

Möglichkeiten der digitalen Erfassung der postoperativen Lebensqualität an ausgewählten Beispielen



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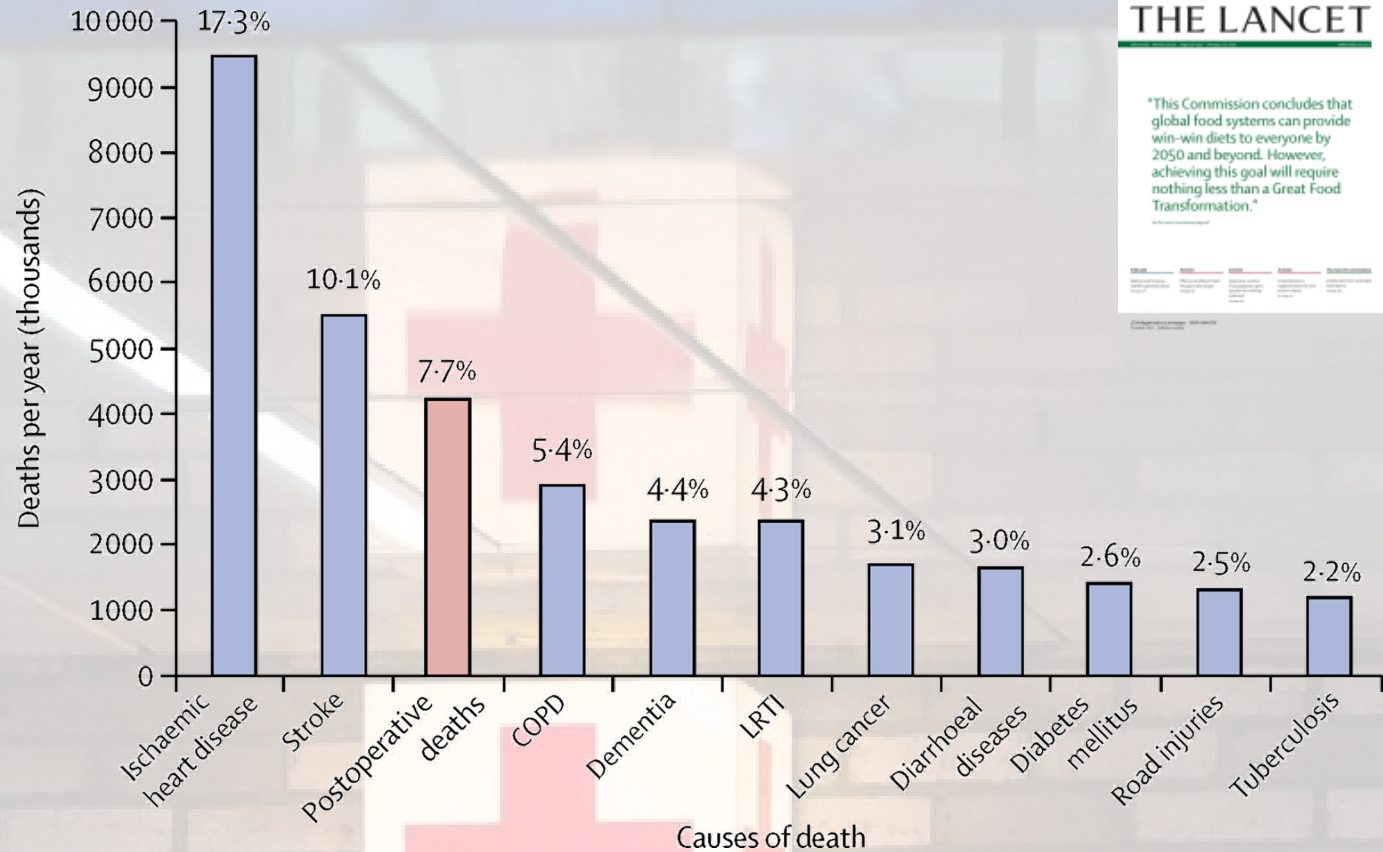
Die Last operativer Todesfälle



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- POMR: 0,7 % – 3 % ^[1,2]

- 2019: 7,7 % aller Todesfälle ^[3]



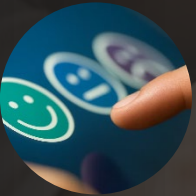
^[1] A. Alvarez et al., "Patient outcomes after surgery in 17 Latin American countries (LASOS): a 7 day prospective cohort study," *Lancet Glob. Health*, vol. 13, no. 4, pp. e635–e645, Apr. 2025, doi: 10.1016/S2214-109X(24)00558-8.

^[2] C. I. Pérez-Rivera et al., "Colombian surgical outcomes study insights on perioperative mortality rate, a main indicator of the Lancet Commission on Global Surgery – a prospective cohort study," *Lancet Reg. Health Am.*, eCollection Oct. 2024, Art. no. 100862, doi: 10.1016/j.lana.2024.100862.

^[3] D. Nepogodiev, I. Martin, B. Biccari, A. Makupe, A. Bhangu et al., "Global burden of postoperative death," *The Lancet*, Bd. 393, Nr. 10170, S. 401, 2. Feb. 2019, doi: 10.1016/S0140-6736(18)3139-8.

Erfassung postoperativer Patientendaten

Notwendigkeit und offene Fragen



Traditionelle Messwerte

- POMR ^[4,5]

World J Surg (2015) 39:856–864
DOI 10.1007/s00268-014-2638-4

World Journal
of Surgery

Perioperative Mortality Rate (POMR): A Global Indicator of Access to Safe Surgery and Anaesthesia

David A. Watters · Michael J. Hollands · Russell L. Gruen · Kiki Maoate ·
Haydn Perndt · Robert J. McDougall · Wayne W. Morriss · Viliami Tangi ·
Kathleen M. Casey · Kelly A. McQueen

“We recommend introducing the perioperative mortality rate (POMR) as an indicator of access to and safety of surgery and anaesthesia. POMR should be measured at two time periods: death on the day of surgery and death before discharge from hospital or within 30 days of the procedure, whichever is sooner. The rate should be expressed as the **number of deaths (numerator) over the number of procedures (denominator).**”

^[4]Meara JG *et al.*, “Global Surgery 2030: evidence and solutions for achieving health, welfare, and economic development,” *Lancet*, vol. 386, no. 9993, pp. 569–624, Aug. 2015, doi: 10.1016/S0140-6736(15)60160-X

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Traditionelle Messwerte

- POMR ^[4,5]
- Weitere Tools:
 - CDC (Clavien–Dindo-Classification) ^[6]

TABLE 1. Classification of Surgical Complications

Grade	Definition
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics, 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
Grade IIIa	Intervention not under general anesthesia
Grade IIIb	Intervention under general anesthesia
Grade IV	Life-threatening complication (including CNS complications)* requiring IC/ICU management
Grade IVa	Single organ dysfunction (including dialysis)
Grade IVb	Multiorgan dysfunction
Grade V	Death of a patient
Suffix “d”	If the patient suffers from a complication at the time of discharge (see examples in Table 2), 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 hemorrhage, ischemic stroke, subarachnoidal bleeding, but excluding transient ischemic attacks.
CNS, central nervous system; IC, intermediate care; ICU, intensive care unit.

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Patient	Complications	Grade of Complication	Weights (MRV _{phys} × MRV _{pat})	CCI
A. Single complication				
Patient 1	Nausea and vomiting	I	300 (15 × 20)	8.7
Patient 2	Pneumonia	II	1750 (35 × 50)	20.9
Patient 3	Pneumothorax	IIIa	2750 (50 × 55)	26.2
Patient 4	Fascia dehiscence	IIIb	4550 (65 × 70)	33.7
Patient 5	Acute renal failure	IVa	7200 (80 × 90)	42.4
Patient 6	Anastomotic insufficiency	IVb	8550 (90 × 95)	46.2
B. Multiple complications				
Patient 7	Pain exacerbation	I	300	17.3
	Nausea and vomiting	I	300	
	Hematoma	I	300	
	Generalized edema	I	300	
Patient 8	Nausea and vomiting	I	300	30.8
	Pneumonia	II	1750	
	Urinary tract infection	II	1750	
Patient 9	Wound infection	I	300	40.5
	Urinary tract infection	II	1750	
	Gastric ulcer	II	1750	
	Pneumothorax	IIIa	2750	
Patient 10	Pneumonia	II	1750	56.1
	Arterial hypertension	II	1750	
	Anastomotic insufficiency	IIIb	4550	
	Gastric ulcer perforation	IIIb	4550	
Patient 11	Wound infection	I	300	88.6
	Urinary tract infection	II	1750	
	Deep venous thrombosis	II	1750	
	Gastric ulcer bleeding	IIIa	2750	
	Pleura empyema	IIIb	4550	
	Anastomotic insufficiency	IIIb	4550	
	Stroke	IVa	7200	
	Central line infection with septic shock	IVb	8550	

Example of the CCI calculated for patient 9: $CCI = \sqrt{(300 + 1750 + 1750 + 2750)/2} = 40.5$
 Death is arbitrarily defined with a CCI of 100.
 ARDS indicates adult respiratory distress syndrome.

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^[6]D. Dindo, N. Demartines, and P. A. Clavien, "Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey," *Annals of Surgery*, Bd. 240, Nr. 2, S. 205–213, Aug. 2004, doi: 10.1097/01.sla.0000133083.54934.ae.

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präoperativer Zustand

$$\begin{aligned} \text{POSSUM} \quad \ln[R/(1 - R)] &= -7 \bullet 04 + (0 \bullet 13 \times \text{PS}) \\ &+ (0 \bullet 16 \times \text{OS}) \\ \text{P-POSSUM} \quad \ln[R/(1 - R)] &= -9 \bullet 065 + (0 \bullet 1692 \times \text{PS}) \\ &+ (0 \bullet 155 \times \text{OS}) \end{aligned}$$

Operationsschwere

^[4]Meara JG *et al.*, "Global Surgery 2030: evidence and solutions for achieving health, welfare, and economic development," *Lancet*, vol. 386, no. 9993, pp. 569–624, Aug. 2015, doi: 10.1016/S0140-6736(15)60160-X

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- geringe Aussagekraft zu funktioneller Erholung, Symptome, Rollenfunktion und gesundheitsbezogene Lebensqualität (HRQoL) in den Wochen/Monaten nach OP

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→ **Komplikationen ≠ Lebensqualität**

wir müssen *die Patientensicht* systematisch miterheben –
Mortalität allein verfehlt das Wesentliche

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Erfassung der Patientenperspektive

Als Indikator der Lebensqualität



Patientenzentrierter Ansatz

Valide Messung von Erholung & Lebensqualität?

→ PROs, *Patient Reported Outcomes* sind Therapieerfolge, die durch den Patienten selbst dokumentiert werden

- QoR-15 (Quality of Recovery-15) ^[9]

^[9] P. A. Stark, P. S. Myles, and J. A. Burke, "Development and psychometric evaluation of a postoperative quality of recovery score: the QoR-15," *Anesthesiology*, vol. 118, no. 6, pp. 1332–1340, Jun. 2013, doi:10.1097/ALN.0b013e318289b84b.

QoR-15 Patient Survey

Date: __/__/__

Study #: _____

Preoperative ☐

Postoperative ☐

PART A

How have you been feeling in the last 24 hours?

(0 to 10, where: 0 = none of the time [poor] and 10 = all of the time [excellent])

- | | |
|---|---|
| 1. Able to breathe easily | None of the time 0 1 2 3 4 5 6 7 8 9 10 All of the time |
| 2. Been able to enjoy food | None of the time 0 1 2 3 4 5 6 7 8 9 10 All of the time |
| 3. Feeling rested | None of the time 0 1 2 3 4 5 6 7 8 9 10 All of the time |
| 4. Have had a good sleep | None of the time 0 1 2 3 4 5 6 7 8 9 10 All of the time |
| 5. Able to look after personal toilet and hygiene unaided | None of the time 0 1 2 3 4 5 6 7 8 9 10 All of the time |
| 6. Able to communicate with family or friends | None of the time 0 1 2 3 4 5 6 7 8 9 10 All of the time |
| 7. Getting support from hospital doctors and nurses | None of the time 0 1 2 3 4 5 6 7 8 9 10 All of the time |
| 8. Able to return to work or usual home activities | None of the time 0 1 2 3 4 5 6 7 8 9 10 All of the time |
| 9. Feeling comfortable and in control | None of the time 0 1 2 3 4 5 6 7 8 9 10 All of the time |
| 10. Having a feeling of general well-being | None of the time 0 1 2 3 4 5 6 7 8 9 10 All of the time |

PART B

Have you had any of the following in the last 24 hours?

(10 to 0, where: 10 = none of the time [excellent] and 0 = all of the time [poor])

- | | |
|--------------------------------|---|
| 11. Moderate pain | None of the time 10 9 8 7 6 5 4 3 2 1 0 All of the time |
| 12. Severe pain | None of the time 10 9 8 7 6 5 4 3 2 1 0 All of the time |
| 13. Nausea or vomiting | None of the time 10 9 8 7 6 5 4 3 2 1 0 All of the time |
| 14. Feeling worried or anxious | None of the time 10 9 8 7 6 5 4 3 2 1 0 All of the time |
| 15. Feeling sad or depressed | None of the time 10 9 8 7 6 5 4 3 2 1 0 All of the time |

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- **QoR-15** (Quality of Recovery-15) ^[9]
- **QLQ** (Quality of Life Questionnaire)
 - z.B. **EORTC QLQ-C30** (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire) ^[10]

	Scale	Number of items	Item range*	Version 3.0 Item numbers
Global health status / QoL				
Global health status/QoL (revised) [†]	QL2	2	6	29, 30
Functional scales				
Physical functioning (revised) [†]	PF2	5	3	1 to 5
Role functioning (revised) [†]	RF2	2	3	6, 7
Emotional functioning	EF	4	3	21 to 24
Cognitive functioning	CF	2	3	20, 25
Social functioning	SF	2	3	26, 27
Symptom scales / items				
Fatigue	FA	3	3	10, 12, 18
Nausea and vomiting	NV	2	3	14, 15
Pain	PA	2	3	9, 19
Dyspnoea	DY	1	3	8
Insomnia	SL	1	3	11
Appetite loss	AP	1	3	13
Constipation	CO	1	3	16
Diarrhoea	DI	1	3	17
Financial difficulties	FI	1	3	28

^[9] P. A. Stark, P. S. Myles, and J. A. Burke, "Development and psychometric evaluation of a postoperative quality of recovery score: the QoR-15," *Anesthesiology*, vol. 118, no. 6, pp. 1332–1340, Jun. 2013, doi:10.1097/ALN.0b013e318289b84b.

^[10] P. M. Fayers, N. Bjordal, K. Groenvold, M. Curran, and A. Bottomley, "EORTC QLQ-C30 Scoring Manual", 3rd ed., Brussels, Belgium: European Organisation for Research and Treatment of Cancer, 2001, ISBN 2-930064-22-6.

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- EQ-5D-5L (European Quality of Life 5 Dimensions, 5 Level version ^[11,12]

5 Dimensionen

- + Mobilität
- + Selbstversorgung
- + alltägliche Tätigkeiten
- + Schmerzen / Beschwerden
- + Angst / Niedergeschlagenheit

5 Levels

- + Level 1: keine Probleme/ Schmerzen/ Ängste
- + Level 2: leichte Probleme/ Schmerzen/ Ängste
- + Level 3: mäßige Probleme/ Schmerzen/ Ängste
- + Level 4: große Probleme/ Schmerzen/ Ängste
- + Level 5: extreme Probleme/ Schmerzen/ Ängste



3125 (5⁵) verschiedene Gesundheitszustände

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^[11] M. Herdman, C. Gudex, A. Lloyd, M. F. Janssen, P. Kind, D. Parkin, G. Bonsel, and X. Badia, "Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L)," *Quality of Life Research*, vol. 20, no. 10, pp. 1727–1736, Dec. 2011, doi:10.1007/s11136-011-9903-x.

^[12] A. Boateng-Kuffour, H. Skrobanski, J. Drahos, P. Kohli, K. Forster, S. Acaster, Z. Pakbaz, N. Li, and K. Williams, "Appropriateness of the EQ-5D-5L in capturing health-related quality of life in individuals with transfusion-dependent β -thalassaemia: a mixed methods study," *Health and Quality of Life Outcomes*, vol. 22, art. no. 54, 2024, doi: 10.1186/s12955-024-02265-8.

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- QoR-15 (Quality of Recovery-15) ^[9]
- QLQ (Quality of Life Questionnaire)
 - z.B. EORTC QLQ-C30 (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire) ^[10]
- EQ-5D-5L (European Quality of Life 5 Dimensions, 5 Level version) ^[11,12]

Empfehlung der Compac-Initiative:

- Kernset zur Vergleichbarkeit von Studien (beeinhaltet kurzfristige und langfristige Erholung) ^[13]

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Quality and Patient Safety

QUALITY AND PATIENT SAFETY

Core Outcome Measures for Perioperative and Anaesthetic Care (COMPAC): a modified Delphi process to develop a core outcome set for trials in perioperative care and anaesthesia

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^[9] P. A. Stark, P. S. Myles, and J. A. Burke, "Development and psychometric evaluation of a postoperative quality of recovery score: the QoR-15," *Anesthesiology*, vol. 118, no. 6, pp. 1332–1340, Jun. 2013, doi:10.1097/ALN.0b013e318289b84b.

^[10] P. M. Fayers, N. Bjordal, K. Groenvold, M. Curran, and A. Bottomley, "EORTC QLQ-C30 Scoring Manual", 3rd ed., Brussels, Belgium: European Organisation for Research and Treatment of Cancer, 2001, ISBN 2-930064-22-6.

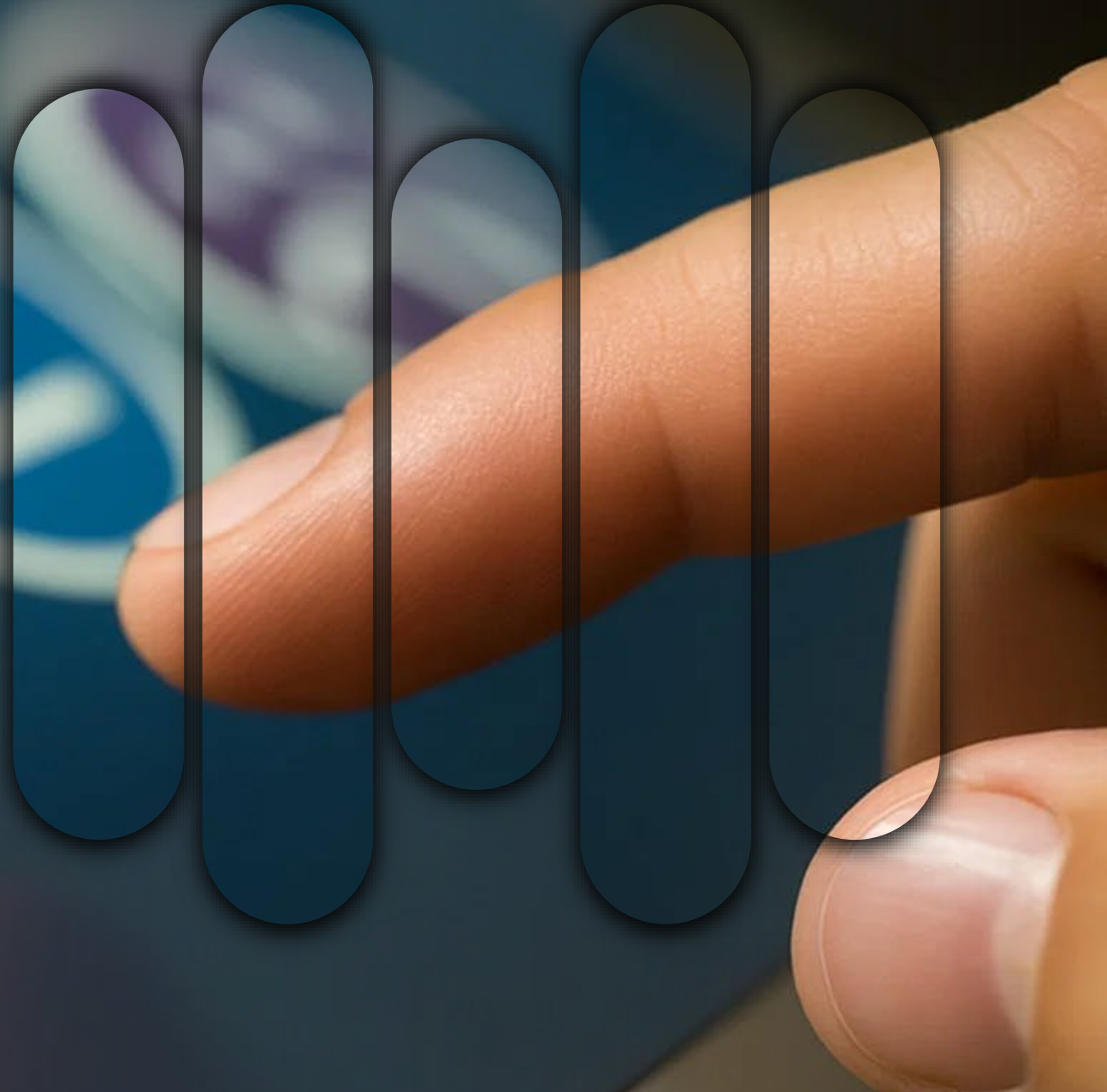
^[11] M. Herdman, C. Gudex, A. Lloyd, M. F. Janssen, P. Kind, D. Parkin, G. Bonsel, and X. Badia, "Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L)," *Quality of Life Research*, vol. 20, no. 10, pp. 1727–1736, Dec. 2011, doi:10.1007/s11136-011-9903-x.

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Digitale Datenerhebung

zur Prozessoptimierung



Digitale Datenerhebung

Typische Hürden bei Papier/Telefon

- hohe Drop-outs, Verzerrungen ^[14]

Table 2.—. Comparison of Headache Parameters*

	Questionnaire	Diary	P Value†	Correlation
Median frequency	9	9	.24	0.16
Median intensity	65	37	.00	0.21
Median duration	4	3	.00	0.21

Table 3.—. Percent of Children Scoring in Each Category of Headache Duration

Duration Categories	Questionnaire	Diary
1 = less than half an hour	3.3	8.5
2 = between half an hour and an hour	14.4	11.3
3 = between an hour and half a day	19.3	54.2
4 = between half a day and a day	27.1	23.7
5 = 1 to 2 days	25.4	1.1
6 = 2 days to a week	6.1	0.6
7 = a week or longer	4.4	0.6
Total	100	100

^[14]M. van den Brink, E. N. G. Bandell-Hoekstra, and H. H. Abu-Saad, "The occurrence of recall bias in pediatric headache: a comparison of questionnaire and diary data," *Headache**, vol. 41, no. 1, pp. 11–20, Jan. 2001, doi:10.1046/j.1526-4610.2001.111006011.x.

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ePROs (electronic PROs) verbessern Qualität & Geschwindigkeit

- „digital erhobene PROs sind schneller, vollständiger und kosteneffizienter“ ^[15]

Table 5. Data quality of electronic questionnaires compared to their pencil-and-paper counterpart.

Study and missing data, unanswered questions, or incomplete forms			
Instrument and outcome unit	Electronic	Paper	P value
Engan et al 2016 [23]			
PAM-13^a, MacNew^b, FQ^c, EORTC^d, QLQ-C30^e, HADS^f			
Mean number of missing answers per patient	0.55	2.15	<.001
Shah et al 2016 [35]			
EQ-5D^g			
Mean number of unanswered questions	1.08	1.30	.083
NutriNet Sante questionnaire			
Data entry mistakes	0	82	
Missing values	0	60	
Inconsistent values	0	57	
Abnormal values	0	3	
Smith et al 2016 [38]			
PSS^h			
Incomplete forms	3	29	<.001
FFI^o			
Incomplete forms	0	20	<.001
ODI			
Incomplete forms	1	10	<.001

^[14]M. van den Brink, E. N. G. Bandell-Hoekstra, and H. H. Abu-Saad, "The occurrence of recall bias in pediatric headache: a comparison of questionnaire and diary data," *Headache**, vol. 41, no. 1, pp. 11–20, Jan. 2001, doi:10.1046/j.1526-4610.2001.111006011.x.

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- Patienten bevorzugen elektronische Tools ^[16,17]

Table 1 Sample and evaluable material

Sample and evaluable material	Total	Center		
		Göttingen	Munich	Berlin
Patients approached to participate	56	23	20	13
Eligible*/distributed devices	37/40	10/10	17/20	10/10
Feedback from patients	30	10	11	9
Feedback from doctors	5	1	1	3
Record sheets from patients	34	10	16	8

*, 3 out of 20 devices from Munich were lost on transport.

Table 2 Evaluation of the average app usage for the daily recording compared to the total investigation period, treatment centers as mean value

Usage	Median in total	Center		
		Göttingen	Munich	Berlin
Days of usage	99.5	93.0	103.0	114.0
Days app was used	70.0 (70%)	68.5 (74%)	72.0 (70%)	71.0 (62%)
Several times used/day	4.0 (4%)	7.0 (8%)	4.0 (4%)	2.0 (2%)

Table 4 Feedback of patients

Ranking	Feedback questions			Mean
	User friendliness	Would use app again	Perceived personal benefit	
Very bad (2-)	0	0	0	0
Poor (1-)	0	0	4 (13%)	1 (3%)
Medium (0)	3 (10%)	3 (10%)	9 (30%)	5 (16%)
Good (1+)	13 (43%)	16 (53%)	10 (33%)	13 (43%)
Very good (2+)	13 (43%)	11 (37%)	6 (20%)	10 (33%)

^[14]M. van den Brink, E. N. G. Bandell-Hoekstra, and H. H. Abu-Saad, "The occurrence of recall bias in pediatric headache: a comparison of questionnaire and diary data," *Headache*, vol. 41, no. 1, pp. 11–20, Jan. 2001, doi:10.1046/j.1526-4610.2001.111006011.x.

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^[17]G. Benze, P. Woehrl, M. Mehnert, A. Weis, T. Söllner, K. Bausewein, and D. Daly, "PROtune: a feasibility study assessing surveillance of electronic patient-reported outcomes and adherence via smartphone app in advanced cancer," *Annals of Palliative Medicine*, vol. 8, no. 5, pp. 467–479, May 2019.

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Praxisleitfäden sorgen für Validität

- ISOQOL ^[18], FDA ^[19]

User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice

Version 2: January 2015

*Produced on behalf of the
International Society for Quality of Life Research by
(in alphabetical order):*

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Thomas Elliott, MD
Joanne Greenhalgh, PhD
Michele Halyard, MD
Rachel Hess, MD
Deborah Miller, PhD
Bryce Reeve, PhD
Maria Santana, PhD
Claire Snyder, PhD



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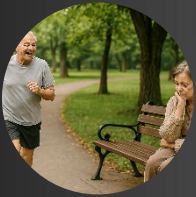
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^[18]N. Aaronson, T. Elliott, J. Greenhalgh, M. Halyard, R. Hess, D. Miller, B. Reeve, M. Santana, and C. Snyder, *User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice, Version 2: January 2015*, International Society for Quality of Life Research (ISOQOL), 2015.

^[19]U.S. Food and Drug Administration (FDA), *Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments Into Endpoints For Regulatory Decision-Making*, Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders, Draft Guidance, U.S. Department of Health and Human Services, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH), Apr. 2023.

Implementierung einer Smartphone-App

zur Durchführung von ePROs bei
Pankreasoperationen



Wissenschaftliche Grundlage

„Psychosomatic Assessment Health Disc“
(PAHD) ^[20]



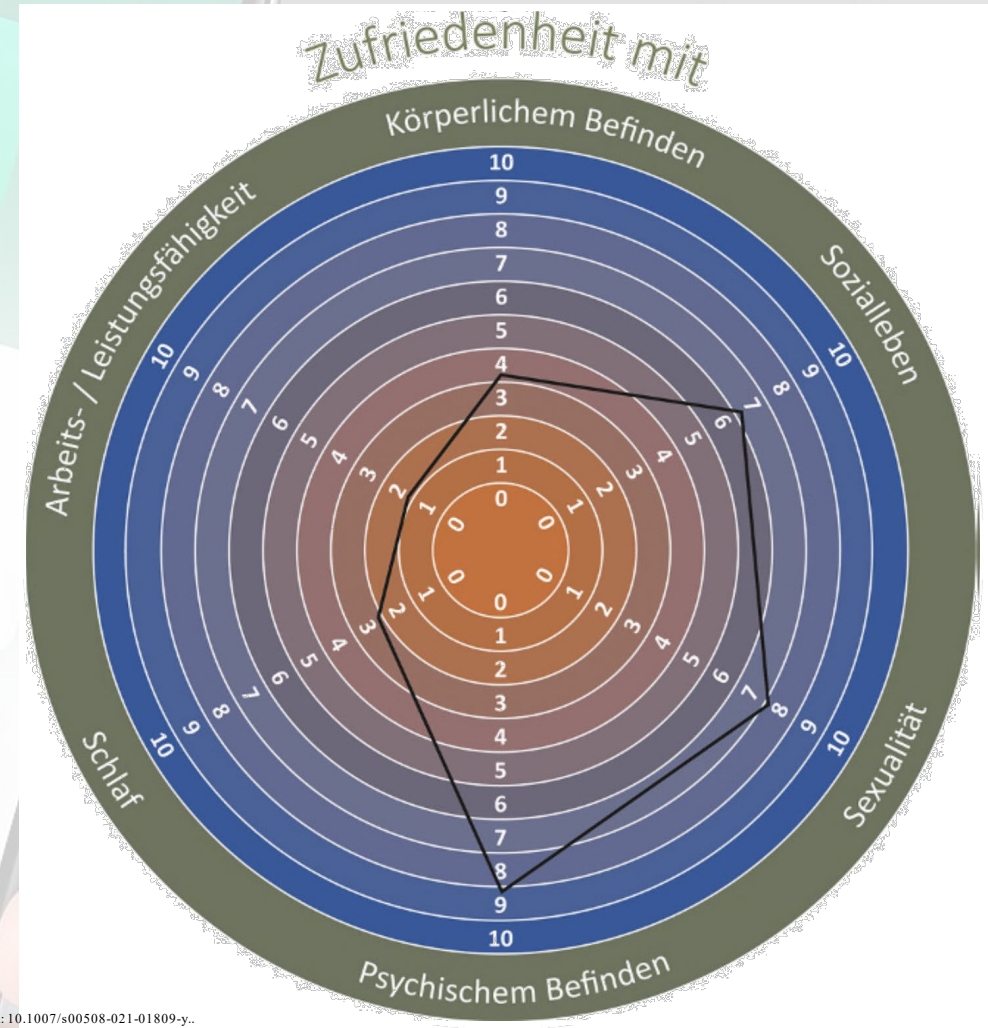
^[20]Fazekas et al. "Development of a visual tool to assess six dimensions of health and its validation in patients with endocrine disorders." Wien Klin Wochenschr, vol. 134, pp. 569–580, 2022. doi: 10.1007/s00508-021-01809-y..

Wissenschaftliche Grundlage

„Psychosomatic Assessment Health Disc“
(PAHD) ^[20]

Spinnendiagramm mit 6 Kern-Dimensionen

- Auswahl durch interdisziplinäres Expertenteam (Endokrinologie, Statistik, Psychologie, Psychosomatik)
- Kriterien: hohe Relevanz für subjektive Gesundheit **und** medizinische Beurteilung
- Fokus auf einfache, schnelle Erhebung



^[20]Fazekas et al. "Development of a visual tool to assess six dimensions of health and its validation in patients with endocrine disorders." Wien Klin Wochenschr, vol. 134, pp. 569–580, 2022. doi: 10.1007/s00508-021-01809-y.

Frontent-Teaser

Aufbau

- Modularer Aufbau mit klar getrennten Aktivitäten (Login, Hauptmenü, Gesundheitscheck, Datenupdate, Kategorien, Radar-Ansicht)
- Verwaltung von Sitzungen & Nutzerdaten über interne Manager
- Moderne, benutzerfreundliche Oberfläche mit eigenem Logo & Icons

Mehrsprachigkeit & Flexibilität

- Unterstützung zahlreicher Sprachen (values-xx) → automatische Anpassung an Gerätesprache
- Responsives Design für verschiedene Bildschirmgrößen
- Einfach erweiterbar für neue Inhalte & Zielgruppen

Vorteile

- **Benutzerfreundlich:** klare Navigation & modernes UI
- **Skalierbar:** neue Module leicht integrierbar
- **Datensicherheit:** Sitzungs- und Datenmanagement integriert
- **Flexibel:** einsetzbar für Gesundheitsdaten, Bildung oder Aufklärung
- **Forschungs- und Evaluationsplattform:** auch einsetzbar in Studienprojekten zur Datenerhebung und Validierung



Frontent-Teaser



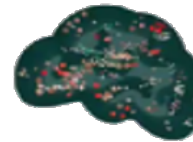
Frontent-Teaser



Marc Ritter



Andreas Sendler



Willkommen beim Projekttest
„Healthdisc“



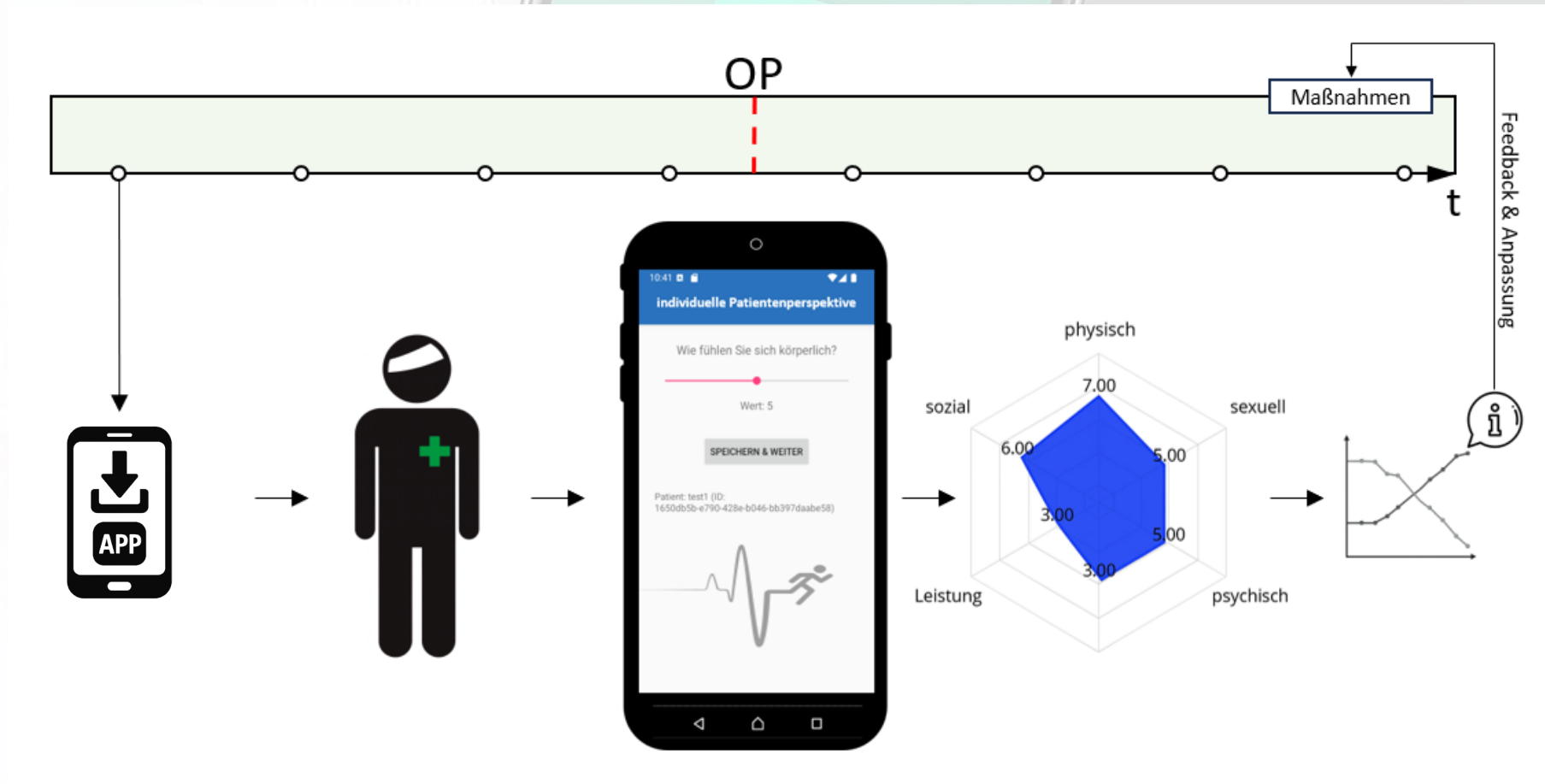
Tommy Bergmann



Martin Bartos



Unsere Vision



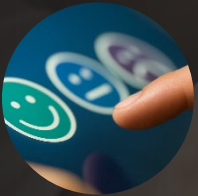
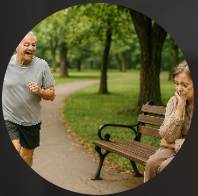
Höhe postoperative Mortalität

ein erheblicher Anteil der Todesfälle
weltweit tritt unmittelbar nach
Operationen auf



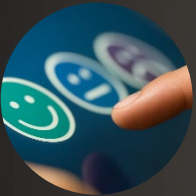
HRQoL: bildet den Gesundheitszustand aus Sicht der Patienten ab

daher wird empfohlen, sie in die
Diagnostik einzubeziehen



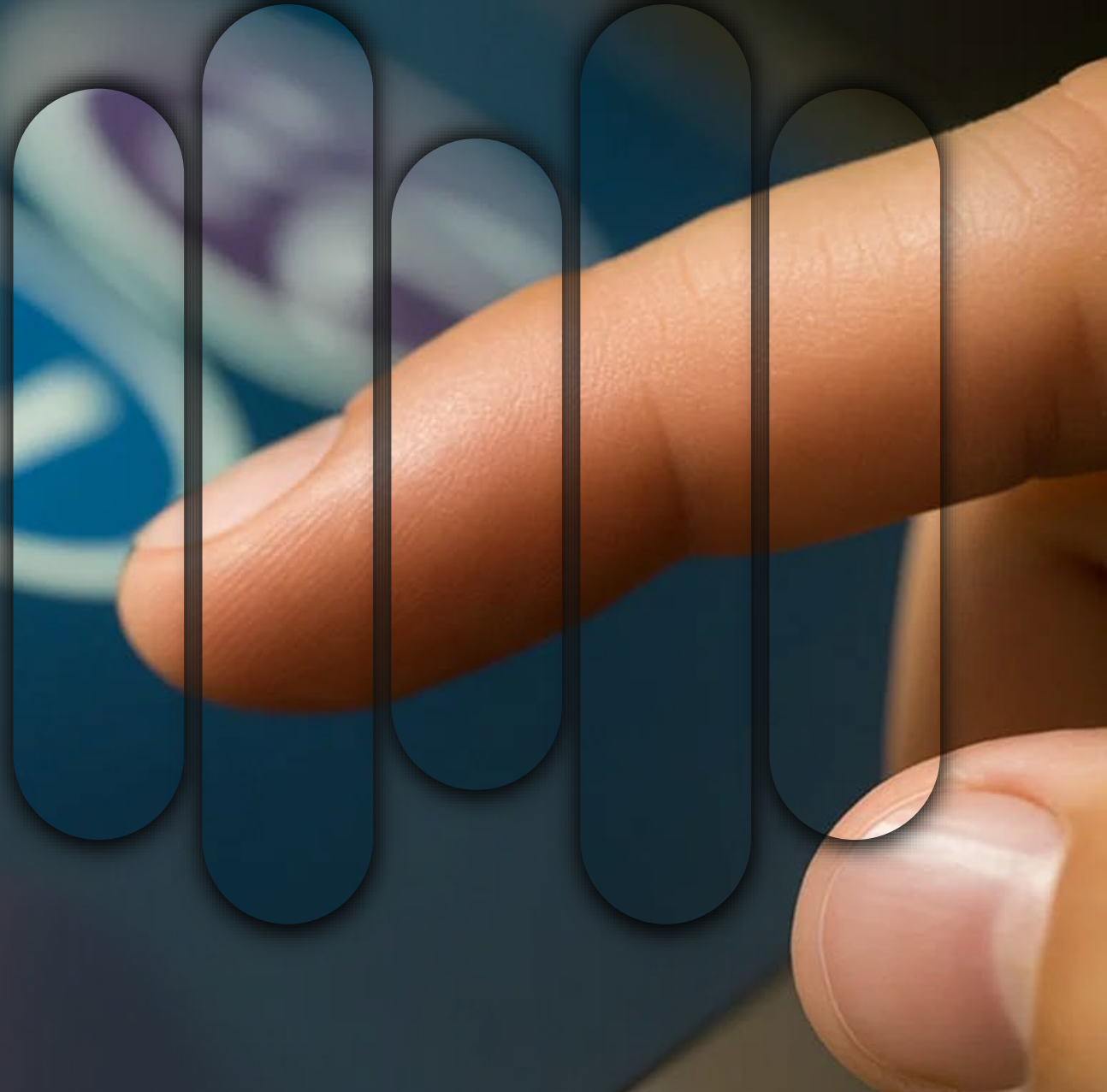
PROs kommen zur Erhebung zum Einsatz

in den einzelnen Disziplinen haben sich
bereits verschiedene Instrumente
etabliert



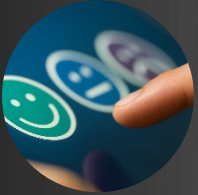
ePROs sind effizienter und werden von Patienten bevorzugt

ihre Entwicklung befindet sich
derzeit in einer entscheidenden
Phase



Chemnitz als Vorreiter

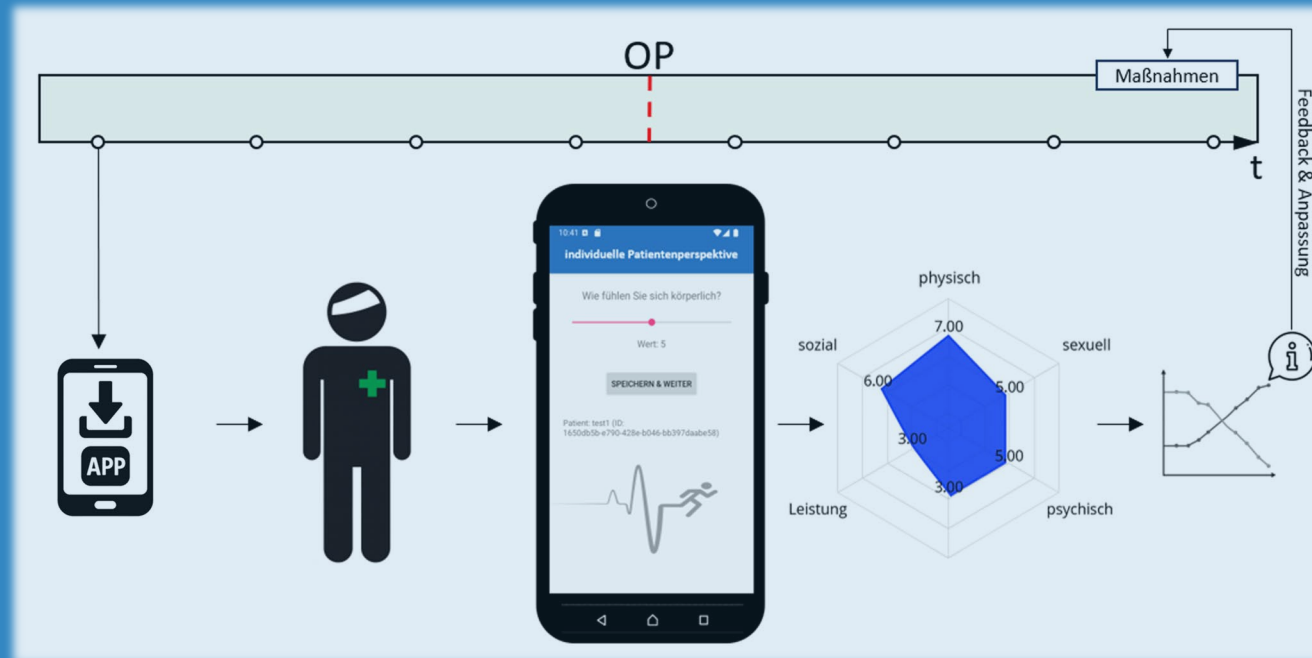
Evaluation einer innovativen
Smartphone- App aus Mittweida in
der Pankreaschirurgie



Vielen Dank für die Aufmerksamkeit !



**HOCHSCHULE
MITTWEIDA**
University of Applied Sciences



Tommy Bergmann M.Sc.

Martin Bartos, Prof. Dr. med. Andreas Sendler, Prof. Dr. rer. nat. Marc Ritter



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