Evaluation and comparison of basic gestures in ex vivo laparoscopic surgery using a robotic instrument and traditional laparoscopic instruments

F.-X. Madec, C. Dariane, J.-N. Cornu

Titre :

Evaluation et comparaison ex-vivo de gestes de base en chirurgie laparoscopique réalisés à l'aide d'un instrument robotisé ou d'instruments de laparoscopie classique.

Auteurs :

F.- X. MADEC [a], C. DARIANE [b], J.-N. CORNU [c]

Affiliations :

[a] Service de chirurgie pédiatrique, Assistance publique – Hôpitaux de Paris (AP-HP) hopital Armand Trousseau 26 avenue du Dr Arnold Netter, 75012 Paris, France

[b] Service d'urologie, hôpital européen Georges-Pompidou, 20 rue Leblanc, 75015 Paris, France

[c] Service d'Urologie, CHU de Rouen Charles Nicolle, 1 rue de Germont, 76000 Rouen

<u>Manuscript :</u>

Introduction :

Laparoscopic surgical approaches are frequently employed in urological surgery. The main benefits of this minimally-invasive surgery rely on the reduction of pain, size of incisions, days of hospitalization and recovery times [1]. The major difficulty of this technique is related to the fact that conventional laparoscopic instruments are not articulated and rely on the abdominal wall to serve as a pivot-point, which reduces the degree of freedom [2]. Robotization of the instruments allows to correct this problem and realize deep and complex laparoscopic gestures, such as cutting with the scissors and stitching with a needle, much easier to perform by granting trocars with 360° of rotation. The robotic arm from DEXTERITE Surgical™ (Dexterite Surgical Inc based in Annecy, France) has been used for general, urologic, and gynecologic surgeries in France since 2010. The distal extremities (the needle holder and the scissors) are free to move in three planes and have 6 degrees of freedom as well as unlimited rotation. In addition, thanks to the ergonomic and articulated handle, the instrument preserves haptic return, or force feedback [Figure 1].

In order to evaluate the benefits of this instrument when using pelvitrainer, we studied the experiments of novice operators using the Dextérité (DEX) arm and compared them to their experiments using conventional laparoscopic instruments.

Methods :

Study design,

This study was conducted in 2014 at the Assistance Publique des Hôpitaux de Paris (APHP) - School of Surgery Fer à Moulin.

Six pelvitrainers were used. Each pelvitrainer was equipped with a synthetic reproduction of the male pelvic skeleton on which a thin layer of foam was fixed to represent the muscles of the pelvic floor. The pelvitrainers thus simulated the spatial constraints involved in urologic operations such as radical prostatectomies. Towards the rear of each model we fixed a silicone plate to enable the operators to conduct their exercises in the frontal plane [Figure 2].

This cross-over comparative study required each participant to carry out 2 exercises, using their dominant hand to successively manipulate the Dextérité (DEX) robotic arm followed by a standard laparoscopic instrument (the needle holder and 5mm scissors from Karl Storz endoscope, Inc).

The endoscope had a 0° laparoscopic optic and its position, as well as that of the model, was standardized in the pelvitrainer. Participants held fenestrated laparoscopic surgical pliers in their non-dominant hand.

DEX is a robotic co-manipulation instrument which contains a console and a 10mm-diameter handle, equipped with micro-motors, to which the surgical instrument (the needle holder or scissors) can be connected.

Participants

All participants were urologists residents, all belonging to the French Association of Urologists in Training (AFUF). Students in their first two years of residency were considered as “beginners”, because they were still in general surgery. The older residents were considered as « experienced » as they were registered for the complementary specialized diploma in urological surgery.

Task and evaluation

The session began with 20 minutes of instructions to cover the objectives of the study and the utilization of the DEX tool. Then, the exercises were carried out without giving the operators any opportunity to practice using the pelvitrainers.

Two exercises were evaluated: the stitching with the needle and the cutting. For the first exercise, a silicone block was used with landmarks on its surface. Each participant was asked to pass the needle in and out of the silicone following each of the landmarks three times. The vertical crossing went from the point 1A to the point 1B (from bottom to top), the horizontal crossing from the point 2A to the point 2B (from left to right) and the oblique crossing from the point 3A to the point 3B. For each vertical, horizontal and oblique crossing, the distance was measured in millimeters between the entry points (1A, 2A and 3A) and the exit points (1B, 2B and 3B). The time spent for each participant to place the needle in the instrument and to pass the stitches was recorded in seconds. Any rips in the silicone caused by the needle were evaluated, on a scale of 0 to 3, depending on the visible constraints. Failure was evaluated if there were more than 10mm between the landmarks and the needle’s actual entry points or if it took the participant more than 20 minutes to begin stitching.

For the second exercise, participants were asked to cut along a marked line in the form of an omega [Figure 3]. The quality of the cut was evaluated following a number of different criteria and the time spent to the participant to carry out the task was recorded. The three criteria were as followed : respecting the 2 extremities that represented the beginning and the end of the omega's circle, the way they followed the rounded line and the amount of "hacking" along the whole line. Each parameter was evaluated following the difference between the results obtained using each tool : we added +1, +2 or +3 points when the result was obtained better with the DEX tool, and we subtracted -1, -2 or -3 points if the use of the classic laparoscopic tool permitted a better result. A score of 0 was attributed if the results using each tool were equivalent. An overall positive score is in favour of DEX tool and a negative for laparoscopic tool.

The exercises were evaluated anonymously, after-the-fact and outside of context by 2 senior surgeons, experts in laparoscopy.

A survey to evaluate the ergonomics, on a scale of 0 to 10, was sent to each participant the day of the study. It included an evaluation of the postural comfort and the simplicity of use of DEX.

Statistical analysis

Data are expressed as percentage with [standard deviation]. The average scores for each participant were calculated and compared with the Mann-Whitney test. A sensitivity analysis using a student test was performed to compare beginners and experienced residents for the second exercise (cutting exercise) using DEX or laparoscopic instrument.

Statistical analysis were done using the Prism 7 software. A p value inferior to 0.05 was considered as statistically significant.

Results :

Twelve urology residents (9 men and 3 women - 5 in their 3rd semester, 5 in their 5th semester and 2 in their 7th semester). Five participants were beginners and 7 were experienced. The residents had spent 2 ± 0.95 rotations in a urological department and 1.6 ± 0.5rotations in visceral surgery,

p<0.05). All participants had at least made 1 pelvitrainer session and assists routinely in the operative room for laparoscopic surgery.

All of the participants were able to use DEX successfully, without additional training, after the 20 minutes included in the exam.

For the first exercise, a total of 36 needle passes with each instrument were analysed. Seven out of 36 needle passes (19.4%) received failure grades when using the laparoscopic needle holder and one (0.3%) when using DEX. For all of the criteria (entry and exit points, rips and time) the results obtained were better when using DEX compared to the classic laparoscopic tool [Table 1]. This difference was statistically significant regarding the horizontal needle passes, with a difference of 2.7mm ± 1.6 in the classic tool group comparing to 0.4mm ± 0.6 in the DEX group (p = 0.002). The rips were significantly reduced in the vertical (p = 0.04) and horizontal (p = 0.003) crossings. There were no significant differences for either group of tools in the time spent for each participant to set up the needle and complete their stitching.

For the second exercise, the global cutting score obtained following the multi-criteria scale was in favor of the DEX tool for 10 of the 12 participants (83.3%) . In this group, the average score was +2.6 (± 2.1). The remaining two participants scored negative points -2 (± 0) in favor of the classic tool. One participant was able to perform the cut using DEX but could not carry out the same task with the classic tool.

The participants obtained positive scores when using DEX when it came to respecting the 2 extremities of the omega's circle, the round contour and the hacking aspect: +1.1 (± 0.9) ; +0.5 (± 1.2) ; +0.3 (± 1.3) respectively.

The times recorded for the cutting exercise were similar for the two groups: 128 seconds (± 76) for DEX and 70 (± 17) for the laparoscopic arm. The average time spent to complete the cutting exercise was longer when using DEX ($p = 0.052$). A sensitivity analyse was performed to compare the quality of cutting between beginners and experienced residents. The analyse didn't find any significant difference between both groups [Figure 4], with a global cutting score of 2 (+/- 3.4) in the experienced groupe and 1.8 (+/- 0.9) in the beginners group ($p > 0.05$). The results were still in favor of DEX in both groups regardless of resident level.

Among the 12 residents, 7 (58.3%) responded to the ergonomic survey. All of the participants noticed that the postural comfort was satisfactory when using the DEX scissors and needle holder (average score: 8.5 ± 1.6). The question concerning the simplicity of use scored 6.9 (± 1.5).

Discussion :

During this study, using DEX, without any prior training, improved novice operator's scores when cutting and suturing compared to the use of conventional laparoscopic instruments.

The precision when passing the needle, as well as the reduction in tearing was statistically improved when using DEX compared to the conventional tool.

As reported by Bensignor et al. [3] using the JAIMY™ robotic needle holder, developed in collaboration with the Endocontrol Company (Grenoble, France), our results showed that DEX improved the effectiveness and quality of sutures obtained with a greater degree of freedom which helps the user to control the needle's trajectory [4].

The overall aspect of the cuts was improved in 83.4% of the participants when they used DEX. This superiority was true for all three evaluation parameters defined. To our knowledge, this important advantage, particularly necessary in excision surgery, had never been associated with the use of co-manipulation robotic instruments.

Using DEX does not seem to prove difficult since the participants were able to use it effectively after only 20 minutes of theoretic training. This compares favorably to the learning curve required for another articulated instrument with a needle holder difficult to use for beginners operators. [5]. Because the participants using DEX did not receive prior training, the results were not over-valued by repeating the gestures.

The time spent to set up the needle and the duration of the cutting exercise were similar between the two instruments, showing that the use of DEX can be intuitive and benefits from a fast learning curve. DEX limits the physical constraints responsible for musculoskeletal discomfort habitually reported when using conventional laparoscopic instruments [6]. This observation was confirmed by the participants.

To date, two types of robotic instruments have been developed in surgery : those with remote-handling capabilities represented by the surgical systems from the DA Vinci Intuitive Surgical Inc (CA, USA), and co-manipulation systems similar to DEX. The training and time pent to suture using the remote surgical techniques seems faster than with conventional laparoscopic instruments [7]. However, the elevated cost of remote-handling surgeries and the absence of benefits provided by laparoscopic tools challenge the idea to generalize the use of this technique [8]. Some experts in minimally-invasive surgery agree that the benefits provided by remote-handling tools are not required for the duration of an operation, but only during some precise steps of the procedure [9]. Robotic co-manipulation arms, such as DEX, are less expensive and offer continuous benefits, and then represent a therapeutic alternative that improves the surgeon's performance while providing a more balanced benefits-to-cost ratio. Another advantage of robotic co-manipulation instruments compared to remote-surgery is the opportunity for the surgeon to remain close to the patient, in sterile conditions, in case a conversion is required. The instruments also preserve the haptic return which is lost in robotic remote surgery [10].

This study was conducted using operators beginners to the laparoscopic instruments. This allowed us to limit any bias towards the habitual use of conventional tools which would have inflated the results. In addition, the use of a synthetic, skeletal pelvic model enabled us to reproduce spatial constraints experienced in real, clinical situations in urologic surgery.

Because the tasks were performed using the pelvitrainer and the pool of participants was small, these first results require confirmation using cadavers or animals so that the different exercises representing urologic interventions can be compared. It would also be equally interesting to carry out a study dedicated to the ergonomic benefits of DEX and to clearly define its required learning curve.

Conclusion :

Using DEX is possible for novice operators after only a short training period. It improves the needle passing techniques while reducing tearing, and improves the quality of cuts compared to conventional laparoscopic instruments, without slowing the operator down.

Acknowledgements :

The authors thank the French Association of Urologists in Training (AFUF) for helping us recruit residents for the study and the management at the Ecole de Chirurgie du Fer à Moulin, and their team, for allowing us to carry out this study.

Disclosures :

Dr FX.MADEC, Dr C.DARIANE, Dr JN.CORNU have no conflicts of interest or financial ties to disclose.

References :

1. Buia A, Stockhausen F, Hanisch H (2015) Laparoscopic surgery: A qualifed systematic review. World J Methodol 5:238–54.

2. Okken LM, Chmarra MK, Hiemstra E, Jansen FW, Dankelman J (2012) Assessment of joystick and wrist control in hand-held articulated laparoscopic prototypes.

Surg Endosc 26:1977–85.

3. Bensignor T, Morel G, Reversat D, Fuks D, Gayet B. (2016) Evaluation of the effect of a laparoscopic robotized needle holder on ergonomics and skills. Surg Endosc 30:446–54.

4. Waseda M, Inaki N, Torres Bermudez JR, Manukyan G, Gacek IA, Schurr MO, Braun M, Buess GF (2007) Precision in stitches: Radius Surgical System. Surg Endosc 21:2056–62.

5. Martinec DV, Gatta P, Zheng B, Denk PM, Swanström LL. (2009) The trade-off between flexibility and maneuverability : task performance with articulating laparoscopic instruments. Surg Endosc 23:2697–701.

6. Dalager T, Søgaard K, Bech KT, Mogensen O, Jensen PT. (2017) Musculoskeletal pain among surgeons performing minimally invasive surgery: a systematic review. Surg Endosc 31:516–26.

7. Yohannes P, Rotariu P, Pinto P, Smith AD, Lee BR. (2002) Comparison of robotic versus laparoscopic skills: is there a difference in the learning curve? Urology 60:39–45.

8. Heemskerk J, Bouvy ND, Baeten CGMI. (2014) The end of robot-assisted laparoscopy? A critical appraisal of scientific evidence on the use of robot-assisted laparoscopic surgery. Surg Endosc 28:1388–98.

9. Tonet O, Focacci F, Piccigallo M, Cavallo F, Uematsu M, Megali G, Dario P (2006) Comparison of control modes of a hand-held robot for laparoscopic surgery. In : Larsen, R, Nielsen M, Sporring J Medical Image Computing and Computer-

Assisted Intervention – (MICCAI), Springer 429–36.

10. Piccigallo M, Focacci F, Tonet O, Megali G, Quaglia C, Dario P. (2008) Hand-held robotic instrument for dextrous laparoscopic interventions. Int J Med Robot 4:331–8.

Legend:

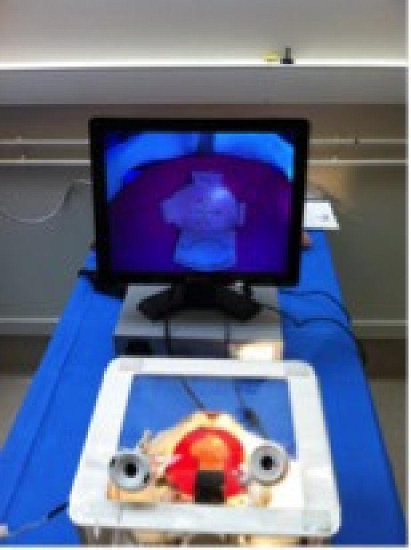
Figure 1. Dextérité Surgical™ robotized instrument (needle holder and scissors).

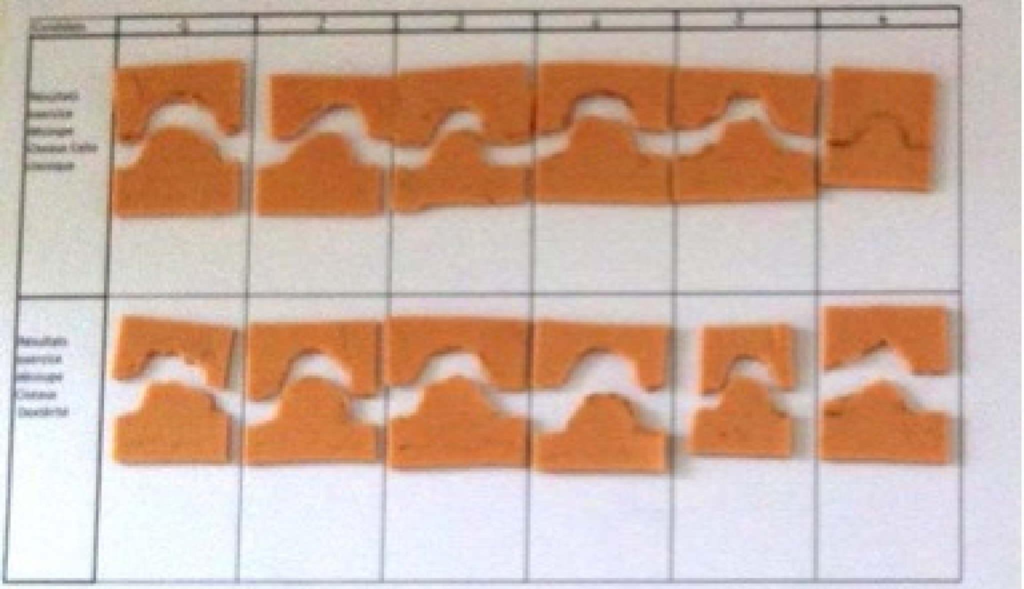
Figure 2. Pelvitrainer model used for both exercises (stitching and cutting).

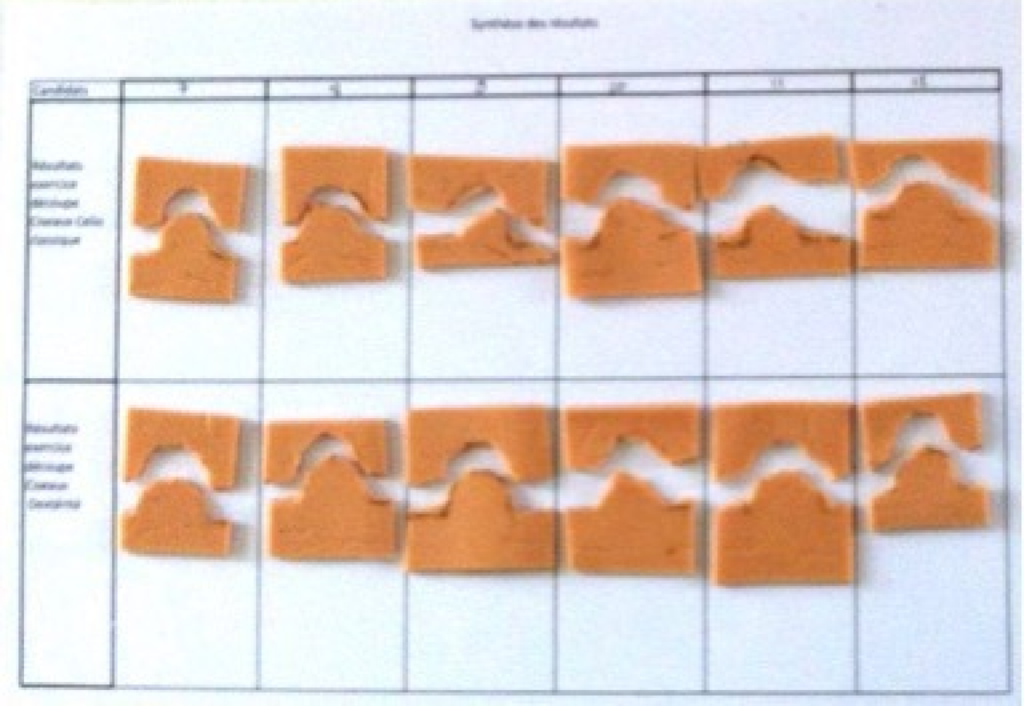
Figure 3. Comparison of the 12 residents' "Omega" cut pattern exercises using conventional laparoscopic instruments (upper line) and DEX (lower line).

Figure 4. Sensitivity analyse of the cutting score between beginners and experienced residents. An overall positive score is in favour of DEX tool and a negative for laparoscopic tool. In the experienced group the global cutting score was 2 (+/- 3.4) and 1.8 (+/- 0.9) in the beginners group without any significant difference ($p > 0.05$).

Table 1. Comparison of average results of needle-passing exercises using conventional laparoscopy and DEX.







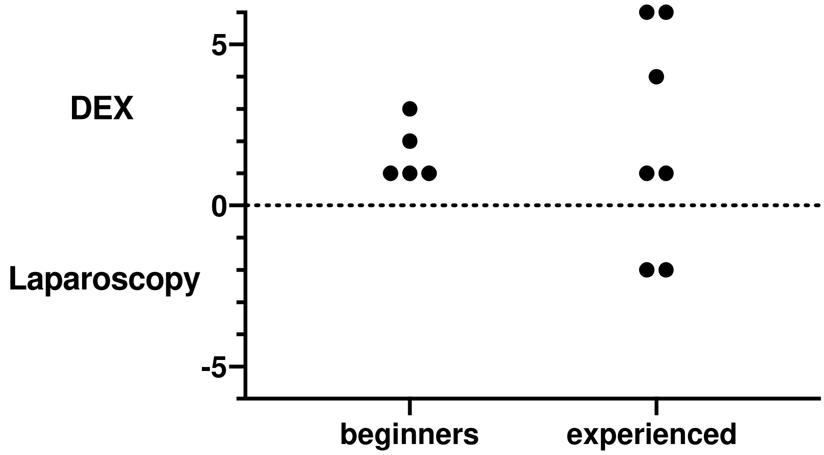

DEX
Laparoscopy
5
0
-5
beginners
experienced

Table 1. Comparison of average results of needle-passing exercises using conventional laparoscopy and DEX.

operating parameters	Conventional laparoscopy	DEX	p
Gap from entry point (1A) for stich 1 (mm)	0.77 ± 1.0	0.66 ± 0.8	0.94
Gap from exit point (1B) for stich 1 (mm)	4.0 ± 2.5	2.9 ± 1.8	0.44
Gap from entry point (2A) for stich 2 (mm)	2.7 ± 1.6	0.4 ± 0.6	**0.002**
Gap from exit point (2B) for stich 2 (mm)	7.0 ± 4.7	3.3 ± 2.1	0.1
Gap from entry point (3A) for stich 3 (mm)	2.2 ± 2.2	0 .75 ± 0.78	0.07
Gap from exit point (3B) for stich 3 (mm)	3.1 ± 2.2	2.9 ± 1.6	0.87
Timing for needle placement on the instrument, before stich 1 (s)	93.0 ± 58.0	63.0 ± 40.0	0.26
Timing for needle placement on the instrument, before stich 2 (s)	162.0 ± 79.0	125.0 ± 85.0	0.33
Timing for needle placement on the instrument, before stich 3 (s)	86.0 ± 83.0	81.0 ± 64.0	1.0
Timing to pass stich 1 (s)	68.0 ± 88.0	47.0 ± 19.0	0.79
Timing to pass stich 2 (s)	55.0 ± 56.0	52.0 ± 45.0	0.64
Timing to pass stich 3 (s)	80.0 ± 99.0	37.0 ± 24.0	0.46
Rip score for stich 1 (scale of 0 to 3)	1.1 ± 1.1	0.25 ± 0.45	**0.04**
Rip score for stich 2 (scale of 0 to 3)	1.75 ± 0.9	0.5 ± 0.5	**0.003**
Rip score for stich 3 (scale of 0 to 3)	0.9 ± 0.9	0.5 ± 0.5	0.29