Temperature Threshold for Burn Injury: An Oximeter Safety Study

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Pulse oximeters have become essential devices for evaluating and monitoring patient oxygenation. The probe emits a small amount of heat into the skin in the process of signal detection. Regulations set by the Food and Drug Administration currently limit the maximum allowable temperature of an oximeter probe to 41°C. As a result of the prolonged exposure of extremities to these devices, we sought to determine the actual temperature threshold for burn injury in patients. Eighteen patients undergoing surgery for removal of redundant skin (abdominoplasty, breast reduction) consented to the application of a temperature-controlled custom probe with four light-emitting diodes that had temperatures set randomly at the expected threshold for burn injury (42.5°C, 43°C, 43.5°C, and 44°C). The probe was left in place for 8 hours (or less if significant pain was noted). The sites covered by the probes were then checked for signs of injury. On the next day, the redundant skin was removed as a scheduled procedure, and histopathology was performed to detect the extent of burn injury. The study was approved by the local institutional research board. Two patients were excluded because of technical problems with the probe, one of whom had the probe turned off because of pain. The only observed sign of injury was either erythema or a superficial blister that was usually unobservable or slightly red at operation. These subtle signs of a burn were noted in one patient at 43°C, four at 43.5°C, and nine at 44°C. No burns were noted in two patients. Minimal or no signs of injury frequently were noted by histopathology. Pulse oximeter probes are safe up to a temperature of 43°C for at least 8 hours in well-perfused skin. Above that temperature, there is a risk of burn injury. Performing temperature threshold tests in redundant skin that is planned for excision is a potential method for testing the safety of devices or materials. (J Burn Care Rehabil 2004;25:411–415)
several reasons. The risk for any burn injury is related to four factors: temperature of the heat source, duration of contact with the heat, blood supply to the contacting skin, and the thickness of the skin.1 Obviously, the risk for burn with oximeter exposure is increased as the threshold temperature for burn injury is approached. Prolonged and continuous exposure also increases the risk. The relationship between burn injury and the duration of heat exposure is best exemplified by burns that result from prolonged exposure to heating pads. Elderly patients will often use heating pads that are heated to around 120°F for hours while they sleep. If left in contact for too long, deep burns can occur. The same risk may exist for the prolonged use of oximeters. The probes frequently are placed on the distal extremities, where blood flow is often reduced. For example, patients with shock will have decreased distal extremity blood flow because of normal compensatory mechanisms. Circulation to the distal extremities is the first area of perfusion to be sacrificed in shock. In addition, decreased blood flow to the distal extremities occurs in people who are cold. After surgery, many patients are hypothermic, with resulting vasoconstriction and decreased circulation to the extremities. Even the mere process of wrapping the probe around the finger may lead to decreased blood flow because of increased pressure as the result of a tourniquet-like effect. Finally, the skin in the fingers may be thinner than other areas of the body, increasing the risk for a more severe injury. Clearly, all factors that may increase the risk of burn injury are present with the use of oximeter probes.

To test the safety of the oximeter probes in patients, we designed a study in patients that would minimize any risk of long-term scarring. After obtaining consent, a specially designed probe with four LEDs that had temperatures set to around the expected threshold for burn injury (42.5°C, 43°C, 43.5°C, and 44°C; Figure 1), controlled by a specially designed LED temperature controller. The temperature of each LED was placed in different and random positions so that the patient did not know the temperature. The probe was placed at the planned area of excised normal skin. The exact location of each LED in the probe was marked on the skin by indelible marker. The probe was left in place for 8 hours (or less if undesirable pain was noted). After completion of the study, the LED sites covered by the probe were then checked for signs of injury. On the next day (18–24 hours later), the redundant skin was removed as a scheduled procedure and the site was fixed in formalin for histologic evaluation by a pathologist who was blinded to the temperature of each probe. The delay in removal of surgery for removal of redundant skin (abdominoplasty, breast reduction) consented to the application of a specially designed probe with four LEDs that had temperatures set to around the expected threshold for burn injury (42.5°C, 43°C, 43.5°C, and 44°C; Figure 1), controlled by a specially designed LED temperature controller. The temperature of each LED was placed in different and random positions so that the patient did not know the temperature. The probe was placed at the planned area of excised normal skin. The exact location of each LED in the probe was marked on the skin by indelible marker. The probe was left in place for 8 hours (or less if undesirable pain was noted). 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On the next day (18–24 hours later), the redundant skin was removed as a scheduled procedure and the site was fixed in formalin for histologic evaluation by a pathologist who was blinded to the temperature of each probe. The delay in removal of
skin was for the convenience of the study patients who could not participate in a study during the night before surgery.

**Probe Design**

The device that was attached to the patients included four modified Nellcor oximeter LED assemblies. A standard LED assembly consists of a copper lead frame, two LED chips, and encapsulants. The assembly that is attached to the patient is a 4-mm × 4.5-mm rectangle that is 1.5 mm thick. Unlike an oximeter sensor, an E-type thermocouple that is calibrated and lot-controlled is added to this assembly. The thermocouple is attached and encapsulated so that it is on the surface of the LED package between the red LED (used in this study to apply heat) and the skin of the patient. The thermocouple measures both the temperature applied to the skin and is used to provide the feedback to control the temperature.

The four LED assemblies are mounted between two adhesive tapes of the types used to manufacture the Nellcor D-25 series of oximeter sensors. Unlike oximeter sensors, these LED assemblies are placed so that they protrude thru holes in the bandaged assemblies. This design is used so that there are no interfering materials for the transfer of heat to the subject. There also are holes in the bandage assemblies for putting reference marks on the skin to find the burn sites. The entire assembly is built on a fixture so that each one is dimensionally identical to each other. The temperature of each probe is then randomly assigned one of the temperatures used in the study.

Because pulse oximeters are not capable of delivering enough power to heat the LED assemblies to the study temperatures, nor are they capable of controlling probe temperature, a specially designed LED temperature controller was developed. This computer operated temperature controller is capable of delivering to the LED five times the power available from a Nellcor pulse oximeter and controls probe temperature to within 0.1°C.

**RESULTS**

The temperature threshold test was well tolerated by the subjects. Two patients were excluded because of technical problems with probe construction, one of whom had the probe turned off before the end of the 8 hours period because of pain. For all of the patients, the only observed sign of injury was either erythema or a superficial blister at one or more of the treatment sites. These subtle signs of a burn injury were noted in one site at 43°C, four at 43.5°C, and nine at 44°C (Table 1). No burns were noted in two patients. We found that healing had already begun by the next day, suggesting that the burns were quite superficial. These burns were frequently unobservable or slightly red at operation 16 to 24 hours later (Figure 2).

Minimal or no signs of injury frequently were noted by histology for the first few patients. As a matter of fact, it became difficult for pathologists to detect the burn injury at approximately 24 hours after the probes were placed. Because of the lack of significant findings, pathologic examination of the sites was

<table>
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<th>Temperature</th>
<th>42.5°C</th>
<th>43.0°C</th>
<th>43.5°C</th>
<th>44°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of burns</td>
<td>0</td>
<td>1</td>
<td>4</td>
<td>9</td>
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Table 1. Number of Superficial Burns That Resulted Beneath Each Probe Light-emitting Diode With the Designated Temperature Within 8 hours

**Figure 2.** Typical appearance of the skin after removal of the probes after 8 hours of exposure (top). The redness or slight blistering was very superficial. At 24 hours (bottom), it is difficult to observe any burn other than a slight erythema.
DISCUSSION

There have been several studies in the past that have tried to determine the threshold of burn injury. Many of these studies were performed nearly a half-century ago. Their detailed studies demonstrated a clear relationship between temperature and duration of contact. The most classic study, by Moritz and Henriquez,\(^1\) is still commonly quoted during legal proceedings that discuss civil or criminal burn cases. Their study also is quoted in prevention efforts to minimize scald injuries from water heaters. Henriquez and Moritz, of the Department of Legal Medicine at Harvard Medical School, were asked by the Office of Scientific Research and the Medical Division of the Chemical Warfare Service to perform the studies. Their initial studies\(^2\) described the physics of transfer of heat to tissues. Because porcine skin is similar to humans, the preliminary studies were performed in pigs to measure the temperature produced beneath the skin. They then developed a device that would deliver a continuous flow of hot water to the surface of the pig. The device consisted of a brass cup with an open area that would expose the skin to the temperature-controlled water. The cup had piping that would pump the water continuously to the skin. They developed the now-classic plot showing the relationship between the duration of contact and the temperature required for second and third degree burns in pigs.

They next exposed the chests or forearms of volunteers to multiple exposures to the same device.\(^1\) It was never specified who the volunteers were or if they gave consent. They noted that pain was noted relatively quickly between 47.5°C and 48.5°C. They also stated that burns would occur at 47°C without pain. The plot of duration of contact and temperature threshold for a burn injury was identical to that of the pig. They followed patients for 8 hours and found that 43°C was required to create a burn. Others have reached the same conclusion that 43°C is the safe temperature for prolonged exposure to a hot object.\(^3\)–\(^5\) Diller\(^4\) published two studies that examined the time required for a heating pad to create a burn. His evaluation, using projections of published studies, suggested that at 40°C it would require between \(10^4\) and \(10^5\) seconds (2.8–28 hours) for a first-degree burn, \(5.5 \times 10^6\) to \(10^9\) seconds (15.3–153 hours) for a second degree burn, and \(2.5 \times 10^8\) to >\(10^9\) seconds (69,444 to >280,000 hours) for a third-degree burn. He extrapolated that it would require 12 to 20 hours for a heating pad to create a second-degree burn.\(^5\) One must wonder whether extrapolated data would apply to risk for injury. Clearly, there is a temperature where no injury would occur.

There are other factors that one must take into account for risk of burn injury after a prolonged exposure to a hot surface. Our study was performed in normal adult tissues with an adequate blood supply. The same safety profile may not exist for neonates or for patients with ischemic tissue. Mohrenschlager et al\(^6\) described two cases of neonates sustaining burns from fabric-covered warming bottles that were placed over their skin for hours. They suggested that the safe temperature would be around 42°C. The question of whether the risk of burn injury was altered in ischemic tissue was addressed by Moritz and Henriquez.\(^1\) In their classic article, they placed their scalding device over pigs with the contacting pressure increased to 80 mm Hg to halt dermal capillary flow. They found that the threshold for injury was not altered. Whether this study answers the question of whether the risk of injury to ischemic tissues is altered is unclear. One would expect that blood flow would dissipate heat and would protect tissues to some degree.

Finally, a comment should be made about the study design of using human tissues destined for removal. It is difficult to perform human studies that would have the potential for leaving a scar in patients. Our study patients tended to have less concerns for scars that would be created in tissues that were about to be excised. Obviously, none of the subjects wanted to suffer undue pain, so the study was stopped as soon as subjects noted significant discomfort. Only one of our patients found the pain to be intolerable. Most tolerated the procedure without problems.

This type of study design also could be used for patients about to undergo amputations for ischemia or infection. Our initial plan was to include patients with ischemic tissues in this study. Clearly, ischemic tissues are at greater risk for burn injury than healthy abdominal or breast tissue. In addition, there may be differences in the degree of keratinization in ischemic tissues. Critically ill patients often are being treated with pressors, which may exacerbate perfusion problems. The hope was to include patients scheduled for amputations because ischemia or infection in the study. The probes would be placed on toes or fingers to mimic the clinical situation. Unfortunately, collaborators felt that it would be too emotionally difficult to include these patients in such a study, so they declined participation. The performance of such a study would lead to helpful information in the design of safer but more accurate probes.
CONCLUSION

Pulse oximeter probes are safe in healthy, well-perfused trunk skin up to a temperature of 43°C for at least 8 hours. At temperatures greater than this, there is a risk of burn injury. The temperature threshold for burning in thinner skin or poorly perfused skin still needs to be determined. Performing temperature threshold tests in redundant skin that is planned for excision is a potential method for testing the safety of devices or materials.

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REFERENCES