

Rebuttal to Dr Wong SpineCor Study

It has come to our attention that an article entitled “The effect of rigid versus flexible spinal orthosis on the clinical efficacy and acceptance of the patients with adolescent idiopathic scoliosis” was published in the May 2008 issue of Spine Journal.[1] The SpineCorporation is the company responsible for production, supply, and training in the use of the SpineCor treatment system and we have serious concerns about the methods and validity of this study.

We would like to point out two serious issues in the way in which this study was conducted and we believe these factors invalidate the data of the SpineCor treatment group and therefore the comparative results of the study.

1) The authors in this study and the facility at which patients were treated with SpineCor are not qualified to a proficient standard in the SpineCor treatment system. They should not be providing this treatment therapeutically to patients, let alone conducting research into its efficacy. We believe this to be seriously unethical and detrimental to the patients involved.

2) This treatment centre has not been supplied with enough initial SpineCor components to effectively brace 22 patients. They also have not received enough replacement components necessary to effectively maintain this amount of SpineCor braces.

In reference to point 1, the SpineCor brace is a unique treatment system for idiopathic scoliosis that is unlike any other type of spinal orthosis ever developed[2]. It does not share the same treatment principles of 3-point pressure that rigid orthoses use and its use requires specific and extensive training. Training and an expertise in rigid bracing does not transfer to SpineCor; specific training and qualification is necessary. To attain the necessary skills to be a safe and effective SpineCor provider, candidates are required to attend an initial Phase 1 theory course. On completion of Phase 1, providers are eligible to complete a Phase 2 practical training which involves treating patients in front of a qualified SpineCor trainer. Distributors of the SpineCor brace are under a contractual obligation only to supply SpineCor braces and components to Phase 2 certified providers. To remain certified, practitioners must see a minimum number of patients using this system each year or re-certification is necessary[3]. These strict systems are in place to ensure quality of treatment and consistency of results.

None of the authors of this paper are certified in SpineCor treatment nor have they ever received significant training in the SpineCor system. Some of the technicians working with these authors at the scoliosis clinic in Hong Kong have received basic introductory training, but they are not certified SpineCor providers and are not considered to have received training to a sufficient standard to use the SpineCor system without supervision.

Despite our best efforts to contact the authors and find out who the treatment providers were, it cannot be confirmed that the providers in this study had any knowledge of the SpineCor system. We are aware that two employees of the former Hong Kong distributor for SpineCor, Mrs. Elaine Ng (R&D Manager) and Mr. Bryan Fu (P&O Orthopaedic Technician) attended the initial Phase 1 introductory training in Montreal in 1999. These two people are not mentioned in the paper, but as the only people in Hong Kong who have had initial training in the SpineCor system, they are presumed to be the treatment providers in this research. A Phase 2 practical training was conducted for these same two individuals in Hong Kong in 2000. However at this training only two patients

were treated as part of the course. The minimum requirement for certification is 6 patient treatments and as a result the Phase 2 training of these individuals still remains incomplete. Further training and follow up was needed to demonstrate proficiency in the SpineCor system and to achieve SpineCor certification. Since 2000, despite attempts of the Spine Corporation to provide further training and follow up, no clinical support has been requested or provided in Hong Kong. As such, no provider in Hong Kong has ever achieved the minimum requirements to be certified in the SpineCor system. Therefore, to protect the public, distribution to this region was stopped in 2006.

A common misunderstanding amongst prescribing doctors, and even some treatment providers, is that SpineCor is a simple brace that can easily be applied by any technician. However SpineCor treatment requires great skill and a significant knowledge of scoliosis. The completely different treatment approach demands that both the prescriber and provider fully understand the approach to obtain success. Clearly this is a significant factor in the failure of the SpineCor (“S”) group in this study. The SpineCor brace is a tool used in conjunction with the SpineCor treatment method. If the method is not understood and the brace is used without the requisite knowledge it will certainly lead to poorer than expected results, as it has in this case.

In reference to point 2, detailed records of supply to each region and distributor exist. According to our records we have supplied braces and components to this centre between 1999 & 2006. These records show that Hong Kong never received sufficient components to brace 22 patients effectively, let alone to maintain 26 months of the replacement components required to provide effective treatment.

To give the reader a basic understanding of the components required to brace a patient with the SpineCor brace and maintain that brace, a brief description of the brace is given below.

The lower half of the SpineCor brace consists of a Pelvic Base, Thigh Bands, and Crotch Straps. The upper half consists of a Bolero (jacket) and four elastic Corrective Bands. Worn underneath the SpineCor brace is a special Body Suit which is recommended for all patients and is considered part of the brace.

Thigh Bands are the components most essential to the stability of the lower part of the brace. These hold the posterior aspect of the Pelvic Base in place, stopping it from riding up under the tension of the Corrective Bands. If the Pelvic Base is not held in place and rides up, it makes the action of the brace ineffective by essentially taking the tension out of the elastics. It will also make the brace uncomfortable, digging into the patient and putting extra tension on the Crotch Bands at the front. This in turn will also lead to a premature wearing of the Crotch Bands.

In total, only 20 sets of Thigh Bands were ever supplied to Hong Kong, meaning that at least two children in this study were fitted without them from the beginning. Fitting a SpineCor brace without these components is negligent and offers no chance of successful treatment.

Further to this, it is usual that with normal wear a new set of Thigh Bands would be required for each brace every 12 months. Taking into account patients that finished in the “S” group early, the minimum order for this study over 26 months should have been 37 sets of Thigh Bands, not 20.

Another missing component to the SpineCor system is the Body Suit undergarment. The Body Suit is essentially a cotton leotard with an adjustable opening around the crotch. It serves two purposes: 1) It is designed to be the most comfortable undergarment to use with SpineCor, stopping the brace from rubbing on the skin and causing irritation 2) It has an adjustable opening in the crotch which allows

for easier toileting for those having problems with normal underwear. Normal clothes worn underneath the brace can separate and fold up under the brace. This can affect both comfort and stability of the Pelvic Base. No Body Suits have ever been ordered or supplied to this centre in Hong Kong.

Apart from Spine Corporation records suggesting that patients included in this trial were braced with inappropriate or missing components, evidence supporting our concerns is supplied in the paper itself. In the picture labeled Figure 2, the SpineCor brace is clearly fitted without the required Thigh Bands. The problems associated with this have been discussed above. Also in this picture it is clear that the correct Body Suit is not being worn underneath the brace and the clothes that are being worn under the brace are inappropriate. Wearing a long t-shirt under the pelvic base and over shorts allows for slippage of the pelvic component, affecting its stability and the overall effectiveness of the brace.

Not previously mentioned is the role of Comfort Bands, which are used with the brace to stop rubbing and irritation of the Bolero against the skin in certain places. Figure 2 shows a Comfort Band fitted incorrectly, attached between two Corrective Bands rather than onto the Bolero component. Attaching Comfort Bands to Corrective Bands is incorrect as it reduces the amplitude of movement allowed by the Corrective Bands, which in turn has a direct effect on the effectiveness of the brace in applying the corrective movement. The correct way to attach a Comfort Band is to the two ends of the Bolero. The fact that the providers in this study have fitted the SpineCor brace in this way shows a worrying lack of knowledge of the SpineCor system.

Added to the issue of incorrect use of Comfort Bands, we also have concerns about the maintenance of the Comfort Bands during treatment. In total only 6 Comfort Bands were ever supplied to Hong Kong. Given that the majority of brace fittings require a Comfort Band, replacement during a period of treatment is always necessary. The minimum amount of Comfort Bands that should have been ordered is 41, not 6.

There are also major issues with the amount of other components used by this group to properly maintain the brace. SpineCor is a flexible, dynamic treatment system that uses a series of elastic bands to reinforce a corrective movement. The concept is more one of neuro-muscular rehabilitation than it is of simple bracing. The components, such as elastic Corrective Bands, need replacing over a period of time, not just because they aesthetically wear out but because they lose their elastic stretch. Not replacing Corrective Bands during treatment means the treatment itself becomes ineffective over time.

In total, 164 Corrective Bands were ordered by this group. The average life of a Corrective Band is between 6-12 months depending on growth, curve correction, and wear & tear. For 22 patients treated over a period of 26 months, and allowing for the 7 dropout patients, approximately 274 corrective bands should have been supplied to keep the braces working effectively. Only 164 were ever supplied, not 274. If the providers were competent in this treatment system and had an understanding of how to maintain the braces correctly, we would ask the authors why they used 41% less corrective bands than would normally be used for effective treatment for this number of patients over this period of time.

There is a similar situation with the rest of the brace components. The Bolero is the jacket to which the Corrective Bands connect. Only 22 of these were ever ordered. If a child grows during treatment they will need a bigger size of Bolero or the corrective movement cannot be effectively applied. Assuming one replacement Bolero per patient is needed during the entire treatment time, 37

would have been required. As only the original 22 were supplied, any patient with significant growth during the treatment period would have had a partially ineffective brace. Since the patients in this study were in early adolescence and scoliotic progression is related to growth, it is certain that these children would have needed a replacement Bolero. We would suggest that this is an obvious reason why some of the patients in the “S” group progressed.

The Pelvic Base is the area to which the Corrective Bands anchor. 26 Pelvic Bases were supplied, which is enough for the initial bracing. Based on clinical data, 25% of SpineCor patients require a change of Pelvic Base during treatment due to growth or wear and tear. Given 22 patients were treated in this study a minimum of 28 Pelvic Bases should have been required.

Finally, 52 Crotch Bands were supplied to Hong Kong, which according to clinical data is 40% more than would be usual for a treatment group of this size over 26 months. The only explanation for the excessive amount of Crotch Bands ordered is if the Thigh Bands were fitted to the Pelvic Base incorrectly or if the Thigh Bands were not fitted at all. In a correct fitting, the Crotch Bands should always be loose and will rarely wear out. However if Thigh Bands are incorrectly or not fitted to the Pelvic Base, the Pelvic Base will ride up, putting excess tension on the Crotch Bands causing premature wear and discomfort.

If we look at success for the first three months of treatment, groups “S” and “R” are essentially the same. The authors report that the “S” group results then deteriorated past this point when compared to the “R” group. We would suggest that one of the reasons for the poor results of the “S” group after three months was the lack of appropriate components required to effectively maintain the brace in good working order. *A comparison would be an orthopedic doctor, not trained in the application of Growing Rods, performing the initial surgery then failing to adjust the rods every 6 months as is the standard practice. If the doctor failed to observe this surgical treatment protocol, no one would be questioning the efficacy of the rods, rather they would be scrutinizing the methods and training of the surgeon.*

Some of the comments written by the authors also demonstrate a worrying lack of understanding in the use of the system. The authors state that “The SpineCor was developed to tackle those inevitable drawbacks found in the conventional rigid spinal orthosis.” This statement shows a complete lack of understanding of the SpineCor system and does not recognize the fact that it was derived from basic science research and the need for a new treatment approach using dynamic forces under compressive loading and not because of the inherent problems with rigid bracing[4].

The authors state that “The subjects in the S group had more problems in toileting”. One only has to look at the brace to realize that there are no components of the brace that inhibit toileting. However, wearing shorts such as those seen in Figure 2, would require the removal of the brace before toileting was possible. This explains the difficulty with toileting reported by the “S group in this study. This problem is completely overcome when using the recommended Body Suits and most patients have little problems toileting even when wearing regular underpants. Apart from the fact that no Body Suits were ever supplied to Hong Kong, further confirmation that patients in this study did not use Body Suits is written in their paper where the authors write “(over 80% in the S group and 64% in the R group) would select some suitable clothes to deal with dressing problem.”. The “S” group simply would not have had a dressing problem had the Body Suit undergarment been prescribed.

A further example of the authors’ lack of understanding of the SpineCor treatment approach is their reference to trunk list. They state, “*The increase in trunk listing of the SpineCor group could be*

explained by its treatment principle in which the primary corrective movements including tilt, detorsion, lateral bending, and lateral shift were adopted". Depending on the category of curve, a different corrective movement or combination thereof is employed to reduce the curve through spinal coupling. For example, the primary corrective movement for a left lumbar curve is right lateral shift and left lateral bending. In a case like this, the lateral bending may indeed create a shift of T1 in reference to S1 to the left. However this is a very positive clinical aspect, indicating that postural overcorrection has been achieved. This is one of the concepts of SpineCor treatment that completely differs from rigid bracing systems where correction to neutral is what is desired.

We also believe that it is important to point out, that although Dr Wong's research is seemingly a well designed study; it has a very small sample size of 43 patients, they did not follow the inclusion and reporting criteria set out by the SRS committee on bracing studies[5], and their results on rigid bracing are not consistent with those reported following the SRS guidelines of only a 20-25% survival rate[6].

In Summary

There must be serious doubt concerning the validity of results from any study undertaken by partially trained and inexperienced practitioners with insufficient resources for the task. After a Phase 1 and full Phase 2 training involving supervised treatment of 6 patients, there is still a serious learning curve. Typically it will take a further 12 patient treatments over six months with significant support to become proficient. To develop the level of skill required to teach SpineCor or undertake research requires a minimum of two years experience and 50 treatments. The providers applying SpineCor in this paper simply would not have time to achieve the level of proficiency for carrying out competent research on SpineCor, let alone applying SpineCor therapeutically without supervision.

We believe that the poorer comparative result of SpineCor compared to rigid bracing in this study is a direct reflection on the authors' or their provider's inability to use the SpineCor system, rather than a true reflection of SpineCor's efficacy and acceptances when used correctly by trained providers. Yet even so, the "S" cohort had a 68% survival rate, which is extraordinary given the lack of training and resources. The authors also rightly point out that another study published on SpineCor by Dr Weiss (who, like these authors, is not formally trained in SpineCor) had only an 8% survival of his "S" cohort[7]. It begs the question why someone with Dr Weiss's scoliosis experience had such a poor result compared to Dr Wong et al, who had insufficient training and demonstrably misused the brace.

Like any spinal orthosis, if SpineCor is not used properly it can be ineffective and even uncomfortable. However when fitted correctly by a certified practitioner the results, as reported by the hundreds of treatment centres worldwide and the 10,000 children that have been properly braced with the system, show that it is vastly more comfortable than rigid bracing with superior compliance. The results achieved by certified practitioners are generally consistent with the treatment results published[8] that show SpineCor to be 4 times more effective than TSLO type rigid bracing in stopping curve progression, and 70% effective in stopping cases going to surgery[9].

Any study is only as good as the validity of its data. Given that these researchers do not know how to correctly fit and use the SpineCor brace and did not have sufficient resources to fit and maintain SpineCor braces effectively, their data cannot be seen as a valid assessment of the SpineCor brace in either effectiveness or comfort. We suggest that the only conclusion that can be made of this study is that practitioners, who apply SpineCor without adequate training in its use or understanding of its

basic principles, are likely to fail their patients in providing adequate care. And if I were the parents of the children involved in this study, I would have serious questions to ask of the practitioners who essentially were negligent in their application of this scoliosis treatment.

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