An In vitro Quantification of Pressures Exerted by Earlobe Pulse Oximeter Probes Following Reports of Device-related Pressure Ulcers in ICU Patients

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Abstract

The earlobe often is used to monitor perfusion when pulse oximeter signal quality is impaired in the fingers and toes. Prompted by intermittent occurrences of roughly circular earlobe pressure ulcers among patients in intensive care units, a convenience sample of seven calibrated pulse oximeter probes was used to quantify earlobe pressure exerted by these devices in vitro. All were tested twice with an electronic load cell, a strain gauge with a transducer that transforms the measured force into a readable numerical signal. The probe was clipped to the load cell just as it is clipped to the earlobe in the clinical setting. The probes exerted an average of 0.24 lb (SD 0.6) of force over an area of 0.3 square inches, equal to an average of 20.7 mm Hg (SD 0.6) pressure on tissue. This value exceeds some empirically derived values of capillary perfusion pressure. The occurrence of device-related pressure ulcers, as well pressure ulcers on the ears, has been documented, but little is known about device-related earlobe pressure ulcers or the actual pressure exerted by these devices. Additional in vitro studies are needed to quantify the pressures exerted by these and other probes, and future prevalence and incidence studies should include more detailed pressure ulcer location and device use documentation. Until more is known about the possible role of these devices in the development of pressure ulcers, clinicians should be cognizant of their potential for causing pressure ulcers, particularly in patients whose conditions can compromise skin integrity.

Keywords: pressure ulcers, earlobe, in vitro, pulse oximetry


Several instances of earlobe pressure ulcers that occurred in the author’s institution prompted a search of literature relevant to the issue. This search revealed little documentation of the occurrence of device-related earlobe pressure ulcers and no data on the degree of pressure exerted by earlobe pulse oximetry probes. Quarterly pressure ulcer prevalence surveys were performed at the author’s institution, but locations other than the sacrum, heels, ischium, knees, elbows, and occiput were simply recorded as “other.” Nonetheless, the problem of earlobe pressure ulcers had been documented with photographs and anecdotally acknowledged by critical care nurses and wound, ostomy, continence nurses. Consultation with clinical nurse specialists in neighboring institutions showed that earlobe pressure ulcers had been encountered in other hospitals. Investigation of one potential cause of these preventable pressure ulcers, excessive pressure by earlobe pulse oximeter probes, followed. This is a report of that study.

Literature Review

Pulse oximetry. Clinical use of pulse oximetry dates to the 1970s. Pulse oximetry relies on the fact that deoxygenated blood absorbs more light than oxygenated blood at selected wavelengths. Pulse oximeters calculate oxygen saturation from the ratio of absorption of two wavelengths of light (red and infrared) by the tissue. Measurement of light absorption is achieved optically, by
either transmittance or reflectance spectroscopy. Both methods require a light source and a detector.

In transmittance spectroscopy, as in finger pulse oximetry, the light source is positioned opposite the detector so light passes through the tissue. In reflectance spectroscopy, used with forehead pulse oximeter probes, the light source and detector are positioned side-by-side. Light is reflected off underlying bone, and an algorithm calculates oxygen saturation from the reflected light. In a comparison study of desaturation and resaturation rates, forehead reflectance pulse oximeters were shown to respond more quickly to changes in oxygen saturation than finger transmittance probes, but either the probe location or the type of oximeter may account for this difference. Other researchers have shown similar performance between the two types of oximeters in a comparison study in vascular surgery patients (N = 20).

Because reflectance pulse oximetry was more recently developed, many intensive care units (ICUs) still employ transmittance probes. Although fingers and toes are most often used for pulse oximetry, nurses choose the earlobe for monitoring when poor perfusion impairs the quality of the signal from fingers or toes.

Different types of pulse oximeters, while employing comparable technology, require different probes placed in different locations; these probes may cause injury. Skin and soft tissue complications have been associated with pulse oximeter probes. Case reports document finger injury and one earlobe pressure ulcer from pulse oximetry probes. One earlobe pulse oximetry study conducted to compare the accuracy and response characteristics of two earlobe devices (N = 10) warned of the potential of distorted readings if excessive spring tension decreased blood flow past the sensor. However, most of these reports of injury are at least two decades old, and newer probes may exert less pressure on tissues because devices have been redesigned.

Pressure ulcers. Texts and reviews of the literature state that pressure ulcers occur from a combination of pressure and time. An integrative review of human, animal, and in vitro studies concluded it takes 1 to 4 hours of excessive pressure, typically over a bony prominence, to cause a pressure ulcer. Although theory indicates that higher pressures are physiologically tolerated for shorter time periods, the precise pressures required to occlude blood flow and the length of ischemic time required to cause a pressure ulcer in a given situation depend upon many factors, including characteristics of the host and the nature of the tissue under pressure. In applying this knowledge to the critically ill population, it is also important to consider other factors that influence tissue tolerance, such as sympathomimetic drugs that reduce peripheral blood flow, hypoxemia, malnutrition, and overall frailty.

Capillary pressure. Capillary pressure refers to the mean pressure exerted on capillary walls and exists on a gradient from the arterial to the venous end of the capillary loop. Ischemia can occur when capillary pressure is exceeded by external compressive forces, occluding vessels.

According to numerous studies, measures of capillary pressure vary considerably. In 1930, Landis published a landmark study of capillary pressure in the fingernail beds of healthy and hospitalized adults, using a micropipette connected to a manometer to cannulate nail bed capillaries under microscopy. A manometer was used to measure pressure with the hand at the level of the manubrium in recumbent study participants. This study revealed average values of 32 mm Hg, 20 mm Hg, and 12 mm Hg in the arterial, mid-capillary, and venous limbs of the capillary loop, respectively. The highest of these values is a commonly accepted value, although actual values ranged from 6 mm Hg to 48 mm Hg, with lower pressures occurring toward the venous end of the capillary loop.

The Landis study was replicated by Levick et al on the fingers and toes of two healthy males, yielding capillary pressures of 7 cm H₂O to 70 cm H₂O (5.15 mm Hg to 51.5 mm Hg) with the limbs at heart level. The investigators attributed the range of pressures to variability in skin temperatures, arterial blood pressures, and venous pressures. Mahler et al secured 33 systolic and diastolic pressure measurements in the fingernail folds of 14 healthy adults (five female, nine male), obtaining values that ranged from 11 mm Hg to 71 mm Hg. The method, used for the first time in this study, permitted dynamic pressure measurement, so changes throughout the cardiac cycle could be seen. Hands were held at heart level. The authors concluded that capillary perfusion is pulsatile and “subject to remarkable fluctuations” in both limbs of the capillary loop. A third, more re-

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Key Points

- Although pulse oximeters are widely used, the amount of pressure they exert on patient skin is unknown.
- Following reports of circular wounds developing on the earlobes of patients in the ICU, the authors conducted an in vitro evaluation of some of the probes used in the hospital.
- Although it is not possible to establish a correlation between the measured pressures and the occurrence of pressure ulcers, study results suggest capillary perfusion may be compromised by these devices.
- Until more is known, the author concludes clinicians should rotate pulse oximeter sites routinely, assess tissue integrity before initiating pulse oximetry at any site, and never place a pulse oximetry probe on damaged tissue.
cent study employed capillaroscopy (cannulation of nail bed capillaries under microscopy) to measure capillary pressure in six women and two men during isometric arm exercises. An exercise-induced increase in arterial blood pressure occurred, but no increase occurred in mean capillary pressure, which changed very little, from 18 mm Hg to 19 mm Hg from baseline with exercise. The largest individual difference observed was -3.5 mm Hg, leading the investigators to conclude that autoregulatory mechanisms blunt the effect of pressure ulcer causation has been established, lower pressures are better tolerated for longer periods and high-risk people, such as patients in ICUs, probably tolerate less pressure on tissues for a shorter time than healthy individuals. Thus, it is useful to quantify the degree of pressure exerted by healthcare devices on vulnerable tissues to inform pressure ulcer prevention practices.

Prompted by intermittent occurrences of roughly circular earlobe pressure ulcers, such as that shown in Figure 1, in the four adult ICUs at the author’s institution, a study was conducted to quantify the pressure exerted by earlobe pulse oximetry probes for comparison to the existing literature on capillary pressure to determine if the probe design might have contributed to the development of these pressure ulcers.

**Figure 1. Earlobe pressure ulcer in an ICU patient.**

**Methods**

A convenience sample of seven Masimo Corporation (Irvine, CA) SET (Signal Extraction Technology) LNCS TC-1 earlobe oximetry probes was obtained from among the probes in active use in the Trauma ICU at the study institution. Measurement validity was ensured by calibration with weights standardized to National Institute of Standards and Technology specifications.

The Masimo SET LNCS TC-1 earlobe probe has a slightly raised circle inside the tip of each arm where the probe contacts the skin. The probe contacts both sides of the earlobe, using the pressure exerted to keep the probe in place. The area of the region of contact was calculated. Pressure was calculated by dividing force by area to calculate pounds per square inch (PSI) and converting to mm Hg using the formula: PSI x 51.7 = mm Hg.

**Procedure.** The force exerted by each probe was tested twice with an electronic load cell, a strain gauge with a transducer that transforms the measured force into a readable numerical signal. The probe was clipped to the load cell just as it is clipped to the earlobe in the clinical setting. Two researchers waited a few seconds until a stable reading was achieved and then agreed on the value before it was recorded. Each probe was retested before the next probe was tested. The circular area inside each arm of the probe that contacted the earlobe was calculated at 0.3 square inches (total tissue contact area = 0.6 square inches).

**Data.** Two pressure readings from each probe were recorded. Mean force was calculated from the 14 force readings, and the reliability of the force measurement was assessed by interclass correlation, an indication of the reproducibility of the force readings. Statistical significance was determined using SPSS version 19 (IBM Corp, Somers, NY).

**Results**

There was variability in the force readings of 0.1 to 0.3 lb. This may be partially attributable to a limitation of the instrument, which measures force only to the first decimal place. Two of the seven paired force measurements differed between measurement 1 and measurement 2 (see Table 1). Force measurements were reliable; the intraclass correlation between the paired values was 0.81 (F = 5.2, df = 6, P = .024). The mean force exerted on the load cell was 0.24 lb (SD .06). Mean pressure exerted by the probes equaled 0.4 PSI, or 20.7 mm Hg (95% confidence interval CI = 18.1 – 24.1).

**Discussion**

Device-related pressure ulcers pose a substantial risk to patient safety. In a secondary analysis of eight sets of quarterly surveillance data from a large, single-hospital study (N = 2,178), 34.5% of hospital-acquired pressure ulcers were attributed to healthcare devices, although the incidence of pressure ulcers linked to specific devices was not documented. A large (N =
multinational prevalence study conducted in 2008 and 2009 identified the ear as the most common anatomical location for device-related pressure ulcers, but the devices implicated in causing these ulcers, and where on the ear they occurred, were not specified. The study examined long-term acute, acute, and rehabilitation settings and did not differentiate device-related PU rates among these sites.

In low peripheral perfusion states, such as shock, hypothermia, and peripheral vascular disease, a central location often is required for accurate pulse oximetry. The earlobe is frequently the central location of choice for use with transmittance oximeters, and earlobe clip-on pulse oximetry probes are commercially available for this purpose. The pressure exerted by the sample of probes in this study exceeded some estimates of capillary perfusion pressure found in the literature, but not all. This may help explain why some patients do not incur harm from use of earlobe pulse oximetry probes. However, comparison of these results to different probes is not possible at this time due to the dearth of published literature on the subject. Factors that decrease capillary perfusion pressure, such as vascular disease, low cardiac output, and vertical distance from the heart, may put certain patients at greater risk. Alternatives to ear clip-style probes may be needed for continuous central pulse oximetry monitoring to prevent earlobe pressure ulcers in vulnerable people. Avoidance of these device-related pressure ulcers may be a rationale for using reflectance pulse oximetry versus transmittance pulse oximetry systems for continuous monitoring in low-perfusion states.

Emphasis on prevention of pressure ulcers from organizations such as the National Database of Nursing Quality Indicators and The Joint Commission, coupled with reduced reimbursement for higher-stage pressure ulcers from the Centers for Medicare and Medicaid Services, provide hospitals with powerful incentives to reduce pressure ulcer incidence. In ICUs, the need for accurate oxygen saturation data to guide therapy provides another incentive to eliminate these preventable pressure ulcers. Because damaged tissue causes inaccurate

### Table 1. Force (lb) exerted by each probe

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<th>Probe number</th>
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pulse oximeter readings, the need for accurate oxygen saturation data to guide therapy in ICUs provides another incentive to eliminate these preventable pressure ulcers.

Alternatives are clearly required in the case of existing tissue damage to the earlobe because erythema in damaged tissue alters the absorption of the red light used in both transmittance and reflectance pulse oximetry, rendering oxygen saturation data inaccurate. Some earlobe pulse oximetry probes are designed with a lightweight arm that extends over the ear, so the probe is not held in place by pressure on the earlobe. This design may be superior in preventing pressure ulcers with transmittance pulse oximetry, but it has not been tested in this fashion.

Because of the potential risk for pressure ulcers due to pulse oximeter probes, and the risk of obtaining inaccurate oxygen saturation values from erythematous tissue, clinicians should rotate pulse oximeter sites routinely, assess tissue integrity before initiating pulse oximetry at any site, and never place a pulse oximetry probe on damaged tissue.

Further research to evaluate the association between earlobe pulse oximeters and device-related pressure ulcers is needed. Nurses conducting pressure ulcer prevalence surveys should note the exact location of pressure ulcers and indicate whether a device was used. Quality improvement efforts should be undertaken to track the incidence of device-related pressure ulcers, identify their sources, and consider the adoption of alternative devices if warranted. Future studies of device-related pressure ulcers should document anatomical location, devices used, and traditional pressure ulcer risk factors such as skin moisture, mobility, and nutrition.

Limitations

The applicability of the study findings to clinical practice is limited by the in vitro study design and small sample size. It is likely that different earlobe probes exert differing degrees of pressure on tissue; this study examined only one type of device in an experimental setting. Although the length of time each probe had been in use clinically is not known, the sample was drawn from probes in use in an ICU, and thus represents devices with some degree of clinical use history. This could have improved the generalizability of the findings, as spring tension likely declines slightly with use over time.

The study does not show causality, only that these devices have the potential to exert pressure that may cause injury. Clinical studies are needed to demonstrate a causal link between the use of earlobe pulse oximeter probes and pressure ulcers.

Conclusion

This study investigated the degree of pressure exerted on an electronic load cell by a convenience sample of earlobe pulse oximetry probes used in the ICUs at the study institution. Earlobe probes were shown to exert a mean pressure of 20.7 mm Hg, a value in excess of some empirically derived values of capillary pressure found in the literature. ICU patients are at high risk for pressure ulcers, particularly patients experiencing low-perfusion states in whom ear pulse oximetry often is employed. Until research has shown that these devices do not present a risk for pressure ulcer development, nursing measures, such as rotation of pulse oximetry probe site, regular skin assessment, and avoiding placement on damaged tissue, should be employed.

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References