Author’s response to reviews

Title: 3D Correction of AIS in Braces Designed Using CAD/CAM and FEM: a randomized controlled trial.

Authors:

Nikita Cobetto (nikita.cobetto@gmail.com)
Carl-Eric Aubin (carl-eric.aubin@polymtl.ca)
Stefan Parent (stefan.parent@umontreal.ca)
Soraya Barchi (soraya.Barchi@umontreal.ca)
Isabelle Turgeon (isabelle.turgeon@recherche-ste-justine.qc.ca)
Hubert Labelle (hubert.labelle@umontreal.ca)

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Answer to reviewers

1. Reviewer #1

Congratulations to the authors and their team for their years of significant and dedicated effort developing this FEM. Quality research in non-operative scoliosis treatment at the RCT level is rare. This study clearly demonstrates that engineers have a critical role and responsibility in advancing our knowledge of optimal 3D brace design. The development of this practical and technical tool promises to be a significant advance in assisting orthotist in designing, constructing and fitting more effective scoliosis braces, which in turn should directly benefit the many patients who have to wear them.

I suggest less length and more strength for the study title! It needs to grab the reader's attention and encourage them to check it out. The order and choice of words implies that it is about 3D correction of braces.... when it seems it is really about... "Optimizing 3D Brace Design for AIS Using Finite Element Simulation and CAD/CAM: A Randomized Controlled Trial"

My suggestion for minor revisions is for final grammatical edits which will be emailed to the authors.

Thank you for your comments. We agree that a shorter and stronger title would be appropriate. We changed the study title from "3D Correction of Braces Designed Using CAD/CAM and
Finite Element Simulation for the Treatment of Adolescent Idiopathic Scoliosis: a randomized controlled trial" to "Optimizing 3D Correction of AIS with Braces Designed Using CAD/CAM and Finite Element Simulation: a randomized controlled trial".

2. **Reviewer #2**

The limitations of the study are well stated, but it would be important to increase the number of patients to be included in the study, and most of all to see the midterm and long-term effect of the braces designed using CAD-CAM finite element simulation.

We completely agree with your comment. A complementary study is underway to further study the mid- and long-term effects (follow-up during the treatment period and 2 years after maturity) of such braces designed using CAD-CAM finite element simulation, as well as the impact of the spinal flexibility on brace treatment effectiveness using a cohort of 120 patients. This complementary study goes beyond the scope and framework of the current study, and would be the subject of another communication when completed.

3. **Reviewer #3**

It is an excellent written manuscript.

**Typo:**

Line 138 - I believe it should be EOS (trademark) - the text "TM" should be superscript.

Line 224 - For the control group, the Cobb angle prior to brace shows 25o(L), but on the table 1 it shows 24o, please correct it.

Thank you for the corrections, the modifications have been applied.

**Questions:**

How did you calculate the apical axial rotation? Do you consider any rotation direction? Do you take the absolute value only?

The apical axial rotation was calculated on the 3D reconstructions of the spine build from the initial visit radiographs and the in-brace radiographs. Details of the 3D reconstruction methods were added between lines 139-146 in the manuscript. When measuring the axial rotation, negative (clockwise) and positive (counter-clockwise) signs were considered. However, because there was no inversion of rotation sign (a negative axial rotation becoming positive or a positive
axial rotation becoming negative), we presented the apical axial rotation using the absolute value only.

Can you add the number of thoracic curves and lumbar curves on both group? Need to see if there are enough number of curves for statistical analysis.

The number of thoracic and lumbar curves was added in Table 1 for both groups.

Number of thoracic curve, Test group: 23

Number of lumbar curve, Test group: 21

Number of thoracic curve, Control group: 20

Number of lumbar curve, Control group: 17

We have verified that the sample size is sufficient for the study to be statistically significant. A value of significance of 0.05 (α type error of 5%) and a statistical strength (1-β) of 90% were used. We also verified that the values of each group followed a normal distribution.

4. Reviewer #4:

The authors have written one of the most fascinating articles on the topic of bracing for adolescent scoliosis. Some of the authors have publications on finite element modeling applied to optimization of bracing for scoliosis dating from at least two decades. Now we see the application of 3D technologies such as surface topography, 3d reconstructions from EOS, finite element simulations and CAD/CAM applied together attempting to make the most effective and comfortable brace for adolescent idiopathic scoliosis. The authors have shown that the addition of finite element modeling data improved the initial in brace corrections in 3D compared to controls. Also, the orthotist is guided in the building of corrective forces into the brace along the plane of maximum curvature (PMC). The true clinical results of this approach will be known with further follow up.

Thank you for the good comments. We completely agree with your last affirmation. We plan on publishing the results of the complete cohort including 120 patients. For this cohort of patients, midterm and long-term results will be studied (follow-up during the treatment period and 2 years after maturity).