Robotic-assisted sleeve gastrectomy in obese patients using the SenhanceTM surgical system – evaluation of the feasibility and safety of a new system

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Research Article

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Abstract

Robotic-assisted surgery is widely integrated into several surgery standards. However, conventional laparoscopy still represents the gold standard in bariatric surgery and robotic-assisted surgery is relatively novel. This study aims to evaluate the feasibility and safety of the Senhance™ surgical system for robotic-assisted sleeve gastrectomy in obese patients. Twenty obese patients (BMI: 36-57) underwent elective robotic-assisted sleeve gastrectomy in the Department for bariatric and metabolic surgery at Sana Hospital Offenbach, Germany. Indication for sleeve gastrectomy followed the general German guidelines of obesity surgery. Median docking time was 7.5 min (4–13), mean console time was 33 min (15-75) and median total operating time was 85 min (47–147). Two cases were converted to conventional laparoscopy (10 %) for bleeding or limited working space, none to open surgery. One complication required reoperation (postoperative hematoma). Median hospitalization time was three days (3–5). The study results underline the feasibility and safety of the Senhance™ surgical system for robotic-assisted sleeve gastrectomy in obese patients.

1. Introduction

New technologies in surgery developed increasingly over the past decades, especially in minimally invasive surgery. With the introduction of robotic-assisted surgery, the surgical experience is extended by tactile force feedback, articulated instruments and three-dimensional visualization. Limitations, such as tremor and inaccuracy, can be reduced simultaneously. Overall, robotic-assisted surgery already represents remarkable advantages in many surgical procedures [1]. The Senhance™ surgical system was introduced to the market in 2017; its predecessor ALF X in 2009. The new system is currently being evaluated in various surgical fields for its application [2]. Consequently, it seems reasonable to investigate its potential in bariatric surgery.

Obesity, defined as a body mass index (BMI) of > 30 kg/m^2, is on the rise worldwide, presenting one of the most significant public health issues [3]. Accordingly, surgical interventions such as sleeve gastrectomy have been performed more frequently over the past decades [4, 5]. Especially in bariatric surgery, laparoscopy has significantly reduced morbidity and mortality and enabled the spread of bariatric procedures (6,7). Studies have already investigated the benefits of minimally invasive surgery in obese people for diverse surgery indications such as Roux-en-Y gastric bypass, hysterectomy and colorectal surgery [8–10]. More specifically, Zhang and colleagues recently indicated the feasibility and safety of robotic procedures in obese patients for bariatric surgery [11]. Therefore, the next step in bariatric surgery could be a standard implementation of robotic-assisted systems.

However, most published literature does not report experiences with the Senhance™ surgical system. It has only been described twice for its use in obese patients, both being gynecological procedures [12, 13]. Hence, reportings on bariatric procedures are lacking in current research.

The present study aims to evaluate the feasibility and safety of the Senhance™ surgical system in obese patients undergoing elective robotic-assisted sleeve gastrectomy.

2. Material And Methods

2.1 Patient selection

Subject to this study were obese patients undergoing primary robotic-assisted sleeve gastrectomy between September 2021 and January 2022 in the Bariatric Department at Sana Hospital Offenbach, Germany. Patients had to fulfill the German guideline criteria for obesity surgery to undergo the procedure and to be included as participants [14]. No further exclusion criteria for selection were defined. Patient characteristics such as sex, age, BMI, Edmonton obesity score (EOSS), Obesity Grade, ASA, comorbidities and previous abdominal surgical procedures were documented. Clinical data were reported as docking time, defined as the time needed to move and adjust the robotic system arms until reaching the final position; console time, defined as the time the surgery is controlled over remotes; and operating time, defined as the time from incision to end of sutures. Early postoperative complications were defined as any adverse events occurring within 30 days from surgery and considered severe if they resulted in readmission, blood transfusion or revisional surgery. The hospitalization days were calculated from the day after surgery (day 1) to the day of discharge. Two experienced laparoscopic surgeons performed surgery, receiving a 3-days training program prior to the first use of the system in humans. The first two days were a dry lab simulation experience, while the last day was in a wet lab. Previous experience with the Senhance™ surgical system of the performing surgeons included robotic cholecystectomy and robotic inguinal hernia repair.

2.2 Surgical technique

Written informed consent to the possible robotic and surgical procedure risks was obtained from all patients prior to surgery.

While under general anesthesia with antibiotic prophylaxis, all patients were positioned in French Position. After sterile washing and covering of the operation area and the robotic arms, access to the abdominal cavity was gained by an incision pararectal, in the left upper quadrant. A 12-mm camera port was inserted here. Once capnoperitoneum was achieved, diagnostic laparoscopy and exclusion of possible injured structures followed. Next, three trocars were placed under direct visualization: two 12 mm ports in a linear arrangement in the right and left upper quadrantsand an additional 5-mm port was placed in the left upper abdominal quadrant. A liver retractor was inserted via a 10 mm trocar placed in the right upper quadrant. Next, left liver lobe was convicted, retracted and fixed. The three 12-mm trocars were docked to the Senhance™ surgical system and surgery was continued robotic-assisted (Fig. 1). The stomach was held up cranial for the Bursa omentalis to be detached. Gastrolysis of the greater curvature of the stomach was performed with the help of ultrasonic scissors (Senhance). Further, robotic-assisted preparation was carried out until 4 cm from to the pylorus. Preparation was continued cranial, which also included diverting the Arteriae und Venae gastricae breves and mobilizing the gastric fundus. Once

complete mobilization of the greater curve of the stomach was reached, console time ended and the Senhance™ was undocked. The gastric sleeve was created by a linear stapler (Signia™ Stapling System, Medtronic), using a 45mm purple cartridge for the first staple line prepyloric followed by 60 mm purple cartridges up to the Angle of His. The sleeve width was determined with a 36 Charrière nasogastric tube. The proximal staple line was reinforced by Vicryl-sutures. An intraoperative overview to control for cessation of bleeding was obtained. The resectate was retrieved and incisions were closed on the fascial layer with Vicryl sutures. The intraoperative field was subject to a final inspection. Lastly, capnoperiteneum was removed, and skin was closed, including the application of sterile dressings.

2.3 Statistics

Statistical analyses were performed in Microsoft Excel 2016, IBM SPSS 27, and GraphPad 7. Microsoft Excel 2016 was used for data cleaning and coding. Further analysis and visualization were performed in IBM SPSS 27 and GraphPad 7. Participants' demographics and clinical data were used for descriptive statistics. Continuous variables were displayed as median and range (minimum and maximum), while categorical parameters were expressed in number and percentage.

3. Results

Twenty obese patients [16 female (80%), 4 male (20%)] underwent robotic-assisted sleeve gastrectomy with the Senhance™ surgical system between September 2021 and January 2022 at the Bariatric Department of Sana Hospital Offenbach, Germany. Patient characteristics are summarized in Table 1. The median age of the study population was 34 years (range 23–55) and the median BMI was 46 kg/m^2 (range 36–57). 80% of the patients presented comorbidities, the most prevalent diseases categorized as metabolic syndrome (40%), hyperuricemia (25%), and obstructive sleep apnea (20%). 2 patients (10%) had previous gastric balloon intervention for obesity and 8 (40%) had previous abdominal surgery (e.g. cesarian, appendectomy, cholecystectomy). 85% of the patient population presented Grade III obesity. To avoid bias related to different teams, all procedures were performed by the same surgical staff. The perioperative data are reported in Table 2. The median docking time was 7.5 minutes (4–13 minutes), the median console time was 33 minutes (15–75 minutes) and the median operating time was 85 minutes (47–147 minutes). There was no relevant blood loss or transfusion. For all 20 procedures, two conversions to laparoscopy were recorded, but none to open procedure. One case required conversion due to too large leverage forces on the robotic instruments with limited workspace. The second conversion to laparoscopy was due to bleeding from a short gastric vein. Evaluating postoperative complications, one patient presented secondary bleeding from the stapler line and required a re-laparoscopic intervention (Clavien Dindo 3b). The same patient was readmitted within 30-days for an incarcerated umbilical hernia. The median hospitalization was 3 days (3–5 days) and there was no mortality recorded. Docking time, console time, and operating time as trend diagrams are shown in Fig. 2. With growing experience of the team, there was a reduction in console time and operating time.

Table 1 Patient Characteristics

Characteristics	N = 20
Age[1]	34 (23–55)
Sex[2]	
Female	16 (80%)
Male	4 (20%)
BMI[1] kg/m²	46 (36–57)
Edmonton Obesity Score[2]	
0	2 (10%)
1	13 (65%)
2	4 (20%)
3	1 (5%)
Obesity Grade[2]	
III	85%
II	15%
ASA[2]	
I	1(5%)
II	16(80%)
III	2 (10%)
IV	1 (5%)
Comorbidities[2]	
No	4 (20%)
Yes	16 (80%)
1	5 (31.2%)
> 1	11 (68.8%)
Metabolic syndrome	8 (40%)
Hyperuricemia	5 (25%)
Obstructive sleep apnea	4 (20%)

[1] median(minimum-maximum)

[2] n (%)

Silent inflammation	3 (15%)
NAFLD	3 (15%)
Chronic obstructive pulmonary disease	1 (5%)
Congestive heart failure/ Coronary artery disease	1 (5%)
[1] median(minimum-maximum)	
[2] n (%)	

Table 2
Perioperative Data

Characteristics	**N = 20**
Previous abdominal surgery[1]	
No	12 (60%)
Yes	8 (40%)
Operating Time[1] [3]	85 (47–147)
Docking Time[1] [3]	7.5 (4–13)
Console time[1] [3]	33 (15–75)
Conversion[2]	
No	18 (90%)
Yes (to conventional laparoscopic)	2 (10%)
Postopertive complication[2]	1 (5%)
Mortality rates[2]	0 (0%)
30-day readmission[2]	1 (5%)
Hospitalization days[1]	3 (3–5)
[1] median(minimum-maximum)	
[2] n (%)	
[3] in minutes	

4. Discussion

The present study reports results from robotic-assisted sleeve gastrectomy with the Senhance™ surgical system in 20 obese patients. The aim was to evaluate the feasibility and safety of the new Senhance™ surgical system in obese patients.

Unlike other systems, the advantages of the new Senhance™ surgical system include tactile force feedback, separately placeable arms, individually and repeatedly adjustable pivot points of the trocars to minimize both resistance and tissue trauma, reusable instruments and a stable three-dimensional camera with eye-tracking [2].

Especially in obese patients, the limited intraabdominal space and the large leverage due to the thick abdominal wall are limiting factors for minimally invasive surgery. Robotic-assisted surgery could overcome these limitations and its better surgical control and estimation could ultimately optimize surgical procedures. Zhang and colleagues even found lower mortality within 90 days (Odds Ratio: 2.40; 95% CI (1.24–4.64); p-value = 0.009) for robotic-assisted surgery compared with laparoscopic bariatric surgery [11].

The Senhance™ surgical system uses 5 mm instruments as a standard size. With this instrument size, high bending forces on the instruments were observed in some obese patients in the present study. Together with the tactile feedback, these forces made repeated recalibration of the pivot point necessary. However, conversion due to too large leverage forces on the instruments and insufficient intraabdominal space was only necessary in one case. In this case, the procedure was completed by using 10 mm instruments and the conversion to standard laparoscopy was performed without a significantly longer operating time. This problem could possibly be addressed with the development of more rigid instruments. The patient for this conversion was male, characterized by a BMI of 44.9 kg/m^2 and a height of 187cm. Noteworthy, he was the tallest but not the most obese in the overall study population. Accordingly, perioperative complications and conversions cannot be generalized to be caused by severe obesity. Of note, when the Senhance™ surgical system was first introduced to the European markets, its CE conform application was restricted to a maximum BMI (40 kg/m^2). By April 2021, this limit was repealed, allowing its use even in severely obese patients with CE conformity. Overall, physical condition and proportion should be carefully evaluated and discussed for robotic-assisted surgery in each case.

The patient selection for the present study was performed according to the criteria for standard laparoscopic sleeve gastrectomy to avoid selection bias. Therefore, patients with previous abdominal surgery were also included. The study results show that 40% of the patients had undergone previous surgery, but the two recorded conversions to laparoscopic surgery were due to bleeding and limited motion. In conclusion, previous abdominal surgery cannot be considered a contraindication for robotic-assisted bariatric surgery, as for example also robotic-assisted revisional procedures are feasible [15].

Regarding the surgical technique, Senhance™ surgical system is based on laparoscopy. Together with the free placement of the robotic arms, surgical technique (e.g. trocar placement) is comparable to the

laparoscopy standard and no adjustments are necessary. This allowed for a rapid adaptation of the system by the laparoscopically experienced surgeons. In the case of conversion to conventional laparoscopy, a smooth and quick conversion without the need to place new trocars was accomplished. This represents a safety advantage of the Senhance™ surgical system, especially in the event of a bleeding complication.

A recent meta-analysis stated longer operating times in robotic-assisted than in standard laparoscopic sleeve gastrectomy (mean operating time: laparoscopic sleeve gastrectomy: 84.18 to 138 min; robotic-assisted surgery: 95.5 to 148) [16]. In contrast, data from the present study with Senhance™ surgical system lies within comparable times reported for laparoscopic sleeve gastrectomy. This could be because the docking time of the Senhance surgical system is relatively short compared to other systems. With the increasing experience of the team, operating time could be even further reduced [17]. The console time, as well as the total operating time, showed a fast reduction to times more similar to that of laparoscopy. Important to emphasize is that the performing surgeons in the present study are well experienced in the field of laparoscopic surgery, while they only performed less than ten robotic-assisted procedures before the time of the study. Taken together, the finding indicates that the learning curve of the laparoscopy-based system is reduced for experienced surgeons. Present findings of hospitalization days (1.7 ± 1.8 to 4 ± 3 days) [16], postoperative complications (2.9 %) [18], and 30-day readmission rates (7.1%) [19] with the Senhance™ surgical system are comparable to other published robotic-assisted and standard laparoscopic sleeve gastrectomy results.

5. Conclusions

Surgery in obese patients is a challenging procedure, also true of robotic-assisted surgery. The present study results indicate robotic-assisted sleeve gastrectomy with the Senhance™ surgical system to be feasible and safe, with a reduced learning curve compared to other robotic systems. In the light of its technical implementations, it might even have indispensable advantages over other methods and systems. Further investigations could help evaluate robotic-assisted surgery benefits and superior outcomes compared to standard laparoscopy.

Declarations

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Competing Interests: The authors have no relevant financial or non-financial interests to **disclose.**

Ethics approval: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000.

Consent to participate: Informed consent was obtained from all individual participants included in the study.

Consent to publish: Not applicable.

Availability of data and materials: Not applicable.

Code availability: Not applicable.

Author Contributions: All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Thomas Haist, Oliver Scheffel, and Michael Pauthner. The first draft of the manuscript was written by Thomas Haist, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Consent to publish: The authors affirm that human research participants provided informed consent for publication of the image in Figure1

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Figures

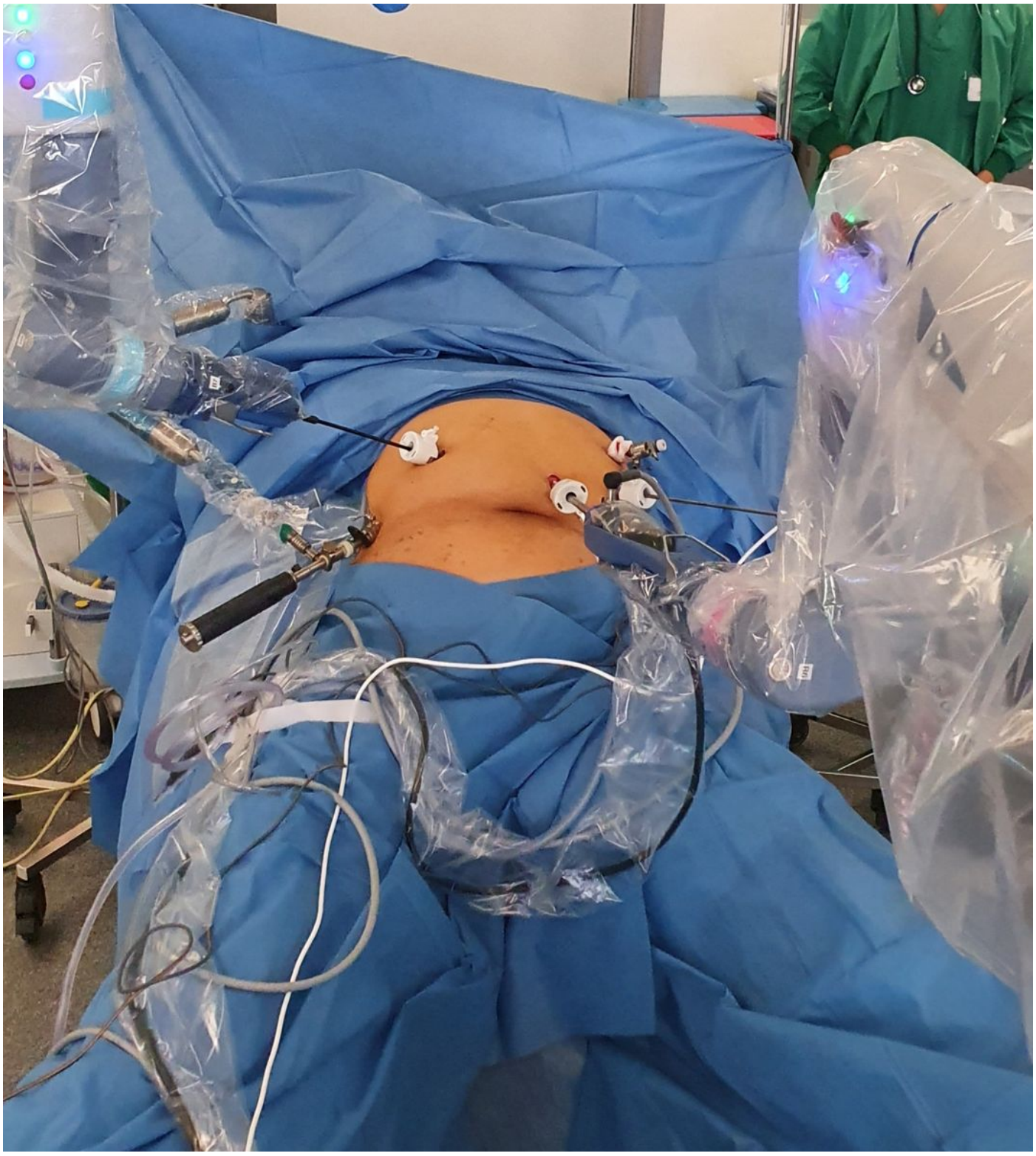

Figure 1

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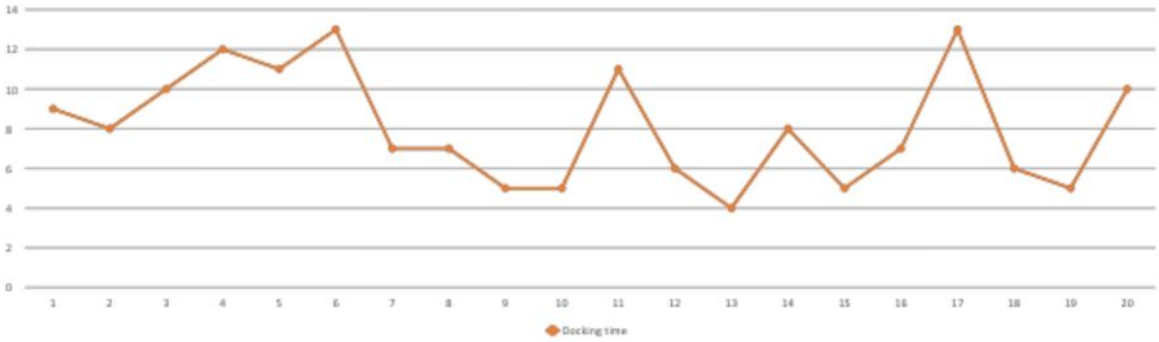

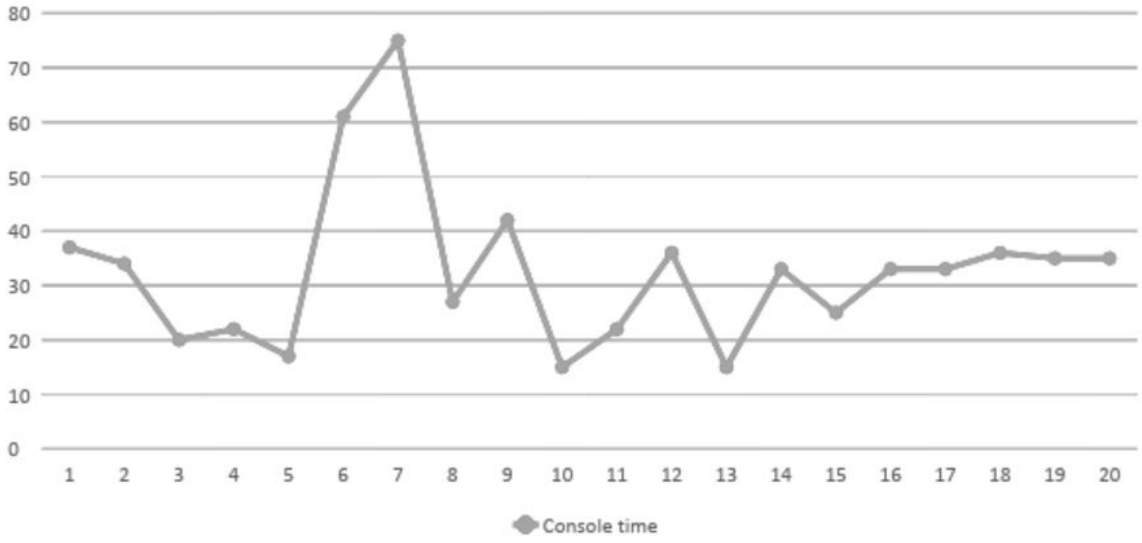

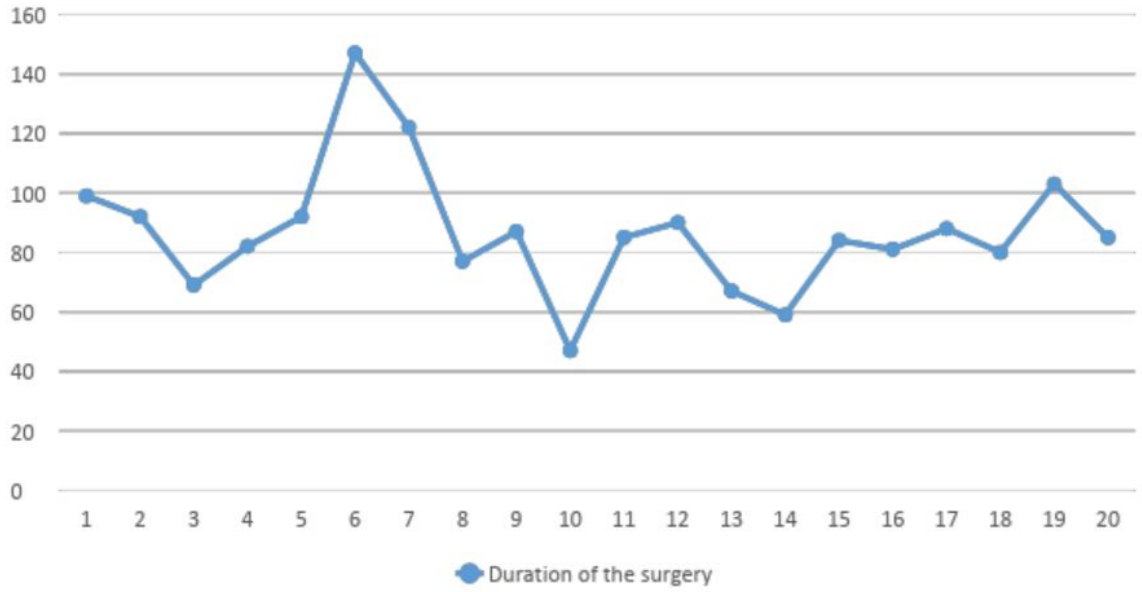

Figure 2

Trend diagrams. Presented as the duration in minutes overtime. Orange: Docking time, grey: Console time, blue: Duration of the surgery (operating time)