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Initial Experience with a new laparoscopic based robotically assisted surgical system for cholecystectomy

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INTRODUCTION

A laparoscopic approach to cholecystectomy was introduced in the late 1980s and very quickly was established as a feasible alternative to open cholecystectomy [1]. Today, laparoscopic cholecystectomy is the gold standard of care for symptomatic cholelithiasis [2]. Usually, laparoscopic cholecystectomy is performed through 4 small incisions, however single incision laparoscopic surgery (SILS) has also been demonstrated to be safe [3].

Cholecystectomy performed robotically via the da Vinci Surgical System (Intuitive Surgical Inc., Sunnyvale, CA, USA) has been described using a multi-port system [4] and a single port system [5]. Robotic surgery addresses many limitations of laparoscopy including enhanced dexterity, ergonomics and visualization [6]. However, disadvantages include added time per case and increased cost [7].

The Senhance™ surgical robotic system, previously known as Telelap Alf-X (TransEnterix, Morrisville,
NC, USA) has recently become available in the UK. It aims to provide the robotic benefits of greater accuracy, dexterity and control with similar operational costs to traditional laparoscopy [8].

The device is a multi-port system with independent robotic arms that replicate familiar laparoscopic instrument motion. These arms are controlled from a console where the primary surgeon sits (fig 1). The console provides the surgeon with 3D-HD vision on the screen, as well as an infrared eyetracking system that enables the surgeon to control the movement of the laparoscopic camera by
focusing their gaze on different areas of the monitor. The surgeon receives haptic force feedback through the handles in the console, restoring the tissue reaction forces experienced in standard laparoscopy.

The system utilizes reusable instruments that are similar to standard 5mm laparoscopic instruments with very minimal disposables. This design allows for the use of standard off the shelf trocars and commercially available accessories such as electrosurgical units.

The first clinical experiences in gynecological surgery [9-12] and colorectal surgery [13] were recently
published demonstrating that the system was feasible and safe. To date, no data have been published about the use of Senhance™ on cholecystectomy.

This research describes the initial, single surgeon experience evaluating feasibility and safety of Senhance™ to perform cholecystectomy. The technique is described including robotic arm and port placement. Clinical outcomes and operative times of the first 20 cases performed at the center are described. These results are compared to a concurrently collected group of patients undergoing cholecystectomy using a standard four port laparoscopic technique.

Materials and Methods

Robotic set up

The Senhance™ Surgical System (shown in Figure 1) has up to four independent manipulator arms that can be positioned around the operating table. For this series, only three arms were used and positioned around the operating room table as shown in Figure 2. We altered our traditional port placement slightly and used a 12mm trocar at the umbilicus for the camera, a 12mm trocar in the left upper quadrant and a 5mm trocar in the right upper quadrant of the abdomen in order to avoid interference of the manipulator arms. A further 5mm trocar was inserted laterally in the right flank for manual retraction of the gallbladder fundus (see Fig 3).

The Senhance™ System has a selection of standard laparoscopic instruments and in this series a 310mm L hook monopolar electrode was used in the right port and a grasper in the left for the majority of the operation. A LigaMAXä5 (Ethicon, Somerville, NJ, USA) clip applier was deployed by
the assistant surgeon at the bedside through the left port to clip the cystic duct and artery. Figure 3 shows the port placement used in this series.

Patient recruitment and data analysis

Patients received either a standard laparoscopic cholecystectomy or the Senhance™ assisted cholecystectomy based on scheduled surgery date. A prospectively maintained database of the first 20 patients undergoing cholecystectomy with the Senhance™ Surgical System was retrospectively

interrogated and compared to a concurrently treated group of 20 laparoscopically treated patients during a similar timeframe performed by the same surgeon and theatre team.
The Senhance™ Surgical System was passed through the new interventional procedures committee (NIPCOM) at the hospital and was sanctioned for use in a clinical environment. Formal ethical approval was not required for this pilot study.
All patients were consented for surgery and for inclusion of their data into the hospital database. All patients were scored for anesthesia score by the attending anesthesiologist. The technical difficulty of each operation was graded (scale 1-3) by the consultant in accordance with predefined criteria as described in [14]. All operations were performed by a single surgeon (SP) and the same team at a central London teaching hospital. The surgeon has performed over 1000 laparoscopic cholecystectomies with only one converted to open during his career.
Surgery duration was collected as both total operative time and console time (Senhance™ cohort only). By subtracting out console time from the total operative time, the efficiency of the operating theatre staff could be assessed. Console time is the surrogate for primary surgeon learning curve. Other operative details were collected including BMI of the patient, estimated blood loss (EBL) as well as any adverse events.
All patients were reviewed in clinic 7 days post operatively and were monitored remotely for up to 30 days to collect complication data.
These methods are further described on the clinicaltrials.gov website (reference number NCT03380572).
Data is summarized using standard summary statistics. For continuous data, results are summarized using mean and standard deviation if data are found to be normal via the Shapiro-Wilk test (p-value greater than 0.05). Otherwise median and interquartile (IQR) range are presented. For normally distributed data, the mean difference between cohorts and 95% confidence interval were assessed. Categorical data is summarized using counts and percentages. Reported differences between cohorts and associated 95% confidence intervals are based on exact methods. The data was analyzed using SAS software (SAS Institute, Cary, NC) Version 9.4.