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Radial pressure wave therapy is not extracorporeal shockwave therapy – not only in insertional Achilles tendinopathy

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We read with great interest the article “Shockwave therapy plus eccentric exercises versus isolated eccentric exercises for Achilles insertional Tendinopathy ” by Mansur and colleagues (1). We appreciate

the hard work of our colleagues, as we are fully aware of how difficult it is to perform randomized controlled trials in this field, having undertaken at least eight such studies on the use of shock wave therapy for soft tissue disorders over the course of the last two decades. Mansur et al. report the use of radial pressure wave therapy using a BTL device vs sham in combination with eccentric exercises did not lead to meaningful gains in functional outcome measures of VISA-A over 24 weeks in a population of 119 patients with insertional Achilles tendinopathy. We congratulate Mansur and colleagues, and we should like to raise some issues.

1) Nomenclature: Ballistic pressure wave therapy has to be differentiated from focused extracorporeal shockwave therapy (ESWT): there are distinct well described differences (2,3). ESWT uses shock waves produced either by an electrohydraulic, an electromagnetic or a piezoelectric generator. Radial ballistic pressure waves apply a certain pressure (in the present study, 1.5-2.5bar in a BTL600 machine) with a certain frequency (in the present study, 7-10Hz) with 2000-3000 shots. When 1.5bar with 2000 shots were applied, the total energy was substantially different to 2.5bar with 3000 shots: simple arithmetic calculation shows that the latter results in 2.5 times total energy being applied. Therefore, the range of radial pressure wave therapy used was broad, and not standardized in this RCT which might have an impact on the clinical results.

Radial pressure wave treatments were applied every two weeks for three sessions, a longer time interval than prior reports that demonstrated favorable response with once weekly sessions. Application of treatment was standardized to an anatomical location without reference to use of clinical focusing technique. Clinical focusing refers to applying the treatment to sites of pain to ensure the tendon pathology is identified during treatment.

Energy-wise, the 1.5-2.5 bar pressure correspond to approximately 0.07mJ/mm² to 0.15mJ/mm²: by definition, this is low to medium energy. The International Society for Medical Shockwave Therapy (ISMST) has highlighted these physical differences from its inception, and in 2016 proposed the more accurate term “radial pressure wave” therapy. Notably, the first report and PhD thesis on radial pressure waves by Gerald Haupt (4) in 1997 describes radial pressure waves as “ballistic wave therapy”. Numerous studies have shown the clinical benefits of focused ESWT in both midportion and insertional Achilles tendinopathy with follow-up of 12 and sometimes up to 18 months (5,6,7).

In the end, the radial pressure wave therapy as applied in this RCT cannot be considered a shockwave therapy comparable to what administered using a focused ESWT device, and therefore the title of the work is misleading.

2) Patients: When considering the clinical features and other characteristics of the patients studied, several

issues are to be considered:

- The mean VISA-A scores of 41 and 44 points for treatment and control arm of the study are low and may suggest advanced tendon disease. Further, the baseline activity levels were not described although higher mean BMI values may suggest less active participants.
- the BMI of the middle-aged patients was high at $29 \pm 4.9 \text{ kg/m}^2$ in the SWT and $28.5 \pm 5.1 \text{ kg/m}^2$ in the eccentric control group. This likely reflects the fact that mostly sedentary, not athletic, patients were recruited
- The level of sport activity in hours per week and discipline remain totally unclear
- The use of rescue medications was not characterized. It is unclear whether non-steroidal anti-inflammatory medications were allowed during treatment; this class of medication may adversely affect Achilles tendon healing response (8).
- The presence of Haglund deformity was evident in 98% of the patients. This has been shown as a negative prognostic indicator for non-operative care including with shockwave (9)
- the authors report a remarkably high dropout rate over 24 weeks (22% in the SWT and 17% in the eccentric control group). As discussed in this very journal loss to follow-up >20% in a clinical study is problematic (10).

3) Compliance: Daily eccentric training necessitates a certain amount of compliance, as the patients need to perform 3 sets of 15 repetitions each with the knee straight and the knee bent twice a day. Compliance rates of 80% have been reported in a 12-week eccentric training regimen in Achilles tendinopathy (11,12). The authors do not report compliance rates in either group, and do not specify what measures were taken to ensure compliance to the eccentric training program.

4) Factors on the treatment delivered, population studied, and compliance to protocol may help explain the small gains in VISA-A score during the intervention that are on average far lower than other published studies. For example, in the RCT by Rompe et al. (13) the low energy radial pressure wave therapy group improved their VISA-A score from 53 to 80 points. In the present RCT, the VISA-A scores at 24 weeks were 63 points in the radial pressure wave group and 62 in the eccentric group, starting from 44 and 41 points respectively. Thus, an improvement of 19 and 21 points is clinically meaningful (14) but the clinical results after 24 weeks are still markedly poorer than what reported from other research groups in this field. We are aware that this may be related to the patients' characteristics and/or execution of the interventions, but this is not specified in the published article.

By highlighting these issues, we aim to inform readers of potential limitations to using this report to determine appropriateness of shockwave treatment for Achilles tendinopathy. The methodology concerns highlighted should also be considered when developing future studies.

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Conflict of Interest:

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