How to report parameters and procedures for shockwave therapy in musculoskeletal disorders

A narrative review

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Abstract
Shockwave therapy (SWT) has been successful in the management of musculoskeletal conditions. The limitations of the use of SWT in clinical practice regard a lack of familiarity with the device and the lack of uniformity in information reported in scientific publications. Standardization in the reporting of these parameters could facilitate the reproduction and interpretation of data in future studies. Most studies fail to offer a detailed description of the parameters. Therefore, the aim of the present paper is to prepare a report on how to standardize the presentation of this information and serve a reference guide to report physical parameters and procedures of SWT when used on patients with musculoskeletal disorders. The terms were selected from the Medical Subject Headings database of controlled vocabulary. An extensive process of systematic searching of databases was performed, after which experts met and discussed on the main findings, and a consensus was achieved. SWT parameters were described, including the physiological meaning and clinical relevance of each parameter. Also, the description of patient and equipment positioning was added. The consensus-based guideline on how to report SWT parameters for the treatment of musculoskeletal conditions was developed to help clinicians and researchers.

Abbreviations: MeSh = medical subject heading, SWT = shock wave therapy.

Keywords: musculoskeletal disorders, report parameters, shockwave therapy

1. Introduction
Shockwave therapy (SWT) has been successfully used for more than 20 years in the management of musculoskeletal conditions.[1–3] SWT is a safe, noninvasive treatment option[4,5] that is well accepted by patients for tendinopathy,[6,7] myofascial pain,[8–10] joint injuries[11–13] and fractures with delayed union.[14,15] The limitations of the use of SWT in clinical practice regard a lack of familiarity with the device and the lack of uniformity in information reported in scientific publications.[4] Differences are found among studies available in the literature with regards to study design, protocol, application technique, duration of treatment and the parameters of the device. This heterogeneity makes it difficult for researchers and therapists to reproduce the methods described in articles and adopt a more assertive approach in clinical practice.[16]

Standardization in the reporting of these parameters could facilitate the reproduction and interpretation of data in future studies. Most studies fail to offer a detailed description of the energy, frequency and number of pulses, type and area of the tip, positioning of the patient, application site, type of device, type of applicator, inclusion of treatments combined with SWT, etc.[16] This type of report has been published and widely used for other electrophysical agents, such as low-level laser therapy[17] and electrotherapy for pelvic floor dysfunction.[18] Therefore, the aim of the present paper is to prepare a report on how to standardize the presentation of this information and serve a reference guide for scholars, clinicians and researchers to report physical parameters and procedures of SWT when used on patients with musculoskeletal disorders.

2. Methods
The present literature review was conducted to identify published studies on shockwave therapy applied to musculoskeletal disorders and detect the type of information missing from these studies. Thus, the authors formed a workgroup to draft guidelines so that future studies can have more complete descriptions, enabling better reproduction of studies in both clinical practice and research. The members of the workgroup had expertise in fields related to musculoskeletal disorders (PD and CGNB) and SWT (REL and ABM) and participated in 4 meetings, at which the conception of the present report was planned. During the meetings, all authors contributed terms and expressions.
Total energy is defined as energy multiplied by the number of pulses per second. It affects the penetration capacity of the energy into biological tissue, with a lower frequency being more effective in deeper tissues. Shockwave generators can be classified as focused (focal) radial, which determines the depth and concentration of energy of the wave. A focused shockwave generator tends to reach deeper tissues and concentrate the energy, meaning that the mechanical effect and cavitation occur closer to the applicator. Radial shockwaves tend to have a larger, more dispersed area for the distribution of cavitation—or divergence. With a focal shockwave focal, there is more convergence at the site that will have the cavitation, with a smaller area of energy concentration, requiring considerable application precision. This precision is extremely important to avoid/prevent possible tissue damage due to the high concentration of energy in a small area and also so that the energy reaches the target tissue. It is through the pulse that the mechanical energy is transferred to the tissue. Thus, the acoustic intensity, number of pulses and form of application determine the amount of energy transferred to the tissue. After the transfer of energy, each tissue may respond in a different manner, depending on the focus of the treatment—whether to accelerate the tissue regeneration process or achieve the disintegration of calcific conditions.

### Table 1

| Parameter (unit of measurement) | Description | Clinical relevance |
|---------------------------------|-------------|-------------------|
| Frequency (Hz)                  | Number of pulses per second | Frequency affects the penetration capacity of the energy into biological tissue, with a lower frequency achieving greater energy penetration. The therapeutic effects of the shockwaves depend on the energy distributed in a broad or focused area of the treatment zone. With better delivery of energy density to the tissue, the significant tissue effect generated is the mechanical effect and the resulting cavitation of the negative phase of the propagation of the shockwave, which can have important consequences regarding the therapeutic bioeffect. |
| Acoustic energy or acoustic intensity | Energy transmitted per unit of area per pulse. Energy transmitted per unit of area per pulse. | The shockwave generator determines the depth and concentration of energy of the wave. A focused shockwave generator tends to reach deeper tissues and concentrate the energy, meaning that the mechanical effect and cavitation occur at a farther distance from the applicator. A radial shockwave generator tends to reach more surface tissues with less concentration of energy; thus, the mechanical effect and cavitation occur closer to the applicator. Radial shockwaves tend to have a larger, more dispersed area for the distribution of cavitation—or divergence. |
| May be expressed as: energy density (mJ/mm²) or pressure (Bar) or total energy (mJ) | Future studies need to add an energy equivalence table for the device employed (pressure in bar × energy density in mJ/mm² × energy in mJ) to enhance the external validity of the study. Total energy is defined as energy multiplied by the number of pulses. | |
| Shockwave generator | Focused (focal) radial | |
| Pulses/ Shots | Number of pulses during treatment | |
The third step was a meeting held to revise the document and propose final recommendations. This step consisted of gathering information collected during the review of the literature. The authors opted for 2 tables—one focused on the parameters of SWT and another describing all that should be reported/Performed for the administration of SWT in musculoskeletal disorders.

3. Results
Table 1 displays the definitions of the parameters for SWT and the clinical relevance of each parameter. Table 2 displays the results of how the use of SWT and its parameters should be described in studies on musculoskeletal disorders.

4. Discussion
Therapists and researchers should always consider the indications and contraindications of shockwave therapy (SWT) to ensure that the patient is eligible for treatment. Researchers and clinicians should certify that all exclusion criteria to the use of SWT were evaluated, such as the use of a pacemaker or coagulation disorders. If SWT is applied directly to the skin, it is necessary to assess contraindications, such as uncorrected bleeding disorders, severe peripheral vascular disease or acute infections. After this initial evaluation, the clinician/researcher must obtain consent from the patient prior to initiating the intervention. An adequate, precise assessment of the entire region to be treated is mandatory to determining the most appropriate type of treatment or study/case trial design. The clinical relevance of each parameter. Table 2 displays the results of how the use of SWT and its parameters should be described in studies on musculoskeletal disorders.

Table 2

| Item                  | Parameter                                                                 | Description                                                                 |
|-----------------------|---------------------------------------------------------------------------|----------------------------------------------------------------------------|
| Patient               | Positioning: describe the position in which the patient received shockwave therapy | Prone or supine, sitting or standing                                         |
| Local anesthesia      | Use of ultrasound or manual palpation to identify the target structure      | Equipment/device on which the patient is positioned (chair or examining table) |
| Coupling mechanism    | Use of conductive gel, lotion or coupling bags                              | Site of use of gel or bags, brand, duration of use                           |
| Device                | Complete description of device                                             | Commercial name, brand and model                                             |
| Type of applicator    | Electrohydraulic (focal)                                                  | The way that the energy is generated varies depending on the type of applicator. Thus, clinicians should describe what applicator was used for the administration of SWT. |
| Form of application   | Static                                                                    | Depends directly on the area and objective of therapy.                      |
| Application area      | Dynamic                                                                    | Depends directly on the form of application and number of pulses in a predetermined area. Ex.: 2000 static shots in the gluteal region is different from 2000 scanning shots in the same region. |
| Tip size and shape    | Describe the size of the tip in mm² and its shape (convex, flat or concave) | The stimulus on the tissue and patient comfort can be affected depending on the size of the tip. The concentration of energy can be affected by the size of the tip. Smaller tips are used for a greater concentration of energy, but this has a direct impact on the patient's sensation level. The shape of the tip directly affects the depth and concentration of energy. Tip shape alters the form of energy transference to the target tissue. |
| Tip material          | Clarify the material of the tip used (metal or polyacetal)                 | The depth of the wave can vary depending on the tip material, type of tissue and adjusted energy. |
| Treatment             | Duration of application                                                    | Time in minutes                                                             |
|                       | Duration of therapy                                                       | Number of sessions in which shockwave therapy was administered               |
|                       | Interval between sessions                                                  | Number of hours or days between sessions                                      |
|                       | Report of patient discomfort                                               | Assessment of discomfort during treatment                                    |
|                       | Reported/observed side effects                                             | Instrument used to assess discomfort (self-report, visual analog scale, etc) |
|                       | Patient adherence to treatment                                             | Any side effects reported or observed during treatment should be described: considerable discomfort after the end of the treatment session, peechiae, redness, etc) |
|                       | Combined treatment: describe any type of therapy performed simultaneously to shockwave therapy | Home-based and/or in-person exercises, medications, educational sessions or any other type of therapy used. Describe each therapy in complete detail. For scientific studies: Functioning, quality of life, pain at rest and when performing activities, range of motion, muscle strength, calcific changes, adverse events, etc. For clinical practice: Clearly indicate the main objective of therapy. |
|                       | Result/outcome: describe what variable is the primary outcome and the methods used to assess the outcome. |
The therapeutic effects of SWT and side effects in different types of tissues have not been fully clarified. It is hypothesized that the therapeutic effects of shockwaves may be due to the direct effect caused by the mechanical pressure and tension that the waves exert on the tissue, with a change in acoustic impedances, and an indirect effect due to the formation of cavitation bubbles that induce shear forces at the site upon bursting.

Numerous factors can affect the success or failure of SWT, such as the use of local anesthesia, the form of application, tip size and material. Some studies have demonstrated that the effect of SWT is dose dependent and can activate or sensitize nociceptive fibers. The use of an anesthetic can substantially alter these biological responses to SWT. Some clinicians/researchers use anesthetics when employing focused applicators, since the application is deeper and, at times, painful or uncomfortable. The use of anesthetics in such cases is to prevent painful side effects following administration, such as intense pain at rest or when moving the treated site, and facilitate patient adherence to treatment.

To date, no clinical studies have evaluated whether tip size and material and form of application exert a direct or indirect influence on the therapeutic and physiological effects. Tip size affects local energy density. Thus, smaller tips are used to obtain a greater concentration of energy, which has a direct impact on the patient’s sensory level. The density of the wave can vary with the tip material, which can also exert a direct influence on patient comfort during the administration of SWT. Regarding the form of application, the 2 possibilities are static and dynamic (scanning over large area horizontally and vertically). We believe that the form of application can exert a direct influence on energy delivery to the target tissue, as scanning can lead to a considerable variation in the distribution of energy delivered to the tissue.

The coupling mechanisms of the devices for the emission of the shockwaves is another factor that needs to be reported. Formerly, SWT was applied in water immersion baths, especially devices developed for lithotripsy. Today, however, the technology does not require a large device and SWT involves the application of a conductor gel with radial devices or coupling bags with focused devices. However, most studies fail to report the type of device that was used. In most countries, necessary maintenance depends on the number of pulses that the apparatus can withstand to avoid device failures. Operating manuals, models, serial numbers and inspection certificates need to be up to date.

The report of the dosimetry is found in a large part of the studies and expressed as energy (mJ), energy density (mJ/mm²) or pressure (bar). This depends on the device being used and type of applicator. However, one should bear in mind that the device available to the clinician/researcher may not have the same configurations, which hinders reproducibility. This can be minimized in future studies by added an energy equivalence table, which would enable greater reproduction of the findings of a clinical study and enhance its external validity.

5. Conclusions

In the present article, we created tables for the successful reporting of parameters and procedures of shockwave therapy for musculoskeletal disorders. We recommend the recognition of these standards in publications related to the use of SWT. We hope that the present report can assist researchers and clinicians involved in the rehabilitation of patients with musculoskeletal disorders, enabling the adequate, complete description of parameters to ensure the reproducibility of the methods, a critical analysis of the results and the advancement of knowledge in this field.

Author contributions

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Claudio Gregório Nuerberg Back - Formal analysis, Resources
Patricia Driusso - Conceptualization
Richard Eloin Liebano - supervision, Project administration
All authors - Writing, review & editing

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