

Inducing Safer Electrosurgical Handpiece Storage

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Abstract: Background Improper storage of the electrosurgical handpiece has been identified as an operating room hazard.

Objective: To test among representative surgical personnel two different methods of improving safety performance: a demonstration/lecture session, and improved equipment arrangement on the operating field.

Methods: A field experiment occurred in the classroom and in the operating room. Subjects were recruited from a surgical department in a single institution. After videotaping baseline behavior, interventions were made in education and subsequently in apparatus layout. Videotaping and behavioral coding were repeated after each intervention. Written tests preceded and followed the training lecture.

Results: Results varied among team members and different aspects of the equipment. The surgeons knew the manufacturers' designated safe practice, but they did not routinely follow it, even after additional instructions and redesign of the equipment setup. Other team members responded to the interventions and changed their storage-related behavior.

Conclusions: This study demonstrates a need for effective means to help surgical teams maintain a safe environment while using hazardous technologies.

Key Words: Electrosurgery, Operating Room, Safety, Medical Device, Medical Education, Surgical Team

A hazard was noted in an earlier pilot study of electrosurgery equipment use in ten surgical cases.¹ The electrosurgery handpiece was often placed on the surgical drape when it was not being used (Video A), rather than into its designated location, a plastic holster. According to the manufacturer, this misplacement creates a fire hazard.² Thermal injury in the operating room is reportedly rare, but can be catastrophic. This study was designed to examine a single aspect of safe use of electrosurgical equipment.

The electrosurgery unit is found in virtually all hospital operating rooms in the United States, and in many outpatient settings. It consists of a generator and a hand-held applicator electrode and various supporting equipment, including the storage holster. In "open" surgical procedures the patient's tissue is handled directly by the surgeon, and the handpiece is used to apply an electrical current. Useful functions of this focused energy include fulguration, desiccation and cutting of tissue. The application is viewed directly in the operating field by the surgeon.

Use of the electrosurgical equipment is learned early during the apprenticeship period of the surgeon-in-training. Every third year medical student will see

the equipment used during his/her surgical rotation. Early in the first postgraduate year the surgical intern will be instructed in use of the electrosurgery unit and be expected to safely and competently use it. Performance standards may be posted by separate surgical specialties, such as the American College of Surgeons.³ Like the surgeons, the nursing operative staff members have on-the-job instruction in managing this equipment.⁴ The American Association of Operating Room Nurses has printed safety standards available to all.⁵

Patient and personnel injuries from errors in electrosurgery occur regularly in small numbers, with occasional fatal or serious injuries; consequently identifying and decreasing error in electrosurgery could help prevent such injuries from occurring. In the United States the number of injuries voluntarily reported to the FDA from operating room fires is between 10 and 20 every year.⁶ There are an additional unknown number of unreported minor injuries and incidents every year. A recent survey by Smith and Smith in which Ear, Nose and Throat doctors were polled about personal experiences relating to electrosurgery injuries suggests that the number is probably greatly in excess of that reported to the

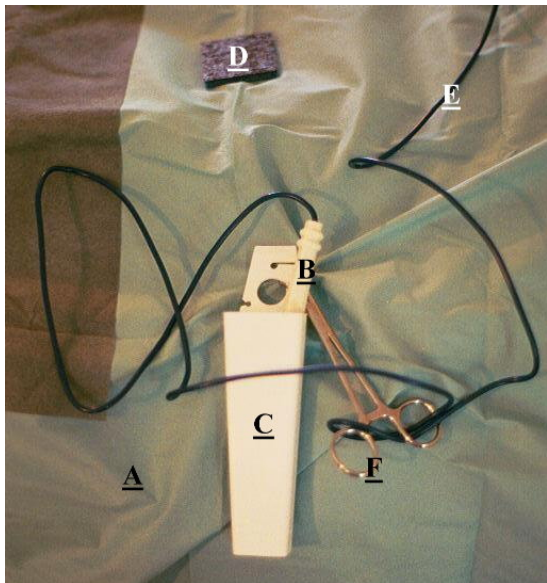


Figure 1 Typical electrosurgery apparatus setup: (A) drape, (B) handpiece, (C) white holster, (D) abrasive cleaning pad, (E) electrical wire crossing over table and (F) towel clip attaching holster to drape.

FDA.⁷ In their study 296 respondents reported a total of 99,664 surgical cases over a year's time. They also reported 324 electrosurgery-related complications for those cases.

The observation of frequent misplacement of the handpiece led to the hypothesis that a change in education and/or a change in instrumentation could reduce the unsafe practice. First, a training intervention would be targeted at the primary individual equipment users, the surgeons. After that training intervention, users would be again observed and results of their behavior recorded. Next, the way the equipment was set up and laid out on the operating table would be changed; this would include a short training session for surgical technicians. Then the users were to again be observed and their behavior recorded. Effective interventions would guide the surgical team members into safer behavior patterns. Success would be measured as a statistically significant positive change in the ratio of storage/use actions. In light of the general standard for a high level of safety in the operating room, and in view of the apparent relative ease of safe storage of the handpiece (safe storage requires virtually no extra equipment or time), a significant change was thought achievable.

Methods

Equipment to be studied - The equipment under study was the electrosurgical handpiece, along

with its accessories: the molded plastic holster, abrasive cleaning pad and metal towel clip used for attaching the holster to the drapes (Figure 1.). The "handpiece" is also called "pencil" by users, but in this paper will be referred to as the "handpiece."

Manufacturers recommend that the handpiece, while not in use, be stored in a molded holster constructed from a non-conductive material (Video B). Such storage prevents accidental activation of the cautery tip by shielding the off-on control switch on the side of the handpiece. The holster isolates the active tip from flammable materials, exposed tissue and other conductive materials. It serves to designate a standard location for the instrument. Manufacturers also recommend that the plastic coated wiring not be looped around anything else, especially metal implements. Looping wire to secure it to a holder (commonly done to prevent the attached handpiece from falling to the floor) increases the chance of capacitance, in which electrical energy is concentrated due to the proximity of several current-bearing wires. Looping the wire to metal then increases the risk of transmitting the electrical energy by conductance to drape or body tissues.⁸ The looping practice also can increase wire casing breakage.

Electrical power generators are used to transform and control the electrical characteristics of the power delivered to the handpiece. Generators are durable pieces of equipment and most operating rooms contain one or more. To prevent burns, a "grounding pad" is attached to both patient and generator; this provides not a true ground, but instead a means of diluting the electrical energy at any one point on the patient's skin, and it is thus a dispersive electrode. Electrosurgical handpieces, holsters and cleaning pads are usually disposable equipment. Multiple commercial brands are available. The accessories may be purchased separately or packaged, depending on local hospital purchasing procedures. The handpiece is a sterile instrument, and it is handled on the operating table by all surgical team members who have scrubbed their hands and donned sterile clothing for the procedure: the surgeon, surgical assistants and surgical technicians or nurses.

The surgeon is responsible for use of the equipment, and the scrub technician is responsible for setup and removal. In practice each sterile team member, regardless of job classification, may participate in the setup, use and storage of the handpiece during any given case. Danger from the equipment results when the hot cautery tip ignites flammable materials, resulting in fire and possibly explosion.

Grounding or dispersing faults may result in electrical shock or burns.

Subjects and Case Selection - The subjects were resident and faculty surgeons from the Obstetrics and Gynecology Department at an academic teaching hospital and the surgical scrub technicians assigned to that department's operating rooms. Faculty and management consultants thought that the work habits in these rooms are representative of other same-specialty professionals in United States. The study took place over a two-year period. The participants were selected on the basis of suitability of the anticipated surgical case listed on the operative schedule. Beginning with the first case on the daily schedule, the cases were evaluated serially until an eligible case was found. To be included in the study surgical cases had to meet the following criteria:

1. Open (as opposed to laparoscopic) abdominal gynecologic cases (*e.g.*, hysterectomy, oophorectomy, exploratory laparotomy) were included.
2. Electrosurgery equipment was set up and used during the case.
3. The principal surgeons (a team of two) on the case were not identical to those in a previous study case in a particular set. Although no two teams would be identical, any particular person could participate more than once.

If a qualifying case were noted, then the faculty surgeon was contacted and recruited for participation in a field study about equipment, using video-based observation. The specific equipment being studied was not identified, in order to reduce user bias during the study. The surgical patients were not identified, nor the operative case numbers retained, in order to maintain patient privacy. The surgeons were identified by code, in order to coordinate participation data. If the faculty surgeon agreed to participation, then the day of surgery the researcher verbally presented the same recruiting statement to the other surgical team members. The presentation was videorecorded, along with the question and answer period. If after further inspection the case met all criteria, videotaping proceeded. The case selection process continued each regular operating day until the series of ten cases was completed. The training intervention was then made and the process repeated. Finally, the equipment setup intervention was made and the filming again repeated. There were thus three study sets of ten cases each: (1) a pre-intervention set, (2) a post demonstration/lecture set, and (3) a post equipment change set. Many persons participated in more than

one study set; a total of 16 faculty surgeons, 27 resident surgeons and 8 surgical scrub technicians participated. In each set of 10 cases, the primary surgeon was different from all others in every case in that set. This method was used to increase the size of the sample in order to give a representative picture of common practice when storing the handpiece.

Equipment used to perform study - Entire cases were recorded using a video camcorder, which was set on a tripod and visible to the team. The camera was placed out of the way of the surgical team at one side of the room and at the end of the operating table, and the investigator tended it throughout the cases. Only the video track of the tapes was used for the study. After the cases were complete, the films were observed to identify and classify surgical team member behavior in using and storing the electrosurgical handpieces. To do this, a time-motion study was performed using behavioral observation coding software.⁹ Additionally, a paper and pencil test of knowledge was given to representative groups.

Study Design, Observations and Interventions

1. A baseline series of ten operative cases was videotaped. The tapes were observed and classified for use and storage actions for the electrosurgical handpiece. Variables were selected and assigned codes according to person (surgeon, nurse, technician or medical student) and tool location (tool-in-use, tool-in-holster, and tool-not-in-holster). "Tool-in-use" included anytime the handpiece was in a surgical team member's hand for use, whether or not the cautery switch was activated. The code remained in effect from the time the handpiece was touched until it was replaced in the holster or laid on the drape. (Holster): noted anytime that the handpiece was placed into the holster. The code remained in effect from the time the handpiece was placed in the holster until its next removal. (Drape): was coded anytime the handpiece was not in use and not in the holster, *i.e.*, it was placed onto the surgical drape. Collection of data began when the handpiece and holster were first placed on the operating table and ended when they were removed from the table or disconnected from the generator, whichever came first.
2. After the first set of ten videotapes was complete, a training session for the surgical teams was arranged and conducted during departmental grand rounds by a manufacturer of electrosurgical equipment; 60% of the 45-minute demonstration/lecture was given to background physics in-

formation and 40% to safe and effective instrument use. The lecturer emphasized safety and in two instances specifically instructed the class to put the handpiece in the holster when not in use and demonstrated how it should be done. The surgical nurses and scrub technicians at this hospital annually fulfill an administrative requirement for attendance at an electrosurgery safety lecture, so they had been exposed to identical information. In order to reduce study bias, the surgeons in the training class were not informed that they would be subsequently observed for compliance in following recommendations for use of this equipment.

3. After the safety lecture, a second set of ten operative cases was videotaped and evaluated for the use and proper storage of the electrosurgical handpiece. Cases in the series were selected using the same participation criteria as the first set, with the addition of the requirement that at least one of the two surgeons on the operating team (either primary surgeon or assistant) would have been present at the safety lecture. The original protocol required both members of the surgical team to have received additional training, but the requirement was not achievable after a single lecture.
4. After the second set of videotapes was complete, the second attempt was made to change the surgeons' preferred action for storing the handpiece.

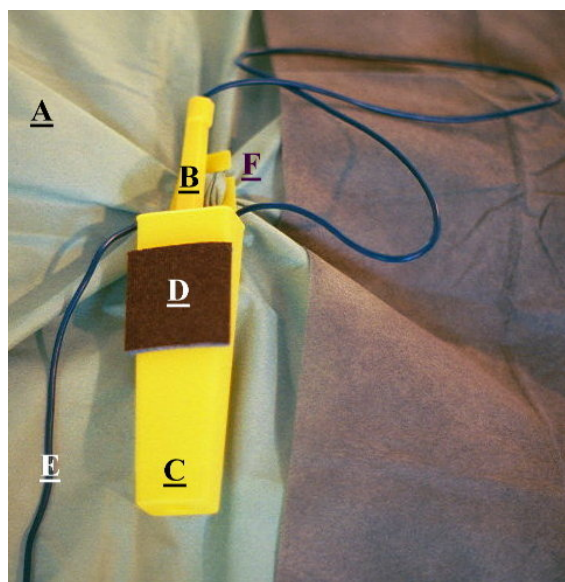


Figure 2 Experimental electrosurgery apparatus setup: (A) drape, (B) handpiece, (C) yellow holster, (D) abrasive cleaning pad, (E) wire leaving table directly to generator and (F) holster attached to drape by self-retaining clip.

A constraint was the need to use only existing equipment already approved by the FDA and in common use (this constraint is the same experienced by all surgeons and operating room supervisors for safe practices in relation to equipment). Standardization for this equipment stops at the operating table; there is variety in how the equipment is selected and placed for use by the surgeons; Figure 1 shows a typical apparatus setup. Figure 2 shows the revised apparatus setup. The intervention was structured to select and arrange the equipment in a way that would facilitate safe performance. To provide a cue to encourage recommended storage, a highly visible color (yellow) was selected. To encourage a habit of touching the handpiece to the holster, the cleaning pad was attached to the surface of the holster; this action might carry over to the action of putting the handpiece into the holster. Video C shows a surgeon using the equipment in the revised setup, cleaning the tip of the handpiece and then placing it into the holster. To reduce a known hazard, the metal towel clip was eliminated from the initial setup, and the surgical scrub technicians were taught how to use the self-attaching features of the plastic holsters, using a simple mock setup. The procedure in this set of operating rooms is for electrosurgery apparatus arrangement to be done at the first of the operative case, after the patient is draped and prior to beginning the surgical incision. The surgical scrub technician hands the handpiece, holster, cleaning pad and towel clip to any one of the operating surgeons or assistants for placement. The elements are placed wherever the person doing the arranging prefers. For standardization, the surgical scrub technicians were recruited to participate in the experiment. They were told the purpose of the experiment and asked to set up the equipment themselves in a standard manner rather than hand it to the physicians to set up. A sample setup was demonstrated to each technician individually in a five minute training session. A functional position directly across the operating table from the surgeons operating hand was designated as preferred location for the holster. This setup procedure was followed for all procedures in the two study rooms for the entire study period of three months, whether or not the case was being recorded for study. In Video D the scrub technician is seen instituting the revised setup. Another series of ten operative cases was then video recorded and observed for behavioral coding of the same actions that were noted previously.

Table 1
Physician Answers to Question about Proper Handpiece Storage on Electrosurgery Test

The technique recommended to prevent burn injury or ignition incident when inadvertent activation of the electrosurgical electrode occurs is...	Pre-test (n=27)	Post-test (n=23)
Select one answer:		
A) placing the electrode in a non-conductive safety holster when not in use	23	19
B) placing the electrode on the flat surface of the drapes when not in use	0	1
C) using the lowest possible power setting in the coagulation mode	2	0
D) instructing the scrub person to monitor the location of the electrode when not in use	0	2
Skipped (no answer)	2	1

5. In addition to the video study, a multiple-choice written test was administered on two different occasions to physicians from the same group. A voluntary sample of faculty and residents attending the training session were first tested to measure their general knowledge about electricity and the operation and safety of the electrosurgery handpiece. Immediately following administration of the pre-test, all participants attended the hour-long, comprehensive lecture about electrosurgery. The session was also attended by non-participant faculty and house staff, and also by medical students and nurses. Two months after the lecture, the same test was administered to another voluntary sample from the same pool of faculty and resident physicians attending a non-related lecture. Response to one test item only on the questionnaire was evaluated for this report. The chosen item asked the participant to identify the safest practice for electrosurgical handpiece storage (Table 1). The rest of the items related to physics and other aspects of electrosurgical performance.

Three series of ten cases each were recorded: a baseline series, a post-instruction series, and a series after the instrument change, for a total of thirty cases. The study was approved by the Institutional Review Board of the institution where the study was conducted, including the method of obtaining informed consent from the human subjects. A performance ratio was developed for the events that were classified. The ratio represents correct storage of the handpiece, as recommended. This measure is the proportion of holster events to use events. The maximum score was 1.0 indicating that for each use event there

was a holster event—i.e., every time the electrosurgical handpiece was used it was either immediately or eventually placed back into the holster. The minimum score was 0.0 indicating that, however many times the handpiece was used, it never was returned to its holster. The scores were subjected to an analysis of variance using SASS Version 7.5.

Results

There were no adverse events observed in any of the test cases; there were no fires, no burns and no electric shocks. Removal of the metal towel clip from the setup by the surgical technician immediately produced 100% compliance. The self-attaching feature of the molded holster was well-accepted by both technicians and surgeons. No one had any comments or questions when the scrub technicians assumed the task of setting up the equipment (investigator direct observation).

Statistical Analysis - In a total of 54:39 hours:minutes of filming 30 surgical cases, 1,146 study-related events were observed (Table 2). Inspection of the data sets showed great variability from case to case in numbers of events. Use events

Table 2
Total numbers of events observed

Variable	Set		
	Baseline	Post Lecture	Post Setup Change
Use	196	212	134
Holster	86	58	76
Drape	122	180	82

Note: There are 10 complete surgical cases in each set. Average case length is 1.82 hours.

Table 3
Average obtained values on the two measures of error shown as arithmetic mean \pm standard deviation

Set	Safe storage ratio
Baseline	0.45 \pm 0.35
After training	0.32 \pm 0.28
After set-up change	0.57 \pm 0.30

Note. See text: Methods, Statistical Analysis, for description of measures of error

ranged from 7 to 71 across the 30 cases that were videotaped and coded. Holster events ranged from 0 to 32. Video E shows a “holster event”. Drape events ranged from 1 to 54. Video F shows a “drape event”. In the worst case the handpiece was used 53 times, placed on the drape 57 times, and returned to the holster 0 times (there were 4 times when someone picked up the handpiece from the drape, did not use it, and then replaced it onto the drape). In the best case the handpiece was used 34 times, placed on the

drape 2 times, and returned to the holster 32 times. Modes for the three types of events were 21-23 use events, 16-17 drape events, and 8 holster events. Consistent with this great variability from case to case, there are large amounts of within-group variability in the measures of error. Average obtained values are shown in Table 3. Analysis of variance, therefore, showed no significant differences in errors between the three series of cases. The data indicate that the handpiece was safely stored at a rate of approximately once for every 2 to 3 times it was used. Figure 3 shows the total data set, demonstrating the extreme case-to-case variability. In Figure 3 the data is adjusted for case time, so that activity in 1 hour of equivalent work for each case is demonstrated. Adjusting for case time results in no change in the final statistical analysis.

Additional observations - In all trials, on occasion a surgeon would place the handpiece on the

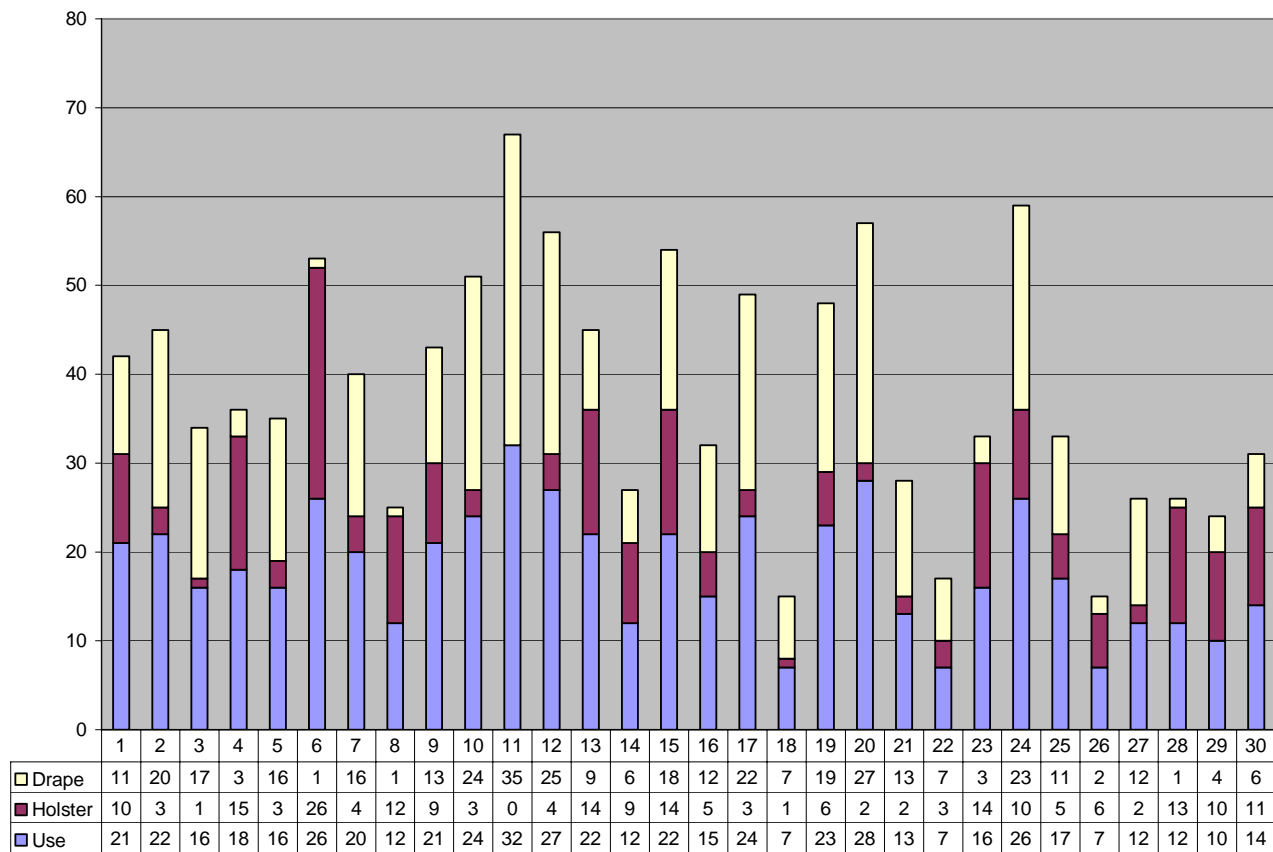


Figure 3. Electrosurgery handpiece storage. Total data set. Each bar is one case. Cases 1-10 are baseline set, cases 11-20 are post-demonstration lecture set, and cases 21-30 are post apparatus change set.

drape and then someone else would pick it up and place it into the holster. In Video G an assistant surgeon can be seen to pick up a misplaced handpiece and return it to the holster. The assistant surgeons, the surgical scrub technicians and medical students were observed to perform this corrective action. Once recruited to the experiment for the second intervention, although not asked to do so, the surgical scrub technicians became active participants and began holstering the handpiece after the surgeon's use.

of the department's surgeons were present at the selected conference.

In summary:

1. In this study electrosurgical handpiece storage frequently did not meet the total set of safety requirements recommended by the manufacturer and professional organizations.

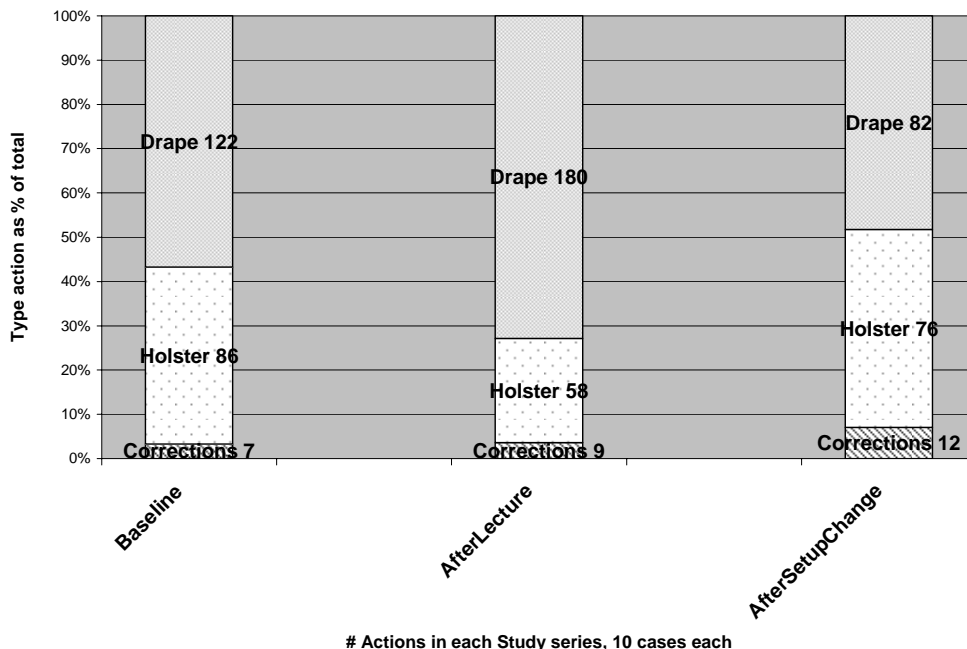


Figure 4. Corrective actions after initial errors in the three series of cases..

Corrective actions were present in all 30 study cases, all parties participated in this activity, and the number of corrective events increased after each intervention (Figure 4).

Written test results from before and after the classroom training show no statistically significant differences in participant's knowledge (Table 1). Before the lecture, 92% of the 27 participants chose the correct answer. At post-test, 86% of 23 participants answered the item correctly. Almost everyone tested already knew the designated correct answer, and there was no loss of this knowledge in the sampled population over the course of the study. Finally, since conference attendance is mandatory, the initial study design included the assumption that almost all potential electrosurgery handpiece users would participate in the educational experience. In reality there are many exceptions to the requirement, and only half

2. The surgeons' behavior was not changed by either the manufacturer's representative explaining the correct procedure in a simple group lecture or by rearranging the available storage apparatus.
3. Storage choice varied widely between individual surgeons.
4. Two hazardous practices, the use of a towel clip to attach the holster and looping the wire around the towel clip, were completely eliminated by individual training for the surgical scrub technicians.
5. The percentage of time the handpiece was holstering was increased by corrective actions of surgical team members other than the surgeon.

Discussion

Organizational practices influence end results for both the equipment and the use of the electrosurgery handpiece. Influencing organizations include manufacturers, hospitals, governments, medical schools and professional specialty organizations. This study was not designed to evaluate all practices in the cascade leading to the hot cautery tip in the operating room. Yet we question whether available resources have been fully and appropriately applied if the end result is a failure to maintain a hazard-free environment. As noted by W.A. Hymen, a noted industrial safety expert, the instrument that is continuously used improperly may not be meeting the needs of its user, and the user is not in a position to alter the tool.¹⁰ In the United States the Food and Drug Administration regulates medical devices.¹¹ The electrosurgical handpiece, with its long history of rare adverse events, is already approved for general surgical use and is unlikely to be subject to review for pertinent human factors engineering requirements.

Study limitations include the following:

1. Following the initial series of cases, one intervention followed the other, so that it is impossible to isolate the effects.
2. Poor attendance at the training intervention. Education intervention studies should have safeguards to assure uniform attendance.
3. Failure to inform the subjects about the performance goal. (In retrospect, this was excessive zeal to avoid the Hawthorne effect!) Training goals should be intentional to their targeted subjects.
4. The surgeons were evaluated as a group, not as individuals. The tremendous amount of individual variation suggests the need for more attention to individual factors.

Why did the surgeons acknowledge and understand the designated safe behavior, but incompletely execute it? Although it seems intuitively valid, there is no empirical evidence that a widespread change in handpiece-storage behavior would reduce operating room injuries. Possible explanations for the lack of change in behavior include the possibility that the surgeons do not believe that the premise is valid that the handpiece is safer when stored in a holster (whether or not it is true). Perhaps they would find the premise more acceptable if the instructions were given by another surgeon. Exploring personnel

attitudes might be a helpful maneuver in future studies. Another possible explanation is that the surgeon is unable to adequately attend to this safety procedure when it competes with other critical surgical processes. Although we have focused on behavior storing the handpiece, it is only one action in a very complex arena of attitudes, cognition and technical skills. When electrosurgical handpiece storage is prioritized, it may fall below the threshold of achievable goals. It might also be helpful to record demographic information such as age, experience and gender, in order to see whether there are any correlations with the observed storage choice.

This intervention study contains an attempt to change behavior that would theoretically help prevent a rare event, thermal injury in the operating room. Because many injurious events in the operating room are rare in the places where they occur, it behooves us to pay attention to the issue of rare events which cause harm to patients and personnel. Other key professionals in the surgery suite are using special techniques to deal with rare injurious events, and we might learn from them. Anesthesiologists have developed error-management programs for the use of their workforce. During the past two decades they have successfully greatly reduced anesthesia-related adverse outcomes through a combination of equipment improvements and changes in training programs.¹² Observations made in this study of electrosurgery user behavior could be useful in developing such programs for the broader operating room team, to include surgeons, nurses, and technicians. That team members other than the surgeon were able to contribute to safe storage practice in this study lends credence to the possibility of a team-as-resource solution. If training and equipment modification goals had been shared with the subject surgeons, then more successful adoption of the prescribed actions might have been observed. If, however, the issue is one of cognitive resources, then attention must be paid to the risk of displacing the surgeon's attention from possibly more critical tasks. Training surgical team members in the principles of workload management would allow them to use their experience to distribute workload. We need research to understand the basic requirements for the processes of attention, decision-making and workload management in this work domain to make a scientific assessment. Furthermore, the information gained from recording and analyzing problems resulting from surgical equipment use could be used for design improvements, which would result in a safer work environment for both patients and the surgical team.

Designing effective means for maintaining a safe environment in the surgical operating room requires that we understand in detail the specific tasks of surgery and the specific work requirements of surgical personnel. Understanding the task requirements for all surgical personnel, the characteristics of the equipment that they use, and the dynamic interactions of the team members in this highly complex environment can ultimately help educators to improve training programs for using that equipment. Improvements in the equipment itself and improvements in individual and team actions should lead to a greater achievement of surgical goals as well as a higher level of safety in the operating room.

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