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Comparison of Daily Motion of the Cervical and Lumbar Spine to ASTM F2423-11 and ISO 18192-1.2011 Standard Testing

ABSTRACT: *Background*–The purpose of this investigation is to measure the normal neck and trunk motion of daily living and to compare this to annualized movements as defined by the ASTM F2423-11 and ISO 18192-1:2011 standards. *Methods*–Ten volunteers wore a custom sensor system that monitored their upper and lower spine motion. The system allows continuous measurement of the frequency and magnitude of spinal motion about all three axes. The angular motion can then be determined for the upper and lower spinal segments. The results were extrapolated to yield the yearly frequency and magnitudes of movements. The data were compared to ASTM and International Organization for Standardization (ISO) standards. *Results*–The median magnitude of neck motion was 14.3°, 13.8°, and 21.6°, and the mean annual frequency of cervical motion was 10.6×10^6, 8.5×10^6, and 5.6×10^6 movements in flexion-extension, lateral bending, and axial rotation, respectively. The observed-to-standard (ASTM) ratio of annual cervical excursion was 1.22, 1.09, and 0.69, and for ISO the ratios were 1.22, 1.09, and 1.04 in flexion-extension, lateral bending, and axial rotation, respectively. The median range of motion for the thorax relative to the iliac crest (lumbar) was 11.2°, 10.3°, and 12.5°, and the estimated number of annual movements was 6.8×10^6, 5.2×10^6, and 3.8×10^6 in flexion-extension, lateral bending, and rotation. The observed-to-standard ratios from ASTM were 0.63, 0.56 and 1.6, and for ISO they were 1.5, 1.68, and 1.59, in flexion-extension, lateral bending, and rotation respectively. *Discussion*–Neck and lumbar movements in healthy young adults are more frequent that 1×10^6 times per annum. The amplitude is smaller than specified in current standards. Overall, the total annual angular excursions specified by ASTM correlated well with results, whereas the ISO specified smaller ranges of motion for the lumbar spine, and therefore the observed angular motions were greater than specified. New testing standards should consider using more physiologic movement patterns.

KEYWORDS: daily living motion, spinal kinematics, disc arthroplasty, ASTM, ISO, prosthetic wear testing

Introduction

One of the essential functions of the spinal column is to allow movement that facilitates essential human functions including locomotion, social interaction, recreation, spirituality, and work. In vivo spinal motion can be assessed by measuring the movement of the entire spinal column, movement in a particular segment, or movement at a single interspace. The latter has been defined as the functional spinal unit (FSU), which includes the two adjoining vertebrae, their articulations (the paired zygoapophyseal joints and an intervertebral disc), and associated ligaments. Spinal motions are complex, having translations and angulations along all three axes, which makes them difficult to measure. Further, spinal movements almost always have coupled angular motions about more than one axis and are combined with translations along the axis.

Many investigations have studied global and isolated FSU motions using a variety of techniques such as goniometric, radiographic, fluoroscopic, and optical. These movements have been correlated to requirements for specific tasks, usually those involving activities of daily living or specific ergonomic jobs. However, the in vivo measurements are limited because they might lack complete movements in all six degrees of freedom, are often performed in an artificial laboratory environment, and do not measure movements of individual FSUs. Although an in vivo FSU can be assessed with cineradiography, the results usually consist of a single arc of movement and are often limited to an exaggerated degree of motion (full

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flexion-extension) that rarely occurs during normal living. These analyses do not assess the regular movements that occur during normal living. The measurement of in vivo daily motion has been attempted for other joints and provides an essential understanding of the requirements for the design and testing of prosthetic devices, especially those having bearing surfaces [1]. Such data are not available for spinal devices.

The cervical and lumbar spine segments have the greatest degrees of mobility and are associated with the highest incidence of derangements, making them candidates for surgical treatment. Recently, artificial disc replacement has been developed to replace fusion as a treatment for some degenerative conditions of the cervical and lumbar spine. Knowledge of the direction, magnitudes, and number of movements occurring over a unit of time is essential for the proper design of the bearing surfaces of these devices. In general, the design of these spinal devices has been based on kinematic data used to determine FSU movements and on total motion data from the experience of the hip and knee. The total movements of the hip and knee are easy to determine by measuring stride length and counting steps using pedometers. In the spine, this is more difficult, as movements are far more complex and include greater magnitudes of coupled movements, varying magnitudes of each motion, and movements occurring even at rest.

Testing standards to assess the in vitro wear of the bearing surfaces for spinal prosthetic devices have been developed by ASTM and the International Organization for Standardization (ISO) [2,3]. These specify sinusoidal motions along all three axes and recommend the simultaneous coupling of two or three of the axes. Further movements can occur both in phase and out of phase, such as left side bending with left or right axial rotation. The motions proscribed are regular sinusoids having large amplitudes relative to the total FSU movement. The standards recommend regular assessments of the bearing surfaces and debris material at the million cycle period and continued testing for up to 10×10^6 cycles, although longer test periods can be employed. It is generally believed that 1×10^6 cycles is conservatively equivalent to a year of in vivo wear [4]. The validity of this assumption has never been tested, and this could be an important limitation of current testing standards.

We have previously reported the design and validation of an in vivo device that can continuously measure angular movements along all three axes for prolonged periods [5–7]. Using this device, we measured the total head movement relative to the thorax over a five-day period in ten young healthy subjects. We also estimated the total number of motions that occur during a variety of activities of daily living. We estimated that subjects move their cervical spine up to 9×10^6 times per year and that the median neck motion in flexion-extension was only 18°, and for the C5-C6 FSU it was only 2° to 3°.

Hypothesis and Study Aims

We hypothesize that the in vivo daily living motion of the spine is significantly different from that specified in testing standards, in that more movements of shorter amplitudes occur during daily living. The differences between standards and daily living motion when applied to wear simulation testing might affect the wear results. In order to test this hypothesis, our specific aim in this study was to determine the in vivo daily living patterns of spinal movements in the cervical and lumbar spine in healthy subjects. We compared these results to the total motions specified in the ASTM F2423-11 and ISO 18192-1.2011 standards. The daily living motion patterns described can then be used to formulate physiologic motion patterns that can be used to design alternative wear simulation models.

Methods

Subjects

The study had approval from the University of Wisconsin Institutional Review Board. Ten healthy subjects were recruited. Each subject signed a voluntary consent, and all completed the study. The average age of subjects was (22.8 ± 1.9) years, and half were female. None of the subjects had any spinal symptoms or known spinal diseases.

Wisconsin Analysis of Spine Motion Performance (WASP) System

Continuous motions of the upper and lower spine were measured using the Wisconsin Analysis of Spine Motion Performance (WASP) system [5,6]. This consists of three sensors, a data logger, and custom software. Each sensor contains two inclinometers that measure angular displacement in the sagittal (flexion-extension) and coronal (lateral bending) planes and a gyroscope to measure angular velocity in the axial plane. Data are recorded (32 Hz) using the data logger and downsampled to 8 Hz prior to analysis. The data are later downloaded to a computer. The battery life enables continuous measurement for up to 24 h.

The sensors were worn continuously over a three-day period (two weekdays and one day on a weekend) during all activities except bathing and swimming and at night. Based on prior investigations, sleeping was associated with few movements. The sensors were applied to the mastoid, the thorax (under the axilla at about the seventh rib), and the iliac crest using medical adhesive (Medical Spirit Gum 2100, Kryolan, Berlin, Germany) (Fig. 1). The data logger was placed on a belt or in a pocket. The subjects were instructed in the proper placement and orientation of the sensors and operation of the data logger. Each subject met daily with a researcher in order to ensure proper use of the system, to download data, and to replace the batteries. Prior to use of the system, the subjects wore the sensors and underwent calibration against an optical motion capture system in order to ensure reliability and accuracy.

The continuous data were reduced using custom software (Matlab v. 7.2, Mathworks, Natick, MA). For axial rotation, the angular velocity was transformed into angular displacement by integration. Independently for each axis, a motion peak was identified by determining when the slope of the line changed sign and when the magnitude between peaks exceeded 5° (Fig. 2). The movement amplitude was the difference in magnitude between two successive peaks. The frequency of movements in 5° increments was reported. Data were recorded for each axis and normalized for daily and estimated yearly motion patterns.

The excursion occurring at a single cervical functional spine unit (C5-C6) was estimated using previously determined in vivo proportional values of 0.18 for flexion-extension, 0.17 for lateral bending, and 0.10 for axial rotation [8]. The excursion occurring at a single lumbar functional spine unit (L4-L5) was estimated using previously determined in vivo proportional values of 0.195, 0.198, and 0.20 for flexion-extension, lateral bending, and axial rotation, respectively [9].

Validation of WASP

The WASP was validated against a standard material testing system (MTS) [5]. Briefly, known pure moments were applied and measurements of the WASP were compared to displacements observed from

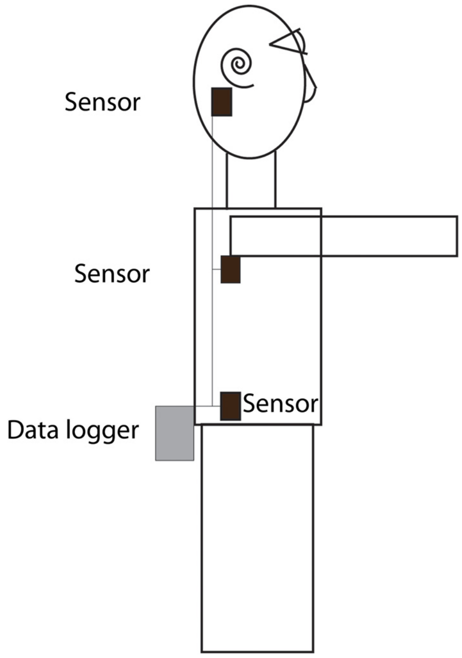

FIG. 1—*Schematic drawing of the location of the sensors (black squares), which are placed over the mastoid, along the chest wall below the axilla, and over the iliac crest. The sensors are connected to a data logger (gray box).*

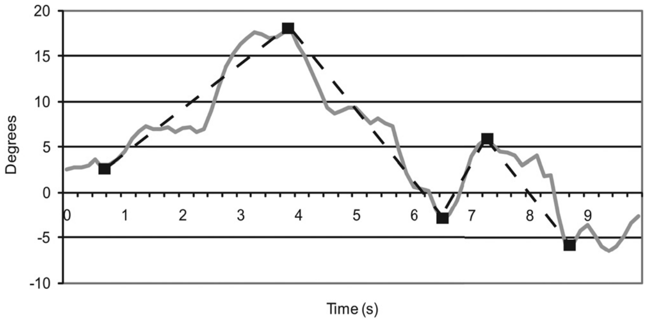

FIG. 2—*Example of data taken from the WASP. The solid gray line represents the observed motion. The squares are at the calculated peaks. The dashed line is the reduction of the continuous data to a linear function. The distance between peaks is the magnitude of motion.*

the MTS. Correlations for the range of motion were very strong for all three axes (r^2 values = 0.99). The correlation for the detection of movement frequency was exact. Further validation was performed with an optical motion capture system that is accurate to 0.5°. Ten subjects were placed in the system wearing the WASP, and they performed various movements, including single plane and complex movements. The root mean square deviation (RMSD) between the WASP device and the optical motion capture system was obtained and divided by the median deviation to obtain a percentage. For both cervical and lumbar motions, all RMSD values were less than 20 %, except for lateral bending in complex coupled motions. The correlation for the detection of movement frequency was exact.

ASTM and ISO Standards

Similar to hip and knee standards, the annual frequency of motion was assumed to be 1×10^6 cycles. The total excursion based on 1×10^6 cycles for each axis was calculated using the amplitudes shown in Table 1. Assuming an equivalency of 1×10^6 cycles to a year, the annual total excursion in degrees is calculated as

$$\text{Total excursion}(^\circ) = 4 * 1000000 * \text{ROM}$$

where ROM is the amplitude specified by the standard. These results were compared to the total excursion observed in our subjects.

TABLE 1—*Range of motion and total excursion after 1 000 000 cycles.*

			Flexion-Extension, deg	Lateral Bending, deg	Axial Rotation, deg
ASTM F2423-11					
	Cervical				
		ROM	± 7.5	± 6.0	± 6.0
		Annual excursion	30 000 000	24 000 000	24 000 000
	Lumbar				
		ROM	± 7.5	± 6.0	± 3.0
		Annual excursion	30 000 000	24 000 000	12 000 000
ISO 18192-1.2011					
	Cervical				
		ROM	± 7.5	± 6.0	± 4.0
		Annual excursion	30 000 000	24 000 000	16 000 000
	Lumbar				
		ROM	± 4.5	± 2.0	± 2.0
		Annual excursion	18 000 000	8 000 000	8 000 000

Note: Range of motion (ROM) is the amplitude of the sinusoidal pattern describing the arc of motion.

Results

ASTM F2423-11 and ISO 18192-1:2011 Standards

Cervical Total Disc Replacement—Both ISO and ASTM standards specify ±7.5° and ±6.0° amplitudes in flexion-extension and lateral bending, respectively (Table 1). Axial rotation amplitudes are ±6° and ±4° in ASTM and ISO. Although not specified in either standard, most users assume that the expected annual frequency of motion is similar to that in hip and knee simulations, i.e., 1×10^6 cycles. Using this estimation, the total simulated annual excursions for both standards are 30×10^6 and 24×10^6 degrees in flexion-extension and lateral bending, respectively. The total annual excursion in axial rotation is 24×10^6 and 16×10^6 degrees for the ASTM and ISO standards, respectively.

Lumbar Total Disc Replacement—ASTM specifies ±7.5°, ±6.0°, and ±3.0° amplitudes for flexion-extension, lateral bending, and axial rotation, and the total annual excursion is 30×10^6, 24×10^6, and 12×10^6 degrees (Table 1). For ISO, the amplitude is ±6.0°, ±2.0°, and ±2.0°, and the total annual excursion is 24×10^6, 8×10^6, and 8×10^6 degrees.

Cervical Spine

Motion Magnitude—The distribution of the range of motion is skewed, and therefore we report the median values (Fig. 3). The median range of motion for the head relative to the thorax (cervical) was 14.3°, 13.8°, and 21.6° for flexion-extension, lateral bending, and rotation, respectively (Table 2). The majority of movements in all three planes were between 5° and 15°. Less than 3 % of movements exceeded 50° in flexion-extension and lateral bending, whereas less than 15 % were less than 50° in axial rotation. At C5-C6, the median range of motion was 2.6°, 2.3°, and 2.2° for flexion-extension, lateral bending, and axial rotation, respectively.

Motion Frequency—The mean daily number of movements was 29 200, 23 300, and 15 200 for flexion-extension, lateral bending, and rotation, respectively (Table 3). In one year, the estimated number of movements was 10.6×10^6, 8.5×10^6, and 5.6×10^6 in flexion-extension, lateral bending, and rotation, respectively.

Total Motion Excursion—The total annual excursion was calculated by multiplying the median range of motion at C5-C6 and L4-L5 by the number of annual movements. The total annual excursion of the cervical spine is estimated to be 151.6×10^6, $117 .3 \times 10^6$, and 121×10^6 degrees in flexion-extension, lateral bending, and rotation, respectively. We used the median range of motion at C5-C6 and L4-L5, which results in lower ranges of motion by between 0.25° and 0.5° compared to results obtained using means. The total annual excursion in degrees at C5-C6 is estimated to be 27.3×10^6, 19.9×10^6, and 12.1×10^6 degrees in flexion-extension, lateral bending, and rotation, respectively (Table 4).

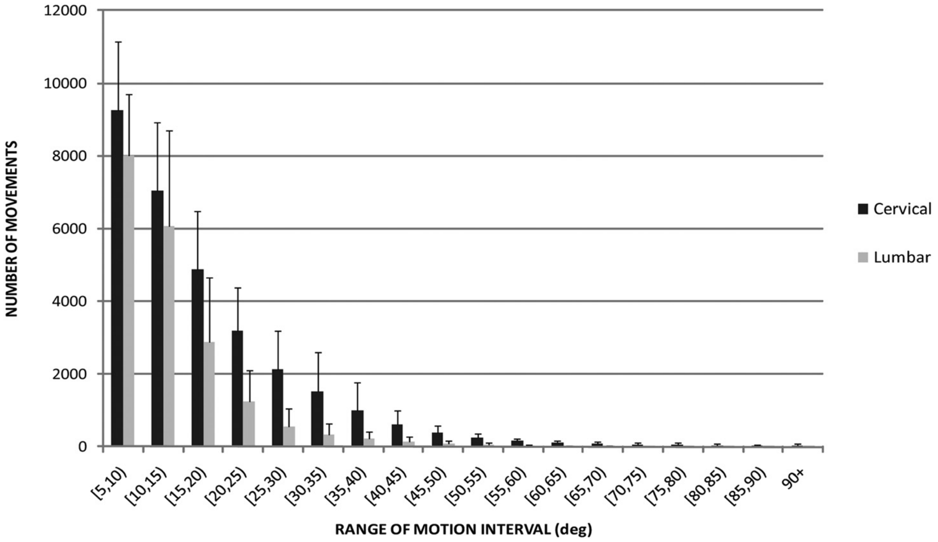

FIG. 3—*The frequency distribution of daily movements in flexion-extension in 5° increments.*

TABLE 2—*Median range of motion compared to ASTM and ISO standards.*

		Observed			
		Median Overall Range of Motion, deg	Functional Spinal Unit, deg	ASTM F2423-11, deg	ISO 18192-1.2011, deg
			C5-C6[a]		
	FE	14.3	2.6	15	15
	LB	13.8	2.3	12	12
	AR	21.6	2.2	12	8
Lumbar			L4-L5[b]		
	FE	11.2	2.2	15	9
	LB	10.3	2.0	12	4
	AR	12.5	2.5	6	4

Notes: FE, flexion-extension; LB, lateral bending; AR, axial rotation. The magnitude of the standards combines positive and negative excursions and is therefore doubled and allows comparison to observed movements.[a]The excursion at C5-C6 is assumed to be 0.18, 0.17, and 0.10 of the observed total excursion of the head and neck.[b]The excursion at L4-L5 is assumed to be 0.195, 0.198, and 0.20 of the observed total excursion of the trunk.

Lumbar Spine

Motion Magnitude—The median range of motion for the thorax relative to the iliac crest (lumbar) was 11.2°, 10.3°, and 12.5° for flexion-extension, lateral bending, and rotation, respectively (Table 2). The majority of movements in all three planes were between 5° and 15°. Less than 3 % of movements exceeded 50° for all three axes. At L4-L5, the median range of motion was 2.2°, 2.0°, and 2.5° for flexion-extension, lateral bending, and axial rotation, respectively.

Motion Frequency—The mean daily number of movements was 18 600, 14 300, and 10 400 for flexion-extension, lateral bending, and rotation, respectively (Table 3). In one year, the estimated number of movements was 6.8×10^6, 5.2×10^6, and 3.8×10^6 in flexion-extension, lateral bending, and rotation, respectively.

Total Motion Excursion—The total annual excursion of the lumbar spine is estimated to be 76.2×10^6, 53.6×10^6, and 47.5×10^6 degrees in flexion-extension, lateral bending, and rotation, respectively. For the L4-L5 FSU, the annual total excursion is 14.9×10^6, 10.6×10^6, and 9.5×10^6 degrees.

Comparison to ASTM and ISO

Cervical—In vivo cyclical movements were three to five times more frequent than specified in testing standards assuming 1×10^6 cycles per year. However, the total angular excursion was surprisingly similar to that in the ASTM 2423-05 standards, with observed-to-standard ratios of 1.22, 1.09, and 0.69 in

TABLE 3—*Daily and annual movements and total excursion.*

		Daily Movements ($\times 10^3$)	Daily "Cycles" ($\times 10^3$)	Total Daily Excursion ($\times 10^6$ deg)	Yearly Movements ($\times 10^6$)	Yearly "Cycles" ($\times 10^6$)	Total Yearly Excursion ($\times 10^6$ deg)
Cervical	FE	29.2 (7.3)	14.6	0.556 (0.209)	10.6 (2.7)	5.3	203.1 (76.37)
	LB	23.3 (7.4)	11.6	0.421 (0.200)	8.5 (2.7)	4.3	153.7 (73.13)
	AR	15.2 (4.6)	7.6	0.454 (0.169)	5.6 (1.7)	2.8	165.7 (61.57)
Lumbar	FE	18.6 (5.8)	9.4	0.267 (0.118)	6.8 (2.1)	3.4	97.36 (43.11)
	LB	14.3 (4.4)	7.2	0.186 (0.072)	5.2 (1.6)	2.6	67.97 (26.45)
	AR	10.4 (4.7)	5.2	0.174 (0.091)	3.8 (1.7)	1.9	63.58 (33.34)

Notes: FE, flexion-extension; LB, lateral bending; AR, axial rotation. Movements are reported as a single angular displacement greater than 5°. Two movements combined constitute one cycle. Standard deviation is given in parentheses.

TABLE 4—*Comparison between observed and ASTM and ISO total annual excursion.*

		Observed Yearly Excursion at FSU ($\times 10^6$ deg)	ASTM F2423-11 Ratio of Observed to Standard	ISO 18192-1.2011 Ratio of Observed to Standard
Cervical C5-C6[a]	FE	36.6	1.22	1.22
	LB	26.1	1.09	1.09
	AR	16.6	0.69	1.04
Lumbar L4-L5[b]	FE	19.0	0.63	1.05
	LB	13.5	0.56	1.68
	AR	12.7	1.06	1.59

Notes: FE, flexion-extension; LB, lateral bending; AR, axial rotation. [a]The excursion at C5-C6 is assumed to be 0.18, 0.17, and 0.10 of the observed total annual excursion of the head and neck. [b]The excursion at L4-L5 is assumed to be 0.195, 0.198, and 0.20 of the observed total excursion of the trunk.

flexion-extension, lateral bending, and axial rotation, respectively. For ISO 18192-1.2011, the observed-to-standard ratios were 1.22, 1.09, and 1.04.

Lumbar—Lumbar in vivo movements were two to three times more frequent than specified in testing standards assuming 1×10^6 cycles per year. The total excursions were, in general, greater than specified by the two standards. This was especially true for the ISO standard, which specified small values for axial rotation and lateral bending (only ±2°). The observed-to-standard ratios for total annual excursion by ASTM 2423-05 were 0.63, 0.56, and 1.6 in flexion-extension, lateral bending, and rotation, respectively. For ISO/CD 18192-1.3, the observed-to-standard ratios were 1.5, 1.68, and 1.59.

Discussion

Restatement of Study Aims

This study was undertaken in order to measure the normal daily living motion of the cervical and lumbar spine. These data could be used to improve the design and testing of prosthetic devices. Additionally, the results could be used to study the etiology of diseases, assess functional effects of interventions, aid in the study of ergonomics, and assess disability impairment. Ultimately, we plan to describe physiologic motion patterns that could be used in spine simulators to test for prosthetic wear. Given the widely variant patterns between the standards and daily living physiology, we would expect to see different wear rates than currently predicted.

Summary of Results

We found that young healthy subjects made measurable movements of their cervical and lumbar spine much more frequently than previously believed. The head and neck annually move cyclically over 3×10^6 to 5×10^6 times in each axis, and the trunk moves approximately 2×10^6 to 3×10^6 times. It is not surprising that the highest frequencies were seen in flexion-extension in the sagittal plane for both the cervical and lumbar spine. Movements in these planes have the greatest range of motion for both spinal regions and are of the most importance for human activities of daily living [10]. In reality, it was rare for a motion to be in only one plane, and almost all were coupled to other planes of movement.

These movements are of a relatively short arc, with the majority between 5° and 15° and less than 3 % being greater than 50°. For a single FSU, the mean movement is between 2° and 3° along any of the axes. These amplitudes are significantly lower than the relatively large amplitudes specified in the testing standards. We studied healthy young adults and would expect symptomatic patients or older subjects to have fewer movements of shorter amplitudes.

One of the most important findings validates the current ASTM testing protocol in regard to the total angular excursion. We found that the total annual excursion was closely approximated by the excursion of 1×10^6 cycles at the amplitudes specified by the ASTM. This implies that a million cycles with large amplitudes in spine simulators accurately model a year of in vivo spinal motion. The ISO had similarly satisfactory results for the cervical spine but was underpowered in all axes for the lumbar spine. The ranges of motion are different between the two standards, with the ISO standard having lower movements in lateral bending and axial rotation, which accounts for the observed differences. Given that the frequencies are far greater than 1×10^6 cycles per year, increasing the axial rotation and lateral bending in the ISO standard might be prudent.

Review of Relevant Literature

Measuring the total numbers of movements of the spine is problematic. Attempts have been made using observers at the workplace, using videotapes, electromagnetically, and by electromyography. These investigations have usually involved specific tasks or have taken place at specific locations. Other studies have evaluated the spine motions required in order to perform activities of daily living or that occur in patients having back symptoms [10]. These investigations do not provide the information needed in order to properly define testing protocols, such as the number and magnitude of movements per day. The measurement of general physical activity over long time periods has been performed using methods similar to ours. Dinger et al. used a single array of accelerometers mounted on a waist belt and accurately monitored general trunk movement [11]. Their instrument reported only the number of trunk movements and did not provide amplitude data. They found that students moved, on average, 40 000 times per day, which is very close to our observed number of movements of the neck in flexion-extension of 30 000 per day.

Prosthetic wear has been characterized by the Archard relationship, according to which volumetric wear is proportional to the normal force (load), a constant, and the total excursion [12]. This would imply that the total angular excursion is one of the most important parameters to consider when designing simulation tests. In this regard, the current standards do appear to adequately cover the observed motions in our subjects. However, the patterns of wear might also influence the testing results. A higher frequency (more total movements) with smaller amplitudes might have different wear behavior than that predicted by the current standards. Further, testing with varying motion amplitudes might have an unknown effect.

Wear testing standards are essential for verifying an adequate level of performance of intervertebral disc prostheses. The ranges of motion specified in the current standards are at or near the limits of full motions determined from kinematic, dynamic fluoroscopic, and cadaveric studies. The coupling of angular motions in two or three axes differs between the two standards, and the patterns chosen (sinusoidal) are largely arbitrary. Further, although not specified in the standards, the number of cycles per year is assumed to be 1 000 000, similar to what is used in hip and knee simulations [4]. However, the current standards have little clinical basis or explant analysis to justify their testing parameters. An analysis comparing explants to wear simulation testing done before adoption of the current ASTM and ISO standards demonstrated similar wear patterns and showed that the wear rate appeared to be much lower than that predicted by simulation testing, thus implying that the testing standards were conservative [4].

Prior Investigations

We have previously reported the daily living range of motion of the cervical spine of ten volunteer subjects. In the current study, we modified the WASP system so that we could evaluate both cervical and lumbar movements simultaneously. Our cervical spine results were similar between the two studies, except for lower observed periods of motion in lateral bending and higher angular displacements in axial rotation. Possible explanations for these discrepancies are the abolishment of nighttime monitoring in the present study, poorer accuracy in lateral bending during complex motion, and the time of year when this study was done (i.e., during the school year, whereas the prior was done in the summer).

Study Limitations

The study limitations relate to the accuracy of the WASP system. In single plane motion, we found the accuracy to be high, but with coupled motion the ability to detect accurately the angular displacements decreased. This was especially true for lateral bending coupled with rotation, for which correlations approximate only 50 %. In an attempt to improve the accuracy, we calibrated the sensors before use with a motion capture system, and we were able to show minimal drift and good reliability in the application of the sensors and their use by the subjects.

We utilized normal young adult volunteers who were active and who exercised regularly. It is likely that generalizing to a diseased population (such as those requiring spinal surgery for degenerative conditions) would overestimate motion. Kinematic studies show that the mean range of motion of a normal C5-C6 FSU is 10° to 15°, whereas in the reports of randomized trials of disc arthroplasty devices, the range of motion preoperatively, postoperative after disc replacement, and at adjacent levels is 7° to 8°. Thus, the reported values in this study are likely an overestimation of the motions of symptomatic or older patients who would be candidates for disc arthroplasty. Further, the analysis assumes that all cervical movement occurs between the occiput and C7 and that lumbar movements are between L1 and S1, thus ignoring contributions of the cervicothoracic and lumbothoracic junctions and the thoracic spine. Therefore, the contributions of in vivo movement credited to C5-C6 and L4-L5 are inflated and overrepresent true values. Although we could have used kinematic data to more accurately model our estimation of the FSU motions, we felt justified in our method, as that would provide a conservative estimate (overrepresenting) the results when comparing simulation testing.

The sensitivity of the device was set at 5°, which could have resulted in missed movements below that threshold. We selected that threshold based on extensive validations previously reported. Most important is that humans are unable to perform neck movements of less than 5°, justifying this threshold.

Clinical Relevance

The clinical relevance of this study is that the patterns of in vivo daily spinal motions are different than specified in testing standards. The overall total angular motions based on 1×10^6 cycles per year are surprisingly close to those specified in the ASTM, but they are less similar to the lumbar ISO standards. The important differences are that movements are more frequent and are of far less amplitude. Further, the in vivo movements have a wide range of amplitudes. The effect of these differences, if applied to in vitro wear simulation, is unknown. Further investigations using these physiologic motion patterns in in vitro wear simulators should be performed.

In designing new testing protocols, the following should be considered: (1) The number of movements is greater than previously considered, and the movements are correspondingly of much lower amplitudes. (2) Designs should consider the total cervical and lumbar amplitudes that vary over a wide distribution from 5° to 50° increments. Up to 2 % might be of large amplitudes past the neutral zone of the FSU or, in the case of prosthesis, where edge impingement might occur. (3) To assume a year of wear, the number of cycles should be 3×10^6 to 5×10^6 times per year for cervical and 2×10^6 to 3×10^6 times per year for lumbar.

Summary and Conclusion

A comparison of testing standards to daily living motion revealed that in vivo movements are three to five times more frequent in the cervical spine and two to three times more frequent in the lumbar spine than specified in standards based on 1×10^6 cycles per year. The majority of spinal segment (cervical and lumbar) movements are between 5° and 15°, and when ascribed to a single FSU they are between 2° and 3°. The annual total excursion correlates well to current ASTM standards, but more motion, especially in the lumbar spine, occurs than tested using ISO standards.

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