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Title: Effectiveness of Braces Designed Using Computer Aided Design and Manufacturing (CAD/CAM) and Finite Element Simulation Compared to CAD/CAM Only for the Conservative Treatment of Adolescent Idiopathic Scoliosis: a Prospective Randomized Controlled Trial.

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Abstract

Purpose:

Clinical assessment of immediate in-brace effect of braces designed using CAD/CAM and FEM vs. only CAD/CAM for conservative treatment of AIS, using a randomised blinded and controlled study design.

Methods:

Forty AIS patients were prospectively recruited and randomized into two groups. For 19 patients (control group), the brace was designed using a scan of patient's torso and a conventional CAD/CAM approach (CtrlBrace). For the 21 other patients (test group), the brace was additionally designed using Finite Element Modeling (FEM) and 3D reconstructions of spine, rib cage and pelvis (NewBrace). The NewBrace design was simulated and iteratively optimized to maximize the correction and minimize the contact surface and material.

Results:

Both groups had comparable age, sex, weight, height, curve type and severity. Scoliosis Research Society standardized criteria for bracing were followed. Average Cobb angle prior to bracing was 27° and 28° for main thoracic (MT) and lumbar (L) curves respectively for the control group, while it was 33° and 28° for the test group. CtrlBraces reduced MT and L curves by 8° (29%) and 10° (40%) respectively, compared to 14° (43%) and 13° (46%) for NewBraces, which were simulated with a difference inferior to 5°. NewBraces were 50% thinner and had 20% less covering surface than CtrlBraces.

Conclusion:

Braces designed with CAD/CAM and 3D FEM simulation were more efficient and lighter than standard CAD/CAM TLSO’s at first immediate in-brace evaluation. These results suggest that long-term effect of bracing in AIS may be improved using this new platform for brace fabrication.

Keywords:

Computer-aided design/computer-aided manufacturing, Scoliosis, Thoraco-lumbo-sacral orthosis, Finite element modeling (FEM), RCT

Manuscript

Introduction

Adolescent Idiopathic Scoliosis (AIS) is a threedimensional (3D) deformity of the spine and rib cage. For Cobb angles between 20°-40°, a conservative brace treatment is generally prescribed [1,2]. Recent studies demonstrated bracing as an effective treatment to prevent curve progression[3-6]. A correlation was found between immediate in-brace correction and brace treatment's long-term effectiveness[7-8]. Brace treatment effectiveness also relies on timing with adolescent growth spurt, spine flexibility and patient compliance to treatment[9-12].

Traditional brace fabrication method for rigid thoraco-lumbo-sacral orthoses (TLSO) involves taking a mold of the patient later filled with plaster to create a positive cast which is then modified by adding/removing plaster at different areas. This manual technique requires time, material consumption and presents a low accuracy[13]. Computer-aided design and manufacturing systems (CAD/CAM) have proven to be as effective compared to plaster-cast methods[14-16]. The trunk surface acquisition can be realized using a surface topography system[17] or optical scanners[17,18]. The CAD/CAM method is also cost and time effective as it increases productivity (2.5 times) compared with plaster-cast methods and allows patient data storing for future references[13]. However, none of these techniques allow testing brace efficacy before the patient wears it.

Finite element models (FEM) have been used to analyze brace biomechanics[19-24]. A detailed and realistic FEM was developed to simulate brace treatment[15,16,23,25]. Combined to a CAD/CAM system, FEM allows brace correction simulation and computation of pressures applied on a patient's torso. Iterative improvement of the brace design and its biomechanical efficiency assessment can be made before brace fabrication. Recently, a clinical evaluation using the FEM was done on a group of 22 scoliotic patients[15,16] to improve functional design of braces. Each participating patient received two braces to compare brace effectiveness. The first brace was fabricated using the CAD/CAM-FEM method while the second brace was fabricated using the conventional plaster-cast technique. These studies showed the feasibility of using CAD/CAM and FEM to fabricate braces as efficient as standard TLSO like the Boston brace system. The predicted correction results were similar to that of the real fabricated brace and comfort parameters were integrated to brace design without compromising biomechanical efficiency. However, these feasibility studies are limited by the fact that patients were not randomized and by the use of the plaster-cast technique as the control group.

The purpose of this study was to perform a randomized and controlled trial (RCT) to assess the braces effectiveness designed using CAD/CAM-FEM vs. only CAD/CAM for the conservative treatment of AIS.

Methods

Experimental study design

40 patients were consecutively recruited on a voluntary basis over a 2 years period. All participants were diagnosed with an AIS, had an immature skeleton presenting a Risser sign 0-2 and were prescribed a full-time TLSO [26]. Patients with a curve magnitude between 20° to 45° were included in the study to take into account the intra-observer measurement variability in the measurement of the Cobb angle. The study was approved by our institutional ethical committee and each participant and their parents gave a written consent.

Patients were assigned to control and test groups using a simple randomization technique. Randomization sequence was generated by a randomization table: a simple block randomization list with a block size of 4 was prepared by a biostatistician not involved in recruitment and follow-up of the patients. In this study, the caregivers were blinded but not the orthotist. The 19 patients from control group received a TLSO fabricated using a scan of their torso and the CAD/CAM approach (CtrlBrace). The 21 patients from the test group received a TLSO also designed using the CAD/CAM approach but additionally simulated using a FEM built from each patient's torso and personalized 3D reconstruction (spine, rib cage and pelvis), and computationally improved for correction (NewBrace)(Protocol for test group). For all patients, the brace was prescribed during their visit at the clinic and calibrated bi-planar postero-anterior (PA) and lateral (LAT) radiographs were taken using a low-dose digital radiography system (EOS™, EOS imaging, Paris, France). All patients had their brace designed by two orthotists having more than 10 years of experience with TLSO and 2 years of experience with CAD/CAM technology. The following radiological indices were measured: main thoracic (MT) and lumbar (L) Cobb angles, kyphosis and lordosis angles. Angle measurement was done using the semi-automatic Fuji Synapse system (Fuji Synapse System, Fujifilm holdings, Tokyo, Japan) and was realized by two experimented operators. Angle measurement accuracy using this system is inferior to 5°. Kyphosis was measured using two different methods: maximal kyphosis using the most inclined vertebrae and constrained kyphosis using vertebrae T4-T12. Lordosis was measured using vertebrae L1-S1. A device recording brace wear time using in-brace temperature measurement was incorporated to all braces to evaluate patient compliance (iButton, Boston Brace, USA).

Protocol for the Control Group (CtrlBrace)

Patient's external torso geometry was obtained using a surface topography system (3-dimensional Capturor, Creaform inc, Levis, Canada)[17]. Orthotists used the Rodin4D CAD/CAM system (Rodin4D, Groupe Lagarrigue, Bordeaux, France) to design the CtrlBrace geometry. Using the software's interactive tools, modifications of the CtrlBrace design were made to add/remove material in order to introduce pressure and relief areas. Tools to apply corrective translations on brace sections and symmetrize its geometry were also used. Braces were then fabricated using a numerically controlled carver (Model C, Rodin 4D, Groupe Lagarrigue, Bordeaux, France) linked to the CAD/CAM system. According to the CAD model, a polyurethane foam bloc was carved and brace shell thermoforming was done using a heated copolymer sheet. The fabricated brace was trimmed and adjusted by the orthotist and brace effectiveness was assessed using simultaneous PA and LAT in-brace radiographs. The brace covering surface was measured using the CATIA CAD/CAM software (CATIA, Dassault Sytemes, Vélizy-Villacoublay, France) by importing the STL file of the brace design and by computing the area of the brace shell. Brace shell thickness and corrective pads thickness were measured by the orthotist following brace adjustment using a caliper tool.

Protocol for the Test Group (NewBrace)

Using the calibrated PA and LAT radiographs, the 3D reconstruction of the patient's spine, rib-cage and pelvis was done[26]. Patient's external torso geometry was obtained using the same surface topography system as with the control group[17]. Radio-opaque markers visible on X-rays and trunk surface were a priori positioned on anatomical points of the patient's torso and were used to register the skeleton reconstruction and the external torso geometry. With a previously validated method, the trunk's overall registered geometry was used to create a personalized FEM using Ansys 14.5 software package (Ansys Inc., Canonsburg, PA, USA)[8,23]. The FEM includes thoracic/lumbar vertebrae, intervertebral discs, ribs, sternum, costal cartilages, ligaments, abdominal cavity and soft external tissues[19-25](Figure 1). Mechanical properties for anatomical structures were taken from published data obtained on typical human cadaveric spine segments [22,23,28,29].

Orthotists used the same CAD/CAM software as for CtrlBraces to design NewBraces. However, the brace design thereby obtained was then simulated using the FEM to assess its effectiveness. A brace FEM using polyethylene mechanical properties was created[24]. A surface-to-surface contact interface was made to model friction and force transfer from the brace shell to the patient's trunk surface[30]. The orthotist had to select sets of nodes on the brace FEM to represent strap fixation localization and had to virtually position the brace on the patient's FEM. The brace installation was then automatically simulated. During all simulation steps, the pelvis was fixed in space and the first thoracic vertebra (T1) was allowed to rotate and translate longitudinally. For a given simulation, the correction was assessed using post-processed Cobb angles, lordosis and kyphosis, as well as computed pressures applied on the torso and space between patient’s skin and brace shell (brace fitting)(Figure 2).

Following brace simulation results, it was possible to modify the brace design to improve brace correction. The brace design was iteratively modified in the CAD/CAM software by varying the corrective pad localization and depth. Other design parameters like trim lines, relief zones, side of trochanteric pad location and openings on the brace were also modified and simulated to improve brace design. Braces were iteratively designed and simulated. Their performance was computationally assessed by the orthotist to maximize the correction using post-processed indices. The criterion for correction maximization was to incrementally accentuate pad depth by 5mm until simulated spinal correction stayed stable even with the corrective region depth increasing (2° Cobb angle). The pad depth was however limited by the corresponding pressure applied on the torso to not exceed a 35 KPa value, a threshold previously established by Cobetto et al. to respect patient comfort in braces[18]. Patient’s comfort was optimized by controlling pressures applied on the torso and minimizing contact surfaces between the brace and the patient’s skin. The numerical process required an average of 3 iterations per patient (minimum 2, maximum 6).

The optimal NewBrace was then fabricated using the same numerical controlled carver and thermoforming process. The NewBrace was trimmed by the orthotist and brace effectiveness was assessed using simultaneous PA and LAT radiographs. Brace covering surface and brace thickness was measured using the same method as for CtrlBraces.

Statistical analysis

Statistical data analysis were performed using STATISTICA 10.0 software package (Statistica, StatSoft Inc., Tulsa, OK, USA). To verify that both groups were statistically comparable, a paired t-test (95% significance level) was apply to compare age, sex, weight, height curve type and curve severity between both groups. A statistical analysis was also realized using a Mann-Whitney test (95% significance level) to analyze if there was a significant difference for in-brace correction (MT and L Cobb angles) and in-brace kyphosis and lordosis angles between both groups. To justify the use of parametric (paired t-test) and non-parametric (Mann-Whitney test) statistical tests, a Shapiro-Wilk's test for normality was realized on each group.

Results

Forty patients aged between 10-16 years were consecutively recruited. Both groups had comparable age, sex, weight, height, skeletal maturity, curve type and severity (Table 1) and presented a normal distribution. The correction indices (MT/L Cobb angles, maximal/constrained kyphosis and lordosis) were measured on radiographs taken prior to brace treatment during the patient's first visit and on the in-brace radiographs (Figure 3). For control group, average Cobb angle prior to bracing was 27° (MT) and 26° (L). For test group, average Cobb angle prior to bracing was 33° (MT) and 28° (L). For both groups, maximal and constrained kyphosis were 25° and 33° respectively and average lordosis was 53° prior to bracing. CtrlBrace reduced MT and L Cobb angles by 8° (29%) and 10° (40%) respectively. NewBrace reduced MT and L Cobb angles by 14° (43%) and 13° (46%) which were simulated with a difference inferior to 5° (Table 2). NewBrace correction was found to be statistically significantly greater than CtrlBrace with a p-value=0.02 ($p<0.05$) for the MT Cobb angle correction. For the L Cobb angle correction, no significant difference was found. For CtrlBraces, maximal and constrained in-brace kyphosis were reduced to 27° and 19° respectively compared to NewBraces for which maximal and constrained in-brace kyphosis were maintained at 30° and 23° respectively. In-brace lordosis was reduced to 45° for both groups (Table 2). No significant differences were found for the in-brace maximal/constraint kyphosis and lordosis angles between both groups. When analyzing normality of both groups using the Shapiro-Wilk's test, results showed that distribution for NewBrace MT curve correction and CtrlBrace L curve correction was not normal (Table 2), justifying the use of the Mann-Whitney statistical test to compare in-brace results between both groups. When analyzing the simulated corrective pressures applied by the brace on patient's torso, highest pressures were located on thoracic and lumbar regions with maximal values between 25-35 KPa. Simulated pressures at axillary and trochanter extension regions were lower with maximal values between 20-25 KPa. The average brace wear time was 15 hours/day for both groups (min 8 hrs, max 22 hrs). Newbraces had an average of 20% less covering surface than CtrlBraces. The thermoplastic sheet thickness used for brace shell was the same for both groups (4 mm). As for the pads added in CtrlBraces, the thickness was 13 mm. For NewBraces, no foam pad (liner) was necessary. Because Foam pads were recovering on average 34% of the brace area, NewBraces were on average 50% thinner than CrtlBraces (Figure 3).

Discussion

Recent evidence has demonstrated that CAD/CAM is as effective in fabricating braces for AIS compared to traditional plaster-cast method[14], while being more cost and time effective. Two preliminary studies[15-16] have suggested that adding a FEM to CAD/CAM may also improve brace efficacy. However, it remained to be demonstrated that the addition of a more complex FEM technology offers any advantage over CAD/CAM alone. The present study indicates that a clinically and statistically significantly greater immediate in-brace thoracic Cobb angle correction and similar (slightly greater) lumbar curve correction can be obtained with the addition of FEM to CAD/CAM, with the additional advantages of 50% thinner braces with 20% less covering body surface. Patient comfort was not evaluated in this study but it would be possible to hypothesize that these design parameters could improve the treatment's comfort and patient's quality of life. It remains to be shown in a future study. The average brace wear time was 15 hours/day for both groups which is comparable to previous studies demonstrating the variability of brace wear time in adolescent population[11,12] presenting average brace wear compliance from 47% [33] to 91% [34] of brace wear prescription. Considering the results of studies showing a significant positive association between brace wear time and treatment's success [35] and showing a significant increase of treatment's success for a brace wear time of more than 18 hours per day [36], evaluating patient's compliance as a factor influencing the long-term outcome of brace would be part of a future study.

Since a correlation has been reported between immediate in-brace correction and brace treatment long-term effectiveness[7-8], these results suggest that the use of a FEM simulation platform may also improve the long-term TLSO treatment efficacy. Using this platform, it is possible to simulate/test different brace designs and better define the treatment plan. It allows orthotists to simulate and predict in-brace correction for different pad configurations as well as for different trim lines and relief zones adjustment to optimize brace design. The use of the simulation platform allowed orthotists to analyze the pressures applied on patient's trunk and the contact surface between brace and patient's skin, in order to avoid excessive pressures and adjust the openings and relief zones on the brace. This has resulted in braces averaging 20% less covering surface and 50% thinner when fabricated with the CAD/CAM-FEM. In addition, pads were added for CtrlBraces during brace fitting to adjust the brace design. This step was not necessary for NewBraces, indicating that the simulation tool can be useful to rationalize and improve the brace design. This simulation platform can also be used to study the biomechanics of other types of braces, as it was realized in a previous study for the Providence and Charleston night-time braces [37, 40]. It could also be used to study or improve the brace design of other brace approaches like the Chêneau brace, an orthosis also used to treat scoliotic thoraco-lumbar curves and presenting possible spinal correction in the sagittal and the transverse planes [38-39].

In sagittal plane, TLSO's fabricated with traditional plaster-cast method have been criticized as causing hypokyphosis, a potentially harmful side-effect as hypokyphosis is already present in most AIS subjects and considered an important part of the deformity. It is reassuring to document that kyphosis was slightly less reduced with NewBraces compared to CtrlBraces, although not statistically significant. We believe that having access to spinal 3D reconstructions with CAD/CAM techniques allows orthotists to better visualize and address this hypokyphotic component, and possibly improve brace design with more proper 3D fitting of the brace.

The main strength of this study is the RCT design, which confirms and supports previous feasibility studies with CAD/CAM and FEM simulations for brace design in AIS. There are, however, limitations to this trial. First, only immediate in-brace effect was measured. Even if a correlation has been found between immediate in-brace correction and brace treatment long-term effectiveness[7,22], measuring only immediate correction may be insufficient. Nevertheless, these encouraging results indicate that a more time consuming and expensive RCT study of long-term effects in a larger cohort appears warranted. Long-term results will allow to evaluate patient's compliance to treatment and patient's flexibility as factors influencing brace outcomes. The second main limitation is that addition of FEM to CAD/CAM techniques is more time consuming and adds another level of complexity to brace fabrication. In the configuration tested, the simulation process adds 20-30 minutes to the design process. However, because the brace was optimized, time needed for the fitting was reduced (approximately 30 min). Time calculation could still be further reduced to favor an even more efficient clinical use by orthotists.

Conclusions

Braces designed with CAD/CAM and FEM simulation are more efficient at correcting thoracic curves at first immediate in-brace evaluation, with the advantages of being lighter than standard CAD/CAM TLSO's and requiring less body surface coverage. These results suggest that long-term effect of bracing in AIS may be improved by the use of this new platform for brace fabrication, and indicate that a study of long-term effects in a larger cohort appears warranted.

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Trial registration: NCT02285621

Compliance with Ethical Standards

<u>Conflict of Interest</u>

Research and development contract was obtained with Groupe Lagarrigue to develop and transfer a license of the simulation platform. Money was given to the university and the contract was not directly related to the presented RCT study. The RCT study presented in this paper was funded by a peer-reviewed grant from the Canadian Institutes of Health Research. The participating orthotists from Orthèse-Prothèse Rive-Sud received nothing of value to realize this study.

Ethical approval

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional ethical research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent

Informed consent was obtained from all individual participants included in the study and their parents.

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Table 1 – Patient data at Initial Visit

	Test Group (NewBrace) (19 females, 2 males)			Control Group (CtrlBrace) (16 females, 3 males)			Statistical comparison between groups	Statistical test for normality for each group
		Mean	**SD**		**Mean**	**SD**	**Paired t-test***	**Shapiro-Wilk****
Age (yrs)		13.2	1.4		13.0	1.3	p = 0.67	NewBrace, p = 0.99 CtrlBrace, p = 0.76
Risser		0.7	0.8		0.5	0.7	p = 0.36	
Weight (kg)		41.2	20.9		44.8	22.5	p = 0.42	NewBrace, p = 0.22 CtrlBrace, p = 0.31
Height (cm)		146.1	72.8		154.7	79.7	p = 0.96	NewBrace, p = 0.20 CtrlBrace, p = 0.20
MT Cobb Angle	n = 17	33.2	6.9	n = 19	27.3	5.1	p = 0.06	NewBrace, p = 0.29 CtrlBrace, p = 0.51
L Cobb Angle	n = 15	27.5	7.3	n = 14	26.3	7.5	p = 0.53	NewBrace, p = 0.31 CtrlBrace, p = 0.66
T4-T12 Kyphosis		25.5	10.8		25.6	14.3	p = 0.84	NewBrace, p = 0.94 CtrlBrace, p = 0.79
Maximal Kyphosis		32.9	8.8		33.6	14.0	p = 0.75	NewBrace, p = 0.93 CtrlBrace, p = 0.97
L1-S1 Lordosis		53.1	11.5		54.3	11.6	p = 0.89	NewBrace, p = 0.52 CtrlBrace, p = 0.80

***Statistically significantly different for $p < 0.05$**
****Normal distribution for $p > 0.05$**

Table 2 – In-brace results for Cobb, kyphosis and lordosis angles

	Test Group (NewBrace)			**Control Group (CtrlBrace)**		
	Mean	**SD**	**Shapiro-Wilk normality test ***	**Mean**	**SD**	**Shapiro-Wilk normality test ***
MT Cobb Angle reduction (degrees)	13.8	5.4	p = 0.05	8.2	5.4	p = 0.91
MT Cobb Angle reduction (%)	43	15	p = 0.11	29	21	p = 0.38
L Cobb Angle reduction (degrees)	12.9	5.9	p = 0.52	10.6	4.9	p = 0.04
L Cobb Angle reduction (%)	46	18	p = 0.26	40	12	p = 0.86
T4-T12 Kyphosis	22.8	9.8	p = 0.30	19.5	10.5	p = 0.19
Maximal Kyphosis	30.1	9.9	p = 0.17	27.1	8.5	p = 0.49
L1-S1 Lordosis	45.7	9.3	p = 0.86	45.8	9.9	p = 0.73

***Normal distribution for p > 0.05**

Figures

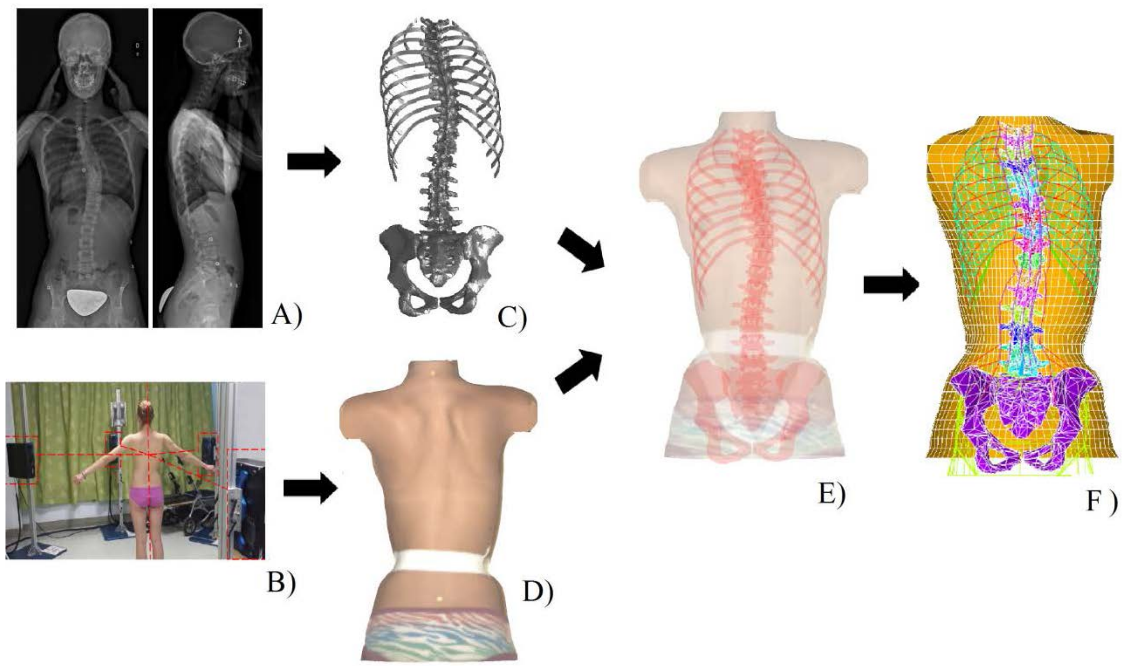

Figure 1-A) Acquisition of the calibrated bi-planar radiographs; B) Surface topography acquisition; C) 3D reconstruction of the spine, rib cage and pelvis; D) Torso 3D geometry E) Geometric registration F) Finite element model of the trunk: vertebrae, intervertebral discs, ribs, sternum, costal cartilages, ligaments and soft external tissues

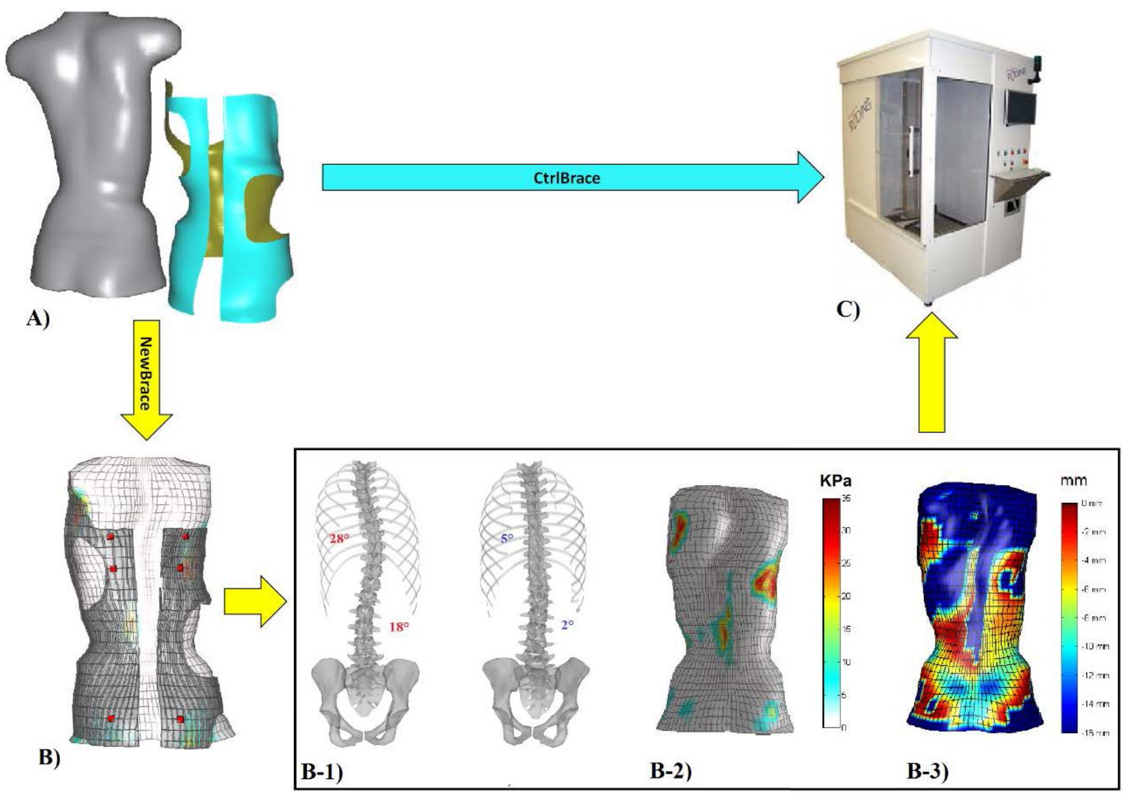

Figure 2-A) CtrlBrace or Newbrace design using the CAD software; B) Simulation of the Newbrace installation; B1) Simulation of the spine correction; B2) Simulation of the applied pressures; B3) Simulation of the distance between the brace shell and the patient's skin (the blue color represents the material in contact with the patient's skin and the green, yellow, orange and red colors represent the brace material situated at more than 6 mm of the patient's skin); C) Brace fabrication using a numerically controlled carver

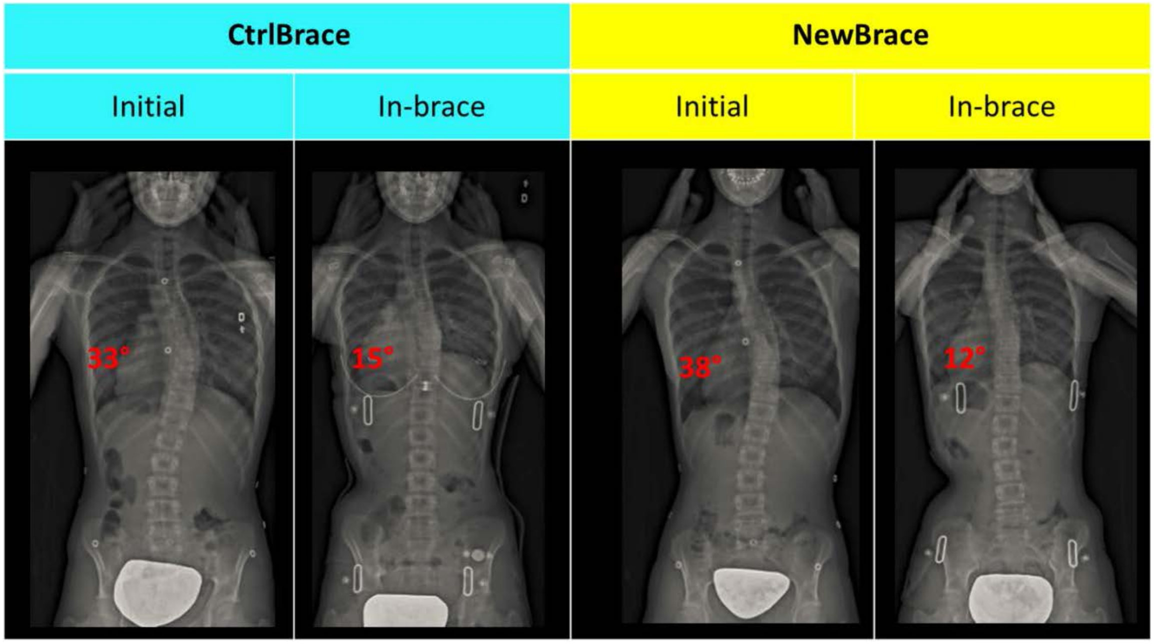

Figure 3 – PA Radiographic results for two typical patients: out of brace initial curve, with the CtrlBrace or with the NewBrace