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ORIGINAL ARTICLE

Initial experience using a robotic-driven laparoscopic needle holder with ergonomic handle: assessment of surgeons' task performance and ergonomics

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Abstract

Purpose The objective of this study is to assess the surgeons' performance and ergonomics during the use of a robotic-driven needle holder in laparoscopic suturing tasks.

Methods Six right-handed laparoscopic surgeons with different levels of experience took part in this study. Participants performed a set of three different intracorporeal suturing tasks organized in ten trials during a period of five weeks. Surgeons used both conventional (Conv) and robotic (Rob) laparoscopic needle holders. Precision using the surgical needle, quality of the intracorporeal suturing performance, execution time and leakage pressure for the urethrovesical anastomosis, as well as the ergonomics of the surgeon's hand posture, were analyzed during the first, fifth and last trials.

Results No statistically significant differences in precision and quality of suturing performance were obtained between both groups of instruments. Surgeons required more time using the robotic instrument than using the conventional needle holder to perform the urethrovesical anastomosis, but execution time was significantly reduced after training ($p < 0.05$). There were no differences in leakage pressure for the anastomoses carried out by both instruments. After training, novice surgeons significantly improved the ergonomics of the wrist ($p < 0.05$) and index finger (Conv: $36.381° \pm 3.587°$, Rob: $30.389° \pm 4.100°$; $p = 0.024$) when using the robotic instrument compared to the conventional needle holder.

Conclusions Results have shown that, although both instruments offer similar technical performance, the robotic-driven instrument results in better ergonomics for the surgeon's hand posture compared to the use of a conventional laparoscopic needle holder in intracorporeal suturing.

Keywords Laparoscopic surgery · Robotic-driven needle holder · Suturing checklist · Ergonomics · Data glove

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Introduction

The constant evolution of laparoscopic surgery has meant a great shift in surgery and its numerous benefits to patients have long since been described [1–3]. However, this surgical approach entails certain technical limitations for surgeons such as the restriction of movements mainly due to the fixed position of the surgical ports. This lack of maneuverability causes the adoption of awkward body postures for long periods of time. This affects the surgeon's ergonomics, increasing the possibilities of suffering from musculoskeletal disorders [4–6].

Several solutions have been created to address the ergonomic issues in laparoscopic surgery, mainly new designs for instrument handles and support systems for surgeons such as surgical chairs and armrests [7–9]. Recently, new handheld robotic devices, controlled by electromechanical technology, have been developed in order to overcome some of the above-mentioned technical limitations for laparoscopic surgeons [10–12]. Most of these devices provide new handle designs and functionalities to improve the instrument triangulation, the range of movement and the surgeon's ergonomics. However, there is limited literature validating the effectiveness of these new devices in laparoscopic practice as well as demonstrating the actual improvement of the ergonomic conditions for surgeons. An example of these is the DEX™ system (Dextérité Surgical, France), which is a robotic-driven needle holder with an ergonomic handle and a flexible tip designed to enhance the surgeon's dexterity and ergonomics in laparoscopic surgery. The aim of this study is to objectively assess the surgeon's technical performance and ergonomics while using this robotic needle holder in laparoscopic suturing. To the best of our knowledge, the present study is the first to describe and objectively evaluate the use of the DEX^{TM} system during laparoscopic practice.

Material and methods

Participants

Six right-handed surgeons took part in this study. Three of them were experienced surgeons in laparoscopic surgery ($>$100 laparoscopic procedures), and the other three novice surgeons ($<$10 laparoscopic procedures). They performed a set of intracorporeal suturing tasks in a box trainer. Participants carried out the tasks using both a conventional laparoscopic needle holder (Conv) and the robotic-driven needle holder (Rob). The instrument (conventional or robotic) to start each trial was randomized. Participants gave informed consent and voluntarily agreed to be included in the study.

Robotic-driven needle holder

The robotic instrument is a motor-driven laparoscopic needle holder (DEX^{TM}, Dextérité Surgical, France), which consists of a console, a wired ergonomic handle and a flexible tip with unlimited rotation. The flexion and rotation of the instrument tip are controlled by an interface on the handle. The instrument handle is a grip-type handle, which is connected by a mechanical joint to the instrument shaft. This grants surgeons greater freedom of movements since the handle works independently from the shaft, which helps avoid forced movements of the wrist. This device provides seven degrees of freedom in comparison with the four degrees of freedom offered by most of the traditional laparoscopic instruments.

Tasks

Participants completed a set of three different intracorporeal suturing tasks organized in ten trials during a period of five weeks. All tasks were accomplished on a validated laparoscopic simulator (SIMULAP®; JUMISC, Spain), with a 10-mm, 30° rigid laparoscope (Olympus, Tokyo, Japan) as vision system. The laparoscopic camera was fixed to prevent movements and changes in the surgical instruments (Fig. 1). The trials were divided in seven training trials and three evaluation trials. The evaluation trials corresponded to the first, fifth and tenth sessions. During the training trials, participants performed a precision task and a suturing task on organic tissue. The evaluation trials also included an urethrovesical anastomosis. The precision task consisted of passing a suture needle through a set of four pair of entry and exit dots marked on a training plate with both vertical and horizontal orientations (Fig. 2). The suturing task consisted of performing three intracorporeal sutures on an ex vivo porcine stomach (Fig. 3). Participants were asked to carry out one double knot followed by two simple knots in opposite directions. The urethrovesical anastomosis was performed on an ex vivo porcine bladder using eight simple interrupted sutures (Fig. 4). For all tasks, surgeons used a Maryland laparoscopic dissector (Richard Wolf GmbH, Knittlingen, Germany) on the left hand. On the right hand, they used a straight laparoscopic needle holder (Karl Storz GmbH & Co. KG) or the robotic needle holder (Fig. 1). All tasks were performed using 2-0 Vicryl sutures.

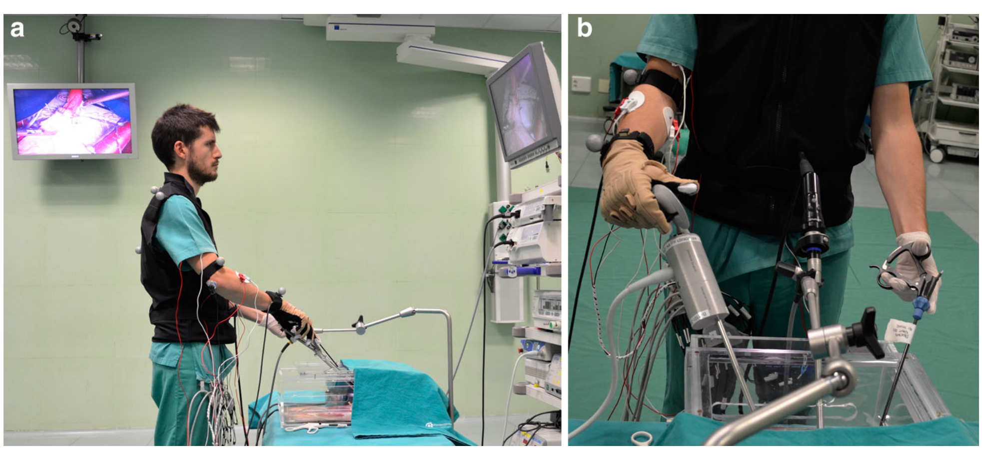

Fig. 1 Experimental setup for the study. Tasks are performed using both the conventional (**a**) and robotic (**b**) needle holders

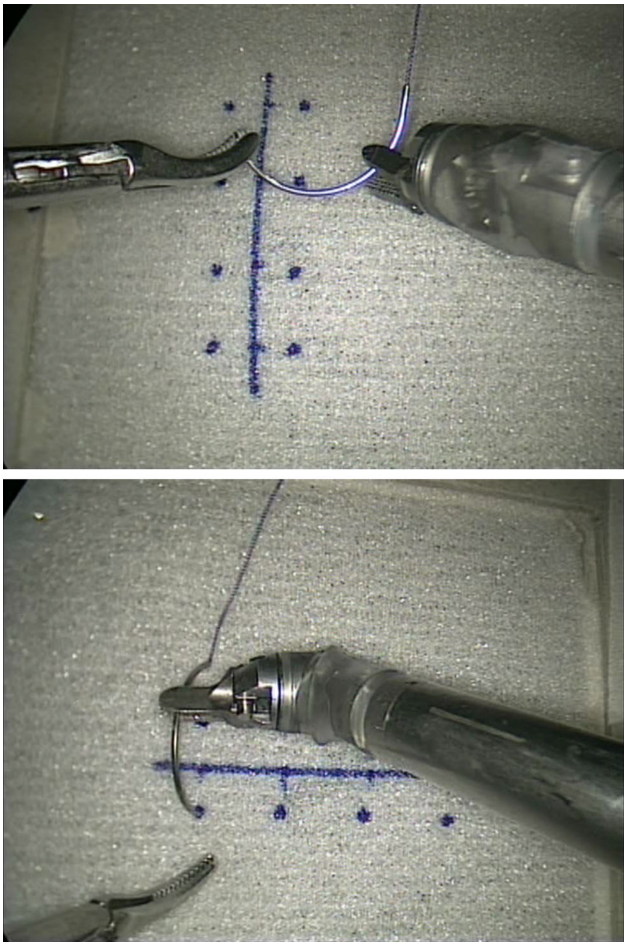

Fig. 2 Precision task performed using the robotic needle holder. The stitches are carried out following horizontal (*top*) and vertical (*bottom*) orientations

Assessment

The evaluation measures were recorded during the first (T1), fifth (T5) and last (T10) repetitions. Execution time was recorded for each task. For the precision task, the precision in using the surgical needle was manually assessed by measuring the distance between the entry and exit points of the needle and the center of the targets using the ImageJ analysis software [13]. For the suturing task, the suturing performance of each knot was assessed by means of a validated suturing-specific checklist [14]. Two experienced surgeons scored the suturing tasks of each subject. Both surgeons were blinded to their respective findings, as well as to the identity and experience level of each subject. The ergonomic assessment was carried out during the urethrovesical anastomosis. The surgeon's posture of the right hand was analyzed using a data glove. Furthermore, a leakage test was performed to assess the integrity of the urethrovesical anastomosis. To do this, after immersing the bladder in a water tank, the pressure at which air leaked from the anastomosis area was recorded using an insufflator (Karl Storz GmbH & Co.KG) connected to the end of the urethra. The maximum pressure was set at 30 mmHg.

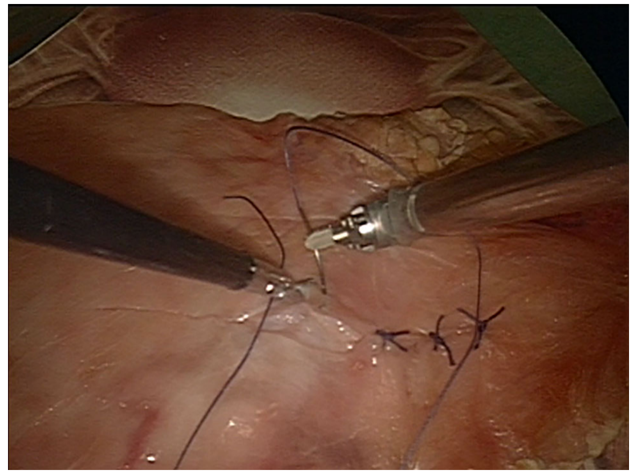

Fig. 3 Use of the robotic needle holder during the intracorporeal suture performed on organic tissue

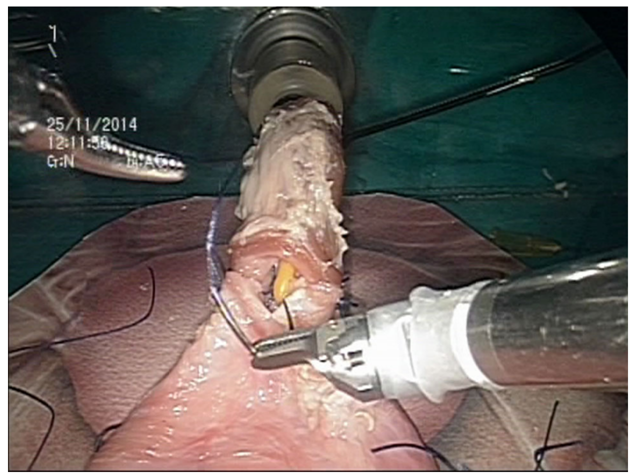

Fig. 4 Use of the robotic instrument during the urethrovesical anastomosis performed on an ex vivo porcine model

Data glove

The motion analysis of the surgeon's hand was performed using a data glove (CyberGlove®; Cyber Glove Systems, USA) (Fig. 1). This device consists of a set of conductive sensors capable of perceiving flexion variations. These sensors record the movements of the fingers and wrist. For this study, the motion of the thumb (sensors 1 and 2), index finger (sensors 4 and 5), middle finger (sensors 11 and 7), and wrist (sensor 16) were analyzed. The separation between the thumb and index fingers (sensor 0) and that between the index and middle fingers (sensor 8) were also evaluated. The device was calibrated in accordance with the morphological features

Table 1 Adaptation of the RULA method for the flexion–extension of the wrist

Score	Position
1	If the flexion–extension angle is $0° \pm 3°$ (the forearm and hand are aligned)
2	If the flexion–extension angle is between 15° and −15°, except for the score 1 case
3	If the flexion–extension angle is more than 15° or less than −15°

of each surgeon's hand. Data were registered at 100 samples per second.

The raw data from the data glove were analyzed using a custom-made software (ErgoStatistics®; CCMIJU, Spain) [15]. Since the software is designed to process the data by blocks or events, data records were organized in blocks of 5 minutes. The angle between the hand and the forearm was used as a reference to evaluate the ergonomics of the wrist posture. The ergonomic risk level was determined by applying a modified RULA (Rapid Upper Limb Assessment) method [5]. Risk values were classified according to the wrist angle (Table 1). A score between 1 and 2 was considered an ergonomically acceptable flexion–extension of the wrist, and a score of 3 was considered inappropriate.

Statistical analysis

For statistical analysis, the Wilcoxon signed-rank test was used to compare the surgeons' performance and hand posture of both study groups. All statistical analyses were carried out using R version 3.2.2 (R Foundation for Statistical Computing, Vienna, Austria). The results are shown as mean and standard deviation and notched box and whisker plots. For all tests, $p < 0.05$ was considered statistically significant. Cronbach's alpha test was used to measure the extent of agreement between the two raters using the suturing checklist (inter-examiner reliability). A value of alpha equal to 0.8 was considered as the threshold for good reliability.

Results

Task performance

No statistically significant differences in precision were shown for the novice surgeons using both surgical instruments (Fig. 5). During the first repetition, experienced surgeons obtained significantly higher precision using the conventional needle holder for the stitches with vertical orientation (Conv: 0.421 ± 0.214 mm; Rob: 0.931 ± 0.485 mm). However, during the fifth and last repetitions, no statistically significant differences were shown using both needle holders.

The inter-examiner reliability was 0.848 for the evaluation using the suturing checklist. Surgeons showed no

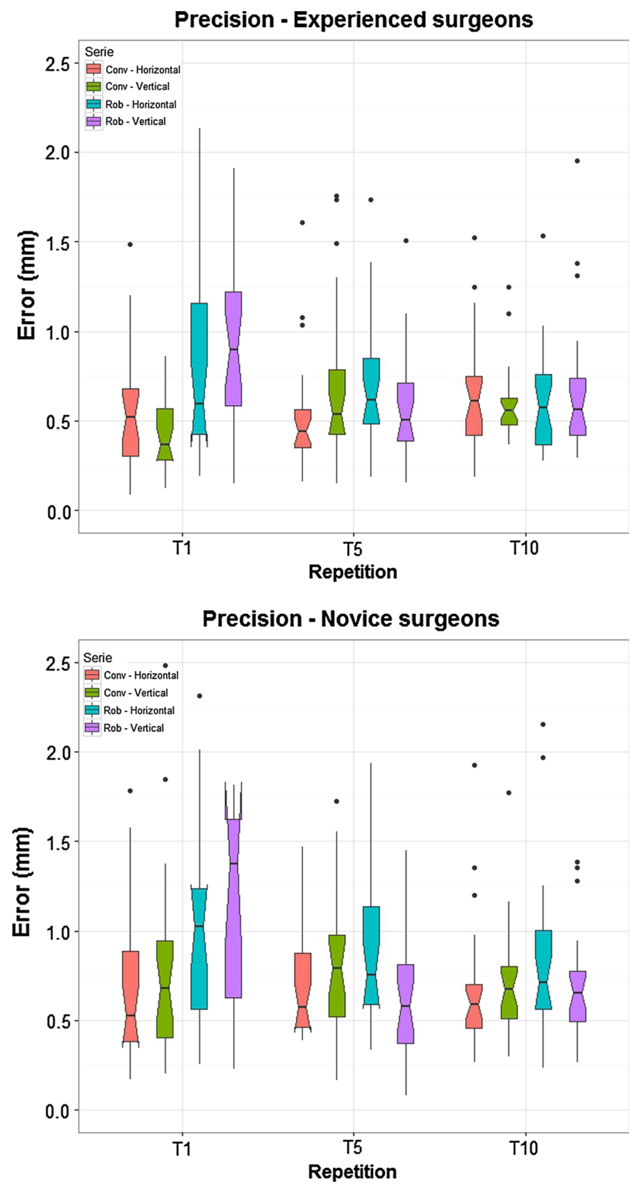

Fig. 5 Precision errors obtained for the group of experienced surgeons (*top*) and the group of novice surgeons (*bottom*) driving the surgical needle with the conventional (Conv) and robotic (Rob) laparoscopic needle holders. Stitches were performed with vertical and horizontal orientations. Results are shown for the first (*T1*), fifth (*T5*) and last (*T10*) repetitions of the precision task. Results are presented as notched box plots, in which every notched box has a line marking the lower, median and upper quartile values. *Whiskers* represent the extent of the remaining data, *with dots* showing the outliers. The boxes whose notches do not overlap are significantly different ($p < 0.05$)

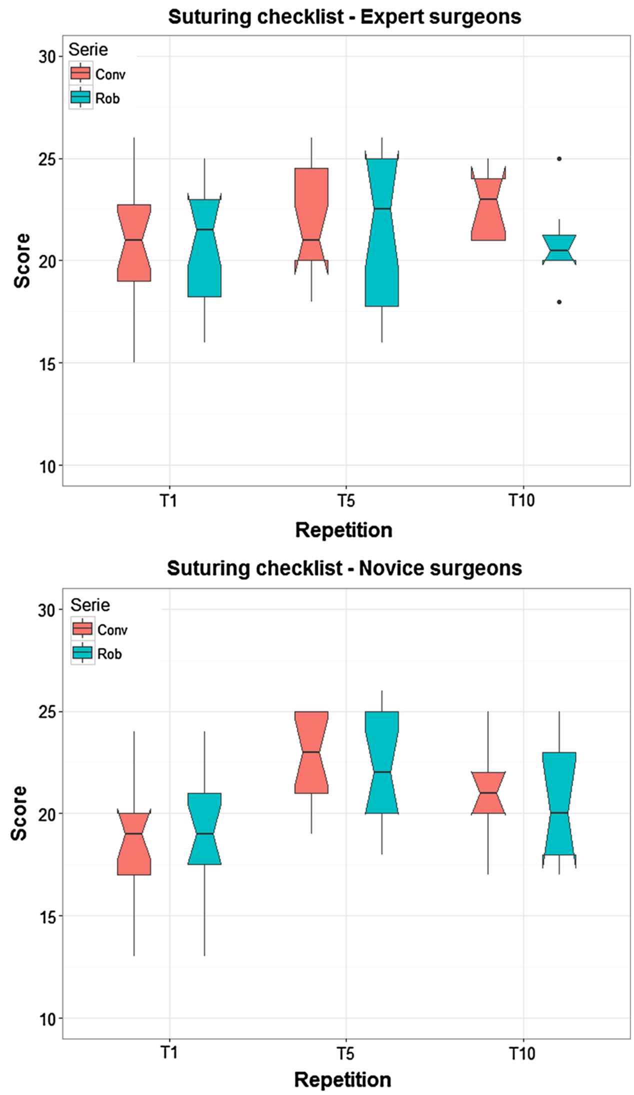

Fig. 6 Checklist score obtained for the group of experienced surgeons (*top*) and the group of novice surgeons (*bottom*) during the performance of the intracorporeal sutures with the conventional (*Conv*) and robotic (*Rob*) laparoscopic needle holders. Results are shown for the first (*T1*), fifth (*T5*) and last (*T10*) repetitions of the suturing task. Results are presented as *notched box* plots, in which every notched box has a line marking the lower, median and upper quartile value. *Whiskers* represent the extent of the remaining data, *with dots* showing the outliers. The boxes whose notches do not overlap are significantly different ($p < 0.05$)

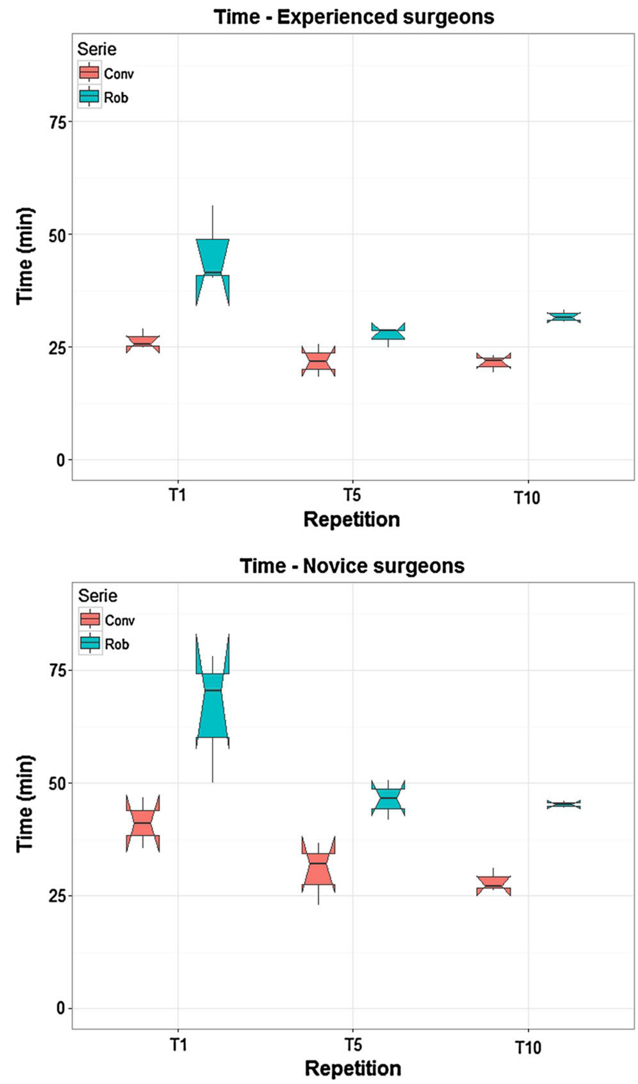

Fig. 7 Time required to perform the urethrovesical anastomosis by the group of experienced surgeons (*top*) and the group of novice surgeons (*bottom*) using the conventional (*Conv*) and robotic (*Rob*) laparoscopic needle holders. Results are shown for the first (*T1*), fifth (*T5*) and last (*T10*) repetitions of the task. Results are presented as *notched box* plots, in which every notched box has a line marking the lower, median and upper quartile values. *Whiskers* represent the extent of the remaining data, with dots showing the outliers. The boxes whose notches do not overlap are significantly different ($p < 0.05$)

significant differences in technical performance for the intracorporeal sutures carried out with both the conventional and robotic needle holders (Fig. 6). Novice surgeons significantly improved the suturing performance using the conventional needle holder during the fifth repetition compared to the first repetition. This was mainly due to a significant improvement in the needle positioning and driving.

Surgeons required more time using the robotic instrument than using the conventional needle holder to perform the urethrovesical anastomosis (Fig. 7). They significantly reduced the execution time using the robotic instrument between the fifth and the first repetitions, and between the last and the first repetitions. Novice surgeons also significantly reduced the execution time for the anastomosis using the conventional needle holder between the last and the first repetitions.

The number of anastomoses with a leakage pressure below 30 mmHg was higher using the robotic needle holder, with a 66.67% of total leakage rate. However, no statistically significant differences in leakage pressure were obtained for the urethrovesical anastomoses performed with both the conventional and robotic needle holders.

Table 2 Average posture of the experienced surgeons' fingers during the urethrovesical anastomosis

Sensor	Repetition	Conv	Rob	p
Thumb (sensor 1)	T1	65.305 ± 18.351	79.835 ± 14.976	0.062
	T5	71.196 ± 25.468	81.846 ± 16.050	0.250
	T10	80.763 ± 8.643	85.292 ± 7.322	0.880
Thumb (sensor 2)	T1	42.667 ± 19.006	39.584 ± 9.142	0.840
	T5	64.741 ± 33.902	43.970 ± 29.251	0.220
	T10	67.464 ± 32.731	50.336 ± 23.836	0.074
Index (sensor 4)	T1	58.489 ± 12.321	63.594 ± 17.113	0.950
	T5	64.213 ± 10.956	60.589 ± 16.162	0.460
	T10	60.128 ± 11.163	61.553 ± 6.973	0.990
Index (sensor 5)	T1	63.006 ± 19.584	54.226 ± 11.288	0.430
	T5	67.052 ± 15.637	61.119 ± 10.323	0.310
	T10	59.185 ± 17.175	56.411 ± 6.068	0.910
Middle (sensor 11)	T1	54.775 ± 20.066	67.943 ± 7.177	0.160
	T5	62.116 ± 17.147	59.495 ± 11.549	0.840
	T10	68.131 ± 19.701	69.345 ± 15.116	0.910
Middle (sensor 7)	T1	36.697 ± 14.117	37.377 ± 5.854	0.990
	T5	35.790 ± 9.293	35.136 ± 5.846	0.840
	T10	**37.763 ± 13.681**	**31.034 ± 6.803**	**0.045**
Separation (sensor 0)	T1	49.068 ± 31.772	63.800 ± 31.306	0.560
	T5	53.998 ± 32.898	46.504 ± 31.284	0.750
	T10	55.487 ± 30.685	40.662 ± 22.032	0.590
Separation (sensor 8)	T1	17.477 ± 11.393	13.320 ± 5.789	0.360
	T5	21.943 ± 17.767	17.807 ± 6.336	0.550
	T10	20.313 ± 11.008	19.250 ± 9.253	0.910

Results show the degrees of flexion of each data glove's sensor for the three repetitions of the task while using the conventional needle holder (Conv) and the robotic instrument (Rob). Statistically significant values are marked in boldface

Ergonomic assessment

Regarding the analysis of the surgeon's hand posture during the performance of the urethrovesical anastomosis, there were no statistically significant differences for the group of experienced surgeons using both surgical instruments, except for the proximal interphalangeal joint of the middle finger. During the last repetition, this joint was significantly less flexed using the robotic instrument (Table 2). After training, novice surgeons had a significantly higher flexed posture of the metacarpophalangeal joint of the thumb using the robotic instrument compared to the use of the conventional needle holder. Moreover, the metacarpophalangeal joint of the index finger and the proximal interphalangeal joints of the index and middle fingers were significantly less flexed using the robotic needle holder. The separation between the index and middle fingers was also significantly lower using the robotic device (Table 3).

After training, the use of the robotic instrument led to a significant less flexion of the wrist than using the conventional laparoscopic needle holder (Fig. 8). According to the ergonomic risk score attributed by the RULA method, the surgeon's wrist posture using the robotic instrument was classified as ergonomically acceptable during the last repetition. On the contrary, surgeons' wrist was significantly more flexed using the conventional needle holder, leading to an ergonomically inappropriate posture.

Discussion

Laparoscopic surgery implies some technical limitations for surgeons, mainly regarding the freedom of movements during surgery. These restrictions often lead surgeons to adopt awkward postures over long periods of time, increasing the risk of musculoskeletal injuries [4,5,16]. New robotic-driven devices have been introduced in the market trying to overcome some of these limitations [10,12,17]. In this study, the DEX^{TM} motor-driven laparoscopic needle holder (Dextérité Surgical, France) has been analyzed. Surgeon's technical performance and ergonomics haven been assessed during its use in different laparoscopic suturing tasks by means of image analysis, a suturing-specific checklist and a data glove. Results showed that the use of this robotic instrument led

Table 3 Average posture of the novice surgeons' fingers during the urethrovesical anastomosis

Sensor	Repetition	Conv	Rob	p
Thumb (sensor 1)	T1	44.240 ± 3.272	51.939 ± 5.948	0.250
	T5	**68.995 ± 18.268**	**76.263 ± 17.641**	**0.001**
	T10	**66.489 ± 17.932**	**80.505 ± 21.300**	**0.016**
Thumb (sensor 2)	T1	74.198 ± 17.871	69.404 ± 22.073	0.110
	T5	86.209 ± 6.324	86.635 ± 7.545	0.840
	T10	77.270 ± 15.295	81.056 ± 14.771	0.120
Index (sensor 4)	T1	**72.297 ± 12.229**	**61.187 ± 11.808**	**0.007**
	T5	78.539 ± 11.040	73.799 ± 6.826	0.067
	T10	**66.281 ± 16.119**	**58.813 ± 17.785**	**0.042**
Index (sensor 5)	T1	**71.550 ± 3.191**	**59.500 ± 5.883**	**0.007**
	T5	**69.059 ± 4.582**	**47.937 ± 13.672**	**0.001**
	T10	**67.371 ± 3.326**	**47.878 ± 11.398**	**0.001**
Middle (sensor 11)	T1	51.611 ± 6.178	41.122 ± 20.395	0.250
	T5	69.180 ± 15.085	72.542 ± 9.281	0.300
	T10	47.189 ± 23.393	59.272 ± 22.275	0.620
Middle (sensor 7)	T1	37.097 ± 3.867	32.204 ± 6.182	0.078
	T5	**37.728 ± 5.333**	**29.006 ± 8.155**	**0.002**
	T10	**36.381 ± 3.587**	**30.389 ± 4.100**	**0.024**
Separation (sensor 0)	T1	52.833 ± 10.672	69.751 ± 11.894	0.120
	T5	78.558 ± 10.962	76.727 ± 10.161	0.350
	T10	70.568 ± 11.684	61.912 ± 12.762	0.200
Separation (sensor 8)	T1	28.927 ± 2.196	21.113 ± 4.594	0.120
	T5	**30.682 ± 10.939**	**37.578 ± 17.216**	**0.024**
	T10	**36.519 ± 13.094**	**26.955 ± 17.229**	**0.024**

Results show the degrees of flexion of each data glove's sensor for the three repetitions of the task while using the conventional needle holder (Conv) and the robotic instrument (Rob). Statistically significant values are marked in boldface

to similar performance with better ergonomics compared to the use of a conventional laparoscopic needle holder during intracorporeal suturing.

After the training period, no significant differences in precision were shown during the use of both the conventional and robotic needle holders. In a study analyzing the performance of the precision-drive articulating surgical system Kymerax™ (Terumo Europe NV, Leuven, Belgium), this instrument showed superior precision to a conventional laparoscopic needle holder for suturing at difficult angles [18]. Moreover, in the present study, the quality of the suturing performance during the intracorporeal suturing task on an ex vivo model was similar using both the conventional and the robotic instruments. A study with the robotic needle holder Jaimy® (Endocontrol, Grenoble, France) obtained a significantly higher qualitative score for the suturing tasks using this robotic instrument than using the conventional needle holder [10]. These results may suggest that the use of robotic instruments with additional degrees of freedom such as flexion and rotation of the tip could offer similar or even higher surgeon's performance than using conventional laparoscopic instruments for certain suturing tasks.

During the urethrovesical anastomosis, surgeons required more time using the robotic needle holder, but they significantly improved this execution time with training. Although the rate of leakage was higher for the anastomoses performed with the robotic instrument, there were no differences in leakage pressure between both groups of instruments. In a study with the Kymerax™ robotic instrument, this device also obtained similar leakage pressure to that obtained with a conventional laparoscopic needle holder during the performance of an urethrovesical anastomosis on an ex vivo porcine model [12].

Regarding the ergonomic assessment, one of the main risk factors of causing musculoskeletal disorders is the body deviation from the neutral position. In order to obtain an ideal posture of the hand during laparoscopic surgery, the hand should grasp the instrument with the wrist slightly extended and with the distal interphalangeal joints almost extended and the metacarpophalangeal and proximal interphalangeal joints flexed at 30°–50°. Fingers should be abducted by about 5°–10°, and the thumb should be opposed to the index finger [19,20]. The results of this study showed no differences in the dominant hand's posture for the experienced surgeon using

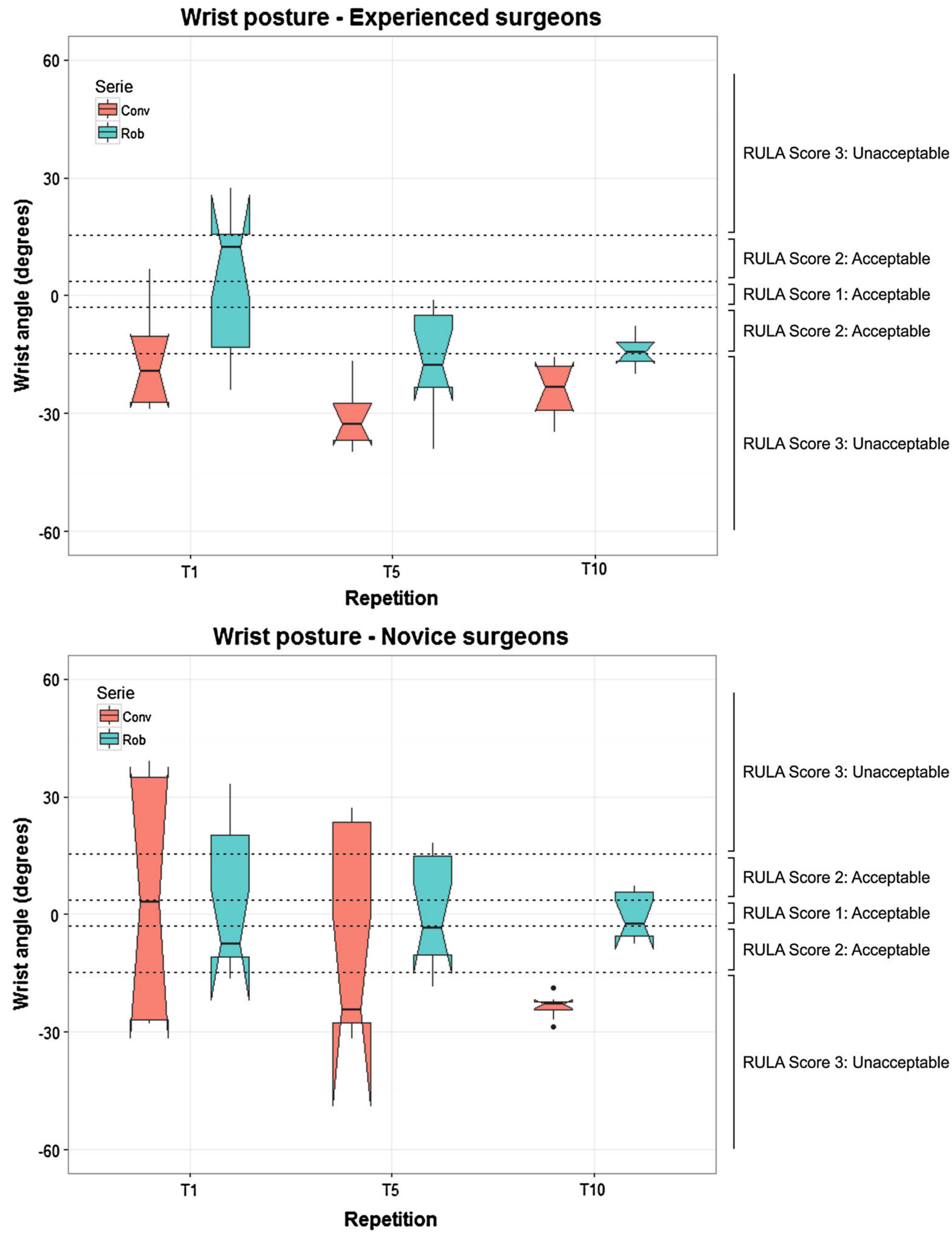

Fig. 8 Wrist posture and the equivalent RULA score for the group of experienced surgeons (*top*) and the group of novice surgeons (*bottom*) using the conventional needle holder (*Conv*) and the robotic instrument (*Rob*) during the urethrovesical anastomosis. Results are presented as *notched box* plots, in which every notched box has a line marking the lower, median and upper quartile values. *Whiskers* represent the extent of the remaining data, *with dots* showing the outliers. The boxes whose notches do not overlap are significantly different ($p < 0.05$)

both the robotic and conventional needle holders, except for the proximal interphalangeal joint of the middle finger that was significantly less flexed with the robotic instrument. The angle of flexion described by this joint was considered ergonomically acceptable. In the case of novice surgeons, differences were obtained for both instruments with regard to the three analyzed fingers (thumb, index and middle fingers). After the training period, the use of the robotic instrument led to an ergonomically more appropriate posture of the index finger.

The ergonomic analysis using the RULA method showed that after training the use of the robotic instrument resulted in an ergonomically acceptable flexion–extension of the wrist, in contrast to the posture acquired by using the conventional needle holder with straight handle. Therefore, we have found evidences of an ergonomically better surgeon's hand posture using the presented robotic-driven instrument than using a conventional needle holder during laparoscopic suturing. In the study of Besignor et al. [10], they also used the RULA method to assess the surgeon's postural ergonomics while using the robotic instrument Jaimy®. They analyzed all segments of the arm, including the wrist. They also obtained a significantly lower RULA score (more ergonomically adequate) for the hand posture using the robotic instrument than using the conventional needle holder during different suturing tasks.

One of the limitations of this study is the reduced number of participants. However, we consider that this study provides an overview of the possible functionalities of the DEX^{TM} system as well as its implications for the suturing performance and the surgeon's ergonomics during laparoscopic surgery. As future work, studies with a higher number of participants and in an actual surgical setting will be designed. Furthermore, additional objective assessment parameters such as the surgeon's muscular activity during the laparoscopic practice could be considered for further studies. The evaluation of the muscle fatigue through surface electromyography could be used for this type of ergonomic analysis.

This study has presented the DEX^{TM} robotic surgical device as well as the objective assessment of the surgeon's performance and ergonomics during its use in laparoscopic suturing. Results have shown that, although the presented robotic-driven needle holder is more time demanding than using a conventional laparoscopic needle holder during intracorporeal suturing, this robotic instrument results in similar suturing performance and better ergonomics of the surgeon's hand posture.

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Compliance with ethical standards

Conflict of interest J. A. Sánchez-Margallo and F. M. Sánchez-Margallo have no conflict of interest or financial ties to disclose.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

Informed consent Informed consent was obtained from all individual participants included in the study.

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