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NEW TECHNOLOGY

Performance of Kymerax© precision-drive articulating surgical system compared to conventional laparoscopic instruments in a pelvitrainer model

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Abstract
Background The Kymerax© Precision-Drive Articulating Surgical System by Terumo© is a handheld laparoscopic robot which permits motion in two additional degrees of freedom (deflection and rotation in the instrument tip). In a pelvitrainer model, we compared the performance of participants with different laparoscopic experiences and compared Kymerax© to conventional laparoscopic instruments.
Methods 20 expert surgeons, performing more than 50 laparoscopic procedures per year, and 25 medical students without any experience in surgery at all were selected. Each participant was randomized into two groups: Group TK performed the tasks using the traditional laparoscopic Instruments (TLI) first and Kymerax© thereafter, group KT vice versa. Six standardized tasks were used: Two instructional exercises and four tasks where time, number of mistakes, and overall precision were measured. Finally, a questionnaire had to be answered.
Results All four tasks were performed significantly more slowly with the Kymerax© device. Improved needle control in stitches towards the surgeon, significantly less deviation while cutting along different lines as well as a significantly reduced fraying of the cutting edge were found when participants were using Kymerax©. By questionnaire more than 90% of the participants indicated clear advantages using Kymerax©. However, participants needed more training time and had an earlier loss of concentration with Kymerax©. Further complaints about Kymerax© were its limitations in rotation and deflection, the impaired view as well as the non-ergonomic instrument handle. Rotation force, instrument weight, digital instrument-tip control, and needle fixation were rated as accurate.
Conclusions This study shows that more time is needed to solve tasks with Kymerax© compared to conventional laparoscopic instruments. Kymerax© is superior to conventional laparoscopy for suturing at difficult angles and cutting along complex structures. Kymerax© can potentially bring benefits for certain laparoscopic tasks, but as seen in this study, further developments are necessary. Terumo© meanwhile closed down its Kymerax© business.

Keywords Kymerax · Handheld robot · Laparoscopy · Pelvitrainer · Degrees of freedom · Gynecology

Laparoscopic surgery offers many advantages compared to laparotomy, such as decreased blood loss, reduced infection rates, shorter hospital stay, and better cosmetic results [1, 2]. However, disadvantages are encountered, such as longer operating time, only four degrees of freedom, and earlier tiring of the surgeon [3, 4]. To reduce these restrictions of laparoscopic surgery, new robotic systems, such as the Da Vinci Surgical System©, have been introduced. Besides offering all seven degrees of freedom, the da Vinci Surgical System shows a steep learning curve and is less tiring for the surgeon [5, 6]. Nevertheless, the benefit for patients operated with the da Vinci System is discussed controversially. Furthermore, robotic systems are less cost-effective than conventional laparoscopic systems [7]. A more economic technology combining both systems—robotic and

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conventional laparoscopic—offers all degrees of freedom and is handheld by the surgeon in a conventional manner. Such instruments include the "Radius Surgical System"© by Tuebingen Scientific [8–12] and the Kymerax© Precision-Drive Articulating Surgical System by Terumo© Medical Corporation, which was used in this study.

This instrument offers an additional 85° deflection of the tip to two sides and an additional tip rotation of max. 270° (Fig. 1), all controlled by digital buttons on the instrument handle (Figs. 2 and 3). The deflection button can be pressed left or right, so that the instrument tip deflects towards the commanded direction at a constant speed. The rotation button is built like a wheel. By moving the wheel to the left or right, the instrument tip rotates towards the commanded direction at a constant speed. Servomotors drive the movements. Two small buttons just below the deflection button serve to return the instrument tip to the neutral position. By pressing those buttons, the instrument tip moves back into a straight, non-rotated position. The instrument itself is connected by cable with the main-console.

Terumo© meanwhile closed down its Kymerax© Business by October 2013. Nevertheless, the technique was bought by KARL STORZ Gmbh & Co. KG© and will be released soon with minor modifications.

This study aimed to compare the performance of Kymerax with traditional laparoscopic instruments (TLI), based on 4 simple tasks (such as suturing and cutting) in a pelvitrainer model. The authors wanted to prove whether Kymerax brings an advantage in speed and accuracy for laparoscopic tasks. Another goal was to find out if the users experience advantages by applying the new technique and whether it is easier to learn laparoscopic procedures with Kymerax than with TLI.

Fig. 1 Instrument tip (Maryland dissector) in different positions. (sunstoneonline.com)

Materials and methods

Study design

A total of 45 candidates were selected according to their experience in laparoscopic surgery: 20 expert surgeons, performing more than 50 laparoscopic procedures per year, and 25 medical students without any surgical experience at all (Table 1). There was no left-handed participant. Each participant was randomly assigned to one of two groups: Group TK performed the tasks by TLI first and by Kymerax thereafter, group KT performed the tasks vice versa.

Two participants of the expert group already had used Kymerax twice in a clinical setting, 6 experts already trained with Kymerax in a pelvitrainer before. All other participants did not have any experience with Kymerax.

In order to get the same conditions for each participant, two instructional tasks were performed with Kymerax, as well as with TLI. Thereafter, the participants performed 4 tasks with each instrument. Time needed, overall precision, and the number of mistakes were registered.

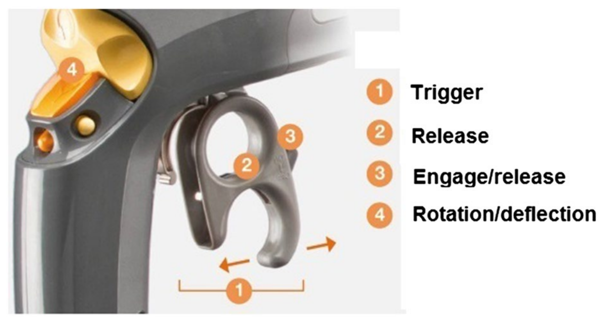

Fig. 2 Kymerax handle: *1* Trigger for opening and closing instrument. *2* Release of engaged trigger. *3* Engage/release trigger. *4* Buttons for tip rotation and deflection. (kymerax.info)

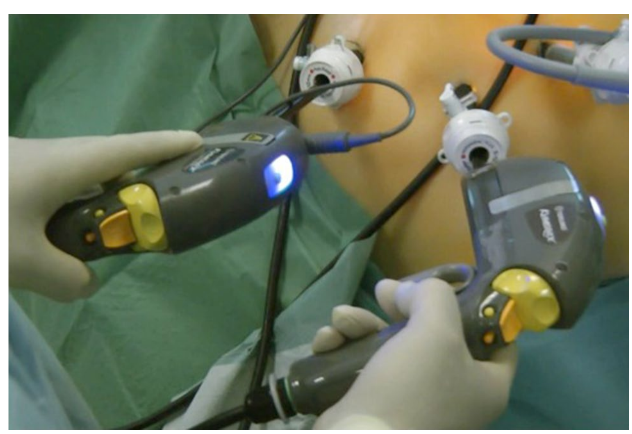

Fig. 3 Two Kymerax handles, intraoperative overview (with many thanks to Dr.med. Robert Oehler)

Before each task, an instructional video was shown to explain the procedure. At the end of the tasks, the participants filled in a questionnaire.

Instrument setup

All tasks were performed in a pelvitrainer to simulate a realistic anatomical situation. The study has been performed from the perspective of gynecology. As reference level, the Douglas space was selected. The distance and angles of the trocar positions in relation to the Douglas space were measured in the operation theatre and adapted to the pelvitrainer.

Due to the weight and the position of the control-elements, Terumo© recommends an ipsilateral access to work with Kymerax. A left-sided paraumbilical and inguinal access port was installed. The same access was used with Kymerax, as well as with TLI.

An umbilical access was used for the fixed optical device (Storz® "Hopkins II 30°" endoscope with a Storz® "Xenon Nova 300" light source and a Storz® "Image 1 H3-Z Full HD" camera). The monitor (Storz® "Wide View HD" 23 inch) was placed in a 45°angle on the left side of the participant, at a distance of 1.5 m.

For the tasks with TLI, the Storz® "Macro needle holder right curved und left curved 5 mm x 33cm" and Storz® "Laparoscopic scissors Clickline 5 mm x 36cm" were used. The participants could always use a TLI needle holder in the left hand, also for the tasks with Kymerax.

Another screen to show the instructional videos was placed in front of the participant at a distance of 1 m.

Instruction exercises

The first two tasks were designed to familiarize the participant with the instruments. They were performed with both: the TLI and the Kymerax System.

In the first exercise, the participant had the possibility to get used to the two-dimensional view and the basic handling of the instruments for 3 min40sec. A clock face was painted on the 6 o'clock wall and a 2-cm messing pin was placed in the middle of the setup. The participants could pick up the pin and practice the rotational movement with the pin as a clock hand (Fig. 4 left). The exercise was explained by means of a video.

In the second instruction exercise, complex moves had to be performed with a marionette within 6 min, as shown in the instruction video (Fig. 4 right). The movements were repeated and gave the participant the possibility to internalize all degrees of freedom.

These two exercises were not part of the evaluation.

Task one: "Pin sticking"

Six messing pins at a length of 2 cm were lying on a table and had to be placed in a vertical position into the designated holes (Fig. 5). With TLI, the pins had to be turned 90° with the second instrument before putting them into the holes. With Kymerax, the deflection and rotation function could be used; a second instrument was not necessary to move the pin into the right position. A mistake was made if the pin was dropped on the floor. Besides the mistakes, the required time (s) was registered.

Task two: "Suturing"

The suturing task consisted of three stitches, each marked with two dots at a distance of 9 mm on a felt pad, measuring 5.5 cm x 5cm (Fig. 6), sutured with Safil 0 thread. Stitch nr.1 was at an angle of 140° (in direction of view), stitch nr.2 at 30°, and nr.3 at 270°. The participants were free to choose the order of stitches, as well as the direction of suturing. We registered the required time (s), the deviation from the dot (mm) and the mistakes. A mistake was counted if the needle was removed from the felt before the stitch was finished.

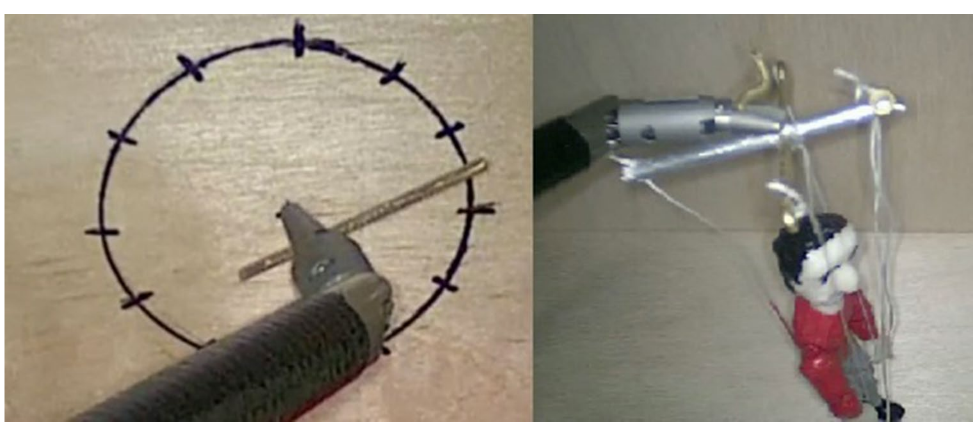

Fig. 4 *Left* Instruction exercise 1 (clock hand), *right* Instruction exercise 2 (marionette)

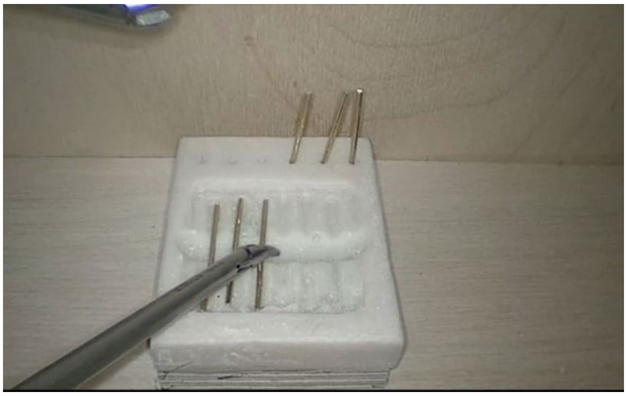

Fig. 5 Task one "pin sticking"

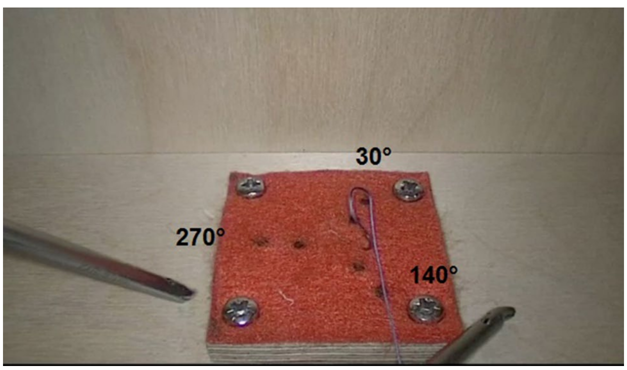

Fig. 6 Task two "suturing"

Task three: "Circular cutting"

On a 6.5 cm × 6.5 cm foam rubber pad, the participants had to cut along a circular line (Fig. 7). The circle was open from 30° to 330° in direction of view. The radius measured 2.5 cm. As starting point, a hole was punched out at 180°. At this point, the participants had to begin cutting along the line. It was forbidden to create a new hole. The required time (s) and the maximum deviation from the drawn line (mm) were registered. We also registered a blind evaluated "fraying factor" (Fig. 9). This factor was defined with an analogue pain scale. If the value was 0, the cutting line was subjectively considered as smooth. A maximum value of 10 meant a strongly frayed line.

Task four: "Straight cutting"

On a 5.5 cm × 8 cm foam rubber pad, the participants had to cut along two straight lines (Fig. 8). Each line measured 6 cm while crossing at an angle of 110°. A starting hole was punched out at the bottom left corner in direction of view. The participants had to begin at this point, but creating a new hole to continue cutting was forbidden. The same parameter as in task three was registered (Fig. 9).

Fig. 7 Task three "circular cutting"

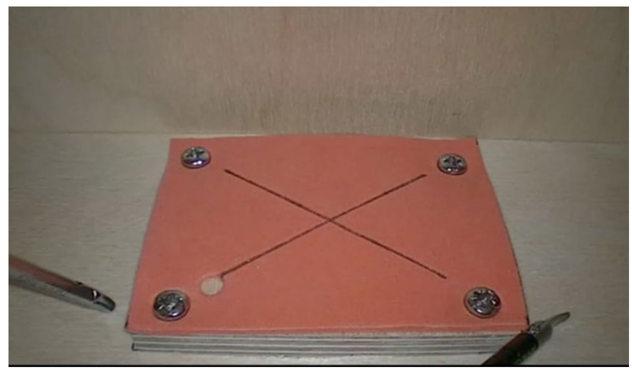

Fig. 8 Task four "straight cutting"

Questionnaire

After having finished task four with the first instrument (either Kymerax or TLI), a questionnaire had to be filled in by the participant. The same questions had to be answered after the use of the second instrument. The questionnaire contained 3 questions, asking at first how difficult each task was on a scale between 1 and 10. Secondly, the participants had to respond after which task they got used to the instrument handling. The third question aimed to find out whether the participants lost the ability to concentrate at a certain task. After the participants finished all tasks with both instruments, a final questionnaire had to be filled in. The questions focused on noticeable advantages of the Kymerax system compared to TLI. Furthermore, the participants were asked about their feeling towards certain features of Kymerax, such as weight, instrument-tip control, rotation and deflection, restriction of view, ergonomy, and force conduction. At the end, the possibility was given to write down personal comments about the study.

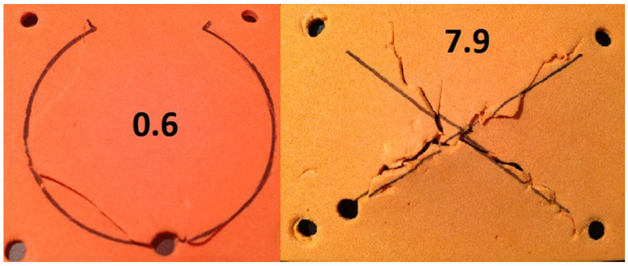

Fig. 9 Two examples of different "fraying factors": *left* smooth surface (fraying factor = 0.6), *right* strongly frayed surface (fraying factor = 7.9)

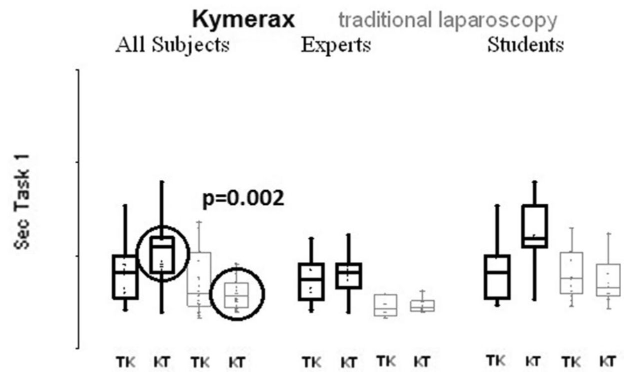

Fig. 10 Time [sec] task one

Statistical analysis

After all data had been registered, an analysis of variance (ANOVA) was made. A *p* value lower than 0.05 was considered being significant. All results are presented in boxplot diagrams.

Results

Task one (pin sticking)

Participants needed 40% more time with Kymerax than with TLI to fulfill task one. Also, the participants starting with Kymerax were significantly faster with TLI ($p = 0.002$), but no such effect could be observed in the group starting with TLI. As in the three following tasks, the experts were significantly faster than the students. There was no significant difference in the number of mistakes (dropping a pin) made between the two instruments. In Fig. 10, the needed time is shown in a boxplot diagram.

Task two (suturing)

On average, the participants needed 35% more time with Kymerax than with TLI ($p = 0.002$). Again, the KT group could improve its speed in the second round with TLI ($p = 0.0014$), but no such effect could be observed in the TK group. The number of mistakes (pulling back the needle) is comparable with the results of task one, which means the participants on average pulled the needle back as often as they dropped a pin in task one. Like in task one, there was no significant difference in the number of mistakes made between the two instruments.

In terms of stitching precision, no significant difference could be observed between the two instruments in stitch 1 (140°) and stitch 3 (270°). Stitch 2 (30°) could be performed 45% more precise with Kymerax than with TLI ($p = 0.004$). The deviation of the needle exit-point is shown in a boxplot diagram in Fig. 11.

Task three (circular cutting)

The expert group needed, similar to the previous tasks, 40% more time with Kymerax than with TLI ($p = 0.000$). Concerning the student group, this is the first task the participants of the group TK could improve their time significantly with Kymerax after using TLI ($p = 0.003$). The results are shown in Fig. 12.

The parameter "maximum deviation from the drawn line" did not show any significant difference between the two instruments.

As shown in the boxplot diagram in Fig. 13, the "fraying factor" was 32% less with Kymerax compared to TLI ($p = 0.000$).

Task four (straight cutting)

Considering the last task, the results in time are comparable to task one and two. The participants in group KT were faster with TLI, but this result was borderline significant ($p = 0.052$). But again, the participants could not improve their speed significantly with Kymerax after using TLI first.

In terms of "maximum deviation," Kymerax was superior to TLI in this task. As shown in Fig. 14, the deviation was on average 18% less with Kymerax ($p = 0.02$).

The fraying factor is comparable to the results in task three. Again, the line was cut 32% smoother with Kymerax than with TLI ($p = 0.000$).

Results Summary

Table 2 shows an overview of the analysis of variance (ANOVA) with all the significant *p*-values. The four tasks are numbered in the first line Table 1. Task two is divided into needle entry- and exit-point of stitch 1 to 3, together with the angle of the stitch. Experience (E) shows if there was a significant difference between the students and the expert group. Order (O) shows if there was a significant

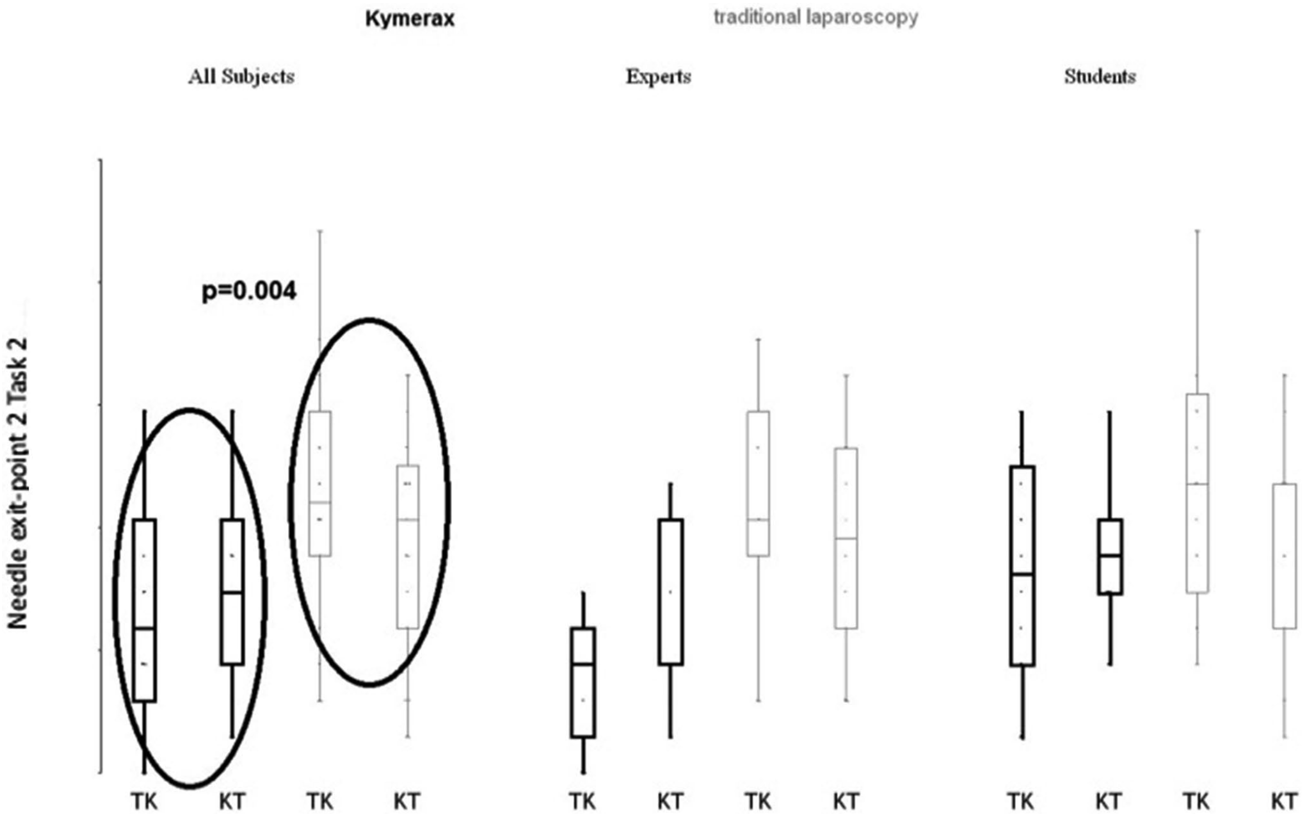

Fig. 11 Needle exit-point stitch 2 (30°) [mm] task two

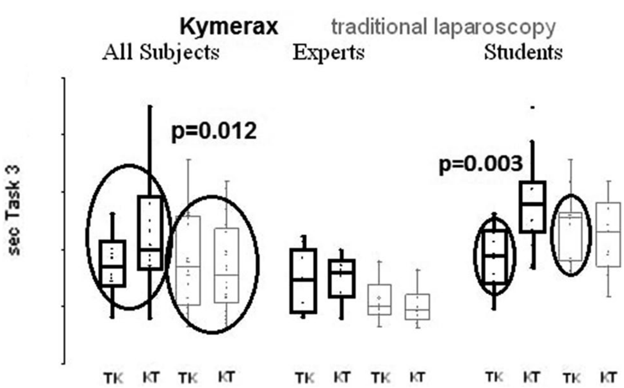

Fig. 12 Time [sec] task three

difference just because of the subdivision of the groups TK and KT. Method (M) illustrates the difference between the two systems – traditional laparoscopy and Kymerax.

Questionnaire results

Experts and students rated the difficulty of the tasks similarly. There was no significant difference between Kymerax and TLI. The most difficult task was number two (suturing), with an average rating of 7.46 out of 10 for both instruments. The easiest task was considered to be number one (pin sticking), with an average rating of 3.95 out of 10 for both instruments.

The second question ("after which task did you get used to the instrument?") showed that 9 participants did not get used to Kymerax at all. This was never the case with TLI. The other participants got used to the handling of Kymerax on average after task two (students) or task three (experts). With TLI, the average of all participants felt familiar with the instruments after task one.

With TLI, 80% of the participants were able to maintain concentration until the end of the study. With Kymerax, only 60% could stay focused until the end. If a participant lost the ability to concentrate on a task during the study, this was usually the case after task two (suturing).

All participants have been asked; whether they felt that Kymerax brings some benefit to solve the tasks compared to TLI or not. More than 90% of all participants think that overall, Kymerax brings an advantage to fulfill the tasks. The second question aimed to find out, for which specific tasks Kymerax brings a benefit. The biggest advantage of Kymerax is seen in task three (circular cutting). The answers are shown in Fig. 15.

The last 8 questions were asking about certain features of Kymerax, such as weight, ergonomy, and others. The

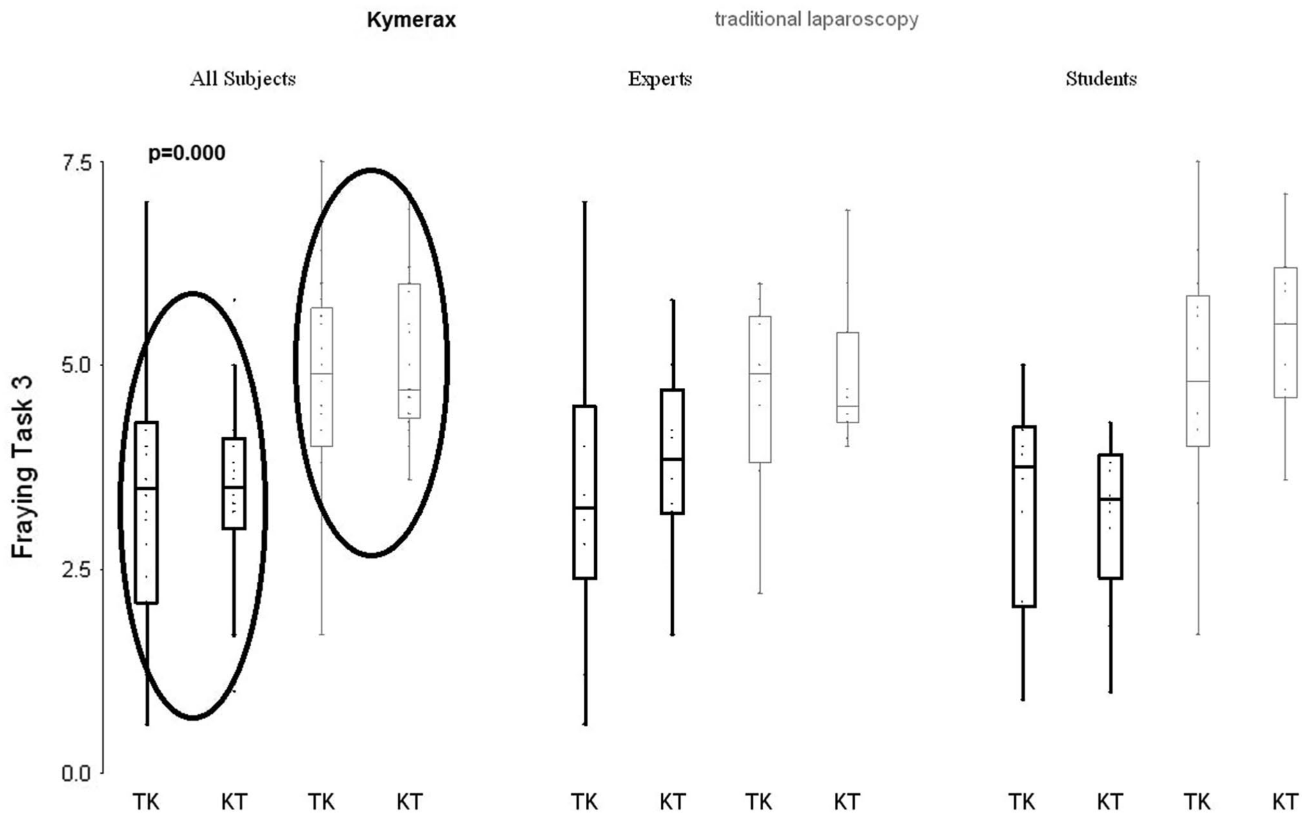

Fig. 13 "Fraying factor" task three

range of answers was from 1 (in favor of Kymerax) to 10 (this issue needs improvement/is not sufficient yet). The answers are shown as boxplots in Fig. 16.

The highest rated issues were the non-free rotation and deviation. The participants were neither comfortable with the impaired view of the 7-mm instrument shaft. The instrument handle is not considered to be very ergonomic according to most participants. The next question in the diagram asked whether the force conduction during the rotation of the instrument tip was adequate or too weak. Boxplots nr. 6 and 7 show the participants' opinions about the weight of the instrument handle (nr.6) and whether they wish to have a control element, which works in an analogue way, instead of a digital one (nr.7). Apparently, the increased weight of the Kymerax handle (725–755 g) and the fact that the control of the instrument tip is digital instead of analogue were not a big problem for the participants. Digital control means that the movement of the instrument tip is either on or off, while no change in speed or force is possible. Likewise, analogue control means that the user can vary the rotation/deflection in speed and force. The last question was about the closing force of the needle holder, which was answered very inhomogeneously.

Comments in the end mostly focused on the instrument handle, which is described as non-ergonomic, especially with big hands, and about the needle holder, which has an insufficient clamping force. Some positive comments stated that Kymerax is easy to learn for beginners and advantageous to work very precisely.

Discussion

To this date, there are no further studies about the Kymerax system. There are several studies about the "Radius Surgical System" (RSS) by Tuebingen scientific [8–12]. This instrument also allows rotating and deflecting the instrument tip, which is controlled mechanically by the surgeon through the instrument handle. The control is therefore analogue instead of digital. The shaft diameter is 10 mm.

In all tasks, the expert group was significantly faster than the student group, which could be interpreted as a correct setting of these two groups. Furthermore, the order in which the instruments were used was never significant. This enforces the assumption that the randomization was correct.

It was not possible to choose a realistic surgical situation like e.g., a colpotomy-closure, because in that case the expert group would have had a great advantage compared to the student group. Therefore, abstract surgical tasks were

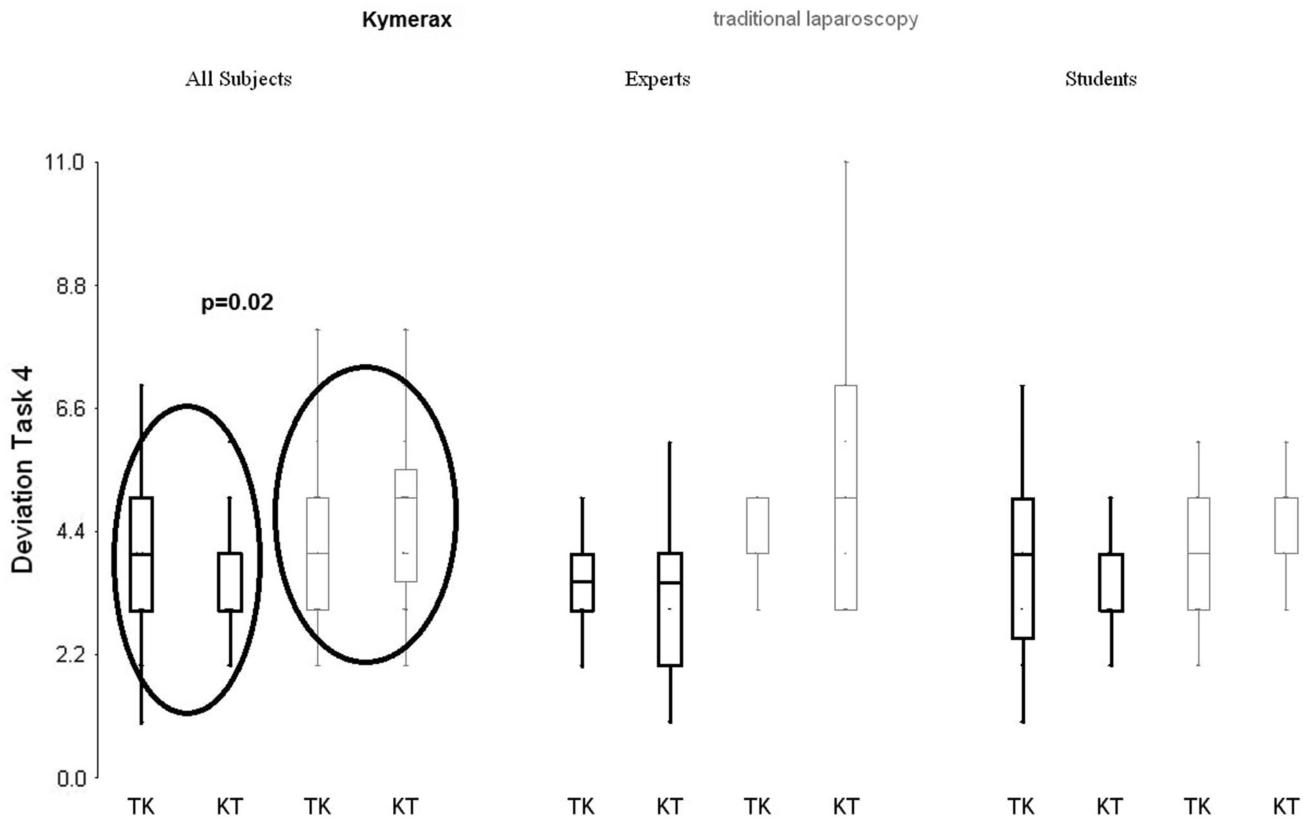

Fig. 14 Maximum deviation [mm] task four

Table 1 Composition of groups

Participants	n	Age	Sex
Students	25	22 (19–26)	f 48%
Experts	20	43.5 (34–58)	f 25%

chosen. The study design did not allow proving the validity of each task in the operating theatre or on a cadaver exercise due to ethical reasons. Nevertheless, the level of construct-validity is reached within this study for each task because the method was capable to distinguish the experienced surgeon from the inexperienced one [13]. Each task was chosen to represent surgical procedures in different realistic levels and angles. Some experts also confirmed the value of the exercises for realistic laparoscopic training, which indicates face validity [13].

To complete the tasks, a three-dimensional movement was necessary. Regardless of that, a contralateral access was not allowed for TLI, as the study setting had to be the same for both instruments. Possibly, a contralateral access could have helped to solve the tasks with TLI, but in this manner, the results would be less reproducible. In order to reach efficient time management, it was important to choose not a wide range, but relevant tasks. Terumo suggests a training program of several hours, which was not realistic for this study setting. Based on this reason, it was necessary to choose two short, but effective instructional exercises to get used to the instrument handling. The study shows some evidence that prolonged training time could have been an advantage for Kymerax due to the decreasing time difference between Kymerax and TLI from one task to another. It is not possible to answer the question whether Kymerax would be superior to TLI with more training time. However, for the RSS, a steep learning curve is described [8]. Another unanswered question is whether Kymerax could save time intraoperative, given the fact that there is no need to change the access points as frequent as with TLI.

It is obvious that participants needed more time to complete the tasks with Kymerax than with TLI. The same phenomenon was observed with the RSS, except the working angle was too difficult to accomplish with TLI [9, 10]. However, it could be shown that working speed correlates with prolonged training time. According to this, the question has to be asked how much training time surgeons are willing to invest to get used to a new instrument like

Table 2 List of all significant *p*-values (<0.05)

	1t	1 m	2t	2 m	2in1 140°	2in2 30°	2in3 270°	2out1 140°	2out2 30°	2out3 270°	3t	3dev	3fra	4t	4dev	4fra
E	0.022	0.027	0.004	0.002				0.022			0.000			0.000		
O																
O*E																
M	0.000		0.002						0.004		0.012		0.000	0.004	0.02	0.000
M*E											0.021					
M*O	0.003		0.049								0.001			0.038		0.049
M*O*E											0.004			0.027		

E Experience, ***O*** Order, ***M*** Method, **1–4**: Number of Task, ***t*** Time, ***m*** Mistakes, **in1-3**: Needle entry-point stitches 1 to 3 task 2 (with angle), **out1-3**: Needle exit-point stitches 1–3 task 2, ***dev*** maximum deviation, ***fra*** fraying factor

* represents and/with

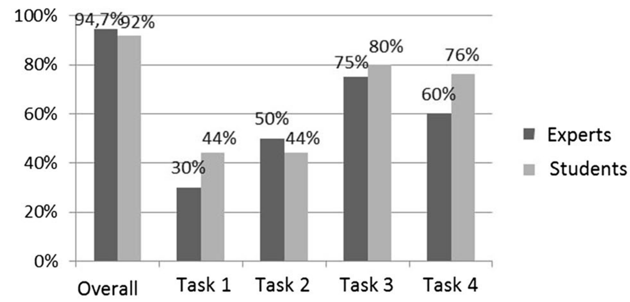

Fig. 15 Perceived advantage by using Kymerax

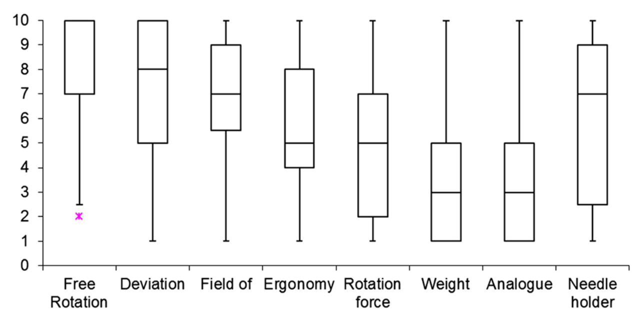

Fig. 16 Kymerax features

Kymerax or RSS. It has to be mentioned that a robot like the da Vinci does not need a long training program to become familiar with [14].

Although the tasks were solved more slowly with Kymerax than with TLI, this study could show some advantages of the Kymerax system in some "extreme situations." For example, stitch nr.2 (30°) in task two was very difficult to accomplish with TLI, but with Kymerax it could be done quite precisely. Similar results could be shown with the RSS, where stitches in the sagittal level were more precise than with TLI [8].

Another advantage of Kymerax was obvious in the cutting exercises three and four. Here, the "fraying factor" was much lower than with TLI. Because the angle of the TLI scissors could not be manipulated, it was inevitable to cut multiple little spikes into the foam rubber and thus, an increased fraying of the cutting edge occurs. Intraoperative, coagulation of these spikes has to be ensured, which means a bigger zone of necrosis is set and a potentially higher risk of compromising surrounding structures occurs. With this in mind, cutting anatomical structures could be less traumatic with Kymerax compared to TLI.

An interesting fact of this study is that students in task three (circular cutting) could profit from Kymerax and finished the task faster if they were using TLI first. Such an effect could never be observed in the expert group. One possible reason is that the experts are used to TLI to an extent that it is difficult for them to switch to a new instrument with only little training. Another hypothesis suggests that young novices do not struggle as much with new digital techniques. Some participants from the student group pointed out similarities between Kymerax and videogames. Unfortunately, there was no question asked about videogames in this study, but there could indeed be a coincidence between frequent consumption of videogames and skills in using Kymerax or similar instruments [15].

Participants were complaining about the impaired view while working with Kymerax. Similar results were observed in studies about the RSS [8, 9], because the shaft diameter (7/10 mm instead of 5 mm) of these instruments is bigger. The fact that a fix-installed camera was used worsened the problem even more. This problem could have possibly been diminished by using a flexible camera guidance, but as a consequence, the setting would not be exactly the same for each participant.

Some features of Kymerax have been heavily criticized by the participants. For example, participants were not comfortable with the very limited rotation and deflection of the instrument tip. Also, the force of the rotation is limited; if the needle gets too much resistance during a rotation, the instrument blocks itself for a few seconds. In such a case, the main console releases a high-frequent tone and the instrument tip cannot be moved for 3–5 s. This problem occurred only in task two (suturing) and might have slightly contributed to the poorer performance of Kymerax in this specific task. These would be issues to keep in mind if a new instrument is developed. The last question in Fig. 16 was answered very controversially. Some participants grabbed the needle or the pin properly, but somehow the needle holder was too weak and the grabbed object moved inside the needle holder or was dropped, because the instrument did not clamp strong enough. Other participants never faced such problems. Due to this reason, people did not answer in the same manner. In a study about the RSS, the needle holder was also criticized to be too weak [8].

Although the handle of the Kymerax is heavier than TLI instruments, participants were not disturbed a lot by the weight. One reason could be the ipsilateral access, so the instruments can both be held with arms in flexion. Nevertheless, the handle has been described as uncomfortable because of its shape and the positions of the controlling buttons.

Conclusions

Using Kymerax, participants solve their tasks more slowly and get tired earlier. The complexity of the instrument might be one of the reasons. The study cannot answer the question whether a longer training period could be a benefit for Kymerax.

Kymerax is a good instrument to work in complex angles and levels. Whether TLI would achieve the same results if a contralateral access would have been allowed is not possible to answer in this study.

The Kymerax shows a great potential for laparoscopic surgery. However, improvements in ergonomy, quality, and intuitiveness still have to be made. And most likely an instrument like Kymerax needs more training effort by surgeons than TLI to benefit from the additional degrees of freedom the instrument provides.

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Compliance with ethical standards

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