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# Patient Assessment In Orthopedics: Spine And Trauma

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# **Patient Assessment in Orthopedics: Spine and Trauma**

A Thesis Submitted to the  
Yale University School of Medicine  
in Partial Fulfillment of the Requirements for the  
Degree of Doctor of Medicine

by  
Ferrin Katarina Ruiz  
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## **Abstract**

### PATIENT ASSESSMENT IN ORTHOPEDICS: SPINE AND TRAUMA.

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In many areas of orthopedics, it is important to have the tools to adequately evaluate a patient. It is sometimes challenging to obtain and quantify both objective and subjective data that contribute to the entire picture of a patient. The goal of this research was to work toward improvement in the quality of different aspects of patient assessment in orthopedics.

The first project focused on the use of outcomes measures in reference to low back pain and mobility. Pain and disability were assessed using patient-report surveys, including the Visual Analog Scale (VAS) and the Oswestry Disability Index (ODI). Mobility was measured using an electrogoniometer while the patient performed full range of motion as well as simulated activities of daily living. ODI appeared to be a better predictor of motion than VAS and may be more useful in the clinical setting when considering functional movement parameters.

In the second project, we considered the common practice of assigning limited weight bearing to orthopedic trauma patients at a level I, academic trauma center. We first surveyed experienced physical therapists (PTs) to understand common practice in teaching touch-down weight-bearing (TDWB). We then evaluated patients' ability to learn and maintain TDWB at both discharge and first follow-up appointment. We found that there was no standard practice among PTs and patient inter-step variability was extreme. At discharge, a majority of steps were under a desired weight range of 15-35 pounds, while at follow-up, a majority of steps were over the prescribed limit. A standardized and improved system to teach limited weight-bearing is clearly needed to ensure compliance.

## **Acknowledgments**

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## **CHAPTER 1: INTRODUCTION**

Medicine has excelled into an era of practicing evidence-based medicine (EBM), using current research in making decisions about the care of a patient.<sup>1</sup> EBM integrates clinical expertise, patients' values and preferences, and the best available evidence from the medical research.<sup>1,2</sup> In the field of orthopedics, one of the challenging aspects of clinical research and practice is the ability to evaluate the patient. It is important to be able to measure and assess both the objective data as well as the subjective data to fully understand the patient and his/her outcome.

The most common way of assessing a patient for an orthopedist is to look at the anatomy using a plain radiograph. On one hand an x-ray is incredibly useful for objective data. X-ray machines are common, cost-effective, and there is a universal language to evaluating the image. While it is important to assess structure, there must be a deliberate focus on the patient's subjective commentary.<sup>3</sup> Pain, mobility, and functionality are all crucial components for the patient's well being. The use of outcomes measures can aid in evaluating the complete picture of the patient.

Outcomes measures attempt to assess both function and quality of life for patients from a general health viewpoint or a disease-specific angle. There are upwards of 400 orthopedics outcomes measures for research and clinical use and over 100 used for spine specifically.<sup>3</sup> Using the appropriate measurement is crucial to research. Certain measurements may elucidate different results in a given study. For example, one treatment protocol or intervention may be deemed better than another based on a specific desired end point (i.e. range of motion), but not as good when based on another end point (i.e. pain relief).<sup>3</sup> Also, the use of a disease-specific instrument will have better patient

acceptance as well as show smaller or more important changes over time.<sup>3</sup> Outcomes measures are overall useful in helping researchers and clinicians better quantify subjective data and responses from patients.

While taking the subjective patient-centered aspects into account is incredibly important, we also need to be able to take objective measurements. Recently, there has been a trend towards research in quality improvement. Quality improvement involves four steps including: defining the project, developing guidelines, analysis of problems with implementation efforts, and lastly measurement and evaluation of results.<sup>4</sup> An adequate measurement tool for that last step is crucial to the whole process. Like an x-ray, it must be easily attainable, cost-effective, and easily interpreted. Often, a measurement tool is missing one of these key factors.

Over the last year, two projects were completed to help improve the quality of different aspects of assessing patients in orthopedic practice. The first project focused on the use of subjective outcomes measures in relation to the common complaint of low back pain. Often imaging in conjunction with a pain score is used as a primary guide to patient status. We used a spine specific outcomes measure to more fully understand a patient's state and compared it to a widely used pain score. This was then correlated with the anatomy by using physical range of motion to determine which was a better indicator of anatomic improvement.

In the second project, we examined a common orthopedic practice that is lacking in an adequate objective measurement tool. Surgeons often prescribe limited weight bearing to a patient after lower extremity trauma or surgery to help with the proper

healing of the injury. This skill is taught by physical therapists to the patient, but there is no standard teaching method and or way to assess the patient's ability to learn and maintain proper weight-bearing status. At a level I academic trauma center, we used surveys to determine the teaching methods and level of confidence of the physical therapists. Subsequently, with the use of a new measurement device we measured patients at both discharge and follow-up to determine the current status of weight bearing.

These projects investigated different aspects of patient assessment in two important areas of orthopedics. We examined the importance of a disease-specific outcomes measure as it correlates with low-back pain and range of motion. We then researched the ability for physical therapists to teach limited weight bearing to orthopedic trauma patients. Both the subjective and objective components of patient assessment are important in good clinical research as well as clinical practice.



## **CHAPTER 2:**

### **Abstract**

Lumbar pathology is often associated with axial pain or neurologic complaints. It is often presumed that such pain is associated with decreased lumbar motion; however, this correlation is not well established. The utility of various outcome measures that are used in both research and clinical practice have been studied, but the connection with range of motion has not been well documented.

The current study was performed to objectively assess the postulated correlation of lumbar complaints (based on standardized outcome measures) with extremes of lumbar range of motion (ROM) and functional range of motion with activities of daily living (fROM) as assessed with an electrogoniometer.

Subjects slated to undergo a lumbar intervention (injection, decompression, and/or fusion) were voluntarily enrolled in the study. Pain and disability scores were assessed with Visual Analog Scale (VAS) for axial, lower extremity, and combined axial and lower extremity, as well as Oswestry-Disability Index (ODI). A previously validated electrogoniometer was used to measure ROM (extremes of motion in three planes) and fROM (functional motion during 15 simulated activities of daily living). Pain and disability scores were analyzed for statistically significant association with the motion assessments using linear regression analyses.

28 males and 42 females were enrolled with an average age of 56.8 years (range 18-90). ODI and VAS were positively associated ( $p < 0.001$ ). Combined axial and lower extremity VAS was associated with lateral and rotational ROM ( $p < 0.05$ ), but not flexion/extension or any fROM. Similar findings were noted for separately analyzed

axial and lower extremity VAS. On the other hand, ODI was inversely correlated with ROM in all planes and fROM in at least one plane for 9 of 15 ADLs ( $p < 0.05$ ).

Extremes of lumbar motion and motions associated with activity of daily living are of growing clinical interest. Even though ODI and VAS are associated with each other, ODI appears to be a better predictor of these motion parameters than VAS (axial, lower extremity, or combined) and may be more useful in the clinical setting when considering functional movement parameters.

## Introduction

Lumbar pathology, including degenerative changes, disc herniation, stenosis, and deformity can be associated with axial and/or lower extremity pain which are significant causes of morbidity in our society. As an example, low back pain affects up to 80% of people at some point in their life and is the most common cause of job-related disability.<sup>5,6</sup> A number of treatments, ranging from physical therapy to surgical intervention, have evolved to address lumbar-related issues. Painless range of motion is considered to be one of the primary outcome goals by patient and physician alike.<sup>7-9</sup> Increasing emphasis has been placed on the maintenance / restoration of motion and clinical outcome measures.

Visual assessment is the most common means of assessing lumbar motion in the clinic setting. However, this is fraught with inaccuracies<sup>1,10</sup> and does not necessarily correlate with motion that is actually utilized during activities of daily living.<sup>2,11</sup> In the laboratory setting, goniometer systems have been developed to better define motions.<sup>3,11-14</sup> Although these devices are generally bulky and difficult to translate to the clinical setting, newer systems are more adaptable and have allowed for real-time assessment of extremes of motion (ROM) and functional ROM (fROM) while a patient performs simulated activities of daily living in the laboratory setting.<sup>3,11</sup>

In addition to clinical exam assessments, outcome measures in the form of validated instruments / questionnaires have become widely accepted and used. In fact, we have come to expect such measures in published studies and such measures are probably as important, if not more important, than the radiographic measures that we had previously accepted. As we evolve to this standard, numerous standardized clinical measures have

been described and validated.<sup>3,15</sup> In the lumbar spine, Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) are clearly the most commonly used.

VAS, in its earliest form, appeared in the 1920's and became more widely applied around the 1960's for both research and clinical purposes.<sup>3,16</sup> It involves indicating a point along a scale indicating the level of pain, mood, etc. in any given area. It is a simple, efficient and widely used measuring tool with established reliability and validity.<sup>4,16</sup> In regards to the lumbar spine, either axial or lower extremity pain can be queried.

The ODI is a condition-specific outcome measure for lumbar disorders that was first published in 1980<sup>5,6,17</sup>, and has been shown to have good validity with consistent test-retest reliability.<sup>7-9,18</sup> It consists of 10 questions that gauge disability—the questions ask how the pain is effecting various life activities like sitting, walking, standing, sleeping, etc. Each question is scored and, as with other disability indexes, the higher the outcome percentage, the more disabled the patient is determined to be.

As it has become standard to utilize outcome measures, the correlation between these measures has become of clear interest. For example, a Finnish study showed that there is moderate correlation between pain intensity (as measured by VAS) and lumbar disability (as measured by ODI) ( $r=0.62$ ).<sup>18</sup> In a subsequent follow-up study, this same group found a modest correlation between motion impairment in three lumbar activities and self reported disability.<sup>19</sup> Nonetheless, despite the fact that this and a number of other studies have been conducted in past years examining pain/disability and motion, the correlation between the two has not been well defined.<sup>7,9,14,20-24</sup>

The goal of this study was to characterize relationships between: motion (ROM and fROM assessed with a validated electrogoniometer), pain (assessed with VAS for axial and lower extremity symptoms), and disability (as assessed with ODI). It was our hypothesis that motion would be associated with both pain and disability.

## Materials and Methods

Subjects slated to undergo lumbar intervention (lumbar injection, decompression, and/or fusion) were voluntarily enrolled in the study. Inclusion criteria included: age greater than 18, English speaker, ability to complete a majority of the movement activities, and willingness to participate.

Subjects were instructed on how to complete two self-report surveys to assess pain and disability. The first was a VAS asking separately about axial and lower extremity pain, for which they were asked to indicate a place along a line with numbers zero to ten (zero being no pain and ten being the most pain) for each, giving a possible total of twenty points. The second was an ODI questionnaire that was scored out of 100 percentage points.

A combined electrogoniometer and torsionmeter (DataLOG W4X8 by Biometrics Ltd, Gwent, United Kingdom) was used to measure ROM (motion at both extremes in 3 planes including flexion/extension, lateral bending and rotation) and fROM (motion during 15 simulated activities of daily living). (Activities shown in table 1 and 2, results will be presented subsequently.) The list of activities was previously compiled from physical therapy and orthopedic literature to represent routine daily activities and the device was validated for such assessments using plain radiographs for accuracy and repeatability.<sup>7</sup> Patients were asked to remove all bulky outerwear, and the sensors were placed at the lower ribcage and the pelvis to span the lumbar spine. (Figure 1) Movements were always performed in the same order, beginning with ROM and following with fROM.

Data were analyzed using STATA<sup>®</sup> version 11.2 (StataCorp, LP, College Station, Texas, USA). Statistical analyses were performed using linear regression. Statistical difference was established at a two-sided  $\alpha$  level of 0.05 ( $p < 0.05$ ).

The study was approved by our institution's hospital investigations committee and informed consent was obtained from each participant.

## Results

Eighty-five patients were eligible for the study and invited to enroll. 70 (82%) patients agreed to participate and constitute the study population. Patients failed to meet inclusion criteria due to: large body habitus that prohibited use of the goniometer device, baseline balance problems, or unwillingness to participate. The patient population included 28 males and 42 females with an average age of 56.8 (range 18-90).

There was a positive association between ODI and combined VAS ( $p < 0.001$ , Figure 2). Similar results were seen when ODI was compared to axial VAS and lower extremity VAS independently. These similarities when VAS analyzed as axial, lower extremity, or combined were similarly seen for the other analyses presented below (combined VAS numbers shown).

For extreme ROM, increasing VAS and ODI were positively associated with decreased motion in all planes except for flexion/extension in the VAS comparison. This is depicted in Figure 3 as the outcome measure versus ROM in the three planes of motion (VAS on the left and ODI on the right for each plane of motion). Linear regression coefficients are given in the first three rows of Tables 2 and 3 for combined VAS and ODI, respectively.

For activity of daily living fROM, ODI was negatively associated with motion for most activities, but this was not seen for VAS. This is depicted in Figure 4 as the outcome measure versus fROM in the plane of greatest movement for representative activities (those with greatest motions in the three planes). Linear regression coefficients are given in lower portions of Table 2 and 3 for combined VAS and ODI, respectively.



Overall, for VAS only 2 of the extremes of motion, lateral bending and rotation, were significant, with none of the ADLs being statistically significant. On the other hand, for ODI, all of the extremes of motion (all three planes) as well as most directions in 9/15 ADLs were significant. The significant ADLs included: washing hands standing, picking up object (squatting), picking up object (bending), tying shoes, putting on socks, backing up car, rising from a chair, walking down hall, and walking down stairs.

## Discussion

Lumbar pathology causing low back and leg pain is a significant cause of morbidity in our culture. When it comes to treatment, there are a number of goals for both the patient and the physician including: decreased pain, decreased disability, and improved mobility, all leading to an improved quality of life. In both research and clinical practice, it is important to have effective and efficient methods to gauge improvement (or lack of improvement).

In our study, patients undergoing intervention were chosen to ensure that adequate levels of pain and disability would be detected. By covering the range of pain and disability indexes (VAS from 2-20 and ODI 10-86) we were able to achieve greater spread of test results than the standard outpatient population and this facilitated power for our regression analyses.

The two most common outcome instruments were used to assess the lumbar spine in a cohort of patients undergoing spinal intervention: VAS and ODI. Initially we just looked to see if there was a positive association between the two measurements. We did find that as pain increased, so did disability. This held true if looking at axial, lower extremity, or combined axial and lower extremity VAS in comparison to ODI. Because of this and pre-existing expectations, we anticipated both pain and disability to be associated with motion.

We then compared the outcome instruments to different types of mobility, including extremes of motion (ROM) and motions associated with activities of daily living

(fROM), testing for statistically significant associations. ROM is most commonly evaluated in the clinical setting, but it is fROM that gives a measure of the motion a patient actually utilizes. Most patients do not use their full ROM on a daily basis, but they do use ADLs. We thus put forth that it is important to assess fROM in a clinical and research setting as an adjunct to the extremes of their ROM in order to better quantify the functional status of patients.

For extremes of motion (ROM), ODI was more positively associated than VAS (in three out of three planes as opposed to two out of three planes of motion). However, it was of even greater note that for motions associated with activities of daily living (fROM), ODI correlated for 9/15 activities while VAS correlated with none. Further, most of the activities of daily living (including washing hair standing, shaving / makeup, cutting and bringing food to mouth, and reading in lap) where ODI was not associated with fROM were the activities requiring the least amount of motion of the lumbar spine and were thus least affected by change in patient pain and disability (less ability to detect a change from an already low degree of motion).

It appears that ODI is a better indicator of range of motion (both full and functional) than VAS. Pain is extremely subjective and all people deal with pain differently. It is possible that someone in 8/10 pain can still get through and function in most of their daily activities while someone at a 4/10 is severely limited in their activities. Some people may also push through the pain, not compromising their motion, while others will severely limit their movements when they feel any pain. In the end, ODI may be less subjective than a pain score.

There are limitations to this study. First of all, the movement measured in a research setting on this population may not be an accurate portrayal of what they are doing at home. Some patients may feel motivation or pressure to push themselves further than they would normally move at home because they know they are being observed. Others may not push themselves far because they are in pain and only mimicking ADLs.

Another limitation is that the patient population was heterogeneous (age, gender, diagnosis) and were patients arriving at a point of treatment. We took the heterogeneous nature of the population to be an advantage showing that study conclusions would be more generalizable than they would be from a more narrowly defined cohort of patients.

## **Conclusion**

Overall, extremes of lumbar motion and motions associated with activity of daily living are of growing clinical interest. Even though ODI and VAS are positively associated with one another, ODI appears to be a better predictor of these motion parameters than VAS. This is true for two out of three planes of extremes of motion (ROM) and activities of daily living associated with the greatest amounts of lumbar motion (fROM). This suggests that ODI may be more useful than VAS in the clinical setting when considering functional movement parameters.

## Tables and Figures

**Table 1.** Associations between degrees of motion and VAS.

	Linear regression coefficient <sup>1</sup>		
	Flex/ex	Lateral bending	Rotation
Extreme motions			
Flex/ex	-0.4		
Lateral bending		*-0.7	
Rotation			*-1.4
Daily activities			
Washing hands standing	-0.2	0	-0.1
Washing hair standing	0.3	0	-0.1
Shaving/makeup	0.1	0	0
Picking up object (squatting)	-0.1	0.1	0.1
Picking up object (bending)	-0.2	-0.1	-0.2
Stand to sit	0.4	0	0
Tying shoes	0.1	-0.1	-0.1
Putting on socks	-0.1	-0.1	-0.4
Bringing food to mouth	0	0	-0.1
Reading in lap	-0.1	0	-0.1
Backing up car	-0.1	-0.2	-0.5
Rising from chair	0.1	0	-0.2
Walking down hall	-0.2	0	-0.2
Walking up stairs	0	-0.1	-0.2
Walking down stairs	0	-0.1	-0.2

<sup>1</sup> Reflects the slope of a line with VAS on the X axis and degrees of motion on the Y axis.

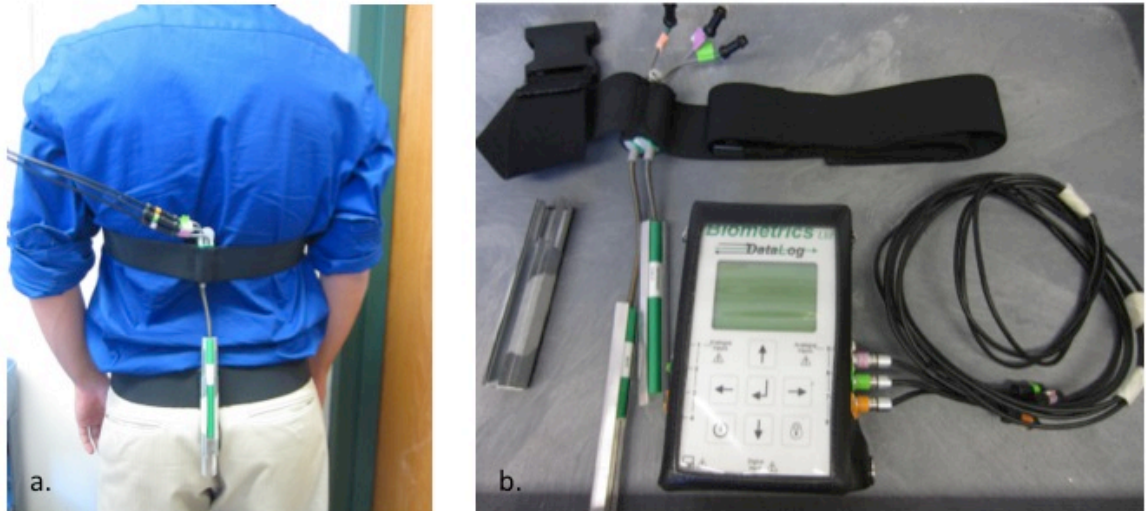
\* Statistically significant association ( $P < 0.05$ ).

**Table 2.** Associations between degrees of motion and ODI.

	Linear regression coefficient <sup>1</sup>		
	Flex/ex	Lateral bending	Rotation
<b>Extreme motions</b>			
Flex/ex	*-0.4		
Lateral bending		*-0.3	
Rotation			*-0.3
<b>Daily activities</b>			
Washing hands standing	*-0.1	0	0
Washing hair standing	0	0	0
Shaving/makeup	0	0	0
Picking up object (squatting)	*-0.3	0	-0.1
Picking up object (bending)	*-0.3	*-0.1	*-0.1
Stand to sit	-0.1	0	-0.1
Tying shoes	*-0.1	0	0
Putting on socks	*-0.1	*-0.1	-0.1
Bringing food to mouth	0	0	0
Reading in lap	0	0	0
Backing up car	*-0.1	*-0.1	*-0.2
Rising from chair	*-0.1	0	0
Walking down hall	*-0.1	*-0.1	*-0.1
Walking up stairs	0	-0.1	-0.1
Walking down stairs	0	*-0.1	*-0.1

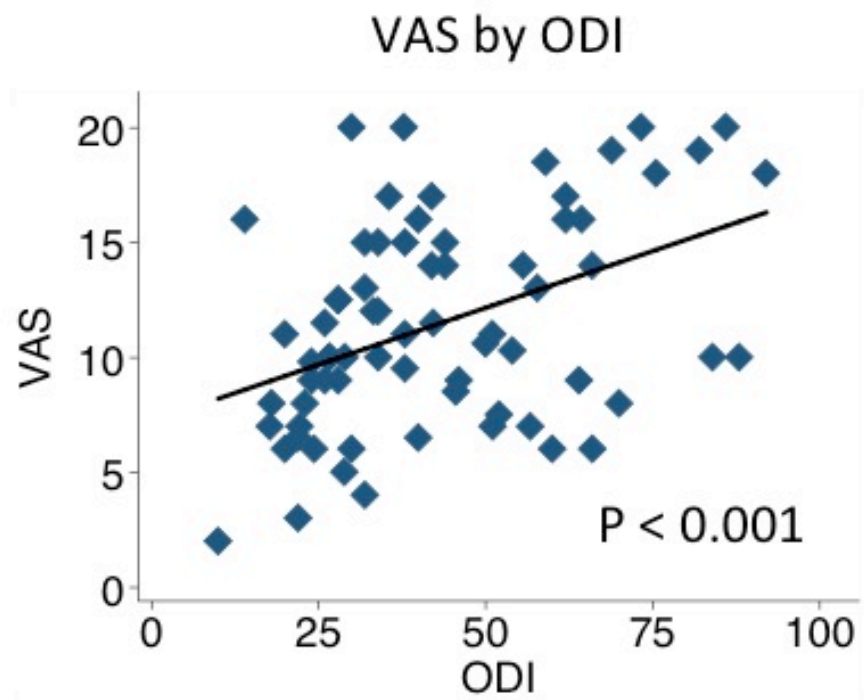
<sup>1</sup> Reflects the slope of a line with ODI on the X axis and degrees of motion on the Y axis.

\* Statistically significant association ( $P < 0.05$ ).

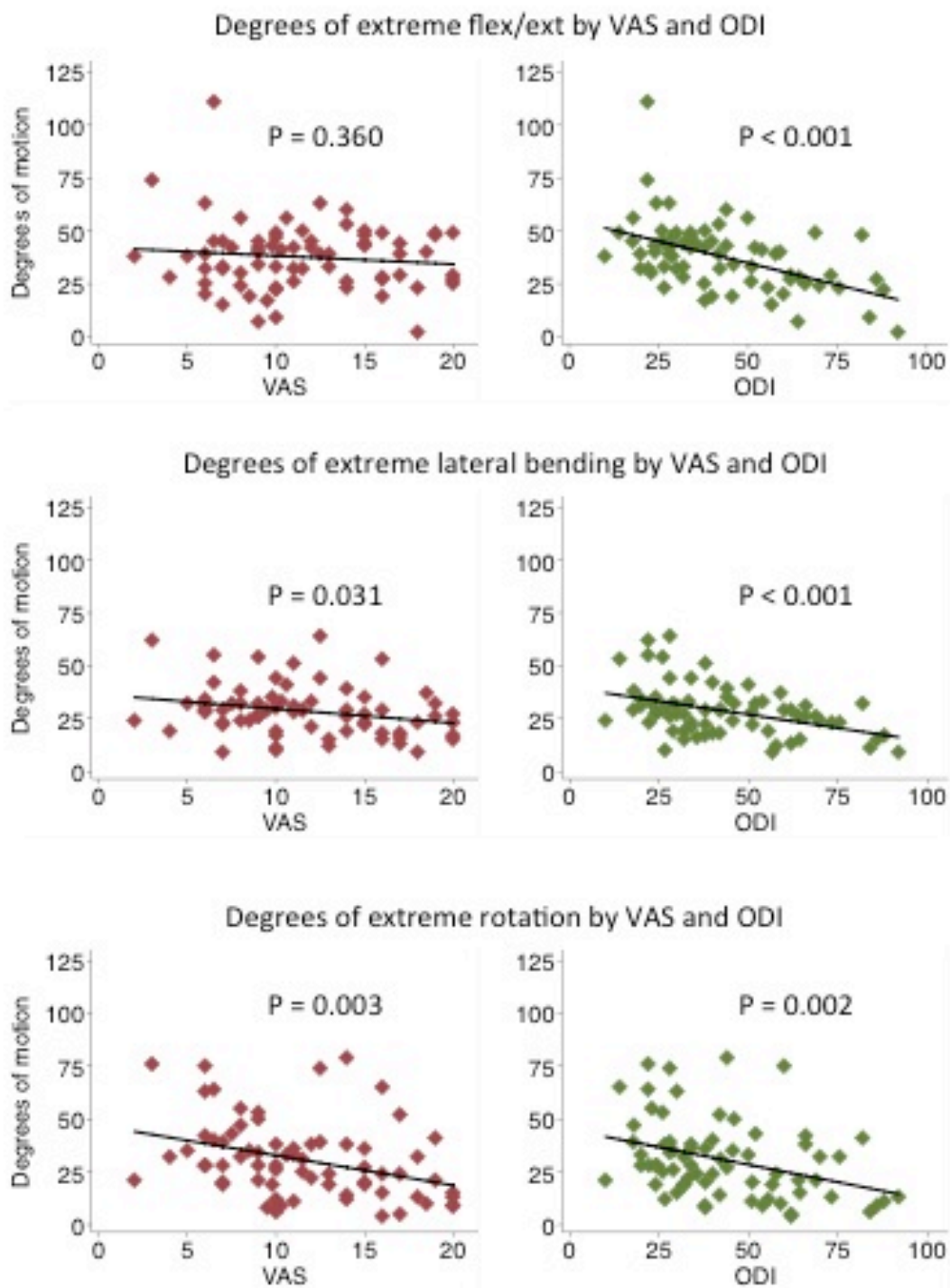


**Figure 1.** a. Placement of the electrogoniometer with harness around lower ribcage and hips to span the entire lumbar spine. b. Electrogoniometer equipment including sensors, harness, and control box.

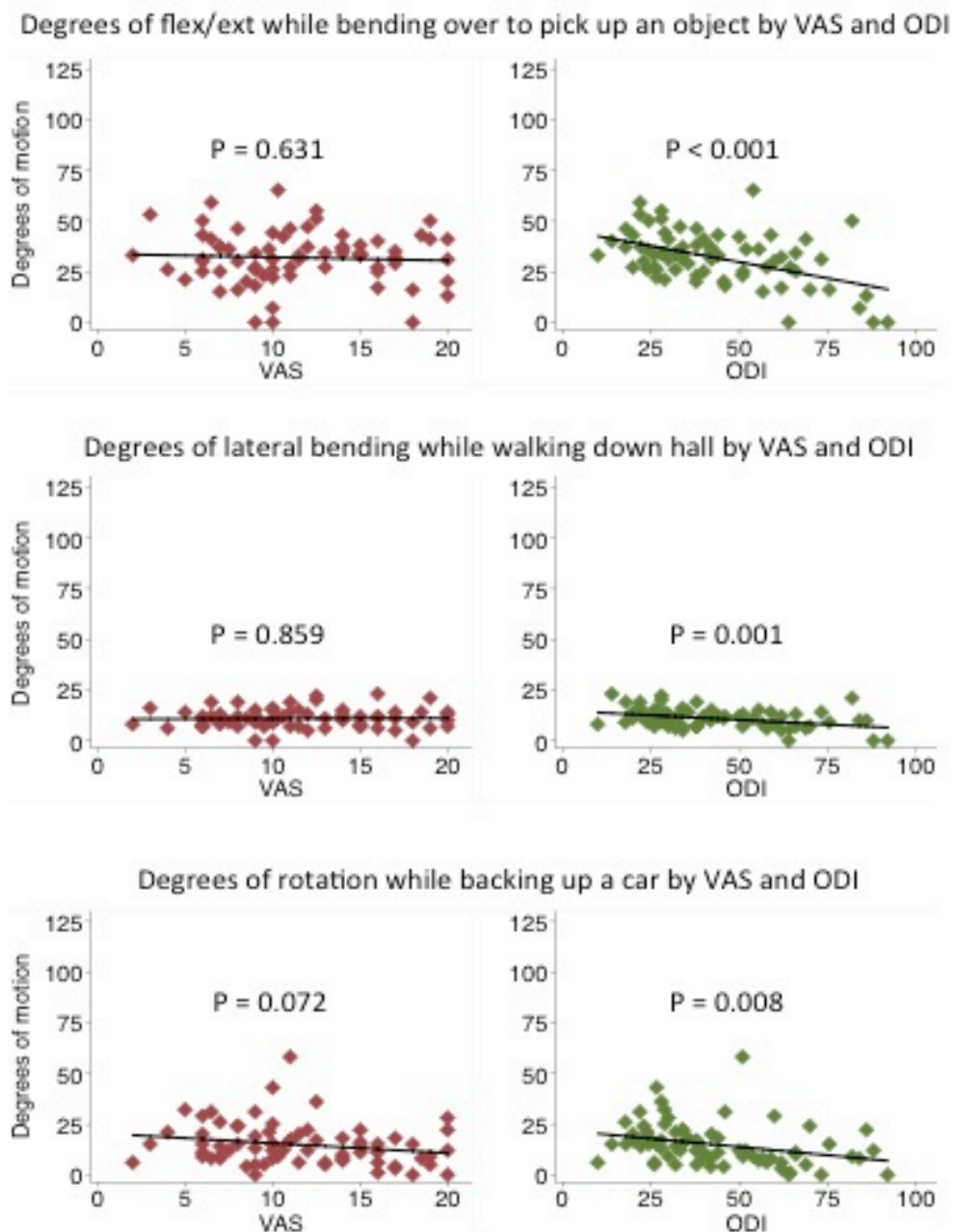




**Figure 2.** Positive association of ODI and VAS.



**Figure 3.** Outcome measure vs. degrees motion in the extremes (flexion/extension, lateral bending, and rotation).



**Figure 4.** Outcome measure vs. degrees of motion for three representative ADLs in the plane of greatest movement. (Picking up object (bending) for flexion/extension, walking down hall for lateral bending, and backing up car for rotation.)

## **CHAPTER 3:**

### **Abstract**

Following lower extremity fracture and/or surgery, physicians often prescribe limited weight bearing on an affected limb. The current study was performed to evaluate teaching and compliance of touch-down weight-bearing (TDWB), defined as 25lbs, at a level I, academic trauma center.

A brief survey was distributed to hospital physical therapists (PTs) from the orthopedic ward to gauge training methods and confidence in their patients' ability to comply. Patients with recommended TDWB were then evaluated on the day of discharge and again at their first follow-up appointment using the SmartStep weight bearing measurement device.

Fifteen PTs completed the survey (with an average of 14 years in practice). There was inconsistency in weight bearing teaching methods: verbal cues were used by 87%, tactile methods (hand or foot under patient's foot) were used by 41%, and a scale was used by 1%. There was not great confidence in the instruction efficacy by those surveyed.

Twenty-one patients were seen at day of discharge and 18 of those were seen at follow-up. At discharge, the average minimum weight bearing was 3.9lbs and the average maximum was 33.6lbs (only 31% of steps were within an acceptable range of 15-35lbs). At follow up, the average minimum weight bearing was 12.2lbs and the average maximum was 50.8lbs (only 27% of steps were within an acceptable range). The

majority of steps were under the prescribed weight at discharge, whereas a majority of the steps were over the prescribed weight at follow-up.

This data suggests that more uniform and effective teaching for prescribed weight bearing orders are warranted if compliance is an important clinical objective.

## Introduction

Following lower extremity orthopedic fracture and/or surgery, patients are often instructed on how much weight to bear through the affected limb. Common instructions include touch-down weight-bearing, partial weight-bearing with a specific weight limit, or weight-bearing as tolerated.

The potential rationale of restricting weight bearing is to limit the load seen by an injured or operative site.<sup>25</sup> There is the potential concern that single load or repetitive loading over a tolerance point could lead to deformation or loss of alignment / fixation. Conversely, the rationale for advancing weight bearing is to expose an injured site to loads, which may facilitate osteoblastic responses consistent with Wolfe's law.<sup>26,27</sup> This may improve early bone strength and remodeling.

While limited weight-bearing is a common recommendation in the rehabilitation of orthopedic patients, there is controversy regarding its effectiveness<sup>26</sup> and the ability for a patient to carry out the proper orders.<sup>28,29</sup> Compliance with limited weight-bearing may be restricted by many factors including the ability of the physician or PT to teach the patient, ability of the teacher to accurately assess if the patient is bearing the correct amount of weight, patient comprehension, and intrinsic patient factors that may limit their ability to carry out the movement (i.e. dementia, poor upper body strength, etc.).

Teaching and methods of assessment of limited weight-bearing vary widely, without a gold standard.<sup>30</sup> No method is without limitation, and each has been shown to be with issue. These include: traditional scale training<sup>31-33</sup>, visual observation of a trainer offering feedback<sup>34</sup>, and tactile methods of having the patient place the foot on top of the trainer's hand/foot in order to feel what the patient is doing<sup>35</sup>.

The most advanced form of training involves auditory or tactile biofeedback. This can include a shoe insert or the use of a force plate to actually measure the force and give the patient real-time feedback. Studies have found this to be a superior form of training because it can be used during dynamic gait, with the patient receiving immediate feedback and good training retention.<sup>28,36-40</sup> However, many of these studies were performed on healthy subjects and almost exclusively in research settings due to the high price and cumbersome quality of the equipment.

The current study is performed to evaluate the mixed practice of physical therapists at a level I, academic trauma center in teaching limited weight-bearing, to assess patient compliance with instructions for TDWB (defined as 25lb) at the time of discharge, and to assess patient compliance with instructions at first out-patient follow up. More than constrained single variable studies, this was believed to be an optimal way to assess a true clinical scenario.

## **Materials and Methods**

### ***Survey study***

Despite being at a level I, academic trauma center, there are no formal guidelines in place at our institution regarding methods of teaching TDWB to fracture / trauma patients. That said, patients are kept in the hospital until medically cleared and found to be safe from a rehabilitation perspective. Accordingly, preparedness for discharge implies some level of confidence from the PT working with the patient that they can comply with recommended mobilization criteria.

A brief, one page survey was distributed to hospital PTs from the orthopedic ward to gauge teaching methods for weight-bearing. Demographic data about the PTs was gathered. Regarding weight-bearing, questions included: percentage of the time different teaching methods were used (including verbal cues, scale training, hand under foot and other), confidence in the training methods and patients' ability to comply (on a scale of not confident to very confident) and the challenges in teaching weight-bearing.

### ***Clinical study***

Patients were voluntarily enrolled in the study that had been approved by our Human Investigations Committee. Inclusion criteria included: touch down weight bearing order (defined at our center as 25lbs), age > 18, English-speaking, not on contact precautions, having worked with PT and been cleared for mobilization with TDWB, able to walk at least 30 steps at discharge, had no other major injuries preventing use of an assist device, and cognitively intact.



Weight-bearing was monitored with the SmartStep device (SmartStep by Andante, White Plains, NY). This system consists of an insole insert and a small receiver strapped to the ankle (Figure 5.) that communicates wirelessly with a computer, continuously monitoring the weight bearing of the patient. Patients that had proximal lower extremity injuries were fitted with an insole and a tennis shoe. Patients with distal lower extremity injuries who were in a cast or splint had the insole wrapped to the bottom of their cast or splint between two pieces of molded plastic.

Once the device was secured and zeroed, patients were asked to walk approximately 50 steps with their recommended / preferred weight-bearing assistive device (crutches or walker). Patients and PTs were blinded to the data obtained from the SmartStep device. There was no further teaching based on the readout of this device.

After discharge, patients returned approximately two weeks later for their standard outpatient clinic follow-up. Prior to seeing the physician or having a cast removed, weight-bearing measurements were re-assessed in the same fashion as before with the SmartStep device.

Data were analyzed using STATA<sup>®</sup> version 11.2 (StataCorp, LP, College Station, Texas, USA). Statistical analysis was performed using a paired T-test, using the 18 patients present at both time points were considered. Standard error of the mean was utilized in the graph due to the fact that each patient contributed a data point that was an average.

## **Results**

### ***Survey Study***

Twenty surveys were distributed to orthopedic ward PTs with 15 surveys completed and returned (75% yield). The average years in practice was 13.8 years.

Regarding training methods, 87% of the time verbal cues were used, 41% of the time tactile methods were used (hand or foot under patient's foot) and only 1% of the time was a scale used. 23% of the time another method was used, such as demonstration.

Only 7% of PTs felt very confident that the patients are learning and maintaining the prescribed weight bearing status while 53% felt moderately confident, 27% felt minimally confident, and 7% felt not at all confident. They attribute the most challenging aspects contributing to low confidence as: patient lack of understanding, lack of precise teaching method and patient pain. Others found that patient fear or poor comprehension to be significant challenges. All PTs were interested in a new teaching method.

### ***Clinical Study***

Thirty-two patients who met inclusion criteria for the study were identified. Of these, 11 patients withdrew, 3 of which were found to be ineligible due to not bearing any weight at either visit. In total, 21 patients were included for day of discharge data of which 18 returned for follow-up.

The study cohort demographics were as follows (Table 3). Age was 41.9 (20-96) [average(range)]. Female:male ratio was 7:14. BMI was 27.7 (21.6-38.2). Affected limb, type of assist device, injury type, and shoe vs. splint were distributed evenly.

On the day of discharge, the average weight bearing was 13.9lbs with an average maximum of 30.2lbs and average minimum of 3.2lbs, illustrated in Figure 6. At follow-up the average weight bearing was 33.0lbs with an average maximum and minimum of 50.8lbs and 12.2lbs respectively (also demonstrated in Figure 6).

Stratification of the data into individual steps showed tremendous inter-step variability in the amount of weight the patients bore. (Table 4 and Figure 7) Of note, we considered 10lbs above and below the prescribed 25lb order to be a clinically acceptable range. At discharge, a majority of the steps (56.6%) were in the 0-14lb range (not enough weight), 31.4% of steps were within an acceptable range (25lbs +/- 10lbs), and 12% of steps were over 35lbs (too much weight). A shift occurs in the results seen at the first outpatient follow up, 32.6% of steps were in the 0-14 range (not enough weight), 26.5% were in an acceptable range (15-35lbs), 40.9% were over 35lbs.

## Discussion

Limited weight bearing orders are commonly prescribed to patients after a lower extremity orthopedic surgery or fracture. This is important in order to balance the needed protection of the injured limb from further injury or hardware failure, while promoting osteoblastic activity and healing. Although TDWB is a common order to prescribe, there is no gold standard of teaching. The most common and convenient methods (scale training, tactile hand under the foot, or using verbal cues) have all been proven to be ineffective.

At a level I, academic trauma center, an excellent group of experienced PTs. had varying degrees of confidence in their ability to teach and in their patients' ability to maintain partial weight bearing. Overall, they rarely use the scale method, with mostly demonstrations, verbal cues and tactile feedback only. They felt that a range of patient factors, as well as a lack of precise teaching methods, contributed to the inability of patients to properly learn good partial weight bearing technique.

In assessing how these current teaching methods are working, the results were acceptable at first glance. We only considered patients who received TDWB orders, and allowed a range of +/- 10lbs, therefore any steps in the range of 15-35lbs were acceptable. At discharge, the average weight bearing for 18 patients with at least one training session was 13.9 lbs. This is just under the accepted range. Similarly at the follow-up, the average weight bearing was 33.0lbs, which is in fact in the acceptable range. Patients, as they begin to heal and have decreased pain, clearly start to put more weight on the affected limb.

While the averages were relatively acceptable, it is the range of average values as well as the percentage of steps above or below the range that are cause for concern. The average maximum weight placed at discharge was 30.2lbs, but the average maximum at follow-up was 50.8lbs, more than double the prescribed limit. Even more concerning was the average percentage of steps the patients are placing on the affected limb at higher and lower weight ranges. At discharge, a majority of the steps (56.6%) are in a low range (0-14lbs) while at follow-up a majority of the steps are in a range greater than 35lbs (40.9%).

If a patient is putting an average of 25lbs on the affected limb, but most of those steps are non-weight bearing and then a few steps are grossly over the limit, the distribution may be unhealthy to the healing leg. There is little feedback to stimulate healing in the bone and there is a chance of hardware failure or further injury with the highly loaded steps. The goal would be to have all steps within an acceptable range to promote healing and the best outcomes.

In previous research, biofeedback training has given the best results for teaching limited weight-bearing. Our group used the SmartStep device to show that TDWB can be taught and maintained by healthy subjects.<sup>38</sup> After gathering data on orthopedic patients at a level I, academic trauma center, it is clear that a better teaching method is needed to help patients learn and maintain partial weight bearing. The future of this project is to apply a biofeedback device to patients in the hospital to see if we can improve our current results.

There were some challenges with the data collection for this study. First of all, while many patients receive a TDWB order post-operatively, it was very difficult to find subjects that fit inclusion criteria. Many injuries were caused by trauma that consequently caused other injuries that made it impossible to work with PT or use an assist device (crutches / walker). Also, it was common for elderly patients to have a single injury due to a fall, but often their mental capacity was not enough to either consent to the study or learn TDWB. We were able to gather a respectable sample size with a wide range of ages despite these difficulties. Additionally, another challenge of this research was the use of the SmartStep device with a splint/cast. The device is originally designed and validated for use in a shoe, which limits it to patients that have injuries above the knee. We constructed a plastic platform that could be ace-wrapped to the bottom of a splint to hold the device and mimic a shoe. This was validated with a bathroom scale and found to be accurate ( $r^2=0.9891$ ). Lastly, 3 patients were excluded from the final data analysis due to the fact that they were unable to place any weight on the affected limb at either time point. These patients would have falsely improved the averages, specifically for the follow-up. For this study, it was important to look at only the patients that were attempting some level of weight bearing.

## Conclusions

Limited weight bearing is often important to patient outcomes after lower extremity orthopedic injury or surgery. The order is given frequently, but in clinical practice, there is no consistent and accurate method of teaching. At a level I, academic trauma center, the PTs are experienced and yet many still feel a low level of confidence in their ability to teach and for a patient to comply with TDWB orders. This is further shown in the actual measurements of patients who have received a TDWB order for the affected limb. While the total averages of all steps for 18 patients at both discharge and follow-up were within a reasonable limit, the range of weight and the percentage of steps outside of the range are worrisome. If a patient is consistently bearing too little or too much weight on a fracture site, it is possible to have slower healing, further injury, or even failure of hardware. It is clear that a more effective method of teaching is necessary. Research has shown that the use of biofeedback devices is incredibly effective, but they remain bulky, expensive, or not ready for use in a clinical setting. In the future, a new device would be easy to use, inexpensive, deliver biofeedback, and be portable. We will then be able to implement this device in a hospital setting to see if we can improve compliance of patients with partial weight bearing orders.

## Tables and Figures

**Table 3.** Subject Demographics.

<b>Patient Characteristics</b>				
<b>Age</b>	41.9 (20-96)			
<b>Gender</b>	7 female	14 male		
<b>BMI</b>	27.7 (21.6-38.2)			
<b>Affected Limb</b>	10 right	11 left		
<b>Assist Device</b>	9 crutches	12 walkers		
<b>Injury Type</b>	2 ankle	10 tibia	8 femur	1 acetabulum
<b>Shoe/Splint</b>	11 shoe	10 splint		

\*n=21 (18 seen at both time points)

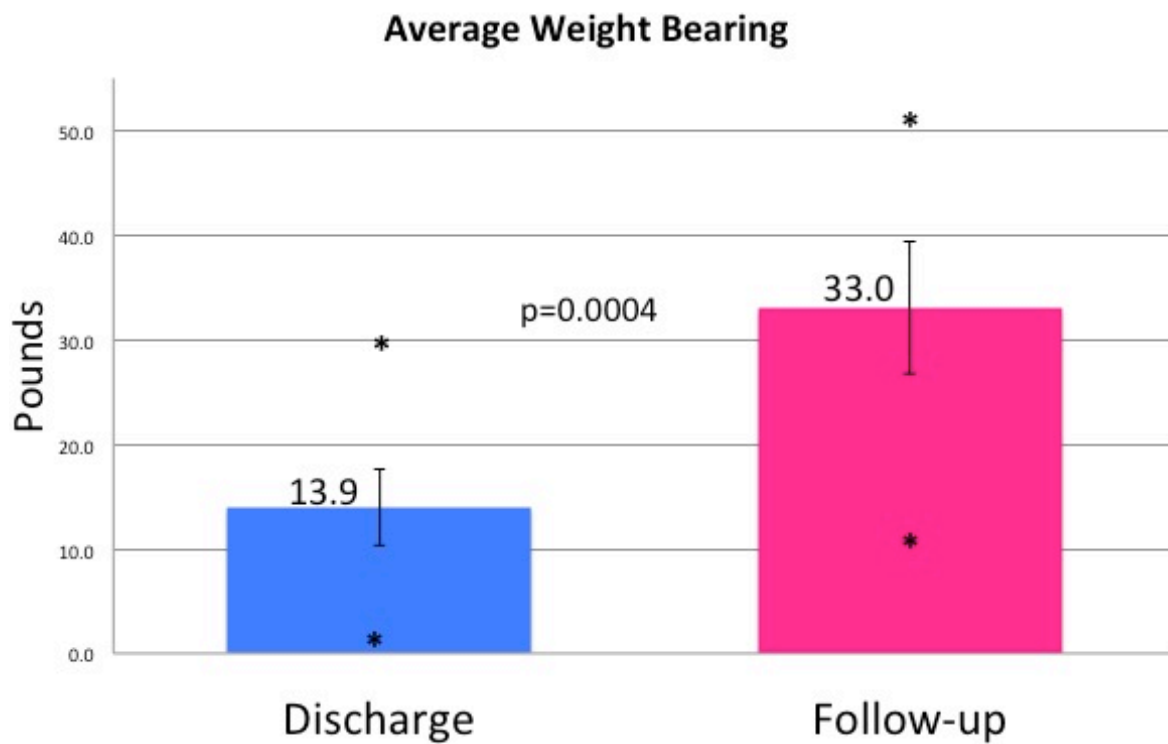


**Table 4.** Percentage of steps in each weight-bearing range.

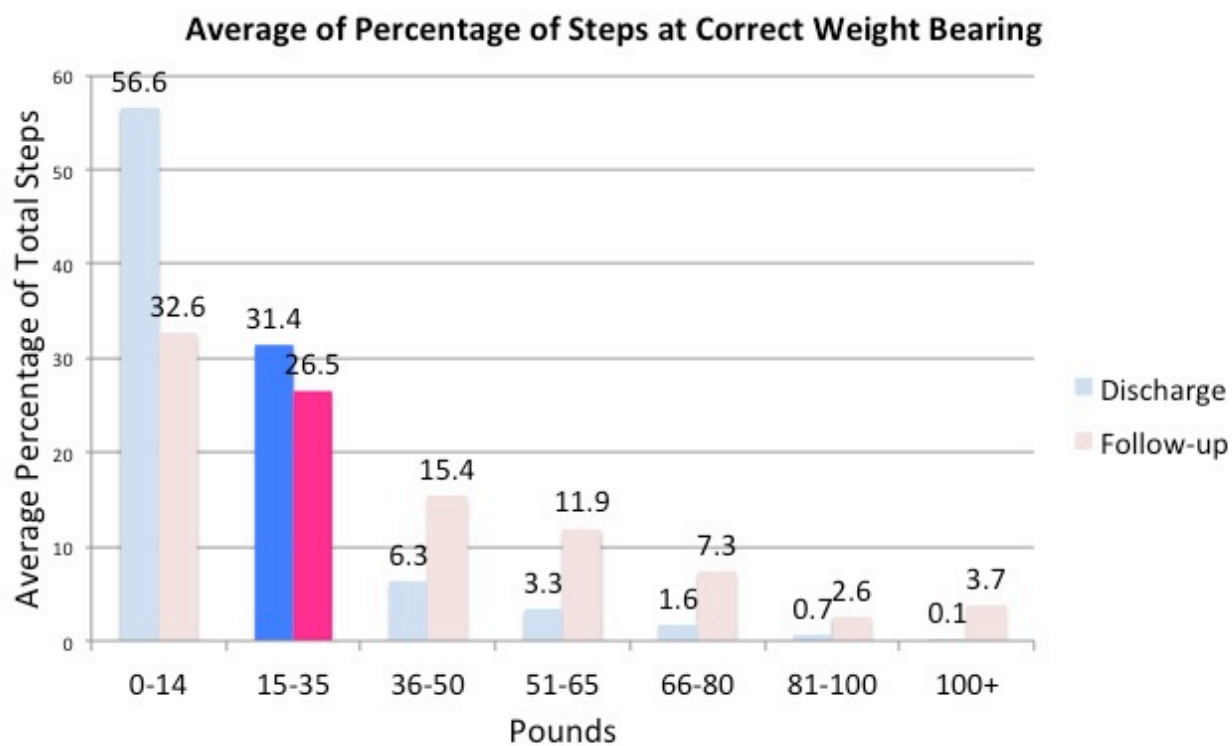
<b>Percentage of Steps</b>	<b>Discharge</b>	<b>Follow-up</b>
<b>0-14lbs (Too light)</b>	<b>56.6%</b>	32.6%
<b>15-35lbs (Ideal)</b>	31.4%	26.5%
<b>&gt; 35lbs (Too heavy)</b>	12.0%	<b>40.9%</b>



**Figure 5.** a. Placement of the SmartStep device with insole in standard shoe and transmitter strapped around the ankle. b. SmartStep equipment including transmitter and insole.



**Figure 6.** Average weight bearing at discharge and follow-up. Bars represent standard error of the means.  $p=0.0004$  derived from paired t-test. \* represent corresponding average max and min.



**Figure 7.** Average percentage of steps in each weight range. Only 31.4% of steps are in the correct range at discharge and 26.5% at follow-up.

## **CHAPTER 4: CONCLUSIONS AND FUTURE DIRECTIONS**

Evidence based medicine and quality improvement are two growing fields in orthopedics research as well as clinical practice. The use of proper assessment tools is imperative in both new research as well as assessing current practices. It is necessary to include both the objective measures, such as imaging, as well as the patient-centered subjective components to track both improvement and outcomes.

When assessing patients with spine pathology, both imaging and subjective measures are important to decide treatment and progress. Lumbar motion can be a good indication of the anatomy and we examined the relationship with pain and disability, two common outcomes measures. Even though ODI and VAS are positively associated with one another, ODI appears to be a better predictor of these motion parameters than VAS. This suggests that ODI may be more useful than VAS in the clinical setting when considering functional movement parameters. The ODI survey is simple, patient-centered, quick, and easily quantified. Implementing the use of this outcomes measure can help surgeons have a more complete picture of a patient.

Limited weight bearing is commonly prescribed in the area of trauma orthopedics. There is no gold standard for teaching or evaluating patients when they are learning this skill. Many of the current teaching methods are inaccurate and subjective. By using a new device, we were able to measure the weight bearing in patients in a level 1 academic trauma center. While the average of the weight placed on the limb was in an acceptable range, the percentage of steps in that range was abysmal. A new system for teaching and evaluating is needed. This new device will need to be cheap, easily useable, lightweight,

and accurate. The implementation of this device would help in the future to evaluate the true value of prescribing limited weight bearing orders.

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