PULSTAR DIFFERENTIAL COMPLIANCE SPINAL INSTRUMENT: A RANDOMIZED INTEREXAMINER AND INTRAEXAMINER RELIABILITY STUDY

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ABSTRACT

Objective: To provide an entry-level, new technology reliability assessment of the PulStar computer-assisted, differential compliance spinal instrument.

Subjects: Eighteen college students (9 male and 9 female) were recruited by announcements and personal contacts.

Methods: Following approval of the consent process by the Institutional Review Board of Mississippi State University, a PulStar Function Recording and Analysis System (PulStarFRAS) device was evaluated for clinical reliability. Two examiners, blinded from data collection, used the instrument on individual subjects in random order (lying prone with their backs exposed) to administer light impulses (≈ 0.9 J which produced a 3- to 4-lb force) at each segmental level throughout the cervical, dorsal, and lumbar spine using probe tips spaced 3 cm apart, straddling the spinous processes, while a computer recorded the findings (resistance on a scale of 0 to 25.5 lb force). Data were analyzed by Exploratory Data Analysis (EDA) with analysis of variance (ANOVA) testing and by use of the intraclass correlation coefficient (ICC). In addition, a mean test (ANOVA) was conducted to determine if a trend in variation occurred as a result of repeated light thrusts to the spine, independent of variance explained by different examiners.

Results: Using EDA analysis and ANOVA, intraexaminer reliability for the 2 practitioners was very high but not perfect. This was confirmed by ICC statistics demonstrating good to excellent reliability for both practitioners (0.89 for the experienced practitioner, 0.78 for the newly trained practitioner). Interexaminer reliability of PulStar was similarly very high but not perfect based on EDA/ANOVA analysis and good to excellent (ICC = 0.87).

Conclusion: The PulStar mechanical adjusting device set to analysis mode appears to have good to excellent reliability when used by either an experienced or a novice (but trained) examiner. In addition, as a measure for resistance to a light thrust or spinal compliance, reliability was similarly good to excellent between the 2 doctors using the PulStar instrument. (J Manipulative Physiol Ther 2003;26:493-501)

Key Indexing Terms: Reliability; Chiropractic; New Technology Assessment

INTRODUCTION

Throughout chiropractic history, spinal lesions—termed subluxation or, more recently, subluxation complex—have typically been described as “tight” or “taut fibers,” tender on palpation, that influence the nervous system and impair health; restricted joint motion has been a clinically relevant associated phenomenon as well.1 According to Sandoz,2 the first chiropractic text pub-

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Fischer\textsuperscript{5} was the first to report a new device used to measure soft tissue compliance, the Tissue Compliance Meter (TCM) (Pain, Diagnostics and Thermography, Great Neck, NY), which uses a 0.5-cm cylindrical rubber tipped probe with a collar that remains at the surface of the skin even as the probe is pushed into the paraspinal tissues. A force gauge attached to the opposite end of the probe measures the subject’s tolerance to pressure deformation. When used on paraspinal surfaces, it is thought to measure the displacement that occurs when force is applied to the skin overlying the muscles and unknown variables, which might include muscle tone, edema, and skin elasticity, parameters that might theoretically be associated with the purported VSC.\textsuperscript{1,6} Jansen et al\textsuperscript{7} were the first chiropractic investigators to report on the device. Initial investigations on 20 asymptomatic male and female subjects revealed that 26\% of the paraspinal sites tested significantly different on retest 10 minutes later, although better correlations were found using 2 kg of force ($r = 0.70$ to 0.92 at L3) than 4 kg of force ($r = 0.12$ to 0.52 at L3).\textsuperscript{7} Others have questioned the reliability of the TCM as well, and even with a much smaller diameter disk, Kawchuk and Herzog,\textsuperscript{6} after 10 trials performed in random order by 5 examiners, found only poor reliability using the TCM on 3 substrates and 1 control surface. In contrast with these studies, Sanders and Lawson\textsuperscript{8} found adequate reliability and stability between 10-minute intervals in 40 asymptomatic subjects, with only 5\% of normal subjects demonstrating significant left/right paraspinal differences. In addition, Waldorf et al\textsuperscript{9} demonstrated excellent interexaminer concordance ($r$ values $> 0.90$) on 50 male and 50 female asymptomatic subjects while lying in the prone position and found test-retest temporal variability after 15 minutes and 2-week intervals was low. Finally, Nansel et al\textsuperscript{10} used the TCM to determine whether lumbar paraspinal muscle tone is altered by cervical spine adjusting: in a blinded randomized trial, they determined that lower cervical diversified adjustments caused significantly more relaxation bilaterally at the L4-5 level than was observed after upper cervical adjustments ($P = .01$). While providing no direct evidence that the TCM measures the elusive VSC, these researchers provided evidence that measures of paraspinal compliance may be affected by chiropractic adjustments.

Recently Evans,\textsuperscript{11} Evans and Collins,\textsuperscript{12} and Leach\textsuperscript{13} reported on a novel device used to deliver a light thrust into the paraspinal tissues and measure the resistance, or spinal compliance, in an effort to identify areas of the spine where “fixation” might indicate VSC and effect improved clinical outcomes. Because the instrument—interfaced with a computer—measures and compares resistance from 1 spinal segment to the next, Evans\textsuperscript{11} terms this differential compliance. Unlike the prior measures of tissue compliance using the TCM, which relied on subjects verbally identifying when tolerance to pressure had been attained, PulStar measures and compares resistance to a light thrust between consecutive spinal segments. Evans et al\textsuperscript{14} proposed that areas of the spine that exhibit increased resistance to a light pulsed thrust might indicate the presence of inflammation, muscle spasm, and/or joint fixation and serve as a mediating variable for VSC. Moreover, they speculate that since the PulStar uses a higher velocity low-amplitude thrust—unlike the TCM which is used to slowly apply greater pressure to examine paraspinal muscles by regions—it may identify intersegmental fixations by identifying significant variance in resistance between consecutive motion segments. However, before subluxation detection strategies and measures of spinal dysfunction can be evaluated for clinical validity and utility, researchers must first develop and identify the most clinically reliable methods for evaluation of spinal function.\textsuperscript{3,15} Computer-aided instruments have the potential to more reliably identify spinal lesions that chiropractors treat, and transducers might arguably be expected to more accurately assess spinal motion restriction and compliance than would manual procedures done by hand and using instruments such as the TCM.

With this in mind, a pilot intraexaminer reliability investigation was completed in April 2001 on a convenience sample of 15 subjects to determine effect size necessary to perform the present randomized intraexaminer and interexaminer reliability study. As expected based on preliminary observations, intraexaminer reliability was best at the C2 spinal level and worst at the C6 level (perhaps owing to easier palpation of the former segment). This preliminary work indicated that at least minimal examiner training was important and that the best protocol included having subjects lying prone with the head slightly flexed (perhaps $25^\circ$). It was found that the instrument’s probes must be held flat prior to discharge, that a gentle downward pressure was necessary to permit the instrument to make a more accurate and repeatable preload measurement and discharge, and that retest repeatability was best when the shaft of the instrument was held at $90^\circ$ perpendicular to the skin’s surface, with the probes equidistant from the spinous process of the vertebral motion segment being tested. Finally, our unpublished pilot study findings seemed to confirm the findings of other PulStar users, who observed that better relaxation and less variability are seen when the clinician first demonstrates the instrument on the subject’s hand, prior to making measurements on the spine with the patient lying prone. The finding that subjects should lie prone for improved interexaminer and intraexaminer reliability was also suggested by another pilot investigation which is being submitted elsewhere.\textsuperscript{16}

Based on findings of the 2 pilot studies, it was determined that 20 normal subjects (10 male subjects, 10 female subjects) would be suitable to yield satisfactory preliminary reliability data for the PulStar, with a minimum of 2 blinded practitioners each randomly performing 2 examinations on each subject.

The purpose of the present investigation was to extend and expand on the pilot studies and perform a randomized,
blinded, new technology assessment of the clinical reliability of a computer-assisted chiropractic analytic device that measures spinal compliance, a measure of resistance to a light pulsed paraspinal thrust. The primary aim then was to determine whether 2 chiropractic doctors could find acceptable agreements, while the PulStar was set to the analysis (ie, measurement) mode. A secondary aim was to provide a preliminary baseline of measures of normal spinal compliance for further research.

**Methods**

**Setting**

The investigation was performed in a privately owned chiropractic clinic in a university town in Mississippi. Data analysis occurred at Mississippi State University (MSU).

**Subjects**

Following protocols established by the Federal Government (45 CFR 46.110 #7) and guidelines established by the US Agency for Healthcare Research and Quality,\(^7\) the principal investigators sought and received approval for the consent procedures used in this research from the Institutional Review Board (IRB) (expedited review, docket 01-266) of MSU prior to initiation of the study. Procedures were in accordance with the Helsinki Declaration of 1975 and included investigator training in the informed consent process at MSU for the 2 chiropractors involved in the research.

Inclusion criteria for prospective research subjects were preset. Subjects were allowed to participate only if their age was in the range of 18 to 25 years. In addition, they were required to have (1) no prior significant problems with spine, neck or back pain, (2) no prior treatment for spine, neck, or back problems by a doctor, (3) no genetic deformity or scoliosis, (4) patient self-rating of overall health as good or excellent, and (5) no obesity by World Health Organization criteria (ie, Body Mass Index \(<30 \text{ kg/m}^2\)).

We chose to limit our investigation to normal subjects for 2 reasons: (1) we suspected that obesity, pain, and muscle spasm might affect reliability and we did not want to introduce these potential sources of variation into our small sample, and (2) we wanted to explore the development of norms for normal subjects, as well as protocols for further research on other populations and with greater numbers of subjects.

Attempts to recruit 20 college students included verbal classroom announcements by 3 professors at MSU, bulletin board postings, as well as contacts made by college-aged staff at the chiropractic clinic where the research was conducted. These contacts were made based on language pre-approved by the IRB at MSU. Announcements included the statement, “Volunteers must be aged 18 to 25, healthy, not obese, with no history of spine problems, back or neck pain.”

Further prescreening for the previously outlined exclusion criteria occurred when subjects called to make an appointment for a data collection session. Because subject recruitment involved a number of individuals asking for referrals, we do not have exact information regarding the number of subjects who did not present to the office for research as a result of the exclusionary criteria. However, to our knowledge, only 2 or 3 were eliminated by this process. Finally, a screening questionnaire was administered in the office, developed to identify exclusionary criteria that would cause a candidate to be dismissed prior to data collection but after the subject read and signed the informed consent statement.

Although no subjects were eliminated based on answers supplied on the screening questionnaire, 2 subjects (1 male subject, 1 female subject) indicated that they had been involved in a car wreck that caused temporary neck pain which resolved with a few chiropractic treatments, and a third subject indicated that he had scoliosis and had injured his back 1 time but was now pain free. A fourth subject indicated episodic low back pain but none on the day of the research; he stated that perhaps once per week he had to lie down for perhaps 2 hours, which resolved his pain. He had not sought treatment from a doctor for his pain episodes. These problems were not deemed significant enough to warrant exclusion from the research but are noted here for reference.

Despite a small financial remuneration (ie, $10 US) for the approximately 30 minutes of time spent participating in the research, there was some difficulty in finding college students for this study. Nevertheless, after several weeks of recruitment, 5 subjects were tested 1 afternoon, and an additional 13 subjects were tested during a second 7-hour session 2 weeks later (total of 9 male subjects and 9 female subjects). Four subjects did not show up and no further recruitment efforts were made. Although no effort was made to exclude appropriately aged noncollege students, all subjects in this investigation presently attend MSU.

**Apparatus**

The PulStar Function Recording and Analysis System device (PulStarFRAS) (Sense Technology, Inc, Pittsburgh, Pa) (Fig 1) holds 2 US Patents (US Pat No 4,841,955 and US Pat No 5,662,122) and has received marketing approval from the Food and Drug Administration (FDA) for use as a medical device. According to the manufacturer, the contact that must be achieved between the impulse head and the skin overlying the spinal segment to be analyzed, in order to trigger the instrument’s thrust, is \(3.0 \text{ to } 4.0 \text{ lb force}\). This is termed the preload. At that point, a preload sensor, which continuously monitors control circuitry of the instrument, located in the hand-held impulse head triggers a precisely controlled energy impulse into a solenoid armature. According to the manufacturer, there is essentially no motion of the armature during the controlled preload pulse. However,
after the energy is delivered to the spine, the coupled system begins to move. A force transducer in the impulse head subsequently monitors resistance, stiffness, or compliance of the muscles, joints, and adjacent structures to the energy generated by the impulse. Evans et al\(^{16}\) term this a complex, highly-coupled, damped-spring mass system. Output of the force transducer is converted from an analog signal to a digital signal and read into a register, with the data integrated over time and stored in a computer. Differences in the mobility of each point tested will result in differences in the resistance to the impulse, which is measured with a force transducer and displayed as a bar graph. In this way, the device measures paraspinal resistance (ie, resistance to thrust on a scale of 0 to 255 lb force \(\times\) 10; hence, the analysis reading may be converted to pounds force by dividing by 10 or 0 to 25.5 lb. force) to the impulse, as recorded by a force transducer, which is stored in a computer program and spreadsheet for subsequent analysis. Based on raw compliance measures made at each spinal segment, the software calculates differential compliance or the change in compliance from segment to segment and provides the chiropractor with information regarding the relative change in compliance from segment to segment. However, the present inquiry focused only on the raw spinal compliance measures generated by the PulStar head set to analysis mode and not on differential compliance based on mathematical computations.

**Protocols**

A flowchart was generated to direct the staff to appropriately follow all research activities, including those necessary for appropriate randomization and for implementation of informed consent procedures (Fig 2). After completion of the screening questionnaire, the female staff assistant (present with research subjects at all times) led patients to the examination room where she demonstrated use of the instrument on the subject’s hand and prepared the subjects for the measurements (female subjects gowned or sport bra/bikini top allowed; male subjects removed shirt).

One of the investigators (R.A.L., Examiner A) has 22 years continuous clinical experience as a chiropractor but only had about 18 months experience using the PulStar device prior to this research. He has used the instrument in a clinical setting on a variety of subjects, from infants to elderly patients.

The second investigator (P.S.V., Examiner B) is also an experienced chiropractic clinician (with 16 years active practice); however, he was trained for only about 4 hours in the PulStar analysis on 2 occasions prior to initiation of this present inquiry (practicing the analysis on only perhaps 6 to 8 volunteers). This novice examiner had not previously seen or used the device in any setting.

The 2 examiners were randomly assigned (according to a computer-generated set of numbers for each of the subjects) (eg, 1212, where doctor 1 enters the room first, doctor 2 second, and so on for the first subject, then another set of numbers for the second subject; all subjects were seen twice by both examiners in this fashion) to perform the PulStar analysis on the subjects, who were already lying prone when the examiner entered the examining room. Subjects were told to flex the head to open the cervical spine for easier palpation. Subjects were also told to let their arms fall to the floor to avoid retraction of the scapulae. Subjects generally did not move between examinations and remained lying prone on the examination table; however, occasionally some head movement occurred, as subjects interacted with the investigators or research assistant.

Each examiner used a similar palpatory technique, distracting the skin from 1 spinous to the next in a caudal direction. Upon contacting the next spinous, the PulStar probe, having already made contact with and straddling the spinous above, was gently pushed toward the spine from the 90° perpendicular angle, until it discharged and recorded the response to its light, pulsed thrust. Each segmental level throughout the cervical, dorsal, and lumbar spine was analyzed in this fashion (ie, occiput to L5), using probe tips...
spaced 3 cm apart and placed equidistant from the spinous processes.

The research assistant entered data from the PulStar computer program into a spreadsheet, as it was collected. At all times, doctors using the PulStar were blinded from the data entry process, and in no case were the doctors allowed to reexamine a segment of the spine, even if they felt they used improper measurement technique (ie, improper level of the spine or holding the instrument at some angle other than the prospectively agreed upon 90° perpendicular from the spinous). At no time were the 2 examiners allowed to view the other doctor while performing the analysis; neither were they allowed to view data until the collection process was completed. The research assistant who prepared the spreadsheet was blinded from data analysis.

With input from other statisticians both within and outside the profession, it was decided that data should be subject to both intraclass correlation coefficient (ICC), as well as Tukey’s Exploratory Data Analysis (EDA) sta-
tics, with analysis of variance (ANOVA) performed as a means test to determine whether variance in the subjects’ compliance measures might be attributable to a biological effect of repeated measures testing with the PulStar and/or extended periods of lying prone. The research scientist was blinded from personal identifiers, which were removed from data before it left the research site, in keeping with concern for privacy of the subjects.

**RESULTS**

EDA is a process of using graphic and summary statistical procedures to get an initial feel for the data set, so as to guide the application of appropriate confirmatory data analysis procedures, such as ANOVA and ICC. The EDA graphic analysis also provided a preliminary set of measures for normal spinal compliance using the PulStar device. Compliance in the normal spine, in this limited sample, appears greatest in the lower cervical and lumbar spines, and lowest compliance is observed over the occiput and upper cervical, as well as upper dorsal spines (Fig 3).

Beyond these preliminary observations on normality, the primary issues of intraexaminer and interexaminer reliability were explored in detail.

**Intraexaminer Reliability**

Using EDA as an initial test of the data, a graph of the 4 trials (ie, 2 trials of data for each of the 2 examiners, A and B; A1 represents the first examiner’s trial on 18 subjects, where data at the occiput are averaged, then data at C1, and so on to L5) alongside each other demonstrates that they vary together to a high degree (Fig 3). ANOVA confirms that there are no significant differences between trials A1 and A2. Similarly, ANOVA confirms that B1 and B2 are statistically significantly different only at the occiput and C3 spinal levels. Overall, EDA and ANOVA would lead us to believe that the intraexaminer reliability of these measures is high but not perfect. Using ICC to quantify the intraexaminer reliability of these 2 examiners, we see ICC = 0.89 for Examiner A and ICC = 0.78 for Examiner B. These are considered good to excellent.

**Interexaminer Reliability**

If large, systematic differences or offsets between the EDA line graphs of the 2 doctors were observed, they would lead us to believe that the interrater reliability was not very high. Instead, the measurements generated by the 2 examiners vary together, though not perfectly. Examination of the graph does not show a systematic offset or difference between the examiners. Using ANOVA to confirm this shows that there are statistically significant differences between A1 and B1, A2 and B1, and/or A1 and B2 trials only at the occiput and C4 spinal levels. Overall, EDA and ANOVA would lead us to believe that the interexaminer reliability of these measures is high but not perfect. Using ICC to quantify the interexaminer reliability between Examiner A and Examiner B, we see ICC = 0.87, considered good to excellent agreement between the 2 doctors.

**Biological Effects**

We want to know if there is a systematic biological or examination-induced change between A1 and A2 or B1 and B2. In other words, is there an examination-induced change caused by the process of taking measures of the subject and then remeasuring repeatedly or caused by lying prone for prolonged periods. ANOVA shows that there are no statistically significant differences between A1 and A2. Between
B1 and B2, there are statistically significant differences only at the occiput (mean differential = 1.42 lb force, \(P = .0009\)) and C3 (mean differential = 0.67 lb force, \(P = .02\)) levels. Overall, the differences are not systematic enough to lead us to believe that there is a significant examination-induced or biological effect caused by using the PulStar in analysis mode.

**Examiner Learning Effects**

We would also like to know if there is an apparent learning or fatigue effect in which the amount of error attributable to the examiners changes over time. We can examine this by calculating the absolute difference between trial 1 and trial 2 for each examiner and for each spinal level. When we do this, we see that absolute change between trials remains relatively constant (\(\sim 1.0 \text{ lb force}\)) for examiner A, while increasing over time \(\sim 0.4 \text{ lb force}\) (ie, over the course of 18 subjects from 0.8 to 1.2 lb force) for examiner B. Examiner B’s error is increasing slightly and his reliability is decreasing slightly over the course of the trials.

**Discussion**

Of all the differential spinal compliance measures made with the PulStar unit, significant variance between 2 examinations by the same doctor occurred only at the occiput and C3 and only for the novice examiner, while significant variance between examiners occurred only at occiput and C4. The measurement at occiput involved placing the probes over the occiput in such a manner that they straddled the external occipital protuberance. It is quite possible that despite stabilizing the probes by resting them against the side of the first finger of the examiner’s free hand, some sliding of the probes during discharge might have created unacceptable reliability at this level. Others using PulStar place the probes directly over the atlanto-occipital joints for the occipital measurement, and this may prove to be a more satisfactory arrangement. Further research will be needed to verify this finding and to determine whether an occipital site is even necessary. Obviously, no other vertebral segment that we tested posed the unique anatomy found at the occiput.

We were only mildly surprised to find poorer agreement at the C3 and C4 levels, after the results of our earlier pilot investigation had revealed poorest reproducibility at the C6 level. Only late in the pilot investigation did we begin having the patient flex the neck, and those were the very subjects that showed improved test-retest reliability. In the present inquiry, all subjects fully flexed the neck while lying prone, which certainly seems to improve palpation of the lower cervical spine, relatively increasing the difficulty in locating the shorter C3 and C4 spinous processes. Others have proposed that midcervical palpation is most difficult as well, and ultrasound has been used to image the spine, as well as “indentation” testing (ie, not a quick pulsed thrust like the PulStar uses, but rather pressure applied at a rate of 2.5 mm/s until a load of 1 N is attained, by use of a flat, rigid, \(3 \times 3 \text{ cm surface}\) combined with ultrasound imaging to improve examiner palpatory reliability. Whether ultrasonic or other imaging is needed to perform more reliable midcervical PulStar compliance measurements remains to be determined. It may be that PulStar used as a more global measure of cervical compliance (rather than differentiating exactly which 2 segments are less compliant) would provide clinically relevant information, even without palpatory determination of the exact locations of the C3 and C4 vertebrae.

We may also speculate that the amount of neck flexion in our subjects might have varied significantly from examination to examination, producing a confounding variable that affected reliability of the C3-4 measure. In this regard, although we are unaware of studies on the cervical spine, certainly there are recent observations on the lumbar spine by Caling and Lee that suggest posteroanterior stiffness varies significantly with the direction of applied force. Further investigations might want to control for this variable by monitoring the degree of cervical flexion during PulStar testing by use of electrogoniometry; however, up to 9° of measurement error in flexion/extension may still be a confounder. Researchers might also utilize an instrument that establishes a 90° perpendicular to the spine, to determine if that is a source of error.

It is worthy to note that in the present study rules for use of the instrument were more stringent than those used in clinical practice and might have actually led to underestimation of clinical reliability. Hence, while researchers generally agree that establishing clinical reliability is easier in an experimental setting following strict protocols than in a busy practice where compensation depends on volume of services and not necessarily quality of care rendered, in the present investigation doctors were not allowed to repeat their examination even if they thought the PulStar probe had slipped, was at an angle other than 90° perpendicular to the spinous, or because they had miscounted the level of spinous that they were checking. In each of these cases, a practicing clinician can do a reexamination to check the data; in contrast, since this was a blinded investigation, doctors were not allowed the opportunity to recheck their work. Further research of PulStar reliability should include the possibility of the clinician repeating his examination and suggesting which examination should be used (while still blinded from data collection). In this way, we might know whether repeat trials, such as would be available to the clinician in private practice, would enhance the reliability of the procedure.

Two experienced clinicians (as opposed to 1 novice clinician and 1 experienced clinician) might not have difficulty with interexaminer reliability using the PulStar in the midcervical spine. However, despite some evidence of fatigue
for the novice examiner, whose variance between trials increased slightly (−0.4 lb force from the 1st to the 18th subject), his overall rate of variance ranged only from −0.8 to −1.2 lb force, not dissimilar from the more constant variance rate of −1.0 lb force observed by the experienced examiner. From the standpoint of clinical reliability, this is a wash; despite some differences, it appears that for both examiners an error range of −1.0 lb force might be expected between any 2 trials. The present investigation then revealed no clinically meaningful difference in reliability between the experienced and novice, but trained, investigator.

Finally, using the EDA graphic analysis, we provide a preliminary view of normal spinal compliance using the PulStar instrument, which may guide further research aimed at developing norms for specific populations. It is noteworthy that averaged data on 18 subjects from all 4 trials (2 doctors × 2 trials) indicate that spinal compliance was greatest in the lower cervical and lumbar spines and lowest over the occiput (control site) and upper dorsal spine. Certainly, further research will be necessary to confirm and extend these preliminary observations, comparing normal populations to patients in pain, for example. Also, it should be understood that this report did not measure the validity of the differential compliance analysis, a computerized analysis which measures the difference in spinal compliance between vertebral segments and triggers the PulStar to provide more pulsed adjustments to areas of fixation or poor compliance. Only further research of trial validity can determine the significance and clinical meaningfulness of the computerized analysis and of the computer-guided PulStar adjustment itself.

It is uncommon, if not rare, to find either spinal fixation or chiropractic subluxation detection strategies that have a high degree of intraexaminer and interexaminer reliability.25 and this has prompted some to suggest abandoning research in this area altogether.3,26,27 Since no individual or panel of chiropractic experts to date has been able to agree on an operational definition or so-called gold standard dependent variable to measure subluxation,28-31 we here make the assumption that if there are subluxation-free spines, it is more likely that we will find them in younger, pain-free individuals, whose spines have not yet been subject to decades of postural and physical insults. While we concede that we cannot rule out the presence of VSC, purported to influence nerves and viscera, in the young college students in our trial (primarily because we do not yet know how to measure subluxation complex), if they did have these lesions they apparently did not adversely affect clinical reliability of the apparatus we tested. Of course, we will only learn whether the PulStar measure correlates with outcomes and whether it is capable of serving as a mediating variable of VSC (ie, becoming part of a gold standard for VSC diagnosis) if clinical research on trial validity of differential compliance is conducted.1

The results then of the present inquiry on the reliability of the PulStar instrument set to the analysis mode, a novel new chiropractic technology assessment utilizing the first patented computer-assisted device developed to measure spinal compliance and possibly fixation, are certainly promising and warrant further research. More research using different doctors and on larger numbers of subjects, including some with pain, would help determine the generalizability of these findings. Protocols we developed may also be used to conduct research aimed at establishing norms for different populations, including potentially patients with pain, obese individuals, and otherwise normal subjects, to verify and extend our initial findings on these healthy college students. Now that there is initial evidence of good to excellent clinical reliability of the PulStar spinal compliance measure, trials should also be designed and implemented to determine what this phenomenon means in terms of chiropractic patient care and outcomes (ie, trial and construct validity).

CONCLUSION

The PulStar mechanical adjusting device set to analysis mode appears to have good to excellent reliability when used by either an experienced or a novice (but trained) examiner. In addition, as a measure of spinal resistance to a light pulsed thrust or spinal compliance, reliability was similarly good to excellent between the 2 doctors using the PulStar instrument. Preliminary results indicate spinal compliance in normal subjects is greatest in the lower cervical and lumbar spines and lowest at the upper cervical and upper dorsal levels. This initial study does not address the validity or clinical significance of the measurement method. Further research will be necessary using greater numbers and a wider variety of subjects and more diverse examiners, to verify these findings and fully understand the generalizability of these results.

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REFERENCES