Reply to: Clinical evaluation of the ability of a proprietary scoliosis traction chair to de-rotate the spine: 6-month results of Cobb angle and rotational measurements

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Dear Sirs,

We appreciate the efforts of Stitzel et al. (doi: 10.4081/cp.2014.642) in publishing an article on CLEAR Institute’s proprietary Scoliosis Traction Chair (STC). However, there are several aspects of this article which may encourage readers to draw inaccurate conclusions.

First, the authors state in the paper that, Protocols should also be established to ascertain how to best predict the future benefit of using the Scoliosis Traction Chair in individual cases. These protocols do exist and were not followed in the study. According to the official CLEAR protocols as they are taught in postgraduate courses at accredited chiropractic universities, the purpose of taking a radiograph of the patient while seated in the Scoliosis Traction Chair is to ensure proper set-up resulting in a corrected spinal alignment. If improvement in radiographic parameters (including vertebral rotation) is not observed, the correct conclusion is that the patient set-up is incorrect and needs to be re-done. Figures 1 and 3 demonstrate incorrect set-up of a patient in the Scoliosis Traction Chair. Despite their previous experience with the CLEAR protocols, the authors of this paper did not follow the official protocols correctly in this study.

Second, when improper set-up leads to worsening of the patient’s spinal rotation as observed in the in-chair x-ray, there are important ethical considerations in allowing the patient to continue using the Scoliosis Traction Chair incorrectly for six months. Was any type of ethical review performed by an independent Institutional Review Board (IRB) regarding this study? According to standard research practices and the Food and Drug Administration (FDA) (whose auspices the STC falls under, as a FDA-registered product), IRB review is required when conducting a review of your own patients’ clinical records (i.e. medical records, x-rays, laboratory values and/or reports) in order to answer a research question. Were the patients informed that the in-chair x-ray of their set-up demonstrated worsening of their spinal rotation? If so, why did they continue using the STC for six months? Again, with correct implementation of the CLEAR protocols, the treating doctor would change the patient set-up in the Scoliosis Traction Chair to demonstrate improvement on radiographs before instructing the patient to use the STC as a part of their home rehabilitation.

Third, the authors claim that the purpose of their study was, to evaluate the device’s ability to de-rotate the spinal curvature in the thoracic spine. However, the study design lacks the ability to achieve this goal. As a retrospective review of files, it lacks external validity; there can be no extrapolation of the observed results beyond the subjects involved in the study. The data is descriptive and best used to judge whether clinical significance has been achieved; it is unreliable for statistical analysis. The sample size was small (involving only 15 subjects) and, with a retrospective design, could not have been predetermined for effect size or statistical power. Furthermore, no attempt was made to account for measurement errors in radiographic analysis, despite the known variability of Cobb angle. Independent analysis of the radiographs was not performed, and readers cannot be assured that the analysis was verified as accurate.

Fourth, the wide variation among the patients, combined with the lack of any table or chart summarizing their individual case presentations, makes it impossible to screen for potential confounding variables. Individual Cobb angles, apical vertebrae, vertebral rotation measurements, ages, Risser signs, and other basic descriptive details were not reported, and no effort was made to screen for variables other than the apical vertebra between the apical-worsening group and the apical-improved group that may have influenced the results at six-month follow-up; in truth, the significantly higher severity of the Cobb angle in the apical-worsening group compared to the apical-improved group (65 versus 40) alone could account for the poorer prognosis observed in this group at follow-up, regardless of what the authors chose to use as the differentiating factor. Also, while the authors claim that patients with a higher apical vertebra were more likely to demonstrate apical worsening in the in-chair x-ray (referencing T11), they also note that patients with an apical vertebra of T10 demonstrated improvement in vertebral rotation in the in-chair x-ray. No attempt was made by the authors to explain why some patients with apices above T11 saw improvement in the in-chair x-ray, and some did not.

Fifth, although several of the authors openly declare conflicts of interests, no efforts appear to have been made to screen out potential biases. Independent radiographic analysis was not done. Independent patient evaluation was not performed. Independent statistical analysis was not done. In each case, analysis was performed by one of the authors. Furthermore, the identity of the treating doctor was never disclosed in the paper and, although the authors claim this individual was appropriately certified, this individual’s failure to correctly follow official CLEAR protocol suggests otherwise; regardless, since the treating doctor was never identified, the authors’ claim cannot be verified.

In this paper, the authors present a small group of patients, retrospectively selected out of an undisclosed number of patient files over a time frame that was never defined. The inclusion criteria is sufficiently vague that a sampling bias could exist. The authors present with conflicts of interest and make no effort to conduct independent analyses. The paper attempts to perform a clinical evaluation but does not utilize a study design which is capable of doing so. No mention is made of the fact that setting up a patient in the Scoliosis Traction Chair incorrectly could also be responsible for the observed results. It is the official position of the CLEAR Scoliosis Institute that this study conducted by former members of our organization does not meet our standards for proper patient case management, nor does it provide unbiased data that can be applied in any meaningful way.

Respectfully submitted,
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Conflicts of interests: Dr. A. Joshua Woggon serves as the Director of Research for the CLEAR Scoliosis Non-Profit; Dr. Dennis A. Woggon is the CEO and Founder of the CLEAR Scoliosis Institute, and the inventor of the Scoliosis Traction Chair. Josh Woggon and Dennis Woggon are part of the Organization which owns the patent on the Scoliosis Traction Chair. No further conflicts of interests exist.

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