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

Ying Zhang, MD\textsuperscript{a}, Yanyan Zhang, MD\textsuperscript{a}, Yafei Wang, MD\textsuperscript{b}, Lili Yang, MD\textsuperscript{a}, Ruying Hu, MD\textsuperscript{a}

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.\textsuperscript{[1–3]}

Reusable electrosurgical instruments are high-risk surgery instruments with high risks of electric leakage.\textsuperscript{[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 many situations. For a wide range of period, 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.

Insulation failure is one of the main causes of electrosurgical syndrome. Many studies have tested the insulation failures of electrosurgical instruments.\textsuperscript{[10–12]} In a study of reusable electro-coagulation hook, the frequency of insulation failure (19%) of reusable instruments was higher than that of disposable instruments (3%)\textsuperscript{[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).\textsuperscript{[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\textsuperscript{[13]} as Spruce et al. mentioned in the “Recommended Practice for Electrosurgical Instruments” of Association of Operating Room Nurses (AORN).\textsuperscript{[14]} On electrosurgical instruments, the common damages are scratches, micro-fractures, etc., in addition, most of the insulation layer breakage cannot be visually recognized.\textsuperscript{[13]} Monopolar wires and bipolar wires for electrosurgical instruments are prone to occur...
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.\cite{12}

It is especially important to study the different packaging and cleaning methods for the influencing factors of the insulation damage of the reusable electrosurgical instruments.\cite{15} To reduce the usage of electrosurgical 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 electrosurgical 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 electrosurgical instruments and reduced the occurrence of electrosurgical 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 electrosurgical instruments

To test the contribution of cleaning method to insulation failure, electrosurgical 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. electrosurgical 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 electrosurgical instruments in this study were within the expiration date and the times of cleaning, sterilizing and transportation. Reusable electrosurgical 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 electrosurgical 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 \( \chi^2 \) 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 electrosurgical instruments

To investigate the insulation failures of reusable electrosurgical instruments, we detected their insulation with an insulation detector DIATEG. The electrosurgical 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 electrosurgical instruments.

| Table 1 | Prevalence of insulation failure per kind of instruments. |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Instruments                      | Packaging | Cleaning | Sterilization | Defective | Non defective | Total |
| Rigid laparoscopes              | 18.4      | 11.5      | 8.8           | 68         | 278           | 346            |
| Electric coagulation hooks      | 21.2      | 12.8      | 12.1          | 46         | 141           | 187            |
| Electric coagulation forceps    | 23.6      | 9.7       | 8.3           | 35         | 172           | 207            |
| Total                           | 20.6      | 11.3      | 9.5           | 129        | 611           | 740            |

\( P<.05 \) was defined to be significant.
3.2. Conduction failures and short-circuits of cables

To investigate the conduction failures and short-circuits of reusable cables of electrosurgical 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 electrosurgical instruments.

3.3. The method of packaging affects the insulation of instruments

As insulation failures are a common problem of electrosurgical 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 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 electrosurgical 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 electrosurgical 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 electrosurgical instruments cleaned by manually brushing with scrub-free cotton and automatic machine (manual + automatic cleaning machine); group B, 100 electrosurgical instruments cleaned by manually brushing with scrub-free cotton and sonication (manual + sonic cleaning); group C, 100 electrosurgical 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 electrosurgical instruments. Insulation failure is defined as a break or defect in

| Table 2 | Prevalence of conduction failure of monopolar wires. |
|---------|---------------------------------|
| Instruments | Packaging | Cleaning | Sterilization | Failure | Success | Total |
| monopolar wires | 18.9 | 11.4 | 10.5 | 9 | 139 | 146 |
| | | | | 6.2% | 93.8% | |

| Table 3 | Prevalence of short-circuit of bipolar wires. |
|---------|---------------------------------|
| Instruments | Packaging | Cleaning | Sterilization | Short-circuit | Non defective | Total |
| Bipolar wires | 23.5 | 13.6 | 11.2 | 16 | 191 | 207 |
| | | | | 7.7% | 92.3% | |

| 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 \(\chi^2\) test.
the insulation, which increases the internal burn risk and may lead to a terrible consequence to patients.\textsuperscript{[5–7,11,12]} However, the insulation problems of reusable electrosurgical instruments are widely existed in the operations. And disposable instruments have a lower incidence of insulation failure than reusable instruments.\textsuperscript{[10]} In our investigation, there are nearly 20% of reusable electrosurgical instruments with insulation failures, which may become serious threats to patients’ health. What’s more, the impact of electrosurgical complication is hard to assess because of the long delay between surgery and the discovery of the injury.\textsuperscript{[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 electrosurgical instruments,\textsuperscript{[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 electrosurgical 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 electrosurgical instruments.

Insulation failures of reusable electrosurgical instruments is mainly caused by excessive use, particularly with repetitive packaging and frequent mechanized cleaning and sterilization processing.\textsuperscript{[11,13]} In addition, high voltages carried with certain electrosurgical power modes can also increase the defects by weakening insulation over time.\textsuperscript{[11]} 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 electrosurgical instruments. The usage of multiplexed electrosurgical instruments places high demands on CSSD,\textsuperscript{[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 electrosurgical 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 electrosurgical 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 electrosurgical instruments that are within the validity period and the specified number of reusage, 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 electrosurgical instruments. However, fixed packaging method and mild cleaning procedure could efficiently reduce the damages to insulating property of reusable electrosurgical instruments, which may decrease the risk of electrical burns of patients during surgery and even casualties caused by insulation failures.

Table 5

| Instruments | Defective  | Non-defective | Total  | \( P \) value \* vs. Group A |
|------------|-----------|---------------|--------|-----------------------------|
| Group A    | 13        | 87            | 100    |                             |
| Group B    | 5         | 95            | 100    | .048                        |
| Group C    | 1         | 99            | 100    | .0009                       |

\( P \) values compared to Group A were analyzed by \( \chi^2 \) test.

\( \textsuperscript{\*} \)

References

\[1\] Massarweh NN, Cosgriff N, Slakey DP. Electrosurgery: history, principles, and current and future uses. J Am Coll Surg 2006;202:520–30.

\[2\] Recommended practices for electrosurgery. Aorn j 2005;81:616–8. 621–623, 629–632 passim.

\[3\] Sakuragi T, Okazaki Y, Mitsuoka M, et al. The utility of a reusable bipolar sealing instrument, BiClamp(R)), for pulmonary resection. Eur J Cardiothorac Surg 2003;23:505–9.

\[4\] Wu MP, Ou CS, Chen SL, et al. Complications and recommended practices for electrosurgery in laparoscopy. Am J Surg 2000;179:67–73.

\[5\] Ferriman A. Laparoscopic surgery: two thirds of injuries initially missed. BMJ 2000;321:784.

\[6\] Amaral JF. Cause and prevention of electrosurgical injuries in laparoscopy. J Am Coll Surg 1999;180:763–5.

\[7\] Nduka CC, Super PA, Monson JR, et al. Cause and prevention of electrosurgical injuries in laparoscopy. J Am Coll Surg 1998;179:67–73.

\[8\] Willson PD, van der Walt JD, Moxon D, et al. Port site electrosurgical (dissathermy) burns during surgical laparoscopy. Surg Endosc 1997;11:633–4.

\[9\] Guzman C, Forrester JA, Fuchshuber PR, et al. Estimating the incidence of stray energy burns during laparoscopic surgery based on two statewide databases and retrospective rates: an opportunity to improve patient safety. Surg Technol Int 2019;34:30–4.
[10] Montero PN, Robinson TN, Weaver JS, et al. Insulation failure in laparoscopic instruments. Surg Endosc 2010;24:462–5.
[11] Tixier F, Garcon M, Rochefort F, et al. Insulation failure in electrosurgery instrumentation: a prospective evaluation. Surg Endosc 2016;30:4995–5001.
[12] Yazdani A, Krause H. Laparoscopic instrument insulation failure: the hidden hazard. J Minim Invasive Gynecol 2007;14:228–32.
[13] Vancaillie TG. Active electrode monitoring. How to prevent unintentional thermal injury associated with monopolar electrosurgery at laparoscopy. Surg Endosc 1998;12:1009–12.
[14] Spruce L, Braswell ML. Implementing AORN recommended practices for electrosurgery. Aorn J 2012;95:373–84. quiz 385-377.
[15] Espada M, Munoz R, Noble BN, et al. Insulation failure in robotic and laparoscopic instrumentation: a prospective evaluation. Am J Obstet Gynecol 2011;205:121.e121-125.
[16] Luciano AA, Soderstrom RM, Martin DC. Essential principles of electrosurgery in operative laparoscopy. J Am Assoc Gynecol Laparosc 1994;1:189–95.