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The mechatronic support system ''HVSPS'' and the way to NOTES

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Abstract

Since the publication of the first paper on NOTES, a dramatic increase of activities in this new surgical field is to be observed. However, a ''pure'' NOTES operation does not yet exist. Only NOTES-like operations have been proposed so far. One of the essential barriers is the limited intraoperative performance due to the lack of suitable mechatronic platforms. Some solutions have already been suggested but they are still far from having any practical impact upon the development of more advanced NOTES procedures. The ''Highly Versatile Single Port System'', a two-armed device with two manipulators and a semi-flexible telescope, was developed to overcome these drawbacks. A transsigmoid cholecystectomy on a NOTES simulator (the ELITE) could be accomplished successfully in 75 minutes. We could therefore show that the HVSPS is in principle applicable for such a NOTES procedure. However, before these mechatronic support systems can be used under clinical conditions, required human machine interface and extended intelligence have to be solved.

Key words: *Single port surgery, natural orifice transluminal endoscopic surgery, NOTES, telemanipulator for NOTES, robotic surgery, flexible instruments*

Introduction

Despite the steady progression of NOTES developments, ''pure'' NOTES operations practically do not yet exist in clinical surgery. What is currently performed are more or less NOTES-like operations (1). There are still too many unsolved barriers which impair the use in humans as presented in the NOTES white paper (2). Among others, one essential barrier is the limited intraoperative performance (limited flexibility and working range, no triangulation, difficult handling etc.). There is a broad consensus that these problems will be overcome as soon as innovative mechatronic platforms are available.

Some solutions have already been suggested (3–6) but they are, evidently, not yet ready for routine clinical use and their current impact is low.

To evaluate the potential role of mechatronic platforms for NOTES procedures the so-called ''Highly Versatile Single Port System'' (HVSPS) as described previously (7) was used.

The idea of this device was, literally spoken, to bring the surgeon's head, shoulders and arms through only one port into the abdominal cavity to regain the same flexibility as in open surgery. Originally, the system was developed for laparoscopic surgery. In this study, it was used to simulate a NOTES procedure in order to evaluate the practical applicability and the prospects of facilitating the new surgical concept of using natural orifices.

Material and methods

The ''Highly Versatile Single Port System'' (HVSPS)

A two-armed device with two manipulators and a semi-flexible telescope was designed using the know-how and partially the hardware of flexible endoscopes.

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Figure 1 shows schematically the kinematic structure of the complete HVSPS mechatronic platform used for NOTES. The flexible manipulators and the telescope are inserted independently through an insert with three lumens. This ensemble is introduced into the abdominal cavity using the "innovative, safe and sterile sigmoid access" (ISSA) instrument set for NOTES (8). In its current dimensions, the HVSPS is only suitable for the rectal or vaginal approach. Since the transanal access is not limited to the female gender alone, and because of the particular experience with the rectal approach (9), the latter was chosen to apply HVSPS in a simulated NOTES procedure.

The hollow manipulators with five degrees of freedom have an outer diameter of 12 mm. Flexible instruments are introduced through the central channels which are controlled and changed manually. The bendable section of the manipulators with two degrees of freedom, resembling the human wrist, has a length of 75 mm followed by a 50 mm length hollow tube and an elbow articulation with one degree of freedom. An additional two degrees of freedom at the distal end of the manipulators provide a rotation of 270° in each direction and a linear movement of 80 mm into the abdominal cavity. Visualization of the operative site by a flexible telescope with 10 mm diameter and five degrees of freedom is realized in a first step using a commercial endoscope with an outer diameter of 6 mm at maximum which is inserted through a 10 mm tube with a proximal deflection of 30°. With this ensemble, providing four degrees of freedom, the telescope can be moved in an S-form so that the instruments of both manipulators can be observed in their entire working range.

Both manipulators are partially automated and controlled over a real-time Matlab-Simulik application. In its current state, two joysticks are used as human machine interfaces, but an integration of the system into the ARAMIS platform, which comprises a telemanipulator to guide minimally invasive instruments, is planned for the future (10). This platform uses two Sensable PHANTOMs as input devices and can be ideally used to steer the HVSPS manipulators by Cartesian control.

The "Endoscopic - Laparoscopic Interdisciplinary Training Entity" (ELITE)

The ELITE trainer as demonstrated in Figure 2 is an *ex-vivo* model offering a highly immersive reconstruction of the abdominal cavity to train laparoscopic surgery and NOTES techniques. This new training model was developed by the research group MITI (Klinikum r. d. Isar, Munich, Germany) and manufactured by Coburger Lehrmittelanstalt (CLA, Coburg, Germany) is a one-to-one reproduction of a female human torso. It consists of an abdominal wall made to permit gas-tight laparoscopic incisions and an abdominal cavity with an adjustable retroperitoneum. All intraabdominal organs (a complete gastrointestinal tract with mesentery and omentum, liver, gallbladder, spleen etc.) are produced from different latex compounds with different characteristics and colors to permit a realistic mockup of the intraabdominal anatomy. The current state of the trainer permits a transanal and a transgastric access using the implemented valves at both sides.

The ELITE system was validated for NOTES cholecystectomy and appendectomy and appeared to be a suitable environment to compare "normal" NOTES and mechatronically supported NOTES (article submitted).

For this study, the transanal access was chosen to perform the cholecystectomy with the semi-flexible HVSPS.

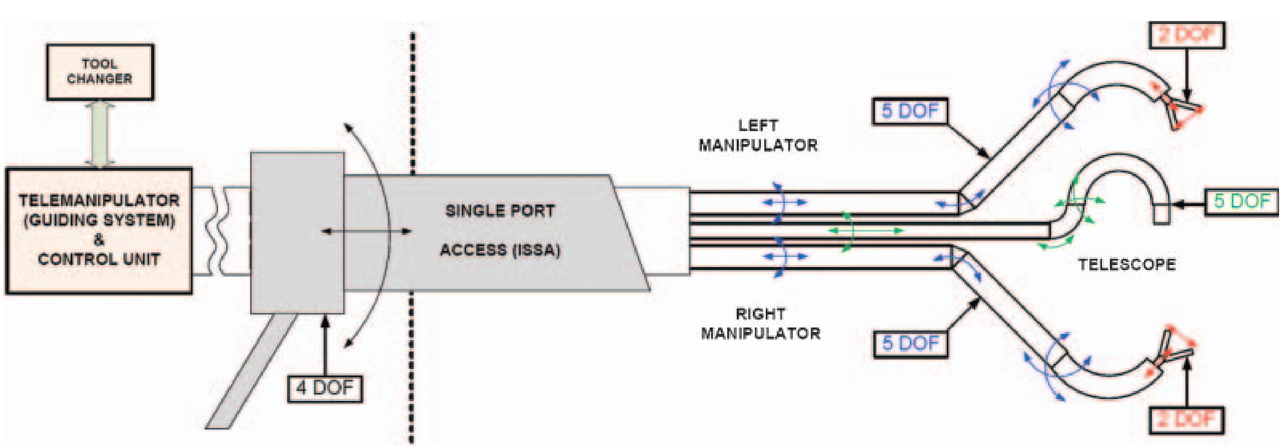

Figure 1. Schematic drawing of the "Highly Versatile Single Port System"

Figure 2. "Endoscopic - Laparoscopic Interdisciplinary Training Entity" (ELITE) trainer for laparoscopic surgery and NOTES

Setup of the surgical intervention and experimental environment

For "manual" NOTES cholecystectomy a flexible standard endoscope (either 13806PKS, Karl-Storz or CF-2T160L/I, Olympus) was introduced via the opening in the rectosigmoid and positioned in the right upper quadrant of the abdomen. The gallbladder and the infundibulum were localized. The use of an additional 2 mm forceps inserted through the navel was allowed to improve the exposition of the operative situs (in particular of the cystic duct).

The cystic duct had to be occluded with three endoscopic clips and to be severed. Then, 20 to 50 ml of 0.9% saline solution was instillated using the endoscopic injection needle into the layer between the gallbladder and the liver. The gallbladder was excised by means of the IT or TT knife (Olympus GmbH, Germany). Transmural forceps had to be used to create sufficient counter-traction. Finally, the gallbladder was pulled out using standard endoscopic grasping forceps.

To perform the identical procedure with the HVSPS, the device was, as demonstrated on Figure 3, likewise, introduced transanally. The manipulators were in straight position during introduction and expanded in the peritoneal space.

The gastroenterologist, controlling the flexible endoscope, observed after introduction the situs and helped guiding the manipulators to face the gallbladder. Two flexible instruments (grasper, scissors or needle knife) were then introduced through the manipulators, which could be exchanged within seconds for different tasks.

Comparable to the real circumstances of a cholecystectomy, the layer between the gallbladder and the liver could be dissected using grasping and cutting instruments. The opposition of the manipulators, as key function of the system, was essential for intuitive working (Figure 4a). The gallbladder could be held with a grasper through the left manipulator and dissected by using a TT knife introduced through the right (Figure 4b).

Results

"Manual" NOTES cholecystectomy

NOTES cholecystectomy can be successfully performed in the ELITE test set within 37 to 75 minutes, depending on the expertise of the endoscopist. Two assistants are needed. One staff member has to care for the flexible instruments, whereas another one supports the intervention with the help of the additional forceps.

The use of the additional transmural instrument is indispensable. Otherwise, sufficient exposition of some "difficult" regions to perform the necessary

Figure 3. First application of the HVSPS for NOTES on the ELITE trainer performing a cholecystectomy using the transanal ISSA approach (abdominal wall removed)

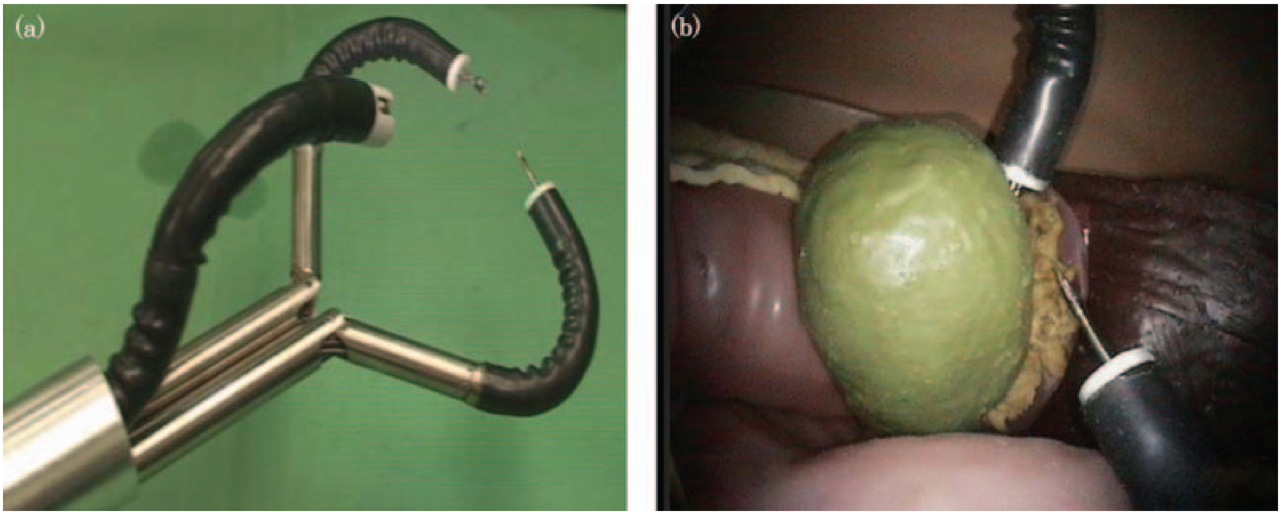

Figure 4. Application of the HVSPS for NOTES cholecystectomy: a) HVSPS manipulators in triangulated configuration with the flexible endoscope R-Scope (Olympus, Japan) b) Grasping of the gallbladder: first application of the scissors in cholecystectomy (ELITE)

operative manipulation even with a two-channel endoscope is impossible.

NOTES cholecystectomy using the HVSPS

The attempts to perform a NOTES cholecystectomy in ELITE using the HVSPS were also successful.

In all cases the complete system had to be operated by a team composed of several physicians and engineers. One person controls the manipulators over two joysticks, a second one controls manually the flexible instruments guided through the manipulators, a further one guides and controls manually the semi-flexible telescope and an engineer operates the remaining manipulators, not motorized degrees of freedom.

As compared with the manual NOTES cholecystectomy, when verbal commands given to the auxilliary staff are sufficient, HVSPS NOTES required a by far more intuitive cooperation between the team members. Even so, the precise positioning of the system of endoscope and manipulators is tedious and time-consuming, leading to a total time of more than three hours.

On the other hand, the possibility to exert traction and counter-traction, and enabling visualization independent of the two manipulators significantly improved the range of manipulations. Using the ''second hand'', the left telemanipulator, makes it possible to move the respective anatomical structure into the ''ideal'' position to apply a very precise and targeted action of the dominant hand (right telemanipulator). In addition, each single surgical maneuver can be observed under the appropriate angle of view, although it takes additional time to coordinate the instruments and the flexible telescope.

Discussion

Multifunctional robotic platforms are currently assumed to be the key to make more advanced NOTES procedures feasible and, perhaps, even suitable for clinical use.

Several research institutes have already developed this type of new instruments with additional intraabdominal flexibility for single port surgery, mainly for laparoscopy, but some of them are also suitable for NOTES (11–16). The Octopus manipulator developed by Swanstrom et al (4) and the Direct Drive Endoscopic System (DDES) form Boston Scientific (6) are two examples proposed so far for NOTES.

However, little is known as to how much these devices really contribute to develop further the technique of NOTES. This may differ between the various designs, but, nevertheless, it is interesting to consider this question in principle.

Since only a few prototypes of these platforms exist worldwide, it was impossible to evaluate all of them in the same simulator, i. e. the ELITE.

Accordingly, we used the so called HVSPS design to simulate NOTES under dry lab conditions. It is admitted that the design differs in several regards from advanced systems such as the Octopus or the DDES, in particular concerning the diameter, the semi-rigid concept and the quality of the man-machine-interface.

However, the main features are similar so that some experience and information gained with this tool may be of general importance.

This first evaluation of a mechatronically supported NOTES procedure as compared to the same ''manual'' NOTES operation in the same simulation environment has demonstrated at least some interesting facts.

The option of triangulation facilitates considerably targeted, highly precise surgical actions such as dissection, clipping, etc. – as soon as both instruments are brought to the desired position.

The quality of surgery is further enhanced by the flexible visualization, making pure NOTES possible as shown in this very preliminary trial.

However, on the other side, procedures are currently very time-consuming due to difficulties controlling various degrees of freedom of the system and the essential coordination of the individual actions of the team members. The current system (and this holds at least partly true also for the other systems) is comparable to a car with different drivers and subdrivers who share the tasks of steering, change of gears, braking, accelerating etc. Under optimal conditions, it would perhaps be possible to drive from one town to another, but, of course, this is completely absurd in the real world.

Likewise, we assume that mechatronic support tools which solve all of the currently still existing barriers to NOTES remain to be closer to vision than to reality. Certainly, the hardware is only one of the challenges. In addition, we need more sophisticated navigation, the development of intelligent and intuitive man-machine-interfaces or workflow organization, just to name a few.

On the other hand, one lesson learned during the introduction of laparoscopic surgery is the fact that some ostensibly crucial technologies (like 3-D visualization) become superfluous with growing dexterity and experience. Whether comparable phenomena will also occur in NOTES as well is unclear. The further development remains to be interesting.

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