ORIGINAL ARTICLE





Use of Activity Tracking in Major Visceral Surgery—the Enhanced Perioperative Mobilization Trial: a Randomized Controlled Trial

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Abstract

Background Early mobilization is one essential item within the enhanced recovery after surgery (ERAS) concept, but lacks solid evidence and a standardized assessment. The aim was to monitor and increase the postoperative mobilization of patients after major visceral surgery by providing a continuous step count feedback using activity tracking wristbands.

Methods The study was designed as a randomized controlled single-center trial (NCT02834338) with two arms (open and laparoscopic surgery). Participants were randomized to either receive feedback of their step counts using an activity tracker wristband or not. The primary study endpoint was the mean step count during the first 5 postoperative days (PODs).

Results A total of 132 patients were randomized. After laparoscopic operations, the average step count during PODs 1–5 was significantly increased by the feedback compared with the control group (P < 0.001); the cumulative step count (9867 versus 6103, P = 0.037) and activity time were also significantly increased. These results could not be confirmed in the open surgery arm. Possible reasons were a higher age and significantly more comorbidities in the open intervention group. Patients who achieved more than the median cumulative step count had a significantly shorter hospital stay and lower morbidity in both arms. The average step count also correlated with the length of hospital stay (R = -0.341, P < 0.001).

Conclusion This study is the first randomized controlled trial investigating the use and feasibility of activity tracking to monitor and enhance postoperative mobilization in abdominal surgery. Our results demonstrate that activity tracking can enhance perioperative mobilization after laparoscopic surgery.

Trial Registration ClinicalTrials.gov: NCT02834338

Keywords Activity tracking · Postoperative recovery · ERAS · Fast-track surgery · Randomized controlled trial

Introduction

Enhanced recovery after surgery (ERAS) programs aim to minimize postoperative stress and accelerate postoperative recovery. 1–3 ERAS protocols have resulted in significantly shorter length of hospital stay and overall complications in colorectal surgery, 4 and consequently have been established in other fields, such as hepatopancreatobiliary and esophageal

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surgery.⁵⁻¹¹ A majority of the ERAS elements are well defined, whereas there is a lack of evidence for early mobilization protocols and their monitoring. Current ERAS guidelines for colonic, rectal, pancreatic, and pelvic surgery recommend early postoperative mobilization for up to 6 h out of bed and its monitoring by the use of diaries or simple monitoring devices, although randomized clinical trials have not yet clearly supported a beneficial effect of postoperative mobilization.³ Compared with colorectal surgery, patients who undergo major oncological visceral (abdominal) surgery, including hepatopancreatic or gastric resections, may not achieve equal mobilization targets in the early postoperative period. In fact, studies reporting on early mobilization targets did not discriminate between the extents of surgery. 12-15 We recently found that many of these patients do not achieve common ERAS mobilization targets when mobilization was assessed diarybased. This study also pointed out that almost 50% of the



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patients lacked intrinsic motivation for enhanced postoperative mobilization following major abdominal surgery.
Consequently, novel or innovative methods have to be evaluated to establish an objective and accurate monitoring of patient mobilization, and to increase the intrinsic motivation for early mobilization after major visceral surgery. One such possibility is the usage of activity tracker devices. In line with this, a cohort trial reported a significant relationship between the early recovery step count and the length of hospital stay in elderly, cardiac surgery patients.
The aim of the present study is to assess postoperative mobilization of patients and the effect of an (auto-) feedback system using activity trackers, versus no feedback on postoperative step count and recovery after major visceral surgery.

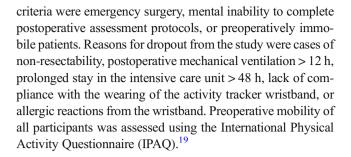
Materials and Methods

Trial Design

The enhanced perioperative mobilization (EPM) trial is a randomized, controlled, single-center, two-arm (open and laparoscopic surgery) trial, comparing the effect of continuous autofeedback plus feedback from the study team on postoperative physical activity using activity tracker wristbands after open and laparoscopic major visceral surgery. The trial design is in accordance with the SPIRIT statement and a detailed study protocol was published recently. This study was registered on ClinicalTrials.gov (NCT02834338) and approved by the local Ethics Committee of the TU Dresden (decision number EK226062016). There was no external funding for this trial. The study results were reported in line with the CONSORT guidelines.

Participants

In brief, the study population consisted of all patients scheduled for elective open and laparoscopic surgery of the colon and rectum (colectomy, hemicolectomy, segment resection, rectum extirpation, deep anterior rectum resection, sigmoid resection, proctocolectomy), of the stomach (total, subtotal, and atypical gastric resections), of the pancreas, and of the liver (hemihepatectomy, atypical resection, anatomical segment resection). According to the ERAS concept, minimally invasive surgery was preferred over open surgery. Selection for open surgery was based on the following criteria: previous major abdominal operations, locally advanced tumors, pancreatic head resection, or major anatomic hepatic resections (e.g., extended hemihepatectomy). All patients were treated within an ERAS setting in accordance with current guidelines. ¹⁶ Further inclusion criteria were age between 18 and 75 years, American Society of Anesthesiology (ASA) score < IV, and a completed informed consent. Exclusion



Objective, Intervention, and Outcomes

The study is based on the superiority hypothesis that a continuous feedback of the daily activity during the first 5 postoperative days (PODs) following major visceral surgery using activity tracking wristbands (intervention) results in a higher mean daily step count, compared with no activity tracking feedback (control). Consequently, the primary endpoint of the study was the average step count during the first 5 PODs in the intervention (feedback) and control groups, respectively. Secondary endpoints were the percentage of patients in the two groups who mastered predefined mobilization (step count) targets, the assessment of the activity data from the devices (cumulative step count, activity time), length of hospital stay, the number of patients who received physiotherapy, 30-day mortality, and the 30-day overall morbidity. 20

The wristbands were continuously worn after the operation to record and monitor the patients' steps until the beginning of POD 6. The Polar Loop activity tracker with the Flow Sync and Polar flow software was used for activity tracking (Polar Electro GmbH, Germany). The device was approved by the Medical Devices Act (EU Medical Device Directive 93/42/ EWG/CD 0537) and is recommended for medical use. Patients in the control group wore an activity tracker wristband with a blinded display, using adhesive tape to prevent auto-feedback of the step count status. The study nurses checked the complete coverage of the display a few times daily. The intervention group received an unblinded wristband. The handling of the activity trackers was explained to the patients in detail and a predefined mobilization target (step count) for each of the first 5 PODs was communicated. The daily target step count was set at the 85% quartile, obtained from our previous pilot study¹⁸ (Table 1). A surgical fellow or a study nurse assessed and monitored the patients in the

 Table 1
 Daily step count targets for the intervention group

	POD 1	POD 2	POD 3	POD 4	POD 5
Open surgery arm	500	620	800	1400	1400
Laparoscopic surgery arm	1900	2300	2900	3400	3400

Data represent the 85% percentile of the daily step count generated in a previous pilot trial $^{\rm L8}$



intervention group twice daily between 09:00 and 11:00 and between 15:00 and 17:00 during the first 5 PODs to read out the step count, to ensure its proper use and functioning, and to communicate the step count results to the patients (feedback). These visits were implemented to ensure that the patients were aware of their current step count and targets.

Randomization

To avoid a systematic bias because of different surgical approaches and stress responses, two study arms were generated before randomization (open versus laparoscopic). The randomization (control versus intervention group) was performed intraoperatively after the surgeon had confirmed the resectability, using a block randomization with fixed block sizes in a 1:1 allocation ratio. The randomization sequence was generated using the R statistical software package (R version 3.1.3, the R Foundation for Statistical Computing). The block size was kept confidential until completion of the recruitment.

Statistical Considerations

Based on a previous pilot trial, ¹⁸ an assumed difference in step count of 250 steps daily (intervention group versus control group) was estimated. These 250 steps/day were the difference between the 85% percentile and the median (50% percentile) of the daily step count in the pilot cohort (see Table 1). Thus, the hypothesis for sample size calculation was that activity tracking feedback could enhance the daily step count from the 50% to the 85% percentile.

To achieve an 80% power with a two-sided P value of less than 0.05, and a dropout rate of 12%, the total sample size was calculated by a two-tailed unpaired t test and resulted in 120 patients with 30 patients in each group.

Statistical analysis was based on an intention-to-treat (ITT) analysis and was performed with the Statistical Package for Social Science (version 18.0; SPSS, Chicago, IL) software. The Mann-Whitney U test was used to compare continuous variables, and the Fisher exact test was used for categorical variables. The difference in daily step counts between the groups was compared using the two-way analysis of variance (ANOVA) test. Logistic regression analyses were computed to identify factors determining the patient cohort that achieved the mobilization targets (secondary endpoint). The following variables were considered for the regression analysis: age, sex, body mass index (BMI), operative time, oncologic versus non-oncologic indications, type of surgery (pancreatic, liver, intestinal, gastric), IPAQ score, and technique of surgery (laparoscopic versus open). Data are presented as mean \pm standard deviation of the mean, if not indicated otherwise. Spearman's rank correlation coefficient was used to determine the correlation between variables.

Results

Patient and Operative Characteristics

Some 173 patients were screened for participation in the study and 132 patients were randomized. The dropout rate was 16.6% (n = 22). The most two frequent reasons for dropout were a prolonged postoperative intensive care unit stay (n = 13) and technical problems with the activity tracker during the postoperative course (n = 4). One hundred ten patients were analyzed (Fig. 1, CONSORT compatible study flow chart).

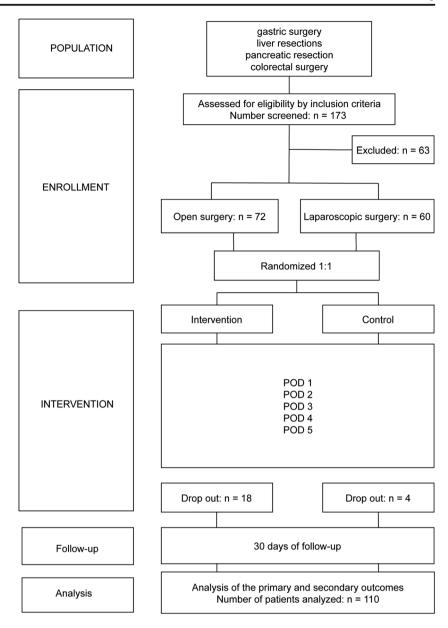
The mean age of the entire study cohort was 58.9 ± 11 years and 59.3% of the patients were male. Fifty-eight percent of the patients had substantial comorbidities. Importantly, the control group patients in the open surgery arm were younger (P =0.052) and had significantly fewer preoperative comorbidities (44.4% versus 81.5%, P = 0.005). The ASA score and BMI were not significantly different (Table 2). In the laparoscopic arm, the demographic data including preoperative comorbidities were not significantly different. The majority of patients underwent surgery for malignant tumors (72.7%): hepatic tumors (23.6%), colon cancer (14.5%), rectal cancer (12.7%), pancreatic cancer (11.8%), and gastric cancer (10%). There was no significant difference between the subgroups regarding the underlying diagnosis, operation time, or blood loss (Table 3). Moreover, the following median ERAS outcome variables did not differ significantly between the intervention and control subgroups: postoperative day of abdominal wound drain removal, discontinuation of epidural anesthesia, removal of urinary catheters, start of oral liquids (POD 0-1), and tolerance of solid food intake. Compared with open cases, an epidural analgesia was not routinely used for laparoscopic cases (Table 2). The urinary catheter was removed within 24 h after the operation (laparoscopic group), or with a median delay of 2-3 days (open group).

Study Endpoints

The mean daily step counts on PODs 1–5 significantly differed and were higher in the open control, compared with the open intervention group (P < 0.001, Fig. 2a). Likewise, the mean cumulative daily step count during the first 5 PODs was significantly lower in the open intervention, compared with the open control group (4635 versus 7483, P = 0.041). This translated into a longer cumulative activity time for the open control patients (462.4 ± 315 min versus 290.3 ± 186.8 min, P = 0.038). Only 33% of the patients in the open intervention group achieved their mobilization targets, compared with 48% in the open control group (P = 0.268). There was no significant difference in postoperative morbidity and the length of hospital stay between the two groups in the open arm (Table 4). Patients with comorbidities in the open group had a significantly lower step count, compared with patients



Fig. 1 Participant flow



without comorbidities (P = 0.045). When only patients without comorbidities (intervention: n = 5; control: n = 15) were compared, there was no significant difference in the step count (P = 0.168).

In the laparoscopic arm, the activity feedback (intervention) significantly increased the mean daily (P < 0.001) and cumulative step count (9867 versus 6103, P = 0.037) of the patients during the first 5 PODs, compared with the control group (Fig. 2b). Further, the cumulative activity time of patients with activity feedback was significantly longer (P = 0.037), and the percentage of patients who achieved their mobilization targets was higher. The percentage of patients who were exercised by professional physiotherapists at least for 3 days, postoperative morbidity, and the length of hospital stay were not significantly different in the respective intervention groups (Table 4).

The mean daily activity time of the patients recorded by the activity tracking devices between the PODs 1–5 ranged between 28 and 138 min (open arm) and 44–115 min (laparoscopic arm).

In the entire study cohort, there was no harm related to the intervention.

Ancillary Factors Affecting Postoperative Mobilization

The cumulative step count of the entire cohort was negatively correlated with the length of hospital stay (Spearman's rank correlation coefficient -0.341, P < 0.001) and age of the patients (Spearman's rank correlation coefficient -0.25, P = 0.009), respectively. No significant correlation was found for BMI, intraoperative blood loss, and operation time.



 Table 2
 Demographic data and patient characteristics

	Open surgery arm			Laparoscopic surgery arm			
	Intervention $(n = 27)$	Control $(n = 27)$	P	Intervention $(n = 29)$	Control $(n = 27)$	P	
Age (years)	61 ± 10.4	55.96 ± 11.1	0.052	59.8 ± 10.8	58.7 ± 11.8	0.902	
Sex (m/w)	16/11	19/8	0.393	16/13	13/14	0.599	
BMI (kg/m ²)	25.8 ± 4.6	25.5 ± 3.9	0.788	25.6 ± 3.4	26.6 ± 4.1	0.318	
ASA score (I/II/III)	0/12/15	1/13/13	0.554	4/17/7	2/19/4	0.489	
Smoking <i>n</i> [%]	6 [22.2%]	7 [25.9%]	0.075	7 [24.1%]	3 [11.1%]	0.203	
IPAQ (high/moderate/low) in n	8/2/2	13/5/0	0.113	10/2/2	7/3/0	0.426	
Preoperative comorbidity in n [%]	22 [81.5%]	12 [44.4%]	0.005	17 [58.6%]	13 [48.1%]	0.432	
Hypertension in n [%]	18 [66.7%]	12 [44.4%]	0.100	16 [55.2%]	10 [37%]	0.174	
Renal failure in n [%]	0 [0%]	3 [11.1%]	0.075	0 [0%]	0 [0%]	1	
Coronary heart disease in n [%]	3 [11.1%]	1 [3.7%]	0.299	3 [10.3%]	1 [3.7%]	0.355	
COPD in <i>n</i> [%]	0 [0%]	1 [3.7%]	0.313	2 [6.9%]	1 [3.7%]	0.596	
Heart failure in n [%]	2 [7.4%]	2 [7.4%]	1	1 [3.4%]	0 [0%]	0.330	
Diabetes in n [%]	7 [25.9%]	3 [11.1%]	0.161	3 [10.3%]	5 [18.5%]	0.382	
Discontinuation of epidural analgesia (median POD [IQR])	4 (0–5)	5 (3–6)	0.08	0*	0*	_	

ASA, American Society of Anesthesiology; BMI, body mass index; COPD, chronic obstructive pulmonary disease; IPAQ, International Physical Activity Questionnaire; IQR, interquartile range; POD, postoperative day. Data are presented as mean \pm standard deviation if not indicated otherwise. *There was only one patient with epidural analgesia in each subgroup

Interestingly, a cox proportional hazard model showed that the step count on POD 1 significantly correlated with a short hospital stay in the entire cohort (P = 0.002) and the laparoscopic group (P < 0.001, Fig. 3).

Logistic regression analysis further revealed that patients with open surgery and a hospital stay shorter than 12 days (= median length of hospital stay in the open arm) had a significantly reduced postoperative morbidity (7.1% versus 57.7%, P < 0.001) and a significantly higher mean cumulative step count (6847 versus 5211, P = 0.048). Comparable, laparoscopically operated patients with a hospital stay of less

than 9 days (= median length of hospital stay in the laparoscopic arm) had significantly fewer complications (3.4% vs. 33.3%, P = 0.004), a higher mean cumulative step count (10,421 versus 5507, P = 0.004), and a shorter mean operation time (234 ± 111 min versus 342 ± 145 min, P = 0.017).

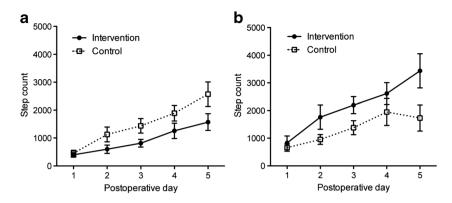
Vice versa, patients who performed less than the median cumulative step count in their respective arm (open, 4000 steps; laparoscopic, 5600) were significantly older (open, 61.3 ± 10.6 versus 55.9 ± 10.7 years, P = 0.043; laparoscopic, 60.9 ± 2.9 versus 57.6 ± 9.1 years, P = 0.015), had a significantly longer hospital stay (open, 16.7 ± 7.7 versus 12.4 ± 10.00

Table 3 Diagnoses and operative data

	Open surgery arm			Laparoscopic surgery arm			
	Intervention $(n = 27)$	Control $(n = 27)$	P	Intervention $(n = 29)$	Control $(n = 27)$	P	
Diagnosis (benign/malignant)	7/20	5/22	0.553	9/20	9/18	0.854	
Malignant liver disease	12 [44.4%]	9 [33.3%]	0.402	3 [10.3%]	3 [11.1%]	0.926	
Colonic cancer	1 [3.7%]	3 [11.1%]	0.299	5 [17.2%]	6 [22.2%]	0.639	
Rectal cancer	2 [7.4%]	5 [18.5%]	0.224	3 [10.3%]	4 [14.8%]	0.613	
Pancreatic cancer	4 [14.8%]	4 [14.8%]	1	4 [13.8%]	1 [3.7%]	0.186	
Gastric cancer	1 [3.7%]	1 [3.7%]	1	5 [17.2%]	4 [14.8%]	0.805	
Benign disease	7 [25.9%]	5 [18.5%]	0.513	9 [31.0%]	9 [33.3%]	0.854	
Operation time (min)	266.2 ± 106.6	282.6 ± 125.9	0.723	252.9 ± 122.2	322.9 ± 148.8	0.113	
Intraoperative blood loss (ml)	506.5 ± 430.5	555.2 ± 395.8	0.427	285.2 ± 324.6	425 ± 468.7	0.256	



Fig. 2 Mean daily step count of the patients in the open (a) and laparoscopic arm (b) during the first 5 postoperative days. Data are plotted as mean ± standard error of the mean. The control group is indicated by the dotted line, respectively



5.9 days, P = 0.017; laparoscopic, 12.5 ± 7 versus 9.1 ± 3.4 days, P = 0.034) and had a higher complication rate (open, 50% versus 14%, P = 0.005; laparoscopic, 31.8% versus 4.3%, P = 0.016) in both arms. However, the presence of preoperative comorbidities was not significantly different between these subgroups.

Discussion

A recent meta-analysis concluded that there were only a few comparative studies, which evaluated the impact of early mobilization protocols on outcomes after abdominal and thoracic surgery, and that the quality of these studies was poor and the results were conflicting.²¹

Previously published studies in pancreatic surgery described mobilization targets of up to 1 h out of bed on the first POD and up to 4 h on POD 3, but it was not reported whether the targets were achieved. 5,22,23 In comparison, only 20–28% of patients were mobilized on the first POD after liver surgery, despite predefined mobilization targets (e.g., "four times daily"). 11,24,25 Others reported that only the minority of patients (23.5%) achieved the mobilization target of more than 6 h out of bed on the first POD, which could not be improved

by the implementation of an ERAS pathway.²⁶ Overall, the mobilization targets described in most of the studies were either imprecisely defined, measured, or monitored.

The daily activity time during the early postoperative course of our cohort ranged between 28 and 138 min (open arm) and 44–115 min (laparoscopic arm), which is much shorter than expected and differs from the ERAS recommendations postulated to date. On the other hand, we report here on a novel and electronically measured parameter, which is compared with a mostly subjective observation of postoperative ambulation. Therefore, the parameter "activity time" of the used devices should be validated for postoperative patients in the future. This parameter includes standing, moving slowly (low-intensity activity and sitting < 1 h), walking, as well as high-intensity activity. Then, pedometer or activity tracking devices allow an objective measurement of postoperative mobilization or activity data and thereby can deliver objective outcome parameters in clinical trials.

Our study further demonstrated that the length of hospital stay was negatively correlated with the cumulative postoperative step count. Cook et al. reported similar results.¹⁷ In this study, a significant relationship between the number of steps during the early recovery period, the length of hospital stay, and discharge disposition was observed in a cohort trial with

Table 4 Study endpoints

	Open surgery arm			Laparoscopic surgery arm			
	Intervention $(n = 27)$	Control $(n = 27)$	P	Intervention $(n = 29)$	Control $(n = 27)$	P	
Mean step count PODs 1–5	927 ± 829.4	1496.6 ± 1212.3	0.04	2227.2 ± 2038.4	1371.5 ± 1251.8	0.068	
Cumulative step count	4635.1 ± 4146.9	7483 ± 6061.6	0.04	9866.7 ± 7912.5	6103.4 ± 5939.1	0.037	
Mobilization target achieved in n [%]	9 [33.3%]	13 [48.1%]	0.268	8 [27.6%]	2 [7.4%]	0.049	
Activity time (min)	290.3 ± 186.8	462.4 ± 315	0.038	482.6 ± 286.4	348.3 ± 253.6	0.037	
Patients received physiotherapy at minimum of 3 of 5 PODs in $n [\%]$	16 [59.3%]	10 [37%]	0.102	10 [34.5%]	11 [40.7%]	0.629	
Hospital stay (mean \pm SD)	16.3 ± 8	12.6 ± 5.7	0.112	10.3 ± 4.9	11.3 ± 6.5	0.888	
Complications in n [grade I/II/IIIa/IIIb]	0/3/6/2	1/0/2/3	0.143	0/2/1/0	0/2/3/2	0.294	

POD, postoperative day; SD, standard deviation. Complications are defined according to the Clavien-Dindo classification of postoperative complications



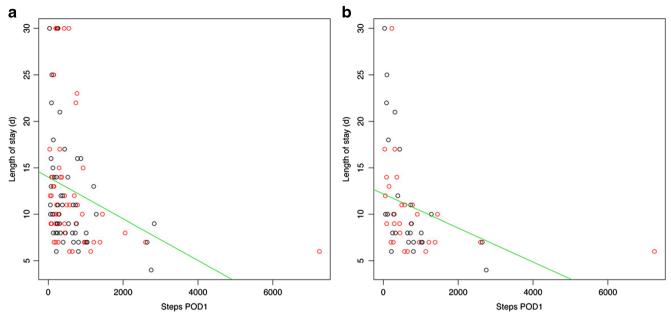


Fig. 3 Length of hospital stay plotted against the step count on postoperative day 1 (POD 1) in the entire study cohort (a) and the laparoscopic arm (b). Study subjects in the intervention subgroups are plotted in red, and control subjects are in black. A linear regression line is plotted in green

150 patients after cardiac surgery.¹⁷ Neither of the studies answers the question whether this correlation is caused by the increased ambulation of the patients or by the selection of the fittest patients and those with no complications. However, the step count on the first postoperative day alone inversely correlated with the hospital stay, which suggests some degree of independency between postoperative mobilization and morbidity, because many complications occur later during the postoperative course.

Most interestingly, the present trial observed a discordant effect of the intervention between the laparoscopic and the open surgery arm. A possible reason may be the fact that the demographic data and preoperative comorbidities were not balanced between the groups in the open arm, although this interaction could not be statistically proved. However, a retrospective analysis of the collected data did not identify any other factor, which might explain the low step counts of the patients in the open intervention subgroup. Other factors, such as the surgical stress response or pain after open surgery, can theoretically mitigate the effect of activity feedback after major abdominal surgery, as seen in the laparoscopic arm. In line with this, more patients in the open group underwent a hemihepatectomy (8 versus 2, P = 0.05) or pancreatic head resection (12 versus none, P < 0.01) compared with the laparoscopic group with a higher percentage of gastric (9 total or subtotal laparoscopic gastrectomies versus 2 in the open group, P = 0.05) or colon resections (17 laparoscopic hemicolectomies or sigmoid resections versus 4 in the open group, P < 0.01).

One could also argue that smoking habits necessitate patients to mobilize more. The percentage of smokers was lower

in the laparoscopic control group compared with the laparoscopic intervention group, but the difference was not significant and the number of smokers was too low for a reliable statistical analysis.

The present trial has some limitations. The anticipated mobilization targets were derived from an own small pilot trial, but, in retrospect, were not optimally chosen; only a minority of the patients achieved these targets (secondary endpoint) in the present trial. Moreover, the trial included many types of operations covering hepatopancreatic, gastrointestinal, and colorectal surgery, which might have a different impact on the postoperative patients' physiology and ability to ambulate. This broad range of operations generated an inhomogeneous study cohort, but it was intentional in order to increase the applicability and generalizability of the study. There were no differences between the groups regarding the preoperative mobility assessed by the IPAQ. However, compliance to complete the IPAQ was very low in our study population (49%). Discrepancies between the self-reported, preoperative mobility assessed by the IPAQ, and the actual, quantitative mobility could not be excluded. In addition, the IPAO was not designed for patients in a hospital setting (inpatients), but is considered an appropriate tool to assess physical activity in daily life.²⁷

Conclusion

This is the first trial reporting on postoperative activity tracking in major abdominal surgery. The study demonstrated that activity tracking in the postoperative course after major abdominal surgery is feasible and has the potential to increase



mobilization after laparoscopic surgery. Furthermore, activity tracking devices enable the monitoring of additional health parameters, which might be useful for postoperative monitoring and intervention. The step count of patients during the first postoperative days might be an early predictor for complications and the length of hospital stay.

Authors' Contributions S.W. designed the study, collected and analyzed the data, and drafted the manuscript. T.M., S.L., B.M., A.B., and A.W. assisted with the data collection. J.W., N.R., and M.D. worked on the study design and the final manuscript. D.S. assisted with the study design. T.W. designed the study and finalized the manuscript.

Compliance with Ethical Standards

All procedures performed were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study. This study was registered on ClinicalTrials.gov (NCT02834338) and approved by the local Ethics Committee of the TU Dresden (decision number EK226062016). This article does not contain any studies with animals performed by any of the authors.

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