Differential Compliance Measured by the Function Recording and Analysis System in the Assessment of Vertebral Subluxation

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Abstract — This study presents the theory of differential compliance and the clinical application of instrumentation designed for its detection in the clinical setting. The engineering principle of using a mechanical impulse to excite a structure coupled to sensors to measure the response, has been employed in the design of the Function Recording and Analysis System (FRAS). This system, linked to software which analyzes input data, is further designed to graphically display relative differences in vertebral compliance. The present study employed assessment of a region of the spine encompassing the occiput to the third thoracic vertebra as a model to demonstrate how compliance measurements can be obtained, graphically displayed, and interpreted. The reliability of the instrumentation to accurately and consistently measure different levels of compliance was tested on three artificial substrates of varying "stiffness" and three human tissue locations exhibiting different "stiffness" including the heel, palm, and finger tip. Moreover, intra- and inter-examiner reliability in the use of the system has also been reported. Statistical evaluation of repeated measures for each of these categories included analysis by chi-square, Pearson product moment correlation, and intraclass correlation coefficients (ICC). Results indicated a high level of consistency of the instrument in measuring substrates of varying compliance. Moreover, strong intra-examiner reliability (ICC ≥ 0.90), and inter-examiner reliability (ICC = 0.65) suggest a consistent use of the instrument among and between practitioners. These findings indicate a useful role for the FRAS in the characterization of vertebral subluxation, as well as serving as one means of assessing changes in flexibility of the spine following the chiropractic adjustment.

Key Words: Tissue compliance, vertebral subluxation, adjusting instrument.

Introduction

The response of tissue to applied force has been investigated using modern instrumentation over the last decade.[1-21] Within the chiropractic profession, the majority of these studies have involved detecting the extent of muscular soft tissue displacement in response to the application of a stylus connected to some form of load cell. In regard to physical therapy, joint compliance has also been investigated with similar instrumentation. Lee and Svensson studied the detection of posterior to anterior vertebral "stiffness" encountered in relation to low back pain.[18] In an effort to overcome the poor inter-examiner reliability of ascertaining "stiffness" among physical therapists, instruments such as the spinal physiotherapy simulator,[18] the spinal mobilis-

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er,[19] and a portable stiffness device[20, 21] were developed utilizing the concept of force and tissue resistance or "displacement" associated with painful segments. The results of these studies supported the rationale that "painful" segments often elicited the least displacement, or exhibited the highest level of "stiffness." Thus, within the objectives of the discipline of physical therapy, such instruments have served to provide objective data to replace the subjective manual estimation of segmental "stiffness." While the concept of measuring tissue resistance has been substantiated by these instruments, the major drawback to these devices has been their general lack of portability,[20] and relative to chiropractic applications, poor sensitivity[10] and poor reliability.[2,4] Consequently, they often have been assessed among asymptomatic patients, with tests of reliability restricted to anthropometric data (bench studies challenging elastic beams) by the same (intra-examiner) user.

The present study presents information on a new instrument which has been developed to overcome the limitations of prior devices, while utilizing the same established engineering principles. Moreover, described herein, is an application of the instrument related to the clinical and practice objectives of subluxation-based chiropractic.

Every vertebral subluxation has a misalignment component,[22] which would likely also exhibit fixation.[23] While there are a number of different approaches used to determine the presence of vertebral subluxation, they all attempt to identify the specific subluxated bony segment. Such identification allows for the most efficacious force, or adjustment, to be introduced into the segment for correction of the condition. Additionally, the ability to detect fixation, and to monitor its reduction serves as an index of success of the adjustment, as well as one indicator of biomechanical change in the patient, thus providing an objective outcome assessment measure.

This study describes the theory and application of an instrument which measures differential compliance of tissue. The system described incorporates a percussive impulse head which is coupled with a force transducer that supplies data to be interpreted and analyzed by a computer-software system.[24-26] The Function Recording and Analysis System (FRAS) is an extension of other instruments which lack the impulse-force instrumentation.[27] The practitioner uses the system to challenge each vertebra with a low energy impulse. The system records and displays the peak force measured at each vertebra. The compliance of the vertebra is inversely proportional to the peak force recorded. Such information relates specifically to what has variously been described as kinesiopathology,[23] or dyskinesis,[28] both of which elaborate a combination of aberrant range of motion and joint fixation. Compliance data allows the practitioner to quantify the relative extent of mobility of individual vertebral segments, as well as the spine as a whole. It is proposed that compliance data can be used with other findings such as those derived from palpation, radiographs, thermography, and the patient's history to determine the appropriate locations to administer an adjustment.

Information presented in this article is provided to explain the basic theory of differential compliance measurement, and to offer preliminary data regarding reliability of the instrument detecting this phenomenon. Additionally, initial estimates of inter and intra-examiner reliability are presented.

Methods

Theoretical Aspects

The instrument described herein measures tissue compliance according to the concept of impulse-response, commonly employed in engineering to examine the response characteristics of structures or electrical circuits.[24-26] This technique uses impulse hammers to excite a structure, and sensors to measure its response. Of particular interest, regarding the presently described instrument, is the single point vibration analysis in which the excitation and response of the structure occur at the same point.

A schematic of the compliance detection instrument is depicted in Figure 1. The impulse head of the instrument is used to initiate single point impulse-response. In this regard, excitation of the "tissue" structure is achieved by the armature within the solenoid body being brought into contact with the anvil of the impulse head. To achieve excitation, the head is first pressed against the patient until a pre-defined pre-load, expressed in lb.
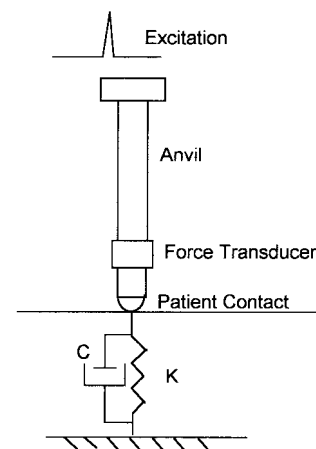

Figure 1 Schematic of the Compliance Detection Instrument Component of the Function Recording and Analysis System (FRAS)
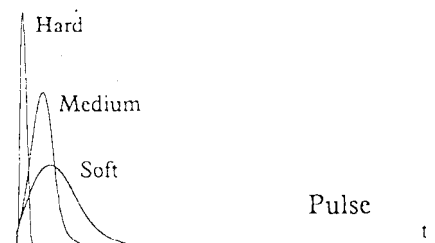

Figure 2 Illustration of Pulse Shapes obtained from Substrates of Varying Stiffness.

force is achieved, assuring that the conditions prior to delivering the excitation impulse (energy) is the same each time. Since the mass of the armature is constant, the velocity of impact of the armature with the anvil is essentially constant, slight variation being due to examiner technique (such as variation in the rate of pre-load application) or differences in overcoming the resting friction within the instrument. Consequently, at the given pre-load, the energy imparted to the solenoid armature to "excite" the tissue will be constant each time the head is activated.

After the anvil has been excited by the armature, it is free to move with respect to the impulse head. The movement of the anvil against the resistance of the substrate (artificial or natural) is measured by the force transducer attached to the front of the anvil. This determines the force between the anvil and the patient's body. Under these circumstances, " the stiffness of the contacting surfaces affects the shape of the force impulse"[24] (Figure 2).

Clinical Application

Utilizing the instrument described, a system of measuring compliance of vertebral segments has been developed. The force exerted by the instrument against the tissue, after being converted into a voltage level by the force transducer and further converted to digital representation by an analog to digital converter is then stored in a computer buffer.[29] Clinical observations have shown that a rigidly fixed portion of the spine will result in a higher peak force for the same level of impulse delivered to a portion of the spine which is easily moved, or compliant. Additionally, the rate at which force rises from the initial contact to the peak force will vary. The rate of increase will be much steeper with a rigid joint versus a compliant joint.

Because of the differences in the muscular and connective tissues, as well as the size and configuration of the bony structure of individuals, no two spines would be expected to have the same compliance measurements. However, comparison of the measurements of different segments of the spine will indicate which joints are fixed, as they will have the lowest compliance.

After the spinal segments have been challenged with the instrument, and the force versus time measurement has been recorded, the maximum force for the region assessed is recorded and stored in the computer buffer. In order to obtain a relative measure of the compliance of the vertebral segments, each lb. force measurement is then divided by the maximum force held in the buffer. This process yields a set of numbers, the maximum of which is one. The numbers are then displayed as a series of bar graphs identified with the vertebral segment under examination. This procedure may then be repeated following an adjustment to record the effects of the adjustment on the compliance of the spinal segments.

The pre-intervention analysis provides the practitioner with a graphic display of the relative compliance of each osseous segment challenged. Low tissue compliance was considered to be a reflection of hypo-mobility of tissues, segmental restriction or fixation. Conversely, the high compliance in tissues was taken to reflect hyper-mobility, laxity of ligaments, or high levels of segmental flexibility.
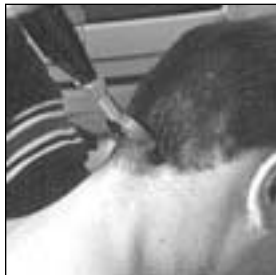

Figure 3a — Occiput

Figure 3b — C-1

Figure 3c — C-2

Figure 3 Compliance Detection Instrument Positioned at Different Anatomical Locations.

Protocol

Cervical Analysis

Although any segmental region of the spine may be assessed, the present paper focuses on the region from the occiput to the third thoracic vertebra, and is herein referred to as the cervical-thoracic analysis (C-TA). To conduct the C-TA, the patient is seated on a bench or chair. This positions the patient at a comfortable height allowing the clinician to stabilize the head and neck in flexion. With the patient in this position, assessment begins by recording compliance of the joint space between the occipital shelf and C1, then descending caudally to the third thoracic vertebra. The tip of the 30mm dual prong extension of the impulse head of the instrument is placed just below the occipital ridge angled at approximately 45 degrees to the back of the neck (Figure 3). The impulse head is pressed evenly against the patient while maintaining the position of the dual prong. The instrument is gently pressed against patient in order to attain the pre-

load force. At this point, a low energy impulse is provided to the tissue. The instrument records the response of the tissue to the impulse and stores it until all pre-intervention testing is completed.

Following the same protocol as described above, compliance of the first cervical vertebra (C1) is recorded by placing the impulse head of the instrument at an angle of 75 to 80 degrees to the patient's neck, on the posterior tubercle of the first cervical vertebra. The second cervical vertebra (C2) is measured by angling the impulse head parallel to the facet with one dual prong on each side of the spinous process. This same angle is used when recording the compliance of the remaining vertebrae in the C-TA. When the C-TA is completed, it is displayed as shown in Figure 4. Post adjustment assessments are performed in the same manner as described for the pre-intervention assessment. The graphic display is arranged such that the post adjustment compliance measures can be readily compared to the pre-intervention assessment. The primary post adjustment result should be a significant reduction in the difference in compliance at the site of adjustment. An optimal result would be when no segment differed from the adjacent segment by more than the expected error of measurement of the instrument ($\cong 6\%$, see Results). Because the spinal segments are interconnected and operate as one functional entity, it is common to observe changes in compliance at sites other than those chosen for adjustment.

The protocol described above represents only a first step in the range of possible clinical applications. Other possibilities include analysis with the cervical spine in neutral, partial and full flexion as well as similar analyses with the addition of left and right rotation. The possibilities and combinations are extensive, but require exploration in the clinical setting.

Thoracic and Lumbar Analysis

The same protocol as described above is employed for analysis of the thoracic and lumbar vertebrae, with the impulse head of the instrument angled to maintain a line of drive that is parallel to either the thoracic facet, or lumbar lamina of the segment under examination.

Sacral Analysis

A detailed description of the use of the instrument for sacral and pelvic analysis is beyond the scope of this paper, but is described elsewhere.[29] However, in deriving data to support these analyses, the impulse head using the dual prong attachment is applied (as described for other segments) at each sacral level (S1 through S5). This approach gives a direct measure of sacral compliance, as well as an indirect measure of the mobility of the sacroiliac (S-I) joint at each level. More complex analyses include the comparison of left and right S-I joints at each level, generally with the impulse head applied bilaterally or uni-laterally to the posterior-superior iliac spine(s).

The Use of the Instrument to Produce an Adjustment

The impulse head of the instrument can also be used to deliver single or multiple high velocity forces sufficient to elicit

an adjustment. If the practitioner chooses this option, the output of the instrument can be pre-set to deliver an impulse ranging from 10 to 35 lb. force, which can be calibrated against an artificial substrate yielding a known compliance. When force is applied in this manner, it is not delivered until the instrument is pressed against the tissue of the patient, and automatically ceases when the response of the tissue/structure stabilizes (i.e. when no further change in the mobility of the underlying segment is elicited by the adjusting impulses), a preset maximum number of impulses is reached or the examiner removes the impulse head from the patient's body.

Reliability Assessment

Instrument

Initial investigation concerning the reliability of the impulse instrument was conducted by repeated measures. An artificial substrate composed of # 6 butyl rubber stopper material was constructed. Two additional substrates of the same material, one

Table 1. Peak Force Measurements* of Twenty Trials Each on Three Different Artificial Substrates[+] and Three Human Tissue Locations.

A. Artificial Surface

	Substrate 1	Substrate 2	Substrate 3
Peak Force (lb.)	15.4 ± 0.63	6.9 ± 0.41	2.3 ± 0.24

B. Human Tissue

	Heel	Palm	Tip of Finger
Peak Force (lb.)	11.4 ± 0.58	5.2 ± 0.33	1.6 ± 0.13

*Values represent the mean and standard deviation of twenty trials, each composed of twenty repeated measures, on each substrate represented.

+ See Methods for a description of the "stiffness" determination for each substrate.

Table 2. Statistical Summary of Inter-Examiner Repeated Compliance Measurements of an Analysis of the Occiput through Third Thoracic Vertebrae.

	Statistic*		
Examiner One	Chi-square Probability	Pearson Coefficient [r]	Intraclass Correlation Coefficient [ICC]
Subject			
1	0.48	0.98	
2	< **0.00**	0.86	
3	0.36	0.85	
4	0.37	0.80	
5	0.32	0.85	
6	0.58	0.80	
7	0.45	0.82	
8	0.36	0.74	
9	0.98	0.97	
10	0.16	0.82	
11	0.19	0.80	
12	0.40	0.84	
13	**0.04**	0.91	
14	0.15	0.82	
15	0.17	0.86	
ICC Across Subjects			0.90
Examiner Two			
Subject			
1	0.07	0.89	
2	0.61	0.95	
3	0.21	0.91	
4	< **0.00**	0.72	
5	0.50	0.86	
ICC Across Subjects			0.93

* See Methods for Description of Statistical Analysis.

Bold numbers represent a significant difference between observations ($p < 0.05$).

approximately half the thickness, and a third of one-fourth the initial thickness were also constructed. This permitted a range of "stiffness" over which the reliability of repeated measures of the instrument could be tested. The impulse head of the instrument was set to an energy level ($\cong$1.7 joules) which produced a response of 15 lb. force on the first artificial substrate. The impulse head was placed on each artificial substrate and activated repeatedly twenty times. The peak force for each impulse was recorded, and the mean and standard deviation for each set of twenty recordings was determined. Each set of twenty impulses was subsequently repeated twenty times on each of the three artificial substrates, for a total of 400 repeated measures (Table 1).

A second test of reliability was conducted on a non-patient volunteer, with measurements made by the author. Three locations were chosen on the subject for compliance determinations. These were the heel of the hand, the palm, and the tip of the index finger. The instrument was again set to the same energy level used on the artificial substrates. The peak force was measured and recorded as described above.

Mean values for both human tissue and artificial substrates were then plotted against their respective standard deviations (Figure 5), and a best line plot determined by linear regression analysis. This approach permitted an evaluation of the reliability of the instrument by analyzing the extent of variation within repeated measures on different substrates.

While these methods served to evaluate the instrument's reliability, other considerations requiring investigation included: (1) the variability of compliance measurements in a normal spine from vertebra to vertebra in consideration of differing body fat content, muscle size, muscle tone, etc., (2) intra-examiner reliability, and (3) inter-examiner reliability.

Tissue Variablility

The first issue was investigated by examining the variability of compliance measurements in the cervical and upper thoracic spine of subjects chosen from patient volunteers in a private practice setting. From among a group of volunteers, ten subjects
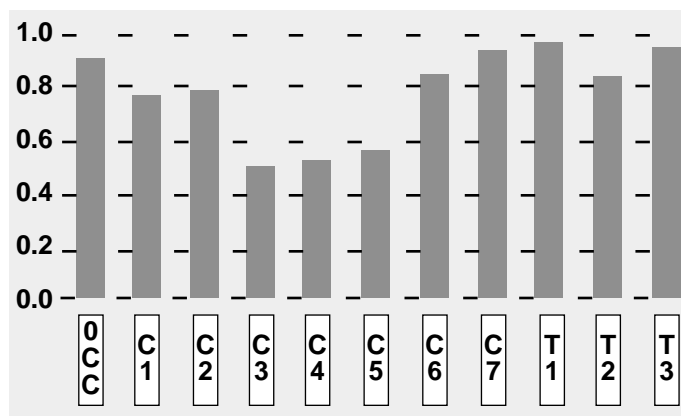

Figure 4 Display of Normalized Compliance Measurements Derived from a C-TA Scan.

were selected to represent a wide range of muscle and fat mass. The examining practitioner explained the protocol for testing, and the purpose and nature of the study to each subject who then granted written consent to participate. The practitioner then obtained one C-TA for each patient.

Intra-and Inter-Examiner Reliability

Intra-examiner reliability of the C-TA was assessed in twenty subjects, from the same private office setting, examined by two practitioners. Fifteen of the subjects were examined by one practitioner, and another five were examined by the second practitioner. These subjects were also selected from a group of volunteers without regard to gender or age, and written consent obtained in the manner described above, by each of the two respective practitioners. Two sets of readings on each subject were determined by each practitioner, one immediately after the first. Data (Table 2) were evaluated by a chi-square analysis (p<0.05) which provided an assessment of the likelyhood of the two data sets being the same. The Pearson product moment correlation was used to provide a measure of the strength of the association (1.00 = perfect correlation). This was coupled to an estimation of the intra-class correlation coefficient (ICC) derived from a one way ANOVA as a more reliable indicator of the strength of significance involving continuous measurements.[30,31] The ICC was determined according to the following relationship:

$$ICC = \frac{\textit{variance within the data - variance between the data sets}}{\textit{variance within the data + (\# of analysis levels-1) variance between the data sets,}}$$

where identical data sets express an ICC equal to 1.0, or a negative value when no agreement exists between data sets, or a positive ICC value which increases as a function of the extent of agreement between data sets.

Inter-examiner reliability relative to the C-TA was investigated with three patients analyzed by two examiners. The second examiner obtained a set of compliance readings immediately after the first examiner. The readings were compared by chi square analysis, Pearson product moment coefficients, and intra-class correlation coefficients as described in Table 3.

Table 3. Statistical Summary of Intra-Examiner Repeated Compliance Measurements of an Analysis of the Occiput through the Third Thoracic Vertebrae.*

	Statistic		
	Chi-square Probability	Pearson Coefficient [r]	Intraclass Correlation Coefficient [ICC]
Examiner 1 vs. 2			
Subject			
1	0.48	0.80	
2	0.67	0.87	
3	0.43	0.75	
ICC Across Subjects for Examiners One and Two			0.65

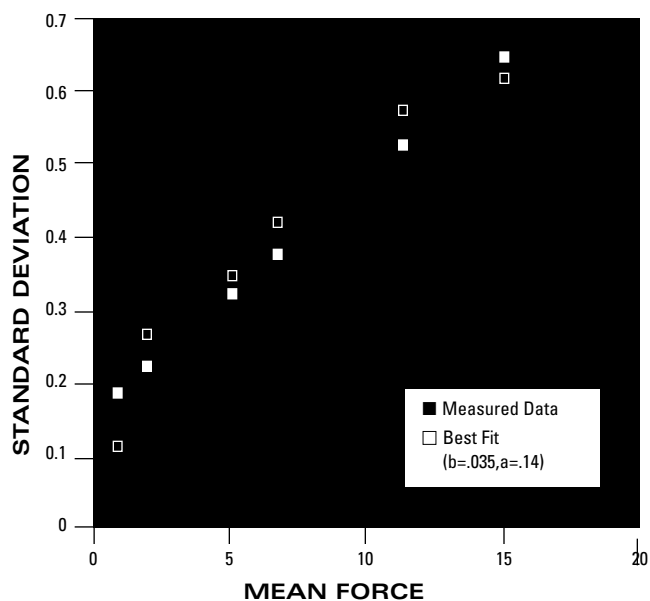* See Methods for description of Statistical Analysis.

Figure 5 Peak Force Versus Standard Deviation*

* Each Mean force value represented twenty repeated measures of twenty samples each. Sample values were derived from three artificial substrates and three anatomical locations as described in Methods. Standard deviations are taken as an index of measurement error.

Results

Reliability

Artificial and Human Tissue Substrates

Means and standard deviations of the 20 trials, of 20 samples each, on three artificial substrates and three regions of human tissue, are presented in Table 1. It can be seen that within the range of reliability measures for each artificial and human tissue substrate, variation was not great. When the variation (standard deviation) for each substrate was plotted against mean force of compliance (lb. force), a near-linear relationship was evident when compared to the straight line derived through linear regression r = 0.97 (Figure 5). This information demonstrated two features of the instrument. First, it was evident that surfaces increasing in resistance (stiffness), would result in lower compliance detected by the instrument. Secondly, throughout repeated measures, the instrument detected the level of compliance of each of the six substrates with approximately the same proportion of variation, reflecting its consistency (reliability).

Moreover, the average deviation around the mean for the three human substrates was 6.5 %. Since the data for each of the six substrates was normally distributed, any compliance value falling outside of three standard deviations, or 20% of the mean for any segment measured, would express a 99.9% probability (p = 0.001) of being derived from a different population (or significantly different from the previous reading).

Variability of Compliance Within a "Typical" Spinal Region

Absolute values (lb. force) varied by as much as 55% among certain osseous segments in the C-TA. This indicated that com-

pliance could likely be related to variations in distribution of body fat and/or muscle. Consequently, since each patient would be expected to exhibit a unique distribution of compliance throughout a given spinal region, values for the various segments were "normalized" by expressing them as a percent of the highest value within the region examined. An example of this method of expression is shown in Figure 4. Furthermore, this approach permitted visualization of the relative compliance of segments which could then be compared "before" and "after" any given intervention.

Intra-Examiner Reliability

A chi square analysis of data from the occiput through upper thoracic segmental levels of 20 subjects, by two respective examiners, revealed significant differences in only two of the 15 repeated measures, by one examiner, and one of five repeated measures by the second examiner. Moreover, Pearson correlation coefficients ranged from 0.74 to 0.98 (median = 0.85) within 15 subjects tested by one of the examiners, and 0.74 to .95 (median = 0.90) for five different subjects tested by the second examiner. The ICC for the examiner testing 15 subjects was 0.90, and 0.93 for the examiner testing five subjects. These results indicated no significant difference between the two repeated measures for either examiner, but did indicate a strong correlation between the two measures for both examiners (Table 2).

Inter-Examiner Reliability

The test of inter-examiner reliability (Table 3) revealed no statistical difference between examiners one and two when recording C-TA. Moreover, Pearson correlation coefficients were 0.75, 0.80, and 0.87 for the three comparisons. These findings were further strengthened by an intraclass correlation coefficient of 0.65 and a linear correlation across the same comparisons of 0.89.

Discussion

The results of the compliance testing, and subsequent analyses, indicate that engineering methodologies may be applied to the problem of quantifying compliance measurements of the osseous tissue of the human body. Although the present study ultimately considered hard tissue underlying a soft tissue covering, further study will consider the application of the instrument to determine soft tissue compliance such as muscle, ligaments, and other viscera. In this regard, it is proposed that quantifiable data, obtained through differential compliance measures may add a new dimension, in lieu of, or complementary to the subjective art of manually determining various gradations of muscle "tone." Moreover, by recording the transmission of a measured impulse introduced into a tissue, the level of reliability and sensitivity is expected to surpass that of previous instruments. [1-21]

In the present study the single point vibration analysis utilizing impulse loading has been demonstrated to explain the force output of the impulse head of the compliance instrument. The peak force has been shown to exhibit a strong positive correlation to the increasing stiffness of the substrate to which the impulse head

of the instrument is applied. Additionally, the peak force has been shown to be essentially constant, and consistently detected with the instrument, for either an artificial or natural substrate. Moreover, statistical analysis reveals that variations of more than 20% in the peak force indicates a significant difference ($p = 0.001$). This finding provides the basis for a model system with a high level of sensitivity to detecting significant change in compliance, such as might result following an adjustment.

In the context of this investigation of the characteristics of the instrument, and its application to subluxation-based chiropractic, compliance of the human spine is thought of as the ease of movement of each individual vertebra. Compliance, considered as the displacement response of a structure when subjected to a unit force, is the inverse of "stiffness" and can be thought of as the flexibility of a structure. Consequently, the initial inter and intra-examiner reliability findings of the present study suggest that the FRAS can also be extended to include a high level of individual practitioner consistency in applying the system. Moreover, these findings indicate a high level of confidence in the reliability of detecting compliance measurements among the general population of practitioners choosing to use the system.

While more descriptive detail has been previously published relative to the clinical application of the system,[24, 29] the present report is presented to identify the system within the framework of its application to subluxation-based chiropractic. In that regard, further study will be required to evaluate information obtained clinically. The Function Recording and Analysis System is in current use among 150 – 200 chiropractic practitioners in the United States and a small number of practitioners in Canada, Japan, Korea and Australia. Data, considering both gender and age of subjects, is being collected from this population of practitioners with the intent of evaluating the extent of quantitative compliance measurements as a benefit to the analysis of vertebral subluxation, and monitoring changes following adjustments affecting that condition.

Acknowledgments

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