J Rehabil Med 2010; 42: 700–702

LETTER TO THE EDITOR

REVIEW CONCLUSION FOR LOW-LEVEL LASER THERAPY IN SHOULDER IMPINGEMENT SYNDROME APPEARS TO BE SENSITIVE TO ALTERNATIVE INTERPRETATIONS OF TRIAL RESULTS

Sir,

In a recently published review of physiotherapy interventions for shoulder impingement syndrome (1), the authors conclude that: "The results for a passive treatment were that ultrasound (2) was not more effective than sham application and evidence for the effect of LLLT [low-level laser therapy] (3, 4) or EMFT [electromagnetic field therapy] was conflicting. Thus, moderate evidence exists that passive treatment modalities are not more effective than sham application and their use can therefore not be recommended."

In my opinion, this statement does not follow strictly from the evidence, and the conclusion for LLLT is not robust in a sensitivity analysis. According to the authors' own definition of "moderate evidence", this should consist of: "Consistent findings among multiple low-quality RCTs [randomized controlled trials] and/or 1 high-quality RCT". As the authors describe the results for LLLT as "conflicting", it is inconsistent to label the evidence as "moderate" for concluding that LLLT is no more effective than sham treatment.

The above conclusion is further weakened by what appears to be an error in Table V, where the effect size for pain on visual analogue scale (VAS) weighted mean difference (WMD) for the Saunders trial (3) is missing. According to the trial report, the WMD for pain on VAS was 25 mm better than placebo. For the other LLLT trial, by Vecchio et al. (4), 4 different pain scores on VAS were reported after the end of treatment. All of these were in favour of LLLT, with WMDs of 3, 12, 17 and 18 mm, respectively, and the negative interpretation of these results in the trial report has been questioned previously (5). By imputing the values for the Saunders trial and the mean of the pain scores for the Vecchio trial into a meta-analysis I find a highly significant ($p < 0.00001$) WMD of 23.74 mm (95% confidence interval (CI): 33.06–14.43), with no sign of heterogeneity ($I^2 = 0\%$, $p = 0.43$). For function, the Vecchio trial found non-significant effects, but again the results were slightly in favour of LLLT (mean: 7 mm on VAS), whereas the Saunders trial reported significantly improved function data for muscle strength ($p < 0.001$). It should also be added that these LLLT trials were of the highest quality in the review, with method scores of 8/10 and 9/10, respectively. Also lacking, is a high-quality LLLT trial, in which comparisons were made with ultrasound and no treatment, without finding plausible reasons for the exclusion (6). These results were also significantly in favour of LLLT for all outcomes compared with no treatment, and significantly better than ultrasound for pain and muscle strength. There is also another large Norwegian trial ($n = 92$) with similar positive results in shoulder impingement (7), which has been omitted because of the language restrictions in the review.

Recently, another 2 trials have been published, claiming to that LLLT is not significantly different from placebo (8, 9). However, these studies were performed without testing the optical output of the therapeutic laser. This is not in compliance with the consensus agreement on the design and conduct of clinical studies with LLLT for musculoskeletal pain and disorders, which has been published by the World Association for Laser Therapy (WALT) (10). Moreover, this particular laser type (Roland, IR 904, Pagani srl, Milano, Italy) has previously been criticized for unclear specifications on mean optical output (11) and insufficient testing of optical output. Consequently, we tested the laser used in these studies, both with several single-diode probes (8) and 4-diode probes (9), during January 2009. The results of these tests showed that both laser probe types did not perform according to the manufacturer's claims (Fig. 1).

Measurements were inconsistent and the results showed that single-diode probes emitted outputs down to only 0.07

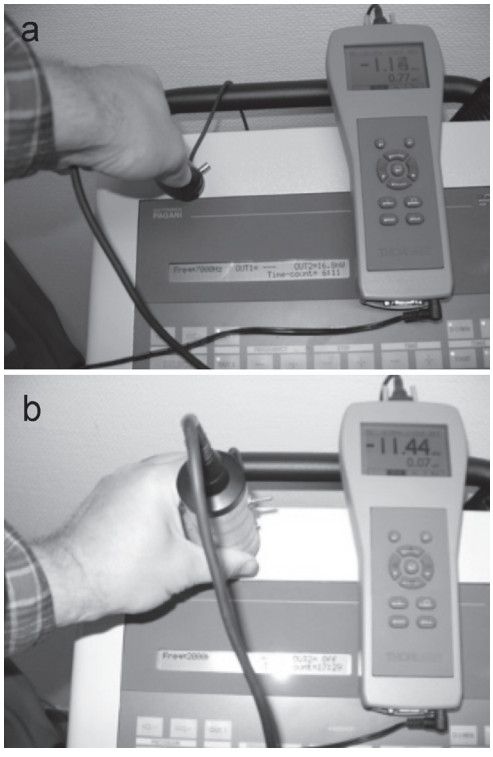

Fig. 1. Pagani laser probes tested for optical laser output in our laboratory. (a) Output at 7000 Hz: 0.77 mW. (b) Measured output at 2000 Hz = 0.07 mW.

mW, which was less than 0.5% of the stated output shown on the display on the laser unit. The status for the 4-diode laser probe was similar, with inconsistent outputs. In addition, the 4-diode laser probe was fitted with a lens, which distributes the laser light to an area of ~15 cm^2. Even with the maximum stated output, this laser probe is incapable of delivering the minimum power density of 5 mW/cm^2, which is required in WALT guidelines for treating tendinopathies with LLLT (available from: http://www.walt.nu/dosage-recommendations.html). We have notified the manufacturer of these problems and they have responded that they recently have initiated testing of optical outputs as a new measure, commencing in spring 2009, for quality control. On the other hand, none of the studies performed or published with the 4-diode laser fall within the category of LLLT as defined by WALT guidelines, due to insufficient power density. For the single-diode laser probe, the results of studies performed before mid-2009 cannot be trusted to have used LLLT according the WALT definition unless there has been explicit testing of the mean laser output.

In my opinion, the negative review conclusion for passive modalities is not consistent with the stated levels of evidence and the content of the available evidence. Whereas the evidence for ultrasound and EMFT seems to be inconclusive rather than moderately negative, the review conclusion about LLLT appears to deviate considerably from the consistent positive evidence. I invite the reviewers to consider whether their LLLT conclusion has been subject to a type 2 error, and to comment on the lack of inclusion of the comparative LLLT/US-trial by Saunders.

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RESPONSE TO LETTER TO THE EDITOR BY BJORDAL

Sir,

Thank you for sending us the comments of Professor Bjordal about the results of low-level laser therapy (LLLT) discussed in our systematic review. We would like to respond to the issues raised.

First, we would like to clarify our conclusion about passive treatments. The stated evidence levels made for LLLT, ultrasound, and electromagnetic field therapy (EMFT) in our results section are according to the evidence levels defined for this systematic review. In the discussion section evidence statements for each of these interventions are repeated, and then these treatments are summarized under the umbrella term "passive treatments". Four of the 5 studies could not find any significant differences in pain levels, and none of them could find any significant differences for functional outcome measures between real and sham treatment. Therefore, we concluded that moderate evidence exists that real treatment is not more effective than sham treatment on pain and functioning, which was the focus of this review. This summary conclusion is made against the background that the evidence found for active treatments is more robust, with positive results not only for pain, but also for functioning. Our summary conclusion does not refer to the evidence levels described by van Tulder et al. (12); if it had, strong evidence should have been stated. In fact we are a little more conservative than van Tulder because we used the umbrella term "passive treatments".

The result for the outcome measure pain on a visual analogue scale (VAS) used in the study of Saunders (3) is listed in Table V. According to the statements of the author, statistically significant results for pain on a VAS and the pain diary are also displayed in Table V. Because the author did not provide any data for standard deviations (SD), means, or mm-improvement on the VAS (except for a table with no figures), the relative risk (RR) was calculated based on the percentage improvement for each group.

In the study of Vecchio et al. (4) 4 pain scores were reported by the authors, and we agree that all of them were in favour of real LLLT. However, as stated by the authors themselves, for pain and functional limitations of activities of daily living (ADL): "… at no time was the perceived difference found to be significantly different".

This, and the conclusions of other reviews (5, 13, 14), are in agreement with our results and the evidence statement made about the effectiveness of LLLT in patients with subacromial impingement syndrome (SIS).

In our opinion, data of the 2 trials could not be pooled due to heterogeneity regarding duration of symptoms, follow-up points, intensity, frequency, duration of the applied interventions, the additionally applied interventions in the study of Vecchio et al. (4), and missing or incomplete data. Therefore the results of a meta-analysis should be handled with care.

However, one of the main problems in reaching a definite conclusion about the effectiveness of interventions for SIS or shoulder pain in general is that only a few high-quality studies per intervention exist and that, for most comparisons, data cannot be pooled for meta-analysis. Although both the study of Saunders (4) and that of Vecchio et al. (4) showed good internal validity, with PEDro scores of 9/10 and 8/10, respectively, other quality aspects, such as sample size, short follow-up periods and allocation concealment, were missing.

Another important point is the question as to what extent pain should be the main criterion when judging the effectiveness of interventions, without considering important aspects such as activity and participation restrictions, sick leave, or quality of life. Our opinion is that pain improvement should be interpreted together with outcome measures for functioning, and not independently from them, even if the pain improvement is statistically significant and is also judged as clinically important. This might be even more important in patients with

chronic symptoms, as seen in the study of Vecchio et al. (4), where the main focus should be on ADL and participation capabilities and less on pain.

As described in our methods section, studies were included if participants had a diagnosis of SIS, or if another diagnosis was given, participants should have at least one positive clinical test indicating SIS. For this reason, clinical impingement signs were defined as a prerequisite for inclusion. The study of Saunders (6) did not fulfil these criteria because none of these clinical impingement tests was used and no other symptoms indicating SIS were mentioned in addition to the diagnosis of supraspinatus tendinosis.

LLLT as a single treatment has shown a positive effect on pain in patients with SIS with short duration of symptoms (3), but not in patients with longer lasting complaints (4). The results of the studies of Yeldan et al. (15) and Bal et al. (8) do support our evidence statement made for the effectiveness of LLLT; results for pain improvement remain conflicting and evidence for a positive effect of LLLT on functioning is still missing. Therefore the results of our systematic review still reflect current evidence for this intervention, and further high-quality trials are needed to clarify its effectiveness in patients with SIS. The respondent elaborates extensively on details of the laser therapy of both studies; however, this was not the focus of our study and was not relevant to our study. We invite the respondent to discuss these points with the primary authors of those studies.

The focus of our systematic review was on the effectiveness of physiotherapy interventions in patients with clinical signs of SIS, with the aim of supporting physiotherapists in their treatment decisions and evidence-based work, and not only on the effectiveness of LLLT, its mechanism of action or its technical background. Since LLLT is frequently applied to patients with shoulder disorders in daily clinical practice as a single intervention, and more often in combination with other physiotherapeutic treatments, the benefits of LLLT and details of its application should be explored as a separate research question.

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REFERENCES

1. Kromer TO, Tautenhahn UG, de Bie RA, Staal JB, Bastiaenen CH. Effects of physiotherapy in patients with shoulder impingement syndrome: a systematic review of the literature. J Rehabil Med 2009; 41: 870–880.
2. Nykanen M. Pulsed ultrasound treatment of the painful shoulder a randomized, double-blind, placebo-controlled study. Scand J Rehabil Med 1995; 27: 105–108.
3. Saunders L. The efficiacy of low level laser therapy in shoulder tendinitis. Clin Rehabil 1995; 9: 126–134.
4. Vecchio P, Cave M, King V, Adebajo AO, Smith M, Hazleman BL. A double-blind study of the effectiveness of low level laser treatment of rotator cuff tendinitis. Br J Rheum 1993; 32: 740–742.
5. van der Heijden GJ, van der Windt DA, de Winter AF. Physiotherapy for patients with soft tissue shoulder disorders: a systematic review of randomised clinical trials. BMJ 1997; 315: 25–30.
6. Saunders L. Laser versus ultrasound in the treatment of supraspinatus tendinosis. Physiotherapy 2003; 89: 365–373.
7. Gudmundsen J, Vikne J.[Laser therapy for tennis elbow and rotatorcuff tendinopathy] Nor Tidskr Idrettsmed 1987; 2: 6–15 (in Norwegian).
8. Bal A, Eksioglu E, Gurcay E, Gulec B, Karaahmet O, Cakci A. Low-level laser therapy in subacromial impingement syndrome. Photomed Laser Surg 2009; 27: 31–36.
9. Yeldan I, Cetin E, Ozdincler AR. The effectiveness of low-level laser therapy on shoulder function in subacromial impingement syndrome. Disabil Rehabil 2008; 1–6.
10. WALT. Consensus agreement on the design and conduct of clinical studies with low-level laser therapy and light therapy for musculoskeletal pain and disorders. Photomed Laser Surg 2006; 24: 761–762.
11. Bjordal JM, Baxter GD. Ineffective dose and lack of laser output testing in laser shoulder and neck studies. Photomed Laser Surg 2006; 24: 533–534; author reply 534.
12. van Tulder M, Furlan A, Bombardier C, Bouter L. Updated method guidelines for systematic reviews in the cochrane collaboration back review group. Spine 2003; 28: 1290–1299.
13. Green SE, Buchbinder R, Hetrick S. Physiotherapy interventions for shoulder pain. Cochrane Database Syst Rev 2003; 2: CD004258.
14. Michener LA, Walsworth MK, Burnet EN. Effectiveness of rehabilitation for patients with subacromial impingement syndrome: a systematic review. J Hand Ther 2004; 17: 152–164.
15. Yeldan I, Cetin E, Ozdincler AR. The effectiveness of low-level-laser therapy on shoulder function in subacromial impingement syndrome. Disabil Rehabil 2009; 31: 935–940.