A Pilot Study to Both

Confirm a Method to Objectively Measure Pain through

Functional Measurement of Physiometric Proxies for Pain

and

Validate Chronic Pain Patient's Self-Reports of Pain Using a Visual Analog Scale,

for Purposes of a Disability Determination Program.

Anne M Skenzich
University of Minnesota School of Public Health
Social Security Administration Disability Determination Project
Small Grant Funding, Cohort 3, 2013-14

Abstract

This is effectively two studies that merge in the results: The first study looks at the functional testing of chronic pain patients to determine if their pain can be measured objectively. The second study is the validation of a visual analog scale [VAS], a 10-point pain measurement tool for use with the chronic pain population. Neither of these processes has been done before and further, no evidence of attempts was found in a literature review.

There were two questions to be answered in this case-control pilot study: can pain be objectively and functionally measured so as to be included within an evaluation in a disability determination process [DDP]; and is it possible to validate a visual analog scale [VAS], a 10-point pain scale, of self-reported pain for use with the chronic pain population to improve the communication of their pain throughout the DDP, as well make the pain comparable across episodes within the patient, and across patients, both in DDP and in clinical settings.

This case-control pilot study was not designed to be the final answer to these questions; It was designed to establish proofs of concept, i.e., are these two things feasible? And if they are feasible, how could they be implemented in a DDP setting to effectively determine the individual's pain as a part of the disability process for either the Social Security Administration [SSA] or the Veteran's Administration [VA]. The testing could effectively determine at what level the person is partially and at what level the person is permanently disabled when using the validated VAS tool.

The answers to both questions are a qualified yes: It is possible to objectively measure pain, and it is possible to validate a VAS for use with a chronic pain population. In both cases there are data limitations because this was only a pilot study to test the feasibility of the concepts. A much larger, full study must be done to confirm all results found here and make them generalizable to the full population. A full study will also determine if the theory of chronic pain measurement is valid, and if the newly validated VAS is effective for communication of pain in that setting.

Background

"How we come to our knowledge of another person's pain is a nice study in communication. It has much in common with the sort of communication attempted by the painter, the poet and the musician – conveying the moods and feelings" (Parkhouse, J. & Holmes, C.M., 1963). Pain is a component of the human experience. Our pain response is a learned experience – one's expression and understanding of "greatest pain ever" changes over time; A broken arm as a teen may be a called a the worst possible pain for that point in life, but that pain will pale in comparison to that experienced during child birth, or from neurological injury (McNamara, Harmon, & Saunders, 2012). Although pain is described in many settings as only a symptom of a disorder or disease, it is a most personal experience that involves the bio-physical, psychological, social, and environmental factors of the person feeling it (Frampton & Hughes-Webb, 2011).

Pain is either acute or chronic: acute pain episodes stem from an injury or a surgical intervention and last no more than approximately 6 weeks (Choate, McDonald, & Scott, 2011). Chronic pain begins after 6 months, leaving a significant gap between the end of the acute pain period (Beard, & Aldington, 2012). The gap between end of acute and start of chronic pain allows for the variation in healing times before someone is diagnosed with a chronic condition (ibid; Choate, et al 2011).

Chronic pain can be either the nociceptive (mechanical pain) or neuropathic (neural-based pain) variety. The difference is moot: both cause pain that is, at times, uncontrollable except with narcotics or electrical assistance (spinal cord stimulation, etc.). Both cause increased pain with movement: the nociceptive pain through the muscles and joints, (i.e., it hurts to move the knee mechanically); the neuropathic pain through neural networks that do not "fire" properly, causing pain signals to overwhelm the processes of movement direction (Arnstein, 2012). Both types of pain are present in studies of chronic pain patients (Majid, 2013). Both types of pain were present in this study's subjects.

The visual analog scale [VAS], a 10-point pain scale used to assist patients in communicating about their pain to others, has been around since the 1920's, but it was not widely in use until the 1950's (Hayes & Patterson, 1921; Freyd, 1923). The VAS is shown as a vertical line across a page, with numbers 0 through 10 showing with "No Pain" on the left end (zero) of the scale and "Worst Possible Pain" on the right end (ten) of the scale. The scale can also be displayed as a series of bricks laid end-to-end, which is called a Numeric Ratings Scale [NRS]; the VAS and NRS have been shown to be equivocal in research and clinical settings (Breivik, Björnsson, & Skovlund, 2000; Hollen, Gralla, Kris, McCoy, Donaldson, & Moinpour, 2005).

In clinical practice, the VAS has been validated multiple times for use with acute pain and post-surgical patient populations, with the first validations occurring more than 60 years ago (Bird & Dickson, 2001). In use within studies, the VAS may only be treated as an ordinal scale with no comparability of results on scales (Kersten, Kucukdeveci, & Tennant, 2012). But with proper validation and establishing of a "bottom" or valid zero point for each subject, the scale has comparability between subjects and is no longer a simple ordinal scale (ibid).

To further expand the possible base of knowledge on all areas of interest prior to the start of testing, experts in pain were contacted and provided input on their experiences working with the chronic pain population and attempting to monitor and communicate on the patient's pain. These expert discussions were with a number of orthopedic surgeons, as well as accredited pain specialists in the area. All repeatedly told me; unscientifically, anecdotally, and parenthetically,

that their chronic pain patients "do not work like 'normal' patients do" in respect to pain communication. I was repeatedly told "a chronic pain patient, when given a 10-point pain scale, will invariably give a pain rating of 7 or higher."

The oddity of scaling was discussed at length with the pain specialists, all of whom concurred with the observation, but without explanation. The theory was presented that the chronic pain patients cannot imagine or recall being without pain therefore only mark at the high end of the scale because that is what they feel on a day-to-day basis. This reinforced the goal for the VAS portion of this project: to validate the VAS for use with a chronic pain population so as to improving the communication about pain for this population. Another result of the validation is that all results from the VAS then become comparable: either between an individual's episodes and between individuals.

It is necessary to require validation of the visual analog scale [VAS] for each subject for the VAS to be used as a preference elicitation device, a device to obtain what a person likes or prefers more than something else (Kind, Dolan, Gudrex, & Williams, 1998; Nyman, Barleen, Dowd, Russell, Coons, & Sullivan, 2007). Though the validation process is typically specific to a Quality of Life [QoL] preference device, the validation process appears appropriate here due to the all-encompassing effect pain has on the patient's life (Rhudy & Meagher, 2003). Also, a simple pain scale, without any validation, and without an attempt to establish in the mind of the patient the "best" case and/or worst case pain situations prior to having them rate their current pain condition, sets a false precedent for how much weight the VAS instruments must bear (Williams, Oakley Davies, & Chadury, 2000).

When a valid zero is established for each subject, the result of each subject's VAS becomes comparable. Even though each subject has a different zero or "bottom," they are all still zero and zero equals zero, etc. If all scales start with the same base, and have the same scale, the same distance between each change in number, and all have the same terminus or top point, the results will be comparable, just as they are within the QoL scale findings (Kind et al, 1998; Nyman et al, 2007). With these VAS scales, when a patient rates a 4 today and a 7 tomorrow, an observer can know that there was a 30% change in pain from the first measure to the second. In a DDP, a validated VAS could inform the process: an adjudicator seeing results listed as from a validated instrument would know that the reports are comparable across time and across people: a 3 in Jim is the same as a 3 in Mary; a 4 in Bob is less severe than a 9 in Tim every day and in every situation the validated VAS is used.

All of the doctors, clinicians, and experts contacted as experts for this study encouraged this VAS validation research as it would give them an evidenced-based means by which to better monitor their chronic pain population, a means of comparing episodes within one patient's care to other episodes, but also to compare episodes between patients (Kane et al, 2005; Nyman et al, 2007).

Literature review and findings

Two literature reviews were done, one prior to starting the pilot study, one following completion of the testing but before the write up, with a gap of 9 months in between. In the first literature review the terms pain (any kind), pain measurement (any kind of pain), and VAS, together and separated were searched in all journals from 1994 to 2013 using EBSCO. The search returned 10,778 articles from 21 countries and 27 specialties or sub-specialties. A few of these articles "hinted" at attempts to objectively measure pain in their titles or abstracts, but these hints were not borne out upon reading the full text (Kramer, Haefeli,& Jutzeler, 2012). There were a large number of articles on use of Visual Analog Scales [VAS] and Numeric

Ratings Scales [NRS] as a means of rating pain in multiple settings, but none showed validation of the instrument, i.e., establishing a bottom or a zero point for each subject, and none showed use with a chronic pain population.

This first literature review was narrowed to look only for any attempts to objectively measure pain, with multiple exclusions (e.g., cancer, labor/labour, etc.), with 1,520 articles were returned. No articles showed any attempts at objective pain measurement of any kind of pain, but many used an unvalidated VAS to measure or monitor the subject's/patient's pain (the reasons for validation of VAS is discussed in the design and results sections) A few articles discussed the emotional or non-physiological aspects of pain, and to what affect these might alter the self-reports, but again, none validated the instrument to improve the potential inter-personal comparability (Ferreira-Valente, Pais-Ribeiro, & Jensen, 2011; Huber, Suman, Rendo, Biasi, Marcolongo, & Carli, 2007; Jensen Hjermstad, Fayers, Haugen, Caraceni, Hanks, Loge, Fainsinger, Aass, & Kaasa, 2011). One study created a method to normalize VAS pain reporting, to provide some standardized comparable responses between subjects, but again, this study did not validate their VAS (Kane, Bershadsky, Rockwood, Saleh, & Islam, 2005).

The second literature review was done with the same terms but only for 2012 to January 2014, with a return of a surprising 1,715 articles from 23 countries and covering 33 specialties or subspecialties. This was a surprisingly high response as 10,778 articles were returned for a 19 year span, so 1,715 articles for only 9 months span is high, by comparison. Many of the articles in the second literature review were the second publications of original items from the first search, and again, none discussed validated VAS, measurement of pain, or functional measurement of pain, (i.e., none were applicable to the range of the studies discussed here).

The first literature review included articles showing an empirical basis for using a proxy for pain, and specifically using the left systolic blood pressure [SBP] as that proxy. The first article by Bruehl, Carlson, & McCubbin (1992) formally establishes using blood pressure as an indicator for pain. Bruehl's (1992) study was designed "to explore the relationship between pain sensitivity and blood pressure" in a normal population" (p 466). And Bruehl et al found"(t)he relationship between resting SBP and pain intensity…remained nearly unchanged over the … pain stimulation…(and) this relationship appears to be independent of the effects of coping styles and emotional state as assessed in this study" (ibid). The Bruehl et al (1992) result was cited in the study by Rhudy & Meagher (2003) in which negative affect (bad mental state) was measured as a means of effecting pain, with SBP again used as the proxy for pain. And Bruehl et al (1992) was cited in the empirically-based study done by Green, Wang, Owen, Xie, Bittar, Stein, Paterson, & Aziz (2006) where the brain was stimulated to find the link between pain and blood pressure; SBP was the link – and the greater the pain, the greater the effect on the SBP in every setting.

The empirical basis for SBP as proxy also gave direction to the confounder by being cited in a study that looked at the relationship between pulse, and exercise as possibly over-sensitizing a subject to pain. Koltyn, Garvin, Gardiner, & Nelson (1996) empirically looked at pain following strenuous aerobic exercise, how exercise altered both the subject's pain thresholds and pain perceptions (sensitivity). Koltyn et al defined exercise by the subjects increase in pulse rate over their resting heart rate: exercise was an increase in pulse by greater than 15%; strenuous exercise an increase in pulse by more than 20% (1996). Koltyn et al (1996) study results were that the subject's pain thresholds were higher but pulse lower following strenuous exercise but the strenuous exercise increased the subject's sensitivity to pain. In other words, if physical activity was high enough to raise the pulse rate, as would happen with exercise, the subject's

would be more sensitive to pain (more aware of it) while simultaneously able to bear more pain (ibid). Koltyn's et al (1996) definition of exercise was the motivation for selecting the conservative 10% increase in pulse rate as the indicator for the start of exercise for this study: this is where the subject's pain sensitivity could start to increase and pain threshold could start to fall. This exercise factor is a confounder of the exposure or issue of interest, and therefore appropriate for exclusion in this paper.

For purposes of disability determination, the Social Security Administration's Disability Determination Process only recognizes pain as a component of another disabling process or disease. There is no rating for pain as a separate and distinct disease or disability process. For example, under section 1.02 Major Dysfunction of a Joint due to any cause "Characterized by gross anatomical deformity … *and chronic joint pain* and stiffness with signs of limitation of motion or other abnormal motion of the affected joint(s)" (emphasis mine, from www.ssa.gov/bluebook/1.00-Musculoskeletal-Adult). Within all categories in section A – adult disability categories, there are a total of eleven notations for pain such as that shown above, all a part of another disorder but never with pain as the primary. In no area and at no time has pain ever been measured, nor has pain been enumerated beyond simply stating its presence.

Measuring pain is important, but considering pain as a primary disabling disorder is an objective of this study. To show that pain can be measured functionally, repetitively, and transparently, and that the effect pain has on the life of the individual can be enumerated in a predictable manner. This writer hopes to make it so that pain is not merely mentioned in a report as 'contributing to disability' but the effect of pain on the life of an individual applying for disability is front of mind for the adjudicator in the DDP process.

Measuring pain objectively as a part of the DDP process is important to this writer as I am disabled due to pain, with secondary injuries to the nerves in my leg from over eight years ago. My DDP took over five years because pain wasn't a disorder, though it was pain that prevented me from working and living a full life: it was all-encompassing, blinding, and prevented me from often doing simple focusing tasks. In those 100's of visits to over 45 doctors, the theory of measuring pain developed -- that chronic pain patients have physiological responses to pain that can be accurately and objectively assessed, by measuring the responses as proxies for measuring their pain directly. If this could be proven, the disability determination services would then rate pain a primary disabler, and also add pain into another disabling diagnosis.

Research Design, Recruitment, Methods

This case-control pilot study was designed to test the concept of pain measurement. In a case-control study, the subjects have an exposure or issue of interest, and the controls do not; the testing condition is that the subjects are different from the controls because of a factor, an element, an issue. In this case-control study, all subjects had chronic pain and none of the controls did. Controls were "normal people: A control could have acute pain during testing, but the controls were different from the subjects in the testing: the control's responses related to any pain were qualitatively and quantitatively different from those the subjects provided.

If a control reported any pain, they were queried about that pain: "How long have you had that pain? When did you first have it? How long has it lasted? Have you ever sought medical help for that pain?" All questions were designed to effectively and finally determine that the control's pain did not rise to the status of chronic pain; lasting for 6 months, all day or nearly all day, every day. One patient had "stubbed" her toe on the way into testing; another reported "I'm

over 70 years old! Things just hurt sometimes!" but it was only periodic pain, never more than a day or two at a time, she didn't miss activities because of it, didn't ever take medication for it, had never seen a doctor, hadn't ever had it for a continuous week, so it did not rise to the chronic threshold.

The core purpose of this case-control study was to look at the chronic pain patient's response to and reports of pain during functional tests. The chronic pain subjects performed functional tasks and their systolic blood pressure [SBP] and pulse were measured after each task as a physiologic proxy for their pain, and then they were asked to rate their pain, with the increases in the physiological readings combined with increases in self-reports of pain to be considered as proof of increases in pain, and support for the theory.

Subjects were recruited through a local chiropractic clinic, with patients self-identifying as "chronic pain sufferers," and verified through clinic staff before subject presented for the scheduled testing. Subjects had one requirement to fulfill to become enrolled: be a chronic pain sufferer, defined as suffering daily and nearly continuous pain for at least six (6) months. In addition, subjects were informed of reasons for exclusion from the study: they could not have used any narcotics within 72 hours due to complications with rebound and withdrawal effects on blood pressure and pulse; no steroids due to its effects on pain response; no internally implanted stimulators for pain control; no use of external pain control devices such as transcutaneous electrical nerve stimulation [TENS] units; able to perform the tasks outlined without assistance; and physically able to take care of their own biological needs during the course of the testing (e.g. did not need personal care attendant).

Of those who volunteered and were appropriate for the study, the actual response rate was very low: 12%. This initial group of volunteer subjects, Group 1 (n = 11). Group 2 was an additional 9 subjects recruited on a later date and went for immediate testing: when they arrived at the partner clinic, they were asked if they would like to participate and if they agreed they were immediately tested (n = 9).

Controls were recruited from the same patient population but did not have chronic pain, but had an even lower response rate (1%), therefore 3 of the aides were tested and included as controls (n = 6). The demographics of the controls were the same as that of the subjects; the demographics and differences between Group 1, Group 2, and Controls are shown in Appendix A.

Testers were blinded to subject information except that which could be observed (gender, race, etc.). Group 1 was evenly split between 2 testers, where all of group 2 testing was done by the primary investigator.

Each subject and control completed a questionnaire which gathered information on exclusions, and demographics, as well as on items about which the data could be confounded or stratified. These possible confounders included: current medications; all of the various medical treatments attempted to control the painful condition; and what activities were avoided due to pain. Those items collected and used for stratification were the demographics. After all forms were reviewed for completion and exclusions, each subject or control began by sitting quietly, and the remote blood pressure/pulse monitors were attached one to each wrist.

VAS Validation Process

Once all monitors were working, an initial reading for blood pressure and pulse were taken, and then the validation process of the VAS was attempted on all subjects. To validate the VAS, a "zero" or "bottom" needed to be established for each subject. As controls do not have chronic pain, they are not included in this part of the study, but proceed with the traditional or

"old," unvalidated VAS for communicating any pain they may have during the functional testing.

The validation process for the VAS begins with each subject being directed to think about his pain, and helped to think specifically about his pain. The questions to get the subject focused on his pain included:

"How long has the subject felt this pain?, When does the pain increase? When does the pain decrease? And – most importantly – when was the last time you felt the lowest pain – the least amount of pain?"

Some of the subjects had difficulty thinking about the <u>least</u> amount of pain, as evidenced by their visual expressions and statements of "I've never thought about that before!" After establishing a bottom point, the researcher reinforced that point by saying or asking;

"Tell me about that time in (Month Year)? What happened before that? What happened that made the pain finally increase again? How did it feel to have so little pain? Are there a lot of things you plan to do the next time you have a day like that, what are some of those things?

After this "bottom," or zero is established for each subject, this lowest point of pain in memory is reinforced and placed firmly front-of-mind of the subject, then came the difficult part for the subject: converting their existing "mental pain scale" to the new analog scale for the study. The conversion instructions to the subjects were:

"Earlier you said your current pain is a 9. Now think of that time you felt the least amount of pain. If that lowest pain is a zero, here (using visual aids, hold the zero as far to the subject's left as possible), how would you rate your current pain now? If your lowest pain is here (hold zero to left, 10 is far to right), and your pain today used to be here on that old scale, where would you put your pain in comparison to that zero?"

Some subjects simply were not able to understand the idea of this new VAS, how taking their own "zero" would alter their pain rating. This difficulty appeared to be closely associated with educational level e.g., those with the lower educational achievement were less likely to be able to grasp the concept of the transition. With the subjects who were not able to grasp the new concept, nothing was done in an attempt to force the issue or push their understanding. It was assumed prior to starting the study that this conceptual task of converting from their existing mental pain scales to a new externally started pain scale would be difficult for some subjects, but it was unknown just how this difficulty would surface; that it appears to closely associate with a person's level of educational achievement was unexpected. Further research is suggested for this issue.

Those subjects who failed validation were unable to use the "new" VAS so they continued to use the traditional or "old," unvalidated VAS to rate their pain. Without establishing a base point for chronic pain patients, there is only "lots of pain," and the patients consistently report high pain all the time, every time they are asked (e.g.,7-10 with the traditional or "old" unvalidated VAS). The subjects who were unsuccessful in their validation of their VAS had ratings clustered in the predictable range at the top of the scale, and their ratings had no comparability. Controls also used this traditional VAS as they have no chronic pain and therefore are not appropriate to validate to this instrument.

Though the unsuccessful validation subjects and controls both used the traditional or "old," unvalidated VAS for the duration of the study, the subjects did not become controls: they were still subjects. These subjects still had chronic pain, they completed all functional measurement tasks as a subject did, were still were grouped in analysis with other subjects, and

were only broken out of one analysis due to their failure in the validation task. The controls did not have chronic pain, so the difference is basic and great.

Functional Testing Process

The functional testing began following validation or validation attempts. Each subject agreed to complete 4 tasks: 2 of timed, 2 at the speed that was most comfortable for the subject. After each task, the subject was asked to report their pain level and their pulse and blood pressure was measured and recorded for each arm. Task 1 was to sit quietly for 3 minutes; task 2 was to stand quietly for 3 minutes (subjects could hold onto a wall but could not lean on it); task 3 was to walk the length of the room and back (approximately 120 feet total); task 4 was to do 10 step-ups (step up 6.5 inches with one foot, step up with other foot, then step down with original foot, step down with second foot = counted as 1 step-up).

All subjects and controls were told that they could stop at any time if their pain became too great; only 1 subject stopped prematurely and that was during the step-ups (after half were completed). After each task, all subjects and controls had blood pressure and pulse recorded for each arm using automatic blood pressure cuffs on each wrist, and both subjects and controls were asked to rate their pain at the same time.

The automatic cuffs were verified as accurate with using a standard blood pressure cuff at least once an hour on using a random subject or control: The automatic cuff used and the standard cuff used were tested against each other immediately after use in a testing session with a subject or control; if there was any variation in the automatic cuff tested, all cuffs were then to be re-calibrated. There never was any variation between automatic cuffs and standard blood pressure cuff, so no automatic cuffs ever needed recalibration either during testing day or between testing days; all automatic cuffs remained accurate throughout testing. The same four blood pressure/pulse cuffs were used on all subjects and controls: there were others available but once these four were in use, there was no reason to remove others from their cases. All cuffs were used interchangeably: no two cuffs were always used together, no cuff was always a left or a right cuff; they were randomly placed on subject/control arms and used throughout the entire experiment in that manner.

There were no breaks once the process started or between tasks (process started with forms); there was no beverage or food allowed in testing site; entire testing process took an average of 15.5 minutes with 12.2 minutes the short measurement and 17.5 minutes the long measurement. All subjects were viewed as "non-obese," and had no difficulty completing the physical tasks; with the pulse confound selected, the principle investigator noted which subjects reached the confound cutoff: one was a former marathoner; another was a former triathlon winner.

Data analysis

The important data for this case-control pilot study is the movement of physiometric measure in relation to the self-reported pain level: "If either the one moves but the other doesn't, the theory doesn't hold and there is nothing to report" (McDonald, p W3, 2009). The data for the functional testing are essentially qualitative-deductive; a hypothesis is being tested, but because of the small n and the small movements, there are few meaningful statistical tests to administer; for example, the confidence intervals for the full sample were so wide as to be statistically meaningless. For the other side of the study, the information about the VAS validation and acceptance by the subjects is entirely qualitative: the subject either understood the validation at the time it was presented, or did not, so there are no statistical tests on that process.

As discussed in the background/literature review section, the physiometric measure of interest was the left systolic blood pressure [SBP], as this was seen in a number of studies as a good proxy measure for pain (Bruehl et al, 1992; Green et al, 2006; Rhudy & Meagher, 2003). Pulse was used as a confounder indicator; if the pulse increased more than 10% between the start and completion, then the physiometric results were viewed as possibly tainted by bias, and that the subjects could have been overly sensitized to pain, or the pain threshold could have altered as a result of the exercise, therefore the results should be viewed with as suspect due to these factors (Koltyn et al, 1996).

Findings/Results

	n	Group's Characteristics	Identifying #'s of Subjects
Group 1	11	Initial recruitment cohort	Subject #'s 1 – 11
Group 2	9	Recruited & immediately tested	Subject #'s 12 - 20
Group 3	5	unsuccessful VAS validation	Subject #'s 1,4,6,8,9 from Group 1
Controls	6	controls	C1 – C6

Only for purposes of analysis, there are three (3) subject or testing groups and a control group, for all other purposes there are only two (2) groups and a control group. As shown above in the explanatory table, the subjects are initially divided into Groups 1 and 2 based on their recruitment: Group 1 is the group that responded to the initial recruitment and had a response rate of 12% for showing up on the scheduled date; Group 2 was recruited a month later when they came in for treatment, and upon confirming their interest, were immediately taken for forms and testing (all of Group 2 subjects had expressed interest in participating in the study to clinic staff at the time of initial recruitment but couldn't enroll due to the times the study testing was scheduled); Group 3 is a group that is not discrete but is made up of the participants of Group 1 who failed the VAS validation task.

For all but one part of the analysis, Group 3 is with their recruitment cohort, their "group of origin." Only for the single analysis of the effectiveness of VAS communication when combined with the results of the functional testing is Group 3 separated out (images 7 and 8 in linear regression). For all other analysis, Groups 1 and 2 and Controls are the three groups of the study.

As previously explained, controls (no chronic pain) and Group 3 (failed validation of VAS) used the traditional or "old," unvalidated VAS for all pain reporting: there is no comparability between their pain reports and that of anyone else's. All other subjects utilized the new validated VAS; therefore all pain reports for these subjects are comparable across episodes and also between different people (i.e., both intra- and inter- personally).

A summary of a subject's average results from the functional testing is found in appendix B, showing movement in the subject's SBP and pain ratings in table 3a; the control's results are shown in table 3.. Then the data is summed to create an "average subject" overall and for each task to provide comparisons for the individual subject's averages. The "average subject" had a average change of SBP of 35.95 from the starting task (sit) to the final task (step ups), with an average change in pain overall of 3.7 units using the validated VAS; in comparison, the controls

showed an average change in SBP (33.17) but had less than half the average increase of pain using the unvalidated VAS that the subjects reported using the validated VAS.

Table 4 stratifies the subjects functional testing data by a number of factors, the ones showing the greatest differences were gender, race and marital status: - women had a 72% greater increase in SBP and a 50% increase in pain (all subjects combined for this stratification); non-white subjects had a 67% increase in SBP but had lower pain than white subjects; and ever married (married, divorced, widowed) had a higher SBP but lower pain than never marrieds. These stratifications do create some questions about linkage between the high SBP and the high pain, but the difference comes down to the differences between the demographic makeup of Group 2 and Group 1, and also between those who understood the VAS validation and those that did not: There were more people in Group 1 who were ever married but who also failed VAS validation, thus their pain reports were not within the theoretical process of the paper.

Appendix C has a number of linear regression examples that show the relationships between the dependent variable – the SBP, on the Y axis – and the independent variable – the pain report, on the X axis. These regression examples provide distinct examples of how the theory of pain measurement is working, and what can be done differently in additional research to better improve the fit of the linear equation to the data. It also shows in one paired set of regressions how well the two theories work together: the theory of functional measurement of the pain and the validated VAS to strengthen the communication of that pain.

Image 1 is a linear regression of all subject's data from completion of all tasks. This relationship is linear of moderate strength, with a positive slope of 1.65. This is considered moderately strong on the basis of the slope, and on basis of the high r^2 value of .0514 when compared to other examples within this data set. In the sets where the inconsistent data are removed: those who did not understand the VAS validation, those who had an exercise response to the tasks, then the relationship is stronger, the slope is higher and the results are clearer.

Image 2 is the linear regression of the control's data, which shows a negatively linear response consistent with the theory as they did not experience increased pain as their task's difficulty increased. And they were using the old, unvalidated VAS for their pain reports.

Images 3 and 4 are for Group 2 and Group 1, respectively. Group 2 (n = 9) is demographically very different from Group 1 in terms of educational achievement, income, and age. In image 3, this is one of the strongest relationships shown, with a slope of 4.58, and an r^2 of 0.4774 for the Group 2 subjects, all of whom understood the VAS validation. In contrast, the image for Group 1 is image 4 which shows a negative slope of -0.10, and an r^2 of 0.0002. The negative slope, the very low r^2, and negative linear relationship is consistent with only 6 of the 11 members of Group 1 being successful on the VAS validation task, and being able to use the new VAS to communicate their pain level, and the remaining 5 being unable to communicate as accurately as the other 6 of their subjects were able to do: The inability to accurately communicate the pain of 45% of the group altered the slope of the groups result.

Images 5 and 6 are for the subjects who experienced an exercise effect (their pulse increased by more than 10% as they performed their tasks, n=8) and those who did not experience an exercise effect (no change in pulse to a change in pulse less than 10% overall, n=12). In the exercise effect group, image 5, the slope is 2.7 and the r^2 is 0.171, but there is a potential confounding here causing a change in the physiometric results and in the pain, so the results for anyone with this possible exercise confound should be excluded, but are noted and included here for complete analysis of the results. Image 6 shows no exercise effect and has a negative slope of -0.07 and another very low r^2 of 0.0034, which is very nearly a horizontal line:

The reasons for this nearly horizontal line are again related to the failure to validate VAS and the incomplete communication of many subjects' pain reports (all of the Group 3 members are in this group).

Images 7 and 8 are for those subjects who understood the VAS validation concept (n=15) and those who did not, Group 3 (n=5). In image 7 shows the results for all who understood the validation VAS: this is the second strongest linear relationship with a slope of 1.9 and an r^2 of 0.0665, and has the greatest volume of data to illustrate the theories of functional pain measurement and the theory of the validated VAS for chronic pain patients are viable theories which deserve further investigation.

Image 8 is for Group 3 subjects, those that failed the VAS validation task. These subjects still completed all their functional testing tasks but their pain data has no individualized start/bottom point, and thus it clusters in the predictable fashion just above 6 on the scale (one subject gave all ones, thus the points at the bottom). For this group, the slope was still positive at 1.1221 and the r^2 is 0.0173 but the relationship is not strong, as the line is a step away from a horizontal line.

The theory of functional pain measurement is strengthened by the of use of the validated VAS with a chronic pain population which improves the level of communication about pain for these individuals, as shown by the strength of relationship shown in image 7, and the poor relationship shown in image 8. Further, the difference between the images 7 and 8 highlights the power that using the validated VAS can bring to the communication of the pain, especially within a specialized testing process such as this functional testing study, where the validated VAS created a stronger relationship with the functional testing result than does the unvalidated VAS.

Finally, images 9a through 9d show the individual tasks as performed by all subjects (n=20 on each). The sit task is negatively linear, but that appeared to be an artifact of the testing environment than anything related to the theory: the Group 1 subjects all had higher initial SBP readings than sit SBP readings, because the forms were creating stress for the subjects due to the educational achievement issues present in Group 1: the subjects were not completing the forms but just flipping pages, so testers assisted with completion of the forms. So the initial SBP was removed from the data and removed from the linear equations. By removing this initial result, the sit task then showed as negatively linear where all other tasks were positively linear.

The combined linear regression graphs show that theory has some strong promise, and could be true: pain could be functionally measured through use of physiometric proxies for pain, and a new, personally validated VAS could allow more nuanced communication about pain.

Despite the problems with the data and the small sample size, this pilot study was able to show proof of concept – that subject's pain could be accurately measured using functional tests and physiometric proxies for pain. The linear relationship shown highlights that this is a predictable change in pain response with each task, and that this could be used in a DDP setting if it is confirmed with a larger study.

Discussion/Implications

This was only a case-control pilot project, with a small n: only 20 subjects were eligible to complete the tasks, and only 6 controls were appropriate for testing. Of those 20 subjects, only 15 understood both tasks of the research study: to complete physical tasks so as to measure pain through physiometric proxies, and to validate and re-calibrate pain using a VAS designed specifically for use with the chronic pain population. 15 subjects is not sufficient to do more

than validate proof of concept, which was done in this pilot study, but further research is necessary on both questions.

Any additional research must be done in a setting so that the proof of painful condition responding to the stimuli in functional test is confirmed, i.e., the tasks cannot be divorced from the physiometric measure, but they must remain linked so as to prove the disability of the individual.

The VAS individual validation must be done in a setting where the preference elicitation of the subject is confirmed, and the re-rating of the current pain is understood by the subject: this may become an issue that confounds on educational achievement, but it was unclear in this pilot study if it was truly educational or simple wording or phrasing may also be an issue.

A full case-control study should be run, partnering with a pain clinic that is based in a local large educational medical center which would allow for selection of controls from the same demographic population as that from which the pain clinic draws. This full study may determine if the theory of chronic pain measurement is possible, and if the newly validated VAS is effective for communication of pain, as well as interpersonal and between episode comparability of pain in that setting.

By being able to consistently and objectively measure pain for patients who are in chronic pain, and being considered for disability, this new process and new VAS tool may allow something not previously possible: comparisons to be made both between times of pain within an individual, and between pain episodes across individuals.

The hope is to standardize the evaluation of process so that pain is considered as either an additive component of a disabling illness/injury, or as a primary disability, with supporting, secondary disabling diagnoses. This could advance the process of disability determination and evaluation for the SSA and VA and eliminate any subjectivity from the process.

The power that the validated VAS brings to the functional testing of pain was shown in the linear regressions, especially in images 7 and 8. In a DDP or similar specialized testing process where this functional testing and the validated VAS could come together, they would create a stronger relationship that the functional testing alone or the functional testing with the unvalidated VAS, as shown in the regressions: the validated VAS strengthen the subject's ability to communicate their pain to the researcher or tester, and this strengthening would improve their results in a possible predictable fashion if this pilot study's results hold up in the next study.

 The results of a combined function physical testing with a validated VAS would be comparable from one person to person because of the validity of the VAS instrument, and of the process: it all starts from zero, so it is all on the same scale for each person going through the process. Used together in a DDP setting, this functional testing of pain process combined with the validation of VAS responses together could make a scalable process by which pain could be used to determine one piece of the disability process rather than just a note or a subjective measurement of the disability claimant's authenticity of claim.

By using a transparent process of objective, consistent, and reliable testing for all individuals who are requesting disability status due to their pain, the Social Security Administration and the Veterans Administration could also respond consistently and objectively that: a score of eight*X (8X) is the threshold for pain that is disabling, seven*X (7X) is borderline, and five*X (5X) is additive to an existing disorder but is not a disability of primacy.

This scalability could move the process of disability rating into an area that would be understandable by the average person. It would take some parts of this process and make it entirely transparent -- so the people who most need to know will know what can happen to them,

and under what circumstances. Having some knowledge of the potential pitfalls makes the future easier to bear.

Pain is poorly understood. This case-control pilot study of objectively measured pain and functionally, consistently, and objectively proves that pain exists and takes the results of the pilot study as simple "proof of concept," but recommends that additional research be done on a full sample.

The full sample case control study's results would increase generalizability, decrease confounding, and improve the scalar predictability of the DDP process. Once a full study is completed, the entire process can be adapted to be used by the Disability Determination Process teams, to be use in the actual testing of individuals applying for Social Security Disability, as well as the Veteran's administration, as the results of a full study would expand the results to be fully generalizable across all subjects or patients.

The scientific questions are: can pain be objectively and functionally measured so as to be included within an evaluation in a disability determination process [DDP]; and is it possible to validate a visual analog scale [VAS] for use with the chronic pain population to improve the communication of their pain throughout the DDP, as well make the pain comparable across episodes within the patient, and across patients, both in DDP and in clinical settings.

The answers to the both questions are a qualified yes - It is possible to objectively measure pain, and it is possible to validate a VAS for use with a chronic pain population. In both cases there are data limitations because this was only a pilot study to test the feasibility of the concepts, and a much larger, full study must be done to confirm all results and make them generalizable to the full population. A full study will determine if the theory of chronic pain measurement is valid, and if the newly validated VAS is effective for communication of pain in that setting.

References

Acute Pain Management Guideline Panel (1992). Acute pain management: Operative or medical procedures and trauma: Clinical practice guideline. *US Department of Health and Human Services.* Washington DC.

Arnstein, P. (2012) *MEDSURG Nursing. Nov/Dec 2012, 21*/6, 388-388

Beard, D.J., & Aldington, D. (2012). Chronic pain after trauma. *Trauma. Jan 2012 14*/1, 57-66.

Bird, S., & Dickson, E. (2001). Clinically significant changes in pain along the visual analog scale. Annals of Emergency Medicine; 38: 639–643

Breivik E., Björnsson G. & Skovlund, E. (2000). A comparison of pain rating scales by sampling from clinical trial data. *Clinical Journal of Pain*; 16: 22–28.

Bruehl, S., Carlson, C.R., & McCubbin, J.A. (1992). The relationship between pain sensitivity and blood pressure in normotensives. *Pain, 48*; 463-467.

Choate, K., McDonald, W., & Scott, D. (2011). Pain management. *Australian Nursing Journal,* 18/11, 40-40

Choiniere, M., & Amsel, R. (1996). A visual analogue thermometer for measuring pain intensity. *Journal of Pain and Symptom Management, 11*; 299-311.

Ditto, B., Lavoie, K.L., Campbell, T., Gordon, J., Arsenault, A., & Bacon, S.L. (2010). Negative association between resting blood pressure and chest pain in people undergoing exercise stress testing for coronary artery disease. *Pain*, 149; 501-505.

Frampton, C.L., & Hughes-Webb, P. (2011). The measurement of pain. *Clinical Oncology. 23*; 381-386.

Ferreira-Valente, M.A., Pais-Ribeiro, J.L., & Jensen, M.P. (2011). Validity of four pain intensity rating scales. *Pain.152*; 2699-2404.

Freyd M. (1923). The graphic rating scale. *Journal of Educational Psychology*; 14: 83–102

Green, A.L., Wang, S., Owen, S.L.F., Xie, K., Bittar, R.G., Stein, J.F., Paterson, D.J., & Aziz, T.Z. (2006). Stimulating the human midbrain to reveal the link between pain and blood pressure. *Pain, 124*; 349-359.

Hayes M, & Patterson, D (1921). Experimental development of the graphic rating method. *Psychology Bull*; 18: 98

Hollen, P., Gralla, R., Kris, M., McCoy, S., Donaldson, G.,& Moinpour, C. (2005). A comparison of visual analogue and numerical rating scale formats for the Lung Cancer Symptom Scale {LCSS): Does format affect patient ratings of symptoms and quality of life? *Quality of Life Resident*; 14: 837-847.

Huber, A., Suman, A.L., Rendo, C.A., Biasi, G., Marcolongo, R., & Carli, G. (2007). Dimensions of "unidimensional" ratings of pain and emotions in patients with chronic musculoskeletal pain. *Pain. 130*; 216-224.

Jensen-Hjermstad, M., Fayers, P.M., Haugen, D.F., Caraceni, A., Hanks, G.W., Loge, J.H., Fainsinger, R., Aass, N., & Kaasa, S. (2011). Studies comparing numerical ratings scales, verbal ratings scales, and visual analogue scales for assessment of pain intensity in adults: A systematic literature review. *Journal of Pain and Symptom Management, 41*; 1073-1093.

Kane, R.L., Bershadsky, B., Rockwood, T., Saleh, K., & Islam, N.C. (2005). Visual analog scale reporting was standardized. *Journal of Clinical Epidemiology, 58.* 618-623.

Kersten, P., Kucukdeveci, A., & Tennant, A. (2012). The use of the visual analog scale (VAS) in rehabilitation outcomes. *Journal of Rehabilitation Medicine.* 44; 609-610.

Kind, P., Dolan, P., Gudrex, C., & Williams, A. (1998). Variations in population health status: results from a United Kingdom national questionnaire survey. *British Medical Journal, 316*; 736-741.

Koltyn, K.F., Garvin, A.W., Gardiner, R.L., & Nelson, T.F. (1996). Perception of pain following aerobic exercise. *Medicine and science in sports and exercise. 28*; 1418-21.

McDonald, J.H. (2009). *Handbook of Biological Statistics, 2nd Edition (Online Edition)*; Sparky House Publishing. Baltimore.

McNamara, M.C., Harmon, D., & Saunders, J. (2012). Effect of education on knowledge, skills, and attitudes around pain. *British Journal of Nursing, 21/*18, 958-964.

Majid, A. (2013). I can't cope with this back pain any longer. *Pulse, Feb 2013*, 54-55

Nyman, J.A., Barleen, N.A., Dowd, B.E., Russell, D.W., Coons, S.J., & Sullivan, P. (2007). Quality-of-life weights for the U.S. population: Self-reported health status and priority health conditions. *Medical Care, 45*; 1143-1153.

Parkhouse, J. & Holmes, C.M. (1963) Assessing post-operative pain relief. *Processes of the Royal Society of Medicine, 56.* 579-585.

Rhudy, J.L. & Meagher, M.W. (2003). Negative affect: Effects on an evaluative measure of human pain. *Pain. 104*; 617-626.

Williams, A.C., Oakley Davies, H.T., & Chadury, Y. (2000). Simple pain rating scales hide complex idiosyncratic meanings. *Pain*. 85: 457-463.

Appendix A
Subject and Control Demographic Information

Gender	13 - Men	7 - Women			
Marital	13 - Single	5 - Married	2 - Divorced		
Race	8 - White	11 - Black	1 - Latino		
Age	2 - 20s	5 - 30s	2 - 40s	6 - 50s	5 - 60s
Income	4 - $0-4K	4 - $9-15K	3 - $25-30K	7 - $35-40K	2 - $60K+
Education	1 - 7th grade	3 – 10th grade	5 – 11&12th grade	10 – 14 to16 yrs	1 – 18 yrs

Table 1a – All Subject's Demographic Data

Subjects: average number of daily prescription medications taken: .72*
*A number of the subjects noted "can't recall" on medication list even though this was mailed to them, and they brought with them on the day of the study. Many of group 1 reported during testing taking a number of medications not listed, for ailments also not listed.

Gender	10 - Men	1 - Women			
Marital	7 - Single	4 - Married			
Race	3 - White	7- Black	1 - Latino		
Age	1 - 20s	2 - 30s	---	3 - 50s	5 - 60s
Income	4 - $0-4K	3- $9-15K	2- $25-30K	2 - $35+	
Education	1 - 7th grade	3 – 10th grade	4 – 11&12th grade	2 – 14-16 yrs	1 – 18 yrs

Table 1b – Group 1 Subject Demographic Data

Gender	3 - Men	6 - Women			
Marital	6 - Single	1- Married	2 - Divorced		
Race	5 - White	4 - Black			
Age	1 - 20s	3 - 30s	2 - 40s	3 - 50s	
Income	---	1 - $9-15K	1 - $25-30K	5 - $35-40K	2 - $60K+
Education	---	---	1 – 11&12th grade	8 - 14 -16 yrs	

Table 1c – Group 2 Subject Demographic Data

Gender	4 - Men	1 - Women			
Marital	4 - Single	1- Married			
Race		5 - Black			
Age	1 - 20s	2 - 30s		1 - 50s	1 - 70s
Income	3- $0-4K	1- $9-15K	1- $25-30K		
Education	----	2 – 10th grade	3 – 11&12th grade		

Table 1d – Group 3 Subject Demographic Data – unsuccessful validations
*5 from Group 1 (#'s 1,4,6,8 & 9)

Gender	5 female	1 male				
Marital	2 single	2 divorced	1 married	1 widowed		
Race	6 white					
Age	1 – 28yo	1 – 55yo	1 – 61yo	1-62yo	1-75yo	1-81yo
Income	3 - $20-23K	1 - $30K	1 - $40K	1 - $100K		
Education	1 – 10th grade	3 – 12th grade	1 – 14 years	1 – 18 years		

Table 2 – Control's Demographic Data
Controls: average number of daily prescription medications taken: 2.83

Appendix B
Subject Results – SBP and pain highs, lows, and stratified by age, gender and race

Subject ID #	avg L SBP	Hi L SBP	Low L SBP	change L SBP	Hi Pain	Low Pain	change pain
3JGSBM20YO	129.6	141	120	21	9	10	1
RJMBF27YO	124.6	152	101	51	3	8	5
3SRSBF29YO	123	139	106	33	1	5	4
3DPMBM33YO	120.2	137	79	58	5	7	2
RCSWF33YO	132.2	150	111	39	3	7	4
MCSBM39YO	121	129	106	23	1	2	1
3RESBF39YO	126.6	154	89	65	1	9	8
LRDBM40YO	143	162	120	42	3	9	6
RRSWM40YO	127.6	141	119	22	4	10	6
LVLMM50YO	161	196	138	58	4	6	2
DRSWM52YO	131.2	146	122	24	2	9	7
JRSWM52YO	146.2	156	132	24	3	8	5
ARSWF53YO	129	144	117	27	4	8	4
ERDWF55YO	136.2	166	121	45	3	8	5
ESSBF59YO	120.4	134	88	46	7	9	2
EJMBM60YO	151.4	181	122	59	3	3	0
DWSWM62YO	129.2	146	115	31	2	9	7
JSMWM63YO	137	147	136	11	7	7	0
EJSBM65YO	123.6	131	115	16	6	9	3
JHSBM72YO	146.2	156	132	24	5	7	2
			Average change	**35.950**		Avg change	**3.70**

Table 3a – Subject Highs and Lows on Systolic Blood Pressure [SBP] and pain, with average change

Control ID #	avg L SBP	Hi L SBP	Lo L SBP	change L SBP	Hi Pain	Low Pain	change pain
NMSWF28YO	85.6	129	106	23	2	2	0
ASMWF55YO	172	187	164	23	0	0	0
GMDWM61YO	108.4	117	104	13	2	0	2
MBSWF62YO	119.6	147	102	45	3	2	1
MLDWF75YO	138.8	150	129	21	6	2	4
GSWWF81YO	140	169	95	74	4	4	0
		Average change		33.1667	Avg change		1.16667

Table 3b – Control Highs and Lows on Systolic Blood Pressure [SBP] and pain, with average change

Stratified by Age		Avg Change		Avg Change		n
20-40 yo	L SBP	39.3333	Pain	3.888889		9
50-72yo	L SBP	33.1818	Pain	2.454545		11
20 yos	L SBP	35	Pain	3.333333		3
30 yos	L SBP	46.2500	Pain	3.25		4
40yos	L SBP	32	Pain	6		2
50 yos	L SBP	37.3333	Pain	3.666667		6
60+ yos	L SBP	28.2	Pain	1		5
Stratified by Gender						
Men	L SBP	31.7692	Pain	2.307692		13
Women	L SBP	43.7143	Pain	4.571429		7
Stratified by Marital Status						
Single	L SBP	30.3846	Pain	3.461538		13
Married/Divorced	L SBP	46.2857	Pain	2.428571		7
Stratified by Race						
White	L SBP	27.875	Pain	4.75		8
Non-White	L SBP	41.3333	Pain	2		12

Table 4 – Subject results stratified by age, gender, marital status and race
Note: Stratification not done on control data, as it was too small to merit this analysis
Group 3 not broken out in this data as this is not a discrete group
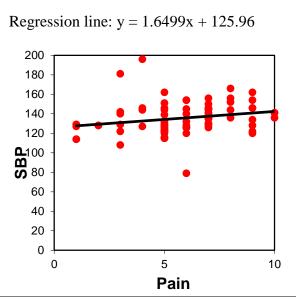
Appendix C
Linear Regression Results

Image 1 – Linear regression of subjects, all tasks:
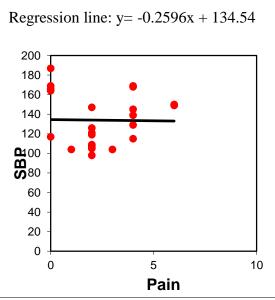Slope = 1.6499, Intercept = 125.96
$r^2 = 0.0514$, p = 0.336

Image 2 – Linear regression controls, tasks:
Slope = -0.2596, Intercept = 134.54
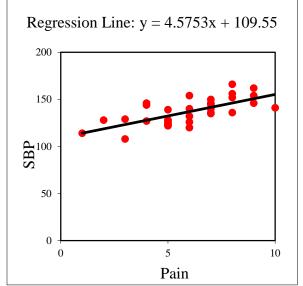$r^2 = 0.000305$, p = 0.974

Image 3 – Group 2 subjects (n=9), all tasks:
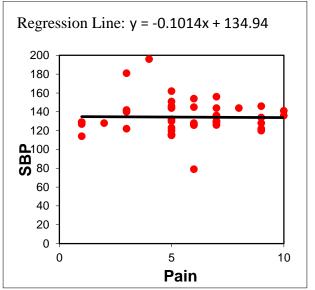Slope = 4.5753, Intercept= 109.55
$r^2 = 0.4774$, p = 0.039

Image 4 – Group 1 subjects (n = 11), all tasks:
Slope = -0.1014, Intercept = 134.94
$r^2 = 0.0002$, p = 0.969

Regression Line: y=2.7383x+119.13

Image 5 – Exercise effect (n = 8):
Slope = 2.7383, Intercept = 119.13
r^2 = 0.171, p = 0.308

Regression Line: y = -0.0745x + 136.12

Image 6 – No exercise effect (n = 12):
Slope = -0.0745, Intercept = 136.12
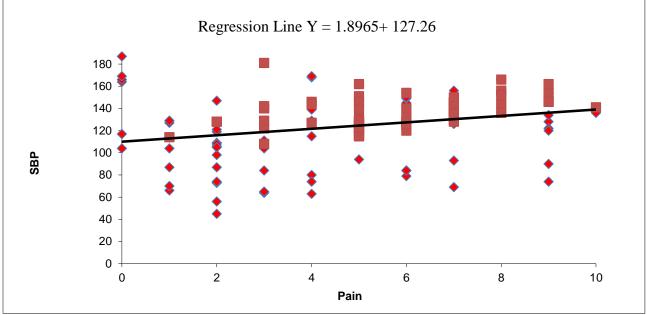r^2 = 0.0034, p = 0.723

Understood the VAS validation process

Image 7 – VAS Understood (n = 15):
Slope = 1.8965, Intercept = 127.26
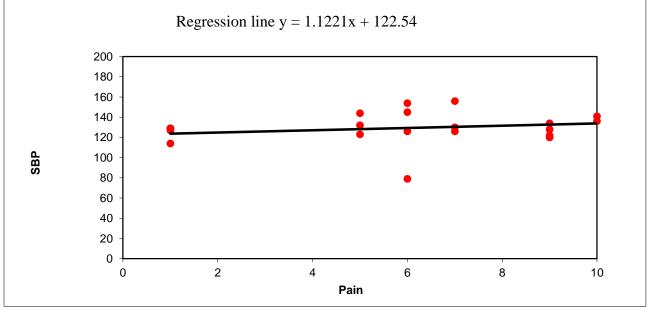$r^2 = 0.665$ p = 0.483

Failed to understand VAS validation

Image 8 - VAS Fail (n = 5):
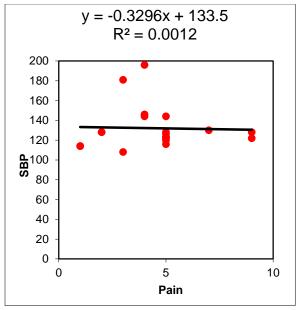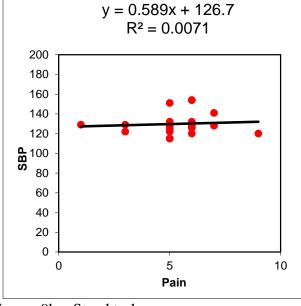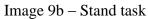Slope = 1.1221, Intercept = 122.54
$r^2 = 0.0173$, p = 0.571

y = -0.3296x + 133.5
R² = 0.0012

Image 9a – Sit task

y = 0.589x + 126.7
R² = 0.0071

Image 9b – Stand task

y = 1.0647x + 127.7
R² = 0.0198

Image 9c – Walk task

y = 1.4488x + 135.5
R² = 0.0882

Image 9d – Step-up task