Supplementary File

"Prospective validation of ClassIntra® v1.0 – Classification of intraoperative adverse events: international, multicentre cohort study"

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Abbreviations

ARC	Acute Risk Change
ASA	American Society of Anesthesiologists
BUPA	British United Provident Association
CCI®	Comprehensive Complication Index
CD	Clavien-Dindo
CI	Confidence interval
CLASSIC	Classification of Intraoperative Complications
ClassIntra®	Classification of Intraoperative adverse events
EC	Ethics Committee
ICC	Intra-class correlation coefficient
iAE(s)	Intraoperative adverse event(s)
IECs	Incidents, events and complications
IQR	Interquartile range
OR	Odds ratios
pLOS	Postoperative length of hospital stay
SAP	Statistical analysis plan
STROBE	Strengthening the reporting of observational studies in epidemiology

Terminology and definitions

Term	Definition
Resident	Qualified doctors in clinical training (equivalent to specialty trainee or registrar)
Junior consultant	Doctors that have completed full medical training in a specialised area of medicine, board-certified (equivalent to locum consultant)
Senior consultant	Experienced and senior doctors in permanent posts (equivalent to Staff Grade, Associate Specialist and Specialty Doctors)
Same-day surgery	Discharge from hospital in less than 24 hours
Follow-up procedures	Follow-up procedures in the same patient during the same hospital stay were excluded
Gastrointestinal surgery	Procedures performed by visceral surgeons

Supplementary File ClassIntra® study - Table of content

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Abbreviations:

STROBE Strengthening the Reporting of Observational Studies in Epidemiology; BUPA British United Provident Association; CCI comprehensive complication index; ClassIntra® Classification of Intraoperative Adverse Events; CI confidence interval;

Supplementary Tables

Table S1. **CLASSIC – Classification of Intraoperative Complications**[1]

Grade	**Definition** The classification exclusively relates to any event occurring between skin incision and skin closure and should be rated directly after surgery. Any event during the index-surgery must be considered, regardless whether it is surgery or anaesthesia-related.* Prerequisite: the indication for surgery and the interventions conform to current guidelines
Grade 0	No deviation from the ideal intraoperative course
Grade I	Any deviation from the ideal intraoperative course • Without the need for any additional treatment or intervention
Grade II	Any deviation from the ideal intraoperative course • With the need for any additional treatment or intervention • Not life-threatening and not leading to permanent disability
Grade III	Any deviation from the ideal intraoperative course • With the need for any additional treatment or intervention • Life-threatening and/or leading to permanent disability
Grade IV	Any deviation from the ideal intraoperative course • With death of the patient

* The following events are not defined as intraoperative complications: sequelae, failures of cure, events related to the underlying disease, wrong-site or wrong-patient surgery or errors in indication

Table S2. **Clavien-Dindo Classification of Postoperative Complications**[2]

Grades	Definition
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological intervention Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications Blood transfusions and total parenteral nutrition are also included
Grade III	Requiring surgical, endoscopic or radiological intervention • IIIa: Intervention not under general anaesthesia • IIIb: Intervention under general anaesthesia
Grade IV	Life-threatening complication (including CNS complications)‡ requiring IC / ICU-management • IVa: Single organ dysfunction (incl. dialysis) • IVb: Multi organ dysfunction
Grade V	Death of a patient
Suffix 'd'	If the patient suffers from a complication at the time of discharge, the suffix 'd' (for 'disability') is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication

‡ Brain haemorrhage, ischemic stroke, subarachnoidal bleeding, but excluding transient ischemic attacks (TIA); CNS: Central nervous system; IC: Intermediate care; ICU: Intensive care unit

Table S3. **Survey with 10 fictitious case scenarios**

Case	Case description
1	An exanthema was observed shortly after the administration of the prophylactic antibiotic without a haemodynamic reaction, but the need for an antihistaminic drug (Correct answer: Grade 2)
2	During a laparoscopic nephrectomy, the cautery was suddenly not functioning anymore. A new instrument had to be organised which led to a minor delay of a few minutes. The patient was stable. (Correct answer: Grade 1)
3	A patient underwent radial fixation in an axillar plexus anaesthesia. Unfortunately, the anaesthesia was incomplete and the patient was in pain. The anaesthetist decided to add a general anaesthesia. Due to difficult intubation condition, several attempts were necessary. After correct placement of the tracheal tube could be confirmed, the anaesthetist realised that one tooth was avulsed (Correct answer: Grade 3)
4	During the insertion of an arterio-venous fistula in a patient with end-stage kidney failure, a wide complex regular tachycardia occurred. The blood pressure became unstable requiring an immediate synchronised cardioversion. (Correct answer: Grade 4)
5	A patient underwent a removal of a polyp on the vocal cords using a CO2 laser. During the procedure, an endotracheal tube fire suddenly occurred. The burning tube was removed immediately. The patient was ventilated with a facemask until reintubation was performed. The subsequent bronchoscopy showed airway damage with oedema not allowing for an extubation. The patient was transferred to the intensive care unit until oedema decreased. (Correct answer: Grade 4)
6	A 75-year old women presented herself with obstructive bowel disease. In her past, she already underwent three abdominal procedures (appendectomy as a child, cholecystectomy at the age of 40 years, and a hysterectomy due to a metrorrhagia at the age of 48 years). A laparoscopic approach was chosen, the obstruction could be resolved, but extended intestinal adhaesiolysis was necessary. There was an unproblematic intra- and postoperative course. (Correct answer: Grade 0)
7	In a patient who is a current smoker (10 pack-years), signs of obstruction in capnography curve were noted. Normocapnia could be maintained with normal peak and plateau pressures. (Correct answer: Grade 1)
8	A woman underwent a Caesarean section for twins. After the delivery of the infants, a postpartum haemorrhage occurred due to an insufficient uterine tone. Antifibrinolytic agents and additional uterotonics were administered. Colloids were given to stabilise blood pressure. Total intraoperative blood loss was 1800 ml. (Correct answer: Grade 3)
9	A small skin lesion occurred due to an unintended cauterisation without the need of any treatment. (Correct answer: Grade 1)
10	A 60-year old man who underwent a decompression and stabilisation of the spine from the levels L2 to L5 in prone position. Preoperative haemoglobin was at 140 g/l. Tranexamic acid 1g was administered for slightly increased bleeding. The haemodynamic was always stable. Total blood loss at the end of the procedure was 1000 ml. Postoperative haemoglobin was at 112 g/l. No further intervention was needed. (Correct answer: Grade 2)

Table S4. **Respondent characteristics to the survey** (*n* = 136 respondents out of 163, response rate 83%)

Characteristic	Category	Value
Primary discipline, *n* (%)	Anaesthesiology	52 (38%)
	Visceral surgery	67 (49%)
	Orthopaedic surgery	3 (2.2%)
	ENT and maxillofacial surgery	4 (2.9%)
	Vascular surgery	4 (2.9%)
	Paediatric surgery	3 (2.2%)
	Neurosurgery	1 (0.7%)
	Oncological surgery	2 (1.5%)
Country, *n* (%)	Switzerland (6 centres)	40 (29%)
	Netherlands	13 (9.6%)
	Spain	5 (3.7%)
	United Kingdom	11 (8.1%)
	Austria (2 centres)	10 (7.4%)
	Italy	8 (5.9%)
	United States of America	4 (2.9%)
	New Zealand	9 (6.6%)
	Greece	10 (7.4%)
	Ireland	10 (7.4%)
	Australia	11 (8.1%)
	Turkey	5 (3.7%)
Years of work experience, *n* (%)	0-5 years	27 (20%)
	6-10 years	38 (28%)
	11-15 years	23 (17%)
	>15 years	48 (35%)

ENT ear, nose, throat

Table S5. **Uni- and multivariable hierarchical proportional odds models for the most severe postoperative complication according to 3-category Clavien-Dindo classification** (n=2520 patients in 18 centres)

Factor		Univariable analysis Odds ratio (95% CI)	Multivariable analysis Odds ratio (95% CI)
ClassIntra®			
	Grade I *vs* 0	1.15 (0.77 to 1.71)	0.99 (0.69 to 1.42)
	Grade II *vs* 0	2.21 (1.55 to 3.16)	1.39 (0.97 to 2.00)
	Grade III *vs* 0	5.30 (2.67 to 10.6)	2.62 (1.31 to 5.26)
	Grade IV *vs* 0	8.28 (3.43 to 20.0)	3.81 (1.19 to 12.2)
Age (per decade increase)		1.15 (1.08 to 1.22)	1.04 (0.99 to 1.09)
ASA class	ASA III-V *vs* ASA I-II	2.23 (1.70 to 2.92)	1.70 (1.40 to 2.06)
Complexity of surgery			
	Intermediate *vs* minor	0.84 (0.53 to 1.33)	0.79 (0.52 to 1.19)
	Major *vs* minor	1.11 (0.63 to 1.96)	0.85 (0.50 to 1.45)
	Major + *vs* minor	2.18 (1.16 to 4.10)	1.20 (0.74 to 1.94)
	Complex major *vs* minor	3.42 (2.09 to 5.61)	1.27 (0.79 to 2.04)
Duration of surgical procedure (per 10-minute increase)		1.07 (1.06 to 1.08)	1.05 (1.03 to 1.07)
Urgency	Emergency *vs* planned	0.99 (0.59 to 1.66)	1.57 (1.04 to 2.35)
Wound class	Non-clean *vs* clean	1.30 (0.92 to 1.84)	1.20 (0.99 to 1.46)
Experience of surgical team		0.66 (0.52 to 0.82)	0.84 (0.69 to 1.03)
Experience of anaesthesia team		0.77 (0.70 to 0.85)	0.88 (0.80 to 0.96)

CI confidence interval; ClassIntra® Classification of Intraoperative Adverse Events; ASA American Society of Anesthesiologists

Table S6. **Multivariable linear mixed model of CCI® adjusted for the most relevant factors** – Comparison of final model (*n* = 2520) and model including only patients with original BUPA (*n* = 2422)

Factor		Final multivariable model Mean difference (95% CI)	Model with original BUPA Mean difference (95% CI)
ClassIntra®			
	Grade I *vs* 0	-0.1 (-2.7 to 2.6)	-0.1 (-2.7 to 2.6)
	Grade II *vs* 0	2.7 (0.6 to 4.8)	2.5 (0.4 to 4.6)
	Grade III *vs* 0	9.7 (6.6 to 13)	10 (6.8 to 13)
	Grade IV *vs* 0	19 (11 to 26)	16 (8.1 to 25)
Age (per decade increase)		0.3 (-0.2 to 0.7)	0.1 (-0.3 to 0.5)
ASA class			
	ASA II *vs* I	1.8 (-0.1 to 3.8)	2.1 (0.2 to 4.1)
	ASA III *vs* I	6.1 (3.8 to 8.4)	6.4 (4.1 to 8.7)
	ASA IV/V *vs* I	15 (11 to 19)	13 (9.0 to 17)
Complexity of surgery			
	Intermediate *vs* minor	-2.7 (-6.1 to 0.8)	-2.2 (-5.7 to 1.3)
	Major *vs* minor	-3.7 (-6.9 to -0.4)	-3.1 (-6.5 to 0.2)
	Major + *vs* minor	-0.9 (-4.4 to 2.7)	0.2 (-3.4 to 3.9)
	Complex major *vs* minor	-1.4 (-5.0 to 2.3)	-1.1 (-4.8 to 2.6)
Duration of surgical procedure (per 10-minute increase)		0.4 (0.3 to 0.5)	0.4 (0.3 to 0.5)
Urgency	Emergency *vs* planned	5.0 (2.8 to 7.2)	4.7 (2.5 to 6.9)
Wound class	Non-clean *vs* clean	1.9 (0.4 to 3.5)	2.2 (0.6 to 3.7)
Experience of surgical team		-1.0 (-2.3 to 0.2)	-1.0 (-2.3 to 0.3)
Experience of anaesthesia team		-0.6 (-1.3 to 0.2)	-0.5 (-1.3 to 0.2)

BUPA British United Provident Association; CI confidence interval; ClassIntra® Classification of Intraoperative Adverse Events; ASA American Society of Anesthesiologists

Table S7. **Multivariable linear mixed model of length of postoperative stay (log-transformed) adjusted for the most relevant factors** – Comparison of final model (n = 2520) and model including only patients with original BUPA (n = 2422); regression coefficients give percentage changes per grade increase of the corresponding covariate

Factor		Final multivariable model Percentage change (95% CI)	Model with original BUPA Percentage change (95% CI)
ClassIntra® (per each grade increase)		6.1% (2.8 to 9.3)	5.8% (2.4 to 9.1)
Age (per decade increase)		4.0% (2.1 to 5.8)	3.0% (1.1 to 5.0)
ASA class (per each class increase)		23% (18 to 27)	23% (19 to 28)
Complexity of surgery			
	Intermediate *vs* minor	-5.3% (-20 to 9.5)	-5.7% (-21 to 9.5)
	Major *vs* minor	3.1% (-11 to 17)	2.3% (-12 to 17)
	Major + *vs* minor	36% (21 to 51)	39% (23 to 54)
	Complex major *vs* minor	32% (17 to 48)	32% (16 to 48)
Duration of surgical procedure (per 10-minute increase)		3.6% (3.2 to 4.0)	3.7% (3.3 to 4.0)
Urgency	Emergency *vs* planned	26% (17 to 36)	24% (14 to 33)
Wound class	Non-clean *vs* clean	10% (3.6 to 17)	12% (5.5 to 19)
Experience of surgical team (per each unit decrease)		-9.3% (-15 to -3.6)	-9.7% (-15 to -4.0)
Experience of anaesthesia team (per each unit decrease)		-4.1% (-7.3 to -1.0)	-4.0% (-7.2 to -0.8)

BUPA British United Provident Association; CI confidence interval; ClassIntra® Classification of Intraoperative Adverse Events; ASA American Society of Anesthesiologists

Table S8. **Multivariable linear mixed model of duration of surgery (log-transformed) adjusted for the most relevant factors** – Comparison of final model (n = 2520) and model including only patients with original BUPA (n = 2422); regression coefficients give percentage changes per grade increase of the corresponding covariate

Factor		Final multivariable model Percentage change (95% CI)	Model with original BUPA Percentage change (95% CI)
ClassIntra® (per each grade increase)		16 % (13 to 18)	16 % (13 to 18)
Age			
	< 6 years vs 18 - 45 years	-36 % (-59 to -13)	-37 % (-59 to -14)
	6 - 17 years vs 18 - 45 years	-13 % (-31 to 4.9)	-13 % (-31 to 4.7)
	46 - 55 years vs 18 - 45 years	9.7 % (2.3 to 17)	7.5 % (-0.2 to 15)
	56 - 65 years vs 18 - 45 years	9.9 % (2.6 to 17)	9.6 % (2.1 to 17)
	66 - 75 years vs 18 - 45 years	-0.1 % (-7.5 to 7.2)	-1.6 % (-9.2 to 5.9)
	76 - 85 years vs 18 - 45 years	-5.8 % (-14 to 2.6)	-6.0 % (-15 to 2.7)
	> 85 years vs 18 - 45 years	-26 % (-41 to -11)	-26 % (-41 to -11)
ASA class (per each class increase)		4.8 % (1.4 to 8.3)	4.7 % (1.2 to 8.3)
Complexity of surgery			
	Intermediate *vs* minor	29 % (17 to 41)	29 % (16 to 41)
	Major *vs* minor	55 % (44 to 66)	54 % (43 to 66)
	Major + *vs* minor	98 % (86 to 110)	98 % (86 to 110)
	Complex major *vs* minor	118 % (106 to 130)	115 % (103 to 128)
Urgency	Emergency *vs* planned	-4.6 % (-12 to 2.9)	-6.0 % (-14 to 1.6)
Wound class	Non-clean *vs* clean	2.0 % (-3.4 to 7.5)	1.8 % (-3.7 to 7.4)
Experience of surgical team (per each unit decrease)		-7.4 % (-12 to -2.9)	-7.0 % (-12 to -2.5)
Experience of anaesthesia team (per each unit decrease)		-4.0 % (-6.5 to -1.5)	-4.3 % (-6.9 to -1.8)

BUPA British United Provident Association; CI confidence interval; ClassIntra® Classification of Intraoperative Adverse Events; ASA American Society of Anesthesiologists

Table S9. **Association between ClassIntra® and mortality*:** Association between ClassIntra® and in-hospital mortality (*n* = 25), 30-day mortality (*n* = 26) or overall mortality (i.e. considering in-hospital and 30-day mortality, *n* = 30)

ClassIntra®	**In-hospital mortality** (*n* = 25, 1%)	**30-day mortality** (*n* = 26, 1.1%)	**Overall mortality** (*n* = 30, 1.2%)
Grade 0	13 (0.7%)	13 (0.7%)	16 (0.8%)
Grade I	1 (0.6%)	0	1 (0.6%)
Grade II	6 (1.9%)	6 (1.9%)	6 (1.9%)
Grade III	4 (3.3%)	6 (4.9%)	6 (4.9%)
Grade IV	1 (5.6%)	1 (5.6%)	1 (5.6%)

* In-hospital mortality was defined as death during the hospital stay, regardless of the length of hospital stay. Thirty-day mortality was defined as death within 30 days of surgery, regardless whether as in-patient or after discharge. Overall mortality was defined as death during the hospital stay or within 30 days of surgery.

Table S10. **Uni- and multivariable hierarchical proportional odds models for the most severe postoperative complication according to 5-category Clavien-Dindo classification** (n=2520 patients in 18 centres)

CAVEAT: The proportional odds assumption is slightly violated.

Factor		Univariable analysis Odds ratio (95% CI)	Multivariable analysis Odds ratio (95% CI)
ClassIntra®			
	Grade I *vs* 0	1.14 (0.78 to 1.67)	1.00 (0.71 to 1.41)
	Grade II *vs* 0	2.33 (1.62 to 3.34)	1.47 (1.02 to 2.11)
	Grade III *vs* 0	5.51 (2.77 to 11.0)	2.72 (1.37 to 5.39)
	Grade IV *vs* 0	9.98 (3.82 to 26.1)	5.04 (1.46 to 17.4)
Age (per decade increase)		1.16 (1.09 to 1.23)	1.05 (0.99 to 1.11)
ASA class	ASA III-V *vs* ASA I-II	2.29 (1.74 to 3.02)	1.74 (1. 42 to 2.12)
Complexity of surgery			
	Intermediate *vs* minor	0.84 (0.53 to 1.33)	0.74 (0.49 to 1.12)
	Major *vs* minor	1.10 (0.63 to 1.92)	0.79 (0.47 to 1.35)
	Major + *vs* minor	2.18 (1.14 to 4.15)	1.15 (0.70 to 1.88)
	Complex major *vs* minor	3.49 (2.15 to 5.68)	1.25 (0.79 to 1.96)
Duration of surgical procedure (per 10-minute increase)		1.07 (1.06 to 1.08)	1.05 (1.03 to 1.07)
Urgency	Emergency *vs* planned	1.01 (0.59 to 1.72)	1.64 (1.07 to 2. 51)
Wound class	Non-clean *vs* clean	1.32 (0.93 to 1.87)	1.20 (1.00 to 1.45)
Experience of surgical team		0.66 (0.53 to 0.82)	0.85 (0.71 to 1.03)
Experience of anaesthesia team		0.77 (0.70 to 0.84)	0.87 (0.79 to 0.96)

CI confidence interval; ClassIntra® Classification of Intraoperative Adverse Events; ASA American Society of Anesthesiologists

Table S11. **Uni- and multivariable multi-level logistic regression models for important risk factors for binary Clavien-Dindo classification**

Factor		Univariable analysis Odds ratio (95% CI)	Multivariable analysis Odds ratio (95% CI)
ClassIntra®			
	Grade I *vs* 0	1.17 (0.73 to 1.89)	0.97 (0.61 to 1.55)
	Grade II *vs* 0	2.27 (1.62 to 3.18)	1.37 (0.95 to 1.98)
	Grade III *vs* 0	5.25 (2.77 to 9.96)	2.54 (1.29 to 4.99)
	Grade IV *vs* 0	21.5 (7.09 to 65.2)	10.4 (2.34 to 45.8)
Age (per decade increase)		1.15 (1.08 to 1.22)	1.05 (0.99 to 1.11)
ASA class	ASA III-V *vs* ASA I-II	2.14 (1.62 to 2.82)	1.63 (1.35 to 1.96)
Complexity of surgery			
	Intermediate *vs* minor	0.93 (0.58 to 1.48)	0.85 (0.56 to 1.28)
	Major *vs* minor	1.24 (0.72 to 2.13)	0.93 (0.55 to 1.59)
	Major + *vs* minor	2.39 (1.30 to 4.40)	1.22 (0.76 to 1.95)
	Complex major *vs* minor	4.06 (2.47 to 6.69)	1.41 (0.86 to 2.31)
Duration of surgical procedure (per 10-minute increase)		1.08 (1.06 to 1.10)	1.06 (1.04 to 1.08)
Urgency	Emergency *vs* planned	0.98 (0.57 to 1.69)	1.59 (1.00 to 2.54)
Wound class	Non-clean *vs* clean	1.25 (0.88 to 1.76)	1.13 (0.93 to 1.38)
Experience of surgical team		0.63 (0.50 to 0.80)	0.81 (0.66 to 0.99)
Experience of anaesthesia team		0.76 (0.70 to 0.84)	0.88 (0.80 to 0.96)

CI confidence interval; ClassIntra® Classification of Intraoperative Adverse Events; ASA American Society of Anesthesiologists

Table S12. **Hierarchical proportional odds model for the most severe postoperative complication according to Clavien-Dindo** – Comparison of the final model (n = 2520) with the results of 100 replications of bootstrapping for 2520 patients

Factor		Final multivariable model Odds ratio (95% CI)	Results of bootstrapping Odds ratio (95% CI)
ClassIntra®			
	Grade I *vs* 0	0.99 (0.69 to 1.42)	0.99 (0.67 to 1.46)
	Grade II *vs* 0	1.39 (0.97 to 2.00)	1.39 (1.05 to 1.84)
	Grade III *vs* 0	2.62 (1.31 to 5.26)	2.62 (1.78 to 3.86)
	Grade IV *vs* 0	3.81 (1.19 to 12.2)	3.81 (1.34 to 10.8)
Age (per decade increase)		1.04 (0.99 to 1.09)	1.04 (0.99 to 1.09)
ASA class	ASA III-V *vs* ASA I-II	1.70 (1.40 to 2.06)	1.70 (1.39 to 2.08)
Complexity of surgery			
	Intermediate *vs* minor	0.79 (0.52 to 1.19)	0.79 (0.44 to 1.42)
	Major *vs* minor	0.85 (0.50 to 1.45)	0.85 (0.47 to 1.54)
	Major + *vs* minor	1.20 (0.74 to 1.94)	1.20 (0.63 to 2.29)
	Complex major *vs* minor	1.27 (0.79 to 2.04)	1.27 (0.66 to 2.47)
Duration of surgical procedure (per 10-minute increase)		1.05 (1.03 to 1.07)	1.05 (1.04 to 1.06)
Urgency	Emergency *vs* planned	1.57 (1.04 to 2.35)	1.57 (1.15 to 2.12)
Wound class	Non-clean *vs* clean	1.20 (0.99 to 1.46)	1.20 (0.93 to 1.54)
Experience of surgical team		0.84 (0.69 to 1.03)	0.84 (0.69 to 1.04)
Experience of anaesthesia team		0.88 (0.80 to 0.96)	0.88 (0.79 to 0.98)

CI confidence interval; ClassIntra® Classification of Intraoperative Adverse Events; ASA American Society of Anesthesiologists

Table S13. **Hierarchical proportional odds model for the most severe postoperative complication according to Clavien-Dindo** – Comparison of final model (*n* = 2520) and complete case analysis with original BUPA (*n* = 2422)

Factor		Final multivariable model Odds ratio (95% CI)	Model with original BUPA Odds ratio (95% CI)
ClassIntra®			
	Grade I *vs* 0	0.99 (0.69 to 1.42)	1.00 (0.69 to 1.43)
	Grade II *vs* 0	1.39 (0.97 to 2.00)	1.37 (0.94 to 1.98)
	Grade III *vs* 0	2.62 (1.31 to 5.26)	2.56 (1.23 to 5.33)
	Grade IV *vs* 0	3.81 (1.19 to 12.2)	3.29 (1.02 to 10.5)
Age (per decade increase)		1.04 (0.99 to 1.09)	1.02 (1.00 to 1.07)
ASA class	ASA III-V *vs* ASA I-II	1.70 (1.40 to 2.06)	1.71 (1.43 to 2.03)
Complexity of surgery			
	Intermediate *vs* minor	0.79 (0.52 to 1.19)	0.83 (0.48 to 1.42)
	Major *vs* minor	0.85 (0.50 to 1.45)	0.89 (0.48 to 1.66)
	Major + *vs* minor	1.20 (0.74 to 1.94)	1.33 (0.76 to 2.34)
	Complex major *vs* minor	1.27 (0.79 to 2.04)	1.26 (0.71 to 2.24)
Duration of surgical procedure (per 10-minute increase)		1.05 (1.03 to 1.07)	1.05 (1.03 to 1.07)
Urgency	Emergency *vs* planned	1.57 (1.04 to 2.35)	1.53 (1.01 to 2.30)
Wound class	Non-clean *vs* clean	1.20 (0.99 to 1.46)	1.24 (0.99 to 1.55)
Experience of surgical team		0.84 (0.69 to 1.03)	0.82 (0.67 to 1.01)
Experience of anaesthesia team		0.88 (0.80 to 0.96)	0.88 (0.80 to 0.96)

BUPA British United Provident Association; CI confidence interval; ClassIntra® Classification of Intraoperative Adverse Events; ASA American Society of Anesthesiologists

Table S14. **Predicted mean CCI and 95% CI at means of the other covariates for all ClassIntra® grades**

	Fractional logit model		**Linear regression model**		**Raw means**
	Mean CCI	95% CI	Mean CCI	95% CI	(SD)
Grade 0	6.4	4.7 to 8.0	7.8	5.6 to 10.1	7.1 (15.9)
Grade 1	7.8	6.4 to 9.2	10.4	8.8 to 11.9	8.0 (16.6)
Grade 2	9.6	7.7 to 11.5	12.9	10.5 to 15.3	14.1 (22.0)
Grade 3	11.7	8.4 to 15.0	15.4	11.6 to 19.3	24.3 (26.9)
Grade 4	14.2	8.7 to 19.8	18.0	12.5 to 23.4	34.4 (24.8)

	Fractional probit model		**Fractional heteroskedastic probit**	
	Mean CCI	95% CI	Mean CCI	95% CI
Grade 0	6.4	4.8 to 8.1	6.4	4.7 to 8.0
Grade 1	8.1	6.7 to 9.5	8.1	6.5 to 9.7
Grade 2	10.0	8.0 to 12.0	10.2	7.9 to 12.4
Grade 3	12.3	8.8 to 15.7	12.6	8.8 to 16.4
Grade 4	14.9	9.3 to 20.4	15.4	9.5 to 21.2

CCI comprehensive complication index; CI confidence interval; SD standard deviation; ClassIntra® Classification of Intraoperative Adverse Events

Table S15. **Examples of the most frequent types of surgical procedures within this study for each complexity grade according to BUPA**

Complexity level	All patients *n* = 2520	Examples of most frequent types of surgical procedures within this cohort study
Minor	105 (4.2%)	Drainage of large subcutaneous abscess/haematoma; Drainage of lesion of skin; Laying open of pilonidal sinus; Drainage through perineal region; Examination of rectum under anaesthetic; Local excision of varicose vein(s) of leg - unilateral; Debridement of wound up to 25 cm_2 in area; Surgical toilet and debridement of deep wound
Intermediate	437 (17%)	Adenotonsillectomy; Laparoscopic repair of incisional or ventral hernia requiring mesh; Primary repair of inguinal hernia; Laparoscopic repair of inguinal hernia - unilateral; Endoscopic resection of lesion of bladder; Laying open of low anal fistula; Percutaneous transluminal angioplasty of artery, +/- insertion of stent; Removal of internal fixation from bone/joint, excluding K-wires; Tenodesis of biceps tendon (as sole procedure); Repair of umbilical hernia; Diagnostic laparoscopy; Haemorrhoidectomy (including sigmoidoscopy)
Major	790 (31%)	Caesarean section; (Laparoscopic) cholecystectomy; Laparoscopic appendicectomy; Closure of ileostomy; (Near) Total/partial thyroidectomy; Creation of ventriculoperitoneal shunt; Gastro-jejunostomy; Transanal resection for rectal cancer; Ureteroscopic extraction of calculus of ureter (including cystoscopy and insertion/removal of stent); Endoscopic resection of prostate (TUR) (including cystoscopy); Laparoscopic repair of inguinal hernia - bilateral; Arthroscopic subacromial decompression and rotator cuff repair; Primary open reduction of short bone with fixation
Major plus (+)	442 (18%)	Gastric bypass; Sleeve/partial gastrectomy; Right hemicolectomy; Laparoscopically assisted right hemicolectomy; (Laparoscopically assisted) Left colon resection; Primary total hip replacement; (Laparoscopic) Distal pancreatectomy; Laparoscopic nephrectomy; Arthroscopic rotator cuff repair greater than 2cm; Decompression for central spinal stenosis (1 or 2 levels); Parathyreoidectomy
Complex major operations (CMO)	648 (26%)	(Laparoscopic) Low anterior resection; Partial hepatectomy; Resection of liver tumour(s); Whipple's Procedure; Carotid endarterectomy; Ablation liver lesion (radiofrequency); Reverse polarity arthroplasty of shoulder; Endarterectomy of femoral artery; Endovascular aneurysm repair (EVAR) of infrarenal aorta; Ablation of atrial fibrillation by isolation of the pulmonary veins (including mapping); Abdominoperineal resection of rectum and anus; Excision of sigmoid colon; Oesophagectomy/oesophagogastrectomy with anastomosis in the chest

Supplementary Figures

Figure S1. **Agreement between respondents and benchmark rating of the core team for 10 fictitious case scenarios**

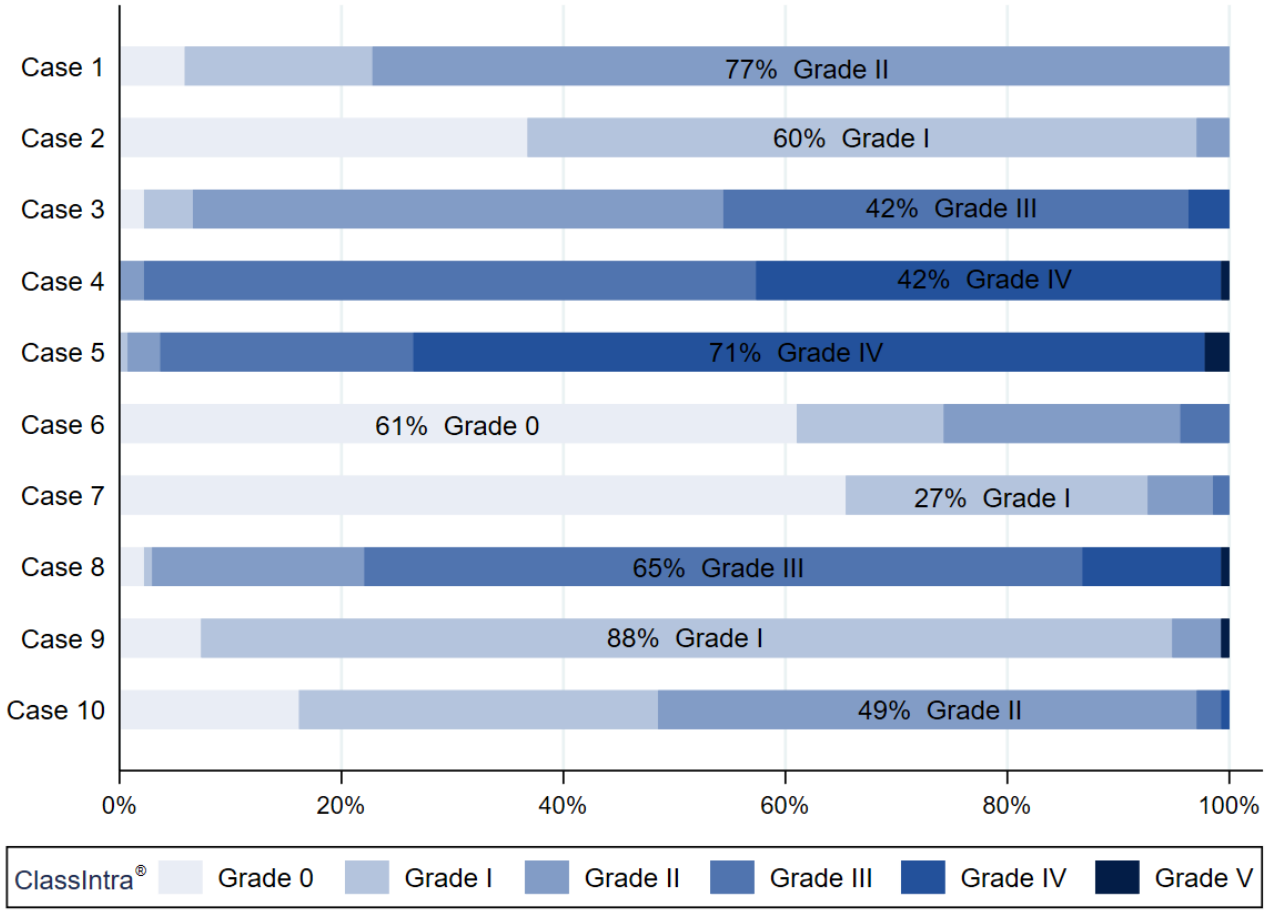
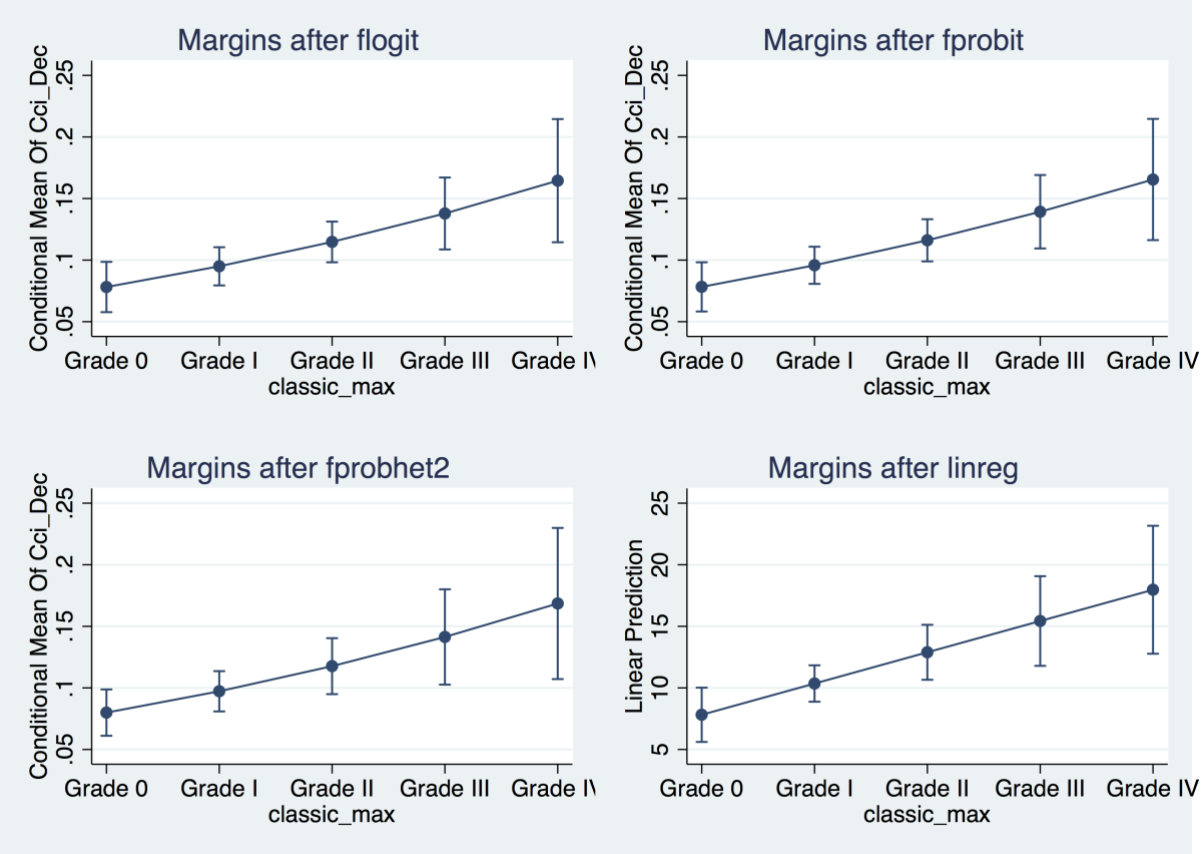


Figure S2. **Marginal means for each ClassIntra® grade:** Marginal means for each ClassIntra® grade predicted from a fractional logit (upper left), fractional probit (upper right), fractional heteroskedastic probit (lower left) model and compared with the marginal means predicted from a standard linear regression model (lower right)



Statistical analysis plan

1. Study oversight

This investigator-initiated external validation study of ClassIntra® v1.0 consists of two parts. First, an international multicentre prospective cohort study was conducted in 18 centres from 12 countries to assess construct validity. Construct validity was explored by estimating the association between severity grades of ClassIntra® and relevant patient outcomes, such as the risk-adjusted association between the most severe adverse event and the most severe postoperative complication classified according to Clavien-Dindo[2] (primary endpoint), the sum of all postoperative complications calculated by the comprehensive complication index (CCI®),[3] the postoperative length of stay, the duration of surgery, the in-hospital and the 30-day mortality. Second, a survey was sent to physicians to assess criterion validity and reliability by comparing the severity ratings of intraoperative adverse events by physicians with the ratings as set by the core team.

2. Sample size determination

Participating hospitals were a voluntary convenience sample, covering a wide range of surgical disciplines from different types of hospitals. The sample size was prespecified in the study protocol according to the number of confounders and the number of factor levels for categorical variables, which added up to 23 factors to be estimated in the final models. Therefore, we anticipated that a sample size of 2500 patients allowed for construction of a robust not overfitted hierarchical multivariable proportional odds and linear regression model for the association between the grade of the most severe adverse event and the most severe postoperative complication and the sum of all postoperative complications,[4, 5] assuming at least one postoperative complication in 10% of the patients (i.e. at least 250 events).

3. Data handling and record keeping

The web-based database used for data entry was accessible using a secure (Secure Socket Layer) connection. The database was password protected and all data were encrypted. The database was hosted on a server in Switzerland and could be accessed through any modern web-browser. The study database was setup with different domains for each participating hospital, ensuring that study personnel can only access data from patients of the same hospital. Access for study personnel was granted using personalised accounts to allow for tracking each data entry to an exact time and study member (audit trail). All custom electronic data capture forms were validated using at least three test data extractions. Plausibility checks were performed by logical data testing on the browser.

4. Data protection

Data generation, transmission, storage and analysis of health-related personal data within this project strictly followed the current Swiss legal requirements for data protection and were performed according to the Ordinance HRO Art. 5.

Health related personal data captured during this project were handled with strict confidentiality, and disclosure to third parties was prohibited. Coding safeguarded participants' privacy.

Project data were handled with utmost discretion and were only accessible to authorized personnel. Direct access to source documents was permitted for purposes of monitoring, audits or inspections only.

5. Archiving and destruction of the data

The investigator will maintain all study-related records, such as medical records and other pertinent data. All records will be retained by the investigator for 10 years after publication.

6. Privacy protection

An audit and access trail as well as central monitoring capabilities were automatically provided by the database system. Each patient was registered in the system with a unique study ID. However, the study plan required a multitude of follow-up data collections entered into the system by various individuals. Therefore, to minimise the risk of patient mix-up, a search function was included to allow the identification of study participants not only by ID, but also by name. To ensure data privacy, the patient names were not saved in clear text, but encrypted using a one-way hash function. This prohibited a decryption of the patient names from the stored data. In addition, only employees of the given hospital were able to search for patients by their names (using access restrictions and a custom hash salt for every hospital). This anonymous database was used for statistical analysis. It was a reversible anonymisation, allowing the principal investigator to consult source documents in case of queries during consistency check and statistical analysis.

7. Monitoring

The monitoring at the local study site was performed by an interdisciplinary team (anaesthesiologists, surgeons, study nurse) from the University Hospital Basel, Switzerland. The monitoring evaluated the progress of the study, verified the accuracy and completeness of the electronic case report forms (eCRFs), ensured that all protocol requirements and investigator's obligations were fulfilled, and resolved any inconsistencies in the study records.

Local project leaders ensured that the data in the eCRF were carefully entered and verified regularly. It was the responsibility of local project leaders to conduct periodic and random checks to ensure data quality in her/his centre.

8. Data management

The database incorporated automated checks for plausibility, consistency and completeness of data entries. Further consistency checks were performed after completion of recruitment by SDK and LG for each centre separately. Missing or implausible data were looked up by the centre PI and corrected if necessary.

There were few remaining missing values in the variable describing the complexity of surgery as classified according to the classification system proposed by BUPA (British United Provident Association)[6, 7] and in the information about the level of experience of the anaesthesia and surgery team. In case of a missing BUPA code (cash value only or procedure not in the BUPA database), these codes were completed by deriving the code from similar procedure through consensus by the core team and clinical experts in the field. If no information about the presence of the anaesthesia resident or nurse and his/her graduation, respectively, was available, it was assumed that this additional team member was not present or was not graduated, respectively. No other missing values in the outcome or covariates were present.

As the preoperative period (hospital admission until day of surgery) was up to 190 days in some patients, we decided to use the postoperative length of stay instead of the overall length of hospital stay.

A continuous index (CCI®) summarising all postoperative complications within one patient was calculated according to the formula described by Slankamenac *et al*.[3, 8]

In order to use anaesthesia and surgical experience to adjust for confounding in multivariable analysis, these variables were differently handled based on their different clinical responsibilities (e.g. senior anaesthesiologists overseeing more than one intervention at the same time). Anaesthesia team experience was built by the presence of all team members as follows: anaesthesia nurse in training, his/her graduation and a resident present in the operating room each contributed one point; a consultant added another 2 and a senior consultant 3 points. In all models, the reference group was the group with maximal cumulative experience to which teams with less cumulative experience were compared. The coefficient, therefore, estimates

the effect on outcome for a one-unit decrease in anaesthesia team experience. This order has been chosen in order to have a large enough reference group, as only few patients were treated by an anaesthesia nurse in training or a resident only.
Surgical experience was defined by the most senior surgeon present in the operating room, with the senior consultant (board-certified and senior position) as the reference group, to which the consultant (board-certified) and the resident (in training) was compared. In all models, surgical experience was also modelled as a continuous term, i.e. the coefficient also estimates the effect on outcome for a one-unit decrease in surgical experience. This order was chosen in order to have a large enough reference group.
We refrained from asking the number of years of experience in their area of expertise (surgery and anaesthesiology, respectively). The classification into 'resident', 'junior consultant' or 'senior consultant' clearly reflects the job responsibilities in the participating hospitals that are assumed to be linked to the experience.

9. Primary endpoint

9.1. Statistical analysis

The primary outcome was the most severe postoperative complication observed in each patient recorded as an ordered 5-categorical variable according to Clavien-Dindo.[2] The unadjusted association between the most severe intra- and postoperative adverse event was investigated using a univariate hierarchical proportional odds model considering clustering within study centres. We then investigated whether this association could still be seen after risk adjustment for the following confounders: American Society of Anaesthesiologists (ASA – Grades III - V vs. Grades I-II) physical status,[9] patient age (per decade), duration of surgery (per 10 minutes), complexity of surgery graded in 5 categories according to the British United Provident Association (BUPA),[6, 7] urgency of the procedure (emergency vs. planned), experience of surgical and anaesthesia team, and wound class.[10] Factors were predefined according to biological plausibility and scientific rationale. The appropriate functional forms of model covariates were determined by exploratory data analyses and model comparison using the log-likelihood ratio test. We did not adjust for clustering within single surgeons due to the large number of different surgeons and the negligible influence of the surgical and the anaesthesia team on patient outcomes as opposed to patient factors.[11]

9.2. Checking model assumptions of the proportional odds model

The proportional odds assumption, i.e. that the relationship between each pair of outcome groups was the same, was assessed using the Brant test of parallel regression assumption. The result of the Brant test showed that the proportionality assumption using a 5-categorical endpoint was slightly violated, which might be due to the sparseness of data with high severity grades for intra- and postoperative adverse events (Supplementary Table S10).[12] In case of violation of this assumption, one possible solution is to reduce the number of outcome categories using a 3-categorical endpoint (CD 0, CD I-II, and CD III-V). The rationale for this cut-off is clinical reasoning allowing distinguishing an uneventful course from any minor or major deviation and is in line with cut-offs used in the majority of publications lumping categories.[13] As there was still borderline evidence for a violation of the proportionality assumption using a 3-categorical endpoint, we also dichotomized the most severe postoperative complication into any versus no postoperative complication (i.e. CD I-V vs. CD 0) using a hierarchical logistic regression (Supplementary Table S11). Based on consistent and robust findings in point estimates and 95% CI in the models with 5-, 3- and 2-category outcome as well as the results from the internal validation using bootstrapping, we were reassured that the borderline violation in the model with the 3-category outcome does not influence the results.
In all three models, the results showed the same trend, i.e. an increase in the odds ratios (ORs) for increasing grades of ClassIntra®, adjusting for the most important risk factors. When including the other risk factors, the results remained consistent. However, as we were losing a lot of information by dichotomising the outcome and we had enough evidence to

conclude that the violation of proportional odds assumption does not influence the results, we decided to report the results from the 3-categorical CD model as our final model (Figure 2; supplementary table S5).

For internal validation of the final model, bootstrapping with 100 replications with samples of 2520 patients was used (supplementary table S12).

9.3. Sensitivity analyses of the multivariable proportional odds model

In case of an undefined complexity grade in the BUPA classification system as it was the case for certain procedures (4%), the grade was replaced with a grade from a similar procedure. The models including all patients was then compared with a complete case analysis including only patients for whom the complexity grade of the surgical procedure was provided by BUPA (supplementary table S13).

A model using a binary endpoint (i.e. any versus no postoperative complication) was used as a sensitivity analysis (supplementary table S11).

10. Secondary endpoints

10.1. Statistical analysis

The association of the most severe intraoperative adverse event and the sum of all postoperative complications calculated using the CCI® [3] was explored using a multivariable two-level mixed effect regression model accounting for correlation between patients from the same study centre.

The associations between the most severe intraoperative adverse event and the secondary endpoints of pLOS and duration of surgery were investigated in a multivariable two-level mixed-effect log-linear regression model accounting for correlation between patients from the same study centre. The same set of confounders, as described in the model for the primary endpoint, was included as fixed factors in the models. The appropriate functional forms of model covariates were determined by exploratory data analyses and model comparison using the log-likelihood ratio test. As the secondary endpoints were all continuous, this allowed us to include ASA physical status as a more refined categorical covariate. As adding a squared age-term to the final model for duration of surgery showed strong evidence against equal fit of the simpler model, categorical age was included in the model to allow the influence to vary between different (biologically relevant) age-categories.

The coefficients of the log-linear regression models were back-transformed in order to obtain easily interpretable results, i.e., percentage changes in hospital days or duration of surgery per one unit increase of the corresponding covariate.[14, 15] These percentage changes were derived from the regression coefficients by using the following formula: percentage change = 100*beta. The corresponding 95% confidence intervals were analogously derived.

Whilst the median time between surgery and postoperative complication would in theory be of interest with the potential for early transfer to the IMC in mind, we refrained from calculating this variable for the following reasons: i) many minor to moderate postoperative complications would not justify a transfer to the IMC/ICU as they can easily be handled on the ward; ii) time should only be considered in patients on the ward and not already on the IMC/ICU; iii) there are many confounders such as age and comorbidities; iv) some elderly patients might not wish to be transferred to the ICU according to their living will, thus the ICU cannot be considered.

In all models, we did not adjust for clustering within single surgeons due to the large number of different surgeons and the negligible influence of the surgical as also anaesthesia team on patient outcomes as opposed to patient factors.[11]

10.2. Checking model assumptions of the models for the secondary endpoints

The model assumptions of the (log-)linear regression models were checked by plotting the standardised residuals and by using the Breusch-Pagen test for assessing heteroscedasticity.

The assumptions of the multivariable linear regression modelling the CCI® were not fulfilled even after log-transformation due to the pronounced skewness of the CCI® and the high percentage of observations with a zero-value for the CCI®. We, therefore, estimated the mean difference in CCI® between different grades of ClassIntra® using a fractional logit model suitable for modelling responses bounded between zero and one, which are often highly skewed.[16] We then compared these mean difference to the mean differences estimated using a linear regression model. Both models used robust standard errors to adjust for centre clustering (supplementary table S14 and Figure S2). Due to the large data set, estimates from both models were almost identical, and thus we only report the output from the linear model in the results section.

10.3. Sensitivity analyses of the models for the secondary endpoints

The final models for the secondary endpoints including all patients were compared in a sensitivity analysis with a complete case analysis including only patients for whom the complexity grade of the surgical procedure was provided by BUPA (supplementary tables S6-8).

The final models were compared with the corresponding models excluding influencing observations (output not shown), as defined by assessing the leverage and the Cook's distance, to assess model robustness.

There were no substantial differences in these sensitivity analyses as compared to the final model.

11. Assessing criterion validity and reliability of ClassIntra® v1.0

In the survey, the average raw agreement was calculated to assess agreement between the physicians' and the core team's ratings. The inter-rater reliability of ClassIntra® v1.0 amongst physicians was assessed using the intra-class correlation coefficient (ICC) based on a mean rating (n = 136), absolute-agreement, and 2-way random effects model.[17, 18] ICC values were interpreted according to Cicchetti.[19]

12. Statistical programme

All analyses and graphs were performed using Intercooled Stata® Version 14 (StataCorp, College Station, TX, USA).

13. Amendments to the study protocol

No major amendments were made to the study protocol in the herewith-presented analyses and results. We only expanded the model checking for the (log-) linear regression model for the CCI by using a fractional logit model.

Confidence intervals for pre-specified secondary outcomes were not adjusted for multiplicity and inferences drawn from these intervals may not be reproducible.

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