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Evaluation of the effect of a laparoscopic robotized needle holder on ergonomics and skills

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Abstract

Background Laparoscopy generates technical and ergonomics difficulties due to limited degrees of freedom (DOF) of forceps. To reduce this limitation, a new 5-mm robotized needle holder with two intracorporeal DOF, Jaimy®, has been developed. The aim of this study was to evaluate its effects on ergonomics and skills.

Methods Fourteen surgeons including eight senior and six residents were crossover randomized and stratified based on experience. Three suturing tasks were performed with both Jaimy® and a classic needle holder (NH): task 1: Peg-Board; task 2: hexagonal suture; task 3: frontal suture. Postural ergonomics of the dominant arm were evaluated with an ergonomics score (RULA score) thanks to motion capture, and muscular ergonomics with electromyography of six muscular groups (flexor and extensor carpis, biceps, triceps, deltoid, trapeze). Performance outcomes are a quantitative and qualitative score, and skills outcomes are the measurement of the number of movements and the path length travelled by the instrument.

Results The RULA score showed a statistically improved posture with Jaimy® ($p < 0.001$). The cumulative muscular workload (CMW) of four muscles was not different. However, the CMW was in favor of the NH for the flexor carpi ulnaris ($p < 0.001$) and the triceps ($p = 0.027$). The number of movements was not different ($p = 0.39$) although the path length was shorter with Jaimy® ($p = 0.012$). The score for task 1 was in favor of the NH ($p = 0.006$) with a higher quantity score. Task 2 score was not different ($p = 0.086$): The quality part of the score was in favor of Jaimy® ($p = 0.009$) and the quantity part was higher with the NH ($p = 0.04$). The score for task 3 was higher with Jaimy® ($p = 0.001$).

Conclusion This study suggests that the use of a robotized needle holder improves both posture and the quality of laparoscopic sutures.

Keywords Laparoscopic needle holder · Robotized instrument · Ergonomics · Skill assessment · Motion capture

Laparoscopic surgery has become the gold standard approach for many operations in the past decades, thanks mainly to decreased postoperative pain and shorter hospital stays. Patients benefit from minimal invasive surgery, but the surgeon encounters new technical and ergonomic problems that do not exist in open surgery [1, 2]. Thus, the operating room needs to be modified to improve the ergonomic installation, with changes such as the height of the screen or the motilities of the table. But the main cause of ergonomics issues is the limited number of degrees of freedom (DOF) of the instruments due to the passage of the shaft through the trocar as well as the fixed position of trocar and the parietal wall thickness that limit the surgeon's freedom of movement. A laparoscopic instrument has only four DOF compared to an arm which has nine DOF. The other consequence is that some basic gestures, such as sutures and intracorporeal knots, become technically difficult to perform. Furthermore, for up to 80 % of laparoscopic surgeons, ergonomics issues can induce musculoskeletal pain of

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the upper members and the neck due to vicious positions [3] in the long run. To overcome these two issues, researchers have developed laparoscopic instrument with intracorporeal DOF. The first type of instrument with intracorporeal DOF has a simple mechanical control of intracorporeal DOF, such as a knee joint between the handle and the shaft. However they do not seem to improve dexterity because of the complexity of the control mode [4]. A research axis to overcome both ergonomic issues and a potentially difficult control mode is the creation of robotized instruments. In partnership with the Endocontrol Company (Grenoble, France), we developed a 5-mm robotized needle holder named "Jaimy®." This innovative instrument possesses two intracorporeal DOF, yaw–roll, controlled by a joystick placed on an ergonomic handle [5–7]. It can be used by right- and left-handed surgeons. We have shown that those two intracorporeal DOF, yaw–roll, provide the same dexterity as three intracorporeal DOF, yaw–pitch–roll, where pitch was the bending of the shaft in the perpendicular plan of yaw. That DOF did not bring extra dexterity, while technologically it is more complex and cannot be performed in a 5 mm diameter [8]. The first added DOF allows the tip of the instrument to bend from 0° to 80°. The second one allows the jaws to rotate around their own axis at a speed controlled through the joystick deviation (Fig. 1). A joystick has been validated as the easiest and best control mode for the end effectors [6, 9]. Jaimy® was developed on the basis of these studies, but its impact on ergonomics and skills has never been evaluated. The aim of this study was to evaluate whether this 5-mm robotized needle holder increases the surgical skills and surgeon ergonomics for various kinds of standard surgical tasks.

Methods

Participants and organization

The study was randomized crossover stratified based on the level of expertise (senior surgeon versus resident). Each surgeon had to perform a set of three suturing tasks of increasing difficulty with Jaimy® and a classic needle holder (NH) (Karl Storz, Tuttlingen, Germany). Participants were randomly assigned to start either with Jaimy® or the NH. The non-dominant hand uses a classic grasper or another NH. Every session starts with explanation of the aim of the study and of the use of Jaimy®. All calibrations explained hereafter are made at the beginning of the session. The participants then have a free training session for each task lasting a few minutes. After the session with the first instrument, participants have at least 2 h of cooldown to avoid practice bias. During these tasks, we have evaluated the (1) postural and (2) muscular ergonomics, (3) the performance for each task and finally (4) the surgical skills.

Task and performance scoring system

A set of three limited time tasks including one pick and place task and two suturing tasks was selected among classic skills evaluation tasks (Fig. 2) [10]. Menhadji et al. [11] developed a scoring system for six different tasks aiming to compare the performance of surgeons during open, laparoscopic or robotic tasks. Each score was composed of a quantitative score and a qualitative score. The global score was the product of these two sub scores (Table 1). Among the six developed tasks, we selected the three focusing on suturing and "pick and place."

Task 1 Peg-Board gripping task: The set was composed of two Peg-Board and six pegs. The six pegs are removed one by one from a Peg-Board with the dominant hand, transferred to the other hand and placed on the other Peg-Board. This was then reversed. We measured the number of peg transfer and the number of dropped pieces.

Task 2 Hexagonal suture: A running suture is to be made around a hexagonal pattern with 2/0 Vicryl thread. The suture has to go through entrance and exit dots. We measured the quantity of stitches and the entry and exit precisions of each stitch.

Task 3 Frontal suture and knots: One stitch was made through an entry and an exit dot on a frontal axis. One

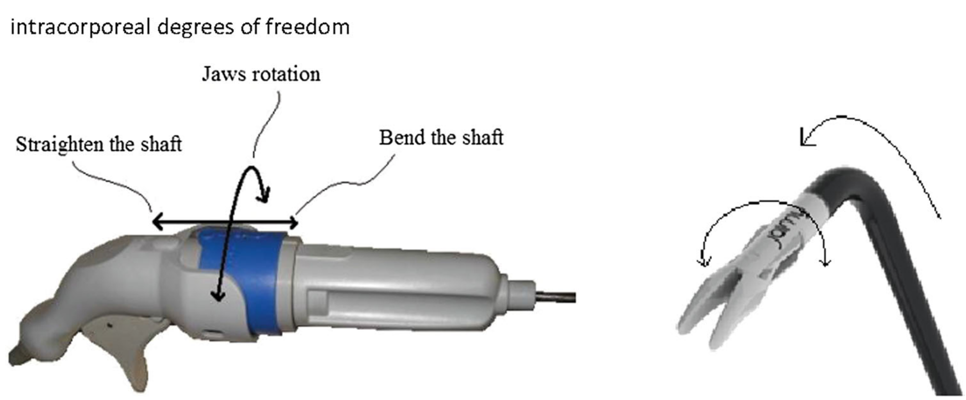


Fig. 1 Description of the robotized needle holder Jaimy®; *Left* handle design; *Right* intracorporeal degrees of freedom

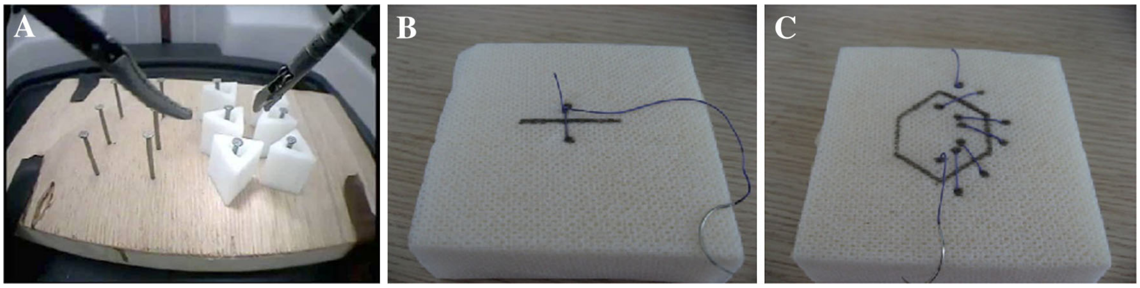
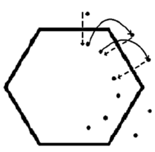
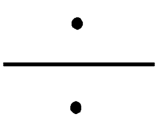


Fig. 2 Photograph of the three tasks; **A** Peg-Board; **B** frontal suture; **C** hexagonal suture

Table 1 Performance assessment score

Task	Quality	Quantity	Score
Peg-Board	0–4	0–12	0–48
2 min	0 = unable to place or remove any rings	Total # of rings placed + removed	
	1 ≥ 80 % of dropped pieces		
	2 = 50–80 % of dropped pieces		
	3 ≤ 50 % of dropped pieces		
	4 = No dropped pieces		
Hexagonal suture	0–4	0–12	0–44
3 min	0 = unable to pass through any dots	Total # of suture throws (2 per side)	
	1 = missed all dots when passing needle		
	2 = missed >50 % of dots when passing needle		
	3 = missed <50 % of dots during suturing		
	4 = missed no dots when passing needle		
Frontal suture	Dot + Knot	0–4	0–32
2 min	0 = needle exit >3 mm from dot	Hit both dots (1)	
	1 = 3 mm from dot; 2 = 2 mm from dot	+	
	3 = 1 mm from dot; 4 = on dot	# of knots (3)	
	+		
	0 = no knots; 1 = all air knots		
	2 = mostly air knots; 3 = occasional air knots		
	4 = all square knots		

double knot followed by two simple knots was then to be performed. We measured the precision between the entry and the exit of the stitch, respectively, and the dots as well as the quantity and quality of the knot.

Evaluation of postural ergonomics

An ergonomic score called the RULA score (Rapid Upper Limb Assessment) has been developed by McAtamney and Corlett and modified by Person et al. and Herman et al for surgery [7, 12, 13]. This score was used to evaluate the ergonomics of the dominant arm. As summarized in Table 2, it takes the angle between the arm and the vertical, the angle between the arm and the forearm, the rotation of the forearm and the angle between the hand and the forearm into account in order to evaluate ergonomics. The RULA score was obtained thanks to motion capture. It ranges from 4 to 15 and increases when the ergonomics decrease. Five motion capture markers are positioned on the subject: hand, forearm, arm, acromion and sternum,

Table 2 RULA score

Upper-arm score	*Arm elevation angle (0° when arm down)*
1	0°–45°
3	45°–90°
5	>90°
+1	If shoulder is raised by >10 mm
Forearm score	*Elbow flexion angle (0° when arm and forearm aligned)*
1	60°–100°
2	<60° or >100°
+1	If hand crosses body midline or is out to side
Wrist posture score	*Wrist flexion angle (0° when forearm and hand aligned)*
1	−5 to +5°
2	−15 to −5° or 5° to 15°
3	<−15° or >15°
+1	If wrist deviation angle >5°
Wrist twist score	*Forearm rotation angle*
1	−45° to 45°
2	<−45° or >45°

together with a marker on the instrument and a reference marker on the pelvitrainer. The Polaris system and the NDI ToolViewer software are used to record markers positions with a 15-Hz frequency. A calibration for each articulation was performed at the beginning of each session. It allowed for finding the center of each articulation using a sphere-fit algorithm [14]. All data were postprocessed using MATLAB. After locating the articulation centers, a model of the dominant arm was created. The angles between the different segments of the upper limb were then calculated at every moment. Each angle was converted into a numerical value over time according to the RULA score. Finally, the mean RULA score for each task and the mean of the three tasks were calculated.

Evaluation of muscular ergonomics

Additionally, EMG data were used to calculate the cumulative muscular workload (CMW), which evaluates the muscular energy spent during performance of a task [10]. Six muscular groups of the dominant arm were evaluated: the flexor carpi ulnaris, the extensor carpi radialis, the biceps brachialii, the triceps, the deltoid and the trapeze. Data were collected using the TeleMyoDTS system and the MyoResearch software with a 1000-Hz frequency. The EMG data were full wave rectified and filtered using a Butterworth low-pass filter with a cutoff frequency of 10 Hz in MATLAB. The measurement of the maximal voluntary contraction of each muscle was recorded at the beginning of the session for calibration purposes. It was then used as a reference to normalize every recording as a percentage of this maximum voluntary contraction. Finally the area under the curve of the filtered EMG signal over the time taken to perform the task was calculated as a measure of the work exerted by each muscle known as the CMW.

Surgical skills evaluation

Similarly to the calculation of the centers of the articulations, the tip of the instrument was located in the instrument marker frame thanks to a sphere-fit algorithm. We used two validated indicators: the length travelled by the tip of the instrument and the number of movements during each task or over the total of the three tasks [15]. The length travelled by the tip of the instrument corresponds to the sum of the paths travelled by the tip of the instrument, and the number of movement is equal of the number of times the speed of the tip of the instrument crosses zero.

Statistical analysis

RULA score, CMW, scores, path length and number of movements are quantitative variable and are presented as median and associated standard deviation. The results of the RULA score and the scores are shown as whisker boxes, where the box spans from the first to third quartile and the short horizontal line in the middle of the box represents the median. The box is extended by lines whose extremities are the minimum and the maximum. The results with Jaimy® and the NH are compared using a Wilcoxon test. For exploratory purposes, the results obtained by the residents and the seniors surgeons are compared using a Mann–Whitney test. The significance level was set at $p < 0.05$. Statistical analysis was run with SPSS version 19 software.

Results

Studied population

Fourteen surgeons participated in this study, including eight senior surgeons and six residents. The median age of the surgeons was 35 years (28–64), 29 years (28–35) for the resident group and 36.5 years (35–64) for the senior group. The sample population contained ten men and four women. Twelve surgeons were right-handed, and two are left-handed. Only one surgeon has already used Jaimy® prior to this evaluation. Seven surgeons (including four senior surgeons and three residents) started with Jaimy® followed by the NH and the seven remaining (including four senior surgeons and three residents) started with the NH.

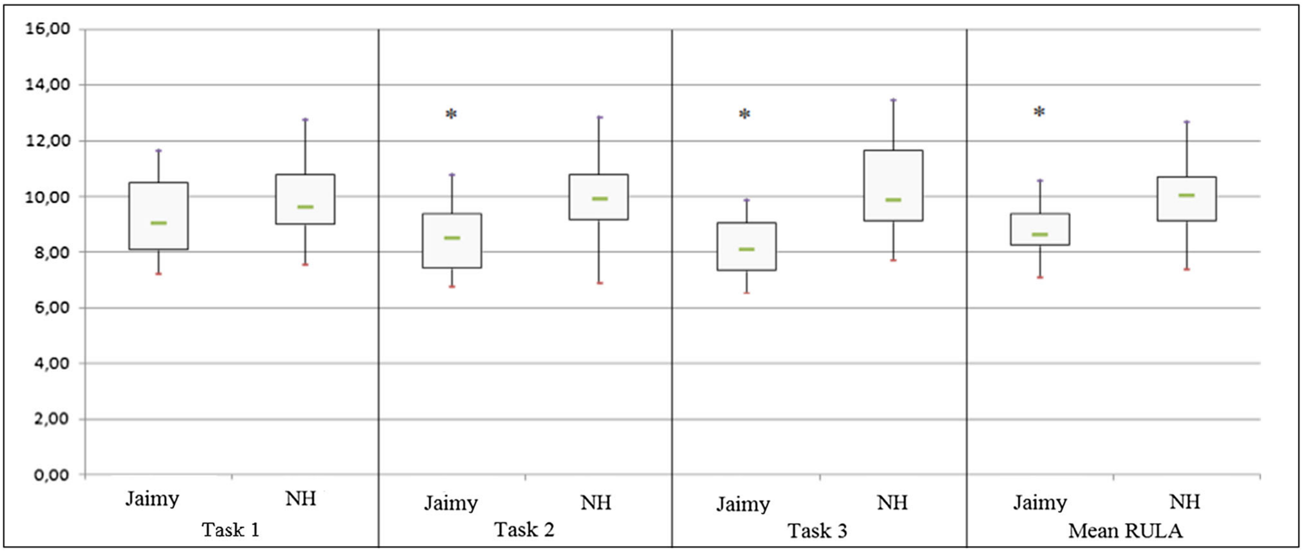


Fig. 3 Result of the RULA score for each task and mean RULA score; *NH* needle holder; $*p < 0.05$ placed above the lower value

Postural ergonomics

The results of the RULA score are summarized in Fig. 3. The mean of the RULA score of the three tasks was significantly lower with Jaimy® than with the NH, that is to say that the postural ergonomics were improved: 8.67 ± 1.1 versus 10.09 ± 1.4 ($p < 0.001$). If analyzed task by task, the difference is still statistically significant and in favor of Jaimy®: 9.13 ± 1.48 versus 9.68 ± 1.45 ($p = 0.049$) for the Peg-Board task, 8.58 ± 1.3 versus 9.98 ± 1.5 ($p = 0.001$) for the hexagonal suture and 8.16 ± 1.1 versus 9.93 ± 1.7 ($p < 0.001$) for the frontal suture.

Muscular ergonomics

The results of the CMW are summarized in Table 3. There was no significant difference of the CMW for extensor carpi radialis, biceps brachialii, deltoid and trapezes between the use of Jaimy® and that of the NH. However, the CMW on the three tasks was in favor of the NH for the flexor carpi ulnaris, with CMWs for Jaimy® and the NH, respectively, of 15.96 ± 7.1 versus 9.85 ± 2.7 ($p < 0.001$) and for the triceps, with CMWs of 18.72 ± 9 versus 11.93 ± 8.6 ($p = 0.027$).

Surgical skills

Considering the three tasks, the total number of movements was not statistically different between the two instruments with a total of movement of 343.1 ± 57 versus 322.9 ± 31 ($p = 0.39$) for Jaimy® and the NH, respectively. There was also no significant difference of number of movements when analyzed task by task. On the other hand, there was a significant difference for the path length travelled by the tip of the instrument. The total path of the three tasks was shorter with Jaimy® than with the NH, with a total path of 926.52 cm ± 189.38 for Jaimy® versus 1131.5 cm ± 224.9 for the NH ($p = 0.012$), respectively. For each task, there was a shorter path travelled by the tip of the instrument with Jaimy®, but it was only significant for Task 1 and Task 2 with a median path of 284.7 cm ± 61 versus 341.9 cm ± 103 ($p = 0.045$) for the Peg-Board and 352 cm ± 75 versus 449 cm ± 116 ($p = 0.029$), respectively.

Table 3 Total cumulative muscular workload on the three different tasks for the six muscular groups of the dominant arm

	Jaimy® (SD)	NH	*p* value
Flexor carpi ulnaris	15.96 ± 7.1	9.85 ± 2.7	<0.001
Extensor carpi radialis	41.59 ± 27.3	35.55 ± 24.7	0.11
Biceps brachialii	16.56 ± 8.9	13.65 ± 14.1	0.24
Triceps	18.72 ± 9	11.93 ± 8.6	0.027
Deltoïd	22.9 ± 11.8	20.03 ± 8.7	0.95
Trapeze	38.74 ± 23.7	41.6 ± 25.7	0.95

SD standard deviation

Performance

The performance for each task is summarized in Fig. 4.

Task 1 For this task, the score was increased with the NH. The score was 22.5 ± 9.3 with Jaimy® versus 34.5 ± 9.8 with the NH ($p = 0.006$). The qualitative score was not statistically different (3 ± 0.6 versus 4 ± 0.7; $p = 0.23$), but the quantitative score was in favor of the NH (7 ± 2.1 versus 10.5 ± 1.8; $p = 0.003$).

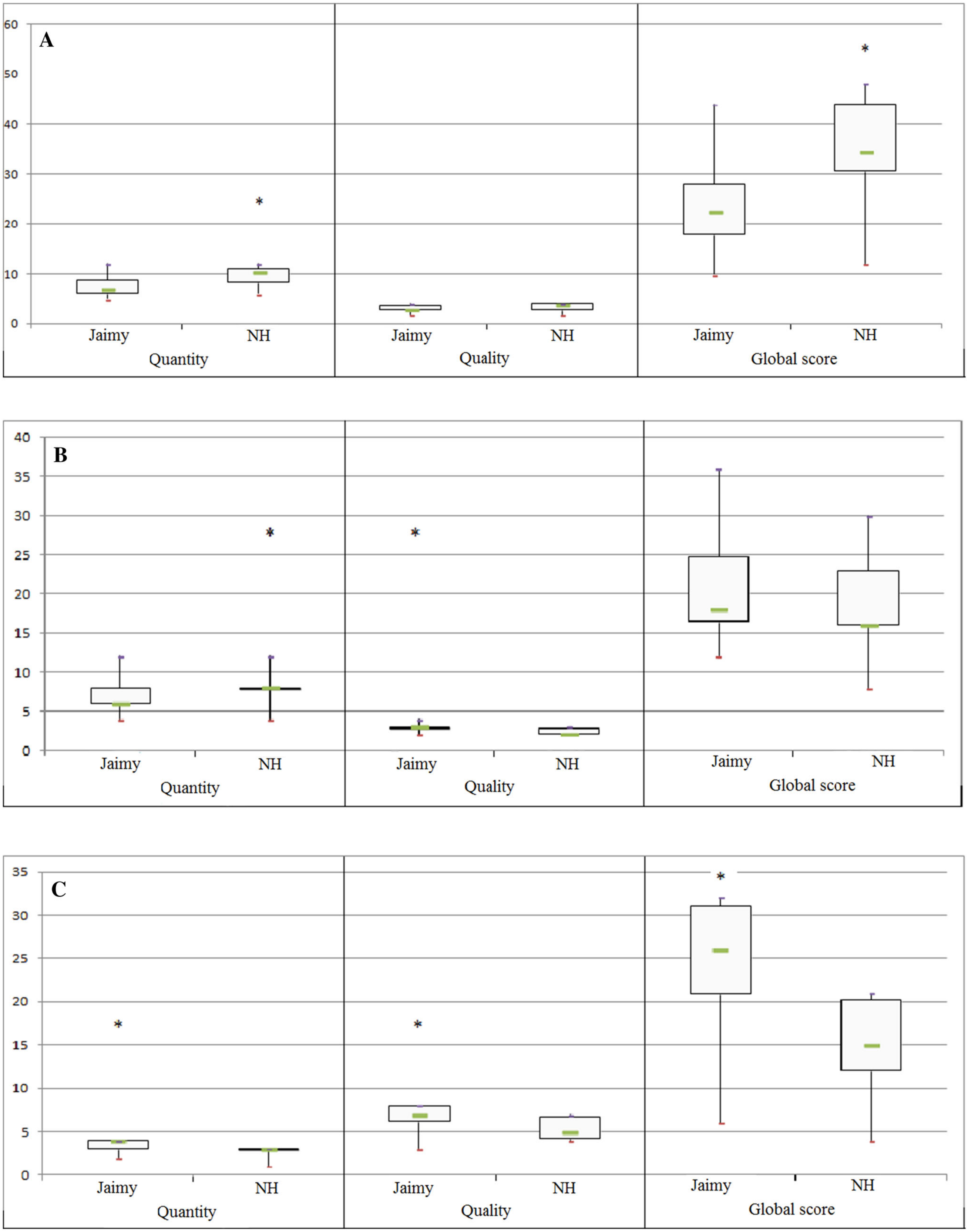


Fig. 4 Performance Scores for each task. **A** Task 1 Peg-Board; **B** Task 2 hexagonal suture; **C** Task 3 frontal suture; *NH* needle holder; *$p < 0.05$ placed above the higher value

Table 4 Comparison of the performance score of the residents and the seniors surgeons according to the instrument used

	Residents ($n = 6$)	Seniors surgeon ($n = 8$)	p value
Performance score			
1—Peg-Board			
Jaimy®	22.5 ± 10	23 ± 9.4	0.98
Needle holder	37 ± 12.8	34.5 ± 7.6	0.79
2—Hexagonal suture			
Jaimy®	18 ± 7.6	18 ± 7.8	0.69
Needle holder	16 ± 4.1	20 ± 6.3	0.12
3—Frontal suture			
Jaimy®	26.5 ± 11.4	26 ± 4.5	1
Needle holder	11 ± 6.6	18 ± 3.4	0.056
RULA score			
RULA global			
Jaimy®	8.3 ± 0.5	9.4 ± 1	0.02
Needle holder	9.3 ± 0.7	10.5 ± 1.8	0.23
1—Peg-Board			
Jaimy®	8.1 ± 1.2	9.9 ± 1.4	0.059
Needle holder	9.6 ± 0.7	10.3 ± 1.8	0.30
2—Hexagonal suture			
Jaimy®	7.8 ± 0.8	9.3 ± 1.3	0.043
Needle holder	9.4 ± 0.7	10.7 ± 1.8	0.14
3—Frontal suture			
Jaimy®	8.1 ± 0.4	9.4 ± 0.5	0.17
Needle holder	9.5 ± 2	11.1 ± 2	0.23

Task 2 The global score was not statistically different, 18 ± 7.5 versus 16 6 ± 6.1 ($p = 0.086$): Jaimy® provided a higher qualitative score (3 ± 0.6 versus 2 ± 0.5; $p = 0.009$), but a lower quantitative score (6 ± 2 versus 8 ± 2.1, $p = 0.04$).

Task 3 The global score was higher with Jaimy® (26 ± 8) than with the NH 15 ± 5.9 ($p < 0.001$). Both qualitative and quantitative scores were also statistically higher with Jaimy®.

Comparison of residents and seniors surgeon

Results by subgroups are shown in Table 4. For the frontal suture with a NH, senior surgeons have a tendency toward higher task scores than residents. With Jaimy®, residents and surgeons obtained the same scores on difficult sutures. The RULA was not statistically different between seniors and residents when using the NH. On the other hand, residents had a lower RULA and thereby a higher posture score than seniors when using Jaimy® on the Peg-Board task, the hexagonal suture and in the global RULA evaluation.

Discussion

New robotized devices seem to be the future of minimal invasive surgery as it can increase both ergonomics and skills and, at the end, improve the quality of the surgical procedure.

Jaimy® is the only 5-mm robotized needle holder available on the market. Another robotized needle holder, Robot Dex® (Dexterite Surgical, Annecy, France), was developed and commercialized, but it is a 10-mm device. The other devices with added intracorporeal DOF are telemanipulated surgical robot such as the da Vinci Surgical Robot® (Intuitive Surgical, Inc., Sunnyvale, CA, USA). The main difference is that this robotized needle holder is a comanipulated instrument, allowing the surgeon to perform his intervention in sterile condition next to the patient and with haptic feedback that telemanipulated surgical devices cannot provide. Haptic feedback remains an important source of information for the surgeon [16]. During suturing, it provides information on the tension in the thread and researchers are even trying to remedy the lack of haptic feedback on telemanipulated surgery robots [17, 18].

For the first time, the present study showed that a robotized needle holder with two additional intracorporeal DOF controlled by a joystick and with an ergonomic handle increased surgical skills for difficult sutures and allows the surgeon to keep a more ergonomic posture.

Furthermore, although experts have a tendency to obtain better results with a classic needle holder, both residents and expert surgeons benefit from this robotized needle holder in the execution of frontal sutures. This result suggests that Jaimy® increases surgical skills for difficult sutures in residents and may help them in easily performing such difficult tasks. Also, residents succeed in keeping a better posture than experts on most tasks. This result may be explained by the fact that experts are more used to classic instruments and may be more challenged by robotized instruments as they have to change their gestures. For example, with Jaimy®, there is no more need to use pronosupination for suturing as the rotation of the jaws replaces this movement. Through discussion with the experts who participated, it stands out that experts still have a tendency to use the rotation of the forearm to make sutures. It may be easier for residents who are free of habits to learn how to use the new device. It is possible that the learning of robotized instrument which can change habits is longer for experts.

It should, however, be noted that all surgeons but one had never used Jaimy® before this study, whereas all of them had surgical experience with classic instruments. After only a few tens of minutes, surgeons can master a robotic instrument with an improvement of both posture and skills. This demonstrates that the use of Jaimy® is intuitive and that the learning curve is quite short.

Interestingly, three results did not show the superiority of Jaimy®: the measure of the flexor carpi ulnaris, the Peg-Board score and the hexagonal suture task.

The first result shows a higher muscular workload with Jaimy®. This muscular group was used for the opening and the closing of the jaws thanks to the trigger under the handle. This function is purely mechanical on Jaimy® and does not involve the robotization. At the time of development, the trigger was tuned with a too high rigidity. This was easily identified as the source of this adverse outcome with EMG where the use of the trigger induces important EMG peaks. This difference has been easily corrected to decrease the muscular workload of the flexor carpi ulnaris.

The second outcome that did not show superiority of Jaimy® was the Peg-Board score, where the quantity score was higher with the classic needle holder and induced a higher global score for the classic instrument. For this pick and place task, careful observation revealed that surgeons tried to use all robotized function of Jaimy®, which was not necessary most of the time. Because of this, surgeons lost time "playing" with the distal mobility of Jaimy® instead of focusing on performance. The result of the Peg-Board task may be explained in part by this observation and does not necessarily negatively impact the use of Jaimy® as needle holder.

Finally, for the hexagonal suturing task, surgeons achieved a slight yet statistically significant higher quantity of sutures with the standard needle holder than with Jaimy®. This observation cannot be explained by the fact that Jaimy® slows the suturing. On the contrary, the suturing itself is faster with Jaimy® thanks to the rotation of the jaws which allows a very controlled suturing with a steady surgeon hand. The time lost was due to the time taken to perfectly place the needle between the jaws. As the jaws rotate around their own axis, the needle has to be perfectly perpendicular to the jaws to avoid a conical movement of the needle. A non-perpendicular needle is not a problem with a classic needle holder as the surgeon compensates an imperfect needle position with his/her hand movement. But every surgeon quickly understands that with Jaimy®, a bad position of the needle either causes a rotation of the needle between the jaws or tissue trauma. This time taken to place the needle is compensated by a much higher quality of the sutures as shown in this study. This observation induced the development of a new jaw design which will facilitate the perpendicular placement of the needle.

There were several limitations to this study. First of all, the number of participants in each subgroup was limited to compare senior surgeons and residents. Furthermore, a study to quantify the learning curve should be performed. Finally, this study is purely experimental on a pelvitrainer and outside of an operative room. Further studies on the use of Jaimy® and its evaluation during different surgeries should be conducted.

Conclusion

The use of a robotized comanipulated laparoscopic needle holder with intracorporeal DOF increases surgeon postural comfort and performance on difficult sutures as shown in our study. Furthermore, these improvements for the surgeon are observed even if the surgeon uses Jaimy® only after a short training period and shows that such robotized instruments have a short learning curve if a few tricks are explained from the beginning.

Such studies also reveal minor technical problems, in this case the trigger stiffness and positioning of the needle. The scientific evidence obtained facilitated a transmission of information on technical problems to the industrial company who can then optimize the instrument.

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Disclosures Guillaume Morel is a scientific advisor for the company Endocontrol who commercializes the robotized instrument Jaimy. To deal with this conflict of interest, he was involved only in the design of the experimental setup and the technical construction of the measurement systems, but he was not present during the experiments and did not participate in the data collection nor in the statistical analysis of the results. He then participated in the analysis of the statistical results (discussion section). Thierry Bensignor, David Reversat, David Fuks and Brice Gayet have no conflict of interest.

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