An Engineering Critical Incident: Direct Current Burn from a Neuromuscular Stimulator

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A patient received a third-degree, direct current (DC) burn on the wrist from a neuromuscular stimulator (NMS) that had been modified by a biomedical technician. The event is used to illustrate the accident process, procedures in investigation of engineering-related incidents, and the mechanisms of burns caused by DC. Similar to most industrial accidents, this one had several contributing causes. It demonstrates the need for thorough review and testing of device modifications; the subtle effects of personnel shortages, the dangers of grounded electrosurgical units, and the ways in which seemingly minor features of a device can contribute indirectly to an injury. Accident investigations should be instituted immediately following an event, but care must be taken to ensure that vital information is neither lost nor altered. (Key words: Complications: burns. Monitoring: neuromuscular junction.)

ACCIDENTS in high technology fields are typically composed of several interacting failures involving people, machines, the environment, management, and other factors. The basic principles of accident causation and prevention apply to medicine as well. Although there are countless case reports of medical misadventures, the case descriptions and analyses typically do not include identification of underlying influences that may have played a critical role in the formation of the accident. We describe here the process by which a third-degree burn was caused by direct current (DC) from a neuromuscular stimulator (NMS). The direct and indirect causes of the incident are identified, and generalized preventive strategies are recommended. The specific mechanism by which burns can be caused by DC are reviewed, and the means by which such injuries can be avoided are suggested.

CASE REPORT

As each of 12 new anesthesia machines (Ohmeda, model Modulus II) was being prepared for service, a new constant current peripheral nerve stimulator was installed in the instrumentation pod. [Because the specific brand of NMS is not particularly relevant to the issues of this case, we refer to the instrument generically to avoid an inappropriate implication of product liability.] Soon after the introduction of these anesthesia machines, it was noted by the biomedical technicians that frequent battery changes were required. This was relatively time-consuming because it involved disassembly of the instrument. To simplify this task a biomedical technician installed a battery holder for the two 9-V batteries on the back of the case of the instrument. Following the modification the device was replaced in the anesthesia machine instrument panel and tested for performance and safety, including DC voltage between the output terminals.

Several weeks after the first NMS was modified, a 68-year-old man arrived in the operating room for elective coronary revascularization. Following routine preanesthetic medication and hemodynamic assessment, general anesthesia was induced with fentanyl 100 μg/kg and enflurane 0.5% in oxygen. Neuromuscular blockade was established initially with vecuronium 0.2 mg/kg and subsequently maintained with metocurine 0.2 mg/kg in the prebypass period, and then d-tubocurarine 0.3 mg/kg during the rewarming phase of cardiopulmonary bypass.

A disposable, electrosurgical dispersive electrode with conductive adhesive (3M Scotchplate, Model #1149) was placed on the left side of the lower back. During the surgical procedure a Ritter model CSV Bovie electrosurgical unit (ESU) was used intermittently. Prior to the initiation of cardiopulmonary bypass, the NMS was applied over the right ulnar nerve proximal to the first volar crease of the wrist via a dual-element foam electrode (Bard PNS, single patient use). The monitor was turned on five times during the operation for brief determinations of blockade via train-of-four measurements (a series of four 0.20-ms pulses at 500-ms intervals).

Following an uneventful procedure and prior to moving the patient from the operating table, the stimulating electrode was removed. A 1 cm² full-thickness burn was noted to be present under the negative electrode, with a slight reddening of the skin under the positive electrode. The skin under the ESU dispersive electrode appeared normal. The skin burn was treated with debridement of eschar on two occasions and 7 days of silveradine dressings followed by 10 days of bid wet-to-dry dressings at home. This treatment resulted in complete healing without requirement for skin grafting.

Immediately following report of the incident, the anesthesia machine and the ESU were removed from service and sequestered. The dispersive and stimulating electrodes had been discarded before they could be inspected. Individuals involved in the incident, including the attending surgeon, attending and resident anesthesiologists, nurses, and biomedical technicians who support the equipment, were interviewed about the sequence of events and observations. The NMS was (inappropriately) removed from the anesthesia machine and tested for stimulus output and DC voltage between the output terminals. The ESU was tested for grounding of the dispersive electrode, for operation of the dispersive electrode cable disconnection alarm, and for function of the output controls. Both instruments passed all tests. The NMS was then reinstalled in the anesthesia machine and safety and functional testing were repeated. Although the NMS functioned correctly, under some conditions of tightening of the mounting bolt a voltage equal to the battery voltage appeared between the negative output terminal and the chassis of the anesthesia machine. Closer inspection suggested that the positive battery terminal was contacting the inside of the rear panel of the anesthesia machine (fig. 1). Two hypotheses were now established for the cause of the burn: misdirected radio frequency (RF) current from the ESU or direct current from the NMS.

Conditions under which the burn occurred were simulated and experiments were conducted to examine both hypotheses (all equipment...
and supply items were of the same brand and model as were in use during the incident).

An electrode pair was affixed firmly on the carcass of a chicken and connected to the NMS output. The carcass was placed on a dispersive electrode, which was connected to the ESU. The NMS was mounted in the anesthesia machine in such a way that a voltage appeared at the output terminals relative to the chassis of the anesthesia machine. RF current through each of the stimulating leads was measured by a Valleylab custom-built meter with a bandwidth of approximately 40 Hz to 10 MHz and with a resolution of approximately 5 mA. DC current through the leads and voltage between the output terminals and chassis ground were measured via a Beckman HD 110T digital multimeter.

ESU Burn Test: The ESU was operated intermittently for several minutes in the cutting mode at maximum output. No discernible RF current was measured through the NMS leads. There was no visible change in the skin under the stimulating electrodes. The dispersive electrode was removed and the ESU was again operated intermittently. Peak RF currents of 135 and 80 mA were measured through the negative and positive leads, respectively. An approximately 0.5 cm² area of blanched tissue was observed below the surface of the skin under the negative electrode.

DC Burn Test: With the NMS again mounted so that a DC voltage appeared at the output terminals and with the electrode pad placed at a fresh site on the carcass, the DC current and voltage were monitored for 2 h. The skin under the electrodes was examined at 15, 30, 60, and 120 min. After 120 min the pH of the fluid on the skin of the chicken was measured via pH sensitive paper with a resolution of 0.5 pH units (pHDrion Vivid 1-11).

Before application of a DC voltage, the pH of the gel moi-stened skin under the electrodes was 6.0. At the start of the 2-h period of application of a DC voltage, the negative and positive output terminals were at negative 9.0 V and 6.4 V relative to the chassis, respectively. A current of 13.7 mA was measured from the negative terminal and 7.6 mA from the positive terminal. The voltage and current appeared with the on/off switch of the NMS in either position. After 15 min an approximate 0.5 cm² area of skin under the negative electrode appeared dissolved. The skin under the positive electrode appeared unchanged. After 120 min the voltages were 8.5 V and 5.9 V, respectively, and currents were 7.5 mA and 6.9 mA, respectively. An approximate 2 cm² area of skin under the negative electrode was darkened and oozing with a clear, viscous fluid. Only a slight discoloration was observed under the positive electrode. The pH of the skin under both electrodes was approximately 10. The pH under the dispersive electrode was between 5 and 6.

Discussion

Immediate Cause of the Burn

Because with the dispersive electrode in place, no RF current was measured in the NMS lead during operation of the ESU and no change was observed in the appearance of the skin, the ESU was ruled out as a likely source of the injury. Although there was a measurable current and some subcutaneous injury with the dispersive electrode removed, this is an unlikely source of the patient's injury because the operating room personnel reported that the dispersive electrode was appropriately affixed to the skin immediately prior to its removal at the end of the procedure. Also, the slight skin discoloration observed with the dispersive electrode removed was not similar to that found on the patient. The type of injury produced with DC current alone was similar to that observed on the patient. The probable path of the DC is illustrated in figures 2 and 3.

This is not the first time that a DC electrolytic burn has been reported. Nine volts is more than sufficient to produce electrolysis of saline, producing sodium hydroxide and hydrogen gas at the cathode. Either chlorine or oxygen or both are likely to appear at the anode. In this case the anode would have been the dispersive electrode because it was connected (inadvertently) to the positive terminal of the battery. The NMS electrodes would both serve as cathodes in the electrolytic cell. This yields a strong alkaline solution, which causes a chemical burn. This mechanism was confirmed in the DC portion of the simulation. The differences in voltage and current through the two output terminals can be explained by the voltage drop across the current-controlling stage of the stimulator (fig. 3). This can also explain the different injuries at the two stimulating electrodes. The large surface area of the dispersive electrode distributes the acid formed over a wide area, preventing sufficient concentration to cause an injury at that location.

Leeming et al. suggested that as little as 3 V DC can produce an injury. The minimum time required would be a function of skin resistance and voltage. Our experiments suggest that at 9 V DC with commonly used electrodes injury can begin to occur in less than 15 min.

In this case it was fortunate that the institution had
developed a firm policy to use only surface electrodes with neuromuscular stimulation for routine monitoring. This derived from a similar incident, 10 yr previously, with a defective instrument supplied by a manufacturer. In that case needle electrodes were used for stimulation with the rationale that this was necessary to ensure sufficient current density for supramaximal stimulation. The intrinsic failure in that instrument caused a DC voltage to appear across the output terminals. A burn resulted, but it was much more severe, causing permanent destruction of the ulnar nerve.

This incident is a reminder that battery operated devices are not inherently safe. Because of the possibility of DC burns, we believe that the use of needle electrodes is contraindicated unless there is a specific, compelling rationale. In that case extra precautions should be taken to inspect for the presence of DC voltage across the electrodes or between any electrode and ground.

**ANALYSIS OF CAUSES AND RECOMMENDATIONS FOR PREVENTION**

In addition to the specific mechanism of the burn, this report illustrates how many factors typically are required to cause an injurious mishap.

**Modification to the Instrument:** Any modification of a device must be submitted to rigorous review by individuals

![Fig. 2. Schematic diagram of the path of DC from the NMS (dotted line).](image)

![Fig. 3. Expanded diagram of the path of DC from the NMS (dotted line) indicating chemical reactions at anode and cathode. The contact of the positive battery terminal to the frame of the anesthesia machine (joint A) effectively became connected to the ESU return plate (B) via the electrical grounding of both the anesthesia machine and the ESU. This created an electrolytic cell, with the return plate acting as an anode and the stimulating electrodes (C) acting as cathodes. The path continued through the stimulating electrode wires to the NMS (D). The path to the negative stimulating electrode was completed through the direct connection between the negative output terminal and the negative battery terminal. The positive stimulating electrode was connected via a higher resistance path through the output–current controller. The 9-V batteries completed the circuit.](image)
EXPERIENCED IN DEVICE DESIGN AND FABRICATION. SUCH REVIEW PROCEDURES SHOULD BE DOCUMENTED.

IN THIS CASE THE INSTRUMENT MODIFICATION WAS DESIGNED AND IMPLEMENTED BY A RELATIVELY INEXPERIENCED TECHNICIAN. THE ENGINEERING GROUP'S NORMAL POLICY FOR INTENSE DESIGN REVIEW WAS NOT FOLLOWED. THIS WAS AT LEAST PARTLY ATTRIBUTABLE TO ORGANIZATIONAL CHANGES OCCURRING AMONG THE HOSPITAL'S VARIOUS ENGINEERING DEPARTMENTS AROUND THE TIME OF THE INCIDENT. ALSO, THE MODIFICATION WAS MADE AT A TIME WHEN THE ENGINEERING STAFF WAS SHORHTENDED. THE FREQUENT DEPLETION OF BATTERIES AND REQUIREMENT FOR PROMPT REPLACEMENT PUT EXTRA PRESSURE ON THE ENGINEERING GROUP TO FIND A SOLUTION TO THE PROBLEM.

THE PERSONNEL SHORTAGE COUPLED WITH THE PRESSURE TO MAINTAIN NORMAL PRODUCTIVITY CREATED AN ACCIDENT PRECURSOR OF A FORM DESCRIBED BY PERROW AND LATER BY GABA AS "PRODUCTION PRESSURE." THERE IS NO SIMPLE REMEDY, BUT HAD THE INCREASED RISK OF ACCIDENT BEEN RECOGNIZED, PERHAPS GREATER CAUTION WOULD HAVE BEEN OBSERVED IN DOING ANYTHING OUT OF THE ORDINARY. THAT WOULD BE REASONABLE ADVICE IN ANY SIMILAR CIRCUMSTANCE. IN THIS INSTANCE THE INADEQUATE STAFFING WAS A RESULT OF NORMAL Turnover AND THE REGIONAL SHORTAGE OF BIOMEDICAL EQUIPMENT TECHNICIANS. YET, WITH THE INCREASING PRESSURE ON AMERICAN HOSPITALS TO REDUCE STAFFING AND MAINTAIN PRODUCTIVITY, SIMILAR SITUATIONS CAN BE EXPECTED TO OCCUR MORE FREQUENTLY.

ELECTRICAL SAFETY TESTING: AS PART OF THE ROUTINE PREVENTIVE MAINTENANCE (PERFORMANCE ASSURANCE) OF MEDICAL EQUIPMENT, OUTPUTS OF AN INSTRUMENT WITH EXPOSED CONDUCTIVE SURFACES AND INTENDED FOR CONNECTION TO A PATIENT SHOULD BE TESTED FOR THE PRESENCE OF A DC VOLTAGE VERSUS GROUND. COMMERCIAL TEST INSTRUMENT PERFORM THAT MEASUREMENT BY MEASURING LEAKAGE CURRENT THROUGH AN IMPOSED RESISTIVE LOAD. BECAUSE THE UNMODIFIED NMS IS BATTERY OPERATED, IT IS NOT GROUNDED, AND HAS NO EXPOSED CONDUCTIVE SURFACES, OUR TEST PROCEDURE DID NOT MEASURE LEAKAGE CURRENT BETWEEN THE ELECTRODES AND SOME OTHER REFERENCE. OUR MODIFICATION CREATED AN EXPOSED CONDUCTIVE SURFACE; THEREFORE, OUR TEST PROCEDURE SHOULD HAVE BEEN CHANGED. THIS DETAIL WAS OVERLOOKED. THE ELECTRODE TO GROUND LEAKAGE TEST SHOULD BE PERFORMED ON A BATTERY OPERATED DEVICE WITH AN EXPOSED CONDUCTIVE SURFACE, PARTICULARLY IF THE DEVICE IS MOUNTED INTO A GROUNDED INSTRUMENT CABINET.

THE TEST FOR DC LEAKAGE TO GROUND ALONE WOULD NOT HAVE DETECTED THE FAILURE OF 10 YEARS EARLIER BECAUSE THE BATTERY ISOLATION WAS INTACT AND THERE WAS NO VOLTAGE BETWEEN EITHER OUTPUT AND GROUND. THIS COULD HAVE


INSTRUMENT DESIGN DEFICIENCY: IF THE NMS IS LEFT IN THE "ON" POSITION WHEN NOT IN USE, THE BATTERIES WILL BE DEPLETED IN APPROXIMATELY 7 DAYS. IN MANY NMS DEVICES A "LEADS OFF" ALARM BRINGS ATTENTION TO THE DEVICE BEING ON WHEN NOT CONNECTED TO A PATIENT. THIS IS NOT A FEATURE OF THIS PARTICULAR MODEL, WHICH CONTRIBUTED TO THE NEED FOR FREQUENT BATTERY CHANGES (ABOUT ONCE EVERY 3 WEEKS VS. ONCE EVERY 3-5 MONTHS AS WOULD BE EXPECTED).

THE ELIMINATION OR AMELIORATION OF ANY ONE OF THESE ELEMENTS INVOLVED IN THE INJURY PROBABLY WOULD HAVE BEEN SUFFICIENT TO PREVENT IT FROM GOING TO COMPLETION. THE INJURY ALSO SERVES AS A REMINDER THAT MONITORING CARRIES WITH IT A DEGREE OF RISK. IRONICALLY, NEUROMUSCULAR MONITORING IS NOT ROUTINE DURING CARDIAC PROCEDURES GIVEN THAT PARALYSIS IS MAINTAINED AFTER THE OPERATION. IN THIS CASE THE ANESTHESIA RESIDENT RAISED A QUESTION REGARDING THE USE OF LARGE DOSES OF NEUROMUSCULAR BLOCKING AGENTS IN CONJUNCTION WITH INDUCED HYPOTHERMIA. IT WAS TO EXAMINE THAT QUESTION THAT THE DEVICE WAS PLACED.

INCIDENT INVESTIGATION AND RISK MANAGEMENT

ALTHOUGH THE DIRECT CAUSE OF THE INCIDENT WAS EVENTUALLY DISCERNED, SOME OF THE STEPS TAKEN IMMEDIATELY FOLLOWING THIS INCIDENT MAY HAVE THROTTLED A REVEALING INVESTIGATION. IN PART PROMPTED BY THIS INCIDENT, THE RISK MANAGEMENT GROUP OF THE HARVARD ANESTHESIA DEPARTMENTS CREATED A GUIDELINE FOR ACTION FOLLOWING AN ADVERSE ANESTHESIA EVENT (MANUSCRIPT IN PREPARATION; COPIES OF THE PROTOCOL AVAILABLE FROM THE FIRST AUTHOR). AMONG OTHER THINGS THE GUIDELINE DESCRIBES HOW TO HANDLE EQUIPMENT IMMEDIATELY FOLLOWING A SUSPECTED PATIENT INJURY. IN THIS CASE THE ANESTHESIA MACHINE WAS APPROPRIATELY SEQUESTRATED, BUT THE NMS CONTROLS SHOULD NOT HAVE BEEN ALTERED NOR SHOULD THE DEVICE HAVE BEEN REMOVED FROM THE CHASSIS. EQUIPMENT THAT MAY HAVE BEEN CAUSALLY RELATED TO THE INJURY, E.G., THE ELECTROSURGICAL GROUNDING PAD AND THE NMS ELECTRODES, WAS INAPPROPRIATELY DISCARDED. THAT COULD HAVE
been important had this event been an ESU-related burn. The investigation should not have proceeded until the hospital risk manager or safety officer was contacted. Furthermore, had any manufacturer’s device been potentially implicated in the injury, the examination of equipment should not have been conducted without careful documentation and the presence of a disinterested observer and perhaps a representative of the manufacturer. Further suggestions for conducting investigations of device-related injuries are available.†

The issues raised by this incident apply to almost any medical specialty in which devices are used. Modifications must be undertaken with an appreciation for subtle injury mechanisms and under thorough supervision by qualified clinical engineers. Although this incident resulted from modification of a device, similar incidents can and have occurred with unaltered devices. To guard against either case, equipment inspection procedures must be capable of revealing potentially injurious faults. Hospitals should be prepared to investigate incidents and injuries using methods and procedures that will reveal the injury mechanism. Serious incidents must lead to corrective actions. The effects of production pressure should be recognized and compensatory mechanisms invoked to the extent possible.


References