

Effectiveness of the Sforzesco Brace According to the Sport Concept of Bracing on Adolescent Scoliosis Deformity: A Systematic Review

Zahra Jiryaie^{a*}, Alireza Jiryaie^b, Mehdi Rezaei^c

^a Department of Orthotics and Prosthetics, School of Rehabilitation, Iran University of Medical Science, Tehran, Iran; ^b Department of Statistics, Faculty of Mathematics and Computer Sciences, Shahid Bahonar university of Kerman, Kerman, Iran; ^c Physiotherapy Research Center, School of Rehabilitation, Shahid Beheshti University of Medicine Sciences, Tehran, Iran

*Corresponding Author: Zahra Jiryaie. Department of Orthotics and Prosthetics, School of Rehabilitation, Iran University of Medical Science, Tehran, Iran. E-mail: jiryaie.z@gmail.com

Submitted: 2019-06-02; Accepted: 2019-09-21; Doi: 10.22037/jcpr.v4i2.28947

Abstract

Introduction: Scoliosis deformity is a complicated, three-dimensional structural deformity. Bracing treatment can achieve a good aesthetic body shaping. Recently, researchers developed a new concept of bracing, named Sforzesco, that they called Symmetric, Patient-oriented, Rigid, Three-Dimensional, active (Sport). **Purpose:** The current review aimed to evaluate the efficacy of Sforzesco brace based on the Sport concept on improvement moderate adolescent scoliosis deformity. **Methods and Materials:** A literature search was conducted using the databases of PubMed, Google Scholar, ISI web of knowledge, Medline and Scopus as well as thorough reviewing the cited references from the appropriate articles. **Results:** Eleven articles were selected for the final evaluation. These articles were evaluated and compared to produce a summary in the following. Generally, the studies reported positive effects of bracing on moderate curve correction (Cobb angle between 25 and 55) in patients with adolescent scoliosis. Many studies described patients' positive opinion of Sforzesco brace aesthetic. **Conclusion:** Sforzesco brace can be effective in improvement of moderate scoliosis deformity in adolescent subjects. It makes aesthetic advantage versus current braces. Because this brace has recently been developed, further works with long-term follow up are needed.

Key words: Brace, Sforzesco, Scoliosis, Spinal Deformity

Please cite this paper as: Jiryaie Z, Jiryaie A, Rezaei M. Effectiveness of the Sforzesco Brace According to the Sport Concept of Bracing on Adolescent Scoliosis Deformity: A Systematic Review. J Clin Physio Res. 2019; 4(4): e22. Doi: 10.22037/jcpr.v4i2.28947.

Introduction

Scoliosis deformity is a complicated, three-dimensional structural disorder of the spine that is described by disorder in all anatomical planes (1). Currently, a principal treatment for moderately moderate adolescent idiopathic scoliosis (AIS) during developmental phase is bracing(2). There is a broad agreement that scoliosis deformity cannot be improved using bracing, and the methodological criteria of the Scoliosis Research Society (SRS) for bracing have avoiding progression as their only aim (3).

Brace treatment can achieve a very good aesthetic body shaping in individual's spine with scoliosis deformity(4). It is proposed a bracing treatment can achieve the optimal radiographic results, while the effect of bracing on quality-of-life (QOF) and subject's compliance should also be considered(5). Researchers have recently developed a new concept of bracing, called Sforzesco (a particular

TLSO), that they called Symmetric, Patient-oriented, Rigid, Three-Dimensional, active (Sport). Two researchers (Negrini S, Marchini G, 2004) in Italy developed the Sforzesco brace, named in honor of the Medieval Sforza family (6)

The compliance for the spinal braces are referred to device appearance and minimum limitation for the Activities of Daily Living (ADL), cognitive-behavioral approach, and assumption of responsibility (7). The Sforzesco brace is a developed custom-made TLSO (8) constructed with a two-piece rigid polycarbonate attached posteriorly at the midline by a vertical aluminum bar and anteriorly by a closure which is rigid over the breast and below is made of soft inelastic straps. The Sforzesco is a full-contact brace. Figure 1 shows the Sforzesco brace in the various dimensions(9). This brace has been used widely for scoliotic subjects since 2007. Also, researchers recommended that individuals with scoliosis can wear it full time (more than 15 hours (10-12)).

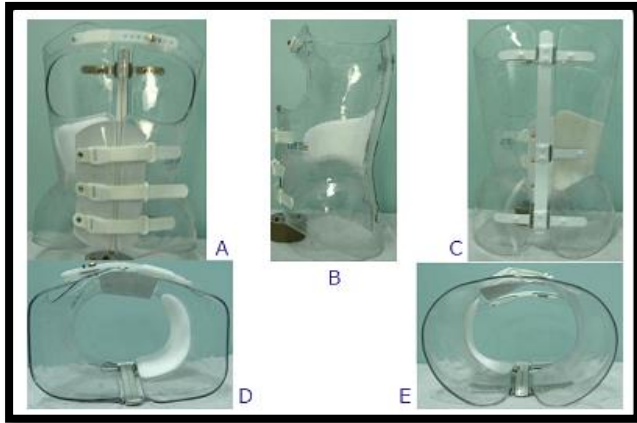


Figure 1. Sforzesco brace. A: anterior view, B:left view, C:posterior view, D: top view and E: bottom view(9).

The aim of this paper was the review of the studies which carried out the effect of the Sforzesco brace (Sport concept) on the moderate adolescent scoliosis deformity (Cobb angle between 25 and 55).

Methods and Materials

A literature search was conducted by two researchers (are referred) using the databases of PubMed, Google Scholar, ISI web of knowledge, Science direct and Scopus as well as thorough reviewing the cited references from appropriate articles since 2006 (because the brace was developed in 2004) to January 2020. The procedure was performed by the PRISMA method (Figure 2). The keywords used were Sforzesco, Sport concept, Scoliosis, orthosis, orthoses, orthotics, Cobb angle, brace and spine deformity. The titles, abstracts, and full texts of the papers were reviewed by two researchers (Z.J and A.D.) to select the papers which met the inclusion criteria. If there were any dispute for the selection process, those were solved by negotiation between the two researchers.

Inclusion criteria for selecting articles were as follows:

- 1- Studies were performed on Sforzesco for AIS
- 2- Sport concept used in the studies was described.
- 3- Publication of the study was in a peer-reviewed journal in English.
- 4- Studies were reported effect of Sforzesco on Cobb angle (curve correction) of scoliosis deformity

Exclusion criteria for the article of this review article were as follows:

- 5- Studies were performed on congenital scoliosis
- 6- Studies were performed on adults' scoliosis or adults' kyphosis
- 7- Studies were performed on sever scoliosis (Cobb angle up 55 degrees)

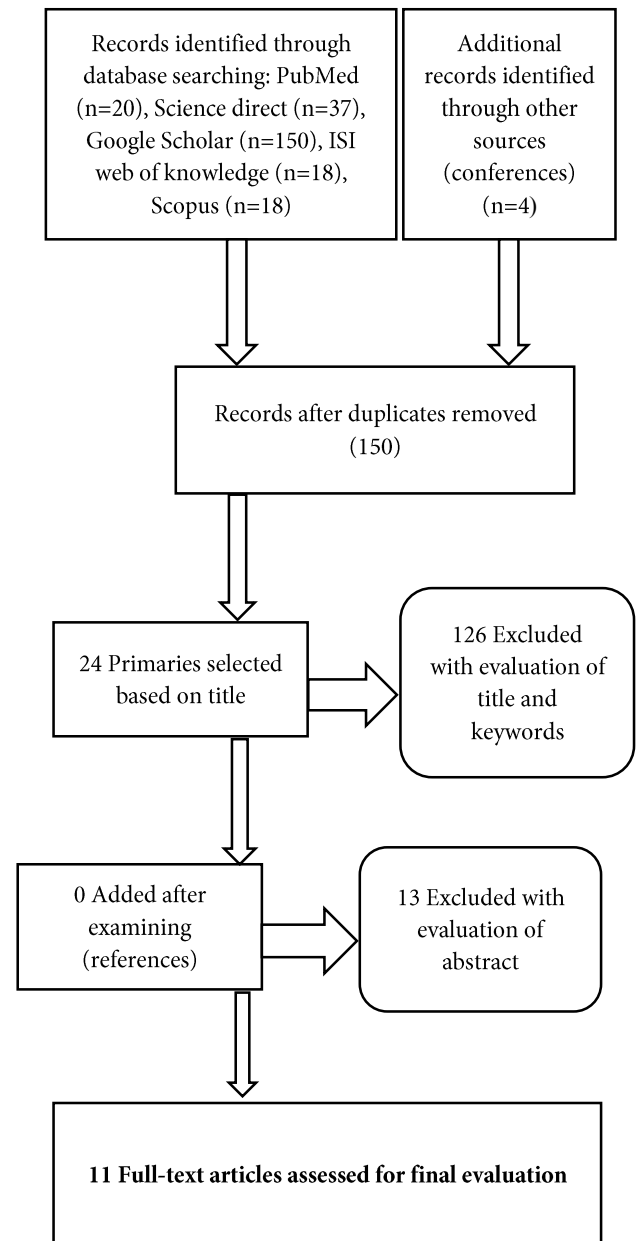


Figure 2. The procedure was followed using the PRISMA method

- 8- If participants had surgical history in their spine
- 9- If participants used of other type of spinal braces

Method quality and the level of evidence

By the Downs and Black scale, the quality of the included papers was assessed (13). It is a 27-item checklist to assess the risk of bias with every one scored ("yes"=1 point, "no"=0 point and "unable to determine"=0 point). In the current study, the checklist was modified to 13 items because of there are some unconformity in the some items for the included studies. Table 1 shows the Downs and Black scales.

Table 1. Modified Downs and Black Quality Index Results, and Inter-Rater Reliability for Each Item and Total Score

Table 1: Modified Downs and Black Quality Index Results, and Inter-Rater Reliability for Each Item and Total Score															
		Report							Internal validity-Biaa			Internal validity-Confounding		Total	
Items		Q1	Q2	Q3	Q4	Q6	Q7	Q9	Q10	Q18	Q19	Q20	Q21	Q22	
Papers		Aim	Main outcomes	Characteristics of the	Interventions	Main findings	Estimate random validity in data	Characteristics of patients lost	Values	Time period	Statistical tests	Compliance	Main outcome measures used accurate	Patients in different intervention groups	
Negrini et al. 2007		1	1	1	1	1	1	0	0	1	1	0	1	0	9
Atanasio et al. 2008		1	1	0	1	1	0	0	0	1	0	0	1	0	6
Negrini et al. 2008		1	1	1	1	1	1	0	0	1	1	1	1	1	11
Zaina et al. 2011		1	1	1	1	1	0	0	0	0	1	0	1	1	8
Negrini et al. 2011		1	1	1	1	1	0	0	0	1	1	1	1	1	10
Tavernaro et al. 2012		1	1	1	1	1	1	1	0	1	1	1	1	1	12
Lusini et al. 2014		1	1	1	1	1	1	1	0	1	1	1	1	0	11
Lusini et al. 2014		1	1	1	1	1	0	0	1	1	1	0	1	0	9
Zaina et al. 2015		1	1	1	1	1	1	0	0	1	1	0	1	1	10
Donzelli et al. 2016		1	1	1	1	1	1	0	1	1	1	0	1	0	10
Donzelli et al. 2018		1	1	1	1	1	0	0	0	1	1	1	1	0	10

Results

Studies description

The present study screened the abstracts and the full texts 11 papers that met the inclusion criteria for the final evaluation. All of the volunteer subjects included in the articles reviewed were adolescents (upper 10 years old) with a moderate AIS (lesser 55° Cobb angle). In all papers, participants treated with a full-time brace (between 15 and 23 hour per day) in first prescription. Participants were performed the regular exercises along with the bracing treatment in eight studies. Three studies didn't perform the exercise wearing the brace for their participants (14-16). Also, the Sforzesco brace was evaluated with Risser cast in five papers (10, 17-20). In two of these papers, Sforzesco brace was compared with Risser cast (17, 18).

Table 1 shows scores of eleven studies in black and down checklist. The scores were between 6 to 12 with the medium score 10. So, studies which got score lower than 10 were considered as a low quality (consist of 4 studies). Score 10 as a medium quality (consist of 4 studies), score upper than 10 as a high quality (consist of 3 studies).

Clinical effect of Sforzesco

The short-term results of the Sport concept (Sforzesco brace) for the first time was perform in 2007 by Negrini *et al.* They considered a Sport (Sforzesco Brace) group included 15 subjects with the mean (SD) scoliosis cobb angle 47° (7°) and a LY (Lyon Brace) group

included 15 patients with 43° (7°) cobb angle in thoracolumbar (T12-L1). The primary outcome criteria were Cobb angle (a difference 5° was considered as a significant variation) and Bunnell degrees (a difference 3° was considered as a significant variation). Their results after use of bracing treatment showed minimum or differences between the groups. A significant reduction in Cobb angles was absereved with braces in both groups, except thoracic Cobb angle in LY. Sforzesco was significantly more effective than LY ($P<0.05$) based on the radiography data for sagittal plane and aesthetics of the shoulders (9 improved and 6 unchanged vs. 5 and 8) and waists. In conclusion, results demonstrated that improvement were more effective in Sforzesco than LY (12 improved and 3 unchanged vs. 8 and 5) (4).

Another clinical effects reported on control and correction of deformity wearing the brace parameters are summarized in Table 2. In this table, all of Cobb angles were measured out-of-brace X-ray. The primary outcome measure in all studies was scoliosis Cobb angle. Also, the secondary outcomes measures were satisfaction, compliant, pain, Aesthetic Index, pelvic incidence and rib hump, that these were referred in some studies. Table 2 shows the most of Cobb angles were reduced to 10° in four articles (8, 10, 18, 20). Also, three articles reported the increased curve in some participants (6% of participants (21), 13% of participants(20), only one participant (19). Out of the 491 participants included in 11 studies, the results showed that deformity scoliosis was worsened in only 8 participants (0.016%) for three studies (19-21).

Table 2. Their clinical effects of Sforzesco brace

No	Authors	Studies type	Patients	Main outcome measures	Clinical effects
1	Negrini et al. 2007 (4)	Prospective study (short-term)	N=30 Lyon brace group: N=15 47±7° Cobb angle, Sforzesco brace group: N=15 43±7° Cobb.	Cobb angle, Bunnell degrees and deformity of spinal in sagittal plane	All foundation was decreased significantly with brace in both groups, except thoracic Cobb angle in LY. Sforzesco had more effective than LY ($P<0.05$) radiography (worst curve $-10\pm5^\circ$ vs $-5\pm7^\circ$, all curves $-8\pm7^\circ$ vs. $-6\pm7^\circ$), for sagittal plane (distance from plumbline: T12 -6 ± 9 mm vs. $+2\pm8$ and L3 -7 ± 12 vs. 0 ± 10)
2	S Atanasio et al. 2008 (18)	Prospective cohort study with a matched retrospective control group	N=30 Scoliosis Cobb angle in lumbar 38	Cobb angle	The Sforzesco brace obtained higher mean radiographic improvements in out-of-brace x-rays (-10 Cobb vs. -5). In terms of Cobb degrees, in the Sforzesco group 80% of patients improved and none worsened, while the Lyon group had respective results of 53% and 13%. We did not notice a difference in regard to prominence.
3	S Negrini et al. 2008 (21)	Prospective study with a retrospective control group	N=30 scoliosis Cobb angle in lumbar=46.7 Sforzesco group: N=32, group:32 Risser cast group:18	Cobb angle	A reduction of 6° Cobb and an important aesthetic gain in both groups ($P<0.05$). Three patients (6%) worsened, while 56% improved (36% at least 10°, and 14% 15° or more).
4	F Zaina et al. 2011 (20)	Prospective study	N=30 Scoliosis Cobb angle in thoracolumbar=38	Cobb angle Aesthetic Index Bunnell degrees Rib Hump Distance from plumbline	Radiographic improvements: (-10 Cobb), without reducing the thoracic kyphosis. Cobb degrees, in the Sforzesco group 80% improved and none worsened. Aesthetic Index : improve 5 (before) to 2 (after) Bunnell degrees: 10 to 7 Rib Hump: 15 to 8 Distance from plumbline: 28 to 25
5	S Negrini et al. 2011 (19)	Retrospective study from a prospective database.	N=28 Scoliosis Cobb angle >45 In thoracolumbar	Cobb angle Satisfaction	Decreased in Cobb angle found in 71% of patients ($P<0.05$) and a 5 Cobb progression in one patient SRS-22 questionnaire: Statistically significant improvements showed in the aesthetic index and Bunnell angle of trunk rotation.
6	M Tavernaro et al. 2012 (12)	A case-control retrospective study	N=38 Scoliosis Cobb angle in lumbar =29.2 Two groups: bracing(13) vs. non treatment(25)	Cobb angle, compliance of brace and pain	Treatments by Braces were: Sforzesco, Sibilla, Lapadula or Maguelone. Exercises: SEAS Bracing group was more compliant to bracing than non-treatment group ($97\pm6\%$ vs. $80\pm24\%$). Pain was perceived by 55% of non-treatment group versus 7% of Bracing group ($P<0.05$).
7	M Lusini et al. 2014 (10)	Prospective study	N=57 Scoliosis Cobb angle in thoracic= 52.5 Bracing group: 39, Control group:18	Cobb angle	Failures were 23.5% in Bracing group and 100% in Control group. Percentage of patients (53.8%) improved. Patients who joined the treatment achieved a 10.4 to 6.1 Cobb improvement.
8	M Lusini et al. 2014(15)	Prospective study	N=12 Cobb angle in thoracic= 41.58°	Cobb angle and pelvic incidence	Scoliosis worst curves improved with brace (12.5 ± 4.98) and brace take-off (6.75 ± 3.79) versus before treatment start. Pelvic incidence changed comparing with brace (45.9 ± 11.6) vs. before brace (48.0 ± 10.5) and brace take-off (48.2 ± 12.3). Lumbar not changing between before treatment start and brace take-off, Thoracic kyphosis did not change significantly
9	F Zaina et al. 2015 (22)	Two outpatient tertiary referral facilities specialized in scoliosis conservative treatment.	N=52, scoliosis Cobb angle >40° in thoracic and thoracolumbar ART brace :N=26 Sforzesco brace: N=26	Cobb angle	No significance (24.3 ± 8.5 vs 28.0 ± 6.8 for thoracic; 23.7 ± 10.4 vs 29.9 ± 4.2 for lumbar / thoracolumbar). At 6 months, results were similar both for thoracic (34.4 ± 10.4 vs 34.8 ± 6.8) and for lumbar/thoracolumbar (32.8 ± 10.8 vs 36.6 ± 5.2).
10	S Donzell et al. 2016 (14)	Cross sectional	N=16 Scoliosis Cobb angle in lumbar=36.44	Cobb angle	The mean Cobb angle changed significantly from 36.44 ± 4 to $28.99\pm3.9^\circ$ ($P=0.01$).
11	S Donzelli et al. 2018 (11)	Case-control study	N=168 Scoliosis Cobb angle in thoracolumbar: 41.1 (11.8)	Cobb angle	follow-up was 4-6 months, Consistent brace wear is associated with a higher probability of improvement in curve magnitude ($P=0.0053$). Inconsistent brace wear is more likely to progress ($P=0.0015$).

In one study, compliance of bracing treatment was reported. The finding showed the satisfaction rates were statistically higher in bracing group than non-treatment group, with 92% versus 48% to the compliance questionnaire and 69% versus 40% for the SRS-22. In this study, pain was also reported. Results showed that pain was perceived by 55% of non-treatment group versus 7% of treatment group ($P<0.05$) (12). Another study examined the impact of the brace use on pelvic incidence. Their results showed that pelvic incidence was reduced when using the Sforzesco brace, but after the completion of re-training, the condition returned to pre-brace status (15).

Discussion

This article reviewed the current state of knowledge on the effect of the Sforzesco brace with Sport concept in reduction of Cobb angle. The literature search demonstrated that the relevant studies mainly involved patients with AIS (Risser sign <4), although kyphosis is common among these patient groups. Studies have shown positive results for the use of Sforzesco brace in improvement and correction of deformity. Many studies have also reported patients' positive opinion of Sforzesco brace aesthetic (4, 18, 21). Negrini *et al.* (2008) showed the Sforzesco brace obtained scoliosis correction similar to Risser cast (17). Atanasio *et al.* (2008) stated the Sforzesco brace obtained higher mean radiographic improvements in out-of-brace x-rays (-10 Cobb angle vs. -5) (18). In other studies, Negrini *et al.* and Lusini *et al.*, participants were treated with Sforzesco brace or Risser cast. These studies didn't compare two brace and all of treated participants with Sforzesco brace or Risser cast located in a group (10, 19). Zania *et al.* (20) compared the Sforzesco brace with the data of Negrini's study which evaluated Risser cast and the data of Negrini's and Marchini's (8) study which evaluated Lyon brace in past studies. They showed that after 6 months, the Sforzesco brace was more effective than the Lyon brace of improvement; also it was equally effective as the Risser cast. Also, it had best compliance among them (20). Finally, these studies showed Sforzesco brace in comparison some of common braces in treatment of AIS had the similar result. Since Sforzesco brace also showed a good compliance, it could be considered as an alternative to others braces (10, 17-20).

The included studies in this review performed on a minimum of 12 (15) and a maximum of 168 (11) participants. Also, average number of participants in all studies was 49.1. However, it is necessary that future studies to be performed with more participants. Also, maximum follow-up was 4 years performed by Zaina *et al.* However, they claimed that

participants had not completed period of their treatments with brace (20). Some of included studies in this review have also been carried out by the same researchers in order to make an accurate decision regarding the use of Sforzesco brace. However, it may create some bias in the results. So, it is needed to conduct further studies in other countries by other researchers.

One of the limitation for this review was lack of any randomize-clinical-trial (RCT) to compare Sforzesco brace with other braces. In order to further develop brace in other countries of the world it is necessary to conduct RCT. On the other hand, all studies have used adolescent participants, and the efficacy of brace in children under the age of ten has not been investigated.

Conclusion

In conclusion, this review showed Sforzesco brace can be effective in improvement of scoliosis deformity for adolescent patients. Also, it make aesthetic versus current braces. Because this brace has recently been developed, it requires a long-term follow up in further works.

Acknowledgments

This article was supported by the Research Institute for Primary Prevention of Non-communicable Disease. We thank the students with cerebral palsy and the normal students who participated in this study.

Conflict of interest:

None

Funding support:

None

Authors' contributions:

Both authors made substantial contributions to the conception, design, analysis, and interpretation of data.

References

1. Perdriolle R, Boffelli N, Ousset M. La scoliose: son étude tridimensionnelle: Maloine; 1979.
2. Negrini S, Aulisa AG, Aulisa L, Circo AB, De Mauroy JC, Durmala J, et al. 2011 SOSORT guidelines: orthopaedic and rehabilitation treatment of idiopathic scoliosis during growth. *Scoliosis*. 2012;7(1):3.
3. Richards BS, Bernstein RM, D'Amato CR, Thompson GH. Standardization of criteria for adolescent idiopathic scoliosis brace studies: SRS Committee on Bracing and Nonoperative Management. *Spine*. 2005;30(18):2068-75.

4. Negrini S, Atanasio S, Negrini A, Negrini A, Negrini A. The evidence-based ISICO approach to spinal deformities. Milan, Boston: ISICO; 2007.
5. Negrini S, Grivas TB, Kotwicki T, Maruyama T, Rigo M, Weiss HR. Why do we treat adolescent idiopathic scoliosis? What we want to obtain and to avoid for our patients. SOSORT 2005 Consensus paper. *Scoliosis*. 2006;1(1):4.
6. Negrini S, Marchini G, Tomaello L. The Sforzesco brace and SPoRT concept (Symmetric, Patient-oriented, Rigid, Three-dimensional) versus the Lyon brace and 3-point systems for bracing idiopathic scoliosis. *Studies in health technology and informatics*. 2006;123:245.
7. Negrini S, Grivas TB, Kotwicki T, Rigo M, Zaina F. Guidelines on "Standards of management of idiopathic scoliosis with corrective braces in everyday clinics and in clinical research": SOSORT Consensus 2008. *Scoliosis*. 2009;4(1):2.
8. Negrini S, Marchini G. Efficacy of the symmetric, patient-oriented, rigid, three-dimensional, active (SPoRT) concept of bracing for scoliosis: a prospective study of the Sforzesco versus Lyon brace. *Europa Medicophysica*. 2007;43(2):171.
9. Negrini S, Marchini G, Tessadri F. Brace technology thematic series- The Sforzesco and Sibilla braces, and the SPoRT (Symmetric, Patient oriented, Rigid, Three-dimensional, active) concept. *Scoliosis*. 2011;6(1):8.
10. Lusini M, Donzelli S, Minnella S, Zaina F, Negrini S. Brace treatment is effective in idiopathic scoliosis over 45: an observational prospective cohort controlled study. *The Spine Journal*. 2014;14(9):1951-6.
11. Donzelli S, Zaina F, Minnella S, Lusini M, Negrini S. Consistent and regular daily wearing improve bracing results: a case-control study. *Scoliosis and spinal disorders*. 2018;13(1):16.
12. Tavernaro M, Pellegrini A, Tessadri F, Zaina F, Zonta A, Negrini S. Team care to cure adolescents with braces (avoiding low quality of life, pain and bad compliance): a case-control retrospective study. 2011 SOSORT Award winner. *Scoliosis*. 2012;7(1):17.
13. Downs SH, Black N. The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. *Journal of Epidemiology & Community Health*. 1998;52(6):377-84.
14. Donzelli S, Zaina F, Lusini M, Minnella S, Respizzi S, Balzarini L, et al. The three dimensional analysis of the Sforzesco brace correction. *Scoliosis and spinal disorders*. 2016;11(2):34.
15. Lusini M, Donzelli S, Poma S, Trenti N, Castelli A, Balzarini L, et al. The second dimension of the Sforzesco brace correction: analysis of the sagittal shape of the spine. *Scoliosis*. 2014;9(S1):O37.
16. Lusini M, Donzelli S, Minnella S, Zaina F, Negrini S. Effectiveness of the Sforzesco brace according to the SRS and SOSORT criteria for bracing studies. *Scoliosis*. 2013;8(S2):O59.
17. Negrini S, Zaina F, Atanasio S. BRACE MAP, a proposal for a new classification of braces. *Studies in health technology and informatics*. 2008;140:299-302.
18. Atanasio S, Zaina F, Negrini S. The Sforzesco brace and SPoRT concept: a brace to replace cast in worst curves. *Disability and Rehabilitation: Assistive Technology*. 2008;3(3):154-60.
19. Negrini S, Negrini F, Fusco C, Zaina F. Idiopathic scoliosis patients with curves more than 45 Cobb degrees refusing surgery can be effectively treated through bracing with curve improvements. *The Spine Journal*. 2011;11(5):369-80.
20. Zaina F, Fusco C, Atanasio S, Negrini S. The SPoRT concept of bracing for idiopathic scoliosis. *Physiotherapy theory and practice*. 2011;27(1):54-60.
21. Negrini S, Atanasio S, Negrini F, Zaina F, Marchini G. The Sforzesco brace can replace cast in the correction of adolescent idiopathic scoliosis: A controlled prospective cohort study. *Scoliosis*. 2008;3(1):15.
22. Zaina F, De Mauroy JC, Donzelli S, Negrini S. SOSORT Award Winner 2015: a multicentre study comparing the SPoRT and ART braces effectiveness according to the SOSORT-SRS recommendations. *Scoliosis*. 2015;10(1):23.