

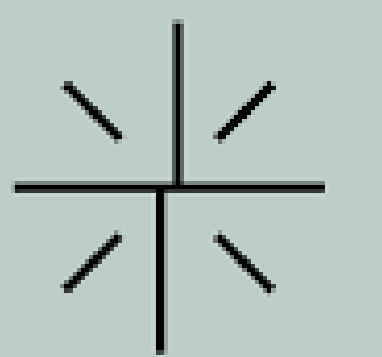


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OBJECTIVE OF THE NEW TECHNOLOGY

The HandX™ technology was designed to improve the ergonomics of laparoscopic surgery, providing a technology that has the functionality of existing robotic platforms more cost-effectively. Additionally, the surgeon's dexterity and precision are boosted by the option to customize the device to the type of procedure and the surgeon's skill level by reducing degrees of freedom or speed if necessary. This could come in hand to shorten the learning curve and make the users more comfortable with this instrumentation.

DESCRIPTION OF THE TECHNOLOGY

HandX™ is a powered laparoscopic, lightweight, hand-held device composed of a sophisticated user interface, a single-use 5 mm interchangeable shaft and a novel, motor-driven articulating tool controlled by the computerized interface. This modular platform could be used by the operating surgeon beside the patient's bed, and, as the manual interface is handled by the surgeon, the movements of the surgeon's fingers are translated to the instrument's fully articulating tip. This technology enables unrestricted hand movements that are translated to the articulating tip of the device resulting in complex movements with 7 degrees of freedom. The system is only connected to a power cord, doesn't require any set-up time, and can be easily moved between regular 5 mm laparoscopic trocars. To date, the complete set of instrumentation consists of a grasper, needle holder, monopolar hook and spatula that allow using this technology for tissue manipulation, suturing and dissection. The HandX technology has been applied to perform several abdominal procedures. This report is to show the feasibility and safety of the combination of this technology with Transanal Endoscopic Microsurgery (TEM).

PRELIMINARY RESULTS

The index case was a 65-year-old female with rectal cancer located in the lower rectum, 2.5 cm from the anal verge.

The patient underwent neoadjuvant radio chemotherapy before surgery and showed a good response. The traditional TEM instrumentation was used.

Dissection was carried out with the HandX™ monopolar hook in order to obtain a full-thickness excision extended to the mesorectal fat of the residual rectal lesion.

The articulating needle holder was used to close the rectal defect with a running suture.

The operative time was 45 minutes, and no blood loss nor intraoperative complications were observed. The patient was discharged the day after the operation. Post-operative histology showed a residual pT1 Sm1 tumour.

CONCLUSIONS

This report demonstrates the feasibility and safety of the new HandX™ platform applied to transanal surgery. TEM is, by nature, a demanding technique with a steep learning curve, and this, among other aspects, has limited its spread. The HandX™ technology can be safely adopted to obtain fine dissection. The higher manoeuvrability and dexterity made this technology exploitable even in the restricted space of the TEM rectoscope. The future of this technology will be the introduction of new means of synthesis together with new tools to enhance the surgeon's performance and democratize the procedure.

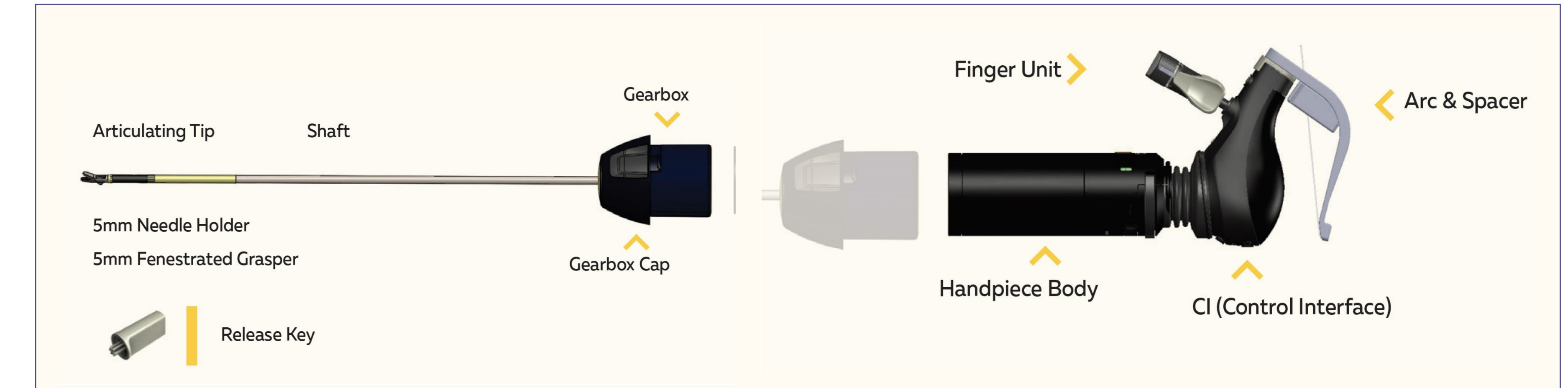


Figure 1. Structural parts composing the HandX™ instrumentation



Figure 2. Operative setting

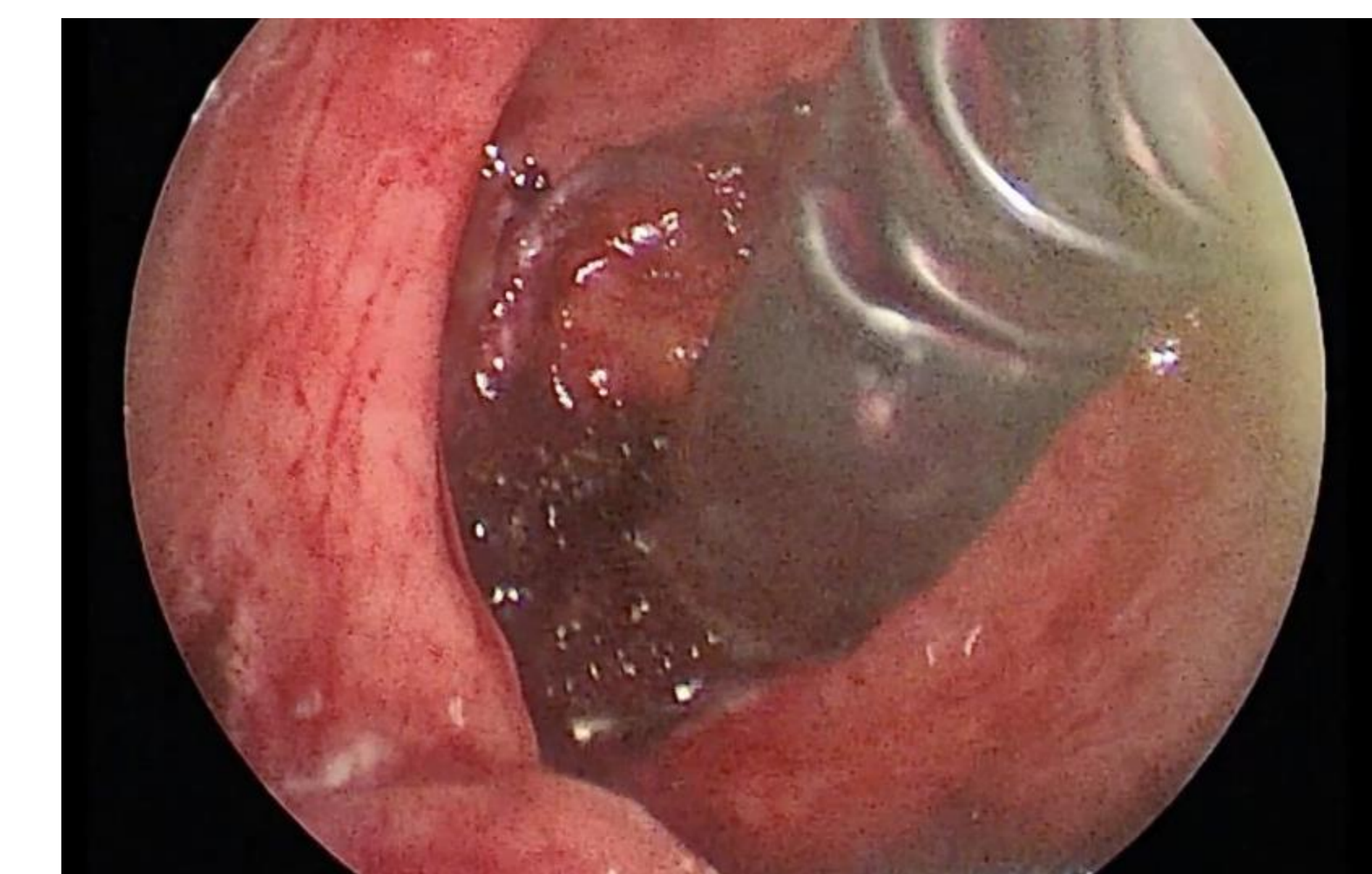


Figure 3. View of the operative field (dissection phase)