Author's response to reviews

Title: The Sforzesco brace can replace cast in the correction of adolescent idiopathic scoliosis. A controlled prospective cohort study

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I thank very much all the reviewers for their contribution.

About the Minor essential revisions asked by Dr. Rigo, we corrected the paper, while we still discuss the major point of the discretionary revisions, i.e. avoiding to propose sagittal plane and aesthetics to strengthen the main point of the paper, that is Cobb degrees result.

In any case, we changed according to suggestions the paper considering all the outcome criteria together and eliminating the distinction between primary and secondary criteria. Moreover, we totally agree with the final sentence in the review that state: “the principle of correction we used here to apply the cast produced more deterioration in the sagittal profile than the principle of correction we used to built the rigid plastic brace”. In fact, this was already written in the discussion, even if with different phrasing, and obviously we maintain this sentences.

The main difference relate to the maintenance or not of the measurements of aesthetics and sagittal profile in the paper. I think that the “Discretionary revision” proposed by Dr. Rigo could serve as a letter to the Editor about the present paper (or an invited commentary to which we could answer), so that we can fully (and in a more disclosed way with regard to the general audience) develop these very interesting points. This will testify on one side how deep we want to go in the analysis of brace results, on the other the importance of outcomes different from Cobb degrees in the analysis of scoliosis treatments.

I think we totally agree that we must take into account different outcomes, while we do not agree on how to do that. I think Dr. Rigo is more “pure” and want perfect measurements, while we are less “pure” and we think that measuring, even if not perfectly, can in any case give improvements to our understanding. And in this case this is testified by the same conclusion on our paper proposed by Dr. Rigo that “the principle of correction we used here to apply the cast produced more deterioration in the sagittal profile than the principle of correction we used to built the rigid plastic brace”: this can be stated because of the geometrical kyphosis change that is in any case was worst for the Risser cast than for the Sforzesco brace.

We agree that theoretically can happen that a geometrical change do not respect a structural change, but in our mind this can be true particularly in real flat back, not when kyphosis is still present, even if reduced. Moreover, a difference between the two is true only if the three points measured fall out of the scoliosis area, i.e. in case of high thoracic structural flat back (rare) or low thoraco-lumbar structural flat back; the last could theoretically be more common, but we all know that usually a thoraco-lumbar curve evolves in a thoraco-lumbar kyphosis: so these situations are both rare. This short discussion is here just to say that the regional/geometrical difference is not yet established, nor we know if we really need for the patients to change the regional kyphosis while it could be enough for their future to maintain the geometrical one. Also names (geometrical/regional) could be not correct, because according to Stoke paper on 3-D nomenclature we should use regional also for what you call geometrical... Anyway, with respect to the rest of the conservative/surgical world we have still to state the importance of respecting kyphosis, not yet to discuss on which kind of kyphosis. And we have to state the importance of measuring the sagittal plane, whichever way, to evaluate and behave correctly, not yet to discuss which is the best measurement system.

Our point of view is that, at this stage of research, we must state the importance of all these outcomes and use the instruments for measurement that we have today, even if what we have is not the best. We are just trying to get out from 50 years of clinical research based only on Cobb angles, considered the gold standard and forgetting all its limitations. If we continue to fight for the best measurement we loose the good measurements, that nevertheless do tell something.

The distances from the plumbline tell something about kyphosis, even if they are based only on a three point measurement: nevertheless this is not different from the Cobb angle, that is even worse because it is based on two points (end-vertebrae only), and x-rays require to move the arms so changing the sagittal curve. As stated in the paper we know the measurement error of the distances from the plumbline, so that we can tell clinically if a patient did change or not; moreover, if we reach a statistical significance in a population study, we can tell that there was a difference on this measurement in the two populations. In any case, with its advantages and disadvantages, this
tell something on kyphosis: a general variation, not particulars on the eventually existing intermediate rigid regions that are not on the point measured (rare but still possible), but it is a change!

This situation is true for any kind of measurement system. Just to go in another field: VAS for pain is not a very satisfactory measurement, but tells something, it’s easy to use and it is widely used. To measure pain e.g. the McGill Pain questionnaire could be considered better in some respects, but its difficult to use and it’s rarely used. We hope in the future we will have something better, but now we all use VAS for pain. It could be the same for kyphosis: three (distances from the plumbline, Arcometer) and two points (Cobb degrees, inclinometer) measurements are easy to use and are widely used, while other tools could in the future show to be more accurate, but as always happen they will have some other limitations for sure. I know that Dr. Rigo is hardly working on the sagittal profile evaluation, but his harmonic/disharmonic tool is not yet ready and require expensive systems like Formetric, or invasive ones like x-rays. In any case, we do not have any other measurement now, so what we have to do? Not to measure?

The situation is even worse about aesthetics, because here we do not have any clinical everyday tool today, a part from subjective patients/parents’ questionnaires, as you will see from the paper on “TRACE and Aesthetic Index” that we are hopefully going to publish in Scoliosis (if it will be accepted); once known the limitations (presented in that paper), we can use such measurements easily everyday. And we are using it today, while we hope on (and work for) something better for the future.

We are all trying to change this world of conservative treatment and outcome criteria are very important key points. We need appropriate measurements, but these are not yet defined, and sometimes not yet developed. We cannot simply flatten ourselves on the actual consensus on Cobb degrees, nor we cannot be too much hard on ourselves pretending to have already the best tool while we do not have it. “The best is enemy of the good”: to me we have to use what we have (once shown its measurement properties, mainly measurement error in clinics), and try to develop something better. Otherwise we will not publish anything in the future with different clinical outcomes from what has already been published in the past. Nor we will educate the rest of the world on the importance of something different from Cobb degrees (that still have their important flaws as measurement tools!).