TYMPANIC-BASED CORE TEMPERATURE MEASUREMENT IN RELATION TO THERMOMETER AND TECHNIQUE

by

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ABSTRACT

Title: Tympanic-based core temperature measurement in relation to thermometer and technique

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Purpose:

To make appropriate decisions in their practice, clinicians need to know the effect that variations in instrument and measurement technique have on tympanic-based temperatures and how tympanic-based temperatures differ from temperatures taken at traditional sites. The purpose of this study was twofold: (a) to compare infrared tympanic-based estimates of core temperature measured using different sides (left versus right), instruments (IVAC® CORE•CHECK™ versus FirstTemp® Genius® thermometer), and techniques (ear tug versus no ear tug); and (b) to compare tympanic-based temperature with a concurrent oral temperature.

Methods:

The subjects were a convenience sample of 50 general medical-surgical inpatients from 6 clinical units, 27 males and 23 females, ranging in age from 20 to 96 years (mean age 63.1 ± 16.9 years). Data were obtained over a two week period at a 188-bed community hospital. Tympanic-based temperatures were measured with two different infrared thermometers, both used in core mode. Oral temperatures were measured with a predictive electronic thermometer before and after the tympanic-based measurements. Each subject had four tympanic-based measurements taken with each thermometer, two on each side, one using the ear tug method and one without, for a total of eight tympanic-based temperature measurements taken in random order.

Results:

An analysis of variance was performed to examine the effect of the 3 within subjects factors of side, instrument, and technique. Mean temperatures were found to be 0.11°C higher in the left ear than in the right ear ($p = .023$) and 0.10°C higher with the ear in its natural position than when the ear tug was used ($p < .001$). Neither value was considered clinically significant. The Genius® thermometer provided mean temperature values that were 0.69°C higher than those obtained with the CORE•CHECK™ thermometer, a difference considered both statistically ($p < .001$) and clinically significant. The greatest impact on tympanic-based temperature values resulted from the choice of instrument and not whether the temperature was taken in a given ear or with the tug technique used.

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CHAPTER I

INTRODUCTION

Nurses routinely monitor body temperature to provide information regarding the patient's health status. As early as 1918, nursing education included temperature monitoring, and variations in temperature were considered a disturbance in health (Goodnow, 1918). Fever, the most common alteration in body temperature, usually indicates the presence of infection, a major cause of illness and death in hospitalized patients. Accurate temperature measurement requires an appropriate site, instrument, and technique in order for fever, or other alterations in temperature to be detected and appropriate therapies initiated.

New technologies in measuring body temperature are frequently introduced into clinical settings. The mercury thermometer of yesterday is no longer the primary instrument. A variety of electronic thermometers is available for intermittent as well as continuous temperature monitoring at numerous sites. These include the mouth, rectum, axilla, pulmonary artery, bladder, esophagus, nasopharynx, and ear canal. The multitude of choices related to temperature measurement requires that nurses at the bedside understand what they are measuring, how to interpret the values they obtain, and what methods provide the most reliable readings.

Statement of the Problem

The newest addition to thermometer technology is the infrared tympanic thermometer, first introduced in 1986. Infrared thermometers provide a temperature measurement in the external ear canal. Five manufacturers currently market infrared thermometers, involving several different modes of operation. For example, some provide a computed estimate of ear canal temperature, while others are programmed to provide "tympanic-based" estimates of core, oral, or rectal temperature based on comparison data from an adult sample.

This new technology offers several important advantages: it is noninvasive, can be used with a variety of patients, and provides rapid readings with values displayed in a few seconds. It also does not require mucous membrane contact, an advantage for infection control. However, the arrival of infrared thermometers also poses new problems for nurses. Tympanic thermometer manufacturers use different equations to estimate the various temperature sites. In addition, recommendations for measurement technique vary. Some manufacturers recommend tugging on the ear to straighten the ear canal, others do not, and still another requires a circular movement of the thermometer in order to obtain a reading. The lack of uniformity in calculating values and measurement technique creates confusion for the practitioner and may promote a lack of confidence in the obtained temperature values. Research is needed to evaluate the accuracy and comparability of infrared tympanic-based measurements, including the effect of variations in instrument and measurement technique in an adult population.

Purpose

The purpose of this study is twofold: (a) to compare infrared tympanic-based estimates of core temperature measured using different sides (right versus left), instruments (IVAC® CORE•CHECK™ versus FirstTemp® Genius® thermometer), and techniques (ear tug versus no ear tug); and (b) to compare tympanic-based temperature with a concurrent oral temperature obtained with an IVAC® TEMP•PLUS® II predictive electronic thermometer. Four specific research questions were asked:

1. Are tympanic-based temperatures measured in the right ear different from those measured in the left ear?
2. Are tympanic-based temperatures measured with the IVAC® CORE•CHECK™ thermometer different from those measured with the FirstTemp® Genius® thermometer?
3. Are tympanic-based temperatures measured with the ear tug technique different from those measured when it is not used?
4. Are tympanic-based temperatures different from oral temperatures?

Significance to Nursing

Nurses make clinical decisions based on the information obtained from body temperature measurement. The knowledge gained from this study could help to identify consistencies or differences in the new technology of infrared tympanic-based temperature measurement. With more accurate information, better clinical decisions could be made. Clinicians must understand the effect that variations in instrument and measurement technique have on tympanic-based temperature measurement and how tympanic-based temperatures differ from those taken at traditional sites.

CHAPTER II

CONCEPTUAL FRAMEWORK AND REVIEW OF LITERATURE

This chapter examines issues related to infrared ear thermometry. This includes the concept of core temperature and sites for temperature measurement. Further exploration of the tympanic site includes anatomy, direct contact and non-direct contact tympanic based temperature measurement, and variables influencing tympanic-based temperature measurement.

Concept of Core Temperature

Clinical temperature measurement at any given site uses core temperature as the reference point. Core temperature can be defined as "a value which is representative of the majority of the most important metabolically active tissues of the body" ("Where to Measure," 1988, p. 1318). Obtaining a core temperature, or a reasonably close estimate, to track trends in core temperature is important since it "provides an index of the metabolic state and a monitor of the thermoregulatory set point in inflammatory states" (Lilly, Boland, & Zekan, 1980, p. 742). The arterial blood flow that supplies the major organs of the body core, including the heart and brain, is considered to be at a nearly uniform temperature (Brengelmann, 1987). Temperatures obtained in or near these organs or their arterial blood supply are thought to be accurate reflections of core temperature.

Three thermal zones have been described: the superficial, intermediate, and core zones (Soukup, 1988). These three zones are pictured in Figure 1. The superficial zone includes the skin. This area is farthest from the core organs and can be

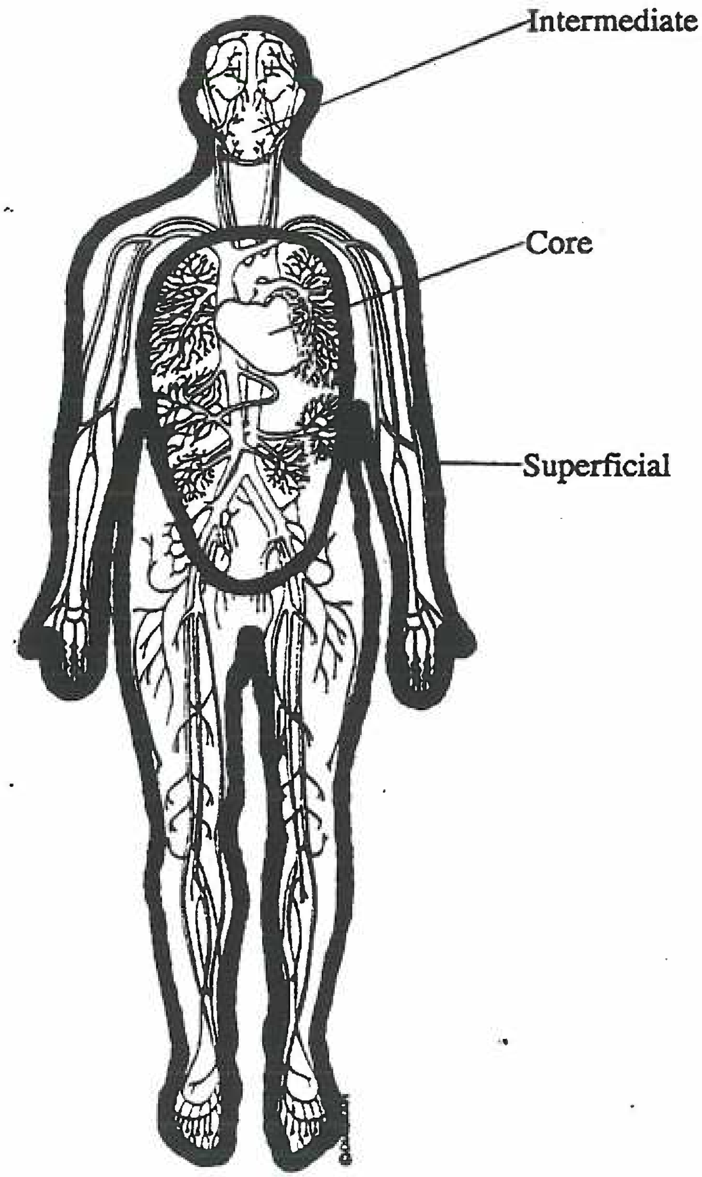


Figure 1. Thermal zones as they relate to core temperature.

influenced by a variety of individual and environmental conditions. The skin surface is considered to provide the least accurate representation of core temperature. Commonly used superficial sites include the axilla and forehead. The intermediate zone is comprised of those sites that fall between the superficial and core zones. Commonly used intermediate measurement sites include the oral cavity and rectum. The tympanic membrane is similar to these sites since they are protected partly from the external environment. Although these are often considered core temperature sites, in reality they are on the margins of the body core (Brengelmann, 1989). The core temperature zone includes the body's inner organs. Pulmonary artery (PA) temperature is considered to be the best "core" representation (Brengelmann, 1989).

Sites for Temperature Measurement

The optimum site used for routine temperature monitoring should accurately reflect core temperature, be convenient, and atraumatic. PA, oral, and tympanic sites will be reviewed because they provide good reflections of core temperature and currently are available to the practitioner.

Pulmonary Artery Site

Temperature in the pulmonary artery is nearly identical to that of the arterial blood supplying the organs of the body core (Brengelmann, 1987). Therefore, the mixed venous blood of the pulmonary artery is the optimal site for measuring core temperature. However, measurements of PA temperature are available only when the patient has a Swan-Ganz catheter with temperature measuring capability that has been inserted for hemodynamic monitoring. Because of the invasive nature of hemodynamic monitoring, PA temperature measurement is not available to the nurse caring for general medical-surgical patients. An alternate, but equivalent site is required for this clinical population.

Oral Site

The oral temperature site is most commonly used in clinical practice. Brengelmann (1987) reviewed the literature regarding oral temperature accuracy and concluded that oral temperature is a reasonable estimate of core temperature, and proper technique was needed to ensure accuracy of the obtained measurement. Erickson (1980) found the posterior sublingual pocket to have the highest oral temperature reading, and recommended the sublingual pocket as the proper site for measurement. The sublingual pocket may have the highest temperature reading due to its blood supply from branches of the external carotid artery (Williams, Warwick, Dyson, & Bannister, 1989). Ilsley, Rutten, and Runciman (1983) compared PA temperature to oral temperature measured with mercury, predictive electronic, and disposable chemical thermometers in 5 adult patients in an intensive care unit (ICU). They found the mean oral temperature readings were 0.4°C lower than the simultaneously measured mean PA temperatures.

A number of factors have been evaluated for their effect on oral temperature measurement. These include the use of oxygen through various delivery methods and the administration of heated or cooled aerosols. Yonkman (1982) studied 30 volunteer women, ages 21 to 35, using an electronic thermometer (type unknown) to measure oral temperature. Heated and cool aerosols were administered through a face mask. Temperatures were taken during aerosol administration, and at 1 and 5 minutes after aerosol removal. The greatest difference between temperatures on a given subject was 0.3°C ($p < .005$), but not considered to be clinically significant. Lim-Levy (1982) studied 100 healthy adults ages 18 to 56. Temperatures were taken with an electronic thermometer (IVAC®) before and 30 minutes after oxygen was initiated at either 2, 4 or 6 liters/minute via nasal cannula. No statistically significant change in oral temperature was found. Hasler and Cohen (1982) studied 40 healthy volunteers ages 18 to 58 years. Different oxygen delivery devices were evaluated: aerosol mask, venti-mask, and nasal prongs. Changes in oral temperature were less than 0.6°F and not considered to be clinically significant.

Tympanic Site

Anatomy

In the adult, the external ear canal is a curved tube, approximately 3.5 cm in length (Fraden & Lackey, 1991). It ends at the tympanic membrane, which lies at an angle of 55 degrees with the floor of the canal and separates it from the tympanic cavity (Williams et al., 1989). To obtain an optimal view of the tympanic membrane with an otoscope, the pinna should be retracted backward and upward in adults to straighten the ear canal (Adams, 1989).

The tympanic membrane lies approximately 3.5 cm from the hypothalamus, which provides central regulation of body temperature (Fraden & Lackey, 1991). Like other structures in the head, both the tympanic membrane and the hypothalamus receive their blood supply from branches of the common carotid artery. The tympanic membrane receives its blood supply from the external carotid artery via the maxillary artery (deep auricular branch), posterior auricular artery, and maxillary artery (tympanic branch) (Williams et al., 1989). The hypothalamus receives its blood supply from the internal carotid artery (Williams et al., 1989). Since both the tympanic membrane and hypothalamus are receiving blood from the common carotid artery, the tympanic membrane should be a good indicator of core body temperature. Figure 2 illustrates the arteries of the head and neck.

Direct Contact Tympanic Temperature Measurement

Tympanic thermometry became available clinically in 1959 (M. Benzinger, 1969). Initially, tympanic temperature was measured by placing a thermocouple against the tympanic membrane. Later it was changed to a thermoelectric technique, which made the thermometer disposable (T. Benzinger, 1969). However, with either method, direct contact measurement of tympanic temperature was uncomfortable (Brengelmann, 1987) and not practical for routine clinical use.

Non-Contact Tympanic Temperature Measurement

In 1986, the first infrared tympanic thermometer became available for clinical use and several other instruments have been introduced since then. An infrared thermometer has a short otoscope-like probe that is inserted into the external ear canal. The thermometer measures natural infrared energy emitted from the surface of the tympanic membrane and surrounding ear canal wall. The instrument does not directly contact the area at which the temperature is measured, but looks at the tissue

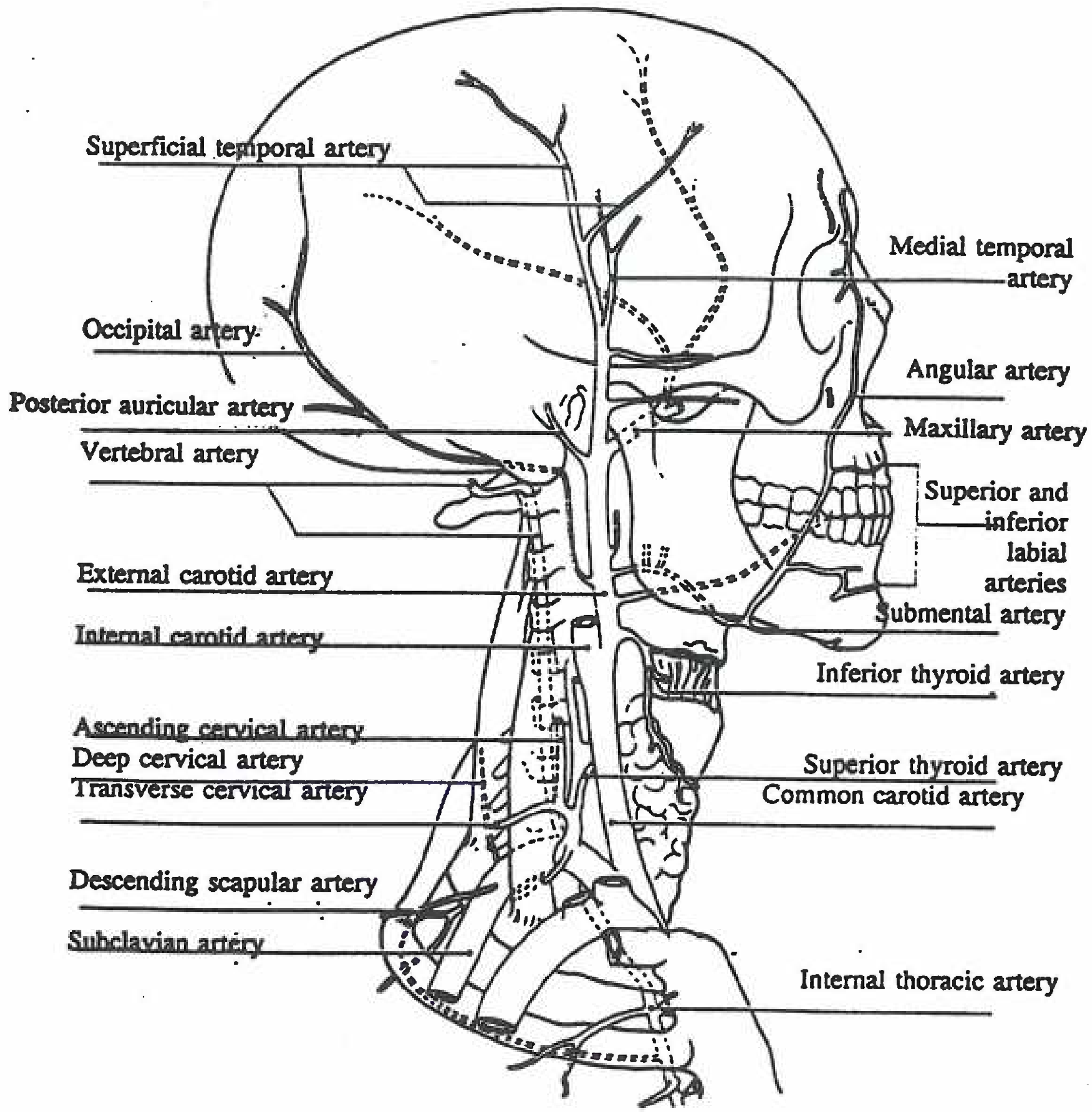


Figure 2. Lateral view of arteries of the head and neck.

From The Human Body on File by R. Swan (Ed.), 1983. New York: Facts on File.

within its field of view. Since the ear canal has a temperature gradient (Cooper, Cranston, & Snell, 1964) and the thermometer sees some tissue that is cooler than the tympanic membrane, it does not provide a true tympanic temperature. The thermometer processes the information to provide a "tympanic-based" estimate of temperature in the ear canal or another site. This estimate is calculated using an equation based on a set of presumably representative data obtained from an adult population. Some thermometers may also include a correction for the effect of ambient temperature on the ear canal. Estimates of values at other sites may also be called "tympanic temperatures", but they are actually statistical estimates of the temperature at those sites based on sampled data. In this study, we will refer to measurements made with an infrared tympanic thermometer as "tympanic-based" temperature measurements.

Alexander and Kelly (1991) did a cost analysis of tympanic-based temperatures (Thermoscan®) versus oral and rectal temperatures using mercury and predictive electronic thermometers in a pediatric population less than 4 years of age. Each type of temperature measurement was evaluated by the amount of time the measurement took, equipment and service costs, and personnel costs. They reported that tympanic thermometry has many advantages: the thermometers are not readily breakable as a glass thermometer can be, do not touch mucous membranes, and are faster and more economical than traditional mercury and electronic thermometers, based on costs associated with equipment and personnel.

Milewski, Ferguson, and Terndrup (1991) performed a prospective study comparing PA, rectal, and tympanic-based temperatures (Thermoscan®) in the right ear canal using the "equal" mode and without retraction of the external ear. They studied nine adult ICU patients, obtaining temperature readings every 1 to 2 hours for 48 hours. Mean temperatures obtained from each site, using pooled data, were: PA 37.5 ± 0.06°C, tympanic-based 37.1 ± 0.08°C, and rectal 37.5 ± 0.07°C. Correlation between PA and rectal temperature (r = .93) was better than between PA and tympanic-based temperatures (r = .74), which might have been related to the larger range of the tympanic-based measurements. The mean temperature differences for PA minus tympanic-based temperature ranged from -0.35 to 0.22°C, which was not considered to be clinically significant. In general, rectal temperatures were higher than PA temperatures, and PA temperatures were higher than tympanic-based temperatures.

Nierman (1991) prospectively studied 15 adult ICU patients to compare temperatures obtained with PA thermistor catheters, urinary bladder thermistor catheters, and an infrared tympanic thermometer (FirstTemp®) in the "core" mode. A total of 21 sets of measurements were obtained, and pooled data were used for the analysis. Results showed good association between PA and bladder temperature (r = .83), with poorer association between tympanic-based and PA temperature (r = .67) and tympanic-based and bladder temperature (r = .61). Tympanic thermometer temperature measurements (38.07 ± 0.47°C) were significantly

($p < .001$) higher than measurements from the bladder (37.74 ± 0.35°C) or PA catheter (37.69 ± 0.34°C). The tympanic-based readings had an offset (difference between the tympanic-based and reference temperature) of 0.3 to 0.4°C higher than the bladder and PA readings throughout the entire study period. Nierman stated that this may have been due to miscalibration of the instrument, since he also found that the infrared thermometer provided readings that were high during water bath testing with a floating black body device.

Erickson and Kirklin (1991) studied 38 intensive care patients, mean age 64.4 ± 9.4 years. PA temperatures were compared with urinary bladder, axillary, oral, and tympanic-based temperatures (IVAC®). Measurements were repeated up to 12 times, usually on the same side with the thermometer in core mode and with an ear tug. They found that tympanic-based, bladder, and oral temperatures were close to the PA temperature with the mean offsets of no more than ±0.1°C, using pooled data. The offset for tympanic-based temperature had a standard deviation of ±0.41°C, indicating a moderate degree of variation, as found with Nierman's study. The bladder and oral temperature offsets were less variable, while axillary temperature substantially underestimated PA values and had a greater variability.

Shinozaki, Deane, and Perkins (1988) compared left and right tympanic-based temperatures (FirstTemp®) with PA and rectal temperatures in an unknown number of adult ICU patients using an unreported mode and technique. The offset values for tympanic-based from PA temperatures were 0.4 ± 0.2°C in the temperature range of 36.5 to 37.9°C. The tympanic-based readings tracked the core temperature with a correlation coefficient of .98, although data appear to have been inappropriately pooled for the calculation.

Multiple studies have been conducted to evaluate the accuracy of the tympanic-based temperature as it relates to the oral site for temperature measurement. The results are conflicting. Gibbons (1967) compared simultaneously measured oral and tympanic membrane temperatures using thermistors in four adult subjects in four clinical trials. Tympanic membrane temperatures (97.52 ± .44°F) were lower than oral temperatures (98.49 ± .45°F), with mean differences after heat stress and at peak oral temperature of 0.99°F and 1.07°F respectively. The lower tympanic membrane temperatures were attributed to variable placement of the thermistor. Terndrup, Allegra, and Kealy (1989) studied 22 adult healthy volunteers using a FirstTemp® and found the mean tympanic-based temperature (37.4 ± 0.4°C) higher than the oral temperature (36.4 ± 0.4°C). Erickson and Yount (1991), in a study of 60 adults having major surgery, found the tympanic-based readings (FirstTemp®) correlated well with the oral readings (*r* = .77 to .85). The tympanic readings were higher than the oral readings 99% of the time. Talo, Macknin and Medendorp (1991) studied patients under 18 years of age. Tympanic-based (Thermoscan®) and oral (IVAC®) temperatures were obtained in 97 subjects. The mean tympanic readings were 36.6 ± 0.73°C and the mean oral readings were 36.8 ± 0.76°C. The mean difference between mean ear and oral measurements was -0.20 ± 0.59°C.

Influencing Variables

A variety of factors may affect the accuracy of tympanic-based temperature readings. These include patient characteristics, environmental factors, and measurement technique.

Patient characteristics. Although temperature differences may exist between the left and right ears in any given individual (Chamberlain et al., 1991), evidence to date does not support a difference of clinical significance. Shinozaki et al. (1988) reported a lack of difference (0.0 ± 0.1°C) between tympanic-based temperatures in the left and right ears. Terndrup et al. (1989) found left and right tympanic-based temperatures to be nearly identical, with a mean temperature of 37.4 ± 0.04°C. Kenney, Fortenberry, Surratt, Ribbeck, and Thomas (1990) studied 964 pediatric patients (newborn to 18 years of age), using a FirstTemp® thermometer. They reported a mean difference between right and left tympanic-based temperatures of 0.01 ± 0.02°C, which was not statistically significant. Chamberlain et al. (1991) studied 184 children aged 6 days to 17 years (mean age 52 months), using a Thermoscan® thermometer and an ear tug. They found that the difference between the left and right ears with otitis media increased the temperature by 0.1°C, which is statistically significant ($p < .05$), but not clinically significant. Repeated measures between ears resulted in a correlation coefficient ranging from .82 to .93. Shenep et al. (1991) studied two types of infrared tympanic thermometers, Thermoscan® and FirstTemp®. Temperature measurements were obtained in pediatric patients, using an ear tug in one ear and with no tug in the other ear. They reported that the temperatures obtained in both ears were essentially identical (left ear 37.52°C and right ear 37.50°C), although they confounded the variables of side and tug by "mixing it up" between patients.

The effect of otitis media on tympanic-based temperature readings have been studied and the results have been inconsistent. Kenney et al. (1990) reported that the agreement between tympanic-based temperature and oral measurement was unaffected by unilateral or bilateral acute otitis media. Similarly, Pransky (1991) indicated that the presence of cerumen, acute infectious processes, and scarring of the tympanic membrane had no effect on the tympanic-based temperature readings in pediatric patients (ages 7 months to 13 years). In contrast, Chamberlain et al. (1991) found an elevation of tympanic-based temperature of 0.1°C ($p < .05$) in pediatric ears with otitis media (standard deviation not reported). Similarly, Kelly and Alexander (1991) found readings obtained in ears with suppurative otitis media to be higher by a mean of 0.2°C (standard deviation not reported) than in the ears without otitis media. However, these noted elevations in tympanic-based temperatures were not considered to be clinically significant.

Environmental factors. Ambient temperature was measured in several studies (Fraden & Lackey, 1991; Milewski et al., 1991) but not reported in the analysis of the data nor its implications discussed. Chamberlain et al. (1991) stated that, through multiple regression analysis, they were able to determine that ambient temperature had a significant interaction with tympanic-based readings, but did not provide any more specific data. Zehner and Terndrup (1991) prospectively studied 21 adult healthy volunteers to determine the effect of cool (18.3°C), warm (35°C), and normal (20°C) ambient temperatures on oral, rectal, and tympanic-based temperatures (Thermoscan®). Oral and tympanic-based temperatures did not change significantly with cooler ambient temperature. However, during warm exposure, oral temperature was elevated 0.5 ± 0.1°C from baseline and tympanic-based temperature was elevated 0.8 ± 0.1°C from baseline. Erickson and Kirklin (1991) found that ambient temperature had no effect on the level of agreement between PA temperature and the tympanic-based core estimate (IVAC®). It was surmised this was because the thermometer computation contained a correction for the effect of ambient temperature on the ear canal (R. Erickson, personal communication, 1992).

Terndrup et al. (1989) studied 22 adult healthy volunteers to determine the effect of ingested ice water, hot water, and smoking on oral, rectal, and tympanic-based temperatures measured with a FirstTemp®. They reported no significant change in the tympanic-based temperature after drinking hot or cold liquids, or smoking, although no specific values were reported.

<u>Measurement technique</u>. Shenep et al. (1991) measured the difference between the first and second temperatures obtained in the same ear in 64 pediatric subjects, finding a difference of -0.02°C with a 95% confidence interval of -0.11°C to -0.07°C. However, Erickson and Kirklin (1991) found that about two thirds of second and third measurements were cooler than the preceding one with a mean of 0.1 to 0.2°C. They attributed this to drawdown, the transient lowering of ear canal tissue temperature caused by contact with the comparatively cool thermometer probe.

Since the adult ear canal has a natural curve that can obstruct the view of the tympanic membrane, the technique of leaving the ear in a natural position versus using a gentle tug to straighten the ear canal may influence the temperature reading. Presumably the temperature probe will have a better view of the warmest part of the ear canal, near the tympanic membrane, when the ear canal is straightened. Pransky (1991) studied 100 patients, ages 7 months to 13 years, using a Thermoscan® in an unreported mode. Tympanic-based temperature was 0.2 ± 0.1°C higher and compared "favorably" to the oral temperature when the ear tug was utilized. Shenep et al. (1991) studied 151 children older than 4 years, 51 of whom were febrile and noted that mean tympanic-based temperatures were 0.2°C (*SD* not reported) higher when the ear tug was used.

Tympanic-based temperature is a convenient way to estimate core temperature. It may be affected by various factors, for example, the instrument used, left versus right ear, ambient temperature, and use of an ear tug. Most of the current research on tympanic-based temperature measurement has been done with pediatric patients in outpatient settings, and the effect that these factors may have on an inpatient adult population is unclear. Research on tympanic-based temperatures obtained with different thermometers, in the left versus right ears, and varying measurement techniques will help to resolve some of these issues.

CHAPTER III

METHODS

Study Design

This quasi-experimental study used a 2 x 2 x 2 repeated measures design to (a) evaluate the effect of three independent variables (side, instrument, and technique) on the dependent variable of tympanic-based temperature and (b) compare oral and tympanic-based temperature values. The investigators were interested in a hospitalized population without hemodynamic monitoring, since this is the type of patient seen by the majority of nurses. Ten temperature readings were obtained from each subject. These included eight tympanic-based temperatures and two oral temperatures, one preceding and one following the tympanic-based readings. In addition, ambient temperatures were obtained before and after the patient measurement procedures.

Sample and Setting

The subjects were adult male and female inpatients between 20 and 96 years of age and located in a 188-bed hospital in the mid-Willamette valley. Staff nurses were approached by the investigators to identify possible subjects (stable condition) on the following nursing units: general medical and telemetry, orthopedic and general surgical, oncology, intensive care, short stay surgical, and postanesthesia.

Patients with conditions or treatments that could potentially affect tympanic-based or oral temperature readings were excluded, such as those with ear, mouth, or throat pathology. Patients requiring oxygen via mask or nasal cannula were not excluded since findings from the literature suggest very little difference in oral temperatures and none with tympanic-based temperatures when patients are receiving oxygen therapy (Hasler & Cohen, 1982; Lim-Levy, 1982; Yonkman, 1982).

Protection of Human Subjects

Approval was obtained from the institutional review boards of the study hospital and Oregon Health Sciences University. The study purpose and procedures were explained to subjects verbally and in writing. All subjects signed an informed consent (Appendix A) prior to participating in the study. Data were kept confidential, with subjects identified by a code number. The only risk of participation was a possible mild, transient discomfort or redness in the outer portion of the ear canal resulting from repeated temperature measurements. Subjects were able to withdraw from the study at any time without affecting their care. While subjects did not benefit directly from participation, information obtained may assist nurses with accurate body temperature measurement in future patients.

Instruments

Tympanic-based temperatures were measured with an IVAC® CORE•CHECK™ infrared thermometer (Model 2090A, IVAC® Corporation, San Diego, CA) and a FirstTemp® Genius® infrared thermometer (Model 3000A, Intelligent Medical Systems, Carlsbad, CA), both used in core mode. Oral temperatures were measured in the right posterior sublingual pocket with the IVAC® TEMP•PLUS® II predictive electronic thermometer (Model 2080A, IVAC® Corporation, San Diego, CA). Refer to Table 1 for thermometer specifications. Ambient temperatures were measured with

Table 1

<u>Specifications for Thermometers</u>

	FirstTemp® Genius® Model 3000A	IVAC® CORE•CHECK™ Model 2090A	IVAC® TEMP•PLUS® II Model 2080A
Manufacturer	Intelligent Medical Systems	IVAC Corporation	IVAC Corporation
Modes	Oral, Rectal, Core. Calibration, Surface	Core	Predictive, Monitor
Ear Tug	No recommendation	No recommendation	Not Applicable
Measurement Range	60-110°F (15.5-43.3°C)	77-110°F (25-43.3°C)	Predictive 88.9-108.0°F (31.6-42.2°C) Monitor 80.0-108.0°F (26.7-42.2°C)
Accuracy	±0.2°F (±0.1°C) at ambient temperature range of 60-104°F	±0.2°F (±0.1°C) at ambient temperature range of 65-90°F	±0.2°F (±0.1°C)
Response Time	1-2 seconds	< than 3 seconds	Predictive mode not specified Monitor > 3 min.
Probe Dimensions			
Length	22.0 mm	20.0 mm	Not Applicable
Diameter	8.0 mm	7.7 mm	
Calibration	Model 3000A-CL Electronic Calibrator	IVAC CORE•CHECK Model 9000 Calibrator	Autocalibration
Warranty	1 year	3 years	1 year

<u>Note</u>. Information obtained from "Infrared Ear Thermometry," 1991 and Operation Manuals for FirstTemp® Genius® 3000A, IVAC® CORE•CHECK™ 2090A and IVAC TEMP•PLUS® II 2080A.

an Omega® HH-22 handheld microprocessor digital thermometer (Omega Engineering, Stamford, CT) with a thermistor probe and digital readout.

The accuracy of all thermometers used for body temperature measurement met or exceeded product specifications. All thermometers used for body temperature measurement were tested before and after data collection. The two tympanic-based infrared thermometers had accuracy guaranteed by the manufacturers to ± 0.1°C. Each was tested using a black body calibrator unit provided by the manufacturer against two test temperatures of approximately 26 and 38°C. The mean error did not exceed ± 0.1°C. The thermistor-based electronic thermometer used to measure oral temperature was tested in a temperature controlled water bath (Model 25, Precision Scientific, Chicago, IL) against a certified mercury laboratory thermometer (Taylor Scientific Instruments, Arden, NC) with accuracy traceable to the National Institute for Standards and Technology. Readings were made at 1° intervals over a range of 32 to 42°C with a mean error of -0.02 ± 0.06°C. Accuracy of the Omega® HH-22 thermometer used for ambient temperature measurement was specified as ±(0.1% rdg + 0.6°C) by the manufacturer. This thermometer was not tested in the water bath.

Pilot Study

A pilot study was conducted to determine interrater reliability of the two investigators, using paired temperature measurements on four healthy adult volunteers with both infrared thermometers and the oral thermometer. Initial interrater agreement to within 0.3°C for the tympanic-based temperatures and oral temperature was 63% and 100%, respectively. The investigators then practiced using both infrared thermometers to perfect their technique. An otoscope was used to determine the proper direction for placement of the tympanic thermometer probe. A three step process for thermometer probe placement was developed: (a) the thermometer, with a disposable probe tip in place, was inserted firmly with the probe aimed into the ear canal and the thermometer handle slightly out from the jaw; (b) the thermometer handle was moved toward the subject's head until it was parallel to the jaw line; and (c) the thermometer was tilted slightly upward, which directed it toward the subject's opposite temple.

A second pilot study, using paired tympanic-based temperatures with both infrared thermometers was conducted on seven healthy adult volunteers. Interrater agreement to within 0.3°C was 75%. Further improvement was not anticipated, and data collection was begun.

Temperature Measurement Procedures

Potential subjects were approached by the investigators, who explained the study requirements and obtained a written consent from each subject who was willing to participate in the study. Subjects were asked to refrain from ingesting foods or fluids prior to the investigators returning to take the temperature measurements, about 10 to 15 minutes later. One investigator obtained all temperature measurements on a given subject while the second investigator served as recorder. These responsibilities were alternated with each subject.

A random number table was used to determine the order in which the tympanic-based measurements were to be taken. Four measurements were made with each infrared thermometer, two on each side, one using the ear tug technique to straighten the ear canal and one with the ear in its natural position. All tympanic-based temperatures were made with the thermometer held in the investigator's dominant (right) hand, with the probe tip aimed at the subject's opposite temple, using the three step process developed during the pilot studies. The ear tug, when applicable, was performed with the non dominant (left) hand. When the ear tug was not used, the non dominant hand supported the opposite side of the subject's head with approximately the same amount of pressure as was being exerted against the experimental ear. If consecutive measurements were to be obtained in the same ear, the investigators waited for 30 seconds between readings to minimize the potential effect of temperature drawdown from contact of the comparatively cool thermometer probe with the warm ear canal tissue.

Before and after the set of tympanic-based temperature measurements, oral temperature was taken with the probe placed in the right posterior sublingual pocket using the predictive electronic thermometer. The ambient temperature was measured before and after all body temperature measurements using an Omega® HH-22 thermometer with the probe placed within 1 foot of the subject's head. The detailed study protocol is contained in Appendix B. All data were recorded on the Data Collection Tool (Appendix C).

Additional information was obtained from the hospital record and by observation to describe the study sample and account for variables that might affect the temperature data. This included patient characteristics of age, gender, diagnosis, and position of the patient. Also noted were environmental factors of oxygen therapy and position of side rails. Finally, subjects were asked if they preferred one thermometer over the other.

Data Analysis

All tympanic-based temperature measurements were referenced to the mean of the two oral temperatures (reference oral temperature). Temperature measurements for the study sample are contained in Appendix D. Oral temperature was chosen as the reference point because PA temperature was not readily available to the investigators. The reference oral temperature value was expected to be approximately 0.3 to 0.4°C below the corresponding PA temperature, the actual value which the two infrared thermometers were intended to estimate (Ilsley et al., 1983; Brengelmann, 1987). Therefore, if the tympanic-based readings accurately estimated PA temperature, they were expected to be offset several tenths °C above the reference oral temperature.

Differences between the tympanic-based temperature values in relation to side, instrument, and technique used for measurements were determined with a three-factor analysis of variance (ANOVA) for repeated measures. To determine if the temperature results differed due to the order in which they were obtained, a one-factor ANOVA was performed with follow-up isolation of significant differences based on the Tukey-A test. Differences between the tympanic-based and reference oral temperatures were evaluated with paired *t* tests. Statistical analysis was completed using the Crunch Statistical Package (Version 3, Crunch Software Corporation, Oakland, CA). Statistical significance was considered to be achieved at $p \leq .05$.

CHAPTER IV

RESULTS

Characteristics of the Study Sample

The subjects were a convenience sample of 50 general medical-surgical inpatients, 27 males and 23 females, ranging in age from 20 to 96 years (mean age 63.1 $\pm$ 16.9 years). The subjects included 26 post-surgical patients and 24 medical patients. Three subjects had temperatures greater than 38.0°C and two had temperatures lower than 36°C. The offsets from the reference oral temperature were reviewed for these five subjects. The mean offset values for each of the five subjects fell within the range of mean offset values for the entire sample. Further analysis was not performed.

Comparison of Tympanic-Based Temperatures

Measurement Method

The major purpose of this study was to compare tympanic-based estimates of core temperature in relation to side, instrument, and technique (ear position) used for measurements. A three factor analysis of variance was performed to examine the effect of the within-subjects (repeated) factors, with an additional between-subjects factor included to determine if the temperature values differed according to which investigator obtained them. Table 2 presents mean tympanic-based temperature values and their offsets from the reference oral temperature in relation to temperature measurement combinations, and Table 3 summarizes the ANOVA results. Table 4 presents the differences in measured tympanic-based temperatures and offsets from

Table 2

Tympanic-Based Temperatures and Offsets from the Reference Oral Temperature for the Eight Measurement Combinations

	CORE•CHECK				GENIUS			
	Right		Left		Right		Left	
	Tug	No tug	Tug	No tug	Tug	No tug	Tug	No tug
	Tympanic-based temperature measurements (°C)							
Mean	36.53	36.76	36.78	36.82	37.37	37.40	37.40	37.49
Standard deviation	±.57	±.48	±.49	±.57	±.68	±.65	±.59	±.59
Minimum	35.3	35.6	35.3	35.6	35.9	35.9	36.0	35.8
Maximum	37.5	37.9	38.0	38.1	39.0	39.2	38.6	38.8
Range	2.2	2.3	2.7	2.5	3.1	3.3	2.6	3.0
	Offsets from reference oral temperature (°C)							
Mean	-0.53	-0.30	-0.27	-0.23	0.32	0.35	0.35	0.43
Standard deviation	±0.46	±0.37	±0.44	±0.47	±0.45	±0.47	±0.51	±0.48
Minimum	-1.80	-1.25	-1.30	-1.75	-1.05	-1.10	-0.85	-0.50
Maximum	0.40	0.70	0.80	0.90	1.40	1.20	1.60	1.70
Range	2.20	1.95	2.10	2.65	2.45	2.30	2.45	2.20

Note. Offset = tympanic-based temperature value minus reference oral temperature value.

Table 3

Three-Way Analysis of Variance Summary for Tympanic-Based Temperatures

Source of variance	df	SS	MSS	*F* value	*p* value
Between-subjects variable	49	91.496			
Investigator	1	0.980	0.980	0.520	.475
Within-subjects variables	350	91.508			
Main effects					
Side	1	1.188	1.188	5.532	.023
Instrument	1	47.748	47.748	307.767	.000
Technique	1	0.960	0.960	17.366	.000
Interactions					
Side x Instrument	1	0.260	0.260	1.750	.192
Side x Technique	1	0.116	0.116	1.091	.301
Instrument x Technique	1	0.144	0.144	1.842	.181
Side x Instrument x Technique	1	0.360	0.360	4.927	.031

Table 4

Measured Tympanic-Based Temperatures and Offsets from Reference Oral Temperature in Relation to Investigator, Side, Instrument, and Technique

	Measured temperature (°C)	Diff (°C)	Offset from reference oral temperature (°C)	Diff (°C)
Investigator				
NK	37.12 ± 0.60		-0.00 ± 0.54	
KG	37.02 ± 0.75	0.10	0.03 ± 0.61	0.03
Side				
Left	37.12 ± 0.64		0.07 ± 0.58	
Right	37.01 ± 0.71	0.11	-0.04 ± 0.58	0.11
Instrument				
Genius	37.41 ± 0.63		0.36 ± 0.48	
CORE•CHECK	36.72 ± 0.54	0.69	-0.33 ± 0.45	0.69
Technique				
No tug	37.12 ± 0.66		0.06 ± 0.55	
Tug	37.02 ± 0.69	0.10	-0.03 ± 0.60	0.09

Note. Values are mean ± standard deviation.

reference oral temperature in relation investigator, side, instrument, and technique.

The tympanic-based temperature readings did not differ between the two investigators ($F = 0.520$, $p = .475$). However, each of the three major factors of interest (side, instrument, and technique) had a significant main effect on the tympanic-based temperature. The strongest difference in tympanic-based temperatures was demonstrated with the choice of instrument (Figure 3). The Genius® thermometer provided mean temperature values that were 0.69°C higher than those obtained with the CORE•CHECK™ thermometer, a difference of both statistical ($F = 307.767$, $p < .001$) and clinical importance. Out of 200 paired measurements with the two thermometers, keeping the side and ear position constant, the Genius® thermometer had higher values in 183 (92%) of the measurements.

In this sample, mean temperatures were slightly higher, by 0.11°C , in the left ear than in the right ear ($F = 5.532$, $p = .023$) and surprisingly, also slightly higher, by 0.10°C, when measurements were made with the ear in its natural position rather than when an ear tug was used ($F = 17.366$, $p < .001$). However, these differences are quite small and clinically of little importance. The actual frequency with which measurements were higher in the left or right ear or when the tug versus no-tug technique was used, was evenly balanced. Out of 200 paired measurements in opposite ears, keeping the thermometer and ear position constant, the left ear had the higher reading in only 101 (51%) of them. Similarly, out of 200 paired measurements using the two ear positions, the no-tug technique provided a higher reading in only 99 (50%) of them.

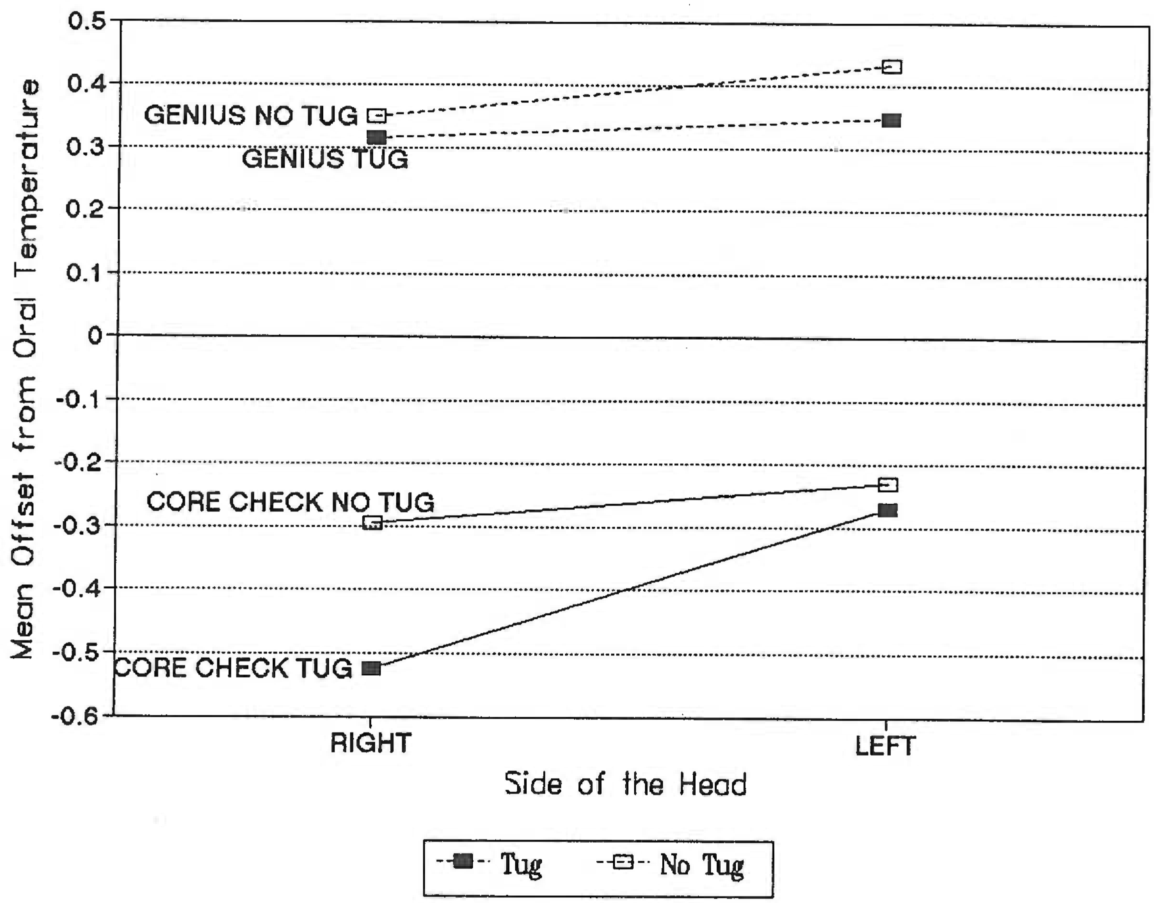


Figure 3. Interaction of side, instrument, and ear position.

The analysis of variance also pointed out a small interaction among the three variables ($F = 4.927$, $p = .031$). The mean tympanic-based temperature values were highest (and had the largest positive offsets from the reference oral temperature) when the Genius® thermometer was used on the left side with the ear in its natural position. In contrast, the lowest temperature values (and largest negative offsets from the reference oral temperature) occurred with the IVAC® thermometer when used in the right ear with a tug.

Measurement Order

In general, the tympanic-based temperature values tended to fall slightly as the measurements proceeded, from a mean of 37.07 ± 0.68°C at the first measurement to 36.83 ± 0.70 at the eighth one. The means of the measured temperatures and their offsets from the reference oral temperature in relation to the order in which they were taken are listed in Table 5. A one-factor ANOVA indicated a significant difference ($F = 3.328$, $p = .002$) among the measurements in relation to their place in the measurement sequence (Table 6). As shown by post hoc Tukey A test, the means of both the first and the third measurements were statistically higher than the mean of the last measurement, by 0.24 and 0.26°C, respectively (both $p = .01$).

Comparison of Tympanic-Based and Oral Temperatures

Frequency distributions were used to display the tympanic-based offsets from the reference oral temperature for each of the eight measurement combinations of side, instrument, and ear position (Figure 4). The means, standard deviations, and ranges

Table 5

Measured Temperatures and Offsets from Reference Oral Temperature in Relation to Place in the Measurement Sequence

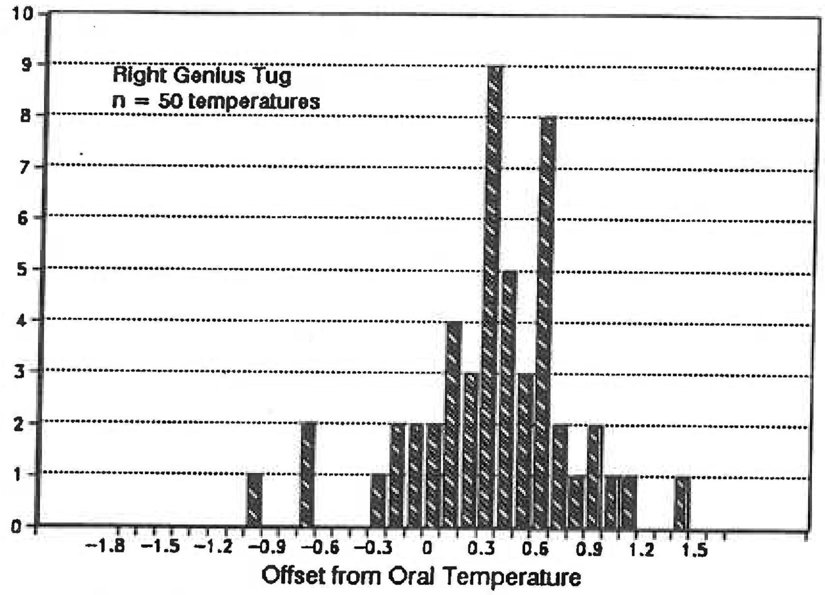
Measurement	Measured Temperature (°C)	Offset from Reference Oral Temperature (°C)
1	37.21 ± 0.63	0.14 ± 0.50
2	37.09 ± 0.77	0.02 ± 0.59
3	37.22 ± 0.57	0.15 ± 0.55
4	37.12 ± 0.82	0.05 ± 0.66
5	37.12 ± 0.69	0.05 ± 0.68
6	36.94 ± 0.60	-0.13 ± 0.53
7	37.07 ± 0.58	-0.00 ± 0.50
8	36.83 ± 0.70	-0.24 ± 0.63

Note. Values are mean ± standard deviation.

Table 6

One-Way Analysis of Variance Summary for Tympanic-Based Temperatures by Measurement Order

Source of variance	df	SS	MSS	*F* value	*p* value
Within-subjects variables	350	93.58			
Order	7	5.95	0.85	3.33	.002



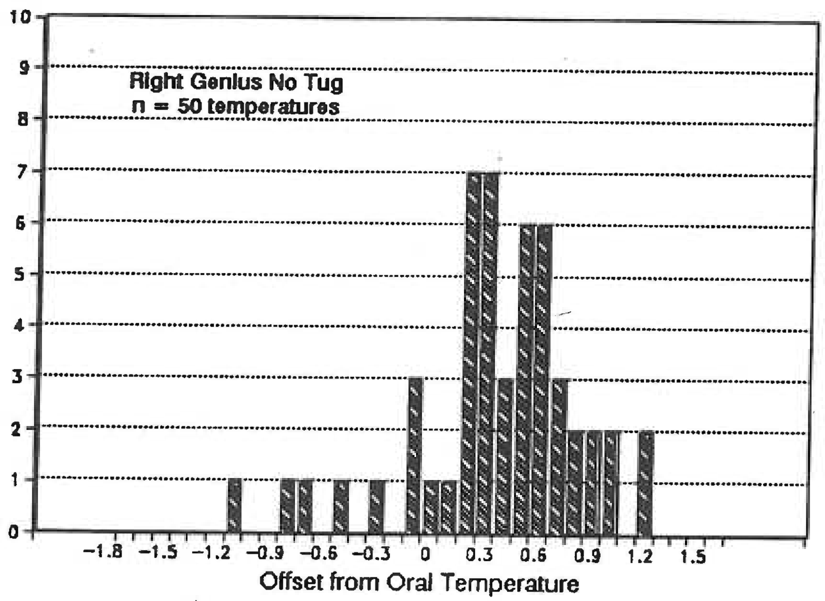
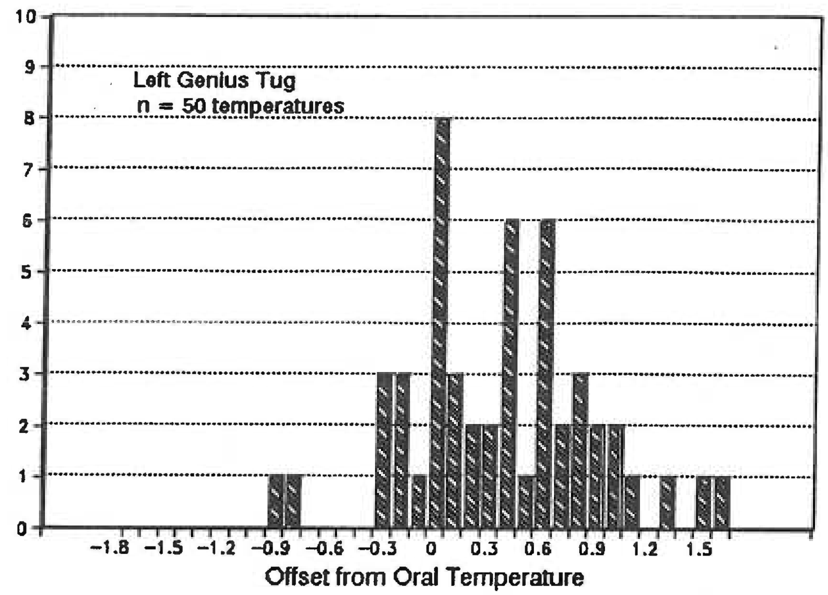
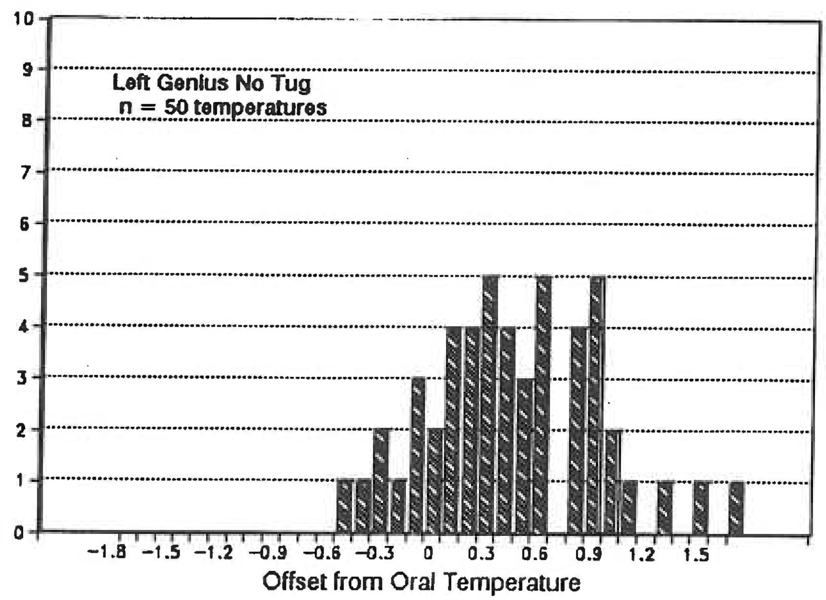


Figure 4. Frequency distributions of the individual offsets for each tympanic-based temperature combination (side, instrument, ear position).





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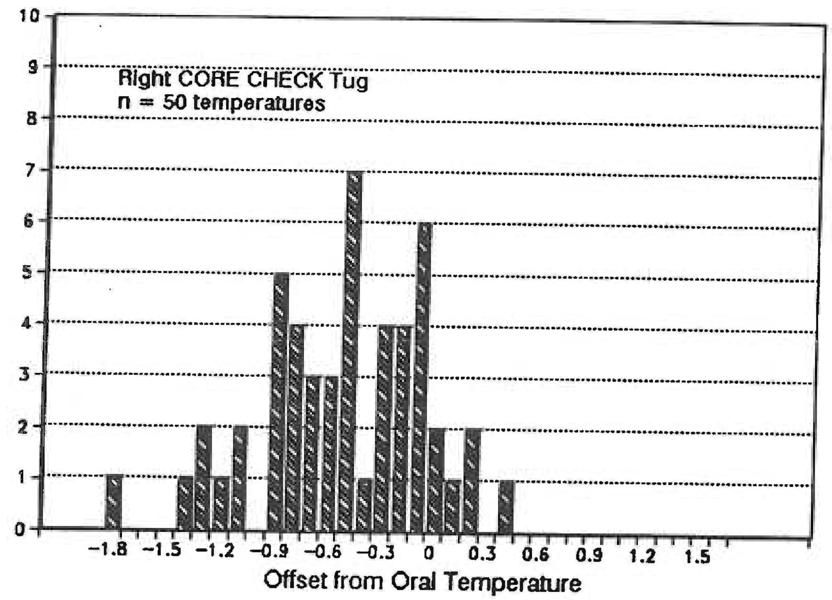


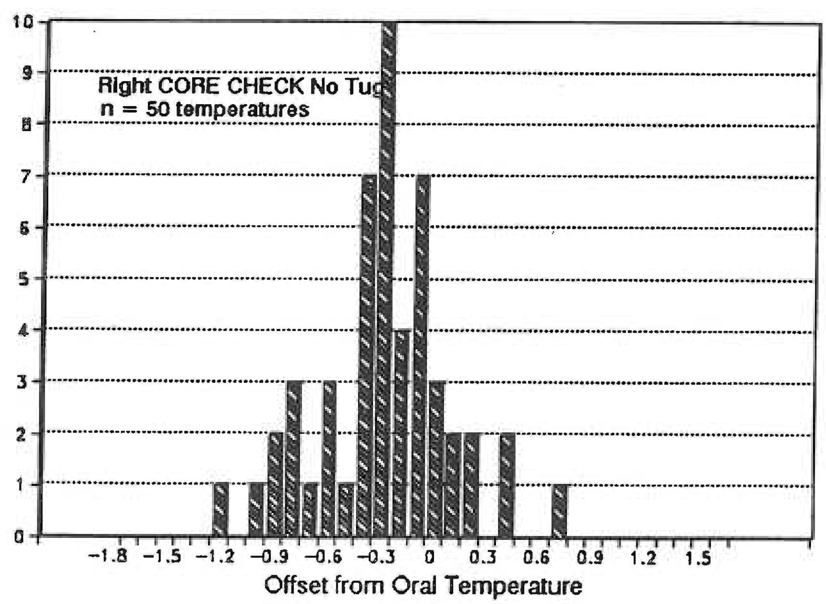
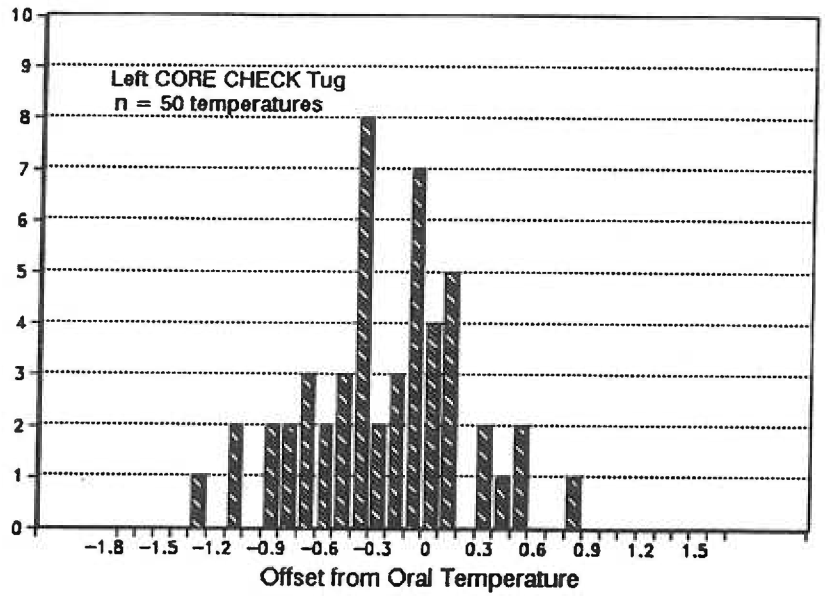


Figure 4. Frequency distributions of the individual offsets for each tympanic-based temperature combination (side, instrument, ear position).



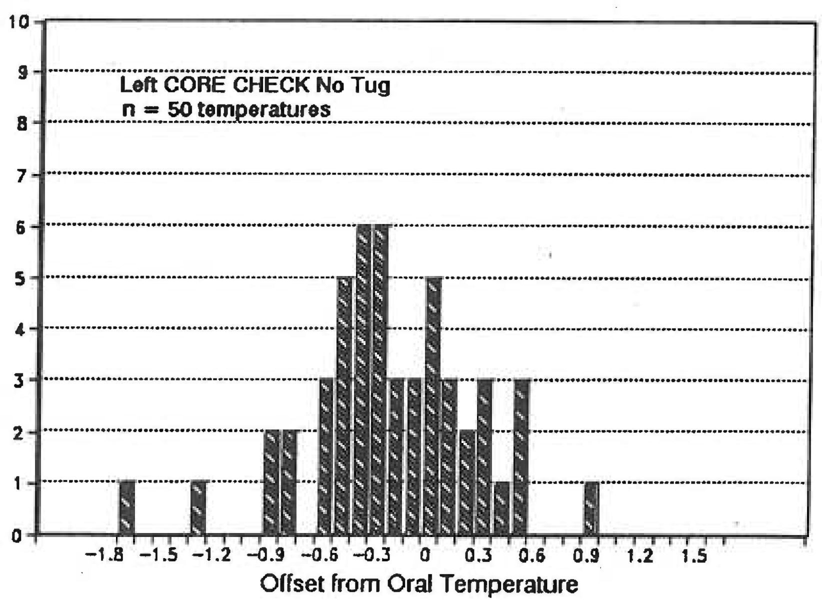


Figure 4. Frequency distributions of the individual offsets for each tympanic-based temperature combination (side, instrument, ear position).

of offset values are found in Table 2. The mean offsets from reference oral temperature for each measurement combination are shown in Figure 5.

Separate paired *t* tests were performed to compare each of the eight mean tympanic-based temperature measurements to the reference oral value (Table 7). A Bonferroni correction, dividing the designated level of significance by the number of comparisons (.05 ÷ 8), was used to maintain the overall level of significance at .05 (Hassard, 1991). This procedure established a critical value of p = .006 for each comparison in order to keep the overall risk of a Type I error at .05. Based on this new critical value, the eight mean tympanic-based temperatures differed significantly ($p < .001$) than the reference oral temperature. Mean readings with the Genius® thermometer were consistently higher by 0.3 to 0.4°C, while those with the CORE•CHECK™ thermometer were consistently lower by 0.2 to 0.6°C.

Background Variables

Additional information was obtained by observation to account for variables that might affect the temperature data. These included: position of the patient, position of the side rails, and use of oxygen therapy. Patients were asked if they preferred one thermometer over the other. Frequency distributions of the background variables are listed in Table 8. Most patients were semi-upright in bed. Generally, the investigators felt that when the patient was sitting upright and the siderails were down, thermometer placement was easier, and therefore may have contributed to more accurate probe positioning. In addition, ambient temperature was noted prior to

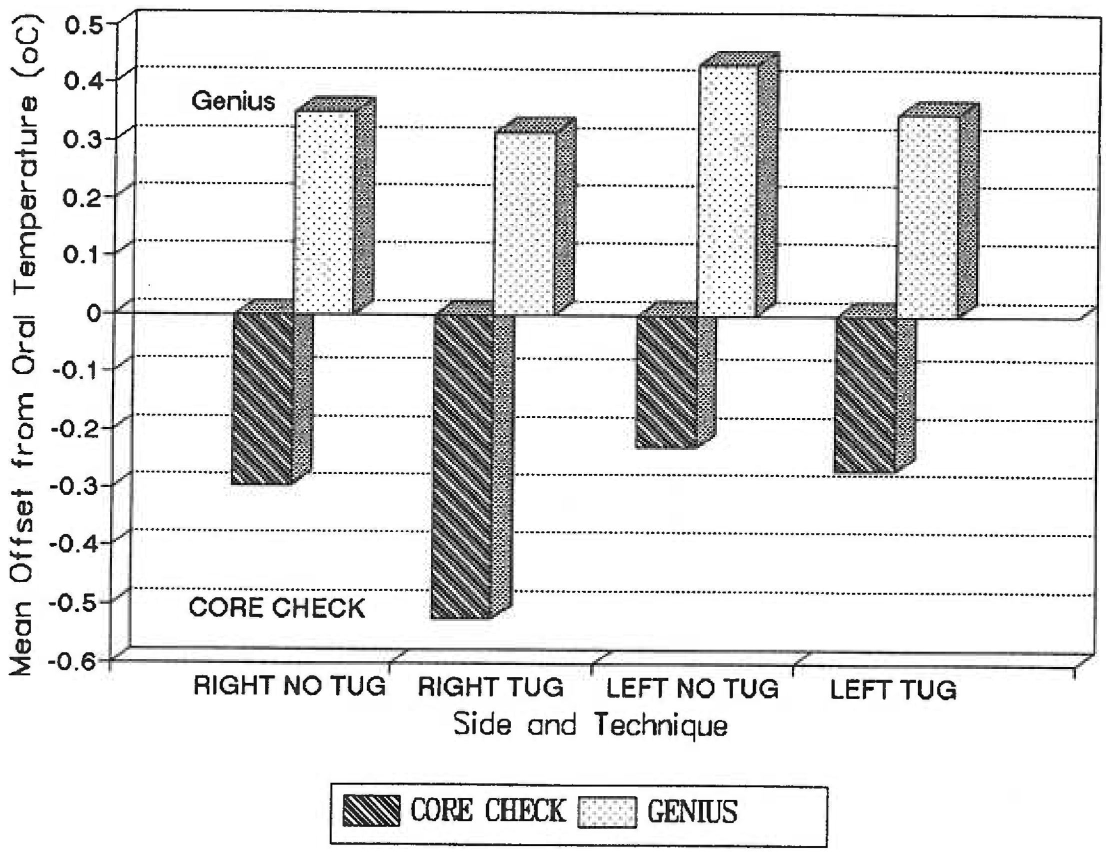


Figure 5. Mean offset from reference oral temperature for each measurement combination.

Table 7

Summary of Paired *t* tests to Compare Each Measurement Combination to the Reference Oral Temperature

Measurement combination	Mean tympanic-based temperature (°C)	Mean reference oral temperature (°C)	*t* value	*p* value
Right IVAC® no tug	36.76 ± .48	37.05 ± .56	-5.620	.000
Right IVAC® tug	36.53 ± .57	37.05 ± .56	-8.085	.000
Right Genius® no tug	37.40 ± .65	37.05 ± .56	5.278	.000
Right Genius® tug	37.37 ± .68	37.05 ± .56	4.983	.000
Left IVAC® no tug	36.82 ± .57	37.05 ± .56	-3.452	.001
Left IVAC® tug	36.78 ± .49	37.05 ± .56	-4.382	.000
Left Genius® no tug	37.49 ± .59	37.05 ± .56	6.354	.000
Left Genius® tug	37.40 ± .59	37.05 ± .56	4.772	.000

Table 8

Frequency Distributions of Background Variables

Background variables	Frequency	Percent
Position		
Flat	4	8
Trendelenburg	1	2
Head of bed elevated 20-90°	39	78
Sitting	6	12
Siderails		
Down	28	56
One or more rails up	22	44
Oxygen		
None	40	80
1-6 liters/minute	10	20
Oxygen delivery system		
Nasal cannula	8	16
Face mask	2	4
Thermometer preference		
None	30	60
IVAC	14	28
Genius	6	12

Note. n = 50.

and at the end of body temperature measurements. The range of ambient temperature values was from 20.7 to 25.4°C; further analysis was not done.

CHAPTER V

DISCUSSION

The major purpose of this study was to compare infrared tympanic-based estimates of core temperature measured using different sides, instruments, and techniques. A secondary purpose was to compare tympanic-based temperature with a concurrent oral temperature. The subjects were a convenience sample of 50 general adult medical-surgical inpatients from six clinical units at a 188-bed community hospital. Tympanic-based temperatures were measured with two different infrared thermometers, both in the core mode. These measurements were taken in random order with a total of eight measurements obtained, two with each thermometer, two on each side with one using the ear tug method and one with the ear in its natural position. Oral temperature and ambient temperature were measured before and after the tympanic-based measurements.

A three-factor ANOVA for repeated measures pointed out differences among the three variables. Tympanic-based temperatures measured with the IVAC® CORE•CHECK™ thermometer were found to be statistically lower ($p < .001$) from those measured with the FirstTemp® Genius® thermometer. The mean difference between these two thermometers was 0.69°C, a clinically significant finding, since treatment decisions might be affected by temperature measurements varying by this amount. The FirstTemp® Genius® thermometer was found to be higher than the mean oral reference temperature by 0.3 t 0.4°C, and the IVAC® CORE•CHECK™ thermometer was lower than the mean oral reference temperature by 0.2 to 0.4°C.

Therefore, if the assumption is true that oral temperature is 0.3 to 0.4°C below PA temperature, then these findings suggest that the FirstTemp® Genius® readings are close to PA temperature and the IVAC® CORE•CHECK™ readings are lower than PA temperature. This is in contrast to Erickson and Yount's (1991) study. A number of factors could have contributed to the difference in thermometers. The microprocessor equation (algorithm) in each thermometer is based on different clinical data and the IVAC® CORE•CHECK™ makes an ambient temperature correction. In addition, the IVAC® CORE•CHECK™ probe cover had a cardboard rim, which at times appeared to interfere with the depth of thermometer probe placement. It also had a shorter probe which made secure placement into the ear canal more difficult. Although the FirstTemp® Genius® thermometer had a slightly greater diameter at the probe tip, the overall probe was longer and narrower, which made placement easier. Subjects in the pilot study stated that the FirstTemp® Genius® thermometer felt as though it occluded the ear canal more completely than the IVAC® CORE•CHECK™ thermometer did. The design of the thermometers and probe covers could have contributed to the differences observed. Studies to date have focused on comparing tympanic-based temperatures to other types of reference temperatures (oral, PA, bladder) and not between the different brands of tympanic-based thermometers. Therefore, these results need to be confirmed by future research.

Tympanic-based temperatures measured in the right ear were found to be lower than those measured in the left ear. Although the difference was found to be statistically significant ($p = .023$), it amounted to only a 0.11°C temperature difference. This was not considered to be clinically significant, since it would be unlikely that alternative treatment decisions would be made based on a difference of this magnitude. This is not consistent with the results found by Kenney et al. (1990), who reported a smaller mean difference between right and left ears of $0.01 \pm 0.02°C$. Other sources found the temperatures in the left and right ears to be nearly identical (Chamberlain et al., 1991; Shinozaki et al., 1988; Terndrup et al., 1989). The difference noted in this study was felt to be related to the operator and not to the subject. Both of the investigators were right-handed and found placement of the thermometers more comfortable when on the subject's left side as compared to the right. This could have contributed to a more optimum placement on the left side.

Tympanic-based temperatures measured with the ear tug technique were found to be lower than those measured when it was not used. The difference between these techniques was statistically significant ($p < .001$), but not considered to be clinically significant since the mean difference only amounted to 0.10°C. A temperature variation this small would be unlikely to influence treatment decisions. Previous studies had found tympanic-based temperatures were higher by a mean of 0.2°C when the ear tug was used (Pransky, 1991; Shenep et al., 1991). We found the opposite to be true; in this sample, tympanic-based temperatures were lower when the ear tug was used. This may be due to a number of factors. The procedure in this study was to place the thermometer and tilt the handle slightly upward, which straightened the ear canal (confirmed with otoscope). The ear tug was performed just prior to taking the measurement and at times it appeared that the tug caused the thermometer to become less securely placed within the ear canal. Since the purpose of the ear tug is to straighten the ear canal, the combination of the three step placement procedure and the ear tug may have resulted in the lower temperature readings because the tug was performed on an already straightened ear canal. Pilot study subjects commented that many times the tug seemed to pull the probe out of the ear canal, especially with the IVAC® CORE•CHECK™. In addition, the tug added one more step to the thermometer placement procedure. With more steps added to the measurement process, consistent placement of the thermometer probe becomes more difficult for the operator. Since the difference between temperature values obtained with and without the ear tug were small, it does not appear to be a critical part of the measurement process.

As expected, tympanic-based temperatures measured in the core mode were found to be different from oral temperatures. A statistically significant ($p < 0.001$) difference was found between each of the eight tympanic-based temperature methods and the oral reference temperature. The literature on this topic is conflicting. Previous investigators using the FirstTemp® thermometer in the core mode found tympanic-based temperatures to be higher than oral temperatures by approximately 0.6 to 1.0°C (Terndrup et al., 1989; Erickson & Yount, 1991). Nierman (1991) found the FirstTemp® thermometer algorithm in the core mode to be set 0.4°C too high, which may explain previous findings. Talo et al., (1991) using a Thermoscan® thermometer (unknown mode) found very little difference between the two measurement sites (-0.20 ± 0.59°C). Even within this study, the results were conflicting; temperatures taken with the FirstTemp® Genius® thermometer were usually higher (by a mean of 0.36°C) than the corresponding oral temperature measurements while temperatures taken with the IVAC® CORE•CHECK™ thermometer were usually lower (by a mean of 0.33°C) than the corresponding oral temperature. Depending on the combination of side, instrument, and technique used, a difference of -0.53 to 0.43°C was found between the tympanic-based and reference oral temperatures. Therefore, the temperature measurements obtained are dependent not only on technique, but on the choice of instrument and mode.

A number of limitations were noted in this study. The sample size was small, especially with regard to the number of variables under investigation. Oral temperature is not considered to be the best reference to measure against, in that PA temperature is a better reflection of core temperature values. However, PA temperature measurement is not readily available in most hospitalized patients. In addition, oral temperatures were taken before and after all tympanic-based temperatures and not as reference with each tympanic-based temperature. Although a range of temperatures was sought when recruiting subjects, patients with extreme temperatures, either very cool or febrile were not available.

Summary and Implications

Based on the information obtained in this study, several recommendations are suggested for clinical practice related to careful thermometer placement, the accessibility of calibration equipment to verify thermometer settings, and the confusion surrounding the various modes available on some infrared thermometers, including the FirstTemp® Genius®. Inconsistent or "sloppy" placement of the thermometer can result in a wide range of temperature values. Proper technique should be taught to nursing staff, with the expectation that practice will be needed so that they can become proficient in this new equipment. It is our recommendation that the three step process used for probe placement be taught to the nursing staff to be used without an ear tug. Calibration equipment must be readily available to check thermometers on a periodic basis and those which provide questionable values at any time. Finally, the infrared thermometers should be set in the same mode, and used within a specified clinical setting to allow consistent interpretation of the values. Having different thermometers set to different modes only serves to confuse the interpretation of the values obtained. The preference of these investigators is that all infrared ear thermometers be set in the core mode, since core temperature is the reference value upon which clinical decisions are made.

This was a small study which scratched the surface of a number of issues related to measurement of body temperature by infrared ear thermometry. Further research is needed on a larger population to determine if similar results occur. Limited numbers of variables should be investigated so that clearer relationships can be established between side, instrument and/or technique. For example, what is the effect of patient position or the presence of siderails on tympanic-based temperature measurements? Can the difference between instruments be replicated if the measurement combinations are limited? Would the same differences be found in subjects whose body temperature is very cool (<36.0°C) or warm (>38.0°C)?

Through research in these areas, more information can be added to the knowledge base regarding tympanic-based temperature measurement and more accurate information about patient temperatures can be obtained, so that better clinical decisions can be made.

Nurses rely on current technology and their knowledge base to make clinical assessments and the appropriate decisions for nursing interventions. Nursing is concerned with and addresses the individual human responses to actual or potential health problems (ANA, 1980). Temperature is a response to an actual disease or can be a warning signal for a potential health problem and both scenarios are within nursing's realm for diagnosis and intervention. Therefore, common temperature measurements, such as tympanic-based measurements, should accurately reflect core temperature. Research needs to continue to focus on determining the accuracy of temperatures obtained from the intermediate zone as compared with those from the core zone. The least invasive way to accurately monitor temperature will be readily welcomed by the staff nurse and the patient.

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Appendix A.

OREGON HEALTH SCIENCES UNIVERSITY
Consent Form

STUDY TITLE: Tympanic-based Temperature Measurement in Relation to Thermometer and Technique

INVESTIGATORS: Kathleen Guthrie, BSN, RN (503) 757-5116
Nancy Keuneke, BSN, RN (503) 757-5168
Graduate Students, School of Nursing
Oregon Health Sciences University

FACULTY ADVISOR: Roberta S. Erickson, PhD, RN (503) 494-7839
Assistant Professor, School of Nursing
Oregon Health Sciences University

PURPOSE:
In this research project, we are comparing temperature measurements in the ear with two different thermometers, pulling on the ear versus not doing so and the left versus the right ear. The ear temperature will be compared to an oral temperature. These readings will be obtained in one visit.

PROCEDURES:
As part of your routine nursing care, your temperature is taken one time or more daily. With your permission, we would like to take your temperature in your mouth and ear using common hospital procedures. For the mouth temperature, a thermometer will be placed under your tongue for about 30 seconds. For the ear temperatures, a special thermometer will be placed in the outer opening for about 5 seconds. We will take your mouth temperature 2 times and your ear temperature 8 times. For the ear temperatures, 2 different thermometers will be used, taking four measurements with each of them, half on the left side, and half on the right. For half of the readings we will pull gently on your ear to straighten the ear canal, much like your doctor does when examining you ear. For the other half, the ear will be in its natural position. We will obtain background information from your hospital record. Temperature readings will take 15-30 minutes. Also note, air temperature will be measured by your head.

RISKS AND DISCOMFORTS:

The study involves common temperature measurement procedures. The only risk of participation is possible mild, transient discomfort and redness in the outer portion of the ear canal from the repeated temperature measurements.

BENEFITS:

You may not benefit personally from participating in this study, but by serving as a subject, you may contribute new information which may benefit patients in the future.

CONFIDENTIALITY:

Neither your name nor your identity will be used for publication or publicity purposes. Your study records will be identified by a code number rather than by name. We will keep the coded data indefinitely and may use it in future related research.

COSTS:

There are no costs to you for participating in the study.

LIABILITY:

The Oregon Health Sciences University, as an agency of the State is covered by the State Liability Fund. If you suffer any injury from the research project, compensation would be available to you only if you establish that the injury occurred through the fault of the University, its officers or employees. If you have further questions, please call Dr. Michael Baird at (503) 494-8014.

OTHER:

The investigators will answer any questions that you might have. Their telephone numbers are on the other side of this form. Your participation in the study is voluntary. You may refuse to participate, or you may withdraw from this study at any time without affecting your relationship with or treatment at Good Samaritan Hospital. You will receive a copy of the consent form. Your signature below indicates that you have read this consent form (or it has been read to you) and that you agree to participate in this study.

______________________________ __________

Subject Date

______________________________ __________

Person Obtaining Consent Date

Copy: Subject

Appendix B.

Protocol

1. Introduce yourself, explain the study and obtain a written informed consent from the subject.

    Hello. My name is ________. I am a Registered Nurse currently enrolled in a Masters program at Oregon Health Sciences University in Portland. I am working with __________, another nurse in the same program on a study of temperatures taken in the mouth and ears. We are looking for people who would be willing to participate in our study. We would take 2 temperatures in your mouth and eight temperatures in your ears. It will take about 5 minutes. The only risk of participating in this study may be a mild, temporary discomfort or redness in the outer portion of the ear canal. If you are willing to participate, we would like to have you read this consent form and we will be back in a short while to answer any questions and take the temperatures.

2. Obtain the subject's signature on the consent form, witness the signature, and give them a copy if they would like one.

3. Ask each subject to refrain from ingesting hot or cold foods/fluids until the investigators return to take the temperature measurements.

4. Measure the ambient temperature with a handheld microprocessor digital thermometer. Insert the battery into the back of the thermometer and place the thermometer probe within 1 foot of the patients head. Take the reading when the display remains constant.

5. Measure the oral temperature in °C using the IVAC® TEMP•PLUS® II predictive electronic thermometer.

    Make sure the instrument is set to Celsius by checking the recessed switch on the left side of the battery compartment. It should be in the right switch position. Grasp the base of the probe and withdraw it from the storage well. The display segments will light and the instrument will beep once. When --- appears, insert the probe firmly into a probe cover. Have the patient open his/her mouth, place the temperature probe in the posterior sublingual pocket and ask the patient to close his/her mouth. Continue to hold the probe in position until the audible tone is heard. Withdraw the probe, read the displayed temperature. Hold probe over a waste receptacle and press the colored ejection button on the probe base to eject the used probe cover. Replace probe in the storage well.

6. Follow the previously identified random order to obtain the tympanic-based temperature measurements. Only one investigator will take temperature measurements from each subject. If consecutive measurements are to be obtained in the same ear, wait 30 seconds between readings.

   a. Place the thermometer with the probe aimed down the ear canal, insert the probe firmly, move the thermometer handle towards the patients face until the handle is parallel to the face at the jaw line, tilt the thermometer up so that the probe is aiming at the patients opposite eye.
   b. When obtaining measurements using the ear tug method, use your non-dominant hand to tug gently on the upper outer portion of the ear pulling toward the back and top of the head. Take the temperature with the instrument in your dominant hand.
   c. When obtaining measurements without the ear tug method, support the opposite side of the subjects head with your non-dominant hand. Take the temperature with the instrument in your dominant hand.
   d. FirstTemp® Genius® Model 3000A Operation:
      Remove probe from base unit. COR should be present in the display window, indicating core mode. If COR is not displayed, press the mode selection button located on the underside of the probe. Press the mode button until COR is displayed. Make sure the temperature is in °C. To change the display, hold the mode button for 2-3 seconds. Place disposable cover on probe tip. Place probe in ear canal and seal opening. Press and release SCAN button. Remove probe from ear as soon as triple beep is heard and display flashes DONE. Read temperature on display. Press blue RELEASE button over waste receptacle to discard probe cover. Return probe to base unit.

   e. IVAC® CORE•CHECK® Model 2090 Operation:
      Remove thermometer and dispenser from the home base. Set the thermometer to Celsius by sliding the recessed switch located on the left side of the battery compartment. Dispense a probe cover by pushing the slide completely in and slowly releasing. Attach a single probe cover by centering probe tip onto the surface of probe cover film; then press firmly until backing material of probe cover engages the base of the probe. Failure to fully load the probe cover results in a REPLACE COVER message. Position the covered probe tip in the ear canal aiming the tip toward the opposite eye and sealing the opening. Press and release the temperature switch to initiate a measurement. Hold the thermometer in place until the temperature reading is displayed, approximately 3 seconds. Remove the thermometer from the patient's ear and peel off the probe cover. Dispose of probe cover and return thermometer to base unit.

7. Take a second oral temperature reading using the IVAC® TEMP•PLUS® II predictive electronic thermometer using the procedure outlined in #4. A mean of the two oral temperatures will be utilized in data analysis.
9. Take a second ambient temperature reading after completing the body temperature measurements.

10. Gather equipment.

11. Thank subject for his/her participation.

Appendix C.

Data Collection Tool

ID #	DATE	TIME	AMBIENT TEMP	ORAL TEMP	RT IV NO	RT IV TUG	RT GE NO	RT GE TUG	LT IV NO	LT IV TUG	LT GE NO	LT GE TUG	ORAL TEMP2	AMBIENT TEMP2	COMMENTS	RECORDER INITIALS
1					1	4	6	2	7	8	5	3				
2					4	5	2	7	3	6	1	8				
3					4	2	3	8	6	5	1	7				
4					1	4	5	2	6	7	3	8				
5					7	1	5	4	3	6	2	8				
6					7	2	1	8	5	3	6	4				
7					3	6	2	5	1	8	7	4				
8					4	5	2	1	7	3	8	6				
9					1	2	8	7	3	5	6	4				
10					6	4	5	1	2	7	8	3				
11					1	4	2	3	8	5	6	7				
12					8	6	1	7	3	4	5	2				
13					7	4	3	5	2	6	1	8				
14					3	8	4	7	6	1	2	5				
15					2	7	8	4	6	1	3	5				
16					7	2	4	8	1	3	5	6				
17					4	3	8	1	2	7	6	5				
18					7	5	4	6	8	1	2	3				
19					6	3	5	4	2	8	7	1				
20					8	6	1	3	7	4	2	5				

ID #	MEDICAL RECORD #	DIAGNOSIS	AGE	SEX	POSITION	OXYGEN
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
16						
19						
20						

Appendix D.

Study Data

Sub #	Ambient Temp #1	Oral Temp #1	Right IVAC No-Tug	Right IVAC Tug	Right Genius No-Tug	Right Genius Tug	Left IVAC No-Tug	Left IVAC Tug	Left Genius No-Tug	Left Genius Tug	Oral Temp #2	Ambient Temp #2
1	21.4	37.3	36.9	36.7	37.5	37.5	36.0	36.0	37.0	37.3	37.3	21.5
2	23.9	37.3	37.1	37.1	37.6	37.2	36.8	37.2	37.4	37.1	37.3	23.9
3	23.7	37.1	36.4	36.6	37.5	37.4	36.7	36.6	37.3	37.1	37.0	23.7
4	22.7	36.2	37.0	36.7	37.5	37.7	37.2	37.1	37.4	37.2	36.4	23.0
5	22.7	36.8	36.6	36.6	37.8	37.4	36.8	36.7	37.1	37.1	36.8	22.4
6	22.2	37.5	37.1	36.2	37.6	38.0	37.0	37.3	36.9	37.4	37.3	22.2
7	22.6	37.6	36.7	36.8	37.5	37.7	37.3	36.8	37.6	38.0	37.6	22.7
8	23.7	37.1	37.2	36.5	37.5	37.7	37.1	37.2	37.4	37.4	37.5	23.6
9	23.4	36.6	36.4	36.5	36.9	37.0	37.1	36.3	36.6	37.1	36.8	23.4
10	22.4	37.2	36.8	37.2	37.5	37.0	37.4	37.0	37.4	37.8	37.2	22.4
11	22.2	36.8	36.3	35.6	36.1	36.6	36.1	36.5	36.5	36.6	37.0	22.4
12	21.2	37.0	36.7	36.7	37.2	37.6	37.4	37.1	37.6	36.2	36.9	21.2
13	21.8	36.5	36.8	35.7	37.6	37.6	36.5	36.6	37.4	37.2	36.7	22.0
14	22.5	37.2	36.9	36.2	37.3	37.7	36.5	37.0	37.4	37.1	37.5	22.4
15	22.7	37.1	37.2	36.9	37.1	37.1	36.2	37.0	37.1	37.1	37.0	21.8
16	22.7	37.1	36.8	36.9	37.6	37.3	37.0	36.9	36.9	37.1	37.0	22.7
17	24.4	37.5	37.4	37.0	38.1	38.1	37.8	37.3	37.9	37.9	37.9	23.6
18	24.8	38.0	36.9	37.3	38.4	38.4	37.8	37.7	38.5	37.9	38.3	25.3
19	21.5	37.7	36.8	37.2	37.4	37.5	37.2	36.6	37.5	37.4	37.7	20.7
20	25.0	37.7	37.5	36.8	37.7	37.7	37.1	36.8	38.2	37.5	37.6	24.9
21	25.4	38.6	37.8	37.5	39.2	39.0	38.1	38.0	38.8	38.6	38.0	24.8
22	23.5	37.2	37.1	37.1	37.9	37.6	37.3	37.2	38.4	37.8	37.0	23.5
23	23.4	37.4	36.7	36.7	38.0	37.9	37.1	36.9	37.8	36.6	37.5	23.7
24	21.9	36.9	36.8	37.1	37.2	37.3	36.6	36.9	37.9	37.6	37.1	21.9
25	23.1	36.6	36.6	35.9	37.3	37.2	36.9	36.7	37.4	37.9	36.7	22.9
26	22.7	37.2	36.2	35.4	36.1	36.5	36.8	36.5	37.7	37.8	37.2	22.4
27	21.2	36.8	36.8	36.2	37.5	37.2	37.2	37.1	37.2	37.7	37.1	21.1
28	24.1	36.8	37.3	36.8	37.4	37.4	36.9	36.9	37.7	37.7	36.9	24.4
29	22.7	36.8	36.5	36.4	37.2	37.3	37.0	37.1	37.3	36.9	36.3	23.1
30	22.0	37.5	37.2	37.1	38.0	37.7	37.1	37.2	37.7	37.5	37.6	22.3
31	23.5	36.0	36.2	36.3	37.3	37.0	36.4	36.5	37.6	37.7	36.2	23.3
32	23.5	36.7	36.6	36.4	37.5	37.9	36.8	36.6	37.1	36.8	36.9	23.4
33	23.1	37.2	37.4	36.7	37.8	38.2	36.8	37.2	38.2	38.4	37.4	24.5
34	22.4	36.1	36.1	35.5	36.4	36.3	36.1	35.7	36.8	36.5	36.2	22.5
35	23.1	35.9	35.6	35.7	36.1	36.2	35.7	35.5	35.8	36.1	35.9	22.6
36	22.8	36.5	36.4	36.1	37.1	36.9	36.2	36.5	37.5	37.5	36.6	22.9
37	22.4	35.9	35.7	35.6	36.3	36.0	36.0	35.3	36.7	36.6	35.8	22.6
38	23.7	36.1	35.9	35.9	36.5	36.1	35.6	36.5	36.4	36.0	36.3	23.8
39	23.5	36.6	35.9	35.3	35.9	35.9	36.0	36.2	37.4	37.0	36.6	22.8
40	22.4	37.1	36.7	36.7	37.2	37.3	36.9	37.0	36.7	37.0	36.9	22.3

Sub #	Ambient Temp #1	Oral Temp #1	Right IVAC No-Tug	Right IVAC Tug	Right Genius No-Tug	Right Genius Tug	Left IVAC No-Tug	Left IVAC Tug	Left Genius No-Tug	Left Genius Tug	Oral Temp #2	Ambient Temp #2
41	23.5	37.5	36.7	37.0	37.1	38.0	37.6	37.1	38.0	38.0	37.6	24.2
42	23.2	36.2	36.5	36.3	37.0	36.8	36.6	36.6	37.8	37.6	36.0	23.1
43	22.8	37.6	37.1	36.6	38.0	37.4	35.7	36.6	37.5	37.6	37.3	22.8
44	22.5	37.1	36.8	37.0	37.4	37.4	36.8	36.4	37.5	37.9	37.1	22.4
45	22.1	37.5	37.2	36.5	38.3	38.2	37.1	36.9	38.2	38.4	37.7	22.0
46	23.7	37.8	37.9	37.4	38.6	38.6	37.6	36.8	38.5	38.5	38.1	23.0
47	22.0	37.1	36.6	36.5	37.4	37.3	36.1	36.8	37.9	37.6	36.9	23.3
48	23.8	37.0	36.6	35.6	37.7	35.9	36.9	37.2	38.0	37.9	36.9	23.4
49	23.8	37.3	36.8	37.3	37.2	37.6	37.1	36.8	37.8	37.7	37.4	23.8
50	24.5	37.7	36.7	36.6	38.1	38.1	37.2	36.7	37.9	37.6	37.3	24.4