

LapMan®-Lapstick® multi-centre clinical evaluation : 88 laparoscopic procedures in Belgian university and private hospitals B.G.E.S. Belgian Group for Endoscopic Surgery (www.bges.org)

Participating centres

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Background and aim

The LapMan® dynamic laparoscope manipulator (MEDSYS, www.medsys.be) has been validated for several years (1)(2)(3)(4) both in Europe (CE) and USA (FDA approved).

A new innovative sterile RF wireless interface - LapStick® - positioned on the shaft of the laparoscopic instrument has been developed to enable the surgeon to manage his laparoscope.

The poster describes the outcome of the first multi-centre study with 9 leading Belgian surgical teams (university and non-university) on the use of the LapMan® dynamic laparoscope manipulator in 88 straightforward laparoscopic cases (cholecystectomy, Nissen fundoplication, inguinal hernia, gastric banding,...).

Methods

A protocol of 22 questions was submitted to all participants and filled in at the end of each procedure. Questions were related to the type of procedure, the set-up, the ease of use and the surgical benefits to the surgeon : stability of image, coordination of hand-eye movements, scope cleaning, ergonomics of Lapstick® interface.

Results

- 88 procedures were performed : 42 cholecystectomies, 15 inguinal hernias, 10 Nissen funduplications, 12 gastric bandings, 9 other including : gastric bypass, sigmoidectomy, appendectomy and rectum suspension.
- No clinical adverse event was reported, nor any conversion due to LapMan®.
- Set-up : 5,3 (2-20) procedures requested to be autonomous, set-up time 4,4 (2-10) minutes after 5 procedures, 2,8 (2-5) human hands in operating field, positioning of LapMan® was easy (95%), trocar positioning was not modified (98%).
- Fixation and release of laparoscope was easy (99%), except initially for Visera® video laparoscope (Olympus), but a dedicated scope holder was developed and solved the problem.
- Use of LapStick® : In/Out and Left/Right movements were considered 'easy' (95%), Up/Down requested learning curve (30%). During the trial, the programming of the LapStick® was adapted to allow all oblique movements on the joystick to be reported as Up/Down, which significantly reduced the learning curve.
- Clinical outcome: the stability of image was improved, scope cleaning was decreased (mean 1,1 per procedure), the number of scope movements was user and procedure dependant. Operating time was not significantly increased after learning curve.

Conclusion

- The LapMan® is a safe and valuable system to assist the experienced laparoscopic surgeon in his daily surgical practice.
- The system should be used first in straightforward cases; it can however be used in more advanced cases once the learning curve has been gone through.
- The system provides a stable third hand to the surgeon, which is useful in a clinical environment with less human assistance, and even allows solo-surgery when a passive holder for liver retraction is used simultaneously.
- The system improves the visual exposure of the operating field by providing a stable image.
- Combining instrument and vision control reduces the frequency of scope cleaning and does not increase operating time.

References

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