

TECHNICAL REPORT

Evaluation Of Efficacy And Biomechanical Characteristics Of Two Spinal Orthoses Manufactured By DeRoyal

Presented to:

DEROYAL INDUSTRIES, INC.

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ABSTRACT

The purposes for this study were to examine efficacy of two spinal orthoses in altering spinal kinematics and to compare their effectiveness. Prolign is a lumbar orthosis (LO) and Ultralign is a lumbosacral orthosis (LSO) and both are made by the DeRoyal Industries, Inc. Seventeen healthy male subjects with no impairments to their trunk at the time of the data collection and no previous history of major spinal pathology participated in the study. A digital video camera (60 Hz) was used to obtain kinematic data from the right sagittal and posterior views of the subject. For the sagittal view, three retroreflective markers were placed on the right side of the body at the mid-trunk, the hip (greater trochanter), and the knee (lateral femoral epicondyle) and three customized marker wands were placed on the spinal process at the 1st thoracic vertebra (T1), and the 1st (L1) and 5th (L5) lumbar vertebrae. For the posterior view, three flat retroreflective markers were placed on the spinal process of T1, L1 and L5. The subjects were instructed to perform three forward flexion trials, three backward extension trials, and three lateral (right) bending trials in each of the two braces and in an un-braced condition in nine test conditions. Selected variables were evaluated using a one-way analysis of variance with post hoc comparisons. The data from this study suggested that both orthoses are effective in restricting lumbar segmental intervertebral movement in flexion, extension and lateral flexion of trunk. The UltraLign provided more significant spinal immobilization and restricted more gross range of motion in all three types of trunk movement. The Prolign LO offered less support for the lumbar spine and restriction on the movements compared to the Ultralign LSO, but was effective in the reduction of lumbar intervertebral segmental mobility.

INTRODUCTION

Injuries to spinal column are most common in the work place, automobile accidents, sports, and other daily activities. Patients subject to these injuries are often prescribed to receive various spinal orthoses. The objectives for spinal orthoses applications include combination of the following: spinal support, maintaining a specific spinal posture, intervertebral segmental immobilization, protection from damaging stresses, or correction of spinal malalignment (White & Panjabi, 1990). A main purpose for applying a spinal orthosis is to alter the existing patterns of deformity and kinematics of the spine, and improve load-bearing tolerance. Low back pain (LBP) is very common and is one of the leading causes in workplace disability and sick leave (van Poppel et al., 2000); 80% of population will have LBP during their lifetime. Many studies have been conducted to examine effects of lumbosacral orthosis (LSO) and thoracolumbosacral (TLSO) (Axelsson et al., 1992; Buchalter et al., 1988; Fidler & Plasmans, 1983; Granata et al., 1997; Howard et al., 1998; Jorgensen & Marras, 2000; Lantz & Schultz, 1986; Lavender et al., 1995; McGill et al., 1994; van Leeuwen et al., 2000; van Poppel et al., 2000; Warren et al., 2001).

In vitro studies (White & Panjabi, 1990) indicated that the thoracic region of the spine has an average of 6.3° of range of motion (ROM) for each thoracic segment and a cumulative ROM of 76° , in combined flexion and extension (in sagittal plane). The lumbar region enjoys a total of 57° of ROM (without L5-S1 link) for the same type of motion. Most research studies have concentrated on the effect of the tested orthoses on limiting the gross ROM in the vertebral column using motion analysis and/or x-ray whereas some researchers focused on other measures such as electromyography (EMG), intra-abdominal pressure, forces and moments (modeled or estimated). Positive effectiveness of the tested orthoses has been shown in many studies

(Axelsson et al., 1992; Buchalter et al., 1988; Fidler & Plasmans, 1983; Granata et al., 1997; Jorgensen & Marras, 2000; Lantz & Schultz, 1986; McGill et al., 1994). Others found minimum effects of the braces on restricting gross ROM, especially in the sagittal plane (Lavender et al., 1995; van Leeuwen et al., 2000). Nachemson (Nachemson, 1987) indicated that LSO offers a reduction in 30 to 60% of normal mobility in flexion/extension and 10 to 40% in lateral flexion (bending). It has been stated that LSO functions include limiting segmental lumbosacral motion, limiting gross lumbosacral motion, reducing muscle activities, reducing intradiscal pressure, and increasing intra-abdominal pressure (Barron & Feverstein, 1991; Calmels & Fayolle-Minon, 1996; Minor, 1996; Perkins & Bloswick, 1995). Therefore, the main purposes for this study were to examine efficacy of two spinal orthoses in altering spinal kinematics and their effectiveness. The tested orthoses, Prolign lumbar orthosis (LO) and Ultralign lumbar sacral orthoses (LSO), are manufactured by DeRoyal Industries, Inc.

METHODS

SUBJECTS

Seventeen healthy recreational male subjects (age: 23 ± 2 yrs, body mass: 83 ± 12 kg, height: 1.82 ± 0.06 m) with no impairments to their spine at the time of the data collection and no history of major spinal pathology, participated in the study. Individual subject's information is provided in Appendix A. Subjects were recruited from the student population at The University of Tennessee. All subjects signed an informed consent form (see Appendix B), approved by The Institutional Review Board at The University of Tennessee, prior to the actual data collection.

INSTRUMENTATION

Kinematics

A digital video camera (60 Hz, JVC GR-DVL1980) was used to obtain kinematic data from the right sagittal and posterior views of the subject. For the sagittal view, three retroreflective markers were placed on the right side of the body at the mid-trunk, the hip, and the knee and three customized marker wands (with distal and proximal reflective spheres, Figure 1) were placed on the spinous process of the 1st thoracic vertebra (T1), and the 1st (L1) and 5th (L5) lumbar vertebrae (Figure 2-A and 3). For the posterior view, three flat retroreflective markers were placed on the spinal process of T1, L1 and L5 (Figure 2-B). To be consistent with literature, these three segments were referred as T1|T2, T12| L1 and L5| S1 respectively in the rest of the report. The recorded video images were digitized to obtain the coordinates of these reflective markers using an Ariel Performance Analysis System (APAS, Ariel Dynamics Inc.).

The digitized coordinates were decoded and imported into a customized program to compute time-histories and discrete events of linear and angular kinematic variables.

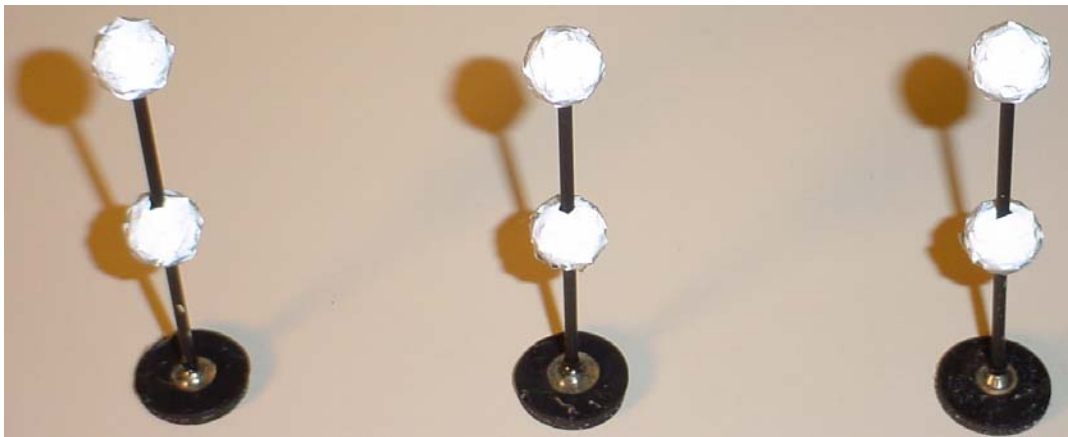


Figure 1.

Mark wand with distal and proximal reflective spheres.

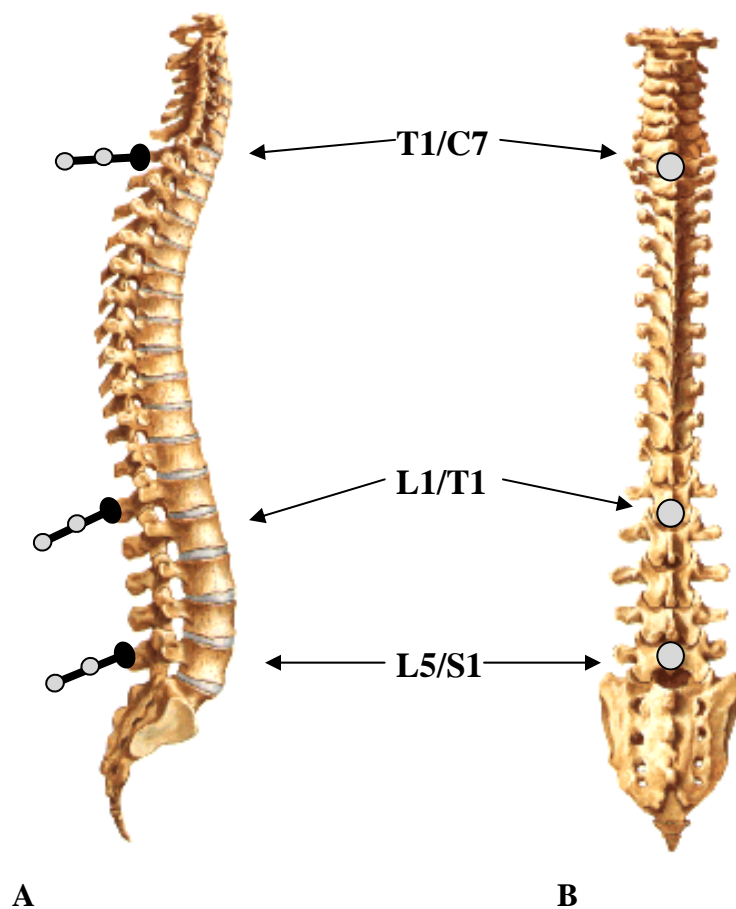


Figure 2. The setup of the reflective wands and marks on the trunk for the sagittal (A) and posterior (B) views.



Figure 3. The setup of the experiment for the trunk flexion test in unbraced (A) and Ultralign (B) conditions.

Spinal Orthoses

Two spinal orthoses were tested in this study. The Prolign is a lumbar orthoses and used for lower lumbar strains and sprains, proprioceptive feedback, postural control, and spinal extension positioning reinforcement of proper body mechanics. The indications for usage of this device include mild low back pain, lumbar muscle weakness, lumbar strain or sprain, spinal instability and mechanical or discogenic lumbar pain. The Ultralign LSO is a lumbosacral brace and used for neutral sagittal lumbar alignment using a regular lumbar sacral orthosis. The indications for usage of the device include postoperative fusion, postoperative laminectomy,

postoperative discectomy, compression fracture, degenerative disc disease, spinal instability, osteoporosis, and chronic low back pain.

Four anthropometric measurements were made prior to applying the braces. The first measurement was taken on the waist with the subject lying supine. The tape was placed underneath the subject's back and wrapped around the subject's waist at the navel to obtain the measurement for the Prolign brace (lumbar orthoses, Figure 4-A). The next three measurements were used to fit the Ultralign brace (lumbo sacral orthoses, Figure 4-B) and were taken with the subject standing upright. The first measurement was of the subject's chest taken one inch below the xiphoid process. The second measurement was of the subject's waist across the navel and the last measurement was a circumferential measurement around the hips at the level of greater trochanters of the subject. In order to reveal the attachment sites for the L1 and L5 wands (sagittal view) and reflective makers (posterior view), the pre-existing cutouts made by the manufacture on the support frames and the padded liner were enlarged without compromising the integrity of the orthoses (Figure 4).

The respective braces were fitted to each subject based on the manufacture's patient instruction manuals and the measurements taken above. When fitting the subject for the Prolign brace, the subject was asked to sit facing forward. The portion of the orthoses that fits against the subject's low back was then aligned to fit as low on the spine as possible, centered to the midline using the spinous processes as reference, preserving the visibility of the reflective markers. The posterior aspect of the brace was held in place while the subject translated from the seated to a supine position. Next the abdominal (anterior) portion of the brace was held in place while the first sets of straps (side panels) were adjusted and firmly secured on each side of the subject. Then the subject's hips were stabilized as the Prolign orthoses straps were tightened

twice. For the Ultralign brace, the same procedure was followed for the lumbar portion of the brace. For the abdominal portion of the brace, the pubic symphysis was located and the inferior aspect of the abdominal portion of the brace was placed two finger widths above this landmark. Again the first straps were secured before the strap tightening process began. The bottom two straps were tightened three times. The top two were tightened three times, however after the third time the top straps were loosened to the subject's comfort and provide normal pulmonary functions of the subject.

A)



B)



Figure 4. The enlarged cutout on the Prolign LO (A) and Ultralign LSO (B).

Experimental Protocol

The subjects were instructed to perform three forward flexion (sagittal plane) trials, three backward extension (sagittal plane) trails, and three right lateral bending (frontal plane) trials in each of the two braces and in an unbraced condition for a total of nine test conditions. In all of the conditions the subject began with feet 18 inches apart, with arms across the chest and hands resting on the top of the shoulders, facing forward with eyes focused horizontally. In the flexion trials the subject was instructed to lower the chin to the chest and bend forward at the waist as far as possible and then return to the neutral position. For the extension trials the subject was instructed to arch backwards as far as possible and then return to the starting (neutral) position. During both flexion and extension trials, subjects were instructed to minimize their anterior/lateral pelvic movements by maintaining a shoulder width base of support and full knee extension. During the lateral bending trials the subject was instructed to flex the trunk to the right side to his end range of motion.

DATA PROCESSING

Kinematics

Images collected from the video camera were used to obtain selected spinal angular displacement and ROM variables. The video images were first captured and then digitized using the APAS biomechanical system. The raw coordinates of the reflective markers were smoothed using a fourth-order and zero-lag Butterworth digital filter (Winter, 1990). The cutoff frequency was individually chosen for the each x and y coordinate of the reflective markers using an optimized algorithm (Jackson, 1979).

For the sagittal view, the lumbar (β_{lumbar}) and thoracic ($\beta_{thoracic}$) intersegmental angle, and hip joint angle (β_{hip}) were computed as follows:

$$\beta_{lumbar} = \theta_{L5} - \theta_{L1} \quad (1)$$

$$\beta_{thoracic} = \theta_{L1} - \theta_{T1} \quad (2)$$

$$\beta_{hip} = \alpha_{Thigh} - \alpha_{Trunk} \quad (3)$$

Where θ_{L5} , θ_{L1} and θ_{T1} are the orientation (tilting) angles of the 5th and 1st lumbar vertebrae and the 1st thoracic vertebra defined by the distal and proximal reflective marks on the maker wands (Figure 5), θ_{thigh} and θ_{trunk} (Figure 6) are the orientation angles of the trunk and thigh segments.

For the rear view, the lateral flexion angle ($\alpha_{lat-flex}$) was calculated:

$$\alpha_{lat-flex} = \varphi_{lumbar} - \varphi_{thoracic} \quad (4)$$

Where φ_{lumbar} and $\varphi_{thoracic}$ are the orientation angles (Figure 5) of the lumbar (defined by the L1|L2 and L5|S1) and thoracic (defined by T1|T2 and L1|L2) segments.

Statistical Analysis

Selected variables were evaluated using a one-way analysis of variance (ANOVA) with post hoc comparisons and significant level set as $p < 0.05$ (SAS 8.2, SAS).

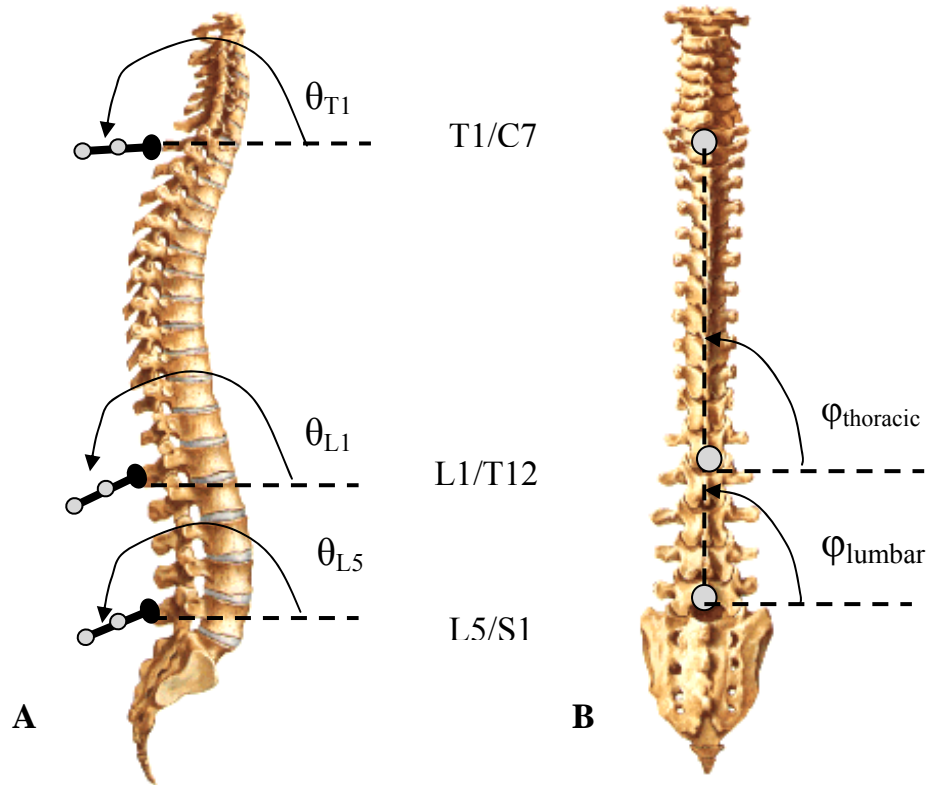


Figure 5. Definitions of θ_{T1} , θ_{L1} and θ_{L5} for the sagittal view (A) and $\phi_{thoracic}$ and ϕ_{lumbar} for the posterior view (B).

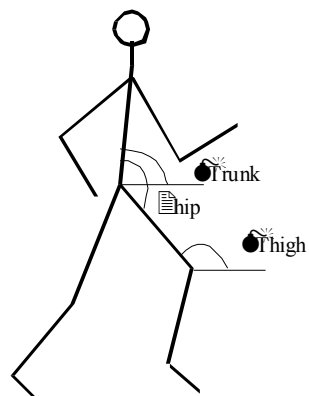


Figure 6. Illustration of the hip joint.

RESULTS

Representative curves for the lumbar and thoracic intersegmental angles in the forward trunk flexion are provided in Figure 7. Representative curves for the lumbar and thoracic intersegmental angles in the trunk extension are provided in Figure 8. A positive angle represents an increase during flexion and a negative angle represents a decrease during extension for the intersegmental spinal segment. The descriptive data for the trunk flexion movement are listed in Table 1. A positive ROM is observed during trunk flexion and a negative ROM represents a change of motion during trunk extension. For intervertebral segment tilting in the sagittal plane, a positive angle represents a posterior tilt and/or its ROM and a negative angle represents an anterior tilt and/or its ROM. The statistical results indicated that both Prolign and Ultralign orthoses significantly reduced L5|S1 anterior tilt and hip flexion ROM compared to the un-braced (control) condition (Table 1). Both braces also reduced more ROM than the control and the Ultralign reduced more ROM than the Prolign, for the anterior L1|L2 and T1|T2 tilts. In addition the Ultralign LSO showed a significantly reduced ROM ($p < 0.05$) than the unbraced and Prolign LO for both lumbar and thoracic intersegmental angles (sagittal plane), further indicating its superior restriction on the motion of lumbar and thoracic spines.

The Ultralign showed a greater reduction in spinal ROM than the other two test conditions during the trunk extension. For the L1|L2 tilt the Ultralign showed smaller ROM than the control condition and Prolign (Table 2). Both orthoses showed significantly reduced T1|T2 tilt ROM than the unbraced condition. In addition, both braces reduced the hip flexion ROM than the control; the Ultralign reduced the hip flexion ROM even more than the Prolign.

Representative curves for the lateral trunk flexion, and lateral lumbar segment flexion are provided in Figure 9. For the lateral flexion, a positive angle for a segment indicates a right

lateral flexion of the trunk and a negative angle represents a right lateral lumbar segmental and thoracic segmental flexion. The Ultralign and Prolign orthoses showed significantly reduced ROM than the control condition for the lumbar and thoracic lateral flexion, and lateral trunk flexion (Table 3). The Ultralign also showed a significant reduction in ROM during the lateral flexion than the Prolign condition.

The average percent changes of ROM in flexion and extension represents the percent reduction of spinal motion compared to normal spinal ROMs obtained in the unbraced conditions (Table 4). The Ultralign LSO was shown to reduce more ROM than the Prolign in all variables during the flexion test (Table 4). It was also more effective in reducing L1|L2 and T1|T2 tilt, and hip joint ROM during the trunk extension. In addition, the average percent reduction of ROM compared to the normal unbraced values in lateral lumbar flexion is provided in Table 5. The Ultralign LSO showed a significantly more reduction in percent ROM than the Prolign LO in the lateral flexion test. The Prolign LO was very effective in reducing L5/S1 ROM, though Ultralign LSO was more effective in the reducing motion in the upper lumbar segments. The Prolign allows for more functional movement while continuing to stabilize the lower lumbar spine effectively.

Table 1. Average ROMs of the examined angles and segments during trunk flexion

Device	L5 S1 Tilt	L1 L2 Tilt	T1 T2 Tilt	Lumbar Angle*	Thoracic Angle*	Hip Flexion
No Brace	-13.2 (11.8)	-37.8 (17.7)	-65.1 (14.9)	26.6 (8.2)	53.7 (9.2)	17.3 (12.6)
Prolign	-3.6 ^a (2.6)	-25.7 ^a (9.2)	-53.2 ^a (6.5)	24.7 (7.9)	52.1 (7.0)	8.9 ^a (5.0)
Ultralign	-3.9 ^a (2.2)	-14.7 ^{a,b} (9.2)	-42.2 ^{a,b} (9.8)	13.8 ^{a,b} (7.1)	41.4 ^{a,b} (9.0)	6.5 ^a (4.6)

Note:

Standard deviations are in parentheses. The unit is in degrees.

*: Lumbar Angle – lumbar intersegmental angle.

*: Thoracic Angle – thoracic intersegmental angle.
 a – significantly different from No Brace ($p < 0.05$).
 b – significantly different from Prolign ($p < 0.05$).
 c – significantly different from Ultralign ($p < 0.05$).

Table 2. Average ROMs of the examined angles and segments during trunk extension

Device	L5 S1 Tilt	L1 L2 Tilt	T1 T2 Tilt	Lumbar Angle*	Thoracic Angle*	Hip Extension
No Brace	6.7 (7.0)	17.1 (6.2)	39.7 (9.1)	-15.9 (8.6)	-37.9 (15.5)	-7.1 (4.2)
Prolign	4.6 (10.6)	14.2 (5.2)	33.7 ^a (9.0)	-19.2 (6.2)	-38.3 (11.6)	-4.5 ^a (2.6)
Ultralign	4.5 (11.6)	9.2 ^{a,b} (5.9)	28.0 ^a (11.4)	-13.2 ^a (8.6)	-31.9 (13.9)	-3.6 ^{a,b} (2.8)

Note: See footnotes of Table 1

Table 3. Average ROMs of the examined angles and segments during lateral trunk flexion

Device	Lateral Lumbar Flexion	Lateral Thoracic Flexion	Lateral Trunk Flexion
No Brace	-17.9 (8.3)	-39.1 (11.3)	21.7 (4.2)
Prolign	-12.7 ^a (7.0)	-29.2 ^a (9.5)	16.7 ^a (4.1)
Ultralign	-9.9 ^{a,b} (4.6)	-21.1 ^{a,b} (6.3)	11.4 ^{a,b} (3.5)

Note: See footnotes of Table 1

Table 4. Average percent ROM changes relative the unbraced condition of different spinal segments during flexion and extension

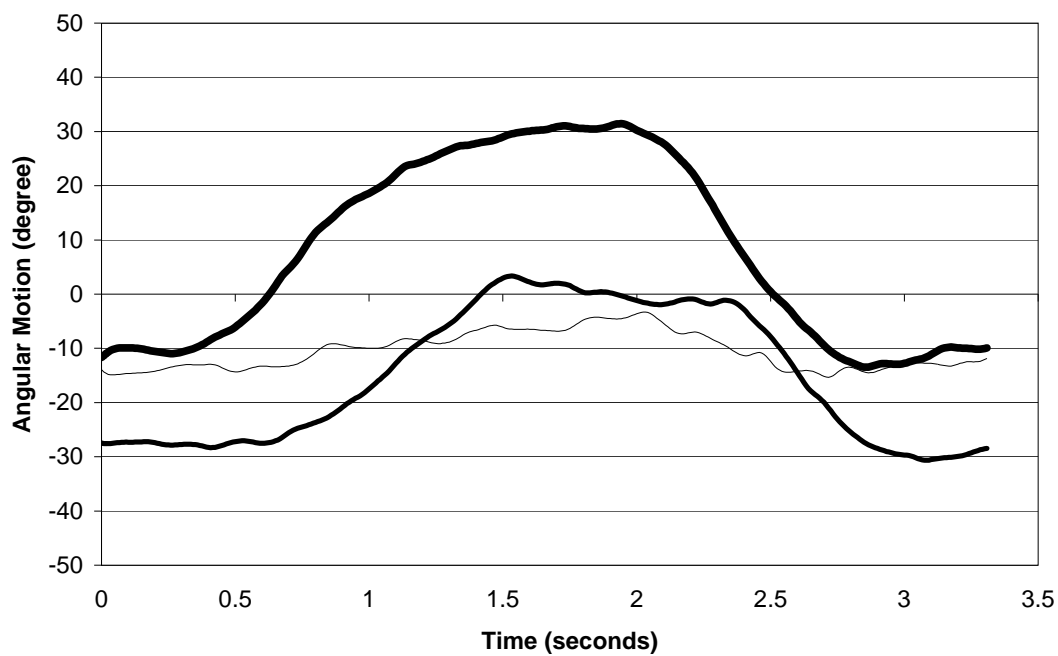
Movement	Device	L5 S1 Tilt	L1 L2 Tilt	T1 T2 Tilt	Hip Motion
Flexion	Prolign	41.9	16.4	14.9	24.8
	Ultralign	42.6 [*]	47.6 [*]	29.9 [*]	25.9 [*]
Extension	Prolign	-8.2	-4.8	18.4	-26.6
	Ultralign	-5.3	40.6 [*]	29.1 [*]	33.4 [*]

Note: * - significantly different from Prolign ($P < 0.05$).

Table 5. Average percent ROM changes of different spinal segments during lateral flexion

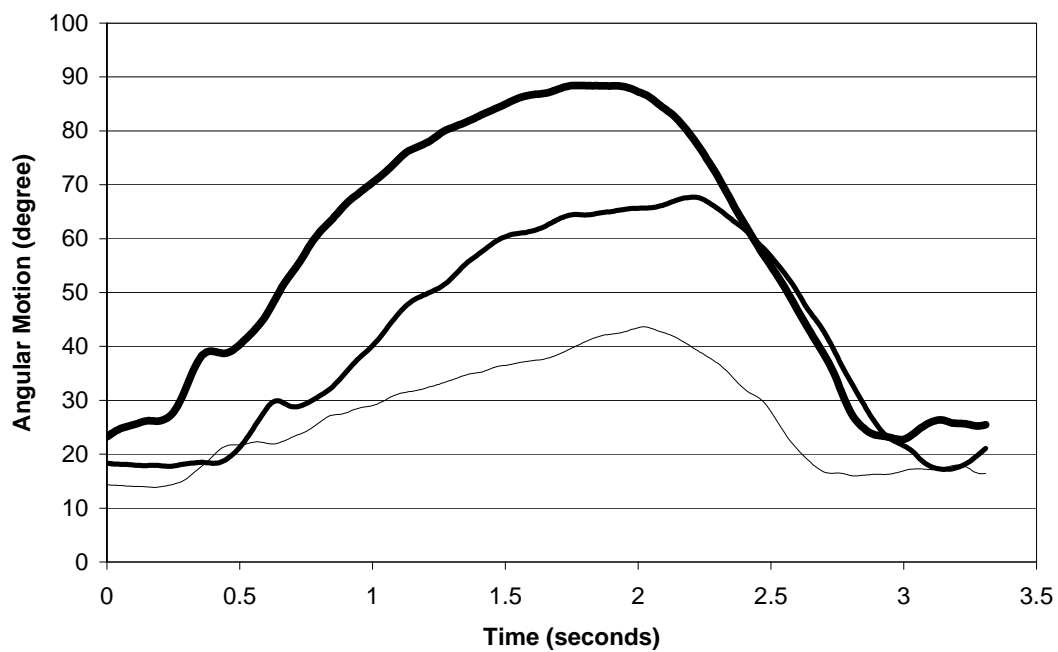
Device	Lumbar Lateral Flexion	Thoracic Lateral Flexion	Trunk Lateral Flexion
Prolign	17.0	23.1	22.8
Ultralign	20.4 *	42.8 *	46.2 *

Note: * - significantly different from Prolign ($P < 0.05$).



A

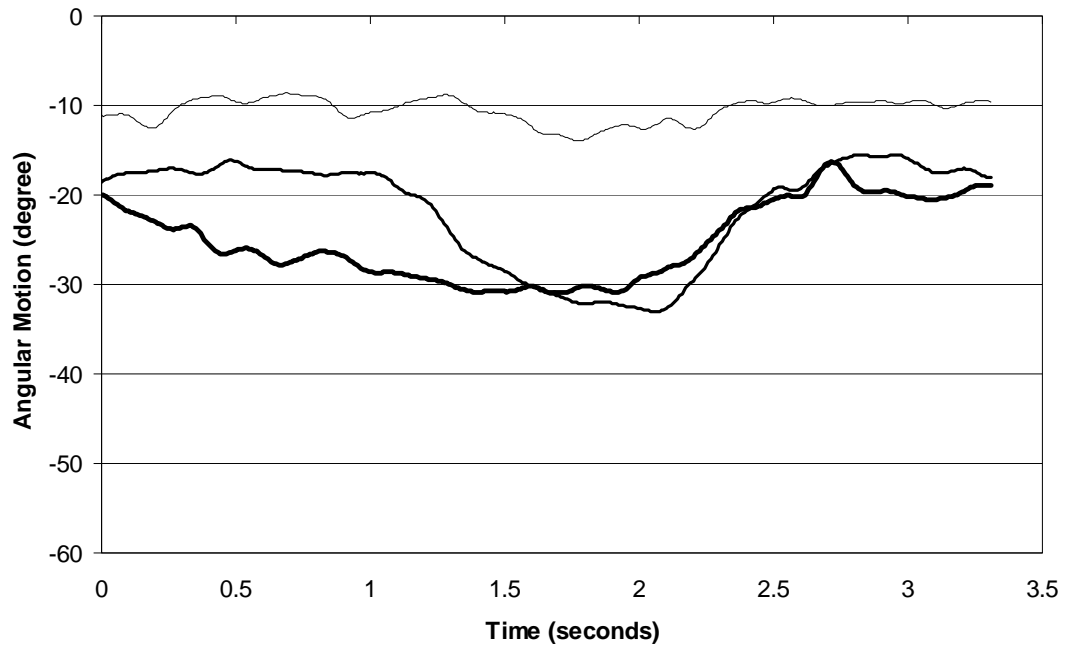
— UltraLign — ProLign — Control



B

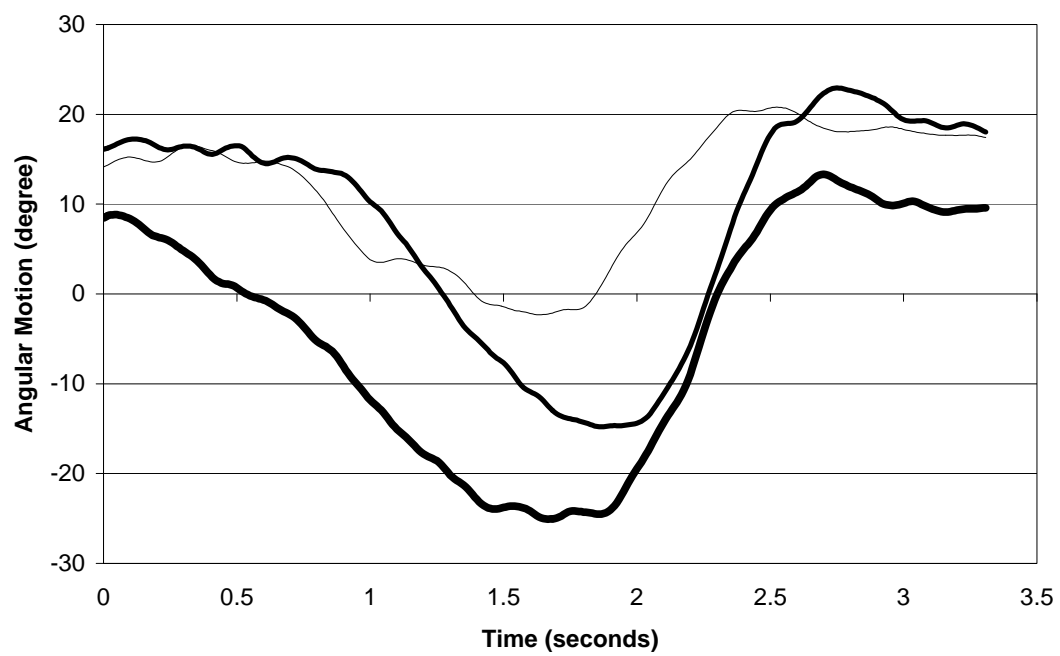
— UltraLign — ProLign — Control

Figure 7. Representative curves for the lumbar (A) and thoracic (B) intersegmental angle during the anterior trunk flexion.



A

— UltraLign — ProLign — Control



B

— UltraLign — ProLign — Control

Figure 8. Representative curves for the lumbar (A) and thoracic (B) intersegmental angle during the trunk extension.

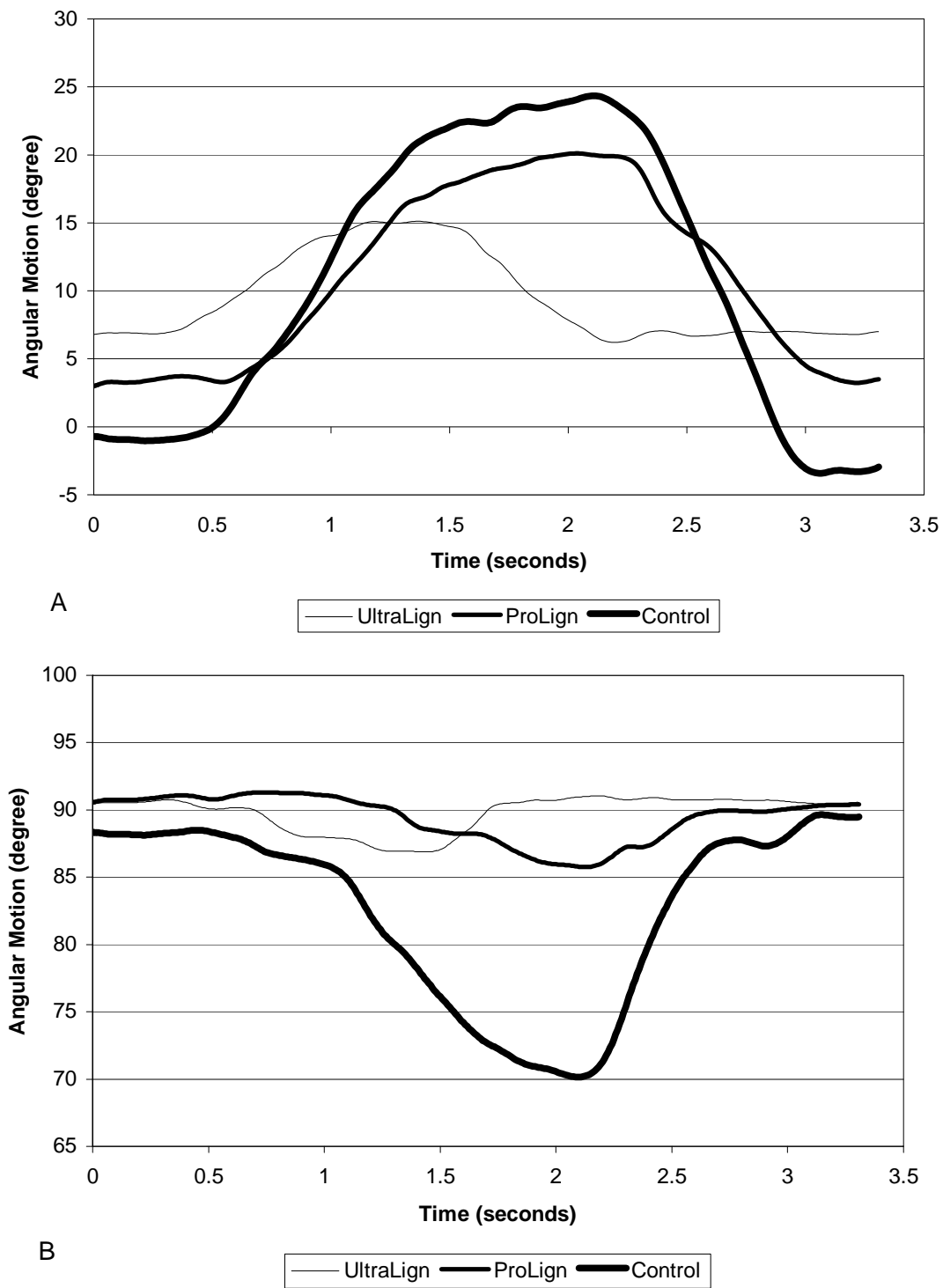


Figure 9. Representative curves for the lateral trunk flexion (A), and lateral lumbar flexion (B).

DISCUSSION

Examinations of the data indicated that the Ultralign and Prolign both limited significantly more intervertebral joint ROM with 42% and 43% reduction for L5|S1 and with 16% and 48% for L1|L2 versus the control conditions during trunk flexion movements (Table 4). Both braces also provided a reduction of T1|T2 intervertebral joint ROM (30% and 17%). In addition, the ROM of the lumbar intersegmental motion was 26.6°, 24.7° and 13.8° for the control (un-braced), and Prolign and Ultralign braces whereas the ROM of the thoracic intersegmental motion was 53.7°, 52.1° and 41.4° for the same three conditions during the trunk flexion. The results suggested that the Ultralign lumbo sacral LSO performed better than the Prolign lumbar LO in restricting the L1|L2 and T1|T2 intervertebral motion. The Ultralign is a lumbosacral LSO with greater support in both lumbar and lower thoracic regions whereas the Prolign is a lumbar orthoses with the support mainly concentrated on the lumbar region. The support frame in the lumbosacral brace is also more rigid than the lumbar orthoses. The data from this study also indicated lower ROMs for the L5|S1 and hip motion for those two braces during the trunk flexion than the un-braced condition.

We also examined the effects of the two braces in reducing the ROM of spinal extension. Similar to what we found during the trunk flexion test, the ROM of the three individual intervertebral segments (L5|S1, L1|L2, and T1|T2) was more limited than the lumbar and thoracic intersegmental ROMs. The Ultralign performed better in restricting the ROM of L1|L2 (41%, $p<0.05$) and T1|T2 (29%, $p<0.05$) motion in trunk extension (Table 4). The Prolign LO provided more restriction on the motion of L1|L2 (18%).

For the lateral trunk flexion test, the ROM of the lateral trunk flexion was 21.7°, 16.7° and 11.4° for the control, Prolign and Ultralign braces respectively (Table 3). Both Ultralign and Prolign orthoses offered significantly more immobilization (46% and 23%) and the Ultralign brace provided more effective immobilization than the Prolign brace (Table 5). Similarly, the Ultralign and Prolign orthoses offered better limitations on the motion of the lumbar (20% and 17%) and thoracic (43% and 23%) segments and the Ultralign LSO provided more restrictions than the Prolign LO.

The data from this study suggested that both Ultralign LSO and Prolign LO are effective in restricting the movement in flexion, lateral flexion and extension of trunk. The Ultralign provided greater support and restricted more ROM in all three spinal movements (Table 1-5 and Figure 7-9) and can be used when a strictest control of the lumbosacral region is warranted. The Prolign LO provided less overall lumbar stabilization than the Ultralign LSO. However, it was significantly effective in controlling intervertebral segmental motion at L5/S1. The Prolign allows for functional spine range of motion needed for the activities of daily living and critical job demands, yet provides effective control for the angular kinematics at the lumbo sacral junction.

The statistical results showed unexpectedly fewer significant numbers of comparisons for the Prolign brace. It demonstrated immobilization effects on spinal flexion in most examined flexion variables but failed to show the significant effects in spinal extension in the lumbar and thoracic regions. This may be due to the initial position of the trunk during the testing. We required the subjects to start the extension with their face forward and the eyes parallel to the ground. This initial position may not guarantee all subjects would have the same trunk position at the beginning of the test due to its arbitrariness and variations in their in their lumbar lordosis.

The range of motion was reduced when the orthoses was applied to the subjects automatically putting the lumbar spine in a 25 degree lordosis or the “0” reference position when initiating the range of motion test trials. With the orthoses encouraging spinal extension upon application, the initial position engages the intervertebral zygoapophyseal joints which in turn increases the spine’s load bearing tolerance. This may also have some influences on the trunk flexion test. However, this differential initial position should have greater influences on the results of the trunk extension than flexion due to less ROM available in normal trunk extension (57° in flexion versus 15° in extension). Other researchers combined ROM of both flexion and extension thus avoided the problems caused by the initial position (Buchalter et al., 1988). Another possible cause for the discrepancy may be due to the amount of hip flexion during the tested trunk movements. Even though we asked subjects to control their hip position during the test by not rotating their pelvis, some hip joint movements were inevitable due to the need to maintain posture balance and their characteristic lumbosacral rhythm. The hip ROMs for both flexion and extension tests find the unbraced condition were significantly greater than the two braced conditions (Table 1 & 2). This compensatory movement in the hip might lead to reduced total ROMs recorded for the un-braced condition during both flexion and extension tests and reduce the differences that may exist otherwise between the control and braced conditions. Due to the reason mentioned above this influence had a greater effect on the results of the extension test. One possible solution for future reference and improvement is to combine the flexion and extension tests into one continuous movement and use an absolute trunk position (such as 90° of vertical) as the starting position to determine the ROM both flexion and extension.

The results from the lateral trunk flexion were more uniform and consistent compared to the other two movements. This may be due to that the subjects have greater lateral base of

support and therefore are easy to find the initial starting position than the anterior/posterior movements.

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APPENDICES

APPENDIX A – Individual and average values of subject information and anthropometric measurements

Table 6. Individual and average values of subject information and anthropometric measurements

Subject	Weight (kg)	Height (cm)	Age (yrs)	Circumference (cm)				
				Waist	Breast Bone	Navel	Greater Trochanter	Waist
1	75	180.34	28	81.788	83.82	86.106	91.44	32.2
2	75	170.18	27	84.328	94.742	87.63	97.79	33.2
3	95	182.88	23	92.964	94.234	93.726	104.902	36.6
6	65	182.88	26	72.136	80.772	76.2	89.408	28.4
7	93	193.04	20	91.44	95.504	96.012	102.108	36
8	93	193.04	22	91.44	88.9	92.964	109.22	36
9	81	185.42	23	83.82	86.868	85.09	92.964	33
10	95	185.42	23	94.742	95.25	97.282	109.22	37.3
11	104	182.88	19	99.06	104.14	106.68	111.252	39
12	84	182.88	24	90.17	90.17	94.742	105.41	35.5
13	91	187.96	21	90.17	93.726	90.17	102.108	35.5
14	77	175.26	24	83.566	90.932	87.63	99.568	32.9
15	68	172.72	23	75.692	78.74	78.232	99.822	29.8
16	68	180.34	24	73.66	83.82	79.248	91.44	29
17	65	175.26	20	76.454	81.28	76.962	95.25	30.1
18	86	177.8	24	82.55	87.884	84.328	96.266	32.5
19	95	177.8	24	111.76	102.87	106.68	106.68	44
Mean	83	182	23	87	90	89	100	34
Std	12	6	2	10	7	9	7	4

APPENDIX B – INFORMED CONSENT FORM

Investigator: Song-Ning Zhang, Ph.D.
Address: Health, Safety, and Exercise Science
The University of Tennessee
1914 Andy Holt Avenue
Knoxville, TN 37996
Phone: (865) 974-4716

You are invited to participate in a research study on back braces entitled, “Evaluation of efficacy and biomechanical characteristics of medical spinal orthotic devices made by DeRoyal” that examine and compare effectiveness of selected DeRoyal spinal braces in altering spinal range of motion and muscle activities.

You are aware that you should be a healthy male, 18 years of age or older and have no history of major injuries to your trunk and lower extremity. If you are qualified and decide to participate, you will need to participate one test session during the study period. As an appreciation for your participation, you will be reimbursed \$15. Each test session will take approximately 40 minutes. At the beginning of the session, you will fill out a questionnaire about your age and height. You will begin with a standard warm-up by using stretching for 5 min. During the test, biomechanics instruments will be used to make measurements. Some of these instruments will be placed/fixed on your body. None of the instruments will impede your ability to engage in normal and effective motions during the test, and cause any injuries to you. You will be asked to perform no more than 40 trials of flexion and lateral flexion of your trunk during the session, which will be video taped. If you have any further questions, interests or concerns about any instrumentation, please feel free to contact the investigator.

Risks associated with this study are minimal. The potential risk may include a sprain of ligaments and/or a strain of tendons of vertebral column muscles due to inappropriate warmup. There may be a slight chance of faint due to increased blood pressure during the movement with the brace on. However, these requirements are not beyond your daily activities. Every effort will be made to reduce these risks through proper and sufficient warmup and stretching. You will be asked to perform the movements at a pace comfortable to you. Gymnastic mats will be placed around the testing area to prevent you from being hurt in case of falling due increased blood pressure. A spotter will be placed close to you in the testing area. All tests will be conducted and the equipment will be handled by the qualified research personnel in the Biomechanics/Sports Medicine lab, who will sign a confidentiality statement. The Biomechanics/Sports Medicine Lab has tested more than 200 subjects in several research projects over the past seven years. None of them was injured in any fashion during the test sessions. You will be encouraged to warm up and stretch actively prior to your testing session so that you feel physically prepared to perform effectively and thus minimize any chances for injury. Should any injury occur during the course of testing, standard first aid procedures would be administered as necessary. At least one researcher with a basic knowledge of athletic training and/or first aid procedures will be present at each test session. In the event of physical injury is suffered as a result of participation in this study, the University of Tennessee does not automatically provide reimbursement for medical care or other compensation. Your benefits include assessment of your normal spinal functions and biomechanics. You are welcome to make an appointment to review the data from your tests. In addition, if you wish to have a copy of the results of the study, please let me know.

Your participation is entirely voluntary and your decision whether or not to participate will involve no penalty. Your identity as a subject will be held in strict confidence and any description of your data will be referred to by a subject number only. Any information including the video images (stored as digital files) that are obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission. Only qualified research personnel from the Biomechanics/Sports Medicine Lab will have access to the data and digital image files. These data files

will be backed up onto CD/Zip disks after the completion of the study, and be kept in a locked file cabinet in my office.

Once you have read this informed consent form and all of your questions have been answered, please sign and date the form below and the attached form. Your signature indicates that you have read and understand the information provided above, that you willingly agree to participate, that you may withdraw your consent at any time and discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. However, if you withdraw before completing the test, you will not receive the \$15 compensation.

Subject Name:

Subject Signature:

Date:

Investigator Signature:

Date:

SPECIFICATIONS OF INDIVIDUAL TESTING SESSION

Devices to be tested

Prolign back brace _____, Ultralign LSO _____,

Other Device _____, Other Device _____

Condition and Trials

Trunk Flexion: _____. Trunk Extension: _____.

Trunk Left Lateral Flexion: _____. Trunk Right Lateral Flexion: _____.

Cervical Spine Flexion: _____. Cervical Spine Left Lateral Flexion: _____.

Cervical Spine Right Lateral Flexion: _____.

Number of trials for each condition _____, Total number of trials: _____.

Instrumentation

_____ Force Platform _____ Video _____ EMG

Muscles for EMG

Erector Spinae Lumborum _____, Erector Spinae Thoracis _____, Erector Spinae Cervicis _____,

Splenius _____, Biceps Femoris _____, Semitendinosus _____, Vastus Lateralis _____, Rectus Femoris _____,

All testing will take place at the University of Tennessee Biomechanics/Sports Medicine Laboratory, Rooms 135 HPER building a. Please wear shorts and a comfortable short-sleeved shirt or tank top to the testing session.