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Time-dependent response of scoliotic curvature to orthotic intervention: When should a radiograph be taken after putting on or taking off a spinal orthosis?

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*Title Page

Title:

Time-dependent response of scoliotic curvature to orthotic intervention: When should a radiograph be taken after putting on or taking off a spinal orthosis?

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*Structured Abstract (300 words)

Abstract

Study Design: A prospective study; two-group design.

Objective: This study aims to assess the time response of scoliotic spines to orthotic intervention using clinical ultrasound (CUS).

Summary of Background Data: Patients with moderate adolescent idiopathic scoliosis (AIS) are generally prescribed with orthotic treatment. However, the time to reach maximum correction after donning spinal orthosis or the time to return to pre-treatment curvature after doffing spinal orthosis is not fully understood.

Method: Subjects were divided into 2 groups, the don-orthosis group and the doff-orthosis group where the time reaching maximum correction and the time returning to pre-treatment curvature were investigated accordingly. To avoid excessive radiation exposure via taking repeated radiographs, a validated method of estimating Cobb's angle using radiation-free CUS was applied at an interval of every 30 minutes up to 180 minutes. The spinal flexibility (estimated from supine radiographs) and BMI were collected from the subjects for analyses.

Result: Nine female patients with AIS were recruited. There was no immediate change in the Cobb's angles. A change of >5° could be observed in both groups only after 30 minutes and maximum change was found at/after 120 minutes. In the doff-orthosis group, the subject with the lowest BMI took the longest time to increase >5º after doffing spinal orthosis. In the don-orthosis group, the subject with the highest BMI took the longest time to achieve curve correction >5º.

Conclusion: This investigation demonstrated that there is a time lag between application of spinal orthosis and its effect on scoliotic curvature. This is likely due to the low-stiff and viscoelastic properties of the spine. The clinical relevance of this study is that for scoliotic patients undergoing orthotic treatment, radiograph should not be taken within 2 hours of putting on or taking off spinal orthosis, as it may not show the maximum effect.

Keywords: adolescent idiopathic scoliosis, spinal orthosis, biomechanical effect, time domain, clinical ultrasound.

Key Points:

1. There is a clinical interest to know the biomechanical effect of spinal orthosis on patients with adolescent idiopathic scoliosis - how long it takes to reach the maximal correction after putting on the spinal orthosis and return to the original curvature after taking off the orthosis .
2. This study demonstrated that scoliotic spine has a time lag on the response of orthotic intervention to the patients with AIS, and the time difference may vary with individuals' spinal flexibilities and BMIs.
3. Further studies are warranted to confirm the current observation and facilitate comprehensive understanding of the mechanism of orthotic intervention to the patients with AIS.

Mini Abstract

In patients with ~~Adolescent~~ adolescent ~~Idiopathic~~ idiopathic ~~Scoliosis~~scoliosis, there is a time lag between donning and doffing of an orthosis and the development of its maximal effect on the spine. It is recommended a radiograph to assess the effect of bracing should only be taken more than 2 hours after the orthotic intervention.

Title: Time-dependent response of scoliotic curvature to orthotic intervention: When should a radiograph be taken after putting on or taking off a spinal orthosis?

Introduction

Spinal orthosis is the most common non-operative treatment for patients with adolescent idiopathic scoliosis (AIS) [1, 2]. Spinal orthosis can be characterized as the application of external corrective forces (three-point pressure system) to the scoliotic spine that requires sufficient force/pressure to maintain correction to the spinal curves[3]. Orthotic intervention could significantly decrease the progression of high-risk curves to the threshold for surgery in patients with AIS and the benefit will increase with longer hours of orthosis wear[4].

The intrinsic stability of spine is maintained by intervertebral discs and immediate surrounding ligaments, while the extrinsic stability of the spine is maintained by spinal muscles, longitudinal ligaments and rib cage[5]. The viscoelastic properties of the spinal structures (including ligaments, joint capsules and intervertebral discs) constitute differences in loading and unloading behavior of the spine (creep-recovery response) [6].

Although, many studies had demonstrated that initial magnitude of deformity, curve patterns, flexibility and gender[7-9] could affect the effectiveness of spinal orthosis on AIS, few studies had investigated the biomechanical effect of spinal orthosis on scoliotic spine versus time among different habitus (e.g. BMI). One study suggested that overweight patients with AIS may have greater curve progression and less successful outcomes from orthotic treatment than those who are not overweight[10], but no solid data were reported. In current clinical practice, it is postulated that the spine will take some time to adapt to the brace after wearing or removal, but it is not known how long or what factors may affect this. However, no studies were to assess the timing of maximal correction or return of original curvature after putting on (donning) or taking off (doffing) spinal orthosis respectively. Perhaps one of the major concerns with studies of this nature, is the concern of the harmful effect of ionizing radiation need for repeated radiographs over a short period of time to assess the timing of changes to the spine after orthotic intervention.

The Cobb's method measures the angle formed by lines drawn parallel to the upper and lower end plate of the relevant end vertebrae ~~vertebral bodies at the beginning and the lower end plate of the curve and the angle between these two lines is equal to the Cobb's angle~~is the method in common use ~~that reveals more the anterior deformity of the spine~~. Spinous process angle (SPA), formed by ~~which reveals more the posterior deformity of the spine, is measured by~~ accumulating the angles formed by every two lines joining three neighboring spinous processes, has also been described. ~~Both Cobb's angle and SPA are referring to the deformity of the spine, but these two parameters are not exactly the same.~~ These two parameters were found highly correlated to each other, with a correlation coefficient of r = 0.80 for the pre-orthosis stage and r = 0.87 for the in-orthosis stage ($p < 0.05$) ~~in relevant research studies~~ and can be converted from each other through some linear formulas (Cobb's Angle = 1.1456 SPA + 1.3847 for pre-orthosis stage and Cobb's Angle = 1.6652 SPA - 8.8479 for in-orthosis stage respectively) as established in literatures[11-~~15~~16]. Moreover, ~~studies[16]~~studies[17-~~21~~-22] have demonstrated that clinical ultrasound could be used to locate and identify the posterior arches of the spine (i.e. lamina, spinous process), and using this approach the SPA can be measured. Thus, the Cobb angle could be estimated by the SPA measured from ultrasound ~~images[13]~~images[13-16]. The aim of the current study is to use CUS to non-invasively document the changes in spinal curvature in patients with adolescent idiopathic scoliosis undergoing bracing, thereby helping to understand the biomechanical effects

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of orthotic intervention and factors that may affect them, without the need for additional radiation exposure to the patients.

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Materials and methods

The subjects were recruited from a scoliosis clinic according to the following selection criteria: 1) female with AIS; 2) Cobb's angle: 20° - 40°; 3) age: 10-15; 4) Risser's sign: ≤ 2; 5) curve pattern: double or single major curve; & 6) after orthosis adaptation period.

Nine female patients (mean age: 12 years and 11 month) with AIS who wore the symmetric underarm rigid spinal orthoses after adaptation period were studied. The type of curves consisted of 1 thoracic, 1 thoracolumbar, 1 lumbar and 6 double major curve pattern.

Study Design:

Subjects were recruited into either the doff-orthosis or the don-orthosis groups or both. Ethical approval was obtained for this pilot study and all the involved subjects and their parents signed on the inform-consent forms.

In the doff-orthosis group, the subjects were requested to wear their spinal orthoses for 23 hours prior to assessment, a standing in-orthosis radiograph was then taken, in order to allow correlation with CUS measurements. After that, the CUS was used to measure spinal curvature before brace removal, immediately after brace removal and at 30-minute, 60-minute, 90-minute, 120-minute and 180-minute after brace removal.

In the don-orthosis group, the subjects were requested not to wear their spinal orthoses for at least 23 hours prior to assessment. On the date of clinical assessment, a standing out-orthosis radiograph was taken. Following that, the CUS was used to measure spinal curvature before orthosis application, immediately after application and at 30-minute, 60-minute, 90-minute, 120-minute and 180-minute after donning the orthosis.

All the ultrasound scans were performed using an ultrasound unit (MyLab 25, Esoate China Ltd., China) with a 7.5 MHZ linear transducer and a 3-D add-on system (Tom Tec 3-D Sono-Scan Pro, Germany) to reconstruct the B-mode ultrasound images into 3-D ~~images~~[17] images[13–~~18~~16].

Doff-orthosis US Scanning

During the out-orthosis ultrasound scanning, the subject was instructed in standing position, which is comparable to the position when taking radiograph (see Figure 1a), with feet at shoulder width and eyes looking at a horizontal steadfast object (see Figure 1b). With the system activated, one set of 3-D ultrasound images was acquired through a single sweep on the region of scoliotic spine and three successful trials of data were captured at each doff-orthosis stage (see Figure 1b). One minute was required for one trial of a single sweep for acquiring the ultrasound images.

Don-orthosis US Scanning

With the tightness of straps prescribed and marked by the experienced orthotist, the width of the posterior opening of spinal orthosis was trimmed to be 6.5 cm so that there is sufficient space for application of the ultrasound probe (width: 6.2 cm). A fast-grip setting was used to maintain the same orthosis tightness during 3-D CUS scanning via using the width of the posterior opening as the indicator. When the fast-grip setting fixed the spinal orthosis onto the subject’s trunk, the upper two straps were unfastened and exposing the subject's scoliotic spine region. A set of 3-D ultrasound images of the spine was obtained through a single sweep (see Figure 2). Three successful trials of data were captured at each don-orthosis stage.

All the ultrasound images acquired from different stages were used to compare the curvature changes versus time domain.

The difference in Cobb's angle between the supine and standing AP radiograph was used as an indication of the subjects' spinal flexibility. Body Mass Index (BMI) of each subject was recorded to investigate the correlation between the BMI and the response time of scoliotic curvature to the spinal orthosis.

Results

A pilot trial was first conducted on a subject for monitoring the doff-orthosis and don-orthosis effects from immediate doff-orthosis up to 120 minutes, and from immediate don-orthosis up to 60 minutes respectively. The degree of the curvature at 120 minutes doff-orthosis tended close to that at 24 hours doff-orthosis. This provided an indication to the likely timing to maximal effect.

After the pilot trial, 8 more subjects were recruited and monitored from immediate doff-orthosis / don-orthosis and up to 180-minute doff-orthosis / don-orthosis (2 out of the 8 subjects were investigated up to 120-minute doff-orthosis / don-orthosis since the data showed that after 120-minute doff-orthosis / don-orthosis, all curves tended to be stable).

The subjects' spinal flexibility index (SFI) was estimated from the change of Cobb's angle from the pre-treatment standing antero-posterior (AP) radiograph to supine AP radiograph (SFI =

[Standing Cobb's Angle - Supine Cobb's Angle]/Standing Cobb's Angle*100)[~~21~~23]. The correlation between spinal flexibility index and BMI was not statistically significant (see Table 1).

In the doff-orthosis group, a typical case is shown in Figure 3. The Cobb's angles estimated from US images representing the curvature changes when doffing the spinal orthosis versus time domain are shown in Table 2 / Graph 1. The immediate doff-orthosis effects were not obvious. The curves might increase > 5º at or after 30-minute doff-orthosis. The time would be different for individuals. In the doff-orthosis group, the subject (Subject A1) with the lowest BMI (15.9 kg/m^2) took the longest time to increase > 5º (90 minutes for both thoracic and lumbar curves) after doffing the spinal orthosis. After 120-minute doff-orthosis, all curves tended to be stable.

In the don-orthosis group, a typical case is shown in Figure 4. The Cobb's angles estimated from US images representing the curvature changes when donning the spinal orthosis versus time domain are shown in Table 3 / Graph 2. The immediate don-orthosis effects were not obvious. The curves might decrease > 5º at or after 30-minute don-orthosis. The time would be different for individuals. In the don-orthosis group, the subject with the highest BMI (24.0kg/m^2) seemed to take the longest time to response to the orthotic intervention (90 minutes for thoracic curve and 60 minutes for lumbar curve to achieve curve corrections > 5º). After 120-minute don-orthosis, all curves tended to be stable.

Discussion

In the recent decades, the spinal flexibilities were assessed via different methods (e.g. side-bending, supine traction, supine side-bending and fulcrum bending). The magnitude of flexibility has been used for predication of orthotic or surgical correction. Supine Cobb's angle before bracing is close to Cobb's angle obtained after orthotic ~~intervention~~~~[22]~~intervention[24, ~~23~~25]. A recent research study proposed to use hanging total spine radiographs to estimate the flexibility of scoliotic spine but the maturity of the patients could influence the correlation between immediate in-brace Cobb angle and the Cobb angle in the hanging ~~position~~~~[24]~~position[26]. In recent years, some scoliosis clinics use the supine Cobb's angle (pre-treatment) as an indicator of spinal curvature flexibility to predict the magnitude of correction that could be obtained by spinal orthosis for the patients with AIS. The current study also took supine Cobb's angle (from radiograph) as an indicator to estimate the spinal curvature flexibility. The spinal flexibility would affect the performance of orthotic treatment to patients with AIS. However, no statistically correlation was found between the spinal flexibility and the response of scoliotic spine to the orthosis in current study. It may be due to the small sample size. Moreover, the subjects in this study tended to be slim cases, thus, the body weight effect on the spinal flexibility might not be obvious.

Gravity is the force by which all bodies are attracted to the earth and it works continuously on the human body. If the effects of gravity are not balanced, the body will collapse and fall onto the ground. In erect body posture, the body alignment and balance are maintained by different muscle groups under a harmonic rhythm. This study found that the trend of the curvature changes of the subject (subject B4) with higher BMI seemed to take the longer time to response to the orthotic intervention (90 minutes for thoracic curve and 60 minutes for lumbar curve for > 5º corrections) than others. There is a suggestion from our study that body weight may have an effect on a scoliotic spine, but few studies have looked into this aspect. It would be interesting to consider this factor when designing spinal orthosis, though more convincing data are required to verify this effect.

The technique of using clinical ultrasound to assess AIS is reliable (intra-rater and inter-rater of this method were both found ICCs > 0.9, $p < 0.05$) and reasonably well established in the literatures[13, -1416, 1718, 1819, 2527, 2628]. This study applied 3-D CUS method to investigate the biomechanical effect of the spinal orthosis on the scoliotic spine versus time domain. According to the trend of the curvature changes, the subjects with higher BMI required longer time to achieve a significant spinal curvature correction (decrease > 5º) after donning the orthosis and the subject with lower BMI required longer time to show significant collapse (increase > 5º) in spinal curvatures after doffing the orthosis. This trend indicated that when testing the don-orthosis effect, the viscoelastic properties of the soft tissues surrounding the spine lagged the time for response; while testing the doff-orthosis effect, the external force disappeared and the gravity force took dominant to cause the scoliotic spine collapsed. These findings also suggested that orthotic treatment may be less effective in the patients with higher body weight than those with lower body weight.

In the current practice of orthotic treatment, the scoliosis clinic refers the patients with AIS to take in-orthosis radiograph to reveal the optimal correction that could be rendered by the spinal orthosis right after orthotist's check-out procedure; while out-orthosis radiograph is taken after the patients taking off the orthosis for 23 hours to monitor the progression of the spinal curves. With reference to the findings in this study, the current practice could be modified since the best correction happened 120 minutes after donning the orthosis and the correction could not be maintained at and after 120 minutes doffing the orthosis. Thus, this study suggests that the orthosis should be removed for at least 2 hours prior to taking an out-orthosis radiograph of the spine to detect possible curve deterioration. Similarly, it is needed to delay 2 hours before taking an in-orthosis radiograph to confirm the maximum correction after putting on the orthosis.

Limitations

The sample size of this study is small, only 9 subjects were recruited. The results could only indicate the trend for the biomechanical effect of spinal orthosis on the scoliotic spine versus time domain. A study with larger sample size is suggested in order to draw a solid conclusion and represent the whole picture on this aspect. The current study would help guide future studies in that the time scale to maximum curvature changes should be around 2 hours.

This study based on an assumption that the subjects were all compliant to the instructions when they were assigned to the corresponding group (i.e. the subjects in the doff-orthosis group were assumed to wear the orthosis at the prescribed strap tightness for 23 hours before the assessment, while those in the don-orthosis group were assumed to take off the orthosis for 23 hours). If the subjects' actual compliance could be monitored, the results would be more convincing.

The subject recruitment in this study is by convenience. The orthotic treatment stages and the curvature types varied among different subjects. There were 3 subjects under orthotic treatment for around 6 months, while the other subjects for at least a year. Among the 9 subjects, 6 subjects had double right thoracic and left lumbar curves, while the other 3 subjects had single right thoraco-lumbar curve. These differences may alter the performance of the spinal orthosis. In the further study, homogeneous subject group should be considered to minimize the potential differences among individual subjects.

Conclusion

This study demonstrated that CUS can follow the response of spine to application and removal of orthoses in a select group of AIS patients with varying flexibility as measured by upright and supine radiographs. The spinal response appears to plateau after approximately 120 minutes for patients who are followed out for 180 minutes.scoliotic spine has a time lag on the response of orthotic intervention to the patients with AIS, and the time difference varies with individuals' spinal flexibilities and BMIs. Further studies are warranted to confirm the current observation and facilitate comprehensive understanding the mechanism of orthotic intervention to the patients with AIS.

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Table1. The Subjects' Flexibility Index and Body Mass Index

Subject Code	**Curve Level**	**Pre-treatment Standing Cobb's Angle (from AP X-ray)**	**Pre-treatment Supine Cobb's Angle (from AP X-ray)**	**Correction in Cobb's Angle**	***Spinal Flexibility Index (%)**		**Body Mass Index (kg/m^2)**
					Individual	**Overall**	
***A1**	T5-T12	34°	30°	4°	11.8%	28.1%	15.9
	T12-L5	30°	16°	14°	46.7%		
A2	T5-T12	30°	24°	6°	20.0%	30.6%	17.5
	T12-L4	32°	19°	13°	40.6%		
A3	T7-T12	31°	Nil	Nil	Nil		15.9
A4	T4-T11	26°	20°	6°	23.1%	32.7%	16.1
	T11-L3	26°	15°	11°	42.3%		
A5	T11-L3	30°	14°	16°	53.3%		19.8
***B1**	T5-T12	34°	30°	4°	11.8%	28.1%	
	T12-L5	30°	16°	14°	46.7%		15.9
B2	T5-T12	30°	21°	9°	30.0%	37.1%	17.6
	T12-L4	40°	23°	17°	42.5%		
B3	T10-L3	33°	17°	16°	48.5%		14.4
B4	T7-T11	14°	14°	0°	0	30.0%	24.0
	T11-L4	26°	14°	12°	46.2%		
B5	T5-T11	33°	18°	15°	45.5%	33.3%	16.9
	T11-L4	36°	28°	8°	22.2%		

*Subjects were coded as An (n=1, 2, 3, 4, 5) for the doff-orthosis group and Bn (n=1, 2, 3, 4, 5) for the don-orthosis group

*A1 and B1 referred to the same subject who participated in both groups in the pilot trial.

*The supine radiographs of subject A3 was missing in the database of the corresponding scoliosis clinic.

*Spinal Flexibility Index (%) = [Standing Cobb's Angle - Supine Cobb's Angle]/Standing Cobb's Angle*100.

*Overall Spinal Flexibility Index = [Standing Cobb's Angle of (Thoracic + Lumbar Curves) - Supine Cobb's Angle of (Thoracic + Lumbar Curves)] / Standing Cobb's Angle of (Thoracic + Lumbar Curves) *100

Table 2. The Cobb's Angle Estimated from CUS of Doff-orthosis Group (Coronal Plane)

Subject Code	Curve Level	Cobb's Angle (X-ray) 23hr Don-orthosis	Cobb's Angle Estimated from Ultrasound Images (Coronal Plane)							
			23 hr Don-orthosis	Immediate Doff-orthosis	30 min Doff-orthosis	60 min Doff-orthosis	90 min Doff-orthosis	120 min Doff-orthosis	150 min Doff-orthosis	180 min Doff-orthosis
A1	T5-T12	Nil	29º	28º	32º	32º	*38º	43º	Nil	Nil
	T12-L5	Nil	29º	24º	27º	30º	*36º	32º	Nil	Nil
A2	T5-T12	22º	20º	20º	23º	*25º	30º	34º	35º	35º
	T12-L4	25º	23º	22º	24º	*28º	32º	33º	34º	34º
A3	T7-T12	25º	21º	20º	24º	*28º	30º	32º	31º	33º
A4	T4-T11	14º	14º	15º	*20º	20º	23º	24º	24º	25º
	T11-L3	13º	11º	11º	14º	*18º	23º	23º	25º	25º
A5	T11-L3	13º	15º	15º	19º	*23º	27º	29º	Nil	Nil

*Compared to the 23 hr don-orthosis curve magnitude, the spinal curvature increased > 5º.

Graph 1. The Curvature Change of Doff-orthosis Group (Coronal Plane)

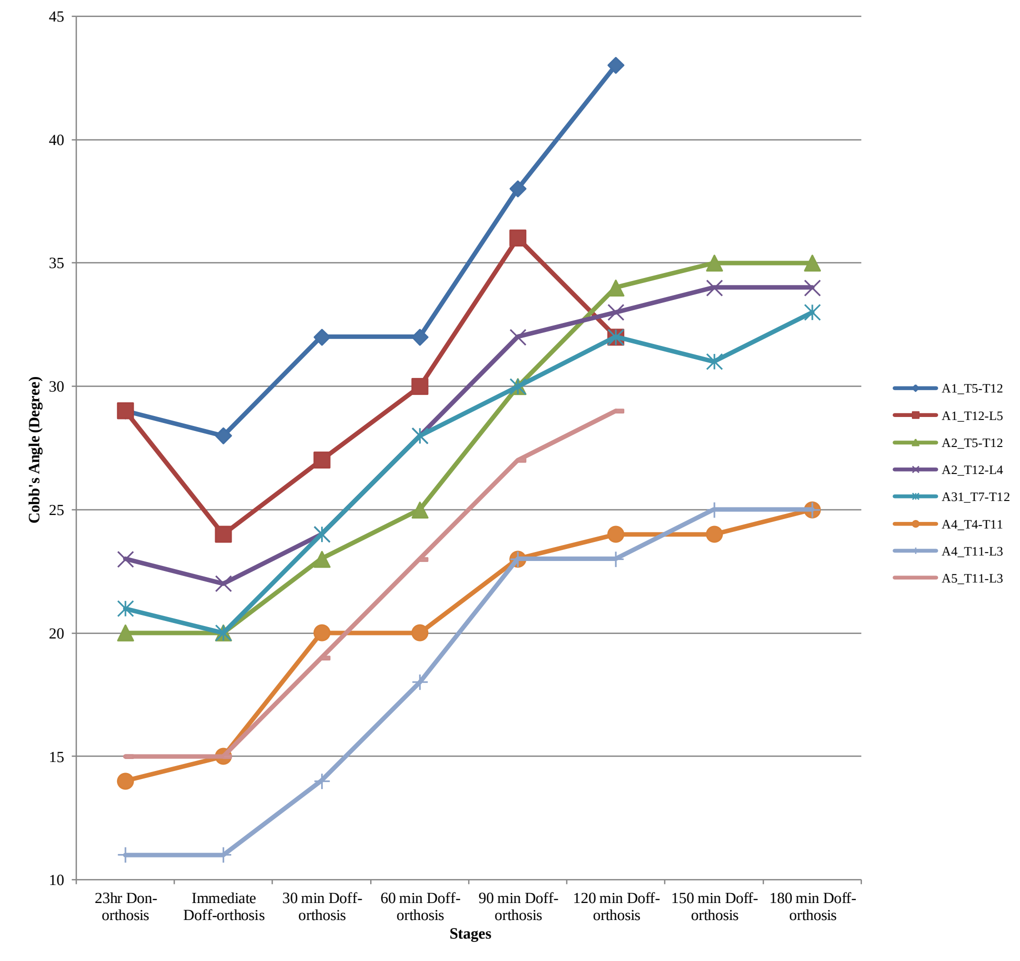
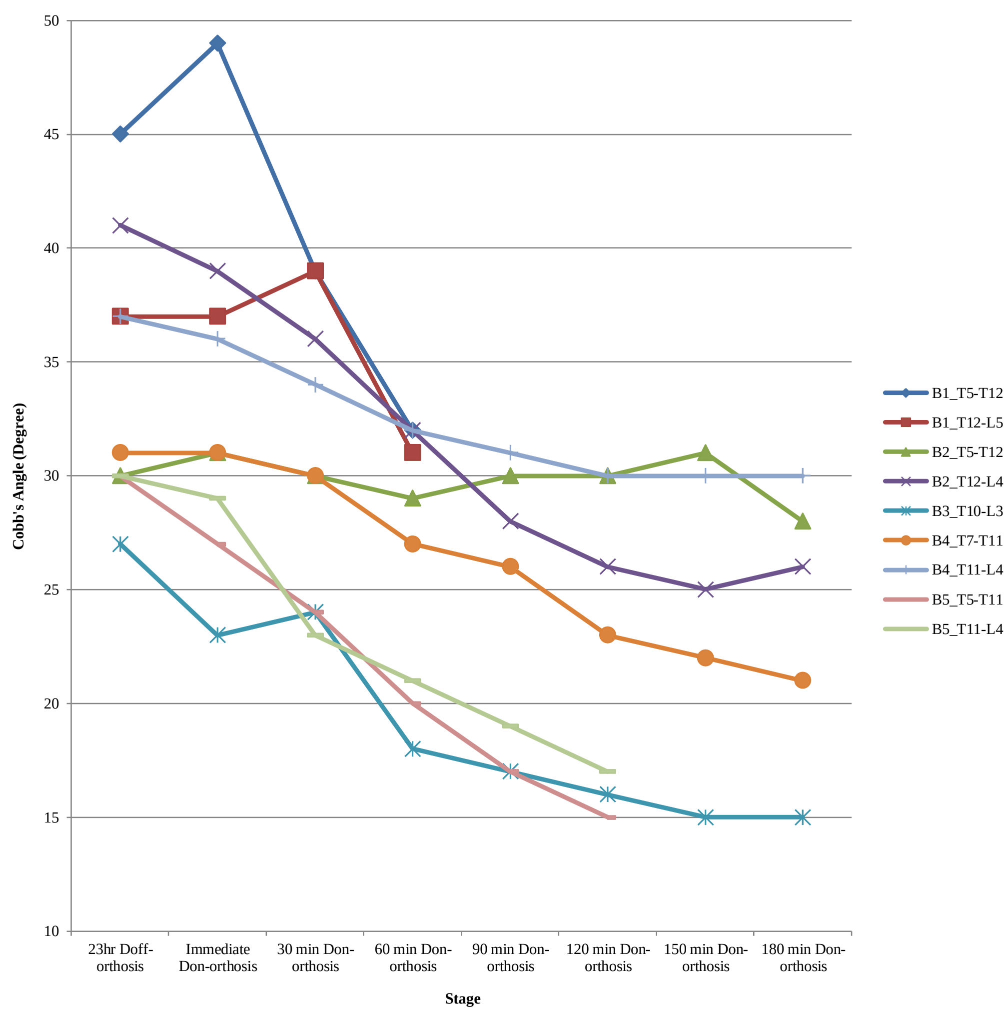


Table 3. Cobb's Angle Estimated from CUS of Don-orthosis Group (Coronal Plane)

Subject Code	Curve Level	Cobb's Angle (X-ray) 23hr Doff-orthosis	Cobb's Angle Estimated from Ultrasound Images (Coronal Plane)							
			23 hr Doff-orthosis	Immediate Don-orthosis	30min Don-orthosis	60 min Don-orthosis	90 min Don-orthosis	120 min Don-orthosis	150 min Don-orthosis	180 min Don-orthosis
B1	T5-T12	50º	45º	49º	*39º	32º	Nil	Nil	Nil	Nil
	T12-L5	30º	37º	37º	39º	*31º	Nil	Nil	Nil	Nil
B2	T5-T12	32º	30º	31º	30º	29º	30º	30º	31º	28º
	T12-L4	37º	41º	39º	*36º	32º	28º	26º	25º	26º
B3	T10-L3	22º	27º	23º	24º	*18º	17º	16º	15º	15º
B4	T7-T11	27º	31º	31º	30º	27º	*26º	23º	22º	21º
	T11-L4	33º	37º	36º	34º	*32º	31º	30º	30º	30º
B5	T5-T11	28º	30º	27º	*24º	20º	17º	15º	Nil	Nil
	T11-L4	30º	30º	29º	*23º	21º	19º	17º	Nil	Nil

*Compared to the 23 hr doff-orthosis curve magnitude, the spinal curvature decreased > 5º.



Graph 2. The Curvature Change of Don-orthosis Group (Coronal Plane)

(a)

(b)

Figure 1. (a) Position for Taking Radiography

(b) Position for Doff-orthosis Ultrasound Scanning

The subjects were instructed to keep erect standing position for both radiography and ultrasound scanning.

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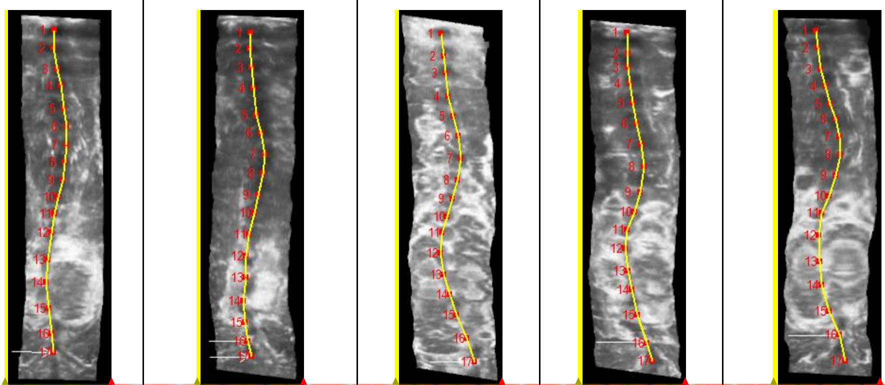
Figure 2. Position for Don-orthosis Ultrasound Scanning. The thoracic and lumbar regions of scoliotic spine were scanned through a single sweep with a fast-grip setting fixing the spinal orthosis onto the patient.



23hr Don-orthosis	Immediate Doff-orthosis	30 min Doff-orthosis	60 min Doff-orthosis	180 min Doff-orthosis
(a)	(b)	(c)	(d)	(e)

Figure 3. The Trend of Doff-orthosis Effect after Doffing the Spinal Orthosis (Subject A4). The subject A4 had double major curves (right thoracic and left lumbar). The first curve ranged from T4 to T11 (apex at T7) and the second curve ranged from T11 to L3 (apex at L2). The right thoracic curve collapsed ≥ 5° at and after 30 min doff-orthosis and the left lumbar curve collapsed ≥ 5° at and after 60 min doff-orthosis.

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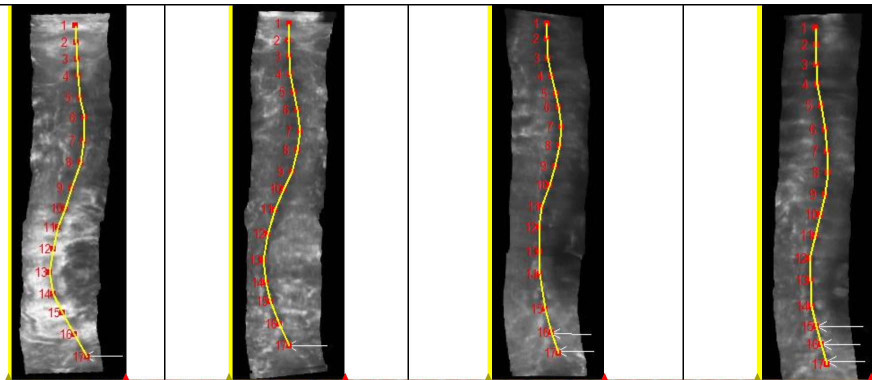

23 hr Doff-orthosis (a)	Immediate Don-orthosis (b)	30 min Don-orthosis (c)	180 min Don-orthosis (d)

Figure 4. The Trend of Don-orthosis Effect after Donning the Spinal Orthosis (Subject B2). The subject B2 had double major curves (right thoracic and left lumbar). The first curve ranged from T5 to T12 (apex at T8) and the second curve ranged from T12 to L4 (apex at L2). The right thoracic curve did not decrease ⩾ 5º even after 180 min don-orthosis, while the left lumbar curve decreased ⩾ 5º at and after 30 min don-orthosis.

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Table 2. The Cobb's Angle Estimated from CUS of Doff-orthosis Group (Coronal Plane)

Subject Code	Curve Level	Cobb's Angle (X-ray) 23hr Don-orthosis	Cobb's Angle Estimated from Ultrasound Images (Coronal Plane)							
			23hr Don-orthosis	Immediate Doff-orthosis	30 min Doff-orthosis	60 min Doff-orthosis	90 min Doff-orthosis	120 min Doff-orthosis	150 min Doff-orthosis	180 min Doff-orthosis
A1	T5-T12	Nil	29º	28º	32º	32º	*38º	43º	Nil	Nil
	T12-L5	Nil	29º	24º	27º	30º	*36º	32º	Nil	Nil
A2	T5-T12	22º	20º	20º	23º	*25º	30º	34º	35º	35º
	T12-L4	25º	23º	22º	24º	*28º	32º	33º	34º	34º
A3	T7-T12	25º	21º	20º	24º	*28º	30º	32º	31º	33º
A4	T4-T11	14º	14º	15º	*20º	20º	23º	24º	24º	25º
	T11-L3	13º	11º	11º	14º	*18º	23º	23º	25º	25º
A5	T11-L3	13º	15º	15º	19º	*23º	27º	29º	Nil	Nil

*Compared to the 23 hr don-orthosis curve magnitude, the spinal curvature increased > 5º.

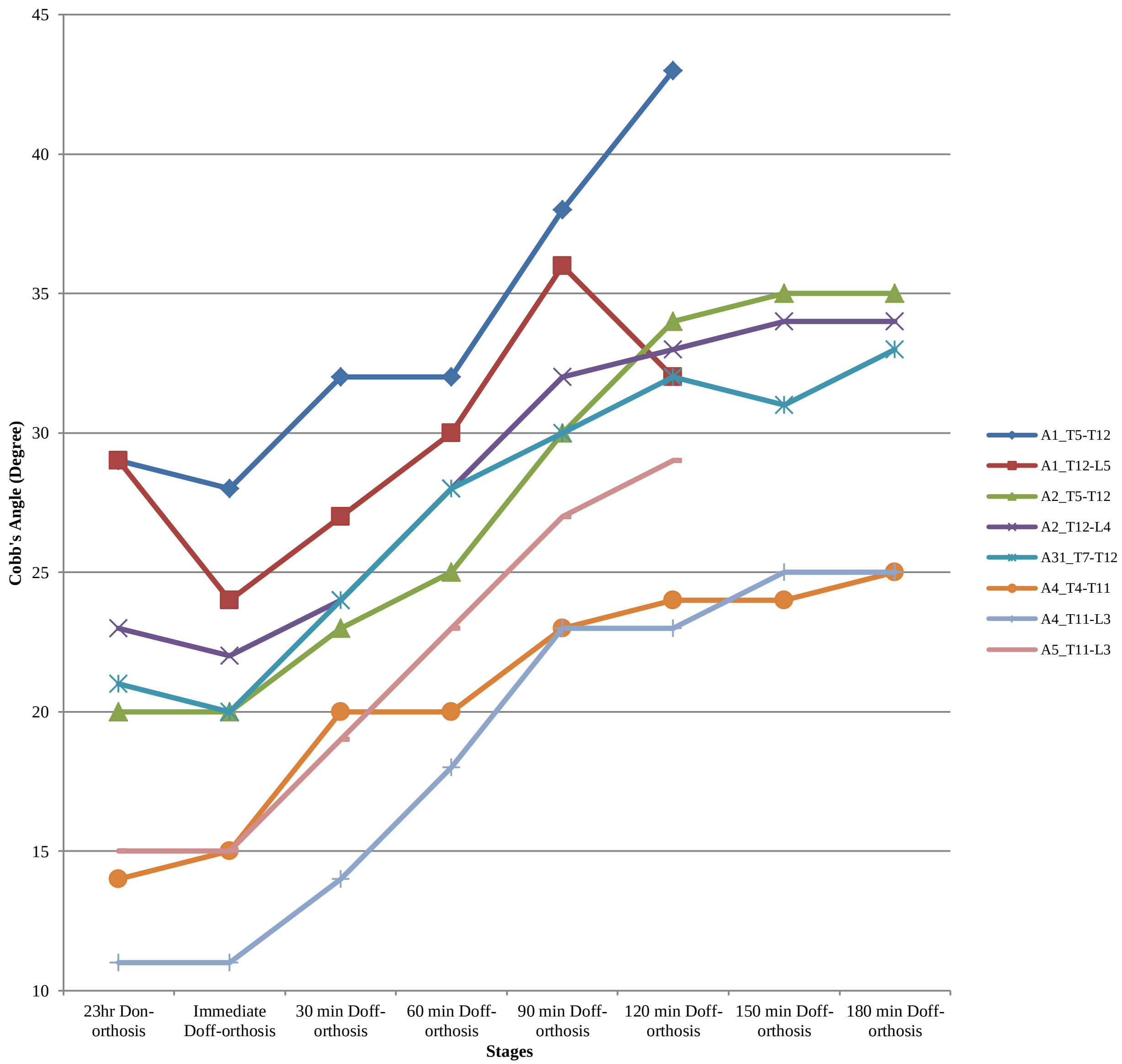
Table 3. Cobb's Angle Estimated from CUS of Don-orthosis Group (Coronal Plane)

Subject Code	Curve Level	Cobb's Angle (X-ray) 23hr Doff-orthosis	Cobb's Angle Estimated from Ultrasound Images (Coronal Plane)							
			23hr Doff-orthosis	Immediate Don-orthosis	30min Don-orthosis	60 min Don-orthosis	90 min Don-orthosis	120 min Don-orthosis	150 min Don-orthosis	180 min Don-orthosis
B1	T5-T12	50º	45º	49º	*39º	32º	Nil	Nil	Nil	Nil
	T12-L5	30º	37º	37º	39º	*31º	Nil	Nil	Nil	Nil
B2	T5-T12	32º	30º	31º	30º	29º	30º	30º	31º	28º
	T12-L4	37º	41º	39º	*36º	32º	28º	26º	25º	26º
B3	T10-L3	22º	27º	23º	24º	*18º	17º	16º	15º	15º
B4	T7-T11	27º	31º	31º	30º	27º	*26º	23º	22º	21º
	T11-L4	33º	37º	36º	34º	*32º	31º	30º	30º	30º
B5	T5-T11	28º	30º	27º	*24º	20º	17º	15º	Nil	Nil
	T11-L4	30º	30º	29º	*23º	21º	19º	17º	Nil	Nil

*Compared to the 23 hr doff-orthosis curve magnitude, the spinal curvature decreased > 5º.

Tables

Graph 1. The Curvature Change of Doff-orthosis Group (Coronal Plane)



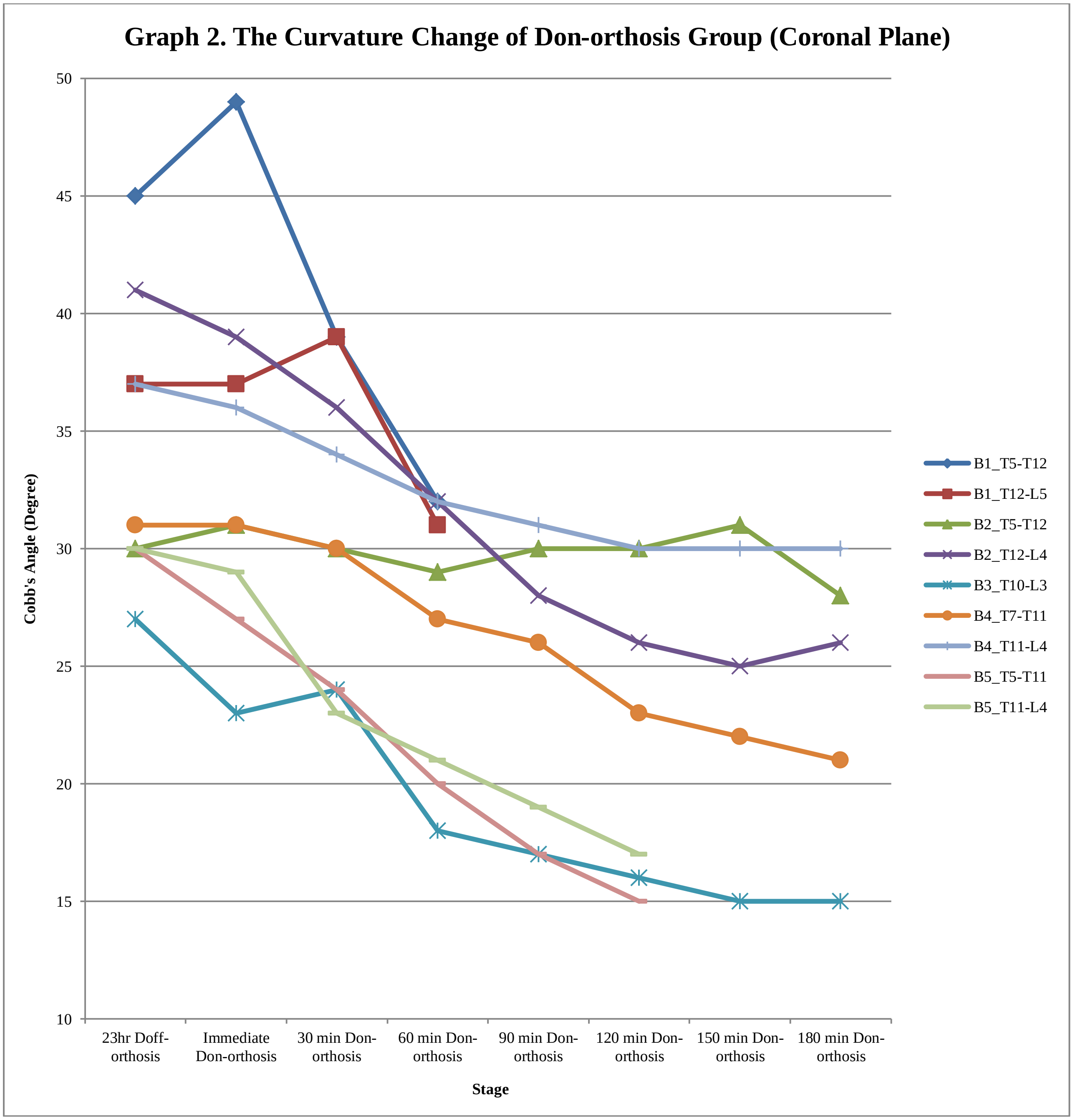

Graph 2. The Curvature Change of Don-orthosis Group (Coronal Plane)
Cobb's Angle (Degree)
50
45
40
35
30
25
20
15
10
23hr Doff-orthosis
Immediate Don-orthosis
30 min Don-orthosis
60 min Don-orthosis
90 min Don-orthosis
120 min Don-orthosis
150 min Don-orthosis
180 min Don-orthosis
Stage
B1_T5-T12
B1_T12-L5
B2_T5-T12
B2_T12-L4
B3_T10-L3
B4_T7-T11
B4_T11-L4
B5_T5-T11
B5_T11-L4

Table1. The Subjects' Flexibility Index and Body Mass Index

Subject Code	Curve Level	Pre-treatment Standing Cobb's Angle (from AP X-ray)	Pre-treatment Supine Cobb's Angle (from AP X-ray)	Correction in Cobb's Angle	*Spinal Flexibility Index (%)		Body Mass Index (kg/m^2)
					Individual	**Overall**	
***A1**	T5-T12	34°	30°	4°	11.8%	28.1%	15.9
	T12-L5	30°	16°	14°	46.7%		
A2	T5-T12	30°	24°	6°	20.0%	30.6%	17.5
	T12-L4	32°	19°	13°	40.6%		
A3	T7-T12	31°	Nil	Nil	Nil		15.9
A4	T4-T11	26°	20°	6°	23.1%	32.7%	16.1
	T11-L3	26°	15°	11°	42.3%		
A5	T11-L3	30°	14°	16°	53.3%		19.8
***B1**	T5-T12	34°	30°	4°	11.8%	28.1%	
	T12-L5	30°	16°	14°	46.7%		15.9
B2	T5-T12	30°	21°	9°	30.0%	37.1%	17.6
	T12-L4	40°	23°	17°	42.5%		
B3	T10-L3	33°	17°	16°	48.5%		14.4
B4	T7-T11	14°	14°	0°	0	30.0%	24.0
	T11-L4	26°	14°	12°	46.2%		
B5	T5-T11	33°	18°	15°	45.5%	33.3%	16.9
	T11-L4	36°	28°	8°	22.2%		

*Subjects were coded as An (n=1, 2, 3, 4, 5) for the doff-orthosis group and Bn (n=1, 2, 3, 4, 5) for the don-orthosis group
*A1 and B1 referred to the same subject who participated in both groups in the pilot trial.
*The supine radiographs of subject A3 was missing in the database of the corresponding scoliosis clinic.
*Spinal Flexibility Index (%) = [Standing Cobb's Angle - Supine Cobb's Angle]/Standing Cobb's Angle*100.
*Overall Spinal Flexibility Index = [Standing Cobb's Angle of (Thoracic + Lumbar Curves) - Supine Cobb's Angle of (Thoracic + Lumbar Curves)] / Standing Cobb's Angle of (Thoracic + Lumbar Curves) *100

Figure 1. (a) Position for Taking Radiography

(b) Position for Doff-orthosis Ultrasound Scanning

The subjects were instructed to keep erect standing position for both radiography and ultrasound scanning.

Figure 2. Position for Don-orthosis Ultrasound Scanning. The thoracic and lumbar regions of scoliotic spine were scanned through a single sweep with a fast-grip setting fixing the spinal orthosis onto the patient.

Figure 3. The Trend of Doff-orthosis Effect after Doffing the Spinal Orthosis (Subject A4). The subject A4 had double major curves (right thoracic and left lumbar). The first curve ranged from T4 to T11 (apex at T7) and the second curve ranged from T11 to L3 (apex at L2). The right thoracic curve collapsed ≥5° at and after 30 min doff-orthosis and the left lumbar curve collapsed ≥ 5° at and after 60 min doff-orthosis.

(a) 23hr Don-orthosis

(b) Immediate Doff-orthosis

(c) 30 min Doff-orthosis

(d) 60 min Doff-orthosis

~~**(e)** 90 min Doff-orthosis~~

~~**(f)** 120 min Doff-orthosis~~

~~**(g)** 150 min Doff-orthosis~~

~~**(h)**~~**(e)** 180 min Doff-orthosis

Figure 4. The Trend of Don-orthosis Effect after Donning the Spinal Orthosis (Subject B2). The subject B2 had double major curves (right thoracic and left lumbar). The first curve ranged from T5 to T12 (apex at T8) and the second curve ranged from T12 to L4 (apex at L2). The right thoracic curve did not decrease ≥5° even after 180 min don-orthosis, while the left lumbar curve decreased ≥5° at and after 30 min don-orthosis.

(a) 23 hr Doff-orthosis

(b) Immediate Don-orthosis

(c) 30 min Don-orthosis

~~**(d)** 60 min Don-orthosis~~

~~**(e)** 90 min Don-orthosis~~

~~**(f)** 120 min Don-orthosis~~

~~**(g)** 150 min Don-orthosis~~

~~**(h)**~~**(d)** 180 min Don-orthosis

Figure 1A
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Figure 2
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Figure 3A
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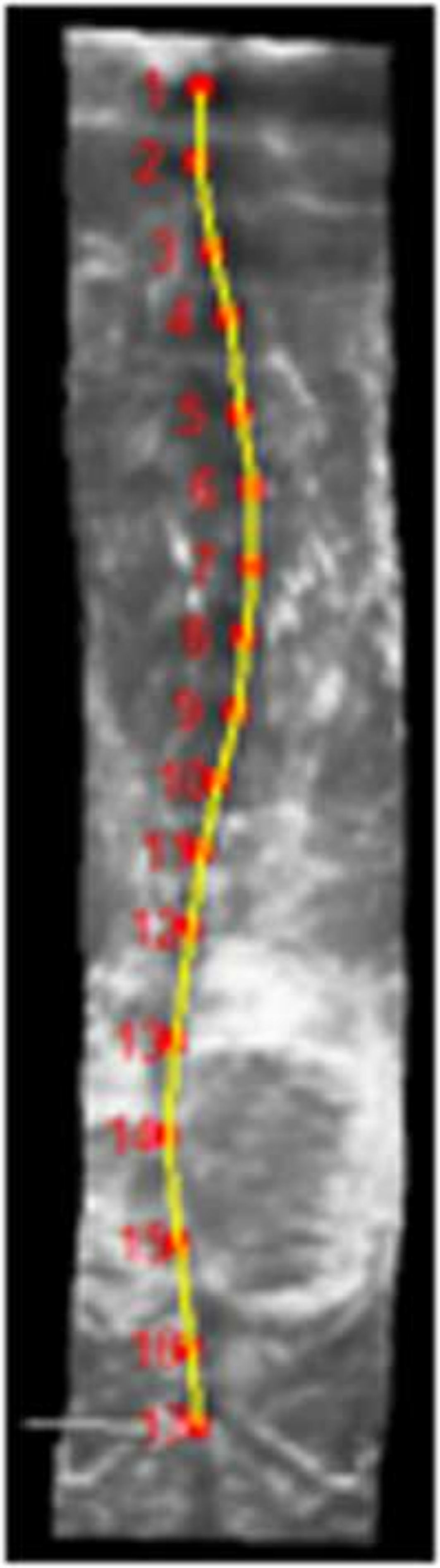

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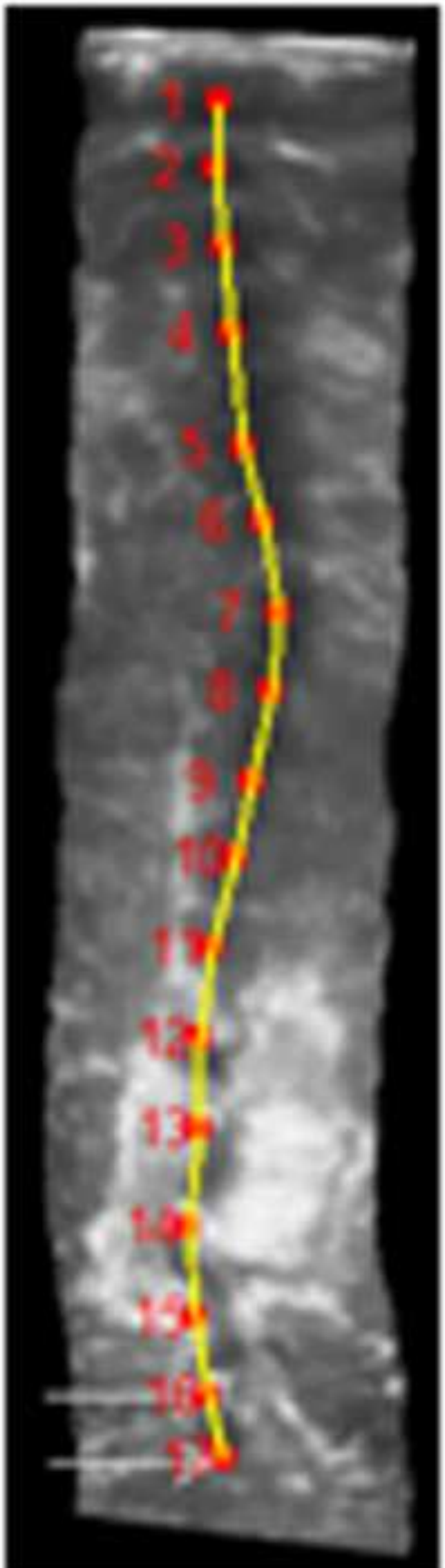

Figure 3C

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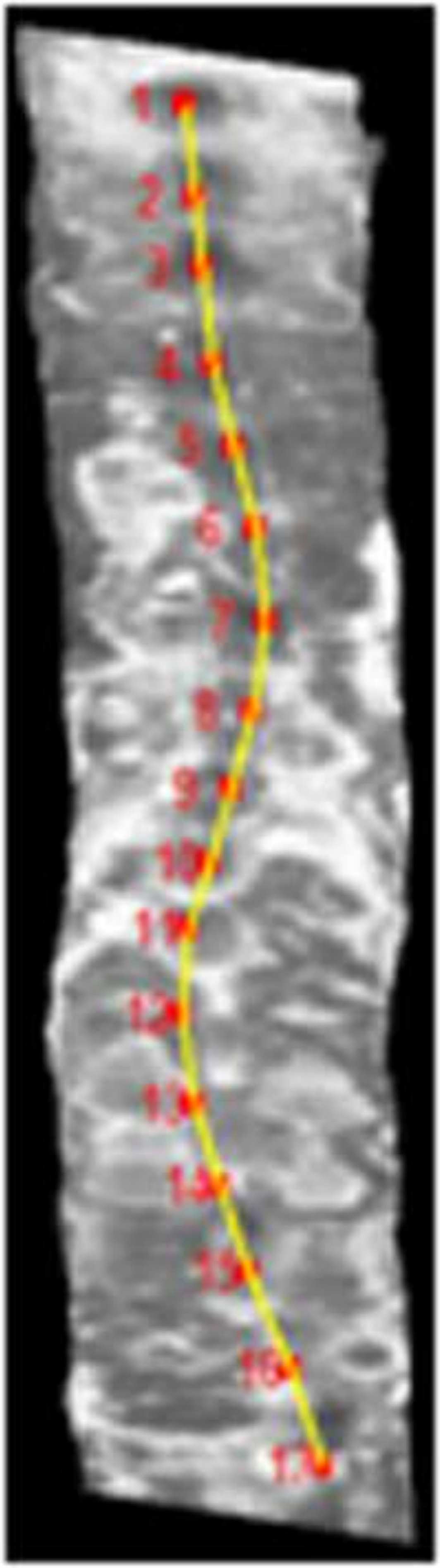

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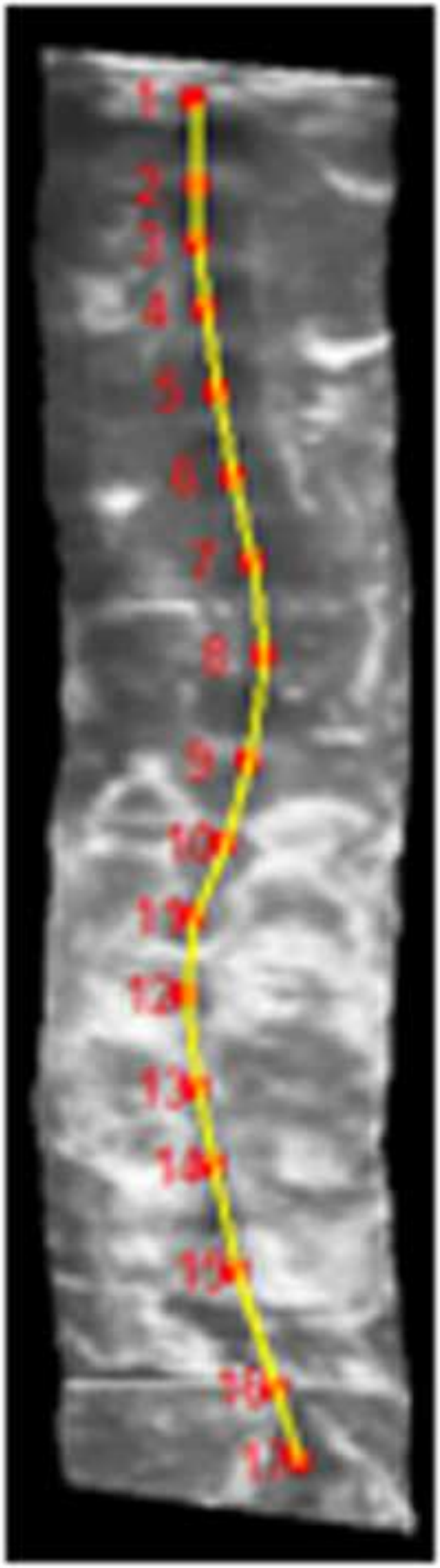

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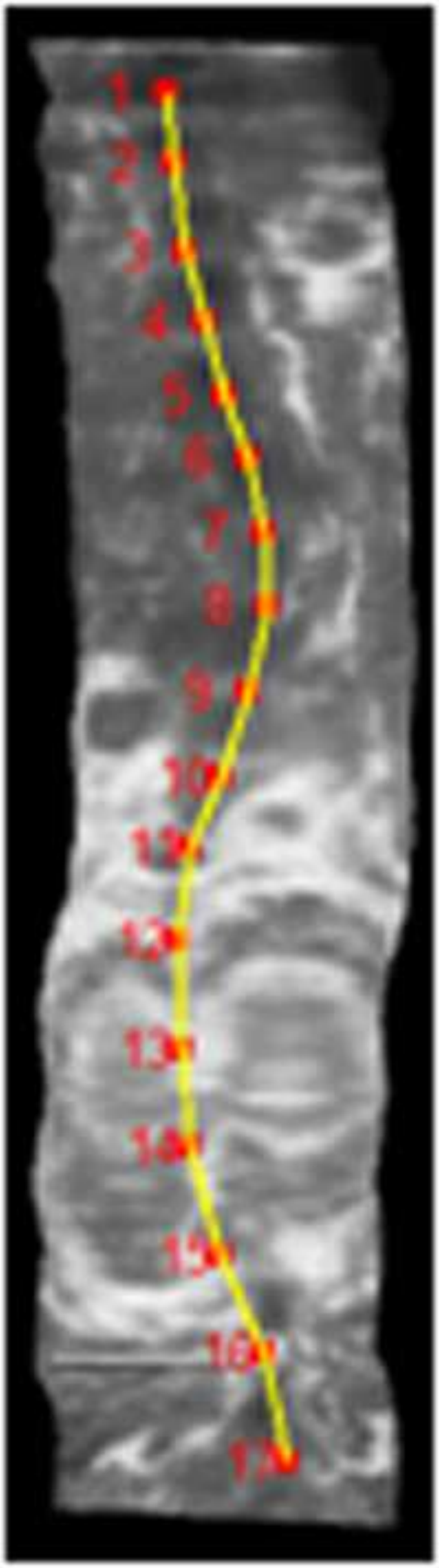

Figure 4A

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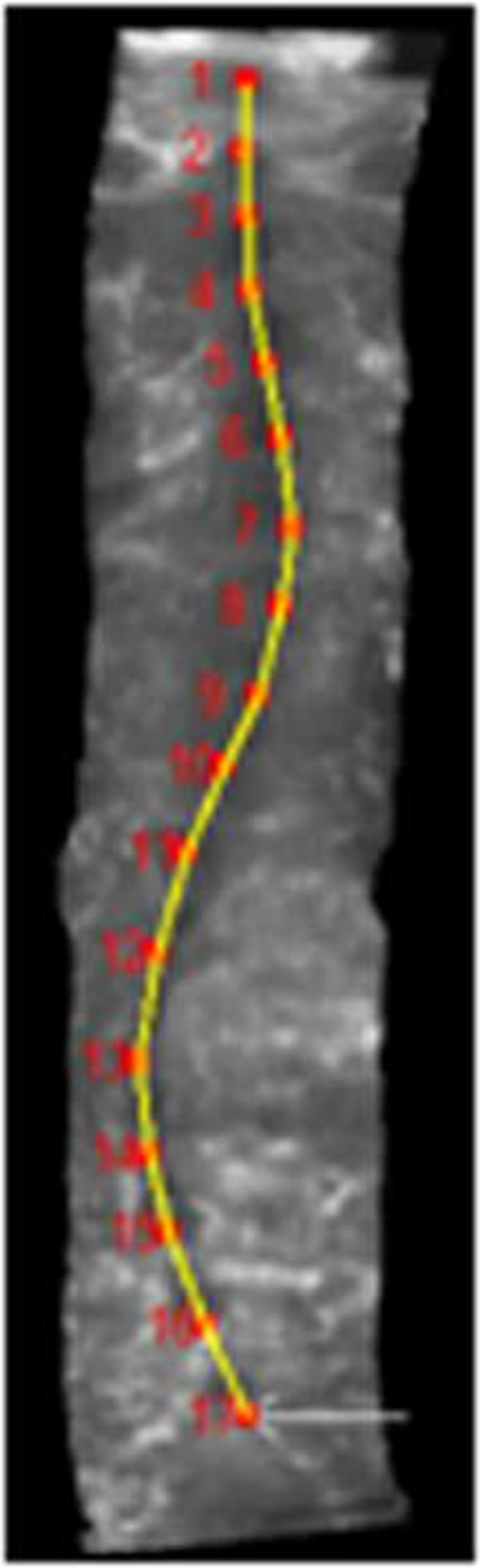

Figure 4C

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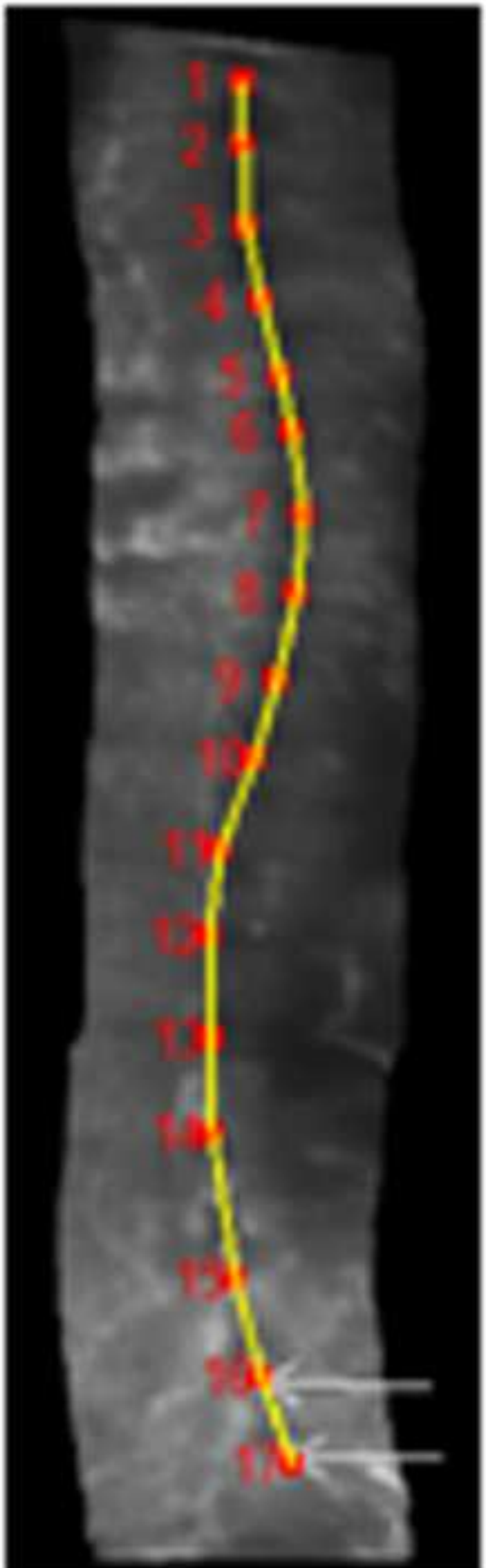

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