Author's response to reviews

Title: In defense of adolescents: They really do use braces for the hours prescribed, if good help is provided. Results from a prospective everyday clinic cohort using Thermobrace. 2011 SOSORT Award winner.

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Version: 2 Date: 17 April 2012

Author's response to reviews: see over
First of all I would like to apologize for the long time to answer to reviewers, due to my change of work and then to the preparation of the SOSORT Meeting

Dr Katz
Thank you so much for your deep, thoughtful and useful comments. Please, find below a response point by point in red below your text

This manuscript serves as a preliminary report on estimating actual brace wear patterns using a heat sensor in 68 adolescent subjects with an average treatment duration of 5.5 months, to which conclusions are drawn regarding the influence a clinical treatment regimen may have on these estimates. Their secondary aim was to determine whether or not the use of an orthosis that is monitored to record actual wear patterns would be of reasonable clinical utility, and would not undermine the physician/patient relationship.

To monitor actual wear patterns, the authors used a temperature data monitor placed with a pressure pad in the brace. To validate the accuracy of this methodology, they recruited 5 subjects that were already wearing an orthosis for the treatment of AIS, two of whom were suspected poor compliers with their prescribed treatment regimen. Over a 27.5 day period of monitored wear, they utilized the patient reports on wear as the basis to determine the accuracy of the interpreted wear from temperature data logger. Using a patient’s reported wear for this point of reference is risky, as Morton et al showed patients typically over-estimate (or overreport) their actual (recorded) amount of brace wear. Further, identifying a patient as “compliant” or “non-compliant” in the absence of monitoring is also unreliable.

You are correct, and this was what we found as well. But, the problem is that any new device must be checked versus a Gold Standard. What is the Gold Standard to check a temperature monitor? In our view, only patients can tell us what they really did.

Since before this study we were not using any monitoring device, the only type of compliance we already knew of these patients was what they referred when inquired in front of their parents. Referred compliance has been shown to underestimate the real brace wearing. We required all these patients to register on a data sheet each time they put on the brace or took it off, and we compared this data with that registered by the TB. We considered their data sheets as the golden standard reference to validate TB measurements. In fact, the data sheets were completely different from referred compliance: pupils had to fill in them during the day reporting exactly not the time of brace wearing, but the hour and minutes of the day so that calculation could be made by us afterwards. Moreover, patients did know that what we were searching for was the validity of the instrument and not their own compliance. Parents were asked not to check this data sheet, and we guaranteed we would have not used them to check their compliance (what we did, in fact). Finally, they had to perform this validation for one month, while the period of observation for their treatment was six months (so detaching compliance to therapy from the observation period of the pilot study)
Using the patient reported, or “Referred” compliance, from the 5 subject trial, the authors determined a temperature sampling every 60 minutes did not compromise the accuracy of the calculated (“Real” compliance) compared to the samples taken every 20 minutes. They then employed a novel algorithm, determining times where the brace was “certainly worn”, “certainly not worn,” and times where they were unable to discern whether the brace was being used by the patient or not. Only a 3 degree difference in temperature was determined to be proper thresholds between the brace being worn (28 degrees) or not worn (25 degrees). It would be of interest to the reader for the authors to report the number of temperature samples that fell into each of the three defined wear categories, as described. The accuracy of the algorithm developed to interpret actual wear is difficult to prove, considering the reliance placed on patient logs as the primary tool for this exercise, but it does appear the authors were diligent in their efforts to determine the most accurate interpretation of the recorded temperatures in the subjects being studied.

Thank you for your consideration. We invite the reviewer to consider also that we used two different algorithms to have a double-check of the computer calculation and test the accuracy of what we hypothesized was the best algorithm. This second method proved to give results almost always identical.

The methods employed to enroll patients into this study make it difficult to draw conclusions from this population to a general population of patients being treated with an orthosis for AIS. Citing a concern of interfering with the physician-patient-family relationship, the prescribing physician self-selected patients the wanted to consider enrolling. The temperature monitors were evidently free of charge, and offered “mainly” to patients already in treatment. At some point, the decision was made to require the patient family to purchase the temperature monitors to participate in the study. Thus there are multiple dynamics that may influence wear patterns: 1) physician bias as to who they wanted to enroll early in the study; 2) some patients with prior treatment and others without; 3) some patients receiving their monitors free of charge while others were required to purchase their data loggers.

Sorry we did not make us understood. In fact, we never had patients who received the TB free of charge. Now this has been specified as follows:

Consequently, at the start it was proposed as complimentary (i.e. the patients and family had to decide if they want to buy it), and mainly to patients already in treatment who were showing problems in the use of the brace. Subsequently, it was also proposed as complimentary to the patients at their first evaluation at our institute, but not to all of them.

Moreover, the patients who were already in treatment were almost not used in the study. Now this has been better specified as follows:

We had two main groups: 48 patients at the first prescription of brace and 20 who were already using the brace for some time. In Table 1 the characteristics of these sub-groups are reported. All the study has been carried out with respect to the first group, while the second was used only to check whether referred compliance changed after starting the use of the TB.

About the generalizability of these data to the general scoliosis population, please consider that Thermobrace entered in our general practice as a clinical tool (that now we use on all braced patients) and not a research tool. Consequently, choice on individual patients were not made at that time on the basis of research needs, but only of clinical needs. The research was made afterwards, independently by clinical usage.
Also the preliminary check of Thermobrace was made before clinical use, and not for research. In any case, the aim of the paper is not to show that ALL patients behave as these patient, but that at least A NUMBER of patients can be highly compliant. This is the first time that this is proven in the literature (after a lot of reports telling us that patients have low compliance), and this is why this paper is worthwhile publishing. Future papers will be more generalizable.

In any case, the aim of the paper is not to show that ALL patients behave as these patient, but that at least A NUMBER of patients can be highly compliant. This is the first time that this is proven in the literature (after a lot of reports telling us that patients have low compliance), and this is why this paper is worthwhile publishing. Future papers will be more generalizable.

Lastly, with regard to patient enrollment, Figure 1 is difficult to understand. The Y-axis appears to be reporting on the number of patients plotted against the X-axis reporting on dates (month and year). With two lines depicting “Start” and “End”, is this illustrating the number of orthoses prescribed and discontinued on a month-to-month basis? If so, this may be of questionable relevance, but if the authors feel it lends important information, a bar chart may be more illustrative than a line graph. Thank you for your comment. We finally decided delete the figure, since it did not convey an important information.

With regard data interpretation, there are some points of clarification worthy of mention. It is unusual to report on median points of data rather than mean. The stated reason for this decision was the finding that the data distribution was not normal, suggesting it is either positively or negatively skewed. This should be clarified. One assumes the data must be positively skewed, with most patients demonstrating high rates of compliance, but more information on this would be helpful. Since most of the reported values pertained to median percentages, a scatter plot or histogram of the compliance percentages could be an excellent way to illustrate this non-normal distribution. Thank you! We added Figure 8
Table 5 reports 100% referred compliance for all subjects, however at least one boy estimated his compliance to be less than 65%, with other lower ranges of compliance ranging from 52 to 81%. This calls into the question of how the median, being the numerical value separating the higher and lower halves of a sample, can be 100% when there are clearly sub-groups of patients with much lower rates of compliance? Perhaps this is the mode, being the most common data point in the distribution for each sub-group. Regardless, these data should be revisited. While it is understandable for the authors to report on the median percentages, they run the risk of creating misleading comparisons to other studies where means are more commonly cited. When making such comparisons, the authors should make every effort to point out the differences between the two statistics being reported.

Thank you for your comment: First of all, the reported number is the median and not the mode: in the reported compliance we had some pupils referring above 100% (up to 116%). Moreover, the fact that in most papers coming from us clinicians mean and standard deviation are used most of the time (and in most cases without verifying at start what the distribution is) does not necessarily make it a correct statistical approach. In reality, this leads to misunderstanding of the data: in this particular case to an important underestimation of the wearing time (8% less). We decided to maintain the statistically correct version in the text and abstract, i.e. median and IC95%. Moreover in Discussion we added the following text:

Since it is very hard to compare results from compliance monitors, there are some more points of clarification worthy of mention: it is unusual to report on median points of data rather than average. We chose this statistical approach because of the abnormal distribution, in fact in cases like this the use of average and standard deviation is statistically not correct, since it leads to misunderstanding of data and in this specific case to an important underestimation (-8%) of the wearing time. We are aware of the limits of this study and we know that comparison of our results with previous published data is quite uneasy, because few studies have been published and they used different types of compliance monitor; moreover, each research had different aim and modalities; nevertheless, we tried to analyze and compare previous compliance results as shown in table 7, with the only aim to arise some interesting issues for further considerations.

Our data suggest us that our patients show a higher compliance to bracing, if compared to what previously reported:

Some details in the Discussion section need to be revisited with regard to inaccuracies in citing some references. For instance, the Discussion section states, “The real compliance previously reported usually ranged between 65 and 78%”, however Katz et al, one of the cited references, reported a compliance rate of only 27% and 35% for subjects asked to wear their orthosis 23 hours and 16 hour per day, respectively.

Sorry for the misunderstanding we correct the discussion as follows:

The best real average compliance previously reported was 78% [22], other authors reported different ranges of compliance with exceptions down to 33% [20] and 47% [19]. In a couple of study a maximum of 90% [13] and 97% [24] have been reported, while the median obtained in this study was 91.7%.

On a similar note, Table 7 states that Katz et al did not report on compliance, which if investigated more thoroughly one can find that overall compliance rates were reported in the context of prescribed wear; comparing rates to those who progressed vs. no progression; and rates where surgery was recommended vs. not.
We modified the table as follows:

the total number of hours of brace wear in patients who didn’t undergo surgery had a mean compliance of 42.4%. A mean compliance of 24.4% in the group of patients needing for surgical treatment.

There are some discrepancies in the authors reported “real compliance.” On page 7 of the Discussion section, the statement “in this study 23 h/d was the median of real brace-wearing.” Table 7, however, clearly shows 3 of 7 subjects having several readings of less than 80% compliance. This statement and the data reported appear to be in conflict, especially when one considers some patients were prescribed to wear their orthosis only 18 hours per day.

Sorry but probably you are referring to the figure 7, in which we showed the compliance in patients with more than one check through Thermobrace: these results concern patients already in therapy when they started the Thermobrace monitoring, while the median of compliance reported in the discussion concerned the group of patient at their first brace prescription. We specify this in the method paragraph:

All the study has been carried out with respect to the first group, while the second was used only to check whether referred compliance changed after starting the use of the TB.

Some of the conclusion statements are not fully supported by this report. For instance, in the abstract: “This study confirms that compliance is neither due to the type of treatment only nor to the patient alone.”

The conclusion has been modified as follows:

This is the first study using a TB in a setting of respect for the SOSORT criteria for bracing, and it states that it is possible to achieve a very good compliance, even with a full time prescription and better than what was previously reported (80% maximum). We hypothesize that the treating team (SOSORT criteria) plays a major role in our results. This study suggests that compliance is neither due to the type of treatment only nor to the patient alone. According to our experience, TB offers valuable insights and do not undermine the relationship with the patients.

There is no evidence in this report suggesting different types of treatment are represented; at least in the context of varying orthosis designs across a spectrum of patients, and “confirm” is a very strong choice of words. In the Conclusion section in the body of the paper, “...and shows much higher compliance to bracing than what was previously reported.” The data reported suggests this may be the case, but it should be pointed out that this was a heterogeneous sampling of patients who were knowingly monitored for actual wear patterns over an average time period of 5.5 months. This is compared to what few reports exist on scientifically monitored wear, such as Takemitsu’s report on 61 subjects monitored for an average of 17 months (range 4 to 31) with a reported mean percentage wear of 75%, or Katz et al’s report where all 100 monitored, but blinded subjects that were followed throughout the entire course of treatment to maturity. Thus, the recommendation is to restate the more global findings using less conclusive language.

Thank you, you are correct. We added the limit of the study in the discussion as follows:

Other limits of this study are the heterogeneous sample of patients analized and the little average period of monitoring (5.5 months).
This study would be significantly strengthened by removing the subjects that were selectively enrolled after treatment had already begun.

Conclusion has been changed:

Compliance is due neither to the type of treatment nor to the patient alone. The SOSORT criteria for bracing clearly state the importance of the treatment team in this respect. [16] This was the first study to use a TB in a setting that was respectful of the SOSORT criteria, and shows a higher compliance to bracing than what was previously reported.

This study would be significantly strengthened if they removed the subjects that were selectively enrolled after treatment had already begun, and if accurate, they should verify whether or not all remaining subjects were enrolled consecutively. If all subjects having no prior treatment were consecutively enrolled, they should report on the number of subjects, if any, that may have met the criteria for inclusion but refused to participate in the study (perhaps due to the additional cost of the data loggers). This information would be helpful to address the potential bias of enrolling a more select sample of patients whose families were willing to pay the additional expense of having a data logger installed within their adolescent’s orthosis. It would also be of interest to the reader to better understand the clinical picture of the subjects being reviewed, such as reporting the average and range of Cobb angles and distribution of Risser signs (rather than just the mean with +/-).

We have now detailed the clinical data as suggested. As already discussed above, this is a quite preliminary report, that will be followed by a more detailed prospective one, looking at the whole recruited population starting from January 1, 2011.

We changed also the conclusion:

This was a preliminary study, the results emphasize the importance of further research with greater and homogenous samples of consecutive patients. Longer monitoring periods are needed, to better understand the efficacy of brace treatment and to point out all factors involved in the adolescent idiopathic scoliosis treatment. The opportunity to measure real compliance by monitoring all patients until the end of therapy, will allow a deeper analysis about the real efficacy of brace treatment.

Lastly, with regard to the secondary aim of this study to determine if the use of monitored orthoses might undermine the physician-patient-family relationship, there were no methods described as to how this was assessed. The authors stated, however, that these relationships were not undermined. Yet only 7 subjects had more than one data reading, and there is no information reported on what information, if any, was shared with the patients after the wear data was interpreted. In the absence of any reported methodology to guide the reader on how this was assessed, let alone to provide future opportunities for researchers to duplicate the efforts, this study aim should be omitted unless additional information may be provided.

We changed the secondary aim in the Introduction as follows:

In 2010 we started the everyday clinical use of a temperature sensor, and the aim of this study is to present our initial results.

We changed the Discussion and we specify that this is our opinion gained after the everyday clinical use of this device

According to our experience, an electronic device does not negatively affect the relationship between the patient and the doctor.

It is clear the authors seek to report on the importance of utilizing a team approach, as described in the SOSORT Bracing Management Guidelines, and provide evidence
that such an approach ultimately benefits the patient by improving overall compliance with a given treatment regimen. They are to be applauded for their efforts, and they have presented evidence that this may indeed be the case. Thoughtful consideration to the comments made in this review may enable this case to be further strengthened.

Thank you so much for your valuable effort to increase the quality of our paper. We hope we were able to tackle all your relevant issues, but we are ready to change the text even more if required. We recognize your authority in the field and the quality of the work you already have done, and hope to meet you personally in the next future.
Best regards
Dr. Rigo

Thank you so much for your useful comment on asymmetric braces. We decided to accept it, and changed the text in the Discussion section as follows:

Nevertheless we have also to consider that in three out of the 10 papers considered in table 7, the brace type is defined, Willmington brace and Boston. Both braces are symmetric and low visible. Contrary, in some of the papers reporting good end results, which would not be possible with bad compliance (not compliant patients were not excluded), the used brace was the Chêneau type brace, which is, by definition, an asymmetric brace producing usually postural over-correction. This demonstrate how some teams using Chêneau type braces are also able to achieve high compliance in their patients, no matter how asymmetric and visible is the brace. A possible conclusion is that, no matter the type of brace, it will produce a certain amount of physical and/or functional discomfort, which will produce secondarily ‘emotional discomfort’. Thus, try to make the brace more comfortable from the physical and functional point of view is a valid strategy. However, ‘emotionally discomfort’ is probably also primarily produced by other different factors, acting even before the patient is able to recognize any ‘physical and/or functional’ distress. While this, let us call it, primary ‘emotional discomfort’ persists, patients will find always a reason for a low compliance, complaining about physical and/or functional discomfort. Once ‘emotional discomfort’ decreases (different strategies can be used to capture emotionally patients and their parents), ‘physical and functional discomfort’ can be at the same time reduced and overcome, improving compliance. Thus, team approach can make theoretically any brace type to be wearable or not wearable. All these considerations leads to a possible conclusion, that the type of brace can matter, but the correct management of patients matter much more.

Reviewer report and discretionary revisions

This paper was one of the three winners of the SOSORT Award 2011 (Annual Meeting of the SOSORT and 8th International Conference on Conservative Management of Scoliosis – Barcelona 19 – 21 May 2011) and is an excellent paper indeed.

It has been shown that end results define success of bracing, at least in changing the natural history of idiopathic scoliosis. Two main factors have been related with end result, in-brace correction and compliance. On the other hand, in-brace correction depends on several factors related with the brace it self (biomechanical principles, curve pattern specific design and technical quality) and the patient (age, curve flexibility, curve pattern, and others), while it is not clear which factors can influence compliance. Compliance is, in any case, essential. No brace can be effective if it is not wore the prescribed time.

This present study raises a very important question. Do patients wear the brace as prescribed? The authors refers several papers were compliance is reported to be low when measured objectively and significantly less than subjectively reported by the patients. In this present study, real and referred compliance are reported to be very similar and much higher than previously reported. According to the authors, the reason for such a high and honestly referred compliance is the team approach following the SOSORT Bracing Management Guidelines [1] and the brace design, SPoRT concept [2]. This is properly addressed in the discussion section and this authors’ point of view is acceptable. The first one, team approach, is unquestionable. Team approach (or patient/parents management) is a constant in those papers reporting successful bracing end results [3, 4, 5, 6]. However, although the second
one, brace concept, can logically be stated, it needs further discussion. Brace type affects differently quality of life (HRQL) [7], so it is right to assume that brace type could be also a reason for different compliance. Consequently, the SPoRT concept could be, at least theoretically, a reason for an increased compliance. Symmetry, low visibility and comfort is even more important for the authors than brace action to make the brace wearable in order to improve compliance. Table 7 from this present study shows a list of 10 papers with significantly lower compliance in comparison with that reported in this present study. In at least two out of the 10 papers the brace type is defined. Willmington brace [8] and Boston [9]. Both braces are symmetric and low visible. Contrary, in all the above mentioned papers reporting good end results [3, 4, 5, 6], which would not be possible with bad compliance (not compliant patients were not excluded), the used brace was the Chêneau type brace, which is, by definition, an asymmetric brace producing usually postural over-correction. Some teams using Chêneau type braces are also able to achieve high compliance in their patients, no matter how asymmetric and visible is the brace. According to this reviewer experience, when using an asymmetric and sometimes visible brace, the brace produces three different types of discomfort at the beginning of the treatment: 1) physical discomfort mainly due to compression effect; 2) functional discomfort due to some functional limitations but due also to postural over correction, which changes the postural schema; and 3) emotional discomfort. No matter the type of brace, it will produce certain amount of physical and/or functional discomfort, which will produce secondarily ‘emotional discomfort’. Thus, try to make the brace more comfortable from the physical and functional point of view is a valid strategy. However, ‘emotionally discomfort’ is probably also primarily produced by other different factors, acting even before the patient is able to recognize any ‘physical and/or functional’ distress. While this, let us call it, primary ‘emotional discomfort’ persists, patients will find always a reason for a low compliance, complaining about physical and/or functional discomfort. Once ‘emotional discomfort’ decreases (different strategies can be used to capture emotionally patients and their parents), ‘physical and functional discomfort’ can be at the same time reduced and overcome, improving compliance. Thus, team approach can make theoretically any brace type to be wearable or not wearable. The attached figure 1 shows an example to document this statement. A girl with a right thoracic scoliosis was treated with a Chêneau type brace (A) and came to our clinic after developing a noticeable skin lesion and rib deformity (B). Her first ‘treatment team’ had decided to cut down the left upper thoracic pad in order to reduce postural over-correction and visibility. The effect of this was that the three point system formed to correct the thoracic curve was ineffective and produced an unacceptable compression effect, cause of the lesion and secondary deformity observed down A and B. In spite of the assumed 'physical discomfort' the girl was fully compliant. Any strategy used by the first team was effective in achieve good compliance but with an unacceptable clinical result. Our team changed the strategy: a new brace was made and adapted (C) producing the desirable postural over-correction (Chêneau principles), from an effective three-point system, making the brace more visible. The girl has continued being compliant and few weeks after changing the brace, she showed a clinical improvement, with less rib deformity and a total resolution of the skin lesion (D). In conclusion, 'physical' first and 'functional' later discomfort was not a reason for this girl to be not compliant. It is clearly acceptable and desirable that the authors of this present study discuss about brace type being a reason for improved compliance, however, improved compliance appears to be more related with the strategy to capture emotionally
patients and parents rather than to the brace design. Discussion and conclusion sections are adequate and could be leaved in its current way, so this reviewer is not asking for a major compulsory revision, but may be the authors could consider in their discussion some of the points raised above by this reviewer.

REFERENCES:
6. Zaborowska-Sapeta K et al: Effectiveness of Chêneau brace treatment for idiopathic scoliosis: Prospective study in 79 patients followed to skeletal maturity. Scoliosis 2011 6:2

Minor essential revisions:
In table 7. Rahman 2010 is incorrect. There is no paper from Rahman published on 2010 on this issue. It should be written Rahman 2005 [22]

Sorry, but we really meant the reference we reported, that is present in Medline.

Thank you so much for your valuable effort to increase the quality of our paper. We hope we were able to tackle all your issues, but we are ready to change the text even more if required. We recognize your authority in the field of bracing and the quality of the work you already have done.

Best regards
Dr. Wong

Thank you for your comments. Please, find below a response point by point in red below your text.

Comments:
It is a very good attempt to track the patient’s compliance of wearing a prescribed spinal orthosis.

Major Compulsory Revisions
- A more specific topic on either the introduction of the Thermobrace or the comprehensive treatment protocol is suggested.

Thank you very much, another reviewer pointed out these aspect so we added the following sections:
Consequently, at the start it was proposed as complimentary (i.e. the patients and family had to decide if they want to buy it), and mainly to patients already in treatment who were showing problems in the use of the brace. Subsequently, it was also proposed as complimentary to the patients at their first evaluation at our institute, but not to all of them.

- Some typos and grammatical mistakes should be corrected.

All the paper has been re-checked.

- The last sentence of the section (Methods) is not clear.
You are right, it has been changed as follows:

Consequently, the prescription of the TB gradually increased with time, but with caution until the first TB results were received, in order to have time to check them as well as the possible consequent difficulties in managing patients (Figure 1). After this test period we began to understand that the regular use of this device should enrich our activity that’s why the prescription of TB increased.

- In Table 1, subjects with different curve patterns are shown. It is supposed not all the subjects with those curves at the proximal thoracic, thoracic thoraco-lumbar and lumbar regions. NA should be used in some rows instead of NS. Some modifications of the table are needed.

We corrected table 1 as you suggested, thank you very much!

- What is the rationale for using every 20 min or 60 min as the sampling rate? A more precise sampling rate such as 1 min per sample would be helpful for assessing the treatment effectiveness of spinal orthosis.
You are perfectly right, but we had some practical limitations. Sorry, but we did detail these reasons in the text. We have now changed it as reported below:

In the choice of the final time-span between each single measurement, we had to make a compromise. In fact, ideally the best solution would have been to measure temperature every minute, but there were memory limitation for an everyday clinical usage where patients are usually seen every 4 to 6 months (with some of them – usually low compliant – not coming back before 8-10 months). In fact, the more memory we used, the higher the costs of the device, and to let patients freely buy it we had to maintain this costs below 80-100 Euros, a threshold that was established after a preliminary informal inquiry with a number of patients. As a consequence, based on the recorded data (every 20 minutes) we checked the minimum time-span in order to discern the real use of the brace without losing precision between two clinical evaluations (usually six months, but with a maximum of up to 8-10 months). Minor Essential Revisions
- In Figure 6, it would be helpful if the prescribed vs referred values are also included.
thank you we modified the figure!

- If the focus of the manuscript is on the Thermobrace, the section (Treatment) may not need to be there.

you are surely right but considering that compliance could be influenced by the type of treatment we thought to make a little digression. We modified and cut the paragraph as follows:

All patients have been treated with braces following the SPoRT principles: [12, 29-32] Sforzesco, Sibilla or Lapadula. The acronym “SPoRT” means “Symmetric, Patient-oriented, Rigid, Three-dimensional, active” and has been defined because these braces are designed to be as much as possible bodily shaped and adherent (Figure 3) so as to be easily masked underneath clothing; moreover, these braces allow complete movement with the limbs so as to permit sports activities, which are frankly encouraged. [33] All the patients also performed exercises according to the SEAS principles. [11, 34-36]

The setting in which treatment has been proposed fulfilled all the requirements of the SOSORT Braced Patients Management Guidelines: answering to the specific questionnaire Excellent Results have been obtained, with 43 out of 44 criteria respected: 1 being not applicable. [37] Accordingly, the patients have been followed by a highly trained team focused on maximizing compliance and minimizing the Quality of Life and psychological impacts of brace treatment. [38]

- An algorithm was developed to cope with the seasonal changes of temperature. However, the device may not be applicable to the regions with hot weather. Such regions can have the room temperature above 31 degree Celsius which is close to the skin temperature. As a result, the users seem always compliant to spinal orthosis, no matter they wear it or not.

Thank you very much, it is a very interesting argue, we analysed the data collected during summer and we added to the discussion the following paragraph:

**Reliability of Thermobrace**

We developed an algorithm to cope with the seasonal changes of temperature. However, we must consider that the device may not be applicable to the regions with hot weather, so we did a further analysis of the collected data: the comparison didn’t show significant differences.

We can’t deny that there is the possibility that in the really worst case the hot weather could allow a little overestimation of real compliance, but it is a very rare event, and the fact that we use always statistically processed data make this event really exceptional. So the problem potentially exists, and should be quantified with experimental study; on the other hand, at our latitudes (continental climate) the phenomenon appear for a limited period of the year, such that the influence on the data does not appear to affect results. The distribution of air conditioners and the fact that during the hottest hour of the day people prefer to stay at home or in cool places, where the temperature is on average lower than the outside, obviously contribute to limit this event.

Moreover we did a supplemental analysis of data and we added the results in the method chapter:

**Reliability of thermobrace and temperature effects**

Environmental clime and temperature didn’t seem to affect data recorded by the heat sensor. This is a very challenging question and we analysed our data in the attempt to
investigate this possibility. So very recently in a group of 312 patients we collected
the moving mean obtained by the TB, for the high and low threshold in each months
of the year. We look for the hottest period of the year and we compared the average
temperature per hour of the day with the mean brace wearing time per hour of the day
in the same month. Moreover we compared the mean moving average obtained from
the TB in a city of the north of Italy and in the South of Italy and the hottest
temperature in the same period in these two places: the trend was similar. The Figure
1 A and B shows the mean temperature per months of the year and the comparison of
temperatures in Milan (north) and in Messina (south).
In the hottest month of the year (august) the threshold has been passed for 208 hours,
the worst possible effect of this is that in a prescription of 23 per day , after six
months of monitoring we may see a wearing period of 23 hours while the real wearing
time was 21.8 hours/day. This is the worst possible case and the underestimation is
quite little. An additional indirect analysis can be done by checking the changes in
wearing rates between the months of August and and the near July and September: on
average in August (the hottest month of the year), the brace has been worn 28 minutes
more than in July, and 1 hour and 20 fewer than in September. Considering that
during summer people goes on holiday and have journeys, these differences are not
significant and cannot be justified only by the hot weather.

Discretionary Revisions
- In the consideration of compliance of wearing orthosis, we should include wearing
time (quantity) and orthosis tightness (quality). The existing device (thermosensor)
can provide the information of quantity but not the quality – how much biomechanical
forces acting on the scoliotic spine via spinal orthosis. If with no such monitoring, the
applied forces may be deviated from the prescribed magnitude. On the whole, wearing
a spinal orthosis only does not mean giving an effective treatment to the patients with
AIS, until the orthosis prescribed tightness is maintained.

You are correct, but using another sensor could raise other issues. We added the
following text to the Discussion section:

Someone should advocate that also the quality of braces is important , so wearing a
spinal orthosis only does not mean giving an effective treatment to the patients with
AIS, until the orthosis prescribed tightness is maintained. Future research should
question not only quantity but also real quality of treatment, by using also
biomechanical monitor measuring forces produced.

Making this considerations we must remember that scoliosis treaent best results are
done of different elements: exercises, braces, team approach …so quality should be
represented by end of growth results as the optimal interaction of all these elements.

Thank you so much for your valuable effort to increase the quality of our paper. We
hope we were able to tackle all your issues, but we are ready to change the text even
more if required. We recognize your authority and the quality of the scientific work
you already have done in this field, and we hope to meet you in the next future.
Best regards