Reviewer's report

Title: Vital capacity evolution in patients treated with the CMCR brace. Statistical analysis of 90 scoliotic patients treated with the CMCR brace

Version: 4 Date: 10 July 2011

Reviewer: Manuel Rigo

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This is a different, third new version. The authors submit here a new paper rather than a revised version of their first submitted papers. The present paper is much better structured and clear than the two previous submitted papers and allow a proper revision and final decision about acceptance or rejection.

The authors developed a new brace design with flexible pads under the assumption that rigid braces have a major deterioration effect on breathing function. The objective of the present study would seem to be to show that the new CMCR should be used to substitute braces with rigid pads in order to prevent breathing function deterioration or even in order to improve breathing function at the end of the treatment. This question can not be answered with a study using the methodology described by the authors in this study. This is a retrospective study, with no control, showing that at the end of the treatment with a CMCR in a group of 90 patients diagnosed with mild idiopathic scoliosis, breathing function was not significantly deteriorated. In fact nothing new.

Korovessis (Spine 1996) already showed in a prospective study that the Boston brace (rigid pads and full contact compressive brace) had only a short term deterioration effect but the results of his study suggested that brace wearing for mild idiopathic scoliosis does not harm adolescent lung function. Thus, the assumption that there is a need for developing a brace with flexible pads to prevent a long term breathing function deterioration associated to braces with rigid pads can not be supported by previous scientific literature. However, it is still clear that rigid braces with rigid pads are associated to a short term breathing function deterioration that could be the reason for a lack of compliance as a consequence of physical discomfort. This could be a good reason to think about developing of a brace like the CMCR. Thus, a first question to be answered could be: 'is, in short term, the CMCR less harmful on breathing function than a brace with rigid pads?'. Obviously, this question can not be answered in this present study. The only possible conclusion of this study is not different than the conclusion already made by Korovessis in 1996 so it is not acceptable to discuss about any disadvantage of rigid pads versus flexible pads taking in consideration the methodology of the present study.

Other points that could be questioned as major compulsory revisions, in case the paper is finally accepted in spite of my negative recommendation, are:

1) is it right to state that breathing impairment is a sign of idiopathic scoliosis
rather than a direct consequence of a thoracic deformity? The study from Barrios (cited by the authors in the discussion section) did not show any difference in static values when comparing patients with mild idiopathic scoliosis and healthy controls. The reason for a reduced initial FVC in this present retrospective series in comparison with the theoretical values could be as simple as: lack of training in the performance of the initial test while by repetition, maturation, training of the breathing technique during the physiotherapy sessions, etc. allow a final proper performance. On the other hand an improvement of 4% related to the theoretical value, although statistically significant, has probably no clinical relevance.

2) It is not acceptable to state in the results section something like ‘comparison of the reduction of the Cobb angle during the treatment clearly show that, on that point the brace is effective, but the study did not meet the criteria defined by Negrini at al about RCTs or CCTs'. It is contradictory. If the criteria are not accomplished the authors can not write that it is clearly showed that the brace is effective. From one side, a population of girls and boys with a mean age of 13 years (nothing said about pre or post menarchial status) and more than 45% with a Risser sign of 2 or higher and a mean initial Cobb angle of 20.6º, can not be defined as a population with documented progressive idiopathic scoliosis. It is unacceptable. Even with a change in the Cobb angle of 5º or more in six months and a significant change in the rib hump. What means a 'significant change in the rib hump'? and what clinically means a change in 5º or more in the Cobb angle in scoliosis under 20º giving after such a assumed progression a mean Cobb angle of 20.6º. Final Cobb angle is reported exactly the same 20.6º, without standard deviation and ranges. This is also unacceptable.

3) Like in previous versions, still some unexplainable contradictions. Mean initial Cobb angle in the abstract is reported to be 20.6º. It is not reported for the whole sample in table 1 and it is differently reported as 23º and 22.3º in two parts of the discussion. Very confusing.

My final recommendation is to reject this paper. After being able, from this third version, to make a more proper revision I must conclude that from the methodological point of view the paper has not sufficient sound. It is highly recognized the clinical experience of the authors in the conservative management of scoliosis and other spinal deformities. It is also appreciated the natural interest in developing treatment systems to improve final results and reduce negative side effects at the same time. The CMCR can be considered a logic evolution of the Lyonnaise school. After years using the CMCR, the authors will be probably convinced about its advantages in comparison with the classical Lyon brace with rigid pads. However, at this time, to make a conclusion about whether the CMCR is more effective than the Lyon brace and whether the breathing function is better preserved in short term or improved in long term by using this brace in comparison with other braces with rigid pads can not be answered from their current database analysis but only suggested. The analysis of their data from their current database, although not publishable in scoliosis, allow them to start further research in order to show the advantages of the CMCR in comparison with other braces. For example, it could be now designed a
prospective study on short term effect in breathing function and primary in-brace correction comparing the CMCR and the classical Lyon brace. It could be also analyzed retrospectively, by using the current database, the end result of the CMCR following SRS and SOSORT inclusion criteria, and at the same time to report about breathing function evolution.

I encourage the authors to use their impressive database to produce studies with a proper methodology and to design new prospective studies to show the benefits and advantages of their very interesting brace design.

**Level of interest:** An article of limited interest

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests’