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Validation of the Surgical Pain Scales in Women undergoing Pelvic Reconstructive Surgery

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Abstract

Objective—Surgical Pain Scales (SPS) consist of 4 items that measure pain at rest, during normal activities, during work/exercise and quantify unpleasantness of worst pain, which are valid and responsive in men undergoing hernia repair. Our objective was to evaluate the psychometric properties of SPS in women undergoing vaginal surgery for pelvic organ prolapse (POP) and stress urinary incontinence (SUI).

Methods—We modified SPS by converting original response scales from a visual analog scale (VAS) to Numerical Rating Scales (NRS). NRS have lower error rates and higher validity than VAS. The sample included 169 women with stage II–IV POP and SUI in a randomized trial comparing sacrospinous ligament fixation to uterosacral vault suspension with and without pelvic floor muscle training. Participants completed SPS and SF-36 at baseline, 2-weeks and 6-months after surgery. Construct validity and responsiveness were examined in cross-sectional and longitudinal data using Pearson's correlation and ANOVA.

Results—Pain at rest, during normal activities and during work/exercise worsened at 2-weeks ($p < 0.05$) and all measures of pain improved from baseline to 6 months ($p < 0.0001$). Construct validity was demonstrated by correlations of .51–.74 between SPS and the SF-36 Bodily Pain Scale ($p < 0.0001$). Pain worsened on SF-36 between baseline and 2-weeks in 63% of participants and this group demonstrated a mean increase in pain of 1.9 (SD 2.8) on the SPS (effect size 0.99) confirming responsiveness of the scale.

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This trial is registered at clinicaltrials.gov under Registration # NCT00597935

Reprints will not be available.

Conclusions—The modified Surgical Pain Scales are valid and responsive in women after pelvic reconstructive surgery.

Keywords

Postoperative Pain; Scales; Pelvic Reconstructive Surgery; Pelvic Organ Prolapse

Introduction

Adequate pain control after surgical procedures significantly affects patient satisfaction.(1) Accurate assessment and quantification of pain is essential to optimize post-operative pain management. The Surgical Pain Scales (SPS) consist of four visual analog scales that measure pain at rest, pain during normal activities, pain during work or exercise, and pain unpleasantness.(2) The SPS are used to compare pain levels between groups at a single point in time or to track changes in pain levels for individual patients over time or after operations. The SPS were originally constructed to assess patient-level outcomes in men enrolled in a multi-center randomized clinical trial of open versus laparoscopic inguinal herniorrhaphy.(2) Longitudinal data from 2,164 men enrolled in this trial confirmed the reliability, validity, and responsiveness of the SPS.(2) Several studies have demonstrated clinically important differences in pain response and experience between men and women.(3–5) Therefore, one cannot assume that the psychometric properties demonstrated in men in the original validation of the SPS will be similar in women.

The visual analog scale (VAS) is widely used to evaluate both acute and chronic pain.(6) However, the VAS has inherent limitations including a high rate of “unscorable” data and low face validity among elderly patients.(7) As such, the VAS may be suboptimal for measuring pain in women undergoing pelvic reconstructive surgery, many of whom are elderly. We, therefore, modified the SPS so that the responses to the 4 scales used a numeric rating scale (NRS) (0–10), which has properties that are not age-dependent.(7) The aim of this study was to assess the psychometric properties of this modified SPS in women undergoing surgery for pelvic organ prolapse and stress urinary incontinence.

Materials and Methods

This was a planned supplementary study of the Operations and Pelvic Muscle Training in the Management of Apical Support Loss (OPTIMAL) trial, a multi-center randomized trial conducted by the Pelvic Floor Disorders Network (PFDN).(8) The principal aims of the OPTIMAL trial are 1) to compare surgical outcomes after sacrospinous ligament fixation versus uterosacral ligament vaginal vault suspension and 2) to assess the role of perioperative behavioral and pelvic floor muscle training versus usual care in women undergoing vaginal surgery for apical prolapse and stress urinary incontinence using a 2x2 randomized factorial design. The PFDN is sponsored by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and consists of seven clinical sites, a data coordinating center, and NIH staff. A detailed description of the OPTIMAL trial design is published.(8)

The study sample for this analysis included a subset of 169 consecutive women enrolled in the OPTIMAL trial between February 2008 and August 2009. All OPTIMAL trial participants are adult women with Stage II – IV pelvic organ prolapse and coexisting stress urinary incontinence symptoms who have prolapse at the vaginal apex (with or without a uterus) and opted for vaginal surgery for prolapse repair. All PFDN sites obtained local institutional review board approval, and all participants completed informed consent. Enrolled participants were randomized to receive either a sacrospinous ligament fixation or

uterosacral vaginal vault suspension as part of their vaginal prolapse repair. In addition, all participants received a tension-free vaginal tape (TVT) to treat their stress urinary incontinence. Participants also underwent a second randomization to either a perioperative behavioral and pelvic muscle training program (PMT) or usual clinical care. Randomization was stratified by site with separate randomization schedules generated by the data coordinating center using permuted blocks. Participants and evaluators remained blinded to treatment assignment. The perioperative behavioral therapy program began two to four weeks prior to surgery and continued for three months after surgery. Follow-up of the OPTIMAL trial is ongoing so for purposes of this analysis, comparisons within and between the surgical and behavioral interventions were not performed and blinding of the participants, investigators and data-coordinating center was maintained.

The original 4 scales of the SPS were modified so that each of the 4 items is scored on an 11-point NRS (0 to 10) rather than a VAS. (Figure) Additionally, we removed “having sex” from the item “How much pain did you have when you were having sex, exercising, doing strenuous work or lifting objects you used to be able to lift comfortably?” as we did not think this activity was consistent with the other activities listed in the item when applied to women. Otherwise, the stems of each of the 4 items of the SPS are unchanged from the original scale.

Demographics, medical history and standardized pelvic examination were completed at enrollment. Participants completed several self-administered questionnaires including the modified SPS and the SF-36.(2, 3) Postoperatively, all participants received a standardized set of postoperative instructions including instructions on resumption of physical activities. Postoperative pain management was administered according to the standard at each clinical site. Participants self-administered the modified SPS and SF-36 again at 2 weeks and 6 months after surgery. At 2 weeks, participants also rated their average pain during normal activities compared to before surgery on a 5-point scale (from “much better” to “much worse”).

The validity of the SPS was assessed using the same general approach as used by McCarthy et al.(2) As these scales are intended to be used in the perioperative period, it is important to establish validity of the scales both pre- and postoperatively. *Construct validity* considers the extent to which a scale or sub-scale produces scores consistent with those of another instrument with known characteristics. A series of correlational analyses examined two of the variants of construct validity, *convergent and discriminant validity*, of the four scales and the eight dimensions of the SF-36.(3) Specifically, we tested the hypothesis that the SPS would have larger correlations with the SF-36 bodily pain scale (convergent validity) and smaller correlations with its other domains such as the mental health subscale (divergent validity). *Construct validity* was assessed at baseline and 6 months postoperatively. Correlations between the SPS and SF-36 bodily pain scale were also evaluated at the 2-week visit, as this is the point of assessment when pain is expected to be the highest.

As with validity, the *responsiveness* of the SPS was assessed using the same general approach used in the original development of the instruments.(2) Although limited, evidence suggests that pelvic organ prolapse does not usually result in pain (9); therefore, we anticipated that the major factor impacting pain and activity level in participants enrolled in OPTIMAL would be the surgery itself and not their prolapse or urinary incontinence. We hypothesized that participants would have low pain scores at baseline with higher pain scores 2-weeks after surgery. By 6-months, pain scores should approach or improve beyond baseline levels. To examine *responsiveness* of the SPS, we evaluated change over two periods: baseline to 2-weeks and 2-weeks to 6-months. Within each time period, participants were classified into one of three pain groups (improved, unchanged, or worse) based on the

change in the SF-36 bodily pain scale. The minimum clinically important difference (MCID) of the SF-36 scale is 2 points for bodily pain scale below 40 and 3 points for bodily pain scale above 40. (3) We considered participants' pain to be "unchanged" if the change in pain scale score was smaller than the MCID. Likewise, we considered participants' pain to be "improved" if bodily pain scale scores increased by more than the MCID and "worse" if they decreased by more than the MCID. The direction and amount of change of the SPS was determined for each group (improved, unchanged and worse) at each of the two periods and compared using ANOVA.

Additionally, 2 weeks after surgery, participants rated their current pain during normal activities to their pain during normal activities before surgery on a 5-point scale from "very much better" to "very much worse". Participants were then classified as "improved," "worse" or "unchanged." As described above, the direction and amount of change of the SPS was determined for each group for each of the two periods and compared using ANOVA. We also evaluated the effect size for the SPS as a third measure of responsiveness. The effect size is the change in mean values between two time points divided by the standard deviation of the baseline value. An effect size of 0.2 – 0.5 is considered small, 0.5–0.7 is considered moderate, and 0.8 and above is considered large.(10)

For convergent and divergent validity, a sample size of 85 participants is sufficient to detect correlations of 0.3 or greater. In the assessment of responsiveness, 150 participants provides at least 80% power (alpha 0.05, two-sided test) to detect differences among the groups using one-way ANOVA defined by improvement, no change and worsening in pain during normal activity of the same magnitude and variability of those seen by McCarthy et al(2), with the additional assumption that the proportion of participants in the 3 categories is roughly 1/2:1/4:1/4, respectively.

Results

Ninety two percent (155/169) of participants completed both the modified SPS and the SF-36 at baseline and 2 weeks postoperatively, and 149 (88%) completed both questionnaires at 6-months. The study sample had a mean±SD age of 58±10 years. The majority was Caucasian (89%) while 6.5% were African American and 4.5% were Asian or other; 20% of the sample identified themselves as Hispanic. At enrollment 54/154 (35%) of the study sample had stage II pelvic organ prolapse, 90/154 (58.5%) were Stage III and 10/154 (6.5%) were Stage IV. Table 1 displays mean and standard deviation for the 4 SPS items at baseline, 2-weeks, and 6-months as well as change in scores from baseline to 2-weeks and 2-weeks to 6-months. Pain at rest, pain during normal activity, and pain during work/exercise were significantly worse 2-weeks after surgery, while pain at rest, pain during normal activity, pain during work/exercise and pain unpleasantness all significantly improved between 2-weeks and 6-months after surgery. Similarly, all four measures of pain improved significantly from baseline to 6-months postoperatively. Overall, mean pain scores were relatively low (range 0.9 to 4.0) at baseline, 2-weeks and 6 months after surgery, although pain scores among individual patients varied over the full spectrum of the scales.

Construct validity for the SPS is demonstrated in Table 2. Convergent validity is confirmed as each of the 4-items on the SPS correlates more strongly with the SF-36 bodily pain subscale ($r=0.57$ to 0.71) than the other SF-36 subscales. Similarly, the modified SPS items correlated less strongly with the SF-36 subscales not expected to be as directly related to bodily pain, such as mental health ($r=0.28$ to 0.42) and social functioning subscales ($r=0.37$ to 0.52) demonstrating the divergent validity of the scales. Similar relationships are noted between the SPS and the SF-36 subscales at 2-weeks and 6-months postoperatively (data not

shown). The mean values for the three pain intensity scales showed higher levels of pain as activity level increased at each time point. (Table 1)

The mean change in the SPS scores for participants whose pain was classified as improved, unchanged or worse based on the SF-36 bodily pain scale from baseline to 2-weeks and 2-weeks to 6-months are shown in Tables 3 and 4, respectively. The SPS scores changed significantly in each of the three groups (improved, unchanged, and worse) during both time periods ($p < .0001$ and $p = .0004$ respectively). Participants whose pain was “worse” based on the SF-36 bodily pain scale (99/155; 63%) from baseline to 2-weeks experienced the largest change in the SPS with a mean change of 1.9 ± 2.8 and a large effect size (0.99). Participants whose pain was “unchanged” had the smallest change in the SPS (mean change -0.77 ± 2.6 ; effect size 0.36). From 2-weeks to 6-months, 75% (112/149) of participants were classified as having “improved” pain by the SF-36 bodily pain scale. This group demonstrated the greatest change in the SPS scores over this time period with a mean improvement of 2.5 ± 2.4 and a large effect size (0.96). Those classified as “unchanged” or “worse” over this time period (12.5% each) had substantially less improvement in SPS score.

Additionally, 2-weeks after surgery participants were asked to rate their average pain during normal activities compared to before their surgery (external anchor). Thirty-two percent (49/154) classified their pain as “a little worse” or “much worse” and this group had the largest change in the SPS score (mean change $+2.0 \pm 3.4$; effect size 0.84). In contrast, 52% ($n=81$) reported that their pain was “a little better” or “much better” and 16% ($n=24$) reported “no change” and the change in the SPS score was substantially less in these groups (mean change 0.2 ± 2.8 and 0.3 ± 3.1 and effect sizes of 0.07 and 0.08 respectively).

Discussion

Pain, often called the “fifth vital sign”, must be assessed and managed for all hospitalized patients and those undergoing office-based procedures. Pain management is an essential component of quality patient care. The Centers for Medicare & Medicaid Services (CMS) considers pain assessment prior to initiation of treatment and follow-up to be a measureable quality indicator (www.cms.gov). In the clinical setting, pain intensity is typically assessed using a 0–10 NRS. This simple measurement of pain is practical, easy for patients to understand and easy for caregivers to interpret. However, pain expression is a complex process with both sensory and emotional components, and this common one-dimensional assessment of pain may not adequately capture the pain experience for postoperative patients. The Surgical Pain Scales were constructed to assess both the sensory and affective components of postoperative pain while remaining simple and efficient. By assessing pain resulting from different levels of activity as well as assessing the “unpleasantness” of pain, the SPS has the advantage of being able to identify the circumstances and associated magnitudes under which pain occurs and assess qualitative features of the patient experience.(2) The simplicity of the modified SPS also makes it ideal for obtaining values at multiple time points, thereby establishing a temporal pattern.

The SPS, as originally constructed, consisted of four 150mm VAS. While VAS have excellent psychometric properties and are commonly used to assess pain, they also have several disadvantages.(6, 11, 12) VAS are difficult to administer to patients with perceptual-motor problems; impractical to administer over the phone and score in a clinical setting; and difficult for elderly and less educated patients to understand and use.(6, 7, 11, 12) The NRS and VAS agree well and are equally sensitive in assessing acute pain after surgery.(11) However, the NRS is more practical, easier to understand for most people, does not require clear vision, dexterity, paper and pen to administer; and, unlike the VAS, its properties are

not age-dependent.(7, 11) The NRS has higher face validity and lower rates of missing or “un-scorable” data among older surgical patients compared to VAS.(7) In one study of 504 patients undergoing surgery, the rate of un-scoreable data from the VAS was 14–18% compared with 4% for the NRS.(7) The average age of women undergoing surgery for pelvic organ prolapse in the United States is 57 +/- 14 years with a large proportion of these women over the age of 65.(13) Therefore, we modified the SPS by converting its responses from VAS to NRS in order to improve its applicability in women undergoing pelvic reconstructive surgery. In this study, we demonstrated that these modified Surgical Pain Scales are valid and responsive and can be used to evaluate various aspects of perioperative pain in women undergoing surgery for pelvic organ prolapse and stress urinary incontinence.

Similar to the study by McCarthy et al, we found that the modified SPS demonstrated both concurrent and divergent validity. The correlations seen in this study between the SPS and the bodily pain scale of the SF-36 ranged from 0.51 to 0.74; these are comparable to if not better than those described in the original manuscript validating the SPS among male hernia patients ($r=0.44$ to 0.60). As predicted, the sensory and affective pain ratings of the SPS were highly correlated with the SF-36 bodily pain scale at each time point while correlations were substantially lower between scales not thought to be directly related to pain. Validity was further confirmed as the modified SPS scores increased with increasing levels of activity. We did not assess the internal consistency or test-retest reliability of the modified SPS in this study, however, these properties were excellent in McCarthy’s study, and NRS generally have excellent internal consistency and good test-retest reliability.(2, 12)

Importantly, the modified SPS was sensitive to change after surgery. The three SPS intensity scales demonstrated a significant increase in reported pain 2-weeks after surgery, and a significant decline in reported pain from 2-weeks to 6-months after surgery. The pain unpleasantness scale did not change from baseline to 2-weeks post-surgery, but did show a significant improvement from 2-weeks to 6-months after surgery. In the 2-week postoperative period, the SPS mirrored the responsiveness of the SF-36 bodily pain scale. The majority of participants reported worsening of pain during this period and the mean SPS scores increased appropriately with an effect size indicating excellent responsiveness. Not surprisingly, participants whose pain was improved by the SF-36 reported less pain on the SPS with a moderate effect size, while those whose pain was unchanged showed the smallest change in SPS. Three quarters of participants demonstrated an improvement in pain by the SF-36 between 2-weeks and 6-months after surgery, and this group showed the largest improvements in SPS scores with an effect size consistent with excellent responsiveness (0.96). In contrast, those who did not indicate improvement in pain by the SF-36 during this time period had significantly less change in their SPS scores.

In addition to classifying patients’ change in pain by the SF-36 Bodily Pain scale, we also asked patients at two weeks post surgery to rate their change in pain during normal activities compared to before surgery. Those who indicated that their pain during normal activities was worse compared to before surgery had a significant worsening of reported pain by the SPS. However, this only represented 32% of the participants, approximately half of the number of participants whose pain worsened during this time period according to the SF-36 Bodily Pain scale. Of those who indicated that their pain was unchanged or improved by this self-rating of change in pain, there was almost no change in average SPS score. In fact, it appears that the global rating of change in pain item used did not correlate well with the SPS or the SF-36 Bodily pain scale. There are several factors that may have contributed to this lack of correlation. First, this item was only assessed at 2-weeks postoperatively, and it seems unlikely that many women would have resumed normal activities by this time period, particularly given the standard postoperative instructions. In addition, external anchors asking for comparisons before a treatment event like the one used in this study are subject to

recall bias. A patient's experience of change in pain over a two week period may not correlate with their current pain or pain within the last 24 hours, as is assessed by the SPS. Other investigators have suggested global ratings of change are potentially problematic because patients' assessment of their past health might be influenced by their current health status.(14, 15) We found similar issues using this type of global rating of change when evaluating the psychometric properties of a functional activity scale in this same study population.(16)

The primary strength of this study is its prospective longitudinal design in a well characterized sample of women with pelvic floor disorders from multiple centers in the United States. The women in our study reported relatively low levels of pain at each time point potentially limiting our ability to demonstrate the full range of variability and responsiveness of the scales. Pelvic organ prolapse and stress urinary incontinence do not, in themselves, typically cause pain.(9) As such, this study principally evaluated the pain associated with pelvic reconstructive surgery and its recovery. All participants in this study underwent surgery using a vaginal approach. One of the primary advantages of vaginal surgery is its quicker recovery and lower postoperative pain relative to other approaches, particularly surgeries requiring laparotomy. There is a risk of a "floor effect" in this study, particularly at 6 months when patients are expected to have completely recovered from surgery. Additional research in different populations using different surgical approaches including those requiring laparotomy and laparoscopy and with larger samples would be valuable to further evaluate the psychometric properties of the SPS.

A number of pain scales and questionnaires exist for use in clinical practice and research.(6, 11) Few are specifically designed for assessing pain in the postoperative period. We demonstrated that a modified-version of the SPS using the NRS to avoid limitations inherent to VAS, is valid, responsive, and ideally suited to assess perioperative pain in women undergoing pelvic reconstructive surgery. The simplicity of the modified SPS makes it well suited for clinical outcomes research as well as to quantify patient's pain in clinical care to improve patient satisfaction and quality of care.

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References

1. Jamison RN, Ross MJ, Hoopman P, et al. Assessment of postoperative pain management: patient satisfaction and perceived helpfulness. *Clin J Pain*. 1997; 13(3):229–36. [PubMed: 9303255]
2. McCarthy M Jr, Chang CH, Pickard AS, Giobbie-Hurder A, et al. Visual analog scales for assessing surgical pain. *J Am Coll Surg*. 2005; 201(2):245–52. [PubMed: 16038823]
3. Ware, JE, Jr. Manual and Interpretation Guide. Boston: Heath Institute, New England Medical Center; 1993. SF-36 Health Survey.
4. Eckardt AJ, Swales C, Bhattacharya K, et al. Open access colonoscopy in the training setting: which factors affect patient satisfaction and pain? *Endoscopy*. 2008; 40(2):98–105. [PubMed: 18253904]
5. Hogg-Johnson S, van der Velde G, Carroll LJ, et al. The burden and determinants of neck pain in the general population: results of the Bone and Joint Decade 2000–2010 Task Force on Neck Pain and Its Associated Disorders. *Spine*. 2008; 33(4 Suppl):S39–51. [PubMed: 18204398]
6. Katz J, Melzack R. Measurement of pain. *Surg Clin North Am*. 1999; 79(2):231–52. [PubMed: 10352653]

7. Gagliese L, Weizblit N, Ellis W, Chan VW. The measurement of postoperative pain: a comparison of intensity scales in younger and older surgical patients. *Pain*. 2005; 117(3):412–20. [PubMed: 16153776]
8. Barber MD, Brubaker L, Menefee S, et al. Operations and pelvic muscle training in the management of apical support loss (OPTIMAL) trial: design and methods. *Contemp Clin Trials*. 2009; 30(2): 178–89. [PubMed: 19130903]
9. Heit M, Culligan P, Rosenquist C, Shott S. Is pelvic organ prolapse a cause of pelvic or low back pain? *Obstet Gynecol*. 2002; 99(1):23–8. [PubMed: 11777505]
10. Crosby RD, Kolotkin RL, Williams GR. Defining clinically meaningful change in health-related quality of life. *J Clin Epidemiol*. 2003; 56(5):395–407. [PubMed: 12812812]
11. Breivik H, Borchgrevink PC, Allen SM, et al. Assessment of Pain. *Br J Anesth*. 2008; 101:17–24.
12. Hadjistavropoulos T, Herr K, Turk DC, et al. An interdisciplinary expert consensus statement on assessment of pain in older persons. *Clin J Pain*. 2007; 23(1 Suppl):S1–43. [PubMed: 17179836]
13. Jones KA, Shepherd JP, Oliphant SS, et al. Trends in inpatient prolapse procedures in the United States, 1979–2006. *Am J Obstet Gynecol*. 2010; 202(5):501.e1–7.
14. Yost KJ, Sorensen MV, Hahn EA, et al. Using multiple anchor- and distribution-based estimates to evaluate clinically meaningful change on the Functional Assessment of Cancer Therapy-Biologic Response Modifiers (FACT-BRM) instrument. *Value Health*. 2005; 8(2):117–27. [PubMed: 15804320]
15. Leidy NK, Wyrwich KW. Bridging the gap: using triangulation methodology to estimate minimal clinically important differences (MCIDs). *COPD*. 2005; 2(1):157–65. [PubMed: 17136977]
16. Barber MD, Kenton K, Janz NK, et al. Validation of the Activities Assessment Scale in women undergoing pelvic reconstructive surgery. *FPMRS*. 2012 in review.

We want to know how much pain or discomfort you had within the last 24 hours. Check the box below to indicate the **average** amount of pain or discomfort you experienced. For instance, if you did not have much pain today you would check a box near the words, No Pain Sensation. If you had a lot of pain today, you would check a box closer to the words, **Most Intense Pain Imaginable**

1. What was the average amount of pain you had when you were at rest?

0	1	2	3	4	5	6	7	8	9	10
No pain sensation					Most intense pain imaginable					

2. How much pain did you have during your **normal activities**?
(for example, walking, climbing stairs, driving a car, getting up from a chair)

0	1	2	3	4	5	6	7	8	9	10
No pain sensation					Most intense pain imaginable					

3. How much pain did you have when you were **exercising, doing strenuous work,** or **lifting** objects you used to be able to lift comfortably?

☐ I have not done any of these activities today

0	1	2	3	4	5	6	7	8	9	10
No pain sensation					Most intense pain imaginable					

4. How **unpleasant or disturbing** was the **worst pain** that you had today?

0	1	2	3	4	5	6	7	8	9	10
Not Bad at All					Most intense bad feeling imaginable					

Figure 1.
Figure Modified Surgical Pain Scales

Table 1

Surgical Pain Scale Values at Baseline, 2-weeks, and 6-months after Surgery.

Surgical Pain Scale	Time	n	Mean (SD)	Median (IQR)	Range	Mean Change (95% CI)	P value *
Average pain at rest	Baseline	155	1.6 (2.0)	1 (0,3)	0-8		
	2 week	155	2.3 (2.5)	1 (0,4)	0-10	0.8 (0.4, 1.1) #	0.0002
	6 month	149	0.6 (1.4)	0 (0,0)	0-7	-1.8 (-2.1, -1.4) ##	<0.0001
Pain during normal activity	Baseline	155	2.2 (2.4)	2 (0,4)	0-9		
	2 week	155	2.9 (2.6)	2 (1,4)	0-10	0.8 (0.3, 1.2) #	0.0018
	6 month	149	0.9 (1.8)	0 (0,1)	0-8	-2.0 (-2.4, -1.6) ##	<0.0001
Pain during work or exercise	Baseline	86	2.6 (2.5)	2 (0,4)	0-9		
	2 week	33	4.0 (3.3)	4 (1,6)	0-10	1.0 (0.2, 1.9) #	.048
	6 month	96	1.1 (2.0)	0 (0,2)	0-9	-2.6 (-3.5, -1.8) ##	<0.0001
Unpleasantness of the worst pain sensation	Baseline	153	2.5 (2.7)	2 (0,4)	0-10		
	2 week	155	2.9 (2.8)	2 (0,5)	0-10	0.4 (0.1, 0.9) #	0.26
	6 month	147	0.9 (1.8)	0 (0,1)	0-8	-2.0 (-2.5, -1.5) ##	<0.0001

SD, standard deviation, IQR, intraquartile range, CI, confidence interval

* Tukey-adjusted p value

Change from baseline to 2 weeks (2 week value minus Baseline) – positive numbers represent an increase in pain, negative numbers represent a decrease in pain

Change from 2 weeks to 6 months (6 month value minus 2 weeks)

Table 2

Correlation between SF-36 Subscales and Surgical Pain Scales at Baseline**

Subscale	Average pain at rest		Pain During work or exercise		Pain during normal activity		Unpleasantness of the pain sensation	
	N	Pearson Correlation (95% CI)	N	Pearson Correlation (95% CI)	N	Pearson Correlation (95% CI)	N	Pearson Correlation (95% CI)
BODILY PAIN	152	-0.57 (-0.67, -0.45)*	84	-0.71 (-0.8, -0.58)*	152	-0.68 (-0.75, -0.58)*	150	-0.57 (-0.67, -0.45)*
GENERAL HEALTH	154	-0.38 (-0.51, -0.24)*	85	-0.46 (-0.61, -0.27)*	154	-0.41 (-0.53, -0.26)*	152	-0.39 (-0.52, -0.25)*
MENTAL HEALTH	154	-0.29 (-0.43, -0.14)#	85	-0.42 (-0.58, -0.23)*	154	-0.3 (-0.44, -0.15)#	152	-0.28 (-0.42, -0.13)#
PHYSICAL FUNCTIONING	155	-0.43 (-0.55, -0.29)*	86	-0.57 (-0.69, -0.4)*	155	-0.5 (-0.61, -0.37)*	153	-0.4 (-0.52, -0.26)*
ROLE EMOTIONAL	153	-0.25 (-0.39, -0.1)#	86	-0.45 (-0.6, -0.26)*	153	-0.3 (-0.44, -0.15)#	151	-0.31 (-0.45, -0.16)*
ROLE PHYSICAL	155	-0.26 (-0.4, -0.11)#	86	-0.45 (-0.6, -0.26)*	155	-0.43 (-0.55, -0.29)*	153	-0.37 (-0.49, -0.22)*
SOCIAL FUNCTIONING	154	-0.37 (-0.5, -0.22)*	85	-0.52 (-0.66, -0.34)*	154	-0.46 (-0.57, -0.32)*	152	-0.46 (-0.58, -0.33)*
VITALITY	154	-0.32 (-0.46, -0.17)*	85	-0.59 (-0.71, -0.43)*	154	-0.45 (-0.56, -0.31)*	152	-0.46 (-0.57, -0.32)*

* p-value <0.0001 for tests on whether correlation is zero.

p-value <0.01 for tests on whether correlation is zero.

** Higher scores on SPS indicate more pain, while higher scores on SF36 indicate less pain

Mean Change and Responsiveness of Surgical Pain Scales from Baseline to 2-weeks after Surgery by Change in SF-36 Bodily Pain Scale.

Table 3

SF-36 Bodily Pain [#]	N Total=155	mean (SD) at baseline	mean (SD) at 2 week follow-up	mean (SD) Change	Effect size (change/SD)	P-value [*]
Improved	40	3.6 (2.7)	2.2 (2.6)	-1.4 (2.7)	-0.53	<0.0001
No Change	13	2.8 (2.1)	2.0 (2.3)	-0.77 (2.6)	-0.36	
Worse	99	1.5 (1.9)	3.3 (2.6)	1.9 (2.8)	0.99	

^{*} F-statistics testing whether SPS change differs among the three categories according to SF-36 physical functioning subscale.

[#] For baseline < 40: +/- 2 points for "no change" category, > 2 for "improving", < -2 for "worsening";

For baseline 40: +/- 3 points for "no change" category, > 3 for "improving", < -3 for "worsening".

Mean Change and Responsiveness of Surgical Pain Scales from 2-weeks to 6-Months after Surgery by Change in SF-36 Bodily Pain Scale.

Table 4

SF-36 Bodily Pain [#]	N Total=149	mean (SD) at 2 week follow-up	mean (SD) at 6 month follow-up	Mean SPS Change (SD)	Effect size	P-value [*]
Improved	112	3.26 (2.62)	0.73 (1.46)	-2.53 (2.44)	-0.96	0.0004
No Change	17	1.24 (1.76)	1.00 (1.94)	-0.24 (1.98)	-0.13	
Worse	17	3.06 (2.88)	2.41 (2.94)	-0.65 (4.08)	-0.22	

^{*} F-statistics testing whether SPS change differs among the three categories according to SF-36 physical functioning subscale.

[#] For 2-week < 40: +/- 2 points for "no change", category, > 2 for "improving", < -2 for "worsening";

For 2-week 40: +/- 3 points for "no change", category, > 3 for "improving", < -3 for "worsening".