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Hybrid test bench for high repetition rate radial shock wave measurement

Abstract: Radial shock wave therapy is used for different therapeutic indications. In order to assess the effect on the treated tissue, it is important to know the sound field parameters. However, it is challenging to measure the pressure curves of ballistic devices, especially at high pulse repetition rates. In the new standard IEC 63045:2020 two possibilities for sound field measurements of non-focusing devices are described, a wet and a dry test bench. The whole sound field can be characterised using a wet test bench, but the process is cumbersome and cavitation is likely to occur at high pulse repetition rates. This effect is avoided using a dry test bench where the measurement position is limited to a single spot. Therefore, a hybrid test bench was developed combining the dry bench's device mounting and coupling with a small water basin. The ballistic device was coupled to the basin filled with degassed ultrapure water using a latex membrane covered with ultrasound gel and the contact pressure was applied with a spring. A fibre optic probe hydrophone was used for the sound field measurements. The pressure curves of every 10th shot were measured on the beam axis in a distance of 1mm to the membrane. The device was analysed at 3.5 bar with different pulse repetition rates (1 Hz, 10 Hz, 20 Hz). The test setup enables an easy handling and reproducible results at all pulse repetition rates. The ballistic device provides constant peak pressures over different frequencies. The small water basin has the advantage that the water quality is easy to control and the measuring process is fast and uncomplicated. Cavitation suppression requires a clean water basin filled with degassed ultrapure water kept at a constant, low temperature. The hybrid test bench can be used to easily study shock wave parameters of ballistic devices at high repetition rates.

Keywords: radial pressure waves, test bench, sound field

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1 Introduction

Ballistic shock wave devices are used in orthopaedic indications such as radial epicondylitis, plantar fasciitis or patella tendinitis [1]. A radial pressure field is generated by a projectile, which is accelerated onto an applicator by compressed air, and coupled into the treatment site using ultrasound gel. Commonly used treatment parameters are a total number of up to 3000 shocks per session and pulse repetition rates (PRR) between 1 Hz and 20 Hz [2]. The mechanisms of action induced by pressure waves are not yet fully understood. Hence, the sound field of ballistic devices and the influence of the treatment parameters should be investigated for all available settings, in order to better assess the effects and side effects of the treatment and to correlate the parameters with a clinical benefit.

There are two methods for measuring the pressure curves of ballistic devices described in the new standard IEC 63045:2020, wet and dry test benches. Wet benches consist of a water tank, a positioning table for the hydrophone and a mechanism for coupling the device to the test bench [3–5]. Cleveland et al. investigated the sound field of a ballistic device and measured constant peak pressures even at high repetition rates, but reported on the challenge of ensuring uninterrupted coupling between the applicator and the membrane at high repetition rates [5]. In other setups the applicator was coupled without a membrane directly to the water [3, 4]. Császár et al. compared individually measured pressure curves of two different ballistic devices at various positions and different pressure levels [4]. The sound field of a ballistic device was characterized measuring single pressure curves at a constant pressure level on lines radial and axial to the beam axis of the device [3].

Especially at high PRR, cavitation is likely to occur [6–8] and can distort the pressure measurements in water [6, 9]. Requirements for cavitation suppression during sound field measurements in water are a clean water tank, degassed ultrapure water and low temperatures [9, 10].

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Dry test benches were developed in order to avoid cavitation effects using a dry transmission medium. Ueberle and Jamshidi-Rad introduced a dry bench comprising a pressure sensor fixed in one position, a 5 mm silicon pad and a mounting unit for the hand piece with a slide and a spring, which simulates the contact pressure [11]. The results measured in the dry bench are comparable to those measured in water [11] and are reproducible even at high PRR [2]. Cosoli et al. performed measurements at different pressure levels and high PRR [12]. The pressure was measured by a piezoelectric load cell and the transmission medium was a 3 mm silicon pad [13]. Advantages of the dry benches are that cavitation is avoided and measurements can be performed even at high repetition rates. However, the measurement is conducted at a single spot and the choice of suitable hydrophones is limited. Hence, this method is particularly suitable for comparing different settings in one measurement spot.

The aim of this work was to develop an easy to test setup for measurements of the whole sound field at low and high repetition rates. The hybrid test bench with a smaller water tank allows to control the water quality and minimizes cavitation effects.

2 Material & Methods

Figure 1: Hybrid Test Bench: Combination of a Dry Bench and a small Wet Bench (top); Position of the Applicator and the Hydrophone (bottom).

The measurement setup enables sound field measurements according to the IEC 63045:2020 standard. It consists of a dry part with a sliding holder for the device and a spring to implement the contact pressure as well as a wet part comprising a small water basin and a hydrophone (see Figure 1, top). The water basin (85mm x 80mm x 80mm) was filled with degassed ultrapure water at 18°C in order to minimize cavitation activity. The coupling of the ballistic device to the basin was realised using a 1 mm latex membrane covered with

ultrasound gel. Sound field measurements were conducted with a fiber optic pressure hydrophone (FOPH 2000, RP acoustics e.K., Leutenbach, Germany), which was triggered on a rising signal amplitude. It was mounted on a positioning table at a 45° angle in order to avoid measurement inaccuracies caused by reflections of the laser.

The radial shock waves were generated using a ballistic shock wave device (DolorClast Evo Blue, EMS Electro Medical Systems S.A., Nyon, Switzerland) with a 15mm applicator. The pressure level driving the projectile was set to 3.5bar. The pressure curves were measured on the beam axis at 1mm distance to the membrane (see Figure 1, bottom) at three different PRR (1Hz, 10Hz, 20Hz). Every 10th pulse was measured. In order to evaluate the shot to shot reproducibility, 3 pressure curves were recorded and compared at each setting. They were averaged for improved visualization. The curves were filtered with a low pass filter with 1 MHz cutoff frequency for the calculation of the pressure curve parameters such as the maximum and minimum peak pressure as well as the pulse intensity integral.

3 Results

Figure 2: Measured pressure curves at 1 Hz PRR (a, b, c) and averaged, filtered pressure curve at 1 Hz PRR (left); Averaged, filtered pressure curves at different PRR (right).

The measured pressure curves show good shot to shot stability for the first positive and negative pressure phase for all settings (see Figure 2, left). In the further course of the signal, the curves deviate from each other. The averaged and filtered curves only show very small variability between 1 Hz and the higher PRR (see Figure 2, right). Measurements at high PRR

are possible and lead to reproducible results using the hybrid test bench.

The maximum and minimum peak pressures ($p_{\max}$, $p_{\min}$) are stable even at high PRR (fig.3, top). The mean calculated pulse intensity integral of the first positive pressure phase (PII^+) was between 0.108 and 0.140 mJ/mm² for all settings (see Figure 3, bottom). With three measurements per setting, the parameters of the pressure curves are in the same range for all PRR.

Figure 3: Mean maximum and minimum peak pressure and standard deviation at different PRR (top); Mean pressure pulse integral of the first positive pressure phase and standard deviation at different PRR (bottom).

4 Conclusion

The hybrid test bench presented here is suitable for pressure measurements at all PRR and can also be used for the determination of sound field parameters of ballistic devices. It can be used to measure the first positive and negative pressure phase. In the further course of the curve, disturbances caused by cavitation or fibre movement appear. The shapes of the curves measured with the hybrid test bench show a good agreement with those measured in wet test benches before [3, 4]. The results are consistent with those of Cleveland et al., who also observed stable peak pressures at high PRR

investigating a comparable device [5]. We did not observe any interruption of the coupling between the device and the membrane due to the elasticity of the latex membrane and the spring induced contact pressure, which was described before by Ueberle and Jamshidi-Rad [11]. Hence, the hybrid test bench can be used for future sound field characterization of different ballistic devices. For the tested device the SW parameters showed no significant drop at higher PRR. However, these results should be validated with a larger number of measurements per setting.

Author Statement

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References

- [1] Gerdemeyer L, Gollwitzer H, Diehl P, Wagner K. Radiale extrakorporale Stoßwellentherapie (rESWT) in der Orthopädie. *Journal für Mineralstoffwechsel*. 2004;11:36–9.
- [2] Ueberle F, Jamshidi-Rad A. Unfocused/Weakly Focused Pressure Pulse Sources for Pain Therapy: Measurements in Water and in a Dry Test Bench. *Acta Phys. Pol. A*. 2015;127:135–7. doi:10.12693/APhysPolA.127.135.
- [3] Jamshidi Rad A, Ueberle F. Field mapping of ballistic pressure pulse sources. *Current Directions in Biomedical Engineering*. 2015;1:26–9. doi:10.1515/cdbme-2015-0007.
- [4] Császár NBM, Angstman NB, Milz S, Sprecher CM, Kobel P, Farhat M, et al. Radial Shock Wave Devices Generate Cavitation. *PLOS ONE*. 2015;10:e0140541. doi:10.1371/journal.pone.0140541.
- [5] Cleveland RO, Chitnis PV, McClure SR. Acoustic field of a ballistic shock wave therapy device. *Ultrasound in Medicine & Biology*. 2007;33:1327–35. doi:10.1016/j.ultrasmedbio.2007.02.014.
- [6] Pishchalnikov YA, Sapozhnikov OA, Bailey MR, Pishchalnikova IV, Williams JC, McAteer JA. Cavitation selectively reduces the negative-pressure phase of lithotripter shock pulses. *Acoust Res Lett Online*. 2005;6:280–6. doi:10.1121/1.2127115.
- [7] Sapozhnikov OA, Khokhlova VA, Bailey MR, Williams JC, McAteer JA, Cleveland RO, Crum LA. Effect of overpressure and pulse repetition frequency on cavitation in shock wave lithotripsy. *The Journal of the Acoustical Society of America*. 2002;112:1183–95. doi:10.1121/1.1500754.
- [8] Reinhardt N, Dietz-Laursonn K, Janzen M, Radermacher K, Bach C, La Fuente Md. Experimental setup for evaluation of cavitation effects in ESWL. *Current Directions in Biomedical Engineering*. 2018;4:191–4. doi:10.1515/cdbme-2018-0047.
- [9] Liebler M, Dreyer T, Riedlinger RE. Focal Pressure Variations in Shock Wave Therapies Caused by Cavitation Bubbles. *Proc. of the Joint Congress CFA/DAGA*. 2004;4:983–4.

- [10] Vlasisavljevich E, Xu Z, Maxwell A, Mancina L, Zhang X, Lin K-W, et al. Effects of Temperature on the Histotripsy Intrinsic Threshold for Cavitation. *IEEE Trans Ultrason Ferroelectr Freq Control*. 2016;63:1064–77. doi:10.1109/TUFFC.2016.2565612.
- [11] Ueberle F, Jamshidi Rad A. Ballistic Pain Therapy Devices: Measurement of Pressure Pulse Parameters. *Biomedical Engineering / Biomedizinische Technik* 2012. doi:10.1515/bmt-2012-4439.
- [12] Cosoli G, Verdenelli L, Scalise L. Metrological Characterization of Therapeutic Devices for Pressure Wave Therapy: Force, Energy Density, and Waveform Evaluation. *IEEE Trans. Instrum. Meas.* 2021;70:1–8. doi:10.1109/TIM.2020.3016071.
- [13] Cosoli G, Scalise L. Metrological characterization of a therapeutic device for pressure wave therapy. *J. Phys.: Conf. Ser.* 2018;1110:12001. doi:10.1088/1742-6596/1110/1/012001.