RAE2020

Ergonomic Brace Wear for Adolescent Idiopathic Scoliosis (AIS)

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Title: Ergonomic Brace Wear for Adolescent Idiopathic Scoliosis (AIS)

Descriptor

In this study, ergonomic brace wear for AIS is designed and developed based on clinical applications, materials science, and garment technology, with the aim to control spinal deformity, reduce the possibility of spinal curve progression, and address the needs of patients as well as taking into consideration their psychological concerns. In order to prevent the progression of spinal deformity, a 3-point pressure system and traction force is applied through the ergonomic brace wear by strategically inserting rigid components, like pre-shaped SMAs and paddings. The straps can exert additional corrective and compression forces onto the torso and spine. Also, the seamless design allows the brace to be worn next to the skin, which also helps to reduce the brace weight, offer a softer touch, and prevent uncomfortable markings. Bonding and ultrasonic welding technologies are applied to eliminate the seams and stitches in the brace wear. Therefore, compared to conventional bracing treatment, the new ergonomic brace wear is more aesthetically pleasing and comfortable, so that the compliance with brace treatment can be improved. In total, 31 subjects were invited to participate, with 21 subjects completing the clinical study. 12 subjects tried first prototype of the Ergonomic brace. It has no significant improvement in Cobb angles when comparing with hard brace. Nine subjects tried the second prototype by adding curved SMA struts. Among these subjects, four of them have >5° improvement, and five of them have <5° improvement. Significant differences ($P<0.05$) were found between out-brace and in-brace Cobb's angle in both non-parametric tests and paired T-tests. The design patent was filed in China, and the results have been communicated in the Annals of Biomedical Engineering journal, at three conferences, and at The Global Healthcare Innovation Academy (GHIA) exhibition.

Principal investigator - Dr. Joanne Yip

Associate Professor, ITC,
The Hong Kong Polytechnic University

Dr. Yip, Joanne graduated with a BSc (Hons) in Textile Technology (with first class Honors) in 1999 from the Hong Kong Polytechnic University and obtained her PhD at the same university in 2003. Dr. Yip research interests include new materials and technology, surface treatments on textiles, moulding or seamless techniques used in Intimate Apparel. Recently, her research focus is related to posture correction and control of spinal deformity using a newly developed functional garments. Dr. Yip has published more than 100 referee and conference papers in Textile and Material Science Journals.

Co-investigators

Prof. Kenneth Cheung, Dr. P.Y. Jason Cheung and Dr. Y.H. Kenny Kwan are the co-investigators from HKU who were responsible for providing clinical opinion and subject recruitment for this project. Prof. Kenneth Cheung is the Jessie Ho Professor in Spine Surgery and the Head of the Department of Orthopedics and Traumatology, The University of Hong Kong, the President of The Hong Kong College of Orthopaedic Surgeons and was the President of the (international) Scoliosis Research Society, widely recognised as one of the leading spine societies globally. Dr. Jason Cheung and Dr. Kenny Kwan are clinical assistant professors at the University of Hong Kong. Dr. Cheung research focuses on the degenerative spine, spine deformity and orthopaedic infection. Dr. Kwan research focuses on basic and clinical research into adult and pediatric spine deformity.

Mr. C. Y. Tse is a prosthetics and orthotics practitioner. He provides orthosis consultation and fitting services. The scope of his services include the lumbar sacral and the cervical and thoracic lumbar sacral orthoses.

Dr K.L. Yick and Dr. S.P. Ng are the co-investigators who have also been carrying out scientific studies in the areas of anthropometric measurements, advanced materials and 3D modeling. Dr. Yick has carried out a number of GRF projects in patient clothing, such as the development of a textile nest and a phototherapy eyepatch protector for neonates in hospitals, pressure therapy gloves for hypertrophic scar treatment, and a corset for children with scoliosis (in the capacity of PI). Dr. Ng focuses on 3D body scanning, body motion capturing and garment pressure modeling. He also specialises in 3D modeling technology and stress analysis of textile composites by using the finite element method. He has formulated biomechanical finite element models for the arm, lower torso and chest, and a girdle-skin pressure prediction model from fabric stress- strain properties, fabric tension and body curvature.

As shown above, **the research team has extensive research experience** on clinical experience with scoliosis patients, anthropometric measurements, evaluation of material properties, garment technology and 3D modeling. In response to the psychological aversion and poor compliance of scoliosis patients in current brace treatment, the team has consolidated some previous research work that is related to the proposed brace development.

Research Output – First published on 27-June 2017

- Ergonomic brace wear with 3-point pressure system and traction forces.
- Selected suitable materials for ergonomic brace wear.
- Applied seamless and bonding techniques for comfort and possibility of mass production.
- Strategically inserted the SMA into the ergonomic brace wear
- Performed wear trial

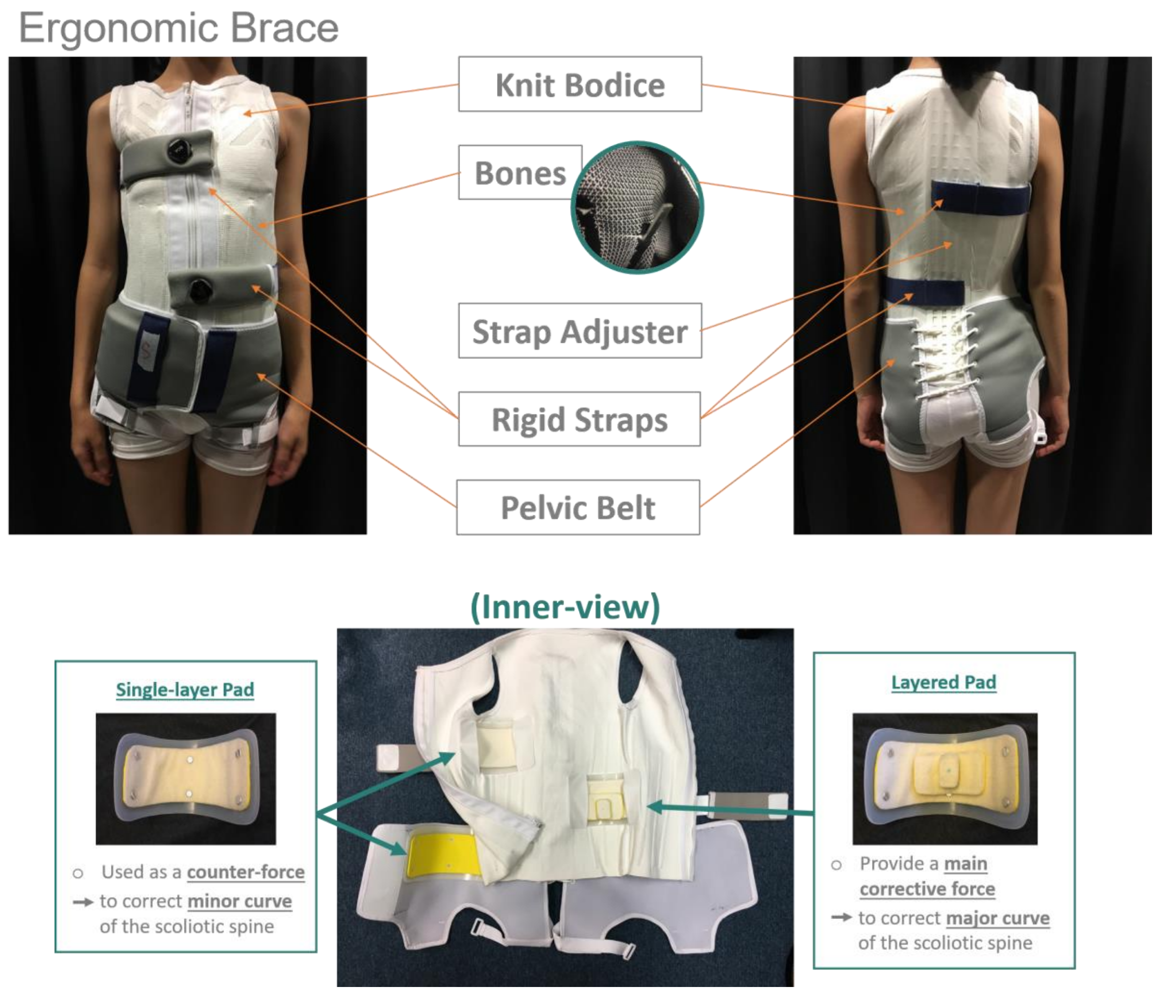


Fig. 1 Different types of braces to treat adolescent idiopathic scoliosis

Research Questions
Background

Adolescent Idiopathic Scoliosis (AIS)

Adolescent idiopathic scoliosis (AIS) is the most prevalent 3-dimensional spinal deformity that primarily affects peripubertal females[1] (**Fig. 2**). This condition involves a curvature of the thoracolumbar spine that is greater than 10° in the coronal plane. The development of scoliosis is attributed to abnormal skeletal growth and overgrowth of the anterior spinal column with uncoupled neuro-osseous growth[2]. Idiopathic scoliosis (IS) is the most common type of scoliosis and affects about 3% of children worldwide[3].

The onset of IS typically coincides with the period of growth during adolescence and affected youths are at risk of increasing deformity until they stop growing[4-5]. As well, the physiological health of patients may be affected, as IS negatively affects their cardiac and pulmonary systems if the spinal deformity is allowed to progress. Consequently, it is very important to monitor and control the spinal curvature once AIS has been diagnosed.

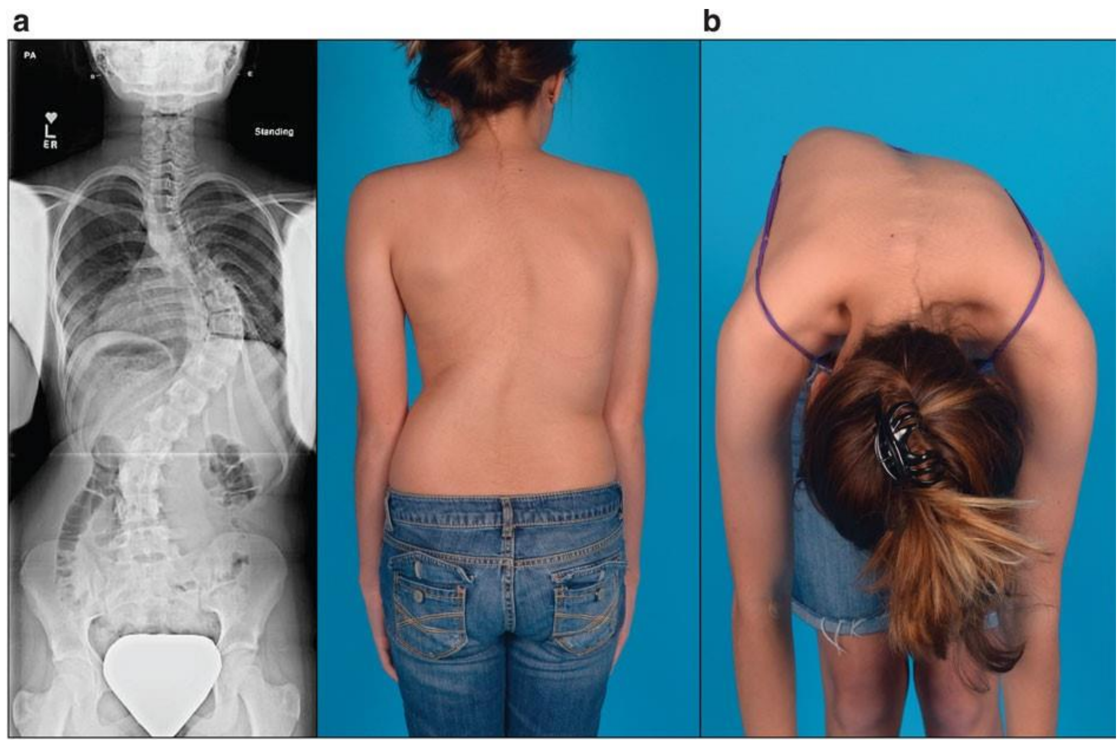


Fig. 2 (**a**) Lateral radiograph image of prototypical right thoracic spinal curvature. Shoulder imbalance evident in clinical photograph. (**b**) Prominent rib hump evident with forward bending[6]

Research Questions
Background

Braces for AIS

The diagnosed treatment for AIS patients is based on the type of curve, age and severity of the spinal curvature (**Fig. 3**). Surgery is recommended for severe deformity in which the spinal curvature is greater than 45 degrees while observation is recommended for more mild cases in which the spinal curvature is less than 20 degrees. The most common non-invasive type of treatment for patients with a smaller spinal curvature is bracing, usually for those with a curve greater than 20 degrees but less than 45 degrees at Risser stages 0, 1 or 2[7-10].

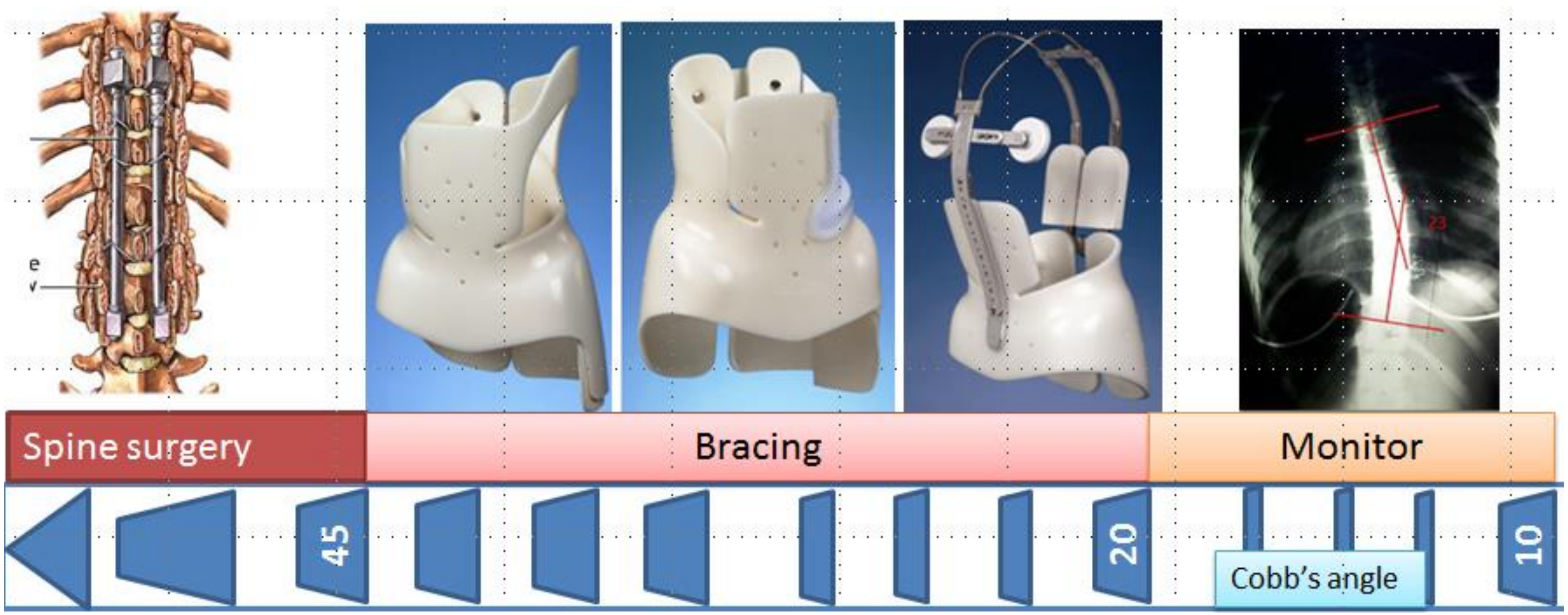


Fig. 3 Scoliosis Research Society Guidelines for Treatment of Scoliosis

Research Questions

Background

Bracing applies external corrective forces onto the spine and trunk by mainly using rigid and flexible braces. These two types of braces have the same objectives to correct scoliosis in the three main planes and reduce its progression which may reduce or avoid the need for spinal fusion surgery. Mechanical forces are applied onto the spine and trunk, such as 3-point pressure or dynamic forces, with the aim to restore the normal contours and alignment of the spine[11-12].

The Boston brace and Progressive Action Short Brace (PASB) (**Fig 4a**) are two examples of rigid braces. Their biomechanical principle is to control the spine dynamics with a special geometric design that would apply external forces and thus reduce spinal deformity with the generation of internal corrective forces during natural movement[13-14]. Then there are semi-rigid braces, in which the TriaC brace is a popular example (**Fig 4b**), because the brace can be used for the treatment of all types of curves except those with an apex at the 12th thoracic and the 1st lumbar vertebra. This brace has three different functional elements: a frame, elastic elements, and pelottes. Corrective forces are produced through a 3-point pressure system. The force system used in the frontal plane of the TriaC brace is similar to that of conventional braces but can only act on the thoracic region in the sagittal plane[15-17]. Finally, there are flexible braces, and SpineCor is a good example (**Fig 4c**). The correction principle of Spinecor is based on spinal coupling mechanics. SpineCor has a pelvic base, crotch bands and thigh bands that act as a fastening point. The bolero and corrective bands correct the scoliosis curve. The placement and tension of the brace can be adjusted before treatment is started[18-19] which allows accommodation of different spinal curvatures.

(a) Rigid brace- PASB (b) Semi-rigid brace- TriaC (c)Flexible brace- SpineCor

Fig. 4 Different types of braces to treat adolescent idiopathic scoliosis

Research Questions
Background

In general, rigid braces provide stronger corrective forces. Rigid brace wear is recommended for up to 23 hours each day until growth is completed (approximately 4-6 years) for its effectiveness. Recently in 2013, Dr. Stuart Weinstein reported the results of an NIH-funded project, Bracing in Adolescent Idiopathic Scoliosis Trial (BrAIST), at the 48th Annual Meeting of the Scoliosis Research Society in Lyon, France. His results showed that bracing significantly reduces the progression of high-risk curves to the threshold for surgery in patients with AIS. The benefit increased with longer hours of brace wear[22]. **Fig. 5** shows the rate of treatment success according to average hours of daily brace wear. On average, the subjects would wear the brace 12.1±6.6 hours per day. The lowest quartile of wear (mean hours per day, 0 to 6.0) is associated with a success rate of 42%.

The low compliance rate is due to ***discomfort***, activity limitations and ***unacceptable appearance of the brace***.

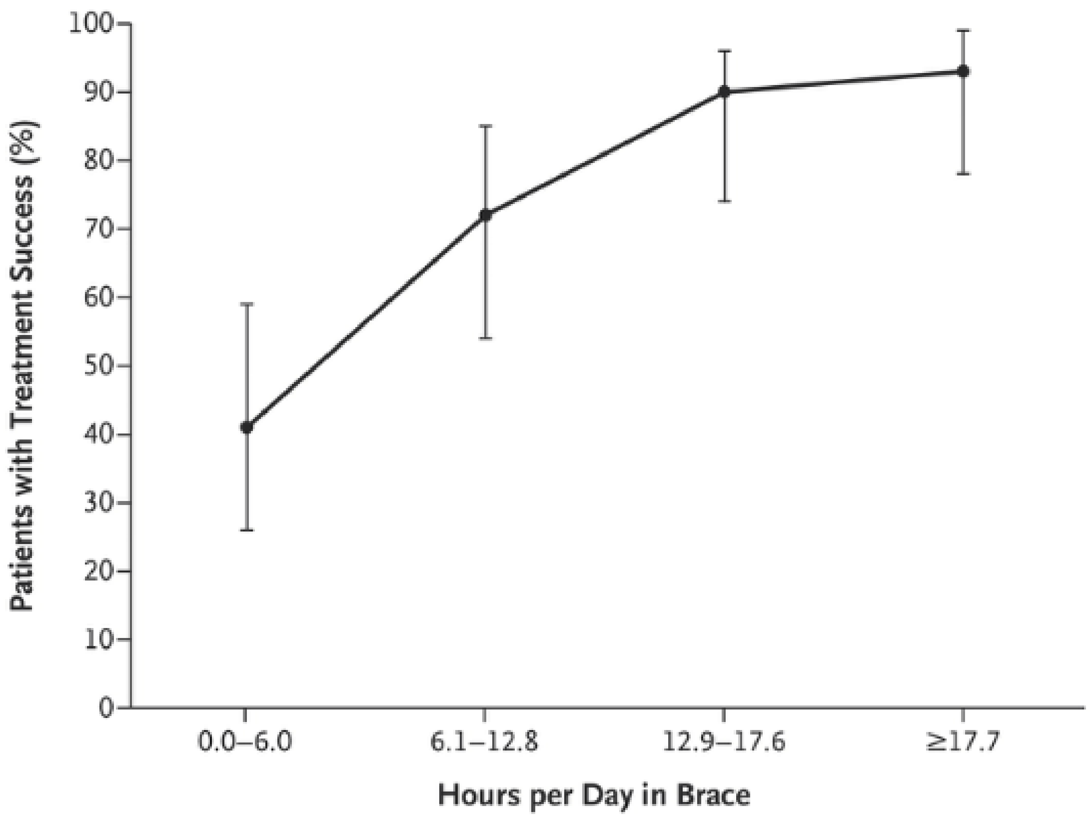


Fig. 5 Rate of treatment success vs. average hours of daily brace wear[22]

Research Questions

AIS is a multi-factorial, three-dimensional deformity of the spine and trunk which is prevalent and sometimes progressive during rapid periods of growth in apparently healthy children. Generally, bracing is suggested for those with AIS and a spinal curve between 20-45 degrees. Longitudinal statistical studies show that most of these patients are prone to depression[23]. There is also low compliance to treatment with a rigid brace because these braces are uncomfortable and have negative psychological effects on wearers due to the awkward and bulky appearance[24]. Most parents and adolescents also find it difficult to accept that an orthosis (regardless whether the brace is rigid, semi-rigid or flexible) is required at such a young age.

Therefore, in response to the low compliance and aversion towards braces, **a garment type of brace wear** that is **aesthetically pleasing** is proposed, which could be more readily accepted by patients and consequently increase user compliance while also addressing psychological barriers to brace use during treatment.

In order to prevent the progression of spinal deformity, **a 3-point pressure system** and **traction forces** will be applied through the ergonomic brace wear by strategically inserting rigid components, like pre-shaped SMAs and paddings. The supportive shoulder straps and waist band can exert additional corrective and compression forces onto the torso and spine. Also, the seamless design allows the brace to be worn next to the skin, which also helps to reduce the brace weight, offer a soft touch, and prevent uncomfortable markings. Bonding and ultrasonic welding technologies will be applied to eliminate the seams and stitches in the brace wear.

Therefore, compared to conventional bracing treatment, the new ergonomic brace wear is more aesthetically pleasing and comfortable to wear so that the compliance with brace treatment can be improved.

Research Field & Key Works Referenced

Biomechanical principles for spinal correction based on:

Rigo Classification – to classify type of scoliosis patients

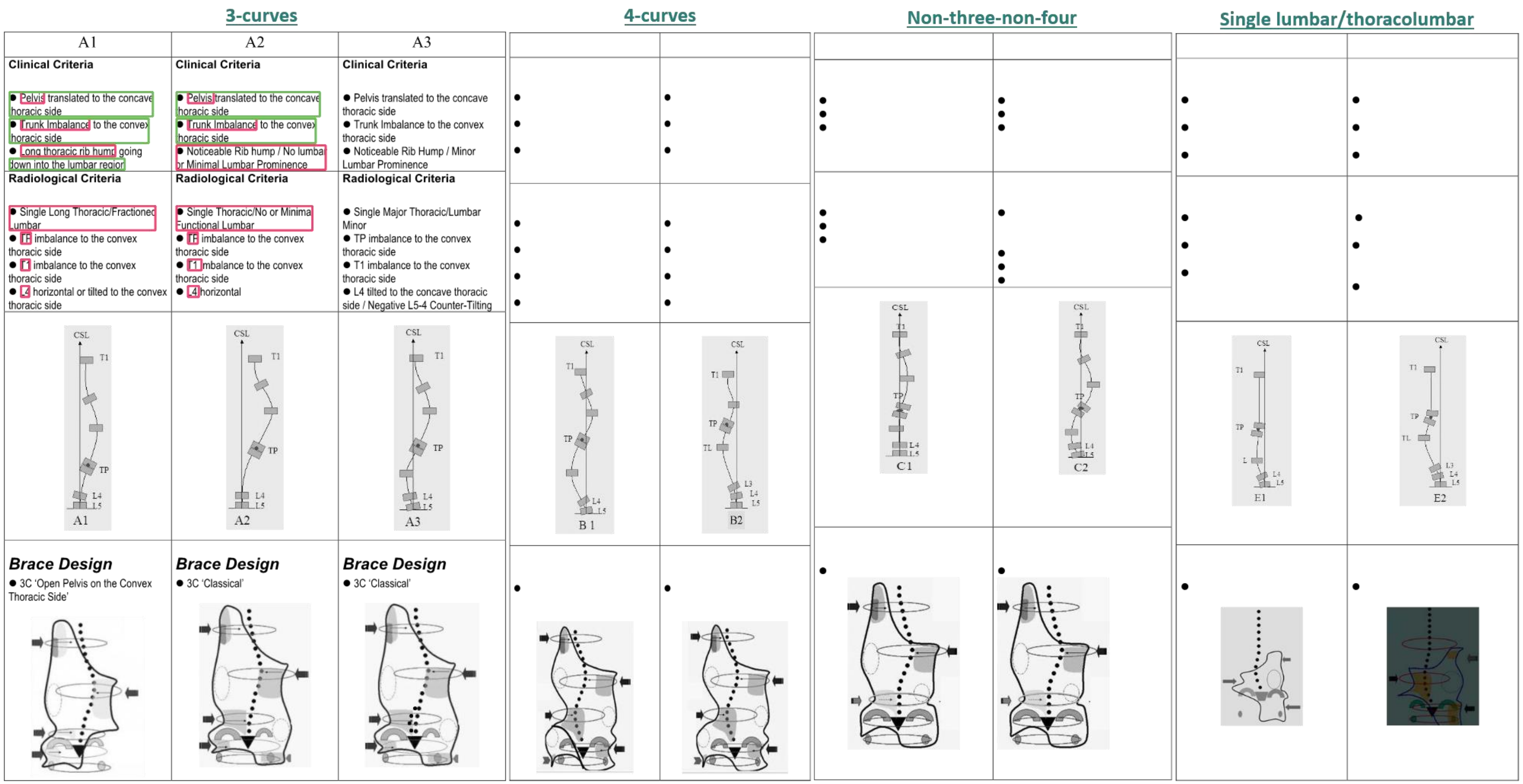
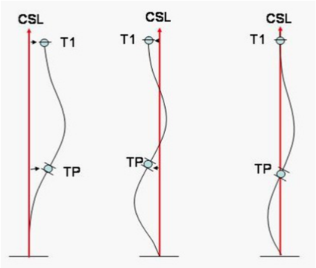


Fig. 6 Rigo classification

Research Field & Key Works Referenced

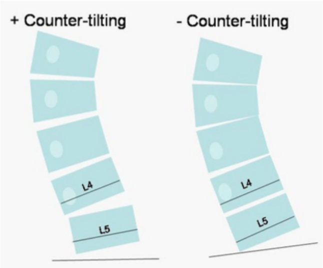
Biomechanical principles for spinal correction based on:

Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) consensus paper on brace action: TLSO biomechanics of correction



Position of T1 and transitional point (TP) on central sacral line (CSL):

- Balanced
- Imbalanced (T1/TP-offset) to the convex/concave thoracic side



Orientation of L4 in frontal plane and its relationship with L5

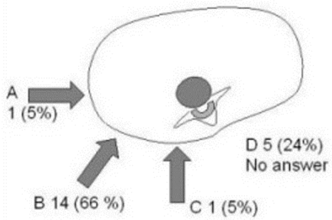


Fig. 7 TLSO biomechanics of correction

Thoracic Pad(s)

Level of the pad:
apical vertebra

Force vector:
oblique (dorso-lateral to ventro-medial direction)

Derotation:
'pair of forces' (ventral + dorsal pad)

Lumbar Pad

Level of the pad:
apical vertebra

Force vector:
oblique (dorso-lateral to ventro-medial direction)

Pelvic Section

Follow the Rigo Classification

Positive L5-4 counter-tilting:
open pelvis (except B2)

Negative L5-4 counter-tilting:
A2, A3 -> asymmetric pelvic design
C1, C2 -> neutral pelvic design

Research Methods & Materials

Milestone 1: Design and develop ergonomic brace wear for youths with adolescent idiopathic scoliosis.

- Task 1: Design and development of ergonomic brace wear with 3-point pressure system and traction forces.
- Task 2: Material selection for ergonomic brace wear.
- Task 3: Seamless and bonding techniques for comfort and possibility of mass production.

Milestone 2: Manufacturing and optimise the pressure and corrective forces applied through the ergonomic brace wear by conducting material testing.

- Task 1: Material testing for choosing the most suitable parameter of materials.
- Task 2: Manufacturing processes for producing the ergonomic brace wear.
- Task 3: Strategically insert the SMA into the ergonomic brace.

Milestone 3: Overall evaluation of the effectiveness of ergonomic brace wear for adolescents with scoliosis.

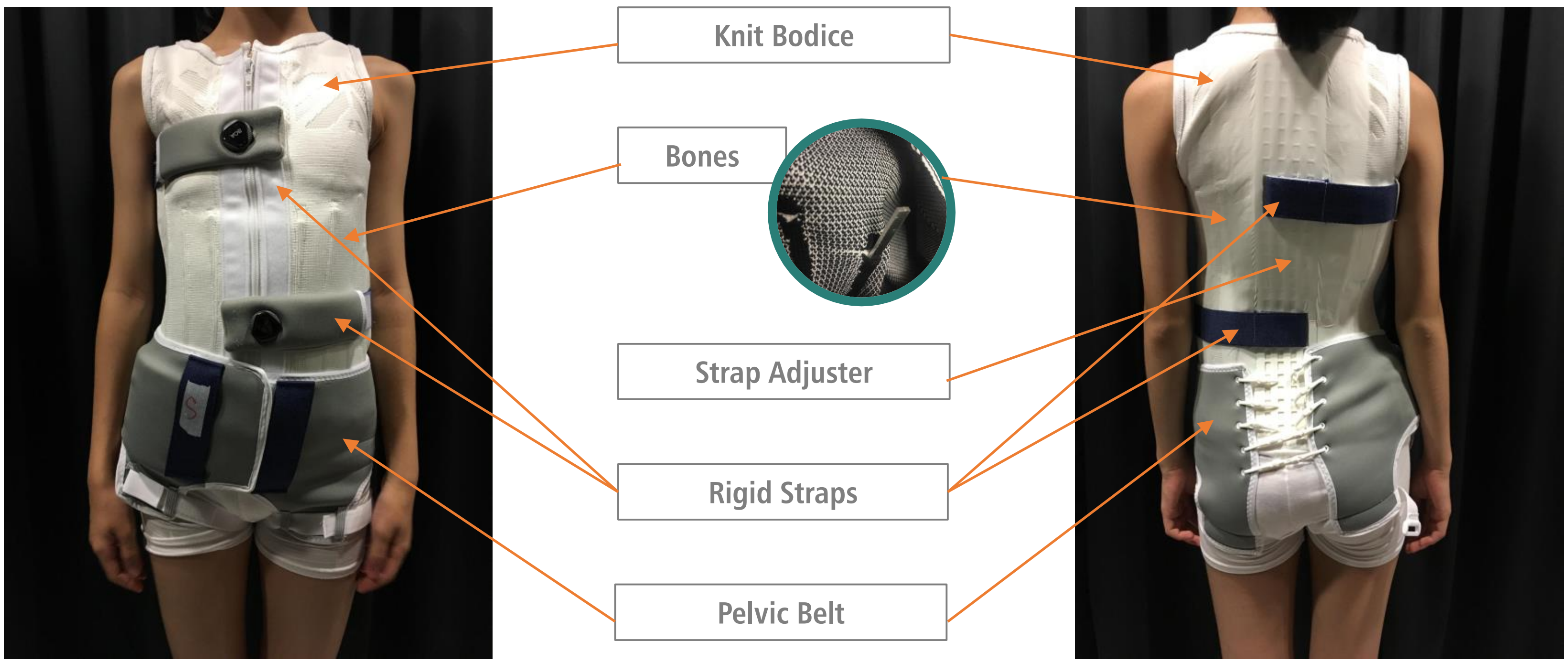
- Task 1: Subject recruitment.
- Task 2: Preliminary tests.
- Task 3: Clinical trial

Research Methods & Materials

Milestone 1: Design and develop ergonomic brace wear for youths with adolescent idiopathic scoliosis.

Task 1: Design and development of ergonomic brace wear with 3-point pressure system and traction forces.

Ergonomic Brace

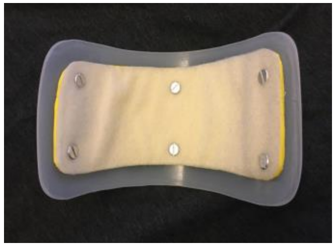


Research Methods & Materials

Task 1: Design and development of ergonomic brace wear with 3-point pressure system and traction forces.

(Inner-view)

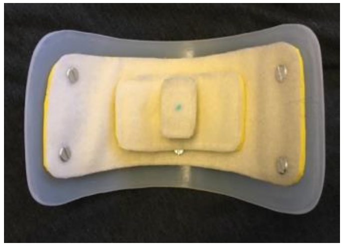
Single-layer Pad



- Used as a **counter-force**

→ to correct **minor curve** of the scoliotic spine

Layered Pad

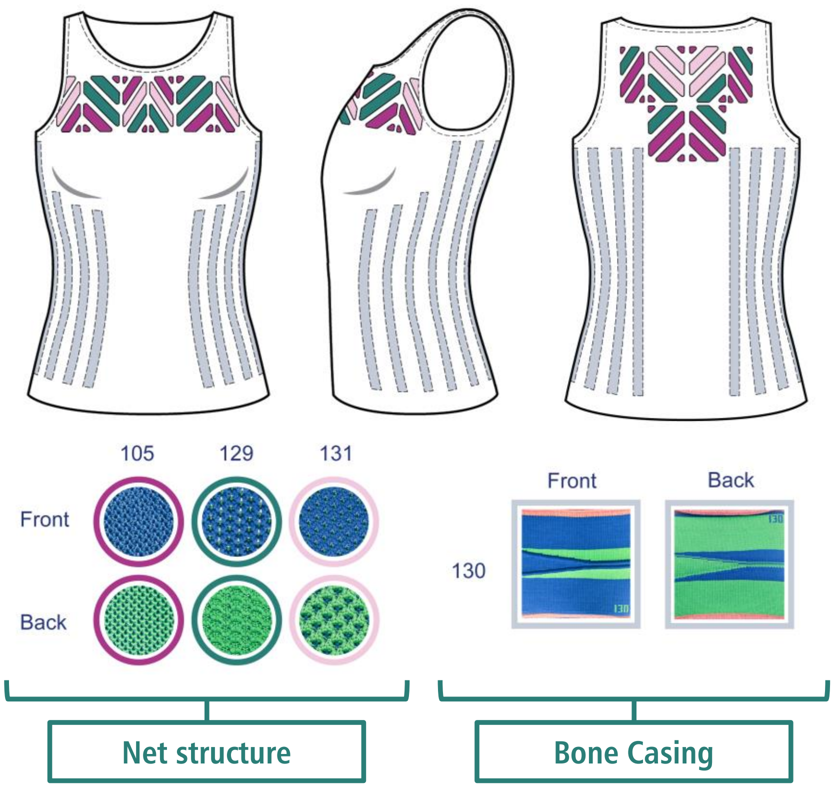


- Provide a **main corrective force**

→ to correct **major curve** of the scoliotic spine

Research Methods & Materials

Task 2: Material selection for ergonomic brace wear.



Features:

1. **Net structure**: breathability
2. **Use of the cool-to-touch and deodorant yarn:** dry and refresh
3. **Bone casing**: to keep the posture of the patient upright and to prevent the bodice from puckering

Prototype

Tight-fitting Bodice

Research Methods & Materials

Task 3: Seamless and bonding techniques for comfort and possibility of mass production.

Seamless knitting machine

Knitted Prototypes

Model:
STOLL CMS ADF 32 BW

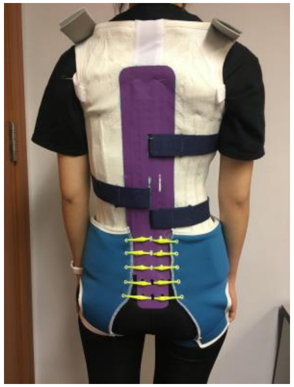
Features:
1. E7.2 fabric gauge
2. 50" (127cm) working width
3. Equipped with weave-in device

Research Methods & Materials

Task 3: Seamless and bonding techniques for comfort and possibility of mass production.

3D printing + Heat welding film

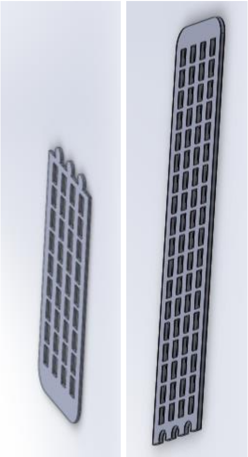
Front



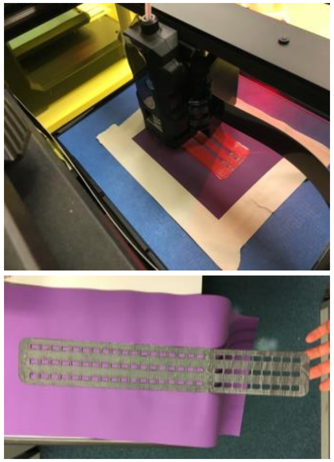
Back

Ergonomic Brace

Steps of making the strap adjuster:



1. Make a 3D drawing with SolidWorks



2. 3D print on the heat welding film

3. Fix onto the bodice by using the heat-press machine

Research Methods & Materials

Milestone 2: Manufacturing and optimise the pressure and corrective forces applied through the ergonomic brace wear by conducting material testing.

Task 1: Material testing for choosing the most suitable parameter of materials.

Tensile Strain and Recovery

Swatches

Knit Structure
Double jersey with inlay

Combination of Yarn
1. 70D/48F Aqua-x
2. 75D/36F Freshgear
3. Inlay: Double covered yarn (DCY)

Tensile Test

Equipment: Instron 4411
Standard: ASTM D6614
Setting:
- 200mm gauge length
- 4lb (17.8N) maximum load
- 300mm/min speed

Steps:
1. **Extend** until reaches the maximum load (4lb)
2. **Hold** at the maximum load for **5 minutes**
3. **Return** to the original gauge
4. **Hold** at the original gauge for **5 minutes**

Research Methods & Materials

Task 1: Material testing for choosing the most suitable parameter of materials.

	Yarn	Stretch (%)	Growth (%)	Recovery (%)
Target swatch	-	45.21	2.18	95.18
Swatch A1	Front: 70D/48F Aqua-x x 4 ends + 75D/36F Freshgear x 4 ends Back: 70D/48F Aqua-x x 4 ends + 75D/36F Freshgear x 4 ends **Inlay: [280D (spandex) + 150D + 150D] 580D DCY x 1 end**	81.57	3.75	95.4
Swatch B1	Front: 70D/48F Aqua-x x 4 ends + 75D/36F Freshgear x 4 ends Back: 70D/48F Aqua-x x 4 ends + 75D/36F Freshgear x 4 ends **Inlay: [350D (spandex) + 140D + 140D] 630D DCY x 1 end**	47.95	5.52	88.5
Swatch C1	Front: 70D/48F Aqua-x x 4 ends + 75D/36F Freshgear x 4 ends Back: 70D/48F Aqua-x x 4 ends + 75D/36F Freshgear x 4 ends **Inlay: [280D (spandex) + 150D + 150D] 580D DCY x 1 end**	70.71	3.91	94.47
Swatch D1	Front: 70D/48F Aqua-x x 4 ends + 75D/36F Freshgear x 4 ends Back: 70D/48F Aqua-x x 4 ends + 75D/36F Freshgear x 4 ends **Inlay: Zimmermann Ultraelastic x 1 end**	104.29	4.99	95.22
Swatch A2	Front: 70D/48F **Aqua-x** x **8 ends** Back: 75D/36F **Freshgear** x **8 ends** **Inlay: [PE 150D (spandex) + 135D + 135D] 420D DCY x 1 end**	87.7	3.74	95.73
Swatch B2	Front: 75D/36F **Freshgear** x **8 ends** Back: 70D/48F **Aqua-x** x **8 ends** **Inlay: [PE 150D (spandex) + 135D + 135D] 420D DCY x 1 end**	**68.34**	**2.36**	**96.55**
Swatch C2	Front: 70D/48F **Aqua-x** x **6 ends** Back: 75D/36F **Freshgear** x **6 ends** **Inlay: [PE 150D (spandex) + 135D + 135D] 420D DCY x 1 end**	109.57	4.83	95.6
Swatch D2	Front: 70D/48F **Freshgear** x **6 ends** Back: 75D/36F **Aqua-x** x **6 ends** **Inlay: [PE 150D (spandex) + 135D + 135D] 420D DCY x 1 end**	83.83	3.78	95.49

Research Methods & Materials

Task 2: Manufacturing processes for producing the ergonomic brace wear.

Ergonomic Brace

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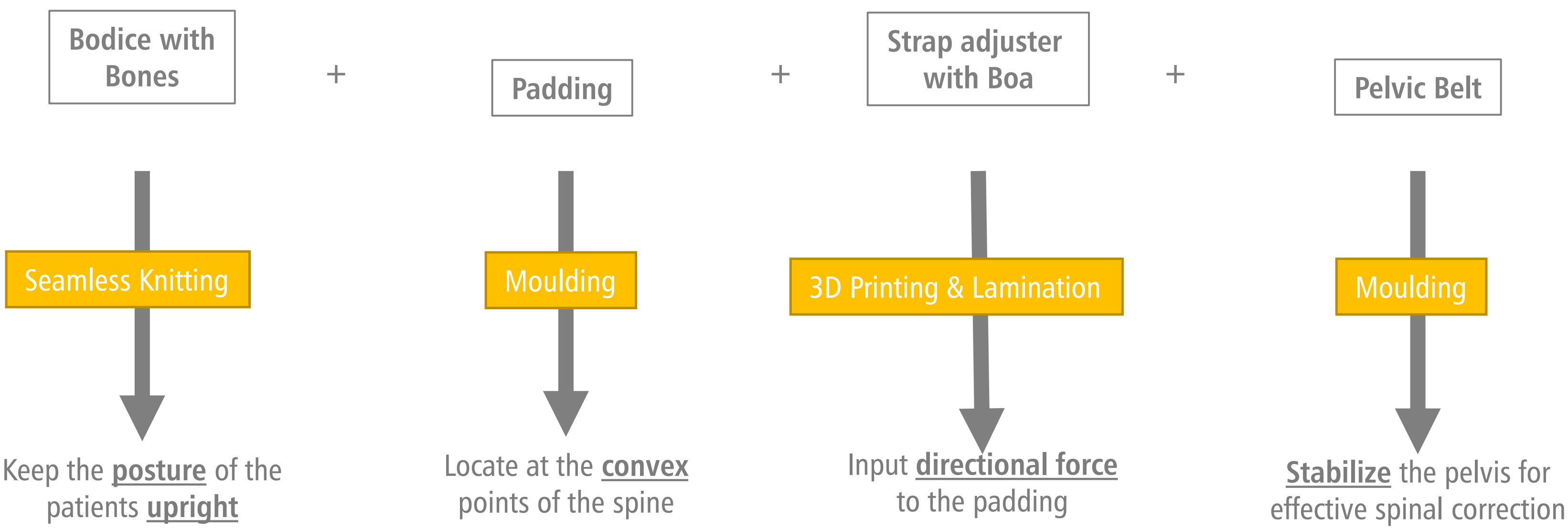
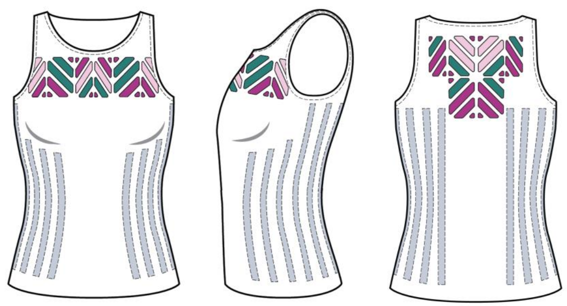
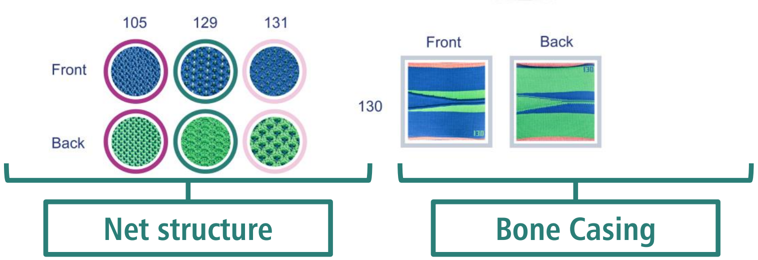


Research Methods & Materials

Task 2: Manufacturing processes for producing the ergonomic brace wear.

(Tight-fitting Bodice with Bones)





Seamless Knitting

Features:

1. **Net structure**: breathability
2. **Use of the cool-to-touch and deodorant yarn:** dry and refresh
3. **Bone casing**: to keep the posture of the patient upright and to prevent the bodice from puckering

Prototype

Research Methods & Materials

Task 2: Manufacturing processes for producing the ergonomic brace wear.

(Auxiliary: Padding)

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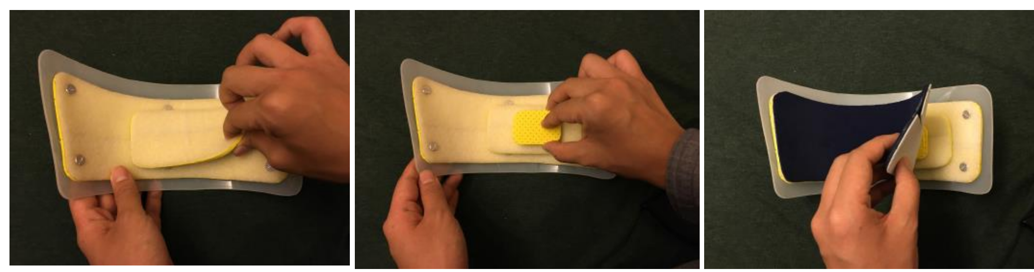
For major curve

For minor curve

Moulding with vacuum forming machine

Padding Layering Idea



1. **Thin edge:** to **prevent bulging** that shown through the brace if padding with thick edge is used
2. **Peak height area:** to give **concentrated** corrective **force** to the spine
3. **Adjustable position of peak height:** to allow **customization** according to the spinal situation of each patient

Research Methods & Materials

Task 2: Manufacturing processes for producing the ergonomic brace wear.

(Auxiliary: Strap adjustor)

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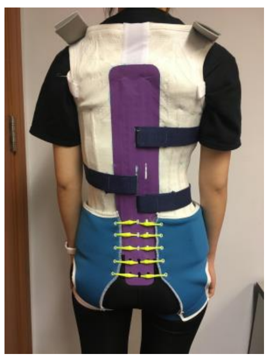
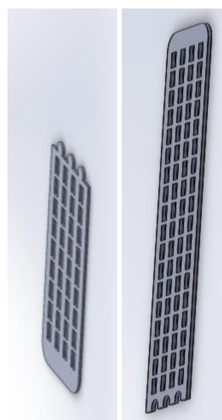


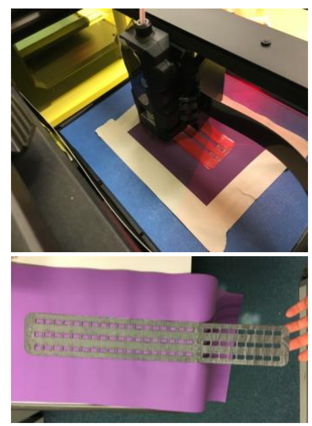
Deformation problem of the strap adjuster:

Resolved by fixing it onto the bodice with heat welding film

Steps of making the strap adjuster:

3D Printing & Lamination



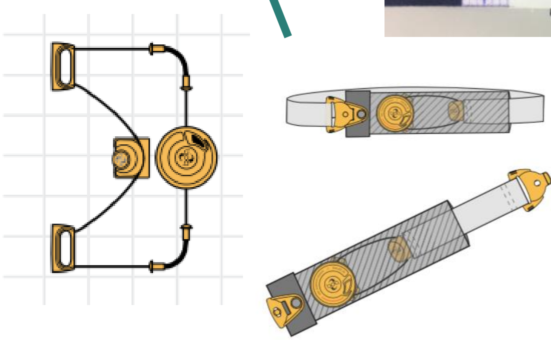


1. Make a 3D drawing with SolidWorks
2. 3D print on the heat welding film
3. Fix onto the bodice by using the heat-press machine

Research Methods & Materials

Task 2: Manufacturing processes for producing the ergonomic brace wear.

(Auxiliary: Strap adjustor)



Pros

1. **Rigid strap:** more **stable force** (verses elastic strap)

2. **Boa technology:** force increment can be easily made with **one hand**

Research Methods & Materials

Task 2: Manufacturing processes for producing the ergonomic brace wear.

Design 1

Problem:
Sliding up with body movements

Design 2

Sliding up problem is **resolved**

Problem:
Bulging, esp. during sitting

Design 3

Sliding up problem is **resolved**

Bulging problem is much **improved**

(Auxiliary: Pelvic Belt)

Research Methods & Materials

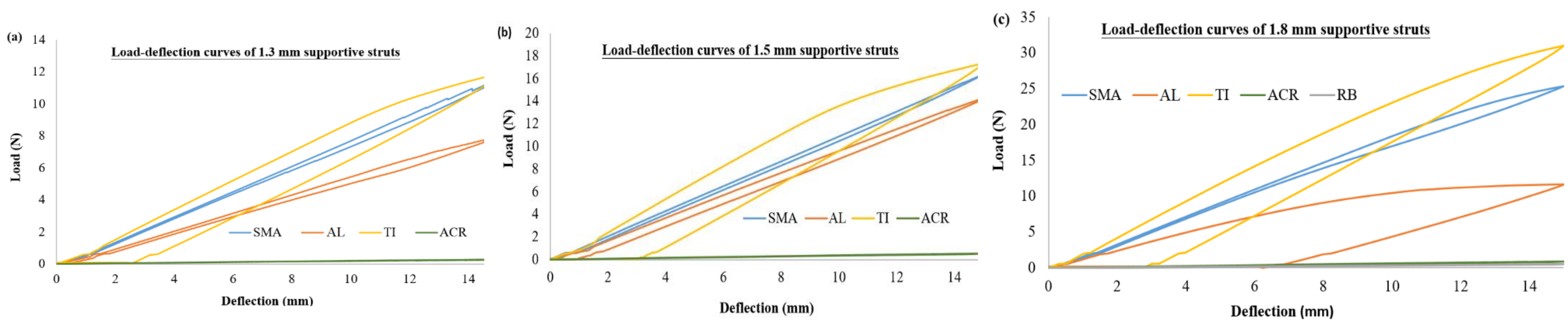
Task 2: Manufacturing processes for producing the ergonomic brace wear.

The materials and accessories mentioned before for making **forty Ergonomic brace** wears were purchased and prepared. The brace wears were assembled according to size of recruited subjects.

Research Methods & Materials

Task 3: Strategically insert the SMA into the ergonomic brace.

- The resin bones (RBs) were used as the supportive struts for the Ergonomic brace and inserted into the channels.
- All of these RBs have the same width (5 mm) but with 3 different thicknesses of 1.3, 1.5 and 1.8 mm.
- In this study, four other types of materials are used as the struts for comparison purposes: acrylic (ACR), aluminum (AL), titanium (TI) and shape memory allow (NiTi) (Ti–55 wt.% Ni).
- The size of these struts was determined in accordance with the original RBs used in the girdle.
- All of the samples were placed in a conditioned room (23°C ± 2°C, 50% ± 10% relative humidity) for 40 hours prior to the commencement of testing.

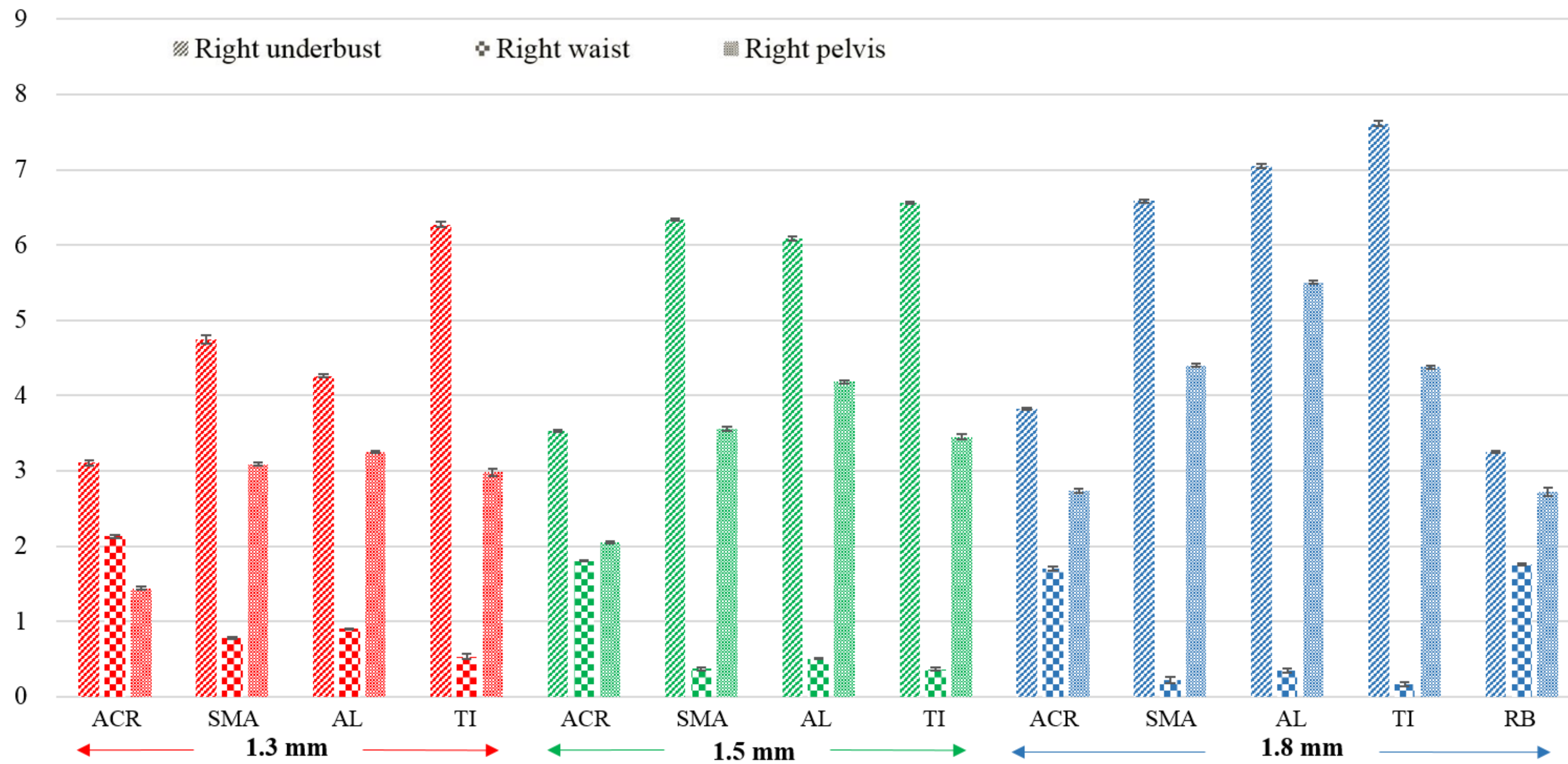


Load-deflection curves of different supportive struts at bending depth of 15 mm
(keys: ACR= Acrylic; SMA= Shape memory alloy; AL= Aluminum; TI= Titanium; RB= Resin bone)

Research Methods & Materials

Task 3: Strategically insert the SMA into the ergonomic brace.

Pressure distribution (kPa)

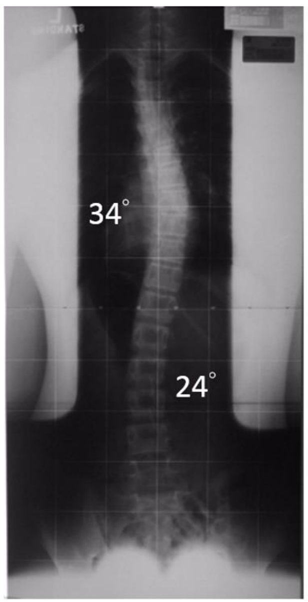


Pressure distribution (kPa) of Ergonomic brace with different supportive materials on soft mannequin

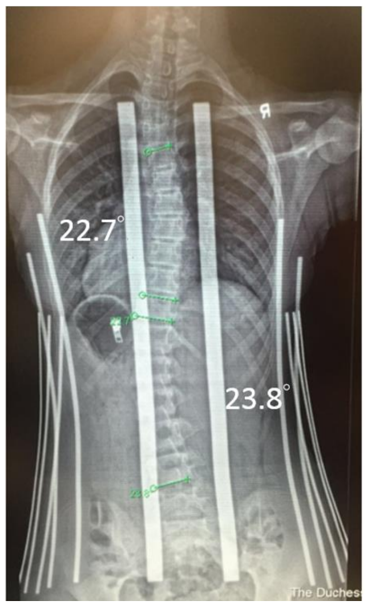
Research Methods & Materials

Task 3: Strategically insert the SMA into the ergonomic brace.

Subject 1:
Without brace



Brace with SMA Struts



Subject 2:
Without brace

Brace with Resin Bones

SMA: 33% in the Cobb's angle in thoracic region, nearly no improvement in lumbar region

Resin: 26% in the Cobb's angle in thoracolumbar region

Research Methods & Materials

How do different struts affect the pressure and spinal correction?

Task 3: Strategically insert the SMA into the ergonomic brace.

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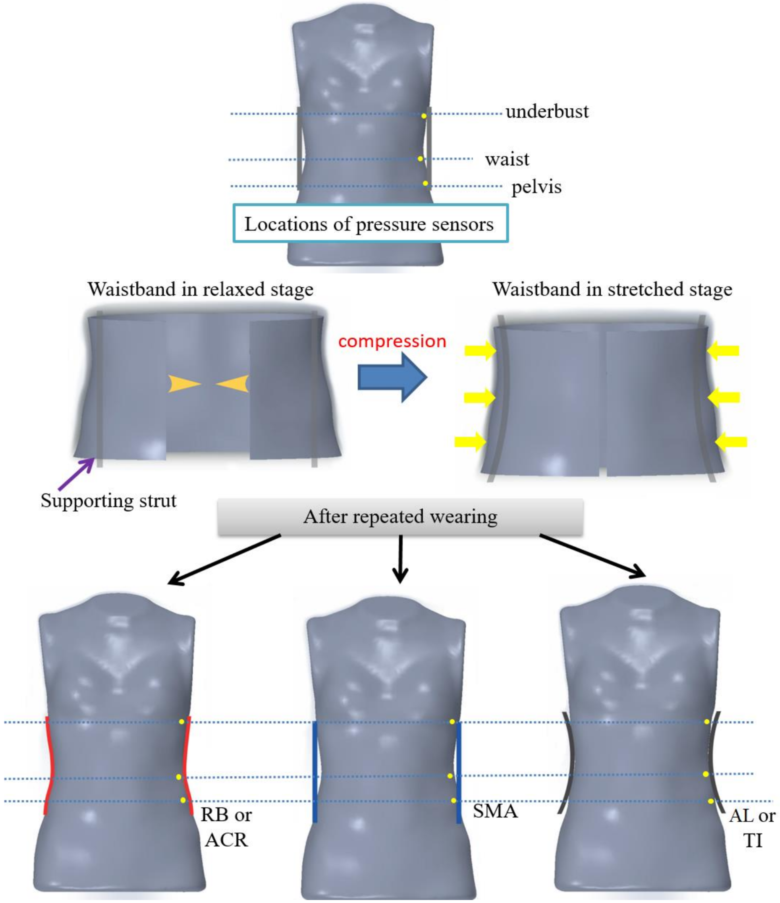


Rigid materials:
Hard to be deformed → Cannot fit to body
→ Induced higher pressure on convex part (underbust and pelvis)
→ Better correction on thoracic curve

Flexible materials:
Easy to be deformed → Fit to the body contour
→ Induce higher pressure on concave part (waist)
→ Better correction on thoracolumbar or lumbar curve

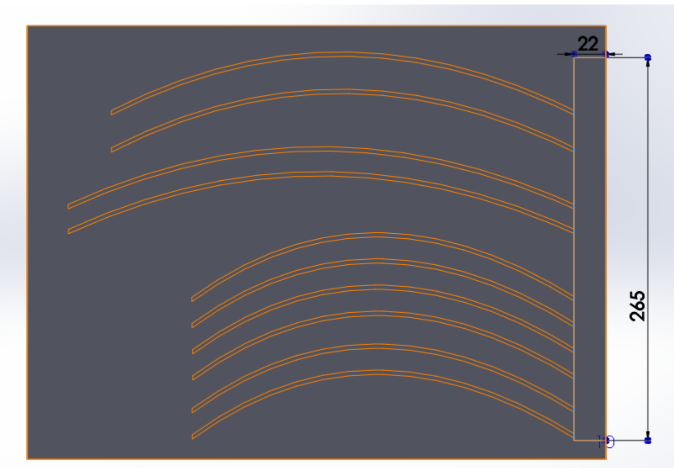
Good recovery materials:
Can keep the original shape → maintain the pressure after repeated use

Research Methods & Materials

How do different struts affect the pressure and spinal correction?

Task 3: Strategically insert the SMA into the ergonomic brace.

Improve fitting by molding SMA



Mold for SMA bones (Curve shape from standard dummy)

At 800°C for 1 hour ->water quenching (Annealing)

At 550°C for 1/2 hour ->water quenching (Tempering)

Before heat treatment

Heat treatment in straight form

After molding

Research Methods & Materials

Milestone 3: Overall evaluation of the effectiveness of ergonomic brace wear for adolescents with scoliosis

Task 1: Subject recruitment.

Subject Recruitment Progress

Location: The Duchess of Kent Children's Hospital (DKCH)

Target no. of subject recruit: 30-40

Inclusion criteria (SRS criteria):

- Age 10 ≥ older when brace is prescribed
- Risser 0-2
- Primary curve angles 25°-40°
- Female (either pre-menarche or <1 year post-menarche)
- Undergoing hard brace treatment

Exclusion criteria (SRS criteria):

- Low risk of curve progression
- Non-idiopathic scoliosis (e.g. congenital, neuromuscular deformities)

Recruitment progress (Total: 31)

Excluded: 1
Withdrawal: 9

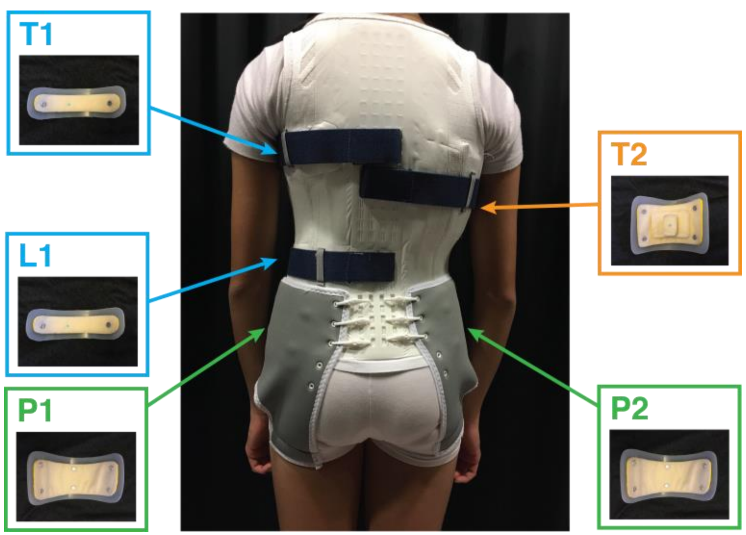
Completed (Total: 21):
2 (pilot study)
10 (original design)
9 (modified design)

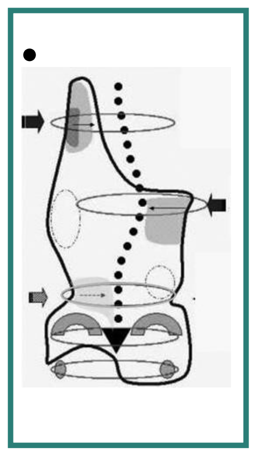
Research Methods & Materials

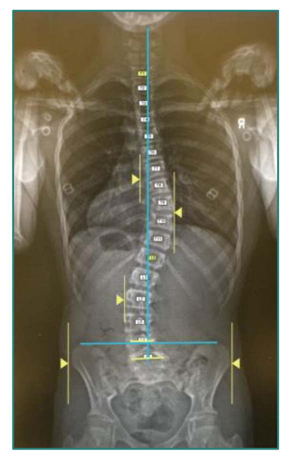
Task 2: Preliminary tests

Subject EB001 (fitting of pads; locations of pressure measurement)

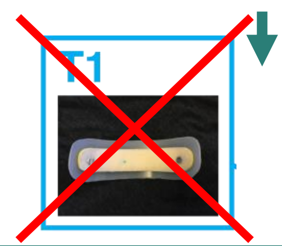
Subject code	Curve type	Rigo	Major(+)/Minor(-) curve	Curve level	Apex	Curve region	Cobb angle (º)				
							OB	HB	EB	OB-HB	OB-EB
EB001	Double Curve	C2	+	T7-T12	T9-T10	T	34.2	23.5	30.9	10.7	3.3
			+	T12-L5	L3	L	27	17.3	23.6	9.7	3.4
EB004	Main Thoracic	A3	+	T5-T12	T9	T	33.4	30.9	41.1	2.5	-7.7
			-	T12-L4	L3-L4	L	21.9	17.6	25.1	4.3	-3.2







Impossible to place pad higher than the level of underarm



Research Methods & Materials

Task 2: Preliminary tests

Subject code	Curve type	Rigo	Major(+)/Minor(-) curve	Curve level	Apex	Curve region	Cobb angle (°)				
							OB	HB	EB	OB-HB	OB-EB
EB005	Double Curve	B1	+	T5-T10	T8	T	34.1	23.6	30.4	10.5	3.7
			+	T10-L4	L2-L3	L	27.9	18.5	25.5	9.4	2.4
EB006	Double Curve	B1	+	T6-T11	T9	T	31.4	8.1	26.1	23.3	5.3
			+	T12-L4	L2-L3	L	27.1	8	25.6	19.1	1.5
EB008	Double Curve	B1	+	T4-L1	T11	T	26.9	24.8	30.5	2.1	-3.6
			+	L1-L5	L3	L	29.4	25.3	31.3	4.1	-1.9
EB009	Main Lumbar	E1	-	T9-L1	T10-T11	T	26.9	20.7	21.6	6.2	5.3
			+	L1-L4	L3	L	35.2	25.4	33.9	9.8	1.3
EB010	Main Lumbar	E1	-	T6-T12	T8-T9	T	20.7	11	17.4	9.7	3.3
			+	T12-L4	L2	L	32	12.6	29	19.4	3
EB011	Double Curve	B1	+	T6-T11	T9	T	28.8	20.7	23.9	8.1	4.9
			+	T11-L4	L2	L	29.7	21.6	35.6	8.1	-5.9
EB013	Main Thoracolumbar	E2	-	T5-T11	T8	T	19.1	18.6	28.8	0.5	-9.7
			+	T11-L3	L1	TL	28.8	19.5	28.9	9.3	-0.1
EB014	Double Curve	B1	+	T6-T11	T8-T9	T	31.8	28.1	39.3	3.7	-7.5
			+	T11-L4	L1	TL	30.8	26.1	36.7	4.7	-5.9
EB015	Main Thoracic	A3	+	T5-T10	T8	T	27.1	19.7	26	7.4	1.1
			-	T11-L3	L2	L	20.6	15.5	19.2	5.1	1.4
EB016	Double Curve	B1	+	T6-L1	T10	T	19.9	13.3	15	6.6	4.9
			+	L1-L5	L2-L3	L	17.6	5.7	10	11.9	7.6

Research Methods & Materials

Task 2: Preliminary tests

Within Samples T-test

(All the major curves of each subject are included)

HB vs OB

$t(15)=6.545$; $\mathbf{p=0.000}$

HB has **<u>significant improvement in Cobb angles</u>** when comparing with OB.

EB vs OB

$t(15)=0.601$; $\mathbf{p=0.557}$

EB has **<u>no significant improvement in Cobb angles</u>** when comparing with OB.

OB-HB vs OB-EB

$t(15)=7.219$; $\mathbf{p=0.000}$

HB is **<u>significantly better</u>** than EB.

Research Methods & Materials

Task 2: Preliminary tests

Brace Efficacy: Correction of Cobb Angles

(All the major curves of each subject are included)

HB vs OB

(OB-HB)/OB]*100

Mean = **35.13%**
Range = 7.81% to 74.20%

EB vs OB

(OB-EB)/OB]*100

Mean = **3.81%**
Range = -23.58% to 43.18%

EB vs HB

3.81/35.13*100

= 10.86%

Research Methods & Materials

Task 2: Preliminary tests

Brace Efficacy: Correction of Cobb Angles

(Curve Regions)

Better efficacy: thoracic curve region (OB-EB : OB-HB -> **1.26°: 8.81°**)

Curve region	OB-HB (Major curves)	OB-EB (Major curves)
Thoracic	**Mean: 8.81°** (Range: 2.10° to 23.30°)	**Mean: 1.26°** (Range: -7.50° to 4.90°)
Thoracolumbar	**Mean: 7.00°** (Range: 4.70° to 9.30°)	**Mean: -3.00°** (Range: -0.10° to -5.90°)
Lumbar	**Mean: 11.69°** (Range: 4.10° to 19.10°)	**Mean: 1.14°** (Range: -5.90° to 7.60°)

Research Methods & Materials

Task 3: Clinical Trial

Design modifications with Curved SMA Struts

Summary of X-ray results of wearing curved SMA Brace

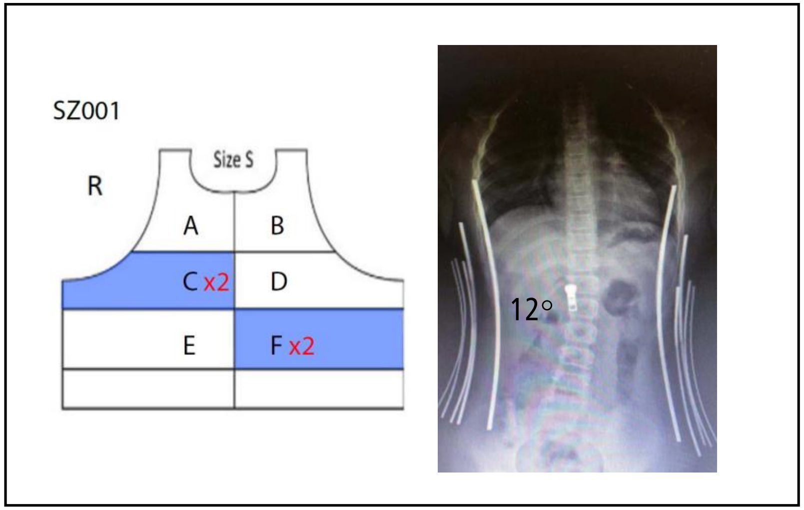
Improvement >5°													
		Out-brace X-ray						In-Brace X-ray			Differences (Out-brace – In-Brace)		
	Brace Size	1st curve position	1st Cobb's angle (°)	2nd curve position	2nd Cobb's angle (°)	3rd curve position	3rd Cobb's angle (°)	1st Cobb's angle (°)	2nd Cobb's angle (°)	3rd Cobb's angle (°)	1st Cobb's angle (°)	2nd Cobb's angle (°)	3rd Cobb's angle (°)
SZ001	S	T11-L4	18	T5-T10	8	/	/	12	0	/	6	8	/
SZ003	S	T11-L4	25	/	/	/	/	18	/	/	7	/	/
HK012	S	T9-L1	19	T6-T9	18	L1-L4	16	4.5	10.6	9.2	14.5	7.4	6.8
HK014	M	T5-T11	26.2	T11-L4	25.7	/	/	20.7	25.1	/	5.5	0.6	/
Improvement <5°													
SZ002	M	T12-L4	28	T5-T11	23	/	/	25	20	/	3	3	/
SZ004	M	T4-T11	28	T11-L5	20	/	/	26	18	/	2	2	/
HK013	M	T11-L3	20.4	T5-T10	15.2	/	/	21.2	17.6	/	-0.8	-2.4	/
HK015	S	T12-L3	21.4	T6-T12	10.9	/	/	17.2	10.7	/	4.2	0.2	/
HK016	M	T5-T11	22.4	T12-L3	17.1	/	/	20.4	14.9	/	2	2.2	/

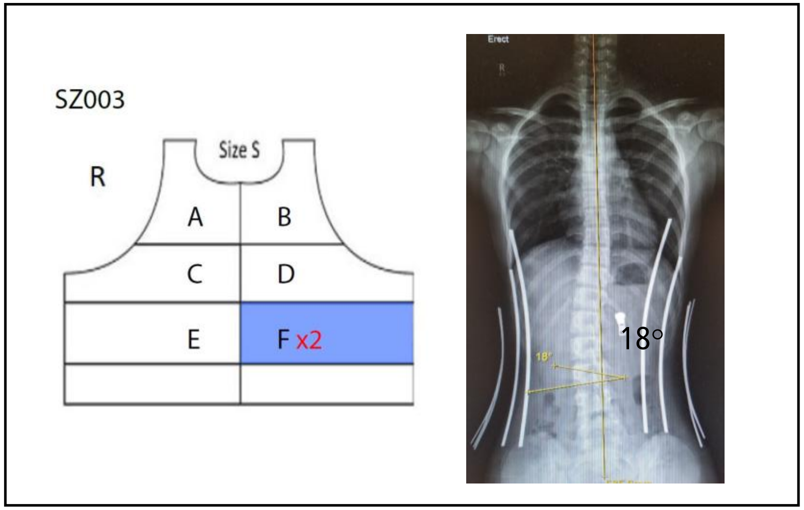
Research Methods & Materials

Task 3: Clinical Trial

Design modifications with Curved SMA Struts

Results – Success Cases (Improvement >5°)





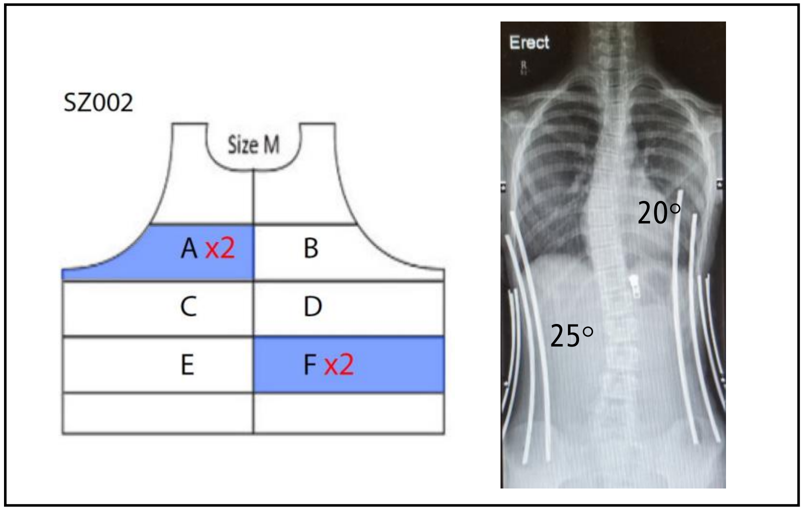
	Out-brace X-ray				In-brace X-ray		Differences (Out-brace – In-brace)	
	1st curve position	1st Cobb's angle (°)	2nd curve position	2nd Cobb's angle (°)	1st Cobb's angle (°)	2nd Cobb's angle (°)	1st Cobb's angle (°)	2nd Cobb's angle (°)
SZ001	T11-L4	18	T5-T10	8	12	0	6	8
SZ003	T11-L4	25	/	/	18	/	7	/

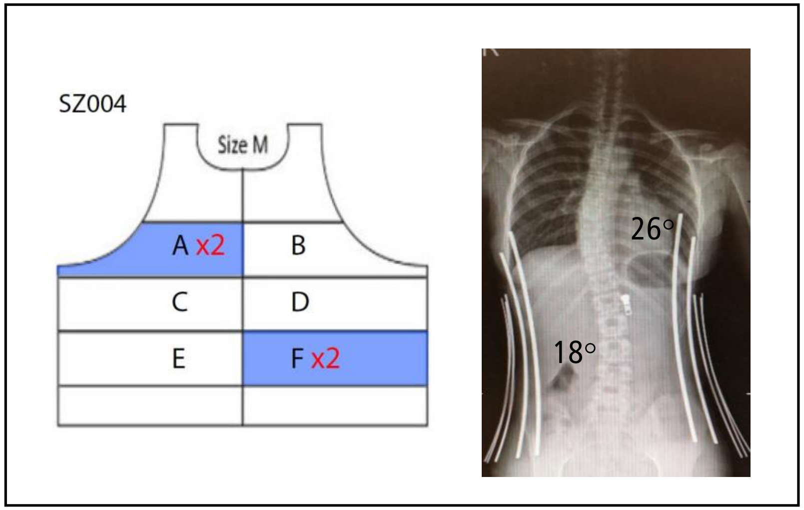
Research Methods & Materials

Task 3: Clinical Trial

Design modifications with Curved SMA Struts

Results – Unsuccess Cases (Improvement <5°)





	Out-brace X-ray				In-girdle X-ray		Differences (Out-brace – In-girdle)	
	1st curve position	1st Cobb's angle (°)	2nd curve position	2nd Cobb's angle (°)	1st Cobb's angle (°)	2nd Cobb's angle (°)	1st Cobb's angle (°)	2nd Cobb's angle (°)
SZ002	T12-L4	28	T5-T11	23	25	20	3	3
SZ004	T4-T11	28	T11-L5	20	26	18	2	2

Research Methods & Materials

Summary of X-ray results of wearing curved SMA Brace

Task 3: Clinical Trial

Design modifications with Curved SMA Struts

Summary of All-curved SMA Brace Results	
Number of subjects	9
Pre-intervention (°)	23.16
Post-intervention (°)	18.33
Average in-girdle correction (°)	4.82
In-girdle correction (%)	20.85%

Non-parametric Test

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The median of differences between OB_greatest and Girdle_greatest equals 0.	Related-Samples Sign Test	.039[1]	Reject the null hypothesis.
2	The median of differences between OB_greatest and Girdle_greatest equals 0.	Related-Samples Wilcoxon Signed Rank Test	.011	Reject the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

[1] Exact significance is displayed for this test.

- Paired T-test

		Paired Differences					t	df	Sig. (2-tailed)
					95% Confidence Interval of the Difference				
		Mean	Std. Deviation	Std. Error Mean	Lower	Upper			
Pair 1	OB_greatest - Girdle_greatest	4.82222	4.35166	1.45055	1.47724	8.16720	3.324	8	.010

Summary of Statistical Analysis Results
Significant differences (P<0.05) are found between out-brace and in-brace Cobb's angle in both non-parametric test and paired T-test

Research Conclusions

In total, 31 subjects were recruited and 21 subjects were completed in the clinical study.

12 subjects have tried 1st prototype of Ergonomic brace.

- It has no significant improvement in Cobb angles when comparing with hard brace.

9 subjects have tried 2nd prototype (adding curved SMA struts)

- Among 9 subjects, 4 of them have >5° improvement, 5 of them have <5° improvement
- Average 4.82 ° (20.85%) in-brace correction could be found
- Significant differences ($P<0.05$) are found between out-brace and in-girdle Cobb's angle in both non-parametric test and paired T-test

Dissemination and distribution of outcomes

Deliverables

01	Demonstration Video
02	One China Patent
03	One US Patent
04	One Journal Paper
05	Three Conference Papers
06	Intervention Exhibition
07	One Award

Dissemination and distribution of outcomes

1. Video – 3D Drawing of the wearing procedure https://youtu.be/_VGx9K3FmD0

Dissemination and distribution of outcomes

2. Patents

China Patent " An orthopaedic pad for improving idiopathic scoliosis in adolescents" 一种供改善青少年特发性脊柱侧凸的矫形垫", filled date: 22-08-2018 Application no.: 201810954428.8

MP1816136

中华人民共和国国家知识产权局

100004
北京市朝阳区建外大街 22 号赛特广场 7 层
北京集佳知识产权代理有限公司 张春水(020-38813588),唐京桥
(020-38813588)

发文日：
2018年08月22日

申请号或请求号： 201810954428.8

申请人或请求人： 香港理工大学

发明或实用新型名称：一种供改善青少年特发性脊柱侧凸的矫形垫

向外国申请专利保密审查意见通知书

申请人于 2018 年 08 月 21 日提出向外国申请专利保密审查请求，根据专利法第 20 条第 1 款的规定，国家知识产权局对上述专利申请或技术方案进行保密审查。

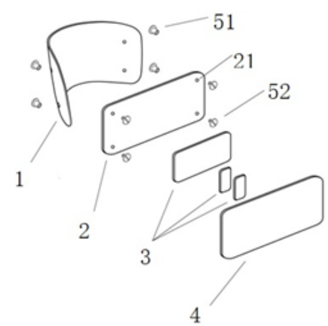
经审查，该专利申请不涉及国家安全或者重大利益，申请人可以向外国申请专利或者向有关国外机构提交专利国际申请。

审查员：黄瑞宏(电子申请)　　审查部门：专利局初审及流程管理部-15

210326 纸件申请，回函请寄：100088 北京市海淀区蓟门桥西土城路 6 号 国家知识产权局受理处收
2010.2 电子申请，应当通过电子专利申请系统以电子文件形式提交相关文件。除另有规定外，以纸件等其他形式提交的文件视为未提交。

MP1816136

摘要附图



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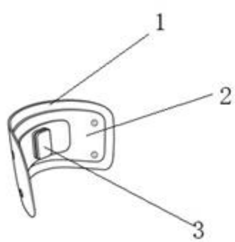

图 2

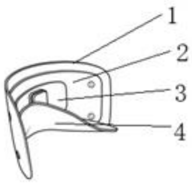

图 3

Dissemination and distribution of outcomes

2. Patents

US Patent "Customizable wearable top to treat scoliosis in a person"

CUSTOMIZABLE WEARABLE TOP TO TREAT SCOLIOSIS IN A PERSON

Field

[0001] The invention relates to a customizable wearable top for the treatment of scoliosis, such as Adolescent Idiopathic Scoliosis (AIS), in a person.

Background

[0002] Scoliosis is generally defined as the three-dimensional deformity of spine, thorax and trunk. A diagnosis is made when the spine deviates laterally with a Cobb angle of 10° or more. The majority of scoliosis cases are idiopathic, in which no known cause can be found with a multifactorial etiology. It occurs mainly in adolescent, namely Adolescent Idiopathic Scoliosis (AIS), during the period of growth spurt from the age of 10 until the reach of skeletal maturity. To halt the progression of AIS and avoid surgery, bracing is the most common non-operative treatment option for adolescents with a spinal curve of 25° to 40°. The external mechanical forces exerted by braces restore the alignment of spine and body contour. However, there are two main problems associated with the existing braces which affect the treatment outcomes: one is the long production lead time for scoliosis brace and the second is the low brace compliance in patients.

[0003] Scoliosis braces are custom-made in accordance with the spinal curvature and body shape of each patient. Treating orthotist is responsible throughout the fabrication process from shape capturing, design, fitting to follow-up adjustments, as trained skills are required to ensure a well-designed orthosis that fits well on patient. Techniques and ways to fabricate braces have been evolving from plaster-cast to prefabrication and to CAD/CAM modelling; however, the required production lead time is still long. Existing fabrication methods include plaster casting, prefabrication, computer-aided-design / computer-aided-manufacturing (CAD / CAM), and simulation of brace fitting. Each of these is briefly discussed below.

1/11

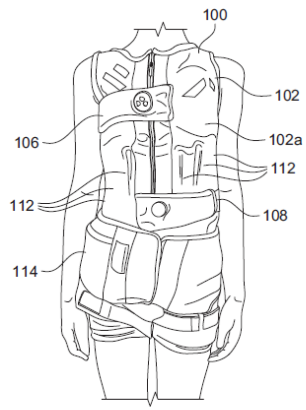

FIG. 1A

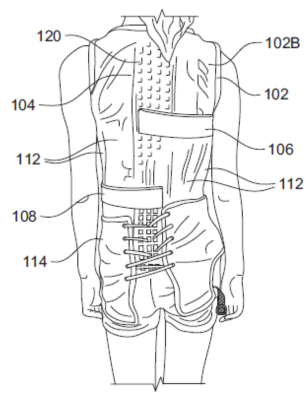

FIG. 1B

2/11

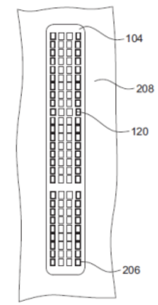

FIG. 2A

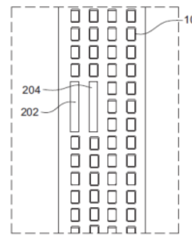

FIG. 2B

4/11

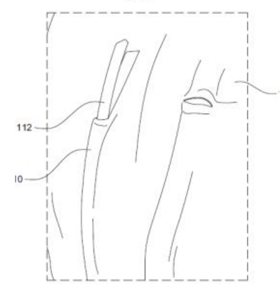

FIG. 3

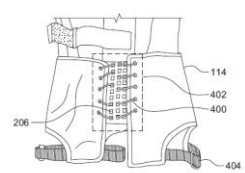

FIG. 4A

5/11

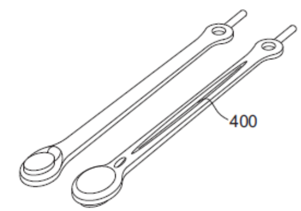

FIG. 4B

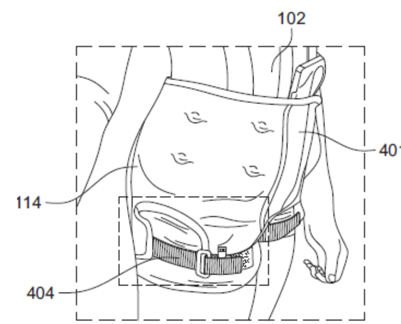

FIG. 4C

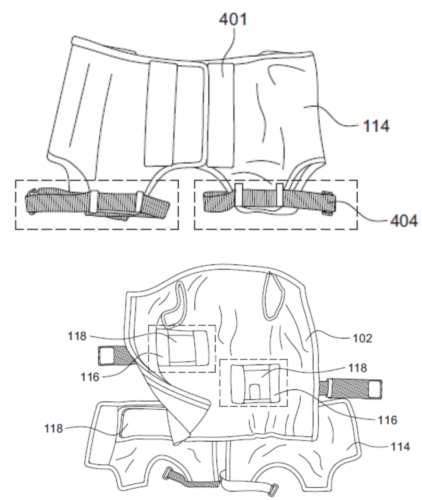

FIG. 6

Dissemination and distribution of outcomes

3. Patents

US Patent " Ergonomic Brace for Patients with Adolescent Idiopathic Scoliosis (AIS)" submitted to ITDO, PolyU

Invention Disclosure Form

I. TITLE OF THE INVENTION
Ergonomic Brace for Patients with Adolescent Idiopathic Scoliosis (AIS)

II. DESCRIPTION OF THE INVENTION

Inventions include new processes, products, apparatus, compositions of matter, living organisms, or improvements to (or new uses for) things that already exist.

(a) **(Background)** What is the present technology? Are there any problems or deficiencies with the present technology?

Scoliosis is generally defined as the three-dimensional deformity of spine, thorax and trunk. A diagnosis is made when the spine deviates laterally with a Cobb angle of 10° or more [1]. The majority of scoliosis cases are idiopathic, in which no known cause can be found with a multifactorial etiology [2]. It occurs mainly in adolescent, namely Adolescent Idiopathic Scoliosis (AIS), during the period of growth spurt from the age of 10 until the reach of skeletal maturity. To halt the progression of AIS and avoid surgery, bracing is the most common non-operative treatment option for adolescents with a spinal curve of 25° to 40° [1]. The external mechanical forces exerted by braces restore the alignment of spine and body contour [3]. However, there are two main problems associated with the existing braces which affect the treatment outcomes: one is the long production lead time for scoliosis brace and the second is the low brace compliance in patients.

1) Long production lead time for scoliosis brace

Scoliosis braces are custom-made in accordance with the spinal curvature and body shape of each patient. Treating orthotist is responsible throughout the fabrication process from shape capturing, design, fitting to follow-up adjustments, as trained skills are required to ensure a well-designed orthosis that fits well on patient. Techniques and ways to fabricate braces have been evolving from plaster-cast to prefabrication and to CAD/CAM modelling; however, the required production lead time is still long. Four existing fabrication methods summarized from Zaina et al. [4] and Grivas et al. [5] will be discussed as follows.

Plaster Casting

Plaster casting is a traditional method introduced by French surgeon Yves Cotrel and American physician Joseph Risser. With the use of a casting frame, patient is put in a supine position with traction and corrective force applied (see Figure 1 (left) below). Plaster or synthetic bandage is then wrapped around the torso until harden, and a corrected trunk impression of patient is captured upon bandage removal

Form itdo-ip-002 (Dec 2016)

The Ergonomic Brace for patients with AIS has a soft tight-fitting knit bodice assembled with plastic resin bones, rigid pads, pad holders, a pelvic belt, rigid straps and a strap adjuster (Figure 1). All of the components are pre-fabricated in mass so that customization based on the spinal curvature of patient can be finished within a short period of time. Further details regarding its construction and mass customization concept are discussed in the following:

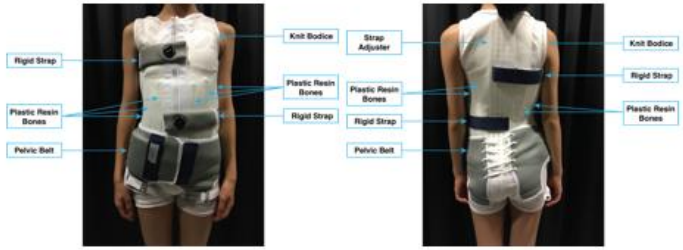

Figure 1. Front of the Ergonomic Brace (left); back of the Ergonomic Brace (right)

Bodice

The knitted structure of the bodice is double jersey with an additional insertion of elastic inlaid yarns in between. The face and the rear side of the double jersey are respectively knitted using the deodorization yarn and the cool-to-touch yarn. The cool-to-touch yarn knitted on the rear side of the bodice touches the skin, thus provides a cool sensation to the wearer. The deodorization yarn, on the other hand, is featured with deodorization, anti-microbial and moisture management functions, which helps stay the brace dry and refresh, especially during summer. To further enhance the comfort of wearer while wearing the brace, part of the bodice is knitted in net structure (Figure 2 right) to achieve a better breathability.

Figure 2. Bodice (left); net structure on bodice (right)

Dissemination and distribution of outcomes

4. Journal paper

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Annals of Biomedical Engineering (© 2018)
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Mechanical and Clinical Evaluation of a Shape Memory Alloy and Conventional Struts in a Flexible Scoliotic Brace

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Associate Editor Peter E. McHugh oversaw the review of this article.

Abstract—Smart materials have attracted considerable attention in the medical field. In particular, shape memory alloys (SMAs) are most commonly utilized for their superelasticity (SE) in orthopaedic treatment. In this study, the resin struts of a flexible brace for adolescent idiopathic scoliosis (AIS) are replaced with different conventional materials and an SMA. The corrective mechanism mainly depends on the compressive force applied by the brace at the desired location. Therefore, the mechanical properties of the materials used and the interface pressure are both critical factors that influence the treatment effectiveness. The results indicate that titanium is the most rigid among the five types of materials, whereas the brace with SMA struts presents the best recovery properties and the most stable interface pressure. A radiographic examination of two patients with AIS is then conducted to validate the results, which shows that the SMA struts can provide better correction of thoracic curvature. These findings suggest that SMAs can be applied in orthoses because their SE allows for continuous and controllable corrective forces.

Keywords—Nitinol, Bending stiffness, Interface pressure, Flexible brace, Material selection, Scoliosis.

INTRODUCTION

Scoliosis is the three-dimensional deformity of the spine and trunk.[14] Adolescent idiopathic scoliosis (AIS) is the most common type of scoliosis, and emerges at or near the beginning of puberty and before skeletal maturity (generally between 10 and 16 years old).[19] Non-surgical treatment, such as immobilization or dynamically correct posture by application of corrective forces with a spinal cast or brace, is an important treatment modality to prevent curve progression and reduce the spinal deformity of AIS patients with moderate scoliosis and a spinal curve that ranges from 20° to 45°.

Conventional rigid scoliotic orthoses, such as the Milwaukee brace, are fabricated with rigid materials, such as polyethylene and stainless steel, to provide support and stabilize the trunk and spine of patients.[4] Recently, rigid braces are being constructed with more lightweight materials, such as carbon[1] and polycarbonate,[15] to improve their wear comfort. Most of these materials are widely used because of their good mechanical properties, low cost, and acceptable biocompatibility[23,24]; however, they may not be able to satisfy the needs of patients because the rigid materials may cause pain, restrict daily activities and affect self-image.[3]

To overcome the problems of rigid scoliotic orthoses, new flexible braces composed of textile fabrics and straps have been developed, such as Spinecor, TriaC, Spinealite[8] and a posture correction girdle.[11] The researchers claim that these braces have greater wear comfort and provide users with a better self-image and greater mobility in daily life. However, the braces can easily deform, which means that they do not offer optimal corrective effects.[21] Therefore, smart materials have attracted considerable attention in the medical field as an alternative option and are expected to play a crucial role in the translation of laboratory findings into clinical devices.[18] Shape memory alloys (SMAs) are an example of a smart material.

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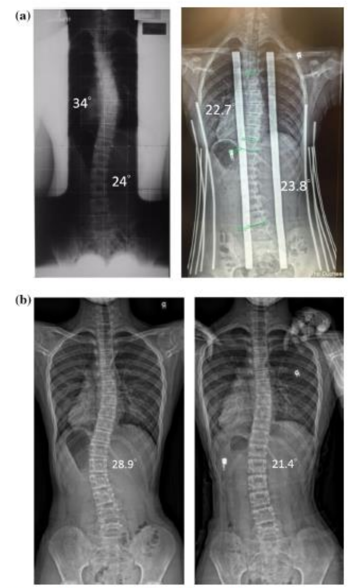

FIGURE 7. X-ray image of scoliosis subject before (left) and after (right) wearing posture correction girdle with (a) SMA supportive struts (b) RB supportive struts.

important because it indicates that the product is durable and allows for the continuous application of pressure/force. Material with more stiffness and good recovery is preferred for the supportive struts of a flexible orthosis because a flexible brace may not be robust enough to apply corrective forces. In addition, the material should be able to maintain its shape after wearing or subjected to daily movement. The bending and recovery results obtained in this study explain why TI has been used in many of the orthoses available today. Although thin TI struts were used, they do not easily deform. Therefore, TI struts are more supportive and lightweight. However, compared to the SMA used in this study, TI is lacking in terms of recovery, and the largest difference in the percentage of recovery between the materials is with a strut thickness of 1.8 mm. Accordingly, the SMA is selected for the posture correction girdle because of its relative high stiffness and excellent recovery properties. Although the TI struts have the highest compressive load, they cannot maintain a good shape after several rounds of bending. Therefore, if TI struts are used on the girdle, they will easily deform, which means that corrective forces cannot be applied continuously. Additionally, overly rigid materials may not be suitable for the flexible brace because compressive forces cannot be applied evenly to the 3D shape of the human body as demonstrated by the pressure tests.

The pressure tests indicate that more rigid materials apply greater pressure onto the bony parts of the body,

Dissemination and distribution of outcomes

5. Conference papers – The design and development process, 3D body shape changes, wear trial results of posture correction girdle were presented in different international conferences held in New Zealand and Hong Kong

Fung H.Y.O., **Yip J.**, Yick K.L. (2017) "Design Framework for Medical Textiles: Anisotropic Textile Brace", *14th Asian Textile Conference*, Hong Kong, 27-30 June 2017, Paper ID 38. https://www.polyu.edu.hk/itc/atc14/

Design Framework for Medical Textiles: Anisotropic Textile Brace

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Abstract

The current challenge of adolescent idiopathic scoliosis (AIS) is the low compliance of patients, which means that the control of spinal deformity becomes very difficult. The greatest obstacle to wearing a brace is the stigma which elicits psychological anxiety. In view of this, a design framework is proposed which identifies the design characteristics for the development of a new scoliosis brace called the Anisotropic Textile Brace that addresses the emotional perceptions of bracewear. The Functional, Expressive and Aesthetic Consumer Needs and design process models are combined, so that gaps between available items and those that are desired by wearers under use situations can be addressed. Additional elements, which may not have been considered with general apparel design but are important for medical textiles and clothing, include the emotional needs of target users, and the efficacy and durability of products, which are incorporated into the framework for a new and effective design.

Keywords: Adolescent idiopathic scoliosis (AIS), brace design, medical apparel design, Functional, Expressive and Aesthetic model, design development

Introduction

Adolescent idiopathic scoliosis (AIS) is the most common three-dimensional spinal deformity [1] that occurs in 2-3% of children [2] and predominantly girls over the age of 10 until skeletal maturity [3]. Patients with AIS manifest physical deformities including rib prominence, uneven shoulders, pelvic asymmetry or truncal shift [4]. If the magnitude of the spinal curve is significant [5], the likelihood of progression of the scoliosis curve is increased, and this is also prevalent with the growth spurt in adolescence [4]. Thus there is an anticipated 16% risk of surgery for those with a spinal curve of 20° and increased to 100% for a curve that is ≥30° at the onset of puberty [6]. In lieu of surgery, there is bracewear as a treatment option, but early diagnosis is an important key for its success, and a brace is to be worn for 23 hours each day [7] to reduce morbidity.

Successful brace treatment can be hindered by various factors, where poor adherence is a prevalent challenge, due to reasons such as its inconvenience, the associated discomfort, the appearance and aesthetics. Patients with AIS are adverse to brace treatment because the design of the brace is not only unappealing but is stigmatizing, thus eliciting psychosocial anxiety [4, 8]. The purpose of this study is to therefore propose a framework for a modified brace design that specifically targets adolescents based on the integration of results in the literature and implications from the Functional, Expressive and Aesthetic (FEA) Consumer Needs Model which incorporates the design process of the model by Lamb and Kallal [8]. As it is often the case that when patients exit treatment, they no longer benefit from bracing, so a new brace design called the Anisotropic Textile Brace will developed accordingly to address user needs within the context of a use-situation rather than focusing on the brace as an issue in which treatment is limited by physical appearance and/or emotional adversity [8, 9].

FEA Consumer Needs Models

The FEA Consumer Needs Model (left side of Fig. 1) is a user-centered model that identifies user needs based on functional, expressive and aesthetic considerations [8]. *Target consumer*, which points to the intended user, is the core of the model. Encircling the target consumer is *culture*, where product requirements or desire varies depending on the cultural surroundings. For example, in this study, Asia is the focus and adolescents are the specific subculture group that is being considered. According to a study by Engel, Blackwell, and Miniard [10], Asian countries, such as Hong Kong, Taiwan, Japan and South Korea, demonstrate a high degree of collectivism while western countries manifest strong individualism. Common traits of both collectivism and adolescence are their *expressive* needs which are realized through clothing. Clothing is thus used to enhance their self-concept, and allow them to fit in and conform to their peer group [11, 12]. Expressive requirements, which are the communicative symbolic aspects of a product, have to be congruent with the *values, roles, status* and *self-esteem* of the users in order to be used or accepted. Therefore, scoliosis braces specifically designed for adolescents with AIS may address their *functional* needs, but at the same time, carry social stigma that sets them apart from their peers, thus causing self-devaluation [9]. Users with or without special needs do not find functional apparel products appealing if aesthetics and personal expression are neglected [13], as the human desire for beauty is inherent [8].

Fig. 1 Original FEA Consumer Needs Model (left, source: Lamb & Kallal [8]); FEA Consumer Needs Model for adolescent girls with disability (right, source: Stokes and Black [9])

To further enhance the FEA Consumer Needs Model, Stokes and Black [9] emphasized the interrelationships among *functional*, *expressive* and *aesthetic* considerations and replaced the solid lines with dotted ones for assessing the clothing needs of adolescent girls with a disability (right of Fig. 1). The model has also been redesigned with an outer ring that includes the near environment in the *body/garment* relationship, for example, weather and social environment may affect the design considerations for body and garment. *Safety*, which would not normally be considered in general apparel design, is further added as a functional consideration, as medical auxiliaries or garments may affect health or safety of use.

Dissemination and distribution of outcomes

5. Conference papers – The design and development process, 3D body shape changes, wear trial results of posture correction girdle were presented in different international conferences held in New Zealand and Hong Kong

Fung, O. H. Y., **Yip, J.**, Yick, K. L., Cheung, K. M. C., Kwan, Y. H., Cheung, J. P. Y., Tse, C.Y. and Ng, S. P. (2018). "Ergonomic Brace - A New Approach to Brace Design for Treating Adolescent Idiopathic Scoliosis (AIS)" CPCE Health Conference 2018, 12 January 2018, College of Professional and Continuing Education, Hong Kong http://healthconf2018.cpce-polyu.edu.hk/

Ergonomic Brace – A New Brace Design Approach in the Treatment of Adolescent Idiopathic Scoliosis (AIS)

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Abstract

Idiopathic Scoliosis is the most common form of three-dimensional spinal deformity [1], which occurs mainly in adolescents from the age of 10 or older until skeletal maturity is reached [2]. Surface deformities, resulting from the progression of spinal curves during growth, are rib hump, unleveled shoulders and asymmetrical waist [3]. This frequently has a negative impact on adolescents, in terms of the quality of life (QoL) and their psychological well-being. Bracing, in general, is used as a non-surgical solution to halt AIS from progression.

Bracing, with the application of external mechanical forces, can restore alignment of the spine and body contour [4]. Braces, which uphold different principal of corrections, can mainly be divided into two main categories as hard brace and soft brace. However, the choice of brace intervention in the treatment of AIS remains controversial. Hard braces, for instance the Chêneau brace and the Boston brace, are considered effective in the prevention of curve progression during growth, but their negative impacts on the QoL and psychological being of patients are concerned [5]. Though soft brace has addressed the shortcomings of hard brace, its efficacy is polarized in different papers [5]. Purpose of the Ergonomic brace development is from seeing the equal importance of the effectiveness in hard brace and the compliance in soft brace to the outcome of brace treatment. A design combining both hard and soft elements in one brace thus proposed, and mass customization is an additional concept included to reduce the lead-time required for conventional brace building, so prompt delivery of treatment is feasible.

Benefits from bracing increased with longer hours of brace wear [4]. Therefore, one of the design approaches is to enhance the brace comfort for a better compliance in return. The Ergonomic brace is designed with a soft tight-fit base that is constructed with the seamless knitting technology. It allows net structures to be created in different parts of the brace for breathability, and the use of cool-to-touch yarn and deodorant yarn helps stay the brace refresh, especially during summer.

Satisfactory correction of spine relies heavily on the brace mechanism and the principals behind. In spite of the improved QoL, one of the soft braces, presented by Coillard, shown to be less effective than hard brace due to its failure in correcting the sagittal profile. In view of this, the Ergonomic brace has put frontal and sagittal plane corrections into the design considerations, with bones, rigid padding, pelvic belt and straps as auxiliaries.

Strap tension and treatment outcomes are regarded as highly correlated [6]. Therefore, adequate corrective force should have applied to ensure the success of brace treatment. In the Ergonomic brace, straps are tightened with the dials, where increment can be made precisely as the prescribed tension. Not only the adjustment is easy with single-hand, but the right amount of corrective force can be ensured.

Braces are custom-made, as the curve shape of spine varies with patients. The conventional plaster-cast method for hard brace [7] takes a long production lead-time before the AIS patients could receive treatment. With the mass customization concept of the Ergonomic brace, thermo-adhesive films can customize the positions of the pad and straps, according to the curve types, in real time, so the AIS patients could receive treatment once diagnosed.

The aim of the Ergonomic brace is to ensure the efficacious of treatment without harming the QoL of patients and, at the same time, shorten the lead-time to treatment. Viabilities of these design concepts are going to be tested with prototypes in the next stage.

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https://healthconf2018.cpce-polyu.edu.hk/doc/CPCE-HealthConf-2018-Program-Book.pdf

Dissemination and distribution of outcomes

5. Conference papers – The design and development process, 3D body shape changes, wear trial results of posture correction girdle were presented in different international conferences held in New Zealand and Hong Kong

Fung, O. H. Y., **Yip, J.**, Yick, K. L., Cheung, K. M. C., Kwan, Y. H., Cheung, J. P. Y., Tse, C.Y. and Ng, S. P. (2018). "Biomechanical Principles of Spinal Correction Applied to the Ergonomic Brace: A New Brace Design for Adolescent Idiopathic Scoliosis" ISERD - 527th International Conference on Medical and Health Sciences (ICMHS), 7-8 Jan 2019, Wellington, New Zealand http://iserd.co/Conference2019/NewZealand/1/ICMHS/

Biomechanical Principles of Spinal Correction Applied to the Ergonomic Brace: *A New Brace Design for Adolescent Idiopathic Scoliosis*

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***Abstract*—The Ergonomic Brace is a newly designed spinal brace, which addresses the equal importance of treatment effectiveness with hard braces and patient compliance with soft braces. The design integrates both hard and soft components to form one single brace. Rigid pads on the Ergonomic Brace primarily exert corrective forces onto the scoliotic spine, and are customized in accordance with the spinal curvature of patients. The position and vector orientation of the rigid pads are based on the *SOSORT consensus paper on brace action for TLSO biomechanics of correction* and the Rigo classification. A highly valid framework of the biomechanical principles for spinal correction is thus constructed for the Ergonomic Brace.**

Keywords—adolescent idiopathic scoliosis, spinal brace, biomechanical principles, spinal correction

I. BACKGROUND

Spinal braces are commonly used as a non-operative treatment option for patients with adolescent idiopathic scoliosis (AIS), i.e. spinal curvature with a Cobb's angle between 25 and 40 degrees [1]. The role of bracing is to halt the progression of the scoliotic curve and avoid the curvature threshold for surgery [2]. Therefore, the spinal brace needs to be able to exert sufficient corrective forces (or pressure) onto the spinal area to correct the scoliosis [3].

II. PROBLEMS WITH EXISTING SPINAL BRACES

Spinal braces are mainly hard and soft braces. The differences mainly lie in the type of material used, fabrication method and biomechanical principles of the spinal correction, which respectively have their own different strengths and weaknesses. Hard braces are considered effective for preventing spinal curve progression during puberty growth, but are rigid, bulky, uncomfortable and aesthetically unappealing to wear [4]. As a result, patient compliance is relatively low, and the negative impacts of hard braces on the quality of life (QoL) and psychological being of patients are some of the concerns [5]. Soft braces, on the other hand, have been developed to address the shortcomings of hard braces and remedy the problems related to comfort and appearance, but their efficacy in spinal correction remains controversial [6].

III. ABOUT THE ERGONOMIC BRACE

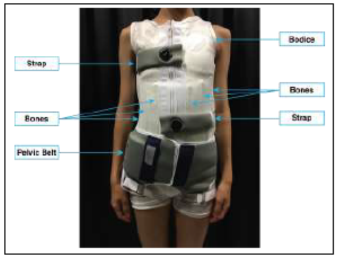

Fig. 1. Ergonomic Brace (front)

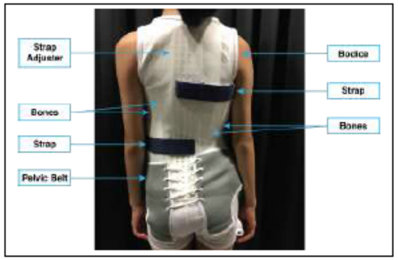

Fig. 2. Ergonomic Brace (back)

To examine the equal importance of the effectiveness of hard braces and the compliance to soft braces on brace treatment outcome, a new spinal brace design called the Ergonomic Brace, has been developed (see Figs. 1 and 2). Taking into account the strengths of existing hard and soft braces, the Ergonomic Brace integrates both of their design elements into one single brace. A soft knit bodice is assembled with plastic resin bones, rigid pads, a pelvic belt, straps and strap adjuster to form the device for spinal correction.

The rigid pads are the most important components of the Ergonomic Brace as they provide corrective forces onto the scoliotic spine. The invention includes two pad designs: (i) a layered pad (Fig. 3) and (ii) single layer pad (Fig. 4). They are placed in accordance with the spinal situation of each individual patient. The layered pad is designed to mainly provide corrective forces onto the major curve of the scoliotic spine, while the single layer pad is meant to correct a minor curve or used as a counter-force. As a minor curve is usually a derivative to counterbalance the major curve, it will be also realigned once the major curve is reduced in severity.

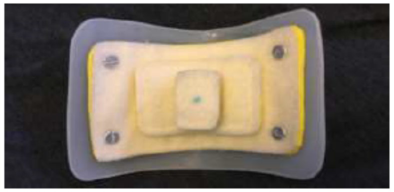

Fig. 3. Layered pad

Fig. 4. Single layer pad

IV. BIOMECHANICAL PRINCIPLES FOR SPINAL CORRECTION

The biomechanical principles of spinal correction that are incorporated into the Ergonomic Brace are based on (i) the SOSORT consensus paper on brace action for the thoracic-lumbar-sacral orthosis (TLSO) biomechanics of correction [7] and (ii) the Rigo classification [8]. The position and vector orientation of the pads on the Ergonomic Brace, which are customized in accordance with the spinal situation of the patient, are thus very accurate.

According to most of the Brace Classification Study Group of SOSORT members who are scoliosis specialists from different parts of the world [7], it is very important to apply the three-point system principle in brace treatment for AIS patients. The three-point system suggests the use of three pressure points to correct the scoliotic curve. The main force is applied at the center of the convex side of the main curve, and at the same time, two counter forces are applied to the ends of the contralateral side of the curve. As for the placement of the pad to correct the thoracic curve of the spine, approximately half of the members indicated that the pad should be positioned at the level of the apical vertebra, and the remaining half stated that it should be placed at the apical ribs which are found slightly below the apical vertebra. More than 80% of the members agreed that an oblique vector in the dorso-lateral to ventro-medial direction works best in correcting the main thoracic curve convexity. On the other hand, nearly 80% of the members agreed that to correct the lumbar curve convexity, the pad should be placed at the level of apical vertebra and nearly 70% suggested an oblique vector in the dorso-lateral to ventro-medial direction. The derotation principle for reducing the amount of vertebral rotation of the scoliotic curve is given high priority in brace treatment among nearly 60% of the members. To implement derotation, they believe that a pad placed against the ventral ribs can act as a counter-force to the pad placed against the dorsal rib hump in order to form a pair of forces. However, there were multiple opinions with no consensus on the design for the pelvic section and thus no conclusions were made.

Dissemination and distribution of outcomes

6. Exhibition

The Global Healthcare Innovation Academy (GHIA) 2018, Date 29-30 Aug 2018 Venue: V322, Jockey Club Innovation Tower, The Hong Kong Polytechnic University, Reg No: R022-E https://www.w21c.org/event/ghia-2018/

Global healthcare innovation academy is initially developed by leading healthcare organizations in Geneva, Switzerland. This event has grown into an international collaboration between Switzerland, Canada and Hong Kong.

The overarching goal of this combined scientific and investment pitch competition is to provide a platform that allows entrepreneurs and healthcare professionals at any level with the encouragement and incentive to identify, nurture, and pioneer innovations in the health system.

Poster design exhibited in the event

https://www.ghiaevent.com/schedule1

Dissemination and distribution of outcomes

7. Award

Year	Title of Award and Name of Awarding Organisation
2018	Annals of Biomedical Engineering Student Award for the paper “Mechanical and Clinical Evaluation of a Shape Memory Alloy and Conventional Struts in a Flexible Scoliotic Brace”, 17-20 October 2018, Atlanta, Georgia, USA.

Annals of
Biomedical Engineering

Annals of Biomedical Engineering
440 Kelly Hall, 325 Stanger St
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August 15, 2018

Chan Wing Yu
Doctoral Candidate
Hong Kong Polytechnic University

Dear Miss Chan Wing Yu,

We will be holding our first annual Athanasiou ABME Student Award Session at the Biomedical Engineering Society's Annual Meeting held this year in Atlanta, Georgia October 17-20. We are pleased to inform you that we have selected your article "Mechanical and Clinical Evaluation of a Shape Memory Alloy and Conventional Struts in a Flexible Scoliotic Brace" for one of our student awards. Please notify your co-authors of this honor.

The award session will take place on Friday, October 19 at 3:30pm. Each award recipient will present their paper, and receive a monetary award at the event. It is very important that you or a co-author attend the awards event so as to present your paper and receive the award in person. Please let me know as soon as possible if you will be attending BMES.

You may also wish to notify your institution's news/media office such that they can write about this award during or immediately after the BMES meeting. Congratulations on an excellent paper, and we hope to see you at the meeting!

Sincerely,

Bethany Rowson

Bethany Rowson
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