



## Pilot Study to Validate a Functional Pain Scale for Orthopedic Patients

Harris W Thomas, Jill Stenson, Lee Holman, Kirtanaa Voralu

Guthrie/ Robert Packer Hospital, Sayre, United States

### Correspondence

Harris W. Thomas BSN RN-BC  
Clinical Pain Resource RN, Guthrie/ Robert  
Packer Hospital, Sayre, United States

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### Abstract

**Objective:** This study was to validate a functional pain scale (FPS) in order to better identify issues of pain as it relates to returning the patient to a functional status.

**Methods:** An observational cohort study was conducted to validate a new pain scale to improve patient experience as well as determine patient and provider preference for a pain scale.

**Results:** The data was analyzed and showed a strong correlation between the RPH-FPS, NRS (NRS:  $r(49) = 0.63, p < 0.001$ ) and Wong-Baker FACES (FACES scale:  $r(49) = 0.65, p < 0.001$ ) scales. The analysis also showed an overwhelming preference for the RPH-FPS over the other two scales.

**Conclusion:** There is a strong significant correlation between the RPH-FPS and the NRS as well as Wong-Baker FACES scales. However, the overwhelming preference by the patients when asked which scale was preferred was in favor of the RPH-FPS. The most common reason for their choice was that the scale was more descriptive and gave the patient more opportunity to describe how pain was affecting their recovery. This was also found to be true of the surgical residents that were completing the assessment and survey.

### Introduction

The Numeric Rating Scale (NRS) has been validated and the main tool for nurses and physicians [1]. The NRS has been a point of contention with healthcare providers due to the disconnect between the subjective report and the observations by healthcare providers [2], i.e. patient reports pain as an eight out of ten, however is seen sleeping comfortably, or conversing without losing concentration. Often times, it has been reported that patient was sleeping when the RN came in to give medications or during hourly rounding, and that is when the patient reports being in severe pain [3]. Healthcare is going through a time of transition. It is no longer considered best practice to medicate to a number due to the increase in opioid usage [4,5]. It is believed that by using this improved pain scale and more in depth discussions of expectations with patients, the provider may be able to improve the patient experience and possibly reduce the use of opioids. The opioid usage will be monitored in the second phase of the study. An interdisciplinary group was formed to discuss the need to improve pain management for patients. This was originally designed as a Quality Improvement project. The group consisted of staff nurses from three different hospitals in the Guthrie healthcare

system, pharmacist, physical and occupational therapists (PT/OT), Quality Improvement Nurses (QI), EPIC personnel and Department of Nursing Education and Research (DNER). A discussion took place regarding a disconnect between patient reported pain and the nurses observation [1]. It was decided that a better pain scale was needed. The pain scale needed to be both subjective and objective. At this point, this project became a research project. A list of criteria was established, i.e. had to be descriptive and numeric, easy to use, and at a fourth grade literacy level. A literature review was completed regarding functional pain scales. The group explored the Clinically Aligned Pain Assessment (CAPA) [4,6], the Indiana Polyclinic Pain Scale (IPCPS) [7], a pain scale from Geisinger Hospital [8] and a pain scale from Salem Healthcare system [9]. CAPA did not fit the numeric requirement to fit the order sets. IPCPS was promising, however seemed to be a longer process for nursing to complete. The Geisinger scale was close to what the group wanted, but did not address how pain affected sleep. The Salem Healthcare was a visual analog scale (VAS) showing a thermometer with descriptive words and not numeric. Each scale was scored per the original criteria. It was decided that a new scale needed to be created. The scale needed to be descriptive, but still have a numeric

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component. The RPH-FPS was created to address the effects of pain on three areas of recovery towards baseline functioning: sleep, ADLs and the use of distractions. Institutional Review Board of the Guthrie Clinic (IRB of the GMC) approval was obtained to conduct a pilot study to validate the new pain scale.

## Background

The group met three times in early 2019 to discuss this issue. During these meetings, the meanings of pain as well as adequately assessing pain was discussed, the need to improve communication between RN and patient in regard to the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAPS) scores were very flat, and showed little or no conversations taking place. It was evident that a better means of assessment was needed [6]. The consensus was to look beyond the NRS to improve assessments for safety and communication with the patient [3]. A literature review for new pain scales was completed. Various pain scales were identified and discussed. Those scales identified were the Clinically Aligned Pain Assessment (CAPA) [4,6], Indiana Polyclinic Pain Scale (IPCPS) [7], The Geisinger Pain Scale [8], and a visual analog scale (VAS) from Salem Healthcare [10]. After discussing the pros and cons of each scale, the group determined that a new scale was needed. Criteria was established for our new scale; descriptive as well as numeric, easy to use, quick and at no more than a fourth grade literacy level. The group looked at the VAS scale from Salem Healthcare, and started to define the descriptive words and assign the number that best fit. Their scale only had four words, and had no associated number rating with them. The entire group thought it would be best if a task force developed the descriptors and definitions. This task force decided that we would start at the lowest number, one, and describe it and how it related to the three areas that we identified as being needed to be addressed. This was listed as "Minimal" and defined as "Hardly noticeable/ no impact on ADLs/ sleep not affected and able to use passive distraction for comfort". The group defined passive and active distractions as well. Passive distractions would be watching TV, listening to music, or talking with friends and family. Active distractions would be those items that took concentration to focus on a task such as reading, knitting, crossword puzzles and/or video games. The group then went through each number of the scale and developed a descriptor and definition for that word with gradual increasing effects on the three areas. The new scale was brought back to the group with the descriptive words, the associated number and definitions of the words with the numbers, and agreed on. The RPH-FPS assesses the patient based on four questions. (1) Does the patient have pain? (2) Is the pain affecting their sleep? (3) Is the pain affecting their ability to complete their ADLs? (4) Is pain affecting their ability to use either passive or active distractions for relief? The unidimensional pain scales [NRS, visual analog scale (VAS), and Wong-Baker FACES] all measure pain intensity, but does not assess the patient's ability to function [4,6]. The RPH-FPS is designed to accurately assess the functional status of the patient in terms of how pain is affecting those areas. The Joint Commission (TJC) has started to use terms such as "discussing the objective used to evaluate treatment progress (for example relief of pain and improved physical and psychosocial function)", or "The hospital reassess and responds to the patient's pain through progress toward pain management goals, including functional ability (for example ability to take deep breath, turn in bed, walk with improved pain control) [10]". The goal of validating the RPH-FPS is

to improve communication between healthcare providers (physicians, nurses, physical and occupational therapists) and the patient. Currently there are very few validated FPS's, and those that have been validated are from small sample sizes [9,11]. One of the first studies was the Gloth study from 2001 and states as one of its limitations is that it was a small sample size, as well as the article by Halm and others for validating their scale in Salem Healthcare which had an n of 68. Geisinger's study did not list number of participants. The group developed an observational cohort study comparing the NRS, Wong-Baker FACES and the RPH-FPS. The population consisted of orthopedic patients having either total knee arthroscopy (TKA) or total hip arthroscopy (THA). This population was chosen for ease of use since they had scheduled surgeries. First, they would go through vetting steps through orthopedic education classes. Preadmission testing area would invite after the complete assessment was done, including functional baseline, opioid risk assessment (ORAT), history of opioid use and literacy level. The list of patients and their scheduled procedures could be created to make assessing and surveying more efficient. A baseline assessment for functioning was completed through the preadmission testing area using the Hip Disability and Osteoarthritis Outcome Score (HOOS) and Knee Injury Osteoarthritis Outcome Score (KOOS). Additional criteria were age greater than 18 years of age, able to read and speak English, and no history of cognitive impairment. A sample size of 50 patients was determined to be adequate by the IRB and later changed to 49 by the statistician. A survey form was created with the help of the Quality Improvement department. The survey consisted of 10 questions (Appendix A). The schedule of assessments was determined to be post-op day 1 and daily until discharge.

## Aims

The specific aim of this study was to develop and validate a functional pain scale in order to improve the patient experience, by improving communication between patient and healthcare provider. The tool was created in order to allow the nurses and physicians to report pain levels using both subjective as well as objective assessments. Additionally, the preferences of both the patient as well as the surgical residents completing the survey were also measured.

## Methods

This is an observational cohort study with the participants being assessed using the three pain scales. Data points were determined in preadmission testing for baseline pain, function, and whether diagnosis was chronic, acute, or combination. Patient preferences with rationale were also asked. Convergent validity is the gold standard in validation research [12]. This analysis represents the degree to which a measure agrees with other valid measures of the same concept [12]. Data entry and analysis were performed with IBM SPSS Statistics (IBM Corp., 2016). Demographic and patient characteristics were obtained for all enrolled subjects. Mean (standard deviation (SD)) and median (range) were obtained for age, pre procedure pain, Wong-Baker FACES scale, NRS and RPH-FPS. Number of observations and percentages were obtained for gender, procedure, first opioid and type of pain. First opioid was the first medication given post operatively, and decided to be assessed in order to compare reported pain score and medications given. Oral (PO) medication from the order set is first line medication, and intravenous (IVP) medications are secondary, or if pain is reported as severe. Spearman rank correlation was

**Table 1.** Characteristics of 49 patients who underwent knee or hip arthroplasty surgery at Robert Packer Hospital from September 2019 to January 2020

Patient Characteristics	N (%)	Mean (SD)	Median (Range)
Age	49 (100)	65.8 (7.47)	67 (45-78)
Pre pain score	48 (98.0)	3.0 (3.18)	2.5 (0-10)
FACES	49 (100)	4.3 (2.23)	3.5 (1.5-7.5)
NRS	49 (100)	4.5 (2.12)	4 (1-8)
FPS	49 (100)	3.7 (1.75)	4 (1-9)
<b>Gender</b>			
Male	21 (42.9)		
Female	28 (57.1)		
<b>Procedure</b>			
TKA	36 (73.5)		
THA	13 (26.5)		
<b>First Opioid</b>			
PO	40 (81.6)		
IVP	9 (18.4)		
<b>Type of pain</b>			
Acute	36 (73.4)		
Chronic	4 (8.2)		
Acute and Chronic	9 (18.4)		

performed to evaluate convergent validity of FPS. Correlation coefficients and p-values were obtained. Comparisons between procedure and first opioid with the pain scales were done by performing Mann-Whitney test. Test statistics, effect size and p-values were reported. Cross-tabulation was performed to compare patients' and surgical residents' preferred pain scale and the reasons. Chi-squared values and p-values were obtained. Statistical significance was set at 0.05.

## Results

Total of 49 subjects were enrolled in this study. Demographic and patient characteristics were presented in Table 1. Spearman rank correlation showed a strong correlation between FPS and the Wong-Baker FACES scale ( $r(49) = 0.65, p < 0.001$ ) and the NRS ( $r(49) = 0.63, p < 0.001$ ) and found as Table 4. Differences in pain scales according to the procedure were presented in Table 2. A Mann-Whitney test indicated that pain scores in Wong-Baker Faces and NRS were higher in total knee arthroscopy (TKA) compared to total hip arthroscopy (THA). The effect size,  $r$ , for both scales was less than 0.30 indicating a small difference in the pain scores between these procedures. There were no differences in all pain scales for first opioid and type of pain. RPH-FPS was preferred by the patients and surgical residents compared to the other pain scales because it describes the pain well (Table 3). A total of 41 (85%) subjects were experiencing pain (Question 1 of the survey: Are you experiencing any pain?) and all enrolled subjects answered yes to Questions 2 and 4: Are you able to get out of bed, walk, or work with PT/OT? Are you able to carry on conversations with visitors or staff; Are you able to concentrate on either passive or active distractions? Twenty-five subjects (51%) answered yes to Question 3: Is pain affecting your sleep or is pain keeping you from sleep?

**Table 2.** Comparisons between pain scales and procedure

Pain scales	Median(Range)		Test Statistics, U	Test Statistics, Z	Effect size, r	p-value
	Total Knee (n=36)	Total Hip (n=13)				
FACES	4.5 (1.5-7.5)	3.5 (1.5-7.5)	146.0	-2.06	0.29	0.039
NRS	5 (2-8)	3 (1-8)	147.5	-1.98	0.28	0.048
FPS	4 (1-9)	3 (1-6)	167.0	-1.56	0.22	0.12

**Table 3.** Comparisons of preferred pain scale and reasons

Reasons	FACES scale	NRS	FPS	Chi-squared values (df)	p-value
Patients				31.21 (6)	<0.001
Descriptive	2	1	17		
Familiar with	2	0	0		
Easy	13	9	1		
Explains well	0	0	4		
Residents				49.08 (6)	<0.001
Descriptive	2	0	34		
Familiar with	0	9	0		
Easy	0	3	0		
Explains well	0	0	1		

**Table 4.** Correlation between RPH-FPS and NRS and Wong-Baker FACES scales

	Correlation Coefficient (p)	P-value
RPH_FPS		
Wong-Baker Faces	0.63	<0.001
NRS	0.65	<0.001

## Discussion

Today, healthcare is in a state of flux. The Drug Enforcement Agency (DEA) and Department of Justice (DOJ) in 2018 [13] are pushing the pharmaceutical companies to cut production of opioids in an attempt to battle the ever growing opioid crisis. There have been national shortages of opioids, and healthcare systems have to think outside the box. Multimodal therapies such as the use of combinations of analgesics, NSAIDS, anticonvulsants and antidepressants are being used in conjunction with opioids. Alternative therapies are also being used in order to save opioids for the most severe surgical patients. These alternative therapies may include guided imagery, distraction, reiki, meditations and biofeedback. The scale that was created uses descriptive words associated with numbers; an algorithm was then devised showing the effects on sleep, ability to complete ADLs, and the use of distractions, either passive (watching TV, listening to music, etc.) versus active distractions (activities that require focus, such as word games, knitting, or carrying on conversations). That algorithm was determined by the group and describes increased disruptions to sleep, ability to complete ADLs and use of distractions, either passive or active. The resulting scale can be seen in Appendix B. Assessments took place over a five month period and results sent to a statistician for analysis. The results validate the RPH-FPS in respect to having a strong correlation with two scales that have already been used and validated for years. The results from the preference questions is overwhelmingly in favor of the RPH-FPS with most of the reasons being that it is a more descriptive pain scale. The question is raised, "why is a new scale needed that tells us the same information?" The answer, this might be a tool that encourages better communication between patient and staff resulting in the patient being able to describe how pain is affecting their lives. This scale has been designed to not replace the NRS pain scale, but rather define what those numbers mean as it relates to the three areas of recovery that had been identified. This tool can also assist the healthcare team to do an objective assessment with better and more realistic recovery goals. In an article [14] there was a recommendation for clinicians to use a validated pain tool to assess and track response to postoperative pain, and adjust treatment plans accordingly. In the same article, another recommendation was that clinicians adjust the pain management plan on the basis of adequacy of pain relief and presence of adverse events. This tool should limit the number of adverse events by discussing with the patient the effects on sleep and function; when a PRN medication is given based on unidimensional pain intensity, the patient is at risk for becoming overly sedated, or somnolent and not able to safely participate with PT/OT for rehab purposes [3]. In a newsletter from the Joint Commission [15], under the standard PC.01.02.07.5 "The hospital involves patients in the pain management treatment planning process through the

following; Develop realistic expectations and measurable goals that are understood by the patient for the degree, duration, and reduction of pain as well as discussing the objectives used to evaluate treatment progress (for example, relief of pain and improved physical and psychosocial function). This scale is monitoring the patient's ability to return to function, while educating and relieving the patient's pain. The patient and health care provider are able to discuss and set realistic expectations by following a plan of care that focuses on the patient's ability to sleep; complete ADLs; and use distractions, such as listening to music or completing a puzzle, instead of dosing to a number [2].

This study used a rather homogenous population. The study consisted only of orthopedic patients; age ranged from 45 years to 78 years; men to women was 21 to 28. The hospital is in a rural area, and most of the patients were identified as Caucasian. There was a mix of patients with chronic, acute and mixed chronic-acute pain. The identification of whether or not a patient had chronic pain NOT associated with the current admission, or if this admission was strictly listed as acute pain, or if the patient had chronic pain, with an acute exacerbation. A larger study is indicated to include medical and surgical patients. The statistician determined, using the Power and Sample size calculations program developed by DuPont and Plummer, a total of 92 patient needs to be assessed for an adequate analysis to be done. As a result of the pilot study, it was also determined that the ranking of the scales would be modified to show the order of preference of the scale, (most preferred being rated 1 and least preferred being rated as 3). This would be rated for both patient and those completing the assessment. Pain does not have to be part of admission diagnosis; however, if pain is present at time of admission, the patient will have an invitation extended to participate in the study. The goal is to find if this scale will be accepted and preferred for those patients that did not have the education prior to going to preadmissions, as well as the medical patients that are coming into the system through the emergency department. The population will be general surgery, traumas, as well as medical patients, 18 year of age or greater, English as primary language, no diagnosis of cognitive impairment and no history of opioid abuse. In the initial study, the assessments were being completed by two surgical residents. This phase will be completed by RN's. The next step should be a good reference point to adopt this tool as an everyday item in the nursing assessment.

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# Appendix

## Appendix A:

MRN: \_\_\_\_\_

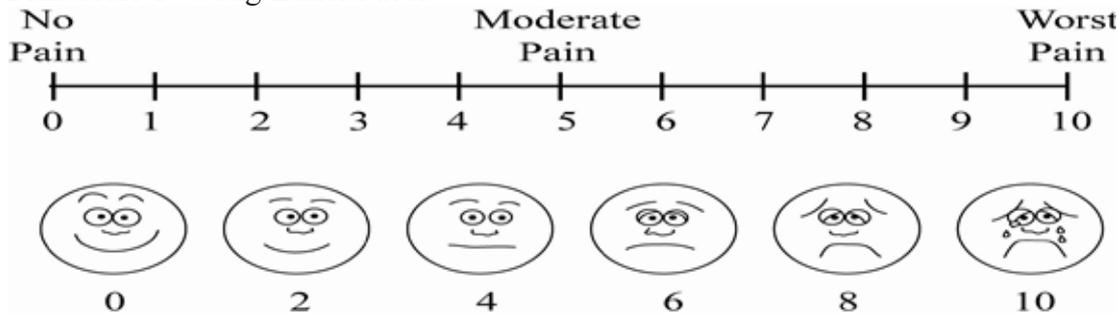
Post-operative day: Dropdown list- Baseline, Day 1, Day 2, Day 3, Day 4, Day 5.

I'd like to ask a few questions about how you are doing:

- Are you experiencing any pain or discomfort? Y or N
- Are you able to get out of bed, walk, or work with Physical Therapy or Occupational Therapy? Y or N
- Is pain keeping you from sleeping? Y or N
- Are you able to talk with visitors or staff; are you able to concentrate on either passive or active distractions? Passive distractions are watching TV, listening to music, talking with friends and family. Active distractions are reading, knitting, crossword puzzles, video games or any task that requires concentration to complete or perform. Y or N

I'd like to ask you your level of pain using three different pain scales:

Pain Scale 1- Wong-Baker Faces



Response: \_\_\_\_\_

**Pain Scale 2 Number Scale-** How would you rate your pain using the numbers 0-10 with 0 being no pain and 10 being the worse pain in your life? Response: \_\_\_\_\_

### Pain Scale 3 Functional Pain Scale:

Using the words below, which one best describes your pain?

Minimal- Hardly noticeable; no impact on completing tasks such as getting out of bed or ambulating; sleep is not affected; can use both passive and active distraction for comfort.

Mild- Noticeable when not distracted; no impact on completing tasks such as getting out of bed or ambulating; sleep is slightly affected; can use both passive and active distraction for comfort.

Uncomfortable- Pain is present but can complete all daily tasks; sleep is slightly affected; passive distraction only gives marginal relief.

Moderate- Constantly aware of pain; can complete tasks with some modification or help; passive distraction is no help, but active distraction gives some relief.

Distracting- Aware of pain; able to complete some activities but limited by pain; sleep is affected; active distractions are only slightly useful.

Distressing- Pain is present; unable to complete most tasks, very limited by pain; sleep is difficult; active distraction only gives marginal comfort.

Unmanageable- Pain interferes with all tasks; nothing seems to help; sleep is very difficult; active distractions are very difficult to concentrate on.

Intense- Cannot complete any task without much assistance; unable to sleep; unable to concentrate, conversation is difficult.

Severe- Cannot do any tasks even with assistance; can barely talk about it; unable to sleep; cannot concentrate on anything.

Immobilizing- Unable to move or talk due to intensity of pain; unable to sleep; unable to concentrate on anything.

Response: \_\_\_\_\_

Which of the pain scales did you like best?

Of the three scales which helped you best describe your pain?

(1)Wong-Baker Faces            (2) Number Scale            (3) Functional Pain Scale

Why did you like this scale best? \_\_\_\_\_

Now I'd like to ask about your functioning, how well you are doing

Was your functioning assessed prior to surgery? Y or N

Was there any discussion about your expected functionality after surgery? Y or N

For the researcher completing the assessment, of the three scales which was easier to complete and why?

(1)Wong-Baker Faces            (2) Number Scale            (3) Functional Pain Scale

Why did you like this scale best? \_\_\_\_\_

## Appendix B:

### RPH-FPS

Descriptor	Definition
No Pain (0)	No pain
Minimal (1)	Hardly noticeable/ no impact on ADL's/sleep not affected and able to use passive distraction for comfort. Mild range order
Mild (2)	Noticeable when not distracted/ no impact on ADL's/sleep only slightly affected and able to use both passive and active distraction for comfort. Mild range order
Uncomfortable (3)	Pain is present but can complete all ADL's/ sleep is slightly affected and passive distraction only gives marginal relief. Mild range order
Moderate (4)	Constantly aware of pain but can complete ADL's with modification/ sleep marginally affected at times/ passive distraction is of no use, but active distraction gives some relief. Moderate range order
Distracting (5)	Aware of pain/ able to complete some ADL's but limited by pain/ sleep is affected and active distractions are only slightly useful. Moderate range order
Distressing (6)	Pain is present/ unable to complete most ADL's limited by pain/sleep is difficult and active distraction is only marginal. Moderate range order
Unmanageable(7)	Pain interferes with normal ADL's/ nothing seems to help/sleep is very difficult/ active distractions are very difficult to concentrate on. Severe range order
Intense (8)	Cannot complete any ADL's without much assistance/ can't concentrate/conversation is difficult/unable to sleep and unable to use distraction. Severe range order
Severe (9)	Cannot do any ADL's even with assistance can barely talk/unable to sleep and unable to use distraction. Severe range order
Immobilizing (10)	Unable to move or talk due to intensity of pain/ unable to sleep and unable to use distraction. Severe range order

Active Distractions- Reading, knitting, crossword, video games, task that require concentration to complete or perform

Passive distractions- Watching TV, listening to music, talking with friends or family