Characterisation and mitigation of gas leaks at laparoscopy — an international prospective, multicentre clinical trial.

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Introduction

Gas leaks are common in laparoscopy and pollute the surgical airspace despite positive pressure room ventilation. Such aerosolization precipitated a global moratorium on minimal access surgery early in the COVID-19 pandemic and continues to generate local environmental concern and discord regarding surgical plume and biological effluvium. Studies defining methods for sensitive leak characterisation and mechanical mitigation in real world settings are lacking.

Methods

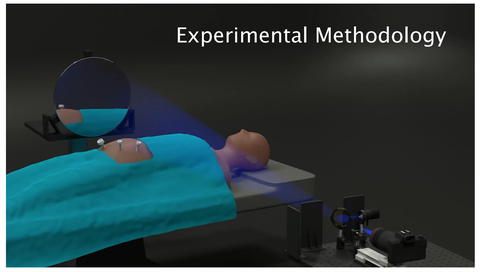
To define gas leaks at laparoscopy, mobile optical gas imaging methodology was developed (both a compact Schlieren system and a tripod-mounted near-infrared carbon dioxide imager (GF343, FLIR)) and deployed in a prospective clinical series of planned laparoscopic interventions at two university hospitals in France and Ireland. Velocity estimation via optical flow (validated with Particle Image Velocimetry) was applied to any recorded spontaneous or instrument exchange related leak using a boutique Matlab-based analyser (now open sourced on GitHub https://github.com/nolankucd/PORSAViz) enabling four-way categorisation (Type 0- No observable leak; Type 1- Marginally detectable leak; Type 2- Short lived plume; Type 3- Energetic, turbulent jet). Concurrently, the usefulness of a novel vacuum-ring device (LeakTrap, Palliare, Ireland) designed as a universal adjunct for standard laparoscopic ports at both abdominal wall and port valve level was determined similarly in a phase I/11 clinical trial along with the device's useability through procedural observation and surgeon questionnaire.

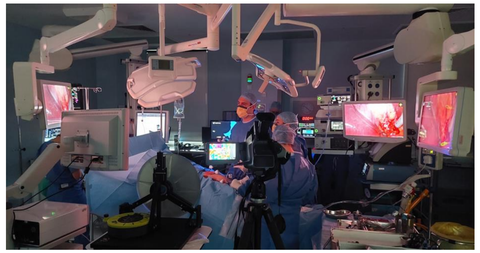
Results

Following ethical and regulatory approval in both countries, 40 patients undergoing planned laparoscopic cholecystectomy (n=36) and hernia repair (n=4) were studied comprising both control (n=20) and device intervention (n=12) cohorts. Patient demographics and operative parameters were typical for such procedures and similar in both groups. Optical gas imaging was successfully performed across all procedures with minimal impact on procedural flow generating 4.7TB of video data. Gas leaks were commonly visualised at all laparoscopic ports, most notably upon instrumentation with significant abrogation in those in the device intervention group. In total, 1244 instrument exchanges were examined, 663 in the control group and 581 in the intervention group with a mean (range) of 44.2 (9-102) and 38.7 (11-101) per procedure respectively. Type 0 leaks were observed in 14.6% (97/663) of instrument exchanges in control patients versus 62.8% (365/581) in interventional group patients ($p<0.05$). Type 3 leaks were observed in 52.3% (347/663) of instrument exchanges in control group patients versus 6.0% (35/581) in the interventional group

Conclusion

Optical methods used to sensitively detect laparoscopic gas leaks demonstrate their effective broad mitigation using straightforward available-now technology with most impact on the commonest, highest energy instrument exchange leaks.



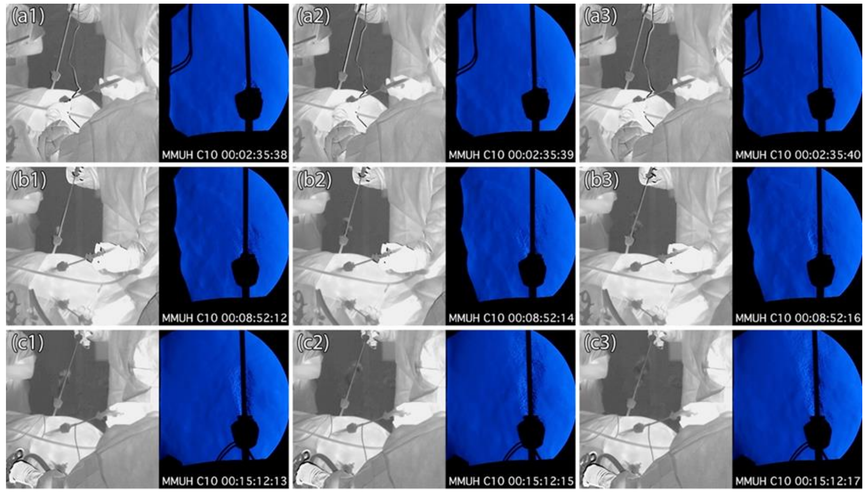


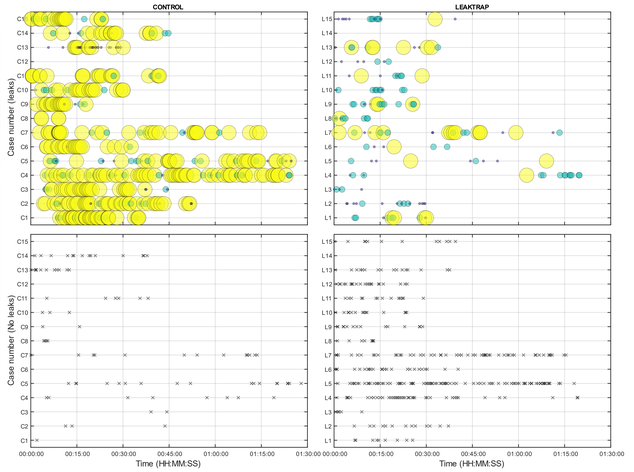


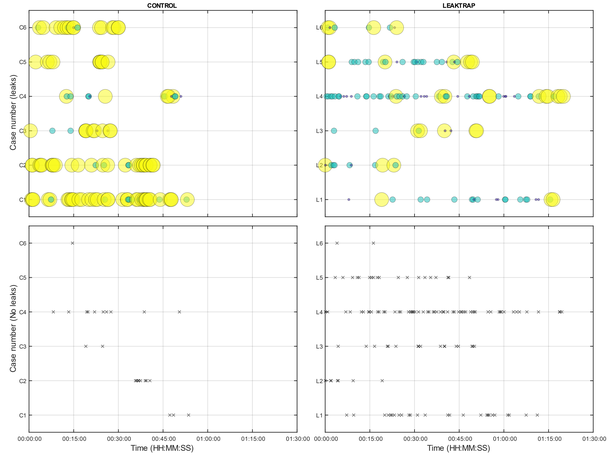
(Above) The Leaktrap™ device being used in an interventional group patient and surgery. Note the two rings applied to each trocar with tubing attached to a vacuum device placed outside the sterile field.

(Left) Operating room set-up showing both the imaging devices being used simultaneously during surgery to record gas leaks occurring at the surgical trocars especially with instrumentation.

(Below) Examples of the three types of leaks for infrared (left) and Schlieren (right) images for the purpose of this study. Evolution of (a1-a3) type 1 marginally detectable leak, (b1-b3) type 2 small leak and (c1-c3) type 3 energetic, turbulent jet.







(Above) Matrix plot indicating the severity of the leaks observed in both the (top) Irish and (bottom) French subgroups of the study. each row of markers shows the timeline of a surgical case. The marker indicates the classification with × indicating class 0 (no leak) and small medium and large circles indicating class 1 to 3 respectively. For clarity the class 0 data is plotted separately. The plots in the left row correspond to control cases while plots in the right row correspond to intervention cases that employed the LeakTrap™ device.