A crossover study on the advantage of an additional rotation function in a needle holder compared to a conventional needle holder in a pelvitrainer model

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Background: Needle-loading is the most challenging step in laparoscopic suturing. The rotational needle holder (RNH) is a handheld laparoscopic instrument, which increases the degree of freedom relative to the needle by the rotation of the instrument's tip. By moving the jaws of the needle holder with a clamped needle a rotational movement is achieved, which allows the needle to be adjusted. The aim of this study was to compare the RNH with the conventional needle holder (CNH) in a pelvitrainer model.

Methods: Twenty medical students with no prior laparoscopic experience performed four standardized exercises. The participants were randomly divided into two groups. Group RC performed the suture exercises using the RNH first and the CNH thereafter. Group CR performed these tasks in the reverse sequence. The number of errors, precision, and time taken were measured. After each task, the students had to answer specific questions about the methods used.

Results: The 270-degree angle task was performed with significantly fewer mistakes (P=0.003) and more rapidly using the RNH in the second period (P=0.008). The students performed the 180-degree angle task more rapidly during the second run, regardless of which technique was used (P=0.042). Neither of the other two tasks showed any significant difference. The precision was very good overall, and in all four tasks it was superior when the rotational method was used, although no significant difference was observed. The students made more mistakes when using the CNH. The questionnaire confirmed a clear advantage for the RNH, but the participants expressed concerns about its counterintuitive handling.

Conclusions: The advantages of the RNH were only partially confirmed. For some angles, the rotational function was beneficial. However, this value was decreased for participants with greater experience and superior laparoscopic skills. More intuitive control of the rotation function may potentially offer an advantage in terms of speed and may be associated with a steeper learning curve.

Keywords: Laparoscopy; rotational needle holder (RNH); degree of freedom; pelvitrainer

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Introduction

Laparoscopic surgery is an increasingly favoured technique among surgeons. In addition to its cosmetic benefits, it is associated with reduced postoperative infection rates, shorter hospitalization periods, and minimal loss of blood, compared to open surgery (1-3). However, laparoscopic surgery is generally longer in duration, and the operating surgeons tire more rapidly (3,4). Robotic-assisted

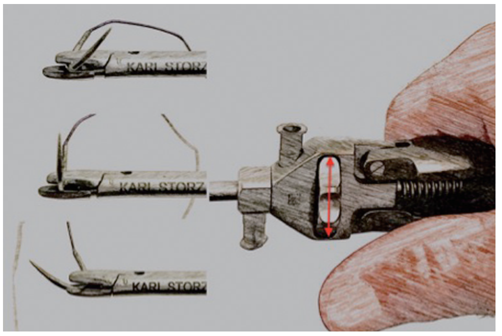

Figure 1 By triggering the rotary knob the clamped needle can be adjusted *in situ*.

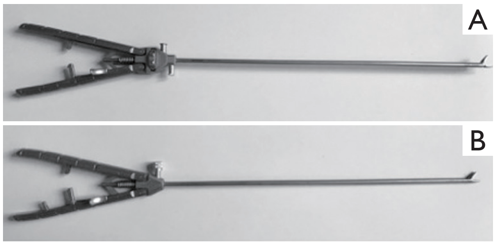

Figure 2 An illustration of the whole (A) rotational needle holder and (B) the conventional needle holder.

laparoscopy offers the potential to mitigate these drawbacks, by improving the instruments' range of motion and ergonomic qualities (5,6). In general, the learning curve of conventional laparoscopic surgery is relatively flat compared to open surgery or robotic-assisted laparoscopy (7-12). The main reasons for this are the commonly used two-dimensional imaging and the limited degrees of freedom available (13,14). While evidence for the benefits of three-dimensional imaging has already been presented (13,15-19), the practical benefits of laparoscopic instruments, which can perform three-dimensional movements, remain to be verified (20-24). Theoretically, the positive advantage of an added feature is clear. We may cite, for example, the flexible endoscope in single-incision multiport laparoscopic surgery, or the Kymerax© precision-drive articulating surgical system, which is advantageous in certain contexts, such as suturing at difficult angles and cutting along complex structures (22,25). Furthermore, the minimally invasive manipulator offers a cost-effective, non-robotic alternative for endoscopy (26). The positioning of the needle is one of the main difficulties in laparoscopic suturing (27,28). While the simplification of this surgical step would be welcomed, the question as to whether its theoretical benefits would be substantiated in practice remains to be answered. We selected a hand-operated needle holder with an additional rotation feature from Storz. Using a rotary control on the handle, it is possible to move the jaws and, consequently, the fixed needle can be rotated and positioned as appropriate to the circumstances (*Figure 1*). This study aimed to compare the rotational needle holder (RNH) from Storz with a conventional needle holder (CNH) from Storz (*Figure 2A,B*). For analysis of the operating devices, a simulation was used. The pelvitrainer has been proven effective in professional training, as well as in the evaluation of laparoscopic instruments (8,22). Using four simple tasks, we aimed to determine whether the RNH has advantages in terms of time, error rate, and precision. The four exercises tested suture competence at different angles in the direction of view. Furthermore, the participants' subjective perceptions of the were determined using a questionnaire.

Methods

Study population

Due to the explorative nature of the evaluation, no setup was required for a formal number of cases. The study represents an initial evaluation of the RNH. A total of 23 participants were selected, all of whom were medical students at the University of Basel who had no prior laparoscopic experience. No left-handed students were recruited for the study. The ethics committee of Northwest and Central Switzerland (EKNZ) confirmed that the project is not defined as a research project according to Human Research Act Art. 2; therefore, IRB approval and written consent were not required.

Study design

All participants were assigned to two different groups. Group RC performed each task using the RNH first and subsequently using the CNH, while Group CR performed the tasks in reverse order. To enable the participants to become accustomed to laparoscopic conditions, one standardized identical instructional task was performed using the RNH and CNH. Subsequently, four tasks were performed using the RNH and CNH. The time taken, the overall precision, and the number of mistakes were recorded. After they had finished each exercise, the participants completed a questionnaire.

Instrument setup

A pelvitrainer with anatomical conditions was used for all exercises. It was full-featured with a 24-inch monitor and a 300W Xenon light source. For the imaging modality, a camera control unit with a capacity for recording videos of up to 720p resolution was installed. Two access points equivalent to the lateral ancillary trocar entry points were used for the needle holders. For the left hand, a CNH from Storz was available. The right hand had alternating access to the CNH and a needle holder with a normal up-righting function from Storz. The only variable that changed during testing was the needle holder (i.e., RNH or CNH).

Instruction

Initially, both needle holders were introduced and their functions explained. Thereafter, before each exercise, an introduction video was shown once to guarantee the reproducibility of the instruction. No questions were allowed. The participants were instructed to find the optimum combination in terms of precision, time, and errors. Precision and minimization of error are of utmost importance; however, efficiency is also crucial. To accustom the participants to the instruments and the pelvitrainer, an adaption task was performed in which the participants completed a simple task by grasping and fixating the needle, and attempting to form stitches.

Exercises

Tasks 1–4 were all suture tasks with the same fundamental principle. Each task consisted of three stitches from left to right or top down with a 20-cm long Variosoft 0 thread with a GS22 needle (Medtronic, Switzerland, Münchenbuchsee). The stitches were marked by two dots separated by a distance of 10 mm on silicone pads measuring 9×9 cm^2. The pads had a consistency similar to that of a uterus. The individual tasks differed in one crucial aspect, namely, the angle in the direction of view. In the first exercise, the angle was 315° in the direction of view and horizontal to the ground; in the second, the angle was 270° (horizontal); in the third, the angle was 0° (horizontal); and the angle in the fourth exercise was 180° (vertically to the ground) (*Figure 3*). Each task was performed once with the CNH and RNH. Three different study parameters were measured: time taken, errors, and precision. Time was measured in minutes and seconds, and the maximum time allowed per exercise was 12 minutes. If the time limit was reached, the participant was obliged to cease work on the exercise instantly, but was not excluded. If the needle had been removed from the pad before the stitch was finished, this amounted to an error. Dropping the needle as part of the learning process did not count as a mistake. Precision was determined by measuring the deviation from the dot to the insertion and extraction points from the tip of the needle in millimetres. After each task, the participants were asked ten questions about their subjective perceptions of the exercise.

Questionnaire

The questionnaire comprised ten questions. The participants were asked the first five questions after each sequence of tasks:

- ❖ How would you describe the task`s difficulty level?
- ❖ Did you familiarize yourself with the instruments while performing the task?
- ❖ Did you familiarize yourself with the rotation function while performing the task?
- ❖ Did you perceive either of the needle holders to have any advantages over the other?
- ❖ Did you lose concentration at any point?

The participants answered the remaining five questions after they had used both devices to complete the exercises:

- ❖ Did the RNH simplify the tasks?
- ❖ Did the advantages (if applicable) of the RNH decrease over time?
- ❖ Was the rotational function intuitive?
- ❖ Would a neutral position of the rotational function improve its performance?
- ❖ Is there any other potential for improvement?

Statistical analysis

An explorative statistical analysis of the primary and secondary endpoints was carried out. To this end, a statistical evaluation of the 2×2 crossover was conducted using a linear mixed-effects model. The results were calculated as the average difference between the rotational and conventional techniques. Moreover, to adjust for a learning and sequence effect, a period and sequence effect was added to the design. The mean difference between time, precision, and errors between methods were evaluated with a 95% confidence interval and the corresponding P value. The questionnaire items were

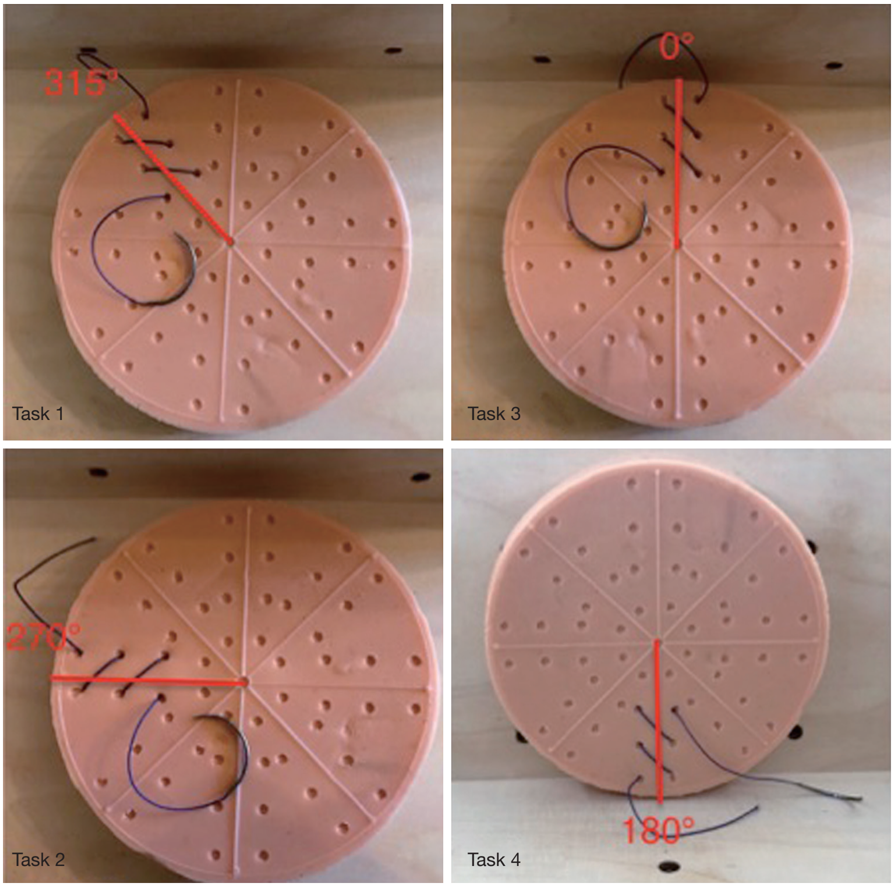

Figure 3 Tasks 1–4 with the angle in direction of view.

compared using McNemar's test or the chi-squared test, as appropriate. A P value <0.05 was considered to be significant. All evaluations were performed using the statistical software R version 3.1.1 (29).

Results

Task 1 was performed at a 315-degree horizontal angle. In terms of time, neither the methods nor comparison of the sequences and periods showed any significant difference (*Figure 4*). The same was true of the parameters' precision and the occurrence of mistakes (*Figures 5,6*) (*Table 1*).

Task 2 was performed at a 270-degree horizontal angle: when utilizing the RNH, the participants made significantly fewer mistakes than when they used the CNH (P=0.003). This could not be confirmed in terms of difference between the sequences (P=0.961) or periods (P=0.200) (*Figure 4*). No apparent improvement in precision was observed (*Figure 5*). The participants finished the second period significantly faster (P=0.008); however, when compared with respect to the methods and sequences, the time difference was not significant (*Figure 6*) (*Table 2*).

Task 3 was performed at a 0-degree horizontal angle: the students could not reduce the time required for the task by using the RNH (*Figure 4*). Precision and incidence of errors were not significantly improved by either method, period, or sequence (*Figures 4-6*; *Table 3*).

Task 4 was performed at an 180-degree vertical angle: regarding the time required for task 4, no significant difference was observed between the methods (P=0.585) or sequences (P=0.336). It was clear that the students performed the task more efficiently during the second run, regardless of which technique was used (P=0.042) (*Figure 4*) (*Table 4*). No significant differences were observed with regard to precision or the incidence of errors. Neither was any significant difference observed between the exercises overall with respect to time taken, incidence of errors, or precision for either method.

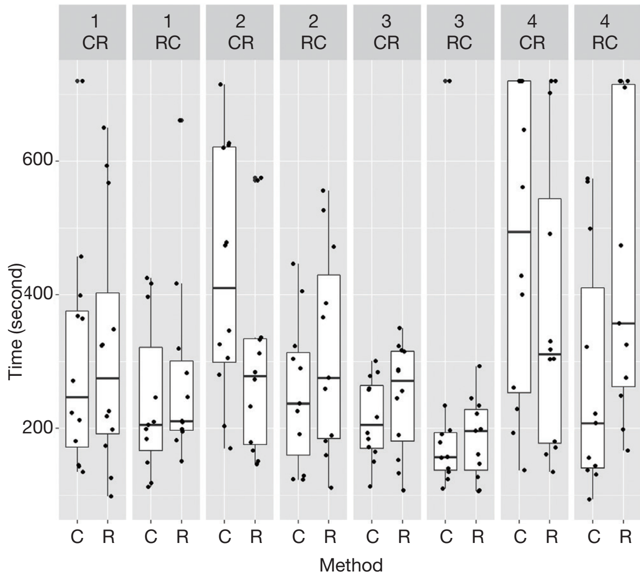

Figure 4 Analysis of time. C, conventional needle holder; R, rotational needle holder; 1–4= tasks.

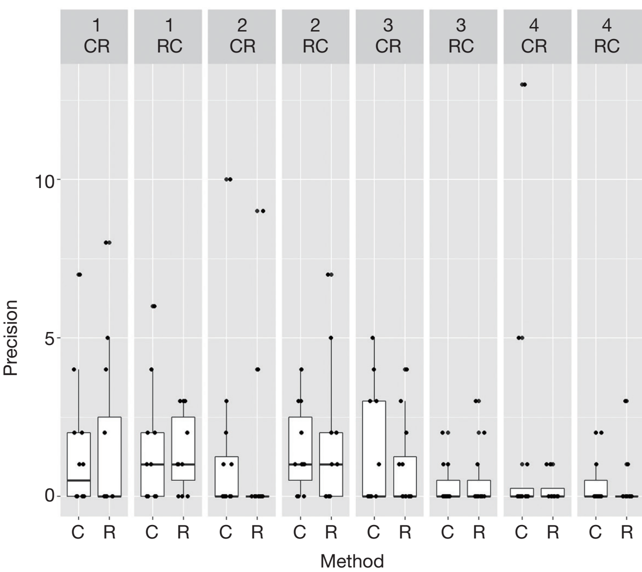

Figure 5 Analysis of precision. C, conventional needle holder; R, rotational needle holder; 1–4= tasks.

Questionnaire results

According to the questionnaire's results, most participants became accustomed to the equipment and to the rotational function after the first task. The students evaluated the level of difficulty of the tasks, giving average ratings of six and

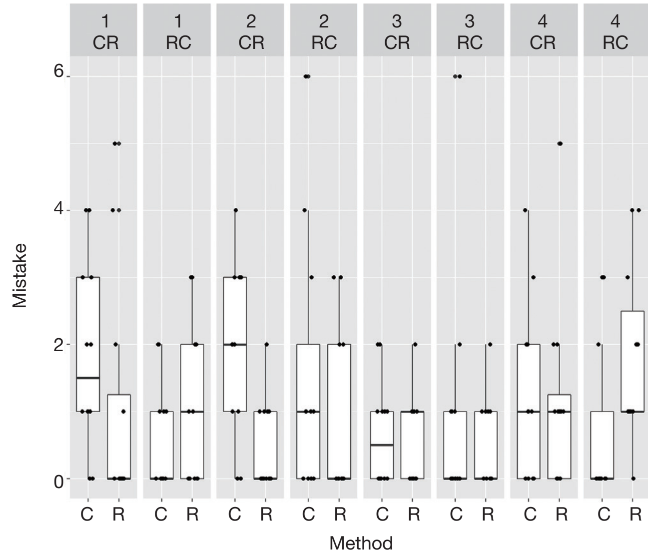

Figure 6 Analysis of mistakes. C, conventional needle holder; R, rotational needle holder; 1–4= tasks.

seven out of ten (1= easiest and 10= most difficult), except for task number 3, which was the easiest with an average rating of five out of ten. More than 65% of the participants had the impression that the RNH was advantageous in the first three exercises, and 87% of the participants expressed the same opinion in relation to task 2. Nevertheless, for the fourth challenge the majority saw no benefit. Less than 50% of the participants lost concentration during the practice, and 69.6% had the impression that the RNH was of benefit to them in performing the exercises, but that this effect decreased as they progressed through the tasks. The handling of the RNH was evaluated as counterintuitive by 69.6% of the students. All but one of the participants considered that a neutral position for the rotation function would be an advantage, and the majority thought that there was room for improvement in terms of the RNH's manipulation.

Discussion

The purported benefits of the RNH are that it offers an improved learning curve and allows surgeons to work with greater speed, more accuracy, and fewer mistakes, resulting in a shorter operation time and cost reduction. In our study, the RNH increased the degrees of freedom relative to the needle. Because the results regarding the advantages and disadvantages of instruments with three-dimensional

Table 1 Results exercise 1: mean difference of time, precision and mistakes and corresponding P value. This was analysed for the sequence, period and method

Parameter	Contrast	Collation	Difference	Lower CL	Upper CL	P value
Time	CR-RC	Sequence	50.31	−63.42	164	0.368
	1-2	Period	9.186	−69.36	87.73	0.8102
	C-R	Method	−28.27	−106.8	50.27	0.4625
Precision	CR-RC	Sequence	0.09091	−1.576	1.758	0.9108
	1-2	Period	−0.1288	−0.8412	0.5836	0.7107
	C-R	Method	−0.03788	−0.7503	0.6745	0.913
Mistake	CR-RC	Sequence	0.553	−0.3547	1.461	0.219
	1-2	Period	0.6439	−0.1042	1.392	0.0879
	C-R	Method	0.1894	−0.5588	0.9375	0.6041

C, conventional needle holder; R, rotational needle holder; CR-RC, the sequence, first with the conventional followed by the rotational needle holder *vs.* the sequence, first with the rotational followed by the conventional needle holder.

Table 2 Results exercise 2: mean difference of time, precision and mistakes and corresponding P value. This was analysed for the sequence, period and method

Parameter	Contrast	Collation	Difference	Lower CL	Upper CL	P value
Time	CR-RC	Sequence	78.17	−33.14	189.5	0.159
	1-2	Period	98.14	27.28	169	0.008959
	C-R	Method	35.86	−35	106.7	0.3045
Precision	CR-RC	Sequence	−0.2955	−2.291	1.7	0.7612
	1-2	Period	0.2576	−0.4142	0.9293	0.4341
	C-R	Method	0.07576	−0.596	0.7475	0.8168
Mistake	CR-RC	Sequence	0.02273	−0.9512	0.9966	0.9618
	1-2	Period	0.4318	−0.2482	1.112	0.2008
	C-R	Method	1.068	0.3882	1.748	0.003685

C, conventional needle holder; R, rotational needle holder; CR-RC, the sequence, first with the conventional followed by the rotational needle holder *vs.* the sequence, first with the rotational followed by the conventional needle holder.

movement depend on the individual tool, we performed a randomized crossover study to validate the effectiveness of the RNH.

We anticipated that beginners in particular would benefit most from this technique, so in this study we chose participants who had no prior experience in laparoscopy. In principle, two techniques may be used to ensure the needle is at the appropriate angle in contact with the tissue: either the tissue is brought into the plane of the needle or the needle's angle is adjusted with respect to the tissue. In our exercises, the latter procedure was necessary. We anticipated that the CNH would offer a clear advantage for this exercise. However, this could be only partially confirmed on the basis of our results. The data presented in *Table 2* demonstrate that the second exercise with an angle of 270° was performed with the RNH with significantly fewer mistakes, and in the second period, significantly faster. Moreover, task 4 was performed faster during the second run, regardless of which technique was used. Neither of the other two tasks showed any significant difference (*Tables 1,3*), and overall comparison of all exercises revealed no significant difference between the two methods.

For all tested exercises, the participants performed the second round more efficiently. This may be attributed to

Table 3 Results exercise 3: mean difference of time, precision and mistakes and corresponding P value. This was analysed for the sequence, period and method

Parameter	Contrast	Collation	Difference	Lower CL	Upper CL	P value
Time	CR-RC	Sequence	31.66	–31.67	94.99	0.3103
	1-2	Period	–30.08	–93.41	33.25	0.3346
	C-R	Method	–2.258	–65.59	61.07	0.9416
Precision	CR-RC	Sequence	0.6705	–0.2822	1.623	0.1581
	1-2	Period	0.2992	–0.3607	0.9592	0.3564
	C-R	Method	0.1174	–0.5426	0.7774	0.7151
Mistake	CR-RC	Sequence	–0.1061	–0.7627	0.5506	0.7403
	1-2	Period	–0.2273	–0.8839	0.4293	0.4796
	C-R	Method	0.2273	–0.4293	0.8839	0.4796

C, conventional needle holder; R, rotational needle holder; CR-RC, the sequence, first with the conventional followed by the rotational needle holder *vs.* the sequence, first with the rotational followed by the conventional needle holder.

Table 4 Results exercise 4: mean difference of time, precision and mistakes and corresponding P value. This was analysed for the sequence, period and method

Parameter	Contrast	Collation	Difference	Lower CL	Upper CL	P value
Time	CR-RC	Sequence	65.59	–73.1	204.3	0.3365
	1-2	Period	134.6	5.114	264.1	0.04233
	C-R	Method	–34.5	–164	94.97	0.5853
Precision	CR-RC	Sequence	0.5076	–0.8627	1.878	0.4497
	1-2	Period	0.6212	–0.5602	1.803	0.2865
	C-R	Method	0.7121	–0.4693	1.894	0.2238
Mistake	CR-RC	Sequence	–0.1061	–0.9271	0.715	0.7908
	1-2	Period	0.5455	–0.2756	1.367	0.1816
	C-R	Method	–0.5455	–1.367	0.2756	0.1816

C, conventional needle holder; R, rotational needle holder; CR-RC, the sequence, first with the conventional followed by the rotational needle holder *vs.* the sequence, first with the rotational followed by the conventional needle holder.

a learning effect. To eliminate this bias, we conducted a crossover analysis. Additionally, the students improved their skills in tasks that included loading the needle on the needle holder, passing the needle through tissue, and manipulating the thread during suturing. Consequently, they performed each subsequent task more efficiently than the previous exercise. For the last exercise, which was more difficult, the participants needed more time (*Figure 1*). This was confirmed by the questionnaire results, wherein most of the participants reported that they became accustomed to the equipment after the first task and to the rotational function after the second task. Task 3 was rated easiest by most participants.

This study's findings indicate that the RNH is superior to some extent, particularly for specific angles, but that this value is reduced for users with more experience and better laparoscopic skills. The results of the questionnaire supported this assessment and emphasized the counterintuitive handling of the RNH. Participants suggested that a neutral position for the rotation function would be superior. Laparoscopy continues to develop, and new methods, such as robot-assisted laparoscopy, improve the learning curve by simplifying execution and using superior equipment, including instruments that offer enhanced three-dimensional views, or laparoscopic devices with more degrees of freedom (5). However, these methods are cost intensive, and the outcomes have yet to be proven superior (30,31). Another strategy is to design mechanisms aimed at simplifying operational steps. For example, the laparoscopic stapler and the coagulation cutting instrument have gained wide appeal (32,33). The RNH is also designed to simplify an operational step, namely loading the needle. This study provides a first assessment of the rotational method. We recommend that the RNH be improved through a more intuitive execution of the needle holder. Future research should focus on whether experts profit from the rotational function, and whether it is associated with any difference in tissue loading. Incorrect placement of a curved needle leads to difficulty in driving the needle and, consequently, tissue force is drastically increased, in turn raising the risk of tissue rupture (34,35).

Procedures that are performed low in the pelvis at difficult angles for suture, such as sacrocolpopexy, could potentially benefit from a RNH with another degree of freedom. Comparison of this added degree of freedom and the superior three-dimensional view offered by robot-assisted laparoscopy is recommended as a topic for future studies.

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Footnote

Conflicts of Interest: The authors have completed the ICMJE uniform disclosure form (available at http://dx.doi.org/10.21037/ls.2019.11.03). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The ethics committee of Northwest and Central Switzerland (EKNZ) confirmed that the project is not defined as a research project according to Human Research Act Art. 2; therefore, IRB approval and written consent were not required.

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