Author's response to reviews

Title: Short-term outcomes of extracorporeal shock wave therapy for the treatment of chronic non-calcific tendinopathy of the supraspinatus: a double-blind, randomized, placebo-controlled trial.

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Version: 4 Date: 15 March 2012

Author's response to reviews: see over
Dear Editor,

My coauthors and I are delighted that you were inclined to reconsider our manuscript for publication in the *BMC Musculoskeletal Disorders*. We noted that most of the reviewers’ comments were minor and we have addressed each, on a point-by-point basis, below. All the changes made to accommodate the reviewer comments are underlined in the revised manuscript.

We hope that our manuscript will be judged worthy of publication in your journal.

Sincerely,

Olimpio Galasso
Author's response to Steve Tumilty

ST: I think the 30 point change in CMS score to measure success has poor justification. The two articles cited to support this give no indication that 30 points is relevant. Thirty points is a large difference considering the CMS is only a 100 point scale and if for instance, 30 points was used in the power calculations, then this would equate to low numbers needed to detect such a change. The authors might consider making it clear that the 30 point difference was their opinion and not derived from research evidence.

A: According to your suggestion this issue was discussed in the text (page 10, lines 8-10)

ST: Again, considering the 30 point change in CMS to measure success; Table 6 displays patient 9 in the treatment group and patient 3 in the placebo group as having successful treatments without reaching the 30 point cut-off. Is this correct?

A: In the Materials and Methods section we wrote: “patients were considered a treatment success if they showed an improvement of at least 30 points, or their CMS at the study’s endpoint was at least 80% of the standard age-related value”. Therefore, we used two different criteria to consider a treatment success (i.e. the 30-point difference and the 80% of normal values). The patient 9 in the treatment group and the patient 3 in the placebo group had successful treatment because their CMS at the study’s endpoint was at least 80% of the standard age- and gender-related value.

However, considering your comment, we found a little inaccuracy in the sentence reported above. In details, we compared the CMS results of our patients to both the age-adjusted (as we originally wrote) and to the gender-adjusted values. Indeed, we compared our results to the normative values for the Constant score based on age and gender as reported in the work of Katolik and colleagues.

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In the revised manuscript we re-wrote this sentence as follows: “patients were considered a treatment success if they showed an improvement of at least 30 points, or their CMS at the study’s endpoint was at least 80% of the standard age- and gender-related value” (page 4, line 22).

The rationale of the comparison to standard age- and gender-related value comes from the observation that the strength of the normal shoulder may differ by gender and deteriorate with age. Thus, the Constant score may also decrease in absolute value while still reflecting a normal score. To account for age- and gender related differences, normal results for this scale were determined across a population of patients without shoulder disease.

Author's response to Kenta Ito

KI: Minor Essential Revisions: The references are not always listed as it appears in the main text.
e.g. Reference 42 (page 10, line 4)
A: We wrote “42” instead of “22”. Now, due to the changes requested by the other referees the number of this reference changed further to “25”. According to your comment the reference was modified (page 10, line 19)

Author's response to Angela Notarnicola

AN: in the rationale of the study the Authors should underline SW are widely applying in the treatment of many tendinopathies , as jumper’s knee, epicondylitis, plantar fasciitis, etc.
A: According to your suggestion this clarification has been added to the Background section (page 3, lines 8-9) and referenced at the end of the manuscript.
AN: The Authors should support the choice of their SW protocol (impulses, sessions, energy flux density) by literature.
A: As stated in the discussion section the protocol we have used has not been previously reported for the treatment of non-calcific shoulder tendinopathy. Indeed, it did not make sense to use the same treatment protocol that appeared to be ineffective in previous investigations on the same
We noted that Gerdesmeyer et al\textsuperscript{3} reported satisfactory outcomes in the treatment of calcifying tendinopathy of the shoulder using a SW treatment protocol similar to the one we chose. Indeed, these authors used the same energy flux density, number of session and interval between treatment we examined in this paper. This clarification has been included in the new manuscript (page 6, lines 7-8). It should be also noted that using this protocol we had a successfully experience treating shoulder tendinopathies over a ten-year period,\textsuperscript{4}

AN: The Authors should introduce some X-rays and MR images before and after treatment of the two groups.

A: We believe that X-ray or MRI images would be of limited interest among the readership of the journal mainly because we demonstrated the effective of ESWT mostly by CMS evaluation. No substantial changes of the tendon morphology has been visualized on imaging studies. However, if the editor would consider such images useful for the manuscript we will be able to provide them.

AN: The discussion is too long and contains lots of general information, which may not be relevant for particular results of the study. The Authors should get the reader attention into focus SW biological effects and comparison their results with the results of other medical treatments for shoulder tendinopathy

\begin{thebibliography}{100}
\item O. Galasso. ESWT and Rheumatic Disorders. 5th ISMST congress 26-29 June 2002 Winterthur.
\item S. Russo, C.de Durante, S. Gigliotti, O. Galasso. Treatment of shoulder calcifications by pre, peri and post- cavional shock wave power. 3rd ISMST Congress 1-3 June 2000 Naples.
\end{thebibliography}
A: Following your suggestion, the discussion has been shortened. Furthermore, a closer comparison of SW with other medical treatments for shoulder tendinopathy has been included (page 11, lines 7-10). The discussion as for the biological effects of SW has been modified (see below).

AN: The Authors should review the literature about SW applied in non-calcific tendinopathies, for example they should introduce “Reduced local perfusion after shock wave treatment of rotator cuff tendinopathy. Notarnicola A, Moretti L, Tafuri S, Forcignanò M, Pesce V, Moretti B. Ultrasound Med Biol. 2011 Mar;37(3):417-25.”

A: The paper you referenced was published after the first submission of our manuscript, therefore it was not evaluated previously. We modified the discussion concerning the biological effects of SW (page 13, lines 13-15) and referenced your article at the end of the manuscript. However, it should be noted that the hypoxic damage throughout the spectrum of pathology of the rotator cuff has been recently confirmed and it remains the cornerstone⁵.

Author's response to Jih-Yang Ko.

JYK: The concerns of the manuscript are small sample size and short-term follow-up.

A: As for the small sample size we believe that an accurate power analysis should overcome this limitation (see comment below). Furthermore, in our opinion, the demonstration of ESWT efficacy in the short-term period is still a valuable finding mainly because we obtained better clinical results in comparison to other medical treatments that are currently and commonly being used to treat shoulder tendinopathies (see new discussion paragraph, page 11, lines 7-10). It should be also noted that other manuscripts have been recently published in well established scientific journals

dealing with the treatment of supraspinatus tendinopathy with or without shock waves on the same follow-up period used in our study.

JYK: The authors stated that the power was 75.5% and 70.3% for the subscale of ROM and the total Constant score between the ESWT (11 patients) and placebo groups (9 patients). From our previous study, under the expectation of an improvement in the Constant score of 10 points, with an SD of 12 points in each group and a power value of 0.8, the minimal number required in each group was 23, by use of an independent samples t test. I believe we need an expert statistician for the analysis.

A: The power analyses are strongly dependent by the pre-fixed conditions. In our case, the test used, the fixed effect sizes and the SDs are very different from those you indicated. Furthermore, the power functions of different statistical tests are not comparable tout court. So, it is not surprising that the required sample sizes resulting from the two power analyses are very dissimilar. In light of your comment we asked our statistician (Dr. Francesca Condino, Institute of Neurological Sciences, National Research Council, Piano Lago di Mangone, Cosenza, Italy. f.condino@isn.cnr.it) to verify the values reported in the text. She confirmed the numbers previously provided.

JYK: I would strongly suggest the latest follow-up of the whole patients who had real ESWT be mentioned in the manuscript. This should include the number of patients who progressed to surgical intervention or other treatment options. The longer term follow-up data will add something to the current knowledge

A: Following your suggestion a telephone recall of the ESWT patients has been carried out and we were able to collect data on 10 out of 11 individuals. No patient progressed to surgical

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intervention. Two patients showed a recurrence of shoulder pain 3 and 4 years after ESWT, respectively. They were successfully treated with ESWT again (1) and medication for pain with a regimen of scapulothoracic and glenohumeral range of motion and strengthening exercise (1). A 100% satisfaction rate with treatment and willingness to undergo the ESWT again was reported. These new data were included in the revised manuscript (page 7, lines 6-9; page 9, lines 8-14).