

Figure 7. Example of load cell signal processing: loading of the raw signal (A), signal calibration (B) and peak location (C)

Finally, histogram and averaged waveform were obtained for each 1050-pulse set.

Then, in order to derive the energy density provided to the tissues, the concerning formula was considered, as reported in 'equation 2'. Finally, the results obtained for silicone rubber were transferred to some biological tissues (i.e. skin, connective tissue and bone), in order to have an early idea on the quantities at stake, so as to compare them with the guidelines indications (4,5).

3. Results

In the following paragraphs, there are reported the results related to the displacement of the unladen tip and to the strength measurement in order to derive the energy density provided to the tissues.

3.1 Displacement of the unladen tip, with no target in contact

With regard to the tip displacement, the results are reported in 'figure 8' in terms of mean ± standard deviation (m±σ) for each test configuration.

Figure 8. Tip displacement results in terms of mean±standard deviation (m±σ) [μm]
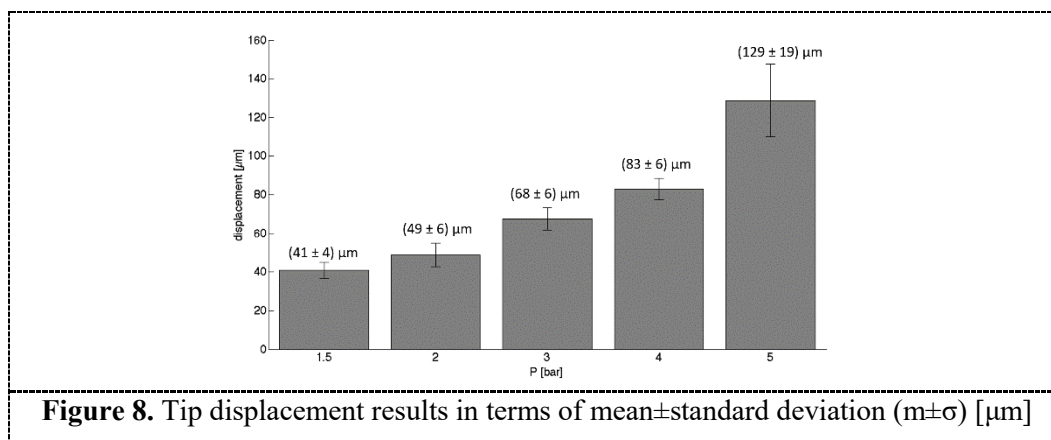
It can be noticed that higher the pressure value, higher the mean displacement, just like it was predictable. It is worth noting that the pulses show a certain variability in the amplitude, maybe due to the fact that the pressure is not always exactly the same.

In 'figure 9' there is an example of a displacement waveform averaged on 1050 pulses (at 1.5 bar).

Figure 9. Displacement waveform averaged on 1050 pulses (at 1.5 bar)
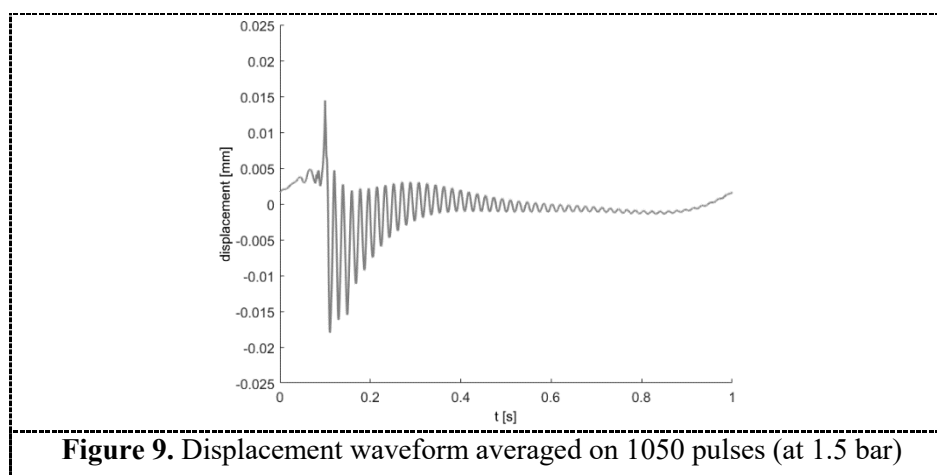
3.2 Transmitted strength and energy provided to the tissues

The force measurement results obtained on a 3-mm silicone rubber are reported in 'table 3'.

Table 3. Force measurement results at different pressure values, reported in terms of mean value and standard deviation

Pressure [bar]	Mean [N]	Standard deviation [N]
1	169	30
2	211	17
3	275	15
4	298	30
5	340	30

In 'figure 10' there are the force measurement results both for 3-mm and 6-mm silicone rubber thicknesses. It is possible to observe that, how it was predictable, the transmitted force increases with a higher pressure created by the solenoid valve pushing the bullet along the barrel. If a double-thickness tissue phantom is used (i.e. 6 mm), the measured force is halved; this is consistent with the law of spherical waves propagation, stating that the amplitude decreases as the squared distance from the source *(14)*. This means that the deeper tissues are less affected by the pressure wave provided by the therapy, which is indeed suitable for surface layers.

Figure 10. Force measurement results on both 3-mm and 6-mm silicone rubber at different pressure values
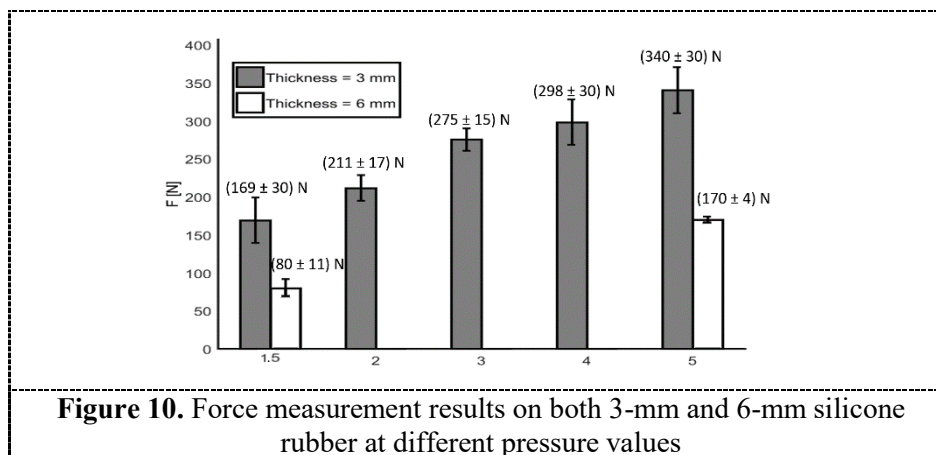
In 'figure 11' there is an example of a force waveform averaged on 1050 pulses (at 1.5 bar).

Figure 11. Force waveform averaged on 1050 pulses (at 1.5 bar)
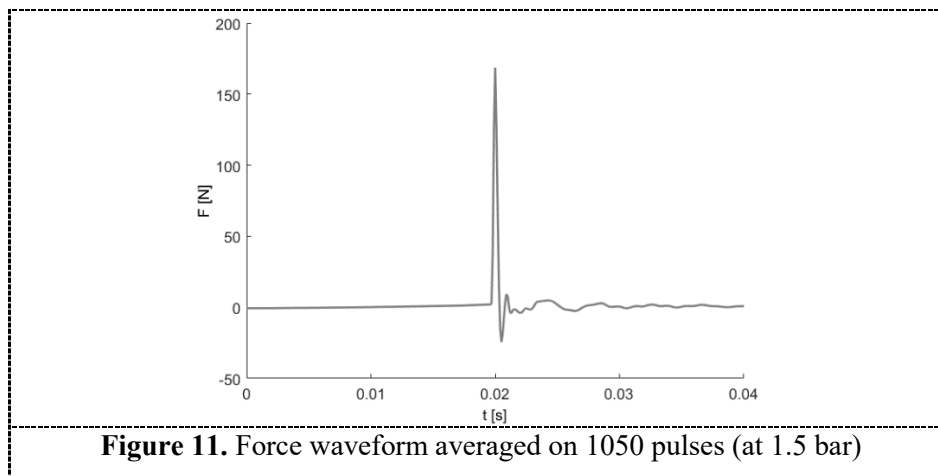
So, by means of the formula reported in 'equation 2', the energy density was computed for different tissues (i.e. skin, connective tissue and bone), using the tissues properties reported in 'table 1'; the results are described in 'table 4'.

Table 4. Energy density results for different tissues (i.e. skin, connective tissue and bone), estimated starting from force measured at different pressure values

Tissue	Pressure [bar]	Energy density [J/m^2]
Skin	1.5	125
	2	198
	3	330
	4	391
	5	493
Connective tissue	1.5	142
	2	225
	3	374
	4	444
	5	560
Bone	1.5	34
	2	53
	3	89
	4	105
	5	132

4. Conclusions

The application of shockwave and pressure wave therapy is continuously spreading, so that it would be important to characterize the therapeutic devices used to provide the treatment in order to have objective parameters to quantify their performance.

The present study examines different quantities of a therapeutic device used for pressure wave therapy; in particular, tip displacement, transmitted force and provided energy density have been considered, in order to give an overview of the system performance.

With regard to the tip displacement, a high variability has been observed (i.e. 10-15% with respect to the obtained mean value); this can be attributable to the frequency of the pressure reservoir refilling, which should be greater when a higher pressure is required. This variability proposes again in force measurements, up to 18% at the lowest pressure value (i.e. 1.5 bar). Therefore, it could be appropriate to rethink the device design in order to make the therapy more uniform in time.

With regard to the energy density estimation, in the DIGEST and ISMST guidelines there are reported no fixed limits, but there are typical values of 300 J/m^2 (i.e. 0.3 mJ/mm^2) for pressure waves. In this study, for certain pressure levels (i.e. ≥ 3 bar) and for soft tissues (i.e. skin and connective tissue), these values are exceeded. Therefore, it is important that the clinician accurately evaluates the potentiality of the therapy taking into account also possible collateral effects on the tissues.

It would be interesting to design a therapeutic apparatus prototype equipped with a load cell, capable to measure the transmitted force directly during a real therapy on a patient, so considering a real tissue. Besides, it could be interesting to carry out some tests with a more realistic tissue phantom, for example by using ex-vivo animal tissues.

All the information obtained from this kind of investigations could be exploited to have useful design directions to improve the performance of different therapeutic devices.

References

1.   Tsaklis P. Presentation of Acoustic Waves Propagation and Their Effects Through Human Body Tissues. Hum Mov. 2010;11(1):58–65.
2.   Wang C-J, Wang F-S, Yang KD, Weng L-H, Hsu C-C, Huang C-S, et al. Shock wave therapy induces neovascularization at the tendon-bone junction. A study in rabbits. J Orthop Res Off Publ Orthop Res Soc. 2003 Nov;21(6):984–9.
3.   Schaden W, Thiele R, Kölpl C, Pusch M, Nissan A, Attinger CE, et al. Shock wave therapy for acute and chronic soft tissue wounds: a feasibility study. J Surg Res. 2007 Nov;143(1):1–12.
4.   Home :: Digest e.V. [Internet]. [cited 2017 Sep 8]. Available from: https://www.digest-ev.de/
5.   ISMST (The International Society for Medical Shockwave Treatment) [Internet]. 2017 [cited 2017 Sep 8]. Available from: https://www.shockwavetherapy.org/the-society/physics-group/
6.   Azhari H. Appendix A: Typical Acoustic Properties of Tissues. In: Basics of Biomedical Ultrasound for Engineers [Internet]. John Wiley & Sons, Inc.; 2010. p. 313–4. Available from: http://onlinelibrary.wiley.com/doi/10.1002/9780470561478.app1/summary
7.   Ludwig GD. The Velocity of Sound through Tissues and the Acoustic Impedance of Tissues. J Acoust Soc Am. 1950 Nov 1;22(6):862–6.
8.   Hasgall PA, Di Gennaro F, Baumgartner C, Neufeld e, Gosselin MC, Payne D, et al. IT'IS Database for thermal and electromagnetic parameters of biological tissues [Internet]. IT'IS Foundation; 2015. Available from: http://www.itis.ethz.ch/db3-0
9.   Cleveland RO, McAteer JA. Physics of Shock-Wave Lithotripsy. In: MD ADS, MD GHB, MD GMP, MD LRK, editors. Smith's Textbook of Endourology [Internet]. Wiley-Blackwell; 2012. p.   527–58.   Available   from: http://onlinelibrary.wiley.com/doi/10.1002/9781444345148.ch49/summary
10. GmbH P. Polytec: PDV-100 Portable Digital Vibrometer [Internet]. 2016 [cited 2016 Nov 30]. Available   from: http://www.polytec.com/it/products/vibration-sensors/single-point-vibrometers/complete-systems/pdv-100-portable-digital-vibrometer/
11. PowerLab   [Internet].   ADInstruments.   [cited   2017   Feb   24].   Available   from: https://www.adinstruments.com/products/powerlab
12. LabChart   [Internet].   ADInstruments.   [cited   2017   Sep   11].   Available   from: https://www.adinstruments.com/products/labchart
13. PCB Piezotronics, Inc.: Sensors to measure vibration, acoustics, force, pressure, load, strain, shock & torque [Internet]. [cited 2017 Sep 11]. Available from: http://www.pcb.com/
14. Morse PM. Vibration and sound. [Internet]. Vol. 2. New York: McGraw-Hill; 1948. Available from: http://www.abdi-ecommerce10.com/asa/images/product/medium/0-88318-767.pdf