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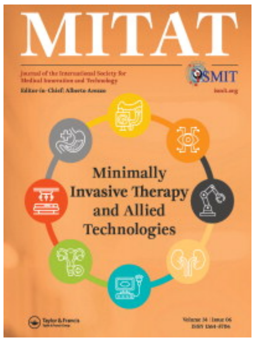

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ORIGINAL ARTICLE

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A pre-clinical application study of the SATA-LRS laparoscopic instrument in a human cadaver model

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ABSTRACT

Background: To validate whether the SATA-LRS, a novel reusable articulating laparoscopic instrument, fits surgical practice, a pre-clinical study was performed.
Methods: Thirteen medical doctors used the instrument in a laparoscopic endoscopic inguinal hernia repair (TEP)-like task inside a cadaver. A set of sensors on the instrument handle detected motion and articulation of the instrument tip. Data from the sensors and video recordings were used to assess the amount and type of movement of the instrument and the time spent on tasks. questionnaire was used to gain insight into the participants' perception of the contextual factors.
Results: There was no difference between task time and instrument tip velocities when using articulation (or not) and all participants used articulation at least half of the task time. Instrument-handle movement, indicating the user's hand and arm movement, was significantly reduced when using articulation. The questionnaire indicated strong acceptance of the instrument and the experimental setup, and a desire to use the instrument in surgery by most participants.
Conclusions: The added articulation feature of the SATA-LRS instrument was deemed beneficial by the participants, showed no increased handling complexity or time spent on the task and was used frequently when enabled, indicating intuitiveness.

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SATA; laparoscopy; clinical; validation; IMU

Introduction

Robot-assisted surgery has gained popularity due (in large part) to the additional degrees of freedom (DOF) of the instrument tips, being able to follow hand motion in dexterous maneuvers [1–3]. However, technical, labor, training, and financial requirements around robotic systems hamper many settings from adopting these advantages and would therefore benefit from a translation into handheld, advanced multi-DOF instruments [4,5]. An added benefit of these manual instruments is that they retain the tactile feedback of laparoscopic surgery, which is not available in robotic surgery [6] and which could translate to more precision during operating compared to robotic surgery [7].

The SATA-LRS (SATA Medical, Delft, The Netherlands) is a novel articulating 5 mm laparoscopic instrument with two additional degrees of freedom at its end-effector, giving it six degrees of freedom instead of the four degrees of freedom of a conventional instrument [8]. As depicted in Figure 1, the effector can be articulated from 70° to 80° left and right. Free rotation of the tip follows articulation at a total of 360°. Figure 2 shows the instrument handle held as intended, with the index finger extended to the large rotation knob to articulate the tip and the thumb resting on the small rotation knob to rotate the tip. This design, which is very similar to a standard ring-handle grip straight stick laparoscopic

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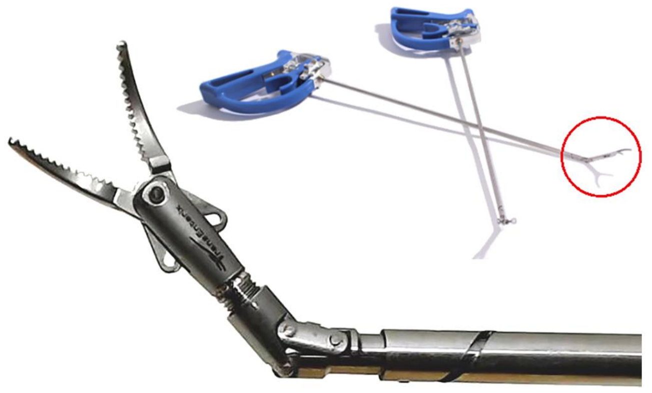

Figure 1. A picture of the instrument's articulated tip with a rotatable end-effector, with two complete sets in the background.

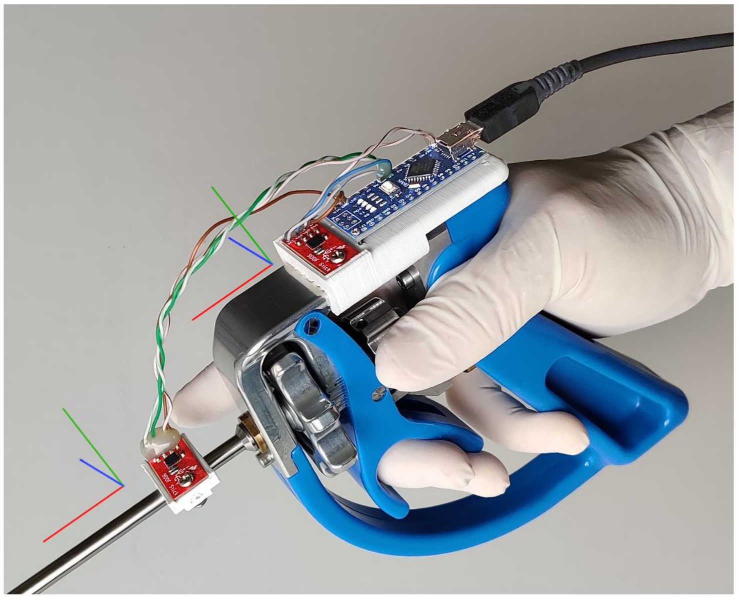

Figure 2. A picture of the instrument's handle with a double IMU, one installed on the handle frame and one on the outer shaft. The two IMU orientations are indicated by the red, green, and blue axes.

instrument, has previously been proven in terms of user learning curves and proficiency in box-trainer tasks [8]. The added value of the extra articulation capacity of this instrument still requires research.

One of the primary questions is whether additional articulation will be used in a task that could be performed without articulation but where it would make executing the task easier. A drawback could be the increase in handling complexity, like increased handle motion and mental effort, which might affect the overall performance [4]. Secondly, increased handle complexity might negatively influence surgeons' handling comfort, which could lead to hand/wrist pain [9]. Finally, it is unclear how increased steering abilities at the instrument's tip influence movement at the hand(le) side, and thereby the surgeon's ergonomics. To study these three aspects, a pre-clinical experiment was performed.

Materials and methods

Instrument set-up

A curved 'Spider' forceps (Asensus Surgical Inc., Durham, NC, USA) was fitted to the tip of the instrument (see Figure 1). The length of the grasper was 28 mm, and the total shaft length was 520 mm, which is the usual length for these types of laparoscopic instruments. To record the orientation and movement, two LSM9DS1 'Inertial Measurement Units' (IMU) (STMicroelectronics, Geneva, Switzerland) were attached to the handle to measure linear accelerations and rotational velocities. Figure 2 shows a 3D-printed chassis at the spine of the handle supporting an Arduino Nano microcontroller (Arduino AG, Turin, Italy) with two IMU's allowing for continuous measurement of the handle's and shaft's orientation relative to gravity. Since articulation of the end-effector is achieved through rotations of the instrument shafts relative to the handle, the difference in orientation between these two IMU's allows for a measurement of the articulation of the end-effector.

Video recordings of the participants were made while using the instrument, together with laparoscope recordings of their actions inside the body.

All participants signed an informed consent form. The study was registered under the number FRECMDS-2021–134 of the Ethical Committee of the Faculty of Medicine and Surgery of the University of Malta.

Clinical set-up

The study was performed in the Anatomy Laboratory of the University of Malta with medical doctors from the University Hospital as participants. A Thiel embalmed [10] cadaver of a 76-year-old male was used for the study. The setup was comparable to a preperitoneal endoscopic inguinal hernia repair (TEP). The operating area was established using a Spacemaker-Plus dissector system (Medtronic, Eindhoven, The Netherlands), which was brought in over the posterior rectus sheath to develop a preperitoneal operating field maintained by CO_2 insufflation. A laparoscopy tower set up (Aesculap, Hazelwood, MO, USA) was used with a 10 mm laparoscope through this port. One 5 mm trocar was placed in the midline caudal to the upper port, comparable to a TEP procedure with the trocars placed in the midline. This is the ergonomically most preferred position, but it makes the operation more complicated when using a standard straight instrument [9,11,12].

Experimental task

An introduction to the instrument's features, control, and intended handling was given. The participants were then encouraged to handle and explore it. A piece of Prolene 0 wire (Johnson & Johnson Medtech, Raritan, NJ, USA) was placed close to the spermatic cord. Participants were asked to pick up the wire and pass it behind the cord from the lateral to the medial side and back using the SATA-LRS instrument (see Figure 3). Touching the spermatic cord and adjacent structures was discouraged. After passing the wire, the participants had to drop the wire near the cord as a reset, after which the task was repeated in the opposite direction. This was repeated while being supervised by one of the researchers, who was also operating the laparoscope. The procedure consisted of three phases:

I. Participants encouraged to use the articulation feature;
II. Articulation disabled;
III. Participants could use the articulation again.

Each phase was targeted to last about three minutes. Prior to the experiment, the clinical team confirmed that the task provided sufficient opportunity for both articulated and un-articulated approaches. Video-recordings of the laparoscope were used to count the number and timing of the passes. Data from the IMU's were used to measure the degree of articulation, velocity, and acceleration of the instrument.

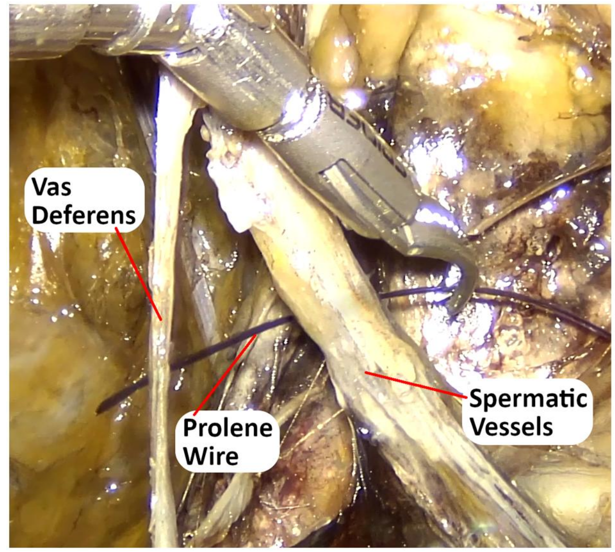

Figure 3. A still from the laparoscopic recordings during the task showing the instrument maneuvering the prolene wire behind the right spermatic cord.

Questionnaire

After completion of the task, the participants were asked to fill in a questionnaire with Likert scale-type response options (Table 1). Afterwards, the participants were also prompted to name a few keywords of impressions and experiences concerning the instrument.

Statistical analysis

The data of all participants were compared through a statistical analysis of the three phases using a t-test (with $p < 0.05$ being significant). Differences between novices and experts were investigated through data selection.

Table 1. Questions asked in the questionnaire and the average response score.

	Instrument mechanics	4.3/5
1-1	The instrument functioned well	4.5/5
1–2	All features of the handle can be reached and used properly	4.0/5
1–3	The use of the features of the handle is clear	4.7/5
1–4	The weight of the instrument is (light/good/heavy)	4.0/5
1–5	The length of the shafts in (short/good/long)	4.8/5
1–6	The instrument looks nice	3.9/5
	Instrument Use	4.5/5
2–1	The instrument was safe to use	4.8/5
2–2	Steering the instrument is intuitive	4.5/5
2–3	Steering of the instrument cost no effort	3.8/5
2–4	The articulation angles are (little/good/much)	4.5/5
2–5	Beak control (opening/closing) is sufficient	4.5/5
2–6	Do you consider the instrument innovative?	4.6/5
2–7	Would you use the instrument yourself?	4.4/5
	Experiment set-up	4.6/5
3–1	The body felt life-like	4.7/5
3–2	The procedure felt life-like	4.5/5
3–3	The experiment set-up was a good representative	4.7/5
3–4	The procedure timing felt (slow/good/fast)	4.5/5
3–5	The instrument added benefit to the procedure	4.5/5
3–6	The instrument performed well in the procedure	4.5/5

Where relevant, a paired t-test was used to measure differences between the phases per participant.

Experimental design

By using a human cadaver and a setup from a frequently performed laparoscopic operation, an endoscopic inguinal hernia repair, the usability of the articulation of the SATA-LRS instrument was studied and compared to using it without this feature. The task is feasible with or without articulation, but with the articulation, challenging angles in the action could possibly be performed more easily or with less strain. This was assessed through measuring the movement at the tip and hand(le) part of the device in both situations, analyzing video recordings and through questionnaires. In the same way, we also analyzed a potential increase in handling awkwardness due to the articulation.

Results

Experimental set-up

A total of 13 medical doctors (mean age: 30 years, standard deviation (SD) = 3.5; seven males, six females) participated in the cadaver task. The group's average experience in surgery was four years (SD = 3.1), with a minimum of one year. The group had an average of 2.8 years (SD = 3.3) experience with laparoscopy. Two participants had no laparoscopic experience, and two had 10 years of experience (experts). All participants were able to perform the task within seconds of initiation and used the instrument appropriately.

Task performance

The participants' goal to pass the wire behind the spermatic cord could be quantitatively measured and compared between the three phases of the experiment. The average pass times were 41.8 (SD = 37.2), 30.3 (SD = 31.1), and 35.6 (SD = 24.2) seconds, respectively. Differences between phases two (no articulation) and three (second time articulation) ($p2-3=0.64$) are non-significant, nor are either of the phases compared to phase one (first time articulation) ($p1-2=0.42$, $p1-3=0.62$). Also, a paired t-test showed non-significant changes between the phases, except for two novices (one and two years of laparoscopic experience) for $p1-2$ at 0.48 and 0.42. The second graph shows the total number of passes each participant performed in each phase, normalized to time. Both phase 2 and 3 had more passes (114 and 106 passes) compared to phase 1 (96 passes). Yet, the passes per second were not significantly higher ($p1-2=0.14$, $p1-3=0.30$, $p2-3=0.50$). Though the experts had significantly more passes overall and shorter time between passes, their p-scores between the phases were similar to those of the novices when viewed separately.

User articulation interaction

Steering actions

Tip articulation could be measured through the difference of the shaft IMU orientation with respect to the handle IMU orientation. Steering actions were defined as shaft rotational velocities of at least 2° per second. Supplemental File 3 shows two boxplots indicating the number of articulations as well as the total absolute articulated degrees per phase for all subjects. The average total articulation actions per phase for all subjects was 21.9 (7.1 SD) and 21.9 (8.9 SD), with an average total articulation of 574 (303 SD) and 506 (264 SD) degrees. The two articulation phases showed a similar articulation activity ($p1-3=0.99$ and $p1-3=0.56$), indicating that the participants used the articulation function neither more nor less as they progressed in the task.

All participants used the articulation, and several articulation strategies were recognized. Some participants intermittently performed the task with a fixed articulation angle, but most of the participants used active articulation. Some participants also straightened the tip between repetitions as a reset position. In some cases, participants did not use articulation until sometime into the re-articulation (third) phase, presumably due to the former non-articulation phase.

Tip articulation use

Using the orientation data of the double IMU system on the instrument, the articulation angle of the instrument tip could be determined during the task. For both articulation phases, a record was made of the tip articulation angle for each time instance. Figure 4 shows the time spent in each articulation angle for all participants and both articulation phases combined. The height of each bar indicates the percentage of the total time spent in the indicated angle. A threshold of ±15° (indicating significant articulation) was used to determine that 49.9% of the time in phases 1 and 3 was spent in an articulated angle, as indicated with dotted lines added to the figure. A significant majority was spent in the right-sided tip articulation at a ratio of about 5:13 left to right. This is consistent with the video-recorded preference to hold the handle in a wrist-pronated orientation for most participants, also visible in Figure 5, which would have required a right-sided tip articulation to steer 'forward'.

Acceleration and velocity

With the data of the handle IMU, the linear accelerations and rotational velocities during use can be determined, giving insight into the way the instrument was handled in terms of general motion. The linear acceleration seems to increase over time with 0.234 (SD = 0.027), 0.244 (SD = 0.244), and 0.256 (SD = 0.034) m/s, respectively, although this is not statistically significant. Velocities seem to increase and stabilize in the second phase with 16.7 (4.3), 19.6 (4.3), and 20.5 (4.6) rad/s, respectively.

Handle orientation

The IMU data of the instrument can be used to find the orientation of the handle during use. Figure 5 shows a so-called 'heat-map' of the handle's orientation. Both axes indicate the degree of rotation with respect to a straight down orientation of the instrument, where X is sideways rotation and Y is frontal rotation. The 'temperature' of the maps illustrates the percentage of time spent per orientation. Comparing the articulation to the non-articulation phases shows that the latter has a more spread-out pattern compared to the more centralized pattern for the articulation-enabled repetitions.

The red dots added to Figure 5 represent the orientations that together account for the top 20% of the total time spent for each map. Calculating the average distance between these points per map shows 9.1° (SD = 2.4°) with the articulation and 16.1° (SD = 6.2°) without ($p < 0.01$). The spread of orientations during the phases shows that there was a 57% reduction in handle movement in the articulation phase. This indicates that with articulation at the tip, less handle motion—and thus, less motion of the surgeon's hand, shoulder, and arm—is required to direct the tip, and therefore such movements are reduced.

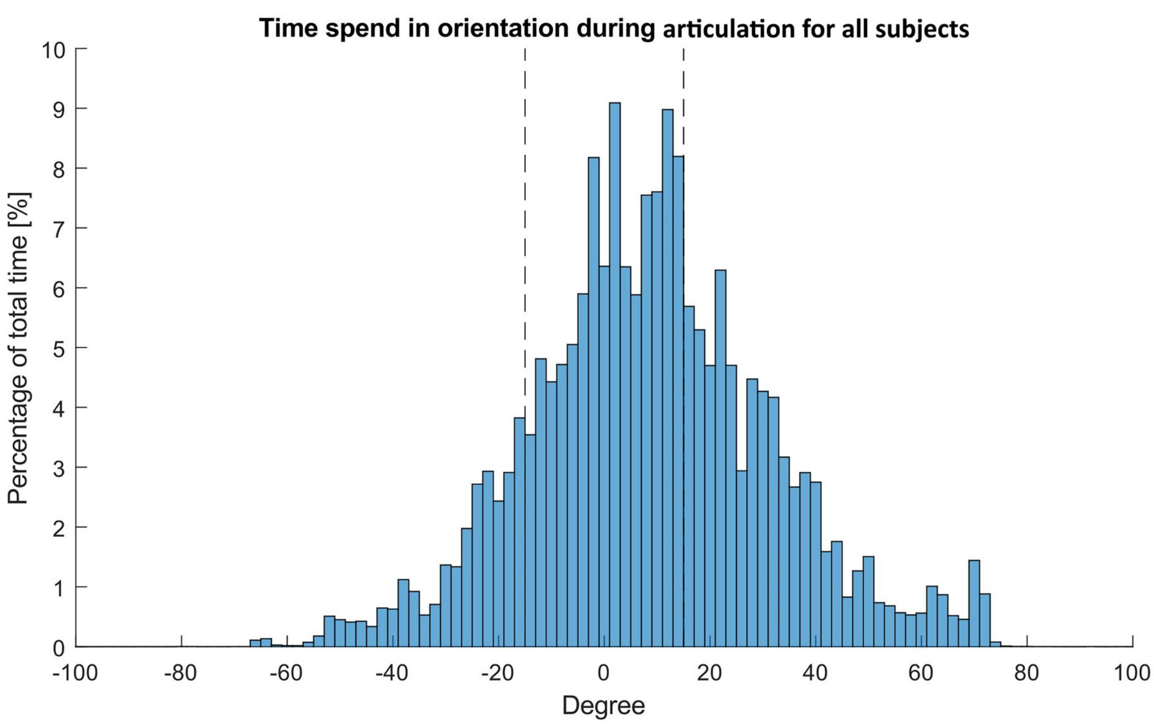

Figure 4. A histogram of the percentage of time spent in a particular articulation angle during the articulation phases of the task for all participants. The two broken lines indicate ±15° articulation.

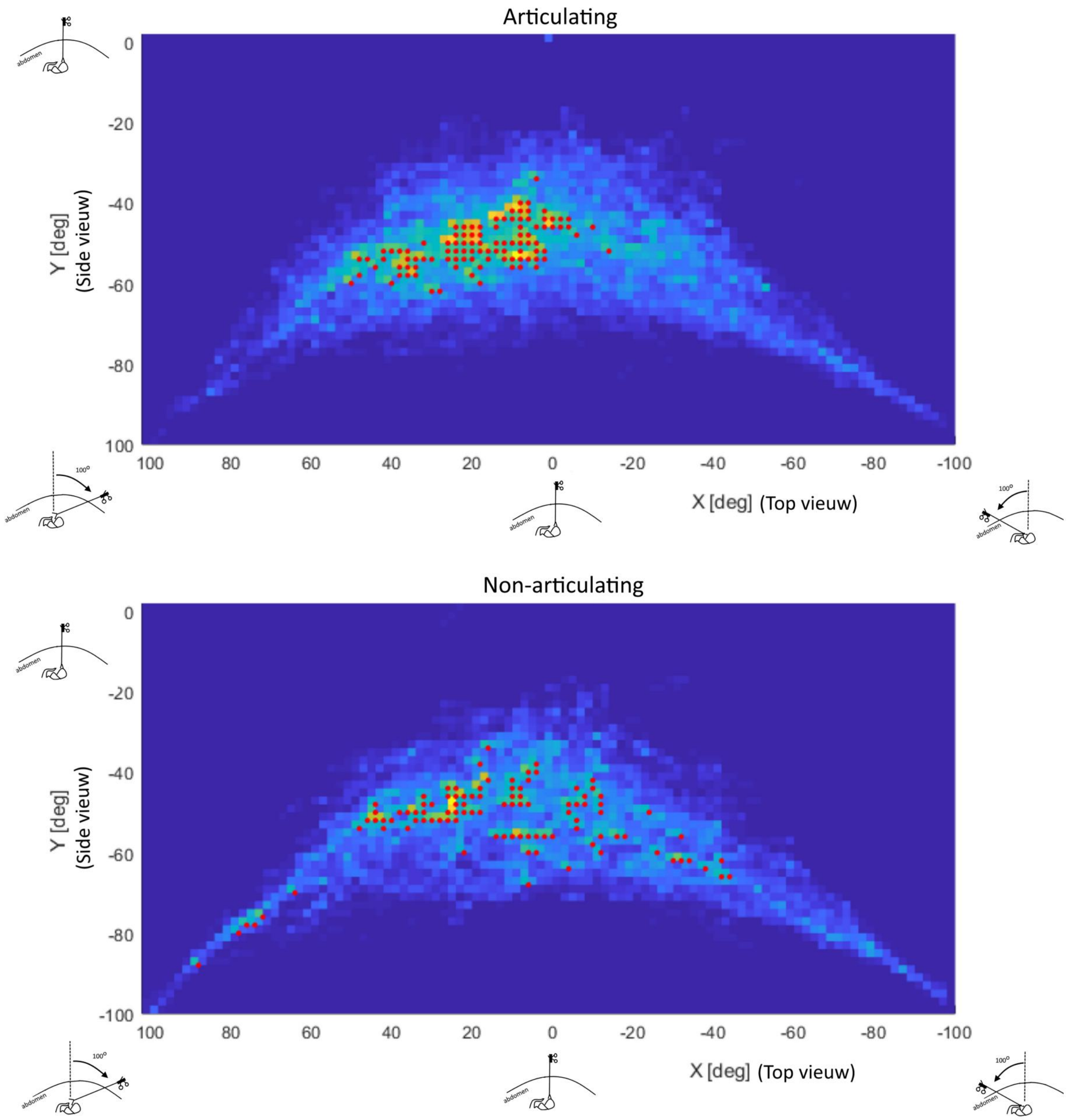

Figure 5. Two heat maps of the time spent in a particular orientation of the handle, indicated by the degree of deflection for the x-axis (left-right) and y-axis (up-down) with respect to a straight down orientation. The red dots show the data population of the top 20% most visited orientations.

Questionnaire

Overall, the responses were abundantly positive at an average of 4.4/5 (Table 1). Some disadvantages in the weight and reach of the features were noted, particularly by two female participants. Articulation of the instrument (questions 2–3) was noted to cost some effort by 3/13 participants. Nevertheless, all participants regarded the instrument as an innovation and would use the instrument themselves at a score of 4.6/5 and 4.4/5, respectively.

Some of the keywords from the additional interview included: 'less traumatic', 'faster', 'heavy', 'intuitive', 'precise', 'adds benefit', 'more efficient'. Many participants indicated that the articulation feature could be useful in clinical interventions and that it allowed them to be less traumatic to the surrounding tissue at the surgical site. As expected, many participants thought they could further improve their handling of the instrument with more training.

Discussion

There is an emerging market for advanced laparoscopic devices with added articulation that bridge the gap between the standard 40-year-old straight stick laparoscopic instruments and robotic systems. The additional two DOF provided by these instruments give the surgeon an amount of DOFs and a level of maneuverability comparable to that in open surgery thereby providing better access to challenging anatomical locations, like, in this case, the endoscopically accessed narrow inguinal region. They also allow for greater freedom of port placement as compared to 'normal' triangulation laparoscopic operating setups because the articulating tip permits precise angular access, even when not aligned with the camera [13]. This can be beneficial in enhancing surgical ergonomics [11,12]. We studied the SATA-LRS, a new articulating hand-held 5 mm laparoscopic instrument with two additional degrees of freedom at its end-effector. This instrument differs from most previously studied hand-held articulating laparoscopic instruments in that it is sterilizable and reusable, can fit through 5 mm trocars, is purely mechanical, has a low weight- and balanced handle, is cordless and in design is very much comparable to a standard laparoscopic instrument, making its handling easily recognizable for surgeons and trainees with (some) laparoscopic experience.

In this study, we analyzed the usability and added benefit of the instrument in a clinical setup in a narrow anatomical space and compared the use of the device with and without articulation.

Clinical application of the SATA-LRS instrument

After use in the experiment, the instrument worked according to design and showed no hindrance or hitch. All participants started to use the extra articulation function within seconds.

User steering and articulation

All participants were able to fully use the instrument after a minimum introduction to its features. Participants were encouraged to avoid contact with the spermatic cord as much as possible, which presumably required extra focus during the articulation phases, while during non-articulation this was hardly feasible and probably ignored. It is possible that the use of the articulation feature required a higher mental effort, thereby decreasing task speed. Yet, all participants used the articulation right away and a considerable percentage of time, as well as the total number of passes, was comparable during both articulation and non-articulation phases. This suggests that during intended use in a clinical setting, the instrument's design is intuitive and easy to use, as also indicated by the outcome of the questionnaire.

Handle orientation, velocity, and acceleration were not significantly different between phases, though the velocity suggests an overall improvement after phase 1, probably indicating a learning curve. The total passes and pass time were much alike between all three phases, indicating that task performance was constant throughout the tasks, indicating that performance was not negatively influenced while using the instrument's advanced features.

The task was designed to be achievable with and without articulation to compare the performance of either mode. Although subjectively articulation showed a benefit, the objective measurements were not able to show a significant benefit, except for the amount of movement at the handle, which was significantly less in the articulation-enabled phases.

This indicates that articulation can mitigate movement on the handle side, thereby reducing the movement of the arm and shoulder of the surgeon, which could improve ergonomics but also reduce force at the tip of the instrument. This could enhance the quality of laparoscopic procedures and, from a clinical perspective, the more subtle use of instruments on tissues could reduce complications and lead to quicker patient recovery.

Questionnaire lessons

The overall positive response to the questionnaire and interview showed a convincing acceptance of the instrument. Most participants stated that the articulation feature allowed for a more precise, less traumatic intervention. Although some remarked on a higher mental effort, none of the participants mentioned the need to slow down during the articulation phases and indicated that they might further improve handling with more exposure to the instrument. Studies involving comparable articulating instruments also suggest that more training can improve outcomes [5,14].

Future work

Future experiments should focus on learning curves and task outcomes in more complex interventions that could benefit from articulation, such as placement of mesh during a hernia repair [14] or laparoscopic suturing, which could benefit considerably from the instrument's articulated tip [15]. Previous experiments with the instrument, in which a training task was only possible with articulation, have already shown quick learning curves [8]. The use of additional objective measurements, such as forces on tissues or tissue displacement, could provide evidence for a more subtle instrument-task-interaction, as already indicated by several participants.

About the SATA-LRS

The SATA-LRS technology can be turned into a monopolar instrument as its core is made from stainless steel and its handle parts from an isolating plastic. The technology can be turned into a monopolar instrument by simply isolating the outer shaft and handle parts, and adding a connector to the back. The modular design allows for the use of all kinds of end effectors as long as they are actuated by a single push/pull rod [8]. This makes it a very low-cost, reusable, and versatile tool, with functionality changeable in seconds. While a full Life Cycle Assessment (LCA) and Health Technology Assessment (HTA) are needed to grasp the full economic potential of this innovation for endoscopic and robotic surgery, the simplicity of the components and similarity of the end effectors suggest a cost of approximately 20% of current standard reusable laparoscopic instruments. This marginal increase provides the surgeon with greater dexterity and the possibility to work around structures with improved tip-tissue alignment.

Limitations of this study

Unfortunately, it was not possible to draw statistical conclusions from the questionnaires as the questions were not validated. Therefore, the responses serve only to illustrate the participant's thoughts regarding the device and the study.

Author contributions

CRediT: **Tomas Lenssen**: Data curation, Formal analysis, Investigation, Project administration, Software, Validation, Visualization, Writing – original draft; **Roelf R. POSTEMA**: Conceptualization, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Writing – original draft; **Christian Camenzuli**: Investigation, Resources, Supervision, Writing – review & editing; **Jean Calleja-Agius**: Writing – review & editing & Supervion; **Jenny Dankelman**: Formal analysis, Supervision, Validation, Writing – review & editing; **Tim Horeman-Franse**: Investigation, Resources, Experiment execution, Supervision, Writing – review & editing.

Disclosure statement

All authors declare that there are no relevant financial or non-financial competing interests to report.

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