

# Evaluating Pain in Orthopedic Patients: Can the Visual Analog Scale be used as a Long-term Outcome Instrument?

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## Abstract

**Study background:** An analysis of the relationship between visual analog scale (VAS) pain scores and Likert pain scores over a period of up to a year in patients who sustained a distal radius fracture (DRF) in order to assess the reliability of using a VAS pain score as a long-term outcome instrument.

**Methods:** Retrospective review was performed of prospectively collected data on all DRF's treated at our institution from 2010-2012 with consented patients. At the initial and each follow-up visit, patients indicated their level of injured extremity pain at rest by using a VAS (VAS-Rest) and when actively using the extremity (VAS-Active). At followup visits, patients completed a question asking what their perceived change in injured wrist pain was since their last orthopedic visit. This "Change in Pain" (CP) question consisted of a five-level Likert item. Patients' clinic visits were grouped into independent data sets consisting of 3 data points (VAS-Rest, VAS-Active, and CP score). Incomplete data sets were excluded. The difference in VAS pain scores between consecutive visits and the CP score were compared using Spearman's correlation coefficient and linear regression analysis.

**Results:** A total of 74 DRF patients and 119 complete two-visit data sets were included in the study. CP scores and VAS-pain scores were collected at periods of two weeks, four weeks, six weeks, eight weeks, three months, six months, and one year post treatment. Spearman's correlation coefficients between VAS pain scores and patients' CP score were minimal ( $r < 0.3$ ). Linear regression analysis showed a weak relationship between VAS pain scores and CP scores.

**Conclusion:** Although VAS pain scores play a vital role in assessing pain in the short-term setting, the VAS seems to be a poor instrument for comparing treatment outcomes of long-term orthopedic interventions. Multi-dimensional pain questionnaires may be preferable for assessing long-term orthopedic outcomes.

**Key words:** Long-Term pain; Visual analog scale; Likert pain scale; Outcome measures; Orthopedics; Fractures

## Introduction

In the United States, pain is a leading public health problem affecting more than 50 million Americans at an annual cost in excess of \$260 billion dollars [1]. This translates into 70 million healthcare visits a year, making pain the leading cause of health care utilization. This is especially true in the field of orthopedics, where pain, acute and chronic, is a leading reason why patients seek medical care. Since pain is a frequent complaint of orthopedic patients and, in one study, the amount of postoperative pain patients experienced was the best predictor of patient satisfaction and their perception of treatment helpfulness; the majority of studies assessing orthopedic conditions use patients' pain intensity as the primary outcome measure [2]. However, accurately assessing levels of pain has proven to be a clinically challenging objective.

Randomized and non-randomized clinical trials are commonly used to determine the clinical effectiveness of medical treatments, where a standardized outcome measure typically serves as the criterion to gauge a patients' response to treatment. Consequently, the outcome measure used to demonstrate treatment effectiveness plays an important role in our ability to provide the best care for our patients. In order to facilitate the practice of evidence-base medicine (EBM), a system to uniformly compare different treatments and their outcomes is needed. Additionally, these outcome measures should ideally be patient-centered, accurate, easy to use, consistent, and highly reliable [3-5]. In orthopedics, the practice of EBM has been challenging to implement in everyday practice because of the varied and rapidly expanding number of treatment options available for each individual condition. Consequently, outcome instruments are constantly being developed and improved to objectively and reliably quantify patients'

subjective and functional outcomes [6-9].

Pain assessments rely on self-reported measures intended to quantify the qualities of pain, such as intensity. One of the most commonly used methods to assess pain is through the use of a visual analog scale (VAS), which is a single-item measure of pain and consists of a 100 millimeter (mm) horizontal line with the labels "No Pain" at the leftmost portion and "Worst Pain" at the rightmost portion of the line [10]. Patients are then instructed to mark at a specific location along the line at a point which accurately characterizes their pain intensity [11,12]. The VAS pain score (VAS-pain) is obtained by measuring how far, in millimeters (mm), the patient mark is along the line starting from the leftmost end ("No Pain" point, 0 mm) with the worst/highest pain intensity being at the rightmost end ("Worst Pain", 100 mm). It is thought that the advantages of using a VAS for measuring pain over a numeric pain scale is that it allows for a wider range of responses, requires no reading skills, and is versatile enough to be used in multiple settings [13]. However, there are limitations to using the VAS for measuring pain as critics often cite the difficulty patients have in converting a pain quality, like their pain intensity, into a linear format through a single marking on a

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horizontal line, as well as trouble with understanding the instructions [12,14]. This difficulty in understanding the complexity of the scale has resulted in non-compliance rates ranging from 7% to 26% being reported [11]. Furthermore, it has been found that photocopying VAS response scales can change the length of the scale by several millimeters [15].

Studies in clinical research routinely use a VAS to document and track changes in pain over a period of weeks to years, yet previous studies have only validated the use of VAS-pain in the clinical setting over very short-time periods, with the test being administered multiple times within a 24-hour period [11,12,16-18]. To our knowledge, no study has validated the utility of the VAS-pain as a long-term outcome measure in any setting. The aim of this study was to analyze the relationship between pain measurements obtained using a VAS in patients who underwent treatment for a distal radius fracture (DRF), with a patient's perceived change in pain over a long-term follow-up period of up to one year.

## Methods

Retrospective review was performed of a prospectively collected database of all DRF treated at our institution by our hand/upper extremity physicians between October 2010 and December 2012. This DRF database is part of an ongoing, IRB approved study, designed to prospectively track patient outcomes; patients are eligible for enrollment into this database if they are above 18 years of age, have sustained a DRF with or without an ulnar styloid fracture, and underwent operative or non-operative treatment. Patients are excluded if they have a concurrent ipsilateral wrist or hand injury, bilateral upper extremity injuries, or a history of prior DRF on either extremity.

At time of enrollment and at each follow-up visit, several outcome measures are obtained, which include the Disability of the Arm, Shoulder and Hand (DASH) questionnaire, the SF-36, hand and wrist range-of-motion, and pain intensity using a VAS. Patients are asked to indicate their pain level in the injured extremity at rest using a VAS (VAS-Rest), and when actively using their injured extremity (VAS-Active). In addition, at the follow-up visits patients also complete a custom-made questionnaire, which includes a question asking, "how much has your wrist pain changed since your last orthopedic visit?". This question, termed "Change in Pain" (CP), consists of 5 answer choices in a Likert scale: "Much less pain", "A little less pain", "No change in pain", "A little more pain", and "Much more pain". The timing of follow-up visits was not standardized for all patients, but was done in accordance with the current standards of care. Typically, patients were seen for follow-up after initial treatment or surgery at 2 and 4 weeks; and 2, 3, 4, 6, and 12 months. Patients are not seen for follow-up greater than one year after sustaining the DRF. All patients in the DRF database were included for analysis.

## Statistical analysis

Pain data from individual patients was grouped into individual data sets consisting of 3 data points: 1) initial visit VAS-pain score (resting or active), 2) follow-up VAS-pain score (resting or active), and 3) follow-up CP score. For the data sets to be considered complete, the two pain scores must correspond with the visits addressed by the CP question (i.e. both VAS pain scores were obtained in the previous and current clinic visit when answering the CP question). Based on the Likert scale, the CP score was defined as 1="much less pain", 2="a little less pain", 3="no change in pain", 4="a little more pain", 5="much more pain".

To evaluate the relationship between the VAS and CP scores, data sets from all patients were pooled together and collectively analyzed.

Data sets were excluded if at any follow-up visits the patient did not indicate their CP score, as well as visits where either of the VAS-pain levels was not marked. After exclusions, the remaining data was analyzed through the calculation of Spearman correlation coefficients between change in VAS-Rest/Active scores between concurrent visits, and CP scores for the latter of those concurrent visits. Linear regression analysis was performed to further characterize the relationship between the VAS-Rest/Active scores and CP score. A p value of less than 0.05 was considered significant.

## Results

A total of 74 patients were included in this study, with a mean age of 54 years (standard deviation, 14.63; range, 19 to 82 years). From these patients, 17 were treated non-operatively, and 57 were treated operatively. There were 54 females and 20 males. From these patients, a total of 280 visits were obtained, of which 42 (15%) were excluded due to a lack of at least one of the three necessary data points for a complete data set. This resulted in 238 complete data sets available for analysis, each with a VAS-Rest/Active score, and 119 visits with a CP score. The mean and standard deviation (SD) of total follow-up time (i.e. time from first to last visit) was 6.85 (3.97) months, and the mean time interval between pain scores (i.e. follow-up visits) was 3.16 (1.42) months. Each patient contributed an average of 1.62 complete data sets (SD, 0.88; median, 1; range, 1 to 4) for final analyses. The means and standard deviations of total follow-up time, time between follow-up visits, and number of complete data sets per patient, can be found stratified by age and sex in Table 1.

Descriptive statistics for the changes in VAS-Rest/Active scores and their corresponding CP response are shown in Table 2. Of note, the mean and median VAS scores for both VAS-Rest/Active scores became increasingly separated as the CP scores moved more toward the extremes (i.e. much less/more pain), and standard deviations of the mean VAS-Rest/Active score changes increased as well.

Spearman's coefficient showed low correlation between patients' CP score, and change in VAS-Rest and VAS-Active pain scores ( $r=0.237$  and  $r=0.251$ , respectively [ $p=0.01$ ]). Additionally, changes in VAS-Rest and VAS-Active pain scores showed poor correlation ( $r<0.2$ ) with patient age at the time of fracture. A paired t-test failed to show a difference

	Mean (SD) Total Follow-Up Time (Months)	Mean (SD) Time Interval Between Follow-Up Visits (Months)	Mean (SD) Number of Complete Data Sets
Sex			
Male	6.58 (3.4)	2.93 (1.36)	1.8 (1.05)
Female	7.38 (4.16)	3.31 (1.44)	1.58 (0.90)
Age (years)			
19-40	6.67 (3.5)	3.81 (2.46)	1.25 (0.43)
41-60	7.58 (3.8)	3.33 (1.43)	1.65 (0.81)
61-82	6.83 (3.7)	2.80 (1.34)	1.90 (0.90)
Legend: (SD) signifies standard deviation. "Mean Total Follow-Up Time" signifies the time interval between a patient's first and last clinical visit. "Mean Time Interval Between Follow-Up Visits" signifies time between collections of two consecutive VAS-Rest/Active pain scores. A "Complete Data Set" signifies a two-visit data point, whereby one "Change in Pain" (CP) score, and two VAS-Rest/Active scores were collected.			

**Table 1:** Descriptive statistics of total follow-up time, time interval between follow-up visits, and number of complete data sets, stratified by sex and age (19-40, 41-60, 61-82).

CP Score	Number of Comparisons Made	Mean Change of VAS-Rest Score	Median Change of VAS-Rest Score	Mean Change of VAS-Active Score	Median Change of VAS-Active Score
"Much less/more"	61	11.6 (14.0)	5.5	20.4 (19.6)	12.5
"A little less/more"	35	4.4 (5.2)	3.0	3.7 (8.5)	6.0
"No change"	23	0.44 (0.5)	0.3	1.2 (1.3)	0.9

Legend: (SD) signifies standard deviation.

**Table 2:** Descriptive statistics of VAS-Rest/Active scores (0-100, mm) and corresponding "Change in Pain" (CP) Scores. Means, standard deviations, and medians are expressed as magnitude changes

( $p > 0.05$ ) between change in VAS-Rest/Active Pain scores when compared by operative and non-operative treatment. Furthermore, linear regression analysis showed that the relationship between VAS-Rest/Active scores and CP score was relatively weak, with an increase of a single point in the CP score (i.e. a patient reporting an increase in pain since their last visit) associated with only a change in the VAS-Rest score of 1.9mm (out of 100 mm total, SE 0.635 mm,  $p = 0.003$ ) and a change in the VAS-Active score of 1.2 mm (SE 0.428 mm,  $p = 0.006$ ).

## Discussion

The utilization of the VAS as a single-item measure to quantify pain continues to gain popularity. In a recent systematic review article by Litcher-Kelly, et al., (2007) which sought to identify the most frequently used pain assessment measures for quantifying chronic musculoskeletal pain in clinical trials, 1476 original research articles were examined, of which 50 studies met the selection criteria. Of the eligible studies, 44% used a single-measure item to assess pain as an outcome, and 64% included pain as their primary outcome. Furthermore, the pain outcome measure most frequently used (60%) in the 50 studies was the VAS and, more importantly, in 20% of these studies the VAS was used as the sole pain outcome measure [10]. The high prevalence and dependence upon the use of the VAS to quantify pain in clinical research is likely due to its quick completion time and high short-term intra-rater reliability [17]. Nonetheless, our results demonstrate that utilizing the VAS for measuring pain has limitations when used as a long-term outcome instrument.

Much criticism for the use of a VAS as a single-item measure to evaluate pain stems from the difficulty patients have with accurately quantifying their pain. This is highlighted by the fact that the VAS presents pain as a linear "phenomenon" or as having a linear relationship. However, patients may not experience pain in this fashion, and consequently may be expressing an exponential relationship on a linear scale. For example, it may not be accurate to assume that a score of 6 represents a pain intensity that is exactly twice as much as a score of 3. Therefore, it may be inappropriate for us to think of pain on a ratio scale. While Myles et al. found that patients rated changes in pain linearly on the VAS, this study focused solely on acute, short-term changes in pain, meaning the results cannot be extrapolated to long-term outcomes [19]. Furthermore, the VAS treats pain as a one-dimensional entity, but chronic long-term pain is likely multi-factorial [10,20]. This is evidenced by the abundance of multi-dimensional pain questionnaires that have been developed and validated, as well as their frequent use in studies that evaluate long-term pain [21-24].

It is believed that the VAS has very good intra-rater reliability when measuring pain because although patients interpret pain differently, the internal scale by which they judge their own pain is relatively constant. This was demonstrated by Price et al. when he applied a thermal

stimulus at incremental degrees which yielded appropriate, incremental changes in patient VAS pain scores reported [16]. However, no published literature has called into question this "internal scale" when asked to produce VAS-pain scores greater than 24 hours apart, despite the fact that the VAS pain score is a widely used measure in long-term studies to assess treatment outcomes. Consequently, this study aimed to look at VAS-Rest/Active scores and their correlation to patients' stated "change in pain" between follow up visits over a period of up to 1 year.

This study's results show a very weak correlation between patients' reported change in pain between visits and changes in VAS scores corresponding to those visits. Additionally, from linear regression analysis, the minimal changes in VAS scores that significantly correlate with CP score are only +/- 1.9 mm for VAS-rest and +/- 1.2 mm for VAS-active. Despite a positive correlation, these changes on the VAS scale are small and likely indicate a misrepresentation by the VAS of pain experienced by patients in the long-term. Furthermore, change in VAS-pain scores were not found to correlate with patient age, and a paired T test failed to show a difference across treatment groups of change in VAS-pain scores. This study's findings support the theory that the VAS poorly represents changes in pain when administered over durations of time greater than 24 hours. Additionally, it calls into question the validity of using the VAS to compare long-term treatment outcomes as well as the conclusions of studies that used the VAS to assess those outcomes.

There are multiple potential causes of failure of the VAS pain scale over long-term periods that are separate from those that have been elaborated upon for the short-term administration of the VAS. Firstly, it is possible that the "internal scale" by which a patient judges changes in pain has limitations. For example, it is conceivably easier for a patient to compare two pain stimuli when given minutes apart because the previous stimuli is vivid in their memory. However, there may be an amnesic effect when the stimuli are days, weeks, or even months apart. Studies that have focused on the intra-rater reliability of the VAS have failed to demonstrate this reliability in the long-term since they have not focused on periods of time greater than 24 hours [14,25-29].

Secondly, pain is not just an experience with only a sensory dimension, but with emotional, behavioral, and psychological dimensions as well. Investigators must be cognizant of the aspects of pain they aim to evaluate as well as the backgrounds of their patients, their communication skills, and their experiences with pain. The use of the VAS for pain measurement neglects to take this multi-dimensional quality of pain into account. Multi-factorial pain questionnaires like the McGill pain questionnaire or the West Haven-Yale Multidimensional Pain Inventory (WHYMPI) have been validated and extensively used to measure and track long-term patient pain across a variety of illnesses and diseases [21-24,30,31]. These questionnaires take into account factors such as previous experiences with pain, social dilemmas caused by pain, emotional effects due to pain, and behavioral perspectives of pain. The VAS focuses directly on the sensory component of pain experienced, but if the goal of treatment is to reduce all dimensions of pain from the illness or injury, then the VAS may be a poor tool to compare long-term treatment outcomes, especially if one treatment affects one of these omitted factors while the other does not. Instead, a validated questionnaire like the ones previously mentioned should be utilized [10]. While longer surveys may increase patient burden, in the non-acute setting that this study focuses on, it is reasonable to believe that these surveys would likely not result in as great a non-compliance rate as in the acute setting. Lastly, the benefits of obtaining a comprehensive pain measure largely outweigh the potential cost of incorrectly comparing treatments through the assessment of pain with

the VAS.

This study has several limitations. The CP score question did not specify to patients whether they should answer the question with regard to when they were actively using the wrist, or simply at rest, while the VAS was administered separately for both of these instances. Furthermore, it is possible that for patients the range of changes in pain that qualify as “a little” is much less than the range of changes in pain that qualify as “much less/more”. In other words, while “a little” may represent a change ranging from 1-5 mm, “Much less/more” may represent a change ranging from 5-95mm. If it is the case that the CP score responses at the ends of its spectrum encompass a wider range of changes in pain, then this could influence the linear regression results into demonstrating a weak relationship between the VAS and CP score. The increasing difference between mean and median change in VAS-Rest/Active scores, and the standard deviations of the changes in these scores, as CP responses move to the extremes of its scale signify that this may have been a contributing factor to the poor correlations. Another limitation is that the span of time that the CP question referred to was not standardized, meaning that this study may not have assessed a consistent duration of time between visits for patients to rate the change in their previous pain levels. However, the low standard deviation of the average time between follow-up visits suggests that this is not a large concern. Furthermore, since some patients contributed more complete data sets to the analysis than others, these patients could skew the results. This appears unlikely though due to the low mean, median, and standard deviation of the number of complete data sets each patient contributed.

This study challenges the reliability of the VAS pain score in trending changes in pain over long-term treatment periods and calls into question results that used the VAS pain score as the sole primary outcome measure to trend post-treatment pain. Further research with standardized time intervals and in a wider variety of subjects is needed to better evaluate the use of the VAS a long-term outcome measure. When possible, multidimensional pain measures should be used to compare treatment outcomes in addition to a VAS.

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