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SATA-LRS: A modular and novel steerable hand-held laparoscopic instrument platform for low-resource settings☆☆

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ABSTRACT

Background: Hospitals in low resource settings (LRS) can benefit from modern laparoscopic methodologies. However, cleaning, maintenance and costs requirements play a stronger role while training and technology are less available. Steerable laparoscopic instruments have additional requirements in these settings and need extra identified adaptations in their design.

Method: Several modular detachability and tip steerability features were applied to the SATA-LRS instrument platform designed specifically for LRS. Ten subjects participated a dis- and reassembly experiment to validate the modularity, and in a steering experiment using a custom made set-up to validate steering.

Results: A new steerable SATA-LRS instrument was developed with the ability to exchange end-effectors through a disassembly of the shafts. Experiments showed an average 34 and 90 s for complete dis- and reassembly, respectively. Participants were able to handle the instrument independently after a single demonstration and 4 rounds of repetitions. Precise tip-target alignment in the box set-up showed a very short learning-curve of 6 repetitions.

Conclusion: A novel instrument platform with articulating and rotating end-effector was designed for LRS. Within a minute the SATA-LRS can be disassembled to component level for inspection, cleaning, maintenance and repair, and can be autonomously reassembled by novices after a minimal training. The modular buildup is expected to reduce purchasing and repair costs. The instrument has been shown intuitive by use without extensive training.

1. Introduction

Laparoscopic surgery has several benefits specifically for Low-Resource Settings (LRS). These environments deal with high rates of trauma and limited diagnostic resources, while having insufficient hospital beds, patients from single-income households, and compromised hygiene [5]. Laparoscopy offers solutions by requiring limited wound exposure with increased recovery-rates [5] and proved to be cost-effective for LRS [1,4,5] especially when re-usable instruments are used [2,7,13].

However, working inside small spaces has several inherent surgical challenges, including the reduction of the instrument's natural 6 Degrees of Freedom (DOFs) to only 4, as well as the required strategic port-placement for proper instrument approach. One of the main focus points in laparoscopic instrument design has been on the steerability of instrument's end-effector where tip-tissue alignment is supported with additional DOFs at the end-effector. However, many designs for steerable laparoscopic instruments require compromises, being that they become difficult or unintuitive to use, have thicker shafts requiring bigger incisions, and are generally too complex for cleaning or maintenance which make them single use [3] while purchasing costs are mostly higher. Moreover, due to the use of cables in long instruments with neck-like joints many of these designs suffer from low joint stiffness [11]. The adoption of steerability in laparoscopic instruments has so-far shown repercussions that hit particularly hard on LRS where re-use of instruments is largely the norm (even when not designed for re-use), training is more difficult, and repair and maintenance is unsupported in terms of local production and human resources [14]. For LRS, the design of steerable laparoscopic instruments requires development with a higher focus on cost-suppressing reusability, meaning cleaning and

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maintenance should be possible, along with an intuitive use that foregoes extra training for surgical, sterilization and maintenance staff. In settings where medical hygiene standards cannot always be achieved, laparoscopy could have great benefits that should not be undermined by secondary negative effects such as unstable joints, large shaft diameter or impaired cleanability. In this design paper the SATA-LRS, a new instrument platform for laparoscopy that adheres to proposed requirements that are specifically beneficial for LRS, is shown and validated.

2. Methods

2.1. Early design choices

As discussed in the work of Anderson et al. [3], there is no apparent consensus on the specific DOFs a steerable instrument should have. There are two trends where either the tip is double articulated by two stacking joints, or the tip is articulated once followed by a rotation of the end-effector. Both have the same number of additional DOFs, yet the change in configuration during alignment of the end-effector with the targeted tissue does differ (Fig. 1). Fig 1A shows the concept of a double articulated instrument. The tip can initially be steered in bi-axial directions, yet the end-effector will subsequently be moved either up, or sideways, which changes the orientation of the beak with respect to the targeted tissue. The double articulated instrument will suffer a pre-determined alignment with the tissue if only the two articulating joints are used (Final 1). The last orientation (Final 2) shows how the double articulating instrument aligns with the tissue in any other radial orientation through a complex 3-DOF motion that would be highly unintuitive for hand-held control. Fig 1B shows a single articulated instrument which can axially rotate the articulation DOF towards the intended steering direction, and is subsequently able to correct for beak orientation by rotating the beak in alignment with the targeted body. The rotation after articulation allows for an intuitive approach from any radial orientation.

A double articulating instrument has previously been developed [8] based on the technology of the Shaft Actuated Tip Articulated (SATA) joint, a particularly ridged articulating joint that operates without cables [9]. This original device used the SATA-joint applied in a stacked manner to achieve two DOFs. The SATA-LRS will be articulated once, followed by a rotation of the beak for orientation corrections, which improves tip-tissue alignment. Aside from the substantial stiffness, the SATA joint has also been chosen as the basis for this device due its hollow geometries, allowing for follow-up mechanics to pass through, as well as its profoundly short articulation radius as a pin-joint, without the need for actuation cables. A short tip-to-joint length is a particular focus in this design to minimize the space required for steering within the laparoscopic environment [3], whereas the lack of cables offers great benefits in terms of cleaning [9].

Many laparoscopic instruments are not, or only partially, detachable after use for cleaning. Without inner access to the instrument for proper inspection the designs rely fully on a feed-forward cleaning approach, yet lack any form of visual inspection. Proper internal inspection to validate the cleaning process requires the instrument to be disassembled. This is especially relevant for LRS where autoclaves are not always available and cleaning often has to resort to chemical baths, gas chambers, soap waters, manual scrubbing and rinsing [6]. The design in this article focuses on accessibility of the instrument's components in the end-effector and shafts.

Additionally, the SATA actuation mechanism offers the possibility to extend the detachability of the system to a modular design. This is especially favorable for LRS as a it reduces costs both in terms of maintenance and refurbishing of single parts. Secondly, a modular design of the end-effector allows for different tips to be connected to the

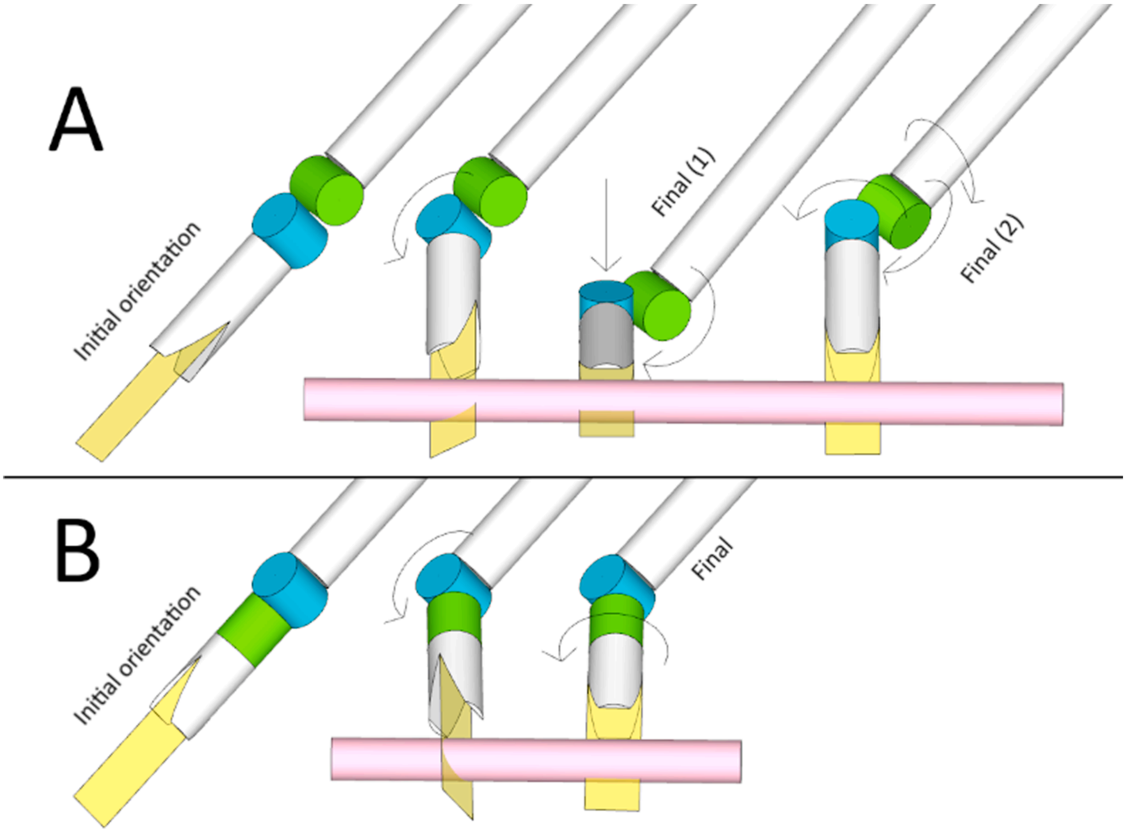

Fig. 1. Schematic drawing of the 2-DOFs end-effectors and their target-aligning ability. (A) double articulating end-effector, (B) articulating and rotating end-effector.

instrument, thereby changing its function while procuring costs increase by only a fraction of the costs of the total device.

2.2. Mechanical design

Several elements of the SATA design [8] were adopted to form the basis of the new SATA-LRS instrument platform. The SATA-joint from [8,9] was adapted to work with three rotating shafts; the outer-most is used to actuate the SATA-joint, the middle as a static guiding rod, and the inner as push-pull rod to control the end-effector. To achieve the dis-attachment of the shafts from the handle an adapted version of the so-called Puzzle-Piece-Connection [8] is used. The interlocking shafts can only dis-attach after alignment of their 'puzzle pieces' in a rotational fashion, so that they can be separated through radial translation. This is normally blocked with an overlapping tube attached to the handle through a quick-release bayonet-connection. In line with the "bare--minimum design" approach used to develop the modular SATA technology [8,9,15], the existing handle design was improved with a trigger-lever for more ergonomic beak-closing with lower actuation force.

Due to the small scale of the components, production used the standard tolerance of ±0.05 mm in accordance with NEN-EN-ISO 1101:2013 on almost all features. Within this prototype phase the entire shaft system and end-effector were made using 304 stainless steel, though final products will be made using 316L. Components in the handle were made of aluminium and an acrylic based fluid produced using the Digital Light Processing (DLP) 3D-printing technique. Material choice in the handle were aimed at significantly reducing production costs and weight, while planning on future use of injection-molding techniques.

2.3. Modular design validation study (Task-1)

A validation study was conducted with regard to the dis-, and reassembling of the instrument at component level. An experiment was set-up to determine the learning curve and success rate of participants unaccustomed to the device in their effort to disassemble and reassemble the device.

A total of 10 participants (postdocs, PhDs, and master students) were recruited within the BioMechanical Engineering department of the Delft University of Technology. They had some basic knowledge of the laparoscopic field and its instruments but lacked practical experience. The participants were invited to participate one-by-one, and were not allowed to meet during participation. All subjects were asked to wear latex gloves during interaction with the instrument, similar to clinical practice. The assembled instrument was presented to the participants but they were not allowed to have immediate hands-on experience. The conductor of the experiment disassembled the device with detailed instructions, after which the instrument was reassembled similarly. Immediately following, the participants were asked to dis-, and reassemble the device. The participant had to repeat the cycle a total of 7 times, which a pilot study showed to be the limit to disinterest. During each iteration the participant was allowed to ask for instructions.

Two measures were recorded during the experiment: the total time of each dis- and reassembly per iteration, and the number of instructions. If the participant kept quiet but seemed to struggle for longer than 10 s the conductor would give a tip or instruction which would be counted. If the participant finished incorrectly, an instruction was given after which the participants continued until correct completion of the task. As such, both the total time and required instructions form learning-curves on the skills and autonomy of the participants. The median of the last two repetitions will be taken as the final competence for each participant.

2.4. End-effector steering validation study (Task-2)

Immediately after Taks-1, all participants were asked to perform in a second Task-2 to test the functional use of the two DOFs steering in the end-effector. The task was set-up inside a custom laparoscopic environment simulation trainer (see Fig. 2 (A)) based on a ForceSense Boxtrainer [10]. More images on this work are shown in [12].

The task consisted of 5 ports, each with a different angle and orientation (see Fig. 2 (B)). Within each port an electric contact element was placed for the instrument's tip to connect with at deep insertion. An algorithm hosted by an Arduino Nano was used to randomly command on the monitor which port had to be contacted. The algorithm determined the total time to make contact from the moment the command was given. Contacts were detected through a low voltage current between the tip and a sensitive element deep in the port.

The ports were designed to be particularly stiff and narrow-fitting to force precise steering. Additionally, each port contained an internal obstacle extending across the diameter of the port which required the beak to be rotationally-aligned before entry would be possible. The orientation of each internal wall was indicated with external markers on the outside of each port. Detailed pictures of the setup can be found in [12].

Each port had to be contacted a total of 10 times at random, resulting in a total of 50 contacts. In case a wrong port was contacted the attempt was discarded. The participants had no experience with steering the instrument and received no instruction on how to handle the instrument, how the rotation knobs worked, or how to hold the handle.

The median time of the last 3 repetitions of each port was used as competence score for each participant.

3. Results

A functional prototype was produced using conventional CNC machining. The device consists of several interlocking shafts bridging between the instrument's tip and handle (see Fig. 3). The middle shaft functions as basis for the tip's mechanisms, and is considered static. The outer shaft rotates over the middle shaft in an axial fashion, thereby actuating the articulation of the tip's SATA joint. An inner shaft is used as push-pull rod and the rotation-rod for the end-effector. All shafts are inserted in the handle, where they converge and connect to their respective docks. The outer and inner shafts are controlled by rotation of the larger and smaller wheel in the handle respectively. The inner shaft can be pulled back by use of the trigger. The handle is designed to be used by one hand. The shape of the handle is largely determined by the plastic parts which can be custom made to fit different hand sizes. By intention, the index-finger will reach to control the larger wheel, while the thumb is used for the smaller wheel. The middle-finger controls the trigger, which has been designed to accommodate both pull and push where necessary, although the trigger is spring-normalized to the 'open' position. Last, the little-finger wraps the base of the handle and ensure a tight fit into the palm. The ring-finger, depending on the size of the hand, supports either the middle-, or little-finger. The weight of the entire instrument is 370 g, whereas the handle alone weighs 285 g. The whole instrument is made of 37 individual parts excluding any end-effector.

3.1. Steering mechanism

The SATA joint has been designed to act as a platform onto which an end-effector can be mounted. An ISO Metric M4 fine threading on both the tip and the platform chamber allows the tip to rotate, guiding the tip on the threading between the two. Full rotation of the tip is blocked to prevent axial drift, while a pitch of 0.5 mm renders the remaining tip translation neglectable. Rotation of the end-effector is realized by rotation of the push-pull rod that also closes the beak. The so-called "Hammer" (see Fig. 4) wedges the beak shut with a high force transmission. It also has its own axis-pin embedded in the head of the beak. With this radial pin any rotation on the push-pull rod is directly transferred to the rotation of the tip while, through the use of a spline, the

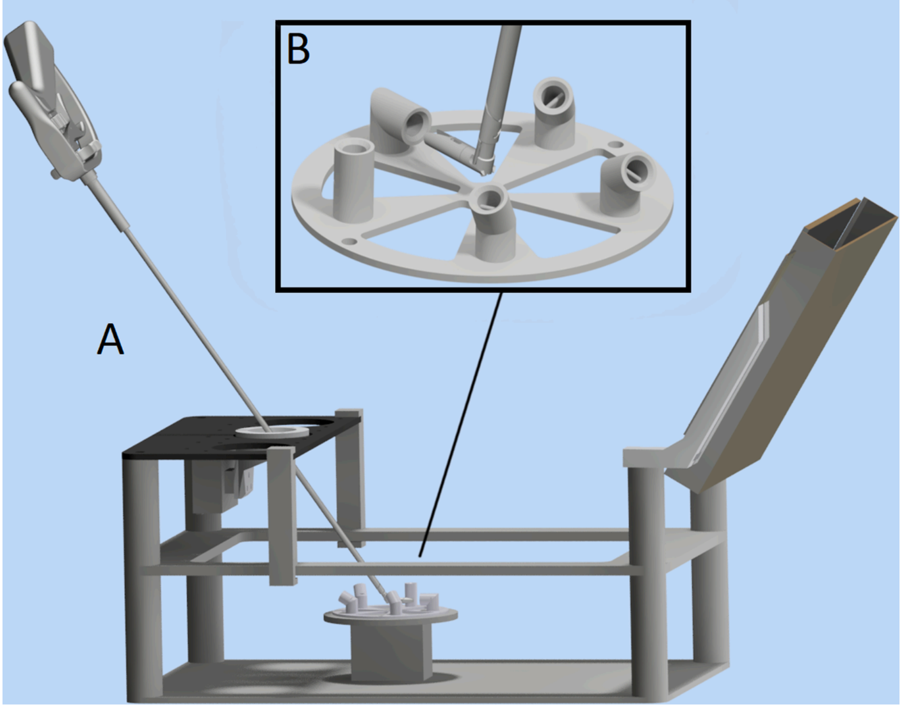

Fig. 2. (A) Task-2 set-up in the laparoscopic environment, (B) close-up of task and instrument interaction.

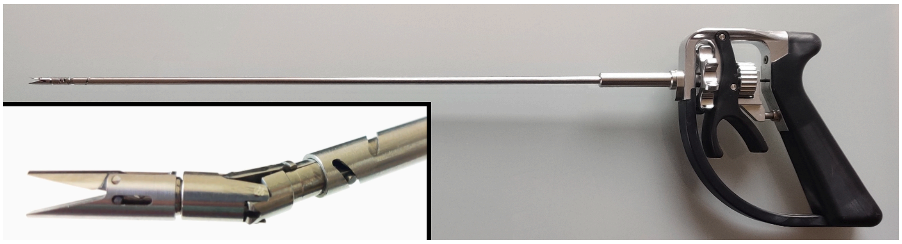

Fig. 3. The complete device with zoom-in of steering element and end-effector (tip).

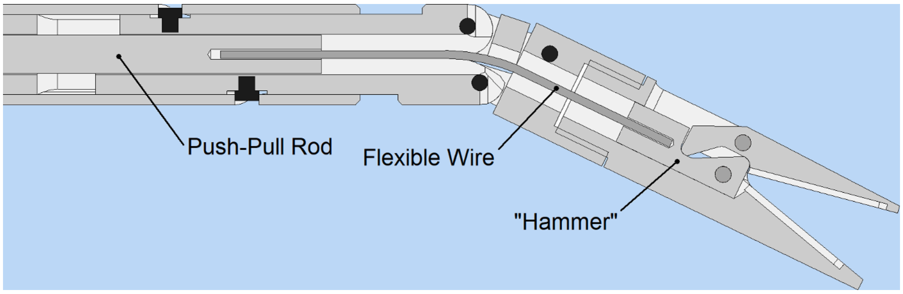

Fig. 4. A technical image of a cut-through of the SATA joint and end-effector.

hammer can still be retracted to close the beak. The spline simultaneously opens the frame of the beak as a cleaning and inspection feature. To pass the articulating SATA joint, the hammer and the push-pull rod are connected with a flexible wire. Tip articulation reaches 70° and 80° left and right, whereas the tip achieves a rotation of 340°. No jamming of the mechanisms occurred during use of the instrument, and beak performance has been on-par with its design. No parts broke or bent, with one exception after unintended use (elaborated further in Section 4.4)

3.2. *Cleaning and inspection*

The device can be disassembled and reassembled without the use of extra tools. After disassembly, two shafts (B1 & B2), the SATA-joint (B3), the handle (A1), shaft-bushing (A2) and end-effectors (C1/3) persist. Fig. 5 shows the completely disassembled device including several end-effectors. The fully disassembled device allows for inspection from all sides, including see-through of the shafts, and are accessible for pipe-brushes. The push-pull rod (C) is exposed along with the flexible wire for the most internal cleaning and inspection. The SATA-joint (B3) is completely isolated and fold open for maximal reach to the most

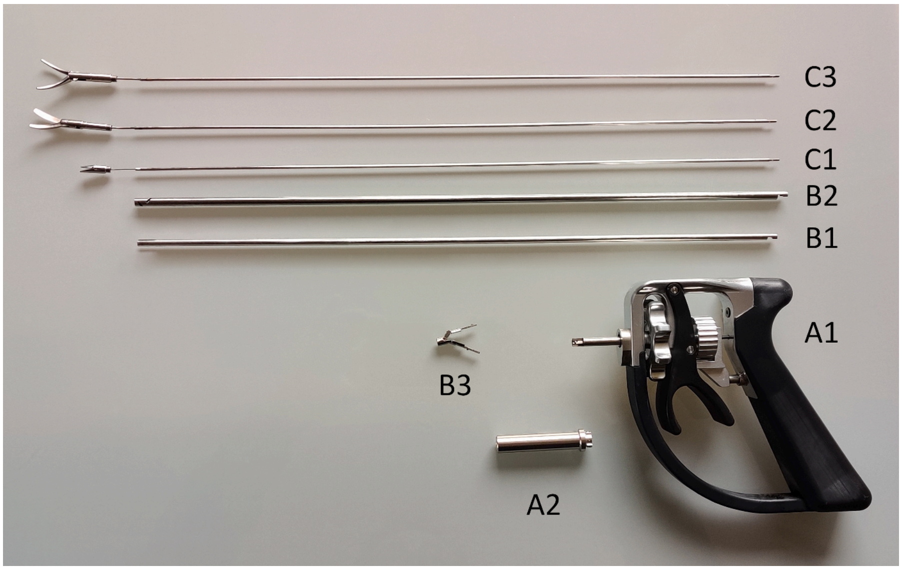

Fig. 5. The device completely disassembled. A1: Handle, A2: Shaft Busing, B1: Middle Shaft, B2: Outer Shaft, B3: SATA-joint, C1/3: Push-pull rod with a clip applier, cutter and grasper tip respectively.

complex part of the instrument. View from both sides, along with unfolding the sliders, ensures all surfaces are directly visible. The end-effector tip is permanently attached to the push-pull rod via the interlocking hammer in the beak. Besides being essential for proper functioning of the beak mechanism, the slots on both sides of the beak expose the internal geometries for direct visibility and improved fluid access during submersion. Since the beak-frame is not a full pipe structure and is internally obstructed by the hammer, an internal surface of 38.6 mm^2 is the only area that is not directly accessible.

3.3. *Modular design, maintenance and multi-functionality*

Theoretically, any end-effector with the proper threading and push-pull rod can be attached to the instrument. As a proof of this concept, both a regular atraumatic “maryland” cutter and grasper (Fig. 5, C2 and C3) have been integrated into the platform and could be steered in both articulation and rotation.

Almost all components are replaceable without the need for destructive measures or permanent connections. As such, the shafts, the SATA-joint, any component within the handle, and each end-effector tip is replaceable with simple tools.

3.4. *Assembly dynamics validation study (Task-1)*

Ten subjects (average age 26, SD 2.5, 8 male, 2 female) were included in the dis- and reassembly study and were all able to complete the sessions successfully. Fig. 6 shows dis- and reassembly time of the instrument by each participant (left axis, boxplot), as well as the

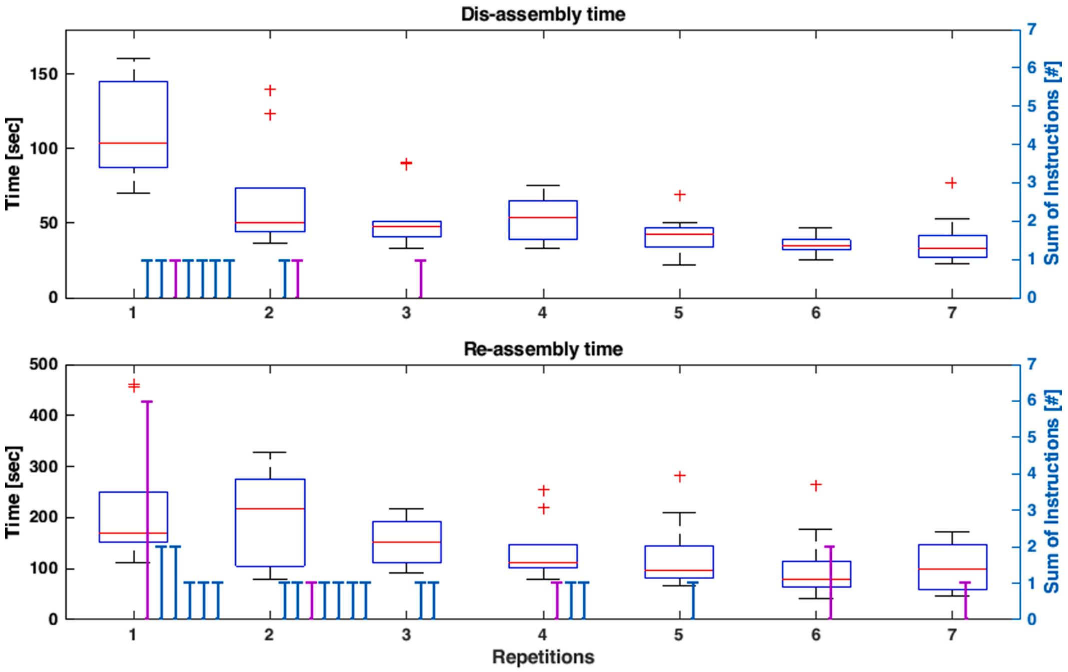

Fig. 6. Total time required in Task-1 for each repetition per subject (left taxis, boxplot), and the total required instructions per subject (right axis, bar-lines). One subject (purple bar-line) is highlighted as an outlier.

required number of instruction (right axis, bar-lines). The disassembly plot shows that 7/10 participants required a single instruction to complete the task in their first attempt. During reassembly, 9/10 participants were able to successfully reassemble the device without any instructions after 5 repetitions. One individual (indicated in purple) contributed 38% of the total instructions required for reassembly and can be considered an outlier in this task. Observations of this participant noted rushed and boorish behavior presumably due to a competitive will to act as fast as possible. Both the dis- and reassembly curves seem to flatten after 4 repetitions. The median of the last two repetitions of all participants was 34 s, with a record of 22 s for the assembly task, and 90 s, with a record of 41 s, for the reassembly task. The median time of all participants on repetition 6 and 7 showed an average improvement of by 313% for disassembly and 226% for reassembly compared to repetition 1.

3.5. *Steering features validation study (Task-2)*

The median completion time for Task-2 was just over 8 min (11 min SD). All participants were able to successfully connect with all 50 assigned ports. A higher time requirement was observed at the start of the task with the average median starting at 17.8 s, which plateaus around the total median of 9.7 s after 6 repetitions. Fig 7 shows the performance of all participants per port. The graphics show for each port the medium required time for the relative repetition of that port. The median of repetition 7 to 10 for each port respectively result in 8.1, 6.1, 15.3, 7.0 and 9.5 s.

None of the participants had questions when first using the instrument and all used the handle with one hand.

4. Discussion

The newly developed SATA-LRS has a range of motion of up to 80° of articulation followed by 340° of rotation of the tip to allow correct outlining with a target tissue. All participants were able to interact with the instrument as intended with minimal to no instruction. Experiments with test subjects have indicated that steering of the device was intuitive as all participants were able to finish all tasks trials completely autonomic within a moderate time-frame. The dis- and reassembly experiment has indicated some points of improvement but was done entirely successful. The device was able to tolerate the use of 14 novices without failure.

4.1. *Modular build-up*

The modular design created in line with the “bare-minimum design” approach allows disassembly of the instrument for maintenance and repair on a component level. Parts can be inspected, repaired or exchanged without the need for the entire device to be replaced. This potentially improves the re-usability of the device significantly, lowers maintenance and repair costs, and allows for refurbishing rather than wasting. Maintenance on component level rather than assembly level allows for relying on simple spare-parts that can possibly be produced locally, lowering the need for trained technicians or engineers, which are key features of a LRS adapted instrument [14].

With the modular design of the instrument end-effectors through a semi-detachment of the shafts, the device can perform the features of the tip installed. This makes it possible to purchase a small set of instrument platforms (shafts and handle) with several separate instrument tips rather than a complete instrument for each feature, which reduces purchasing costs. The device is capable of switching end-effectors prior to the procedure without the need for extra tools. End-effectors such as a needle holder or clip applier are future candidates for such tip-only purchases. However, the practical implications of switching between end-effectors within a procedure remains to be tested in a future experiment.

4.2. *Assembly dynamics validation study (Task-1)*

The results of Task-1 showed that 10 participants without any experience in laparoscopic instrument handling were able to quickly and autonomously dis- and reassemble the device. Although it is therefore expected that western medical and sterilization personnel are able to handle the assembly of the device with relative ease, the target market for this specific device is in low and middle income countries. Therefore, it should be investigated if surgeons, scrub nurses and sterilization personnel without knowledge about laparoscopic instruments can process these instruments in a safe and comfortable way. The participants were given minimal training and had to rely largely on their resent understanding of the instrument despite their lack of prior contact. In the reassembly task, the second repetition required more time than the first, presumably because the participants started to rely on long-term memory. This is supported by the increase in required instructions at the second repetition.

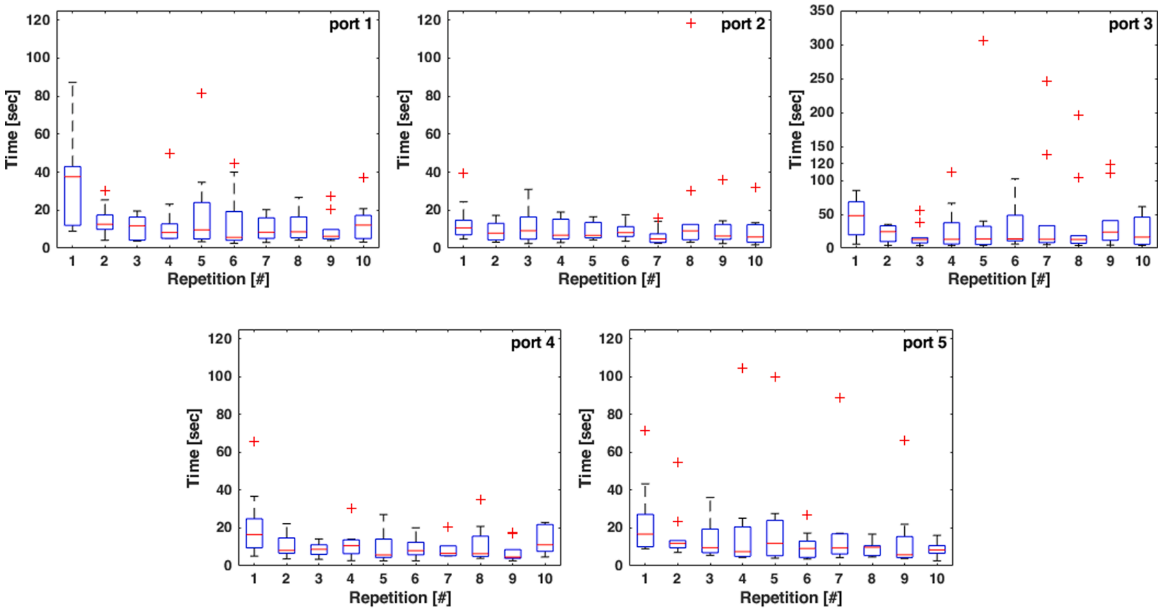

Fig. 7. Boxplot showing the required time per repetition for each port.

The data of the (dis)assembly experiment showed a relatively large standard deviation for the reassembly time in repetition 6 to 7, indicating several bottlenecks in the reassembly steps. Particularly the correct insertion of the tip and its sliders with correctly lodged pins in the outer shaft, as well as the matching of the Puzzle-Piece-Connection after aligning of all axes, were the main points of struggle as observed during Task-1. Technical improvements of these areas to further reduce assembly time need to be made in the future.

4.3. Steering features validation study (Task-2)

The ports in Task-2 were made from hard plastic tubes with a narrow fit on the instrument during insertion. These tubes were particularly stiff compared to soft tissue expected within a surgical environment. This rather unforgiving task was chosen to maximize steering requirements of the tip-target alignment, which might have contributed to the learning-curve of the novice participants. It is expected that more flexible tissues require far lower steering precision, and that more clinical tasks will need less steering time.

Only one of the participants was left-handed. Any differences in conditions was cancelled by putting the set-up on the right corner of the table rather than the left to support the advantage many participants seemed to have in standing somewhat besides the box to have elbow alignment with the instrument.

Particularly port 1 and 3 needed some familiarizing as they required an extreme pronation or supination of the handle. Fig. 2 shows the handle in a particularly supinated position to align the tip with the horizontal port 1. The 1-DOF articulation requires an axial twist to be aimed in this direction. This needed some exploration with most participants, especially in their first attempt in Fig. 7. Nevertheless, the following repetitions show a quick gain of skill. In spite of the unique ports with different steering requirements, overall skill is shown to be intuitively gained after minimal contact with the instrument.

4.4. Instrument validation after use

After being handled and used by 14 participants (including 4 participants in a pilot study) the instrument shows no signs of fatigue, wear or tear, with an exception in one feature. Participants had dislodged the push-pull rod through a twig-snap motion rather than a clean shear motion. After the experiments, signs of material fatigue were detected as cracks. Redesign of this feature to either allow, avoid or resist this kind of undesired motions should be implemented in later models.

4.5. Future work

Though immediate short-term skill retention has been shown in this study, a follow-up study should investigate if dis- and reassembly skills are maintained over a longer period. Further validation of the instrument platform should continue in a clinical setting. Future work is aimed at hernia repair mesh placement tasks as well as tubal clip placement after proper alignment by surgeons in cadaver studies. Secondly, interviews and handling experiments around cleanability, and (re)assembly will be held in sterilization departments. Both these studies will rely on learning-curve examination, observations and questionnaire scores. Further improvements of the design will focus on reassembly bottlenecks as found in this study. Subsequent end-effector replacement tasks should investigate whether intraoperative tip exchanges are feasible.

5. Conclusion

A novel instrument platform with an articulating and rotating end-effector and adaptions to LRS has been developed and tested successfully. Within a reasonable time-frame the device can be disassembled to component level for inspection, cleaning, maintenance and repair. It can autonomously be reassembled by novices after a minimum training. This shows the potential for this new type of steerable, modular instrument design for LRS as detachability to component level supports local cleaning and inspection, as well as component exchange to reduce maintenance time and costs where no specific training or tools are required. Direct exchange of the end-effector also allows for real-time feature substitution, both increasing functional ability, while partial procurement options keep costs low.

Though the device itself has performed well, several bottlenecks in the reassembly process indicates further improvement of the design may be beneficial. Overall the device has been shown to have intuitive control as novices were able to precisely steer the tip after a few minutes of use.

Declaration of Competing Interest

Please note that Tim Horeman is founder of the Department's MedTech starter "Surge-On Medical" that integrates new cable-less steering mechanisms developed at the Delft University of Technology into new endoscopic instruments. The other authors have no conflict of interest to disclose.

Acknowledgments

Tim Horeman is founder of the Department's MedTech start-up Surge-On Medical that integrates technologies developed at the Delft University of Technology into new surgical products. There are no further conflicts of interest to disclose.

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This work is reviewed and approved by HREC, Delft Technical University, submission number 1331.

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