Original article

Simple questionnaire for assessing core outcomes in inguinal hernia repair

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Background: Patient-oriented questionnaires are indispensable in the assessment of surgical outcome. The psychometric properties of a brief multidimensional instrument were examined in patients with inguinal hernia undergoing surgery.

Methods: Fifty-one patients (mean(s.d.) age 50·6(17·4) years; 48 men) participated. The following questionnaire properties were assessed for the Core Outcome Measures Index adapted for patients with hernia (COMI-hernia) and the EuroQol: practicability, floor and ceiling effects, test–retest reliability (over 2 weeks), construct validity (by comparison with other relevant scales) and responsiveness 9 months after surgery as standardized response mean (SRM).

Results: The questionnaires were easy to implement and well accepted by the patients. Ceiling effects at baseline were 2 per cent for the COMI-hernia, 8 per cent for EuroQol – visual analogue scale (EQ-VAS) and 35 per cent for EuroQol – Five Dimensions (EQ-5D); no instrument showed floor effects. The reproducibility of individual COMI-hernia items was good, with test–retest differences within one grade ranging from 41 of 45 for 'social/work disability' to 44 of 45 for 'general quality of life'. The intraclass correlation coefficients were moderately high for COMI-hernia (0·74) and EQ-VAS (0·77), but low for EQ-5D (0·43). COMI-hernia scores correlated in the expected manner with related scales ($r = 0·42–0·72$, $P < 0·050$). COMI-hernia was the most responsive instrument (SRM 1·42).

Conclusion: The COMI-hernia and EQ-VAS general health scale represent reliable, valid and sensitive tools for assessing multidimensional outcome in patients with inguinal hernia undergoing surgical treatment.

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Introduction

There is increasing focus on the occurrence of long-term postoperative pain, discomfort and impaired quality of life after groin hernia repair as important outcomes in addition to hernia recurrence[1]. Long-term postoperative pain is reported to occur in 1–32 per cent of patients[2–5]. The lack of a uniform definition and standardized measurement of such pain may in part explain the divergent numbers reported.

The use of patient-oriented questionnaires is considered to be indispensable in assessing treatment outcome. Standardization of the instruments used is essential to allow comparisons across studies, but currently no particular recommended instrument exists for assessing outcome after inguinal hernia repair[6]. There is a paucity of reports describing the use and evaluation of outcome tools in inguinal hernia repair, despite the fact that it is one of the most frequently performed operations in general surgery. Furthermore, most studies investigating chronic pain and quality of life after inguinal hernia repair have been conducted retrospectively[7,8], with baseline values for the patients being unknown. Systematic assessment of patient-oriented attributes and score changes from baseline through the early postoperative phase are of importance in evaluating the development of chronic conditions in the long term. Short, simple, validated instruments for measuring symptoms (pain), functioning, disability and quality of life are available in other areas of medicine[9–13], and cover the domains recommended for inclusion in monitoring the long-term outcome of inguinal hernia repair[14,15]. Owing to their brevity, and ease of understanding, completion and

scoring, compliance with these 'core measures' instruments has been particularly good in clinical practice. Accordingly, such instruments have been able to confer high external validity on the outcome studies in which they have been used and have successfully addressed one of the concerns of the high non-response rates experienced when using multiple full-length questionnaires in routine care[16].

The aim of this study was to investigate the psychometric properties of an adaptation of a short, multidimensional patient-oriented outcome instrument (Core Outcome Measures Index; COMI) and of an established short quality-of-life questionnaire (EuroQol) in patients scheduled for inguinal hernia surgery.

Methods

The study was approved by the local medical ethics committee. The aim was to have a sample size of at least 50 patients, based on previously published quality criteria for measurement properties of health status questionnaires[17]. Fifty-one patients (48 men, 3 women; mean(s.d.) age 50·6(17·4) years) with 69 hernias (18 bilateral) took part. Seven hernias were recurrent.

Patients were recruited from the abdominal surgery department of two regional hospitals in Switzerland. Inclusion criteria were: at least 18 years of age, diagnosis of a groin hernia (primary or recurrent) and fluency in the German language. Exclusion criteria were emergency surgery or status after irradiation of the groin.

After consultation and giving written informed consent, patients were given a first questionnaire booklet to complete at home before surgery and return by post. As soon as the booklet had been returned to the study personnel, a second was sent out, also to be returned by post (again, before surgery). A follow-up questionnaire was sent out a mean of 9 (range 4–12) months after hernia repair.

Questionnaires

The questionnaire battery was based on previously validated questionnaires, adapted for patients with groin pain/inguinal hernia.

First, an adaptation of the COMI[9–11,13], a multidimensional instrument was used with a single item each for the domains pain (graphic rating scale ranging from 0 to 10), function, symptom-specific well-being, general quality of life, and social and work disability (each on a five-point adjectival scale). The questions were originally put together for use in patients with back pain[9–11,13]. In the present study, the questions were simply modified by enquiring about pain, disability and other variables related to hernia-related problems rather than back problems (*Appendix S1*, supporting information). In first developing the set[9], questions were chosen from widely used instruments that had been validated previously (such as the Short Form 36 (SF-36®; Medical Outcomes Trust, Waltham, Massachusetts, USA), World Health Organization Quality of Life – BREF, Agency for Health Care Policy and Research 'Patient Outcome Research Teams', US National Health Interview Survey). In further developments[18], follow-up questions enquiring about global treatment outcome, satisfaction with the treatment received, and patient-rated complications and their bothersomeness were introduced. The full COMI-hernia questionnaire is shown in *Appendix S1* (supporting information).

Second, the EuroQol – Five Dimensions (EQ-5D) and the EuroQol – visual analogue scale (EQ-VAS) for overall health state were used. The EuroQol is a standardized instrument for use as a measure of health outcome; it is applicable to a wide range of health conditions and treatments, and has been validated in many languages[19]. It comprises five single items – mobility, self-care, usual activities, pain/discomfort and anxiety/depression – each rated with a three-point adjectival scale, and a vertical 0–100 VAS for 'overall health state'.

Third, questions enquiring about demographics and various adjectival scales for pain severity, pain medication intake, main symptom, and circumstances exacerbating symptoms were used (modified from Mannion and colleagues[11]; *Table 1*).

Statistical analysis

Score calculation

The COMI-hernia sum score was calculated as described in the original validation papers[11,18]. Briefly, the category items scored 1–5 were first rescored on a scale from 0 to 10 (raw score minus 1, multiplied by 2·5). These items and the pain score (already scored from 0 to 10) were then averaged to provide a COMI-hernia total score ranging from 0 to 10. The EQ-5D was scored without weightings as described by Prieto and Sacristán[12], to give values ranging from −0·59 (death) to 1·00 (best possible health). Scores are given as mean(s.d.).

Floor and ceiling effects

Floor and ceiling effects were determined by calculating the number of individuals obtaining the worst or best score possible for the given attribute, which indicates the proportion of patients for whom it would not be possible to measure any meaningful deterioration or improvement in their condition respectively (as they were already at the extreme of the range).

Table 1 Group demographic and clinical data derived from the first questionnaire

	No. of patients ($n = 51$)
Mean(s.d.) age (years)	50·6(17·4)
Sex ratio (M : F)	48 : 3
Highest level of education	
Primary	5 (10)
Secondary	4 (8)
Apprenticeship	31 (61)
Polytechnic/college degree	7 (14)
University degree	4 (8)
Marital status	
Unmarried	16 (31)
Married/cohabiting	31 (61)
Divorced	4 (8)
Widowed	0 (0)
Living conditions	
Live alone	7 (14)
Live with partner	26 (51)
Live with children	1 (2)
Live with partner and children	11 (22)
Live together with others	6 (12)
Work status	
Full time	31 (61)
Part time	3 (6)
Unable to work because of groin problem	1 (2)
Unable to work for other reasons	0 (0)
Disability pension because of groin problem	0 (0)
Disability pension because of other problems	2 (4)
Old-age pensioner	12 (24)
Housewife, student, school child	1 (2)
Other	1 (2)
Pain medication use for groin pain	
Never	47 (92)
Occasional (few times per month)	1 (2)
Often (few times per week)	2 (4)
Always (daily)	1 (2)
Current pain	
No pain	13 (25)
Mild pain (no limitations)	28 (55)
Moderate pain (cannot do certain activities)	10 (20)
Severe pain (marked limitations in daily activities)	0 (0)
Situation in which most troubled by groin problems	
Not troubled	7 (14)
At rest	1 (2)
Upon loading (e.g. lifting heavy objects, during defaecation)	19 (37)
Prolonged sitting, walking, standing, changing position	14 (27)
Sport (cycling, jogging, etc.)	5 (10)
Other	5 (10)
Most severe problem	
Men	
Groin pain	32 (67)
Testicular pain	1 (2)
Pain during ejaculation/sexual intercourse	2 (4)
Pain during urination	0 (0)
Sensory disturbance in the groin/inner thigh	1 (2)
No problem	12 (25)
Women	
Groin pain (area to be operated on)	2 (67)
Pain during ovulation or menstruation	0 (0)
Pain during sexual intercourse	0 (0)
Pain during urination	0 (0)
Sensory disturbance in the groin/inner thigh	1 (33)
No problem	0 (0)

Values in parentheses are percentages unless indicated otherwise.

Construct validity and convergent validity

Validity essentially refers to whether the questionnaire actually measures what it intends to measure. Construct validity refers to whether a test indeed measures the trait it is supposed to measure. Variables such as pain, disability and quality of life are not measurable in an objective way with standard measures; instead, one examines the convergent validity of questionnaires designed to measure these attributes, by examining the extent to which the scores correlate with (or are related to) those of other instruments measuring the same or a related construct. Spearman rank ρ correlation coefficients (corrected for ties) depicted the correlation between the COMI-hernia scores and the Likert scale data for pain/disability, and between the COMI-hernia individual domain items and corresponding items from the EQ-5D and EQ-VAS overall health state; ρ values above 0·40 but less than 0·80 in at least 50 patients were considered evidence of adequate construct validity[17].

Reproducibility

Reproducibility indicates the extent to which the same results are obtained on repeated administrations of a given instrument when no notable changes in condition are expected. For the five-point ordinal scales, reproducibility was assessed by examining the proportion of participants recording test–retest differences for each item within a reference value of ±1 point[20].

For scales yielding normally distributed values, the differences in means for the repeated trials were examined using paired t tests, and the intraclass correlation coefficients (ICCs; model $ICC_{agreement\ 2,1}$) and standard errors of measurement (SEMs) (or typical errors of measurement) for the repeated trials, each with their

95 per cent confidence intervals, were calculated. ICCs greater than 0·7 are generally considered acceptable[17]. The SEM was used to calculate the minimum detectable change ($MDC_{95\%}$) for the instruments, that is the degree of change required in an individual's score in order to establish it (with a given level of confidence) as being a real change, over and above measurement error. At the 95 per cent confidence level, this is defined as $1{\cdot}96 \times \sqrt{2} \times$ SEM, which is equivalent to $2{\cdot}77 \times$ SEM.

Responsiveness

The responsiveness or sensitivity to change of an instrument indicates its ability to detect clinical change over time, and this was expressed as the standardized response mean (SRM): the group's mean change in score divided by the standard deviation of the change in score. An SRM value of more than 1 was considered to be indicative of adequate responsiveness.

Statistical significance was accepted at the $P < 0{\cdot}050$ level.

Results

The demographic and baseline clinical data for all 51 patients who answered the first baseline questionnaire (which was used for determining floor and ceiling effects, and convergent validity) are shown in *Table 1*. Overall, pain levels were generally quite low, with the groin problem generally manifesting itself only in specific situations; quality of life was correspondingly high.

Floor and ceiling effects

Ceiling effects (best reported health status) were 6 per cent for COMI-hernia pain, 2 per cent for the COMI-hernia total score, 8 per cent for EQ-VAS health state and 35 per cent for EQ-5D; no instrument showed floor effects (worst reported state).

Validity

There was a significant correlation between the ratings on the COMI-hernia pain scale and the adjectival pain scale ($\rho = 0{\cdot}72$, $P < 0{\cdot}001$) and adjectival pain medication scale ($\rho = 0{\cdot}42$, $P = 0{\cdot}002$). In advancing through the categories of the adjectival pain scale there was a corresponding stepwise increase in the mean COMI-hernia pain score and COMI-hernia total score (*Fig. 1a,b*). The COMI-hernia total score showed a moderate, significant correlation with the EQ-5D ($\rho = -0{\cdot}49$, $P < 0{\cdot}001$) and the EQ-VAS health state ($\rho = -0{\cdot}41$, $P = 0{\cdot}003$).

Reproducibility

Forty-five (88 per cent) of 51 patients (42 men, 3 women) returned a second preoperative ('retest') questionnaire, a mean(s.d.) of 14·6(10·0) (range 1–62) days after the first.

Differences in response to each domain on the COMI-hernia were ±1 category in 43 of 45 patients for the domain 'function', 41 of 45 for 'symptom-specific well-being', 44 of 45 for 'general quality of life', 41 of 45 for 'social disability' and 41 of 45 for 'work disability'.

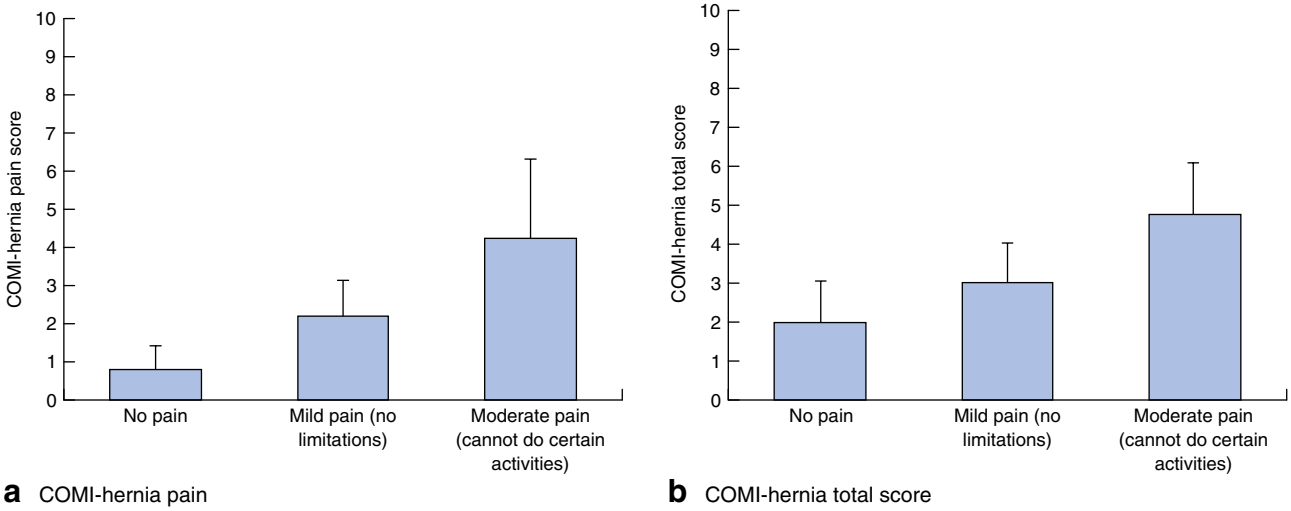

Fig. 1 Core Outcome Measures Index – hernia (COMI-hernia) **a** pain and **b** total scores in relation to categories in the adjectival pain scale

Table 2 Test–retest reliability for the different instruments, assessed in 45 patients

	Range	Mean(s.d.) score		ICC*	SEM	$MDC_{95\%}$	*P* (trial 1 *versus* trial 2)†
		Trial 1	Trial 2				
COMI-hernia pain	0–10	2·2(1·7)	2·6(1·8)	0·79 (0·65, 0·88)	0·79	2·19	0·029
COMI-hernia total score	0–10	3·1(1·5)	2·8(1·3)	0·74 (0·57, 0·85)	0·72	1·99	0·110
EQ-5D	−0·59 to 1·00	0·83(0·17)	0·81(0·19)	0·43 (0·16, 0·64)	0·13	0·36	0·391
EQ-VAS	0–100	81·1(17·7)	79·7(15·5)	0·77 (0·62, 0·87)	7·98	22·10	0·418

*Values in parentheses are 95 per cent confidence intervals. ICC, intraclass correlation coefficient; SEM, standard error of measurement; $MDC_{95\%}$, minimum detectable change at 95 per cent level; COMI-hernia, Core Outcome Measures Index – hernia; EQ-5D, EuroQol – Five Dimensions; EQ-VAS, EuroQol – visual analogue scale. †Paired *t* test.

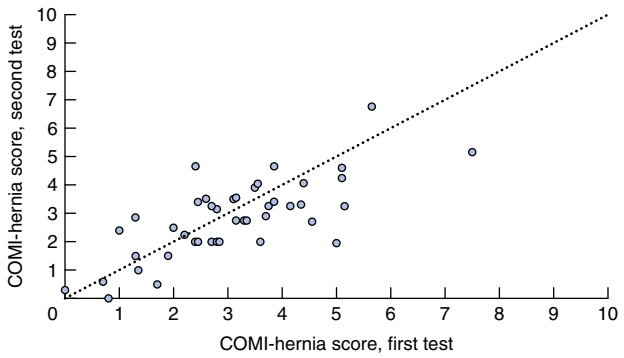

Fig. 2 Test *versus* retest for Core Outcome Measures Index – hernia (COMI-hernia) total scores. The dotted line shows the line of equivalence if exactly the same values had been recorded on both occasions

Table 3 Baseline and follow-up scores for the different instruments in 49 patients

	Mean(s.d.) score		*P* (baseline *versus* follow-up)*	Mean(s.d.) score difference	SRM
	Baseline	Follow-up			
COMI-hernia pain	2·24(1·65)	0·93(1·36)	< 0·001	1·31(2·03)	0·65
COMI-hernia total score	3·06(1·44)	0·71(1·13)	< 0·001	2·35(1·65)	1·42
EQ-5D	0·83(0·19)	0·96(0·08)	< 0·001	0·13(0·20)	0·65
EQ-VAS	81·3(17·7)	89·0(15·5)	0·004	7·7(17·8)	0·43

SRM, standardized response mean (mean score difference/s.d. of score difference); COMI, Core Outcome Measures Index; EQ-5D, EuroQol – Five Dimensions; EQ-VAS, EuroQol – visual analogue scale. *Paired *t* test.

Table 4 Global outcome, satisfaction and patient-rated complications reported by 49 patients at follow-up, a mean of 9 months after surgery

	No. of patients	
Global outcome (how much did the operation help?)		
Helped a lot	35	Good outcome
Helped	13	
Helped only a little	1	Poor outcome
Did not help	0	
Made things worse	0	
Satisfaction with treatment		
Very satisfied	42	Satisfied
Somewhat satisfied	4	
Neither satisfied nor dissatisfied	1	Not satisfied
Somewhat dissatisfied	1	
Dissatisfied	1	
Patient-rated complications		
Sensory disturbance	3	
Groin problem	3	
Testicular pain	4	
Haematoma	2	
Bothersomeness of complication		
Not at all	1	
Slightly	6	
Moderately	4	
Very	1	

There was no systematic bias (significant difference in mean scores) in the test–retest scores, with the exception of COMI-hernia pain, which had a slightly but significantly higher value (by 0·4 points) on the second test occasion compared with the first (*Table 2*). The ICC for the EQ-5D score was relatively low (0·43), but the reproducibility was very good for all the other scales (0·74–0·79) (*Table 2*), including the COMI-hernia total score (*Fig. 2*).

The SEM and $MDC_{95\%}$ values for the various scales are shown in *Table 2*. Expressed as a percentage of the maximum score range, the SEMs were similar for all scales, at about 7–8 per cent.

Responsiveness

Forty-nine (96 per cent) of 51 patients (46 men, 3 women) returned a questionnaire at follow-up. The baseline and follow-up scores for the various questionnaires are shown in *Table 3*. Significant improvements were found for all

instruments, but the COMI-hernia proved to be most responsive, with a SRM of 1·42.

Global outcome, satisfaction and patient-rated complications

At follow-up, 48 of 49 patients reported that the operation helped or helped a lot and 46 of 49 were satisfied or very satisfied. Complications following surgery were reported by 12 of 49 patients (*Table 4*). No patient had undergone further surgery by the time of follow-up.

Discussion

This study found that the COMI-hernia and EQ-VAS general health scale represent valuable tools for use in assessing outcome after inguinal hernia repair. The relatively low reproducibility and the rather high ceiling effects question the usefulness of the EQ-5D in inguinal hernia surgery. Because the COMI-hernia shows more favourable psychometric properties, is similarly brief and shows a moderately strong relationship with the EQ-5D, the COMI-hernia may well serve as an adequate stand-alone questionnaire for patients with inguinal hernia.

One limitation of the study is that the COMI-hernia was not compared with another disease-specific questionnaire, such as the Inguinal Pain Questionnaire (IPQ)[7]. However, as the IPQ was developed only for long-term follow-up, enquiring retrospectively about symptoms and recovery, with some questions using a reference time frame of up to 2 years after surgery, the value of such a comparison would have been questionable. Another limitation is the relatively small sample size; it was considered sufficient to assess the measurement properties of the questionnaire[17], but for greater generalizability COMI-hernia should be evaluated in a larger group of patients, including more women.

Patient-oriented assessments of outcome are important in those with inguinal hernia and groin pain. Some studies have suggested that these assessments should be multidimensional, including various domains of relevance to the patient, such as symptoms, function and quality of life[7,16,21] and patient-rated complications[14]. However, the corollary of this is that the number and length of the questionnaires to be completed by the patient can become a burden. In a drive to provide a practicable solution to the same problem in the field of low back pain, Deyo and colleagues[9] proposed the use of a parsimonious set of 'core outcome measures', the consistent use of which was expected to improve standardization, facilitate comparability among studies, allow pooling of data, and promote the development of more multicentre studies. In the meantime, the COMI has been translated into different languages and validated by various research groups[10,11,22,23]; it is now used as the official patient-oriented outcome instrument in the European Spine Surgery Registry, Spine Tango[24].

As the same outcome domains were considered to be of relevance to patients with inguinal hernia, and issues such as comparability among studies and pooling of data also pertain to the hernia research community, the questions in the original COMI questionnaire were adapted to enquire in relation to the groin problem rather than a back problem (thereby forming the COMI-hernia). Although symptom severity and impairment of function and quality of life were not as severe before surgery in patients with hernia as in those with back pain, the questionnaire performed admirably in terms of its psychometric properties.

The COMI-hernia questionnaire was shown to be feasible for use in everyday clinical practice. Most patients who were invited to participate chose to do so and, overall, there were no missing data. Moreover, the mid-term follow-up rate was very high (96 per cent), reflecting the readiness of patients to comply with it. The brevity of the questionnaire suggests that it will be similarly promising in terms of the compliance with repeated longer-term follow-up over the years. The authors' ongoing investigations using the questionnaire will hopefully shed further light on this.

Floor and ceiling effects are important psychometric properties of an instrument because they can affect its ability to reveal further deterioration or improvement in the given health state. It is not uncommon for assessments of health-related quality of life to result in skewed distributions. However, by obscuring further improvements or worsening of the patient's condition, high floor and ceiling effects can render an instrument less responsive and decrease its ability to discriminate between patients. Ideally, floor and ceiling effects should be below 15 per cent. In the present study, floor and ceiling effects were acceptable for all questionnaires except the EQ-5D, which showed high ceiling effects at baseline. This may, in part, explain the lesser ability of the EQ-5D to detect improvement after treatment compared with the COMI.

Convergent validity of the COMI-hernia was examined by investigating the strength of its relationship with other indicators of groin pain severity, such as the adjectival rating for groin pain and disability. The correlation was moderately high and significant. The COMI-hernia total score and the COMI quality-of-life item score each correlated significantly with those of other quality-of-life indicators (EQ-5D, EQ-VAS), although the coefficients were only low to moderate. This suggests reasonable

construct validity for the COMI-hernia, but indicates that the two instruments (COMI- hernia and EuroQol) are not delivering overlapping information; indeed, a very high correlation between the two would not be desirable, as it would suggest that one of the two was redundant.

In the present study, the COMI-hernia showed good reliability, with an ICC of 0·74 for a mean time between the repeated measures of just over 2 weeks. This time interval was chosen because, compared with shorter intervals, it minimizes the possible memory effect and provides a more realistic view of the degree of score change that may occur for non-specific reasons (random error). ICCs are also influenced by the range of values reported within the group: they are highly dependent on the between-subject variance; the range of values was low in the present study because not many patients had very extreme symptoms or severely impaired function and quality of life. This may explain the slightly lower ICCs for the COMI-hernia than reported in previous studies of patients with chronic back pain (0·85–0·91)[10,11,23]. This is substantiated by the finding that the absolute measurement error (SEM), which is not dependent on the range of values recorded, was fairly comparable to the previously reported value (0·63 points[11], compared with 0·72 points in the present study). The SEM is another expression of the error associated with repeated measurements and is used to determine the MDC for an instrument ($MDC_{95\%}$ being 2·77 times the SEM). The $MDC_{95\%}$ for the COMI-hernia in the present study was 1·99 points. This value represents the minimum difference in an individual's score required to state with 95 per cent confidence that real change is responsible for the difference, as opposed to just measurement error ('noise' in the system). The data collected at 9 months' follow-up indicated that the surgical treatment of inguinal hernia effected a change (2·35 points) that exceeded this level of error and hence that the COMI-hernia displays the same adequate 'signal-to-noise' ratio as the COMI-back[18,25,26].

Patient-rated complications were reported by approximately one-quarter of the patients in the present study. This concurs with the findings of Fränneby and co-workers[27] for the Swedish Hernia Register where the rate of complications within a month of surgery was 27 per cent, contrasting with the 5 per cent reported by the clinicians in the register itself[27]. The impact of such complications was assessed in the present study and almost half were at least moderately bothersome. There were too few to make a valid examination of the consequences in terms of satisfaction, or the impact on longer-term outcome; however, in a large study of patients with back pain such complications were shown to be strongly associated with patient satisfaction[28]. Hence, this important aspect of patient evaluation should not be overlooked, but should become an integral part of the routine, structured, postoperative assessment[27].

The two existing hernia-specific questionnaires, the IPQ[7] and the Carolina Comfort Scale[15], are not used widely at present. Both instruments are relatively long, with 23 and 18 items respectively, and the IPQ can be used only retrospectively. The present authors are convinced that, in the future, so-called 'core outcome measures' will be used widely in various fields in medicine. Such short questionnaires are well accepted by patients and have been shown to deliver comparable information to much longer questionnaires[8,11,18]. The performance of this questionnaire is currently undergoing investigation within a large prospective multicentre trial with long-term follow-up in Switzerland.

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Supporting information

Additional supporting information may be found in the online version of this article.

Appendix S1 Core Outcome Measures Index – hernia (COMI-hernia) questionnaire for preoperative and post-operative assessment (Word document)

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