Ear Thermometer Design Reduces Measurement Variability

Abstract

Background: Ear thermometers provide a rapid means of measuring body temperature. Thermometers that provide accurate data with a high degree of measurement repeatability are preferred for patient assessment. The purpose of this investigation was to assess the accuracy and measurement repeatability of a new ear thermometer.

Setting: Hospitalized inpatient and outpatient subjects including adults (n=110), children aged 1 month to 17 years (n=60) and newborns (n=30).

Methods: Two commercially available ear thermometers were compared, the Braun ThermoScan® PRO 4000 (PRO 4000) and the Tyco Health Care FirstTemp Genius® (Genius). Multiple measurements using each thermometer in turn were compared to pulmonary artery (PA) temperature readings as a standard reference. All temperature measurements were obtained by trained clinical staff.

Results: Bland & Altman analysis indicates that the PRO 4000 ear thermometer provides greater precision and smaller variance than does the Genius thermometer when ear temperatures are directly compared to PA temperature measurements. Further analysis of repeatability measurement suggests that the PRO 4000 has less variability among temperature readings obtained from repeated measurements on the same subject.

Implications: Based on the data from this study, the PRO 4000 ear thermometer demonstrates low measurement variance as well as high repeated measurement consistency. The PRO 4000 is a suitable choice for routine temperature assessment and an acceptable alternative for core temperature when a PA catheter reading is not possible.

Introduction:

The temperature of the human body as an indicator of illness is an important part of patient assessment for health care providers throughout the world. Because a change in temperature can signal a significant change in health status, rapid and accurate measurement is important in all health care environments and even more so in situations where patients may be uncooperative or otherwise noncommunicative.

Information about the temperature of the human body as an indicator of its condition has been recognized since Galen (AD 130-200), who used a summary number to describe the "complexion" of a person. The first thermometer used to measure body temperature was likely that of Santorio Santorii of Padua (1611), who used an air thermometer to estimate the heat of a patient's heart by measuring expired air.[1] It was in 1892 that Le ChanteLier introduced the first laboratory radiation thermometer for measuring the temperature of a heated surface.[2]

While the mercury thermometer and its derivatives served well for over 100 years, these devices were limited. The thermometer had to remain in the temperature site for three minutes or more. Not only was this method time consuming, but at times, uncomfortable for the patient.

Mercury thermometers are breakable and the vapors that escape are toxic. The use of mercury-based devices has been banned in many states and countries.

Subsequent technological advances in temperature measurement that eliminated the limitations and dangers of the mercury thermometer allowed for the measurement of temperature using electronic devices that accessed body temperature through the ear canal.

Because the ear canal provides an easy access site for measuring body temperature, ear thermometry has become a viable alternative for obtaining patient temperatures. In the US, for example, many clinicians as well as family physicians and pediatricians routinely use electronically obtained ear temperature measurements in their daily practice.[3]

An electronic ear thermometer senses radiation emissions arising from the tissues. A microprocessor calculates any anticipated offset between the temperature at the ear and the body's core temperature, thus providing an estimate of the true core temperature. As is well documented in the literature however, issues with early ear thermometers raised questions regarding their accuracy and measurement repeatability.[4]
The purpose of this investigation was to demonstrate that a new ear thermometer would assure the initial accuracy of temperature measurements as well as continued accuracy of repeated measurements.

Clinical accuracy and repeatability studies were performed using the Braun ThermoScan® PRO 4000 (PRO 4000) ear thermometer (Figure 1) and the Tyco Health Care FirstTemp Genius® (Genius) ear thermometer. For the accuracy segment of the study, temperature readings were directly compared to those taken from an indwelling pulmonary artery (PA) catheter that was already inserted for other medical reasons. PA readings have long been considered the "gold standard" for temperature accuracy. For repeatability, results were derived by calculating the average standard deviations pooled across three successive readings on the same subject.

The PRO 4000 ear thermometer is specifically designed to address prior well-known limitations of ear thermometry, including measurement inconsistency, difficulty of probe placement to assure reliable readings, and lack of consistent demonstrable relationships of device readings to PA measurements. To address these issues, the PRO 4000 incorporates a heated probe tip, an ergonomic probe design, and an innovative ExacTemp™ technology. The ExacTemp design incorporates a feedback light that indicates stable probe placement and provides an audible/visual signal when a temperature has been successfully

Figure 1 **Braun ThermoScan® PRO 4000 ear thermometer**

taken. The heated probe tip and the ergonomic probe design both allow for the overall enhanced accuracy performance of the PRO 4000 ear thermometer.

Methods:

The study was conducted in a hospital and outpatient setting, after Institutional Review Board approval was granted. For investigations of accuracy, a convenience sample of 110 data sets was obtained from adult subjects in an inpatient Intensive Care Unit (ICU). The PRO 4000 and the Genius ear temperature readings were taken simultaneously with temperature readings from each patient's PA catheter. For investigations of repeatability, the initial 110 data sets were augmented with an additional 110 obtained from adults and children in general care areas. With each device, three repeated measurements were taken in the same ear, two minutes apart on each subject. A subsample of 30 newborns was included in the PRO 4000 data series of measurements on children. The subsample was constrained by a request from the clinical staff to limit the number of readings permitted on newborns, and therefore the Genius device was not included.

For data collection, three critical care nurses used three different ear thermometers of each brand, PRO 4000 and Genius. All data were collected equally on each thermometer and by each clinician.

PA temperatures were obtained only on those subjects in the initial accuracy segment of the study. For repeatability, no PA temperature readings were necessary.

Prior to use, the laboratory accuracy of each ear thermometer was validated using a blackbody target with the thermometer set in calibration mode. All Genius thermometers were then set in the Core Mode.

For data collection, the PRO 4000 and Genius devices were alternated as the first or second ear thermometer with a waiting period of at least two minutes between all ear temperature readings. Stability of a patient's PA temperature was determined as a minimum difference of no greater than 0.28 ˚C between two PA readings measured at the start and finish of data collection on each subject (approximately 12-15 minutes). No subjects were excluded from this study due to temperature instability.

All data were entered into a Microsoft Excel® spreadsheet. Data analysis was undertaken using SAS-PC for Windows V 9.1.3™ (www.sas.com) for the main analysis and MedCalc™ (www.medcalc.be) for Bland & Altman plots. Initial data reduction included the development of descriptive analyses. Differences in instrument measurements and measurements over time were evaluated using repeated measures ANOVA. Repeatability results were verified by calculating the average standard deviations pooled across three successive readings on the same subject.

Results:

Patient temperatures ranged from 35.0 ˚C to 39.7 ˚C. Thirty percent of all data represent fevers ≥ 38 ˚C.

Bland & Altman plots[5,6], were prepared to examine the differential accuracy of the two units compared to the PA standard. Figure 2 presents findings for the PRO 4000 device. Figure 3 is for the Genius device. As can be seen, the relative variation in readings is significantly less dispersed for the PRO 4000 with a mean difference from the PA standard of about one-third that demonstrated by the Genius and a smaller variance provided by the PRO 4000 instrument.

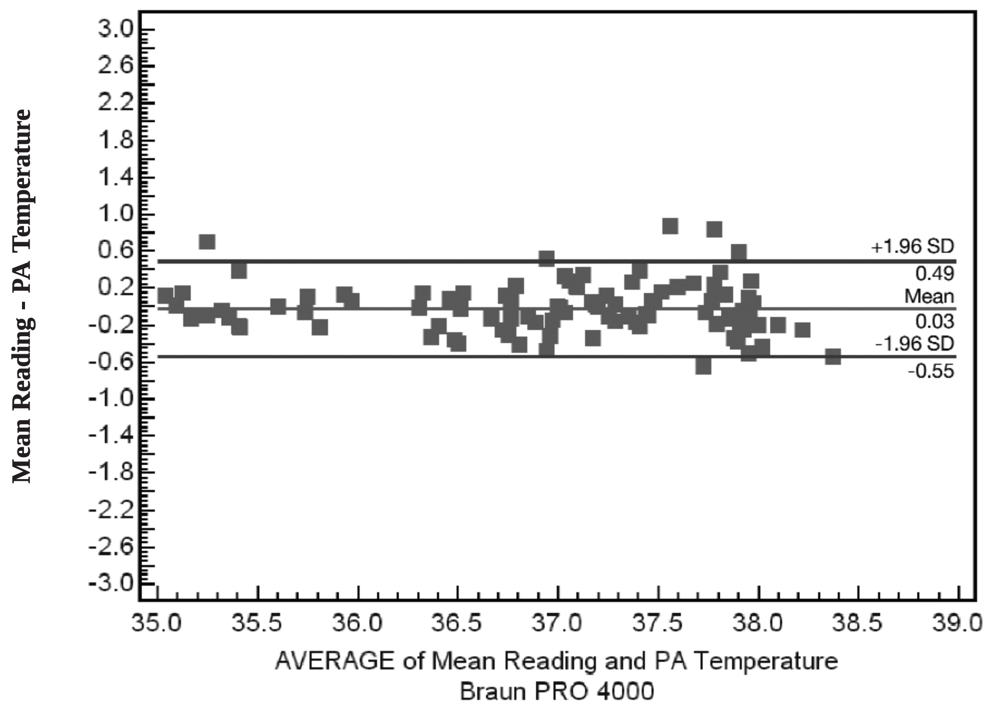

Figure 2 **Bland & Altman plot for PRO 4000 against PA standard**

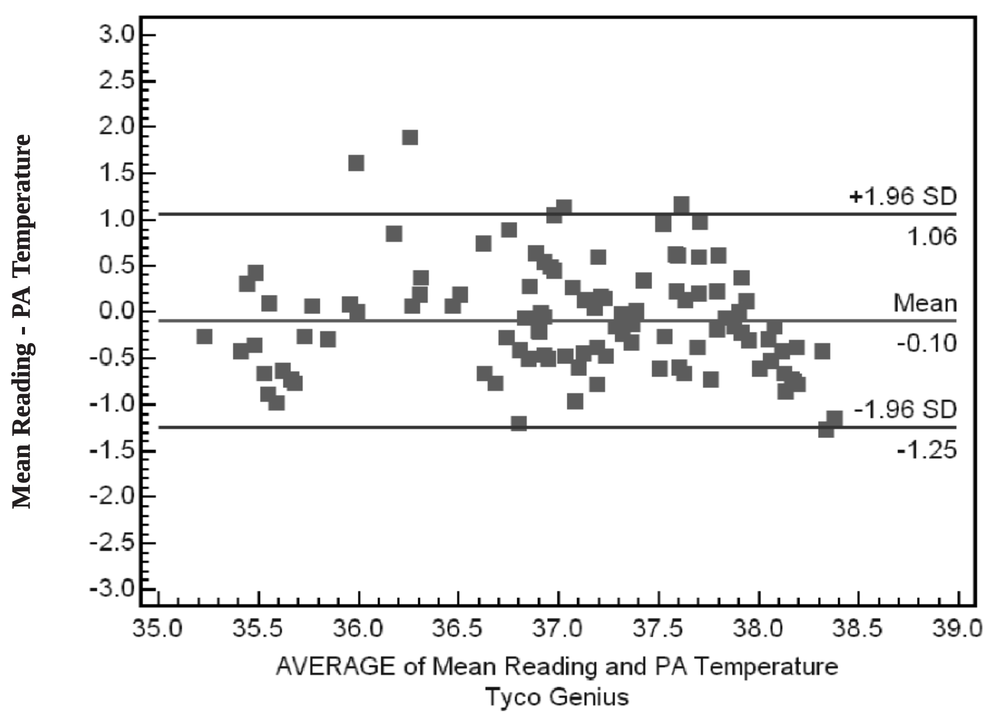

Figure 3 **Bland & Altman plot for Genius against PA standard**

For repeatability studies, three consecutive measurements were taken on a single subject two minutes apart. Measurement variation was pooled across the measurements on the single subject, and then averaged across the entire group of subjects. A higher pooled standard deviation suggests lack of consistency in measurement. Table 1 includes data from the 110 ICU subjects coupled with the 110 general care subjects.

This relationship is illustrated graphically in box-and-whiskers plots of the pooled standard deviation for each of the instruments (Figure 4).

Device	Sample Size	Average Pooled Standard Deviation
PRO 4000	220	.10 ºC
Genius	220	.18 ºC

Table 1 **Repeated Measurement Error Estimates**

Repeatability Measurement—Adults

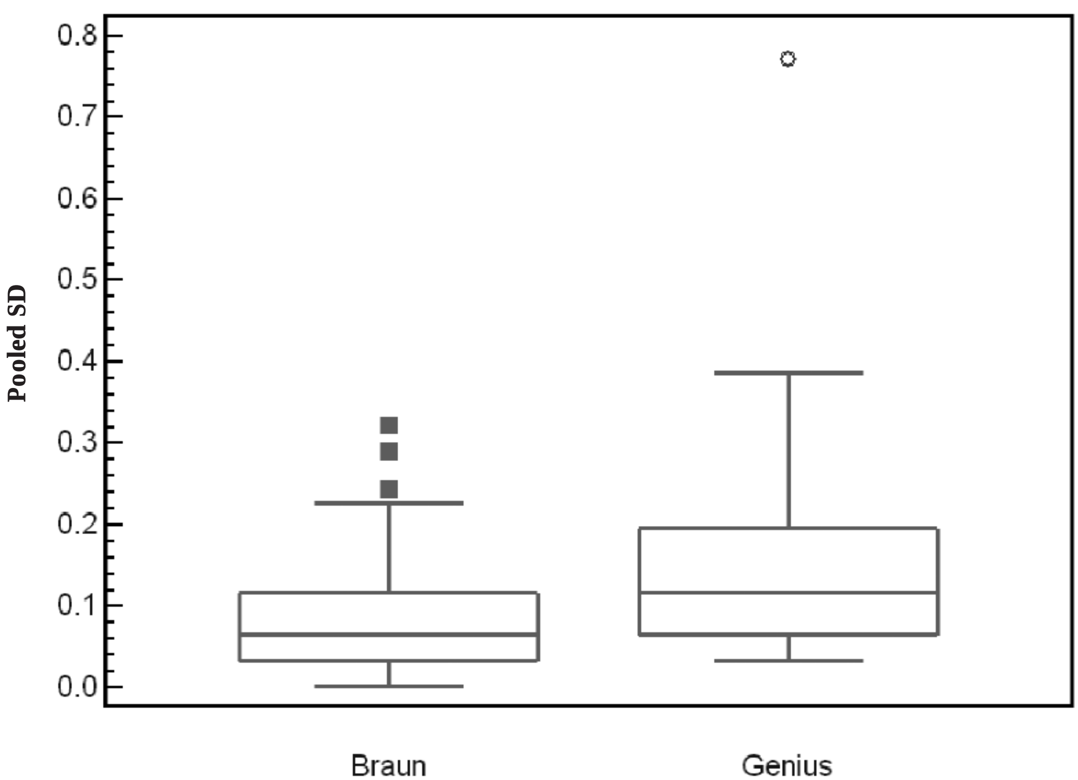

Figure 4 **Repeatability by subject**

Combined data sets of 60 children in each group aged 1 month to 17 years and an additional 30 newborns in the PRO 4000 group displayed similar differences in distribution patterns as seen for adult subjects. (Table 2 and Figure 5).

Device	Sample Size	Average Pooled Standard Deviation
PRO 4000	90 (30 newborns)	.10 ºC
Genius	60 (no newborns)	.14 ºC

Table 2 **Differences for Children and Newborns**

Repeatability Measurement—Children 1 month to 17 years

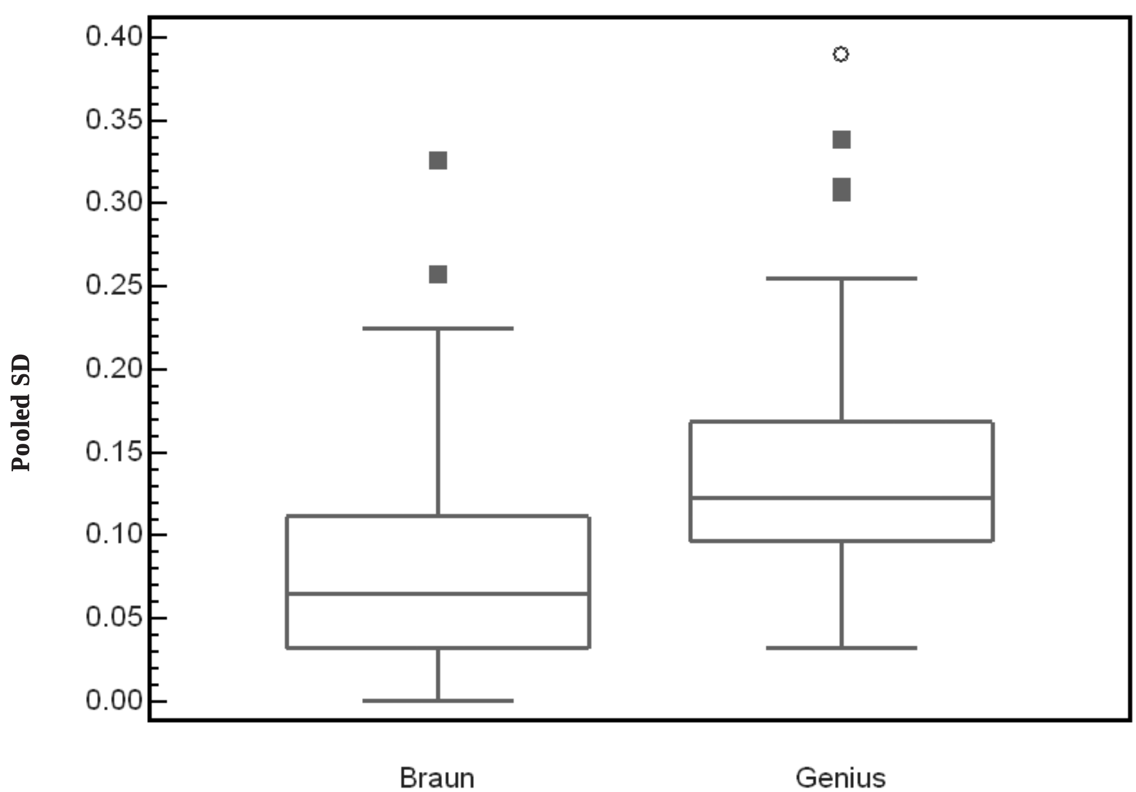

Figure 5 **Repeatability by subject**

A repeated measure ANOVA was used to examine the stability of the measurements over time. For the original 110 data sets, there was a significant difference in temperatures noted over time for the Genius unit, but this was not noted for the PRO 4000 (Table 3). A similar pattern of temperature measurements over time was noted for the 1 month to 17 years age group, although this did not reach statistical significance. (Table 4)

	Time 1 Mean		Time 2 Mean		Time 3 Mean	
Device	**Temp ˚C**	**SD**	**Temp ˚C**	**SD**	**Temp ˚C**	**SD**
PRO 4000	37.048	0.891	37.026	0.888	37.019	0.858
Genius	37.097	0.896	37.097	0.903	37.120	0.950
F = 3.45, p = 0.0329, dF = 2						

Table 3 **Repeated Measures ANOVA — Adult Subjects**

	Time 1 Mean		Time 2 Mean		Time 3 Mean	
Device	**Temp ˚C**	**SD**	**Temp ˚C**	**SD**	**Temp ˚C**	**SD**
PRO 4000	37.210	0.278	37.218	0.271	37.229	0.269
Genius	37.204	0.356	37.242	0.392	37.278	0.421
F = 1.29, p = 0.279, dF = 2						

Table 4 **Repeated Measures ANOVA — Subjects Aged 1 Month - 17 years**

Discussion:

The Braun ThermoScan® PRO 4000 ear thermometer provides very precise temperature readings when compared to those from the pulmonary artery. Data also show that the PRO 4000 exhibits a low degree of variability with repeated measurements.

Although not directly assessed in this study, performance differences may be due to the presence of both a heated probe tip and the ExacTemp™ technology. ExacTemp incorporates a feedback light that indicates stable probe placement and provides an audible/visual signal when a temperature has been successfully taken. These features may significantly contribute to the accuracy and measurement repeatability of the PRO 4000.

Conclusion:

In the fast-paced health care environment, clinicians require the means to rapidly obtain medically important information with confidence when precision is crucial. With proven low measurement variability and high repeated measurement consistency, the PRO 4000 is a suitable choice for routine temperature assessment and an acceptable alternative for core temperature when a PA catheter reading is not possible.

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