

Technological assessment of laparoscopic monopolar electrosurgery instruments at CSSS du Lac-des-Deux-Montagnes

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INTRODUCTION

- *Thermal injuries observed during two recent interventions at the CSSS LDDM's surgical unit*
- *Long term shift to Single Use Devices could be costly to CSSS LDDM*
- *This study aims to identify the cause of the incidents reported at the operating rooms at CSSS LDDM and*
- *To issue recommendations regarding the purchase of new reusable electro-surgical laparoscopic instruments*
- *Results and recommendations acceptable by medical doctors*
- *Sharing of this experience with peers*

MATERIALS AND METHODS

- **Scope of the assessment**

- *Duration: 2 months during which single use devices are purchased*
- *Laparoscope assessment was limited to 8 electro-surgical hooks and 2 spatulas*

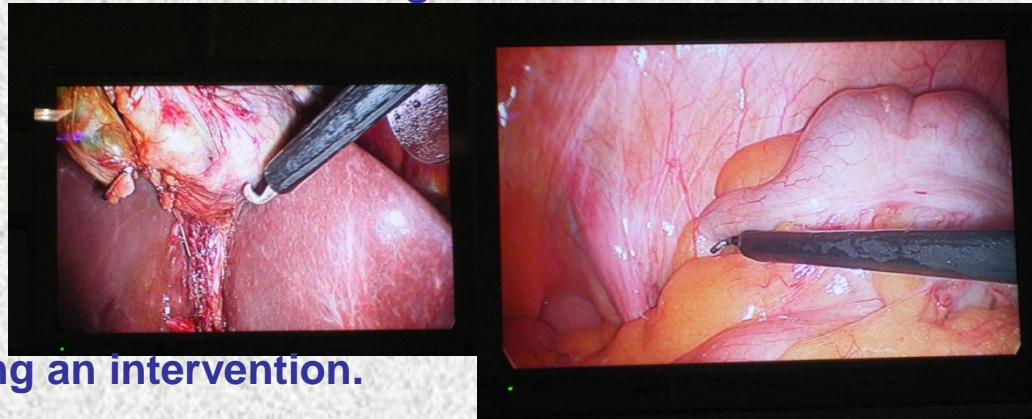
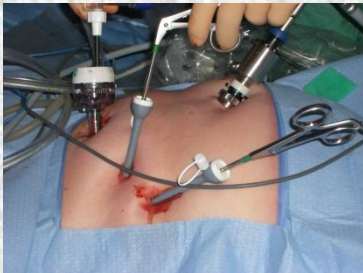


- **Factors analyzed to determine the specific problem causing the reported thermal injuries**

- **Instrument handling and wear**
- **Electrode insulation testing**
- **Isolative sheathing thickness measurement**
- ***Current CSSS LDDM sterilization parameters vs. surgical hooks/spatulas' manufacturer instructions***

Instrument handling and wear

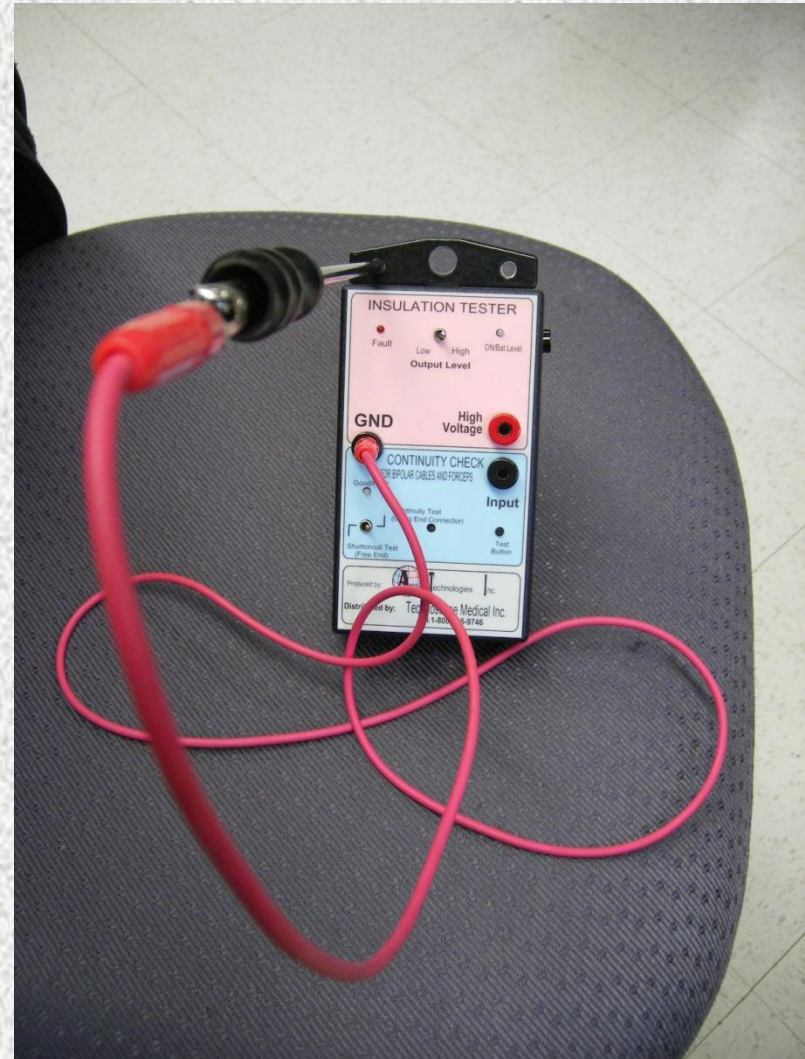
- Two members of the biomedical engineering department witnessed a laparoscopic cholecystectomy to observe the normal usage of the instruments.
- Observations focused on contact between internal organs and instruments during cauterization (local zoom)



- Normal wear of instruments during an intervention.
- Friction of the laparoscope during its insertion into the trocar is also observed for resulting in potential mechanical damage.
- The number of procedures done with each instrument is unknown (no traceability system for surgical instruments)
 - *This information could have helped to determine if normal insulation wear led to the reported incidents.*

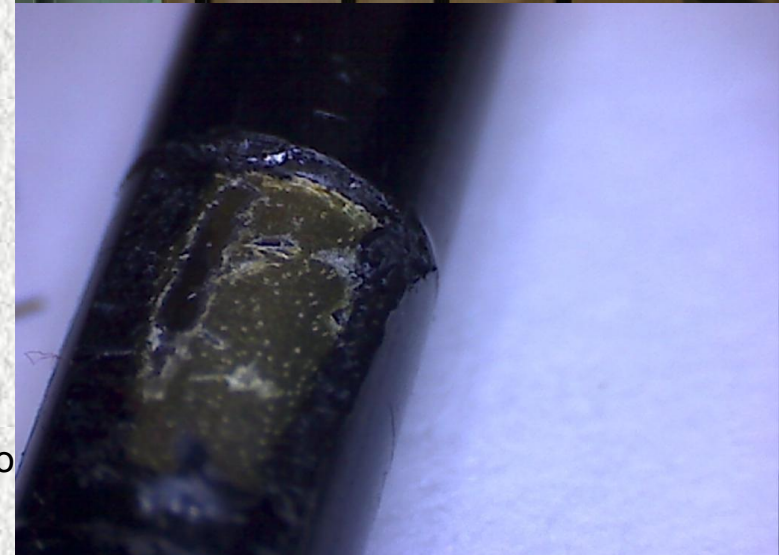
Electrode insulation testing

- Insulation layer was tested with an insulation tester (Atlas Technology Inc., ATI-013)
 - *A beep indicates a leakage if any*
- Only four (4) models of instruments tested for isolative sheathing thickness measurement
 - *3 surgical hooks*
 - *1 spatula*



Isolative sheathing thickness measurement

- Among the ten reusable instruments, four models of laparoscopes (3 hooks and 1 spatula)
- A section of the insulation material was removed on a limited mid-to-distal portion of the diameter of the laparoscope
 - *representing the area outside the field of view and outside the trocar*
 - *possibly in contact with surrounding organs*
- Insulation thickness was defined as the difference, measured by a caliper, between the unaltered instrument and the section missing a portion of insulation material



Current sterilization parameters vs. manufacturer instructions

Steam Sterilization	Ethylene Oxide Sterilization	Enzymatic Solution	Pasteurization
<ul style="list-style-type: none"> ▪ Equipment : Amsco Evolution ▪ Available Cycles ▪ Vacuum ▪ Gravity ▪ Liquid ▪ SFPP ▪ Rapid SFPP ▪ 121 à 135°C ▪ Cycle Validated à 132°C, 5 min 	<ul style="list-style-type: none"> ▪ Equipment : 3M Steri-Vac / 5XL aerator ▪ Hot Cycle ▪ 55°C ▪ 1 h exposition ▪ 10 h aeration ▪ Cold Cycle ▪ 37°C ▪ 3 h exposition ▪ 20 h aeration ▪ 35 à 80% relative humidity ▪ OE 100% Cartridge 	<ul style="list-style-type: none"> ▪ Neutral Ph Detergent 	<ul style="list-style-type: none"> ▪ Equipment : Olympic PMC 85-3 ▪ Thermal Disinfection ▪ 74°C ▪ 30 min exposition

132 to 135°C during 3 to 4 min

RESULTS

- Visual inspections of laparoscopes have revealed that the **material used for joints** in the instrument tends to become degraded first.
- *Electrode insulation testing*
 - A few designs were considered to test the insulation of laparoscopes before every sterilization cycle.
 - Even though only the distal third of the instruments would need to be verified, none of the designs were simple and efficient enough to ensure it could **be successfully added to the nursing staff's workload**.
 - The major issue in optimizing insulation testing is the need to insulate the tip of the electrode in order to test exclusively the insulative sheathing.
- *Insulative sheathing thickness*
 - Insulation layer thickness for the four tested instruments were of **0.27 mm, 0.39 mm, 0.49 mm and 0.53 mm**. The model involved in the incidents has the thinnest insulation thickness (**0.27 mm**).
- **Sterilization parameters vs. Manufacturer recommendations**
 - The instructions provided by the manufacturer of the instrument involved in the incidents are to steam sterilize it from 132 to 135°C during 3 to 4 minutes. The cycle used by the CSR of the hospital is 132°C during **5 minutes**
 - **1 minute more.**
 - The sterilization settings currently under validation to replace the current cycle are **134°C during 4 minutes**.

DISCUSSION

- The availability of single use laparoscopes – during the assessment of the reusable laparoscopes – has **re-established surgeons' confidence** in the instruments and reduced the risk of a third incident occurring.
- Considering the necessity of safely cauterizing even when the **insulative sheathing** is in contact with patient organs, this layer must imperatively be of **great quality** especially **in the distal third** of the instrument (*a very small portion of the instrument is visible during cauterization*)
- The insulation layer **must be strong enough** to withstand normal usage due to intra- and peri-operative handling.
- **Problems** reported with the instrument with the **thinnest insulative layer (0.27mm)**.
 - is almost half the thickness of the thickest layer (0.53 mm)
 - sheathing thickness is critical in assuring patient safety.
 - **A thicker (≥ 0.4 mm)** and more flexible insulative layer would reduce the probability of electrical breakdown when the instrument heats up from the flow of high intensity current.
 - Risks associated with wear are also reduced since the same chink in a thicker layer is, overall, a smaller flaw in the material
 - Thicker insulative layer may result in a longer useful life for the instrument.

DISCUSSION (Cont'd)

- The absence of **visible joints** should also be favoured since these tended to degrade faster than the other materials in the instrument.
- The sterilization procedure at the CSSS LDDM (132°C, 5 min) is a minute longer than the manufacturer's instructions.
 - Even though this difference is small, it could compromise material integrity over a large number of cycles. The sterilization cycle of 134°C during 4 minutes currently under analysis could allow to follow the manufacturer' instructions.
 - *Ultimately, it is essential to consider the hospital's sterilization cycles when purchasing reusable devices.*
- The establishment of a surgical instrument **traceability system** would allow quantification of laparoscope usage.
 - A **threshold**, slightly more restrictive than manufacturer recommendations, could be established to dictate when an instrument should be retired.
 - For example, an annual replacement of instruments could be considered
 - In the absence of a traceability system, we recommend replacing the monopolar instruments after **two years** on an amortization basis and not on their useful life.

RECOMMENDATIONS & CONCLUSION

- Patient safety can be compromise by:
 - Quality of the electrode insulation sheathing material,
 - handling of instruments during surgery and
 - non-compliant sterilization cycle parameters can.
- The following guidelines should be followed when purchasing monopolar surgical instrument in laparoscopy:
 - minimal insulation thickness of 0.4 mm,
 - compatibility with the institution's sterilization cycles, and
 - visual inspection.
- A periodic insulation testing in the normal validation cycle of the laparoscopic instruments

ACKNOWLEDGEMENTS

- *We would like to thank Mrs. Laurette Aubé, assistant head nurse in the central sterilization room, for sharing helpful knowledge regarding sterilization issues.*