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# Design and Initial Implementation of HerQLes: A Hernia-Related Quality-of-Life Survey to Assess Abdominal Wall Function

David M Krpata, MD, Brian J Schmotzer, MS, Susan Flocke, PhD, Judy Jin, MD, Jeffrey A Blatnik, MD, Bridget Ermlich, RN, Yuri W Novitsky, MD, Michael J Rosen, MD, FACS

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- BACKGROUND:** Success of a surgical intervention is often measured by hard clinical outcomes. In ventral hernia repair (VHR) these include wound morbidity and hernia recurrence. These outcomes fail to account for a surgical intervention's effect on a patient's quality of life (QoL). Our objective was to design a hernia-specific QoL instrument with a focus on abdominal wall function, evaluate its measurement properties, and assess the impact of VHR on QoL using this new instrument.
- STUDY DESIGN:** A 16-question QoL survey tool, HerQLes, was constructed. Patients presenting for elective VHR completed the survey. Rasch modeling was used to evaluate the items; fit statistics, person-item mapping, separation index, and reliability were examined. Associations between baseline characteristics and QoL were assessed.
- RESULTS:** Eighty-eight patients completed the survey before assessment for VHR. Mean age was 57.2 years ( $\pm 12.4$  years), mean American Society of Anesthesiologists score was 2.8 ( $\pm 0.5$ ), and mean body mass index was 34.9 kg/m<sup>2</sup> ( $\pm 9.3$  kg/m<sup>2</sup>). Based on Rasch modeling, 12 of 16 items met model fit criteria. The 4 poorly fitting items were eliminated from further analysis. The 12 items retained have good internal consistency reliability (0.86). On a 0- to 100-point scale, mean QoL score was 47.2 ( $\pm 15.6$ ). Patients with higher grade hernias had lower HerQLes scores ( $p = 0.06$ ). Patients showed significant improvement in abdominal wall function and QoL 6 months after VHR ( $p < 0.01$ ).
- CONCLUSIONS:** Quality-of-life is an important component of surgical management of ventral hernias. The 12-question QoL survey, HerQLes, is reliable and valid. At baseline, patients with more complex hernias tended to have a decreased abdominal wall function and QoL. Six months after surgical repair, HerQLes scores change in the predicted direction. We believe HerQLes is potentially a valuable tool to assess patient-centered abdominal wall functional improvements after VHR. (J Am Coll Surg 2012;215:635–642. © 2012 by the American College of Surgeons)
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Ventral hernia repair is one of the most common procedures performed by general surgeons. Measuring the effectiveness of a surgical procedure can be viewed differently

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Correspondence address: David M Krpata, MD, University Hospitals Case Medical Center, 11100 Euclid Ave, Cleveland, OH 44106. email: david.krpata@uhhospitals.org

through the eyes of the patient, physician, and payer. The outcomes that define a hernia surgeon's success are often limited to hard clinical measures such as overall wound morbidity and hernia recurrence. Although these outcomes are pertinent as direct measures of a surgeon's success at keeping a sterile field, adequate postoperative management, and technical abilities, they tend to ignore the most basic outcomes for a patient, their functionality, and quality of life. Increasingly, quality-of-life measures are finding their way into patient outcomes assessments and will continue to play a key role in how we define treatment successes in the future.

Generic quality-of-life instruments, such as the Short-Form-36 (SF-36), were developed to assess the functional health status of large populations of patients over time.<sup>1</sup> Additionally, disease specific quality-of-life measurement tools have been designed and implemented for chronic diseases<sup>2,3</sup> as

### Abbreviations and Acronyms

HerQLes	= Hernia-Related Quality-of-Life Survey
QoL	= quality of life
SF-36	= Short Form-36
VHR	= ventral hernia repair

well as various surgical diseases.<sup>4-7</sup> Generic measures are useful to compare outcomes across different populations and interventions, particularly for cost-effectiveness studies; disease-specific measures assess the special states and concerns of diagnostic groups.<sup>8</sup> To date, few hernia-specific quality-of-life surveys exist.<sup>9,10</sup> The ones that do were predominantly designed to prospectively study inguinal hernia repair.<sup>10,11</sup> With the recent growth of advanced reconstructive techniques for ventral hernia repairs, it is important to accurately evaluate the effect on quality of life and abdominal wall function of these innovative procedures. The purpose of this study was to design a hernia-specific quality-of-life instrument with a focus on abdominal wall function, prospectively validate the questionnaire, and assess the impact of ventral hernia repair on quality of life.

## METHODS

To construct a candidate questionnaire, a panel of 4 general surgeons constructed a 16-question hernia quality-of-life survey tool, HerQLes. In the development of this questionnaire, an emphasis was placed on creating items centered on abdominal wall functionality. After development of this Likert-style questionnaire, Institutional Review Board approval was obtained for prospective implementation and evaluation of the instrument. Ninety consecutive patients presenting to a single surgeon (MJR) at University Hospitals Case Medical Center for elective ventral hernia repair completed the survey before hernia repair. Patients who underwent ventral hernia repair completed the HerQLes survey at 2 weeks, 4 weeks, and 6 months after surgery. On completion of all surveys, HerQLes was assessed for validity and reliability, and a single HerQLes score was calculated. To determine if patient characteristics were associated with baseline HerQLes scores, *t*-tests were used to compare mean scores between levels of categorical variables and simple linear regression models were used to estimate the mean response to a unit change in continuous variables. The changes from baseline to follow-up HerQLes scores were estimated with paired *t*-tests. A *p* < 0.05 was considered statistically significant.

### Measurement evaluation

Evaluation of the instrument included an evaluation of dimensionality, item fit, item-person mapping, item gap-

ping, reliability, and validity. First, items were tested to determine dimensionality through factor analysis, because unidimensionality is a major assumption of Rasch modeling. Next, a Rasch Rating Scale Model was applied to examine the measurement properties of the items and the precision of the instrument.<sup>12,13</sup> Rasch analysis allows an examination of item fit statistics, the spread of the items along a continuum of item difficulty, gapping in the item difficulty, item redundancy, reliability, and separation index. In Rasch modeling, both persons and items are placed on a common metric that is then used to evaluate how a person responds to an item and the difficulty levels of the items.<sup>14</sup> A Wright item-person map can depict the location and distribution of both items and respondents on that common metric.

The following criteria were applied to evaluation of the items. Item infit and outfit mean square between 0.5 and 1.5 were considered a good fit. Items with mean square < 0.5 indicate the item is overly predictable and redundant; items with mean square > 1.5 indicate that the item represents more error variation than useful information.<sup>15</sup> Item-total correlations  $\geq 0.25$  show that each item is generally consistent in measuring the same latent construct as the overall scale.

Next, the Wright item-person map, which displays the relative position of respondent ability levels and item difficulties on the same common metric, was examined for item-person overlap, item difficulty spread (range), and item difficulty gapping. Distance between items of greater than 0.35 was considered a "gap" and implies that the precision of the instrument at these points on the scale is low. The suitability of the response format was also evaluated through an examination of the distribution of responses for each item and ordering of the response categories. Overall, the spread of the items should be similar to the spread of the respondents, and items should cover the range with few or no gaps in the continuum (gapping indicated by a greater than 0.35 difference between items along the continuum). The Rasch person reliability statistic is equivalent to the traditional Cronbach's alpha. Item reliability represents the likely reproducibility of the item order by item difficulty level in another sample. Reliability statistics greater than 0.90 are excellent.

## RESULTS

In total, 90 consecutive patients who presented for ventral hernia repair consented to and completed HerQLes. Eighty-eight patients went on to have their hernias repaired. Two patients were not appropriate surgical candidates and were excluded from further analysis. Patient demographics are reported in Table 1. Follow-up surveys were completed at 2

**Table 1.** Patient Demographics and Hernia Defect Characteristics (n = 88)

Variable	Mean $\pm$ SD or n (%)
Age, y	57.2 $\pm$ 12.4
Sex, male	35 (39.8)
ASA classification	
1	1 (1.1)
2	16 (18.2)
3	67 (76.1)
4	4 (4.5)
Mean ASA classification	2.8 $\pm$ 0.5
Body mass index, kg/m <sup>2</sup>	34.9 $\pm$ 9.3
Smoker	17 (19.3)
Diabetes mellitus	38 (43.2)
COPD	16 (18.2)
Immunosuppressed	10 (11.4)
Previous abdominal operations	3.1 $\pm$ 2.6
Previous hernia repairs	1.2 $\pm$ 1.8
Defect area, cm <sup>2</sup>	285.2 $\pm$ 274.1
Hernia grade	
I	22 (25.0)
II	51 (58.0)
III	11 (12.5)
IV	4 (4.5)
Operation type	
Open	47 (53.4)
Laparoscopic	41 (46.6)
Incarcerated	38 (43.2)
Fistula	0 (0.0)
Previous mesh infection	5 (5.7)
Active abdominal infection	5 (5.7)

ASA, American Society of Anesthesiologist classification system; HerQLes, Health-Related Quality-of-Life Survey.

weeks (n = 78, 88.6%), 4 weeks (n = 81, 92.1%), and 6 months (n = 78, 88.6%) after surgery. A total of 22 subjects were missing at least 1 follow-up measurement. The baseline characteristics of these subjects were no different from those of subjects with complete follow-up data (results not shown).

The factor analysis identified 1 latent construct formed by the 16 variables. Based on Rasch modeling, 12 of 16 items showed adequate fit and ordinal response patterns. The 12 HerQLes items that were retained are presented in Table 2 and comprise the most updated HerQLes survey (Fig. 1). The 4 items that were not included were, "I am not as healthy as an average person my age," "My abdominal wall interferes with my bowel movements," "I feel people stare at me more because of my abdominal wall," and "I cannot go on living without fixing my abdominal wall." Overall, item difficulty ranged from  $-0.86$  to  $0.91$ , with

"My abdominal wall interferes when I perform strenuous activities, eg, heavy lifting" as the most easily endorsed item (lowest difficulty item) and "I often stay home because of my abdominal wall" as the highest difficulty item (ie, individuals who endorsed this item tended to have the poorest quality of life). The items have very good internal consistency reliability (0.86). Figure 2 shows a Wright item-person map that displays both items and respondents on the same metric, with low hernia quality of life at the bottom and high hernia quality of life at the top. The distribution of respondents is on the left side and the distribution of items is on the right. This figure shows a good overlap of distribution of items and respondents, meaning that the items have good coverage and precision to measure hernia quality of life for these respondents. However, as indicated by the circle, the current scale lacks items to assess the quality of life of individuals with the highest levels of quality of life.

To improve ease of interpretation, the scores from the Rasch modeling were transformed to a 100-point scale (0 to 100, with high scores indicating a high quality of life) to establish the final HerQLes score. With this scale, mean baseline HerQLes score was 47.2 ( $\pm 15.6$ ). Associations between baseline quality of life and demographics are presented in Table 3. Notably, patients with higher grade hernias and an active smoking history had lower baseline HerQLes scores on average ( $p = 0.06$ ;  $p = 0.03$ , respectively). On average, there was a significant increase from baseline HerQLes scores at 4 weeks and 6 months after surgery (Table 4). Patients continued to show a significant improvement in quality of life between 4 weeks and 6 months ( $p < 0.01$ ).

## DISCUSSION

Disease-specific quality-of-life assessment is increasingly being used as an outcome measure for surgical interventions. In this study, we developed a disease-specific quality-of-life measurement tool for ventral hernias that allows for assessment of quality of life as it relates to abdominal wall function. Implementation of this 16-item ventral hernia-specific survey, HerQLes, was undertaken on 88 consecutive patients who underwent ventral hernia repair. This new instrument has a high completion rate, presents a very low burden with just 12 items, and the analyses presented in this paper indicate that the instrument has very good internal consistency, reliability, and good evidence of validity. Specifically, among patients undergoing ventral hernia repair, postoperative completion of the survey at 4 weeks and 6 months demonstrated an overall significant improvement in quality of life after ventral hernia repair.

Postoperatively, measures of success of a ventral hernia repair are typically centered on durability and long-term

**Table 2.** Estimates of Item Difficulty, Standard Error, Fit Statistics, and Item-Total Correlations for the 12 HerQLes Items

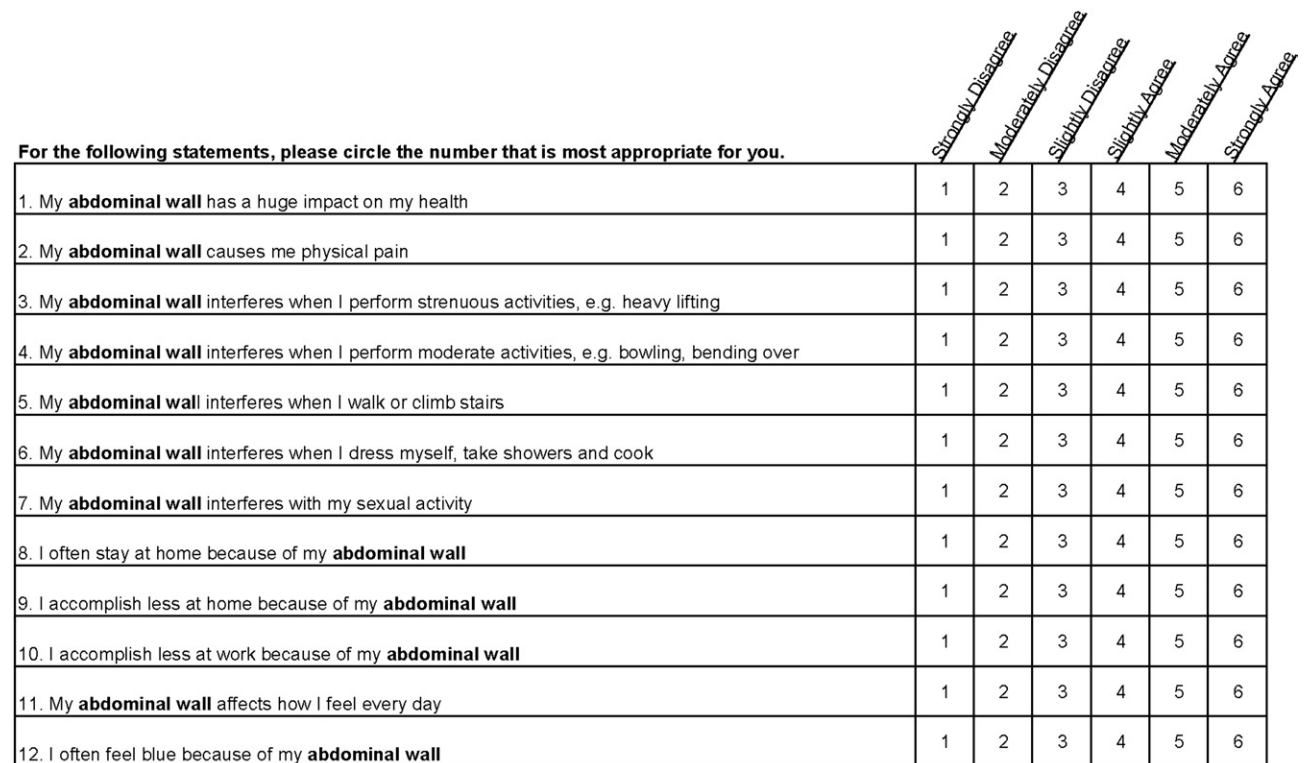
Abbreviated item content	Item	SE	Infit*	Outfit*	ITC
I often stay home because of my abdominal wall.	0.91	0.10	0.96	0.77	0.73
I accomplish less at work because of my abdominal wall.	0.42	0.09	1.12	1.01	0.67
My abdominal wall interferes when I dress myself, take showers, and cook.	0.36	0.09	1.05	0.97	0.70
My abdominal wall interferes with my sexual activity.	0.30	0.09	0.82	0.67	0.72
I often feel blue because of my abdominal wall.	0.16	0.08	1.14	1.23	0.67
My abdominal wall interferes when I walk or climb stairs.	0.09	0.09	0.78	0.70	0.74
I accomplish less at home because of my abdominal wall.	0.08	0.08	1.07	0.96	0.67
My abdominal wall causes me physical pain.	-0.28	0.09	0.73	0.89	0.70
My abdominal wall affects how I feel every day.	-0.42	0.09	0.69	0.57	0.73
My abdominal wall has a huge impact on my health.	-0.53	0.09	0.76	0.59	0.72
My abdominal wall interferes when I perform moderate activities, eg, bowling, bending over.	-0.68	0.10	0.68	0.63	0.67
My abdominal wall interferes when I perform strenuous activities, eg, heavy lifting.	-0.86	0.10	0.99	0.70	0.64

\*Infit and outfit statistics.

HerQLes, Hernia-Related Quality-of- Life Survey; ITC, item-total correlations; SE, standard error.

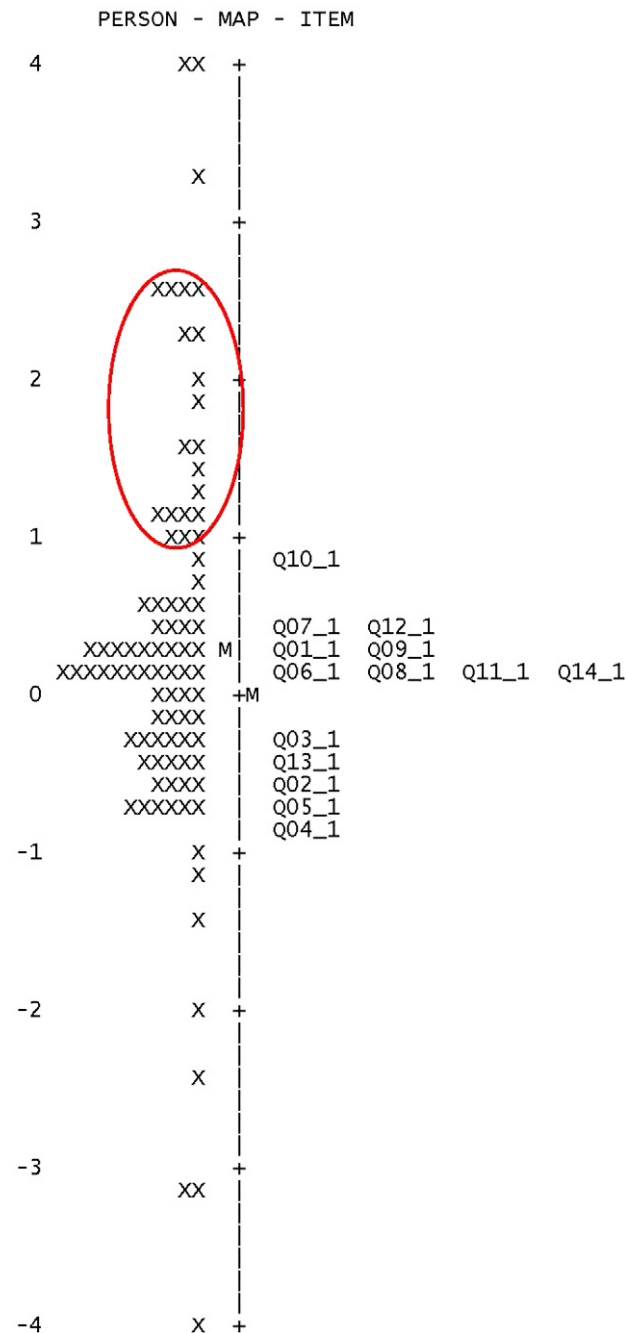
hernia recurrence rates. Arguably, the largest contribution to the field of hernia surgery comes from Luijendijk and colleagues,<sup>16</sup> who demonstrated a significant reduction in hernia recurrence with the addition of a prosthetic mesh. Additionally, more recent literature focuses on improving hernia recurrence rates with other modifications in repair

technique, including the Rives-Stoppa retrorectus repair, posterior component separation (transversus abdominis release), and modifications of anterior components separation originally introduced by Ramirez and associates in 1990.<sup>17-20</sup> Although hernia recurrence is a very important outcome measure, often from a patient’s perspective other



**Figure 1.** HerQLes, final hernia-related quality-of-life assessment tool.





**Figure 2.** Wright person-item map displaying distribution of items and respondent scores. The Wright person-item map displays both items and respondents on the same metric, with low hernia quality of life at the bottom and high hernia quality of life at the top of the map. The distribution of respondents is on the left side and the distribution of items is on the right.

factors contribute to a successful result. In particular, the effect of a surgical intervention on quality of life can be critical to patient satisfaction. For example, patients undergoing complex open ventral hernia repair with a fistula,

infected prosthetic, and a large abdominal wall defect might consider a healed wound, re-establishment of gastrointestinal continuity, and a small epigastric recurrent hernia a successful outcome. Currently, investigators have no way to quantify the impact of abdominal wall reconstruction on quality of life.

Generic quality-of-life forms such as the SF-36 are a potential option for measuring quality of life after incisional hernia repair.<sup>21-24</sup> Generic outcomes measurement instruments such as the SF-36 were designed to compare large populations over time and are not particularly suited to evaluate the impact of a specific operation on quality of life.<sup>1</sup> So, the development of a brief, self-report, quality-of-life instrument such as the HerQLes has great utility for assessing the patient-centered health outcomes of abdominal wall reconstruction. With this in mind, we set out to create a quality-of-life instrument for patients with ventral hernias. Specifically, our goal was to measure quality of life as it pertains to abdominal wall function. Of the 16 original questions, 15 specifically use the words *my abdominal wall* as a part of the question, and all 12 questions comprising the final questionnaire include the phrase. Core abdominal function plays a major role in people’s lives and weakening of the core muscles has been correlated with symptoms such as low back pain, poor gastrointestinal function, and difficulty with micturition.<sup>25,26</sup> For this reason, we asked questions pertaining to patient’s overall impact on his or her health, pain, and activities (strenuous and moderate activity, walking, climbing stairs, and essential activities of daily living). With additional concern that these physical limitations may have a psychosocial impact, questions were designed to address patients’ feelings about their abdominal wall (ie, “My abdominal wall affects how I feel every day.”).

To date, we are aware of 1 hernia-specific, quality-of-life measurement tool that has been designed to include incisional hernias in its assessment. The Carolina Comfort Scale was designed by Heniford and coworkers<sup>9</sup> and initially validated in 2008. Carolina Comfort Scale is a 23-item Likert-type questionnaire that measures severity of pain, sensation, and movement limitations from the mesh used to repair the patient’s hernia.<sup>9</sup> According to the developers of the Carolina Comfort Scale it was “specifically designed to evaluate quality-of-life related to mesh after hernia repair,” compared with HerQLes, which was designed specifically to evaluate patient abdominal function as it relates to the patients’ hernia and hernia repair.<sup>9</sup> The Carolina Comfort Scale provides detailed assessment of the effect of a prosthetic on a patient’s quality of life. As such, it cannot be administered preoperatively in the absence of mesh, and therefore cannot assess the impact of the proce-

**Table 3.** Association of Demographics and Baseline HerQLes Score

Variable	Mean $\pm$ SD	Effect size*	p Value
Age, y	—	-0.2 (-0.4, 0.1)	0.21
Sex			
Female	47.4 $\pm$ 13.1	-0.5 (-7.3, 6.2)	0.88
Male	46.9 $\pm$ 18.9		
ASA	—	0.19 (-6.5, 6.9)	0.96
Body mass index, kg/m <sup>2</sup>	—	-0.02 (-0.4, 0.3)	0.91
Smoker			
No	48.9 $\pm$ 14.1	-9.0 (-17.1, -0.8)	0.03
Yes	39.9 $\pm$ 19.4		
Diabetes mellitus			
No	47.5 $\pm$ 16.0	-0.8 (-7.5, 5.9)	0.81
Yes	46.7 $\pm$ 15.1		
COPD			
No	47.8 $\pm$ 14.4	-3.6 (-12.1, 5.0)	0.41
Yes	44.3 $\pm$ 20.2		
Immunosuppression			
No	47.0 $\pm$ 15.9	1.1 (-9.4, 11.5)	0.84
Yes	48.1 $\pm$ 13.6		
Mesh			
No	53.7 $\pm$ 3.1	-6.7 (-28.9, 15.5)	0.55
Yes	47.0 $\pm$ 15.7		
Hernia grade	—	-4.2 (-8.5, 0.2)	0.06
Incarceration			
No	45.3 $\pm$ 17.5	4.3 (-2.4, 10.9)	0.20
Yes	49.6 $\pm$ 12.3		
Mesh infection			
No	47.2 $\pm$ 15.9	-0.5 (-14.9, 13.8)	0.94
Yes	46.7 $\pm$ 7.5		
Abdominal infection			
No	47.3 $\pm$ 15.6	-1.4 (-15.7, 12.9)	0.85
Yes	45.9 $\pm$ 17.0		
Previous abdominal operations	—	0.7 (-0.6, 1.9)	0.31
Previous hernia repairs	—	-1.0 (-2.8, 0.9)	0.30
Defect area, 100 cm <sup>2</sup>	—	0.4 (-0.8, 1.6)	0.49

\*For categorical variables, the effect size is the difference between means between levels of the variable. For continuous variables, the effect size is the expected mean change for a unit increase in the variable.

ASA, American Society of Anesthesiologist classification system; HerQLes, Hernia-Related Quality-of-Life Survey.

ture itself on quality of life. The HerQLes provides a complementary tool to the Carolina Comfort Scale to address specific measurements of core functioning and its effect on quality of life and abdominal wall function. HerQLes will

**Table 4.** Postoperative Change in HerQLes Score from Baseline

Time since operation	HerQLes score, mean $\pm$ SD	Comparison with baseline, p value
Baseline (n = 88)	47.2 $\pm$ 15.6	—
2 wk (n = 78)	50.1 $\pm$ 14.1	0.13
4 wk (n = 81)	52.3 $\pm$ 11.2	0.002
6 mo (n = 78)	61.5 $\pm$ 13.7	<0.001

HerQLes, Hernia-Related Quality-of-Life Survey.

be particularly useful when comparing various methods of abdominal wall reconstruction such as those that involve re-establishing the midline vs those that result in a large prosthetic mesh spanning the defect.

In this study, we have demonstrated the potential for HerQLes to measure the change in quality of life from pre- to postrepair of patients' ventral hernias. On average, as early as 4 weeks after surgery, there was an increase in patients' HerQLes scores. Patients continued to show improvement as time and the healing process progressed, as shown by patients' HerQLes scores significantly increasing at the 6 months postoperative time point when compared

with baseline scores. Previously, few studies have attempted to compare preoperative and postoperative quality of life. One such study, by Hope and colleagues,<sup>22</sup> used both the SF-36 and the Carolina Comfort Scale. This study demonstrated a significant difference in postoperative quality of life for patients undergoing laparoscopic ventral hernia repair compared with those undergoing open repair. Unfortunately, this study had only preoperative SF-36 scores and not preoperative Carolina Comfort Scale scores because the test cannot be administered preoperatively. This study, although showing differences between the laparoscopic and open techniques, failed to compare preoperative quality of life with postoperative quality of life regardless of technique. To the best of our knowledge, our study is the first to demonstrate the potential to measure significant improvement in quality of life with a disease-specific quality-of-life survey after treatment of an incisional hernia. Although these findings are promising, future research to further the evidence of validity for this measure should include comparison of HerQLes change scores among patients who do vs do not undergo surgery, and comparison of HerQLes with other general and abdominal-specific measures of quality of life and with physiologic measures of abdominal strength. Objective strength measurements of trunk performance after ventral hernia repair have been performed using isokinetic dynamometry in other studies,<sup>27-29</sup> and we expect HerQLes to be positively associated with an objective measure of core abdominal strength.

One of the limitations of our study is the coverage of the 12 items across the spectrum of quality of life. Although the instrument performed well, there is room for improvement in selectively expanding the pool of items to more precisely estimate the quality of life among patients. Additional work to establish the validity of the instrument should include testing the association of the HerQLes with core abdominal strength. Finally, the instrument needs to be applied to independent sets of patients in various settings to determine if the findings are reproducible, which will allow surgeons to build confidence that the instrument is useful.

Additional avenues for HerQLes use are in measuring different techniques of repair including investigation into the effect of component separation and the sacrifice of core abdominal muscles on quality of life and core function. Other outcomes measures such as wound morbidity and hernia recurrence should also be evaluated for an association with HerQLes scores.

## CONCLUSIONS

In conclusion, quality of life is an important component of surgical management of ventral hernias. Disease-specific

and generic quality-of-life measures should be used in conjunction with one another. The HerQLes is a 12-item quality-of-life tool that has shown good reliability and validity properties in its first application to assess quality of life specific to abdominal wall function. The HerQLes has the potential to be a valuable tool to assess abdominal wall functional improvement after ventral hernia repair and should be considered for future studies evaluating quality of life.

## Author Contributions

Study conception and design: Jin, Ermlich, Rosen

Acquisition of data: Krpata, Jin, Blatnik, Ermlich, Rosen

Analysis and interpretation of data: Krpata, Schmotzer, Flocke, Blatnik, Novitsky, Rosen

Drafting of manuscript: Krpata, Flocke, Rosen

Critical revision: Schmotzer, Flocke, Jin, Blatnik, Ermlich, Novitsky

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