Parameter Reproducibility in Photobiomodulation

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REPRODUCIBILITY IS A KEY FACTOR IN SCIENCE.¹ A single medical scientific result is not enough for reliability; it takes at least another identical study with the same outcome to make the claims credible. A major problem in photobiomodulation (PBM) is the lack of proper reporting of the involved parameters and, further to that, the control of the parameters. Too often, the reporting of the parameters used in a study is incomplete, and the use of specific parameters is *ad hoc*. Parameters seem to be those of the equipment at hand, rather than being chosen specifically to, for example, replicate those used in a previous study or fall within an already-known effective range applicable to current work. This lack of quality control among too many researchers and scientific journals creates an obstacle in finding reproducibility in meta-analyses. Frequently, such efforts end up with the conclusion that no definite conclusion can be made, because of the great variety in the reported parameters, no matter how many positive studies there are.

Researchers do not have to stick to parameters used in other studies; they are free and encouraged to explore all the available parameters within the supposed therapeutic window. Without a full and correct reporting of all pertinent light source parameters, however, nobody can perform a control study even of the best studies. What is needed is a close cooperation between researchers and journals. The definition of light parameters is only basic physics, and no guesswork is required. However, researchers in the PBM field generally come from professions for which physics has not been on the curriculum. Although they are very qualified in their own professional field, they may lack understanding of PBM. Our suggestion is to include a physicist on the team to make sure that the actual “medicine” to be tested is not flawed before the study even has begun.

The majority of submitted articles have to undergo one or several revisions before being accepted; however, often the parameters are still incorrect or incomplete upon publication. Therefore, solving the problem requires vigilance and action at multiple levels. Reviewers must assess the reported parameters and request revision where they do not meet the requirements of the journal; and journal editors and staff must ensure that only articles that meet their stated standards are published. And it is important not to forget the obligation of manufacturers to report the parameters of their devices accurately and honestly, and to refrain from highlighting factors that sound good in marketing materials but that lend little to the utility of the device and/or reproducibility of outcomes.

Ultimately, however, it is the author who is charged with the fundamental responsibility, to first obtain and then report an accurate and complete set of parameters, thus ensuring that the work may be reproduced and, therefore, add to the overall body of knowledge. In other words, it is the author’s responsibility to produce good science.

The most flawed parameters are the energy (J) and the dose (J/cm²). Too often, only one of them is reported, but both need to be within the so-called therapeutic window. A seemingly reasonable dose may just be the effect of a thin fiber,² and a high energy may be dispersed over a large area, thus resulting in a low dose.³ Qualified readers of an article may be able to calculate what is missing if other parameters such as the spot size (cm²) is reported. However, anyone should be able to have access to all the necessary

TABLE 1. DEVICE INFORMATION

Manufacturer	XYZ Co.
Model	XYZ-810
Year produced	2016
Number of emitters	1
Emitter type	Laser diode GaAlAs
Beam delivery	Emitter mounted in hand-held probe with beam-correction optics and convex glass lens

TABLE 2. IRRADIATION PARAMETERS

Parameter (unit)	Value	Measurement method or information source
Center wavelength (nm)	810	Manufacturer’s specification
Spectral bandwidth (nm)	±3	Manufacturer’s specification
Operating mode	Continuous Wave	Manufacturer’s specification
Radiant power (mW)	100	Independent testing
Aperture diameter (cm)	0.8	Manufacturer’s specification
Irradiance at aperture (mW/cm ²)	200	Independent testing

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TABLE 3. TREATMENT PARAMETERS

<i>Parameter (unit)</i>	<i>Value</i>	<i>Additional notes</i>
Beam spot size at target (cm ²)	0.5	
Irradiance at target (mW/cm ²)	200	
Exposure duration (sec)	40	Per point
Radiant exposure (J/cm ²)	8	Per point
Radiant energy (J)	4	Per point
Number of points irradiated	3	Transverse carpal ligament, 1× directly over median nerve, and 1× each on the ulnar and radial sides of the median nerve.
Area irradiated (cm ²)	0.5×3 points	Total area covered per session is 1.5 cm ²
Application technique	Skin contact	Firm pressure applied
Number and frequency of treatment sessions	1× daily for 5 days	
Total radiant energy (J)	12/day (60 total)	

parameters. Jenkins and Carroll⁴ proposed a tabular format for reporting parameters in a clear, concise, comprehensive, and standardized manner.

Tables 1–3 show the work of some fictional authors, Smith et al., who use the tabular method to include necessary detail for their treatment of carpal tunnel syndrome.

Although the inclusion of all these parameters would significantly improve the quality of research, the complexity of the light parameters often requires the inclusion of details such as the polarization, shape, profile, and divergence of the beam, and – for switched/pulsed beams – the frequency, pulse duration, duty cycle, and waveform. Such details should be available to authors from the equipment manufacturer or as a product of in-house and/or independent measurement and testing.

In the Abstract to their article, our fictional authors Smith et al. write that “...an 810 nm, 100 mW continuous wave laser, spot size 0.5 cm², was placed in contact with the skin and firm pressure applied. Three points over the transverse carpal ligament were irradiated for 40 sec each, delivering 4 J (8 J/cm²) per point, for a total energy of 12 J per session. Laser irradiation was performed once daily for 5 days, with the total energy delivered being 60 J.” This is quite a comprehensive summary of the important parameters, and – although not a complete list – practically sufficient within itself to allow the laser irradiation aspect of this study to be accurately reproduced.

At the very least, these are the parameters that should be included in the Abstract. The majority of readers of a study actually only read the PubMed abstract, and abstracts with incorrect or omitted parameters can be misleading. The creation of “PubMed Commons” offers an opportunity for researchers and readers to add pertinent information about studies being incomplete or flawed; however, we should not rely on this to remedy such fundamental errors and omissions.

Being meticulous about the reporting of light parameters is mandatory but not sufficient. When information about previous studies in the area, in the Introduction and the Discussion, is added, readers are often left in the dark. With the great variation in the possible combinations of light parameters, apples and bananas are too frequently compared. Our suggestion is to include the most important parameters when referring to other studies. For example, Jones et al. (810 nm, 100 mW, 3 points × 4 J [8 J/cm²] per point, 12 J total, 1× daily × 5 days). Such writing will make it possible for a reader to understand the relevance of the reference in its context.

On the subject of references, we can see room for improvement. References of very old articles can be justified as historical references. However, with ~20 PBM articles in PubMed in 2000 and 4200 in 2016, it is obvious that literature reviews and meta-analyses from the 1990s are less relevant.

Finally, there must be an end to the nomenclature confusion. The topic has been discussed in this journal before,⁵ and the implementation of a common nomenclature is important for “outsiders” to understand what we are talking about.

PBM has been used for >50 years, and no serious side effects have been reported. In a decade when side effects of pharmaceuticals are alarming and antibiotic resistance is a threat, this treatment modality appears to be much needed in the medical armamentarium, but first the scientific strength needs to be increased, and this can only occur if the basic use and reporting of light parameters are improved.

References

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