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TECHNICAL REPORT

Initial clinical experience using a novel laparoscopy assistant

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Abstract

This article presents the first clinical and experimental experiences of the PMASS (Postural Mechatronic Assistance Solo Surgery) from a prospective study carried on on thirteen laparoscopic procedures. Also, their advantages and disadvantages are identified. The PMASS is a system with three articulations; two articulations are passive and one is active; this handles the optic in real time, reducing the latency time by spatial relocation. The surgeons assisted themselves visually in 13 surgical procedures, having direct and intuitive control in real time of the laparoscopic vision field using the PMASS. The surgical and delay time was documented for each surgery. The surgical procedures were: Laparoscopic appendicectomy, ovarian cystectomy and laparoscopic sterilization. In all procedures, surgeons were able to auto-navigate in real time and there was no visual tremor while using the system. The global average times taken to perform the self-assisted surgery with the PMASS for the laparoscopic appendicectomies were 45 ± 4.5 minutes, ovarian cystectomies 49 ± 3.5 minutes and for the laparoscopic sterilization 22 ± 2 minutes. The approximate set-up time of PMASS was one minute, and removal almost a minute (the time required by the surgeon to remove the harness after completing the surgery). The laparoscope itself disengages from the PMASS in a couple of seconds approximately. There were no transoperative or postoperative complications during the procedures. Thirteen laparoscopic procedures were performed, the design of the mechatronic assistance allowed the surgeon to self-assist visually in real time and in an autonomous way in the *solo-surgery* mode, without compromising the surgical performance and the morbidity. Additionally, the latency times are also reduced by space relocation and coupling of the telescope.

Key words: *Novel surgical assistance, real-time self-assistance, camera holder, solo surgery*

Introduction

The skill of surgeons and technological advances have made such surgery the option of choice in more and more specialties (1,2). On occasion, however, the surgery is significantly altered, not only by the surgeon, but also by the human laparoscopic assistant (3). Optimal or ideal results are modified because the surgeon does not have direct control of the visual feedback and depends on the human laparoscopic assistant to control optimal visualization of the surgical target (4).

A human laparoscopic assistant can help or hinder the work of the surgeon, so communication between the two must be natural and not cause any cooperation conflict in which the visual or motor perception of the human laparoscopic assistant hampers the optimal vision and concentration of the surgeon. In addition, the human laparoscopic assistant is subject to fatigue and sub-optimal use of the field of vision, which, in prolonged procedures, can cause postural conflicts and unnecessary delays, in addition to the delays associated with cleaning and spatial relocation of the telescope (5).

The robotic and passive systems (Fips Endoarm (6), Aesop robot (7), Endofreeze (8), Endoassist (9), Tiska (10), Tonatiuh (11)) allow an advantageous solving of the visual assistance problem during the procedure. But with these systems, due to their electromechanical nature, the performance is not real-time. And this technology has not entered the surgical scene completely, due, among other things, to the

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initial cost, maintenance cost and by the required human infrastructure, usually requiring the presence of biomedical engineers among other factors. In addition, downtime due to manual or voice-activated repositioning of the laparoscope is cumulative and generally not taken into account during the evaluation process. Nevertheless, downtime can be reduced if the laparoscope is handled intuitively and, preferably, in real time.

Material and methods

To manipulate the laparoscope along with the visual perception, we propose an intuitively mechatronic system with three degrees of freedom, the PMASS as an assistant.

The PMASS assistant

The PMASS design was made using the *Mechanical Desktop*® software and the dynamic simulation of their movements was made in the *Visual Nastram*® software. The design started from a previously reported model called PMAT (postural mechatronic training) (12) whose design concept is for dynamic training. The new system called PMASS overcomes some of the limitations observed during the tests and consists of a harness that is placed over the surgeon's shoulders. Two articulations are passive and one is active (Figure 1a). The first degree of freedom is attached to the harness and is active and rotary (1). The second articulation (2) is rotary, but passive; it operates in the same plane as the first articulation. The third articulation (3) is passive and rotary; it operates in the plane perpendicular to that of the first two articulations.

The system was designed to use the entrance port as the fixed and invariant point for exploration and navigation. Laparoscopic navigation requires only six basic movements: Right, left, up, down, in and out. To horizontally pan right or left, the surgeon turns his/her torso right or left. The third articulation (3) and the point of insertion complete this movement (Figure 1b).

To establish the entry angle, which corresponds to the change in optical orientation above and below the laparoscope, the system uses the first articulation, which is active and rotary, together with the second articulation, which is passive. This mechanism has an almost linear displacement, so there is no visual loss when moving in or out from tissues and organs during the procedure as shown in Figure 1c. The surgeon activates this articulation by means of two proximal switches (Figure 1d).

Test

The prototype was evaluated using chicken pieces and was tested by two groups, the first consisting of three expert surgeons, and the second of three residents in the last year of the specialty who performed dissection, suturing and cutting. Maneuvers to change the optical perspective and to explore the surrounding areas were also performed. As a 0° laparoscope, a 480-line resolution mini-camera was used. Surgeons used postural movements and visual feedback to achieve the required positions while keeping both hands free to perform their procedures (Figure 2a and b).

In those pre-clinical trials, residents took approximately seven minutes, slightly more than the experts, in order to get adapted and establish the proper hand-eye coordination.

The following stage was carried out in an animal model: Three ovariectomies were performed on mongrel bitches with an average weight of 40 kg (Figure 3a). All surgeries were performed using 0° optics. Trials were also made on pigs using a 30° optics (Figure 3b), where it was evaluated and confirmed that the PMASS uses the point of insertion as the invariant point for navigation and has a workspace that closely resembles an inverted cone.

The PMASS can be sterilized and was manufactured from medical-grade stainless steel, with a weight of 0.5 kg. The telescope is attached to the distal portion of the PMASS by means of a device that allows for rotation and quick manual removal of the laparoscope. The device is made of Teflon. The new mechatronic system was developed at the Department of Electrical Engineering of the Center for Research and Advanced Studies (CINVESTAV) of the National Polytechnic Institute (IPN) in Mexico.

Clinical application

The study included a total of 13 patients, whose clinical cases were carefully evaluated by three expert surgeons appointed by the head of the surgery department, establishing the following exclusion criteria: The patient's risk, the patient not having previous surgeries to avoid complications of adhesions and that there was no presence of one or more additional pathologies to the primary illness, or any other condition that could affect the surgical outcome. Moreover, according to the Helsinki Treaty, relatives were informed and gave their written consent. The procedures – five appendicectomies, four ovarian cystectomies and four laparoscopic sterilizations – were performed by three experienced surgeons. Prior to each surgery, the PMASS was sterilized by placing its

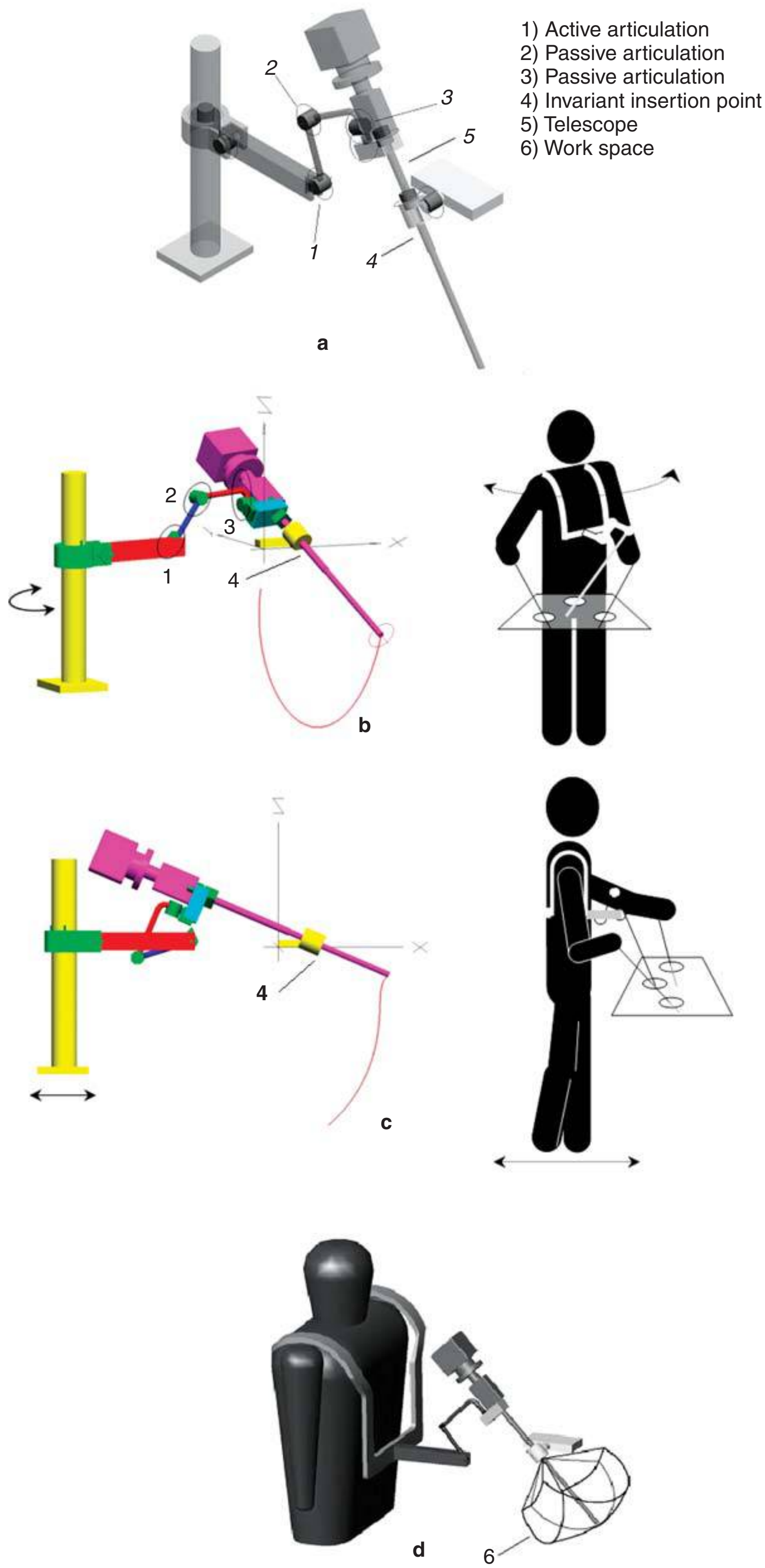

Figure 1. PMASS: (a) Concept design of the mechatronic assistant. (b) Model of the system for right–left perspective change. (c) Model of the system for above–below perspective change. (d) Work space of the mechatronic system using *Visual Nastram 4D®* and *Mechanical Desktop®* software. The point of entry is invariant throughout the entire navigation.

Figure 2. (a) From the design concept to the physical model, (b) hand – eye adaptation in training boxes suturing chicken pieces.

passive degrees of freedom in solution for 20 minutes, and its electrical components in a sterilization chamber.

During surgery, 0° and 30° optics were used, according to the procedure demands, and a human laparoscopic assistant was present in the operating room at all times during all of the surgeries to assist in the event of any contingency.

Results

The mechatronic system was fitted onto the surgeons in an average time of two and half minutes, in three steps.

Step 1: The harness is fitted and adjusted to the surgeon's body.

Step 2: The motor which drives the active articulation is placed on the harness.

Step 3: The laparoscope is attached to the assistant mechatronic.

A total of 13 self-assisted visual surgeries were performed with the mechatronic assistance. Total surgery duration was taken to be the time elapsed between placement of the mechatronic system and the end of the surgery, of which the average global time to carry out appendicectomy using the PMASS was 45 ± 4.5 minutes. Time for the ovarian cystectomy was 49 ± 4 minutes and time for the laparoscopic sterilization was 22 ± 2 minutes, respectively (Figure 4).

The average times include the following stages:

- A 59 second set-up time (the time required to install and configure the PMASS and locate the surgical target, with the ports in place),
- cleaning for approximately one minute per event (the sum of the times required to retract, clean and insert the telescope, and locate the surgical target),
- removal, almost a minute (the time required by the surgeon to remove the harness after completing the surgery) (Figure 5); the laparoscope

Figure 3. (a) Laparoscopic ovariohysterectomy solo surgery in a dog and (b) solo surgery on pork.

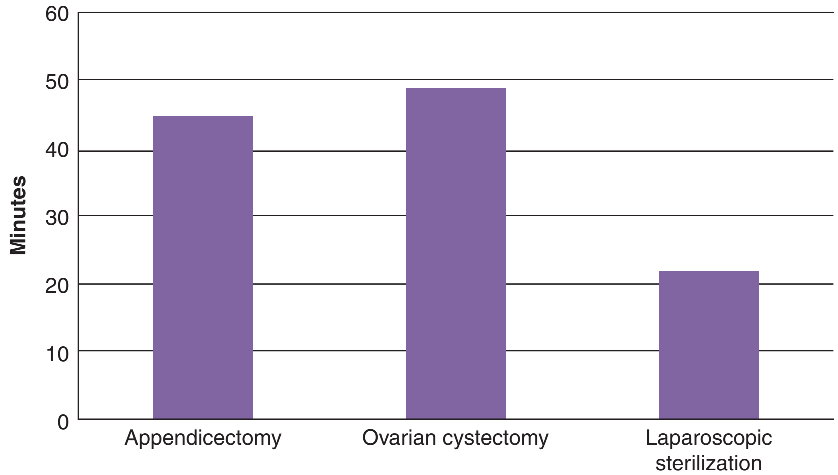

Figure 4. Average duration of the surgeries.

itself disengages from the PMASS in a couple of seconds.

At the end of the surgeries and with the aid of a questionnaire, each surgeon gave a grade to the PMASS in which the highest grade was 5; the evaluation points were the following: Autonomy, comfort and optics control (Figure 6). The three surgeons reported that the PMASS was comfortable, with no autonomy loss and a good overall performance. They also reported that, initially, they felt tethered to the patient, restricted in their movements and short of range to reach the objective, but that approximately five minutes into the surgery they had adapted naturally to the system. Additionally, they reported feeling shoulder and neck fatigue after using it consecutively for a period of more than one and a half hour, but with the advantage that the system maintains its performance regardless of whether the surgeon is standing or sitting, i.e. the surgeon's posture does not affect visual perception.

During surgery the visual selection of 0° and 30° is performed manually. The cleaning of the lens was required, on average, on two occasions. In order to do this cleaning, the surgeon steps back from the patient, cleans the laparoscope, and inserts it again, maintaining the last visual configuration mechanically, without the need to configure PMASS again. The average time required for cleaning and repositioning was one minute, which is less than the time required by the human assistant (4,5), and much less than that required by the Aesop robot, Endofreeze, Endoassist, Tiska, Tonatiuh (6,7,8,9,10). During the execution of the proceedings, there was no need to disengage the telescope, just in the beginning and at the end in order to explore the surrounding anatomy.

During the proceedings, it was observed that the image on the monitor did not show tremor during the

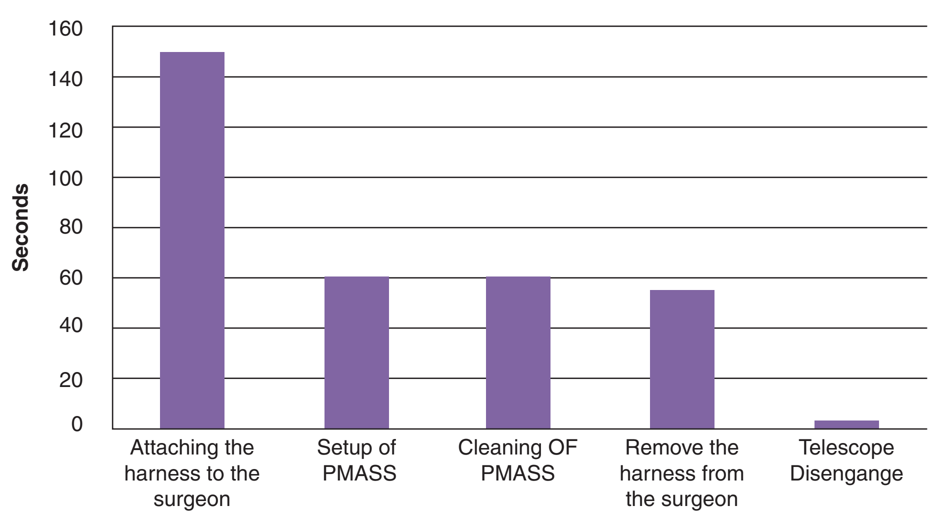

Figure 5. Times of the mechatronic assistant.

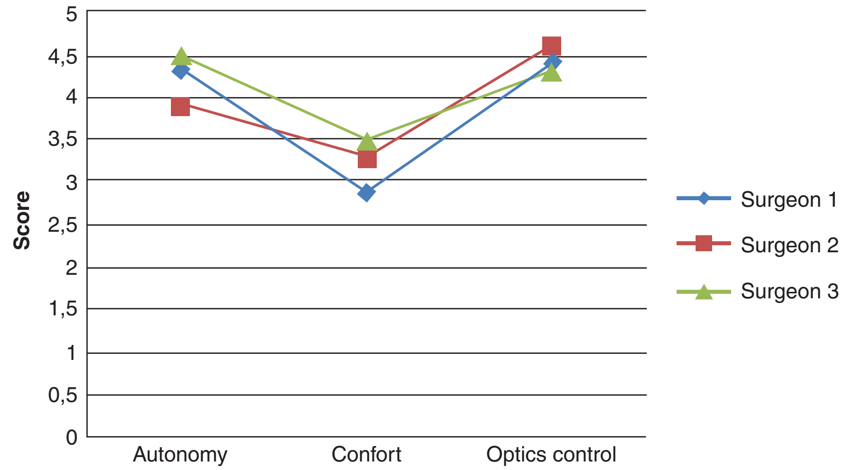

Figure 6. Performance evaluation of the mechatronic assistant.

movements carried out by the surgeon in an intuitive manner and in real time. Also, the PMASS does not affect the distribution of surgical equipment in the operating room. Figure 7 shows the arrangement of the PMAT in the surgical scenario. Additionally there were no significant perioperative or postoperative complications, such as blood loss, morbidity or delayed recovery.

After the initial clinical experience of this surgical study and additionally after the dynamic tests of the PMAT in the visual software Nastram®, test in training boxes and applications in animal models, the following features of the mechatronic system were determined:

Advantages

- Hands-free auto-navigation system which handles optics in real time with reduced latency by cleaning and repositioning of optics keeping the last established configuration.
- Sterilizable modular mechatronic system, of low weight and fast installation.
- Minimum adaptation time to establish hand-eye coordination with the system (approximately five minutes).
- System allows a quick disconnection of the laparoscope in order to explore the surrounding anatomy.

Figure 7. Configuration and arrangement of the PMASS in the surgical scenario.

- Low cost (tentative cost 1000 USD)

Disadvantages

- The present design is recommended for small surgical targets where the surgeon alignment with the telescope, surgical target and monitor is maintained in a straight line. Additionally, it requires that the optics is placed between the two working instruments and does not allow side visualization. (e.g. when the optics is placed into the umbilicus and the two working instruments on the right side of the patient.)
- Its continous use at an hour and a half and beyond generates tiring at the shoulder and neck levels.
- It requires training.

Discussion

The use of new technology in surgery enables surgeons to operate solo in some procedures. The advantages are adequate work space on the operating table and maneuverability. However, although active and passive systems offer these advantages, the time required to relocate or reaccommodate optics and clean the laparoscope between operations has not been reduced. In addition, there is a perceptual difference between what the surgeon wishes to see and the proximity he/she achieves with the active or passive system via the robot. There will always be the feeling that there exists a greater visual perspective to perform the procedure. The new mechatronic system shows that it is possible to have solo surgery in which the surgeon auto-manipulates the laparoscope to obtain the best optical perspective and has both hands free to perform the procedure.

One of the maneuvers that causes most delay during surgery is cleaning the laparoscope when it is soiled or steamed up. Such delays, which are cumulative, are greater for robotic systems than for human assistants, given the set of verbal orders that must be given to the robot and the time required to mechanically couple and uncouple the laparoscope. The new design reduces the latency time of space relocation and coupling of the telescope during the cleaning time.

This assistant facilitates work on the operating table, as do active and passive assistants. Still pending, the implementation of the PMASS in a pilot clinical study aimed at more common pathologies present in our country. This study will, without a doubt, help characterize in an objective and trustful manner its application regarding other assistants. Moreover, another study focused on the cost-benefit of the PMASS application comparing it with the existing technologies is still pending as well.

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