

# TECHNOLOGICAL ASSESSMENT OF LAPAROSCOPIC MONOPOLAR ELECTROSURGERY INSTRUMENTS AT CSSS DU LAC-DES-DEUX-MONTAGNES

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## ABSTRACT

Thermal injuries observed at the distal end of the insulative sheathing of monopolar laparoscopes during two recent interventions at the CSSS du Lac-des-Deux-Montagnes' surgical unit prompted this technological assessment of monopolar laparoscopes. This type of incident occurring rarely – no incident had been previously reported – the biomedical engineering department recommended, in agreement with the surgical unit manager and the chief of general surgery, the assessment of all our reusable monopolar laparoscopic instruments. Results indicate that quality of the electrode insulation sheathing, handling of instruments during surgery and non-compliant sterilization cycle parameters can compromise patient safety. The following guidelines should be followed when purchasing monopolar laparoscopes: minimal insulation thickness of 0.4 mm, compatibility with the institution's sterilization cycles, and visual inspection. A system ensuring instrument traceability is strongly recommended to monitor their actual usage and better predict a physical damage timeline. In the absence of such a system, we recommend a periodic insulation testing in the normal validation cycle of the laparoscopic instruments and their replacement after two years on a financial amortization basis instead of using them up to their average useful life cycle.

**Key words:** *Laparoscopy, Electrosurgery, Electrode insulation, Quality control, Thermal injury, Managing Burn Risks, Instrument insulation testing.*

## INTRODUCTION

The laparoscopic approach is a minimally invasive surgical technique growing in popularity in operating rooms due to the better short term outcomes for patients such as shorter recovery times and lower complication rates, postoperative pain, and blood loss during the procedure [1, 2, 3, 4]. Electrosurgery is a common technique used during laparoscopic procedures. However, this technology holds many risks for the patients. In less than a month, two incidents caused thermal injuries during laparoscopic interventions at the CSSS du Lac-des-Deux-Montagnes (CSSS LDDM). These burns appeared when contact was made between the sheathing of the instrument and an adjacent organ; the liver, in one case, and the bowel, in the other.

This safety issue has been previously reported in the literature for monopolar laparoscopes; these lack a return electrode causing the current to flow through the patient [5]. The cause of the reported injuries can be either insulation failure, direct or capacitive coupling [6, 7]. Suggested solutions include visual inspection of the electrode and

insulative sheathing [6, 7], personnel training on electrosurgical instruments and associated risks [6, 7], purchase of single use instruments only [8], more delicate handling [7], usage of the minimum voltage required and of conductive trocars [5, 6, 7], active electrode monitoring [5, 6, 9] or bipolar electrodes [5, 6]. Specific devices and laparoscopes designed to reduce risks by facilitating the identification of faulty instruments are currently available on the market. These devices do not serve as a replacement for prevention and proper handling of laparoscopes and are specific to one type of possible instrument failure [7].

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 electrosurgical laparoscopic instruments.

## MATERIALS AND METHODS

### *Design*

Several theories were considered as to the cause of the insulation failure which led to the current

leak. The following factors were analyzed in order to determine the specific problem causing the reported thermal injuries:

- Handling and wear of the instruments;
- Quality of electrode sheathing;
- Mechanical deterioration of the sheathing during the procedure;
- Sterilization parameters.

Following this analysis, recommendations were issued regarding purchasing considerations for reusable electro-surgical laparoscopic instruments.

### **Scope of the assessment**

Laparoscope assessment was limited to 8 electro-surgical hooks and 2 spatulas used in the surgical unit at the CSSS LDDM (Fig.1).



Figure 1: Laparoscopes involved in the leakage assessment study: 8 electro-surgical hooks (from left) and 2 spatulas (from right)

### **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 as well as 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.

Considering that CSSS LDDM does not currently benefit from a traceability system for surgical instruments, the number of procedures done with each instrument is unknown. This information could have helped to determine if normal insulation wear led to the reported incidents.

### **Electrode insulation testing**

Following the second incident, all monopolar electro-surgical laparoscopes were replaced by single-use instruments, then visually inspected and the insulation layer was tested with an insulation tester (Atlas Technology Inc., ATI-013): Fig. 2.

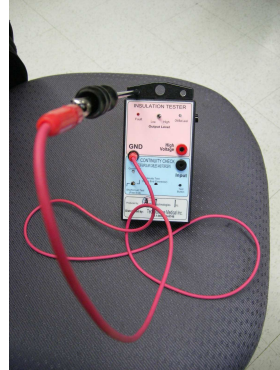


Figure 2: Laparoscope layer insulation test. A beep indicates a leakage if any.

### **Isolative sheathing thickness measurement**

Among the ten reusable instruments, four models of laparoscopes (3 hooks and 1 spatula), representative of the fleet used at the CSSS LDDM, were measured for insulation thickness. Among these was one model involved in the incidents. A section of the insulation material was removed on a limited portion of the diameter of the laparoscope (Fig. 3A), representing the area outside the field of view and possibly in contact with surrounding organs. Insulation thickness was defined as the difference, measured by a caliper, between the unaltered area of the instrument and the section missing a portion of insulation material (Fig. 3B).

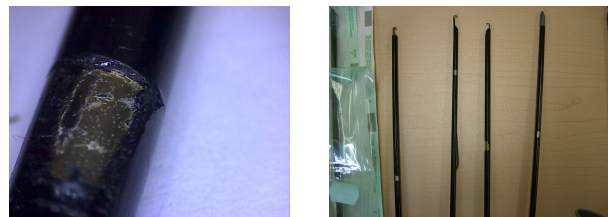


Figure 3: A(left). Partially unsheathed monopolar laparoscopic hook, in the distal third portion (adjacent to the pre-cauterization field of view). B(right). Laparoscope sheathing layer removed on the distal 3<sup>rd</sup> portion of the isolative material.

### **Current sterilization parameters vs. manufacturer instructions**

Sterilization procedures were analyzed to assess the risk of damaging the insulation layer during

reprocessing. Instruments' sterilization instructions were compared to the cycle currently used in our Central Sterilization Room (CSR) as well as a cycle currently under examination which might be implemented in the following months. Inadequate sterilization parameters can lead to premature or abnormal deterioration of the insulative sheathing which can result in current leakage [7]. Considering that no traceability system is currently in place, it seems impossible to verify this assumption.

## RESULTS

### *Instrument handling and wear*

During the witnessed surgery, it became apparent that the risk of insulation failure causing injury to the patient is limited to the distal third section of the instrument, the greater portion of the instrument staying either outside the patient or in the trocar (Fig. 4A). Contact between the distal third and patient organs is inevitable during certain procedures due to the zoom necessity prior to cauterization.

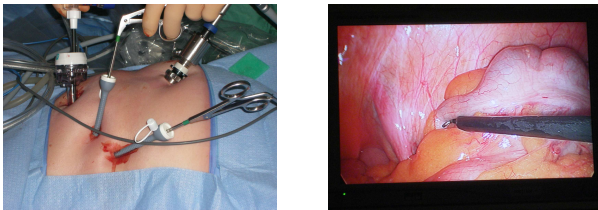


Figure 4 : Surgical setup (A, left). Pre-cauterization field of view (B, right)

Considering the field of view during the procedure is limited to the image relayed by the camera inserted into the patient (Fig. 4B), it can become quite limited during cauterization when there is a need to zoom into the area of interest. Thus, only a small distal portion of the insulative sheath is visible when current flows through the instrument.

Normal instrument handling, in both the surgical unit and the CSR, is likely to cause microscopic cracking of the insulation material which would pass visually undetected.

### *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. An ATI-013 insulation tester was installed in the CSR and used by the trained staff prior to sterilization of any reusable electro-surgical laparoscopic instrument.

Visual inspections of laparoscopes have revealed that the material used for joints in the instrument tends to become degraded first.

### *Insulative sheathing thickness*

Insulation layer thickness for the four tested instruments were of 0.27 mm, 0.39 mm, 0.53 mm and 0.49 mm. The model involved in the incidents has the thinnest insulation thickness.

### *Sterilization parameters vs Manufacturer recommendations*

The instructions provided by the manufacturer of the instrument involved in the incidents are to steam sterilize from 132 to 135°C during 3 to 4 minutes. The cycle used by the CSR of the CSSS LDDM is 132°C during 5 minutes. The settings currently under study 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 for 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 portion of the instrument. This is of critical importance considering that a very small portion of the instrument is visible during cauterization. This can cause undetected lesions leading to severe complications including peritonitis [7, 10]. Thus, 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 (0.27 mm), which is almost half the thickness of the thickest layer (0.53 mm),

indicate sheathing thickness is critical in assuring patient safety. A thicker ( $\geq 0.4$  mm) and more flexible insulative layer 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 compared to a thinner sheathing. This results in a longer useful life for the instrument with a thicker layer. 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 is compliant to the manufacturer's instructions. Ultimately, it is essential to consider the hospital's sterilization cycles when purchasing reusable equipment.

The establishment of a surgical instrument traceability system would allow quantification of laparoscope usage. With the information provided by this system, the risk of normal usage leading to insulation deterioration and causing thermal injuries could be assessed and prevented. 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 [7]. 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.

This assessment has led to four recommendations to be taken into account when purchasing monopolar electrodes for laparoscopy :

1. Sheathing thickness  $\geq 0.4$  mm;
2. Manufacturer sterilization instructions compatible with sterile processing department processes;
3. Visual inspection of the instrument (no visible joint);
4. Establishment of instrument traceability and maximal usage ceiling.

## CONCLUSION

The outcome of this study has been to identify critical factors when purchasing monopolar reusable electro-surgical laparoscopic instruments. The establishment of a traceability system will ensure a better monitoring of instruments and contribute to reduce risks for patients. Since March 6, 2013 we have started in the CSR periodic insulation testing in the normal validation cycle of the laparoscopic instruments.

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