# ORIGINAL ARTICLE

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# Development of a procedure-specific tool for skill assessment in left- and right-sided laparoscopic complete mesocolic excision

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# Abstract

**Aim:** To (1) develop an assessment tool for laparoscopic complete mesocolic excision (LCME) and (2) report evidence of its content validity.

**Method:** Assessment statements were revealed through (1) semi-structured expert interviews and (2) consensus by the Delphi method, both involving an expert panel of five LCME surgeons. All experts were interviewed and then asked to rate LCME describing statements from 1 (strongly disagree) to 5 (strongly agree). Responses were returned anonymously to the panel until consensus was reached. Statements were directly included as content in the assessment tool if  $\geq$ 60% of the experts responded "agree" or "strongly agree" (ratings 4 and 5), with the remaining responses being "neither agree nor disagree" (rating 3). Interclass correlation coefficient (ICC) was calculated for expert agreement evaluation. All included statements were subsequently reformulated as tool items and approved by the experts.

**Results:** Four Delphi rounds were performed to reach consensus. Disagreement was reported for statements describing instrument handling around pancreas; visualisation of landmarks before inferior mesenteric artery ligation; lymphadenectomy around the inferior mesenteric artery, and division of the terminal ileum and transverse colon. ICC in the last Delphi-round was 0.84. The final tool content included 73 statements, converted to 48 right- and 40 left-sided items for LCME assessment.

**Conclusion:** A procedure-specific, video-based tool, named complete mesocolic excision competency assessment tool (CMECAT), has been developed for LCME skill assessment. In the future, we hope it can facilitate assessment of LCME surgeons, resulting in improved patient outcome after colon cancer surgery.

#### KEYWORDS

assessment tool, colorectal surgery, competency, Delphi technique, laparoscopy, technical skills

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# INTRODUCTION

Complete mesocolic excision (CME) has been associated with improved cancer-specific survival, especially for patients with stage III cancer [1, 2]. The procedure can be carried out laparoscopically (LCME) with similar oncological results and the advantages of minimal-invasive surgery [3–5]. The complexity of the procedure has raised safety concerns as increased risks of blood vessel injury have been reported [6], and most data on its safety and oncological complexity derive from centres with highly specialised expertise [3, 7]. Although LCME is considered to be technically demanding, previous results suggest it is achievable by experienced laparoscopic surgeons. Currently, there are no tools available to objectively assess the surgical performance and quality of such procedures.

Tools to objectively measure surgical performance and monitor proficiency gain during the surgeon's learning period have been previously described and validated [8-10]. The most widely used tool is the Objective Structured Assessment of Technical Skill (OSATS) by Martin et al. [11], which is used to evaluate general aspects of operative performance. However, adequate evaluation of specific procedural steps is crucial when performing complex procedures such as laparoscopic colon resection. When new assessment tools are developed, content is often based on practical surgical experience from single centres, evidence from the literature, expert opinions, and/or adaptation of other tools from similar surgical procedures [8-10]. Although such tools might be useful in a local clinical setting, the overall scientific validity of the tool content is questionable. Guidelines towards a structured scientific approach to assessment tool development are available [12, 13]. First, they suggest establishing an explicit theoretical basis of the tool content, and second to evaluate the tool content by a systematic expert review. One scientific method to create such evidence-based content is the Delphi method [14-16]. As the Delphi method can be applied in a virtual setting, experts can be recruited from diverse geographical locations avoiding single expert/single centre biases. As a result, it has become increasingly attractive in establishing content validity for tools reflecting practice across diverse institutions [17-23].

Tools for skill assessment in laparoscopic colon resection exist and are already incorporated in certification processes of surgeons in training [10]; among these is the Japanese Endoscopic Surgical Skill Qualification System (ESSQS) evaluating the operative performance of a Japanese D3 resection [24], and the Competence Assessment Tool (CAT) applied to laparoscopic colorectal procedures in the National Training Programme in England [17]. However, none of the existing tools evaluates the important procedural aspects of the LCME procedure: meticulous dissection within the embryological planes; application of a high tie to ensure lymph node dissection around the tumour-supplying central vessels; and sufficient longitudinal resection of bowel on both sides of the tumour [1, 25, 26]. Existing tools seem to focus on instrument handling and tissue care, but less on the oncological resection quality. Dissection performed in the wrong plane or mesocolon damage challenges the oncological principles of LCME and compromise the specimen quality [27]. Such

#### What does this paper add to the literature?

This is the first paper to present a procedure-specific tool for skill assessment during laparoscopic complete mesocolic excision and describe the process for developing tool content.

breaches reduce the odds of successful sign-off assessments among laparoscopic colorectal trainees [28] and have been incorporated into a performance tool for rectal surgery (LapTMEpt) [29]. However, evaluation tools with focus on specimen quality have never been described in laparoscopic colon surgery.

To secure the surgical quality of the LCME procedure and facilitate its implementation beyond highly specialised surgical centres, there is a need for a scientific sound LCME assessment tool, which evaluates surgical technique, procedural steps, and oncological resection quality. Such a tool will help standardise surgical training and expectantly improve patient outcome after colon cancer surgery. Therefore, the aim of this study was to develop an assessment tool for LCME surgery and to report evidence of its content validity.

# METHODS

### Study design

The study was designed according to the standards described by Beckman and Ghaderi [12, 13]. The items of the tool were sought by (1) qualitative expert interviews, (2) quantitative evaluation by an expert panel according to the Delphi standards, and (3) conversion to an assessment tool format (Figure 1). The study was conducted virtually from September 2018 to October 2020.

#### Expert panel

Members of the expert panel were selected from high-volume LCME units in Norway, Spain, the UK, and Germany. Five colorectal surgeons with an established practice of LCME were approached, and all were included in the panel. The experts had a combined experience of 1700 LCME cases with a range of 100–700 per expert.

#### Interviews

Two investigators, including one researcher and one colorectal consultant performed semi-structured interviews independently with members of the expert panel. The interview aimed to disclose which skill domains and operative steps the experts deemed essential for maintaining clinical and oncological safety during LCME surgery. No further literature review was performed as the experts were

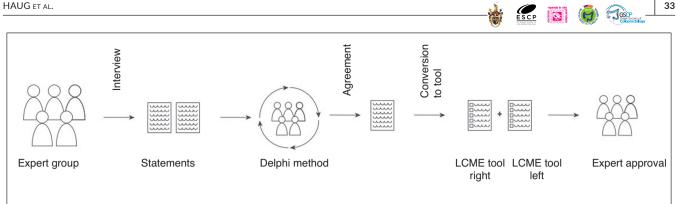


FIGURE 1 Overview of the study process.

thought to be up to date with the technique in practice and to maintain an open-ended interview approach for the experts to describe their technical aspects. All interviews were audio-recorded and transcribed before data was extracted. Data were rephrased into statements and dichotomised into "oncological safety" or "clinical safety" sections. The oncological safety section included statements regarding lymphadenectomy, vascular exposure, plane dissection, and surgical specimen, whereas clinical safety covered statements describing exposure, tissue handling, surgical field, and intraoperative behaviour. Each statement was then changed into a format that could be evaluated by the Delphi method.

## The Delphi method

The Delphi method was applied to the statements collected from the interviews. The method has previously been described in detail [15. 16, 30]. In short, the process allows experts to reach consensus on which survey statement they find essential for an assessment tool, by responding anonymously to survey items. Subsequently, answers are shared between panel members and a new survey is made based on the results. The process of "survey-response-result" is repeated until final consensus on all survey statements is reached.

For this study, the online survey tool, RedCap (Vanderbilt University, 2004), was used [31, 32]. The expert panel was asked to rate each statement with respect to its relevance for technical skill assessment during LCME, while preserving clinical and oncological safety. The rating scale ranged from "strongly disagree" [1] to "strongly agree" [5], with 3 being "neither agree nor disagree". Experts in disagreement with a statement were asked to add a comment and make an alternative statement. All results were anonymously reported to the panel afterwards. The Delphi method continued until members of the expert panel agreed on including or excluding statement items. Statements where  $\geq 60\%$  of the experts answered "agree" or "strongly" agree" were directly included as content in the assessment tool, on the condition that the remaining ≤40% of experts graded the item as "neither agree nor disagree". Statements with any level of disagreement or with more than 40% "neither agree nor disagree"-responses were rephrased and/or divided into more specific statements and incorporated into the next round.

#### **Development of assessment tool**

The content of the LCME tool was designed based on consensual statements from the Delphi method. The statements were converted into items and split into two versions: right-sided and leftsided LCME resections. Items not describing side-specific steps were included in both versions. Further, all items were divided into sections of "instrumental handling", "tissue handling", "clinical safety", and "oncological safety". Two authors constructed assessment categories, representing four competence levels: "inadeguate", "suboptimal", "adequate", and "optimal". "Not applicable" was provided as a fifth answer if the laparoscopic video material was insufficient for evaluation to make a judgement. Finally, the expert group received the tool for evaluation.

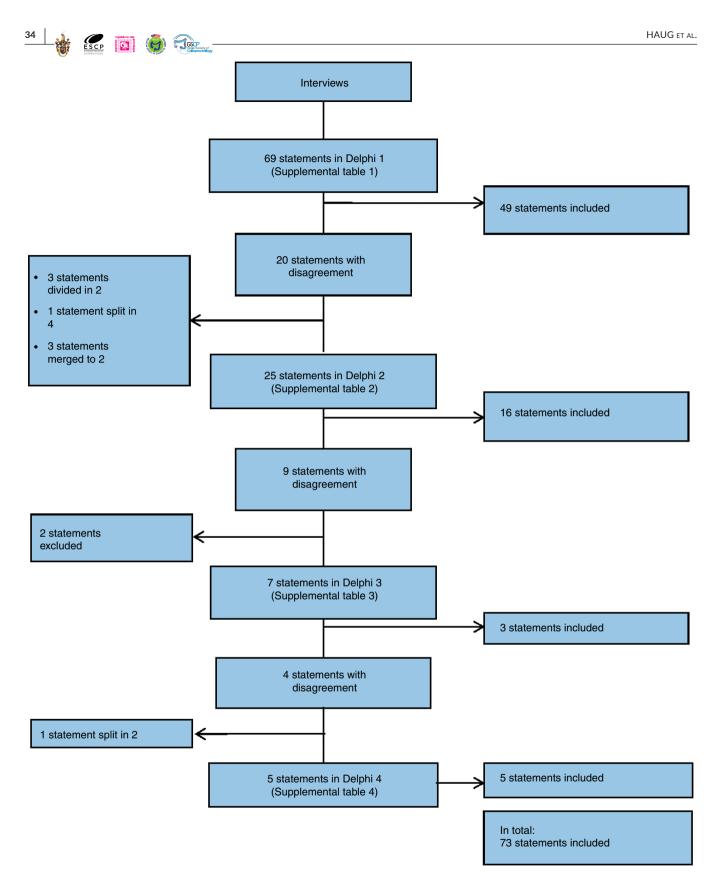
# Statistical analysis

To evaluate the level of agreement between experts (inter-rater reliability) in each Delphi round, a mixed effect model was used to calculate the interclass correlation coefficient (ICC) in a fully crossed design [33]. The calculation of ICC was based on statements transferred from the previous Delphi round. Thus, statements directly included as tool content in the previous round, were not involved in the ICC calculation of the next round. However, in case the responses displayed ceiling or floor effect (complete agreement or disagreement) we estimated an ICC with fixed total variance (ICC-f), for which we assumed the total variance was equal to that of a uniformly distributed 5-point Likert-scale  $((5^2-1)/12) = 2.0$ . All statistical analysis was conducted using STATA (StataCorp. 2019. Stata Statistical Software: Release 16).

# RESULTS

# Interview and Delphi method

An overview of the process is described in Figure 2. Sixty-nine statements were extracted from the interviews and included in the Delphi method and four Delphi rounds were performed



**FIGURE 2** Statements included and excluded in the Delphi process. A total of 69 statement items were incorporated in the first round, from which 49 were accepted. The remaining 20 statements were rephrased and divided into more specific statements, as the panel found them unclear: three statements were split in two; one statement was split in five; and three statements were shortened to two. A total of 25 statements were included in the second round. Of those, 16 statements were agreed upon; the remaining nine statements generated disagreement. Of these, two statements were excluded as these were graded as "disagree" and "strongly disagree" by 80% of the experts, and the remaining seven statements were rephrased. In the third round, three statements were readily accepted, one was divided into two, and the rest were rephased. Subsequently, five statements were included in the fourth round, where all statements were accepted.

# TABLE 1 Response characteristics of the Delphi panel

#### Frequency (%) of the responses in the Delphi process

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	Delphi 1	Delphi 2	Delphi 3	Delphi 4			
Answer category	(n = 69)	(n = 25)	$(n = 6^{a})$	(n = 5)			
Strongly disagree	2.0	10.4	-	-			
Disagree	8.1	8.0	16.7	-			
Neither agree nor disagree	6.4	12.0	-	4.0			
Agree	35.9	36.0	30.0	36.0			
Strongly agree	47.5	33.6	53.3	60.0			
Interclass correlation coefficient							
ICC-f (95% CI)	0.65 (0.59-0.71)	0.65 (0.55-0.74)	0.72 (0.57–0.86)	0.84 (0.75-0.93)			
ICC	0.30	0.57	6.87e-13	2.38e-16			

Note: The percentage of item responses for all experts.

Abbreviations: ICC, interclass correlation coefficient; ICC-f, ICC with fixed variance; n, total number of items.

<sup>a</sup>In the third round of Delphi, one statement was not included, as the answer categories were designed differently.

before consensus was reached (Figure S1). In the first round, the responses ranged from "strongly disagree" to "strongly agree", with few responses being "strongly disagree" (2%) or "disagree" (8.1%; Table 1). In the second round, the "strongly disagree"-percentages increased to 10.4%. A ceiling effect was observed in the fourth round, with 96% of the responses being "agree" or "strongly agree". The ICC-f ranged from 0.65 (95% CI: 0.59–0.71) in the first Delphi round to 0.84 (95% CI: 0.75–0.93) in the final fourth Delphi round.

## Left-sided LCME procedure

In the first round, consensus was reached for all statements describing plane dissection, intraoperative behaviour, and surgical specimen, whereas statements on (1) lymphadenectomy, (2) vascular exposure, (3) exposure, and (4) tissue handling spurred discussion (Figure S1).

- Statement L2, describing lymphadenectomy and clearance of fatty tissue around the inferior mesenteric artery (IMA), needed elaborate revision; only after inclusion of how the para-aortic nerve plexus should be spared, it reached consensus in the third round.
- 2. Statement L3 stated that the same vessels should be ligated for transverse and right-sided tumours. Due to a high level of "strongly disagree" responses, this statement was excluded in the second round (L3a). In contrast, experts readily "agreed"/"strongly agreed" to statement L3b stating that the common middle colic artery and vein should be divided at their origin or at the level of the superior mesenteric vessel for transverse colon tumours.
- 3. In the exposure section, statements describing the protection and visualisation of landmarks before IMA ligation, generated debate in the first three rounds (statement L9, L10). It was argued that the visualisation of the left ureter was unnecessary if other landmarks

ensured dissection anterior to the retroperitoneal structures. After this comment was added, the expert panel reached consensus in the fourth round.

4. Statement L31a, encouraging surgeons to avoid sharp dissection during mobilisation of the mesocolon was graded with 80% disagreement and excluded. Further, two statements describing instrument handling around the pancreas, were first accepted in the fourth round (statement L25I, L25II).

# **Right-sided LCME procedure**

In the first round for right-sided LCME, consensus was reached for statements describing exposure, surgical specimen, and intraoperative behaviour (Figure S1). Statements regarding lymphadenectomy reached consensus in the second round. However, statements regarding (1) vascular exposure, (2) plane dissection, and (3) tissue handling incited discussion.

- 1. All exposure-describing statements were accepted in the first round, except statement R8. It stated that the same vessels should be ligated for transverse and right-sided tumours (corresponding to L3), which again provoked strong disagreement and was excluded.
- For plane dissection, a group of closely related statements (statement R9, R10, R11), describing the distal resection margin for ascending colon tumours and the division of terminal ileum in regard to the ileocaecal valve, all generated debate with ≥60% "disagreeing" respondents in the first round. Consensus on the division of the terminal ileum was reached in the second round, whereas consensus regarding the distal resection margin for ascending colon tumours was first established in the fourth round.
- Statement R35, encouraging surgeons to avoid sharp dissection during mobilisation of the mesocolon, received 80% "disagreeing" responses and was thus excluded from the process. Further,



statement R29 (corresponding to L25), describing instrumental handling around pancreas was first accepted in the fourth round.

### Development of the assessment tool

The accepted statements from all four Delphi rounds for left- and right-sided procedures were included in a final assessment tool (Figures 3A,B). The tool items were designed to reflect the consensus statements. Four labelled rating levels were created for each item, ranging from 1 to 4 points. A fifth answer category was added: "not applicable" for insufficient video material. The tool was developed for left- and right-sided LCMEs and named the complete meso-colic excision competency assessment tool (CMECAT).

The score of CMECAT was calculated as an overall mean: each assessable item in a section was given 1 to 4 points (0 points = "not applicable"), and the total score was summed up and divided by the item number (section mean). Finally, all section-means were summed up and divided by the number of sections in the left-side or right-side CMECAT (overall mean). This value ranged from 1 (suboptimal) to 4 (optimal).

# DISCUSSION

A novel LCME assessment tool, CMECAT has been developed and its content validity has been reported. As left- and right-sided LCME procedures differ substantially in technical complexity and operative steps, the tool has been designed in side-specific versions. CMECAT is aimed towards all LCME surgeons regardless of experience, so even self-evident procedural steps were converted into scoring items: an example could be the visualisation of the ureter for left LCME; although ureter identification is crucial for a LCMEnovice, it might not be necessary for an established LCME surgeon.

CMECAT was developed from semi-structured interviews and the Delphi method, which has several particularly attractive advantages: First, experts were not obligated to meet physically or virtually and could be recruited from diverse geographical locations. Second, the expert panel could rate the statements on their own time schedules, improving process feasibility. Third, the anonymous character of Delphi ensured that neither expert evaluation had a disproportional impact on the final consensual statements. Nevertheless, the method also has disadvantages. Innate to its design, the process excludes direct discussion between experts. Therefore, the statement consensus relied heavily on the interpretation of expert ratings by the facilitating researcher. To circumvent this, initial Delphi statements were generated from semi-structured interviews to convey the experts' perspectives. Moreover, experts were encouraged to comment on refused statements, and these comments were then incorporated by the facilitator in the item rephrasing process.

The literature reports no consensus on the optimal number of experts in a Delphi process [14]. In theory, a large expert group improves consensus reliability [30]. However, it concomitantly increases the risk of additional Delphi rounds, which aggravates the risk of panel fatigue and "false consensus" [16, 34, 35]. Our process included five experts. This is a small number compared to similar studies [20–22, 36, 37], but at study initiation a limited number of surgeons were engaged in LCME training. As LCME surgery is more widely adopted today, the number of experts at surgical centres worldwide could surely be increased if the study was repeated. This would, however, not necessarily change the final result. As shown, the expert panel agreed on the majority of statements in the first two Delphi rounds independently of country of origin and there seems to be a consensus on the elementary technical steps of LCME.

Another methodological aspect to consider is the definition of "expert consensus", as no formal criteria exists. Previously, 70% "agree" or "strongly agree" responses have been defined as a cutoff for statement inclusion [35]. As only five experts were included in the present study, 60% agreement were accepted as a cutoff, but only if the remaining experts answered "neither agree nor disagree". A cutoff of 70% may have changed the number of Delphi rounds and the consensual statements. To evaluate expert consensus, ICC and ICC-f were calculated. The computation of ICC should be considered when interpreting the results. Based on a casual observation of response data, the ICC seems surprisingly small, given the substantial percentage of "agree" and "strongly agree" responses. However, this is a consequence of the ceiling effect which arises when the variance level among experts is compared to the total variance based almost solely on the two response categories: "agree" and "strongly agree". For that reason, ICC-f is a more appropriate model, as it accounts for the ceiling effect. ICC-f increased through all rounds, suggesting that a minimal and acceptable amount of measurement error was introduced by the independent expert (ICC-f 0.84 in round 4).

As a relatively new technique, LCME implementation in a wider surgical community is still lacking. Though it has been defined as a concept [1], the exact difference between a LCME and a "conventional" laparoscopic hemicolectomy is challenged by the lack of a standard definition for the latter: Although the pathological standards of CME resection specimens have been described by Benz et al. in 2019 [38], the surgical community needs to define the operative steps that are crucial to maintain the oncological quality. As a procedure-specific tool aimed towards LCME surgery, CMECAT might provide a framework for this. Supplementing the work of Benz and his colleagues, the use of CMECAT as a checklist could help differentiate when a laparoscopic colon resection is adherent to the LCME concept or not. Moreover, it may be valuable in pointing out specific procedural steps where more training and supervision is needed, although not formatively how to do it, as the tool is designed for summative assessment. In the future, CMECAT may be used as a sign-off tool in an LCME certification process, like the ESSQS is used for certificating of laparoscopic surgeons in Japan [24]. It is, however, important that the cutoff score discriminating between "pass" and "fail"-surgeons is carefully determined based on sound scientific evidence. As the CMECAT only assesses technical skills, it is essential, in an LCME certification process, to consider the nontechnical skill, pathological reports and the holistic care of

Name:

CMECAT Laparoscopic Complete Mesocolic Excision Competency Assessment Tool Assessor: Video: **EXPOSURE** 1) Patients positioning to support exposure SUBOPTIMAL ADEQUATE OPTIMA NOTAPPLICABLE 2) Positioning of small bowel is performed NOT APPLICABLE HARMFULLY SUBOPTIMAL COMPETENT OPTIMAL 3) Use of the assistant INADEQUATE SUBOPTIMAL ADEQUATE OPTIMAL NOT APPLICABLE 4) Were there any risks of thermal injuries? DEFINITELY POTENTIALLY UNLIKELY NEVER NOTAPPLICABLE 5) Key structures and landmarks were demonstrated INADEQUATE SUBOPTIMAL ADEQUATE OPTIMAL NOT APPLICABLE 6) During the exposure of the operating field the bowels/tissue were INJURED POTENTIALLY DAMAGED SAFELY HANDLED PROTECTED THROUGHOUT NOT APPLICABLE 7) If bleeding occurred, it was controlled OPTIMAL NOTAPPLICABLE INADEQUATE SUBOPTIMAL ADEQUATE 8) Damage to the mesentery during exposure can be described as ONCOLOGICAL SIGNIFICANT NOT APPLICABLE CONCERNING MINIMA NO DAMAGE OBSERVED Score: 1 INFERIOR MESENTERIC VEIN ÓPUMAI COMPETENT 9) Use of dissection instruments DAMACOVIE NOT APPLICABLE 10) Use of retracting tools (A-frame, swab, atraumatic retractor) when the COMPETENT SURGETIMAL OPTIMAL DANGEROUS NOT APPLICABLE mesentery and colon is retracted 11) Tissue dissection technique of the planes around IMV DANGEROUS SUBOPTIMAL COMPETENT OPTIMAL NOT APPLICABLE 12) The perivascular 360° exposure with clearance of fatty tissue around the IMV INADEQUATE SUBOPTIMAL ADEQUAT OPTIMAL NOT APPLICABLE 13) The planes around the IMV (Gerota's/surface of pancreas) NOT RESPECTED NOT CLEAR CLEARLY DEMONSTRATED RESPECTED NOT APPLICABLE 14) The protection and exposure of landmarks prior to transection of the IMV, as duodenojejunal-junction, pancreas and Gerota's fascia INADEQUATE SUBOPTIMAL ADEQUATE OPTIMAL NOT APPLICABLE 15) Unintended tissue damage and bleeding during dissection SIGNIFICANT CONCERNING NO DAMAGE OBSERVED NOT APPLICABLE 16) If bleeding occurred, it was controlled INADEQUATE SUBOPTIMAL ADEQUATE OPTIMAL NOTAPPLICABLE 17) The level of IMV transaction in relation to the inferior border of pancreas/ SIGNIFICANTLY OFF SUBOPTIMAL ADEQUATE OPTIMAL NOTAPPLICABLE duodenojejunal-junction 18) Lymphadenectomy along the central aspects of IMV NOTAPPLICABLE NOT PERFORMED SUBOPTIMAL ADEQUATE OPTIMAL Score: 1 INFERIOR MESENTERIC ARTERY 19) Use of dissecting instruments SUBOPTIMAL DANGEROUS NOT APPLICABLE 20) Use of retracting tools (A-frame, swab, atraumatic retractor) to retract the COMPETENT SUBOPTIMAL OPTIMAL colon and mesentery DANGEROUS NOTAPPLICABLE 21) Tissue dissecting technique of the planes around IMA DANGEROUS SUBOPTIMAL COMPETENT OPTIMAL NOT APPLICABLE 22) The perivascular 360° exposure of the IMA with clearance of fatty tissue OPTIMAL INADEQUATE SUBOPTIMAL ADEQUATE NOT APPLICABLE around the vessel origin 23) The planes around the IMA (Gerota/paraaortic nerves/ureter) NOT RESPECTED NOT CLEAR RESPECTED CLEARLY DEMONSTRATED NOT APPLICABLE 24) The protection and exposure of landmarks prior to transection of the IMA, SUBOPTIMAL such as superior rectal artery, hypogastric plexus, gonadal vein and left ureter INADEQUATE ADEQUATE OPTIMAL NOT APPLICABLE 25) Damage to the paragortic nerve plexus/hypogastric nerves SIGNIFICANT CONCERNING MINIMAL NOT DA MAGE OBSERVED NOT APPLICABLE 26) Unintended tissue damage and bleeding during dissection SIGNIFICANT CONCERNING MINIMAL NOT DA MAGE OBSERVED NOT APPLICABLE 27) If bleeding occurred, it was controlled INADEQUATE SUBOPTIMAL ADEQUATE NOT APPLICABLE OPTIMAL 28) The level of IMA transection in relation to the aorta SIGNIFICANTLY OF SUBOPTIMAL ADEQUATE OPTIMAL NOT APPLICABLE 29) Lymphadenectomy along the central aspects of the IMA/left colic artery NOT APPLICABLE NOT PERFORMED SUBOPTIMAL ADEQUATE OPTIMAL

Colour description:

Instrument handling

Clinical safety **Oncological safety**  1/2

1

FIGURE 3 Laparoscopic complete mesocolic excision competency assessment tool (left- and right-sided version).

Tissue handling

Score:

L

# CMECAT

- 🙀 🕵 🔯 🚺 🥳 🐨

38

Laparoscopic Complete Mesocolic Excision Competency Assessment Tool

MOBILISATION AND ANASTOMOSIS Rease mark the answer box which best describes your response to the following statements.	0	0	3	9	
30) Use of dissecting instruments during mobilisation	DANGEROUS		COMPETENT	OPTIMAL	NOT APPLICABLE
31) Use of retracting tools (A-frame, swab, atraumatic retractor) to retract the colon and mesentery	DANGEROUS	SUBOPTIMAL	COMPETENT	OPTIMAL	NOT APPLICABLE
32) Use of stapling device	DANGEROUS	SUBOPTIMAL	COMPETENT	OPTIMAL	NOT APPLICABLE
33) The mobilisation of the left colon with safe division of the gastrocolic and splenocolic attachments	DA NGERÕUS	SUBOPTIMAL	COMPETENT	OPTIMAL	NOT APPLICABLE
34) The mobilisation of transverse mesocolon and safe exposure of the lesser sac	DANGEROUS	SUBOPTIMAL	COMPETENT	OPTIMAL	NOTAPPLICABLE
35) (If needed) The mobilisation of the rectum required in the TME planes			ADEQUAT E	OPTIMAL	NOT APPLICABLE
36) The protection of vital structures (eg. left gonadal vessels, ureter, hypogastric nerve plexus, tail of pancreas, smooth retroperitoneal surface and Gerota's)			ADEQUATE	OPTIMAL	NOTAPPLICABLE
37) Transection of colon and anastomosis was performed			ADEQUATE		NOTAPPLICABLE
38) If bleeding occurred, it was controlled			ADEQUATE	OPTIMAL	
39) Damage to the mesocolic side of the specimen can be described as		CONCERNING	MINIMAL		
40) Proximal and distal resection margin in relation to tumour	TOO CLOSE		ADEQUATE	OPTIMAL	NOT APPLICABLE
Score:					/

TOTAL SCORE:

Feedback/Commentary:

Colour description: Instrument handling

/

CMECAT					R
Laparoscopic Complete Mesocolic Excision (	Jompetenc	y Assessr	nent Too		
Name: Assessor:				Video:	
EXPOSURE					
Yease mark the answer box which best describes your response to the following statements.	0	0	0	9	
<ol> <li>Patients positioning to support exposure</li> </ol>	INADEGUATE	SUBOPTIMAL	ADEQUATE	OPTIMAL	NOT APPLICABLE
2) Positioning of small bowel is performed	HARMFULLY	SUBOPTIMAL	COMPETENT	OPTIMAL	NOT APPLICABLE
<ol> <li>Tissue dissection technique of the planes around pancreas and duodenum</li> </ol>	DANGEROUS	SUBOPTIMAL	COMPETENT	OPTIMAL	NOT APPLICABLE
i) Use of the assistant		SUBOPTIMAL	ADEQUATE	OPTIMAL	NOT APPLICABLE
i) Were there any risks of thermal injuries?	DEFINITELY	POTENTIALLY		NEVER	NOT APPLICABLE
<ol><li>Key structures and landmarks were demonstrated</li></ol>	INADEQUATE	SUBOPTIMAL	ADEQUATE	OPTIMAL	NOT APPLICABLE
7] During the exposure of the operating field the bowels/tissue were	INJURED	POTENTIALLY DA MAGED	SAFELY HANDLED	PROTECTED THROUGHOUT	NOT APPLICABLE
<ol> <li>If bleeding occurred, it was controlled</li> </ol>	INADEQUATE	SUBOPTIMAL	ADEQUATE	OPTIMAL	NOT APPLICABLE
P) Damage to the mesentery during exposure can be described as	ONCOLOGICAL SIGNIFICANT	CONCERNING	MINIMAL	NO DAMAGE OBSERVED	NOT APPLICABLE
Score:				_	/
LEOCOLIC VESSELS. Yease mark the answer box which best describes your response to the following statements:	0	2	0	(4)	
10) Use of dissection instruments to expose the ileocolic vessels	0				
<ol> <li>Use of retracting tools (A-frame, swab, atraumatic retractor) to retract the colon and mesentery</li> </ol>	DANGEROUS			OPTIMAL	NOT APPLICABLE
<ol> <li>Tissue dissection technique of the planes around the ileocolic pedicles and superior mesenteric artery and vein</li> </ol>	DANGEROUS		COMPETENT	OPTIMAL	NOT APPLICABLE
13) The perivascular 360° exposure of the ileocolic vein		SUBOPTIMAL	ADEQUATE	OPTIMAL	
14) The perivascular 360° exposure of the ileocolic artery		SUBOPTIMAL	ADEQUATE	OPTIMAL	NOT APPLICABLE
15) The protection and exposure of landmarks before transection of the leocolic vessels such as superior mesenteric vessels and pancreas		SUBOPTIMAL	ADEQUATE	OPTIMAL	
16) Unintended tissue damage and bleeding during perivascular dissection of the superior mesenteric vein	SIGNIFICANT	CONCERNING	MINIMAL	NO DAMAGE OBSERVED	NOT APPLICABLE
7) If bleeding occurred, it was controlled	INADEQUATE	SUBOPTIMAL	ADEQUATE	OPTIMAL	NOT APPLICABLE
(8) The level of ileocolic vein transection in relation to the lateral border of uperior mesenteric vein		SUBOPTIMAL	ADEQUATE	OPTIMAL	NOTAPPLICABLE
9) The level of ileocolic artery transection in relation to its origin	SIGNIFICANTLY OFF	SUBOPTIMAL	ADEQUATE	OPTIMAL	NOT APPLICABLE
20) Lymphadenectomy along the central aspects of the ileocolic pedicle	NOT PERFORMED	SUBOPTIMAL	ADEQUATE	OPTIMAL	NOT APPLICABLE
Score:				_	/
MIDDLE COLIC VESSELS Mease mark the answer box which best describes your response to the following statements.	0	0	0	9	
21) Use of dissecting instruments to expose the middle colic vessels	DANGEROUS	SUBOPTIMAL	COMPETENT	OPTIMAL	NOT APPLICABLE
22) Use of retracting tools (A-frame, swab, atraumatic retractor) to retract the colon and mesentery			COMPETENT	OPTIMAL	NOT APPLICABLE
23) Tissue dissection technique of the planes around middle colic pedicles and superior mesenteric artery and vein	DANGEROUS		COMPETENT	OPTIMAL	NOT APPLICABLE
24) The perivascular 360° exposure of the MCV or the branch of the MCV		SUBOPTIMAL	ADEQUATE	OPTIMAL	NOT APPLICABLE
25) The perivascular 360° exposure of the MCA or the branch of the MCA				OPTIMAL.	NOT APPLICABLE
26) The protection and exposure of landmarks prior to transection of the niddle colic vessels, such as the superior mesenteric vessels and pancreas		SUBOPTIMAL	ADEQUATE	OPTIMAL	NOT APPLICABLE
27) Unintended tissue damage and bleeding during perivascular dissection of the superior mesenteric vein	SIGNIFICANT	CONCERNING	MINIMAL	NOT DA MAGE OBSERVED	NOT APPLICABLE
28) If bleeding occurred, it was controlled					

Indling Tissue handling

Clinical safety Oncological safety

1/2

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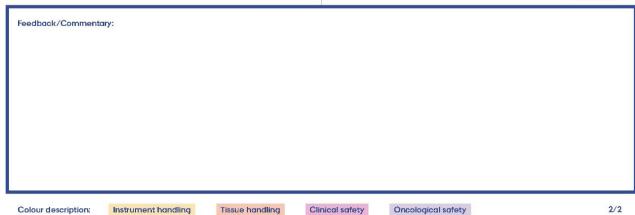
# CMECAT

40

Laparoscopic Complete Mesocolic Excision Competency Assessment Tool



TOTAL SCORE:



1

the patient. If CMECAT is clinically implemented, it may improve progression feedback to CME surgeons-in-training and facilitate implementation of the LCME technique, though future studies are required to provide evidence hereof.

For tools aimed towards cancer surgery, particular attention should be directed to the relationship between performance scores and pathological evaluation, as the plane of surgery has been associated with improved patient outcome [27]. Such relationship has been examined for the CAT for laparoscopic hemicolectomies, where lower ratings have been associated with shorter distal resection margin clearance and a reduced number of harvested lymph nodes [39]. Not considered in CAT, but of equal significance, is the quality of the removed specimen and the appearance of the surgical site. In the CMECAT, this has been addressed by items in the "oncological safety"-section questioning the integrity of the mesocolon, the plane of dissection, and the resection margins. Whether evaluation of these items corresponds to the pathological reports is an interesting relationship that needs further examination. If evident, systematic use of CMECAT could help bring attention to procedural indicators of poor resection quality.

A limitation applying to the CMECAT design is that the case complexity has not been included, leaving the assessors blinded to patient data (e.g., obesity, history of abdominal surgery) and tumour characteristics (location and degree of progression). Although these are components that challenge the operative performance, some may contain sensitive personal information and thereby challenge patient data security. Further, it is difficult to ensure the CMECAT assessors consider these data equally when evaluating a case. However, in the clinical validation of the CMECAT, attention should be drawn to the case complexity as severe cases may cause lower CMECAT ratings. Finally, when the tool is subsequently used in clinical evaluation, the assessors are encouraged to notice the case complexity and leave comments where it has obstructed excellent performance.

Expert selection is another limitation of our study, as all experts were from Europe. However, at the time the study was initiated, few surgical units performed LCME routinely; In the United States, extensive lymphadenectomy as LCME surgery is currently not recommended by the American Society of Colon and Rectal surgeons' guidelines [40]; and for Asian countries, the Japan Society for Endoscopic Surgery recommended D3 resections [41]. To create a tool specifically designed for LCME, included in the panel were only surgeons who practised LCME in line with what previously has been defined by Hohenberger [1]. If the study was to be repeated, experts from other locations may have expanded the LCME versions and thereby increased the generalizability of the tool.

# CONCLUSION

In conclusion, we have established CMECAT, a procedure-specific tool for LCME surgery and provided content validity evidence. Further studies are planned to provide evidence of other validity dimensions and to describe correlation between CMECAT and clinical/pathological findings. Our long-term objective is to validate CMECAT as a tool for assessment and certification of LCME performing-surgeons to ensure surgical competency and thereby improve patient outcome.

### AUTHOR CONTRIBUTIONS

TH and AB performed the interviews and facilitated the Delphi method. DM contributed to the study design and the tool design. AS, KS, MG, DM and SB contributed to the data collection process. JV and TH analysed the data and prepared figures and tables. MBØ and TH wrote the manuscript. SP, LI, AH and DM supervised and contributed to the critical review of the manuscript. AH was responsible for the founding acquisition. All authors discussed the results and approved the final version of the manuscript.

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# DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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#### SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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