

## 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 Editor,

Thank you for the opportunity to allow us to address the comments and concerns raised by Donzelli *et al.*<sup>1</sup> We appreciate the time they took to read and voice their concerns of the present study. With regard to ongoing treatment, the authors have not been using the scoliosis traction chair clinically or for home use on thoracic curvatures since this data was collected and discovered. In fact, when knowledge of this data was initially presented to the manufacturer, the lead author of the paper (CS) was subsequently mailed a Cease & Desist letter from its attorney.

While we understand and share Donzelli *et al.*'s concern for patient safety, the data did suggest that patients with lower curve apices improved, clinically significantly in some cases,<sup>2</sup> so it is difficult to simply make a general statement when the study's design (a retrospective chart review) makes such statements impossible. To draw causality from a retrospective chart review, for any observed deterioration or improvement, is simply not possible or appropriate. However, that is why we are urging for more data to be published on this device. Since it has been taught and used clinically since at least 2005,<sup>3</sup> we felt it important to look at how the chair may have contributed to the observed results in a retrospective collection of patient charts.

With respect to surgical intervention, all of the patients selected in this chart review sought exercise-based treatment because they emphatically denied surgical treatment. Of these, 6 of the patients had previously participated in bracing treatment and still saw their curves progress. Four of these six patients went on to surgery following the treatment discussed in our study. A total of 7 patients ended up having fusion surgery, of which 6 of these had a curve apex above T10. Bracing treatment has also been suggested to potentially contribute to curve progression in scoliosis

patients with larger curves.<sup>4</sup> Since the overall comparative effectiveness of non-operative treatment across all types is equivocal when assessing near end-growth and adult patients,<sup>5,6</sup> we feel that these patients made an informed decision at initiation of treatment. Our cohort of patients simply exhausted their non-surgical options before electing to have surgery. Additionally, the bracing study to which<sup>7</sup> Donzelli *et al.* refer discusses a brace (Sforzesco) that is not widely available in the United States to our knowledge. Risser casting is typically considered in infantile or progressive juvenile cases where immobilization prior to surgery is the primary objective.<sup>8</sup>

According to the US Department of Health and Human Services Office of Human Research Protections,<sup>9</sup> an IRB review is not required when: i) the study is a records review; ii) when patients can be identified neither directly nor from any unique modifier; and iii) the patients' reputation, employability, liability, and financial standing are not at risk. Our study met this criteria in all facets: the data was collected after all treatment had been rendered, and prior to the organization of this study, patients gave their consent to treatment, and none of the information used can identify them directly or indirectly. This gives clinical researchers in private practice the ability to gather information from their respective clinics and contribute to the broader research base, especially with scoliosis treatment specifically.

We have been very careful to not have any knee-jerk reaction to our results. To extrapolate our data to any broader group, or to make any generalized recommendations to other patient samples would be inaccurate. Likewise, it is equally important to publish this type of research to further refine treatments and equipment that are currently used in clinical practice and to better identify the potential clinical utility, or lack thereof, of such treatments.

Sincerely,

Mark W. Morningstar, DC, PhD

## References

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