PRELIMINARY INVESTIGATION OF SIX DEGREE OF FREEDOM HUMAN STEADINESS MEASUREMENT USING A PERFORMANCE THEORY FRAMEWORK

by

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ABSTRACT

PRELIMINARY INVESTIGATION OF SIX DEGREE OF FREEDOM
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Tremor is an undesired oscillatory movement of a body segment which limits a person's ability to accomplish tasks. A conceptually sound, single number measure reflecting steadiness (defined as the inverse of tremor) of body segment is desired. Technology has advanced to make six degree of freedom (DOF) characterization of motion feasible, but the challenge remains regarding how to process time series data from multiple DOFs to achieve the single number composite measure. Previous conceptual work has applied General Systems Performance Theory (GSPT) to this problem. This thesis reports the investigation of steadiness composite measure formation. Three composite formation candidates were identified (simple average, vector-based, and GSPT-based). Simple average (i.e., employing addition of component measures) and GSPT-based approaches were extensively evaluated conceptually and experimentally.

Conceptually, GSPT-based composites exhibited predictive validity in simple engineering-like decision-making tasks, whereas the simple average composite failed and provided misleading interpretations. The GSPT-based composite was shown to be intrinsically

more sensitive than the simple average method. In addition, simple average and other addition-based methods were shown to have a major conceptual flaw associated with summing of quantities with different units.

For the experimental aspects, six DOF inertial data was collected from subjects (n = 26) with a newly developed Steadiness Measurement Device (SMD) affixed to their hand. Subjects executed a series of 15s test tasks (maintain maximal steadiness and simulation of selected possible pathologic tremor). The maximal steadiness test was executed twice in order to determine short-term reliability. Translational acceleration and angular velocity signals were processed to obtain intermediate displacement time series records that were further processed to yield single number steadiness capacity measures for each DOF. These were then combined using the candidate composite formation methods under evaluation. The GSPT-based composite showed superior discriminating ability between simulated pathologic and healthy tremor motion as evidenced by high sensitivity (ratio of most steady to least steady subject, on the order of 2×10^{14}:1). It also exhibited the best test/retest reliability (Pearson r = 0.786) of all considered test cases and was comparable to previous results reported for similar test subject characteristics.

It is concluded that GSPT-based composite steadiness measures ($mm^{-3}deg^{-3}$) are the best option for truly representing the concept of hand (or other body segment) steadiness. The resultant orders of magnitude difference in GSPT-based measures between pathologic and healthy tremor cases is believed to shed new light on explaining the vast difference in performance observed between individuals. Ultimately, this thesis lays the foundation for additional work in defining a standard approach to body segment steadiness measurement and characterization.

TABLE OF CONTENTS

LIST OF ILLUSTRATIONS

Figure Page

LIST OF TABLES

CHAPTER 1

INTRODUCTION

1.1 Tremor and Steadiness

Tremor is the involuntary oscillatory movement of a person's body segment (e.g., hand, head, foot, etc.). Broad categories of tremor have been defined clinically. Resting tremor occurs when a body segment is in a relaxed, neutral state; no voluntary motor task involving the segment of interest is being executed. The term sustention tremor is used when a body segment is involved in a static, voluntary task (e.g., holding the arms straight out in front of the body while acted upon by gravity) and oscillatory motion occurs about a relatively fixed position. Intention tremor is tremor that occurs when the body segment is involved in a dynamic, voluntary motor task; i.e. the segment is moving in space with oscillatory motion superimposed on the basic trajectory. Even healthy individuals exhibit some tremor that is associated with normal, closed-loop neuromuscular control. In pathological cases, some tremor types are the symptom of a broader pathologic condition (e.g., Parkinson's disease). When there is no basis for a broader diagnosis and tremor is the sole symptom, it is considered to be a movement disorder of its own. Temporal characteristics (i.e., frequency and amplitude) of waveforms derived from a variety of sensing methods have been used to characterize tremor in clinical studies, where tremor is commonly observed to take a generally sinusoidal form.

It is certainly easy to see why characterization of tremor severity is an area of interest for a researcher when one considers the role that it plays in everyday life. For example, consideration of tremor arises when inserting a key into a door, drinking a glass of water, or threading a needle. For reasons to be described, it is chosen not to ultimately focus on the concept of the amount of *movement* observed (i.e., tremor), but rather on the concept of the *absence of movement* (i.e., steadiness.) If tremor was the factor detracting from steadiness, as is frequently the case, then steadiness could be argued to be the inverse of tremor. With this assumption in place, it is straightforward to see that a *lesser* amount of tremor will lead to a *greater* amount of steadiness.

1.2 Steadiness/Tremor Measurement: Degrees of Freedom

The first objective tremor measurement was performed in 1889 (Peterson, 1889) using a blackened, revolving drum which was marked on by a sharpened wire stylus attached to a finger. Historically, many different methods of measuring tremor have been used, including ultrasonic transducers (Prinsloo et al., 1998), stereophotogrammetry (i.e., 3D motion tracking using reflective markers and cameras) (Cappello et al., 1997), laser-based systems (Wastensson et al., 2006), magnetic field sensors used with small ceramic magnets on the target (Humayun, 1997), as well as single or dual-axis accelerometers (Marshall et al., 1956; Frost, 1978; Ang et al., 2004), digitizing tablets (Huang et al., 2003; Caligiuri et al., 2006) and even mechanical systems which attach to the hand and produce a waveform output directly onto scrolling paper or record a digitized analog voltage (Fischer, 1996; Matsumoto et al., 1999).

Figure 1.1 Example of tube-style accelerometer double diode DDR100 (left) (Harmer, 2009) versus newer micro-electromechanical system (MEMS) IC accelerometer, ADXL335 (right) (Sparkfun, 2009).

Complete characterization of the motion of a body in space requires inclusion of six degrees of freedom (DOF); three translational and three rotational. In almost all previous work, only limited degree of freedom (DOF) tremor data has been captured and analyzed, typically from individuals who are suffering from an obvious, gross inability to properly control the motion of one or more body segments (e.g., tremor in the hands associated with Parkinson's disease). This partial representation of the complete motion was either not justified or justified based on limitations of existing sensing technology or by asserting without supporting experimental data that the majority of tremor appeared to occur primarily within the one or two DOFs measured.

It would be erroneous to suggest that limited DOF inertial data was not at all useful. However, full six DOF inertial data is thus not only desired for complete observation of movement (see Fig. 1.1), but advances in sensor and related technologies has now made it feasible for collection with relative ease and reasonable cost. Such sensors include micro-electro mechanical systems (MEMS) multi-axis accelerometers and angular rate gyros (i.e., so-called inertial sensors) in small, lightweight integrated circuit packaging. Therefore, it is now possible to evaluate the contribution of each of the 6 DOFs to the "total tremor" (or steadiness) in given contexts.

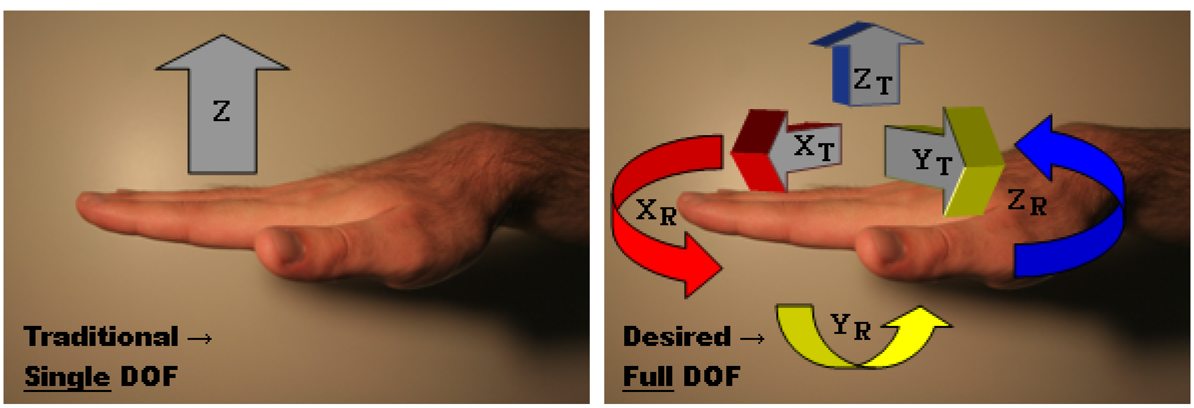

Figure 1.2 The image on the left represents only one (1) DOF inertial axis, while the right-hand image shows all six (6) possible DOFs.

While it is true that some tasks in which the human participates may require extreme steadiness in only one DOF for sufficient performance, it is possible to visualize that some minimum amount of steadiness is required in all DOFs. Therefore, it is reasonable to assume that a measure of steadiness taken without regard to any particular task (i.e., an intrinsic capacity that human's bring to tasks) must consider the complete, total motion possible by the body segment of interest.

1.3 The Challenge – How Steady is "Norm"?

Consider a person that we shall name "Norm". Given a desire to measure steadiness and also given that full six DOF inertial time series data is available for this purpose, how then should it be reconciled into a single numerical value that represents "overall steadiness"?

A single numerical value of overall steadiness is attractive for several reasons. However, it is not intended to supplant the lower level characterizations associated with one or more DOFs. While computing high level parameters (i.e., "overall" steadiness) from low level constituent parts means a loss of specificity, using high level measures (i.e., such as amount of steadiness, visual acuity, strength) allows for a simplification that can make interpretation easier at high levels. As an example, real gross domestic product (real GDP, the output of goods and services produced by labor and property located in a country's borders adjusted for price changes) is computed from private consumption, gross investment, and other low level measures. Once computed, real GDP is then a high level measure which is used, by tracking over time, to indicate economic growth or decline. A high level analysis utilizing real GDP (e.g., percent growth yearly between 1990 and 1999) would then not necessarily require visibility of its constituent low level measures. Thus, measures at different hierarchical levels convey different information and each has strengths and shortcomings. There is a fundamental tradeoff of specificity for simplicity.

Furthermore, the approach to forming a composite measure (i.e., again, a single numerical value) should be done in a way that does not simply lead to a number that gives "some indication" of overall steadiness, but which also withstands more rigorous tests of validity.

Steadiness is clearly a performance characteristic of the neuromuscular *system* associated with the body segment of interest. A generic framework for characterizing system performance has been introduced by Kondraske, and it offers a possible source of guidance to address the problem of combining two or more (e.g., six) DOF information to obtain a composite measure (e.g., "overall" steadiness). Discussed further in later sections, General Systems Performance Theory (GSPT) provides a solid conceptual basis for forming composite measures. Other candidate methods of composite formation from various fields and methods reported in the literature are also considered.

1.4 Specific Objectives

To summarize, with few exceptions, steadiness (tremor) measurement has been limited previously to one or two dimensional cases. No known previous researchers have wrestled with the issue of combining six DOF information to realize a single composite steadiness measure. Recently, we have explored the feasibility of combining 2 DOF data into a composite steadiness measure conceptually using hypothetical data and performance theory concepts (Armstrong et al., 2007). Using a Steadiness Measurement Device (SMD) currently under development that can provide 6 DOF inertial motion data, the goal is to investigate the formation of high-fidelity quantitative composite measures of overall steadiness and optimal computational methods.

Given the circumstances outlined above, the objectives of this thesis are to:

1. Collect high quality six DOF hand steadiness data using a 6 DOF inertial sensing unit in a selected population of healthy adults stressed to produce maximum steadiness and also to mimic "unsteady" (tremor) conditions.
2. Use collected data to establish a steadiness/tremor database to support investigation of steadiness composite measures.
3. Formulate and evaluate conceptually, performance theory based and selected other candidate composite steadiness measures.
4. Determine test-retest reliability for composite steadiness candidate measures using selected records from the database.

5. Investigate the validity of composite steadiness candidate measures using conceptual arguments (for construct validity), in combination with experimental results from the database, focusing on the sensitivity of each candidate.
6. Formulate recommendations for a composite steadiness measure and for additional future work related to steadiness measurement.

CHAPTER 2

BACKGROUND

2.1 Tremor Measurement

Traditionally, tremor has been measured subjectively. In research contexts, a clinician will grade a patient's tremor severity based on direct observation of the subject. In Parkinson's disease, a five point key-worded scale is then used to obtain a numerical result (Goetz et al., 2008). Such evaluations are often performed for different body segments and different modes (e.g., resting, sustention, etc.).

The most common objective (non-subjective) approach to tremor measurement involves accelerometers. In general, accelerometers (also inertial sensors) detect acceleration of a moving mass (Hsu, 2002). More recently, Micro-Electro-Mechanical-Systems (or MEMS, which are 3D structures manufactured using micromachining techniques and traditional CMOS wafer fabrication processes) accelerometers were built which have the benefit of low cost (a few dollars in 2009 versus hundreds of dollars for traditional accelerometers in the past) as well as high performance, and which are packaged in small (~1 cm^2) integrated circuit (IC) packages that allow for the inclusion of onboard analog conditioning circuitry, as well as easy placement on printed circuit boards. In 1979, Stanford University was home to the first demonstration of a *micromachined* accelerometer (Maluf, 2000). However, it took another 15 years for this type of device to be used in mainstream applications. Acceptance and cost reduction came largely from use of MEMS accelerometers in automotive applications, such as sensing for airbag crash deployment, electronic car suspension control, and vehicle traction control. While the automotive industry is the primary user of microaccelerometers, the environmental and medical industries are also large markets (Gardner et al., 2001).

Marshall and Walsh measured tremor using an accelerometer “double diode” which is about the size of the human thumb, and whose impedance changes when subjected to an acceleration (Marshal and Walsh, 1956).

Frost used a single tri-axial piezoelectric accelerometer assembly which is 35 cm^3 in size and weighs 21 grams (Frost, 1978). Ang, Pradeep, and Riviere used three dual-axis miniature microaccelerometers from Analog Devices Inc., which have properties similar to those described previously. All signal conditioning is performed on chip, with each sensed axis acceleration waveform output as a voltage on a dedicated analog output pin (Ang, Pradeep, and Riviere, 2004).

A wide variety of other devices and schemes have been directly utilized for tremor measurement. Some have made use of electromyography (EMG) to observe muscle activity (Lauk et al., 1999). This measurement method has been considered by some as too expensive and the equipment too cumbersome for routine clinical testing (Prinsloo et al., 1998). Electromyography requires consistent placement of sense electrodes, and wiring run to the target body segment which may interfere with motion. Noise must also be considered when deciding whether or not sensing only motion of the body limb or underlying muscle activity is required.

Digitizing tablets have also been used to characterize tremor (Prinsloo et al., 1998; Connor et al., 2001). Apparently, these authors feel that most unsteadiness in the hands or arms will manifest primarily in motion axes readily observable by the tablet (i.e., the two translational dimensions in the plane of the tablet).

2.2 Steadiness Measurement

Whereas tremor has traditionally emerged as a quantity of interest in the medical field, one finds the directly related concept of steadiness in the vocational/occupational evaluation context.

Perhaps the first device aimed at measuring steadiness is an instrument called the Hole Steadiness Tester (HST). A typical HST consists of a metal panel with 9 holes (e.g., hole diameters of 12.5, 8.0, 6.5, 5.0, 4.5, 4.0, 3.5, 3.0, and 2.5mm) and a stylus with a 1mm diameter cylindrical metal tip (Potvin et al., 1975; Lafayette Instrument, 2007). During testing, the subject is instructed to start with the largest hole and insert the stylus into the hole without allowing the stylus tip to touch the metal panel forming the perimeter of the hole. If the stylus tip touches the metal panel, it completes an electric circuit and sounds an alarm. The subject proceeds to progressively smaller holes until unsuccessful. The smallest hole for which the subject can successfully complete the task then represents the final measure of steadiness. Another version of this type of test requires the subject to place the stylus into a hole for a fixed period of time during which a counter counts the number of contacts between the stylus and the panel. This is repeated for progressively smaller holes. Similarly, a groove type steadiness tester uses a similar contact principle, but using a channel which narrows at one end (Louis et al., 2000). Others have used these tests, and give scores which are an average of best scores obtained in a trial where subjects are allowed only one touch of the current hole edge to continue, or scores based on the average distance they are able to successfully navigate along a channel (e.g., groove test) (O'Conner et al., 2008). The HST has also been used to characterize tremor in clinical research contexts (Potvin et al., 1975).

Figure 2.1 Example of a commercial Hole Steadiness Tester (Lafayette Instruments, 2007).

Previous work addressing measurement of motion quality (Fischer, 1996) included discussion of the concept of steadiness. In this work, steadiness was defined as "a measure of noise" in the movement present in the system (e.g., a hand) which is "intended to be at rest (i.e., movement while no movement is intended)." This noise is thus analogous to the tremor which has been discussed up to this point.

Interestingly, the term steadiness also appears in studies concerning postural stability. Force platforms are sometimes used in postural stability analysis. In one study, a "sway" distance was calculated for both a force platform (strain gauge-based) and a head position monitor (ultrasonic transducer-based), as an indication of whole body steadiness (Murray et al., 1975).

2.3 Formation of Composite Measures

Single number composite performance measures that reflect the integration of multiple lower level measures are commonly needed and used in medical and non-medical contexts. For example, in the context of multiple sclerosis (MS), researchers state that a "single score is desirable for evaluating progression in clinical trials of MS therapy." (Mickey, 1984) The Unified Parkinson's Disease Rating Scale (UPDRS) and its scoring represents another example of this need in a different context.

2.3.1 Traditional Approach

While there have been relatively few reports of tremor or steadiness measurement that include more than one DOF, when necessary there have been a few efforts to form single numerical values as the final score. Averaging is a traditional approach to composite formation, and it is sometimes used to directly produce a composite measure from several unlike resources by adding them together. Averaging may also be deemed an addition-based or additive approach since, from a computational perspective, averaging requires mathematical addition. "Addition-based" is a more broad term that encompasses averaging and approaches similar to averaging (with or without weighting terms). This includes regression models with weighted coefficients and normalization approaches used to combine unlike resources of different units. Adding apparently unitless items on a rating scale or averaging scores is the simplest computationally of the composite formation candidates considered here.

The addition-based approach has major flaws. When used by others, it is never conceptually justified or explained. Addition of performance resources with different units does not make good conceptual sense (i.e., adding speed to strength, or translational to rotational steadiness). Normalization is frequently employed to handle this obstacle. That is, the constituent parts used to form the composite, while representing physical quantities that should have units of measure, are normalized (by dividing by some reference value of the quantity) to produce an apparently unitless result. However, the normalized terms that are summed still represent the same physical quantities that they represented prior to normalization.

Composite measure formation procedures certainly appear in contexts outside of tremor/steadiness measurement. A representative example of composite formation that includes tremor, but involves a number of different performance characteristics is the Unified Parkinson's Disease Rating Scale (UPDRS) (Goetz et al., 2008). Items from different categories (e.g., tremor, movement speed, balance, gait, etc.) are graded by a clinician while observing a subject. Each item typically describes a different symptom and/or impairment (vs. desirable attributes such as steadiness.) Sub-scores are computed from items within each category, and then an overall score is obtained from addition of the sub-scores. "Similar methods are used in rating scales for other diseases or injuries (e.g., head injury). The use of addition to combine scores reflecting conceptually different quantities such as tremor, slowness of movement (bradykinesia), mental status, coordination, balance, and gait (for example) in such scales is by far the standard, but is never justified." (Kondraske, 2006b)

2.3.2 Other Approaches

Frost (Frost, 1978) agrees that there are limitations to single-axis tremor measurement (i.e., states that translational motion is possible in three dimensions), and that the collection of multi-axis data then requires subsequent consideration of approaches to multi-dimensional analysis. He also mentions that Sälzer has previously collected three-axis acceleration data, and used power-spectrum analysis techniques on each axis individually (Sälzer, 1972). The alternative proposed by Frost is to combine each channel output from a tri-axial accelerometer in a vector fashion, resulting in a single channel output representing the absolute magnitude of acceleration over time (Frost, 1978). Mean power frequency was computed as a characteristic of the higher frequency motion components (i.e., tremor) and average peak acceleration was used as a single number performance-related index. Nonetheless, Frost only considered three translational DOFs and ignored rotational motion.

In another study, "Three-dimensional amplitude was calculated as the root mean square of tremor in the three orthogonal planes" (i.e., X, Y, and Z) in a similar effort to form a composite measure from estimated peak-peak tremor amplitude. Each X, Y, Z tremor amplitude was calculated from three displacement time series data sets where tremor motion was measured using an electromagnetic tracking system. (O'Suilleabhain, 2001)

A different vector-based approach was taken by Singh and Riviere in the measurement of tremor in healthy individuals (surgeons) in an occupational context. "Using an instrumented surgical tool, high-precision recordings of hand tremor were taken during vitreoretinal microsurgery." (Singh et al., 2002) These investigators did employ 6 DOF motion characterization, using a compact inertial sensor unit providing three acceleration and three angular rate signals. This unit was attached to the end of a surgical probe that is held in the surgeon's hand. The 3-D velocity and displacement of the instrument tip (i.e., the "other" end of the probe) was computed from Z-Y-X Euler angle formulation of the 6 DOF inertial sensor readings and knowledge of the distance between the sensor unit and the probe tip. Tremor motion (displacement) at the probe tip is in fact their computed result, so the key point here is that while 6 DOF sensors are used their interest is only on the 3 DOF steadiness of the probe tip. This arrangement is interesting in that the probe itself serves to "convert" rotational motion at the surgeon's hand to translational motion at the probe tip. The displacement and acceleration at the probe tip were then calculated using differentiation and integration respectively, and data is band-pass filtered to extract components in the range between 7-17 Hz (considered by the authors to be relevant to tremor present in healthy individuals). Overall tremor estimation is made by first finding the root mean square (RMS) amplitude of tremor displacements, for the x, y, and z axes separately over time. Then the vector magnitude of these three RMS amplitudes is found. For single subject studies, a result of *38 μm* was reported as the root mean square vector magnitude at the tip. This particular analysis was performed on a 20 second data set representing the most critical portion of the surgical procedure. While a three dimensional plot of the surgical instrument tip trajectory is shown for this critical period (so that the ability of the surgeon to remain fixed in this very tiny "volume" is more evident), the volume mapped out by tip excursions itself is not discussed as a possible single number measure of steadiness.

2.3.3 General Systems Performance Theory (GSPT)

GSPT and application of it to human performance measurement contain conceptual perspectives relevant to the stated challenge of forming composite performance measures, such as those that reflect disease or symptom severity (Kondraske, 2000a; Kondraske, 2006a). In GSPT, all aspects of system performance are modeled as "performance resources." GSPT uses a first principles approach to system performance measurement and provides a framework to address the complex, multidimensional and hierarchical nature of human performance.

Briefly, GSPT requires that performance measures be defined using a resource construct (representing desirable quantities in contrast to impairments; e.g., speed vs. bradykinesia, steadiness vs. tremor, etc.). For a given system, these performance resources define the axes (or "dimensions of performance") of a multi-dimensional performance space in which a performance capacity envelope (PCE) can be generated using measures of individual performance capacities (Fig. 2.2). Each such measure reflects the amount of *availability* of a given performance resource for use in tasks performed by the corresponding system. The logic of GSPT explains that the volume enclosed by the PCE represents the system's capacity to perform tasks that draw on the constituent performance resources. For example, if the dimensions of performance in Fig. 2.2 were "vertical hand steadiness" and "horizontal hand steadiness", the product of measures representing the availability of these two performance resources would reflect the capacity of the system to execute tasks that make demands on the system's vertical AND horizontal hand steadiness. A key element of this logic is the recognition that the *enclosed* points represent specific tasks imposing demands that are "within the limits" of the system's capacity. Thus, the most simple strategy for forming a performance theory-based composite is to simply measure each performance resource availability and multiply to obtain an estimate of the the volume of the PCE (the actual PCE may not be "rectangular" as shown in Fig 2.2). The multiplication-based approach to composite formation suggested by GSPT has been explored in a number of different contexts of scientific and clinical relevance (Kondraske, 1987; Kondraske, 1989; Fischer, 1996; Vasta and Kondraske, 1997; Kondraske, 2000; Kondraske and Vasta, 2000; Stewart, 2004; Kondraske, 2006). Each of these efforts is summarized below.

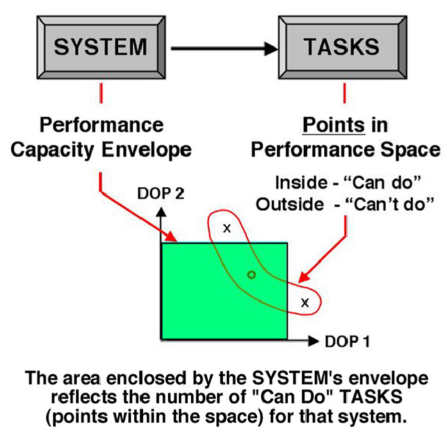

Figure 2.2 Key concepts leading to formation of product-based measures of composite performance capacity are illustrated for a system with two dimensions of performance (DOPs). A larger product-based composite reflects a larger volume enclosed by the performance capacity envelope; more "points" (tasks) are thus enclosed.

Kondraske considered the functional capacity (i.e., as represented by the volume of the PCE) of the shoulder as formed from four lower level performance capacity measures including abductor strength, abductor-adductor range-of-motion, flexion-extension speed, and flexion-extension steadiness (Kondraske, 1987). Focus was placed on the concept of a general approach to forming composite scores from low level functions in a multiplicative fashion. This method was counter to additive approaches that utilized normalization schemes to avoid the issue of adding quantities of different units that were common at the time in both subjective rating scales as well as in objective measurement methods. Assuming that abductor strength, adductor range-of-motion, flexion-extension speed, and flexion-extension steadiness are significant contributors to the overall shoulder's capability to execute tasks, it was argued that this overall ability may be expressed as the joint probability (i.e., multiplication) of the percentage normal of the contributors. Normal (i.e., 1.00) is estimated to be the average amount of a contribution present in people who are able to execute all tasks of daily living successfully. Therefore, assuming that daily living task requirements are uniformly distributed with a probability between 0.00 and 1.00, a particular person with an overall shoulder capacity of 0.75 (i.e., 75% normal) would be able to accomplish 75% of the tasks typically encountered in daily life.

Another GSPT-based effort involved prediction of performance in a high level task (HLT) (i.e., putting on a shirt as quickly as possible) from three low-level performance measures including A=information processing speed, B=shoulder internal/external movement speed, and C=shoulder abductor strength. "These measures are compared with regard to differences obtained when used to reflect overall age-related performance changes and with respect to prediction of directly measured performance (speed) in the high level task (putting on a shirt)." (Kondraske, 1989) One conclusion reached in this report is that for multiplicative-based composites, all <u>non-limiting resources</u> may be considered to have a 1.00 multiplier. Another conclusion reached is that multiplicative models are suggested as superior to additive models due to their high sensitivity to contributing low-level measures and their increased applicability/adaptability to individual people as compared with statistical models which depend on a reference population.

Determination of a system's "performance capacity envelope" (PCE) is central to GSPT-based analyses. The key from another effort (Vasta & Kondraske, 1997) is identification of the merit and utility of forming a PCE representation for all neuromuscular subsystems and a description of the relevant methodology. A specific example addressed by the authors involves formation of the PCE for a specific neuromuscular subsystem, the knee extensor. The example makes it clear that the volume of this or any other system's PCE is very important, and may be used as a composite performance capacity score.

In Kondraske 2000a, an updated summary is provided of GSPT and the Elemental Resource Model (ERM), where the ERM is the result of GSPT and other major conceptual constructs applied to the human system. GSPT has been summarized previously in this section, and the ERM has been described as being related to human system performance in the same way that the periodic table is related to chemistry (Kondraske, 2006a). That is, in the same manner that complex chemical compounds (i.e., gasoline) may be formed from simpler finite sets of elements (i.e., carbon, hydrogen, etc.), the human system is modeled as being composed of a finite set of simpler structures which may be characterized not only by structure (i.e., eye, hand) and function (i.e., to see, to grasp) which has been done extensively, but also by elemental performance capacities (i.e., visual acuity, grip strength). It is crucial to recognize that while the type and variety of tasks that may be undertaken by the human system are infinite, the physical structures of the body and their associated performance capacities are limited in number and therefore may be systemically catalogued and studied. Unlike chemistry or economics, where elements are tangible resources (i.e., hydrogen, coal, wood), performance resources are intangible quantities such as speed, endurance, etc. The main goal of both GSPT and the ERM is to move the study of performance theory out of an age analogous to alchemy, and into the light of what would be analogous to modern chemistry. An additional discovery was made by the author when looking at plots of low-level measures vs. HLT performance after applying GSPT in several venues. A resource economic “threshold” effect may be used to identify the low-level resource which is currently limiting improvement of HLT performance (a powerful finding for analysis using performance theory concepts).

Another paper discusses additional validation of neuro-motor channel capacity (NMCC), a composite measure of the commonly used “speed-accuracy” tradeoff (Kondraske & Vasta , 2000). The concept and formation of NMCC composites relies on GSPT and provides results that correlate to an extremely high degree the simple multiplication of speed x accuracy with the Fitts’ index of performance.

Stewart, Kondraske, and Sanghera, 2004 compares both additive and composite measures as formed from various combinations of performance resources representative of the cognitive, motor, and balance domains in Parkinson’s patients “on” and “off” their medications. “‘Percent change’ values ranged from 1.4 to 22.6% (greatest for lower extremity NMCC) for individual measures and composites based on averaging (traditional) and from 4.3 to 109% for the product-based composites (performance).” Because the product-based (multiplication) composite is more sensitive to individual measures and has a more sound conceptual basis, it was suggested that a change of 109% versus the change of only 22.6% for averaged-composites is more characteristic of the high level changes observed when a Parkinson’s patient is in the “on” state. Said again, it was asserted that a 109% (i.e., product-based composite) improvement more accurately embodies (i.e., is in greater agreement with clinician perceptions) the change in quality of life (i.e., ability to execute activities of daily living) actually experienced by the patient than the 29% (i.e., additive-based composite) improvement would lead us to believe. Some additional commentary by the authors also deals with the lack of justification for forming composite measures by averaging. Addition of fundamentally different quantities for averaging has no justification and is argued in fact to be invalid, although normalization is enlisted to make individual components appear unitless, allowing addition to proceed. In contrast, multiplicative composites are stated to retain dimensionality (i.e., component units) and do not require a reference measure (whose values may differ between investigators) as normalization requires for additive composite formation.

Referring to the Fischer study previously mentioned, GSPT concepts relevant to composite score formation were used in the context of motion quality. Further elaboration is warranted. Fischer “determined a set of primitives called ‘dimensions of performance’ (DOPs), each of which describes a unique aspect of how well a motion system performs its task (speed, accuracy, smoothness, volume appropriateness, stability). A motion quality measure was created based on a multiplicative combination of DOP measures.” Perhaps the most important general finding, Fischer found that “human raters appear to use some form of multiplicative combination in motion quality perception.” (Fischer, 1996). It was further noted that human raters (e.g., neurologists, etc.) are the gold standard against which any objective method must be initially judged.

CHAPTER 3

COMPOSITE MEASURE FORMATION MODELS

3.1 Performance Resources

While GSPT was cited in the previous chapter as having features that are directly applicable to composite score formation, it has other modeling constructs considered to be useful across all composite measure formation models considered. GSPT provides a framework that guides classification and description of hierarchically arranged performance resources in a system. In traditional use, resources are anything which it is beneficial to possess, such as apples or coal. GSPT asserts that all aspects of a system's performance should be characterized in terms of a set of "performance resources". Concern is placed here on performance of a human subsystem (i.e., the hand) and one type of dimension of performance (i.e., steadiness). Performance resources such as hand steadiness may be drawn upon by the human to accomplish tasks that demand some amounts of one or more performance resources.

For the human system, performance resources are cataloged using the Elemental Resource Model (ERM), which has been previously mentioned as a model resulting from the application of GSPT and other concepts to the human system. According to the ERM, the human is modeled as possessing a finite number of unique and distinct basic performance resources (BEP) to draw upon in accomplishing tasks. Once these BEPs are defined and measured for a given individual or population, the complete performance capacity of that person or group is known. Performance resources at a higher hierarchical level (such as when the human is "configured" to be a "car polisher") may then be formed from combinations of the lower level BEPs.

Ultimately, as 6 DOF inertial data is required to completely characterize motion, it seems reasonable to assign a lower level performance resource to each DOF and then use selected formation methods to form a higher level overall hand steadiness performance resource from each of these six constituent parts. Therefore, for steadiness composite measurement formation, the steadiness associated with each DOF is considered to be a separate, lower level performance resource. While "overall" steadiness is then a composite performance resource that is likely to be used in high level analyses, it is conceivable that an analysis of performance in a particular task such as writing or threading a needle may include consideration of one or more individual steadiness performance resources. As opposed to the "overall" steadiness measure, these individual performance resources are referred to as "X translational" steadiness, "Z rotational" steadiness and so on for each of the six DOFs.

3.2 Displacement vs. Acceleration

Accelerometers were previously cited as the most commonly used sensor for capturing inertial tremor data. Most often, acceleration data is directly used to reflect the amount of tremor or steadiness. However, it seems clear that displacement data is really the desired quantity. Some researchers (such as Ang and Riviere, 2004) used inertial sensors (acceleration and angular rate), but processed results to obtain displacement. Others who used accelerometers simply used characteristics such as "average acceleration" as their final measure. In one effort using an electromagnetic tracking system, the authors state that "[b]ecause position rather than acceleration is tracked, tremor amplitude can be stated in readily comprehensible units." (O'Suilleabhain, 2001) Kondraske (1986) also discussed problems associated with use of acceleration data in the description of a two-axis capacitive displacement sensor for tremor measurement. In presenting composite formation models that follow, it is assumed that the starting point is a set of time series data representing translational and rotational *displacements*. From this time series data, a set of six (one per DOF) single number steadiness performance resource measures are computed.

Displacement time series samples are further assumed to be defined such that they take on both positive and negative values in relation to a reference point of "0". Given this starting point, Fig. 3.1 shows the steps used to obtain individual composite steadiness measures. With a particular displacement time series in mind, the steps are 1) take the absolute value of each point in the time series, 2) average across time (all values resulting from first step), and 3) take the inverse of the average to get individual component steadiness measures.

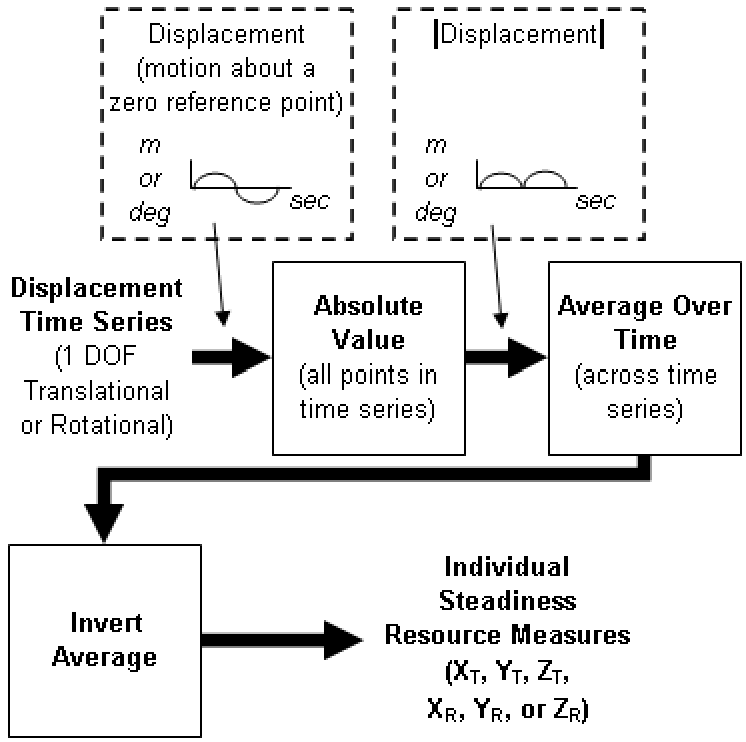

Figure 3.1 Processing of displacement time series to obtain individual composite steadiness measure.

The nomenclature for the resulting steadiness performance resources is shown in Table 3.1. X, Y, or Z refers to the sensed axis, and subscript 'T' indicates translation while subscript 'R' indicates rotation. These six steadiness performance resource quantities are then combined to form the overall steadiness composite measure using candidate formation methods discussed next. Fig. 3.2 indicates the relationship between each of these performance resources and the axes physically sensed with the Steadiness Measurement Device (SMD, discussed in chapter 4) shown on the hand as situated during testing.

Table 3.1 Nomenclature and Units of Measure for Individual Steadiness Performance Resources

Performance Resource (Translational or Rotational)	**Designation**	**Units**
X Translational Steadiness	X_T	mm^{-1}
Y Translational Steadiness	Y_T	mm^{-1}
Z Translational Steadiness	Z_T	mm^{-1}
X Rotational Steadiness	X_R	deg^{-1}
Y Rotational Steadiness	Y_R	deg^{-1}
Z Rotational Steadiness	Z_R	deg^{-1}

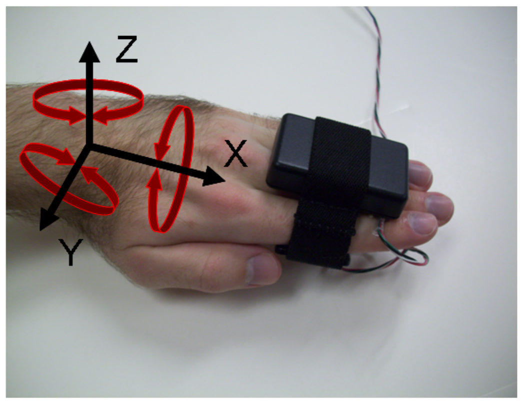

Figure 3.2 Steadiness Measurement Device (SMD) with axis conventions shown.

3.3 Overview - Composite Formation Methods

Several major approaches to composite formation were discussed in chapter 2. These approaches fit into three broad categories that are used as the basis of candidate composite formation models. Each of these models is described below.

3.3.1 Composite Candidate 1: "Simple Averaging"

Averaging of constituent performance resources to form a composite measure was described in chapter 2 as the most common approach to composite formation. However, major flaws with this approach were noted. Nonetheless, this approach is entertained here as one of the candidate approaches.

The approach to forming an overall steadiness composite using averaging is given in Eq. 3.1, which uses the nomenclature summarized in Table 3.1. The parameters with the subscripted "T_norm" or "R_norm" represent values used to normalize the actual measures for a given subject. The choice of the normalization is not critical. However, if used to produce standardized measures (which is not the current goal), the values used should not change. One option is to use a value representing the steadiest individual component, when looking across all subjects in a specified group. That approach will be employed in the studies described in chapter 4.

$$\begin{array}{c} Averaging \\ Composite \\ (unitless) \end{array} = \frac{1}{6}\left(\frac{X_T}{X_{T\_norm}} + \frac{Y_T}{Y_{T\_norm}} + \frac{Z_T}{Z_{T\_norm}} + \frac{X_R}{X_{R\_norm}} + \frac{Y_R}{Y_{R\_norm}} + \frac{Z_R}{Z_{R\_norm}} \right) \quad \text{(Eq. 3.1)}$$

3.3.2 Composite Candidate 2: Vector-Based

Forming a composite using a spatial vector-based approach was discussed previously. One example (Frost, 1978) is that reported by Frost who used analog signal processing to obtain a vector magnitude "by squaring initially the output from each accelerometer unit and then extracting the square root of the sum of these squared values." This resulted in a vector magnitude variable as a function of time from which several single numerical values were computed (e.g., average displacement over time). As previously noted, rotational motions were not considered or discussed at all by Frost.

The most promising vector-based approach for the present purpose is an adaptation of one of the computations used by Singh (Singh and Riviere, 2002). This emerges from their requirement that tip motion (displacement) of a surgical probe must be calculated when 6 DOF sensors are located not at the probe tip, but at the rear end of the probe. Using data from the 6 DOF sensors, the length (L) of the probe, and Euler angle formulations, the 3D translational displacement at the tip can be determined. The root mean square of the tip displacement over time (or other similar average computation) then gives a single value composite measure. Note that this procedure does utilize information from all six DOFs of the 6 DOF sensor, but eliminates the problem of summing translational and rotational components because rotation components are effectively converted to translation components via the probe. That is, when the rear end of the probe rotates about a given axis, the tip of the probe translates in space (translation = L * change in angle (in radians)).

This methodology could be adapted for steadiness measurement and composite formation. There is no probe present, but it could be replaced by a hypothetical "rod" of length L projecting from the body segment (a rigid body) for which steadiness is of interest. The 6 DOF sensor would be placed on the body segment for measurement.

The result of this approach is given by Eq. 3.2, where X_{TIP}, Y_{TIP}, and Z_{TIP} are defined as the time series representation of the X, Y, and Z tip displacement vector components. The displacement vector magnitude time series is then the square root of the sum of the squares of these quantities. The vector-based composite could then be obtained using the processing steps shown in Fig. 3.2.

$$\begin{matrix} Displacement \\ Vector \\ Magnitude \end{matrix} = \sqrt{X_{TIP}(t)^2 + Y_{TIP}(t)^2 + Z_{TIP}(t)^2} \qquad \text{(Eq. 3.2)}$$

However, this candidate formation approach was ultimately not pursued formally since:

1. it requires the inclusion of a hypothetical rod (the equivalent of the probe described above) of some arbitrary length, which complicates the interpretation of the result,
2. due to the mathematics involved, the behavior of numerical values obtained can be expected to be similar to those obtained from simple averaging, and
3. the absence of rotational units in the final result (only displacement units would be obtained for the final result).

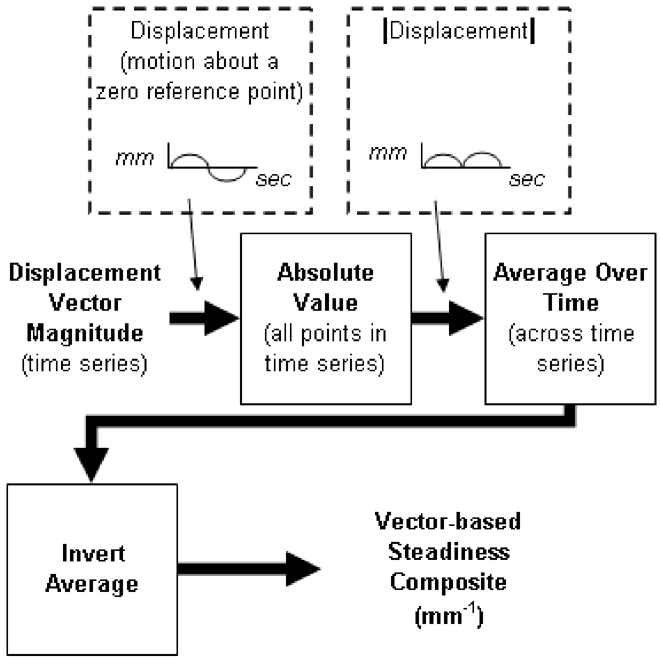

Figure 3.3 Processing of displacement vector magnitude time series to obtain a vector-based composite steadiness measure.

3.3.3 Composite Candidate 3: GSPT-Based

As noted in chapter 2, the GSPT-based or multiplicative composite formation approach is derived from a first principles type of consideration. It has been argued to address the shortcomings of the addition-based approach in that units of individual constituent resources are retained and no reference value is required for any forced normalization procedure. Thus, even prior to further evaluation, this approach is believed to be conceptually superior to other composite formation procedures. The computation of the GSPT-based steadiness composite is given by Eq. 3.3.

$$\begin{array}{c} GSPT-Based \\ Composite \\ (mm^{-3}\deg^{-3}) \end{array} = X_T * Y_T * Z_T * X_R * Y_R * Z_R \qquad \text{(Eq. 3.3)}$$

Several recent efforts directly related to this thesis have considered the GSPT-based composite formation method in the context of steadiness/tremor both conceptually (i.e., including analysis/discussion of a “simple” needle-threading task) (Armstrong et al., 2008) and experimentally. Experimental efforts used previously collected data with two translational and two rotational DOFs represented (Armstrong et al., 2007) and a single subject with 6 DOF data (Armstrong et al., 2009). Both conceptual and experimental results were promising.

CHAPTER 4

EVALUATION STUDIES

In chapter 3, three composite candidates were described. Due to the computational similarity between the simple averaging and vector methods (i.e., both require addition of constituent components) and the fact that the vector-based approach requires inclusion of a hypothetical rod (and its “tip steadiness” is reflected by the composite), only the simple average and GSPT-based composites are included in evaluation studies.

4.1 Criteria for Composite Evaluation (Validity and Reliability)

Evaluation of the candidate composite measures includes two components: 1) conceptual and 2) experimental. Clearly, if a conceptual flaw is found with regard to a given method, one could argue that it does not make sense to include it in experimental evaluations. However, it was decided to subject the composite candidates considered to both types of evaluation regardless of the conceptual evaluation outcome.

When subjected to conceptual scrutiny, a steadiness composite measure should provide an accurate reflection of the common notion of “body segment steadiness”. Computations required, units of measure, and characteristics of measures should reflect proper adherence to established basic principles and expectations. These issues relate to construct validity (i.e., ability to translate a composite into operationalization) and predictive ability (i.e., the ability to use the composite in the prediction of a result that agrees with other established analyses or common knowledge). (Trochim, 2006)

Any lack of steadiness in one DOF should be reflected in the composite measure; i.e., the composite measure should be sensitive to each of the individual components of the composite. Table 4.1 lists the evaluation items and criteria considered.

Table 4.1 Evaluation checklist for candidate composite measures

Evaluation Item	Type of Evaluation		Criterion
	Conceptual	Experimental	
Units of Measure	X		"Pass" evaluation
Construct and Predictive Validity	X		"Pass" evaluation
Sensitivity	X	X	High sensitivity is desirable.
Reliability (Repeatability)		X	Commensurate with previous steadiness/tremor tests in studies with comparable parameters.

4.2 Conceptual Evaluation

4.2.1 Composite Measure - Units

It is reasonable to expect that the units of measure of any composite score reflect the units of the constituent components. For example, work can be viewed as a composite measure of force (N) and displacement (m) and has units of N-m.

For the simple average composite, the addition steps in the computations clearly cannot be performed on values with different units (e.g., one cannot add mm^{-1} to deg^{-1}, as is required to combine translational and rotational components). As discussed previously, researchers in other measurement contexts have attempted to circumvent this by using "normalization" (i.e., dividing by a reference value with the same units as the numerator). This makes each individual component *appear* unit-less, thus avoiding the roadblock to adding components as is required when averaging. The quantities still reflect different constructs (e.g., as applied here for steadiness, linear translation-related vs. angular rotation-related quantities). This commonly used ploy (especially used in many clinical rating scales) never addresses one key question: "What are the units of the composite measure resulting from this process?" Of lesser importance, uncertainty exists with regard to what should be used as a normalization factor. This could ultimately result in confusion in developing normative reference data and in comparing data across different studies.

The GSPT-based multiplicative approach to composite formation retains the units of included components. For the 6 DOF steadiness composite model described in chapter 3, the units are $mm^{-3}deg^{-3}$. Seeing only the units, one can infer the units and type of the constituent components. No normalization or arbitrary scaling is required.

4.2.2 Composite Measure – Construct Validity, Predictive Validity, and Interpretation

Consider again the Hole Steadiness Tester (HST) discussed previously. The HST may be considered a two DOF steadiness measurement device, with separate steadiness components measured along “X” and “Y” dimensions. For this example, assume that they are measured in general purpose Steadiness Units (SU).

Referring to Fig. 4.1, assume that $d_x = d_y = d$. In order for a subject to succeed in avoiding contact with the hole perimeter, the stylus must remain “within an area” smaller than the current hole area. That is, the stylus excursions along the X dimension must be less than d_x AND the excursions along the Y dimension must be less than d_y If X stylus excursions were 2d (i.e., X Steadiness = 1/(2d) = 0.5/d) and Y excursions were 0.67d (i.e., Y Steadiness = 1/(0.67d) = 1.5/d), a subject would grossly fail the Hole 8 test due to insufficient X steadiness. However, a steadiness composite determined using simple averaging (2 DOF Steadiness = (0.5/d + 1.5/d)/2 = 1.0/d; corresponding to an “average excursion” of 1d) would suggest adequate steadiness for success.

A corresponding GSPT-based steadiness composite ($0.5/d * 1.5/d = 0.75/d^2$) corresponds to an area of $1.33d^2$ which exceeds the area ($1.0d^2$) of a square into which Hole 8 is inscribed. That is, this composite can be used to correctly predict failure in real-world situations such as that represented by the HST. Such situations include placing a key in a lock, assembly of components, bringing an eating utensil to the mouth, etc.

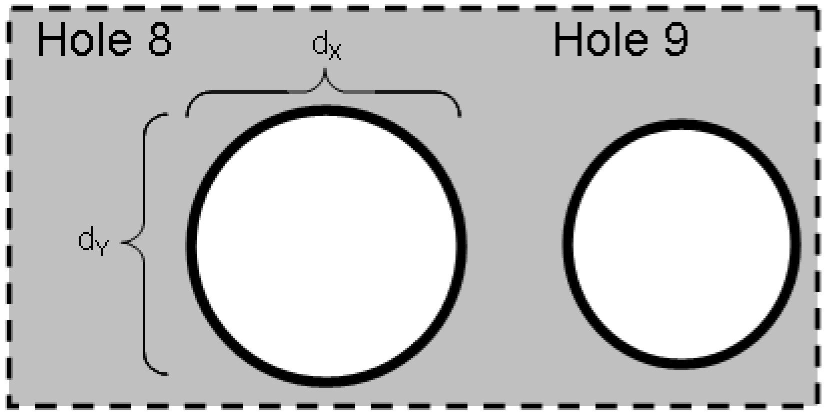

Figure 4.1 Remaining “within an area” (i.e., inside the hole) requires sufficient steadiness for both the X AND the Y dimensions.

Thus, the simple average composite fails with regard to basic interpretation expectations in real-world steadiness tasks, whereas the GSPT-based composite succeeds. This is considered to be a component of both construct and predictive validity of the composite measures. While a 2 DOF example is considered, the results are applicable to the 6 DOF case of interest without loss of generality.

4.2.3 Composite Measure - Sensitivity

Consider an example with two translational degrees of freedom. Table 4.2 lists component steadiness measures from three hypothetical subjects, where steadiness is again defined as the inverse of the average displacement amplitude to ensure that larger numerical values indicate “more steadiness” and therefore reflect a measure of performance resource availability.

Table 4.2 also lists corresponding composite scores for the two candidates under evaluation. For the simple average composite, normalization is not employed, because only two DOF translational movements are considered and the units are the same across DOFs. Thus, the 6 DOF case, involving both translational and rotational units would present even more complex challenges. Nonetheless, this 2 DOF example provides useful insights into the intrinsic sensitivity of the simple average and GSPT-based approaches.

Subject A clearly has the best individual component steadiness scores (i.e., for both X and Y steadiness). However, determination of which candidate (i.e., B or C) has the worst overall steadiness is less clear and this is where a steadiness composite measures should be of value.

Table 4.2 Comparison of steadiness composite behavior in hypothetical subjects

Measure	**Subject A**	**Subject B**	**Subject C**
X Steadiness Component (mm^{-1})	1.00	0.50	0.90
Y Steadiness Component (mm^{-1})	1.00	0.50	0.10
Composite Steadiness – Simple Average (mm^{-1})	1.00	0.50	0.50
Composite Steadiness – GSPT-Based (mm^{-2})	1.00	0.25	0.09
Subject (B or C) Steadiness as Fraction of Subject A Steadiness: *Using Simple Average Composite*	100%	50%	50%
Subject (B or C) Steadiness as Fraction of Subject A Steadiness: *Using GSPT-based Composite*	100%	25%	9%

Since Subject B has half the X steadiness and half the Y steadiness of Subject A, a lower overall steadiness is expected. The real question of interest is, however, “To what degree should the overall steadiness differ when comparing Subjects A and B”? The simple average composite reflects that Subject B is 50% as steady as Subject A, while in contrast the GSPT-based composite indicates that Subject B is only 25% as steady as Subject A.

Subject C displays an even more pronounced example of this sensitivity behavior. Table 4.2 makes it obvious that Subject C would be much less equipped to, for example, thread a needle than Subject B and even less equipped when compared to Subject A. However, Subject C’s simple average composite steadiness values are identical to Subject B’s! Subject C has fairly good X steadiness, but very poor Y steadiness. The simple average composite obscures the poor overall steadiness performance of Subject C, while the GSPT-based composite correctly indicates that Subject C’s steadiness is only 9% of the steadiness of Subject A.

It is concluded that the GSPT-based composite is intrinsically more sensitivity to differences among subjects than is the simple average composite. The differences demonstrated can be expected to be of greater magnitude for the 6 DOF case. These analysis results could also be applied to not only differences in steadiness across subjects, but also changes in performance over time within a given subject as is often of interest in clinical trials.

4.2.4 Conceptual Evaluation Summary

The simple average composite suffers from several conceptual problems, some of which are absolute (e.g., the units issue and predictive validity) and others which are relative to the GSPT-based composite (e.g., sensitivity).

Table 4.3 Summary of conceptual evaluation of steadiness composites

Evaluation Item	**Simple Average Composite**	**GSPT-Based Composite**
Units of Measure	Fails	Passes
Construct and Predictive Validity	Fails	Passes
Sensitivity	Fair	Excellent

4.3 Experimental Evaluation Methods

An experiment was devised to obtain data to support additional validity investigations and also to evaluate reliability (repeatability) (Walter et al., 1998) of candidate composite formation approaches. The study protocol was reviewed and approved by the University of Texas at Arlington's Institutional Review Board. A copy of the approval and informed consent document are included in Appendix B.

4.3.1 Subjects

A total of 26 subjects (19 males, 20-62 years, mean 28.6 ± 12.1 years; 7 females, 20-63 years, mean 33.0 ± 17.1 years) were recruited from faculty, staff, and students from within the university community. All subjects were self-declared to be healthy without any known neurologic conditions. Informed consent was obtained. Specific test instructions (Appendix C) were verbally read to the test subject as required throughout the protocol. Explanation of the test procedure also included use of two videos that show hands with moderate and severe tremor conditions.

4.3.2 Instrumentation

The Steadiness Measurement Device (SMD) used for experimental evaluation incorporates one Analog Devices ADXL330 tri-axial MEMS accelerometer and two Invensense IDG-300 dual-axis angular rate sensors providing full 6 DOF inertial measurement (one IDG-300 axis is redundant and is therefore ignored). The SMD is attached to a PC via a serial data connection during testing and a custom PC application was used to instruct the SMD to begin collecting and subsequently transmit inertial data for a selectable period of time. The SMD is affixed to the body segment (i.e., hand, or more specifically, the dorsal surface of digits 2 through 5 as shown below) using an adjustable strap where an additional loop of fabric has been sewn atop the strap to hold the SMD snugly in place. Additional details of the SMD are given in Appendix A. Fig. 3.2 shows the SMD placed on the hand as during testing, with appropriate axis conventions shown.

Inertial sensor signals were low pass filtered in hardware at 25 Hz and sampled at 57 Hz for all trials. A 24-bit value is retrieved from the analog-to-digital (A/D) converter for each collected sample/channel, although only the most significant 16-bits are saved and considered useful due to previous noise evaluation tests. During sampling, raw acceleration and angular rate data is sent to the PC where it is saved in a tab-delimited format and each file is coded based on subject ID and trial designation.

4.3.3 Test Protocol

Subjects were randomly selected to begin each test case using either their dominant (D) or non-dominant (ND) hand. Each subject executed a total of 18 trials during the test protocol summarized in Table 4.4 and described below. A small SMD module was affixed to the dorsal surface of the fingers of the hand of each subject using an adjustable strap fastened snugly around the fingers. When switching to acquire data from “the other” hand, the SMD required a repeat of the attachment procedure. Any issues potentially impacting placement of the device (i.e., removal of jewelry, etc.) were handled on an individual subject basis. Each test trial start and end was relayed to the subject verbally by the test administrator as indicated automatically by the PC data collection software.

The first test condition ("steady", D or ND hand - randomly selected to start) involved the subject outstretching his or her arm in front of them (parallel to the floor) and holding their hand as steady as possible while seated properly in a chair (i.e., sitting up straight with the non-tested hand resting on their knee and the subject looking forward). These trials lasted for 15 seconds each and three trials were performed for a given hand. At least a 10 second rest break was taken in between each trial. After finishing three trials on the hand first tested, three additional trials were performed on the opposite hand using the same procedure.

A similar procedure is followed for the next test condition (mimic moderate tremor), except that instead of remaining as still as possible the subject was asked to mimic tremor-like hand motions. To this end, before beginning these trials, a video of a hand exhibiting moderate tremor was shown to the subject, and they were asked to mimic this motion while assuming the same general posture used for the "steady" test condition. Subjects were allowed to practice this task before data collection commenced. As in the first test case, three 15 second trials were performed (dominant hand only) with a 10 second rest break between trials.

The next test condition is identical to the second, except that the video of a hand exhibiting severe tremor (vs. moderate tremor) was used and the subject was asked to mimic this motion.

Finally, the last test condition (retest of "steady" condition) was initiated after a 5 minute break following the third test case. This fourth test case follows identical procedures used in the "steady" condition described above.

Table 4.4 Summary of test cases (steady test/retest, moderate tremor, and severe tremor)

Condition => (3 trials each)	Steady (1st Test)	Steady (2nd Test)	Moderate Tremor	Severe Tremor	Steady (1st Retest)	Steady (2nd Retest)
Hand =>	Start* Hand	Opposite Hand	Dominant Hand	Dominant Hand	Start* Hand	Opposite Hand
Description =>	hold outstretched hand as steady as possible		mimic moderate tremor	mimic severe tremor	repeat holding outstretched hand as steady as possible	
* Note: the start hand is randomly chosen for each subject as either their dominant or non-dominant hand.						

4.3.4 Data Analysis

4.3.4.1 Preliminary Processing

Data files were processed using *MAT*rix *LAB*oratory scripting. Each raw data file consists of a column containing a sample ID, as well as six columns for each of the six inertial sensor channel values (a seventh, redundant column exists for testing purposes and is ignored). The inertial processing script begins by reading values from each sensor channel into six individual row arrays. The sample ID serves as an index of the time series ordering of sampled values.

Raw A/D values from each channel were next converted to millivolts (mV) based on an A/D reference voltage of 3300 mV which established the A/D input dynamic range. Offset is removed from each channel by computing the average value over the discrete time series and subtracting this from the channel values. Finally, acceleration channel arrays are converted to acceleration values using reported ADXL330 accelerometer sensitivity of 330 mV/g and then converted to m/s^2 assuming 9.8 $m/s^2/g$. Similarly, IDG-300 angular rate channel arrays are converted to deg/s using the stated sensitivity of 2 mV/deg/s.

Next, time series signals were further filtered using MATLAB's FIR1 function which implements a window-based finite impulse response filter. Filter parameters were set to specify an n = 30 order band-pass filter with pass-band frequency range of 2-17 Hz; this range was based on filtering reported in the literature. In order to further reduce significant amplitude components attributable to low frequency drift of the hand during testing, data is again filtered using FIR1 as a high-pass n = 50 order filter with a cutoff frequency of 3 Hz.

4.3.4.2 Obtaining Translational and Rotational Displacements

Translational and rotational displacements are easily obtained using integration techniques from acceleration and angular rate time series. Table 4.5 shows symbol conventions for time series data obtained throughout the integration process. Eq. 4.1-4.5 show examples of each step in a symbolic integration process assuming tremor motion as a pure sinusoid model. However, this model is not assumed in the actual calculations. Instead, numeric integration is performed directly on collected time series data. Actual processing steps are described next.

Table 4.5 Conventions for integrated time-series inertial data sets

Symbol	Meaning	Units	Comment
x''_N	Acceleration	$\frac{m}{s^2}$	Data is sampled directly from sensor outputs
x'_N	Velocity	$\frac{m}{s}$	Calculated by computing the integral of acceleration
x_N	Position	m	Calculated by computing the integral of velocity
ω'_N	Angular rate	$\frac{\circ}{s}$	Data is sampled directly from sensor outputs
ω_N	Angle	$\circ$	Calculated by computing the integral of angular rate
Note: The subscript N is a placeholder for X, Y, or Z-axis which follows the convention shown in Fig 3.2.			

$$x''_N(t) = A_A \sin(2\pi ft) \qquad \text{(Eq. 4.1)}$$

$$x'_N(t) = \int x''_N(t) = \frac{-A_A}{2\pi ft}\cos(2\pi ft) \qquad \text{(Eq. 4.2)}$$

$$x_N(t) = \int x'_N(t) = \frac{-A_A}{(2\pi ft)^2}\sin(2\pi ft) \qquad \text{(Eq. 4.3)}$$

$$\omega'_N(t) = A_R \sin(2\pi ft) \qquad \text{(Eq. 4.4)}$$

$$\omega_N(t) = \int \omega'_N(t) = \frac{-A_R}{2\pi ft}\cos(2\pi ft) \quad \text{(Eq. 4.5)}$$

The inertial data collected includes three acceleration (m/s^2) and three angular rate (deg/s) time series data sets for each trial, from which we require three translational displacement (m) and three rotational displacement (degrees) sets of time series data respectively. One way that discrete time series data may be integrated is by approximating the slope between neighboring data points as a straight line and calculating the area directly beneath this straight line and the horizontal axis (bounded vertically by lines drawn perpendicular to the horizontal axis and each data point). This forms a collection of trapezoids, and these may be summed as the data set is traversed in order to calculate a new time series which represents the integration of the source data (Kaw, 2008; Kaw et al., 2009). The MATLAB function CUMTRAPZ was used for this purpose.

Velocity time series data is obtained from the acceleration data using numerical integration based on the trapezoidal method. Displacement time series data is then obtained from velocity time series data by again numerically integrating. After each integration step is performed, offset is again removed from the resultant series and results are again high-pass filtered using the same filter parameters to eliminate cumulative integration error. Then, one second is removed from both the beginning and the end of the displacement time series to discard values which have been added due to the window filtering process.

Rotational time series data was obtained from angular rate data using only a single integration step, although all other steps are identical to the process used to obtain translational displacement.

The translational and rotational displacement time series records were then processed as described in chapter 3 to obtain the six individual component steadiness measures.

4.3.4.3 Processing the 6 DOF Steadiness Measures

The six individual component steadiness time series are then displayed on screen as either millimeters (mm) for translational displacement data or degrees for rotational displacement data, and stored to an output file. All 18 trial data files for each subject are batch processed. Plots of processed time series are saved to files as processing steps are completed.

As already mentioned, six individual component values are output for each trial, and these are entered into Microsoft Excel where the inverse is taken to produce measures reflecting "steadiness" (not tremor) with proper units (i.e., either mm^{-1} or deg^{-1}). Then, simple average and GSPT-based (multiplicative) composites were computed for each trial using Eq. 3.1 and Eq. 3.3. The average of the best two of three trials of each test condition is computed.

4.3.4.4 Statistical Analyses

The mean, standard deviation (SD), and coefficient of variation (CV) were computed for each individual steadiness component as well as for overall composite measures across all subjects.

Test/re-test reliability was assessed using the Pearson product moment correlation coefficient for individual steadiness component measures, as well as for the simple average and GSPT-based composites.

Sensitivity is explored by computing the ratio of the "most steady" to the "least steady" subject's composite measures, looking across: 1) "test" and "retest" results for the "steady" condition, 2) "test" and "retest" results for the "steady condition" as well as the simulated moderate tremor condition, and 3) and "test" and "retest" results for the "steady condition" as well as the simulated severe tremor conditions.

4.4 Experimental Results

4.4.1 Descriptive Statistics

Statistical calculations across all subjects for individual component measures are given in Table 4.6. Pearson r correlation coefficients are calculated only for the steady cases with test/retest trials and not for tremor mimicking test cases.

Table 4.6 Mean, standard deviation, coefficient of variance, and Pearson r (retest vs. test) for individual components across all subjects for all test cases

Condition and Statistical Parameters	**X_T (mm^{-1})**	**Y_T (mm^{-1})**	**Z_T (mm^{-1})**	**X_R (deg^{-1})**	**Y_R (deg^{-1})**	**Z_R (deg^{-1})**
Dominant Hand – Steady, Test						
• Mean	25.569	19.066	16.000	44.956	57.734	55.020
• SD	6.779	4.164	3.815	27.656	12.769	14.655
• CV (%)	26.51	21.84	23.84	61.52	22.12	26.64
• Pearson r (Retest vs. Test)	0.410	0.526	0.703	0.894	0.379	0.145
Dominant Hand – Steady, Retest						
• Mean	25.957	18.524	15.823	42.663	57.364	53.800
• SD	5.420	6.516	4.095	25.012	16.774	12.794
• CV (%)	20.88	35.18	25.88	58.63	29.24	23.78
Non-Dominant Hand – Steady, Test						
• Mean	26.442	19.233	15.777	43.022	52.898	53.959
• SD	5.939	5.187	3.755	27.964	15.667	13.182
• CV (%)	22.46	26.97	23.80	65.00	29.62	24.43
• Pearson r (Retest vs. Test)	0.259	0.655	0.751	0.920	0.620	0.571
Non-Dominant Hand - Steady, Retest						
• Mean	25.798	18.121	14.855	40.111	55.114	51.955
• SD	9.013	4.755	3.750	30.639	18.788	12.956
• CV (%)	34.94	26.24	25.24	76.39	34.09	24.94
Dominant Hand – Simulated Moderate Tremor						
• Mean	2.164	2.536	2.143	15.929	3.409	5.375
• SD	1.482	2.086	1.722	34.424	4.077	7.093
• CV (%)	68.47	82.26	80.36	216.11	119.58	131.98
Dominant Hand – Simulated Severe Tremor						
• Mean	0.318	0.597	0.329	15.826	0.605	0.733
• SD	0.245	0.633	0.316	36.634	0.973	0.527
• CV (%)	76.98	105.91	96.08	231.48	160.91	71.92

4.4.2 Sensitivity Results

Results of sensitivity analyses are shown in Tables 4.7 and 4.8. Sensitivity here is defined as the ratio of the most steady to the least steady subject within each test case.

Table 4.7 For the simple average composite, mean and standard deviation for the indicated group, as well as the ratio of best to worst subject performance (sensitivity)

Group =>	**Steady, Test, Dominant**	**Steady, Test, ND**	**Steady, Retest, Dominant**	**Steady, Retest, ND**	**Steady - Test & Steady - Retest & Moderate Tremor**	**Steady - Test & Steady - Retest & Severe Tremor**
Mean (units unknown)	0.503	0.479	0.490	0.469	0.066	0.029
SD (units unknown)	0.076	0.101	0.095	0.103	0.057	0.050
Best: Worst	1.731	2.305	2.194	2.373	74.930	168.661

Table 4.8 Ratio of best: worst subject performance (sensitivity), mean, and standard deviation for GSPT-based composites over all test conditions

Group =>	**Steady, Test, Dominant**	**Steady Test, ND**	**Steady, Retest, Dominant**	**Steady, Retest, ND**	**Steady - Test & Steady - Retest & Moderate Tremor**	**Steady - Test & Steady - Retest & Severe Tremor**
Mean ($mm^{-3}deg^{-3}$)	1.11E+09	1.05E+09	1.20E+09	9.87E+08	2.24E+04	1.07E+01
SD ($mm^{-3}deg^{-3}$)	8.81E+08	9.91E+08	1.28E+09	1.24E+09	8.87E+04	4.86E+01
Best: Worst	30.68	150.58	113.16	201.77	1.52E+12	2.25E+14

The discrimination provided by the GSPT-based composite as shown in Figure 4.3 and Figure 4.4 is huge compared with the simple average composite when evaluating very steady individuals relative to individuals simulating severe tremor. In these plots, dominant and non-dominant side data are now pooled prior to searching for “best” and “worst” steadiness within each of the specified groups. Thus, the plots represent different data than that presented in Tables 4.7 and 4.8.

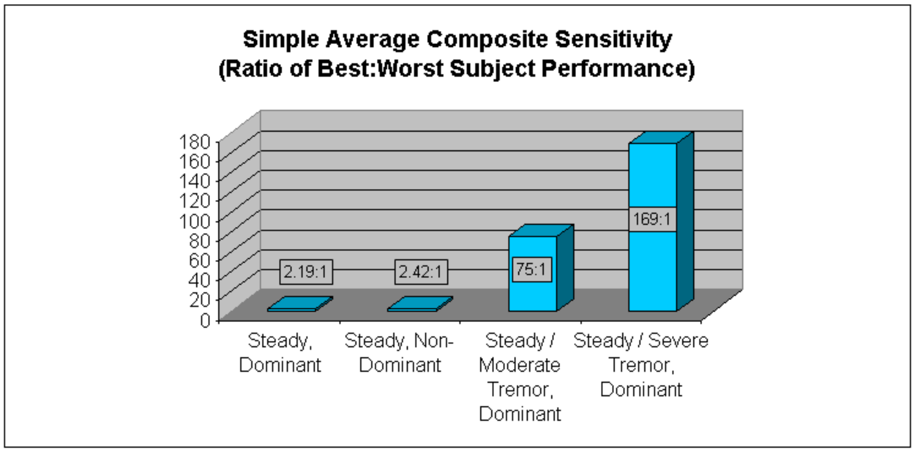

Figure 4.3 Ratio of best: worst subject performance for the simple average composite and selected test conditions.

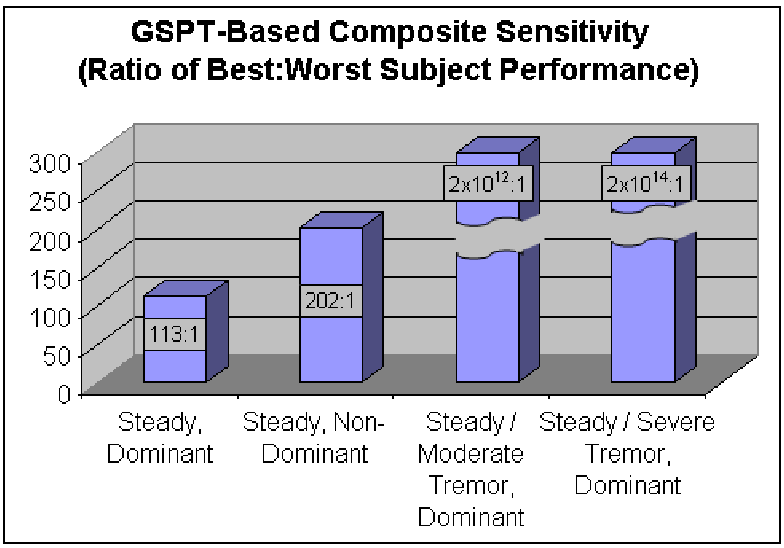

Figure 4.4 Ratio of best: worst subject performance for the GSPT-based composites.

Figure 4.5 provides a geometric illustration of GSPT-based steadiness composites separated into intermediate translational and rotational composite measures. An interpretation of these volumes (i.e., 3 DOF for translational and 3 DOF for rotational) illustrates that healthy individuals have "orders of magnitude" greater amounts of steadiness over individuals with tremor.

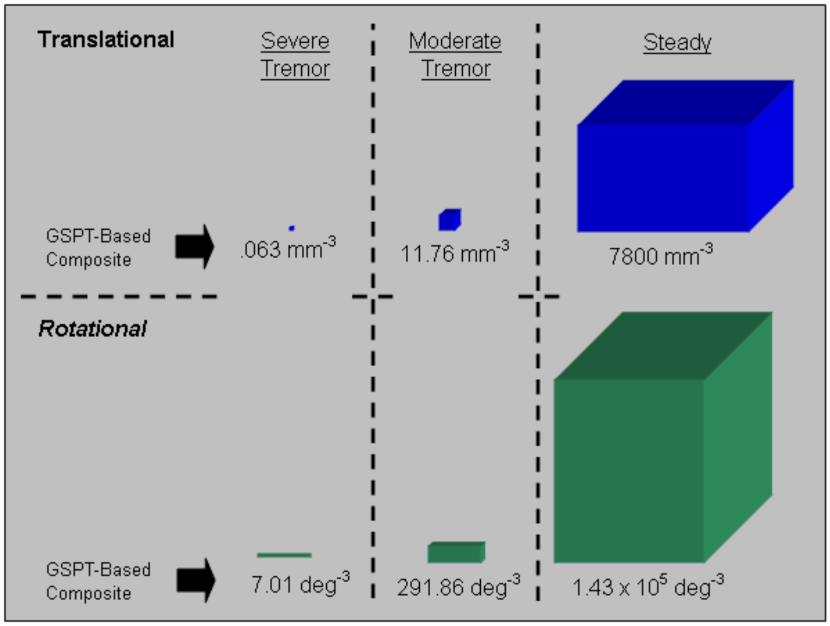

Figure 4.5 Comparison of differences between GSPT-based composites using group average data for the respective test conditions.

4.4.3 Reliability

Reliability was determined using a test-retest paradigm, as is common in psychological or medical studies involving humans. The Pearson product moment correlation coefficient was computed between "test" and "retest" data sets for the "steady" condition and was separately determined for dominant and non-dominant body sides. Better reliability (i.e., repeatability) is obtained for components which exhibit a wider variance in the measure across subjects included in the study. This can be seen for the $X_{Rotational}$ component and for the $Z_{Translational}$ component for both dominant and non-dominant cases. The worst repeatability is seen in the $X_{Translational}$ and $Z_{Rotational}$ graphs. Again, these cases represent the narrowest variance in the measures for this healthy group of subjects.

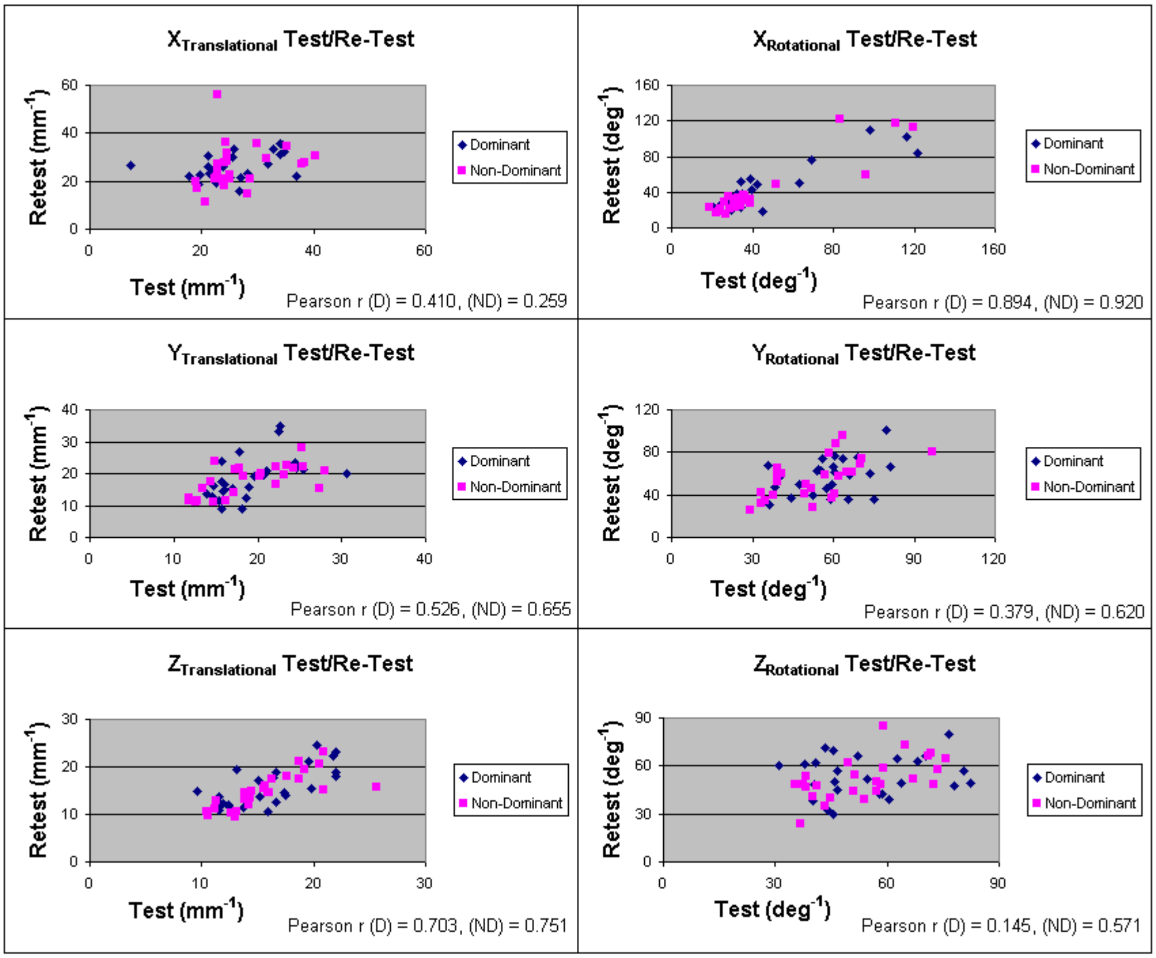

Figure 4.6 Test/retest reliability of individual components.

Note in Figure 4.7 the comparable Pearson r values for the simple average and GSPT-based composites. However, the GSPT-based composites show the highest test/retest reliability out of all composite-condition combinations (for the steady, non-dominant case).

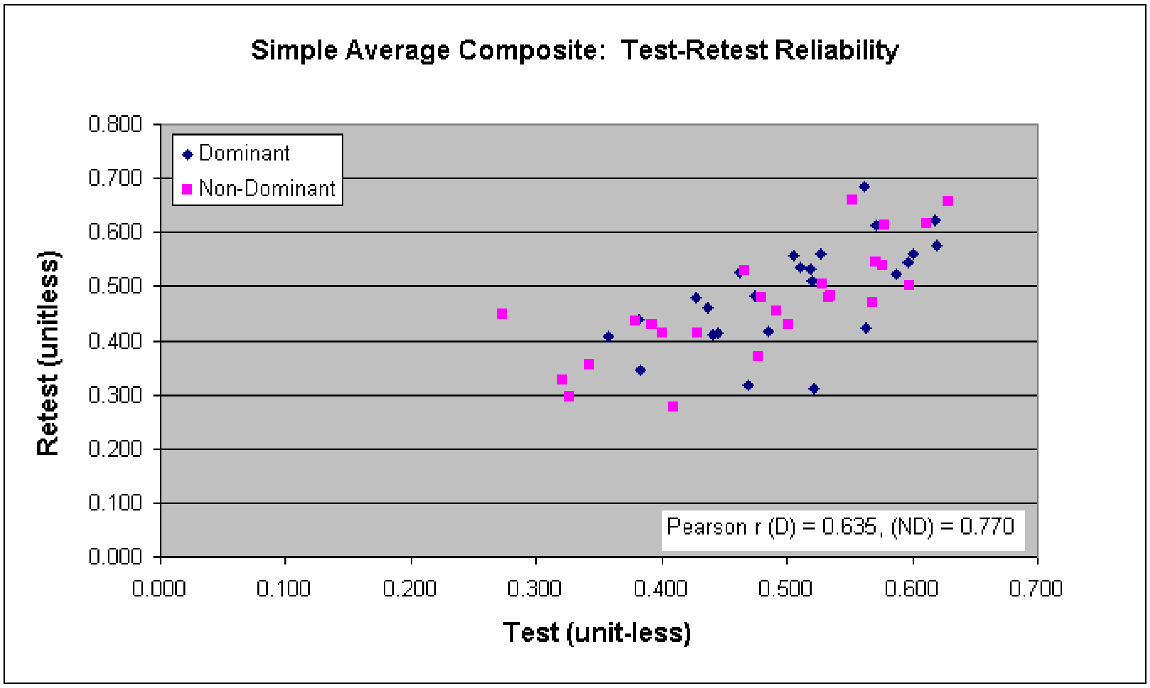

Figure 4.7 Test/retest reliability of simple average composite

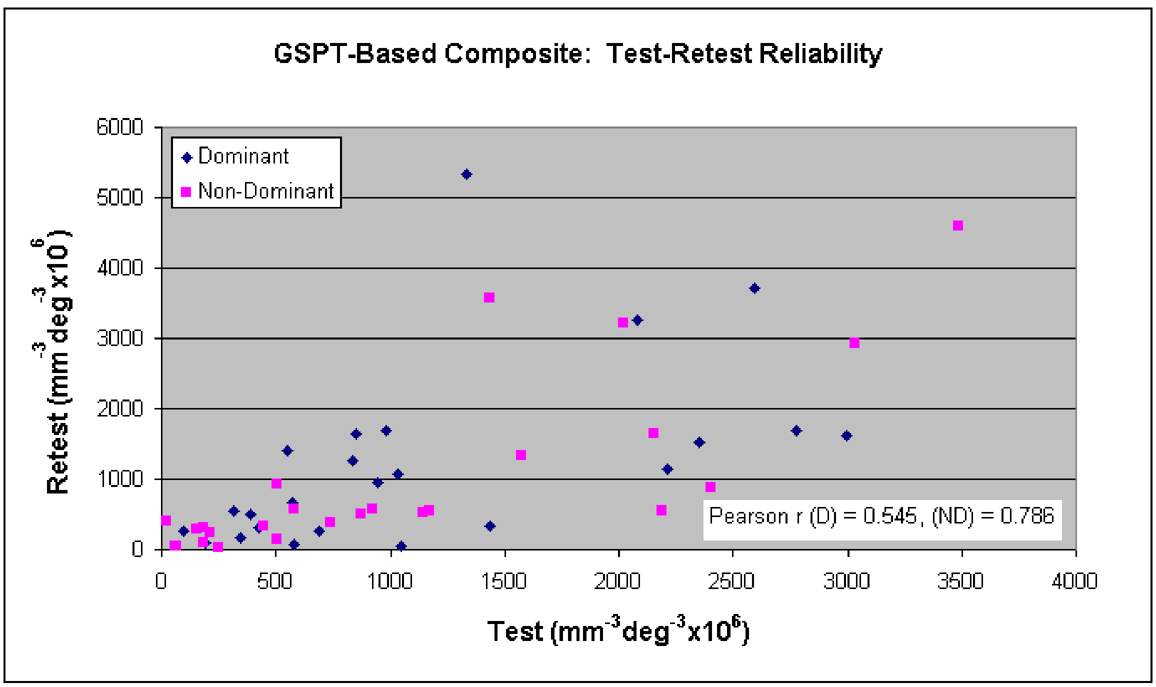

Figure 4.8 Test/retest reliability of GSPT-based composite

CHAPTER 5

CONCLUSIONS

While no gold standard exists for characterizing measures which claim to reflect steadiness, GSPT-based composite steadiness measures appear to be the best option for truly representing how much steadiness is exhibited by the hand (or other) body segment when all six degrees of freedom are considered. Any additional approaches to forming a composite measure proposed in the future, whether for steadiness or other aspect of performance, may also be evaluated using a similar approach.

5.1 Objectives - Revisited

Repeating from chapter 1, the objectives which have been addressed include:

1. Collect high quality six DOF hand steadiness data using a 6 DOF inertial sensing unit in a selected population of healthy adults stressed to produce maximum steadiness and also to mimic “unsteady” (tremor) conditions.
    - 26 subjects were recruited for this research requiring 20 testing hours
    - Protocol instructions are given in Appendix C which describe test cases designed to stress subject’s steadiness by having them hold the involved body segment (e.g., hand-arm) as steady as possible, as well as having them mimic moderate and severe tremor-like movement
2. Use collected data to establish a steadiness/tremor database to support investigation of steadiness composite measures.
    - A steadiness/tremor raw inertial motion database has been created, as well as tools for processing and analysis of the database in a variety of ways.

3. Formulate and evaluate conceptually, performance theory based and other candidate composite steadiness measures (performance theory based and selected other candidates).

   - Three types of composites were formulated: 1) simple average, 2) vector-based, and 3) GSPT-based. The vector-based approach required the incorporation of a hypothetical object and was not included in further analyses.
   - From conceptual evaluation, GSPT-based steadiness measures are shown to retain units reflecting constituent components, while the simple average composite encounters problems with units due to the need to combine translational and rotational steadiness components.
   - The GSPT-based composite exhibits predictive validity in simple engineering-like decision-making tasks (i.e., relating performance capacity to required performance), whereas the simple average composite fails and provides misleading interpretation.

4. Determine test-retest reliability for composite steadiness candidate measures using selected records from the database.

   - Of the four cases for which a Pearson product moment correlation coefficient were computed, (i.e., dominant and non-dominant hands for both the simple average and GSPT-based composites), the case corresponding to the highest reliability was for the GPST-based composite (non-dominant hand). The dominant hand GSPT-based composite test-retest reliability was at least comparable to the simple average case. Overall, both composites exhibited reliability comparable to that obtained previously with other high resolution steadiness measures evaluated in healthy populations with relatively small inter-individual differences (i.e., a worst-case condition for reliability evaluation).

5. Investigate the validity of composite steadiness candidate measures using conceptual arguments (for construct validity) in combination with experimental results from the database focusing on the sensitivity of each candidate.
    - Conceptual evaluation is discussed under Objective 3 (above).
    - GSPT-based composite measures demonstrate excellent sensitivity to individual components incorporated by the composite measure and discriminated subjects with different amounts of steadiness with much higher sensitivity than the simple average composite.
6. Formulate recommendations for a composite steadiness measure and for additional future work related to steadiness measurement.
    - More detail is given in the next section, although clearly a GSPT-based composite deserves further consideration as it appears to display numerous advantages over traditional composite formation approaches such as simple averaging.

It is now asserted that a performance-theory based steadiness composite measure is a valid measure of how much steadiness a body segment exhibits, and that the multiplicative procedure for formation of this single number composite measure from full six DOF inertial data is valid.

GSPT-based steadiness measures can be both very large (e.g., for healthy, steady individuals) or very small (e.g., severe tremor case) due to the sensitivity of formed composites. Interestingly, this dynamic range is much like that of the Richter scale (a logarithmic scale) used to characterize earthquake severity. These results are suggested to shed new light on clinical considerations concerning the vast difference in performance amongst individuals.

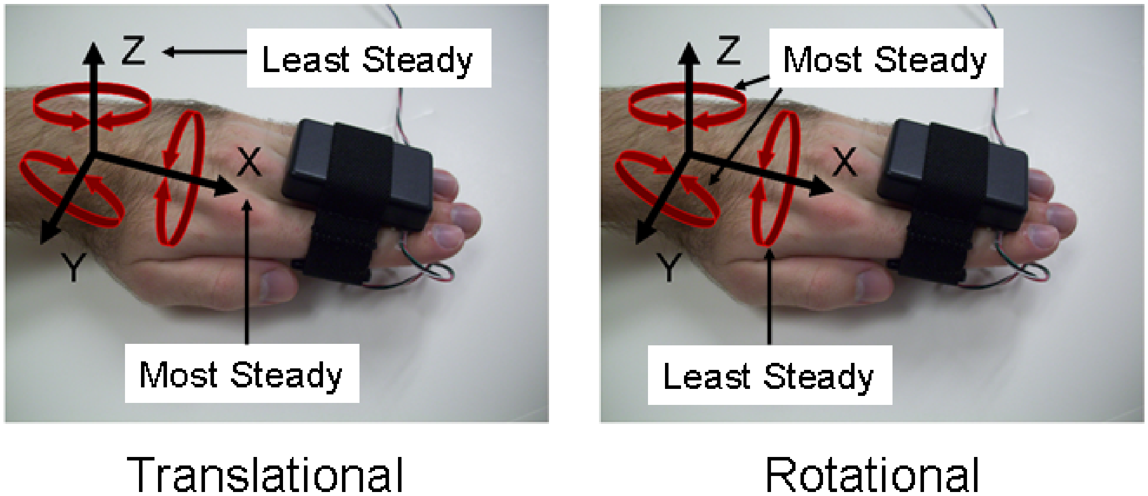

Figure 5.1 Individual Component Steadiness for Steady Test Case – Both Dominant and Non-Dominant Hands

As illustrated in Fig. 5.1 (and also Table 4.5), the $X_{Translational}$ and $Z_{Rotational}$ individual components exhibit the *most* steadiness across subjects, whereas the $Z_{Translational}$ and $X_{Rotational}$ components exhibit the *least* steadiness. This result is expected based on the physiology/biomechanics of the hand, arm, and shoulder as well as the posture used in the test procedure. While a subject is attempting to hold steady with their hand held straight out in front of their body, it is reasonable that more motion will be observed vertically (i.e., $Z_{Translational}$) as opposed to the situation where the rest of the body is effectively bracing the hand against moving in an anterior-posterior fashion (i.e., $X_{Translational}$). The same sort of observation can be made for rotational steadiness, where the wrist more naturally allows rotation of the hand about the long axis of the forearm (i.e., $X_{Rotional}$), but does not easily allow a "wiping" motion to occur when the arm and shoulder are held firm (i.e., $Z_{Rotational}$). There is also more limited range of motion for radial and ulnar deviation at the wrist than for flexion-extension.

5.2 Future Work

Further work will include addition to the database of high quality inertial data to support continued analysis. It is predicted that incorporation of more varied population data under test-retest conditions will result in improved reliability estimates.

The data set as it currently exists, however, is suitable for a number of different analyses. For example, the relative magnitudes and correlations between all combinations of the six constituent steadiness components should be explored. This may reveal, for example, that it is or is not necessary to directly measure all six DOFs. As described in chapter 2, most previous work has ignored one or more of the DOFs required to fully describe motion of a rigid body.

Confusion exists in the literature as to the basic definition of steadiness and tremor, as directly communicated in descriptive language and also indirectly communicated by what is actually measured. Different techniques reported obtain either: 1) acceleration, 2) translational displacement, or 3) single axis rotational displacement. This is perhaps because regardless of the quantity, one obtains a measure that changes as the amount of steadiness (tremor) changes. Little if any consideration is given to which of these (or which combination) is the most valid. However, the true gold standard against which any objective method must be measured is the subject estimation of steadiness (tremor) by experts such as neurologists who appear to visually observe and focus on displacement amplitude as the key indicator of severity. Video recordings made during testing should be evaluated by neurologists to determine tremor severity. These “scores” could then be correlated with simple average and GSPT-based composites to determine which agrees most closely with the impression of a trained expert.

Subtle differences in processing to obtain displacement time series data are also worth consideration and are not well explained in the literature. For example, while we have taken the absolute value of the displacement time series and determined an average value across said time series, this really represents one-half of the average displacement that the body segment undergoes. A final measure could thus include a multiplication of the intermediate displacement values by a factor of two or even an estimate of the “average” peak-to-peak displacement. Ultimately, the processing approach should not only work to faithfully represent a valid steadiness measure, but the entire construction of the steadiness concept. Other processing approaches could prove more useful in system-task analyses as well (e.g., best/worst case vs. average case), and a consensus on the definition of steadiness measures (as well as other basic elements of performance) is needed.

Techniques that directly sense displacement must literally rely on a reference frame to detect a change in position of the target. Ultrasonic, optical, and capacitance position sensing apparatus require specific setups, and it can be costly and/or difficult to for example monitor hand, arm, and head position all at the same time. Image based tracking systems have this global tracking capability within a room, but they are also quite expensive, the systems still require careful setup in a carefully prepared environment, and generally do not have sufficient spatial resolution. In the end, an accelerometer/angular rate sensor based device is very inexpensive, and may be used to monitor most any desired body segment in most any environment. Thus, it is recommended that this approach be pursued vigorously and further refined, emphasizing reduction in the size of the sensor unit and incorporation of wireless technology to further improve testing by eliminating cables.

Acceleration data does not tell us directly "how much" steadiness (tremor) a person's body segment exhibits. To illustrate, imagine that a person "speeds up" their motion while moving their hand between two points a fixed distance apart. Obviously, the hand will experience higher amplitude accelerations, even though displacement amplitude is the same. The hand is traveling more quickly so the sinusoidal acceleration will now occur at a higher frequency; therefore, any attempt to quantify tremor motion with acceleration data should consider both the amplitude and frequency of acceleration waveforms. A further hint is obtained by noting that, as part of the integration process (and assuming sinusoidal motion), displacement is obtained by dividing acceleration by the square of frequency. This relationship between acceleration amplitude and frequency is also worth further exploration and description in the literature as part of future work. Previous work in the literature is believed to have made overly simplistic assumptions about using acceleration to characterize tremor/steadiness.

While this work focused on steadiness, it represents putting GSPT under scrutiny in yet another context. The results provide further support for the merits of GSPT constructs, especially the performance resource and performance capacity envelope constructs as they apply to composite formation. Future work should therefore also consider application of these concepts and evaluation methods to composite formation in other contexts.

APPENDIX A

STEADINESS MEASUREMENT DEVICE – RESOLUTION AND ERROR CONSIDERATIONS

While each raw inertial sensor waveform is sampled (using an analog to digital converter or ADC) with n_{max}-bits, not all of these bits are meaningful and the amount of useful bits available is limited by noise. "This noise is due to thermal noise within the ADC, and quantization noise due to the analog-to-digital conversion process." (McCarthy, 2003) Thermal noise refers to the undesired effect whereby samples taken of a constant input at different temperatures will incorrectly yield differing sample measurements. Quantization error is due to the fact that we are only able to represent a continuous waveform by rounding to the most appropriate discrete "bin" during the sampling process (e.g., an 8-bit ADC will have $2^8 = 256$ bins). This measurement error may be eliminated from the raw sampled data by performing a calibration procedure. The results of the calibration will be the peak-to-peak resolution of each ADC channel in bits. This will tell us the number of bits which may be retained from the total available/sample so that flicker-free operation is assured (i.e., the ADC discrete output code will not change unless the actual sensor waveform changes.) The calibration procedure is as follows, after obtaining a sufficiently lengthy amount of inertial data while the measurement device is sitting still on a flat table. Signal-to-Noise (SNR) ratio may then be determined using the expression:

$$SNR = 20 * \log\left(\frac{peak.noise}{full.scale.input}\right) \quad \text{(Eq. A.1)}$$

This may then be used to determine peak-to-peak resolution by solving for N_{pp}.

$$SNR = 6.02N_{pp} + 1.76 \quad \text{(Eq. A.2)}$$

N_{pp} is then the number of most significant bits which should be retained out of the total (i.e., n_{max}-bits) number of bits available for each sample.

$$N_{pp}(bits) = \frac{SNR - 1.76}{6.02} \quad \text{(Eq. A.3)}$$

Another way to determine how many bits are actually available from an inertial sensor channel given the presence of noise involves a programmatic approach. By iterating through the values collected from one channel and counting which Most Significant Bits (MSBs) remain the same throughout the entire set of values the peak-peak resolution in bits is now known and may be determined for each channel.

A simpler approach involves determining how many “bins” are available given the peak-peak noise and input range of the ADC. From here the number of useful bits may be calculated using log and floor functions as shown in Eq. A.4.

$$N_{pp}(bits) = \left\lfloor \log_2 \frac{input\_range}{noise} \right\rfloor \qquad \text{(Eq. A.4)}$$

Table A.1 Estimate of the amount of “flicker-free”, useful bits for each inertial sensing channel based on a 30 second calibration procedure, with corresponding channel sensitivity

Sensor Channel	**Sensitivity**	**Usable Bits**
X Acceleration (mg)	39.063	8
Y Acceleration (mg)	78.125	7
Z Acceleration (mg)	78.125	7
X Angular Rate (°/s)	3.223	9
Y Angular Rate (°/s)	6.445	8
Z Angular Rate (°/s)	6.445	8

During data processing an alternative to retaining only “flicker-free” bits is to retain a majority of the MSb (Most Significant Bits) and then use digital filtering (in addition to hardware filtering already in place) to reduce most of the noise by focusing only on the smallest bandwidth of interest. For example, out of 24-bits possible, 16-bits may be retained and a moving average filter or similar used to remove a significant amount of noise while retaining data in the 3-20 Hz frequency range where “normal” and “near normal” tremor occur.

APPENDIX B

IRB APPROVAL AND INFORMED CONSENT

October 20, 2009

THE UNIVERSITY
OF TEXAS
AT ARLINGTON

Office of Research Administration
Box 19188
202 E. Border St., Suite 214
Arlington, Texas
76019-0188

T 817.272.3723
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http://www.uta.edu/research
Expertise at UT Arlington
http://www.uta.edu/expertise

Dr. George Kondraske
Jonathan Armstrong
The University of Texas at Arlington
Electrical Engineering
Box 19015

RE: Expedited Approval of Protocol

TITLE: *Investigation of a Performance Theory Based Steadiness Composite Score for Any Body Segment*

IRB No.: 2010-0081

The University of Texas Arlington Institutional Review Board (UTA IRB) has determined that this research is eligible for expedited review in accordance with Title 45 CFR 46.110(a)-(b)(1), 63 FR 60364 and 63 FR 60353, categories (4)(6)(7).

The IRB Chairman (or designee) approved the protocol effective October 19, 2009. IRB approval for the research shall continue until October 18, 2010. In order for the research to continue beyond the first year, Continuation Review must be completed within the month preceding the date of expiration indicated above. A reminder notice will be forwarded to the attention of the Principal Investigator (PI) at that time.

The approved subject sample size is 45.

Important Note: The IRB approved and stamped informed consent document (ICD), showing the approval and expiration date of the article must be used when prospectively enrolling volunteer participants into the study. The use of a copy of any consent form on which the IRB-stamped approval and expiration dates are not visible, or are replaced by typescript or handwriting is prohibited. The signed consent forms must be securely maintained on the UT Arlington campus for the duration of the study plus three years. The complete study record is subject to inspection and/or audit during this time period by entities including but not limited to the UT Arlington IRB, Regulatory Services staff, OHRP and by study sponsors (if the study is funded).

Please be advised that as the principal investigator, you are required to report local adverse (unanticipated) events to this office within 24 hours. In addition, pursuant to Title 45 CFR 46.103(b)(4)(iii), investigators are required to, "promptly report to the IRB ***any*** proposed changes in the research activity, and to ensure that such changes in approved research, during the period for which IRB approval has already been given, are **not initiated without prior IRB review and approval** except when necessary to eliminate apparent immediate hazards to the subject."

Be A Maverick™

All investigators and key personnel identified in the protocol must have documented *Human Subjects Training* or *CITI* Training on file with this office.

If applicable, approval by the appropriate authority at a collaborating facility is required prior to subject enrollment. If the collaborating facility is *engaged in the research*, an OHRP approved Federalwide Assurance (FWA) may be required for the facility (prior to their participation in research-related activities). To determine whether the collaborating facility is engaged in research, go to: http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm

The UT Arlington Office of Research Administration Regulatory Services appreciates your continuing commitment to the protection of human research subjects. Should you have questions or require further assistance, please contact Robin Dickey by calling 817-272-9329.

Sincerely,

Patricia Turpin

Digitally signed by Patricia Turpin
DN: o=The University of Texas System, ou=The University of Texas at Arlington CA, ou=www.verisign.com/repository/CPS Incorp. by Ref.,LIAB.LTD(c)99, cn=Patricia Turpin, email=pturpin@uta.edu
Date: 2009.10.26 10:09:04 -05'00'

Patricia Turpin, Ph.D., RN, NEA, BC
Clinical Associate Professor
UT Arlington IRB Chair

INFORMED CONSENT

PRINCIPAL INVESTIGATOR NAME:
George V. Kondraske, Ph.D.

TITLE OF PROJECT:
INVESTIGATION OF A PERFORMANCE THEORY BASED STEADINESS COMPOSITE SCORE FOR ANY BODY SEGMENT

INTRODUCTION:
You are being asked to participate in a research study. Your participation is voluntary. Please ask questions if there is anything you do not understand.

PURPOSE:
The purpose of this study is to evaluate different methods for obtaining a single number that represents how steady you can hold your hand. This is important in medical and non-medical situations.

DURATION:
Your participation in the study will require approximately 30 minutes.

PROCEDURES:
You are being asked to participate in a study involving measurement of hand steadiness. The data collected will be used to better understand how a surplus or lack of steadiness contributes to performance in any task that involves a steadiness component.

A small, lightweight sensor will be temporarily attached by a Velcro strap to your hand. You will be asked to hold your hand as steady as you possibly can in an outstretched position for several brief periods of time (15 seconds each time) and aslo to mimic problems known as tremor after watching video clips of individuals who have hand tremor. A video camera will be used to record the motion of your hand. Only your hand and part of your arm will be included in the video frame. Your left and right hands will be separately involved in these evaluations.

After a 5 minute break, you will be asked to repeat the overall process in which you will again attempt to hold the hand being tested as steady as possible.

This entire process should take no longer than 30 minutes, and you may stop participating at any time. The steadiness data collected from you will be uniquely identified using a randomly assigned number which will in no way be linked to you.

All participating subjects will be included in the same group and subjected to the same experimental procedures.

OCT 19 2009
APPROVED
OCT 18 2010
Institutional Review Board

POSSIBLE BENEFITS:
You will have the opportunity to contribute to the ultimate development of new performance capacity measurements that may eventually impact neurology, physical therapy, rehabilitation and vocational testing. You may additionally increase your own knowledge regarding the various aspects of steadiness performance, an important facet of everyday life.

COMPENSATION:
No compensation is provided to participants.

POSSIBLE RISKS/DISCOMFORTS:
Participation in the study may involve very minimal discomfort as you will need to hold one of your hands as steady as possible for 15 seconds at 12 different times, and also perform other intentional small movements with your hand.

This research does not involve more than a very minimal risk.

ALTERNATIVE PROCEDURES/TREATMENTS:
At any time, you may choose to not participate in or withdraw from this study with no consequences.

WITHDRAWAL FROM THE STUDY:
At any time, you may choose to withdraw from this study with no consequences.

NUMBER OF PARTICIPANTS:
We expect 45 participants to enroll in this study.

CONFIDENTIALITY:

If in the unlikely event it becomes necessary for the Institutional Review Board to review your research records, then The University of Texas at Arlington will protect the confidentiality of those records to the extent permitted by law. Your research records will not be released without your consent unless required by law or a court order. The data resulting from your participation may be made available to other researchers in the future for research purposes not detailed within this consent form. In these cases, the data will contain no identifying information that could associate you with it, or with your participation in any study.

Video recordings of only your hand and part of your arm will be obtained as part of the study. Video recordings (tapes and any other forms) will be coded so that no personally identifying information is visible on them. They will be kept in a locked cabinet in Dr. Kondraske's office (Nedderman Hall, Room 215). They will be viewed only for research purposes by the investigator and his associates. After completion of the study, recordings will be retained for possible future analyses.

If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

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CONTACT FOR QUESTIONS:
Questions about this research or your rights as a research subject may be directed to Jonathan Armstrong at (817)272-3454. You may contact George Kondraske at (817)272-3473 in the event of a research-related injury to the subject.

CONSENT:
Signatures: [Dr. George V. Kondraske]

As a representative of this study, I have explained the purpose, the procedures, the benefits, and the risks that are involved in this research study:

Signature and printed name of principal investigator or person obtaining consent Date

Dr. George V. Kondraske, Ph.D

By signing below, you confirm that you have read or had this document read to you.

You have been informed about this study's purpose, procedures, possible benefits and risks, and you have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits, to which you are otherwise entitled.

SIGNATURE OF VOLUNTEER **DATE**

We may wish to present some of the video clips from this study at scientific conventions or as demonstrations in classrooms. Please sign below if you are willing to allow us to do so with your recorded data.

SIGNATURE OF VOLUNTEER **DATE**

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APPROVED

OCT 18 2010

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APPENDIX C

TEST PROTOCOL - INSTRUCTIONS

SESSION 1

"Today, I will be collecting motion data from your hands under several conditions. Now for the first set of tests I will ask you to hold your hand in this posture (DEMONSTRATE) as STEADY AS YOU CAN for a brief period. Place the hand that is not being tested on your knee. During the test, look straight ahead and keep your whole body, including your hand, as still as possible. I will tell you when the test should start and when 15 seconds has elapsed, after which you may then relax. We will repeat this first test three times on both of your hands."

...Affix SMD

...Three 15 sec. steady trials for randomly selected D or ND hand with 10 sec. breaks

...Switch SMD to other hand, and again three steady trials

"Now, I am going to show you a short video clip of a person with MODERATE tremor. For the next set of tests I would like you to move your hand like the person in the video. I can replay the clip several times, and you may practice mimicking the motion a few times before we begin testing again."

...Affix SMD to D hand if necessary

...Three 15 sec. simulated moderate tremor trials with 10 sec. breaks

"Now, I am going to show you another short clip of a person with MORE SEVERE tremor, and like the last set of tests I would like you to mimic this motion. Again, I can replay the clip and you may practice before we begin."

...Three 15 sec. simulated severe tremor trials with 10 sec. breaks

...Remove SMD

...5 minute break including a casual walk in the hallway

SESSION 2

"Now, we are simply going to repeat the first set of tests for both hands and then testing will be done! Remember, that for this set of tests you should remain as STEADY AS YOU CAN for the duration of the test."

...Affix SMD

...Three 15 sec. steady trials for same randomly selected D or ND hand with 10 sec. breaks

...Switch SMD to other hand, and again three steady trials

"That's all for today, thanks for your participation!"

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BIOGRAPHICAL INFORMATION

Jonathan Armstrong is currently pursuing a doctorate in electrical engineering at the University of Texas at Arlington. His primary research interests are in systems design, embedded design, and human performance modeling and measurement. His other interests include reading interesting books, running, and spending time with friends and loved ones. His next project will involve use of a car repair manual to troubleshoot an intermittent problem with his 1999 Pontiac Grand Am.