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Robotic-assisted cholecystectomy with DEXTER®: the first prospective multicenter study

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Abstract

Introduction Despite advancements in minimally invasive surgery, access to robotic-assisted cholecystectomy remains limited, largely due to robot availability and high costs for this procedure. The DEXTER® Robotic Surgery System offers a small, mobile, and cost-effective alternative designed for ease of use and seamless integration into routine surgical workflows. The present study aimed to confirm the safety and performance of robotic-assisted cholecystectomy using DEXTER®.

Methods A prospective study of robotic-assisted cholecystectomy was conducted by six surgeons across four centers in three countries. The primary objectives were to document the successful completion of the surgeries without conversion to laparoscopic or open surgery and the occurrence of serious adverse events (Clavien–Dindo grade ≥ III) up to 30 days post-surgery. Secondary endpoints included surgical performance metrics such as operative time.

Results A total of 51 patients underwent surgical intervention for the management of symptomatic Cholecystolithiasis, Cholecystitis, choledocholithiasis, and biliary pancreatitis. The median patient age was 59 years (IQR 42–65), and BMI was 28.0 kg/m^2 (IQR 24.9–29.6). All procedures were completed successfully without device deficiencies or conversions to open surgery. The median operative time was 58 min (IQR 49–78), including a median docking time of 3 min (IQR 2–5) and a median console time of 25 min (IQR 21–36). The median estimated blood loss was 5 mL (IQR 0–10) and no blood transfusions were required. One Clavien–Dindo grade IIIa event occurred in one patient requiring an ERCP for postoperative Choledocholithiasis, which was resolved without the need for reoperation. 26 patients (51%) were discharged within 24 h of the surgery.

Conclusion This study confirmed that DEXTER® enables safe and effective cholecystectomy in a non-emergent setting, including in outpatient sites of care.

Keywords Cholecystectomy · Robotic-assisted surgery · DEXTER® Robotic Surgery System · Robotic surgical procedures · Gallbladder removal · Outpatient surgery

Laparoscopic cholecystectomy (LC) is one of the most performed surgeries worldwide. Approximately, 900,000 gallbladder surgeries are conducted in Europe annually, the majority laparoscopically [1]. In the US, 10–15% of the population has been estimated to have asymptomatic gallstones and more than 750,000 cholecystectomies are performed every year [2]. Outpatient laparoscopic cholecystectomy has gained traction globally due to its proven benefits, including lower costs, and enhanced pa tient experience. As a result, cholecystectomies for uncomplicated gallstone disease are increasingly conducted in ambulatory surgical centers (ASCs) [3, 4].

Laparoscopic cholecystectomy has long been established as the standard of care for gallbladder disease [5, 6], yet

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improved ergonomics and instrument maneuverability could enhance performance, particularly in complex or inflammatory cases. Robotic-assisted surgery has introduced enhanced dexterity, significantly improved surgeon ergonomics and has the potential to reduce the learning curve, making it an attractive tool even for less complex procedures such as cholecystectomy. Robotic-assisted cholecystectomy (RC) is commonly utilized as an introductory procedure for general surgeons adopting a robotic surgery technique. Some studies have suggested that RC may reduce the risk of conversion to open surgery and bile leakage when compared to laparoscopic surgery [7]. However, the largest retrospective review conducted to date has raised concerns about higher rates of bile duct injury in patients who underwent RC compared to LC and its use as a training case for credentialing in the context of the learning curve with conventional robotic platforms [8].

The high cost and operational rigidity of conventional robotic systems have largely restricted their use to complex cases and inpatient settings, limiting access for many general surgery departments, training environments, and ASCs [9]. Newer, more accessible platforms may increase access to robotic-assisted surgery for a broader range of surgeons and sites of care, while facilitating the safe acquisition of robotic surgery skills for procedures such as cholecystectomy. The DEXTER® Robotic Surgery System is a compact, mobile platform that integrates into existing operating room (OR) infrastructure and workflows. Every component of the DEXTER® system, including the surgeon's console, is sterile draped for the procedure. This configuration offers the surgeon the option to maintain sterility while operating the robot, thereby ensuring immediate access to the patient's side when desired or required. The DEXTER® robot was designed such that it does not require a dedicated robotic OR and a full suite of robotic technologies and instrumentation; rather it can be moved from OR to OR and utilize readily available laparoscopic visualization and instrumentation to facilitate accessible use, particularly for high-volume, routine procedures. Previous studies have reported a safe implementation of the DEXTER® robot for cholecystectomy [10, 11], with the DEXTER® learning curve stabilizing after 10–15 cases for both experienced robotic surgeons and novices [12]. The flexibility of the system allows a surgeon to move rapidly from operating robotically at the sterile console to operating laparoscopically at the patient bedside when desired to complete specific steps or to complete the case laparoscopically. In addition to the flexibility in surgical approach as desired, this ensures a safe procedure even during the learning phase, which can be particularly beneficial in the event of bleeding from the cystic artery or when gallbladder inflammation is more pronounced than previously diagnosed [12].

We have conducted the first prospective multicenter study to confirm the perioperative and early postoperative safety and clinical performance of robotic-assisted cholecystectomy using DEXTER®.

Materials and methods

Study design and population

The prospective, single-arm, multicenter study was performed at four centers in France, Germany, and Switzerland. The study was conducted according to the Declaration of Helsinki, the European regulation on medical devices 2017/745, ISO 14155:2020 and 21 CFR 812.28. The study protocol was approved by the relevant ethics committees in accordance with local requirements and registered in the ClinicalTrials.gov database (NCT06473688) before the start of the recruitment. Informed consent, including agreement to perform the 30-day follow-up assessments per standard of care, was obtained from all participants, aged 18 years or older who were planned to undergo robotic-assisted cholecystectomy. Gallbladder surgeries wereperformed with DEXTER® for indications including non-emergent and acute disease, according to its intended use. The exclusion criteria included BMI > 40 kg/m^2, subjects with history of major abdominal surgery or suspicion of gallbladder cancer, relative or absolute contraindications for the use of conventional endoscopes and endoscopic surgical instruments, pregnancy and objection to the collection of their data for research purpose. All patients fulfilling eligibility criteria were considered for participation to the study. Every patient was given sufficient time to review the informed consent, and reason for non-inclusion was collected in a study log.

The primary objectives of the study were to report the occurrence of major adverse events (Clavien–Dindo grades III to V) perioperatively up to 30 days and to document the successful completion, without any conversion to an open or fully laparoscopic approach, of the cholecystectomy with the DEXTER® Robotic Surgery System. The procedures were performed by six surgeons with varying levels of experience: median 13 years in laparoscopy (range 9–37 years) and median 5 years in robotic-assisted surgery (range 2—13 years).

In clinical practice, several grading systems have been established to help characterize the severity of cholecystitis either preoperatively or intraoperatively, to better prognosticate outcomes for patients [13]. In our study, we classified patients according to the modified Nassar operative difficulty scale [14]. The scale is based on three operative criteria to assess the degree of inflammation of the gallbladder, cystic pedicle, and adhesions. The grades, from I to V, increase

from minimal inflammation to severe, including Mirizzi syndrome type 2 or higher.

The DEXTER® Robotic Surgery System

The DEXTER® Robotic Surgery System (Distalmotion, Epalinges, Switzerland) is comprised of modular, mobile components, including the sterile surgeon console with hand controllers to manipulate wristed robotic instruments, two patient carts where the instruments fit onto robotic arms, and one endoscope arm, all of which are placed around the operating table. The sterile console is open to facilitate communication between the surgeon and the OR staff (Fig. 1). From the surgeon console, the operator can control the movements of the endoscope and the two instruments arms. The endoscope arm is compatible with any endoscopic system available in the OR for laparoscopic practice. In our study, the video endoscope used coincidentally by all sites was a TIPCAM® 1 Rubina™ 3D (Karl Storz GmbH, Germany). The DEXTER® instruments portfolio includes a needle holder, bipolar Johann grasper, bipolar Maryland dissector, monopolar scissors, and monopolar hook. The DEXTER® instruments are fully articulated, offering seven degrees of freedom. The active instruments are compatible with any standard electrosurgical unit present in the OR such as Erbe VIO 300D or Erbe VIO 3 electrosurgical systems (Erbe Elektromedizin GmbH, Germany) that were used in this study. The costs related to the system and instruments are dependent on the sales model and vary across countries and institutions, like other robotic systems. In this study, all participating centers acquired the required instruments according to their own negotiated commercial agreements.

Surgical technique

The surgical technique for cholecystectomy with DEXTER® was previously described by two of the participating sites [10, 12] and closely mirrored a conventional and familiar

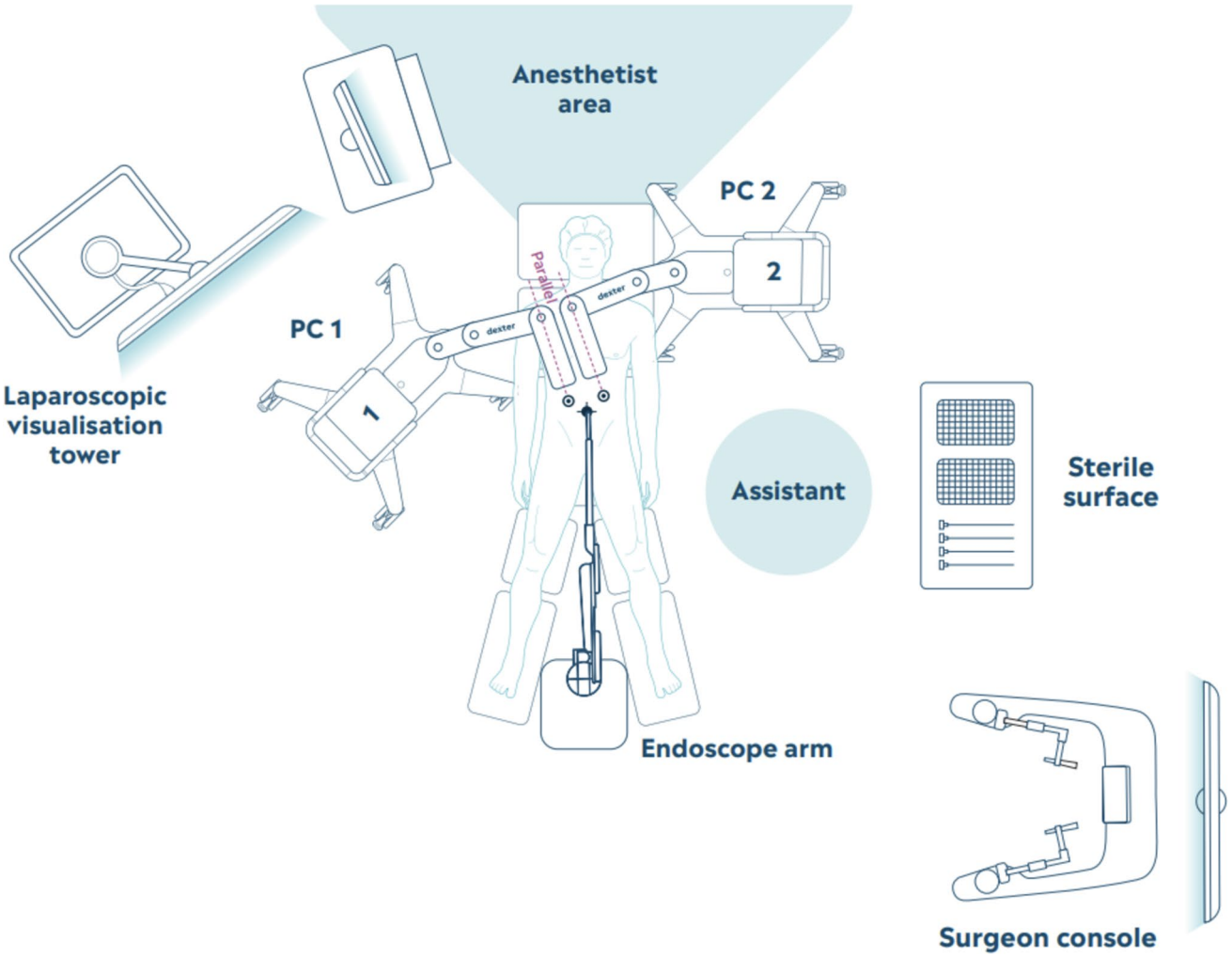

Fig. 1 DEXTER® operating room setup

laparoscopic setup. Patients were placed in the supine position with reverse Trendelenburg (10–20°) and a slight right-side tilt (up to 5°). The endoscope was positioned at the umbilicus or just above the umbilicus using a Hasson or Veress needle technique. An epigastric port left to the midline with an 8 or 11 mm trocar served as the robotic instrument port for the right hand of the surgeon, and a port in the right upper abdomen with an 8 or 11 mm trocar served as the robotic instrument port for the left hand of the surgeon. A 4th ancillary port with a 5-mm trocar was positioned to the left of the endoscope port as needed (Fig. 2). This ancillary trocar was used for gallbladder retraction and exposure. This could generally be performed by the sterile bedside assistant such as the scrub nurse.

Initial adhesiolysis, if indicated, dissection of the hepatocystic triangle and of the gallbladder were all performed robotically. After clear identification of the cystic duct and cystic artery, each was ligated laparoscopically using Hem-o-lok clips (Teleflex, US). Routine cholangiography was not performed unless indicated due to uncertainty of biliary anatomy or suspicion of retained stones in the biliary tree. The cystic duct was palpated for any remaining intraductal stones. If found, they were mobilized into the gallbladder before applying the clips. Division of the cystic duct and the cystic artery were performed either robotically or laparoscopically, according to surgeon preference, while dissection of the gallbladder from the fossa was performed robotically. The gallbladder was then placed in an endoscopic retrieval bag and removed through the umbilical incision. Patients were discharged according to routine practice of each site.

Data collection and statistical analysis

Safety and performance data was collected intraoperatively, and patients were followed up for 30 days after the surgery. Operative time was measured from the time of the first skin incision until skin closure. Robot docking time was measured from time of the order to push the patients' carts toward the subject until the last incision pointer was removed from the trocar, or the endoscope is inserted into the trocar and attached to the endoscope arm, whichever occurred last. Surgeon console time was defined as total time the robot was used.

For descriptive statistics, median and interquartile range (IQR) were used to present continuous data. Numbers and percentages were used for categorical variables. Data were analyzed using StataCorp. (2023. Stata Statistical Software: Release 18. College Station, TX: StataCorp LLC).

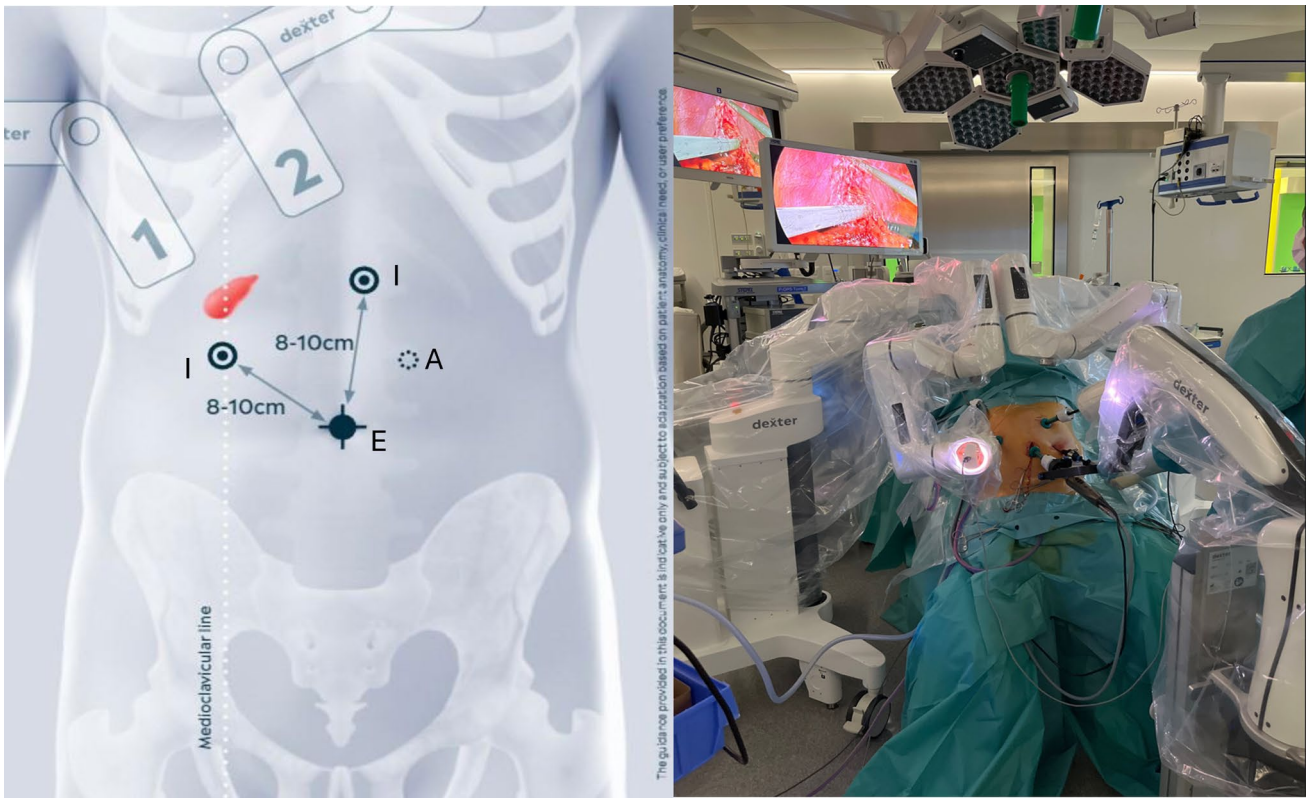

Fig. 2 Trocar placements. E = endoscope port, I = robotic Instruments ports, A = optional ancillary port

Results

Fifty-one patients were operated predominantly for symptomatic cholecystolithiasis (62.7%), cholecystitis (19.6%), and choledocholithiasis (11.8%) (Table 1). Other indications included biliary pancreatitis, gallbladder polyps, and gallbladder hydrops. According to the Nassar grading scale, most patients were of grade II (45.1%), although a substantial proportion of grade III (27.5%) and IV patients (5.9%) were enrolled, representing various level of surgical difficulty (Table 1).

Most procedures (90%) were performed using four trocars: two for robotic instruments, one for the endoscope, and one for 5 mm ancillary port. The ancillary port was used primarily to facilitate gallbladder exposure, particularly in inflamed cases. These tasks required minimal intervention and were easily performed by a sterile assistant, usually the scrubbed nurse, who had ample space and unobstructed access at the bedside, even with the robotic arms in position (Fig. 2). In none of the cases intraoperative cholangiography was necessary before clipping the cystic duct. In four straightforward cases, a three-port technique was used, relying solely on the three robotic arms operated by the surgeon who also had immediate access to the bedside to deploy the laparoscopic clip applier through a robotic port, given the sterility barrier maintained by the draped console.

All procedures were successfully completed without intraprocedural complications, conversion to open surgery, or major technical failures. In one case, the surgery was not fully completed with the robotic system due to a surgeon's personal time constraint; rather, the surgeon completed the case laparoscopically at the bedside after completing the ligation of cystic duct and cystic artery. This conversion was fully unrelated to the patient, the procedure, or to any performance issue, or safety concern associated with the robot.

The median duration of the operative time was 58 min (IQR 49 – 78) including 3 min (IQR 2 – 5) of docking time and 25 min (IQR 21 – 36) of console time (Table 2). As expected, there was an increase in the operative times, particularly the console time, for more complicated cases according to the Nassar grading scale (Fig. 3). No bile duct injury or bile leak was reported. There was minimal blood loss during the surgeries, with a median blood loss of 5 mL (IQR 0 – 10).

Twelve patients from the French site (23.5%) were released within the first 12 h of the surgery, and a total of 26 patients (52%) were discharged within 24 h. The overall median number of days to discharge was 1 day (IQR 1.0 – 2.0). There were 2 intraoperative events categorized as ClassIntra grade 2 that were not related to the use of DEXTER® and 8 postoperative complications up to the 30-day follow-up in 7 subjects (Table 2). Only one event was categorized as Clavien–Dindo grade IIIa. In this case, the patient was re-hospitalized after 18 days for a postoperative ERCP due to migration lithiasis of stones from the

Table 1 Patients characteristics

Characteristics	N = 51
Age (years), median (IQR)	59.0 (42.0 – 65.0)
Gender, male/female	19 / 32
BMI (kg/m^2), median (IQR)	28.0 (24.9 – 29.6)
ASA Status, n (%) ASA I	4 (7.8%)
ASA II	43 (84.3%)
ASA III	4 (7.8%)
Gallbladder and biliary conditions, n (%) symptomatic cholelithiasis	32 (62.7%)
Choledocholithiasis	6 (11.8%)
Cholecystitis	10 (19.6%)
Pancreatitis	3 (5.9%)
Other	5 (9.8%)
Nassar difficulty scale grading, n (%) Grade I	11 (21.6%)
Grade II	23 (45.1%)
Grade III	14 (27.5%)
Grade IV	3 (5.9%)
Grade V	0 (0%)

IQR Interquartile range

Table 2 Perioperative variables

Parameter	Value
Number of trocars used	
3 robotic trocars	4 (8%)
3 robotic trocars + 1 ancillary trocar	46 (90%)
3 robotic trocars + 2 ancillary trocars	1 (2%)
Conversion to laparoscopy, n (%)	1 (2%)
Conversion to open surgery, n (%)	0 (0%)
Total operative time in min, median (IQR)	58.0 (49.0 – 78.0)
Docking time in min, median (IQR)	3.0 (2.0 – 5.0)
Console time in min, median (IQR	25.0 (21.0 – 36.0)
Intraoperative blood loss (mL), median (IQR)	5.0 (0.0 – 10.0)
Complications	
Clavien–Dindo grade I	4 (8%)
Clavien–Dindo grade II	3 (6%)
Clavien–Dindo grade IIIa	1 (2%)
Rehospitalization, n (%)	2 (4%)
Reoperation, n (%)	0 (0%)
Patients discharged within 0-12 h of surgery	12 (23.5%)
Patients discharged within 0-24 h of surgery	26 (51%)
Length of hospital stay (days), median (min, max)	1.0 (1.0 – 2.0)

IQR Interquartile range

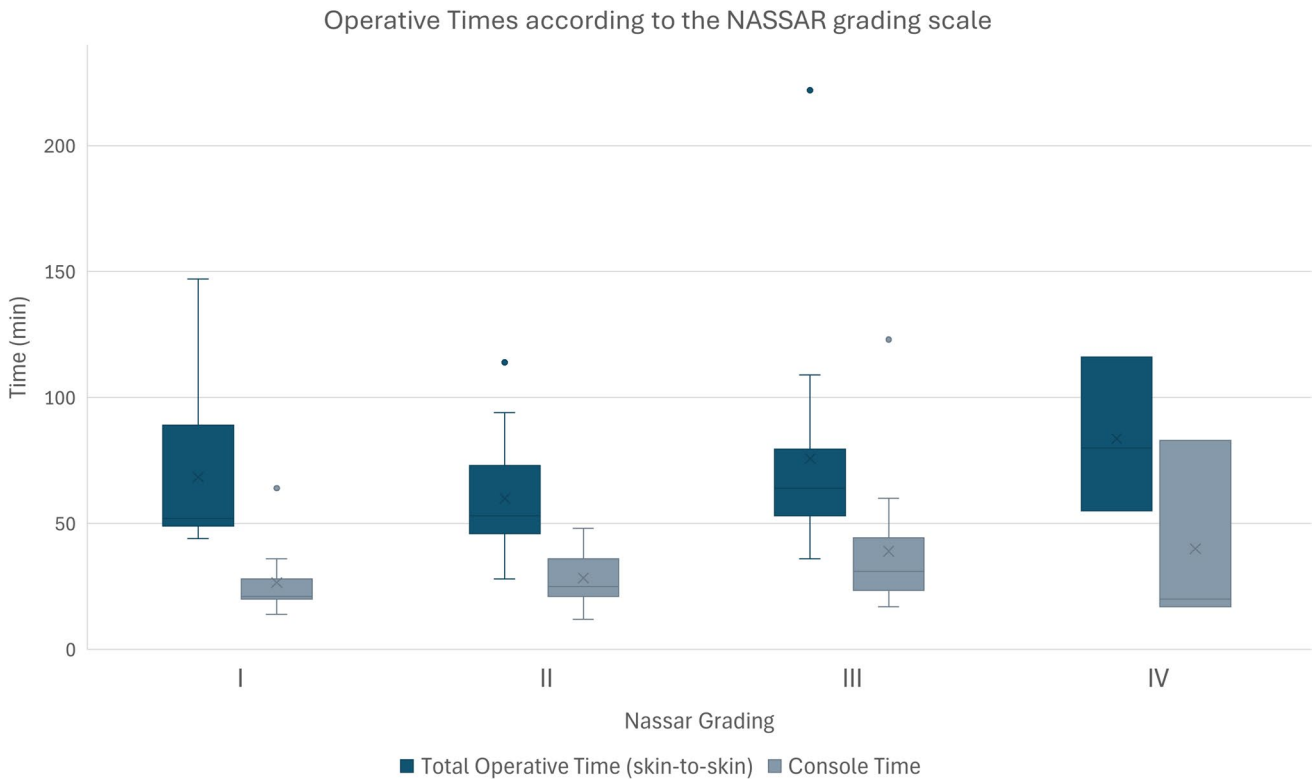

Fig. 3 Correlation between the Nassar grade and operative times

remainder of the cystic duct. The condition resolved within three days and without sequelae.

Discussion

Our findings indicated that robotic-assisted surgery with DEXTER® is a safe and effective approach for treating gallbladder disease, including cases with important inflammation. The DEXTER® system enabled a simple set-up process with a standard and familiar port placement and efficient docking of the robotic arms. The performance of the system and bedside access afforded by the sterile console enabled surgeons to perform simple cases with three ports and enabled completion of all procedures without conversion to open surgery, suggesting a similarly invasive and potentially safer alternative to the conventional laparoscopic technique, which has reported conversion rates ranging from 0.1 to 9.7% [15, 16].

Major complication rates reported in the literature for robotic-assisted Cholecystectomies range from 0 to 10%, depending on surgical difficulties and patient comorbidities [17–21]. One major complication (Clavien-Dindo IIIa) occurred in our study population, representing a major complication rate of 2%. We did not observe any bile duct injury or bile leaks in our sample. One patient experienced postoperative passage of retained stones from the cystic duct. In this case, an ECRP was performed nine weeks before the surgery due to choledocholithiasis. Subsequently and up to the operation, the patient did not present any suspicion of retained stones. Therefore, no intraoperative cholangiography was planned as is in line with the SAGES-guidelines [2]. The cystic duct was short and of small caliber, and it was palpated for stones before applying the clips and no stones were found. Postoperatively, we noted an increase in liver enzymes and bilirubin and accordingly interpreted the situation as a passage of stones from the cystic duct during or directly after the surgery. This adverse event was not related to the use of the DEXTER® device. This phenomenon has been reported in approximately 1.8% of patients following laparoscopic cholecystectomy [22]. However, postoperative choledocholithiasis is not directly linked to the specific cholecystectomy technique; rather, it is a general potential complication. Considering the various levels of experience with robotic surgery and with DEXTER® used for cholecystectomy in particular, our study revealed a very safe performance compared with that of other robotic platforms reported in the literature [17, 18, 21, 23, 24].

Laparoscopic cholecystectomy encompasses a wide spectrum of technical difficulties. When performed by surgeons using a standard technique, most procedures are relatively routine and uncomplicated and are typically completed

within an hour. However, certain operative findings can hinder various steps of the operation and present significant surgical challenges, increasing its complexity and leading to a higher incidence of adverse outcomes [25–27]. LC is also the leading cause of bile duct injury, which predominantly occurs when the procedure is complicated by inflammation or scaring [25]. In our study, there was no report of any bile duct injury, even in more complicated cases of Nassar grade IV cholecystectomies.

The Nassar scale is a validated tool to compare operative complexity, and previous studies have demonstrated that higher Nassar grades—particularly grade IV—are linked to increased operative complexity, longer surgical times, higher complication rates, and a greater likelihood of conversion to open surgery [28, 29]. In our study, the majority of cases were classified as grade II and one-third was classified as grades III and IV. This distribution mirrors the spectrum of clinical presentations typically encountered in both ambulatory and inpatient settings, supporting the relevance and potential generalizability of our findings to the population of patients operated on in both settings. In line with expectations, increasing Nassar grades were associated with longer operative and console times in our cohort.

Laparoscopic cholecystectomy is conventionally performed using four laparoscopic ports. Despite the observed benefits of the standard four-port technique, numerous efforts have been made to further minimize the invasiveness of LC by decreasing the number of ports, aiming to decrease postoperative pain and the need for analgesia [30, 31]. The three-port technique has also been associated with shorter operative times, as well as reduced postoperative complications and hospital stays, compared to the four ports, mini laparotomy or single-incision cholecystectomy [32]. In our study, one participating surgeon utilized the three-port technique without the need for an ancillary port. This was facilitated by the DEXTER® sterile console and laparoscopy mode feature, which enabled the surgeon to push a button on the system to retract the robotic arms, providing ample bedside working space and enabling laparoscopic access through a robotic port as needed (e.g., for clip application). By pressing the robotic mode button on the system, the surgeon was then able to quickly return the robot arms to their original position, without redocking, to resume robotic surgery. The majority of surgeons participating in our study, however, preferred the use of an ancillary port reserved for the bedside assistant. This was easily accomplished given the compact physical size of DEXTER®, which provided significant space around the patient and an unobstructed view of the surgical site.

Other studies have reported the feasibility and safety of robotic-assisted cholecystectomy with various robotic systems [17, 18, 21, 23, 33]. Median skin-to-skin operative time varies from 55 to 92 min [18, 19, 22], and conversion to open surgery was rare [21, 24]. Conversion to laparoscopy was frequently reported with these systems, occurring in up to 10% of cases in some studies [17, 23] and sometimes attributed to device-related limitations [21]. Our results are consistent with findings from other teams using modular robotic systems and ultimately demonstrated improved performance with DEXTER®, especially showing a lower conversion rate to laparoscopy.

Outpatient laparoscopic Cholecystectomy was first promoted in 1990 by Reddick and Olsen [34]. Since then, outpatient procedures have gained traction globally due to its benefits, including shorter hospital stays, reduced costs, and enhanced patient experience [35]. Studies addressing postoperative complication rates consistently found no significant difference between outpatient and inpatient procedures [36]. Although outpatient LC has been established in several countries for years [37], in Germany and Switzerland it continues to be performed primarily on an inpatient basis due to reimbursement policies. With the progressive ambitions for more outpatient care across many healthcare systems, outpatient cholecystectomies will likely increase, ultimately shifting toward ASCs [38]. However, the cost of robotic Cholecystectomy using traditional robotic systems remains up to 2.5 times higher than that of conventional LC [39, 40] and there is a significant need for an alternative system that offers a more cost-effective robotic approach and can be easily integrated into any types of OR. The mobile and compact design of DEXTER® makes it well suited for any site of care, including ambulatory settings, and its compatibility with existing OR technologies and workflows makes it an effective alternative to other robotic systems. In our study, where half of the patients were discharged within 24 h after the surgery, we demonstrated that outpatient cholecystectomy can be safely and efficiently performed with DEXTER®.

We conducted a prospective, multicenter study on the use of DEXTER® for cholecystectomy. The study however has several limitations. The single-arm design lacked a control group, and comparisons were made to data reported in the literature, which is generally based on retrospectively collected data. The relatively small sample size of 51 patients limited generalisability and the short follow-up period limited analysis to early postoperative outcomes. Larger, randomized studies with longer follow-up times are needed. Differences in surgeons' prior experience with DEXTER® also influenced the results, particularly impacting console time. Further research should analyze larger datasets from surgeons who routinely use DEXTER® to strengthen conclusions on the safety and clinical performance of this modular robotic platform, as well as to assess the cost-effectiveness of its flexible design.

In conclusion, this study demonstrated that the DEXTER® Robotic Surgery System enables safe and

effective cholecystectomy in a non-emergent setting, including in outpatient surgery.

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Declarations

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