Review Article

Novel, hand-held, agile surgical operating systems

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Abstract: Over the past decade, there has been a surge in the development of mechanical and robotized laparoscopic instruments to improve the surgeon's dexterity, precision and ergonomics in a cost-effective manner, as an alternative to the expensive "master-slave" surgical robotic systems currently on the market. Due to the overhead costs, robotic minimally invasive procedures have nil advantage to patients or hospitals when compared to laparoscopic procedures when looking into the cost-effectiveness profile. In addition, to date robotic surgery has statistically not been proven to be superior to conventional laparoscopy for a majority of surgeries. Robotic surgery however continues to grow with increased demand from both patients and surgeons, despite high initial and recurrent costs. As competition expands those costs will inevitably decrease but investing in hand-held robotized laparoscopic devices enabling safe performance of advanced minimally invasive procedures at a much more sustainable cost can enable scaling this technology, especially as every laparoscopic surgeon can easily use those with rapid additional training only to achieve a specific surgical approach. Multiple reports including potential instruments providing those solutions required have been written, however, surprisingly not all of those featured instruments are available today. In this article we review the current status of smart tools for laparoscopic procedures, highlighting new market entries with a potential to change the landscape of minimally invasive surgery.

Keywords: Robotics; minimal invasive surgery; enhanced articulation; hand-held

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Conventional laparoscopic instruments are not ergonomic and are restricted to 4 degrees of freedom (compared to 36 in open surgery). This results in severe limitations in performing simple, let alone complex tasks in surgery, holding many surgeons back from engaging in a variety of minimally invasive manoeuvres and procedures. Until recently there were only two categories of laparoscopic instruments: conventional straight manual instruments and a large, console-based, robotic system. Those surgical robotic systems offer increased dexterity, articulation and 3D vision, but at substantial financial costs and logistic complexity, as has been summarized by Perez and Schwaitzberg last year (1).

Even though in a recent study (2) a robotized device did not show superiority compared to conventional laparoscopic instruments in a non-clinical setting, the development of non-robotic and therefore low-cost laparoscopic instruments that enable better dexterity has recently taken off. Anderson *et al.* reviewed a multitude of mechanical articulating hand-held laparoscopic devices (3). Current articulated mechanical surgical instruments exhibit a wide range of user interfaces, wrist mechanisms and capacities, however, there currently is no clear consensus on what makes an articulated mechanical instrument easy to use. Some articulated mechanical instruments have reached the commercial market and others are under development. As articulated mechanical surgical instruments mature, they have the potential to impact the minimally invasive surgery market by providing some of the capabilities currently only found in robotic systems at a lower cost.

Outside the scope of that review are dexterous

Table 1 Summary of mechanical and robotized hand-held laparoscopic devices

Device	Type	Instrument	DOF	Market availability
FlexDex® (FlexDex Inc., Brighton, MI, USA)	Mechanical	Needleholder	6	Worldwide
SILS® Hand (Medtronic, Minneapolis, MN, USA)	Mechanical	Interchangeable	7	Worldwide
r2 CURVE (Tuebingen Scientific Medical GmbH, Tübingen, Germany)	Mechanical	Interchangeable	7	Available, mostly Europe
r2 DRIVE (Tuebingen Scientific Medical GmbH, Tübingen, Germany)	Mechanical	Interchangeable	7	Available, mostly Europe
JAiMY® (Endocontrol, Grenoble, France)	Robotized	Multifunctional	6	Available, mostly Europe
DEX™ Robot (Dexterite Surgical, Annecy, France)	Robotized	Interchangeable	7	Available, mostly Europe
HandX™ (Human Xtensions, Netanya, Israel)	Robotized	Interchangeable	7	Available, mostly Europe
Autonomy LaparoAngle® (Cambridge Endoscopic Devices, Framingham, MA, USA)	Mechanical	Needleholder	7	Not available
Realhand® (Novare Surgical System, Cupertino, CA, USA)	Mechanical	Interchangeable	7	Not available
Kymerax® (Terumo Europe NV, Leuven, Belgium)	Robotized	Interchangeable	5	Not available

DOF, degrees of freedom.

instruments that are partially motorized. A number of hand-held, partially motorized/robotized devices for laparoscopic surgery have been developed, providing additional flexibility in transmitting movement from the user interface to the instrument wrist. These devices however require motors and software, placing them at some cost disadvantage compared to fully mechanical instruments. In *Table 1*, a summary of all available mechanical and robotized laparoscopic instruments can be found. In this short review we will focus on the robotized instruments, as there are the JAiMY®, the DEX™ Robot and the HandX™, in addition to the most widely available mechanical instrument, the FlexDex®.

The FlexDex® is based on a simple and mechanical design, translating the movements of the forearm, wrist and fingers to the tip of the instrument without electrical components (3,4). It provides articulated control and successfully enables suturing in limited spaces. The tool frame is attached as a forearm brace, thus changing instruments may be challenging and time consuming (5-7). In addition, it is compatible with an 8-mm trocar only. Although mechanical, since it is a single use device the cost profile is not low, and currently only a needle holder is available.

The JAiMY® has a one-finger control of motorized movements and an ergonomic handle for improved surgical posture, evaluated and proven to be significantly better by Bensignor *et al.* (8). It is a 5-mm fully articulated reusable instrument, with an unlimited jaw rotation and precise speed control, providing an advantage under ergonomically difficult conditions (9). The device is designed for the purpose of grasping, retracting, mobilizing, dissecting, and suturing of tissues and vessels and is connected by a cable to a control box.

The DEX™ Robot is a robotized instrument with a grip-type handle, working independently from the shaft, has a complete range of reusable tools and is compatible with any electrosurgical unit. An 8-mm trocar is required. In a small study its use revealed similar results when compared to a conventional instrument for the surgical performance and outcome of an urethrovesical anastomosis. It was therefore concluded that a surgeon's autonomy, dexterity in driving the needle and workload could be improved but with a comprehensive training with the new device. Surgeons did acquire a better body posture using the novel robotic needle holder (10) as were better ergonomics for the surgeon's hand posture observed (11).

In New Horizons in Laparoscopic Surgery (2018), a chapter was dedicated to handheld devices (12). Of all the devices that were described to be still in the prototype phase, only the HandX™ by Human Xtensions from Israel, has been officially launched since. The device received FDA clearance and CE mark. The smart, robotized surgical system integrates all the components required for a modular

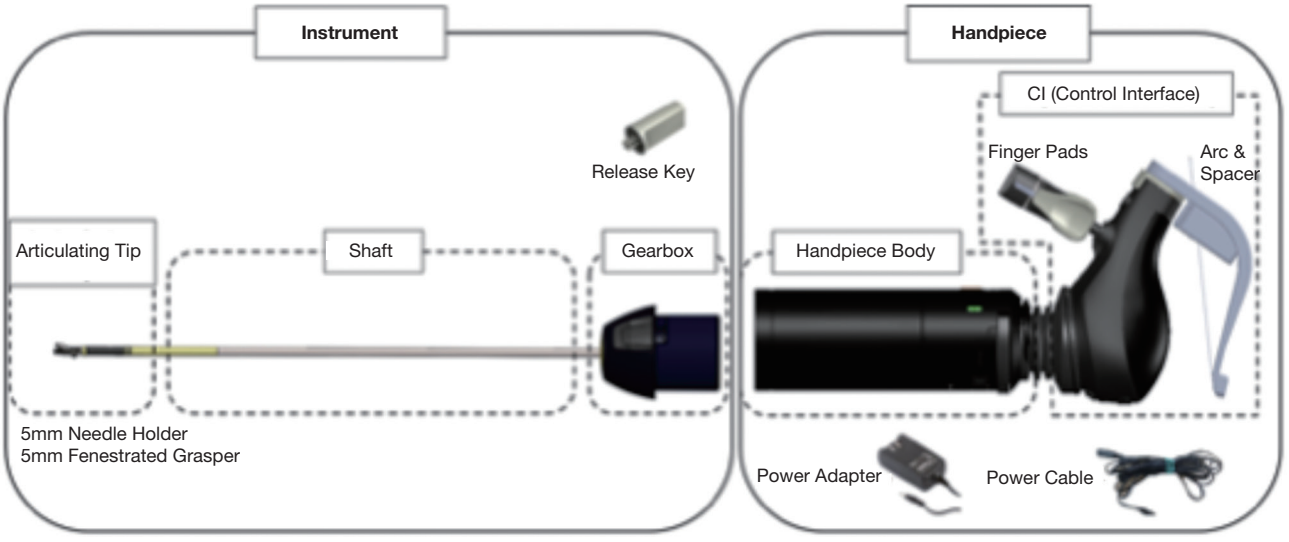

Figure 1 HandX^{TM} device and its component.

platform, of which HandX is the first launched and FDA cleared. It is currently distributed in Europe by Aesculap AG, a subsidiary of B. Braun.

HandX^{TM} (*Figure 1*) is designed as a light-weight, hand-held device that translates natural unrestricted hand motions into complex movements inside the patient during laparoscopy. The instrument is composed of a sophisticated user interface and a novel, motor driven articulating tool that is controlled by the interface. These components are reusable. The shaft and instrument at the tip are single-patient use and currently a needle holder and grasper are available, although most laparoscopic instruments will be launched soon. The system doesn't require any set up time, and can be easily moved between commercially available laparoscopic 5-mm trocars. Since it was clinically launched over 200 procedures have been performed with the use of this novel device, in multiple countries in Europe as well as in the United States and Israel. The operations included upper gastrointestinal (GI) procedures (sleeve gastrectomies, paraesophageal hernia repairs, gastric bypasses), inguinal and ventral hernia repairs, cholecystectomies, hysterectomies, colectomies, solid organ procedures, thoracic procedures and prostatectomy for benign and malignant disease. The device enabled complex motions and tissue manipulation as well as suturing in difficult angles and in narrow, hard to access spaces. Several clinical trials are now underway to study the use of the device in different settings, and the cost-effectiveness profile of its use.

In conclusion, there are ongoing, interesting and promising developments of smart devices in the area of minimal invasive surgery as an alternative to the currently available robotic systems that are very complicated and costly. In addition, telemanipulated surgical systems lack haptic feedback during the surgical performance, which hand-held devices do provide. Finally, most new motorized instruments are reusable, and the cost-profile of this robot-like dexterity is therefore low. Considering the fact that many of those devices are still in early stages of development, the future for the use of those innovative solutions looks bright.

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Footnote

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