

Program # : P010

ROBOTIC MINIMALLY INVASIVE INGUINAL HERNIA REPAIR WITH THE DEXTER ROBOTIC SYSTEM™: A PROSPECTIVE MULTICENTER CLINICAL INVESTIGATION

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Introduction

The Dexter robotic system is a versatile platform that provides all the dexterity, precision and ergonomic advantages of surgical robotics in a small, modular, and simple format (Fig 1) - all while fully integrating into laparoscopic workflows as the surgeon can use the robot while remaining sterile.

This clinical investigation was conducted to confirm the perioperative and early postoperative safety and effectiveness of the Dexter system.

Study design

A single-arm, prospective, multicenter, open-label clinical investigation was conducted in France, Germany and Switzerland. Three surgeons recruited 50 patients undergoing primary transperitoneal unilateral or bilateral inguinal hernia repair. The patients were followed up for a period of 30 days postoperatively.

Surgical technique

- Patients placed in a supine position at a 15° Trendelenburg angle.
- Three standard 10/12 mm transparent Trocars positioned at umbilical level for the camera port and for the robot working arms at each sides of the abdomen, 8-9cm from the umbilical line (Fig. 2).
- Robot set up in the OR (Fig 3).
- Inguinal hernia repair performed with the TAPP technique (Video – Fig 4).

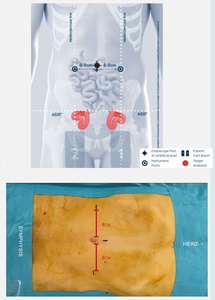


Figure 2 : Trocars placement

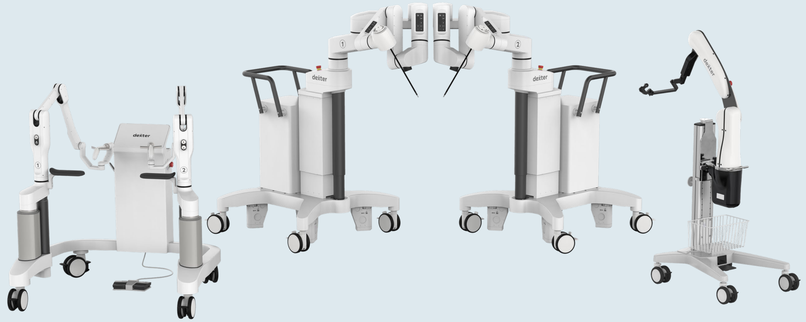


Figure 1 : The Dexter Robotic System : from left to right : open surgeon console, two patient carts with robotic instrument arms and the endoscope arm

Results

Table 1 Patient characteristics (N=50)

Parameter	Value
Age (years), mean ± SD	60.1 ± 15.2
BMI (kg/m2), mean ± SD	25.7 ± 3.3
Gender (male/female)	47/3 (94%/3%)
ASA Score	
I	26.0% (13/50)
II	66.0% (33/50)
III	8.0% (4/50)
Ethnicity*	
Asian (%, n/N)	0.0% (0/50)
Black or African-American (%, n/N)	2.0% (1/50)
White/Caucasian (%, n/N)	58.0% (29/50)
Unspecified (%, n/N)	40.0% (20/50)
Hernia	
Unilateral (n)	33
Bilateral (n)	17
Right/left	38/29
Number of patients per surgeon	20/20/10

*Sensitive data not documented in France (n=20)

Table 2 Safety and effectiveness outcomes

Parameter	Value
Conversion to open, n (%)	0 (0)
Conversion to LAP, n (%)	1 (2)
Operative time (skin-to-skin) (min), mean ±SD	
Unilateral	54.5 ± 14.2
Bilateral	94.6 ± 22.2
Console time (min), mean ±SD	
Unilateral	34.4 ± 11.6
Bilateral	68.3 ± 20.7
Docking time (min), mean ±SD	4.2 ± 2.0
Length of Hospital stay (days), mean ± SD	0.5 ± 0.6
Same day discharge, n (%)	26 (52%)
Return to activities (days), mean ± SD	8.1 ± 8.3
Estimated Blood Loss (mL), mean ± SD	5.5 ± 7.3
Intraoperative complications, n (%)	0 (0)
Adverse Events (30 days), n (%)	12 (24%)
Clavien-Dindo (C-D) Classification	
Grade I	11
Grade II	1
Grade III - V	0
Mortality n (%)	0 (0)

OR Set up and r-TAPP video

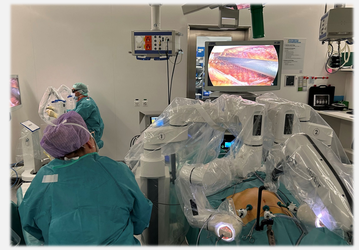


Figure 3 : The sterile surgeon is operating from the surgeon console. Dexter's robot arms are placed on each side of the operating table and the endoscope arm near the head of the patient. The scrub nurse is the only assisting operator.

Figure 4 : Video of r-TAPP procedure with Dexter

Discussion

None of the adverse events were device related and the postoperative complications were generally mild (C-D I-II). No serious (C-D III-V) complications occurred.

One patient was readmitted due to a small intestine occlusion with possible adhesion in the right iliac fossa. The event had resolved without sequelae at the 30 day follow up.

The only conversion to laparoscopic surgery was due to non-optimal placement of the trocars, limiting access to the surgical area.

Due to the lack of reimbursement of the surgical procedure in Europe, some patients remained hospitalized at least one night to ensure sufficient coverage.

Dexter was simple to use and, as shown in the OR set up, no assistant surgeon was present for the procedure.

Conclusion

This experience with robotic TAPP using the Dexter system confirms its safety and effectiveness for primary unilateral or bilateral inguinal hernia repair.

The Dexter robotic system is a simple and accessible device providing robotic excellence for the treatment of inguinal hernias.

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