

The packaging and clean method contribute to insulation failure of electrosurgical instruments

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Abstract

With the rapid development of medical technology, the use of electrosurgical instruments is dramatically increased in various types of surgery. However, the damage of the insulation layer of the reusable electrosurgical instrument often causes surgical accidents. The procedures of packaging and cleaning contribute to many damages to insulating layer of reusable electrosurgical instruments.

Various types of reusable electrosurgical instruments were detected for insulation failures, conduction failures, short-circuit by using a high-voltage detector, DIATEG (Morgate company). In addition, reusable electrosurgical instruments were detected for insulation failures after packaging and cleaning by different procedures.

13.1% (129/740) electrosurgical instruments had an insulation test failure; 6.2% (9/146) monopolar wires were with conduction failure; and 7.7% (16/207) bipolar wires were with short-circuit. Different packaging and cleaning procedures contribute to various degrees of damages to insulating property of reusable electrosurgical instruments.

Insulation failure was a wide problem of reusable electrosurgical instruments, while fixed packaging method and mild cleaning procedures result in fewer damages to insulating property of reusable electrosurgical instruments.

Abbreviations: AORN = Association of Operating Room Nurses, CSSD = Central Sterilization Service Department.

Keywords: central sterilization service department, electrosurgical instruments, insulation failure, insulation monitor, packaging and cleaning procedure

1. Introduction

With the rapid development of medical technology, minimally invasive surgery has become more and more popular in the clinic due to its advantages such as less trauma, less scarring, fewer surgical complications, faster postoperative recovery, and less pain. Electrosurgical instruments have become irreplaceable tools for minimally invasive surgery, which are widely used in many important surgeries in hospital, such as general surgery, gynecology, and cardiac surgery.^[1–3]

Reusable electrosurgical instruments are high-risk surgery instruments with high risks of electric leakage.^[4] However, surgeons need to use them for various surgical operations in many situations. For a wide range of period, electrosurgical instruments and accessories have been closely related to fires and patient injuries caused by human and technical errors. As a result, patient burns during electrosurgeries have also attracted much attention.^[5] Vangie Dennis's report disclosed the risks of burns to patients with the usage of electrosurgical instruments, and that some patients suffered from sustained injuries and some unfortunately died from severe burns.^[6–9]

Insulation failure is one of the main causes of electrosurgical syndrome. Many studies have tested the insulation failures of electrosurgical instruments.^[10–12] In a study of reusable electrocoagulation hook, the frequency of insulation failure (19%) of reusable instruments was higher than that of disposable instruments (3%)^[10]. The incidence of insulation failures for reusable instruments was approximate in hospitals where insulator failures were routinely inspected (19%) or not (33%). They also found that compared to the middle or proximal third of the instrument, insulation failures existed more often at the distal third (54%; 25/46).^[10]

It is the outer layer of insulation that guarantees the insulation of electrosurgical instruments. However, the insulation layer can be damaged during the operation, transfer from the operating room to Central Sterilization Service Department (CSSD), and the cleaning process,^[13] as Spruce et al. mentioned in the "Recommended Practice for Electrosurgical Instruments" of Association of Operating Room Nurses (AORN).^[14] On electrosurgical instruments, the common damages are scratches, micro-fractures, etc., in addition, most of the insulation layer breakage cannot be visually recognized.^[11] Monopolar wires and bipolar wires for electrosurgical instruments are prone to occur

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internal continuity and short-circuit problems. Moreover, the problems in such cables are invisible to the naked eye, which, however, are often found during the operation because of the occurrence of injuries on patients, such as electrical burns.^[12]

It is especially important to study the different packaging and cleaning methods for the influencing factors of the insulation damage of the reusable electro-surgical instruments.^[15] To reduce the usage of electro-surgical instruments with insulation failure, insulation detector should be used to identify the insulation failures as they cannot be visually inspected.

In this study, we detected the insulation failures of various reusable electro-surgical instruments. In addition, by comparing the methods of packaging and cleaning, we found that fixed packing and mild cleaning procedures dramatically reduced the insulation failure of instruments. Our study may offer scientific procedures for the packing and cleaning for reusable electro-surgical instruments and reduced the occurrence of electro-surgical injuries during operations.

2. Materials and methods

2.1. Detection of insulation, conduction and short-circuit

Ethical approval was not necessary, as this study did not involve any animals or humans. The insulation failure, conduction failure and short-circuits were detected with the detector DIATEG (Morgate company). Monopolar and bipolar outputs are provided in the detectors. An alarm sound allows the insulation failure to be detected. For the insulation failure, in monopolar mode, voltage was set at 4 kV, and in bipolar mode, voltage was set at 2 kV. The detection of conduction failures and short-circuits followed the instruction of the detector.

2.2. The packaging method for rigid laparoscopes

Rigid laparoscopes were packaged with fixing frames (Genze company, Shanghai) and loaded into a plastic basket with non-woven fabric cushions, or loaded into a plastic basket with non-woven fabric cushions directly. Before the insulation examining, the rigid laparoscopes were transported 20 times in CSSD for a total distance of 5 km along the same route by the same staff.

2.3. The cleaning method for electro-surgical instruments

To test the contribution of cleaning method to insulation failure, electro-surgical instruments were grouped to four cleaning procedures:

1. cleaned by manually brushing with scrub-free cotton for 1 min, and then cleaned by automatic machine (Zhongxiyuanda Tech., JR55-C100) followed the instruction of standard procedure;
2. cleaned by manually brushing with scrub-free cotton for 1 min and sonicated by ultrasonic cleaners (Shengxi Tech., Shanghai) for 5 min,
3. electro-surgical instruments were fixed in frames first, and then cleaned by manually brushing with scrub-free cotton for 1 min and sonicated by ultrasonic cleaners (Shengxi Tech., Shanghai) for 5 minutes. After being cleaned 10 times (2 days interval between two times) in CSSD by the same staff, the insulation of them was detected.

2.4. Study design

All the reusable electro-surgical instruments in this study were within the expiration date and the times of cleaning, sterilizing and transportation. Reusable electro-surgical instruments were daily randomly tested. Prevalence of insulation failures was calculated for the total of instruments tested. Single-use instruments and cables were excluded. All electro-surgical instruments and cables (unipolar and bipolar) tested in this study were packaged and cleaned by the same staff, and tested by the same person. Before testing, instruments and cables were required with no organic contaminants and cleaned in the same procedure. In addition, the statistical analysis was performed using χ^2 test to evaluate the significance between different transportation or cleaning methods, and $P < .05$ was defined to be significant.

3. Results

3.1. Insulation failures of electro-surgical instruments

To investigate the insulation failures of reusable electro-surgical instruments, we detected their insulation with an insulation detector DIATEG. The electro-surgical instruments tested in this study are described in Table 1. A total of 740 instruments were tested with DIATEG. Among these instruments, there were three groups: 346 rigid laparoscopes, 187 electric coagulation hooks and 207 electric coagulation forceps. Among 346 rigid laparoscopes, 68 (19.6%) of them were with insulation failures. 46 of 187 (24.6%) electric coagulation hooks and 35 of 207 (16.9%) electric coagulation forceps were with defective insulation. The overall prevalence of insulation failures was 17.4% (129/740), tested by the detector, which showed a common problem with electro-surgical instruments.

Table 1
Prevalence of insulation failure per kind of instruments.

Instruments	Average repetitive times			Defective	Non defective	Total
	Packaging	Cleaning	Sterilization			
Rigid laparoscopes	18.4	11.5	8.8	68 19.6%	278 80.4%	346
Electric coagulation hooks	21.2	12.8	12.1	46 24.6%	141 75.4%	187
Electric coagulation forceps	23.6	9.7	8.3	35 16.9%	172 83.1%	207
Total	20.6	11.3	9.5	129 17.4%	611 82.6%	740

Table 2**Prevalence of conduction failure of monopolar wires.**

Instruments	Average repetitive times			Failure	Success	Total
	Packaging	Cleaning	Sterilization			
monopolar wires	18.9	11.4	10.5	9 6.2%	139 93.8%	146

Table 3**Prevalence of short-circuit of bipolar wires.**

Instruments	Average repetitive times			Short-circuit	Non defective	Total
	Packaging	Cleaning	Sterilization			
Bipolar wires	23.5	13.6	11.2	16 7.7%	191 92.3%	207

3.2. Conduction failures and short-circuits of cables

To investigate the conduction failures and short-circuits of reusable cables of electro-surgical instruments, we collected the monopolar and bipolar wires of the instruments to test the conduction and short-circuit, respectively. As described in Table 2, 9 of 146 (6.2%) monopolar wires were with conduction failures. Table 3 presents the results of short-circuits, in which 16 of 207 (7.7%) bipolar wires were tested with short-circuits. Our detection suggested that conduction failures and short-circuits are widely occurred in cables of electro-surgical instruments.

3.3. The method of packaging affects the insulation of instruments

As insulation failures are a common problem of electro-surgical instruments and lead to serious consequence to patients,^[10,11] it has become an urgent requirement to find out the ways to reduce insulation damages. We divided the rigid laparoscopes without insulation failures into two groups: group A, 100 rigid laparoscopes which were packaged with appropriate fixing frames and loaded into a plastic basket with non-woven fabric cushions; group B, 100 rigid laparoscopes which were loaded into a plastic basket with non-woven fabric cushions directly. After being transported 20 times in CSSD with regular usage and 10 times of general cleaning (manually brushing with scrub-free cotton and automatic machine), the insulation of instruments was tested by the detector. According to the test, there was fewer instruments with insulation failures in group A than group B, (2/100 vs 14/100) ($P=.0018$) (Table 4). The results showed that fixed packaging method could significantly reduce the damages of the insulation layer of reusable electro-surgical instruments.

3.4. The method of cleaning is a factor of the insulation of insulation failures

Besides the packaging method, the cleaning procedure could also lead to the insulation failure of reusable electro-surgical instruments.^[14] To reduce the damage of the insulation, we investigated the cleaning methods for the instruments. In detail, we grouped the rigid laparoscopes with intact insulation: group A, 100 electro-surgical instruments cleaned by manually brushing with scrub-free cotton and automatic machine (manual + automatic cleaning machine); group B, 100 electro-surgical instruments cleaned by manually brushing with scrub-free cotton and sonication (manual+sonic cleaning); group C, 100 electro-surgical instruments which were fixed and cleaned by manually brushing with scrub-free cotton and sonication (manual+fixing+sonic cleaning). After being cleaned 10 times in CSSD with regular usage and 20 times of transport (loaded into a plastic basket with non-woven fabric cushions), the insulation of them was detected. Our results showed that different cleaning procedures result in different outcomes. There were fewest insulation failures in group C (1/100 vs 13/100) ($P=.0009$), and fewer failures in group B than group A (5/100 vs 13/100) ($P=.048$) (Table 5). As a result, milder cleaning procedure contributes to dramatically fewer insulation damage, and the cleaning procedure, fixing and cleaning by manually brushing with scrub-free cotton followed by sonication, was recommended, leading to fewest insulation damages.

4. Discussion

Insulation layer is an important component of electro-surgical instruments. Insulation failure is defined as a break or defect in

Table 4**Contribution of packaging method to insulation failure.**

Instruments	Defective	Non defective	Total	P value*
Group A	2	98	100	.0018
Group B	14	86	100	

Group A: fixed packaging, Group B: unfixed packaging.

*The P value was analyzed by χ^2 test.

Table 5
Contribution of cleaning procedure to insulation failures.

Instruments	Defective	Non-defective	Total	<i>P</i> value* vs. Group A
Group A	13	87	100	
Group B	5	95	100	.048
Group C	1	99	100	.0009

Group A*: manual +automatic cleaning machine.

Group B*: manual+sonicleaning; Group C*: manual+fixed+sonicleaning.

* The *P* values compared to Group A were analyzed by χ^2 test.

the insulation, which increases the internal burn risk and may lead to a terrible consequence to patients.^[5-7,11,12] However, the insulation problems of reusable electro-surgical instruments are widely existed in the operations. And disposable instruments have a lower incidence of insulation failure than reusable instruments.^[10] In our investigation, there are nearly 20% of reusable electro-surgical instruments with insulation failures, which may become serious threats to patients' health. What's more, the impact of electro-surgical complication is hard to assess because of the long delay between surgery and the discovery of the injury.^[5-7,12] As a result, it should be an essential work to find out and exclude the surgical instruments from the operations. So, the detection of insulation failures should be generalized in routine work in the hospitals, as it could reduce the usage of insulation defected electro-surgical instruments,^[4,14] thereby reducing the cost of hospital equipment supplies.

Besides the insulation layer of reusable instruments, the wires of them should also deserve our attention, as conduction failures and short-circuits are also common incidences for monopolar wires and bipolar wires, respectively. In our investigation, about 6%–7% cables of reusable electro-surgical instruments are with conduction failures or short-circuits. Our study suggested that the cables of instruments can also be an important factor of the defective of reusable electro-surgical instruments.

Insulation failures of reusable electro-surgical instruments is mainly caused by excessive use, particularly with repetitive packaging and frequent mechanized cleaning and sterilization processing.^[13,14] In addition, high voltages carried with certain electro-surgical power modes can also increase the defects by weakening insulation over time.^[16] According to our study, different methods of packaging and cleaning results in various output of the insulation failures on reusable instruments. For example, fixed packaging of instruments leads to reduced damage to insulation layer, and mild cleaning procedures (e.g. fixed and cleaned by manually brushing with scrub-free cotton followed by sonication) would also result in few insulation failures of electro-surgical instruments. The reuse of multiplexed electro-surgical instruments places high demands on CSSD,^[12] and the training to CSSD staff should be a key movement to effectively reduce the insulation damages. To extend the service life of reusable electro-surgical instruments, it should be important to choose the appropriate packaging equipment and cleaning procedure for the instruments.

As was well known, the caducity or number of times that reusable electro-surgical instruments can be employed would be paramount to eliminate the risks to the patients. However, due to various reasons, such as improper using, transportation or cleaning, reusable electro-surgical instruments that are within the validity period and the specified number of reuse, transportation, and cleaning always have the quality problems with a low

probability, which brings high risks to patients. Therefore, by optimizing the methods of transportation and cleaning, we can significantly reduce the probability of accidents, as just indicated in this study.

5. Conclusion

In a word, insulation failures were wide problems of reusable electro-surgical instruments. However, fixed packaging method and mild cleaning procedure could efficiently reduce the damages to insulating property of reusable electro-surgical instruments, which may decrease the risk of electrical burns of patients during surgery and even casualties caused by insulation failures.

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