ISMST – Recommendation Statement

Recommendation statement of the Conjoint Physics Working Group of ISMST and DIGEST on ESWT study design and publication

Edited by:

Dr. Matias de la Fuente

Dr. Vinzenz Auersperg

Kristin Dietz-Laursonn

Dr. Siegfried Ginter

Christian Dorfmüller

Dr. Whala Khaled

Prof. Friedrich Ueberle

Maxime Fournier

Dr. Rainer Pecha

Peter Vallon

Dr. Werner Schwarze

Ralph Reitmajer

ISMST – International Society for Medical Shockwave Therapy

This statement is the final conclusion of the editors mentioned above as the result of a conjoined meeting of the Physics Working Group of ISMST and DIGEST, which was held at Berlin on October 21st, 2015.

The group has been called together under auspices of ISMST and DIGEST due to the ongoing discussion about the physical parameters used for the description of ESWT setup.

The editors conclude, that the use of currently established shockwave parameters to describe the physical conditions during in-vitro or clinical studies is insufficient as:

• We don‘t know yet the key effect of shock waves on tissue, the biological response is not clear as well as the best “shape” (spatial and temporal pressure distribution) of the shock waves to be the most effective.

• Therefore it is unclear, which shockwave parameters (as defined in IEC 61846) should be used to describe the clinical efficacy and to compare devices or if even new parameters need to be introduced.

• Currently only few parameters are used by the ESWT community, such as:

- o Peak positive and negative acoustic pressure
- o Derived pulse intensity integral (= ED)
- o Total energy (-6dB)
- o Focal extension in x-, y- and z-direction
- o Number of pulses
- o Pulse repetition rate (Hz)

But these usually don’t suffice to describe the sound field, because of the complex 3-dimensional distribution of the sound pressures and the influence of the tissue..

• We have to be cautious as one has to know how to read and interpret the parameters. Depending on the measurement setup and on the SW technology the meaning and significance of the parameters may vary a lot.

• Without further investigation, it cannot be expected in near future, that there will be a way to improve the comparability of different devices and techniques:

- o Electrohydraulic applicators versus electromagnetic or piezoelectric ones: The measurements at electrohydraulic devices are usually mean values because each spark varies a little, so that each spark produces different shock waves
- o Radial and focusing applicators: The sound fields are very different and the

parameters are not defined in the same way, especially as most shockwave parameters from

IEC 61846 refer to the focal point.

- We need a rating and ranking of all measurable parameters
  - Which parameters could be interesting (& should therefore be mandatory to be published in clinical studies)
  - At the moment not enough parameters are mentioned at the publications
- It should be investigated, which additional parameters could be helpful to improve the physical description of what is used performing ESWT with all the different devices and their different techniques

(focal, radial,planar, and defocused ESWT).

- Device approval is one reason for the problems:
  - Currently, it is shown by “technical equivalence” or “substantial equivalence” based on few (unimportant?) technical parameters?
  - But safety alone does not show clinical effectiveness.
  - Clinical equivalence has to be shown.

The editors came to an agreement for the following recommendations:

1. For clinical studies and in-vitro studies:

1.1. Get support from technicians of the device manufacturer from the beginning of the planning of the experimental study design until the interpretation of the outcome.

1.2. Clinicians should perform studies in conformance with „good clinical practice“ and describe every variable which might influence the clinical outcome

1.2.1. Description of indication

1.2.2. Description of the target to be treated

1.2.3. Measurement and documentation of the success including the definition of “success“

1.2.4. Documentation of all additional (non-shockwave) treatments (including anesthesia)

1.2.5. Number of sessions

1.2.6. Time between sessions

1.2.7. Number of pulses per session

1.2.8. Pulse repetition rate (my influence cavitation)

1.2.9. Navigation technique (how to find the target, e.g. Ultrasound, focused shockwave to find most painful spot, …)

1.3. Furthermore specify all parameters for the treatment settings of their devices which influence the sound field:.

1.3.1. Shockwave device

1.3.2. Shockwave head / applicator (name, model number, physical principle,focused/radial/,…)

1.3.3. Intensity levels

1.3.4. All material interfaces the sound has to penetrate during in-vitro experiments (geometries and materials between the transducer head and a few cm behind the focal point)

1.3.5. Coupling medium used and how it was applied

1.3.6. Penetration depth of focused device (skin to focal spot distance)

1.3.7. Treatment protocol (e.g. changes of device settings over time, movement of transducer…)

1.4. If not device settings but shockwave parameters (according to IEC 61846) are published, the origin of the data has to be referenced.

2. For companies:

2.1. Provision of sound field parameters (as well as information concerning their measurement) in a database, which will be created and published online by ISMST and DIGEST and support researches by interpretation of the parameters by direct contact.

2.2. Support of researchers in planning of in-vitro and in-vivo studies (setup, execution) and interpretation of the sound field data, especially when results are compared to other studies.