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

Elena Siri<sup>1+</sup>, MD, Patrice Crochet<sup>1,\*,+</sup>, PhD, Axelle Charavil<sup>1</sup>, MD, Antoine Netter<sup>1</sup>, MD, Noémie Resseguier<sup>2</sup>, PhD, Aubert Agostini<sup>1</sup>, MD

<sup>1</sup> Department of Obstetrics and Gynecology, Assistance Publique - Hôpitaux de Marseille, La Conception Hospital, 13005 Marseille, Aix Marseille Université, France.

<sup>2</sup> Support Unit for Clinical Research and Economic Evaluation, Assistance Publique-Hôpitaux de Marseille, Aix Marseille Université, 13005 Marseille, France

\* Corresponding Author

Email: [pcrochet.marseille@gmail.com](mailto:pcrochet.marseille@gmail.com)

Tel: +33 688384803

147 boulevard Baille, 13005 Marseille, FRANCE

+ these authors contributed equally to this work

## **Short title:**

Training with a robotized needle holder

## **Author contributions :**

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

**ABSTRACT**

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

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

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

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

## Introduction

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

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

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

Robotic-assisted laparoscopy was developed in particular to improve surgeon's operative dexterity and comfort.<sup>6</sup> However, this technique remains very expensive. It requires specific equipment and involves longer operative times.<sup>7,8</sup> On the other hand, robotized instruments have been developed for use during conventional laparoscopy, combining the advantages of conventional laparoscopy and the ergonomics associated with robotic-assisted laparoscopy.<sup>9</sup> Although still rarely used, these instruments must be evaluated relative to the known conventional instruments that have been mastered by laparoscopic surgeons. This evaluation must be particularly focused on the learning phase and on performances in terms of surgical dexterity.



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

## **Material and methods**

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

### **Execution of the study**

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

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

### **Design**

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

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

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

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

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

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

### **Criteria for evaluation**

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

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

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

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

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

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

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

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

### **Statistical analysis**

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

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

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

## **Results**

### **Participants**

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

### **Peg transfer task**

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

### **Intracorporeal knot-tying task: baseline and post-training evaluation**

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

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

### **Learning curve**

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

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

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

### **Performances with ergonomically difficult exercises**

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

### **NASA Task Load Index**

#### **a. Intracorporeal knot-tying task:**

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

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

b. Ergonomically difficult conditions:

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

## Discussion

The improvement of ergonomics in the operating theatre is increasingly recognized as an important issue<sup>15</sup>, thus resulting in the development of new surgical instruments. The use of articulated and robotized instruments in laparoscopic surgery is of interest as it allows for a very precise surgical gestures while also improving the surgeon's operative comfort.<sup>16</sup> Consequently, it is important to compare the training required for the use of these new instruments relative to conventional instruments.

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



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

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

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

The benefit of using the JAIMY robotized needle holder with the frontal suture can be explained by the instruments characteristics. Indeed, the instrument's ability to bend allows the needle to be maintained at a right angle to the suture without having to angulate it between the forceps. The possibility of rotating the forceps allows the movement to be followed without performing pronosupination.<sup>21</sup> Takazawa et al. demonstrated that an instrument with several degrees of freedom greatly improved the performances in the vertical plane.<sup>22</sup> This is probably why these two functionalities were used by all the group A participants during the exercises under ergonomically difficult conditions. Moreover, the ergonomic handle allows the wrist to be maintained in a neutral position, thereby improving the surgeon's comfort.<sup>23</sup> Under conventional suturing conditions, however, a robotized needle holder was not superior to conventional instruments. In this setting, the angles between the instruments and the target plan did required very little or no use of an articulated mechanism. There was no significant difference between the two groups for the hexagonal suture. This is probably because this exercise presented fewer ergonomic difficulties than the frontal suture with regard to the angle between the instruments and the target plan, and it did not require knot tying. The experienced workload was not different when the two groups were compared at the same time during the study process. This confirms that the JAIMY robotized needle holder was not harder (or easier) to use than a conventional needle holder. The equivalent learning curves are in keeping with this result. By contrast, the experienced workload decreased within the groups between the baseline and the post-training evaluation (in a significant manner for group A and nearly significant for group B). This difference is to be expected and is probably due to the effect of the participants' training and familiarization with the allocated instruments.<sup>24</sup> Studying surgical novices' learning curves on a FLS pelvitrainer is relevant, as the use of laparoscopic simulators has been proven to be effective for surgeons' learning and performance.<sup>25,26</sup> The intracorporeal knot-tying exercise is a classic FLS task. The exercises

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

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

## Conclusions

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

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

## Disclosure

Elena Siri, Patrice Crochet, Axelle Charavil, Antoine Netter, Noémie Resseguier, and Aubert Agostini have no competing interest or financial ties to disclose.

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## Figure legends

Figure 1: The JAIMY robotized needle holder

Figure 2: Study design

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

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

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

	<b>Group A (n=10)</b> <b>JAIFY robotized needle holder</b>	<b>Group B (n=10)</b> <b>Conventional needle holders</b>	<i>p-value</i>
<b>Age (years)</b>	24.0	23.4	0.844
<b>Gender</b>			
Female	7	6	-
Male	3	4	-
<b>Dominant hand</b>			
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).

	<b>Group A (n=10)</b> <b>JAIFY robotized needle holder</b>	<b>Group B (n=10)</b> <b>Conventional needle holders</b>	<i>p-value</i>
<b>Time (s)</b>			
Baseline	317.5 (285-337)	450.5 (308-561)	0.143
Post-test	127 (113-156)	125.5 (111-142)	0.677
<b>FLS score</b>			
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



**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).

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

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

	<b>Group A (n=10)</b> <b>JAIMY robotized needle holder</b>	<b>Group B (n=10)</b> <b>Conventional needle holders</b>	<i>p-value</i>
<b>Frontal suture</b>			
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
<b>Hexagonal suture</b>			
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







