Minimally Invasive Therapy. 2015; Early Online, 1–8

informa healthcare

ORIGINAL ARTICLE

A novel, intuitive instrument positioner for endoscopy, involving surgeons in design and feasibility

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Abstract

Background: Existing laparoscopic instrument holders do not seem to sufficiently fulfil the needs of surgeons performing minimally invasive surgery (MIS) in several respects. Therefore, we developed and tested a novel laparoscopic instrument positioner in close cooperation between surgeons and engineers. **Material and methods**: Design requirements were established by attending laparoscopic interventions, interviews and involving surgeons during the design cycle by evaluation of early mock-ups and prototypes. **Results**: Two concepts, based on a scissor- and a deflectable ball principle, were elaborated and evaluated yielding a simple, affordable system, fixating all degrees of freedom in the centre of motion. A sterile functional prototype was fabricated and successfully tested during three clinical interventions. Users reported a stable image, easy and intuitive handling and no interference with other surgical instrumentation. The posture was conceived to be more ergonomic and surgeons liked the ability to control the positioning of the endoscope directly themselves. **Conclusions**: Three successful interventions show that involving surgeons in the design and testing phase of product development leads to a novel instrument positioner that can be used safely in a clinical setting. It can be concluded that the system is simple and intuitive to use, as there was no learning curve.

Key words: *Endoscope, instrument positioner, intuitive, ergonomics, assistant*

Introduction

Minimally invasive surgery (MIS) has become more and more common since the introduction of laparoscopic cholecystecomy in 1987 (1). MIS comprises operations in the abdomen, performed through small incisions. Through these incisions, the surgeon carries out the procedure using a plurality of medical instruments. It is, in conventional MIS, not possible for a surgeon to control more than two instruments; therefore he depends on one or more assistants to control the other ones. This results in a number of drawbacks, including the need for three or more persons in the sterile field, wherein one assistant is performing a rather static task of holding instruments. Furthermore, the surgeon has no direct control over his viewing direction when an assistant holds the endoscope. This can lead to communication problems and disturbs the surgeon's eye-hand coordination (2). Moreover, the laparoscopic image is often unstable due to tremors and sudden movements of the surgical assistant as the task is often a time-consuming (3) and fatiguing job, performed in limited space, leading to unergonomic circumstances (4).

Technology can be a valuable addition to the dexterity and precision of surgical performance (5–9). Instrument positioners can take over the assistant's unergonomic, semi-static jobs and provide a stable holding system (10). They also offer the benefit for the surgeon to have control over the static instruments himself. A number of systems with an instrument positioning function have been assessed in the past and most of them turned out to be bulky, complex, substantially adding to operation costs or not very intuitive to use (11–14). Breedveld et al. (12) divided instrument positioners into passive and active

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ISSN 1364-5706 print/ISSN 1365-2931 online © 2015 Informa Healthcare
DOI: 10.3109/13645706.2015.1039547

systems. Passive holders keep the instrument in place by means of friction after repositioning, whereas active holders reposition and hold the instrument electromechanically. Examples of passive systems are the Martin arm (14) (Gebrüder Martin, Tuttlingen, Germany), TISKA Endoarm (15,16) (Karlsruhe Research Center, Germany/Karl Storz Endoscopy, Tuttlingen, Germany), and Endofreeze (17) (BBraun Aesculap, Melsungen, Germany). Required investments are many times lower than for active systems, but they usually require two hands to reposition and fixate the instrument, which is not very user-friendly. Mishra et al. (18) examined the possibilities of solo surgery (14) with a simple, low cost endoscope holder, mounted on a harness. It gives the surgeon direct control over the endoscopic view but is not very ergonomical nor intuitive, as can be concluded from the reported increased neck and shoulder load and need for training. Active instrument positioners, such as ViKY (19) (EndoControl, Grenoble, Fr/Dover, DE, USA), EndoAssist (11) (Armstrong Healthcare, High Wycombe, UK), Aesop (20) (Intuitive Surgical, Sunnyvale, CA, USA), Einstein Vision (21) (B. Braun, Aesculap AG, Tuttlingen, Germany), LapMan (22) (Medsys, Sauvenière, Belgium), FIPS Endoarm (23) (Karlsruhe Research Center, Germany) and The Freehand System (24) (Guilford, UK/San Jose, CA, USA), can offer the surgeon the benefit of controlling the system without the need to release instrumentation. A drawback, however, is that the action of the surgeon is not directly coupled to the action of the system. User input is interpreted by the system and transformed to an electromechanical action. By (visual) feedback the user evaluates the resulting action and has to decide whether or not to correct it with another command. This is not much different from the situation where a surgeon commands the assistant to perform an instrument steering action. It is hard to describe the exact direction and magnitude of the desired position change in words. In practice, the resulting action is prone to overshoot, instrument collisions, time delay and can disturb the focus on the job (3). Steering systems such as these are considered to be second order systems (25). They are more complex to operate than first order systems, such as on/off actuation. Moreover, the investments for such systems are substantial (11,26).

Breedveld et al. (12) concluded that passive endoscope holders are the most intuitive to use, simplest in construction, most slender and cost-effective. Although passive holders force the surgeon to release an instrument to reposition the endoscope, Jaspers et al. (13) showed that a simple, passive instrument positioner can perform as well as or better than a robotic positioning device, especially when they can be repositioned with one hand. Jaspers (27) also showed that solo surgery with a passive system is feasible. Solo surgery could bring along economical as well as ergonomical advantages and may contribute to counteract the problem of the global shortage of health care professionals (28). However, it is still not commonly performed. It seems that currently available instrument holders do not sufficiently fulfil the requirements of MIS surgeons in practice. In this article we describe the result of a design process that aimed at the design of a new instrument positioner that complies better with the needs of the users.

Material and methods

At the University Medical Center Utrecht (UMCU), medical device development is embedded in clinical practice. Close cooperation between the Medical Technology & Clinical Physics Department and MIS surgeons has been the basis of our design strategy. Due to the strong relationship between the two departments, it was possible to keep the intended users in the design loop by organising user meetings, attending laparoscopic interventions and early evaluation of concepts and mock-ups. Also, the sterile medical devices expert was consulted frequently.

Requirements

The team of technicians and surgeons decided that the device should be designed for holding a 10mm endoscope as a starting point and that the clamping mechanism should be operated single-handed. Literature research convinced us to design a passive positioning system comprising a stationary rotation point. This means that the instrument pivots about a mechanically invariant point in, or close to, the incision point in the abdominal wall (13,16). Consequently, the abdominal wall is not subjected to instrument pivoting reaction forces. The system should have a short set-up time and must interfere neither with the surgeon's workspace nor the standard laparoscopic procedure. Trocar friction during instrument manipulation should be low when the clamp is unengaged, as high friction of the trocar can distort feedback and precision during surgical manipulation (29). Also, the device should be simple and affordable to be able to pave the way for solo surgery.

Concept development and evaluation

An endoscope has four degrees of freedom (DOFs), defined by rotation of the trocar in two directions around the incision point and rotation and translation of the instrument about the instrument axis. In order to fixate all DOFs with one compact clamping mechanism, we came up with the idea of clamping it in the point where all DOFs intersect: the "center of motion". Therefore, the mechanism should be constructed in a way that it clamps the instrument *through* the trocar shaft.

For the sake of intuitiveness of man-machine interaction, the type of control should comply with the action (25). During normal use, the surgeon or assistant has to grab an instrument physically in order to reposition it. Hence we designed the operating button of the clamping system in such a way that the user is able to operate the control button in the same action. Engaging the button removes the fixation of the degrees of freedom of trocar and instrument, while releasing the button freezes the instrument in the desired position instantaneously, yielding a "drag 'n drop" system. A schematic overview of the idea, of which we developed two concepts, is shown in Figure 1.

Scissor mechanism principle

The first concept we came up with is derived from a scissor- or pliers mechanism. It consists of a trocar, a clamping mechanism, an actuation lever, a cable from the actuation lever to the clamping mechanism and a linked arm to connect the system to the OR table. A major advantage of this concept is that the trocar design resembles a standard disposable trocar, except for a minor change in the trocar shaft in order to receive the clamping mechanism. Figure 2 shows an overview of the system and its DOFs.

The working axes of the DOFs intersect in the shaft of the trocar, in the centre of motion. Spring force is applied to the "legs" of the scissor-shaped clamp. The distal ends of the legs are captured in small "brake pads" that are integrated in the trocar shaft in a way that they can slide inwards and push against the instrument. Consequently, the force loop is closed. Because all joints are serially connected, the force generates friction in all joints simultaneously, freezing all DOFs. A lever, connected to the camera head and the clamping mechanism with a Bowden cable, enables the user to counteract the clamping force, so that the instrument can be repositioned freely.

A mock-up, depicted in Figure 3a, was created and discussed with a team of MIS surgeons. Their enthusiastic feedback about the mock-up's slenderness and one-button-control made us decide to elaborate this idea to a functional concept, depicted in Figure 3b.

The functional concept was designed to be sterilizable, but it was used for user tests only. We observed that it was possible to generate sufficient force to keep the instrument in position and that one-handed operation of the device was easy and intuitive. On the other hand, a relatively large lever was needed to keep the required user force low. Moreover, the friction was unevenly distributed over the joints, so that it was

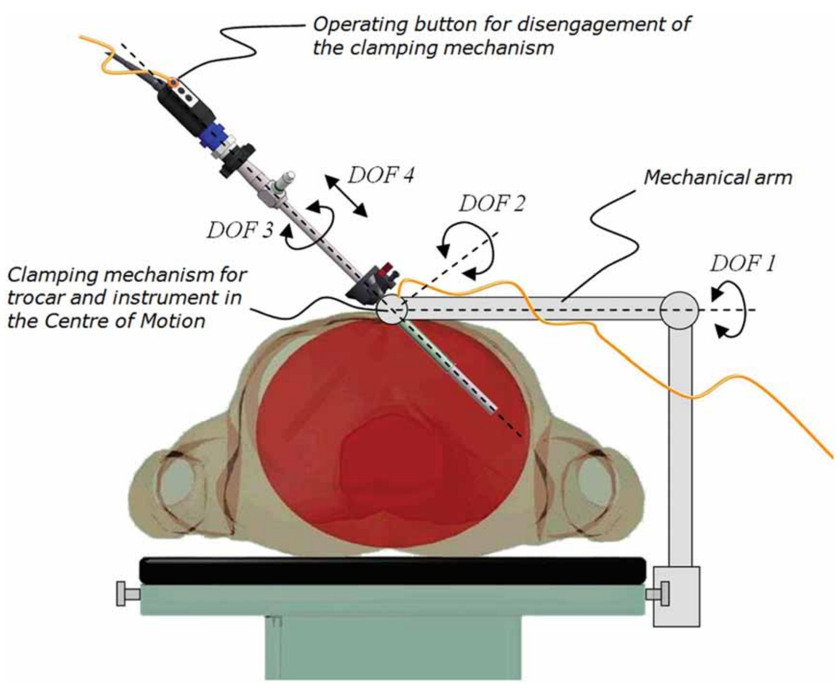

Figure 1. Schematic overview of the novel instrument positioner idea.

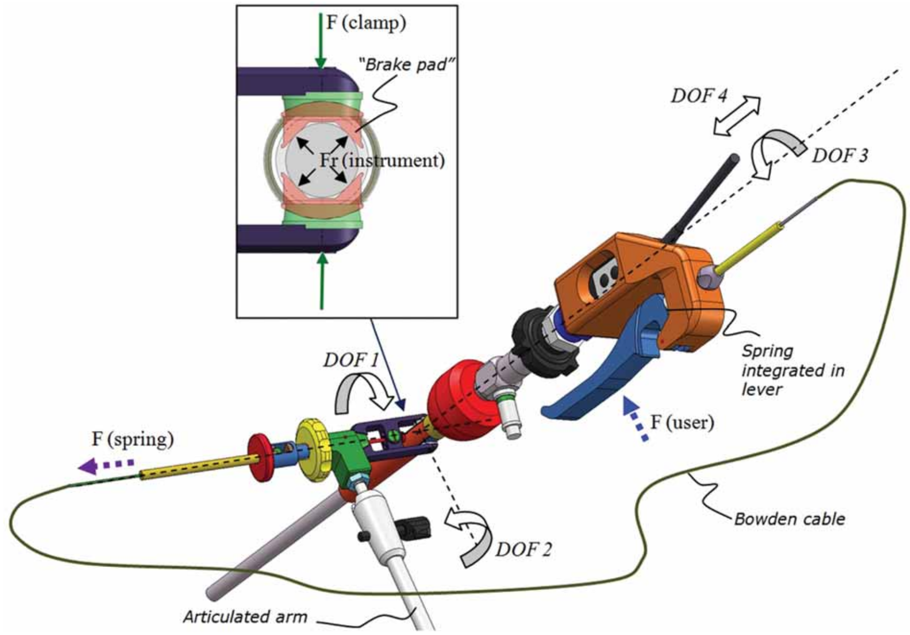

Figure 2. Schematic overview of the scissor mechanism concept and its DOFs.

difficult to balance the system under all angles. Another drawback was that the high friction in the Bowden cable consumed a lot of clamping force. Also, adequate sealing of braking pads in the trocar shaft, crucial for maintaining the pneumoperitoneum, turned out to be problematic. From these findings we concluded that the idea of single-handed control was promising, but the concept was not sufficiently robust and reliable, thus a different approach should be chosen.

Deformable ball joint principle

The alternative concept is based on the principle of a ball joint, as depicted in Figure 4a. The clamping mechanism is attached to the operating table by means of an articulated arm. A ball-shaped part, integrated in the trocar shaft, is enclosed by the ring-shaped part of a clamping mechanism. Spring force is applied, so that the ring contracts and clamps the ball. Due to the construction and mechanical properties of the trocar material, the ball-shaped part is deformable, so that the instrument inside it will be clamped as well. As a result, all DOFs are being fixated by friction resulting from the spring force. This force can be neutralized by user actuation. Initially, we chose to use hydraulics for this, since hydraulic forces can be easily scaled and friction is low. The actuation force is conveyed to a plunger, which is connected to one leg of the incised clamp ring, while the cylinder is mounted to the other leg. When the user pushes the button, the legs are being pushed outwards, opening the ring. As a result, the clamping force and the inherent friction are lowered so that the instrument can be repositioned.

A proof-of-concept was fabricated (Figure 4b). The trocar and clamping mechanism were manufactured in our workshop. We used saline solution as hydraulic fluid and a syringe as an actuator. A board of MIS surgeons reviewed the concept; they liked the direct response and intuitive operation of the clamping mechanism. Also, it generated enough clamping force and was relatively easy to manufacture. Drawbacks were the need for a relatively large operating button, complicated air bleeding and no possibility to introduce the trocar first and to attach the clamping system afterwards.

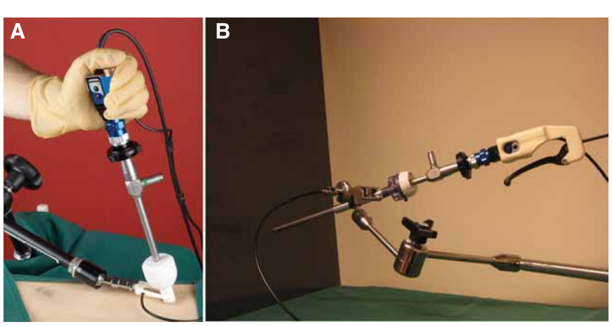

Figure 3. (a) Mock-up and (b) functional concept of the scissor mechanism instrument positioner.

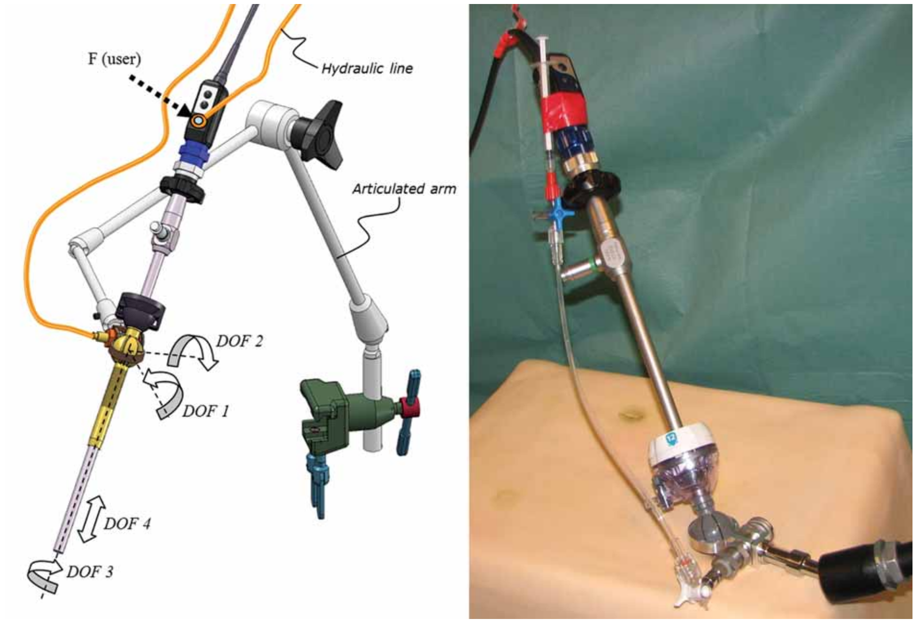

Figure 4. (a) Schematic overview and (b) proof of principle of the deformable ball joint concept.

Results

It was decided that a clinical prototype should be developed, based on the deformable ball principle. User evaluation of the concept led to a major design change; we decided to use electronic actuation for disengagement of the clamping mechanism in the prototype. As a result, a more compact and lighter operating button could be used, so that it could be placed on the instrument more conveniently. The required clamping force, resulting from the mass of the instrument and the attached button, could also be reduced. The ring is now contracted by a motor-driven self-braking threaded spindle. No motor torque is needed after the clamping action. For safety reasons the trocar could manually be removed from the clamping system, independent from the motor function. The trocar head was a screw-on reusable type trocar head (Trocar AUF11097A, Trokamed, Geisingen, Germany), the trocar shaft was fabricated in our workshop. It was machined from a medical grade polymer and the-ball shaped part was incised longitudinally for flexibility. These cavities were filled with soft medical grade silicone rubber so that the shaft was sealed and airtight. In order to avoid extra friction and stick slip in the trocar shaft, the inner diameter was controlled carefully and the silicone rubber was casted by means of a die. The inside of the shaft was fitted with longitudinal grooves, allowing for pneumoperitoneum gas flow.

The actuation unit, including the electromotor, was designed to be sterilisable, as was the cable to connect it to the motor driver/power supply unit. A reusable, non-sterile push button and cable were attached to the camera head before covering it with standard sterile camera drape. A sterilisable articulated arm (Fisso 3.500, Baitella AG, Zürich, Austria) was used to connect the system to the OR table. The clamping mechanism should be disassembled in order to clean and disinfect it after use. The trocar shaft was found to be not reusable because it could not be cleaned effectively due to its construction.

Approval on the clinical use of the device was obtained from the Minimal Invasive Committee, as advised by the Medical Ethics Committee. It was used as an endoscope

Figure 5. Clinical use of the novel instrument positioner during a simple nephrectomy.

Table I. Demographics of the subjects who underwent surgery with the novel instrument positioner.

Intervention	Sex/age	History	Adverse events during operation	Blood loss	Post-op adverse events	Length of stay	Setup time	OR time
Right sided simple nephrectomy	Female/50 yr	Resection of cervix carcinoma with lymph node dissection, hydronephrosis of a non-functional kidney at the right side	None	50 ml	None	2 days	20 minutes	125 minutes
Right sided radical nephrectomy	Female/58 yr	Rectum carci-noma, renal cell carcinoma at the right side	None	100 ml	Non-device port-site bleeding, re-intervention with minilaparatomy	10 days	10 minutes	145 minutes
Laparoscopic cholecystectomy	Female/16 yr	Cholelithiasis	None	0 ml	None	2 days	15 minutes	65 minutes

holder during three interventions (Figure 5). One simple laparoscopic nephrectomy and a laparoscopic radical nephrectomy were performed by an urologist. A general surgeon performed a cholecystectomy with assistance of the earlier mentioned urologist who was involved with the design process. During all procedures the assisting surgeon or urologist in training were asked to handle the device. The OR staff was trained on handling the setup of the device in a half hour session. Before starting the procedure the most ideal positioning of both the device and the patient was tested on a model. Table I shows demographics of the subjects who underwent the procedures. There were no device related complications. Set-up was easy, and the device did not lead to excess duration of the procedures. The device was introduced under direct vision in the patients undergoing nephrectomy and with open introduction in the patient undergoing cholecystectomy.

The sterile set-up functioned without technical failure. Users reported that it provided a much more stable image than human endoscope handling, it was easy and intuitive to use and did not interfere with the other instrumentation in the sterile field. The surgeon not involved in the design process could use the instrument positioner instantaneously. This was also true for the urologist and surgeons in training. The posture was conceived to be more ergonomic than in the situation with an assistant holding the endoscope. Also, the surgeons indicated that they were pleased with the ability to control the position of the endoscope directly themselves.

Discussion

Designing, building and testing different concepts during the development of this device, with frequent interactions with surgeons, seems time-consuming. But it resulted in a prototype for clinical use that was as intuitive and easy to use as intended. Although we would have preferred a system without electronics, such an approach would have compromised the intuitiveness and robustness of the system.

In the clinical test, we observed there was virtually no learning curve in the use of the device. The surgeons indicated that the interventions could be performed more ergonomically. However, the initial set-up time of the device was 20 minutes, after one training session with the OR staff. This included the time needed to find out the preferred mounting position. After the first intervention we noticed a decrease in set-up time. We expect that more time can be saved after additional interventions, as the OR team becomes more experienced with the set-up. One-handed control means that the surgeon needs to let go of one instrument. We found that this was no problem in the two nephrectomies and the one cholecystectomy we performed. A broader study is needed to investigate which other interventions benefit most from this type of instrument positioner.

One of the aims of the instrument positioner design was to cut the operation costs by enabling solo surgery. Obviously, the benefits of labour reduction should justify the needed investments. We used simple, affordable technology, although the costs could be reduced further by avoiding autoclavable electronics. Moreover, further development is necessary in order to reduce the need for time-consuming disassembly during the sterilization process.

One of the next steps will be a more extensive study on the clinical value and possibilities and valorization of the device. A patent was obtained and cooperation with industry was established. The design is currently being elaborated to a mass producible device, using disposable trocars.

Conclusions

Involving surgeons in developing a new surgical tool and testing concepts with them in a mock-up phase resulted in a novel instrument positioner prototype for MIS. Three successful interventions showed that the device can be used safely in a clinical setting, sparing one hand in the sterile field. The system was experienced to be easy and intuitive to use with practically no learning curve. Feedback from the surgeons indicated that the posture during the interventions was more ergonomic. Further steps are needed to improve per-operative handling and to proof the efficacy and ergonomics during surgery in a larger trial.

Acknowledgements

We would like to express our gratitude to J.J. van Veldhuijzen, precision instrument maker at UMCU, for the fabrication of the prototypes.

Declaration of interest: The co-authors Jesse Bosma and Joris Jaspers are the inventors of the Intellectual Property (IP) of the described device. They have no interest in the company to which the IP is licensed to.

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