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Title:

Braces Optimized with Computer-Assisted Design and Simulations Are Lighter, Comfortable and More Efficient than plaster-casted braces for the treatment of Adolescent Idiopathic scoliosis

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Abstract

Study design

Feasibility study to compare effectiveness of two brace design and fabrication methods for treatment of adolescent idiopathic scoliosis: a standard plaster/cast method and a computational method combining CAD/CAM (Computer Aided Design and Fabrication) and finite element simulation.

Objectives

To improve brace design using a new brace design method.

Summary of background data

Initial in-brace correction and patient's compliance to treatment are important factors for brace efficiency. Negative cosmetic appearance and functional discomfort resulting from pressure points, humidity and restriction of movement can cause poor compliance with prescribed wearing schedule.

Methods

15 consecutive patients with brace prescription were recruited. Two braces were designed and fabricated for each case: a standard TLSO brace fabricated using plaster/cast method and an improved brace for comfort (NewBrace) fabricated using a computational method combining a CAD/CAM software (Rodin4D) and a simulation platform. 3D reconstructions of the torso and the trunk skeleton were used to create a personalized finite element model, which was used for brace design and predict correction. Simulated pressures on the torso and distance between the brace and patient's skin were used to remove ineffective brace material situated at more than 6 mm of patient's skin. Bi-planar radiographs of the patient wearing each brace were taken to compare their effectiveness. Patients filled out a questionnaire to compare their comfort.

Results

NewBraces were 61% thinner and had 32% less material than standard braces with an equivalent correction. NewBraces were more comfortable (11/15 cases) or equivalent (4/15 cases) than standard braces. Simulated correction was simulated within 5° as compared to in-brace result.

Conclusions

This study demonstrated the feasibility of designing lighter and more comfortable braces with an equivalent correction as compared to standard braces. This design platform has the potential to further improve brace correction efficiency and its compliance.

Level of evidence

Level II

Keywords

Scoliosis; thoraco-lumbo-sacral orthosis; brace simulation; CAD/CAM; comfort

Manuscript

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Introduction

Adolescent Idiopathic Scoliosis (AIS) is a complex deformity of spine and rib cage. For moderate spinal curvatures (Cobb angle 20° to 40°) an orthopaedic brace treatment is generally prescribed to control curve progression. For thoraco-lumbar and lumbar curves, a common brace prescribed is a thoraco-lumbo-sacral orthosis (TLSO)[1]. Bracing has been the mainstay regarding non-operative treatment for AIS but has not gained complete acceptance; the treatment's long-term effectiveness is still questioned[2, 3]. Other studies demonstrated bracing as an effective non-surgical treatment to prevent curve progression compared to no bracing[4-8]. A correlation was found between immediate in-brace correction and brace treatment's long-term effectiveness[9, 10]. Treatment's final results depend on multiple factors; timing with adolescent growth curve acceleration phase, initial brace correction, patient's flexibility, brace wear time and patient compliance to treatment[1, 11-13].

Negative cosmetic appearance, physical and functional discomfort resulting from pressure points, humidity and restriction of movement can cause poor compliance with prescribed wearing schedules[14-18]. Groups have studied brace wear time by embedding small temperature or pressure sensors to the brace to record average wear time[1, 19-21]. Compliance ranged around 33% to 82% of prescribed wear time and 80% of patients had a tendency to overestimate their compliance[20, 22, 23]. Studies suggest that brace efficiency is related to brace wear time. The more patients complied with brace treatment, the better were their chances to obtain a positive outcome[23-25].

Brace comfort is evaluated qualitatively by the patient during brace installation and at follow-up visits. The comfort notion has a triple origin: psychological, physical and functional[26]. Pressure and friction ulcers are frequent in brace that exerts excessive pressures. To our knowledge, no published studies describe optimal pressure distribution and maximal pressures that can be applied by brace in regard to patient's comfort. There are studies defining pressure pain thresholds for different anatomical regions indicating that all body regions are not equally sensitive[27-31]. These data do not consider AIS patient characteristics and brace design. Visser[32] studied brace discomfort using a Visual Analog Scale (VAS) and pressure sensors. Results showed that discomfort increases with the corrective pad height. Pham[33] used pressure sensors to investigate daily activities pressure variations at different locations in brace. Comfort was not evaluated and tolerable pressure thresholds remained unknown.

Finite element models (FEM) were developed to analyze brace biomechanics[34-37] and rationalize brace design[38, 39]. Combined to a Computer-Aided-Design and Computer-Aided Manufacturing (CAD/CAM) system, FEM now allows the simulation of brace correction, as well as the computation of pressures applied[40]. A clinical evaluation of the in-brace predicted correction using FEM was done on scoliotic patients[40]. So far this work did not include brace design optimization to improve comfort and compliance.

The goal of this study was to improve the design of braces by integrating physical and functional comfort criteria in this new brace design method.

Materials and methods

Experimental study design

15 female patients aged between 11 and 14 years were consecutively recruited over a 6 months period. All participants received a AIS diagnosis, had a curve between 20° and 45° of Cobb angle, an immature skeleton presenting a Risser sign of 0 or 1 and received a standard full-time TLSO prescription. The study was approved by our institutional ethical committee and each participant and their parents gave a written consent.

To compare brace effectiveness, two braces were designed and fabricated for each participating patient: a standard TLSO Boston brace-type (StdBrace) and a TLSO brace computationally improved for comfort (NewBrace). Both braces were installed on the patient by the same orthotist. The StdBrace was fabricated using plaster/cast method. A mould of the patient's body was formed for brace fabrication. A 5 mm foam layer and a heated copolymer sheet were moulded on the plaster to create the brace shell. 15 mm corrective pads were added towards trochanter, thoracic and lumbar regions. The NewBrace was fabricated using a CAD/CAM and simulation brace design method linked to a carving machine. A polyurethane foam bloc was carved according to the CAD model for the brace fabrication. A heated copolymer sheet was employed for brace shell thermoforming. No foam layer and no corrective pads were added as the brace was including corrective regions in its shape. The orthotist knew the study purpose but did not participate in the NewBrace design and only intervened during installation (cutting edges and openings). Using the brace simulator, it was possible to choose between horizontal and oblique tightening straps. The final strap orientation was the result of brace optimization showing the best spinal correction.

Simultaneous bilateral low-dose radiographs (postero-anterior and lateral) (EOSTM, EOS imaging, Paris, France) were taken with both braces to evaluate immediate brace efficacy. Following correction indices were measured on the patient's spine: main thoracic (MT) and thoraco-lumbar/lumbar (TL/L) Cobb angles, kyphosis (T4-T12) and lordosis (L1-L5) angles.

Brace design simulation

The CAD/CAM and simulation brace design method was based on the design platform described by Desbiens-Blais[40]. A 3D reconstruction of the patient's spine, rib-cage and pelvis was done using the calibrated postero-anterior (PA) and lateral (LAT) radiographs[41](Fig.1A). The patient's external torso geometry was obtained using a surface topography system (3-dimensional Capturor, Creaforminc, Levis, Canada)[41](Fig.1B). Radio-opaque markers visible on both X-rays and trunk surface were a priori positioned on anatomical points of the patient's torso and used to register the internal and external geometry reconstructions(Fig.1C). With a previously validated method, the trunk's overall geometry was used to create a personalized FEM using Ansys 13.0 software package (Ansys Inc., Canonsburg, PA, USA)[9, 39](Fig.1D). The FEM principal structure includes thoracic and lumbar vertebrae, intervertebral discs, ribs, sternum, costal cartilages, pelvis, ligaments, abdominal cavity and external soft tissues. The spine model can act in bending, flexion/extension and torsion. Mechanical properties for anatomical structures were taken from published data obtained on typical human cadaveric spine segments[37, 39, 40, 42-45]. A "corrected" model of the patient's torso was generated by applying virtual forces on vertebrae, in such a way to realign the spine in frontal plane. Since the patient's internal and external geometries are linked together, forces applied on selected vertebrae created a correction of the external trunk model using an iterative non-linear resolution method. This corrected torso geometry was introduced into a CAD/CAM software specialized for orthoses design (Rodin4D, Groupe Lagarrigue, Bordeaux, France) and used as a basis for the brace design. Using software's virtual tools, design parameters were methodically tested to obtain a maximized spinal correction. Each time a parameter was modified, brace installation was simulated to observe the effect on spinal correction. The trochanteric pad location (right or left) was first tested. Depending of the type of curve, the corrective regions were then incrementally accentuated by 5 mm until the simulated spinal correction stays stable even with the corrective region depth increasing (±2° Cobb angle). Material was added in order to define relief zones for iliac crests. Using this strategy, between 5 to 10 designs were iteratively simulated for each patient. Design showing the best biomechanical efficiency based on in-brace spinal correction was selected.

The resulting brace was used to generate a brace FEM modeled by 4-node quadrilateral linear elastic shell elements using polyethylene mechanical properties[24]. In order to model friction and force transfer from the brace shell to the patient's trunk surface, a surface-to-surface contact interface was made[46]. The simulation boundary conditions included a fixed pelvis in rotation/translation. T1 vertebra was limited to the transverse plan movements. For each patient, brace installation was simulated using the personalized FEM[47, 48].

<u>Integration of comfort parameters in the brace design method</u>

Brace installation simulation provided the spinal correction with main curves initial and predicted in-brace Cobb angles, T4-T12 kyphosis and L1-L5 lordosis angles were computed using a validated method[49]. Applied pressures on the torso and distance between the brace and patient's skin surface were also computed (Fig.2).

Pressure threshold values, found in the literature, were established for anatomical regions of the torso to represent maximum pressures that could be applied by the brace to be comfortable (Fig.3). Applied pressures simulation was used to verify if the NewBrace design met the pre-establish pressure thresholds.

Using the simulation of the distance between the brace and patient's skin (Fig.2D), brace material situated at more than 6 mm of patient’s skin was removed. This width was selected for the necessary expansion related to the thorax breathing movement and to ensure that pressure regions were large enough to avoid pressure points and pinching patient’s skin. The shape of openings was determined by the shape of regions included in the 6 mm limit (as shown on Fig.2D, green, yellow, orange and red regions were included). Using this strategy, one-third of brace material covering abdomen was removed and large openings were created on brace (at the opposite side of corrective areas and at each iliac crest relief area) in order to lighten the brace design. The lightened brace design was simulated again to verify biomechanical efficiency. Brace thickness and total surface area of both braces were measured for comparison purposes. In order to biomechanically compare both braces' immediate pressure application on patient's torso, a thin and flexible pressure mat was inserted under both braces for a 30 second period acquisition[50]. Measured pressures were compared to simulated pressures to assess the simulation tool. A questionnaire on comfort related to pressures was developed and validated using a small sample of patients and professionals. For each brace, all patients had to fill out the questionnaire. Using a color code (green, yellow and red) corresponding to three different discomfort levels (respectively light, moderate and severe discomfort), participants were asked to draw the location and intensity of discomfort felt during brace wear on figures similar to those shown on Fig.3. An absence of color was considered as an absence of discomfort.

Results

Average Cobb angle prior to bracing was 31° for the main thoracic curve (MT) and 32° for the thoraco-lumbar/lumbar curve (TL/L). Average initial T4-T12 kyphosis and L1-L5 lordosis angles were respectively 21° and 62°.

The NewBrace reduced Cobb angles by 42% (39% for MT curve and 49% for TL/L curve) which were predicted with a difference of less than 5° by the simulation. The StdBrace reduced these angles by 43% (42 % for MT curve and 45% for TL/L curve).

Mean kyphosis and lordosis angles were slightly less reduced with the NewBrace than with the StdBrace (respectively 17° and 55° for the NewBrace vs. 16° and 51° for the StdBrace), which were predicted by the simulation with a difference of less than 7°. Both braces corrected similarly patient's balance. Mean initial imbalance was 10 mm and was corrected to 5 mm for the NewBrace versus 4 mm for the StdBrace.

Globally, 92% of NewBrace measured pressures were similar to the simulation with regard to pressure localization and intensity. Highest pressures were located at thoracic and lumbar regions and at axillary and trochanter extensions. Comparison between simulated and measured pressures is shown for a typical patient in Fig.4.

For 13 patients, NewBrace pressures did not exceed light or moderate discomfort (shown on questionnaire figures). Eleven patients found the NewBrace more comfortable than the StdBrace. Other 4 patients considered the Newbrace as comfortable as the StdBrace. Results obtained using the questionnaire are summarized in Table 1.

The NewBrace did not include a foam layer and corrective pads; therefore, it was in average 61% thinner than the StdBrace. Approximately 32% of the NewBrace material was removed to create large openings. Detailed results for one clinical case comparing the NewBrace to the StdBrace are shown on Fig.5.

Discussion

This study is a first attempt to define and include physical and functional comfort criteria in an optimized brace design method using a FEM (brace simulator) associated to a CAD/CAM system. The outcomes show that comfort integration is possible with consistent clinical results. This study allows a further extension of the simulation platform established by Desbiens-Blais[40]. Results demonstrate the feasibility of an approach to design braces with optimal efficacy while minimizing discomfort parameters.

NewBrace correction was equivalent compared to StdBrace correction for all cases (in-brace Cobb angle difference less or equal to 5°). The design platform allows testing different brace design which can be useful to establish a personalized treatment strategy. The difference between predicted and clinical results for frontal and sagittal angles can be partly explained by boundary conditions imposed for the simulation. It can also be explained by the fact that a TLSO brace has less control over the thoracic segment above T6[51]. This couldn't be considered by the simulation since T1 was constrained by the boundary conditions.

Since the simulation tool helps optimizing immediate in-brace correction, results combining muscle activation and passive forces and long-term progression of the deformity can still not be predicted. However, the correlation between immediate in-brace outcomes and long-term treatment effectiveness was already reported by different studies[6, 9, 11, 52]. Evaluation of only the braces' immediate effect in terms of spinal correction and pressure application can be a limitation. Further studies are required to analyze the mid- and long-term effectiveness of braces designed with the computer approach. A RCT is currently underway in our institution to fully validate the efficiency of braces resulting from this novel design approach.

NewBraces were more comfortable than StdBraces based on the pressures applied and the lightened brace design. Since the torso geometry was acquired in a standing position, NewBraces were found to better fit the patient's physiological shape (plaster mould was taken in a supine position). As it was observed, positioning the patient in a supine position changed the patient's natural shape by flattening the back and abdomen regions and creating greater pressures on rib cage and abdomen.

Using the brace simulator, it was also possible to observe pressure application in 3D like in the study of Labelle et al [53]. Therefore, it could be possible to adjust the brace if needed.

Time allocated for the NewBrace design and installation was reduced in comparison to the StdBrace (half of time needed for plaster method). The external geometry acquisition process was also simplified. It was acquired during the medical visit and took less than one minute. In comparison, the plaster mould method required 24h for plaster application and drying time. This approach has a potential for the treatment of AIS patients requiring a TLSO, but in the current format could have limited use in non-ambulant neuromuscular and early-onset-scoliosis patients. However, these limitations could be overcome by adapting the geometry acquisition process using a manual scanner and modifying the simulation process by changing boundary conditions.

Differences between simulated and measured pressures were mainly located at the pressure mat extremities (at axilla, trochanter and gluteal regions). Aside from this technical detail, this lack of data does not constitute an obstacle for validating the pressures predicted by the simulation. Simulated pressures concurred with 92% of the clinically monitored pressures showing that the pressure simulation can be used as a reliable tool to verify pressure thresholds or to predict intensity and location of the corrective pressures, as also demonstrated by Labelle[53].

Using the same pressure thresholds for all patients remains a limitation since each person has a different tolerance. Pressure thresholds data used for this study were collected from healthy subjects and may not be adapted for AIS patients. Even if pressure thresholds were respected, patients still felt discomfort. However, pressure thresholds can be used as a guide for brace design.

Conclusion

This study demonstrated the feasibility of integrating comfort parameters in brace design, while maintaining biomechanical efficiency. This platform allowed the iterative design of improved brace for comfort using a CAD/CAM system combined with a computational simulation tool. Each patient received a standard TLSO brace and an improved brace for comfort and biomechanical efficiency was clinically assessed using the 3D reconstruction of the spine and a patient's measurement software. NewBraces were 61 % thinner and had 32% less material. They were considered more comfortable in most instances. Simulated correction and pressures were similar to those measured and NewBraces were equivalent in correction compared to StdBraces. This study should be repeated with a larger sample of patients to pursue validation of the design platform and verify the long-term effect of braces conceived with this computerized approach. Finally, we demonstrated that this design platform has the potential to improve brace design by fully integrating comfort parameters without compromising the correction.

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Figures:

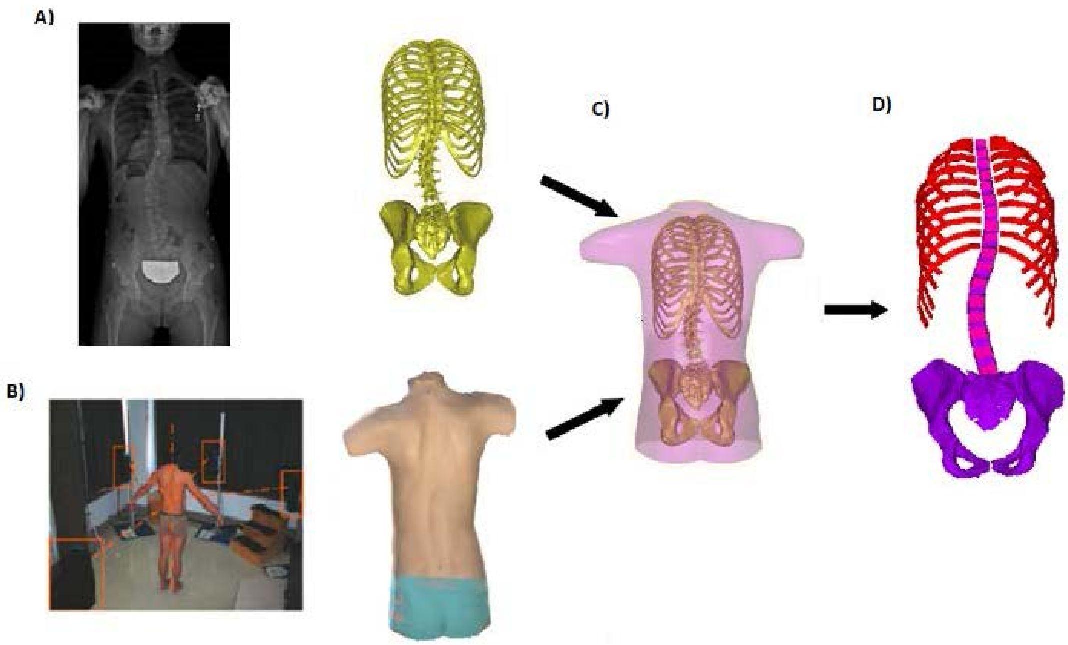

Figure 1-A) Acquisition of the internal geometry using the bi-planar radiographic 3D reconstruction technique; B) Acquisition of the external geometry using a surface topography system; C) Geometries registration; D) Finite element model of the trunk (for clarity, only the skin, spine, partial ribs and pelvis are shown)

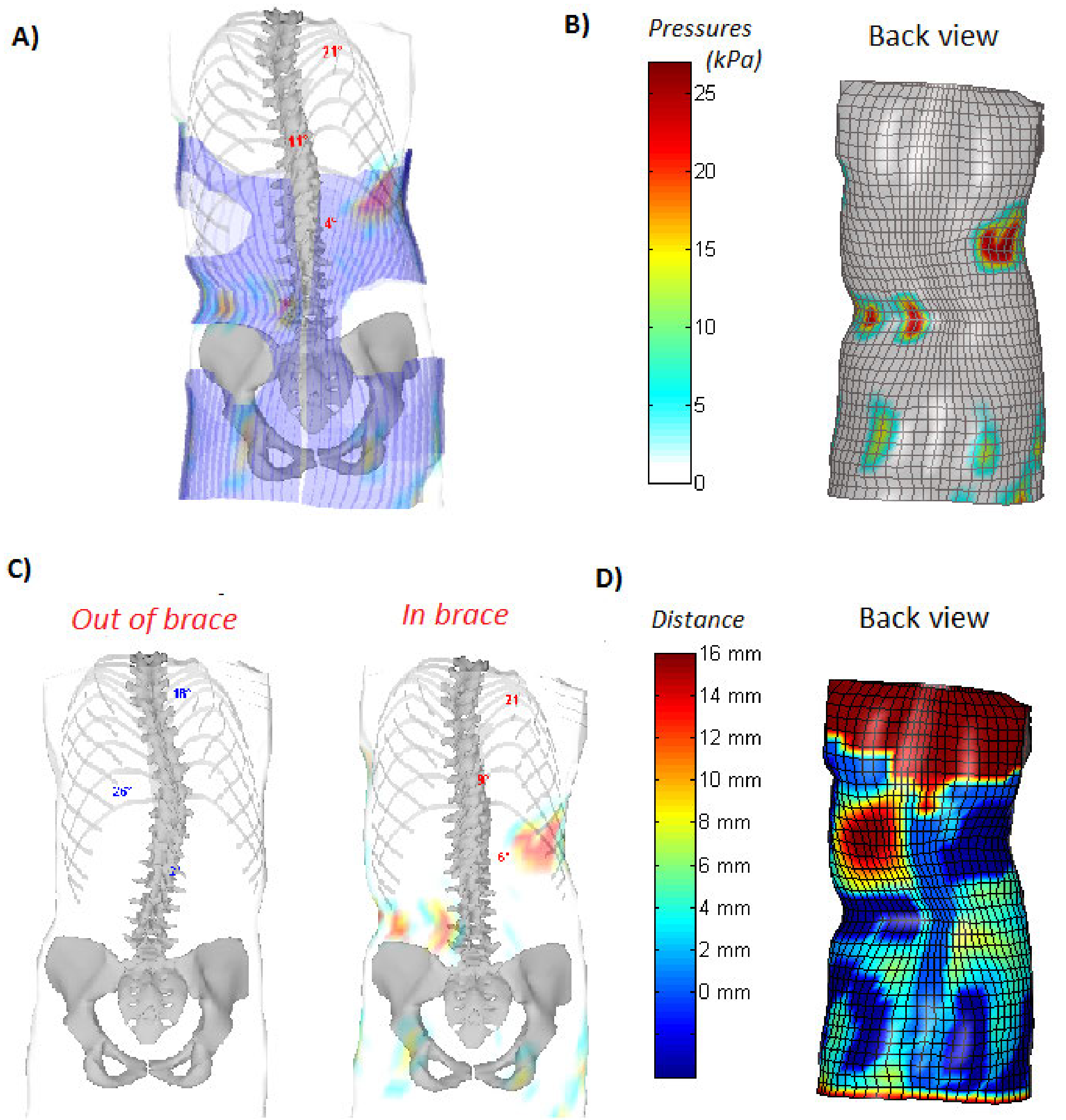

Figure 2-A) Simulation of the brace installation; B) Simulation of the applied pressures (higher pressures are shown by orange and red areas); C) Simulation of the spine correction; D) Simulation of the distance between the brace shell and the patient's skin (the blue color represents the material in 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)

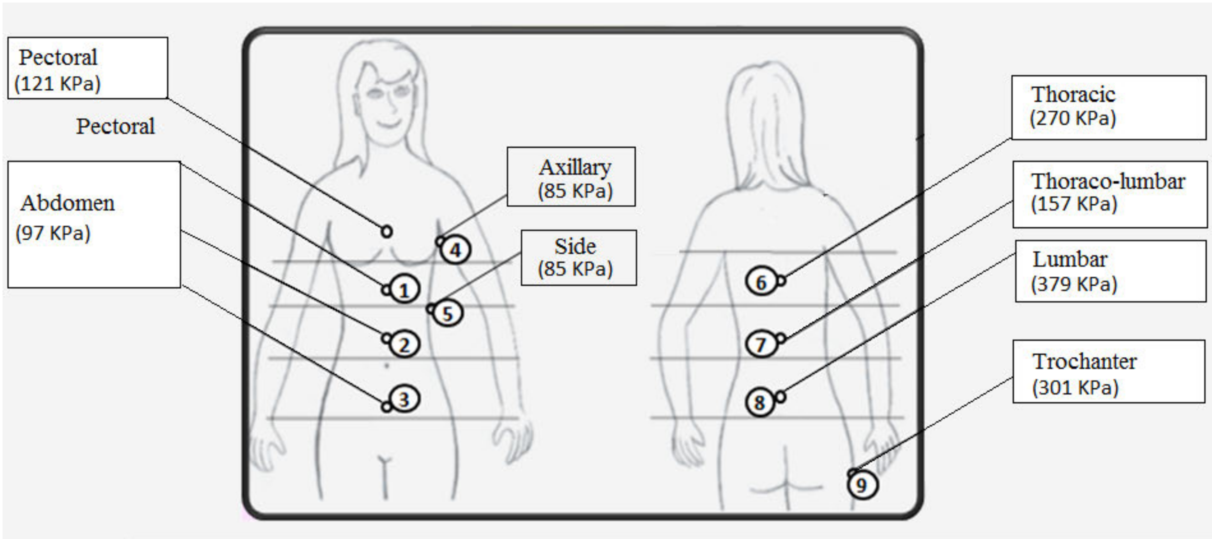

Figure 3-Pressure thresholds used as a guide for brace design (the torso is divided in 9 anatomical regions for which a corresponding specific threshold was found)

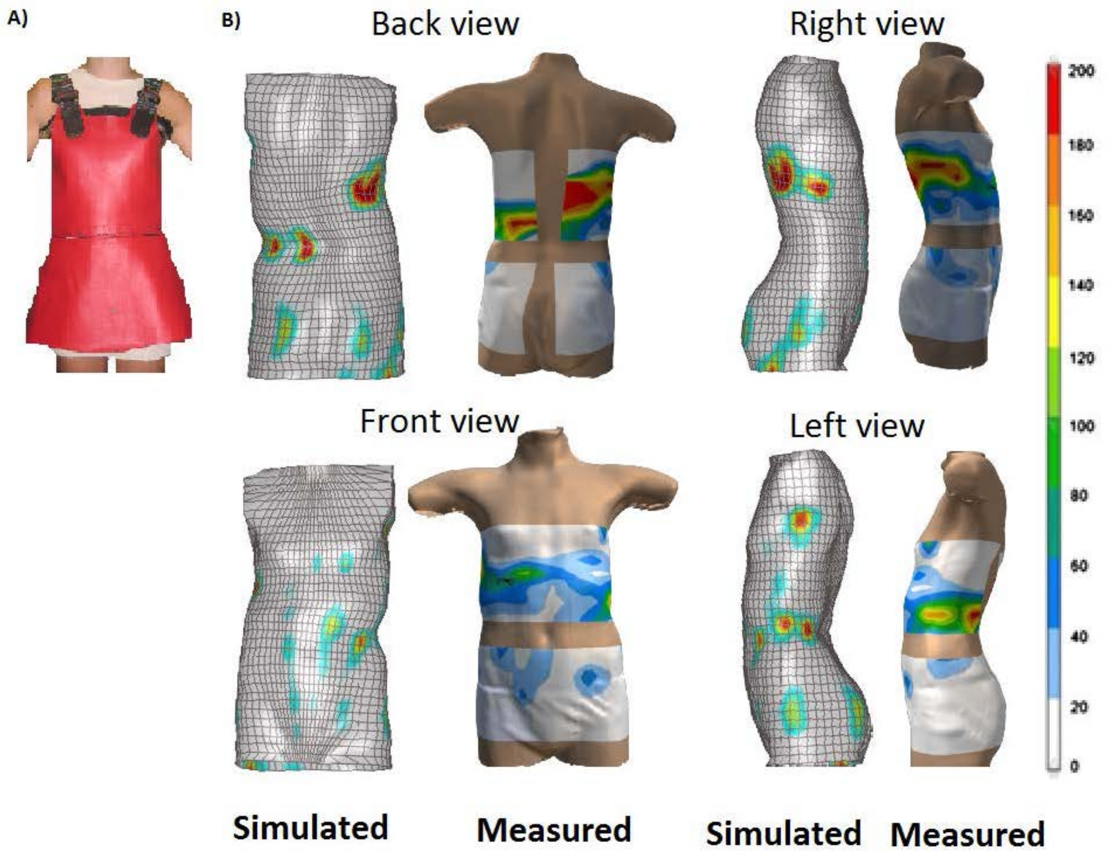

Figure 4-A) The pressure mat worn by a patient (before installing the brace); B) An example of the comparison between the simulated and the measured pressures. For the simulated pressures, the grey color represents an area without pressures and higher pressures are shown by orange and red colors. For the measured pressures, the white color represents the area without pressures and higher pressures are shown by orange and red colors.

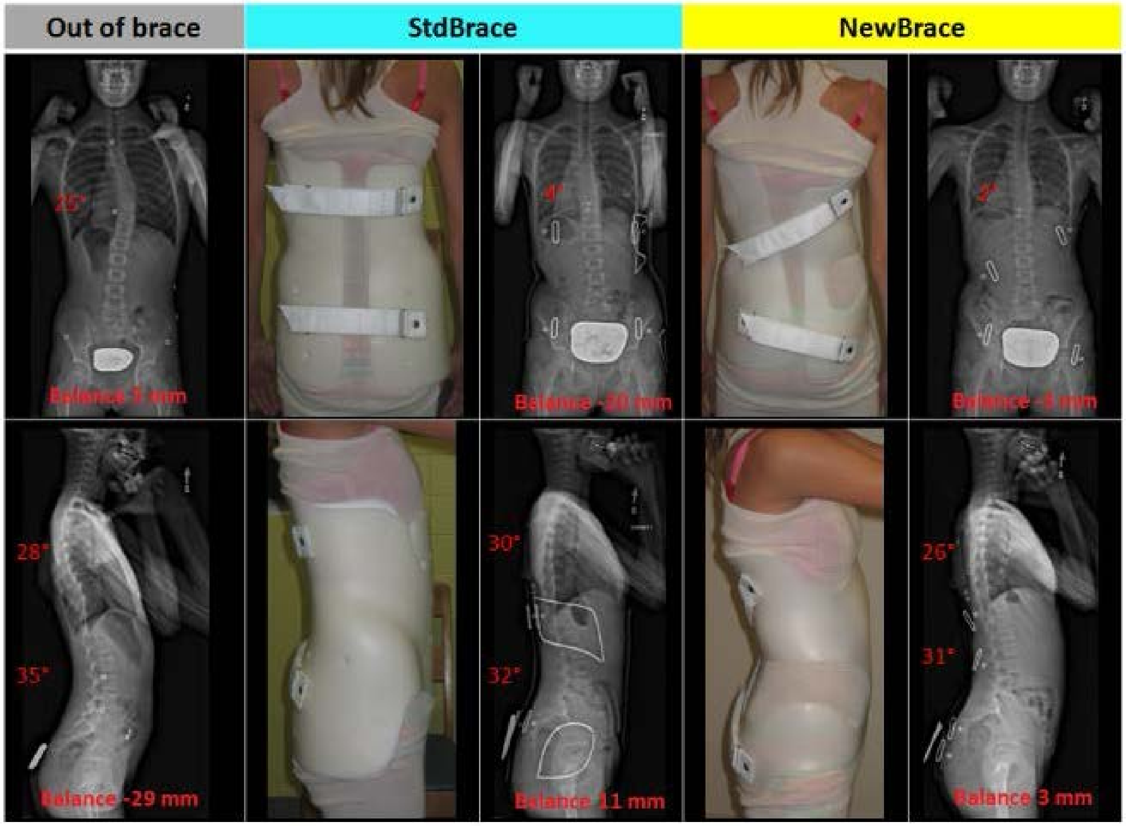

Figure 5-Radiographic results for a typical patient: out of brace (initial curve), with the StdBrace and with the NewBrace, in the postero-anterior and lateral views. Patient's balance is shown in millimeters.

Table1 -Questionnaire results obtained from each patient during brace installation. "No color" reprensents a region were no discomfort is felt. The green color represents a light discomfort, the yellow color a moderate discomfort and the red color a severe discomfort. Only the coloured regions are listed below.

PATIENT	STDBRACE		NEWBRACE	
	Anatomical Region	Level of discomfort	Anatomical Region	Level of discomfort
Patient 1	Thoracic, left side	RED	Thoracic, left side	YELLOW
Patient 2	Thoracic, right side Trochanter, left side	YELLOW GREEN	Thoracic, right side Trochanter, left side	NO COLOR GREEN
Patient 3	Thoraco-lumbar, right side	RED	Thoraco-lumbar, right side	RED
Patient 4	Lumbar, left side	YELLOW	Lumbar, left side	YELLOW
Patient 5	Axillary, left side Trochanter, right side	YELLOW GREEN	Axillary, left side Trochanter, right side	GREEN GREEN
Patient 6	Lumbar, left side	RED	Lumbar, left side	RED
Patient 7	Thoracic, right side Lumbar, left side	GREEN YELLOW	Thoracic, right side Lumbar, left side	NO COLOR YELLOW
Patient 8	Thoracic, right side	GREEN	Thoracic, right side	NO COLOR
Patient 9	Lumbar, left side	RED	Lumbar, left side	YELLOW
Patient 10	Lumbar, right side	YELLOW	Lumbar, right side	NO COLOR
Patient 11	Thoracic, right side Lumbar, left side	YELLOW GREEN	Thoracic, right side Lumbar, left side	NO COLOR YELLOW
Patient 12	Abdomen Lumbar, left side	GREEN GREEN	Abdomen Lumbar, left side	GREEN GREEN
Patient 13	Abdomen Thoracic, right side Lumbar, left side	YELLOW RED GREEN	Abdomen Thoracic, right side Lumbar, left side	GREEN NO COLOR YELLOW
Patient 14	Thoraco-lumbar, right side	YELLOW	Thoraco-lumbar, right side	GREEN
Patient 15	15 Lumbar, left side	RED	15 Lumbar, left side	NO COLOR

Explanatory legend: GREEN = light discomfort, YELLOW = moderate discomfort, RED = severe discomfort