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1 **Learning intracorporeal suture on pelvitrainer using a robotized versus conventional**
2 **needle holder**

3

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18 **Short title:**

19 Training with a robotized needle holder

20

21 **Author contributions :**

22 E.S., P.C. and A.A. were involved in concept and design of the study. E.S., A.C., and P.C.
23 were involved in data collection. E.S., P.C., A.N. and N.R. were involved in analysis and
24 interpretation of data. E.S, P.C., A.C., A.N., N.R. and A.A. were involved in drafting the
25 article. All authors read and approved the final version of the paper.

26 **ABSTRACT**

27 **Background:** Laparoscopy is the gold standard approach in numerous surgical procedures. A
28 new generation of robotized instruments has been developed to compensate for the ergonomic
29 constraints of conventional instruments. The main objective was to compare the learning
30 curves of novices for intracorporeal suturing on a laparoscopy pelvitrainer, using either a
31 robotized needle holder or conventional needle holders. The post-training performances under
32 ergonomically difficult conditions were also analyzed.

33 **Materials and methods:** Fifth-year medical students were randomized in Group A using a
34 robotized needle holder (JAIMY, Endocontrol, Grenoble, France) and Group B using straight
35 conventional needle holders. They undertook four training sessions (intracorporeal knot-tying
36 task) followed by an evaluation session (intracorporeal knots-tying task, frontal suture, and
37 hexagonal suture).

38 **Results:** Twenty participants were included. The performances of the two groups (n=10) were
39 not significantly different at baseline. During the training sessions, there was a learning curve
40 with a plateau at the third session for both of the groups. At the final evaluation session, there
41 was no significant difference between group A and group B for the intracorporeal knot-tying
42 task (median FLS score: 468 versus 474.5 respectively, $p=0.762$). There was a significant
43 difference between group A and group B for the frontal suture (median global score: 15.75
44 versus 3.75 respectively, $p= 0.005$) but not for the hexagonal suture (median global score: 18
45 versus 15 respectively, $p= 0.284$).

46 **Conclusions:** Learning curves were equally fast using the robotized needle holder versus
47 conventional instruments and led to equivalent performances. Under ergonomically difficult
48 conditions, the robotized needle holder provided an advantage relative to conventional
49 instruments.

50

51 **Introduction**

52 Laparoscopy is a minimally invasive surgical technique launched in the 1980s, which has
53 been widely used since the start of the millennium.¹ This approach has become the gold
54 standard for numerous procedures. It presents many advantages for patients relative to open
55 surgery: a shorter hospitalization duration, a reduction in postoperative pain, and
56 improvement in the postoperative course.²

57 The principle of laparoscopy is the creation of a neocavity of gas allowing operation with
58 specific instruments inserted into the transparietal trocars. The rigidity of conventional
59 laparoscopy instruments and the fixity of trocars across the abdominal wall represent
60 ergonomic constraints and impose specific learning on the surgeon relative to open surgery.
61 Furthermore, laparoscopy leads to muscle fatigue and poor posture for the surgeon.^{3,4}

62 To limit the ergonomic constraints for the operator, customization of the workspace and
63 operating theatre are necessary, such as the height of the table and the positioning of the
64 screens and the trocars.⁵ Another element that can contribute to the operator's comfort is the
65 use of instruments in which the intra-abdominal part allows for movements with multiple
66 degrees of freedom.

67 Robotic-assisted laparoscopy was developed in particular to improve surgeon's operative
68 dexterity and comfort.⁶ However, this technique remains very expensive. It requires specific
69 equipment and involves longer operative times.^{7,8} On the other hand, robotized instruments
70 have been developed for use during conventional laparoscopy, combining the advantages of
71 conventional laparoscopy and the ergonomics associated with robotic-assisted laparoscopy.⁹

72 Although still rarely used, these instruments must be evaluated relative to the known
73 conventional instruments that have been mastered by laparoscopic surgeons. This evaluation
74 must be particularly focused on the learning phase and on performances in terms of surgical
75 dexterity.

76 The main objective of this study was to compare the learning curves of surgery novices for
77 intracorporeal suturing on a pelvitrainer, using either conventional needle holders or a
78 robotized needle holder. The secondary objectives were to compare the participant's post-
79 training performances under conventional and ergonomically difficult conditions as well as
80 the workload experienced by the operators in these different situations.

81

82 **Material and methods**

83 This prospective randomized study was carried out at La Conception University Hospital in
84 Marseille between March and December of 2016. The ethics committee of the faculty of Aix-
85 Marseille faculty issued a favorable ruling regarding this project. The participants were
86 volunteer, fifth-year medical student surgical novices. The participants provided signed
87 consent before inclusion in the study.

88 **Execution of the study**

89 The sessions took place in a dedicated simulation room, during the ten weeks of students
90 practical rotations in the gynecology unit. During these sessions, a qualified observer
91 collected the Fundamentals of Laparoscopic Surgery (FLS) score data and monitored video-
92 recording of performances when appropriate.

93 Training sessions were undertaken on a classic FLS pelvitrainer.¹⁰ The needle holders used
94 were: straight conventional laparoscopy needle holders and a JAIMY robotized laparoscopic
95 needle holder with a diameter of five millimeters (Endocontrol, Grenoble, France) (Fig 1).
96 This instrument includes a robotic arm that allows for an additional two degrees of movement
97 relative to the axis of the forceps: bending from 0 to 80° and 360° of rotation on its axis. It is
98 controlled manually using an ergonomically-shaped handle usable by right- and left-handed
99 surgeons. The forceps are powered by an electric generator connected to a power outlet.

100 **Design**

101 Each participant initially received a two-hour theoretical lesson regarding the fundamentals in
102 laparoscopy. A demonstration of the FLS exercises (i.e peg transfer task and intracorporeal
103 knot-tying task) was then performed by a qualified senior surgeon.

104 Over the course of the first two sessions, each participant performed the peg transfer task
105 twenty times per session, to familiarize with the use of laparoscopic instruments and the
106 fulcrum effect. The baseline performances for the laparoscopy suturing were then evaluated,
107 with participants performing two consecutive intracorporeal knots-tying tasks with two
108 conventional needle holders. The participants were randomized into groups A and B, using
109 the sealed envelope system. The participants of these two groups undertook four training
110 sessions with the pelvitrainer, performing ten intracorporeal knots-tying tasks per session. The
111 sessions were distributed over their time at the hospital as follows: Two sessions per week
112 and no more than one session per day.

113 The group A participants used a JAIMY robotized needle holder in their dominant hand and a
114 conventional needle holder in their nondominant hand. The group B participants used two
115 straight conventional needle holders. At the start of each session, participants watched an
116 educational video demonstrating the performance of an intracorporeal knot-tying task using a
117 robotized (group A) or conventional instrument (group B). There was no feedback from the
118 observer during the sessions.

119 After the four training sessions, the participants of each group underwent a post-training
120 evaluation: performing two intracorporeal knots-tying tasks and then performing exercises —
121 two frontal sutures and two hexagonal sutures — under more ergonomically difficult
122 conditions. For each group, the laparoscopy instruments used during this post-training
123 evaluation were the same as those used during the four training sessions.

124 Regarding the ergonomically difficult exercises, the frontal suture corresponded with the
125 performance of a stitch made through an entry and an exit point on a frontal axis.³ The entry

126 and exit points were predefined on a pad, as a double knot followed by two single knots then
127 had to be performed. The hexagonal suture consisted of performing a running stitch with
128 several passes by following as semi-hexagonal outline based on the predefined entry and exit
129 points on a pad.^{3,11} Vicryl 2/0 was used for all of the training and evaluation sessions. Fig. 2
130 summarizes the study design.

131 **Criteria for evaluation**

132 The performance evaluation at baseline, during the four training sessions and during the post-
133 training evaluation was done using the data recorded by a qualified observer. For all of the
134 intracorporeal knot-tying tasks, the raw FLS score was calculated.¹⁰ This accounts for the
135 time, the margin of error (in millimeters), and the quality of the knot. In group A, the use of
136 manual rotation control and/or bending of the robotized forceps were recorded for each
137 attempt, as well as the finger used to exert the manual control.

138 A qualitative evaluation of the intracorporeal knot-tying performances at baseline and during
139 the post-training evaluation was carried out using two different assessment tools: GOALS and
140 the Moorthy checklist.^{12,13} Therefore, GOALS score and Moorthy checklist score are
141 presented separately. These two scores were determined by two qualified assessors based on
142 an anonymized video-review. The GOALS score assesses five criteria: depth perception,
143 bimanual dexterity, efficiency, handling of the tissues, and autonomy. Each criterion was
144 scored from 1 to 5 points. The last criterion, “autonomy,” was not evaluated as the
145 participants did not receive any assistance, thus providing a GOALS score between 4 and 20.
146 In the Vassiliou et al. study, the construct validity of the GOALS was not only established on
147 total score but also on each of the 5 GOALS items; hence, a score using only 4 of the 5
148 GOALS items has construct validity.¹² The Moorthy checklist was specifically developed for
149 assessment of laparoscopic intracorporeal suturing skills. This validated checklist scores
150 technical features of the task, such as needle positioning and drive, and the technique used for

151 tying the knots.¹³ Three of the 29 item checklist differed from the technique described in the
152 FLS curriculum and were not taken into account, giving a total score out of 26.

153 The frontal suture evaluation considered the margin of error between the needle's entry point
154 and the predefined point in millimeters as well as the number and quality of the knots. The
155 global score was obtained by multiplying the qualitative score with the quantitative score.³

156 Regarding the hexagonal suture, the quantitative score corresponded with the number of entry
157 and exit points that were crossed, and the qualitative score corresponded with the margin of
158 error in millimeters between the needle's entry site and the predefined point. The global score
159 for the hexagonal suture was obtained by multiplying the qualitative score with the
160 quantitative score.^{3,11} The suturing performances under ergonomically difficult conditions
161 were evaluated by two qualified observer (ES and PC) based on anonymized video-reviews.

162 The NASA Task Load Index was used to measure the workload. Initially developed in 1988
163 in the aviation and aeronautics fields, this index has also been increasingly used in the surgery
164 field in recent times.¹⁴ It allows evaluation of the workload experienced by the participants
165 and it presents in the form of a visual scale evaluating six items: mental and physical
166 difficulty, temporal perception, level of frustration, level of satisfaction, and overall difficulty
167 of the effort required. The rating for the NASA score ranged from 0 to 20 for each of the six
168 items. The overall result was expressed in terms of a "summative score."

169 Participants entered the NASA self-assessment score on three occasions:

- 170 - At the end of the baseline evaluation for the intracorporeal knot-tying task
- 171 - At the end of the post-training evaluation for the intracorporeal knot-tying task
- 172 - At the end of the two exercises under ergonomically difficult conditions

173 **Statistical analysis**

174 A descriptive and a comparative analysis of the student's initial characteristics was carried out
175 as a function of their randomization group. The qualitative variables were described by their

176 value and as percentages, and compared using a chi-2 test when the conditions for its
177 application were met, and by a Fisher's test for the other cases. The quantitative variables
178 were described by their medians and interquartile intervals and compared using a Mann-
179 Whitney test given the size of the groups. For the baseline and post-training evaluations, the
180 second trial of each task was taken into account and provided as a result.

181 An analysis of the retained assessment criteria allowed the student's performances to be
182 described and compared as a function of their randomization group. Changes in the student's
183 performances as a function of their group were described by means of a learning curve. The
184 Friedman test was used to test the existence of a learning effect and to assess the session for a
185 plateau in the performances. All the statistical analyses were carried out with R version 3.3.1
186 software and were performed as two-tailed tests. A threshold of 0.05 was used to define
187 significance.

188

189 **Results**

190 **Participants**

191 Twenty participants were included in the study. They were randomized into two groups of ten
192 people: group A (JAIMY robotized needle holder) and group B (conventional straight needle
193 holder). There were 13 women (65%) and 7 men (35%). Their characteristics are presented in
194 Table 1.

195

196 **Peg transfer task**

197 At the end of the second peg transfer session, performances were not significantly different
198 between groups A and B in terms of time (66 versus 69 secs, $p=0.360$).

199

200

201 Intracorporeal knot-tying task: baseline and post-training evaluation

202 Both the baseline and post-training performances were not significantly different for group A
203 relative to group B in terms of time and FLS score. These results are detailed in Table 2.

204 Regarding the evaluation by GOALS and the Moorthy checklist, a random sample of the
205 anonymized videos (n=18; 46%) was reviewed by the two independent assessors (ES and
206 PC). The inter-assessor correlation coefficient for the total GOALS score and the checklist
207 were ICC= 0.894 (p< 0.001) and ICC=0.817 (p<0.001) respectively. Given the obtained inter-
208 assessor reliability, the remaining procedures were blindly evaluated by one of the two
209 assessors (PC) and this evaluation is presented as a result. At baseline, the median total
210 GOALS score was not significantly different for group A relative to group B (9 versus 6.5,
211 p=0.135). For the post-training evaluation, the median total GOALS score was not
212 significantly different for group A relative to group B (14 versus 14, p=0.787). These results
213 are illustrated in Fig. 3. At baseline, the median checklist score was not significantly different
214 for group A relative to group B (11.5 versus 11, p=0.422). For the post-training evaluation,
215 the median checklist score was not significantly different for group A relative to group B
216 (20.5 versus 18, p=0.319).

217

218 Learning curve

219 The FLS scores for the ten intracorporeal knots-tying tasks performed during each training
220 session were grouped together, and the medians were then compared. There was no
221 significant difference between the two groups for each of the four consecutive sessions. The
222 results are presented in Table 3.

223 For both groups A and B, there was a significant learning curve between session 1 and session
224 4 (p<0.001), with a plateau as of session 3. These results are illustrated in Fig. 4.

225 In terms of the use of the rotation function in group A over the course of the four training
226 sessions: 62% of the participants used it in the first training session versus 76% in the last
227 training session. As for the use of the bending function in group A over the course of the four
228 training sessions: 31% of the participants used it in the first training session versus 28% in the
229 last training session. Eight participants (80%) of group A engaged the manual control using
230 their thumb and two participants (20%) used their index finger.

231

232 **Performances with ergonomically difficult exercises**

233 A random sample of the anonymized videos (n=18; 46%) was reviewed by the two
234 independent assessors (ES and PC). The inter-assessor correlation coefficient for the
235 qualitative score for frontal suture and hexagonal suture was ICC=0.982 ($p < 0.001$) and
236 ICC=0.798 ($p < 0.001$) respectively. Given the obtained inter-assessor reliability, the remaining
237 procedures were blindly evaluated by one of the two assessors (PC) and this evaluation is
238 presented as a result. Regarding the frontal suture, the scores were significantly higher for
239 group A compared to group B. Regarding the hexagonal suture, there was not a significant
240 difference in the scores between group A and group B. These results are detailed in Table 4.
241 In regard to the use of rotation and bending during the two ergonomically difficult exercises:
242 100% of group A participants used these functions.

243

244 **NASA Task Load Index**

245 a. Intracorporeal knot-tying task:

246 For the baseline evaluation, the total NASA score was not significantly different between
247 group A and group B (74.5 versus 75.5, $p = 0.911$). For the post-training evaluation, the
248 NASA score was not significantly different between group A and group B (62.5 versus 56, $p =$
249 0.858). For group A, the total NASA score for the baseline evaluation was higher than that for

250 the post-training evaluation: 74.5 versus 62.5, $p= 0.041$. For group B, the total NASA score
251 for the baseline evaluation tended to be higher than that for the post-training evaluation: 75.5
252 versus 56, $p= 0.066$.

253 b. Ergonomically difficult conditions:

254 For the ergonomically difficult exercises, the total NASA score was not significantly different
255 between group A and group B (78.5 versus 79.5, $p= 0.909$).

256

257 **Discussion**

258 The improvement of ergonomics in the operating theatre is increasingly recognized as an
259 important issue¹⁵, thus resulting in the development of new surgical instruments. The use of
260 articulated and robotized instruments in laparoscopic surgery is of interest as it allows for a
261 very precise surgical gestures while also improving the surgeon's operative comfort.¹⁶
262 Consequently, it is important to compare the training required for the use of these new
263 instruments relative to conventional instruments.

264 In this study the two groups of novice surgeons had an equal skill level at baseline. Each of
265 the two groups learned how to make intracorporeal knots on a pelvitrainer using either a
266 robotized needle holder or conventional needle holders. The skill level reached upon
267 completion of the training sessions was equivalent for the two groups according to all
268 assessment tools (time, FLS score, GOALS score, Moorthy checklist). The study of the
269 learning curve revealed that learning laparoscopy using a robotized needle holder was not
270 more difficult than learning using conventional instruments: based on the total FLS score, a
271 plateau was reached as of the third session irrespective of the kind of needle holder used.
272 Although no significant differences were found between the two instrument types under
273 conventional suture conditions, the use of a robotized needle holder allowed for better

274 performances under ergonomically difficult conditions, such as with the frontal suture
275 exercise.

276 Articulated laparoscopic instruments are developed to overcome the limitations of the range
277 of conventional instruments. Several examples have been tested. The obtained results confirm
278 that articulated instruments comprise a new approach that warrants exploration. The non-
279 robotized articulated RADIUS forceps has been proven to perform better than conventional
280 instruments for the execution of complex sutures by experienced and trainee surgeons and by
281 novices.^{17,18} Another team has published their findings for an evaluation of the JAIMY
282 robotized needle holder by comparing it with conventional instruments.³ The participants
283 were experienced or trainee surgeons. The two randomly devised groups of surgeons
284 performed peg transfer, hexagonal suture, and frontal suture exercises. Suturing in classical
285 conditions (i.e the FLS intracorporeal knot-tying task) and learning curves were not evaluated.
286 The performances of the group using the JAIMY robotized needle holder were significantly
287 improved for the frontal suture, and equivalent for the hexagonal suture, which is in keeping
288 with the results obtained in our study. A recent study on the robotized Kymerax[®] forceps
289 showed that surgeons considered it advantageous for complex sutures, although performances
290 in terms of ergonomics had not been evaluated.¹⁹

291 Robot-assisted surgery allows the surgeons to operate while seated, thereby decreasing their
292 muscle fatigue. The incidence of muscle fatigue in surgeons is high when conventional
293 laparoscopy is used due to the unsuitable ergonomic conditions.²⁰ Ergonomic criteria for the
294 position of the surgeon were studied and the JAIMY robotized needle holder was shown to
295 provide advantages in terms of ergonomics when used with a pelvitainer.³ However, the
296 advantage of such a robotized instrument for surgeon's ergonomic strain remains to be
297 demonstrated in the operating room.

298 The benefit of using the JAIMY robotized needle holder with the frontal suture can be
299 explained by the instruments characteristics. Indeed, the instrument's ability to bend allows
300 the needle to be maintained at a right angle to the suture without having to angulate it between
301 the forceps. The possibility of rotating the forceps allows the movement to be followed
302 without performing pronosupination.²¹ Takazawa et al. demonstrated that an instrument with
303 several degrees of freedom greatly improved the performances in the vertical plane.²² This is
304 probably why these two functionalities were used by all the group A participants during the
305 exercises under ergonomically difficult conditions. Moreover, the ergonomic handle allows
306 the wrist to be maintained in a neutral position, thereby improving the surgeon's comfort.²³
307 Under conventional suturing conditions, however, a robotized needle holder was not superior
308 to conventional instruments. In this setting, the angles between the instruments and the target
309 plan did required very little or no use of an articulated mechanism. There was no significant
310 difference between the two groups for the hexagonal suture. This is probably because this
311 exercise presented fewer ergonomic difficulties than the frontal suture with regard to the
312 angle between the instruments and the target plan, and it did not require knot tying.

313 The experienced workload was not different when the two groups were compared at the same
314 time during the study process. This confirms that the JAIMY robotized needle holder was not
315 harder (or easier) to use than a conventional needle holder. The equivalent learning curves are
316 in keeping with this result. By contrast, the experienced workload decreased within the groups
317 between the baseline and the post-training evaluation (in a significant manner for group A and
318 nearly significant for group B). This difference is to be expected and is probably due to the
319 effect of the participants' training and familiarization with the allocated instruments.²⁴

320 Studying surgical novices' learning curves on a FLS pelvitrainer is relevant, as the use of
321 laparoscopic simulators has been proven to be effective for surgeons' learning and
322 performance.^{25,26} The intracorporeal knot-tying exercise is a classic FLS task. The exercises

323 under ergonomically difficult conditions were more complicated but nonetheless readily
324 reproducible, as the needle entry and exit points were identified in a standardized manner on
325 pads. Other exercises could have been considered (e.g., suturing of cadavers or live animals),
326 but the evaluation using objective criteria would have been harder to implement. Suturing in
327 the vertical plane or following a frontal axis can be necessary in the operating theatre during
328 surgical interventions for diverse specialties, such as hysterectomies, myomectomies and
329 sacrocolpopexy in gynecology. The present study suggests that robotized instruments could
330 be considered in the OR to improve the completion of such ergonomically difficult tasks.

331 This study has several limitations. The participants were medical students whose experience
332 of the operating room was limited to observation during their rotation. Consequently the
333 learning curves evaluation could not be influenced by previous surgical experience.
334 Nonetheless, ideal participants would be first-year surgical residents. There were a small
335 number of participants. Given the absence of previous studies on this topic, no sample size
336 was calculated. Consequently, the outcomes that revealed no difference between the groups
337 were potentially due to a lack of power. Learning curves were established taking into account
338 the FLS score, which mainly relied on time. Lastly, the video-based assessment of the post-
339 training performances could not be blinded as the JAIMY robotized needle holder could be
340 clearly identified on videos. However, this evaluation bias probably did not affected the
341 results, as they differed depending on the testing conditions (i.e. no difference between the
342 groups on the conventional intracorporeal knots-tying and hexagonal suture, and a difference
343 on the frontal suture).

344

345 **Conclusions**

346 Under conventional conditions, the JAIMY robotized needle holder allowed for learning at
347 the same rate as with conventional instruments and led to equivalent performances. Under

348 difficult ergonomical conditions, it provided an advantage relative to conventional
349 instruments. Continued research would be useful to evaluate skill retention using this
350 robotized needle holder. The next steps will be to evaluate performances in the operating
351 theatre under classical and ergonomically difficult conditions. Additionally, a performance
352 comparison between residents and senior surgeons would be of interest, so as to determine for
353 whom the use of a robotized needle holder has the greatest benefit.

354

355 **Disclosure**

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357 Agostini have no competing interest or financial ties to disclose.

358

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362

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434 **Figure legends**

435 Figure 1: The JAIMY robotized needle holder

Figure 2: Study design

436 Figure 3: Intracorporeal knot-tying performances at baseline and during the post-training
437 evaluation, in terms of GOALS score. Group A (JAIMY robotized needle holder) and group
438 B (conventional needle holder). Horizontal lines within boxes, boxes and whiskers represent
439 median, inter-quartile range and range, respectively.

440 Figure 4: Intracorporeal knot-tying performances, in terms of FLS score: Learning curves for
441 groups A (JAIMY robotized needle holder) and group B (conventional needle holder).
442 ($p < 0.001$; Friedman test; plateau at 3rd session).

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447 **Tables****Table 1:** Characteristics of the participants

| | Group A (n=10) JAIMY robotized needle holder | Group B (n=10) Conventional needle holders | <i>p-value</i> |
|----------------------|---|---|----------------|
| Age (years) | 24.0 | 23.4 | 0.844 |
| Gender | | | |
| Female | 7 | 6 | - |
| Male | 3 | 4 | - |
| Dominant hand | | | |
| Right | 10 | 9 | - |
| Left | 0 | 1 | - |

Table 2:

Intracorporeal knot-tying performances at baseline and during the post-training evaluation, in terms of time and FLS score. Comparison between group A and group B. The results are presented as medians (quartile 1- quartile 3).

| | Group A (n=10) JAIMY robotized needle holder | Group B (n=10) Conventional needle holders | <i>p-value</i> |
|------------------|---|---|----------------|
| Time (s) | | | |
| Baseline | 317.5 (285-337) | 450.5 (308-561) | 0.143 |
| Post-test | 127 (113-156) | 125.5 (111-142) | 0.677 |
| FLS score | | | |
| Baseline | | | |
| • Error | 0 | 0 | 1 |
| • Quality | 10 (0-10) | 5 (0-18) | 0.689 |
| • Total | 281.75 (258-312) | 172.25 (89-294) | 0.143 |
| Post-test | | | |
| • Error | 0 | 0 | 1 |
| • Quality | 0 (0-7.5) | 0 | 0.618 |
| • Total | 468 (440-487) | 474.5 (456-489) | 0.762 |

448 **Table 3:**

Intracorporeal knot-tying performances during the four training sessions, in terms of FLS score.

Comparison between group A and group B. The results are presented as medians (quartile 1- quartile 3).

| | Group A (n=10) JAIMY robotized needle holder | Group B (n=10) Conventional needle holders | <i>p-value</i> |
|-----------------------|---|---|----------------|
| Knots 1 to 10 | 403.6 (374.1 - 422.4) | 371.8 (337.7 - 420.6) | 0.436 |
| Knots 11 to 20 | 456.1 (435.3 - 467.1) | 462.4 (439.7 - 495.8) | 0.393 |
| Knots 21 to 30 | 479.5 (449.1 - 492.4) | 501 (465.1 - 511.8) | 0.529 |
| Knots 31 to 40 | 492.8 (478.3 - 504.8) | 498.2 (481.3 - 506.8) | 0.820 |

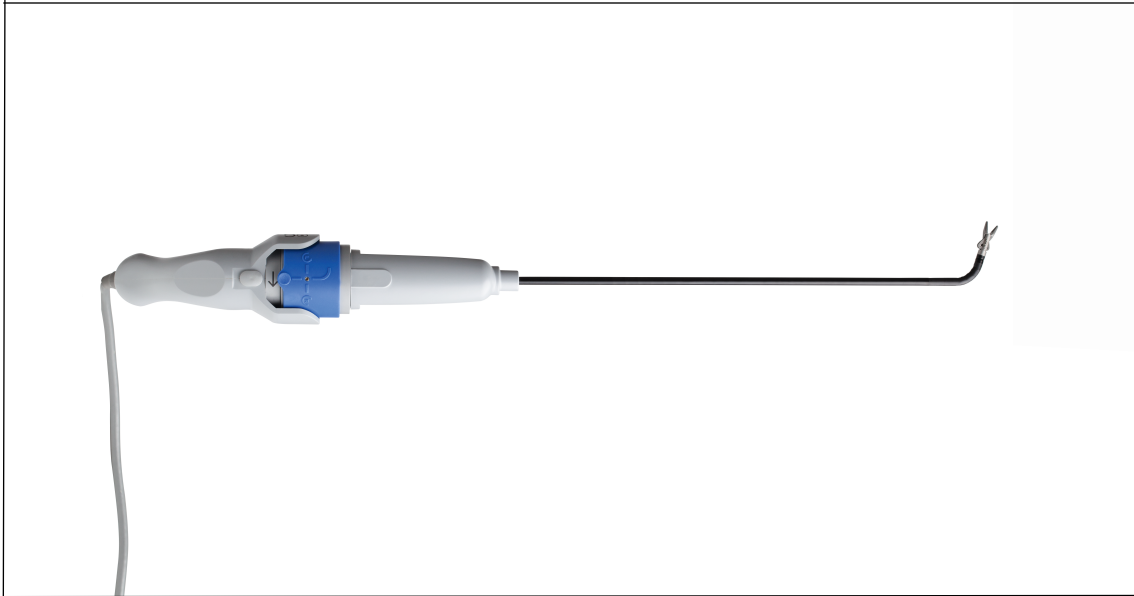
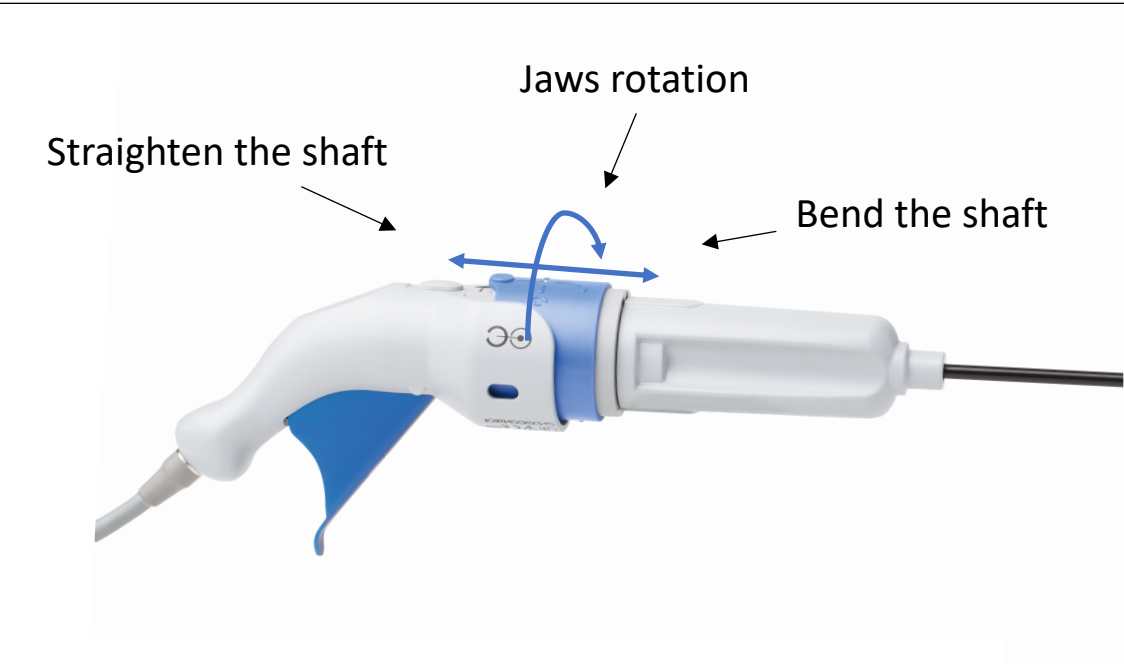
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451 **Table 4:** Performance scores for two ergonomically difficult exercises: frontal suture and hexagonal
452 suture. Comparison between group A and group B. The results are presented as the median (quartile 1-
453 quartile 3)

| | Group A (n=10) JAIMY robotized needle holder | Group B (n=10) Conventional needle holders | <i>p-value</i> |
|-------------------------|---|---|----------------|
| Frontal suture | | | |
| Global score | 15.75 (11-20) | 3.75 (1.63-7.88) | 0.006 |
| Quantitative score | 3 (2.13-3.88) | 1.25 (0.63-1.5) | 0.003 |
| Qualitative score | 5 (3.75-6.13) | 2.75 (1.13-3.5) | 0.022 |
| Hexagonal suture | | | |
| Global score | 18 (15-20.75) | 15 (6.75-19.5) | 0.285 |
| Quantitative score | 6 (5-6.25) | 5 (3.25- 8.5) | 0.501 |
| Qualitative score | 2.75 (2.5-3.5) | 2.25 (1.63-2.88) | 0.124 |

454



2 sessions
Peg transfer task (x10 per session)

Baseline testing evaluation
intracorporeal knots-tying task (x2), using conventional needle holders

Randomization (n=20)

Group A (n=10)
JAIMY robotized needle holder

4 training sessions
intracorporeal knot-tying task
(x10 per session)

Post-training evaluation
intracorporeal knot-tying task (x2)
frontal suture (x2)
hexagonal suture (x2)

Group B (n=10)
conventional needle holders

4 training sessions
intracorporeal knot-tying task
(x10 per session)

Post-training evaluation
intracorporeal knot-tying task (x2)
frontal suture (x2)
hexagonal suture (x2)

