EFFECT OF CERUMEN ON
INFRARED EAR TEMPERATURE MEASUREMENT

by

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ABSTRACT

Title: Effect of Cerumen on Infrared Ear Temperature Measurement.

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Purpose:

To ensure accurate assessment of temperature, health care providers need to understand the effect of different variables on the readings they obtain. The purpose of this study was to determine whether the occlusion of one ear canal by cerumen affected the usual temperature difference between the ears, as measured with an infrared thermometer in elderly nursing home residents.

Methods:

The subjects were a convenience sample of 14 residents of a rural nursing home, 5 males and 9 females, ranging in age from 78 to 99 years (mean 87.3 $\pm$ SD 6.2), who had at least one ear occluded by cerumen so that the tympanic membrane could not be visualized. Temperature was measured three times in each ear using an infrared thermometer (FirstTemp® Genius®) in the core mode both before and after irrigation of the experimental (occluded) ear. The highest value of each set of triplicate ear-based temperatures was used for analysis.

Results:

A two-factor analysis of variance for repeated measures indicated a trend for an interaction between the presence of cerumen and the temperature difference between the ears (p=.08). When the experimental ear was occluded with cerumen (Time 1), the temperature reading was lower than in the control ear by a mean of 0.22 $\pm$ 0.73°F (0.12 $\pm$ 0.41°C). In contrast, when both ears were clear of cerumen (Time 2), no temperature difference between the two ears was apparent, with the mean values higher in the experimental ear by a negligible 0.02 $\pm$ 0.71°F (0.01 $\pm$ 0.39°C). Neither of the difference values was considered clinically significant. The large standard deviation found reflects the variability of this method of temperature measurement. The extended irrigation had a tendency to cause an inflammation of the ear necessitating a delay of 3 to 4 days between the initial set of triplicate ear-based temperature readings (Time 1) and the second set (Time 2).

Discussion:

Thus, occlusion of the ear canal by cerumen had a tendency to affect what was assumed to be the usual temperature difference between the ears, lowering the reading that was obtained. However, the effect was small, about 0.2°F (0.1°C). Therefore, measurement of infrared ear-based temperature for clinical use may be made without considering whether cerumen is present. However, clinicians must be aware of the large variability in this method of temperature measurement, for which the presence of cerumen is probably one contributing factor. If precision of measurement is important, clinicians may want to take more than one measurement 1 minute apart and use the highest value. In addition, using the same ear each time the temperature is measured would probably decrease variability.

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CHAPTER I

INTRODUCTION

Body temperature has been assessed as part of vital signs for almost 200 years. Temperature measurement is done by nurses as part of their daily care for patients, whether in the community, in nursing homes, or in acute care settings. Temperature is assessed to follow trends of change as well as identify critical levels, since normal physiologic function depends on a relatively narrow body temperature range. Treatment is often based on identification of an elevated body temperature as an early indicator of infection.

Core temperature reflects the temperature of the metabolically active organs of the body, such as the brain, heart, liver, and kidneys. In clinical practice, absolute accuracy of body core temperature measurement is neither possible nor necessary. However, measurements must be accurate enough to detect clinically important temperature changes or levels. The usual method of following temperature trends has been to measure at more peripheral sites such as oral, rectal, or axillary, hoping to closely reflect changes in core temperature. With the recent introduction of ear-based measurements with infrared thermometers, a new concept for estimating core temperature is at the disposal of clinicians. As with other methods, accurate interpretation of temperature readings depends on understanding the possible factors that influence it.

Statement of the Problem

Assessing temperature with an infrared ear thermometer has many advantages and is already gaining wide use. Nurses caring for the elderly often ask if the presence of cerumen in the ear canal makes a difference in infrared temperature readings, but little information is available to guide them in answering this question. It is widely assumed that the presence of cerumen has little or no effect on measurements, but the only study that attempted to look at the problem was done on children, and even then, the data were inadequate to allow any conclusions (Chamberlain et al., 1991). Some researchers have used the presence of cerumen in the ear canal as an exclusionary factor for their infrared thermometry studies, while others have totally ignored this factor. The issue has special relevance for the elderly in whom the incidence of impacted cerumen is reported to be 35% (Lewis-Cullinan & Janken, 1990). Research is needed to determine whether presence of cerumen in the ear canal is a variable that needs to be considered when measuring ear-based temperatures with an infrared thermometer.

Purpose

The purpose of this study was to determine whether the occlusion of one ear canal by cerumen affected the usual temperature difference between the ears, as measured with an infrared thermometer in elderly nursing home residents.

Significance to Nursing

Since nurses assess body temperature routinely, they need to know which instruments provide accurate information and what factors in the patient and environment can affect the readings. Because infrared thermometers are easy to use and very fast, recording a temperature in 5 seconds or less, they are very attractive to nurses. In addition, the reading is not affected by factors such as ingestion of cold or hot liquids that often interfere with oral readings (Terndrup, Allegra & Kealy, 1989). Because no contact with mucous membranes occurs, infrared thermometry is in keeping with universal precautions. However, clinicians need to understand the effect of potential influencing factors to accurately assess ear-based temperature measurements. This study will evaluate the effect of cerumen in the ear on the usual temperature difference between the ears as measured with an ear-based thermometer in the elderly.

CHAPTER II

CONCEPTUAL FRAMEWORK AND REVIEW OF LITERATURE

Concept of Core Temperature

When measuring temperature, the value sought has been the one that most accurately reflects the true "core" temperature. Core temperature refers to the temperature of the critical organs in the body, such as the heart, brain, and kidneys. The basis of the concept of core temperature is that "convective stirring action of the circulation results in a nearly uniform temperature throughout the inner core of the body" (Brengelmann, 1989). We need to measure the temperature of the media (arterial blood) that is also being received by the integrative centers of thermoregulation, with the pulmonary artery being the optimal representation of core temperature (Brengelmann, 1987).

Because heat is dissipated or conserved through vasodilation and vasoconstriction of the vessels near the skin surface, a temperature gradient develops with progressive decline of temperature outward toward the skin surface. The superficial zone represents the shell or periphery of the body, such as the extremities and skin or outer covering of the body. The inner zone represents the core or center of the body, specifically the vital organs within the head and trunk.

The optimal site to measure core temperature is in the pulmonary artery via a pulmonary artery catheter with a thermistor probe (Brengelmann, 1987). The esophagus, in the region where it is contiguous with the left atrium, also is regarded as an excellent site for approximating core temperature. The peripheral sites for temperature measurement include the axilla and other skin surfaces, such as the forehead, and are highly influenced by external factors. The oral and rectal sites are on the outer edge of the core and differ less markedly from arterial blood temperature. The ear canal temperature is similar to these core-margin sites in that the external factors have less influence than on the peripheral sites such as the axilla and forehead.

Temperature Measurement in the Ear

Assessing body temperature with an infrared thermometer that gathers infrared energy emitted by the walls of the ear canal as well as a portion of the tympanic membrane has been shown to reflect core temperature while still utilizing a clinically accessible site. This method of measurement is referred to in the literature as tympanic membrane, tympanic-based, or ear-based temperature. The term ear-based will be used in this paper, since it is more descriptive of what the thermometer actually measures.

Direct Contact Tympanic Temperature Measurement

Indwelling contact-type tympanic membrane or auditory canal temperature probes have been used for many years in operating rooms and compare well to other measures of core margin temperature. Since the tympanic membrane's blood supply comes from several branches of the external carotid as well as one from the internal carotid artery (Brinnel & Cabanac, 1989), it closely reflects the temperature of the blood supplying the vital organs considered part of body core. The temperature values reported, however, lag behind pulmonary artery and esophageal values during rapid temperature changes (Shiraki, Konda, & Sagawa, 1986). The special training needed for placement and insulation of the contact probe make its use inappropriate for most health care providers. In addition, trauma to the tympanic membrane and patient discomfort have been documented (Tabor, Blaho & Schriver, 1981; Wallace, Marks, Adkins & Mahaffey, 1974). For these reasons, routine use in alert patients is not practical.

Non-Contact Ear-based Temperature Measurement

A new generation of non-contact ear-based infrared-sensitive thermometers was introduced in the mid-1980s. There are currently two different types of infrared thermometers, one using a thermopile infrared detector and the other, a pyroelectric infrared detector, which for the user are very similar. The probes used resemble an otoscope ear piece and are placed in the outer third of the ear canal. No contact with the tympanic membrane is needed or possible. When activated the infrared thermometer measures the wavelengths of infrared energy emitted from the ear canal walls and a portion of the tympanic membrane, then uses a microprocessor to compute a nearly instantaneous temperature readout (Figure 1). The probe is inserted firmly enough to seal the ear canal from ambient air and maximize insertion depth, but cause the patient little or no discomfort. The pinna of the ear is often positioned for the reading by pulling back and up for an adult and down and back for a child to straighten the ear canal for better viewing of the tympanic membrane. Early reports suggested that higher and presumably better readings were obtained when the ear was pulled on, but recent studies have shown no advantage to doing so in either adults or young children (Erickson & Meyer, 1993; Erickson & Woo, 1993; Guthrie & Keuneke, 1992).

Cooper, Cranston, and Snell (1964) demonstrated a temperature gradient down the external auditory meatus, with the warmest temperature at the tympanic membrane. They noted that similar responses occur at different points in the ear canal to changes in blood temperature, providing a good indication of temperature changes in arterial blood. Since the infrared ear thermometers gather infrared

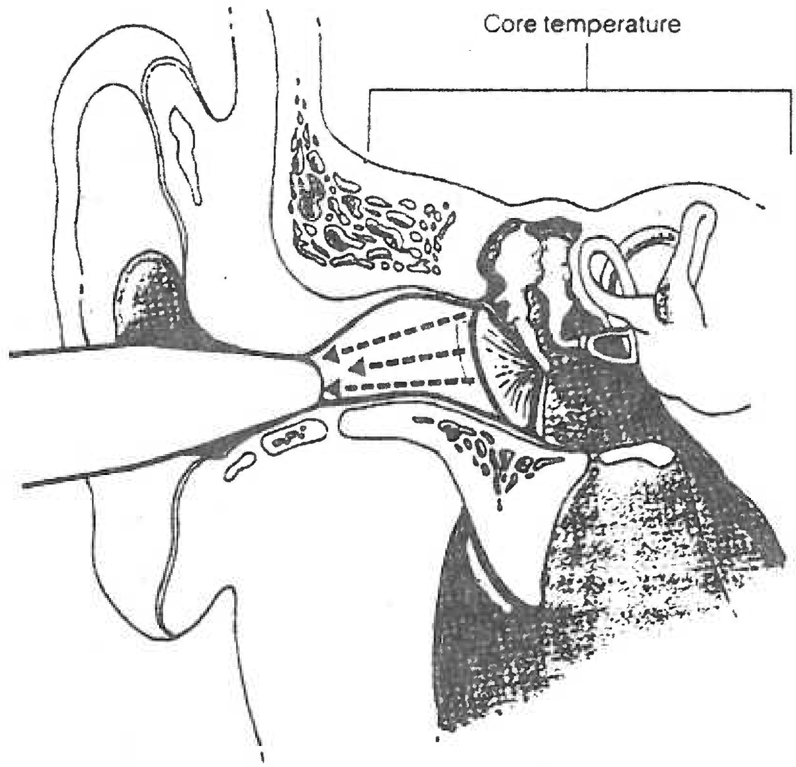

Figure 1. How ear-based thermometry works. An infrared sensor placed in the ear canal records emissions from the tympanic membrane and walls of the canal.

From "Tympanic thermometry: Temperatures without tears" by A.J. Schuman, 1991, Contemporary Pediatrics Technology, (9), p. 4. Reprinted by permission.

emissions from a portion of the tympanic membrane as well as the surrounding ear canal wall, the readings are not strictly a measurement of tympanic temperature. Because of the gradient, it is possible that improper aiming or obstruction, as from curvature of the ear canal, could result in lower temperature measurements (Health Devices, 1991).

Because clinical personnel are not familiar with the actual numerical values of the ear-based temperatures, some manufacturers have incorporated modes with additive offsets into the thermometers to estimate temperature at more familiar sites. For example, the displayed temperature may be an estimate of core, oral, or rectal temperatures based on the mean differences between ear temperature as measured with the device and the temperature of the other sites in selected patient samples. In addition, some infrared thermometers also correct for ambient air temperature because of its influence on the temperature at least partway into the ear canal. Because the various modes are confusing, it is recommended that clinicians use the infrared thermometer in either the "actual" or "core" modes, depending on the model, thus either avoiding the offset value the manufacturer adds to the reading or at least estimating core temperature. In addition, clinicians should learn the normal ear temperature of individuals of different ages and sizes (Health Devices, 1991; Erickson & Kirklin, 1991). However, different models of instruments can provide different values, even when used in the same mode, depending on the accuracy of the algorithm used in the instrument's microprocessor and factors of design and use that affect the instrument's field of view and positioning in the ear canal (Erickson & Meyer, 1993; Erickson & Woo, 1993; Nierman, 1991).

Green, Danzl, and Praszker (1989) compared oral, ear-based temperature readings in 411 emergency department patients ages 14 to 91 using the originally available FirstTemp® ear thermometer in unspecified mode. Subjects with otitis media, cerumen impaction, or tympanic membrane perforation were not included in the study. Mean ear-based temperature was 1.10 ± 0.04°F (0.61 ± 0.02°C) higher than oral temperature (p=.00001), while there was no significant difference from rectal temperatures (Green et al., 1989). The findings are consistent with other studies using the original FirstTemp thermometer; however, they probably reflect inaccuracies of the thermometer's core adjustment as indicated in other studies (Erickson & Yount, 1991; Nierman, 1991).

Shinozaki, Deane, and Perkins (1988) found a high correlation (r=0.98) between pulmonary artery temperature and ear-based temperature over a range of 93.2°F to 103.1°F (34°C to 39.5°C), with no significant difference between the left and right ears 0.0 ± 0.18°F (0.0 ± 0.1°C). The FirstTemp ear thermometer was used but the mode was not specified.

Mahan (1990) has also studied the correlation between ear-based and pulmonary artery temperatures using an Ototemp 300 infrared thermometer that is used with a scanning technique to detect the highest temperature. In 36 critically ill adult surgical patients, she found a mean difference between ear-based temperature and pulmonary artery temperature of 1.0°F (0.56°C) with a correlation of r=.89, with ear-based temperature lower (Mahan, 1990).

Milewski, Ferguson, and Terndrup (1991) compared pulmonary artery, rectal, and ear-based temperatures in 9 adult patients in an intensive care unit. Using an infrared thermometer (Thermoscan Pro-1®)in the "equal" or calibration mode, data were collected at 1 to 2 hour intervals for up to 48 hours. Pulmonary artery temperatures and ear-based temperatures were not significantly different and had a moderate correlation (r=0.74). The researchers did not control or account for the presence of cerumen. The tendency for the ear-based temperature to be cooler than pulmonary artery (Mahan, 1990) has been reported in previous studies (Muma, Treolar, & Wurmlinger, 1991), although different infrared instruments were used. In contrast, Nierman (1991) found the ear-based temperature to be higher with the FirstTemp thermometer, suggesting that the instruments' algorithm was set too high, not necessarily that the temperature was really different.

Using a convenience sample of 50 adult medical-surgical patients, Guthrie & Keuneke (1992) compared ear-based readings made with two infrared instruments in the core mode (FirstTemp Genius, CORE.CHECK), pulling versus not pulling on the ear to straighten the ear canal, and readings in the right and left ear along with a concurrent oral temperature. They found that mean temperatures were slightly higher in the left ear than the right ear (0.2°F or 0.11°C, p=.023) and, surprisingly, higher with the ear in its natural position than when the ear tug was used (0.18°F or 0.10°C, p<.001). They concluded that neither value was clinically significant. The FirstTemp Genius thermometer provided a mean temperature value that was 1.24°F (0.69°C) higher than did the CORE.CHECK thermometer, a difference they considered both statistically (p<.001) and clinically significant. They concluded that the greatest impact on ear-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. Presence of cerumen in the ear canal was not accounted for in this study.

Erickson and Kirklin (1991) compared ear-based estimates of core temperature with a CORE·CHECK infrared thermometer in core mode to bladder, oral, and axillary measurements in 38 critically ill patients, using pulmonary artery temperature as the reference. Data were collected at 20-minute intervals over a 4-hour period, during postoperative rewarming when possible. Ear-based, bladder, and oral temperatures agreed closely with concurrent pulmonary artery temperature, with mean offsets of no more than 0.18°F (±0.1°C) using either pooled data or averaged individual means. The mean offset was 0.13 ± 0.74°F (0.07 ± 0.41°C) for ear-based temperature. Oral temperature was probably elevated by use of mechanical ventilation with warmed gases in most subjects (R. Erickson, personal communication, 1992).

Temperature of Right versus Left ear

A number of studies have been done investigating the temperature difference that may occur between the right and left ears. Evidence suggests that while there may be very slight temperature differences in individual subjects (Chamberlain et al., 1991), the difference is not clinically significant. Kenney, Fortenberry, Surratt, Ribbeck, and Thomas (1990) used the FirstTemp to study 964 pediatric patients ages newborn to 18 years of age, finding a mean difference between left and right ear-based temperature readings of 0.2 ± 0.04°F (0.01°C ± 0.02), although the value was not statistically significant (*p* value not given). The investigators only used the left ear-based measurements in the analysis. Guthrie and Keuneke (1992) also found a slightly higher temperature [0.2°F (0.1°C)] in the left ear. Shinozaki et al. (1988) reported no difference between the left and right ear-based reading (0.0 ± 0.18°F or 0.0±0.1°C).

Shenep et al. (1991) studied 101 pediatric patients using the Thermoscan infrared thermometer, and found that the mean temperature of the left versus the right ear canal was essentially identical [99.54°F versus 99.5°F (37.52°C versus 37.50°C), *p*=.72]. Mahan (1990) studied 36 critically ill adults using a First Temp and reported a mean difference between right and left ear-based temperatures of 0.07°F (0.04°C). Most investigators have not reported if one ear was consistently higher than the other, but a few either used only one ear for the analysis (Kenney et al., 1990), or restricted all the measurements to one side (Terndrup & Milewski, 1991).

Prevalence of Cerumen

Lewis-Cullinan & Janken (1990) investigated the prevalence of impacted cerumen in a population of hospitalized elderly patients and evaluated the effect of cerumen removal in reversing hearing impairment. A geriatric version of the AudioScope® was used to measure hearing, as it tests frequencies of 500, 1000, 2000 and 4000 Hertz at an intensity of 40 decibels, the standard criteria for screening of hearing loss in the elderly. The maximum score requires hearing a total of eight tones or all four frequencies in both ears. Impacted cerumen was observed in 35% (79/226) of the subjects, more often bilaterally (*n*=45) than unilaterally (*n*=34). Improved hearing scores were obtained in 75% (93/124) of the irrigated ears, with subjects hearing one to three more tones per ear after the cerumen was removed (Lewis-Cullinan & Janken, 1990).

Brister, Fullwood, Ripp, and Blodgett (1986) studied the incidence of occlusion due to impacted cerumen in mentally retarded adolescents (*n*=44). One ear was occluded in 25% (*n*=11) and both ears in 9% (*n*=4). When a comparison group of 44 nonretarded adolescents was examined, none had occlusion of either ear. These findings suggest that mentally retarded adolescents are another population that may benefit from the findings of this study.

Only a few researchers have mentioned the possible effect of cerumen in the ear canal on the readings of the ear-based thermometer. Kenney et al. (1990) stated cerumen does not appear to affect values, citing a presentation given by Phillips (1985) which included an undocumented statement that ear wax is essentially transparent to infrared light, so poses no real problem for ear-based thermometers. Kenny et al. (1990), however, did not report the collection or analysis of data regarding cerumen in their study, although Talo, Macknin, and Medendorp (1991), citing Kenney as their reference, stated that a previous study had showed cerumen had no effect on the obtained ear temperature. Green et al. (1989) excluded any patient with cerumen impaction without explanation. Terndrup et al. (1989) checked their subjects for cerumen occlusions but found none. Chamberlain et al. (1991) attempted to study the effect of cerumen on ear-based temperature in pediatric patients, but could not draw conclusions because of inadequate sample size. The number was not specified, but the researcher stated that "few patients" had totally obscured tympanic membranes. Pransky (1991) stated that there was no impact on temperature measurement from a normal mild-moderate amount of cerumen (not defined) in his study of 100 pediatric patients, but did not disclose any data or analysis. Therefore, no evidence is available to directly evaluate the effect of cerumen in the ear canal on temperature measurement with an infrared ear-based thermometer. This factor needs to be studied if clinicians are to rely on the results of infrared ear-based thermometers, especially in view of the evidence that 34% of elderly patients may have at least one ear impacted with cerumen (Lewis-Cullinan & Janken, 1990).

CHAPTER III

METHODS

Study Design

This study used a quasi-experimental, one-group pretest-posttest design to determine if occlusion of one ear canal by cerumen affected the usual temperature difference between the ears as measured with an infrared ear-based thermometer. Subjects were selected who had at least one ear canal occluded with cerumen so that the tympanic membrane could not be visualized; if both ear canals were occluded, one ear was irrigated to remove the impacted cerumen. Because the independent variable, occlusion of one ear canal with cerumen, was the initial condition, the experimental data were collected first. After the experimental ear was irrigated, so that both ears were cleared of cerumen, then the control data were obtained. Each subject, therefore, served as his or her own control. Variables other than cerumen that might affect temperature in the ear canal were assumed to affect both ears equally.

Subjects and Setting

The desired convenience sample was 30 subjects ages 65 years or older residing in a rural eastern Oregon nursing home. Of the total population of 71 residents in the nursing home, 14 were identified by the staff as not appropriate for participation because of inability to cooperate with an otoscopic examination or tolerate irrigation of an occluded ear. Of the remaining 58 residents, 25 had at least one occluded ear canal. However, 9 were unable to tolerate the irrigations, 1 died before final data could be collected, and the irrigation could not be successfully completed for 1 subject. Therefore, the sample available for study consisted of 14 nursing home residents, 5 males and 9 females, ranging in age from 78 to 99 years with a mean age of 87.3 $\pm$ 6.2 years (Table 1). Eleven of subjects had dementia as their primary diagnoses followed by 3 each with diabetes or cerebrovascular accident, and 1 each with Parkinson's disease or chronic obstructive lung disease. Several subjects had more than one diagnoses. None of the subjects had documentation of perforated tympanic membrane in the medical record, and no perforations were observed following the irrigations. In addition no subjects had a history of trauma or birth anomaly involving the ears. All subjects were positioned so their ears were exposed to the air for a minimum of 1 hour prior to data collection. One subject wore a hearing aid which was removed for 1 hour prior to data collection.

At the time of ear-based temperature measurement, ambient temperature was measured within 1 foot of the subject's head and ranged from 70.9°F to 79.2°F (mean 74.2 $\pm$ 2.3°F) during the initial set of readings and 69.9°F to 76.7°F (mean 72.8 $\pm$ 2.0°F) during the final set of readings.

Table 1

Characteristics of the Study Sample

Subject ID #	Age	Gender	Primary Diagnosis	Experimental Ear
1	84	Female	Dementia	Right
2	87	Male	Dementia	Right
3	83	Male	Dementia	Right
5	90	Female	Dementia	Right
6	82	Female	COPD, CVA	Left
7	89	Female	Dementia, Diabetes	Right
8	78	Male	CVA	Left
9	97	Female	Dementia	Right
10	88	Female	Dementia	Right
11	90	Male	Diabetes, CVA	Right
12	81	Female	Diabetes, Dementia	Left
13	81	Female	Parkinson's disease, Dementia	Right
14	99	Female	Dementia	Right
16	93	Male	Dementia	Right

Protection of Human Subjects

Approval of the study was obtained from the institutional review board of Oregon Health Sciences University as well as the Administrator and Medical Director of the study nursing home. After consultation with the Director of Nursing Service (DNS) to select appropriate residents, potential subjects were approached by the investigator. The study purpose and procedures were explained (Appendix A) and verbal consent was obtained. Of the 9 residents who were unable to tolerate the procedure, 3 were able to refuse verbally, and for 6, nonverbal refusal was honored. Data were kept confidential, with subjects identified by a code number.

The risks of participation in this study included a slight temporary inflammation and discomfort in the outer portion of the ear canal resulting from the irrigation procedure and repeated temperature measurements, a slight chance that a sensation of dizziness or nausea could occur during irrigation, and a very small chance of damage to the ear drum during irrigation. Subjects were able to withdraw from the study at any time without affecting their care. Benefits of the study included leaving the subjects with clear ear canals which could possibly increase hearing acuity, although this was not specifically assessed.

Procedure

Ear Preparation

Using an otoscope, the ear canals were inspected for occlusion of the tympanic membrane by cerumen. An initial irrigation was done for 7 subjects to ensure that each had one occluded (experimental) and one non-occluded (control) ear. Unless completely free of wax, the control ear was irrigated prior to starting data collection. When both ears were occluded, the ear that appeared the least occluded was irrigated and designated the control ear, with the left ear irrigated in 5 of the 7 subjects and the right ear in the remaining 2. This resulted in 11 subjects (79%) with only the right ear occluded and 3 with only the left ear occluded (21%) (Table 1). Three days after the irrigation, an initial set of triplicate ear-based temperature measurements was obtained in each ear. The experimental ear was then irrigated to remove the cerumen. Three days later, a second set of triplicate ear-based temperature measurements was obtained in each ear. When the subject only had one ear canal that was occluded, no initial irrigation was needed, and the three day wait occurred only after the irrigation of the experimental ear canal.

Cerumen removal from the ear canal was accomplished with warm water (100 to 110°F) irrigation using an oral water jet irrigator (Water Pik™, Teledyne Company, Ft. Colling, CO and/or Sunbeam®, Northern Electric Company, Chicago, IL).

Prior to data collection, a pilot study was conducted to determine the time required after irrigation for the ear to return to about the same temperature as the nonirrigated ear. Two middle-aged subjects, 1 female and 1 male, were included, one of whom had an occluded ear canal. After obtaining initial ear-based temperature readings in both ears, the irrigation was completed using water at 100°F in the irrigation device following the study protocol (Appendix A). Ear-based temperature measurements were made in both the experimental (irrigated) and control (nonirrigated) ears every minute for the first 10 minutes, then every 5 minutes for one hour with a final reading at the end of 2 hours. The pilot study suggested that the irrigation procedure would take about 8 minutes and temperature measurements would return to normal in about 2 hours.

Once actual data collection began, however, the investigator found that one of the first two subjects experienced itching of the experimental ear after requiring 1½ hour for the irrigation. The ear-based temperature was increased from the subject rubbing his external ear. His ear-based temperatures as well as the behavior of rubbing the ear were monitored daily for 4 days. Based on this information, the protocol was modified to allow 3 to 4 days between irrigation and subsequent temperature measurements to allow the tissue time to recover from any inflammation that might result from irrigation. In addition, the time allowed for the irrigation was lengthened. Because the temperature readings were taken 3 days after the irrigation, water temperature was not measured with a thermometer, but was adjusted to the preference of the subjects. When subjects were unable to convey their preference, a water temperature of 100 to 110°F was used. The water jet irrigator was set on the lowest power setting, "L" for the Water Pik™, and for the Sunbeam® turned on enough to produce a stream of water with no "sting" as perceived by the investigator when the stream was directed against a finger. During irrigation the force of the stream was directed toward the walls of the ear canal rather than at the tympanic membrane to minimize risk of damage to the tympanic membrane (Dinsdale, Roland, Manning, & Meyerhoff, 1991). Irrigation continued until cerumen returned with the irrigant and the canal was found to be free of cerumen on otoscopic examination. Mean irrigation time was 64 minutes per ear. One subject, however, required three separate irrigations totaling 4 hours 15 minutes due to the extent and hardness of the cerumen. Otherwise, the longest time was 2 hours 45 minutes, the shortest 10 minutes. Alternating between two jet irrigators was necessary as the extended time needed to complete the irrigations caused the machines to overheat.

Temperature Measurements

Ear-based temperature measurements were made with a FirstTemp Genius infrared thermometer (Intelligent Medical Systems, Carlsbad, CA) in the core mode. This instrument used a thermopile detector to sense infrared energy emitted by tissue within its field of view in the ear canal, then added an offset of 2.4°F (1.33°C) to estimate core temperature (Intelligent Medical Systems, personal communication, 1992). The Fahrenheit scale was selected because of the smaller increments in comparison to the Celsius scale. At each of the two measurement times, three readings were taken in each ear. The side for the initial measurement in the first subject was determined by a coin toss and then alternated in subsequent subjects. The temperature measurements were alternated between the right and left ear so that a reading was recorded every 30 seconds, but readings in the same ear were made 1 minute apart to avoid the phenomenon of drawdown. Drawdown refers to the decrease in tissue temperature that can occur because the thermometer probe tip is cooler than the tissue, causing the temperature of the tissue to be drawn down.

The thermometer probe tip, with a disposable cover, was inserted firmly but gently into the outer part of the ear canal while using an ear tug to straighten the canal. The thermometer probe was aimed just above the midpoint of a line between the patient's opposite eye and ear canal. This technique sealed the ear canal from ambient air while maximizing insertion depth. The activating button was pressed and a temperature value was displayed in approximately 2 seconds. Data were recorded on the Data Collection Tool (Appendix B).

The thermometer was tested for accuracy before and after data collection and met or exceeded product specifications. It was calibrated according to manufacturer's directions using a temperature-controlled two-point black-body infrared reference unit (Genius® Electronic Calibrator Model 3000A-CL, Intelligent Medical Systems, Carlsbad, CA) with low and high test temperatures of approximately 98.2°F (36.8°C) and 102°F (38.9°C). The average error at both points was -0.08 ± .04°F (0.04 ± .02°C) prior to data collection, -0.12 ± .04°F (-0.7 ± .02°C) after data collection. The manual calibration offset for the thermometer was +0.30 prior to testing, and no further adjustment was made.

Thermometer accuracy was further tested using a temperature controlled water bath (Model 25, Precision Scientific, Chicago, IL) with a floating black body as the infrared heat source (Exergen Corporation, Newton, MA). Testing was done at 1.8°F (1°C) intervals over a range of 89.6 to 107.6°F (32°C to 42°C) in comparison to a certified mercury laboratory thermometer (Taylor Scientific Instruments, Arden, NC) with accuracy traceable to National

Institute of Standards and Technology. Mean error prior to data collection was 0.04 ± .18°F (0.02 ± 0.1°C) and after data collection was -0.05 ± .18°F (-0.03 ± 0.1°C). Again, no manual adjustment was made following testing.

<u>Other Data</u>

Background data included the subject's age, gender and medical diagnosis. In addition, ambient air temperature was measured within 1 foot of the subject's head using a thermocouple thermometer with a type K probe (Model HH22, Omega, Stamford, CT) immediately prior to and after each of the two sets of ear-based temperature measurements with the two values averaged.

Data Analysis

Differences between ear-based temperatures in the experimental and control ears and at the two measurement times (before and after irrigation of the experimental ear) were examined with a two-factor analysis of variance for repeated measures. If the presence of cerumen significantly affected the temperature difference between the ears, an interaction between the factors of measurement time and ear would occur. The temperature difference when both ears were free of cerumen was assumed to reflect the usual temperature difference that existed between the two ears. The highest of the three temperature readings at each measurement time was presumed to be the most accurate, and was used for the analysis. The level of statistical significance was designated as $p=.05$ and clinical significance was designated as a temperature difference of 0.5°F (0.3°C). Data analysis was completed using the Crunch® Statistical Package, version 4 (Crunch® Software Corporation, Oakland, CA).

CHAPTER IV

RESULTS

Effect of Cerumen on Ear-Based Temperature

Mean ear-based temperature measurements before and after cerumen removal from the experimental ear are shown in Table 2 and illustrated in Figure 2. As summarized in Table 3, the two-factor analysis of variance indicated a trend for an interaction between the presence of cerumen and the temperature difference between the ears (p=.08). When the experimental ear was occluded with cerumen (Time 1), the temperature reading was lower than in the control ear by a mean of -0.22 ± 0.73°F (0.12 ± 0.41°C). In contrast, when both ears were clear of cerumen (Time 2), no temperature difference between the two ears was apparent, with the mean values higher in the experimental ear by a negligible 0.02 ± 0.71°F (0.01 ± 0.39°C). Thus, occlusion of the ear canal by cerumen had a tendency to affect what was assumed to be the usual temperature difference between the ears, lowering the reading that was obtained by a small amount. The large standard deviations indicate considerable variability in the readings.

Right Versus Left Ears

An additional analysis was done to determine if a bias existed in the temperature readings in relation to right versus left ears. A possible effect of the side used was of concern for two reasons: (a) the right ear was occluded in

Table 2

Mean Temperatures (°F) Before and After Cerumen Removal from the Experimental Ear (n=14)

	Experimental ear	Control ear	Experimental minus control
	Time 1		
	(Before cerumen removal from experimental ear)		
Mean	99.29	99.51	-0.22
S.D.	±0.84	±0.86	±0.73
Minimum	97.6	97.6	-1.7
Maximum	100.9	100.6	1.0
Range	3.3	3.0	2.7
	Time 2		
	(After cerumen removal from experimental ear)		
Mean	99.56	99.54	0.02
S.D.	±0.57	±0.73	±0.71
Minimum	98.6	98.4	-1.6
Maximum	100.5	100.5	1.1
Range	1.9	2.1	2.7

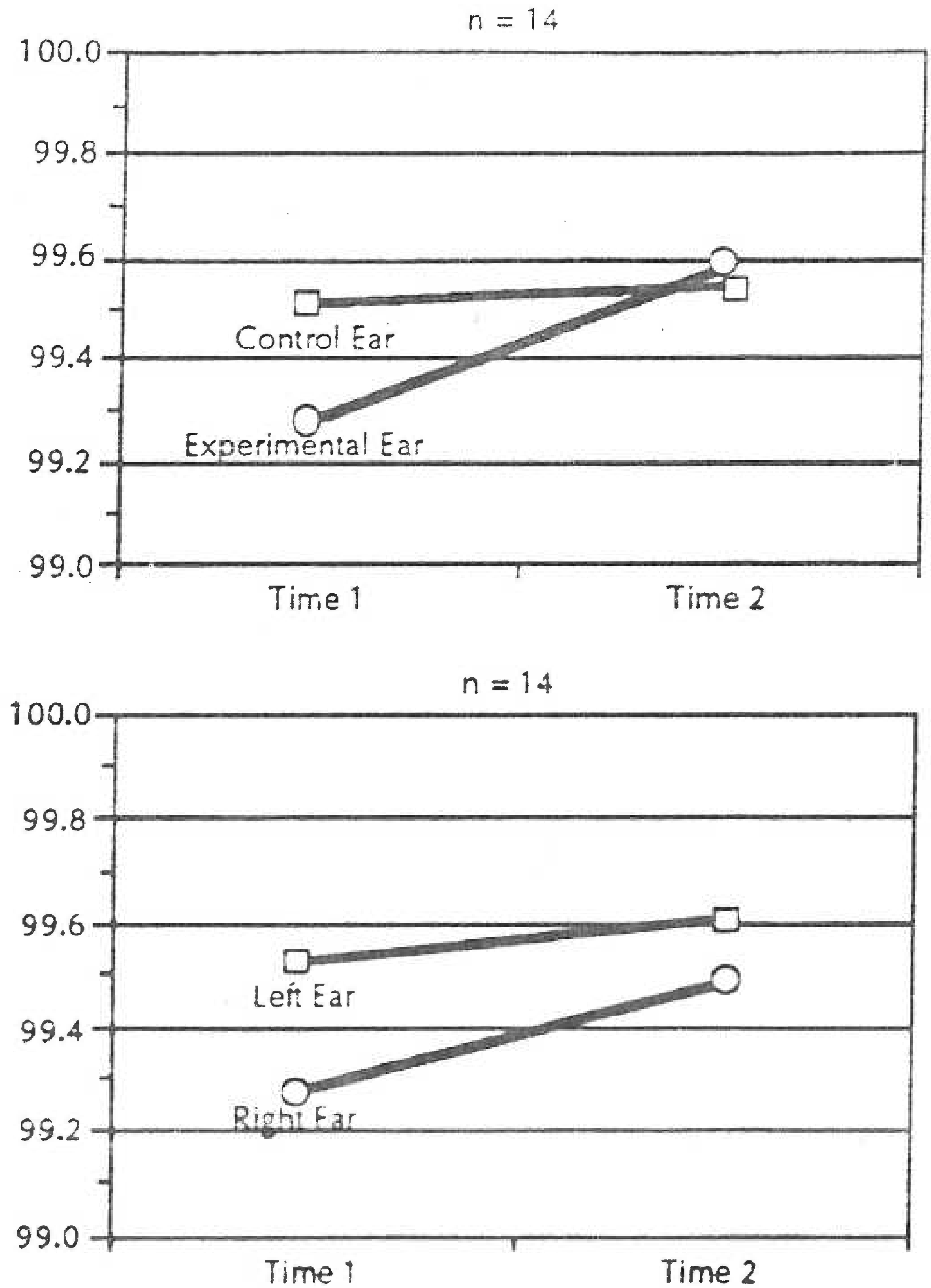

Figure 2. Comparison of mean ear-based temperatures in the experimental and control ears (top) and in the right and left ears (bottom) at Time 1, when experimental ear was occluded with cerumen, and at Time 2 when both ears were clear.

Table 3

Two-Way Analysis of Variance Summary for Ear-based Temperatures Before and After Cerumen Removal From Experimental Ear

Source	df	SS	MSS	*F*	*p*
Between-subjects variable	13	13.54			
Within-subjects variables	42	16.75			
Time	1	0.29	0.29	0.40	0.54
Ear (Cerumen)	1	0.14	0.14	0.30	0.59
Time x Ear	1	0.21	0.21	3.68	0.08

the majority of subjects (11/14), and (b) the investigator was right handed. Mean temperature measurements from each side are shown in Table 4 and illustrated in Figure 2. Although mean readings were slightly higher in the left ear than in the right ear, 0.25 ± 0.72°F (0.14 ± 0.40°C) at Time 1 and 0.14 ± 0.71°F (0.08 ± 0.39°C) at Time 2, a two-factor analysis of variance (Table 5) indicated that the difference was not significant ($p=0.29$). Again, the large standard deviations indicate a considerable variability in the readings.

Variability of the Three Measurements

Each ear-based temperature value in the previous analysis was the highest in a set of three readings taken 1 minute apart to determine how much measurement variation occurred. The range between the highest and lowest values was examined. Table 6 shows the ranges found at each measurement time in the experimental and control ears and similarly in the right and left ears. With one exception, the range was no more than 0.6°F (0.33°C) for the triplicate measures. In one subject, a single value in the experimental ear at the second measurement time was 0.9°F (0.5°C) cooler than the highest temperature measurement obtained in that ear. Although she had been showered earlier, a full hour elapsed prior to the temperature readings and the range found was probably a chance occurrence.

Table 4

Mean Temperatures (°F) of the Right and Left Ears Before and After Cerumen Removal from the Experimental Ear (*n*=14)

	Right ear	Left ear	Right ear minus left ear
	Time 1		
	(Before cerumen removal from experimental ear)		
Mean	99.28	99.53	-0.25
S.D.	±0.81	±0.88	±0.72
Minimum	97.6	97.6	-1.7
Maximum	100.9	100.6	1.0
Range	3.3	3.0	2.7
	Time 2		
	(After cerumen removal from experimental ear)		
Mean	99.48	99.61	-0.14
S.D.	±0.64	±0.66	±0.70
Minimum	98.5	98.4	-1.6
Maximum	100.5	100.5	1.0
Range	2.0	2.1	2.6

Table 5

Two-Way Analysis of Variance Summary for Ear-based Temperatures in Right and Left Ears Before and After Cerumen Removal From Experimental Ear

Source	df	SS	MSS	*F*	*p*
Between-subjects variable	13	13.54			
Within-subjects variable	42	16.75			
Time	1	0.29	0.29	0.40	0.54
Ear (Side)	1	0.52	0.52	1.20	0.29
Time x Ear	1	0.05	0.05	0.67	0.43

Table 6

Range of Triplicate Ear-based Temperature Measurements (°F) (n=14)

Ear	Time 1	Time 2
Experimental	0.1 - 0.5	0.1 - 0.9
Control	0.1 - 0.6	0.1 - 0.6
Right	0.1 - 0.5	0.1 - 0.4
Left	0.1 - 0.6	0.1 - 0.9

The highest of the triplicate measurements was not clearly the first, second or third reading. At Time 1, the highest reading in the experimental ear was also the first reading in 9 of the subjects, while in the control ear, only 7 had the first reading as also the highest. The findings were even less consistent at Time 2, with 8 measurements in the experimental ear having the first as also the highest, and only 1 in the control ear.

Prevalence of Cerumen

Of the 58 patients originally assessed for the presence of cerumen, 25 (43%) had one or both ear canals totally occluded with cerumen. In 18 of these (72%) both ears were occluded, in 6 (24%) the right ear only was occluded, and in 1 (4%) the left ear only was occluded.

Time Required for Irrigation

Successful removal of cerumen by irrigation in this study required a mean time of 64 minutes with a range of 10 minutes to 4 hours, 15 minutes. The extended period of time was very tiring for most patients. It was sometimes necessary to break the time required for irrigation into two or three sessions. The extended irrigation had a tendency to cause an inflammation of the ear, necessitating a delay in the time selected for the second set of ear-based temperature readings.

CHAPTER V

DISCUSSION

Patients are seldom if ever assessed for the presence of cerumen in the ear canal prior to infrared ear-based temperature measurements, although clinicians have questioned whether cerumen might affect the readings. This concern has particular relevance for the elderly, a group known to have a high prevalence of cerumen (Lewis-Cullinan & Janken, 1990). In this study, involving a small sample of elderly nursing home residents, the occlusion of one ear by cerumen tended to reduce the temperature reading in that ear by approximately 0.2°F (0.1°C). This finding suggests that occlusion of the ear canal by cerumen may make a small difference in the measured temperature value. Previously, there has been the assumption in the literature that cerumen had no affect on infrared ear-based temperature measurement (Chamberlain et al., 1991; Kenney et al., 1990; Phillips, 1985; Pransky, 1991). This study suggests that there may be a small effect although the findings are limited by the small number of subjects.

Cerumen, the ear canal wall, and the tympanic membrane may emit different distributions of infrared and visible light wavelength for a given temperature. However, both the type of infrared thermometer used in this study, which has a thermopile detector, and instruments which use a pyroelectric detector are broad band in nature; that is, they sense all wavelengths equally. Therefore, any difference in wavelengths emitted by the different tissue surfaces and substances in the ear canal should not have a significant effect in the ability of the instrument to detect them. Cerumen farther out in the canal could theoretically reflect the temperature of the canal at that point, so the temperature gradient found in the ear canal could be a factor in the temperature measurement (T. Herrmann, Ph.D., personal communication, September 18, 1992).

In clinical practice, the usual procedure is to take only one reading, although it may not always reflect the highest and presumably most accurate reading. This may contribute to the measurement variability and increases the difficulty of following temperature trends.

The ear-based temperature measurements in the study show relatively good repeatability, with a slight temperature difference noted between ears. The large amount of variability in the measurements is consistent with the findings of previous studies of ear-based temperatures such as those comparing pulmonary artery temperature to ear-based temperatures (Erickson & Kirklin, 1991; Nierman, 1991). This method of temperature measurement has a large variability, whether the ear canal is occluded or clear of cerumen, and clinicians need to be aware of that. If precision of measurement is important, clinicians will need to use another method of temperature measurement, or evaluate the effect of the following suggested guidelines. Using the same ear each time the temperature is measured would probably decrease variability. In addition, clinicians may want to take more than one measurement 1 minute apart and use the highest value. Careful attention to correct probe placement will maximize depth of insertion while sealing the canal from environmental influences.

The use of pre- and post-irrigation measurements, allowing comparison to the usual temperature differences between the ears for each subject, was a strength of the study. Past studies of other ear conditions, for example, the effect of otitis media, have not compared the temperature differences obtained between the ears with the usual temperature differences, but have assumed equal temperatures in both ears (Chamberlain et al., 1991; Kenney et al., 1990; Pransky, 1991). This study and others (Guthrie & Keuneke, 1992) indicate that temperature differences between the ears are likely to occur.

Previous research has indicated that a large percentage of the elderly have occlusive amounts of cerumen in the ear canal. Lewis-Cullinan and Janken (1990) found a prevalence of 35% of impaction of at least one ear with cerumen in a sample of 226 elderly patients, 7% of whom were nursing home residents. This study, involving 14 nursing home residents, found a 43% incidence of cerumen totally occluding visualization of the tympanic membrane in at least one ear. Although occlusion by cerumen has been reported to adversely affect hearing acuity (Lewis-Cullinan & Janken, 1990), this study indicates that it may also affect measurement of ear-based temperatures with infrared thermometry.

Limitations

The major limitation of this study was the small sample size. However, all 14 subjects had a large amount of cerumen occluding the ear canal, and thus provided a representative sample of the variable being studied. The study sample included a limited age range, 78 to 99 years. Although the sample was probably representative of the population of most nursing homes, the findings of the study cannot be generalized to other age groups. The subjects also had a limited temperature range, with none being febrile or hypothermic. Therefore, the effect of cerumen in patients at more extreme temperature values could not be studied.

Since all data were obtained by a right handed investigator, and mostly right ears were occluded, these factors may have been a limitation if they affected positioning of the thermometer probe. However, although the mean temperature was slightly higher in the left ear than the right, the value was not statistically significant (p=.29). Some right handed investigators have obtained similarly higher readings in the left ear which did reach statistical significance (Guthrie & Keuneke, 1992), while others (Erickson & Yount, 1990, unpublished data) have found no right-left difference. No studies involving left-handed data collectors have been reported. These findings suggest that the small temperature differences between ears could be due to the presence of cerumen occluding the ear canal or perhaps to chance.

Recommendations for Future Studies

A further study with a larger number of subjects is needed to test the results of this study. An equal distribution of right and left occluded ear canals would also help address the issue of sidedness. Studies that include other age groups are needed before findings can be generalized. In addition, including subjects with a larger temperature range, febrile as well as hypothermic, would provide data on that population. Following the ear-based temperature in subjects with one ear canal occluded with cerumen during periods of rapid temperature change would provide data regarding how long the cerumen takes to equilibrate to reflect core temperature. If both left handed and right handed persons collected data, the question of how handedness might influence data could be investigated. Evaluating the effect of lying on one side with that ear covered with a pillow, presumably warming the canal, should be studied to evaluate the amount of time required for ear-based temperature to return to its normal value when the ear canal is again exposed to ambient air.

In summary, this study suggests that infrared ear-based temperature measurements may be affected by the presence of cerumen, lowering the temperature by a small amount in the occluded ear. Infrared thermometry provides a rapid and convenient method of temperature measurement. However, this method of temperature measurement has a large variability and that needs to be understood by clinicians using this method. Temperature measurements at this site remain highly variable, regardless of whether the ear canal is occluded or clear of cerumen.

Implications for Practice

This study suggests that the occluded ear has an ear-based temperature of about 0.2°F (0.1°C) lower than the usual temperature difference found between that ear and the clear ear. Although this value approached statistical significance (p=.08), it has limited clinical importance. The small advantage of removing the cerumen from the ear canal when the ear-based temperature measurements are being made is offset by the considerable time and inconvenience involved in the irrigation procedure. The effect of this variable should be consistent so that when following the trend of temperature readings, the readings measured in the occluded ear would all be affected the same. Therefore, measurement of infrared ear-based temperature for clinical use may be made without considering whether cerumen is present. On the other hand, removal of the cerumen may also increase hearing acuity and thus benefit the patient. In any event, the presence of cerumen may be one additional factor that contributes to the variability inherent in ear-based temperature measurements. Environmental factors also could influence ear-based temperatures, such as lying on one side with one ear covered by a pillow which might warm the ear or a fan directed at the face (Brinnel & Cabanac, 1989). In addition, variations in probe placement influence the accuracy of measurements as the probe needs to be firmly seated in the ear canal. This seals the canal from environmental influences and maximizes depth of insertion in the ear canal. If precision of measurement is important, clinicians may want to take more than one measurement 1 minute apart and use the highest value. Using the same ear each time the temperature is measured would probably also decrease variability. Subjects in this study had large amounts of cerumen, so any effect on lowering the ear-based readings should not be larger with less dense or smaller amounts of cerumen.

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Appendix A.

<u>Protocol</u>

EQUIPMENT AND SUPPLIES

1. Forms
   - Data Collection Protocol
   - Consent Form
   - Clipboard

2. Thermometers
   - FirstTemp Genius
   - Omega HH22

3. Other items
   - Timer (inside plastic bag)
   - Pencil/pen
   - Zip-lock bags
   - Towels
   - Self-stick notes
   - Extra probe covers

4. Check equipment to verify it is functioning. Ear-based thermometer should be in core setting with the five dip switches in the right-hand position.

5. Thermometers must be at room temperature for one hour prior to data collection.

PROCEDURE

1. Consult with DNS of the facility to select subjects appropriate for consideration for the study.

2. Introduce yourself to the subject and explain the study.

   Hello. My name is Karen Hasel. I am a Registered Nurse currently enrolled in a Masters program at Oregon Health Sciences University on the campus of Eastern Oregon State College in La Grande. I am doing study of temperatures taken in the ear. I am looking for people who have at least one ear plugged with wax who would be willing to participate in my study. I would take three temperatures in each of your ears. Then I would wash the wax out of your ear. About an hour later, I would take the temperature readings again. It will take about 5 minutes each time to take your temperature readings, and about one to two hours to wash out your ear. The only risk of participating in this study may be a slight temporary discomfort in the outer portion of the ear canal. There is a very small chance that washing out the wax from the ear could cause some damage to the ear drum. This is an accepted way, however, to clean wax from ears. If you are willing to participate, I would like to first look in your ears to see if you have wax in at least one ear so you could be included in the study. Do you have any questions before I look in your ears?

3. Obtain the subject's verbal permission and use an otoscope to visualize the ear canals to see if he/she meets the criteria of having at least one ear canal occluded with cerumen. If the subject does not wish to be examined or to participate, thank her/him for considering participation in the study. Subject may decline through body language as well as by verbal response. In addition, the subject has the right to decline at any point in the data collection.

4. If the subject has both ear canals occluded with cerumen, the one that is the least occluded will be irrigated (follow procedure in step 9). If the ear canals are similarly occluded, the ear canal of the first subject will be selected randomly. Unless completely free of wax, one ear will be irrigated. Three days following this initial irrigation, the first set of data may be collected. If the patient only has one occluded ear, proceed to step 5 immediately.

5. Measure the ambient air temperature. Place the Omega® microprocessor digital thermometer (Model HH22) within 1 foot of the subject's head. Record the reading.
   a. Put thermometer in a clear plastic bag in a convenient place, such as on bed, bedside stand, overbed table, or hanging from an IV pole.
   b. Position probe tip within 1 foot of subjects's head so tip is not touching anything. Attach probe to the input.
   c. Press ON/OFF control to turn on thermometer. Display in °F.

6. Obtain the ear-based temperature measurement and record the data correctly.
   a. Select the side for the initial temperature measurement randomly then alternate between right and left.
   b. Tug on the outer ear, pulling upward and back to straighten the ear canal to facilitate probe placement. Holding the instrument in your dominant hand, place the thermometer in the ear canal with the probe aimed at the midpoint of an imaginary line drawn from the opposite ear to the eye that is also on the opposite side. The probe should be seated firmly enough to exclude ambient air, but not cause discomfort.
   c. Obtain three readings in each ear, alternating

from the right to the left ear, allowing 30 seconds between readings, with 1 minute between repeated readings in the same ear.

d. FirstTemp Genius Model 3000A Operation:
   1) 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.
   2) The temperature should be in °F. To change the display, hold the mode button for 2-3 seconds until °F is displayed.
   3) Place disposable cover on probe tip.
   4) Place probe in ear canal and seal opening.
   5) Press and release SCAN button.
   6) Remove probe from ear as soon as triple beep is heard and display flashes DONE.
   7) Read temperature on display.
   8) While holding probe over a waste receptacle, press blue release button to discard probe cover.
   9) Return probe to base unit.

7. Measure ambient air temperature again as detailed in step 5.

8. Revisualize the subject's ear canals with an otoscope to confirm which ear is occluded with cerumen; double check recorded entry.

9. Irrigate the subject's occluded ear canal using an oral jet irrigator to remove the cerumen occlusion. Use tepid water (100 to 110°F), or temperature that the subject prefers, in the oral jet irrigator set on the lowest power setting. Direct the force of the stream toward the wall of the ear canal rather than at the tympanic membrane to avoid excessive pressure on the membrane. Continue irrigation until cerumen returns with the irrigant. Use an otoscope to visualize the tympanic membrane and check for any remaining cerumen. Use towels or disposable diaper as well as an emesis basin positioned under the ear during irrigation to avoid getting subject wet.

10. Three days following the irrigation, measure the ambient air temperature, triplicate ear-based temperatures (this time start with the opposite ear), and then ambient air temperature again as detailed in steps 5 and 6.

11. Gather equipment.

12. Thank subject for his/her participation.

Appendix B.

Data Collection Tool

ID#	Medical Record #	Diagnosis	Age	Sex	TM perf? Y/N	Initially Occl? Rt &/or Lt	Irrigated R/L	Time 1 (days)	Remains occl. R/L
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									
16									
17									
18									
19									
20									

ID#	Date	Hour	Ambient Temp.$_a$	Start	Rt. ear	Lt. ear	Ambient Temp.$_a$	Occl. ear? R/L
1								
2								
3								
4								
5								
6								
7								

ID#	Date	Hour	Time 2 (days)	Ambient Temp.	Start	Rt. ear	Lt. ear	Ambient Temp.
1								
2								
3								
4								
5								
6								
7								