
Comparison of Generic Versus Specific Quality-of-Life Scales for Mesh Hernia Repairs

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- BACKGROUND:** With the use of mesh shown to considerably reduce recurrence rates for hernia repair and the subsequent improvement in clinical outcomes, focus has now been placed on quality-of-life outcomes in patients undergoing these repairs, specifically, as they relate to the mesh prosthesis. Traditionally, quality of life after hernia surgery, like many other medical conditions, has been tested using the generic SF-36 survey. The SF-36 quality-of-life survey, although well studied and validated, may not be ideal for patients undergoing hernia repairs. We propose a new quality-of-life survey, the Carolinas Comfort Scale (CCS), pertaining specifically to patients undergoing hernia repair with mesh; our goal was to test the validity and reliability of this survey.
- STUDY DESIGN:** The CCS questionnaire was mailed to 1,048 patients to assess its acceptability, responsiveness, and psychometric properties. The survey sample included patients who were at least 6 months out after hernia repair with mesh. Patients were asked to fill out the CCS and the generic SF-36 questionnaires, four questions comparing the two surveys, and their overall satisfaction relating to their hernia repair and mesh.
- RESULTS:** The reliability of the CCS was confirmed by Cronbach's α coefficient (0.97). Test-retest validity was supported by the correlation found between two different administrations of the CCS; both Spearman's correlation coefficient and the kappa coefficient were important for each question of the CCS. Assessment of its discriminant validity showed that both the mean and median scores for satisfied patients were considerably lower than those for dissatisfied patients. Concurrent validity was demonstrated by the marked correlations found between the CCS and SF-36 questionnaire scales. When comparing the two surveys, 72% of patients preferred the CCS questionnaire, 80% believed it was easier to understand, 66% thought it was more reflective of their condition, and 69% said they would rather fill it out over the SF-36.
- CONCLUSIONS:** The CCS better assesses quality of life and satisfaction of patients who have undergone surgical hernia repair than the generic SF-36. (*J Am Coll Surg* 2008;206:638–644. © 2008 by the American College of Surgeons)
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Hernia repairs represent one of the most common general surgical operations, with more than 800,000 inguinal hernias repaired in the US in 2003 and an estimated 90,000 ventral hernias repaired annually.¹ Impairment in quality of life is a major reason why hernia patients seek surgical repair, and changes in health-related quality of life are how patients evaluate the efficacy of their operations.² Quality-

of-life assessments explore the repercussions of the medical condition and treatments as perceived by the patient.³

Currently, the SF-36 is the "gold standard" for measuring quality of life for patients who have undergone hernia repairs with mesh in the US. But it has been demonstrated that the SF-36 is not an adequate measure of quality of life for those who suffer from a chronic condition. For these patients, a disease-specific quality-of-life questionnaire has been shown to provide a better assessment of patient health-related quality of life.⁴

Traditionally, chronic medical conditions, such as diabetes or irritable bowel syndrome, persist for long periods of time and are often resistant to medical treatment. Although patients undergoing hernia repair are not often thought of as having a chronic medical condition, it is important to realize that placement of a mesh, a foreign body, may lead to longterm physical and mental impairment. So the use of

Competing Interests Declared: None.

Winner of the 2007 Annual American Hernia Research Award.

Received May 31, 2007; Revised November 7, 2007; Accepted November 19, 2007.

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Table 1. Surgical Technique

Type	Dissatisfied patients		Satisfied patients	
	n	%	n	%
Laparoscopic	9	60	64	79
Open	6	40	17	21

a disease-specific quality-of-life questionnaire for patients undergoing hernia repair with surgical mesh is well justified. The purpose of our study was to design and validate a hernia-specific questionnaire, the Carolinas Comfort Scale (CCS), for patients undergoing hernia repair with mesh.

METHODS

Inclusion criteria for this study consisted of patients who had undergone hernia repair with mesh from 2002 to 2005 at Carolinas Medical Center in Charlotte, NC. Patients were asked to fill out both the SF-36 and CCS questionnaires and to state their overall satisfaction with their hernia repair and mesh. Patients were mailed questionnaires and provided with stamped, self-addressed envelopes to be mailed back to the project administrator. Patients were re-tested with the same questionnaire 6 months after receipt of the first questionnaire. This type of method is well justified; it has been previously demonstrated that mailed questionnaires are as valid as in-person responses or replies obtained by telephone.⁵

The SF-36 measures the following eight domains of quality of life: physical functioning (PF), role-physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role-emotional (RE), and mental health (MH). Scores for these domains range from 0 to 100, with 100 being the optimal level of function.⁴ The CCS is a 23-item, Likert-type questionnaire that measures severity of pain, sensation, and movement limitations from the mesh in the following eight categories: laying down (LD), bending over (BO), sitting up (SU), activities of daily living (ADL), coughing or deep breathing (CB), walking (W), stairs (S), and exercise (E). The CCS score is derived by adding the scores from each of the 23 items. The best possible score is 0 and the worst possible score is 115.

In addition, patients were asked the following four questions: 1. Which questionnaire do you like best? 2. Which questionnaire is easier to understand? 3. Which questionnaire is more reflective of the problems you have with your mesh? 4. Given the choice, which questionnaire would you rather fill out?

Statistical analysis

Mean values were compared by the Wilcoxon rank-sum test and categorical data by the Fisher's exact test. Correla-

Table 2. Hernia Type

Type	Dissatisfied patients		Satisfied patients	
	n	%	n	%
Ventral	10	66.7	33	40.2
Umbilical	0	0	3	3.7
Incisional	1	6.6	3	3.7
Inguinal	4	26.7	42	51.2
Lumbar	0	0	1	1.2

tions were tested for significance using the Spearman's nonparametric correlation coefficient test. Acceptability of the CCS questionnaire was assessed by the number of missing data, a method that has been previously described by Chassany and colleagues,⁶ and by four questions measuring the patient's response to the surveys, previously used by Velanovich⁴ in comparing a disease-specific quality-of-life survey to the SF-36. The psychometric properties of the CCS questionnaire were analyzed in five ways. First, reliability of the scales was evaluated by Cronbach's α , which measures the overall correlation between items within a scale. A level of 0.7 or higher is desirable.⁶ Second, test-retest reliability was assessed by administering the CCS a second time and correlating those answers with the answers from the first administration; test-retest was also assessed by computing the kappa coefficients between the two administrations. Third, concurrent validity was assessed by correlating the scores with those for the SF-36 scales. Fourth, discriminant validity explores the ability of the CCS to discriminate between groups of patients who are satisfied and those who are dissatisfied with their quality of life as it pertains to hernia repair with mesh. Last, principal component analysis was used to determine if any of the CCS questions could be deleted. SAS software, Version 8 (SAS Institute) and a significance level of $p < 0.05$ were used for all statistical analyses.

RESULTS

Patient characteristics

There were 136 questionnaires returned and used in this study. The patient satisfaction rate was 85%. There were no notable differences among satisfied and dissatisfied patients in regard to surgical technique ($p = 0.1$, Table 1) or hernia type ($p = 0.2$, Table 2). But there was a notable difference in satisfaction with mesh type ($p = 0.02$, Table 3).

Acceptability of the questionnaire

Acceptability was measured by the number of missing items and by four questions assessing patient attitude toward the surveys. Of the returned CCS questionnaires, 14.7% ($n = 20$) had at least one missing item and 16.2% ($n = 22$)

Table 3. Mesh Type

Type	Dissatisfied patients		Satisfied patients	
	n	%	n	%
3DMax (Davol)	0	0	16	19.51
DUALMESH (WL Gore and Associates)	1	6.7	1	1.22
DUALMESH PLUS (WL Gore and Associates)	9	60	24	29.3
Kugel (Bard)	0	0	1	1.2
Marlex (Davol)	4	26.6	38	46.3
Prolene (Ethicon)	1	6.7	2	2.4

of the SF-36 questionnaires had at least one missing item. In addition, 72% of patients preferred the CCS questionnaire, 80% thought it was easier to understand, 66% believed it was more reflective of their condition, and 69% said they would rather fill out the CCS than the SF-36.

Reliability

The global Cronbach's α coefficient was 0.979 and the deleted variable coefficients ranged from 0.978 to 0.979 (Table 4).

Test-retest validity

Correlation coefficients between the two separate administrations for each question of the CCS ranged from 0.42 to 0.75, with all of the correlations being pronounced. In addition, the kappa coefficient for each question was pronounced, with the coefficients ranging from 0.18 to 0.58 (Table 5). According to an article published in *Biometrics*, kappa values between 0.40 and 0.60 can be interpreted as moderate agreement; so, with the exception of one question, all of the kappa coefficients for the CCS suggest moderate agreement between the two separate administrations.⁷

Concurrent validity

Concurrent validity was assessed by the correlations between the scores of the CCS and SF-36 questionnaires. Except for general health, all Spearman rank correlation coefficients between the CCS total score and the SF-36 domains were pronounced ($p < 0.05$, Table 6). In addition, all of the CCS domains were notably correlated with all of the SF-36 domains ($p < 0.05$, Table 7), except for general health. The marked correlations ranged from 0.36 to 0.71 in absolute value, with the highest correlation being between the SF-36 bodily pain and the CCS category stairs. Indeed, the lack of notable correlation in general health may be considered a positive outcomes because the CCS does not attempt to assess general well being.

Table 4. Scale Reliability of the Carolinas Comfort Scale

Domain	Cronbach's α coefficient	Content
Laying down	0.979	Sensation of mesh
	0.980	Pain
Bending over	0.980	Sensation of mesh
	0.979	Pain
	0.979	Movement limitations
Sitting	0.979	Sensation of mesh
	0.979	Pain
	0.979	Movement limitations
ADL	0.980	Sensation of mesh
	0.979	Pain
	0.979	Movement limitations
CB	0.979	Sensation of mesh
	0.979	Pain
	0.979	Movement limitations
Walking	0.979	Sensation of mesh
	0.979	Pain
	0.979	Movement limitations
Stairs	0.980	Sensation of mesh
	0.979	Pain
	0.979	Movement limitations
Exercise	0.980	Sensation of mesh
	0.979	Pain
	0.979	Movement limitations
Global	0.980	

ADL, activities of daily living; CB, coughing or deep breathing.

Discriminant validity

Discriminant validity was assessed by comparing the CCS scores for patients who were satisfied and dissatisfied. For all CCS domains and total score, the mean scores for satisfied patients were notably different than those for dissatisfied patients ($p < 0.05$, Fig. 1). In addition, when stratifying data by mesh type, all CCS domains and total score remained pronounced ($p < 0.05$). In comparison, mean scores for satisfied patients were not considerably different than those for dissatisfied patients ($p < 0.05$, Fig. 2) in the SF-36 domains of general health and mental health, and the mental condition summary score (MCS). After stratifying data by mesh type, all SF-36 domains except bodily pain were not notably associated with satisfaction for patients with Marlex mesh (Davol).

Principal component analysis

Principal component analysis identified two components with a relatively good distribution of variance, with the first component explaining approximately 70% of the variance. The loadings for the first component were extremely similar in weight.

Table 5. Test-Retest Validity (n = 72)

Domain	Correlation coefficient	p Value	Kappa coefficient	p Value	Content
Laying down	0.44	<0.0001	0.30	<0.0001	Sensation of mesh
	0.48	<0.0001	0.30	<0.0001	Pain
Bending over	0.66	<0.0001	0.45	<0.0001	Sensation of mesh
	0.65	<0.0001	0.36	<0.0001	Pain
	0.60	<0.0001	0.34	<0.0001	Movement limitations
Sitting	0.63	<0.0001	0.45	<0.0001	Sensation of mesh
	0.63	<0.0001	0.41	<0.0001	Pain
	0.42	0.0002	0.18	0.0125	Movement limitations
ADL	0.60	<0.0001	0.49	<0.0001	Sensation of mesh
	0.50	<0.0001	0.30	<0.0001	Pain
	0.61	<0.0001	0.43	<0.0001	Movement limitations
CB	0.64	<0.0001	0.56	<0.0001	Sensation of mesh
	0.58	<0.0001	0.30	<0.0001	Pain
	0.64	<0.0001	0.42	<0.0001	Movement limitations
Walking	0.60	<0.0001	0.40	<0.0001	Sensation of mesh
	0.73	<0.0001	0.49	<0.0001	Pain
	0.63	<0.0001	0.48	<0.0001	Movement limitations
Stairs	0.64	<0.0001	0.39	<0.0001	Sensation of mesh
	0.73	<0.0001	0.48	<0.0001	Pain
	0.68	<0.0001	0.58	<0.0001	Movement limitations
Exercise	0.75	<0.0001	0.53	<0.0001	Sensation of mesh
	0.69	<0.0001	0.45	<0.0001	Pain
	0.66	<0.0001	0.48	<0.0001	Movement limitations

ADL, activities of daily living; CB, coughing or deep breathing.

DISCUSSION

With the concept of tension-free hernia repair and the subsequent improvement in clinical outcomes of recurrence, there has been new focus placed on functional outcomes of hernia repair, specifically, quality of life. Because of the complexities involving quality-of-life measures, it is very important to consider what purpose the measure is going to serve when choosing between various quality-of-life surveys.⁴ Disease-specific quality-of-life measures may be

Table 6. Correlation of Total Carolinas Comfort Scale Score with SF-36 Domains

Category	p Value	Correlation
Physical functioning	<0.0001	-0.40
Role-physical	<0.0001	-0.42
Bodily pain	<0.0001	-0.66
General health	0.4	0.079
Vitality	<0.0001	-0.42
Social function	<0.0001	-0.42
Role-emotional	<0.0001	-0.37
Mental health	<0.0001	-0.44
PCS	<0.0001	-0.45
MCS	0.0001	-0.36

MCS, mental component summary score; PCS, physical component summary score.

more sensitive for detection and quantification of small changes that are important to clinicians or patients. Disease-specific quality-of-life measurements have been promoted for years by many investigators in oncology^{8,9} and in diseases such as gastroesophageal reflux disease^{10,11} and Crohn's disease.¹² In contrast, generic measures are used primarily to compare outcomes across different populations and interventions.¹³ So, our goal was to design a quality-of-life questionnaire that is sensitive enough to detect small, but important, changes in quality of life, but could also measure up to the SF-36, the "gold standard" of generic instruments. Satisfaction was chosen as an endpoint because the primary goal of surgical therapy is to leave the patient without symptoms.⁴

The SF-36 measures eight domains of health-related quality of life, mentioned previously. Although none of these measures explicitly addresses hernia repair and mesh symptom severity, clearly, living with a prosthetic mesh can affect each of these domains. But for the majority of the patients sampled, living with mesh did not seem to affect one's general health or mental health (Fig. 2).

So the question is raised about the use of generic instruments, such as the SF-36, for surgical therapy of hernias. In a previous study involving patients with an inguinal hernia, the

Table 7. Correlation of Carolinas Comfort Scale Domains with SF-36 Domains

Category	Carolinas Comfort Scale domains (p Value)							
	Laying down	Bending over	Sitting	ADL	CB	Walking	Stairs	Exercise
Physical functioning	-0.46 (<0.0001)	-0.61 (<0.0001)	-0.56 (<0.0001)	-0.62 (<0.0001)	-0.62 (<0.0001)	-0.66 (<0.0001)	-0.56 (<0.0001)	-0.57 (<0.0001)
Role-physical	-0.39 (<0.0001)	-0.54 (<0.0001)	-0.49 (<0.0001)	-0.56 (<0.0001)	-0.56 (<0.0001)	-0.57 (<0.0001)	-0.50 (<0.0001)	-0.54 (<0.0001)
Bodily pain	-0.63 (<0.0001)	-0.69 (<0.0001)	-0.58 (<0.0001)	-0.61 (<0.0001)	-0.61 (<0.0001)	-0.66 (<0.0001)	-0.71 (<0.0001)	-0.59 (<0.0001)
General health	-0.04 (0.61)	-0.04 (0.65)	0.01 (0.89)	0.11 (0.22)	-0.02 (0.74)	0.03 (0.66)	0.01 (0.86)	0.04 (0.65)
Vitality	-0.44 (<0.0001)	-0.53 (<0.0001)	-0.46 (<0.0001)	-0.53 (<0.0001)	-0.53 (<0.0001)	-0.57 (<0.0001)	-0.56 (<0.0001)	-0.50 (<0.0001)
Social function	-0.47 (<0.0001)	-0.52 (<0.0001)	-0.52 (<0.0001)	-0.51 (<0.0001)	-0.55 (<0.0001)	-0.55 (<0.0001)	-0.54 (<0.0001)	-0.60 (<0.0001)
Role-emotional	-0.36 (<0.0001)	-0.51 (<0.0001)	-0.46 (<0.0001)	-0.50 (<0.0001)	-0.55 (<0.0001)	-0.55 (<0.0001)	-0.50 (<0.0001)	-0.50 (<0.0001)
Mental health	-0.41 (<0.0001)	-0.52 (<0.0001)	-0.52 (<0.0001)	-0.57 (<0.0001)	-0.61 (<0.0001)	-0.57 (<0.0001)	-0.52 (<0.0001)	-0.57 (<0.0001)
PCS	-0.54 (<0.0001)	-0.66 (<0.0001)	-0.59 (<0.0001)	-0.64 (<0.0001)	-0.61 (<0.0001)	-0.64 (<0.0001)	-0.62 (<0.0001)	-0.59 (<0.0001)
MCS	-0.36 (<0.0001)	-0.47 (<0.0001)	-0.46 (<0.0001)	-0.50 (<0.0001)	-0.55 (<0.0001)	-0.52 (<0.0001)	-0.50 (<0.0001)	-0.52 (<0.0001)

ADL, activities of daily living; CB, coughing or deep breathing; MCS, mental component summary score; PCS, physical component summary score.

SF-36 could not measure the difference between pretreatment and posttreatment quality of life.¹⁴ This study demonstrated that the SF-36 has poor discriminatory powers for satisfied and dissatisfied patients who have undergone hernia repair. It has been shown that some conditions, such as gastroesophageal reflux disease, which are amenable to surgical therapy but affect only a limited aspect of the patient's quality of life, may not be best measured by such generic scales.⁴ Based on the results of this study, it is apparent that hernia repair is one such condition, so a mesh-specific or hernia-specific instrument is crucial to effectively understand how surgical repair with mesh affects patient quality of life.

One argument against a disease-specific quality-of-life survey is that it may be too specific and detects insignificant changes that do not affect overall mental and physical well being. It is true that the CCS is concerned only with physical well being and seems to have more power when comparing mesh types or repair techniques. But it still represents a powerful tool for overall health because the total CCS score is highly correlated with the physical and mental summary scores for the SF-36, providing evidence that the CCS does measure overall mental and physical well being.

Recent evidence indicates that 3% to 6% of patients will have severe pain, and up to 31% will have chronic pain after inguinal hernia repair.¹⁵⁻¹⁸ But the extent to which postoperative chronic pain interferes with function has not been well described.¹⁴ In a study comparing laparoscopic and open repair of inguinal hernias, laparoscopic hernia repair offered an advantage to patients in terms of their early postoperative pain.¹⁹ Longterm results showed that laparoscopic repairs of inguinal hernia are associated with considerably less parasthesia and groin pain than open repairs are at least 5 years after operation.²⁰ Despite such differences in specific aspects of patient health state for laparoscopic and open surgical techniques, they were not reflected in the general perceptions of health on the SF-36.¹⁹ Advantages of the laparoscopic technique were evident in the categories of movement and coughing, but not at rest,¹⁹ categories that the CCS specifically addresses. It is clear that the CCS is superior to the SF-36 in its content and focus when specifically applied to hernia repairs.

The goal of any quality-of-life survey should be to accurately assess the participant's condition in an easy to understand, concise manner. Although validation of the CCS is important to verify the scale's efficacy, preference of the CCS over the SF-36 lends acceptance to a more "patient friendly" survey. Given the generally low response rate to surveys in medical studies, creation of a new, shorter, easier to understand, and more liked quality-of-life survey is a breakthrough that may shed insight into functional outcomes of patients undergoing hernia repair with mesh.

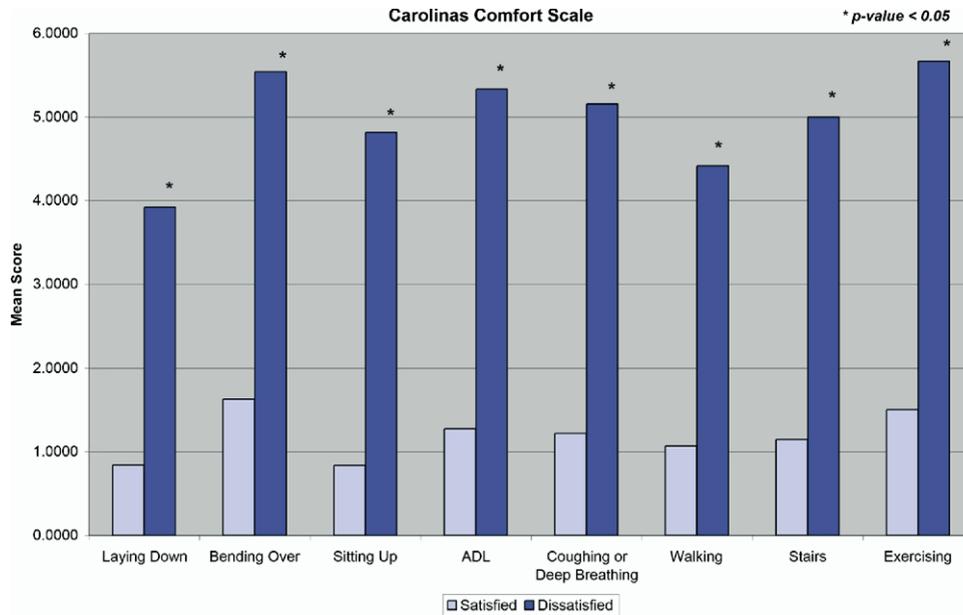


Figure 1. Carolinas Comfort Scale scores for satisfied and dissatisfied patients. ADL, activities of daily living.

Several recent reports have highlighted quality-of-life and patient-satisfaction outcomes using validated instruments in hernia repair.²¹⁻²³ Other “home-grown” instruments are being developed, but are not adequately tested.⁴ The uniqueness of our survey is that it is specifically designed to evaluate quality of life related to the mesh after hernia repair. So to test the appropriateness of the CCS for

the purpose of quantifying patient quality of life as it pertains to surgical mesh, it was validated by assessing its acceptability, responsiveness, and psychometric properties. After assessing all of the psychometric properties, it is apparent that the CCS exhibits internal consistency, test-retest reliability, concurrent validity, and discriminant validity. In addition, this study suggests that the CCS is superior

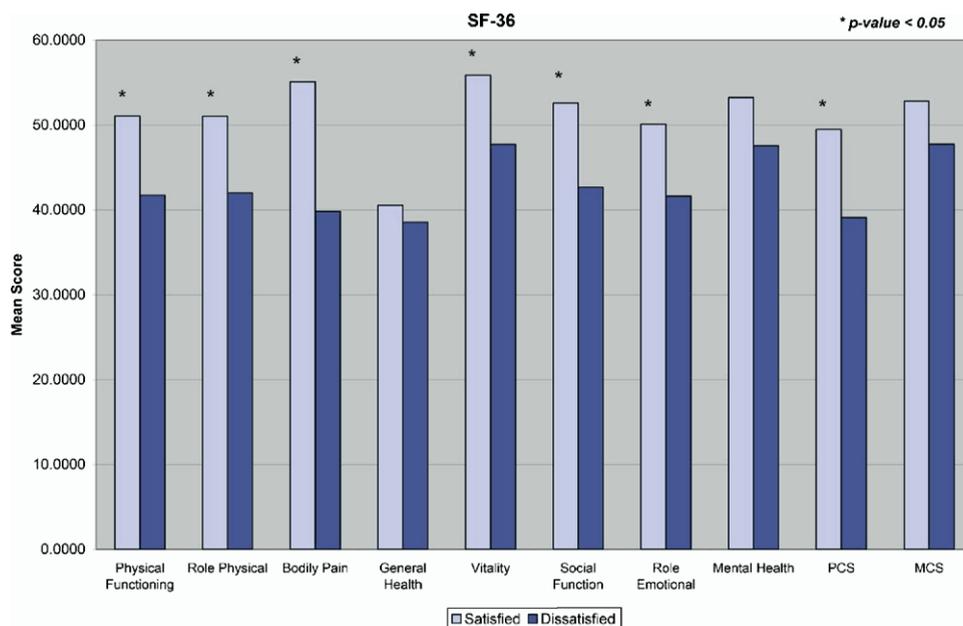


Figure 2. SF-36 scores for satisfied and dissatisfied patients. MCS, mental component summary score; PCS, physical component summary score.

to the SF-36 for measuring symptom severity and quality of life in patients who have undergone mesh hernia repairs.

One limitation of our study is the low rate of return of our mailed questionnaires, which may have had some impact on our results. Our low response rate might have been from several factors, such as lack of incentives to participants and inadequate followup with additional mailings or phone calls. To assess whether this group of responders was an adequate representation of the patient population, we compared demographic variables of the responders versus a randomly selected representative group of nonresponders. We found no differences in gender or surgical technique (open, laparoscopic, converted), but the nonresponders were notably younger and were considerably more likely to have undergone an umbilical hernia repair. The finding of older patients being more responsive to surveys is not unique to our study and has been reported previously.²⁴⁻²⁶ Future directions for this survey tool include a revised CCS that will assess pain and movement limitations of patients preoperatively to serve as a baseline of function and allow us to compare patients before and after operations.

In conclusion, this study demonstrated that the CCS, a short, disease-specific quality-of-life questionnaire, is a better predictor of patient-perceived symptoms and satisfaction for mesh hernia repairs than the generic SF-36. The CCS should be the preferred quality-of-life survey of patients undergoing hernia repair with mesh.

Author Contributions

Study conception and design: Heniford, Lincourt, Novitsky, Kercher

Acquisition of data: Walters, Lincourt

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