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Guest Editorial

Low Level Laser Therapy (LLLT) and World Association for Laser Therapy (WALT) Dosage Recommendations

Jan Magnus Bjordal, Ph.D.

It is very encouraging that the annual scientific output now is exceeding 400 publications about laser phototherapy. This is a 20-fold increase from publication rates for low-level laser therapy (LLLT) a decade ago. Six years ago, another editorial in the journal announced that "low-level laser therapy" is not low, and a debate to change this MeSH term was initiated. At the time, we were worried that "low level" would be associated with inferior scientific quality.[1]. With the progress that has been made in terms of scientific output, and LLLT publications in high-ranked medical journals, this fear has somewhat ceased. Some guidelines and reputed treatment advisory boards (American Physical Therapy Association, National Cancer Institute, Clinical Evidence at BMJ) now recommend varying strengths of LLLT use for conditions such as Achilles tendinopathy, cancer-therapy-induced oral mucositis, and tennis elbow.

Still, the most crucial factors for treatment effects are optimal dosing and hitting a sufficient part of the target pathology. In the *Cochrane Database of Systematic Reviews*, two of three LLLT reviews fail to address the issue of dosing. It is, however, encouraging that one systematic review cites the guidelines of World Association for Laser Therapy (WALT) and addresses dosage by subgrouping trials by doses that are optimal and ones that are not. The review's overall conclusion is inconclusive and contains only the usual phrase, stating that more studies are needed. However, the "implications for practice" are more descriptive to read. The authors find that although LLLT may be beneficial for pain relief and disability, they also insist that LLLT should not substituted for other beneficial interventions in low back pain. In the jungle of potentially harmful low back pain interventions, I wonder why it is so important to discourage clinical use of LLLT, which the review otherwise finds both harmless and modestly effective.

The evidence-based WALT guidelines for LLLT dosage in musculoskeletal disorders were published for the first time in August 2005. What makes the WALT guidelines stronger than guidelines for other empirically based modalities such as acupuncture, is that sound and credible biological mechanisms can explain LLLT actions. The therapeutic windows were first identified by careful investigation of dose–response patterns in pre-clinical studies. For soft tissue inflammation and soft tissue repair, we found consistent evidence of effects from several independent research groups.[2] These pre-clinical findings, combined with the results from clinical LLLT studies, form the rationale for WALT dosage recommendations.

The idea with the first generation of WALT guidelines was that they would serve two purposes. On the one hand they could serve as a treatment guide to clinicians, and on the other hand, they could make it possible to identify trials with obviously ineffective doses. The latter was needed because there are a great number of published trials with low fidelity caused by errors in dosing and treatment procedures. These low-fidelity LLLT trials would invariably be included in systematic reviews and meta-analyses such as the Cochrane reviews, which ended up with largely negative conclusions. Before 2005, LLLT devices were largely operating with mean outputs in the lower part of the Class 3 B range and we did not know if there were upper limits for effective doses. To serve both these purposes, we decided to design the first WALT guidelines with minimum dose thresholds for effectiveness. Since 2005, a new generation of more powerful LLLT devices has entered the market. Several dose-finding laboratory studies have recently shown us that more is not necessarily better, and that the positive effects may in fact be lost in overdosing LLLT. This development has prompted us to take the WALT guidelines one step further. I think that the first-generation guidelines served well, and they were also validated by a review finding that 91% of tendinopathy trials with WALT-recommended doses reported positive effects.[3] The value of WALT dosage recommendations to predict clinical effectiveness also led to the discovery of a massive attempt at fraudulent publication. I received two manuscripts for review from different journals, and both reported significant results in spite of LLLT doses well below the threshold normally needed for effectiveness. My skepticism led to a closer scrutiny of the results, and they proved to report exactly the same mean and variance results in both manuscripts. This is a statistical coincidence that is almost impossible in real life. Further explorations revealed that several manuscripts from the same source, with forged results and plagiarized text, were in editorial circulation. With the joint efforts of editors they were stopped and the superiors of the source were informed for further judgment.

There are now at least 125 randomized controlled trials investigating the pain-relieving effects of LLLT. Where possible, we have calculated the doses in most of these trials and

Department of Evidence-Based Practice, Bergen University College, Bergen, Norway.

correlated them with the results. In 2005, we took the position that superpulsed 904 nm laser should be separated from the other GaAlAs lasers (780–860 nm). And we feel that the recent literature has confirmed that this decision was wise and that there is a true difference between the two wavelengths or output types.

Our goals for the new generation of the guidelines are that WALT-recommended doses shall have at least 80% positive predictive value for LLLT effectiveness in future trials. We also expect that at least 80% of the studies with doses outside the identified therapeutic windows will report negative trial results. And there is the "department of error" in at least 10% of the literature. Factors such as device failure, miscalculation of doses, errors in the irradiation procedure, and errors in or lack of laser output testing, will continue to pollute the overall picture.

Since the first WALT guidelines were published, we have seen that the number of laboratory and clinical trials has more than doubled. The LLLT literature now allows for a more precise identification of optimal doses and treatment procedures in some pain conditions, and more distinct thresholds and upper limits for therapeutic windows. Consequently, WALT will now present location-specific therapeutic windows and a "best practice" section describing recommended treatment procedures and optimal doses for those diagnoses for which scientific evidence is sufficient.

In the near future, we think that we will also be able to identify therapeutic windows in nerve repair and peripheral nerve analgesia. The limited available evidence suggests already that this therapeutic window will have a somewhat higher dose range and, possibly, a higher power density than the WALT musculoskeletal dosage recommendations. Only the future will show if we reach our ambitious goals of providing clinicians with the best recommendations. However, we sincerely believe that these are currently the best guidelines to be found for optimal administration of LLLT for musculoskeletal pain.

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Address correspondence to:
Jan Magnus Bjordal
Bergen University College
Physiotherapy
Mollendalsvn. 6
Bergen
5009
Norway

E-mail: Jan.Magnus.Bjordal@hib.no

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