Author’s response to reviews


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Author’s response to reviews:

Scoliosis and Spinal Disorder
Amsterdam, November 9th 2017

Dear reviewer and editors,

We would like to thank you for your time and effort in evaluating our letter for potential publication. We appreciate the chance to resubmit our letter. We have attempted to address each of the concerns mentioned point-by-point and we made some changes in the letter. Please find our responses below.

We hope that the quality of the letter has increased satisfactorily for publication in your journal and we hope for an interesting scientific debate. We are looking forward to hearing from you.

Please contact me in case of any questions or ambiguities.

Sincerely yours,

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Response to reviewer

R = Reviewer’s comment

A = Author’s reply

R: The contested conclusion is: “patients treated with RCOs were substantially less likely to progress to spinal surgery than those treated with Boston-style TLSOs” The authors suggest that the surgical indications differ according to the brace used. Cobb angulation greater than 45° can remain stable without surgery. Conversely, an imbalance of the spine, a high rotation, a flat back may justify the discontinuation of the conservative treatment and a surgical orientation between 40° and 45°. All results are in favor of the asymmetrical RCO brace, which is logical, since it is the only way to allow hyper-correction.

A: Apart from the progression to surgery, the results show significant changes in major curve from baseline (6.0° versus 6.9° in the RCO and TLSO group, respectively) and percent change in major curve from baseline (18.6% versus 21.3% in the RCO and TLSO group, respectively). However, these changes do not explain the indication for surgery. Furthermore, there was no significant difference in the number of patients with curves exceeding a Cobb angle of 45° and 50° at maturity (see table 2 in the article). In the RCO group, 2 patients had a major curve of 45° at skeletal maturity and even one of them had a curve bigger than 50°. None of these patients in the RCO group underwent spinal surgery. In the TLSO group, 30 patients had a major curve of 45° at skeletal maturity, while 36 patients were surgically treated or had a curve of >45°. This suggests that 6 patients were surgically treated for curve magnitudes below 45°.

Thus, we miss variables in the article which were significant more presented in the TLSO group which resulted in more surgery.

R: 115-16 "have a significant lower rate of spinal surgery" is not the same as "were substantially less likely to progress to spinal surgery" The sentence "have a significant lower rate of spinal surgery" does not exist in the text of Minsk.

A: The sentence "have a significant lower rate of spinal surgery" does exist in the text of Minsk. The first sentence of the conclusion of the abstract is “Patients treated with RCOs compared with Boston-style TLSOs had similar baseline characteristics and brace wear time yet significantly lower rates of spinal surgery”.
"The generally agreed indication for surgery in adolescents idiopathic scoliosis is curve progression to a Cobb angle of 45° to 50°" Weinstein confirms risk of average progression of 1° per year after skeletal maturity for scoliosis between 40°-50° at skeletal maturity. Lonstein ends his discussion on natural history and progression by commenting that "the cosmetic aspect of scoliosis must be borne in mind and should not be minimized" Lebel confirms the importance of the sagittal plane and notes with EOS system that delordosis is -13.3% in Boston and only -6.6% in TLSO Chêneau.

"These differences in curve magnitudes and surgically treated patients suggest a selection bias in surgical candidates." Such a sentence would mean that only the Cobb angulation is a surgical criterion.

We totally agree with the reviewer that the Cobb angle is not the only surgical indication for surgery. There are more variables that are in the “algorithm” in deciding when to operate (e.g. fast progression, vertebral rotation, sagittal plane, preference of the patient, cosmetic problems). However none of these variables are reported in the article of Minks et al. So we don’t know if these variables were similar in both groups at baseline. We have changed this in our letter.

The conclusion does not mislead the reader: "Future studies should examine differences in outcomes by brace type in other settings and in larger samples, and they should investigate the impact of the rotational dimension of correction with RCOs."

We agree that the conclusion is more modest in the conclusion section of the full article. They conclude that patients treated with RCOs were substantially less likely to progress to spinal surgery than those treated with Boston-style TLSOs. An that patients treated with RCOs had smaller mean change and smaller percent increase in major curves from treatment initiation through follow-up. However the exact indication for surgery is not reported. A curve of >50° was apparently not the only indication, since patients with a 50° curve in the RCO group were not operated. One of the main methodological errors in scoliosis research is selection bias1. We totally agree that more patients in the TLSO groups are operated, but we don’t know why. This may lead to wrong interpretations of the results. However, there is also a risk of bias from insensitivity to sample size (also known as “law of small numbers”) due to the large difference in group sizes. One case progressing to surgery in the 13 RCO patients influences the outcome and conclusions of the study. We therefore encourage the authors to continue their good work and report their results again in similar group sizes.

1) Research quality in scoliosis conservative treatment: state of the art’ of Fabio Zaina, Michele Romano, Patrick Knott, Jean Claude de Mauroy, Theodoros B. Grivas, Tomasz Kotwicki, Toru Maruyama, Joseph O’Brien, Manuel Rigo, and Stefano Negrini,
Our revised letter to the editor.

Dear editor,

We read with great interest the article by Minsk et al.1 We congratulate the authors with this study and for using the recommendations of the Scoliosis Research Society (SRS) and the Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) committee on bracing and non-operative Management.2, 3 It is one of the few available studies comparing the Boston-style thoracolumbosacral orthoses (TLSO) and the Rigo Cheneau orthoses (RCO) and we encourage research in the field of conservative treatment of scoliosis. However, the conclusion of this open access article raised some confusion.

The authors conclude in the abstract that “patients treated with a RCO brace had similar baseline characteristics and brace wear time yet significant lower rate of spinal surgery”. In their conclusion, they state that “patients treated with RCOs were substantially less likely to progress to spinal surgery than those treated with Boston-style TLSOs”. Although the conclusion is supported by the significant differences between the RCO and TLSO groups, the other study results in combination with no clear description of the indication for surgery raised confusion.

Apart from the progression to surgery, the results show significant changes in major curve from baseline (6.0° versus 6.9° in the RCO and TLSO group, respectively) and percent change in major curve from baseline (18.6% versus 21.3% in the RCO and TLSO group, respectively). However, these changes do not explain the indication for surgery. Furthermore, there was no significant difference in the number of patients with curves exceeding a Cobb angle of 45° and 50° at maturity (see table 2 in the article). In the RCO group, 2 patients had a major curve of 45° at skeletal maturity and even one of them had a curve bigger than 50°. None of these patients in the RCO group underwent spinal surgery. In the TLSO group, 30 patients had a major curve of 45° at skeletal maturity, while 36 patients were surgically treated or had a curve of >45°. This suggests that 6 patients were surgically treated for curve magnitudes below 45°.

Although progression of the curve to a Cobb angle of 45° to 50° is a frequently reported indication for spinal surgery4, 5, we realize that other patient characteristics may also influence treatment decisions and curves above 45 or 50 degrees may remain stable without surgery. Apparently, indication for surgery was not only based on progression of the Cobb angle. If the indication and risk for surgical treatment differs between the groups, this may lead to bias and wrong interpretations of the results. Zaina et al mentioned to be aware for this kind of
methodological errors in scoliosis research. Since there is currently no clear description of the indication for surgery, the influence of a selection bias on study results is not clear in this study.

Due to the need for long-term follow up and difficulty to measure all variables, it is difficult to design studies comparing scoliosis braces. The retrospective study by Minks et al is one of the first good studies implementing the study recommendations of different societies. However, there is also a risk of bias from insensitivity to sample size (also known as “law of small numbers”) due to the large difference in group sizes. One case progressing to surgery in the 13 RCO patients influences the outcome and conclusions of the study. We therefore encourage the authors to continue their good work and report their results again in similar group sizes.

Yours sincerely,

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References


